

Chapter I

The USRDS and Its Products

Key Words:

Data files
Database
Data access

World Wide Web
Standardized mortality

This is the ninth *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:

- The full USRDS Annual Data Report is now available on the World Wide Web (<http://www.med.umich.edu/usrds>). This 1997 ADR will be available on the WWW before the paper version is printed and distributed.
- This 1997 ADR generally includes data through calendar 1995, although some data for 1995 from the patient database must be treated as preliminary. USRDS Special Study data and other limited data are presented for 1996.
- USRDS Standard Analysis Files continue to be provided on CD-ROM. Medicare payment data

from Medicare claims for 1989 to 1995 are now in the USRDS database.

- In December 1996 the USRDS produced a second round of dialysis unit-specific reports on mortality, transplantation, and hospitalization. These reports were distributed to over 2,000 dialysis units through the ESRD Networks. This round of reports included data through 1995 and 1996.

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.

United States Renal Data System (USRDS)

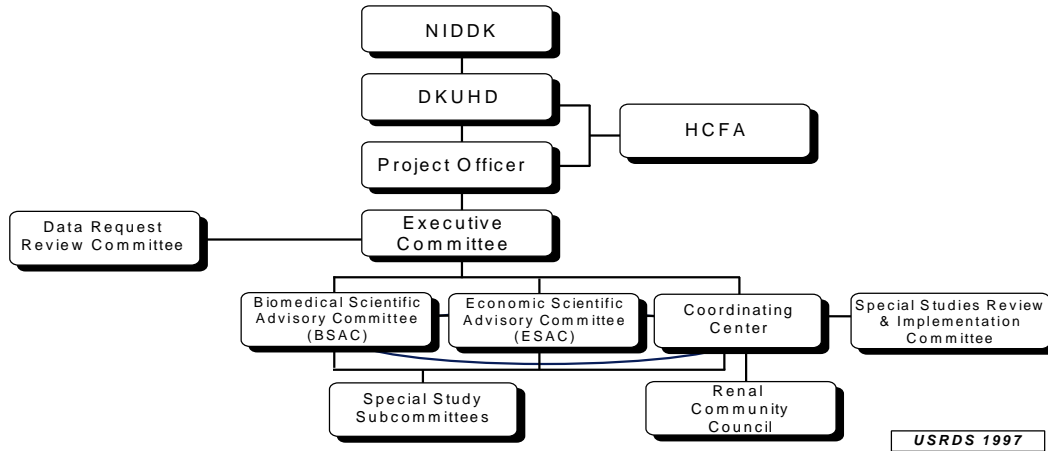


Figure I - 1

- 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.

and responsibilities of NIDDK and 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 topics, a HCFA Project Officer directly supervises all such projects.

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 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) oversees the USRDS, ensuring that the scientific and technical goals of the USRDS are consistent with the mission

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 (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 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.

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 <i>agodoal@ep.niddk.nih.gov</i>
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 <i>jonesc@ep.niddk.nih.gov</i>
USRDS Coordinating Center (CC)	USRDS 315 W. Huron St., Suite 240 Ann Arbor, MI 48103	Phone (313) 998-6611 Fax (313) 998-6620
CC Director	Philip J. Held, Ph.D.	Phone (313) 998-6611 <i>held@umich.edu</i>
CC Deputy Director	Friedrich K. Port, M.D., M.S.	Phone (313) 998-6611 <i>portb@umich.edu</i>
CC Data File Contact	Randall L. Webb	Phone (313) 998-6608 <i>rlwebb@umich.edu</i>
Standardized Mortality / Hospitalization Rate Methodology	Robert A. Wolfe, Ph.D	Phone (313) 998-6611 <i>bobwolfe@umich.edu</i>
CC Data Request Contact Publication Orders	Dora Smith	Phone (313) 998-6611 <i>adorable@umich.edu</i>
Internet World Wide Web		<i>http://www.med.umich.edu/usrds/</i>

Table I-1

USRDS 1997

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 made an hour-long presentation to a special session of ASN. This presentation is expected to be an annual event and will take the place of a report to the RCC.

The **Data Request Review Committee (DRRC)** advises the Project Officer. It includes

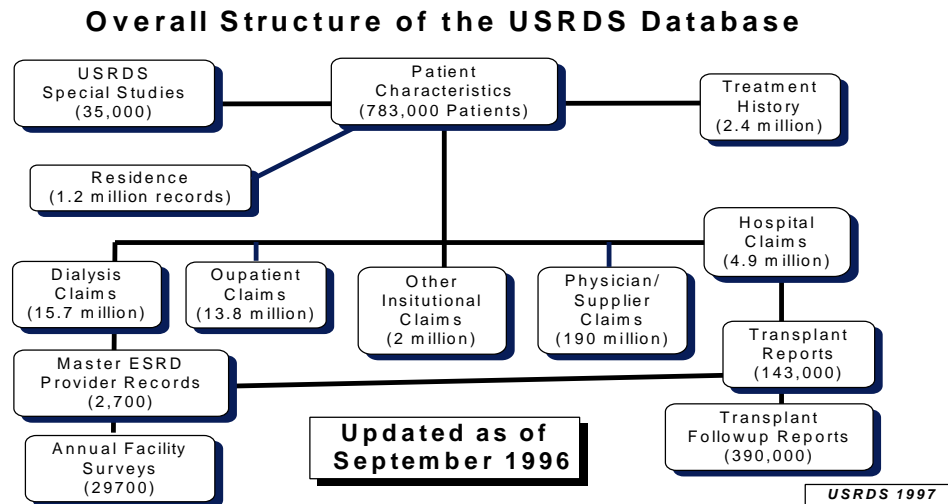


Figure I-2

Overall structure of the USRDS research database with counts of patient and facility records as of September 1996.

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 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 one representative 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. Data collection began in March 1995 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 national sample of 24,000 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.

USRDS Products

For ESRD Researchers and for the General Renal Community

<i>Annual Data Reports</i>	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, (703) 487-4650. Text portion of the report will be published in the <i>American Journal of Kidney Diseases</i> . The entire report is available on the WWW (see below).
<i>Annual Data Report Slides</i>	100+ color slides of all graphics in the current <i>Annual Data Report</i> . Cost is about \$70. Also on the WWW.
Internet World Wide Web	The entire ADR, including Reference Tables and color slides, the <i>Researcher's Guide</i> , and other USRDS publications are available electronically on the Internet using World Wide Web at http://www.med.umich.edu/usrds/
Data Requests	The USRDS CC staff respond to more than 350 requests for data and for general information about the USRDS each year. Responses are limited to those that can be accomplished in 2 hours or less of staff time.
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 and are used in the Unit-Specific Reports.
<i>Dialysis Unit-Specific SMR/SHR Reports</i>	The USRDS has produced dialysis unit-specific mortality, transplantation, and hospitalization reports, which have been distributed to over 2,400 dialysis units through the ESRD Networks. These reports are not available except through the individual dialysis units.
<i>Researcher's Guide to the USRDS Database</i>	This <i>Guide</i> 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. Also on the WWW.
Standard Analysis Files	These data files provide patient-specific data from the USRDS database to support ESRD research, at an affordable price. Under Federal law, the user must sign a data release agreement with NIH. More information is provided in this chapter and in the <i>Researcher's Guide</i> .
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 (313) 998-6611 or by e-mail at usrds@umich.edu, or see the contact list in Table I-1. Products are free except as indicated above.

Table I-2

USRDS 1997

U.S. Renal Data System

<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:

<i>Annual Data Report</i>	in WWW browser format, 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
<i>Researcher's Guide</i>	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
Links to related WWW sites	opens the door to a network of sites with material related to ESRD

Table I-3

Address and contents of the USRDS site on the World Wide Web.

USRDS 1997

The USRDS database is updated every year. The last update was in the Winter of 1996, using data collected through September 1996. Because of delays in processing data through the Medicare system, the USRDS generally has waited 15 months before reporting patient-specific data for a given time period. Thus, tables in the 1996 ADR generally reported data through December 1993. Because of improvements in the flow of data to the USRDS, this 15-month rule is relaxed in this 1997 ADR. Data generally are reported through 1995, although the 1995 data should be treated as preliminary. Data from the HCFA Annual Facility Surveys are current through 1995. Some USRDS Special Studies data are reported through 1996.

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

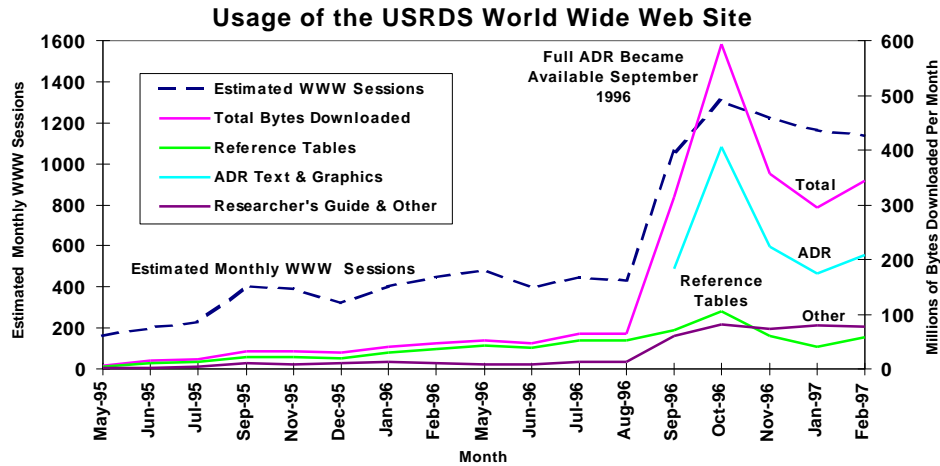
Table I-2 shows the various "products" of the USRDS through which the USRDS disseminates the results of ESRD research to the renal community and to the general public and provides data to support ESRD research. Except where a cost is mentioned in Table I-2, these products are free. Table I-1 lists specific contacts for further information 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. Table I-3 summarizes the material available at this site. The address of the site is:

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

The USRDS WWW site is accessed more than 1000 times each month, and more than 200 million



USRDS 1997

Figure I-3

Monthly usage of the USRDS World Wide Web site between 1995 and 1997. Data are not available for some months.

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. Figure I-3 shows monthly usage of the site.

The full 1996 USRDS Annual Data Report now available on the World Wide Web, will be replaced by this 1997 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.

The USRDS is developing an SMR methodology that adjusts for other meaningful comorbid conditions such as hypertension, a previous history of cardiac disease, and peripheral vascular disease.

Dialysis Unit-Specific SMR/SHR Reports

Early in 1996 and again in January 1997, the USRDS produced over 2,300 unit-specific reports containing information about the dialysis patients treated in each facility. These reports were distributed to dialysis facilities through the 18 ESRD Networks. In January 1997, each facility received an 8-page report containing information on:

- patient characteristics
- mortality rates
- hospitalization rates
- causes of hospitalization

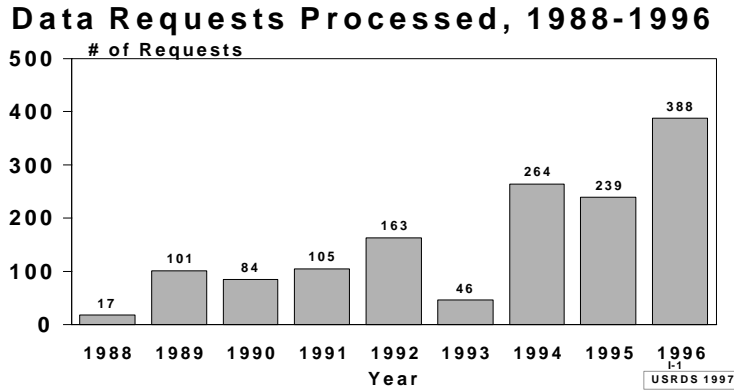


Figure I-4

Data requests processed by the USRDS, 1988-1996. These are data requests filled under the “2-hour rule” which limits data requests to those requiring up to 2 hours of staff or computer time to fill.

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

The highlight of these reports was a series of SMRs, SHRs, and STRs for each facility. The SMR, SHR, and STR were calculated for each facility for each year from 1993-95 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 1996 USRDS Unit-Specific Reports for Dialysis Patients: Overview, Methodology and Interpretation*). The methods used to 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.

This is the second time the USRDS has produced unit-specific reports. The USRDS plans to produce a similar report each year. Topics under consideration

for future reports include separate summaries for hemodialysis and peritoneal dialysis, and Medicare reimbursement data.

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-4 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 1996 on average one to two 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

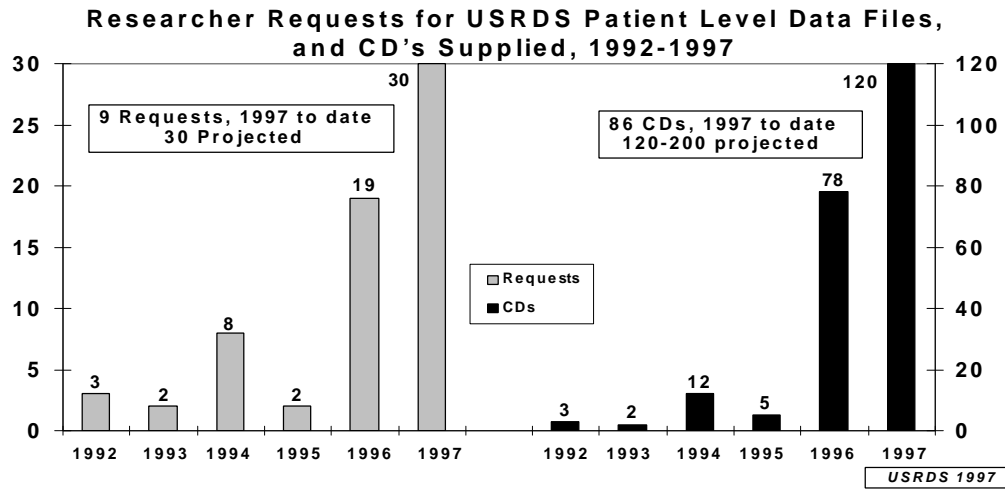


Figure I-5

Researcher requests filled for USRDS patient level data files, 1992- 1997. For 1997, pending requests and the range of projected total requests are shown. 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.

be met by the ADR or by 2-hour data requests probably can be met obtaining the Standard Analysis Files or custom data files described later in this chapter.

USRDS Analysis Files for Researchers

The USRDS has been sharing research data with other researchers for many years. Figure I-5 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 January 1997, including pending requests. The figure shows the number of CD-ROMs provided to researchers by calendar year. Note that over 600 high density floppy disks fit on one compact disk (CD). Thus, 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 continued in 1996 and is projected to be even greater in 1997. 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.

There has also been a marked growth in the amount of data provided. For requests which were filled on 9-track magnetic tape (1992 through early 1996), we have estimated the number of CDs which would have been required for the request. High and low projections are provided for 1997. The volume of data is affected heavily by the number of requests which include the Medicare claims data files.

Composition of Requests for Data Files, 1994 - Jan. 1997

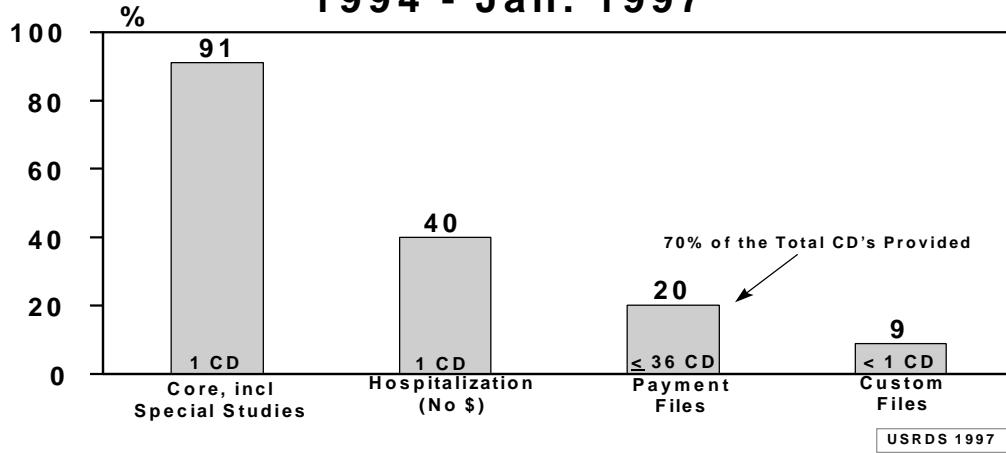


Figure I-6

Composition of the requests for data files. Counts of CD's by type of data file requested, 1994-January, 1997. Percentage of requests which included files of each type.

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. Most researchers requesting custom files have not also requested the SAFs. Figure I-6 Shows the type of data released during 1994 to January 1997.

All requests except custom requests include the Core SAF CD (91 percent). This CD includes basic patient data, each patient's treatment history, full transplant and transplant followup data, and all data from the USRDS special studies. Half of the researchers using the USRDS SAFs need only this CD. 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 70 percent of

the C Ds provided. A full set of Medicare payment files requires 36 CDs.

CD-ROM technology has been crucial to the growth in the use and the usability of the USRDS SAFs. Half of the researchers have needed only one CD in order to carry out their research. The full Medicare payment data would require 120 9-track magnetic tapes instead of 36 CDs. Providing this volume of data on tape would not be practical.

A wide variety of research topics have been addressed by researchers outside the USRDS using the USRDS SAFs. Table I-4 shows the research topics for the requests for data files which were filled from 1994 through 1996 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 1996 meetings of the American Society of Nephrology which cite USRDS data in the abstract. About half of these abstracts used data from the ADR Reference Tables rather than the SAFs.

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 1996, a total of 78 CDs of data were provided to 19 researchers.

Independently Supported Research for Which USRDS Standard Analysis and Custom Files Provided to Researchers Since 1992

Year	State	Topic
1992	OH	Pericarditis in hemo and peritoneal dialysis patients
	SC	Profit and not-for-profit dialysis facilities
1993	GA	Employment and rehabilitation of ESRD Patients
	MO	Pre-treatment characteristics and early treated blood pressures associated with development of end-stage renal disease in hypertensive men during 15 years of follow-up
1994	CA	Modeling outcomes in renal replacement therapy
	CT	Estimate treatment effects of different dialysis modalities while correcting for selection bias
	IL	Does the Current Point System Provide Maximum Benefit in the Allocation of Cadaveric Kidneys? NIH review 9/95
	MA	Comparison of Case Mix Models for Hemodialysis Patients
	MD	Race, Comorbidity and Survival of Dialysis patients
	MI	Incidence Trends in End-Stage Renal Disease
	VA	Hyperoxaluria
1995	FL	Estimating production and cost models for dialysis services
	MI	Comparison of All Cause and Cause-Specific Mortality Between PD and HD Treated ESRD Patients
	MI	Comparison of Causes of Death by Race and Gender
	MN	Ischemic Heart Disease and End Stage Renal Disease
1996	AL	The Relationship Between Dialysis Dosage and Serum Albumin, Phosphorus and Mortality of Patients Receiving Hemodialysis.
	CA	Cost and Nutritional Status in End-Stage Renal Disease.
	CA	Evaluate Time Trends in Incidence, Treatment and Outcomes of Patients with ESRD.
	CA	Reimbursement and Cost-Effectiveness Analyses of Dialysis and Kidney Transplant.
	IL	Transplantation
	MD	Estimates of intraclass correlation among dialysis units and the clinical applications.
	MD	Incidence and Prognosis of Septicemia
	MD	Match USRDS to dataset provided by American Dental Assn. to determine risk of ESRD associated with mercury exposure.
	MI	An Epidemiological Study on Hip Fractures in End Stage Renal Disease Using USRDS Data.
	MI	An Evaluation of ESRD Mortality by Race and Gender
	MI	Analyzing Hospitalization and Mortality in ESRD Patients.
	MI	Effect of Diminished Renal Alograft Function Soon After Transplant on Long Term Graft Survival.
	MN	Ischemic Heart Disease and End Stage Renal Disease
	MO	ESRD incidence among veterans screened for hypertension
	MO	Influence of donor and recipient CMV serologic status upon renal transplant outcomes.
	MO	Investigate the association of serologic markers and glomerulonephritides of various types.
	UT	Dose of Dialysis As Assessed by Middle Molecule Clearance.
	VA	Hyperoxaluria
	WA	Estimates of intraclass correlation among dialysis units and the clinical applications.
	WA	Ownership type and quality of care in the US end-stage renal dialysis program.
1997	GA	Estimating production and cost models for dialysis services
	MA	Case mix models for end-stage renal disease patients
	NC	Predictors of DRG day outliers among end stage renal disease patients
Pending	OH	Extent and implications of compliance with CDC recommendations for HbsAg testing of ESRD patients.
	NC	Determining risk factors for patient mortality following transplantation
	OK	Relationship of various factors with risk of hospitalization in ESRD patients
	OK	Effect of specific market characteristics on the costs and outcomes of subacute care episodes for ESRD patients

State is state of investigator's institution. Year is year in which data were provided.

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Table I-4

The SAFs are 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.

Abstracts Presented At 1996 American Society of Nephrology Meetings Citing USRDS Data

Author	Title of Abstract	Data Used
Bloembergen ¹	Why do Males with ESRD have Higher Mortality Rates than Females	SAF
Carroll ¹	Do Racial Differences in Comorbidity or Treatment Explain Higher Mortality Observed among Whites with ESRD?	SAF
Orzol ¹	Differences in the Cost of Hemodialysis by Dialyzer Membrane	SAF
Collins ²	Acute and Chronic Survival of Dialysis Patients with Acute Myocardial Infarction	SAF
Govaerts ²	Renal Transplantation of ESRD due to Sickle Cell Disease: The U.S. Experience	SAF
Leypoldt ²	Removal of Middle Molecules Enhances Survival in Hemodialysis (HD) Patients	SAF
Powe	Incidence and Risk Factors for Septicemia in U.S. Dialysis Patients	SAF
Appel	Hypertensive End Stage Renal Disease in Older White Patients	ADR
Brazy	Survival of ESRD Patients at an Active Transplant Center	ADR
Keightley	Total Yearly Patient Costs in an Academic Hemodialysis Program	ADR
Levy	Does Reduction in Cardiovascular Death Account for the Increase in ESRD? An Examination of the Mortality Hypotheses	ADR
Lorch	Disease Management in Chronic Dialysis	ADR
Lundin	Black Men Gain Body Mass Despite Purportedly Inadequate Hemodialysis and a Serum Creatinin > 14 mg/dl	ADR
Madore	Clinical Characteristics of Long-Term Survivors on Dialysis	ADR
Shapiro	Effect of Adequate Dialysis and Nutrition on Mortality and Morbidity in Hemodialysis Patients	ADR
von Albertini	Long-Term Survival Outcomes with High-Efficiency Dialysis: Effects of Time, Membrane, and Reuse	ADR

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; ² = was a secondary author

Abstracts which were produced under the USRDS contract are listed in Appendix A.

Table I-5

USRDS 1997

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 multiple SAFs to be merged when needed.

Core Standard Analysis File CD-ROM

The USRDS SAFs are now available on CD-ROM disks that can be used on virtually any PC that has a CD-ROM reader. One CD now contains the most frequently used SAFs, where previously four magnetic tapes were required. 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.

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.

USRDS Core Standard Analysis File CD

File Name	Unit of Observation	Uses
Patient	ESRD Patient 627,000 patients	Incidence, prevalence, patient survival. Most other files will need to be linked to this file using the encrypted ID.
Residence	For each patient, one record for each period in a different residence.	Regional analyses
Medical Evidence (HCFA 2728)	One record for each HCFA Form 2728 filed using the April 1995 version of the form.	Cause of ESRD, comorbid conditions, employment status, laboratory values, Medical Review Board review, dialysis start date. Cause of ESRD and dialysis start date from old and new versions of the 2728 also are included on the Patient file.
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.
Transplant	Transplant. Can have multiple transplants for one patient. 124,000 transplants	Transplant and transplant outcome analyses. Includes file of denominators for rates of transplantation per patient year on dialysis.
Transplant Followup	For each patient, one record for each followup (discharge, 6 months, annually).	Immunosuppressive therapy, rehabilitation, rejection episodes.
Dialysis Mortality and Morbidity (DMMS) (USRDS Special Study)	5,670 patients included in Wave 1. A national random sample.	Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values, nutrition, vascular access. See Chapter 4. Preliminary data from Wave 1 of this study are available. Wave 2 available early in 1998.
Case Mix Adequacy (USRDS Special Study)	7,096 patients included in the study. A national random sample.	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. A national random sample.	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. A national random sample.	Growth, development, and other issues relating to pediatric ESRD patients
CAPD Peritonitis (USRDS Special Study)	3,385 patients included in the study. A national random sample.	CAPD and peritonitis.

Table I-6

These files are provided on a single CD

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. A SAF was added to make available the full data from the new version of the HCFA 2728.

Transplant

The Transplant SAF contains one record for each transplant in the USRDS database. For patients with more than one transplant, there will be one record for each transplant for that patient. These transplants will appear together in the file and can be linked based on the encrypted patient ID number. The order of the transplant is indicated by the transplant dates.

Transplant Followup

Transplant followup reports are completed at discharge, 6 months after the transplant, on each anniversary of the transplant, and at graft failure. These records include immunosuppressive therapy, patient status, rejection episodes, and reason for graft failure.

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. The Dialysis Morbidity and Mortality Study (DMMS) is described in Chapter IV. The data collection forms used for several of the Special Studies are in Appendix B.

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 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)

This study is currently under way and is described in Appendices A and B. Preliminary data are now available from Wave 1 of the DMMS study, and are included on the USRDS Core SAF CD ROM (Table I-3). Wave 2 will be available late in 1997. There are three files from Wave 1:

- DMMSWAV1 patient data from the core, anemia, nutrition, and vascular access forms
- DMMSFACS facility data from the facility form
- DIALYZER dialyzer characteristics for dialyzers reference on the core patient form

As described in Appendix A 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. The plans for this study include 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.

These initial DMMS Wave 1 files should be regarded as interim. Complete data for Network 2 will be available in early 1997, while data for Network 10 will not be available until DMMS Wave 2.

Another caveat concerns information in the Dialyzer file. These data 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.

Hospitalization 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.

Medicare Payment Data

SAFs containing Medicare payment data are now available. For institutional claims, data are available for 1989 through 1995. For physician/supplier claims, data are available for 1991 through 1995.

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 file: 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.

Sizes of USRDS SAFs: Core, Hospital, and Medicare Claims

File Type	Years	Million	Billion	CDs	Cost
		Records	Bytes		
Core SAF CD	77-95	8	.4	1	\$536
Hospital CD	77-95	5	.4	1	\$119
Institutional Claims	89-95	37	3	5	\$595
Institutional Claim Details	89-95	78	6	10	\$1190
Physician/Supplier Claims	91-95	190	14	21	\$2499
Case Mix Adequacy Study CD	91-95			1	\$536

Table I-7

Sizes of the various USRDS Standard Analysis Files, shown in terms of millions of records, billions of bytes, and the number of CDs required to store the files. The Core SAF CD contains all the files shown in Table I-6. The Core SAF always is needed for use with the hospital or claims files. The Case Mix Adequacy Study CD is a stand-alone CD that contains extracts from all of the other SAFs. A similar CD will be produced for the DMMS study. Subsets of the claims files may be provided based on year or other simple categories.

The file includes dollar amounts, dates of service, diagnosis and procedure codes, and type and place of service.

Table I-7 shows the huge size of the Medicare payments files compared to the size of the Core SAF CD and the Hospital CD.

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. Note that data from Wave 2 of the DMMS will be available early in 1998.

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.

What You Need to Use the SAFs

Computer: A 486 or Pentium PC. The USRDS CC uses Pentium 133s and 166s and Pentium Pro 200s. 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.

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 full set of Medicare reimbursement data SAFs requires about 23 gigabytes (billions of bytes) of disk storage. Table I-7 and the *Researcher's Guide to the USRDS Database* provides more detailed specifications of file size. 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 basic CD-ROM is \$536. Each additional CD in a single order costs \$119. 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 is being 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. This 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 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 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, who will release 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 1 year after the data have been collected, edited, and entered into the database.

Reference

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.

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 be 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)