NEFROLOGÍA. Vol. XX. Suplemento 5. 2000

United States Renal Data System (USRDS)

L. Agodoa
National Institutes of Health

INTRODUCTION

Renal disease is a major public health problem in most developed and developing countries. There are indications that the incidence and prevalence rates continue to increase[1]. It is desirable, therefore, that programs be instituted to reduce or eliminate the increase. Unfortunately, however, in most cases, renal disease remains silent until it has progressed to or near end stage. The causes of renal disease are many and varied among populations, therefore, the strategies for approach to reducing progression to end stage vary. Without relevant and successful strategies many patients will continue to progress to end-stage.

End stage renal disease (ESRD) is a major disease entity causing significant morbidity and mortality in most populations, and leading to enormous financial and personal costs. Fortunately, however, at end stage, when the kidneys can no longer sustain life, death is avoided through the use of renal replacement therapy (RRT). Over the past four decades, there has been impressive improvement in the available modalities of therapy. Not only can the afflicted individual be kept alive, quality of life continues to improve for those on RRT. The cost of providing RRT is very high, and continues to increase with improvement in technologies that allow provision of better care. Therefore, some countries, especially developing countries, are not able to offer their citizens with ESRD with the needed RRT.

Most countries that have the resources to offer RRT have instituted a method of evaluating patients on various forms of therapeutic modalities through the use of renal (replacement therapy) registries. These renal registries are useful in many ways. At the very least, they provide a small window to the larger problem of undiscovered and untreated chronic renal disease. Very importantly, however, they can provide information on the outcome of specific modalities of therapy, and how they can be improved. They can also be used to estimate the human and fiscal resource needs in treating ESRD patients.

In many of the Western European countries there have been complete renal disease registries for many years, and most have been reporting data to the European Dialysis and Transplant Association (EDTA) Registry for nearly three decades[2]. Other well established national renal registries include The Australian and New Zealand Dialysis and Transplant Registry[3] and the Canadian Organ Replacement Register[4].

ESTABLISHMENT OF THE USRDS

Although the United States Health Care Financing Administration (HCFA) has maintained a data collection system, gathering information on Medicare beneficiary-specific entitlement, demographic, cost and utilization data, and Medicare facility-specific certification data, a comprehensive ESRD database was not available. Specifically, detailed information, including both clinical and laboratory information on the etiology of the underlying renal disease, method of treatment, and overall outcomes for the ESRD-Medicare patient population was not available.

At the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) it was felt that such information and database on the ESRD patient population was vital to understanding the problems confronting these patients, and to be able to develop relevant research programs to improve their management. Therefore, a decision was made to create a system to collect and analyze information on the incidence, prevalence, morbidity, and mortality of ESRD in the U.S. It was felt that a Contract mechanism would permit maximum use of resources and direction from the program office. The first Contract, N01-DK-8-2234 was awarded to The Urban Institute, Washington, DC, and the period of performance was from May 1, 1988 through April 30, 1993. The system was named the United States Renal Data System (USRDS). The four goals for the USRDS at the outset were to:

1. Design and implement a consolidated renal disease data system to provide biostatistical, data ma-

Correspondence: Dr. Lawrence Agodoa
Project Officer, USRDS
Division of Kidney, Urologic and Hematologic Diseases
National Institutes of Health
Building 45, Room 6AS13B
45 Center Drive
Bethesda, Maryland 20892-6600, USA

nagement, and analytical expertise necessary to characterize the total renal patient population and describe the distribution of patients by socio-demographic variables across modalities

2. Report on the incidence, prevalence, and mortality rates and trends over time by primary diagnosis, treatment modality, and other socio-demographic variables.

3. Develop and analyze aggregate data on the effect various modalities of treatment by disease and patient group, including examination of the prevention and progression of renal disease with special emphasis on mortality, morbidity and quality of life criteria.

4. Identify problems and opportunities for more-focused special studies of renal research issues currently not addressed by the USRDS.

Evaluation of the project at the end of the five year contract period led to the conclusion that it was a success, and should, therefore, be continued. The contract was funded for a second five year period. During the second period, two more goals were added:

5. To conduct cost effectiveness studies, and other economic studies of ESRD.

6. To make the data available to investigators, and by supporting investigator-initiated projects to conduct biomedical and economic analyses of ESRD patients.

The period of performance was increased from five to six years. Currently, the USRDS operates with the 6 goals[5].

After 11 successful years with this project, the NIDDK has decided to continue funding for the USRDS. A new Contract for the Coordinating Center, has just been awarded, and the database will move from its current location at the University of Michigan, Ann Arbor, Michigan, to the Minneapolis Medical Research Foundation, Minneapolis, Minnesota. The format for the new USRDS will be different, as described below.

DATA SOURCE FOR THE USRDS

In the USA, there is mandatory reporting of some basic information on all patients who are maintained on renal replacement therapy. The US government pays for RRT for the majority (more than 96%) of ESRD patients. At the outset, the health care provider must certify that a patient has ESRD by completing a required form, the Medical Evidence Form (HCFA Form 2728). In addition to the basic demographic information on the patient, this form also requires information on the primary cause of ESRD. Some of the basic laboratory data reported at initiation of RRT include serum creatinine and creatinine clearance, serum albumin, blood urea nitrogen, hemoglobin, and hematocrit. Information is also sought concerning the use of erythropoietin in the pre-ESRD period, renal transplantation status, and the type of RRT being initiated. All of this information must be provided to the HCFA, the Agency of the US government that is responsible for providing reimbursement for all aspects of RRT. Information concerning all hospitalizations and procedures that require payment must also be reported to the HCFA. By an interagency agreement, the data collected by the HCFA on these patients is forwarded to the NIDDK, which then forwards it to the Coordinating Center of the USRDS for analysis. Renal transplant data collected by the United Network for Organ Sharing (UNOS), the contractor for the Health Resources and Services Administration (HRSA), is also made available to the USRDS through a similar mechanism of inter-agency agreement.

In addition to the «standard» core data collected and provided to the USRDS, new data collection is implemented through Special Studies. Goal #4, described above, requires that special emphasis areas be explored through the design and implementation of new studies. Execution of these new studies leads to new data collection for analysis. The Special Studies new data are ultimately integrated into the database. The size and complexity of the new data depends on the complexity of the question being addressed. During the first contract period, 6 Special Studies were designed and carried out. During the second contract period, one very complex Special Study, the Dialysis Morbidity and Mortality Study (DMMS), was carried out. The DMMS comprised 4 separate waves of data collection over a 5 year period. All of the relevant data from these special studies have been incorporated into the USRDS database.

FUNDING FOR THE USRDS

The Coordinating Center for the USRDS (USRDS-CC) has been responsible for all of the analytical activities carried out by the Project. The NIDDK provided all the funds for the USRDS-CC during the first project period. However, it should be noted that the cost of collection of the existing core data has been borne entirely by the HCFA throughout both project periods. During the second project period, HCFA also provided some funds to support Goal #5, conduct of cost effectiveness and economic studies of ESRD. The cost for the collection of renal transplantation data

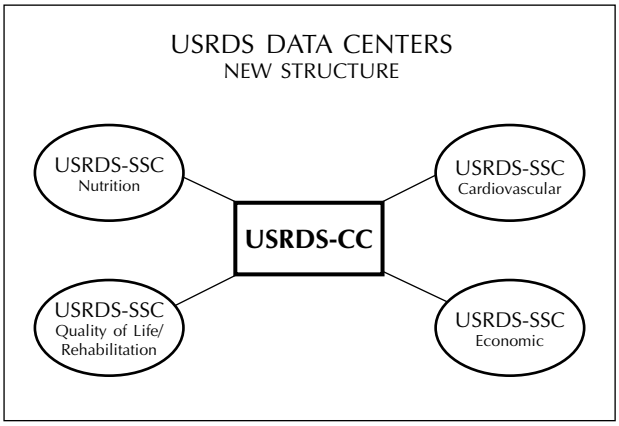

Fig. 1.—USRDS DATA CENTERS: New Structure. The new structure of the USRDS includes the Coordinating Center (USRDS-CC), 3 Biomedical Research Special Studies Centers (USRDS-SSC Nutrition, USRDS-SSC Quality of Life/Rehabilitation, and USRDS-SSC Cardiovascular) and 1 Economic Research Special Studies Center (USRDS-SSC Economic).

has been supported primarily by the HRSA. In summary, the USA government (through the various Agencies) provides all of the funding required for the USRDS project. The total cost to the NIDDK over the 6 fi years of the second period of the USRDS project was approximately $11m (eleven million US dollars).

THE FUTURE OF USRDS

As mentioned above, the contract for the third period for the USRDS-CC has just been awarded to the Minneapolis Medical Research Foundation (MMRF). The project is funded for 5 years, beginning August 1999. There are several differences between the past USRDS and the new projects. First, the research team at the USRDS-CC will be responsible primarily for formatting and analyzing the existing core data. The USRDS-CC will be responsible for implementing goals 1-3, and 6.

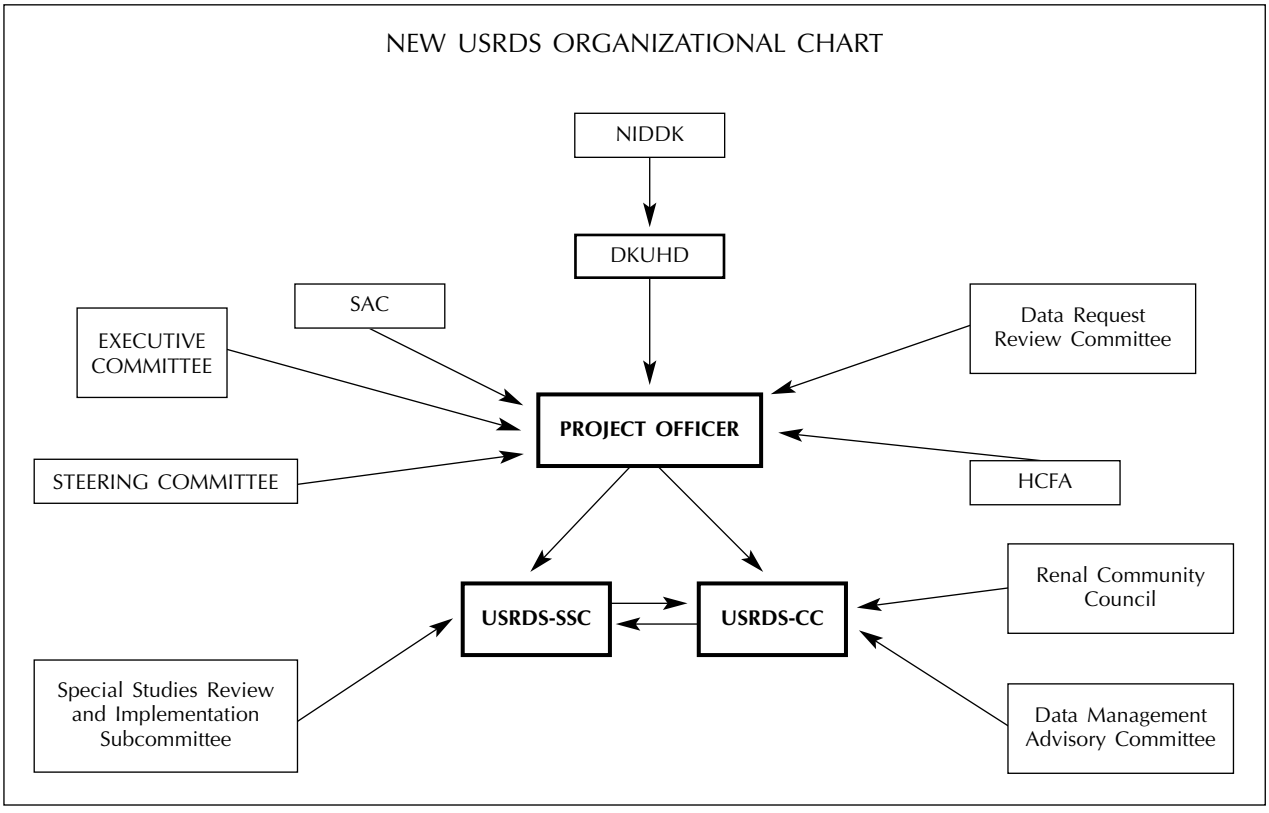

Fig. 2.—New USRDS Organizational Structure: The USRDS Coordinating Center (USRDS-CC) and the Special Studies Centers (USRDS-CC) and the Special Studies Centers (USRDS-SSC) will be under the technical direction of the Project Officer in the Division of Kidney, Urologic and Hematologic Diseases (DKUHD) of the National Institute of Diabetes, and Digestive and Kidney Diseases (NIDDK). The Project Officer will consult with the Scientific Advisory Committee (SAC), the Executive Committee, the Steering Committee, the Data Request Review Committee, and the Health Cre Financing Administration (HCFA). The Studies Review and Implementation Subcommittee will provide advice to the Special Studies Centers (USRDS-SSC), and the Coordinating Center (USRDS-CC) will consult with the Data Management Advisory Committee and the Renal Community Council.

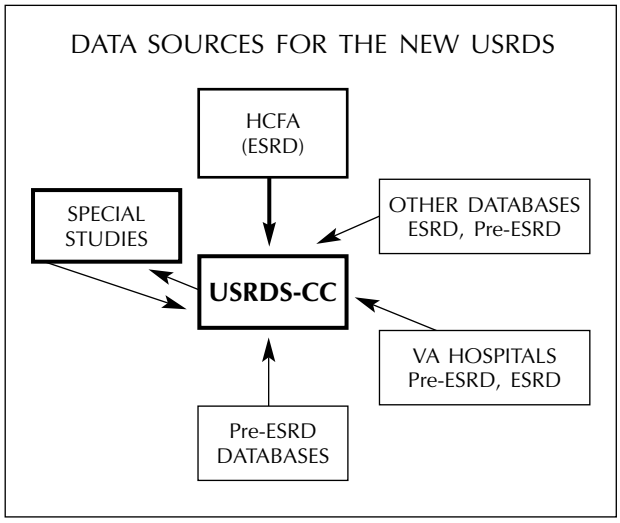

Fig. 1.—Data Sources for the USRDS: The Core dataset going to the Coordinating Center (USRDS-CC) will come from the End Stage Renal Disease Program of the Healthcare Financing Administration (HCFA-ESRD). The USRDS-CC will provide data to support research conducted at the Special Studies Centers. Data resulting from the special studies will ultimately be provided to the USRDS-CC for incorporation into the core dataset. Data from the Veterans Administration program (VA Hospitals Pre-ESRD, ESRD) will be incorporated when available. Special efforts will be made to seek and incorporate Pre-ESRD data into the USRDS.

In addition, the new USRDS will ultimately include 4 additional separate contracts for four new and separate research centers to implement goals 4 and 5. These Special Studies Centers (SSCs) will be responsible for the design, pilot-testing, and implementation of the special studies in specific biomedical and economic research areas. Currently, the emphasis areas include:

1. Cardiovascular diseases in ESRD patients.
2. Economic costs and cost effectiveness of ESRD treatment.
3. Nutrition in ESRD patients undergoing RRT.
4. Quality of Life and Rehabilitation of ESRD patients.

The organization of the new USRDS project is illustrated in figures 1 and 2. The entire project will be directed and coordinated at the project office at the NIDDK. Several advisory groups will be convened to accomplish the task.

Funding of the USRDS-CC and most of the SSCs (the Cardiovascular Diseases, Nutrition and Rehabilitation/Quality of Life) will be provided by the NIDDK. Funds for the Economic SSC will be provided by the HCFA.

As in previous years, the core data for the project will be provided by the responsible agencies (HCFA and HRSA) through the inter-Agency agreements. The new data collected by the SSCs will ultimately be incorporated into the main USRDS database. Other data sources, such as pre-ESRD data, are anticipate, but not yet accurately defined, figure 3.

REFERENCES

1. US Renal Data System, USRDS 1998 Annual Data Report, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD Chapter XII, April 1998.
2. Berthoux F: Epidemiological data concerning End Stage Renal Failure in the European Union during the year 1996; Registry Report, XXXVI Congress of the European Renal Association, European Dialysis and Transplant Association, September 1999.
3. ANZDATA Report 1998. Australia and New Zealand Dialysis and Transplant Registry, Editor: Disney APS, Adelaide, South Australia 1999.
4. Annual Report 1999, Canadian Organ Replacement Register, Canadian Institute of Health Information, Ottawa, Ontario, May 1999.
5. U.S. Renal Data System, USRDS 1999 Annual Data Report. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, Maryland, April 1999.