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# ■ Appendices Glossary Index

For such will be our ruin if you, in the immensity of your public abstractions, forget the private figure, or if we in the intensity of our private emotions forget the public world. Both houses will be ruined, the public and the private, the material and the spiritual, for they are inseparably connected.

*Virginia Woolf, Three Guineas*

# Appendix A

## ANALYTICAL METHODS

This appendix describes the USRDS database and its standardized working datasets, specialized code definitions, and common data processing practices. It also details the statistical methods used in this 2003 ADR. The Researcher's Guide to the USRDS Database, published separately, provides additional detail about the database and Standard Analysis Files.

### ■ Data sources

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

#### REBUS/PMMIS DATABASE

The major source of ESRD patient information for the USRDS is the CMS (formerly HCFA) Renal Beneficiary and Utilization System (REBUS), which was 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.

CMS regularly updates the REBUS/PMMIS database, using the Medicare Enrollment Database (EDB), Medicare inpatient and outpatient claims, the United Network for Organ Sharing (UNOS) transplant database, ESRD Medical Evidence forms (2728) provided by the ESRD networks, and ESRD Death Notification forms (2746) obtained from renal providers.

#### CMS MEDICARE ENROLLMENT DATABASE

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

#### CMS PAID CLAIMS RECORDS

Inpatient transplant and outpatient dialysis claims records are used to identify new ESRD patients for whom no Medical Evidence form has

been filed. These patients, primarily non-Medicare patients, or beneficiaries who develop ESRD while already on Medicare because of age or disability, will eventually be entered into the REBUS/PMMIS—and hence the USRDS—database through the claims records. For patients without Medical Evidence forms these claims are the only reliable information from which to determine first service dates for ESRD. These paid claims records are, however, only a supplement to, rather than a replacement of, other sources of information on incidence and prevalence.

It is important to note that some Medicare-eligible patients may not have bills submitted to and paid by Medicare, including MSP patients covered by private insurance, HMOs, Medicaid, or the Department of Veterans Affairs (DVA).

#### UNOS TRANSPLANT DATABASE

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

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

- All UNOS transplants are accepted into the database.
- All CMS transplants before 1988 are accepted.

- CMS transplants from 1988 to 1993 are accepted if there is no UNOS transplant record for that patient within 30 days of the CMS transplant.
- Transplants indicated on Medical Evidence 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 Medical Evidence form.

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

CMS's Standard Analytic Files contain data from final action claims, submitted by Medicare beneficiaries, in which all adjustments have been resolved.

For Part A institutional claims the USRDS uses the following data:

- inpatient, 100 percent SAF
- outpatient, 100 percent SAF
- home health agency (HHA), 100 percent SAF
- hospice, 100 percent SAF
- skilled nursing facility (SNF), 100 percent SAF

For Part B physician/supplier claims:

- physician/supplier, 100 percent SAF
- 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 2003 ADR includes all claims up to December 31, 2001. Patient-specific demographic and diagnosis information, however, includes data as recent as September 2002.

#### **STANDARD INFORMATION MANAGEMENT SYSTEM (SIMS) DATABASE (ESRD NETWORKS)**

For this ADR, the USRDS has collaborated with CMS and the ESRD networks to address data tracking issues relating to the non-Medicare ESRD population. Past issues of the ADR have documented the lack of consistent Medicare claims data among non-Medicare patients. Working solely with data from the Medical Evidence form, the USRDS could establish the first ESRD service date for these patients, 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-followup patients, and look as well at patients for whom there previously were no data on initial modality or death. This new data integration is detailed on page 185.

#### **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, which all dialysis units and transplant centers 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 information, they do provide independent patient counts used to complement the CMS patient-specific records.

#### **CDC SURVEILLANCE**

The Centers for Disease Control and Prevention use their National Surveillance of Dialysis-Associated Diseases to collect information from U.S. dialysis facilities on patient and staff counts, membrane types, reuse practices, water treatment methods, therapy types, vascular access use, antibiotic use, hepatitis vaccination and conversion rates for staff and patients, and the incidence of HIV, AIDS, and tuberculosis. None of the information is patient-specific. The CDC did not conduct a survey in 1998.

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

For the 2003 ADR, the USRDS has used the CMS Dialysis Facility Compare data to define chain and ownership information for each renal facility. Prior to this year's ADR, similar data were extracted from the Independent Renal Facility Cost Report (CMS 265-94).

#### **UNITED STATES CENSUS**

In rate calculations throughout this edition of the ADR we use census estimates based on the 1990 U.S. census, rather than the more recent 2000 census. These estimates are described on pages 212.

### **■ Data management & preparation**

The main computer system of the USRDS is a Compaq Alpha system consisting of one Compaq AlphaServer ES45 with dual EV-68 (1 GHz) and two Compaq AlphaServers DS20 with dual EV-6 (500 MHz) processors, with a total of 12 GB of RAM memory and 4 terabytes (4,000 gigabytes) of RAID-5 (Redundant Array of Independent Disks, level 5) disk farms, all managed by five interconnecting high-speed storage clusters.

We use the 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 has been integrated into the new database, and its continuity and completeness have been maintained.

#### **DATA LOADING & CLEANING**

Data files come to the USRDS in IBM 3490 cartridges/CD-ROMs with EBCDIC, ASCII, or SAS formats. Once loaded, files are converted into SAS data sets 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 September 2002, and Medicare Part A and Part B claims are collected through December 31, 2001.

## ESRD PATIENT DETERMINATION

A person is identified as having ESRD when a physician certifies the disease on the CMS Medical Evidence form, or when there is other evidence that he or she has received chronic dialysis or a kidney transplant. Patients who experience acute renal failure and are on dialysis for days or weeks, but who then recover kidney function, are excluded from the database as much as possible. Patients who die soon after kidney failure without receiving dialysis are sometimes missed.

The first ESRD 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 renal failure, as reported on the Medical Evidence form,
- the date of a kidney transplant, as reported on a CMS or UNOS transplant form, a Medical Evidence form, or a hospital inpatient claim, or
- the date of the first Medicare dialysis claim.

Most FSDs are obtained from the Medical Evidence form. In the absence of this form, the date of the first Medicare dialysis claim or transplantation 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 Medical Evidence form, the earliest claim date is used as the FSD.

## MEDICARE & 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 entitlement:

- age 65 and over
- disabled
- ESRD program
- Railroad Retirement Board (RRB)

Most ESRD patients are eligible to apply for Medicare as their primary insurance payor. Some patients, 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), must wait 30–33 months before becoming eligible to have Medicare as their primary payor, and are therefore not in the EDB database during the waiting period. Some of these patients, particularly new patients since 1995, have FSDs established by Medical Evidence 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 therefore be included in patient counts for incidence, prevalence, and treatment modality. Calculations of standardized mortality ratios (SMRs), standardized hospitalization ratios (SHRs), and standardized transplantation ratios (STRs), 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 or may not be possible to link 'ZZ' patients to their ESRD Death Notification forms (CMS 2746) or to the UNOS transplant data, and it may be impossible to determine comorbid conditions or Part A and Part B services. Because such data are limited, event rates that include these patients must be assessed with caution.

To duplicate the methods used by the previous USRDS contractor we continue to include 'ZZ' patients in the mortality rate calculations of the ADR. We are collaborating with CMS and other interested researchers to establish a consistent approach to managing the data for these patients.

## LOST-TO-FOLLOWUP METHODOLOGY

The USRDS draws on all available data to create a "treatment history" for each patient in the database, showing 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. When these gaps occur the USRDS assumes that a treatment modality continues until death or the next modality-determining event. A patient with a functioning transplant is assumed to maintain that transplant 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-followup 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-followup 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 new three-year rule has significantly reduced the number of lost-to-followup 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-followup:

- The patient may have recovered renal function and no longer have ESRD.
- 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 UNOS.
- 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 DATABASES

Patient 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. To improve the tracking of these patients in the USRDS database, and of patients lost-to-followup, we have this year incorporated treatment-specific information from the SIMS event database, compiled by the ESRD networks.

One of the surprise findings from this data integration has been the significant presence in the SIMS database of the "recover function" event. There are two types of this event: Type 1 (n=15,919) is followed by one or more treatment events, while Type 2 (n=22,760) is the last recorded event in a patient's treatment history. Patients with these events, especially Type 2, have undoubtedly contributed to the higher point prevalent counts established by the USRDS compared to the CMS Facility Survey. In addition, the median ESRD exposure time of Type 2 events is 75 days, implying that more than half of the 22,760 patients regained renal function in the first 90 days. The USRDS had classified these patients as being on dialysis for the first three years, and then labeled them "lost-to-followup." This discrepancy declined steadily between 1994 and 2001, and the USRDS and Facility Survey counts are now almost equal (see Figure 2.1 on page 49).

For the 2003 ADR, we have taken a conservative approach to incorporating SIMS data into the USRDS treatment history; as we learn more about the data, we may expand this approach. We have so far made the following updates:

- The USRDS database was updated with mortality data from the SIMS event database (n=541).
- The database was also updated for each incident patient whose initial modality was listed as "unknown dialysis," and for whom the SIMS database listed a known dialytic modality within 90 days of the established first ESRD service date (n=40,000).
- Data on non-Medicare "lost-to-followup" patients were substituted with treatment information when found in the SIMS database (n=12,000).

The Type 2 "recover function" event is an important data issue that may significantly influence prevalent counts of U.S. patients with ESRD. We plan to collaborate further with CMS and the ESRD networks to analyze this issue before implementing permanent corrective actions.

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

This rule requires that a treatment modality continue for at least 60 days before it is considered a primary or switched mo-

dality. 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. All descriptive data appearing in the incident, prevalent, and modality sections of the 2003 ADR 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: FOR 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, this rule is used primarily when calculating survival rates and comparing outcomes by modality at several points in time. Use of this 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.

### ■ Database definitions

#### MODALITIES

Because different patient modality categories are used throughout the ADR, these categories are defined in the methods sections for each chapter.

#### PAYOR SEQUENCE FILE

This year the Medicare-only incident cohorts generally have fewer patients than reported in last year's ADR, discrepancies which are largely due to our improved methods of defining each patient's payor status. We previously determined Medicare as primary payor status from the Medical Evidence form at the time of ESRD initiation, using an "intent-to-treat" model. Throughout the 2003 ADR, however, we have systematically applied our newly adopted payor sequence file to identify Medicare eligibility status and other insurance payors.

The construction of this file is very similar in concept to that of the USRDS 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. Data from the Medicare Enrollment Database and Medicare dialysis claims information are used to categorize a patient as having Medicare as primary payor, Medicare as secondary payor, Medicare+Choice, Medicaid, or one of many other combinations. With this approach, the USRDS is now able to apply the payor status information in all outcome analyses using the "as-treated" model (see page 209).

#### PRIMARY CAUSE OF RENAL FAILURE

Information on the primary cause of renal failure is obtained directly from the Medical Evidence form. For the Annual Data

Report these disease codes have been grouped into 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 Medical Evidence form, with the exception of 799.9
- unknown cause: 799.9 and other ICD-9-CM codes not covered in the list of primary causes on the Medical Evidence form
- missing cause: no ICD-9-CM code listed

### LESS COMMONLY OCCURRING DISEASES

Chapters Two and Five present data on patients whose ESRD is caused by one of the less commonly occurring diseases. These diseases are identified by the following ICD-9-CM codes: IgA nephropathy, Berger's disease, IgM nephropathy, 583.81; Wegener's granulomatosis, 446.4; lupus erythematosus, 710.0; other secondary glomerulonephritis/vasculitis, 283.1, 287.0, 446.0, 446.2, 446.4, and 583.9; polycystic kidney disease, 753.13, and 753.14; Alport's and other hereditary/familial diseases, 759.8; multiple myeloma and light chain nephropathy, 203.0; and AIDS nephropathy, 042.9.

### RACE & ETHNICITY

Information on patient race and ethnicity is obtained from the Medical Evidence form, the CMS Medicare Enrollment Database, and the REBUS identification file. Because they are addressed in separate questions on the Medical Evidence form, racial and ethnic categories can overlap.

Data on Hispanic patients are included throughout the ADR. Patient ethnicity became a required field on the revised Medical Evidence form, released in 1995; because data for this year are incomplete, information on Hispanic patients is presented starting in 1996. The non-Hispanic category includes all non-Hispanics and patients whose ethnicity is unknown.

Because of the small number of ESRD patients of some races, as well as the construction of the U.S. census data, we have concentrated in the ADR on white, black, Native American (includes Alaskan Native), and Asian (includes Pacific Islander) populations. As the numbers of patients of other races increase, data on them will be presented in the ADR.

### ■ Précis

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

Figures p.7–8 show hospitalization rates, including total admissions and hospital days per patient year, for period prevalent ESRD patients. Period prevalent patients are defined as those alive on renal replacement therapy on January 1 and

with a first service date at least 90 days prior to the beginning of the year, in addition to those reaching day 91 of ESRD treatment during the year. Methods used generally follow those described for Chapter Six and Reference Section E. 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, and patients with missing age or gender information, are excluded. Rates are adjusted for age, gender, race, and primary diagnosis using the model-based adjustment method, described further in the discussion of Reference Section E and the statistical methods section of this appendix. The reference cohort includes 2001 period prevalent ESRD patients, and vintage is calculated as the time from the first ESRD service date until the first of the year for prevalent patients, or as less than one year for incident patients. Principal ICD-9-CM diagnosis codes used for cardiovascular and infectious hospitalizations are listed in the discussion of Figures 6.8–10.

Figure p.9 shows trends in mortality rates by modality and vintage, and includes period prevalent patients on hemodialysis, peritoneal dialysis, or with a transplant in a calendar year. For all populations, we include both Medicare and non-Medicare patients and patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with unknown age or gender, or of races other than white, black, Native American, and Asian, are excluded. Dialysis patients are followed from January 1 until death, transplantation, or the end of the year, while transplant patients are followed from January 1 until death or the end of the year. All-cause and cause-specific mortality rates are adjusted for age, gender, race, primary diagnosis, and vintage using generalized mixed models. Because the reference population consists of 2001 period prevalent ESRD patients, adjusted rates across modalities can be compared.

Figure p.10 illustrates five-year survival by first modality. The populations for the 1987–1991 and 1992–1996 cohorts include incident patients on hemodialysis or peritoneal dialysis on the first ESRD service date, and patients who receive their first renal transplant in a calendar year. All cohorts include both Medicare and non-Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories, and exclude those with unknown age, gender, or primary diagnosis, and those with a listed age greater than 110. In the dialysis cohort we also exclude those who die or are transplanted in the first 90 days. Dialysis patients are followed from day 91 until death, transplantation, or the end of 2001, while transplant patients are followed from the first transplant date until death or the end of 2001. Survival probabilities are adjusted for age, gender, race, and primary diagnosis. The reference population consists of 1996 incident ESRD patients, and adjusted probabilities can be compared across modalities.

Figure p.11 presents first- to fourth-year mortality rates by modality, using incident patients on hemodialysis, peritoneal dialysis, or any dialysis on the first ESRD service date,

and those receiving their first renal transplant in a calendar year. Patient inclusion, exclusion, and followup are the same as in Figure p.10. Mortality rates are computed from the Cox model using the model-based adjustment method, and are adjusted for age, gender, race, and primary diagnosis. The reference population consists of 1996 incident ESRD patients, and adjusted death rates can be compared across modalities.

For a description of the provider data used in Figure p.12, see the discussion of Reference Section J on page 207.

Figures p.15–16 present data on the NHANES III (1988–1994) population. CKD patients are identified by an estimated glomerular filtration rate of less than 30 or 45 ml/min/1.73 m<sup>2</sup>, and eGFR is calculated using the modified MDRD method. Information on Medicare patients presented in Figure p.15 represents patients from the Medicare 5 percent sample who are alive, non-ESRD, non-HMO, and with Medicare as primary payor for the entire year. Patients are identified as having CKD if they have one inpatient or two outpatient or Part B Physician/Supplier claims with an ICD-9-CM diagnosis of CKD during the year. These diagnoses include: 016.0, 095.4, 189.0, 223.0, 236.91, 250.4, 271.4, 274.1, 283.11, 403.x1, 404.x2, 404.x3, 440.1, 442.1, 447.3, 572.4, 580.x–588.x, 591.x, 642.1, 646.2, 753.12–753.17, 753.19, 753.2, and 794.4. Figures p.17–19 and p.21 also use the NHANES III population, though data here are limited to patients age 20 and older. Comorbidities are identified through medical history questionnaires, and the “all” category includes patients with at least one of the six listed comorbidities.

Figure p.20 illustrates the percent of patients in the eligible Medicare 5 percent sample who are identified as having CKD during the year. The definition of each year’s patient population is the same as that described for Figure p.15.

In Figures p.22–23 we look at the relation of survival to creatinine, on its own and in association with anemia, in NHANES I and II populations age 30–75. The event is all-cause mortality, as defined by the NHANES I Epidemiological Follow-up Study and the NHANES II Mortality Study. Data are adjusted by age, gender, and race, and by four self-reported comorbidities (stroke, CHF, diabetic status, and AMI), using the model-based adjustment method (described later in this appendix). Participants are divided into two groups based on serum creatinine levels: normal renal function (less than or equal to 137  $\mu$ mol/l for men and 104  $\mu$ mol/l for women) and renal deficiency (greater than 137  $\mu$ mol/l for men and 104  $\mu$ mol/l for women). Anemia is defined by criteria from the World Health Organization.

## ■ Healthy People 2010

The 2010 targets in this chapter come directly or are estimated from data supplied in the Healthy People 2010 chapters on chronic kidney disease and immunizations.

Objective 4.1: Incident rates for Figures hp.2–3 and hp.4 (first graph), and for Table hp.a, are calculated using the methods

described for Chapter Two. Incident rates of diabetes in the general population (second graph in Figure hp.4) are obtained from the CDC’s Behavioral Risk Factor Surveillance System.

Objective 4.2: The study cohort here includes period prevalent ESRD patients, 1991–2001. Cause-specific cardiovascular mortality is defined using CMS codes 27 and 31 (congestive heart failure), 26 (atherosclerotic heart disease), 02 and 23 (myocardial infarction), and 01, 04, 25, 28–30, and 36–37 (other cardiovascular disease). Age is calculated for point prevalent patients as of January 1, and for incident patients as of the first ESRD service date. A patient is excluded if he or she has no information on age, gender, or race listed on the Medical Evidence form or has an age calculated to be less than zero. Cardiovascular mortality rates are estimated as the number of patients who die from cardiovascular disease in each year per 1,000 patient years at risk.

Objective 4.4: For Figures hp.9–10, the calculation of fistula, graft, and catheter insertion rates follows methods used in Chapter Five. For Table hp.c and Figure hp.8, data are obtained from the CMS Clinical Performance Measures (CPM) Project. To obtain consistent information on race and ethnicity, patients included in the CPM dataset are matched to those in the ESRD database using UID numbers.

Objective 14.29: The cohort for influenza vaccinations includes all ESRD patients initiating therapy 90 days prior to September 1 of each year and alive on December 31. For pneumococcal pneumonia vaccinations, cohorts include all ESRD patients initiating therapy 90 days before January 1 of the graphed time period and alive on December 31. Influenza vaccinations are tracked between September 1 and December 31 of each year, while pneumococcal pneumonia vaccinations are tracked during the time periods graphed. Patients in both analyses have Medicare Part A and Part B coverage during the study periods.

Objective 4.5: The study cohort for Figures hp.14–15 and Table hp.e includes patients from 1991–2001 who are younger than 70. Proportions are calculated as the number of patients on the transplant waiting list on December 31 of the calendar year divided by all prevalent dialysis patients alive on the same day. Waiting list counts are obtained from UNOS data.

Objective 4.6: The study cohort includes patients from 1991–1998 who are younger than 70 at the time of 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 4.7: Incident rates for Figures hp.18–20 and Table hp.g are calculated using methods described for Chapter Two.

Objective 4.8: The three diabetic preventive health tests monitored here are eye examinations, lipid testing, and glycosylated hemoglobin (HbA1c) testing, and we calculate percentages and select the study populations using methods

similar to those described for Chapter Five. The pre-ESRD population includes incident ESRD patients age 67 or older at the start of ESRD, with diabetes diagnosed one year prior to initiation; patients enrolled in a managed care program or with Medicare as their secondary payor are excluded. Diabetic eye examinations are tracked for the two years prior to ESRD initiation, while lipid and HbA1c testing are tracked for the one year prior. The general Medicare population includes individuals diagnosed with diabetes in each year, continuously enrolled in Medicare Part A and B during the diagnosis year and the previous year, and age 67 or older on the last day of each diagnosis year. Eye examinations for these patients are tracked during the diagnosis year and the previous year, while lipid and HbA1c testing are tracked during the diagnosis year. Patients are excluded if they are enrolled in a managed care program (HMO), become a Medicare as secondary payor patient, or are diagnosed with ESRD during any of the two-year study periods. Because of categorizations in the general Medicare database, racial and ethnic categories are mutually exclusive.

## ■ Chronic kidney disease

### CHAPTER ONE

Figure 1.1 shows trends in the number of general Medicare patients with chronic kidney disease. Cohorts are derived from the 5 percent Medicare Denominator files, and include patients continuously enrolled in Medicare Part A and B in any two consecutive calendar years from 1992–2001, alive on the last day of this entry period, and residing in the 50 states, the District of Columbia, Puerto Rico, and the Territories.

To identify patients diagnosed with ESRD we link the 5 percent Medicare Denominator files to the USRDS database, which includes information from the Medical Evidence form on all patients entering the program for treatment. We exclude from the study those diagnosed with ESRD any time during the entry period, and those enrolled in a managed care program (HMO).

According to a previously validated methodology for using Medicare claims to identify diabetic patients, a patient is diabetic if, within a two-year observation period, he or she has an ICD-9-CM diagnosis code of diabetes on one or more Part A institutional claims (inpatient hospitalization, skilled nursing facility, or home health agency), two or more Part A institutional claims (outpatient), or two or more Part B physician/supplier claims. Using this method we identify the number of CKD patients with or without diabetes during each entry period, multiplying this number by 20 to estimate total CKD patients, with or without diabetes, in the general Medicare population. Codes used throughout this chapter to identify patients with CKD and diabetes are as follows:

- CKD: 016.0, 095.4, 189.0, 189.9, 223.0, 236.91, 250.4, 271.4, 274.1, 283.11, 403.x1, 404.x2, 404.x3, 440.1, 442.1, 447.3, 572.4, 580–588, 591, 642.1, 646.2, 753.12–753.17, 753.19, 753.2, and 794.4
- diabetes: 250, 357.2, 362.0x, and 366.41

Figure 1.2 shows trends in adjusted first-year ESRD and mortality rates in the general Medicare population (5 percent sample), 1992–2000. Constructed with the same method used Figure 1.1, the study cohorts are limited to patients age 67 and older on the last day of the entry period. Patients are categorized by their CKD and diabetic status during each two-year entry period: CKD/DM, CKD/NDM, non-CKD/DM, and non-CKD/NDM. To track outcomes we follow each patient for up to one year from January 1 of the year after the entry period. If the ESRD diagnosis date and death date are the same, we define the patient's outcome as ESRD. For all-cause mortality, we censor a patient's followup time at ESRD diagnosis or December 31 of the year, while for incident ESRD, we censor a patient's followup time at death or December 31.

For each two-year cohort and study group, a separate Cox proportional hazards model is used to estimate the predicted first-year all-cause mortality rate and incident ESRD rate, with age, gender, and race as covariates. Using the model-based adjustment method (described in the section on statistical methods), and with 1999–2000 cohort patients as the reference population, these mortality and incident ESRD rates are further adjusted for age, gender, and race.

In Figures 1.3–6, which show adjusted hospital admission rates and hospital days, a two-year entry period is used to characterize patients in the period prevalent general Medicare cohort as CKD or non-CKD. The cohort includes patients continuously enrolled in Medicare Parts A and B, with no HMO coverage, and without ESRD. The prevalent dialysis cohort includes patients with Medicare Parts A and B as a primary payor, and excludes those with MSP or HMO status anytime during the period at risk. Patients are followed from the first day of the year with Medicare coverage until the earliest of death, the last day with Medicare coverage, or December 31 of the year after the entry period. For dialysis patients, followup time is censored at transplant. For both cohorts, patients residing outside the fifty states, the District of Columbia, Puerto Rico, and the Territories are excluded, as are those with AIDS as a primary or secondary cause of death.

Comorbidity status is identified from ICD-9-CM diagnosis codes: one from Part A inpatient, skilled nursing facility, or home health claims; two from Part A outpatient claims; or two from Part B claims during the entry period. The codes to identify patients with CKD are as the same as those used in Figure 1.1. Cause-specific hospitalization categories are defined by principal ICD-9-CM diagnosis codes, as follows:

- Cardiovascular disease (overall): 276.6, 394–398.99, 401–405, 410–420, 423–438, and 440–459
- Congestive heart failure: 398.91, 425, 428, 402.x1, 404.x1, and 404.x3
- Ischemic heart disease: 410–414
- “Other”: other hospitalizations classified as cardiovascular
- Infection (overall): 001–139, 254.1, 320–326, 331.81, 372–372.39, 382–382.4, 383.0, 386.33, 386.35, 388.60, 390–393, 421–422, 460–466, 472–474.0, 475–477.9, 478.22–478.24, 478.29, 480–491, 494, 510–511, 513.0,



518.6, 522.5, 522.7, 527.3, 528.3, 540–542, 566–567.9, 569.5, 572–572.2, 573.1–573.3, 575–575.12, 590–590.9, 595–595.4, 597–597.89, 599.0, 601–601.9, 604–604.9, 607.1, 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, 996.6–996.69, 997.62, 998.5, 999.3, V01–V069, V08, and V09

- Bacteremia/sepsis: 038–038.9 and 790.7
- Pulmonary infections: 460–466, 473–474.0, 475–477.9, 478.22–478.24, 480–491, 510–511, 513.0, and 518.6
- Urinary tract infections: 590–590.9, 595–595.4, 597–597.89, 601–601.9, 599.0, 604–604.9, 607.1, 614–616.1, 616.3–616.4, and 616.8

Hospitalization rates are adjusted using the direct adjustment method for age (0–19, 20–44, 45–64, 65–74, and 75+), gender, race (white, black, Native American, Asian, and other), and primary diagnosis (diabetes and non-diabetes). Patients in the 2001 cohort are used as the reference population.

Figure 1.7 shows all-cause mortality rates for dialysis and general Medicare patients age 67 and older. The period prevalent dialysis cohort includes patients with Medicare coverage during the year. A two-year entry period is used to characterize patients as CKD or non-CKD, as defined in Figures 1.3–6.

Figure 1.8 presents all-cause mortality rates by the presence of cardiovascular disease and infection. The period prevalent dialysis cohort includes patients surviving a one-year entry period and with Medicare Part A and B coverage; the general Medicare cohort includes those surviving a two-year entry period, continuously enrolled in Medicare Part A and B, and without ESRD. Both cohorts are limited to patients age 67 and older on the first day of followup, and residing in the fifty states, the District of Columbia, Puerto Rico, and the Territories. ICD-9-CM diagnosis codes in Part A and B claims during the entry period are used to identify patients with cardiovascular disease or infection. These codes are the same as those used in Figures 1.3–6. For Figures 1.7–8, patients are followed from the first day of the year with Medicare coverage until the earliest of death, December 31 of the year, or transplant.

Figures 1.10–15 report the development of cardiovascular comorbidities in the general Medicare population (5 percent sample), while Figure 1.9 illustrates the study design. The study cohort consists of patients continuously enrolled in Medicare Parts A and B in 1998–1999, alive and age 67 or older on December 31, 1999, and residing in the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients are excluded if they are enrolled in an HMO or diagnosed with ESRD anytime during 1998–1999, if they do not survive to the end of 2000, if they do not continue their enrollment in both Medicare Part A and Part B, or if they are enrolled in an HMO in 2000. They are also excluded if they develop ESRD (CKD patients identified in 1998–1999), or CKD and/or ESRD (non-CKD patients identified in 1998–1999), in 2000.

The total observation time in this study consists of the entry period (January 1, 1998 through December 31, 1999), the study period (January 1, 2000 through December 31, 2000), and the outcome period (January 1, 2001 through December 31, 2001). For the entry period we use the methods described for Figure 1.1, identifying a patient's CKD status and cardiovascular comorbidities through ICD-9-CM diagnosis codes in the Medicare Part A and B claims. Cardiovascular comorbidities include atherosclerotic heart disease (ASHD), congestive heart failure (CHF), peripheral vascular disease (PVD), cerebrovascular accident/transient ischemic attack (CVA/TIA), and other cardiac disease (valvular heart disease, dysrhythmia, and pacemaker). Codes used to identify CKD patients are the same as those described for Figure 1.1, while those for cardiovascular disease are as follows:

- ASHD: 410–414, V45.81, and V45.82
- CHF: 398.91, 425, 428, 402.x1, 404.x1, and 404.x3
- CVA/TIA: 430–438
- PVD: 440–444, 447, 451–453, and 557
- Other cardiac disease: 420–424.9, 426, 427, 429, 785.0–785.3, V42.1, V42.2, V43.3, V45.0, and V53.3

We investigate the cumulative probability for incident CVD in the study period by looking at CKD status in 1998–1999 and outcomes in 2001, using the life-table estimation method. We also use a Cox proportional hazards model to estimate the relative risk for incident CVD between CKD and non-CKD patients, with age, gender, and race as covariates.

In the outcome period, we classify patients into three study groups according to their outcomes:

- ESRD or CKD/ESRD: CKD patients who develop ESRD, and non-CKD patients who develop CKD and/or ESRD in 2001.
- death: patients who die in 2001 before they develop ESRD or CKD.
- no event: patients who are alive on December 31, 2001, and have not been diagnosed with ESRD or CKD.

To track the outcomes of patients with CKD, we follow them to the earliest of death, ESRD diagnosis, end of Medicare Part A and Part B enrollment, or December 31, 2001; non-CKD patients are followed to the earliest of death, CKD and/or ESRD diagnosis, end of Medicare Part A and Part B enrollment, or December 31, 2001.

Figure 1.10 presents the prevalence of ASHD, CHF, CVA/TIA, and any CVD (ASHD, CHF, CVA/TIA, PVD, and other cardiac disease) in 1998–1999, while Figure 1.11 displays the percent of patients who develop these conditions, and the unadjusted incident rate per 1,000 patient years at risk. Figures 1.12–15 describe, by patient CKD status in 1998–1999 and outcomes in 2001, the cumulative probability for incidence of CVD, ASHD, CHF, and CVA/TIA.

### Preventive healthcare in CKD patients

Methods and codes used to determine rates of glycosylated hemoglobin testing (HbA1c) and screening rates for diabetic nephropathy, breast cancer, and cervical cancer are taken di-

rectly from HEDIS 2002 specifications (HEDIS 2002 is a program of the National Committee for Quality Assurance, and is used to monitor the performance of managed health care plans). Because HEDIS 2002 does not address lipid testing, influenza vaccinations, or prostate cancer screening, we have created algorithms for these analyses. Patients with Medicare as a secondary payor, not eligible for Medicare, enrolled in an HMO, or diagnosed with ESRD during the study period are omitted from all analyses, as are those who have a missing date of birth or who do not survive the entire reporting period. Non-diabetic patients are omitted from data on HbA1c and lipid testing, and data on diabetic nephropathy monitoring exclude patients who are non-diabetic or who have steroid-induced or gestational diabetes.

To identify patients with diabetes, chronic kidney disease, and cardiovascular disease, we use the method explained in the discussion of Figure 1.1, with one diagnosis code from inpatient or skilled nursing claims, or two diagnosis codes from outpatient or Part B claims.

For Figures 1.16–17, cardiovascular disease is identified using the codes listed for Figures 1.10–15, with the exception of PVD, for which we here use ICD-9-CM diagnosis codes 440–447, 451–453, and 557. Patients are enrolled in Medicare before January 1 of each year, and have CHF, ASHD, CVA/TIA, PVD or other cardiovascular disease diagnosed during the year. Lipid testing is identified through CPT codes 80061, 82465, 83715–83721, and 84478, while influenza vaccinations are documented by CPT codes 90724, 90657, 90658, 90659, and 90660, and HCPCS code G0008.

In Figures 1.18–20 we use CPT code 83036 to identify HbA1c testing, and CPT codes for microalbuminuria and macroalbuminuria testing, along with evidence of diagnosis of or treatment for nephropathy, to identify diabetic nephropathy. Cohorts for the first two figures include patients enrolled in Medicare before January 1 of each study period, and with CKD and diabetes diagnosed in the first year of the study period. HbA1c or lipid claims are searched in the second year of the period, and claims made within 30 days of the last claim for each patient are excluded. For diabetic nephropathy monitoring, the cohort includes patients enrolled in Medicare before January 1 of each period, and with diabetes diagnosed in the period.

For cancer screenings (Figures 1.21–23), cohorts include patients enrolled in Medicare prior to January 1 of each period; data are searched for patients receiving one screening test during the period. The population examined for breast cancer screening includes females age 52–69; for cervical cancer screening, females age 21–64; and for prostate cancer screening, males age 50 or older. All ages are calculated at the start of the reporting periods.

As in HEDIS 2002, patients with bilateral mastectomies or with hysterectomies before or during the study period are excluded in data on breast cancer and cervical cancer screening, respectively. For prostate cancer screening, patients are

excluded if they had prostatectomies before or during the period (identified through ICD-9-CM procedure codes of 60.2, 60.21, 60.29, 60.3, 60.4, 60.5, and 60.62, or CPT codes of 52601, 52612, 52614, 55801, 55810, 55812, 55815, 55821, 55831, 55840, 55842, and 55845). Codes used to identify patients who receive screening include CPT code 84153; revenue codes 0300 and 0310, associated with an ICD-9-CM diagnosis code of 185 or 233.4; and ICD-9-CM procedure codes of 60.11, 60.12, 60.18, 87.92, and 91.39.

## ■ Incidence & prevalence

### CHAPTER TWO & REFERENCE SECTIONS A & B

In this chapter, 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, such as the European Dialysis and Transplantation Association, 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.

As discussed earlier, patients with ESRD for at least three years, but no reported data on dialysis, death, or transplant for one year, are reported as lost-to-followup. Beginning with the 1992 ADR, these patients are not included in the point prevalent counts; they are, however, reported separately in Tables B.1 and B.a of the Reference Tables.

### PROJECTED GROWTH IN THE ESRD POPULATION

Figures 2.18–24 use data from a variety of sources to project the size of the ESRD population in 2030. Population estimates by age and race are obtained from the U.S. Census Bureau for 1981–2030. Diabetes prevalence estimates are obtained by age and race for 1981–1990 (Boyle et al.), and are linearly extrapolated backward and forward to obtain prevalence for 1978–2030. These estimates are then multiplied by census estimates each year to obtain the estimated number of diabetic and non-diabetic individuals, by age and race.

ESRD incident counts by age, race, and diabetic status for 1978–1999 are divided by diabetic and non-diabetic population counts in these years to obtain ESRD incident rates, and these rates are linearly extrapolated forward to obtain rates

through 2030. Rates are then multiplied by expected diabetic and non-diabetic population counts for 1978–2030 to obtain expected incidence counts by diabetic status.

The model used is a discrete time, non-stationary Markov model. There are two main blocks of the model, an incident block and a prevalent block. The model operates on a calendar clock—patients who become incident any time during a year and remain alive through the end of the year are moved to the prevalent block for the beginning of the next year. Within the incident and prevalent blocks, there are two states, diabetic and non-diabetic, representing individuals with a primary diagnosis of diabetes versus those with another main cause of renal failure. There are also sub-states within the diabetic and non-diabetic states, created by the cross classification of seven age groups (0–18, 19–40, 41–64, 65–69, 70–74, 75–79, and 80+) and three race groups (white, black, and other). This results in 21 cells within each of the four diabetic states, for a total of 84 possible states.

Actual prevalence in 1978 is used in the model, and modeled from 1979–2030. For the prevalent population, for each year from 1978 through 1999, the one-year probability of death is calculated for 42 groups created by the seven age groups, three race groups, and two cause-of-renal failure groups. Similarly, for incident patients, the probability of death by the end of the year in each of the 42 groups is calculated. For both incident and prevalent transition probabilities, lines are fit through time points, and extrapolated through 2030.

Each year of the model is implemented by multiplying numbers of individuals in each cell by the corresponding transition probability for each possible model transition. Numbers of prevalent patients and numbers of deaths in each cell are recorded, and remaining patients are aged one year. This process is repeated for each year through 2030, using actual incident counts each year through 1999, and extrapolated incident counts through 2030.

#### 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-followup patients.

Because the U.S. population figures (presented in Reference Section L) used for this report include only residents of the 50 states and the District of Columbia, tables focus on patients from these areas as well. The exceptions are Tables A.1, A.a, A.9–15, and A.c–i, 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.

#### Reference Section B

With the exception of Tables B.1, B.2, B.11, and B.b, these tables focus on patients residing in the 50 states and the District of Columbia. Age is calculated as of December 31.

## ■ Patient characteristics

### CHAPTER THREE & REFERENCE SECTION C

Data used here are obtained from the Medical Evidence form, which is completed at the dialysis unit for each new ESRD patient treated at that unit, and sent to CMS through the ESRD networks. It establishes Medicare eligibility for individuals who previously were not Medicare beneficiaries, reclassifies previously eligible Medicare beneficiaries as ESRD patients, and provides demographic and diagnostic information on all new ESRD patients.

Before 1995, units were required to file the Medical Evidence form only for Medicare-eligible patients. With the adoption of the revised form in 1995, however, providers are now required to complete the form for all new ESRD patients, regardless of Medicare eligibility. The revision also introduced new fields for comorbid conditions, employment status, race, ethnicity, and biochemical data at the start of ESRD therapy.

This form is the only source of information about the cause of a patient's ESRD. Because the list of diseases was revised for the new form, the USRDS stores the codes reported on each version so that detail is not lost through trying to convert one set of codes to the other.

The data in Tables C.4–16 are restricted to patients for whom the first Medical Evidence form is the revised form and is certified within 12 months of the first service date; total patient counts for this group, and for patients with no 2728 form, are presented in Table C.3.

Figures 3.28–30 display, by estimated glomerular filtration rate (eGFR), event curves for first hospitalization and survival in 1999 and 2000 incident dialysis patients. Adjusted probabilities in Figures 3.28–29 are adjusted for age, gender, race, ethnicity, primary diagnosis, and body mass index, while Kaplan-Meier estimates are used to create the unadjusted event curves.

For Figure 3.28, patients are followed from day 91 of ESRD until the earliest of the following: first hospitalization, death, transplant, loss-to-followup, or the end of one year. Measures of height, weight, and serum creatinine at the initiation of dialysis are obtained from the Medical Evidence form in order to calculate eGFR (from the Levey four-variable formula) and BMI. The following patients are excluded from the cohorts: patients with missing age, BMI, or eGFR; patients age 0–19; non-residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories; patients without Medicare as a primary payor; and patients with a bridge hospitalization that spans the start of the followup period. The Cox proportional hazards model is used with all possible two-way interactions of the following variables: age (20–44, 45–64, 65–74, and 75+ years), gender, race (white, black, and other), primary cause of ESRD (diabetes and non-diabetes), ethnicity (Hispanic and non-Hispanic), body mass index (<20, 20–<25, 25–<30, and 30+ kg/m<sup>2</sup>), and eGFR (<5, 5–<7, 7–<10, and 10+ ml/min/1.73 m<sup>2</sup>). These methods are repeated for Figures 3.29–30, with death rather than first

hospitalization as the event. These mortality analyses, however, include patients with bridge hospitalizations, and include all 1999 and 2000 incident dialysis patients, rather than only those with Medicare as a primary payor.

## ■ Treatment modalities

### CHAPTER FOUR & REFERENCE SECTION D

Chapter Four 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-followup.

Treatment modalities are defined here 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
- other peritoneal dialysis: primarily intermittent peritoneal dialysis (IPD), a small category except among very young children, and 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 (IPD) 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 cadaveric 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)

Reference Section D is divided into three sections. The first, Tables D.1–7 and D.11–13, provides counts and percentages, by demographics and treatment modality, of incident and prevalent patients alive at the end of each year. Because these tables include both Medicare and non-Medicare patients, there are significant numbers of patients in the categories of unknown age, gender, race, primary diagnosis, network, and state. Age is computed as of the start of ESRD for incident patients, and December 31 for point prevalent patients.

Table D.8 shows modality at 90 days and two years after first service for all incident Medicare patients beginning renal replacement therapy from 1997 to 1999. 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.9–10, presents counts of prevalent patients alive at the end of each year, by ESRD exposure time and modality. Table D.9 shows counts by the number of years the patient has had ESRD, while Table D.10 shows 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.

For a description of the provider data used in Figures 4.11–16, see the discussion of Reference Section J on page 207.

## ■ Clinical indicators & preventive care

### CHAPTER FIVE

Data underlying the figures in this chapter are obtained from several sources. Erythropoietin (EPO) dose information and hemoglobin values (calculated from hematocrit values) in Figures 5.1–12, 5.20–24, and the even-numbered figures from 5.26–40 are obtained from EPO claims data, while in Figures 5.17–19 and the odd-numbered figures from 5.27–41 Part B physician/supplier claims data supply the CPT codes indicating the insertion of temporary and permanent central venous accesses and simple fistulas. Information in Figures 5.13–17 is obtained from the CMS ESRD Clinical Performance Measures Project (and combined with provider data from the USRDS database) as is some information in Figures 5.18–19 and 5.25. Data on urea reduction ratios in the odd numbered Figures 5.27–41 come from Part A institutional outpatient claims. All figures include data for Medicare patients only.

Figure 5.1 shows, for hemodialysis patients, the mean hemoglobin, weekly EPO dose, and percent receiving IV iron each month. Data on mean EPO dose per week include patients with at least one EPO claim during their prevalent year and  $\leq 20$  administrations per month; data on mean hemoglobin per month include patients with at least one EPO claim during their prevalent year with a hematocrit between 10 and 50 percent. EPO claims with a dose per administration of less than 500 or greater than 80,000 units are omitted. Time at risk begins on January 1 for prevalent patients and day 91 of ESRD for incident patients, is censored at the earliest of modality change, loss-to-followup, death, or December 31, and excludes days in which the patient is in an inpatient setting. Each patient's yearly mean hemoglobin (hematocrit divided by three) is calculated from claims during the time at risk, and the average of these values is calculated for each year.

The weekly EPO dose for each patient is calculated as the total units in the year divided by the number of "outpatient weeks" at risk during the year. (While this calculation does remove time spent in an inpatient hospital from the time at risk, it does not take into account the actual number of weeks

that EPO is administered, for there may be gaps in administrations due to missed or held doses.) The mean weekly dose for each patient is then averaged across all patients to obtain the yearly mean dose per week.

Figures 5.2–4 include data from all incident hemodialysis patients with an EPO claim in the first 30 days of ESRD therapy, and at least one EPO claim during each of the following five months (a total of 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 2001, patients are incident prior to June 1, to allow them to have six months of EPO and/or IV iron claims after their incident date. For graphs by starting hemoglobin, patients are included only if they have a hematocrit listed on the Medical Evidence form, and their starting hemoglobin is determined from this value. In Figure 5.2, a mean hemoglobin for each patient is calculated from claims during the month, and the average of these values is then calculated for each month. For Figure 5.3, an average EPO dose per week is calculated, for each patient in each month, as the total units for the month divided by the number of “outpatient weeks” at risk during the month (patients may not be at risk during the entire first month of dialysis if they became incident in the middle of the month). In Figure 5.4, for each month, each patient is classified as receiving IV iron if he or she has an iron claim in that month or in one of the previous months (but after becoming ESRD). The percent of patients receiving IV iron then represents a cumulative percent of patients receiving IV iron since starting ESRD therapy.

Figures 5.5–8 include prevalent dialysis patients with at least one EPO claim during their prevalent year and a hematocrit on that claim between 10 and 50. Mean hemoglobin and weekly EPO dose are calculated with the same method used in Figure 5.1. Diabetics are defined as patients whose primary cause of renal failure is diabetes.

Figure 5.9 presents the distribution of patients by mean hemoglobin group on a monthly basis, in which each month contains all patients with at least one EPO claim during the month. Figure 5.10 shows the mean hemoglobin, by month, for prevalent dialysis patients with EPO claims, along with the monthly EPO dose per week for prevalent dialysis patients with EPO claims and  $\leq 20$  administrations per month. There are two methods used to calculate the mean weekly EPO dose presented in this figure. The “old method” reflects the method used in the 2002 Annual Data Report, in which patients’ means were weighted based on the number of monthly administrations they received to obtain the overall mean. The “new method” represents the method described for Figure 5.1, in which patients are not weighted by the number of administrations, but their time at risk only includes days in which they are not in an inpatient hospital setting. (Because inpatient claims data for 2002 were not available when this ADR went to press, time spent in an inpatient hos-

pital setting is not removed from the time at risk in the 2002 EPO doses calculated with the new method.)

Figures 5.11–12 display mean hemoglobin levels and EPO doses per week by geographic region, calculated as in previous figures. The maps are smoothed using the Bayesian method, described in the discussion of statistical methods at the end of this appendix.

Figures 5.13–14 present data on urea reduction ratios (URRs) from CMS’s Clinical Performance Measures Project (CPM). For each hemodialysis patient in the sample, the URR for each of at most three study months is calculated from pre-dialysis and post-dialysis BUN measurements, which represent the first pre-dialysis and post-dialysis measurements of the month. Each URR measurement is categorized into one of five ranges, and the median URR range is calculated; for patients with two measurements, we assign a weight of 0.5 to each. The year reported here represents the year in which the data were collected—1999 data, for example, come from the 2000 CPM study period.

Figures 5.15–16 illustrate weekly Kt/V levels, again using CPM data. For each peritoneal dialysis patient in the sample, a weekly Kt/V for each of at most three two-month study periods is collected, and a mean weekly Kt/V is calculated from these measurements.

For a description of the provider data used in Figures 5.14 and 5.16, see the discussion of Reference Section J on page 207.

In Figures 5.17–19 we present information on vascular access insertion rates. Data from the CPM project are used for the first figure, and data from Medicare claims are used for Figures 5.18–19. Insertion events are identified through the presence of the following CPT codes on Part B physician/supplier claims:

- temporary catheters: 36489, 36491, and 36800
- permanent catheters: 36533
- fistulas: 36819, 36821, and 36825
- grafts: 36830
- angioplasties: 35460, 35476, and 75978
- de clot procedures: 35875, 36550, 36831, 36860, 36861, 36870, 37201, 75896, and G0159
- revisions: 35190, 35876, 35900, 35903, 35910, 36534, 36535, 36815, 36832, 36834, 36833, 37190, 37607, and M0900
- stents: 37205, 37206, 37207, 37208, and 75960

In the calculation of insertion rates for temporary and permanent central venous catheters, we use additional methods to exclude catheters inserted for purposes other than dialysis. A CPT code of 36489, 36491, or 36533 is included, for example, only if it is associated with either a line-level diagnosis code or a claim-level principal diagnosis code that is among the following ICD-9-CM codes concerning dialysis and renal failure: 250, 403, 580–589, 593, 996.1, 996.62, 996.73, V45.1, and V56. Additionally, we search Part B physician/supplier claims and durable medical equipment claims

for chemotherapy claims (CPT codes 96408, 96410, and 96412) and parenteral nutrition claims (CPT codes B4164–B5200, B9004, B9006, and B9999). Patients with any of these codes during the year are excluded.

For Figure 5.18, physician specialty is indicated by the following physician specialty codes on Part B physician/supplier claims:

- anesthesiology: 05 and 43
- nephrology: 39
- radiology: 30 and 94
- surgery: 02, 23, 33, 77, and 78

Figures 5.20–25 display mean weekly EPO dose per patient weight (kg). Figures 5.20–5.24 include incident patients as defined in Figures 5.2–4, with the additional requirements that patients have a valid weight listed on the Medical Evidence form, and a known unit affiliation. Patients with a recorded weight of over 175 kg are omitted, as are those over age 18 with a weight under 40 kg, and EPO claims are omitted if they represent 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 or greater than 10,000. Patients included are those whose calculated mean weekly EPO dose per kg (with inpatient hospital days removed) is between 10 and 1,000 units, representing approximately the first and 99th percentiles.

For Figure 5.22, diabetics are defined as patients whose primary diagnosis is diabetes, while non-diabetics are those with another known diagnosis. Hypertensive and non-hypertensive patients in Figure 5.23 are identified the same way. For Figure 5.24, the starting hemoglobin group is calculated from the hematocrit value on the Medical Evidence form, and chains are grouped by the mean weekly EPO dose per kg for those initiating with a hemoglobin level less than 10 g/dl in 2001.

Figure 5.25 includes prevalent patients from the USRDS database who also appear in the CPM project data. Their weight represents an average of the post-dialysis weight reported in each of the CPM sample periods during the year, while their hemoglobin group represents the average of either the hematocrit values reported in each of the CPM sample periods divided by three (for 1996 through 1999) or the hemoglobin values during those periods (for 2000 and 2001). Mean weekly EPO dose represents an average of the weekly prescribed EPO dose reported in each of the CPM periods.

For a description of the provider data used in Figures 5.24–25, see the discussion of Reference Section J on page 207.

The odd-numbered figures from 5.27–41 illustrate urea reduction ratios (URR) and catheter utilization rates of period prevalent hemodialysis patients with rare diseases. Each patient's URR is obtained from the G-modifier attached to CPT code 90999, with a revenue code of 821 or 825. Catheter utilization is defined by the same methods used in Figures 5.18–19, and the rare diseases are identified using the principal diagnosis codes and trailer codes in the USRDS database.

Mean hemoglobin and mean weekly EPO dose per week in the even-numbered figures from 5.26–40 are calculated with the same method used in Figure 5.1.

Figures 5.42–60 present data on diabetic and cardiovascular preventive care. ESRD patients without Medicare Part A and B coverage during the entire study period are omitted from all analyses here, as are general Medicare patients enrolled in an HMO or diagnosed with ESRD during the study period. Also omitted are those 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-followup during the study period.

Age is generally calculated immediately before the study period. Comparisons of diabetic care in ESRD and general Medicare patients are limited to those age 65–75, data on diabetic care in the ESRD population include patients age 18–75, and, for our analyses in Figures 5.49–54 of those with a history of cardiovascular disease, we look at patients age 66 and older.

Methods and codes used to determine screening rates for diabetic eye examinations and glycosylated hemoglobin (HbA1c) testing are taken directly from HEDIS 2002 specifications (HEDIS 2002 is a program of the National Committee for Quality Assurance, and is used to monitor the performance of managed health care plans). HEDIS 2002 does not, however, address lipid testing, so we have created an algorithm for these analyses, identifying lipid testing through CPT codes 80061, 82465, 83715–83721, and 84478. Claims with tests occurring less than 30 days after the previous claim are excluded from calculations of the number of tests.

As explained in the discussion of Chapter One, we identify diabetes, chronic kidney disease, and cardiovascular disease through diagnosis codes in one or more Part A institutional claims, or two or more outpatient or Part B claims. Diagnosis and procedure codes for diabetes, CKD, atherosclerotic heart disease, congestive heart failure, CVA/TIA, and other cardiac disease are the same as those used for Chapter One analyses. Coronary revascularization is identified through ICD-9-CM procedure codes 36.01, 36.02, 36.05, 36.06, and 36.1x, and CPT codes 92980, 92981, 92982, 92984, 92995, and 92996, while amputation for peripheral vascular disease is determined through ICD-9-CM diagnosis codes 440–447, 451–453, and 557, and CPT codes 23900, 23920, 24920, 24900, 25900, 25905, 25920, 25927, 27295, 27590, 27591, 27592, 27598, 27880, 27881, 27882, 27889, 28800, and 28805.

Figure 5.42 illustrates rates of diabetic eye examinations in ESRD and general Medicare populations. The ESRD cohort includes patients starting therapy prior to January 1, 2000, alive on December 31, 2001, and with diabetes in 2001. The general Medicare population includes patients continuously enrolled in Medicare Part A and B in 2000 and 2001, and with diabetes in 2001. Examinations are counted during 2000 and 2001.

For comparisons of diabetic lipid monitoring and glycosylated hemoglobin testing (Figures 5.44, 5.46, and 5.48), the

ESRD population includes patients initiating therapy prior to January 1, 2001, alive on December 31, 2001, and with diabetes in 2001. The general Medicare population consists of patients continuously enrolled in Medicare Part A and B in 2001, and with diabetes in 2001. Rates include patients receiving at least one test during 2001. In Figure 5.48, glycosylated hemoglobin claims made within 30 days of the last claim for each patient are excluded.

Figures 5.43, 5.45, and 5.47 compare diabetic testing in dialysis and transplant patients. For eye examinations, the cohort includes patients initiating therapy prior to January 1, 2000, alive on December 31, 2001, and carrying a diagnosis of diabetes in 2001. For patients whose primary diagnosis is diabetes, rates are calculated for patients receiving one examination in 2001; for other diabetic patients, rates are calculated for 2000 and 2001. Cohorts for lipid and glycosylated hemoglobin testing include patients initiating therapy prior to January 1, 2001 and with diabetes in 2001; rates are calculated for patients receiving one test during 2001.

Figures 5.49–54 compare lipid monitoring in non-diabetic CKD, dialysis, and transplant patients with a history of cardiovascular disease. The cohort for CKD patients includes general Medicare patients age 65 or older who enter the program before January 1, 2000, remain in the program and alive through December 31, 2001, have no diabetes in 2000, and have CKD and specific cardiovascular disease diagnosed in 2000. For dialysis and transplant patients, the cohort includes 2001 point prevalent patients age 66 or older initiating therapy prior to January 1, 2001, alive on December 31, 2001, with no diabetes claims six months prior to January 1, 2001, and diagnosed with specific cardiovascular disease during that six-month period. Lipid testing is tracked in 2001.

The cohorts for Figures 5.55–60 include point prevalent patients with no diabetes or cardiovascular claims one year prior to January 1 of each year, diagnosed with specific cardiovascular disease during the current year, and surviving one year after the cardiovascular event. Lipid testing is tracked one year prior to and one year following each cardiovascular event.

## ■ Outcomes: hospitalization & mortality

### CHAPTER SIX & REFERENCE SECTIONS E, H, & I

#### Hospitalization

Methods used for the hospitalization figures in this chapter generally echo those used for the tables in Reference Section E (described below). Inclusion and exclusion criteria are generally the same, as are the methods for cleaning the hospitalization claims, counting hospital admissions and days, and defining the follow-up time at risk. One difference is the exclusion in Reference Section E of patients of races that are unknown or other than white, black, Native American, or Asian; these patients are included in the Chapter Six figures, except where data are presented by race.

Part A inpatient institutional claims are used for the analyses, and only patients with Medicare as a primary payor and

dialysis patients with evidence of dialysis claims are included, as detailed in the discussion of Section E. Adjusted rates are calculated using the direct adjustment method on the observed category-specific rates, except in Figures 6.1 and 6.8, where a model-based adjustment method is used. This method is described further in the discussion of Section E, and in the statistical methods section (page 211).

Figure 6.1 presents the percent change in adjusted hospital admission rates for period prevalent dialysis patients, 1993–2001. Values presented for all patients are adjusted for age, gender, race, and primary diagnosis, while rates presented by one of these factors are adjusted for the remaining three. As noted in the caption, these adjustments for different factors mean that rates across the individual graphs are not directly comparable. We use a model-based adjustment method here, with 2001 dialysis patients as the reference cohort. Vascular access admissions are defined through a principal ICD-9-CM diagnosis code of 996.1, 996.62, or 996.73, or a specified DRG (112, 120, 315, 442, 443, 478, or 479) in combination with a principal procedure code of 39.27, 39.29, 39.42, 39.43, 39.49, 39.53, 39.59, 39.93, or 39.94. Principal diagnosis codes of 390–459 identify circulatory admissions, and codes of 460–519 identify respiratory admissions.

Figures 6.2–4 and 6.8–10 present adjusted rates of total hospital admissions and hospital days per patient year. With the exception of Figure 6.3, study populations contain period prevalent dialysis patients, and the 2001 cohort is used as the reference. Because in Figure 6.3 we wish to present adjusted rates reflecting the 2001 transplant patient distribution, 2001 period prevalent transplant patients are used as the reference cohort; these rates should not be compared to those of dialysis patients. Patient vintage in Figure 6.4 is calculated as the time from the first ESRD service date to the first of the year for prevalent patients, or as less than one year for incident patients. Because each of these figures is adjusted for a different set of factors (see figure captions), comparison of rates is appropriate only within a figure, not across figures. Rates presented for Hispanic patients in Figure 6.10 are unadjusted.

In Figures 6.8–10, the cause-specific hospitalization categories are defined by principal ICD-9-CM diagnosis codes. The cardiovascular category consists of codes 276.6, 394–398.99, 401–405, 410–420, 423–438, and 440–459, while infection is indicated by the same codes used for Figures 1.5–6. The “other” category includes hospitalizations that are not classified as either cardiovascular or infectious.

Figures 6.14–16 compare rates of all-cause and cause-specific admissions and hospital days across 1991–2001, using 2001 period prevalent ESRD patients as the reference cohort. In Figure 6.15, the cause-specific hospitalization categories of cardiovascular, infection, and other are defined through the same codes used in Figures 6.8–10. In Figure 6.16, principal ICD-9-CM codes are as follows: for pulmonary infection, 460–466, 473–474.0, 475–477.9, 478.22–478.24, 480–491, 510–511, 513.0, and 518.6; for vascular access infection, 996.62; for peritonitis, 567.2 and 567.9; for cardio-

vascular procedures (including vascular access procedures), 35–40, excluding 39.95; and for heart catheterizations, 37.21, 37.22, and 37.23.

### Mortality

Patient cohorts for all mortality figures here include both Medicare and non-Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories.

Figures 6.5–6 present five-year survival by modality for 1987–1991 and 1992–1996 incident patients, with modality defined on the first ESRD service date. Patients with unknown age, gender, or primary diagnosis, and those with a listed age greater than 110, are excluded, as are dialysis patients who die or receive a transplant in the first 90 days. Dialysis patients are followed from day 91 until death, transplantation, or the end of 2001, while transplant patients are followed from the first transplant date until death or the end of 2001. All probabilities are adjusted for age, gender, and race; overall probabilities are also adjusted for primary diagnosis. The reference population consists of 1996 incident ESRD patients, and adjusted probabilities are comparable across modalities.

Figure 6.7 shows trends in mortality rates by patient vintage for period prevalent dialysis patients, who are defined as being 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, black, Native American, and Asian, are excluded. Patients are followed from January 1 until death, transplantation, or the end of the year, and all-cause mortality rates are adjusted for age, gender, race, primary diagnosis, and vintage using generalized mixed models. The reference population consists of 2001 prevalent dialysis patients, and adjusted mortalities across vintages are comparable.

Figures 6.11–13 present trends in cause-specific mortality by age, gender, and race/ethnicity. Patient cohorts, exclusions, and followup are the same as in Figure 6.7, and mortality rates are estimated using generalized mixed models. Rates by age are adjusted for gender, race, and primary diagnosis; rates by gender are adjusted for age, race, and primary diagnosis; and rates by race are adjusted for age, gender, and primary diagnosis. The reference population consists of 2001 prevalent dialysis patients, and adjusted mortalities are comparable within each figure.

For data in Figure 6.17 on five-year survival by modality, the population includes incident patients who are on hemodialysis or peritoneal dialysis on their first ESRD service date, and who survive and remain on dialysis for the first 90 days. Patients with unknown age, gender, or primary diagnosis, or a listed age greater than 110, are excluded. Patients are followed from day 91 until death, transplant, or the end of 2001, and survival probabilities are adjusted for age, gender, race, and primary diagnosis. The reference population consists of 1996 incident ESRD patients, and adjusted probabilities across modalities are comparable.

All-cause mortality rates by vintage, and cause-specific mortality rates by modality, are presented in Figures 6.18–19. Populations for both figures include period prevalent patients on hemodialysis and peritoneal dialysis in a calendar year. Patients with unknown age or gender, or of race other than white, black, Native American, or Asian, are excluded. Patients are followed from January 1 until death, transplant, or the end of the year. Rates are adjusted, using generalized mixed models, for age, gender, race, and primary diagnosis, and all-cause rates in Figure 6.18 are also adjusted for vintage. The reference population consists of 2001 prevalent dialysis patients, and adjusted mortalities across modalities are comparable.

Table 6.a shows the expected remaining lifetimes for dialysis patients, renal transplant patients, and the general U.S. population. For period prevalent ESRD patients in 2001, expected lifetimes are calculated using the adjusted death rates in Reference Tables H.8 and H.11, assuming constant survival and mortality within each age group. Patient inclusion and exclusion criteria are those used in Tables H.8 and H.11, and the method for calculating expected remaining lifetimes is described in the section on statistical methods at the end of this appendix (page 212). Deaths due to AIDS, accidents (“accidents unrelated to treatment” on the ESRD Death Notification), and illegal drugs (“drug overdose (street drugs)”), are excluded, so the reported lifetimes correspond to hypothetical populations in which these causes of death do not occur. Data for the general population are obtained from the CDC’s National Vital Statistics Reports.

### Sepsis

The cohorts used here include 1991–1999 (Figures 6.20–23) and 1996–1999 (Figures 6.24–29) incident ESRD patients on either hemodialysis or peritoneal dialysis on day 90. Patients enrolled in an HMO or with Medicare as secondary payor are excluded. Patients are followed one year for sepsis hospital admissions, and until December 31, 2000 for mortality, first AMI hospitalizations, and CHF hospitalizations.

ICD-9-CM diagnosis code 038 is used to identify sepsis hospital admissions; 038.1 is defined as staphylococcal sepsis, while 038.4 is defined as gram-negative organism sepsis. AMI is identified through 410, excluding 410.x2, and CHF through 402.x1, 425, 428, 518.4, and 398.91. Claims overlapping the starting point of the follow-up period are excluded.

Raw first-year total admission rates are calculated using the number of admissions over the time at risk, and raw first-year first hospitalization rates for staphylococcal and gram negative sepsis are obtained in a similar way. A Poisson model is used to calculate adjusted sepsis hospitalization rates and relative risks, and rates are adjusted for age, gender, race, and primary diagnosis.

A time-dependent interval Poisson model, with first sepsis hospitalization as the time-dependent variable, is used to calculate adjusted rates and relative risks for mortality, AMI hospitalization, and CHF hospitalization. Rates are adjusted for age, gender, race, modality, and primary diagnosis. For



mortality, patients are censored at transplant, loss-to-followup, and end of the followup period; for sepsis hospitalizations, patients are also censored at modality change and death; for AMI and CHF hospitalizations, patients are censored at transplant, death, loss-to-followup, and the end of the followup period. Adjusted rates are calculated using the model-based adjustment method, described on page 211.

### Reference Section E

New to this year's ADR, hospitalization reference tables now present only total admission and hospital day rates, without first admission rates. Rates are adjusted and presented by year from 1993 to 2001. 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 on page 211 in the statistical methods section of the appendix.)

Because hospitalization data may be incomplete for non-Medicare patients, the analyses in this section include only patients with Medicare as their primary payor. Hospitalization data are obtained from Part A institutional inpatient claims, with the following exceptions: Table E.12 also includes REBUS hospitalization data, and supplementary tables E.1.3–E.5.3, E.1.4–5.4, E.7.3–11.3, and E.7.4–11.4 (on our website) use only the REBUS inpatient data.

Tables E.1–11 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, black, 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 using the following categories:

- 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 who have been on hemodialysis for at least 60 days as of the start of the period at risk
- CAPD/CCPD: patients who have been 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 are classified as MSP, and who therefore have in-

complete hospitalization data, dialysis patients failing to reach a certain level of Medicare paid dialysis bills are excluded from Tables E.1–11. Dialysis patient start dates (January 1 for prevalent patients and day 91 of ESRD for incident patients) must fall between start and end dates based on Medicare paid dialysis claims, as follows:

- start date: the first day of the first month in which there are at least \$675 of Medicare paid dialysis claims
- end date: the end of a three-month period in which there are less than \$675 of paid claims in each month

If a patient's start date does not fall between these dates, he or she is excluded from the analysis for that year. The paid claims dates are analyzed only for the dialysis patient start date. The end date remains the earliest of death, three days prior to transplant, or December 31 of the year.

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, 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 or December 31 of the year; 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, 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 hospitalizations 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 hospitalizations with a discharge the day after admission, are both counted as one day.

In this year's hospitalization data, similar to data in the 2002 ADR, all overlapping and only certain adjacent hospitaliza-

tions 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 1991–2001 institutional inpatient claims, for example, 4.3 percent of the hospitalizations were combined using these criteria. 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 total discharges reported in Table E.12, in contrast, include all hospitalizations, and no overlapping or adjacent hospitalizations are combined. These tables present total hospital discharges by DRGs, and no exclusions are made for patients dying of AIDS or for MSP status. Total discharges are presented by modality group and the year of discharge. For each year the total discharges are counted from January 1 or the first ESRD service date until the end of the period at risk, as defined previously. In this case, however, the period at risk for transplant patients in the transplant and all-ESRD groups is not censored at three years following the date of transplant. Inpatient REBUS data are combined with Part A institutional inpatient claims data, and duplicate observations from both sources with identical hospitalization start dates, end dates, and DRG codes are omitted.

The methodology used for computing total admission and hospital day rates uses the model-based adjustment method (discussed in the statistical methods section). The predicted rates for each subgroup combination of age, gender, race, primary diagnosis, and year are obtained using a model with the Poisson assumption. This model uses data from the current and previous two years, with respective weights of 1,  $\frac{1}{4}$ , and  $\frac{1}{8}$ . Adjusted rates are then calculated using the direct adjustment method, with all 2001 ESRD patients as the reference cohort. New to this year's ADR, standardized hospitalization ratios (SHRs) by state (Table E.6) are now calculated using the Bayesian method, described in the discussion of standardized mortality ratios on page 212.

Also new this year, supplementary tables providing rates of admissions per 1,000 patients and days per patient, rather than per patient year, are available on our website. The rates in these tables (E.1.1–5.1 and E.7.1–11.1) are calculated with denominators consisting of the total patients, rather than the total time at risk in patient years. Additional supplementary tables (E.1.2–5.2 and E.7.2–11.2) display the counts of the total admissions or hospital days, patient years at risk, and total patients that are used to calculate the rates.

Long-term trends in hospitalization data are also available in supplementary tables on our website (E.1.3–5.3 and E.7.3–11.3). Total admission rates per 1,000 patient years and hospital day rates per patient year are presented from 1980–2001 in E.1.3–3.3 and E.7.3–9.3 for all ESRD, dialysis, and hemodialysis patients. Due to the instability of rates in earlier years,

these rates are presented from 1983 in E.4.3 and E.10.3 for peritoneal dialysis patients, and from 1986 in E.5.3 and E.11.3 for transplant patients. Rather than using Part A inpatient claims data, which are unavailable in earlier years, these tables use only REBUS inpatient claims data. All one-day hospitalizations with a discharge date on the same or next day as the admission date are excluded from these tables, since, prior to 1991, the REBUS data include no hospitalizations of less than 24 hours. To enable comparison of rates across years, therefore, only hospitalizations with a length of at least two days are included. As a result, these rates are lower than the rates in Tables E.1–5 and E.7–11, which use all Part A inpatient claims. Other methods (rate calculation, model-based adjustment, etc.) generally follow those discussed for Tables E.1–5 and E.7–11. In the supplemental tables, however, we do not exclude dialysis patients failing to reach a certain level of Medicare paid dialysis bills, since this economic information is unavailable for the earlier years. Since only those patients classified as having Medicare as a primary payor are included, incomplete claims due to MSP status should not be a problem. Additionally, supplementary tables E.1.4–5.4 and E.7.4–11.4 present counts of total admissions or days, patient years at risk, and total patients, which correspond with the rates presented in E.1.3–5.3 and E.7.3–11.3.

#### Reference Section H

Counts of deaths are reported in H.1 for 1980–2001, while predicted mortality rates for period prevalent cohorts are presented in H.7–11 for 2001. New to this year's ADR, adjusted annual death rates per 1,000 patient years (Tables H.2–6, and their supplemental tables on our website) are reported from 1980–2001 for all ESRD, all dialysis, and hemodialysis patients, and from 1984–2001 for peritoneal dialysis and transplant patients. Standardized mortality ratios (SMRs, Table H.12) and cause-specific death rates (Tables H.13–18, and supplemental tables H.13.1–17.1, H.13.2–17.2, and H.a.1–4 on our website) are reported for prevalent cohorts of 1999–2001. Adjusted first-, second-, and third-year death rates for incident cohorts are reported in Tables H.19–21. Residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories are included in each of these tables, as are all non-Medicare patients.

Tables H.1, H.2–6, H.13–18, H.a.1–4, and H.19–21 include all causes of death. Tables H.7–11 exclude patients dying of AIDS. While patients dying of street drug overdoses or accidents unrelated to treatment are not counted in the rates, their time at risk is counted until death.

Tables H.2–18 include both incident and prevalent patients. As defined earlier, prevalent cohorts include patients who are 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. Incident cohorts are limited to patients who reach day 91 of ESRD treatment during the year. Because calculations in these tables include only one-year of followup, a prevalent patient surviving until 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 of these 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-followup at the beginning of the year are excluded. The period at risk is not censored at the start of a lost-to-followup period, however; if a patient enters the lost-to-followup 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 subgroups—hemodialysis or CAPD/CCPD—if he or she has been on that modality for at least the previous 60 days. Dialysis patients who are not on hemodialysis or CAPD/CCPD, or who have been on that modality for fewer than 60 days, are included only in the all-ESRD and all-dialysis categories.

Both adjusted and unadjusted death rates for prevalent cohorts are reported for the following groups (definitions are the same as those used in the hospitalization analyses; see the discussion of Section E on page 197):

- all-dialysis (includes unknown dialysis), hemodialysis, or CAPD/CCPD; if a transplant occurs during the year the period at risk is censored at the transplant date
- functioning 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 only at the end of the year
- all-ESRD; the period at risk is censored only at the end of the year

Patient populations for Tables H.19–21 are the same as those used in Reference Section I. The population groups include all dialysis, hemodialysis, CAPD/CCPD, and first transplant (known deceased and living donors only).

Generalized mixed models are used to calculate the smoothed rates in Tables H.7–11; these methods are described on page 211 later in this appendix. After obtaining smoothed rates from the generalized mixed models in Tables H.2–6, direct adjustment methods are used. Overall mortality rates are adjusted for age, gender, race, and primary diagnosis, while rates for diabetes, hyperten-

sion, glomerulonephritis, and other causes of ESRD are adjusted for age, gender, and race. The reference population for Tables H.2–6 includes 2001 ESRD patients, so rates among modalities are comparable. Standardized mortality ratios (SMRs) are calculated using the Bayesian method after obtaining smoothed rates from generalized mixed models in Table H.12. For each of these tables, patients whose gender or date of birth is missing, or who are of races other than white, black, Native American, or Asian, are excluded; those with no listed diagnosis are included in the “other” diagnosis group.

In Tables H.13–17, mortality rates are reported by primary cause of death for patients prevalent at the beginning of, or incident during, 1999–2001. Subgroups are characterized by age, gender, race, and modality at the start of each cohort year for prevalent patients, and at 90 days of ESRD for incident patients. Dialysis patients are censored at transplant or the end of the year, while transplant patients and patients in the all-ESRD category are censored only at the end of the year. The mortality rate for a specific primary cause of death in each subgroup is obtained by dividing the total deaths from that cause by the subgroup’s total followup time, and the sum of rates for each cause in a subgroup is equal to the overall mortality rate of that subgroup. Rates for collapsed categories of death (Table a.a, below) are presented in Tables H.13–17, while Tables H.a.1–4 (supplemental tables on the USRDS

<b>a.a · Collapsed categories of death</b>	
<i>used for Reference Tables H.13–17</i>	
<b>Collapsed categories</b>	<b>Individual categories</b>
Acute myocardial infarction	Myocardial infarction, acute
Hyperkalemia	Hyperkalemia
Pericarditis	Pericarditis, including cardiac tamponade
Atherosclerotic heart disease	Atherosclerotic heart disease
Cardiomyopathy	Cardiomyopathy
Cardiac dysrhythmia	Cardiac dysrhythmia
Cardiac arrest	Cardiac arrest, cause unknown
Valvular heart disease	Valvular heart disease
Pulmonary edema	Pulmonary edema
Cerebrovascular disease	Cerebrovascular accident including intracranial hemorrhage; ischemic brain damage/anoxic encephalopathy
G.I. hemorrhage	Hemorrhage from transplant site; hemorrhage from vascular access; hemorrhage from dialysis circuit; hemorrhage from ruptured vascular aneurysm; hemorrhage from surgery; other
Septicemia	Septicemia, due to peritonitis; septicemia, due to peripheral vascular disease, gangrene; septicemia, other
Pulmonary infection	Pulmonary infection (bacterial); pulmonary infection (fungal); pulmonary infection (other); tuberculosis
Viral infection	Viral infection, CMV; viral infection, other; Hepatitis B; other viral hepatitis
AIDS	AIDS
Other infection	Infection, other; fungal peritonitis
Cachexia	Cachexia
Malignant disease	Malignant disease, patient ever on immunosuppressive therapy; malignant disease
Other cause	Pulmonary embolus; mesenteric infarction/ischemic bowel; liver-drug toxicity; cirrhosis; polycystic liver disease; liver failure, cause unknown or other; pancreatitis; perforation of peptic ulcer; perforation of bowel; bone marrow depression; dementia, including dialysis dementia, Alzheimer's; seizures; diabetic coma, hyperglycemia, hypoglycemia; chronic obstructive pulmonary disease (COPD); complications of surgery; air embolism; accident related to treatment; accident unrelated to treatment; suicide; drug overdose (street drugs); drug overdose; other identified cause of death.
Unknown cause	Unknown
Missing forms	Missing forms

website) list rates for each specific cause of death. Table H.18 presents rates by cause of withdrawal.

In Tables H.19–21 the adjusted first-, second-, and third-year mortality rates for incident cohorts—including all-dialysis, hemodialysis, CAPD/CCPD, and first transplant patients—are computed from the Cox model using the model-based adjustment method described later in this appendix. A separate Cox model is used for each incident year. These mortality rates are presented using aggregate categories for age, gender, race, and primary diagnosis, and a rate presented for one of these variables is adjusted for the remaining three. Overall mortality rates for all patients are adjusted for each of the four variables. Mortality rates for Hispanic and non-Hispanic patients, however, are unadjusted (crude) rates calculated as the number of deaths over patient-years at risk. The reference population for adjusted rates consists of 1996 incident ESRD patients.

### Reference Section I

These tables, which include only incident cohorts, present patient counts and patient 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 from the cohorts.

Patient selection criteria are the same for both unadjusted and adjusted survival probabilities. All new ESRD patients who have a first ESRD service date between January 1, 1980 and December 31, 2000 are included in the analysis. These patients are followed until December 31, 2001, a maximum followup time of 20 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 followup
- 65 and over at start of ESRD: all ESRD patients age 65 and over who begin renal replacement therapy in a calendar year; patients are grouped in two-year periods to increase cell size, and are censored only at the end of followup
- dialysis only: all ESRD 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 followup

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. Unadjusted probabilities for Hispanics are new to this ADR.

To limit imprecision due to small cell sizes, adjusted survival probabilities are presented using aggregate categories for age, gender, race, and primary diagnosis. For each co-

hort, 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, as described later in the discussion of statistical methods. The reference population consists of 1996 incident ESRD patients.

## ■ Transplantation

### CHAPTER SEVEN & REFERENCE SECTIONS F & G

#### Chapter Seven

In addition to the analyses conducted for the reference tables (discussed below), several additional methods are used for the figures in this chapter.

Figure 7.1 presents transplant counts by donor type. These counts are obtained through a combination of UNOS data and data from CMS. Living-related donors include parents, children, identical twins, full siblings, and half siblings, while living distant/unrelated donors include other relatives, spouses, and other unrelated donors.

Figure 7.2 contrasts the incident rate of ESRD per million population with the transplant rate, estimated per 100 patient years on dialysis. Geographic variations in transplant rates are presented in Figures 7.3 and 7.6, in which the state is the recipient's last known state of residence, not necessarily the state where the transplant was performed.

Figures 7.9–10 show the number of patients on the UNOS kidney waiting list on December 31 of the given year. These patients are listed on the kidney-only waiting list; patients listed on the kidney-pancreas waiting list are not included.

Figures 7.11–13 detail organ donation rates. We have made several changes this year to the methodology used for calculating these rates. In the case of both kidneys from a deceased donor being transplanted, a donation was previously counted twice. Figure 7.11 presents the donation rate using this method, but also presents data using the new method of counting a donation only once, even if both kidneys are eventually transplanted. As expected, with the second method the rate per million population is reduced by approximately half.

Maps of donation rates were previously based on the location of the recipient, rather than the location where the donation was made. This year, however, every attempt has been made to determine the county of residence of the organ donor, and the maps in Figures 7.12–13 are now based on donor location. Given that the mortality rate may vary by Health Service Area, Figure 7.13 presents deceased donor donations per million deaths by HSA; death counts for this figure are obtained from the U.S. Census Bureau.

Tables 7.a–b list results from separate Cox proportional hazards models, modeling all-cause graft failure (including death), death-censored graft failure (return to dialysis), and death with a functioning graft. New this year, because of factors and circumstances unique to each type of transplant, we

have run separate models for recipients of organs from deceased and living donors. All first-time, kidney-only transplants between 1995 and 2001 with known recipient age and donor type are included.

Figures 7.14–15 present graft survival curves, trends in first-year survival, and trends in conditional half-lives for recipients of kidneys from deceased and living donors. Estimates are made from Cox proportional hazards models adjusted for all covariates presented in Table 7.a or 7.b, and are based on the population's average survival curves, rather than on curves of the average patient in the population. Estimates of conditional half-lives are conditional on first-year graft survival, and are estimated from the cumulative hazard between years one and two. The median (half-life) is calculated as the estimated mean multiplied by the natural log of 2, and the estimated mean is calculated as the inverse of the estimated hazard between years one and two.

New this year is information on post-transplant complications (Figures 7.16–27). With a few minor exceptions, the methods for each of the four complications (fractures, diabetes, infections, and malignancies) are the same. The population includes all first-time, kidney-only recipients, 1995–2001, with known age and donor type who are deemed to have Medicare as primary payor (Parts A and B) over the date of transplantation (N=35,765). Medicare primary payor status is determined using a three-step process: the transplant claim is located by searching Medicare claims for DRG 302, the payor fields on the claim are checked to see if Medicare is the primary payor, and the Medicare enrollment database is checked to verify Medicare primary coverage. Note that the primary/secondary payor fields on the UNOS forms are not used to determine Medicare payor status.

To identify de novo post-transplant diabetes, patients are further required to have six months of Medicare primary payor coverage prior to transplant. This period is searched for claims indicating diabetes, and patients with these claims are omitted; this reduces the sample for the diabetes figures to 19,612.

To identify complications, Part A and B claims are searched for the appropriate ICD-9-CM diagnosis codes. For fractures, infections, and malignancies, one diagnosis code is sufficient to identify the condition, while patients must have one inpatient or two outpatient/Part B codes within a year to be considered diabetic. Only the first three years post-transplant are searched for each condition, as most recipients are no longer eligible for Medicare following this period. For each complication, we illustrate the cumulative incidence over the three-year post-transplant period; this incidence is estimated from a Cox proportional hazards model, adjusting for the covariates in Tables 7.a–b, and estimated from the population average curve rather than the curve of the average patient.

Relative risk estimates for the effect of these post-transplant complications on graft failure and mortality are obtained from a time-dependent Cox proportional hazards model where the time of first fracture, infection, or malignancy, or the time of

diabetes diagnosis, is entered into the model as a time-dependent covariate. We also present data on the relative risks associated with several covariates of interest. These estimates are obtained from Cox proportional hazards models, considering time to first complication or diabetes diagnosis.

#### Reference Section F

Transplant counts are presented in Tables F.1–8. All known transplant events are included unless specified in the footnote, and all counts include non-Medicare patients.

Calculations of transplant rates per 100 patient years on dialysis begin in Table F.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-followup in a given year are not censored at the lost-to-followup 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.

In Table F.10, first transplant rates per 100 patient-years at risk are calculated using a generalized mixed model (described on page 211 later in this appendix) to stabilize the rates.

Table F.12 shows standardized first transplant ratios by state and territory. A state's observed first transplant rate, calculated using a generalized mixed model as in Table F.10, is compared to the rate expected from national rates for patients with similar characteristics. The standardized first transplant ratio is calculated as the ratio of the observed number of first transplants in the state to the expected number.

#### Reference Section G

This section presents probabilities of graft survival, death-censored graft survival, survival with a functioning graft, and patient survival for various demographic groups and followup times. Patients are followed from the transplant date to graft failure, death, or the end of the followup period (December 31, 2000); death in the analysis of graft survival is considered a graft failure, whereas death is censored in the death-censored graft failure analysis. Because a minimum of one year of followup is required, 2000 is the most recent year reported.

To produce a standard patient cohort, patients with unknown age, gender, or race 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 with the Kaplan-Meier method and Greenwood's formula, while the Cox model is used for adjusted probabilities. Probabilities are adjusted for age, gender, race, and primary diagnosis, and standardized to 1996 patient characteristics.

## ■ Pediatric ESRD

### CHAPTER EIGHT

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

Figures 8.3–4 display the mean hemoglobin and mean weekly EPO dose for prevalent pediatric patients on dialysis; calculations are made and patients are identified using the same methods described for Figure 5.1. Because of the small number of pediatric patients within some categories, multiple years are grouped together. In addition, the small numbers make the means susceptible to the influence of outliers, so the mean weekly EPO dose in Figure 8.4 includes only patients with a mean dose less than 200,000 units.

Figure 8.5 shows the percentage of pediatric and adult patients with a carnitine lab test and receiving levocarnitine. Included prevalent dialysis patients are alive with Medicare as primary payor during the entire year; are residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories; and have non-missing age information. Part A outpatient and Part B physician supplier claims are used to identify patients with at least one claim during the year. A HCPCS code of J1955 indicates a levocarnitine claim, while a CPT code of 82379 (first used in 1999) indicates a carnitine lab test.

For Figures 8.6–10, the mean hemoglobin and mean weekly EPO dose are calculated in the same way described for Figures 5.9–10. Due to the small numbers of pediatric patients, however, the distribution of mean hemoglobin groups is presented quarterly instead of monthly.

The cohort examined for influenza vaccinations (Figure 8.16) includes patients starting ESRD therapy at least 90 days prior to September 1, 2001, alive on December 31, 2001, and with Medicare Part A and B coverage for the entire year; age is calculated on December 31, 2001. Influenza vaccinations are identified through CPT codes of 90724, 90657, 90658, 90659, and 90660, and a HCPCS code of G0008; rates are calculated for patients receiving a vaccination in the last four months of 2001. For pneumococcal pneumonia vaccinations, the cohort includes prevalent patients initiating therapy at least 90 days prior to January 1, 2000, age 0–19 prior to January 1, 2000, and alive on December 31, 2001, with Medicare Part A and B coverage during 1999–2000; vaccinations are identified through CPT codes 90669 and 90732 and HCPCS codes J6065 and G0009, and rates are calculated for patients receiving one vaccination during 2000–2001. Similar rules are used for analyses of hepatitis B vaccinations and lipid testing, though cohorts here include patients initiating therapy 90 days prior to January 1, 2001. Hepatitis vaccinations are identified through CPT codes 90636, 90740, 90743–90744, and 90746–90748, and rates are calculated for patients receiving one vaccination in 2001. Lipid testing is identified through CPT codes 80061, 82465, 83715–83721, and 84478. The primary cause of renal failure is obtained from the Medical Evidence form.

Figures 8.20–24 present the incidence of post-transplant complications in the pediatric population. Only recipients transplanted in 1995–2001 and with Medicare as primary payor at the time of transplantation are included (N=1,045). Figure 8.23, on post-transplant diabetes, further eliminates patients with known diabetes at the time of transplantation, leaving 760 patients. Medicare Part A and B claims are searched for the occurrence of the specific post-transplant complication codes, and the cumulative incidence of each complication is estimated using the Kaplan-Meier methodology.

Methods used for the hospitalization data in Figures 8.25–27 and 8.31–33 generally follow those described for Chapter Six and Reference Section E. Here, however, total admission and hospital day rates per patient year are unadjusted. 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, and those with missing age or gender information, are excluded. In Figure 8.27, vintage is calculated as the time from the first ESRD service date until the first of the year for prevalent patients, or as less than one year for incident patients. For Figures 8.31–33, principal ICD-9-CM diagnosis codes used for cardiovascular, infectious, and other hospitalizations are listed in the discussion of Figures 6.8–10. In Figure 8.33, “other” race includes those with race that is missing, unknown, or other than black or white.

Patient cohorts for all mortality figures here include both Medicare and non-Medicare patients in the 50 states, the District of Columbia, Puerto Rico, and the Territories.

Figures 8.28–29 present five-year survival by modality for 1987–1991 and 1992–1996 incident patients age 0–19. Patients with unknown age, gender, or primary diagnosis are excluded, as are dialysis patients who die or receive a transplant in the first 90 days. Dialysis patients are followed from day 91 until death, transplantation, or the end of 2001, while transplant patients are followed from the first transplant date until death or the end of 2001. All probabilities are adjusted for age, gender, and race; overall probabilities are also adjusted for primary diagnosis. The reference population consists of 1995–1996 incident pediatric ESRD patients, and adjusted probabilities can be compared across modalities.

Figure 8.30 shows trends in unadjusted mortality rates by patient vintage, while Figures 8.34–35 present trends in unadjusted cause-specific mortality by age and gender. The cohort for each figure includes period prevalent pediatric dialysis patients, who are followed from January 1 until death, transplantation, or end of the year. Patients with unknown gender or age, or of a race other than white, black, Native American, and Asian, are excluded.

## ■ Cardiovascular special studies

### CHAPTER NINE

This chapter addresses hemoglobin and survival after acute myocardial infarction (AMI) in Medicare dialysis patients,

cardiovascular events after transplant, and the diagnosis and treatment of cardiac disease in renal transplant patients as well as those on the transplant wait-list.

Figure 9.1 presents geographic variations in unadjusted one-year incident rates of AMI in dialysis patients. The study cohort consists of period prevalent dialysis patients in 1991–1993 and 1998–2000. To limit the impact of non-Medicare patients with incomplete claims data, analysis of the incidence of AMI is restricted to point prevalent dialysis patients with Medicare as their primary payor on January 1, 1991 (1991–1993 cohort) or January 1, 1998 (1998–2000 cohort), and incident dialysis patients with Medicare as their primary payor on the ESRD first service date during 1991–1993 and 1998–2000.

Followup begins on January 1, 1991 for 1991 point prevalent dialysis patients; January 1, 1998 for 1998 point prevalent dialysis patients; and, for incident dialysis patients in both cohorts, the first ESRD service date. Patients are followed to the earliest of AMI, death, transplant, loss-to-followup, end of Medicare as primary payor status, or one year after the followup start date. The AMI event is identified from either the date of death due to AMI (from the Death Notification form) or the date of hospitalization for AMI (from Part A institutional inpatient claims). Rates are estimated as the number of AMI events per 1,000 patient years at risk for each Health Service Area, and are not adjusted for demographic risk factors.

Figures 9.2–7 look at hemoglobin and mortality in dialysis patients after AMI. In Figures 9.2–3, which present demographics and comorbidity of AMI patients, the study cohort consists of point prevalent dialysis patients, 1991–2001, with Medicare as their primary payor on January 1 of each year. Incident patients with AMI in each year are identified either by death due to AMI (from the Death Notification form) or a hospitalization for AMI (from Part A institutional inpatient claims). A patient is excluded if he or she has no information on age, gender, or race listed on the Medical Evidence form, or has an age calculated to be less than zero or greater than 110. Age and major comorbid conditions are determined at the time of the AMI event. Major comorbid conditions are defined from Medicare Part A and B claims, and include atherosclerotic heart disease (ASHD), congestive heart failure (CHF), peripheral vascular disease (PVD), cerebrovascular accident/transient ischemic attack (CVA/TIA), and other cardiac disease (valvular heart disease, dysrhythmia, and pacemaker).

Figures 9.4–5 illustrate mean hemoglobin levels in patients with and without an AMI. Study cohorts are defined with the methods used in Figures 9.2–3, and patients who have at least one monthly EPO claim with a hemoglobin of 3.33–16.67 g/dl are included in the analyses. For non-AMI patients, the mean hemoglobin is calculated from January to the month of transplant, loss-to-followup, death, end of Medicare as primary payor status, or December of the year, whichever is earliest; for AMI patients, the mean hemoglobin is calculated

for the month of the AMI and for the previous two months. The mean hemoglobin by HSA is an average of the patient-level mean hemoglobins weighted by the number of months in which a patient has hemoglobin reports.

Figure 9.6 illustrates geographic variations in unadjusted one-year mortality rates for dialysis patients who have an AMI event. The study cohort includes period prevalent Medicare dialysis patients, 1991–1993 and 1998–2000, who are admitted to the hospital for AMI before transplant, loss-to-followup, end of Medicare as primary payor status, December 31, 1993 (1991–1993 cohort), or December 31, 2000 (1998–2000 cohort), whichever is earliest. Patients are followed from the date of hospitalization for AMI to the earliest of death, transplant, loss-to-followup, or one year after the AMI hospitalization. Rates are estimated as the number of deaths per 100 patient years at risk for each state, and are not adjusted for demographic risk factors.

Figure 9.7 shows adjusted one-year mortality rates after AMI, by hemoglobin level. The cohort consists of point prevalent dialysis patients, 1995–2000, who have Medicare as their primary payor on January 1 of the year; who are admitted to the hospital for AMI before the earliest of transplant, loss-to-followup, end of Medicare as primary payor status, or December 31 of the year; and who have at least one monthly EPO claim with a hemoglobin of 3.33–16.67 g/dl in the month of the AMI or in the previous two months. Patients with no Medical Evidence form information on age, gender, or race, or an age at the time of AMI that is calculated to be less than zero or greater than 110, are excluded.

A patient's mean hemoglobin is calculated in the month of the AMI and the previous two months, and characterized as <10 g/dl, 10–<11 g/dl, 11–<12 g/dl, or 12+ g/dl. A Cox proportional hazards model, stratified on the year of AMI and on hemoglobin level, is used to estimate the predicted one-year all-cause mortality rate, with age, gender, race, primary diagnosis, and dialysis time before AMI as covariates. Using the model-based adjustment method (described on page 211 in the section on statistical methods), and with AMI patients from 2000 as the reference population, these rates are further adjusted for the same five covariates.

Figures 9.8–25 present the demographic distribution and comorbidity of transplant patients, cardiovascular event rates after renal transplantation, and data on the diagnosis and treatment of cardiac disease before and after transplantation. The study cohort includes first renal transplant recipients in 1995–2001, regardless of the year of first ESRD service, who have Medicare as their primary payor. Patients whose donor type is listed as other or unknown are excluded.

Figures 9.8–9 illustrate demographics and comorbidity at the time of transplant. Age is calculated on the date of the first transplant, while major comorbid conditions are defined from either the Medical Evidence form at the initiation of ESRD treatment or from Medicare Part A or B claims, and include the same comorbidities described for Figures 9.2–7.

Figures 9.10–17 show trends in cardiovascular event rates, and use event-free probabilities to describe the likelihood of cardiovascular disease in transplant patients. Patients are classified as having a particular cardiovascular event as of the first occurrence of claims (Part A or B) with ICD-9-CM diagnosis or procedure codes.

Cardiovascular events of AMI, CHF, cardiac arrest, and CVA/TIA are identified from both non-fatal and fatal events. The event date for a non-fatal event is defined as the date of the first appearance of an ICD-9-CM diagnosis code in Part A inpatient claims only (for AMI), in all Part A claims (for CHF and CVA/TIA), or in either Part A or Part B claims (for cardiac arrest). For fatal events, the event date is the date of death due to the event, obtained from the Death Notification form.

For coronary revascularization, the date is defined through ICD-9-CM procedure codes in Part A institutional claims and/or Current Procedural Terminology (CPT) codes in Part B physician/supplier claims. For PVD, the date is defined through ICD-9-CM diagnosis codes in Part A claims and/or CPT codes in Part B claims.

Codes used to identify patients with cardiovascular disease are as follows:

- AMI: 410, 410.x0, and 410.x1 (ICD-9-CM diagnosis codes)
- CHF: 428 (ICD-9-CM diagnosis codes)
- CVA/TIA: 430–437 (ICD-9-CM diagnosis codes)
- cardiac arrest: 427.4 and 427.5 (ICD-9-CM diagnosis codes)
- PVD: 440–444, 447, 451–453, and 557 (ICD-9-CM diagnosis codes); 23900, 23920, 24900, 24920, 25900, 25905, 25920, 25927, 27295, 27590, 27591, 27592, 27598, 27880, 27881, 27882, 27888, 27889, 28800, and 28805 (CPT codes)
- coronary revascularization: 36.01, 36.02, 36.05, 36.06, and 36.1x (ICD-9-CM procedure codes); 92980–92982, 92984, 92995, and 92996 (CPT codes)

For each endpoint—including cardiovascular events, all-cause death, and combined events of any cardiovascular event or death—we use a separate Cox proportional hazards model, stratified on donor type, to estimate event-free probabilities and calculate the predicted cardiovascular event rates, with age, gender, race, primary diagnosis, and dialysis time before transplant as covariates. Using the model-based adjustment method (described in the section on statistical methods), and with the entire study cohort as the reference population, these event rates and event-free probabilities are further adjusted for the same five covariates.

Patients are followed up to three years after transplant to track occurrences of cardiovascular events or all-cause death. For cardiovascular events, a patient's followup time is censored at the earliest of death, graft failure, end of Medicare as primary payor status, three years after the transplant date, or December 31, 2001. For all-cause death, followup time is censored at these same events, with the exclusion of death. Ad-

justed event rates are presented as monthly rates during the first six months after transplant, and as mean monthly event rates during each following six-month interval.

Figures 9.18–25 describe the diagnosis and treatment of cardiac disease during the three years pre- and post-transplant, including stress test, coronary angiography and/or catheterization, echocardiogram, lipid testing, electrocardiogram (ECG), and coronary revascularization. A stress test is defined as any of the following: stress echocardiogram, stress nuclear test, and/or stress ECG test. For pre-transplant tests and treatment, patients are followed back in time from one day before their first transplant date to their ESRD diagnosis or three years before their transplant, whichever is latest. For post-transplant tests and treatment, they are followed from their first transplant date to the earliest of graft failure, death, three years after transplant, or December 31, 2001.

Echocardiograms, lipid testing, and ECGs are defined through CPT codes in Part B claims, while stress tests and coronary angiography and/or catheterizations are defined through ICD-9-CM procedure codes in Part A claims and/or CPT codes in Part B claims. Coronary revascularization is defined with the same method used earlier. Codes used to identify patients receiving these tests are as follows:

- stress tests: 89.41–89.44 (ICD-9-CM procedure codes); 78459, 78460, 78461, 78464, 78465, 78469, 78472, 78473, 78478, 78480, 78481, 78483, 78491, 78492, 93015–93018, and 93350 (CPT codes)
- echocardiograms: 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93318, 93320, 93321, and 93325 (CPT codes)
- coronary angiography and/or catheterization: 37.22–37.23 and 88.53–88.57 (ICD-9-CM procedure codes); 93508, 93510, 93511, 93524, 93526, 93527, 93529, 93531–93533, 93539, 93540, 93543, 93545, and 93555 (CPT codes)
- lipid testing: 80061, 82465, 84478, and 83715–83721 (CPT codes)
- ECG: 93000, 93005, 93010, 93012, 93014, 93224–93227, 93230–93233, 93235–93237, 93268, 93270–93272, and 93278 (CPT codes)

Figures 9.18–24 illustrate the percent of patients receiving at least one test or treatment within each year during the three years pre- and post-transplant. Figures 9.18–22 also present unadjusted first testing or treatment rates in the first, second, and third years before and after transplant. The first pre-transplant test or treatment in each year is defined as the latest one in that year, while the first post-transplant testing or treatment is defined as the earliest in that year. The unadjusted rates are estimated using the Kaplan-Meier method and presented as the number of tests or treatments per 1,000 patient years at risk. Figure 9.25 describes the percent of patients who received at least one diagnostic test or treatment in the three years pre- or post-transplant.

Figure 9.26 shows the cumulative percent of wait-listed patients who receive diagnostic tests and treatment related to



cardiac disease. The study population includes ESRD patients wait-listed for the first time during 1995 and 1999, with Medicare as primary payor (MPP) for Part A and B when wait-listed, and receiving their first renal transplant, if they have one, after entering the wait-list. To ensure the availability of Medicare claims data for every wait-listed patient following their first wait-listed date, patients are excluded if they are diagnosed with ESRD after that date. Patients are followed from the first wait-listed date to the earliest of wait-list stop date, MPP end date, first transplant date, death, or three years later. During the followup period, the cumulative percent of patients who receive a stress test, coronary angiography and/or catheterization, an echocardiogram, or coronary revascularization are calculated.

## ■ Rehabilitation & quality of life

### CHAPTER TEN

#### Self-reported health status

The DMMS Wave 2 data, available on the USRDS Core Standard Analysis File (SAF; see Appendix B), include 4,024 incident dialysis patients. A total of 3,614 remain after excluding those with an ID number of zero, with duplicate ID numbers, or without demographic data; those who received a transplant at the time of first ESRD service; and those who received their first ESRD services before 1996 or after 1997.

A total of 1,214 patients have missing values for all health status and work variables collected on the baseline Dialysis Patient Questionnaire. After excluding these patients, data for the analyses reported in Figures 10.1–21 are available from 2,400 incident dialysis patients. These patients differ from those with missing health status/work values in diabetic status (42 vs. 46 percent) and educational status (32 vs. 37 percent, 32 vs. 35 percent, and 33 vs. 30 percent for less than 12 years, high school graduate, and some college or more, respectively). The patients for whom we analyze health status and work/disability thus differ from those with missing data in being less likely to have diabetic ESRD and in having completed a higher level of education.

Diabetic status is obtained from question B1 (primary cause of ESRD) in the Medical Questionnaire for DMMS Wave 2; information on the primary cause of ESRD is missing for 18 patients. Of the remaining patients, 1,012 (42 percent) have a primary diagnosis of diabetes.

Data on educational status are obtained from question C11 on the Medical Questionnaire. For the analyses in this chapter, the question's original four categories are collapsed into three: less than 12 years of education, high school graduate, and some college + (combining the categories of some college and college graduate). Educational status is missing for 215 patients; of those remaining, the distribution is 692 (32 percent), 767 (35 percent), and 726 (33 percent), respectively.

Cardiovascular comorbidity status (CVD) is determined using questions B3a, B3c, B3g, B4a, B5a, and B6a on the Medical Questionnaire. If the answer to at least one of these

questions is either “yes” or “suspected,” cardiovascular comorbidity status is treated as positive. CVD information is missing on 147 patients; of those remaining, 1,347 (60 percent) have CVD.

Age is defined as the age at the first ESRD visit, using the Patients file in the 2001 SAF. Five patients have missing age information, and 1,471 of the remaining patients (61 percent) are at least 55 years old.

Figures 10.2–17 show mean scores for the patient-reported generic and disease-specific health status scales that comprise the Kidney Disease Quality of Life (KDQOL) instrument (Part 1 in the Dialysis Patient Questionnaire for DMMS Wave 2). The program used to calculate the scores can be found at <http://gim.med.ucla.edu/kdqol/index.html>.

Results from the generic health status scales are reported in Figures 10.2–9. These multi-item scales, defined as follows, have adequate internal consistency reliability estimates (0.7 or higher); the frequency of missing data ranges from 1 to 106.

- physical functioning: based on ten items related to the activities a patient might do during a typical day (questions 3–12).
- role-functioning physical: based on four items measuring the extent to which physical health interfered with work or other activities during the past 30 days (questions 13–16).
- pain: based on two items measuring the intensity of pain and extent that pain interfered with normal work activity during the past 30 days (questions 21–22). The Rand 36-item Health Survey 1.0 scoring method (Hays et al.) was used to calculate this score.
- general health perceptions: based on five items measuring personal evaluations of current health, health outlook, and resistance to illness (questions 1 and 33–36). The Rand 36-item Health Survey 1.0 scoring method (Hays et al.) was used to calculate this score.
- emotional well-being: based on five items measuring the frequency of anxiety, depression, and happiness during the past 30 days (questions 24–26, 28, and 30).
- role-functioning emotional: based on three items measuring the extent to which emotional problems interfered with work or other activities during past 30 days (questions 17–19).
- social function: based on two items measuring the extent to which physical health or emotional problems interfered with normal social activities during the past 30 days (questions 20 and 32).
- energy/fatigue: based on four items measuring the frequency during the past 30 days of feeling energetic and full of pep rather than tired and worn out (questions 23, 27, 29, and 31).

Mean scores for the eight disease-specific health status scales, each with adequate internal consistency reliability estimates (0.7 or higher), are presented in Figures 10.10–17. The frequency of missing data ranges from 24 to 79.

- symptoms/problems: based on 12 items measuring the extent that the patient was bothered during the past 30 days by issues such as cramps, nausea, and itchy skin (questions 47–58).
- effects of kidney disease: based on seven items measuring the extent to which the patient was bothered by issues such as fluid restriction, dietary restriction, and sex life (questions 59–65).
- burden of kidney disease: based on four items measuring the extent to which kidney disease interfered too often with the patient's time, made the patient feel frustrated, and made the patient feel like a burden on his/her family (questions 37–40).
- cognitive function: based on three items measuring impaired thinking (questions 42, 44, 46).
- sleep: based on a single item measuring the quality of sleep during the past 30 days (question 71).
- social support: based on two items measuring satisfaction with family and social life (questions 72–73).
- staff encouragement: based on two items measuring the extent to which the staff encourages the patient to be independent and supports the patient in coping with kidney disease (questions 77–78).
- patient satisfaction: based on a single item measuring satisfaction with care received for dialysis (question 76).

### Work & disability

Information on patients' work and disability status, also based on questions in Part I of the Dialysis Patient Questionnaire for DMMS Wave 2, is presented in Figures 10.18–21. Patients' self-reported ability to work is defined here as *able to work full time* if the answer to question 74b is *yes*; *able to work part time* if the answer to 74a is *yes*; *not at all* if answers to both 74a and 74b are *no*; and otherwise defined as *missing*.

For those who report being able to work (full time or part time), question 75 is used to report work status at the start of the study. The original eight response categories are grouped here into five, with patients who report that they are unemployed, retired, keeping house, or none of the above combined into the "other" category, along with patients whose answers are missing. For those who report being unable to work, question 4 in Part 6 of the Dialysis Patient Questionnaire is used to report their desire to return to work.

Five patients with missing age information are not included in Figure 10.18; of the 2,395 remaining, 577 report being "able to work" and 1,581 report being "not able to work." Eighteen patients with missing diabetic status information are omitted from Figure 10.19; of the 2,382 remaining, 574 report being "able to work" and 1,569 report being "not able to work."

One hundred forty-seven patients with missing cardiovascular comorbidity information are omitted from Figure 10.20; of the 2,185 remaining, 536 patients report being "able to work" and 1,492 report being "not able to work." Two hundred fifteen patients with missing education status informa-

tion are omitted from Figure 10.21; of the remaining 2,185, 529 report being "able to work" and 1,437 are "not able to work."

### Rehabilitation services

For these analyses we use institutional claims and physician/supplier claims data from 1998–2000. Physical therapy services examined here consist of therapeutic exercise, neuromuscular education, and gait training, identified through CPT-4 codes of 97110, 97112, and 97116, respectively. Cardiac rehabilitation services include non-monitored and monitored exercise, identified through CPT-4 codes of 93797 and 93798. We use ICD-9-CM codes to identify stroke (430–437), amputation (18.39, 21.4, 64.3, 67.4, 71.4, 77.59, 84–84.19, and 84.91), cardiovascular procedures (35–40, excluding 38.95, 39.27, 39.42, 39.43, 39.93, 39.94, which are codes for vascular access procedures, and 39.95), and acute myocardial infarction (410, 410.x0, and 410.x1).

We consider here whether diabetic status, stroke, and/or amputation are reasons for physical therapy services, and whether diabetic status, cardiovascular procedures, and/or AMI are reasons for rehabilitation services. We found that a stroke, amputation, cardiovascular procedure, or AMI usually occurs in the three months before such services; services received before April 1, 1998 are thus excluded from the analysis.

Between April 1, 1998 and December 31, 2000, 57,621 patients had therapeutic exercise, 15,928 had neuromuscular education, 26,447 had gait training, 740 had monitored exercise, and 3,405 had non-monitored exercise. Vintage is defined as the time between the first date (variable BEGDATE) in the Patient History file (rxhist.sd2) in the 2001 SAF CD and the date of the first physical therapy after April 1, 1998.

Figure 10.22 gives the age and gender distribution for patients receiving physical therapy services. The figure includes 52,761, 14,597, and 24,349 patients receiving therapeutic exercise, neuromuscular education, and gait training, respectively; information on age or gender is missing for 4,860, 1,331, and 2,098 patients.

In Figure 10.23 we present the gender and vintage distribution for patients receiving physical therapy services. The figure includes 53,357, 14,687, and 24,476 patients receiving therapeutic exercise, neuromuscular education, and gait training, respectively; information on gender or vintage is missing for 4,264, 1,241, and 1,971 patients.

Figure 10.24 shows geographic variations in the percent of patients receiving at least one of the physical therapy services ( $n=58,706$ ), while Figure 10.28 shows the percent receiving at least one of the cardiac rehabilitation services ( $n=3,606$ ). Percentages are unadjusted and smoothed. Geographic information is obtained from the Patients file in the 2001 SAF. Only the 50 states are shown in the maps, but all patients, including those in U.S. Territories, are used in the calculations.

Figure 10.25 provides the distribution of stroke, amputation, and diabetic status for patients receiving cardiac rehabilitation.

The figure includes 36,540, 10,739, and 17,986 patients receiving therapeutic exercise, neuromuscular education, and gait training, respectively; 21,081, 5,189, and 8,461 patients are excluded because of missing information on diabetic status.

In Figure 10.26 we present the age and gender distribution of patients receiving cardiac rehabilitation services. The figure includes 660 and 3,017 patients receiving monitored and non-monitored exercise; 80 and 388 patients, respectively, are excluded because of missing age or gender information.

Figure 10.27 illustrates the gender and vintage distribution of cardiac rehabilitation patients. The figure includes 665 and 3,027 patients receiving monitored and non-monitored exercise; 75 and 378 patients, respectively, are excluded due to missing information on gender or vintage.

Figure 10.29 presents the distribution of cardiovascular procedure, AMI status, and diabetic status for patients receiving cardiovascular rehabilitation. The figure includes 474 and 2,203 patients receiving monitored and non-monitored exercise; 266 and 1,202 patients, respectively, are excluded because of missing information on diabetic status.

## ■ Provider characteristics

### ATLAS CHAPTERS & REFERENCE SECTION J

Throughout the atlas and in Reference Section J the USRDS defines a chain-affiliated unit as one of a group of 20 or more freestanding dialysis units owned or operated by a corporation and located in more than one state. For this ADR six chains met this criterion; throughout the book these chains are rank ordered from largest to smallest.

Data are obtained from the CMS Annual Facility Survey for 1988–2001, the CMS Independent Renal Facility Cost Report (Form 265-94) for 1994–2000, the CMS Dialysis Facility Compare database for 2001, and the CDC National Surveillance of Dialysis-Associated Diseases in the United States for 1988–2001 (excluding 1998, when the CDC did not conduct a survey). The CMS data is available at <http://cms.hhs.gov/data/download/default.asp>.

Chain identification is determined from the “Provider Name” field of the Facility Survey, the “Chain Name” field of the Dialysis Facility Compare database, and the “Chain Organization Name” field of the Cost Report. The third and fourth digits of the provider number assigned to each dialysis unit by CMS indicate whether that unit is hospital-based or freestanding. Profit status is indicated on the CMS facility survey, which is also the source for staffing data.

Only facilities that have returned CMS and/or CDC surveys are included in the analyses. In 2001, 4,273 unique provider units submitted surveys; 3,743 were common to both the CMS and CDC data. Eighty-eight providers submitted a survey to the CDC but not to CMS, while 442 submitted a survey to CMS but not to the CDC.

## ■ Economic costs of ESRD

### CHAPTER ELEVEN & REFERENCE SECTION K

#### Chapter Eleven

The majority of the economic analyses in this year’s ADR use the as-treated model, described in detail below.

#### Payor sequence

New this year to the economic section, 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 claim information, are used to categorize payor status as Medicare primary payor (MPP), Medicare secondary payor (MSP), Medicare+Choice (HMO), or non-Medicare. The claims database contains data only for MPP and MSP patients, so the economic analyses are restricted to these categories. In addition, since it is impossible to determine the complete cost of care for ESRD patients for whom Medicare is the secondary payor, most analyses exclude patients during the periods when they have this coverage.

#### HCFA model

This model, described in the HCFA (now CMS) research report on ESRD (1993–1995), is used for Figures 11.9–14 and, in the Précis, p.13–14. 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 who have a kidney transplant during the calendar year
- functioning graft: ESRD patients who have 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 always classified in the transplant category

#### Methods

Table p.a in the Précis summarizes data on the costs of ESRD treatment. Total Medicare spending in 2001 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 2001 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 2001 (obtained from the CMS managed care organization file) in conjunction with the 2001 AAPCC rate.

Non-Medicare spending by Employer Group Health Plans (EGHPs) is estimated by separately computing the per year at-risk costs for EGHP and non-EGHP patients, then multi-

plying the difference by the EGHP years at risk for 2001. Patient obligations are estimated as 17.3 percent of the sum of Medicare payments, non-federal EGHP costs, and patient obligations (1999 ADR, page 149). 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 2000–2001 are obtained from Table K.1, without the 2 percent adjustment for late claims. Calculations per patient year at risk are based on patients for whom Medicare is the primary payor during the study period (Tables K.19–20), again using non-inflated results. The range for inflation-adjusted costs is calculated using the overall Consumer Price Index (1.6 percent) and the Medical Consumer Price Index (1.7 percent). Calculations per patient per year at risk by modality for 1997–2001 are taken from Table K.4; these data include MPP patients only, and are not adjusted for late claims.

For a description of the provider data used in Figure 11.24, see the discussion of Reference Section J, on the previous page.

Information about the construction of other figures and tables is provided in the captions.

**Reference Section K: Medicare claims data**

Cost information in this section is derived from Medicare Part A and B claims data in the CMS Standard Analytic Files, which are created annually six months after the end of each calendar year. The data for 1997–2001 are comprised of approximately 30 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 200 million line items from physician/supplier claims. Claims data are obtained for all patient ID numbers in the USRDS database, and the Renal Beneficiary Utilization System (REBUS) 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 down into several categories, as shown in Table a.b (below). 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 of 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

a.b Medicare categories of payment	
Medicare payment categories	Basis for categorizing claim
<b>Total</b>	Sum of all payments
<b>Total inpatient</b>	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
Other DRG	Inpatient SAF, DRG not included in the above categories
Non-transplant pass-throughs	Inpatient SAF, DRG not 302, calculated from per diem and covered days
Transplant pass-throughs	Inpatient SAF, DRG 302, calculated from per diem and covered days
<b>Total outpatient</b>	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 EPO	Outpatient SAF, revenue codes and/or HCPCS code
Outpatient Calcijex	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
<b>Total physician/supplier</b>	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 EPO	Physician/supplier SAF, HCPCS codes
Physician/supplier iron	Physician/supplier SAF, HCPCS codes
Immunosuppressive drugs	Physician/supplier SAF, HCPCS codes
Durable 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

the sum of line item payment amounts to the total paid amount for the claim. Since complete data on line item payments are available for the 2001 Outpatient SAF, the estimates for outpatient payment categories are taken directly from the claims data for calendar year 2001, with adjustments as noted.

### **As-treated model**

In an as-treated model patients are initially classified by their modality at entry into the analysis, and they retain that classification until a change in modality. When such 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 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 five years from January 1, 1997 to December 31, 2001, and ESRD patients prevalent on January 1, 1997 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 the following:

- January 1, 1997
- the first ESRD service date in the USRDS database for that patient
- 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+Choice program are excluded until payor status changes to Medicare (either as primary or secondary payor). Patients classified as MSP are included in Tables K.1–2, 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, trans-

plant, modality change, loss-to-followup, or December 31, 2001. Patients incurring no Part A or B Medicare costs for the entire period are excluded.

Medicare payment amounts are linearly prorated for claims that span the start or end date of a modality period or of the study itself.

In order to express the costs as dollars per year at risk, total costs during the followup period are divided by the length of the followup period. Costs per 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.

## **■ International comparisons**

### **CHAPTER TWELVE**

The international dialysis and transplant data for this ADR have been collected from the following sources, using a data form designed by the USRDS (see page 229 for a copy of the form): the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA), the Austria OEDTR, the Bangabandhu Sheikh Mujib Medical University, the French-Belgian Nephrologists Registry, Centre Hospitalier Etterbeek-Ixelles, the Ripas Hospital of Brunei, Bulgaria First Hemodialysis Center, the Canadian Organ Replacement Registry, the Catalan Renal Registry, the Chilean Renal Registry, the Czech Society of Nephrology, the ERA-EDTA Registry, the Finnish Registry for Kidney Diseases, the QuaSi-Niere in Germany, the Greek Hellenic Renal Registry, the Department of Transplantation and Surgery in Hungary, the Italian Registry of Dialysis and Transplantation, Jalisco State Dialysis and Transplant Registry (Mexico), the Japanese Society of Dialysis Therapy, the Catholic University of Korea (Republic of South Korea), Registre Néphrologique du Grand Duché de Luxembourg, the Netherlands Dialysis Registry, the National Renal Registry of Malaysia, the Norwegian National Hospital, the Kidney Foundation of Pakistan, the Philippines Renal Disease Registry Project, the Polish Dialysis Registry, Hamad Medical Corporation in Qatar, the Society of Dialysis in Russia, the Swedish Renal Registry, the Taiwan Society of Nephrology, the Thailand Renal Replacement Therapy Registry, the Turkish Society of Nephrology, the Uruguay Dialysis and Transplant Renal Registry, and the USRDS.

We are particularly grateful to Dr. Kitty Jager at the ERA-EDTA Registry for her help in coordinating much of the data presented in this chapter.

If you would like to contribute data for this section from your country's registry, please complete the form found on pages 229–230 and return it to the USRDS.

## ■ Census population base

### REFERENCE SECTION L

The 2000 U.S. census, which became available in the fall of 2002, introduced a new race category with additional racial groupings. To use these data and to ensure consistent racial distribution for the rates presented in the ADR, however, requires new estimated data, based on the 2000 census, for the 1990s. We have submitted a request to the Census Bureau for these estimates, but because they will not be available until late fall of 2003, we have continued in this ADR to use population estimates based on the 1990 census, and have estimated the 2001 population.

We have used a time series model with other regressors to estimate the 2001 population by age, race, and gender, and at levels of HSA, state, and ESRD network. For ages five and older, the estimate is based on previous populations of the same age and the next younger age, and of the same race and gender. For ages 0–4, estimates are based on the previous year's population of children the same age and race, and of women age 25–39 and the same race. Census data from 1990–2000 have been used to check the model fit, and more than 99.9 percent of the groups fit very well. More details on this method can be found in the discussion of statistical methods, below.

## ■ Statistical methods

### METHODS FOR CALCULATING RATES

#### Raw rate (observed)

The calculation of observed rates is straightforward, with some based on counts and others on followup time. The ESRD incident rate in 2001, for example, is the observed incident count divided by the population in 2001 and multiplied by one million if the unit is per million population; the 2001 death rate for prevalent ESRD patients is the number of deaths in 2001 divided by the total followup time (patient years) of the 2001 prevalent patients, and multiplied by a thousand if the unit is per thousand patient years. Standard deviations of estimated rates are based on the assumption of the data; the observed count has a Poisson or binomial distribution.

#### Model-based rates

Some patient groups may be very small, and their observed rates therefore unstable. A model-based method can improve the stability of these estimates. In this ADR, for example, we have used the generalized mixed Poisson model to estimate prevalent patient mortality rates in Reference Section H.

#### Measurement unit for rates

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

Take, for example, a calculation of 1997 first hospitalization rates for two groups of dialysis patients, all receiving dialysis therapy on January 1, 1997. Group A consists of three patients: patient 1 had a first hospitalization on March 31, 1997; patient 2 was hospitalized on June 30, 1997; and patient 3 was on dialysis through December 31, 1997, with no hospitalizations. Group B also has three patients: patient 4 was first hospitalized on December 31, 1997; patient 5 was hospitalized on September 30, 1997; and patient 6 was on hemodialysis the entire year, with no hospitalizations through December 31, 1997.

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 1997. But the first hospitalization rate per thousand patient years at risk is 1,143 for Group A and 727 for Group B (calculated as  $[2 \text{ total events} / 1.75 \text{ total patient years at risk}] \times 1,000$  for Group A and  $[2 \text{ total events} / 2.75 \text{ patient years at risk}] \times 1,000$  for Group B). The resulting rate is lower for Group B because of the longer total followup 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 followup time at risk, in contrast, count only the actual time that a patient is at risk for an 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). With this method, the adjusted rate is derived by applying the observed category-specific rates to a single standard population, i.e. the adjusted rate is a weighted average of the observed category-specific rates, using as weights the proportion of each category in the reference population. The 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, black, and other) and two gender groups (male and female), there are six categories: white males, white females, black males, black females, males of other races, and females of other races.

Suppose, for example, that we try to compare state-level incident rates in 2001, using the assumption that race distributions in all states are the same. To do this, we need to calculate the standardized incident rate, adjusted for race, for each state.

Because racial distributions in each state are quite different, we use as reference the national population—in this case the population at the end of 2001—with five race groups (white, black, Native American, Asian/Pacific Islander, and other).

Assuming the incident rate of state A in 2001 is 173 per million population, and the race-specific rates (per million population) 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 whole country, its incident rate would be 158.73 instead of 173.

	Incident rate of State A	National Population (%)
White	153	75.1
Black	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. It is also used 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 category has 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 directly calculate adjusted rates using these estimates with a given reference population. There is, unfortunately, no straightforward way here to calculate standard deviations of the adjusted rates for some models; the bootstrap approach works well, but is time consuming.

Model-based adjustments are used in this ADR to calculate adjusted mortality rates, adjusted survival probabilities based on the Cox regression model, adjusted hospitalization rates using the Poisson model, adjusted incident and prevalent rates based on the Bayesian spatial model, and some other rates.

## DEATH RATES & SURVIVAL PROBABILITIES

### Unadjusted survival probabilities

In this ADR, unadjusted survival probabilities are calculated using the Kaplan-Meier method, and corresponding standard deviations are calculated with Greenwood's formula (Kalbfleisch JD, Prentice RL). Survival probabilities in Reference Section I are expressed as percentages from 0 to 100.

### 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 the survival probabilities that would have arisen in each year for patients in 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 in Reference Section H are calculated using similar methods.

### GENERALIZED LINEAR MIXED MODEL

We use the generalized linear mixed model with log link and Poisson sampling distribution to calculate mortality rates and first transplant rates for prevalent patients. While rates are reported only for 2001, three years of prevalent data (1999–2001) with different weights are used to improve the stability of the estimates.

The generalized linear mixed model, which considers both fixed and random effects, is implemented using the SAS macro GLIMMIX. The Poisson 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 these variables. 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.

For the tables we have used a single model to calculate all rates (for both intersecting and marginal groups) in a single 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 deviations for some of these estimated rates; the bootstrap method is therefore used instead.

### Generalized linear model for hospitalization rates

In this year's ADR, hospitalization reference tables present only total admission and hospital day rates, without first admission rates. We have used a generalized linear model, instead of a generalized linear mixed model, with log link and Poisson sampling 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 difference weights. Year and all two-way interactions of year with age, gender, race, and primary diagnosis are also included in the model.

### STANDARDIZED MORTALITY RATIOS

The standardized mortality ratio (SMR) compares the mortality of a group of patients relative to a specific norm, or reference. In Table H.12, for example, SMRs are used to com-

pare the mortality for prevalent dialysis patients in each state to national mortality rates from 1999 to 2001, and to show how relative mortality rates have changed, using as the reference the national dialysis population in the corresponding year. The SMRs are calculated from a Bayesian hierarchical model with the logarithm of SMRs as random effects (Liu et al.) based on the observed number of deaths and the expected number of deaths, which accounts for patient age, gender, race, primary diagnosis, and vintage, in each state. The expected number of deaths in each category of the observed population is calculated by multiplying the category-specific standard rates by the total followup time at risk of the observed patients. Category-specific standard rates come directly from the generalized mixed model. The total expected number in a state is then calculated by summing the expected numbers in all categories. 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.

Standardized hospitalization ratios (SHRs) for total admissions and standardized first transplantation ratios (STRs), calculated using similar methods, are reported in Tables E.6 and F.12.

### 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, calculated using observed death rates. Let  $r(X)$  denote the death rate for a five-year age group, with  $X$  identifying one of the listed age ranges. Death rates for successive age intervals,  $r(X)$ , are plotted versus age,  $X$ , and the area under the curve up through age  $A$  is denoted by  $R(A)$ . The survival function at age  $A$ ,  $S(A)$ , is related to the death rates by the equation  $S(A) = \exp(-R(A))$ , where “exp” denotes the exponential function. 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  $A + X = 100$ .

### 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 researchers stabilize data and show geographic patterns while still maintaining geographic resolution. The methods described

here have been used in most maps presented in the 2003 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.

The majority 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). 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.”

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 on organ donation rates in Chapter Seven), and, 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 & adjusting 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 relative risks for the regions, as random effects, follow the Conditional Autoregressive (CAR) Normal distribution, and the precision of the relative risks has a beta distribution. The model smoothes 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. The exponential offsets in the model are the internally standardized incident counts. 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 for smoothing prevalent rates and for calculating some percentages.

To smooth maps of mean hemoglobin, estimated glomerular filtration rates, and creatinine levels, this model is extended to assume that the means have a normal distribution of gamma precision; the model used for rates assumes a Poisson distribution.

### POPULATION ESTIMATES FOR 2001

The 2001 national population data is estimated at levels of HSA, state, and ESRD network by age (every five years), race/ethnicity (white, black, Native American, Asian, Hispanic, and non-Hispanic), and gender (male and female).









### Transplant Waiting List

Beginning with 2001 data, this CD has been updated to include basic patient demographic data and, from UNOS, all unique wait-list periods for each dialysis patient.

### Dialysis Morbidity & Mortality Study (DMMS)

The DMMS was an observational study in which data on demographics, comorbidity, laboratory values, treatment, socioeconomic factors, and insurance were collected for a random sample of U.S. patients, using dialysis records. Waves 1, 3, and 4 are historical prospective studies in which data were collected for patients on in-center hemodialysis on December 31, 1993. Data were abstracted from medical records, and patients were followed to the earliest of data abstraction, death, transplant, change in modality, or transfer to another facility. Wave 2 is a true prospective study of incident hemodialysis and peritoneal dialysis patients for 1996.

### Case Mix Adequacy Study of Dialysis

The objectives of this study were to:

- establish the relationship between the dose of delivered dialysis therapy and mortality

- determine the strength of this relationship when data are adjusted for comorbidity
- assess how this relationship changes with dialysis dose
- assess how this relationship is affected by dialyzer reuse
- assess the impact of different dialysis membranes on patient morbidity and mortality

The study consisted of two groups: an incident sample of ESRD patients who began hemodialysis in 1990, and a prevalent sample of hemodialysis patients whose ESRD began prior to 1990. A total of 7,096 patients from 523 dialysis units were included, with approximately 3,300 patients having both the pre- and post-BUN values needed to calculate delivered dialysis dose. Ninety-four percent of these cases were matched to the USRDS database. The ESRD networks collected these data in conjunction with their Medical Case Review data abstraction.

### Case Mix Severity Study

For this study data were collected on 5,255 patients incident in 1986–87 at 328 dialysis units nationwide. Objectives were to:

- estimate the correlation of comorbidity and other factors existing at the onset of ESRD to subsequent mor-

#### b.b Contents of the USRDS Core Standard Analysis File CD-ROMs

*This 2-CD set is needed in order to use any of the other Standard Analysis Files*

File Name	Unit of observation	Uses
Patient	One record for each ESRD patient	Incidence, prevalence, patient survival. Most other files will need to be linked to this file using the encrypted patient ID.
Residence	For each patient, one record for each period in a different residence.	Regional analyses.
Treatment History	One record for each period a patient is on one modality.	Modality distribution and treatment patterns.
Payor History	One record for each period a patient is covered by one payor; each patient can have many records.	The impact of insurance payors on clinical outcomes.
Medical Evidence	One record for each 2728 form filed (1995 version).	ESRD first service date, initial treatment modality, comorbid conditions, patient status at start of ESRD.
Transplant	One record for each transplant event; patients can have multiple events.	Transplant and transplant outcome analyses.
Transplant Waiting List	One or more records for each patient ever on waiting list.	Comparison of transplanted patients to dialysis patients who are transplant candidates. Patient selection to waiting list.
Dialysis Morbidity and Mortality (DMMS; Special Study)	Wave 1: 5,670 patients; Wave 2: 4,024 patients; Wave 3: 11,142 patients.	Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values, nutrition, vascular access.
Case Mix Adequacy (Special Study)	7,096 patients.	Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory values.
Case Mix Severity (Special Study)	5,255 patients.	Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory values.
Pediatric Growth and Development (Special Study)	3,067 patients.	Growth, development, and other issues relating to pediatric ESRD patients.
CAPD Peritonitis (Special Study)	3,385 patients.	CAPD and peritonitis.
Facility	One record for each year facility has operated.	Merge with the treatment history, transplant, or annual summary SAFs for analyses involving provider characteristics by encrypted ID.
Facility Cost Reports	One record per facility per year (1989–1995).	Costs and staffing of dialysis facilities.
Dialyzers	Information on dialyzer characteristics; to be matched to patient dialyzer information in other files on CD.	Relation of dialyzer characteristics to patient outcomes.
CLMCODES	One record for each diagnosis, procedure, or HCPCS code appearing in claims files.	Frequency of occurrence of each code. A starting point for analyses that will use diagnosis and procedure codes.
FORMATS.SC2	All USRDS-defined SAS formats used by SAFs.	Format library used to format values of categorical variables.

tality and hospitalization rates, while adjusting for age, gender, race, and primary diagnosis

- evaluate possible associations of these factors with reported causes of death
- assess the distribution of comorbidity and other factors among patients using different treatment modalities
- compare relative mortality rates by treatment modality, adjusting for comorbid conditions and other factors

#### **Pediatric Growth & Development**

The objectives of the USRDS Pediatric Growth and Development Study were to:

- establish a baseline for assessing the relation of pediatric patient growth and sexual maturation to modality
- establish a prototype for the ongoing collection of pediatric data

All patients prevalent in 1990 and born after December 31, 1970 were included in the study, a total of 3,067 patients at 548 units.

#### **CAPD & Peritonitis Study**

The USRDS CAPD and Peritonitis Study examined the relation of peritonitis episodes in CAPD patients to connection device technology and other factors. The study population included all patients newly starting CAPD in the first six months of 1989, a maximum of 14 patients per dialysis unit. All units providing CAPD training participated in the study. The sample contains data on 3,385 patients from 706 units.

#### **Facility**

The CMS annual End-Stage Renal Disease Facility Survey is the source of data for the Facility SAF, which can be linked to the Facility Cost Report files using the USRDS provider ID. Geographic variables that could identify facilities are deleted. The survey period is January 1 through December 31.

#### **Facility Cost Reports**

CMS hospital and independent facility cost reports for 1989–1995 and 1989–1993, respectively, are available as SAFs. All geographic variables are deleted to ensure confidentiality. The file may be linked to the Facility SAF using the USRDS provider ID, though analyses at less than a regional or network level are not possible. Because these files are rarely used, additional data will be added only if there is sufficient demand.

#### **Dialyzers**

The Case Mix Severity, Case Mix Adequacy, and DMMS Special Studies all collected information on patient dialyzers. The SAFs for these studies describe the dialyzer through a code, which must be matched to information in the Dialyzer file to find the dialyzer's manufacturer and model along with characteristics such as membrane type and clearance. The data in this file come from published sources available at the time of the study. We believe these data accurately represent the dialyzer characteristics, but they should be used with caution.

#### **TRANSPLANT CD**

Due to changes in data collection sources over the years, data related to transplants are now presented in six separate SAFs.

The first two are included on the Core CD, and the remaining four are included on the separate Transplant CD.

- TX: includes minimum details about all transplants from all sources
- TXWAIT: contains one record for each patient in the USRDS database who is also identified on the unos wait-list file
- TXHCFA: includes transplant information collected by CMS's PMMIS system prior to 1994
- TXUNOS: includes transplant information collected since 1987 by UNOS, currently the main source of transplant data for the USRDS
- TXFUHCFA: includes transplant followup reports collected by CMS prior to 1994; reports are completed at discharge, six months, each year post-transplant, and at graft failure
- TXFUUNOS: includes transplant followup reports collected by UNOS since 1988

Tables in Section F of the reference section are produced primarily from the main and UNOS transplant files.

In July 1994 CMS and the Health Resources Services Administration (HRSA) consolidated transplant data into a single collection by UNOS under its contract with HRSA. The expanded transplant data are shared among HRSA, CMS, and the NIH, and are thus available to the USRDS. This has resulted in the addition of data on a substantial number of non-Medicare transplant patients, including children.

CMS and UNOS transplant files overlap for 1988–1993, and some Medical Evidence forms and institutional claims records indicate transplants not included in either file. To resolve conflicts among the sources and create the transplant SAF, all UNOS transplants are first accepted into the file, with all CMS transplants prior to 1988 accepted next. CMS transplants from 1988–1993 are then accepted if there is no transplant in the file for that patient within 30 days of the CMS transplant (it is common for dates to differ by one day between these sources). Finally, transplants indicated on the Medical Evidence form are accepted if no transplant is listed for the patient within 30 days of the Medical Evidence transplant date.

#### **HOSPITAL CD**

Hospitalization inpatient data are a subset of the data in the Institutional Claims file. No payment or cost variables are included on this CD, which is for researchers who need data on hospital inpatient stays and on diagnoses and procedures for those stays, but who do not need payment data.

#### **DIALYSIS MORBIDITY & MORTALITY CD**

This CD contains files from the Dialysis Morbidity and Mortality Study, with data extracted from all other SAFs for the patients in this study. All data on Medicare payments for these patients are followed to the currently reported claims year.

#### **CASE MIX ADEQUACY CD**

This CD contains the Case Mix Adequacy Special Study file and extracts data from all other SAFs for the study patients.

Data on Medicare payments for these patients are followed to the currently reported claims year. This file is useful for developing analyses to be run on full Medicare payment files.

### CDs OF MEDICARE PAYMENT DATA

Medicare payment data on institutional claims are available for pre-1989 through 2001, while data on physician/supplier claims are available for 1991–2001. The 2001 claims will be available, along with other updated USRDS SAF CDs, by the end of 2003.

Institutional claims consist of all Part A claims (inpatient, outpatient, skilled nursing facility, home health agency, and hospice) and some Part B claims, notably outpatient dialysis. All physician/supplier claims are Part B; these claims account for 80 percent of the claims but only 20 percent of the dollars.

The structure and content of the two types of claims differ, as do the files derived from them. Institutional claims are provided in two types of files: the Institutional Claims file, indicating the type of claim, the dollar amounts, the DRG code, the type of dialysis involved (if any), and the dates of service; and the Institutional Claims Detail file, containing details such as diagnosis and procedure codes. Many analyses require only the Institutional Claims files. Physician/supplier claims are contained in one type of file with one record for each claim line-item. The file includes dollar amounts, dates of service, diagnosis and procedure codes, and type and place of service.

### CPM/USRDS CDs

To allow researchers to perform outcomes analyses with data collected from CMS's annual Clinical Performance Measures (CPM) project, the USRDS has this year generated a set of merged CPM/USRDS data files. The initial data set contains CPM data collected from 1994 to 2000, combined with the 2001 USRDS SAF research files. The CPM project has focused on assessing quality of care in the delivery of dialysis therapy, including anemia management, vascular access, and dialysis adequacy. Data have also been collected on additional risk parameters such as albumin and blood pressure.

For details on these files, please visit our website or email us at [usrds@usrds.org](mailto:usrds@usrds.org).

### FILE MEDIA & FORMATS

SAFs are provided on CDs as SAS files, and can be used by SAS on any 486 or Pentium PC with a CD reader. The USRDS has chosen a SAS format because it is widely used, easily transported, and largely self-documenting. SAS is a commercially available data management and statistical analysis software system that runs on most computers, and is almost universally available on university

b.c • Prices for the USRDS Standard Analysis Files				
<i>checks must be made payable to the Minneapolis Medical Research Foundation</i>				
Standard Analysis File CD-ROMs				
CD Description	CDs	Price		
Core CD	2	\$600	The Core CD is needed in order to use any of the other CDs.	
Transplant CD	2	\$200	Detailed transplant data from CMS and UNOS.	
Hospital CD	2	\$200	The Hospital CD is derived from the Institutional Claims and Institutional Claims Details CDs. It contains diagnosis and surgical procedure codes for each stay but does not include the cost data from the Institutional Claims records.	
DMMS claims CD set	4	\$400	The DMMS claims CD set contains all of the Institutional and Physician/Supplier claims data for the patients in the USRDS Dialysis Morbidity and Mortality (DMMS) Special Study. The data from the Special Study data collection forms are included on the Core CD.	
Case Mix Adequacy CD	1	\$100	The Case Mix Adequacy Claims claims CD contains all institutional and physician/supplier claims data for patients in the USRDS Case Mix Adequacy Special Study. Data from the Special Study data collection forms are included.	

  

Medicare payment data					
	Institutional claims			Physician/supplier claims	
	Claims CDs	Details CDs	Price	CDs	Price
pre-1989*	1	1	\$200		
1989	1	1	\$200		
1990	1	1	\$200		
1991	1	2	\$300	4	\$400
1992	1	2	\$300	4	\$400
1993	1	2	\$300	4	\$400
1994	1	2	\$300	5	\$500
1995	1	3	\$400	5	\$500
1996	1	3	\$400	6	\$600
1997	1	3	\$400	7	\$700
1998	1	3	\$400	7	\$700
1999	1	3	\$400	7	\$700
2000	1	5	\$600	7	\$700
2001^	1	5	\$600	7	\$700

\* CDs for years prior to 1989 include only hospital inpatient stays and quarterly summaries of outpatient dialysis; no cost data are included.  
 ^ Costs for 2001 are subject to change.

b.d • Outline for research proposals using USRDS data	
<i>A data request applies only to the project stated in the proposal; a new request must be submitted for each additional use of the data</i>	
I Research topic title and submission date	VII Investigator information For Principal Investigator and co-authors, supply: Name Affiliation Business address Business phone & fax Email address
II Background information	
III Study design Objectives Hypothesis Analytical methods	
IV Data being requested List of Standard Analytical Files needed, or fields needed in custom data file Description of data security: responsible party, computer access, etc. Timeframe for the project Statement that data will be returned to the USRDS or destroyed at the end of the project.	Submit to: Paul Eggers, PhD NIDDK 6707 Democracy Blvd, Room 615 Bethesda, MD 20892-5458 Phone 301.594.8305 Fax 301.480.3510 eggersp@extra.nidk.nih.gov
V Outline of estimated costs of requested data; source of funding	
VI Agreement for Release of Data, signed by all researchers	

computer systems. The SAFs take full advantage of the program's ability to incorporate detailed documentation into the file.

Researchers needing a different format or medium must arrange for the conversion. The USRDS may be able to convert files, but it will be at a substantial cost.

### **COSTS**

File prices cover reproduction and shipment of files and documentation, administrative costs of handling the sales, and costs of technical support to researchers. Prices are subject to change.

### **DOCUMENTATION**

*The Researcher's Guide to the USRDS Database* provides most of the SAF documentation. It includes a codebook of variables, copies of data collection forms used by the Special Studies, and a chapter on techniques for using the SAFs in SAS®. Copies of the Researcher's Guide may be downloaded from the USRDS website, or requested from the Coordinating Center.

## **■ Data use acknowledgement**

Publications using USRDS data should include an acknowledgment and this notice: *The data reported here have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the U.S. government.*

## **■ Data release policy**

Since the SAFs and custom data files contain confidential, patient-specific data, their release requires the approval process described here. Investigators may contact the USRDS Project Officer at the NIDDK to discuss requests before preparing a proposal. To request and use USRDS data files, investigators should do the following:

- Provide the USRDS Project Officer (PO) with a detailed description of the proposed investigation (see Table b.d). The summary must include goals, background data, an in-depth description of study design and methodology, and resources available for completing the project, and may be the description from a grant proposal or other application. The project must comply with the Privacy Act of 1974, and the summary should provide enough information to enable assessment of compliance. Guidelines for Privacy Act adherence are found in the "Agreement for Release of Data," page 227.
- Indicate needed USRDS SAFs. If these SAFs cannot meet requirements of the proposed research, investigators must specify precisely which data elements are needed, and budget for a substantially higher cost.
- If the project is approved, return a signed copy of the USRDS "Agreement for Release of Data" to the PO. The investigator and the CC will resolve any technical questions. The investigator will arrange payment with the CC, and payment must be received before the files will be released. Checks must be made payable to the Minneapolis Medical Research Foundation.

The NIH will review the project for technical merit and conformity with the Privacy Act. The PO will notify the investigator(s) in writing of the outcome, and if the project is not approved will discuss reasons for the decision. The PO will send a copy of the approval letters to the USRDS CC. The process of reviewing the data request, generating the data file, and releasing the data will take the CC approximately three months. When both a copy of the signed "Agreement for Release of Data" and payment for the files have been received by the CC, the CC will prepare the files and documentation and send them to the investigator.

Any reports or articles resulting from use of the USRDS data must be submitted to the PO prior to submission for publication to assure adherence to the Privacy Act. The PO must respond within 30 days. If a report or article is determined not to adhere to the Privacy Act, it shall not be published until compliance with the Act is achieved. Assessment of compliance will not depend on the opinions and conclusions expressed by the investigators, nor will the PO's approval indicate government endorsement of the investigator's opinions and conclusions.

All publications using released data must contain the standard acknowledgement and disclaimer presented above. Investigators are requested to send copies of all final publications resulting from this research to both the PO and the USRDS CC.

## **■ Caveats**

This policy establishes conditions and procedures for the release of data from the USRDS, and is intended to ensure that data are made available to investigators in the pursuit of legitimate biomedical, cost-effectiveness, or other economic research.

The USRDS will not release data that identify individual patients, providers, or facilities. Since it might be possible, however, to infer identity from SAF data, these data are considered confidential. The USRDS "Agreement for Release of Data" contains a number of general and specific restrictions on the use of USRDS data, and investigators are expected to abide by these restrictions. If individually identifiable data are needed, the request should be submitted directly to CMS. Use of these data to identify and/or contact patients, facilities, or providers is prohibited by USRDS policy and by the Privacy Act of 1974.

The USRDS CC will provide data in any of the usual media (tape, disk, or hard copy). Analytical services other than review of the proposal and preparation of the data file will not be provided under the USRDS contract, though CC personnel may participate in analyses funded by other sources.

Standard Analysis Files or other data files from USRDS Special Studies will become available one year after the data have been collected, edited, and entered into the database.

# Glossary

## OF TERMS

**Acquired immunodeficiency syndrome (AIDS)** An epidemic disease caused by the human immunodeficiency retrovirus that leads to immune system failure.

**Acute myocardial infarction (AMI)** An event which causes injury to the heart muscle.

**Adjusted average per capita costs (AAPCC)** An estimate of how much Medicare will spend in a year for an average beneficiary.

**Adult polycystic kidney disease** An inherited disease in which the kidneys contain multiple cysts.

**Anemia** A condition marked by a reduced number of red cells in the blood stream.

**Angioplasty** A procedure in which a balloon catheter is inserted into a blocked or narrowed vessel in order to re-open the vessel and allow normal blood flow.

**Arteriovenous fistula** A type of vascular access used in hemodialysis patients, and created by the anastomosis of the radial artery and the cephalic vein.

**Arteriovenous graft** A type of vascular access used in hemodialysis patients and created via a connection between an artery and vein using either a native vessel (saphenous vein) or a synthetic material such as Teflon.

**Atherosclerotic heart disease (ASHD)** A disease of the arteries of the heart, characterized by a thickening and/or loss of elasticity of the arterial walls.

**Blood urea nitrogen (BUN)** A by-product of the breakdown of amino acids and endogenous and injected protein.

**Body mass index (BMI)** A measure of height to weight ratio: Weight (kg)/Height (m<sup>2</sup>).

**Conventional hemodialysis** Dialysis therapy using small surface area hemodialyzers that are made with conventional membranes and have low solute clearance and low fluid removal capabilities. Does not require the use of delivery systems with ultrafiltration control.

**Coronary artery disease** A disease that causes narrowing or occlusion of the arteries surrounding the heart.

**Continuous ambulatory peritoneal dialysis (CAPD)** A type of dialysis in which dialysate is continuously present in the abdominal cavity. Fluid is exchanged by using gravity to fill and empty the cavity four to five times each day.

**Continuous cyclic-assisted peritoneal dialysis (CCPD)** A type of dialysis in which the abdominal cavity is filled and emptied of dialysate using an automated cyclic machine.

**Cancer** A disease that causes abnormal cell growth.

**Cardiac arrest** A complete cessation of cardiac activity.

**Cardiomyopathy** A general diagnostic term indicating a primary non-inflammatory disease of the heart muscle.

**Catheter** A vascular access used in hemodialysis patients, commonly implanted into the jugular or subclavian vein.

**Centers for Disease Control & Prevention (CDC)** The lead federal agency for protecting the health and safety of people

at home and abroad; serves as the national focus for disease prevention by developing and applying programs designed to improve the health of the people of the United States.

**Centers for Medicare & Medicaid Services (CMS)** Formerly the Health Care Financing Administration (HCFA). Federal agency that administers the Medicare, Medicaid, and State Children's Health insurance programs.

**Cerebrovascular disease (CVD)** A disease that causes narrowing or occlusion of the arteries supplying blood to the brain. Cerebrovascular accidents (CVA) and transient ischemic attacks (TIA) can result from this condition.

**Chain provider** A single business entity that owns 20 or more dialysis units located in more than one state (USRDS definition). This definition applies to all chain affiliation references in the USRDS's 2000–2002 Annual Data Reports. An alternative definition from the Centers for Medicare and Medicaid Services can be found under "definitions" in the Health Care Provider/Supplier Application Form, CMS 855.

**Charlson score** A measure of overall comorbidity. Categories of comorbidity are determined using inpa-

tient hospital claims, and each category is weighted based on the severity of the condition and the associated risk of one-year mortality. The weights are added together and the cumulative score reflects the burden of comorbidity and the likelihood of one-year mortality.

**Chronic obstructive pulmonary disease (COPD)** A progressive disease characterized by coughing, wheezing, or difficulty in breathing.

**Clinical Performance Measures Project** Formerly the Core Indicator Project. A project in which CMS and the ESRD networks cooperatively maintain a clinical database of key elements related to the quality of dialysis care. These elements are used as indicators in quality improvement initiatives.

**Common Working File (CWF) System** The Medicare Part A and Part B benefit coordination and claims validation system. Under the CWF, CMS maintains both institutional and physician supplier claims-level data. CWF claims records are the data source for most claims and utilization files used by the USRDS.

**Congestive heart failure (CHF)** A condition caused by ineffective pumping of the heart and subsequent fluid accumulation in the lungs.



**Creatinine** A waste product of protein metabolism found in the urine; often used to evaluate kidney function. Abnormally high creatinine levels indicate kidney failure or renal insufficiency.

**Creatinine clearance** Used as an indicator to predict the onset of uremia, which develops when creatinine clearance falls below 10 ml/minute/1.73 m<sup>2</sup>.

**Death Notification Form (CMS-2746)** A form submitted following the death of an ESRD patient, and containing basic patient demographic information in addition to information on the primary cause of death.

**Diabetes mellitus, insulin-dependent** A condition in which insulin is necessary to regulate abnormally high levels of glucose (sugar) in the blood.

**Diagnosis Related Groups (DRGs)** Used by Medicare to determine payment for inpatient hospital stays; based on diagnosis, age, gender, and complications.

**Dialysis & transplant center** A facility that combines the functions of a dialysis center and a transplant center.

**DVA** Department of Veterans Affairs.

**Employer Group Health Plan (EGHP)** A health plan of or contributed to by an employer, providing medical care directly or through other methods such as insurance or reimbursement to current or former employees, or to these employees and their families.

**End-stage renal disease (ESRD)** A condition in which an individual's kidney function is not adequate to support life.

**ESRD Facility Survey** Data for this survey are collected annually by CMS from all facilities certified to provide Medicare-covered renal dialysis and transplantation. The survey uses CMS form 2744, and encompasses the full calendar year. Geographic data are included to the level of facility ZIP code. Each record contains facility information and data on the number of patients served, dialysis treatments provided, and kidney transplants performed. The data include services to both Medicare and non-Medicare patients.

**ESRD network** Regional organizations, established by law in 1978, contracted by CMS to perform quality oversight activities to assure the appropriateness of services and protection for dialysis patients.

**Erythropoietin (EPO)** A hormone secreted chiefly by the adult kidney; acts on bone marrow to stimulate red cell production. Also produced in a formulated version, used to treat anemia.

**For-profit facility** A dialysis facility which is owned, leased, or, through any other devices, controlled by a single business entity.

**Freestanding facility** A unit licensed to provide outpatient and home maintenance dialysis; sometimes referred to as an independent unit.

**Glomerular filtration rate (eGFR)** Estimated rate in ml/min/1.73 m<sup>2</sup> of the volume of plasma filtered by the kidney. Rates of filtration are based on an individual's age, gender, and height, and on levels of serum creatinine, serum blood urea nitrogen, and serum albumin. GFR is traditionally considered the best overall index to determine renal function.

**Glycosylated hemoglobin test** Used to help determine how well a patient's diabetes is being controlled, this test measures the level of glucose-bound hemoglobin in the bloodstream.

**Health Care Financing Administration (HCFA)** Created in 1977, the federal agency responsible for administration of Medicare and Medicaid, the nation's largest healthcare programs. HCFA was renamed the Centers for Medicare and Medicaid Services (CMS) in June 2001.

**Health Maintenance Organization (HMO)** A competitive medical plan, such as Medicare+Choice, that has contracts with CMS on a prospective capitation payment basis for providing healthcare to Medicare beneficiaries.

**Health Plan Employer Data & Information Set (HEDIS®)** Established by the National Committee for Quality Assurance, HEDIS 2002 is a set of standardized performance measures created to aid

## Abbreviations

<b>AAPCC</b>	adjusted average per capita costs
<b>AMI</b>	acute myocardial infarction
<b>ASHD</b>	atherosclerotic heart disease
<b>BMI</b>	body mass index
<b>BUN</b>	blood urea nitrogen
<b>CAPD</b>	continuous ambulatory peritoneal dialysis
<b>CCPD</b>	continuous cycler peritoneal dialysis
<b>CHF</b>	congestive heart failure
<b>CKD</b>	chronic kidney disease
<b>CMS</b>	Centers for Medicare & Medicaid Services
<b>COPD</b>	chronic obstructive pulmonary disease
<b>CVA/TIA</b>	cerebrovascular accident/transient ischemic attack
<b>CPT</b>	Current Procedure and Terminology
<b>CVD</b>	cerebrovascular disease
<b>DM</b>	diabetes, diabetic
<b>DRG</b>	diagnosis related group
<b>DVA</b>	Department of Veterans Affairs
<b>EGHP</b>	employer group health plan
<b>EPO</b>	erythropoietin
<b>ESRD</b>	end-stage renal disease
<b>eGFR</b>	estimated glomerular filtration rate
<b>GN</b>	glomerulonephritis
<b>HbA1c</b>	glycosylated hemoglobin
<b>HCFA</b>	Health Care Financing Administration
<b>HD</b>	hemodialysis
<b>HEDIS</b>	Health Plan Employer Data Information Set
<b>HMO</b>	health maintenance organization
<b>HSA</b>	Health Service Area
<b>HTN</b>	hypertension
<b>ICD-9-CM</b>	International Classification of Diseases, 9 <sup>th</sup> revision, Clinical Modification
<b>IPD</b>	intermittent peritoneal dialysis
<b>ISHD</b>	ischemic heart disease
<b>K/DOQI</b>	Kidney Disease Outcomes Quality Initiative
<b>MI</b>	myocardial infarction
<b>MPP</b>	Medicare as primary payor
<b>MSP</b>	Medicare as secondary payor
<b>NDM</b>	non-diabetic
<b>NHANES</b>	National Health & Nutrition Examination Survey
<b>NKF</b>	National Kidney Foundation
<b>PD</b>	peritoneal dialysis
<b>PMPM</b>	per member per month
<b>PVD</b>	peripheral vascular disease
<b>Tx</b>	transplant
<b>UNOS</b>	United Network for Organ Sharing

consumers in comparing managed healthcare plans.

**Health Service Area (HSA)** A group of counties described by the authors of the CDC *Atlas of United States Mortality* as an area that is relatively self-contained with respect to hospital care.

**Healthy People 2010** A national agenda for health promotion and disease prevention, with objectives and goals aimed at improving the health of the American people ([www.health.gov/healthypeople](http://www.health.gov/healthypeople)).

**Hemoglobin** The oxygen-carrying protein in the erythrocyte (red blood cell).

**Hepatitis** An inflammation of the liver that may be caused by a viral infection, poisons, or the use of alcohol or other drugs. Forms

include Hepatitis A, usually transmitted by contaminated food or water; Hepatitis B, more serious than Hepatitis A and transmitted through blood and body fluids; Hepatitis C, also transmitted through blood and body fluids; and Hepatitis D, which causes symptoms only when an individual is already infected with the Hepatitis B virus.

**High-efficiency hemodialysis** Dialysis therapy that is provided using hemodialyzers with larger surface areas than conventional hemodialyzers. Enhanced solute clearance is achieved through increased blood flow rates of 300 to 400 milliliters per minute, allowing treatment times to be reduced to approximately three hours.

**High-flux hemodialysis** Dialysis therapy using hemodialyzers with synthetic membranes and large surface areas that, combined with high blood and dialysate flow rates, allow enhanced solute clearance and fluid removal. Delivery systems with ultrafiltration control are required for this therapy.

**Hospital-based facility** A dialysis unit attached to or located in a hospital and licensed to provide outpatient dialysis services directly to ESRD patients.

**Hospital center unit** A dialysis unit located in or attached to a hospital and licensed to furnish inpatient and outpatient dialysis plus diagnostic, therapeutic, and rehabilitative services.

**Incident ESRD patient** A patient starting renal replacement therapy for ESRD during the calendar year. Excludes patients with acute renal failure, those with chronic renal failure who die before starting ESRD treatment, and those whose treatments are not reported to CMS.

**Incident population** The people in a population who are newly diagnosed with a disease in a given time period, typically a year.

**Ischemic heart disease (ISHD)** A disease of the heart evidenced by a lowered oxygen supply to the heart tissue caused by occlusion or narrowing of the arteries supplying the heart muscle.

**Kidney Disease Outcomes Quality Initiative (K/DOQI)** Established in 1995 by the National Kidney Foundation to improve patient outcomes and survival by providing recommendations for optimal clinical practices in the areas of dialysis adequacy, vascular access, and anemia.

**Kt/V** An indicator of the dialysis dose per treatment, calculated by multiplying the urea clearance (K) by the treatment duration (t) and dividing by the urea distribution (V). The urea distribution volume is approximately equal to the volume of total body water.

**Medical Evidence form (CMS-2728)** A form which provides source data about ESRD patients, including information on patient demographics, primary cause of renal disease, comorbidity, biochemical data, dialysis treatment,

transplant, dialysis training, employment status, initial insurance coverage, and first ESRD service date.

**Medicare as Secondary Payor (MSP) patient** A Medicare beneficiary with a health insurer other than Medicare (e.g. an Employer Group Health Plan) that has primary responsibility for payment of the beneficiary's medical bills.

**Medicare risk patient** A patient enrolled in a Managed Care Organization under contract with CMS and for whom health care costs are paid by CMS on a per capita basis.

**Modality** A method of treatment. Treatment for end-stage renal disease (ESRD) is comprised of three modalities: hemodialysis, peritoneal dialysis, and transplantation.

**Myocardial infarction (MI)** An event which causes injury to the heart muscle.

**National Claims History (NCH) 100 percent Nearline File** A file which contains all Common Working File (CWF) Part A (provider) and Part B (physician-supplier) Medicare claims and adjusted claims information.

**National Health and Nutrition Examination Survey (NHANES)** A survey conducted by the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention; uses home interviews and health tests to collect information on health and diet in the United States.

**National Institutes of Health (NIH)** The federal focal point for medical research in the U.S. and one of eight health agencies of the Public Health Services, which are part of the Department of Health and Human Services.

**Period prevalent patient** A patient receiving treatment for ESRD at some point during a period of time, usually six months or a year. Patients may die during the period or be point prevalent at the end of the period. Period prevalence is a useful measure for cost analysis, since it indicates total disease burden over the course of a year.

**Peripheral vascular disease (PVD)** A progressive disease that causes narrowing or occlusion of

the arteries supplying the extremities of the body.

**Peritoneal dialysis** Dialysis in which fluid (dialysate) is introduced into the abdominal cavity and uremic toxins are removed across the peritoneum.

**Point prevalent patient** A patient reported as receiving treatment for ESRD on a particular day of the calendar year (e.g. December 31).

**Program Medical Management & Information System for ESRD, & Renal Beneficiary & Utilization System (PMMIS/REBUS)** The major source of data for the USRDS. This CMS file incorporates data from the Medical Evidence form (CMS 2728), the Death Notification form (CMS 2746), the Medicare Enrollment Database, CMS paid claims records, and the UNOS transplant database.

**Prevalent ESRD patient** A patient on renal replacement therapy or with a functioning kidney transplant (regardless of when the transplant was performed). This definition excludes patients with acute renal failure, those with chronic renal failure who die before receiving treatment for ESRD, and those whose ESRD treatments are not reported to CMS.

**Prevalent population** The people in a population who have a disease at a given point in time (point prevalence) or during a given time period (period prevalence).

**Proteinuria** The existence of protein in the urine that is indicative of kidney damage.

**Pyrogen** A substance which is bacterial in nature and capable of producing low-grade fevers.

**Pyrogen reaction** A condition in which a patient afebrile prior to dialysis experiences a low-grade fever during the run, caused by pyrogens in the dialysate fluid. The fever disappears after the dialysis is complete, distinguishing the reaction from an actual infection.

**REMIS** CMS's Renal Management Information System (REMIS), which is to replace the existing Renal Beneficiary and Utilization System (REBUS). REMIS will include an operational interface to the SIMS Central Repository.

**Reuse** A process through which a hemodialyzer is cleaned and disinfected, allowing it to be used multiple times on the same patient.

**Reuse germicide** A chemical used during the reuse process to disinfect the hemodialyzer.

**SIMS** CMS's Standard Information Management System (SIMS), which became operational at the beginning of 2000. Supports CMS reporting requirements and the business processes of the ESRD networks; provides communication and data exchange links for the networks, CMS, and other parts of the renal community; supplies standard core data functionality for previous network data systems; and provides improved electronic communication capabilities, data standardization, and information management tools.

**Standard Analytical Files (SAFs)** CMS files containing final action Medicare Part A claims data: Inpatient, Outpatient, Home Health Agency, Hospice, Skilled Nursing Facility, Clinical Laboratory, Durable Medical Equipment, and 5 percent Sample Beneficiary.

**Standardized hospitalization ratio (SHR)** Used to compare hospitalization rates for a selected group of patients by computing the ratio of the group's observed hospitalization rate to the expected hospitalization rate for the national ESRD population.

**Standardized mortality ratio (SMR)** Used to compare dialysis patient mortality rates from year to year. Mortality rates for a subgroup of patients are compared to a set of reference rates, with adjustments for age, race, gender, and diabetes as a cause of ESRD.

**Standardized transplantation ratio (STR)** Used to compare transplant rates for a subgroup of patients to national transplant rates.

**Transplant center** A hospital unit licensed to provide transplantation and other medical and surgical specialty services for the care of kidney transplant patients, including inpatient dialysis furnished directly or under arrangement.

**United Network for Organ Sharing (UNOS)** A private, non-profit

organization that maintains the organ transplant list for the nation and coordinates the matching and distribution of organs to patients awaiting transplant.

**Urea reduction ratio (URR)** A means of measuring dialysis dose by calculating the change in BUN over the course of a dialysis treatment.  $URR = (\text{pre-dialysis} - \text{post-dialysis BUN}) / \text{pre-dialysis BUN} * 100$ .

**Valvular heart disease (VHD)** A condition in which a patient has one or more abnormal heart valves.

**Vintage** Time in years that a patient has had ESRD.

**The VISION project** CMS's Vital Information System to Improve Outcomes in Nephrology (VISION) will provide customized data entry and reporting for the nearly 4,000 U.S. dialysis facilities, and will capture and securely communicate ESRD patient and provider data collected via the CMS 2728, 2746, 2744, 820, and 821 forms. This project is designed to meet the goals of the Hemodialysis Facilities of Achievement Project (FOA) as outlined in the Federal Register (April 29, 1997).

**Wait list** A list, maintained by the United Network for Organ Sharing (UNOS), of patients awaiting an organ transplant.

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# United States Renal Data System (USRDS) Agreement for Release of Data

In this agreement, "Recipient" means \_\_\_\_\_

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- A. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), through the United States Renal Data System (USRDS) Coordinating Center (CC), will provide the Recipient with tapes, disks, and/or hard copies containing data extracted from the USRDS research database.
- B. The sole purpose of providing the data is the conduct of legitimate and approved biomedical, cost-effectiveness, and/or other economic research by the Recipient.
- C. The Recipient shall not use the data to identify individuals on the file.
- D. The Recipient shall not combine or link the data provided with any other collection or source of information that may contain information specific to individuals on the file, except where written authorization has been obtained through the approval process.
- E. The Recipient shall not use the data for purposes that are not related to biomedical research, cost-effectiveness, or other economic research. Purposes for which the data may not be used include, but are not limited to,
  - the identification and targeting of under- or over-served health service markets primarily for commercial benefit
  - the obtaining of information about providers or facilities for commercial benefit
  - insurance purposes such as redlining areas deemed to offer bad health insurance risks
  - adverse selection (e.g., identifying patients with high risk diagnoses)

Any use of the data for research not in the original proposal must be approved by the USRDS Project Officer (PO).

- F. The Recipient shall not publish or otherwise disclose the data in the file to any person or organization unless the data have been aggregated (that is, combined into groupings of data such that the data are no longer specific to any individuals within each grouping), and no cells (aggregates of data) contain information on fewer than ten individuals or fewer than five providers or facilities. The Recipient shall not publish or otherwise disclose data that identify individual providers or facilities, or from which such identities could be inferred. However, the Recipient may release data to a contractor for purposes of data processing or storage if (1) the Recipient specified in the research plan submitted to the USRDS Project Officer that data would be released to the particular contractor, or the Recipient has obtained written authorization from the PO to release the data to such contractor, and (2) the contractor has signed a data release agreement with the PO.
- G. A copy of any aggregation of data intended for publication shall be submitted to the PO for review for compliance with the confidentiality provisions of this agreement prior to submission for publication and, if not approved, shall not be published until compliance is achieved. The PO must respond within 30 days.
- H. Appropriate administrative, technical, procedural, and physical safeguards shall be established by the Recipient to protect the confidentiality of the data and to prevent unauthorized access to it. The safeguards shall provide a level of security outlined in OMB Circular No. A-130, Appendix III—Security of Federal Automated Information System, which sets forth guidelines for security plans for automated information systems in Federal agencies.
- I. No copies or derivatives shall be made of the data in this file except as necessary for the purpose authorized in this agreement. The Recipient shall keep an accurate written account of all such copies and derivative files, which will be furnished upon request to the PO. At the completion of the activities in the research plan, the file shall be returned to the USRDS CC at the Recipient's expense, and any derivative files and copies shall be destroyed.
- J. For the purpose of inspecting security procedures and arrangements, authorized representatives of the PO and/or of CMS will, upon request, be granted access to premises where data in this file are kept.

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*Project title*

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*Recipient typed name, title, & organization*

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*Recipient telephone number*

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*Recipient signature & date*

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*Contractor typed name, title, & organization, as appropriate*

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*Contractor telephone number*

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*Contractor signature & date*

Lawrence Y. C. Agodoa, MD, NIDDK, NIH or  
Paul W. Eggers, PhD, NIDDK, NIH  
*USRDS Project Officer name & organization*

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*USRDS Project Officer signature & date*

Revised June 1994



# United States Renal Data System (USRDS) International Data Collection Form

This form is designed to solicit information on the population of End-Stage Renal Disease (ESRD) patients in your country. The information you provide will be returned to you along with comparable information from other countries participating in the voluntary effort.

The form has been changed and expanded to provide more detail in age-specific categories. If you cannot provide data in the age categories listed, please provide the total numbers. The format has also been changed to more clearly separate incident and prevalent population counts from transplant counts.

- A) Population: the population of your country for the most recent year available
- B) Incidence: the count of patients who start any form of renal replacement therapy during the year. These are first-time patients only; patients who start dialysis after a failed transplant, for example, should not be included.
  - B2) The subset of total incident patients whose failure is due to diabetic nephropathy. Subtracting B2 from B1 should give the total number of incident patients for all non-diabetic nephropathy causes.
- C) Prevalence: the point prevalent count of patients at the end of the calendar year (December 31).
  - C1) All patients on some form of treatment, dialysis or transplantation.

- C2) Patients with a functioning kidney transplant as of December 31.
- C3) All dialysis patients. C2 and C3 should sum to C1 unless there are lost-to-follow-up patients. If there are lost-to-follow-up patients, please note this fact and whether these patients are captured in C2.
- C4) All patients treated with in-center hemodialysis as of December 31.
- C5) All patients treated with CAPD or CCPD as of December 31.
- C6) All patients treated with home hemodialysis as of December 31.
- C4, C5, and C6 are subsets of all dialysis patients (C3). They should not total to more than C3. They may, however, sum to less than C3 due to unknown or other types of dialysis.
- D) Transplant activity: This is meant to be a count of transplants, not transplanted patients. If a patient receives multiple transplants during the year, all should be counted. If you report only transplanted patients, please provide these numbers and note that they refer to patients. D1 (cadaveric transplants) and D2 (living donor transplants) should sum to the total number of transplants. If there are a number of transplants with unknown donor types, or if you cannot separate transplants by donor type, please report the total number of transplants.

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<b>A) Population of country</b>	<b>0-19</b>	<b>20-44</b>	<b>45-64</b>	<b>65-74</b>	<b>75+</b>
1999	_____	_____	_____	_____	_____
2000	_____	_____	_____	_____	_____
2001	_____	_____	_____	_____	_____
2002	_____	_____	_____	_____	_____
<b>B1) Incidence: Total number of incident (new) patients starting renal replacement therapy during the year</b>	<b>0-19</b>	<b>20-44</b>	<b>45-64</b>	<b>65-74</b>	<b>75+</b>
1999	_____	_____	_____	_____	_____
2000	_____	_____	_____	_____	_____
2001	_____	_____	_____	_____	_____
2002	_____	_____	_____	_____	_____
<b>B2) Incidence: Total number of incident patients starting renal replacement therapy during the year due to diabetes</b>	<b>0-19</b>	<b>20-44</b>	<b>45-64</b>	<b>65-74</b>	<b>75+</b>
1999	_____	_____	_____	_____	_____
2000	_____	_____	_____	_____	_____
2001	_____	_____	_____	_____	_____
2002	_____	_____	_____	_____	_____

<b>C1) Prevalence: Total number of ESRD patients (all treatment categories) at the end of the year (December 31)</b>					
	<b>0-19</b>	<b>20-44</b>	<b>45-64</b>	<b>65-74</b>	<b>75+</b>
1999	_____	_____	_____	_____	_____
2000	_____	_____	_____	_____	_____
2001	_____	_____	_____	_____	_____
2002	_____	_____	_____	_____	_____

<b>C2) Prevalence: Total number of ESRD patients with a functioning graft at the end of the year (December 31)</b>					
	<b>0-19</b>	<b>20-44</b>	<b>45-64</b>	<b>65-74</b>	<b>75+</b>
1999	_____	_____	_____	_____	_____
2000	_____	_____	_____	_____	_____
2001	_____	_____	_____	_____	_____
2002	_____	_____	_____	_____	_____

<b>C3) Prevalence: Total number of ESRD patients on dialysis at the end of the year (December 31)</b>					
	<b>0-19</b>	<b>20-44</b>	<b>45-64</b>	<b>65-74</b>	<b>75+</b>
1999	_____	_____	_____	_____	_____
2000	_____	_____	_____	_____	_____
2001	_____	_____	_____	_____	_____
2002	_____	_____	_____	_____	_____

<b>C4) Prevalence: Total number of ESRD patients on in-center hemodialysis at the end of the year (December 31)</b>					
	<b>0-19</b>	<b>20-44</b>	<b>45-64</b>	<b>65-74</b>	<b>75+</b>
1999	_____	_____	_____	_____	_____
2000	_____	_____	_____	_____	_____
2001	_____	_____	_____	_____	_____
2002	_____	_____	_____	_____	_____

<b>C5) Prevalence: Total number of ESRD patients on CAPD/CCPD at the end of the year (December 31)</b>					
	<b>0-19</b>	<b>20-44</b>	<b>45-64</b>	<b>65-74</b>	<b>75+</b>
1999	_____	_____	_____	_____	_____
2000	_____	_____	_____	_____	_____
2001	_____	_____	_____	_____	_____
2002	_____	_____	_____	_____	_____

<b>C6) Prevalence: Total number of ESRD patients on home hemodialysis at the end of the year (December 31)</b>					
	<b>0-19</b>	<b>20-44</b>	<b>45-64</b>	<b>65-74</b>	<b>75+</b>
1999	_____	_____	_____	_____	_____
2000	_____	_____	_____	_____	_____
2001	_____	_____	_____	_____	_____
2002	_____	_____	_____	_____	_____

<b>D1) Transplant: Total number of cadaveric transplants during the year</b>					
	<b>0-19</b>	<b>20-44</b>	<b>45-64</b>	<b>65-74</b>	<b>75+</b>
1999	_____	_____	_____	_____	_____
2000	_____	_____	_____	_____	_____
2001	_____	_____	_____	_____	_____
2002	_____	_____	_____	_____	_____

<b>D2) Transplant: Total number of living donor transplants during the year</b>					
	<b>0-19</b>	<b>20-44</b>	<b>45-64</b>	<b>65-74</b>	<b>75+</b>
1999	_____	_____	_____	_____	_____
2000	_____	_____	_____	_____	_____
2001	_____	_____	_____	_____	_____
2002	_____	_____	_____	_____	_____