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In recognition of the importance of chronic renal disease as one of the impairments of man essentially related to heart disease, cancer, and stroke, the Regional Medical Programs Service, with the advice of the National Advisory Council and a number of recognized experts in the field of nephrology, offers the following guidelines to Regional Medical Programs for the planning and development of kidney disease activities as components of individual regional programs or as cooperative enterprises of two or more neighboring Regional Medical Programs.

Recognizing the competition for both funds and manpower in the further development of comprehensive kidney disease capabilities within the health care system, the Regional Medical Programs Service and the National Advisory Council will exert their best judgement in allocating the limited amount of funds available for this purpose in FY 1971 and 1972 to Regional Medical Programs which propose the investment of grant funds ---

- . To encourage wider and more effective cooperative arrangements among selected institutions and resources which together can form comprehensive systems of care; and
- . To strengthen existing institutional resources competent and willing to reach beyond the confines of the medical centers within which they exist for development of systems of services and training.

EXPANDED STATEMENT OF KIDNEY DISEASE CONTROL

GUIDELINES FOR REGIONAL MEDICAL PROGRAMS\*

These Guidelines supplement existing Guidelines of the Regional Medical Programs Service relating to programs, and grant application procedures under Title IX of the Public Health Service Act. The Kidney Disease Guidelines emphasize programmatic aspects of kidney disease programs which may be developed within Regional Medical Programs, and interregional, multi-program services. Overall RMPS policies and administrative procedures relating to the development and submittal of grant applications are contained in the three previously published RMPS guideline texts:

• Guidelines for Regional Medical Programs, News, Information, and Data, May 15, 1968, Volume 2, No. 13S

• Addendum Guidelines, News, Information, and Data, March 27, 1970 Volume 4, No. 16S

• Guidelines for Multi-Program Services Project Grants, News, Information, and Data, September 8, 1970, Volume 4, No. 36S

\* Issued May 1969 Council Meeting

GUIDES FOR PLANNING A COMPREHENSIVE REGIONAL  
(OR INTER-REGIONAL) KIDNEY DISEASE PROGRAM

BACKGROUND

Between 1960 and 1967, grants were made by the Kidney Disease Control Program (then a Branch of the Division of Chronic Disease Control) to 14 institutions to develop methodology for, and demonstrate the practicality of providing large-scale kidney dialysis services in the hospital setting. In 1967 and 1968, the Congress appropriated funds for the development of home dialysis, and contracts were made with 12 institutions to develop methods and techniques to train patients to perform dialysis in the home setting. More recently, transplantation capability was built into these institutions.

Work is now being carried out to devise methods to increase the supply of cadaver kidney organs, to develop computerized data retrieval for rapid matching of donated organs with recipients through a tissue-typing system and investigation of low cost dialysis, the provision of chronic hemodialysis in low-overhead facilities which assures a site for care of those patients who are ineligible for home dialysis training. The form of a system of care for terminal kidney disease patients has emerged from this experience. Now that a level of competence has been reached to effectively organize a comprehensive system of care for patients with renal disease, there remains the need to further the development of the national capability to provide this care.

A number of salient attitudes have evolved through developments which have occurred over recent years:

- a. Hemodialysis performed in the patient's home costs about one-fourth as much as the same therapy performed in the hospital setting. With the potential "kidney" load on available hospital beds, "self-dialysis" offers the best pathway to the development of adequate resources for dialysis therapy without an equivalent need to increase hospital facilities. Comparatively, it can be demonstrated that a 4-bed hospital unit dialyzing patients 3 times a week, 2 shifts a day, 6 days a week will reach saturation with 16 patients. A 4-bed patient home dialysis training unit, also dialyzing 3 times a week, for 2 shifts, 6 days a week can produce 60-70 trained patients year, after year.

Dialysis provides a twofold function in the end-stage therapy system: (1) dialysis performed in the patient's home, and in low-overhead facilities, is the most economical way to develop a large graft recipient pool; (2) dialysis performed on a limited scale in the transplantation center assures good pre- and post-operation patient care.

- b. Transplantation is increasingly becoming the treatment of choice for a growing proportion of the patients with terminal renal disease. Dialysis and transplantation are complementary therapies, with dialysis as a necessary adjunct to large-scale transplantation programs. As the point of exit from chronic kidney hemodialysis, surgical transplantation facilities provide the logical hub of the dialysis-transplantation complex around which end-stage treatment programs should be constructed. In such a system, transplantation centers must assume responsibility to serve the patient population encompassed in a transplantation-dialysis network of patient services.
- c. Full employment of these modes of treatment (dialysis and transplantation) requires the systematic integration of other related functions. These include: the provision of facilities to provide artificial kidney therapy in all available modes to satisfy the various treatment needs of patients (hospital, low-overhead site, and home training center); out-patient services to identify and refer "good" dialysis candidates; centralized tissue typing facilities; organization to provide sufficient numbers of cadaver organs compatible with the transplant recipients; organ preservation capability; communications for rapid transmittal of organ-recipient tissue matching information; sources of third-party financing of therapy; and training program to assure adequate numbers of training personnel to operate and improve the system.
- d. Experience indicates that there are minimum service levels below which the provision of end-stage therapy services cannot be efficiently employed. It is estimated that a home dialysis patient training unit should train at least 12 patients per year to operate efficiently, and this requires an estimated population base of 500,000 people. It is further estimated that a transplantation center, incorporating pre-graft, back-up dialysis, tissue typing and related medical and paramedical training should serve a population of 1,000,000 people to operate efficiently.
- e. Attention to pre-terminal kidney disease patients is needed to develop a comprehensive program to prevent and control kidney disease. Nearly 8,000,000 persons are afflicted with kidney disease in the United States each year. The term, kidney disease, is used here to include diseases of the genitourinary tract, and includes ailments categorized as: Infections; Hypertensive diseases; Hypersensitive diseases; Metabolic diseases; and, Others, which include developmental, functional, obstructive disorders, and neoplastic diseases. Efforts heretofore to achieve effective intervention in the progress of early kidney disease have been diffused, and there is not now an organized attack on kidney disease detection, diagnosis and early therapy. Thus promising techniques for disease detection and improved management have not been brought forward into general practice.

The area of work which currently appears immediately responsive to coordinated action is urinary tract infections. Methodology is

available to detect, diagnose and treat urinary tract infections, and the dissemination of such experience and knowledge is urgently needed.

With respect to the other kidney diseases, we need to identify the points at which effective intervention could be made in the progression of disease, and the appropriate therapies to employ. Programs for organized progress in these and related aspects of kidney disease will be necessary if we are to reduce morbidity, and organ-weakening conditions resulting from infections, hypersensitivity diseases, congenital disorders of the urinary tract and hypertensive renal disease.

#### Principal Requirements for a Comprehensive Kidney Program

1. Integration of hospital center dialysis with transplantation capability to provide dialysis back-up capabilities for home-patients who develop complications, and for the pre- and post-operative needs of transplanted patients.
2. Development of communications incorporating automated data on patient tissue types to effect fact identification and delivery of organs to "best match" patients.
3. Development of home training dialysis program which serve populations of no less than 500,000 persons, coordinated with integrated dialysis and transplantation facilities.
4. Establishment of affiliated satellite institutions to identify and refer patients needing intensive end-stage care and home training and to provide post-home training follow-up care.
5. Development of limited care dialysis facilities to provide services to patients as an alternative to home dialysis.
6. Provision of temporary, categorical financial assistance until third party and personal payments can meet the cost of end-stage treatment.
7. Development of programs to provide early detection and treatment of
  - (a) structural abnormalities of the genitourinary tract, and
  - (b) bacteriuria among high-risk groups.
8. Development of programs to reduce and prevent infection associated with the use of catheters, and urinary drainage systems.
9. Continuing investigation in a wide variety of pressing renal disease problems, including: evaluation of current diagnostic techniques for infection; development and evaluation of streptococcal vaccines; evaluation of therapeutic agents, including steroids and immunosuppressants; improved dialyzing techniques, and equipment; tissue typing; organ preservation; and circulatory, metabolic, neoplastic and functional renal disorders.

10. Provision for training of medical, paramedical and non-physician personnel sufficient to maintain the growth of coordinated renal disease services.

#### PREPARATION OF APPLICATIONS

In addition to the budget and related supporting materials, the narrative portion of an application for a comprehensive regional kidney disease program should describe regional or multi-regional activities to expand the resources and capacity to provide integrated, coordinated health systems for the provision of improved renal patient care services.

In the application, projects should relate to an overall plan for meeting the kidney disease problem. The application should identify the renal disease-related problems to which the activity is addressed, and document the needs which it will satisfy and how it fits into existing geographic or medical service area plans. The application should justify the proposed site of operations in terms of accessibility to an area, or regional patient population which it will serve without duplicating existing facilities and services.

Existing resources and facilities for kidney disease prevention and control must be identified and development beyond the existing base must be described in detail.

The application should document the commitment of the cooperating institutions, groups and health practitioners whose collaboration is essential to insure the success of the program in developing a network of integrated services for the care of renal patients in the area to be served.

Other available funding sources must be documented and those non-Federal sources which can be stimulated, or increased identified. It should indicate how efforts will be made to expand non-Federal payment sources.

The application should project successive years' funding by the Government and the applicant, including cooperating institutions and groups, and reflect successively lower percentages of support by the Government. It must indicate termination of Government funding by meeting the objective or the realization of adequate non-Federal support.

Projects within the application concerned with training should be directed to the personnel needs of the projects comprising the plan. Additional training needs should be met through programs in a limited number of central institutions with facilities for efficient training services. Emphasis should be placed on the creation of a cadre of physicians to serve as teachers. With maturity of kidney disease activities, institutions and patient care systems should become self-sufficient with respect to the provision of staff training.

The application should include a reporting system which will permit the collection of uniform data on the magnitude of the problem, and progress in solving it.