USRDS
UNITED STATES RENAL DATA SYSTEM

Volume 2: ESRD Analytical Methods

Table of Contents

Volume 2: ESRD Analytical Methods....545
Introduction....547
Data Sources....547
- History of CMS Data Collection....547
- CROWNWeb....548
- CMS Medicare Enrollment Database (EDB)....548
- ESRD Medical Evidence Form (CMS 2728)....548
- ESRD Death Notification Form (CMS 2746)....549
- Annual Facility Survey (CMS 2744)....549
- Organ Procurement and Transplantation Network Database (OPTN)....549
- Medicare ESRD Claims Files....550
- Medicare Prescription Drug Event File (PDE)....550
- Medicare 5% Standard Analytical Files (SAF)....550
- CMS Dialysis Facility Compare Data....551
- CDC National Surveillance Data....551
- United States Census....551
- Optum Clinformatics™ Data Mart Database (OptumInsight, Eden Prairie, MN)....552

Database Definitions....553
- Identifying ESRD Patients....553
- Death Date Determination....554
- Transplant Dates....554
- Graft Failure....554
- Medicare and Non-Medicare Patients....554
- Lost to Follow-up Methodology....556
- Serum Albumin Data....556
- Modalities....556
- Payers....557
- Primary Cause of Renal Failure....558
- Race and Ethnicity....560

Analytical Methods Used in the ESRD Volume 561
Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities 561
Chapter 2: Clinical Indicators and Preventive Care 562
Chapter 3: Vascular Access 568
Chapter 4: Hospitalization 569
Chapter 5: Mortality 572
Chapter 6: Transplantation 574
Chapter 7: ESRD Among Children, Adolescents, and Young Adults 576
Chapter 8: Cardiovascular Disease[claims] 578
Chapter 9: Medicare Expenditures for Persons with ESRD[claims] 583
Chapter 10: Prescription Drug Coverage in Patients With ESRD[claims] 583
Chapter 11: International Comparisons 586
Chapter 12: USRDS Special Study Center on End-of-Life Care for Patients With ESRD 587
ESRD Reference Table Methods 587
Reference Tables A: Incidence and B: Prevalence 587
Reference Table C: Patient Characteristics 591
Reference Table D: Treatment Modalities 592
Reference Table E: Transplantation Process 593
Reference Table F: Transplantation: Outcomes 594
Reference Table G: Morbidity and Hospitalization[claims] 594
Reference Table H: Mortality and Causes of Death 598
Reference Table I: Patient Survival 599
Reference Table J: Providers 599
Reference Table K: Medicare Claims Data[claims] 600
Reference Table L: Vascular Access[claims] 601
Reference Table M: Census Populations 602
Reference Table N: International Comparisons 602
Statistical Methods 603
Methods for Calculating Rates 603
Methods for Adjusting Rates 604
Survival Probabilities and Mortality Rates 605
Generalized Linear Models 606
Standardized Mortality Ratios 606
Standardized Hospitalization Ratios[claims] 607
Expected Remaining Lifetimes 607
Median Time (Half-Life) 607
Mapping Methods 608
References 608

Introduction

The ESRD Analytical Methods chapter describes the data, analytical, and statistical methods for Volume 2 of the Annual Data Report (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, we report on data through December 31, 2015. Some of the analyses depend on Medicare Claims data, therefore careful construction of appropriate denominators based on Medicare enrollment and primary payer status is required. These chapters and reference tables are marked with "[CLAIMS]" for easy identification. 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*.

Data Sources

The United States Renal Data System (USRDS) maintains a database of the medical and demographic characteristics of all end-stage renal disease (ESRD) patients who are Medicare beneficiaries. As the ESRD population is typically entitled to Medicare (although Medicare is not necessarily the primary payer), the primary data source for this database is the Centers for Medicare & Medicaid Services (CMS).

These data include information on ESRD incidence, prevalence, morbidity, mortality, and related biochemical laboratory results. Also incorporated are Medicare claims for care received in inpatient (IP), outpatient (OP, including dialysis), skilled nursing facility (SN), home health agency (HH), and hospice (HS) settings. This information is complemented by details of physician/supplier services (PS), treatment histories (useful for modality determination), and payer histories (essential for determining denominators for Medicare claims data as shown below), modality events, and provider characteristics.

History of CMS Data Collection

This section summarizes the history of federally organized data collection for U.S. ESRD patients.

In October 1972, ESRD patients became eligible for health insurance coverage through the Medicare Program (Public Law 92-603, expansion of the Social Security Act [U.S. Government Publishing Office, 1972]). Soon after, the development of computer systems to manage the data generated from the new ESRD program began.

In 1977, the Health Care Financing Administration (HCFA) was established to oversee Medicare's financing and claims processing. To organize and assure quality of medical care, collect data, and adjudicate patient grievances, HCFA created 18 regional ESRD Networks.

In June of 1978, Public Law 95-292 facilitated significant improvements to ensure cost-effective quality of care in the ESRD program. The ESRD Program Management and Medical Information System (PMMIS) was established to provide medical and cost information for ESRD program analysis, policy development, and epidemiologic research (Rettig and Levinsky, 1991; CMS Fact Sheet, 2012).

Data were compiled from Medicare claims and ESRD-specific data forms: the Medical Evidence form (CMS 2728), the Death Notification form (CMS 2746), and the Facility Survey form (CMS 2744). Initially 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 certification, and a new Medical Evidence form was introduced.

Throughout the 1980s, efforts continued to create a comprehensive ESRD registry with reporting beyond that which the PMMIS provided. The Omnibus Budget Reconciliation Act of 1986 called for the Department of Health and Human Services to establish a "national end-stage renal disease registry". A Request for Proposal was issued for the development of the United States Renal Data System (USRDS). The contract was awarded in May 1988 to the Urban Institute by NIDDK, with a subcontract to the University of Michigan, and the first USRDS Annual Data Report on the ESRD population was released in 1989.

In 1995, HCFA replaced its Medicare ESRD Support Subsystem with the Renal Beneficiary and Utilization System (REBUS). Also in 1995, non-Medicare patients were included in the database as the ESRD Medical Evidence form (CMS 2728) was made mandatory for all ESRD patients.

In 2001, HCFA was renamed the Centers for Medicare and Medicaid Services.

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.

SIMS collected the CMS Medical Evidence, Death Notification, and Facility Survey forms, and 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. SIMS was replaced by CROWNWeb in 2012.

CROWNWeb

The Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) is a web-based data collection system that captures clinical and administrative data from Medicare-certified dialysis facilities for all ESRD patients in the U.S. This system was implemented nationally in May 2012. In addition to replacing the existing 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.

CMS Medicare Enrollment Database (EDB)

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, employer group health plan 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 enrolled in Medicare, reclassifies existing 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 revised 1995 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 included new data collection methods and new variables. The revision allows users to specify whether the Medicare registration is initial (new ESRD patient), a 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 completed for the same patient. Data fields for nephrologist care, dietitian care, and access type were added, indicating their respective time intervals relative to ESRD onset. Data on the laboratory values hematocrit, creatinine clearance, BUN, and urea clearance were no longer collected. Added laboratory values were hemoglobin A1c (HgbA1c) and lipid profiles (total cholesterol, low-density lipoprotein, high-density lipoprotein, and triglycerides). Additional fields relate to whether patients have been informed of transplant options, and if not, why not, and discussed donor type.

Effective in October 2015, CMS updated the 2728 form with ICD-10-CM codes to reflect "primary cause of renal failure" (Field 15). ICD-10-CM codes provide more diagnoses and procedure detail as compared to those of ICD-9-CM, resulting in a better

understanding of the patient's health. In addition to updating the form, CMS implemented options of "<6 months" for Field 18, "Prior to ESRD therapy".

The Medical Evidence form is the only reliable group source of information about the cause of a patient's ESRD. Because the list of causal diseases has been revised, the USRDS stores the diagnosis codes from each version so that detail is not lost through conversion of one set of codes to another.

Most ESRD patients have only one Medical Evidence form completed during their entire ESRD treatment period. Multiple forms may be submitted, however, especially for transplant patients. Medicare entitlement for transplant patients with a functioning graft ends after three years 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.

All versions of the CMS 2728 form (2015, 2005 and 1995) 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 an ESRD patient. According to CMS policy this form must be submitted by dialysis or transplant providers within 30 days of a patient's death. It 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 the USRDS ESRD database, 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 data due to the prohibitive cost of obtaining this for the entire 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 died during the year. Both Medicare and non-Medicare end-of-year patients are counted. While AFS files do not contain 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. Upon publication of 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. Since 2012, the USRDS has received the facility survey data directly from CROWNWeb.

Organ Procurement and Transplantation Network Database (OPTN)

In the early 1980s, CMS began collecting data on all Medicare-paid 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 all organ transplants, not just those paid for by Medicare.

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.

Medicare ESRD Claims Files

The CMS ESRD Claims Standard Analysis Files (SAFs) contain data from final action claims for medical services provided to Medicare beneficiaries, in which all adjustments have been resolved. To compile institutional claims, the USRDS uses the following 100% SAFs:

- Inpatient (IP)
- Outpatient (OP)
- Skilled Nursing Facility (SN)
- Home Health Agency (HH)
- Hospice (HS)

For non-institutional claims, the USRDS uses the following 100% SAFs:

- Physician/Supplier (PS)
- Durable Medical Equipment (DME)

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 they are finalized at 18 months, after which files are frozen and will not include late arriving claims. The data lag for the ascertainment of death and graft loss is about nine months. The annual files used in the ADR are approximately 98% complete. The USRDS 2017 SAF includes all claims up to December 31, 2015.

Medicare Prescription Drug Event File (PDE)

In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), amending the Social Security Act by adding the Part D prescription benefit under Title XVIII. With this new Part D coverage, health plans must submit a summary record called the prescription drug event (PDE) to CMS whenever a Medicare beneficiary fills a prescription. Each drug is identified by a National Drug Code (NDC). The prescription record also contains 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 2017 ADR includes 2006-2015 PDE data.

Medicare 5% Standard Analytical Files (SAF)

The CMS 5% general Medicare SAFs are a random sample of 5% of the entire Medicare population. These 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). Once in the sample, a beneficiary will remain a part of all future data files until death or a change in the HIC number. The sample design has the effect of creating a built-in longitudinal panel dataset. Since 2012, the USRDS has received the 5% sample from the CMS Chronic Conditions Warehouse.

The SAFs include the Master Beneficiary Summary File (formerly the Denominator file), that contains 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, distinguished by the type of medical service received—inpatient, outpatient, home health agency, hospice, or skilled nursing facility. Physician and Supplier claims (also referred to as Carrier Claims) contain two separate files for durable medical equipment and 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. Table 14.1 shows the codes used to identify CKD and its stages. The total Medicare 5% sample is used to develop total Medicare cost and utilization data for comparison to the diagnosis-specific cohorts.

vol 2 Table 14.1 ICD-9-CM and ICD-10-CM diagnosis codes used to define chronic kidney disease in the health insurance claim data files

Condition name	ICD-9-CM codes	ICD-10-CM codes
Chronic kidney disease (CKD)	016.0; 095.4; 189.0,189.9; 223.0; 236.91; 250.4; 271.4; 274.1; 283.11; 403; 404; 440.1; 442.1; 477.3; 572.4; 581-588; 591; 642.1; 646.2; 753.12-753.19; 753.2; 794.4	A18.11, A52.75, B52.0, C64.x, C68.9, D30.0x, D41.0x-D41.2x, D59.3, E08.2x, E09.2x, E10.2x, E10.65, E11.2x, E11.65, E13.2x, E74.8, I12.xx, I13.0, I13.1x, I13.2, K76.7, M10.3x, M32.14, M32.15, N01.x-N08.x, N13.1, N13.1x-N13.39, N14.x,N15.0, N15.8, N15.9, N16, N17.x, N18.1-N18.5, N18.8, N18.9, N19, N25.xx, N26.1, N26.9, O10.4xx, O12.xx, O26.83x, O90.89, Q61.02, Q61.1x-Q61.8, Q26.0-Q26.39, R94.4
Staging of chronic kidney disease		
Stage 1	585.1	N18.1
Stage 2	585.2	N18.2
Stage 3	585.3	N18.3
Stage 4	585.4	N18.4
Stage 5	585.5 or 585.6 with no CMS 2728 form	N18.5
Stage unknown or unspecified	Patient only has no claims with codes 585.1-585.6 but has: 016.0; 095.4; 189.0,189.9; 223.0; 236.91; 250.4; 271.4; 274.1; 283.11; 403; 404; 440.1; 442.1; 477.3; 572.4; 581-584; 585.9; 586-588; 591; 642.1; 646.2; 753.12-753.19; 753.2; 794.4	Patient has no claims with codes N18.1-N18.6 but has: A18.11, A52.75, B52.0, C64.x, C68.9, D30.0x, D41.0x-D41.2x, D59.3, E08.2x, E09.2x, E10.2x, E10.65, E11.2x, E11.65, E13.2x, E74.8, I12.xx, I13.0, I13.1x, I13.2, K76.7, M10.3x, M32.14, M32.15, N01.x-N08.x, N13.1, N13.1x-N13.39, N14.x,N15.0, N15.8, N15.9, N16, N18.8, N18.9, N19, N25.xx, N26.1, N26.9, O10.4xx, O12.xx, O26.83x, O90.89, Q61.02, Q61.1x-Q61.8, Q26.0-Q26.39, R94.4

Source: ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification. ICD-9-CM diagnosis codes can have up to five digits with a decimal point between the 3rd and 4th digit, while ICD-10-CM codes have seven digits. Codes listed with three digits include all existing 4th and 5th digits, and those listed with four digits include all existing 5th digits.

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. This included 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. The information was aggregate and not patient-specific. Because the CDC terminated this program in 2003, the last surveillance report was for 2002 data. The CDC did not conduct a survey in 1998.

United States Census

The U.S. population data are obtained from the 2000 and 2010 U.S. Census and 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.

Both intercensal and postcensal estimate datasets are available at http://www.cdc.gov/nchs/nvss/bridged_race/data_documentation.htm. The USRDS summarizes this data by racial grouping, at state and national levels.

Optum Clinformatics™ Data Mart Database (OptumInsight, Eden Prairie, MN)

The Optum Clinformatics™ Data Mart provides paid medical and prescription claims and enrollment information for participants in commercial insurance plans and Medicare Advantage plans of a large U.S. managed care health insurance company. The data are purchased from OptumInsight and include plan members enrolled in both a medical and a prescription plan. All areas of the country are represented in the data. With our data delivery in 2017, OptumInsight expanded the number of diagnosis and procedure codes in the MEDICAL claims table to 25 from the previous five diagnosis codes and three procedure codes. Because of this, our analyses detect more disease conditions and procedures than in the 2016 ADR.

The Optum Clinformatics™ data license requires that their data not be merged with any other files, so we are unable to match these individuals with the USRDS ESRD databases to comprehensively identify ESRD patients. Therefore, we assign these individuals a first service date for ESRD as the earliest date of either the first claim with a diagnosis of ESRD, a procedure code for outpatient dialysis, or a diagnosis related group (DRG) code for a kidney transplant surgery. See Table 14.2 for specific code values. We present Optum Clinformatics™ data from 2005 through 2015 in the 2017 ADR.

To comply with the Health Insurance Portability and Accountability Act of 1996 (HIPPA) and prevent the re-identification of individuals in the database, certain combinations of sensitive data elements are not permitted. OptumInsight provides the data as different "views", each containing a limited amount of sensitive data. For this report, we used the Date of Death (DOD) view of the data; detailed geographic and socio-economic data are not available in the files, but date of death is included. The other available data views do not contain death date. Enrollment and member information, such as year of birth, sex, race/ethnicity, state of residence, and plan participation are contained in the MEMBER and MEMBER_DETAIL data tables. All services for both inpatient and outpatient care are located in the MEDICAL claims data table, with the confinement ID variable indicating inpatient institutional claims. With the admission and discharge dates from the inpatient institutional claims, we then identify all medical services performed for the patient during that period as inpatient services.

vol 2 Table 14.2 ICD diagnosis, HCPCS procedure, and DRG codes used to define ESRD in the Optum Clinformatics™ dataset

Type of code		Code values
ICD-9-CM diagnosis codes		585.6, 996.81, V42.0, V45.1, V56.0, V56.1, V56.2, V56.3, V56.31, V56.32, V56.8, E879.1
ICD-10-CM diagnosis codes		N18.9, T86.10-T86.13, T86.19
HCPCS codes		90935, 90937,90940, 90945, 90947, 90951-90970, 90989, 90993, 90997, 90999; *codes from earlier years: 90918-90925*
DRG codes	Prior to FY2007:	302,512
	FY2007-present:	652,008

Abbreviations DRG, diagnosis related group, FY, fiscal year (10/1/06 to 9/30/07), HCPCS, Healthcare Common Procedure Coding System, ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification.

The MEMBER and MEMBER_DETAIL tables are processed to create an enrollment table by deleting observations with data inconsistencies and combining enrollment periods with a non-coverage gap of less than one month. Enrollment observations are dropped if: (1) the year of birth variable, *yrdob*, is missing or zero, (2) the year of the plan coverage effective date, *eligeff*, is before the year of birth, (3) the year of plan coverage effective date is after the year of the death date, (4) the coverage ending date, *eligend*, is the same as or earlier than the coverage start date, or (5) the member has more than one year of birth reported and these differ by more than one year. Observations from MEMBER_DETAIL with overlapping enrollment periods (defined as *eligeff* through *eligend*) are combined into one. Observations where the gap between the end date (*eligend*) of the first period (i.e., observation) and the start (*eligeff*) of the second period is less than one month are also combined, as beneficiaries with brief coverage lapses do not present as significantly different than those with continuous coverage.

Date of death information is provided as month and year only, and not a specific date. We set all deaths to the first day of the reported month to create a specific death date from the month and year combination. Insurance claims do not have information on death unless the death occurred during a covered inpatient stay as identified through the discharge status (*dstatus*). The insurance company may only be informed that the member's coverage has ended. However, the Optum Clinformatics™ Data Mart is augmented with data from the Social Security Death Master File (SSDMF). In November of 2011, some states stopped reporting death information to the SSDMF, causing a 30% drop in the number of death records contained in the database (OptumInsight 2015). This may overstate the survival statistics as more deaths will go undetected. For this reason, we do not present analysis of mortality rates for the Optum Clinformatics™ dataset, although other chapters do use date of death to censor time to event analyses.

Optum Clinformatics™ information on expenditures for medical services is included for the first time in the 2017 ADR, as are analyses of prescription drug usage. To account for differences in pricing across health plans and provider contracts, OptumInsight applies standard pricing algorithms to the claims data in the Optum Clinformatics™ Data Mart. These algorithms are designed to create standard prices that reflect allowed payments across all provider services. Standard pricing amounts are included in the MEDICAL and the RX claims tables.

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. Renal providers must immediately complete a Medical Evidence form for all ESRD patients; this registers them in the CMS ESRD database, and allows them 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, when there is other evidence of chronic dialysis that meets the criteria of ESRD, or upon registering as a candidate for kidney transplant though the OPTN. The identification of ESRD patients does not rely on the International Classification of Diseases (ICD) codes for ESRD.

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 often are not included in the CMS ESRD database.

ESRD first service date

The ESRD first service date is the single most important data element in the USRDS database; 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, or
- the first Medicare dialysis claim.

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

- If (1) the CROWNWeb event and Medical Evidence form agree (within 30 days of each other) and (2) 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 (1) the Medical Evidence form date is one year earlier than the first CROWNWeb event date, and (2) 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 next most critical piece of information in the USRDS 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, and inpatient claims. Because multiple sources report death information for the same patient, an individual may have several reported dates. For these patients, the accepted death date is based on the priority order below:

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

Transplant events can be identified from the OPTN data, Medical Evidence forms indicating transplant as the initial modality, CROWNWeb transplant events, and inpatient claims. Each transplant event found in the Transplant file of the USRDS Core SAF dataset is a unique event. To resolve any conflicts among the data sources and to 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.
- 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.
- After 1994, all transplant events found in OPTN files are used.
- Additionally, transplant events for patients who are reported incident on the Medical Evidence form are used if the date is at least 30 days before or after a previously accepted transplant event. Transplant events found in CMS inpatient claims records are also included, as are transplants found in the CROWNWeb patient events data.

Graft Failure

We assume a graft failure date is correct as reported in the OPTN transplant follow-up or REMIS identification file 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, or
- 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% of individuals are eligible for Medicare. Those who are younger than 65 tend to

have more serious health conditions than do others their age in the general population as they become 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. 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. All ESRD patients, regardless of their Medicare Eligibility status, are included in the CROWNWeb system.

The USRDS recognizes that non-Medicare patients are true ESRD patients and should be included in patient counts for incidence, prevalence, and treatment modality, as well as in mortality and transplant rate calculations. Calculations of hospitalization statistics or any outcomes derived from Medicare claims (e.g., 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 in the USRDS database fulfills Medicare primary payer criteria at any given time. For this reason, the ADR analyses construct a denominator cohort using the PAYHIST file. See the *Payers* section below for more details.

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. We use this history to identify incident and prevalent cohorts and to determine censoring points and outcomes for observational studies.

Vol 2 Table 14.3 CROWNWeb events

Event
New ESRD Patient
Transfer In
Restart
Dialysis after Transplant Failed (at Dialysis Facility)
Transfer Out for a Transplant
Transfer Out
Discontinue
Death
Recover Function
Lost to Follow-Up
Modality Change
Transplant
Continuing
Transplant Failure (at Transplant Facility)
Interruption in Service
Resume Service

The CROWNWeb event database is the primary source of the modality sequence file, and 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 do not appear in the CROWNWeb events file, whose only event is "New ESRD Patient", or who have gaps in facility assignment, the Medicare dialysis claim file is used.

For "Transfer Out" and "Transfer Out for a Transplant" events followed by gaps of seven days or more, claims falling in those gaps are included, unless the "Transfer Out for a Transplant" event has a corresponding transplant or transplant failure event within 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, 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", "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 are also treated as lost to follow-up, beginning one year after the first service date. A number of different events can result in the lack of dialysis data, and eventual reclassification of a patient as lost to follow-up, including:

- recovery of renal function,
- no longer a resident of the United States, or
- the patient has died, but this was not reported to the Social Security Administration or to CMS.

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 who had 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 data sources are evaluated in the following order: CROWNWeb data, Medical Evidence form, claims data, and transplant data. The modality indicated in CROWNWeb and the Medical Evidence form may be temporary, as patients often change to a new modality during the first 90 days of treatment; it can be difficult to track modality during this time. Patients aged 65 and older or those with disabilities have Medicare claims in the first 90 days that contain revenue codes designating modality. Most patients younger than 65 and in employer group health plans (EGHP), 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 outcomes from their data should be viewed with caution. These patients are not considered 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.

60-day Stable Modality Rule: Treatment History File

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.

Recovered Renal Function (RRF)

A new modality event—recovered renal function (RRF)—was introduced in the 2007 ADR. Prior to the 2016 ADR, this event required the recovery of function to occur within 180 days of the first service date and to persist for at least 90 days. Starting with the 2016 ADR, every indication of 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; they are defined in the chapter-specific analytical methods sections that follow this section.

Payers

For analyses using claims data, it is important to know whether Medicare is the primary payer (MPP) for the beneficiary, since claims are only filed with Medicare for those beneficiaries. Information on payers is obtained primarily from the Medicare Enrollment Database (EDB). We also examine Medicare outpatient claims to find beneficiaries with at least three consecutive months of dialysis treatment covered by Medicare. Regardless of their status in the EDB, these patients are designated as having MPP coverage.

From these two data sources we construct a Payer Sequence file to provide payer history, identifying 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, 2015.

Payer status information prior to the start of ESRD (ESRD first service date) is available from the back-casted Payer Sequence file. The Pre-ESRD Payer Sequence file is similar to the standard ESRD Payer Service file, except it begins at the first evidence of Medicare enrollment from the EDB, rather than ESRD first service date. The Pre-ESRD payer sequence ends the day before the ESRD first service date.

Constructing denominators based on payer history is essential for analyses using Medicare claims-defined outcomes—any outcome using a specific diagnostic or procedure code. International Classification of Diseases (ICD) diagnosis codes are used for all claims, while ICD procedure codes are used for inpatient claims. Healthcare Common Procedure Coding System (HCPCS) codes are used in the Physician Supplier claims and the revenue portion of the institutional claims.

Only a minority of dialysis patients have Medicare primary payer status when they start dialysis, which increases to about 60% of patients 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. 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 during a given period of time as MPP (established in the SAF PAYHIST), Medicare as secondary payer (MSP) with an employer group health plan (EGHP), MSP non-EGHP, Medicare Advantage (Medicare + Choice), Medicare or Medicaid only, or a combination of payers (see the *Researcher's Guide to the USRDS Database* for more information).

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 ICD-9-CM and ICD-10-CM codes.

vol 2 Table 14.4 Diagnosis codes for primary cause of ESRD

Primary Cause of ESRD	ICD-9-CM or CMS 2728 codes	ICD-10-CM codes
Diabetes	250.00, 250.01, 250.40, 250.41	E10.22, E10.29, E10.9, E11.21, E11.22, E11.65, E11.9
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	I10, I12, I12.0, I12.9, I13.10, I13.2, I15.0, I15.8, 175.81
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, 710fhc.0, and 710.1	N00.8, N01.9, N02.8, N03.0, N03.1, N03.2, N03.3, N03.4, N03.5, N03.6, N03.7, N03.9, N03.9, N04.0, N04.1, N04.2, N04.3, N04.4, N04.5, N04.6, N04.7, N04.8, N04.9, N05.1, N05.9, N07.0
Cystic kidney	583.9, 753.1, 753.13, 753.14, and 753.16	Q56.0, Q61.91, Q61.2, Q61.3
Other urologic	223.0, 223.9, 274.1, 590.0, 591.0, 592.0, 592.9, 599.0, and 599.6	D30.00, D30.01, D30.02, D30.9, M10.30-M10.39, N13.1, N13.2, N13.30, N13.39, N13.9, N20.0, N20.2, N20.9, N22, N39.0
Other known 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, 590.9, 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	C64.1, C64.2, C64.9, C65.1, C65.2, C65.9, C68.9, C82.53, C82.55, C82.56, C84.93, C84.95, C84.96, C84A3, C84A5, C84A6, C84Z3, C84Z5, C84Z6, C85.13, C85.15, C85.16, C85.23, C85.25, C85.26, C85.83, C85.85, C85.86, C85.93, C85.95, C85.96, C86.2, C86.3, C88.0, D57.00-D57.20, D57.811-D57.819, E20.1, E72.00, E72.02, E72.04, E72.09, E72.52, E72.53, E74.4, E74.8, E75.21, E75.22, E75.240-E75.3, E77.0-E77.9, E78.71, E78.72, E83.59, I76, K76.7, M05.412, M05.531-M05.59, M05.70, M05.711-M06.09, M06.20-M06.639, M06.80-M06.9, M1A.10X0, M1A.10X1, M1A.1110-M1A.1791, M1A.18X0, M1A.18X1. M1A.19X0, M1A.19X1, M31.1, M35.4, M62.20-M62.28, M62.89, M72.8, N00.8, N03.0, N03.8, N05.0, N05.1, N05.6-N06.1, N06.6-N06.8, N07.0, N07.1, N07.6-N07.8, N14.0-N15.0, N15.8, N15.9, N17.0-N17.2, N20.0, N28.82, N28.89, N28.9, N29, N39.0, O08.4, Q60.0-Q606, Q62.0-Q62.2, Q63.0-Q63.9, Q79.4, Q79.51, Q85.1, Q87.2, Q87.3, Q87.5, Q87.81, Q87.89, Q89.8, T39.1X1A-T39.1X4A, T39.91XA-T3994XA, T50.8X1A-T50.8X4A, T52.4X1A-T528X4A, T5291XA-T5294XA, T56.0X1-T56.0X4, T86.00-T86.49, T86.810-T86.819, T86.830-T86.839, T86.850-T86.899
Unknown cause	239.5, 428.0, 500, 582.0, 586.0, 589.0, 589.1, 589.9, 592.1, 593.1, 799.9, 999.9, and ICD-9-CM codes not covered by the causes listed above	D49.5, I50.20-I50.9, J60, N03.2, N13.2, N19, N20.1, N20.2, N27.0-N27.9, N28.81, R69, R99, T81.81XA, T88.4XXA, T88.7XXA, T88.8XXA, T88.9XXA
Missing cause	no code listed	no code listed

Abbreviations: CMS 2728, Medical Evidence form, ESRD, end-stage renal disease, ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Edition.

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. The Medical Evidence form asks patient race and Hispanic ethnicity in two separate questions, so they can be treated independently or combined. Patient ethnicity became a required field on the 1995 revision of the Medical Evidence form, but because the form did not go into effect until midway through 1995, data for that year are incomplete. Therefore, information on Hispanic patients is presented starting in 1996. The non-Hispanic category includes all non-Hispanics, but does not include those of unknown ethnicity, which is a separate category.

Because of the small number of ESRD patients of some races, and the specifics of race categorization in the U.S. Census data, we present our results with the racial populations of White, Black/African American, American Indian or Alaska Native, Asian, Native Hawaiian or Pacific Islander, and Other or Multiracial. We will present data on patients of other races 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 highest to lowest priority):

- 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 14.5 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.

vol 2 Table 14.5 Race categories used in the USRDS ESRD database data sources

USRDS race categories	CROWNWeb patient list	Medical Evidence form	REMIS	Medicare Enrollment Database
White	White; Mid-East Arabian	White; Mid-East Arabian	White; Mid-East Arabian	White
Black/African American	Black	Black	Black	Black
American Indian or Alaska Native	American Indian or Alaska Native	American Indian or Alaska Native	American Indian orAlaska Native	Native American
Asian	Asian; Indian Sub-Continent	Asian; Indian Sub-Continent	Asian; Indian Sub-Continent	Asian
Native Hawaiian or Pacific Islander	Pacific Islander	Pacific Islander	Pacific Islander	
Unknown	Unknown; Missing	Unknown; Missing	Unknown; Missing	Unknown; Missing
Other or Multiracial	Other or Multiracial	Other or Multiracial	Other or Multiracial	Other or Multiracial

The data sources for ethnicity are (from highest to lowest priority):

- Medical Evidence form
- CROWNWeb Patient list
- Clinical Performance Measures (CPM)
- 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 get 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. The methodologies used to create the figures and tables in Volume 2 are described below in the corresponding chapter of the *Analytical Methods Used in the ESRD Volume* section. When figure or table data are drawn directly from a particular reference table, please refer to the *ESRD Reference Table Methods s*ection for additional detail.

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

Incidence of ESRD: Counts, Rates, and Trends

Adjustments for the rates in this chapter were as follows:

- Overall rates (including those in the maps) were adjusted for age, sex, and race.
- Rates by age were adjusted for sex and race.
- Rates by race or ethnicity were adjusted for age and sex.
- Rates by primary cause of ESRD were adjusted for age, sex, and race.

Race has been standardized across the ADR, and this year the Native Hawaiian/Pacific Islander racial group is presented as separate from Asian. Direct adjustment was used as described in the *Methods* section of the chapter. Rates per million population used Census data that are now based on intercensal estimates; for details, see the section on the *United States Census* in the *Data Sources* section of this chapter.

Incidence rates are presented in Tables 1.1 and 1.2 and Figure 1.1, while Figure 1.2 shows the number of incident patients by modality. Figure 1.3 presents adjusted rates geographically by Health Service Areas (HSA).

For Figures 1.4-1.6, incidence rates were taken directly from Reference Table A.2(2). For details on the methods used and rate calculations, refer to the sections *Reference Tables A: Incidence and B: Prevalence* and *Statistical Methods,* both later in this chapter.

All maps were created using five years of data; results were suppressed for the HSAs with 10 or fewer total cases.

Prevalence of ESRD: Counts, Prevalence, and Trends

In the chapter, point prevalence was as of December 31, while period prevalence was reported for a calendar year. Annual period prevalent data thus consists both of patients who had the disease at the end of the year, and those who had the disease during the year and died before the year's end. Patients with a functioning transplant were counted as prevalent patients.

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

Prevalence adjustments in this chapter were the same as the corresponding incidence rates detailed above. Prevalence also used direct standardization and intercensal population estimates.

Statistics for Table 1.3, Figures 1.7, 1.10, and 1.12 were taken directly from Reference Table B. Specifically, prevalent cases correspond to those found in B.1 and prevalence rates correspond to those found B.2(2). Table 1.4 results were taken from Reference Table B.10 and special analyses. For details on the methods used and rate calculations, refer to the sections *Reference Tables A: Incidence and B: Prevalence* and *Statistical Methods,* both later in this chapter. Figure 1.8 data is found in *Reference Table D: Treatment Modalities*.

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 were not classified as lost to follow-up or as having recovered renal function (RRF). Unless noted otherwise, incident and point prevalent cohorts without the 60-day stable modality rule were used in these analyses. Treatment modalities are defined in Table 14.6.

vol 2 Table 14.6 ESRD treatment modality definitions

Modality	Description
Center Hemodialysis	Hemodialysis treatment received at a dialysis center
Center Self Hemodialysis	Hemodialysis administered by the patient at a dialysis center, usually combined with Center Hemodialysis
Home Hemodialysis	Hemodialysis administered by the patient at home; cannot always be reliably identified in the database
CAPD	Continuous Ambulatory Peritoneal Dialysis
CCPD	Continuous Cycling Peritoneal Dialysis
Peritoneal Dialysis	Includes intermittent peritoneal dialysis
Other Peritoneal Dialysis	Primarily intermittent peritoneal dialysis. This is a small group of patients, common among very young children
Uncertain Dialysis	A period in which the dialysis type is unknown of multiple modalities occur but do not last 60 days
Unknown Dialysis	A period in which the dialysis modality is not known such as in-hospital dialysis
Renal Transplantation	A functioning graft from either a living or deceased donor
Death	A category not appearing in the year-end modality tables, which report only on living patients. Often used as an outcome.
Larger Groupings	
Center Hemodialysis	Center hemodialysis and Center Self hemodialysis
Peritoneal Dialysis	CAPD, CCPD, Peritoneal Dialysis, Other peritoneal dialysis
Other/Unknown Dialysis	Uncertain dialysis, Unknown dialysis

Facilities began submitting patient data via CROWNWeb 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 1.7, 1.8, and 1.9, and Figures 1.17-1.20, laboratory values and treatment characteristics were derived from questions on the ESRD Medical Evidence form. All estimated glomerular filtration rate (eGFR) values were calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation from data acquired from the ESRD Medical Evidence form.

Chapter 2: Clinical Indicators and Preventive Care

Clinical Indicators

Figure 2.1 data were obtained from CROWNWeb clinical extracts for May 2016. The adequacy (Kt/V) analyses were restricted to patients at least 18 years old as of May 1, 2016. Patients must have been alive as of May 31, 2016, and must have had ESRD for at least one year as of the time of the measurement. If multiple measurements are available for a patient, the last one in the month was used. In Figure 2.1.b, all adult (aged 18 and older) patients who were on dialysis for at least 90 days as of May 1, 2016, and alive as of May 31, 2016, were included. If multiple hemoglobin (Hgb) measurements were available for a patient, the last one in the month was used. The categorical distributions of Hgb are shown for both HD and PD patients. In Figure 2.1.c, the hypercalcemia

measure was calculated as a 3-month rolling average for both HD and PD patients, who were alive as of May 31, 2016, and had ESRD for at least 90 days as of the time of measurement of an uncorrected serum calcium value.

Anemia Treatment by Modality[claims]

All of the findings in this section are based on Medicare claims data. The modality of the patient in each month was determined from the primary modality that was indicated on the claim for the Hgb, iron dose, and epoetin alfa (EPO) dose variables in the given month. For transfusion analyses, patients with at least one claim for HD or PD therapy were assigned to HD or PD in that month. Very few patients were treated with both modalities within the same month.

Dialysis claims were identified by revenue center codes 0800-0809, 0820-0889, and 0989. Hematocrit level was determined by value code 49 and hemoglobin by value code 48. EPO was identified using HCPCS codes J0885, J0886, and Q4081, and value code 68, darbepoetin by codes J0881 and J0882, epoetin beta by codes J0887, Q9972, and Q9973. Several types of iron were identified by HCPCS codes: sodium ferric gluconate (codes J2915 and J2916), iron dextran (J1750, J1751, J1752, and J1760), iron sucrose (J1755 and J1756), iron carboxymaltose (J1439 and Q9970), and ferumoxytol by (Q0139).

Hemoglobin levels are shown in Figures 2.2, 2.3, 2.8, and 2.9. Hemoglobin values were based upon the first reported claim in each month for HD patients (Figures 2.2-2.3) and PD patients (Figure 2.8-2.9). When Hgb levels were not available in claims data, any available hematocrit values were divided by three to serve as a proxy estimate. Patients were excluded in a given month if the Hgb level (or Hgb 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 2.2, 2.3, 2.8, and 2.9, 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 Hgb 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 2.2.d and 2.8.c, hemoglobin levels are also provided for all patients, with the same restrictions as in statement (2) above; these analyses were not limited to patients with an ESA claim within the given month.

Mean monthly EPO dose is shown for HD patients in Figure 2.2 and PD patients in Figure 2.8. To be included in the analysis sample, patients must have had an EPO claim in the given month, been 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 <250 units or >400,000 units per week; these criteria resulted in <0.001% of patients being excluded. Figure 1.1.a shows mean monthly EPO dose for those on erythropoetin alpha, Figure 2.2.b those on darbopoetin, and Figure 2.2.c those on pegylated (PEG)-EPO beta. Figure 2.2.d shows the percent of all patients with erythropeotin stimulating agent (ESA) use. Figure 2.3 shows categorical levels of Hgb for ESA using patients.

Intravenous (IV) iron use and IV iron dose are shown in Figures 2.4 (HD) and 2.10 (PD). The sample for monthly intravenous iron use contained patients on dialysis for 90 days or longer and who were 18 years or older at the start of the given month. For patients receiving IV iron during a month, the mean dose was calculated for the iron sucrose and ferrous gluconate they received. This analysis was restricted to those patients who had more than six but 18 or less IV iron sessions in a month. The permissible range of values considered for sucrose and ferrous gluconate were 50-1800 mg and 12.5-1800 mg.

The categorical distribution of iron store measures, transferrin saturation (TSAT) and serum ferritin for May 2014, May 2015, and May 2016, from CROWNWeb, are shown in Figures 2.5 (TSAT) and 2.6 (serum ferritin) for HD patients. Similar statistics for PD patients are shown in Figures 2.11 and 2.12. For Figure 2.5, the study cohort included dialysis patients receiving treatment for at least 90 days at the time of TSAT value measurement, who were 18 years or older as of May 1 of that year, and were alive through May 31. For each year, the latest non-missing TSAT value during March-May was used. For Figure 2.6, the same criteria apply to serum ferritin. Similar analyses were performed for PD patients. Figure 2.7.a shows the percentage of Medicare patients with one, two, three,

or four or more red blood cell transfusions per year from 2011-2015. 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. The numerator consisted of the total number of claims for transfusions a patient had in a given year. Patients' modality is the modality was determined by the first treatment of the year. Similarly, Figure 2.13.a shows the distribution of the number of red blood cell transfusions received by PD patients, by year.

The percentages of dialysis patients with one or more claims for red blood cell transfusions in a given month (2011-2015) are shown in Figures 2.7.b (HD) and 2.13.b (PD). For this calculation, the numerator consisted of dialysis patients with one or more red blood cell transfusion claims in a given month; the denominator included all patients having a claim for at least one session during the month and who were 18 years or older at the start of the month. Codes used to identify transfusions are shown in Table 14.7.

Mineral and Bone Disorder

Distributions of serum calcium levels from CROWNWeb data for HD and PD patients are shown in Figures 2.14 and 2.15 for May 2014, May 2015, and May 2016. Analyses for Figure 2.14 included HD patients with ESRD for at least one year at the serum calcium laboratory result, 18 years or older as of May 1 of that year, and were alive through May 31 of that year. Serum phosphorous analyses shown in Figure 2.16 used the same sample restrictions as defined above. Similar analyses were completed for PD patients, and are shown in Figures 2.15 and 2.17.

vol 2 Table 14.7 Transfusion codes identifying a red blood cell transfusion

Code	Code Type	Code Description
36430	HCPCS	Transfusion, blood or blood components
P9010	HCPCS	Blood (whole), for transfusion, per unit
P9011	HCPCS	Blood, split unit
P9016	HCPCS	Red blood cells, leukocytes reduced, each unit
P9021	HCPCS	Red blood cells, each unit
P9022	HCPCS	Red blood cells, washed, each unit
P9038	HCPCS	Red blood cells, irradiated, each unit
P9039	HCPCS	Red blood cells, deglycerolized, each unit
P9040	HCPCS	Red blood cells, leukocytes reduced, irradiated, each unit
P9051	HCPCS	Whole blood or red blood cells, leukocytes reduced, CMV-negative, each unit
P9054	HCPCS	Whole blood or red blood cells, leukocytes reduced, frozen, deglycerol, washed, each unit
P9056	HCPCS	Whole blood, leukocytes reduced, irradiated, each unit
P9057	HCPCS	Red blood cells, frozen/deglycerolized/washed, leukocytes reduced, irradiated, each unit
P9058	HCPCS	Red blood cells, leukocytes reduced, CMV-negative, irradiated, each unit
99.03	ICD-9	Other transfusion of whole blood; transfusion: blood NOS, hemodilution, NOS
99.04	ICD-9	Transfusion of packed cells
30233H1	ICD-10	Transfuse Nonaut Whole Blood in Peripheral Vein, Percutaneous Approach
30233N1	ICD-10	Transfuse Nonaut Red Blood Cells in Peripheral Vein, Percutaneous Approach
30233P1	ICD-10	Transfuse Nonaut Frozen Red Cells in Peripheral Vein, Percutaneous Approach
30243H1	ICD-10	Transfuse Nonaut Whole Blood in Central Vein, Percutaneous Approach
30243N1	ICD-10	Transfuse Nonaut Red Blood Cells in Central Vein, Percutaneous Approach
30243P1	ICD-10	Transfuse Nonaut Frozen Red Cells in Central Vein, Percutaneous Approach
30253H1	ICD-10	Transfuse Nonaut Whole Blood in Peripheral Artery, Percutaneous Approach
30253N1	ICD-10	Transfuse Nonaut Red Blood Cells in Peripheral Artery, Percutaneous Approach
30253P1	ICD-10	Transfuse Nonaut Frozen Red Cells in Peripheral Artery, Percutaneous Approach
30263H1	ICD-10	Transfuse Nonaut Whole Blood in Central Artery, Percutaneous Approach
30263N1	ICD-10	Transfuse Nonaut Red Blood Cells in Central Artery, Percutaneous Approach
30263P1	ICD-10	Transfuse Nonaut Frozen Red Cells in Central Artery, Percutaneous Approach

Data Source: USRDS ESRD Database. Abbreviations: CMV, cytomegalovirus, HCPCS, Healthcare Common Procedure Coding System, ICD-9/10, International Classification of Diseases, Ninth/Tenth Revision; Nonaut, Nonautologous, NOS, not otherwise specified.

Preventive Care[claims]

Figure 2.18 presents statistics on diabetic preventive care. The claims data analysis for this figure used a one-year entry period to determine the presence of diabetes, referred to as 'year one.' Patients were required to have started ESRD treatment at least 90 days prior to January 1 of year one. Patient cohort criteria included alive, with a valid birth date, residing in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, Medicare Parts A and B coverage with no Medicare Advantage participation, and not lost to follow up in both years one and two. Claims from year one were then searched for diagnoses indicating diabetes mellitus (DM). The presence of testing was ascertained in the following year (year two); tests were at least 30 days apart. Age was calculated at the end of year two.

Patients were 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. Table 14.8 shows the various diagnosis and procedure codes used to define each diabetes-care measure. Comprehensive diabetic care includes at least one hemoglobin A1c (HgbA1c) test, at least one lipids test, and at least one eye exam. HgbA1c and lipid tests should occur at least 30 days apart

Table 14.8 Diagnosis and procedure codes used for diabetes-related care

	ICD-9 Diagnoses	ICD-10 Diagnoses	HCPCS	ICD-9 Procedures	ICD-10 Procedures
Diabetes Mellitus	250; 357.2; 362.0; 366.41 or Medical Evidence form	E08.311-E08.36; E08.40; E08.42; E09.311-E09.36; E09.40; E09.42; E10.10-E13.9 or Medical Evidence form	*<none>*	*<none>*	*<none>*
Testing					
Hemoglobin A1c	*<none>*	*<none>*	83036; 83037	*<none>*	*<none>*
Diabetic eye exam	V72.0	Z01.00; Z01.01	67028-67113; 67121-67228; 92002-92014; 92018; 92019; 92225; 92226; 92225-92260; S0620; S0621, S0625; S3000	14.1-14.5; 14.9; 95.02; 95.11; 95.12; 95.16	085E3ZZ; 085F3ZZ; 08943ZX; 08953ZX; 089A0ZX; 089A3ZX; 089B0ZX; 089B3ZX; 089E3ZX; 089F3ZX; 089G3ZX; 089H3ZX; 08B43ZX-08B53ZZ; 08B6XZZ ; 08B7XZZ; 08BA0ZX; 08BA3ZX; 08BB0ZX; 08BB3ZX; 08BE3ZX-08BF3ZZ; 08H031Z; 08H031Z; 08H0X1Z; 08H131Z; 08H1X1Z; 08J0XZZ; 08J1XZZ; 08QA0ZZ-08QB3ZZ; 08QE3ZZ; 08QF3ZZ; 08U00JZ; 08U03JZ; 08U10JZ; 08U13JZ; 08UE0JZ; 08UE3JZ; 08UF0JZ; 08UF3JZ; 3E0C3GC; 3E0CXSF; B30N0ZZ-B30NYZZ; C8191ZZ-C81YYZZ
Lipids	*<none>*	*<none>*	80061; 82465; 82470; 83695; 83700-83705; 83715-83721; 84478	*<none>*	*<none>*

Abbreviations: HCPCS, Healthcare Common Procedure Coding System; ICD 9/10, International Classification of Diseases, Ninth/Tenth version.

Figure 2.19 (a-d) presents data on influenza vaccinations for prevalent ESRD patients overall and by age, race/ethnicity, and modality. Claims were searched between August of one year and April of the following year. The cohort for influenza vaccinations included all ESRD patients initiating therapy at least 90 days prior to August 1 of the first year. Patients must have been alive, with a valid birth date, residing in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, have Medicare Parts A and B coverage with no Medicare Advantage participation, and not be lost to follow up. Age was calculated at the end of the study period. HCPCS codes used to identify influenza vaccinations were 90724, 90657, 90658, 90659, 90660, and G0008.

Chapter 3: Vascular Access

Vascular Access Use at Initiation of Hemodialysis

Data for Figures 3.1-3.3 and Table 3.1 were obtained from the Medical Evidence form (CMS 2728). Data were restricted to the 2005 and 2015 versions of the CMS 2728 form and incorporated the recent change in diagnosis codes from ICD-9-CM to ICD-10-CM. Patients with missing vascular access data were excluded. Figure 3.1 presents data for patients who began hemodialysis during 2005-2015. Table 3.1 and Figures 3.2-3.3 present data for patients beginning dialysis in 2015. Age was calculated as of the date that regular, chronic dialysis began. Race and ethnicity categories changed this year from previous ADRs (see *Race and Ethnicity* in the *Database Definitions* section above for details); tables 3.1, 3.2, 3.4, 3.6, and 3.7 reflect those adjustments.

In Figures 3.2 and 3.3 we illustrate geographic variation in the 2014 percentages of catheter-only use and arteriovenous (AV) fistula use at hemodialysis initiation. There figures 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 3.2 and Figures 3.4-3.6.

For Table 3.2, CROWNWeb data was used to determine vascular access use for December 2015. Catheter use included any catheter, whereas AV fistula and AV graft use were without the use of a central venous catheter.

Figures 3.4 and 3.5 show geographic variation in the percentages of catheter-only and AV fistula use among prevalent hemodialysis patients by HAs; these analyses used CROWNWeb data from December 2015, and excluded patients not living in the 50 states or the District of Columbia.

Figure 3.6 presents data as reported from the Fistula First Initiative from July 2003 to April 2012 and CROWNWeb from June 2012 to May 2016. May 2012 data was not included in the analysis to denote the breakpoint between the two sources. The denominator was obtained from the treatment history file, and limited to hemodialysis patients beginning dialysis between January 1, 2013 and May 30, 2016, who were not transplanted, and were alive at the end of each month. The numerator was obtained from vascular access extract files in CROWNWeb for the same time period. Access type at initiation was from the Medical Evidence form; vascular access data for all other time points were obtained from CROWNWeb. There was a 15-day look-back and 15-day look-forward period to determine vascular access.

Change in Type of Vascular Access during the First Year of Dialysis

Figure 3.7.a and Tables 3.3-3.5 include a cross-section of patients who were incident and alive at each time point in 2013. They used data from January 1, 2013 to May 30, 2016, from the Medical Evidence form (CMS 2728) data at initiation and CROWNWeb for subsequent time periods. Data were restricted to the 2005 and 2015 versions of the Medical Evidence form (CMS 2728). Patients with missing vascular access data were excluded.

Figure 3.7.b follows a cohort of patients (N=101,453) from dialysis initiation to one year after initiation. As with Figure 3.7.a, Figure 3.7.b used 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.

Predictors of AV Fistula Use at Hemodialysis Initiation

Table 3.6 presents two models of the odds of AV fistula use at initiation and AV fistula or AV graft use at initiation. These two multiple logistic regression models used vascular access type at initiation, demographic, and facility information from the 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.

Fistula Maturation

Table 3.7 includes patients with a fistula placed at any point between June 1, 2014 and May 31, 2015 who were already on ESRD at time of placement, with follow-up through June 2016. Fistula placement was identified through inpatient, outpatient, and physician/supplier Medicare claims using the HCPCS codes 36818, 36819, 36820, 36821 and 36825.

Subsequent first use of the placed fistula was determined by finding evidence in CROWNWeb through June of 2016. In order to be included in the analyses, patients were required to have vascular access use data in CROWNWeb following the fistula placement. If fistula use following the placement (and prior to any later fistula placements) was indicated in CROWNWeb, the fistula was considered to have successfully matured for use. If the fistula use following placement was not present in CROWNWeb, it was assumed to have failed to mature. Time to maturation was determined using the date of fistula placement and the date of first use in CROWNWeb, given that the exact time of "fistula maturity" cannot currently be determined from CROWNWeb. Patients that died following the fistula placement were also included in the analysis.

Chapter 4: 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*[claims] (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. Included patients have Medicare as primary payer, with Part A coverage at the start of follow-up, and without Medicare Advantage 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. Hospitalization data do not exclude inpatient stays for the purpose of rehabilitation therapy.

Statistical models

Inpatient institutional claims were used for the analyses, and methods for cleaning claims follow those described for *Reference Table G*. Adjusted rates were calculated using the model-based adjustment method on the observed category-specific rates. Predicted rates were calculated with a Poisson model, and adjusted rates were 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*[CLAIMS], and in the *Statistical Methods* section later in this chapter.

Unless otherwise indicated, in all analyses where adjustments were made, rates were adjusted for age, sex, race, ethnicity, primary cause of ESRD, vintage, and their two-way interactions (except for race and ethnicity) with the 2011 ESRD cohort used as the reference.

Trends in Hospitalization rates

Methods in Figures 4.1-4.2 and 4.4 follow those for *Reference Table G: Morbidity and Hospitalization*[CLAIMS]. Figure 4.1 presents adjusted rates of total hospital admissions per patient year for prevalent ESRD patients.

Figure 4.2 shows the hospitalization rates since 2006 for period prevalent ESRD patients. Included patients had Medicare as primary payer and are

residents of the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. Patients with AIDS as a primary or secondary cause of death were excluded, as were patients with missing age or sex information.

New dialysis access codes for PD patients appeared in late 1998. For PD patients, dialysis access hospitalizations were those defined as "pure" inpatient vascular/dialysis access events, as described for Reference Tables G.11-G.15. For HD patients, vascular access hospitalizations included "pure" inpatient vascular access events, and vascular access for HD patients excluded codes specific to PD catheters (996.56, 996.68, and V56.2).

Principal ICD-9-CM and ICD-10-CM diagnosis codes were used to identify cardiovascular and infection admissions. Table 14.9 shows the ICD-9-CM and ICD-10-CM codes used to classify a hospitalization as cardiovascular or infectious. Codes for vascular access related hospitalizations are listed in Table 14.14 in the section describing the methods for *Reference Table G: Morbidity and Hospitalization*[CLAIMS] .

Figure 4.3 shows the all-cause hospitalization rates by treatment modality and number of years after the start of dialysis for the cohorts of incident patients in 2004, 2007, 2010, and 2013. This figure did not include adjustment for vintage. For prevalent ESRD patients, Figure 4.4 presents unadjusted and adjusted rates of total hospital admissions per patient year by Health Service Area in 2014 and 2015.

Hospitalization Days

Figure 4.5 shows adjusted hospital days per patient year by treatment modality among prevalent ESRD patients. Figure 4.6 shows adjusted infectious and cardiovascular hospital days per patient year among prevalent ESRD patients. Principal ICD-9-CM and ICD-10-CM codes for cardiovascular and infection hospitalizations are shown in Table 14.9.

vol 2 Table 14.9 Diagnosis codes used to characterize cause of hospitalization for the chapter

	Principle diagnosis for hospital stay	
Hospitalization cause	**ICD-9-CM codes**	**ICD-10-CM codes**
Cardiovascular hospitalizations	276.6; 394-398; 401-405; 410-420; 421.9; 422.90, 422.99, 423-438; 440-459	E08.51; E08.52; E09.51; E09.52; E10.51; E10.52; E11.51; E11.52; E13.51; E13.52; G45.0-G46.8; I05.0-I09.1; I09.81-I32; I33.9-I38; I40.1; I40.9; I42-I67.82; I67.841-I87.9; I89.0-I97.2; I99.8; I99.9; K64.0-K64.9; M30.0-M31.9; M32.11; M32.12; N26.2; R00.0; R58; T80.0XXA; T81.72XA;T82.817A; T82.818A
Infectious hospitalizations	001-139; 254.1; 320-326; 331.81; 372.0-372.3; 373.0-373.2;382.0-382.4; 383; 386.33, 386.35; 388.6; 390-391; 392.0, 392.9; 393; 421.0, 421.1; 422.0, 422.91-422.93; 460-466; 472-473; 474.0; 475; 476.0, 476.1;478.21, 478.22, 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; 569.5; 572.0-572.1; 573.1-573.3; 575.0-575.12; 590; 595.1-595.4;597; 598.0; 599.0; 601; 604; 607.1-607.2; 608.0, 608.4; 611.0; 614-616.1, 616.3, 616.4, 616.8; 670; 680-686; 706.0; 711; 730.0-730.3, 730.8-730.9; 790.7, 790.8; 996.6; 998.5; 999.3	A00.0-A32.9; A35-B99.9; D86.0-D86.9; E32.1; E83.2; G00.0-G04.02;G04.2-G09; G14; G37.4; G92; G93.7; H00.011-H10.9; H16.251-H16.269; H32; H66.001-H66.43; H67.1-H67.9; H70.001-H70.93; H75.00-H75.83; H83.01-H83.09; H92.10-H92.13; H95.00-H95.199; I00-I02.9; I09.2; I32; I33.0; I39-I40.8; I41;I67.3; J00-J18.1; J18.8-J21.9; J31.0-J32.9; J35.01-J35.03; J36;J37.0; J37.1; J39.0-J39.2; J40; J41.1; J47.0-J47.9; J85.0-J85.2;J86.0-J92.9; J94.0-J94.9; J95.02; K04.6; K04.7; K11.3; K12.2;K35.2-K37; K50.014; K50.114; K50.814; K50.914; K51.014;K51.214; K51.314; K51.414; K51.514; K51.814; K51.914; K57.00; K57.01; K57.20; K57.21; K57.40; K57.41; K57.80;K57.81; K61.0-K61.4; K63.0; K65.0-K65.9; K67-K68.9; K71.0-K71.9; K75.0-K75.3; K75.81-K75.9; K76.4; K77; K81.0-K81.9;K90.81; L01.0-L08.9; L44.4; L70.2; L88; L92.8; L94.6; L98.0;L98.3; M00.00-M01.X9; M02.10-M02.19; M02.30-M02.89;M35.2; M46.20-M46.39; M86.00-M86.9; M90.80-M90.89;N10-N12; N13.6; N15.1; N15.9; N16; N28.84-N28.86; N30.0-N30.31; N30.80; N30.81; N34.0-N34.3; N35.111-N35.12; N37-N39.0; N41.0-N41.9; N45.1-N45.4; N47.6; N48.1-N48.29; N49.0-N49.9; N51; N61; N70.01-N74; N75.1; N76.0-N76.4; N77.1; N98.0; O85; O86.12; O86.81; O86.89; R09.1; R11.11; R78.81;T80.211A-T80.29A; T81.4XXA; T82.6XXA; T82.7XXA; T83.51xXA-T83.6XXA; T84.50XA-T84.7XXA; T85.71XA-T85.79XAT86.842; T87.40-T87.44; T88.0XXA
Vascular access-related hospitalizations	See Table 14.14	See Table 14.14
Vascular access infections	996.62; 999.31	T80218A; T80219A; T827XXA
Acute myocardial infarction	410.00; 410.01; 410.10; 410.11; 410.20; 410.21; 410.30; 410.31; 410.40; 410.41; 410.50; 410.51; 410.60; 410.61 410.70; 410.71; 410.80; 410.81; 410.90; 410.91	I21.02-I22.9
Heart failure	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 425; 428;	A18.84; I09.81; I11.0; I13.0; I13.2; I42.0-I43; I50.1-I50.9;
Stroke	430-434	I60.00-I66.9
Dysrhythmia	426; 427	I44.0-I49.9; R00.1

Abbreviations: ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth version.

Rehospitalization rates

Figures 4.7-4.12 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 were identified as index hospitalizations; the latter date provided a 30-day period following the latest discharge to evaluate rehospitalization. The unit of analysis was hospital discharge rather than patients. Transfers and discharges with a same-day admission to long-term care or a critical access hospital were excluded.

For HD patients in Figures 4.7-4.12, discharges with a transplant, loss to follow-up, or end of payer status before 30 days after discharge were excluded. For ESRD patients in Figure 4.7, the same exclusions applied except as related to transplant. As transplant patients lose their Medicare entitlement three years after transplant, discharges for transplant patients are excluded if they occur after two years and 11 months following the most recent transplant, to ensure that complete claims are available during the 30-day post-discharge period.

Figure 4.7 shows the 30-day disposition of hospital discharges in 2015: died without rehospitalization, rehospitalized and died by day 30, and rehospitalized and alive on day 30. This is shown for three patient groups: general Medicare, CKD, and ESRD. The sample includes point prevalent Medicare patients on December 31, 2014, who were aged 66 and older. For general Medicare patients with and without CKD, CKD was defined during 2014, and patients in the sample were without ESRD, had continuous enrollment in Medicare Parts A and B, and were without Medicare Advantage coverage. Live hospital discharges from January 1 to December 1, 2015 were included.

Figures 4.7 and 4.8 included all-cause index hospitalizations, while in Figures 4.9-4.12 categories of cause-specific admissions were based on principal ICD-9-CM and ICD-10-CM diagnosis codes of the index hospitalization. Codes to define the specific causes of hospitalization are shown in Table 14.9.

Chapter 5: Mortality

Unless otherwise specified, patient cohorts underlying the analyses presented in Chapter 5 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 5.1 shows trends in mortality rates by modality among incident ESRD patients during 2001-2015. Modalities include ESRD, dialysis, HD, CAPD/CCPD (peritoneal dialysis), 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, 2015. Transplant patients begin follow-up at the date of transplant and are censored on December 31, 2015.

Adjusted mortality rates for each period after first treatment are computed separately by taking an appropriately 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 generalized linear model serves as the basis for the predicted rates, adjusted for age, sex, race, ethnicity, vintage, and primary cause of ESRD. The reference population consists of 2011 period prevalent ESRD patients.

All-cause mortality by ESRD Network and Modality

Table 5.1 shows both adjusted and unadjusted all-cause mortality by ESRD network and modality during 2013-2015. The adjusted rates are based on the predicted rates from separate generalized linear models within each modality and overall ESRD population. The reference population consists of 2011 period prevalent ESRD patients.

Mortality by Duration of Dialysis, Including Trends Over Time

Figure 5.2 shows adjusted all-cause mortality among incident patients during each year after

incidence. The rates are based on the predicted cumulative hazard for patients in the reference dataset from an adjusted Cox model of survival based on incident patients in 2013, adjusted to period prevalent patients in 2011.

Mortality During the First Year of ESRD

Figure 5.3 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 (5.3.a) and aged 65 and over (5.3.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 5.2.

Mortality by Age and Race

Table 5.2 shows the death rates by race and age categories (5.2.a) and by sex and age categories (5.2.b) among period prevalent transplant and dialysis patients in 2015. Adjusted rates are calculated as described in the *Statistical Methods* section, under *Methods for Adjusting Rates*. The table showing death rates by race and age is adjusted for sex and primary cause of ESRD, and the table showing death rates by sex and age is adjusted for race and primary cause of ESRD.

Cause-Specific Mortality Rates

Figure 5.4 shows unadjusted cause-specific mortality percentages by modality (dialysis patients and transplant recipients). 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), coronary artery disease, cardiomyopathy, cardiac arrhythmia, cardiac arrest (cause unknown), valvular heart disease, pulmonary edema due to exogenous fluid, heart failure, cerebrovascular accident including intracranial hemorrhage, and ischemic brain damage/anoxic encephalopathy. Infectious causes of death included: septicemia 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, AIDS, 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 5.3 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 5.3, 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 2014 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 5.

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

Table 5.4 presents expected remaining lifetimes in years for the 2013 general U.S. population, and for 2014 prevalent dialysis and transplant patients. For period prevalent ESRD patients in 2014, 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 and calculating the area under this piecewise-exponential survival curve. The method for calculating expected remaining lifetimes is described in the *Statistical Methods* section, under *Expected Remaining Lifetimes*. 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 5.5 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 not in a Medicare Advantage plan available on December 31 of the preceding year. Follow-up for ESRD patents 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 5.5 presents adjusted all-cause mortality in the ESRD, dialysis, transplant populations, and among general Medicare patients from the 5% sample with cancer, diabetes mellitus, heart failure, cerebrovascular accident/transient ischemic attack, and acute myocardial infarction. 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. The current analysis does not use race in the standardization. The form change in 2005 resulted in altered definitions of some of the racial groups, particularly "other" race. Adjusting for these categories resulted in mortality trends that reflected the changing racial definition more than underlying case-mix-adjusted mortality rates. We have limited the adjustments used in this analysis to factors which were not affected by the form change.

Chapter 6: Transplantation

Kidney Transplant Waiting List

Figure 6.1 shows the number of patients on the waiting list for kidney transplant by first and subsequent listings, 1998-2015. Waiting list counts include all candidates listed for a kidney transplant on December 31 of each year. The data source is Reference Table E.3.

Figure 6.2 shows the percentage of dialysis patients on the kidney waiting list, 1998-2015. The data source is Reference Table E.4.

Figure 6.3 shows the percentage of incident patients waiting for or receiving a deceased or living donor kidney-alone or kidney plus additional organ transplant within one year of ESRD initiation, 0-74 years old, stratified by age, during 1998-2014. The data source is Reference Table E.5(2).

Figure 6.4 shows the median waiting time (in years) from wait-listing to kidney transplant 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 on the waiting list in each given year during 1998-2010. The data source is Reference Table E.2.

Table 6.1 displays the median waiting time (in years) from wait-listing to kidney transplant for candidates for kidney transplant, by blood types and panel reactive antibodies (PRA), during 1998-2010. The same methods used to calculate the median waiting time in Figure 6.4 are used for Table 6.1. Median waiting time cannot be calculated if the estimated time to transplant probability had not reached 50% (median) at the end of the follow up. Data are obtained from the USRDS ESRD database and OPTN.

Table 6.2 displays the reported outcomes within five years since first listing for kidney-alone transplant in 2010, by blood type, PRA, and age. Patients were followed until five years after being listed. The reported outcomes include receiving a living donor transplant, receiving a deceased donor transplant, still waiting for a transplant by end of follow-up, or being removed from waiting list due to death or other reasons other than transplant. Among patients with

blood type AB, PRA is not dichotomized as among the other blood types, due to small sample size. Data are obtained from the USRDS ESRD database and OPTN.

Transplant Counts and Rates

Figure 6.5 shows the number of transplants by donor type during 1998-2015. The data source is Reference Tables E.8, E.8(2), and E.8(3).

Figure 6.6 shows the prevalent counts of patients with a functioning kidney-alone or kidney-pancreas transplants as of December 31 of each year during 1998-2015. The data source is Reference Table D.9.

Figure 6.7 shows the unadjusted transplant rates by donor type for all dialysis patients, 1998-2015. The data source is Reference Table E.9.

Table 6.3 displays the unadjusted kidney transplant rates of all donor types, by age, sex, race, and primary cause of ESRD, per 100 dialysis patient years, during 2006-2015. The data source is Reference Table E.9.

Figure 6.8 illustrates the geographic distribution of the unadjusted transplant rate per 100 dialysis patient years by state in 2015. Both deceased and living donor transplants are included.

Figures 6.9-6.12 present the counts and unadjusted rates of deceased donor kidney-alone and simultaneous kidney-pancreas transplants by age, sex, race, and recipient primary cause of ESRD, during 1998-2015. The data source is Reference Tables E.8(2) and E.9(2).

Figures 6.13-6.16 present the counts and unadjusted rates of living donor kidney-alone and simultaneous kidney-pancreas transplants by age, sex, race, and recipient primary cause of ESRD, during 1998-2015. The data source is Reference Tables E.8(3) and E.9(3).

Figure 6.17 shows the number of kidney paired donation transplants and the percent of all living donor transplants that were kidney paired donation during 2001-2015. 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." For the percent of living donor transplants, the denominator is any kidney-alone or kidney plus at least one other organ transplant from a living donor. Data are obtained from OPTN.

Deceased Donation Counts and Rates Among All-cause Deaths

Figures 6.18-6.20 present 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 2001-2015. 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.

Deceased Donation Counts and Rates Among Traumatic Deaths

Figures 6.21-6.23 present the counts and unadjusted rates of deceased donor donation among traumatic deaths within the U.S. population younger than 75 years old, by age, sex, and race, during 2001-2015. 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.

Transplant Outcomes

Table 6.4 displays one-, five-, and ten-year graft and patient outcomes for recipients who received a first kidney transplant from a deceased donor during 1998-2014. Data sources for one-, five-, and ten-year trends are from Reference Tables F.2, F.14, I.26; F.5, F.17, I.29; and F.6, F.18, I.30, respectively.

Table 6.5 displays one-, five-, and ten-year graft and patient outcomes for recipients who received a first kidney transplant from a living donor during 1998-2014. Data sources for one-, five-, and ten-year trends are Reference Tables F.8, F.20, I.32; F.11, F.23, I.35; and F.12, F.24, I.36, respectively.

In both Tables 6.4 and 6.5, data are reported as unadjusted probabilities of each outcome, computed using Kaplan-Meier methods. All-cause graft failure is defined as any graft failure, including repeat transplant, return to dialysis, and death. Death outcome is not censored at graft failure, repeat transplant, or return to dialysis.

Chapter 7: ESRD Among Children, Adolescents, and Young Adults

Information on children, adolescents, and young adult 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 1996-2015, from the Medical Evidence form and CROWNWeb data, a data cleaning process was deemed necessary for this chapter. There were 244 patients with unreasonable height and weight values for children under four, 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 relevance. 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 7.1 due to 10 or fewer total pediatric patients for year categories. See the section on Reference Table A for conversion of the 2015 Medical Evidence form to the categories on the 2005 Medical Evidence form.

Growth

Growth status at the time of ESRD initiation was presented. Stature reported for age < 21 per growth percentile guidelines. Percentiles for children greater or equal to 24 months of age and up to less than 20 years of age are calculated following Centers for Disease Control and Prevention (CDC) growth charts. Percentiles for children less than 24 months of age are calculated following World Health Organization (WHO) growth charts. Short stature is defined as height less than 3rd percentile for sex and age. BMI categories are defined differently for patients by age:

- For those younger than 18:
    - Underweight: BMI < 5th percentile
    - Normal: 5th percentile ≤ BMI < 85th percentile
    - Overweight: 85th percentile ≤ BMI < 95th percentile
    - Obese: BMI ≥ 95th percentile
- For patients 18 and older:
    - Underweight: BMI < 18.5
    - Normal: 18.5 ≤ BMI < 25 percentile
    - Overweight: 25 ≤ BMI < 30
    - Obese: BMI ≥ 30

Hospitalization[claims]

Figures 7.5-7.7 present adjusted admission rates in the first year of ESRD, by age, and modality, for incident patients younger than age 22 in 2005-2009 and 2010-2014. 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 patients who are younger than 65 and not disabled cannot bill Medicare 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, 2015, 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 population is incident ESRD patients aged 0-21 years in 2010-2011. Principal ICD-9-CM and ICD-10-CM diagnosis codes used for infectious hospitalizations are shown in Table 14.9 in the Hospitalization section. Changes are made for the cardiovascular hospitalization codes in order to reflect the events considered appropriate for children. The cardiovascular category consists of:

- Principal ICD-9-CM diagnosis codes 391.0-391.9, 398.0-398.99, 402.00-402.91, 404.02, 404.03, 404.12, 404.13, 404.92, 404.93, 411.0, 411.1, 412, 413.0-414.02, 414.05-414.9, 420.91, 421.0, 422.91, 424.0, 424.0, 424.1, 424.3, 425.0, 425.2-425.9, 426.0-426.13, 426.3, 426.4, 426.6, 426.7, 426.9-427.41, 427.5, 427.81-428.9, 429.0-429.9, 430-432.9, 434.00-434.11, 435.0-437.1, 437.3-438.22, 438.81-438.85, 438.9, 440.1, 440.21-440.29, 440.4-440.9, 441.3, 441.4, 441.9, 443.21-443.29, 443.9, 442.0, 442.2, 442.3, 442.82, 443.0, 443.1, 443.82, 444.21, 446.1, 446.5, 447.0-447.5-449, 459.10-459.9, 471.0, 745.0-745.9, 746.1-746.89, 747.0, 747.11-747.60, 747.62-747.9, V43.3
- Principal ICD-10-CM diagnosis codes – Contact usrds@usrds.org to request a detailed listing of all ICD-10-CM code values.

Mortality and Survival

Table 7.3 shows expected remaining lifetimes by modality while Figures 7.8-7.9 present adjusted all-cause and cause-specific mortality in the first year of ESRD, by age and modality, for 2005-2009 and 2010-2014 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) and 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, 61

Mortality due to infection is also defined using codes from past and current Death Notification forms:

- 10, 11, 12, 13, 33, 34, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 62, 63, 64, 65, 70, 71, 74

Figure 7.11 shows five-year survival rates for 2006-2010 incident ESRD patients aged 0-21 years, by age and modality. Methods follow those of Figures 7.8 and 7.9 above.

Vascular Access

Data for Figure 7.12 and Figure 7.13 are obtained from the Medical Evidence form; data are restricted to the 2005 and 2015 versions. Figure 7.13 also includes data from CROWNWeb. Patients with missing vascular access data are excluded. Figure 7.12 presents statistics for pediatric patients who began dialysis during 2006-2015; age is calculated as of the date regular chronic dialysis began. In Figure 7.13, 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 7.14 presents an overview of the transplant population among children and adolescents.

Figure 7.14.a shows the incidence rate of ESRD among those aged 0-21 years in the U.S. population and the rate of transplantation in patients 0-21 at transplant during 1996- 2015. Pre-emptive transplant patients were included in both the numerator and the denominator.

Figure 7.14.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 7.14.c-7.14.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 7.15 presents transplant rates per 100 dialysis patient years among dialysis patients (0-21 years old). Figure 7.15.a presents rates by age group and donor type (living v. deceased). Figure 7.15.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 7.16 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 7.16.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 7.16 includes pediatric patients (0-21 years old) starting initiation of HD or PD in 1996-2014, and having the first transplant before 12/31/2015. Primary cause of ESRD in Figure 7.16.c is from the Medical Evidence form.

Table 7.4 presents adjusted ten-year patient 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. Statistics shown are reported as adjusted probabilities of each outcome happening 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, probabilities are adjusted for age, sex, race, primary cause of ESRD, and first versus subsequent transplant. They are then 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 retransplant 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 8: Cardiovascular Disease[claims]

This chapter describes the prevalence of cardiovascular comorbidities and selected cardiovascular procedures in eligible fee-for-service, Medicare enrollees. According to a previously validated method for using Medicare claims to identify diabetic patients, a patient is considered to have diabetes 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 and ICD-10-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 coronary artery disease (CAD), acute myocardial infarction (AMI), heart failure (HF), valvular heart disease (VHD), cerebrovascular accident/transient ischemic attack (CVA/TIA), peripheral arterial disease (PAD), atrial fibrillation (AF), 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 or ICD-10-CM code values in Table 14.10.

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 diagnosis or a claim for a procedure. Table 14.11 shows the codes and type of claims used to identify each procedure.

vol 2 Table 14.10 ICD-9-CM and ICD-10-CM diagnosis codes used to define cardiovascular disorders

Condition name	ICD-9-CM diagnosis codes	ICD-10-CM diagnosis codes
Any cardiovascular disease (CVD)	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 410-414; 422; 425-428; 430-438; 440-444; 447; 451-453; 557; V42.1, V45.0, V45.81, V45.82, V53.3	A18.84; E08.51 E08.52; E09.51; E09.52; E10.51; E10.52; E11.51; E11.52; E13.51; E13.52; G45.0-G45.2; G45.4-G46.8; I09.81; I11.0; I12.00-I22.9; I13.0; I13.2; I21.01-I22.9; I24.0-I25.9; I25.2; I34.0-I39; I40.0-I43; I46.2-I47.0; I47.2; I48.0-I48.92; I49.01; I49.02; I49.3; I49.49; I50.1-I50.9; I60.00-I66.9; I67.0; I67.1; I67.2; I67.4-I67.82; I67.841-I69.998; I70.0-I74.9; I77.0-I77.9; I79.0-I79.8; I81-I82.91; K55.0; K55.1; K55.8; K55.9; M31.8; M31.9; M32.11; Z48.21; Z48.280; Z94.1; Z94.3; Z95.1; Z95.5; Z98.61
Acute myocardial infarction (AMI)	410; 412	I21.01-I22.9; I25.2
Atrial fibrillation (AFIB)	427.3	I48.0-I48.92
Cerebrovascular accident/ transitory ischemic attack (CVA/TIA)	430–438	G45.0-G45.2; G45.4-G46.8; I60.00-I66.9; I67.1; I67.2; I67.4-I67.82; I67.841-I69.998
Coronary artery disease (CAD)	410-414; V45.81, V45.82	I12.00-I22.9; I24.0-I25.9; Z95.1; Z95.5; Z98.61
Heart failure (CHF)	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 422[a]; 425[a]; 428; V42.1[a]	A18.84; I09.81; I11.0; I13.0; I13.2; I40.0-I43; I50.1-I50.9; Z48.21; Z48.280; Z94.1; Z94.3
Systolic or both systolic & diastolic	428.2, 428.4	I50.20-I50.23; i50.40-I50.43
Diastolic only	428.3	I50.30-I50.33
Heart failure, unspecified	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 422[a]; 425[a]; 428 (not 428.2-428.4); V42.1[a]	A18.84; I09.81; I11.0; I13.0; I13.2; I40.0-I43; I50.1; I50.9; Z48.21; Z48.280; Z94.1; Z94.3
Peripheral arterial disease (PAD)	440–444; 447; 557	E08.51; E08.52; E09.51; E09.52; E10.51; E10.52; E11.51; E11.52; E13.51; E13.52; I67.0; I70.0-I74.9; I77.0-I77.9; I79.0-I79.8; K55.0; K55.1; K55.8; K55.9; M31.8; M31.9
Sudden cardiac arrest/ventricular arrhythmias (SCA/VA)	427.1, 427.4, 427.41, 427.42, 427.5, 427.69	I46.2-I47.0; I47.2; I49.01; I49.02; I49.3; I49.49
Valvular heart disease (VHD)	424	A18.84; I34.0-I39; M32.11
Venous thromboembolism and pulmonary embolism (VTE/PE)	452-453.9	I81-I82.91

Data Source: ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification. ICD-9-CM diagnosis codes have up to five digits with a decimal point between the 3rd and 4th digit, while ICD-10-CM codes are seven digits. 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.

vol 2 Table 14.11 Procedure codes (ICD-9-CM and HCPCS) & claims files used to define cardiovascular procedures in the USRDS ADR

Peripheral arterial disease (PAD)	
ICD-9-CM Procedure codes:	
Claims files searched: IP, OP, SN	
Values:	*39.25, 39.26, 39.29; 84.0, 84.1, 84.91*
ICD-10-CM Procedure codes:	
Claims files searched: IP, OP, SN	
Values:	*All of: 0312090-031309K; 0315091-031G0ZG; 031K09J-031N0ZK; 0414093-041N4ZS; 051707Y-051V4ZY; 061307Y-061V4ZY; 061307Y-0X6W0Z3; 0Y620ZZ-0Y6Y0Z3. All except xxxxxx3, xxxxxx4, xxxxxx5: 0410090-04104ZR; All except xxxxxxM, xxxxxxN: 03130J0-03140ZK; All except xxxxxxG: 031H09J-031J0ZK*
HCPCS codes:	
Claims files searched: PB, OP-revenue	
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*
Percutaneous coronary interventions (PCI)	
ICD-9-CM Procedure codes:	
Claims files searched: IP, OP, SN	
Values:	*00.66; 36.01, 36.02, 36.05, 36.06, 36.07*
ICD-10-CM Procedure codes:	
Claims files searched: IP, OP, SN	
Values:	*02703ZZ; 02704ZZ; 02713ZZ; 02714ZZ; 02723ZZ; 02724ZZ; 02733ZZ; 02734ZZ*
HCPCS codes:	
Claims files searched: PB, OP-revenue	
Values:	*92980-92982, 92984, 92995-92996, G0290, G0291*
Coronary artery bypass graft (CABG)	
ICD-9-CM Procedure codes:	
Claims files searched: IP	
Values:	*36.1*
ICD-10-CM Procedure codes:	
Claims files searched: IP, OP, SN	
Values:	All of: 0210083-02100ZF; 0210483-02104ZF; 211088-021108C; 021208C; 021208W; 021209C; 021209W; 02120AC; 02120AW; 02120JC; 02120JW; 02120KC; 02120KW; 02120ZC; 021248C; 021248W; 021249C; 021249W; 02124AC; 02124AW; 02124JC; 02124JW; 02124KC; 02124KW; 02124ZC; 021308C; 021308W; 021309C; 021309W; 02130AC; 02130AW; 02130JC; 02130JW; 02130KC; 02130KW; 02130ZC; 021348C; 021348W; 021349C; 021349W; 02134AC; 02134AW; 02134JC-02134JW; 02134KC; 02134KW; 02134ZC; All except xxxxxxF, xxxxxx3, xxxxxx4: 211088-02110ZC; 211488-02114ZC

Table 14.11 continued on next page.

vol 2 Table 14.11 Procedure codes (ICD-9-CM and HCPCS) & claims files used to define cardiovascular procedures in the USRDS ADR *(continued)*

Implantable cardioverter defibrillators & cardiac resynchronization therapy with defibrillator (ICD/CRT-D)	
ICD-9-CM Procedure codes:	
Claims files searched: IP, OP, SN	
Values:	*00.51; 37.94*
ICD-10-CM Procedure codes:	
Claims files searched: IP, OP, SN	
Values:	*02H60KZ; 02H63KZ; 02H64KZ; 02H70KZ; 02H73KZ; 02H74KZ; 02HK0KZ; 02HL3KZ; 02HL4KZ; 02PA0MZ; 02PA3MZ; 02PA4MZ; 02PAXMZ; 0JH608Z; 0JH609Z; 0JH638Z; 0JH639Z; 0JH808Z; 0JH809Z; 0JH838Z; 0JH839Z; 0JPT0PZ; 0JPT3PZ*
Carotid artery stunting and carotid artery endarterectomy (CAS/CEA)	
ICD-9-CM Procedure codes:	
Claims files searched: IP, OP, SN	
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*
ICD-10-CM Procedure codes:	
Claims files searched: IP, OP, SN	
Values:	*037x34Z, 037x3DZ, 037x3ZZ, 037x44Z, 037x4DZ, 037x4ZZ, for x=G to Q, except I & O; 03Bx0ZZ, 03Bx4ZZ, for x=G to V, except I & O; 03CG0ZZ, 03CG3Z6, 03CG3ZZ, 03CG4Z6, 03CG4ZZ, 03Cx0ZZ, 03Cx3ZZ, 03Cx4Z6, 03Cx4ZZ for x=H to V, except I & 0; 03Cx3Z6 for x=R to V; 03RG07Z-03RV4KZ; 057L3DZ, 057L4DZ, 057M3DZ, 057M4DZ, 057N3DZ, 057N4DZ, 057P3DZ, 057P4DZ,057Q3DZ, 057Q4DZ, 057R3DZ, 057R4DZ, 057S3DZ, 057S4DZ, 057T3DZ, 057T4DZ, 05Bx0ZZ, 05BLx4ZZ for x=L to V, except O. 05RL07Z-05RV4KZ; 06R307Z-06R34KZ*
HCPCS codes:	
Claims files searched: PB, OP-revenue	
Values:	*37215, 37216*

Data Source: ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification. ICD-9-CM procedure codes have up to four digits with a decimal point between the 2nd and 3rd digits, while ICD-10-CM codes have seven 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.

Cardiovascular Disease Prevalence and Outcomes in ESRD Patients[claims]

Table 8.1 displays the prevalence of cardiovascular comorbidities and procedures, by modality, age, race and gender, among ESRD patients in 2015. The cohort includes point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older on January 1, 2015, who are continuously enrolled in Medicare Parts A and B and with Medicare as primary payer from January, 1, 2015 to December 31, 2015, and whose ESRD first service date is at least 90 days prior to January 1, 2015. We exclude patients with unknown gender or race and those with an age calculated to be less than zero or greater than 110. The denominators for the cardiovascular procedures were not "all patients in the cohort," which was the denominator for the prevalence statistics for cardiovascular comorbidities. The percent with PCI or CABG were out of cohort members with CAD, the percent with ICD/CRT-D was out of cohort members with HF, and the percent with CAS/CEA was out of cohort members with CAD, CVA/TIA, or PAD.

Figures 8.1 and 8.2 show the percentage of patients who had cardiovascular comorbidities, by modality and age, respectively, among adult ESRD patients in 2015. The cohort is the same one used for Table 8.1.

Figure 8.3 illustrates the adjusted survival of patients by cardiovascular diagnosis or procedure. The cohort includes point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older on January 1, 2013, who are continuously enrolled in Medicare Parts A and B and with Medicare as primary payer from January, 1, 2013 to December 31, 2013, whose ESRD first service date is at least 90 days prior to January 1, 2013, and who survived past 2013. Patients with HF, PAD, and CVA/TIA are those whose Medicare claims indicated the diagnosis or procedure in 2013 or Medical Evidence forms reported the comorbidities. Patients with CAD, AMI, VHD, AF, SCA/VA, VTE/PE, PCI, CABG, ICD/CRT-D, or CAS/CEA are those whose Medicare claims indicate the diagnosis or procedure in 2013. Patients are followed from January 1, 2014, until the earliest date of death, modality change, transplant, lost to follow-up, recovery of renal function, or December 31, 2015. The adjusted probability of survival was calculated using the results of a Cox model, in which significant factors included age group and sex.

Table 8.2 uses the same methods as Figure 8.3, and shows the adjusted two-year survival by cardiovascular comorbidity/procedure.

Cardiovascular Disease and Pharmacological treatments

Table 8.3 shows the percentage of patients prescribed pharmacological treatments by cardiovascular diagnosis or procedure. The cohort is the same one used for Table 8.1, except patients must also be enrolled in Medicare Part D for the entire calendar year. The percentages shown in the table are the row percentages, because the denominator is the number of patients with the cardiovascular diagnosis or procedure, by modality.

Heart Failure Among ESRD Patients[claims]

Type of heart failure (HF) for the calendar year was determined by frequency of diagnoses and a hierarchy. The presence of systolic (428.2x or 428.4/I50.2x or I50.4x), diastolic (428.3x/I50.3x), and unspecified (all other HF diagnosis codes in Table 14.10) 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 8.4 shows the distribution of heart failure type by modality in 2015 for the same study cohort as

in Table 8.1, 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 9: Medicare Expenditures for Persons with ESRD [claims]

Overall & per Person per Year Costs of ESRD

For the 2017 ADR, reported costs of ESRD include only those ESRD beneficiaries covered by Original Medicare (fee-for-service) for their Medicare Part A, B, and D benefits. Medicare expenditures can be calculated from the claims submitted for payment for health care provided to these individuals, but not for those enrolled in Medicare Advantage (managed care) plans. The Medicare program pays for services provided through Medicare Advantage plans on a risk-adjusted, per-capita basis and not by specific claims for services.

Figure 9.1 displays Medicare paid amounts for period prevalent ESRD patients from 2004-2015, as well as patient obligations, which were estimated as the difference between Medicare allowable and Medicare paid amounts. Patient obligations may be paid by the patient, by a secondary insurer, or may be uncollected. Medicare expenditures for managed care (Medicare Advantage) plans are estimated using the total equivalent eligible managed care months (determined from the USRDS payer sequence) multiplied by the monthly payment rates published by CMS (https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html).

In Figure 9.2, total Medicare costs from each year were abstracted from the Medicare Trustees Report, Table B.1, which is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/TrusteesReports.html. Part C costs were deducted to show the fee-for-service Medicare costs.

Funding Sources for the ESRD Population

Figure 9.3 presents point prevalence of Medicare as primary payer, Medicare as secondary payer, Medicare Advantage, and non-Medicare ESRD patients by year using the USRDS ESRD database.

Figure 9.4 describes the percent change in ESRD Medicare spending in total and per patient year, including claims with Medicare as primary payer only. Medicare spending was abstracted from Reference Table K.4.

Figure 9.5 shows the total ESRD Medicare fee-for-service expenditures by type of service, which was taken from Reference Table K.1. The analysis includes period prevalent patients, specifically, all ESRD patients with at least one Medicare claim.

Figure 9.6 presents total Medicare fee-for-service inpatient spending by cause of hospitalization during 2004-2015.

ESRD Spending by Modality

Figure 9.7 describes total Medicare ESRD expenditures by modality. Medicare costs are from claims data.

Figure 9.8 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 10: Prescription Drug Coverage in Patients With ESRD [claims]

This chapter describes prescription drug coverage and usage. New for the 2017 ADR, it shows prescription drug utilization from the Optum Clinformatics™ dataset for both those in Medicare Advantage plans and those in commercial plans.

For inclusion in the analyses, general Medicare enrollees had to be enrolled in Medicare Parts A and B in the calendar year of interest. To create HD, PD, and kidney transplant cohorts, we identified all point prevalent patients (the total ESRD population). Point prevalent cohorts include all patients alive and enrolled in Medicare on January 1 of the calendar year, with ESRD onset at least 90 days earlier; treatment modality is identified on January 1. Incident cohorts include all patients alive and enrolled in Medicare exactly 90 days after ESRD onset before January 1

through December 31 of the index year; modality is identified on this date (first service date + 90 days).

For beneficiaries selected from the Clinformatics™ data, we applied the same eligibility algorithm as for the Medicare population. Beneficiaries were required to be covered by either a Medicare Advantage plan or commercial insurance on January 1 of the calendar year of interest. Those with Medicare Advantage have prescription drug coverage at least as generous as the stand-alone Part D plans. Dialysis and transplant cohorts were identified by claims- based diagnosis codes (see table m.2) and many of these codes did not distinguish HD from PD patients, so dialysis as a whole is shown. All of the beneficiaries in the Clinformatics™ dataset had prescription drug coverage.

Medicare Part D Coverage Plans and Medicare Part D Enrollment Patterns

Figures 10.1-10.3 summarize the prescription drug insurance coverage for Medicare beneficiaries by source, comparing the General Medicare and ESRD populations, showing results overall and by age and race categories. The sources of coverage across the calendar year are combined into mutually exclusive and exhaustive categories in a hierarchical manner. Enrollment in a Part D plan is determined by the first digit of the Part D Plan Contract Number variable (one for each month) being "E" (an employer direct plan, a valid value starting in 2007), "H" (a managed care organization other than a regional preferred provider organization (PPO)), "R" (a regional PPO), or "S" (a stand-alone prescription drug plan). A beneficiary is considered to be enrolled in a Part D plan for the year if he or she was enrolled for one month or more of the analysis year. If a beneficiary is enrolled in a Part D plan and received a low-income subsidy (LIS) in at least one month, he or she is classified as "Part D with LIS", and as "Part D without LIS" otherwise. The receipt of a low income subsidy is determined by the monthly Cost Sharing Group Code values "01" through "08." For beneficiaries not enrolled in a Part D plan, there are several options for non-Medicare prescription drug coverage as reported to the Medicare program. Beneficiaries are classified as "Retiree Drug Subsidy" if they are not enrolled in a Part D plan but have at least one month with a Part D Retiree Drug Subsidy Indicator value of "Y" (yes), indicating he or she is enrolled in an employer-sponsored prescription drug plan that qualifies for Part D's retiree drug subsidy. If the patient is not in a Part D plan or employer-sponsored plan, they are classified as "Other Creditable Coverage" if the Creditable Coverage Switch has a value of "1", indicating another form of drug coverage that is at least as generous as the Part D benefit. This alternate coverage is known as creditable coverage because beneficiaries who maintain it do not have to pay a late enrollment penalty if they subsequently enroll in Part D. If a beneficiary meets none of the situations described above, he or she is classified as "No Known Coverage." Figure 10.1 presents the distribution of this categorical variable for the General Medicare and ESRD cohorts described above.

Table 10.1 shows the percent of beneficiaries with Part D coverage for the past five years in the General Medicare and ESRD cohorts. Table 10.2 is an adaptation of data presented in the 2015 Medicare Outlook section of the www.q1medicare.com web site and has no analyses. Figure 10.2 shows the categories of prescription drug coverage (described above for Figure 10.1) by age groups (20 to 44/45 to 64/65 to 74/75 and older) for dialysis patients (Panel A) and transplant patients (Panel B), while Figure 10.3 shows it by race groups (White/Black or African American/Asian/Other).

Table 10.3 is limited to beneficiaries who are enrolled in Part D prescription plans for at least one month of the analysis year. Part D plan enrollment and receipt of LIS are determined as described for Figures 10.1. Table 10.3 shows the percent of Part D enrollees with LIS within each race group ("all ages" row) and by age groups within the race group (also defined as above) for the General Medicare cohort and the ESRD cohort. Figure 10.4 is limited to those enrolled in a Part D plan with LIS and shows the different types of LIS, as determined by the values of the Cost Sharing Group Code, for the General Medicare and ESRD cohorts.

Insurance Spending for Prescriptions

Costs for ESRD patients are based on the 100 percent ESRD population, using the period prevalent, as-treated actuarial model (model 1 described in ESRD reference table K). Per person per year (PPPY) costs

are calculated as dividing the total cost amount by the person years at risk. Person years at risk are calculated for the ESRD and general populations separately. For ESRD patients, person years at risk are calculated by subtracting the start date (the latest of prescription coverage start date, date of developing ESRD, and January 1 of the year) from the end date (the earliest of prescription coverage end date, death, and December 31 of the year). For the general population, person years at risk is calculated by subtracting the start date (the latest of prescription coverage start date and January 1 of the year) from the end date (the earliest of prescription coverage end date, date of developing ESRD, death, and December 31 of the year).

Table 10.4 and Figure 10.5 present data on Medicare spending for Part D benefits. The Part D benefit expenditure for a prescription drug event (PDE) is the sum of the amount of cost sharing for the drug that is paid by the Part D low-income subsidy (LIS Amount) and the net amount that the Part D plan pays for the PDE (Covered Part D Plan Paid Amount). Table 10.4 shows the total Medicare Part D benefit expenditures for the General Medicare and ESRD cohorts (defined above) for beneficiaries enrolled in stand-alone Part D plans (i.e., spending for Medicare Advantage prescription drug plans is not submitted to Medicare). These cost numbers are, therefore, comparable to the statistics presented in Chapter 9, which show Medicare spending on Parts A and B benefits for those not in Medicare Advantage plans.

Figure 10.5, Panel A shows spending and patient out-of-pocket amounts per-person, per-year for the General Medicare plan member and ESRD cohorts for those in fee-for-service Part D plans, Panel B shows Optum Clinformatics™ Medicare Advantage plans, and Panel C shows Optum Clinformatics™ commercial insurance plans. Out-of-pocket cost is the sum of the amounts the patient pays without being reimbursed by a third party (for fee-for-service Medicare, the Patient Payment Amount) which includes all copayments, coinsurance, deductible, or other patient payment amounts, and for fee-for-service Medicare, the amount of any payment made by other third-party payers that reduced the beneficiary's liability for the PDE or prescription claim (Other True Out-of-Pocket Amount).Two examples of this are payments by qualified state pharmacy assistance programs or charities. Panel D breaks out these costs by whether the patient receives any low income subsidies.

Table 10.5 shows PPPY spending by age, sex, and race for the General and ESRD cohorts by fee-for-service Medicare with LIS, fee-for-service Medicare without LIS, Optum Clinformatics™ Medicare Advantage plans and Optum Clinformatics™ commercial insurance plans.

Prescription Drug Classes

Tables 10.6.and 10.7 list the top 15 drug classes used among ESRD patients by insurance coverage, modality, the percent of patients with at least one prescription filled in the class (Table 10.6) and insurance spending on the drug class (Table 10.7). All drugs in the PDE file and Optum Clinformatics™ RX table are matched to a therapeutic category according to the American Hospital Formulary Service classification system. Note that the Medicare cohort for Tables 10.6 and 10.7 is limited to those in the ESRD cohort who have stand-alone prescription drug coverage. Each therapeutic category is summarized and the percent of patients with ESRD who filled at least one prescription for a drug in the given class is calculated, as well as the total amount spent by Medicare or the plans in the Optum Clinformatics™ dataset on each drug class and its percentage of total prescription drug plan expenditures.

Table 10.6 shows the top 15 drug classes ranked by the highest percent of ESRD patients with at least 1 prescription filled in that class for fee-for-service Medicare, Optum Clinformatics™ Medicare Advantage and Optum Clinformatics™ commercial insurance. Table 10.7 shows the top 15 drug classes ranked by spending. The column following the drug class name shows the total amount spent by Medicare (panel A), Optum Clinformatics™ Medicare Advantage (panel B) and Optum Clinformatics™ commercial insurance (panel C) on each drug class for ESRD patients and the next column shows that drug class' cost as a percentage of all plan expenditures for these patients.

New for the 2017 ADR, this chapter has a special focus on the analgesics drugs. Analgesics are identified as members of the AHFS classes 280804 – nonsteroidal anti-inflammatory agents (NSAIDs), 280808 – opiate agonists, and 280812 – opiate partial agonists. The cohort is the same as the Medicare

cohort used in Tables 10.6 and 10.7; it excludes those with Medicare Advantage Part D plans. Analgesic use in patients with ESRD is defined as having filled or refilled at least one prescription for a drug in the drug classes listed above. The state of residence is from the Medicare Enrollment Database. Figure 10.6 tabulates the use of NSAIDs (yes/no) by state, divides the states by quintiles, and shows the results in a map. Figure 10.7 does the same with the use of opiates.

Chapter 11: International Comparisons

Data Collection

Each country was provided a data-collection form spreadsheet (Microsoft Excel) to complete for years 2011 through 2015. Countries were asked to report patient count data for each year, if available, for the entire population, by sex (male, female), and by five different age categories (0-19, 20-44, 45-64, 65-74, 75+) for: (1) the country's or region's general population; (2) patients new to ESRD during the year; (3) patients new to ESRD during the year 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 31st of the given year; (6) total number of kidney transplants performed during the year, by type of donor (deceased, living, other); and (7) the number of dialysis patients, HD patients, CAPD/APD/IPD patients, and home HD patients on December 31st of the indicated year. Prevalence was reported for all patients at the end of the calendar year (December 31, 2015), except where otherwise noted. Data for the United States is taken directly from Reference Tables *M: Census Populations*, *A: Incidence and 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. Follow-up with the registries occurred as needed.

Incidence rate of treated ESRD

The incidence rate for Figures 11.1, 11.2, 11.7, and 11.8 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 11.3.a presents the countries with the highest percent increase in incidence rate and 11.3.b presents the countries with the largest percent decline in incidence rate from 2002/03-2014/15. The percent change in incidence rate was calculated as the percent difference between the average incidence rate in 2015 and 2014 and the average in 2002 and 2003.

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 contributes to observed changes in the percentage of patients with diabetes as cause of ESRD in incident patients. Figure 11.4 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 11.5 presents the ten countries with the highest percent increase from 2002/03-2014/15. 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 2015 and 2014 and the average in 2002 and 2003. Figures 11.6 through 11.8 show the correlation between change in ESRD incident rate and incident rate for ESRD patients with diabetes as primary cause of ESRD, incidence of treated ESRD by age and country, and incidence of treated ESRD by sex and country.

Prevalence of ESRD

The prevalence for figures 11.9 and 11.10 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 11.11 presents the ten countries with the highest percent increase in prevalence of ESRD from 2002/03-2014/15. The percent change in prevalence of ESRD was calculated as the percent difference between the average prevalence of ESRD in 2015 and 2014 and the average in 2002 and 2003. Figure 11.12 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 11.13 was the total number of ESRD patients on dialysis divided by the total population for that year, multiplied by one million. Figure 11.14 presents the ten countries with the highest percent increase in prevalence of dialysis from 2002/03-2014/15. The percent change in prevalence of dialysis was calculated as the percent difference between the average prevalence of dialysis in 2015 and 2014 and the average in 2002 and 2003. Figure 11.15 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 11.16.a is calculated as the total number of kidney transplants divided by the population total, multiplied by one million and the rate in Figure 11.16.b is calculated as the total number of kidney transplants divided by the prevalent number of dialysis patients, multiplied by 1000. Figure 11.17 presents the ten countries with the highest percent increase in the kidney transplantation rate from 2002/03-2014/15. The percent change in kidney transplantation rate was calculated as the percent difference between the average transplantation rate in 2015 and 2014 and the average in 2002 and 2003. Figure 11.18 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 11.19 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 12: USRDS Special Study Center on End-of-Life Care for Patients With ESRD

Methods for the creation of the figures and tables in Chapter 12 are described within the chapter itself.

ESRD Reference Table Methods

Reference Tables A: Incidence and B: Prevalence

The data sources for information on both incident and prevalent patients are CROWNWeb, OPTN, ESRD Medical Evidence form (CMS 2728), and Medicare claims. 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 rates and prevalence are adjusted to a reference population using the direct method.

The 2017 ESRD Reference Tables present parallel sets of counts and rates for incidence (Table A) and December 31 point prevalence (Table B) from 1996 to 2015 for counts and 2000 to 2015 for rates because census data for the seven categories of race are limited. 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.

Patients with unknown age are dropped in all tables. Patients with unknown/other or multiracial race, sex or ethnicity are dropped in some tables. Unknown and other/multiracial races are removed in tables A1(2), A1.1-A1.4, A4, A4.1, A5 and all A5.1, A8.1, A8.1(2). Unknown sex, ethnicity, unknown and

multiracial races are dropped in rate tables A2, A2(2), A2.1-A2.4, A3, A3.1, and A9.

Table A11 excludes unknown network as well as unknown sex, ethnicity, unknown and multiracial races. No exclusion is applied to tables A1, A6, A6.1, A7, A7(2), A8, A8(2), A8(3), and A10.

“Other cause” for the primary cause of ESRD includes patients with cystic kidney disease, other urologic, other cause, unknown cause, and missing.

"Other race” includes American Indian or Alaska Native, Asian, Native Hawaiian and Pacific Islander.

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 2015. 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.

A new Medical Evidence form (2728) version was released in 2015 to switch to ICD-10-CM diagnosis codes. To continue the detailed diagnosis categories in tables A.7 and B.7, clinicians reviewed the diagnoses listed on the 2015 Medical Evidence form and classified them into the pre-2015 detailed cause of ESRD groupings. Table 14.12 shows this mapping.

vol 2 Table 14.12 Mapping to pre-2015 detailed diagnosis groups from the Medical Evidence Form (2728)

Pre-2015 Diagnosis Grouping	2015 ICD-10-CM codes for Primary Cause of ESRD
Diabetes	
Diabetes with renal manifestations Type 2	E11.21, E11.22, E11.29, E11.65, E11.9, E13.9
Diabetes with renal manifestations Type 1	E10.22, E10.29, E10.9
Glomerulonephritis	
Glomerulonephritis (GN) (histologically not examined)	N00.8, N03.0, N03.8, N03.9, N04.0, N04.8, N04.9, N05.8, N05.9
Focal glomerulosclerosis, focal sclerosing GN	N03.1, N04.1, N05.1
Membranous nephropathy	N03.2, N04.2
Membranoproliferative GN type 1, diffuse MPGN	N03.5, N04.5
Dense deposit disease, MPGN type 2	N03.6, N04.6
IgA nephropathy, Bergers disease (proven by immunofluorescence)	N02.8
IgM nephropathy (proven by immunofluorescence)	*Not on 2015 version of Form 2728 and not in data*
With lesion of rapidly progressive GN	N01.9
Post infectious GN, SBE	*Not on 2015 version of Form 2728 and not in data*
Other proliferative GN	N03.3, N03.4, N03.7, N04.3, N04.4, N04.7
Secondary GN/Vasculitis	
Lupus erythematosus, (SLE nephritis)	M32.0, M32.10, M32.14, M32.15
Henoch-Schonlein syndrome	D69.0
Scleroderma	M34.89
Hemolytic uremic syndrome	D59.3
Polyarteritis	M31.7
Wegeners granulomatosis	M31.31
Nephropathy due to heroin abuse and related drugs	*Not on 2015 version of Form 2728 and not in data*
Other Vasculitis and its derivatives	I77.89
Goodpastures syndrome	M31.0
Secondary GN, other	M31.1
Interstitial Nephritis/Pyelonephritis	
Analgesic abuse	N14.0
Radiation nephritis	*Not on 2015 version of Form 2728 and not in data*
Lead nephropathy	N14.3
Nephropathy caused by other agents	N14.1, N14.2
Gouty nephropathy	M10.30
Nephrolithiasis	N20.0
Acquired obstructive uropathy	N13.8
Chronic pyelonephritis, reflux nephropathy	N13.70
Chronic interstitial nephritis	N11.9
Acute interstitial nephritis	N10
Urolithiasis	*Not on 2015 version of Form 2728 and not in data*
Other disorders of calcium metabolism	E83.52
Hypertensive/Large Vessel Disease	
Unspecified with renal failure	I10, I12.0, I12.9, I13.10, I13.2, I15, I15.0, R03.0
Renal artery stenosis	I15.8
Renal artery occlusion	*Not on 2015 version of Form 2728 and not in data*
Cholesterol emboli, renal emboli	I75.81

Table 14.12 continued on next page.

vol 2 Table 14.12 Mapping to pre-2015 detailed diagnosis groups from the Medical Evidence Form (2728)

Pre-2015 Diagnosis Grouping	2015 ICD-10-CM codes for Primary Cause of ESRD
Cystic/Hereditary/Congenital Diseases	
Polycystic kidneys, adult type (dominant)	Q61.2
Polycystic, infantile (recessive)	Q61.19
Medullary cystic disease, including nephronophthisis	Q61.5
Tuberous sclerosis	Q85.1
Hereditary nephritis, Alports syndrome	N07.0, N07.8, Q87.81
Cystinosis	E72.04
Primary oxalosis	E72.53
Fabrys disease	E75.21
Congenital nephrotic syndrome	*Not on 2015 version of Form 2728 and not in data*
Drash syndrome, mesangial sclerosis	Q56.0
Congenital obstruction of ureterpelvic junction	Q62.11
Congenital obstruction of uretrovesical junction	Q62.12
Other Congenital obstructive uropathy	N31.9
Renal hypoplasia, dysplasia, oligonephronia	Q61.4
Prune belly syndrome	Q79.4
Other (congenital malformation syndromes)	Q60.0, Q60.2, Q61.3, Q61.8, Q63.8, Q64.2, Q86.8, Q87.1
Neoplasms/Tumors	
Renal tumor (malignant)	C64.9, C80.1
Urinary tract tumor (malignant)	*Not on 2015 version of Form 2728 and not in data*
Renal tumor (benign)	*Not on 2015 version of Form 2728 and not in data*
Urinary tract tumor (benign)	D30.9
Renal tumor (unspecified)	D41.00
Urinary tract tumor (unspecified)	D41.9
Lymphoma of kidneys	C85.93
Multiple myeloma	C90.00
Other immunoproliferative neoplasms (including light chain nephropathy)	C88.2
Amyloidosis	E85.9
Complications of transplanted organ	
Complications of transplanted organ unspecified	T86.90-T86.99
Complications of transplanted kidney	T86.10
Complications of transplanted liver	T86.40
Complications of transplanted heart	T86.20
Complications of transplanted lung	T86.81, T86.819
Complications of transplanted bone marrow	T86.00
Complications of transplanted pancreas	*Not on 2015 version of Form 2728 and not in data*
Complications of transplanted intestine	T86.85, T86.859
Complications of other specified transplanted organ	T86.89, T86.899
Miscellaneous Conditions	
Sickle cell disease/anemia	D57.1
Sickle cell trait and other sickle cell (HbS/Hb other)	D57.3
Post partum renal failure	O90.4
AIDS nephropathy	B20
Traumatic or surgical loss of kidney(s)	S37.00, S37.009, S37.009A, Z90.5
Hepatorenal syndrome	K76.7
Tubular necrosis (no recovery)	N17.0, N17.1, N17.9, N28.0
Other renal disorders	A18.10, N15.9, N28.9, I50.9, N25.89, N26.9, N28.89
Etiology Uncertain	Not on 2015 version of Form 2728 and not in data
Missing	E87.5, I29 <not valid code>, I43, I43.17 <not valid code>, N18.5, N18.6, N18.9, R69

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.

Patients with unknown age are dropped in all tables. Unknown and other/multiracial races are removed in tables B1(2), B1.1-A1.4, B4, B4.1, B5 and all B5.1, B8.1, B8.1(2); unknown sex, ethnicity, unknown and multiracial races are dropped in rate table B2, B2(2), B2.1-B2.4, B3, B3.1, B9; B11 excludes unknown network as well as unknown sex, ethnicity, unknown and multiracial races; No exclusion is applied to tables B1, B6, B6.1, B7, B7(2), B8, B8(2), B8(3), B10, and B12.

"Other cause" in primary diagnosis includes patients with cystic kidney disease, other urologic, other cause, unknown cause, and missing.

"Other race" includes American Indian or Alaska Native, Asian, Native Hawaiian or Pacific Islander.

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 B.1, B.6, B.8, and B.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.

Rates in Reference Tables 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 and 2015 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". Extreme and implausible values are excluded from the analysis, see table m.13 for acceptable ranges.

vol 2 Table 14.13 Acceptable values for laboratory results

Measurement Name	Range	Units
Serum Albumin	0.5-6.5	g/dl
Serum Creatinine	0.1-33.0	mg/dl
Hematocrit	9-60	%
Hemoglobin	3-20	g/dl
Hemoglobin A1c	3-30	%
Height	15-250	cm
Weight	0.45-250	kg
Total Cholesterol	30-1200	mg/dl
Low-Density Lipoprotein	30-350	mg/dl
High-Density Lipoprotein	1-110	mg/dl
Triglycerides	10-10,000	mg/dl
Body Mass Index	10-80	kg/m^2
Age	0-120	years

Abbreviations: cm, centimeters, dl, deciliter, g, grams, kg, kilograms, m, meter, mg, milligrams

Each table in this section shows population characteristics by age, sex, race, ethnicity, and primary cause of ESRD. Mid-East/Arabian race and Indian Subcontinent race were dropped from the 2005 form; therefore, Mid-East/Arabian and Indian Subcontinent are no longer values in the race group. Hispanic, non-specific ethnicity was 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.

Table C.1 contains data on biochemical markers (item 19 on CMS 2728) from 2007-2015. Glycosylated hemoglobin (HbA1c), total cholesterol (TC), low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglycerides (TG) were added to the Medical Evidence form in 2005. Blood urea nitrogen (BUN) was dropped from the 2005 form; therefore, BUN data are not shown in Table C.1.

Table C.2 shows the patient's prior and current employment status (item 16 on CMS 2728) from 2007-2015. Employment status is collected at the time the form is filled out and for six months prior. 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 blank (employed full time, employed part time, homemaker, retired due to age/preference, retired (disability), and medical leave of absence). Only student and unemployed data are shown for patients under 14.

Table C.3 shows patient medical insurance coverage (items 11 and 12 on CMS 2728) from 2007-2015. There are eight categories of insurance coverage for item 12 — Medicare, Medicaid, Employer Group Health Insurance, Department of Veterans Affairs (DVA), Medicare Advantage, Other, and None. Item 11, "Is the patient applying for ESRD Medicare coverage?", allows an additional category to be added to insurance status.

Table C.4 presents patient comorbidity from 2010-2015 (item 17 on 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 on CMS 2728) from 2010-2015.

Table C.6 presents the whether patients on dialysis were informed about kidney transplant options (items 26 and 27 on CMS 2728) from 2010-2015. Patients who are not informed of transplant options have additional information on the reason for not being informed (item 27). A single patient could have multiple reasons for not being informed.

Tables C.7-C.10 describes care received prior to ESRD therapy (item 18 on CMS 2728) from 2011-2015. 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 on CMS 2728) from 2011-2015. The 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 of incident and prevalent patients alive at the end of each year by demographics, geographic location, and treatment modality. 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 the date of first service for all incident patients from 2011 to 2013. 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 ESRD first 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., 2007, 2011, 2015), 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 (Medicare as primary payer)
- Medicare/Medicaid (dually eligible)
- MSP (Medicare as secondary payer): employer group health plan (EGHP) and non-EGHP
- HMO (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 cause of ESRD, 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-to-follow-up, death, or the end of the analysis period (which is 2015 for the 2017 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 2017 Table E.2 only shows data up to year 2010.

Table E.2 reports data by demographics, primary cause of ESRD, 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 cause of ESRD, transplant number, blood type, PRA level, and time on the list.

Table E.4 includes point prevalent dialysis patients on the waiting list for a kidney on December 31 of the given year. Table E.4 reports data by demographics and primary cause of ESRD. 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 on the waiting list 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. Patients receiving a deceased or living 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 cause of ESRD; 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 cause of ESRD, blood type, transplant number, and PRA level determined from the OPTN Recipient Histocompatibility form, and shows a cross-tabulation 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 Outcomes 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, 2015). 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 ESRD first 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[claims]

Reference Table G presents adjusted total admission and hospital day rates, by year, 2004-2015. The model-based adjustment method used in these tables is discussed later in this section and in the *Statistical Methods* section.

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 4, 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 at 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 Medicare Advantage coverage, and who therefore have incomplete hospitalization data, cohorts include only patients with fee-for service 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 fee-for-service 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, switch to Medicare Advantage plan, 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, switch to a Medicare Advantage plan, 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, switch to a Medicare Advantage plan 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 a new admission, 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 distribution. For prevalent patient cohorts, this model uses data from the current and previous two years, with respective weights of 1, ¼, and ⅛Adjusted 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 2007-2009, 2010-2012, and 2013-2015 (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 or ICD-10-CM principal diagnosis code, or an ICD-9-CM or ICD-10-CM principal procedure code in conjunction with a certain diagnosis-related group (DRG) code. Codes for vascular access hospitalizations are listed in Table 14.14. 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 shown in Table 14.15.

vol 2 Table 14.14 DRG, ICD-9-CM, and ICD-10-CM codes for vascular access and peritoneal dialysis access hospitalizations

DRG codes[a]: prior to October 1, 2007
112 Percutaneous cardiovascular procedure
120 Other circulatory system OR procedure
315 Other kidney and urinary tract OR procedure
442 Other OR procedure for injuries with complication
443 Other OR procedure for injuries without complication
478 Other vascular procedure with complication
479 Other vascular procedure without complication

DRG codes[a]: after September 30, 2007
252 Other vascular procedures with Major complicating conditions (MCC)
264 Other circulatory system O.R. procedures
673 Other kidney & urinary tract procedures with MCC
674 Other kidney & urinary tract procedures with CC
675 Other kidney & urinary tract procedures without CC/MCC
907 Other O.R. procedures for injuries with MCC
908 Other O.R. procedures for injuries with CC
909 Other O.R. procedures for injuries without CC/Medicare

ICD-9-CM procedure codes[a]	ICD-10-CM procedure codes[a]
38.95 Venous catheterization for renal dialysis 39.27 Arteriovenostomy for renal dialysis 39.42 Revision of arteriovenous shunt for renal dialysis 39.43 Removal of arteriovenous shunt for renal dialysis 39.93 Placement of vessel-to-vessel cannula 39.94 Replacement of vessel-to-vessel cannula 86.07 Placement of totally implantable vascular access device	031n0xD, 031n0xF for n=2-8 and x=9, A, J, K, Z; 031n0xF for n=9, A-C and x=9, A, J, K; 03PYx7Z, 03PYxJZ, 03PYxKZ for x=0, 3, 4; 03WY0JZ; 03WY3JZ; 03WY4JZ; 03WYXJZ; 05HY33Z; 06HY33Z; 0JH83XZ; 0JHD0WZ; 0JHD0XZ; 0JHD3WZ; 0JHD3XZ; 0JHF0WZ; 0JHF0XZ; 0JHF3WZ; 0JHF3XZ; 0JHL0WZ; 0JHL0XZ; 0JHL3WZ; 0JHL3XZ; 0JHM0WZ; 0JHM0XZ; 0JHM3WZ; 0JHM3XZ

ICD-9-CM diagnosis codes[b]	ICD-10-CM diagnosis codes[b]
996.1 Mechanical complication of vascular device, implant, graft 996.56 Mechanical complication due to peritoneal dialysis catheter 996.62 Infectious complication of vascular device, implant, graft 996.68 Infectious complication due to peritoneal dialysis catheter 996.73 Other complication due to renal dialysis device, implant, graft 999.31 Infection due to central venous catheter V56.1 Fitting and adjustment of extracorporeal dialysis catheter V56.2 Fitting and adjustment of peritoneal dialysis catheter	T80.218A; T80.219A; T82.310A-T82.531A; T82.511A; T82.513A-T82.518A; T82.520A; T82.521A; T82.523A-T82.531A; T82.533A-T82.538A; T82.590A; T82.591A; T82.593A-T82.598A; T82.7XXA; T82.818A; T82.828A; T82.838A; T82.848A; T82.858A; T82.868A; T82.898A; T85.611A; T85.621A; T85.631A; T85.691A; T85.71XA; Z49.01; Z49.02

[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.

vol 2 Table 14.15 Diagnosis codes used to define cause of hospitalization in Reference Table G

Cause of Hospitalization	ICD-9-CM	ICD-10-CM
Circulatory	390-459	A18.83; E08.51; E08.52; E09.51; E09.52; E10.51; E10.52; E11.51; E11.52; E13.51; E13.52; G45.0-G45.2; G45.4-G46.8; I00-I67.2; I67.4-I6.782; I67.841-I87.9; I89.0-I95.9; I97.0-I97.2; I99.8; I99.9; K64.0-K64.9; M30.0-M31.9; M32.11; M32.12; N26.2; R00.1; R58; T80.0XXA; T81.1718A; T81.73XA; T82.817A; T82.818A
Digestive	520-579	A69.0; B25.1; B25.2; E08.43; E08.630; E08.638; E09.43; E09.630; E09.638; E10.43; E10.630; E11.43; E11.630; E13.43; E13.630; J86.0; K00.0-K31.6; K31.811-K63.4; K63.81-K63.9; K65.0-K67; K68.12-K904; K90.89-K91.2; K91.5; K91.850; K91.858; K91.89-K95.89; M26.00-M27.9; N99.4; R11.10; R11.13; R18.8; R68.2
Genitourinary	580-629	A18.14; A56.01; A56.02; A56.11; B52.0; E08.21-E08.29; E09.21-E09.29; E23.0; M32.14; M32.15; M35.04; N00.0-N22; N25.0-N39.3; N39.8-N97.9; N99.110-N99.3; N99.510-N99.518; N99.518; R10.2; R31.0-R31.9; R36.1; R80.2; R83.711A; R83.721A
Endocrine and Metabolic	240-279	C88.0; C96.5; C96.6; D47.2; D80.0-D849; D89.0-D89.9; E00.0-E03.4; E03.8-E07.1; E07.89-E35; E40-E74.9; E75.21; E75.22; E75.240-E75.249; E75.3; E75.5-E78.70; E78.79-E78.9; E79.1-E83.19; E83.30-E89.6; H49.811-H49.819; M10.00-M10.9; M1A.00X0-M1A.09X0; M1A.20X0-M1A.9XX1; M35.9; M83.0-M83.9; N20.0; N98.1
Respiratory	460-519	A22.1; A37.01; A37.11; A37.81; A37.91; B25.0; B44.0; B44.81; B77.81; D57.01; D57.211; D57.411; D57.811; J00-J01.91; J02.8; J02.8; J02.9; J03.80-J95.3; J95.811-J95.822; J95.84; J96.00-J99; M32.13; M33.01; M33.11; M33.21; M33.91; M34.81; M35.02; R09.1; R09.81
Infectious	001-139	A00.0-A329; A35-A48.0; A48.2-B44.7; B44.89-B78.0; B78.7-B99.9; D86.0-D86.9; G02; G14; H32; I32; I39; I67.3; J02.0; J03.00; J03.01; J17; J20.0-J20.7; K90.81; L08.1; L44.4; L94.6; M00.00-M00.89; M02.30-M02.39; M60.009; N34.1; R11.11
Cancer	140-172, 174-208, 230-231, 233-234	C00.0-C43.9; C45.0-C75.9; C76.0-D03.9; D05.00-D09.9
Other	*codes not listed above*	*codes not listed above*

Abbreviations: ICD-9/10, International Classification of Diseases, Ninth/Tenth version.

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. Reference Table H does not apply the 60-day stable modality rule and 90-day rule.

The cohorts in Tables H.1-H.12 are comprised of period prevalent patients, including those alive on January 1 and those incident during the calendar year. All patients are followed from either January 1 (for prevalent patients) or from the date of onset of ESRD (for incident patients). 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 the transplant waiting list); H.6 (dialysis patients on the 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 supplemental Table 7 of the *National Vital Statistics Report (NVSR), Deaths: Final Data for 2014*. 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 an ESRD first service date between January 1, 1996 and December 31, 2015, are included in the analysis. These patients are followed from day one (ESRD onset) until death, loss to follow-up, or December 31, 2015. 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 CDC National Surveillance of Dialysis-Associated Diseases in the United States (1996-2002, excluding 1998, when the CDC did not conduct a survey). The CDC discontinued the National Surveillance of Dialysis-Associated Diseases after 2002.

In Reference Table J, a chain-affiliated unit is defined 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 2014-2015) 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 2015 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[claims]

Cost information in this section is derived from the 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. There are no subcategories excluded. Cross-year claims are claims that start in one calendar year and end in the following year and are included only in the following year's costs. Cross-payer claims are when a patient is Medicare Primary when claim starts and not primary when the claim ends and are considered to be associated with the payer status that exists at the start of the claim.

Note that originally, the distinction between ESRD and pre-ESRD claims was made by the claim start date and only claims that started on or after the ESRD first service date were considered ESRD claims. Starting with the 2016 ADR, the pre-ESRD v. ESRD distinction is made using the claim end date instead thereby including claims that overlapped with the first service date as ESRD claims. This change was implemented for 2010 claims onward, so users may see a slight jump between 2009 and 2010 that is the result of an increased number of claims being designated ESRD.

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 claims associated with the transplant. Claims data are obtained for all patient identification numbers in the USRDS 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 is added.

In tables that report on a specific modality, only claim records whose start and end dates overlap with a patient's modality start and end dates are included in the cost analysis.

Payer File

The payer sequence file is similar in concept to the USRDS treatment history. Payer status is tracked for each ESRD patient from the ESRD first service date until death, loss to follow-up 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 (MP), Medicare secondary payer (MS), or non-Medicare. The claims database contains data only for MP and MS 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 and direct medical education costs, and an estimate of organ acquisition costs ($25,000 in 2017).

Model 1: As-treated actuarial model

Model 1 and Model 2 differ by how modality is treated. In Model 1, 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.

Tables K.5-9, K.a, K.b, and K.b.1-53 are all primary payer only and Model 1 modality. Model 1 modality is derived from the patient treatment history and is one of:

- Hemodialysis (HD)
- CAPD/CCPD (peritoneal dialysis)
- Other
- Transplant
- 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.

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

Outpatient bundling

In 2011 CMS implemented a new prospective payment system for dialysis. Facilities now receive a standard payment for a bundle of dialysis services instead of billing each individual service such as drugs, laboratory tests and supplies. This is why there are significant increases and decreases between 2010 and 2011 in some Outpatient subgroups in sheets K1 and K4.

Time at risk

Time at risk is the time in which the patients qualify to be included on a particular reference table sheet. The claims for a patient will only be included in a particular table if their time at risk overlaps. For example, if a Medicare primary payer, dialysis patient's time at risk was March 3 – October 5, only claim that overlap that same time period are included. If the patient had ten different claims for that year, and one of them was January 1 – March 2, that cost would not be included.

Time at risk is 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

Reference Table L: Vascular Access[claims]

Within Reference Table L, Tables L.1-L.6 include period prevalent HD patients with Medicare as primary payer. Vascular access placements are identified from inpatient, outpatient, and physician-supplier Medicare claims. Rates represent the total number of events divided by the total time at risk and are converted from days to patient years. Time at risk is defined as the time between the first day of a given year and the 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

Note that data collection methods vary considerably across countries, and therefore direct comparisons should be made with caution.

See Data Collection in the section on Chapter 11: International Comparisons for how the data was obtained.

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 2014 and 2015 and the averages in 2002 and 2003, except in N.3. In N.3, the percent change is defined as the percent difference between the average incidence rates in 2014 and 2015 and the averages in 2006 and 2007 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, then multiplied by one million. Table N.1 shows the trends in the incidence of treated ESRD patients, 2001-2015. Table N.2 shows the trends in the incidence of treated ESRD patients due to diabetes, 2001-2015. N.1 uses total incident patient count, and the count for N.2 is a subset of total incident patients whose kidney 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, 2001-2015. 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 2015 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, 2001-2015. 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, 2001-2015. 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 2015, for example, is the observed incident count divided by the 2015 population size and, if the unit is per million population, multiplied by one million. The 2015 death rate for prevalent ESRD patients is the number of deaths in 2015 divided by the total follow-up time (patient years) in 2015 of the 2015 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 that 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.

vol 2 Table 14.16 Example data for time at risk calculation

			Time at risk			
Patient	**Group**	**Event date**	**Begin date**	**End date**	**Days**	**Patient-years**
1	A	3/31/15	1/1/15	3/31/15	90	0.25
2	A	6/30/15	1/1/15	6/30/15	180	0.50
3	A		1/1/15	12/31/15	365	1.00
4	B	12/31/15	1/1/15	12/31/15	365	1.00
5	B	9/30/15	1/1/15	9/30/15	270	0.75
6	B		1/1/15	12/31/15	365	1.00

	Overall	**Group A**	**Group B**
Number of events	4	2	2
Patient-years at risk	4.5	1.75	2.75
Hospitalization rate	889	1143	727

Take, for example, a calculation of 2015 first hospitalization rates for two groups of patients, all receiving dialysis therapy on January 1, 2015. Group A consists of three patients as shown in Table 14.16. Group B also has three patients.

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 889 for all patients (in either group) in 2015. But the first hospitalization rate per thousand patient years at risk is 1,143 for Group A and 727 for Group B. The rate for Group A is calculated as (2 total events / 1.75 total patient years at risk) x 1,000 and for Group B is (2 total events / 2.75 patient years at risk) x 1,000. 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 2015 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 2015 — with five race groups (White, Black/African American, Native American, Asian, and Other).

Assuming the incidence rate of state A in 2015 is 173 per million population, and the race-specific rates and race distribution of the national populations are as shown in Table 14.17, the adjusted incidence rate of state A with the national population as reference is (153 x 75.1%) + (250 x 12.3%) + (303 x 0.9%) + (174 x 3.6%) + (220 x 8%) = 158.73 per million population. This means that if state A had the same racial distribution as the entire country, its 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.

vol 2 Table 14.17 Example of adjusted incident rate calculation

	Incidence rate of state A	National population (%)
White	153	75.1
Black/African American	250	12.3
Native American	303	0.9
Asian	174	3.6
Other	220	8.0

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 model 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(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 (such as different causes of death) exist, the estimate of the cumulative incidence function of a specific cause of death 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 dying from cause k before time t (including time t), Prob(T≤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 $t_1, t_2, \ldots, t_m$, the cumulative incidence function of cause k at time t is estimated by

$$I_k(t) = \sum \hat{\lambda}_\kappa(t_j)\hat{S}(t_j\text{-}1)$$

where $\hat{\lambda}_\kappa(t_j)=D_{kj}/n_j$, $\hat{S}(t_j\text{-}1)$ is the Kaplan-Meier estimate of survival at time t_j-1, D_{kj} is the number of patients dying 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[CLAIMS]

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, diabetes (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[claims]

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, diabetes mellitus (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 and some will live less than 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.

Median Time (Half-Life)

Conditional Half-life

The conditional half-life is conditional on having survived a given period of length T_0 without the event, where 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 T_o.

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

Estimate the survival probabilities $S(t_o)$ and $S(t_1)$ using the Kaplan-Meier method from the data available, where $t_o<t_1$ and t_1 is within the follow-up

$$\mu = \frac{t_1 - t_o}{(\ln[S(t_o)] - \ln[S(t_1)])},$$

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

This method can be used only when the hazard is a constant after t_o and t_1 is chosen to be big enough to obtain a stable estimate of $\ln(S(t_o))-\ln(S(t_1))$.

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

Blagg CR, Bovbjerg RR, Fitzsimmons SC. Here are (almost all) the data: The evolution of the U.S. Renal Data System. *Am J Kidney Dis* 1989 14(5):347-353.

Breslow NE, Day NE. *Statistical methods in cancer research. Volume II — The design and analysis of cohort studies*. Lyon: International Agency for Research on Cancer, Scientific Publications Series. 1987;82:1-406.

Centers for Disease Control and Prevention. Table 7. Life expectancy at selected ages, by race, Hispanic origin, race for non-Hispanic population, and sex: United States, 2012. *Natl Vital Stat Rep* 2015;63(9):29. http://www.cdc.gov/nchs/data/nvsr/nvsr63/nvsr63_09.pdf. Accessed September 2, 2016

Centers for Medicare & Medicaid Services. Fact sheet: Medicare End-stage Renal Disease (ESRD) Network Organization Program, 2012. https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations/Downloads/ESRDNWBackgrounder-Jun12.pdf. Accessed September 2, 2016

Centers for Medicare & Medicaid Services. Privacy Act of 1974; Report of a modified system of record. *Fed Regist* 2007;72(88):26126-26131. https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/Downloads/0520-PMMIS.pdf. Accessed September 2, 2016

Centers for Medicare & Medicaid Services. Renal Management Information System (REMIS), 2012. http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/IdentifiableDataFiles/RenalManagementInformationSystem.html. Accessed September 2, 2016

Centers for Medicare & Medicaid Services. Systems of records. http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/CMS-Systems-of-Records.html. Accessed September 2, 2016

Collett D. Modeling *Survival data in medical research*. London, England: Chapman and Hall; 1994.

Cook RJ, Lawless JF. *The statistical analysis of recurrent events*. New York: Springer; 2007.

Cox DR. Regression models and life-tables. *J R Stat Soc Series B Stat Methodol* 1972;34:187-220.

Davids MR, Marais N, Jacobs JC. South African Renal Registry Annual Report, 2012. Cape Town, South Africa: South African Renal Society; 2014.

Elzein H. National kidney registry in Lebanon annual report, 2012. Beirut, Lebanon: Lebanese Society of Nephrology and Hypertension; 2012. http://kidneyregistrylb.com/wp-content/uploads/2013/09/UploadAR-Covers-R21.pdf. Accessed September 2, 2016

Health Care Financing Administration. End Stage Renal Disease Research Report, 1993-1995. Baltimore, MD: U.S. Dept. of Health and Human Services; 1997.

Herbert PL, Geiss LS, Tierney EF, Engelgau MM, Yawn BP, McBean AM. Identifying persons with diabetes using Medicare claims data. *Am J Med Qual*. 1999;14(6):270-277.

Italian Registry of Dialysis and Transplant. Annual report of the Italian registry, 2010. Rome, Italy: Italian Society of Nephrology.

Kalbfleisch JD, Prentice RL. *The statistical analysis of failure time data*. 2nd ed. New York: John Wiley & Sons; 2002.

Kolesnyk I, Noordzij M, Kolesnyk M, Kulyzky M, Jager KJ. Renal replacement therapy in Ukraine: epidemiology and international comparisons. *Clin Kidney J* 2014;7(3):330-335.

Lawless JF, Nadeau C. Some simple robust methods for the analysis of recurrent events. *Technometrics* 1995;37(2):158-168.

Lin DY, Wei LJ, Yang I, Ying Z. Semiparametric regression for the mean and rate functions of recurrent events. *J R Stat Soc Series B Stat Methodol* 2000;62(4):711-730.

Liu D, Schaubel DE, Kalbfleisch JD. Computationally efficient marginal models for clustered recurrent event data. *Biometrics* 2012;68(2):637-647.

Liu J, Louis TA, Pan W, Ma JZ, Collins AJ. State-level adjusted ESRD incident rates: use of observed vs model-predicted category-specific rates. *Kidney Int* 2006;69(8):1459-1463.

Marinovich S, Lavorato C, Celia E, et al. Registro Argentino de Diálisis Crónica 2014-2015. Buenos Aires, Argentina: Sociedad Argentina de Nefrología (SAN) and Instituto Nacional Central Unico Coordinador de Ablación e Implante (INCUCAI); 2016.

McDonald S, Clayton P, Hurst K, eds. 36th Annual ANZDATA Registry Report. Adelaide, South Australia: Australia and New Zealand Dialysis and Transplant Registry; 2013. http://www.anzdata.org.au/v1/report_2013.html. Accessed September 2, 2016

Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Public Law 108-173. *USC* 117;2003:2066-2480. https://www.gpo.gov/fdsys/pkg/PLAW-108publ173/pdf/PLAW-108publ173.pdf. Accessed September 2, 2016

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].

Murphy SL, Xu J, Kochanek KD. Deaths: Final data for 2010. Natl Vital Stat Rep. Hyattsville, MD: National Center for Health Statistics 2013; Vol 61:4. http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_04.pdf. Accessed September 2, 2016

National Organ Transplant Act of 1984. Public Law 98-507. *USC* 42;1984:2339-2348. https://www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg2339.pdf. Accessed September 2, 2016

Omnibus Budget Reconciliation Act of 1986. Public Law 99-509. *USC* 42;1986:1874-2078 https://www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg1874.pdf. Accessed September 2, 2016

National Committee for Quality Assurance. HEDIS 2008. Washington, DC: National Committee for Quality Assurance; 2007 (Vol 2).

Pickle LW, White AA. Effects of the choice of age-adjustment method on maps of death rates. *Stat Med* 1995;14(5-7):615-627.

Putter H, Fiocco M, Geskus RB. Tutorial in biostatistics: Competing risks and multi-state models. *Stat Med* 2007;26:2389-2430.

Richard A. Rettig and Norman G. Levinsky, Eds., Kidney failure and the federal government. Committee for the Study of the Medicare End-Stage Renal Disease Program. Institute of Medicine. Division of Health Care Services. Washington, D.C., National Academy Press: 1991

SAS Institute Inc. 2004. SAS/STAT 9.1 User's guide. Cary, NC: SAS Institute Inc.: 3213-3329.

Social Security Amendments of 1972. Public Law 92-603. *USC* 86;1972:1329-1493 www.gpo.gov/fdsys/pkg/STATUTE-86/pdf/STATUTE-86-Pg1329.pdf. Accessed September 2, 2016

Wilson EB, Hilferty MM. The distribution of chi-square. *Proc Natl Acad Sci U S A* 1931;17(12):684-688.

Notes