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THE OPTIMAL FACILITIES NECESSARY

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DIAGNOSIS AND MANAGEMENT

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PATIENTS WITH END-STAGE RENAL DISEASE

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I. INTRODUCTION

Uremia, or end-stage renal disease, is responsible for significant patient morbidity and mortality in the United States. Uremia respects neither age, sex, race, nor socioeconomic background. Although precise figures are not available, it is estimated that 10,000 patients die each year even with treatment modalities available. This lack of availability of care is not restricted to any specific geographic or economic group. This seems to be a deplorable situation when one considers the great advances made in the management of end-stage renal disease. Now we have two complementary therapeutic approaches, i.e., renal transplantation and dialysis.

Unfortunately, because of a lack of adequate resources as well as a unified plan to combat these diseases, there has been a great delay in the development of centers for therapy. Therefore, it is essential that a plan be formulated for a concerted attack on chronic end-stage renal disease, and that technological advances be applied to all patients in need. Attainment of such a goal would result in the rehabilitation of the many patients who would otherwise be lost during their most productive years.

The National Kidney Foundation, under contract from the Regional Medical Programs Service of the Department of Health, Education, and Welfare, convened a committee selected for their knowledge of the special problems related to renal disease. The names and affiliations of the members of this committee are listed in the appendix. In addition, a number of consultants were called upon to review the final draft of this document. This committee was charged with establishing the criteria for optimal care for patients with end-stage renal disease.

It became immediately apparent that two important concepts would pervade this document.

First, the ultimate care for patients undergoing hemodialysis or renal transplantation requires highly developed medical facilities which are not as yet available in many regions of the country. It is appreciated that such facilities are not necessary for many patients who are undergoing hemodialysis or who have a functioning transplanted kidney. This group of patients can and should be cared for by the primary physician working in concert with consultants who have expertise in the many and varied aspects of the management of patients with end-stage renal disease.

Secondly, an equally important concept deals with the integration and coordination of delivery of care in an organized manner and to provide a mechanism for the primary physician to have available multidisciplinary consultation and assistance. Such a system integrates patient referral, patient registry, dialysis, organ procurement, transplantation, laboratory services, and continued patient supervision.

With these concepts in mind, this report attempts to develop the guidelines for a coordinated regional system capable of delivering optimal care to all patients with end-stage renal disease, and, further, to promote an effective planning document for different communities and regions to assess their individual needs and effectively deliver high quality medical care.

While this document describes the necessary framework for an effective system, it is not intended to explore in depth all the areas alluded to within the system. Plans are being developed to further elaborate and expand these

guidelines to include other aspects of renal disease such as prevention, diagnosis, and therapy. In addition, with the advent of newer knowledge and greater experience, significant advances will be made in our understanding of diagnosis and management of patients with renal disease. As these advances are made, more effective methods of caring for patients with renal disease will be developed so that these guidelines will, by necessity, be modified from time to time.

In conclusion, I would like to express my gratitude to all the members of the committee and the consultants who gave so willingly of their expertise and contributed so much of their time to complete this project.

II. DEFINITION AND IDENTIFICATION OF END-STAGE RENAL DISEASE

Irreversible, far advanced renal failure, or so-called end-stage renal disease, is defined as that stage of renal functional impairment which can no longer be favorably influenced by conservative management and which requires dialysis (hemo- or peritoneal) or transplantation to maintain life and health. The diagnosis of end-stage renal disease may need to be established or confirmed through:

A. The distinction between acute reversible renal insufficiency and chronic renal disease.

B. The exclusion of certain chronic systemic or localized disorders of the extrarenal or intrarenal vasculature, renal parenchyma or urinary excretory system which might be corrected by medical or surgical treatment.

C. The observation and monitoring of the patient with progressive loss of renal function from renal disease of known or unknown etiology, with demonstrated failure of the process to stabilize or improve despite all reasonable and appropriate therapy. To assist in a more uniform description of patients with chronic renal disease, attempts should be made to use the criteria recently developed and subsequently modified by the Council on the Kidney in Cardiovascular Disease of The American Heart Association (Appendix 1).

III. RESOURCE CAPABILITIES DESIRED FOR END-STAGE RENAL DISEASE

A. Background

The advances in medical knowledge and the "hardware" of medicine now permit utilization of renal transplantation and chronic intermittent hemodialysis as established therapy for chronic renal failure. It seems fundamental that the organization of a system of health care delivery for patients with end-stage renal disease must permit effective management of the patient's problem, the best possible expenditure of medical resources, and the accumulation of as much new information and knowledge as possible. Within any system designed to care for all patients with terminal renal disease, it is apparent that various factors must be carefully considered during planning and the early implementation phases. The need for appropriate public and professional awareness of the various aspects of this system is of great importance to insure ease of access to the system for a patient, as well as to insure the availability of multidisciplinary consultation to the primary physician. In addition, to insure continued optimum care for these patients, a mechanism of review should be implemented so that the various components may be reevaluated and

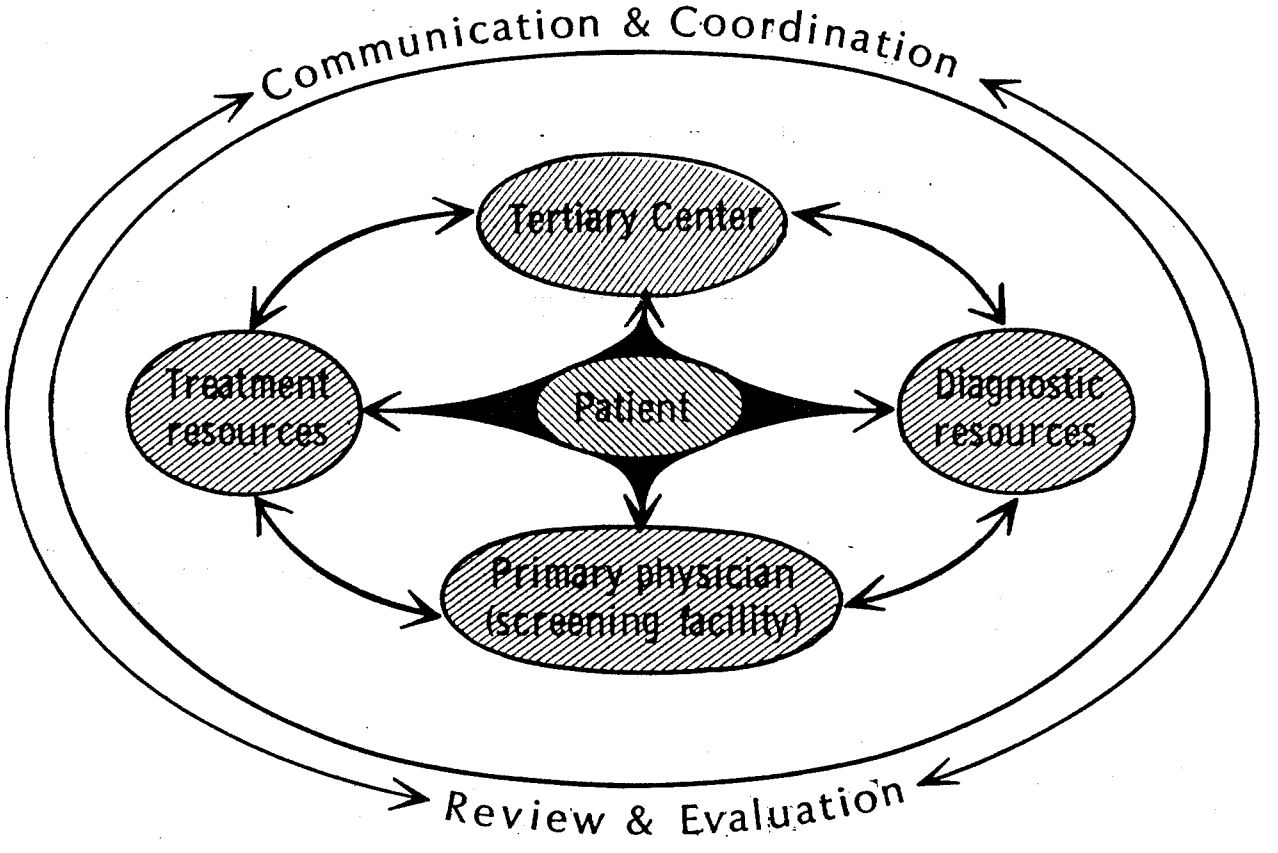

FIGURE 1. Schematic representation of patient flow in the health care system for end-stage renal disease described within this document

replaced as newer concepts and modifications are introduced. Finally, it is important to realize that many patients undergoing dialysis, or who have a well-functioning transplanted kidney generally, can be cared for by their primary physician. The in-depth expertise usually found in the tertiary centers are actually required by only a few dialysis patients and by those patients undergoing a renal transplantation. In the ensuing sections, these aspects of this health care system will be described.

B. Planning and Determination of Need

The importance of the developmental aspects of an effective system for diagnosis and treatment of patients with end-stage renal disease cannot be overemphasized. Paramount among the considerations made in the development of such a health care system should be:

1. The determination of the potential patient population and region to be served.
2. The evaluation and appraisal of those resources currently available to the renal team and the primary physician.
3. The determination of the number, type, and location of facilities needed for optimal patient care.
4. The effectiveness of treatment in terms of patient rehabilitation and restored productivity.
5. The development of an effective information and communications system to assist in accomplishing goals 1 through 4. A registry and use of common classification and data collecting system in selected areas of disease reporting will greatly improve disease classification and treatment evaluation.

C. Resources Desired for End-Stage Renal Disease

1. Primary Treatment and Diagnostic Centers

The primary treatment and diagnostic center will be the local physician whether he be a family practitioner, an internist, a pediatrician, a nephrologist, etc. He will be in many instances the physician who was first consulted by the patient with end-stage renal disease. This physician will be responsible for (1) the primary evaluation, (2) the initiation and the followup of all diagnostic procedures, and (3) the initiation of appropriate therapy. However, if it is the opinion of the primary physician that adequate diagnostic and treatment facilities are not immediately available, he will be in a position to refer the patient to appropriate diagnostic and/or treatment facilities. Depending upon the individual situation, this may be the secondary or tertiary center. The development of the capacity to include the primary physician as a member of the Health Care Team is most important.

The two therapeutic modalities requiring more complex facilities are transplantation and hemodialysis. The former, because of its nature, requires the services of the full Health Team and as such should be confined to tertiary centers. The latter, however, ranges in complexity from dialysis, in the immediate post-transplant period requiring tertiary facilities, to the stable, medically well, and sociopsychologically rehabilitated individual dialyzing himself at home with the assistance of a companion.

Certain general principles must govern the care of a dialysis patient as he becomes ill and requires hospitalization, moves in and out of a transplant program, or as his needs change from time to time for more or less complex facilities. At any one point in time the goal is to secure optimum care commensurate with the patient's medical, psychological, sociological, and economic needs. Ideally, the least expensive, most "normal" type of setting for treatment consistent with medical demands should be available. For this reason, multiple steps away from the most complex (most expensive and personally threatening to the patient) facility are required in his health care system in order to permit ready movement up and down the scale as his medical condition warrants.

To facilitate patient movement, cooperation and communication between all components is mandatory. That is, every patient must have a clearly delineated course open to him which permits movement to the most complex medical capability as the need arises and insures his ability to move back. This requires one physician to be responsible for the general health care of the patient, who is knowledgeable enough concerning dialysis and transplantation to recognize the need of the patient for a more complex treatment facility if and when the need arises. In addition, the physician must be involved in the system to such an extent that he will be able to secure this care. In less populous areas, this physician must be the primary physician. In more populous areas, it is likely that the combined effort of a primary physician and nephrologist, or the latter alone, will assume this role.

2. Secondary Treatment and Diagnostic Centers

The secondary treatment and diagnostic centers refers to the local general hospital that will be in the position to provide more definitive diagnostic and treatment resources. These centers may also have the capabilities to provide conservative management of the patient with terminal renal disease with appropriate nutritional and medical programs. Furthermore, these centers may have the capabilities to provide the patient with chronic maintenance dialysis in a setting that will permit continued care by the primary physician as well as optimal rehabilitation. It should be anticipated that there exist communication ties between the secondary treatment center and the tertiary center for purposes of providing transplantation, as well as additional consultation if needed. The composition of secondary centers should include an integrated Health Care Team, consisting of:

a. Medical services

(1) Primary physician

(2) Consulting nephrologist

(3) Consulting urologist

(4) Consulting transplant surgeon

(5) Consulting radiologist

(6) Consulting pathologist

(7) Consulting psychiatrist or psychologist

b. Other health professionals

(1) Nursing service

(2) Social service workers

(3) Vocational rehabilitation

(4) Nutritionists

(5) Technical personnel necessary to operate special units or facilities

c. Special units or facilities

(1) Capabilities to perform chronic maintenance hemodialysis as needed to deliver optimal care to patients with end-stage renal disease within a specific area. This may include capabilities in home or self-care hemodialysis training, limited care dialysis, and backup in-hospital dialysis for patients requiring hospitalization.

(2) Organ procurement and preservation facility in support of the regional procurement-preservation program is desirable.

(3) An information and communications system linked to the regional system is necessary.

3. Tertiary Treatment and Diagnostic Centers

The purposes of the tertiary center should be (1) to provide capabilities in transplantation, and (2) to be available for consultation, when necessary, to the primary physician and/or the secondary center to assist in the optimal management of the patient with end-stage renal disease.

Since patients with end-stage renal disease may have complex medical problems with multisystem involvement, the tertiary centers providing transplantation as well as consultation should have available broad

capabilities in medicine, surgery, and related subspecialties. Composition of such a tertiary center might include:

a. Medical services

(1) Department of Medicine with a Division of Nephrology

(2) Department of Pediatrics with a Division of Nephrology

(3) Department of Transplantation or Department of Surgery with a Division of Transplantation

(4) Department of Urology

(5) Department of Radiology with an associated Division of Nuclear Medicine

(6) Department of Pathology with special capabilities for interpreting kidney tissue by light, fluorescence, and electronmicroscopy

(7) Department of Clinical Pathology or of Laboratory Medicine (or otherwise structured) with capabilities in Clinical Pathology, Microbiology, Virology, Immunology, Hematology and Coagulation, Blood Banking, Chemistry, and other diagnostic laboratory services

(8) Department of Neurology

(9) Department of Psychiatry with an affiliated Clinical Psychology Service

(10) Department of Physical Medicine

b. Other health professionals

(1) Department of Nursing

(2) Section of Social Service

(3) Section of Vocational Rehabilitation

(4) Section of Clinical Dietetics

(5) Technician services in various diagnostic and laboratory areas

c. Special units or facilities

(1) Transplantation Unit and/or Intensive Care Ward

(2) Transplantation Clinic (may be separate from, or part of, the Renal Clinic with a transplant-dialysis consulting group)

(3) An In-Hospital Dialysis Program in association with, or as part of, the Transplant Unit

(4) An Artificial Kidney Complex

(5) Renal/Transplantation Clinic

(6) Laboratory for special procedures relating to diagnosis of renal and electrolyte abnormalities

(7) Renal Physiology and Nephrology Research Laboratory

(8) Blood Bank, Tissue Typing, and Clinical Immunology Facility in support of Transplant Unit capable of measuring lymphocyte antibodies (tissue typing may be regional)

(9) Organ Procurement and Preservation Facility and Service in support of Transplant Unit (This could be on a regional basis.)

(10) An Information and Communications System with linkages to various dialysis facilities in its region

D. Role of the Professional Services

Advances in the management of patients with chronic renal disease have resulted primarily through application of fundamental knowledge gained in many disciplines including renal physiology, pathology, immunology, pharmacology, and biochemistry. Capabilities of professional services in a tertiary treatment center should include:

1. Department of Medicine

   a. Full-time clinician-teachers with inpatient and outpatient facilities necessary for the care of patients with a wide variety of medical and surgical problems.

   b. A Division of Nephrology with broad capabilities which might include in addition to the above:

      (1) The availability of a faculty trained in renal physiology, pharmacology, pathology, biochemistry, immunology, and water and electrolyte metabolism at clinical and laboratory levels

      (2) A nephrology research laboratory

      (3) A research training program in nephrology

      (4) Residency and fellowship program in nephrology

      (5) Laboratory for special procedures relating to diagnosis of renal and electrolyte abnormalities

      (6) A renal clinic for consultations and management of complex problems in renal and genitourinary medicine

      (7) An artificial kidney complex

2. Department of Pediatrics With a Division of Nephrology

Children who have end-stage renal disease face the following special problems:

a. The diseases leading to renal failure often stunt growth and impair development. For that reason, earlier detection of children who might develop renal failure is important.

b. Transplantation is a goal in therapy in the case of virtually all children. Following transplantation, however, both growth and development (social, not intellectual) may be modified.

c. For these reasons, and because dialysis also is associated with less than optimal growth, dialysis and nutrition supervision in children must be especially comprehensive.

d. Children are dependent members of a family, competing with other members of the family for resources of time, money, and energy. Their disease should have the least possible adverse effect on other members of the family.

e. Because children, by definition, are affected prior to completion of their maturation, and because an increased life expectancy is a rational goal for all, the followup care into maturity must be continuous and comprehensive.

f. The number of children so affected is probably limited to 400-600 new cases a year in the United States.

For these reasons, the organization of centers for children under the care of a "renal failure" pediatric nephrologist will differ both in design and delivery system, and in the number required. Transplantation of children should be restricted to those transplant centers

having a Pediatric Renal Failure Unit or to a center with a qualified pediatric nephrologist who can coordinate care with a Pediatric Renal Failure Unit and its information system.

3. Department of, or Division of, Transplantation

Centers performing transplantation should have a separate Department or Division of Transplantation headed by a transplant surgeon. The transplant surgeon, whose basic surgical training may be in general surgery, urology, vascular surgery, etc., must have special training and competence in transplantation medicine and surgery, as well as a full-time commitment. Another surgeon, whose basic training may be in one of the areas enumerated above, should be a member of the team on at least a 50-percent basis (see Section IV,C,4). In addition, the transplantation program must have ready access to those various components, such as tissue typing, organ procurement, etc., as subsequently outlined in the section on transplantation.

4. Department of Urology

The participation of a urologist is necessary in the diagnostic evaluation and assessment of the patient and for the development of medical and surgical treatment regimens for renal and genitourinary problems. Moreover, the expertise of the urologist is necessary for the care of the patient who has a disorder of the bladder or collecting and drainage system.

5. Other Professional Services and Their Roles in the Tertiary Center

The evaluation of patients with impaired renal function requires the expertise of the adult and pediatric nephrologist and urologist with strong support from colleagues in multiple disciplines in clinical and laboratory medicine. Complexities of techniques and technology alone require that many specialized facilities be developed in other departments. It is understood that any minimum criteria for specific services must be regularly reviewed so that any demands which are restrictive or archaic may be deleted.

Accordingly, these professional services for end-stage renal disease patient care might include:

a. Department of Radiology With Capabilities in Nuclear Medicine

(1) Personnel

(a) Full-time coverage by Board-certified radiologist(s) and specialists in nuclear medicine

(b) Residency training program in radiology

(c) Professional and technical personnel skilled in special procedure radiology and nuclear medicine, particularly as related to the renal and genitourinary systems, cardiovascular hemodynamics, and angiography

(2) Facilities as required to accomplish:

(a) Radiologic studies such as roentgenograms of the chest, abdomen, excretory urography, nephrotomography, and retrograde pyelography

(b) Mobile chest and abdominal roentgenograms

(c) Laminagraphy

(d) Visceral angiography

(e) Cine cystourethrography and other procedures requiring cine capability

(f) Fluoroscopic facilities to support percutaneous renal biopsy activities

(g) Renal scans and rapid sequence scintiphotography

(h) Isotope renography

(i) Radioisotope renal function testing

b. Department of Pathology

(1) Personnel

(a) Full-time coverage by Board-certified pathologist(s) with at least one member with special knowledge of renal diseases

(b) Residency training program in pathology

(c) Professional and technical personnel skilled in special procedure pathology, particularly as related to the renal and genitourinary systems

(2) Facilities as required to accomplish:

(a) Morphologic and histologic studies of renal tissues. Electronmicroscopic examination of renal tissue, as indicated, must be available.

(b) Necropsy examination of human and animal tissues

(c) Experimental pathology laboratories sufficient to support research studies on cells, tissues, or whole animals

c. Department of Clinical Pathology or of Laboratory Medicine

(1) Personnel

(a) Full-time coverage by a Board-certified clinical pathologist or other individual(s) legally qualified to operate such a laboratory. The laboratories involved must meet qualifications of State and Federal licensing.

(b) Full-time coverage by other specialists in clinical pathology or laboratory medicine including specialists in microbiology, virology, coagulation and special hematologic disorders, nuclear medicine, and other sub-specialty laboratory areas likely to be required in renal and genitourinary medicine.

(c) Residency or graduate training programs or both in the various disciplines of clinical pathology or laboratory medicine.

(2) Facilities as required to accomplish:

(a) Routine hematology, urinalysis, serology, blood bank procedures, routine chemistries, and certain other laboratory procedures commonly required in a nephrology center

(b) Cultures for aerobic and anaerobic organisms and anti-biotic sensitivity testing

(c) Radioimmuno assay (e.g., angiotensin and parathyroid hormone)

(d) Tissue culture for routine viral studies, complement fixation test, and other related studies

(e) Special coagulation studies and other aspects of specialized hematology

(f) Morphologic and histologic examination of tissue at a light and electronmicroscopic level with immunofluorescent studies (might preferably be accomplished in the Department of Pathology, as defined earlier)

d. Department of Nursing

For an effective program, active involvement of nurses with specialty training in the care of adult and pediatric patients with end-stage renal disease is essential.

Nursing participation in dialysis and transplantation units is mandatory for effective operation of these units.

e. Supporting Resources

Institutional capabilities in neurology, psychiatry, clinical psychology, immunology, rheumatology, cardiology, genetics, nutrition, infectious diseases, physiology, pharmacology, ophthalmology, radiation therapy, and in the various surgical, pediatric, and medical subspecialty programs should be available. Indeed, professional personnel and facilities for neurologic studies (to include electroencephalography and electromyography), psychiatric and psychological evaluation, and other aspects of overall patient investigation and management must be available to the medical and surgical renal team as part of the overall institutional commitment to a center for the care of patients with end-stage renal disease.

E. Resource Coordination and Communication

Integration of the primary professional services in medicine, pediatrics, urology, and surgery with the primary physician and nephrologist will assure consultation in all instances where renal failure is to be managed by dialysis or transplantation. This will provide the best therapeutic approach for the patient, as well as permit interdisciplinary planning for immediate and long-term management of the patient and appropriate use of facilities and medical manpower in the secondary center and the tertiary end-stage renal disease center. In addition, because of the complexities of treatment programs, requirements for the processing of large volumes of data and the necessity of close and careful communication between the staff of the tertiary center, the secondary center, and the primary physician, each region should have available a system for information storage and retrieval which might be a part of a national network. The development of such a renal registry for all patients with end-stage disease could assist in the daily management of the patient, in the monitoring of ongoing programs, in planning for new and developing programs, and in more effective and rapid distribution of information and knowledge valuable in program development and operation. In addition, this system would be used as the source of information for patients awaiting transplantation within a region. Specific efforts should be directed toward the development of a national communications linkage as it relates to all patients with end-stage renal disease, in order to gain maximum utilization of medical information generated by these programs and to insure that patients awaiting transplants will receive matched kidneys.

F. Evaluation of Quality of Care

The evaluation of a regional health care delivery system for patients with end-stage renal disease is necessary. A system of ongoing and/or periodic assessment of the various components of a regional program in terms of resources and performance must be established in order to disseminate to all regions, information concerning the highest standards in any region in the country. The mechanism employed to assess and review the resources and performance should be in the hands of a national kidney commission representative of both the academic and practice communities.

IV. THERAPEUTIC RESOURCES FOR END-STAGE RENAL DISEASE

A. Adult Hemodialysis Resources

1. General Considerations

a. The three major operating components of a complete hemodialysis program include:

(1) A self-dialysis training program for training patients to dialyze themselves either in the home or in a limited care dialysis facility.

(2) A facility to provide followup support for self-dialysis patients, including backup dialysis and source of supplies and equipment maintenance, and to provide maintenance dialysis for patients who are not trained in self-dialysis.

(3) An in-hospital dialysis program to provide dialysis to any patient who requires hospitalization and must receive maintenance dialysis at the same time.

b. Since a hemodialysis program must have the three major components, and since each component is expensive to establish and operate, it is mandatory that hemodialysis programs be organized and operated on a regional basis and that the region to be served be adequate in population to provide enough patients to fully utilize the services of the program. Regionalized coordination of hemodialysis programs is essential in order to avoid both costly duplication on the one hand and gaps in service on the other. Regulations for the licensing, certification, or approval of all hemodialysis facilities should be established and, further, should be subject to periodic review.

c. The actual composition, organization, and operation of a regional dialysis program will vary depending upon the region being served. Furthermore, the type and scope of operation of the individual facilities which make up a regional program will be varied and evolving. Indeed, new types of facilities are being created as dialysis technology continues to evolve and improve.

d. In terms of cost, it is important to understand that the actual cost of a dialysis is far cheaper in the home than anywhere else. If the cost of a dialysis in the home = X, then the cost of self-dialysis in a limited care facility = 2X to 4X; in an affiliated hemodialysis program = 4X to 6X; and the cost of a dialysis in-hospital = 6X to 10X or more. At the same time, a given patient, because of medical and/or social reasons, may require a certain type of dialysis and be harmed if forced to accept a less expensive type. Hence, the type of dialysis provided a given patient must be determined by the physician in charge. However, depending on the

local situation, a large number of patients could be on home dialysis. Also, there is a substantial group of patients not on home dialysis who could be dialyzing themselves in a limited care facility.

e. Because a routine hemodialysis carried out either in a limited care facility or in the home does not require the presence of a physician, certain special problems exist relative to establishing equitable physician professional fees for maintenance hemodialysis. Physician fees for the supervision of patients undergoing maintenance dialysis should directly relate to the professional time expenditure.

f. Techniques now have been developed for using special forms of peritoneal dialysis for long-term maintenance of patients with end-stage kidney disease. However, since the techniques are not yet fully evaluated or generally available, the guidelines in this document are applicable only to hemodialysis.

2. Classification of Programs and Facilities for Hemodialysis

a. General considerations

(1) A complete hemodialysis program must provide a wide diversity of services which range from hemodialysis of a critically ill patient in an intensive care unit to the maintenance of hemodialysis equipment in the patient's home.

(2) Since regular maintenance dialysis does not require hospitalization, all hemodialysis facilities other than those required for in-hospital dialysis should be located outside the

expensive, active bed area of a hospital and may be geographically separate. They should be administratively and financially independent of a parent hospital so that the high overhead of the hospital does not raise the cost of dialysis in the facility.

(3) Since in-hospital dialysis is the most expensive and least frequently used type of dialysis, and since this type of dialysis must be available 24 hours a day, 7 days a week, hospitals which can provide this service should serve large areas of population. Whenever possible, the regional kidney transplant program should be located in the same institution.

b. An artificial kidney complex

(1) General Considerations

(a) The organizational and operational complex of any complete hemodialysis program, as previously defined in Section IV,A,1, shall be designated as the artificial kidney complex.

(b) An artificial kidney complex may be part of a secondary and/or tertiary center or an independent facility. However, in the latter situation, it must be closely associated with an in-hospital dialysis program so that its patients can be dialyzed in-hospital when necessary.

(c) The various components that make up an artificial kidney complex may be located in geographically separate areas or even in geographically separate institutions, provided a clearly delineated plan of integrated operation of the various facilities is in existence. This plan should be a matter of public record.

(d) The medical director of an artificial kidney complex shall be an experienced nephrologist. An organizational structure of the center's program delineating the program director's and the program members' authorities and responsibilities and their places in the institution's organizational structure should be provided. The other professional personnel necessary for functioning of the various components of the artificial kidney complex are described in their respective sections.

(e) It should be the responsibility of the staff of an artificial kidney complex, in conjunction with the tertiary center, to develop a renal registry to record all patients with end-stage renal disease (see III,E, Resource Coordination and Communication).

(f) The artificial kidney complex shall be responsible to clearly delineate the commitment of this facility to the continued optimum care of the patient requiring hemodialysis.

(2) Functional Components

(a) A self-dialysis training program

1. The purpose of such a program is to train patients and their companions in the technique of self-dialysis. After completion of training, the procedure would be performed either in the home or in a limited care facility.

2. Any self-dialysis training program should be coordinated with and under the surveillance of the artificial kidney complex to assure the highest standards

of care for these patients and to provide in-center or in-hospital dialysis when required. There should be documentation of the cooperative arrangements with the artificial kidney complex in the region.

3. Self-dialysis training programs should be staffed by physicians, nurses, and technicians who are trained and/or experienced in dialysis techniques.

(b) A limited care dialysis program

1. The basic concept of limited care dialysis is to provide dialysis in a low-cost area, utilizing an absolute minimum of professional support.

2. The patient on limited care dialysis might be trained to dialyze himself without specific professional support in this low-overhead unit.

3. Limited care dialysis provides an inexpensive substitute for home dialysis to be used by patients who cannot dialyze at home for one reason or another.

4. A limited care dialysis facility can be located almost anywhere, including a vacated storefront or a trailer parked near a hospital. Mobile limited care units can move through rural areas servicing patients on a regular schedule.

5. A limited care dialysis program should be coordinated with the artificial kidney complex to assure the highest standards of care for these patients and to provide in-center or in-hospital dialysis when required. There should be documentation of the cooperative arrangements with the artificial kidney complex in

the region, and this should be a matter of public record.

6. Staffing of a limited care facility can be by the patients themselves or with a minimum of technical help, although supervised by a responsible nephrologist.

(c) An in-hospital dialysis program

An in-hospital dialysis program should function primarily as a supporting service to the transplant program and/or as a backup program for hospitalized patients who usually are dialyzing at home or in a limited care facility.

c. An affiliated hemodialysis program

(1) General Considerations

(a) Any hemodialysis program that does not offer the full gamut of facilities and services outlined for the artificial kidney complex /(3)(a)—(c), above/ shall be designated an affiliated hemodialysis program.

(b) An affiliated hemodialysis program shall be accredited to perform only those services for which it was established.

(c) The working relationship which must exist between the affiliated unit and the parent artificial kidney complex shall be fully documented as part of the ongoing accreditation procedure. This affiliation should be a matter of public record.

d. An in-hospital dialysis program

(1) General Considerations

(a) An in-hospital dialysis program should be located in a secondary or tertiary center capable of evaluating and treating patients with all types of renal disease.

(b) In-hospital dialysis should be provided in a special facility created for that purpose or by moving the hemodialysis equipment to the bedside of the patient when considered medically necessary.

(c) An in-hospital dialysis program should function primarily as a supporting service to the transplant program and/or as a backup program for hospitalized patients who usually are dialyzing at home or in a limited care facility.

3. Services of Programs and Facilities for Hemodialysis

a. In order to maintain the highest standards of care for patients undergoing chronic hemodialysis, the artificial kidney complex shall provide the following:

(1) The establishment of a formal review mechanism for the evaluation of suitable candidates for chronic hemodialysis, including primarily medical, but also social, and psychiatric evaluation, either directly or from patient records, and a followup of patient experience.

(2) The establishment of a formal review mechanism for the evaluation of suitable candidates for homotransplantation.

(3) The artificial kidney complex shall be responsible to clearly delineate the commitment of this facility to the continued optimum care of the patient requiring hemodialysis.

(4) Suggested guidelines in choosing patients for hemodialysis and transplantation should be available to all primary physicians as well as to nephrologists and other members of the Health Care Team.

(5) Appropriate outpatient facilities for followup of patients on limited care and home hemodialysis.

(6) Consultative services to affiliated hemodialysis programs in a broad scope of matters related to chronic dialysis, including equipment selection, operation and maintenance, patient management, and patient training and rehabilitation.

(7) Treatment service capabilities shall include:

(a) Blood access (cannulas or fistulas), surgery and recovery

(b) Maintenance dialysis of patients who cannot dialyze themselves, and backup dialysis for patients at home or in limited care facilities

(c) Home dialysis training and supervision for patients and their families

(d) Followup of patients in affiliated programs, limited care units, and home, as indicated

(e) Laboratory facilities with necessary tests to evaluate and manage patients undergoing chronic maintenance hemodialysis including immunological facilities

(f) Vocational counseling and guidance for training, appropriate to the age and skills of the individual

(g) Education and training of medical and paramedical staff, and, when indicated, the patient and his family

(h) Collaboration and coordination with affiliated artificial kidney programs

(i) Affiliation with a renal homotransplantation program and its associated immunological laboratories

b. A self-dialysis training program shall provide:

(1) A training program that is capable of providing the patient with the complete breadth and depth of knowledge and confidence necessary for successful self-dialysis at home or in a limited care facility.

(2) A program of periodic review and updating of the patient's competence.

(3) The social and psychological supporting services which are essential to initial and long-term adjustment to home dialysis.

(4) Adequate capability for emergency servicing of equipment and preventive maintenance to minimize breakdowns.

(5) Up-to-date information on the best sources of hemodialysis supplies and drugs for self-dialysis.

c. A limited care dialysis program shall provide:

(1) The space and equipment for dialysis with the assistance of technical personnel or for self-dialysis with the assistance of family or friend.

(2) Since the chief reason for the existence of a limited care facility is to provide an inexpensive substitute for home hemodialysis, all other services should be provided through an artificial kidney complex.

d. An affiliated hemodialysis program shall provide only those services for which it is accredited to provide. All other services shall be provided by the sponsoring artificial kidney complex.

e. In-hospital dialysis programs should provide:

(1) Hemodialysis to all patients who require hospitalization. Even though there may be a separate in-hospital dialysis facility for backup dialysis of patients on chronic dialysis, the program should have the capability of providing acute hemodialysis at the bedside in certain other designated areas of the hospital, such as the intensive care unit or a transplantation unit.

(2) The full gamut of diagnostic and therapeutic services that are required to diagnose and treat any hospitalized patient with renal disease.

B. Pediatric Hemodialysis Resources

1. General Considerations

a. The incidence and problems of end-stage renal disease in the pediatric population is considerably different from those seen in the adult population. Therefore, the hemodialysis resources necessary for treatment are different and should be carefully planned based upon the population to be served as well as existing pediatric treatment facilities within the region. On the basis of present experience it can be estimated that one center providing comprehensive care for end-stage renal disease in children could effectively serve the needs of a population of 5-10 million.

b. The treatment facility for children in renal failure should ideally be located in a tertiary center which has an active program for management of renal failure in adults. Some programs have been developed or may be developed in the setting of a children's hospital. Strong working ties with proximate tertiary centers with programs for adults and the provision of all of the supportive departments and services described below are desirable.

2. Classification of Programs and Facilities for Hemodialysis of Children

a. General considerations

(1) Although one comprehensive treatment facility could serve a described region, every effort should be made to develop integrated programs with secondary or satellite centers in physically separate medical centers in the region where special expertise in diagnosis and management of pediatric renal disease exists. These secondary centers should possess the capability for diagnosis and management of chronic renal disease in children, including peritoneal dialysis, but would not have the capability for chronic hemodialysis and transplantation. They should serve as feeder satellites to the tertiary center and participate in management and followup of the successful transplantation.

b. Tertiary pediatric hemodialysis complex

(1) This center will have a similar description, as outlined in IV,A,2b(1) and 3a. In addition, since this facility deals primarily with children, specific additional characteristics are mandatory, as outlined below.

(2) The ability to assess the physical and emotional growth and development in the patient, and to evaluate the effects of the illness and its treatment on the family structure, and to develop effective means of dealing with these complex problems.

(3) The ability to provide acute and chronic dialysis and general pediatric support to an affiliated transplantation program, and to assist in the evaluation and management of children after transplantation, with particular regard to growth and development, social, psychological, and educational problems.

(4) The ability to provide consultative service and continuing education to referring physicians and secondary resources of the child's care.

(5) The ability to serve as training resources for all levels of health personnel involved in the center's programs.

(6) There should be ideally two or more pediatric nephrologists having 2 or more years' training in the diagnosis and care of children with renal disease who are responsible for the operation of this facility.

3. Services

In order to maintain the highest standards of care for children undergoing chronic hemodialysis, the regional pediatric hemodialysis center shall provide similar services as outlined under the artificial kidney complex services /IV,A,3a (105)/.

C. Transplantation Resources

1. General Considerations

a. Renal transplantation is defined as transplantation of a kidney from one individual to another. The kidney to be transplanted may be obtained from a living or cadaveric donor. Insofar as possible, transplantation should be effected on the basis of histocompatibility and the matching of major blood groups, and not performed when the crossmatch is positive.

b. The major criterion for designating a kidney transplantation center shall be its demonstration of potential ability to attract patients in sufficient numbers to maintain the competent expertise demanded by a superior program. A transplant center would qualify if any one of the following situations existed:

(1) The center should have the capability within 1 to 2 years of performing 50 or more kidney transplants per year. A center that has performed more than 50 transplants in the preceding year would be immediately designated as a transplant facility. If a center cannot demonstrate its potential of performing 50 or more transplants per year, it can qualify if it satisfies one of the following additional criteria.

(2) It must serve exclusively a population base of at least two million.

(3) If located within 50 miles of another center, as defined under (1), above, it must serve exclusively a population base of at least two million, or the combined population of the metropolitan area surrounding the two centers must exceed four million.

(4) If a center has satisfactorily demonstrated an outstanding research capability in the field of transplantation or would be located in a geographic isolated area (i.e., Hawaii), it could qualify as a transplant center.

(5) If the transplantation program is part of a total program specifically caring for children with end-stage renal disease and serving a population base, as outlined.

2. Essential Requirements

a. The renal transplant center shall be located in a general hospital, providing all the diagnostic and treatment facilities for patients with all forms of kidney disease, including general medical, both adult and pediatric, immunological, anatomic and clinical pathology surgical, urological, and radiological services, as needed. Operational integration or affiliation with a tertiary center or its equivalent is necessary to assure the availability of the full gamut of required consultative services.

b. Renal transplantation centers serving children shall have pediatric facilities as previously described within Section B. Such standards shall include the availability of a Board-certified pediatrician trained and experienced in pediatric nephrology assisted by a pediatric surgeon or urologist to supervise those pediatric cases.

c. Each renal transplantation center must have acute hemodialysis facilities to assure that all patients requiring dialysis prior to surgery or upon rejection of a donor kidney will have such treatment available to them.

d. Each renal transplantation center will have the capabilities of providing chronic hemodialysis within the institution, or have arrangements with qualified chronic hemodialysis units, to assure that those patients accepted for renal transplantation, who subsequently require chronic hemodialysis, will have such treatment available to them.

e. Accreditation of tertiary center by the Joint Commission on Accreditation of Hospitals is necessary for approval of the transplant center.

f. Each transplant center shall have two-way access to the information/communications system.

3. Services

a. The transplant center should have a committee with the chief of the transplant service as its chairman to supervise all renal transplantation activities in the institution.

b. Diagnostic and treatment facilities for chronic renal disease, as outlined in previous sections.

c. Consultative services to provide care for all problems related to transplantation and treatment of patients with end-stage renal disease, as outlined in Section III,C,D,E,F. In addition to the Professional Services as outlined, a transplant center should have ready access to the following:

(1) Tissue typing laboratory staffed by appropriately trained technician (supervised by a physician), with appropriate

space and resources to perform required histocompatibility testing and crossmatch.

(2) An organ procurement system supervised by a surgeon capable of procuring adequate number of organs for the transplant program.

(3) An organ preservation program. The basic requirements should include at least one pulsatile perfusion apparatus or other equipment of proven merit, and a technician capable of preparing a donor kidney for placement on the preservation apparatus. In addition, appropriate space should be available for maintenance and storage of equipment required for this function.

4. Staff Requirements

a. Medical

(1) This department of transplantation should consist of a minimum of one full-time surgeon (he may be a general surgeon or urologist) and another surgeon who is spending at least half time participating in the care of transplant patients. They should be Board-certified in their respective specialties. They should provide evidence of special training and experience in appropriate aspects of transplant surgery to insure high proficiency in renal transplantation.

(2) The transplant surgeon should participate in both the short-term and long-term post transplant care of the patient. The general long-term care of the patient should be in the hands of the patient's primary physician who, in most cases, will b an internist or a general practitioner, or a nephrologist.

The patient should be cared for, during early and late rejection, by a member of the team or the transplant surgeon. Other problems involving the patient, in which rejection is not a problem, may be cared for by the patient's primary physician.

(3) A nephrologist shall supervise the nephrology activities. For facilities serving children, a pediatric nephrologist or a pediatrician with experience and training in renal disease shall be on the staff, available to provide care for children with chronic renal disease, to participate in the selection of children for renal transplantation, and to provide followup care for patients treated by renal transplantation.

(4) A Board-certified urologist must be available to participate both in the preoperative and postoperative surgical evaluation and management of the transplant patient.

(5) Pathologists and other laboratory scientists who are certified in their respective specialties should supervise laboratory operations and coordinate these operations so that they may meet the needs of the clinical services promptly and effectively.

(6) Psychiatric or psychological consultation should be readily available for support and care of patients and families undergoing such treatment. For the care of the pediatric patient, a child psychiatrist or psychologist is essential.

(7) Each center must provide in-house physician coverage during the time patients are in the hospital. Centers may use the services of residents as part of a regular rotation system with other institutions.

b. Nursing

(1) Nurses participating in the care of patients undergoing renal transplantation shall have special training, with emphasis on the post-transplant care of the patient. Nurses caring for patients requiring hemodialysis post-transplantation will be required to be trained in hemodialysis procedures and techniques. Nurses caring for the pediatric patients, in addition to the above qualifications, should have specific training in the care of the acutely ill pediatric patients.

(2) Professional nurses may be assisted by licensed practical nurses and nurses' aides.

(3) In-service education must be an integral part of the operation of a transplantation unit.

c. Technicians

Technicians are frequently required to assist in the operation of the organ perfusion apparatus as well as in preparation and maintenance of the artificial kidneys that may be used during post-transplantation periods.

d. Social worker

Because of the intense social and emotional implications with patients and families requiring services from transplantation centers, social services should be available to assist during all stages of care.

e. Dietitians

Dietary aspects of patients post-transplantation shall be under the direction and supervision of the primary physician working with a professionally qualified dietitian meeting the American Dietetic Association standards, with training and experience in the management of therapeutic diets.

f. Vocational counseling

Vocational counseling, or its equivalent services, shall be provided by the Department of Rehabilitation.

g. Clinical and administrative personnel

Appropriate clinical and administrative personnel are required to assure maintenance of records, keeping up the inventory, handling personnel, public relations, and to compile patient followup data.

5. Physical Facilities

a. Operating room which shall be equipped with necessary equipment to accomplish transplantation performed on adults or children.

b. Provision shall be made for an intensive care unit, or an equivalent services thereof, for a minimal of 72 hours following transplant surgery.

c. Dialysis facilities for those patients requiring hemodialysis post-transplantation. The dialysis facilities should conform to the requirements described in the section dealing with hemodialysis.

d. Outpatient service shall be provided for the post-transplantation patients.

V

APPENDICES

APPENDIX I

CRITERIA FOR THE EVALUATION OF THE SEVERITY OF ESTABLISHED RENAL DISEASE

I. CLASSIFICATION OF SIGNS AND SYMPTOMS BY SEVERITY

This classification is designed to describe the severity of the clinical manifestations of renal disease which are displayed by the patient. The patient should be placed in the highest Class whose criteria are fulfilled.

Class I: Requires (a) plus one or more of (b) through (f):

- (a) No symptoms directly referable to renal disease
- (b) Fixed proteinuria ($>$200 mg/24 hours)
- (c) Repeatedly abnormal urine sediment or bacteriuria in properly obtained urine specimens
- (d) Demonstrable radiographic abnormality of the upper GU tract
- (e) Hypertension attributable to past or active renal disease
- (f) Biopsy-proven parenchymal renal disease

Class II: Any two or more of the following:

- (a) Symptomatic because of symptoms directly referable to the kidney (e.g., hypoproteinemic edema, dysuria, flank pain, renal colic, nocturia)
- (b) Radiographic evidence of osteodystrophy
- (c) Stable anemia attributable to renal disease
- (d) Metabolic acidosis attributable to renal disease
- (e) Severe hypertension (diastolic BP $>$ 110 mm. Hg)

Class III: Any two or more of the following:

- (a) Symptomatic osteodystrophy
- (b) Symptomatic peripheral neuropathy
- (c) Nausea and vomiting without primary GI cause
- (d) Limited ability to conserve or excrete usual dietary load of sodium and water; tending to sodium depletion, dehydration or congestive heart failure
- (e) Impaired mentation attributable to renal disease

Class IV: Any two or more of the following:

- (a) Uremic pericarditis
- (b) Uremic bleeding diathesis
- (c) Asterixis and severely impaired mentation, with or without convulsion
- (d) Hypocalcemic tetany

Class V: Coma

II. CLASSIFICATION OF RENAL FUNCTIONAL IMPAIRMENT

Exact classification (primary criterion) should be based on measurement of the glomerular filtration rate (commonly approximated by the creatinine clearance) when possible, since the plasma creatinine concentration may vary in the presence of muscular wasting and decreased creatinine production. When clearance values are unavailable, the plasma creatinine concentration (secondary criterion) may be used, but the subscript "c" should be added to the classification, e.g., Class D_c.

	PRIMARY	SECONDARY
Class A:	GFR normal	Serum creatinine normal
Class B:	GFR reduced 50%	Serum creatinine normal to 2.4 mg%
Class C:	GFR 20-50% of predicted normal	Serum creatinine 2.5-4.9 mg%
Class D:	GFR 10-20% of predicted normal	Serum creatinine 5.0-7.9 mg%
Class E:	GFR 10% of predicted normal	Serum creatinine 8-12 mg%
Class F:	GFR 5% of predicted normal	Serum creatinine 12 mg%

III. PERFORMANCE CLASSIFICATION

A description of what the patient thinks he is able to do and not what the physician thinks he should be able to do.

Class 1: Capable of performing all his usual types of physical activity

Class 2: Unable to perform the most strenuous of usual types of physical activity for that particular patient, e.g., sports activity, fast walking, running, shoveling, lawn mowing, etc.

Class 3: Unable to perform all his usual daily physical activities on more than a part-time basis, e.g., household duties, employment, driving an automobile, playing with children, etc.

Class 4: Severe limitation of usual physical activity. May need assistance for some facets of self-care, i.e., shaving, etc. Mentation may or may not be impaired. May be confined to bed.

Class 5: Semi-coma or coma

APPENDIX II

THE AD HOC COMMITTEE TO ESTABLISH CRITERIA FOR THE OPTIMAL FACILITIES NECESSARY FOR DIAGNOSIS AND MANAGEMENT OF PATIENTS WITH END-STAGE RENAL DISEASE

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RMPS POLICY STATEMENTS

The major thrusts of the health manpower efforts of RMPS are related to more effective utilization of existing manpower. Some of the ways of accomplishment are through linkages of educational and health care resources to make optimum use of limited resources and manpower; regionalization of resources and services; updating of knowledge and skills of health workers at all levels; redefinition of roles; expansion of functions of existing health manpower; development of interdisciplinary programs; attitudinal learning to overcome obstacles to changes in health care practices. In short, the manpower emphasis of RMPS is primarily on continuing education as a process to affect the manpower problem rather than on basic education to increase the manpower supply.

DEFINITION OF CONTINUING EDUCATION AND TRAINING

As an operational definition of continuing education, the following has been accepted: "Those educational endeavors which are above and beyond those normally considered appropriate for qualification or entrance into a health profession or an occupation in a health related field." Continuing education activities must not be designed principally to qualify one for a degree, diploma or certification; therefore, internship and residency programs have been excluded from primary consideration.

Continuing education and training activities should lead to the assumption of new responsibility in the already chosen career field, update knowledge and skills in the chosen career or add knowledge and skill in a different but basically related health field but not provide for career change.

POSITION ON BASIC EDUCATION AND TRAINING

Generally speaking, other agencies exist whose primary efforts are aimed at supporting supply and training of health manpower at the basic and post-graduate levels. However, because of the critical need in regions for basic training support not usually available from other Federal and non-Federal sources, Regional Medical Programs Service has developed policy in three areas affecting support of basic training: (1) health careers recruitment; (2) basic training in established allied health professions; and (3) basic training for the development of new types of health personnel.

(1) Health careers recruitment

RMP grant funds are not to be used for direct operational grant support of health careers recruitment projects. Regions are

encouraged however, to use staff assistance to stimulate cooperative efforts between professional associations, clinical resources, educational institutions and other appropriate agencies to provide new opportunities for recruitment into health careers. RMP funds may also be used in planning health careers recruitment activities as a part of and coordinated with the overall manpower strategy for the region.

(2) Basic training in established allied health professions

A health profession will be considered established if a Board of Schools of the AMA Council in Medical Education, or some similarly recognized mechanism, has been set up to approve schools, outline standards for admission, curriculum requirements and certification procedures, and/or if definitive formal educational programs in the particular health occupation have already been instituted in the educational and training systems of hospitals, technical schools, junior and senior colleges.

No RMP grant funds may be used for the cost of providing basic education and training in established allied health professions as defined above.

The use of professional staff assistance is encouraged as well as direct support of special planning studies to simulate educational institutions in conjunction with clinical resources to provide new educational and training opportunities in established allied health disciplines and to add new disciplines.

(3) Basic training for the development of new types of health personnel

Grant funds may be used for innovative training approaches and the development of new types of health personnel or new arrangements of health personnel to meet the Region's goal of improved patient care for those suffering from heart disease, cancer, stroke or related diseases. Some of these activities may fall into the category of basic education.

Training of new types of health personnel is defined as that training which relates to newly developing technologies of new modalities of diagnosis and treatment for which no standard curriculum is yet recognized, no minimum national standards for certification or licensure are yet established and which is not generally part of the regular offerings of the health-related educational and training system of hospitals and/or technical schools, junior and senior colleges.

DEFINITIONS OF SHORT AND LONG TERM TRAINING

(1) Training conferences and seminars

Presentations which are planned full-time participation for periods from one full day to five consecutive days, or intermittently on a regular basis.

(2) Short-term training

Activities which are planned for full-time participation for more than five consecutive days, but not more than a single academic session (quarter or semester).

(3) Long-term training

Activities requiring full-time participation for more than a single academic session (quarter or semester).

SPECIFIC POLICIES

(1) Training for coronary care unit

Coronary care unit training projects are to disengage Regional Medical Program funding at the end of their current project periods or within a reasonable time thereafter (no more than 18-24 months is considered as a "reasonable period of time").

(2) Cardiopulmonary resuscitation training

Regional Medical Program grant funding for projects in cardiovascular resuscitation training must be limited to activities which are directed principally to medical and allied health personnel. Such personnel must be employed in hospitals and other in-patient facilities, or in out-patient or emergency facilities operated by or directly related to institutions which can provide immediate follow-up care.

STIPENDS*, PER DIEM AND TRAVEL

(1) Training conferences and seminars

Stipends are not authorized for training conferences and seminars.

(2) Short-term training

Grant funds may not be used for the payment of stipends, either directly or on the "maintenance of income principle", to participants in short-term continuing education and training projects.

Grant funds may be requested and awarded for 50 percent of the total amount budgeted for per diem and travel for the trainees. The awarded funds may then be paid to the enrolled trainees as considered appropriate by the project personnel, depending on the participants' ability to provide these costs for themselves, and/or the willingness of their employers to provide them. No single individual may receive per diem or travel allowance at a rate higher than that prescribed by the present Addendum-Guidelines.

Grant funds may not be rebudgeted, from within or without the project budget, to increase the total amount awarded for per diem and travel above the 50 percent level.

(3) Long-term training

Payment of stipends and other participant costs for long-term post-doctoral support at the senior resident and post-resident levels, particularly in the clinical sub-specialties of importance in patient management in the diseases targeted by Regional Medical Programs Service, may not be made from operational grant funds awarded under Section 904 of Title IX of the Public Health Service Act.

*EXCEPTION

Stipends for training for new types of health personnel is an exception and may be supported with RMP funds.

EDUCATIONAL TECHNOLOGY

An advice letter to the Regions covering the planning, equipment requirements, costs, utilization and evaluation of technology for educational purposes was sent to the Coordinators in January, 1971. The theme of the letter is guidance for effective use of technology within the context of Regional Medical Program operation.

AN ECONOMIC MODEL AS A HEALTH DECISION MAKING TOOL*

Implementation of A National Kidney Program

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I. INTRODUCTION

Nowhere in the health care industry does the same gap exist between technology and delivery as in the area of treatment of patients with end-stage renal disease. Technologic developments in the past ten years have made possible the rapid expansion of programs to provide patients with chronic dialysis therapy. The development of remarkable innovations that allow self-dialysis by the patient or a member of his family in their home has been a major step in making this a practical approach. Techniques of organ harvesting, preservation, and transplantation have made renal homotransplantation a service entity and no longer a research tool. However, the funding mechanisms to develop the resources have lagged far behind. A conservative estimate is that annually 7,000 ideal candidates for end-stage therapy will die of renal disease unless they receive either a successful transplant or chronic hemodialysis therapy. Hard data are lacking but best estimates indicate that one half of the ideal candidates for treatment and many others who would benefit from treatment are not receiving vital therapy.

Severe restraints to development of necessary resources have been the high costs, particularly the costs of institutional dialysis. This paper presents a plan in which an integrated approach to end-stage therapy is proposed.

Transplantation and home dialysis will be the treatments emphasized. The goal of the plan is to provide access to care for all Americans suffering from end-stage renal disease who meet medical criteria for maintenance therapy. Details of this plan will be provided in succeeding pages. The benefit-cost model described has been developed to help guide the implementation and evaluation of the "life plan". Criticisms of the benefit-cost models are particularly welcome since these models are constantly being modified and changes can quickly be analyzed.

II. BACKGROUND

Most past and current federal initiatives in the kidney disease area have had an orientation toward research or demonstration. NIH funding has played a prominent role in the development of much of the technology currently being applied in renal disease treatment. The Kidney Disease Control Program of the Regional Medical Programs Service has funded a series of demonstration projects to prove the feasibility of center dialysis, home dialysis, limited-care dialysis, and organ procurement systems. These demonstration projects are being completed and their success has been such that new federal initiatives are being directed toward the provision of these services to all Americans with end-stage renal disease. The Veterans Administration has an extensive program which is expected to treat 400 new patients each year using

equal mixes of dialysis and transplantation. The Social and Rehabilitation Service of DHEW is providing funds to kidney disease patients for vocational rehabilitation. In many states, Medicare, Medicaid, and specific state legislation provide additional moneys for kidney disease. Local criteria determine the coverage and regional variation is extreme.

The Division of Professional and Technical Development of the Regional Medical Programs Service has assumed responsibility for development of a plan to be implemented through the local Regional Medical Programs to ensure the efficient use of resources in a national endeavor to provide end-stage renal therapy (primarily transplantation and home dialysis training) in a limited number of tertiary treatment centers. A limited investment of $80 million over five years for developmental costs has been requested. Long-range, direct patient-care costs would be met by the usual medical payment mechanisms.

III. THE "LIFE PLAN"

The goal of the proposed health initiative is the efficient provision of medical care to all suitable candidates for end-stage renal therapy. The initiative consists of a five-year program providing major thrusts in areas of prevention; public education; research; and, particularly, development of resources for patient care. The following paragraphs will discuss each of these thrusts.

A. Prevention

Methods of primary prevention are essentially nonexistent. Research and development efforts will be pursued to develop methods. Secondary prevention is possible to a significant degree in the areas of urinary tract infections and hypertension. The initiative would fund screening programs for high-risk groups with these diseases and rely on regular patient-care reimbursements to pay for treatment costs. Estimates are that 6% of the funds allocated would be used in this field.

B. Public Education

Emphasis would be placed on consumer education concerning the warning signs of renal disease, high-risk population groups, preventive measures, services available and importance of continuity of care. A side benefit from this program should be an increase in organ donations so that cadaver kidney organ procurement would be facilitated. Some funds will be used to provide continuing education of primary physicians to acquaint them with the entire initiative. Plans are to use 6% of the funds available in this area.

C. Research and Development

Efforts will be geared toward two major activities. The first deals with etiology and prevention, and the second deals with the

technology of maintaining "end-stage" patients. Basic research is still needed to elucidate the mechanisms of development of chronic renal disease. As these are clarified, primary preventive measures can be developed.

The technology needed to maintain patients revolves around better matching of donors and recipients, control of the rejection phenomenon, improved home and/or portable dialysis units, etc. These activities will continue to be monitored by the National Institutes of Health. Twenty percent of the funds would be used in this research and development effort.

D. Tertiary Treatment Centers

The first assumption made during this planning effort was that any patient with irreversible chronic renal disease in the United States, who met the medical criteria, should have access to care. This means that sufficient facilities should be available to accept all such patients and that these facilities should be reasonably accessible. Further, all patients should have care without regard to income or social status. It was especially felt that no family should have to become "pauperized" before financial assistance was available.

In determining resources, it has been the feeling that every effort should be made to use renal transplantation as the treatment

of choice for patients with irreversible chronic renal failure. Home hemodialysis would be utilized as a second choice for those patients in whom transplantation was not feasible or donor organs were not available. As a last resort, some form of chronic institutional dialysis would be offered. It is our expectation that three-quarters of all newly referred cases will be candidates for transplantation and approximately three-quarters of the remainder will be candidates for home hemodialysis. Institutional facilities will have to be available for the remaining patients and those in whom rejection of the transplant occurs. Specific objectives are to develop tertiary treatment centers with facilities for renal homotransplantation and home dialysis training located throughout the country at an average of approximately 1 per 3-4 million population. Transplant centers would be expected to perform a minimum of 50 transplants per year with a goal of 75-100. Plans for the treatment of pediatric renal disease indicate a caseload of 600 new patients annually. Ten centers would need to be identified to treat this special group of patients.

The Department of Health, Education and Welfare, through the Health Services and Mental Health Administration and the Regional Medical Programs Service, has already provided funds for start-up costs

for renal transplantation units and has selectively funded start-up costs for home dialysis training programs. Completion of this activity would utilize 62% of the projected program cost.

E. Referral Linkages

The key to efficient utilization of the tertiary treatment centers lies in the development of effective patient referral patterns. Primary treatment will be provided by local physicians who will treat most of the acute events of kidney patients and provide local surveillance of home dialysis and post-transplant patients. Secondary care centers are represented by selected physician offices and designated community hospitals which are ordinarily within an hour's travel of the patients served. These secondary centers will provide specialized diagnostic evaluation and maintain close linkage with tertiary centers for hemodialysis and homotransplantation. Tertiary care centers will be located in major medical facilities. These centers will initiate dialysis, provide home dialysis training, coordinate cadaver kidney organ procurement, provide transplantation surgery and intensive care services, and support research to improve end-stage kidney disease patient care. Physician education and the communication system will be two tools used to strengthen relationships among the three levels.

F. Communication System

To coordinate the activities of this life plan and to develop information for better organ procurement and sharing, a national communication network has been proposed. Information about all patients with end-stage renal disease, whether or not they have begun dialysis or have had a transplant, would be fed into this communication network. Six percent of the funds requested would be used to develop the Communications System.

IV. BENEFIT COST MODEL

A. Problem

The central question addressed in the model can be expressed as follows: Assuming all 7,000 candidates for end-stage therapy are treated in a given year, what are the discounted costs and benefits to society over a 20-year period. Once this question has been answered for a specific set of assumptions, the sensitivity of the model to variations in the assumptions will be examined and the effects of possible advances in the state of the art can be investigated.

B. Methods

All the benefits and costs were obtained by cohort analyses. The basic cohort studied in this paper consists of the 7,000

ideal candidates for end-stage treatment in a given year. Analysis of long-range costs and benefits involves prediction of future events. Assumptions regarding the probabilities of significant events form the heart of this model and will be explicitly stated in every case. Table 1 presents the assumptions used in deriving the results in the basic model. Many of the assumptions listed in Table 1 are subject to dispute. We have some evidence, obtained from our contractors and the literature, to support all assumptions, but an important aspect of the model is an investigation of the effect of variations in the assumptions.

A computer program has been written which carries out the entire analysis shown in this paper. It is thus a simple matter to consider any particular set of assumptions and derive a complete benefit-cost analysis. Tables 2, 3 and 4 reflect the assumptions detailed in Table 1.

Table 2 shows the number of patients expected in each category during each year. Notice that we are considering in this first model only the cohort of 7,000 patients presenting themselves in a given year. A more complete analysis will follow in the discussion section where a new cohort of 7,000 patients is analyzed each year over a ten-year period. It is assumed that 5,000 of the 7,000 patients will receive a transplant. Extensive use of

cadaveric kidneys will be required, and some national system for efficient utilization of potential donors will be necessary.

Table 3 lists the costs and benefits discounted to the first year in order to provide a common frame of reference.* The assumed transplantation cost of $13,750 includes $3,750 for 6 months of maintenance dialysis before the operation and $10,000 for cost of the operation and follow-up. An annual cost of $1,000 is assumed for each year after the transplant to cover follow-up and any necessary treatment. The "average" dialysis cost of $7,500 assumes primary use of home dialysis, with moderate-cost training methods, secondary use of a low-overhead facility, and only very limited use of hospital dialysis.

The data presented in Table 4 summarize the information contained in the model. A conservative approach has been adopted wherever the assumptions had the least validation. For example, no benefits are assumed for the first year, although certainly some dialysis patients can be quickly trained and rehabilitated, and some transplant recipients will be working soon after the operation. The benefit-cost ratio is calculated by summing the total

* Discounted annual transplantation cost is computed by multiplying the discount factor by the sum of the product of the number of operations during the year times the cost of an operation and the product of the number of surviving transplant patients times the annual maintenance cost. Total transplantation cost is calculated by summing these discounted annual costs. Other costs and benefits are calculated similarly.

discounted dialysis and transplantation benefits and dividing by the sum of the total discounted dialysis and transplantation costs. Notice that, under this set of assumptions, benefits outweigh costs in the second and all subsequent years, but the heavy load of costs in the first year is never balanced.

C. Discussion

The model described in Section III has an obvious use in the immediate assessment of the economic benefits involved in a particular medical expenditure pattern. Probably a more practical use of such a model is in the economic comparison of alternative approaches to disease treatment. A single benefit-cost ratio provides limited information; a comparison of benefit-cost ratios for alternative programs can provide an efficient tool for decision making.

The following example illustrates one possible application of benefit-cost analysis. A change in the first year treatment pattern to 6,000 transplants and 1,000 dialysis patients substantially increases the benefit-cost ratio if other factors are unchanged. However, it is likely that such a change in treatment pattern would raise transplant mortality and rejection rates. The assumption made here is that first year transplant mortality and rejection rates would increase from 20% to 25%. Table 5

presents benefit-cost figures for these changes in treatment pattern and mortality-rejection rates. Comparisons with Table 4 indicate that, under these assumptions, the increased number of transplants can be performed only at the cost of a small drop in the benefit-cost ratio.

A myriad of questions suggest themselves. Using the computer program, a numerical analysis can easily be performed providing a benefit-cost ratio figure for any specific set of assumptions.

Another approach to the investigation of sensitivity in the model uses an analytical expression for the benefit-cost ratio. Derivatives are calculated using methods of elementary calculus. These derivatives provide an approximation to the change in the benefit-cost ratio per change in any independent variable. Table 6 shows the results of a sensitivity analysis performed using these methods for those independent variables where differentiation is practical. Note that results shown in Table 6 are on an absolute basis. The practical range of possible change in any assumption must be weighed in evaluating the results shown in Table 6.

Discussions to this point have been limited to the simplistic model of one cohort followed for 20 years. Planning a long-range

federal program requires the use of models in which the new cohort of patients presenting themselves each year is analyzed. Results are based on examination of a series of cohorts. If each cohort is followed for the same length of time (for example, 20 years), the benefit-cost ratio has the same value for a single cohort as it has for a series of cohorts. However, a different type of question is often asked by program administrators. At the end of ten years of this program, what will be the realized benefits and costs? Note that patients first treated in the first year will have nine years of possible benefits, whereas patients first treated in the tenth year will have no opportunity to accrue any benefits before the time of accounting. Obviously, benefit-cost ratios calculated under this cut-off method will be substantially lower than under the 20-year follow-up system. Table 7 contrasts BCR's calculated using the two models with several sets of assumptions.

Criticisms of potential earned income as a measure of benefits have led to an alternative form of analysis. Cost-effectiveness analysis is a method wherein costs of treatment are weighed against increased years of patient survival to provide an estimate of cost per life year of treatment. Table 8 lists cost per life year for several sets of assumptions. Notice that the dialysis

cost per life year is calculated to be less than the assumed annual dialysis cost because of the discounting procedure.

The approach taken here is that estimated benefits are useful enough to provide comparisons with estimated costs that can lead to benefit-cost ratios which may serve as one criterion in policy planning. Since many benefit and cost elements may not be measurable, either because they are indirect, or because they are not quantifiable with present techniques, policy decisions can never be made using benefit-cost criteria alone.

V. CONCLUSION

The state of the art in technology and medical care delivery have reached a point where a coordinated national kidney program would have maximum impact. Benefit-cost models show such a program to be feasible. The current level of RMPS spending for kidney disease projects is in excess of $8 million per year. These funds and future RMPS funds are being channeled into projects designed in accordance with the "life plan" concept. Renal specialists will continue to be used to review projects and evaluate progress in fulfilling the national program.

TABLE 1

ASSUMPTIONS USED IN BASIC MODEL

1.	Annual Mortality Rate for Dialysis Patients	15%
2.	Average Annual Cost for Dialysis	$ 7,500
3.	Transplant Death Rate in First Year	20%
	Second Year	10%
	Subsequent Years	5%
4.	Transplant Rejection Rate in First Year	20%
	Second Year	10%
	Subsequent Years	5%
5.	One half of transplant rejections receive another transplant within one year.	
6.	Cost of Transplant Operation (Include 6 months dialysis)	$ 13,750
7.	Average Annual Maintenance Cost After Transplant	$ 1,000
8.	Mean Annual Income (Member of Labor Force)	$ 8,000
9.	Transplant Rehabilitation Rate	80%
10.	Dialysis Rehabilitation Rate	60%
11.	Discount Rate	4%
12.	No benefits are credited for first year.	

TABLE 2

PATIENT DISTRIBUTION

Year	Number of Transplants Performed	Number of Surviving Transplant Recipients	Number of Dialysis Patients	Number of Deaths
1	5000	0	2000	0
2	500	3000	2200	1300
3	200	2700	2070	730
4	95	2520	1854	500
5	75	2313	1652	429
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10	47	1498	936	250
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15	30	970	546	152
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20	20	628	327	93
21	18	576	296	85

TABLE 3

DISCOUNTED BENEFITS AND COSTS

Year	Transplant Costs	Transplant Benefits	Dialysis Costs	Dialysis Benefits
1	$ 71,000,000	$ 0	$ 14,000,000	$ 0
2	10,000,000	18,000,000	15,000,000	10,000,000
3	5,000,000	15,000,000	14,000,000	9,000,000
4	3,000,000	14,000,000	12,000,000	8,000,000
5	3,000,000	12,000,000	10,000,000	7,000,000
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10	1,500,000	6,500,000	4,800,000	3,000,000
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15	800,000	3,500,000	2,000,000	1,500,000
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20	400,000	1,800,000	1,100,000	700,000
21	370,000	1,600,000	1,000,000	600,000

TABLE 4

RESULTS IN BASIC MODEL

Total Discounted Dialysis Costs	$ 122,000,000
Total Discounted Transplant Costs	109,000,000
Total Discounted Dialysis Benefits	69,000,000
Total Discounted Transplant Benefits	137,000,000
Benefit-Cost Ratio	.89
Dialysis Cost Per Life Year	$ 6,288
Transplant Cost Per Life Year	3,515

TABLE 5

RESULTS IN MODIFIED* MODEL

Total Discounted Dialysis Costs	$ 96,000,000
Total Discounted Transplant Costs	128,000,000
Total Discounted Dialysis Benefits	57,000,000
Total Discounted Transplant Benefits	139,000,000
Benefit-Cost Ratio	.87
Dialysis Cost Per Life Year	$ 5,924
Transplant Cost Per Life Year	4,038

* Change number of transplants in first year from 5,000 to 6,000
Change number of dialysis patients in first year from 2,000 to 1,000
Change first year transplant mortality rate to 25%
Change first year transplant rejection rate to 25%

TABLE 6

SENSITIVITY ANALYSIS

Variable	Sensitivity Per Unit Increase
Transplant Cost	-.024/1,000 dollars
Annual Transplant Maintenance Cost	-.11/1,000 dollars
Dialysis Rehabilitation Rate	.007/percentage point
Transplant Rehabilitation Rate	.008/percentage point
Annual Dialysis Cost	-.09/1,000 dollars
Mean Annual Income	.13/1,000 dollars

TABLE 7

BENEFIT-COST RATIO EXAMPLES

	B.C.R. 20 Year Follow-Up	B.C.R. 10 Year Cut-Off
Basic Model	.89	.59
Modifications of Assumptions*		
6,000 Transplants in First Year	.98	.62
Annual Income $10,000	1.11	.73
Cost of Transplant $7,500	1.06	.75
Annual Dialysis Death Rate 20%	.92	.58
Dialysis Cost $5,000	1.08	.68
Transplant Rehabilitation 60%	.74	.49
Dialysis Rehabilitation 40%	.79	.52
Annual Dialysis Death Rate 10%	.86	.59

* Each example depicts a change in only one assumption. Multivariate comparisons of simultaneous variations have also been undertaken using the computer programs. Results are not tabulated here.

TABLE 8

COSTS PER LIFE YEAR

	Dialysis Cost Per Life Year	Transplant Cost Per Life Year
Basic Model	$ 6,288	$ 3,515
Modifications of Assumptions*		
6,000 Transplants in First Year	5,880	3,515
Annual Income $10,000	6,288	3,515
Cost of Transplant $7,500	6,288	2,317
Annual Dialysis Death Rate 20%	6,702	3,515
Dialysis Cost $5,000	4,192	3,515
Transplant Rehabilitation 60%	6,288	3,515
Dialysis Rehabilitation 40%	6,288	3,515
Annual Dialysis Death Rate 10%	5,860	3,515

* Each example depicts a change in only one assumption.

HEALTH INITIATIVE

CONTROL OF THE RAVAGES OF KIDNEY DISEASE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Health Services and Mental Health Administration

Regional Medical Programs Service

February 14, 1972

Table of Contents

APPENDICES

SUMMARY

The proposed federal health initiative "Control of the Ravages of Kidney Disease" is a five-year program totaling $80,000,000 of new investments that will provide a major thrust at prevention, public education, research and development for patients with kidney disease. The treatment phase would assure that an adequate number of tertiary renal treatment centers would be developed to provide the resources for treatment of all patients with end-stage renal disease who were medically suitable as candidates for therapy. Th cost benefit model (Appendix E) describes how this investment would result in a net economic gain of $273,000,000 over ten years.

INTRODUCTION

The economic impact of diseases of the urinary tract was estimated to be $3,635,000,000 in 1965 for the United States. The Kidney Disease Control Program of the United States Public Health Service estimated that during that fiscal year there was a prevalence of 7,847,000 cases of kidney disease leading to 139,939,000 days of restricted activity including 63,494,000 days of bed disability, 16,729,000 days of work loss in the United States, and nearly 50,000 deaths. It is estimated that on a National basis the death rate from primary renal diseases is 28 per 100,000. Deaths from urinary tract disease are only exceeded by deaths due to heart disease, cancer, cerebral vascular accidents and accidents. It is estimated that 7,000 to 10,000 of the patients who die with chronic renal disease are suitable candidates for chronic hemodialysis and/or renal transplantation and that an additional 10,000 to 20,000 would benefit from such treatment but other systemic illnesses render them poor medical risks. This initiative would provide the resources to treat those 7,000 to 10,000 patients. At the present time there are approximately 5,000 patients on dialysis throughout the country. Between 1,000 and 3,000 of them are awaiting renal homotransplantation.

The primary functions of the kidney are to:

1. regulate water balance,
2. regulate dissolved solute balance,
3. eliminate nitrogenous and other waste products, and
4. regulate blood pressure.

The majority of patients with chronic renal disease come to the physician with an inability to regulate one or more of the above functions.

There is little information concerning the natural history of the various renal diseases that lead to the patient with terminal renal disease. It is felt that many of the patients with chronic pyelonephritis (chronic infection of the kidney) result from inadequately treated cases of acute pyelonephritis. It is estimated that four to six million cases of unknown infections of the urinary tract exist in the United States. Thus the prevalence of renal disease may be much higher than the estimates listed above. Bacteriuria in pregnancy is a forerunner of essentially all cases of acute pyelonephritis of pregnancy and many of these are thought, if inadequately treated, to become chronic pyelonephritis. It is known that with hypersensitivity diseases the majority of the patients with acute poststreptococcal glomerulonephritis ("Bright's Disease") who survive the initial acute episode have complete recovery. Some investigators feel that essential hypertension is often associated with chronic pyelonephritis.

Current knowledge allows no primary prevention of chronic renal disease with the exception of those patients:

1. who are detected to have abnormalities of the collecting and excretory system which may be surgically corrected,

2. those who have prompt treatment of cases of beta hemolytic streptococcal infections which in some patients may prevent acute glomerulonephritis.

Secondary prevention is possible in three areas:

1. Bacteriuria and urinary tract infections. At the present time a large number of patients with bacteriura and/or acute urinary tract infections are receiving inadequate antibiotic therapy. There is no accepted length for antibiotic therapy but a minimum course should be fourteen days and possibly longer. There have been studies that suggest that a urinary antiseptic should be continued for six months after the initial treatment. Many patients with bacteriuria and/or infection have anatomic abnormalities which should be carefully sought for and corrected whenever possible. Patients with indwelling urinary catheters are very likely to develop urinary tract infections unless scrupulous care and "closed system" drainage are used. Men with prostatic hypertrophy are prone to infection unless prostatic resection is performed. Children with bed-wetting problems are frequently found to have mild congenital anomalies and secondary infections.

2. Hypersensitivity diseases. There are certain hypersensitivity diseases in which it is felt that prompt treatment with corticosteroids may reduce the incidence of renal complications. These include some cases of periarteritis nodosa and disseminated lupus erythematosus.

3. Hypertension. It has been demonstrated that control of severe hypertension will prolong life and reduce morbid events. There is recent evidence to show that the treatment of mild to moderate hypertension will lower morbidity and/or mortality rates; thus, hypertension control will improve the outlook of thousands of patients.

During the past 15 years the technique of hemodialysis has been demonstrated to be practicable for the treatment of acute renal insufficiency and more recently for the maintenance of patients with chronic renal disease on a prolonged basis. Hemodialysis is the "cleansing of blood" by passing it along semipermeable membranes with a specially prepared bath solution on the outside. The blood is then returned to the patient. Unwanted substances are removed during this process. Hemodialysis may be performed in hospitals or other centers on an inpatient or an outpatient basis and in selected candidates may be performed in the home by members of the family. This form of therapy has passed through the investigative phase and is currently accepted as a conventional form of therapy for those patients in whom it is indicated.

More recently transplantation of kidneys from living donors or from cadaveric donors has proven to be an effective method of prolonging life for patients in whom it is indicated. Over two-thirds of these patients become rehabilitated to a level equivalent to their pre-illness state.

HEALTH INITIATIVE

The health initiative is focused on 4 key elements:

Prevention

Public Education

Research and Development

Tertiary Treatment Centers

Over the course of 5 years the Federal Government can develop adequate resources to assure access to health information and treatment for all citizens suffering from renal disease. The estimated total cost is $80,000,000 allocated as follows:

Prevention	$ 5,000,000
Public Education	$ 5,000,000
Research and Development	$15,000,000
Tertiary Treatment Centers	$50,000,000
Communication System	$ 5,000,000

The lead agency for implementation and evaluation would be the Regional Medical Programs Service. The National Institute of Health would assume responsibility for administering the Research and Development portions ($15,000,000) through the National Institute of Allergy and Infectious Diseases and the National Institute of Arthritis and Metabolic Diseases. Parts of the budget are detailed in Tab B.

PREVENTION

As mentioned previously, methods of primary prevention are essentially non-existent. Research and Development efforts will be pursued to develop methods.

Secondary prevention is possible to a significant measure in two areas:

Urinary Tract Infections

Hypertension

Urinary Tract Infections. Attention will be devoted to high-risk populations (e.g., young girls, pregnant women, men over 45) for screening and referral for acute treatment. The initiative will fund screening programs and rely

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be utilized as a second choice for those patients in whom transplantation was not feasible or donor organs were not available. As a last resort, some form of chronic institutional dialysis would be offered. It is our expectation that three-quarters of all newly referred cases will be candidates for transplantation and approximately three-quarters of the remainder, candidates for home hemodialysis. Institutional facilities will have to be available for the remaining patients and for those in whom rejection of the transplant occurs.

The paucity of information about the natural history of renal disease makes planning a difficult and imprecise tool. Figure 1. illustrates some of the "uncontrollable variables" which must be considered in establishing a regional plan. Technologic or other research advances will lessen the need for expansion of dialysis centers. The "controllable variables" represent items that society in general and the medical profession in particular can alter. These two sets of variables lead to "value variables" which are the outcome or effectiveness measures of the system. At this time, there is insufficient information to allow construction of a true "cost-effectiveness model."

Figure 1.

Factors Involved in
Planning a Renal Disease Program

Uncontrollable Variables	Controllable Variables	Value Variables
1. Number of cases occurring	1. Registry of all cases	1. Preventable deaths
2. Predilection for race, sex or socio-economic factors	2. Criteria for acceptance of patients into program	2. Decreased disability days
3. Geographic location of cases	3. Level of financing available	3. Decreased hospitalizations for chronic renal disease patients on treatment
4. Intercurrent illness or other disease developing	4. Capacity of centers for Dialysis and Transplantation	4. Extended years of life
5. Technology and other research advances	5. Level of staffing available	5. Rehabilitation potential
	6. Therapeutic method selected: Transplantation Dialysis, home Dialysis, institutional	6. Lack of welfare need for patient and/or family
		7. Contribution to economy (income tax, etc.)
		8. Resource utilization (dollars, space, manpower)

A "Life-Plan" for the treatment of patients with end-stage renal disease is proposed. The goal of the plan is to provide tertiary treatment center resources for home dialysis training and renal homotransplantation so that all Americans who suffer from end-stage renal disease and meet the medical criteria for maintenance therapy will have access to care. Specific objectives are to develop a minimum of 50 tertiary treatment centers with facilities for renal homotransplantation and home dialysis training located throughout the country at an average of approximately 1 per 3-4 million population. A second objective is to prevent duplication and under-utilization of services. The specific elements to achieve these objectives are that a Federal program, administered by the Health Services and Mental Health Administration (through the Regional Medical Programs Service), will selectively fund medical centers which demonstrate the capacity to perform this service. A decremental funding pattern will be utilized. Continuation costs of these centers will be borne by patient care reimbursement mechanisms. The plan makes the following assumptions:

1. The average life extension will be seven years or more;

2. The rate of entry will be unchanging over the next five years;

3. Mechanisms for payment for direct patient services will develop as the resources to provide the services become available (through Title XVIII, XIX, NHISA, Blue Plans, etc). There will be Federal-State cooperation in developing these mechanisms.

4. A coordinated plan can be implemented with the voluntary cooperation of the health providers. This type of plan has already been enthusiastically endorsed by leading nephrologists.

The special kidney elements to be developed in major medical centers so that they may be designated tertiary treatment centers are listed in figure 2, page 8.

System for Delivery of Care to Patients with Renal Disease

Figure 2 is a schematic model of the proposed system. Three levels of care will be available. The primary treatment center will be the local physician whether generalist, internist, pediatrician, urologist, etc. Essentially all cases of acute renal disease will be seen at this level. With proper education during training years and a strong postgraduate continuing education program, these physicians will provide a high level of expertise and care to patients. It is expected that supervision of most of the patients in the post-transplantation period and those on home dialysis will occur at this level. These physicians are already in practice and needs here are to provide continuing education and to strengthen the referral mechanisms.

The secondary care centers will involve physicians with specialty training in dealing with patients with acute and chronic renal disease. Some will be physicians' offices, some will be clinics and some will be hospitals. These centers would also be referral centers for patients from both primary and tertiary care centers. They should be strategically located throughout the region ideally so that no patient would have to travel more than one hour to receive care (40-60 miles).

The tertiary level of care will be centered in major medical centers. Services available at this level are listed in Figure 2. Organ procurement and sharing and tissue typing must be coordinated with the other regions as well.

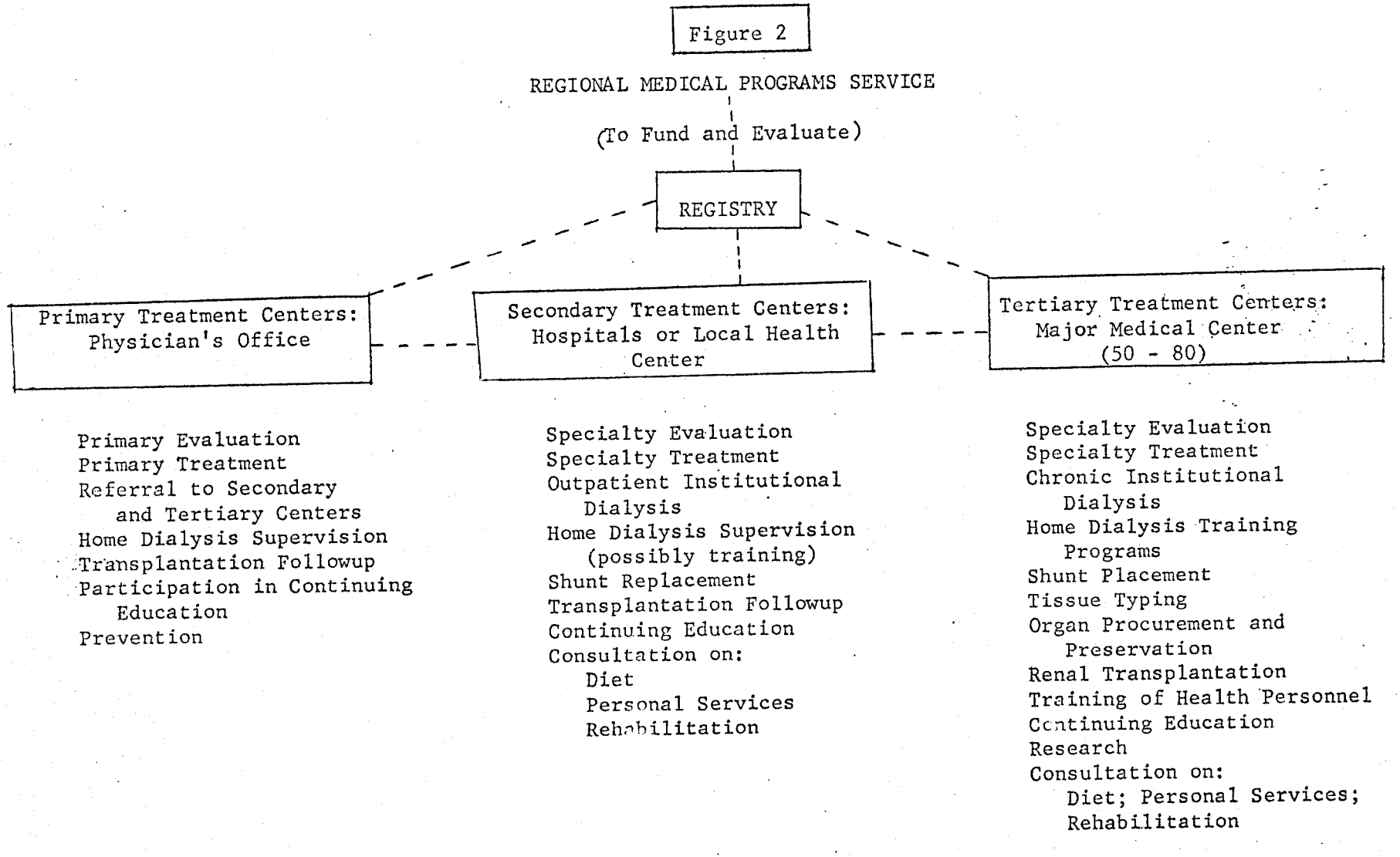
Primary and secondary treatment centers are to be developed from existing resources. Tertiary treatment centers will be developed in existing major medical centers. The emphasis will be to develop this system as a subsystem of a comprehensive health care delivery system.

Plan

It was estimated by the Gottschalk Report submitted in 1967 to the Bureau of the Budget that 7,000 to 10,000 patients are considered to be suitable candidates for supportive care and would be expected to achieve a 75% level of rehabilitation to their pre-terminal illness activities. Therefore, it would seem appropriate that a strategy be developed for the entrance of these 7,000 to 10,000 patients per year into a coordinated plan of health care delivery.

Tertiary Treatment Centers for Renal Disease Patients are to be developed for every three to four million residents. These Centers will combine the resources of hemodialysis and renal homotransplantation with conservative management as modalities of treatment for patients identified. As soon as a patient is diagnosed as having chronic progressive renal disease he is to be entered into the registry and referred to the center for that region to be entered into the long-range "life plan." Emphasis in this "life plan" will be placed upon early homotransplantation. At the present time cadaveric transplantation seems to be the most practical.

Figure 2


REGIONAL MEDICAL PROGRAMS SERVICE
(To Fund and Evaluate)
REGISTRY
Primary Treatment Centers: Physician's Office
Secondary Treatment Centers: Hospitals or Local Health Center
Tertiary Treatment Centers: Major Medical Center (50 - 80)
Primary Evaluation
Primary Treatment
Referral to Secondary and Tertiary Centers
Home Dialysis Supervision
Transplantation Followup
Participation in Continuing Education
Prevention
Specialty Evaluation
Specialty Treatment
Outpatient Institutional Dialysis
Home Dialysis Supervision (possibly training)
Shunt Replacement
Transplantation Followup
Continuing Education
Consultation on:
Diet
Personal Services
Rehabilitation
Specialty Evaluation
Specialty Treatment
Chronic Institutional Dialysis
Home Dialysis Training Programs
Shunt Placement
Tissue Typing
Organ Procurement and Preservation
Renal Transplantation
Training of Health Personnel
Continuing Education
Research
Consultation on:
Diet; Personal Services; Rehabilitation

It is estimated that 60 to 80 percent of the patients entering the program will be suitable candidates for transplantation. Of the remaining 20 to 40 percent of patients, some form of long term hemodialysis is indicated. It is estimated that of the hemodialysis patients, three quarters will be entered in a home dialysis training program for treatment in their homes or at low cost satellite ambulatory care centers. The remaining will require institutional treatment because of the severity of their condition or for some other medical or social reason.

The Department of Health, Education and Welfare through the Health Services and Mental Health Administration and the Regional Medical Programs Service will fund the start-up costs for renal transplantation units and selectively fund start-up costs for home dialysis training programs.

Communication System

To coordinate the activities of this life plan and to develop information for better organ procurement and sharing, a national communication network will be established that will be operated centrally with one central computer system. Information will be fed into this communication network about all patients with end-stage renal disease whether or not they have begun dialysis or have had a transplant. Further Information is contained in Tab A.

Current Related Programs

Currently there are 340 institutions in the country providing dialysis services to kidney patients and 95 hospitals providing kidney transplants. However, most of these are poorly utilized and not staffed with full time personnel. Until very recently all dialysis facilities were located in or affiliated with public and non-profit hospitals. During the past two years there has been a small number of privately owned dialysis facilities emerging in the largest metropolitan areas.

Transplantation programs are all affiliated with medical schools including 12 programs located in Veterans Administration Hospitals and two programs in private foundations.

By selective support of 50-80 tertiary treatment centers, DHEW would encourage their development and continuance. Most of the other centers would be expected to phase out.

At present there are several systems by which dialysis care is delivered. They are: (1) Training of the patient in a hospital for routine, chronic care in the patient's home or in a low-overhead self-care facility both affiliated with a medical center, (2) Provision of total care in a low-overhead facility or (3) Provision of total care in a hospital. Each year a smaller proportion of patients are receiving all their care in a hospital setting. In-hospital dialysis care centers are continuing to serve an important role as patient diagnostic and referral centers and for treating emergency conditions which arise while patients are enrolled in the alternate delivery systems. Hospitals continue to be the main resource providing dialysis care immediately before and after transplant surgery. Tab D lists the current expenditures for all types of renal disease.

Rationale for Governmental Initiative

The financial impact on the economy of kidney disease is in excess of $3,635,000,000. Estimates of the prevalence of kidney disease exceed 7,847,000 (or 3.7% of the total population). Thus a major initiative to decrease the morbidity and mortality rate is imperative.

Nowhere in the health care industry does the same gap exist between technology and delivery as in the area of treatment of patients with end-stage renal disease. Technologic developments in the last few years have made possible the rapid expansion of programs to provide patients with hemodialysis, in an institutional setting. The development of remarkable technologic innovations that allow self dialysis by the patient or a member of his family at their home has been a major step in making this a practical approach. Techniques of organ harvesting, preservation, and transplantation have made renal homotransplantation a service entity and no longer a research tool. However, the funding mechanisms to develop the resources and provide patient care reimbursement have lagged far behind. A management plan to prevent duplication, establish a nationwide network, assure high quality, and assure access for all is necessary. Because of this disparity, and the need for a national network, it is an appropriate function of the Federal government to bridge the gap by providing funds to develop the resources with the expectation that patient care reimbursement mechanisms such as Title XVIII, Title XVIX, the National Health Insurance Standards Act, the Blue Plans, etc., will provide the payment of the direct services once the resources, are present. This program is a five-year funding effort that will be utilized as start-up costs to assist the health care industry to develop these additional resources.

Two methods may be employed to prevent duplication of tertiary treatment centers. This is absolutely necessary to prevent a spiraling of costs to treat end-stage renal patients and further contribute to "health care inflation". The first method is a regulatory approach and consists of a system of franchising dialysis-transplantation centers through either the State Health Department or 314a agency. The advantage of this system is that it is an absolute prohibition against unnecessary services, the disadvantage is that this would require modification of existing State laws in most areas. The second disincentive to unnecessary duplication of hemodialysis and renal transplantation centers is the voluntary cooperation of four major health financing agencies with support of the National Kidney Foundation and the American Society of Nephrology. This approach would utilize third party reimbursement mechanisms as the disincentive. Specifically, if the Social Security Administration, Social and Rehabilitation Service, Health Insurance Association of America, and the Blue Plans were to agree that they would only reimburse care given to patients in approved, certified centers, this would provide a mechanism for preventing duplicatory services. Several leading nephrologists have discussed elements of this plan with the Regional Medical Programs Service over the past several weeks. Their enthusiastic support of this approach would imply that it would be possible to receive essentially complete support of the members of the American Society of Nephrology and the National Kidney Foundation to back a Federally controlled program. This voluntary health agency and professional association support coupled with a funding decision by the third party payors would assure the success of the proposed plan.

A question may be raised as to why the Federal Government should support a complete program for one specialized health problem such as end-stage renal disease without insisting that it be part of a total comprehensive system. The answer lies in the fact that health care delivery must be comprehensive at a primary and secondary level but tertiary care requires highly specialized skills and facilities on a regionalized basis. Dialysis-transplantation centers are a specialized form of tertiary care. The investment in training, technology, and other resources to provide tertiary levels of care is of such a magnitude and is so demanding on health manpower training facilities and resources that optimal utilization must be made of them. Not only are the resource requirements large but they cannot function in isolation from other tertiary levels of care. That is to say transplantation centers cannot exist without immunologists, good clinical pathology laboratories, good operating rooms, and recovery room; dialysis centers cannot function without blood banks, nephrologists, psychiatrists, urologists and social workers. The aggregation and interdigitation of tertiary skills has a synergistic effect upon productivity. The climate that develops in a medical center is conducive to further testing and development of innovative technologies.

Further, the skills are of such a high degree of specialization that a minimum level of activity is necessary to maintain quality. Coordination is necessary to assure linkages of primary and secondary services to the tertiary services to prevent duplication.

The second reason behind this special Federal program is that there is a finite group of patients with a predictable frequency thus the supply of resources can be geared to the demand of the patients by effective centralized planning. There are few other health care delivery problems that fit this category. The third answer is that this systematic approach to the delivery of one health care problem has proven to be successful on a regional basis in this country and on a National and International basis in other countries. Thus, the development of a National coordinated network, that sets as its goal the provision of access to resources for all medically eligible citizens and the fulfillment of this goal, establishes a systems model that can be applied to other health care problems as technology becomes more advanced.

During the past decade significant inroads have been made in the treatment of patients with end-stage renal disease. With demonstration that patients can be readily maintained for years by regular hemodialysis over a decade ago, efforts have been directed towards the development of low cost, practical and simple methods of treatment. These efforts have lead to the development of home hemodialysis, a procedure that has drastically reduced the cost of this therapy (from $200 per inhospital dialysis to $25 per home dialysis).

With the demonstration of the long term patient survival on hemodialysis coupled with the advances in immunosuppressive therapy, renal transplantation has become the acceptable mode of therapy. Significant strides have been made in organ procurement and preservation, thereby, increasing the availability and improving the quality of donor kidneys.

In conclusion, the technology necessary to treat patients with end-stage renal disease is now a reality. Further investigative efforts are still being directed towards the improvement of existing techniques. A further discussion of technologic system is contained in Tab A.

Management Plan

The development of hemodialysis and transplantation over the past decade as complementary modes of end-stage kidney disease patient care has indicated striking need to organize integrated systems of delivery. The efficient delivery of dialysis therapy requires concentration of expensive dialyzers and dialyzate delivery systems at central points where scarce medical and paramedical manpower can be employed in treating large numbers of patients. Such centralization provides the patient with high quality services while he is being stabilized, and permits the medical center to fully classify the patient as a potential kidney transplantation recipient. A comprehensive program that provides center, home training and limited care dialysis treatment and transplantation can be responsive to the individual medical requirements and needs of each patient requiring treatment. It has been demonstrated that transplantation facilities with adequate dialysis (pre-and-post transplant) can serve large population groups. As the hub of a network of dialysis centers, transplantation offers patient egress from long-term dialysis.

Thus, the most effective delivery system of end-stage kidney disease treatment requires aggregates of hospitals and other health facilities interrelated in an organized network which assures accessibility of care to the patient, and interdigitates patient referral, patient registry, dialysis, organ procurement, transplantation, laboratory services and continued patient follow-up.

Such a system lends itself to a national program of coordinated dialysis-transplantation networks such as has been under development by the Regional Medical Programs Service, HSMHA. The kidney disease control activity of the RMPS has intensively demonstrated dialysis and transplantation modalities in various settings, and the Regional Medical Programs across the country have begun to organize regional kidney programs incorporating existing medical and health facilities, private patient care funding and manpower; they relate to State and local planning agencies, and Veterans Administration, vocational rehabilitation and other Federal, State and local medical and health programs.

RMPS authority to develop and coordinate interregional end-stage treatment delivery systems is contained in Section 910, Title IX, PHS Act. Inquiries and proposals for broad, interregional end-stage kidney disease programs to coordinate dialysis, organ procurement, and transplantation activities for large sections of the country are being received. Such programs typically propose cadaver organ procurement, and donor-recipient matching and registry facilities for a number of transplantation centers, which are related to supporting dialysis facilities. A broad program which provides contractual support for such "super regional" activities would assure

coordination and monitoring capabilities at the national level to obtain efficient, non-duplicating deployment of resources, and effective coordination with related health programs at Regional, State, and local levels.

Project Schedule

1. Fiscal Year 01:

   a. Grants to RMP's for Prevention and Public Education Program.
   b. Contract for the development of the communications system.
   c. Fund 30 transplant centers - either completely new or supplementing existing incomplete centers.
   d. Fund 25 home dialysis training programs - either completely new or supplementing existing incomplete centers.
   e. Grants and/or contracts for Research and Development.

2. Fiscal Year 02:

   a. Continue funding Prevention and Public Education.
   b. Continue funding the communication system.
   c. Continue funding 30 transplant centers.
   d. Start funding 20 additional transplant centers (as above).
   e. Start funding 25 home dialysis training programs (as above).
   f. Continue Research and Development funding.

3. Fiscal Years 03, 04, 05:

   a. Continue funding Prevention and Public Education.
   b. Continue funding the communication system.
   c. Continue decremental funding of 50 transplant centers
   d. Continue Research and Development funding.

Manpower Resources Plan

The direct manpower required to fulfill the objective of providing full resources in the tertiary treatment centers includes the following:

1. For each Transplant Center

   a. Transplant Surgeon (full-time)
   b. Assistant Transplant Surgeon (at 50% time)
   c. Administrative Coordinator
   d. Secretary
   e. Perfusion Technician
   f. 3 Tissue-typing Technicians

2. For each Home Dialysis Training Program

   a. Physician
   b. Administrative Coordinator
   c. Secretary
   d. 2 RN's
   e. 2 LPN's
   f. 4 Dialysis Technicians

3. For the Center Communications System

   a. Coordinator
   b. 3 to 5 Computer Systems Technologists
   c. Also included here will be a significant but as yet undetermined number of personnel utilized in designing and implementing the system. These personnel will be computer programmer and systems analyst specialists.

If 50 centers are developed, this gives us a total of 925 direct personnel (exclusive of communications people) who will be supported with Federal funds. There are, however, other personnel who will be directly involved in the program, i.e., dieticians, social workers, psychiatrists, and psychologists. In most cases, this group of personnel will already be a part of the existing medical staff and will not require any recruitment.

The availability of trained medical and allied health personnel to fulfill these positions is adequate in most cases. However, 400 trained paramedical technical personnel are required, and it is anticipated that a shortage in this personnel areas may develop. To offset any shortage, discharged armed forces corpsmen and other

technical specialists who have already been extensively trained in general patient care and/or laboratory work, will be recruited, trained and employed in the appropriate center.

Wherever possible, already existing hospital facilities will be used for the centers. No new construction is anticipated but some renovation of the existing facilities is expected.

The initial source of funds for the establishment and operation of the centers will come from the Federal government. Federal support for the first five years of the program will allow the centers to become firmly established and develop adequate direct patient reimbursement mechanisms, thus becoming self-sufficient.

Desired Impact

Renal disease is not a respector of age, sex, race, or socioeconomic background. Lack of access to care is not restricted to a specific geographic or economic group. It has been noted that there is a higher incidence of end-stage renal disease in minorities and in high density residential areas than in other portions of an urban community; renal disease secondary to hypertension is more prevalent in young and middle age Negro males. The described program of providing a national network of Tertiary Treatment Centers would provide access to all citizens with medical indications for hemodialysis and/or renal homotransplantations. At the end of five years the program goal of treatment resource availability for all citizens with this condition would have been reached. The impact upon the rest of the health care delivery system would be negligible as far as diversion of resources from other priority areas. Progress should have been made in research and development, prevention and public education which would begin to show a decreased number of disability days and other morbidity indices. This systematic approach to handling a major health issue will provide a model that may be emulated to solve other health care problems. Proper implementation of this program will strengthen the concept of regionalization and non-duplication of health care services. It will not be a perpetuation of further fragmentation of care. A cost benefit model is developed in Tab E. The total impact of the program cannot be accurately estimated as preventive methods are rudimentary as yet.

Evaluation Plan

It has been estimated that 7,000 to 10,000 lives are lost each year which are salvageable by the provision of proper treatment modalities. Not only are these lives salvageable but over 75% of them are rehabilitatible to a level approaching their activities before the terminal

illness began. Thus, the criteria for evaluation are:

(1) access to care for those diagnosed as having end-stage renal disease with medical indication for maintenance therapy;

(2) degree of rehabilitation of those so treated;

(3) acceptability of the care by the patient and his family;

(4) cost containment. With the present system the average annual cost for patients in home dialysis, institutional dialysis and renal homotransplantation programs, has been quite high. With a systematic approach, improved utilization of resources and coordination of repayment mechanisms, it is expected that the average annual cost will decrease (or remain stable). No patient is to be denied care because of financial barriers;

(5) the quality of medical care delivered is to be evaluated by a national renal peer review mechanism. Standards of optimal care will be developed and maintained for selection of patients, determination of medical management, degree of rehabilitation and end results. National optimal standards can assure the finest quality of care in each of the renal centers.

Management Review Procedure

A kidney disease control program already exists in HSMHA in the Division of Professional and Technical Development of the Regional Medical Programs Service; procedures for the receipt, review, and approval of proposals for kidney disease programs have been operational for some years. An important element of this procedure is the requirement that applicant groups obtain State and Regional certifications of program need, evidence of non-duplication of existing medical and health resources, and that plans provide effective linkage with other programs for planning, operations and patient referral.

A Kidney Disease Advisory Committee will be established to advise the Administrator, HSMHA, on the administration of the national kidney disease program. The committee should be comprised of outstanding individuals in the fields of nephrology and related medical specialties, health administration, consumers, and technological specialty areas which are contributing to advanced medical delivery systems. The committee will evaluate the administration of the national kidney disease program, and advise the Administrator on matters of criteria, program performance, opportunities for technical innovation, and organization and employment of appropriate health resources.

Criteria applicable to the selection of participating institutions are being developed under the provisions of Section 907, Title IX, and will be available soon. Development and implementation of the program will be monitored by the Regional Medical Programs in cooperation with comprehensive health planning agencies. Evaluation of program performance will be carried out by RMPS through established regional and interregional reporting systems, and centralized registries of patients entering and being served by the national program.

The Research and Development portion of the Initiative would be managed by NIH using present mechanisms. Proposals will be sought which fulfill the objectives of the program.

Technologic Systems

I. Communications System

An efficient communications system containing records of all chronic renal disease patients must be an integral part of the kidney initiative. The system would first list a particular patient whenever a diagnosis of irreversible chronic renal disease is established. Data in the system would help in the general planning for allocation of end-stage resources as well as in the selection of the most compatible recipient for each donor kidney appearing in the transplant system.

The budgetary allocation of 5 million dollars for the system includes substantial start-up costs during the first year when developmental costs will predominate. Each of the 50-80 cooperating tertiary treatment centers will have a terminal linked to a central computer operating 24 hours a day 7 days a week. The treatment centers would need no special computer technicians since the terminals can be programmed to operate in a conversational mode. Costs for systems design of both hardware and software would be enormous during the first year, but costs should level out in the second year and be constant thereafter. Solicitation of bids for this proposal should result in a total cost of 5 million dollars or less.

Prototypes of a computer matching system already existent are: a) The National Communications Network currently operated by Dr. Paul Terasaki, UCLA, and supported by contract with DHEW, and b) The Southeastern Organ Procurement and coordinated activity of organ exchange and cooperative utilization of computerized tissue-typing data for Virginia, Georgia, Maryland, North Carolina and New Jersey.

Dr. Terasaki's computerized information system houses data on the clinical results, tissue-typing, and current status of 4,000 transplants performed across the country (74 medical centers) as well as tissue-typing data on 1,000 potential recipients (again at 74 medical centers) who are awaiting transplantation. When a donor kidney and his tissue-typing become available at any one of the participating centers, the data for these 1,000 recipients is available on a 24-hour basis and the best possible match can therefore be obtained, occasionally involving inter-center organ or patient transport. Indeed, since March 1969, 408 kidneys (or patients) have been transported between medical centers utilizing this communications network.

The Southeastern Organ Procurement Program also supported in part by RMPS has utilized and demonstrated the feasibility of a central computer

matching system, allowing 24-hour availability of matching of donors with potential recipients, and utilizing organ exchange within the participating states.

Both of these pilot efforts have demonstrated the feasibility and potential value of a computerized national matching system.

Although all the questions regarding the pragmatic use of tissue-typing for cadaveric transplants are yet to be answered, the need for tissue-typing for living related donors, and the superior results of utilizing "A" matches in cadaveric transplants is well established. If for no other than these reasons alone, a national system of matching and organ exchange is highly desirable.

II. Trends in Current Technology of Kidney Disease Related Equipment

In the field of dialysis there are a number of potential advances relating to hardware that are currently receiving intense clinical evaluation. This equipment, if found clinically applicable, may significantly modify and improve the present dialysis treatment modalities.

Subsequent to the development of the capillary kidney, significant interest has been generated toward the use of ultra-thin cellulose acetate flat membranes. This type of membrane appears to be superior to the existing membranes for removal of "uremic toxins". The use of this type of membrane may significantly shorten the period of time a patient may be required to dialyze per day, thereby increasing potential for rehabilitation. Clinical trials are just underway. In addition, significant strides are being made in the prolongation of function of cannulas. By the development of an appropriate tissue interfacing substance, as well as minimal thrombogenic surfaces, external cannulas may enjoy significant improvement in survival rates.

With regard to the development of new dialysis systems, there are two promising avenues presently undergoing clinical trials. The first is the low volume (1-2 liters) sorbent dialysis system, in which the dialysate is being constantly recirculated as it is being regenerated with the aid of a spectrum of selected adsorbents. This development alone is extremely valuable because for the first time hemodialysis may become independent of the "kitchen sink and the toilet drain" in home dialysis. This drastic reduction in the amount of dialysate required also promises to solve a whole series of problems which have beset dialysis, namely, the quality of tapwater available for dialysis and the preparation of large volumes of dialysate with the aid of proportioning pumps and concentrate solutions. The second deals with a system called hemodiafiltration which has not as yet undergone sufficient clinical pre-testing.

In addition, there has been the introduction of micro-encapsulated particles which are ingested by the patient and theoretically adsorb the 'uremic toxins' in an amount sufficient enough to reduce the frequency of dialysis.

Finally, peritoneal dialysis has received renewed interest with the development of an automatic delivery system. This system removes most of the complications associated with peritoneal dialysis and enables one to perform the procedure quite readily.

In conclusion, there are a number of significant advances that are on the horizon that have the potential of significantly altering the complexion of dialysis.

III. Current Status of Home Dialysis Technology

Home hemodialysis was initiated in Boston in 1963 and in Seattle and London in 1964. Initially, home treatment was a cumbersome experimental endeavor but has evolved rapidly into a practical and successful means of treating end-stage renal disease. Maintenance dialysis now can be made available to almost anyone who is capable of learning to treat himself in his own home. Furthermore, treatment in the home rather than the center can provide an opportunity for more dialysis and, therefore, better control of the azotemic state and at less than half the cost.

At the present time, in a treatment program designed for training patients for home dialysis, a period of approximately six to eight weeks of instruction serves to train a patient adquately. Initially, patients trained for home dialysis primarily used the Kiil-type dialyzer with a simple hydraulic dialysate delivery system. Rapid advances during the ensuing years have lead to the introduction of more sophisticated and safer dialysate delivery systems. With these advances coil dialyzers at home became more of a reality than in the past. In recent years, the introduction of such dialyzers as the 'capillary kidney' has offered an acceptable alternative to the usual dialyzers. Presently, significant inroads are being made into the development of compact disposable dialyzers. In addition, the use of small and compact recirculating dialysate delivery systems are presently undergoing clinical trials. The potentials these advances hold for the future are impressive. Indeed, it would realistically appear that a patient with renal failure will only have to dialyze himself one - two hours a day with a system that could readily fit within a suitcase.

IV. Procurement and Preservation of Donor Kidneys

The basic principal of providing each transplant recipient with the best

possible donor organ would be greatly enhanced by the ability to effectively assay potential donor organs for viability and transplantability prior to the actual surgery. Presently, two preservation methods are available which have been used extensively in clinical organ transplant: 1) simple hypothermic storage with or without brief initial cold perfusion and 2) prolonged pulsatile perfusion. Storage by simple hypothermia has been used extensively and appears to be a safe procedure for less than ten hours. On the other hand, the method of pulsatile perfusion of the kidney allows for considerably greater advantages: 1) adequate preservation for at least thirty hours, 2) assessment of viability of donor kidney, 3) removes transplant surgery from that of an emergency procedure to that of an elective one, 4) allows for potential sharing of a kidney with the best matched recipient wherever he may be, 5) allows for presurgery reassessment of potential recipients. Presently, devices have been developed which can be easily transported in a small van or even an airplane seat. This then allows for the transportation of organs from region to region and potentially from country to country.

Currently, the scarcity of available cadaver organs is probably the most important factor in limiting the number of transplants being performed. Hence, it is of utmost importance that an aggressive organ procurement program be established as part of the public education program. In addition, the support of local legislation to make it easier to obtain organs is of vital concern.

Budget

The federal expenditure over a five-year period of time is estimated to be 50 million for tertiary treatment centers, 15 million for R & D, 5 million for prevention, 5 million for public education and 5 million for communications network or a total of 80 million dollars over five years (which averages 16 million dollars per year.) It should be noted that there are already in existence several transplantation centers that would not need additional support to become self-sufficient (approximately 7-10). It should also be noted that there are already in existence home dialysis training programs that would not need further support to become self-sufficient. At this time an exact estimate of the number of these is not available, but will be developed shortly. The funds saved by not having to support the full quota of transplant centers or home dialysis centers will be utilized to fill the gap where additional tertiary treatment centers or satellite, low cost, hemodialysis centers are needed to provide for the patients who can not care for themselves at home or receive a renal homotransplant.

Several States have already established State-wide funding mechanisms to pay for the direct patient care costs. This national plan will be coordinated with these States. Federal-State cooperation in this network approach to a priority health issue is a model that can be followed by other programs.

The direct economic impact of this proposal upon equipment manufacturers is:

1.	Perfusion and dialysis equipment	$2,000,000
2.	Computer systems	$5,000,000

The direct full-time employment impact of this program in tertiary treatment centers is

1.	Physicians	125
2.	Nursing personnel (RN and LPN)	200
3.	Technicians (Perfusion, Dialysis, Tissue Typing)	400
4.	Administrative staff	100
5.	Clerical	100
	Total	925

Transplantation Centers

Transplantation Centers will be funded at an average of three to four million people per center for 50 to 80 transplantation centers. These will be supported at medical centers in areas in which the Health Planning

Agencies have determined that a need exists. It is expected that a total of 5,000 to 7,000 transplants will be performed annually by the fifth year. No new transplantation center will be planned in a region until any existing center is approaching 75 transplants per year. The desired level of activity will be 75-100 transplants per year per center. The Federal Government will fund on a decremental basis (up to 100 percent year one and two, 75 percent year three, 50 percent year four and 25 percent year five) the following categories provided that they do not currently exist in that region. If one or more of these budget items are available, the center will be funded for the remaining portions.

Transplant Surgeon	$35,000	
Assistant Surgeon (50% of the time)	15,000	
Administrative Coordinator	15,000	
Secretary	8,000	
Perfusion Equipment	20,000	
Perfusion Technician	10,000	
Supplies	5,000	
Hospital expenses for cadaveric organ-harvesting	75,000	
Typing Lab - 3 technicians	30,000	
Supplies	5,000	
	Sub-Total	$218,000
Overhead		60,000
	Total	$278,000

The program being considered would provide funds to support transplantation surgeons at the various medical centers. The critical importance of this stems from consideration of several factors. First, most University-affiliated hospitals cannot find funds for the sole support of a surgeon who only does transplantation surgery as a separate categorical activity, as opposed to general surgery or vascular surgery with part-time activities in transplantation. Yet, it has been clearly demonstrated that the success and progressive growth of a renal transplantation program is critically dependent upon the presence of a full-time surgeon devoted exclusively to transplantation and probably requires a minimum equivalent of 1½ full-time surgeons. It has further been demonstrated that in most instances, the

initial support of such individuals, once a program has developed, no longer requires outside financial support for the salary of the surgeon, this being subsequently obtainable through funds gathered via 3rd party payment mechanisms. Alternatively, funds often become available through the hospital administration, as it sees the source of increasing incoming funds generated by the transplantation service.

Home Dialysis Training Programs

Making the assumption that each Home Dialysis Training Program will operate two shifts per day, two cycles per week (Monday, Wednesday and Friday and Tuesday, Thursday and Saturday) and will have a minimum of four beds, this will allow at least 12 patients per training cycle and at least 6 cycles per year; thus each unit will be expected to train 72 patients per year. As the total number expected would be between 700 and 3,000 per year, 50 home dialysis training programs can support this national end-stage renal disease life plan. DHEW would fund one home training program per tertiary treatment center with the above assumptions and with any necessary elements of the following budget (provided that they do not previously exist):

1 Physician	$30,000
2 RN's	30,000
2 LPN's	18,000
4 Technicians	32,000
1 Administrative Coordinator	15,000
1 Secretary	6,000
Equipment, Supplies and Renovation	35,000
Sub-Total	166,000
Overhead	65,000
Total	$231,000

This would be funded for <u>one time only</u> with the expectation that revenue from patient care reimbursement mechanisms would be adequate by the second operational year to bear the continuing expenses of salaries.

Incidence of Patients with Treatable End-Stage Renal Diseases

In 1967, the Gottschalk Report was submitted to the Bureau of the Budget. This report concerned itself with the problem of developing programs to care for persons with chronic kidney disease. Special note was made of the incidence in the United States of chronic kidney disease. At the same time, a study from the National Institute of Health addressed itself to the same question. These two reports are in remarkably close agreement and have accurately defined the problem when examined against recent statistical analysis.

These reports estimated that approximately 50,000 persons die each year from chronic renal disease. This works out to 35 patients per million per year who are treatable. Of those with kidney failure 7,000 to 10,000 are suitable candidates for prolonged medical treatment. Medical treatment consists of conservative therapy, chronic dialysis, and transplantation.

This prediction has been borne out by the experience of the majority of physicians who care for persons with chronic kidney disease. Indeed, the incidence of 35 suitable patients per one million population per year has stood the test of four years time.

A National Plan for Establishing Patient Referral Patterns

One of the factors that limits care for patients with chronic kidney disease is the lack of a system for patients to enter a well-defined referral pattern. A system of this nature has been proven effective in the United Kingdom; Scandia-Transplant which serves Benelux, Germany, Austria, and Switzerland. From their experience we feel this type of program could be planned and adopted in the United States. The patient referral pattern is best established at a national level.

The program which is proposed establishes close knit cooperation between facilities. The activities of these facilities include prevention of kidney disease, education, case detection and treatment, organ procurement, tissue-typing, dialysis networks, and transplantation. Information between the various facilities will be

coordinated by a national registry. All information on a particular patient must be exchanged between the centers of excellence and those primarily concerned with a patient's care.

The overriding purpose of this system is to care for a greater number of patients, refer patients to the optimum level of medical treatment needed and to return them to useful lives as quickly as possible.

In order to not overload the centers, it is planned to return the patient to the primary physician. The primary physician, therefore, must have continued training. Continuing education will also be made available to nurses, dietitians, technicians and other paramedical personnel who are involved with the patient's care.

The flow of patient referral is outlined diagramatically in the introduction. This system is not unlike the pattern of referral that is used today in some areas of the United States. However, the development of a more organized national program will allow for more patients to reach the quality of care that is necessary.

Expected Case Loads and Growth Rates

I. Transplantation

Information from the National Dialysis Registry suggests that there are approximately 5,000 patients on dialysis in the United States today. Dr. Paul Terasaki has data indicating that there are approximately 1,000 patients awaiting transplantation across the country. His data are not complete, however, and an estimate of the actual current backlog of patients who are candidates for transplantation would be somewhere between 2,000 and 3,000. Data from the Gottschalk Committee Report suggests that approximately 35 patients per million population per year are candidates for transplant or dialysis therapy -- this works out to be approximately 7,000 patients in the United States each year.

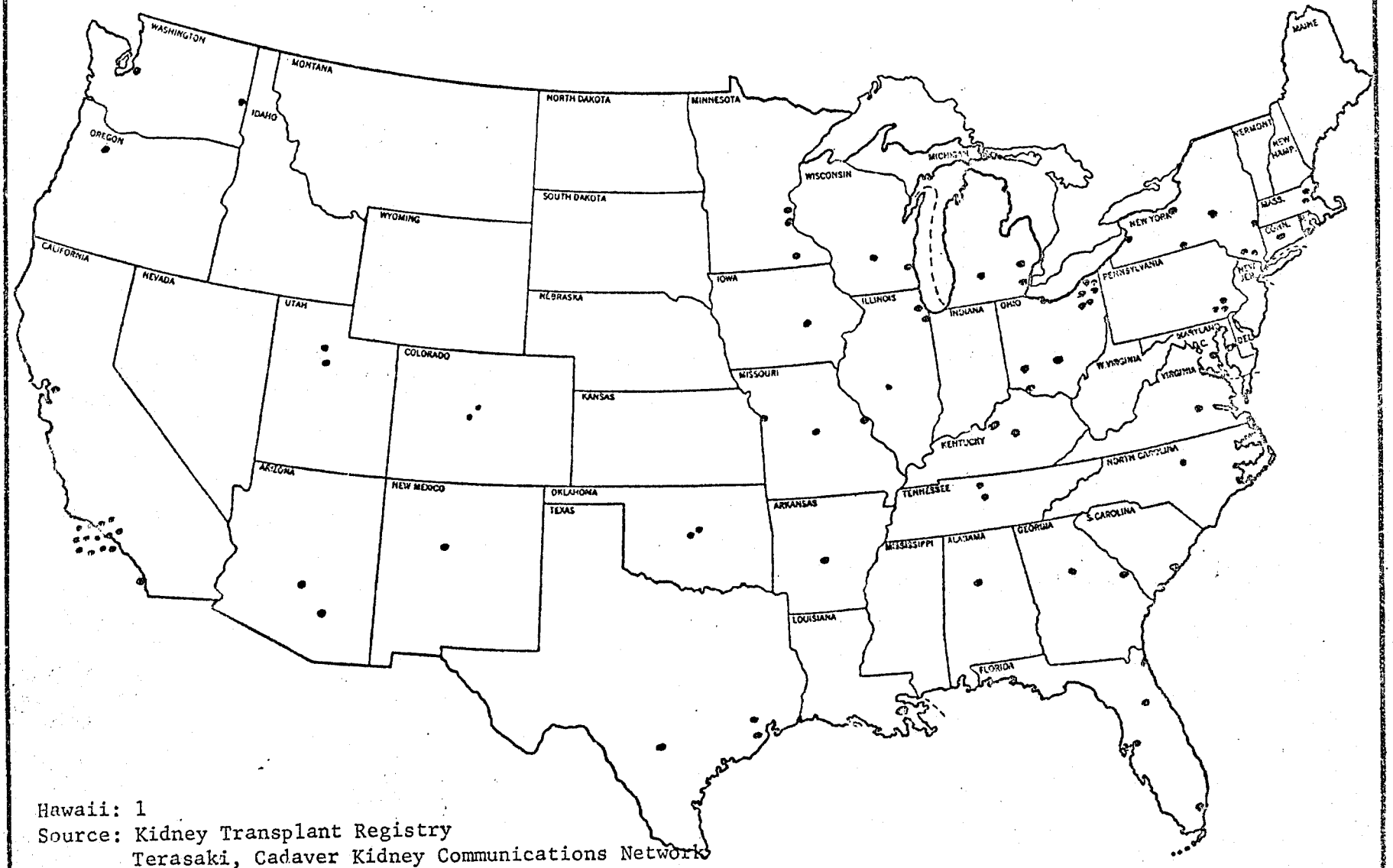
The program for end-stage renal disease would be expected to progressively increase the national capacity for transplantation over a five-year period and over a somewhat longer period, result in a stabilization of transplantation capacity such that a steady state would be reached. Assuming that 80% of all patients with end-stage renal disease who are treatable will be transplanted, then the rate of new transplant candidates for the nation per year will be approximately 5,000 per year. If the rate of expansion of transplantation case load capability averages 30 patients per center per year during year 1, 40 per year for year 2, 60 per year 3, 80 per year for year 4, 100 per year for year 5, and finally, reaching 150 per year by year 6, then the following predictions can be made: At the end of five years such a transplantation

program will have reached a capability of handling the subsequent yearly rate of entry of transplant candidates into the system. In an additional three years (a total of eight years after the inception of the program) the backlog of patients encountered in the system (the initial backlog plus the yearly backlog resulting from progressive increase in transplant capability) will also have been transplanted. Therefore, it is predicted that a total of eight years is required for a steady state to be achieved with respect to transplantation, and thereafter, transplantation capability will be fully adequate to meet the yearly need. This projection does not include second and third transplantation due to rejection. If this remains a problem, more than 50 centers will be needed; a total of 80 centers should take care of this eventuality. Another assumption that is made in these calculations is that all of the 35 patients per million that are potential candidates will be identified in the proposed program and therefore treated. The experience to date is that there is initially a significant lag in identifying all of these potential candidates so that the predicted case load in the first few years is probably excessive. With proper emphasis by the program to further public and physician education, it is anticipated that all or nearly all potential candidates for therapy will be identified. This will not significantly alter the predictions for the time required for the system to reach a steady state. The predictions regarding the expected rate of transplantation are realistic in view of the present data showing that in 1969, 900 transplants were done in the United States; in 1970, 1,000 were done and by the end of 1971 between 1,100 and 1,500 will be done. The expectations for the proposed program of transplanting 1,500 patients in year 1, and progressively increasing to 5,000 patients transplanted in year 5, is attainable.

II. Dialysis

Dialysis supportive aspects of the life-plan will reach a steady state earlier because of the progressively decreasing case load as transplantation capability increases. It is predicted that the dialysis case load will begin at approximately 5,500 patients for year 1 and decrease to approximately 2,000 patients for year 5 and all subsequent years. The proposed program entails supporting current home dialysis training programs by providing increased home dialysis training capacity to each of the 50 centers, and adding an additional four home training beds to each of the centers (operating on a three dialysis per week, two shifts per day schedule). It is proposed that such a system allows for the handling of the dialysis load and achieves full capacity to do so by as early as year 3, and thereafter, a progressive decrease in dialysis need and capacity could be effected.

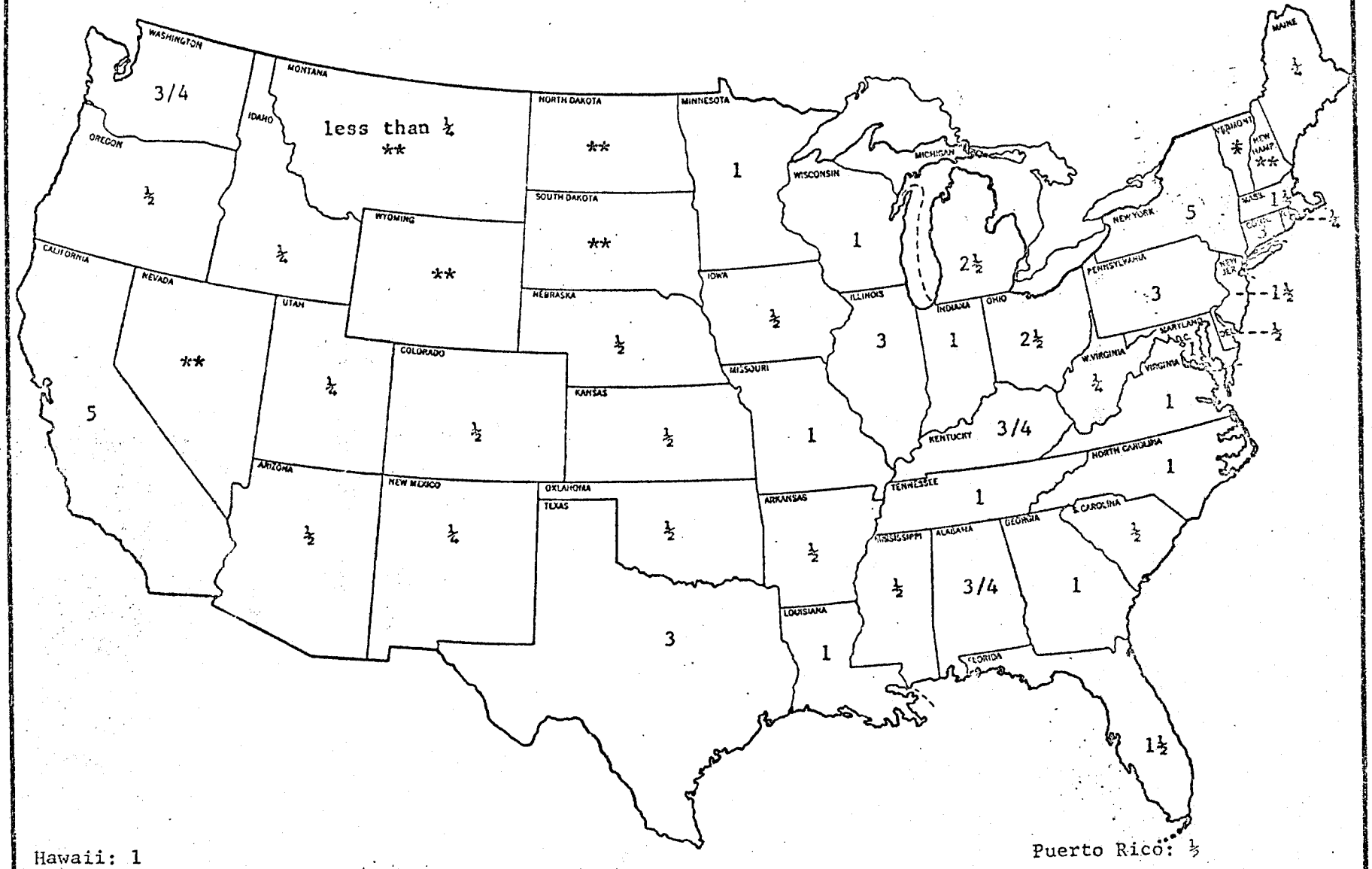
Existing Kidney Transplant Centers



Hawaii: 1

Source: Kidney Transplant Registry
Terasaki, Cadaver Kidney Communications Network

Number of Transplantation Centers for which each State is Eligible*



Hawaii: 1

Puerto Rico: ⅓

* based on ratio: 1 center per 4 million population

** Eligible for less than ½ center

HEW-111

CURRENT EXPENDITURES

I. Current annual expenditures for treatment of patients with 2nd stage kidney disease

A. Hemodialysis:	
Total number of patients treated	4,500
Annual number of dialyses per patient	156
Average cost per dialysis	$150
Total current annual expenditure for dialysis	$105,300,000
B. Transplantation:	
Total number of patients treated annually	1,000
Total cost per patient	$10,000
Total current annual expenditure for transplant	$ 10,000,000

II. Average unit expenditures for therapy

A. Hemodialysis	
In-hospital dialysis[1]	$200
Low-overhead facility	125
Home self-dialysis	25
B. Transplant	
Ttoal average cost per patient[2]	$10,000

NOTES:

1 - From financial reports of Federal contracts monitored by Regional Medical Program.

2 - This figure is an estimate. The range of costs extends from $5,000 to $50,000.

III. Distribution of expenditures

A. Hemodialysis[1]

Source	Amount	Percent of Total
Patient out-of-pocket	12,600,000	12%
Patient insurance	46,300,000	44%
Public and other	46,400,000	44%

B. Transplants[2]

Source	Amount	Percent of Total
Patient out-of-pocket	1,000,000	10%
Public and other	9,000,000	90%

IV. Estimated Total Cost of Kidney Disease (National)

Item(1)	
Indirect costs, annual	$2,875,000,000
Morbidity	1,173,000,000
Mortality	1,702,000,000
Direct costs, annual(2)	1,458,000,000
Estimated annual total:	$4,333,000,000

NOTES:

1 - Telephone survey February 1970 of 17 dialysis centers. Selection of patients significantly affects these ratios: data from 12 home training dialysis centers under contract show lower out-of-pocket costs due to greater selection of indigent patients.

2 - Estimated.

(1) Data presented were developed in 1968. The renal disease data was developed from 1964 census data and are adjusted for 1971 prices.

(2) Includes hospital, nursing home care, physician, dentists, nurses, other health professional personnel.

V. Chronic renal disease insurance coverage trends

A. Benefits - No coherent data is now available. Through individual physician efforts during the 1960s, and more recent RMPS staff discussions with major health insurance carriers, insurance support is rapidly increasing. Blue Cross/Blue Shield, for instance, administers 74 autonomous plans and coverage varies widely from total to none. Blue Cross/Blue Shield has surveyed its plans, and may have data analyzed by February or March 1972.

B. Current premium costs are those charged for coverage selected. Actuarial estimates based on the experience of Blue Cross/Blue Shield indicate a potential premium levy for renal disease coverage at between $1.00 and $2.00 per year. Informal estimates of premium required for national coverage for renal disease are below $1.00 per year.

C. Insurance carrier expenditures for chronic renal disease;

Unknown. Initial information from the Blue Cross/Blue Shield survey mentioned above indicates that of 70 plans reporting,

66 provide inpatient coverage (Dialysis overnight).
54 provide outpatient coverage (Dialysis during the day).
44 provide home self-dialysis coverage.

No information has been provided on transplantation, although costs have been covered in some areas. The 70 reporting plans encompass 9,643,000 members with coverage complementary to Medicare, while 132,100,000 members are under age 65. At an end-stage disease incidence of 35 per 1,000,000 an estimated kidney disease population of 4,600 is projected in the latter figure.

D. No Social Security Administration or Social and Rehabilitation Service expenditures for chronic renal disease are available. Coverage is determined locally. SRS reports that program covering only Counseling and Training provide only $250 per year, per patient. Where full coverage for end-stage renal disease is provided, a range of $12,000 - $25,000 per patient per year is provided.

California and New York are examples of States with essentially full coverage for their end-stage renal disease populations.

It should be noted that more than 25 States have enacted legislation to develop renal disease control programs and/or to help support patient care. Funds appropriated vary from none to $1,000,000.

End Stage Kidney Disease
"Cost-Benefit" Model (10 Years)

I. Costs

A. Assumptions

1. 7000 ideal patients will be identified and treated each year

2. Equilibrium will be reached with 5000 of those ideal patients receiving a transplant

3. Transplant capacity will grow from current level of 1500 to 5000 within 4 years. Meanwhile, dialysis facilities will treat all other ideal candidates.

4. Constant mortality rate of 15% per year on dialysis

5. First year graft failure 25%, and mortality rate of 25%, subsequent yearly mortality of 5% following transplant operation.

6. Cost of transplant is $10,000 in first year and $1000 per year thereafter.

7. Cost of Dialysis is $15,000 per year (combining home, low cost satellite and hospital-based dialysis).

B. Caseloads

Year	Dx Backlog DxB	Tx Backlog TxB	New Dx Dx	New Tx Tx	Deaths D
1	5000	1000	5000	2000	2050
2	9000	1950	4000	3000	2798
3	11800	3353	3000	4000	3388
4	13580	5185	2000	5000	3846
5	14493	7426	2000	5000	4095
6	15269	9554	2000	5000	4318
7	15929	11576	2000	5000	4518
8	16490	13497	2000	5000	4698
9	16967	15322	2000	5000	4861
10	17372	17056	2000	5000	5009
11	17716	18703			

$$DxB_{k+1} = .85\ DxB_k + .85\ Dx_k + .25Tx_k$$

$$TxB_{k+1} = .95\ TxB_k + .50Tx_k$$

$$D_{k+1} = .15\ DxB_k + .05TxB_k + .15Dx_k + .25\ Tx_k$$

C. Yearly Costs

Year	Dx Backlog	Tx Backlog	New Dx	New Tx	Total
1	$ 75M	$ 1M	$75M	$20M	$ 171M
2	135M	2M	60M	30M	227M
3	180M	3M	45M	40M	268M
4	204M	5M	30M	50M	289M
5	218M	7M	30M	50M	305M
6	230M	10M	30M	50M	320M
7	239M	12M	30M	50M	331M
8	248M	13M	30M	50M	341M
9	255M	15M	30M	50M	350M
10	261M	17M	30M	50M	358M
Total	2045M	85M	390M	440M	296[illegible]M

TOTAL COST $2,960,000,000

fits

Assumptions

1. Average annual income for fully rehabilitated patient is $8000

2. Transplant patients will achieve 80% rehabilitation after the first year

3. Dialysis patients will achieve 60% rehabilitation.

Social Benefits (cumulative over 10 years)

1. Years of Life on dialysis 148,616

2. Years of Life after transplant 103,622

3. Future lives of 17,716 persons undergoing dialysis at end of ten-year period

4. Future lives of 18,703 transplant recipients living at the end of ten-year period.

Economic Benefits

1. Dialysis: (10 years)
   148,616 patient years x $8000 x 60%/patient year = $713M

2. Transplantation: (10 years)
   103,622 patient years x $8000 x 80%/patient year = $[illegible]

3. Future earnings of dialysis patients
   0

4. Future earnings of transplant recipients
   Average life expectancy is 15 years

   15 years x(income minus treatment cost) 6400-1000/patient year x 18,703 patients = $1515M

   TOTAL ECONOMIC BENEFIT = $2,891,000,000

III. Cost-Benefit Analysis

A. We estimate the total cost of this program to be $2,960,000,000. Of this total, $80,000,000 would be government "seed" money, the remainder would be provided through the usual medical payment mechanisms.

B. The 76,000 patients treated under this program can be estimated to earn $2,891,000,000 as a result of receiving this end stage therapy.

C. Our cost figures should be weighed against an average cost of death of $4500/patient (assumption of 30-day terminal hospitalization at $150/day). If the ideal end stage kidney disease patients were not treated during the next ten years, death of those 76,000 patients would be expected to cost $342,000,000.

D. Combining the results shown in paragraphs A, B, and C, we have an expected economic gain (B + C - A) = gain):
$2891M + $342M - $2960M = $273M
Gain = $273,000,000

E. No assumptions or projections are made for improvements in rehabilitation rates, breakthrough in treatment modalities or improved preventive techniques. The indirect gains of reduced "disability days," increased employment (of rehabilitated patients), increased by revenue and decreased "welfare" needs are likewise not included. These factors should substantially increase the expected economic gain of this program.

F. Modifying our model to include the following more optimistic assumptions gives even better 10-year results.

1. Modified Assumptions

a. Average dialysis cost will fall from present level of $15,000 per year to $7500 per year at the end of 10 years. We will use a figure of $10,000 per year as a representative cost for 10-year period.

b. Transplantation capability will increase beyond levels necessary to treat new patients in order to reduce pool of long-term dialysis patients. Maximum level will be 7500 transplants per year.

c. Graft survival will average 60% in first year and 95% each year thereafter following transplant operation. Patient survival will average 80% in first year and coincide with graft survival each year thereafter.

2. Caseloads

Year	Dialysis Backlog DxB	Transplant Backlog TxB	New Dialysis Dx	New Transplants Tx	Deaths
1	5000	1000	5000	2000	1950
2	8900	2150	4000	3000	2639
3	11565	3843	3000	4000	3177
4	13180	6051	2000	5000	3580
5	13903	8748	2000	6000	3872
6	13868	11911	2000	7000	[illegible]
7	13188	15515	2000	7500	4179
8	12285	19239	2000	7500	4230
9	11517	22777	2000	7500	4292
10	10864	26138	2000	7500	43[illegible]
11	10309	29331			

$$DxB_{k+1} = .85 \left[DxB_k - \{(Tx-5000) \vee 0\} \right] + .85\, Dx_k + .20\, Tx_k$$

$$TxB_{k+1} = .95\, TxB_k + .60\, Tx_k$$

$$D_k = .15 \left[DxB_k - \{(Tx-5000) \vee 0\} \right] + .05\, TxB_k + .15\, Dx_k + .20 Tx_k$$

3. Yearly Costs

Year	Dx Backlog	Tx Backlog	New Dx	New Tx	Total
1	$ 50M	$ 1M	$50M	$20M	$ 121M
2	89M	2M	40M	30M	161M
3	116M	4M	30M	40M	190M
4	132M	6M	20M	50M	208M
5	139M	9M	20M	60M	228M
6	139M	12M	20M	70M	241M
7	132M	16M	20M	75M	
8	123M	19M	20M	75M	237M
9	115M	23M	20M	75M	233M
10	109M	26M	20M	75M	230M
Total	1144M	118M	260M	570M	2092M

TOTAL COST $2,092,000,000

4. Benefits (10 Years)

a. Years of life on dialysis
119,579 years Economic benefit $640M

b. Years of life after transplant
145,703 years Economic benefit $932M

c. Future lives of patients on dialysis at end of period
10,309 patients Economic benefit 0

d. Future lives of transplant recipients living at end of period
29,331 patients Economic benefit $2,376M

TOTAL ECONOMIC BENEFIT $3,954,000,000

5. Cost-benefit comparison

As before, we assume cost of death of $4500 per patient which gives us cost of $342M if we allow 76,000 dialysis patients to die

Hence

Economic Gain = 3954M + 342M - 2092M = $2,204,000,000

DRAFT

Kidney Disease

Position Paper

Division of Professional and Technical Development

Regional Medical Programs Service

January 7, 1972

It has been generally accepted that access to comprehensive health services of high quality must be available to all Americans. Comprehensive systems of care must be developed throughout the Country. One of the components of this system is a method of prompt detection, diagnosis and treatment of patients with renal disease. To this end a series of primary, secondary, and tertiary centers with renal treatment capability and effective linkages should be provided on a planned basis.

The primary centers will revolve around practicing physicians' offices, public health clinics, and other facilities. Upon detection of a recurring or chronic problem, referral should be made to a secondary or tertiary center. Secondary centers will exist in multispecialty clinics, hospitals, clinics, and community medical centers. Sophisticated specialized diagnostic skills should be provided.

Tertiary centers will usually be located in a university health science center and should have a full range of kidney services available. This would include the usual diagnostic and therapeutic services as well as training facilities for medical and ancillary personnel. Specialized resources will include hemodialysis and renal homotransplantation facilities. These centers should be dispersed in such a way that all sections will have adequate medical coverage but without duplication. This is

approximately one center per 4 million residents.

For patients with end-stage renal disease, the disparity between technology and delivery is greater than any other phase in the health care industry. During the past fifteen years, two mutually supportive and dependent therapies have evolved in the treatment of kidney failure: hemodialysis and renal homotransplantation. Due to the lack of adequate patient care reimbursement mechanisms, sufficient resources have not developed to match patient needs. With both techniques becoming widely accepted, it is important to develop coordinated plans indicating the proper relationship between dialysis and transplantation, and develop the financial support needed to bridge the gap.

A system for patients to enter a well-defined referral pattern is to be established, with national coordination. Once established, this centrally operated communication network would feed information back to the practicing physician about their patients with end-stage renal disease. The patient would be entered into the renal center's long-range "life-plan."

Tertiary treatment centers should establish a life-plan for each patient identified as having end-stage renal disease. This plan should provide for conservative medical management

as soon indicated. When the patient begins to develop complications of his disease, a decision to transplant should be the treatment of choice. If, however, the patient is not medically suitable for transplant, or an organ is not available, or the patient declines, training should be initiated for home dialysis. If circumstances do not permit this therapeutic modality, treatment at a satellite, low-cost ambulatory care center or hospital dialysis center should be provided.

The scarcity of available cadaver organs is probably the most important factor in limiting the number of transplants being performed. An aggressive organ procurement program to increase the national capacity for transplantation is necessary. Support of local legislation and education of the public to make them aware of the use of cadaver kidneys is necessary to make it easier to obtain organs. Another major deficiency is the lack of full-time center-based transplantation surgeons.

As a further step, improvements in the techniques of organ harvesting, preservation, transplantation, and a computer matching system could be developed. Other programs to further public and physician education, support current home dialysis training programs, provide increasing home

dialysis training, and develop a close knit cooperation between facilities would prevent duplication of efforts.

The development of a national coordinated network can be applied to other health care problems as technology becomes more advanced. The development of a communication system, funding of transplant centers, funding of home dialysis training programs, and other continuing education programs, will make the management of end-stage kidney disease progress rapidly in the immediate future. In the next ten years, the goal of adequate dialysis and transplantation resources can be met.

Guidelines are being developed for RMPS support of Regional Medical Programs to assist them in providing the resources necessary to develop comprehensive treatment plans and dialysis and transplantation centers.

regional medical programs service

SPECIAL ISSUE
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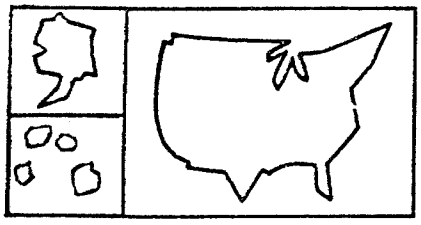

•news •information •data

A communication device designed to speed the exchange of news, information and data on Regional Medical Programs and related activities.

KIDNEY DISEASE ACTIVITIES - Policy Statement and Guidelines

November 27, 1970 - Vol. 4, No. 53S

Included in this issue is the policy endorsed for kidney disease activities by the National Advisory Council on Regional Medical Programs.

Also included are Guidelines for Planning a Comprehensive Regional (or Inter-Regional) Kidney Disease Program.

For guidance in developing and submitting grant applications incorporating kidney disease activities, please refer to . . .

- Guidelines for Regional Medical Programs, revised May 1968.
- Addendum to Guidelines for Regional Medical Programs - February 1970.
- Guidelines for Multi-Program Services Project Grants - Regional Medical Programs Service - August 1970.

Distribution:
- Coordinators of Regional Medical Programs
- Members of National Advisory Council and Review Committee on Regional Medical Programs
- Staff of Regional Medical Programs Service
- Regional Health Directors and Regional Medical Programs Service Representatives of Health, Education, and Welfare Regional Offices.

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service • Health Services and Mental Health Administration • Rockville, Maryland 20852

Old Life Plan

"LIFE-PLAN"

for

END STAGE RENAL DISEASE

Department of Health, Education, and Welfare
Health Services and Mental Health Administration

Regional Medical Programs Service

December 10, 1971

December 10, 1971

Program Summary

Nowhere in the health care industry is the disparity between technology and delivery as great as it is for the patients with end-stage renal disease. Over 50,000 Americans die each year from some form of renal disease. Of these, 7,000 to 10,000 have medical indications for maintenance therapy by hemodialysis or renal homotransplantation. A "Life-Plan" for the treatment of patients with end-stage renal disease is proposed. The goal of the plan is to provide the resources for home dialysis training and renal homotransplantation so that all Americans who suffer from end-stage renal disease that meet the medical criteria for maintenance therapy will have access to care. Specific objectives are to establish a minimum of 50 "Life-Plan" Renal Centers with facilities for renal homotransplantation and home dialysis training located throughout the country on an average of approximately 1 per 4 million population, a total of 50 centers. A second objective is to prevent duplication and under-utilization of services. The specific elements to achieve these objectives are that a Federal program, administered by the Health Services and Mental Health Administration (through the Regional Medical Programs Service), will selectively fund medical centers which demonstrate the capacity to perform this service. A decremental funding pattern will be utilized with 100% funding for the first 2 years, 75% the third, 50% the fourth and 25% the fifth year. Continuation costs of these centers will be borne by patient care reimbursement mechanisms. The plan makes the following assumptions:

1. The average life extension will be seven years or more;

2. The rate of entry will be unchanging over the next five years;

3. Mechanisms for payment for direct patient services will develop as the resources to provide the services become available (through Title XVIII, XIX, NHISA, Blue Plans, etc.). There will be Federal-State cooperation in developing these mechanisms.

4. A coordinated plan can be implemented with the voluntary cooperation of the health providers. This type of plan has already been enthusiactically endorsed by leading nephrologists.

Plan

The following Federal strategy is recommended for development of a "Life Plan" for the treatment of end-stage renal disease patients by selective funding of dialysis and transplantation centers. It has been estimated that approximated 50,000 Americans die each year of some form of chronic renal disease. Of these, it was estimated by the Gottschalk Report submitted in 1967 to the Bureau of the Budget that 7,000 to 10,000 are considered to be good candidates for supportive care and would be expected to achieve a 75% level of rehabilitation to their pre-terminal illness activities. Therefore, it would seem appropriate that a strategy be developed for the entrance of these 7,000 to 10,000 patients per year into a coordinated plan health care delivery.

An end-stage Renal Disease Center is to be developed for every four million residents, a total of 50 centers. This Center will combine the resources of hemodialysis and renal homotransplantation as modalities of treatment for patients identified. As soon as a patient is diagnosed as having chronic progressive renal disease he is to be referred to the center for that region to be entered into the long-range life-plan. Emphasis in this life-plan will be placed upon early homotransplantation. At the present time cadaveric transplantation seems to be the most practical.

It is estimated that 60 to 80 percent of the patients entering the program will be suitable candidates for transplantation. Of the remaining 20 to 40 percent of patients, some form of long term hemodialysis is indicated. It is estimated that of the hemodialysis patients, 10 to 30 percent will be entered in a home dialysis training program for treatment in their homes or at low cost satellite ambulatory care centers. The remaining 10 percent will require institutional treatment because of the severity of their condition or for some other medical or social reason.

The Department of Health, Education and Welfare through the Health Services and Mental Health Administration and the Regional Medical Programs Service will fund the start-up costs for renal transplantation units and selectively fund start-up costs for home dialysis training programs.

Communication System

To coordinate the activities of this life plan and to develop information for better organ procurement and sharing, a national communication network will be established that will be operated centrally with one central computer system. Information will be fed into this communication network about all patients with end-stage renal disease whether or not they have begun dialysis or have had a transplant.

Current Related Programs

Currently there are 340 institutions in the country providing dialysis services to kidney patients and 95 hospitals providing kidney transplants. However, most of these are poorly utilized and not staffed with full time personnel. Until very recently all dialysis facilities were located in or affiliated with public and non-profit hospitals. During the past two years there has been a small number of privately owned dialysis facilities emerging in the largest metropolitan areas.

Transplantation programs are all affiliated with medical schools including 12 programs located in Veterans Administration Hospitals and two programs in private foundations.

To-day there are several systems by which dialysis care is delivered. They are: (1) Training of the patient in a hospital for routine, chronic care in the patient's home or in a low-overhead self-care facility both affiliated with a medical center, (2) Provision of total care in a low-overhead facility or (3) Provision of total care in a hospital. Each year a smaller proportion of patients are receiving all their care in a hospital setting. In-hospital dialysis care centers are continuing to serve an important role as patient diagnostic and referral centers and for treating emergency conditions which arise while patients are enrolled in the alternate delivery systems. Hospitals continue to be the main resource providing dialysis care immediately before and after transplant surgery.

Rationale for Governmental Innitiative

As previously stated, nowhere in the health care industry does the same gap exist between technology and delivery as in the area of treatment of patients with end-stage renal disease. Technologic developments in the last few years have made possible the rapid expansion of programs to enter patients in hemodialysis, in an institutional setting. The development of remarkable technologic innovations that allow self dialysis by the patient or a member of his family at their home has been a major step in making this a practical approach. Techniques of organ harvesting, preservation, and transplantation have made renal homotransplantation a service entity and no longer a research tool. However, the funding mechanisms to develop the resources and provide patient care reimbursement have lagged far behind. A management plan to prevent duplication, and establish a nationwide network and high quality to assure total coverage is necessary. Because of this disparity, and the need for a national network, it is an appropriate function of the Federal government to bridge the gap by providing funds to develop the resources with the expectation that patient care reimbursement mechanisms such as Title 18, Title 19, the National Health Insurance Standards Act, the Blue Plans, etc., will provide the payment of the direct services once the resource is present and to coordinate the program. This program is a five-year funding effort that will be utilized as startup costs to assist the medical centers to develop these additional resources.

Two methods may be employed to prevent duplication of services. This is absolutely necessary to prevent a spiraling of costs to treat end-stage renal patients and further contribute to "health care inflation". The first method is a regulatory approach and consists of a system of franchising dialysis-transplantation centers through either the State Health Department or 314a agency. The advantage of this system is that it is an absolute prohibition against unnecessary services, the disadvantage is that this would require modification of existing State laws in most areas. The second disincentive to unnecessary duplication of hemodialysis and renal transplantation centers is the voluntary cooperation of four major health financing agencies with support of the National Kidney Foundation and the American Society of Nephrology. This approach would utilize third party reimbursement mechanisms as the disincentive. Specifically, if the Social Security Administration, Social and Rehabilitation Service, Health Insurance Association of America, and the Blue Plans were to agree that they would only reimburse care given to patients in approved, certified centers, this would provide a mechanism for preventing duplicatory services. Several leading nephrologists have discussed elements of this plan with the Regional Medical Programs Service over the past several weeks. Their enthusiastic support of this approach would imply that it would be possible to receive essentially complete support of the members of the American Society of Nephrology and the National Kidney Foundation to back a Federally controlled program. This voluntary health agency and professional association support coupled with a funding decision by the third party payors would assure the success of the proposed plan.

A question may be raised as to why the Federal Government should support a complete program for one specialized health problem such as end-stage renal disease without insisting that it be part of a total comprehensive system. The answer lies in the fact that health care delivery must be comprehensive at a primary and secondary level but tertiary care requires highly specialized skills and facilities on a regionalized basis. Dialysis-transplantation centers are a specialized form of tertiary care. The investment in training, technology, and other resources to provide tertiary levels of care is of such a magnitude and is so demanding on health manpower training facilities and other resources that optimal utilization must be made of them. Not only are the resource requirements large but also they cannot function in isolation from other tertiary levels of care. That is to say transplantation centers cannot exist without immunologists, good clinical pathology laboratories, good operating rooms, and recovery room; dialysis centers cannot function without blood banks, nephrologists, psychiatrists, urologists and social workers. The aggregation and interdigitation of tertiary skills has a synergistic effect upon productivity. The climate that develops in a medical center is conducive to further testing and development of innovative technologies.

Further, the skills are of such a high degree of specialization that a minimum level of activity is necessary to maintain quality. Coordination is necessary to assure linkages of primary and secondary services to the tertiary services to prevent duplication.

The second reason behind this special Federal program is that there is a finite group of patients with a predictable frequency thus the supply of resources can be geared to the demand of the patients by effective centralized planning. There are few other health care delivery problems that fit this category. The third answer is that this systematic approach to the delivery of one health care problem has proven to be successful on a regional basis in this country and on a National and International basis in other countries. Thus, the development of a National coordinated network, that sets as its goal the provision of access to resources for all medically eligible citizens and the fulfillment of this goal, establishes a systems model that can be applied to other health care problems as technology becomes more advanced.

Technological Plan

During the past decade significant inroads have been made in the treatment of patients with end-stage renal disease. With demonstration that patients can be readily maintained for years by regular hemodialysis over a decade ago, efforts have been directed towards the development of low cost, practical and simple methods of treatment. These efforts have lead to the development of home hemodialysis, a procedure that has drastically reduced the cost of this therapy.

With the demonstration of the long term patient survival on hemodialysis coupled with the advances in immunosuppressive therapy, renal transplantation has become the acceptable mode of therapy. Significant strides have been made in organ procurement and preservation,thereby, increasing the availability and improving the quality of donor kidneys. With the recent introduction of anti-lymphocyte globulin to bolster the already existing immuno-suppressive drugs, further improvement in cadaver kidney survival may be on the horizon.

In conclusion, the technology necessary to treat patients with end-stage renal disease is now a reality. Further investigative efforts are still being directed towards the improvement of existing techniques.

Management Plan

The development of hemodialysis and transplantation over the past decase as complementary modes of end-stage kidney disease patient care has indicated striking need to organize integrated systems of delivery. The efficient delivery of dialysis therapy requires concentration of expensive dialyzers and dialyzate delivery systems at central points where scarce medical and paramedical manpower can be employed in treating large numbers of patients. Such centralization provides the patient with high quality services while he is being stablized, and permits the medical center to fully classify the patient as a potential kidney transplantation recipient. Acomprehensive program that provides center, home training and limited care dialysis treatment and transplantation can be responsive to the individual medical requirements and needs of each patient requiring treatment. It has been demonstrated that transplantation facilities with adequate dialysis (pre-and-post transplant) can serve large population groups. As the hub of a network of dialysis centers, transplantation offers patient egress from long-term dialysis.

Thus, the most effective delivery system of end-stage kidney disease treatment requires aggregates of hospitals and other health facilities interrelated in an organized network which assures accessibility of care to the patient, and interdigitates patient referral, patient registry, dialysis, organ procurement, transplantation, laboratory services and continued patient follow-up.

Such a system lends itself to a national program of coordinated dialysis-transplantation networks such as has been under development by the Regional Medical Programs Service, HSMHA. The kidney disease control activity of the RMPS has intensively demonstrated dialysis and transplantation modalities in various settings, and the Regional Medical Programs across the country have begun to organize regional end-stage programs incorporating existing medical and health facilities, private patient care funding and manpower; they relate to State and local planning agencies, and Veterans Administration, vocational rehabilitation and other Federal, State and local medical and health programs.

RMPS authority to develop and coordinate interregional end-stage treatment delivery systems is contained in Section 910, Title IX, PHS Act. Inquiries and proposals for broad, interregional end-stage kidney disease programs to coordinate dialysis, organ procurement, and transplantation activities for large section of the country are being received. Such programs typically propose cadaver organ procrement, and donor-recipient matching and registry facilities for a number of transplantation centers, which are related to supporting dialysis facilities. A broad program which provides contractual support for such "super regional" activities would assure coordination and monitoring capabilities at the national level to obtain efficient, non-duplicating employment of resources, and effective coordination with related health programs at Regional, State, and local levels.

Project Schedule

1. Fiscal Year 01:

    a. Contract for the development of the communications system.
    b. Fund 30 transplant centers - either completely new or supplementing existing incomplete centers.
    c. Fund 25 home dialysis training programs - either completely new or supplementing existing incomplete centers.

2. Fiscal Year 02:

    a. Continue funding the communication system.
    b. Continue funding 30 transplant centers.
    c. Start funding 20 additional transplant centers (as above).
    d. Start funding 25 home dialysis training programs (as above).

3. Fiscal Years 03,04,05:

    a. Continue funding the communication system.
    b. Continue decremental funding of 50 transplant centers.

Resources Plan

The direct manpower required to fulfill the objectives of the "Life-Plan" for End-State Renal Disease includes the following:

1. For the Transplant Center

    a. Transplant Surgeon
    b. Assistant Transplant Surgeon (at 50% time)
    c. Administrative Coordinator
    d. Secretary
    e. Perfusion Technician
    f. 3 Tissue-typing Technicians

2. For the Home Dialysis Training Program

    a. Physician
    b. Administrative Coordinator
    c. Secretary
    d. 2 RN's
    e. 2 LPN's
    f. 4 Dialysis Technicians

3. For the Communications System

    a. Coordinator
    b. 3 to 5 Computer Systems Technologists
    c. Also included here will be a significant but as yet undetermined number of personnel utilized in designing and implementing the system. These personnel will be computer programmer and systems analyst specialists.

For the entire program, this gives us a total of 925 direct personnel (exclusive of communications people) who will be supported with Federal funds. These are, however, other personnel who will be directly involved in the program, i.e., dieticians, social workers, psychiatrists, and psychologists. In most cases, this group of personnel will already be a part of the existing medical staff and will not require any recruitment.

The availability of trained medical and allied health personnel to fulfill these positions is adequate in most cases. However, 400 trained paramedical technical personnel are required, and it is anticipated that a shortage in this personnel areas may develop. To offset any shortage, discharged armed forces corpsmen and other technical specialists who have already been extensively trained in general patient care and/or laboratory work, will be recruited, trained and employed in the appropriate center.

Wherever possible, already existing hospital facilities will be used for the centers. No new construction is anticipated but some renovation of the existing facilities is expected.

The initial source of funds for the establishment and operation of the centers will come from the Federal government. Federal support for the first five years of the program will allow the centers to become firmly established and develop adequate direct patient reimbursement mechanisms, thus becoming self-sufficient.

Desired Impact

End-stage renal disease is not a respector of age, sex, race, or socio-economic background. Lack of access to care is not restricted to a specific geographic or economic group. It has been noted that there is a higher incidence of end-stage renal disease in minorities and in high density residential areas than in other portions of an urban community. The described program of providing a national network of Life-Plan Renal Treatment Centers would provide access to all citizens with medical indications for hemodialysis and/or renal homotrans-plantations. At the end of five years the program goal of treatment resource availability for all citizens with this condition would have been reached. The impact upon the rest of the health care delivery system would be negligible as far as diversion of resources from other priority areas. This systematic approach to handling a major health issue will provide a model that may be emulated to solve other health care problems. Proper implementation of this program will strengthen the concept of regionalization and non-duplication of health care services. It will not be a perpetuation of further fragmentation of care.

Evaluation Plan

It has been estimated that 7,000 to 10,000 lives are lost each year that are salvageable by the provision of proper treatment modalities. Not only are these lives salvageable but over 75% of them are rehabilitatible to a level approaching their activities before the terminal illness began. Thus, the criteria for evaluation are: (1) access to care for those diagnosed as having end-stage renal disease with medical indication for maintenance therapy; (2) degree of rehabilitation of those so treated;

(3) acceptability of the care by the patient and his family; (4) Cost containment. With the present system the average annual cost for patients in home dialysis, institutional dialysis and renal homotransplantation programs, has been quite high. With a systematic approach, improved utilization of resources and coordination of repayment mechanisms, it is expected that the average annual cost will decrease (or remain stable). No patient is to be denied care because of financial barriers; (5) the quality of medical care delivered is to be evaluated by a national renal peer review mechanism. Standards of optimal care will be developed and maintained for selection of patients, determination of medical management, degree of rehabilitation and end results. National optimal standards can assure the finest quality of care in each of the renal centers.

Management Review Procedure

A kidney disease control program already exists in HSMHA in the Division of Professional and Technical Development of the Regional Medical Programs Service; procedures for the receipt, review, and approval of proposals for kidney disease programs have been operational for some years. An important element of this procedure is the requirement that applicant groups obtain State and Regional certifications of program need, evidence of non-duplication of existing medical and health resources, and that plans provide effective linkage with other programs for planning, operations and patient referral.

A Kidney Diseae Advisory Committee will be established to advise the Administrator, HSMHA,on the administration of the national kidney disease program. The committee should be comprised of outstanding individuals in the fields of nephrology and related medical specialties, health administration, consumer and technological specialty areas which are contributing to advanced medical delivery systems. The committee will evaluate the administration of the national kidney disease program, and advise the Administrator on matters of criteria, program performance, opportunities for technical innovation, and organization and employment of appropriate health resources.

Criteria applicable to the selection of participating institutions are being developed under the provisions of Section 907, Title IX, and will be available soon. Development and implementation of the program will be monitored by the Regional Medical Programs in cooperation with comprehensive health planning agencies. Evaluation of program performance will be carried out by RMPS through established regional and interregional reporting systems, and centralized registries of patients entering and being served by the national program.

Tab Budget

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Budget

The federal expenditure over a five-year period of time is estimated to be 35 million for transplantation centers, 10 million for home dialysis training centers and 5 million for communications network or a total of 50 million dollars over five years (which averages 10 million dollars per year.) It should be noted that there are already in existence several transplantation centers that would not need additional support to become self-sufficient (approximately 7-10). It should also be noted that there are already in existence home dialysis training programs that would not need further support to become self-sufficient. At this time an exact estimate of the number of these is not available, but will be developed shortly. The funds saved by not having to support the full quota of transplant centers or home dialysis centers will be utilized to fill the gap where satellite, low cost, hemodialysis centers are needed to provide for the patients who can not care for themselves at home or receive a renal homotransplant.

Several States have already established State-wide funding mechanisms to pay for the direct patient care costs. This national plan will be coordinated with these States. Federal-State cooperation in this network approach to a priority health issue is a model that can be followed by other programs.

The economic input of this proposal upon equipment manufacturers is:

1.	Perfusion and dialysis equipment	$2,000,000
2.	Computer systems	$5,000,000

The employment impact of this program is:

1.	Physicians	125
2.	Nursing personnel (RN and LPN)	200
3.	Technicians (Perfusion, Dialysis, Tissue Typing)	400
4.	Administrative staff	100
5.	Clerical	100
	Total	925

Transplantation Centers

Transplantation Centers will be funded at an average of four million people per center for up to 50 transplantation centers. These will be supported at medical centers in areas in which the Health Planning

Agencies have determined that a need exists. It is expected that a total of 5,000 to 7,000 transplants will be performed annually by the fifth year. No new transplantation center will be planned in a region until any existing center is approaching 150 transplants per year. The desired level of activity will be 100 transplants per year per center. The Federal Government will fund on a decremental basis (up to 100 percent year one and two, 75 percent year three, 50 percent year four and 25 percent year five) the following categories provided that they do not currently exist in that region. If one or more of these budget items are available, the center will be funded for the remaining portions.

Transplant Surgeon	$35,000	
Assistant Surgeon (50% of the time)	15,000	
Administrative Coordinator	15,000	
Secretary	8,000	
Perfusion Equipment	20,000	
Perfusion Technician	10,000	
Supplies	5,000	
Hospital expenses for cadaveric organ-harvesting	75,000	
Typing Lab - 3 technicians	30,000	
Supplies	5,000	
	Sub-Total	$218,000
Overhead		60,000
	Total	$278,000

The program being considered would provide funds to support transplantation surgeons at the various medical centers. The critical importance of this stems from consideration of several factors. First, most University-affiliated hospitals cannot find funds for the sole support of a transplant surgeon (who only does transplantation surgery), as a separate categorical activity as opposed to general surgery or vascular surgery with part-time activities in transplantation. Yet, it has been clearly demonstrated that the success and progressive growth of a renal transplantation program is critically dependent upon the presence of a full-time surgeon devoted

exclusively to transplantation and probably requires a minimum equivalent of 1½ full-time surgeons. It has further been demonstrated that in most instances, the initial support of such individuals, once a program has developed, no longer requires outside financial support for the salary of the surgeon, this being subsequently obtainable through funds gathered via 3rd party payment mechanisms. Alternatively, funds often become available through the hospital administration, as it sees the source of increasing incoming funds generated by the transplantation service.

Home Dialysis Training Programs

Making the assumption that each Home Dialysis Training Program will operate two shifts per day, two cycles per week (Monday, Wednesday and Friday and Tuesday and Saturday) and will have a minimum of four beds, this will allow at least 12 patients per training cycle and at least 6 cycles per year; thus each unit will be expected to train 72 patients per year. As the total number expected would be between 700 and 3,000 per year, 50 home dialysis training programs can support this national end-stage renal disease life plan. DHEW would fund one home training program per transplant center with the above assumptions and with any necessary elements of the following budget (provided that they do not previously exist):

1 Physician	$30,000
2 RN's	30,000
2 LPN's	18,000
4 Technicians	32,000
1 Administrative Coordinator	15,000
1 Secretary	6,000
Equipment, Supplies and Renovation	35,000
Sub-Total	166,000
Overhead	65,000
Total	$231,000

This would be funded for <u>one time only</u> with the expectation that revenue from patient care reimbursement mechanisms would be adequate by the second operational year to bear the continuing expenses of salaries.

Technologic Systems

December 10, 1971

I. Communications System

An efficient communications system containing records of all end-stage patients must be an integral part of the life-plan system. The system would first list a particular patient whenever a diagnosis of irreversible chronic renal disease is established. Data in the system would help in the general planning for allocation of end-stage resources as well as in the selection of the most compatible recipient for each donor kidney appearing in the transplant system.

The budgetary allocation of 5 million dollars for the system includes substantial start-up costs during the first year when developmental costs will predominate. Each of the 50 cooperating transplant centers will have a terminal linked to a central computer operating 24 hours a day 7 days a week. The treatment centers would need no special computer technicians since the terminals can be programmed to operate in a conversational mode. Costs for systems design of both hardware and software would be enormous during the first year, but costs should level out in the second year and be constant thereafter. Solicitation of bids for this proposal should result in a total cost of 5 million dollars or less.

Prototypes of a computer matching system already existent are: a) The National Communications Network currently operated by Dr. Paul Terasaki, UCLA, and supported by contract with RMPS, and b) The Southeastern Organ Procurement and coordinated activity of organ exchange and cooperative utilization of computerized tissue-typing data for Virginia, Georgia, Maryland, North Carolina and New Jersey

Dr. Terasaki's computerized information system houses data on the clinical results, tissue-typing, and current status of 4,000 transplants performed across the country (74 medical centers) as well as tissue-typing data on 1,000 potential recipients (again at 74 medical centers) who are awaiting transplantation. When a donor kidney and his tissue-typing become available at any one of the participating centers, the data for these 1,000 recipients is available on a 24-hour basis and the best possible match can therefore be obtained, occasionally involving inter-center organ or patient transport. Indeed, since March 1969, 408 kidneys (or patients) have been transported between medical centers utilizing this communications network.

The Southeastern Organ Procurement Program also supported in part by RMPS has again utilized and demonstrated the feasibility of a central computer

matching system, allowing 24-hour availability of matching of donors with potential recipients, and utilizing organ exchange within the participating states.

Both of these pilot efforts have demonstrated the feasibility and potential value of a computerized national matching system.

Although all the questions regarding the pragmatic use of tissue-typing for cadaveric transplants are yet to be answered, the need for tissue-typing for living related donors, and the superior results of utilizing "A" matches in cadaveric transplants is well established. If for no other than these reasons alone, a national system of matching and organ exchange is highly desirable.

II. Trends in Current Technology of Kidney Disease Related Equipment

In the field of dialysis there are a number of potential advances relating to hardware that are currently receiving intense clinical evaluation. This equipment, if found clinically applicable, may significantly modify and improve the present dialysis treatment modalities.

Subsequent to the development of the capillary kidney, significant interest has been generated toward the use of ultra-thin cellulose acetate flat membranes. This type of membrane appears to be superior to the existing membranes for removal of "uremic toxins". The use of this type of membrane may significantly shorten the period of time a patient may be required to dialyze per day, thereby increasing potential for rehabilitation. Clinical trials are just underway. In addition, significant strides are being made in the prolongation of function of cannulas. By the development of an appropriate tissue interfacing substance, as well as minimal thrombogenic surfaces, external cannulas may enjoy significant improvement in survival rates.

With regard to the development of new dialysis systems, there are two promising avenues presently undergoing clinical trials. The first is the low volume (1-2 liters) sorbent dialysis system, in which the dialysate is being constantly recirculated as it is being regenerated with the aid of a spectrum of selected adsorbents. This development alone is extremely valuable because for the first time hemodialysis may become independent of the "kitchen sink and the toilet drain" in home dialysis. This drastic reduction in the amount of dialysate required also promises to solve a whole series of problems which have beset dialysis, namely, the quality of tapwater available for dialysis and the preparation of large volumes of dialysate with the aid of proportioning pumps and concentrate solutions. The second deals with a system called hemodiafiltration which has not as yet undergone sufficient clinical pre-testing.

In addition, there has been the introduction of micro-encapsulated particles which are ingested by the patient and theoretically adsorb the 'uremic toxins' in an amount sufficient enough to reduce the frequency of dialysis.

Finally, peritoneal dialysis has received renewed interest with the development of an automatic delivery system. This system removes most of the complications associated with peritoneal dialysis and enables one to perform the procedure quite readily.

In conclusion, there are a number of significant advances that are on the horizon that have the potential of significantly altering the complexion of dialysis.

III. Current Status of Home Dialysis Technology

Home hemodialysis was initiated in Boston in 1963 and in Seattle and London in 1964. Initially, home treatment was a cumbersome experimental endeavor but has evolved rapidly into a practical and successful means of treating end-stage renal disease. Maintenance dialysis now can be made available to almost anyone who is capable of learning to treat himself in his own home. Furthermore, treatment in the home rather than the center can provide an opportunity for more dialysis and, therefore, better control of the azotemic state and at less than half the cost.

At the present time, in a treatment program designed for training patients for home dialysis, a period of approximately six to eight weeks of instruction serves to train a patient adequately. Initially, patients trained for home dialysis primarily used the Kiil-type dialyzer with a simple hydraulic dialysate delivery system. Rapid advances during the ensuing years have lead to the introduction of more sophisticated and safer dialysate delivery systems. With these advances coil dialysis at home became more of a reality than in the past. In recent years, the introduction of such dialyzers as the 'capillary kidney' has offered an acceptable alternative to the usual dialyzers. Presently, significant inroads are being made into the development of compact disposable dialyzers. In addition, the use of small and compact recirculating dialysate delivery systems are presently undergoing clinical trials. The potentials these advances hold for the future are impressive. Indeed, it would realistically appear that a patient with renal failure will only have to dialyze himself one - two hours a day with a system that could readily fit within a suitcase.

IV. Procurement and Preservation of Donor Kidneys

The basic principal of providing each transplant recipient with the best

possible donor organ would be greatly enhanced by the ability to effectively assay potential donor organs for viability and transplantability prior to the actual surgery. Presently, two preservation methods are available which have been used extensively in clinical organ transplant: 1) simple hypothermic storage with or without brief initial cold perfusion and 2) prolonged pulsatile perfusion. Storage by simple hypothermia has been used extensively and appears to be a safe procedure for less than ten hours. On the other hand, the method of pulsatile perfusion of the kidney allows for considerably greater advantages: 1) adequate preservation for at least thirty hours, 2) assessment of viability of donor kidney, 3) removes transplant surgery from that of an emergency procedure to that of an elective one, 4) allows for potential sharing of a kidney with the best matched recipient wherever he may be, 5) allows for pre-surgery reassessment of potential recipients. Presently, devices have been developed which can be easily transported in a small van or even an airplane seat. This then allows for the transportation of organs from region to region and potentially from country to country.

Currently, the scarcity of available cadaver organs is probably the most important factor in limiting the number of transplants being performed. Hence, it is of utmost importance that an aggressive organ procurement program be established. The importance of public and physician education, so that the pool of potential donors will be increased, is absolutely vital to the future of cadaver organ procurement. In addition, the support of local legislation to make it easier to obtain organs is of vital concern.

In conclusion, organ procurement relies heavily on public education and acceptance of organ transplantation.

December 10, 1971

Patients with Incidence of Treatable
End Stage Renal Diseases

In 1967, the Gottschalk Report was submitted to the Bureau of the Budget. This report concerned itself with the problem of developing programs to care for persons with chronic kidney disease. Special note was made of the incidence in the U.S. of chronic kidney disease. At the same time, a study from the National Institute of Health addressed itself to the same question. These two reports are in remarkably close agreement and have accurately defined the problem when examined against recent statistical analysis.

These reports estimated that approximately 50,000 persons die each year from chronic renal disease. This works out to 35 patients per million per year who are treatable. Of those with kidney failure 7,000 to 10,000 are suitable candidates for prolonged medical treatment. Medical treatment consists of conservative therapy, chronic dialysis, and transplantation.

This prediction has been borne out by the experience of the majority of physicians who care for persons with chronic kidney disease. Indeed, the incidence of 35 suitable patients per one million population per year has stood the test of four years time.

A National Plan for Establishing Patient Referral Patterns

One of the factors that limits care for patients with chronic kidney disease is the lack of a system for patients to enter a well defined referral pattern. A system of this nature has been proven effective in the United Kingdom; Scandia-Transplant which serves Sweden, Finland, Norway, Denmark, and Northern Germany; and Euro-Transplant which serves Benelux, Germany, Austria, and Switzerland. From their experience we feel this type of program could be planned and adopted in the United States. The patient referral pattern is best established at a national level.

The program which is proposed establishes close knit cooperation between facilities within 50 dialysis-transplant centers. The activities of these facilities include prevention of kidney disease, education, case detection and treatment, organ procurement, tissue typing, dialysis networks, and transplantation. Information between the various facilities will be coordinated by a national registry. All information on a particular patient must be exchanged between the centers of excellence and those primarily concered with a patient's care.

The overriding purpose of this system is to care for a greater number of patients, refer patients to the most sophisticated source of medical treatment, and to return them to useful lives as quickly as possible.

In order to not overload the centers of excellence it is planned to return the patient to the primary physician. The primary physician, therefore, must have continued training from the centers of excellence. Continuing education will also be made available to nurses, dietitians, technicians and other paramedical personnel who are involved with the patient's care.

The flow of patient referral is outlined diagramatically below. This system is not unlike the pattern of referral that is used today in some areas of the United States. However, the development of a more organized national program will allow for more patients to reach the quality of care that is presently available.

Expected Case Loads and Growth Rates of the Life-Plan Renal System

I. Transplantation

Information from the National Dialysis Registry suggests that there are approximately 5,000 patients on dialysis in the United States today. Dr. Paul Terasaki has data indicating that there are approximately 1,000 patients awaiting transplantation across the country. His data are not complete however, and an estimate of the actual current backlog of patients who are candidates for transplantation would be somewhere between 2,000 and 3,000. Data from the Gottschalk Committee Report suggests that approximately 35 patients per million population per year are candidates for transplant or dialysis therapy -- this works out to be approximately 7,000 patients in the United States each year.

The life plan program for end-stage renal disease would be expected to progressively increase the national capacity for transplantation over a five-year period and over a somewhat longer period, result in a stabilization of transplantation capacity such that a steady state would be reached. Assuming that 80% of all patients with end-stage renal disease who are treatable will be transplanted, then the rate of new transplant candidates for the nation per year will be approximately 5,000 per year. If the rate of expansion of transplantation case load capability averages 30 patients per center per year during year 1, 40 per year for year 2, 60 per year for year 3, 80 per year for year 4, 100 per year for year 5, and finally, reaching 150 per year by year 6, then the following predictions can be made: At the end of five years such a transplantation program will have reached a capability of handling the subsequent yearly rate of entry of transplant candidates into the system. In an additional

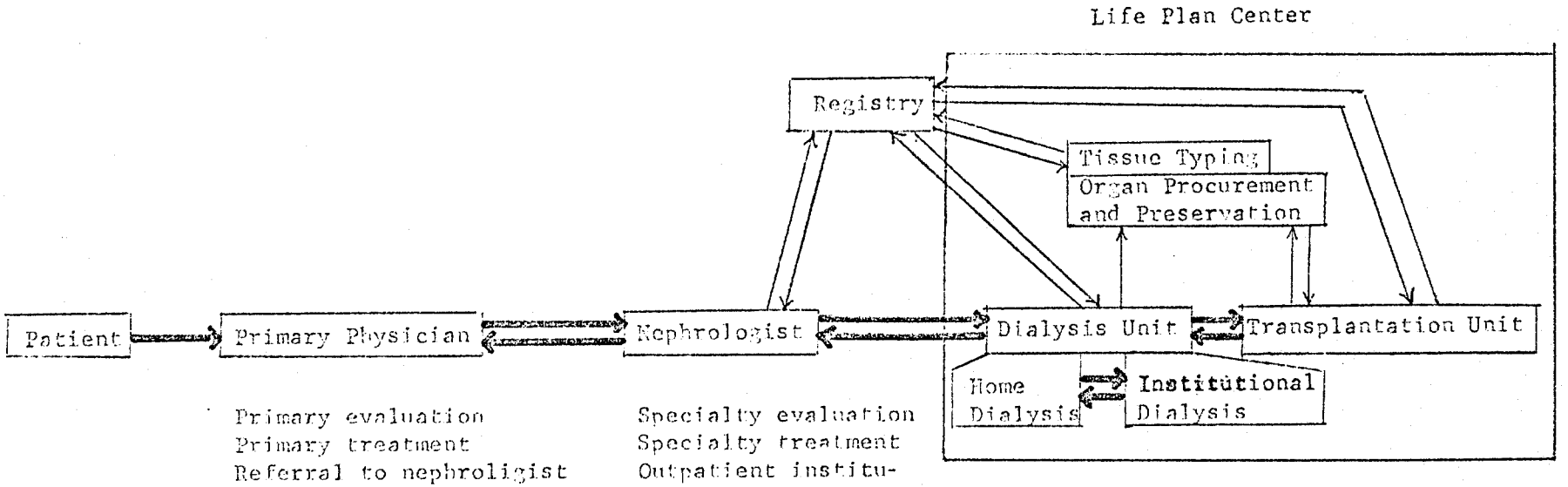
three years (a total of eight years after the inception of the program) the backlog of patients encountered in the system (the initial backlog plus the yearly backlog resulting from progressive increase in transplant capability) will also have been transplanted. Therefore, it is predicted that a total of eight years is required for a steady state to be achieved with respect to transplantation, and thereafter, transplantation capability will be fully adequate to meet the yearly need.

Another assumption that is made in these calculations is that all of the 35 patients per million that are potential candidates will be identified in the proposed program and therefore treated. The experience to date is that there is initially a significant lag in identifying all of these potential candidates so that the predicted case load in the first few years is probably excessive. With proper emphasis by the program to further public and physician education, it is anticipated that all or nearly all potential candidates for therapy will be identified. This will not significantly alter the predictions for the time required for the system to reach a steady state. The predictions regarding the expected rate of transplantation are realistic in view of the present data showing that in 1969, 900 transplants were done in the United States;in 1970, 1000 were done and by the end of 1971 between 1100 and 1500 will be done. The expectations for the proposed program of transplanting 1500 patients in year 1, and progressively increasing to 5000 patients transplanted in year 5, is attainable.

II. Dialysis

Dialysis supportive aspects of the life-plan will reach a steady state earlier because of the progressively decreasing case load as transplantation capability increases. It is predicted that the dialysis case load will begin at approximately 5500 patients for year 1 and decrease to approximately 2000 patients for year 5 and all subsequent years. The proposed program entails supporting current home dialysis training programs by providing increased home dialysis training capacity to each of the 50 centers, and adding an additional four home training beds to each of the centers (operating on a three dialysis per week, two shifts per day schedule). It is proposed that such a system allows for the handling of the dialysis load and achieves full capacity to do so by as early as year 3, and thereafter, a progressive decrease in dialysis need and capacity could be effected.

A NATIONAL PLAN FOR PATIENT REFERRAL PATTERNS



Primary evaluation
Primary treatment
Referral to nephroligist and Life Plan Center
Home Dialysis Supervision
Transplantation follow-up
Continuing education
Prevention

Specialty evaluation
Specialty treatment
Outpatient institutional dialysis
Home dialysis supervision (possibly training)
Shunt replacement
Transplant follow-up
Continuing education
Consultation on: diet, personal services, rehabilitation

Specialty Evaluation
Specialty treatment
Chronic institutional dialysis
Home dialysis training
Shunt placement
Tissue typing
Organ procurement and preservation
Renal transplantation
Training of health personnel
Continuing education
Consultation on: diet, personal services, rehabilitation

Key: Patient referral and exchange of information ——
Exchange of information only ——

Number of Transplantation Centers for which each State is Eligible*

Hawaii: 1

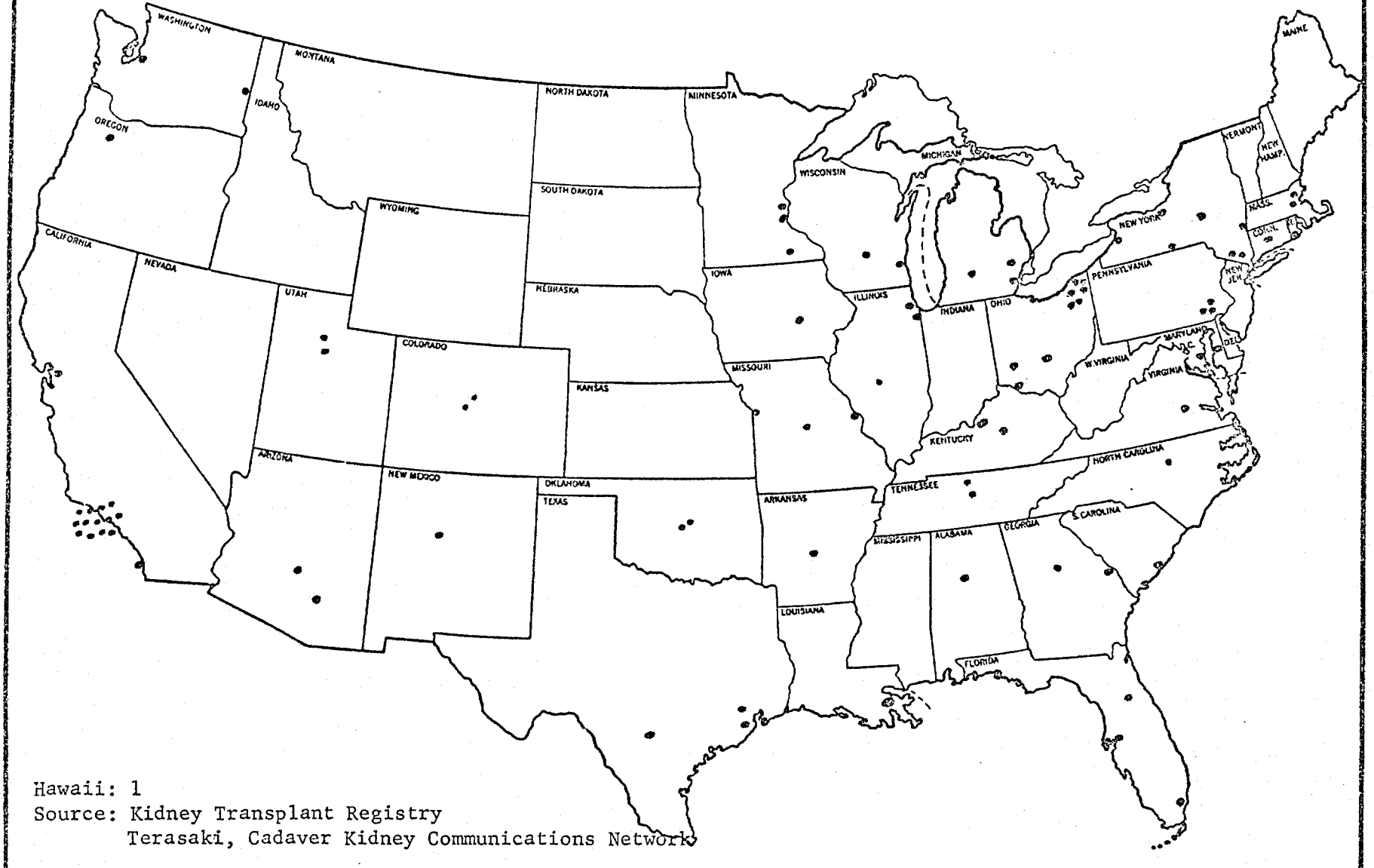
Puerto Rico: ½

* based on ratio: 1 center per 4 million population

** Eligible for less than ½ center

HEW-111

Existing Kidney Transplant Centers



Hawaii: 1

Source: Kidney Transplant Registry
Terasaki, Cadaver Kidney Communications Network

regional medical programs service

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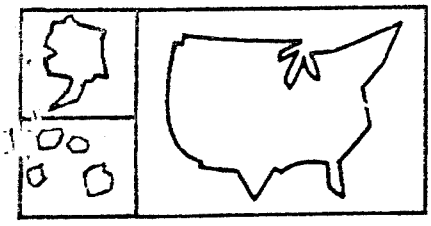

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A communication device designed to speed the exchange of news, information and data on Regional Medical Programs and related activities.

KIDNEY DISEASE ACTIVITIES -- Guidelines and Review Procedures Statement

May 3, 1972 - Vol. 6, No. 9S

This issue presents revised guidelines and local and national review procedures for kidney disease activities.

These guidelines supersede all previous RMPS materials relative to the submission of kidney disease applications, specifically including those appearing in the News Information Data, "Policy Statement and Guidelines" published on November 27, 1970, Vol. 4, No. 53S, and the "Interpretation of Guidelines." published on March 1, 1971, Vol. 5, No. 5S.

Distribution:
- Coordinators of Regional Medical Programs
- Members of National Advisory Council and Review Committee on Regional Medical Program
- Staff of Regional Medical Programs Service
- Regional Health Directors and Regional Medical Programs Service Representatives of Health, Education, and Welfare Regional Offices.

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service • Health Services and Mental Health Administration • Rockville, Maryland 20852

Dr. Hinman

GUIDELINES AND REVIEW PROCEDURES STATEMENT

Kidney Disease

BACKGROUND

Nowhere in medicine does the same gap exist between technology and delivery as in the area of treatment of patients with end-stage renal disease. Technological developments in recent years have made possible the rapid expansion of programs to provide patients with hemodialysis in institutional settings. Innovations which allow self-dialysis by the patient in his home, or in a low overhead facility, vastly extend the utilization of delivery resources, and reduce the cost to the patient. Techniques of organ harvesting, preservation, and transplantation have made renal homotransplantation a service entity, no longer a research tool.

It is estimated that of the approximately 50,000 persons who die each year from kidney disease, 7,000 to 10,000 are suitable candiates for chronic hemodialysis and/or renal transplantation, and that an additional 10,000 to 20,000 might benefit from each treatment. At present, the annual increment of new patients being offered treatment for terminal kidney disease is probably not more than 3,000.

CURRENT RMPS PROGRAM EMPHASIS FOR KIDNEY DISEASE PROPOSALS

Although national priorities for kidney disease programs will be established and modified over time as appropriate by a panel of renal authorities, for the present it is necessary to focus on improvement and expansion of the delivery of care to end-stage kidney disease patients. RMPS is primarily concerned with the development and implementation of kidney disease programs which will provide the therapeutic tertiary care services of dialysis and transplantation to patients who do not now have access to such life-saving care.

The substance of such programs includes:

1. Procedures to assure early identification of patients in, or approaching a terminal stage of renal failure.

2. Rapid referral of such patients from the level of primary care (private physician) to tertiary care facilities for dialysis and transplantation.

3. Early patient classification with regard to tissue type, and other pertinent factors.

4. Dialysis and transplantation facilities which assure treatment alternatives to both the patient and physician.

5. Effective cadaver kidney procurement operations, coupled with rapid kidney donor-recipient matching.

6. Selective training to meet the specific needs of the above program.

The characteristics of such programs include:

1. The patient has access to conservative management before kidney function has ceased.

2. The patient is registered in shared recipient rosters to assure optimum tissue matching, and maximum utilization of harvested cadaver kidneys.

3. The patient can be trained to carry out dialysis at home, or if not eligible for this mode of care delivery, has access to satellite dialysis, or in-center care.

4. Dialysis facilities encompassing all three of the above modes of dialytic treatment will serve, or be an integrated part of a system which serves a population of no less than 500,000.

5. The patient can gain access to transplantation if such therapy is his choice, with his physician's concurrence.

6. Transplantation facilities are centralized to:

   a. limit duplication of high cost facilities and services.

   b. assure maximum utilization of full-time transplantation surgeons.

   c. assure availability of complementary backup services required for special patient evaluations and treatment.

   d. provide the coordinating point for patient referral, donor-recipient matching, patient data exchange, and organ sharing.

7. Transplantation centers will serve populations of 3-4 million persons.

8. Maximum utilization is made of services and facilities for kidney disease patients.

9. Continued development of third-party payment mechanisms is pursued to support expanding kidney patient care services.

10. Integration of renal disease patient services with other patient services and facilities is organized at all levels.

11. Pediatric dialysis and transplantation services are coordinated with adult facilities to provide optimal use of services.

REVIEW PROCEDURES

The openly categorical nature of end-stage kidney disease activities, and the need to effectively coordinate integrated dialysis and transplantation systems indicate the need for continued central direction for development of a national program. Thus, applications for kidney activities will be handled in a manner different from other Regional Medical Program applications, but modified from the procedures followed heretofore.

1. Policy Preclearance - immediately upon an indication of interest in the submission of a kidney proposal by a source within an RMP, the RMP should contact the appropriate RMPS Branch in the Division of Operations and Development (DOD). It is suggested that a brief abstract or letter of intent be submitted which outlines the nature of the prospective activity, the probable role the proposal would play in the Regional program, and the need which will be satisfied within the overall renal disease program of the Region. The Branch which serves the Region will utilize the Region's written inquiry to confer with staff of the Division of Professional and Technical Development (DPTD). RMPS will advise the Region whether it is desirable to proceed further. The RMP, of course, may accept or reject this advice.

2. Technical Program Review - prior to submitting application for a renal disease program, the RMP is expected to obtain a technical review of the proposal by a group which has not participated in the program's development. The technical review group must be comprised of at least 3 renal authorities from outside the geographic area served by the Region. Payment of the costs of such consultant services will be made by the requesting RMP.

   The Region may obtain the names of consulting renal experts by calling the appropriate Operations Branch for assistance. The Division of Professional and Technical Development maintains a list of renal consultants, and is responsible for coordinating their assignment. Should the RMP desire to choose its own review panel, the names and curriculum vitae of prospective consultants must be cleared with the DPTD.

   Technical reviews of renal programs need not always be made by consultant site visits, but may be accomplished by mail when appropriate. The RMP will negotiate any compromise needed should conflicting technical advice be given by the technical reviewers.

3. Forwarding Proposals - only those proposals which are recommended favorably by the local Technical Review Group (paragraph 2., above) shall be eligible for consideration by RMPS. In addition, an opportunity must be provided prior to consideration of the proposal by the RAG for review and comment by the appropriate CHP agency(ies) as required by Section 904(b) of the Act.

The RAG shall consider any CHP comments and comment on the ability of the RMP to manage the kidney project without hindering the development of the overall RMP program, and the reasonableness and adequacy of the kidney budget proposed. The RAG is responsible also for indicating how major issues raised by the local technical review group will be resolved.

Since kidney proposals are reviewed separately at the national level, the RAG need not give priority ranking to kidney proposals in relation to other non-kidney RMP operational activities. Kidney proposals shall be considered by RMPS in relation to national priorities.

The complete comments of the members of the Technical Review Committee, and any CHP agency comments, must be included in the forwarded proposal.

4. RMPS Staff Review - the initial review at RMPS shall include:

   a. the contribution of the project toward kidney program objectives.

   b. the completeness and nature of the comments of the RAG (point 3., above).

   c. comments of CHP agencies.

   d. the preferred method of funding.

5. RMPS Review Committee - RMPS staff will summarize for the RMPS Review Committee available information as to how each kidney proposal proposes to support the National Kidney Program objectives, and the substantive points developed through local review processes by the Technical Review Committee, the RAG, and the CHP Agency. For those applications for which the RAG; CHP Agency; Director, RMPS, or RMPS Review Committee has indicated a concern apart from the technical merits of the project, the RMPS Review Committee will be asked to make a recommendation to the National Advisory Council.

   The RMPS Review Committee specifically will not review on a technical basis the merit of the proposal, or establish formal numerical ratings for individual proposals.

6. Council Review - all kidney proposals shall be submitted to the National Advisory Council for final recommendation. In keeping with the categorical nature of the kidney disease program within RMPS, the Council will review and recommend funding levels for kidney proposals separately from the funding level of the specific RMP. Kidney program funding will be in addition to other RMP program funding.

PREPARATION OF APPLICATIONS

Effective July 1, 1973, all kidney proposals must be submitted as part of the RMP's regular annual application in accordance with the Region's assigned anniversary date. Prior to July 1, 1973, kidney proposals may be submitted in accordance with the document "Procedures for Requesting Supplements to RMPS Grants, April 7, 1972".

Sponsors of applications for support of kidney disease projects should submit them to the appropriate RMP in the format which the RMP prescribes. An application involving 2 or more RMP's may be submitted where appropriate. In such cases, one RMP should be designated to act as "applicant" and submit a single application. Such applications must be approved by each RAG and shall include a description of mutually agreed upon arrangements for administration of the project. In view of the preliminary clearances which are called for in these guidelines, it may be helpful to develop and submit a letter of intent to the appropriate RMP's before an application is prepared.

In addition to the summary information to be provided on the forms specified for applications, narrative should address in detail the program elements specified below. Descriptions which are comprised only of generalized narrative will not be acceptable; disease control needs and the applicability of the proposed program must be presented on the basis of solid data relating to patient populations and distribution, specification of existing services and resources, and clearly documented commitments of cooperation and participation from key persons and institutions. Assistance can be obtained from the program staff of the RMP.

Program elements to be addressed are:

1. the magnitude of the renal disease problem.

2. facilities and programs currently in operation and the needs they are meeting.

3. the needs which the new proposal will meet and how the program will integrate with existing programs to improve patient care services without duplication of existing services or facilities.

4. existing and potential sources of third-party payment for care and how these resources will be developed.

5. the commitment of cooperating institutions, groups and health practitioners whose collaboration is essential to insure the success of the program.

6. training, when pertinent to the plan, which is directly related to the projects comprising the plan, or judicious expansion of existing programs.

7. the system or method of program evaluation which will be employed.

8. a decremental rate or proportion of Federal (RMPS)contribution to the program over time.

9. the program's phase-out as an RMP-supported activity.

Program costs related to the Federal share of support should normally be identified with personnel and equipment requirements in tertiary care facilities.

RMPS will not fund ALG-related activities. Such funding may be included in the future if standardized production and testing is achieved and its efficacy is demonstrated. The NIH is sponsoring research in ALG through a contract.

AWARDS

Awards for kidney projects will be issued as a part of the total award to the Regional Medical Program. The amount allocated for the kidney activity will be specified in Item 14, under "Remarks", of the Notice of Grant Award, Form HSM-457. Funds awarded for kidney activities must be spent for such activities, except that unexpended balances may be rebudgeted in certain cases provided that prior approval for such reprogramming is first obtained from RMPS.

In some cases, a kidney proposal may be approved by RMPS but unfunded. An RMP may fund such a kidney project through rebudgeting other RMP funds to the kidney activity. Rebudgeting of this nature should be undertaken only after the RAG has carefully considered the effect of such action on the remainder of the RMP program. Likewise, a kidney project may be expanded as determined by the RAG by rebudgeting of funds to the kidney activity in addition to those specifically earmarked for kidney in the Notice of Grant Award.

OTHER

A glossary of kidney disease terms is enclosed for your information.

GLOSSARY OF KIDNEY TERMS

1. ALG, ALS - Abbreviations for AntiLymphocyte Globulin; AntiLymphocyte Serum. Both are products of animal serum used to prevent rejection of transplanted organs, especially kidneys.

2. Artificial Kidney - Total system used for hemodialysis consisting of dialyzer and dialysate delivery system.

3. Belzer Machine - Special type of perfusion equipment developed by Dr. F. Belzer. There are others, some devised by local hospitals. Perfusion machines preserve harvested cadaver kidneys in a viable condition, sometimes for periods of up to 48 hours.

4. Backup Dialysis - Dialysis given patients trained for self care who, under special circumstances, are unable to perform dialysis without additional assistance. Also, pre- and postoperative dialysis provided transplantation patients, particularly when the newly grafted organ is unable to assume its full function immediately.

5. Cannula - Surgically prepared, exposed connection made between an artery and a vein. The exposed connection between artery and vein is made with plastic tubing.

6. Care Facilities

   Primary - The initial facility to which a patient seeks medical advice and care; may be the physician's office.

   Secondary - A general hospital or equivalent capable of rendering definitive diagnosis and treatment. Also, a satellite dialysis facility.

   Tertiary - Sophisticated medical center. In the case of kidney end-stage disease, it is a facility capable of performing transplantation, supportive dialysis therapy, and consultation to primary and secondary facilities.

7. Decremental Funding - System of phased reduction of the Federal share of the costs of an activity, usually by increased assumption of costs through earned income and local third-party payments.

8. Dialysate - The solution used in an artificial kidney to rid the body of accumulated waste products in the blood.

9. Dialysate Delivery System - That part of the artificial kidney which supplies the dialysate and regulates such critical items as rate of flow, temperature, and concentration of dialysate.

10. Dialysis - Process by which waste products are removed from the blood by diffusion from one fluid compartment to another across a semipermeable membrane. In the case of kidney dialysis, blood is one of the fluids and the bath solution or dialysate is the other.

11. Dialyzer - That part of the artificial kidney through which waste products pass from the blood to the bath solution or dialysate.

12. End-Stage (Renal) Disease - That stage of renal impairment which cannot be favorably influenced by conservative management and which requires dialysis and/or kidney transplantation to maintain life and health.

13. End-Stage (Renal) Treatment - Refers to either dialysis or kidney transplantation or both forms of therapy.

14. Fistula - Surgically prepared unexposed connection made directly between an artery and a vein to allow repeated and ready access to the blood stream. Dialysis access to the blood stream is obtained with large hollow needles, creation of a fistula is an alternative to surgical insertion of a cannula.

15. Functions of the Kidney - The normal kidney's work includes 1) control of electrolyte concentration in the body, 2) maintenance of proper water balance, 3) maintenance of the body buffer system, 4) excretion of the by-products of cellular metabolism (urea, creatinine, and uric acid).

16. Kidney Disease - Spectrum of ailments which directly or indirectly affect the kidneys and compromise their function. (Frequently involves the entire urinary tract.)

17. Low Overhead Facility - Any kind of a building where the expensive operating costs of a general hospital can be avoided. Such facilities are used for dialysis services, making minimal use of physician time in staff required.

18. Organ Preservation - Maintenance of the kidney after it has been removed from the donor and until it has been transplanted into a recipient. Organ preservation is an integral part of a kidney transplantation program.

19. Organ Procurement - The identification of a prospective donor; the surgical removal and transportation of a donor kidney.

20. Peritoneal Dialysis - An alternative to hemodialysis - the process by which the dialysate is introduced into the abdominal cavity using the peritoneum as the semipermeable membrane.

21. Satellite Facility - A resource providing limited, specific services under the general direction of a secondary or tertiary care facility.

22. Self-Dialysis - Dialysis performed by a trained patient at home or in a special facility with or without the assistance of a family member or friend.

23. Shunt (noun) - The means by which blood is passed through other than the usual channels. There are two types of shunts used in dialysis 1) the cannula, 2) the fistula.

24. Tissue Typing - Laboratory procedure used to determine the degree of compatability between the donor organ and the recipient of a kidney transplant.

25. Urinary Tract - Collective term referring to the kidneys, ureters, bladder, and urethra.

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Tabs

KIDNEY PROGRAM REVIEW

Program Review Guidelines for Technical Consultation

BACKGROUND

RMPS has developed a program aimed at addressing the service delivery problems of Kidney Disease. This program is based on documented needs and the existence of technically sound treatment modalities which currently are not available to a large number of patients with end stage renal disease. It recognizes the fact that a finite amount of funds are available for attacking this problem. This program evolved from the activities of non-government and governmental professionals who identified the resources that are necessary for such an attack on the problems. This program, which has been termed the RMPS kidney disease "Life Plan" is the result of previous kidney program developments, and it is generally in concert with such documents as the "Optimal Facilities, Necessary for Diagnosis and Management of Patients with End State Renal Disease" which was recently prepared by the National Kidney Foundation.

The framework of this program is based upon a comprehensive regional plan covering the multiple aspects of renal disease. The matrix of the system requires the establishment of primary, secondary, and tertiary care mechanisms for the identification, referral, and treatment of the patient with kidney disease. The realities of currently available treatment for end stage renal disease necessitate the establishment of a limited number of tertiary kidney disease centers with the technical expertise and service capabilities to provide comprehensive care to a large number of patients on a regional basis. Studies indicating physical resources and available monies, compared with projected costs and cost effectiveness data, show that any effort aimed at treating end stage kidney patients must be linked with such tertiary centers in order to provide a complete spectrum of high quality care at a reasonable price.

We believe that RMPS can provide adequate "seed money" support in a decremental fashion to develop such programs in a manner such that they are ongoing and self sustaining. As an aid in instituting this program, RMPS has developed guidelines for the regions use in creating programs to meet their regional needs.

These Guidelines and Review Procedures Statement were distributed to the regions in May 1972, and a Clarification statement concerning certain aspects of guidelines was issued in early September 1972.

ROLE OF THE RENAL TECHNICAL CONSULTANT

RMP renal program review by peer professionals from outside the applicant Region is required by the Kidney Disease Guidelines issued in May 1972. Because RMP functions on a decentralized basis, technical review is done at the regional level prior to submission to RMPS for funding. The use of expert consultants from outside the region is aimed at giving a particular Region an objective evaluation and critique of regional kidney programs.

RMPS supplies the Regions with the names of Renal Technical Consultants on request from the Regions. The outside Renal Technical Consultant services are official services provided to the Regional Advisory Group (RAG) of a particular Region. The renal consultant is a private agent responsible for conducting his own negotiation on fee, time and site of consultation with the RMP which requests his services. The negotiated agreements reached between the consultant and the RMP represent a contractual arrangement between the two parties for consultant personal services. The payment for the consultants services cannot be part of the renal program grant budget, nor can it be contingent upon successful project funding.

There are three (3) basic circumstances when outside consultation will be requested, two (2) of which are required of renal program sponsors by the guidelines:

1. Renal program planning. Before a specific proposal has been developed, a region may wish assistance in planning its regional program. (Not required by guidelines, but frequently desirable).

2. A specific project or program has been developed and requires technical review so that the RAG is provided objective information to support its decision concerning approval or disapproval of the proposal. (Required by Guidelines).

3. A project (s) or program will be reviewed progress. (Required by Guidelines).

Consultants who assist a region in planning a projects should not participate in the technic assessments. Consultants who review the initi ject proposals should normally participate in assessment. A minimum of three (3) consultant in the initial technical review; two (2) consu the progress assessments.

Since the consultant's official relationship i written report of the consultant's program rev for the RAG and presented to the RMP Coordinat who is the RAG's agent. The reviewers' report parameters which are considered in the technic should have a recommendation section which cle suggested action, such as approval/disapproval and changes or modifications necessary to meri Dialogue with the project/program sponsoring i individual should make clear the consultants' and recommendations, but the consultant has di whether he will provide the sponsor a copy of RAG.

TECHNICAL REVIEW - GENERAL

Technical review of kidney grant programs requi assessment of all the substantiative activitie ments concerning the qualifications of the majc specific goals; and efficiency of the program s

We believe that the Kidney Disease Program prov opportunity to establish a prototype for delive patient care. For this reason, a Regional Kidn should be aimed at having the following impacts

1. improvement of the availability of care to
2. enhancement of the capability of health an resources to provide patient care;
3. assurance of high quality of the care provi
4. establishment of linkages between primary, and tertiary care providers; and
5. establishment of collaborative and cooperat ments among institutions.

Regional kidney programs must address factors of patient need, program site, organization, staffing, avoidance of duplication of expensive resources, financing and the overall relationship of the program with the care programs and institutions of the region. The technical reviewers should attempt to ascertain the sponsors' past collaborative performance and commitment concerning these factors which contribute to the future development of viable patient services. The review should also verify that the sponsors have indicated how they will seek out data for use in evaluation.

A. PROGRAM DEVELOPMENT

The project (s) under review should have been preceded by, or be a part of, a comprehensive renal plan. The comprehensive regional renal plan should not be confused with the grant application for RMP support of specific projects. The plan provides the objectives and overall system; the projects represent successive steps over time to realize the comprehensive program based on the plan.

The comprehensive renal plan should identify and describe the:

1. geographic area to be served.
2. population area to be served.
3. estimated or established number of renal patients.
   a. If only estimated; how will accurate confirmation of this estimate be achieved?
   b. How will patients gain entrance into the program? Are there any factors concerning minorities or patients with cultural, economic or environmental uniqueness effecting entrance into this system which must be considered? What are the selection criteria of the institutions within the region?
4. existing personnel and facilities providing care, and the quantity and physical characteristics of the care being delivered by these facilities, such as, in-center dialysis, home training programs, low overhead limited care dialysis, transplantation, etc.
5. the proposed resources which are necessary to meet the regional needs identified by the parameters above.

The proposed (or operational) program or project should indicate:

1. the unmet needs which it is designed to resolve.
2. how the activity relates to the overall framework of the regional plan for end stage renal disease.

B. ORGANIZATIONAL SETTING

Efforts should be taken to ascertain the readiness of renal program sponsors to undertake an operation which will be viable and become self sustaining within a finite period of time. Several areas which should be assessed are as follows:

1. Does the RAG consider kidney needs as having relatively high priority?
2. What are the attitudes of officials in institutions and groups whose cooperation in implementing such a program is necessary?
3. Has a regional renal committee been established to provide guidance for the continued development, evaluation and integration of the renal program as a service program in the overall health care delivery program? Is there strong kidney leadership?
4. To what extent have other hospitals, clinics, etc., who are involved with delivery of care to kidney patients been invited to participate in the renal program, and what is the extent of their pledged support in terms of real delivery of care to patients now, or in the future?
5. What are the regulatory statutes and mechanisms concerning kidney disease within the region?

C. PROGRAM OR PROJECT PROPOSAL

The proposed program/project should include:

1. Specific objectives that are appropriate, clearly defined, quantifiable, and achievable by the proposed activity. Details concerning limitation of chronic institutional dialysis and attempts to assure that all acceptable patients will receive appropriate therapies such as transplantation and low cost maintenance dialysis should be presented.
2. Details concerning measurement of progress for each project period should be presented and expressed in terms of capabilities established, services initiated, problems encountered, and number of patients served.
3. How the evaluation of services proposed will indicate acceptable quality of care. The individual/individuals responsible for evaluating the program should be identified as well as to whom the results of the evaluation will be reported.

Program Review

ion of Resources:
n(s) and size(s) of facilities to be used.
y of facilities to accomplish project.
t should be identified by kind and number,
acquisition plan set forth.
hanism of the funding of consumable equip-
pplies necessary to carry out the program
also be identified.
g and staff acquisition should be carefully
ed on a progressive pattern that reasonably
the development and implementation of ser-

ion and alteration of facilities should be
efully scrutinized, and all non-RMPS support
. RMPS is very reluctant to provide scarce
funds for this purpose beyond the barest
necessary to help activate the program.
renovation and alteration expenditure from
sources are acceptable as the institutions'
r" commitment to the program.

non-RMPS funds to meet patient care costs should
scribed. Problems faced in achieving availability
ds, and specific actions and time table planned
third-party sources of support should be enu-
articipating institutions should be advised that
e ready to cover unreimbursed costs of care.
ent of the plan should address the applicants'
hieving project or program independence from
g by the end of the third project year. Its
must reflect assumption of successive year's
funded by RMPS. The individuals carrying out
of the program should be named, as well as the
or office which will exercise direct review and
of funding source development activities.

and meaning of decremental RMP funding must be
xamined, as many applicants do not fully under-
Decremental funding means that, generally,
grant year of a specific project should require
llars that the first year, and the third year
re less than the second. This does not mean
n's renal funding will necessarily cease.
of successive projects which are part of a com-
lan may maintain a comparable level of RMP
ecremental funding underscores the need for
nt service programs to be built into the ongoing
program, <u>including the billing practices of</u>

hospitals and physicians. The identification of appropriate third party payments, and the initiation and increased billing over time should occur as early as possible to offset the reduction of RMP support in successive years. This will help assure continued program viability when RMP support terminates after the third project year.

6. Regional Medical Programs are not the appropriate source for support of degree oriented programs, such as A.A., R.N., and M.D. programs. Other basic training necessary for certification such as internships, residencies, and fellowships are also not available for RMP support. However, RMP will support, when it is appropriate to the goals of a comprehensive renal program, training in continuing education of physicians (excluding fellowships), post graduate renal nurses, and other health professionals. As is the case with other RMP programs, the training program must achieve independence from RMP support by the end of the grant period.

7. Relative staffing and cost patterns are helpful in judging whether or not a program or project is being executed effectively and efficiently. RMPS is only interested in reimbursing that portion of the staff member's time which is required to execute specific renal program duties (or such renal program duties which are in excess of those being otherwise continued for the institution or other programs). Renal programs require a relatively wide range of medical and allied health personnel. However, many of these people will continue their other established duties on behalf of the institution, and such work should not be charged against the renal grant program.

D. FOLLOW-UP REVIEW - PERFORMANCE

There will be annual review during the period of program performance. The purpose of the annual follow-up review will be to evaluate the accomplishment of program objectives. The follow-up reviews of programs/projects should consider the items mentioned above in the proper time frame so that accomplishments are compared to the original program goals. If the original goals of the program are not being met, the reason/reasons for this should be sought. It should also be determined whether or not the sponsors' initiative and actions have been appropriate to attempt to rectify the program's poor performance.

The follow-up report will be prepared for the RAG in the same fashion as specified for the original program review. If a program is not functioning successfully and meeting its goals, the report should detail the options necessary to bring the program into conformance with the guidelines.

E. STANDARDS ASSESSMENT

To help analyze and provide counsel on these matters, consultants will need to draw on their own knowledge and experience. In addition, we are providing some very general guidelines as follows:

1. Home Dialysis Training:
   a. Patient Load: A home dialysis training facility should run 6 shift days per week and should train a minimum of 12 patients per year per bed.
   b. Suggested Staffing Patterns: There should be 1 physician per 24 patients trained; 1 nurse or technician per bed per shift; 1 social worker per 24 pts; and 1/2 full time equivalent (FTE) dietician per 24 patients. Psychiatrists and psychologists should be utilized on a fee basis, and a surgeon should be utilized on a fee basis for fistulae and cannulae work.
   c. Equipment: Initially, a new delivery system must be acquired for each patient trained. Delivery systems should be kept in the training center at all times to provide backup and acute treatments. The cost of a coil delivery system plus ancillary equipment (alarms, blood pump, etc.) is $3,000 to $3,500. The kiil delivery system plus ancillary equipment (artificial kidney, alarms, etc.) is $4,700 to $5,200. It should be noted that it is not always necessary to purchase all machines in that Vocational Rehabilitation and the "blue" plans in many states have leasing arrangements. Capital equipment cost would not be expected to be projected beyond the first year.
   d. Supplies: Consumable supply costs in the training center and the home will be virtually the same. For the coil, the costs per dialysis would be $25 to $30. This includes the coil, tubing, dialysate, heparin, saline, etc. For the kiil the costs per dialysis would be $15 to $20 including the membranes, dialysate, tubing, saline, heparin, etc. These items are costs which can reasonably be expected to be reimbursed by third party sources.

e. Laboratory: Direct patient care mechanisms should support the costs of laboratory services.
f. Travel: Some staff travel to patients homes should be indicated. Follow-up visits after training and occasional maintenance will be necessary.

2. Transplantation:
   a. A Transplantation Program has one or more hospitals doing transplantation surgery, one (1) tissue typing facility or contractural agreement, one (1) organ procurement and sharing program, linkages to dialysis services (backup and home dialysis training), and is characterized by strong leadership. Such a program should do a minimum of 25 transplants per unit per year and should aim ultimately at 50-100 transplants per year and meeting the Region's needs.
   b. The patient hospitalization runs, generally, 14 to 21 days for uncomplicated identical living related donor transplants, and may run up to 30 to 90 days for non-identical HLA transplants, with several rejection episodes. Thus, an accurate cost analysis of transplantation is difficult. Charges should be cost-accountable on the basis of physicians' fees, operating room expenses, patient care daily charges, lab fees, etc., and should be analyzed in the framework of 3 year decremental funding, with a strong emphasis on getting continuing support from third-party collections. RMPs cannot pay direct hospitalization costs. Its support is indirect, and usually in the form of staff salaries and/or equipment costs. A number of existing transplant programs have now successfully shifted the major portion of their funding to third-party carriers.
   c. Staffing: At least one full-time transplant surgeon and a part-time transplant surgeon are highly desirable; a nurse coordinator is highly desirable; a dietician is usually a 1/2 FTE; and a social worker as needed. Again psychiatrists and psychologists are utilized on a fee basis.
   d. Laboratory: Laboratory services for transplant patients should be available through existing hospital facilities which must be of a standard required for caring for transplant patients. Again, these services are generally reimbursable by third-party sources.

3. Organ Procurement: A program should show capability of harvesting sufficient kidneys so that at least 50 transplants can be performed each year. Generally, about one-third of the kidneys harvested are unusable. Again, cost of organ procurement is becoming imminently recoverable from third-party carriers.

4. Histocompatibility Testing: Wherever possible, a transplantation program should utilize a tissue typing lab already in existence, especially where geographic proximity permits this. The tissue typing director must be a qualified immunologic leader, and the lab should serve a geographic region performing 50 to 75 transplants per year in order to maintain a full-time technical staff with 24-hour on-call capabilities. Third-party carriers have indicated willingness to assume tissue-typing costs, and funding should be directed towards their takeover of payment.

5. Limited Care Dialysis: A limited care center may be considered as an integral part of a regional program dependent upon a region's needs.

Kidney Disease Activities Eligible for Separate RMPS Funding

The program activities of the "Life Plan" for Kidney Disease which are eligible to compete for RMPS kidney funds generally fall into the category of service resources for end-stage renal disease. These activities will receive RMPS support in the form of "separate" decremental funding which provides less RMPS funding each subsequent year of program operation as developed third-party sources of funds support an increasing share of the program cost. Kidney disease programs are expected to be fully operational independently from RMPS support after the third year of grant support.

Separate funds are available for the following program areas:

1. Transplantation - RMPS funds will be provided on a decremental basis for establishing programs in transplantation in areas of need. Direct patient-care costs are not appropriate for support.

2. Organ Procurement Activities - RMPS will finance the start-up of a region's organ-procurement activities in the framework of decremental RMP funding with assumption of costs by other sources over time.

3. Tissue Typing - RMPS will pay for start-up costs in this activity provided that the tissue-typing labs are not redundant and duplicative. Tissue-typing costs also must be assumed by other sources of funds.

4. Organ Procurement and Communication Activities - These are designed to provide optimal use of harvested organs shared among many transplant centers over several regions. These activities should also become self-sufficient by the time RMPS seed money is withdrawn. It is, however, more difficult for these activities to be financed by third-party carriers and the costs of managing the organ-procurement network may be added to the individual cost per organ harvested.

5. Home Dialysis Training - RMPS will provide seed money for the development of home dialysis training programs where the need has been demonstrated. Such programs must be affiliated with a transplantation program and provide or have access to acute medical resources.

6. Low Overhead Limited Care Dialysis - Where documented regional needs exist, RMPS will support the development of low-cost limited-care programs having access to acute medical care resources and affiliated with a tertiary-care program.

7. Satellite Dialysis Facilities - Where appropriate, RMPS may support the development of satellite-dialysis resources to serve the backup needs of patients who are geographically removed from the tertiary-care facilities.

8. Dialysis and Transplantation Programs for Children - RMPS will provide the start-up costs for pediatric end-stage renal activities in selected areas of need. Since an estimated total of only 600 children each year are believed to be good candidates for dialysis and transplantation, we anticipate providing support for only a few highly centralized pediatric nephrology units. As with adult facilities, pediatric nephrology units must be based on a decremental RMP funding sequence, with assumption of costs by non-RMPS sources in time.

9. Education - RMPS will support, when appropriate to the goals of a comprehensive renal program, training in continuing education of physicians (excluding fellowships), postgraduate renal nurses, and other allied health professionals aimed at improving care for patients with end-stage renal disease. RMPS is not the appropriate source for support of degree or certificate-oriented programs, such as A.A., R.N., and M.D. programs; internships, residencies, and fellowships also are not suitable for RMP support.

10. Public Education - RMPS will provide limited support for appropriate public education activities which are clearly related to specific output of the end-stage renal program.

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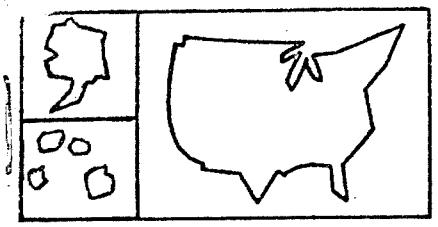

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LEGISLATION EXTENDED AND AMENDED FOR Regional Medical Programs - Public Law 91-515

November 20, 1970 - Vol. 4, No. 51S

On October 30, 1970, the President signed Public Law 91-515 which extends and amends the Regional Medical Programs legislation, as well as that of Comprehensive Health Planning and Services, the National Center for Health Services Research and Development and the National Center for Health Statistics.

To reflect the details of this action, a copy of Title I of the new law (P.L. 91-515) referring to Regional Medical Programs specifically, and parts of certain other titles relevant to Regional Medical Programs, are reproduced in the first part of this issue.

To indicate how the total Regional Medical Programs law now reads as part of the Public Health Service Act, all changes have been interpolated into the original law (Public Law 89-239, as amended by Public Law 90-574) on the pages that follow. Deletions in the previous law are shown in [brackets] , while the new legislative language is underscored.

Distribution:
- Coordinators of Regional Medical Programs
- Members of National Advisory Council and Review Committee on Regional Medical Programs
- Staff of Regional Medical Programs Service
- Regional Health Directors and Regional Medical Programs Service Representatives of Health, Education, and Welfare Regional Offices

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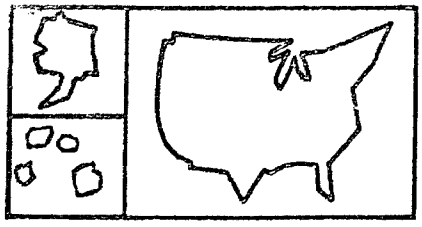

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KIDNEY DISEASE ACTIVITIES -- Guidelines and Review Procedures Statement

May 3, 1972 - Vol. 6, No. 9S

This issue presents revised guidelines and local and national review procedures for kidney disease activities.

These guidelines supersede all previous RMPS materials relative to the submission of kidney disease applications, specifically including those appearing in the News Information Data, "Policy Statement and Guidelines" published on November 27, 1970, Vol. 4, No. 53S, and the "Interpretation of Guidelines" published on March 1, 1971, Vol. 5, No. 5S.

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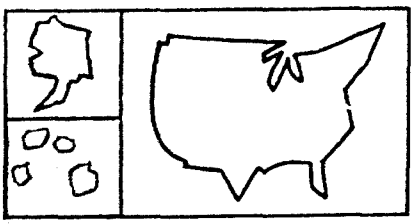

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CLARIFICATION OF KIDNEY DISEASE GUIDELINES

September 14, 1972 - Vol. 6, No. 16S

This issue presents clarification of the "Kidney Disease Guidelines - Guidelines and Review Procedures Statement," issued in the May 3, 1972 issue of News, Information, and Data, Vol. 6, No. 9S. Three areas are more fully described in this issuance.

1. At the request of the Advisory Council at its meeting on June 5-6, 1972, a definition of full-time transplantation surgeon is provided.

2. Pediatric Nephrology applications have been refused by some RMP's because of the wording in the Guidelines. A broader interpretation is proposed in this explanatory statement.

3. Outside Consultant Review of kidney programs is required for a new kidney disease proposal, and for subsequent years of its RMPS grant support. As a prototype for organized patient care delivery to a finite population, the kidney disease activity needs continued assessment with regard to progress made in treating identified patient population, program cost control, and achievement of increased financial independence.

Distribution:
- Coordinators of Regional Medical Programs
- Members of National Advisory Council and Review Committee on Regional Medical Programs
- Staff of Regional Medical Programs Service
- Regional Health Directors and Regional Medical Programs Service Representatives of Health, Education, and Welfare Regional Offices.

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