

Chapter I

The USRDS

The United States Renal Data System (USRDS) began operations in May, 1988, and is in its sixth year of operation. The USRDS is operated by the National Institute of Diabetes and Digestive and Kidney Diseases in conjunction with the Health Care Financing Administration. This national data system collects, analyzes, and distributes information about end-stage renal disease (ESRD) in the United States. It includes comprehensive data needed to describe the incidence and prevalence of treated ESRD, modality of treatment (including both dialysis and kidney transplantation), causes of death, patient survival, hospitalization and institutional providers of ESRD treatment.

Project Goals

Since its inception in 1988, the USRDS has had four primary objectives:

- Design and implement a consolidated renal disease data system that will provide the biostatistical, data management and analytical expertise necessary to characterize the total renal patient population, and to describe the distribution of patients by sociodemographic variables across treatment modalities.

- Report on the incidence, prevalence, mortality rates and trends over time of renal disease by primary diagnosis, treatment modality and other sociodemographic variables.
- Develop and analyze aggregate data on the effect of various modalities of treatment by disease and patient group categories. These data will be used to analyze the prevention and progression of renal disease with special emphasis on morbidity and mortality.
- Identify problems and opportunities for more focused special studies of renal research issues currently not addressed by the consolidated data system.

With the start of the new five year contract in July, 1994, the USRDS has added two additional primary objectives:

- Conduct cost effectiveness and other economic studies pertaining to biomedical and epidemiological aspects of ESRD.
- Support investigator-initiated research by making data from the database widely available in convenient formats to the biomedical and economic research community.

Economic analyses and dissemination of data are important additions to the

scope of work for the USRDS. Cost-effectiveness and economic studies represent a natural extension of the tasks performed by the USRDS. The consolidation of biomedical and cost information in the USRDS database will support the advancement of studies integrating economic and biomedical investigation of ESRD. Support for investigator-initiated research is essential to the overall mission of this project. The USRDS database is rich, broadly used and frequently quoted. Maximizing its utility by increasing the availability of the data for research in an efficient fashion is vital to the welfare of the ESRD patient community.

United States Department of Health and Human Services is a major contributor to the project, providing expertise and most of the primary data in the system. The Health Care Financing Administration, with the start of the new five year contract, is now also funding the cost-effectiveness and economic studies performed by the USRDS.

The USRDS is operated by a Coordinating Center (CC) at the University of Michigan in Ann Arbor. Figure I-1 shows the organization of the USRDS. The USRDS is managed and operated through the collaborative efforts of all of the organizations and committees listed on pages v-ix of this report.

Organizational Structure

The USRDS is funded and directed by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH). The Health Care Financing Administration (HCFA) of the

NIDDK's Division of Kidney, Urologic and Hematologic Diseases (DKUHD) oversees the USRDS, ensuring that the scientific and technical goals of the USRDS are consistent with the mission and responsibilities of NIDDK and NIH. Two NIDDK Project

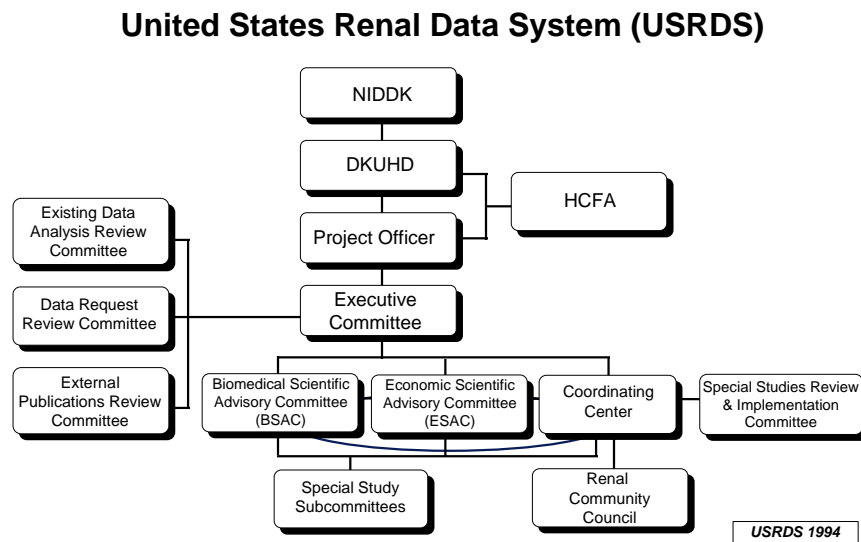


Figure I-1

USRDS organization chart.

Officers have responsibility for monitoring the Coordinating Center's technical progress in meeting the six primary objectives. A HCFA Project Officer works cooperatively with the NIDDK Project Officers to direct cost-effectiveness and economic studies performed by the Coordinating Center. While the NIDDK must approve all cost-effectiveness and economic topics, the HCFA Project Officer directly supervises all such projects.

USRDS Committees

NIDDK makes all final decisions regarding the studies pursued by the USRDS as implemented by the CC. Seven major committees have assisted in this process by providing advisory input to NIDDK and the CC:

The **Scientific Advisory Committees (SACs)** draw on the expertise of researchers and practitioners in the fields of ESRD research, pediatric nephrology, quality of life, transplantation, hemodialysis, peritoneal dialysis, biostatistics, epidemiology and health economics. The Biomedical SAC (B-SAC) has the role of providing epidemiological, clinical and biostatistical advisory input to the NIDDK and the CC, while the Economic SAC (E-SAC) has the role of providing economic advice to the NIDDK, HCFA, and the CC. Both of the Scientific Advisory Committees recommend priorities for research by the USRDS. In doing so, they review and make recommendations to NIDDK and HCFA (for economic issues) on proposed special studies and on findings of studies conducted by the USRDS. Fulfilling these responsibilities requires individuals who have a broad

understanding of the issues surrounding renal research.

The **USRDS Executive Committee (EC)** is comprised of the NIDDK Project Officers, the HCFA Project Officer, a staff member from HCFA, the Chairperson of the Biomedical Scientific Advisory Committee, and the Director and Co-Director of the Coordinating Center. Its role is to advise the NIDDK Project Officers on the overall data management and research plan, to ensure cooperative participation among all components of the project, and to identify and address any other major issues related to the project.

The **Renal Community Council (RCC)** is comprised of more than 30 professional/scientific/advocacy groups with an interest in ESRD and the USRDS. The USRDS makes a presentation to the RCC at the annual meeting of the American Society of Nephrology. The RCC also provides feedback and advice to the CC, which transmits this information to the NIDDK Project Officer.

The **Data Request Review Committee (DRRC)** serves in an advisory capacity to the Project Officer. It was established in mid-1991 and includes representatives from NIDDK, HCFA, and the CC. (When they are needed, two additional reviewers are selected from the SAC.). Since making data available to investigators in the community will be a major focus of the USRDS during years six through ten, the DRRC will play an important role in the review of data requests and will make recommendations to the Project Officer concerning the appropriateness of the data requests. The DRRC reviews

requests to the USRDS for release of data files to supplement any research files produced by HCFA or the Coordinating Center for use by the research community. This helps to ensure that USRDS data are made available to investigators in the pursuit of legitimate biomedical and economic research.

The **Special Studies Review and Implementation Committee (SSRIC)** is chaired by HCFA and is comprised of staff from the NIH, HCFA and the CC, as well as one representative of the ESRD Networks. The SSRIC's focus is on the design, implementation and progress of USRDS Special Studies.

The **USRDS Advisory Group (UAG)** is a newly established committee established to help monitor and review all aspects of the performance of the Coordinating Center. This committee is comprised of members from the renal community chosen by the NIDDK.

The USRDS Database

The Health Care Financing Administration (HCFA) provides most of the existing data in the USRDS database. In addition to all of the data from its ESRD Program Management and Medical Information System (PMMIS) and the Annual Facility Survey, HCFA shares data on transplant follow-up and Medicare Parts A and B services. These HCFA supplied data are used to form the core of the USRDS database, which is summarized in Figure I-2. In fulfilling the new objective of performing cost-effectiveness and other economic studies, the USRDS will begin to incorporate HCFA cost data contained in the Common Working Files and the National Claims History Files (HCFA 1994).

In addition, HCFA helps the USRDS with Special Studies. Most of the new, primary data for Special Studies are collected through the 18 ESRD

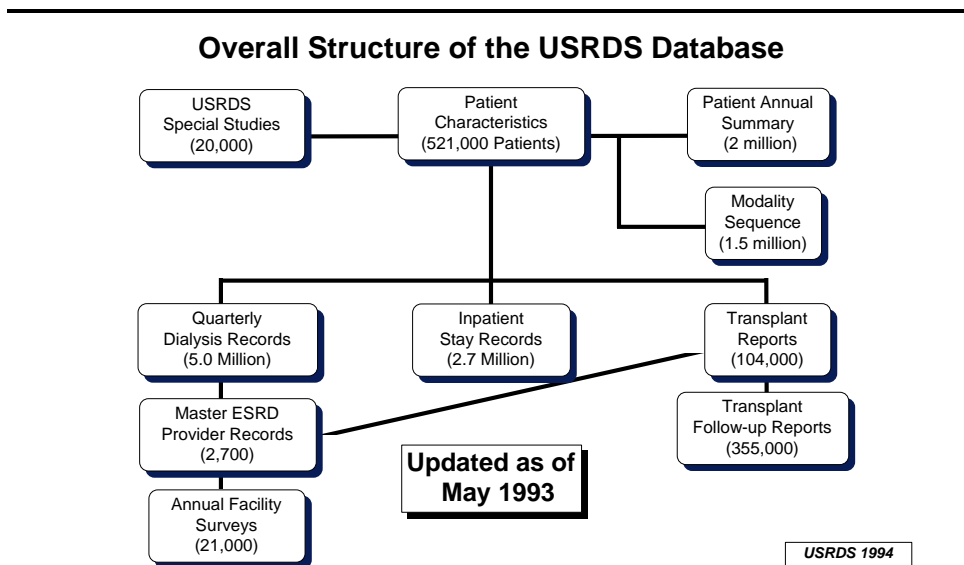


Figure I-2

Overall structure of the USRDS research database with counts of patient and facility records as of May, 1993.

Networks, which are funded by HCFA under separate contracts. Chapter XIII describes these studies in some detail. Data from the first six Special Studies are now fully integrated into the USRDS database. Plans are underway for an important new USRDS Special Study: the Dialysis Morbidity and Mortality Study. Data not otherwise contained in the USRDS database will be collected from a sample of 24,000 patients. These data will support research initiatives important to the prevention and treatment of ESRD.

Since July, 1990, selected data reported to the ESRD Networks on non-Medicare patients treated by United States Department of Veterans Affairs (DVA) facilities have also been collected for the USRDS. The primary source of these data is the Annual Facility Survey completed by all dialysis facilities each year. With respect to transplant data, HCFA and the Health Resources and Services Administration (HRSA) are collaborating on a project which, when completed, will replace the current dual transplant data collections by HCFA and by the United Network for Organ Sharing (UNOS) with a single expanded data collection by UNOS under its contract with HRSA. (It is expected that this consolidation will occur in July, 1994). The expanded transplant data will be shared among HRSA, HCFA and NIH, and will thus become available to the USRDS.

Data in the USRDS database collected by HCFA's ESRD Networks, federal insurance carriers and fiscal intermediaries are supplemented by data from the Social Security System, the United States Bureau of the Census, local and national ESRD provider

databases and from international ESRD registries. In the long term, there are plans to explore the feasibility of including or linking data from other existing provider databases.

The USRDS database is updated every year, with the last update taking place in the Summer of 1993, using data collected through May of 1993. Because of delays in processing of data through the Medicare system, the USRDS generally waits 15 months before reporting patient specific data for a given time period. This explains why the patient specific reference tables in this 1994 ADR report data through December, 1991. Data obtained from the Annual Facility Surveys is based on data from 1992. In some tabulations reported in the 1994 ADR, this "15 month rule" is relaxed in order to provide more current data to the research community. Researchers are cautioned, however, to pay close attention to the completeness of the data.

The content and structure of the USRDS database are maintained in a computerized Data Dictionary, which occupies over 500 pages in printed form. Chapter XIV of this report describes the structure and content of the database. The *Researcher's Guide to the USRDS Database* provides more detailed documentation of the database.

For further information pertaining to use of the USRDS database see Chapter II, "Access to the USRDS Data."

References

- U.S. Department of Health and Human Services, Health Care Financing Administration, Office of Statistics and Data Management, Public Use Files Catalog as of January 1, 1994, Medicare/Medicaid Data Files.

