### Appendix A: Analytical methods

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### Appendix B: USRDS services

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n this appendix we describe the USRDS database and its standardized working datasets, specialized code definitions, and common data processing practices. We also detail the statistical methods used in this 2004 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 with data on diagnoses and demographic characteristics of ESRD patients, along with biochemical data, dialysis claims, and information on treatment and payor histories, hospitalization events, deaths, physician/supplier services, and providers.

REBUS/PMMIS DATABASE

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

CMS regularly updates the REMIS/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, as well as the SIMS database from the ESRD networks. CMS has also established a new set of data integrity rules to help ensure accurate identification of ESRD patients between the SIMS and CMS ESRD databases. Each ESRD patient (old and new) will now be identified with a unique patient identification number common to both databases, ensuring that all patients are consistently managed over time.

CMS MEDICARE ENROLLMENT DATABASE (EDB)

CMS’s Enrollment Database is the designated repository of all Medicare beneficiary enrollment and entitlement data, and provides current and historical information on residence, Medicare as secondary payor (MSP) and employee group health plan (EGHP) 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 REMIS/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 ESRD service dates. These paid claims records are, however, only a supplement to, rather than a replacement of, other sources of information on incidence and prevalence.
The creative phase of an idea coincides with the period during which it insists, cantankerously, on its boundaries, on what makes it different; but an idea becomes false and impotent when it seeks reconciliation, at cut-rate prices, with other ideas.

Susan Sontag
Against Interpretation

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 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 we use the following data: inpatient, 100 percent SAF; outpatient, 100 percent SAF; home health agency (HHA), 100 percent SAF; hospice, 100 percent SAF; and skilled nursing facility (SNF), 100 percent SAF. For Part B physician/supplier claims, we use: physician/supplier, 100 percent SAF; and durable medical equipment (DME), 100 percent SAF.

CMS SAFs are updated each quarter through June of the next year, when the annual files are finalized. Datasets for the current year are created six months into the year and updated quarterly until finalized at 18 months, after which they are not updated to include late arriving claims. Annual files are thus approximately 98 percent complete. The USRDS 2004 ADR includes all claims up to December 31, 2002. Patient-specific demographic and diagnosis information, however, includes data as recent as December 2003.

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 229.

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

CMS ESRD CLINICAL PERFORMANCE MEASURES PROJECT
CMS developed its ESRD Clinical Performance Measures Project (CPM, formerly the ESRD Core Indicators Project) to collect information on the quality of care provided to dialysis patients. The data originate from surveys completed by primary care facilities, and focus on dialysis adequacy measures, anemia management, and vascular access. Additional clinical parameters such as albumin are available as well. These data have been collected annually since 1994, using a random sample of adult (age 18 and older) patients alive and on dialysis at the end of each calendar year; to date, more than 67,000 hemodialysis and 10,800 peritoneal dialysis surveys have been conducted. Data collection for all pediatric patients age 12–17 years was begun in 2000, and in 2002 was expanded to all in-center hemodialysis patients younger than 18. The USRDS Coordinating Center, in collaboration with CMS, is now making this CPM data available to the general research community.

MINIMUM DATA SET
The CMS Minimum Data Set (MDS) contains data on the ESRD population in long-term care facilities. Since June 22, 1998, CMS has required nursing homes participating in Medicare and/or Medicaid programs to supply MDS information, which is collected by staff at the nursing homes and reported to CMS through the Nursing Home Resident Assessment and Care Screening form. For this ADR we have used data spanning the reporting period.
New to this ADR, we present Employer Group Health Plan (EGHP) data to illustrate healthcare trends in the younger and healthier segments of the population. These data are obtained from the Medstat MarketScan Databases—specifically, the Commercial Claims and Encounters database, combined with the Medicare Supplemental and COB database—which are constructed from private sector data contributors that include approximately 45 large employers, health plans, and government and public organizations. Paid medical and prescription claims are collected from approximately 100 payors, including commercial insurance companies, Blue Cross and Blue Shield plans, and third-party administrators. These data represent healthcare utilization by insured active employees and their dependents, early retirees, and COBRA enrollees. Claims evidence includes inpatient and outpatient medical/surgical encounters as well as outpatient pharmaceutical claims, and claims are linked to person-level enrollment data including age, gender, and geographic location.

**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 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 (CDC) use their National Surveillance of Dialysis-Associated Diseases to collect data from U.S. dialysis facilities on patient and staff counts, membrane types, reuse practices, water treatment 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.

**UNITED STATES CENSUS**

In rate calculations throughout this year’s ADR we use, for the first time, data from the 2000 U.S. census, and also incorporate CDC population estimates by race. Our methods are described on page 254.

**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 interconnected 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 was integrated into the new database, and its continuity and completeness are maintained.

**DATA LOADING & CLEANING**

Data files come to the USRDS in IBM 3490 and 3490e 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 December 2003, and Medicare Part A and Part B claims are collected through December 31, 2002.

**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: age 65 and over, disabled, ESRD program, and Railroad Retirement Board (RRB).

Most ESRD patients are eligible to apply for Medicare as their primary insurance payor. Some, however, are not immediately eligible for Medicare coverage because of their employment status and insurance benefits. These patients are usually covered by Employer Group Health Plans (EGHPs), 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 not be possible to link "ZZ" patients to their ESRD Death Notification forms (CMS 2746) or the UNOS transplant data, or to determine comorbidity or Part A and 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 uses all available data to create a treatment history for each patient in the database, including all modality events, their duration, and the renal providers involved in each patient's care. Gaps frequently exist in the billing data upon which modality periods are based. 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**

For this year’s ADR we have worked to reconcile ESRD patients in the SIMS, REMIS, and USRDS databases. Each database is incomplete in some way. The USRDS database used for the 2003 ADR lacks data on patients incident after approximately March 2002, while in the REMIS database patients dying prior to 1995 are dropped. The SIMS database contains some of these dropped patients, but not all of them. To build a comprehensive database for this ADR, it is therefore necessary to integrate all three databases.

To accomplish this, we first analyzed each database for duplicate records, consolidated these records, and integrated the databases. These integrated data were then re-analyzed for duplicates, which were themselves consolidated. Through these efforts the 1994–1995 "spike" in incident patients has been corrected, and the 2001 incident count decreased. This consolidation of patients will be an ongoing collaborative effort between the ESRD Networks, CMS, and the USRDS.

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. Beginning with the 2003 ADR, we have incorporated treatment-specific information from the ESRD Networks’ SIMS event database to improve the tracking of these patients in the USRDS database, and of patients who are considered lost-to-followup.

One of the surprise findings from this data integration has been the significant presence in the SIMS database of the "recover function" event; we present some of this new data in Chapter Four. Some patients listed as regaining function have received at least a year of dialysis therapy; as their listing is likely due to a coding error, we will be collaborating further with CMS and the ESRD networks to clarify the data.

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

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

**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 modality. It is used to construct a patient’s modality sequence, or treatment history, so that incident and prevalent patients are known to have stable and established modalities. Starting with the 2003 ADR, all descriptive data appearing in the incident, prevalent, and modality sections are based on incident and prevalent cohorts produced from the modality sequence without using this rule. In analyses of patient outcomes such as hospitalization and mortality, in contrast, this rule is applied.

**90-DAY RULE: 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.
**SERUM ALBUMIN DATA**

The Medical Evidence form reports a patient’s serum albumin level along with the lower limit of the test, which indicates the testing method used. There are currently two laboratory methods in use: bromocresol purple and bromcresol green, with lower limits of 3.2 and 3.5 g/dl, respectively.

While producing the 2004 ADR we uncovered severe problems in data quality related to albumin information on the Medical Evidence form. We found that, from 1995 to 2003, almost 50 percent of the forms contained lower limit values equal to “zero,” while another 25 percent reported values other than the expected 3.2 and 3.5 g/dl. Only 25 percent (n= 173,000) of incident patients had legitimate lower limit values for determining normal serum albumin. Further analyses have shown that these patients are a representative cohort sample, with a similar demographic distribution by age, gender, race, and cause of ESRD to that of the overall ESRD population. For all figures in the 2004 which present data on serum albumin from the Medical Evidence form, we have therefore included only those incident patients with both an albumin lower limit of 3.2 or 3.5 g/dl and an albumin value.

**Database definitions**

**MODALITIES**

Because we use different modality categories throughout the ADR, they are defined in the methods sections for each chapter.

**PAYORS**

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

| Network 1 | Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont |
| Network 2 | New York |
| Network 3 | New Jersey, Puerto Rico, Virgin Islands |
| Network 4 | Delaware, Pennsylvania |
| Network 5 | Virginia, West Virginia, Maryland, District of Columbia |
| Network 6 | Georgia, North Carolina, South Carolina |
| Network 7 | Florida |
| Network 8 | Alabama, Mississippi, Tennessee |
| Network 9 | Illinois, Indiana, Kentucky, Ohio |
| Network 10 | Minnesota, Michigan, North Dakota, South Dakota, Wisconsin |
| Network 11 | Iowa, Kansas, Missouri, Nebraska |
| Network 12 | Alaska, Idaho, Montana, Oregon, Washington |

**Appendix A**

**ESRD Networks**

| Network 13 | Arkansas, Louisiana, Oklahoma |
| Network 14 | Texas |
| Network 15 | Arizona, Colorado, Nevada, New Mexico, Utah, Wyoming |
| Network 16 | Northwest Renal Network |
| Network 17 | American Samoa, Guam, Mariana Islands, Hawaii, Northern California |
| Network 18 | Southern California |

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**Analytical methods**

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vide payor history, and starting with the 2003 ADR we have used this file to identify Medicare eligibility status and other payors. The construction of this file is similar to that of the treatment history file. Payor status is maintained for each ESRD patient from the first ESRD service date until death or the end of the study period. Payor data are used to categorize a patient as MPP, Medicare as secondary payor, Medicare+Choice, Medicaid, or a combination of payors. With this approach, the USRDS is now able to apply the payor status information in all outcome analyses using the “as-treated” model (see the discussion of Chapter Twelve).

PRIMAR Y 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, 582.1, 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 One and Two present data on patients whose ESRD is caused by one of the less commonly occurring diseases. The ICD-9-CM codes used in Chapter One to identify patient cohorts are listed in the discussion of Table 1.a (page 235); in Chapter Two, diseases are identified from the Medical Evidence form.

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.

EGHP COHORT
EGHP data in this year’s ADR are derived, as mentioned above, from Medstat MarketScan Database products. To examine the demographic segment not represented by Medicare, we use enrollment information to construct yearly cohorts of enrollees younger than 65. To ensure that we select enrollees with the potential to generate claims evidence appropriate to the demands of analytical methods, rules for inclusion also include 12 months of continuous coverage in a fee-for-service plan with no more than a 40-day gap between plan changes, and, for analyses of drug utilization, continuous prescription drug coverage.

ESRD COHORT IN THE EGHP POPULATION
Since the Medstat Database does not provide data that allow patients to be identified, we are unable to link it directly to the USRDS ESRD registry. To identify ESRD patients, we therefore use an alternative process similar to that used in the registry. Transplant patients are identified by evidence of a kidney transplant procedure or an adverse graft event, and chronic dialysis patients by evidence of continuous history of dialysis therapy, with at least three consecutive months of dialysis service and with dialysis service claims in at least 70 percent of treatment months. Treatment months are defined by the period from the first dialysis claim to the earliest of kidney transplant, death, or end of enrollment. Both inpatient and outpatient claims are evaluated for evidence of dialysis service history.

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

Précis

Figure 2 shows trends in the number of patients with chronic kidney disease (CKD), by insurance type, for the general Medicare population and a selected EGHP population. Cohorts of general Medicare patients are derived from the 5 percent Medicare Denominator files, 1992–2002, and include patients continuously enrolled in Medicare Parts A and B for an entire calendar year and alive on the last day of the year. We exclude from the study those diagnosed with ESRD any time before the end of each calendar year, and those enrolled in a managed care program (HMO) any time during the calendar year. For the EGHP population, cohorts are derived from the Medstat MarketScan Databases, 1999–2002, and include patients age 65 and younger who are continuously enrolled in a fee-for-service plan for an entire calendar year with no gaps of coverage greater than 40 days.

According to a previously validated methodology for using Medicare claims to identify diabetic patients, a patient is diabetic if, within a one-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), or two or more Part A institutional claims (outpatient) or Part B physician/supplier claims. Using this methodology, we identify CKD patients with or without diabetes or hypertension in each calendar year. Codes used to define the diseases 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; and hypertension, 307.4, 401.x–405.x, and 437.2.

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

Figures p.7–9 show total admission rates for prevalent ESRD patients. Methods used generally follow those described for Chapter Six and Reference Section E. Included patients have Medicare as a primary payer and are residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories. Patients with AIDS as a primary or secondary cause of death are excluded, as are patients with missing age or gender information. Rates are adjusted for age, gender, race, and primary diagnosis using the model-based
adjustment method, described in the discussions of Reference Section E and the statistical methods sections of this appendix. The reference cohort includes period prevalent ESRD patients, 2002, 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 for congestive heart failure (CHF) and ischemic heart disease (ISHD) are as follows: CHF, 398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 425.4x, 425.5x, 425.7x, 425.8x, 425.9x, and 428.xx; and ISHD, 410.xx–414.xx. Principal ICD-9-CM diagnosis codes used for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 6.1. The “other cardiovascular” category includes cardiovascular hospitalizations with a principal ICD-9-CM diagnosis code other than those for CHF or ISHD. Principal ICD-9-CM diagnosis codes for the other infectious categories are as follows: bacteremia/sepsisemia, 038.xx–038.9 and 790.7; urinary tract infection, 590.xx–590.9, 595.0–595.4, 597.0–597.89, 599.0, 601.0–601.9, 604.0–604.9x, 607.1, 614.0–616.1x, 616.3–616.4, and 616.8; and infection due to internal device (related to vascular access device or peritoneal dialysis catheter), 996.62 and 996.68.

Figure p.10 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.

Figures p.11–12 present adjusted mortality rates, by modality and vintage, for cardiovascular disease and infection. The populations and statistical methods are same as those used in Figure p.10. The reference population consists of 2001 period prevalent ESRD patients.

Figure p.13 illustrates five-year survival by first modality. The populations for the 1988–1992 and 1993–1997 cohorts include incident patients on hemodialysis or peritoneal dialysis on the first ESRD service date, and patients receiving 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 2002, while transplant patients are followed from the first transplant date until death or the end of 2002. 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.

Figures p.14–15 include prevalent hemodialysis patients in the CPM database with at least one valid URR measurement. For each patient, each valid URR is transformed into five categories (<60, 60–<65, 65–<70, 70–<75, 75+), and a median URR is calculated. If a patient’s median lies between two categories, 0.5 patients are added to each category above and below the median. Although actual URR measurements are available from the CPM data, this method is used in order to mirror the method used when obtaining the URR in claims, where only the category is reported. Patients in Figure p.15 only include those who reside in one of the 50 states.

Figures p.16–17 include prevalent hemodialysis patients in the CPM database whose current access is known; Figure p.17 includes only patients who reside in one of the 50 states.

Data in Figures p.18–19 include prevalent dialysis patients in the CPM database who have at least one valid hematocrit or hemoglobin value, or a valid value for the prescribed EPO dose. For each patient, hematocrit values are divided by three to convert them to hemoglobin values. For data collected in 1997 and 1998, a hemoglobin value is substituted if the corresponding hematocrit value is missing or invalid, and for data collected after 1998, hemoglobin values are used instead of hematocrit values. A mean hemoglobin value is calculated for each patient, then the mean is calculated for all patients across a given year.

Figure p.20 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. The figure also 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 ≥20 administrations per month. The mean EPO dose is adjusted in the same way used in Chapter Five, with a patient’s time at risk including only those days in which he or she is not in an inpatient hospital setting. (Because inpatient claims data for 2003 were not available when this ADR went to press, time spent in an inpatient hospital setting is not removed from the time at risk in the 2003 EPO doses calculated with the new method.)

Figure p.21 compares inpatient and total monthly costs from six months before to six months after the initiation of renal replacement therapy for ESRD patients incident during 2001. The Medicare ESRD patients include all patients age 67 years or older at the initiation of therapy and with Medicare as primary payer for two years prior to initiation. The Employer Group Health (EGHP) data includes ESRD patients incident in 2001 and eligible for EGHP coverage for the entire 12-month period (the EGHP database is described on page 228). Costs are aggregated from the respective inpatient files for the inpatient total, and from the entire claims databases for total costs; they are then totaled on a monthly basis, based on the from date of each claim. Figure p.22 shows the cumulative percentages of these patients who were seen by nephrologists, internists, cardiologists, and general practitioners during the same 12-month period. Physician specialty is determined using the specialty codes supplied in the physician/supplier claims data.

Figures p.23–24 show Medicare costs for Medicare ESRD patients, using the HCFA methods presented in the discussion of Chapter Twelve.

Table p.c describes the adjusted odds ratios, for demographics and self-reported diseases, of the presence of CKD (defined as an eGFR <60 ml/min/1.73m2) in the NHANES III (1988–1994) population, age 20 and older. Covariates in the model include age; gender; race/ethnicity; self-reported hypertension, cardiovascular disease, and diabetes mellitus; years of education; income; and insurance coverage. For each factor the reference group is, respectively, patients age 20–39, males, non-Hispanic whites, patients with no self-reported hypertension, patients with no self-reported cardiovascular disease, and patients no self-reported diabetes. SUDAAN (Research Triangle Institute, Research Triangle Park, NC) is used to analyze all data from this complex survey, and a weighted logistic regression model is used to examine the relationship between CKD and each cardiovascular risk factor.
Figures p.25–28 present data on the NHANES III and NHANES 1999–2000 populations, age 20 and older. CKD stages are defined by the estimated glomerular filtration rate (eGFR, in ml/min/1.73/m²), calculated by the modified MDRD method (Levey et al.). Participants are classified into four groups: Stage 1 (eGFR ≥ 90), Stage 2 (60 ≤ eGFR < 90), Stage 3 (30 ≤ eGFR < 60), and Stage 4–5 (eGFR < 30). To define anemia we use criteria from the World Health Organization: a hemoglobin concentration below 13 g/dl in men and below 12 g/dl in women. Both hypertension and diabetes are self-reported comorbidities identified through the survey's medical history questionnaires.

Table p.d describes adjusted odds ratios, for treatable cardiovascular risk factors, of the presence of CKD in the NHANES III (1988–1994) population, age 20 and older. Odds ratios for each risk factor are adjusted by age, gender, race/ethnicity, self-reported hypertension, self-reported cardiovascular disease, self-reported diabetes mellitus, years of education, income, and insurance coverage. Reference groups for the factors listed in the table are as follows: non-smoker, BMI <30 kg/m², blood pressure <120/80 mmHg, total cholesterol <200 mg/dl, glycosylated hemoglobin <7 percent, C-reactive protein <1 mg/dl, homocysteine 2.0–6.9 µmol/l, absence of anemia, urinary albumin/creatinine ratio <30 mg/g, and no treatable cardiovascular risk factors.

Treatable cardiovascular risk factors here and in Figure p.29 include smoking, BMI ≥30 kg/m², total cholesterol ≥240 mg/dl, systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥90 mm Hg, glycosylated hemoglobin ≥8 percent, homocysteine <12 g/dl in females and <13 g/dl in males, C-reactive protein ≥1 mg/dl, homocysteine >11 µmol/l, and urinary albumin/creatinine ratio ≥30 mg/g. Figure p.30 excludes glycosylated hemoglobin, as this measure was not included in NHANES 1999–2000, but otherwise uses the same risk factors.

The total number of treatable cardiovascular risk factors was studied only in Phase II subjects of NHANES III. A weighted logistic regression model is used in both Table p.d and Figures p.29–31 to examine the relationship between CKD and each risk factor, and CKD stages are the same as those used in Figures p.25–28.

**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, 1991–2002. 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. Patients not residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories are omitted from the study, as are those who have a missing date of birth, who have ESRD for fewer than 90 days prior to the start of the reporting interval, or who are lost-to-follow up during the study period. 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 Parts A and B coverage during the study periods. All ages are calculated at the end of the graphed time period. Influenza vaccinations are identified by CPT codes 90724, 90657, 90658, 90659, and 90660, and HCPCS code G0008; pneumococcal vaccinations are identified through CPT codes 90669 and 90731, and HCPCS codes J6065 and G0008.

Objective 4.5: The study cohort for Figures hp.14–15 and Table hp.e includes patients from 1991–2002 who are younger than 70. Percentages are calculated as the number of patients placed on the deceased donor organ waiting list or receiving a deceased donor transplant within one year of initiating ESRD therapy divided by the number of patients without a living donor available (i.e., patients receiving a living donor transplant are excluded.) Percentages are estimated using the Kaplan-Meier method. Note that this method differs from those used in previous ADRs, which showed the percent of point prevalent dialysis patients on the waiting list as of December 31 of the given year.

Objective 4.6: The study cohort here includes patients from 1991–1999 who are younger than 70 at ESRD certification. Patients are followed for three years, from ESRD certification until the first of death, transplant, or censoring at three years post-transplant. Percentages are calculated using the Kaplan-Meier methodology.

Objective 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. Methods and codes used to determine rates of HbA1c testing and eye exams 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), while those for lipid testing are described in the methods for Chapter One. 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 Parts 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. For both populations, patients with a missing date of birth are omitted, as are those not residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories.

**Chronic kidney disease**

**CHAPTER ONE**

Figure 1.1 shows trends in the numbers of patients with chronic kidney disease (CKD), by diabetic and hypertensive status, for the general Medicare and selected EGHP populations. Patient cohorts here are the same as those used for Figure 2 in the Précis.

According to a previously validated methodology for using Medicare claims to identify diabetic patients, a patient is diabetic if, within a one-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), or two or more Part A institutional claims (outpatient) or Part B physician/supplier claims. Using this methodology, we identify CKD patients with or without diabetes or hypertension in each calendar year. Codes used to define CKD, diabetes, and hypertension 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; and hypertension: 362.12; 401.x–405.x; and 437.2.

Figures 1.2–5 show trends in unadjusted incident CKD rates, by diabetic and hypertensive status, for the general Medicare and selected EGHP populations. Included general Medicare patients are those continuously enrolled in Medicare Parts A and B for any two consecutive calendar years from 1992 to 2002, not enrolled in an HMO any time during the two-year period, and age 20 and older. For the selected EGHP population, patients are those continuously enrolled in a fee-for-service plan for any two consecutive calendar years, 1999–2002, with no gaps of coverage greater than 40 days, and age 20–65. We exclude from the study those diagnosed with ESRD any time before the end of the first year of the two-year period. Disease status, including CKD, diabetes, and hypertension, is defined in the first year using the methods described above. Patients are categorized into four groups: diabetes/hypertension, diabetes/non-hypertension, non-diabetes/hypertension, and non-diabetes/non-hypertension. For each group, those not identified as having CKD in the first year are followed in the second year to track CKD events. The incident CKD rate per 1,000 patients at risk at the beginning of each calendar year is calculated for 1993–2002 (Medicare) or 2000–2002 (EGHP). Figure 1.6 shows the geographic variations in unadjusted incident CKD rates for both populations in 2002; this figure includes patients younger than 20.

Figures 1.7–10 present trends in unadjusted prevalent CKD rates, by diabetic and hypertensive status, for the general Medicare and EGHP populations. Study cohorts are constructed in the same way as those for Figure 1.1; we further exclude from the study patients younger than 20. The prevalent CKD rate per 1,000 patients is calculated for each calendar year from 1992 to 2002 (Medicare) or from 1999 to 2002 (EGHP). Figure 1.11 illustrates geographic variations in unadjusted prevalent rates of CKD for the general Medicare and selected EGHP populations in 2002; this figure includes patients younger than 20.

Figures 1.12–16 show adjusted cause-specific hospital admission rates for general Medicare patients in 1993–2002 and EGHP patients in 2000–2002, using the 2002 cohort as reference group. The prevalent Medicare cohort includes patients continuously enrolled in Medicare Parts A and B, with no HMO coverage, without ESRD, and age 20 and older on the last day of the one-year entry period. The prevalent EGHP cohort is comprised of patients age 20–65 with fee-for-service coverage during the entire calendar year, and alive on the last day of the entry period. Each patient is followed up to one year from January 1 of the year after the entry period.

CKD and non-CKD patients are defined using the same methodology described for Figure 1.1. Principle ICD-9-CM diagnosis codes for the cause-specific inpatient hospitalization categories are as follows: CHF, 398.91, 425, 428, 402.X1, 404.x1, and 404.x3; ISHD, 410–414; arrhythmia, 426 and 427; pneumonia, 480–487.0, and bacteremia/ septicemia, 038–038.9 and 790.7.

For general Medicare patients, adjusted admission rates are calculated using the direct adjustment method (described in the section on statistical methods). Rates by age are adjusted for gender, race, and diabetic status; rates by gender are adjusted for age, race, and diabetic status; and rates by race are adjusted for age, gender, and diabetic status. Methods are the same for the EGHP patients, but race is ignored since it is not included in the database. Adjusted rates are not directly comparable for data using different adjustment factors.

Figures 1.17–22 present adjusted mortality rates and relative risks of mortality after hospitalization for AMI, ISHD, CHF, bacteremia/septicemia, pulmonar yinfections, and urinary tract infections. The cohort includes prevalent general Medicare CKD patients, 2000, who are enrolled continuously in Medicare Parts A and B. Those diagnosed with ESRD any time during the entry period of 1998–1999, and those enrolled in a managed care program (HMO), are excluded, as are patients with the relevant diagnosis in 1998; 1999 is used to define case and control groups. Patients are assigned to the case group if they have a cause-specific hospitalization between January 1, 1999 and December 31, 1999, while the control group is comprised of patients with no cause-specific hospitalization during the same period. Cases are followed from the first cause-specific hospitalization until death, Medicare payor change, or December 31, 2002; patients in the control group are followed from January 1, 2000 until death, cause-specific hospitalization, Medicare payor change, or December 31, 2002. Six-month intervals are used in the Poisson model; data are adjusted for baseline age, race, gender, and comorbidity.

Principle ICD-9-CM diagnosis codes from inpatient claims are used to identify the hospitalizations. Codes for ASHD, CHF and bacteremia/septicemia are the same as those used in Figures 1.12-16. Other codes are as follows: AMI, 410, 410.xb, and 410.x1; pulmonary infections, 460–466, 473–474.0, 475–477.9, 478.22–478.24, 480–491, 510–511, 513.0, and 518.6; and 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.

**Preventive healthcare in CKD patients**

Methods and codes used to determine rates of glycosylated hemoglobin (HbA1c) testing are taken directly from HEDIS 2002 specifications. Because HEDIS 2002 does not address lipid testing, influenza vaccinations, pneumococcal vaccinations, oral vitamin D hormone use, calcium phosphorus testing, or parathyroid hormone testing, we have created algorithms for these analyses. For the Medicare population, patients with Medicare as a secondary payor, ineligible for Medicare, or enrolled in an HMO are omitted, as are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories, who have a missing date of birth, or who do not survive the entire reporting period. In the EGHP population, patients age 65 and older and those without a fee-for-service plan covering the entire study period are excluded, and in Figure 1.28, showing oral vitamin D use, patients without
continuous prescription drug coverage are excluded as well. For both populations, patients diagnosed with ESRD before or during the study period are omitted from all analyses, and data on diabetic HbA1c testing exclude non-diabetic patients. Age is calculated at the end of the testing year for the Medicare population, and at the testing year for the EGHP population, since only birth year information is available for this population.

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

For Figures 1.23–24, patients are enrolled in each program (Medicare or a fee-for-service plan) before January 1 of each study period, and have 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. HbA1c testing is identified by CPT code 83036, and lipid testing by CPT codes 80061, 82465, 83715–83721, and 84478.

For Figure 1.25, patients are enrolled in each program before January 1 of each study period. Pneumococcal vaccinations are identified during this period through CPT codes 90669 and 90731, and HCPCS codes J6065 and G0008. Claims during this period are also searched for CKD and diabetes.

Cohorts for Figures 1.26–1.27 and 1.29–30 include patients enrolled in each program before January 1 of each year. For influenza vaccinations, claims are searched between September 1 and December 31; for all other testing, claims are searched during the entire year. CKD and diabetes are also diagnosed during each one-year period. Influenza vaccinations are documented by CPT codes 90724, 90657, 90658, 90659, and 90660, and HCPCS code G0008; lipid testing codes are the same as those used for Figure 1.21; calcium phosphorus testing is identified through CPT codes 82330, 82310, and 84100; and parathyroid hormone testing is identified by CPT code 83970.

Figure 1.28 illustrates trends in oral vitamin D hormone therapy in CKD patients. We use data from the Medicare Current Beneficiary Survey (MCBS)—a national survey of older, disabled, and institutionalized beneficiaries—to measure therapy use in Medicare patients age 65 and older. To ensure that we obtain information on all therapy received by each person during each study year, included patients are continuously enrolled in Medicare Parts A and B during the entire year, survive until the end of the year, and have a completed survey, are not enrolled in a managed care organization, and do not have ESRD; they also reside in the 50 states and the District of Columbia. Drug use information is from the MCBS Cost and Use data file “Prescribed Medicine Events,” and SUDAAN (Research Triangle Institute, Research Triangle Park, NC) is used to analyze all data. For the EGHP population we measure hormone use in CKD patients age 20–64 who have fee-for-service coverage. Diabetes is defined by ICD-9-CM diagnosis codes 250, 357.2, 362.0x, and 366.41, and CKD by ICD-9-CM diagnosis codes 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—one code from Part A inpatient, skilled nursing facility, or home health claims; or two from Part A outpatient claims or Part B claims.

Oral vitamin D hormone use is identified from the following drug names: Calcifediol, Calciferol, Calciferol drops, Calcitriol, Calcerol, DHT, DHT intensol, Dihydrotachysterol, Doxercalciol, Drisdol, Drisdol drops, Ergocalciferol, Hectorol, Hytakerol, and Rocaltrol.
Incidence & prevalence

CHAPTER TWO & REFERENCE SECTIONS A & B

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

Because data are available only for patients whose ESRD therapy is reported to CMS, patients who die of ESRD before receiving treatment or whose therapy is not reported to CMS are not included in the database. We therefore qualify the terms incidence and prevalence as incidence and prevalence of reported ESRD. Some ESRD registries use the term “acceptance into ESRD therapy.” We believe, however, that “incidence of reported ESRD therapy” is more precise, because “acceptance” implies that remaining patients are rejected, when they may simply not be identified as ESRD cases or may not be reported to CMS.

Beginning with the 1992 ADR, lost-to-followup 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.

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 M) 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, completed at the dialysis unit for each new ESRD patient treated at that unit and sent to CMS through the ESRD networks. This form establishes Medicare eligibility for individuals previously 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; total patient counts for this group, and for patients with no 2728 form, are presented in Table C.3.

Figures 3.2–5 include incident patients, 1984–2001, who are age 20 and older, survive at least one year plus 90 days after initiating dialysis, and have Medicare Parts A and B coverage. Data on diabetes as the cause of renal failure are obtained from the Medical Evidence form. The period from 90 days after initiation to one year plus 90 days is searched for inpatient claims with diagnosis codes for cardiovascular causes and hypertension. The first three diagnosis fields are searched across all years.

Using EGHP patients in the Medstat MarketScan Database, Figures 3.6–9 illustrate trends in the cumulative percentage of incident dialysis patients receiving prescription drug therapy. Included patients have a confirmed ESRD status, a first service date that is not in the current year and not less than 60 days after the enrollment start date, and, for transplant patients, a transplant date later than the current year. Analyses of prescription drug use are censored during the observation period at transplant. For comorbidity definitions and drug libraries, please refer to the discussion of Figures 1.31–34. Lists of the specific medications included in these analyses can be found on our website.

Table 3.a displays the odds ratios of having experienced congestive heart failure at the initiation of renal replacement therapy or in the ten preceding years. Odds ratios are estimated from separate but identical logistic models for white (n=107,626), black (n=44,823), Native American (n=2,204), Asian (n=5,393), and Hispanic (n=18,087) patients for whom a Medical Evidence (ME) form was submitted between May 1, 1995, and July 1, 2003. Patients with missing measurements of albumin, blood urea nitrogen, or creatinine are excluded, as are those with a value other than 3.2 or 3.5 in the serum albumin field on the ME form (see page 230 for details). The response covariate, congestive heart failure, is indicated on the ME form, and all prognostic covariates are taken or calculated directly from this form.

Table 3.b displays the odds ratios of having an estimated glomerular filtration rate (eGFR) greater than the population’s gender-specific mean. Odds ratios are estimated from separate but identical logistic models for white (n=107,051), black (n=44,823), Native American (n=2,198), Asian (n=5,389), and Hispanic (n=18,087) patients for whom a Medical Evidence (ME) form was submitted between May 1, 1995, and July 1, 2003. Patient exclusions are the same as in Table 3.a. GFR is estimated using the Schwartz formula for patients age 0–18, and the four-variable formula of Levey et al. for patients 19 and older. The population mean eGFR is equal to 8.3 ml/min/1.73 m² among female patients, and 9.1 ml/min/1.73 m² among male patients. All prognostic covariates are taken or calculated directly from the Medical Evidence form.

Nursing home ESRD patients

Data on nursing home patients with ESRD are obtained from the CMS Minimum Data Set (MDS). We define an incident ESRD cohort within the nursing home as those patients who develop ESRD while they are in the nursing home, rather than as ESRD patients who go into the nursing home after their first service date. Prevalent nursing home ESRD patients are those who are nursing home residents and also ESRD on December 31, 1999.

These definitions allow us to estimate the percent of all incident and prevalent ESRD patients who were in the nursing home in 1999, but not the percent of all nursing home patients who
were ESRD. The definitions reflect limitations in the MDS-USRDS merged data. The calendar year 1999 was the first and only year that complete MDS data were available on the USRDS population, and nursing home residence status is transitional. Since we have no longitudinal data, we cannot determine which ESRD patients moved in or out of the nursing home prior to and after 1999, and are thus unable to define them as incident or prevalent nursing home patients. We also do not have the entire MDS cohort data that include non-ESRD nursing home residents, so we are unable to calculate what percent of nursing home patients in 1999 were incident or prevalent ESRD patients.

Several criteria are used to define a patient as a nursing home resident at a particular point in time:

- If he or she is in the nursing home on the evaluation date, the length of time from the nursing home admission date to the evaluation date is at least 15 days, and either:
  - the length of the nursing home stay period surrounding the evaluation date is at least 90 days, or
  - the length of the nursing home stay period surrounding the evaluation date is at least 90 days, including temporary departures no longer than 15 days each, or
  - the length of the nursing home stay period surrounding the evaluation date is less than 90 days, terminating with the patient's death.
- If he or she is out of the nursing home on the evaluation date, and
  - the length of time from the nursing home discharge date to the evaluation date is no more than 15 days, and
  - the length of the discharge period is no more than 90 days, and
  - the previous nursing home stay period is at least 90 days.
- If he or she is a new nursing home patient admitted no more than 15 days after the evaluation date, and the length of the following nursing home stay period is at least 90 days.

Note that it is possible for a patient to be an incident nursing home ESRD patient for a given year, yet not a prevalent nursing home ESRD patient for that year, even when he or she is still alive at the end of the year. To be included in a nursing home ESRD cohort, a patient must be both a nursing home resident and an ESRD patient. Someone who leaves and returns to the nursing home might be a nursing home ESRD patient on the first service date, but not on the following December 31. Similarly, an incident ESRD patient might not be a nursing home resident on the first service date, but may be one on the following December 31. In this case, the patient would appear in the nursing home ESRD prevalent cohort for that year, but not in the corresponding incident cohort.

Figure 3.40 illustrates cognitive and physical impairment in nursing home ESRD patients. This is determined by looking at the most recent MDS form reported within the six months prior to the first service date, for incident patients, and within the six months prior to December 31, for prevalent patients. Note that every patient does not have a form reported within that time period, and of those who do have forms, not every one reports a value for every item. The percentage for each item calculated here includes only patients for whom forms are found, and the value reported. Thus the denominator for each percentage calculation can be a different number.

Table 3.d shows pre-existing diseases in prevalent nursing home ESRD patients. These are determined by examining all MDS forms for each patient, and noting whether the particular disease is reported prior to December 31, 1999.

Figure 3.42 shows unadjusted annual death rates for the 1999 period prevalent cohort of nursing home patients with ESRD, followed through March 31, 2002. These rates are compared to death rates for the entire ESRD period prevalent cohort in 1998–2000, as reported in the 2002 Annual Data Report.

Figure 3.43 presents data on patient inability to ambulate and to transfer, as reported on the Medical Evidence form. Values for incident nursing home patients with ESRD are reported for the 1999 incident cohort and the 1998–2000 (combined) incident cohort, and compared to corresponding values for all ESRD patients incident in 1999.

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. Unless noted otherwise, incident and point prevalent cohorts without the 60-day stable modality rule are used in the analyses.

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; 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)

In Chapter Four this year we have introduced new data on treatment modality by ESRD exposure time (Figure 4.9), the cumulative probability of changing modalities (Figures 4.10–12), and patients who are listed as regaining renal function (Figures 4.19–22 and Table 4.g).

Figures 4.9–12 use the combined 1995–1997 ESRD incident cohort with the built-in 60-day stable modality rule. All incident patients are followed from the day of ESRD initiation to a maximum of five years. The cumulative probabilities are estimated...
using the Kaplan-Meier method, censoring at change in dialysis modality, transplantation, and the end of the follow-up period.

For a description of the provider data used in Figures 4.13–18, please see the discussion of Chapter Eleven.

In Figures 4.19–23 and the associated table, the cohort includes incident dialysis patients who are documented in the SIMS database and are diagnosed with “regained” function as of December 31, 2003. The cumulative probabilities in Figures 4.21–23 are estimated using the Kaplan-Meier method, censoring at dialysis, transplantation, and the end of the follow-up period.

Reference Section D is divided into three sections. The first, Tables D.1–5 and D.9–11, 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 as of December 31 for point prevalent patients.

Table D.6 shows modality at 90 days and two years after first service for all incident Medicare patients beginning renal replacement therapy from 1998 to 2000. 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.7–8, presents counts of prevalent patients alive at the end of each year, by ESRD exposure time and modality. Table D.7 shows counts by the number of years of ESRD, while Table D.8 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.

Clinical Care

CHAPTER FIVE & REFERENCE SECTION L

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 and 5.24–33 are obtained from EPO claims data, while in Figures 5.34–45 Part B physician/supplier claims data as well as the CMS ESRD Clinical Performance Measures (CPM) Project supply information regarding venous accesses and fistulas. Data on urea reduction ratios (URR) in Figure 5.1 come from Part A institutional outpatient claims. Data on Kt/V and vascular access in Figure 5.1 come from the CPM Project, while data on albumin come from the Medical Evidence form.

All figures not related to prescription drug therapy include data for Medicare patients only.

Figure 5.1 shows information on adult dialysis patients from a number of sources. For both Kt/V measurements, 2002 CPM data are used to calculate a mean Kt/V value for each patient from the 1–3 values present for each patient, and the percent of patients with a mean Kt/V over a certain threshold is determined. For prevalent hemodialysis patients in 2002, each patient’s URR is obtained from the G-modifier attached to CPT code 90999, with a revenue code of 821 or 825. Each measurement is categorized with a mean Kt/V over a certain threshold is determined. For prevalent hemodialysis patients, data are calculated as the percent of those beginning dialysis between 1991 and 2001 and using a fistula at the time of the 2002 CPM data collection. Hemoglobin is calculated for EPO-treated, 2002 prevalent hemodialysis patients, using available EPO claims during the year. EPO claims with a dose per administration of less than 500 or greater than 80,000 units, or with a hematocrit value less than 10 or greater than 50, are omitted. For each patient a yearly mean hemoglobin is calculated as the mean of all hematocrit values divided by three. Data on albumin are obtained for incident hemodialysis patients in 2002 who have a valid value on their Medical Evidence form; those with a lower limit equal to zero are omitted.

Figures 5.2–10 present data on diabetic preventive care. ESRD patients without Medicare Parts 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 do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories, who have a missing date of birth, who do not survive the entire reporting period, who have ESRD for fewer than 90 days prior to the start of the reporting interval, or who are lost-to-followup during the study period.

Age is generally calculated at the end of the study period. Comparisons of diabetic care in ESRD and general Medicare patients are limited to those age 67–75, while data on diabetic care in the ESRD population include patients age 18–75.

Methods and codes used to determine screening rates for diabetic HbA1c and lipid testing are described in the methods for Chapter One. HCPCS codes A4253–A4256, A2558–A2459, E0607, and E0609 are used to identify diabetic testing supplies. Patients are defined as having diabetes either through medical claims (one Part A, two Part B, or two outpatient), or if diabetes is listed on the Medical Evidence form as the primary cause of ESRD or as a comorbid condition.

Figures 5.2, 5.5, and 5.8 compare rates of diabetic preventive care in ESRD and Medicare populations, while Figures 5.4, 5.7, and 5.10 compare rates in dialysis and transplant patients. The ESRD population includes patients initiating therapy at least 90 days prior to January 1, 2001, alive on December 31, 2002, and with diabetes defined in 2001. The general Medicare population consists of patients continuously enrolled in Medicare Parts A and B in 2001, alive on December 31, 2002, and with diabetes defined in 2001. Rates include patients receiving at least one test during 2002. For Figures 5.4, 5.7, and 5.10, patients with unknown dialysis type are excluded.

For Figures 5.3, 5.6, and 5.9, the ESRD cohort includes patients starting therapy at least 90 days prior to January 1 of the first year of each study period and with diabetes in the first year. The general Medicare population includes patients enrolled in Medicare Parts A and B before January 1 of the first year of each study period, continuously enrolled in the program for the entire period, and with diabetes in the first year. Diabetic HbA1c testing, diabetic lipid testing, and diabetic testing supplies are tracked in the second year of each period. HbA1c and lipid testing claims made within 30 days of the last claim for each patient are excluded. Code A4253 (blood glucose test or reagent strips for home blood glucose monitor, per 50 strips) is used to determine the number of blood glucose tests per day, and patients with a missing service unit here are not included. Patients are categorized as having no tests recorded or as averaging one or fewer tests per day, 1–2 tests per day, or more than two tests per day.

Figures 5.11–18 display trends in the cumulative percentage of diabetic ESRD patients who receive prescription drug therapy, using EGHP patients in the Medstat MarketScan Database. Analyses are censored at the date of ESRD initiation. In Figures 5.19–23 we illustrate trends in the cumulative percentage of prevalent di-
alysis patients who receive prescription drug therapy, using the same database. Included patients have a confirmed ESRD status, a year of first service that is not later than the current year, and, for transplant patients, a transplant date later than the current year and a first service date earlier than the transplant date. Prescription drug usage is censored during the observation period at transplant. For commonality definitions, please refer to the discussion of Section 1.31-34. Lists of the specific medications included in these analyses can be found on our website.

Data on mean EPO dose per week in Figures 5.24–33 include patients with at least one EPO claim during the time period and ≤20 administrations per month; data on mean hemoglobin per month include patients with at least one EPO claim during the time period 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 mean hemoglobin (hematocrit divided by three) is calculated from claims during the time at risk, and the average of these values is calculated.

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.

Figures 5.24–26 include 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). Figures 5.24–25 display the mean weekly EPO dose per patient weight (kg), and therefore require that patients have a valid weight listed on the Medical Evidence form, along with a known unit affiliation. Patients with a recorded weight of greater than 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. Figure 5.26 includes only patients who are in both the USRDS and CPM databases, and uses CPM Project data on patient weight. Dose represents the prescribed dose from the CPM data.

Figures 5.27–32 include prevalent hemodialysis patients with at least three months of dialysis prior to June of 2002, who have a valid EPO claim during each month of June through December, and who dialyze at an identifiable provider (without switching) through their last valid EPO claim of 2002. It is also restricted to patients from providers with at least ten patients meeting this criterion. Mean EPO doses are adjusted for inpatient days. 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 during or after June 2002).

Figures 5.33–37 include incident hemodialysis patients who begin dialysis during 1999–2001, who have at least one valid EPO claim during five out of the first six months of dialysis after day 90, and who remain alive and on hemodialysis. Patients categorized as “Hemoglobin <11 g/dl” are those whose mean hemoglobin at least five out of those first six months is less than 11.0 g/dl. Mean EPO doses are adjusted for inpatient days. Figure 5.34 includes only patients who are also in the CPM database, and access, determined from the 2002 CPM data, is the access used at the time of data collection.

In Figure 5.35, patients are identified as having a disease if they have at least one Part A or Part B claim during those first six months with an ICD-9-CM diagnosis code for that disease, as follows: solid tumors, 140.x–202.x, excluding 173.x (skin cancer); chronic blood loss, 150.x–154.x, 280.0, 286.0–286.6, 448.0, 456.0, 531.4, 531.6, 532.4, 532.6, 533.4, 533.6, 534.4, 534.6, 578.9, 626.8, 218.9, 456.20, 530.82, 537.83, 562.02, 562.03, 562.12, 562.13, and 569.85; AIDS, 042.x, 08V0.8, and 079.53; inflammatory disease, 720.x, 710.x, 446.x, 556.x, 557.x, 714.0–714.2, 721.0–721.3, 721.9, 447.6, 447.8, 695.2, 555.9, 273.2, 714.30–714.32, 728.89, and 728.19; CVD, 410.x, 411.x, 430.x–438.x, 440.x–444.x, 447.x, 451.x–453.x, and 557.x; and CHF, 425.x, 428.x, 398.91, 402.x1, 404.x1, and 404.x3.

For Figures 5.36–37, Medicare claims are used to identify infections and clotting events. CPT codes used to identify clotting infections include 35875, 36550, 36831, 36860, 36861, 36870, 37201, 75896, and G0159. ICD-9-CM codes, used for the remaining infections and events, include: device infection, 996.62 and 996.68; sepsis, 038.x; bacterial infection, 001.x–004.x, 010.x–018.x, 020.x–027.x, 030.x–036.x, 038.x–041.x, 073.x, 076.x, 080.x–083.x, 087.x, 088.x, 091.x–094.x, 100.x–107.x, and 008.0–008.5; fungal infection, 102.x–109.x, 110.2, 110.4, 110.9, 121.2, 121.5, 122.1, 121.21–121.85, and 112.89; viral infection, 045.x–051.x, 055.x–057.x, 060.x–066.x, 071.x, 072.x, 074.x, 075.x, 042.x, 052.x–054.x, 008.6, 008.x, 078.2–078.7, 070.0–070.3, 070.6, 070.9, 079.51–079.53, 079.81, 070.41–070.44, 070.49, 070.51–070.54, and 070.59; and parasitic infection: 006.x, 007.x, 084.x–086.x, 120.x–131.x, and 136.2–136.5.

Figures 5.38–41 include hemodialysis patients who are prevalent prior to October 1 of the prevalent year and who are also in the CPM database. Data on age, race, gender, access, and URR are all obtained from the CPM data.

Figures 5.42–45 include incident dialysis patients, 2001, who have Medicare as their primary payor and are also in the CPM database. Vascular access is determined from CPM data, while infections and complications are identified from Medicare claims during the first 12 months of incidence, and censored at loss of Medicare as the primary payor, death, or a change in modality. CPT codes used to identify infections and complications not already described are as follows: catheter removal, 36535; catheter insertion, 36489, 36491, 36800, and 36533; fistula removal, 37607; fistula insertion, 36189, 36821, and 36825; graft removal, 35900 and 35903; graft insertion, 36830; angioplasty, 35460, 35476, and 75978; declotting procedure, 35875, 36550, 36831, 36860, 36861, 36870, 37201, 75896, and G0159; revision, 35190, 38576, 35900, 35903, 35910, 36534, 36535, 36815, 36832–36834, 37190, 37607, and M0900; peritoneal dialysis catheter removal, 49422; and peritoneal dialysis catheter insertion, 49412, 49419, 49420, and 49421. ICD-9-CM codes include: hemodialysis device infection, 996.62; peritoneal dialysis device infection, 996.68; and peritonitis, 567.x, 540.0, 540.1, 614.5, and 614.6.

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 followup time at risk. One difference is the exclusion in Reference Section E of patients of races that are unknown or other than black, 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 model-based adjustment method on the observed category-specific rates. This method is described further in the discussion of Section E, and in the Statistical Methods section later in this appendix.

Figure 6.1 presents the percent change in adjusted hospital admission rates for period prevalent dialysis patients, 1993–2002. 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 2002 dialysis patients as the reference cohort. Vascular access admissions include both complications and procedures: complications are defined through a principal ICD-9-CM diagnosis code of 996.1, 996.62, or 996.73; and procedures are defined through a principal procedure code of 38.95, 39.27, 39.42, 39.43, 39.93, or 86.07. 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 codes 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, 996.6–996.99, 997.62, 998.5, 999.3, V01–V069, V08, and V09.

Figures 6.2–3, 6.7–9, and 6.31–33 present adjusted rates of total hospital admissions per patient year (and hospital days per patient year in 6.31–32). Figures 6.2–3 and 6.31–33 include period prevalent ESRD patients, with the 2002 ESRD cohort as the reference. Figures 6.7–9 include period prevalent dialysis patients age 20 and older, with the 2002 dialysis cohort as the reference. Because the rates in Figures 6.2–3 and 6.7–9 are adjusted for different sets of factors (see figure captions), comparison of rates is appropriate only within a figure, not across figures. Patient vintage in Figure 6.3 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. The categories for cardiovascular disease and infection (in Figures 6.7–9 and 6.32) are defined by the codes listed for Figure 6.1; the infection codes for Figures 6.7–9, however, exclude those due to internal device. For Figures 6.7–9, the principal ICD-9-CM diagnosis codes used for infection due to internal device (related to a vascular access device or peritoneal dialysis catheter) are 996.62 and 996.68. In Figure 6.32, the “other” category includes hospitalizations that are not classified as either cardiovascular or infectious. In Figure 6.33, 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, or 518.6; for vascular access infection, 996.62; for peritonitis, 567.2 or 567.9; for cardiovascular procedures 35–40 (excluding hemodialysis, 39.93, and vascular access procedures, 38.95, 39.27, 39.42, 39.43, and 39.93–39.94); and for heart catheterization, 37.21, 37.22, and 37.23.

Figures 6.10–12 show adjusted admission rates for hospitalizations with a cardiovascular procedure. Period prevalent adult (age 20 and older) dialysis patients are included. While the cause-specific admission rates in 6.7–9 and 6.31–33 include only principal diagnosis and procedure codes, the rates in Figures 6.10–12, in contrast, include any hospitalization with at least one principal or secondary ICD-9-CM procedure code for the cardiovascular procedure category. Therefore, the more inclusive rates here reflect all hospitalizations with a cardiovascular procedure, rather than only hospitalizations for the primary purpose of a cardiovascular procedure (as in Figure 6.33). The cause-specific categories are not mutually exclusive, for a hospitalization that includes more than one type of cardiovascular procedure will be counted under each category. The cardiovascular procedure category includes ICD-9-CM procedure codes listed in the discussion of Figure 6.33 (excluding vascular access procedures), but here all secondary codes are included in addition to principal codes. Other principal and secondary procedure codes are as follows: bypass, 36.1x; stent/angioplasty, 36.01, 36.02, 36.05, and 36.06; and valve procedures, 35.0x–35.2x and 35.31–35.33.

Figures 6.13–15 display adjusted vascular access insertion rates for period prevalent adult hemodialysis patients. These are not hospital admission rates; rather, they are procedure rates that reflect vascular access insertions occurring in an inpatient setting. Vascular access insertions are obtained from CPT codes on Part B physician supplier claims, and are restricted to those occurring in the hospital (during an inpatient stay or emergency room visit). Categories include the following CPT codes: catheters, 36489, 36491, 36533, and 36800; fistulas, 36819, 36821, and 36825; and grafts, 36830. The category of all vascular access insertions includes all of the above CPT codes. Methods are also employed to exclude vascular accessed used for purposes other than dialysis. Rates for catheter and all vascular access insertions exclude patients with specific chemotherapy or parenteral nutrition claims during the year. Part A institutional, Part B physician/supplier, and durable medical equipment claims indicate chemotherapy (CPT codes 96408, 96410, and 96412) or parenteral nutrition (CPT codes B4164–B5200, B9004, B9006, and B9999). Also, catheter insertions with CPT codes 36489, 36491, and 36533 are included only if they are accompanied by an ICD-9-CM line-level diagnosis code or claim-level principal diagnosis code related to dialysis or renal failure (250, 403, 580–589, 593, 996.1, 996.62, 996.73, V45.1, or V56).

Figures 6.47–52 show incident fracture rates in incident adult dialysis patients, 1992–2001. Included patients have Medicare as a primary payor, are followed starting at day 91 after initiation of dialysis until the first fracture event, and are censored at the earliest of the following dates: death, transplant, loss-to-followup, end of Medicare as primary payor status, December 31, 2002, or after one year of followup. Fracture events are defined from principal and secondary ICD-9-CM diagnosis codes in Part A institutional inpatient claims: vertebral, 805.00–806.9; rib, 807.0x–807.1x; long bone, 810.0–810.13, 812.0–812.59, 813.0–813.93, 820.0–821.39, 823.00–823.9, and 824.0–824.9; and hip, 808.0. (Note that fracture of the neck of the femur, ICD-9-CM 820.xx, is included as a long bone fracture, rather than a hip fracture.) Fractures occurring prior to the start of followup and those after the first fracture in the followup period are not counted. Rates are adjusted using the model-based adjustment method with a Poisson model, with 2000–2001 dialysis patients as the reference cohort.

Complications & pregnancy in women with ESRD

Figures 6.57–59 present new data on cancer trends in adult female dialysis patients. The cohort includes 1991–1999 incident female dialysis patients age 20 and older. A one-year entry period is defined following initiation of dialysis (starting at day 91, during months 4–15). Included patients are alive, with Medicare as a
primary payor, and without a transplant through the end of the entry period, and are without breast, cervical, uterine, or ovarian cancer defined during the entry period. Each cancer type is identified by the method of one or more Part A institutional claims (inpatient, home health, or skilled nursing), two or more Part B claims, two or more outpatient claims, or a combination of one Part B and one outpatient claim (on different dates) during the one-year entry period. Patients are followed for up to one year after the end of the entry period to obtain the first hospitalization with breast, cervical, uterine, or ovarian cancer. Followup is censored at the earliest of the following: death, transplant, loss-to-followup, end of Medicare as primary payor status, or one year. A hospitalization with cancer is identified by any institutional inpatient principal or secondary ICD-9-CM diagnosis code: breast, 174.x; cervical, 180.x; uterine, 179 and 182.x; and ovarian, 183.x. A model-based adjustment method is used to calculate adjusted new cancer hospitalization rates. Included 1997–1999 (combined) incident patients are used as the reference cohort.

Figure 6.60 shows treatment distributions among adult female dialysis patients with a new cancer hospitalization. Included patients (N=371) are incident in 1991 to 1999 with a new cancer hospitalization (breast, cervical, uterine, or ovarian) during the followup period (as defined above for 6.57–59). Institutional (inpatient, outpatient, home health, and skilled nursing) and physician/supplier sources provide chemotherapy and radiation claims during the followup period and for up to one year after the first cancer hospitalization. Chemotherapy is identified by revenue codes 0331 or 0335, CPT/HPCPS codes 96400–96549 or J9000–J9999, or an ICD-9-CM procedure code 99.25; radiation is identified by revenue code 0333; CPT/HPCPS codes 77332–77334, 77401–77416, 77427, or 77520–77523; or ICD-9-CM procedure codes 92.2 or 92.3.

Figures 6.61–66 display pregnancy and pregnancy-associated event rates in ESRD patients, 1992–2002. For each calendar year, the period prevalent cohort consists of female patients initiating dialysis or receiving a renal transplant at least 90 days prior to December 31 of the previous year, between 14 and 45 years of age on January 1 of the calendar year, and alive on December 31 of the calendar year. Renal transplant patients whose most recent transplant is more than three years prior to December 31 of the previous year are excluded, as their claims histories are likely to be incomplete. All patients carry Medicare as primary payor and Medicare Part B supplemental insurance during the calendar year. Modality is determined on December 31 of the previous year, and assumed to be fixed during the ensuing calendar year. Diabetic status is determined from the Medical Evidence form.

Because of the longitudinal nature of pregnancy, pregnancy and pregnancy-associated events are determined in the following manner. All pregnancy-associated claims of female patients from 1991 to 2002 are collected. For each patient, claims are ordered chronologically, then divided into disjoint collections on the assumption that consecutive claims within nine months of one another are indications of a single pregnancy. A pregnancy event is defined as a collection of claims with at least one Medicare Part A institutional (inpatient, home health, hospice, or skilled nursing) claim or any combination of at least three Part A outpatient or Part B claims, and the date of the pregnancy event corresponds to the date of the first claim within the collection. A pregnancy-associated event is defined by the presence of at least one Medicare Part A institutional, Part A outpatient, or Part B claim within a collection of claims already defined as a pregnancy event, and the date of that pregnancy-associated event again corresponds to the date of the first claim within the collection. Because of this convention, pregnancy-associated event rates displayed in Figures 6.62–66 must be strictly interpreted as event rates for those pregnancies that began during the calendar year in question.

Figure 6.61 displays pregnancy rates. A pregnancy is indicated by ICD-9-CM diagnosis codes ("diagnosis codes") 630–674, V22–24, or V30–39; ICD-9-CM procedure codes ("procedure codes") 72–75; or CPT codes 59800–59899.

Figure 6.62 displays rates of antepartum complications, identified by the following diagnosis codes: infection, 646.61, 646.63, 647.91, 647.93, 658.4, and 658.8; antepartum hemorrhage, 640.0, 640.9, 641, 656.0, 663.5, 663.8, 674.01, and 674.03; antepartum pre-eclampsia, 642.41, 642.43, 642.51, 642.53, 642.61, 642.63, 642.71, and 642.73; and early labor, 644.

Rates of pregnancy outcomes are illustrated in Figures 6.63–64. Early termination is defined by claims indicating an ectopic or molar pregnancy, an induced abortion, or a spontaneous abortion, while a live birth is defined by claims indicating caesarean section or vaginal delivery. Ectopic or molar pregnancy is indicated by diagnosis codes 630, 631, and 633, and by CPT codes 59120–59151 and 59870; induced abortion, by diagnosis codes 635–636 and CPT codes 59100 and 59840–59857; and spontaneous abortion, by diagnosis codes 632, 634, and 656.4 and CPT codes 59812–59821. Evidence of otherwise unspecified early termination is indicated by diagnosis codes 637 and 639, CPT code 59830, or patient death within nine months of the date of the pregnancy event. If claims for multiple types of early termination are made for a single pregnancy event, the type with the maximum number of claims is selected. Ties are broken in the following descending order of selection: ectopic or molar pregnancy, spontaneous abortion, induced abortion, and unspecified early termination.

Live births are identified through a primary, secondary, and tertiary search of claims. In the primary search, caesarean sections are identified by procedure code 74 and CPT codes 59514–59515 and 59620–59622; vaginal deliveries are identified by procedure codes 72 and 73.5–9, and CPT codes 59409–59410 and 59612–59614. If the primary search fails to identify either type of live birth we conduct a secondary search, in which caesarean section is indicated by diagnosis codes 652, 653, 660, 663, 669.7, 674.2, and V30–39 with delivery suffix 01, and by CPT codes 59510, 59525, and 59618. Vaginal delivery is indicated by diagnosis codes 644.2, 650, 664, 669.3–6, 674.1, V24.0, and V30–39 with delivery suffix 00, 1, or 2, and by CPT codes 59300, 59412, and 59610. For cases in which this search also fails to ascertain live births, we conduct a tertiary search in which evidence of an otherwise unspecified live birth is indicated by diagnosis codes 661, 662, 666–668, 669.8–9, 674.3, 674.8, V22–23, and V24.1–2, and by procedure codes 73.0–4, 75.6, 674.91, 674.93, 658.4, and 658.8; antepartum hemorrhage, 640.0, 640.9, 641, 656.0, 663.5, 663.8, 674.01, and 674.03; antepartum pre-eclampsia, 642.41, 642.43, 642.51, 642.53, 642.61, 642.63, 642.71, and 642.73; and early labor, 644.

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 6.4–5 present five-year survival by modality for 1988–1992 and 1993–1997 incident patients, with modality defined on
the first ESRD service date. Transplant is defined as the first transplant in the incident year. Patients with unknown age, gender, or primary diagnosis, and those with a listed age greater than 110, are excluded, 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 2002, while transplant patients are followed from the first transplant date until death or the end of 2002. All probabilities are adjusted for age, gender, and race; overall probabilities are also adjusted for primary diagnosis. As in the 2003 ADR, the reference population consists of 1996 incident ESRD patients, and adjusted probabilities are comparable across modalities.

Figure 6.6 shows trends in mortality rates by patient vintage for period prevalent dialysis patients alive on renal replacement therapy on January 1, with a first service date at least 90 days prior to the beginning of the year, and reaching day 91 of ESRD treatment during the year. Patients with unknown age or gender, or of a race other than white, 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. Also consistent with the 2003 ADR, the reference population consists of 2001 prevalent dialysis patients, and adjusted mortalities across vintages are comparable.

Figures 6.16–24 present trends in cause-specific mortality by vintage for prevalent dialysis and transplant patients. Patient cohorts, exclusions, and followup are the same as in Figure 6.6, and mortality rates are estimated using generalized mixed models. Causes of death include AMI, ASHD, cardiomyopathy, cardiac arrhythmia, cardiac arrest, cerebrovascular disease, bacteremia/septicemia, pulmonary infection, and malignancy. The collapsed categories of death are presented in Table a.a., on page 245. All rates are adjusted for age, gender, race, and primary diagnosis. The reference population consists of 2001 prevalent ESRD patients, and adjusted mortalities across vintages are comparable.

Figures 6.25–30 present adjusted relative risks of mortality in each six months, up to 48, for incident ESRD dialysis patients, 1992–2000 combined, using the 90-day rule. Relative risks are presented for patients with the following hospitalization events: AMI, heart failure, CVA/TIA, PVD, pneumonia, and vascular access. Patients with the corresponding comorbidity listed on the Medical Evidence form are excluded, as are those enrolled in an HMO or with Medicare as secondary payer, those who have a missing date of birth, and those without Medicare Part B coverage. One-year data from day 91 after the ESRD date are used for defining case and reference: if a patient has a corresponding hospitalization event during the year, he or she is classified into the case group; if a patient survives the year and has no specific hospitalization event, he or she is classified into the reference group. Patients who die in the year and have no specific hospitalization event are excluded, as are those for whom the death date and morbidity date are the same.

Patients in the case group are followed from the incident date of the hospitalization event to death or the censoring date (loss-to-followup or December 31, 2002), while patients in the reference group are followed from day 456 (90 + 365 + 1) after the ESRD date to death or the censoring date (the incident date of the hospitalization event, loss-to-followup, or December 31, 2002). An interval Poisson model is used to obtain the adjusted relative risks, which are adjusted for age, gender, race, primary diagnosis, and vintage. ICD-9-CM diagnosis codes are as follows: AMI, 410–410.01, 410.10–410.11, 410.20–410.21, 410.30–410.31, 410.40–410.41, 410.50–410.51, 410.60–410.61, 410.70–410.71, 410.80–410.81, and 410.90–410.91; heart failure, 402.x1, 425.xx, and 428.xx; CVA/TIA, 430.xx–438.xx; PVD, 440.xx–444.xx, 447.xx, 451.xx–453.xx, and 357.xx; pneumonia, 480.xx–487.0; and vascular access, 996.1, 996.62, and 996.73.

For data in Figure 6.34 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 or gender, or primary diagnosis, or a listed age greater than 110, are excluded. Patients are followed from day 91 until death, transplantation, or the end of 2002, 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 6.35–36. 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 6.35 are also adjusted for vintage. The reference population consists of 2001 prevalent dialysis patients, and adjusted mortalities across modalities are comparable.

Figures 6.53–56 present adjusted relative risks of mortality in each six months for incident ESRD dialysis patients, 1992–2000 combined, using the 90-day rule. The relative risks of mortality—overall and for primary diagnosis, gender, and race—are calculated for patients hospitalized for vertebral, rib, and long bone fractures. The population, study design, and statistical methods are the same as those used in Figures 6.25–30, discussed above. ICD-9-CM diagnosis codes are 805 and 806 for vertebral fracture; 807.0 and 807.1 for rib fracture; and 810.00–810.13, 812.00–812.59, 813.00–813.93, 820.00–821.39, 823.00–823.9, and 824.0–824.9 for long bone fracture.

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 2002, 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. 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.

### Major infections & cardiovascular events

The cohorts used here include 1991–2001 (Figures 6.37–38 and 6.41–42) and 1996–2000 (Figures 6.39–40 and 6.43–46) incident dialysis ESRD patients treated on either hemodialysis or peritoneal dialysis on day 90. Patients enrolled in an HMO or with Medicare as secondary payer are excluded. Also excluded are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories, who have a missing date of birth, or, for Figures 6.39–40 and 6.43–46, who do not have Medicare Part B coverage. For bacteremia/septicemia admissions and for pneumonia events, patients are followed for one year; for mortality and cardiovascular events, they are followed until December 31, 2002.
ICD-9-CM diagnosis code 038.xx is used to identify sepsis hospital admissions, while 480.xx–486.xx and 487.0 identify pneumonia. Cardiovascular disease (CVD) includes acute myocardial infarction (AMI), stroke, congestive heart failure (CHF), and peripheral vascular disease (PVD), identified through the following codes: AMI, 410.xx (excluding 410.x2); stroke, 430.xx–434.xx; CHF, 402.x1, 425, 428, 518.4, and 398.91; and PVD, 440.xx–444.xx (excluding 443.0) and 447.xx (excluding 447.0, 447.6, 447.8, and 447.9). Patients with claims overlapping the starting point of the followup 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 pneumonia rates are obtained in a similar way (Figures 6.37 and 6.41). A Poisson model is used to calculate adjusted sepsis hospitalization rates and adjusted first pneumonia rates (Figures 6.38 and 6.42), and rates are adjusted for age, gender, race, and primary diagnosis. Primary diagnosis is obtained from the Medical Evidence form. All patients are censored at modality change, transplant, death, payor status change, loss-to-followup, and end of the followup period.

For Figures 6.39–40 and 6.43–46, the study design and statistical method are similar to those of Figures 6.25–30. All patients are followed one year after ESRD + 90 days for the first sepsis hospitalization (Figure 6.39–40) and the first pneumonia (Figure 6.43–46). Those with a sepsis hospitalization or pneumonia event (case group) are followed from the incident date of the first event to December 31, 2002 for mortality and the first CVD hospitalization, and those who do not die and have no sepsis hospitalization or pneumonia event during the first year (reference group) are followed from one year after ESRD + 90 to December 31, 2002. For mortality, patients in the case group are censored at transplant; patients in the reference group are censored at transplant and the incident date of the first sepsis or pneumonia event. For CVD hospitalizations, patients in the case group are censored at transplant, death, loss-to-followup, and payor status change; reference patients are censored at transplant, death, loss-to-followup, payor status change, and the incident date of the first pneumonia. Patients who die in the first year and have no sepsis or pneumonia event are excluded from all analyses, as are those with a sepsis or pneumonia event who die or are hospitalized for CVD on the same day. For CVD hospitalizations, patients with AMI, stroke, CHF, or PVD listed as a comorbid condition on their Medical Evidence form are excluded. An interval Poisson model is used to obtain the adjusted relative risks and rates.

All adjusted rates are calculated using the model-based adjustment method, described later in the statistical methods section.

**Standardized mortality & hospitalization ratios**

The traditional method of calculating provider-specific standardized mortality ratio (SMRs) is straightforward, but because differences in provider size may cause very large differences in the variances of the estimated SMRs, direct comparisons of estimated SMRs are unfair, especially for small units. Bayesian hierarchical models, however, can stabilize estimated SMRs to make the comparisons more appropriate. Both methods are described in the section on statistical methods. We use the term BMR here to identify an SMR estimated with the Bayesian method.

The study cohort for figures presenting SMRs consists of 2002 period prevalent dialysis patients. Criteria for including and excluding patients, for considering death as an event, and for censoring are same as those used for the tables in Reference Section E, and are described below. The study cohort for figures presenting standardized hospitalization ratios (SHRs) includes 2002 period prevalent dialysis patients, identified as described for Reference Section E. The total number of admissions, instead of the first hospitalization, is used for the SHRs.

Figure 6.67 displays provider-level SMRs and their 95 percent confidence intervals, estimated with the traditional and Bayesian methods for a random sample of providers so as to compare the differences in variance of the estimates. Remaining figures use all providers. All mortality and hospitalization ratios are adjusted for age, gender, race, primary diagnosis, and ESRD vintage.

**Reference Section E**

Hospitalization reference tables present adjusted total admission and hospital day rates by year from 1993 to 2002. They begin in 1993 because Medicare inpatient claims are available beginning in 1991, and the model-based adjustment method uses data from the current and previous two years to obtain the predicted rates. (This method is further discussed later in this section and in the statistical methods section later in this appendix.)

Because hospitalization data for non-Medicare patients may be incomplete, analyses in this section include only patients with Medicare as their primary payor. Hospitalization data are obtained from 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:

- 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 incomplete 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 analy-
ses 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 current year. In the
total ESRD transplant categories, the period is censored at the earliest
death, three years after the transplant date, or December 31 of
the year; a modality change is not used as a
censoring event. For transplant patients in the all-ESRD and
transplant categories, the period is censored at the earliest of
death, three years after the transplant date, or December 31 of
the year. The censoring of transplant patients at three years fol-
lowing 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 addi-
tional 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 be-
fore 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 hospital-
izations 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 2003
ADR, all overlapping and only certain adjacent hospitalizations
are combined, due to the fact that many adjacent claims may ac-
tually be legitimate separate hospitalizations. Specifically, hospi-
talizations 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 1991–2002
institutional inpatient claims, for example, 4.5 percent of the hospi-
talizations 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 hospi-
talizations, 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, in-
clude all hospitalizations, and no overlapping or adjacent hospi-
talizations are combined. These tables present total hospital
discharges by DRGs, and no exclusions are made for patients dy-
ing 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 fol-
lowing the date of transplant. Inpatient REBUS data are combined
with Part A institutional inpatient claims data, and duplicate ob-
servations from both sources with identical hospitalization start
dates, end dates, and DRGs codes are omitted.

The methodology for computing total admission and hospital
day rates uses the model-based adjustment method (discussed in
the statistical methods section). 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 year and previous years, with presi-
tive weights of 1, 1/4, and 1/8. Adjusted rates are then calculated
using the direct adjustment method, with all 2002 ESRD patients
as the reference cohort. Standardized hospitalization ratios (SHRs)
by state (Table E.6) are calculated using the Bayesian method, also
described in the statistical methods section.

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)
include 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 1980–2002 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 ear-
lier 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, there-
fore, 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.) gener-
ally 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 Table H.1 for 1980–2002, while
predicted mortality rates for 2002 period prevalent cohorts are
shown in H.7–11. Adjusted annual death rates per 1,000 patient
years (Tables H.2, and their supplemental tables on our website)
are reported from 1980–2002 for all ESRD, all dialysis, and hemo-
dialysis, and from 1984–2002 for peritoneal dialysis and trans-
plant. SMRs (Table H.12) and cause-specific death rates (T ables
H.1–4) are reported for prevalent cohorts of 2000–2002. Ad-
justed first-, second-, and third-year death rates for incident co-
horts are reported in Tables H.19–21. Residents of the 50 states,
the District of Columbia, Puerto Rico, and the Territories are in-
cluded in each of these tables, as are all non-Medicare patients.

Analytical methods

Appendix A

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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 dialysis 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, Section E): 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 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, hypertension, glomerulonephritis, and other causes of ESRD are adjusted for age, gender, and race. The reference population for H.2–6 includes 2001 ESRD patients (the same population used in the 2003 ADR), so rates among modalities are comparable. 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, 2000–2002. 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 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. These mortality rates

(a.a) Collapsed categories of death (used for Figures 6.16–24 & Reference Tables H.13–17)

<table>
<thead>
<tr>
<th>Collapsed categories</th>
<th>Individual categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute myocardial infarction</td>
<td>Myocardial infarction, acute</td>
</tr>
<tr>
<td>Hyperkalemia</td>
<td>Hyperkalemia</td>
</tr>
<tr>
<td>Pericarditis</td>
<td>Pericarditis, including cardiac tamponade</td>
</tr>
<tr>
<td>Atherosclerotic heart disease</td>
<td>Atherosclerotic heart disease</td>
</tr>
<tr>
<td>Cardiomyopathy</td>
<td>Cardiomyopathy</td>
</tr>
<tr>
<td>Cardiac dysrhythmia</td>
<td>Cardiac dysrhythmia</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>Cardiac arrest, cause unknown</td>
</tr>
<tr>
<td>Valvular heart disease</td>
<td>Valvular heart disease</td>
</tr>
<tr>
<td>Pulmonary edema</td>
<td>Pulmonary edema</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>Cerebrovascular accident including intracranial hemorrhage; ischemic brain damage/anoxic encephalopathy</td>
</tr>
<tr>
<td>G.I. hemorrhage</td>
<td>Hemorrhage from transplant site; hemorrhage from vascular access; hemorrhage from dialysis circuit; hemorrhage from ruptured vascular aneurysm; hemorrhage from surgery; other</td>
</tr>
<tr>
<td>Septicemia</td>
<td>Septicemia, due to peritonitis; septicemia, due to peripheral vascular disease, gangrene; septicemia, other</td>
</tr>
<tr>
<td>Pulmonary infection</td>
<td>Pulmonary infection (bacterial); pulmonary infection (fungai); pulmonary infection (other); tuberculosis</td>
</tr>
<tr>
<td>Viral infection</td>
<td>Viral infection, CMV; viral infection, other; Hepatitis B; other viral hepatitis</td>
</tr>
<tr>
<td>AIDS</td>
<td>AIDS</td>
</tr>
<tr>
<td>Other infection</td>
<td>Infection, other; fungal peritonitis</td>
</tr>
<tr>
<td>Cachexia</td>
<td>Cachexia</td>
</tr>
<tr>
<td>Malignant disease</td>
<td>Malignant disease, patient ever on immunosuppressive therapy; malignant disease</td>
</tr>
<tr>
<td>Other cause</td>
<td>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</td>
</tr>
<tr>
<td>Unknown cause</td>
<td>Unknown</td>
</tr>
<tr>
<td>Missing forms</td>
<td>Missing forms</td>
</tr>
</tbody>
</table>
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. As in the 2003 ADR, 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, 2001 are included in the analysis. These patients are followed until December 31, 2002, a maximum followup time of 22 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.

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 cohort, a probability presented for one variable is adjusted for the remaining three. Overall probabilities for all patients are adjusted for each of the four variables, as described later in the discussion of statistical methods. As in the 2003 ADR, 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.

Organ donation rates are presented in Figures 7.11–13. In Figure 7.11, two methods are presented for the calculation of deceased donor donations, one counting a donation twice if both kidneys are eventually transplanted, the other counting each donation only once, regardless of whether both kidneys are transplanted.

Maps of donation rates are based on the location where the donation is made. Every attempt has been made to determine the county of residence of the organ donor, and the maps in Figures 7.12–13 are based on this 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.

Figures 7.14–21 present data on the numbers of patients returning to dialysis or receiving a preemptive transplant following a graft failure. A preemptive retransplantation is counted here as a return to dialysis. Time trends, geographic variations, and outcomes following graft failure are presented.

Table 7.4 details the standardized transplantation ratio (STR) comparing results from the standard method to those of the Bayes method adopted this year by the USRDS. STRs are presented by state. The section on statistical methods, later in this appendix, contains a detailed description of this methodology.

Figures 7.23 and 7.25 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 transplant year, age, gender, race, and primary diagnosis, 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.

Figures 7.24 and 7.26 displays patient distribution by age, gender, race, ethnicity, donor age, and dialysis vintage, and the effects of each on graft and patient outcomes for recipients of deceased donor and living donors kidney (separately). All first-time, kidney-only transplants between 1998 and 2002 with known recipient age and donor type are included. Estimates of relative risk are obtained from Cox proportional hazards models, modeling all-cause graft failure (including death), death-censored graft failure (return to dialysis), death with a functioning graft, and patient death (not censored at graft failure). Deceased donor models are adjusted for age, gender, race, ethnicity, donor age, and dialysis vintage, transplant year, hepatitis C serology, education level, employment status, donor gender, donor race, donor traumatic death, HLA mismatches, cold ischemia time, body mass index, PRA, and donor-recipient CMV matching. Living donor models are adjusted for age, gender, race, living donor type, donor age, body mass index, transplant year, hepatitis C serology, education level, employment status, donor gender, donor race, HLA mismatches, PRA, and donor-recipient CMV matching.

Data on patients receiving various preventive healthcare measures are presented in Figures 7.27–31. Included transplant patients have Medicare as primary payor during the measurement period, and are alive with a functioning graft for the entire study period.
period. Data on influenza vaccinations and lipid monitoring are presented for the entire Medicare transplant population. For the diabetic Medicare transplant population, we look at HbA1c and lipid testing and at diabetic eye exams. Detailed descriptions of how these measures are ascertained in Medicare claims are presented in the discussion of Chapters One and Five.

Figures 7.35–36 and Table 7.b present data on pre- and post-transplant blood transfusions. Data on pre-transplant transfusions are obtained from the UNOS Transplant Recipient Registration Form. Figure 7.35 illustrates the relationship between pre-transplant transfusions and estimated waiting times for a deceased donor kidney. Waiting times are estimated from a Cox proportional hazards model, adjusting for age, gender, race, and PRA. Table 7.b presents characteristics associated with pre-transplant blood transfusions. Odds ratios are estimated from a logistic regression model, adjusting for age, gender, race, ethnicity, dialysis vintage, primary diagnosis, PRA, CMV, education level, employment status, and body mass index. Figure 7.36 illustrates the effects of pre- and post-transplant transfusions on graft and patient outcomes. Post-transplant transfusions are identified in Medicare claims on a subset of the population with Medicare as primary payor at transplantation (39 percent of the total population). Blood transfusions are identified through ICD-9-CM procedure codes 99.03 and 99.04 and CPT codes 36430, 36450, 36455, and 36440, and the time of the first post-transplant transfusion is included as a time-dependent covariate in the Cox proportional hazards model.

Figures 7.37–39 and the associated tables present data on hepatitis B and C and their effects on transplant outcomes. Hepatitis B and C status is determined from the UNOS data at the time of transplantation for both recipient and donor. Trends in positive hepatitis B and C status during 1995–2002 are presented, along with tables displaying hepatitis B and C matching between donors and recipients over the same time period for deceased and living donors (separately). Characteristics associated with hepatitis status at the time of transplantation are presented in Table 7.c. Odds ratios are obtained from a logistic regression model, adjusting for transplant year, age, gender, race, ethnicity, dialysis vintage, primary diagnosis, PRA, CMV, education level, employment status, body mass index, donor type, and the number of previous blood transfusions.

Figures 7.40–42 and the associated tables present data on transplantation in HIV-positive recipients. All patients with first kidney transplants, 1995–2001, are included in this analysis. In the subpopulation with Medicare as primary payor for the two years prior to transplantation, claims are searched for evidence of HIV infection using ICD-9-CM codes 042 (HIV) and 079.53 (HIV-2). A patient is considered HIV-positive if one inpatient code or two outpatient or Part B codes are found within a 365-day period. Kaplan-Meier curves and adjusted relative risks are presented comparing HIV-positive patients to HIV-negative patients. Cox proportional hazards models are adjusted for transplant year, race, ethnicity, gender, primary diagnosis, donor type, donor age, donor race, gender, primary diagnosis, donor type, donor age, donor gender, prior dialysis time, PRA, CMV matching, education, employment, HLA mismatches, hepatitis B and C serology, baseline immunosuppression, and induction antibodies.

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 in the statistical methods section of 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, 2002); 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, 2001 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 8.8–11 show rates of preventive heathcare in pediatric ESRD patients. Methods and codes used to determine rates of influenza vaccinations, pneumococcal vaccinations, and lipid testing are similar to those described in Chapter One. Hepatitis B vaccinations are identified through CPT codes 90636, 90740, 90743-90744, 90748, 90731, and 90723. All patients are age 0–19 at the beginning of each study period; reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories; and have Medicare Parts A and B coverage for the whole period.

For influenza vaccinations (Figure 8.8), the cohort includes patients starting ESRD therapy at least 90 days prior to September 1 and alive on December 31 of each year; rates are calculated for patients receiving a vaccination in the last four months of each year. For pneumococcal vaccinations (Figure 8.9), the cohort includes prevalent patients initiating therapy at least 90 days prior to January 1 of the first year of each two-year period and alive on December 31 of the second year of each two-year period; rates
are calculated for patients receiving one vaccination during each period. For hepatitis B vaccinations and lipid testing (Figures 8.10–11), the cohorts include prevalent patients initiating therapy 90 days prior to January 1 and alive on December 1 of each year; rates are calculated for patients receiving one vaccination or testing in each year.

Figures 8.12 includes incident hemodialysis patients who are in both the USRDS and the CPM databases. Demographic and vascular access information is obtained from the CPM data, and incident years 1999–2001 are combined.

In Figure 8.13 we include prevalent hemodialysis patients from the 1999–2002 combined CPM data who are also in the USRDS database, and who have Medicare as their primary payer as of January 1 of the CPM year. Events and complications are obtained from Medicare claims, as described in the methods for Figures 5.42–44. Figure 8.14 includes incident peritoneal dialysis patients who have Medicare as primary payer on their first service date. Events and complications are obtained from Medicare claims, as described in the methods for Figure 5.45.

Figures 8.15–16 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 5.24–33. Because of the small number of pediatric patients within some categories, multiple years are grouped together.

Figure 8.17 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 a primary payer during the entire year; are residents of the 50 states, the District of Columbia, Puerto Rico, or 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 8.18–22, the mean hemoglobin and mean weekly EPO dose are calculated on a quarterly basis, and each quarter includes only patients with at least one valid EPO claim during that time. Doses are adjusted for inpatient days.

Data on infectious complications, in Figures 8.23–27, include incident dialysis patients with Medicare as their primary payer at incidence. Infectious hospitalizations represent inpatient stays with a principle diagnosis of infection. Figure 8.27 includes peritoneal dialysis patients only, and for Figures 8.23–27, transplant patients are first-time, kidney-only transplant recipients with Medicare as the primary payer as of the date of transplant. Figures 8.28–30 include the same patient population used in Figures 8.23–27, except that incident years 1991–1999 are combined. Bacterial infections are identified by codes 001.x–004.x, 010.x–018.x, 020.x–027.x, 030.x–036.x, 038.x–041.x, 073.x, 076.x, 080.x–083.x, 087.x, 088.x, 091.x–104.x, 137.x, and 008.x–008.x. Viral infection codes include 042.x, 045.x–051.x, 055.x–057.x, 060.x–066.x, 071.x, 072.x, 074.x, 075.x, 052.x–054.x, 008.6, 008.8, 078.2–078.7, 070.0–070.3, 070.6, 070.9, 070.41–070.44, 070.51–070.54, 079.51–079.53, and 079.81. Codes that identify parasitic infections include 006.x, 007.x, 084.x–086.x, 120.x–131.x, and 136.2–136.3, and fungal infections are identified by 114.x–117.x, 112.0, 112.4, 112.5, 112.81, 112.83–112.85, 112.89, and 112.9.

Methods used for the hospitalization data in Figures 8.31–33 and 8.37–39 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 primary payer 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 8.33, 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 8.37–39, principal ICD-9-CM diagnosis codes used for infection due to internal device (related to a vascular access device or peritoneal dialysis catheter) are listed in the discussion of Figures 6.7–9, while those for cardiovascular and infectious hospitalizations are listed in the discussion of Figures 6.1 and 6.7–9. However, here the overall infection category excludes infections due to an internal device. In Figure 8.39, “other” race includes those with a 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 8.34–35 present five-year survival by modality for 1988–1992 and 1993–1997 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, transplant, or the end of 2002, while transplant patients are followed from the first transplant date until death or the end of 2002. All probabilities are adjusted for age, gender, and race; overall probabilities are also adjusted for primary diagnosis. The reference population consists of 1996–1997 incident pediatric ESRD patients, and adjusted probabilities can be compared across modalities.

Figure 8.36 shows trends in unadjusted mortality rates by patient vintage, while Figures 8.40–41 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

Figures 9.1–8 and 9.11–12 compare demographic characteristics, comorbidities, and event rates in dialysis and general Medicare patients with cardiovascular events, including acute myocardial infarction (AMI), congestive heart failure (CHF), and cardiac arrest. In each figure the dialysis cohort includes period prevalent dialysis patients with Medicare Parts A and B as primary payer; patients who die or receive a transplant in the 90 days following initiation are excluded. The Medicare cohort is derived from the 5 percent Medicare Standard Analytic Files, and includes patients consecutively enrolled in Medicare Parts A and B and without ESRD during the study period. A two-year entry period is used to define CKD and non-CKD patients; methods and codes used to identify CKD patients are described in the discussion of Chapter One. All figures include only patients residing in the 50 states, the District of Columbia, Puerto Rico, and the Territories.

Figure 9.1 presents adjusted event rates of heart failure, AMI, and cardiac arrest for dialysis patients and for general Medicare patients with and without CKD. Incident dialysis patients are followed from day 90 after initiation, while point prevalent dialysis patients are followed from January 1 of the year; followup continues until the earliest of a cardiac event, death, transplant, end of Medicare as primary payer status, or December 31 of the year. General Medicare patients are followed from January 1 of the year until the earliest of a cardiac event, death, the last day of Medicare coverage, or December 31 of the year after the entry period.

Events are identified using ICD-9-CM diagnosis codes from Medicare Part A institutional claims and Part B physician/sup-
pler claims: CHF, 428; AMI, 410, 410.x0, and 410.x1; and cardiac arrest, 427.4 and 427.5. So as to allow comparisons across the three populations, we define the event date for each as the date of the first appearance of an ICD-9-CM code in Medicare Part A or B claims. Adjusted rates are calculated using the direct adjustment method (described in the section on statistical methods), and adjusted for age, gender, race, and diabetic status; the 2002 cohort is used as the reference group.

Figures 9.2–4 compare demographic characteristics of patients experiencing a cardiac arrest, looking at dialysis patients and at general Medicare patients (age 67 and older) with and without CKD. Age is determined at the beginning of the followup—day 90 after initiation for incident dialysis patients, and January 1 for prevalent dialysis and general Medicare patients; those with missing values for age, gender, or race are excluded. All patients are followed to the end of the year to identify the cardiac arrest event. We use two approaches to define dialysis patients with the event: in the Dialysis I method, ICD-9-CM codes 427.4 and 427.5 on Medicare Part A and B claims define the cardiac arrest event; for the Dialysis II method, patients are also identified through a primary cause of death, on the ESRD Death Notification form, of cardiac arrhythmia or cardiac arrest. Since Medicare claims alone are used to define cardiac arrest in the general Medicare patients, direct comparisons are appropriate only between the Dialysis I and general Medicare populations.

Figures 9.5 and 9.11 illustrate previous comorbidities in these same four populations, using the same methods to identify patients. Data on comorbidities are obtained from Medicare Part A and B claims or, for incident dialysis patients, the Medical Evidence form. Comorbid conditions are identified from ICD-9-CM codes as follows: AMI, 410, 410.x0, and 410.x1; CHF, 428; coronary revascularization: 36.01, 36.02, 36.05, 36.06, and 36.1x; peripheral vascular disease (PVD), 440–444, 447, 451–453, and 557; CVA/TIA, 430–437; diabetes, 250, 357.2, 362.0x, and 366.41; and hypertension, 362.11 401.x–405.x, and 437.2. CPT codes are also used to identify PVD (23900, 23920, 24900, 24920, 25900, 25905, 25920, 25927, 2795, 27590, 27591, 27592, 27598, 27880, 27881, 27882, 27888, 27889, 28000, and 28805) and coronary revascularization (92980–92982, 92984, 92995, and 92996).

Figure 9.6 displays geographic variations in unadjusted one-year incident rates of cardiac arrest, using the Medicare prevalent dialysis population and the general Medicare population. For the 1994–1995 cohort, followup for dialysis patients begins on January 1, 1994 or day 90 after ESRD initiation; for prevalent Medicare patients it begins on January 1, 1994 or the date of Medicare enrollment. Followup is the same in the 2001–2002 cohort, except that the date for prevalent patients changes to January 1, 2001. Dialysis patients are followed to the earliest of cardiac arrest, death, transplant, change of Medicare as primary payor, or one year after the start of followup, while general Medicare patients are followed until the earliest of cardiac arrest, death, the last day with Medicare coverage, or one year after the start of followup. Rates are estimated as the number of cardiac events per 1,000 patient years at risk for each state.

Figures 9.7 and 9.12 illustrate geographic variations in unadjusted incident rates of AMI and CHF in dialysis and general Medicare patients; Figure 9.12 includes diabetic patients only. The study cohort consists of prevalent patients age 67 or older in 1998–2002. In the dialysis population followup begins on January 1, 1998 for point prevalent patients and on day 90 after ESRD initiation for incident patients; it continues until the earliest of cardiac arrest, death, transplant, end of Medicare as primary payor status, or December 31, 2002. General Medicare patients are followed from January 1, 1998 or the time of Medicare enrollment until the ear-liest of cardiac arrest, death, the last day with Medicare coverage, or December 31, 2002. Rates are estimated as the number of AMI or CHF events per 1,000 patient years at risk for each HSA.

In Figure 9.8 we look at unadjusted cardiac arrest rates by diabetic status, using the same cohort as in Figure 9.7. For dialysis patients, diabetes is determined from the primary cause of ESRD listed on the Medical Evidence form; for general Medicare patients it is defined in the two-year entry period. Rates are estimated as the number of cardiac arrests per 1,000 patient years at risk for each Health Service Area.

Figure 9.9 illustrates trends in drug therapy for Medicare beneficiaries; patient cohorts are defined using the methods described for Figure 1.28.

Figure 9.10 reports one-year adjusted mortality rates, by location of event, for period prevalent dialysis patients with sudden cardiac death (SCD). Followup begins on January 1 of the year for point prevalent patients, and 90 days after ESRD initiation for incident patients, and lasts until the earliest of death, transplant, end of Medicare as primary payor status, or December 31 of the year. Using the model-based adjustment method (described in the statistical methods section), rates are estimated by the Cox proportional hazard model. Rates for “all” are adjusted for age, gender, race, renal diagnosis, and vintage; rates by diabetic status are adjusted for age, gender, race, and vintage. The 2002 cohort is used as the reference group.

Patients whose SCD occurs outside of the hospital (i.e. at home, or in a skilled nursing facility or hospice) are identified through ICD-9-CM codes 427.4 and 427.5 on Part A or B Medicare claims, as well as through an indication of cardiac death on the Death Notification form; in the absence of claims evidence, patients are identified through a primary or secondary cause of death, listed on the 2746 form, due to a cardiac event or disease. Patients whose SCD occurs in the hospital are identified through inpatient claims, using the same ICD-9-CM codes, and through a primary cause of death of cardiac disease. In the absence of inpatient claims indicating cardiac arrest, they are identified through a primary cause of death due to cardiac arrest or cardiac arrhythmia.

Figures 9.13–29 illustrate demographic characteristics and comorbidity at dialysis initiation, cardiovascular event rates after initiation, and data on the diagnosis and treatment of cardiac disease after initiation for incident hemodialysis and peritoneal dialysis patients. Figures 9.23–29 also include data on the diagnosis and treatment of cardiac disease before and after initiation for all incident dialysis patients age 67 or older, including those with unknown dialysis modality.

Figures 9.13–14 show the demographic distribution and comorbidity of incident dialysis patients. The cohort includes incident hemodialysis and peritoneal dialysis patients who survive at least 90 days after dialysis initiation, have Medicare as their primary payor, and are age 20 or older. Age is calculated on day 90 after initiation, while major comorbid conditions are defined from the Medical Evidence form at the initiation of ESRD treatment, 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 9.15–22 show trends in cardiovascular event rates, and use event-free probabilities to describe the likelihood of cardiovascular disease in incident dialysis patients, 1998–2000 combined. 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 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.

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

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 dialysis modality, to estimate event-free probabilities and calculate the predicted cardiovascular event rates, with age, gender, race, and primary diagnosis 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 four covariates.

Beginning at day 90 after dialysis initiation, patients are followed up to three years 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, transplant, modality change, loss-to-followup, end of Medicare as primary payor status, three years after day 90, or December 31, 2002. For all-cause death, followup time is censored at these same events, with the exclusion of death and the end of Medicare as primary payor status. Adjusted event rates are presented as monthly rates during each of the first six months after day 90, and as mean monthly event rates during each following six-month interval.

Figures 9.23–29 describe the cumulative percent of incident hemodialysis and peritoneal dialysis patients receiving diagnostic tests or treatment for cardiac disease in the three years beginning on day 90 after dialysis initiation, as well as the cumulative percent of all incident dialysis patients (including those with unknown dialysis modality), age 67 or older at initiation, receiving tests or treatment during the two years pre- and three years post-dialysis. A stress test is defined as any of the following: stress echocardiography, lipid testing, and ECGs. Patients are followed from day 90 after dialysis initiation (for hemodialysis and peritoneal dialysis patients) or from two years before initiation (for all incident dialysis patients aged 67 years or older) to the earliest of death, transplant, modality change (for hemodialysis and peritoneal dialysis patients only), loss-to-followup, end of Medicare as primary payor status, three years after dialysis initiation, or December 31, 2002.

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); 78439, 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)

Figure 9.30 shows the cumulative percent of hemodialysis and peritoneal dialysis patients who receive diagnostic tests and treatment related to cardiac disease during the two years for all patients before and one year for surviving patients, i.e. alive on the day of cardiac arrest) after a cardiac arrest. This figure also presents the life-table estimates of the probability of receiving a diagnostic test or treatment after a cardiac arrest for patients who survive an arrest. In addition to the diagnostic tests and treatment described above, data here also include the use of implantable cardioverter defibrillators, defined through an ICD-9-CM procedure code of 37.94 in Part A claims. The study population includes period prevalent dialysis patients in 2001, age 20 and older, and with a cardiac arrest (fatal or non-fatal) in the same year. Patients who survive a cardiac arrest are followed from the date of the arrest to the earliest of death, transplant, modality change, loss-to-followup, end of Medicare as primary payor status, or one year after the event.

Nutrition special studies

CHAPTER TEN

Data in this chapter are obtained from three sources: the Medical Evidence form, CMS’s Clinical Performance Measures project (CPM, formerly the ESRD Core Indicators Project), and the National Health and Nutrition Examination Survey (NHANES). To obtain national estimates of each statistic in the NHANES data, survey design and sampling weights are implemented by SUDAAN (Research Triangle Institute, Research Triangle Park, NC).

Data on incident ESRD patients are obtained from the Medical Evidence form, and include patients age 20 and older with a first service date between 1996 and 2002. Patients with missing values for BMI or albumin are excluded in the related figures. (For information on processing of albumin data, see page 230.)

For Figures 10.1 and 10.10–17, data on prevalent ESRD patients are obtained from the CPM dataset, which includes a random sample of dialysis patients alive and dialyzing at the end of each calendar year. Data for hemodialysis patients are collected in three monthly periods, October through December, while data for patients on peritoneal dialysis are collected in three bimonthly periods, typically October through March. Clinical data for BMI and serum albumin are linked to USRDS patient data for age, race, gender, primary diagnosis, and vintage, and BMI is calculated using an average of available post-dialysis body weights and patient height. BMI data are available for hemodialysis patients in 1996–2001 (n=45,193), and for peritoneal dialysis patients in 1994–2001 (n=9,559). Albumin information represents the last available test value reported along with an indication of the method used, and is available for both hemodialysis and peritoneal dialysis patients in
CHAPTER TWELVE & REFERENCE SECTION K

Economic costs of ESRD

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

Payor sequence

The payor sequence is similar in concept to the USRDS treatment history. Payor status is tracked for each ESRD patient from the first ESRD service date until death or the end of the study period. Data from the Medicare Enrollment Database, as well as dialysis claims information, are used to categorize payor status as Medicare primary payor (MPP), Medicare secondary payor (MSP), Medicare+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 12.9-14 and, in the
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.

Chapter Twelve
Table p.a in the Précis summarizes data on the costs of ESRD treatment. Total Medicare spending in 2002 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 2002 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 2002 (obtained from the CMS managed care organization file) in conjunction with the 2002 AAPCC rate.

Non-Medicare spending by EGHPs is estimated by separately computing the per year at-risk costs for EGHP and non-EGHP patients, then multiplying the difference by the EGHP at risk for 2002. 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 (obtained from the USRDS payor sequence) multiplied by the AAPCC rate.

Changes in Medicare spending from 2001–2002 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 (4.7 percent). Calculations per patient per year at risk by modality for 1998–2002 are taken from Table K.4; these data include MPP patients, then multiplying the difference by the EGHP years at plant or death. All diagnostic codes from Medicare claims in 2001 are again collected from hospital inpatient, outpatient, and physician files, and the actual Medicare PMPM payment in 2002 is calculated as described above, but with censoring at transplant or death in the same year. The predicted Medicare PMPM payments in 2002 for both the AAPCC and CMS HCC methods are also calculated as above, without using the rescaling factor. The risk factor here is calculated using the same software, in conjunction with the coefficients for the CMS-HCC End-Stage Renal Disease Model for 2005 (obtained from the same CMS source).

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 1998–2002 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 (right). 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 (claims)] * 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 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 years 2001 and 2002, 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 retain that classification until a modality change. When a change is encountered in the data, the beginning modality is censored at the change date plus 60 days, and a new observation with the new modality is created. The first 60 days after a change are attributed to the previous modality to account for any carryover effects. If the change is from dialysis to transplant, however, the modality is censored, and the transplant modality begins on the date of the transplant hospital admission. In the case of changes involving only a change from one type of dialysis to another, the new modality must last at least 60 days in order to be counted. Aggregation of Medicare payments is done on an as-treated basis, attributing all payments to the patient’s modality at the time of the claim.

In Section K 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, 1998 to December 31, 2002, and ESRD patients prevalent on January 1, 1998 or incident at any time during the period are potentially eligible for inclusion. The initial study start date for a given patient is defined as the latest of January 1, 1998; the first ESRD service date in the USRDS database for that patient; or the earliest ESRD 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, transplant, modality change, loss-to-followup, or December 31, 2002. Patients incurring no Part A or B Medicare costs for the entire period are excluded, and Medicare payment amounts are linearly prorated for claims that span the start or end date of a modality period or of the study itself.

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**

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 273): the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA); the Austria OEDTR; the Bangabandhu Sheikh Mujib Medical University

<table>
<thead>
<tr>
<th>Medicare payment categories</th>
<th>Basis for categorizing claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total inpatient</td>
<td>Sum of all payments</td>
</tr>
<tr>
<td>Medical DRG</td>
<td>Sum of all payments originaing from the inpatient SAF, including pass-throughs</td>
</tr>
<tr>
<td>Surgical DRG</td>
<td>Inpatient SAF DRG</td>
</tr>
<tr>
<td>Transplant DRG</td>
<td>Inpatient SAF DRG 302</td>
</tr>
<tr>
<td>Other DRG</td>
<td>Inpatient SAF, DRG not included in the above categories</td>
</tr>
<tr>
<td>Non-transplant pass-throughs</td>
<td>Inpatient SAF, DRG not 302, calculated from per diem and covered days</td>
</tr>
<tr>
<td>Transplant pass-throughs</td>
<td>Inpatient SAF, DRG 302, calculated from per diem and covered days</td>
</tr>
<tr>
<td>Total outpatient</td>
<td>Sum of all payments originating from the Outpatient SAF</td>
</tr>
<tr>
<td>Outpatient hemodialysis</td>
<td>Outpatient SAF, hemodialysis revenue codes</td>
</tr>
<tr>
<td>Outpatient peritoneal dialysis</td>
<td>Outpatient SAF, peritoneal dialysis revenue codes</td>
</tr>
<tr>
<td>Outpatient other dialysis</td>
<td>Outpatient SAF, dialysis revenue codes other than HD or PD</td>
</tr>
<tr>
<td>Outpatient EPO</td>
<td>Outpatient SAF, revenue codes and/or HCPCS code</td>
</tr>
<tr>
<td>Outpatient Calcijex</td>
<td>Outpatient SAF, revenue and HCPCS codes</td>
</tr>
<tr>
<td>Outpatient iron</td>
<td>Outpatient SAF, revenue and HCPCS codes</td>
</tr>
<tr>
<td>Outpatient other injectables</td>
<td>Outpatient SAF, revenue and/or CPT codes</td>
</tr>
<tr>
<td>Radiology</td>
<td>Outpatient SAF, revenue codes</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>Outpatient SAF, revenue codes</td>
</tr>
<tr>
<td>Ambulance</td>
<td>Outpatient SAF, revenue codes</td>
</tr>
<tr>
<td>Laboratory/pathology</td>
<td>Outpatient SAF, revenue and/or CPT codes</td>
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<td>Home health SAF</td>
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<tr>
<td>Hospice</td>
<td>Hospice SAF</td>
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<tr>
<td>Total physician/supplier</td>
<td>Sum of physician/supplier payments</td>
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<td>Physician/supplier SAF, CPT codes</td>
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<td>Inpatient surgery</td>
<td>Physician/supplier SAF, CPT and place of service codes</td>
</tr>
<tr>
<td>Outpatient surgery</td>
<td>Physician/supplier SAF, CPT and place of service codes</td>
</tr>
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<td>Physician/supplier SAF, CPT, place of service and specialty codes</td>
</tr>
<tr>
<td>E&amp;M nephrologist outpatient</td>
<td>Physician/supplier SAF, CPT, place of service and specialty codes</td>
</tr>
<tr>
<td>E&amp;M non-nephrologist inpatient</td>
<td>Physician/supplier SAF, CPT, place of service and specialty codes</td>
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<tr>
<td>E&amp;M non-nephrologist outpatient</td>
<td>Physician/supplier SAF, CPT, place of service and specialty codes</td>
</tr>
<tr>
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<td>Physician/supplier SAF, CPT codes</td>
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<tr>
<td>Home dialysis</td>
<td>Physician/supplier SAF, HCPCS and place of service codes</td>
</tr>
<tr>
<td>Vascular access</td>
<td>Physician/supplier SAF, CPT codes</td>
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<tr>
<td>Peritoneal access</td>
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</tr>
<tr>
<td>Physician/supplier EPO</td>
<td>Physician/supplier SAF, HCPCS codes</td>
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<td>Physician/supplier iron</td>
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<td>Physician/supplier SAF, HCPCS codes</td>
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<tr>
<td>Durable medical equipment</td>
<td>Physician/supplier SAF, HCPCS codes</td>
</tr>
<tr>
<td>Physician/supplier radiology</td>
<td>Physician/supplier SAF, CPT and specialty codes</td>
</tr>
<tr>
<td>Physician/supplier lab/pathology</td>
<td>Physician/supplier SAF, CPT codes</td>
</tr>
<tr>
<td>Physician/supplier ambulance</td>
<td>Physician/supplier SAF, HCPCS and place of service codes</td>
</tr>
<tr>
<td>Other physician/supplier</td>
<td>Physician/supplier SAF; does not qualify for any other category</td>
</tr>
</tbody>
</table>

**E&M: Evaluation and management**

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of Bangladesh; the French-Belgian Nephrologists Registry; Centre Hospitalier Etterbeek-Ixelles; the Kips Hospital of Brunei; Bulgaria First Hemodialysis Center; the Canadian Organ Replacement Registry; the Division of Nephrology, University Hospital of Canary Islands; the Chilean Renal Registry; the Croatian Society of Nephrology, Dialysis, and Transplantation; the Czech Society of Nephrology; the ERA-EDTA Registry; the Finnish Registry for Kidney Diseases; the Quasi Nikkei in Japan; the Greek Hellenic Renal Registry; the Department of Transplantation and Surgery in Hungary; Landspritali University Hospital, Iceland; the Israeli Renal Registry; 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; the Latvian Medical Academy; 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, Russia; the Scottish Renal Registry; Sociedad Española de Nefrologia; the Swedish Renal Registry; the Taiwan Society of Nephrology; the Thailand Registration of Renal Replacement Therapy; the Turkish Society of Nephrology; the Uruguayan Dialysis and Transplant Renal Registry; the U.S. Census Bureau International Database; and the USRDS.

We are particularly grateful to Drs. Kitty Jager and Paul van Dijk at the ERA-EDTA Registry for their help in coordinating much of the data presented in this chapter.

To contribute data from your country’s registry, please complete the form on pages 273–274 and return it to the USRDS.

Vascular access

REFERENCE SECTION L

The vascular access events and complications in Reference Section L are identified through the same codes used in Chapter Five.

Incident patients in this section include those who have Medicare as primary payor on their first service date, and rates reported reflect information from claims during the first year after initiation, censored at death, modality change, or a change in payor status. Prevalent patients include those with Medicare as primary payor as of December 31 of the previous year, and rates reported reflect information from claims during the calendar year, censored at death, modality change, or a change in payor status.

Census population base

REFERENCE SECTION M

The 2000 U.S. census, which became available in the fall of 2002, introduced a new race category with additional racial groupings. Census estimates for 1990–1999 were back-calculated based on the actual 2000 census. For 2000–2002, however, the actual census data include racial groups that do not coincide with those in the ESRD data. For 2000–2002 rate calculations throughout the ADR, we have thus used the CDC’s Bridged Race Dataset, which estimates white, black, Native American, and Asian populations. The data and methods for these estimates are available at www.cdc.gov/nchs/about/major/dvs/popbridge/popbridge.

Statistical methods

METHODS FOR CALCULATING RATES

Raw rate (observed)

The calculation of observed rates is straightforward, with some rates based on counts and others on followup time. The ESRD incident rate in 2002, for example, is the observed incident count divided by the 2002 population and, if the unit is per million population, multiplied by one million; the 2002 death rate for prevalent ESRD patients is the number of deaths in 2002 divided by the total followup time (patient years) of the 2002 prevalent patients, and, if the unit is per thousand patient years, multiplied by one thousand. Standard errors of estimated rates are based on the assumption of the data; the observed count has a Poisson or binomial distribution.

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 linear mixed Poisson model to estimate prevalent patient mortality rates for Reference Section H.

Measurement unit for rates

Both raw and model-based rates are calculated per unit of population (such as per 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 total events / 1.75 total patient years at risk] x 1,000 for Group A and [2 total events / 2.75 patient years at risk] x 1,000 for Group B). The resulting rate is lower for Group B because of the longer total 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 vari-
pressed as percentages from 0 to 100.

Errors are calculated with Greenwood’s formula (Kalbfleisch JD, Prentice RL). Survival probabilities in Reference Section I are ex-

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 

\[\frac{(153 \times 75.1\%) + (250 \times 12.3\%) + (303 \times 0.9\%) + (174 \times 3.6\%) + (220 \times 8\%)}{158.73} = 158.73\text{ per million population.} \]

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

### MODEL-BASED ADJUSTMENT

Under some circumstances there are disadvantages to the direct adjustment method. Suppose we are calculating mortality rates for a set of groups, and adjusting for potential confounding variables. If one category in a group has only a few patients or deaths, its estimated mortality rate will be unstable, likely making the adjusted rate unstable as well. In addition, if one 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 calculate direct adjusted rates using these estimates with a given reference population. There is, unfortunately, no straightforward way here to calculate standard errors of the adjusted rates for some models; the bootstrap approach works well, but is time consuming.

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

### SURVIVAL PROBABILITIES & MORTALITY RATES

#### Unadjusted survival probabilities

In this ADR, unadjusted survival probabilities are calculated using the Kaplan-Meier method, and corresponding standard errors are calculated with Greenwood’s formula (Kalbfleisch JD, Prentice RL). Survival probabilities in Reference Section 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 probabilities that would have arisen in each year if the patients had had the same attributes as the reference population. Since the probabilities in each table are adjusted to the same reference set of patient attributes, any remaining differences among cohorts and years are due to factors other than age, gender, race, and primary diagnosis. The adjusted mortality rates for incident cohorts in Reference Section H are calculated using similar methods.

### GENERALIZED LINEAR MODELS

#### Generalized linear mixed model for mortality rates

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

The generalized linear mixed model, which considers both fixed and random effects, is implemented using the SAS macro GLIMMIX. The Poisson rates for the intersections of age, gender, race, and diagnosis are estimated using the log linear equation

\[
\text{Log (rate)} = (\text{fixed effects}) + (\text{random effect})
\]

Fixed effects include year, age, gender, race, and primary diagnosis, and all two-way interactions among age, gender, race, and primary diagnosis. Assumed to be independently and identically distributed with a normal distribution, the random effect is the four-way interaction of age, gender, race, and primary diagnosis. Age is used as a categorical variable in main effect and four-way interactions, and as a continuous variable in the two-way interactions.

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

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

#### Generalized linear model for hospitalization rates

In this ADR, hospitalization reference tables present rates of total admissions and hospital days. We have used a generalized linear 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 different weights. Year is also included in the model. The adjusted hospitalization rates are calculated using the direct adjustment method based on the category-specific admission rate from the generalized linear models.

#### Interval Poisson model

When the hazards of risk groups defined by a risk factor are not proportional, use of the Cox regression model is not appropriate. But when the time interval is short enough the assumption that the hazards are constant is valid, and the hazards of groups defined by the risk factor, therefore, are proportional. In Chapters Six and Nine, instead of Cox regression models, we use interval
Poison models for some analyses because the hazards of the risk factors we are interested in are not proportional. We cut the followup time to several intervals, and assume that in each all hazards are constant. The number of intervals and the length of each depend on the densities of events and the slopes of the hazards.

**STANDARDIZED MORTALITY RATIOS**

The standardized mortality ratio (SMR) compares the mortality of a group of patients relative to a specific norm, or reference, after adjusting for some important risk factors. In Table H.12, for example, the SMR is used to compare mortality in prevalent dialysis patients—after adjusting for age, gender, race, primary diagnosis, and ESRD vintage—in each state, and to show how relative mortality rates have changed over time, using the national dialysis population in the corresponding year as the reference. An SMR of 1.05 for a state indicates that patients in this state have a risk of death approximately five percent higher than that of patients in the reference population of all U.S. dialysis patients.

**Traditional method of SMR calculation**

The traditional approach used to calculate unit-specific SMRs is straightforward: produce unit-specific expected death counts and compute the “observed/expected” ratio. There are two methods of producing unit-specific expected death counts: the indirect and the model-based. In the indirect method, the expected death count is the weighted sum of category-specific death rates in the reference population, and the weights are the category-specific total followup times in the units. In the model-based method, a statistical model is employed to estimate the category-specific death rate for the reference population, and the indirect method is then used to produce the expected death count for each unit based on the estimates of category-specific death rates of the reference population from the model.

**Bayesian method of SMR calculation**

When using the traditional method of calculating unit-specific SMRs, differences in unit sizes may cause very large differences in variations of the estimated SMR, making direct comparisons unfair, especially for small units. The Bayesian hierarchical model, however, provides a good alternative for stabilizing estimated SMRs to make comparisons more appropriate. The model assumes that the observed death count follows a Poisson distribution with mean \( \mu_\theta \), and that \( \theta \), the logarithm of SMR, has a normal distribution with Gamma precision, where \( \mu \) is the expected death count from a generalized linear mixed model incorporating patient age, gender, race, primary diagnosis, and ESRD vintage (Liu et al.). To distinguish the two estimation methods, we use the term BMR to designate the estimated SMR from the Bayesian model. SMRs and BMRs on the level of dialysis provider are compared in Chapter Six, and state-level BMRs are presented in Reference Table H.12.

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

**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 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.” The methods described here have been used for all HSA-level maps in the ADR. Because the distribution of age, gender, and race in a population can affect incident and prevalent ESRD rates, we have included maps in which data are adjusted for these variables as well as smoothed.

In many figures, data ranges have been standardized to invite comparisons across years, modalities, or patient characteristics. In remaining maps, HSAs are divided into quintiles. Throughout the ADR, data in maps and graphs are unadjusted unless otherwise noted. HSA-level information is mapped according to the patient’s residence (with the exception of some maps of organ donation rates in Chapter Seven). Because of area size and limitations in the mapping software, data for Puerto Rico and the U.S. Territories are not included in the maps.

**Methods for smoothing & adjusting map data**

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

This model is also used 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.

**Miscellaneous**

**SPECIAL STUDIES & DATA COLLECTION FORMS**

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

CAPTIONS
Captions in the ADR provide descriptions of patient cohorts and data adjustments, along with other general information regarding the figures and tables, and should be read in conjunction with the explanations provided in this appendix.

Bibliography


Appendix B: USRDS services & data requests

Appendix B describes the products and services the USRDS provides to support the work of the renal community. The entire ADR is available at www usrds org, with PowerPoint slides of all figures and Excel files of the data behind the graphs; included as well are PDF files of the Researcher’s Guide. The site’s RenDER system allows users to create customized data sets and regional maps. Data on website use are presented in Figure b.1.

SMR/SHR reports & spreadsheets

From 1996 to 1999 the USRDS produced 2,300 unit-specific reports each year, compiling data on the patients treated in each dialysis facility, and calculating Standardized Mortality Ratios (SMRs) and Standardized Hospitalization Ratios (SHRs). These reports are now created by the Kidney Epidemiology and Cost Center (KECC) at the University of Michigan (www.med.umich.edu/kidney). Beginning with the 2003 ADR, the USRDS has also stopped producing SMR and SHR spreadsheets. All questions pertaining to these reports and spreadsheets, and to SMR/SHR/STR calculations, should be directed to the KECC.

Data requests

Making information on ESRD available to the renal community is a primary objective of the USRDS, and we are committed to the timely fulfillment of data requests. In many cases these requests can be answered by providing data published in the ADR or elsewhere. Requests for data not available in material published by the USRDS, but that require two hours or less of staff time, are fulfilled by the Coordinating Center without charge, usually within one week. More complex requests—those requiring more than two hours of staff time—as well as requests for Standard Analysis Files and custom files, must be accompanied by a written proposal (see details below), and will be completed only upon written approval by the NIDDK Project Officer.

Research files

The Coordinating Center maintains a set of Standard Analysis Files (SAFs) to meet diverse research needs and provide easy access to the data used in the ADR. The SAFs were introduced in 1994, as the NIDDK began awarding a new group of grants focusing on research using the USRDS data. The result has been an annual increase in the number of files provided by the USRDS. Prior to 1994 all researcher files were created for specific projects. Since the introduction of the SAFs, however, custom files are generally limited to cases in which a researcher provides a patient finder file to be matched with the USRDS database.

The two-CD Core SAF set contains basic patient data, and is needed to use any of the other SAFs. Included are each patient’s demographic information, payor and treatment history, limited transplant data, provider data, and all data from the USRDS Special Studies. Approximately half of the researchers using the USRDS SAFs need only this CD set. Full transplant information is provided on a separate CD that contains detailed transplant and transplant followup data collected by CMS and UNOS. Data on hospital inpatient stays are found on the hospitalization CD, and Medicare payment data are available either in a full set or by individual year (see Table b.c).

Standard analysis files

The use of Standard Analysis Files is governed by the USRDS policy on data release for investigator-initiated research (page 262). Research proposals must be approved by the USRDS Project Officer, and researchers must sign the USRDS “Agreement for Release of Data” (page 271). File prices are listed in Table b.c.

Most SAFs provide patient-specific data. All patient identifiers are removed from the files or encrypted, but data confidentiality is still a serious concern. The “Agreement for Release of Data” describes restrictions on the use and disposition of the SAFs. The SAFs include an encrypted ID number to allow patient data from multiple SAFs to be merged.
Core Studies collected information on patient dialyzers. SAFs for these studies describe the dialyzer through a code, which must be matched to information in the Dialyzer file to find the manufacturer and model along with characteristics such as membrane type and clearance. We believe that these data, from published sources available at the time of the study, accurately represent the dialyzer characteristics, but they should be used with caution.

Topics for USRDS Special Studies are approved by the NIDDK, with recommendations from CMS, the Scientific Advisory Committee, the ESRD networks, and the Renal Community Council. Design and sampling plans are developed, samples are selected, and data collection forms and instructions are drafted, tested, and finalized. The main studies to date are summarized below, and are detailed in the Researcher’s Guide.

Dialysis Morbidity & Mortality Study (DMMS) The DMMS was a USRDS Special Study in which data on demographics, comorbidity, laboratory values, treatment, socioeconomic factors, and insurance were collected, using dialysis records, for a random sample of U.S. patients. 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 prospective study of incident hemodialysis and peritoneal dialysis patients for 1996.

Case Mix Adequacy Study of Dialysis The objectives of this USRDS Special 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, and examine 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 USRDS Special 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 mortality 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 on different modalities; and compare relative mortality rates by treatment modality, adjusting for comorbidity 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, and 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

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### (b.a) USRDS products & services

- **Products** are provided without charge except as noted

### Reports & guides

- **Annual Data Reports**
  - Available from the National Kidney and Urologic Disease Information Clearinghouse, 3 Information Way, Bethesda, MD 20892-3560; 301.654.4415; nludi@info.niddk.nih.gov. ADR material is also published in the American Journal of Kidney Disease.

- **Annual Data Report CD**
  - Contains the text and graphics of the ADR, data tables, Powerpoint slides, and the Researcher’s Guide.

- **USRDS Database**
  - Provides a detailed description of the USRDS database and of the USRDS Standard Analysis Files; the basic reference for researchers who use USRDS data files.

- **www.usrds.org**
  - Contains PDF files of the chapters, reference tables, and the Researcher’s Guide; Powerpoint slides of atlas figures and USRDS conference presentations; Excel files of the data tables; notices regarding current news and analyses; links to related Internet sites; and email addresses for contacting the USRDS.

### RenDER

- The USRDS Renal Data Extraction and Referencing (RenDER) System is a querying application that allows users to create data tables and interactive maps. It can be accessed at www.usrds.org/adr/ xrender_home.asp following a short registration; a tutorial is also available on this site to help new users.

### Requests for data

- **Data requests: two-hour**
  - Questions and data requests that are not answered directly by the ADR can be addressed to the Coordinating Center, those that require less than two hours of staff time to fulfill will be processed without charge.

- **Data requests: more than two hours**
  - Questions and data requests that require over two hours of staff time must be submitted in writing and approved by the NIDDK Project Officer. Fulfillment of these requests is subject to staff availability, and costs are assessed on a case-by-case basis.

### Standard Analysis Files

- SAFs provide patient-specific data from the USRDS database to support ESRD research. A standard price list has been established for the files (Table b.c), and users must sign a Data Release Agreement with the NIDDK.

### Custom data files

- Custom files can be created by the Coordinating Center for projects requiring data other than those provided in the Standard Analysis Files. An hourly rate of $72.70 will be assessed for time spent on the request, and users must sign a data release agreement with the NIDDK.

### Publications & presentations

- Most USRDS research studies result in published papers or presentations at national meetings. Figures from abstracts and presentations can be found on the website, while published abstracts and papers can be found in the relevant journals.

### Contact information

- **Data requests & publication orders**
  - USRDS Coordinating Center
  - 914 South 8th Street, Suite D-206
  - Minneapolis, MN  55404
  - 612.347.7776 or 1.888.99USRDS
  - Fax 612.347.5878  www.usrds.org

- **Data file contact**
  - Shu Chen, MS, schen@usrds.org

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

- **File name**, unit of observation, & uses; this two-CD set is needed in order to use any of the other Standard Analysis Files

- **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, comorbidity 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 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: 5,679 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 file
  - 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.
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.

**TRANSPLANT CD**

Due to changes in data collection sources over the years, data related to transplants are now presented in eight separate SAFs. The first two are included on the Core CD, and the remaining six are included on two separate Transplant CDs.

- **TX:** includes minimum details about all transplants from all sources
- **TXWAIT:** contains one record for each patient in the USRDS database per wait list event
- **TXHCEA:** 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
- **TXRUNOS:** includes information on immunosuppressive drugs collected by UNOS 1993-present
- **TXFUHCF:** 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
- **TXIFUNOS:** includes information on immunosuppressive drugs, collected by UNOS at follow-up visits

Tables in Section F of the reference section are produced primarily from the CMS 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 (ME) 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 pre-1988 CMS transplants 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 between sources to differ by one day). Finally, transplants indicated on the ME 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 CLAIMS CD**

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

**CASE MIX ADEQUACY CLAIMS CD**

This CD contains the Case Mix Adequacy Special Study file, and extracts data for the study patients from all CMS Medicare payment data. Medicare payment data 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.

**MEDIARE PAYMENT DATA CDs**

Medicare payment data on institutional claims are available for pre-1989 through 2002, while data on physician/supplier claims are available for 1991–2002. The 2002 claims will be available, along with other updated USRDS SAF CDs, by the end of 2004.

Institutional claims consist of all Part A claims (inpatient, outpatient, skilled nursing facility, home health agency, and hospice), excluding outpatient dialysis claims. Physician/supplier claims are Part B, and 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 MERGED CDs**

CMS's annual Clinical Performance Measures (CPM) project assesses quality of care in the delivery of dialysis therapy, including anemia management, vascular access, and dialysis adequacy. Data are also collected on risk parameters such as albumin and blood pressure. To allow researchers to perform outcomes analyses with project data, the USRDS generates a set of merged CPM/USRDS data files. The initial dataset contains CMS data collected in surveys from 1994–2000, combined with the 2001 USRDS SAF research files; also included are institutional claims from pre-1989 to 1999 and physician/supplier claims from 1991–1999.


The CPM survey data are available separately for those who want only the CPM survey data, or who may already possess relevant USRDS SAF products.

For details on these files, please visit our website or email us at 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 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 there will be 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; a hard copy will be sent to those who order SAFs.

**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 from 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 271.

### (b.d) Prices for the USRDS Standard Analysis Files

**checks must be made payable to the Minneapolis Medical Research Foundation**

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

^ 2002 claims will be available in early 2005; prices subject to change.

**USRDS services & data requests**

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- Indicate needed USRDS SAFs. If these files 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 Coordinating Center (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 for conformity with the Privacy Act. The Project Officer 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.
ACE inhibitors  Antihypertensive agents that inhibit the production of angiotensin II. Can delay progression to diabetes or kidney disease.

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 cost (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 bloodstream.

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

ARB  Angiotensin II receptor blockers; antihypertensive agents that inhibit the actions of angiotensin II, a substance which causes narrowing of blood vessels.

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.

Beta blockers  Antihypertensive medications that block production of norepinephrine, slowing the heart rate and preventing the constriction of blood vessels.

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 (m²).

C-reactive protein  A protein produced by the liver in response to infection or injury; high levels are associated with an increased risk of heart disease and stroke.

Calcium channel blockers  Antihypertensive agents that work by blocking the access of calcium to muscle cells in artery walls.

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 the abdominal cavity is filled and emptied of dialysate using an automated cycler 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 Childrens’ 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 af-
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 m².

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.

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 person’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 networks 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 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 m² 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 (HbA1c) 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 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.
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).

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.

HCC Hierarchical condition category. A risk adjustment methodology used by CMS and developed to address severity of illness and actual expenditures.

High-efficiency hemodialysis A type of hemodialysis that uses hemodialyzers with larger surface areas than conventional hemodialyzers. Enhanced solute clearance is achieved through increased blood flow rates 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.

HCC Hierarchical condition category. A risk adjustment methodology used by CMS and developed to address severity of illness and actual expenditures.

High-flux hemodialysis 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.

Homocysteine An amino acid present in the blood. High levels can accompany kidney disease, and can indicate an increased risk of cardiovascular disease and stroke.

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 a 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 (IHD) 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 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 Current Beneficiary Survey (MCBS) An ongoing national survey of aged, disabled, and institutionalized Medicare beneficiaries. Sponsored by the Centers for Medicare and Medicaid Services, and used to study the health status, health care use and expenditures, health insurance coverage, and socioeconomic and demographic characteristics of Medicare beneficiaries.

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

Microalbuminuria A condition in which small amounts of albumin are present in the urine; indicates early kidney damage.

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 (CWFI) 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 A type of 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 and Information System for ESRD, and Renal Beneficiary and 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 the transplant date). 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 presence of protein in the urine; indicative of kidney damage.

Pyogen 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.

REMSIS CMS's Renal Management Information System (REMSIS), which has replaced the Renal Beneficiary and Utilization System (REBUS). Includes 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, gender, race, primary diagnosis, and ESRD vintage.

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

Statins Medications that lower cholesterol through action on an enzyme in the liver.

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 = (pre-dialysis – post-dialysis BUN) / 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 of patients awaiting an organ transplant; maintained by the United Network for Organ Sharing (UNOS).

Some of these definitions are obtained from the On-Line Medical Dictionary, found at http://cancerweb.ncl.ac.uk/omd/.
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United States Renal Data System (USRDS)
Agreement for Release of Data

Project title

In this agreement, “Recipient” means

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. The USRDS data files covered in this data use agreement may be retained by the Recipient until _______________. 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.
Lawrence Y. C. Agodoa, MD, NIDDK, NIH or
Paul W. Eggers, PhD, NIDDK, NIH
USRDS Project Officer name & organization

USRDS Project Officer signature & date
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

<table>
<thead>
<tr>
<th>Year</th>
<th>0–19</th>
<th>20–44</th>
<th>45–64</th>
<th>65–74</th>
<th>75+</th>
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</table>

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.

B1) Incidence: Total number of incident (new) patients starting renal replacement therapy during the year

<table>
<thead>
<tr>
<th>Year</th>
<th>0–19</th>
<th>20–44</th>
<th>45–64</th>
<th>65–74</th>
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B2) Incidence: Total number of incident patients starting renal replacement therapy during the year due to diabetes

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<th>Year</th>
<th>0–19</th>
<th>20–44</th>
<th>45–64</th>
<th>65–74</th>
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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.

<table>
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<th>Year</th>
<th>0–19</th>
<th>20–44</th>
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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.

<table>
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<th>Year</th>
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</table>
### C1) Prevalence: Total number of ESRD patients (all treatment categories) at the end of the year (December 31)

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<th>0–19</th>
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### C2) Prevalence: Total number of ESRD patients with a functioning graft at the end of the year (December 31)

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### C3) Prevalence: Total number of ESRD patients on dialysis at the end of the year (December 31)

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### C4) Prevalence: Total number of ESRD patients on in-center hemodialysis at the end of the year (December 31)

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### C5) Prevalence: Total number of ESRD patients on CAPD/CCPD at the end of the year (December 31)

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### C6) Prevalence: Total number of ESRD patients on home hemodialysis at the end of the year (December 31)

<table>
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<th>Year</th>
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### D1) Transplant: Total number of cadaveric transplants during the year

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### D2) Transplant: Total number of living donor transplants during the year

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<th>45–64</th>
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</table>
END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT
MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION

A. COMPLETE FOR ALL ESRD PATIENTS

1. Name (Last, First, Middle Initial)

2. Health Insurance Claim Number

3. Social Security Number

4. Full Address (Include City, State, and Zip)

5. Phone Number

6. Date of Birth

7. Sex
   Male
   Female

8. Ethnicity
   Hispanic: Mexican
   Hispanic: Other
   Non-Hispanic

9. Race (Check one box only)
   White
   Black
   American Indian/Alaskan Native
   Asian
   Pacific Islander

10. Medical Coverage (Check all that apply)
   a. Medicaid
   b. DVA
   c. Medicare
   d. Employer Group Health Insurance
   e. Other Medical Insurance
   f. None

11. Is Patient Applying for ESRD Medicare Coverage? (if YES, enter address of Social Security office)
   Yes
   No

12. Primary Cause of Renal Failure (Use code from back of form)

13. Height

14. Dry Weight

15. Employment Status (6 mos. prior and current status)
   Prior
   Unemployed
   Employed Full Time
   Employed Part Time
   Homemaker
   Retired due to Age/Preference
   Retired (Disability)
   Medical Leave of Absence
   Student
   Current

16. Co-Morbid Conditions (Check ALL that apply currently or during last 10 years) *See instructions
   a. Congestive heart failure
   b. Ischemic heart disease, CAD*
   c. Myocardial infarction
   d. Cardiac arrest
   e. Cardiac dysrhythmia
   f. Pericarditis
   g. Cerebrovascular disease, CVA, TIA*
   h. Peripheral vascular disease*
   i. History of hypertension
   j. Diabetes (primary or contributing)
   k. Diabetes, currently on insulin
   l. Chronic obstructive pulmonary disease
   m. Tobacco use (current smoker)
   n. Malignant neoplasm, Cancer
   o. Alcohol dependence
   p. Drug dependence*
   q. HIV positive status
   r. AIDS
   s. Inability to ambulate
   t. Inability to transfer

17. Was pre-dialysis/transplant EPO administered?
   Yes
   No

18. Laboratory Values Prior to First Dialysis Treatment or Transplant *See Instructions.

<table>
<thead>
<tr>
<th>LABORATORY TEST</th>
<th>VALUE</th>
<th>DATE</th>
<th>LABORATORY TEST</th>
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<tbody>
<tr>
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<td>e. Serum Creatinine (mg/dl)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Hemoglobin (g/dl)*</td>
<td></td>
<td></td>
<td>f. Creatinine Clearance (ml/min)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Serum Albumin (g/dl)</td>
<td></td>
<td></td>
<td>g. BUN (mg/dl)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Serum Albumin Lower Limit (g/dl)</td>
<td></td>
<td></td>
<td>h. Urea Clearance (ml/min)*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B. COMPLETE FOR ALL ESRD PATIENTS IN DIALYSIS TREATMENT

19. Name of Provider

20. Medicare Provider Number

21. Primary Dialysis Setting
   Hospital Inpatient
   Dialysis Facility/Center
   Home

22. Primary Type of Dialysis
   Hemodialysis
   IPD
   CAPD
   CCPD
   Other

23. Date Regular Dialysis Began
   MM/DD/YY

24. Date Patient Started Chronic Dialysis at Current Facility
   MM/DD/YY

25. Date Dialysis Stopped
   MM/DD/YY

26. Date of Death
   MM/DD/YY
I certify that the above self-dialysis training information is correct and is based on consideration of all pertinent medical, psychological, and sociological factors as reflected in records kept by this training facility.

Attending Physician

44. Attending Physician (Print)

45. Physician’s Phone No.

46. UPIN of Physician in Item 44

I certify, under penalty of perjury, that the information on this form is correct to the best of my knowledge and belief. Based on diagnostic tests and laboratory findings, I further certify that this patient has reached the stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplant to maintain life. I understand that this information is intended for use in establishing the patient’s entitlement to Medicare benefits and that any falsification, misrepresentation, or concealment of essential information may subject me to fine, imprisonment, civil penalty, or other civil sanctions under applicable Federal laws.

Attending Physician’s Signature of Attestation (Same as Item 44)

47. Date

48. Date

49. Remarks

I hereby authorize any physician, hospital, agency, or other organization to disclose any medical records or other information about my medical condition to the Department of Health and Human Services for purposes of reviewing my application for Medicare entitlement under the Social Security Act and/or for scientific research.

Signature of Patient (Signature by Mark Must Be Witnessed.)

50. Date

51. Date

The collection of this information is authorized by section 226A of the Social Security Act. The information provided will be used to determine if an individual is entitled to Medicare under the End Stage Renal Disease provisions of the law. The information will be maintained in system No. 09-70-0520, “End Stage Renal Disease Program Management and Medical Information System (ESRD PMMIS)”, published in the Privacy Act Issuance, 1991 Compilation, Vol. 1, pages 436–437, December 31, 1991, or as updated and republished. Collection of your Social Security number is authorized by Executive Order 9397. Furnishing the information on this form is voluntary, but failure to do so may result in denial of Medicare benefits. Information from the ESRD PMMIS may be given to a congressional office in response to an inquiry from the congressional office made at the request of the individual; an individual or organization for a research, demonstration, evaluation, or epidemiologic project related to the prevention of disease or disability, or the restoration or maintenance of health. Additional disclosures may be found in the Federal Register notice cited above. You should be aware that P.L. 100-503, the Computer Matching and Privacy Protection Act of 1988, permits the government to verify information by way of computer matches.

Network Confirmed as ESRD

52. Network Confirmed as ESRD

53. Authorized Signature

54. Date

55. Network Number

Yes

No

H. FOR ESRD NETWORK USE ONLY IN CASES REFERRED TO ESRD MEDICAL REVIEW BOARD

CMS-2728-U3 (6-97)
13. IF DECEASED RECEIVED A TRANSPLANT
   a. Date of most recent transplant
      MONTH DAY YEAR
   b. Was kidney functioning (patient not on dialysis) at time of death?
      Yes No Unknown
   c. Did transplant patient resume chronic maintenance dialysis prior to death?
      Yes No

14. REMARKS

15. NAME OF PHYSICIAN

16. SIGNATURE OF PERSON COMPLETING THIS FORM
   DATE
### DIALYSIS PATIENTS

#### Additions During Survey Period

<table>
<thead>
<tr>
<th>Patients Receiving Care</th>
<th>Started for first time ever</th>
<th>Restarted</th>
<th>Transferred from other dialysis unit</th>
<th>Returned after transplantation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Fields 01 thru 02</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>01</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>03</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

#### Losses During Survey Period

<table>
<thead>
<tr>
<th>Deaths</th>
<th>Recovered kidney function</th>
<th>Received transplant</th>
<th>Transferred to other dialysis unit</th>
<th>Discontinued dialysis</th>
<th>Other (LTFU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>08A</td>
<td>09A</td>
<td>10A</td>
<td>11A</td>
<td>12A</td>
<td>13A</td>
</tr>
<tr>
<td>08B</td>
<td>09B</td>
<td>10B</td>
<td>11B</td>
<td>12B</td>
<td>13B</td>
</tr>
</tbody>
</table>

### Patients Receiving Care at End of Survey Period

<table>
<thead>
<tr>
<th>Outpatient Dialysis</th>
<th>Self-Dialysis Training</th>
<th>Total Outpatient Dialysis</th>
<th>Home Dialysis</th>
<th>Total Home Dialysis</th>
<th>Total Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemodialysis</td>
<td>IPD</td>
<td>Hemo-Dialysis</td>
<td>IPD</td>
<td>CAPD</td>
<td>Fields 21 thru 24</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CCPD</td>
<td>Fields 20 and 25</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>15</td>
<td>16</td>
<td>17</td>
<td>18</td>
<td>19</td>
</tr>
</tbody>
</table>

### Self-Dialysis Completing Training

<table>
<thead>
<tr>
<th>Patient Eligibility Status End of Survey Period</th>
<th>Self-Dialysis Completing Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Currently enrolled in Medicare</td>
<td>Hemodialysis</td>
</tr>
<tr>
<td>Medicare application pending</td>
<td></td>
</tr>
<tr>
<td>Non-Medicare</td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>30</td>
</tr>
<tr>
<td>28</td>
<td></td>
</tr>
<tr>
<td>29</td>
<td></td>
</tr>
</tbody>
</table>

### TREATMENT LOAD

<table>
<thead>
<tr>
<th>Outpatient Dialysis Treatments</th>
<th>Dialysis Training Treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemodialysis</td>
<td>Hemodialysis</td>
</tr>
<tr>
<td>IPD</td>
<td>IPD</td>
</tr>
<tr>
<td>36</td>
<td>38</td>
</tr>
<tr>
<td>37</td>
<td>39</td>
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<tr>
<td></td>
<td>40</td>
</tr>
<tr>
<td></td>
<td>41</td>
</tr>
</tbody>
</table>

**REMARKS REGARDING INFORMATION PROVIDED ON THIS SURVEY SHOULD BE ENTERED ON THE LAST PAGE OF THE SURVEY**

This report is required by law (42 USC 426; 42 CFR 405.2133). Individually identifiable patient information will not be disclosed except as provided for in the Privacy Act of 1974 (5 USC 552a; 45 CFR, Part 5a).
### PART TWO — KIDNEY TRANSPLANTS

#### PATIENTS TRANSPLANTED AND DONOR TYPE

<table>
<thead>
<tr>
<th>Patients Transplanted at This Facility</th>
<th>Eligibility Status of Patients Transplanted at this Facility During the Survey Period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Currently enrolled in Medicare</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>42</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Transplants Performed at This Facility</th>
<th>Patients Awaiting Transplant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Living Related Donor</td>
<td></td>
</tr>
<tr>
<td>Living Unrelated Donor</td>
<td></td>
</tr>
<tr>
<td>Cadaveric Donor</td>
<td></td>
</tr>
<tr>
<td>Total Fields 47 thru 49</td>
<td></td>
</tr>
<tr>
<td>47</td>
<td>48</td>
</tr>
<tr>
<td>51</td>
<td>52</td>
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</tbody>
</table>

#### CADAVER KIDNEYS

<table>
<thead>
<tr>
<th>Source of Cadaver Kidneys</th>
<th>Disposition of Cadaver Kidneys</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transplanted at this facility</td>
<td>Sent to another U.S. facility</td>
</tr>
<tr>
<td>Harvested at this center</td>
<td></td>
</tr>
<tr>
<td>Obtained from another transplant hospital</td>
<td>58</td>
</tr>
<tr>
<td>Obtained from Independent OPOs</td>
<td>63</td>
</tr>
<tr>
<td>Obtained from Non-transplant hospital</td>
<td>68</td>
</tr>
<tr>
<td>Total</td>
<td>73</td>
</tr>
</tbody>
</table>

#### Source of Cadaver Kidneys

- Harvested at this center
- Obtained from another transplant hospital
- Obtained from Independent OPOs
- Obtained from Non-transplant hospital

#### Disposition of Cadaver Kidneys

- Transplanted at this facility
- Sent to another U.S. facility
- Sent Outside the U.S.
- Non-Viable Kidneys
- Total

#### Remarks

- Remarks regarding information provided on this survey should be entered on the last page of the survey.

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PART THREE

REMARKS

According to the Paperwork Reduction Act of 1995, no persons are required to complete a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information is 0938-0447. This time required to complete this information collection is estimated to average 8 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, N2-14-26, Baltimore, Maryland 21244-1850.

REMARKS REGARDING INFORMATION PROVIDED ON THIS SURVEY SHOULD BE ENTERED ON THIS PAGE OF THE SURVEY

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