# Executive Summary

Since its creation in May 1988 the United States Renal Data System (USRDS) has pursued the collection and analysis of information on the incidence, prevalence, treatment, morbidity, and mortality of end-stage renal disease (ESRD) in the United States. The USRDS is operated by the Coordinating Center (CC) at The University of Michigan, and is funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health. The Health Care Financing Administration (HCFA), of the U.S. Department of Health and Human Services, participates with NIDDK on the project and supplies expertise and most of the original data. Much of the HCFA data and Special Study data are collected by the ESRD Networks.

The present USRDS *1997 Annual Data Report* is the ninth volume based on these ESRD data. The annual data reports represent one major vehicle for disseminating information from the USRDS.

The report addresses each of the six goals that are defined for the USRDS. The first three goals are addressed throughout the report: 1) to characterize the total ESRD patient population and describe the distribution of patients by sociodemographic variables across treatment modalities; 2) to report on the incidence, prevalence, mortality rates, and trends over time of ESRD by primary diagnosis, treatment modality, and other sociodemographic variables; and 3) to develop and analyze data on the effect of various modalities of treatment by disease and patient group categories.

The fourth goal is to identify problems and opportunities for more focused special studies of renal research issues. This goal has been addressed with eight special studies requiring new data collection. A description of these eight special studies is provided in Chapter I, "The USRDS and Its Products." Data collection for the eighth special study, the Dialysis Morbidity and Mortality Study, is ongoing having begun in March of 1995. Early results from Wave 2 of this study are presented in Chapter IV.

Two additional goals were added to the USRDS's mission and have been reflected in the data reports since *1994*. Goal five is to conduct cost effectiveness studies and other economic studies of ESRD. Chapter X presents an analysis of the total resource spending for ESRD care in the United States. Other economic analyses presented in Chapter X include an analysis of Medicare spending for vascular access and for alternative modalities of treating ESRD (hemodialysis, CAPD and CCPD, and kidney transplantation).

Goal six puts new emphasis on supporting investigator-initiated projects to conduct biomedical and economic analyses of ESRD patients. Chapter I of this report describes the recently developed USRDS Standard Analysis Files (SAFs) and their availability on CD-ROM. Since 1992, we have supplied our SAFs and custom data files to researchers outside the USRDS, for a total of 33 requests. Six requests came in January 1997 alone. An additional 72 files have been provided to the 18 ESRD Networks. Chapter I summarizes research done by investigators outside the USRDS using USRDS data.

These analysis files are also described in a separate publication, the *Researcher's Guide to the USRDS Database*, which is available through the USRDS Coordinating Center. Essential parts of the Researcher's Guide are available from the World Wide Web as are the full ADR, including the reference tables and color slides of all graphics. The USRDS World Wide Web site **(http://www.med.umich.edu/usrds/)** is accessed more than 1,000 times each month, and more than 600 megabytes of data are downloaded from the site each month.

We will also be providing the complete version of the USRDS *1997 Annual Data Report* (including all reference tables) at the USRDS WWW site and on CD-ROM. Please contact the USRDS CC for further information if you would like to request a copy of the 1997 ADR on CD-ROM.

## Changes from Previous Reports and Continuing Notes of Importance

The USRDS has issued eight previous reports, the most recent of which was published in 1996. The current report is based on an update of biomedical information from HCFA dated September 1996, which is 13 months later than the update file used for our previous (1996) report. The USRDS added nearly 60,000 new patients since the last update. In addition to the biomedical information, the Medicare billing data incorporated into the USRDS for 1991-95, which underlie much of the current analyses of cost in Chapter X, consists of over 180 million paid Medicare claims. All of these 1991-95 records are currently on-line, occupying over 20 billion bytes of computer disk storage. Data records for more than 30,000 patients from the eight Special Studies are currently in the database as well.

The ESRD data in this report are current through 1995 for all patient-specific, biomedical, and Medicare payment data; through 1995 for ESRD providers; and through 1996 for the most recent Special Study (DMMS, Chapter IV). Patient-based data are an accumulation of many records for each patient from numerous sources. There is a variable lag time before the patient data are considered complete, and the USRDS generally does not emphasize patient data that occur less than 15 months from the last update. ESRD provider data and much of the payment record data are generally completed within 6 months of the end of the calendar year.

Our objective in preparing this report has been to present data for a span of 10 or more years for biomedical information (5 years for cost information) using consistent definitions, so that valid comparisons can be made across years and among subgroups in the database. Because of year-to-year changes in the data and in the methodologies used, comparisons of data between ADRs should be avoided. We attempt to alert the reader to those cases where changes in the data collection process over the years result in problems in making valid comparisons across years. These warnings appear in the text, in reference table introductions and footnotes, and in Chapter XIII, "Analytical Methods."

The primary methodological and data changes in this report include the following:

**Data System Changes.** HCFA has implemented a new data system that will substantially improve our ability to update and track information on a more timely basis. However, 1993, 1994, and 1995 may represent a transition period and some data may have idiosyncratic characteristics, some known at this point and some not. One specific problem we address below is the rate of growth in the count of incident patients for 1994-95. Some of the other issues suspected but not confirmed relate to the overall count of ESRD patients as revealed in the Medicare paid claims data and measured hospitalization. Future experience may identify other issues. Non-Medicare patients are included, starting in 1994, although there are no paid claims information for these patients.

**Prevalent Dialysis Patient Mortality.** One of the most important results in this chapter is that mortality rates are continuing to decrease based on adjusted mortality rates for incident patients. There was no decrease in mortality among prevalent patients in 1995 compared to 1994 however.

**Growth in Incident Patients.** The Annual Facility Survey (AFS), which includes both Medicare and non-Medicare patients, suggests approximately 2.4 percent growth in incidence counts from 1994 to 1995 down from more than 6.0 percent over the previous 2 incident years. Growth indicated by the USRDS database also indicates a slow-down in the last 3 years compared to the 10.2 percent average annual rate from both sources over 1986 through 1992. These data suggest that the United States is possibly seeing some reduction in the growth in the number of new ESRD patients starting in 1993.

**Results from the Dialysis Morbidity and Mortality Study (DMMS), Wave 2.** Wave 2 of the USRDS DMMS began data collection in August 1996. Wave 2 is unique in that it is a true prospective study. It includes both hemodialysis and peritoneal dialysis patients and is a random sample of both Medicare and non-Medicare incident patients initiating dialysis in 1996 and 1997. In addition to collecting "Core" data, additional information was gathered on peritoneal dialysis prescription and delivery, residual renal function, medications, quality of life, pre-ESRD care, modality choice, transportation, and rehabilitation.

**Race Code.** Patient race is determined based on data from the Medicare database, the Medical Evidence Form, and transplant records. Each of these sources uses a different coding scheme. The USRDS combines these sources to determine a race code for each patient. Changes in the coding schemes has

resulted in an increase in the number of patients classified as "Other" race.

**Standard Population for Adjustment.** The adjusted incidence, prevalence, survival, graft survival, and death rates in this ADR now all use the most recent year as the standard population for adjustment. For this 1997 ADR, the 1994 Census Bureau population data were used for adjusting incidence and prevalence rates, the 1994 ESRD population was used for adjusting survival rates, and the 1993 and 1994 transplant population was used for adjusting graft survival rates.

**Primary Disease Codes.** In 1995, HCFA implemented a new coding scheme for the Medical Evidence (2728) form. All diseases reported prior to that time have been assigned according to the best-fitting code from 1995 on. As a result of grouping diseases in eight primary categories for this report, there is some inconsistency in the way some diseases are grouped before and after the re-codes.

## Summary Statistics

Selected statistics for the ESRD program for 1993 are shown in Table ES-1 at the end of this chapter. These data provide a succinct reference for frequently asked questions.

## Chapter I. The USRDS and Its Products

Regular readers of these Annual Data Reports will find this chapter a very familiar description of the USRDS and its products. It does discuss the following new features:

- The USRDS World Wide Web site.
- The USRDS has produced a second round of facility-specific mortality and hospitalization reports, which have been distributed to dialysis units through the ESRD Networks.

This chapter describes the various products available to the researcher who wants to work with USRDS data and the recent utilization of USRDS data and methodologies by independent researchers. The Standard Analysis Files (SAFs) developed by the USRDS make the database available to researchers in an easy to use and well documented format. This approach reduces production costs and the cost to researchers. These analysis files have patient-specific information, but patient and facility identifiers are encrypted. 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 file would require 120 9-track magnetic tapes instead of 36 CDs. Sharing of USRDS data has allowed more investigators to pursue independent research and assist the renal community through responses to specific questions.

The USRDS has developed several methodologies such as the Standardized Mortality Ratios (SMR), Standardized Hospitalization Ratios (SHR), and Standardized Transplantation Ratios (STR). Each of these methods allow comparison to national data, while adjusting for differences in age, sex, race, and cause of ESRD distribution in the study population. This method has been employed for research, quality improvement, and other purposes on a dialysis facility level, at a state or ESRD Network level and in dialysis chains.

Shorter requests for data were filled in increasing numbers. During 1996, on average 1 to 2 requests were filled per working day. There has been a seasonal increase in requests around the American Society of Nephrology meeting.

The *Researcher's Guide to the USRDS Database* and the entire USRDS Annual Data Report, including 400 pages of reference tables and color slides of all ADR graphics are available electronically on the Internet at:

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

The USRDS WWW site is accessed from around the world more than 1,000 times each month, and more than 600 megabytes of data are downloaded from the site each month. Thus, the USRDS is providing more information to more researchers than ever before.

## Chapter II. Incidence and Prevalence of ESRD

This chapter contains basic information about the number of individuals with treated ESRD. A total of 257,266 U.S. patients were reported as being treated for ESRD as of 12/31/95. During 1995, a total of 68,870 patients were reported as being newly treated for ESRD in the United States. The chapter begins with a description of the ESRD registration process and the epidemiologic tools and concepts used to construct the incidence and prevalence data.

Incidence, prevalence, and growth for the entire population and for selected subgroups are also addressed.

The ESRD Medical Evidence Form (2728) was changed in 1995 to include a more modern and less circumspect list of choices for the cause of ESRD, baseline laboratory values, and comorbid conditions at the time of ESRD initiation. Providers now enter a primary cause of ESRD from a relatively complete and contemporary coded list of 72 diagnoses and is organized into 10 primary disease categories.

Several comparisons are made between incident and prevalent patients. ESRD incidence and prevalence increase dramatically with age, is more common in males than females, and are highest for Blacks followed by Native Americans, Asian/Pacific Islanders, and Whites. Diabetes, hypertension, and primary glomerulonephritis are the three most common attributed causes of ESRD. The relative difference between the diagnosis-specific prevalence and incidence rates indicates variations in average survival with smaller differences suggesting higher mortality rates.

The number of patients undergoing ESRD therapy (prevalence count) continues to increase, but the rate of increase is down to 7 percent from 9-10 percent in most of the pre 1993 era. Similarly, the number of patients starting ESRD therapy appear to increase at a slower pace than in earlier years. There is some uncertainty in these estimates in part because the reporting of non-Medicare patients has changed.

## Chapter III. Treatment Modalities for ESRD Patients

The growth of the number of patients has been similar for each treatment modality so that the percent distribution of modalities has remained virtually constant. The number of patients on the transplant waiting list continues to show a steep growth, while the number of cadaveric renal transplants performed per year has increased to a lesser degree. This has led to a widening gap between supply and need. There has been an increase in CCPD with a corresponding decrease in CAPD. This change likely reflects an effort to increase the dose of peritoneal dialysis. The delivered hemodialysis dose has been increasing over time. There is a trend toward increased use of synthetic membranes and decreased use of cellulose membranes over time. Treatment of anemia with human recombinant erythropoietin has continued to show an increase in dose and also in resultant hematocrit.

## Chapter IV. The USRDS Dialysis Morbidity and Mortality Study (Wave 2)

The Dialysis Morbidity and Mortality Study (DMMS) is a USRDS special study that plans to collect data on 22,000-25,000 dialysis patients over 3 years, in 4 "waves" of data collection (4,500 to 6,000 patients each). A "core" data collection instrument is being used for all patients to address important research questions about adequacy of dialysis, membranes, dialyzer reuse, etc. In addition, Waves 1 and 2 both include "non-core" components designed to address additional research questions. Wave 2 is also unique in that it is a true prospective study, including new patients initiating either peritoneal or hemodialysis in 1996. Additional data are also being collected for this Wave on peritoneal dialysis prescription and delivery, residual renal function and medications. In addition, a patient questionnaire is being administered that includes questions about quality of life, pre-ESRD care, modality choice decisions, transportation and rehabilitation. Initial descriptive data from Wave 1 were in the 1996 Annual Data Report. Data collection for Wave 2 of the DMMS is currently in progress. This chapter includes highlights of preliminary descriptive results of initial patient data from Wave 2, collected by March 1, 1997 (N=3,468). Some of the main observations include the following:

Among patients treated with HD, 39 percent reported that they were first seen by a nephrologist 3 or fewer months prior to starting dialysis, with 25 percent reporting they were seen less than 1 month before. These percentages were slightly lower among PD patients. Fifty percent of HD patients and 43 percent of PD patients did not see a dietitian prior to the initiation of dialysis.

Among patients treated with peritoneal dialysis, 68 percent reported that in-center HD was discussed as a treatment option. However, of patients receiving HD only 25 percent reported that CAPD was discussed. Automated PD was reportedly presented as an option in 60 percent of patients on PD. The medical team played a larger role in modality selection among patients treated with HD.

Among the sample of new patients initiating HD in 1996, only about 68 percent had a permanent vascular access at 60 days after HD initiation. An

additional 19 percent used a permanent cuffed catheter. Almost 50 percent of patients reported that they were not advised to avoid blood draws or IV lines to protect veins in one arm for a permanent access pre-ESRD. Although there has been a reduction in the use of the subclavian site for temporary access from the 1993 incident sample presented in the last ADR, the 1996 sample still shows a frequent use of this site (66 percent).

Patient-reported compliance is described for both HD and PD patients. Over 10 percent of HD patients reported that they skipped and 16 percent shortened at least one session in a 1 month period. Approximately 12 percent of patients on CAPD reported that they miss one exchange per week. Approximately 10 percent of patients on automated PD reported that they skipped and 17 percent that they shortened a treatment in a 2-week period.

A description of employment status among patients aged 18-60 years is also presented in this chapter. Of the patients sampled, 26 percent reported that they worked (full or part-time) or were looking for work, and about 10 percent of patients were keeping house.

As these preliminary DMMS Wave 2 data are based on a national random sample of U.S. hemodialysis patients, the results presented in this chapter are likely to be a description of the characteristics and actual treatment practices of dialysis patients in the United States. More detailed analyses are planned to determine the relationships of these factors to patient outcomes when data collection is completed.

## Chapter V. Patient Mortality and Survival

There are six major sections in this chapter, which focuses on patient survival among treated ESRD patients. Transplanted patients are included in some of the results, but the primary focus is on dialyzed patients.

An incident cohort consists of patients who started ESRD therapy in a particular year. For the incident patient results, patients are categorized by the calendar year of first treatment for ESRD in all analyses. In selected analyses they are also categorized by the number of years of treatment. Observed differences in mortality among incident cohorts could be due to several factors, such as changes in enrollment criteria for ESRD treatment or in treatment patterns for those cohorts.

A prevalent cohort includes all patients being treated in a particular year, both new and continuing patients, without distinguishing among the patients by the number of years of prior treatment. The calculation of results for prevalent patients is based upon categorizing the years of followup for each patient by calendar year. Differences in mortality among prevalent years would primarily reflect factors, such as innovations in treatment, that tend to affect all patients being treated in that year.

Patients from Puerto Rico and the U.S. Territories are included in results that are derived from the HCFA Annual Facility Survey, but are not included in results derived from the USRDS database. Until 1994, the USRDS data were largely limited to Medicare insured patients, while after 1994, both incident Medicare and non-Medicare patients are included in the database. This change might cause results based on pre-1994 data to differ from results based on post-1994 data.

The six sections are:

1. Trends in adjusted first-year death rates among *incident patients* for the years 1984-1994. These trends, in mortality during the first year of ESRD therapy, are shown for several patient subgroups. Adjusted mortality rates during the first year of ESRD therapy have decreased for nearly all successive cohorts of incident patients between 1984 and 1994.

2. *Long-term survival.* The 5-year survival rates are 88.2 percent and 46.1 percent among 15-19-year-olds and 50-54-year-olds, respectively, in the 1990 incident cohort of ESRD patients, and the 10-year survival rates are 74.7 and 21.6 percent for the same two age groups, respectively, for the 1985 ESRD incident cohort. One-, 2-, and 5-year survival rates are also compared for the various incident cohorts of dialysis patients. Long term survival (through 5 years) is better for the 1990 cohort than for the 1985 cohort, although most of the gains are seen in the early years of therapy.

3. Standardized mortality rates for *prevalent patients* over the years 1984-1996. Mortality among prevalent patients decreased between 1988 and 1994, and has remained nearly constant since 1994.

4. Projected *remaining years of life* for ESRD patients, by patient age (regardless of duration of ESRD). The expected remaining years of life or life expectancies for the entire U.S. population are between 2.1 and 5.5 times those for corresponding ESRD patient groups, while the ratio is between 2.7 and 6.3 compared to dialysis patients.

5. *Facility-specific* standardized mortality ratios for 1993-1995. The average patient age and percent of patients who are diabetic varies substantially among facilities, so the standardized mortality ratio is a more useful tool for facilities for evaluating mortality than the crude mortality rate. Standardized mortality ratios vary by ± 15 percent (standard deviation) among facilities, representing 1 in 6 extra or fewer deaths than would be expected based on the age, race, sex, and diabetes mix (but not the severity of concomitant disease) of the patients at a facility.

6. Methods for calculating *national death rates*. There were several major changes in the analysis methods used for this year: deaths not plausibly related to dialysis were excluded and a regression model was used to stabilize the year-to-year variation in the rates.

## Chapter VI. Causes of Death

In this chapter, the USRDS reports on more than 100,000 ESRD patients who died in the United States between 1993 and 1995. This chapter focuses on the specific causes of their high mortality and may serve as a source to help lower the death rates of ESRD patients through further in-depth epidemiological and clinical research. The death rates for specific causes of death for various subgroups of prevalent dialysis and transplant patients are described.

Cardiac causes (cardiac arrest, acute myocardial infarction, and other cardiac) account for almost half of the reported causes of adult ESRD patient deaths. Infection, cerebrovascular disease, and malignancy account for 15.5 percent, 6.1 percent, and 4.1 percent of adult ESRD deaths, respectively. As in our previous report (1996 ADR), this report again presents cause-specific death rates for dialysis patients adjusted for several demographic characteristics, allowing comparisons between patient subgroups by modality (PD and HD), race, gender, age and diabetes status. Death rates due to many causes were higher among PD than HD treated patients, among males than females, and among Whites than Blacks.

In particular, this chapter emphasizes outcomes of diabetic versus non-diabetic patients. Among dialysis patients, diabetics have substantially higher adjusted death rates due to acute myocardial infarction, cardiac arrest, other cardiac causes, septicemia, cerebrovascular disease and hyperkalemia than nondiabetics. However, the death rate due to malignancy is almost 2-fold higher for nondiabetics than diabetics.

Similarly, adjusted cause-specific death rates for transplant patients are presented. As expected, nondiabetics have lower death rates than diabetics across all causes for functioning transplant patients, failed transplant patients, and never transplanted patients with the exception of patients who have AIDS. Death rates due to AIDS were much lower among diabetics than nondiabetics, probably due to competing risks. Of interest is that all-cause death rates for diabetic dialysis patients with a failed transplant are 13 percent higher than those for diabetic dialysis patients who had never been transplanted. This is in direct contrast to the non-diabetic population where all-cause death rates were 35 percent lower among failed transplant patients than never transplanted patients.

Overall, 19 percent of dialysis patients withdrew from dialysis prior to death. Death rates following withdrawal from dialysis increased with age and was about three times higher in diabetics aged 20 to 44 than nondiabetics in the same age group. While diabetes is associated with a higher rate of withdrawal in all age categories, its effects diminish with age. The majority of withdrawals are reported to be due to chronic failure to thrive and acute medical complications. The reasons for withdrawing from renal replacement therapy are similar for diabetics and nondiabetics.

## Chapter VII. Renal Transplantation: Access and Outcomes

This chapter provides an overview of the trends in access and outcomes of kidney transplantation in the United States. For the first time, the Annual Data Report includes both Medicare and non-Medicare kidney transplants starting in 1994.

The epidemiology and clinical outcomes of 101,429 transplants performed between 1985 and 1995 are presented. Most of the growth in kidney transplantation during 1994-95 was due to a sharp increase in the number of living donor transplants (Figure VII-9). Living unrelated transplantation (LUR) increased by 33 percent between 1993 and 1994 and by 61.8 percent between 1994 and 1995. Although LUR showed the steepest growth, living related donor transplantation (LRD) also increased substantially (by 5 percent) between 1993 and 1995, a growth rate twice that of cadaveric donor transplants (CAD) in the same period. Repeat transplantation comprised 10.8 percent of the 11,876 kidney transplant procedures in 1995. The repeat transplant candidates accounted for 12.2 percent and 8.2 percent of CAD and LRD procedures, respectively. These trends suggest that LUR and repeat transplantation will continue to occupy increasingly larger roles in kidney transplantation in the future. Throughout the period studied, recipients of CAD transplants had uniformly lower 1-year survival rates than did recipients of LRD transplants. For LRD recipients, survival increased from 91 percent in 1985-86 to 96 percent in 1993-94, a 5.5 percent gain. There was a 15 percent increase in CAD graft survival over this period (from 75 percent in 1985 to 86 percent in 1994) and LRD graft survival also showed a marked but relatively smaller improvement from 87 percent in 1985 to 92 percent in 1994, a 6 percent increase. In 1995, Whites and Blacks had the highest transplanted organ donation rate, 37.2 (per million population) and 29.6 pmp, respectively. Asians and Native Americans had significantly lower donation rates, 12.6 pmp and 21.9 pmp, respectively. The reason for the relatively lower rates of CAD kidney donation in non-White groups are multifarious. There exist an enduring partial dependence of access to kidney transplantation on income, race, and other sociodemographic characteristics.

## Chapter VIII. Pediatric End-Stage Renal Disease

The incidence of treated ESRD is many times higher among adults than among children. A higher ESRD incidence with older age is also found across 5-year age groups within the pediatric cohort when adjusting for differences in sex and race. Average incidence rates for the combined years 1993-95 were more than twice as high among children 15-19 years (26 per million) as they were for children 10-14 years (13 per million), and almost four times higher than rates for children 0-4 (7 per million) and 5-9 (7 per million).

Children with ESRD continue to have high transplantation rates. Forty-two percent of children starting ESRD therapy during the 1991-95 period received a transplant during the first year, compared to 10 percent of patients 20-64 years of age at ESRD incidence. Children received dialysis less frequently than adults, with only 29 percent of children 0-9 years old and 44 percent of children 10-19 years having received some form of dialysis. In contrast, 56 percent of adults in the 20-44 age group were receiving some form of dialysis. The differences in patterns of treatment between younger and older children can be summarized by noting that younger children are more likely to be treated with a transplant and older children are more likely to be treated with hemodialysis.

Pediatric transplant patients had lower death rates than pediatric dialysis patients overall, with the largest benefit of transplant observed in the youngest patients (0-4 years). Pediatric patients with a living related graft had slightly lower death rates than patients with a cadaveric graft. Since there was no adjustment for race, sex, primary diagnosis, or case severity in these estimates, it would be inappropriate to assign any causal relationship to a particular modality of care.

Death rates were lower in pediatric patients than in adult patients. Deaths per 100 patient years at risk were analyzed by cause of death for all prevalent ESRD patients aged 0-19 years who were alive at the start of 1993, 1994, or 1995, and followed until death or until the end of the year. The overall death rate was 1.9 per 100 patient years for patients 0-19 years, substantially lower than the rates for patients 20-44 (5.2 per 100 patient years), patients 45-64 (14.0 per 100 patient years) and patients over 65 (33.4 per 100 patient years).

## Chapter IX. Hospitalization

Hospitalization rates reflect a number of important aspects of ESRD therapy. Various factors often make it difficult to accurately measure and interpret data on hospitalization. The use of the HCFA Standard Analysis Files, introduced first in the 1996 ADR, has improved the ability of the USRDS to analyze such data, and the screening process used by the USRDS (the "60-Day Rule") has allowed us to include prevalent, incident and previously transplanted patients currently receiving dialysis therapy in the analyses. It should be noted that this

year we have included 2 additional years of hospitalization data relative to the 1996 ADR, which covered data obtained through 1993; most analyses in this year's ADR are based on data obtained through the end of 1995.

This chapter evaluates trends in admissions and hospital length-of-stay in a variety of ways. It also utilizes the Standardized Hospitalization Ratio (SHR), an improved comparison measure introduced in the 1996 ADR, which employs "first hospital admission" rates in a given time period as a way to compare the hospitalization of patients at the dialysis facility level with national trends. Similar to the SMR, the latter has been further improved for this years report by using a new model-based methodology to obtain the national first admission rates. This new approach helps to reduce the variability in the actual yearly observed rates in patient subgroups that contain very small numbers of patients; that is, it helps to pick out a "signal" (i.e., the trend in rates) through the "noise" (i.e., year-to-year variability). The model for national rates is constructed in such a way that the model-based rates for relatively large patient subgroups are nearly indistinguishable from their actual observed first admission rates.

Distributions of hospital admissions and days are positively skewed with more patients having zero admissions and days in the hospital than any other number. There is some evidence of a decrease between 1993 and 1995 in mean admissions and days, while median values stayed approximately the same. There is regional variation in hospitalization that also reflects national trends in that hospitalization is generally higher east of the Mississippi than west of it. Similar to last year, the Northeast has one of the lower SMRs while having the highest SHR; the Pacific, Mountain, and West North Central regions all have SMRs and SHRs that reflect mortality and hospitalization experience below national levels. Freestanding non-profit dialysis units have both a lower SMR and SHR than for-profit and hospital dialysis units. Also interesting is the high inter-year correlation between SHRs at the facility level; this trend is evaluated using data collected during 1991-1995. The SMR is not nearly as stable in this respect. Hence, a unit with both a low SMR and low SHR is reasonably likely to have a low SHR the next year, but somewhat less likely to also have a low SMR. Finally, it was found that there has been a significant decrease in ESRD hospitalization over 1991-1995. For example, for the same population mix, observed first admissions in 1991 are approximately 17 percent above the corresponding number for 1995.

## Chapter X. The Economic Cost of ESRD, Vascular Access, and Medicare Spending by Modality

Three separate analyses are reported in this chapter. Two focus on the spending for ESRD. The first addresses total 1995 spending (public and private sources) for ESRD in 1995 the United States. A second analysis provides considerable detail on Medicare spending for the 1991-95 period by patient characteristics and is fundamentally focused on patterns of spending as they might affect the design of an ESRD capitation plan.

The third analysis estimates the cost of vascular access for hemodialysis patients in 1994. Using a narrow definition of vascular access procedure codes, the total Medicare spending was $743 million, with an average cost per patient year at risk of $6,228. Using a broader definition of vascular access procedures, which probably includes some non-vascular access procedures, the cost was $939 million. On a patient year at risk basis, this high estimate would be $7,871.

In 1995, the total spending for ESRD treatment in the United States was an estimated $13.1 billion**.** This includes Medicare payments of $9.7 billion, $2.2 billion for Medicare patients' obligations (usually paid by public and private insurance) and another $0.98 billion for non-Medicare patients (generally paid by private and public sources, e.g., Medicaid which is in part federally funded).

A comparison of the components of the growth in total Medicare program spending continues to show that the growth in patient counts remains the primary driver of increased total spending. For the 1991-95 period, the rate of increase in spending per patient year was 1.1 percent. Depending on which Consumer Price Index (CPI) one uses, the rate of increase in real spending per patient year was either 0 or minus 2 percent. Thus, spending per patient year, in real (i.e. inflation adjusted terms, has either remained constant or has decreased in recent years.

An intent to treat analysis for the 1991-95 period carefully selected patients insured by Medicare to avoid bias due to inclusion of patients with Medicare as Secondary Payer and simultaneously counted the appropriate time at risk as well as spending. In this

analysis the Medicare payment per year at risk was estimated. For all Medicare services, including inpatient, outpatient, physicians and other suppliers, the average Medicare payment (1991-95) was $37,900 per year at risk. (Since not all patients are at risk for a full calendar year the cost per calendar year would be less by approximately 10 percent.) For all dialysis patients total Medicare payments (1991-95) were $45,400 per year at risk, while for transplant patients it was $16,400 per year. (This transplant estimated payment includes the transplant procedure but does not include organ acquisition costs). Patient obligations would increase these statistics by 18 percent to a total of $53,600 for dialysis and $19,400 for transplant, respectively. CAPD Medicare payments were lower per year at risk ($35,300) than were hemodialysis payments per year at risk ($40,000). In 1995 Medicare spending per patient year at risk was: $40K for all ESRD; $50K for hemodialysis; $45K for peritoneal dialysis and $17K for transplanted patients.

A new set of reference tables (Section K) provides considerable detail on Medicare spending, including a major section on the distribution of spending by patient characteristic and type of provider. This latter set of statistics is designed to provide an indication of the financial risk facing a potential capitation plan. For example, the 99$^{th}$ percentile of Medicare spending per calendar year includes a cell with $147,000 per patient.

Note, the estimates of spending level per year for 1991 in this 1997 report produced anomalous results in comparison with the estimates for 1991 in the 1996 report. Some caution is warranted in the interpretation of these and all analyses.

## Chapter XI. Annual Facility Survey of Providers of ESRD Therapy

The facility survey information remains fairly smooth. One additional year has been added in this report. Note that dialyzer reuse increased from 72.2 percent to 80.8 percent and glutaraldehyde use increased from 3.7 percent to 8.8 percent between Waves 1 (1993-94) and 2 (1996), respectively.

## Chapter XII. International Comparisons of ESRD Therapy

Incidence rates of treated ESRD continue to rise in all regions of the world according to registries of Europe, North America, Australia and Japan.

Prevalence rates are highest in Japan, exceeding 1,200 per million population in 1995, followed by the United States with nearly 1,000 per million population. Thus, approximately 1 in 1,000 people in Japan and the United States is a treated ESRD patient. Corresponding rates in Canada and Europe range from 400 to 600 per million.

Home HD and CAPD/CCPD are utilized to markedly different degrees. However in most countries there has been a marked decline in Home HD and an increase in CAPD/CCPD in recent years.

Austria, the United States, Spain, and Sweden have the highest reported transplantation rates per population. Transplantation from living donors varies widely and does not correspond well with the overall transplantation rate by country.

Important insights can be gained from international comparisons. More could be learned from future comparative studies of different approaches, health systems, and ESRD prescriptions. Future international comparative studies of survival should have prospective data collection with close participation between collaborating registries and consideration of demographics, known risk factors and comorbid conditions.

## Chapter XIII. Analytical Methods

Chapter XIII describes the technical details of analytical methods used in this ADR. It also points out areas in which data or methods have changed since the last ADR.

## Errata to the USRDS 1996 Report

Chapter 4*;* Figure IV-28

**Distribution of Transferrin Saturation**

| | Was Reported | Should Have Been |
|---|---|---|
| Mean | 19.8 | 23.7 |
| Median | 18.0 | 20.4 |
| 0.01-9 | 23 | 10.5 |
| 10-19 | 31 | 37.7 |
| 20-29 | 26 | 28.7 |
| 30-39 | 12 | 12.4 |
| 40-49 | 5 | 5.6 |
| 50-59 | 2 | 1.8 |
| 60-69 | 1 | 1.3 |
| 70+ | 0.8 | 2.0 |

## Conclusion

In summary, the USRDS 1997 Annual Data Report provides an ongoing and continuing status report on many dimensions of the incidence, prevalence, cost, treatment, and outcomes of ESRD in the United States. Incidence of ESRD continues to grow but may have slowed starting in 1993. (We will have to wait for future data to be sure of this news.) Mortality of dialysis patients remains high by any standard, although there are some continuing signs of improved survival. Delivered hemodialysis dose appears to be higher than in past reports, but until we have a standardized method of drawing the post-dialysis blood sample, even this positive indicator should be treated with caution. ESRD continues to be a disease that affects Blacks and Native Americans at a rate 3 to 5 times the rate of White Americans. ESRD remains very expensive to treat both on a per patient basis and a program basis. The medical, social, and financial implications of this disease continue to make ESRD a major public health and public policy problem.

**Summary Statistics on Reported ESRD Therapy in the U.S., 1995[a]**

| Patient Characteristic | ESRD Incidence Count[b] | ESRD Incidence Adjusted Rate[c] | December 31 ESRD Point Prevalence Count[b] | December 31 ESRD Point Prevalence Adjusted Rate[c] | Adjusted Counts By Modality[d] Dialysis | Adjusted Counts By Modality[d] Tx | Medicare Kidney Tx Performed by Donor Type[e] CAD | Medicare Kidney Tx Performed by Donor Type[e] LRD | ESRD Deaths[f] |
|---|---|---|---|---|---|---|---|---|---|
| **Age[g]** | | | | | | | | | |
| 0-19 | 1,173 | 14 | 4,658 | 60 | 1,712 | 3,256 | 435 | 438 | 118 |
| 20-44 | 12,627 | 116 | 68,327 | 648 | 36,687 | 33,965 | 4,053 | 1,734 | 4,529 |
| 45-64 | 24,985 | 540 | 97,670 | 2,120 | 71,355 | 29,812 | 3,592 | 1,002 | 14,420 |
| 65-74 | 19,346 | 1,101 | 54,163 | 3,273 | 51,113 | 4,836 | 491 | 95 | 16,297 |
| 75 plus | 13,744 | 1,038 | 32,448 | 2,587 | 33,128 | 362 | 16 | * | 14,863 |
| **Race** | | | | | | | | | |
| White | 44,039 | 191 | 160,587 | 704 | 3089 | 822 | 94 | 45 | 659 |
| Black | 21,213 | 831 | 82,105 | 3,186 | 6405 | 2355 | 291 | 95 | 1,195 |
| Asian/Pacific Islande | 2,285 | 383 | 8,303 | 1,248 | 71810 | 12597 | 2,309 | 630 | 13,879 |
| Native American | 1,131 | 757 | 3,807 | 2,449 | 108900 | 55620 | 5,762 | 2,421 | 33,556 |
| Other | 1,406 | | 2,001 | | 3791 | 837 | 85 | 44 | 702 |
| Unknown | 1,801 | | 463 | | w/other | w/other | 46 | 40 | 236 |
| **Sex** | | | | | | | | | |
| Male | 37,702 | 311 | 138,910 | 1,148 | 100046 | 43300 | 5,331 | 1,875 | 26,366 |
| Female | 34,173 | 224 | 118,356 | 818 | 93949 | 28931 | 3,254 | 1,399 | 23,861 |
| **Primary Disease** | | | | | | | | | |
| Diabetes | 28,740 | 107 | 80,667 | 303 | 68070 | 15073 | | | 18,919 |
| Hypertension | 18,476 | 69 | 64,902 | 245 | 55724 | 9735 | | | 14,746 |
| Glomerulonephritis | 7,774 | 29 | 46,684 | 175 | 27672 | 20610 | | | 4,609 |
| Cystic Kidney Diseas | 1,887 | 7 | 12,635 | 48 | 6950 | 5921 | | | 1,079 |
| Urologic Diseases | 1,337 | 5 | 4,835 | 18 | 9344 | 4789 | | | 739 |
| Other Known Cause | 7,913 | 29 | 29,146 | 110 | 13237 | 6888 | | | 4,849 |
| Unknown Cause | 2,646 | 10 | 13,404 | 50 | 9634 | 5614 | | | 2,274 |
| Missing Data | 3,102 | 6 | 4,993 | 18 | 3364 | 3601 | | | 3,012 |
| **Total** | **71,875** | **261** | **257,266** | **965** | **193,995** | **72,231** | **8,585** | **3,274** | **50,227** |
| **Unadjusted Rate[h]** | | **262** | | **967** | | **Total Tx[i]** | **11,937** | | |

**Total Spending for ESRD in 1995: All sources: $13.1B Medicare: $9.7B Non-Medicare $3.3B**

**Change in Medicare Spending 1995 vs. 1994: Total 17%; Per pat. year 3%; Adj. for Inflation 0 to -2%**

**Medicare $/pat. year 1995: ESRD, $ 40K; HD, $50K; PD, $45K; Tx, $17K[j]**

[a] USRDS Patient Database Updated from HCFA PMMIS September 1996, Quality Control Filters Applied. Includes only ESRD patients reported through HCFA as receiving renal replacement therapy for ESRD, or approximately 93 percent of the total number of U.S. ESRD patients. See Chapter XIII, "Analytical Methods: Technical Notes," for discussions of the database and of the methodologies used.

[b] Incidence = new patients starting ESRD therapy during 1995. Incidence and prevalence counts and rates include residents of the 50 states and the District of Columbia only. All other data in this table (modality, transplant, and death counts) include residents of Puerto Rico and U.S. Territories.

[c] Rates were adjusted for age, race, and/or sex using the July 1, 1993 U.S. resident population as the standard population. All rates are per million population. Rates by age were adjusted for race and sex. Rates by sex were adjusted for race and age. Rates by race were adjusted for age and sex. Rates by disease group and total adjusted rate were adjusted for age, race and sex. Adjusted rates do not include patients with other or unknown race.

[d] Patients were classified as receiving dialysis or with a functioning transplant. Those with treatment modality unknown on December 31 were assumed to be receiving dialysis.

[e] Kidney Tx Performed = number of transplants performed during 1995.

[f] Deaths = number of ESRD patient deaths during 1995.

[g] Age was computed at start of therapy for incidence, on 12/31 for point prevalence, at time of transplant for transplants, and on date of death for death.

[h] Unadjusted total rates include all ESRD patients in the 50 states and the District of Columbia.

[i] Source: 1995 HCFA Facility Survey. This total count of kidney transplants performed during 1995 includes 61 additional transplants not shown in thedemographic categories from the patient database. These additional cases are generally not covered by Medicare. As well, this number reflects 13 "other", or living unrelated transplants, not included in the columns in this table.

[j] Excludes cost of organ procurement.

USRDS 1997

**Table ES- 1**