

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, 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 United States Department of Health and Human Services, participates with NIDDK on the project and supplies expertise and most of the original data to the USRDS.

The USRDS was operational by early 1989 and produced its first annual data report in August 1989. The present **USRDS 1994 Annual Data Report** is the sixth volume based on these ESRD data. The annual data reports represent one major vehicle for disseminating information from the USRDS.

This report addresses the first two goals of the USRDS: 1) to characterize the total renal patient population and describe the distribution of patients by sociodemographic variables across treatment modalities, and 2) to report on the incidence, prevalence, mortality rates, and trends over time of renal disease by primary diagnosis, treatment modality, and other sociodemographic variables. Additionally, this report

continues work on the third goal: 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 and has been addressed with seven special studies requiring new data collection. A report on these seven special studies is provided in Chapter XIII. The eighth special study is currently in the planning phase, and will be implemented in October 1994.

Two new goals have been added to the USRDS's mission. 5) The USRDS is to conduct economic cost effectiveness studies and other economic studies of ESRD. Chapter X provides a primer on cost effectiveness and is an initial product that is consistent with this new goal. 6) While the USRDS has always produced data for other researchers, there is a new emphasis on the goal of supporting investigator initiated projects to conduct biomedical and economic analyses of ESRD patients with the provision of USRDS data files. Towards this objective, the USRDS CC has developed a new format for convenient and low cost access to all the data, including the more interesting data from the USRDS Special Studies. See Chapter II for more details on access to the USRDS database.

Changes from Previous Reports and Continuing Notes of Importance

The USRDS has issued five previous reports, the most recent of which was published in 1993. The current report is based on an update from HCFA dated May 1993, which is 14 months later than the update file used for our previous (1993) report. The USRDS accumulates more than 5,000 new patient-based records per working day. Since the time of the last update of the database in 1993, 59,000 additional patients have been added to the database. Over 1 million new records have been added from the Medicare information system, and records for more than 20,000 patients from the seven special studies are currently in the database. In addition, the USRDS generates more than 4 million derived records to track treatment modality over time and to summarize patient status and hospitalization.

The ESRD data in this report are current through 1991 for patient data, and through 1992 for ESRD providers and patient counts. Patient-based data are an accumulation of many records for each patient (see Chapters II and XIII) 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, in contrast, are based primarily on one source, HCFA's Annual Facility Survey, which is completed within six months of the end of the calendar year. Thus, information from the Annual Facility Survey is one year

more recent (end of 1992) than all other data in this report.

There have been a series of major technical changes in the preparation of this report that should be noted:

1. An entirely new system to standardize i.e., "adjust", patient survival estimates for age, sex, race, modality and disease has been implemented. This method involves adjusting rates to the 1991 USRDS ESRD population distribution rather than to the 1986 distribution. Rates are also calculated by adjusting rates to the Bureau of the Census population counts for 1990.
2. In response to requests from the renal community, we have made major changes to the manner in which we compute prevalent mortality. The new prevalent mortality estimates, (Chapter VI and Reference Tables D) include incident patients and patients previously transplanted. The impact of these changes is discussed in Chapter VI. These changes should make our Standardized Mortality Rates more useful and complete than in the past.
3. An entirely new system for creating clean, user friendly, low cost, and flexible data files for use outside the USRDS has been implemented. As previously stated, supporting investigations by outside researchers is a major new task of the USRDS. Access to data is further discussed in a

- new chapter, "Access to the USRDS Database" (Chapter II).
4. A new death notification form, instituted in 1990, is providing more interesting and accurate causes of death information. See Chapter VII.
 5. All graphics now provide the source (e.g. reference tables) of the underlying data on which they are based.

Past Technical Changes Of Significant Note

1. The 1990 Census of Population became available in 1993 and led to many changes in the underlying data on which most rates (incidence, prevalence etc.) are calculated. Consequently, all the rate estimates which use the US population as a base, e.g. incidence and prevalence rates, have been revised all the way back to 1981. While the changes implied by these Census revisions tend to be small in the aggregate, the reader should be cautioned that all population-based rate estimates have been revised in both the 1993 and the current report for all previous years (see Chapter XV for more details).
2. Recent publications of the 1990 Census of Population made clear that in previous years the USRDS was inconsistently treating population estimates for Puerto Rico and the United States Territories in some population-based rate calculations. The Bureau of the Census provides a different and sometimes less complete set of estimates for Puerto Rico and the US Territories (e.g., no population race distribution) compared to the population resident in the 50 states and the District of Columbia. Consequently, starting with the 1993 report, all population-based rates, such as prevalence and incidence, generally treat Puerto Rico and the United States Territories separately. The captions of Figures and Reference Tables usually distinguish which procedure was followed. This set of changes does not affect the calculation of rates which use ESRD patients as the base, e.g. transplants per 100 dialysis patient years.
3. As first described in the 1992 report, the USRDS has created a new patient modality called "lost to follow-up" which removes approximately 10,000 patients from the 1991 prevalence counts. The HCFA data system currently does not have a method to consistently remove patients who have regained renal function or who for other reasons lack treatment information in the patient data base while they are most probably alive but not on renal replacement therapy. While these populations may be small in a single year (usually less than two percent), over time there is likely to be an accretion of these errors. For example, as reported in the 1993 report, there

- was an increasing discrepancy in the count of Medicare dialysis patients as indicated by the USRDS patient database and the HCFA Annual Facility Survey (see Chapter III and XV). This procedure change by the USRDS, starting in 1992, which defines a lost to follow-up status, has brought these two sources of information back into agreement. As a consequence of this change, there was a substantial decrease in the prevalence counts and rates starting in the 1992 report compared to previous USRDS reports. This change also increases the prevalence mortality rates (see Chapter VI and VII) and increases the estimate of cost per patient year (see Chapter III).
4. In almost all instances the changes are small, but comparison across USRDS reports should be done with caution. As in previous years this report contains an internally consistent set of tables for at least 10 years.
 5. A major addition to these reports was first made in 1993 and is continued in this report, Chapter XIV ("A Researcher's Guide to the USRDS Database") is designed to facilitate analyses of the USRDS database by independent investigators. The process to apply for USRDS data by independent investigators is described in Chapter II, "Access to the USRDS Data."
 6. The appendices with the USRDS's Special Study Forms have been shortened to include only the more recent and frequently cited Special Studies (Case Mix Severity; Peritonitis; Case Mix Adequacy; Pediatric Growth and Development). These forms are frequently referred to, both in this document and in other USRDS publications.
 7. As in the 1991 and 1993 reports, text and reference tables have been expanded to include more detail on racial distributions for ESRD patients. Since the total number of Native American and Asian/Pacific Islander minorities is relatively small, we have often combined multiple years of information to generate more stable estimates. We have followed this process of combining several years in many situations where small cell size may generate unstable estimates. We continue the practice, first started in 1991, of reporting many statistical estimates by Network. In almost every chapter, we have provided one figure or table categorized by Network. The 18 ESRD Network areas are similar in total population, and provide a good balance between geographic detail and adequate population size for statistical analysis. We have generally identified Networks by the State in which the Network office is located. The reader should be cautioned that over half of the Networks

cover more than one state (see Table III-2 for a precise listing of Networks). The 18 ESRD Networks are a central part of the USRDS (see Chapter I). Network organizations and state health departments frequently ask the USRDS for data by geographic area.

Our objective in preparing this report has been to present data for the full span of years, using consistent definitions, so that valid comparisons can be made across years and among subgroups in the database. 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 footnotes, and in Chapter XV, "Analytical Methods."

Summary Statistics

Selected statistics for the ESRD program for 1991 are shown in Table ES-1. These data provide a succinct reference for information most frequently asked of the USRDS.

Salient Trends; Notable Changes in Statistical Results

Prevalence and Cost (Chapter III)

At the end of 1992 there were over 220,000 patients with ESRD in the US. This includes Medicare and non-

Medicare patients, patients receiving dialysis and patients with a functioning graft. Treated patients with kidney failure are increasing at over 9 percent per year, which if continued will double the prevalence count in just over seven years. Looking back the count has doubled in just over seven years. There is no immediately apparent reason to suggest that this growth will not continue. In fact, increases in the dose of dialysis and other changes in treatment may well increase the rate of growth in the prevalence counts.

The total estimated direct medical charges for ESRD by public and private payers was \$8.6 billion during 1991. At least \$6.2 billion, or 72 percent of the total, was paid by the Federal government. The estimated Medicare payments per capita (Federal only) during 1991 averaged \$38,400 with patient and private insurance obligations representing an additional \$8,600, for a total of \$47,000 per patient per year. Trends over the 1987-91 period reveal aggregate costs and costs per capita that are both rising in nominal dollars (not adjusted for inflation). When adjusted for inflation, the per capita costs are increasing minimally or possibly decreasing, a most unique situation in American medical care. But aggregate costs are increasing at over eight percent per year even with adjustment for inflation. The most recent past has seen a somewhat higher rate of increase than over the longer term.

Table ES-1
Summary Statistics on Reported ESRD Therapy in the U.S., 1991^a

Patient Characteristic	ESRD Incidence		December 31 ESRD Point Prevalence				Medicare Kidney Tx Performed by		ESRD Deaths ^f
	Count ^b	Adjusted Rate ^c	Count ^b	Adjusted Rate ^c	Counts By Modality ^d		Donor Type ^e		
					Dialysis	Tx	CAD	LRD	
Age^g									
0-19	822	11	4,113	55	1,629	2,544	321	350	97
20-44	9,635	96	56,397	557	29,850	27,199	3,779	1,288	3,302
45-64	16,925	392	69,002	1,576	51,627	18,496	2,695	464	9,860
65-74	13,901	846	37,257	2,292	35,565	2,122	304	20	11,166
75 plus	8,626	725	19,492	1,643	19,606	107	5	0	8,808
Race									
White	33,337	150	120,707	547	82,212	40,455	5,195	1,765	23,092
Black	14,211	595	56,508	2,298	48,977	7,829	1,574	281	8,849
Asian/Pacific Islander	1,023	205	3,885	686	2,897	1,078	202	33	472
Native American	619	464	2,272	1,571	1,748	534	76	30	351
Other	631		2,364		2,443	572	49	13	348
Unknown	88		525				8	0	121
Sex									
Male	26,839	239	101,069	860	72,063	30,539	4,341	1,205	17,763
Female	23,070	162	85,192	607	66,214	19,929	2,763	917	15,470
Primary Disease									
Diabetes	17,888	70	48,274	188	39,997	9,072	1,623	453	11,361
Hypertension	14,495	57	43,724	171	38,486	5,625	1,092	204	9,987
Glomerulonephritis	5,782	23	34,329	134	20,813	14,110	1,804	591	3,509
Cystic Kidney Disease	1,456	6	9,244	36	5,641	3,679	582	104	773
Urologic Diseases	2,449	10	11,478	45	7,952	3,668	423	172	1,797
Other Known Cause	3,306	13	11,370	44	7,696	3,757	480	248	1,864
Unknown Cause	2,651	10	12,312	48	8,604	3,858	507	139	2,090
Missing Data	1,882	6	15,530	55	9,088	6,699	593	211	1,852
Total	49,909	195	186,261	721	138,277	50,468	7,104	2,122	33,233
		Unadjusted Rate^h :					All Txⁱ :		
		198		732			10,052		

^a USRDS Patient Database Updated from HCFA PMMIS May 1993, 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 1991. 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, 1990 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 1991.

^f Deaths = number of ESRD patient deaths during 1991.

^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: 1992 HCFA Facility Survey. This total count of kidney transplants performed during 1991 includes 717 additional transplants not shown in the demographic categories from the patient database. These additional cases are generally not covered by Medicare.

The essence of the story is that the rise in cost for ESRD is for practical purposes almost totally driven by the increase in the number of patients treated. If the goal is to reduce these total costs, then prevention of ESRD is the logical alternative.

☑ Incidence and Causes of ESRD (Chapter IV)

The incidence rate for newly treated ESRD patients continues to rise at an exponential rate in excess of eight percent per year. The largest increases continue to be in the elderly population, in diabetics, and in hypertensive patients. There have been no increases in the treated incidence rate for children, but modest increases are observed for patients in the 20-44 age group. While there appear to be large increases in the incidence of Native American and Asian Pacific Islander populations, these reported growths may be artifacts of changes in reporting.

☑ Methods of ESRD Treatment (Chapter V)

Hemodialysis and CAPD treatments continue to grow at previous levels. CCPD has the most vigorous rate of growth among treatment methodologies, although the base on which this growth is measured is relatively small.

Both the number of cadaver and living related donor transplants have shown very little increase. However, the kidney transplant waiting list continues to grow so that the gap between the supply and the need for donor organs is even greater than in previous years. At the end of 1992, there were over 22,000 patients on the kidney transplant waiting list at a time when less than 8,000

cadaver transplants were performed each year. The supply of donor organs continues to be a major problem.

National estimates of the delivered dose of hemodialysis in 1991 have been calculated for the first time. These estimates, from the USRDS's Case Mix Adequacy Study, show that the delivered dose of dialysis for many patients is below the standards established by previous clinical trials. For example, 38 percent of patients on dialysis for more than one year (who are likely to have little or no residual renal function) had a delivered KT/V of 1.0 or less, the minimum recommendation from the National Cooperative Dialysis Study.

Examination of the dose of delivered dialysis also revealed that diabetic patients received a lower quantity of dialysis.

Recombinant human erythropoietin was approved by the Food and Drug Administration to treat anemia in ESRD patients in 1989. Since Medicare's coverage of this drug in the same year, the proportion of Medicare patients using this drug on an outpatient basis had increased by the end of 1992 to 88 percent for center hemodialysis and to 52 percent for CAPD patients. In January of 1991, the reimbursement method was changed from a per administration payment to a per unit reimbursement. (The reporting requirements were changed at the same time). There was an apparent increase in dose per administration for incenter hemodialysis patients at the time of these changes. By the end of 1992, the average hematocrit for patients treated with EPO had increased to 29.6 percent. There was also a dramatic decrease in the

administration of blood to dialysis patients during this period.

Comparison of laboratory values for the 1986-87 incident patients with the level for the 1990 incident patients suggests that the initial hematocrit at start of ESRD may have risen in the interim. Assessment of vascular access used at the start of ESRD from the two case mix studies revealed an increase in the use of synthetic PTFE grafts and a reduction for AV fistulas from 1986/87 to 1990.

Patient Survival (Chapter VI)

Improvements in the survival of incident i.e. new dialysis patients, first reported for cohorts in 1989 and 1990, continued through 1991. For all dialysis cohort subgroups, the gains of recent years are either sustained or enhanced. In addition, the previously reported decreases in patient mortality for transplanted patients also continued through 1991.

Similarly, previously reported decreases in prevalent mortality rates for 1989 and 1990 have continued through 1991. Therefore we can report unequivocally that mortality rates of all ESRD patients were decreasing through 1991.

As reported above, our methods of calculating prevalent mortality has been changed substantially and the new statistics should be more useful and complete.

Causes of Death (Chapter VII)

Cardiac causes continue to dominate the reason for deaths among this population.

There appears to be an increase in the rate of withdrawals from dialysis as the listed cause of death. This is in part related to changes in reporting.

As mentioned above, the revised Death Notification Form is now producing more useful and precise indicators of the cause of death for ESRD patients. For the first time, for example, we can report that the primary reasons for withdrawal from dialysis are chronic failure to thrive and acute medical complications.

Transplant Outcomes (Chapter VIII)

There continues to be a substantial improvement in cadaver graft survival. Previously reported preliminary results (1993 ADR) showing first year survival for cadaver rates in excess of 80 percent are now found to hold up even with more complete data.

It is becoming increasingly clear that cadaver graft survival has been improving in the longer term (up to 5 years) as well as the short term.

Graft survival rates and loss rates have been adjusted. In previous years crude rates were presented. The adjustment had the effect of smoothing changes in the rates. Instead of somewhat "helter-skelter" values the rates exhibit monotonic changes across years.

Through 1991 there has been an allocation of cadaver donor organs towards older patients and less so to younger patients. Previously reported greater transplant rates for whites compared to blacks, and for males compared to females continued through 1991. We also note that the diabetic

graft survival rate continues to converge with the rates for other causes of ESRD.

Pediatric ESRD (Chapter IX)

Children continue to be aggressively transplanted; As of 1991, 82% of 5-9 year olds were transplanted by 2 years of onset of ESRD. While there has been some decrease in the cadaver transplant rate for pediatric cases through 1991, increases in living related transplants have partially offset this trend.

Living related transplant rates now dominate in every pediatric age group except 15-19. In the 1993 ADR, cadaver transplant rates dominated in every age group.

Convergence of cadaver transplant rates for both sex and race occurred between 1990 (1993 ADR) and 1991 (1994 ADR).

Incidence and prevalence of ESRD for pediatric Americans are similar to estimates reported in the last ADR (1993) and have remained nearly constant since 1982.

Substantial differences in survival continue to be observed between dialysis and transplant patients, with the latter having a higher survival.

Pediatric patient survival remains high relative to adult age groups, with 96 percent survival in the first year and 70 to 82 percent at ten years.

Cost Effectiveness In ESRD (Chapter X)

The new goal of the USRDS to conduct and support cost effectiveness studies and other cost studies will be supported by a wealth of charge and reimbursement information from HCFA.

The current chapter provides a primer on the conceptual basis of cost effectiveness as applied to ESRD.

The Annual Facility Survey of ESRD Providers (Chapter XI)

Through 1992, the number of dialysis units continued to grow at 7 percent per year. Almost all of this growth was in free standing units, with approximately equal percentage growth in profit and not-for-profit units. But in absolute terms, the for-profit units are a much larger proportion of the total. Between 1991 and 1992, there were an additional 105 for-profit units and 19 not-for profit units added to the Medicare list of approved providers. There was no growth in the number of kidney transplant centers between 1991 and 1992. In fact the total number of Medicare approved transplant centers decreased from 232 to 231.

Crude mortality rates by year from 1983-92 have been added to this chapter. The change in rate exhibits a fairly flat bell curve shape, i.e. peaks in the late 1980s.

International Comparisons of ESRD (Chapter XII)

In all countries reported, the incidence rate of treatment for ESRD continues to rise compared to the rates shown in our last report. The US continues to have the highest treated ESRD incidence rate in the world. Japan however has an incidence rate very close to the US and continues to narrow the gap between the two countries.

While the US has a higher incidence rate than does Japan, Japan's prevalence rate is higher than in the US. The most likely explanation for this difference is

the lower mortality rate in Japan, which we note is achieved with almost no

transplantation.