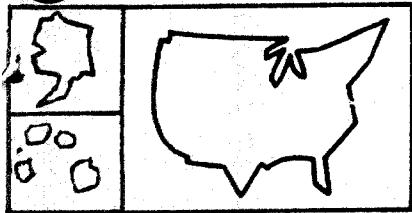


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KIDNEY DISEASE ACTIVITIES --
Guidelines and Review Procedures Statement

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.

Distribution: . Coordinators of Regional Medical Programs
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Programs Service Representatives of Health,
Education, and Welfare Regional Offices.

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

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 candidates 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 ^{commitment} 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 compatibility between the donor organ and the recipient of a kidney transplant.
25. Urinary Tract - Collective term referring to the kidneys, ureters, bladder, and urethra.