The truth in a calm world,
In which there is no other
meaning, itself
Is calm, itself is summer and
night, itself
Is the reader leaning late
and reading there.

Wallace Stevens, “The House Was
Quiet and the World Was Calm”
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.

**REMIS/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 had 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 (OPTN) 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 Standard Information Management System (SIMS) database of the ESRD networks. CMS has also established data integrity rules to ensure accurate identification of patients in the SIMS and CMS databases. Each ESRD patient (old and new) will now be identified with a unique patient identification number common to both databases, ensuring that data on all patients are consistently managed over time.

**CMS MEDICARE ENROLLMENT DATABASE**

CMS’s Enrollment Database (EDB) 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.

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

The ESRD Medical Evidence Form is used as the official form for registering individual patients at the onset of ESRD. This form must be submitted by dialysis or transplant providers within 45 days of ESRD initiation. The CMS, USRDS, and renal research communities rely on this form to ascertain basic patient demographic attributes, primary cause of renal failure, major comorbidities, and biochemical test results at the time of ESRD initiation.

The third major revision of the Medical Evidence Form was released in May, 2005. This latest revision was intended to remedy several shortcomings found in the 1995 form and its earlier version. Key additions target pre-ESRD care and vascular access use, and additional new fields collect information on HbA1c and lipid testing, on the frequency of hemodialysis sessions, and on whether patients are informed of their transplant options. This new form will help federal and private researchers gain better insights into the health and care of ESRD patients prior to their entry into the program.

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

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).

**OPTN TRANSPLANT DATABASE**

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

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

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

CMS STANDARD ANALYTICAL FILES (SAFS)
These files contain billing data from final action claims, submitted by Medicare beneficiaries, in which all adjustments have been resolved.

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

CMS SAFs are updated each quarter through June of the next year, when the annual files are finalized. Datasets for the current year are created six months into the year and updated quarterly until finalized at 18 months, after which they are not updated to include late arriving claims. Annual files are thus approximately 98 percent complete. The USRDS 2007 ADR includes all claims up to December 31, 2005. Patient-specific demographic and diagnosis information, however, includes data as recent as October, 2006.

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

CMS DIALYSIS FACILITY COMPARE DATA
The USRDS uses the CMS Dialysis Facility Compare data to define chain and ownership information for each renal facility.

Prior to the 2003 ADR, similar data were extracted from the Independent Renal Facility Cost Report (CMS 265-94).

ESRD CLINICAL PERFORMANCE MEASURES PROJECT
CMS developed its ESRD Clinical Performance Measures Project (CPM, formerly the ESRD Core Indicators Project) to collect information on the quality of care provided to dialysis patients. The data originate from data collection forms completed by staff at primary care facilities, and focus on dialysis adequacy measures, anemia management, and vascular access. Additional clinical parameters such as albumin are available as well. These data have been collected annually since 1994, using a random sample of adult (age 18 and older) patients alive and on dialysis at the end of each calendar year; on average, roughly 8,500 adult in-center hemodialysis patients and 1,500 peritoneal dialysis patients are surveyed each year. Data collection for all hemodialysis patients age 12–17 was begun in 2000. In 2002 it was expanded to all in-center hemodialysis patients younger than 18, and in 2003 to all peritoneal dialysis patients of this age. The USRDS Coordinating Center, in collaboration with CMS, is now making these ESRD CPM data available to the general research community.

MINIMUM DATA SET
The CMS Minimum Data Set (MDS) contains data on ESRD patients 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.

NATIONAL HEALTH & NUTRITION EXAMINATION SURVEY (NHANES)
NHANES is a series of health examination surveys conducted by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC). Begun in 1960, NHANES is designed to monitor the health and nutritional status of the non-institutionalized civilian population in the United States. NHANES III was conducted in two phases between 1988 and 1994. In 1999, NHANES became a continuous annual survey to allow annual estimates, with release of public-use data files every two years. Both NHANES III and NHANES 1999–2004 were nationally representative cross-sectional surveys and used a complex, stratified, multistage probability cluster sampling design that included selection of primary sampling units (counties), household segments within the counties, and sample persons from selected households. Survey participants were interviewed in their homes and/or received standardized medical examinations in mobile examination centers. Both surveys oversampled African Americans, Mexican Americans, and individuals age 60 or older to improve the estimates for these subgroups.

ANNUAL FACILITY SURVEY (AFS)
Independent ESRD patient counts are available not only from the CMS ESRD database, but also from CMS’s Annual Facility Survey (CMS 2744), which all dialysis units must complete at the end of each year. The AFS reports counts of patients being treated at the end of the year, new ESRD patients starting treatment during the year, and patients dying during the year. Both
Medicare and non-Medicare end-of-year patients are counted. While AFS files do not carry patient-specific demographic and diagnosis data, they provide independent patient counts used to complement the CMS patient-specific records. Starting with the 2005 AFS, CMS stopped its effort in posting data from these surveys on the web. For the 2007 ADR, the USRDS has extracted the relevant data directly from the SIMS database.

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

**UNITED STATES CENSUS**
In rate calculations throughout this year’s ADR we use data from the 2000 U.S. Census, and also incorporate CDC population estimates by race. Our methods are described on page 291.
Our main computer system is based on a VMS cluster running Alpha EV6 processors. We currently maintain three nodes in the cluster: two 4-CPU 16-GB systems, and the other a dual CPU with 4-GB of memory. Through the HP Advanced Server System, we map VMS directories to network shares accessible to Windows clients as mapped network drives. The Alpha EV6s are one-GB CPUs and are connected to an 16 terabytes of RAID-5 (Redundant Array of Independent Disks, level 5) disk farms, all managed by five interconnected high-speed disk controllers.

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

DATA LOADING & 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 October, 2006, and Medicare inpatient/outpatient and physician/supplier claims through December 31, 2005.

ESRD PATIENT DETERMINATION

A person is identified as having ESRD when a physician certifies the disease on the CMS Medical Evidence (ME) form, or when there is other evidence of chronic dialysis or a kidney transplant. Patients with acute kidney failure who are on dialysis for days or weeks, but who then recover kidney function, are excluded from the database if their Medical Evidence forms have not been submitted. Patients who die soon after kidney failure without receiving dialysis are sometimes missed.

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

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

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 (EGHPPs), 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 OPTN transplant data, or to determine comorbidity or inpatient/outpatient and physician/supplier services. Because such data are limited, event rates that include these patients must be assessed with caution.

We continue to include ‘ZZ’ patients in the mortality rate calculations of the ADR. We are collaborating with CMS and other interested researchers to establish a consistent approach to managing the data for these patients. USRDS, in working with CMS, have been able to resolve most of the ‘ZZ’ patients since the release of ESRD Patient Database, REMIS, in the fall of 2003. According to the most recent assessment performed during the production of 2007 ADR, we have determined that at least 99 percent of ‘ZZ’ patients have been resolved due to significant advancements in the REMIS/REBUS database system over the past five years.

LOST-TO-FOLLOW-UP METHODOLOGY

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

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

Because Medicare may be the secondary payor for up to the first 3–33 months of ESRD, delaying the submission of Medicare dialysis claims, lost-to-follow-up categorization cannot begin until the end of the third year after the start of ESRD service. This “first three-year rule” is particularly important for non-Medicare patients, who may be followed for up to three years with limited event or mortality data. These patients would contribute dialysis or transplant days to the denominator of rate calculations, but only questionable event data to the numerator. In comparison to the two-year rule used in the 2001 ADR, this three-year rule significantly reduces the number of lost-to-follow-up patients in the prevalent population.

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

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

INTEGRATION OF THE USRDS, SIMS, & REMIS DATABASES

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

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 incorporate treatment-specific information from the ESRD Networks’ SIMS event database to improve the tracking of these patients in the USRDS database, and of patients who are considered lost-to-follow-up. The consolidation efforts from database integration among USRDS, SIMS, and REMIS continue to pay dividends—10,765 in 2002 (2007 ADR), for example compared to 24,726 in 2002 (2004 ADR).

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

The USRDS database is updated with mortality data from the SIMS event database.

The database is updated for each incident patient whose initial modality is listed as “unknown dialysis,” and for whom the SIMS database lists a known dialytic modality within 90 days of the established first ESRD service date.

Data on non-Medicare “lost-to-follow-up” patients are substituted with treatment information when found in the SIMS database.

Starting with this ADR, we have introduced the recovered renal function (RRF) event in the modality sequence, which in turn will directly reduce the lost-to-follow-up episodes within the prevalent population. Presently, an RRF event is established in the USRDS database only if such an event occurs within the first 180 days of FSD and lasts for at least 90 days. This definition is much more conservative than that in the SIMS event database.

60-DAY STABLE MODALITY RULE: TREATMENT HISTORY

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

90-DAY RULE: OUTCOMES ANALYSES

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

SERUM ALBUMIN DATA

The Medical Evidence form reports a patient’s albumin level along with the test’s lower limit, which indicates the testing method. There are currently two methods in use: brom cresol purple and brom cresol 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 ME form. We found that, from 1995 to 2003, almost 50 percent of forms contained lower limit values equal to “zero,” while another 25 percent reported values other than the expected 3.2 and 3.5 g/dl. Only 25 percent (n=173,000) of incident patients had legitimate lower limit values for determining normal serum albumin. Further analyses have shown that these patients are a representative cohort sample, with a similar demographic distributions by age, gender, race, and cause of ESRD to that of the overall ESRD population. For all figures in the 2005 and later ADRs...
which present data on serum albumin from the ME 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.

**MODALITIES**

The Coordinating Center and the ESRD group at CMS have worked extensively on methods of categorizing patients by ESRD modality. While the Medical Evidence form is the primary source of data on modality at ESRD initiation, the modality it indicates may be temporary, as patients often change to a new one within the first 90 days, and it can be difficult to track modality during this time. Patients age 65 and older have Medicare claims in the first 90 days; these claims contain revenue codes that designate modality. Patients younger than 65 who are in employer group health plans or Medicare risk programs, however, have no such claims. Modality may thus not be determined until Medicare becomes the primary payor at day 91 or, for EGHP patients, at 30–33 months after the first ESRD service date. These limitations influence our ability to determine a patient’s exact modality at any one point in time.

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

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

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

**PAYORS**

Information on payors is obtained from the CMS Medicare Enrollment Database (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 provide payor history, and, starting with the 2003 ADR, we use this file to identify Medicare eligibility status and other payors.

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

**PRIMARY CAUSE OF RENAL FAILURE**

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

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

**RACE & ETHNICITY**

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

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

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

**EGHP COHORT**

EGHP data in this year’s ADR are derived, as mentioned above, from Medstat MarketScan databases. To examine the demographic segment not represented by Medicare, we use enrollment information to construct yearly cohorts of enrollees younger than 65. To ensure that we select enrollees with the potential to generate claims evidence appropriate to the demands of analytic 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 medication analyses, continuous prescription drug coverage. Comorbidities are identified using claims. Patients with at least one inpatient claim or at least two outpatient claims during the period of interest and with a diagnosis code of a particular comorbidity are identified as having that comorbidity.

**ESRD COHORT IN THE EGHP POPULATION**

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

**Précis**

For Figure p.1 we identify chronic kidney disease (CKD), congestive heart failure (CHF), and diabetes in patients from the 5 percent Medicare sample using methods described for Chapter One; these methods are also used to determine diabetic status and CHF in the ESRD population. Costs for the "cost year" are determined for the entire calendar year for patients who have fee-for-service coverage and Medicare as primary payer. Because this analysis combines the ESRD cohort with the 5 percent Medicare sample, ESRD patients in the 5 percent sample are excluded. Dual enrollment is determined from the payor sequence, based on the state buy-in code.

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

**TRENDS IN QUALITY OF CARE**

Vascular access use in Figure p.11 represents data from 1999–2005 ESRD CPM reports on the current access used at the last dialysis session. The methods for Figure p.12 are the same as those used for Figure hp.13 in the HP2010 chapter.

Figure p.13 includes prevalent hemodialysis patients who are in both the USRDS and ESRD CPM databases, and the access represents the current access according to the ESRD CPM data; complication rates are calculated as the number of events (from Medicare claims) divided by the time at risk, which is censored at death, change in modality, change in payment status, or the placement of a different type of access. Vascular access codes are listed in the methods for Chapter Eleven.

Figure p.14 includes prevalent hemodialysis patients in the ESRD CPM database with at least one valid URR measurement. For each patient, we calculate a mean URR measurement from all measurements available, then the percentage of patients whose mean URR is in each category. Figure p.15 includes prevalent peritoneal dialysis patients in the ESRD CPM database with at least one valid Kt/V measurement. For each patient, we calculate a mean Kt/V measurement from all those available, then the percentage of patients whose mean Kt/V is in each category.

Figure p.16 presents the distribution of patients by mean hemoglobin group on a monthly basis, in which each month contains all patients with at least one valid EPO claim during the month. The hemoglobin is calculated as the reported hematocrit value divided by three. Figure p.17 shows the mean hemoglobin, by month, for prevalent dialysis patients with EPO claims, along with the monthly EPO dose per week for patients with 20 or fewer administrations per month. 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.

For Figure p.18, an archived PMMIS quarterly dialysis record is used to track transfusions in ESRD patients in years prior to 1991. The percentage of hemodialysis patients receiving transfusions is calculated as the number of patients receiving at least one transfusion in a given quarter divided by the number of hemodialysis patients with at least one dialysis record in that quarter. Since the archived data are current only to the third quarter of 1995, we emulate this method, using Medicare claims generated by ESRD facilities, to update the trend.

The method and cohort used for Figure p.19, on diabetic care in prevalent patients, are the same as those used for Figures 5.20, 5.24, and 5.28.

**HOSPITALIZATION & MORTALITY**

Hospitalization data are shown in Figures p.20–22. Included patients have Medicare as a primary payor and are residents of the 50 states and the District of Columbia; residents of Puerto Rico and the Territories are also included in Figures p.20 and p.22, but are excluded from the maps in Figure p.21. Patients with AIDS as a primary or secondary cause of death are excluded, as are patients with missing age or gender information.

Figure p.20 shows one-year probabilities of hospitalization, death, and a combined endpoint of hospitalization or death. The cohort includes 2000–2004 incident dialysis patients age 20 and older. Patients are followed from day 91 of ESRD until the event or censoring. For death, patients are censored at loss to follow-up, transplant, December 31, 2005, or at one year. For first hospitalization, patients are censored at the above and also at death, end of Medicare primary payor status, and three days prior to transplant rather than the transplant date (to avoid counting the transplant hospitalization). Also, for the combined endpoint, censoring follows that for first hospitalization, except that death is an event rather than a censoring criterion. Patients with a bridge hospitalization that spans day 91 are excluded from the hospitalization and combined endpoint analyses. Event probabilities are computed from the Cox model using the model-based adjustment method, described in the statistical methods section, adjusting for age, gender, race, and primary ESRD diagnosis. The reference cohort consists of all included 2000–2004 incident patients.

Figures p.21–22 show total admission rates and the percent change in admission rates for period prevalent ESRD patients. Methods generally follow those described for the prevalent patient cohorts in Chapter Six and Reference Section G. In Figure p.22, rates are adjusted for age, gender, race, and primary diagnosis using the model-based adjustment method. The reference cohort includes period prevalent ESRD patients, 2005. Principal ICD-9-CM diagnosis codes for cardiovascular and infectious hospitalizations are listed in the discussion of Figures 6.5–6. Vascular access hospitalizations are those defined as "pure" inpatient vascular access events, as described for Table G.11.

Figure p.23 illustrates trends in mortality rates by patient vintage for period prevalent dialysis patients alive on renal replacement therapy on January 1, with a first service date at least 90 days prior to the beginning of the year, and reaching day 91 of ESRD treatment during the year. Patients with unknown age or gender, or of a race other than white, African American, Native American, or Asian, are excluded. Patients are followed from
January 1 until death, transplantation, or the end of the year, and all-cause mortality rates are adjusted for age, gender, race, and primary diagnosis using generalized mixed models. The reference population consists of 2001 prevalent dialysis patients, and adjusted mortalities across vintages are comparable.

Figure p.24 presents adjusted first-, second-, third-, and fourth-year mortality rates, by modality, for incident ESRD patients. Patients are followed from day 91 until death or December 31, 2005. Dialysis patients are also censored at transplant. Rates are computed from the Cox model using the model-based adjustment method, described later in this appendix, and adjusted for age, gender, race, and primary cause of ESRD. The reference population consists of 1996 incident ESRD patients, and these rates are comparable across modalities.

Figure p.25 illustrates five-year survival by first modality. Populations for the 1991–1995 and 1996–2000 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, as well as those with a listed age greater than 110; in the dialysis cohort, patients who die or are transplanted in the first 90 days are also excluded. Dialysis patients are followed from day 91 until death, transplantation, or the end of 2005, while transplant patients are followed from the first transplant date until death or the end of 2005. 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.

ESRD EXPENDITURES
Methods used for Figures p.26–34 and Table p.b are described in the text for Chapter Eleven and in the figure captions.

CKD POPULATIONS & EXPENDITURES
In Figures p.35–42, CKD, CHF, and diabetes are determined using methods from Chapter One. The population for the 5 percent Medicare data is limited to those with fee-for-service coverage and Medicare as primary payor.

Figure ei.1 illustrates adjusted first-year mortality rates, by modality, for incident dialysis patients. The study cohort includes hemodialysis and peritoneal dialysis patients with a first service date between January 1, 1995, and December 31, 2004, who live in the 50 states, the District of Columbia, Puerto Rico, and the Territories, and excludes those with unknown age, gender, or primary diagnosis, as well as those with a listed age greater than 110. Patients are followed from the first service date up to one year. The intent-to-treat method is used, and patients are censored at transplant or kidney recovery. Rates are computed from the Cox model. Variables for the basic adjustment include age, gender, race, and primary cause of ESRD, and those for the composite adjustment include hemoglobin, BMI, eGFR, and comorbidities, obtained from the Medical Evidence form. The reference population consists of incident hemodialysis and peritoneal dialysis patients, 1995, and adjusted probabilities can be compared across modalities.

Figure ei.2–3 display rates of intravenous vitamin D and iron administration from 1992 to 2005 among period prevalent dialysis patients. For each calendar year, the cohort consists of patients who initiate ESRD therapy at least 90 prior to the start of the year and are receiving dialysis on December 31 of the previous year. All patients survive, continue dialysis, and carry Medicare as primary payor (with physician/supplier coverage) during the ensuing year. In Figure e.2, Calcijex is indicated by HCPCS codes J0635–J0636; Hectorol by HCPCS J1270; and Zemplar by HCPCS J2500–J2501. In Figure e.3, Ferlecit is indicated by HCPCS codes J2915–J2916; INFeD by HCPCS J1750, J1755, J1760, J1770, J1780; and Veneno by HCPCS J1755–J1756.

Erythropoietin (EPO) dose information and hemoglobin values (calculated from hematocrit values) for Figures ei.4–8 are obtained from the EPO claims data.

The cohort for Figures ei.4–8 includes incident dialysis patients age 65 and older, 1995–2004, with Medicare as primary payor, and receiving EPO during the first six months after incidence. Patients who die or are transplanted in the first six months are excluded, as are patients who have missing initial hemoglobin values or a hemoglobin value over 11 g/dl. Patients are censored at a missing hemoglobin value. Cumulative probabilities are calculated using Kaplan-Meier method.

Figure ei.6 illustrates the time to return to a hemoglobin above 12 g/dl in patients who exceed 12, 12.5+ , 13+. 13.5+, and 14+ g/dl. The average time above 12 g/dl is calculated using the Kaplan-Meier method. Figure ei.8 illustrates the EPO dose used to achieve particular hemoglobin levels. For patients hitting 11+ g/dl in month 2, for example, the average dose is the mean dose in months 1 and 2. EPO doses in this figure are adjusted for inpatient days.

Figure ei.12 characterizes the number of comorbidities during the two years prior to ESRD initiation. Included ESRD patients are at least 67 years old, have a first ESRD service date between January 1, 1995, and December 31, 2005, have Medicare inpatient/outpatient and physician/supplier coverage for the complete two-year period prior to initiation, and have at least one claim in the two-year period prior to initiation. Comorbidities are identified from claims in the two years prior to initiation.

Figures ei.13–14 characterize hospital visits and admissions during the two years prior to ESRD initiation. Included ESRD patients are at least 67 years old, have a first ESRD service date between January 1, 1995, and December 31, 2005, and have Medicare inpatient/outpatient and physician/supplier coverage for the complete two-year period prior to initiation. Methods for counting hospital days and admissions follow those described for Reference Section G later in this appendix.

Figures ei.15–17 and Table ei.a characterize the number of comorbidities during the two years prior to ESRD initiation. Included ESRD patients are at least 67 years old, have a first ESRD service date between January 1, 1995, and December 31, 2005, have Medicare inpatient/outpatient and physician/supplier coverage for the complete two-year period prior to initiation, and have at least one claim in this period. Comorbidities are identified from claims during the two years prior to initiation. Estimated GFR information for Figures ei.9–10 and Table ei.a, and laboratory information in the table, come from the Medical Evidence form; age is calculated at ESRD initiation. Adjustments for Figure ei.10 are standardized to the 1995 data using general linear model-based adjustments.

Figure ei.18 includes incident hemodialysis patients who are in both the USRDS and ESRD CPM databases, and whose day 91
Analytical Methods

Appendix A

begins prior to October 1 of the incident year. The access represents the access being used on day 90 according to the CPM data.

Figures ei.19–22 and Table ei.b include incident hemodialysis patients, 1995–2005, age 67 and older at initiation. Catheter placements are determined from physician/supplier claims prior to initiation, and from any inpatient hospital stays for acute dialysis initiation that indicate a catheter was placed during that stay. Acute dialysis initiation is determined from inpatient hospital stays at initiation with a primary procedure code of hemodialysis (ICD-9-CM 39.95), an admission source of "Emergency Room," and an admission type of either "urgent" or "emergency." Those dialyzing with catheters at initiation are those who a) have only a catheter placement claim and not a fistula/graft placement claim prior to initiation, or b) have both types of placement claims but either the fistula/graft placement is less than one month prior to initiation or the catheter placement is more recent. Comorbidities in Figure ei.22 and Table ei.b are identified from claims.

Table ei.c and Figures ei.23–26 present monthly mortality rates in dialysis patients. The study cohort includes dialysis patients with a first service date between January 1, 1993, and December 31, 2004, who reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Patients with unknown age, gender, or primary diagnosis are excluded, as are those with a listed age greater than 110. Patients are followed from the first service date up to one year, and are censored at transplant or recovery of kidney function. Overall adjusted mortality rates are adjusted for age, gender, race and primary diagnosis, and adjusted mortality rates for one of the four variables are adjusted for the remaining three. The reference population consists of 1993 incident dialysis patients, and adjusted mortality rates can be compared across years.

Figure ei.27 illustrates adjusted first-year mortality rates, by modality, for dialysis patients. The study cohort is constructed with the method used in Figure ei.1. Patients are followed from the first service date up to one year. The intent-to-treat method is used, and patients are censored at transplant or recovery of kidney function. Unadjusted mortality rates are calculated using the Kaplan-Meier method, while adjusted mortality rates use the model-based method based on a Cox model, as described in the section on statistical methods. Adjusted rates are adjusted for age, gender, race, primary diagnosis, comorbidity, eGFR, BMI, and hemoglobin. The reference population consists of incident hemodialysis and peritoneal dialysis patients, 1996, and adjusted probabilities can be compared across modalities.

The Cox model is used to obtain the hazard ratios in Table ei.d. The study cohort includes incident hemodialysis and peritoneal dialysis patients, 1996–2004, who reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Patients with unknown age, gender, or primary diagnosis are excluded, as are those with a listed age greater than 110. Patients are followed from the first service date up to one year. The intent-to-treat method is used, and patients are censored at transplant or recovery of kidney function.

Healthy People 2010

Targets come directly or are estimated from published HP2010 objectives on chronic kidney disease and immunizations.

Objective 4.1: Incident rates in Figures hp.2–3, hp.4 (first graph), and hp.26, and in Table hp.a, are calculated using the methods described for Chapter Two. Rates of diabetes in the general population (second graph in Figure hp.4) are obtained from the CDC’s Behavioral Risk Factor Surveillance System, at www.cdc.gov/brfss.

Objective 4.2: The study cohort includes period prevalent ESRD patients, 1991–2005. Cause-specific cardiovascular mortality is defined using CMS codes 27, 31, and 32 (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. We exclude patients with unknown age, gender, or race, and those with an age calculated to be less than zero. Rates are estimated as the number of patients who die from cardiovascular disease in each year per 1,000 patient years at risk.

Objective 4.3: Table hp.c and figure hp.8 use data from the newest version of the Medical Evidence form for patients initiating ESRD on hemodialysis. Information on pre-ESRD care is obtained directly from the Medical Evidence form. The cohort for Figures hp.9–10 includes incident ESRD patients, age 67 and older at initiation; pre-ESRD nephrologist care is identified through at least one physician/supplier claim with a physician specialty code of “nephrologist.” Albumin tests are identified from Medicare claims during the two-year period prior to ESRD.

Objective 4.4: For Figures hp.12–13, the calculation of placement rates follows methods used in Chapter Five. For Table hp.d (ESRD CPM year 2005) and Figures hp.11 and hp.29 (ESRD CPM years 1999–2003), data are obtained from the CMS ESRD Clinical Performance Measures (CPM) Project. Patients included in these two figures and the table are those whose date of dialysis initiation, according to the CPM data, occurs in the same year as the data collection, and the access type represents the access used during the last quarter of the year. 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 4.5: The cohort for Figures hp.14–15 and Table hp.e includes patients younger than 70 in 1991–2003. Percentages are calculated as the number of patients placed on the deceased donor organ wait list or receiving a deceased donor transplant within one year of initiating ESRD therapy, divided by the number of patients without a living donor available (i.e., patients receiving a living donor transplant are excluded), and are estimated using the Kaplan-Meier method. Note that this method differs from those used in previous ADRs, which showed the percent of point prevalent dialysis patients on the wait list as of December 31 of the given year.

Objective 4.6: The study cohort here includes patients from 1991–2002 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: For Figures hp.18–20 and hp.32, and for Table hp.g, incident rates of ESRD due to diabetes are calculated using the methods described for Chapter Two.

Objective 4.8: Methods and codes used to determine rates of glycosylated hemoglobin (HbA1c) testing and eye exams are taken from HEDIS 2002 specifications (HEDIS 2002, an NCQA program, is used to monitor the performance of managed health
Prescribed Medicine Events, “ and SUDAAN (Research Triangle Institute, Research Triangle Park, NC) is used to analyze all data. According to a previously validated method for using Medicare data on parathyroid hormone, individuals under 65 or older at the beginning of the year. Testing is tracked during the entire year, while pneumococcal pneumonia vaccinations are tracked between September 1 and December 31 of each year. ESRD patients initiating therapy at least 90 days before January 1 of the graphed time period and alive on December 31. Patients are excluded if they are enrolled in a managed care program (HMO), acquire Medicare as secondary payor, are institutionalized beneficiaries—to measure cost 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 the Medicare inpatient/outpatient and physician/supplier program during the entire year, survive until the end of the year, have a completed survey, are not enrolled in a managed care organization, and do not have ESRD; they also reside in the 50 states or the District of Columbia and are community-dwelling respondents. Comorbidities, including CKD and diabetes, are defined from the claims information, using the same method used with the 5 percent data. Drug use information is obtained from the MCBS Cost and Use data file “Prescribed Medicine Events,” and SUDAAN is used to analyze all data.

Objective 14.29: The cohort for influenza vaccinations includes all ESRD patients initiating therapy at least 90 days prior to September 1 of each year and alive on December 31. For pneumococcal pneumonia vaccinations, cohorts include all ESRD patients initiating therapy at least 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 inpatient/outpatient and physician/supplier 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, 90667, 90658, 90659, and 90660, and HCPCS code G0008; pneumococcal vaccinations are identified through CPT codes 90669 and 90731, and HCPCS codes J6065 and G0008.

PREDICTORS OF CKD IN THE NHANES POPULATION

Figures 1.1 and 1.5–7 and Table 1.b present data from the NHANES III and NHANES 1999–2004 populations. Pregnant and menstruating female subjects are not excluded. Microalbuminuria is defined by the ratio of urinary albumin to urinary creatinine (albumin/creatinine ratio, or ACR). Participants age 19 or younger are excluded from the analyses. The eGFR is estimated separately for NHANES III, NHANES 1999–2000, NHANES 2001–2002, and NHANES 2003–2004, using the MDRD method based on the adjusted creatinine value. Participants with a valid ACR are classified as having a positive microalbuminuria if this value is not less than 30 mg/dL. Hypertension and diabetes are self-reported comorbidities identified through the survey’s medical history questionnaires. As per the recommendations from NHANES (http://www.cdc.gov/nchs/data/nhanes) serum creatinine values are standardized as follows:

- NHANES III: standardized creatinine = 0.960 * reported creatinine – 0.184
- NHANES 1999-2000: standardized creatinine = 1.013 * reported creatinine + 0.147

The formula used to estimate GFR is as follows (Levey et al., 2006): estimated GFR = 175 * (standardized serum creatinine in mg/dL)^1.154 * age^-0.203 * (0.742 if female) * (1.212 if black).

Figure 1.1 uses two methods of estimating CKD prevalence. One method defines Stage 4–5 CKD as eGFR < 30, Stage 3 as 30 ≤ eGFR < 60, Stage 2 as ACR ≥ 30 and 60 ≤ eGFR ≤ 89, and Stage 1 as ACR ≥ 30 and eGFR ≥ 90. The other adjusts for the non-gender-specific persistence of albuminuria (Coresh et al.), with Stage 4–5 as eGFR < 30, Stage 3 as 30 ≤ eGFR < 60, Stage 2 as PCT(ACR ≥ 300 | 60 ≤ eGFR ≤ 89) * PCT(60 ≤ eGFR ≤ 89) + 0.75 * PCT(30 ≤ ACR ≤ 299 | 60 ≤ eGFR ≤ 89) * PCT(60 ≤ eGFR ≤ 89). Stage 1 as PCT(ACR ≥ 300 | eGFR ≥ 90) * PCT(eGFR ≥ 90) + 0.599 * PCT(30 ≤ ACR ≤ 300 | eGFR ≥ 90) * PCT(eGFR ≥ 90).

Table 1.b and Figures 1.5–7 show the percentage of patients with eGFR < 60, ACR ≥ 30, or (eGFR < 60 or ACR ≥ 30). In Figure 1.8, eGFR < 60 and ACR ≥ 30 are used as the standard to detect individual metabolic abnormalities.

Sensitivity and specificity in Figure 1.8 are from NHANES 1999–2004, with the exception of data on parathyroid hormone, which are from NHANES 2003–2004. The following thresholds were used: potassium > 4.62 mmol/l, hemoglobin < 12.01 g/dl, bicarbonate < 19.70 mmol/l, phosphorus > 4.54 mg/dl, and PTH > 83.76 pg/ml.
**DISEASE BURDEN & CARE**

Figures 1.9–10 include non-ESRD patients from the 5 percent general Medicare sample, 2005, who are alive and Medicare eligible for the entire year. Comorbidities (including CKD) are identified from claims during 2005. Dually-enrolled patients include patients identified as such at any time during 2005.

Figures 1.11–12 and 1.14 compare the cumulative probabilities of CKD preventive care in general Medicare and dually-enrolled (with both Medicare and Medicaid coverage) patients, using the Kaplan-Meier estimation method.

For influenza vaccinations in Figure 1.11, the prevalent Medicare cohort includes patients entering Medicare before January 1, 2004, alive and remaining in the program through August 31, 2005, and diagnosed with CKD during 2004. For pneumococcal vaccinations, the cohort includes patients entering Medicare before January 1, 2003, remaining alive and in the program though December 31, 2003, and diagnosed with CKD during 2003. Patients enrolled in an HMO, with Medicare as secondary payor, or diagnosed with ESRD during 2004 (for pneumococcal vaccinations, during 2003) are excluded, as are patients not residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories. The first influenza vaccination is tracked between September 1 and December 31, 2005. The first pneumococcal vaccination is tracked during 2004 and 2005. Methodologies and codes used to define CKD and diabetes are described under “CKD populations and costs.”

The prevalent Medicare cohort for Figure 1.12 includes patients entering Medicare before January 1, 2004, alive and age 66 or older on December 31, 2004, and with CKD diagnosed during 2004. Patients enrolled in an HMO, with Medicare as secondary payor, or diagnosed with ESRD during the year are excluded, as are patients who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories. For glycosylated hemoglobin testing and eye examinations, patients are also diagnosed with diabetes in 2004. Methodologies and codes used to define CKD with diabetes are described under “CKD populations and costs.”

**HOSPITALIZATION RATES IN CKD & NON-CKD PATIENTS**

Figures 1.15 and 1.17–20 show adjusted all-cause and cause-specific hospitalization admission rates, by the presence of diabetes and CHF, for general Medicare and dually-eligible patients, 1993–2005, with and without CKD. The prevalent Medicare cohort includes patients age 66 or older who are continuously enrolled in the Medicare inpatient/outpatient and physician/supplier program, who are not enrolled in HMO during the one-year entry period, and who reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories. The dually-enrolled patients are included under the same criteria, except that they are also enrolled in the Medicaid program at any time during the one-year entry period. Patients diagnosed with ESRD before or during the entry period are omitted from the study. The period at risk for the hospitalization analysis is a maximum of one year, from January 1 until the earliest of death, end of Medicare inpatient/outpatient and physician/supplier coverage, or December 31 of the year.

The same methodology described for Figure 1.1 is used to define patients with CKD, diabetes, or CHF. Principle ICD-9-CM diagnosis codes used to define cause-specific inpatient hospitalization categories are as follows: CHF, 398.91, 422, 425, 428, 402.x1, 404.x1, and 404.x3; ASHD, 410–414; pneumonia, 480–486 and 487.0; and bacteremia/septicemia, 038–038.9 and 790.7. An admission for a hospitalization spanning the start of the analysis period is excluded from the total admissions for that period. All overlapping and certain consecutive hospitalizations are combined using the methods described for Chapter Six.

Admission rates are adjusted for age, gender, and race, using the direct adjustment method (described in the section on statistical methods), with the 2005 Medicare cohort used as the reference group.

Figure 1.16 displays geographic variations in unadjusted all-cause admission rates for general Medicare CKD and non-CKD patients in 2005. The cohort includes general Medicare patient age 66 or older, enrolled in the Medicare inpatient/outpatient and physician/supplier program, and with no HMO coverage during 2004. Patients diagnosed with ESRD before January 1, 2005, and those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories, are omitted from the study. CKD is identified from 2004 using the same methodology in Figure 1.1. Follow-up begins on January 1, 2005, and continues until death, the last day of Medicare coverage, or December 31, 2005.

Table 1.c show the adjusted odds ratios for hospitalization and death following an influenza vaccination for 2005 CKD patients. The cohort includes general Medicare CKD patients age 66 or older on January 1, 2005, enrolled in the Medicare inpatient/outpatient and physician/supplier program, and with no HMO coverage during 2004. Patients diagnosed with ESRD before January 1, 2005, are omitted. The period from January 1, 2004, to August 31, 2004, is used as an entry period to characterize comorbidities and hospitalization days. Influenza vaccinations are identified from September 1, 2004, to December 31, 2004, and outcomes are assessed in the first three months of 2005. Cause-specific hospitalizations are determined from principle ICD-9-CM diagnosis codes on Medicare inpatient claims, including influenza/pneumonia (ICD-9-CM, 480–487), bacteremia/viremia/septicemia (038, 790.7, 790.8), and respiratory infection (472–474.0, 475–477.9, 478.22–478.24, 480–491, 494, 510–511, 513.0, and 518.6). Logistic models are used to estimate the odd ratios, adjusting for influenza vaccination, age, race, gender, comorbidity, and hospital days.

**ACUTE KIDNEY INJURY**

For Figures 1.21–28, hospitalization for acute kidney injury (AKI) is identified through the 584 ICD-9-CM code appearing on Medicare inpatient claims as any diagnosis code (except in Figure 1.27), and the methodology to identify CKD is essentially the same as that for in Figure 1.1, with the exception of the use of the 584 ICD-9-CM code. Patients who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories are omitted from the analysis.
Figures 1.21 display the demographic characteristics of patients suffering AKI, using the general Medicare population. The two cohorts consist of 1993–1995 and 2003–2005 patients. Patients with an AKI hospitalization are identified from inpatient claims any time during those periods. For both cohorts, patients with ESRD diagnosed before the AKI hospitalization admission are omitted. For patients with multiple AKI hospitalizations through the years, the first one in the time frame is counted. Dually-enrolled patients are those also enrolled in Medicaid program at the time of the AKI hospitalization.

Figure 1.22 presents hospital admission rates for AKI in the general Medicare population, 1993–2005. Patients with an AKI hospitalization are identified from inpatient claims, using CPT codes 90658, 90659, and 90660, and HCPCS G0008; and lipid testing: CPT codes 80061, 82465, 83715, 83721, and 84478. Patients are categorized into two groups based on whether they see nephrologist in the follow-up period after AKI discharge. Patients are censored at death, ESRD diagnosis, and the end of Medicare inpatient/outpatient and physician/supplier coverage. The Kaplan-Meier method is used to present the cumulative unadjusted probability of receiving a test for microalbumin at each month during the follow-up period.

Figure 1.26 shows the probability of patients receiving follow-up testing post-discharge for AKI. Testing includes HbA1c tests and eye examinations (diabetics only), lipid testing, and influenza vaccinations. For the first three, patients with AKI are identified from the general Medicare population in 2004, and are followed from the AKI discharge up to one year. Diabetic status is determined from the one-year entry period before the AKI hospitalization. For influenza vaccinations, patients with AKI are identified in March through August, 2004, and followed from September through December, 2004. Codes for testing are as follows: HbA1c tests, CPT 83063 (at least two tests, each 30 days apart); eye examinations: taken directly from HEDIS 2003 specifications; influenza vaccinations: CPT codes 90724, 90567, 90568, 90659, and 90660, and HCPCS G0008; and lipid testing: CPT codes 80061, 82465, 83715–83721, and 84478. Patients are censored at death, ESRD diagnosis, and the end of Medicare inpatient/outpatient and physician/supplier coverage. The Kaplan-Meier method is used to present the cumulative unadjusted probability of testing at three-month intervals during the one-year follow-up period.

Figure 1.27 displays the pattern of ESRD development and death in Medicare patients with an AKI hospitalization. The study cohort is the same as that used in Figure 1.25. Patients are followed up to three years after the first AKI hospitalization discharge until the earliest of death, ESRD diagnosis, or December 31, 2005. A one-year entry period before the first AKI hospitalization discharge date is used to define CKD. Rates for ESRD development or death in each three-month interval are estimated by the Poisson model, adjusted for baseline age, race, and gender.

Figure 1.28 shows the cumulative probability of dialysis or CKD following discharge for AKI. The study cohort is the same as that used in Figure 1.27, except that patients with prior CKD before AKI hospitalization are omitted. Hospitalization for AKI is identified through the 584 ICD-9-CM code, appearing on Medicare inpatient claims, by two methods, 1) as a primary diagnosis code, and 2) as a secondary diagnosis code (not a primary diagnosis code). Patients are followed up to three years after the first AKI hospitalization discharge until the earliest of death, ESRD diagnosis, end of Medicare inpatient/outpatient and physician/supplier coverage, or December 31, 2005. Dialysis service is defined by ESRD. The Kaplan-Meier method is used to investigate the cumulative unadjusted probability of receiving dialysis service or having ESRD at each month during the follow-up period.

**COMPARISON OF CARE IN CKD PATIENTS**

Figures 1.29–32 show the differences in preventive care of CKD patients and pre-ESRD patients by insurance status. For Figure 1.29, the general Medicare population includes patients entering Medicare before January 1, 2005, alive and age 67 or older on December 31, 2005, and with CKD and diabetes diagnosed during 2005. The pre-ESRD population includes 2005 incident patients age 67 or older at initiation, and with diabetes one year prior to start of ESRD. Cohorts in Figures 1.30–31 are similar,
In Figure 1.32 the general Medicare population is the same as that used for Figure 1.31, but testing is tracked between September 1 and December 31, 2005. The pre-ESRD population includes ESRD patients initiating therapy between January 1 and August 31, 2005, and age 67 or older at initiation. Tracking is started between September 1 and December 31, 2004. For all cohorts, patients enrolled in an HMO, with Medicare as secondary payor, or diagnosed with ESRD during the year (for the pre-ESRD population, in the year prior) are excluded, as are patients who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Methodologies and codes used to define CKD, diabetes, and anemia are described above. Age is calculated on December 31, 2005.

Methods and codes used to determine rates of glycosylated hemoglobin (HbA1c) testing and eye examinations are taken from HEDIS 2002 specifications. Codes used to identify testing are as follows: diabetic HbA1c testing, CPT code 83036 (claims made within 30 days of the last claim for each patient are excluded, and at least two HbA1c claims must be counted); microalbuminuria or proteinuria, CPT codes 82042, 82043, and 82044; lipid testing, CPT codes 80061, 82465, 83715–83721, and 84478; parathyroid hormone, CPT code 83970; calcium and phosphorous, CPT codes 80069, 80073, 82310, 82315, 82320, 82325, 82330, and 84100; diabetic eye exams, CPT codes 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92230, 92235, 92240, 92250, 92260, 92287, 67101, 67105, 67107, 67108, 67110, 67112, 67141, 67145, 67208, 67210, 67218, 67227, and 67228, ICD-9-CM procedure codes 14.1–14.5, 14.9, 19.02, 95.03, 95.04, 95.11, 95.12, and 95.16, and ICD-9-CM diagnosis code V80.2; influenza vaccinations, CPT codes 90724, 90657, 90658, 90659, and 90660, and HCPCS code G0008; pneumococcal vaccinations, CPT codes 90669 and 90732, and HCPCS codes J6065 and G0009; ESA use, revenue code 0635, 0636, value code 68, and HCPCS codes Q0136, Q0137, Q0454–Q0455, Q9920–Q9940, and J0880.

Figures 1.33 and 1.34 use the same cohorts as Figures 1.31 and 1.30, respectively. Patients are identified as seeing a nephrologist if they have a physician/supplier claim with a physician specialty code of 39. For pre-ESRD patients these claims are searched during the one-year period prior to dialysis initiation; for general Medicare patients these claims are searched during 2005.

Table 1.d shows the adjusted relative risks for ESRD, death, or both. The cohort includes general Medicare patients entering Medicare before January 1, 2004, alive and age 66 or older on December 31, with CKD, anemia, and diabetes diagnosed during 2004. Patients enrolled in an HMO, with Medicare as secondary payor, or diagnosed with ESRD during 2004 are excluded. Also excluded are patients not residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Preventive testing and ESA use are tracked during 2004. Data on HbA1c testing include two or more tests at least 30 days apart. Patients are then followed during 2005 for ESRD, death, or both. For ESRD, patients are censored at death; for death, patients are censored at ESRD. A proportional hazards model is used to obtain the relative risks. Covariates include age, gender, race, two or more HbA1c tests, microalbuminuria or proteinuria testing, lipid testing, PTH testing, calcium and phosphorous testing, eye examinations, influenza vaccinations, and ESA use. Reference groups are age 65–69 at the beginning of 2004, male, white, no corresponding preventive testing, and no ESA use.

Figures 1.35–36 include incident hemodialysis patients in 1996–2005, age 67 or older at initiation. Nephrology claims prior to initiation include all physician/supplier claims in the two years prior to initiation with a physician specialty code of “nephrologist.” Fistulas in Figure 1.36 are also obtained from physician/supplier claims during the two-year period. A subset of this cohort, including only those initiating in 2003, is used for Figure 1.37. Figures 1.38 and 1.40 include patients incident in 2004, and use Medicare claims after initiation to identify complications and infections.

Figure 1.39 shows the percent of patients with at least one hospitalization during three-month intervals from 24 months prior to six months after ESRD initiation. We include Medicare ESRD patients at least 67 years old with a first ESRD service date between January 1, 2004, and June 30, 2005. Included patients have Medicare coverage (inpatient/outpatient and physician/supplier) in the two-year period prior to initiation. Principal ICD-9-CM diagnosis codes for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 6.6. Vascular access hospitalizations are those defined as “pure” inpatient vascular access events, as described for Table G.11.

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

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

Beginning with the 1992 ADR, lost-to-follow-up patients are not included in the point prevalent counts; they are, however, reported in Table B.1 of the Reference Tables.

REFERENCE SECTION A

The Reference Tables present parallel sets of counts and rates for incidence (Section A) and December 31 point prevalence (Section B). Section B also presents annual period prevalent counts and counts of lost-to-follow-up patients.

Because the U.S. population figures (shown in Reference Section M) used in the ADR include only residents of the 50 states and the District of Columbia, tables also focus on patients from these areas. Exceptions are Tables A.1, A.9, A.6, A.8, A.10, and A.11, 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.
With the exception of Tables B.1, B.6, B.8, and B.10, these tables focus on patients residing in the 50 states and the District of Columbia. Age is calculated as of December 31.

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 a revised form in 1995, however, providers are now required to complete the form for all new ESRD patients, regardless of their Medicare eligibility. The 1995 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 has been revised, the USRDS stores the codes from each version so that detail is not lost through trying to convert one set of codes to the other.

A new revision of the Medical Evidence form was released in the spring of 2005, introducing new fields related to comorbidity, laboratory test values, pre-ESRD care, and vascular access.

Figures 3.12–14 include incident hemodialysis patients. Figure 3.13 uses the hemoglobin and/or hematocrit value from the Medical Evidence form, while Figures 3.12 and 3.14 use EPO claims and therefore only include patients who have valid EPO claims during each of the first four months after dialysis initiation. Patients are linked to altitude data on a county level based on their county of residence.

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-follow-up or having recovered renal function (RRF). The RRF event, introduced in this 2007 ADR, is defined as an event that occurs within the first 180 days of the ESRD initiation and lasts for at least 90 days. This definition is much more conservative than that used in the SIMS event database. Unless noted otherwise, incident and 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)

Modality and provider characteristics are presented in Figures 4.7–12. For a description of the provider data used in these figures, please see the discussion of Chapter Ten. All provider-related figures include only dialysis patients.

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

Table D.12 shows modality at 90 days and two years after first service for all incident Medicare patients beginning renal replacement therapy from 2001 to 2003. The 90-day rule is used to exclude patients who die during the first 90 days of ESRD, and age is computed as of the first ESRD service date.

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

In Figure 5.1, for both Kt/V measurements, 2004 ESRD CPM data are used to calculate a mean Kt/V value for each patient from the 1–3 values present for each, and the percent of patients with a mean Kt/V over a certain threshold is determined. For prevalent hemodialysis patients in 2005, each patient’s URR is obtained from the G-modifier attached to CPT code 99999, with a revenue code of 821 or 825. Each measurement is categorized into one of five ranges, and the median URR is calculated; for patients whose median lies between two ranges, we assign a weight of 0.5 to each. Information on new hemodialysis patients
with an arteriovenous fistula as the first access is calculated as described for Figure hp.11. Hemoglobin levels are calculated for EPO-treated, 2005 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 2005 who have a valid value on their Medical Evidence form; those with a lower limit equal to zero are omitted.

ANEMIA TREATMENT
The methods for Figures 5.2–3 are described in the discussion of Figures p.16–17. Figures 5.4–6 include data from all incident dialysis patients with an EPO claim in the first 30 days of ESRD therapy, and at least one EPO claim during each of the following six months. EPO claims with a dose per administration of less than 500 units or more than 80,000 units are omitted, as are those with an average dose per day (calculated as the total EPO units on the claim divided by the number of days spanned by the claim) of less than 100 units or greater than 10,000 units. For 2005, patients are incident prior to June 1, to allow them to have six months of EPO and/or iron claims after their incident date. For graphs by starting hemoglobin, patients are included only if they have a hematocrit listed on the Medical Evidence form, and their starting hemoglobin is determined from this value. In Figure 5.4, a mean hemoglobin is calculated for each patient from claims during the month, and the average of these values is then calculated for each month. For Figure 5.5, the mean EPO dose per week is adjusted by only including days during a month in which a patient is not in an inpatient hospital setting, so that the mean EPO dose represents outpatient dosing only. And for Figure 5.6, an average monthly iron dose is calculated for each patient during the first six months of dialysis.

Methods for Figures 5.7–12 are described in the captions.

OVERSHOOTING OF TARGET HEMOGLOBIN LEVELS:
Cumulative probabilities in this section are calculated using the Kaplan-Meier method, and patients are censored at a missing hemoglobin value.

The cohort for Figures 5.13 and 5.15 includes incident dialysis patients with a first service date between July 1, 2004, and June 30, 2005, with Medicare as primary payor, and receiving EPO during the first six months after incidence. Patients who die or are transplanted in the first six months are excluded. The cohort for Figure 5.14 includes point prevalent dialysis patients, 2004, with a valid hemoglobin value in each of the first six months.

Figures 5.16 includes incident dialysis patients with a first service date between July 1, 2004, and June 30, 2005, with Medicare as primary payor, receiving EPO or DPO, and with at least one hemoglobin value less than 11 g/dl during the first six months after incidence. Patients who die or are transplanted in the first six months are excluded. Figure 5.17 includes hemodialysis patients age 20 and older in the USRDS and ESRD CPM databases. Only patients with at least one hemoglobin value of 11–12 g/dl in the CPM period and with EPO treatment during the first six months after the CPM period are included. Patients are followed from the CPM period up to six months.

Figure 5.18 includes point prevalent dialysis patients, 2004, with Medicare as primary payor on January 1, 2004, receiving EPO, and with at least one hemoglobin value less than 11 g/dl during the first six months after January 1, 2004.

DIABETIC PREVENTIVE CARE
Figures 5.19–34 present data on diabetic preventive care in patients age 18–75. ESRD patients without Medicare inpatient/outpatient and physician/supplier coverage during the entire study period are omitted from these analyses, as are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories; who have a missing date of birth; who do not survive the entire reporting period; who have ESRD for fewer than 90 days prior to the start of the reporting interval; or who are lost-to-follow-up during the study period. Patients who reside in the District of Columbia, Puerto Rico, and the Territories are also omitted from the maps. Age is generally calculated at the end of the study period.

Methods and codes used to determine rates of diabetic glycated hemoglobin (HbA1c) testing, lipid testing, and eye exam are described in the methods for Chapter One. Patients are defined as having diabetes either through medical claims (one inpatient/outpatient, two physician/supplier, two outpatient, or one physician/supplier and one outpatient), or through a listing of diabetes on the Medical Evidence form as the primary cause of ESRD or as a comorbid condition. ICD-9-CM diagnosis codes used to define diabetes are described in the methods for Chapter One.

Figures 5.19, 5.23, 5.27, and 5.31 show rates of diabetic preventive care in 2005; Figures 5.21, 5.25, and 5.29 show the amount of diabetic testing by modality; and Figures 5.22, 5.26, 5.30, and 5.34 compare rates in dialysis and transplant patients. The population for these figures includes ESRD patients initiating therapy at least 90 days prior to January 1, 2004, alive on December 31, 2004, and with diabetes defined in 2004. Rates include patients receiving at least four HbA1c tests, at least two lipid tests, at least one eye exam, or, for comprehensive diabetic monitoring in Figures 5.31 and 5.34, all of the above during 2005.

Figures 5.20, 5.24, and 5.28 show the number of tests by year, Figure 5.32 shows overall trends, and Figure 5.33 shows trends by modality. The cohort for those figures 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. Diabetic HbA1c and lipid testing, and eye examinations, are tracked in the second year of each period. HbA1c, lipid testing, and eye examination claims made within 30 days of the last claim for each patient are excluded. In Figures 5.32 and 5.33, "comprehensive" diabetic monitoring means at least four HbA1c tests, at least two lipid tests, and at least one eye examination.

PREVENTIVE CARE
Figures 5.35–38 show rates of lipid testing for ESRD patients. Cohorts for Figures 5.35 and 5.37–38 are 2005 ESRD patients initiating therapy at least 90 days before January 1, 2005, with Medicare inpatient/outpatient and physician/supplier coverage at initiation, and alive and remaining in the program through December 31. For Figure 5.35, patients residing in Puerto Rico and the Territories are excluded. The cohort for Figure 5.36 includes ESRD patients initiating therapy at least 90 days before January 1 of each year, with Medicare inpatient/outpatient and physician/supplier coverage at initiation, and alive and remaining in the program through December 31. For all figures, testing is tracked during each year, and tests are at least 30 days apart.
Figures 5.39–44 show rates of influenza, pneumococcal pneumonia, and hepatitis B vaccinations for prevalent ESRD patients by modality, age, race/ethnicity, and time period. Cohorts for Figures 5.39–42 are the same as those described for Objective 14.29 in the HP2010 chapter, while the cohorts for Figures 5.43–44 are the same as those for Figures 5.36 and 5.35, respectively. Patients who reside in Puerto Rico and the Territories are omitted from the maps. Age is generally calculated at the end of the study period. Hepatitis B vaccinations are identified through CPT codes 90636, 90740, 90743–90744, 90748, 90731, and 90723.

VASCULAR ACCESS IN PREVALENT PATIENTS

Figures 5.45–51 include prevalent hemodialysis patients who are in both the USRDS and ESRD CPM databases, and whose day 91 begins prior to October 1 of the prevalent year. The access represents the current access being used according to the CPM data. Claims are then searched during the following calendar year for events and complications. Figure 5.51 includes incident peritoneal dialysis patients from the USRDS database. For Figures 5.48–51, complication rates are calculated as the number of events (from Medicare claims) divided by the time at risk, which is censored at death, change in modality, change in payment status, or the placement of a different type of access. Vascular access codes are listed in the methods for Chapter Eleven.

HOSPITALIZATION

Methods used for the prevalent patient hospitalization figures in this chapter generally echo those used for the tables in Reference Section G (described below). Inclusion and exclusion criteria are generally the same, as are the methods for counting hospital admissions and days, and defining the follow-up time at risk. One difference is the exclusion in Reference Section G of patients of races that are unknown or other than white, African American, Native American, or Asian; these patients are included in the Chapter Six figures, except where data are presented by race. Inpatient institutional claims are used for the analyses, and methods for cleaning claims follow those described for Section G. Adjusted rates are calculated using the model-based adjustment method on the observed category-specific rates. This method is described further in the discussion of Section G, and in the statistical methods section later in this appendix.

Figure 6.2 presents adjusted rates of total hospital admissions and days per patient year. Prevalent ESRD patients are included, with the 2005 ESRD cohort used as the reference. Methods for rates in Figures 6.2–3 follow those described for Reference Section G. In Figure 6.3, methods are similar to those described for Figure p.22 in the Précis, with admissions for pneumonia, bacteremia/septicemia, and cellulitis in Figure 6.3 replacing the categories of all-cause, infection, and cardiovascular disease in p.22. Principal ICD-9-CM diagnosis codes used to identify cause-specific admissions: pneumonia, 480–486 and 487.0; bacteremia/septicemia, 038.0–038.9 and 790.7; and cellulitis, 998.2. Vascular access hospitalizations are “pure” inpatient vascular access events, as described for Table G.11 later in this appendix. Due to new vascular access codes for peritoneal dialysis patients in 1998, vascular access hospitalizations are shown for hemodialysis patients only.

Figure 6.4 presents unadjusted rates for period prevalent ESRD patients in 2005 by HSA and state. (Rates for peritoneal dialysis and transplant patients are presented by state rather than by HSA due to few patients and events in many HSAs.) Maps by HSA are smoothed using the Bayesian method.

Figure 6.5 shows adjusted admission rates for principal diagnoses for prevalent ESRD patients. Principal ICD-9-CM codes for pneumonia, bacteremia/septicemia, and cellulitis are listed above for Figure 6.3. Other principal ICD-9-CM codes are as follows: for vascular access infection (hemodialysis patients only), 996.62; and for peritonitis (peritoneal dialysis patients only), 567.

Figure 6.6 presents the percent change in adjusted hospital admission rates for period prevalent dialysis patients, 1995–2005. 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 differ for different rates and across the individual graphs are not directly comparable. We use the model-based adjustment method here, with 2005 dialysis patients as the reference cohort. Vascular access hospitalizations (hemodialysis patients only) are “pure” inpatient vascular access events, as described later for Table G.11. The cardiovascular category consists of codes 276.6, 394–398.99, 401–405, 410–420, 421.9, 422.90, 422.99, 433–438, and 440–459, while infection is indicated by codes 001–139, 254.1–302, 331.81, 372–372.39, 373.0–373.2, 378–382.4, 383.0, 386.33, 386.35, 388.60, 390–393, 421–421.1, 422.0, 422.91–422.93, 460–466, 472–474.0, 475–476.1, 478.21–478.24, 478.29, 480–490, 491.1, 494, 510–511, 513.0, 518.6, 519.01, 522.5, 522.7, 527.3, 528.3, 540–542, 566–567.9, 569.3, 572–572.1, 573.1–573.3, 575–575.12, 590–590.9, 595–595.4, 597–597.89, 598, 599.0, 601–601.9, 604–604.9, 607.1, 607.2, 608.0, 608.4, 611.0, 614–616.1, 616.3–616.4, 616.8, 670, 680–686.9, 706.0, 711–711.9, 730–730.3, 730.8–730.9, 790.7–790.8, 996.60–996.69, 997.62, 998.5, and 999.3.

Tables 6.a–c present adjusted hospital admission rates by vintage for adult (age 20 and older) period prevalent ESRD patients in 1995 and 2005. Patient vintage 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. Rates in the “all” row are adjusted for age, gender, race, and primary ESRD diagnosis, while rates presented by one factor are adjusted for the other three.

Figures 6.7–9 show rates by age, adjusted for gender, race, and primary diagnosis using the model-based adjustment method. These figures include period prevalent dialysis patients age 20 and older, with the 2005 dialysis cohort as the reference. Figure 6.7 presents adjusted rates of cause-specific hospital admissions per patient year. The categories for cardiovascular disease and infection are defined by the codes listed for Figure 6.6; the infection codes for Figure 6.7, however, exclude those due to internal device. 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.

Figure 6.8 shows adjusted event rates for inpatient coronary revascularization. Patients are followed until the first coronary revascularization event, and are censored at the earliest of death, three days prior to transplant, or the end of the calendar year. Events are identified from inpatient and physician/supplier claims occurring within a hospital stay. The following ICD-9-CM procedure and CPT codes are used to identify events: angioplasty, procedure codes 00.66, 36.01, 36.02, and 36.05, and CPT codes 92982, 92984, 92995, and 92996; coronary stents, proce-
Figure 6.9 displays adjusted vascular access placement rates for period prevalent adult hemodialysis patients. These are not hospital admission rates, but procedure rates for vascular access placements in an inpatient setting. Vascular access placements are obtained from CPT codes on 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, 36488–36491, 36533, 36555–36558, 36565, 36800, and 76937; fistulas, 36818–36821 and 36825; and grafts, 36830. The category for all vascular access placements includes all of the above CPT codes. Methods are also used to exclude vascular access used for purposes other than dialysis. Rates for catheter and all vascular access placements exclude patients with specific chemotherapy or parenteral nutrition claims during the year, inpatient/outpatient institutional, 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 placements with CPT codes 36488–36491, 36533, 36555–36558, 36565, and 76937 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 6.10–11 display geographic variations in cause-specific admission rates by state. Codes used to identify cardiovascular and infectious admisions are listed in the discussion of Figure 6.6, and vascular access admissions represent “pure” inpatient vascular access events as later described for Table G.11. Inpatient catheter placement rates in Figure 6.11 follow the methods described for Figure 6.9, except that rates by state here are unadjusted.

**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.

Figure 6.1 shows trends in mortality rates by modality for incident ESRD patients, 1980–2004. The population groups include all-ESRD, hemodialysis, CAPD/CCPD, and first transplant (known deceased and living donors only). Adjusted first-, second-, third-, fourth-, and fifth-year mortality rates for incident cohorts—including all-ESRD, hemodialysis, CAPD/CCPD, and first transplant patients—are computed from the Cox model using the model-based adjustment method, described later in this appendix. Mortality rates for all patients are adjusted for age, gender, race, and primary diagnosis. The reference population for adjusted rates consists of 1996 incident ESRD patients.

Figure 6.12 shows all-cause mortality by age for 2005 prevalent ESRD, dialysis, transplant, and general Medicare patients. General Medicare patients are non-ESRD patients with at least one month of Medicare eligibility in 2005; they are followed from the first day of the first month with Medicare eligibility until death or December 31, 2005. ESRD patients are followed from January 1 until December 31, 2005. All-cause mortality rates by age are calculated using generalized mixed models, and are adjusted for gender and race. Medicare patients from 2005 are used as the reference cohort.

Figure 6.13 presents unadjusted all-cause mortality, by HSA, for 2005 prevalent ESRD, dialysis, transplant, and general Medicare patients. The populations are those used in Figure 6.12, except that general Medicare patients are age 65 and older.

Table 6.4 shows expected remaining lifetimes for dialysis patients, renal transplant patients, and the general U.S. population. For period prevalent ESRD patients in 2005, expected lifetimes are calculated using the death rates from the mixed model with 16 age groups, assuming constant survival and mortality within each age group. Patient inclusion and exclusion criteria are those used in Tables H.4.4 and H.28.4, and the method for calculating expected remaining lifetimes is described in the section on statistical methods at the end of this appendix. Data for the general population are obtained from the CDC’s National Vital Statistics Reports.

Figure 6.14 illustrates trends in mortality rates by patient vintage for period prevalent dialysis patients alive on renal replacement therapy on January 1, with a first service date at least 90 days prior to the beginning of the year, and reaching day 91 of ESRD treatment during the year. Patients with unknown age or gender, or of a race other than white, African American, Native American, or Asian are excluded. Patients are followed from January 1 until death, transplantation, or the end of the year, and all-cause mortality rates are adjusted for age, gender, race, and primary diagnosis using generalized mixed models. The reference population consists of 2001 prevalent dialysis patients, and adjusted mortalities across vintages are comparable.

Figures 6.15 and 6.17 show all-cause mortality and survival rates for general Medicare and ESRD patients with cardiovascular disease, malignancy, and septicemia. Figure 6.15 presents annual mortality rates for the 2005 general Medicare and ESRD populations, while Figure 6.17 shows one- and five-year survival rates for 1992–2004 general Medicare, dialysis, and transplant patients. Using Medicare claims in a calendar year, diseases are identified through the appearance of ICD-9-CM codes at least once in inpatient/outpatient claims or at least twice in outpatient or physician/supplier claims. The ICD-9-CM codes are 390.xx–398.xx, 402.xx, 404.xx, and 410.xx–419.xx for heart disease; 140.xx–208.xx for malignancy, and 038 for septicemia. Mortality rates in Figure 6.15 are calculated using generalized mixed models, and are adjusted for gender and race. Survival rates in Figure 6.17 are calculated using Cox regressions, and are adjusted for age, gender, and race. In both figures, 2005 general Medicare patients are used as the reference cohort.

Figure 6.16 presents five-year survival by modality for 1991–1995 and 1996–2000 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 2005, while transplant patients are followed from the first transplant date until death or the end of 2005. All probabilities are adjusted for age, gender, and race; overall probabilities are also adjusted for primary diagnosis. As in the 2003–2006 ADRs, the reference population consists of 1996 incident ESRD patients, and adjusted probabilities are comparable across modalities.

Figures 6.18–22 display adjusted all-cause and cause-specific mortality in incident dialysis patients. Cohort includes dialysis patients, 1991–2004, residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Patients with unknown age, gender, primary diagnosis are excluded, as are
those with a listed age greater than 110. Patients are followed from the first service date up to one year, and censored at transplant or recovery of kidney function. Overall mortality rates are adjusted for age, gender, race, and primary diagnosis. Adjusted mortality rates for one of the four variables are adjusted for the remaining three. The reference population consists of 1996 incident ESRD patients, and adjusted mortality rates can by compared across year and cause of mortality.

Hazard ratios from a Cox model are shown in Figure 6.e. The cohort for this analysis includes incident dialysis patients in 2004. Exclusion and inclusion criteria from Figures 6.18–22 are applied here. Patients are followed from the first service date up to one year, and censored at transplant or recovery of kidney function.

**DISABILITY IN CKD & ESRD PATIENTS**

Figures 6.23–26 display measures describing the state of four different disabilities (blindness, amputation, limb paresis/paralysis, and dementia), as informed by Medicare claims, among point-prevalent CKD and ESRD patients age 67 and older on January 1, 2003. For the ESRD cohort, patients are alive on December 31, 2002, become ESRD-incident no later than that date, and carry Medicare as primary payor (MPP) from January 1, 2001, to December 31, 2002. The modality of each ESRD patient is determined on December 31, 2002. CKD patients are alive on December 31, 2002, and similarly carry MPP from January 1, 2001, to December 31, 2002. CKD is identified by the submission of at least one inpatient or two outpatient claims with an applicable diagnosis code between January 1, 2002, and December 31, 2002.

Figures 6.23 and 6.26 illustrate prevalence. Dementia is defined by the submission of at least one inpatient or two outpatient claims with a diagnosis code of 290.x or 331.0 during the two calendar years preceding January 1, 2003. Blindness is defined by the submission of at least one inpatient or outpatient claim with a diagnosis code of 369.0x–369.4, 369.6x, or 369.7x during the two calendar years preceding January 1, 2003. Limb paresis/paralysis (including hemiparesis/hemiplegia) is defined by the submission of at least one inpatient or outpatient claim with a diagnosis code of 342.x or 344.x–344.5 during the two calendar years preceding January 1, 2003. And amputation is defined by the submission of at least one inpatient or outpatient claim between January 1, 2002, and December 31, 2002, with a diagnosis code of 23900, 23920, 23921, 24900, 24920, 24925, 24930, 24931, 24940, 25900, 25905, 25907, 25909, 25915, 25920, 25922, 25924, 25927, 25929, 25931, 26910, 27290, 27295, 27591, 27352, 27592, 27594, 27596, 27598, 27880, 27881, 27882, 27884, 27885, 27886, 27889, 28800, 28805, 28810, 28820, and 28825 to identify an incident event. Figure 6.28 includes only patients with at least one disability; they are followed one more year from the first day of each disability to calculate costs for each patient for each type of disability. Figure 6.29 includes patients with or without any disabilities; the number of the four different types of disabilities is counted in the first year from the first ESRD date, and patients are then followed one more year from the end of the first year since the first ESRD date to calculate costs for each patient. In both of these figures, patients are censored at the earliest of death, loss to follow-up, recovery of renal function, transplant, or loss of Medicare as primary payor status.

Figures 6.30–33 show the cumulative probabilities of incident disability in incident dialysis patients age 67 and older and point prevalent CKD patients, 2003. Patients with at least one of the four disabilities in the two years before January 1, 2003, are excluded from the CKD cohort, as are patients in the incident dialysis cohort who have at least one of the four disabilities in the two years before the first service date. Codes and methods used to define the four disabilities and diabetes are those used for Figures 6.23–26, and the method used to define diabetes in Figures 6.23–29 is applied as well to ASHD. Patients are followed for two years to observe the incidence of disabilities. Dialysis patients are censored at death, transplantation, kidney recovery, loss-to-follow-up date, or loss of Medicare coverage, while CKD patients are censored at death, ESRD date, or loss of Medicare coverage. Cumulative probabilities are calculated from the Cox model using the model-based adjustment method, and adjusted for age, gender, race, diabetes, and ASHD. The reference cohort consists of 2003 incident dialysis patient age 67 and older and without any disabilities in the two years prior to the first service date, and adjusted probabilities are comparable between CKD and dialysis patients.

**EFFECTS OF HURRICANE KATRINA ON PATIENT OUTCOMES**

Figures 6.34–40 and Table 6.f display pre- and post-storm trends among non-ESRD Medicare and ESRD patients residing in 30 counties directly affected by Hurricane Katrina. These counties include: in Alabama, Mobile; in Louisiana, Jefferson, Orleans,
Saint Bernard, Saint Charles, Saint James, Saint John Baptist, Saint Tammany, Tangipahoa, Terrebonne, and Washington; and in Mississippi, Copiah, Covington, Forrest, George, Hancock, Harrison, Hinds, Holmes, Jackson, Jasper, Jones, Marion, Pearl River, Perry, Simpson, Stone, Walthall, Wayne, and Wilkinson.

The ESRD cohort utilized for Figures 6.34–36 and 6.40 consists of period prevalent dialysis patients between September 1, 2004, and December 31, 2005, who survived at least 90 days following ESRD incidence. Follow-up begins on September 1, 2004 (for prevalent patients), and at day 90 (for incident patients), and continues until the earliest of death, transplantation, loss to follow-up, change in Medicare coverage, or December 31, 2005.

The ESRD cohort used for Figures 6.37–39 consists of period prevalent dialysis patients between September 1, 2004, and December 31, 2005, with no survival requirement following ESRD incidence. Follow-up begins on September 1, 2004 (for prevalent patients), and at day 1 (for incident patients), and continues until the earliest of death, transplantation, loss to follow-up, or December 31, 2005.

For Figures 6.36–39, the non-ESRD Medicare cohort consists of period prevalent patients between September 1, 2004 and December 31, 2005. Follow-up continues during Medicare coverage.

Finally, for Table 6.1, the ESRD cohort consists of period prevalent dialysis patients between August 1, 2005, and September 30, 2005, who receive dialysis therapy during both months.

In addition to patients residing in the 30 aforementioned counties, all ESRD cohorts include patients not residing in this area but receiving dialysis from a provider located there. In Figure 6.34, dialysis treatments are derived from inpatient/outpatient claims with revenue code 082. In Figure 6.40, hemoglobin levels are derived from inpatient/outpatient claims for erythropoietin therapy.

REFERENCE SECTION G
Hospitalization reference tables present adjusted total admission and hospital day rates by year from 1993 to 2005. They begin in 1993 because Medicare inpatient claims are available beginning in 1991, and the model-based adjustment method uses data from the current and previous two years to obtain the predicted rates. (This method is further discussed later in this section and in the statistical methods section at the end of this appendix.)

Because hospitalization data for non-Medicare patients may be incomplete, analyses in this section include only patients with Medicare as their primary payor. Hospitalization data are obtained from inpatient/outpatient institutional inpatient claims, with the following exceptions: Tables G.12 and G.12.1 also include REBUS hospitalization data, and supplementary tables G.1.4–G.10.4 and G.1.5–G.10.5 (on our website and CD-ROM) use only REBUS inpatient data.

Tables G.1–10 include dialysis and transplant patients on their modality for at least 60 days, reaching day 91 of ESRD by the end of the year, and residing in the 50 states, the District of Columbia, Puerto Rico, and the Territories. Excluded are patients with AIDS as a primary or secondary cause of death; patients with missing values for age, gender, or race; and patients of races that are unknown or other than white, African American, Native American, or Asian. Age is determined on January 1 of each year. Patients are also classified according to their primary cause of ESRD, in which the “other” category includes patients with missing data or causes other than diabetes, hypertension, or glomerulonephritis.

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

- all dialysis: patients on hemodialysis, CAPD/CCPD, or dialysis of an unknown type, as well as those on more than one modality in the past 60 days
- hemodialysis: patients 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 G.1–10. Dialysis patient start dates (January 1 for prevalent patients and day 91 of ESRD for incident patients) must fall between start and end dates based on Medicare paid dialysis claims, as follows:

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

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

For patients in the all-dialysis, hemodialysis, and peritoneal dialysis categories, the period at risk for all hospitalization analyses is from January 1 or day 91 of ESRD until the earliest of death, three days prior to transplant, or December 31. Modality change is considered a censoring event only in the case of a change from dialysis to transplant. For dialysis patients in the all-ESRD category, in contrast, the analysis period is censored only at death or December 31 of the year; 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 following the transplant is necessary because Medicare eligibility may be lost and hospitalization data may be incomplete for these patients.

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

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

As in previous ADRs, all overlapping and only certain adjacent hospitalizations are combined, due to the fact that many adjacent claims may actually be legitimate separate hospitalizations. Specifically, hospitalizations with an admission on the same day or the day after a previous discharge are combined only when there is a discharge transfer code or indication of an interim claim. In the 1991–2005 institutional inpatient claims, for example, 4.4 percent of the hospitalizations were combined using these criteria. In the case of two hospitalizations combined into one, the principal diagnosis and procedure codes are retained from the first of the two hospitalizations, with the combined hospitalization extending from the first admission date to the last discharge date.

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

The methodology for computing adjusted 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. For prevalent patient cohorts, this model uses data from the current and previous two years, with respective weights of 1, ¼, and ¼. Adjusted rates are then calculated using the direct adjustment method, with all 2005 ESRD patients as the reference cohort. Standardized hospitalization ratios by state (Table G.12) are calculated using the Bayesian method, also described in the statistical methods section.

Table G.11 shows inpatient utilization in period prevalent ESRD patients. Methods—including modality definitions, inclusion criteria, data cleaning, follow-up time definitions, and rate calculations—generally follow those previously described for the total admission rates in Tables G.1–5, but some differences do exist. While patients races other than white, African American, Native American, or Asian are excluded from G.1–5, they are included in G.11, except where rates are given by race. Rates are unadjusted and reflect total admissions per 100 patient years for 2003–2005 (pooled) prevalent patients. While the rates for all causes are computed similarly to the unadjusted rates in G.1–5, the other eight cause-specific categories only include admissions for specific diseases. Vascular access hospitalizations are those classified as “pure” inpatient vascular access events. Such vascular access events are defined as admissions with a specified ICD-9-CM principal diagnosis code (996.1, 996.56, 996.62, 996.68, 996.73, V56.1, or V56.2), or an ICD-9-CM principal procedure code (38.95, 39.27, 39.42, 39.43, 39.93, 39.94, or 86.07) in conjunction with a certain DRG code (112, 120, 315, 442, 443, 478, or 479). If an admission does not qualify as vascular access, it is classified by the principal diagnosis code into one of seven other mutually exclusive groups. Categories and ICD-9-CM codes are as follows: circulatory diseases, 390–459; digestive diseases, 520–579; genitourinary diseases, 580–629; endocrine and metabolic diseases, 240–279; respiratory diseases, 460–499; and infectious diseases, 001–139. Hospitalizations that do not fall under any of these categories are counted under all others.

Supplementary tables providing additional rates and counts are available on our website and CD-ROM. Tables G.1.1–10.1 present adjusted rates similar to those shown in G.1–10, but include more patient subgroups. Rates of admissions per 1,000 patients and days per patient, rather than per patient year, are also available. The rates in these tables (G.1.2–10.2) are calculated with denominators consisting of the total patients, rather than the total time at risk in patient years. Additional tables (G.1.3–10.3) display the counts of the total admissions or hospital days, patient years at risk, and total patients that are used to calculate the rates.

Long-term trends in hospitalization data are also available in supplementary tables (G.1.4–10.4). Total admission rates per 1,000 patient years and hospital day rates per patient year from 1980–2005 are presented in G.1.4–3.4 and G.6.4–8.4. Due to the instability of rates in earlier years, these rates are presented from 1983 in G.4.4 and G.9.4 for peritoneal dialysis patients, and from 1986 in G.5.4 and G.10.4 for transplant patients. Rather than using institutional inpatient claims data, which are unavailable for earlier years, these tables use only REBUS inpatient claims data. All one-day hospitalizations with a discharge date on the same or next day as the admission date are excluded from these tables, since, prior to 1991, the REBUS data include no hospitalizations of less than 24 hours. To enable comparison of rates across years, therefore, only hospitalizations with a length of at least two days are included. As a result, these rates are lower than those in Tables G.1.1–10.1, which use all institutional inpatient claims. Other methods (rate calculation, model-based adjustment, etc.) generally follow those discussed for Tables G.1.1–10.1. In supplemental tables G.1.4–10.4, 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. Additionally, supplementary tables G.1.5–10.5 present counts of total admissions or days, patient years at risk, and total patients, which correspond with the rates presented in G.1.4–10.4.

**REFERENCE SECTION H**

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

Cohorts in Tables H.1–31 include both incident and prevalent patients. Incident cohorts are limited to patients who reach day 91 of ESRD treatment during the year, while prevalent cohorts include patients alive on renal replacement therapy on January 1 and whose first service date is at least 90 days prior to the beginning of the year. Because calculations include only one year of follow-up, a prevalent patient surviving to the end of the year contributes one year at risk, while a prevalent patient dying during the year contributes less than one year. Since the calculation for incident patients begins on day 91 of ESRD, most patients contribute less than one year at risk; a full year is contributed only if day 91 of ESRD is January 1 and the patient survives to the end of the year. Patients considered lost-to-follow-up at the beginning
of the year are excluded. The period at risk is not censored at the start of a lost-to-follow-up period, however; if a patient enters the lost-to-follow-up category during a calendar year, he or she remains in the death rate computation until the end of that year. Patient cohort populations often overlap. Patients with a functioning transplant on the start date, for example, are included in the all-ESRD and functioning transplant categories, while patients on dialysis are defined as both all-ESRD and all-dialysis. A patient in the all-dialysis category may also be reported in one of two subgroups—hemodialysis or CAPD/CCPD—if he or she has been on that modality for at least the previous 60 days. Dialysis patients who are not on hemodialysis or CAPD/CCPD, or who have been on that modality for fewer than 60 days, are included only in the all-ESRD and all-dialysis categories.

Cohorts in Tables H.32–46 include incident ESRD, dialysis, hemodialysis, CAPD/CCPD, and transplant patients who survive the first 90 days. Patient selection criteria are the same for both unadjusted and adjusted mortality rates. All new ESRD patients who have a first ESRD service date between January 1, 1987, and December 31, 2004, are included in the analysis. For incident ESRD and transplant cohorts, these patients are followed from day 91 until death or December 31, 2005; for incident dialysis, hemodialysis, and CAPD/CCPD cohorts, patients are followed from day 91 until death, transplant, or December 31, 2005.

Tables H.1, H.2, and H.2.1–2.4 present mortality information for all-ESRD patients. Total patient deaths are presented in Table H.1. Overall unadjusted and adjusted annual mortality rates by age, gender, race/ethnicity, primary diagnosis, and vintage are presented in Table H.2. The unadjusted mortality rates are calculated by dividing total patient deaths in a category—male, for example—by total follow-up time in the same category. For the adjusted rates, generalized mixed models are used to calculate the smoothed rates; these methods are described later in this appendix. After obtaining smoothed rates from the generalized mixed models, direct adjustment methods are used. Overall mortality rates are adjusted for age, gender, race, primary diagnosis, and vintage, while rates for each category (age, gender, race, primary diagnosis, and vintage) are adjusted for the remaining four categories. The reference population includes 2001 prevalent ESRD patients.

Table H.2.1 presents adjusted mortality rates by primary diagnosis. The method for calculating the adjusted rate is same as that in Table H.2, except that vintage is not included. 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 difference between Table H.2.1 and H.2.2 is that the mortality rate is expressed as per 1,000 patients years in H.2.1 and per 1,000 patients in H.2.2. Table H.2.3 shows total death counts, total follow-up years, and total patient counts. Table H.2.4 presents mortality rate by patient age, gender, race, and primary diagnosis for 2005 prevalent ESRD patients. Mortality rates in Table H.2.4 are smoothed and unadjusted using a generalized mixed model.

The same methods are used for Tables H.3, H.4, and H.4.1–4.4 (dialysis); Tables H.11, H.12, and H.12.1–4 (hemodialysis); Tables H.19, H.20, and H.20.1–20.4 (CAPD/CCPD); and Tables H.27, H.28, and H.28.1–4 (transplant). Tables H.5–10 (dialysis), H.13–18 (hemodialysis), and H.21–26 (CAPD/CCPD) include total patient deaths and annual unadjusted and adjusted mortality rates for patients who have never been on the transplant waitlist, for those who have been listed, and for those who have returned to the modality after a transplant.

In Table H.29, unadjusted mortality rates are reported by primary cause of death for patients prevalent at the beginning of, or incident during, 2003–2005. The unadjusted 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 follow-up time, and the sum of rates for each cause in a subgroup is equal to the overall mortality rate of that subgroup. Two new categories of primary cause of death due to congestive heart failure and withdrawal from dialysis have been added, based on the new ESRD Death Notification form introduced in October, 2005.

Patient populations for Tables H.32–46 are the same as those used in Reference Section I. The population groups include all-ESRD, all dialysis, hemodialysis, CAPD/CCPD, and first transplant (known deceased and living donors only). Adjusted first-, second-, and third-year mortality rates for incident cohorts—including all-ESRD, 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 rates are presented using

<table>
<thead>
<tr>
<th>Acute myocardial infarction</th>
<th>Myocardial infarction, acute</th>
</tr>
</thead>
<tbody>
<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 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</td>
</tr>
<tr>
<td>G.1. hemorrhage</td>
<td>Hemorrhage from tx 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 (fungal); 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; pancreatic; 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>
These tables, which include only incident cohorts, present patient counts and survival probabilities. All causes of death are included, as are all non-Medicare patients and patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with unknown gender or age, or whose listed age is greater than 110, are excluded.

Patient selection criteria are the same for both unadjusted and adjusted survival probabilities. All new ESRD patients who have a first ESRD service date between January 1, 1980, and December 31, 2004, are included in the analysis. These patients are followed until December 31, 2005, a maximum follow-up time of 24 years and a minimum of one year.

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

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

To limit imprecision due to small cell sizes, adjusted probabilities use aggregate categories for age, gender, race, and primary diagnosis. For each cohort, a probability presented for one variable is adjusted for the remaining three. Overall probabilities for all patients are adjusted for each of the four variables, as described later in the statistical methods section. As in recent ADRs, the reference population consists of 1996 incident ESRD patients.

**REFERENCE SECTION I**

Transplantation patients with a functioning transplant at the start of the period and who have had the transplant for at least 60 days; the period at risk is censored at the end of the year.

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

Patient selection criteria are the same for both unadjusted and adjusted survival probabilities. All new ESRD patients who have a first ESRD service date between January 1, 1980, and December 31, 2004, are included in the analysis. These patients are followed until December 31, 2005, a maximum follow-up time of 24 years and a minimum of one year.

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

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

To limit imprecision due to small cell sizes, adjusted probabilities use aggregate categories for age, gender, race, and primary diagnosis. For each cohort, a probability presented for one variable is adjusted for the remaining three. Overall probabilities for all patients are adjusted for each of the four variables, as described later in the statistical methods section. As in recent ADRs, the reference population consists of 1996 incident ESRD patients.

**REFERENCE SECTION I**

Transplantation patients with a functioning transplant at the start of the period and who have had the transplant for at least 60 days; the period at risk is censored at the end of the year.

**REFERENCE SECTION I**

Transplantation patients with a functioning transplant at the start of the period and who have had the transplant for at least 60 days; the period at risk is censored at the end of the year.

**REFERENCE SECTION I**

Transplantation patients with a functioning transplant at the start of the period and who have had the transplant for at least 60 days; the period at risk is censored at the end of the year.

**REFERENCE SECTION I**

Transplantation patients with a functioning transplant at the start of the period and who have had the transplant for at least 60 days; the period at risk is censored at the end of the year.

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Transplantation patients with a functioning transplant at the start of the period and who have had the transplant for at least 60 days; the period at risk is censored at the end of the year.

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Transplantation patients with a functioning transplant at the start of the period and who have had the transplant for at least 60 days; the period at risk is censored at the end of the year.

**REFERENCE SECTION I**

Transplantation patients with a functioning transplant at the start of the period and who have had the transplant for at least 60 days; the period at risk is censored at the end of the year.
Figure 7.19 juxtaposes the growing rate of ESRD with the decrease in transplant rates per 100 dialysis patient years, by state, in 2005. The state is the recipient’s last known state of residence, not necessarily the state where the transplant was performed.

Figure 7.20 presents transplant rates per 100 dialysis patient years, by state, in 2005. These rates are estimated from a Poisson regression, adjusting for age, gender, race, and primary cause of renal failure, then standardized to the age, gender, race, and primary cause of renal disease makeup of the national population of dialysis patients incident in 2005. The state is the recipient’s last known state of residence, not necessarily the state where the transplant was performed.

The percent of patients willing to accept an ECD kidney, by state and by OPTN region, are illustrated in Figures 7.13–14. OPTN regions are as follows:

1. Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island
2. District of Columbia, Delaware, Maryland, New Jersey, Pennsylvania, West Virginia
3. Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
4. Oklahoma, Texas
5. Arizona, California, Nevada, New Mexico, Utah
7. Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
8. Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming
9. New York, Vermont
10. Indiana, Michigan, Ohio
11. Kentucky, North Carolina, South Carolina, Tennessee, Virginia

Figure 7.15 presents the likelihood of receiving a transplant within one year of listing for all patients and for those willing or not willing to accept an ECD kidney. Patients are censored at death before transplant or at one year after listing. This figure also shows the likelihood of receiving a living donor or deceased donor transplant. For living donor transplants (or deceased donor transplants), patients are censored at death before transplant, at a deceased donor transplant (or living donor transplant), or at the end of one year after listing. Figure 7.16 shows the likelihood of dying while awaiting transplant in the 1–5 years after listing. Patients are censored at removal from list, and end of the follow-up period. And Figure 7.17 presents the likelihood of being alive one year after listing, with patients censored at the end of one year of follow-up. Probabilities in these figures are calculated using the Kaplan-Meier method.

Figure 7.18 illustrates outcomes for patients first listed in 2000. Patients are classified at five years post-listing as having received a transplant, having died awaiting a transplant, having been removed from the list prior to transplantation, or still waiting.

ORGAN DONATION

Organ donation information is presented in Figures 7.27–32. Figure 7.27 shows the percentage of transplants using a kidney from what would qualify as an ECD through factors listed on the OPTN Deceased Donor Registration form, and includes only first-time, kidney-only recipients of a deceased donor kidney. Expanded Criteria Donors (ECDs) are age 60 or older, or age 50–59 with two or more of the following: death attributed to CVA, history of hypertension, or creatinine > 1.5 mg/dl. Donors who are not classified as ECD are Standard Criteria Donors (SCD). Figure 7.28 shows the causes of death of deceased donors. This information is provided by OPTN. Figure 7.29 shows increases in the percentages of non-heart beating donors from 1995 to 2005. In Figure 7.30, a deceased donor is counted only once, regardless of whether both kidneys are eventually transplanted. Maps of donation rates, in Figure 7.31, are based on the location where the donation is made. Figure 7.32 presents unadjusted rates per hundred deaths in the state. Population and death count estimates for the year from July, 2004, to July, 2005, are obtained from the U.S. Census Bureau.

Graft Survival

Figure 7.33 shows the percentage of transplants with primary non-function, defined as kidney failure within seven days of transplant. Figures 7.34 looks at patients with evidence of delayed graft function (defined by a need for dialysis in the first week after transplantation) by donor status and ECD status, as reported to the OPTN.

Figure 7.35 presents statistics on graft failures that necessitate long-term dialysis or retransplantation; graft failures due to death are excluded from these counts. Subsequent treatment is determined from a combination of Medicare claims and OPTN data.

Figures 7.36–37 present graft survival curves for three-month and first-, five-, and ten-year survival, as well as conditional half-lives for recipients of kidneys from deceased and living donors. All estimates are made from Cox proportional hazards models, adjusted for transplant year, age, gender, race, and primary diagnosis, and based on the population’s average survival curves, rather than on curves of the average patient in the population. Estimates of conditional half-lives are conditional on first-year graft survival, and estimated from the cumulative haz-

Appendix A
ard between years one and two. Conditional half-lives are interpreted as the estimated median survival of grafts surviving the first year, while half-lives are interpreted as the estimated median survival of all grafts.

Figure 7.38 presents the mean serum creatinine, as reported to OPTN, for patients with a functioning graft by year post-transplant, and includes 1995–2005 patients.

Figure 7.39 shows the percentage of patients retransplanted within one year of graft failure. Preemptive retransplantations are included. Age is determined on the day of graft failure, and percentages are calculated using the Kaplan-Meier methodology.

Figures 7.40 describe the length of time a transplant survives prior to failure. The median time of kidney function is displayed along with first and third quartiles of the distribution. The year is the year of graft failure, and failures due to death are excluded.

In Figure 7.42 we present the rate of return to dialysis/preemptive retransplantation and the rate of death with a functioning graft. Rates are estimated from a Poisson regression, adjusting for age, gender, and race.

Figure 7.43 details the cumulative incidence of acute rejections at one-year post-transplant as reported to the OPTN through the Kidney Transplant Recipient Follow-up form. Percentages are estimated using the Kaplan-Meier methodology.

Figure 7.44 details rates of kidney biopsies post-transplant. Only patients transplanted between 2001 and 2003 and with Medicare inpatient/outpatient and physician/supplier primary insurance coverage are included in this analysis, and biopsies during the first seven post-transplant days are censored. Biopsies are identified in Medicare claims data, using CPT codes 50200, 50205, 10022, 50555, and 50574. The unadjusted rates are estimated from a Poisson regression.

Figure 7.45 displays Bayesian graft failure ratios among U.S. transplant centers performing kidney-only transplantations between January 1, 1995, and December 31, 2004. Follow-up begins at transplantation, and concludes at the earliest of graft failure (including death), December 31, 2005, or ten years subsequent to transplantation. The minimum and maximum possible lengths of follow-up are thus one and ten years, respectively. Expected graft failures are derived from a Cox proportional hazards model with adjustments for donor status (living or deceased); donor age, gender, race, cause of death (for deceased donors), documented history of diabetes and hypertension (deceased donors), and expanded criteria qualification (deceased donors); recipient age, gender, race, BMI, educational attainment, employment status, ethnicity, primary cause of ESRD, hepatitis B and C serology, Medicare coverage status, and vintage (i.e., pre-transplantation dialysis time); body surface area donor-recipient matching, cold ischemia time (for deceased donors), cytomegalovirus donor-recipient matching, transplantation year, HLA mismatches, baseline immunosuppressive regimen, and percent reactive antibody; and significant (p < 0.05) interaction effects of aforementioned predictors with donor status. In the Bayesian model, observed graft failures during a center-year are assumed to follow a Poisson distribution with mean μN, where μ is equal to the expected graft failures and log 8 is equal to a normally-distributed center effect, with mean α and precision τ, the prior distribution of which is almost non-informative.

### COMPLICATIONS: HOSPITALIZATIONS

Figures 7.46–47 present post-transplant hospital admission rates by year of transplant. Figure 7.46 shows rates in the first year after transplant, beginning after discharge from the transplant hospitalization. Figure 7.47 shows rates in the subsequent two years (years two and three post-transplant). Hospital admission rates are censored at graft failure, loss of Medicare coverage, or December 31, 2005. Statistical methods for computing hospital admission rates are similar to those described for Reference Section G, but cohorts are constructed differently. Instead of computing hospital admission rates in point prevalent transplant patients within a given year, we define the cohort based on transplant year and examine hospital claims up to three years post-transplant.

Figure 7.48 presents primary cause of hospitalization in patients hospitalized for cardiovascular problems or infection up to three years post-transplant, and includes all transplants from 2001–2003 with Medicare as primary payor. Patients are censored at graft failure or loss of Medicare coverage. Causes of hospitalization are obtained from ICD-9-CM codes on the Medicare claims.

### COMPLICATIONS: CARDIOVASCULAR SCREENING & EVENTS

Figures 7.49–52 describe the diagnosis and treatment of cardiac diseases in transplanted and wait-listed patients. "High risk" patients are over age 50 at first listing or transplant, or with a history of diabetes or cardiovascular disease as identified on OPTN Transplant Candidate Registration form or the ESRD Medical Evidence form. Data on wait-list patients are provided from one year pre-listing to five years post-listing. Wait-list patients are censored at the time of transplant. Data on transplant patients are provided from one year pre-transplant to three years post-transplant. Transplant patients are censored at graft failure.

Diagnostic tests and treatment related to cardiac disease here include stress test, coronary angiography and/or catheterization, echocardiogram, and coronary revascularization. A stress test is defined as any of the following: stress echocardiogram, stress nuclear test, and/or stress ECG test. For pre-listing diagnostic tests or treatment, patients are followed back in time from one day before the date of first listing date to their ESRD diagnosis or one year before the list date, whichever is latest. For post-listing tests or treatment, they are followed from the date of first listing to the earliest date of transplant, death, loss-to-follow-up, five years after the first list date, or December 31, 2005. For pre-transplant diagnostic tests or treatment, patients are followed back in time from one day before their first transplant date to their ESRD diagnosis or one year before their transplant, whichever is latest. And for post-transplant tests or treatment, they are followed from their first transplant date to the earliest date of graft failure, death, loss-to-follow-up, three years after transplant, or December 31, 2005.

Echocardiograms are defined through CPT codes in physician/supplier claims, while stress tests and coronary angiography and/or catheterization are defined through ICD-9-CM procedure codes in inpatient/outpatient claims and/or CPT codes in physician/supplier claims. Coronary revascularization is defined with the same method used earlier. Codes used to identify patients receiving diagnostic tests for cardiac disease are as follows:

- **stress:** 89.41–89.44 (ICD-9-CM procedure codes); 78449, 78446, 78461, 78464, 78465, 78469, 78472, 78473, 78478.
Figures 7.49–53 present unadjusted first testing or treatment rates in the first year post-transplant and the first, second, and third years post-transplant. The first pre-transplant test or treatment in each year is defined as the latest one in that year, while the first post-transplant testing or treatment is defined as the earliest one in that year. The unadjusted first test or treatment rates are estimated using the Kaplan-Meier method and presented as the number of tests or treatments per 100 patient-years at risk. Similar methods apply to wait-listed patients.

Figure 7.54 shows the cumulative incidence of cardiovascular diseases in the three years following transplant. Patients are classified as having a particular cardiovascular event as of the first occurrence of claims (inpatient/outpatient or physician/supplier) with ICD-9-CM diagnosis or procedure codes. Cardiovascular events of AMI, congestive heart failure (CHF), cardiac arrest, and cerebrovascular accident/transient ischemic attack (CVA/TIA) are identified from both non-fatal and fatal events. For non-fatal AMI, CHF, and CVA/TIA events, the event date is defined as the date of the first appearance of an ICD-9-CM diagnosis code in the inpatient/outpatient institutional claims, while for a non-fatal cardiac arrest, the date is that on which an ICD-9-CM diagnosis code first appears in either inpatient/outpatient or physician/supplier claims.

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 inpatient/outpatient institutional claims and/or Current Procedural Terminology (CPT) codes in physician/supplier claims. For peripheral arterial disease (PAD), the date is defined through ICD-9-CM diagnosis or procedure codes in inpatient/outpatient claims and/or CPT codes in physician/supplier claims.

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

- **AMI**: 410, 410.X0, and 410.X1 (ICD-9-CM diagnosis codes)
- **CHF**: 428 (ICD-9-CM diagnosis codes)
- **CVA/TIA**: 430–437 (ICD-9-CM diagnosis codes)
- **cardiac arrest**: 427.4, 427.5 (ICD-9-CM diagnosis codes)
- **PAD**: 441, 442.1–442.3, 442.82, 444.0, 444.1, 444.22, 444.81, 444.89, 445.02, 445.8 (ICD-9-CM diagnosis codes); 84.0, 84.1, 84.91, 39.25, 39.26, 39.29 (ICD-9-CM procedure codes); 24900, 24920, 25900, 25905, 25920, 25927, 27295, 27590, 27591, 27592, 27598, 27880, 27881, 27882, 27887, 27889, 28800, 28805, 34900, 35131, 35132, 35141, 35142, 35152, 34051, 34151, 34201, 34203, 34800–34834, 35081–35103, 35331, 35341, 35351, 35355, 35361, 35363, 35371, 35372, 35381, 35450, 35454, 35456, 35459, 35470, 35471, 35472, 35473, 35474, 35480, 35481, 35482, 35483, 35485, 35490, 35491, 35492, 35493, 35495, 35521, 35531, 35533, 35541, 35546, 35548, 35549, 35551, 35555, 35556, 35558, 35563, 35565, 35566, 35571, 35583, 35585, 35587, 35621, 35623, 35646, 35647, 35651, 35654, 35656, 35661, 35665, 35666, 35666, and 35671 (CPT codes)
- **coronary revascularization**: 36.01, 36.02, 36.05, 36.06, and 36.1x (ICD-9-CM procedure codes); 92980–92982, 92984, 92995, and 92996 (CPT codes)

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

Patients are followed up to three years after transplant to track occurrences of cardiovascular events or all-cause death. For cardiovascular events, a patient’s follow-up time is censored at the earliest of death, graft failure, loss-to-follow-up, end of Medicare as primary payor status, three years after transplant date, or December 31, 2005. For all-cause death, follow-up time is censored at these same events, with the exclusion of death. Cumulative incidence is presented as 1-(event-free probability).

**COMPLICATIONS: DIABETES & CANCER, IMMUNOSUPPRESSION**

Figures 7.35–36 present data on post-transplant diabetes and malignancies. The patient population includes all first-time, kidney-only recipients, 1995–2002, with known age and donor type who are deemed to have Medicare as primary payor (inpatient/outpatient or physician/supplier) over the date of transplantation. To identify de novo post-transplant diabetes, patients are further required to have six months of Medicare primary payor coverage prior to transplantation. This entry-period is searched for any claim indicating diabetes, and patients with these claims are omitted. To identify post-transplant malignancies, inpatient/outpatient and physician/supplier claims are searched for the appropriate ICD-9-CM diagnosis codes. Only the first three years post-transplant are searched for each condition, given that most transplant recipients are no longer eligible for Medicare following this period. For each complication, we illustrate the cumulative incidence over the three-year post-transplant period; this incidence is estimated from a Cox proportional hazards model, adjusting for age, gender, race, Hispanic ethnicity, primary cause of renal failure, year of transplantation, donor type, hepatitis B and C serology, education level, employment status, time on dialysis, donor age, donor gender, donor race, HLA mismatches, recipient-donor body surface area matching, body mass index, panel reactive antibodies, cytomegalovirus matching, baseline maintenance immunosuppression (cyclosporin, Neoral, Tacrolimus, Rapamycin, Azathioprine, Mycophenolate Mofetil), and anti-lymphocyte receptor antibody use (IL-2, other), and estimated from the population average curve rather than the curve of the average patient.

Figures 7.57–62 present data on immunosuppressive medications used at the time of transplantation, 1995–2005, as reported on the OPTN Immunosuppression Treatment form. All such medications (apart from induction antibodies) are indicated as...
maintenance immunosuppression on the form. Figure 7.58 highlights the switch over time from Azathioprine to MMF as the common anti-metabolite. Figure 7.59 contrasts the percent of patients using rapamycin at baseline and one year after transplant.

PATIENT FOLLOW-UP & PREVENTIVE CARE

Figure 7.63 details the number of patients with a follow-up form on file with OPTN, by year post-transplant. Prevalent transplant patients receiving their transplants in 1995 or later are included within each year. The location of follow-up care presented in Figure 7.64 is taken from the OPTN follow-up form for prevalent transplant patients within the given year who received their transplants in 2000 or later.

Figures 7.65–66 illustrate Medicare coverage of transplant patients. Figure 7.65 shows Medicare coverage annually for up to five years post-transplant in patients age 62 and younger with first transplants between 1998 and 2002. Patients are censored at death, graft failure, or December 31, 2005. Figure 7.66 shows the distribution of Medicare coverage at the time of transplant by the year of transplant.

Data on patients receiving various preventive healthcare measures are presented in Figures 7.67–71. Included transplant patients have Medicare as primary payor during the measurement period, and are alive with a functioning graft for the entire study period. General Medicare estimates are obtained from a random 5 percent sample of Medicare beneficiaries.

Figure 7.67 presents glycosylated hemoglobin (HbA1c) testing results. For the transplant population, diabetic patients with functioning grafts in each post-transplant year are included. Diabetes as the primary cause of renal failure or a comorbid condition is determined form the Medical Evidence or OPTN forms. HbA1c tests are identified from Medicare claims data by HCPCS code 83036, and must be at least 30 days apart to be counted. Two-year intervals are used for the general Medicare population, and patients who survive the entire two-year interval are included. Diabetic status is determined from claims data during year one, and HbA1c testing is determined during year two.

For lipid monitoring, in Figure 7.68, diabetic and non-diabetic patients are included in the analyses. Methods are the same as those used for HbA1c testing, except that the general Medicare estimates are made for one-year intervals rather than two-year intervals since no determination of diabetic status is made. Lipid monitoring is determined from HCPCS codes 80061, 82465, 83715, 83716, 83717, 83718, 83719, 83720, 83721, and 84478.

Tests within 30 days of a previous test are not counted.

For diabetic testing supplies, in Figure 7.69, methods are similar to those of Figure 7.67. Diabetic test strips are identified using HCPCS code A4253. As the claim indicates the number of packs of test strips, the number of strips per day is calculated as the number of test packs multiplied by 50 and divided by 365.

For eye examinations, Figure 7.70, methods are similar to Figures 7.67 and 7.69. For patients with diabetes as the primary cause of ESRD, claims for eye examinations are searched during the measurement year; for other diabetics, claims are searched during the measurement year and previous year. Eye examinations are identified using the following codes: 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92226, 92230, 92235, 92240, 92250, 92260, 92287, 67101, 67105, 67107, 67108, 67110, 67112, 67123, 67141, 67145, 67208, 67210, 67218, 67227, 67228 (HCPCS); 141–145, 149, 9502, 9503, 9504, 9511, 9512, and 9516 (ICD-9-CM procedure codes); and V802 (ICD-9-CM diagnosis codes).

Data on influenza vaccinations in Figure 7.71 include both diabetic and non-diabetic patients. Influenza vaccinations are identified using HCPCS codes 90724, 90657, 90658, 90659, 90660, and Go008.

Cancer screening measures are presented in Figures 7.72–75. For all measures, only transplant recipients between 2001–2005 with Medicare as primary payor are included.

Pap smears are identified using CPT codes 88141, 88142, 88143, 88144, 88145, 88147, 88148, 88150, 88152, 88153, 88154, 88155, 88156, 88158, 88164, 88165, 88166, and 88167, ICD-9-CM diagnosis code V762, ICD-9-CM procedure code 91.46, and revenue code 923. Women age 21–64 at three years post-transplant are included in the transplant population, and general Medicare beneficiaries age 21–64 at the end of 2005 are included.

For mammograms, the population includes female transplant patients age 52–69 at two years post-transplant, and female general Medicare beneficiaries age 52–69 at the end of 2005. Mammograms are identified using CPT codes 76090, 76091, and 76092, ICD-9-CM procedure codes 87.36 and 87.37, ICD-9-CM diagnosis codes V76.11 and V76.12, and revenue codes 401 and 403.

For prostate screening, the transplant population includes males age 53 and older at three years post-transplant, and the general Medicare population includes patients age 53 and older at the end of 2005. Prostate screenings are identified using CPT code 84153, revenue codes 300 and 310 (in combination with ICD-9-CM diagnosis codes 185 and 233.4), and ICD-9-CM procedure codes 60.11, 60.12, 500-508, and 91.39. For all measures, the percents are estimated for the transplant population using the Kaplan-Meier methodology, and for the general Medicare population as the number screened over the number of patients in the prevalent population.

For colonoscopies, the transplant population includes men and women age 53 and older at three years post-transplant, and the general Medicare population includes men and women age 53 or older at the end of 2005. Colonoscopies are identified using CPT codes 44388, 44389, 44392, 44394, 45378, 45380, 45383, 45384, 45385, G0105, G0121, 45300, 45305, 45306, 45309, 45355, 45357, 45359, 45361, 45363, 45365, 45367, G0104, 74270, 74280, G0106, G0120, G0122, G0127, G0128; ICD-9-CM procedure codes 45.23, 45.24, 45.25, 45.26, 45.27, 45.28, and 45.29; and ICD-9-CM diagnosis code V76.51.

REFERENCE SECTION E

Tables E.1–4 present various measures regarding the wait list for renal transplantation. Tables E.1–2 present counts of patients wait-listed for a kidney or kidney-pancreas transplant on December 31 of the given year. Patients listed at multiple transplant centers are counted only once. Table E.2 presents counts for patients that have been certified as having ESRD, and Table E.3 the percent of prevalent dialysis patients on the kidney wait list. In Table E.3, point prevalent dialysis patients on December 31 of the given year are included. Table E.4 presents the percent of patients wait-listed or receiving a deceased-donor transplant within one year of ESRD initiation; patients receiving a transplant from a living donor are not included in the measure. Percentages are calculated using the Kaplan-Meier methodology. This measure is modeled after Healthy People 2010 Objective 4.5.

Transplant counts are presented in Tables E.5–8. All known transplant events are included unless specified in the footnote, and all counts include non-Medicare patients.
Transplant rates per 100 patient years on dialysis are shown in Table E.9. All hemodialysis patients, peritoneal dialysis (CAPD/CCPD) patients, and patients on an unknown form of dialysis are included, as are all non-Medicare patients. A patient’s dialysis days are counted from the beginning of the specified year, or day one of ESRD dialysis therapy if treatment begins mid-year, until the first of transplant, death, or the end of the year. Patients lost-to-follow-up in a given year are not censored at the lost-to-follow-up date, but are followed until the end of the calendar year. Dialysis time for patients returning from transplant is counted. Transplant rates are calculated as the number of transplant events divided by the total number of dialysis patient years for each year. In Table E.10, treatment status two years after first transplant is shown by age at first transplant for patients transplanted between 2001 and 2003.

Table E.11 shows patients transplanted, by PRA level. Levels are determined from the OPTN Recipient Histocompatibility form.

Table E.12 presents a cross-tabulation of recipients and donors in terms of cytomegalovirus antibody status at the time of transplantation. A recipient/donor is considered positive if any applicable OPTN data source indicates positive, and “unknown” status is applied only in the event that no applicable test is performed. Table E.13 presents similar data for Hepatitis C antibody status.

Table E.14 presents transplant counts based on cold ischemia times in hours. Cold ischemia times are taken from OPTN Transplant Recipient Registration form.

REFERENCE SECTION F

This section presents probabilities of graft survival and graft failure necessitating dialysis or retransplantation, by donor type, for various groups and follow-up times. In previous ADRs, “graft failure necessitating dialysis or retransplantation” was referred to as “death-censored graft failure.” Due to some confusion regarding terminology, we have decided to rename this outcome. This section now seeks to address two major issues: the probability of graft survival at various times post-transplant, and the probability that a patient will return to dialysis or require retransplantation at various times post-transplant. Patients are followed from the transplant date to graft failure, death, or the end of the follow-up period (December 31, 2005). In the analysis of graft survival, death is considered a graft failure. In the analysis of graft failure necessitating dialysis or retransplantation, patients are followed until graft failure (excluding death), and patient follow-up is censored at death. To produce a standard patient cohort, patients with unknown age or gender are omitted. Unknown age is defined as a missing age at transplant, or an age calculated to be less than zero or greater than or equal to 100. Patients are also excluded if their first ESRD service date is prior to 1977.

Unadjusted survival probabilities are estimated using the Kaplan-Meier methodology, while the Cox proportional hazards model is used for adjusted probabilities. Probabilities are adjusted for age, gender, race, primary diagnosis, and first versus subsequent transplant, and standardized to 1996 patient characteristics.

Tables E.25–26 present the relative risk of graft failure, return to dialysis (including preemptive retransplantation), and death with a functioning graft for first-time recipients of deceased donor and living donor kidneys, respectively. Relative risks are estimated using Cox proportional hazards models, one for each donor type cohort and outcome. Patients transplanted between 2000 and 2005 are included. Follow-up is censored at December 31, 2005, for a maximum follow-up of six years. For the graft failure outcome, death is considered a graft failure; for return to dialysis, patients are censored at death with a functioning graft; and for death with function, follow-up is censored at return to dialysis.

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

MODALITY & VASCULAR ACCESS

Figure 8.19 includes incident hemodialysis patients from the 2000–2005 ESRD CPM data. Year represents the incident year, and access the reported as being used at the time of data collection during that year. Figures 8.20–21 include incident hemodialysis patients in both the USRDS and ESRD CPM datasets. Patients are age 0–19 at dialysis initiation, and have Medicare as primary payor on January 1 of the following year. CPM data are used to determine the access used at the time of data collection in the incident year. Patients are followed from January 1 of the year following incidence, and Medicare claims are used to identify access infections and sepsis. Included events occur between January 1 and the censoring date, which is the earliest of death, modality change, change in payor status, placement of a different vascular access, or December 31. For Figure 8.20, time at risk is calculated as the number of days between January 1 and the censoring date. Figure 8.21 also includes incident peritoneal dialysis patients from the USRDS database who are age 0–19 and have Medicare as primary payor on day 91 after incidence. Medicare claims during the one-year period after day 91 are used to identify the first occurrence of either sepsis or an infection of the peritoneal dialysis catheter, censored by death, modality change, change in payor status, or placement of a hemodialysis access. For Figure 8.21, the event-free probability represents the survival probability from an unadjusted Kaplan-Meier curve, using patients from 1999–2004 combined.

ANEMIA & OVERSHOOTING OF TARGET HEMOGLOBIN LEVELS

For Figures 8.22–24, 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. Figure 8.25 includes prevalent hemodialysis and peritoneal dialysis patients who are alive and remain on the modality for the entire prevalent year. Patients are identified as receiving iron if they have at least one claim for it during the year.

The cohort for Figures 8.26 and 8.28 includes incident dialysis patients, age 0–19, with a first service date 90 days prior to July 1, 2001, or June 30, 2005, with Medicare as primary payor, and receiving EPO during the first six months after day 91. Patients who die or are transplanted in the first six months are excluded. Patients are censored at a missing hemoglobin value, and cumulative probabilities are calculated using Kaplan-Meier method.

Figure 8.27 includes point prevalent dialysis patients, age 0–19, with a valid hemoglobin value in each of the first six months. The 90-day rule is applied in this analysis.
PREVENTIVE CARE & INFECTIOUS COMPLICATIONS

Figures 8.29–32 show rates of preventive healthcare in pediatric ESRD patients by modality and race. Methods and codes used to determine rates of influenza and pneumococcal pneumonia vaccinations and lipid testing are similar to those described for Chapter One. For hepatitis B vaccinations, methods are similar to those described in Chapter Five. All patients are age 0–19 at the beginning of each study period; reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories; and have Medicare inpatient/outpatient and physician/supplier coverage for the entire period.

For influenza vaccinations (Figure 8.29), the cohort includes patients starting ESRD therapy at least 90 days prior to September 1 and alive on December 31 of each year; rates are calculated for patients vaccinated in the last four months of each year. For pneumococcal pneumonia vaccinations (Figure 8.30), the cohort includes prevalent patients initiating therapy at least 90 days prior to January 1 of the first year of each two-year period and alive on December 31 of the second year; rates are calculated for patients receiving one vaccination in each period. And for hepatitis B vaccinations and lipid testing (Figures 8.31–32), cohorts include prevalent patients initiating therapy 90 days prior to January 1 and alive on December 31 of each year; rates are calculated for patients receiving one vaccination or test each year. Years 1998–2001 and 2002–2005 are grouped in Figures 8.29 and 8.31–32, and 1998–1999 and 2000–2001, and 2002–2003 and 2004–2005, are grouped in Figure 8.30.

Data on infectious complications in Figure 8.33 include incident dialysis patients with Medicare as primary payor at ESRD initiation. Infectious hospitalizations represent inpatient stays with a principal diagnosis of infection. Pneumonia represents diagnosis codes 480.x–486.x, and device infections include diagnosis codes of 996.62 (hemodialysis) and 996.68 (peritoneal dialysis).

OVERALL HOSPITALIZATION & MORTALITY

Methods used for the hospitalization data in Figures 8.34–36 and 8.39–41 generally follow those described for Chapter Six, with adjusted rates computed using the model-based adjustment method. Included period prevalent dialysis patients have Medicare as primary payor and are residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with AIDS as a primary or secondary cause of death, and those with missing age or gender information, are excluded. The reference cohort includes period prevalent ESRD patients, age 0–19, in 2001. For Figures 8.39–41, principal ICD-9-CM diagnosis codes used for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 6.6. In Figure 8.41, “other” race includes those with a race that is missing, unknown, or other than African American or white.

Figure 8.37 presents five-year survival by modality for 1991–1995 and 1996–2000 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 2005; transplant patients are followed from the first transplant date until death or the end of 2005. 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 8.38 presents adjusted mortality rates for prevalent ESRD, dialysis, and transplant patients age 0–19, for the 1991–2005 cohorts. Rates are computed from the generalized mixed model and are adjusted for age, gender, and race. The reference population for the adjusted rates consists of 2001 ESRD patients age 0–19.

Figure 8.42 presents adjusted all-cause and cause-specific mortality, by age, for prevalent dialysis patients, 1991–2005. These rates are also computed from the generalized mixed model. Rates for all patients age 0–19 and age 20 and older are adjusted for age, gender, and race; rates for patients age 0–9 and 10–19 are adjusted for gender and race. The reference population for the pediatric cohort consists of 2001 ESRD patients age 0–19, and for the adult cohort includes 2001 ESRD patients age 20 or above.

Figure 8.43 presents adjusted all-cause and cause-specific mortality by gender for prevalent dialysis patients, 1991–2005; these are computed from the generalized mixed model, and adjusted for age and race. The reference population consists of 2001 ESRD patients age 0–19.

GROWTH & DEVELOPMENT

Figures 8.44–51 and Table 8.a utilize the 2002 ESRD CPM data and supplement. Heights reported in the CPM data are standardized for age and gender using a method developed by the CDC and based on their 2000 growth charts. We used some SAS code provided on the CDC’s website, at http://www.cdc.gov/nccdphp/dnpa/growthcharts/sas.htm.

Figures 8.45–51 and Table 8.a include patients with a standardized height more than two standard deviations below the mean. This cutoff was chosen because it is included as one of the criteria for recombinant human growth hormone (rhGH) use in the “Guidelines for use of Human Growth Hormone” published by the American Society of Pediatric Nephrology. Biochemical data and information about rhGH prescriptions are obtained from the 2002 ESRD CPM supplement. The percent with an HGH prescription includes only those patients for whom it is known whether or not they were prescribed rhGH. Insurance status (Medicare as primary payor) in Figure 8.47 is obtained for patients also in the USRDS database.

Figures 9.1–2 present trends in the incidence and prevalence of CHF in prevalent patients. The study population includes CKD patients point prevalent on January 1, from 1993 to 2005, who are enrolled in the Medicare inpatient/outpatient and physician/supplier program for at least one year, and who are age 66 or older on January 1 of each cohort year; January 1 point prevalent dialysis patients, 1991–2005, with Medicare as primary payor and receiving hemodialysis or peritoneal dialysis at 90 days after ESRD initiation; and January 1 point prevalent transplant patients, 1991–2005 with Medicare as primary payor. We exclude those patients who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories. For the Medicare CKD study cohort, we also exclude those diagnosed with ESRD or enrolled in an HMO any time before January 1 of the cohort year. The same exclusion criteria are applied in the following figures. The year prior to the point prevalent cohort year is identified as the entry period.

For the prevalent CKD cohort, patients are followed from January 1 of the cohort year to the earliest of December 31 of
The event date for a non-fatal event is defined as the date of the
first ESRD service, with Medicare as primary payor. For prevalent
dialysis and transplant patients we use the Medicare claims
in the one year before CKD diagnosis, with Medicare as primary payor.

The incidence of CHF is calculated as the number of peo-
ple newly diagnosed with CHF in the follow-up period divided
by the number of patients at risk at the beginning of follow-up,
while the prevalence of CHF is computed as the number who
have CHF at baseline and in the follow-up period divided by all
patients at the beginning of follow-up. Direct adjustment meth-
ods are used. For CKD patients, adjustments are for age, gen-
der, race, and diabetic conditions, with point prevalent CKD
patients on January 1, 2005, used as the reference group. For
ESRD patients: percentages are adjusted for age, gender, race,
and dialysis vintage, and point prevalent ESRD patients on Janu-
ary 1, 2005, are used as the reference group.

The following diagnosis codes are used to identify CHF at
baseline: 398.91, 422, 425, 428, 402.X1, 404.X1, 404.X3, and V42.1.
A CHF event is 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 one or more
institutional inpatient, skilled nursing facility, or home health
agency claims, or two or more institutional outpatient and/or
physician/supplier claims. For fatal events, the date of death
due to the event is obtained from the Death Notification form.
The codes of cause-specific death for CHF are 27, 31, and 32,
and the same diagnosis codes are used to determine CHF at baseline
except V42.1 and 422.

Figures 9.3–4 shows the distribution of incident and prev-
alent patients with CHF, by demographic characteristics, comor-
bidity conditions, and diabetic status. The study cohort of Medicare
patients with incident CKD includes Medicare enrollees with no
Medicare CKD claims for at least one year before the first CKD
claim in 2003–2005, age 66 or older, and enrolled in the Medicare
inpatient/outpatient and physician/supplier program for at least
one year before the first CKD claim. The dialysis cohort includes
incident ESRD patients receiving hemodialysis or peritoneal
dialysis at day 90 of ESRD onset, 2003–2005, and enrolled in the
Medicare inpatient/outpatient and physician/supplier program
at day 90 after onset. The incident transplant cohort includes first
renal transplant recipients in 2003–2005, regardless of the year of
first ESRD service, with Medicare as primary payor.

The study cohort of prevalent patients includes January 1,
2005, point prevalent CKD patients, and January 1, 2005, point
prevalent ESRD patients, as described for Figures 9.1–2.

Different sources of information are used to identify comor-
bidity for the different study cohorts. For incident CKD patients,
we use Medicare claims in the one year before CKD diagnosis,
while for incident dialysis and transplant patients we use the
Medical Evidence form and its listed primary cause of ESRD;
transplant patient comorbidity is also determined from the
Medicare claims during the year before the first transplant date.
For prevalent CKD patients, we use Medicare claims in the entry
period, while for prevalent dialysis and transplant patients we
use Medicare claims along with the Medical Evidence form and
its listed primary cause of ESRD.

According to a previously validated methodology for using
Medicare claims to identify diabetic patients, a patient is dia-
betic if, within a one-year observation period, he or she has an
ICD-9-CM diagnosis code of diabetes on one or more inpatient/
outpatient institutional claims (inpatient hospitalization, skilled
nursing facility, or home health agency), or two or more inpa-
tient/outpatient institutional claims (outpatient) or physician/
supplier claims. With this methodology, we identify patients
with comorbid conditions, using the following ICD-9-CM diag-
nosis codes: AMI, 410 and 412; HTN: 362.11, 401.X–405.X, 437.2;
PVD, 440–444, 447, 451–453, and 557; and diabetes, 250, 357.2,
362.0x, and 366.41. Peripheral vascular disease is also defined
from Medicare claims for amputation. Amputation is identified
through ICD-9-CM procedure codes in inpatient/outpatient
claims and/or Current Procedural Terminology (CPT) codes in
physician/supplier claims: amputation: 84.0x, excluding 84.01–
84.02, and 84.1x, excluding 84.11 (ICD-9-CM procedure codes),
23900, 23920, 24900, 24920, 25900, 25905, 25920, 25927, 27295,
27590, 27591, 27592, 27598, 27880, 27881, 27882, 27888, 27889,
28800, and 28805 (CPT codes).

Patients with CHF at baseline are excluded. Incident CKD
patients are followed from the date of CKD diagnosis to the ear-
liest of one year after CKD diagnosis or a censoring date of death,
ESRD diagnosis, or change of Medicare inpatient/outpatient
and physician/supplier enrollment. Incident hemodialysis and peri-
toneal dialysis patients are followed from day 90 of dialysis ini-
tiation to the earliest of one year after day 90 or a censoring date
of death, transplant, loss to follow-up, recovery of renal function,
or end of Medicare as primary payor status. And patients in the
first transplant cohort are followed from the first transplant date
to the earliest of one year after transplant or a censoring date
of death, transplant failure, or the end of Medicare as primary payor
status. For the prevalent cohort, patients are followed from
January 1, 2005, to the earliest of December 31, 2005, or a censor-
ing date, as described for Figures 9.1–2. For death as the cause
of CHF, follow-up time is censored at these same events, with
the exclusion of death and the end of Medicare as primary payor
status. Age is computed as of the beginning of follow-up.

PROBABILITY OF CHF
Figures 9.5–16 illustrate overall probabilities of having CHF, as
well as probabilities by age, gender, race, and comorbidity. Fig-
ures 9.5–10 address these issues in the incident population. The
study cohort of incident CKD and ESRD patients age 20 or older
is constructed as described for Figures 9.3–4, identified here for
2001–2003. Figures 9.11–16 address these issues in the prevalent
population. The study cohort includes January 1, 2003, prevalent
CKD and January 1, 2003, ESRD patients age 20 or older, and is
constructed in the same way described for Figures 9.1–2.

Patients with CHF at baseline are excluded. Incident CKD
patients are followed from the date of CKD diagnosis to the ear-
liest of the censoring date, three years after CKD diagnosis, or
December 31, 2005. Incident hemodialysis and peritoneal dialy-
sis patients are followed from day 90 of dialysis initiation to the
earliest of the censoring date, three years after day 90, or Decem-
ber 31, 2005. And patients in the first transplant cohort are fol-
lowed from the first transplant date to the earliest of censoring
date, three years after transplant, or December 31, 2005. For the
prevalent cohort, patients are followed from January 1, 2003, to
the earliest of the censoring date or December 31, 2005.

For each endpoint in Figures 9.5–16 we use the Kaplan–Meier
method to estimate the overall event probability, and a sepa-
rate Cox proportional hazards model—stratified on the sub-
groups—to estimate event-free probabilities for each subgroup. The covariates included in the Cox model depend on the choice of subgroup: gender, race, and diabetic status are included in the model for comparing event probabilities by age; age, race, and diabetic status for comparing by gender; age, gender, and diabetic status for comparing by race; age, gender, and race for comparing by diabetic status; and age, gender, race, and diabetic status for comparing by comorbidity. Using the model-based adjustment method (described below in the section on statistical methods), and with the CKD and ESRD (hemodialysis, peritoneal dialysis, and transplant) populations as reference cohorts, respectively, these event-free probabilities are further adjusted for the same covariates included in the Cox model. The adjusted event probabilities are obtained by subtracting the adjusted event-free probabilities from one.

**DIAGNOSIS & TREATMENT OF CHF**

Figures 9.17–22 and 9.24 describe the cumulative percent of incident congestive heart failure patients with CKD or ESRD who receive diagnostic tests or treatment for cardiac disease in the three years following their CHF diagnosis, looking at the 1996, 1999, 2002, and 2004 cohorts. The cohorts are identified from the Medicare database (5 percent sample). We first identify Medicare enrollees with a first CHF claim during the 1996–2005 period who are continuously enrolled in the Medicare inpatient/outpatient and physician/supplier program and not enrolled in an HMO during the one year before CHF diagnosis, who are age 66 and older on the date of CHF diagnosis, and who reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories. From this cohort we identify those with CKD based on Medicare claims during the year prior to CHF diagnosis. The study cohorts of incident CHF patients with ESRD are identified from the Medicare ESRD database, and include ESRD patients with a first CHF claim during 1996–2005, with Medicare as primary payor, age 20 and older on the date of CHF diagnosis, and who reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories. From this cohort we identify those with CKD based on Medicare claims during the year prior to CHF diagnosis. The study cohorts of incident CHF patients with ESRD are identified from the Medicare ESRD database, and include ESRD patients with a first CHF claim during 1996–2005, with Medicare as primary payor, age 20 and older on the date of CHF diagnosis, initiating ESRD therapy at least 90 days before CHF diagnosis, and residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Modality type is determined on the date of CHF diagnosis.

The cumulative percentage is calculated as the cumulative number of patients receiving diagnostic tests or treatment divided by the total number of patients at the beginning of follow-up. Patients are followed from the date of CHF diagnosis to the earliest of death, change in Medicare as primary payor status, ESRD diagnosis (for CKD patients) or modality change (for ESRD patients), three years after CHF diagnosis, or December 31, 2005.

Different sources of information are used to identify diagnostic tests and treatment for cardiovascular disease. Echocardiograms are defined through CPT codes in physician/supplier claims. Implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy with defibrillator (CRT-D) are defined through ICD-9-CM procedure codes in inpatient/outpatient claims. And stress tests (including stress echocardiogram, stress nuclear test, and stress ECG), coronary angiography and/or catheterization, percutaneous coronary interventions (PCI), and coronary artery bypass graft surgery (CABG surgery) are defined through ICD-9-CM procedure codes in inpatient/outpatient claims and/or CPT codes in physician/supplier claims.

**SURVIVAL AFTER DIAGNOSIS OF CHF**

Figures 9.25–36 describe survival following the diagnosis of CHF in ESRD and general Medicare patients with CKD. Age is computed on the date of CHF diagnosis.

Figures 9.25–30 examine these issues in the incident population, 2002. The study cohort includes incident CKD patients age 66 and older, and incident dialysis and transplant patients age 20 or older. Incident CKD patients are followed from the date of CKD diagnosis for up to one year until the first CHF or censoring date. Incident dialysis patients are followed from day 90 after dialysis initiation for up to one year until the first CHF or censoring date. And patients in the first transplant cohort are followed from the first transplant date up to one year until the first CHF or censoring date. Patients are then followed from the CHF diagnosis date up to three years until December 31, 2005, or a censoring date to track survival (the incident transplant cohort is not censored at the end of Medicare as primary payor status). Figure 9.25 presents unadjusted overall survival probabilities. Figure 9.26–29 are stratified by age, gender, race, and diabetic status, using the model-based adjustment method (described below in the section on statistical methods); survival probabilities here are estimated by the Cox proportional hazards model, and data by one variable are adjusted for the remaining three. Figure 9.30 is stratified by comorbidity, and adjusted for age, gender, race, and diabetic status.

Figures 9.31–36 examine these issues in the prevalent population. The study cohort is constructed in the same way as the prevalent cohort in Figures 9.11–16. For the prevalent CKD cohort, patients are followed from January 1, 2003, up to one year until the first CHF or censoring date. Patients in the prevalent ESRD cohort are followed from January 1, 2003, up to one year until the first CHF or censoring date. Patients are then followed from CHF diagnosis date up to three years until December 31, 2005, or a censoring date. Adjustments are as described for the equivalent figures on the incident population.

Figures 9.37–42 demonstrate trends in survival following the diagnosis of CHF in ESRD and general Medicare patients with CKD. All patients are followed up to one year to define incident
analytical methods
APPENDIX A

CHF, using the same method described for Figures 9.25–36. Age is computed on the date of CHF diagnosis.

Figures 9.37–39 examine these issues in the incident population. Yearly cohorts constructed for 1996–2003 include incident CKD patients age 66 and older, and incident dialysis and transplant patients age 20 or older in the cohort year. Incident CKD patients are followed from the date of CHF diagnosis to the earliest of a censoring date or one year after the CHF date. Incident ESRD patients are followed from the CHF date to the earliest of a censoring date or one year after the CHF date to track survival.

Figures 9.40–42 examine these issues in the prevalent population. Yearly cohorts of prevalent CKD and ESRD patients are constructed for 1993–2004 and 1991–2004, respectively. The ESRD cohort includes dialysis and transplant patients in the cohort year, age 20 or older. Patients in this cohort are followed from the CHF date to the earliest of a censoring date or one year after the CHF date (the incident transplant cohort is not censored at the end of Medicare as primary payor status).

Figures 9.37 and 9.40 present unadjusted overall survival probabilities. Figure 9.38–39 and 41–42 are stratified by race and diabetic status, using the model-based adjustment method (described below in the section on statistical methods). Survival probabilities are estimated by the Cox proportional hazards model; in Figures 9.38 and 9.41 they are adjusted for age, gender, and diabetic status, and in Figures 9.39 and 9.42 for age, gender, and race. Overall probabilities are unadjusted, and the most recent populations of CKD and ESRD (hemodialysis, peritoneal dialysis, and transplant) patients are used as reference cohorts, respectively.

Figure 9.43 describes all-cause survival after CHF treatment in 1996–2003 incident CHF patients with CKD or ESRD who receive treatment for CHF within one year after CHF diagnosis. The study cohorts (CKD, dialysis, and transplant) are constructed with the method described for Figures 9.17–22 and 9.24. We then identify patients receiving treatment for CHF within one year of CHF diagnosis. Treatment includes coronary revascularization (PCI and CABG surgery) and ICDs/CRT-Ds, and is defined with the method used in Figures 9.17–22 and 9.24. The Kaplan-Meier method is used to estimate cumulative survival probability after treatment for CHF. Patients are followed from the date of treatment to the earliest of death, ESRD diagnosis (for CKD patients) or modality change (for ESRD patients), three years after treatment, or December 31, 2005. Survival probabilities are unadjusted.

L-CARNITINE IN HEMODIALYSIS PATIENTS WITH CHF

Figure 9.44 displays the number of patients using L-carnitine—as indicated by HCPCS code J1955—in the year following CHF diagnosis for incident CHF patients during 1998–2004, and in each calendar year for point prevalent CHF patients during 1998–2005. Incident CHF patients on hemodialysis are identified with the method described for Figures 9.17–22 and 9.24. Point prevalent CHF patients on hemodialysis are identified with a similar method, and include patients with a CHF claim prior to January 1 of each calendar year 1998–2005, age 20 and older, with Medicare as primary payor on January 1 of the year, initiating ESRD therapy at least 90 days before that date, and residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories. The one-year period evaluating L-carnitine use extends from the CHF diagnosis date (for incident CHF patients) or January 1 of each calendar year (for point prevalent CHF patients) to the earliest of death, modality change, end of Medicare as primary payor status, one year after CHF diagnosis (for incident CHF patients), or December 31 of the year (for point prevalent CHF patients).

Figure 9.45 compares survival after CHF diagnosis in those who do and do not use L-carnitine, looking at incident CHF patients on hemodialysis, 1998–2003. L-carnitine status is defined in the first three months following CHF diagnosis. Patients are followed from the fourth month to the earliest of death, modality change, three years after day 90 of CHF diagnosis, or December 31, 2005. The unadjusted cumulative survival probability is estimated using the Kaplan-Meier method.

ICDs/CRT-Ds: USE AND SURVIVAL

Figure 9.46 describes the use of implantable cardioverter defibrillators (ICDs) or cardiac resynchronization therapy with defibrillator (CRT-D) in Medicare CKD, Medicare non-CKD, and ESRD patients. Yearly prevalent CKD and non-CKD cohorts are identified from the Medicare database (5 percent sample), and include Medicare enrollees who are continuously enrolled in the Medicare inpatient/outpatient and physician/supplier program, not enrolled in an HMO, not diagnosed with ESRD during the one year prior to January 1 of the years 1993–2005, and age 66 and older on January 1 of the year. Yearly prevalent dialysis and transplant patients are identified from the Medicare ESRD database, and include period prevalent dialysis and transplant patients in each year, 1991–2005, who have Medicare as primary payor, and are age 20 and older on January 1 of the year. The one-year period used to identify ICD/CRT-D recipients is from January 1 of each year to the earliest of death, end of Medicare as primary payor status, ESRD diagnosis (for CKD and non-CKD patients) or modality change (for ESRD patients), or December 31 of the year. ICD/CRT-D is defined with the method used earlier. Cohorts are limited to those residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories.

Figures 9.47–53 describe patient demographics and comorbidity, the use of diagnostic tests prior to ICD/CRT-D implantation, and all-cause survival after implantation in patients receiving their first implantation of ICD/CRT-D during 1996–2005. The CKD and non-CKD study cohorts are identified from the Medicare database (5 percent sample), and include Medicare enrollees with a first implantation of ICD/CRT-D during 1996–2005, continuously enrolled in the Medicare inpatient/outpatient and physician/supplier program, not enrolled in an HMO for at least one year before implantation, and age 66 and older on the date of implantation. CKD status is identified during the one year before ICD/CRT-D implantation. The study cohorts of dialysis and transplant patients are identified from the Medicare ESRD database, and include ESRD patients with a first implantation of ICD/CRT-D during 1996–2005, continuously enrolled in the Medicare inpatient/outpatient and physician/supplier program, not enrolled in an HMO for at least one year before implantation, and age 66 and older on the date of implantation. ESRD patients in each year, 1991–2005, who were Medicare as primary payor on December 31 of the year, and age 66 and older on the date of implantation. Cohorts are limited to those residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories.

Figures 9.47–48 illustrate the demographics and comorbidity of patients receiving their first ICD/CRT-D. Major comorbid conditions are defined from Medicare claims during the one year prior to ICD/CRT-D treatment, using the methodology described earlier. For ESRD patients, comorbid conditions are also obtained from the Medical Evidence form submitted at the
initiation of ESRD treatment. Figures 9.49–52 describe the percentage of patients receiving diagnostic tests in each month of the two years prior to ICD/CRT-D implantation. Diagnostic tests are defined with the method used in Figures 9.17–22 and 9.24. Figure 9.53 describes all-cause survival after implantation of ICD/CRT-D by indication of implantation (primary versus secondary prevention). Secondary prevention is defined as the indication of ICD/CRT-D implantation if there are claims with ICD-9-CM diagnosis codes 427.1 (paroxysmal ventricular tachycardia), 427.4 (ventricular fibrillation and flutter), or 427.5 (cardiac arrest) during the hospitalization for ICD/CRT-D implantation. Otherwise, primary prevention is defined. Patients are followed from the date of the first ICD/CRT-D implantation to the earliest of death, ESRD diagnosis (for CKD and non-CKD patients) or modality change (for dialysis and transplant patients), the date of the second ICD/CRT-D, three years after the first ICD/CRT-D implantation, or December 31, 2005. Unadjusted survival probabilities are estimated using the Kaplan-Meier method for primary prevention and secondary prevention, respectively.

This year the USRDS has changed its definition of a dialysis chain. Throughout the atlas and in Reference Section J, we now define a chain-affiliated unit as one of a group of 20 or more freestanding dialysis units which are owned or operated by a corporation at the end of a year. The requirement for a chain to have units in two or more states has been dropped.

We have also introduced a new affiliation category of “small dialysis organization,” or SDO, which includes all organizations meeting our definition of a chain but having fewer than 50 units. Chain affiliation is determined from the “Provider Name” field of the Facility Survey, the “Chain Name” field of the Dialysis Facility Compare database, and the “Chain Organization Name” field of the Cost Report.


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

Figures 10.8–20 show differences by provider in comorbidity, biochemical test results, and pre-ESRD care and vascular access for incident dialysis patients. In this 2007 ADR the USRDS is taking the first look at the new data elements on the recently revised Medicare Evidence form (introduced in the spring of 2005), especially in the areas of pre-ESRD care, vascular access, and new biochemical data (including HbA1c and lipid panel results) at the initiation of ESRD.

PREVENTIVE CARE & ANEMIA

Figures 10.21–22 and 10.25–26 use the methods described for Figure 5.1. Figures 10.23–25 and Figures 10.44–49 illustrate differences by provider in preventive care for dialysis patients. Cohorts for Figures 10.23–24 are the same as those used for Figures 5.22 and 5.26, but are limited to dialysis patients. The cohort in Figure 10.25 is the same as that used for Objective 14.29 in Chapter HP2010, limited to dialysis patients. Figures 10.44–46 use the same cohort as Figure 5.20, here for periods 2001–2002 and 2004–2005; Figure 10.47 uses the cohort from Figure 5.39, here for 2002 and 2005; Figure 10.48 uses the cohort from Figure 5.41, here for 2001–2002 and 2004–2005; and Figure 10.49 uses the cohort from Figure 5.43, here for 2002 and 2005. All are limited to dialysis patients.

Figure 10.27 includes period prevalent dialysis patients in 2000 and 2005. Data for mean hemoglobin include only patients with valid EPO claims. A mean is calculated for each patients from all valid claims during the year.

Figure 10.28 shows the number of months in which patients have a hemoglobin value of 11–12 g/dl. The study cohort includes point prevalent dialysis patients, 2005, with a valid hemoglobin value in each of the first six month after January 1, 2005.

The cohort for Figures 10.29–31 includes incident dialysis patients with a first service date between July 1, 2003, and June 30, 2005, with Medicare as the primary payor, and receiving EPO during the first six months after incidence. Patients with unknown age or gender, or with a missing initial hemoglobin value, are excluded, as are those who die or are transplanted in the first six months. Patients are censored at the missing hemoglobin value. Cumulative probabilities and hazard ratios are calculated using the Kaplan-Meier method. Figures 10.32–36 include prevalent hemodialysis patients in 2005; tests are identified from outpatient and physician/supplier claims during the year.

Figures 10.38–43 display rates of intravenous vitamin D and iron administration during 2000 and 2005. For Figures 10.38 and 10.41, the cohort consists of incident ESRD patients surviving at least nine months, and whose calendar months 4–9 of ESRD occur wholly within calendar year 2005. All patients continue dialysis and carry Medicare as primary payor during months 4–9. In Figure 10.38, vitamin D is indicated by HCPCS codes J0635–J0636, J1270, and J3500–2501. In Figure 10.41, iron is indicated by HCPCS codes J1750, J1755–J1756, J1760, J1770, J1780, and J2915–J2916. For Figures 10.39–40 and 10.42–43, the cohort consists of patients who initiate ESRD therapy at least 90 days prior to the start of the year, and are receiving dialysis on December 31 of the previous year. All patients survive, continue dialysis, and carry Medicare as primary payor during the ensuing year. Chain affiliation is defined by the dialysis provider on December 31 of the previous year.

HOSPITALIZATION & MORTALITY RATIOS

Figures 10.50–54 compare mortality and hospitalization ratios among dialysis chains, over time, using standardized mortality ratios (SMRs) and standardized hospitalization ratios (SHRs). The SMRs and SHRs in Figure 10.50 are estimated by the Bayesian method, while the remaining figures use the traditional
SMR calculation method. Criteria for including and excluding patients, for considering death as an event, and for censoring are same as those used in Reference Section H. The cohort for the SHRs includes period prevalent dialysis patients, identified as described for Reference Section G. The total number of admissions, instead of the first hospitalization, is used for the SHRs.

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

**PAYOR SEQUENCE**

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

**CHAPTER ELEVEN**

Table 11.1 in the Précis summarizes data on the costs of ESRD treatment. Total 2005 Medicare spending is calculated from the claims data, and includes all paid claims for ESRD patients in the USRDS database. Cost aggregation for each patient begins at the first ESRD service date. Total 2005 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 2005 (obtained from the CMS managed care organization file) in conjunction with the 2005 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 years at risk for 2005. Patient obligations are estimated as the difference between Medicare allowable and net payment amounts. Non-Medicare patient spending is estimated as the number of patient months at risk for non-Medicare patients (determined from the USRDS payor sequence) multiplied by the AAPCC rate.

Changes in Medicare spending from 2004 to 2005 are obtained from Table K.2, without the 2 percent adjustment for late claims. Calculations of PPPY at-risk costs are based on patients for whom Medicare is primary payor during the study period (Table K.6), again using non-inflated results. The range for inflation-adjusted costs is calculated using the overall Consumer Price Index (3.4 percent) and Medical Consumer Price Index (4.2 percent).

Data on costs for vascular access services (Figures 11.31–35) are obtained from event-based analyses. Physician/supplier vascular access procedures and costs are identified through CPT codes (Table a,b). Because some CPT codes are not specific to an ESRD access (e.g., central venous catheter, radiological procedures), our selection process requires that certain CPT codes be accompanied by a renal-related diagnosis code for inclusion in the analysis (these codes are identified with an asterisk in Table a,b). Facility costs are more difficult to identify. For inpatient facility costs, vascular access procedures in the inpatient setting are matched with inpatient claims, and all procedures performed during a given inpatient stay (admission date through discharge date) are considered a single vascular access event. Because vascular access procedures are often performed when a patient is hospitalized for another reason, costs for inpatient facilities are included in the analysis only if the cause of hospitalization can be reasonably attributed to vascular access, using Diagnosis Related Grouping (DRG) and ICD-9-CM principal procedure codes, or ICD-9-CM principal diagnosis codes (Table a,c). Such hospitalizations are labeled “pure” inpatient vascular access events.

For outpatient facility costs, physician/supplier claims with vascular access procedures performed in the outpatient setting are linked to outpatient claims, using service dates and CPT codes. These costs are included in the analysis only if a matching CPT code is found on both physician/supplier and outpatient claims. Once again, all procedures and costs for the entire

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**Complication**

| 34101, 35190, 35321, 35458, 35460, 35475, 35476, 35484, 35875, 35876, 35900, 35903, 35910, 36005, 36145, 36334, 36535, 36530, 36575, 36580, 36581, 36584, 36589, 36596, 36597, 36631, 36832, 36833, 36834, 36838, 36860, 36861, 36870, 37190, 37201, 37205, 37206, 37207, 37208, 37607, 49222, 75790, 75820, 75860, 75865, 75960, 75962, 75978, 76937, 75998, 75999, 00532, 01784, 01844, 90039, 90040, G0159, and M0900

**Hemodialysis catheter placement**

36011, 36488, 36489, 36490, 36491, 36533, 36535, 36536, 36557, 36558, 36559, 36560, and 36800

**Peritoneal dialysis catheter placement**

49419, 49420, and 49421

**Synthetic graft placement**

36830

**Fistula placement**

36810, 36818, 35820, 36821, and 36825

* Requires accompanying diagnosis code for inclusion.

**DRG codes**

| 111 | Percutaneous cardiovascular procedure |
| 120 | Other circulatory system OR procedure |
| 315 | Other kidney and urinary tract OR procedure |
| 442 | Other OR procedure for injuries with complication |
| 443 | Other OR procedure for injuries without complication |
| 478 | Other vascular procedure with complication |
| 479 | Other vascular procedure without complication |
| 38.95 | Venous catheterization for renal dialysis |
| 39.27 | Arteriovenostomy for renal dialysis |
| 39.42 | Revision of arteriovenous shunt for renal dialysis |
| 39.43 | Removal of arteriovenous shunt for renal dialysis |
| 39.93 | Placement of vessel-to-vessel cannula |
| 39.94 | Replacement of vessel-to-vessel cannula |
| 86.07 | Placement of totally implantable vascular access device |

**ICD-9-CM diagnosis codes**

| 996.1 | Mechanical complication of vascular device, implant, graft |
| 996.62 | Infectious complication of vascular device, implant, graft |

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

* The presence of any of these diagnosis codes as the “Principal Diagnosis Code” is sufficient to define an inpatient pure vascular access event
matching outpatient claim are considered part of a single vascular access event. Since the CPT code is not a required element on outpatient claims, not all outpatient facility costs for vascular access can be identified. Events that can be identified in the outpatient claims are labeled “pure” outpatient vascular access events.

Although vascular access procedures can be identified from claims data, it is not possible to determine with certainty the type of vascular access being used for dialysis at any given time. In order to compare overall and vascular access costs by type of vascular access, data are analyzed for the hemodialysis cohort from the CMS ESRD Clinical Performance Measures Project (CPM) for 1999 through 2005. The CPM project collects data annually on a random sample of hemodialysis and peritoneal dialysis patients, including the type of vascular access being used for hemodialysis at the time of data collection. The CPM data for hemodialysis patients are collected from October through December of the year prior to the cohort year (e.g., CPM data were collected from October through December, 2004 for the 2005 cohort). For Figures 11.31–32 we classify patients by the vascular access in use at the time of the CPM data collection, and aggregate costs for the following calendar year, with follow-up until the earliest of death, transplant, modality change, or the end of the calendar year. This analysis is limited to patients with Medicare as primary payer.

For Figure 11.36, prevalent hemodialysis patients from 1998–2004 are matched to the ESRD CPM data to obtain their current vascular access in use at the end of their prevalent year. Inpatient hospital stays during the following calendar year (censored by change in modality or a placement event for a different type of access) are identified as being for a vascular access infection if the principle diagnosis is 996.62, “Infection of Internal Device.” The total payment amount from that inpatient stay is used to calculate a raw PPPY cost. These costs are then adjusted for inflation to 2000 dollars using the Consumer Price Index published by the Bureau of Labor Statistics so that costs could be compared across years.

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 inpatient/outpatient and physician/supplier claims data in the CMS Standard Analytic Files, which are created annually six months after the end of each calendar year. The data for 2001–2005 are comprised of approximately 38 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 300 million line items from physician/supplier claims. Claims data are obtained for all patient ID numbers in the USRDS database, and the Renal Management Information System (REMIS) 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 inpa-
tient claims and reimburses the provider for capital-related costs, direct medical education costs, and kidney acquisition costs.

**PAYMENT CATEGORIES**

Medicare payments are broken into several categories, as shown in Table A.d. 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) = \([\text{total charge (line)} / \text{total charge (claim)}]\) \(*\) payment (claim). In August of 2000 CMS added to the Outpatient SAF a field containing line item payment amounts. According to CMS documentation, the total of these payments may not equal the total paid amount for the claim. In such cases, each line item cost is discounted by the ratio of 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 2001–2005, with adjustments as noted.

**MODEL 1: AS-TREATED ACTUARIAL MODEL**

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

In Section K 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 15 years from January 1, 1991, to December 31, 2005, and ESRD patients prevalent on January 1, 1991, or incident at any time during the period are potentially eligible for inclusion. The initial study start date for a given patient is defined as the latest of January 1, 1991, the first ESRD service date in the USRDS database for that patient, or the earliest Medicare eligibility date from the payor sequence. Because it is impossible to characterize the total cost of their care, patients for whom Medicare is the secondary payor at any time during the study period are classified as MSP for the duration of the MSP status in the payor sequence. If the payor status changes to Medicare as primary payor, a new sequence begins at the change date. Patients who are non-Medicare or enrolled in a Medicare+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.1–3, and are excluded for the rest of the tables in Section K.

For each modality period, Medicare payments are aggregated from the modality start date until the earliest of death, transplant, modality change, loss to follow-up, or December 31, 2005. Patients incurring no inpatient/outpatient or physician/supplier Medicare costs for the entire period are excluded, and Medicare payment amounts are linearly prorated for claims that span the start or end date of a modality period or of the study itself.

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

**MODEL 2: CATEGORICAL CALENDAR YEAR MODEL**

This model, described in the HCFA (now CMS) research report on ESRD (1993–1995), is used for Figures 11.7–8, 11.15–20, and, in the Précis, Figure p.31 and Table p.b, as well as Reference Tables K.9–12. 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 classified in the transplant category.

The international data for this ADR have been collected from the following sources, using the data form shown at the end of this section:

- the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA)
- the Austria OEDTR
- the Bangladesh Renal Registry
- the French-Belgian Nephrologists Registry
- Centre Hospitalier Etterbeek-Ixelles, Belgium
- Clinical Center University of Sarajevo, Bosnia and Herzegovina
- the Canadian Organ Replacement Registry
- the Chilean Renal Registry
- the Croatian Society of Nephrology, Dialysis, and Transplantation
- the Czech Society of Nephrology
- the Danish Society of Nephrology
Figure 12.28 compares ACE-I/ARB use in Taiwan and the U.S., using data from the NIH and the Medicare Current Beneficiary Survey (MCBS, Cost and Use data 2000–2003), and looking at CKD patients with and without diabetes. Medication use is identified through at least one pharmacy claim within each calendar year. Patient cohorts in MCBS data are defined as described for Figure p.21 in the Healthy People 2010 chapter.

Figures 12.29–30 compare preventive care testing in the U.S. Medicare population and the Taiwan NHI elderly population with diabetes and CKD. Cumulative probabilities are calculated using the Kaplan-Meier method, and patients are censored at dialysis initiation, death, or the end the calendar year. The cumulative probability of diabetic glycosylated hemoglobin (HbA1C) testing in Figure 12.29 is based on at least two tests within each calendar year, each at least 30 days apart. In Figure 12.30, at least one microalbuminuria or proteinuria tests is considered the event. HbA1C and microalbuminuria/or proteinuria testing are identified through CPT codes, as described in Chapter Five. For the Taiwanese NHI population, the use of preventive testing is identified by medical codes for testing and examination.

Tables L.1–3 and L.11–13 include point prevalent dialysis patients from 1999 to 2005 who have Medicare as their primary payor. Placements are identified from Medicare claims, and rates represent the total number of events divided by the time at risk. Follow-up time is censored at death, change in modality, change in payor status, or the end of the prevalent year. For Tables L.11–13, data from 2005 is used, and vintage represents the amount of time between the first service date and January 1, 2005.

Tables L.4–9 include prevalent hemodialysis patients with Medicare as their primary payor who are also in the ESRD CPM report for the corresponding year. Their current access is determined from the CPM data as the access used at the time of the most recent data collection, i.e., during the months of October, November, and December of the year prior to the prevalent year. Complications and intervention events are obtained from claims during the time at risk during the prevalent year, which is censored at death, change in modality, change in payor status, or a claim for the placement of a different hemodialysis vascular access. Patients who have a placement claim after the time of the CPM data collection but prior to the start of the prevalent year are excluded.

Table L.10 includes prevalent peritoneal dialysis patients with Medicare as their primary payor. Complications and intervention events are obtained from claims during the time at risk in the prevalent year, which is censored at death, change in modality, change in payor status, or a claim for the placement of a hemodialysis vascular access.

**COSTS & CARE IN TAIWAN**

In Figures 12.26–30 we use data from the Taiwan National Health Insurance (NHI) dataset, which, like Medicare claims data, uses ICD-9-CM diagnosis codes.

For Figure 12.26, we use the same ICD-9-CM codes described in Chapter One to identify patients with chronic kidney disease (CKD), congestive heart failure (CHF), and diabetes in the 1 percent random sample of the entire NHI population. To allow comparisons with the Medicare data in Figure p.1 (Précis), the cohort includes only patients age 65 and older and all-age ESRD patients. Patient counts are estimated using the methods defined for Figure p.1, and costs for the “cost year” are determined for the entire calendar year.

Thank you to all who provided data for this year’s Annual Data Report. We are especially grateful to Drs. Kitty Jager and Paul van Dijk at the ERA-EDTA Registry for their help in coordinating much of the European data presented in this chapter.

Data for some countries do not represent 100 percent of the ESRD population; interpretation of changes in incident and prevalent rates must therefore be performed with caution. Notations are made in the captions for those countries reporting only dialysis patients.

To contribute data from your country’s registry, please complete the form on pages 307–308 and return it to the USRDS.

**REFERENCE SECTION M**

The 2000 U.S. census, available in 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 2000–2005, however, the actual data include racial groups that do not coincide with those in the ESRD data. For 2000–2005, however, the actual data include racial groups that do not coincide with those in the ESRD data.

- the ERA-EDTA Registry
- the Finnish Registry for Kidney Diseases
- the French Renal Epidemiology and Information Network (REIN) registry
- the QuaSi-Niere in Germany
- the Hellenic Renal Registry, Greece
- the Hong Kong Renal Registry
- the Department of Transplantation and Surgery in Hungary
- Landspitali University Hospital, Iceland
- the Israeli Renal Registry
- the Italian Registry of Dialysis and Transplantation
- the Jalisco State Dialysis and Transplant Registry, Mexico
- the Japanese Society of Dialysis Therapy
- the Catholic University of Korea, Republic of South Korea
- Registre Néphrologique du Grand Duché de Luxembourg
- the Netherlands Dialysis Registry
- the National Renal Registry of Malaysia
- the Norwegian National Hospital
- the Kidney Foundation of Pakistan
- the Philippines Renal Disease Registry Project
- the Society of Dialysis, Russia
- the Scottish Renal Registry
- the Shanghai Jiao Tong University
- Spanish National Renal Diseases Registry
- the Swedish Renal Registry
- the Taiwan Society of Nephrology
- the Thai Registration of Renal Replacement Therapy
- the Turkish Society of Nephrology
- the United Kingdom Renal Registry
- the Uruguayan Registry of Dialysis
- the U. S. Census Bureau International Database
- the USRDS
2000–2005 rate calculations throughout the ADR, we thus use the CDC’s Bridged Race Dataset, which estimates white, African American, Native American, and Asian populations. The data and methods for these estimates are available at www.cdc.gov/nchs/about/major/dvs/popbridge/popbridge.

**METHODS FOR CALCULATING RATES**

The calculation of observed rates is straightforward, with some rates based on counts and others on follow-up time. The ESRD incident rate in 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 follow-up 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 follow-up time (such as per thousand patient years). Calculating rates per unit of follow-up time can account for varying lengths of follow-up among patients. Patient years are calculated as the total number of years, or fractions of a year, of follow-up time for a group of patients.

Take, for example, a calculation of 1997 first hospitalization rates for two groups of 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 follow-up time.

Rates per unit of population may be influenced by the proportion of patients who are followed for only a fraction of a year. The event rate per unit of population is likely to be lower, for example, in a group of patients followed for only one month until censoring than in a group whose patients are each followed for up to a full year. Rates per unit of follow-up time at risk, in contrast, count only the actual time that a patient is at risk for 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). Here the adjusted rate is derived by applying the observed category-specific rates to a single standard population, i.e. the adjusted rate is a weighted average of the observed category-specific rates, using as weights the proportion of each category in the reference population. The categories are defined by the adjusting variables. For example, if a rate is adjusted for race and gender and there are three race groups (white, African American, and other) and two gender groups (male and female), there are six categories: white males, white females, African American males, African American females, males of other races, and females of other races.

Suppose we try to compare state-level incident rates in 2001 after removing the difference caused by race. To do this, we need to calculate the adjusted incident rate, adjusted for race, for each state. Because racial distributions in each state are quite different, we use as reference the national population—here, the population at the end of 2001—with five race groups (white, African American, Native American, Asian/Pacific Islander, and other). Assuming the incident rate of state A in 2001 is 173 per million population, and the race-specific rates and national populations are as shown in the following table, the adjusted incident rate of state A with the national population as reference is (153 x 75.1%) + (250 x 12.3%) + (303 x 0.9%) + (174 x 3.6%) + (220 x 8%) = 158.73 per million population. This means that if state A had the same racial distribution as the entire country, its incident rate would be 158.73 instead of 173. If state B had an adjusted incident rate of 205, we could say that state B had a higher incident rate than state A if they both had the same racial distribution as the whole country.

<table>
<thead>
<tr>
<th>Incident rate of State A</th>
<th>National Population (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>153</td>
</tr>
<tr>
<td>African American</td>
<td>250</td>
</tr>
<tr>
<td>Native American</td>
<td>303</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>174</td>
</tr>
<tr>
<td>Other</td>
<td>220</td>
</tr>
</tbody>
</table>

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 described above. 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. This methods can also be extended to adjustments with continuous adjusting variables (Liu et al., 2006). There is, unfortunately, no straightforward way here to calculate standard errors of the adjusted rates for some models; the bootstrap approach works well, but is time consuming.

In this ADR we use model-based adjustments to calculate adjusted mortality rates, adjusted survival probabilities based on the Cox regression model, adjusted hospitalization rates and state-level adjusted incident and prevalent rate 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 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 \( \log (\text{rate}) = (\text{fixed effects}) + (\text{random effect}) \). Fixed effects include year, age, gender, race, and primary diagnosis, and all two-way interactions among age, gender, race, and primary diagnosis. Assumed to be independently and identically distributed with a normal distribution, the random effect is the four-way interaction of age, gender, race, and primary diagnosis. Age is used as a categorical variable in main effect and four-way interactions, and as a continuous variable in 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.

**STANDARDIZED MORTALITY RATIOS**

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

**traditional method of SMR calculation**

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

**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 \( \mu \), and that \( \theta \), the logarithm of SMR,
has a normal distribution with Gamma precision, where $m$ is the expected death count from a generalized linear mixed model incorporating patient age, gender, race, primary diagnosis, and ESRD vintage (Liu et al., 2006). To distinguish the two estimation methods, we use the term BMR to designate the estimated SMR from the Bayesian model. The standardized hospitalization ratios and standardized transplant ratios in reference tables were also calculated using the Bayesian method.

**EXPECTED REMAINING LIFETIMES**

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

For a subgroup of ESRD patients of a particular age, the expected remaining lifetime is calculated using a survival function, estimated for the group. Let $S(A)$ denote the survival function of patients at time $A$. Among patients alive at age $A$, the probability of surviving $X$ more years is $S(A|A) = S(A+X)/S(A)$. For a given starting age $A$, the expected remaining lifetime is then equal to the area under the curve of $S(A|A)$ 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 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 to smooth prevalent rates and calculate some percentages. To smooth maps of mean hemoglobin, eGFRs, and creatinine levels, the model is extended to assume that the means have a normal distribution.

**SPECIAL STUDIES & DATA COLLECTION FORMS**

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

**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**


Centers for Disease Control and Prevention. The third National Health and Nutrition Examination Survey (NHANES
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 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.

The Coordinating Center maintains a set of Standard Analysis Files (SAFs) to meet diverse research needs and provide easy access to data used in the ADR. The SAFs were introduced in 1994, as the NIDDK began awarding new 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. For more information on merged data requests, please contact the Coordinating Center at usrds@usrds.org.

The three-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 follow-up data collected by CMS and UNOS. Data on hospital inpatient stays are found on the hospitalization CD. All Medicare billing data are available by individual year (see Table b.c.).

The use of Standard Analysis Files is governed by the USRDS policy on data release for investigator-initiated research (page 305). Research proposals must be approved by a USRDS Project Officer, and researchers must sign the USRDS “Agreement for Release of Data” (page 303). 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 CDS**

The Core Standard Analysis File CDs contain the most frequently used SAFs, including those from the Special Studies, and are needed for use of the Transplant CD, the Hospital CD, or any CD based on Medicare claims data. Included files are as follows (and are also listed in Table b.b).

- **Patient** Contains one record per patient in the USRDS database, and gives basic demographic and ESRD-related data.
- **Residence** A longitudinal record, to ZIP code level, of patient residence.
- **Payor History** Contains a new record for each patient at each change in insurance payor.
- **Modality Sequence** Contains a new record for each patient at each change in modality or dialysis provider.
- **Medical Evidence** Contains full data from the 1995 version of the CMS Medical Evidence form, the data source for the primary disease causing renal failure and the start date of chronic renal failure.
- **Transplant** Contains basic data for all transplants (reported by CMS and UNOS), including the date of graft failure.
- **Transplant Wait List** Beginning with 2001 data (used in the 2002 ADR), this CD has been updated to include basic patient demographic data and, from UNOS, all unique wait-list periods for each dialysis patient.
- **Facility** Conducted annually, the CMS End-Stage Renal Disease Facility Survey is the source of data for the Facility SAF, which can be linked to the Facility Cost Report files using the USRDS provider ID. Geographic variables that could identify facilities are deleted. The survey period is January 1 through December 31.
- **Facility Cost Reports** CMS hospital and independent facility cost reports for 1989–1995 and 1989–1993, respectively, are available as SAFs. All geographic variables are deleted to ensure confidentiality. The files may be linked to the Facility SAF using the USRDS provider ID, though analyses at less than a regional or network level are not possible. Because these files are rarely used, additional data will be added only if there is sufficient demand.
- **Dialyzers** The Case Mix Severity, Case Mix Adequacy, and DMMS Special Studies 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.
DATA FROM SPECIAL STUDIES
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 and early 1997.

**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 70,996 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 3,355 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 comorbid conditions and other factors.

**Pediatric Growth & Development** The objectives of the USRDS Pediatric Growth and Development Study were to establish a baseline for assessing the relation of pediatric patient growth and sexual maturation to modality, 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 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 CDS
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
- TXHCFA: includes transplant information collected by CMS’s PMMIS system prior to 1994
- TXUNOS: includes transplant information collected since 1987 by UNOS, currently the main source of transplant data for the USRDS
- TXIRUNOS: includes information on immunosuppressive drugs collected by UNOS at the time of transplantation events
- TXFUHCFA: includes transplant follow-up 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 follow-up reports collected by UNOS since 1988
- TXIFUNOS: includes information on immunosuppressive drugs, collected by UNOS at follow-up visits

Tables in Reference Sections E and F 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 SAFs, 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 CDS
Hospitalization inpatient data are a subset of the data in the Institutional Claims file. No payment or cost variables are included on this two-CD set, 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.

MEDICARE PAYMENT DATA CDS
Medicare payment data on institutional claims are available for pre-1989 through 2005, while data on physician/supplier claims are available for 1991–2005. The 2005 claims will be available, along with other updated USRDS SAF CDs, by the end of 2007.

Institutional claims consist of all inpatient/outpatient claims (inpatient, outpatient, skilled nursing facility, home health agency, and hospice), including outpatient dialysis claims. Physician/supplier claims account for 80 percent of the claims but only 20 percent of the dollars. The structure and content of the two types of claims differ, as do the files derived from them. Institutional claims are provided in two types of files: the Institutional Claims file, indicating the type of claim, the dollar amounts, the DRG code, the type of dialysis involved (if any), and the dates of service; and the Institutional Claims Detail file, containing details such as diagnosis and procedure codes. Many analyses require only the Institutional Claims files. Physician/supplier claims are contained in one type of file with one record for each claim line-item. The file includes dollar amounts, dates of service, diagnosis and procedure codes, and type and place of service.

CLINICAL PERFORMANCE MEASURES: DATA PRODUCTS
The Clinical Performance Measures (CPM) data is a CMS project developed to collect information on the quality of care provided to the ESRD dialysis population. The data originates from yearly surveys of approximately 10,000 people completed by the patients’ primary care facilities, and was formerly known as the ESRD Core Indicators Project. This project results in a rich source of detailed information, useful in analyses of healthcare delivery in a sample of the dialysis population.

To further expand the value and use of the CPM data, we have linked patient data from the USRDS SAFs, enabling complete claims extraction from the SAFs for all identified patients. The resulting claims history has been combined with the CPM data to form a complete mini-set of the USRDS data products with supporting files. This enables researchers to add patient-level laboratory and dialysis prescription detail to a broad range of healthcare service event data over many years.

The USRDS Coordinating Center has made the CPM data available as USRDS Standard Analysis Files (SAF). The dataset contains CPM data collected in surveys from 1994–2004. A listing of available files and the corresponding costs can be found in Table b,e on page 301, or you may contact the USRDS Coordinating Center for further information.

DISEASE-BASED COHORT CDS & 5 PERCENT GENERAL MEDICARE PAYMENT DATA CDS
Three disease-based cohort CD sets—for CKD, diabetes, and CHF—are built from the 5 percent general Medicare Claims SAFs. Patients on the diabetes CD, for example, are those with at least one diabetes ICD-9 diagnosis code (250.xx, 357.2, 362.0x, 366.41) identified during 1992–2003 in the 5 percent general Medicare IP, OP, HH, HS, SNF, and PB SAFs, and the other cohorts are created similarly.

Each CD contains a patient master file, a payor sequence file, and a set of comorbidity files. For details on these files, please visit our website or email us at usrds@usrds.org.

Separately, 5 percent general Medicare claims SAFs (IP, OP, SNF, HH, HS, PB, and DME) are also available in single or multiple years from 1992 to 2003. Data on the CDs are derived from data in the IP claims SAF files. No payment or cost variables are included, so these data are for researchers who need data on hospital inpatient stays and on diagnoses and procedures for those stays, but do not need payment data.

FILE MEDIA & FORMATS
SAFs are provided on CDs and DVDs as SAS files, and can be used by SAS on any 486 or Pentium PC with a CD/DVD reader. The SAS format 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 another format or medium must arrange for the conversion.

COSTS
File prices cover reproduction of files, 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, cop-
USRDS products & services

2007 USRDS Annual Data Report

Reports & guides

Annual Data Reports Available from the National Kidney and Urologic Disease Information Clearinghouse, 3 Information Way, Bethesda, MD 20892-3560; 301.544.4415, nkudicinfo.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.

Researcher’s Guide to the 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/odr/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 2 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 $103.97 will be assessed for time spent on this 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 file contact Shu Chen, MS, schen@usrds.org

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, comorbid conditions, patient status at start of ESRD.

Transplant one record for each transplant event; patients can have multiple events Transplant and transplant outcome analyses.

Transplant Wait 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 wait list.

Dialysis Morbidity and Mortality (DMMS; Special Study) Wave 1: 6,679 patients; Wave 2: 4,524 patients; Wave 3: 11,142 patients Co-morbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values, nutrition, vascular access.

Case Mix Adequacy (Special Study) 7,996 patients Co-morbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory values.

Case Mix Severity (Special Study) 3,335 patients Co-morbid 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.

CLM CODES one record for each diagnosis, procedure, or HCPCS code appearing in claims files Frequency of occurrence of each code. A starting point for analyses that will use diagnosis and procedure codes.

FORMATS.SC2 all USRDS-defined SAS formats used by SAFs Format library used to format values of categorical variables.
Standard Analysis Files

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Medicare payment data

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Prices for the USRDS Standard Analysis Files

Checks must be made payable to the Minneapolis Medical Research Foundation

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Outline for research proposals using USRDS data
ies of data collection forms used by CMS, UNOS, and the USRDS Special Studies; a chapter on techniques for using the SAFs in SAS is also provided. The guide may be downloaded from the USRDS website, and a copy on CD-ROM will be sent to researchers with the purchase of the SAFs.

**Data release policy**

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

Provide the USRDS Project Officer (PO) with a detailed description of the proposed investigation (see Table b.d). The summary must include goals, background data, an in-depth description of study design and methodology, and resources available for completing the project, and may be the description from a grant proposal or other application. The project must comply with the Privacy Act of 1974, and the summary should provide enough information to enable assessment of compliance. Guidelines for Privacy Act adherence are found in the "Agreement for Release of Data," page 305. With your completed research proposal, please include a signed agreement for release of information from each investigator and analyst who will use the data files.

Indicate needed USRDS SAFs by name (i.e. Core, Transplant etc). 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.

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. When payment for the files has 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.

**Prices for the ESRD CPM/USRDS files**

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Claims are available for the years pre-1989 through 2004. Checks must be made payable to the Minneapolis Medical Research Foundation.

**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.
glossary of terms

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 noradrenaline, 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 (m)².

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.

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; develops and applies programs designed to improve the health of the people of the United States.

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

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

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

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

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

Common Working File (CWF) System The Medicare inpatient/outpatient and physician/supplier 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.

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

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

Continuous ambulatory peritoneal dialysis (CAPD) A type of dialysis in which dialysate is continuously present in the abdominal cavity. Fluid is exchanged by using gravity to fill and empty the cavity 3-5 times each day.

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

Creatine 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.

Darbepoetin alfa (DPO) One of a class of medications called erythropoietic proteins. Used to treat anemia in patients with serious kidney disease.

Death Certification Form (UCI-174) 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.

Diagnos 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.

Dually enrolled Patients enrolled in both Medicare and Medicaid.

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 a person’s kidney function is inadequate to support life.

Erythropoiesis stimulating agent (ESA) Used to increase the production of red blood cells; includes erythropoietin (EPO) and darbepoetin alfa (DPO).

Erythropoietin (EPO) A hormone secreted chiefly by the adult kidney, acts on bone marrow to stimulate red cell

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 causing 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.

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

Chronic kidney disease (CKD) A disease characterized by a progressive loss of kidney function that affects the ability of the kidneys to remove wastes and excess substances from the body.

Continuous ambulatory peritoneal dialysis (CAPD) A type of dialysis in which dialysate is continuously present in the abdominal cavity. Fluid is exchanged by using gravity to fill and empty the cavity 3-5 times each day.

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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 to treat anemia.

**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 appropriate-ness of services and protection for dialysis patients.

**Expanded criteria donors (ECDs)** Older kidney donors or donors whose health issues in the past would have prevented their acceptance into the donor program.

**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 (GFR)** 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 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** 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.

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

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

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

**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-2744)** 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 Payer (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.

**Medication possession ratio (MPR)** Used to measure patient compliance with medication regimens.

**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) 900 percent baseline file** A file which contains all Common Working File (CWFI) patient/outpatient (provider) and physician/supplier Medicare claims and adjusted claims information.

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

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

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

**Peripheral vascular disease (PVD)** A progressive disease that causes narrowing or occlusion of the arteries supplying the extremities of the body.

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

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

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 existence of protein in the urine; indicative of kidney damage.

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

Pyrogen reaction A condition in which a patient is 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.

Recombiant human growth hormone (rHGH) Also called somatropin; a substance identical in its amino acid sequence to human growth hormone, and used to treat growth hormone deficiency.

REMIS CMS's Renal Management Information System (REMIS), 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 permedic 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 Analysis Files (SAFs) CMS files containing final action Medicare inpatient/outpatient claims data. In Patient, 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.

Statistics 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).

AA100 adjusted average per capita cost
AMI acute myocardial infarction
ARB angiotensin receptor blocker
ASHD atherosclerotic heart disease
BMI body mass index
BUN blood urea nitrogen
CAPD continuous ambulatory peritoneal dialysis
CCPD continuous cycler peritoneal dialysis
CCR creatinine clearance rate
CHF congestive heart failure
CKD chronic kidney disease
CMS Centers for Medicare and Medicaid Services
COPD chronic obstructive pulmonary disease
CPM Clinical Performance Measures Project
CVA/TIA cerebrovascular accident/transient ischemic attack
CPT Current Procedure and Terminology
CRT-D cardiac resynchronization therapy defibrillator
CVD cerebrovascular disease
DM diabetes, diabetic
DFO darbepoetin alfa
DRG diagnosis related group
DVA Department of Veterans Affairs
ECG expanded criteria donor
EGHP employer group health plan
EPO erthropoietin
ESA erythropoiesis stimulating agent
ESRD end-stage renal disease
eGFR estimated glomerular filtration rate
GN glomerulonephritis
HbA1c glycosylated hemoglobin
HCC hierarchical condition category
HCPA Health Care Financing Administration
HD hemodialysis
HEDIS Health Plan Employer Data Information Set
HGH human growth hormone
HMO health maintenance organization
HSF Health Service Area
HTN hypertension
ICD implantable cardioverter defibrillator
ICD-9-CM International Classification of Diseases, 9th revision, Clinical Modification
IPD intermittent peritoneal dialysis
ISHD ischemic heart disease
K/DOQI Kidney Disease Outcomes Quality Initiative
MCBS Medicare Current Beneficiary Survey
MI myocardial infarction
MPM Medicare as primary payor
MPP medication possession ratio
MSCP Medicare as secondary payor
NDM non-diabetic
NHANES National Health and Nutrition Examination Survey
NKF National Kidney Foundation
PDC percutaneous coronary intervention
PD peritoneal dialysis
PDI per person per month
PPM per person per year
PVD peripheral vascular disease
Tx transplant
UNOS United Network for Organ Sharing
WHO World Health Organization
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.
Recipient typed name, title, & organization

Recipient telephone number

Recipient signature & date

Contractor typed name, title, & organization, as appropriate

Contractor telephone number

Contractor signature & date

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

USRDS Project Officer signature & date

May 2004
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>Country</th>
<th>Population of country</th>
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<tbody>
<tr>
<td></td>
<td>0–19</td>
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<tr>
<td>2003</td>
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<td>2005</td>
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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></th>
<th>0–19</th>
<th>20–44</th>
<th>45–64</th>
<th>65–74</th>
<th>75+</th>
<th>Total</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></th>
<th>0–19</th>
<th>20–44</th>
<th>45–64</th>
<th>65–74</th>
<th>75+</th>
<th>Total</th>
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</table>

C) Prevalence: the point prevalent count of patients at the end of the calendar year (December 31).

C1) All patients on some form of treatment, dialysis or transplantation.

C2) Patients with a functioning kidney transplant as of December 31.

C3) All dialysis patients. C2 and C3 should sum to C1 unless there are lost-to-follow-up patients. If there are lost-to-follow-up patients, please note this fact and whether these patients are captured in C2.

C4) All patients treated with in-center hemodialysis as of December 31.

C5) All patients treated with CAPD or CCPD as of December 31.

C6) All patients treated with home hemodialysis as of December 31.

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.

You may return this form to us by email or fax: usrds@usrds.org, and 1.612.347.5878.
### Prevalence

#### Total number of ESRD patients (all treatment categories) at the end of the year (December 31)

<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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#### Total number of ESRD patients with a functioning graft at the end of the year (December 31)

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<th>Year</th>
<th>0–19</th>
<th>20–44</th>
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<th>65–74</th>
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#### Total number of ESRD patients on dialysis at the end of the year (December 31)

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

<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>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
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<tr>
<td>2006</td>
<td></td>
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</tbody>
</table>

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

<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>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td></td>
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</tbody>
</table>

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

<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>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
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</tbody>
</table>

### Transplant

#### Total number of cadaveric transplants 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>
<th>75+</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
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<tr>
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<td>2005</td>
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</tr>
</tbody>
</table>

#### Total number of living donor transplants 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>
<th>75+</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>2004</td>
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<tr>
<td>2005</td>
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<tr>
<td>2006</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT
MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION

A. COMPLETE FOR ALL ESRD PATIENTS  
Check one: ☐ Initial ☐ Re-entitlement ☐ Supplemental

1. Name (Last, First, Middle Initial)

2. Medicare Claim Number

3. Social Security Number

4. Date of Birth MM/DD/YYYY

5. Patient Mailing Address (Include City, State and Zip)

6. Phone Number ( )

7. Sex ☐ Male ☐ Female

8. Ethnicity ☐ Not Hispanic or Latino ☐ Hispanic or Latino (Complete Item 9)

9. Country/Area of Origin or Ancestry

10. Race (Check all that apply)

☐ White ☐ Native Hawaiian or Other Pacific Islander*

☐ Black or African American ☐ American Indian/Alaska Native

Print Name of Enrolled/Principal Tribe ___________________________  *complete item 9

11. Is patient applying for ESRD Medicare coverage?

☐ Yes ☐ No

12. Current Medical Coverage (Check all that apply)

☐ Medicare ☐ Medicaid ☐ Medicare Advantage ☐ Other ☐ None

☐ DVA ☐ Medicare Group Health Insurance

13. Height INCHES _____ OR CENTIMETERS _____

14. Dry Weight POUNDS _____ OR KILOGRAMS _____

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

16. Employment Status (6 mos prior and current status)

Prior to ESRD therapy:

a. Did patient receive exogenous erythropoietin or equivalent? ☐ Yes ☐ No ☐ Unknown
   If Yes, answer: ☐ 6-12 months ☐ >12 months

b. Was patient under care of a nephrologist? ☐ Yes ☐ No ☐ Unknown
   If Yes, answer: ☐ 6-12 months ☐ >12 months

c. Was patient under care of a dietitian? ☐ Yes ☐ No ☐ Unknown
   If Yes, answer: ☐ 6-12 months ☐ >12 months

d. What access was used on first outpatient dialysis?

   If not AVF, then: Is maturing AVF present? ☐ Yes ☐ No
   Is maturing graft present? ☐ Yes ☐ No

17. Co-Morbid Conditions (Check all that apply currently and/or during last 10 years) *See instructions

a. Congestive heart failure ☐

b. Atherosclerotic heart disease ASHD ☐

c. Other cardiac disease ☐

d. Cerebrovascular disease, CVA, TIA* ☐

e. Peripheral vascular disease* ☐

f. History of hypertension ☐

g. Amputation ☐

h. Diabetes, currently on insulin ☐

i. Diabetes, on oral medications ☐

j. Diabetes, without medications ☐

k. Diabetic retinopathy ☐

l. Chronic obstructive pulmonary disease ☐

m. Tobacco use (current smoker) ☐

n. Malignant neoplasm, Cancer ☐

o. Toxic nephropathy ☐

p. Alcohol dependence ☐

q. Drug dependence* ☐

r. Inability to ambulate ☐

s. Inability to transfer ☐

t. Needs assistance with daily activities ☐

u. Institutionalized ☐

   ☐ 1. Assisted Living
   ☐ 2. Nursing Home
   ☐ 3. Other Institution

v. Non-renal congenital abnormality ☐

w. None ☐

18. Laboratory Values Within 45 Days Prior to the Most Recent ESRD Episode. (Lipid Profile within 1 Year of Most Recent ESRD Episode).

<table>
<thead>
<tr>
<th>LABORATORY TEST</th>
<th>VALUE</th>
<th>DATE</th>
<th>LABORATORY TEST</th>
<th>VALUE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum Albumin (g/dl)</td>
<td>_____</td>
<td>_____</td>
<td>HbA1c</td>
<td>_____</td>
<td>.%</td>
</tr>
<tr>
<td>Serum Albumin Lower Limit</td>
<td>_____</td>
<td>_____</td>
<td>Lipid Profile</td>
<td>TC</td>
<td>________</td>
</tr>
<tr>
<td>Serum Creatinine (mg/dl)</td>
<td>_____</td>
<td>_____</td>
<td>LDL</td>
<td>________</td>
<td></td>
</tr>
<tr>
<td>Hemoglobin (g/dl)</td>
<td>_____</td>
<td>_____</td>
<td>HDL</td>
<td>________</td>
<td></td>
</tr>
</tbody>
</table>

B. COMPLETE FOR ALL ESRD PATIENTS IN DIALYSIS TREATMENT

20. Name of Dialysis Facility

21. Medicare Provider Number (for item 20)

22. Primary Dialysis Setting

☐ Home ☐ Dialysis Facility/Center ☐ SNF/Long Term Care Facility

23. Primary Type of Dialysis

☐ Hemodialysis (Sessions per week _____hours per session _____)

☐ CAPD ☐ CCPD ☐ Other

24. Date Regular Chronic Dialysis Began MM/DD/YYYY

25. Date Patient Started Chronic Dialysis at Current Facility MM/DD/YYYY

26. Has patient been informed of kidney transplant options?

☐ Yes ☐ No

27. If patient NOT informed of transplant options, please check all that apply:

☐ Medically unfit ☐ Patient declines information

☐ Unsuitable due to age ☐ Patient has not been assessed

☐ Psychologically unfit ☐ Other

Instructions for filling out the ME form, along with previous versions of the form, can be found in the Researcher's Guide & on our website, www.usrsds.org.
C. COMPLETE FOR ALL KIDNEY TRANSPLANT PATIENTS

<table>
<thead>
<tr>
<th>28. Date of Transplant</th>
<th>29. Name of Transplant Hospital</th>
<th>30. Medicare Provider Number for Item 29</th>
</tr>
</thead>
<tbody>
<tr>
<td>MM DD YYYY</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date patient was admitted as an inpatient to a hospital in preparation for, or anticipation of, a kidney transplant prior to the date of actual transplantation.

<table>
<thead>
<tr>
<th>31. Enter Date</th>
<th>32. Name of Preparation Hospital</th>
<th>33. Medicare Provider number for Item 32</th>
</tr>
</thead>
<tbody>
<tr>
<td>MM DD YYYY</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>34. Current Status of Transplant (if functioning, skip items 36 and 37)</th>
<th>35. Type of Donor:</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Functioning</td>
<td>☐ Deceased</td>
</tr>
<tr>
<td>☐ Non-Functioning</td>
<td>☐ Living Related</td>
</tr>
<tr>
<td></td>
<td>☐ Living Unrelated</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>36. If Non-Functioning, Date of Return to Regular Dialysis</th>
<th>37. Current Dialysis Treatment Site</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐ Home</td>
</tr>
<tr>
<td></td>
<td>☐ Dialysis Facility/Center</td>
</tr>
<tr>
<td></td>
<td>☐ SNF/Long Term Care Facility</td>
</tr>
</tbody>
</table>

MM DD YYYY

D. COMPLETE FOR ALL ESRD SELF-DIALYSIS TRAINING PATIENTS (MEDICARE APPLICANTS ONLY)

<table>
<thead>
<tr>
<th>38. Name of Training Provider</th>
<th>39. Medicare Provider Number of Training Provider (for Item 38)</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>40. Date Training Began</th>
<th>41. Type of Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>MM DD YYYY</td>
<td>☐ Hemodialysis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>42. This Patient is Expected to Complete (or has completed) Training and will Self-dialyze on a Regular Basis.</th>
<th>43. Date When Patient Completed, or is Expected to Complete, Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes</td>
<td>MM DD YYYY</td>
</tr>
<tr>
<td>☐ No</td>
<td></td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>44. Printed Name and Signature of Physician personally familiar with the patient’s training</th>
<th>45. UPIN of Physician in Item 44</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.) Printed Name</td>
<td></td>
</tr>
<tr>
<td>b.) Signature</td>
<td></td>
</tr>
<tr>
<td>c.) Date MM DD YYYY</td>
<td></td>
</tr>
</tbody>
</table>

E. PHYSICIAN IDENTIFICATION

<table>
<thead>
<tr>
<th>46. Attending Physician (Print)</th>
<th>47. Physician’s Phone No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Print)</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>48. UPIN of Physician in Item 46</th>
</tr>
</thead>
</table>

F. OBTAIN SIGNATURE FROM PATIENT

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.

<table>
<thead>
<tr>
<th>54. Signature of Patient (Signature by mark must be witnessed.)</th>
<th>55. Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MM DD YYYY</td>
</tr>
</tbody>
</table>

G. PRIVACY STATEMENT

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 PPMIS)”, published in the Federal Register, Vol. 67, No. 116, June 17, 2002, pages 41244-41250 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 PPMIS 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 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.
**LIST OF PRIMARY CAUSES OF END STAGE RENAL DISEASE**

Item 15. Primary Cause of Renal Failure should be completed by the attending physician from the list below. Enter the ICD-9-CM code to indicate the primary cause of end stage renal disease. If there are several probable causes of renal failure, choose one as primary. **Code effective as of September 2003.**

<table>
<thead>
<tr>
<th>DIABETES</th>
<th>CYSTIC/HEREDITARY/CONGENITAL DISEASES</th>
</tr>
</thead>
<tbody>
<tr>
<td>25040</td>
<td>Diabetes with renal manifestations Type 2</td>
</tr>
<tr>
<td>25041</td>
<td>Diabetes with renal manifestations Type 1</td>
</tr>
<tr>
<td>5829</td>
<td>Glomerulonephritis (GN) (histologically not examined)</td>
</tr>
<tr>
<td>5821</td>
<td>Focal glomerulosclerosis, focal sclerosing GN</td>
</tr>
<tr>
<td>5831</td>
<td>Membranous nephropathy</td>
</tr>
<tr>
<td>58321</td>
<td>Membranoproliferative GN type 1, diffuse MPGN</td>
</tr>
<tr>
<td>58322</td>
<td>Dense deposit disease, MPGN type 2</td>
</tr>
<tr>
<td>58381</td>
<td>IgA nephropathy, Berger’s disease (proven by immunofluorescence)</td>
</tr>
<tr>
<td>58382</td>
<td>IgM nephropathy (proven by immunofluorescence)</td>
</tr>
<tr>
<td>5834</td>
<td>With lesion of rapidly progressive GN</td>
</tr>
<tr>
<td>5800</td>
<td>Post infectious GN, SBE</td>
</tr>
<tr>
<td>5820</td>
<td>Other proliferative GN</td>
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</table>

<table>
<thead>
<tr>
<th>SECONDARY GN/VASCULITIS</th>
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</thead>
<tbody>
<tr>
<td>7100</td>
<td>Lupus erythematosus, (SLE nephritis)</td>
</tr>
<tr>
<td>2870</td>
<td>Henoch-Schonlein syndrome</td>
</tr>
<tr>
<td>7101</td>
<td>Scleroderma</td>
</tr>
<tr>
<td>28311</td>
<td>Hemolytic uremic syndrome</td>
</tr>
<tr>
<td>4460</td>
<td>Polyarteritis</td>
</tr>
<tr>
<td>4464</td>
<td>Wegener’s granulomatosis</td>
</tr>
<tr>
<td>58392</td>
<td>Nephropathy due to heroin abuse and related drugs</td>
</tr>
<tr>
<td>44620</td>
<td>Other Vasculitis and its derivatives</td>
</tr>
<tr>
<td>44621</td>
<td>Goodpasture’s syndrome</td>
</tr>
<tr>
<td>58391</td>
<td>Secondary GN, other</td>
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</table>

<table>
<thead>
<tr>
<th>INTERSTITIAL NEPHRITIS/PYELONEPHRITIS</th>
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<tbody>
<tr>
<td>9659</td>
<td>Analgesic abuse</td>
</tr>
<tr>
<td>5830</td>
<td>Radiation nephritis</td>
</tr>
<tr>
<td>9849</td>
<td>Lead nephropathy</td>
</tr>
<tr>
<td>5909</td>
<td>Nephropathy caused by other agents</td>
</tr>
<tr>
<td>27410</td>
<td>Gouty nephropathy</td>
</tr>
<tr>
<td>5920</td>
<td>Nephrolithiasis</td>
</tr>
<tr>
<td>5996</td>
<td>Acquired obstructive uropathy</td>
</tr>
<tr>
<td>5900</td>
<td>Chronic pyelonephritis, reflux nephropathy</td>
</tr>
<tr>
<td>58389</td>
<td>Chronic interstitial nephritis</td>
</tr>
<tr>
<td>58089</td>
<td>Acute interstitial nephritis</td>
</tr>
<tr>
<td>5929</td>
<td>Urolithiasis</td>
</tr>
<tr>
<td>27549</td>
<td>Other disorders of calcium metabolism</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>HYPERTENSION/LARGE VESSEL DISEASE</th>
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<tbody>
<tr>
<td>40391</td>
<td>Unspecified with renal failure</td>
</tr>
<tr>
<td>4401</td>
<td>Renal artery stenosis</td>
</tr>
<tr>
<td>59381</td>
<td>Renal artery occlusion</td>
</tr>
<tr>
<td>59383</td>
<td>Cholesterol emboli, renal emboli</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NEOPLASMS/TUMORS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1890</td>
<td>Renal tumor (malignant)</td>
</tr>
<tr>
<td>1899</td>
<td>Urinary tract tumor (malignant)</td>
</tr>
<tr>
<td>2230</td>
<td>Renal tumor (benign)</td>
</tr>
<tr>
<td>2239</td>
<td>Urinary tract tumor (benign)</td>
</tr>
<tr>
<td>23951</td>
<td>Renal tumor (unspecified)</td>
</tr>
<tr>
<td>23952</td>
<td>Urinary tract tumor (unspecified)</td>
</tr>
<tr>
<td>20280</td>
<td>Lymphoma of kidneys</td>
</tr>
<tr>
<td>20300</td>
<td>Multiple myeloma</td>
</tr>
<tr>
<td>20308</td>
<td>Other immuno proliferative neoplasms (including light chain nephropathy)</td>
</tr>
<tr>
<td>2773</td>
<td>Amyloidosis</td>
</tr>
<tr>
<td>99680</td>
<td>Complications of transplanted organ unspecified</td>
</tr>
<tr>
<td>99681</td>
<td>Complications of transplanted kidney</td>
</tr>
<tr>
<td>99682</td>
<td>Complications of transplanted liver</td>
</tr>
<tr>
<td>99683</td>
<td>Complications of transplanted heart</td>
</tr>
<tr>
<td>99684</td>
<td>Complications of transplanted lung</td>
</tr>
<tr>
<td>99685</td>
<td>Complications of transplanted bone marrow</td>
</tr>
<tr>
<td>99686</td>
<td>Complications of transplanted pancreas</td>
</tr>
<tr>
<td>99687</td>
<td>Complications of transplanted intestine</td>
</tr>
<tr>
<td>99689</td>
<td>Complications of other specified transplanted organ</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MISCELLANEOUS CONDITIONS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>28260</td>
<td>Sickle cell disease/anemia</td>
</tr>
<tr>
<td>28269</td>
<td>Sickle cell trait and other sickle cell (HbS/Hb other)</td>
</tr>
<tr>
<td>64620</td>
<td>Post partum renal failure</td>
</tr>
<tr>
<td>042</td>
<td>AIDS nephropathy</td>
</tr>
<tr>
<td>8660</td>
<td>Traumatic or surgical loss of kidney(s)</td>
</tr>
<tr>
<td>5724</td>
<td>Hepatorenal syndrome</td>
</tr>
<tr>
<td>5836</td>
<td>Tubular necrosis (no recovery)</td>
</tr>
<tr>
<td>59389</td>
<td>Other renal disorders</td>
</tr>
<tr>
<td>7999</td>
<td>Etiology uncertain</td>
</tr>
</tbody>
</table>
# ESRD DEATH NOTIFICATION
## END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM

<table>
<thead>
<tr>
<th>1. Patient’s Last Name</th>
<th>First</th>
<th>MI</th>
<th>2. Medicare Claim Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Patient’s Sex</th>
<th>4. Date of Birth</th>
<th>5. Social Security Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. ☐ Male</td>
<td>Month / Day / Year</td>
<td></td>
</tr>
<tr>
<td>b. ☐ Female</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Patient’s State of Residence</th>
<th>7. Place of Death</th>
<th>8. Date of Death</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>a. ☐ Hospital</td>
<td>c. ☐ Home</td>
</tr>
<tr>
<td></td>
<td>b. ☐ Dialysis Unit</td>
<td>d. ☐ Nursing Home</td>
</tr>
<tr>
<td></td>
<td>e. ☐ Other</td>
<td>Month / Day / Year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9. Modality at Time of Death</th>
<th>10. Provider Name and Address (Street)</th>
<th>11. Provider Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. ☐ Incenter Hemodialysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. ☐ Home Hemodialysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. ☐ CAPD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. ☐ CCPD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. ☐ Transplant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>f. ☐ Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>12. Causes of Death (enter codes from list on back of form)</th>
<th>13. Renal replacement therapy discontinued prior to death: ☐ Yes ☐ No</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Primary Cause</td>
<td></td>
</tr>
<tr>
<td>b. Were there secondary causes?</td>
<td></td>
</tr>
<tr>
<td>☐ No</td>
<td></td>
</tr>
<tr>
<td>☐ Yes, specify:</td>
<td></td>
</tr>
<tr>
<td>C. If cause is other (98) please specify:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If yes, check one of the following:</th>
<th>14. Was discontinuation of renal replacement therapy after patient/family request to stop dialysis?</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. ☐ Following HD and/or PD access failure</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>b. ☐ Following transplant failure</td>
<td>☐ Unknown ☐ Not Applicable</td>
</tr>
<tr>
<td>c. ☐ Following chronic failure to thrive</td>
<td></td>
</tr>
<tr>
<td>d. ☐ Following acute medical complication</td>
<td></td>
</tr>
<tr>
<td>e. ☐ Other</td>
<td></td>
</tr>
<tr>
<td>f. Date of last dialysis treatment</td>
<td>Month / Day / Year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>15. If deceased ever received a transplant:</th>
<th>16. Was patient receiving Hospice care prior to death?</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Date of most recent transplant</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>Month / Day / Year</td>
<td></td>
</tr>
<tr>
<td>b. Type of transplant received</td>
<td>☐ Living Related ☐ Living Unrelated ☐ Deceased ☐ Unknown</td>
</tr>
<tr>
<td>c. Was graft functioning (patient not on dialysis) at time of death?</td>
<td>☐ Yes ☐ No ☐ Unknown</td>
</tr>
<tr>
<td>d. Did transplant patient resume chronic maintenance dialysis prior to death?</td>
<td>☐ Yes ☐ No ☐ Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>17. Name of Physician (Please print complete name)</th>
<th>18. Signature of Person Completing This Form</th>
<th>Date</th>
</tr>
</thead>
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### CARDIAC
- 23 Myocardial infarction, acute
- 25 Pericarditis, incl. Cardiac tamponade
- 26 Atherosclerotic heart disease
- 27 Cardiomyopathy
- 28 Cardiac arrhythmia
- 29 Cardiac arrest, cause unknown
- 30 Valvular heart disease
- 31 Pulmonary edema due to exogenous fluid
- 32 Congestive Heart Failure

### LIVER DISEASE
- 64 Hepatitis B
- 71 Hepatitis C
- 65 Other viral hepatitis
- 66 Liver-drug toxicity
- 67 Cirrhosis
- 68 Polycystic liver disease
- 69 Liver failure, cause unknown or other

### GASTRO-INTESTINAL
- 72 Gastro-intestinal hemorrhage
- 73 Pancreatitis
- 75 Perforation of peptic ulcer
- 76 Perforation of bowel (not 75)

### METABOLIC
- 24 Hyperkalemia
- 77 Hypokalemia
- 78 Hypernatremia
- 79 Hyponatremia
- 100 Hypoglycemia
- 101 Hyperglycemia
- 102 Diabetic coma
- 95 Acidosis

### ENDOCRINE
- 96 Adrenal insufficiency
- 97 Hypothyroidism
- 103 Hyperthyroidism

### OTHER
- 80 Bone marrow depression
- 81 Cachexia/failure to thrive
- 82 Malignant disease, patient ever on Immunosuppressive therapy
- 83 Malignant disease (not 82)
- 84 Dementia, incl. dialysis dementia, Alzheimer's
- 85 Seizures
- 87 Chronic obstructive lung disease (COPD)
- 88 Complications of surgery
- 89 Air embolism
- 104 Withdrawal from dialysis/uremia
- 90 Accident related to treatment
- 91 Accident unrelated to treatment
- 92 Suicide
- 93 Drug overdose (street drugs)
- 94 Drug overdose (not 92 or 93)
- 98 Other cause of death
- 99 Unknown

---

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0448. The time required to complete this information collection is estimated to average 30 minutes 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, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.
**END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM**

**ESRD FACILITY SURVEY (DIALYSIS UNITS ONLY)**

**FOR THE PERIOD**

- **Facility Physical Address**
  - Suite/Room: __________________________
  - Street: ____________________________
  - City: __________________________
  - State/Zip Code: ______________________

- **Number of Dialysis Stations:** ____________
- **Facility Telephone:** (___________)

- **Facility Ownership Type:**
  - ☐ Profit
  - ☐ Non-Profit

- **Facility Local/National Affiliation/Chain Information**
  - (i.e. Gambro, etc.)

- **Types of dialysis services offered:**
  - ☐ Incenter Hemodialysis
  - ☐ Peritoneal Dialysis
  - ☐ Home Hemodialysis Training

- **Does your facility offer a dialysis shift that starts at 5:00 p.m. or later?**
  - ☐ Yes
  - ☐ No

---

**DIALYSIS PATIENTS AND TREATMENTS**

**DIALYSIS PATIENTS**

- **Patients Receiving Care**
  - Beginning of Survey Period
    - Incenter: ____________
    - Home: ____________
    - Total: ____________

- **Incenter Dialysis**
  - Started for first time ever: ____________
  - Restarted: ____________
  - Transferred from other dialysis unit: ____________
  - Returned after transplantation: ____________

- **Home Dialysis**
  - In-center: ____________
  - Home: ____________

- **Losses During Survey Period**
  - Deaths: ____________
  - Recovered kidney function: ____________
  - Received transplant: ____________
  - Transferred to other dialysis unit: ____________
  - Discontinued dialysis: ____________
  - Other (LTFU): ____________

- **Additions During Survey Period**
  - 01: ____________
  - 02: ____________
  - 03: ____________

---

**TREATMENT AND STAFFING**

- **Incenter Dialysis Treatments** (Include Training Treatments)
  - Hemodialysis: ____________
  - Other: ____________

---

**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).

Instructions for filling out the ESRD Facility Survey can be found in the Researcher’s Guide & on our website, www.usrds.org.
## Patients Transplanted and Donor Type

<table>
<thead>
<tr>
<th>Patients who received transplant at this facility</th>
<th>Eligibility Status of Patients Transplanted at this Facility During the Survey Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>42</td>
<td>Currently enrolled in Medicare</td>
</tr>
<tr>
<td></td>
<td>Non-Medicare</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
</tbody>
</table>

### Transplant Procedures Performed at This Facility

<table>
<thead>
<tr>
<th>Living Related Donor</th>
<th>Living Unrelated Donor</th>
<th>Deceased Donor</th>
<th>Total Fields 47 thru 49</th>
</tr>
</thead>
<tbody>
<tr>
<td>47</td>
<td>48</td>
<td>49</td>
<td>50</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Dialysis</th>
<th>Nondialysis</th>
</tr>
</thead>
<tbody>
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<td>51</td>
<td>52</td>
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</tbody>
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