

# analytical methods: ESRD glossary data forms

usrds products and services 400

glossary 406

agreement for release of data 409

cms forms 411

colophon 418

data sources 372

Précis 378

Healthy People 2020 378

incidence, prevalence,  
patient characteristics, and  
treatment modalities 379

CHAPTER ONE

clinical indicators  
and preventive care 380

CHAPTER TWO

hospitalization 382

CHAPTER THREE

cardiovascular disease 384

CHAPTER FOUR

mortality 385

CHAPTER FIVE

prescription drug

coverage in ESRD patients 387

CHAPTER SIX

transplantation 388

CHAPTER SEVEN

pediatric ESRD 390

CHAPTER EIGHT

special studies 390

CHAPTER NINE

ESRD providers 390

CHAPTER TEN

costs of end-stage

renal disease 391

CHAPTER ELEVEN

international comparisons 394

CHAPTER TWELVE

vascular access 394

CHAPTER THIRTEEN

census populations 394

statistical methods 395

special studies and data

collection forms 397

bibliography 398

I go out walkin' after midnight  
Out in the moonlight  
Just hopin' you may be  
Somewhere a-walkin' after midnight,  
searchin' for me

Donn Hecht & Alan Block, "Walkin After Midnight"

In this appendix we present details on the USRDS database, its standardized working datasets and specialized code definitions, and our common data processing practices. We also describe the statistical methods used in this ADR. The Researcher's guide to the USRDS database, available online, provides additional information about the database and standard analysis files.

#### **DATA SOURCES**

The USRDS maintains a stand-alone database with data on diagnoses and demographic characteristics of ESRD patients, along with biochemical data, dialysis claims, and information on treatment and payor histories, hospitalization events, deaths, physician/supplier services, and providers.

#### **REMIN/REBUS/PMMIS DATABASE**

The major source of ESRD patient information for the USRDS is the Renal Beneficiary and Utilization System (REBUS) of the Centers for Medicare and Medicaid Services (CMS, formerly HCFA), adopted in 1995 as the On-Line Transaction Processing system from the previous Program Management and Medical Information System (PMMIS) database. The REBUS/PMMIS database contains demographic, diagnosis, and treatment history information for all Medicare beneficiaries with ESRD. The database has also been expanded to include non-Medicare patients, as discussed later in this appendix. Having advanced its database technology, CMS migrated the REBUS database into an Oracle relational database in the fall of 2003, including all patients who were alive and had ESRD as of January 1, 1995, or who were incident after this date. This database is known as the Renal Management Information System (REMIN).

CMS updates the REMIN/REBUS/PMMIS database on a regular basis, using the Medicare Enrollment Database (EDB), Medicare inpatient and outpatient claims, the Organ Procurement and Transplantation Network (OPTN) transplant database, ESRD Medical Evidence forms (2728) provided by the ESRD networks, and ESRD Death Notifica-

tion forms (2746) obtained from renal providers, as well as the Standard Information Management System (SIMS) database of the ESRD networks. CMS has also established data integrity rules to ensure accurate identification of patients in the SIMS and CMS databases. Each ESRD patient is now identified with a unique patient identification number common to both databases, ensuring that data on all patients are consistently managed over time.

#### **CMS MEDICARE ENROLLMENT DATABASE (EDB)**

The Medicare Enrollment Database is the designated repository of all Medicare beneficiary enrollment and entitlement data, and provides current and historical information on residence, Medicare as secondary payor (MSP) and employer group health plan (EGHP) status, and Health Insurance Claim/Beneficiary Identification Code (HIC/BIC) cross-referencing.

#### **ESRD MEDICAL EVIDENCE FORM (CMS 2728)**

The ESRD Medical Evidence (ME) form is used to register patients at the onset of ESRD, and must be submitted by dialysis or transplant providers within 45 days of initiation. The form establishes Medicare eligibility for individuals previously not Medicare beneficiaries, reclassifies previously eligible beneficiaries as ESRD patients, and provides demographic and diagnostic information on all new patients. The CMS, USRDS, and renal research communities rely on the form to ascertain patient demographics, primary diagnosis, comorbidities, and biochemical test results at the time of ESRD initiation. Before 1995, units were required to file the ME form only for

Medicare-eligible patients. Since the 1995 revision, however, providers are required to complete the form for all new ESRD patients.

The third major revision of the ME form, in May, 2005, remedied several shortcomings of the 1995 form and its earlier version. Key additions target pre-ESRD care and vascular access use, and additional new fields collect information on glycosylated hemoglobin and lipid testing, on the frequency of hemodialysis sessions, and on whether patients are informed of transplant options.

This form is the only source of information about the cause of a patient's ESRD. Because the list of diseases has been revised, the USRDS stores the codes from each version so that detail is not lost through conversion of one set of codes to the other.

#### **ESRD DEATH NOTIFICATION FORM (CMS 2746)**

The ESRD Death Notification form is used to report the death of ESRD patients. According to CMS policy, this form must be submitted by dialysis or transplant providers within 30 days of a patient's death, and provides the date and causes of death (primary and secondary), reasons for discontinuation of renal replacement therapy, if applicable, and evidence of hospice care prior to death. It is the primary source of death information for CMS and the USRDS, identifying more than 99 percent of deaths. The USRDS also utilizes the Social Security Administration's (SSA) Death Master File as a supplemental data source for ascertaining death in a small group of lost-to-follow-up ESRD patients; this file, however, identifies only all-cause deaths.

#### **OPTN TRANSPLANT DATABASE**

In the early 1980s CMS began collecting data on all Medicare kidney transplants. In 1988, the United Network of Organ Sharing (now OPTN) was created to provide a national system for allocating donor organs. OPTN also began collecting data on all transplants. These two efforts were consolidated in 1994, and OPTN became the single source of data on transplant donors and recipients.

The CMS and OPTN transplant data files overlap for 1988–1993, and some patients with ME forms indicating transplant as the initial modality are not included in either file. To resolve conflicts among the three sources, the USRDS adopts the following procedure:

- » OPTN transplants are accepted into the database.
- » CMS transplants before 1988 are accepted.
- » CMS transplants from 1988 to 1993 are accepted if there is no OPTN transplant record for that patient within 30 days of the CMS transplant.
- » Transplants indicated on ME forms are accepted if there is no previously accepted record of a transplant for that patient within 30 days of the date listed on the ME form.

#### **CMS STANDARD ANALYTICAL FILES (SAFS)**

These files contain billing data from final action claims, submitted by Medicare beneficiaries with ESRD, in which all adjustments are resolved. For inpatient/outpatient institutional claims we use the following data: inpatient, 100 percent SAF; outpatient, 100 percent SAF; home health agency (HHA), 100 percent SAF; hospice, 100 percent SAF; and skilled nursing facility (SNF), 100 percent SAF. For physician/supplier claims, we use: physician/supplier, 100 percent SAF; and durable medical equipment (DME), 100 percent SAF.

CMS SAFS are updated each quarter through June of the next year, when the annual files are finalized. Datasets for the current year are created six months into the year and updated quarterly until finalized at 18 months, after which they are not updated to include late arriving claims. Annual files are thus approximately 98 percent

complete. The USRDS 2011 ADR includes all claims up to December 31, 2009. Patient-specific demographic and diagnosis information, however, includes data as recent as October, 2010.

Inpatient transplant and outpatient dialysis claims records are used to identify new ESRD patients for whom no ME form has been filed. These patients, primarily non-Medicare patients, or beneficiaries who develop ESRD while on Medicare because of age or disability, will eventually be entered into the REMIS/REBUS/PMMIS — and hence the USRDS — database through the claims records. For patients without ME forms these claims are the only reliable information from which to determine first ESRD service dates. These paid claims records are, however, only a supplement to, rather than a replacement of, other sources of data on incidence and prevalence.

The problem of timely identification has lessened with the revision of the ME form in April 1995, and the amended ESRD entitlement policy that now requires the form to be submitted for all ESRD patients regardless of insurance and eligibility status.

#### **CMS 5 PERCENT STANDARD ANALYTICAL FILES (SAFS)**

These files contain billing data from final action claims submitted by Medicare beneficiaries, in which all adjustments have been resolved. The claims data are selected randomly from general Medicare claims (final action claims) using five combinations of the last two digits of the CMS Health Insurance Claims (HIC) number: 05, 20, 45, 70, and 95. Since the same two-digit numbers are used each year, one should expect to see the same beneficiaries in these annual datasets. These claims are categorized into the inpatient (IP), outpatient (OP), home health agency (HHA), hospice (HS), skilled nursing facility (SNF), physician/supplier (PB), and durable medical equipment (DME) SAFS.

The files are updated each quarter through June of the next year, when annual files are finalized. Datasets for the current year are created six months into the year and updated quarterly until finalized at 18 months, after which they are not updated to include late arriving claims. Annual files are thus approximately 98 percent complete. The USRDS 2011 ADR includes all claims up to December 31, 2009.

#### **STANDARD INFORMATION MANAGEMENT SYSTEM (SIMS)**

##### **DATABASE (ESRD NETWORKS)**

The USRDS continues to collaborate with CMS and the ESRD networks to address data tracking issues relating to non-Medicare ESRD patients. Past ADRs have documented the lack of consistent Medicare claims data among these patients. Working solely with data from the ME form, the USRDS could establish the first ESRD service date, but could not generate a more detailed treatment history. With the integration of the SIMS event data into the USRDS database, however, we can now address issues in the non-Medicare ESRD population such as the large and growing number of lost-to-follow-up patients, and look as well at patients for whom there previously were no data on initial modality or death. This data integration is detailed in the section on data management and preparation.

#### **CMS DIALYSIS FACILITY COMPARE DATA**

The USRDS uses the CMS Dialysis Facility Compare data to define chain and ownership information for each renal facility. Prior to the 2003 ADR, similar data were extracted from the Independent Renal Facility Cost Report (CMS 265-94).

#### **ESRD CLINICAL PERFORMANCE MEASURES PROJECT**

CMS developed its ESRD Clinical Performance Measures Project (CPM, formerly the ESRD Core Indicators Project) to collect infor-

mation on the quality of care provided to dialysis patients. The data originate from data collection forms completed by staff at primary care facilities, and focus on dialysis adequacy measures, anemia management, and vascular access. Additional clinical parameters such as albumin are available as well. These data have been collected annually since 1994, using a random sample of adult (age 18 and older) patients alive and on dialysis at the end of each calendar year; on average, roughly 8,500 adult in-center hemodialysis patients and 1,500 peritoneal dialysis patients are surveyed each year. Data collection for all hemodialysis patients age 12–17 was begun in 2000. Collection was then expanded in 2002 to all in-center hemodialysis patients younger than 18, and in 2005 to all peritoneal dialysis patients of this age. The USRDS Coordinating Center, in collaboration with CMS, is now making these ESRD CPM data available to the general research community.

In anticipation of the national release of the CROWNWEB system and its supporting performance measures reports, CMS concluded its CPM project in 2009, making 2008 its final survey year. CMS is currently working with ESRD communities to develop new CPM measures on the CROWNWEB system.

#### MEDICARE CURRENT BENEFICIARY SURVEY (MCBS)

The Medicare Current Beneficiary Survey is a longitudinal survey of a nationally representative sample of aged, disabled, and institutionalized Medicare beneficiaries. The MCBS contains information on the health status, health care use and expenditures, drug prescriptions, health insurance coverage, and socioeconomic and demographic characteristics of the entire spectrum of Medicare beneficiaries. Data are made available by CMS in two datasets: Access to Care (1992–2008), and Cost and Use (1992–2007), with the 2008 and 2007 files, respectively, the latest updates for the 2011 ADR.

In the fall of 1991, the MCBS began to be conducted three times per calendar year (winter, summer, and fall), and in 1994 a sample rotation scheme was introduced. Survey participants are kept in the sample for four years, with approximately one-third rolling off, and with new participants added each fall to keep the overall sample size at approximately 12,000 each calendar year.

#### CMS PRESCRIPTION DRUG EVENT (PDE) FILE

In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), amending the Social Security Act by adding Part D under Title XVIII. With this new Part D coverage, health plans must submit a summary record called the prescription drug event (PDE) record to CMS whenever a Medicare beneficiary fills a prescription. The PDE record contains 37 data elements; the USRDS receives PDE records with 30 data elements and excluding a few non-critical fields. Each drug is identified by a National Drug Index (NDC) code; the record also contains prescription dosing information, drug costs above and below the out-of-pocket threshold, other true out-of-pocket (TROOP) amounts, plan paid amounts, and low-income cost-sharing subsidy amounts.

Due to delays in the availability of the data, only the 2006 and 2007 PDE files were available for the 2010 ADR; 2008 PDE data are included in this ADR.

#### THOMSON REUTERS MARKETSCAN DATA

The Thomson Reuters MarketScan Commercial Claims and Encounters Database includes specific health services records for employees and their dependents in a selection of large employers, health plans, and government and public organizations. The database includes nine files: Annual Enrollment Summary Table, Enroll-

ment Detail Table, Inpatient Admissions Table, Inpatient Services Table, Outpatient Services Table, Outpatient Pharmaceutical Claims Table, Facility (Inpatient and Outpatient) Header Table, Aggregated Populations Table, and the Red Book (prescription drug information by National Drug Code). The strength of this database lies in the quality of its cost information, where claims data include actual paid dollars and net payments by the insurer.

The MarketScan database links billing and encounter data to detailed patient demographic and enrollment information across sites and types of providers, and over time from 1999 to 2009, and includes commercial health data from approximately 100 payors. About 80 percent of those covered are self-insured. Each year the database contains health data for about 10.5 million people. For details about the MarketScan data, please visit [www.usrds.org](http://www.usrds.org).

#### INGENIX i3 DATA

The Ingenix i3 database is a commercial and non-capitated health plan database covering employees from multiple employers within a single insurer. In addition to the usual service encounter and drug data, similar to that of the MarketScan database, this database also includes laboratory data, allowing for comparisons between claims-based and lab-based definitions of diseases. In order to protect the discount structure of its business, the billing data of this single insurer discloses only charged dollars without actual paid amounts or the portion paid by the insurer.

The Ingenix i3 database links billing and encounter data to detailed demographic and enrollment information of individual employees from 2000 to 2009, and contains health data for approximately 14 million people annually. For details about what is contained in the Ingenix i3 data, please visit our website at [www.usrds.org](http://www.usrds.org).

#### NATIONAL HEALTH & NUTRITION EXAMINATION SURVEY (NHANES)

NHANES is a series of health examination surveys conducted by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC). Begun in 1960, NHANES is designed to monitor the health and nutritional status of the non-institutionalized civilian population in the United States. NHANES III was conducted in two phases between 1988 and 1994. In 1999, NHANES became a continuous annual survey to allow annual estimates, with release of public-use data files every two years. Both NHANES III and NHANES 1999–2008 were nationally representative cross-sectional surveys and used a complex, stratified, multi-stage probability cluster sampling design that included selection of primary sampling units (counties), household segments within the counties, and sample persons from selected households. Survey participants were interviewed in their homes and/or received standardized medical examinations in mobile examination centers. Both surveys over-sampled African Americans, Mexican Americans, and individuals age 60 or older to improve the estimates for these subgroups.

#### ANNUAL FACILITY SURVEY (AFS)

Independent ESRD patient counts are available not only from the CMS ESRD database, but also from CMS's Annual Facility Survey (CMS 2744), which all Medicare-certified dialysis units must complete at the end of each year. The AFS reports counts of patients being treated at the end of the year, new ESRD patients starting treatment during the year, and patients dying during the year. Both Medicare and non-Medicare end-of-year patients are counted. While AFS files do not carry patient-specific demographic and diagnosis data, they

provide independent patient counts used to complement the CMS patient-specific records. Starting with the 2005 ADR, CMS stopped posting data from these surveys on the web. And beginning with the 2007 ADR, the USRDS has extracted the relevant facility survey data directly from the SIMS database.

#### CDC SURVEILLANCE

The CDC used its National Surveillance of Dialysis-Associated Diseases to collect data from U.S. dialysis facilities on patient and staff counts, membrane types, reuse practices, water treatment, therapy, vascular access use, antibiotic use, hepatitis vaccination and conversion rates, and the incidence of HIV, AIDS, and tuberculosis. No data are patient-specific. The CDC did not conduct a survey in 1998, and terminated this program after 2002.

#### UNITED STATES CENSUS

In rate calculations throughout this year's ADR we use data from the 2000 U.S. Census, and also incorporate CDC population estimates by race. Our methods are described on later in this appendix.

#### DATA MANAGEMENT AND PREPARATION

Our main computer system is based on a VMS cluster running Alpha EV6 processors. We currently maintain three nodes in the cluster: three 4-CPU (i.e. Alpha EV6 processor) servers, each with 16-GB RAM memory. Through the HP Advanced Server System, we map VMS directories to network shares accessible to Windows clients as mapped network drives. The Alpha EV6s are connected to 30 terabytes of RAID-5 (Redundant Array of Independent Disks, level 5) disk farms, which are managed by three interconnecting high-speed disk controllers via Fibre Channel. All data in disk farms are independently accessible through Alpha server nodes.

We use SAS database management system and development tools as our core database technology platform; this differs from the Oracle RDBMS system used by the previous contractor only in physical data allocation and management. All information in the earlier system was integrated into the new database, and its continuity and completeness are maintained.

#### DATA LOADING AND CLEANING

The USRDS receives data files in IBM 3490 and 3490e cartridges/CD-ROMs with EBCDIC, ASCII, or SAS formats. Due to increased awareness of and concerns over data security and patient privacy protection, in 2008 CMS began delivering most of the USRDS requested data via a dedicated and secured T1 line connection. CMS has also instituted data encryption procedures on all out-bound data regardless of file format and transportation medium. Once loaded and decrypted, files are converted into SAS datasets for processing, and a series of data verification steps is completed to ensure data quality and integrity before updating the USRDS database.

#### DATABASE UPDATES

For this ADR, patient demographic and diagnosis data are updated through October, 2010, and Medicare inpatient/outpatient and physician/supplier claims through December 31, 2009.

#### ESRD PATIENT DETERMINATION

A person is identified as having ESRD when a physician certifies the disease on the CMS ME form, or when there is other evidence of chronic dialysis or a kidney transplant. Patients with acute kidney failure who are on dialysis for days or weeks, but who then recover kidney function, are excluded from the database if their ME forms

have not been submitted. Patients who die soon after kidney failure without receiving dialysis are sometimes missed.

The ESRD First Service Date (FSD) is the single most important data element in the USRDS database, and each patient must, at a minimum, have a valid FSD. This date is used to determine the incident year of each new patient and the first year in which the patient is counted as prevalent. The date 90 days after the FSD is used as the starting point for most survival analyses.

The FSD is derived by taking the earliest of the date of the start of dialysis for chronic kidney failure, as reported on the ME form; the date of a kidney transplant, as reported on a CMS or OPTN transplant form, an ME form, or a hospital inpatient claim; or the date of the first Medicare dialysis claim. Most FSDs are obtained from the ME form. In the absence of this form, the date of the first Medicare dialysis claim or transplant usually supplies the FSD. In the few cases in which the date of the earliest dialysis claim precedes the first dialysis date reported on the ME form, the earliest claim date is used as the FSD. However, starting with the 2007 ADR, a patient entering into the ESRD program after December 31, 1994, has his or her FSD defined solely by the regular dialysis start date or the preemptive transplant date, whichever is earliest, on the ME form. This new method of determining the FSD aligns more closely to the methods used by CMS. After careful monitoring and repeated comparative analyses of the traditional USRDS method to the new ME method, the USRDS began applying the ME method to incident patients entering into the ESRD program on or after January 1, 1995.

#### MEDICARE AND NON-MEDICARE ('ZZ') PATIENTS

Beneficiaries are enrolled in Medicare based on criteria defined in Title XVIII of the Social Security Act of 1965, and in subsequent amendments to the act. A person in one of these four categories is eligible to apply for Medicare: age 65 and over, disabled, ESRD program, and Railroad Retirement Board (RRB).

Most ESRD patients are eligible to apply for Medicare as their primary insurance payor. Some, however, are not immediately eligible for Medicare coverage because of their employment status and insurance benefits. These patients are usually covered by employer group health plans (EGHPS), and must wait 30–33 months before becoming eligible to have Medicare as their primary payor. Some of these patients, particularly new patients since 1995, have FSDs established by ME forms, but have no dialysis claims or hospitalization events in the CMS claims database. In the REBUS/PMMIS database all non-Medicare ESRD patients are assigned a code of 'zz' in the two-character Beneficiary Identification Code field. CMS does not generally include these patients in the datasets released to researchers.

The USRDS recognizes that 'zz' patients are true ESRD patients, and should be included in patient counts for incidence, prevalence, and modality. Calculations of standardized mortality ratios, standardized hospitalization ratios, and standardized transplantation ratios, however, should not include these patients because of the small number of claims available in the first 30–33 months after their first ESRD service. Furthermore, it may not be possible to link 'zz' patients to their ESRD Death Notification forms or the OPTN transplant data, or to determine comorbidity or inpatient/outpatient and physician/supplier services. Because such data are limited, event rates that include these patients must be assessed with caution.

We continue to include 'zz' patients in the mortality rate calculations of the ADR. The USRDS, in working with CMS, has been able to resolve most of the 'zz' patients since the release of the ESRD Patient Database, REMIS, in the fall of 2003. According to our most recent assessment — performed during production of the 2007 ADR — we

have determined that at least 99 percent of ‘zz’ patients have been resolved due to significant advancements in the REMIS/REBUS database system.

#### DEATH DATE DETERMINATION

After the ESRD First Service Date, the date of death is the most critical piece of information in the ESRD database. Death dates are obtained from several sources, including the CMS Medicare Enrollment Database, CMS forms 2746 (ESRD Death Notification form) and 2728 (ESRD Medical Evidence form), the OPTN transplant follow-up form, the ESRD Network SIMS database, and the Social Security Death Master File. Because multiple sources report death information for the same patient, one patient may have several reported dates. The USRDS therefore uses an algorithm to determine the date of death. EDB information is given first priority, and, in the absence of an EDB death date, other sources are evaluated in the following order: form 2746, form 2728, SIMS data, the transplant follow-up form, and, if no other death date is available, the Death Master file.

#### LOST-TO-FOLLOW-UP METHODOLOGY

The USRDS uses all available data to create a treatment history for each patient in the database, including all modality events, their duration, and the renal providers involved in each patient's care.

Gaps frequently exist in the billing data upon which modality periods are based. The USRDS assumes that a modality continues until death or the next modality-determining event. A patient with a functioning transplant is assumed to maintain it unless a transplant failure or death notification is encountered in the data. In the absence of a death notification, dialysis claims, or other confirmation of a continuing modality, a dialysis modality, in contrast, is assumed to continue for only 365 days from the date of the last claim. After this period the patient is declared lost-to-follow-up until the occurrence of a dialysis claim or transplant event.

Because Medicare may be the secondary payor for up to the first 30–33 months of ESRD, delaying the submission of Medicare dialysis claims, lost-to-follow-up categorization cannot begin until the end of the third year after the start of ESRD service. This “first three-year rule” is particularly important for non-Medicare patients, who may be followed for up to three years with limited event or mortality data. These patients would contribute dialysis or transplant days to the denominator of rate calculations, but only questionable event data to the numerator. In comparison to the two-year rule used in the 2001 ADR, this three-year rule significantly reduces the number of lost-to-follow-up patients in the prevalent population.

A number of events can result in a lack of dialysis data and eventual reclassification of a patient as lost-to-follow-up:

- » The patient may have recovered renal function (RRF) and no longer have ESRD. For a valid patient classification, this event must occur within 180 days of the FSD, and the RRF period must persist for at least 90 days.
- » The patient may have left the country.
- » The patient may receive dialysis covered by a payor other than Medicare, or have received a transplant not paid for by Medicare or reported to OPTN.
- » The patient may be enrolled in a Medicare HMO, so that Medicare dialysis claims are not generated even though the patient is eligible for Medicare coverage.
- » The patient's death may not have been reported to the Social Security Administration or to CMS.

#### INTEGRATION OF THE USRDS, SIMS, AND REMIS DATABASES

We have worked to reconcile ESRD patients in the SIMS, REMIS, and USRDS databases. We have analyzed each database for duplicate records, consolidated these records, and integrated the databases. Data were then re-analyzed for duplicates, which were themselves consolidated. This consolidation of patients is an ongoing collaborative effort between the ESRD Networks, CMS, and the USRDS.

Treatment histories compiled by the USRDS rely on Medicare dialysis billing records, which contain no information on dialysis therapy or modality changes in non-Medicare patients. Beginning with the 2003 ADR, we incorporate treatment-specific information from the ESRD Networks' SIMS event database to improve the tracking of these patients in the USRDS database, and of patients who are considered lost-to-follow-up. Efforts to integrate the USRDS, SIMS, and REMIS databases continue to pay dividends in reducing the number of lost-to-follow-up patients.

We continue to take a conservative approach to incorporating SIMS Event History data into the USRDS treatment history; as we learn more about the data, we may expand this approach. We currently make the following updates on an annual basis:

- » The USRDS database is updated with mortality data from the SIMS event database.
- » The database is updated for each incident patient whose initial modality is listed as “unknown dialysis,” and for whom the SIMS database lists a known dialytic modality within 90 days of the established first ESRD service date.
- » Data on non-Medicare “lost-to-follow-up” patients are substituted with available SIMS treatment information.

Since 2007 we have included the RRF event in the modality sequence, reducing lost-to-follow-up episodes for prevalent patients. This event is now established in our database only if it occurs within the first 180 days of the FSD and lasts for at least 90 days, a definition more conservative than that in the SIMS event database.

#### 60-DAY STABLE MODALITY RULE: TREATMENT HISTORY

This rule requires that a modality continue for at least 60 days before it is considered a primary or switched modality. It is used to construct a patient's modality sequence, or treatment history, so that incident and prevalent patients are known to have stable and established modalities. Starting with the 2003 ADR, all descriptive data in the incident, prevalent, and modality sections are based on incident and prevalent cohorts produced from the modality sequence without using this rule. In analyses of patient outcomes such as hospitalization and mortality, in contrast, this rule is applied.

#### 90-DAY RULE: OUTCOMES ANALYSES

This rule defines each patient's start date, for data analyses, as day 91 of ESRD. Allowing outcomes to be compared among all ESRD patients at a stable and logical point in time, it is used primarily to calculate survival rates and compare outcomes by modality at several points in time. Use of the rule overcomes the difficulties of examining data from the first three months of ESRD service (an unstable time for new patients as renal providers try to determine the best treatment modality), and from in-center hemodialysis patients younger than 65 and not disabled, who cannot bill Medicare for their dialysis treatments and hospitalizations until 90 days after the first ESRD service date. Patients on peritoneal dialysis or home dialysis, or with transplant as the first modality, can bill immediately.

## SERUM ALBUMIN DATA

The ME form reports albumin level along with the test's lower limit, which indicates the testing method: bromcresol purple or bromcresol green, with lower limits of 3.2 and 3.5 g/dl, respectively.

In producing the 2004 ADR we found that, in 1995–2003, almost 50 percent of forms contained lower limit values equal to “zero,” while another 25 percent reported values other than the expected 3.2 and 3.5 g/dl. Only 25 percent (n=173,000) of incident patients had legitimate lower limit values. Further analyses, however, showed that these patients are a representative cohort sample, with similar demographic distributions by age, gender, race, and cause of ESRD to those of the overall ESRD population. For all figures in the 2005 and later ADRs which present serum albumin data from the ME form, we therefore include only those incident patients with both an albumin lower limit of 3.2 or 3.5 g/dl and an albumin value.

## database definitions

### MODALITIES

The USRDS and the CMS ESRD group have worked extensively on methods of categorizing patients by ESRD modality. While the ME 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 in the first 90 days, and it can be difficult to track modality during this time. Patients age 65 and older have Medicare claims in the first 90 days; these claims contain revenue codes designating modality. Patients younger than 65 and in employer group health plans (EGHPs) or Medicare risk programs, however, have no such claims. Modality may thus not be determined until Medicare becomes the primary payor at day 91 or, for EGHP patients, at 30–33 months after the first ESRD service date. These limitations influence our ability to determine a patient's modality at any one point in time.

Of particular concern are patients categorized as having an unstable modality (i.e., on a modality for fewer than 60 consecutive days) in the first 90 days, and who are thus not recognized as being hemodialysis or peritoneal dialysis patients. Because these patients tend to have higher death and hospitalization rates, interpretations of modality-specific outcome data including them 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.

As mentioned earlier, a new modality/event — recovered renal function — was introduced in the 2007 ADR. This event can be established only if it occurs within first 180 days of the FSD and if the RRF period persists for at least 90 days. The RRF event is similar to the lost-to-follow-up event in that patients with an RRF event will not be included in the prevalent populations for outcomes analyses. However, as with lost-to-follow-up events, we keep them in the modality sequence so that subsequent renal failure episodes can be tracked closely and in a timely manner.

Individual analyses categorize modalities in different ways; these are defined in the methods sections for each chapter.

### PAYORS

Information on payors is obtained from the CMS Medicare Enrollment Database. We also examine Medicare outpatient claims to identify patients for whom the EDB does not indicate Medicare as primary payor (MPP), but who have at least three consecutive months of dialysis treatment covered by Medicare; these patients are also designated as having MPP coverage. From these two data sources we construct a payor sequence file to provide payor history,

and, starting with the 2003 ADR, we use this file to identify Medicare eligibility status and other payors.

The construction of this file is similar to that of the treatment history file. Payor status is maintained for each ESRD patient from the first ESRD service date until death or the end of the study period. Payor data are used to categorize a patient as MPP, MSP with EGHP, MSP non-EGHP, Medicare Advantage (Medicare + Choice), Medicaid, or a combination of payors. With this approach, the USRDS is now able to apply payor status information in all outcome analyses using the “as-treated” model (see the discussion of Chapter Eleven).

## PRIMARY CAUSE OF RENAL FAILURE

Information on the primary cause of renal failure is obtained directly from the ME form. For the ADR we use eight categories, with ICD-9-CM codes as follows:

- » diabetes: 250.00 and 250.01
- » hypertension: 403.9, 440.1, and 593.81
- » glomerulonephritis: 580.0, 580.4, 582.0, 582.1, 582.9, 583.1, 583.2, 583.4, and 583.81
- » cystic kidney: 753.13, 753.14, and 753.16
- » other urologic: 223.0, 223.9, 590.0, 592.0, 592.9, and 599.6
- » other cause: all other ICD-9-CM codes covered in the list of primary causes on the ME form, with the exception of 799.9
- » unknown cause: 799.9 and ICD-9-CM codes not covered in the list of primary causes on the ME form
- » missing cause: no ICD-9-CM code listed

## RACE AND ETHNICITY

Data on patient race and ethnicity are obtained from the ME form, the CMS Medicare Enrollment Database, and the REMIS/REBUS identification file. Because they are addressed in separate questions on the ME form, racial and ethnic categories can overlap.

Patient ethnicity became a required field on the 1995 revised ME form; because data for 1995 are incomplete, information on Hispanic patients is presented starting in 1996. The non-Hispanic category includes all non-Hispanics and patients with unknown ethnicity.

Because of the small number of ESRD patients of some races, as well as the construction of the U.S. census data, we concentrate on white, African American, Native American (including Alaskan Native), and Asian (including Pacific Islander) populations. Data on patients of other races will be presented as their numbers increase.

## EGHP COHORT

As mentioned, EGHP data in this year's ADR are derived from the MarketScan and Ingenix i3 databases. To examine the demographic segment not represented by Medicare, we use enrollment information to construct yearly cohorts of enrollees younger than 65. To ensure that we select enrollees with the potential to generate claims evidence appropriate to the analytical demands, rules for inclusion also include 12 months of continuous coverage in a commercial fee-for-service plan, and, for medication analyses, continuous prescription drug coverage. Comorbidities are identified using claims. Patients with at least one inpatient claim or at least two outpatient claims during the period of interest and with a diagnosis code of a particular comorbidity are identified as having that comorbidity.

## ESRD COHORT IN THE EGHP POPULATION

As the MarketScan and i3 databases provide no identifiable data elements, we cannot link them directly to the USRDS ESRD registry. To identify ESRD patients we thus use a process similar to that of the

registry. Transplant patients are identified by evidence of a transplant procedure or adverse graft event, and chronic dialysis patients by evidence of continuous history of dialysis therapy, with at least three consecutive months of dialysis service and with service claims in at least 70 percent of treatment months. Treatment months are defined from the first dialysis claim to the earliest of kidney transplant, death, or end of enrollment. Both inpatient and outpatient claims are evaluated for evidence of dialysis service history.

The first ESRD service date is set to the earliest of the first dialysis service date or the transplant date. If neither is available, the start of enrollment is used. Incidence is defined by a first ESRD service date at least 60 days after the start of enrollment.



### PRÉCIS

For Figure p.1 we identify chronic kidney disease (CKD), congestive heart failure (CHF), and diabetes in patients from the 5 percent Medicare sample, using methods described for Chapter Eleven; these methods are also used to determine diabetic status and CHF in the ESRD population.

Costs for the "cost year" are determined for the entire calendar year for patients who have fee-for-service coverage and Medicare as primary payor. Because this analysis combines the ESRD cohort with the 5 percent Medicare sample, ESRD patients in the 5 percent sample are excluded.

Methods for the portion of Table p.a that addresses Medicare spending are addressed in the discussion of Chapter Eleven.

Total transplant counts shown in Table p.a include all transplants performed in 2009, as reported by the OPTN. Transplants of unknown donor type are excluded from by-donor counts. New wait list counts include all patients added to the list for a kidney-alone or kidney-pancreas transplant in 2009; patients added at multiple centers are counted once. The total N on the wait list includes all patients listed for a kidney-alone or kidney-pancreas transplant as of December 31, 2009, regardless of when they first listed. If patients are added to the list in early 2009 and removed from the list before the end of the year, it is possible for a group to have more new patients than existing patients. Median time on the list is shown for patients on the list on December 31, 2009.

Data for Table p.2 are from the CMS Annual Facility Survey.

### Healthy People 2020

**Objective CKD-3** Data for this objective include all patients in the 5 percent Medicare sample who are age 65 and older and who have hospitalized acute kidney injury (AKI) events in the given year (1992–2009). Hospitalized AKI is defined by ICD-9-CM diagnosis code 584 in inpatient claims,

and renal evaluation is identified by having a microalbumin test. Patients are followed from the discharge date to the earliest date of death, ESRD, end of Medicare coverage, or six months after the discharge date. CPT codes for urinary microalbumin measurement are identified from HEDIS 2008 specifications (HEDIS 2008, an NCQA program, is used to monitor the performance of managed health care plans), and include 82042, 82043, 82044, and 84156.

**Objective D-12** The cohort includes general Medicare patients diagnosed with diabetes in each year, continuously enrolled in Medicare Parts A and B during the whole year, and age 65 or older at the beginning of the year. CPT codes for urinary microalbumin measurement are those used in Objective CKD-3, above. Testing is tracked during each year. Methods of defining diabetes are described in the appendix of the CKD volume.

**Objective CKD-4.1** The cohort here is similar to that used for Objective D-12, but includes all CKD patients. Testing is tracked during each year. Patients are excluded if they are enrolled in a managed care program (HMO), acquire Medicare as secondary payor, are diagnosed with ESRD during the year, have a missing date of birth, or do not live in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Racial and ethnic categories are mutually exclusive. Methods of defining CKD are described in the appendix of the CKD volume. Serum creatinine is identified through CPT codes 80047–80050, 80053–80054, 80069, and 82565, while lipid testing is identified through CPT codes 80061, 82465, 82470, 83695, 83705, 83715–83721, 84478, 83700, 83701, and 83704. CPT codes for urinary microalbumin measurement are the same as those used for Objective CKD-3, above.

**Objective CKD-4.2** Methods and codes used to determine rates of glycosylated hemoglobin (A1C) testing and eye examinations are taken from HEDIS 2008 specifications. CPT codes 83036 and 83037 are used to identify A1C testing. Codes used to identify diabetic eye examinations are as follows: CPT codes, 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92226, 92230, 92235, 92240, 92250, 92260, 67101, 67105, 67107, 67108, 67110, 67112, 67141, 67145, 67208, 67210, 67218, 67227, 67228, 67028, 67030, 67031, 67036, 67038, 67039, 67041, 67042, 67043, 67113, 67121, 67221, 67228, S0625, S0620, S0621, and S3000; ICD-9-CM procedure codes, 14.1–14.5, 14.9, 95.02, 95.03, 95.04, 95.11, 95.12, and 95.16; and ICD-9-CM diagnosis code V72.0. The cohort is similar to that used for Objective CKD-4.1, but includes all diabetic CKD patients. Methods of defining diabetes are described in the appendix of the CKD volume.

**Objective CKD-5** The cohort includes general Medicare patients diagnosed with both diabetes and chronic kidney disease in each year, continuously enrolled in the Medicare inpatient/outpatient and physician/supplier program during the entire year, and age 65 or older at the beginning of the year. Additionally, for 2006, patients are enrolled in Medicare Part D for at least six months; in 2007–2008, patients are enrolled in Medicare Part D during the entire year. Use of angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin II receptor blockers (ARBs) is defined by at least one prescription fill from either drug class during the year.

**Objective CKD-8** Incident rates are calculated using the methods described for Chapter One. Overall rates are adjusted by age, gender, and race; rates by age are adjusted for gender and race; rates by gender are adjusted for age and race; and rates by race and ethnicity are adjusted by age and gender.

**Objective CKD-9.1** Rates of kidney failure due to diabetes are also calculated using the methods described for Chapter One, and adjustments are the same as those described for Objective CKD-8, above.

**Objective CKD-9.2** This table uses data from the National Health Interview Survey (NHIS), 2006–2010; all ages are included. Three-year data are used to estimate the prevalence of diabetes in the middle year, and the size of the population with diabetes is based on U.S. census data. The incident rate per million of ESRD caused by diabetes is calculated as the number of incident ESRD patients with a primary diagnosis of diabetes divided by the size of the population with diabetes in that group.

**Objectives CKD-10 & CKD-11.3** These tables use data from the newest version of the ME form. The cohorts include incident hemodialysis patients, with CKD-11.3 limited to those age 18 and older at initiation and with a known vascular access at that time. CKD-10 includes only patients for whom it is known whether they saw a nephrologist prior to initiation.

**Objectives CKD-11.1 & CKD-11.2** use data from the CMS ESRD Clinical Performance Measures (CPM) project. Included patients are those whose date of dialysis initiation, according to the CPM data, occurs in the same year as the data collection, and access type represents the access used during the last quarter of the year, according to the CPM data.

**Objective CKD-12** The cohort here includes patients younger than 70 in 1991–2008. Percentages are calculated as the number of patients placed on the deceased donor organ wait list or receiving a deceased donor transplant within one year of initiation, divided by the number of patients without a living donor available (i.e., patients receiving a living donor transplant are excluded), and are estimated using the Kaplan-Meier method.

**Objective CKD-13.1** Data include patients from 1991–2006 who are younger than 70 at ESRD certification. Patients are followed for three years, from ESRD certification until the first of death, transplant, or censoring at three years post-transplant. Percentages are calculated using the Kaplan-Meier methodology.

**Objective CKD-13.2** The cohort includes patients from 1992–2009 who are younger than 70 at the initiation of ESRD. Pre-emptive transplants are those in which ESRD initiation date is the date of transplant. Percentages are calculated in the usual way:  $100 * (N/D)$ , where N = the number of preemptive transplants in the year and D = the number of ESRD patients in the year.

**Objectives CKD-14.1 & CKD-14.3** Cohorts for these tables include period prevalent dialysis patients in each calendar year, 1992–2009, whose first ESRD service date is at least 90 days prior to the beginning of the year (point prevalent patients on January 1) or who reach day 91 of ESRD treatment during the year (incident patients). We exclude patients with unknown age, gender, or race, and those with an age calculated to be less than zero, as well as patients who are not residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories. Age is calculated on January 1, and race is defined from the ME form. Cardiovascular mortality is defined using codes from past and current Death Notification forms: 01, 02, 03, 04, 1, 2, 3, 4, 23, 25, 26, 27, 28, 29, 30, 31, 32, 36, and 37. Patients are followed from January 1 (for point prevalent dialysis patients) or day 91 of ESRD (for incident dialysis patients) until death, transplant, or December 31 of the year. Rates are estimated as the number of patients who die from any cause (Objective 14.1) and who die from cardiovascular disease (Objective 14.3) in each year, per 1,000 patient years at risk.

**Objective CKD-14.2** Cohorts here include incident dialysis patients in each calendar year, 1999–2009. In addition to applying the same exclusion criteria described for Objectives 14.1 and 14.3, we further exclude patients with recovered kidney function. Age is calculated on the first ESRD service date. Patients are followed from the first service date until death, transplant, or 90 days after ESRD. Rates are estimated as the number of patients who die from any cause per 1,000 patient years at risk.

**Objectives CKD-14.4–5** Patient cohorts here include period prevalent transplant patients, 1992–2009, whose first ESRD service date is at least 90 days prior to the beginning of the year (point prevalent patients on January 1) or who reach day 91 of ESRD treatment (incident patients). Exclusion criteria are the same as those described for Objectives 14.1 and 14.3. Patients are followed from January 1 (for point prevalent dialysis patients) or day 91 of ESRD (for incident dialysis patients) until death or December 31 of the year. Rates are estimated as the number of patients who die from any cause (Objective 14.4) and who die from cardiovascular disease (Objective 14.5) in each year, per 1,000 patient years at risk.



## INCIDENCE, PREVALENCE, PATIENT CHARACTERISTICS, AND TREATMENT MODALITIES

### CHAPTER ONE

#### INCIDENCE & PREVALENCE

Here and throughout the ADR, the USRDS generally reports point prevalence—the type of prevalence used throughout most of the book—as of December 31, while period prevalence is reported for a calendar year. Annual period prevalent data thus consist both of patients who have the disease at the end of the year and those who have the disease during the year and die before the year's end. Because the USRDS treats successful transplantation as a therapy rather than as a "recovery" from ESRD, patients with a functioning transplant are counted as prevalent patients.

Because data are available only for patients whose ESRD therapy is reported to CMS, patients who die of ESRD before receiving treatment or whose therapy is not reported to CMS are not included in the database. We therefore qualify the terms incidence and prevalence as incidence and prevalence of reported ESRD. Some ESRD registries use the term "acceptance into ESRD therapy." We believe, however, that "incidence of reported ESRD therapy" is more precise, because "acceptance" implies that remaining patients are rejected, when they may simply not be identified as ESRD cases or may not be reported to CMS. Beginning with the 1992 ADR, lost-to-follow-up patients are not included in the point prevalent counts; they are, however, reported in Table B.1 of the Reference Tables.

Rate adjustments in this chapter are as follows: overall rates (including those in the maps) are adjusted for age, gender, and race; rates by age are adjusted for gender and race; rates by race or ethnicity are adjusted for age and gender; and rates by primary diagnosis are adjusted for age, gender, and race.

In Figure 1.2, absolute standardized differences are shown for matching variables, before and after the match. An absolute value of standardized differences greater than 10 percent indicates significant imbalance. The definition depends on the type of variable:

##### » Continuous variables

$$d = \frac{100(\bar{x}_{\text{treatment}} - \bar{x}_{\text{control}})}{\sqrt{\frac{s^2_{\text{treatment}} + s^2_{\text{control}}}{2}}}$$

##### » Binary variables

$$d = \frac{100(p_{\text{treatment}} - p_{\text{control}})}{\sqrt{\frac{p_{\text{treatment}}(1-p_{\text{treatment}}) + p_{\text{control}}(1-p_{\text{control}})}{2}}}$$

## PATIENT CARE AND LABORATORY VALUES

Table 1.f and Figures 1.17–19 includes 2009 incident hemodialysis patients with ME forms. Access type is identified from the ME form, and data exclude patients with unknown access type.

Data for Figures 1.20–23 and Table 1.g are also obtained from the ME form.

## REFERENCE SECTION A

The Reference Tables present parallel sets of counts and rates for incidence (Section A) and December 31 point prevalence (Section B). Section B also presents annual period prevalent counts and counts of lost-to-follow-up patients. Because the U.S. population figures (shown in Reference Section M) used in the ADR include only residents of the 50 states and the District of Columbia, tables also focus

on patients from these areas. Exceptions are Tables A.1, A.6, A.8, and A.10, all of which present data specific to patients in Puerto Rico and the Territories, or include these patients in the patient population. Age is computed as of the beginning of ESRD therapy.

Rates in Table A.9 are calculated using the model-based method (described in the Statistical Methods section later in this appendix), and adjusted for age, race, and gender, with the 2005 national population as reference.

#### REFERENCE SECTION B

With the exception of Tables B.1, B.6, B.8, and B.10, these tables focus on patients in the 50 states and the District of Columbia. Age is calculated as of December 31. Table B.9 is constructed similarly to Table A.9.

#### REFERENCE SECTION C

Data used in these tables are obtained from the ME form.

#### TREATMENT MODALITIES

Modality figures and the associated reference tables describe the treatment modalities of all known ESRD patients, both Medicare and non-Medicare, who are not classified as lost-to-follow-up or having recovered renal function (RRF). The RRF event, introduced in the 2007 ADR, is defined as an event that occurs within the first 180 days of ESRD initiation and lasts for at least 90 days. By definition, patients classified as having RRF post-initiation are included in the incident counts. Unless noted otherwise, incident and point prevalent cohorts without the 60-day stable modality rule are used in the analyses. Treatment modalities are defined as follows:

- » center hemodialysis: hemodialysis treatment received at a dialysis center
- » center self-hemodialysis: hemodialysis administered by the patient at a dialysis center; a category usually combined with center hemodialysis
- » home hemodialysis: hemodialysis administered by the patient at home; cannot always be reliably identified in the database
- » CAPD: continuous ambulatory peritoneal dialysis; usually combined with CCPD
- » CCPD: continuous cycling peritoneal dialysis; usually combined with CAPD
- » peritoneal dialysis: analyses typically consist of CAPD and CCPD only, unless stated otherwise
- » other peritoneal dialysis: primarily intermittent peritoneal dialysis (IPD), a small category except among very young children; usually combined with unknown dialysis and uncertain dialysis to form an other/unknown dialysis category
- » uncertain dialysis: a period in which the dialysis type is unknown or multiple modalities occur but none last 60 days; usually combined with other peritoneal dialysis and unknown dialysis to form an other/unknown dialysis category
- » unknown dialysis: a period in which the dialysis modality is not known (e.g. when dialysis sessions are performed in a hospital); usually combined with other peritoneal dialysis (IPD) and uncertain dialysis to form an other/unknown dialysis category
- » renal transplantation: a functioning graft from either a living donor (a blood relative or other living person) or a deceased donor

- » death: a category not appearing in the year-end modality tables, which report only living patients, but used as an outcome (e.g. in tables showing living patients followed for a period of time for their modality treatment history)

In Tables 1.d–e, rates by age are adjusted for gender and race, rates by gender are adjusted for age and race, rates by race and ethnicity are adjusted for age and gender, and rates by primary diagnosis are adjusted for age, gender, and race.

#### REFERENCE SECTION D

Reference Section D is divided into four parts. The first, Tables D.1–11 and D.15–16, provides counts and percentages — by demographics, geographic location, and treatment modality — of incident and prevalent patients alive at the end of each year. Age is computed as of the start of ESRD for incident patients, and as of December 31 for point prevalent patients.

Table D.12 shows modality at day 90 and at two years after first service for all incident Medicare patients beginning renal replacement therapy from 2005 to 2007. The 90-day rule is used to exclude patients who die during the first 90 days of ESRD, and age is computed as of the first ESRD service date.

The third section, Tables D.13–14, presents counts of prevalent patients alive at the end of each year, by ESRD exposure time and modality. Table D.13 shows counts by the number of years of ESRD, while Table D.14 presents counts by the number of years on the end-of-year treatment modality. For the duration of ESRD exposure, zero should be read as less than one year, one as at least one full year but less than two, and so on.

The fourth section, Tables D.17–24, presents counts of incident and prevalent patients alive at the end of selected years (i.e. 2001, 2005, 2009), by demographic characteristics, payor category, and treatment modality. Again, age is computed as of the start of ESRD for incident patients, and as of December 31 for point prevalent patients. The definitions of payor categories can be found in the section on database definitions at the beginning of this appendix.

#### PATIENT CARE AND LABORATORY VALUES

Table 1.f and Figures 1.17–19 include 2009 incident hemodialysis patients with ME forms. Access type is identified from the ME form, and data exclude patients with unknown access type.



#### CLINICAL INDICATORS AND PREVENTIVE CARE CHAPTER TWO

In Figure 2.1, for both kt/v measurements, 2008 ESRD CPM data are used to calculate a mean kt/v value for each patient from the 1–3 values present for each, and the percent of patients with a mean kt/v over a certain threshold is determined. For prevalent hemodialysis patients in 2009, each patient's URR is obtained from the G-modifier attached to CPT code 90999, with a revenue code of 821 or 825. Each measurement is categorized into one of five ranges, and the median URR is calculated; for patients whose median lies between two ranges, we assign a weight of 0.5 to each. Information on new hemodialysis patients with an arteriovenous fistula as the first access is calculated from combined USRDS and CPM data. Vascular access represents the access used during the CPM collection period for patients who initiated hemodialysis during that same year. Hemoglobin levels are calculated for EPO-treated, 2009 prevalent hemodialysis patients, using available EPO claims during the year. EPO claims with a dose per administration of less than 500

or greater than 80,000 units, or with a hematocrit value less than 10 percent or greater than 50, are omitted. For each patient a yearly mean hemoglobin is calculated as the mean of all hematocrit values divided by three. Data for diabetic care are from obtained from Figures 2.8, 2.9, and 2.11, while data for influenza, pneumococcal pneumonia, and hepatitis B vaccinations are from Table 2.a.

#### ANEMIA TREATMENT

Figure 2.2 presents the monthly distribution of patients by mean hemoglobin group, with each month containing all patients with at least one valid EPO claim during the month. The hemoglobin is calculated as the reported hematocrit value divided by three. Figure 2.3 shows the mean hemoglobin, by month, for prevalent dialysis patients with EPO claims, along with the monthly EPO dose per week for patients with 20 or fewer administrations per month. A patient's time at risk includes only those days in which he or she is not in an inpatient hospital setting.

Figures 2.4–7 include data from all incident dialysis patients with an EPO claim in the first 30 days of ESRD therapy and with at least one EPO claim during each of the following six months. EPO claims with a dose per administration of less than 500 units or more than 80,000 units are omitted, as are those with an average dose per day (calculated as the total EPO units on the claim divided by the number of days spanned by the claim) of less than 100 units or greater than 10,000 units. For 2009, patients are incident prior to June 1, to allow them to have six months of EPO and/or iron claims after their incident date. For graphs by starting hemoglobin, patients are included only if they have a hematocrit listed on the ME form, and their starting hemoglobin is determined from this value. In Figure 2.4, a mean hemoglobin is calculated for each patient from claims during the month, and the average of these values is then calculated for each month. For Figure 2.5, the mean EPO dose per week is adjusted by only including days during a month in which a patient is not in an inpatient hospital setting, so that the mean EPO dose represents outpatient dosing only.

#### PREVENTIVE CARE

Figures 2.8–11 present data on diabetic preventive care. ESRD patients without Medicare inpatient/outpatient and physician/supplier coverage during the entire study period are omitted from these analyses, as are general Medicare patients enrolled in an HMO or diagnosed with ESRD during the study period. Also omitted are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories; who have a missing date of birth; who do not survive the entire reporting period; who have ESRD for fewer than 90 days prior to the start of the reporting interval; or who are lost-to-follow-up during the study period.

Age is generally calculated at the end of the study period. Methods and codes used to determine rates of glycosylated hemoglobin (A1c) testing and eye examinations are taken from HEDIS 2008 specifications. CPT codes 83036 and 83037 are used to identify diabetic glycosylated hemoglobin testing (A1c; claims made within 30 days of the last claim for each patient are excluded, and at least two A1c claims must be counted). Codes used to identify diabetic eye examinations are as follows: CPT codes, 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92226, 92230, 92235, 92240, 92250, 92260, 67101, 67105, 67107, 67108, 67110, 67112, 67141, 67145, 67208, 67210, 67218, 67227, 67228, 67028, 67030, 67031, 67036, 67038, 67039, 67041, 67042, 67043, 67113, 67121, 67221, 67228, S0625, S0620, S0621, and S3000; ICD-9-CM procedure codes, 14.1–14.5, 14.9, 95.02, 95.03, 95.04, 95.11, 95.12, and 95.16; and ICD-9-CM diagnosis code V72.0. Lipid

testing is identified through CPT codes 80061, 82465, 83715–83721, 84478, 83700, 83701, and 83704. Patients are defined as having diabetes either through medical claims (one inpatient/outpatient, two physician/supplier, two outpatient, or one physician/supplier and one outpatient), or through a listing of diabetes on the ME form as the primary cause of ESRD or as a comorbid condition. ICD-9-CM diagnosis codes used to define diabetes are 250, 357.2, 362.0x, and 366.41. Comprehensive diabetic care includes at least four A1c tests, at least two lipids tests, and at least one eye exam. A1c and lipid tests are at least 30 days apart.

The ESRD population includes patients initiating therapy at least 90 days prior to January 1 of the first year of each study period and with diabetes in the first year. Testing is tracked in the second year of each study period, and tests are at least 30 days apart.

Table 2.a shows rates of influenza, pneumococcal pneumonia, and hepatitis B vaccinations for prevalent ESRD patients by modality, age, race/ethnicity, and time period. The cohort for influenza vaccinations includes all ESRD patients initiating therapy at least 90 days prior to September 1 of each year and alive on December 31. For pneumococcal pneumonia vaccinations, the cohort includes all ESRD patients initiating therapy at least 90 days before January 1 of the graphed time period and alive on December 31. And the cohort for hepatitis B vaccinations includes patients initiating therapy at least 90 days before January 1 of each year and alive on December 31. Patients without Medicare inpatient/outpatient and physician/supplier coverage during the study period are omitted, as are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories; who have a missing date of birth; who have ESRD for fewer than 90 days prior to the start of the study period; or who are lost-to-follow-up during the study period. Influenza vaccinations are tracked between September 1 and December 31 of each year, pneumococcal pneumonia vaccinations are tracked during the time periods reported, while hepatitis B vaccinations are tracked in each year. All ages are calculated at the end of the graphed time period. Influenza vaccinations are identified by CPT codes 90724, 90657, 90658, 90659, and 90660, and HCPCS code G0008; pneumococcal vaccinations through CPT codes 90669 and 90732, and HCPCS codes J6065 and G0009; and hepatitis B vaccinations through CPT codes 90636, 90740, 90743–90744, 90748, 90731, 90723, and G0010.

#### VASCULAR ACCESS

Data for Figures 2.12–14 are obtained from the ME form. Tables 2.b–c include prevalent hemodialysis patients who are in both the USRDS and ESRD CPM databases, and whose day 91 begins prior to October 1 of the prevalent year. Access represents the current access being used, according to the CPM data, and claims are searched during the following calendar year for events and complications. Additionally, Table 2.c includes incident peritoneal dialysis patients from the USRDS database. For Table 2.c, complication rates are calculated as the number of events (from Medicare claims) divided by the time at risk, which is censored at death, change in modality, change in payment status, or the placement of a different type of access. Vascular access codes are listed in Table a.a on page 385.

#### MEDICARE PART D USE

In Figures 2.15–21 we analyze point-prevalent cohorts of dialysis and transplant patients enrolled in Medicare Part D from October to December, 2007; alive and enrolled in Medicare on January 1, 2008, with ESRD onset at least 90 days before January 1; and enrolled in Part D for at least one calendar month in 2008. Treatment modality is defined on January 1.

In Figure 2.15, low-income subsidy (LIS) status is defined by at least one month of LIS receipt during 2008. The cumulative number of Part D medications is equal to the cumulative number of unique generic product identifier (GPI) codes among Part D transactions (1) in October to December, 2007, with sufficient supply for continued treatment in 2008, and (2) in 2008. In counting GPI codes, we exclude vaccines (GPI code header 17), toxoids (18), passive immunizing agents (19), allergenic extracts (2010), diagnostic products (94), chemicals (96), medical devices (97), and pharmaceutical adjuvants (98). In Figure 2.16, the daily number of Part D medications is equal to the mean number of medications per day, across all days; a filled prescription is presumed to be taken on each day between the fill date and  $D$  days after the fill date, with  $D$  equal to the days supplied. Anti-hypertensives include central alpha agonists, peripheral alpha antagonists, beta blockers, calcium channel blockers, diuretics, aliskiren, angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, hydralazine, and minoxidil.

In Figure 2.20, combination use of phosphate binders is defined by concurrent use of two binding agents (among sevelamer, lanthanum, and calcium acetate) for at least 30 days. In Figure 2.21, other anti-diabetic medications include amylin analogues, incretin mimetic agents, and alpha-glucosidase inhibitors.



## **hospitalization**

### CHAPTER THREE: G TABLES

Methods used to examine hospitalization in prevalent patients generally echo those used for the tables in Reference Section G (described below). Inclusion and exclusion criteria are generally the same, as are the methods for counting hospital admissions and days, and defining the follow-up time at risk. One difference is the exclusion in Section G of patients of races that are unknown or other than white, African American, Native American, or Asian; these patients are included in the Chapter Three figures. Included patients have Medicare as primary payor, with Parts A and B coverage at the start of follow-up, and without HMO coverage. Rates include total admissions or hospital days during the time at risk divided by patient years at risk. The period at risk begins at the latest of January 1 or day 91 of ESRD, and censoring occurs at death, end of Medicare Parts A and B coverage, or December 31, in addition to other censoring criteria which vary by modality as described below. Since a currently hospitalized patient is not at risk for admission, hospital days are subtracted from the time at risk for hospital admissions.

Hospitalization data exclude inpatient stays for the purpose of rehabilitation therapy. Inpatient rehabilitation claims are identified by provider numbers; numbers for inpatient rehabilitation facilities include values 3025–3099 in the third through sixth positions or “R” or “T” in the third position.

Inpatient institutional claims are used for the analyses, and methods for cleaning claims follow those described for Section G. Adjusted rates are calculated using the model-based adjustment method on the observed category-specific rates. Predicted rates are calculated with a Poisson model, and adjusted rates are then computed with the direct adjustment method and a reference cohort. This method is described further in the discussion of Section G, and in the statistical methods section later in this appendix.

Methods in Figures 3.1–2 follow those for Reference Section G. Figure 3.1 shows the percent change in admission rates since 1993 for period prevalent ESRD patients. Included patients have Medicare as primary payor and are residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with AIDS as a

primary or secondary cause of death are excluded, as are patients with missing age or gender information. Rates are adjusted for age, gender, race, and primary diagnosis using the model-based adjustment method. The reference cohort includes period prevalent ESRD patients, 2005. New dialysis access codes for peritoneal dialysis patients appeared in late 1998; dialysis access values are therefore shown for peritoneal dialysis patients as change since 1999 rather than 1993. For peritoneal dialysis patients, dialysis access hospitalizations are those defined as “pure” inpatient vascular/dialysis access events, as described for Tables G.11–15. For hemodialysis patients, vascular access hospitalizations include “pure” inpatient vascular access events, and vascular access for hemodialysis patients excludes codes specific to peritoneal dialysis catheters (996.56, 996.68, and v56.2). Principal ICD-9-CM diagnosis codes are used to identify cardiovascular and infectious admissions. The cardiovascular category consists of codes 276.6, 394–398.99, 401–405, 410–420, 421.9, 422.90, 422.99, 423–438, and 440–459, while infection is indicated by codes 001–139, 254.1, 320–326, 331.81, 372–372.39, 373.0–373.2, 382–382.4, 383.0, 386.33, 386.35, 388.60, 390–393, 421–421.1, 422.0, 422.91–422.93, 460–466, 472–474.0, 475–476.1, 478.21–478.24, 478.29, 480–490, 491.1, 494, 510–511, 513.0, 518.6, 519.01, 522.5, 522.7, 527.3, 528.3, 540–542, 566–567.9, 569.5, 572–572.1, 573.1–573.3, 575–575.12, 590–590.9, 595–595.4, 597–597.89, 598, 599.0, 601–601.9, 604–604.9, 607.1, 607.2, 608.0, 608.4, 611.0, 614–616.1, 616.3–616.4, 616.8, 670, 680–686.9, 706.0, 711–711.9, 730–730.3, 730.8–730.9, 790.7–790.8, 996.60–996.69, 997.62, 998.5, and 999.3.

Figure 3.2 presents adjusted rates of total hospital admissions and days per patient year. Prevalent ESRD patients are included, and rates are adjusted for age, gender, race, and primary diagnosis, with the 2005 ESRD cohort used as the reference.

Figure 3.3 shows adjusted admission rates for principal diagnoses among prevalent ESRD patients. Again, rates are adjusted for age, gender, race, and primary diagnosis, with ESRD patients in 2005 used as the reference cohort. Principal ICD-9-CM codes for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 3.1, while other infectious groups are as follows: vascular access infection (hemodialysis patients only), 996.62 and 999.31; peritoneal dialysis catheter infection (peritoneal dialysis patients only), 996.68; and peritonitis (peritoneal dialysis patients only), 567.

Table 3.a presents unadjusted and adjusted admission rates among adult (age 20 and older) period prevalent hemodialysis patients. Principal ICD-9-CM diagnosis codes are used to identify cause-specific admissions: codes for cardiovascular and infectious admissions are listed in the discussion of Figure 3.1, while codes for vascular access infection are the same as those for Figure 3.3. Rates are adjusted for age, gender, race, and primary ESRD diagnosis; values presented by one factor are adjusted for the other three. For adjusted rates, hemodialysis patients in 2005 are used as the reference cohort. Values by age, gender, race, and primary diagnosis are shown for 2008–2009 prevalent hemodialysis patients.

Figures 3.4–5 and Table 3.b show rates of rehospitalization and rehospitalization or death among prevalent hemodialysis patients age 20 and older, 30 days after hospital discharge. Live hospital discharges from January 1 to December 1 of the year are identified as index hospitalizations; the latter date provides a 30-day period following the latest discharge to evaluate rehospitalization. The unit of analysis includes hospital discharges rather than patients. Hospitalization data exclude rehabilitation claims and transfers. Discharges with a same-day admission to long-term care or a critical access hospital are excluded, as are discharges with a transplant, loss to follow-up, or end of payor status before day 30 after discharge.

Figures 3.4–5 indicate the percentage of discharges with readmission and/or death within 30 days after discharge. The groups indicate status at day 30 after discharge from the index hospitalization, and do not consider events after day 30. Categories of cause-specific admissions are based on principal ICD-9-CM diagnosis codes of the index hospitalization and the rehospitalization. Codes for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 3.1; vascular access infection are 996.62 and 999.31. Categories of cause-specific rehospitalization also include non-vascular access infections, defined by infection codes excluding 996.62 and 999.31, and other, defined by codes other than cardiovascular and infectious.

Rates in Table 3.b are adjusted for age, gender, race, and primary diagnosis using the direct adjustment method. Rates by one factor are adjusted for the other three, and the reference group includes all-cause discharges in 2005. Rates are shown for rehospitalization as well as for the combined endpoint of death or rehospitalization. Unadjusted rates were also computed (not shown) and were similar to the adjusted rates.

Figure 3.6 and Table 3.c show infectious admission rates by organ system among prevalent ESRD patients. In Table 3.c, the model-based adjustment method is used for the adjusted rates, and rates are adjusted for age, gender, race, and primary diagnosis, with hemodialysis patients in 2005 used as the reference cohort. Rates presented by one factor are adjusted by the other three. Principal ICD-9-CM codes for all infectious hospitalizations are the same as those listed for Figure 3.1, while groups are as follows: skin, 006.6, 017.0, 031.1, 032.85, 039.0, 054.0, 103, 110–111, 112.3, 116.2, 680–686.9, and 706.0; circulatory, 038–038.9 and 790.7–790.8; cardiac, 032.82, 036.4, 074.2, 093.2, 093.81–82, 098.83–85, 112.81, 115.x3, 115.x4, 130.3, 391–392.0, 393, 421–421.1, 422.0, and 422.91–422.93; lung, 006.4, 011, 031.0, 039.1, 055.1, 073.0, 112.4, 114.0, 114.4–114.5, 115.x5, 466, 480–486, 487.0, 490, 491.1, 494, 513.0, and 518.6; genitourinary, 016, 032.84, 054.1, 098.0–098.3, 112.1–112.2, 590–590.9, 595–595.4, 597–597.89, 598.0, 599.0, 601–601.9, 604–604.9, 607.1–607.2, 608.0, 608.4, 614–616.1, 616.3–616.4, and 616.8; musculoskeletal, 015, 098.5, 711–711.9, 730–730.3, and 730.8–730.9; abdominal, 001–003.1, 003.8–006.3, 007–009, 014, 032.83, 039.2, 070, 098.86, 112.85, 540–542, 567, 569.5, 572–572.1, 573.1–573.3, and 575–575.12; dialysis access, 996.62 and 999.31 (hemodialysis) and 996.68 (peritoneal dialysis); and nervous, 006.5, 013, 036.0–036.1, 045–049, 053.0–053.1, 054.3, 054.72, 054.74, 055.0, 058.2, 062–064, 072.1–072.2, 094, 098.82, 112.83, 114.2, 320–326, and 331.81.

Figure 3.7 shows adjusted rates of hospital admissions and days per patient year among incident hemodialysis patients, peritoneal dialysis patients, and hemodialysis patients matched to peritoneal dialysis patients. Included patients have Medicare as a primary payor and are residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with AIDS as a primary or secondary cause of death, with missing age or gender information, or without a Medical Evidence form filed at initiation of dialysis are excluded. Propensity scores for peritoneal dialysis at day 90 after initiation are estimated with logistic regression, and the cohort of hemodialysis patients matched to peritoneal dialysis patients is constructed using these scores; peritoneal dialysis patients without a hemodialysis match are excluded. Rates are adjusted for age, gender, race, and primary diagnosis, with 2005 incident hemodialysis and peritoneal dialysis patients used as the reference. Since in-center hemodialysis patients who are younger than 65 and not disabled cannot bill for hospitalizations until 90 days after ESRD initiation, the 90-day rule is applied. Patients are required to survive the first

90 days after initiation, modality is indicated at day 90, and patients are followed for admissions for up to one year after initiation. Censoring occurs at death, loss to follow-up, end of Medicare payor status, three days prior to transplant, or the end of the year. Censoring does not occur at dialysis modality change; these are, therefore, intent-to-treat analyses.

Figures 3.8–10 and Table 3.d present unadjusted admission rates among hemodialysis patients, peritoneal dialysis patients, and hemodialysis patients matched to peritoneal dialysis patients. Methods follow those of Figure 3.7. Figures 3.8–10 show rates during both the first and second year after initiation among pooled 2006 and 2007 incident dialysis patients. Second-year rates include patients alive and uncensored at the end of the first year. Principal ICD-9-CM codes for all infectious hospitalizations are the same as those listed for Figure 3.1. Codes 996.62, 999.31, and 996.68 are used for dialysis access infection; this infection is inclusive here, and codes for both vascular access infection and peritoneal dialysis catheter infection are used for each modality group.

## REFERENCE SECTION G

Hospitalization reference tables present adjusted total admission and hospital day rates, by year, 1993–2009. They begin in 1993 because Medicare inpatient claims are available beginning in 1991, and the model-based adjustment method uses data from the current and previous two years to obtain the predicted rates. (This method is further discussed later in this section and in the statistical methods section at the end of this appendix.)

Because hospitalization data for non-Medicare patients may be incomplete, analyses in this section include only patients with Medicare as their primary payor. Hospitalization data are obtained from institutional inpatient claims. As in Chapter Six, hospitalization data in Reference Section G also now exclude inpatient stays for the purpose of rehabilitation therapy.

Tables G.1–15 include dialysis and transplant patients on their modality for at least 60 days, reaching day 91 of ESRD by the end of the year, and residing in the 50 states, the District of Columbia, Puerto Rico, and the Territories. Excluded are patients with AIDS as a primary or secondary cause of death; patients with missing values for age, gender, or race; and patients of races that are unknown or other than white, African American, Native American, or Asian. Age is determined on January 1 of each year. Patients are also classified according to their primary cause of ESRD, in which the “other” category includes patients with missing data or causes other than diabetes, hypertension, or glomerulonephritis.

Patients are classified by modality at the beginning of the year:

- » all dialysis: patients on hemodialysis, CAPD/CCPD, or dialysis of an unknown type, as well as those on more than one modality in the past 60 days
- » hemodialysis: patients on hemodialysis for at least 60 days as of the start of the period at risk
- » CAPD/CCPD: patients on CAPD/CCPD for at least 60 days as of the start of the period at risk
- » transplant: patients with a functioning transplant, and who received the transplant less than three years prior to the start of the period at risk
- » all-ESRD: all patients

To limit the contribution of patient years at risk from patients who do not have Medicare coverage but do have Medicare as a secondary payor or HMO coverage, and who therefore have incomplete hospitalization data, cohorts include only patients with Medicare

Parts A and B coverage at the start of follow-up. The follow-up period is censored when a patient's payor status changes to no longer having Medicare Parts A and B coverage or Medicare as a primary payor.

For patients in the all-dialysis, hemodialysis, and peritoneal dialysis categories, the period at risk for all hospitalization analyses is from January 1 or day 91 of ESRD until the earliest of death, three days prior to transplant, end of Medicare Parts A and B coverage, or December 31. Modality change is considered a censoring event only in the case of a change from dialysis to transplant. For dialysis patients in the all-ESRD category, in contrast, the analysis period is censored only at death, end of Medicare Parts A and B coverage, or December 31 of the year; a modality change is not used as a censoring event. For transplant patients in the all-ESRD and transplant categories, the period is censored at the earliest of death, three years after the transplant date, end of Medicare Parts A and B coverage, or December 31 of the year. The censoring of transplant patients at three years following the transplant is necessary because Medicare eligibility may be lost and hospitalization data may be incomplete for these patients.

Time at risk is calculated differently for hospital days and total admissions. Since a hospitalized patient remains at risk for additional hospital days, rates for hospital days include hospital days in the time at risk. Since a currently hospitalized patient is not, however, at risk for new admissions, hospital days for each year are subtracted from the time at risk for total admissions. In the case of a hospitalization in which admission occurs the same day as discharge, zero days are subtracted from the time at risk for total admissions. When bridge hospitalizations span the start of the analysis period, only the days within the period are subtracted from the time at risk for total admissions.

All admissions and hospital days during the analysis period are included, respectively, in the total admissions and hospital days for each year. An admission for a hospitalization that occurs before and spans the start of the analysis period is excluded from the total admissions for that period, and only the hospitalization days within the period are counted in the total days for hospital day rates. The minimum length of stay is one day, and hospitalizations with an admission and discharge on the same day, as well as those with a discharge the day after admission, are both counted as one day.

As in previous ADRS, all overlapping and only certain adjacent hospitalizations are combined, due to the fact that many adjacent claims may actually be legitimate separate hospitalizations. Specifically, hospitalizations with an admission on the same day or the day after a previous discharge are combined only when there is a discharge transfer code or indication of an interim claim. In the case of two hospitalizations combined into one, the principal diagnosis and procedure codes are retained from the first of the two hospitalizations, with the combined hospitalization extending from the first admission date to the last discharge date.

The methodology for computing adjusted total admission and hospital day rates uses the model-based adjustment method (discussed in the section on statistical methods). Predicted rates for each subgroup combination of age, gender, race, primary diagnosis, and year are obtained using a model with the Poisson assumption. For prevalent patient cohorts, this model uses data from the current and previous two years, with respective weights of 1, 1/4, and 1/8. Adjusted rates are then calculated using the direct adjustment method, with all 2005 ESRD patients as the reference cohort.

Tables G.11–15 show inpatient utilization in period prevalent ESRD patients. Methods—including modality definitions, inclusion criteria, data cleaning, follow-up time definitions, and rate calcu-

lations—generally follow those described for the total admission rates in Tables G.1–5, but some differences do exist. While patients of races other than white, African American, Native American, or Asian are excluded from G.1–5, they are included in G.11–15, except where rates are given by race. Rates are unadjusted and reflect total admissions per 100 patient years for 2001–2003, 2004–2006, and 2007–2009 (pooled) prevalent patients. While the rates for all causes are computed similarly to the unadjusted rates in G.1–5, the other nine cause-specific categories only include admissions for specific diseases. Vascular access and peritoneal dialysis access hospitalizations are those classified as “pure” inpatient vascular/dialysis access events. Such access events are defined as admissions with a specified ICD-9-CM principal diagnosis code, or an ICD-9-CM principal procedure code in conjunction with a certain DRG code. Codes are listed in Table a.b. If an admission does not qualify as vascular/dialysis access, it is classified by the principal diagnosis code into one of eight other mutually exclusive groups. Categories and ICD-9-CM codes are as follows: circulatory diseases, 390–459; digestive diseases, 520–579; genitourinary diseases, 580–629; endocrine and metabolic diseases, 240–279; respiratory diseases, 460–519; infectious diseases, 001–139; and cancer, 140–172, 174–208, 230–231, and 233–234. Hospitalizations that do not fall under any of these categories are counted under all others.

Supplementary tables providing additional rates and counts are available on our website and CD-ROM. Tables G.1.1–5.1 present adjusted rates similar to those shown in G.1–5, but include more patient subgroups. Additional tables (G.1.2–5.2) display the counts of the total admissions, patient years at risk, and total patients that are used to calculate the total admission rates. Standard errors of the rates in Tables G.1–10 and G.1.1–5.1 are also available.



## CARDIOVASCULAR DISEASE

### CHAPTER FOUR

Data for Figure 4.1 are obtained from Reference Table H.12.

The cohorts for Table 4.a and Figures 4.2–4 include period prevalent dialysis patients in each calendar year from 1991 to 2009 whose first ESRD service date is at least 90 days prior to the beginning of the year (point prevalent patients on January 1) or who reach day 91 of ESRD treatment during the year (incident patients). We exclude patients with unknown age, gender, or race, and those with an age calculated to be less than zero. We also exclude patients who are not residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories. Age is calculated on January 1. Cardiovascular mortality is defined using codes from past and current Death Notification forms: 01, 02, 03, 04, 1, 2, 3, 4, 23, 25, 26, 27, 28, 29, 30, 31, 32, 36, and 37. The codes used to define cause-specific cardiovascular mortality are as follows: congestive heart failure: 27, 31, and 32; myocardial infarction: 02, 2, and 23; cardiac arrest/arrhythmia: 28 and 29; and cerebrovascular accident/transient ischemic attack (CVA/TIA): 04, 4, 36, and 37. Patients are followed from January 1 (for point prevalent dialysis patients) or day 91 of ESRD (for incident dialysis patients) until death, transplant, or December 31 of the year. Rates are estimated as the number of patients who die from cardiovascular disease in each year per 1,000 patient years at risk. Figure 4.4 illustrates geographic variations in unadjusted (crude) cardiovascular mortality rates in 1999 and 2009, by HSA.

Table 4.b and Figures 4.5–10 describe prescription drug therapy in Medicare hemodialysis, peritoneal dialysis, and kidney transplant patients with their first diagnosis for cardiovascular disease (CVD)

or receiving their first treatment for CVD in 2008. Index events for CVD include acute myocardial infarction (AMI), atrial fibrillation (AF), CVA/TIA, congestive heart failure (CHF), and peripheral arterial disease (PAD), while index events for CVD treatment include percutaneous coronary interventions (PCI), coronary artery bypass graft surgery (CABG), and use of an implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy with defibrillator (CRT-D).

For each of the eight index events, a study cohort is identified from the 2008 Medicare ESRD database. Patients have the index event during 2008, are continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage during the one year preceding the date of the index event, and are not enrolled in an HMO during that year. The one-year period preceding the date of the index event is the baseline period. Patients with a pre-existing condition of the index event are also identified during the baseline period, but are not excluded from the analyses. AMI, AF, CVA/TIA, CHF, PAD, first PCI and CABG surgery, and the first implantation of ICD/CRT-D are defined on the date of the first appearance of a diagnosis or procedure code in the 2008 claims. Applicable codes include the following:

- » AF: 427.3 (ICD-9-CM diagnosis code)
- » AMI: 410, 410.X0, and 410.X1 (ICD-9-CM diagnosis codes)
- » CHF: 398.91, 425.X, 428.XX, 402.X1, 404.X1, and 404.X3 (ICD-9-CM diagnosis codes)
- » CVA/TIA: 430–437 (ICD-9-CM diagnosis codes)
- » PAD: 440–444, 447, and 557 (ICD-9-CM diagnosis codes); 84.0, 84.1, 84.91, 39.25, 39.26, and 39.29 (ICD-9-CM procedure codes); 24900, 24920, 25900, 25905, 25920, 25927, 27295, 27590, 27591, 27592, 27598, 27880, 27881, 27882, 27888, 27889, 28800, 28805, 34900, 35131, 35132, 35141, 35142, 35151, 35152, 34051, 34151, 34201, 34203, 34800–34834, 35081–35103, 35331, 35341, 35351, 35355, 35361, 35363, 35371, 35372, 35381, 35450,

#### **a ii CPT codes for vascular access & peritoneal dialysis access services**

Complication 34101\*, 35190\*, 35321\*, 35458\*, 35460\*, 35475\*, 35476\*, 35484\*, 35875\*, 35876\*, 35900\*, 35903\*, 35910\*, 36005\*, 36145, 36534\*, 36535\*, 36550\*, 36575\*, 36580\*, 36581\*, 36584\*, 36589\*, 36593, 36596\*, 36597\*, 36815, 36831, 36832, 36833, 36834\*, 36838, 36860, 36861, 36870, 37190\*, 37201\*, 37205\*, 37206\*, 37207\*, 37208\*, 37607, 49422, 75790, 75820\*, 75860\*, 75896\*, 75960\*, 75962\*, 75978\*, 75998\*, 76937\*, 77001, 00532\*, 01784\*, 01844\*, 90939, 90940, G0159, G0392, G0393, and M090

Hemodialysis catheter placement 36011\*, 36488\*, 36489\*, 36490\*, 36491\*, 36533\*, 36555\*, 36556\*, 36557\*, 36558\*, 36565\*, and 36800

Peritoneal dialysis catheter placement 49419, 49420, and 49421

Synthetic graft placement 36830

Fistula placement 36818, 36819, 36820, 36821, and 36825

Other placement 36810, 36835

\*Requires accompanying renal diagnosis code for inclusion.

This list is comprehensive and includes codes that are now obsolete, but that were in use at some point during the study period (1991–2009).

#### **a b ii DRG & ICD-9-CM codes for vascular access & peritoneal dialysis access services**

DRG codes<sup>a</sup>: prior to October 1, 2007

- 112 Percutaneous cardiovascular procedure 120 Other circulatory system OR procedure 315 Other kidney and urinary tract OR procedure 442 Other OR procedure for injuries with complication 443 Other OR procedure for injuries without complication 478 Other vascular procedure with complication 479 Other vascular procedure without complication

DRG codes<sup>a</sup>: after September 30, 2007

- 252 Other vascular procedures with Major complicating conditions (MCC) 264 Other circulatory system O.R. procedures 673 Other kidney & urinary tract procedures with MCC 674 Other kidney & urinary tract procedures with CC 675 Other kidney & urinary tract procedures without CC/MCC 907 Other O.R. procedures for injuries with MCC 908 Other O.R. procedures for injuries with CC 909 Other O.R. procedures for injuries without CC/Medicare

ICD-9-CM procedure codes<sup>b</sup>

- 38.95 Venous catheterization for renal dialysis 39.27 Arteriovenostomy for renal dialysis 39.42 Revision of arteriovenous shunt for renal dialysis 39.43 Removal of arteriovenous shunt for renal dialysis 39.93 Placement of vessel-to-vessel cannula 39.94 Replacement of vessel-to-vessel cannula 86.07 Placement of totally implantable vascular access device

ICD-9-CM diagnosis codes<sup>b</sup>

- 996.1 Mechanical complication of vascular device, implant, graft 996.56 Mechanical complication due to peritoneal dialysis catheter 996.62 Infectious complication of vascular device, implant, graft 996.68 Infectious complication due to peritoneal dialysis catheter 996.73 Other complication due to renal dialysis device, implant, graft V56.1 Fitting and adjustment of extracorporeal dialysis catheter V56.2 Fitting and adjustment of peritoneal dialysis catheter

a DRG and procedure codes are used in conjunction to define inpatient pure vascular access events (both must be present).

b The presence of any of these diagnosis codes as the "Principal Diagnosis Code" is sufficient to define an inpatient pure vascular access or peritoneal dialysis access event.

- 35452, 35454, 35456, 35459, 35470, 35471, 35472, 35473, 35474, 35480, 35481, 35482, 35483, 35485, 35490, 35491, 35492, 35493, 35495, 35521, 35531, 35533, 35541, 35546, 35548, 35549, 35551, 35556, 35558, 35563, 35565, 35566, 35571, 35583, 35585, 35587, 35621, 35623, 35646, 35647, 35651, 35654, 35656, 35661, 35663, 35665, 35666, and 35671 (CPT codes)
- » CABG surgery: 36.1X (ICD-9-CM procedure codes); 33510–33523 and 33533–33536 (CPT codes)
- » PCI: 00.66, 36.01, 36.02, 36.05, and 36.06 (ICD-9-CM procedure codes); 92980–92982, 92984, and 92995–92996 (CPT codes)
- » ICD: 37.94 (ICD-9-CM procedure code)
- » CRT-D: 00.51 (ICD-9-CM procedure code)

Table 4.b and Figures 4.5–10 include Medicare enrollees with a CVD event between January 1, 2008, and November 30, 2008, discharged within two weeks of the date of the index event (if hospitalized at the time of the event), remaining outside the hospital at one month after the date of the index event, and carrying continuous Medicare Part D coverage during the interval from one month before to one month after the date of the index event; use of a particular drug is defined by at least one fill of a prescription for the drug during this interval. Drugs are identified from National Drug Codes included on Part D claims, and linked with the 2010 edition of the Medi-Span Master Drug Data Base.

## **mortality CHAPTER FIVE**

Unless otherwise specified, patient cohorts for mortality figures include both Medicare and non-Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories.

VOL 2  
ESRD

Figure 5.1 shows trends in mortality rates, by modality, for incident ESRD patients, 1980–2008. The population groups include all ESRD, hemodialysis, CAPD/CCPD, and first transplant (known deceased and living donors only). In defining the population for all ESRD, hemodialysis, and CAPD/CCPD, the 90-day rule is applied and patients are followed from day 91 after the onset of ESRD until January 31, 2009. Hemodialysis and CAPD/CCPD patients are censored at transplant and loss to follow-up; the ESRD and first transplant populations are censored at loss to follow-up only. Adjusted first-, second-, third-, fourth-, and fifth-year mortality rates for each incident cohort are computed from the Cox model using the model-based adjustment method, described later in this appendix. Mortality rates for all patients are adjusted for age, gender, race, and primary diagnosis, and the reference population consists of 2005 incident ESRD patients.

Figure 5.2 shows all-cause mortality, by age, for 2009 prevalent ESRD, dialysis, transplant, and general Medicare patients, calculated using generalized mixed models, and adjusted for gender and race. Medicare patients from 2009 are used as the reference cohort.

Figure 5.3 displays adjusted all-cause and cause-specific mortality for incident hemodialysis patients. Patients with unknown age, gender, or primary diagnosis are excluded, as are those with a listed age greater than 110. Patients are followed from the first service date up to one year, and censored at loss to follow-up, transplant, or recovery of kidney function. Overall rates are adjusted for age, gender, race, and primary diagnosis, and adjusted rates can be compared across years and causes of mortality. The reference population consists of 2005 incident hemodialysis patients.

Figure 5.4 illustrates trends in mortality rates, by patient vintage, for period prevalent dialysis patients alive on renal replacement therapy on January 1, with a first service date at least 90 days prior to the beginning of the year, and reaching day 91 of ESRD treatment during the year. Patients with unknown age or gender, or of a race other than white, African American, Native American, or Asian, are excluded. Patients are followed from January 1 until death, transplantation, or the end of the year, and all-cause rates are adjusted for age, gender, race, and primary diagnosis using generalized mixed models. The reference population consists of 2005 prevalent dialysis patients, and adjusted mortalities are comparable across vintages.

Table 5.a presents five-year survival by modality, with modality defined on the first ESRD service date. Transplant is defined as the first transplant in the incident year. Patients with unknown age, gender, or primary diagnosis, and those with a listed age greater than 110, are excluded. All patients are followed from day 1 until death, transplantation, loss to follow-up, recovery of function, or the end of 2009, while transplant patients are followed from the first transplant date until death or the end of 2009. All probabilities are adjusted for age, gender, and race; overall probabilities are also adjusted for primary diagnosis. The reference population consists of 2005 incident ESRD patients, and adjusted probabilities are comparable across modalities.

Table 5.b presents unadjusted and adjusted all-cause mortality in ESRD, dialysis, transplant, and general Medicare patients with cancer, diabetes, CHF, CVA/TIA, and AMI. All cohorts are defined on January 1, and include patients age 65 and older. Follow-up for ESRD patients is from January 1 to December 31 of each year, and for transplant patients is censored at transplant patients. For general Medicare patients, follow-up is from January 1 to December 31 of each year, censored at ESRD and at the end of Medicare entitlement. Adjusted mortality is adjusted for age, gender, race, and comorbidities defined in the previous year. ESRD patients in 2005 are used as the reference cohort.

Figure 5.5 illustrates geographic variations in unadjusted mortality among 2009 prevalent ESRD and general Medicare non-ESRD patients with at least one month of Medicare eligibility in 2009. Patients residing in Puerto Rico and the Territories are excluded.

Figures 5.6–7 present adjusted all-cause mortality in the ESRD, dialysis, transplant, and general Medicare populations in 2009. The cohorts and adjustment method are same as those used in Table 5.b; 2009 ESRD patients are used as the reference cohort.

#### REFERENCE SECTION H

Cohorts for tables in Section H include both Medicare and non-Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories.

Cohorts in Tables H.1–12 include both incident and prevalent patients. Incident cohorts are limited to patients who reach day 91 of ESRD treatment during the year, while prevalent cohorts include patients alive on renal replacement therapy on January 1 and whose first service date is at least 90 days prior to the beginning of the year. Because calculations include only one year of follow-up, a prevalent patient surviving to the end of the year contributes one year at risk, while a prevalent patient dying during the year contributes less than one year. Since the calculation for incident patients begins on day 91 of ESRD, most patients contribute less than one year at risk; a full year is contributed only if day 91 of ESRD is January 1 and the patient survives to the end of the year. Patients considered lost-to-follow-up at the beginning of the year are excluded. The period at risk is not censored at the start of a lost-to-follow-up period, however; if a patient enters the lost-to-follow-up category during a calendar year, he or she remains in the death rate computation until the end of that year. Patient cohort populations often overlap. Patients with a functioning transplant on the start date, for example, are included in the all-ESRD and functioning transplant categories, while patients on dialysis are defined as both all-ESRD and all-dialysis. A patient in the all-dialysis category may also be reported in one of two sub-groups—hemodialysis or CAPD/CCPD—if he or she has been on that modality for at least the previous 60 days. Dialysis patients not on hemodialysis or CAPD/CCPD, or on that modality for fewer than 60 days, are included only in the all-ESRD and all-dialysis categories.

Tables H.1, H.2, and H.2.1 present mortality data for all ESRD patients. Total deaths are presented in Table H.1. Overall unadjusted and adjusted annual mortality rates by age, gender, race/ethnicity, primary diagnosis, and vintage are presented in Table H.2. The unadjusted mortality rates are calculated by dividing total patient deaths in a category—male, for example—by total follow-up time in the same category. For the adjusted rates, generalized mixed models are used to calculate the smoothed rates; these methods are described in the statistical methods section later in this appendix. After obtaining smoothed rates from the generalized mixed models, direct adjustment methods are used. Overall mortality rates are adjusted for age, gender, race, primary diagnosis, and vintage, while rates for each individual category are adjusted for the remaining four. The reference population includes 2005 prevalent ESRD patients. Table H.2.1 presents unadjusted mortality rates by patient age, gender, race, and primary diagnosis for 2009 prevalent ESRD patients; rates are smoothed using a generalized mixed model.

The same methods are used for Tables H.3, H.4, and H.4.1 (dialysis); H.5 (dialysis patients, never on transplant waitlist); H.6 (dialysis patients on transplant waitlist); H.7 (dialysis patients, returned to dialysis from transplant); H.8 and H.8.1 (hemodialysis); H.9 and H.9.1 (CAPD/CCPD); and H.10 and H.10.1 (transplant).

## REFERENCE SECTION I

These tables, which include only incident cohorts, present patient counts and survival probabilities. All causes of death are included, as are all non-Medicare patients and patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with unknown gender or age, or whose listed age is greater than 110, are excluded.

Patient selection criteria are the same for both unadjusted and adjusted survival probabilities. All new ESRD patients with a first ESRD service date between January 1, 1980, and December 31, 2007, are included in the analysis. These patients are followed until December 31, 2009, with a maximum follow-up time of 24 years and a minimum of one year.

Results are reported for the following groups:

- » all ESRD: all ESRD patients beginning renal replacement therapy in a calendar year and surviving beyond day 90; patients are censored only at the end of follow-up
- » dialysis only: all dialysis patients starting renal replacement therapy in a calendar year, surviving beyond day 90, and not receiving a transplant by day 91; patients are censored at transplant or the end of follow-up
- » hemodialysis only: all hemodialysis patients starting renal replacement therapy in a calendar year, surviving beyond day 90, and not receiving a transplant by day 91; patients are censored at transplant or the end of follow-up
- » peritoneal dialysis only: all peritoneal dialysis patients starting renal replacement therapy in a calendar year, surviving beyond day 90, and not receiving a transplant by day 91; patients are censored at transplant or the end of follow-up
- » transplant: patients with a functioning transplant at the start of the period and who have had the transplant for at least 60 days; the period at risk is censored at the end of the year

Unadjusted patient survival probabilities are estimated using the Kaplan-Meier method, while the Cox model and the model-based adjustment method are used for adjusted probabilities.

To limit imprecision due to small cell sizes, adjusted probabilities use aggregate categories for age, gender, race, and primary diagnosis. For each cohort, a probability presented for one variable is adjusted for the remaining three. Overall probabilities for all patients are adjusted for each of the four variables. The reference population consists of 2005 incident ESRD patients.

## PRESCRIPTION DRUG COVERAGE IN ESRD PATIENTS CHAPTER SIX

In figures and tables regarding enrollment and utilization of Medicare Part D, we analyze cohorts of Medicare enrollees in 2006, 2007, and 2008 without chronic kidney disease (CKD), with non-dialysis-dependent CKD, receiving hemodialysis, receiving peritoneal dialysis, or with a functioning kidney transplant. For enrollees without CKD or with non-dialysis-dependent CKD, we require continuous enrollment in Medicare Parts A and B during the previous calendar year; no participation in Medicare Advantage during the previous year; and Medicare enrollment in January of the index year. CKD is identified from diagnosis codes on claims during the previous calendar year. For hemodialysis, peritoneal dialysis, and kidney transplant cohorts, we identify point prevalent and incident cohorts. Point prevalent cohorts include all patients alive and enrolled in Medicare on January 1 of the index year, with ESRD onset at least 90 days earlier; treatment modality is identified

on January 1. Incident cohorts include all patients alive and enrolled in Medicare exactly 90 days after ESRD onset, with this date between January 1 and December 31 of the index year; modality is identified on this date.

In Figure 6.1, diagnoses of hypertension, cardiovascular disease (arrhythmia, cerebrovascular disease, congestive heart failure, ischemic heart disease, peripheral vascular disease, or valvular disease), and diabetes are ascertained from claims during 2007. Here, and in Figures 6.2–3, type of prescription drug coverage is defined sequentially. That is, we first classify patients as “Part D with LIS” if there exists at least one calendar month in 2008 with Part D enrollment and receipt of low-income subsidy (LIS). In patients without one such month, we classify remaining patients as “Part D without LIS” if there exists at least one calendar month with Part D enrollment. In patients without one such month, we classify remaining patients as “retiree drug subsidy” if there exists at least one calendar month with employer receipt of the subsidy. In patients without one such month, we classify remaining patients as “other creditable coverage” if there exists at least one calendar month with enrollment in military, government employee, or employer group health plans. And we classify all remaining patients as “no known coverage.” In Figures 6.4–5, the proportion enrolled in Part D is the sum of those enrolled in Part D with LIS and without LIS.

In Figures 6.6–9, we classify Part D enrollees as LIS recipients if there exists at least one calendar month in 2008 with LIS receipt.

In Figures 6.11–13, we consider only those Part D enrollees who are not LIS recipients during any calendar month of the index year. In all figures, patients enrolled in Medicare Advantage Part D (MA-PD) plans are excluded.

In Figures 6.20–22 and Tables 6.a–b, we consider only those Part D enrollees who are not LIS recipients during any calendar month of 2008. In all figures, patients enrolled in employer group waiver plans or national Programs of All-inclusive Care for the Elderly (PACE) are excluded, as these types of plans do not report data concerning coverage phase progression of enrollees. In Figure 6.21, follow-up begins on January 1, 2008, and in Figure 6.22, follow-up begins on the date of entry into the coverage gap. In Table 6.a, diagnoses of hypertension, cardiovascular disease, diabetes, and cancer are ascertained from the Medical Evidence form alone. In the final analysis in Table 6.a, regarding the association of fills per month in 2007 with probability of entry into the coverage gap in 2008, we necessarily limit analysis to the subset of patients also enrolled in Part D in 2007. Here and in Table 6.b, a fill is simply defined as a transaction that billed to Part D.

Part D costs for ESRD patients are based on the 100 percent ESRD population, using the period prevalent, as-treated model (Model 1) described for Chapter 11. Some figures also compare the general Medicare population (all Part D enrollees) based on the 5 percent Medicare sample, as well as point prevalent CKD patients from the 5 percent sample. The CKD population includes only persons who survive all of year one, are continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage for this period, are not enrolled in an HMO, and have a qualifying CKD diagnosis (but do not have ESRD) during the prevalent year. Costs are then aggregated for the subsequent year. Costs are presented as the total Part D net payment, estimated as the Medicare covered amount plus the low income subsidy amount (LIS) in Figures 6.14, 6.18, 6.24, and 6.26, and Tables 6.c–d, and as the per person per year (PPPY) Part D net payment in Figures 6.15–17, and 6.19.

Figure 6.15 compares total Part D expenditures for general Medicare, CKD, and ESRD populations in 2006–2008 (the only years with

available Part D data). Figures 6.15–16 present PPPY net payment and out-of-pocket expenditures for general Medicare, CKD (Figure 6.15 only) and ESRD Medicare populations. Figure 6.17 shows PPPY Part D net payments by race and LIS status for dialysis patients in calendar year 2008. Figures 6.18 (total net payment) and 6.19 (PPPY) show total expenditures for Part B prescription drugs (injectable drugs and immunosuppressive agents) compared to Part D net payments in the ESRD population.

Tables 6.c (hemodialysis) and 6.d (transplant) show the top 15 Part D drugs by generic name and frequency (measured as total prescribed days supply) and cost for ESRD patients. Figures 6.23 and 6.25 show the top 15 prescribed Part D drugs by cumulative frequency for hemodialysis and transplant patients, respectively, while Figures 6.24 and 6.26 show these drugs by cumulative net payments.



## TRANSPLANTATION

### CHAPTER SEVEN

Figure 7.1 presents an overview of the transplant population. The first panel juxtaposes the growing rate of ESRD with the falling rate of transplantation in patients age 20 and older at transplant, 1988–2009. Most adult-only figures are limited to

patients age 18 and older, but this figure is limited to age 20 and older because census population data are provided in five-year increments. The second panel summarizes the wait list, showing, by prior transplant status, the number of patients age 20 and older on the OPTN kidney or kidney-pancreas wait list on December 31 of the year, and the median wait time for a deceased-donor kidney. Patients with overlapping listings at more than one center are counted once. Median wait time is plotted only when the Kaplan-Meier median is observed, and is thus missing for patients listed more recently. The third panel presents transplant counts for patients 20 and older, by donor type, obtained through a combination of OPTN and CMS data.

#### WAIT LIST AND DONATION

Figure 7.2 shows the percentage of patients wait-listed or receiving a deceased donor kidney transplant within one year of ESRD initiation, stratified by age, while Figures 7.3–4 illustrate the number and distribution of adult (age 18 and older) patients on the OPTN kidney or kidney-pancreas wait list on December 31 of the year. Because patients may list at multiple transplant centers, Figure 7.3 shows, by status (active/inactive), the number of unique patients and the proportion of patients listed at multiple centers. Figure 7.4 reports, by blood type, proportions of adult patients who receive a deceased donor transplant, receive a living donor transplant, or die within three years of listing. Because these outcomes are subject to competing risks, we use cumulative incidence estimates.

In Figure 7.5 we illustrate three-year outcomes for adult patients first listed in 2006. Outcomes are classified into five groups: 1) received a deceased donor transplant, 2) received a living donor transplant, 3) died awaiting a transplant, 4) removed from the list prior to transplantation, or 5) still waiting.

Figure 7.6 shows median wait times, by state, for adults receiving a deceased donor kidney during 2009. Wait time is calculated as the transplant date minus the date the patient is added to the kidney or kidney-pancreas wait list, not necessarily the date he or she is first listed at the center where the transplant is performed.

Figure 7.7 presents adjusted one-year mortality, by state of residence, for January 1, 2009 point prevalent wait-list patients. A Poisson regression is used to estimate rates, adjusting for age, gender,

white/non-white race, willingness to accept an ECD donor, and time on the list prior to 2009. Patients are followed for up to one year.

Figure 7.8 shows the likelihood of adult patients dying while awaiting transplant in the first through fifth year after listing, looking at those first listed in 1991–2008. The likelihood of dying is estimated from Cox proportional hazard models, adjusted for listing year, age, gender, race, primary diagnosis, and PRA level at listing; the 2005 period prevalent cohort is used as reference. Patients are censored at removal from the list and end of follow-up.

In Figure 7.9 we present the three-year cumulative incidence of transfusion among wait-listed patients by PRA level at listing. The cohort is limited to wait-list patients with primary Medicare coverage, and transfusion data are obtained from Medicare claims. Incidence is estimated using Kaplan-Meier methods, with censoring at transplant, death, removal from the waiting list, or loss of Medicare coverage.

Figure 7.10 shows rates of organ donation per million population by age, gender, and race. A deceased donor is counted once, regardless of how many organs are transplanted. Figure 7.11 presents unadjusted donation rates per 1,000 deaths, by state. Population and death count estimates for the year from July 1, 2008 to July 1, 2009 are obtained from the US Census Bureau.

#### TRANSPLANT AND OUTCOMES

Figures 7.12 and 7.14 illustrate the number of deceased and living donor transplants for both kidney and kidney-pancreas recipients, while Figures 7.13 and 7.15 present transplant rates by age, gender, race, and primary diagnosis; rates by one factor are adjusted for the remaining three. Figure 7.16 shows adjusted transplant rates (per 100 dialysis patient years) by state of patient residence and donor type in 2009.

Figures 7.17–18 present one-, five-, and ten-year graft survival for adult recipients of kidneys from deceased and living donors. All estimates are made from Cox proportional hazards models, adjusted for transplant year, age, gender, race, and primary diagnosis, and based on the population's average survival curves, rather than on curves of the average patient in the population.

Figure 7.19 presents the one-year cumulative incidence of acute rejections in adult, first-time, kidney-alone transplant patients discharged from the transplant hospitalization with a functioning graft. A patient is assumed to have acute rejection if OPTN data collection forms note 1) acute rejection episodes, 2) that medications were given for acute rejection, or that 3) acute rejection was the primary or secondary cause of graft failure. Biopsy-proven status was available starting in 1991 on the OPTN Transplant Recipient Registration, which identifies early rejection; it was not, however, added to the Transplant Recipient Follow-up form until April, 2003. Rejections that are a primary or contributing cause of graft failure are assumed to be biopsy-proven, while rejections identified by treatment status are not. Cumulative incidence is estimated using Kaplan-Meier methods, censored at death or graft failure.

Figure 7.20 reports the percentage of patients with evidence of delayed graft function (defined by a need for dialysis in the first week after transplantation), by donor type and ECD and DCD status, as reported to the OPTN.

Figure 7.21 presents first-year and second-year post-transplant hospital admission rates for adult Medicare patients receiving their first kidney-alone transplant in 2007. Data are collected from Medicare claims occurring within two years of discharge from the transplant hospitalization, and exclude the hospitalization itself. Admission rates are censored at graft failure, loss of Medicare coverage, or

December 31, 2009. Statistical methods for computing admission rates are similar to those described for Reference Section G, but cohorts are constructed differently. Instead of computing rates in point prevalent patients within a given year, we define the cohort based on the transplant year, and examine hospital claims up to a year post-transplant for first-year data and two years post-transplant for second-year data. Figure 7.22 illustrates the primary cause of hospitalization for cardiovascular problems and infection in the first and second years post-transplant in Medicare patients with a first kidney-alone transplant in 2005–2007.

Figure 7.23 presents data on the three-year incidence of post-transplant lymphoproliferative disorder (PTLD). The population includes first-time, kidney-only transplant recipients, 2002–2006. PTLD is identified from the OPTN Post-Transplant Malignancy form and the Transplant Recipient Follow-Up form.

Figure 7.24 illustrates the three-year cumulative incidence of new onset diabetes following transplant, looking at Medicare patients transplanted during 2002–2006. To identify de novo post-transplant diabetes, the cohort is limited to patients with six months of Medicare primary payor coverage prior to transplantation; patients with claims for diabetes during this period are omitted. Cumulative incidence in the three years following the transplant is estimated using a Cox proportional hazards model, as above. Events are censored at graft failure, death, or loss of Medicare coverage.

In Figure 7.25 we show the rate of return to dialysis/preemptive retransplantation, the rate of death with a functioning graft, and the rate of any graft failure, which includes failure due to death. Rates are limited to adult patients, and estimated from a Poisson regression, adjusting for age, gender, and race.

Figure 7.26 displays causes of death for adult patients transplanted in 2005–2009 who subsequently die with a functioning graft. Causes of death are ascertained from OPTN transplant follow-up data, or, if unknown, from the ESRD Death Notification form.

#### FOLLOW-UP CARE

Figure 7.27 presents data on immunosuppressive medications used in adult recipients at the time of transplantation, as reported on the OPTN Immunosuppression Treatment form. All such medications are indicated on the form as maintenance immunosuppression. Mycophenolate data include mycophenolate mofetil and mycophenolate sodium, while mTOR inhibitors include sirolimus and everolimus. Data on mTOR inhibitors and steroids are also shown at one year post-transplant. Figure 7.28 highlights changes in the use of induction antibodies over the last decade, with data shown for first-time, kidney-alone transplants in 1999, 2004, and 2009.

Figures 7.29–31 address medication use in the first six months post-transplant. The cohort for these figures includes adult patients receiving a first-time, kidney-only transplant between July 1, 2007, and June 30, 2008, who remain alive with function and who have Medicare Part D coverage during the six months post-transplant. Medication use is defined by at least one prescription fill in this period. In Figure 7.30, other lipid lowering agents include cholesterol absorption inhibitors, niacin, and omega-3 fatty acids. For Figure 7.31, diabetic status is based on primary diagnosis (as recorded on the Medical Evidence form), and other anti-diabetes agents include alpha-glucosidase inhibitors, incretin mimetic agents, and amylin analogs.

Figure 7.32 displays the percentage of patients with Medicare claims for influenza vaccinations, lipid testing, and CBC panels. The cohort is limited to adult patients with Medicare coverage, transplanted in 1991–2009, and discharged alive with graft function. To

avoid counting inpatient procedures done as part of the transplant hospitalization, claims are searched from one day after the discharge date to one year post-transplant. Percentages are estimated using Kaplan-Meier methods, with censoring at graft failure, death, or loss of Medicare coverage. HCPCS codes for testing are as follows: influenza vaccination, 90724, 90657, 90658, 90659, 90660, and G0008; lipid panel, 80061, 82465, 83715, 83716, 83717, 83718, 83719, 83720, 83721, and 84478; and CBC panel, 85025, 85027, 80050, and 80055.

#### REFERENCE SECTION E

Tables E.1–5 present data on the kidney transplant wait list. Wait list data prior to 1988 are not shown; the OPTN wait list began in earnest in 1987. All wait list data are limited to ESRD certified patients. Table E.1 presents counts of patients newly added to the wait list for a kidney or kidney-pancreas transplant on December 31 of the given year. Patients listed at multiple transplant centers are counted only once. Table E.2 presents wait times, defined as the median time in days from first listing to transplant among patients listed for a kidney-alone transplant, and estimated with the Kaplan-Meier method. Patient listed at multiple centers are counted from the time of the first listing. Table E.3 presents counts of patients on the wait list at any center on December 31 of the given year, regardless of when the first listing occurred. Table E.4 includes point prevalent dialysis patients on December 31 of the given year. And Table E.5 presents the percentage of patients wait-listed or receiving a transplant within one year of ESRD initiation; patients receiving a transplant from a living donor are excluded from the measure in the first half of the table and included in the second half. Percentages are calculated using the Kaplan-Meier methodology.

Transplant counts are presented in Tables E.6–8. All known transplant events are included unless specified in the footnote, and all counts include non-Medicare patients. Table E.8 illustrates the distribution of transplanted patients by donor type and PRA level, determined from the OPTN Recipient Histocompatibility form, and shows as well a cross-tabulation of recipients and donors in terms of CMV antibody status, hepatitis C antibody status, and Epstein-Barr antibody status at the time of transplantation. A recipient/donor is considered positive for any of these antibodies if any applicable OPTN data source indicates positive. “Unknown” status is applied when no applicable data fields indicate “positive” or “negative.” Cold ischemia time (in hours) is reported for deceased donor transplants only, and is taken from the OPTN Transplant Recipient Registration form.

Transplant rates per 100 dialysis patient years are shown in Table E.9. All hemodialysis patients, peritoneal dialysis (CAPD/CCPD) patients, and patients on an unknown form of dialysis are included, as are all non-Medicare patients. A patient’s dialysis days are counted from the beginning of the specified year, or day one of ESRD dialysis therapy if treatment begins mid-year, until the first of transplant, death, or the end of the year. Patients lost to follow-up in a given year are not censored at the lost-to-follow-up date, but are followed until the end of the calendar year. Dialysis time for patients returning from transplant is counted. Transplant rates are calculated as the number of transplant events divided by the total number of dialysis patient years for each year.

#### REFERENCE SECTION F

This section presents probabilities of graft survival and graft failure necessitating dialysis or retransplantation, by donor type, age, gender, race, ethnicity, primary diagnosis, and transplant number. Data are presented for outcomes at 90 days, one year, two years, three

years, five years, and ten years post-transplant. In ADRs prior to 2010, “graft failure necessitating dialysis or retransplantation” was referred to as “death-censored graft failure.” Due to confusion regarding terminology, we renamed this outcome in the 2010 ADR. This section now seeks to address two major issues: the probability of graft survival at various times post-transplant, and the probability that a patient will return to dialysis or require retransplantation at various times post-transplant. Patients are followed from the transplant date to graft failure, death, or the end of the follow-up period (December 31, 2009). In the analysis of graft survival, death is considered a graft failure. In the analysis of graft failure necessitating dialysis or retransplantation, patients are followed until graft failure (excluding death), and patient follow-up is censored at death. To produce a standard patient cohort, patients with unknown age or gender are omitted. Unknown age is defined as a missing age at transplant, or an age calculated to be less than zero or greater than or equal to 100. Patients are also excluded if their first ESRD service date is prior to 1977.

Unadjusted survival probabilities are estimated using the Kaplan-Meier methodology, while the Cox proportional hazards model is used for adjusted probabilities. Probabilities are adjusted for age, gender, race, primary diagnosis, and first versus subsequent transplant, and standardized to 2005 patient characteristics.

## PEDIATRIC ESRD CHAPTER EIGHT

Information on pediatric patients is a subset of ESRD patient data used throughout the ADR; methods used for most figures are therefore the same as those described in the related chapter discussions.

### PREVENTIVE CARE

Figures 8.5–6 show rates of preventive healthcare in pediatric ESRD patients by modality and race. Methods and codes used to determine vaccination rates are similar to those described for Chapter Two. All patients are age 0–19 at the beginning of each study period; reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories; and have Medicare inpatient/outpatient and physician/supplier coverage for the entire period.

For influenza vaccinations, the cohort includes patients starting ESRD therapy at least 90 days prior to September 1 and alive on December 31 of each year; rates are calculated for patients vaccinated in the last four months of each year. For pneumococcal pneumonia vaccinations, the cohort includes prevalent patients initiating therapy at least 90 days prior to January 1 of the first year of each two-year period and alive on December 31 of the second year; rates are calculated for patients receiving one vaccination in each period. Years 2006–2009 are grouped in Figures 8.5, and 2006–2007 and 2008–2009 are grouped in Figure 8.6.

### HOSPITALIZATION

Figures 8.2–4 and 8.7–9 show admission rates among pediatric ESRD patients. Patients have Medicare as their primary payor and are residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with AIDS as a primary or secondary cause of death, and those with missing age or gender information, are excluded.

Figures 8.2–4 include period prevalent ESRD patients age 0–19 during pooled years 2006–2009; rates are unadjusted. Age is determined on January 1 of each year. Cohorts and admission rate calculations follow those described for Reference Section G. Principal ICD-9-CM codes for bacteremia/septicemia include 038.0–038.9

and 790.7, and for pneumonia include 480–486 and 487.0; those for respiratory infection exclude pneumonia and are as follows: 460–466, 472–474.OX, 475–476.1, 478.21–478.24, 487.1–487.8, 488–490, 491.1, 494, 510–511, 513.0, 518.6, and 519.01.

Figures 8.7–9 present adjusted admission rates in the first year among incident ESRD patients age 0–19 in 2001–2008. Since in-center hemodialysis patients who are younger than 65 and not disabled cannot bill for hospitalizations until 90 days after ESRD initiation, the 90-day rule is applied. Patients are required to survive the first 90 days after initiation, and are followed for admissions for up to one year. Data cleaning, and counting of admissions and time at risk for admissions, generally follow methods described for Reference Section G; here, however, incident patients are followed during intervals following day 90 rather than during prevalent years. Censoring occurs at death, loss to follow-up, end of payor status, December 31, 2008, or one year. Censoring also occurs three days prior to transplant for dialysis patients, and three years after the transplant date for transplant patients. Rates by age are adjusted for gender, race, and primary diagnosis, and those by modality are adjusted for age, gender, race, and primary diagnosis. Adjusted rates are calculated with a model-based adjustment method and an interval Poisson model. The reference cohort includes incident ESRD patients age 0–19 in 2004–2005. Principal ICD-9-CM diagnosis codes used for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 3.1.

### MORTALITY AND SURVIVAL

Figure 8.10–12 present adjusted all-cause and cause-specific mortality in the first months of ESRD, by age and modality, for 2001–2008 incident patients younger than 20. Dialysis patients are followed from the day of ESRD onset until December 31, 2009, and censored at loss to follow-up, transplantation, or recovered function. Transplant patients who receive a first transplant in a calendar year are followed from the transplant date to December 31, 2009. Rates are adjusted for gender, race, and primary diagnosis. Incident ESRD patients younger than 20, 2004–2005, are used as the reference cohort.

Figure 8.13 presents five-year survival for 2000–2004 incident ESRD patients age 0–19. Dialysis patients are followed from the day of ESRD onset until December 31, 2009, and censored at loss to follow-up, transplantation, or recovered function. Transplant patients who receive a first transplant in a calendar year are followed from the transplant date to December 31, 2009. Probabilities by age are adjusted for gender, race, and primary diagnosis; probabilities by modality are adjusted for age, gender, race, and primary diagnosis. The reference population consists of 2004–2005 incident pediatric ESRD patients.

### SPECIAL STUDIES

#### CHAPTER NINE

Methods for the ACTIVE/ADIPLOSE study are presented in the chapter itself.

## ESRD PROVIDERS CHAPTER TEN

Throughout the atlas and in Reference Section J, we define a chain-affiliated unit as one of a group of 20 or more freestanding dialysis units owned or operated by a corporation at the end of a year. The category of small dialysis organization (SDO) includes all organizations meeting our definition of a chain but having 20 or more and fewer than 200 units. In previous years, chain affiliation

was determined from the “Provider Name” field of the CMS Annual Facility Survey and the “Chain Organization Name” field of the CMS Independent Renal Facility Cost Report. Currently, however, it is determined solely from the “Chain Name” field of the CMS patient-accessible, web-based Dialysis Facility Compare database (DFC).

Data are obtained from the Facility Survey (1988–2009), the Cost Report (Form 265-94, 1994–2000), the DFC database (2001 to the present), and the CDC National Surveillance of Dialysis-Associated Diseases in the United States (1988–2002, excluding 1998, when the CDC did not conduct a survey). The CDC discontinued the National Surveillance of Dialysis-Associated Diseases after 2002. In 2009, there were 5,760 facilities in the Facility Survey.

A facility’s hospital-based or freestanding status is determined from the third and fourth digits of the provider number assigned to each unit by CMS. For years prior to 2002, we determine profit status through the ownership type field on the CMS survey. In the 2002 CMS survey the profit status variable was dropped, so for that and subsequent years we use the profit status field of the DFC database. There are, however, a small number of facilities in the CMS survey that are not in the DFC database; these facilities have an unknown profit status, and are omitted from any figure showing profit status.

For provider-specific analyses, unless otherwise noted, the dialysis provider for individual patients is assigned as follows: for prevalent studies, the patient is assigned to the facility providing dialysis services at the prevalent date, as determined from the treatment history. For incident analyses, the patient is assigned to the facility providing dialysis services at the incident date, as determined from the treatment history. In either case, if provider data are unavailable from the patient’s treatment history, the patient is assigned to “unknown provider” or excluded, depending on the analysis.

Figure 10.1 shows the distribution of units and patients for large dialysis organizations (LDOs) and SDOS from the 2009 Facility Survey. Figure 10.2 presents the number of dialysis facilities and patients by renal network, while Figure 10.3 compares chain affiliations for 2004 and 2009. Figure 10.4 compares chain ownership and time under chain ownership for facilities in 2004 and 2009.

Figure 10.5 includes period prevalent dialysis patients in 2009. Hemoglobin data include only patients with valid EPO claims. A mean is calculated for each patient from all valid claims in the year, and chain affiliation is defined at the final patient claim of the year.

Figure 10.6 illustrates IV iron use, by dialysis unit affiliation and product type. The cohort consists of patients initiating ESRD therapy at least 90 days prior to the start of 2009, and receiving dialysis on December 31, 2008. All patients survive, continue dialysis, and carry Medicare as primary payor during all of 2009. Iron use is indicated by inpatient/outpatient claims with HCPCS codes J1750, J1755–J1756, J1760, J1770, J1780, and J2915–J2916. For iron use, chain affiliation is defined at the beginning of follow-up.

Figures 10.7–8 include data from all incident dialysis patients with an EPO claim in the first 30 days of ESRD therapy, and at least one EPO claim during each of the following six months. Figure 10.9 includes 2009 point prevalent dialysis patients with a first service date 90 days prior to January 1, 2009, and alive through the end of the year. Rates represent patients with one or more transfusions within the year. In the case of an overlap in transfusion dates, only one event is used. If both inpatient and outpatient claims indicate a transfusion event and have the same “from” date, we use the inpatient claim; if inpatient and outpatient claims partially overlap, we use the claim with the earliest date; and if one or more short-period claims indicating a transfusion are within a long-period claim indicating a transfusion, we use the long period claim.

Figures 10.10–12 employ the same cohort as Figure 2.8, here for 2008–2009 and limited to dialysis patients. The cohort for Figure 10.13, on influenza vaccinations, includes all dialysis patients initiating therapy at least 90 days prior to September 1 and alive on December 31, 2009. For Figure 10.14, on pneumococcal pneumonia vaccinations, the cohort includes all dialysis patients initiating therapy at least 90 days before January 1 of 2008 and alive on December 31, 2009. And the cohort for Figure 10.15, on hepatitis B vaccinations, includes all dialysis patients initiating therapy at least 90 days before January 1 and alive on December 31, 2009. Patients without Medicare Part A and B coverage during the year are excluded, as are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories; who have a missing date of birth; who have dialysis for fewer than 90 days prior to the start of the reporting interval; or who are lost-to-follow-up during the study period.

Influenza vaccinations are tracked between September 1 and December 31, 2009, while pneumococcal pneumonia and hepatitis B vaccinations are tracked during 2009. Codes are as follows: influenza, CPT codes 90724, 90657, 90658, 90659, and 90660, and HCPCS code G0008; pneumococcal vaccinations: CPT codes 90669 and 90732, and HCPCS codes J6065 and G0009; hepatitis B: CPT codes 90636, 90740, 90743–90744, 90748, 90731, 90723, and G0010.

Figures 10.16–17 use the Model 1 (as-treated actuarial model) methods described for Chapter Eleven. Costs for clinical services are taken from outpatient facility claims for period prevalent dialysis patients, and expressed as per person per month costs.

Figures 10.18–25 compare mortality and hospitalization among dialysis provider types, chains, and regions, using standardized mortality ratios (SMRs) and standardized hospitalization ratios (SHRs). Both are estimated by the traditional SMR calculation method. A patient’s dialysis provider is defined on January 1, 2009. Patients are followed from January 1, 2009, to the first of death, transplant, or December 31, 2009. Patients dying of AIDS are excluded; those dying of drug overdose (street drugs) or of an accident not related to treatment are censored at the date of death. SMR calculations include all January 1, 2009, point prevalent hemodialysis patients, while SHR calculations include only hemodialysis patients with Medicare as primary payor, and use the number of hospital admissions as the endpoint. Both SMRs and SHRs are adjusted for age, gender, race, primary diagnosis, and vintage, with 2009 point prevalent hemodialysis patients as the reference cohort for the SMR calculations, and Medicare patients used for the SHR data.



## costs of end-stage renal disease

### CHAPTERELEVEN

The majority of economic analyses in this ADR use the as-treated model, described later in this section.

### PAYOR SEQUENCE

The payor sequence is similar in concept to the USRDS treatment history. Payor status is tracked for each ESRD patient from the first ESRD service date until death or the end of the study period. Data from the Medicare Enrollment Database, as well as dialysis claims information, are used to categorize payor status as Medicare primary payor (MPP), Medicare secondary payor (MSP), Medicare Advantage (HMO), or non-Medicare. The claims database contains data only for MPP and MSP patients, so economic analyses are restricted to these categories. In addition, since it is impossible to determine the complete cost of care for ESRD patients with MSP coverage, most analyses exclude patients during the periods when they have this coverage.

## CHAPTER ELEVEN

Table p.a in the Précis summarizes data on the costs of ESRD treatment. Total 2009 Medicare spending is calculated from the claims data, and includes all paid claims for ESRD patients in the USRDS database. Cost aggregation for each patient begins at the first ESRD service date. Total 2009 Medicare spending is inflated by 2 percent to account for incomplete claims, and organ acquisition costs are estimated with the same methods used in the 1999 ADR (pages 149–150). HMO costs are estimated using the total HMO months for 2009 (obtained from the CMS managed care organization file) in conjunction with the 2009 AAPCC rate.

Non-Medicare EGHP spending is estimated by separately computing the per year at-risk costs for EGHP and non-EGHP patients, then multiplying the difference by the EGHP years at risk for 2009. Patient obligations are estimated as the difference between Medicare allowable and net payment amounts. Non-Medicare patient spending is estimated as the number of patient months at risk for non-Medicare patients (determined from the USRDS payor sequence) multiplied by the AAPCC rate.

Changes in Medicare spending from 2008 to 2009 are obtained from Table K.2, without the 2 percent adjustment for late claims. Calculations of per person per year (PPPY) at-risk costs are based on patients for whom Medicare is the primary payor during the study period (Table K.e), again using non-inflated results. The range for inflation-adjusted costs is calculated using the overall Consumer Price Index (-0.4 percent) and Medical Consumer Price Index (3.2 percent).

Figures 11.12–18 describe PPPY costs for items billed in the outpatient SAFs, particularly injectable drugs, for period prevalent dialysis patients with Medicare as primary payor.

Figures 11.19–25 present PPPY costs for the services described in Figures 11.12–18, by modality and race. Modalities are determined using Model 1 (as-treated actuarial model) methodology, as described below. Data are also presented for a subset of hemodialysis patients who are matched to peritoneal dialysis patients, using a propensity score technique. In the cohort of dialysis patients, we first estimate the propensity for peritoneal dialysis prescription by fitting a logistic model of dialytic modality, with age, race (white, black, other), gender, primary cause of ESRD (diabetes, hypertension, glomerulonephritis, cystic kidney disease, other known, unknown), cumulative ESRD duration, and seven diagnosed comorbid conditions (cardiovascular disease, hypertension, diabetes, COPD or tobacco use, cancer, alcohol or drug dependence, and in need of assistance) as predictors. Age and ESRD duration are parameterized with quadratic polynomials. The propensity for peritoneal dialysis prescription is defined as the estimated probability of peritoneal dialysis as dialytic modality. We then assemble a matched cohort by matching to each peritoneal dialysis patient with propensity  $p$  a hemodialysis patient with propensity  $q$ , such that  $|p - q|$  is minimized, and we use a greedy matching algorithm.

Figures 11.26–36 and Table 11.a present cost data for the Medicare Part D prescription drug benefit. Data are currently available only for calendar years 2006 (the first year of the benefit) through 2008. Costs are estimated net pay, calculated as the sum of the plan payment amount and the low income subsidy (LIS); they do not include out-of-pocket expenditures. Figures 11.26–28 and Table 11.a include all Part D claims for ESRD patients, starting on January 1, 2008 (or the first ESRD service date if after this date), regardless of payor status; total Medicare costs for Part D (estimated from the 5 percent Medicare sample) are included for comparison. Figures 11.29–36 include 2008 period prevalent ESRD patients enrolled in

Part D for all of 2008. LIS status is determined from the Part D enrollment file. Costs are estimated net pay or true out-of-pocket costs (Figure 11.30), are presented separately for dialysis and transplant patients, and, for Figures 11.31–36, are restricted to drugs in the specific categories addressed in each figure; combination drugs which cross categories (e.g., a beta blocker with a lipid lowering agent) are not included, unless specifically noted in the figure caption.

## REFERENCE SECTION K: MEDICARE CLAIMS DATA

Cost information in this section is derived from Medicare inpatient/outpatient and physician/supplier claims data in the CMS SAFs, which are created annually six months after the end of each calendar year. The data for 2005–2009 are comprised of approximately 43 million institutional claims for hospital inpatient and outpatient facilities, outpatient dialysis facilities, skilled nursing facilities, hospice facilities, and home health agencies, as well as over 390 million line items from physician/supplier claims. Claims data are obtained for all patient identification numbers in the USRDS database, and the Renal Management Information System (REMS) is used to gather all CMS ID numbers under which patients may have claims. The claims data are then merged with patient demographic data and modality information in the USRDS database.

The economic analyses for this section focus on two amounts found in the claims data: the claim payment amount, which is the amount of the payment made from the Medicare trust fund for the services covered by the claim record; and the pass-through per diem amount, which applies to inpatient claims and reimburses the provider for capital-related costs, direct medical education costs, and kidney acquisition costs.

## PAYMENT CATEGORIES

Medicare payments are broken into several categories, as shown in Table K.c. Estimates of costs from the Outpatient SAF are derived for the individual services provided. Since actual payment amounts are provided only for the entire claim, cost estimates for dialysis, EPO, iron, and so forth are calculated from the claim-level "Total Charge," the payment amount, and the revenue line-level "Total Charge," as follows: payment (line) = [total charge (line) / total charge (claim)] \* payment (claim). In August, 2000 CMS added to the Outpatient SAF a field containing line item payment amounts. According to CMS documentation, the total of these payments may not equal the total paid amount for the claim. In such cases, each line item cost is discounted by the ratio of the sum of line item payment amounts to the total paid amount for the claim. Since complete data on line item payments are available starting with the 2001 Outpatient SAF, the estimates for outpatient payment categories are taken directly from the claims data for calendar years 2001–2009, with adjustments as noted.

## MODEL I: AS-TREATED ACTUARIAL MODEL

In an as-treated model patients are first classified by their modality at entry into the analysis, and retain that classification until a modality change. When a change is encountered in the data, the beginning modality is censored at the change date plus 60 days, and a new observation with the new modality is created. The first 60 days after a change are attributed to the previous modality to account for any carryover effects. If the change is from dialysis to transplant, however, the modality is censored, and the transplant modality begins on the date of the transplant hospital admission. In the case of changes involving only a change from one type of dialysis to another, the new modality must last at least 60 days in order to be counted. Aggregation of Medicare payments is done on

an as-treated basis, attributing all payments to the patient's modality at the time of the claim.

In Section K of the Reference Tables we classify patients into four as-treated modality categories: hemodialysis, CAPD/CCPD, other dialysis, and transplant. The "other dialysis" category includes cases in which the dialysis modality is unknown or is not hemodialysis or CAPD/CCPD, while the transplant category includes patients who have a functioning graft at the start of the period or who receive a transplant during the period. Some tables also include categories for all dialysis (hemodialysis, CAPD/CCPD, and other dialysis) and all ESRD (all-dialysis and transplant).

The study spans the 19 years from January 1, 1991, to December 31, 2009, and ESRD patients prevalent on January 1, 1991, or incident at any time during the period are potentially eligible for inclusion. The initial study start date for a given patient is defined as the latest of January 1, 1991, the first ESRD service date in the USRDS database for that patient, or the earliest Medicare eligibility date from the payor sequence. Because it is impossible to characterize the total cost of their care, patients for whom Medicare is the secondary payor at any time during the study period are classified as MSP for the duration of the MSP status in the payor sequence. If the payor status changes to Medicare as primary payor, a new sequence begins at the change date. Patients who are non-Medicare or enrolled in a Medicare Advantage program are excluded until their payor status changes to Medicare (either as primary or secondary payor). Patients classified as MSP are included in Tables K.1–4, and are excluded for the rest of the tables in Section K.

For each modality period, Medicare payments are aggregated from the modality start date until the earliest of death, transplant, modality change, loss to follow-up, or December 31, 2009. Patients incurring no inpatient/outpatient or physician/supplier Medicare costs for the entire period are excluded, and Medicare payment amounts are linearly prorated for claims that span the start or end date of a modality period or of the study itself.

To express costs as dollars per year at risk, total costs during the follow-up period are divided by the length of the period. Costs per patient year at risk are calculated by patient category, and stratified by age, gender, race, modality, and diabetic status. Diabetic status is based on the primary diagnosis, as recorded on the Medical Evidence form. A patient with a non-diabetic cause of renal failure may have diabetes, but the disease is not judged to be the cause of ESRD. Patient age is calculated at the study start date, and patients with a missing date of birth are excluded from the analysis.

#### **MODEL 2: CATEGORICAL CALENDAR YEAR MODEL**

This model, described in the HCFA (now CMS) research report on ESRD (1993–1995), is used for Figure 11.8, as well as Reference Tables K.10–13. With this method, patients are classified into four mutually exclusive treatment groups:

- » **dialysis:** ESRD patients who are on dialysis for the entire calendar year, or for that part of the year in which they are alive, ESRD, and Medicare entitled.
- » **transplant:** ESRD patients receiving a kidney transplant during the calendar year.
- » **functioning graft:** ESRD patients with a functioning graft for the entire calendar year, or for that part of the year in which they are alive, ESRD, and Medicare entitled.
- » **graft failure:** ESRD patients who have had a transplant, but return to dialysis due to loss of graft function during the calendar year; patients with a graft failure and a transplant in the same calendar year are classified in the transplant category.

<b>a Cii</b>	<b>Medicare categories of payment &amp; basis for categorizing claim</b>
Total	Sum of all payments
Total inpatient	Sum of all payments originating from the inpatient SAF, including pass-throughs
Medical DRG	Inpatient SAF, DRG
Surgical DRG	Inpatient SAF, DRG
Transplant DRG	Inpatient SAF, DRG 302 & 512
Other DRG	Inpatient SAF, DRG not included in the above categories
Non-transplant pass-throughs	Inpatient SAF, DRG not 302 or 512, calculated from per diem and covered days
Transplant pass-throughs	Inpatient SAF, DRG 302, calculated from per diem and covered days
Total outpatient	Sum of all payments originating from the Outpatient SAF
Outpatient hemodialysis	Outpatient SAF, hemodialysis revenue codes
Outpatient peritoneal dialysis	Outpatient SAF, peritoneal dialysis revenue codes
Outpatient other dialysis	Outpatient SAF, dialysis revenue codes other than HD or PD
Outpatient ESA	Outpatient SAF, revenue codes and/or HCPCS code
Outpatient vitamin D hormones	Outpatient SAF, revenue and HCPCS codes
Outpatient iron	Outpatient SAF, revenue and HCPCS codes
Outpatient other injectables	Outpatient SAF, revenue and HCPCS codes
Radiology	Outpatient SAF, revenue and/or CPT codes
Pharmacy	Outpatient SAF, revenue codes
Ambulance	Outpatient SAF, revenue codes
Laboratory/pathology	Outpatient SAF, revenue and/or CPT codes
Outpatient other	Outpatient SAF, does not qualify for any other cost category
Skilled nursing facility	Skilled nursing facility SAF
Home health agency	Home health SAF
Hospice	Hospice SAF
Total physician/supplier	Sum of physician/supplier payments
Transplant surgery	Physician/supplier SAF, CPT codes
Inpatient surgery	Physician/supplier SAF, CPT, and place of service codes
Outpatient surgery	Physician/supplier SAF, CPT and place of service codes
E&M nephrologist inpatient	Physician/supplier SAF, CPT, place of service and specialty codes
E&M nephrologist outpatient	Physician/supplier SAF, CPT, place of service and specialty codes
E&M non-nephrologist inpatient	Physician/supplier SAF, CPT, place of service and specialty codes
E&M non-nephrologist outpatient	Physician/supplier SAF, CPT, place of service and specialty codes
Dialysis capitation	Physician/supplier SAF, CPT and/or type of service codes
Inpatient dialysis	Physician/supplier SAF, CPT codes
Home dialysis	Physician/supplier SAF, HCPCS and place of service codes
Vascular access	Physician/supplier SAF, CPT codes
Peritoneal access	Physician/supplier SAF, CPT codes
Physician/supplier ESA	Physician/supplier SAF, HCPCS codes
Physician/supplier iron	Physician/supplier SAF, HCPCS codes
Immunosuppressive drugs	Physician/supplier SAF, HCPCS codes
Duralean medical equipment	Physician/supplier SAF, HCPCS codes
Physician/supplier radiology	Physician/supplier SAF, CPT and specialty codes
Physician/supplier lab/pathology	Physician/supplier SAF, CPT codes
Physician/supplier ambulance	Physician/supplier SAF, HCPCS and place of service codes
Other physician/supplier	Physician/supplier SAF, does not qualify for any other category
E&M: Evaluation and management	

#### EGHP PATIENTS

Figure 11.8 includes data for EGHP patients. Patients in the MarketScan database who are identified as having ESRD, are younger than 65, and do not have evidence of Medicare payments (either as primary or secondary payor) are included in these analyses. Medicare payments are identified in the MarketScan database, and patients are excluded on the basis of these payments in order to obtain a more accurate estimate of ESRD costs in the private sector. The payment amounts presented are the net payments and do not include deductibles and copayments.



#### INTERNATIONAL COMPARISONS

##### CHAPTER TWELVE

The international data for this Annual Data Report have been collected from the following sources, using the data collection form at the end of this section:

- » Marinovich S, Lavorato C, Celia E, Bisignano L, Soratti M, Hansen Krogh D, Tagliafichi V, Moroñigo C, Rosa Diez G and Fernandez V. Registro Argentino de Diálisis Crónica 2009.
- » Sociedad Argentina de Nefrología (SAN) and Instituto Nacional Central Unico Coordinador de Ablación e Implante (INCUCAI). Buenos Aires, Argentina, 2011.
- » the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA)
- » the Austria OEDTR
- » the Bangladesh Renal Registry
- » the French-Speaking Belgium ESRD Registry, Bruxelles
- » Nederlandstalige Belgische Vereniging voor Nefrologie (NBVN)
- » Clinical Center University of Sarajevo, Bosnia, and Herzegovina
- » Sociedade Brasileira de Nefrologia and Associação Brasileira de Transplante de Órgãos
- » the Canadian Organ Replacement Register (CORR)
- » the Chilean Renal Registry
- » the Asociación Colombiana de Nefrología
- » the Croatian Society of Nephrology, Dialysis, and Transplantation
- » the Czech Dialysis Registry
- » the Danish Society of Nephrology
- » the ERA-EDTA Registry
- » the Finnish Registry for Kidney Diseases
- » the French Renal Epidemiology and Information Network (REIN) Registry
- » the Hellenic Renal Registry, Greece
- » the Hong Kong Renal Registry
- » the Landspítali University Hospital, Iceland
- » the Israeli Renal Registry
- » the Jalisco State Dialysis and Transplant Registry, Mexico
- » the Japanese Society of Dialysis Therapy
- » the Korean Society of Nephrology ESRD registry
- » Registre Néphrologique du Grand-Duché de Luxembourg
- » the National Renal Registry, Malaysia
- » Instituto Mexicano De Trasplantes, Cuernavaca Morelos, Mexico
- » Netherlands Dialysis Registry
- » the Norwegian National Hospital
- » the Philippines Renal Disease Registry Project

- » the Polish Renal Registry
- » the Romanian Renal Registry
- » the Society of Dialysis, Russia
- » the Scottish Renal Registry
- » the Registro Español de Enfermos Renales and Organización Nacional de Trasplantes, Spain
- » the Swedish Renal Registry
- » the Taiwan Society of Nephrology
- » the Thailand Renal Replacement Therapy Registry and the Nephrology Society of Thailand
- » the Turkish Society of Nephrology
- » the UK Renal Registry
- » the Uruguayan Dialysis Registry and Uruguayan Registry of Renal Transplantation
- » the U.S. Census Bureau International Database

Thank you to all who provided data for this year's ADR. We are especially grateful to staff at the ERA-EDTA Registry for their help in coordinating much of the European data presented in this chapter. Data for some countries do not represent 100 percent of the ESRD population; interpretation of changes in incident and prevalent rates must therefore be performed with caution. Notations are made in the captions for countries reporting prevalent data only for dialysis patients. Data from Belgium and from England, Wales, and Northern Ireland do not include patients younger than 20 and 18, respectively. To contribute data from your country's registry, please complete the International Data Collection Form and return it to the USRDS at [usrds@usrds.org](mailto:usrds@usrds.org).

#### VASCULAR ACCESS

##### L TABLES

Tables L.1–3 include period prevalent hemodialysis patients, 1999–2008, who have Medicare as their primary payor. Placements are identified from Medicare claims, and rates represent the total number of events divided by the time at risk. Follow-up time is censored at death, change in modality, change in payor status, or the end of the prevalent year. Tables L.4–6 include January 1, 2008 point prevalent hemodialysis patients. Vintage represents the amount of time between the first service date and January 1, 2008.

Tables L.7–14 include point prevalent hemodialysis patients with Medicare as primary payor who are also in the ESRD CPM report for the corresponding year. Current access is determined from the CPM data as the access used at the time of the most recent data collection, i.e., during the months of October, November, and December of the year prior to the prevalent year. Complications and intervention events are obtained from claims during the time at risk in the prevalent year, which is censored at death, change in modality, change in payor status, or a claim for the placement of a different hemodialysis vascular access. Patients who have a placement claim after the time of the CPM data collection but prior to the start of the prevalent year are excluded.

Tables L.14–15 include point prevalent peritoneal dialysis patients with Medicare as primary payor. Complications and intervention events are obtained from claims during the time at risk in the prevalent year, which is censored at death, change in modality, change in payor status, or a claim for the placement of a hemodialysis vascular access.

#### CENSUS POPULATIONS

The 2000 U.S. Census, available in 2002, introduced a new race category with additional groupings. Estimates for 1990–1999 were

back-calculated based on the actual 2000 census. Later data, however, include racial groups that do not coincide with those in the ESRD data. For rate calculations throughout the ADR we thus use the CDC's Bridged Race Dataset, which estimates white, African American, Native American, and Asian populations. The data and methods for these estimates are available at <http://tinyurl.com/28kppqj>.

## statistical methods

### METHODS FOR CALCULATING RATES

The calculation of observed rates is straightforward, with some rates based on counts and others on follow-up time. The ESRD incident rate in 2009, for example, is the observed incident count divided by the 2009 population size and, if the unit is per million population, multiplied by one million; the 2009 death rate for prevalent ESRD patients is the number of deaths in 2009 divided by the total follow-up time (patient years) in 2009 of the 2009 prevalent patients, and, if the unit is per thousand patient years, multiplied by one thousand. Standard errors of estimated rates are based on the assumption of the data; the observed count has a Poisson or binomial distribution. The count-based rate describes the proportion of having "event" and the time-based rate tells how often the "event" happens when the "event" rate is invariant over time.

### model-based rates

Some patient groups may be very small, and their observed rates therefore unstable. If follow-up time is considered, the hazard of an event may change over time. A model-based method can improve the stability of these estimates and incorporate changes of hazard over time. In this ADR, for example, we have used the generalized linear mixed Poisson model to estimate prevalent patient mortality rates for Reference Section H.

### measurement unit for rates

Both raw and model-based rates are calculated per unit of population (such as per 1,000 patients) or per unit of follow-up time (such as per 1,000 patient years). Calculating rates per unit of follow-up time can account for varying lengths of follow-up among patients. Patient years are calculated as the total number of years, or fractions of a year, of follow-up time for a group of patients.

Take, for example, a calculation of 2009 first hospitalization rates for two groups of patients, all receiving dialysis therapy on January 1, 2009. Group A consists of three patients: Patient 1 had a first hospitalization on March 31, 2009; Patient 2 was hospitalized on June 30, 2009; and Patient 3 was on dialysis through December 31, 2009, with no hospitalizations. Group B also has three patients: Patient 4 was first hospitalized on December 31, 2009; Patient 5 was hospitalized on September 30, 2009; and Patient 6 was on hemodialysis the entire year, with no hospitalizations through December 31, 2009.

Patients 1 to 6 contribute 0.25, 0.5, 1.0, 1.0, 0.75, and 1.0 patient years at risk, respectively. The first hospitalization rate per thousand patients is 667 for both groups in 2009. But the first hospitalization rate per thousand patient years at risk is 1,143 for Group A and 727 for Group B (calculated as [2 total events / 1.75 total patient years at risk] x 1,000 for Group A and [2 total events / 2.75 patient years at risk] x 1,000 for Group B). The resulting rate is lower for Group B because of the longer total follow-up time.

Rates per unit of population may be influenced by the proportion of patients who are followed for only a fraction of a year. The event rate per unit of population is likely to be lower, for example, in a group of patients followed for only one month until censoring than in a group whose patients are each followed for up to a full year.

Rates per unit of follow-up time at risk, in contrast, count only the actual time that a patient is at risk for the event.

### METHODS FOR ADJUSTING RATES

Because each cohort contains a different patient mix, unadjusted event rates may not be comparable across cohorts. Adjusted analyses make results comparable by reporting rates that would have arisen had each cohort contained patients with the same distribution of confounders — such as age, gender, race, and primary diagnosis — as the reference population.

### direct adjustment

There are several rate adjustment methods, but only the direct method allows rates to be compared (Pickle LW, White AA). Here the adjusted rate is derived by applying the observed category-specific rates to a single standard population, i.e. the rate is a weighted average of the observed category-specific rates, using as weights the proportion of each category in the reference population. Categories are defined by the adjusting variables. For example, if a rate is adjusted for race and gender and there are three race groups (white, African American, and other) and two gender groups, there are six categories: white males, white females, African American males, African American females, males of other races, and females of other races.

Suppose we try to compare state-level incident rates in 2009 after removing the difference caused by race. To do this, we need to calculate the adjusted incident rate, adjusted for race, for each state. Because racial distributions in each state are quite different, we use as reference the national population — here, the population at the end of 2009 — with five race groups (white, African American, Native American, Asian/Pacific Islander, and other).

Assuming the incident rate of state A in 2009 is 173 per million population, and the race-specific rates and national populations are as shown in the following table, the adjusted incident rate of state A with the national population as reference is  $(153 \times 75.1\%) + (250 \times 12.3\%) + (303 \times 0.9\%) + (174 \times 3.6\%) + (220 \times 8\%) = 158.73$  per million population. This means that if state A had the same racial distribution as the entire country, its incident rate would be 158.73 instead of 173. If state B had an adjusted incident rate of 205, we could say that state B had a higher incident rate than state A if they both had the same racial distribution as the whole country.

	Incident rate of State A	National population (%)
White	153	75.1
African American	250	12.3
Native American	303	0.9
Asian/Pacific Islander	174	3.6
Other	220	8.0

This method is used to produce some adjusted incident and prevalent rates in Chapters Two and Three and in Reference Sections A and B, as well as in the model-based adjustment method.

### model-based adjustment

Under some circumstances there are disadvantages to the direct adjustment method. Suppose we are calculating mortality rates for a set of groups, and adjusting for potential confounding variables. If one category in a group has only a few patients or deaths, its estimated mortality rate will be unstable, likely making the adjusted rate unstable as well. In addition, if one includes category no patients, the method is not valid for calculating an adjusted mortality rate for

the group. An attractive alternative is a model-based approach, in which we find a good model to calculate category-specific estimated rates for each group and then calculate direct adjusted rates using these estimates with a given reference population. This method can also be extended to adjustments with continuous adjusting variables (Liu et al., 2006). There is, unfortunately, no straightforward way here to calculate standard errors of the adjusted rates for some models; the bootstrap approach works well, but is time consuming.

In this ADR we use model-based adjustments to calculate adjusted mortality rates; adjusted survival probabilities based on the Cox regression model; adjusted hospitalization rates and state-level adjusted incident and prevalent rates using the Poisson model; adjusted HSA-level incident and prevalent rates based on the Bayesian spatial hierarchical model, and some other rates, described in the text on the individual figures.

#### SURVIVAL PROBABILITIES & MORTALITY RATES

##### unadjusted survival probabilities

In this ADR, unadjusted survival probabilities are calculated using the Kaplan-Meier method, and corresponding standard errors are calculated with Greenwood's formula (Kalbfleisch JD, Prentice RL). Survival probabilities in Reference Section 1 are expressed as percentages from 0 to 100. The mortality/event rate in the period of (0,t) is calculated by  $-\ln(\text{Survivor at time } t)$ . This event rate will be the same as that estimated by event time divided by follow-up time after adjustment of the unit if the event rate is a constant over time.

##### survival probability with competing risks

When competing risks exist, the estimate of the cumulative incidence function of a specific cause may be biased if the other competing risks are ignored. If we have  $K$  competing risks, the cumulative incidence function of cause  $k$ ,  $k=1, 2, \dots, K$ , at time  $t$ ,  $I_k(t)$ , is defined as the probability of failing from cause  $k$  before time  $t$  (including time  $t$ ),  $\text{Prob}(T \leq t, D=k)$ . Then

$$I_k(t) = \int_0^t \lambda_k(s)S(s)ds$$

where  $\lambda_k(s)$  is the hazard of event from cause  $k$  at time  $s$  and  $S(s)$  is the survival probability at time  $s$ . If we have failing time  $t_1, t_2, \dots, t_m$ , the cumulative incidence function of cause  $k$  at time  $t$  is estimated by

$$\hat{I}_k(t) = \sum_{j:t_j \leq t} \hat{\lambda}_k(t_j) \hat{S}(t_{j-1})$$

where  $\hat{\lambda}_k(t_j) = d_{kj}/n_j$ ,  $\hat{S}(t_{j-1})$  is the Kaplan-Meier estimate of survival at time  $t_{j-1}$ ,  $d_{kj}$  is the number of patients failing from cause  $k$  at time  $t_j$ , and  $n_j$  is the number of patients at risk at prior time  $t_j$  (Putter et al.).

##### adjusted survival probabilities

Adjusted survival probabilities are reported in Reference Sections G and I, with age, gender, race, and primary diagnosis used as adjusting risk factors. The model-based adjustment method is used, with survival probabilities predicted from the Cox regression model (Kalbfleisch JD, Prentice RL). This process yields estimates of probabilities that would have arisen in each year if the patients had had the same attributes as the reference population. Since the probabilities in each table are adjusted to the same reference set of patient attributes, any remaining differences among cohorts and years are due to factors other than age, gender, race, and primary diagnosis. The adjusted mortality rates for incident cohorts in Reference Section H are calculated using similar methods.

#### GENERALIZED LINEAR MODELS

##### generalized linear mixed model for mortality rates

We use the generalized linear mixed model with log link and Poisson distribution to calculate mortality and first transplant rates for prevalent patients. While rates are reported for a year, data from the previous two years with different weights are also used to improve the stability of the estimates. The generalized linear mixed model is used as well for SMR calculations, described later in this section.

The generalized linear mixed model, which considers both fixed and random effects, is implemented using the SAS macro GLIMMIX. Rates for the intersections of age, gender, race, and diagnosis are estimated using the log linear equation  $\text{Log}(\text{rate}) = (\text{fixed effects}) + (\text{random effect})$ . Fixed effects include year, age, gender, race, and primary diagnosis, and all two-way interactions among age, gender, race, and primary diagnosis. Assumed to be independently and identically distributed with a normal distribution, the random effect is the four-way interaction of age, gender, race, and primary diagnosis. Age is used as a categorical variable in main effect and four-way interactions, and as a continuous variable in two-way interactions.

For tables with mortality rates for both intersecting and marginal groups we have used a single model to calculate all rates in each table. The marginal rates are simply the weighted averages of the estimated, cross-classified rates, with cell-specific patient years as weights. For this approach the use of a single model means that GLIMMIX cannot give the standard errors for some of these estimated rates; the bootstrap method is therefore used instead.

The adjusted mortality rates for prevalent cohorts in Section H are calculated using the direct adjustment method based on the category-specific mortality rates from the generalized linear mixed models.

##### generalized linear model for hospitalization rates

In this ADR, hospitalization reference tables present rates of total admissions and hospital days. We use a generalized linear model with log link and Poisson distribution; the model includes age, gender, race, primary diagnosis, and their two-way interactions.

To stabilize the estimates, three years of data are used with different weights. Year is also included in the model as a covariate. The adjusted hospitalization rates are calculated using the direct adjustment method based on the category-specific admission rate from the generalized linear models.

#### STANDARDIZED MORTALITY RATIOS

The standardized mortality ratio (SMR) compares the mortality of a group of patients relative to a specific norm, or reference, after adjusting for some important risk factors. For example, the state-level SMR is used to compare mortality in prevalent dialysis patients—after adjusting for age, gender, race, primary diagnosis, and ESRD vintage—in each state using the national dialysis population in the corresponding year as the reference. An SMR of 1.05 for a state indicates that patients in this state have a risk of death approximately five percent higher than that of patients in the reference population of all U.S. dialysis patients.

##### traditional method of SMR calculation

The traditional approach used to calculate unit-specific SMRs is straightforward: produce unit-specific expected death counts and compute the “observed/expected” ratio. There are two methods of producing unit-specific expected death counts. In the indirect method, the expected death count is the weighted sum of category-specific death rates in the reference population, and the weights

are the category-specific total follow-up times in the units. In the model-based method, a statistical model is employed to estimate the category-specific death rate for the reference population, and the indirect method is then used to produce the expected death count for each unit based on the estimates of category-specific death rates of the reference population from the model.

#### **EXPECTED REMAINING LIFETIMES**

The expected remaining lifetime for a patient group is the average of the remaining life expectancies for the patients in that group. Some patients will live longer than, and some will live less than, the average. Although the average cannot be known until all patients in the cohort have died, the expected remaining lifetime can be projected by assuming that patients in the cohort will die at the same rates as those observed among groups of recently prevalent ESRD patients.

For a subgroup of ESRD patients of a particular age, the expected remaining lifetime is calculated using a survival function, estimated for the group. Let  $S(A)$  denote the survival function of patients at time A. Among patients alive at age A, the probability of surviving X more years is  $S(X|A) = S(A+X)/S(A)$ . For a given starting age A, the expected remaining lifetime is then equal to the area under the curve of  $S(X|A)$  plotted versus X. Because few patients live beyond 100, this area is truncated at the upper age limit  $A + X = 100$ .

#### **HALF-LIVES**

##### **conditional half-life**

The conditional half-life is conditional on having survived a given period of length  $T_0$  without the event, the point at which 50 percent of patients who survived the given period remain alive. In other words, it is the median remaining lifetime conditional on surviving a given period  $T_0$ .

The conditional half-life is estimated using the Kaplan-Meier method if the median survival time falls in the duration of follow-up. Otherwise, the conditional half-life is estimated as the following:

- » Estimate the survival probabilities  $S(T_0)$  and  $S(T_1)$  using the Kaplan-Meier method from the data available, where  $T_0 < T_1$  and  $T_1$  is within the follow-up
- »  $\mu = \frac{T_1 - T_0}{(\ln[S(T_0)] - \ln[S(T_1)])}$
- » the estimate of the conditional half-life =  $\mu \cdot \ln(2)$

This method can be used only when the hazard is a constant after  $T_0$  and  $T_1$  is chosen to be big enough to obtain a stable estimate of  $\ln(S(T_0)) - \ln(S(T_1))$ .

##### **adjusted conditional half-life**

When comparing the conditional half-time of different groups, the difference of conditional half-lives may partially reflect the difference of patient characteristics among groups. To remove the part of the difference attributable to patient characteristics, the adjusted conditional half-life can be estimated. For example, if patient age, race, and gender are different among groups and are factors for survival, we can calculate the adjusted conditional half-life by adjusting for age, race, and gender with a given reference population. The method for estimating the adjusted conditional half-life is the same as described above for the unadjusted conditional half-life estimate, with the exception of step 1. Usually a Cox regression model is fit for each group, with age, race, and gender as the covariates. The log survival at time  $T_0$  and  $T_1$  is calculated from the Cox model estimates for each cross-sectional subgroup of age\*race\*gender. The weighted average of the  $\ln(\text{survival})$ s over the subgroups at each time point

is then calculated, with the patient proportion of each subgroup in the reference population as the weight. The  $\ln(S(T_0))$  and the  $\ln(S(T_1))$  in the first step above are replaced by the corresponding weighted averages.

#### **MAPPING METHODS**

Mapping is an important tool for assessing environmental determinants and illustrating spatial patterns and temporal trends. Geographic resolution is enhanced by mapping at the level of small regions, but this can increase data instability. The use of smoothing methods, however, can help stabilize data and show geographic patterns while still maintaining geographic resolution.

Much of disease mapping within the ADR is by Health Service Area (HSA), an approach we continue to adopt from the Atlas of United States Mortality (Centers for Disease Control and Prevention). Remaining maps are by state or census division. Each HSA is a group of counties described by the CDC authors as “an area that is relatively self-contained with respect to hospital care.” The methods described here have been used for all HSA-level maps in the ADR. Because the distribution of age, gender, and race in a population can affect incident and prevalent ESRD rates, we have included maps in which data are adjusted for these variables as well as smoothed. Maps by state and census division are not smoothed.

In many figures, data ranges have been standardized to invite comparisons across years, modalities, or patient characteristics. In remaining maps, HSAs are divided into quintiles.

Throughout the ADR, data in maps and graphs are unadjusted unless otherwise noted. HSA-level information is mapped according to the patient's residence (with the exception of some maps of organ donation rates in Chapter Seven). Because of area size and limitations in the mapping software, data for Puerto Rico and the U.S. Territories are not included in the maps.

#### **methods for smoothing and adjusting map data**

To smooth map data we use a Bayesian spatial hierarchical model (Waller et al.). This method is a statistical approach that uses the log linear model (Poisson regression model) to fit the incident counts of the regions. The region effects, as random effects, follow the Conditional Autoregressive (CAR) Normal distribution, and the precision of the effects has a Gamma distribution. The model smooths the incident counts by borrowing information for each HSA from its neighbors through the relationship defined by CAR; neighbors, in our definition, are HSAs sharing a boundary. Smoothed incident rates are obtained by dividing the predicted counts by the corresponding population sizes. For adjusted maps, an almost non-informative prior is assigned to fixed effects of age, gender, and race with the Bayesian model. Adjusted incident rates are calculated using the model-based adjustment method based on the predicted values from the Bayesian spatial hierarchical model, with the national population as reference.

This model is also used to smooth prevalent rates and calculate some percentages. To smooth maps of mean hemoglobin, eGFRs, and creatinine levels, the model is extended to assume that the means have a normal distribution.

#### **SPECIAL STUDIES AND DATA COLLECTION FORMS**

The USRDS website includes complete copies of the CMS Medical Evidence (2728) and Death Notification forms (2746); the OPTN Transplant Candidate Registration form, Kidney Transplant Recipient Registration form and Kidney Transplant Recipient Follow-up form; and forms used for data collection in USRDS Special Studies.

## bibliography

Analytic and reporting guidelines: the Third National Health and Nutrition Examination Survey, NHANES III (1988–1994). <http://www.cdc.gov/nchs/data/nhanes/nhanes3/nh3gui.pdf>. Accessed October, 2002.

Arias E. United States life tables, 200. National vital statistics reports 57 (14). Hyattsville, Maryland: National Center for Health Statistics, 2009.

Baigent et al. The effects of lowering LDL cholesterol with simvastatin plus ezetimibe in patients with chronic kidney disease (Study of Heart and Renal Protection): a randomised placebo-controlled trial. *Lancet*. 2011 Jun 25; 377(9784): 2181–92.

Centers for Disease Control and Prevention. NHANES 1999–2000 data files, available at the National Center for Health Statistics, [http://www.cdc.gov/nchs/about/major/nhanes/nhanes99\\_00.htm](http://www.cdc.gov/nchs/about/major/nhanes/nhanes99_00.htm).

Centers for Disease Control and Prevention. NHANES 2001–2002 Data Files, available at National Center for Health Statistics, <http://www.cdc.gov/nchs/about/major/nhanes/nhanes01-02.htm>.

Centers for Disease Control and Prevention. The third National Health and Nutrition Examination Survey (NHANES III 1988–94) reference manuals and reports [CD-ROM]. Bethesda MD: National Center for Health Statistics, 2004.

Chan KE, Lazarus JM, Thadhani R, Hakim RM. Warfarin use associates with increased risk for stroke in hemodialysis patients with atrial fibrillation. *J Am Soc Nephrol*. 2009 Oct; 20(10): 2223–33. Epub 2009 Aug 27.

Chronic Kidney Disease Prognosis Consortium, Matsushita K, van der Velde M, Astor BC, Woodward M, Levey AS, de Jong PE, Coresh J, Gansevoort RT. Association of estimated glomerular filtration rate and albuminuria with all-cause and cardiovascular mortality in general population cohorts: a collaborative meta-analysis. *Lancet*. 2010 Jun 12; 375(9731): 2073–81. Epub 2010 May 17.

Cohen LM, Ruthazer R, Moss AH, Germain MJ. Predicting six-month mortality for patients who are on maintenance hemodialysis. *Clin J Am Soc Nephrol*. 2010; 5(1): 72–79.

Foley RN, Murray AM, Li S, Herzog CA, McBean AM, Eggers PW, and Collins AJ. Chronic kidney disease and the risk for cardiovascular disease, renal replacement, and death in the United States Medicare population, 1998 to 1999. *J Am Soc Nephrol*, 2005; 16: 489–95.

Go AS, Chertow GM, Fan D, McCulloch CE, Hsu CY. Chronic kidney disease and the risks of death, cardiovascular events, and hospitalization. *N Engl J Med*. 2004 Sep 23; 351(13): 1296–305.

Gooley, T.A., Leisenring, W., Crowley, J. and Storer, B.E. Estimation of Failure Probabilities in the Presence of Competing Risks: New Representation of Old Estimators. *Statistics in Medicine*, 1999, 18, 695–706.

Herzog CA. Cardiovascular Disease and Dialysis Patients: Is Therapeutic Nihilism Justified? *Seminars in Dialysis* 12(5), 1999, 285–7.

Herzog CA, Li S, Weinhandl ED, Strief JW, Collins AJ, Gilbertson DT. Survival of dialysis patients after cardiac arrest and the impact of implantable cardioverter defibrillators. *Kidney Int* 2005 Aug; 68(2): 818–25.

Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. *N Engl J Med*. 2009 Apr 2; 360(14): 1418–28.

Kalbfleisch JD, Prentice RL. The statistical analysis of failure time data. New York: Wiley, 1980.

Kaplan EL, Meier P. Nonparametric estimation from incomplete observation. *J Amer Stat Assoc* 1958; 3: 457–481.

Levey AS, Berg RL, Gassman JJ, Hall PM, Walker WG. Creatinine filtration, secretion and excretion during progressive renal disease. Modification of Diet in Renal Disease (MDRD) Study Group. *Kidney Int Suppl* 1989 Nov 27: S73–80.

Levey AS, Bosch JP, Lewis JB, et al. A more accurate method to estimate glomerular filtration rate from serum creatinine: a new prediction equation. Modification of Diet in Renal Disease Study Group. Ann Intern Med 1999; 130 (6): 461–70.

Levey AS, Coresh J, Greene T, Stevens LA, Zhang YL, Hendriksen S, Kusek JW, Van Lente F; Chronic Kidney Disease Epidemiology Collaboration. Using standardized serum creatinine values in the modification of diet in renal disease study equation for estimating glomerular filtration rate. Ann Intern Med 2006 Aug 15; 145(4): 247–54.

Levey AS, Stevens LA, Schmid CH, Zhang YL, Castro AF 3<sup>rd</sup>, Feldman HI, Kusek JW, Eggers P, Van Lente F, Greene T, Coresh J; CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration). A new equation to estimate glomerular filtration rate. Ann Intern Med. 2009 May 5; 150(9): 604–12.

Liu J, Louis TA, Pan W, Ma JZ, Collins AJ. Methods for estimating and interpreting provider-specific standardized mortality ratios. J Health Serv and Outcomes Res Methodology Sept 2003; 4 (3): 135–149.

Liu J, Louis TA, Pan W, Ma JZ, Collins AJ. State-level adjusted ESRD incident rates: use of observed versus model-predicted category-specific rates. Kidney Int. 2006 Apr; 69(8): 1459–63.

Mungoile M, Pickle LW, Simonson KH. Application of a weighted head-banging algorithm to mortality data maps. Statistics in Medicine 1999; 18, 3201–3209.

National Committee for Quality Assurance. HEDIS 2008 technical specifications. Washington DC: National Committee for Quality Assurance; 2007.

National Kidney Foundation K/DOQI Clinical Practice Guidelines for Cardiovascular Disease in Dialysis Patients. AJKD 2005; 45: S1–S154 (Suppl 3).

NHANES Analytic Guidelines. [http://www.cdc.gov/nchs/data/nhanes/nhanes\\_general\\_guidelines\\_june\\_04.pdf](http://www.cdc.gov/nchs/data/nhanes/nhanes_general_guidelines_june_04.pdf).

Pickle LW, Mungoile M, Jones GK, White AA. Atlas of United States Mortality. Hyattsville (MD): National Center for Health Statistics; 1996.

Pickle LW, White AA. Effects of the choice of age-adjustment method on maps of death rates. Statistics in Med 1995; 14, 615–627.

Putter H, Fiocco M, Geskus RB. Tutorial in biostatistics: Computing risks and multi-state model. Statistics in Medicine, 26 (2007), 2389–2430.

Research Triangle Institute (2004). SUDAAN language manual, Release 9.0 Research Triangle park. NC: Research Triangle Institute.

SAS Institute Inc. SAS system for mixed models, Cary (NC): SAS Institute Inc.; 1996.

SAS Institute Inc. SAS/ETS User's Guide. Cary (NC): SAS Institute Inc.; 1993.

SHARP Collaborative Group. Study of Heart and Renal Protection (SHARP): randomized trial to assess the effects of lowering low-density lipoprotein cholesterol among 9,438 patients with chronic kidney disease. Am Heart J. 2010 Nov; 160(5): 785–794.e10. Epub 2010 Sep 18.

Tonelli M, Wiebe N, Culleton B, House A, Rabbat C, Fok M, McAlister F, Garg AX. Chronic kidney disease and mortality risk: a systematic review. J Am Soc Nephrol. 2006 Jul; 17 (7): 2034–47.

Waller LA, Carlin BP, Xia H, Gelfand AE. Hierarchical spatio-temporal mapping of disease rates. J Amer Stat Assoc 1997; 92, 607–617.

Winkelmayer WC, Charytan DM, Levin R, Avorn J: Poor short-term survival and low use of cardiovascular medications in elderly dialysis patients after acute myocardial infarction. Am J Kidney Dis 47: 301–308, 2006.