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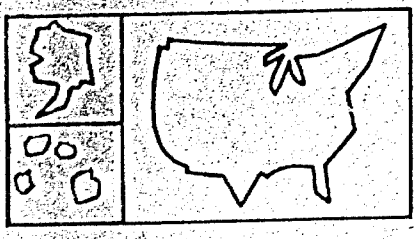

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A communication device designed to speed the exchange of news, information and data on Regional Medical Programs and related activities.

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

Continued Review of Kidney Disease Programs

Technical Review of RMP Kidney Disease Programs

After the First Application

The kidney disease guidelines, "Kidney Disease Activities - Guidelines and Review Procedures Statement" (News, Information, Data, May 3, 1972 - Vol. 6, No. 9S) require technical review of RMP renal programs by renal experts from outside the sponsoring Region. The principal provisions are contained in item 2, Technical Program Review, on page 3, under Review Procedures.

Questions have been raised by several Regions about the need to obtain this outside technical review for kidney programs submitted as continuation applications.

The answer is, yes. Each application for RMP support for kidney disease program requires a peer review by outside renal experts and the incorporation of their comments and subsequent Regional review actions as a part of the Region's submittals to RMPS. The present state of development of end-stage kidney dialysis and transplantation therapies, and the finite patient population involved, provides outstanding opportunity to establish a prototype for delivery of sophisticated patient care. We believe that such a prototype can have major implications in the overall pattern of delivery of other advanced therapies. The requirement for continued technical review of kidney disease programs is a key factor to monitor the start-up, development and coordination of renal programs carried out through all RMP's. As indicated in the Guidelines, critical elements in the success of renal programs include patient access to care, control of costs through nonduplication of facilites and maximum utilization of resources, and the development of third-party sources for payment of patient care.

The referral of outside technical consultants for kidney program progress assessment should be accomplished by the same process as was followed in obtaining the initial outside review (see page 3, Kidney Guidelines). However, for these follow-up reviews only two (2) outside consultants are required. They will be selected, insofar as possible, from the reviewers who performed the initial renal program technical review. These reviews usually should be conducted on-site at the RMP, or grantee premises.

Preparation for these anniversary technical reviews requires more than simply negotiating consulting time, place, and reimbursement. To adequately review program progress after the first and second grant years, the technical reviewers will need to be provided a statement of the program undertaken in the first year, the comments of the initial reviewers, a complete statement on program achievements (including numbers of patients treated, program staff development, costs of treatment services), and related information as is indicated on page 2, May 3, 1972 Kidney Guidelines. The RMP submittal of the renal project report to RMPS should contain, in addition to the Form 15 summary statement and the RAG report, the review comments of the outside technical consultants.

STATEMENT ON THE DEVELOPMENT OF PEDIATRIC NEPHROLOGY SERVICES

New guidelines for kidney disease programs were issued May 3, 1972, which included provision for grant applications related to pediatric nephrology services (News, Information, Data, "Kidney Disease Activities - Guidelines and Review Procedures Statement," May 3, 1972, Vol. 6, No. 9S). The specific reference is item 11, on page 2, which states:

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

We have been advised that in some Regions this statement has been interpreted to mean that proposed pediatric nephrology services must be housed and extended within adult nephrology facilities. This is an erroneous intrepretation and, we believe, one that could seriously circumscribe the extraordinary attention to uniquely pediatric problems which end-stage renal care to children requires.

We are not prepared to offer a fixed definition of what "coordinated" means in each situation. Since an estimated total of only 600 children each year are believed to be good candidates for dialysis and kidney transplantation, we cannot anticipate providing support beyond the development of a few highly centralized pediatric nephrology units. The relation of these services to an adequate population base, and their reasonable coordination with adult nephrology services, requires very judicious consideration and should seldom be addressed without competent outside counsel.

The range of "coordination" possible with established renal services will vary from pediatric facilities physically adjacent, spatially, to adult facilities, to development of services in a geographically separate children's hospital. The choice will probably be deduced only after careful weighing of needs and analytically relating service costs to the special treatment needs of pediatric renal patients for a defined service area.

We need opportunity to consider a number of carefully structured applications for support of development of pediatric nephrology services before we can provide clear answers to the problems presented by extension of services to this patient group.

The concept of the full-time transplantation surgeon is a keystone to the integrated system of care for renal patients which we envision as both necessary and attainable within the existing state of the art. Without conscious development of active and efficient transplantation centers, care for terminal renal patients will stagnate at a level which emphasizes closed-end dialysis care at unnecessarily high psychological and financial cost to patients and with underutilization of available facilities.

Definition of Full-Time Transplantation Surgeons

The Kidney Guidelines issued May 3, 1972, included the term "full-time transplantation surgeon." This term is clarified as follows: A full-time transplantation surgeon is defined as a surgeon who is committed to the full-time, vocational conduct of planning, organizing and performing transplantation services.

The phrase appears in item 6.b., page 2, of the "Kidney Disease Activities - Guidelines and Review Procedures Statement," News, Information, Data, Vol. 6, No. 9S, May 3, 1972. The full item, with underscoring provided, is as follows:

> "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."

The full item is repeated here because it reflects critical aspects of the structure of end-stage kidney disease service programs which must be satisfied before adequate patient access to care can be realized. Access to kidney transplantation already exists on the basis that some surgeons can effect the kidney transplant procedure in a medically acceptable manner. There also exist sophisticated medical facilities in which the necessary complementary, specialized departments and backup services are available to effectively support successful transplant operations. The development of both of these components must clearly be accelerated, however, if we are to provide access to transplantation of all of the medically acceptable patients each year who suffer terminal uremia.

Our experience with renal programs to date convinces us that without full-time surgeon dedication to programs of end-stage kidney patient care, the logistical and organizational problems of making available volume organ grafts of high quality will not be surmounted in the forseeable future. Many kidney grafts have been performed over the past 10 years. However, in terms of annual institutional output, the events are typically infrequent and reflect an avocational approach which fails to address the admitted shortage of transplantable organs, provides little input to organized research, presents no career incentive to students of surgery, eludes effective contact by patient referral channels, and is incapable of routinizing the access to existing advanced clinical services or immunology, pathology, psychiatry and others which the successful performance of kindey transplantation therapy requires.