**Volume 2: ESRD Analytical Methods**

**Contents**

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume 2: ESRD Analytical Methods</td>
<td>1</td>
</tr>
<tr>
<td>Introduction</td>
<td>3</td>
</tr>
<tr>
<td>Data Sources</td>
<td>3</td>
</tr>
<tr>
<td>History of CMS Data Collection</td>
<td>3</td>
</tr>
<tr>
<td>CROWNWeb and Standard Information Management System Database</td>
<td>5</td>
</tr>
<tr>
<td>CMS Medicare Enrollment Database</td>
<td>5</td>
</tr>
<tr>
<td>ESRD Medical Evidence Form (CMS 2728)</td>
<td>5</td>
</tr>
<tr>
<td>ESRD Death Notification Form (CMS 2746)</td>
<td>6</td>
</tr>
<tr>
<td>Annual Facility Survey (CMS 2744)</td>
<td>6</td>
</tr>
<tr>
<td>Organ Procurement and Transplantation Network Database</td>
<td>6</td>
</tr>
<tr>
<td>CMS Standard Analytical Files</td>
<td>6</td>
</tr>
<tr>
<td>CMS Prescription Drug Event File</td>
<td>7</td>
</tr>
<tr>
<td>CMS 5% Standard Analytical Files</td>
<td>7</td>
</tr>
<tr>
<td>CMS Dialysis Facility Compare Data</td>
<td>7</td>
</tr>
<tr>
<td>CDC National Surveillance Data</td>
<td>7</td>
</tr>
<tr>
<td>United States Census</td>
<td>8</td>
</tr>
<tr>
<td>Database Definitions</td>
<td>8</td>
</tr>
<tr>
<td>Identifying ESRD Patients</td>
<td>8</td>
</tr>
<tr>
<td>Death Date Determination</td>
<td>8</td>
</tr>
<tr>
<td>Transplant Dates</td>
<td>9</td>
</tr>
<tr>
<td>Graft Failure</td>
<td>9</td>
</tr>
<tr>
<td>Medicare and Non-Medicare Patients</td>
<td>9</td>
</tr>
<tr>
<td>Lost-to-follow-up Methodology</td>
<td>10</td>
</tr>
<tr>
<td>60-day Stable Modality Rule: Treatment History</td>
<td>11</td>
</tr>
<tr>
<td>90-day Rule: Outcomes Analyses</td>
<td>11</td>
</tr>
<tr>
<td>Serum Albumin Data</td>
<td>11</td>
</tr>
<tr>
<td>Modalities</td>
<td>11</td>
</tr>
<tr>
<td>Payers (Essential to establish proper denominators for Medicare Claims defined outcomes, including hospitalizations)</td>
<td>12</td>
</tr>
<tr>
<td>Primary Cause of Renal Failure</td>
<td>12</td>
</tr>
<tr>
<td>Race and Ethnicity</td>
<td>13</td>
</tr>
<tr>
<td>Analytical Methods Used in the ESRD Volume</td>
<td>14</td>
</tr>
<tr>
<td>Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities</td>
<td>14</td>
</tr>
<tr>
<td>Chapter 2: Healthy People 2020</td>
<td>16</td>
</tr>
</tbody>
</table>
## 2016 USRDS Annual Data Report | Volume 2—ESRD in the United States

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Clinical Indicators and Preventive Care</td>
<td>18</td>
</tr>
<tr>
<td>4</td>
<td>Vascular Access</td>
<td>22</td>
</tr>
<tr>
<td>5</td>
<td>Hospitalization</td>
<td>23</td>
</tr>
<tr>
<td>6</td>
<td>Mortality</td>
<td>25</td>
</tr>
<tr>
<td>7</td>
<td>Transplantation</td>
<td>27</td>
</tr>
<tr>
<td>8</td>
<td>ESRD Among Children, Adolescents, and Young Adults</td>
<td>28</td>
</tr>
<tr>
<td>9</td>
<td>Cardiovascular Disease</td>
<td>31</td>
</tr>
<tr>
<td>10</td>
<td>Providers</td>
<td>35</td>
</tr>
<tr>
<td>11</td>
<td>Medicare Expenditures for Persons with ESRD</td>
<td>36</td>
</tr>
<tr>
<td>12</td>
<td>Prescription Drug Coverage in Patients With ESRD</td>
<td>37</td>
</tr>
<tr>
<td>13</td>
<td>International Comparisons</td>
<td>38</td>
</tr>
<tr>
<td>14</td>
<td>USRDS Special Study Center on End-of-Life Care for Patients With ESRD</td>
<td>39</td>
</tr>
</tbody>
</table>

### ESRD Reference Table Methods

| Reference Table A: Incidence | 39 |
| Reference Table B: Prevalence | 40 |
| Reference Table C: Patient Characteristics | 40 |
| Reference Table D: Treatment Modalities | 41 |
| Reference Table E: Transplantation Process | 41 |
| Reference Table F: Transplantation: Outcomes | 42 |
| Reference Table G: Morbidity and Hospitalization | 43 |
| Reference Table H: Mortality and Causes of Death | 46 |
| Reference Table I: Patient Survival | 46 |
| Reference Table J: Providers | 46 |
| Reference Table K: Medicare Claims Data | 47 |
| Reference Table L: Vascular Access | 48 |
| Reference Table M: Census Populations | 49 |
| Reference Section N: International Comparisons | 49 |

### Statistical Methods

| Methods for Calculating Rates | 50 |
| Methods for Adjusting Rates | 51 |
| Survival Probabilities and Mortality Rates | 52 |
| Generalized Linear Models | 52 |
| Standardized Mortality Ratios | 53 |
| Standardized Hospitalization Ratios | 54 |
| Expected Remaining Lifetimes | 54 |
| Half-lives (Median Time) | 54 |
| Mapping Methods | 55 |
Introduction

In the ESRD Analytical Methods chapter, we present details on the United States Renal Data System (USRDS) database, its standardized working datasets and specialized code definitions, and the common data processing practices applied to the data used in the production of this Annual Data Report (ADR). We also describe the statistical methods used in the ADR. The Researcher's Guide to the USRDS Database, available through www.usrds.org, provides additional information about the database and standard analysis files (SAFs). For this ADR, data are reported through December 31, 2014. Some of the outcomes referred to depend on ascertainment of Medicare Claims data, for which careful construction of appropriate denominators based on Medicare as primary payer eligibility are required, and will be indicated by “$”.

Data Sources

The USRDS maintains a relational database of diagnostic and demographic characteristics of end-stage renal disease (ESRD) patients, including information on the incidence, prevalence, morbidity, and mortality of this population, as well as biochemical lab results, dialysis and other institutional claims, physician/supplier services, treatment histories (useful for modality determination), and payer histories (essential for determining denominators for Medicare Claims data as shown below), hospitalization and modality events, and details regarding providers. As the ESRD population are typically Medicare beneficiaries (although not always Medicare as primary payer), the main data source for this database is the Centers for Medicare & Medicaid Services (CMS).

History of CMS Data Collection

This section traces the history of data collection for ESRD patients, and discusses the systems that have evolved to house the data. Detailed discussions about the data and analytical methods that are used in each chapter are found in the section titled Analytical Methods Used in the ESRD Volume.

In October 1972, by Public Law 92-603, which expanded the Social Security Act (U.S. Government Publishing Office, 1972), ESRD patients were included as beneficiaries in the Medicare Program. With the provision of insurance coverage for ESRD care now instituted, a means of collecting and utilizing data about that care was sought. The government made efforts to contract out a project to implement a national data collection system, or ESRD registry, between 1974 and 1977, but the effort was not successful. Meanwhile, Medicare expenditures and the number of ESRD beneficiaries began to grow significantly, and both government and the renal community became more concerned with the development of such a national registry (Blagg et al., 1989).

In accordance with the Privacy Act of 1974, which established a formal Systems of Records (SOR) for the protection of collected personal information such as name and Social Security number, a SOR was created for the ESRD program titled the End Stage Renal Disease (ESRD) Program Management and Medical Information System (PMMIS) — SOR system number 09-70-0520 (CMS SOR). This progress toward a data collection system, along with the 1975 and 1976 legislative amendments to the Social Security Act expanding Medicare coverage to ESRD patients, furthered the push for the development of a national ESRD Registry.

In 1977, the Health Care Financing Administration (HCFA), an agency that oversaw Medicare’s financing (later renamed the Centers for Medicare & Medicaid Services (CMS)), was established under the department of Health Education and Welfare (HEW), which was renamed Health and Human Services (HHS) in 1979. CMS handles payment and administrative functions for all Medicare recipients on a regional (e.g., state) level. Originally, this was done through contracted intermediaries (Part A services) and carriers (Part B services). In recent years, the Parts A and B bill processing function has been combined into Medicare Administrative Contractors (MACs). Furthermore, CMS contracts with 18 regional ESRD Network offices that perform research and data collection activities, assure quality of medical care, and adjudicate patient grievances.

In June of 1978, Public Law 95-292 addressed the need for significant improvements to ensure cost-effective quality of care in the ESRD program. This
finally led to the development of a comprehensive Medicare-based data system for the ESRD program within the HCFA (Rettig and Levinsky, 1991; CMS Fact Sheet, 2012). Thus, the original data storage system was created and it was known by the same name as the official SOR title, the ESRD Program Management and Medical Information System (PMMIS). It was established to provide medical and cost information for ESRD program analysis, policy development, and epidemiologic research (CMS Fact Sheet, 2012).

The PMMIS gathered information on Medicare ESRD patients and Medicare-approved ESRD hospital-based and independent dialysis facilities. Data were compiled via Medicare claims and data forms that were collected through the Medicare intermediaries. The forms included the Medical Evidence form (CMS 2728), the Death Notification form (CMS 2746), and the Facility Survey form (CMS 2744). Other files maintained in the system included the Patient Identification File, the Transplant File, the Transplant Follow-up File, the Quarterly Dialysis File, and the Hospital Inpatient Stay Record File. There was no mandatory compliance for data collection, so early data is quite incomplete. In 1981, reporting on the incidence of ESRD was mandated as a requirement for Medicare Entitlement and a new Medical Evidence form was introduced. Since that time, there has been continuous improvement in the completeness of the data (CMS Fact Sheet, 2012). The PMMIS was maintained on HCFA computers, and was a batch-oriented Model 204 (M204 IBM Mainframe) data system.

Initially, HCFA was required to submit an annual report to Congress on the ESRD program and three reports were published (HCFA 1979, 1980, 1982). Due to the burden for HCFA of compiling many related reports, Congress rescinded the requirement for a separate report and the agency was permitted to include the ESRD program in its annual report on the whole Medicare program (CMS, Fact Sheet, 2012). This level of reporting did not, however, adequately meet the needs of the renal community for reliable data collection and reporting on outcomes and quality of care. Throughout the 1980s, efforts continued to create a comprehensive ESRD registry with reporting beyond that which the PMMIS provided. This need was recognized politically as well as among researchers, and in the Omnibus Budget Reconciliation Act of 1986, Congress called for HHS to establish a “national end-stage renal disease registry”. An interagency committee was formed between HHS and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and a Request for Proposal was shortly thereafter issued for the development of the United States Renal Data System (USRDS) to establish a complete ESRD Registry, which was to be built upon and surpass the HCFA data collected by the PMMIS. The contract was awarded by NIDDK in May 1988 to the Urban Institute, with a subcontract to the University of Michigan, and the first USRDS Annual Data Report on the ESRD population was released in 1989.

The specific data systems utilized by CMS to manage the ESRD database have evolved over the years as technology has changed and the need for improvements was identified. In 1995, CMS transitioned from the way data were stored in the original PMMIS, replacing its Medicare ESRD Support Subsystem (MESS) with an enhanced online M204 data system known as the Renal Beneficiary and Utilization System (REBUS). Also in 1995, non-Medicare patients began to be included in the database as the ESRD Medical Evidence Report form (CMS 2728) was again revised and made mandatory for all ESRD patients.

In 2003, the REBUS database was converted into an Oracle relational database known as the Renal Management Information System (REMIS), and the Standard Information Management System (SIMS) database of the ESRD networks was also established.

REMIS calculates Medicare ESRD coverage periods for renal patients and includes operational interfaces to the SIMS Central Repository and the Medicare Enrollment Database (EDB). REMIS also includes sophisticated data quality problem resolution support (CMS REMIS, 2012).

SIMS collected the CMS Medical Evidence, Death Notification, and Facility Survey forms mentioned above, and also included information to track patient movement in and out of ESRD facilities, and their transitions from one treatment modality to another. With the integration of the SIMS events data into the USRDS Database, it became possible to better track
patients beyond the initiation of treatment. The SIMS events data, along with the mandate for the Medical Evidence form beginning in 1995, allowed for inclusion of patients for whom there previously were no data on initial modality or death. SIMS was replaced by CROWNWeb in 2012.

**CROWNWeb and Standard Information Management System Database**

CROWNWeb is a web-based data collection system that captures clinical and administrative data from Medicare-certified dialysis facilities for all ESRD patients, and allows authorized users to securely submit, update, and verify data provided to Medicare. This system was rolled out nationally in May 2012. In addition to replacing the patient tracking functionality of SIMS, CROWNWeb also collects new data to support calculation of clinical measures (e.g., Kt/V, hemoglobin, and calcium), and integrates these data with the REMIS system.

Thus, the USRDS Database contains demographic, diagnostic, and treatment history information for all patients with ESRD, regardless of whether they are Medicare beneficiaries. The data are updated on a regular basis using the Medicare EDB, ESRD Medical Evidence and Death Notification Report forms (CMS 2728 and 2746), Medicare Institutional and Carrier claims, and the Organ Procurement and Transplantation Network (OPTN) transplant database. CMS has also established data-integrity rules to ensure accurate identification of patients in the CMS databases.

**CMS Medicare Enrollment Database**

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

**ESRD Medical Evidence Form (CMS 2728)**

The CMS ESRD Medical Evidence Report form (CMS 2728) is used to register patients at the onset of ESRD, and must be submitted by dialysis facilities or transplant centers within 45 days of treatment initiation. The form establishes Medicare eligibility for individuals previously not Medicare beneficiaries, reclassifies previously eligible beneficiaries as ESRD patients, and provides demographic and diagnostic information on all new ESRD patients regardless of Medicare entitlement. The CMS, USRDS, and renal research communities rely on the form to ascertain patient demographics, primary cause of ESRD, comorbidities, and biochemical test results at the time of ESRD initiation.

Prior to 1995, providers were required to file the Medical Evidence form only for Medicare-eligible patients. Since the 1995 revision, however, providers are required to complete the form for all new ESRD patients regardless of Medicare eligibility status. The 1995 revised form included new fields for comorbid conditions, employment status, expanded race categories, ethnicity, and biochemical data at ESRD initiation.

The third major revision of the Medical Evidence form in May 2005 remedied several shortcomings of the 1995 form and its earlier versions. It includes new data collection methods and new variables. It allows users to specify whether the Medicare registration is initial (new ESRD patient), re-entitlement (reinstating Medicare entitlement after a lapse due to no claims being filed for 12 or more months or a functioning graft for 36 or more months), or supplemental (updating missing or incorrect information). This clarifies the intended use of the form without recourse to the “First Regular Dialysis Start Date,” and helps chronicle the historical sequence of multiple forms for the same patient. Data fields for nephrologist care, dietitian care, and access type were added, with their respective time intervals relative to ESRD onset. Data on the laboratory values hematocrit, creatinine clearance, BUN, and urea clearance are no longer collected. Added laboratory values are HbA1c and lipid profiles (total cholesterol, low-density lipoprotein, high-density lipoprotein, and triglycerides). Additional fields relate to whether patients were informed of transplant options, and if not, why not, and donor type. The Medical Evidence form is the only source of information about the cause of a patient’s ESRD. Because the list of diseases has been revised, the USRDS stores the codes from each version so that detail is not lost through conversion of one set of codes to another.
Only one Medical Evidence form is expected for each ESRD patient for the entire ESRD treatment period; however, multiple forms may be filed for patients whose insurance eligibility changes due to therapy changes. For example, transplant patients with functioning grafts after three years lose Medicare benefits if ESRD was the sole qualification for Medicare eligibility. If such a patient experiences graft failure and returns to dialysis, a second Medical Evidence Report must be filed to reestablish Medicare eligibility. Dialysis patients who discontinue dialysis for more than 12 months also lose Medicare ESRD benefits. If such a patient returns to dialysis or undergoes kidney transplant, a second Medical Evidence form must be filed to reestablish Medicare eligibility.

Both the 2005 and 1995 versions of the CMS 2728 form are provided in the USRDS Core SAF dataset and are available in the USRDS Researcher’s Guide, Appendix D: Data Collection Forms on the USRDS website: www.usrds.org/research.aspx.

ESRD Death Notification Form (CMS 2746)

The ESRD Death Notification form (CMS 2746) is used to report the death of ESRD patients. According to CMS policy, this form must be submitted by dialysis or transplant providers within 30 days of a patient’s death, and provides the date and causes of death (primary and secondary), reasons for discontinuation of renal replacement therapy, if applicable, and evidence of hospice care prior to death. It is the primary source of death information for CMS and the USRDS, identifying more than 90% of deaths. The USRDS also utilizes several supplemental data sources for ascertaining death (see the Death Date Determination section below for more details). The USRDS has not used the National Death Index due to the prohibitive cost of obtaining this for the U.S. dialysis population.

Annual Facility Survey (CMS 2744)

In addition to the CMS ESRD databases, independent ESRD patient counts are available from the CMS Annual Facility Survey (AFS) (CMS 2744). Every facility approved by Medicare to provide services to ESRD patients must provide the information requested in the AFS. It is also the facility’s responsibility to provide patient and treatment counts to their local ESRD Network upon termination of operations. Facilities certified as only providing inpatient services are not requested to complete a survey. The AFS reports the counts of patients being treated at the end of the year, new ESRD patients starting treatment during the year, and patients who die 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. In addition, CMS 2744 includes facility level information such as ownership, services offered, number of stations, and detailed staffing data. Starting with the 2005 AFS, CMS stopped posting data from these surveys on the Internet. Beginning with the 2007 ADR, the USRDS extracted the relevant facility survey data directly from the SIMS database. Beginning in 2012, when SIMS was replaced by CROWNWeb, the USRDS received the facility survey data directly from CROWNWeb.

Organ Procurement and Transplantation Network Database

In the early 1980s, CMS began collecting data on all Medicare kidney transplants in the PMMIS data system. In 1984, the National Organ Transplant Act established the Organ Procurement and Transplant Network (OPTN) to collect data and maintain a registry for organ matching and transplantation. The United Network for Organ Sharing (UNOS) was awarded the OPTN contract in 1988 to provide a national system for allocating donor organs and to maintain a centralized data depository for organ transplants. OPTN also began collecting data on all transplants. The OPTN and CMS collection efforts were consolidated in 1994 and only OPTN continued to collect data on transplant donors and recipients. In addition to these sources, transplants are also identified from Medical Evidence forms that indicate transplant as the initial modality, from CROWNWeb transplant events, and from institutional inpatient claims.

CMS Standard Analytical Files

The CMS ESRD SAFs contain data from final action claims submitted by Medicare beneficiaries, in which all adjustments have been resolved. For Part A
Institutional Claims, the USRDS uses the following 100% SAF claims:
- Inpatient
- Outpatient
- Skilled Nursing Facility
- Home Health Agency
- Hospice

For Part-B Physician/Supplier, the USRDS uses the following 100% SAF claims:
- Physician/Supplier
- Durable Medical Equipment

CMS SAFs are updated each quarter through June of the following 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 files are frozen and will not include late arriving claims. The data lag behind assessments of death and graft loss by about nine months. Annual files are thus approximately 98% complete. The USRDS 2015 SAF includes all claims up to December 31, 2013. Patient-specific demographic and diagnosis information, however, includes data as recent as June 2015. The 2016 ADR includes claims up to December 31, 2014.

**CMS Prescription Drug Event File**

In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), amending the Social Security Act by adding Part D under Title XVIII. With this new Part D coverage, health plans must submit a summary record called the prescription drug event (PDE) record to CMS whenever a Medicare beneficiary fills a prescription. Each drug is identified by a National Drug Code (NDC). The record also contains prescription dosage information, drug costs above and below the out-of-pocket threshold, other true out-of-pocket (TrOOP) amounts, plan paid amounts, and low-income cost sharing subsidy amounts. The USRDS 2016 ADR includes 2006-2014 PDE data.

**CMS 5% Standard Analytical Files**

The CMS 5% general Medicare SAFs are a random sample of 5% of the entire Medicare population, and contain billing data from final action claims submitted for Medicare beneficiaries in which all adjustments have been resolved. CMS and its contractors produce the Medicare 5% datasets by selecting all final action claims for Medicare beneficiaries whose CMS Health Insurance Claim (HIC) number ends in 05, 20, 45, 70, or 95. These five two-digit pairs were randomly selected to create a sample containing 5% of the total number of Medicare beneficiaries (Merriman and Asper, 2007). The sample design has the effect of creating a built-in longitudinal panel dataset. Once in the sample, a beneficiary will remain a part of all future data files until death or a change in the HIC number. Since 2012, the USRDS has received the Master Beneficiary Summary File (formerly the Denominator file), containing demographic information on each beneficiary in the sample, as well as dates of enrollment in the various Medicare programs (Hospital Insurance [Part A], Supplemental Medical Insurance [Part B], Medicare Advantage managed care plans [Part C], and Prescription Drug Benefit [Part D]). Institutional claims for beneficiaries in the Medicare 5% sample are received in five files, which are based on type of medical service: inpatient, outpatient, home health agency, hospice, and skilled nursing facility. Physician and Supplier claims (also referred to as Carrier Claims) are comprised of one file for durable medical equipment and another file for all other Part B covered services. These files collectively are referred to as the Medicare 5% files in the ADR. The 5% files are used to conduct studies on Healthy People 2020 objectives, comparing preventive care and other non-ESRD disease treatments in general Medicare and ESRD patients. The 5% files are also used to construct CKD, diabetes, and congestive heart disease cohorts based on billing data. The total Medicare 5% sample is used to develop total Medicare cost and utilization data for comparison purposes.

**CMS Dialysis Facility Compare Data**

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

**CDC National Surveillance Data**

During 1993-1997 and 1999-2002, the Centers for Disease Control and Prevention (CDC) used its survey
National Surveillance of Dialysis-Associated Diseases in the United States to collect information from dialysis facilities on patient and staff counts, membrane types, reuse practices, water treatment methods, therapy types, vascular access use, antibiotic use, hepatitis vaccination and conversion rates (for both staff and patients), as well as the incidence of HIV, AIDS, and tuberculosis. None of the information is patient-specific. Because the CDC terminated this program in 2003, the last surveillance report is for 2002 data. The CDC did not conduct a survey in 1998.

**United States Census**

The U.S. population data are from the 2000 and 2010 U.S. Census, and also incorporate CDC postcensal and intercensal population estimates. The data and methods for these estimates are available at [http://www.cdc.gov/nchs/nvss/bridged_race.htm](http://www.cdc.gov/nchs/nvss/bridged_race.htm). Both intercensal and postcensal estimate datasets are available at [http://www.cdc.gov/nchs/nvss/bridged_race/data_documentation.htm](http://www.cdc.gov/nchs/nvss/bridged_race/data_documentation.htm). USRDS summarizes the data with different race categories at state and national levels.

**Database Definitions**

ESRD is defined as chronic renal failure requiring renal replacement treatment — dialysis or transplant — to sustain life. It is not the same as acute renal failure, from which patients are expected to recover within weeks or months. A Medical Evidence Report form must be completed immediately by renal providers for all ESRD patients to register them in the CMS ESRD database and to apply for Medicare eligibility if they were not previously eligible.

**Identifying ESRD Patients**

A person is identified as having ESRD when a physician certifies the disease on the Medical Evidence form, or when there is other evidence of chronic dialysis that meets the criteria of ESRD or eligibility for a kidney transplant. The identification of ESRD patients does not rely on International Classification of Diseases (ICD)-9 or ICD-10 codes for ESRD (ICD-9 code: 585.6; ICD-10 code: N18.6) or dependence on dialysis (ICD-10 code: Z99.2).

Patients with acute kidney failure who are on dialysis for days or weeks, but who subsequently 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 omitted.

**First ESRD Service Date**

The ESRD first service date is the single most important data element in the USRDS Database, and each patient must, at a minimum, have a valid first service date. This date is used to determine the incident year of each patient and the first year in which the patient is counted as prevalent.

In most cases, the first service date is derived by identifying the earliest date of any of the following potential indicators:

- The start of dialysis for chronic kidney failure as reported on the Medical Evidence form
- The first CROWNWeb event
- A kidney transplant as reported on a CMS or OPTN transplant form, a Medical Evidence form, or a hospital inpatient claim
- The first Medicare dialysis claim

There are two exceptions to the first ESRD service date determination:

- If the CROWNWeb event and Medical Evidence form agree (within 30 days of each other) and are more than 90 days after the first Medicare dialysis claim, and, if there is no transplant event between the first dialysis claim and the earlier of either the CROWNWeb event date or Medical Evidence form date, then first service date is defined as the earlier of the CROWNWeb event date or the Medical Evidence form date.
- If the Medical Evidence form date is one year earlier than the first CROWNWeb event date, and if the first claim date or first transplant date agrees with the first CROWNWeb event date, then the CROWNWeb first event date is used as the first service date.

**Death Date Determination**

After the ESRD first service date, the date of death is the most critical piece of information in the ESRD database. Death dates are obtained from several sources, including the CMS Medicare EDB, CMS forms
2746 and 2728, the OPTN transplant follow-up form, CROWNWeb database, inpatient claims, and, where allowed by regulation, the Social Security Death Master File. Because multiple sources report death information for the same patient, one patient may have several reported dates. For these patients, the death date is based on the hierarchy order below, with lower numbers having a higher priority:

1. CMS 2746 Death Notification form
2. CMS Enrollment Database
3. CROWNWeb Events
4. OPTN Transplant data
5. CMS 2728 Medical Evidence form
6. CMS Institutional Claims
7. CMS Patient List

**Transplant Dates**

The CMS and OPTN transplant data files overlap for 1988-1993, and transplants can also be identified from Medical Evidence forms that indicate transplant as the initial modality, from CROWNWeb transplant events, and from institutional inpatient claims. To resolve any conflicts among these sources, and create a complete list of unique transplant events, the USRDS has adopted the following procedure:

- Before 1988, all transplant events found in CMS PMMIS/REBUS/REMIS Transplant Files are used.
- After 1994, all transplant events found in OPTN Files are used.
- Between 1988 and 1993, all transplant events found in OPTN Files are used, and additional transplant events from the CMS PMMIS/REBUS/REMIS Transplant File are used only if they occur at least 30 days before or after a previously accepted transplant event.
- Additionally, transplant events associated with reported incident transplant patients from the Medical Evidence Report are used if they occur at least 30 days before or after a previously accepted transplant event. Transplant events found in CMS inpatient claims records are also included as transplants found in the CROWNWeb patient events data.

Each transplant event found in the Transplant File of the USRDS Core SAF dataset is thus a unique event derived from the OPTN database, the CMS Transplant database, Medical Evidence Report records, CROWNWeb patient events, or Institutional Claims Files.

**Graft Failure**

We assume a graft failure date reported in the OPTN transplant follow-up or REMIS identification file is correct unless death or a new transplant occurs before this date. A graft failure date may not be recorded in either file, however. In this case, we use the earliest of the following events:

- Date of death
- Date of subsequent transplant
- Date of return to regular dialysis, indicated by a continuous period of dialysis billing records covering a minimum of 60 days with at least 22 reported treatments
- Date of return to dialysis reported on the Medical Evidence form, or the date of graft nephrectomy from the OPTN follow-up record or a Medicare claim

**Medicare and Non-Medicare Patients**

Beneficiaries who are enrolled in Medicare due to their age are representative of the U.S. population aged 65 and older, as 98% are eligible for Medicare. Those who are younger than 65 tend to have more serious health conditions than the U.S. population their age, since they are entitled to Medicare due to disability or ESRD.

Most ESRD patients under age 65 are eligible to apply for Medicare as their primary insurance payer at the start of their third month following the start of ESRD treatment. Some, however, may not immediately enroll in Medicare if they have private insurance such as employer group health plans (EGHPs). For a person with private insurance, that insurance is the primary payer for the first 30 months of ESRD treatment, after which Medicare becomes primary. The patient may choose to enroll in Medicare at the start of ESRD or may wait to enroll until the 30-month coordination of coverage period is completed. These patients will have first service dates established by Medical Evidence forms or CROWNWeb events, but have no dialysis claims or hospitalization events in the CMS claims database. In the REMIS database, all non-Medicare ESRD patients are assigned a code of ‘ZZ’ in the two-character Beneficiary Identification...
The USRDS recognizes that these non-Medicare (ZZ) patients are true ESRD patients and should be included in patient counts for incidence, prevalence, and treatment modality, as well as mortality and transplant rate calculations. Calculations of hospitalization statistics, or possibly of any outcomes derived from Medicare claims including outpatient claims or in any other setting (i.e., any specific diagnostic or therapeutic code), 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. It is important to understand that only a fraction of the patients on the USRDS files fulfill Medicare primary criteria at any given time. For this reason, constructing a denominator cohort using the PAYHIST file, as discussed in the Payers (Essential to establish proper denominators for Medicare Claims defined outcomes, including hospitalizations) section below, is suggested.

**Integration of the CROWNWeb and CMS Claims Databases**

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. The treatment history data can be found in the public SAFs RXHIST (detailed treatment history) and RXHIST6o (condensed treatment history with 60-day stable modality rule applied; see 60-day Stable Modality Rule: Treatment History section below). More information about RXHIST and RXHIST6o data files can be found in the Researcher’s Guide to the USRDS Database. This history can be used to identify incident and prevalent cohorts and determines censoring points and outcomes for observational studies. The CROWNWeb event database is the primary source of the modality sequence file, and the dialysis claims are used as a way of confirming placements and resolving problem cases. As described in previous sections, we use all available sources to determine first service dates, deaths, transplants, and graft failures. For patients who either do not appear in the CROWNWeb events file or for whom the only event is “New ESRD Patient,” and patients who have transfer-out gaps, the Medicare dialysis claim file is used. For “Transfer Out” and “Transfer Out for a Transplant” events followed by large gaps (seven days or more), claims falling in gaps are included, with the exception that no claims data are included if the “Transfer Out for a Transplant” event has a corresponding transplant/transplant failure event that occurred within (before or after) 30 days. Claims data are also included for the periods after “Transplant Failure” events and “Discontinued Dialysis” modality if the periods are longer than seven days. Because the claims data capture the modality “Center Self-Hemodialysis” more accurately than the CROWNWeb data, this claims-based designation overrides other dialysis modalities from CROWNWeb. Any CROWNWeb dialysis event that falls into a “Center Self-Hemodialysis” period as determined by claims is recoded as “Center Self-Hemodialysis.”

Events that are implausible are removed. These include events that occur before a patient’s first service date, those falling between “Transplant” and “Transplant Failure,” and “Transfer Out for a Transplant” events that occur 60 days or less after the corresponding “Transplant,” and events occurring after “Death.”

**Lost-to-Follow-up Methodology**

Gaps frequently exist in the CROWNWeb and 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 new CROWNWeb event, claim event, or death date is encountered in the data. A dialysis modality, in contrast, is assumed to continue for only 365 days from the date of the last claim, in the absence of a new CROWNWeb event, a transplant date, a death date, or dialysis claims. After this period, the patient is declared lost-to-follow-up, until the occurrence of a new CROWNWeb event, dialysis claim, or transplant event.

Patients are considered lost-to-follow-up beginning 365 days after a “Transplant Failure” event or “Discontinued Dialysis” modality with no subsequent events. Patients for whom the only event is a first service date, and who do not exist in any other files
were also treated as lost-to-follow-up, beginning one year after the first service date. 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. Unlike in prior ADRs, which required that to be classified as having RRF the recovery had to occur within 180 days of the first service date and persist for at least 90 days, starting with the 2016 ADR, every indication of RRF is considered valid.
- The patient may no longer reside in the United States.
- The patient’s death may not have been reported to the Social Security Administration or to CMS.

60-day Stable Modality Rule: Treatment History

The 60-day stable modality rule requires that a modality continue for at least 60 days before it is considered a primary or switched modality. The rule is used to construct a second modality sequence, or treatment history, for each patient and assigns the patient a modality only if it is a stable or established modality. The hospitalization statistics shown by modality and the vascular access analyses in the ADR use the 60-day rule to define a stable modality. Most of the other data reported in the ADR do not apply this rule.

90-day Rule: Outcomes Analyses

This rule defines each patient’s start date for data analyses as day 91 of ESRD and is used primarily to calculate hospitalization rates.

Serum Albumin Data

The Medical Evidence form reports patient albumin levels along with the test’s lower limit, which indicates the testing method: bromcresol purple or bromcresol green, with lower limits of 3.2 and 3.5 g/dL, respectively. For all figures in the ADRs that present serum albumin data from the Medical Evidence form, the USRDS ESRD Database includes only those incident patients with both an albumin value and an albumin lower limit of 3.2 or 3.5 g/dL.

Modalities

USRDS and CMS have worked extensively on methods of categorizing patients by ESRD treatment modality. The initial modality for a patient is determined using an algorithm based on a hierarchy of data sources. The hierarchy of sources is evaluated in the following order: CROWNWeb data, Medical Evidence form, claims data, and transplant data. The modality indicated in the CROWNWeb and Medical Evidence form may be temporary, as patients often change to a new modality during the first 90 days of treatment, and it can be difficult to track modality during this time. Patients aged 65 and older have Medicare claims in the first 90 days that contain revenue codes designating modality. Patients younger than 65 and in EGHPs or Medicare risk programs, however, have no such early claims. Thus, modality may not be determined until Medicare becomes the primary payer at day 91 or, for EGHP patients, at 30-33 months after the ESRD first service date. These limitations influence our ability to determine a patient’s modality at any one point in time.

Of note are patients categorized as having an unstable modality (i.e., on a modality for fewer than 60 consecutive days) in the first 90 days of treatment. Because these patients tend to have higher death and hospitalization rates, interpretations of modality-specific outcome data including them should be viewed with caution. These patients are not recognized as being either stable hemodialysis (HD) or stable peritoneal dialysis (PD) patients in analyses of patients with stable modality (e.g., hospitalization rates in the ADR). When the 60-day stable modality rule is used, these patients are included in the “all ESRD” category, which provides a more complete view of outcomes with the least biasing of the data.

As mentioned earlier, a new modality/event — recovered renal function (RRF) — was introduced in the 2007 ADR. Prior to the 2016 ADR, this event could be established only if it occurred within the first 180 days following the first service date, and if the RRF period persisted for at least 90 days. Starting with the 2016 ADR, every indication of a RRF is now considered valid. The RRF event is similar to the lost-to-follow-up event in that such patients will not be included in the prevalent populations for outcomes analyses. However, as with lost-to-follow-up events, we retain
these patients in the modality sequence so that subsequent renal failure episodes can be tracked closely and in a timely manner.

ESRD treatment modalities may be categorized in different ways within the analyses in each chapter; these are defined in the chapter-specific analytical methods sections that follow this section.

**Payers (Essential to establish proper denominators for Medicare claims defined outcomes, including hospitalizations)**

Information on payers is obtained from the Medicare EDB. We also examine Medicare outpatient claims to identify patients for whom the EDB does not indicate Medicare as primary payer (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 Payer Sequence file to provide payer history, and, beginning with the 2003 ADR, we use this file to identify Medicare eligibility status and other payers. The construction of this file is similar to that of the Treatment History file. Payer status is maintained for each ESRD patient from the ESRD first service date until death or December 31, 2014.

Payer status information prior to the start of ESRD (ESRD first service date) is available from the backcasted Payer Sequence file. The Payer Sequence file is similar to the standard ESRD Payer Service file, except that the pre-ESRD Payer Sequence file begins at the first evidence of Medicare enrollment from the Enrollment Database, rather than first ESRD service date, as is the case with the ESRD Payer Sequence. The pre-ESRD payer sequence ends the day before the first ESRD service date.

Constructing denominators based on payer history is essential for proper ascertainment of studies assessing Medicare claims defined outcomes, which is any outcome using a specific diagnostic or procedure code, such as ICD, current procedure and terminology (CPT), or HCPCS (Healthcare Common Procedure Coding System) codes. Only a minority of dialysis patients have Medicare primary payer status when they start dialysis (and thus would not be included in claims-defined outcomes), which increases to about 60% of patients after several months after the start of dialysis. Prior ADRs and some medical journal articles have suggested using the 90-day after dialysis start rule to assume Medicare primary payer eligibility, but this is only a guideline. Both the percent of patients with Medicare coverage at incidence and the average time from initiation of dialysis to Medicare coverage for those not covered at incidence have changed over time (as shown in Figure 4ii, Incident patient distribution by first modality & payer, in the 2010 ADR, [https://www.usrds.org/2010/pdf/V2_04.pdf](https://www.usrds.org/2010/pdf/V2_04.pdf), page 28i). Because of this, using actual payer status and dates, as described above, is much more precise and is the recommended method.

Payer data are used to categorize a patient as MPP (established in the SAF PAYHIST), Medicare as secondary payer (MSP) with EGHP, MSP non-EGHP, Medicare Advantage (Medicare + Choice), Medicare or Medicaid, or a combination of payers (see the Researcher’s Guide to the USRDS Database for more information) during a given period of time.

**Primary cause of renal failure**

Information on the primary cause of renal failure is obtained directly from the Medical Evidence form (CMS 2728). For the ADR, we use eight categories with corresponding International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes as follows:

- Diabetes: 250.00, 250.01, 250.40, 250.41
- Hypertension: 401.0, 401.1, 401.9, 403.0, 403.1, 403.9, 403.91, 404.0, 404.1, 404.9, 440.1, 593.81, and 593.83
- Glomerulonephritis: 283.1, 283.11, 287.0, 443.1, 446.0, 446.2, 446.21, 446.29, 446.4, 580.0, 580.4, 580.9, 581.1, 581.8, 581.9, 582.0, 582.1, 582.9, 583.1, 583.2, 583.21, 583.22, 583.4, 583.81, 583.82, 583.9, 583.91, 583.92, 695.4, 710fbc.0, and 710.1
- Cystic kidney: 583.9, 753.1, 753.13, 753.14, and 753.16
- Other urologic: 223.0, 223.9, 274.1, 590.0, 591.0, 592.0, 592.9, 599.0, and 599.6
- Other cause: 016.0, 042.0, 042.9, 043.9, 044.9, 135.0, 189.0, 189.1, 189.9, 202.8, 202.83, 202.85, 202.86, 203.0, 203.08, 239.50, 239.51, 239.52, 270.0, 271.8, 272.7, 273.3, 274.1, 274.11, 275.4, 275.49, 277.3, 282.6, 282.61, 282.62, 282.63, 282.69, 282.83, 282.86, 287.3, 446.6, 572.4, 580.89, 582.89, 583.0, 583.6, 583.7, 583.89, 584.5, 587.0, 591.8, 590.0, 593.89, 593.9,
599.0, 639.3, 646.2, 714.0, 728.89, 753.0, 753.2, 753.21, 753.22, 753.29, 753.3, 753.39, 756.7, 756.71, 759.5, 759.8, 759.89, 866.0, 965.4, 965.9, 977.8, 982.8, 984.9, 996.8, 996.81, 996.82, 996.83, 996.84, 996.85, 996.86, 996.87, and 996.89

- Unknown cause: 239.5, 428.0, 500.0, 582.0, 586.0, 489.9, 589.0, 589.1, 589.9, 592.1, 593.1, 799.9, 799.99, 888.88, 899.9, 999.99, 999.9, and ICD-9-CM codes not covered by the lists of codes above

- Missing cause: no ICD-9-CM code listed

**Race and Ethnicity**

Data on patient race and ethnicity are obtained from the Medical Evidence form, the CMS Medicare Enrollment Database, the REMIS patient identification file, and the CROWNWeb patient roster. Because they are addressed in separate questions on the Medical Evidence form, patients can be assigned a racial category and an ethnic category independently. Patient ethnicity became a required field on the 1995 revised Medical Evidence form, but because the form did not go into effect until midway through 1995, data for 1995 are incomplete. Therefore, 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 how race is categorized in the U.S. Census data, we concentrate on White, Black/African American, Native American (including Alaskan Native), and Asian (including Pacific Islander) populations. Data on patients of other races will be presented as their numbers increase. The race and ethnicity categorization presented in each chapter remains consistent with that of the specific data sources used.

The data sources for race are (from high priority to low):

- The CROWNWeb patient list
- The Medical Evidence (2728) form,
- The REMIS patient lists
- The Medicare Enrollment Database.

The race categories in each source are regrouped to USRDS race categories. See Table m.1 for the race categories in each source. If information is missing from the CROWNWeb patient list, then the other three sources are checked in the order above to supply race information.
The data sources for ethnicity are (from high priority to low):

1. Medical Evidence form
2. CROWNWeb Patient list
3. Clinical Performance Measures (CPM)
4. Medicare Enrollment Database

Similar to the race categorization, if information is missing from the CROWNWeb patient list, then the other three sources are checked in the order above to fill in ethnicity information.

Analytical Methods Used in the ESRD Volume

Data sources are indicated in the footnotes of each table and figure in Volume 2: End-Stage Renal Disease (ESRD) in the United States. Additional information on these sources is also available in the Data Sources section above. Methodology used for the figures and tables in Volume 2 is described below in the corresponding chapter or ESRD Reference Table Methods section. When figure or table data come directly from a particular Reference Table, please refer to the appropriate ESRD Reference Table Methods section for additional detail.

Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities

Incidence of ESRD: Counts, Rates, and Trends

Because data are available only for patients whose ESRD therapy is reported to CMS, we qualify the term “incidence” as “incidence 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.

Rate adjustments in this chapter are as follows: overall rates (including those in the maps) are adjusted for age, sex, and race; rates by age are adjusted for sex and race; rates by race or ethnicity are adjusted for age and sex; and rates by primary cause of ESRD are adjusted for age, sex, and race. Direct adjustment, as described in the Statistical Methods section of the chapter, was used. Census data rate is now based on intercensal estimates; for details, see the section on the United States Census in the Data Sources section of this chapter.

For Figures 1.4-1.7, incident cases and incidence rates are taken directly from Reference Table A. More specifically, cases come from A.1 and rates come from A.2(2) and A.2(3). For details on the methods used, refer to the section for Reference Table A: Incidence and the section for Statistical Methods used for rate
calculations. Figure 1.17 reports the home dialysis patient distribution by therapy type and among incident populations.

For all maps by Health Service Area (HSA), data were suppressed for HSAs with 10 or fewer cases.

**Prevalence of ESRD: Counts, Prevalence, and Trends**

Here and throughout the ADR, the USRDS generally reports point prevalence 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, we qualify the terms prevalence as prevalence of reported ESRD. 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.

Prevalence adjustments in this chapter are as follows: overall prevalence (including those in the maps) is adjusted for age, sex, and race; prevalence by age is adjusted for sex and race; prevalence by race or ethnicity is adjusted for age and sex; and prevalence by primary cause of ESRD is adjusted for age, sex, and race. Direct adjustment, as described in the Statistical Methods section of the chapter, was used. Census data rate and prevalence calculations are now based on intercensal estimates; for details, see the section on the United States Census in the Data Sources section of this chapter.

Data for Figures 1.13-1.16 come directly from Reference Table B. Specifically, prevalent cases correspond to those found in B.1 and prevalence corresponds to that found B.2.2 and B.2.3. For details on the methods used, refer to the sections for Reference Table B: Prevalence and the section for Statistical Methods for rate calculations.

Figure 1.19 reports the home dialysis patient distribution, by therapy type and among point prevalent populations.

For all maps by Health Service Area (HSA), data were suppressed for HSAs with 10 or fewer cases.

**Modality of Renal Replacement Therapy**

Modality figures and the associated Reference Tables describe the treatment modalities of all known ESRD patients, both Medicare and non-Medicare, who are not classified as lost-to-follow-up or as having RRF. Treatment History Files RXHIST and RXHIST60 are used to determine modality. Unless noted otherwise, incident and point prevalent cohorts without the 60-day stable modality rule are used in the analyses. Treatment modalities are defined as follows:

- **Center HD**: HD treatment received at a dialysis center
- **Center self-HD**: HD administered by the patient at a dialysis center; a category usually combined with center HD
- **Home hemodialysis**: HD administered by the patient at home; cannot always be reliably identified in the database
- **CAPD (continuous ambulatory peritoneal dialysis)**: usually combined with CCPD and other PD
- **CCPD (continuous cycling peritoneal dialysis)**: usually combined with CAPD and other PD
- **Peritoneal dialysis (PD)**: analyses typically consist of CAPD, CCPD and intermittent peritoneal dialysis (IPD)
- **Other peritoneal dialysis**: primarily IPD, a small category except among very young children; usually combined with CAPD and CCPD to form PD category
- **Uncertain dialysis**: a period in which the dialysis type is unknown or multiple modalities occur but do not last 60 days; usually combined with 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 uncertain dialysis to form an other/unknown dialysis category
Renal transplantation: a functioning graft from either a living donor (a blood relative or other living person) or a deceased donor

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

Facilities began submitting patient data via CROWNWeb beginning in 2012. This information was previously submitted by facilities via the ESRD Networks. The new method of data input and submission may lead to unanticipated changes in trends beginning in 2012.

**Patient and Treatment Characteristics at ESRD Onset**

For Tables 1.4, 1.5, and 1.6, and Figures 1.21, 1.22, 1.23, and 1.24, laboratory values and treatment characteristics were derived from questions on the Medical Evidence form. All eGFR values are calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation from data acquired from the Medical Evidence form.

**Chapter 2: Healthy People 2020**

**Objective CKD-3: Increase the proportion of hospital patients who incurred acute kidney injury who have follow-up renal evaluation in 6 months post-discharge**

Data for this objective include all patients in the Medicare 5% sample who are aged 65 and older and who have either a hospital-associated acute kidney injury (AKI) event or a primary discharge diagnosis of an AKI in the given year (2001-2014). Because this is a Medicare defined event, a Medicare Primary cohort is required. Hospitalized AKI is defined by the presence of ICD-9-CM diagnosis code 584 in any field of the inpatient claims, and renal evaluation is identified by a microalbumin test. Patients are followed from the discharge date to the earliest date of death, ESRD, end of Medicare coverage, or six months after the discharge date. Current procedure and terminology (CPT) codes for urinary microalbumin measurement are identified from Healthcare Effectiveness Data and Information Set (HEDIS) 2008 specifications (HEDIS 2008, a National Committee for Quality Assurance (NCQA) program, is used to monitor the performance of managed health care plans), and include 82042, 82043, 82044, and 84156.

**Objective D-12: Increase the proportion of persons with diagnosed diabetes who obtain an annual urine albumin measurement**

The cohort includes general Medicare patients diagnosed with diabetes mellitus (DM) in each year, continuously enrolled in Medicare Parts A and B during the whole year, and aged 65 or older at the beginning of the year. CPT codes for urinary microalbumin measurement are those used in Objective CKD-3, above. Testing is tracked during each year. Diabetes is defined by a qualifying ICD-9-CM diagnosis code of DM on one or more Part A institutional claims (inpatient, skilled nursing facility, or home health agency), or two or more institutional outpatient claims and/or physician/supplier claims within a one-year observation period. Qualifying ICD-9-CM codes for DM are as follows: 250.XX, 357.2, 362.0X, and 366.41.

**Objective CKD-4.1: Increase the proportion of persons with chronic kidney disease who receive medical evaluation with serum creatinine, lipids, and urine albumin**

The cohort here is similar to that used for Objective D-12, but includes all CKD patients. Testing is tracked during each year. Patients are excluded if they are enrolled in a managed care program (HMO), acquire Medicare as secondary payer, are diagnosed with ESRD during the year, have a missing date of birth, or do not live in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. Racial and ethnic categories are mutually exclusive. Methods of defining CKD are described in the CKD Analytical Methods chapter of Volume 1: Chronic Kidney Disease (CKD) in the United States. Serum creatinine is identified through CPT codes 80047-80050, 80053-80054, 80069, and 82565, while lipid testing is identified through CPT codes 80061, 82465, 82470, 83695, 83705, 83715-83721, 84478, 83700, 83701, and 83704. CPT codes for urinary microalbumin measurement are the same as those used for Objective CKD-3 above.
**Objective CKD-4.2: Increase the proportion of persons with type 1 or type 2 diabetes and chronic kidney disease who receive medical evaluation with serum creatinine, urine albumin, Hgba1c, lipids, and eye examinations.**

Methods and codes used to determine rates of Hba1c testing and eye examinations are taken from HEDIS 2008 specifications. CPT codes 83036 and 83037 are used to identify Hba1c testing. Codes used to identify diabetic eye examinations are as follows:

- CPT codes, 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92226, 92230, 92235, 92240, 92250, 92260, 67101, 67105, 67107, 67108, 67110, 67112, 67141, 67145, 67208, 67210, 67218, 67227, 67228, 67028, 67030, 67031, 67036, 67038, 67039, 67041, 67042, 67043, 67113, 67121, 67221, 67228, S0625, S0620, S0621, and S3000; ICD-9-CM procedure codes, 14.1-14.5, 14.9, 95.02, 95.03, 95.04, 95.11, 95.12, and 95.16; and ICD-9-CM diagnosis code V72.0. The cohort is similar to that used for Objective CKD-4.1, but includes all diabetic CKD patients.

**Objective CKD-8: Reduce the rate of new cases of end-stage renal disease.**

Incident rates are calculated using the methods described for Chapter 1. Overall rates are adjusted by age, sex, and race; rates by age are adjusted for sex and race; rates by sex are adjusted for age and race; and rates by race and ethnicity are adjusted by age and sex.

**Objective CKD-9.1: Reduce kidney failure due to diabetes.**

Rates of kidney failure due to DM are also calculated using the methods described for Chapter 1, and adjustments are the same as those described for Objective CKD-8, above.

**Objective CKD-9.2: Reduce kidney failure due to diabetes among persons with diabetes.**

This table uses data from the National Health Interview Survey; all ages are included. Three-year data are used to estimate the prevalence of DM in the middle year, and the size of the population with DM is based on U.S. Census data. The incident rate per million of ESRD caused by DM is calculated as the number of incident ESRD patients with a primary cause of ESRD of DM, divided by the size of the population with DM in that group.

**Objectives CKD-10: Increase the proportion of chronic kidney disease patients receiving care from a nephrologist at least 12 months before the start of renal replacement therapy & CKD-11.3: Increase the proportion of adult hemodialysis patients who use arteriovenous fistulas or have a maturing fistula as the primary mode of vascular access at the start of renal replacement therapy.**

These tables use data from the newest version of the Medical Evidence form. The cohorts include incident HD patients, with CKD-11.3 limited to those aged 18 and older at initiation who have a known vascular access at that time. CKD-10 includes only patients for whom it is known whether they saw a nephrologist prior to initiation.

**Objective CKD-11.1: Increase the proportion of adult hemodialysis patients who use an arteriovenous fistula as the primary mode of vascular access & CKD-11.2: Decrease the proportion of adult hemodialysis patients who use catheters as the only mode of vascular access.**

These tables use data from CROWNWeb. The cohort includes prevalent HD patients from 2012 to 2014 who are aged 18 and older. Access type represents the last access type used in the year, according to CROWNWeb data.

**Objective CKD-12: Increase the proportion of dialysis patients wait-listed and/or receiving a deceased donor kidney transplant within 1 year of end-stage renal disease start (among patients under 70 years of age).**

The cohort includes patients from 2000-2014 who are younger than age 70 at the initiation of ESRD. Percentages are calculated as the number of patients placed on the deceased donor organ waiting list or receiving a deceased donor transplant within one year of initiation, divided by the number of patients without a living donor available (i.e., patients receiving a living donor transplant are excluded), and are estimated using the Kaplan-Meier methodology.
**Objective CKD-13.1: Increase the proportion of patients receiving a kidney transplant within 3 years of end-stage renal disease**

The cohort includes patients from 1998-2011 who are younger than age 70 at the initiation of ESRD. Patients are followed from ESRD certification to transplant, censoring at death or three years after the initiation of ESRD. Percentages are calculated using the Kaplan-Meier methodology.

**Objective CKD-13.2: Increase the proportion of patients who receive a pre-emptive transplant at the start of end-stage renal disease**

The cohort includes patients from 2001-2014 who are younger than age 70 at the initiation of ESRD. Pre-emptive transplants are those in which ESRD initiation date is the date of transplant. Percentages are calculated as 100 (N/D), where N=the number of preemptive transplants in the year and D=the number of ESRD patients in the year.

**Objectives CKD-14.1: Reduce the total death rate for persons on dialysis & CKD-14.3: Reduce the cardiovascular death rate for persons on dialysis**

Cohorts for these tables include period prevalent dialysis patients in each calendar year, 2001-2014, whose first ESRD service date is at least 90 days prior to the beginning of the year (point prevalent patients on January 1) or who reach day 91 of ESRD treatment during the year (incident patients). We exclude patients with unknown age or sex and those with an age calculated to be less than zero, as well as patients who are not residents of the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. Age is calculated on January 1, and race is defined from the Medical Evidence form. Cardiovascular mortality is defined using codes from past and current Death Notification forms: 01, 02, 03, 04, 1, 2, 3, 4, 23, 25, 26, 27, 28, 29, 30, 31, 32, 36, and 37. Patients are followed from January 1 (for point prevalent dialysis patients) or day 91 of ESRD (for incident dialysis patients) until death, transplant, or December 31 of the year. Rates are estimated as the number of patients who die from any cause (Objective 14.1) and who die from cardiovascular disease (Objective 14.3) in each year, per 1,000 patient years at risk.

**Objective CKD-14.2: Reduce the death rate in dialysis patients within the first 3 months of initiation of renal replacement therapy**

Cohorts here include incident dialysis patients in each calendar year, 2001-2014. In addition to applying the same exclusion criteria described for Objectives 14.1 and 14.3, we further exclude patients with recovered kidney function. Age is calculated on the first ESRD service date. Patients are followed from the first service date until death, transplant, or 90 days after ESRD. Rates are estimated as the number of patients who die from any cause per 1,000 patient years at risk.

**Objectives CKD-14.4: Reduce the total death rate for persons with a functioning kidney transplant & CKD-14.5: Reduce the cardiovascular death rate in persons with a functioning transplant**

Patient cohorts here include period prevalent transplant patients, 2001-2014, whose first ESRD service date is at least 90 days prior to the beginning of the year (point prevalent patients on January 1) or who reach day 91 of ESRD treatment (incident patients). Exclusion criteria are the same as those described for Objectives 14.1 and 14.3. Patients are followed from January 1 (for point prevalent dialysis patients) or day 91 of ESRD (for incident dialysis patients) until death or December 31 of the year. Rates are estimated as the number of patients who die from any cause (Objective 14.4) and who die from cardiovascular disease (Objective 14.5) in each year, per 1,000 patient years at risk.

**Chapter 3: Clinical Indicators and Preventive Care**

**Clinical Indicators**

In Figure 3.1, all data are obtained from CROWNWeb clinical extracts for December 2015. The adequacy (Kt/V) analyses are restricted to patients at least 18 years old as of December 1, 2015. Patients must have been alive as of December 31, 2015, and must have had ESRD for at least one year as of the time of the measurement. If multiple measurements were available for a patient, the last one in the month was used. In Figure 3.1.b, all adult (aged 18 and older) patients who are on dialysis for at least 90 days as of December 1, 2015, and alive as of December 31, 2015,
are included. If multiple hemoglobin measurements were available for a patient, the last one in the month was used. The categorical distribution of hemoglobin is shown for both HD and PD patients. In Figure 3.1.c, the hypercalcemia measure was calculated as a 3-month rolling average for both HD and PD patients, who were alive as of December 31, 2015, and had ESRD for at least 90 days as of the time of measurement of an uncorrected serum calcium value.

**Anemia Treatment by Modality**

All of the findings in this section are based on Medicare claims data. Efforts have been made for the figures and tables to be as fully representative as possible of the U.S. dialysis patient population represented by CMS claims data, resulting in substantially larger sample sizes in some of the tables associated with this anemia section as compared with the 2015 ADR. The modality of the patient in each month is determined from the primary modality that is indicated on the claims file associated with each claim for hemoglobin, iron dose, and epoetin alfa (EPO) dose variables in the given month. For transfusion analyses, patients were assigned to HD or PD if having at least one claim for HD or PD therapy, respectively, in that month. There were very few patients having dual modality use within the same month.

Calculation of hemoglobin levels are shown in Figures 3.2, 3.3, 3.8, and 3.9. Hemoglobin values were based upon the first reported claim in each month for HD patients (Figures 3.2, 3.3) or for PD patients (Figure 3.8, 3.9). When hemoglobin levels were not available in claims data, hematocrit values, if available, were divided by 3 to serve as a proxy estimate. Patients were excluded in a given month if the hemoglobin level (or hemoglobin values estimated from hematocrit values) was <5 g/dL or >20 g/dL. Results are shown for erythropoiesis-stimulating agent (ESA)-treated patients in Figures 3.2, 3.3, 3.8, and 3.9, in which case analyses were restricted to patients who: (1) within the indicated month had a claim for ESA use and a claim for either hemoglobin or hematocrit level, and (2) at the start of the month, were on dialysis for 90 days or more and were aged 18 or older. In Figures 3.2 and 3.8, hemoglobin levels are also provided for all patients, and the same restrictions were used as described in statement 2 above, but not limited to patients with an ESA claim within the given month in 2012. In addition, hemoglobin levels for patients not on any ESA drugs in a month were also shown for HD patients (Figure 3.2) and PD patients (Figure 3.8).

Calculation of mean EPO dose levels is shown in Figures 3.2 and 3.8. Mean monthly EPO dose is provided for HD patients in Figure 3.2 and for PD patients in Figure 3.8. Mean monthly EPO dose is shown for patients who within a given month had an EPO claim, were on dialysis for 90 days or longer, and were 18 years and older at the start of the month. EPO dose is expressed as mean EPO units per week, averaged over all EPO claims within a given month. Patients were excluded from these calculations for a given month if their monthly average EPO dose was either less than 250 units per week (resulting in 0.4% being excluded) or if their monthly average EPO dose was greater than 400,000 units per week; these criteria resulted in <0.001% of patients being excluded. Monthly ESA use for HD patients is shown in Figure 3.2.b and for PD patients in Figure 3.8.b. Monthly “EPO only” use (EPO and not Darbopoetin), “Darbopoetin only” use (Darbopoetin and not EPO), and “Any ESA” use (either or both EPO and Darbopoetin) are calculated among patients who are on dialysis for at least 90 days and 18 years or older at the start of the given month. Calculation of intravenous iron use is shown in Figures 3.4 and 3.10. Intravenous iron use and IV iron dose for HD patients is presented in Figure 3.4 and for PD patients in Figure 3.10. Monthly intravenous iron use was among patients on dialysis for 90 days or longer and 18 years or older at the start of the given month. Mean IV iron dose was calculated as the average dose of IV iron (iron sucrose and ferrous gluconate) a patient received, among patients receiving iron during the month. This analysis was restricted to only those patients who had more than 6 sessions but less than or equal to 18 sessions in a month. The permissible range of values considered for sucrose and ferrous gluconate are (50-1800 mg) and (12.5-1800 mg), respectively.

Categorical distribution of iron store measures, transferrin saturation (TSAT) and serum ferritin for December 2013, December 2014, and December 2015, using CROWNWeb data are shown in Figures 3.5 and 3.11.
3.6, respectively, for HD patients. For PD patients, iron store measures, TSAT and serum ferritin are shown in Figures 3.11 and 3.12, respectively. For Figure 3.5, dialysis patients on treatment for ESRD at least 90 days at the time of measurement of TSAT value for that year, ≥18 years old as of December 1 of that year and who were alive through December 31 of that year are included in the study. For each year, the latest non-missing TSAT value during October-December was used. Similar analyses were done for PD patients.

Figure 3.6 analyses include dialysis patients who were treated for ESRD for at least 90 days at the time of measurement of serum ferritin for that year, who were ≥18 years old as of December 1 of that year, and who were alive through December 31 of that year. For each year, the latest non-missing serum ferritin value during October-December, a 3-month time period, was used. Similar analyses were done for PD patients.

Percentage of all HD patients according to the number of red blood cell transfusions in a year is shown in Figure 3.7.a, which was calculated from Medicare claims data for years 2010-2014. Here, the denominator included all patients having a claim for at least one dialysis session during the month and who were 18 years or older at the start of the month, and the numerator consisted of the total number of claims for transfusions a patient had in a year. The modality of the first treatment in the year determines the modality of the patient for that year. Similarly, Figure 3.13.a, shows the distribution of the number of red blood cell transfusions received by PD patients, by year.

Calculations of the percentage of dialysis patients with one or more claims for a red blood cell transfusion in a given month from 2010-2014 are shown in Figures 3.7.b (HD patients) and 3.13.b (PD patients). For this calculation, the numerator consisted of dialysis patients with one or more red blood cell transfusion claims in a given month (the transfusion claims were identified using the codes as listed in Table m.2); the denominator included all patients having a claim for at least one dialysis session during the month and who were 18 years or older at the start of the month.
**Table m.2** Transfusion codes used in defining a red blood cell transfusion

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Type</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>36430</td>
<td>CPT</td>
<td>Transfusion, blood or blood components</td>
</tr>
<tr>
<td>P9010</td>
<td>HCPCS</td>
<td>Blood (whole), for transfusion, per unit</td>
</tr>
<tr>
<td>P9011</td>
<td>HCPCS</td>
<td>Blood, split unit</td>
</tr>
<tr>
<td>P9016</td>
<td>HCPCS</td>
<td>Red blood cells, leukocytes reduced, each unit</td>
</tr>
<tr>
<td>P9021</td>
<td>HCPCS</td>
<td>Red blood cells, each unit</td>
</tr>
<tr>
<td>P9022</td>
<td>HCPCS</td>
<td>Red blood cells, washed, each unit</td>
</tr>
<tr>
<td>P9038</td>
<td>HCPCS</td>
<td>Red blood cells, irradiated, each unit</td>
</tr>
<tr>
<td>P9039</td>
<td>HCPCS</td>
<td>Red blood cells, deglycerolized, each unit</td>
</tr>
<tr>
<td>P9040</td>
<td>HCPCS</td>
<td>Red blood cells, leukocytes reduced, irradiated, each unit</td>
</tr>
<tr>
<td>P9051</td>
<td>HCPCS</td>
<td>Whole blood or red blood cells, leukocytes reduced, CMV-negative, each unit</td>
</tr>
<tr>
<td>P9054</td>
<td>HCPCS</td>
<td>Whole blood or red blood cells, leukocytes reduced, frozen, deglycerol, washed, each unit</td>
</tr>
<tr>
<td>P9056</td>
<td>HCPCS</td>
<td>Whole blood, leukocytes reduced, irradiated, each unit</td>
</tr>
<tr>
<td>P9057</td>
<td>HCPCS</td>
<td>Red blood cells, frozen/deglycerol/washed, leukocytes reduced, irradiated, each unit</td>
</tr>
<tr>
<td>P9058</td>
<td>HCPCS</td>
<td>Red blood cells, leukocytes reduced, CMV-negative, irradiated, each unit</td>
</tr>
<tr>
<td>99.03</td>
<td>ICD-9</td>
<td>Other transfusion of whole blood; transfusion: blood NOS, hemodilution, NOS</td>
</tr>
<tr>
<td>99.04</td>
<td>ICD-9</td>
<td>Transfusion of packed cells</td>
</tr>
</tbody>
</table>

Data Source: USRDS ESRD Database. Abbreviations: CMV, cytomegalovirus; CPT, Current procedure and terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-9, International Classification of Diseases, Ninth Revision; NOS, nitrous oxide synthase.

**MINERAL AND BONE DISORDER**

Distributions of calcium levels for HD and PD patients for December 2013, December 2014, and December 2015, using CROWNWeb data are shown in Figures 3.14 and 3.15. Figure 3.14 analyses include HD patients on treatment for ESRD at least 1 year at the time of measurement of serum calcium value for that year, who were ≥18 years old as of December 1 of that year, and who were alive through December 31 of that year. Similar analyses were done for PD patients in Figure 3.15.

Distributions of phosphorus levels for HD and PD patients for December 2013, December 2014, and December 2015, using CROWNWeb data are shown in Figures 3.16 and 3.17. For Figure 3.16, analyses include HD patients on treatment for ESRD for at least 1 year at the time of measurement of serum phosphorus value for that year, who were ≥18 years old as of December 1 of that year, and who were alive through December 31 of that year. Similar analyses were done for PD patients in Figure 3.17.

**PREVENTIVE CARE**

Figure 3.18 presents data on diabetic preventive care. The ESRD population includes patients initiating therapy at least 90 days prior to January 1 of the first year of each study period and with DM in the first year. Testing is tracked in the second year of each study period, and tests are at least 30 days apart. ESRD patients without Medicare inpatient/outpatient and physician/supplier coverage during the entire study period are omitted, as are general Medicare patients enrolled in an HMO or diagnosed with ESRD during the study period. Also omitted are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories; who have a missing date of birth; who do not survive the entire reporting period; who have ESRD for fewer than 90 days prior to the start of the reporting interval; or who are lost to
follow-up during the study period. Age is calculated at the end of the study period.

Patients are defined as having DM either through medical claims (one inpatient/home health/skilled nursing facility claim, or two outpatient or physician/supplier claims), or through a listing of DM on the Medical Evidence form as the primary cause of ESRD or as a comorbid condition. ICD-9-CM diagnosis codes used to define DM are 250.xx, 357.2, 362.0x, and 366.41. Methods and codes used to determine rates of HgbA1c testing and eye examinations are taken from HEDIS 2008 specifications. CPT codes 83036 and 83037 are used to identify HgbA1c testing. Codes used to identify diabetic eye examinations are as follows: CPT codes, 67028, 67030, 67031, 67036, 67038, 67039, 67040, 67041, 67042, 67043, 67047, 67051, 67057, 67088, 67110, 67112, 67113, 67121, 67141, 67145, 67208, 67210, 67218, 67220, 67221, 67227, 67228, 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92230, 92235, 92240, 92250, 92260, S0620, S0621, S0625, S3000; ICD-9-CM procedure codes, 14.1-14.5, 14.9, 95.02, 95.03, 95.04, 95.11, 95.12, and 95.16; and ICD-9-CM diagnosis code V72.0. Lipid testing is identified through CPT codes 80061, 82465, 82470, 83695, 83700, 83701, 83704, 83705, 83715, 83716, 83717, 83718, 83719, 83720, 83721, 84478. Comprehensive diabetic care includes at least one HgbA1c test, at least one lipids test, and at least one eye exam. HgbA1c and lipid tests should occur at least 30 days apart.

Figure 3.19 (a-d) presents data on influenza vaccinations for prevalent ESRD patients by overall claims, age, race/ethnicity, and modality. The cohort for influenza vaccinations includes all ESRD patients initiating therapy at least 90 days prior to August 1 of the first year of the study period and alive on April 30 of the second year. Patients without Medicare inpatient/outpatient and physician/supplier coverage during the study period are omitted, as are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. Also omitted are those who have a missing date of birth; who have ESRD for fewer than 90 days prior to the start of the study period; or who are lost-to-follow-up during the study period. Age is calculated at the end of the study period. Influenza vaccinations are tracked between August 1 of the first year and April 30 of the second year in the study period. Influenza vaccinations are identified by CPT codes 90724, 90657, 90658, 90659, and 90660, and Healthcare Common Procedure Coding System (HCPCS) code G0008.

CHAPTER 4: VASCULAR ACCESS

VASCULAR ACCESS USE AT INITIATION OF HEMODIALYSIS

Data for Figures 4.1-4.3 and Table 4.1 are obtained from the Medical Evidence form (CMS 2728); data are restricted to the most recent version. Patients with missing vascular access data are excluded. Figure 4.1 presents data for patients who began hemodialysis during 2005-2014. Table 4.1 and Figures 4.2-4.3 present data for patients beginning dialysis in 2014. Age is calculated as of the date regular chronic dialysis began.

Figures 4.2 and 4.3 show the geographic variation in percentage of catheter-only use and percentage of AV fistula use, respectively, at hemodialysis initiation in 2014. Figures 4.2-4.3 exclude patients not living in the 50 states or the District of Columbia.

VASCULAR ACCESS USE AMONG PREVALENT HEMODIALYSIS PATIENTS

Vascular access use among prevalent patients is described in Table 4.2 and Figures 4.4-4.6.

For Table 4.2, CROWNWeb data is used to obtain vascular access use for December 2014. Catheter use implied any catheter use, whereas, arteriovenous (AV) fistula and AV graft use shown are without the use of a central venous catheter.

Figures 4.4 and 4.5 show geographic variation in percentage of catheter-only and percentage of AV fistula use, respectively, among prevalent hemodialysis patients by Health Service Area using CROWNWeb data from December 2014. These figures exclude patients not living in the 50 states or the District of Columbia.

Figure 4.6 presents data as reported from Fistula First from July 2003 to April 2012 and CROWNWeb data from June 2012 to December 2014. May 2012 was not included in the analysis to denote the breakpoint between the two sources. This figure shows prevalence of the vascular type used and for June 2012 to December 2014. The denominator is obtained from the
treatment history file, limited to hemodialysis patients who are non-transplanted and are alive at the end of each month. The numerator is obtained from vascular access extract files in CROWNWeb. Access type at vascular access initiation includes data obtained from the Medical Evidence form for patients beginning dialysis between January 1, 2013 and December 31, 2014; vascular access data for all other time points are obtained from CROWNWeb. There is a 15-day look-back and 15-day look-forward time period to determine vascular access.

**Change in Type of Vascular Access During the First Year of Dialysis**

Figure 4.7.a and Tables 4.3-4.5 include a cross-section of patients (who were incident in 2014) alive at each time point. They use data from January 1, 2014 to December 31, 2014, using the Medical Evidence form (CMS 2728) at initiation and CROWNWeb for subsequent time periods. Data are restricted to the most recent version of the CMS 2728. Patients with missing vascular access data are excluded.

Figure 4.7.b follows the same set of patients from dialysis initiation to 1 year after initiation, so each time point has the same number of patients. (N =102,367). As with Figure 4.7a, Figure 4.7b uses the Medical Evidence form (CMS 2728) to find access type at initiation and CROWNWeb for subsequent time periods. Patients with a maturing AV fistula/AV graft with a catheter in place were classified as having a catheter. The apparent decrease in AV fistula and AV graft use at 1 month is related to missing data due to the different data sources used for incident and prevalent patients.

**Predictors of AV Fistula Use at Hemodialysis Initiation**

Table 4.6 presents two models of the odds of AV fistula use at initiation and AV fistula or AV graft use at initiation using vascular access type data at initiation (as well as demographic and facility information) from Medical Evidence form (CMS 2728). Demographic variables included gender, age, race/ethnicity, pre-ESRD nephrology care, diabetes as cause of ESRD, facility census, and ESRD network. Two multiple logistic regression models were used to create this table.

**Fistula Maturation**

Table 4.7 includes patients with a fistula placed at any point between January 1, 2014 and December 31, 2014 who are already on ESRD at time of placement. Fistula placement was identified through inpatient, outpatient, and physician/supplier Medicare claims using the following HCPCS codes: 36818, 36819, 36820, 36821 and 36825. Subsequent first use of the placed fistula was determined by finding evidence of fistula use in CROWNWeb through the end of 2015. If the fistula was indicated to be used in CROWNWeb following the placement (and prior to any later fistula placements), the fistula was considered to have successfully matured for use. If CROWNWeb did not indicate the fistula was used following placement, the fistula was assumed to have failed to mature. In order to be included in the analyses, patients were required to have vascular access use data in CROWNWeb following the fistula placement and the date of first use in CROWNWeb, given that the exact time of “fistula maturity” is currently not determinable from CROWNWeb. Patients that died following the fistula placement were also included in the analysis.

**Chapter 5: Hospitalization**

**Inclusion and Exclusion of Subjects**

Methods used to examine hospitalization in prevalent patients generally echo those used for the tables in Reference Table G: Morbidity and Hospitalization (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 Table G of patients of races that are unknown or other than White, Black/African American, Native American, or Asian, however, these patients are included in the Chapter 5 figures. Included patients have Medicare as primary payer, with Part A coverage at the start of follow-up, and without HMO coverage. Rates include total admissions or hospital days during the time at risk, divided by patient years at risk. The period at risk begins at the later date of either January 1 or day 91 of ESRD, and censoring occurs at death, end of Medicare
Part A coverage, or December 31, in addition to other censoring criteria that vary by modality as described below. Since a currently hospitalized patient is not at risk for admission, hospital days are subtracted from the time at risk for hospital admissions. Additionally, rehospitalization rates include the percentage of live hospital discharges that are followed by a subsequent hospital admission within 30 days. Hospitalization data do not exclude inpatient stays for the purpose of rehabilitation therapy.

**Statistical models**

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

**Trends in Hospitalization rates**

Methods in Figures 5.1-5.3 follow those for Reference Table G: Morbidity and Hospitalization. Figure 5.1 presents adjusted rates of total hospital admissions and days per patient year. Prevalent ESRD patients are included, and rates are adjusted for age, sex, race, primary cause of ESRD, and their two-way interactions with the 2011 ESRD cohort used as the reference.

Figure 5.2 shows the admission rates since 2005 for period prevalent ESRD patients. Included patients have Medicare as primary payer and are residents of the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories. Patients with AIDS as a primary or secondary cause of death are excluded, as are patients with missing age or sex information. Rates are adjusted for age, sex, race, and primary cause of ESRD, and their two-way interactions using the model-based adjustment method. The reference cohort includes period prevalent ESRD patients in 2011. New dialysis access codes for PD patients appeared in late 1998. For PD patients, dialysis access hospitalizations are those defined as “pure” inpatient vascular/dialysis access events, as described for Tables G.11-G.15. For HD patients, vascular access hospitalizations include “pure” inpatient vascular access events, and vascular access for HD patients excludes codes specific to PD catheters (996.56, 996.68, and V56.2). Principal ICD-9-CM diagnosis codes are used to identify cardiovascular and infection admissions. The cardiovascular category consists of codes 276.6, 394-398.99, 401-405, 410-420, 421.9, 422.90, 422.99, 423-438, and 440-459, while infection is indicated by codes 001-139, 254.1, 300-301, 304.8, 310-311, 312.0, 382-382.4, 383, 386.33, 386.35, 388.60, 390-393, 421-421.1, 422.0, 422.91-422.93, 460-466, 472-474.0, 475-476.1, 478.21-478.24, 478.29, 480-490, 491.1, 494, 510-511, 513.0, 518.6, 519.01, 522.5, 522.7, 527.3, 528.3, 540-542, 566-567.9, 569.5, 572-572.1, 573.1-573.3, 575-575.12, 590-590.9, 595-595.4, 597-597.89, 598.0, 599.0, 601-601.9, 604-604.9, 607.1, 607.2, 608.0, 608.4, 611.0, 614-616.1, 616.3-616.4, 616.8, 670, 680-686.9, 706.0, 711-711.9, 730-730.3, 730.8-730.9, 790.7-790.8, 996.60-996.69, 997.62, 998.5, and 999.3.

Figure 5.3 presents unadjusted and adjusted rates of total hospital admissions per patient year by Health Service Area in 2014. Prevalent ESRD patients are included, and rates are adjusted for age, sex, race, and primary cause of ESRD with the 2011 ESRD cohort used as the reference.

Table 5.1 presents unadjusted and adjusted admission rates among adult (aged 22 and older) period prevalent HD patients. Principal ICD-9-CM diagnosis codes are used to identify cause-specific admissions: codes for cardiovascular and infectious admissions are listed in the discussion of Figure 5.2, while codes for vascular access infection are listed in Table m.5 in the section describing the methods for Reference Table G: Morbidity and Hospitalization. Rates are adjusted for age, sex, race, primary ESRD diagnosis, and their two-way interactions; values presented by one factor are adjusted for the other three. For adjusted rates, HD patients in 2011 are used as the reference cohort. Values by age, sex, race, and primary cause of ESRD are shown for 2012-2013 prevalent HD patients.

**Hospitalization Days**

Figure 5.4 shows adjusted hospital day rates by treatment modality among prevalent ESRD patients.
Again, rates are adjusted for age, sex, race, primary cause of ESRD, their two-way interactions with ESRD patients in 2011 used as the reference cohort. Treatment modalities are listed in the discussion of Figure 5.2.

Figure 5.5 shows adjusted infectious and cardiovascular hospital day rates among prevalent ESRD patients. Again, rates are adjusted for age, sex, race, primary cause of ESRD, their two-way interactions with ESRD patients in 2011 used as the reference cohort. Principal ICD-9-CM codes for cardiovascular and infection hospitalizations are listed in the discussion of Figure 5.2.

REHOSPITALIZATION RATES

Figures 5.6-5.11 show rates of rehospitalization and/or death among prevalent HD patients of all ages, 30 days after hospital discharge. Live hospital discharges from January 1 to December 1 of the year are identified as index hospitalizations; the latter date provides a 30-day period following the latest discharge to evaluate rehospitalization. The units of analyses include hospital discharges rather than patients. Hospitalization data exclude transfers. Discharges with a same-day admission to long-term care or a critical access hospital are excluded. For HD patients in Figures 5.6-5.11, discharges with a transplant, loss to follow-up, or end of payer status before day 30 after discharge are excluded. For ESRD patients in Figure 5.6, the same exclusions apply as related to transplant; discharges from transplant patients are excluded if they occur after 2 years and 11 months following the most recent transplant to ensure that complete claims are available during the 30-day post-discharge period.

Figure 5.6 shows overall percentages of discharges with 30-day rehospitalization and/or death in the general Medicare, CKD, and ESRD populations. Data include point prevalent Medicare patients on December 31, 2013, who are aged 66 and older. Patients are grouped by younger or older than age 66 so they have at least one year of CKD or ESRD care. For general Medicare patients with and without CKD, CKD is defined during 2013, and patients remain who are without ESRD, with continuous enrollment in Medicare Parts A and B, and without HMO coverage. Live hospital discharges from January 1 to December 1, 2014 are included.

Figures 5.6-5.8 and 5.10-5.11 indicate the percentage of discharges with readmission and/or death within 30 days after discharge. The groups indicate status at day 30 after discharge from the index hospitalization, and do not consider events after day 30. Figures 5.6-5.7 include all-cause index hospitalizations, while in Figure 5.8, categories of cause-specific admissions are based on principal ICD-9-CM diagnosis codes of the index hospitalization. Codes for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 5.2; vascular access infection codes are 996.62 and 999.31. Figures 5.10-5.11 include the codes for discharges from cardiovascular hospitalizations listed for Figure 5.2, and Figure 5.11 includes the codes for acute myocardial infarction (AMI), congestive heart failure (CHF), stroke and dysrhythmia. ICD-9 CM codes for AMI: 410.x0 and 410.x1; CHF: 398.91, 402.x1, 404.x1, 404.x3, 425, and 428; stroke: 430-434; and dysrhythmia: 426-427. Figure 5.9 indicates the percentage of hospital discharges followed by a 30-day rehospitalization by cause-specific groups for both the index hospitalization and the rehospitalization. Categories of cause-specific rehospitalization also include non-vascular access infections, defined by infection codes excluding 996.62 and 999.31, and other, defined by codes other than cardiovascular and infectious.

CHAPTER 6: MORTALITY

Unless otherwise specified, patient cohorts underlying the analyses presented in Chapter 6 include Medicare and non-Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories.

MORTALITY AMONG ESRD PATIENTS, OVERALL, AND BY MODALITY

Figure 6.1 shows trends in mortality rates by modality among incident ESRD patients during 1996-2013. Modalities include ESRD, dialysis, HD, CAPD/CCPD, and first transplant; results aggregating across modalities are also presented. Patients are classified by year based on date of ESRD onset. Dialysis patients are followed from ESRD onset (i.e., day one) censored at the earliest of date of transplant,
loss to follow-up, 90 days after recovery of native renal function, or December 31, 2013. Transplant patients begin follow-up at the date of transplant and are censored on December 31, 2013. Adjusted mortality rates for each period after first treatment are computed separately by taking an appropriate weighted average of Cox-regression based predicted rates. The adjustment is made through model-based direct standardization, and is described later in the Statistical Methods section of this chapter. The Cox proportional hazard model serves as the basis for the predicted rates, adjusted for age, sex, race, and primary cause of ESRD. The reference population consists of 2011 period prevalent ESRD patients.

Mortality by Duration of Dialysis, Including Trends Over Time

Figure 6.2 shows adjusted all-cause mortality among incident patients by year after incidence. The rates are based on the predicted cumulative hazard for patients in the reference dataset from an adjusted Cox model on survival based on incident patients in 2012, adjusted to period prevalent patients in 2011.

Mortality During the First Year of ESRD

Figure 6.3 displays adjusted mortality for incident patients in the first year by modality. Patients are followed from ESRD onset (day one; as reflected by first service date) up to one year, and censored at loss to follow-up, transplant, or 90 days after recovery of kidney function. The analyses are conducted separately for dialysis patients under the age of 65 (6.3.a) and aged 65 and over (6.3.b). Note that patients with unknown age, sex, or primary cause of ESRD are excluded from the analysis. Rates are adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD, with the 2011 incident ESRD patients serving as the reference population. The adjustment method is similar to that used for Figure 6.2.

Mortality by Age and Race

Table 6.1 shows the death rates for different race and age (6.1.a) and sex and age (6.1.b) categories among period prevalent transplant and dialysis patients in 2012. Adjusted death rates within each category are determined by calculating the weighted average across the sex, diagnosis, and race categories. Weighting is calculated according to the age, race, sex, and diagnosis category prevalence within the 2011 period prevalent reference data.

Cause-Specific Mortality Rates

Table 6.2 shows cause-specific mortality percentages by modality. Cardiovascular disease causes of death included: pericarditis (including cardiac tamponade), acute myocardial infarction, cardiac (other than pericarditis or myocardial infarction), cerebrovascular (including spontaneous subdural hematoma), atherosclerotic heart disease, cardiomyopathy, cardiac arrhythmia, cardiac arrest (cause unknown), valvular heart disease, pulmonary edema due to exogenous fluid, congestive heart failure, cerebrovascular accident including intracranial hemorrhage, and ischemic brain damage/anoxic encephalopathy. Infectious causes of death included: sepsis due to internal vascular access, septicemia due to vascular access catheter, septicemia due to peripheral vascular disease (gangrene), septicemia (other), peritoneal access infectious complication (bacterial or fungal), peritonitis (complication of peritoneal dialysis), central nervous system infection (brain abscess, meningitis, encephalitis, etc.), pulmonary infection (bacterial, fungal, or other), viral infection (CMV), viral infection (other, excepting hepatitis), tuberculosis, A.I.D.S., infections (other), cardiac infection (endocarditis), pulmonary infection (pneumonia, influenza), abdominal infection (peritonitis [not complication of PD], perforated bowel, diverticular disease, gallbladder), hepatitis B, hepatitis C, other viral hepatitis, genitourinary infection (urinary tract infection, pyelonephritis, renal abscess), or fungal peritonitis.

Survival Probabilities for ESRD Patients

Table 6.3 presents adjusted three-month, one-year, two-year, three-year, and five-year survival by modality. Data are obtained from Reference Table I: Patient Survival.

In the discussion for Table 6.3, we conducted an analysis in order to estimate three-year survival in the general population, matching on the age and sex distribution in specific ESRD populations. We used the 2013 life table from the Social Security Administration to obtain three-year survival at each
year of age for males and for females. These data were matched by year of age at incidence for all ESRD patients, hemodialysis patients, peritoneal dialysis patients, deceased-donor kidney recipients, and living-donor kidney recipients in 2009. The mean three-year survival was calculated for this age- and sex-matched group and reported in Chapter 6.

**Expected Remaining Lifetime: Comparison of ESRD Patients to the General U.S. Population**

Table 6.4 presents expected remaining lifetimes in years for the 2012 general U.S. population, and for 2013 prevalent dialysis and transplant patients. For period prevalent ESRD patients in 2013, expected lifetimes are calculated using the death rates from a generalized linear model with 16 age groups, assuming a constant mortality rate within each age group. The method for calculating expected remaining lifetimes is described in the Statistical Methods section at the end of this chapter. Data for the general population are obtained from the National Vital Statistics Report, Table 7, “Life expectancy at selected ages, by race, Hispanic origin, race for non-Hispanic population, and sex: United States, 2012” (CDC, 2012).

**Mortality Rates: Comparisons of ESRD Patients to the Broader Medicare Population**

Table 6.5 shows adjusted all-cause mortality in the ESRD and general Medicare populations (over the age of 65) using the Medicare 5% sample. Each prevalent sample is defined by the Medicare Part A and B beneficiaries available on December 31 of the preceding year. Follow-up for ESRD patients is from January 1 to December 31 of each year. For general Medicare patients, follow-up is from January 1 to December 31 of each year, censored at ESRD and at the end of Medicare entitlement or switching to managed care (Medicare Advantage). Adjusted mortality is adjusted for age, sex, and race, with 2014 ESRD patients serving as the reference population.

Figure 6.4 presents both unadjusted and adjusted all-cause mortality in the ESRD, dialysis, transplant, and among general Medicare patients from the 5% sample with cancer, DM, CHF, cerebrovascular accident/transient ischemic attack (CVA/TIA), and AMI. Patients can be in more than one comorbidity category. All cohorts are defined on December 31 of the preceding year, and include patients aged 65 and older. Adjustment methods and follow-up are as defined for Table 6.5, except the reference population is 2012 ESRD patients.

**Chapter 7: Transplantation**

**Overview**

Figures 7.1-7.4 present an overview of trends in kidney transplantation.

Figure 7.1 juxtaposes the percentage of dialysis patients wait-listed for a kidney transplant with the falling rate of transplantation in dialysis patients at all ages, 1997-2014. The data source is Reference Tables E.4 and E.9.

Figure 7.2 shows the number of ESRD-certified candidates on the OPTN kidney transplant waiting list on December 31 of each year during 1997-2014, for first and subsequent kidney-alone or kidney plus other organ transplants. Figure 7.2 also shows the median waiting time from wait-listing to kidney transplantation for candidates for kidney-alone transplants (i.e., the time by which 50% of these candidates had received a kidney transplant). Candidates listed at more than one transplant center on December 31 are counted only once. Median waiting time is calculated for all candidates enrolled on the waiting list in each given year during 1997-2009. The data source is Reference Tables E.2 and E.3.

Table 7.1 shows the median waiting time from wait-listing to kidney transplantation for candidates for kidney-alone transplants, by blood types and panel reactive antibodies (PRA), during 1997-2009. The same methods used to calculate the median waiting time in Figure 7.2 are used for Table 7.1.

Figure 7.3 presents the number of transplants by donor type during 1997-2014. The data source is Reference Tables E.8, E.8(2), and E.8(3).

Figure 7.4 shows the cumulative number of functioning kidney-alone and kidney-pancreas transplants as of December 31 of each year during 1997-2014. The data source is Reference Table D.9.

**Kidney Transplant Waiting List**

Figure 7.5 shows the percentage of patients wait-listed or receiving a deceased or living donor kidney-
alone or kidney plus other organ transplant within one year of ESRD initiation, stratified by age, during 1997-2013. The data source is Reference Table E.5(2).

Figure 7.6 shows the annual mortality rates of dialysis patients who were wait-listed for a kidney-alone or kidney plus other organ transplant, per 1,000 dialysis patient years at risk, by time since listing, during 1997-2014. The data source is Reference Table H.6.

**Transplant Counts and Rates**

Table 7.2 shows the unadjusted kidney transplant rates of all donor types, by age, sex, race, and primary cause of ESRD, per 100 dialysis patient years, during 2005-2014. The data source is Reference Table E.9.

Figures 7.7-7.10 illustrate the counts and unadjusted rates of deceased kidney-alone and simultaneous kidney-pancreas transplants by age, sex, race, and recipient primary cause of ESRD, during 1997-2014. The data source is Reference Tables E.8(2) and E.9(2).

Figures 7.11-7.14 portray the counts and unadjusted rates of living donor kidney-alone and simultaneous kidney-pancreas transplants by age, sex, race, and primary cause of ESRD, during 1997-2014. The data source is Reference Tables E.8(3) and E.9(3).

Figure 7.15 shows the number of kidney paired donation transplants and percent of all living donor transplants during 2012-2014. The denominator is any kidney-alone or kidney plus at least one other organ transplant from a living donor. A kidney paired donation transplant is defined as any living donor kidney transplant for which the donor type (as reported on the OPTN Living Donor Registration form) was coded as “non-biological, unrelated: paired donation.” Data are obtained from OPTN.

**Deceased Donation Counts and Rates Among All-Cause Deaths**

Figures 7.16-7.18 show the counts and unadjusted rates of deceased donor donation among all deaths within the U.S. population younger than 75 years old, by age, sex, and race, during 2000-2014. Traumatic deaths include motor vehicle accident, suicide, or homicide. Donors had at least one kidney recovered. Data on the deceased donors are obtained from OPTN, and data on the annual number of deaths in the U.S. population are obtained from the Centers for Disease Control and Prevention.

**Chapter 8: ESRD Among Children, Adolescents, and Young Adults**

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

After reviewing the height and weight of patients aged 0-4 years old from 1996-2014, from the Medical
Evidence form and CROWNWeb data, a data cleaning process was deemed necessary for this chapter. There were 217 patients with unreasonable height and weight values, which we considered to be adults mistaken as pediatric patients. These patients have been excluded from all special analyses in this chapter.

**Incidence and Prevalence**

Methods for this section should refer to the discussion of methods for Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. Data sources are the same with the exception of the data cleaning mentioned above.

**Etiology**

The underlying etiologies of ESRD are generated from the ESRD Medical Evidence Form (CMS 2728). New primary disease groups CAKUT (congenital anomalies of the kidney and urinary tract) and transplant complications are created and some of the diseases are regrouped based on clinical review this year. Diseases such as scleroderma, nephropathy due to heroin abuse and related drugs, analgesic abuse, radiation nephritis, lead nephropathy, gouty nephropathy, acute interstitial nephritis, urolithiasis, Other disorders of calcium metabolism, tuberous sclerosis, Fabry’s disease, sickle cell trait and other sickle cell (HbS/Hb other), urinary tract tumor, lymphoma of kidneys, multiple myeloma, other immunoproliferative neoplasms, amyloidosis, postpartum renal failure, hepatorenal syndrome are suppressed from Table 8.1 due to 10 or fewer total pediatric patients for year categories.

**Hospitalization**

Figures 8.4-8.6 present adjusted admission rates in the first year of ESRD, by age, and modality, for 2004-2008 and 2009-2013 incident patients younger than age 22. The patients are divided into five age groups (ages 0-4, 5-9, 10-13, 14-17, and 18-21) or three modality groups (HD, PD, and transplant). Since in-center hemodialysis patients who are younger than 65 and not disabled cannot bill for hospitalizations until 90 days after ESRD initiation, the 90-day rule is applied. Patients are required to survive the first 90 days after initiation, and are followed for admissions for up to one year after day 90. Data cleaning and counting of admissions and time at risk for admissions generally follow methods described for Reference Table G: Morbidity and Hospitalization. Censoring occurs at death, loss to follow-up, end of payer status, December 31, 2014, or at one year. Censoring also occurs three days prior to transplant for dialysis patients, and three years after the transplant date for transplant patients. Rates are adjusted for sex, race, Hispanic ethnicity, and primary cause of ESRD. Adjusted rates are calculated with a model-based adjustment method and an interval Poisson model. The reference includes incident ESRD patients aged 0-21 years in 2010-2011. Principal ICD-9-CM diagnosis codes used for infectious hospitalizations are listed in the discussion of Figure 5.2. Changes are made this year for the cardiovascular hospitalization codes in order to reflect the appropriate events considered for children. The cardiovascular category consists of principal ICD-9-CM diagnosis codes 390, 391, 394-398.99, 402, 404, 404.01, 404.03, 404.91, 410-414, 414.00-414.02, 414.05-414.07, 414.8, 414.9, 414.14, 416, 420-429.9, 430-438, 440-449, 459. 525.8, 745, 746.0-746.9, 779.89, V43.3.

**Mortality and Survival**

Figures 8.7-8.9 present adjusted all-cause and cause-specific mortality in the first year of ESRD, by age and modality, for 2004-2008 and 2009-2013 incident patients younger than 22 years old. The patients are divided into five age groups (ages 0-4, 5-9, 10-13, 14-17, and 18-21) or three modality groups (HD, PD, and transplant). Dialysis patients are followed from the day of ESRD onset until December 31, 2014, and censored at loss to follow-up, transplantation, or recovered renal function. Transplant patients who receive a first transplant in a calendar year are followed from the transplant date to December 31, 2014. Rates by age are adjusted for sex, race, Hispanic ethnicity, and primary cause of ESRD; rates by modality are adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD. Incident ESRD patients who were younger than 22 years in 2010-2011 are used as the reference cohort. Cardiovascular mortality is defined using codes from past and current Death Notification forms: 01, 02, 03, 04, 1, 2, 3, 4, 23, 25, 26, 27, 28, 29, 30, 32, 36, and 61; infection mortality is defined using codes from past and current Death Notification forms: 10, 11, 12, 13, 33, 34, 45, 46, 47, 48,
Figure 8.10 presents five-year survival rates for 2005-2009 incident ESRD patients aged 0-21 years, by age, modality, and ethnicity. The patients are divided into five age groups (age 0-4, 5-9, 10-13, 14-17, and 18-21) or three modality groups (HD, PD, and transplant). Dialysis patients are followed from the day of ESRD onset until December 31, 2014, and censored at loss to follow-up, transplantation, or recovered kidney function. Transplant patients who receive a first transplant in a calendar year are followed from the transplant date until December 31, 2014. Probabilities by age are adjusted for sex, race, Hispanic ethnicity, and primary cause of ESRD; probabilities by modality are adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD. The reference population consists of 2010-2011 incident pediatric ESRD patients.

Vascular Access

Data for Figure 8.11 and Figure 8.12 are obtained from the Medical Evidence form; data are restricted to the most recent version. Figures 8.11 also include data from CROWNWeb. Patients with missing vascular access data are excluded. Figure 8.10 present data for pediatric patients who began dialysis during 2006-2014; age is calculated as of the date regular chronic dialysis began. In Figure 8.11, all HD pediatric patients who had ESRD at least 90 days at the time vascular access was reported were included. Patients must have been alive as of December 31, 2015.

Transplantation

Figure 8.13 presents an overview of the transplant population among children and adolescents.

Figure 8.13.a shows the rate of ESRD among those aged 0-21 years in the U.S. population, and the rate of transplantation in dialysis patients aged 0-21 at transplant during 1996-2014. Pre-emptive transplant patients were included in both the numerator and the denominator.

Figure 8.13.b shows the number of ESRD-certified candidates 0-21 years old on the OPTN kidney transplant waiting list on December 31 of each year, and the median waiting time from wait-listing to kidney transplantation for new candidates (i.e., the time by which 50% of newly wait-listed candidates had received a kidney transplant). Candidates listed at more than one center on December 31 are counted only once. Median waiting time is reported for patients listed in each given year.

Figure 8.13.c-8.13.e present counts for all transplant recipients 0-21 years old, by donor type, and by patient age group 0-17 years vs. 18-21 years.

Figure 8.14 presents transplant rates per 100 dialysis patient years among dialysis patients (0-21 years old). Figure 8.14.a presents rates by age group. Figure 8.14.b presents rates by race. Asian and Native American groups were not displayed, however, because of the fluctuation due to small populations. Rates were calculated among dialysis patient years in that specific subgroup.

Figure 8.15 shows the median waiting time from initiation of HD or PD in incident pediatric ESRD patients (0-21 years old) to first transplant. Patient age in Figure 8.15.b was defined as the age at initiation of HD or PD. Incident dialysis and transplant patients are defined at the onset of dialysis or the day of transplant using the 60-day rule. Figure 8.15.b includes pediatric patients (0-21 years old) starting initiation of HD or PD in 1996-2013, and having the first transplant before 12/31/2015.

Table 8.2 presents patient adjusted ten-year outcomes for pediatric recipients (ages 0-21) who received a kidney transplant from a deceased or living donor. Death outcome probabilities are calculated among first-time transplants. Data are reported as adjusted probabilities of each outcome, and are computed using Cox proportional hazards models. The death outcome is not censored at graft failure, and includes deaths that occur after repeat transplantation or return to dialysis. These probabilities are adjusted as described below.

For the all-cause graft failure analyses, data are reported as adjusted probabilities of each outcome, and are computed using Cox proportional hazards models. Probabilities are adjusted for age, sex, race, primary cause of ESRD, and first versus subsequent transplant, and standardized to 2011 patient characteristics. All-cause graft failure includes re-transplant, return to dialysis, and death.
For the probability of death analyses, the Cox model and the model-based adjustment method are used for adjusted probabilities. The adjusted survival probability for a cohort is based on expected survival probability for the cohort and the reference population. The survival/conditional probabilities are modeled separately for each period: 0-90 days, 91 days to one year, one year to two years, two years to three years, three years to five years, and five years to ten years. The expected survival probabilities for 90 days, one year, two years, and so on are calculated based on the survival/conditional survival probabilities. We fit one model for each cohort to obtain adjusted probabilities overall and for age, sex, race, and primary cause of ESRD. The reference population consists of 2011 incident ESRD patients. The death outcome is not censored at graft failure, and includes deaths that occur after re-transplant or return to dialysis.

**Young Adults**

Analytical methods in the young adult section are similar to the pediatric section. The reference population consists of 2010-2011 incident young adult ESRD patients who were 22-29 years old.

**Chapter 9: Cardiovascular Disease**

This chapter describes the prevalence of cardiovascular comorbidities and selected cardiovascular procedures in fee-for-service, eligible Medicare enrollees. According to a previously validated method for using Medicare claims to identify diabetic patients, a patient is considered diabetic if within a one-year observation period, he or she: (1) had a qualifying ICD-9-CM diagnosis code of DM on one or more Part A institutional claims (inpatient, skilled nursing facility, or home health agency), or (2) had two or more institutional outpatient claims and/or Part B physician/supplier claims (Herbert et al., 1999). Using the same approach, we identified patients with comorbid conditions related to cardiovascular diseases using ICD-9-CM diagnosis codes over a one-year observation period. In contrast to these diagnoses, procedures were identified when one procedure code appeared for the patient during the observation period.

Cardiovascular comorbidities include atherosclerotic heart disease (ASHD), acute myocardial infarction (AMI), congestive heart failure (CHF), valvular heart disease (VHD), cerebrovascular accident/transient ischemic attack (CVA/TIA), peripheral arterial disease (PAD), atrial fibrillation (AFIB), sudden cardiac arrest and ventricular arrhythmias (SCA/VA), and venous thromboembolism and pulmonary embolism (VTE/PE). The algorithm above is used to define these cardiovascular conditions using the ICD-9-CM code values in Table m.3.
vol 2 Table m.3  ICD-9-CM diagnosis codes used to define cardiovascular disorders in the USRDS ADR, Volume 2, Chapter 9

<table>
<thead>
<tr>
<th>Condition name</th>
<th>ICD-9-CM diagnosis codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any cardiovascular disease (CVD)</td>
<td>398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 410-414; 422; 424-425,427-428; 430-438; 440-444; 447; 452-453; 557; V42.1, V45.81, V45.82</td>
</tr>
<tr>
<td>Atherosclerotic heart disease (ASHD)</td>
<td>410-414; V45.81, V45.82</td>
</tr>
<tr>
<td>Acute myocardial infarction (AMI)</td>
<td>410; 412</td>
</tr>
<tr>
<td>Congestive heart failure (CHF)</td>
<td>398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 422; 425; 428; V42.1</td>
</tr>
<tr>
<td>Systolic or both systolic &amp; diastolic</td>
<td>428.2, 428.4</td>
</tr>
<tr>
<td>Diastolic only</td>
<td>428.3</td>
</tr>
<tr>
<td>Heart failure, unspecified</td>
<td>398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 422; 425; 428 (not 428.2-428.4); V42.1</td>
</tr>
<tr>
<td>Valvular heart disease (VHD)</td>
<td>424</td>
</tr>
<tr>
<td>Cerebrovascular accident/transitory ischemic attack (CVA/TIA)</td>
<td>430-438</td>
</tr>
<tr>
<td>Peripheral arterial disease (PAD)</td>
<td>440-444; 447; 557</td>
</tr>
<tr>
<td>Atrial fibrillation (AFIB)</td>
<td>427.3</td>
</tr>
<tr>
<td>Sudden cardiac arrest/ventricular arrhythmias (SCA/VA)</td>
<td>427.1, 427.4, 427.41, 427.42, 427.5, 427.69</td>
</tr>
<tr>
<td>Venous thromboembolism and pulmonary embolism (VTE/PE)</td>
<td>452, 453</td>
</tr>
</tbody>
</table>

Data Source: ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification. Diagnosis codes can have up to five digits with a decimal point between the 3rd and 4th digit. Codes listed with three digits include all existing 4th and 5th digits, and those listed with four digits include all existing 5th digits. Peripheral arterial disease is defined as having a diagnosis and/or a procedure. Cardiovascular procedures include percutaneous coronary interventions (PCI), coronary artery bypass grafting (CABG), the placement of implantable cardioverter defibrillators (ICD) and cardiac resynchronization devices with defibrillators (CRT-D), and carotid artery stenting (CAS) and carotid artery endarterectomy (CEA). Procedures require only one claim with the procedure code. The presence of PAD is determined by the diagnosis or a claim for a procedure. Table m.4 shows the codes and type of claims used to identify each procedure.
<table>
<thead>
<tr>
<th>Procedure category</th>
<th>ICD-9-CM Procedure codes</th>
<th>HCPCS codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral arterial disease (PAD)</td>
<td>Claims files searched: IP, OP, SN</td>
<td>Values: 39.25, 39.26, 39.29; 84.0, 84.1, 84.91</td>
</tr>
<tr>
<td>ICD-9-CM Procedure codes:</td>
<td>Claims files searched: PB, OP-revenue</td>
<td>Values: 24900, 24920, 25900, 25905, 25920, 25927, 27295, 27590, 27591, 27592, 27598, 27880, 27881, 27882, 27888, 27889, 28800, 28805, 34900, 35131, 35132, 35141, 35142, 35151, 35152, 34051, 34151, 34201, 34203, 34800-34834, 35081-35103, 35331, 35341, 35351, 35355, 35361, 35363, 35371, 35372, 35381, 35450, 35452, 35454, 35456, 35459, 35470, 35471, 35472, 35473, 35474, 35480, 35481, 35482, 35483, 35485, 35490, 35491, 35492, 35493, 35495, 35521, 35531, 35533, 35541, 35546, 35548, 35549, 35551, 35556, 35558, 35563, 35565, 35566, 35571, 35583, 35585, 35587, 35621, 35623, 35646, 35647, 35651, 35654, 35656, 35661, 35663, 35665, 35666, 35671</td>
</tr>
<tr>
<td>Percutaneous coronary interventions (PCI)</td>
<td>Claims files searched: IP, OP, SN</td>
<td>Values: 00.66; 36.01, 36.02, 36.05, 36.06, 36.07</td>
</tr>
<tr>
<td>Coronary artery bypass graft (CABG)</td>
<td>Claims files searched: IP</td>
<td>Values: 36.1</td>
</tr>
<tr>
<td>ICD-9-CM Procedure codes:</td>
<td>Claims files searched: IP, OP, SN</td>
<td>Values: 00.51; 37.94</td>
</tr>
<tr>
<td>Implantable cardioverter defibrillators &amp; cardiac resynchronization therapy with defibrillator (ICD/CRT-D)</td>
<td>Claims files searched: IP, OP, SN</td>
<td>Values: 00.61; 00.62; 00.63; 00.64; 00.65; 17.53; 17.54; 38.11; 38.12; 38.31; 38.32; 38.41; 38.42; 39.74</td>
</tr>
<tr>
<td>Carotid artery stenting and carotid artery endarterectomy (CAS/CEA)</td>
<td>Claims files searched: IP, OP, SN</td>
<td>Values: 37215, 37216</td>
</tr>
</tbody>
</table>

Data Source: ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification. ICD-9-CM procedure codes have up to four digits with a decimal point between the 2nd and 3rd digits. Codes listed with three digits include all possible 4th digits. HCPCS codes have 5 digits without a decimal point. Peripheral arterial disease is defined as having a diagnosis and/or a procedure. Abbreviations: HCPCS, Healthcare Common Procedure Coding System, IP, inpatient, OP, outpatient services during inpatient stay, SN, skilled nursing facility, PB, physician and supplier services covered by Part B, OP-revenue, outpatient revenue claims during inpatient stay.
Figure 9.1 shows the causes of death in prevalent dialysis patients during 2012-2014. The data source is a special analysis using the data in Reference Table H.12. There are two versions of the pie chart presented in parts (a) and (b) of Figure 9.1. In (a), the percentages shown in the pie chart are among known causes of death; the denominator excludes missing/unknown causes of death. In (b), the percentages shown in the pie chart are among all deaths; the denominator includes missing/unknown causes of death. Unknown causes of death include records from the CMS 2746 ESRD Death Notification form that specifically designate an unknown cause of death. Deaths with missing causes include records in the ESRD database that are missing the CMS 2746 ESRD Death Notification form, or have the form but are missing or have recording errors in the primary cause of death field.

Table 9.1 displays the prevalence of cardiovascular comorbidities and procedures, by modality, age, race and gender, among ESRD patients in 2014. The cohort includes point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older with Medicare as primary payer on January 1, 2012, who are continuously enrolled in Medicare Parts A and B from January, 1, 2011 to December 31, 2011, whose first ESRD service date is at least 90 days prior to January 1, 2012, and who survived past 2012. Patients with CHF, PAD, and CVA/TIA are those whose Medicare claims indicated the diagnosis or procedure in 2012 or Medical Evidence forms reported the comorbidities during ten years before the first ESRD service date. Patients with ASHD, AMI, VHD, AFIB, SCA/VA, VTE/PE, PCI, CABG, ICD/CRT-D, or CAS/CEA are those whose Medicare claims indicate the diagnosis or procedure in 2012. Patients are followed from January 1, 2013, until the earliest date of death, modality change, transplant, loss to follow-up, recovery of renal function, or December 31, 2014. The adjusted probability of survival was calculated using the results of a Cox model, in which significant factors included age group and sex.

**Congestive Heart Failure Among ESRD Patients**

Type of heart failure for the calendar year was determined by frequency of diagnoses and a hierarchy. The presence of systolic (428.2x or 428.4), diastolic (428.3x), and unspecified (all other CHF diagnosis codes in Table m.3) diagnoses was determined by searching all reported diagnoses on all claims for a given calendar day. Each day was counted as systolic if there were any systolic diagnoses, as diastolic if there were no systolic diagnoses but at least one diastolic diagnosis, and as unspecified if there were no systolic or diastolic diagnoses but at least one unspecified diagnosis. The number of days with systolic, diastolic, and unspecified diagnoses was then summed for the calendar year. The patient’s type of heart failure for the year was then determined by a hierarchy similar to that applied for each calendar day: if the patient had any systolic heart failure and no diastolic-only heart failure, he/she was classified as systolic heart failure; if the patient had diastolic heart failure and no systolic, he/she was classified as diastolic heart failure; and if the patient had only unspecified heart failure, he/she was classified as unspecified heart failure. When a patient had both systolic and diastolic-only diagnosis days during the year, he/she was assigned to the heart failure type that was most frequent during the year.
Figure 9.5 shows the distribution of heart failure type by modality in 2014 for the same study cohort as in Table 9.1, except that patients who received a transplant were excluded. The denominators were the total numbers of patients for each modality, and the numerators were the numbers of patients with the given heart failure type within that modality.

**CHAPTER 10: PROVIDERS**

The methods and data sources used to identify dialysis facilities are the same as those used in Reference Table J. Please refer to the section on Reference Table J: Providers, found later in this document, for detailed methods and data source description.

A facility’s hospital-based or freestanding status is determined from the third and fourth digits of the provider number assigned to each unit by CMS. A facility’s profit status is determined through the ownership type field on the CMS survey (for years prior to 2001) or the profit status field of the DFC database (2001 to the present).

**提供商增长**

Figures 10.1 and 10.2 show the counts of units and patients for all provider types from the 2011-2014 Annual Facility Survey.

**选择的透析方式**

Figure 10.3 presents the percentage of patients who are being treated by PD and home HD by provider type and patient characteristics.

**血管通路的类型**

Figures 10.4 and 10.5 present the percentage of patient-months in 2014 during which a hemodialysis patient had a particular type of access: catheter, fistula, graft, or other/missing type for incident and prevalent HD patients, respectively. Both sets of figures show the percentages for all patients and are stratified by patient characteristics (gender and race).

Figure 10.6 describes the facility level distribution of percentage of patient-months in each of the above vascular access types for 2014 incident and prevalent HD patients, respectively.

**等待listing肾脏移植**

Figure 10.7 shows the percentage of dialysis patients on the kidney transplant waiting list in 2011, 2012, 2013, and 2014, all patients and stratified by patient characteristics (gender and race). This set of figures measures wait-listing only among patients younger than age 70, because transplantation occurs much less frequently in people aged 70 and older.

**标准化的临床结局指标**

Tables 10.1 and 10.4 compare mortality and hospitalization among dialysis provider types and chains, using standardized mortality ratios (SMRs) and standardized hospitalization ratios (SHRs). Both measures are estimated using a two-stage Cox proportional hazards model (described in the Statistical Methods section below). SMR and SHR calculations include all 2011, 2012, 2013, and 2014 period prevalent dialysis patients; SHR calculations include only dialysis patients with Medicare as primary payer.

**调整**

Both SMRs and SHRs are adjusted for patient age, race, ethnicity, sex, DM, duration of ESRD, nursing home status, patient comorbidities at incidence, and body mass index (BMI) at incidence. The SMR is additionally adjusted for race-specific population death rates.

To facilitate comparison of the SMR and SHR across years, Table 10.1 (SMR) and Table 10.3 (SHR) report these measures with the year adjustment removed from the model. That is, the measures do not compare outcomes for each year to the national norm for that year, but rather compare each year to the national averages over the entire reporting period combined (e.g., four years). Because all years are reported relative to the same standard, values can be compared across years, facilitating identification of short-term trends over time. Tables 10.2 (SMR) and 10.4 (SHR) present one-year versions of the respective measures.

**置信区间**

Given the large number of observations that go into the SMR and SHR models, we choose to
approximate rather than directly calculate the 95% confidence intervals for the respective measures. This approach gains efficiency with minimal loss of precision. In particular, the exact 95% confidence intervals are derived by applying the Wilson-Hilferty Approximation (Wilson and Hilferty, 1931), which approximates chi-square percentiles using percentiles of the standard normal distribution (Breslow and Day, 1987).

**Patient Placement**

We identified each patient’s dialysis provider at each point in time using data from a combination of Medicare-paid dialysis claims, the Medical Evidence form (CMS 2728), and paid dialysis claims. Starting with day 91 after onset of ESRD, we attribute a patient to a facility according to the following rules. A patient is attributed to a facility once the patient has been treated there for 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility. In particular, a patient is attributed to their current facility on day 91 of ESRD if that facility had treated him or her for at least 60 days. If on day 91, the facility had treated a patient for fewer than 60 days, we wait until the patient reaches day 60 of treatment at that facility before attributing the patient to the new facility. When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we do not attribute that patient to any facility. Patients were censored upon receiving a transplant. Patients who withdrew from dialysis or recovered renal function remained assigned to their treatment facility for 60 days after withdrawal or recovery. If a period of one year passed with neither paid dialysis claims nor CROWNWeb/SIMS information to indicate that a patient was receiving dialysis treatment, we considered the patient lost to follow-up and did not include that patient in the analysis from that point forward. When dialysis claims or other evidence of dialysis reappeared, the patient was included in the analysis again starting after 60 days of continuous therapy at a single facility.
period prevalent patients, specifically, all ESRD patients with at least one Medicare claim.

Figure 11.6 presents total Medicare fee-for-service inpatient spending by cause of hospitalization during 2004-2014.

**ESRD Spending by Modality**

Figure 11.7 describes total Medicare ESRD expenditures by modality. Medicare costs are from claims data.

Figure 11.8 shows the total Medicare ESRD expenditures per person per year by modality. The analysis includes period prevalent ESRD patients, and is restricted to patients with Medicare as primary payer only. Data sources are Reference Tables K.7, K.8, and K.9.

**Chapter 12: Prescription Drug Coverage in Patients With ESRD**

In figures and tables regarding enrollment and utilization of Medicare Part D, we analyze data on cohorts of Medicare enrollees in 2011-2014 based on 100% of the ESRD population receiving hemodialysis, receiving peritoneal dialysis, or with a functioning kidney transplant, along with cohorts of Medicare enrollees in 2011-2014 based on the Medicare 5% sample (general Medicare enrollees). For general Medicare enrollees, we require continuous enrollment in Medicare Parts A and B during the previous calendar year, and Medicare enrollment in January of the index year. For hemodialysis, peritoneal dialysis, and kidney transplant cohorts, we identify all point prevalent patients alive and enrolled in Medicare on January 1 of the index year, with ESRD onset at least 90 days earlier; treatment modality is identified on January 1. Several tables and figures in this chapter are limited to beneficiaries who were enrolled in Part D plans for at least one month of the analysis year. See the following section for more information on Part D enrollment classification.

**Part D Coverage Plans**

Table 12.2 reports the proportion of Medicare beneficiaries enrolled in Part D.

**Part D Enrollment Patterns**

In Figures 12.1-12.3, the type of prescription drug coverage is defined sequentially. That is, we first classify patients as “Part D with low-income subsidy (LIS),” if there exists at least one calendar month in 2014 with Part D enrollment and receipt of LIS. In patients without one such month, we classify remaining patients as “Part D without LIS,” if there exists at least one calendar month with Part D enrollment. In patients without one such month, we classify remaining patients as “retiree drug subsidy,” if there exists at least one calendar month with employer receipt of the subsidy. In patients without one such month, we classify remaining patients as “other creditable coverage,” if there exists at least one calendar month with enrollment in military, government employee, or employer group health plans. And we classify all remaining patients as “no known coverage.” For Figure 12.4 and Table 12.3, we classify Part D enrollees as LIS recipients if there exists at least one calendar month in 2014 with receipt of the LIS.

**Spending Under Stand-alone Part D Plans**

Part D costs for ESRD patients are based on Part D enrollees with traditional Medicare (Parts A and B), using the period prevalent, as-treated model. ESRD patients in Medicare Advantage Part D plans and Medicare secondary payer are excluded. 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. Some figures also include the general Medicare population (not enrolled in a Medicare Advantage Part D plan) based on the Medicare 5% sample. Costs in Tables 12.4, 12.5, and 12.7, and Figure 12.5 are presented as the total Part D spending, estimated as the Medicare covered amount plus the LIS amount. Out-of-pocket cost is estimated as patient pay amount plus the True Out-of-Pocket Costs (TrOOP) amount. Per person per year (PPPY) costs are calculated as dividing the total cost amount by the patient years at risk. Person years
at risk are calculated for the ESRD and general populations separately. For ESRD patients, person years at risk is calculated as subtracting the start date (the latest of Part D coverage start date, date of developing ESRD, and January 1 of the year) from the end date (the earliest of Part D coverage end date, death, and December 31 of the year). For general population, person years at risk is calculated as subtracting the start date (the later of Part D coverage start date and January 1 of the year) from the end date (the earliest of Part D coverage end date, date of developing ESRD, death, and December 31 of the year).

**Prescription Drug Classes**

Tables 12.6 and 12.7 list the top 15 drug classes used among Part D-enrolled dialysis patients by percentage of patients with any prescription filled and Medicare Part D spending. Part D covered prescriptions are grouped by their therapeutic purposes using the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification System.

**Chapter 13: International Comparisons**

**Data Collection**

Each country was provided a data-collection form spreadsheet (Microsoft Excel) to complete for years 2010 through 2014. Countries were asked to report patient count data for each year, if available, for the entire population, by sex (male, female), or by five different age categories (0-19, 20-44, 45-64, 65-74, 75+) for: (i) the country’s or region’s general population; (2) patients new to ESRD during the year; (3) patients new to ESRD during the year among new ESRD patients for whom diabetes was the primary cause of ESRD; (4) the point-prevalent count of ESRD patients living on December 31 of the given year; (5) total number of patients with a functioning kidney transplant on December 31 of the given year; (6) total number of kidney transplants performed during the year, by type of kidney transplant (deceased, living donor, other donor); and (7) the number of dialysis patients, HD patients, CAPD/APD/IPD patients, and home HD patients on December 31 of the indicated year. Prevalence was reported for all patients at the end of the calendar year (December 31, 2014), except where otherwise noted. Data for the United States is taken directly from the following Reference Tables: M: Census Populations; A: Incidence; B: Prevalence; D: Treatment Modalities; and E: Transplantation Process. Data provided by Argentina may be supplemented by Marinovich et al., 2016.

**Data Loading and Cleaning**

The data were imported into SAS from Microsoft Excel and data quality checks were performed with follow-up with registries, as needed.

**Incidence Rate of Treated ESRD**

The incidence rate for Figures 13.1, 13.2, 13.7, and 13.8 was calculated as the number of patients new to ESRD during the year divided by the total population for that year, multiplied by one million. For age-specific and sex-specific categories, the incidence rate was calculated as the count in each category divided by the total population in the respective category, multiplied by one million. Figures 13.3.a presents the countries with the highest percent increase in incidence rate and 13.3.b presents the countries with the largest percent decline in incidence rate from 2001/2002-2013/2014. The percent change in incidence rate was calculated as the percent difference between the average incidence rates in 2014 and 2013 and the averages in 2001 and 2002.

**Diabetes as Primary Cause of ESRD in Incident Patients**

Ascertainment of primary ESRD cause may have changed over the reporting period in some countries and thus potentially contributed to observed changes in the percentage of patients with diabetes as cause of ESRD in incident patients. Figure 13.4 presents the percentage of incident ESRD patients with diabetes as the primary cause. The denominator is the total number of patients new to ESRD. Figure 13.5 presents the 10 countries with the highest percent increase from 2001/2002-2013/2014. The percent change in incidence of treated ESRD due to diabetes was calculated as the percent difference between the average incidence of treated ESRD due to diabetes in 2014 and 2013 and the averages in 2001 and 2002.
**Prevalence of ESRD**

The prevalence for Figures 13.9 and 13.10 was calculated as the total number of ESRD patients receiving renal replacement therapy divided by the total population for that year, multiplied by one million. For age-specific and sex-specific categories, the prevalence was calculated as the count in each category divided by the total population in the respective category, multiplied by one million. Figure 13.11 presents the 10 countries with the highest percent increase in prevalence of ESRD from 2001/2002-2013/2014. The percent change in prevalence of ESRD was calculated as the percent difference between the average prevalence of ESRD in 2014 and 2013 and the averages in 2001 and 2002. Figure 13.12 presents the type of renal replacement therapy modality. The denominator is calculated as the sum of patients receiving HD, PD, home HD, or kidney transplantation.

**Prevalence of Dialysis**

The prevalence for Figure 13.13 was the total number of ESRD patients on dialysis divided by the total population for that year, multiplied by one million. Figure 13.14 presents the 10 countries with the highest percent increase in prevalence of dialysis from 2001/2002-2013/2014. The percent change in prevalence of dialysis was calculated as the percent difference between the average prevalence of dialysis in 2014 and 2013 and the averages in 2001 and 2002. Figure 13.15 presents the percent distribution of the type of renal replacement therapy modality. The denominator is calculated as the sum of patients receiving HD, PD, home HD, and does not include patients with other/unknown modality.

**Kidney Transplant**

The kidney transplant rate is shown two ways: the transplant rate in Figure 13.16.a is calculated as the total number of kidney transplants divided by the population total, multiplied by one million; the rate in Figure 13.16.b is calculated as the total number of kidney transplants divided by the prevalent number of dialysis patients, multiplied by 1000. Figure 13.17 presents the 10 countries with the highest percent increase in the kidney transplantation rate from 2001/2002-2013/2014. The percent change in kidney transplantation rate was calculated as the percent difference between the average transplantation rates in 2014 and 2013 and the averages in 2001 and 2002. Figure 13.18 presents the percentage of kidney donor type (deceased, living, unknown). The denominator is calculated as the sum of deceased, living, and unknown donor. The prevalence in Figure 13.19 is calculated as the total number of patients with a functioning kidney transplant divided by the total population for that year, multiplied by one million.

To contribute data from your country’s registry, please contact international@usrds.org.

**Chapter 14: USRDS Special Study Center on End-of-Life Care for Patients With ESRD**

Methods for the creation of the figures and tables in Chapter 14 are described within the chapter itself.

**ESRD Reference Table Methods**

**Reference Table A: Incidence**

The data sources for both incidence and prevalence patients are CROWNWeb, OPTN, ESRD Medical Evidence form (CMS 2728), and Medicare billing records. Incidence refers to the new cases of ESRD during a given time period. Incidence is expressed as a rate (number/million population/year). Prevalence refers to all patients receiving ESRD treatment at a particular time (December 31) and is expressed as a proportion (number/million population). A patient is considered incident at the time of first transplantation or first regular dialysis for chronic renal failure. A patient is considered prevalent if he/she is known to be receiving dialysis treatment or to have a functioning kidney transplant. Both incidence and prevalence rates are adjusted to a reference population using the direct method: this means the adjusted rate assumes a constant reference population, thus permitting meaningful comparison across years.

The 2016 ESRD Reference Tables present parallel sets of counts and rates for incidence (Table A) and December 31 point prevalence (Table B) from 1996 to 2014. Reference Table B also presents annual period prevalent counts and counts of lost-to-follow-up patients who lack any evidence of payment activity in the Medicare database for one year. Because the U.S.
population figures (shown in Reference Table M) used in the ADR include only residents of the 50 states and the District of Columbia, tables focus on patients from these areas. Exceptions are Tables A.1, A.6, A.8, and A.10, all of which present data specific to patients in Puerto Rico and the U.S. territories, or include these patients in the patient population. For incident patients, age is computed as of the beginning of ESRD therapy, while for prevalent patients, age is calculated as of December 31. Tables A.3 and B.3 are adjusted by the CDC diabetes population.

Rates in Reference Tables A.2, A.9, and A.11 are adjusted for age, sex, race, and ethnicity with the 2011 national population as reference.

Due to the lag time until reports of ESRD counts are complete, the data in these Reference Tables should be considered preliminary for 2014. The prevalence or incidence counts for a given year may change at a later date, in addition to this lag time, other factors contribute to uncertainty about the counts: for example, patients with recovered renal function, patients who die before chronic treatment is fully established; incident patients who stop chronic dialysis and then restart are counted as prevalent; incident patients who have a modality change, i.e., return to dialysis after a failed transplant, are not counted as incident ESRD patients.

Reference Table B: Prevalence

Reference Table B focuses on patients in the 50 states and the District of Columbia, with the exception of Tables B.1, B.6, B.8, and B.10. Rates in Table B.2, B.9, and B.11 are adjusted for age, sex, race, and ethnicity with the 2011 national population as reference.

Reference Table C: Patient Characteristics

Data in Reference Table C are based on information collected with 2005 Medical Evidence forms (CMS 2728). The full title of the form is “End-Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration”.

Each table in this section shows population characteristics by age, gender, race, ethnicity, and primary diagnosis. Mid-East/Arabian race and Indian Subcontinent race were dropped from the 2005 form; therefore, Mid-East/Arabian and Indian Subcontinent are removed from the race group. Hispanic, non-specific ethnicity is also dropped from the 2005 form, but the category is retained since some records still provide this information. Data shown are based on the incident population with a completed Medical Evidence form within the given year range.

Table C.1 contains data on biochemical markers (item 19 in CMS 2728) from 2006-2014. Glycosylated hemoglobin (HbA1c), total cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglycerides are added to the Medical Evidence form introduced in 2005. Blood urea nitrogen (BUN) is dropped from the 2005 form; therefore, BUN data are not shown in Table C.1.

Table C.2 shows patient prior and current employment status (item 16 in CMS 2728) from 2006-2014. Employment status is collected currently and for six months prior to renal failure. There are eight employment categories for both current and prior employment status and only one should be selected for each. If the patient is under 6 years old, the employment status questions are left blank. For patients under 14, we leave six employment statuses (employed full time, employed part time, homemaker, retired due to age/preference, retired (disability), and medical leave of absence) blank. Only student and unemployed data are shown for patients under 14.

Table C.3 shows patient insurance coverage (items 11 and 12 in CMS 2728) from 2006-2014. There are eight categories of insurance coverage in item 12 — Medicare, Medicaid, Employer Group Health Insurance, DVA, Medicare Advantage, Other, and None — plus an additional category in item 11 — applying for ESRD Medicare coverage.

Table C.4 presents patient comorbidity from 2009-2014 (item 17 in CMS 2728). A single patient could have multiple comorbidities.

Table C.5 describes the frequency and duration of prescribed therapy for hemodialysis patients (item 23 in CMS 2728) from 2009-2014.

Table C.6 presents distribution of patients on dialysis treatment receiving or not receiving transplant options (item 26 and 27 in CMS 2728) from 2009-2014. Patients who are not informed of transplant options have additional data for the reason
for not being informed (item 27). A single patient could have multiple reasons for not getting informed.

Table C.7-C.10 describes care received prior to ESRD therapy (item 18 in CMS 2728) from 2010-2014. Table C.7 shows data for pre-ESRD nephrology care. Table C.8 shows data for pre-ESRD dietician care. Table C.9 shows data for vascular access at initiation of renal replacement therapy. If arteriovenous (AV) fistula access was not used, whether a maturing AV fistula or graft is present was further assessed. Table C.10 shows data for erythropoiesis stimulating agent (ESA) use prior to ESRD therapy.

Table C.11 presents primary dialysis setting at initiation of renal replacement therapy (item 22 in CMS 2728). Three primary dialysis settings are home, dialysis facility/center and skilled nursing facility/long-term care facility.

**REFERENCE TABLE D: TREATMENT MODALITIES**

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

The second part, Table D.12 shows modality at day 90 and at two years after first service for all incident patients from 2010 to 2012. 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 part, Tables D.13-D.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 year as at least one full year but less than two, and so on.

The fourth part, Tables D.17-D.24, presents counts of incident and prevalent patients alive at the end of selected years (i.e., 2006, 2010, 2014), by demographic characteristics, payer category, and treatment modality. Again, age is computed as of the start of ESRD for incident patients and as of December 31 for point prevalent patients. The payer categories are:

- Medicare Fee for Service (FFS) (i.e., Medicare as primary payer)
- Medicare/Medicaid (i.e., dually eligible)
- MSP (i.e., Medicare as secondary payer): EGHP and non-EGHP
- HMO (i.e., Medicare Advantage or Medicare+Choice plans)
- Other and unknown payers

A detailed discussion of payer categories can be found in the *Database Definitions* section of this chapter.

**REFERENCE TABLE E: TRANSPLANTATION PROCESS**

Reference Tables E.1-E.5 present data regarding the kidney transplant waiting list. Table E.1 presents counts of ESRD-certified candidates added to the waiting list for a kidney or kidney-pancreas transplant during the given year, by demographics, primary diagnosis, transplant number, active status, blood type, and panel reactive antibody (PRA) level. Patients listed at multiple transplant centers are counted only once. Table E.2 presents waiting times, defined as the median time in days from first listing to transplant among patients listed for a kidney-alone transplant, and is estimated with the Kaplan-Meier method. Patients listed at multiple centers are counted from the time of the first listing. The data are censored at the loss-of-follow-up, death, or the “end-of-study” (which is 2014 for the 2016 Reference Table). Given that the median waiting time for most subgroups of patients is between three to five years, the value cannot be estimated reliably without at least five years of follow-up. As a result, the 2016 Table E.2 only shows data up to year 2009. Table E.2 reports data by demographics, primary diagnosis, blood type, PRA level, and first or subsequent transplant. Table E.2.2 reports data by state/territory and Table E.2.3 reports data by renal network. Table E.3 presents counts of ESRD-certified patients on the waiting list at any transplant center on December 31 of the given year, regardless of when the first listing occurred, by demographics, primary diagnosis, transplant number, blood type, PRA level, and time on the list. Table E.4 includes point prevalent dialysis patients wait-listed...
for a kidney on December 31 of the given year. Table E.4 reports data by demographics and primary diagnosis. E.4.2 reports data by state/territory and Table E.4.3 reports data by renal network. Table E.5 presents the percentage of patients either wait-listed or receiving a kidney transplant within one year of ESRD initiation, using the Kaplan-Meier method. Patients receiving a deceased donor kidney transplant are included in Tables E.5, E.5.3, and E.5.4, and patients receiving a deceased or live donor kidney transplant are included in Tables E.5.2, E.5.5, and E.5.6. Tables E.5 and E.5.2 report data by demographics, primary diagnosis; Tables E.5.3 and E.5.5 report data by state/territory; and Tables E.5.4 and E.5.6 report data by renal network. Note that residents of the 50 states, the District of Columbia, Puerto Rico, and U.S. territories are all included in these tables.

Tables E.6-E.8 present renal transplant counts by various combinations of factors. All kidney transplants, including kidney-alone and kidney plus at least one other organ, are included unless specified in the footnote, and all counts include non-Medicare patients. Table E.6 presents transplant counts by donor type. Table E.7 shows transplant counts for recipients whose age is younger than 22 years, by demographics, donor type, transplant number, and blood type. Table E.8 illustrates the distribution of recipients by donor type. Each E.8 table subsets transplant counts by demographics, primary diagnosis, blood type, transplant number, and PRA level, determined from the OPTN Recipient Histocompatibility form, and shows a crosstabulation of recipients and donors in terms of cytomegalovirus antibody status, hepatitis C antibody status, and Epstein-Barr virus antibody status at the time of transplantation. A recipient/donor is considered positive for any of these antibodies if any applicable OPTN data source indicates positive. Unknown status is applied when no applicable data fields indicate “positive” or “negative.” Table E.8 reports data for all donor types. Table E.8.2 reports data for deceased donors. Cold ischemia time (in hours) is reported for deceased donor transplants only, and is taken from the OPTN Transplant Recipient Registration form. Table E.8.3 reports data for living donors, and donor relation is reported for living donor transplants only.

Table E.9 presents transplant rates per 100 dialysis patient years by donor type. Table E.9 reports data for all donor types. Table E.9.2 reports data for deceased donors and Table E.9.3 reports data for living donors. All HD patients, PD (CAPD/CCPD) patients, and patients on an unknown form of dialysis are included, as are all non-Medicare dialysis patients. A patient’s dialysis days are counted from the beginning of the specified year, or from day one of ESRD dialysis therapy if treatment begins within the specified year, until transplant, death, or the end of the year, whichever comes first. Dialysis time for patients returning to dialysis from transplant is counted. Transplant rates are calculated as the number of transplants, including kidney-alone and kidney plus at least one other organ, divided by the total number of dialysis patient years for each year.

Reference Table F: Transplantation: Outcomes

Reference Table F: Transplantation presents probabilities of graft survival and graft failure necessitating dialysis or repeat transplantation, by donor type, age, sex, race, ethnicity, primary cause of ESRD, and first versus subsequent transplant. Data are presented for outcomes at 90 days, one year, two years, three years, five years, and ten years post-transplant. The probabilities are expressed as percentages varying from 0 to 100 (rather than as probabilities varying from 0 to 1). This section seeks to address two major issues: the probability of graft survival at various times post-transplant, and the probability that a recipient will return to dialysis or require repeat transplantation at various times post-transplant. Recipients are followed from the transplant date to graft failure, death, or the end of the follow-up period (December 31, 2014). In the analysis of graft survival, death is considered a graft failure. In the analysis of graft failure necessitating dialysis or repeat transplantation, 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 sex are omitted. Unknown age is defined as a missing age at transplant, or an age calculated to be less than zero or greater than 100 years. Transplant patients for whom the donor type is recorded as other or unknown are excluded. Patients are also excluded if
their first ESRD service date is prior to 1977. Residents of the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories are included in these tables.

Unadjusted survival probabilities are estimated using the Kaplan-Meier method, while the Cox proportional hazards model is used for adjusted probabilities. Probabilities are adjusted for age, sex, race, primary cause of ESRD, and first versus subsequent transplant, and standardized to 2011 recipient characteristics.

**Reference Table G: Morbidity and Hospitalization**

Reference Table G presents adjusted total admission and hospital day rates, by year, 2003-2014. The model-based adjustment method used in these tables is discussed later in this section and in the Statistical Methods section at the end of this chapter.

Because hospitalization data for non-Medicare patients may be incomplete, analyses in this section include only patients with Medicare as their primary payer. Hospitalization data are obtained from institutional inpatient claims. As in Chapter 5, hospitalization data in Reference Table G do not exclude inpatient stays for the purpose of rehabilitation therapy.

Tables G.1-G.15 include dialysis and transplant patients who are 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 U.S. territories. Excluded are patients with AIDS as a primary or secondary cause of death; patients with missing values for age, sex, or race; and patients of races that are unknown or other than White, Black/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 DM, hypertension, or glomerulonephritis.

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

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

To limit the contribution of patient years at risk from patients who do not have Medicare coverage but do have Medicare as a secondary payer or HMO coverage, and who therefore have incomplete hospitalization data, cohorts include only patients with Medicare Part A and B coverage at the start of follow-up. The follow-up period is censored when a patient’s payer status changes to no longer having Medicare Part A and B coverage or Medicare as a primary payer.

For patients in the all-dialysis, HD, and PD categories, the period at risk for all hospitalization analyses is from January 1 or day 91 of ESRD until the earliest of death, three days prior to transplant, end of Medicare Part A and B coverage, or December 31. Modality change is considered a censoring event only in the case of a change from dialysis to transplant. For dialysis patients in the all-ESRD category, in contrast, the analysis period is censored only at death, end of Medicare Part A and B coverage, or December 31 of the given year; a modality change is not used as a censoring event. For transplant patients in the all-ESRD and transplant categories, the period is censored at the earliest of death, three years after the transplant date, end of Medicare Part A and B coverage, or December 31 of the given year. 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 value. Since a currently hospitalized patient is not, however, at risk for new admissions, hospital days for each year are subtracted from the time at risk for total admissions. In the case of a hospitalization in which
admission occurs the same day as discharge, zero days are subtracted from the time at risk for total admissions. When hospitalizations span the start of the analysis period, only the days within the period are subtracted from the time at risk for total admissions.

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

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

The methodology for computing adjusted total admission and hospital day rates uses the model-based adjustment method (discussed in the section on Statistical Methods). Predicted rates for each subgroup combination of age, sex, race, primary cause of ESRD, 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 ⅛. Adjusted rates are then calculated using the direct adjustment method, with all 2011 ESRD patients as the reference cohort.

Tables G.11-G.15 show inpatient utilization in the period prevalent ESRD patients. Methods — including modality definitions, inclusion criteria, data cleaning, follow-up time definitions, and rate calculations — generally follow those described for the total admission rates in Tables G.1-G.5, but some differences do exist. While patients of races other than White, Black/African American, Native American, or Asian are excluded from G.1-G.5, they are included in G.11-G.15, except where rates are given by race. Rates are unadjusted and reflect total admissions per 100 patient years for 2006-2008, 2009-2011, and 2012-2014 (pooled) prevalent patients. While the rates for all causes are computed similarly to the unadjusted rates in G.1-G.5, the other nine cause-specific categories only include admissions for specific diseases. Vascular access and PD access hospitalizations are those classified as “pure” inpatient vascular/dialysis access events. Such access events are defined as admissions with a specified ICD-9-CM principal diagnosis code, or an ICD-9-CM principal procedure code in conjunction with a certain diagnosis-related group (DRG) code. Codes are listed in Table m.5. If an admission does not qualify as vascular/dialysis access, it is classified by the principal diagnosis code into one of eight other mutually exclusive groups. Categories and ICD-9-CM codes are as follows: circulatory diseases, 390-459; digestive diseases, 520-579; genitourinary diseases, 580-629; endocrine and metabolic diseases, 240-279; respiratory diseases, 460-519; infectious diseases, 001-139; and cancer, 140-172, 174-208, 230-231, and 233-234. Hospitalizations that do not fall under any of these categories are counted under all others.
**vol 2 Table m.5 DRG & ICD-9-CM codes for vascular access & peritoneal dialysis access variables**

<table>
<thead>
<tr>
<th>DRG codes (^a): prior to October 1, 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>112 Percutaneous cardiovascular procedure</td>
</tr>
<tr>
<td>120 Other circulatory system OR procedure</td>
</tr>
<tr>
<td>315 Other kidney and urinary tract OR procedure</td>
</tr>
<tr>
<td>442 Other OR procedure for injuries with complication</td>
</tr>
<tr>
<td>443 Other OR procedure for injuries without complication</td>
</tr>
<tr>
<td>478 Other vascular procedure with complication</td>
</tr>
<tr>
<td>479 Other vascular procedure without complication</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DRG codes (^a): after September 30, 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>252 Other vascular procedures with Major complicating conditions (MCC)</td>
</tr>
<tr>
<td>264 Other circulatory system O.R. procedures</td>
</tr>
<tr>
<td>673 Other kidney &amp; urinary tract procedures with MCC</td>
</tr>
<tr>
<td>674 Other kidney &amp; urinary tract procedures with CC</td>
</tr>
<tr>
<td>675 Other kidney &amp; urinary tract procedures without CC/MCC</td>
</tr>
<tr>
<td>907 Other O.R. procedures for injuries with MCC</td>
</tr>
<tr>
<td>908 Other O.R. procedures for injuries with CC</td>
</tr>
<tr>
<td>909 Other O.R. procedures for injuries without CC/Medicare</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-9-CM procedure codes (^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>38.95 Venous catheterization for renal dialysis</td>
</tr>
<tr>
<td>39.27 Arteriovenostomy for renal dialysis</td>
</tr>
<tr>
<td>39.42 Revision of arteriovenous shunt for renal dialysis</td>
</tr>
<tr>
<td>39.43 Removal of arteriovenous shunt for renal dialysis</td>
</tr>
<tr>
<td>39.93 Placement of vessel-to-vessel cannula</td>
</tr>
<tr>
<td>39.94 Replacement of vessel-to-vessel cannula</td>
</tr>
<tr>
<td>86.07 Placement of totally implantable vascular access device</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-9-CM diagnosis codes (^b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>996.1 Mechanical complication of vascular device, implant, graft</td>
</tr>
<tr>
<td>996.56 Mechanical complication due to peritoneal dialysis catheter</td>
</tr>
<tr>
<td>996.62 Infectious complication of vascular device, implant, graft</td>
</tr>
<tr>
<td>996.68 Infectious complication due to peritoneal dialysis catheter</td>
</tr>
<tr>
<td>996.73 Other complication due to renal dialysis device, implant, graft</td>
</tr>
<tr>
<td>999.31 Infection due to central venous catheter</td>
</tr>
<tr>
<td>V56.1 Fitting and adjustment of extracorporeal dialysis catheter</td>
</tr>
<tr>
<td>V56.2 Fitting and adjustment of peritoneal dialysis catheter</td>
</tr>
</tbody>
</table>

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

\(^b\) The presence of any of these diagnosis codes as the “Principal Diagnosis Code” is sufficient to define an inpatient pure vascular access or peritoneal dialysis access event.

Tables G.1.1-G.5.1 present adjusted rates similar to those shown in G.1-G.5, but include more patient subgroups. Additionally, Tables G.1.2-G.5.2 display the counts of the total admissions, patient years at risk, and total patients that are used to calculate the total admission rates.
**Reference Table H: Mortality and Causes of Death**

Cohorts for Reference Table H include both Medicare and non-Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories. The 60-day stable modality rule and 90-day rule are not applied to tables in Table H.

The cohorts in Tables H.1-H.12 are comprised of period prevalent patients, including those alive on January 1 and those incidents during a calendar year. All patients are followed from either January 1 (for those alive on January 1) or from the date of onset of ESRD (for those patients incident in a calendar year). Follow-up is censored at loss to follow-up, date of transplant (for dialysis patients), 90 days after recovery of function, or December 31 of the year. Age is defined at the beginning of follow-up. In calculating adjusted mortality, beginning in 1996, we have adjusted for and reported five race groups (White, Black/African American, Native American, Asian, and Other), as well as adjusted for ethnicity (Hispanics and non-Hispanics).

Tables H.1, H.2, and H.2.1 present mortality data for all ESRD patients. Total deaths are presented in Table H.1. Overall unadjusted and adjusted annual mortality rates by age, sex, race/ethnicity, primary cause of ESRD, and years of ESRD treatment are presented in Table H.2. Category-specific unadjusted mortality rates are calculated as total patient deaths divided by total follow-up time. Adjusted rates are computed by an appropriately weighted average of predicted category-specific rates, with the predicted rates based on generalized linear models. Such methods, akin to direct standardization, are described in the Statistical Methods section later in this chapter. Overall mortality rates are adjusted for age, sex, race, primary cause of ESRD, and years of ESRD treatment, while rates for each individual category are adjusted for the other four factors. The reference population includes 2011 prevalent ESRD patients. Table H.2.1 presents unadjusted mortality rates by age, sex, race, and primary cause of ESRD for 2013 prevalent ESRD patients; rates are again smoothed using a generalized linear model.

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

For Table H.13, general U.S. population life expectancy, the data source is Table 7 in the National Vital Statistics Report (NVSR), Deaths: Final Data for 2012. The methodology used is different from previous years: the expected remaining lifetime reported for a five year age range is the mean of the values for the starting age and the ending age. For example, the value reported for the 15-19 year old age group is the average of the values at the exact ages 15 and 20. For the age group 0-14 years old, the number reported is the mean of the values for the exact ages of 0, 1, 5, 10 and 15. Similarly, the life expectancy of the 85+ age group is the mean of the values for the exact ages of 85, 90, 95, and 100.

**Reference Table I: Patient Survival**

Reference Table I presents patient survival probabilities, based on incident cohorts. 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 U.S. territories. Patients are excluded if sex is unknown, or if age is unknown. All new ESRD patients with a first ESRD service date between January 1, 1996 and December 31, 2012, are included in the analysis. These patients are followed from day one (ESRD onset) until death, loss to follow-up, or December 31, 2013. For dialysis patients, both HD and PD, follow-up is also censored at recovery of native renal function and at receipt of a kidney transplant. Unadjusted patient survival probabilities are estimated using the Kaplan-Meier method, while adjusted survival is computed through model-based direct standardization using Cox regression. Incident 2011 ESRD patients served as the reference population for both overall and subgroup-specific adjusted survival.

**Reference Table J: Providers**

For Reference Table J, data are obtained from the CMS ESRD Facility Survey (CMS 2744, 1996 to the present), Renal Dialysis Facilities Cost Report (CMS 265-94, 1996-2000), and Dialysis Facility Compare (DFC) database (2001 to the present), as well as the

In Reference Table J, we define a chain-affiliated unit as a freestanding dialysis unit owned or operated by a corporation at the end of a year. The category of "Others" includes all organizations meeting our definition of a chain but not owned by DaVita, Fresenius Medical Care (Fresenius), or Dialysis Clinic, Inc. (DCI).

A facility’s hospital-based or freestanding status is determined from the third and fourth digits of the provider number assigned to each facility by CMS. A facility’s profit status is determined through the ownership type field on the ESRD Facility Survey (1996-2001 and 2014) or the profit status field of the DFC database (2001-2013).

Residents of the 50 states, the District of Columbia, Puerto Rico and the Territories are all included in these tables.

Table J.1 shows counts of the facilities by year for 1996 through 2014 by type of facility. Also, the number of patients in these facilities is shown. These facilities are the source for all tables reported in this section.

**REFERENCE TABLE K: MEDICARE CLAIMS DATA**

Cost information in Reference Table K is derived from ESRD Medicare inpatient, outpatient, skilled nursing facility, hospice, home health, physician/supplier, durable medical equipment, and Part D claims data in the CMS SAFs, which are created annually six months after the end of each calendar year. A small number of pre-ESRD records are included in cases where a patient had a transplant within 30 days of their first service date; claims are checked for the previous 30 days to include any cost records associated with the transplant. Claims data are obtained for all patient identification numbers in the USRDS ESRD Database. Each type of claim is processed separately, with their data collapsed into the type categories that can be seen in K.1, K.4, K.a, K.b, and K.b.1-53. The individual types of claims are then set together and patient demographic data are added.

**PAYER FILES**

The payer sequence (available in the file PAYHIST) is similar in concept to the USRDS treatment history. Payer 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 and dialysis claims information are used to categorize payer status as Medicare primary payer (MPP), Medicare secondary payer (MSP), or non-Medicare. The claims database contains data only for MPP and MSP patients, so economic analyses are restricted to these categories. In addition, as it is impossible to determine the complete cost of care for ESRD patients with MS coverage, analyses of costs per person per year exclude patients during the periods when they have this coverage.

**PAYMENT INFORMATION**

The economic analyses for this section focus on 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. These analyses also include the pass-through per diem amount, which applies to inpatient claims and reimburses the provider for capital-related costs, direct medical education costs, and an estimate of organ acquisition costs ($25,000 in 2016).

**Model 1: As-treated actuarial model**

Tables K.5-K.9, K.a, K.b, and K.b.1-53 are all processed by primary payer and model 1 modality. Model 1 modality is derived from the patient treatment history, and combines the treatment modality into an overall model: hemodialysis, CAPD/CCPD, other, transplant, and unknown. The category “other” includes cases in which the dialysis modality is not HD, CAPD, or 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.

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 initial modality is censored, and a new observation with the new modality is created. Under this method, aggregation of Medicare payments is done on an as-treated basis,
attributing all payments for a particular claim to the patient’s modality at the time of the claim.

Model 2: Categorical calendar year model

This model, described in the Health Care Financing Administration (now CMS) research report on ESRD (1993-1995), is used for Reference Tables K.10-K.13. With this method, patients are classified into four mutually exclusive treatment groups:

- Dialysis: ESRD patients who are on dialysis for the entire calendar year, or for that part of the year in which they are alive and have ESRD
- Transplant: ESRD patients receiving a kidney transplant during the calendar year
- Functioning graft: ESRD patients with a functioning graft for the entire calendar year, or for that part of the year in which they are alive and have ESRD
- 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

Changes in 2016

1. Change to the definition of pre-ESRD versus ESRD

A change to what claims should be considered ESRD versus pre-ESRD has caused a significant change to the number of cost records included this year. In the previous year, only claims that started on or after first service date were included in ESRD. In 2016, that was changed. Now, if a claim overlaps a first service date, that claim is considered ESRD. This is most noticeable in Reference Tables K.1, K.4, K.a, K.b, and K.b.1-53, where cost types have the following categories:

   In Inpatient Institutional claims:
   - Medical DRG
   - Surgical DRG
   - Non-TX pass-through

   In Physician/Supplier claims:
   - E&M nephrologist IP
   - E&M non-nephrologist IP
   - Inpatient dialysis

2. Change to Time at Risk

There was a change to time at risk calculations for Reference Tables K.5-K.13, K.a, K.b, and K.b.1-53 that can result in a smaller time at risk for some patients.

For 2016, time at risk was calculated by taking the latest date from:
- First of the year
- First service date
- Start of modality
- Start of primary payer history range
- And the earliest date from:
- End of the year
- Death date
- End of modality
- End of primary payer history range

Prior to the 2016 ADR, the start and end dates of a primary payer date range were not included in the algorithm.

3. Change to what cost records are included

There is another significant change in methodology this year that can result in lower costs reported than in the previous year for the same modality, payer, and time frame. Prior to the 2016 ADR, time at risk was calculated and either displayed on the worksheet, or used in calculating the sheet’s average cost per time at risk. While that is still true in 2016, only cost records that overlap the same time frame as time at risk are included.

For example, if a patient’s time at risk as a primary payer and dialysis patient was March 3-October 5, only claims records that overlap that same time period are included. If the patient had 10 different cost records for that year, and one of them was January 1-March 2, that cost would not be included.

Reference Table L: Vascular Access

Within Reference Table L, Tables L.1-L.6 include period prevalent HD patients with Medicare as primary payer. Placements are identified from inpatient, outpatient, and physician-supplier Medicare claims, and rates represent the total number of events divided by the time at risk and are converted to be in
terms of patient years. Time at risk is defined as the
time between the first day of a given year and end of
follow-up in the given year. Follow-up is censored at
death, change in modality, change in payer status, or
the end of the prevalent year.

Tables L.7-L.8 include point prevalent PD patients
with Medicare as primary payer. Complications are
obtained from inpatient Medicare claims during the
time at risk in the prevalent year. Table L.7 shows the
count of PD patients who experienced a complication
in the prevalent year. Table L.8 show the percentages
of PD patients who had at least one event in the given
complication category (sepsis, peritonitis, infection) in
the prevalent year. Follow-up on these patients is
censored at death, a change in modality, a change in
payer status, a claim for HD vascular access
placement, or at the end of the prevalent year.

**Reference Table M: Census Populations**

Reference Table M.1 includes the U.S. resident
population on July 1 by year, age, gender and race for
years 1996-2014. The data sources are U.S. Census,
intercensal, and postcensal population estimates from
the CDC Bridged-Race Population Database. U.S.
population data are used to calculate incidence and
prevalence rates. The total U.S. population in 2011 is
used as the reference population for analysis, which is
adjusted for age, sex, and race or ethnicity in ADR
chapters or other Reference Tables. The rates per
million population are calculated based on the
population of the corresponding year.

**Reference Table N: International Comparisons**

This section presents trends, similarities, and
differences in incidence, prevalence, treatment
modality, and transplantation of treated end-stage
renal disease (ESRD) in different countries. Data
collection methods vary considerably across countries,
and therefore direct comparisons should be made with
care.

Each country was provided a data-collection form
spreadsheet (Microsoft Excel) to complete for years
2010 through 2014. Countries were asked to report
patient count data for each year, if available, for the
entire population, by sex (male, female), or by five
different age categories (0-19, 20-44, 45-64, 65-74, 75+)
for: (i) the country’s or region’s general population; (2)
patients new to ESRD during the year; (3) patients
new to ESRD during the year among new ESRD
patients for whom diabetes was the primary cause of
ESRD; (4) the point-prevalent count of ESRD patients
living on December 31 of the given year; (5) total
number of patients with a functioning kidney
transplant on December 31 of the given year; (6) total
number of kidney transplants performed during the
year, by type of kidney transplant (deceased, living
donor, other donor); and (7) the number of dialysis
patients, HD patients, CAPD/APD/IPD patients, and
home HD patients on December 31 of the indicated
year. Data for the United States is pulled from the
following Reference Tables: M: Census Populations; A:
Incidence; B: Prevalence; D: Treatment Modalities; and
E: Transplantation: Process. Data for years before 2008
are pulled from historical files.

Prevalence was reported for all patients at the end
of the calendar year (December 31), except where
otherwise noted. The percent change is defined as the
percent difference between the average incidence
rates in 2013 and 2014 and the averages in 2001 and
2002, except in N.3. In N.3, the percent change is
defined as the percent difference between the average
incidence rates in 2013 and 2014 and the averages in
2005 and 2006 since more countries had incidence by
age group starting in 2005.

Tables N.1-N.3 present trends in the incidence of
ESRD patients in different countries. Incidence was
calculated as the count of patients who start any form
of renal replacement therapy during the year divided
by the total population for that year, and then
multiplied by one million. Table N.1 shows the trends
in the incidence of treated ESRD patients, 2001-2014.
Table N.2 shows the trends in the incidence of treated
ESRD patients due to diabetes, 2001-2014. N.1 uses
total incident patient count, and the count for N.2 is a
subset of total incident patients whose failure is due to
diabetic nephropathy. Table N.3 shows the changes in
the incidence of treated ESRD by five age groups, 0-19,
20-44, 45-64, 65-74, and 75+. Age-specific incidence
was calculated as the count in each age category
divided by the total population in the respective
category, multiplied by one million.

Tables N.4-N.5 present the prevalence of ESRD in
different countries, 2001-2014. Prevalence was
calculated as the point prevalent count divided by the total population for that year, multiplied by one million. Table N.4.a shows the number of ESRD patients receiving some form of renal replacement therapy (dialysis and kidney transplantation). Table N.4.b shows the prevalent ESRD patient counts. Table N.5 specifically presents 2014 ESRD prevalence in different countries, by five age groups, 0-19, 20-44, 45-64, 65-74, and 75+.

Tables N.6-N.7 present dialysis therapy for ESRD, 2001-2014. Table N.6 shows trends in the unadjusted prevalence of patients receiving dialysis. Table N.7 shows the distribution of different modality use in prevalent dialysis patients, including percentage of in-center hemodialysis (N.7.a), percentage of CAPD/APD/IPD (N.7.b), and percentage of home hemodialysis (N.7.c). The denominator is calculated as the sum of patients receiving HD, PD, or home HD, and does not include patients with other/unknown modality.

Tables N.8-N.10 present data regarding kidney transplantation in different countries, 2001-2014. Table N.8 calculates the unadjusted kidney transplantation rate for each country. The kidney transplantation rate is defined as the total number of kidney transplants (sum of deceased, living donor, and unknown donor) divided by the total population for that year, multiplied by one million. Table N.9 shows the unadjusted prevalence of treated ESRD patients with a functioning kidney transplant. Table N.10 shows the percent of treated ESRD patients living with a functioning kidney transplant. The denominator is the prevalent number of patients receiving renal replacement therapy.

**Statistical Methods**

**Methods for Calculating Rates**

The calculation of observed rates is straightforward, with some rates based on counts and others on follow-up time. The ESRD incident rate in 2014, for example, is the observed incident count divided by the 2014 population size and, if the unit is per million population, multiplied by one million. The 2014 death rate for prevalent ESRD patients is the number of deaths in 2014 divided by the total follow-up time (patient years) in 2014 of the 2014 prevalent patients, and, if the unit is per thousand patient years, multiplied by one thousand. Standard errors of estimated rates are based on the assumption of the data; the observed count has a Poisson or binomial distribution. The count-based rate describes the proportion having the “event,” and the time-based rate tells how often the “event” occurs.

**Model-based Rates**

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

**Measurement Unit for Rates**

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

Take, for example, a calculation of 2014 first hospitalization rates for two groups of patients, all receiving dialysis therapy on January 1, 2014. Group A consists of three patients: patient 1 had a first hospitalization on March 31, 2014; patient 2 was hospitalized on June 30, 2014; and patient 3 was on dialysis through December 31, 2014, with no hospitalizations. Group B also has three patients: patient 4 was first hospitalized on December 31, 2014; patient 5 was hospitalized on September 30, 2014; and patient 6 was on HD the entire year, with no hospitalizations through December 31, 2014.

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 2014. But the first hospitalization rate per thousand patient years at risk is 1,143 for Group A and 727 for Group B (calculated as [2 total events / 1.75
total patient years at risk] x 1,000 for Group A and [2
total events / 2.75 patient years at risk] x 1,000 for
Group B). The resulting rate is lower for Group B
because of the longer total follow-up time.

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

**Methods for Adjusting Rates**

Because each cohort contains a different patient
mix, observed 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, sex, race,
and primary cause of ESRD — as the reference
population.

**Direct Adjustment**

There are several rate-adjustment methods, but
only the direct method allows rates to be compared
(Pickle & White, 1995). Here the adjusted rate is
derived by applying the observed category-specific
rates to a single standard population (i.e., the rate is a
weighted average of the observed category-specific
rates, using as weights the proportion of each category
in the reference population). Categories are defined by
the adjusting variables. For example, if a rate is
adjusted for race and sex and there are three race
groups (White, Black/African American, and Other)
and two sex groups, there are six categories: White
males, White females, Black/African American males,
Black/African American females, males of other races,
and females of other races.

Suppose we try to compare state-level incidence
rates in 2014 after removing the difference caused by
race. To do this, we need to calculate the incidence
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 2014 — with five race groups
(White, Black/African American, Native American,
Asian, and Other).

Assuming the incidence rate of state A in 2014 is 173
per million population, and the race-specific rates and
race distribution of the national populations are as
shown in Table m.6 below, the adjusted incidence rate
of state A with the national population as reference is

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

This means that if state A had the same racial
distribution as the entire country, its incidence rate
would be 158.73 instead of 173. If state B had an
adjusted incidence rate of 205, we could say that state
B had a higher incidence rate than state A if they both
had the same racial distribution as the whole country.

<table>
<thead>
<tr>
<th>Incidence rate of state A</th>
<th>National population (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>153</td>
</tr>
<tr>
<td>Black/African American</td>
<td>250</td>
</tr>
<tr>
<td>Native American</td>
<td>303</td>
</tr>
<tr>
<td>Asian</td>
<td>174</td>
</tr>
<tr>
<td>Other</td>
<td>220</td>
</tr>
</tbody>
</table>

This method is used to produce some adjusted
incidence and prevalence rates in *Chapter 1: Incidence,
Prevalence, Patient Characteristics, and Treatment
Modalities; Chapter 3: Clinical Indicators and
Preventive Care; and Reference Table A: Incidence and
Reference Table B: Prevalence*, as well as in the model-
based adjustment method.

**Model-based Adjustment**

Under some circumstances, there are
disadvantages to the direct adjustment method.
Suppose we are calculating mortality rates for a set of
groups, and adjusting for potential confounding
variables. If one category in a group has only a few
patients or deaths, its estimated category-specific
mortality rate will be unstable, likely making the
adjusted rate unstable as well. In addition, if one
includes a category with no patients, the method is
not valid for calculating an adjusted mortality rate for
the group. An attractive alternative is a model-based
approach, in which we find a good model to calculate category-specific estimated rates for each group, and then calculate direct adjusted rates using these estimates with a given reference population. This method can also be extended to adjustments with continuous adjusting variables (Liu et al., 2006). As in previous ADRs, standard errors of the adjusted rates are calculated using a bootstrap approach. In general, the bootstrap approach works well, but is time consuming. Convergence problems occur in a few bootstrap replications and such cases are ignored in the calculation. In this ADR, we use model-based adjustments to calculate adjusted mortality rates, adjusted hospitalization rates, and state-level adjusted incidence and prevalence rates using the Poisson method and some other rates, as described in the text on the individual figures.

**Survival Probabilities and 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 & Prentice, 2002). Survival probabilities in Reference Table I: Patient Survival are expressed as percentages from 0 to 100. The mortality/event rate in the period of (0,t) is calculated by [-\ln(\text{Survival at time } t)]. This event rate will be the same as that estimated by event time divided by follow-up time after adjustment of the unit, if the event rate is a constant over time.

**Survival Probability with Competing Risks**

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

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

where \( \lambda_k(s) \) is the hazard of event from cause k at time s and S(s) is the survival probability at time s (the probability of no event happening). If we have failing time \( t_1, t_2, ..., t_m \), the cumulative incidence function of cause k at time t is estimated by

\[
I_k(t) = \sum \hat{\lambda}_k(t_j)S(t_{j+1}-t)
\]

where \( \hat{\lambda}_k(t_j)=D_{kj}/n_j \) is the Kaplan-Meier estimate of survival at time \( t_{j+1}-t \), \( D_{kj} \) is the number of patients failing from cause k at time \( t_j \), and \( n_j \) is the number of patients at risk at prior time \( t_j \) (Putter et al., 2007).

**Adjusted Survival Probabilities**

Adjusted survival probabilities are reported in Reference Table I: Patient Survival, with age, sex, race, Hispanic ethnicity, and primary cause of ESRD used as adjusting risk factors. The model-based adjustment method is used, with survival probabilities/conditional survival probabilities predicted from the Cox regression model (Kalbfleisch & Prentice; 1980, 2002). 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, sex, race, Hispanic ethnicity, and primary cause of ESRD. The adjusted mortality rates for incident cohorts are calculated using similar methods as discussed in the methods section on Reference Table H: Mortality and Causes of Death.

**Generalized Linear Models**

**Generalized Linear Model for Mortality Rates**

We use the generalized linear model with log link and Poisson distribution to calculate mortality and first transplant rates for prevalent patients. While rates are reported for a year, data from the previous two years with different weights are also used to improve the stability of the estimates.

The generalized linear model is fitted in SAS using PROC GLIMMIX. Models used to calculate adjusted rates incorporated age (categorical), ethnicity, race, sex, diabetes status (unless stratified by diabetes) and year, and all the two-way interaction terms (not between race and ethnicity). Models in the “_adj” worksheets also adjusted for vintage and all the two-
way interaction terms (but, not between race and ethnicity).

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. Standard errors for the estimated rates were obtained using the bootstrap method.

The adjusted mortality rates for prevalent cohorts in Reference Table H: Mortality and Causes of Death are calculated using direct standardization and based on the category-specific mortality rates from the generalized linear models.

**Generalized Linear Model for Hospitalization Rates**

In this ADR, Reference Table G: Morbidity and Hospitalization presents rates of total admissions and hospital days. We use a generalized linear model with log link and Poisson distribution; the model includes age, sex, race, primary cause of ESRD, and their two-way interactions.

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

**Standardized Mortality Ratios**

The standardized mortality ratio (SMR) compares the mortality of a group of patients relative to a specific norm, or reference, after adjusting for some important risk factors. For example, the dialysis chain-level SMR is used to compare mortality in prevalent dialysis patients — after adjusting for age, race, ethnicity, sex, DM, duration of ESRD, nursing home status, patient comorbidities at incidence, and BMI at incidence in each dialysis chain. Qualitatively, the degree to which the facility’s SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the national death rates for patients with the same characteristics as those in the facility. For example, an SMR=1.10 would indicate that the facility’s death rates typically exceed national death rates by 10% (e.g., 22 deaths observed where 20 were expected, according to the facility’s patient mix). Similarly, an SMR=0.95 would indicate that the facility’s death rates are typically 5% below the national death rates (e.g., 19 observed versus 20 expected deaths). An SMR=1.00 would indicate that the facility’s death rates equal the national death rates, on average. Note that if multiple years are included in fitting the model, the interpretation of the SMR for a particular year is different depending on whether calendar year is included in the model. If calendar year is included as an adjustment, the SMR for a particular year compares facility outcomes to the national average rates for that particular year. On the other hand, if calendar year is not included, the comparison is to the national rates over the entire period included in fitting the model.

**Method of SMR Calculation**

The SMR is designed to reflect the number of deaths for the patients at a facility, relative to the number of deaths that would be expected based on overall national rates and the characteristics of the patients at that facility. Specifically, the SMR is calculated as the ratio of two numbers; the numerator (“observed”) is the actual number of deaths, excluding deaths due to abused drugs and accidents unrelated to treatment, over a specified time period. The denominator (“expected”) is the number of deaths that would be expected if patients at that facility died at the national rate for patients with similar characteristics. The expected mortality is calculated from a Cox model (Cox, 1972; SAS Institute Inc., 2004; Kalbfleisch and Prentice, 2002; Collett, 1994). The model used is fit in two stages. The Stage I model is a Cox model stratified by facility and adjusted for patient characteristics. This model allows the baseline survival probabilities to vary between strata (facilities), and assumes that the regression coefficients are the same across all strata. Stratification by facility at this stage avoids biases in estimating regression coefficients that can occur if the covariate distributions vary substantially across centers. The results of this analysis are estimates of the regression coefficients in the Cox model and these provide an estimate of the relative risk for each patient. This is based on a linear predictor that arises from the Cox model, and is then used as an offset in the Stage II model, which is unstratified and includes...
an adjustment for the race-specific age-adjusted state population death rates.

**Standardized Hospitalization Ratios**

The Standardized Hospitalization Ratios (SHR) for Admissions is designed to reflect the number of hospital admissions for the patients at a dialysis facility, relative to the number of hospital admissions that would be expected based on overall national rates and the characteristics of the patients at that facility. Numerically, the SHR is calculated as the ratio of two numbers: the numerator (“observed”) is the actual number of hospital admissions for the patients in a facility over a specified time period, and the denominator (“expected”) is the number of hospital admissions that would have been expected for the same patients if they were in a facility conforming to the national norm.

The denominator of the SHR stems from a proportional rates model (Lawless and Nadeau, 1995; Lin et al., 2000; Kalbfleisch and Prentice, 2002). This is the recurrent event analog of the well-known proportional hazards or Cox model (Cox, 1972; Kalbfleisch and Prentice, 2002). To accommodate large-scale data, we adopt a model with piecewise constant baseline rates (e.g., Cook and Lawless, 2007) and the computational methodology developed in Liu, Schaubel, and Kalbfleisch (2012). The modeling process has two stages. At Stage I, a stratified model is fitted to the national data with piecewise-constant baseline rates, stratification by facility and adjusting for age, sex, DM, duration of ESRD, nursing home status, comorbidities at incidence, BMI at incidence, and calendar year. The baseline rate function is assumed to be a step function with break points at 6 months, 1 year, 2 years, 3 years, and 5 years since the onset of dialysis. This model allows the baseline hospitalization rates to vary between strata (facilities), but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated. The stratification on facilities is important in this phase to avoid bias due to possible confounding between covariates and facility effects. At Stage II, the relative risk estimates from the first stage are used to create offsets, and an unstratified model is fitted to obtain estimates of an overall baseline rate function.

**Expected Remaining Lifetimes**

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

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

**Half-lives (Median Time)**

**Conditional Half-life**

The conditional half-life is conditional on having survived a given period of length T₀, without the event, the point at which 50% of patients who survived the given period remain alive. In other words, it is the median remaining lifetime conditional on surviving a given period T₀.

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

\[
\mu = \frac{t₁ - t₀}{\ln(S(t₂)) - \ln(S(t₁))}
\]

the estimate of the conditional half-life = \(\mu \cdot \ln(2)\).

This method can be used only when the hazard is a constant after \(t₀\) and \(t₁\) is chosen to be big enough to obtain a stable estimate of \(\ln(S(t₀)) - \ln(S(t₁))\).
**Mapping Methods**

Throughout the ADR, data in maps and graphs are unadjusted unless otherwise noted. 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.

**References**


Lin DY, Wei LJ, Yang I, Ying Z. Semiparametric regression for the mean and rate functions of


Merriman K, Asper FM. Differences in how the Medicare 5% files are generated. Minneapolis, MN: Research Data Assistance Center, University of Minnesota; March 2007 [ResDAC Publication Number TN-011].


