Chapter I

The USRDS and Its Products

Key Words:
Data files
Database
Data access
World Wide Web
Standardized mortality ratio

This is the eleventh *Annual Data Report* of the United States Renal Data System (USRDS), which began operations in 1988. 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, cost and cost effectiveness, and institutional providers of ESRD treatment.

What's New?

Regular readers of the ADRs will find this chapter very familiar but should look for the following new features:

- This 1999 ADR includes data through calendar year 1997, although some data for 1997 from the patient database must be treated as preliminary. Limited data are presented for 1998.
- Section L has been added to the Reference Tables to present data from the 1995 version of the Medical Evidence Form (HCFA-2728) for new ESRD patients. Chapter IV uses these data to describe the characteristics of new ESRD patients, including Hispanic ethnicity employment status, comorbid conditions, and laboratory values at the start of ESRD.
- A number of sections of the Reference Tables have been expanded. Because the paper edition of the *ADR* already is so large, the supplemental tables will be available only on the USRDS Web site (http://www.med.umich.edu/usrds) and on the ADR CD.
- The patient and graft survival tables in Section E and G of the Reference Tables are now adjusted using Cox proportional hazard models. See chapter XIII.
- A number of corrections and revisions have been made to the cost chapter and the cost section of the reference tables. These changes are discussed in Chapters X and XIII.

About this ADR

The USRDS ADR is designed to serve a number of functions:

- To provide an introduction to ESRD, the USRDS, and ESRD data for persons new to the subject.
- To provide a reference for all members of the renal community.
- To report trends over time and to call attention to changes indicated by the addition of the most recent year of USRDS data.
- To report on findings from USRDS Special Studies.
- To report on special topics, which vary from year to year.

Most analyses presented in the USRDS ADR are descriptive in nature and involve relatively simple statistical techniques. Studies which rigorously test hypotheses and which use sophisticated statistical techniques are submitted to peer-reviewed publications.

Because the ADR functions as an introduction and a reference, much of it remains very similar from year to year. For each chapter, we have tried to identify the most important facts about the topic and to present those facts clearly in the graphics and text. Our rule of thumb is that half or more of the graphics in most chapters will be unchanged from year to year, except for updating to reflect the most recent year of data.

Usually, one or two chapters of the ADR will report new material. In the prior three ADRs, the DMMS and Cost Effectiveness chapters have served this function. In this ADR, the Patient Characteristics chapter reports new material from the HCFA 2728 form.

Project Goals

The USRDS now has six 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.
- 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.

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 United States Department of Health and Human Services is a major

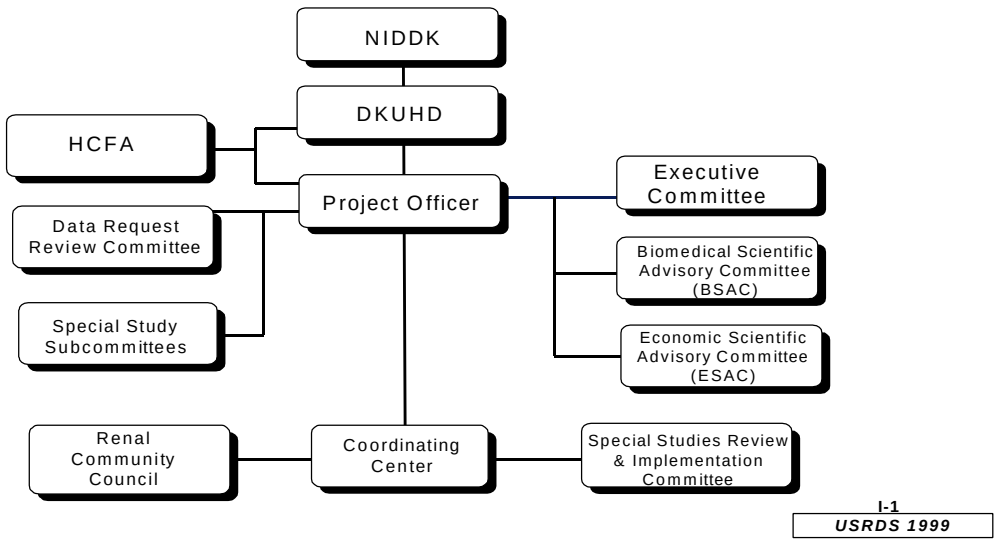

Figure I-1

The organizational structure of the United States Renal Data System.

contributor to the project, providing expertise and most of the primary data in the system. The HCFA also funds 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. Table I-1 lists USRDS contact persons.

NIDDK's Division of Kidney, Urologic, and Hematologic Diseases (DKUHD) directs the USRDS project, ensuring that the scientific and technical goals of the USRDS are consistent with the mission and responsibilities of the NIDDK and the NIH. The NIDDK Project Officer has responsibility for monitoring the Coordinating Center's technical progress in meeting the six primary objectives.

A HCFA Project Coordinator monitors cost-effectiveness and economic studies performed by the Coordinating Center, and assists with other issues related to the USRDS project. While the NIDDK must approve all cost-effectiveness and economic

List of USRDS Contacts

CONTACT	ADDRESS	Phone / e-mail
NIDDK Project Officer	Lawrence Y.C. Agodoa, M.D. United States Renal Data System NIDDK Natcher Building – 6AS-13B 45 Center Drive – MSC 6600 Bethesda, Maryland 20892-6600	Phone (301) 594-7717 Fax (301) 480-3510 agodoal@extra.niddk.nih.gov
NIDDK Deputy Project Officer	Camille A. Jones, M.D., M.P.H. United States Renal Data System NIDDK Natcher Building – 6AS-13K 45 Center Drive – MSC 6600 Bethesda, Maryland 20892-6600	Phone (301) 594-7717 Fax (301) 480-3510 jonesc@extra.niddk.nih.gov
USRDS Coordinating Center (CC)	USRDS 315 W. Huron Street, Suite 240 Ann Arbor, Michigan 48103	Phone (734) 998-6611 Fax (734) 998-6620
CC Director	Robert A. Wolfe, Ph.D.	Phone (734) 998-6611 bobwolfe@umich.edu
CC Deputy Director	Friedrich K. Port, M.D., M.S.	portb@umich.edu
CC Data File Contact	Randall L. Webb	rlwebb@umich.edu
Standardized Mortality/ Hospitalization Rate Methodology	Robert A. Wolfe, Ph.D.	bobwolfe@umich.edu
CC Data Request Contact Publication Orders	Dora Smith	adorable@umich.edu
Internet World Wide Web		http://www.med.umich.edu/usrds/

Table I-1

topics, a HCFA Staff Coordinator 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/or the CC:

The **Scientific Advisory Committees** (**SAC**s) 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 advice to the NIDDK and the CC, while the Economic SAC (E-SAC) provides economic advice to the NIDDK, HCFA, and the CC. Both recommend priorities for research by the USRDS and review and make recommendations to NIDDK on proposed special studies and on USRDS study results.

The USRDS **Executive Committee** (**EC**) is comprised of the NIDDK Project Officers, the HCFA Project Coordinator, a staff member from HCFA, the Chair of the Biomedical Scientific Advisory Committee, and the Director and Co-Director of the Coordinating Center. The EC advises 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, and advocacy groups with an interest in ESRD and the USRDS. Until 1996, the USRDS made a presentation to the RCC at the annual meeting of the American Society of Nephrology (ASN). Starting in 1996, the USRDS hour-long presentation to a special session of ASN has taken the place of a report to the RCC.

The **Data Request Review Committee** (**DRRC**) advises the Project Officer. It includes representatives from NIDDK, HCFA, and the CC. When they are needed, two additional reviewers are selected from the SAC. The DRRC reviews requests to the USRDS for release of data files to supplement

Overall Structure of the USRDS Database

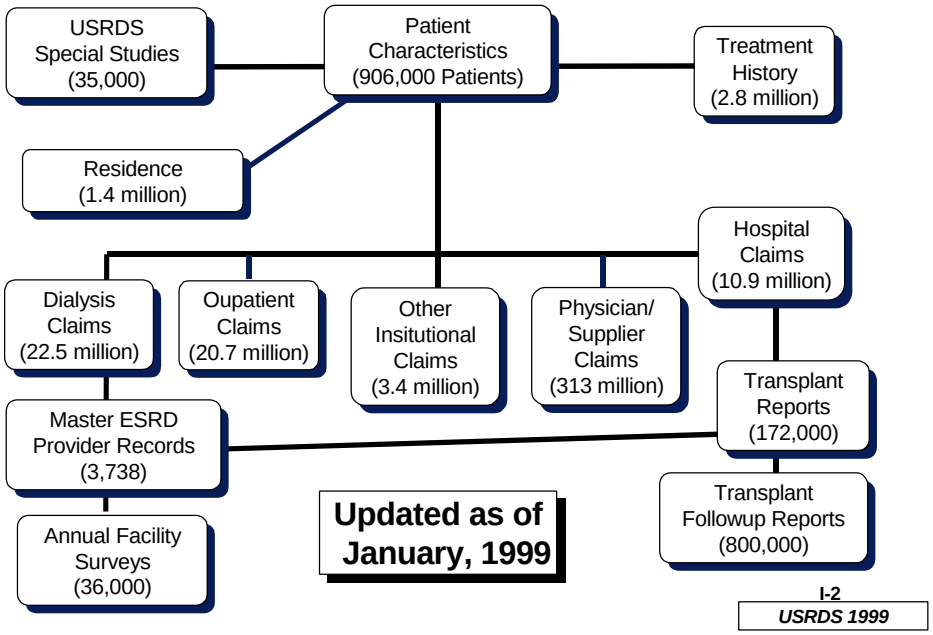

Figure I-2

Overall structure of the USRDS database with counts of patient and facility records as of January, 1999.

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, the CC, and two representatives of the ESRD Networks. The SSRIC focuses on the design, implementation and progress of USRDS Special Studies.

The USRDS Database

The Health Care Financing Administration (HCFA) provides most of the existing data in the USRDS database. In addition to all the data from its ESRD Program Management and Medical Information System (PMMIS) and the Annual Facility Survey, HCFA shares data on transplant followup and Medicare Parts A and B services derived from Medicare claims. These HCFA-supplied data are the core of the USRDS database, as summarized in Figure I-2.

In addition, HCFA helps the USRDS with Special Studies. Most of the new, primary data for Special Studies are collected through the 18 ESRD Networks, which are funded by HCFA under separate contracts. Data from the Special Studies are fully integrated into the USRDS database. The most recent USRDS Special Study, the Dialysis Morbidity and Mortality Study, collected data not otherwise contained in the USRDS database from a national sample of nearly 20,000 patients drawn from all dialysis units.

Since July 1990, selected data on non-Medicare patients treated by U.S. Department of Veterans Affairs (DVA) facilities have also been incorporated into the USRDS database. In July 1994, HCFA and the Health Resources Services Administration (HRSA) consolidated transplant data into a single collection, the United Network for Organ Sharing (UNOS), under its contract with HRSA. The expanded transplant data are shared among HRSA, HCFA, and NIH and, thus, are available to the USRDS. The HRSA-collected transplant data include non-Medicare as well as Medicare patients.

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 U.S. Bureau of the Census, local and national ESRD provider databases, and international ESRD registries.

The USRDS database is updated every year. The last update was in the Winter of 1998-99, using data collected through September 1998. Because of delays in processing data through the Medicare system, the USRDS has waited 15 months before reporting patient-specific data for a given time period. Thus, tables in the 1996 ADR for example, generally reported data through December 1993. Because of improvements in the flow of data to the USRDS, this 15-month rule was relaxed starting with the 1997 ADR. Data generally are reported in this 1999 ADR through 1997, although the 1997 data should be treated as preliminary. Data from the HCFA Annual Facility Surveys are current through 1997. Some data from the HCFA 2728 Form are reported through early 1998.

The discussion below of the USRDS Standard Analysis Files provides a good overview of the USRDS database. The *Researcher's Guide to the USRDS Database* provides more detailed documentation of the database (see Table I-2).

USRDS Products

Table I-2 shows the various products of the USRDS through which the USRDS disseminates the results of ESRD research to the renal community and to the general public and provides data to support ESRD research. Except where a cost is mentioned in Table I-2, these products are free. For further information, see Table I-1 for contacts within the USRDS.

USRDS on the Internet World Wide Web

The entire ADR, including Reference Tables and color slides, the *Researcher's Guide*, and other USRDS publications are available electronically on the Internet using the World Wide Web. Also included are supplements to the ADR Reference Tables. Table I-3 summarizes the material available at this site. The address of the site is: http://www.med.umich.edu/usrds/

USRDS Products

For ESRD Researchers and for the General Renal Community

Annual Data Reports	The principal vehicle for dissemination of USRDS data. Available in print and microfiche from the National Technical Information Service (NTIS), United States Department of Commerce, Springfield, Virginia, 22161, 1-800-553-NTIS. Text portion of the report will be published in the American Journal of Kidney Disease.
Annual Data Report CD	The CD gives you direct access on your PC to the ADR text, Reference Tables, supplementary Reference Tables not included in the paper ADR, color slides, The *Researcher's Guide*, and *USRDS Unit-Specific Reports for Dialysis Patients – A summary*.
Annual Data Report Slides	100+ color slides of all graphics in the ADR with printed Speaker's Guide. Cost is about $70.
Internet World Wide Web	The Reference Tables, text, and color slides of this ADR and other USRDS publications are available electronically on the Internet using World Wide Web at http://www.med.umich.edu/usrds/
"2-Hour" Data Requests	The USRDS CC staff responded to more than 700 requests for data and for general information about the USRDS in 1998. Limited resources are available for simple computer tabulations.
SMR/SHR Methodology	Chapters V, IX, and XIII describe the USRDS Standardized Mortality Rate (SMR) and Standardized Hospitalization Rate (SHR) methodologies. These methodologies can be used to compare local outcomes with national norms for quality improvement purposes.
SMR/SHR Spreadsheets	The USRDS produces a spreadsheet that calculates Standard Mortality Ratios (SMR) for dialysis facilities or other aggregates with up to 500 patients. It allows each dialysis facility to compare their dialysis patients' mortality to national rates based on the actual mortality of U.S. ESRD patients. The Standardized Hospitalization Ratio (SHR) Spreadsheet is also available.
Dialysis Unit- Specific SMR/SHR Reports	The USRDS produces annually dialysis unit-specific mortality, transplantation, and hospitalization reports, which have been distributed to over 2,800 dialysis units through the ESRD Networks. These reports are not available except through the individual dialysis units. Dialysis chains can obtain a copy for all their units on a single CD.
Researcher's Guide to the USRDS Database	This Guide is the basic reference for researchers who use USRDS data files. It provides a detailed description of the USRDS database and of the USRDS Standard Analysis Files.
Standard Analysis Files	These data files provide patient-specific data from the USRDS database to support ESRD research, at an affordable price. User must sign a data release agreement with NIH. More information is provided in this chapter and in the Researcher's Guide.
Custom Data Files	For research needs not met by the Standard Analysis Files. Researcher pays costs of production and must sign a data release agreement.
Papers, abstracts, and publications	Most USRDS research studies result in published papers or presentations at professional meetings. A list of publications and presentations is in Appendix A.

To request any of these products, contact the USRDS Coordinating Center at (734) 998-6611 or by e-mail at usrds@umich.edu, or see the contact list in Table I-1. Products are provided without charge except as mentioned in the descriptions above.

Table I-2

Address and Contents of the USRDS Site on the World Wide Web

http://www.med.umich.edu/usrds/

With a World Wide Web browser like Netscape, Internet Explorer, or America OnLine, you can view a variety of material from the USRDS and can easily download it for use on your PC. Contents include the following:

Annual Data Report	In WWW browser format, as PDF files, as Microsoft Word documents, and as Microsoft PowerPoint slides.
ADR Color Slides	Graphics from the ADR as Microsoft PowerPoint color slides can be downloaded for your presentation.
ADR Reference Tables	Text files can be imported into spreadsheet programs. Includes a number of supplementary tables not included in the printed ADR.
Researcher's Guide	Documentation of data files available to researchers and procedures for accessing the files.
E-mail to the USRDS	Send e-mail to USRDS contact persons.
Data requests	Send e-mail to the USRDS to request data.
Links to related WWW sites	Opens the door to a network of sites with material related to ESRD.
Current Notices	Any items of current interest such as changes in mortality rates, errata, and other events.

Table I-3

The USRDS WWW site is accessed more than 2,000 times each month, and approximately 1 billion bytes of data are downloaded from the site each month. The site is accessed from all around the U.S. and from many other countries.

The full 1998 USRDS Annual Data Report now available on the World Wide Web, will be replaced by this 1999 ADR.

SMR/SHR/STR Methodology

The USRDS has developed a methodology for calculating annual mortality statistics for ESRD patients. Rates of deaths per 1,000 patient years at risk are published every year in the Annual Data Report and are grouped according to gender, age, race, primary cause of ESRD, and modality of treatment. Chapters V, IX, and XIII provide a

description of this methodology. This methodology has now been extended to include standardized rates for hospitalization (SHR) and transplantation (STR) as well as mortality.

The availability of published mortality tables allows dialysis and transplant units and ESRD Networks to compare their mortality rates with the national rates published by the USRDS. The USRDS methodology includes computation of a Standard Mortality Ratio (SMR), which is a comparative measure of mortality, adjusted for age, gender, race, primary diagnosis, and treatment modality. SMRs are used to standardize observed mortality in specific patient subgroups relative to the national death rates.

Dialysis Unit-Specific SMR/SHR Reports

Each year since 1996, the USRDS has produced over 2,300 unit-specific reports containing information about the dialysis patients treated in each dialysis facility. These reports were distributed to dialysis facilities through the 18 ESRD Networks. Each facility received an 8-page report containing information on:

- patient characteristics
- mortality rates
- hospitalization rates
- causes of hospitalization
- causes of death
- rates of vascular access procedures in inpatient and outpatient settings
- data completeness and validation

The highlight of these reports has been a series of SMRs, SHRs, and STRs for each facility. For the 1999 reports, the SMR, SHR, and STR were calculated for each facility for each year from 1995-97 and for the combined 3-year period. Each report also allowed facilities to compare the SMR, SHR, STR, and other information for their facility with summaries among all facilities in the same state, ESRD Network and the United States. The information in these reports could thus be interpreted in the context of local and national norms.

Each facility also received a 23-page document that provides further detail about the methodologies used to prepare the reports (*Guide to the 1999 USRDS Unit-Specific Reports for Dialysis Patients: Overview, Methodology and Interpretation*). This guide may be found on the World Wide Web site as well as the USRDS ADR CD. The methods used to

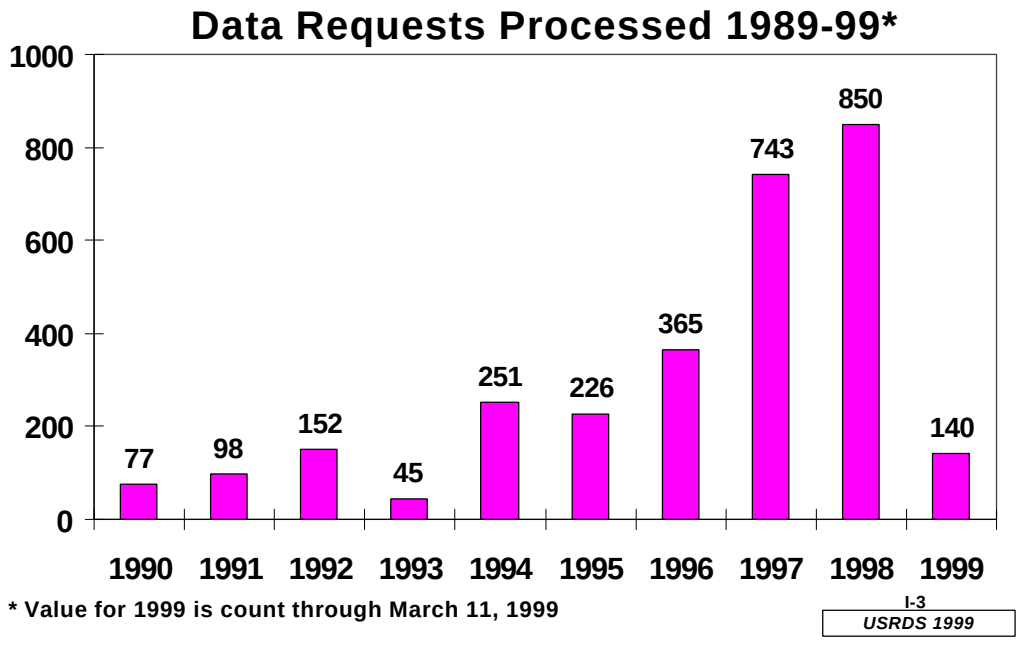

Figure I-3

Data requests processed by the USRDS, 1990-1999. These are data requests filled under the "2-hour rule" which limits requests to those requiring up to 2 hours of staff or computer time to fill.

calculate an SMR, SHR, or STR and some recent analyses involving unit-specific SMRs and SHRs are also presented in Chapters V and VIII of this ADR.

The reports were distributed to the facilities through the 18 ESRD Networks. *The reports are not available except through the individual dialysis units.* Each of the ESRD Networks was provided with data files on CD with all the statistics reported for facilities in that Network.

Data Requests

The USRDS has a primary objective of making data available to the renal community. One of the important means of making data available is through timely response to data requests made by researchers, practitioners, and other members of the renal community.

As shown in Figure I-3 the number of requests has steadily increased over the years. The year 1993 was the year of transition between USRDS contracts, with a temporary interruption of USRDS Coordinating Center activities. During 1997 an average of almost three requests were filled per working day. There has been a seasonal increase in requests around the American Society of Nephrology meeting. Several requests were filled regarding specific analysis files and several have led to scientific publications (Bloembergen).

In many cases these requests can be answered by providing data published in the Annual Data Report or elsewhere. Requests for data not available in the Annual Data Reports, but that would require 2 hours or less of computer programmer/analyst time can be provided by the Coordinating Center, usually within one week of the request.

Requests that require more than 2 hours of computer programmer/analyst time will be undertaken only upon written approval by the NIDDK Project Officer. Research needs that cannot be met by the ADR or by 2-hour data requests probably can be met by obtaining the Standard Analysis Files or custom data files described later in this chapter.

Because of limited resources for filling data requests which require a computer run, such requests must be made in writing (by e-mail, fax, or classic mail). These requests will be completed as resources allow.

USRDS Analysis Files for Researchers

The USRDS has been sharing research data with other researchers for many years. Figure I-4 shows the number as well as the size of requests for data files for researchers outside of the USRDS that were filled from 1992 through March 1999, and a

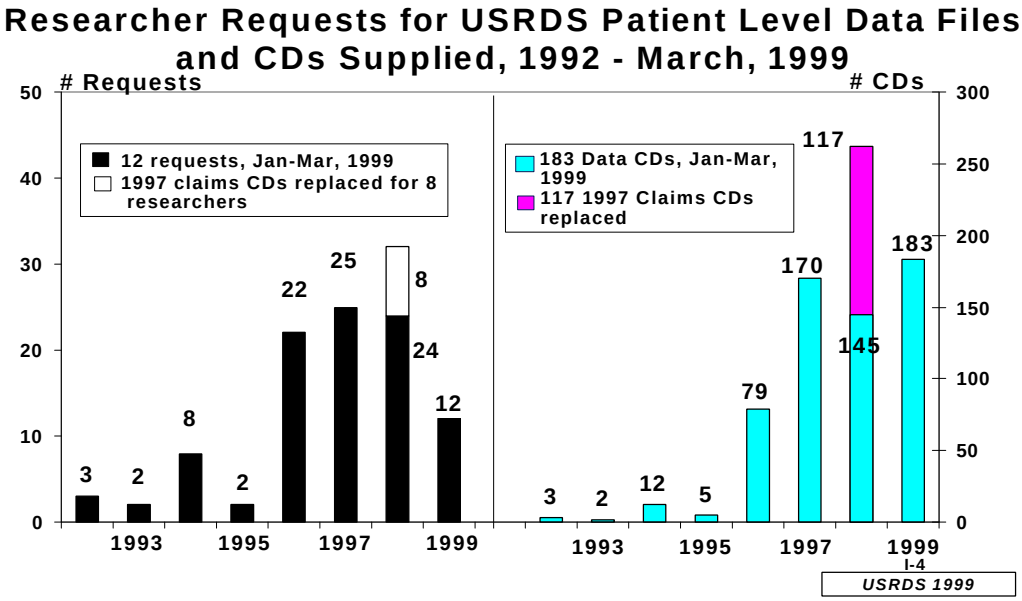

Figure I-4

Researcher requests filled for USRDS patient level data files, 1992-1999. Also shown is the number of 9-track magnetic tapes and CDs supplied. Prior to early 1996, files were supplied on 9-track magnetic tape.

projection for the remainder of 1999. The figure shows the number of CD-ROMs provided to researchers by calendar year. Note that the data that can be stored on one CD would require about 450 high density floppy disks or 4 nine-track computer tapes. There has been a clear increase in both the number of researchers and in the amount of information released for research during the recent years.

As experience regarding the most common requests for research files grew, the Coordinating Center developed a set of Standard Analysis Files (SAFs) designed to meet the needs of a wide variety of research, including production of all the Reference Tables in the ADRs. The SAFs were introduced in 1994, and at the same time NIDDK began awarding a new group of research grants focusing on research using the USRDS data. The result was a sharp increase in the number of files provided by the USRDS. The growth has continued in each subsequent year. In addition, a complete set of files is sent to NIH and HCFA each year. Files also have been provided to the 18 ESRD Networks containing the data from the USRDS Special Studies collected by the Networks.

The Standard Analysis Files make the USRDS database available to researchers in an easy to use and well documented format. This approach allowed a major reduction in the production costs and thus a cost saving for researchers. These analysis files have patient-specific information; however, patient identifiers and facility identifiers are encrypted. Further discussion of the SAFs appears later in this chapter.

Prior to 1994, all files were custom files created based on the needs of a specific research project. Since the introduction of the SAFs, custom files are generally limited to cases in which the researcher provides a file of patients to the USRDS for matching with the USRDS database. Typically, the researcher wants to know which patients in his or her file developed ESRD or had certain outcomes with ESRD. The USRDS returns the researcher's file with specific key ESRD data items added. In these cases all patient identifiers are removed in order to protect the confidentiality of the patient data.

All requests except custom requests include the Core SAF CD. This CD includes basic patient data, each patient's treatment history, limited transplant data, and all data from the USRDS special studies. About half of the researchers using the USRDS SAFs need only this CD. This year the increased size of the Core files made it necessary to add a separate transplant CD. This CD contains the detailed transplant and transplant followup data collected by HCFA and UNOS. The hospitalization CD includes data about hospital inpatient stays except for payment data items. This file is too large to be included on the Core CD. About 40 percent of researchers need this file in addition to the Core CD. The Medicare payment SAFs are used by only about 20 percent of the researchers, but these files account for almost 80 percent of the CDs provided. A full set of Medicare payment files requires 65 CDs. The claims data may be purchased by year. See Table I-7 for details.

A wide variety of research topics have been addressed by researchers outside the USRDS using the USRDS SAFs. Table I-4 shows research topics from the requests for data files which were filled in the past year or currently are pending. The Reference Tables in the ADRs also are used extensively. As an example of the wide use of these data, Table I-5 shows titles of abstracts presented at the 1998 meetings of the American Society of Nephrology which cite the USRDS data in the abstract.

Standard Analysis Files

The USRDS Standard Analysis Files (SAFs) are designed to meet the needs of most such research at minimal cost to the researcher. In 1998, a total of 117 CDs of data were provided to 32 researchers.

The use of the SAFs is governed by the USRDS "Policy on Data Release for Investigator-Initiated Research," which appears near the end of this chapter. Use of the SAFs requires that the research investigator's proposal be approved and that the researcher sign the USRDS "Agreement for Release of Data" (included with this chapter), agreeing to observe the prescribed restrictions.

Most SAFs provide patient-specific data. All patient identifiers (name, address, Social Security number, Medicare beneficiary ID, etc.) are removed from the files or are encrypted, but the confidentiality of the data is still a serious concern. The "Agreement for Release of Data" therefore includes restrictions on the use and disposition of the SAFs. The SAFs include an encrypted ID number to allow data for a given patient from multiple SAFs to be merged when needed.

Recent Independently Supported Research Which Used USRDS Standard Analysis and Custom Files

MD	ESRD patient's access to kidney transplantation	NC	Clinical characteristics of patients with hypertensive ESRD
CA	Optimal dialysis management using mathematical and epidemiological models	OH	Clinical and demographic predictors of blood pressure in the DMMS Wave 1.
OH	Relationships between nutritional parameters in DMMS wave1 data and resource utilization and mortality.	MA	Research plan for evaluation of Southern California Kaiser Permanente's pre-ESRD and ESRD program.
AL/MI	Treatment of End-Stage Sickle Cell Nephropathy in USA	DC	Socioeconomic status and outcome in ESRD population.
PA	Impact of Preemptive Transplantation in Recipients of Kidneys from Live Donors.	NC	Relationship of various factors with risk of hospitalization in ESRD patients.
MD	What type of dialysis units are most likely to deliver inadequate dialysis dose relative to prescription.	MO	Influence of donor and recipient CMV serologic status upon renal transplant outcomes.
MD	A cohort study of health outcomes of and **utilization** by ESRD patients enrolled in managed care organizations compared to the standard fee-for-service health plan.	MD	Predictors of DRG day outliers among end-stage renal disease patients. Extent and implications of compliance w/CDC recommendation for HBsAG testing of ESRD patients.
WA	Estimates of intraclass correlation among dialysis units and the clinical applications.	Germany	Validation of global health measures through USA ESRD microdata.
MN	Ischemic Heart Disease and ESRD	MA	Donor and Recipient Determinants of Late Renal Allograft Outcome.
MO	Fundamental study of the economics of renal transplantation using the USRDS database	MD	Immunosuppressive drugs for transplantation.
PA	Impact of Preemptive transplantation in recipients of kidneys from live donors.	WA	Role of secondary hyperparathyroidism in fracture risk among patients with end-stage renal disease.
MA	Effect of Pre-ESRD care on dialysis outcomes		Risk factors for mortality within pediatric patients with end-stage renal disease.
NC	An Investigation of the effect of antihypertensive medications on sudden, cardiac and overall death rates in dialysis patients.		Outcome and resource utilization of dialysis patients who undergo mechanical ventilation.
NC	Cost effectiveness of triple-drug therapy in renal transplantation		Predictors of type of vascular access placed and of vascular access failure among end-stage renal disease patients.

State/country is location of investigator's institution.

Table I-4

Core Standard Analysis File CD-ROM

The USRDS SAFs are available on CD-ROM disks that can be used on virtually any PC that has a CD-ROM reader. The Core CD contains the most frequently used SAFs, including those from the USRDS Special Studies. The Core CD is needed in order to be able to use the Transplant CD, the Hospital CD or any of the CDs based on Medicare claims data. Table I-6 lists the SAFs on this Core Standard Analysis CD-ROM. The two central files are the Patient file and the Treatment History file.

Because of the continued growth in the USRDS database, it has been necessary to put three of the detailed transplant files on a separate CD.

Patient

The Patient file has one record per patient in the USRDS database and gives the basic demographic and ESRD-related data about the patient.

Residence

The Residence SAF provides a longitudinal record of place of residence for each patient down to the ZIP code level.

Treatment History

The Treatment History file is also referred to as the Modality Sequence file. For each patient, a new record occurs whenever the patient's treatment modality or dialysis provider changes.

Medical Evidence

The HCFA Form 2728, Chronic Renal Disease Medical Evidence Form, is the source of data about the primary disease causing renal failure and the start date of chronic renal dialysis which appear on the Patients SAF. In April 1995, a new version of the form went into use, including data on comorbid conditions, employment status, lab values at start of dialysis, and review by the Network Medical Review Boards. The new version also includes a question on Hispanic ethnicity. The MEDEVID SAF makes available the full data from the new version of the HCFA 2728.

Facility

The HCFA ESRD Annual Facility Survey is the source of data for the Facility SAF. The survey period is January 1 through December 31. The Facility SAF can be linked to the Facility Cost Report files using the USRDS provider ID. Because of this linkage, any geographic variables which could be used to identify facilities have been deleted.

Facility Cost Reports

The HCFA hospital and independent facility cost reports for the years 1989-1995 are available as Standard Analysis Files. To ensure confidentiality, all geographic variables have been deleted. The file may be linked with the Facility SAF by using the USRDS provider ID; however, geographic analyses at less than a regional or ESRD Network level are not possible. Because there has been minimal use of these files, data for additional years will be added only if sufficient demand develops.

Transplant

While the detailed transplant data have been moved to a separate CD, the Core CD still contains a file with basic data, including graft failure date, for all transplants. The various transplant files are described in more detail below.

Transplant Waiting List

This file contains one record for each patient in the USRDS database who also can be identified in the UNOS transplant waiting list file. This file is useful for identifying dialysis patients who were candidates for transplantation. This is useful for studies which compare transplanted patients with dialysis patients who were healthy enough to be candidates for a transplant.

This file contains one variable, the date the patient first was listed on the waiting list. Because of the complexity and variability of the patterns of movement of patients on and off of the waiting list, we have not attempted to derive more complex indicators of transplant waiting list experience.

USRDS Special Studies

The USRDS has carried out a number of Special Studies, most of which result in SAFs. All these studies have been based on national random samples. Special Study topics are approved by NIDDK, with recommendations from HCFA, the USRDS Scientific Advisory Committees, the ESRD Networks, and the Renal Community Council (RCC). For each study, design and sampling plans were developed; samples were selected; and data collection forms and instructions were drafted, tested, and finalized. The studies that have resulted in SAFs are described below. These special studies are described in detail in the *Researcher's Guide* to the USRDS Database.

Abstracts Presented at the 1998 American Society of Nephrology Meetings Citing USRDS Data

Author	Abstract Title	Data Used	I.D. Number
Ashby[1]	The effect of comorbidities on facility standardized mortality ratios.	SAF	M374, S1050
Astor	Predictors of vascular access complications.	SAF	M336
Becker	The impact of transplantation on patient survival.	ADR	S1101
Beddhu	Stratification of comorbidity by Charlson Comorbidity Index (CCI) and comparison of outcomes in hemo (HD) and peritoneal dialysis (PD).	ADR	M379
Billa	Survival on renal replacement therapy - an international comparison.	SAF	A0722
Bleyer	The relationship between intermittent hemodialysis and sudden and cardiac death events.	SAF	M1130, S286
Brown	Effect of dialysis adequacy on morbidity and mortality in elderly dialysis patients.	ADR	A1030
Daugirdas	Survival in Asian-American ESRD patients.	SAF	M371, S1049
Gaylin	Capitation modeling for end-stage renal disease	SAF	T162, M1059
Germain	Withdrawal from dialysis: promise of a good death.	ADR	M364
Hirsch	Peritoneal dialysis reduces the use of non-native fistula access in dialysis programs.	ADR	O884
Hirth[1]	Predictors of hospitalization of ESRD patients (PTS).	SAF	M372, S1055
Jones	Quality of life in incident hemodialysis and peritoneal dialysis patients by time of referral to a nephrologist and nutrition.	SAF	T198
Katz	Improved growth velocity with intensive dialysis - consequence or coincidence?	ADR	A1515
Lamping	Clinical outcomes, quality of life (QOL) and costs in elderly dialysis patients: results from the North Thames dialysis study (NTDS).	ADR	M332
Lei	Family history of end-stage renal disease (ESRD) in white and black dialysis patients: a report from the choice study.	ADR	S207
Levey	Predicting GFR from serum creatinine in the MDRD study: a correction.	ADR	A0784
Longenecker	Validation of comorbid conditions on the ESRD medical evidence report by medical record review: the choices for healthy outcomes in caring for ESRD (choice) study.	ADR	S1051, M366
Mange	Preemptive living donor kidney transplantation in the United States.	SAF	A3498
Manley	Hemodialysis Outpatient Medication Audit as the Impetus to Assess and Improve Drug Therapy.	SAF	A1117
Moist	Predictors of loss of residual renal function (RRF) among new dialysis patients.	SAF	S213
Orzol[1]	Characteristics of patients not reusing dialyzers in units practicing dialyzer reuse.	SAF	S1056, M373
Parekh	Cardiac mortality in pediatric ESRD.	SAF	S192
Perrone	Autosomal dominant polycystic kidney disease (ADPKD): survival after end-stage renal disease (ESRD).	SAF	T148
Pflederer	The cost of coordinated access care.	ADR	M255
Rosas	Synthetic graft vs AVF-A cost effectiveness analysis.	ADR	M339
Saborio	Transplantation for primary hyperoxaluria (PH) in the USA.	SAF	S893
Sarnak	Cardiovascular mortality in ESRD compared to the general population.	ADR	S211
Stack	Congestive heart failure among incident U.S. dialysis patients: predictors and clinical correlates.	SAF	S288
Stack	Predictors and clinical correlates of coronary artery disease among incident U.S. dialysis patients.	SAF	S290
Vonesh	Further comparisons of mortality between hemodialysis (HD) and peritoneal dialysis (PD).	ADR	S1053, M370
Vonesh	Subgroup comparisons of mortality between hemodialysis (HD) and peritoneal dialysis (PD).	ADR	M359
Wish	Iron management and HCT control in hemodialysis (HD) patients. Report from the 1997 HCFA core indicators project (CIP).	ADR	S265
Wolfe[1]	The association between regional death rates and standardized mortality ratios (SMR) by health service areas (HAS) and race and sex group.	SAF	S1052, M368
Wolfe[1]	Mortality and costs in the first year of dialysis: a comparison between hemodialysis (HD) and peritoneal dialysis (PD) controlling for costs prior to ESRD.	SAF	T186, T1126
Wolfe	Dose of hemodialysis, body size, and mortality: results from the USRDS special studies.	SAF	M369
Woodward[1]	CMV immune globulin and kidney graft survival.	SAF	T828

Data Used: ADR = cited data from USRDS Annual Data Report; SAF = used USRDS Standard Analysis Files
Authors: 1 = a USRDS Coordinating Center staff member was first author

Table I-5

The data collection forms used for the DMMS are in Appendix B. The forms for all of the USRDS Special Studies are included in the *Researcher's Guide*.

Case Mix Severity Study

The objectives of the USRDS Case Mix Severity Study were to:

- Estimate the correlation of comorbid conditions and other potential factors existing at onset of ESRD regarding their association with subsequent mortality rates and hospitalization rates, while adjusting for age, gender, race, and primary diagnosis.
- Evaluate possible associations of these factors with reported causes of death.
- Assess the distribution of comorbid and other factors among patients utilizing different treatment modalities.
- Compare relative mortality rates by treatment modality with adjustment for selected comorbid conditions and other factors.

Data were collected on 5,255 patients incident in 1986-87 at 328 dialysis units nationwide.

CAPD and Peritonitis Study

The objective of the USRDS CAPD and Peritonitis Rates Study was to compare peritonitis episodes in CAPD patients with respect to connection device technology and other factors. The study population includes all patients newly starting CAPD in the first 6 months of 1989, up to a maximum of 14 patients per dialysis unit. All units providing CAPD training participated in the study. The sample contains 3,385 patients from 706 dialysis units.

Pediatric Growth and Development

The objectives of the USRDS Pediatric ESRD Growth and Development Study were to:

- Establish a baseline for assessing pediatric ESRD patient growth and sexual maturation by modality choice.
- Establish a prototype for ongoing collection of pediatric data.

All patients prevalent in 1990 who were born after December 31, 1970, are included in the study. The study population includes 3,067 patients at 548 dialysis units.

Case Mix Adequacy Study (CMAS)

The objectives of the USRDS Case Mix Adequacy Study of Dialysis were to:

- Establish the relationship between the dose of delivered dialysis therapy and patient mortality.
- Determine the strength of this relationship when adjusting for comorbid conditions.
- Assess how this relationship changes at different doses of dialysis.
- Assess how this relationship is affected by reuse of dialyzers.
- Assess the impact of different dialysis membranes on patient morbidity and mortality.

The study consists of two groups of patients: an incident sample of patients starting hemodialysis for ESRD during 1990 and a prevalent sample of hemodialysis patients with onset of ESRD prior to 1990. There are 7,096 patients from 523 dialysis units in this study. Approximately 3,300 patients have the pre- and post- BUN values needed to calculate delivered dose of dialysis. We have matched 94 percent of these cases to the USRDS database, which will allow the data to be used for many extensive analyses. The ESRD Networks have collected these data in conjunction with their Medical Case Review data abstraction.

Dialysis Morbidity and Mortality Study (DMMS)

The DMMS is an observational study in which demographic, comorbidity, laboratory, treatment, socioeconomic, and insurance data are collected for a large random sample of U.S. dialysis patients, using the patients' dialysis records. This study includes 4 phases ("waves") of data collection on 6,000 ESRD patients in each of Waves 1, 3, and 4 and 4,500 patients in Wave 2, for a total sample of 22,500 patients over 3 years. Waves 1, 3, and 4 are each historical prospective studies in which data are collected for patients receiving in-center hemodialysis on 12/31/93. In each of these "waves," data are abstracted from the patient's medical record with patient status followed from 12/31/93 through the earliest of date of data abstraction, death, transplant, change in modality, or transfer to another facility. Wave 2, which began in 1996, is a true prospective study of incident hemodialysis and peritoneal dialysis patients for 1996.

Dialyzers

The Case Mix Severity, Case Mix Adequacy, and DMMS Special Studies all collected manufacturer and model of the dialyzer used for the patient at a specific time. The SAFs for these studies include only a code number indicating the dialyzer. This code must be matched to the Dialyzer file to get the manufacture, model, and characteristics of the dialyzer, such as membrane type and clearance. The data in the Dialyzer file come from published sources available at the time of the study. We believe these data accurately represent the characteristics of the dialyzers, but they should be used with caution.

Transplant CD

Due to changes in data collection sources over the years, data pertaining to transplants are now presented in six separate SAFs. Because of space considerations, only the first two files listed below are included on the Core CD, and the remaining four are included on the separate Transplant CD.

- TX includes a minimum of details about all transplants from all sources.
- TXWAIT has one record for each patient in the USRDS database who also can be identified on the UNOS kidney transplant waiting list. The only variables are the date of first listing and USRDS_ID.
- TXHCFA includes transplant details collected by HCFA's PMMIS system for the years 1976-93.
- TXUNOS includes transplant details collected by the United Network for Organ Sharing, currently our main source of transplant data, for the years since 1987.
- TXFUHCFA includes transplant followup reports collected by HCFA prior to 1988. Reports are completed at discharge, 6 months, each year post transplant, and at graft failure.
- TXFUUNOS includes transplant followup reports collected by UNOS from 1988 on.

In July 1994, HCFA and the Health Resources Services Administration (HRSA) consolidated transplant data into a single collection by the United Network for Organ Sharing (UNOS) under its contract with HRSA. The expanded transplant data are shared among HRSA, HCFA, and NIH and thus are available to the USRDS. This has resulted in the addition of data on a substantial number of non-Medicare transplants starting in 1994. Children are disproportionately represented in these non-Medicare transplants.

The HCFA and UNOS transplant data files overlap for the years 1987-1993. Additionally, some Medical Evidence Forms and institutional claims records indicate transplants which are not included in either the HCFA or the UNOS file.

The main transplant SAF, SAF.TX, provides a roster of all of the transplants indicated by the four sources. In order to resolve the conflicts among the four sources, the following procedure is used. First, all of the UNOS transplants are accepted into the file. Second all HCFA transplants from before 1987 are accepted. Third, HCFA transplants from 1987-1993 are accepted if there is not already a transplant for that patient within 30 days of that HCFA transplant. It is common for the transplant dates to differ by one day between these two sources. Next, transplants indicated on the Medical Evidence 2728 Forms are accepted if there is not already a transplant for that patient within 30 days of the Medical Evidence transplant date. Finally, transplants from institional claims are added if there is not already a transplant for that patient within 30 days from one of the other sources.

The main transplant SAF (TX) has a small number of variables describing the recipient and the donor and indicating the graft failure date computed by the USRDS. The UNOS transplant SAF (TXUNOS) contains the detailed data from the UNOS transplant file, and the HCFA transplant details file (TXHCFA) contains the detailed data from the HCFA transplant file. A researcher who needs additional variables can merge the file with either the UNOS or the HCFA details file. The tables in Section F of the Reference Tables are produced primarily from the main and UNOS transplant files.

Hospital CD

The hospitalization data from the USRDS database will not fit on the same CD with the files on the Core SAF CD, but are provided on a second CD. The hospital inpatient data on this CD are a subset of the data in the Institutional Claims file. No payment or cost variables are included on this CD. This CD is for researchers who need data on hospital inpatient stays and diagnoses and procedures for those stays but who do not need payment data.

USRDS Core Standard Analysis File CD

The files listed below are provided on a singe CD.

File Name	Unit of Observation	Uses
Patient	ESRD Patient . 906,000 Patients	Incidence, prevalence, patient survival. Most other files will need to be linked to this file using the encrypted patient ID.
Residence	For each patient, one record for each period in a different residence.	Regional analyses.
Treatment History	Patient. One record for each spell a patient spends on one modality.	Modality distribution and treatment patterns. Treatment modality at a point in time and changes in modality over time.
Medical Evidence	One record for each 2728 form filed. From 1995, 254,000 records.	Comorbid conditions, patient status at start of ESRD.
Transplant	Transplant. Can have multiple transplants for one patient. 172,000 Transplants	Transplant and transplant outcome analyses.
Transplant Waiting List	One record for each patient ever on waiting list. Only data item is date first listed.	Comparison of transplanted patients to dialysis patients who are transplant candidates. Patient selection to waiting list.
Dialysis Mortality and Morbidity (DMMS) (USRDS Special Study)	5,670 patients included in Wave 1. 4,024 patients in Wave 2. 11,142 patients in Waves 3 & 4.	Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values, nutrition, vascular access. See Chapter 4. Data from Wave 1 of this study is now available.
Case Mix Adequacy (USRDS Special Study)	7,096 patients included in the study.	Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values.
Case Mix Severity (USRDS Special Study)	5,255 patients included in the study.	Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values.
Pediatric Growth and Development (USRDS Special Study)	3,067 patients included in the study.	Growth, development, and other issues relating to pediatric ESRD Patients.
CAPD Peritonitis (USRDS Special Study)	3,385 patients included in the study.	CAPD and peritonitis.
Facility	One record for each year during which each facility was in operation.	Merge with the treatment history, transplant, or annual summary SAFs for analyses involving provider characteristics by encrypted ID.
Facility Cost Reports	One record per facility per year. (1993-1995 only).	Costs and staffing of dialysis facilities.
CLMCODES	One record for each diagnosis, procedure, or HCPCS code appearing in claims files.	Frequency of occurrence of each code. A starting point for analyses that will use diagnosis and procedure codes.
FORMATS.SC2	All USRDS-defined SAS formats used by the SAFS.	This is a SAS format library to format values of categorical variables.

Table I-6

Medicare Payment Data

SAFs containing Medicare payment data are now available. For institutional claims, data are available for pre-1989 through 1997. For physician/supplier claims, data are available for 1991 through 1997. The claims data CDs now can be purchased by year.

There are two types of Medicare claims: institutional and physician/supplier. All the physician/supplier claims are Medicare Part B. The institutional claims consist of all Part A claims (Inpatient, Outpatient, Skilled Nursing Facility, Home Health Agency, and Hospice) and some Part B claims, notably outpatient dialysis. Physician/supplier claims account for about 80 percent of the claims but only 20 percent of the dollars.

The structure and content of the two types of claims are different, and so are the files derived from them. For institutional claims, there are two types of files: the Institutional Claims (Claims) file and the Institutional Claims Detail file. The Claims file indicates the type of claim, the dollar amounts, the type of dialysis involved (if any), and the dates of service. The Claims Detail file contains details like DRG, diagnoses, and procedures. For many analyses, the Claims Details file would not be needed.

For the physician/supplier claims, there is one type of file with one record for each claim line-item. The file includes dollar amounts, dates of service, diagnosis and procedure codes, and type and place of service.

As indicated in Table I-7, the claims data CDs are now available by year. Starting in 1999, we will add data for one year of claims with each annual update. We also will update the preceding four years for institutional claims and the preceding one year for physician/supplier claims. Thus early in 1999 we will produce files for 1997 and will issue updated files for 1994 through 1996 for the institutional claims and for 1996 for the physician/supplier claims. We update prior years to make sure that we have complete data for past years for patients who have newly entered the database. We will continue to evaluate how many prior years of claims should be updated each year.

Note that the claims files have all claims for a given patient, including claims for dates before the patient's first ESRD service date. This allows at least limited analysis of medical care in the pre-ESRD period.

Case Mix Adequacy CD

This CD contains the Case Mix Adequacy Special Study file and extracts from all the other SAFs for the patients in this study. All the Medicare payments data for these patients are included. This file is useful for analysis using the Case Mix Adequacy data. It also is useful as test data for developing analyses that later will be rerun on the full Medicare payments files.

DMMS CD

This CD is similar to the Case Mix Adequacy CD. It contains the files from the Dialysis Mortality and Morbidity Study and extracts from all the other SAFs for the patients in this study. All the Medicare payments data for these patients are included.

File Media and Formats

The SAFs are provided on CD-ROM disks as SAS (Statistical Analysis System) files. The CDs can be used directly by SAS on any 486 or Pentium PC with a CD-ROM reader.

In order to keep the SAFs affordable, the files are provided only in SAS format. Researchers who require a different format or a medium other than CD-ROM are responsible for arranging for the conversion themselves and should have little difficulty obtaining help in doing so from any university computer center. The USRDS also may be able to convert files to alternative formats or media, but the cost will be substantially greater.

SAS format was chosen for the USRDS SAFs because it is widely used, easily transported, and largely self-documenting. SAS is a commercially available data management and statistical analysis software system that runs on most computers, from mainframes to PCs. It is almost universally available on university computer systems. The USRDS SAFs take full advantage of the ability of SAS data sets to incorporate a large amount of documentation into the file. The current price structure for the USRDS SAFs is listed in Table I-7.

What You Need to Use the SAFs

Computer: A 486 or Pentium PC. The USRDS CC currently uses Pentium Pro 200s and Pentium II 450s. Smaller runs have been done on 486/100 PCs. The files can be converted to SAS transport format for use on any computer on which SAS runs.

Current Price Structure for USRDS Standard Analysis File CDs

CD	Description of CD	CDs	Price
Core CD	The Core CD is needed in order to use any of the other CDs.	1	$500
Transplant CD	Detailed transplant data from UNOS and HCFA.	1	$100
Hospital CD	The Hospital CD set is derived from the Institutional Claims and Institutional Claims Details CDs. It contains diagnosis and surgical procedures codes for each stay but does not include the cost data which are included in the Institutional Claims records.	1	$100
DMMS Claims CD set	The DMMS Claims CD set contains all of the Institutional and Physician/Supplier claims data for the patients in the USRDS Dialysis Mortality and Morbidity (DMMS) Special Study. The data from the Special Study data collection forms are included on the Core.	3	$300
Case Mix Adequacy claims CD	The Case Mix Adequacy Claims CD set contains all of the Institutional and Physician/Supplier claims data for the patients in the USRDS Case Mix Adequacy Special Study. The data from the Special Study data collection forms are included on the Core CD.	1	$100

	Institutional Claims			Physician/Supplier Claims	
Years	**Claims CDs**	**Details CDs**	**Price**	**CDs**	**Price**
Before 1989 [1]	1	1	$200		
1989	1	1	$200		
1990	1	1	$200		
1991	1	2	$300	4	$400
1992	1	2	$300	4	$400
1993	1	2	$300	4	$400
1994	1	2	$300	5	$500
1995	1	3	$400	5	$500
1996	1	3	$400	6	$600
1997	1	3	$400	7	$700

[1] Before 1989 includes only hospital inpatient stays and quarterly summaries of outpatient dialysis. No cost data.

Table I-7

CD-ROM drive: Any PC with a CD-ROM drive should be able to use the SAF CDs.

Disk Storage: For the files on the basic CD, between 10 megabytes and 600 megabytes, depending on the files being used. The data on each CD shown in Table I-6 requires from 550 to 650 megabytes of disk storage. Keep in mind that you will need space for temporary work files and for the files that you will create.

Software: SAS. If you convert the files to SAS transport format, they can be used by SPSS, or other software that can read a SAS transport data file.

People with software experience: The SAF documentation provides some of the basics of loading the files into SAS and using them, but you need people with SAS experience. The USRDS CC cannot provide technical assistance with running SAS. If you plan to use other software, then people with other appropriate software experience will be needed.

Cost

The price of the files is intended to cover the incremental cost of reproducing and shipping the file and documentation, the administrative cost of handling the sales of the files, and the cost of technical support to researchers in selecting the correct files and in using the files.

The cost of the Core CD is $500. This CD is needed in order to be able to use any of the other CDs. Additional CDs cost $100 each. See Table I-7 for more specific pricing. Checks ***must be payable to the University of Michigan***. These prices are subject to change.

Documentation

The *Researcher's Guide to the USRDS Database* provides most of the documentation of the SAFs. It includes a codebook of variables on the files and copies of the data collection forms used by the Special Studies. A chapter on techniques for using the SAFs in SAS has been developed.

Acknowledgment for Use of USRDS Data

All users of USRDS data should acknowledge that use. Publications that use USRDS data should include such acknowledgment and the following notice:

The data reported here have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the U.S. Government.

Policy on Data Release for Investigator Initiated Research

Since the Standard Analysis Files and tailored data files contain confidential, patient-specific data, release of these files requires the approval process described in this section. The investigator may contact the USRDS Project Officer (PO) at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to discuss their data request before preparing a written proposal. (See Table I-1, USRDS contact list). To request research data files for analysis from the USRDS:

1. The investigator will provide the USRDS Project Officer (PO) with a detailed description of the proposed investigation. A suggested outline appears at the end of this chapter. The proposal may be the project description from an application for a grant or for other sources of funding. The project summary must include goals, background data, an in-depth description of the study design and analytic methodology, and resources available for completing the project. It is necessary for the proposed project to comply with the Privacy Act of 1974, and the project summary should provide enough information to enable assessment of compliance. The guidelines for adherence to the Privacy Act are contained in Section F of the USRDS "Agreement for Release of Data" which is provided at the end of this chapter.

2. The proposal must indicate which USRDS Standard Analysis Files will be needed, and must provide for sufficient funding to cover the cost of the data files, as determined from the SAF price list. If the USRDS Standard Analysis Files cannot meet the requirements of the proposed research, the proposal must specify precisely which data elements are needed, and must budget for a substantially higher cost for obtaining the files. The investigator may contact the USRDS CC with questions about the files (Data File Contact in Table I-1).

3. The project will be reviewed by NIH for technical merit and for conformity with the Privacy Act. The PO will notify the investigator(s) in writing of the approval or disapproval, discussing the reason for a disapproval. The PO will send a copy of the

approval letters to the USRDS CC. The process of reviewing the written data request, generating the data file, and releasing the data will take approximately 3 months.

4. After approval, the investigator will return a signed copy of the USRDS Agreement for Release of Data to the PO. A copy of the Agreement appears at the end of this chapter. The investigator and the USRDS CC will resolve any technical questions. The investigator will arrange payment with the USRDS CC, *and payment must be received before the files will be released. Checks* ***must be payable to the University of Michigan.***

5. When both a copy of the signed "Agreement for Release of Data" and payment for the files have been received by the USRDS CC, the CC will prepare the files and documentation and will send them to the investigator.

6. Any reports or articles resulting from use of the USRDS data must be submitted to the PO prior to submission for publication for review to assure adherence to the Privacy Act. The PO must respond within 30 days. If the report or article is determined not to adhere to the Privacy Act, it shall not be published until compliance with the Act is achieved. Assessment of compliance will not depend on the opinions and conclusions expressed by the investigators. On the other hand, approval does not indicate endorsement of the investigator's opinions and conclusions by the Government.

7. All publications using the released data must contain the standard disclaimer, "The data reported here have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy of or interpretation by the U.S. Government." The investigator is requested to send copies of all final publications resulting from this research to both the PO and the USRDS CC.

Caveats

1. This policy establishes conditions and procedures for the release of data from the USRDS and is intended to ensure that data are made available to investigator(s) in the pursuit of legitimate biomedical, cost-effectiveness, or other economic research.

2. The USRDS will not release data that identify individual patients, providers, or facilities. If individually identifiable data are needed, the request should be submitted directly to the Health Care Financing Administration. However, since it might be possible to infer the identity of individual patients, providers, or facilities from the data in the Standard Analysis Files, the data in these files are considered confidential. The USRDS Agreement for Release of Data contains a number of both general and specific restrictions on the use of USRDS data, and investigators are expected to abide by these restrictions.

3. Use of these data to identify and/or contact patients, facilities, or providers on the files is prohibited by USRDS policy. Identifying or contacting patients also is prohibited by the Privacy Act of 1974.

4. The USRDS CC will provide data in any of the usual forms, such as on tape, disk, and/or hard copy. Analysis services by the USRDS CC (other than to review the proposal and to prepare the data file if approved by the PO) will not be provided for these data requests under the USRDS contract. However, USRDS CC personnel may participate in analyses funded by sources other than the USRDS contract.

5. Standard Analysis Files or other data files from USRDS Special Studies will become available one year after the data have been collected, edited, and entered into the database.

References

Bloembergen WE, Port FK, Mauger EA, Briggs JP, Leichtman AB: Gender discrepancies in living related renal transplant donors and recipients. *J Am Soc Nephrol* 1996, 7: 1139-1144.

U.S. Renal Data System, *Researcher's Guide to the USRDS Database*, The National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 1996.

Research Proposal to the U.S. Renal Data System

Suggested Outline

I Research Topic Title and Date of Submission

II Background

III Study Design
Objectives
Hypotheses
Analysis Plan

IV Data Requested
List Standard Analysis Files needed or specify custom data file

V Proposed by

For Principal Investigator and co-authors, supply
Name
Affiliation
Address
Phone and Fax

Please submit to:

Lawrence Y.C. Agodoa, M.D.
United States Renal Data System
NIDDK
Natcher Building – 6AS-13B
45 Center Drive – MSC 6600
Bethesda, Maryland 20892-6600

Phone (301) 594-7717
Fax (301) 480-3510
agodoal@extra.niddk.nih.gov

UNITED STATES RENAL DATA SYSTEM (USRDS)

AGREEMENT FOR RELEASE OF DATA

In this agreement, "Recipient" means _____

_____

A. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), through the United States Renal Data System (USRDS) Coordinating Center (CC), will provide the Recipient with tapes, disks, and/or hard copy containing data extracted from the USRDS research database.

B. The sole purpose of providing the data is the conduct of legitimate and approved biomedical, cost-effectiveness, and/or other economic research by the Recipient.

C. The Recipient shall not use the data to identify individuals on the file.

D. The Recipient shall not combine or link the data provided with any other collection or source of information that may contain information specific to individuals on the file, except where written authorization has been obtained through the approval process.

E. The Recipient shall not use the data for purposes that are not related to biomedical research, cost-effectiveness, or other economic research. The purposes for which the data may not be used include, but are not limited to:

- identification and targeting of under- or over-served health service markets primarily for commercial benefit;
- obtaining information about providers or facilities for commercial benefit;
- insurance purposes such as redlining areas deemed to offer bad health insurance risks; and
- adverse selection (e.g., identifying patients with high risk diagnoses).

Any use of the data for research not in the original proposal must be approved by the PO.

F. The Recipient shall not publish or otherwise disclose the data in the file to any person or organization unless the data have been aggregated (that is, combined into groupings of data such that the data are no longer specific to any individuals within each grouping) and no cells (aggregates of data) contain information on fewer than 10 individuals or fewer than 5 providers or facilities. The Recipient shall not publish or otherwise disclose data that identify individual providers or facilities, or from which such identities could be inferred. However, the Recipient may release data to a contractor for purposes of data processing or storage if (1) the Recipient specified in the research plan submitted to the USRDS Project Officer (PO) that data would be released to the particular contractor, or the Recipient has obtained written authorization from the PO to release the data to such contractor and (2) the contractor has signed a data release agreement with the PO.

G. A copy of any aggregation of data intended for publication shall be submitted to the PO for review for compliance with the confidentiality provisions of this agreement prior to submission for publication and, if not approved, shall not be published until compliance is achieved. The PO must respond within 30 days.

H. Appropriate administrative, technical, procedural, and physical safeguards shall be established by the Recipient to protect the confidentiality of the data and to prevent unauthorized access to it. The safeguards shall provide a level of security outlined in OMB Circular No. A-130, Appendix III — Security of Federal Automated

Information System, which sets forth guidelines for security plans for automated information systems in Federal agencies.

I. No copies or derivatives shall be made of the data in this file except as necessary for the purpose authorized in this agreement. The Recipient shall keep an accurate written accounting of all such copies and derivative files made, which will furnished upon request to the PO. At the completion of the activities in the research plan, the file shall be returned to the USRDS CC at the Recipient's expense, and any derivative files and copies shall be destroyed.

J. Authorized representatives of the PO and/or of HCFA will, upon request, be granted access to premises where data in this file are kept for the purpose of inspecting security procedures and arrangements.

Revised June 1994

Signatures:

_____
(Recipient typed name, title, and organization)

_____
(Recipient telephone number)

_____
(Recipient signature) (Date)

_____
(Contractor typed name, title, and organization)
(As appropriate)

_____
(Contractor telephone number)

_____
(Contractor signature) (Date)

Lawrence Y. C. Agodoa, M.D., NIDDK, NIH or
Camille A. Jones, M.D., NIDDK, NIH
(USRDS Project Officer typed name and organization)

_____
(USRDS Project Officer Signature)(Date)