Volume 2: ESRD Analytical Methods

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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, 2016. 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. 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), 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 Proposals was issued for the development of the United States Renal Data System (USRDS). NIDDK awarded the contract in May 1988 to the Urban Institute, with a subcontract to the University of Michigan, and the first USRDS Annual Data Report on the ESRD population was released in 1989.

In 1995, HCFA transitioned PMMIS to 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 & 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. Integrating SIMS events data into the USRDS Database improved the tracking of patients beyond treatment initiation. 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 United States. This system was implemented nationally in May 2012. In addition to replacing the existing patient tracking functionality of SIMS, CROWNWeb 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. Laboratory values for hematocrit, creatinine clearance, blood urea nitrogen (BUN), and urea clearance were no longer collected. Added laboratory values were hemoglobin A1c (HbA1c) 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 diagnosis and procedure detail as compared to ICD-9-CM codes, resulting in a better understanding of the patient's health. In addition, CMS implemented options of "<6 months" for Fields 18a-c, "Prior to ESRD therapy".

The Medical Evidence form is the only reliable 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, 1995, 1987) are provided in the USRDS Core SAF dataset and are available on the USRDS website in the USRDS Researcher's Guide, Appendix D: Data Collection Forms: *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 it 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. From 2007 to 2011, 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 (OPTN) DATABASE

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 Transplantation 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, 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 ESRD 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 2018 SAFs include all claims up to December 31, 2016.

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 2018 ADR includes 2006-2016 PDE data.

MEDICARE 5% STANDARD ANALYSIS FILES (SAFS)

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 the 2015 ADR, the USRDS has received the 5% sample from the CMS Chronic Conditions Warehouse.

The Medicare 5% 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 sets of files, distinguished by the type of medical service received — inpatient, outpatient, home health agency, hospice, or skilled nursing facility. Physician/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 seven sets of

files collectively are referred to as the Medicare 5% files in the ADR.

The Medicare 5% files are used for Healthy People 2020 objectives and comparing preventive care and other non-ESRD disease treatments in general Medicare and ESRD patients. The Medicare 5% files are also used to construct CKD, diabetes, and congestive heart disease cohorts based on billing data. Table 13.1 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 13.1 ICD-9-CM and ICD-10-CM diagnosis codes used to define chronic kidney disease in the Medicare claims files

	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; 581-583; 585; 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; 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; N18.1-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 CKD		
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 or N18.6 with no CMS 2728 form
Stage unknown or unspecified	Patient 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; 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 digits, 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).

UNITED STATES CENSUS

For the 2016 and prior ADRs, the U.S. population data were 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.

Starting with the 2017 ADR, the U.S. population data are obtained from the Census unbridged postcensal file. The USRDS summarizes this data by race, age, and sex at state and national levels.

Database Definitions

ESRD is defined as chronic renal failure requiring renal replacement treatment — dialysis or transplant — to sustain life. It is not the same as acute renal failure, from which patients are expected to recover within weeks or months. Renal providers must complete a Medical Evidence form for all ESRD patients, this registers them in the CMS ESRD database via CROWNWeb and allows them to apply for Medicare 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 through 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 worksheet/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 (1995-2005), the OPTN transplant follow-up worksheet/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 (1995-2005)
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 procedures:

- 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 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 a fraction of the patients in the USRDS database does not have Medicare as their primary payer 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 13.2 CROWNWeb events

Events	
New ESRD Patient	Recover Function
Transfer In	Lost to Follow-Up
Restart	Modality Change
Dialysis after Transplant Failed (at Dialysis Facility)	Transplant
Transfer Out for a Transplant	Continuing
Transfer Out	Transplant Failure (at Transplant Facility)
Discontinue	Interruption in Service
Death	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. See Table 13.2 for a list of CROWNWeb events. 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 claims 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 ADR 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, 2016.

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. See Table 13.3.

vol 2 Table 13.3 Diagnosis codes for primary cause of ESRD

Primary Cause of ESRD	ICD-9-CM	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; 593.83	I10; I12; I12.0; I12.9; I13.10; I13.2; I15.0; I15.8; I75.81
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; 710.0; 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; 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; 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; 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 Revision, Clinical Modification.

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.

The standard race categories used by the USRDS since the 2016 ADR are White, Black/African American, American Indian or Alaska Native, Asian, Native Hawaiian or Pacific Islander, Other or Multiracial, and Unknown.

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 13.4 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 13.4 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[a]	White; Mid-East Arabian	White
Black/African American	Black	Black or African American	Black	Black
American Indian or Alaska Native	American Indian or Alaska Native	American Indian or Alaska Native	American Indian or Alaska Native	Native American
Asian	Asian; Indian Sub-Continent	Asian; Indian Sub-Continent[a]	Asian; Indian Sub-Continent	Asian
Native Hawaiian or Pacific Islander	Pacific Islander	Native Hawaiian or Other Pacific Islander[a]	Pacific Islander	--
Unknown	Unknown; Missing	Unknown[a]; Missing	Unknown; Missing	Unknown; Missing
Other or Multiracial	Other or Multiracial	Other[a] or Multiracial	Other or Multiracial	Other or Multiracial

[a] On 2728 form in use from 1995-2005, Pacific Islander used instead of Native Hawaiian or Pacific Islander.

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

- Medical Evidence form
- CROWNWeb patient list
- Medicare Enrollment Database

Similar to the race categorization, if information is missing from the CROWNWeb patient list, then the other two 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. The methods used to create the figures and tables for Volume 2 chapters are described below in a section corresponding to each chapter. When figure or table data are drawn directly from a particular reference table, please refer to the *ESRD Reference Table Methods* section for additional details.

CHAPTER 1: INCIDENCE, PREVALENCE, PATIENT CHARACTERISTICS, AND TREATMENT MODALITIES

INCIDENCE OF ESRD: COUNTS, RATES, AND TRENDS

Disease incidence in a population may be quantified in two ways: as a rate and as a risk. Risk of ESRD is newly added in the 2018 ADR.

Race has been standardized across the ADR. In the 2017 ADR, for the first time, the Native Hawaiian/ Pacific Islander racial group was presented as separate from Asian, except for Table 1.3 and Figure 1.7. Direct adjustment was used as described in the *Methods* section of Chapter 1. Rates per million population used Census data that are 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 standardized rates geographically by Health Service Areas (HSA).

For Figures 1.4-1.6, incidence rates were from special analyses using the same standardized method. 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.

RISK: CUMULATIVE INCIDENCE BY AGE, SEX, RACE, AND DURATION OF FOLLOW-UP

A full description of the methods for this section can be seen in the paper by Albertus et al. (2016). They are summarized here.

Risks (probabilities) of being diagnosed with ESRD during a given age interval were estimated using DevCan software (version 6.7.2) developed at the National Cancer Institute. A competing-risks framework is used to estimate risks (cumulative incidences) from incidence data. The challenge is to obtain risk estimates for any age interval during the life span based on age-specific incidence rates obtained for a given calendar period, taking into account competing causes of death. DevCan applies the incidence and mortality rates of ESRD and mortality rates of all other causes of death (competing events) to a large hypothetical cohort that is "aged" from birth until death.

The age-sex-race/ethnicity distribution at birth for this hypothetical cohort is the same as the age-sex-race/ethnicity distribution of the United States in that year. Five-year age intervals were used to estimate rates and generate a hypothetical cohort, stratifying on sex and race/ethnicity (non-Hispanic White, non-Hispanic Black, non-Hispanic Native American, non-Hispanic Asian/Pacific Islander, and Hispanic). DevCan incorporates a "piecewise mid-age group joinpoint model" to smooth out risk estimates within 5-year age intervals, effectively assuming incidence rates are constant within half-year age intervals. Figure 1.7 shows the cumulative incidence of ESRD by race and sex — male in 1.7.a and female in 1.7.b. Table 1.3 shows this by age and sex — male in 1.3.a and female in 1.3.b.

PREVALENCE OF ESRD: COUNTS, PREVALENCE, AND TRENDS

In the chapter, point prevalence is as of December 31, while period prevalence is 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 are counted as prevalent patients.

Beginning with the 1992 ADR, lost to follow-up patients are not included in the point prevalent counts, they are reported in *Volume 2 Reference Table B.1.*

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

Results for Table 1.4, Figures 1.8, 1.10, 1.11, 1.12, and 1.13 were from 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.

Statistics for Table 1.5 were taken from *Reference Table B* and special analyses. Table 1.5 shows prevalence counts, crude and standardized prevalence, and count by modality (hemodialysis, peritoneal dialysis, and transplant). Specifically, prevalent cases correspond to those found in B.10 and prevalence was from special analyses. Figure 1.9 shows prevalence counts over time by modality and used Reference Table D1 and special analyses.

MODALITY OF RENAL REPLACEMENT THERAPY

Modality figures and the associated reference tables describe the treatment modalities of all known ESRD patients, both Medicare and non-Medicare, who are not classified as lost to follow-up or as having 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 13.5.

vol 2 Table 13.5 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 or 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 through 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.

Figures 1.14 shows incident counts by home dialysis modality across time using data from *Reference Table D.1* and special analyses. Table 1.6 counts were taken from *Reference Table D.10* with additional special analyses. The maps in Figures 1.15 and 1.17 were created by tabulating modality data by HSA. Figure 1.16 shows the prevalent counts across time and was taken from *Reference Table D.1*. Table 1.7 used data from *Table D.11*.

PATIENT AND TREATMENT CHARACTERISTICS AT ESRD ONSET

For Tables 1.8, 1.9, and 1.10, and Figures 1.18-1.21, 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. See the chapter, *CKD Analytical Methods*, for the full CKD-EPI equation.

CHAPTER 2: CLINICAL INDICATORS AND PREVENTIVE CARE

CLINICAL INDICATORS

Figure 2.1 data were obtained from CROWNWeb clinical extracts for May 2017. The adequacy (Kt/V) analyses (Figure 2.1.a) were restricted to patients at least 18 years old as of May 1, 2017. Patients must have been alive as of May 31, 2017, and must have had ESRD for at least one year at the time of measurement. If multiple measurements were 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, 2017, and alive as of May 31, 2017, 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, 2017, and had ESRD for at least 90 days as of the time of measurement of an uncorrected serum calcium value. In Figure 2.1.d, all adult (aged 18 and older) patients who were on dialysis for at least 90 days as of May 1, 2017, and alive as of May 31, 2017 were included. If multiple serum albumin measurements were available for a patient, the last one in the month was used. The categorical distribution of serum albumin (g/dL) is shown for both HD and PD patients.

ANEMIA TREATMENT BY MODALITY

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 erythropoietin stimulating agent (ESA) 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. Epoetin alfa (EPO) was identified using HCPCS codes J0885, J0886, and Q4081, and value code 68, darbepoetin by codes J0881 and J0882, and 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 (Q0139).

Hemoglobin levels are shown in Figures 2.2, 2.3, 2.8, and 2.9. Hemoglobin values are based upon the first reported claim in each month for HD patients (Figures 2.2, 2.3) or for PD patients (Figures 2.8, 2.9). When hemoglobin levels were not available in claims data, hematocrit values, if available, were divided by 3 to serve as a proxy estimate. Patients were excluded in a given month if the hemoglobin level (or hemoglobin values estimated from hematocrit values) was <5 g/dL or >20 g/dL. Results are shown for 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 hemoglobin or hematocrit level, and (2) at the start of the month, were on dialysis for 90 days or more and were aged 18 or older. In Figures 2.2 and 2.8, hemoglobin levels are also provided for all patients, and the same restrictions were used as described in statement 2 above, but not limited to patients with an ESA claim within the given month. In addition, hemoglobin levels for patients not on any ESA drugs in a month are also shown for HD patients (Figure 2.2) and PD patients (Figure 2.8).

Figures 2.2.a (HD) and 2.8.a (PD) show trends in mean hemoglobin (for EPO alfa-only patients, for non-ESA patients and for all patients) and mean EPO alfa-only weekly dose. Mean monthly EPO alfa dose is shown for patients who, within a given month, had an EPO alfa claim only (no darbepoetin or epoetin beta), were on dialysis for 90 days or longer, and were 18 years or older at the start of the month. EPO alfa dose is expressed as mean EPO alfa 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 alfa dose was either less than 250 units per week or greater than 400,000 units per week. These criteria resulted in <0.001% of patients being excluded.

In exactly the same way, Figures 2.2.b (HD) and 2.8.b (PD) respectively show mean monthly Hgb for darbepoetin-only patients and mean monthly darbepoetin-only dose for HD and PD patients. Mean monthly Hgb for epoetin beta dose-only patients and mean monthly epoetin beta dose (only) are shown for HD patients in Figure 2.2.c and PD patients in Figure 2.8.c. Darbepoetin and epoetin beta doses were calculated in the same way as EPO alfa dose, but no upper or lower limits were imposed. Sensitivity analyses precluded the need for dosage limits on darbepoetin and epoetin beta, as a very small number of patients on these drugs received doses outside the acceptable clinical range.

Monthly ESA use is shown for HD patients in Figure 2.2.d and for PD patients in Figure 2.8.d. Monthly "EPO alfa only" use (EPO alfa and not darbepoetin or epoetin beta), "darbepoetin only" use (darbepoetin and not EPO alfa or epoetin beta), "epoetin beta only" use (epoetin beta and not EPO alfa

or darbepoetin), and "Any ESA" use (any or a combination of EPO alfa, darbepoetin, or epoetin beta) were calculated among patients who were on dialysis for at least 90 days and 18 years or older at the start of the given month. Figure 2.3 shows categorical levels of Hgb for ESA-using HD patients, and Figure 2.9 shows the same for ESA-using PD patients.

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

CROWNWeb data is used for the iron storage measures—transferrin saturation (TSAT) and serum ferritin. Categorical distributions of the iron store measures for May 2015, May 2016, and May 2017, are shown for HD patients in Figures 2.5 and 2.6. Figures 2.11 and 2.12 show the same categorical distributions of TSAT and serum ferritin for PD patients. Tables 2.1 and 2.2 stratify the categorical distributions of TSAT and serum ferritin, among HD patients for May 2017, by age, sex, race, and primary cause of ESRD. Tables 2.3 and 2.4 provide the same stratifications of categorical TSAT and serum ferritin distributions among PD patients.

Figures 2.5 and 2.11 include dialysis patients treated for ESRD for at least 90 days at the time of TSAT measurement for 2015, 2016, and 2017. Patients were required to have been ≥18 years old as of May 1 of the given year and alive through May 31 of the given year. For each year, the latest non-missing TSAT value during March-May was used.

Figures 2.6 and 2.12 include dialysis patients treated for ESRD for at least 90 days at the time of serum ferritin measurement for 2015, 2016, and 2017, who were ≥18 years old as of May 1 of the given year, and who were alive through May 31 of the given year. For

each year, the latest non-missing serum ferritin value during March-May was used.

Figures 2.7.a (HD) and 2.13.a (PD) show the percentage of Medicare patients with one, two, three, or four or more red blood cell transfusions per year from 2012-2016 using Medicare claims. Here, the denominator includes all patients having a claim for at least one dialysis session during the month who were 18 years or older at the start of the month. The numerator consists of the total number of transfusion claims a patient had in a given year. Patients' modality was determined by the first treatment of the year.

The percentages of dialysis patients with one or more claims for red blood cell transfusions in a given month (2012-2016) 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 dialysis session during the month who were 18 years or older at the start of the month. Codes used to identify transfusions are shown in Table 13.6.

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 2015, May 2016, and May 2017. Analyses for Figure 2.14 and 2.15 included HD (Figure 1.14) or PD (Figure 1.15) patients with ESRD for at least one year at the time of serum calcium measurement who were 18 years or older as of May 1 of each year and alive through May 31 of each year. Serum phosphorous analyses shown in Figure 2.16 (HD patients) used the same sample restrictions as defined above. Similar analyses were completed for PD patients, as shown in Figure 2.17.

vol 2 Table 13.6 Codes identifying a red blood cell transfusion

Code	Code Type	Code Description
36430	HCPCS	Transfusion, blood or blood components
36430	HCPCS	Blood (whole), for transfusion, per unit
36430	HCPCS	Blood, split unit
36430	HCPCS	Red blood cells, leukocytes reduced, each unit
36430	HCPCS	Red blood cells, each unit
36430	HCPCS	Red blood cells, washed, each unit
36430	HCPCS	Red blood cells, irradiated, each unit
36430	HCPCS	Red blood cells, deglycerolized, each unit
36430	HCPCS	Red blood cells, leukocytes reduced, irradiated, each unit
36430	HCPCS	Whole blood or red blood cells, leukocytes reduced, CMV-negative, each unit
36430	HCPCS	Whole blood or red blood cells, leukocytes reduced, frozen, deglycerol, washed, each unit
36430	HCPCS	Whole blood, leukocytes reduced, irradiated, each unit
36430	HCPCS	Red blood cells, frozen/deglycerolized/washed, leukocytes reduced, irradiated, each unit
36430	HCPCS	Red blood cells, leukocytes reduced, CMV-negative, irradiated, each unit
36430	ICD-9	Other operations on heart and pericardium
36430	ICD-9	Other transfusion of whole blood; transfusion: blood NOS, hemodilution, NOS
36430	ICD-9	Transfusion of packed cells
36430	ICD-10	Transfuse Nonaut Whole Blood in Peripheral Vein, Open Approach
36430	ICD-10	Transfuse Nonaut Whole Blood in Peripheral Vein, Percutaneous Approach
36430	ICD-10	Transfuse Nonaut Whole Blood in Central Vein, Open Approach
30243H1	ICD-10	Transfuse Nonaut Whole Blood in Central Vein, Percutaneous Approach
30250H1	ICD-10	Transfuse Nonaut Whole Blood in Peripheral Artery, Open Approach
30253H1	ICD-10	Transfuse Nonaut Whole Blood in Peripheral Artery, Percutaneous Approach
30260H1	ICD-10	Transfuse Nonaut Whole Blood in Central Artery, Open Approach
30263H1	ICD-10	Transfuse Nonaut Whole Blood in Central Artery, Percutaneous Approach
30230N1	ICD-10	Transfuse Nonaut Red Blood Cells in Peripheral Vein, Open Approach
30230P1	ICD-10	Transfuse Nonaut Frozen Red Cells in Peripheral Vein, Open 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
30240N1	ICD-10	Transfuse Nonaut Red Blood Cells in Central Vein, Open Approach
30240P1	ICD-10	Transfuse Nonaut Frozen Red Cells in Central Vein, Open 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
30250N1	ICD-10	Transfuse Nonaut Red Blood Cells in Peripheral Artery, Open Approach
30250P1	ICD-10	Transfuse Nonaut Frozen Red Cells in Peripheral Artery, Open 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
30260N1	ICD-10	Transfuse Nonaut Red Blood Cells in Central Artery, Open Approach
30260P1	ICD-10	Transfuse Nonaut Frozen Red Cells in Central Artery, Open 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

Figure 2.18 presents statistics on diabetic preventive care across time. 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 patients being alive, with a valid birth date, and residing in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. Patients were also required to have Medicare Parts A and B coverage with no Medicare Advantage participation. Patients were required not to have been lost to follow-up in both years one and two. Claims from year one were searched for diagnoses indicating diabetes mellitus (DM; see Table 13.3 for diagnosis codes). 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 13.7 shows the various diagnosis and procedure codes used to define each diabetes care measure. Comprehensive diabetic care includes at least one hemoglobin A1c (HbA1c) test, at least one lipids test, and at least one eye exam. HbA1c and lipid tests should occur at least 30 days apart.

vol 2 Table 13.7 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					
Lipids	*<none>*	*<none>*	80061; 82465; 82470; 83695; 83700-83705; 83715-83721; 84478	*<none>*	*<none>*
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; 95.02-95.04; 95.11; 95.12; 95.16; V72.0	
	ICD-10 Procedure Codes:	085G3ZZ; 085H3ZZ; 08943ZX; 08953ZX; 089A00Z; 089A0ZZ; 089A0ZX; 089A30Z; 089A3ZX; 089A3ZZ; 089B00Z; 089B0ZZ; 089B0ZX; 089B30Z; 089B3ZX; 089B3ZZ; 089E30Z; 089E3ZX; 089E3ZZ; 089F30Z; 089F3ZX; 089F3ZZ; 089G30Z; 089G3ZX; 089G3ZZ; 089H30Z; 089H3ZX; 089H3ZZ; 08B43ZX; 08B53ZX; 08B6XZZ ; 08B7XZZ; 08BA0ZX; 08BA3ZX; 08BB0ZX; 08BB3ZX; 08BE3ZX; 08BE3ZZ; 08BF3ZZ; 08CG3ZZ; 08CH3ZZ; 08H031Z; 08H0X1Z; 08H131Z; 08H1X1Z; 08J0XZZ; 08J1XZZ; 08NA0ZZ; 08NA3ZZ; 08NB0ZZ; 08NB3ZZ; 08NE3ZZ; 08NF3ZZ; 08NG3ZZ; 08NH3ZZ; 08QA0ZZ-08QB3ZZ; 08QE3ZZ; 08QF3ZZ; 08QG3ZZ; 08QH3ZZ; 08RG37Z; 08RG3JZ; 08RGKZ; 08RH37Z; 08RH3JZ; 08RH3KZ; 08SG3ZZ; 08SH3ZZ; 08U00JZ; 08U03JZ; 08U10JZ; 08U13JZ; 08UE07Z; 08UE0JZ; 08UE0KZ; 08UE37Z; 08UE3JZ; 08UE3KZ; 08UF07Z; 08UF0JZ; 08UF0KZ; 08UF37Z; 08UF3JZ; 08UF3KZ; 08UG07Z; 08UG07Z; 08UG37Z; 08UG3JZ; 08UG3KZ; 08UH07Z; 08UH0JZ; 08UH0KZ; 08UH37Z; 08UH3JZ; 08UH3KZ; 3E0C3GC; 3E0CXSF; B30N0ZZ-B30NYZZ; C8191ZZ; C819YZZ; C81YYZZ			

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

Figure 2.19 presents data on influenza vaccinations for prevalent ESRD patients overall (2.19.a), by age and HD treatment (2.19.b), by age and PD treatment (2.19.c), by age and transplantation (2.19.d), by race (2.19.e), and by ethnicity (2.19.f). 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 on April 30 of year two, with a valid birth date, residence in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, and Medicare Parts A and B coverage with no Medicare Advantage participation, Patients were also required not to have been lost to follow-up. Age was calculated at the end of the study period. Influenza vaccination was assessed between August 1 of year one and April 30 of year two. 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 are obtained from the Medical Evidence form (CMS 2728). Data are restricted to the 2005 and 2015 versions of the CMS 2728 form and incorporate 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 2005-2016. Table 3.1 and Figures 3.2-3.3 present data for patients who began dialysis in 2016. Age was calculated as of the date on which regular, chronic dialysis began.

In Figures 3.2 and 3.3 we illustrate geographic variation by state in the 2016 percentages of catheter-only use and arteriovenous (AV) fistula use at hemodialysis initiation. These figures exclude patients not living in the 50 states or the District of Columbia.

Table 13.8 shows the various codes used for vascular access in *Volume 2, Chapter 3: Vascular Access*.

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 were used to determine vascular access use for May 2017. Catheter use included any catheter, whereas AV fistula and AV graft use excluded the use of a central venous catheter.

Figures 3.4 and 3.5 show geographic variation by state in the percentages of catheter-only and AV fistula use among prevalent hemodialysis patients, these analyses used CROWNWeb data from May 2017, 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 2017. 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, 2017, 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 taken 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 TWO YEARS 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 2014-2015. Data from January 1, 2014 to May 30, 2017 were used. Data at initiation were from the Medical Evidence form (CMS 2728) and from 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 from dialysis initiation to two 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.

vol 2 Table 13.8 Diagnosis and procedure codes used for vascular access

(a) HCPCS codes for vascular access
All vascular access HCPCS codes
00532; 01784; 01844; 34101; 35190; 35321; 35458; 35460; 35475; 35476; 35484; 35875; 35876; 35900; 35903; 35910; 36005; 36011; 36145; 36488; 36489; 36490; 36491; 36533; 36534; 36535; 36550; 36555; 36556; 36557; 36558; 36565; 36575; 36580; 36581; 36584; 36589; 36593; 36596; 36597; 36800; 36810; 36815; 36818; 36819; 36820; 36821; 36825; 36830; 36831; 36832; 36833; 36834; 36835; 36838; 36860; 36861; 36870; 37190; 37201; 37205; 37206; 37207; 37208; 37607; 49419; 49420; 49421; 49422; 75790; 75820; 75860; 75896; 75960; 75962; 75978; 75998; 76937; 90939; 90940; G0159; M0900; 77001; G0392; G0393; 36147; 36148; 75791; 37238; 37239
Insertion codes
36011; 36488; 36489; 36490; 36491; 36533; 36800; 36810; 36818; 36819; 36820; 36821; 36825; 36830; 36835; 36555; 36556; 36557; 36558; 36565; 36580; 36581; 36584; 49419; 49420; 49421; 76937
Fistula insertion
36819; 36820; 36821; 36825; 36818
Graft insertion
36830
Catheter insertion
36488; 36489; 36490; 36491; 36533; 36800; 36555; 36556; 36557; 36558; 36565; 36580; 36581; 76937
PD catheter insertion
49419; 49420; 49421
Complications
34101; 35190; 35321; 35458; 35460; 35475; 35476; 35484; 35875; 35876; 35900; 35903; 35910; 36005; 36534; 36535; 36550; 36575; 36580; 36581; 36584; 36589; 36593; 36596; 36597; 36815; 36831; 36832; 36833; 36834; 36838; 36860; 36861; 36870; 37190; 37201; 37205; 37206; 37207; 37208; 37607; 49422; 75790; 75820; 75860; 75896; 75960; 75962; 75978; 75998; 76937; 90939; 90940; G0159; M0900; 77001; G0392; G0393; 36147; 36148; 75791; 37238; 37239
Codes needing a confirmatory diagnosis
00532; 01784; 34101; 35190; 35321; 35458; 35460; 35475; 35476; 35484; 35875; 35876; 35900; 35903; 35910; 36005; 36011; 36488; 36489; 36490; 36491; 36533; 36534; 36535; 36550; 36555; 36556; 36557; 36558; 36565; 36575; 36580; 36581; 36584; 36589; 36596; 36597; 36834; 37190; 37201; 37205; 37206; 37207; 37208; 75820; 75860; 75896; 75960; 75962; 75978; 75998; 76937; 77001
Revisions
01844; 35190; 36534; 36815; 36832; 36833; 36834; 37190
Non-specific codes indicating an access but not what type
01844; 34101; 35190; 35321; 35458; 35460; 35475; 35476; 35484; 36005; 36145; 36593; 36834; 37190; 37201; 37205; 37206; 37207; 37208; 75790; 75820; 75860; 75896; 75960; 75962; 75978; 75998; M0900; 36593
Catheter
00532; 36011; 36488; 36489; 36490; 36491; 36533; 36534; 36535; 36550; 36800; 36555; 36556; 36557; 36558; 36565; 36575; 36580; 36581; 36584; 36589; 36596; 36597; 76937; 75998; 49419; 49420; 49421; 49422
Fistula
01784; 35190; 36818; 36819; 36820; 36821; 36825; 36831; 36832; 36833; 37607
Fistula or graft
36870; 90939; 90940; G0159; 36838
Graft
35875; 35876; 35900; 35903; 35910; 36830
Shunt
36810; 36815; 36835; 36860; 36861
To define PD
49419; 49420; 49421; 49422

Table 13.8 continued on next page.

vol 2 Table 13.8 Diagnosis and procedure codes used for vascular access (continued)

(b) ICD inpatient procedure codes

All vascular access codes – ICD-10
05HY33Z; 06HY33Z; 03130ZD; 03140ZD; 03150ZD; 03160ZD; 03170ZD; 03180ZD; 03190ZF; 031A0ZF; 031B0ZF; 031C0ZF; 031209D; 031209F; 03120AD; 03120AF; 03120JD; 03120JF; 03120KD; 03120KF; 03120ZD; 03120ZF; 031309D; 031309F; 03130AD; 03130AF; 03130JD; 03130JF; 03130KD; 03130KF; 03130ZD; 03130ZF; 031409D; 031409F; 03140AD; 03140AF; 03140JD; 03140JF; 03140KD; 03140KF; 03140ZD; 03140ZF; 031509D; 031509F; 03150AD; 03150AF; 03150JD; 03150JF; 03150KD; 03150KF; 03150ZD; 03150ZF; 031609D; 031609F; 03160AD; 03160AF; 03160JD; 03160JF; 03160KD; 03160KF; 03160ZD; 03160ZF; 031709D; 031709F; 03170AD; 03170AF; 03170JD; 03170JF; 03170KD; 03170KF; 03170ZD; 03170ZF; 031809D; 031809F; 03180AD; 03180AF; 03180JD; 03180JF; 03180KD; 03180KF; 03180ZD; 03180ZF; 031909F; 03190AF; 03190JF; 03190KF; 03190ZF; 031A09F; 031A0AF; 031A0JF; 031A0KF; 031A0ZF; 031B09F; 031B0AF; 031B0JF; 031B0KF; 031B0ZF; 031C09F; 031C0AF; 031C0JF; 031C0KF; 031C0ZF; 03PY07Z; 03PY0JZ; 03PY0KZ; 03PY37Z; 03PY3JZ; 03PY3KZ; 03PY47Z; 03PY4JZ; 03PY4KZ; 03130JD; 03140JD; 03150JD; 03160JD; 03170JD; 03180JD; 03190JF; 031A0JF; 031B0JF; 031C0JF; 031B0JF; 031C0JF; 03PY0JZ; 03PY3JZ; 03PY4JZ; 03WY0JZ; 03WY3JZ; 03WY4JZ; 03WYXJZ; 0JH60WZ; 0JH60XZ; 0JH63WZ; 0JH63XZ; 0JH80WZ; 0JH80XZ; 0JH83WZ; 0JH83XZ; 0JHD0WZ; 0JHD0XZ; 0JHD3WZ; 0JHD3XZ; 0JHF0WZ; 0JHF0XZ; 0JHF3WZ; 0JHF3XZ; 0JHL0WZ; 0JHL0XZ; 0JHL3WZ; 0JHL3XZ; 0JHM0WZ; 0JHM0XZ; 0JHM3WZ; 0JHM3XZ

All vascular access codes – ICD-9
38.95; 39.27; 39.42; 39.43; 39.93; 39.94; 86.07

Insertion codes – ICD-10
05HY33Z; 06HY33Z; 03130ZD; 03140ZD; 03150ZD; 03160ZD; 03170ZD; 03180ZD; 03190ZF; 031A0ZF; 031B0ZF; 031C0ZF; 03130JD; 03140JD; 03150JD; 03160JD; 03170JD; 03180JD; 03190JF; 031A0JF; 031B0JF 031C0JF; 0JH60WZ; 0JH60XZ; 0JH63WZ; 0JH63XZ; 0JH80WZ; 0JH80XZ; 0JH83WZ; 0JH83XZ; 0JHD0WZ; 0JHD0XZ; 0JHD3WZ; 0JHD3XZ; 0JHF0WZ; 0JHF0XZ; 0JHF3WZ; 0JHF3XZ; 0JHL0WZ; 0JHL0XZ; 0JHL3WZ; 0JHL3XZ; 0JHM0WZ; 0JHM0XZ; 0JHM3WZ; 0JHM3XZ

Insertion codes – ICD-9
38.95; 3927; 3993; 8607

Complications – ICD-10
031209D; 031209F; 03120AD; 03120AF; 03120JD; 03120JF; 03120KD; 03120KF; 03120ZD; 03120ZF; 031309D; 031309F; 03130AD; 03130AF; 03130JD; 03130JF; 03130KD; 03130KF; 03130ZD; 03130ZF; 031409D; 031409F; 03140AD; 03140AF; 03140JD; 03140JF; 03140KD; 03140KF; 03140ZD; 03140ZF; 031509D; 031509F; 03150AD; 03150AF; 03150JD; 03150JF; 03150KD; 03150KF; 03150ZD; 03150ZF; 031609D; 031609F; 03160AD; 03160AF; 03160JD; 03160JF; 03160KD; 03160KF; 03160ZD; 03160ZF; 031709D; 031709F; 03170AD; 03170AF; 03170JD; 03170JF; 03170KD; 03170KF; 03170ZD; 03170ZF; 031809D; 031809F; 03180AD; 03180AF; 03180JD; 03180JF; 03180KD; 03180KF; 03180ZD; 03180ZF; 031909F; 03190AF; 03190JF; 03190KF; 03190ZF; 031A09F; 031A0AF; 031A0JF; 031A0KF; 031A0ZF; 031B09F; 031B0AF; 031B0JF; 031B0KF; 031B0ZF; 031C09F; 031C0AF; 031C0JF; 031C0KF; 031C0ZF; 03PY07Z; 03PY0JZ; 03PY0KZ; 03PY37Z; 03PY3JZ; 03PY3KZ; 03PY47Z; 03PY4JZ; 03PY4KZ; 031B0JF; 031C0JF; 031B0JF; 031C0JF; 03PY0JZ; 03PY3JZ; 03PY4JZ; 03WY0JZ; 03WY3JZ; 03WY4JZ; 03WYXJZ

Complications – ICD-9
39.42; 39.43; 39.94

Table 13.8 continued on next page.

vol 2 Table 13.8 Diagnosis and procedure codes used for vascular access (continued)

(c) Diagnosis codes
ICD-10 diagnosis codes whose presence confirms that certain HCPCS codes are dialysis-related
E10.10; E10.11; E10.21; E10.29; E10.311; E10.319; E10.36; E10.39; E10.40; E10.51; E10.618; E106.20; E10621; E10.622; E10.628; E10.630; E10.638; E10.641; E10.649; E10.65; E10.69; E10.8; E10.9; E11.00; E11.01; E11.21; E11.29; E11.311; E11.319; E11.36; E11.39; E11.40; E11.51; E11.618; E11.620; E11.621; E11.622; E11.628; E11.630; E11.638; E11.641; E11.649; E11.65; E11.69; E11.8; E11.9; I12.0; I12.9; N0.03; N0.08; N0.09; N01.3; N02.2; N03.2; N03.3; N03.5; N03.8; N03.9; N04.0; N04.3; N04.4; N04.8; N04.9; N05.2; N05.5; N05.8; N0.59; N08; N17.0; N17.1; N17.2; N17.8; N17.9; N18.1; N18.2; N18.3; N18.4; N18.5; N18.6; N18.9; N19; N25.0; N25.1; N25.81; N25.89; N25.9; N26.9; N27.0; N27.1; N27.9; T82.390A; T82.391A; T82.392A; T82.49XA; T82.590A; T82.591A; T82.593A; T82.595A; T82.598A; T82.7XXA; T82.818A; T82.828A; T82.838A; T82.848A; T82.858A; T82.868A; T82.898A; Z49.01; Z49.02; Z49.31; Z49.32; Z91.15; Z9.92
ICD-9 diagnosis codes whose presence confirms that certain HCPCS codes are dialysis-related
250.xx; 403.xx; 580.xx-589.xx; 593.xx; 996.1x; 996.62; 996.73; V45.1; V45.11; V45.12; V56.xx
ICD-10 diagnosis codes
T80.219A; T82.390A; T82.391A; T82.392A; T82.49XA; T82.590A; T82.591A; T82.593A; T82.595A; T82.598A; T82.7XXA; T82.818A; T82.828A; T82.838A; T82.848A; T82.858A; T82.868AT82898A; T85.691A; T85.71XA; Z49.01; Z49.02
ICD-9 diagnosis codes
996.1x; 996.62; 999.31; 996.73; 996.56; 996.68; V56.1; V56.2
ICD-10 codes for hemodialysis
T80.219A; T82.390A; T82.391A; T82.392A; T82.49XA; T82.590A; T82.591A; T82.593A; T82.595A; T82.598A; T82.7XXA; T82.818A; T82.828A; T82.838A; T82.848A; T82.858A; T82.868A; T82.898A; Z49.01
ICD-9 codes for hemodialysis
996.1x; 996.62; 9967.3; 999.31; V56.1
ICD-10 codes for peritoneal dialysis
T85.691A; T85.71XA; Z49.02
ICD-9 codes for peritoneal dialysis
996.56; 996.68; V56.2
PD device infection
ICD-9 = 996.68; ICD-10 = T8571XA
Peritonitis – ICD-9
540.0x; 540.1x; 567.xx614.5; 614.6
Peritonitis – ICD-10
K35.2; K35.3; K65.0; K65.1; K65.2; K65.3; K65.4; K65.8; K65.9; K67; K68.12; K68.19; K68.9; N73.3; N73.6
Sepsis
ICD-9 = 03.8; ICD-10=A40.3; A40.9; A41.01; A41.02; A41.1; A41.2; A41.3; A41.4; A41.50; A41.51; A41.52; A41.53; A41.59; A41.89; A41.9
Abbreviations: HCPCS, Healthcare Common Procedure Coding System, ICD-9/10, International Classification of Diseases, Ninth/Tenth Revision, PD, peritoneal dialysis.

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, sex, age, race, ethnicity, pre-ESRD nephrology care, and diabetes as cause of ESRD from the Medical Evidence form (CMS 2728). The facility census was from the Annual Facility Survey and ESRD network.

FISTULA MATURATION

Table 3.7 includes patients with a fistula placed at any point between June 1, 2014 and May 31, 2016 who were already determined to be ESRD at time of placement, with follow-up through May 2017. 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 2017. 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 AND EMERGENCY DEPARTMENT VISITS

INCLUSION AND EXCLUSION OF SUBJECTS

Methods used to examine hospitalization in prevalent patients generally echo those used for the tables in *Reference Table G: Morbidity and Hospitalization* (described below). Inclusion and exclusion criteria are generally the same, as are the methods for counting hospital admissions and days, and defining the follow-up time at risk. 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*, 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.

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

Figure 4.2 shows the adjusted hospitalization rates since 2007 for period prevalent ESRD patients. Included patients had Medicare as primary payer and were 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.

For PD patients, dialysis access hospitalizations were those defined as "pure" inpatient dialysis access events, as described for Reference Tables G.11-G.15. For HD patients, vascular access (VA) hospitalizations included "pure" inpatient VA events, and VA 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 are used to identify cardiovascular and infection admissions. Table 13.9 shows the ICD-9-CM and ICD-10-CM codes used to classify a hospitalization as cardiovascular or infectious. Codes for VA-related hospitalizations are listed in Table 13.14 in the section describing the methods for *Reference Table G: Morbidity and Hospitalization*.

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 2005, 2008, 2011, and 2014. This figure did not include adjustment for vintage. For prevalent ESRD patients, Figure 4.4 presents unadjusted (4.4.a) and adjusted (4.4.b) rates of total hospital admissions per patient-year by Health Service Area in 2013 through 2016.

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 infectious hospitalizations are shown in Table 13.9.

vol 2 Table 13.9 Diagnosis codes used to characterize cause of hospitalization for the chapter

Hospitalization cause	Principal diagnosis for hospital stay	
	ICD-9-CM codes	ICD-10-CM codes
Cardiovascular	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	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-T85.79XA; T86.842; T87.40-T87.44; T88.0XXA
Vascular access-related	See Table 13.14	See Table 13.15
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 Revision; Clinical Modification.

READMISSION RATES

Figure 4.7 shows the 30-day disposition of live hospital discharges: died without readmission, 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 January 1, 2016, who were aged 66 and older on December 31, 2016. For general Medicare patients with and without CKD, CKD was defined during 2016, 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 all-cause hospitalizations) from January 1 to December 1, 2016 were included, the latter date providing a 30-day period following the latest discharge. 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.

Figure 4.8 shows the fraction of patients with discharges that were followed by readmission (with or without death) by ESRD modality. If a patient has a transplant, was lost to follow-up, or changed payer status during the 30 days after discharge, that discharge was excluded. Patients with a modality of transplant are those alive with a functioning graft from a transplant that occurred before the index admission. These patients are censored at two years and 11 months following the transplant to ensure that complete claims are available during the 30-day post-discharge period. Medicare coverage ends for those who were entitled to Medicare because of ESRD at three years post-transplant. For hemodialysis patients discharged alive from the index hospitalization, Figure 4.9 shows readmission and/or death by age group (4.9.a) and race/ethnicity (4.9.b).

Figures 4.10-4.13, categories of cause-specific index admissions are based on principal ICD-9-CM and ICD-10-CM diagnosis codes of the index hospitalization. The primary (or first) procedure code of the index hospitalization is used to identify VA, heart catheterization, and other cardiovascular procedures. Codes to define the specific causes of hospitalization are shown in Table 13.9. Cause-specific readmissions are defined the same way as cause-specific index

hospitalizations, using the readmission claim principal diagnosis and procedure. Figure 4.10 shows the three rehospitalization categories (death with no readmission, readmission and alive, readmission and death) for three categories of cause of hospitalization — cardiovascular, VA infection, and non-VA infection. Figure 4.11 shows a cross-tabulation of cause of index hospitalization by cause of readmission, among those readmitted within 30 days of the index hospitalization discharge. Figure 4.12 shows the readmission categories by age group for cardiovascular (4.12.a) and infectious (4.12.b) index hospitalizations. Figure 4.13 shows further detailed diagnoses within the cardiovascular category, among those with a cardiovascular index hospitalization.

EMERGENCY DEPARTMENT VISITS AND OBSERVATION STAYS

Figures 4.14 through 4.16 show unadjusted rates of emergency department (ED) visits. This data came from inpatient and outpatient claims from 2007 to 2016 using the following Revenue Center codes: 0450-0459 and 0981. Figures 4.17 and 4.18 show unadjusted rates of observation stays. This data came from outpatient claims from 2007 to 2016 using Revenue Center code 0762. ED visits were then combined with inpatient claims (IP) where the discharge date of the ED visit is the admission date of a hospitalization. Table 4.2 shows the top ten most common principal diagnoses for all hospitalizations, readmissions, ED with inpatient claim, ED without inpatient claim, and observation stays.

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 2001-2016. Modalities for Figure 5.1.a are ESRD (overall category), dialysis, and first transplant, while modalities for Figure 5.1.b are HD and peritoneal

dialysis. 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, 2016. Transplant patients begin follow-up at the date of transplant and are censored on December 31, 2016.

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 2014-2016, combined to increase sample size. 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 followed for each year after the first service date for cohorts of patients incident in 1997, 2002, 2007, and 2012 by modality — hemodialysis (5.2.a) and peritoneal dialysis (5.2.b). 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 each of the years used, stratified by year, and 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 (hemodialysis or peritoneal dialysis). 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 native 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 per 1,000 patient-years by race and age categories (5.2.a) and by sex and age categories (5.2.b) among period prevalent transplant, dialysis, and all ESRD patients in 2016. 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 and missingness — dialysis patients (5.4.a) or transplant patients (5.3.b) without missing/unknown causes of death and with missing and unknown causes of death included in the denominator for dialysis (5.4.c) and transplant patients (5.8.d). The distributions of causes of death are derived from the rates presented in *Reference Table H: Mortality and Causes of Death*, Tables H.12_Dialysis and H.12_Tx.

SURVIVAL PROBABILITIES FOR ESRD PATIENTS

Table 5.3 presents adjusted three-month, one-year, two-year, three-year, and five-year survival by modality (hemodialysis, peritoneal dialysis, deceased

donor transplant, and living donor transplant) and incident year. Data are obtained from *Reference Table I: Patient Survival, Tables* I.1_adj through I.36_adj.

For the comparison with the general population in the discussion in the chapter 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 2015 Period 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 2015. The mean three-year survival was calculated for these age- and sex-matched estimates within each modality.

EXPECTED REMAINING LIFETIME: COMPARISON OF ESRD PATIENTS TO THE GENERAL U.S. POPULATION

Table 5.4 presents expected remaining lifetimes in years for the 2015 general U.S. population and for 2016 prevalent dialysis and transplant patients. For period prevalent dialysis and transplant patients in 2016, 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 3, "Life expectancy at selected ages, by race and Hispanic origin, and sex: United States, 2015" (CDC, 2017).

MORTALITY RATES: COMPARISONS OF ESRD PATIENTS TO THE BROADER MEDICARE POPULATION

Table 5.5 shows adjusted all-cause mortality in the dialysis and transplant and general Medicare populations (those with the comorbidities of cancer, diabetes mellitus, heart failure, cerebrovascular accident or transient ischemic attack, and acute myocardial infarction) over the age of 65 using the Medicare 5% sample, for male and female sex. Patients can be in more than one comorbidity category. Each

prevalent sample is defined by the Medicare Parts A and B beneficiaries not in a Medicare Advantage plan available on December 31 of the preceding year. Follow-up for ESRD patients is from January 1 to December 31 of each year. For general Medicare patients, follow-up is from January 1 to December 31 of each year, censored at ESRD and at the end of Medicare entitlement or switch to managed care (Medicare Advantage). Adjusted mortality is adjusted for age and race, with 2015 Medicare patients serving as the reference population. Figure 5.5 shows the same without the breakdown by sex.

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, 1999-2016. Waiting list counts include all candidates listed for a first or subsequent kidney transplant on December 31 of each year. The data source is *Reference Table E: Transplantation: Process*, Table E.3.

Figure 6.2 shows the percentage of dialysis patients that were on the kidney waiting list, 1999-2016. The data source is *Reference Table E, Transplantation: Process*, Table E.4.

Figure 6.3 shows the percentage of incident ESRD patients who were waiting for or received a kidney transplant within one year of ESRD initiation, stratified by age, from 1999 to 2015. The data source is *Reference Table E, Transplantation: Process*, 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 from listing when 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 from 1999 to 2011. The data source is *Reference Table E, Transplantation: Process*, Table E.2.

Figure 6.5 displays trends over time in the percent of patients transplanted (deceased or living donor) within one year of their wait-listing date. The

percentage is calculated as the number of patients who received a transplant within one year following their most current listing divided by the total number of people on the wait list for each calendar year.

Table 6.1 displays the reported outcomes within three years since first listing for kidney-alone transplant in 2013, by blood type, panel reactive antibody score (PRA), and age, and Table 6.2 shows these results for five years. Patients from 2013 are followed for three years (Table 6.1), and patients form 2011 are followed for five years after listing (Table 6.2). The reported outcomes included 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 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.

TRANSPLANT COUNTS AND RATES

Figure 6.6 shows the number of transplants by donor type during 1999-2016. The data source is *Reference Table E, Transplantation: Process*, Tables E.8, E.8(2), and E.8(3).

Figure 6.7 shows the prevalent counts of patients with a functioning kidney-alone or kidney-pancreas transplants as of December 31 of each year during 1999-2016. The data source is *Reference Table D: Treatment Modalities*, Table D.9.

Figure 6.8 shows the unadjusted transplant rates by donor type for all dialysis patients, 1999-2016. The data source is *Reference Table E, Transplantation: Process*, 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 2007-2016. The data source is *Reference Table E, Transplantation: Process*, Table E.9.

Figure 6.9 illustrates the geographic distribution of the unadjusted transplant rate per 100 dialysis patient-years by state in 2016. Both deceased and living donor transplants are included.

Figures 6.10-6.13 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 1999-2016. The data source is *Reference Table E, Transplantation: Process*, Tables E.8(2) and E.9(2).

Figures 6.14-6.17 present the counts and unadjusted rates of living donor kidney transplants by age, sex, race, and recipient primary cause of ESRD, during 1999-2016. The data source is *Reference Table E, Transplantation: Process*, Tables E.8(3) and E.9(3).

Figure 6.18 shows the number of kidney paired donation transplants and the percent of all living-donor transplants that were kidney paired donation during 2002-2016. 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/worksheet) 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 the OPTN database.

DECEASED DONATION COUNTS AND RATES AMONG ALL-CAUSE DEATHS

Figures 6.19-6.21 present the counts and unadjusted rates of deceased donation among all deaths within the U.S. population younger than 75 years old, by age, sex, and race, during 2002-2016. Donors had at least one kidney recovered. Data on the deceased donors are obtained from OPTN data, 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 6.22-6.24 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 2002-2016. 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 data, 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

Figure 6.25 displays one-, five-, and ten-year graft outcomes for recipients who received a first kidney transplant during 1999-2015 for deceased donor (5.25.a) and living donor (5.25.b) transplant. One-year graft survival needs a year of follow-up so only the years through 2015 are included. By the same logic, five-year graft survival includes 1999-2011, and ten-year graft survival includes 1999-2006. Data sources for one-, five-, and ten-year trends are from *Reference Table F: Transplantation: Outcomes*, Tables F.2, F.14, F.5, F.17, F.6, and F.18, respectively.

Figure 6.26 displays one-, five-, and ten-year patient survival for recipients who received a first kidney transplant from a deceased (5.26.a) or living (5.26.b) donor during 1999-2015. Data sources for one-, five-, and ten-year trends are *Reference Table I: Patient Survival*, Tables I.26, I.29, I.30, I.32, I.35, and I.36, respectively.

In both Figures 6.25 and 6.26, 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 1996-2016, from the Medical Evidence form and CROWNWeb data, a data cleaning process was deemed necessary for this chapter. There were 273 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, PREVALENCE, AND MODALITY

For a discussion of methods for this section, 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. Age and weight are at the time of ESRD initiation and taken from the ESRD Medical Evidence Form (CMS 2728 form).

ETIOLOGY

The underlying etiologies of ESRD are generated from the CMS 2728 form. 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, complications of transplanted intestine, complications of other specified transplanted organ, urolithiasis, other disorders of calcium metabolism, Fabry's disease, sickle cell trait and other sickle cell (HbS/Hb other), urinary tract tumor (malignant), renal tumor (benign), lymphoma of kidneys, multiple myeloma, other immunoproliferative neoplasms, amyloidosis, cholesterol emboli and renal emboli, and hepatorenal syndrome are suppressed from Table 7.1 due to the diagnosis having 10 or fewer total pediatric patients. See the section on methods for *Reference Tables A: Incidence and B: Prevalence* 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 is presented. Stature is 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 (CDC, 2000). 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:

  o Underweight: BMI < 5th percentile
  o Normal: 5th percentile ≤ BMI < 85th percentile
  o Overweight: 85th percentile ≤ BMI < 95th percentile
  o Obese: BMI ≥ 95th percentile

- For patients 18 and older:

  o Underweight: BMI < 18.5
  o Normal: 18.5 ≤ BMI < 25 percentile
  o Overweight: 25 ≤ BMI < 30
  o Obese: BMI ≥ 30

HOSPITALIZATION

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 2006-2010 and 2011-2015. 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). For Figure 7.5, we divided hospitalizations into two groups, surgical and nonsurgical, using the diagnosis related group (DRG). Since patients who are younger than 65 and not disabled cannot enroll in Medicare 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, 2016, 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 13.9 in the section on *Chapter 4: Hospitalization and Emergency Department Visits*. Changes are made for the cardiovascular hospitalization codes 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; 424.1; 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; 447.0-449; 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

Figures 7.8 presents adjusted all-cause mortality in the first year of ESRD, by age (7.8.a) and modality (7.8.b), for 2006–2010 and 2011-2015 incident patients younger than 30 years old (7.8.a) or age 0-21 (7.8.b). For Figure 7.8.a the patients are divided into five age groups (ages 0-4, 5-9, 10-13, 14-17 and 18-21) with an additional comparison group of those aged 22-29.

Table 7.3 presents the expected remaining lifetime in years of prevalent patients by initial ESRD modality. The method for calculating expected remaining lifetimes is described in the *Statistical Methods* section. Life expectancy of the general population was obtained from the U.S. Social Security Administration Period Life Table 2015.

Figures 7.9 and 7.10 show adjusted one-year mortality from cardiovascular causes and infectious causes of death in patients aged 0-21 by age (7.9.a, 7.10.a) and modality (7.9.b, 7.10.b). Categories of age and modality are the same as in Figure 7.8 without the comparison to those aged 22-29. Figure 7.11 shows five-year adjusted survival rates for 2007-2011 incident ESRD patients aged 0-21 years, by age (7.11.a) and modality (7.11.b). Methods follow those of Figures 7.8.

Modality at incidence is determined without using the 60-day stable modality rule (see *60-day Stable Modality Rule: Treatment History File* in the *Database Definitions, Modalities* section at the beginning of this

chapter). Dialysis patients are followed from the day of ESRD onset until December 31, 2016, and censored at loss to follow-up, transplantation, or recovered renal function. Transplant patients who receive a first transplant in a given calendar year are followed from the transplant date to December 31, 2016. Rates by age are adjusted for sex, race, Hispanic ethnicity, and primary cause of ESRD (i.e., not adjusted for age) while rates by modality are adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD. Incident ESRD patients who were younger than 22 years in 2010-2011 are used as the reference cohort.

Cardiovascular mortality is defined using codes from past and current Death Notification forms:

- 01, 02, 03, 04, 1, 2, 3, 4, 23, 25, 26, 27, 28, 29, 30, 32, 36, and 61

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, and 74

Vascular Access

Figure 7.12 shows vascular access type at initiation of hemodialysis in pediatric hemodialysis patients who began dialysis during 2006-2016, by year and age. Data are obtained from the CMS 2728 Medical Evidence form, restricted to the 2005 and 2015 versions. Age is calculated as of the date regular chronic dialysis began. Figure 7.13 shows data from CROWNWeb. All HD pediatric patients who had ESRD for at least 90 days prior to May 1, 2017, were included. Patients must have been less than 22 years old as of May 1, 2017 and alive as of May 31, 2017. Patients with missing vascular access data are excluded from each figure. Catheter includes those with a maturing fistula or graft that are still using a catheter. Arteriovenous fistula and graft only include patients not using a catheter.

Transplantation

Figure 7.14 presents an overview of the transplant population among children and adolescents. Figure 7.14.a shows the incidence rate and prevalence of ESRD among those aged 0-21 years and the percent of incident dialysis patients and point prevalence on 12/31 of each year of prevalent dialysis patients for 1996-2016. Pre-emptive transplant patients were included in both the numerator and the denominator. Figure 7.14.b shows the number of transplants during the calendar year for all listing and by first listing or listing for those with a prior transplant. It also shows the count 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 listing to kidney transplantation for new candidates (i.e., the time by which 50% of newly wait-listed candidates had received a kidney transplant) by whether the it's the first listing or a return to listing after a transplant failure. 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 groups 0-17 years and 18-21 years.

Figure 7.15 presents three-year rolling average transplant rates per 100 dialysis patient-years among dialysis patients (0-21 years old). Three-year rolling average rate is the mean among the rates of the current year and of the two years prior. Figure 7.15.a presents rates by recipient age group for patients with a living donor transplant, while Figure 7.15.b shows the same for those with a deceased donor transplant. Figure 7.15.c presents rates by Black/African American and White recipient race for living donor transplants, and Figure 7.15.d shows the same for deceased donor transplants.

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. Figure 7.16.a shows this by initial modality, and Figure 7.16.b shows this by age. Patient age in Figure 7.16.b was defined as the age at initiation of HD or PD. Figure 7.16.c shows median waiting time by primary cause of ESRD, which is taken from the Medical Evidence form. Figure 7.16.d shows this by Black/African American or White race, and Figure 7.16.e by donor type. 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 1996-2015, and having the first transplant before 12/31/2017.

Table 7.4 presents adjusted one-year, five-year and ten-year patient outcomes of all-cause graft failure, probability of returning to dialysis or having a repeat

transplant, and probability of death for pediatric recipients (ages 0-21) who received a kidney transplant from a deceased donor by year from 1996 to 2015. Table 7.5 shows the same statistics as Table 7.4 for living donor 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. For the all-cause graft failure analyses, probabilities are adjusted for age, sex, race, primary cause of ESRD, and first versus subsequent transplant. The probabilities are then standardized to the characteristics of pediatric patients receiving a kidney-only transplant in 2011. 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. 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.

Young Adults with Childhood Onset ESRD

Young adults with childhood onset ESRD are defined as individuals who initiated ESRD care before the age of 19 years and survived beyond their nineteenth birthday. Methods for Figure 7.17 are the same as those for Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. The prevalence of adult survivors of childhood onset ESRD is shown for the years 1978 to 2016. The sample used for Table 7.6 is adult survivors of childhood onset ESRD who initiated care between 1995 and 2016. They were required to have survived to adulthood by the end of 2016 and to have complete Medical Evidence form (CMS 2728) information. This includes patients who reached adulthood but died before the end of 2016.

Chapter 8: Cardiovascular Disease in Patients with ESRD

This chapter describes the prevalence of cardiovascular comorbidities and selected cardiovascular procedures in patients with ESRD. 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-9/10-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 was used to define these cardiovascular conditions using the ICD-9-CM or ICD-10-CM code values in Table 13.10.

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 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 13.11 shows the codes and type of claims used to identify each procedure.

vol 2 Table 13.10 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 (AF)	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 (HF)	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 digits, 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. [a]These codes are used when heart failure is an outcome variable.

vol 2 Table 13.11 Procedure codes (ICD-9-CM, ICD-10-CM, and HCPCS) & claims files used to define cardiovascular procedures in the USRDS ADR

(a)

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
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 xxxxxxxF; xxxxxx3; xxxxxx4: 211088-02110ZC; 211488-02114ZC

Table 13.11 continued on next page.

vol 2 Table 13.11 Procedure codes (ICD-9-CM, ICD-10-CM, and HCPCS) & claims files used to define cardiovascular procedures in the USRDS ADR (continued)

(b)

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 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

Table 8.1 displays the prevalence of cardiovascular comorbidities and procedures, by modality, age, race and sex, among ESRD patients in 2016. The cohort includes point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older on January 1, 2016, who are continuously enrolled in Medicare Parts A and B and with Medicare as primary payer from January, 1, 2016 to December 31, 2016, and whose ESRD first service date is at least 90 days prior to January 1, 2016. We exclude patients with unknown sex 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 is out of cohort members with CAD, the percent with ICD/CRT-D is 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 all patients who had cardiovascular comorbidities by modality (Figure 8.1) and age and modality (Figure 8.2), respectively, among adult ESRD patients in 2016. The cohort is the same one used for Table 8.1.

Figures 8.3 and 8.4 illustrate the adjusted survival of patients by cardiovascular diagnosis (Figure 8.3) or procedure (Figure 8.4). The cohort includes point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older on January 1, 2014, who were continuously enrolled in Medicare Parts A and B and with Medicare as primary payer from January, 1, 2014 to December 31, 2014, whose ESRD first service date was at least 90 days prior to January 1, 2014, and who survived past 2014. Patients with HF, PAD, and CVA/TIA are those whose Medicare claims indicated the diagnosis or procedure in 2014 or whose 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 2014. Patients are

followed from January 1, 2015, until the earliest date of death, modality change, transplant, lost to follow-up, recovery of renal function, or December 31, 2016. The adjusted probability of survival was calculated using the results of a Cox model, in which significant factors included age group and sex.

Tables 8.2 and 8.3 use the same methods as Figures 8.3 and 8.4, and show the adjusted two-year survival by cardiovascular comorbidity (Table 8.2) and procedure (Table 8.3).

CARDIOVASCULAR DISEASE AND PHARMACOLOGICAL TREATMENTS

This section of the chapter uses data from the Medicare Part D program, which include enrollment information and claims for prescription fills and refills for medication prescribed by a healthcare professional and filled through Part D insurance (the prescription drug event, PDE, file). Enrollees are not required to fill all of their medications through Part D and may pay out of pocket for some. Use of over the counter medications is not included in the Part D data, therefore, we have no information on such medication use.

Table 8.4 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 were also required to be enrolled in Medicare Part D for the entire calendar year. The percentages shown in the table are the row percentages, and the denominator is the number of patients with the cardiovascular diagnosis or procedure, by modality.

All drugs in the PDE file were matched to a therapeutic category according to the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification©. Claims for 2016 were searched for each drug class, and a patient was defined as having a medication in a given drug class if they had a claim for at least one filled or refilled medication in the drug class during 2016. The prescription must be part of the AHFS Classification group and have a generic name as specified in Table 13.12.

vol 2 Table 13.12 Drug classes used in Volume 2, Chapter 8 of the USRDS ADR

Drug class	AHFS classification	Generic drug name
Beta blockers	242400	*<no restriction>*
Statins	240608	*<no restriction>*
P2Y$_{12}$ inhibitors	201218	prasugrel, ticagrelor, or clopidogrel
Warfarin	201204	warfarin
Direct oral anticoagulants	201204	apixaban, rivaroxaban, dabigatran
Angiotensin converting enzyme inhibitors (ACEs) or angiotensin II receptor blockers (ARBs)	243204; 243208	*<no restriction>*

Abbreviations: AHFS, American Hospital Formulary Service, P2Y$_{12}$, a group of antiplatelet medications.

HEART FAILURE AMONG ESRD PATIENTS

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 13.10) 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 8.5 shows the distribution of heart failure type by modality in 2012-2016 for the same study cohort as in Table 8.1, except 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: HEALTHCARE EXPENDITURES FOR PERSONS WITH ESRD

OVERALL & PER PERSON PER YEAR COSTS OF ESRD

For the 2018 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. Amounts shown are nominal costs that are not adjusted for inflation.

Figure 9.1 displays Medicare paid amounts for period prevalent ESRD patients from 2004-2016, 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 history files (PAYHIST) 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 II.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 (December 31) of Medicare as primary payer, Medicare as secondary payer, Medicare Advantage, and non-Medicare ESRD patients by year using the payer history file.

Figure 9.4 describes the percent change in ESRD Medicare spending in total and per patient per year, for patients with Medicare as primary payer only. Medicare spending was abstracted from *Reference Table K: Healthcare Expenditures for ESRD*, 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, Healthcare Expenditures for ESRD*, 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. Cardiovascular and infectious hospitalizations are defined in the same way as *Chapter 4: Hospitalization and Emergency Department Visits*, with codes shown in Table 13.9.

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 Table K, Healthcare Expenditures for ESRD,* Table K.7, K.8, and K.9.

CHAPTER 10: PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH ESRD

This chapter describes prescription drug coverage and usage. New for the 2018 ADR, we investigate the spending and utilization rates of antivirals in Medicare Part D enrollees.

For inclusion in the analyses, general Medicare enrollees had to be enrolled in Medicare Parts A and B in the calendar year of interest. General Medicare estimates use the Medicare 5% sample. 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 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).

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 those with no months of low-income subsidy are classified as "Part D without LIS". 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 the beneficiary is enrolled in an employer-sponsored prescription drug plan that qualifies for Part D's retiree drug subsidy. In previous years, if the patient was not in a Part D plan or employer-sponsored plan, they were classified as "Other Creditable Coverage" if the Creditable Coverage Switch had 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 met none of the situations described above, the beneficiary was classified as "No Known Coverage." However, in the data received from the Chronic Conditions Warehouse for claim year 2016, the Creditable Coverage Switch was not available. For the 2018 ADR, the categories of "No Known Coverage" and "Other Creditable Coverage" are combined into one category. 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 2011-2016 in the General Medicare and ESRD cohorts. Table 10.2 is an adaptation of data presented in the 2016 Medicare Outlook section of the *https://q1medicare.com* website 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, and 75 and older) for dialysis patients (Figure 10.2.a) and transplant patients (Figure 10.2.b). Figure 10.3 shows the prescription drug coverage categories by race groups (White, Black/African American, Native American or Alaska Native, Asian, Native Hawaiian or Pacific Islander, Other or multiracial, and Unknown or missing) for dialysis patients (10.3.a) and transplant patients (10.3.b).

Table 10.3 is limited to beneficiaries who were 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, the ESRD cohort, and by ESRD modality. 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 and by dialysis or transplant.

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 Volume 2 *Reference Table K: Healthcare Expenditures for ESRD*). Per person per year (PPPY) costs are calculated by dividing the total cost amount by the person years at risk. Person years at risk are separately calculated for the ESRD and general populations. 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) and by ESRD modality 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, Healthcare Expenditures for Persons with*

ESRD, which show Medicare spending on Parts A and B benefits for those not in Medicare Advantage plans.

For those in fee-for-service Part D plans, Figure 10.5.a shows Part D spending by Medicare and patient out-of-pocket amounts PPPY for the General Medicare and ESRD cohorts and by ESRD modality. Figure 10.5.b shows these expenditures by LIS status. 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.

Table 10.5 shows PPPY spending by age, sex, and race for the General and ESRD cohorts broken out by use of the low-income subsidy (LIS) and by ESRD modality.

PRESCRIPTION DRUG CLASSES

Tables 10.6.and 10.7 list the top 15 drug classes used among ESRD patients by 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 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 on each drug class and its percentage of total prescription drug plan expenditures.

Figures 10.6 and 10.7 show utilization of 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.

New for the 2018 ADR, this chapter has a special focus on antiviral drugs. Figure 10.8.a shows the prevalence of Human Immunodeficiency Virus (HIV) in Medicare Part D enrollees by ESRD modality, and Figure 10.8.b shows the same for Hepatitis C virus (HCV). Diagnosis codes for HIV are 042 (ICD-9) and all of B20 (ICD-10). For HCV, the codes are 070.54 (ICD-9) and B18.2x (ICD-10) — all of the codes beginning with B18.2.

The antiviral class of drugs was defined as AHFS class 0818. We focused on antiretrovirals (081808), nucleosides and nucleotides (0818320), and protease inhibitors (081840). Figure 10.9 shows the utilization of these three drug classes over time, and Figure 10.10 shows per-patient per-year spending on these drugs by the Medicare program.

CHAPTER 11: INTERNATIONAL COMPARISONS

DATA COLLECTION

Each country was provided a data-collection form spreadsheet (Microsoft Excel) to complete for years 2012 through 2016. 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 given year. Prevalence was reported for all patients at the end of the calendar year (December 31, 2016), except where otherwise noted. Data for the United States is taken directly from *Volume 2 Reference Tables M: Census Populations, A: Incidence, B: Prevalence, D: Treatment Modalities*, and *E: Transplantation: Process*.

DATA LOADING AND CLEANING

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

ANALYSIS OF COUNTRY-LEVEL TRENDS OVER TIME

Simple linear regression was used throughout the chapter for ease of interpretation in describing country-level trends in incidence, prevalence, and transplantation rates among the international ESRD population. Though linear regression assumes a linear trend in the outcome of interest over time (year-by-year), results should be interpreted with caution, as the true country-level data do not always adhere to this assumption. To be included in linear regression models, countries needed to have reported relevant data for either 2003 or 2004, at least five of the years from 2005-2013, and for either 2015 or 2016. Additionally, percent change from 2003/04 to 2015/16 is also used to reflect trends in incidence, prevalence, and transplantation rates over time. To be included in this calculation, countries needed to have reported relevant data for 14 years overall, and at least one of the first two years (2003 and 2004) and one of the last two years (2015 and 2016).

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 from 2003/04-2015/16. The percent change in incidence rate was calculated as the percent difference between the average incidence rate in 2015 and 2016 and the average in 2003 and 2004. Figure 11.3.b presents the average yearly change in the incidence rate (per million population) for each country from 2003-2016, based on a univariate linear regression model.

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.a 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 11.4.b presents the incidence rate of treated ESRD due to diabetes as the assigned primary ESRD cause, by country, for 2016. The incidence rate was calculated as the number of patients new to ESRD during the year, where diabetes was the designated primary cause of ESRD, divided by the total population for that year, multiplied by one million. Figure 11.5 presents the average yearly change in incidence rate (per million population) of treated ESRD due to diabetes for each country from 2003-2016, based on a univariate linear regression model. Figure 11.6 presents three regional scatter plots showing the country-level correlation of the percent change in ESRD incidence with the percent change in ESRD incidence due to diabetes from 2003/04-2015/16. Percent change was calculated as the percent difference between the average incidence of treated ESRD or treated ESRD due to diabetes in 2015 and 2016 and the average in 2003 and 2004.

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 the sex-specific category, 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.a presents the ten countries with the highest percent increase in prevalence of ESRD from

2003/04-2015/16. The percent change in prevalence of ESRD was calculated as the percent difference between the average prevalence of ESRD in 2015 and 2016 and the average in 2003 and 2004. Figure 11.11.b presents the average yearly change in the prevalence of ESRD (per million population) for each country from 2003-2016, based on a univariate linear regression model. Figure 11.12 presents each country's distribution of the type of renal replacement therapy modality for prevalent patients. 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 is the total number of ESRD patients on dialysis divided by the total population for that year, multiplied by one million. Figure 11.14.a presents the ten countries with the highest percent increase in prevalence of dialysis from 2003/04-2015/16. The percent change in prevalence of dialysis was calculated as the percent difference between the average prevalence of dialysis in 2015 and 2016 and the average in 2003 and 2004. Figure 11.14.b presents the average yearly change in the prevalence of dialysis (per million population) for each country from 2003-2016, based on a univariate linear regression model. 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, 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 1,000. Figure 11.17.a presents the ten countries with the highest percent increase in the kidney transplantation rate from 2003/04-2015/16. The percent change in kidney transplantation rate was calculated as the percent difference between the average transplantation rate in 2015 and 2016 and the average in 2003 and 2004. Figure 11.17.b presents the average yearly change in the kidney transplantation rate (per million

population) for each country from 2003-2016, based on a univariate linear regression model. Figure 11.18 presents the percentage of kidney transplantations by kidney donor type (deceased, living, unknown). The denominator is calculated as the sum of deceased, living, and unknown donors. 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. Figure 11.20 presents the average yearly change in the prevalence of ESRD patients with a functioning kidney transplant (per million population) for each country from 2003-2016, based on a univariate linear regression model.

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

CHAPTER 12: USRDS SPECIAL STUDY ON END-OF-LIFE CARE FOR PATIENTS WITH ESRD, 2000-2015

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

ESRD Reference Table Methods

Downloadable ESRD Reference Tables are found on this page: https://www.usrds.org/reference.aspx.

REFERENCE TABLES A: INCIDENCE AND B: PREVALENCE

The data sources for information on both incident and prevalent patients are CROWNWeb, OPTN, the 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 transplantation on a certain date (point prevalence) or within a specified time period (period prevalence). Both incidence rates

and prevalence are adjusted to a reference population using the direct method.

The 2018 ESRD Reference Tables present parallel sets of counts and rates for incidence (Table A) and December 31 point prevalence (Table B) from 1996 to 2016 for counts and 2000 to 2016 for rates. The rates for years earlier than 2000 are not presented because census data for the seven categories of race are limited. Reference Table B also presents annual period prevalent counts (B.12) and counts of lost to follow-up patients (those who lack any evidence of payment activity in the Medicare database for one year).

The data in Reference Tables A and B should be considered complete for 2016, although the prevalence or incidence counts for a given year may have small changes at a later date due to lag time, patients with recovered renal function, and patients who die before chronic dialysis treatment is fully established. Note that the incident patients who stop chronic dialysis and then restart are counted as prevalent, and incident patients who have a modality change, i.e., return to dialysis after a failed transplant, are not counted as incident ESRD patients.

Patients with unknown age are dropped in all tables. For incident patients, age is computed as of the beginning of ESRD therapy while for prevalent patients, age is computed as of December 31 of the year. Patients with unknown/other or multiracial race, sex or ethnicity are dropped based on different requirements as presented below.

- No exclusions (except unknown age) are made for these tables:
  o A.1; A.6; A.6(1); A.7; A.7(2); A.8; A.8(2); A.8(3) and A.10
  o B.1; B.6; B.6(1); B.7; B.7(2); B.8; B.8(2); B.8(3); B.10 and B.12

- Unknown and other/multiracial races are dropped in these tables:
  o A.1(2); A.1.1-A.1.4; A.2; A.2(2); A.2.1-A.2.4; A.3; A.3.1; A.4; A.4.1; A.5; all A.5.1; A.8.1; A.8.1(2); A.9; A.9(2); A.9(3) and A.11
  o B.1(2); B.1.1-B.1.4; B.2; B.2(2); B.2.1-B.2.4; B.3; B.3.1; B.4; B.4.1; B.5; all B.5.1; B.8.1; B.8.1(2); B.9; B.9(2); B.9(3) and B.11

- Unknown sex and unknown ethnicity are dropped in these tables:
  o A.2; A.2(2); A.2.1-A.2.4; A.3; A.3.1; A.5; all A.5.1; A.9; A.9(2); A.9(3) and A.11
  o B.2; B.2(2); B.2.1-B.2.4; B.3; B.3.1; B.5; all B.5.1; B.9; B.9(2); B.9(3) and B.11

- Unknown ESRD network is dropped in Tables A.11 and B.11.

- The "Other cause" category in primary diagnosis (cause of ESRD) in Tables A.4, A.5, B.4, and B.5, includes patients with cystic kidney disease, other urologic diseases, other causes, unknown cause, and missing cause categories that are listed in the eight category primary diagnosis groups used in Table A.1 and B.1.

- "Other race" includes American Indian or Alaska Native, Asian, and Native Hawaiian or Pacific Islander in these tables:
  o A.2.1; A.2.2.; A.2.3; A.2.4 and A.3
  o B.2.1; B.2.2.; B.2.3; B.2.4 and B.3

- Because the U.S. population (shown in Reference Table M) used in the ADR includes only residents of the 50 states and the District of Columbia, most tables are limited to patients from these areas. However, the following tables present data specific to patients in Puerto Rico and the U.S. territories, or include these patients in the total patient population.
  o A.1; A.6; A.8; and A.10
  o B.1; B.6; B.8; and B.10

- Rates in these tables are adjusted for age, sex, race, and ethnicity with the 2011 national population as reference:
  o A.2(2); A.2.1-A.2.4; A.3.1; A.5; all A.5.1; A.9; A.9(2); A.9(3) and A.11
  o B.2(2); B.2.1-B.2.4; B.3.1; B.5; all B.5.1; B.9; B.9(2); B.9(3) and B.11

- Rates in Tables A.3 and B.3 unadjusted and adjusted for age, sex, and race with the CDC diabetes population estimates used as the denominator.

A new Medical Evidence form (CMS 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 13.13 shows this mapping.

vol 2 Table 13.13 Mapping to pre-2015 detailed diagnosis groups from the Medical Evidence Form (2728)

(a)

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; E13.9**
Diabetes with renal manifestations Type 1	**E10.2**; E10.22; E10.29; **E10.9**
Glomerulonephritis	
Glomerulonephritis (GN) (histologically not examined)	N00.8; **N00.9;** 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	**N02.2**; N03.2; N04.2; **N05.2**
Membranoproliferative GN type 1, diffuse MPGN	N03.5; N04.5; **N05.5**
Dense deposit disease, MPGN type 2	N03.6; N04.6
IgA nephropathy, Berger's 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**; M32.0; M32.10; M32.14; M32.15
Henoch-Schonlein syndrome	D69.0
Scleroderma	**L94.0;** M34.89
Hemolytic uremic syndrome	D59.3
Polyarteritis	M31.7
Wegener's granulomatosis	**M31.30**; 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
Goodpasture's 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	**N11.0**; 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**; **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 13.13 continued on next page.

vol 2 Table 13.13 Mapping to pre-2015 detailed diagnosis groups from the Medical Evidence Form (2728) *(continued)*

(b)

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, Alport syndrome	N07.0; N07.8; **N07.9**; Q87.81
Cystinosis	E72.04
Primary oxalosis	E72.53
Fabry 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, **Q61.3**
Renal hypoplasia, dysplasia, oligonephronia	Q61.4
Prune belly syndrome	Q79.4
Other (congenital malformation syndromes)	**Q60.0**; Q60.2; Q61.8; **Q62.6;** 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	**T86.89**-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	*Not on 2015 version of Form 2728 and not in data*
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	**K70.30**; 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; **Z87.44**
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

Codes in boldface type are those that have appeared in the data but are not listed on the 2015 Medical Evidence form (CMS 2728). Abbreviations: AIDS, acquired immunodeficiency syndrome, GN, glomerulonephritis, HbS/Hb other, sickle hemoglobin/hemoglobin other, MPGN, membranoproliferative glomerulonephritis, SBE, subacute bacterial endocarditis, SLE, systemic lupus erythematosus.

REFERENCE TABLE C: PATIENT CHARACTERISTICS

Data in Reference Table C are based on information collected with the 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 laboratory results values are excluded from the analysis, see Table 13.14 for acceptable ranges.

vol 2 Table 13.14 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 Reference Table C 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 not shown in the tables. Data shown are based on the incident population with a completed Medical Evidence form within the given year. Tables C1-C3 use data for three years combined for three time periods (2008-2010, 2011-2013, and 2014-2016). Tables C.4-C.6 and C.11 show two time periods (2011-2013 and 2014-2016) while Tables C.7-C.8 show all years from 2012-2016.

Table C.1 contains data on biochemical markers (item 19 on CMS 2728) for 2008-2010 (C.1), 2011-2013 (C.1(2)), and 2014-2016 (C.1(3)). Glycosylated hemoglobin, total cholesterol, low-density lipoprotein, high-density lipoprotein, and triglycerides were added to the 2005 Medical Evidence form. Blood urea nitrogen (BUN) was dropped from the 2005 form, therefore, BUN data are not shown in Table C.1.

Table C.2 shows patients' prior and current employment status (item 16 on CMS 2728) for 2008-2010 (C.2), 2011-2013 (C.2(2)), and 2014-2016 (C.2(3)). 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 category should be selected for each. If the patient is under 6 years old, the employment status questions should be left blank according to form instructions. 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 categories are shown for patients under 14.

Table C.3 shows patient medical insurance coverage (items 11 and 12 on CMS 2728) for 2008-2010 (C.3), 2011-2013 (C.3(2)) and 2014-2016 (C.3(3)). There are seven 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 (item 17 on CMS 2728) for 2011-2013 (C.4) and 2014-2016 (C.4(2)). 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) for 2011-2013 (C.5) and 2014-2016 (C.5(2)).

Table C.6 presents whether patients on dialysis were informed about kidney transplant options (items 26 and 27 on CMS 2728) for 2011-2013 (C.6) and 2014-2016 (C.6(2)). Patients 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 describe care received prior to ESRD therapy (item 18 on CMS 2728) for 2012-2016. Table C.7 shows data for pre-ESRD nephrology care (item 18.b). Table C.8 shows data for pre-ESRD kidney dietician care (item 18.c). Table C.9 shows data for vascular access at initiation of renal replacement therapy (item 18.d). 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 (item 18.a).

Table C.11 presents primary dialysis settings at initiation of renal replacement therapy (item 22 on CMS 2728) for 2011-2013 (C.11) and 2014-2016 (C.11(2)). 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 at 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 for 2012-2014 combined. 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 (vintage) 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 (2008, 2012, and 2016), by demographic characteristics, payer category, and treatment modality. Age is computed at 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)

- Medicare as secondary payer: with employer group health plan (EGHP) or not with EGHP

- Medicare Advantage or Medicare+Choice plans also called HMO (health maintenance organization)

- 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 (first vs. subsequent transplant), 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. Median waiting time 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 loss to follow-up, death, or the end of the analysis period (which is 12/31/2016 for the 2018 Reference Tables).

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 2018 Table E.2 only shows data up to year 2011.

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, time on the list, and active status.

Table E.4 is the percent of dialysis patients that are on the kidney wait list by year. The denominator is the count of point prevalent dialysis patients on 12/31 of each year, and the numerator is the count of the point prevalent dialysis patients on the waiting list for a kidney on 12/31 of each year. Table E.4 reports this by demographics and primary cause of ESRD. E.4.2 reports it by state/territory and Table E.4.3 by renal network.

Table E.5 presents the percent 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 and 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 (American

Samoa, Guam, Northern Marianas, and Foreign) 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 one or more other organs, are included, 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 worksheet/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 worksheet/form. Table E.8.3 reports data for living donors, and donor relationship 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 at risk 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 one or more other organs, 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 (on the day of transplant), sex, race, ethnicity, primary cause of ESRD, and first vs. 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, 2016). 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. "Other cause" in the primary cause of ESRD stratification includes patients with missing data, unknown cause, and causes other than diabetes, hypertension, and glomerulonephritis.

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, ethnicity, primary cause of ESRD, and first vs. subsequent transplant, and standardized to 2011 recipient characteristics. Adjusted survival probabilities presented by each of the covariates (age, sex, race, ethnicity, primary cause of ESRD or first vs. subsequent transplant) are standardized to the distribution of the remaining five covariates using the 2011 ESRD cohort as the standard population. For example, survival by age is adjusted for sex, race, ethnicity, primary cause of ESRD, and first vs. subsequent transplant.

REFERENCE TABLE G: MORBIDITY AND HOSPITALIZATION

Reference Table G presents adjusted total admission and hospital day rates, by year, 2004-2016. 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 Primary Payer patients may be absent or 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.

Reference Table G includes 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. Tables G.1–G.10 exclude records where the age or sex is unknown. Age is determined on January 1 of each year. Patients are also classified according to their primary cause of ESRD, in which the "other" category includes patients with missing data or causes other than diabetes, hypertension, or glomerulonephritis. Patients are classified by modality at the beginning of the year:

- All dialysis: patients on HD, CAPD/CCPD, or dialysis of an unknown type, as well as those on more than one dialysis 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 at the start of the period at risk

- Transplant: patients with a functioning transplant received less than three years prior to the start of the period at risk

- All-ESRD: all patients

Patients who do not have Medicare coverage, have Medicare as a secondary payer or have Medicare Advantage coverage will have incomplete or no hospitalization data in the claims files. For that reason, cohorts for these tables include only patients with fee-for service Medicare Parts 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 Parts A and B coverage or Medicare as a primary payer.

For patients in the all dialysis, HD, and CAPD/CCPD 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 Parts A and B coverage, or December 31. Modality change is considered a censoring event only in the case of a change from dialysis to transplant.

For dialysis patients in the all ESRD category, in contrast, the analysis period is censored only at death, end of Medicare Parts A and B coverage, or December 31 of the given year, a modality change is not used as a censoring event.

For transplant patients in the all-ESRD and transplant categories, the period is censored at the earliest of death, three years after the transplant date, end of Medicare Parts A and B coverage, or December 31 of the given year. Censoring of transplant patients at three years following the transplant is necessary because Medicare eligibility may be lost, and hospitalization data may be incomplete for these patients.

Time at risk is calculated differently for hospital days and total admissions. Since a hospitalized patient remains at risk for additional hospital days, rates for hospital days include hospital days in the time at risk value. Since a currently hospitalized patient is not, however, at risk for a new admission, hospital days for each year 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 and 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 methods for computing adjusted total admission and hospital day rates use 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, one-fourth, and one-eighth. Adjusted rates are then calculated using the direct adjustment method with all 2011 ESRD patients as the reference cohort.

Tables G.11-G.15 show inpatient utilization in 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. Rates are unadjusted and reflect total admissions per 100

patient-years for 2008-2010, 2011-2013, and 2014-2016 (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. "Dialysis access" contains both vascular access and PD access hospitalizations that are 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 13.15. 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 13.16.

vol 2 Table 13.15 DRG and ICD-9-CM procedure and diagnosis 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 OR 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 OR procedures for injuries with MCC

908 Other OR procedures for injuries with CC

909 Other OR procedures for injuries without CC/MCC

ICD-9-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

ICD-10-CM procedure codes[a]

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]

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

ICD-10-CM diagnosis codes[b]

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. Abbreviations: CC, complicating conditions, DRG, diagnosis-related group, ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, clinical modification, MCC, major complicating conditions, OR, operating room.

vol 2 Table 13.16 Diagnosis codes used to define cause of hospitalization in Reference Table G

Cause of hospitalization	ICD-9-CM diagnosis codes	ICD-10-CM diagnosis codes
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	140-234	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-CM, International Classification of Diseases, Ninth/Tenth Revision, clinical modification.

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 <u>not</u> 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 seven race groups (White, Black/African American, American Indian and Alaska Native, Asian, Native Hawaiian and Pacific Islander, Other or multiracial, and Unknown), as well

as adjusted for ethnicity (Hispanic, non-Hispanic, and Unknown). A small number of patients missing sex were excluded (0.01%).

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 (H.2_unadj) and adjusted (H.2_adj) annual mortality rates by age, sex, race, ethnicity, primary cause of ESRD, and years of ESRD treatment (vintage) 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, ethnicity, primary cause of ESRD, and years of ESRD treatment, while rates for each individual category are adjusted for the other five factors. The reference population includes 2011 prevalent ESRD patients. Table H.2_1 presents unadjusted mortality rates by age, sex, race, and ethnicity, within primary cause of ESRD categories for 2016 prevalent ESRD patients, rates are again smoothed using a generalized linear model.

The same methods are used for Tables H.3, H.4_unadj, H.4_adj, and H.4_1 (dialysis), H.5_unadj and H5_adj (dialysis patients never on the transplant waiting list), H.6_unadj and H.6_adj (dialysis patients on the transplant waiting list), H.7_unadj and H7_adj (dialysis patients returned to dialysis from transplant), H.8_unadj, H.8_adj, and H.8_1 (HD), H.9_unadj, H.9_adj and H.9_1 (CAPD/CCPD), and H.10_unadj, H.10_adj and H.10_1 (transplant).

For Table H.13_gen_pop, general U.S. population life expectancy, the data source is supplemental Table 3 of the *National Vital Statistics Report (NVSR), Deaths: Final Data for 2015* (see *References* at the end of this chapter). 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. We used a different methodology for the remaining lifetime tables of prevalent patients (H.13_Dial, H.13_Tx, H.13_Dial_DM, H.13_Tx_DM, H.13_Dial_NDM, H.13_Tx_NDM). Mortality rates were estimated using patient level data and then aggregated by age group, sex, race, and ethnicity. We then calculated average remaining lifetime.

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 or age is unknown. All new ESRD patients with an ESRD first service date between January 1, 1996 and December 31, 2016, are included in the analysis. These patients are followed from day one (ESRD onset) until death, loss to follow-up, or December 31, 2016. For dialysis patients, both HD and CAPD/CCPD, 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: PROVIDER CHARACTERISTICS

For Reference Table J, data are obtained from the CMS ESRD Facility Survey (CMS 2744, 1996 to the present), the Renal Dialysis Facilities Cost Report (CMS 265-94, 1996-2000), the Dialysis Facility Compare (DFC) database (2001-2013), the CROWNWeb database (2012-present) and 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. Facilities switched

from submitting form CMS 2744 via the ESRD Networks to submitting via CROWNWeb in 2012. This new method of input and submission may lead to unanticipated changes in trends beginning in 2012.

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 2014-2016) or the profit status field of the DFC database (2001-2013).

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

Table J.1 shows counts of the facilities by year for 1996 through 2016 by type of facility. The number of patients in these facilities is also shown. These facilities are the source for all tables reported in this section. Tables J.2-J.11 present data from fields in form CMS 2744.

REFERENCE TABLE K: HEALTHCARE EXPENDITURES FOR ESRD

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. Our claims databases are created annually six months after the end of each calendar year and are downloaded directly from CMS. 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. For example, a claim that starts in December of Year 1 and ends in January of Year 2 will be counted in Year 2. Cross-payer claims are considered to be associated with the payer status that exists at the start of the claim. For example, a patient that is Medicare Primary when the claim starts and not Primary when the claim ends is categorized as Medicare Primary for that 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 vs. 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.

For K.1 and K.2, 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 collected for 30 days prior to the transplant date 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 detailed service type categories that are shown in K.1, K.4, K.a, K.b, and K.b.1-54.

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

PAYER FILE

The payer history file is similar in concept to the USRDS treatment history file (RXHIST). Payer status is tracked for each ESRD patient from the ESRD first service date until death or the end of the study period. Data from the Medicare Enrollment Database and dialysis claims information are used to categorize payer status as Medicare Primary payer (MP), Medicare Secondary payer (MS), or non-Medicare. The claims database contains data only for MP and MS patients, so expenditure calculations 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 when they have this MS coverage.

PAYMENT INFORMATION

The expenditure calculations for this section focus on the claim payment amount, which is the amount of the payment made from the Medicare trust fund for the services covered by the claim record. These analyses also include the pass-through per diem amount, which applies to inpatient claims and

reimburses the provider for capital-related costs, direct medical education costs, and an estimate of organ acquisition costs ($25,000 in 2018).

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.1-54 are all Medicare 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 payment system for dialysis, adding a set of dialysis-related drugs, laboratory tests and supplies to the dialysis payment bundle. Prior to 2011, outpatient spending for these services was reported on claim detail lines. Beginning in 2011, total spending appears on one detail line while other related details are zero (with the exception of dialysis facilities who elected to transition to the new payment system over a four year period, for which partial spending amounts for the newly bundled services still appear on individual claim lines). This is why there are significant increases and decreases between 2010 and 2011 in some Outpatient subgroups in sheets K.1 and K.4.

TIME AT RISK

Time at risk is the time in which the patients are contributing claims to the cost aggregation. For this to happen, they must be alive, an ESRD patient, and have Medicare Primary payer status. For tables by modality, the aggregation begins at the start day of the modality. More specifically, time at risk is calculated by taking the latest date from (1) the first of the year, (2) the first service date, (3) the start of modality, or (4) the start of Medicare Primary payer, as the start date of the time at risk. The end date of the time at risk is considered the earliest of (1) the end of the year, (2) the date of death, (3) the end of modality, or (4) the end of primary payer status. Claims are only counted in the total expenditure calculations if they occur within the patient's time at risk.

REFERENCE TABLE L: VASCULAR ACCESS

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 shows the percentages of PD patients who had at least one event in the given complication category (sepsis, peritonitis, PD catheter infection) in the prevalent year. Follow-up on these patients is censored at death, change in modality, change in payer status, a claim for HD vascular access placement, or the end of the prevalent year.

See Table 13.8 for HCPCS, and ICD-9 /10 diagnosis, and procedure codes used for identifying access placements and complications.

REFERENCE TABLE M: CENSUS POPULATIONS

Reference Table M.1 includes the U.S. resident population on July 1 by year, age, sex and race for years 2000-2016. For the 2016 and earlier ADRs, the data source was the U.S. Census, intercensal and postcensal population estimates from the CDC Bridged-Race Population Database. Starting with the 2017 ADR, data are now taken from the U.S Census unbridged postcensal file. 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 that 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 direct comparisons should be made with caution.

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

Prevalence was reported for all patients at the end of the calendar year (December 31), except where otherwise noted. The percent changes in Tables N.1.b, N.2, N.4.b, N.6.b, N.8.b, and N.9.b are defined as the percent difference between the average in 2015 and 2016 and the average in 2003 and 2004, which are used to reflect trends in incidence, prevalence, and transplantation rates over time. To be included in this calculation, countries needed to have reported relevant data for 14 years overall, for at least one of the first two years (2003 and 2004), and for one of the last two years (2015 and 2016). The estimates of the average yearly change from 2003-2016 in these tables were determined from a univariate linear regression model, using year as the only independent variable. Though linear regression assumes a linear trend in the outcome of interest over time (year-by-year), results should be interpreted with caution, as the true country-level data do not always adhere to this assumption. To be included in linear regression models, countries needed to have reported relevant data for either 2003 or 2004, at least five of the years from 2005-2013, and for either 2015 or 2016.

Tables N.1-N.3 present the incident counts and incidence of ESRD patients in different countries. Incidence was calculated as the count of patients who started 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.a and N.1.b show the trends in the incident counts and incidence rates of treated ESRD patients, 2003-2016. Table N.2 shows the trends in the incidence of treated ESRD patients due to diabetes, 2003-2016. N.1.a and N.1.b use total incident patient count, while the count for N.2 is a subset of total incident patients whose kidney failure was due to diabetic nephropathy. Tables N.3.a and N.3.b show the 2016 incident counts and incidence rates 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 prevalent counts and prevalence of ESRD in different countries, 2003-2016. 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 prevalent ESRD patient counts. Table N.4.b shows the trends in unadjusted prevalence of ESRD patients. Tables N.5.a and N.5.b present the 2016 ESRD prevalent counts and prevalence in different countries, by five age groups, 0-19, 20-44, 45-64, 65-74, and 75+.

Tables N.6-N.7 present the prevalence counts and prevalence of patients treated with dialysis therapy for ESRD, 2003-2016. Tables N.6.a and N.6.b show the trends in the prevalent counts and unadjusted prevalence of patients receiving dialysis. Tables N.7.a-N.7.f show the distribution of different modality use in prevalent dialysis patients, including counts and percentage of in-center hemodialysis (N.7.a, N.7.d), counts and percentage of CAPD/APD/IPD (N.7.b, N.7.e), and counts and percentage of home hemodialysis (N.7.c, N.7.f). The denominator was calculated as the sum of patients receiving HD, PD, or home HD, excluding patients with other/unknown modality.

Tables N.8-N.9 present data regarding kidney transplantation in different countries, 2003-2016. Tables N.8.a and N.8.b present the counts and 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. Tables N.9.a and N.9.b show the trends in the prevalent counts and unadjusted prevalence of treated ESRD patients with a functioning kidney transplant. Table N.9.c 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 in one year divided by the 2015 population size in one year and, if the unit is per million population, multiplied by one million for rates measured as per million per year. The 2015 death rate for prevalent ESRD patients, meanwhile, 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. A count-based rate describes the proportion having the "event," and a 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. A model-based method can improve the stability of these estimates by smoothing the estimates across calendar years. 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: Mortality and Causes of Death*.

MEASUREMENT UNIT FOR RATES

Both observed and model-based rates are calculated per unit of population (e.g., per 1,000 patients) and per unit of follow-up time (e.g., 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 13.17 Example data for time at risk calculation

| Patient | Group | Event date | Time at risk | | | |
			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	1,143	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 13.17. Group B also has three patients.

Patients 1 to 6 respectively contribute 0.25, 0.5, 1.0, 1.0, 0.75, and 1.0 patient-years at risk. The first hospitalization rate per thousand patients is 889 for all patients (in either group) in 2015. However, 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. The rate for Group B is calculated as (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.

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

Direct adjustment is a rate-adjustment method that allows rates to be compared adjusting for differences in the patient population. 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 want 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 prevalent population at the end of 2015 — with five race groups (White, Black/African American, Native American, Asian, and Other).

Using the State A's incidence rates which come from State A's race-specific incidence rates and its

own population's racial distribution, it has an overall unadjusted incidence rate in 2015 is 196.2 per million population per year. The race-specific rates of State A, State A's race distribution and the racial distribution of the national population are as shown in Table 13.18. The adjusted incidence rate of state A (with the national population as reference) is calculated by using State A's unadjusted race-specific incidence rates multiplied by the U.S. national racial

distribution, as in this equation: (153 x 75.1%) + (250 x 12.3%) + (303 x 0.9%) + (174 x 3.6%) + (220 x 8.0%) = 172.2 per million population. This means that if state A had the same racial distribution as the entire country, its incidence rate would be 172.2 instead of 196.2. If state B had an adjusted incidence rate of 205 (calculated the same way), we could say that state B had a higher incidence rate than state A if both states had the same racial distribution as the whole country.

vol 2 Table 13.18 Example of adjusted incident rate calculation

	Incidence rate of state A	State A racial distribution (%)	National population racial distribution (%)
White	153	50	75.1
Black/African American	250	20	12.3
Native American or Alaska native	303	10	0.9
Asian	174	10	3.6
Other	220	10	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 2: Clinical Indicators and Preventive Care*, *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 (i.e., varying greatly from year to year), 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). 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. 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, …, 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 incorporate age (categorical), ethnicity, race, sex, diabetes status (unless stratified by diabetes) and year, and all the two-way interaction terms except between race and ethnicity. Models in the "_adj" worksheets are also adjusted for vintage and all the two-way interaction terms except 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.

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

GENERALIZED LINEAR MODEL FOR HOSPITALIZATION RATES

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

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

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, the expected remaining lifetime is calculated using a survival function based on conditional piecewise exponential survival, where the death rate is assumed to be constant within each age group (mostly 5-year age groups). For a given starting age A, the expected remaining lifetime is then equal to the area under this piecewise exponential survival curve. Because few patients live beyond 100, this area is truncated at the upper age limit of 100 years.

MEDIAN TIME (HALF-LIFE)

CONDITIONAL HALF-LIFE

The conditional half-life is conditional on having survived a given period of length T_o 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. Some maps are by health service areas (HSAs). HSAs are defined as one or more counties that are relatively self-contained with respect to the provision of hospital care (Makuc et al., 1991).

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