Chapter I

The USRDS and Its Products

This is the eighth *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 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:

- USRDS Standard Analysis Files are provided on CD-ROM.
- Medicare payment data from Medicare claims for 1989 to 1994 are now in the USRDS database.
- USRDS Standard Analysis Files containing Medicare payment data and additional detail on diagnosis and procedures are available.
- Early in 1996 the USRDS produced facility specific mortality and hospitalization reports, which have been distributed to over 2,000 dialysis units through the ESRD Networks.

Project Goals

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

- Design and implement a consolidated renal disease data system that will provide the biostatistical, data management and analytical expertise necessary to characterize the total renal patient population, and to describe the distribution of patients by sociodemographic variables across treatment modalities.
- Report on the incidence, prevalence, mortality rates and trends over time of renal disease by primary diagnosis, treatment modality and other sociodemographic variables.
- Develop and analyze aggregate data on the effect of various modalities of treatment by disease and patient group categories. These data will be used to analyze the prevention and progression of renal disease with special emphasis on morbidity and mortality.
- Identify problems and opportunities for more focused special studies of renal research issues currently not addressed by the consolidated data system.

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

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

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

United States Renal Data System (USRDS)

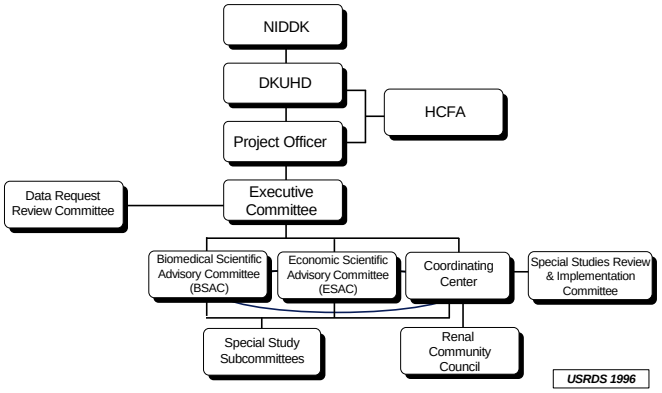

Figure I-1

USRDS organization chart.

most of the primary data in the system. The Health Care Financing Administration 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.

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

A HCFA Project Coordinator directs 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, the HCFA Project Officer directly supervises all such projects.

USRDS Committees

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

The **Scientific Advisory Committees** (**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 advisory input to the NIDDK and the CC, while the Economic SAC (E-SAC) has the role of providing economic advice to the NIDDK, HCFA, and the CC. Both of the Scientific Advisory Committees recommend priorities for research by the USRDS. In doing so, they review and make recommendations to NIDDK (for biomedical issues) and HCFA (for economic issues) on proposed special studies and on findings of studies conducted by the USRDS. Fulfilling these responsibilities requires individuals who have a broad understanding of the issues surrounding renal research.

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

The **Renal Community Council** (**RCC**) is comprised of more than 30 professional/scientific/advocacy groups with an interest in ESRD and the USRDS. The USRDS makes a presentation to the RCC at the annual meeting of the American Society of Nephrology. The

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-13D 45 Center Drive - MSC 6600 Bethesda, Maryland 20892-6600	Phone (301) 594-7717 Fax (301) 480-3510 *agodoal@ep.niddk.nih.gov*
NIDDK Deputy Project Officer	Camille Jones, M.D., MPH 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@ep.niddk.nih.gov*
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 *held@umich.edu*
CC Deputy Director	Friedrich K. Port, M.D., M.S.	Phone (313) 998-6611 *portb@umich.edu*
CC: Data File Contact	Randall L. Webb	Phone (313) 998-6608 *rlwebb@umich.edu*
Standardized Mortality / Hospitalization Rate Methodology	Robert A. Wolfe, Ph.D	Phone (313) 998-6611 *bobwolfe@umich.edu*
CC: Data Request Contact Publication orders	Dora Smith	Phone (313) 998-6610 *adorable@umich.edu*
Internet World Wide Web		*http://www.med.umich.edu/usrds/*

Table I-1

RCC also provides feedback and advice to the CC, which transmits this information to the NIDDK Project Officer.

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

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

The **Special Studies Review and Implementation Committee** (**SSRIC**) is chaired by HCFA and is comprised of staff from the NIH, HCFA and the CC, as well as one representative of the

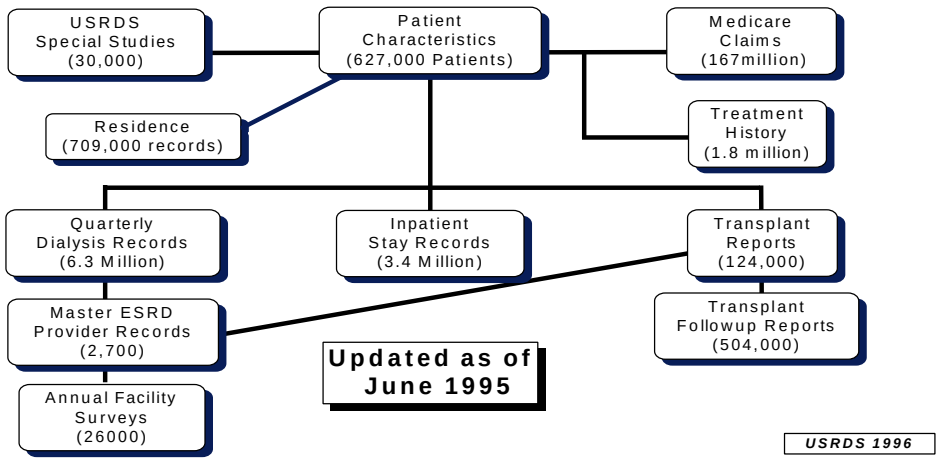

Figure I-2

Overall structure of the USRDS research database with counts of patient and facility records as of June 1995.

ESRD Networks. The SSRIC's focus is 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 of 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 used to form 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. These data will support research initiatives important to the prevention and treatment of ESRD.

Since July 1990, selected data on non-Medicare patients treated by United States Department of Veterans Affairs (DVA) facilities have also been incorporated into the USRDS database. Starting in July 1994, HCFA and the Health Resources and Services Administration (HRSA) have consolidated the collection of transplant data collections by HCFA and by the United Network for Organ Sharing (UNOS) into a single expanded data collection by 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 includes information for 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 United States Bureau of the Census, local and national ESRD provider databases and from international ESRD registries. In the long-term, there are plans to explore the feasibility of including or linking data from other existing provider databases.

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 microfich 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 *American Journal of Kidney Disease.*
Internet World Wide Web	The Reference Tables of this ADR and other USRDS publications are available electronically on the Internet using World Wide Web at http://www.med.umich.edu/usrds/
Diskettes of ADR Tables	These diskettes are provided for those who cannot easily download the tables from the Internet.
Data Requests	The USRDS CC staff respond to more than 100 requests for data and for general information about the USRDS each year. Limited resources are available for simple computer tabulations.
SMR/SHR Methodology	Chapters V, VIII, and XII 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.
Facility Specific SMR/SHR Reports	The USRDS has produced facility specific mortality and hospitalization reports, which have been distributed to over 2000 dialysis units through the ESRD Networks.
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 (313) 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

The USRDS database is updated every year, with the last update taking place in the Winter of 1995, using data collected through June of 1995. Because of delays in processing of data through the Medicare system, the USRDS generally has waited 15 months before reporting patient specific data for a given time period. This explains why most of the Reference Tables in this 1996 ADR generally report data through December 1993. Tables in which this "15 month rule" is relaxed are clearly noted and are generally labeled preliminary. Data from the HCFA Annual Facility Surveys are current through 1994. In addition, this ADR includes projections of incidence and prevalence through the current year.

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 provided on request without charge. Table I-1 provides a list of specific contacts for further information about various aspects of the USRDS.

USRDS on the Internet World Wide Web

The USRDS has a World Wide Web home page at http://www.med.umich.edu/usrds/ which provides a variety of information in addition to the Reference Tables from this 1996 ADR. The Reference Tables will be available from this WWW site by May, 1996, which will be before the ADR is printed.

The USRDS WWW site is accessed more than 400 times each month, and more than 40 megabytes of data are downloaded from the site each month. The site is accessed from all around the U.S. and from many other countries.

SMR/SHR 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. Chapter XII provides a description of this methodology.

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 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 working toward development of an SMR methodology that adjusts for other meaningful comorbid conditions such as hypertension, a previous history of cardiac disease, peripheral vascular disease, and other conditions.

Facility-Specific SMR/SHR Reports

Early this year the USRDS produced over 2,000 facility-specific reports containing information about the dialysis patients treated in each facility. These reports were distributed to dialysis facilities through the 18 ESRD Networks. Each facility received a 6-page report containing information on the following topics:

- patient characteristics
- mortality
- hospitalization
- data completeness and validation

The highlight of these reports was a series of Standardized Mortality Ratios (SMRs) and Standardized Hospitalization Ratios (SHRs) for each facility. An SMR and an SHR were calculated for each facility for each year from 1991-93 and also for the combined three-year period. Each report also allowed facilities to compare the SMR, SHR and other information for their facility with summaries among all facilities in the same state, ESRD Network and the U.S. The information in these reports could thus be interpreted in the context of local and national norms.

Each facility also received a 19-page document that provides further detail about the methodologies used to prepare the reports (*Guide to the 1995 USRDS Unit-Specific Reports for Dialysis Patients: Overview, Methodology and Interpretation*). The methods used to calculate an SMR or SHR and some

recent analyses involving facility-specific SMRs and SHRs are also presented in Chapters V and VIII of this ADR.

This is the first time the USRDS has produced facility-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, cause-specific hospitalization rates 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. From the inception of the USRDS in May 1988 through February 1995, CC staff have responded to over 500 formal requests for data, in addition to many more requests for general information on the USRDS and its publications.

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 which require two hours or less of computer programmer/analyst time can be provided by the Coordinating Center, usually within 1 week of the request depending on work load.

Requests that require more than two hours of computer programmer/analyst time will be undertaken only upon written approval by the NIDDK Project Officer.

Research needs which cannot be met by the ADR or by 2-hour data requests probably can be met using the Standard Analysis Files (SAFs), or Custom Data Files described later in this chapter. Requests for Medicare ESRD program data that are not within the scope of the USRDS project objectives are referred directly to HCFA.

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. As of April 1996, thirty six requests for SAFs have been filled and ten are pending. These requests included providing all 18 ESRD Networks with data from the Special Studies in which they participated and providing NIH and HCFA with a complete set of files each year.

The SAFs are governed by the USRDS Policy on Data Release for Investigator Initiated Research, which appears at 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 do 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 which can be used on virtually any PC which has a CD-ROM reader. One CD now contains the most frequently used SAFs, where previously four magnetic tapes were required. Table I-3 lists the SAFs contained on this Core Standard Analysis CD-ROM. The two central files are the Patient file and the Treatment History file. The contents of both files are discussed in greater detail in the *Researcher's Guide*.

Patients

The Patients 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

The files listed below are provided on a singe 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
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 Morality and Morbidity (DMMS) (USRDS Special Study)	5,670 patients included in Wave I.	Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values, nutrition, vascular access. See Chapter 4. Data from Wave I of this study will be available in October, 1996.
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.

Table I-3

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 immunosupressive 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. Special Study topics are approved by NIDDK, with recommendations from HCFA, the USRDS Scientific Advisory Committees (Biomedical and Economic-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 which 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 six 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 are 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 are 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 of which 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

Sizes of USRDS Core, Hospital, and Medicare Claims Standard Analysis Files

File Type	Years	Million Records	Billion Bytes	CDs
Core SAF CD	77-94	7.1	.60	1
Hospital CD	80-94	5.0	.60	1
Institutional Claims	89-94	24.0	2.25	4
Institutional Claim Details	89-94	78.2	3.13	5
Physician/Supplier Claims	91-94	143.0	9.87	16

Table I-4

Size 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 of the files shown in Table I-3.

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

This study is currently under way and is described in Chapter IV. Data from Wave I will be available in October, 1996.

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. There are three files on this CD. The Pre-1989 file contains data in the for years before 1989 and has no payment or cost variables. The Hospital Claims file and Hospital Claims Details file consist of inpatient hospitalization records from the larger Institutional Claims and Institutional Claims Details files described under Medicare Claims Data. These files cover years starting in 1989.

Medicare Claims Data

In May, 1996, the USRDS will make available SAFs containing Medicare payment data. For institutional claims, data will be available for 1989 through 1994. For physician/supplier claims, data will be available for 1991 through 1994.

There are two types of Medicare claims: institutional and physician/supplier. All of 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, and 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.

Table I-4 shows the huge size of the Medicare claims files compared to the size of the Core SAF CD and the Hospital CD.

Case Mix Adequacy CD

The USRDS CC plans to develop a CD which contains the Case Mix Adequacy special study file and extracts from all of the other SAFs for the patients in this study. All of the Medicare claims data for these patients would be included. This file is expected to be available in May 1996.

File Media and Formats

CD-ROM is the preferred medium for providing USRDS SAFs. The files are provided as SAS (Statistical Analysis System) system files or as ASCII files. The CDs can be used directly by SAS on any 486 or Pentium PC with a CD-ROM reader. Files also can be provided on 4-mm DAT tape or on 9-track 6250 bpi tape.

In order to keep the SAFs affordable, the files are provided only in SAS and ASCII 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

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 which runs on most types of 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 in Order to Use the SAFs

Computer: A 486 or Pentium PC. The USRDS CC uses Pentium 133s for most of its heavier processing, including runs which read 10 gigabytes or more of Medicare claims data. Smaller runs have been done on 486/33 and 486/100 PCs. The files can be converted to SAS transport format for use on any computer on which SAS runs. The ASCII versions of the files can also be moved to other types of computer.

CD-ROM drive: Any PC with a CD-ROM drive should be able to use the SAF CDs. If you want the files on 4mm DAT tape, then you will need an appropriate tape drive.

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 would require about 15 gigabytes (billions of bytes) of disk storage. The R*esearcher's Guide to the USRDS Database* provides more detailed specifications of file size.

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

People with software experience: The SAF documentation provides some of the basics of loading the files into SAS and using them, but you will 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. If files are provided on 4-mm DAT tape or 9-track tape, then the first unit of media is $536 and each additional unit is $119. Checks should be payable to the University of Michigan. These prices are subject to change.

Documentation

The *Researcher's Guide to the USRDS Database* is included with the documentation of each SAF. If multiple SAFs are ordered, then a technical memo about linking the SAF files is included. The remaining documentation generally includes the following elements:

- Codebook of variables on the files.
- Data collection forms used by the study.
- Sample SAS code for loading the data from the transport file.
- Tabulation of the distribution of values for categorical variables and univariate statistics for continuous variables.
- Discussions of issues of study objectives, sampling methodology, editing performed on the raw data, and derived analytical variables which may be included in the file.

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 his/her data request before preparing a written proposal. (See Table I-1 for 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 other 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 in the Researcher's Guide to the USRDS Database.

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 three 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 is contained in the *Researcher's Guide.* 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.

5. When both a copy of the fully executed 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 the files and documentation to the PO, who will release the materials 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 opinions and conclusions of the investigators 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 or interpretation of the United States 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 which identify individual patients, providers, or facilities. If individually identifiable data are needed, the request should be submitted directly to the Health Care Financing Administration for processing. 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 is also 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.

UNITED STATE 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 benefits;
- 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 which 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 Office (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 it will furnish 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 any 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 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)