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- **clinicians**
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- **researchers**
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Atlas of End-Stage Renal Disease in the United States

United States Renal Data System
Treating chronic disease requires a multitude of skills and a mind-set that will not allow adversity to fog our final vision. We dedicate this book to all individuals—patients, clinicians, and researchers—who continue to steer a course towards health and wellness for everyone afflicted with end-stage renal disease.
The paths to the house I seek to make,
But leave to those to come the house itself.

Walt Whitman
Leaves of Grass
Introduction

Healthy People 2010

One Chronic Kidney Disease

Two Incidence & Prevalence of ESRD

Three Patient Characteristics

Four Treatment Modalities

Five Clinical Care
or this year’s Annual Data Report (ADR) we introduce new data and new analyses, again broadening our exploration of the ESRD population—its characteristics, treatment, and outcomes. We present here Medicare payment data up to 2002, with incident information through June 2003. And using the Medstat MarketScan Database, we have added new information on Employer Group Health Plan (EGHP) enrollees with end-stage renal disease (ESRD) and chronic kidney disease (CKD). This database is constructed from private sector data contributors that include approximately 45 large employers, health plans, and government and public organizations.

In place of last year’s chapter from the Rehabilitation and Quality of Life Special Studies Center, we have included a chapter from the Nutrition Special Studies Center. We have added information on prescription drug use in both Medicare and EGHP enrollees, and provided data on dialysis patients in nursing homes, assessing their demographics, physical limitations, cognitive impairment, and mortality. We have also expanded our focus on morbidity, examining complications and pregnancies in women with ESRD, and looking at the relation between fractures and long-term survival. And the reference tables contain a new section addressing vascular access.

The quality of care delivered to the ESRD population remains a focus of the ADR. We have again included a chapter on providers and the care they deliver, and this year, in Chapter Six, we present two new spreads addressing Bayesian versus traditional methods of calculating standardized mortality and hospitalization ratios, and examining these ratios by provider. Addressing the variability in outcomes that occurs between small and larger providers, our new Bayesian method is detailed in Appendix A.

This year we have again placed on the book’s frontispiece two information maps—one organized by broad topics of interest, and the second by some of the book’s different audiences. We hope that with these maps, along with the table of contents and index, readers can more easily navigate the large amounts of data presented here.

Because the U.S. Census Bureau was last year in the process of using the 2000 census to estimate population counts back to 1991, we continued to use our own estimates to calculate rates. This year, however, the Bureau has completed its backcasting of the data, and we have incorporated its estimates into our analyses. New racial and ethnic groupings on the 2000 census have made it more challenging to track minority populations, and the Bureau has reported that approximately 10 million people were undercounted during the 1990s. Based on new estimates from the Bureau and the CDC’s National Center for Health Statistics, for example, the Native American population is larger than previously reported. These significant changes in the census counts directly influence ESRD rates. With the larger base populations reported in the newest estimates, incident and prevalent rates of ESRD are now lower than those reported in previous ADRs. We have used the Census Bureau’s newest estimates to recalculate all rates presented in the ADR from 1991 onward.

We have continued to work with both the Centers for Medicare and Medicaid Services (CMS) and the ESRD networks to

After the 2000 census, the Census Bureau revised its population estimates for the 1990s. Incident & prevalent rates in the 2004 ADR incorporate these revised estimates, & are approximately 4½% lower than those in previous ADRs.
address the accurate counting of patients by modality. Difficulties in tracking non-Medicare patients and their transition to Medicare have resulted in some patients being counted twice. In the 2003 ADR, we used the treatment event file of the SIMS database from the ESRD networks to obtain a more accurate patient treatment history. Using this file also enabled us to reconcile many patients previously defined as lost-to-followup.

For the 2004 ADR, we have made further advances in consolidating ESRD patient information from the CMS REMIS/REBUS database, the SIMS database, and the USRDS ESRD database. This effort has physically united these independent but similar data sources, producing one integrated, consistent ESRD database for the first time. The patient census reported by the USRDS is now very close to that of the ESRD Facility Survey, with prevalent counts now showing more patients under treatment than previously reported, and incident counts adjusted downward.

**Chapter overview**

In the Précis we provide a broad overview of the ESRD program, showing patient counts, Medicare expenditures, hospitalization and mortality rates by vintage, and trends in the provider community. We also include information on delivered dialysis therapy, vascular access, and anemia management, each covered by clinical practice guidelines from the National Kidney Foundation’s Kidney Disease Outcomes Quality Initiative (K/DOQI), and look at data from the National Health and Nutrition Examination Survey (NHANES) on treatable risk factors for CKD.

The next chapter presents data related to Healthy People 2010, a program sponsored by the Department of Health and Human Services. HP2010 objectives related to kidney disease include reducing the incidence of ESRD overall and of kidney disease caused by diabetes. To address progress toward these objectives we have included data from the Medicare 5 percent sample, which provides information on the general Medicare population, and which we use later in the book to analyze hospitalizations and preventive healthcare services.

In Chapter One we use data from the Medicare 5 percent sample to examine CKD in the general population, and this year we look as well at CKD in EGHP enrollees. We focus particularly on patients with diabetes and hypertension, as they account for 71 percent of those beginning ESRD therapy. Data here include cardiovascular and infectious hospitalization rates, rates of mortality associated with cardiovascular disease and infection, preventive healthcare, prescription drug use, and hospitalization rates in patients with rare diseases. We also address the association between acute events and long-term survival. Cardiovascular events have been identified as strong predictors of poor survival, a finding now apparent as well for infectious events such as pneumonia, sepsis, and urinary tract infections.

Here and in Chapters Three and Five we examine prescription drug use in Medicare patients by using data from the Medicare Current Beneficiary Survey (MCBS), which surveys individuals in their homes. Prescription drug use in the EGHP population is assessed using data from the Medstat EGHP dataset.

Chapter Two, on the incidence and prevalence of ESRD, illustrates long-term trends in the ESRD population, and presents rates using the newly calculated census data. Incident rates of ESRD due to diabetes have fallen for whites age 20–29, and have begun to decline for those age 30–39; this is in contrast to a continued increase in the black population. In this chapter, as in Chapter One, we again present data on some of the less common causes of ESRD, hoping that this information will continue to prompt new awareness of the patients affected by these diseases.

In Chapter Three we examine patient characteristics at the start of ESRD therapy, looking in particular at the prevalence of cardiovascular disease since 1984. We include data on EPO use and anemia at initiation, biochemical characteristics, and predictors of CHF and of Stage 3 and higher CKD—body mass index, albumin, and the BUN/creatinine ratio. This year we have also added a spread on ESRD patients residing in nursing homes, looking at their demographic characteristics, cognitive and physical impairment, and annual mortality rates.

Information on treatment modalities is provided in Chapter Four. We include data on the distribution of payors for incident and prevalent patients, and on geographic trends in rates by modality. We also present new analyses of the cumulative probability of patients switching modalities, and the outcomes of patients who regain kidney function.

Chapter Five focuses on clinical care of the ESRD population, presenting new data on drug therapy for diabetes and cardiovascular disease. We have also created a new summary of K/DOQI targets and actual delivered care. As in previous years, we assess in this chapter the monitoring of risk factors for cardiovascular dis-
ease and diabetes, the use of diabetic testing supplies, and provider management of anemia. And we conclude the chapter with new data on vascular access, looking at patient demographics, urea reduction ratios, and relative risks of events and complications.

We continue this year to juxtapose hospitalization and mortality data in one chapter, allowing readers to compare these outcomes. Chapter Six includes several expanded analyses. Data by patient vintage—time on ESRD therapy—illustrate the significant relation between vintage and outcomes, while new analyses address the relative risk of mortality after cardiovascular events, pneumonia, and vascular access events. And it is in this chapter that we have added new analyses of fractures and mortality, of cancers and pregnancies in women with ESRD, and of Bayesian versus traditional methods of calculating standardized mortality and hospitalization ratios.

Renal transplantation data in Chapter Seven include trends in the number of transplants, patient demographics, information on wait-listed patients, and donation rates by state and population. This year’s ADR also presents new information on transplant patients who return to dialysis, and, continuing the exploration of hospitalization and mortality ratios in Chapter Six, includes analyses of new and traditional methods of calculating standardized transplant ratios. Post-transplant care is more thoroughly assessed this year, with particular attention given to cardiovascular disease and to viral and infectious complications, such as HIV.

In Chapter Eight we explore long-term trends in children with ESRD, including patient counts, anemia treatment, L-carnitine use, and hospitalization and mortality—particularly for cardiovascular disease and infection. We also examine trends in vaccinations for influenza, pneumococcal pneumonia, and hepatitis B, and introduce data on vascular access events.

The Cardiovascular Special Studies Center focuses in Chapter Nine on cardiovascular events that include AMI, CHF, and cardiac arrests, assessing rates and geographic distributions in both CKD and ESRD patients. Cardiovascular event and mortality rates illustrate the impact of sudden death in the dialysis population, and data on the diagnosis and treatment of cardiac disease show the percent of patients evaluated for modifiable risk factors before and after initiating ESRD treatment.

The Nutrition Special Studies Center this year makes its first contribution to the ADR. Chapter Ten examines the relationship between obesity and serum albumin in both CKD and dialysis patients, and presents data from the NHANES population on inflammatory markers. It also includes information on treatment interventions—IV vitamin D, L-carnitine, IV iron, and parenteral nutrition services.

For this ADR we have brought back our assessment of dialysis providers, looking in Chapter Eleven at trends in growth, patient demographics, achieved hemoglobin levels and EPO use, vascular access, vaccination rates, and reuse practices.

Our chapter on the economics of ESRD again explores program costs and their distribution by payer, therapy type, and patient group; changes in costs are presented in total and on a per patient basis. Expenditures by individual dialysis chains can be examined together with data on the clinical treatment of anemia in Chapter Five. The new Medicare Advantage payment system for managed care ESRD patients is slated to begin in January of 2005; we present information in Chapter Twelve on the old AAPCC payment system compared to this new system, showing areas of improvement and of concern.

As in previous editions of the ADR, we conclude the chapters with data from the international renal community. Thirty-one countries responded to our survey this year, compiling data on incidence, prevalence, ESRD related to diabetes, dialysis therapy,
and transplantation. We are very grateful to the renal registries in these countries, and for the broad perspectives their information provides.

Most of the 2004 ADR contains data through December 31, 2002, with data on patient characteristics from the Medical Evidence form complete through June 2003.

**www.usrds.org**

On our website users can download PDF files of the printed ADR, Excel files of the Reference Tables and the data underlying the graphs, and PowerPoint slides of ADR figures and USRDS presentations. (Due to the size of the files, downloading time may be substantial; we provide estimated times for a 56 kbs modem.) All data are aggregated in order to comply with USRDS confidentiality policies, and data for cells with ten or fewer patients are omitted.

Supplemental reference tables are again included on our website; these consist of standard errors for all rates, as well as tables for subgroups of patients. A complete list of these tables is provided on the first page of the Excel file of each reference section.

Also available on the website are supplemental tables on ESRD patients covered by Medicare. These tables parallel tables in the printed ADR, and include information on incidence and prevalence, modalities, hospitalization, transplant, mortality, survival, and the costs of ESRD.

**RenDER**

We continue to improve our real-time online query system, which allows users to build data tables and maps based on query specifications. The Renal Data Extraction and Referencing System (RenDER) can be accessed on the USRDS website.

**Researcher’s Guide**

To assist users of the USRDS data, the Coordinating Center has again updated and revised the Researcher’s Guide, which provides information on all analytical methods used by the CC, along with a detailed index of files and variables in the USRDS researcher datasets. It is available on our website, and a hard copy will be sent to researchers who order Standard Analysis Files.

**USRDS database**

The Coordinating Center frequently responds to concerns about changes in reported counts of incident and prevalent patients and in counts by modality. The USRDS dataset is a living record of ESRD care in the United States, and is continually updated with new information on the ESRD population. Delays in the reporting of data are unavoidable, and we add late information to the database as soon as it becomes available. This information includes data from the Medical Evidence form, claims for hospital and physician services, and updates of the Medicare Enrollment Database that are received after the ADR has gone to press.

Throughout this ADR we have applied a newly adopted payor history file to identify Medicare eligibility status and other insurance payors; see Appendix A for details. And to close some of the gaps noted in past ADRs we have continued to collaborate with the Centers for Medicare and Medicaid Services (formerly HCFA) and the ESRD networks. Information obtained from the Medical Evidence form, the Facility Survey form, and the Standard Information Management System (SIMS) database has been reviewed to identify discrepancies.

We have extensively revised the process by which we reconcile patients in the database, working to account for duplicate patients and resolve data on those lost-to-followup. Because we cannot track non-Medicare patients over time, this latter group has posed particular problems. We will continue to refine our patient reconciliation system through use of the SIMS database, and for the transplant population will focus as well on tracking patient events and followup.

CMS and the USRDS are also sharing additional datasets in order to advance research.
on the ESRD population. Since 1994 CMS has collected information on a random sample of dialysis patients through the Clinical Performance Measures Project (CPM, formerly the Core Indicator Project). The data include information on dialysis adequacy, anemia treatment, vascular access, and, more recently, pediatric patients.

The USRDS and CMS have created a joint steering committee to guide this collaborative research, and have developed datasets in a format similar to that of the Special Studies data files, using universal identifiers to link the CPM data to the main USRDS data files. These merged datasets are now available to researchers.

**U.S. population estimates**

The USRDS uses U.S. Census data to calculate incident and prevalent rates, as well as rates of organ donation. In Appendix A, in the discussion of Reference Section M, we explain our use of these data in rate calculations throughout the ADR.

**Types of ESRD treatment**

The CC and the REBUS group at CMS have worked extensively on methods of categorizing patients by ESRD treatment modality. While the Medical Evidence form is the primary source of data on modality at ESRD initiation, the modality it indicates may be temporary, as patients often change to a new one within the first 90 days. It can therefore be difficult to track modality during this period. A patient’s modality may thus not be determined until Medicare becomes the primary payor at day 91 or, for patients in employer group health plans or Medicare risk programs, however, have no claims in this period. A patient’s modality may thus not be determined until Medicare becomes the primary payor at day 91 or, for patients in employer group health plans, at 30–33 months after the first ESRD service date. These limitations influence the CC’s ability to determine a patient’s exact modality at any one point in time.

Of particular concern are patients categorized as having an unstable modality (i.e., treated on that modality for fewer than 60 consecutive days) in the first 90 days, and who are therefore not recognized as being hemodialysis or peritoneal dialysis patients. These patients tend to have higher death and hospitalization rates, and unless they are identified and assigned to modalities, interpretations of modality-specific outcomes should be viewed with caution. These patients are included in the “all ESRD” category, which provides a more complete view of mortality and hospitalization with the least biasing of the data.

The Coordinating Center and CMS will continue working to reconcile the claims and ESRD network census data, reducing the number of patients classified as having unknown or unstable dialysis modalities.

**Administrative oversight**

Lawrence Agodoa, MD and Paul Eggers, PhD provide direct oversight of the Coordinating Center and Special Studies Centers, and members of CMS, the ESRD networks, and the renal community provide crucial input and feedback through their committee participation.

The Steering Committee functions as the governing body of the USRDS, and is responsible for the operations of the CC and SSCs. It works under the direction of the Project Officers, and includes representatives from CMS, the NIH, the CC, and each of the SSCs. Its responsibilities include coordination among the centers, study design, project tracking, data management and validation, assurance of data availability for researchers and government officials, and oversight of Annual Data Report production.

The USRS External Advisory Committee plays a major role in ad-
vising Project Officers on appropriate and necessary special studies, data studies, and analyses. This committee is also responsible for reviewing manuscripts and Annual Data Reports. Members are listed in Table i.d.

The Data Management Advisory Committee (DMAC) includes CMS members, Network Forum representatives, database technical staff, and others appointed by the Project Officers. DMAC addresses the accuracy and completeness of data provided to the USRDS, and works to ensure timely fulfillment of data requests.

The Annual Data Report Committee (ADRC) reviews data sections of previous ADRs, proposals for future editions, and ideas for expanded availability of data on the USRDS website.

The Information Systems Committee (ISC) reviews hardware requirements, systems configuration, documentation, and performance, and evaluates technologies that may enhance database structure, function, and management.

The Special Studies Review and Implementation Committee (SSRIC) serves as the operations committee for SSC proposals and support of CC projects. It is a collaboration of CMS, the ESRD networks, and the providers.

The Data Request Review Committee (DRRC) reviews data requests requiring more than two hours of staff time to fulfill, and makes recommendations to the Project Officers based on the types of data sets requested and the ways in which the CC can improve the availability of data.

The Renal Community Council (RCC), with 30 professional, scientific, and advocacy groups, serves as a significant liaison between the USRDS and the ESRD community.

Reading the maps

The majority of disease mapping within this atlas is by Health Service Area (HSA), a group of counties described by the authors of the CDC Atlas of United States Mortality as “an area that is relatively self-contained with respect to hospital care.”

Maps throughout the ADR present data divided into quintiles. Each data range in a legend contains approximately one-fifth of the data points included in the map. In the sample map here, for example, one-fifth of all data points displayed have a value of 10.8 or above.

To facilitate comparisons of maps that present data for several different years or time periods, we have applied a single legend to each of the maps in a series, e.g., rates of diabetes in...
10.8+ (12.2) 9.9 to <10.8 9.2 to <9.9 8.2 to <9.2 <8.2 (7.6)

In an effort to be more sensitive to transplant donors, recipients, and their families, we now employ the term “deceased donor” rather than “cadaveric donor.”

The Annual Data Report could not be produced without the extraordinary work of members of the ESRD community—including the staff of CMS and the ESRD networks—and the dedicated efforts of the USRDS staff and investigators. The efforts of providers are crucial in the collection of data used by the USRDS, and their dedication in collecting data is greatly appreciated.

Feedback on the ADR and on other USRDS work is welcomed, and all comments are reviewed by the Director, Deputy Director, and staff in order to improve future materials and ensure a strong working relationship between the USRDS and clinicians, researchers, patients, and others involved in ESRD care.