
2018 USRDS Annual Data Report: Executive Summary

Introduction

This year marks the publication of the 29th Annual Data Report (ADR) of the United States Renal Data System (USRDS). Broadly, the mission of the USRDS is to characterize the kidney disease population in the country and serve as a comprehensive, regularly updated, online resource for descriptive epidemiology of kidney disease in the United States. In addition, supporting investigator initiated research by data provisioning to the community of researchers is one of the key functions of the USRDS. To this end, the USRDS prepares and regularly updates the standard analysis files (SAFs) for researchers, and fulfills data merge requests from researchers or organizations seeking to examine the outcomes of populations of interest with respect to the occurrence of end-stage renal disease (ESRD) and related complications. Last but not least, the USRDS Coordinating Center staff responds to a variety of queries related to kidney disease, ranging from simple to complex, from individuals as well as governmental and non-governmental agencies.

Federal agencies have done much to raise awareness of kidney disease as a significant public health problem. Only few decades ago kidney failure was a fatal disease. When dialysis was developed and made available as a chronic therapy, lack of insurance coverage represented a barrier to treatment. This resulted in the passage of the landmark Medicare ESRD program in 1972 to fund ESRD care for all Americans.

In 1988, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) established the USRDS, the largest and most comprehensive national, ESRD and chronic kidney disease (CKD) surveillance system. The initial USRDS ADRs offered a detailed descriptive epidemiology of ESRD alone. A chapter addressing CKD was introduced in 2003, and was

subsequently expanded into a multi-chapter CKD volume from 2008 onward.

Since 2000, CKD has received increasing attention. The consensus definition and staging classification of CKD / KDOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification were first published in 2002. That year also marked the launch of NIDDK's National Kidney Disease Education Program (NKDEP). NKDEP provides information for patients and providers regarding the detection of CKD and care of people with the disease. In 2006, the Centers for Disease Control and Prevention launched a broad CKD initiative, with the CDC CKD Surveillance System as its major component. This project prioritizes the earlier stages of CKD, as opposed to ESRD, or the late transitions of care from advanced stages of CKD to ESRD.

In the 2018 ADR, we continue to characterize the spectrum of CKD and ESRD patient populations, and describe the distributions of patients by attributes such as age, sex, race, and comorbid conditions. The topic of Acute Kidney Injury (AKI) continues to receive attention, by virtue of both its bidirectional relationship with CKD and recent policy changes that now provide reimbursement to outpatient dialysis units for AKI patients who are dialysis dependent.

The two current USRDS special studies investigate the transition of care from CKD to ESRD and end-of-life care for those with advanced kidney disease. These studies continue to contribute valuable findings to guide practice and policy in the renal community.

Our primary audiences are healthcare providers involved in care of patients with kidney disease — nephrologists, transplantation specialists, and general physicians. This report is also of value for healthcare facilities and organizations that provide comprehensive kidney care and renal replacement therapies, and to researchers, policy makers, and service or charitable organizations. We dedicate this work to the individual

patients and their families and caregivers whose daily lives are affected by kidney disease.

What's New (or Relatively New) in the 2018 USRDS Annual Data Report

Beginning on October 1, 2015, the newly revised International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) coding system was implemented. Many of our data sources utilize these diagnosis codes to identify specific stages of kidney disease and common comorbid conditions. We continue to build on the challenge of transitioning our data and analyses from ICD-9-CM diagnosis and procedure codes to the ICD-10-CM codes. This has allowed us to provide continuity with the data trends and analyses presented in previous ADRs. Our CKD and ESRD Analytical Methods chapters include detailed comparisons of the ICD-9-CM and ICD-10-CM diagnosis codes used to define medical conditions in the health insurance claim data files throughout the ADR.

No individual data source exists that captures the disease experiences of all Americans who live with kidney disease. A large proportion of our information is drawn from Medicare beneficiaries; however, they are not a nationally representative population.

Since 2017 we have included two new data sources that have expanded our coverage of the U.S. population.

- We continue to examine data purchased from the Optum Clinformatics™ Data Mart Database (OptumInsight, Eden Prairie, MN). The Optum Clinformatics™ Data Mart provides paid medical and prescription claims and enrollment information for participants in commercial insurance plans (e.g. HMOs), and the Medicare Advantage plans of a large U.S. managed care health insurance company. Included are plan members who were enrolled in both a medical and a prescription plan. These data allow us to examine the experience of younger, employed individuals, and all areas of the country are represented in the samples. The Optum Clinformatics™ cohorts include information on about nine million lives per year.

- We continue to expand our analyses of Veterans Health Administration Data (VHA). This national health system-derived data represents more than six million veterans.

As in the 2017 ADR, in the interest of drawing attention to disparities whenever possible, we continue to characterize the ESRD population by race *and* ethnicity categories, as opposed to race *or* ethnicity. In previous ADRs, we considered ethnicity separately from race, based on whether a person was Hispanic, or not. As the Hispanic population in America grows, it becomes more meaningful and accurate to examine separate cohorts of non-Hispanic White, non-Hispanic Black, and Hispanic patients, the majority of whom identify themselves as White. Whenever possible, our race categories match those of the U.S. Census. Census definitions change periodically, most recently in 2000. We report data prior to 2000, but in the 2018 ADR employ the most recent census categories wherever possible. However, race and ethnicity categorizations are limited by the categorizations available in the source datasets. We were unable to replicate the current census race and ethnicity characterization in the CKD volume for this reason.

In the interest of examining regional differences, and to provide information salient to our audiences in different areas of the country, we continue to report geographic variations by health service area or ESRD network.

A new chapter on CKD in children and adolescents has been included in 2018, along with continued expanded coverage of ESRD among children, adolescents and young adults, including information about childhood onset ESRD among patients who have transitioned to adulthood. The ESRD hospitalization chapter now includes emergency department visits and observation stays in addition to the continued emphasis on inpatient stays and readmissions.

DATA SOURCES AND ANALYTICAL METHODS

Originally, the ADR was the product of a stand-alone ESRD database that served as a source of descriptive epidemiology of ESRD patients covering

areas such as incidence, prevalence, modality of renal replacement and treatment history, along with biochemical data, dialysis claims, and information on medication use, payer histories, hospitalization events, deaths, physician/supplier services, dialysis providers, and renal transplantation. The findings presented in the ADR are now drawn from numerous data types and sources. Details of these are described in the Data Sources sections of the *CKD Analytical Methods* and *ESRD Analytical Methods* chapters. We also describe data preparation and management, variable definition, and the analytic methods used to generate the study cohorts, and produce the statistics, figures, and tables presented in the ADR.

Downloadable PowerPoint files containing tables and figures in each chapter are available on the [USRDS website](#). In addition, readers should be aware that the underlying data tables used to generate the figures in individual chapters are available for download as Microsoft Excel spreadsheets on the USRDS website. Thus, in order to supplement the figures presented in the ADR chapters, readers may opt to examine the data tables in the Excel download files.

RENAL DATA EXTRACTION AND REFERENCING (REN DER) SYSTEM

The USRDS Renal Data Extraction and Referencing (RenDER) System is an online data querying application available through the USRDS website, allowing access to a wealth of information regarding ESRD in the United States. It quickly returns an accurate table of data or interactive map based upon the user's query specifications. Tables can then be copied into a spreadsheet application on the user's computer for further manipulation and investigation. Map images can be copied or saved to local applications. In addition, a dBase file of the data, which can be opened in MS Excel, is also offered for download. We are continuing to develop RenDER and plan to continue enhancing the functionality of the interface. We plan to eventually add the capability for additional rate calculations and graphing capabilities, as well as an expanded database.

SUMMARY OF DATA SOURCES

Data on CKD in the non-institutionalized, general population come from the National Health and Nutrition Examination Survey (NHANES) and the Behavioral Risk Factor Surveillance System (BRFSS), both conducted by the Centers for Disease Control and Prevention.

The majority of USRDS analyses employ claims-based and enrollment data obtained from the Centers for Medicare & Medicaid Services (CMS). Files for Medicare Parts A and B contain billing data from final action claims submitted for Medicare beneficiaries in which all adjustments have been resolved. The Medicare Prescription Drug Event File includes data submitted by health plans whenever a Medicare beneficiary fills a prescription; Part D coverage data has been available since its introduction in 2006.

For patients with CKD, acute kidney injury, and related comorbidities, analyses are performed on the Medicare 5% sample. These Standard Analytical Files (SAFs) are a random sample of 5% of the entire Medicare population. Medicare ESRD Claims SAFs contain data from claims for medical services provided to Medicare beneficiaries with ESRD. Institutional claims include those for inpatient, outpatient, skilled nursing facility, home health agency, and hospice services. Non-institutional claims include those for physicians and suppliers, and for durable medical equipment.

The Medicare Enrollment Database (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 and employer group health plan status, and Health Insurance Claim/Beneficiary Identification Code cross-referencing.

Other CMS data files consist of information submitted through ESRD specific forms completed by providers or facilities. These include the Medical Evidence form (CMS 2728), used to register patients at the onset of ESRD, the Death Notification form (CMS 2746), and the Facility Survey form (CMS 2744). The latter 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. CMS Dialysis Facility Compare data define corporation name and ownership type for each renal facility.

CROWNWeb is a web-based data collection system that was implemented nationally in May 2012. It captures clinical and administrative data from Medicare-certified dialysis facilities for all ESRD patients. Clinical measures are also available in the VHA data and to a lesser degree in NHANES.

CDC National Surveillance Data was collected during 1993-1997 and 1999-2002. It was a non-patient specific survey of dialysis facilities on patient and staff counts, membrane types, reuse practices, water treatment methods, therapy types, vascular access use, antibiotic use, hepatitis vaccination, and conversion rates (for both staff and patients), as well as the incidence of HIV, AIDS, and tuberculosis.

Population data are from the 2000 and 2010 United States Census, and incorporate CDC postcensal and intercensal population estimates. USRDS summarizes the data with different race and ethnicity categories at state and national levels.

Summary/Key Findings

Readers are referred to the 2018 USRDS ADR Infographic on the USRDS website for an overview of key highlights. The following paragraphs represent only an outline of some of the salient findings reported in the 2018 ADR. More detailed commentary and the USRDS Special Studies reports are presented within the individual chapters of the ADR.

VOLUME 1: CHRONIC KIDNEY DISEASE IN THE UNITED STATES

Volume 1 of the 2018 USRDS ADR provides an analysis of chronic kidney disease (CKD) in the United States. It includes the following chapters as a road map to the early stages of kidney disease: *CKD in the General Population* (Chapter 1); *Identification and Care of Patients with CKD* (Chapter 2); *Morbidity and Mortality in Patients with CKD* (Chapter 3); *Cardiovascular Disease in Patients with CKD* (Chapter

4); *Acute Kidney Injury* (Chapter 5); *Healthcare Expenditures for Persons with CKD* (Chapter 6); *Prescription Drug Coverage in Patients with CKD* (Chapter 7); and the USRDS Special Study Center report on *Transition of Care in Chronic Kidney Disease* (Chapter 9).

Through the analyses and investigations in these chapters, we tell the story of CKD — one that is important not only to the domestic and international renal communities, but for the general population as well. It is important for everyone to understand and care about the growing implications of kidney disease. These chapters synthesize a wealth of data and describe how this often silent condition can be recognized. Throughout these chapters, we present status and trends. We discuss risk prediction and prevention, disease management, and opportunities to slow disease progression. We discuss the interactions with common comorbid conditions and emphasize the need for interventions before reaching the often-irreversible need for renal replacement therapy.

CHAPTER 1: CKD IN THE GENERAL POPULATION

Overall, chronic kidney disease (CKD) prevalence has remained relatively stable during the last two decades. Prevalence of CKD (Stages 1-5) in the general U.S. adult population was 14.8% in 2013-2016, based on NHANES data. CKD Stage 3 (6.4%) was the most prevalent (Figure 1.1). In the general U.S. population during the years 2013-2016, the prevalence of a urinary albumin-to-creatinine ratio (ACR) of >10 mg/g of creatinine was 33%, including 8.5% with ACR 30-300 mg/g and 1.6% with ACR >300 mg/g (Figure 1.3). In the future, we anticipate that a subset NHANES sample will undergo repeat testing of both blood and urine, allowing assessment of CKD prevalence using the persistence criterion of the KDIGO definition.

In light of the 2017 blood pressure guidelines from the American College of Cardiology/American Heart Association (ACC/AHA), this year we examine hypertension control at both 130/80 mm Hg and 140/90 mm Hg. In a comparison of four cohorts of NHANES participants (2001-2004, 2005-2008, 2009-2012, and 2013-2016), little change was seen among individuals without CKD, but among individuals with CKD, the percentage within the ACC/AHA guidelines has improved from

40.4% to 48.8% for BP <130/80 and from 61.5% to 68.4% for BP <140/90 (Figures 1.10.b & 1.10.a).

The prevalence of self-reported CKD remains very low in the U.S. general population. Comparing these same four NHANES cohorts, we continue to see little improvement in the percentage of individuals with CKD who were aware of their disease in the early stages, but among individuals in Stage 4, CKD awareness increased from 36% to 57%. Even for individuals with hypertension (HTN) and diabetes mellitus (DM), only 15% were aware of their kidney disease.

CHAPTER 2: IDENTIFICATION AND CARE OF PATIENTS WITH CKD

Over half of patients in the Medicare 5% sample (aged 65 and older) had at least one of three diagnosed chronic conditions – chronic kidney disease (CKD), cardiovascular disease (CVD), or diabetes mellitus (DM), while 19.9% had two or more of these conditions. Within a younger population derived from the Optum Clinformatics™ Data Mart (ages 22-64 years), 10.6% had at least one of the three conditions, and 1.6% had two or more. As indicated by diagnosis claims and biochemical data from the Department of Veterans Affairs (VA), 15.6% of patients had at least one of the three conditions, while 2.4% had at least two (Table 2.2.b).

The proportion of patients with recognized CKD in the Medicare 5% sample has grown steadily, from 2.7% in 2000 to 13.8% in 2016 (Figure 2.2). In the Medicare 5% sample and VA data, 13.8% and 14.9% of patients had a diagnosis of CKD in 2016, as opposed to only 2.0% of patients in the Optum Clinformatics™ population (Table 2.4).

Testing for urine albumin is recommended for patients with DM. Among Medicare patients with a diagnosis of DM, claims data indicated that testing for urine albumin has become more common, but was conducted for less than half of these patients—41.8% in 2016, up from 26.4% in 2006. In 2016, urine albumin testing was performed in 49.9% of diabetic Medicare patients who also had diagnoses of CKD and hypertension (HTN). Patterns were similar in the Optum Clinformatics™ population, but with somewhat lower rates of testing (Figures 2.3 and 2.4).

Among Medicare patients with recognized CKD in 2015, patients who saw a nephrologist were roughly twice as likely to have a claim for urine albumin testing in 2016 (55.4%) than those who saw only a primary care physician (26.7%; Figure 2.5).

CHAPTER 3: MORBIDITY AND MORTALITY IN PATIENTS WITH CKD

This chapter considers mortality, hospitalization and readmissions among chronic kidney disease (CKD) patients using the Medicare 5% sample and Optum Clinformatics™ data from a commercial insurer.

In 2016, Medicare patients with CKD experienced a mortality rate of 122.6 per 1,000 patient-years. When adjusted for sex, age, and race, the rate remained more than double the 43.1 per 1,000 patient-years of those without CKD. Mortality rates increased with CKD severity, but the gap has narrowed between CKD and non-CKD patients from 2004 to 2016 (Table 3.1 and Figure 3.1). Male patients without CKD experienced higher adjusted mortality rates of 48.2 per 1,000 patient-years than did females, at 39.2. This relative difference was similar among those with CKD, with an adjusted mortality rate of 114.4 per 1,000 patient-years for males and 94.9 for females (Table 3.1 and Figure 3.4). In 2016, Medicare age and sex adjusted mortality rates were 104.2 per 1,000 patient-years for Whites and 106.6 per 1,000 patient-years for Blacks/African Americans (Figure 3.5).

Adjusted hospitalization rates declined from 2015 to 2016 in both the Medicare and Optum Clinformatics™ CKD and non-CKD patients. The decline was greater for CKD patients than for patients without CKD in both populations (Figure 3.7). Not surprisingly, among Medicare patients, after adjustment for sex and race, rates of hospitalization in older patients were greater than for younger age cohorts. In the CKD group, hospitalization rates for those over 85 years was 39.7% higher than among those aged 66 to 69 years: 706.2 vs. 505.4 admissions per 1,000 patient-years at risk (Figure 3.12). Black patients with CKD had higher adjusted rates of hospitalization than did Whites and Other races (651.8 vs. 568.3 vs. 471.1 per 1,000 patient-years). Disparities in outcomes increased with disease severity (Figure 3.14). At 21.6%, unadjusted rates of hospital

readmission in Medicare patients with CKD were higher than the 15.3% for those without CKD (Table 3.3).

CHAPTER 4: CARDIOVASCULAR DISEASE IN PATIENTS WITH CKD

The prevalence of cardiovascular disease (CVD) was 64.5% among patients aged 66 and older who had chronic kidney disease (CKD), compared to 32.4% among those who did not have CKD (Table 4.1). The presence of CKD is associated with worsened short- and long-term prognosis for many common cardiovascular diseases. For example, the adjusted two-year survival of patients with acute myocardial infarction (AMI) and without a diagnosis of CKD was 82%, compared with 75% for CKD Stage 1-2 patients and 59% for Stage 4-5 patients (Figure 4.2). The presence of cardiovascular disease is also associated with worsened short- and long-term prognosis for patients with CKD. Over a two-year period, Medicare patients with both heart failure and CKD had an adjusted survival probability of 77.8%, compared to 90.2% for those with CKD alone (Figure 4.5).

Atrial fibrillation (AF) was common among Medicare patients with CKD (23.8%). The prevalence of AF was higher among males, older persons, and patients with hypertension (HTN), advanced stages of CKD, and heart failure (HF). Nearly half of CKD patients with heart failure had a diagnosis of AF (Table 4.5).

Angiotensin converting enzyme inhibitors (ACEs) and angiotensin receptor blockers (ARBs) are mainstays of heart failure therapy and were prescribed to 59.9% of CKD patients with HF, compared to 61.2% of non-CKD patients with HF. Although direct oral anticoagulants have been less studied among patients with CKD, these drugs were prescribed to 30.9% of patients with AF and CKD, as compared with 33.2% of patients with AF and no CKD (Table 4.4).

CHAPTER 5: ACUTE KIDNEY INJURY

In 2016, 4.4% of Medicare fee-for-service beneficiaries experienced a hospitalization complicated by acute kidney injury (AKI), double the proportion of 2.2% in 2006 (Figure 5.1). Risk of AKI increases with age and in the presence of comorbidities such as chronic kidney disease (CKD) and diabetes mellitus (DM). About 1 in 5 hospitalized

Medicare patients with both CKD and DM experience a hospitalization with AKI each year (Figure 5.5).

Among hospitalized veterans aged 22+ years, 25.4% met Kidney Disease: Improving Global Outcomes (KDIGO) guidelines for AKI as defined using serum creatinine-based criteria (Table A). This included 21.4%, 0.8%, and 3.2% of patients with Stage 1, Stage 2, and Stage 3 AKI (Table 5.2). Just over half (52.6%) of patients meeting criteria for AKI were given a diagnosis of AKI. In 2014, Medicare patients aged 66+ years who were hospitalized for AKI had a 36% cumulative probability of a recurrent AKI hospitalization within one year (Figure 5.6.a). For Optum Clinformatics™ patients aged 22+ years, the probability of recurrent AKI hospitalization was 23% (Figure 5.7.a).

Among Medicare patients without a pre-existing diagnosis of CKD, 30.8% were given a new diagnosis of CKD in the year following an AKI hospitalization (Figure 5.10.a). In the Optum Clinformatics™ population, 33.8% of patients with an AKI hospitalization were newly classified as having CKD in the subsequent year (Figure 5.10.b). In contrast, among Medicare patients with a “new” diagnosis of CKD in 2016, 25% had an AKI hospitalization in the preceding year.

CHAPTER 6: CKD AMONG CHILDREN AND ADOLESCENTS

For the first time, the 2018 ADR includes a chapter on chronic kidney disease (CKD) among children in the United States, using data from a single commercial payer. Among those with healthcare coverage, a diagnosis of CKD was made among 2.7 per 1,000 children (Table 6.2). Hospitalization rates were 12 times higher for children with CKD than for all children (Table 6.3). Between 2006 and 2016, healthcare expenditures increased by 50% for children with CKD, compared to 25% for children without CKD (Figure 6.3). Healthcare expenditures for children with CKD in 2016 were 7.6 times higher than expenditures for children without CKD (Figure 6.3).

CHAPTER 7: HEALTHCARE EXPENDITURES FOR PERSONS WITH CKD

In the 2018 Annual Data Report (ADR), we introduce information from the Optum

Clinformatics™ DataMart for persons with Medicare Advantage and commercial managed care coverage to provide a more comprehensive examination of the financial costs necessary to provide care to beneficiaries with chronic kidney disease (CKD). Medicare spending for all beneficiaries who had CKD (12.5% of total) exceeded \$79 billion in 2016, an increase of 23% from 2015 (Tables 7.1 and 7.3). When adding an additional \$35 billion for end-stage renal disease (ESRD) costs (Figure 9.2), total Medicare spending on both CKD and ESRD was over \$114 billion, representing 23% of total Medicare fee-for-service (FFS) spending. In 2016, Medicare spending for beneficiaries with CKD aged 65 and older exceeded \$67 billion, representing 25% of all Medicare spending in this age group (Figure 7.1). Medicare expenditures for CKD were 20% higher in 2016 than in 2015 (\$55 billion). This was mostly due to an 18% increase in the ascertainment of CKD. Medicare spending for beneficiaries with CKD who were younger than age 65 (8% of total) exceeded \$12 billion in 2016, representing 18% of total spending in this age group (Table 7.3). Growth in total CKD spending has primarily been driven by an increase in the number of identified cases, particularly those in the earlier stages (CKD Stages 1-3). Over half of 2016 Medicare spending for beneficiaries aged 65 and older was for those who had diagnoses of CKD, diabetes mellitus (DM), or heart failure (HF; Figure 7.1). Spending per patient-year for those with all three chronic conditions of CKD, DM, and HF was more than twice as high (\$39,506) as for beneficiaries with only CKD (\$16,176; Table 7.1). The analysis of expenses for beneficiaries with CKD indicates the effect of cost-containment efforts in this population, and avenues for potential savings. Reduction in expenditures could be achieved through the prevention of disease progression to later stages of CKD, and prevention of the development of concurrent chronic conditions such as DM and HF.

CHAPTER 8: MEDICARE PART D PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH CKD

Approximately 73.7% of chronic kidney disease (CKD) patients enrolled in Medicare Part D in 2016, including both the fee-for-service stand-alone and Medicare Advantage plans. The Part D enrollment rate for the CKD group was slightly higher than in the

general Medicare population (69.5%; Figure 8.1). The percentage of Medicare beneficiaries who received the Low-income Subsidy (LIS) was higher for CKD patients across all age and race categories than in the general Medicare population (Figures 8.2 and 8.3). As compared to White beneficiaries (29.3%), much higher proportions of Asian (73.8%) and Black/African American (62.8%) CKD Part D beneficiaries qualified for the LIS (Figure 8.3).

Among patients with stand-alone Part D plans, per person per year (PPPY) insurance spending on prescriptions was 1.6 times higher for Medicare patients with CKD than for general beneficiaries (\$4,941 vs. \$3,027) in 2016. Spending for CKD patients with Medicare Advantage plans was 1.6 times higher (\$2,926, vs. \$1,834), and 4.1 times higher for those with managed care coverage (\$4,164 vs. \$1,013; Figure 8.5.a). Total spending for Part D-covered medications in 2016 was more than twice as high for patients with the LIS than for those without, regardless of the presence of CKD. Patient out-of-pocket costs for LIS patients represented only a 1.2%-1.3% share of these total expenditures, as compared to 25.3%-27.0% in each of the non-LIS populations (Figure 8.5.b). Prescriptions for lipid-lowering agents, antibacterials, renin-angiotensin-aldosterone system inhibitors, and β -adrenergic blocking agents (beta blockers) were each filled by more than 50% of Medicare CKD patients during 2016 (Table 8.6). CKD patients with Medicare Advantage and managed care coverage showed similar patterns of use for these drug classes. By drug class, the highest medication expenditures for patients with CKD were for antidiabetic agents, followed by antineoplastic agents, antivirals, and lipid-lowering agents (Table 8.7). The overall proportions of CKD patients using prescription non-steroidal anti-inflammatory agents (NSAIDs) and opioids were 16.4% and 43.8%, respectively (Figures 8.6-8.7).

VOLUME 2: END-STAGE RENAL DISEASE IN THE UNITED STATES

Volume 2 of the ADR provides key statistics on end-stage renal disease (ESRD) in the United States and includes the following chapters: *Incidence, Prevalence, Patient Characteristics, and Treatment Modalities* (Chapter 1); *Clinical Indicators and*

Preventive Care (Chapter 2); *Vascular Access* (Chapter 3); *Hospitalizations, Readmissions, Emergency Department Visits, and Observation Stays* (Chapter 4); *Mortality* (Chapter 5); *Transplantation* (Chapter 6); *ESRD among Children, Adolescents, and Young Adults* (Chapter 7); *Cardiovascular Disease in Patients with ESRD* (Chapter 8); *Healthcare Expenditures for Persons with ESRD* (Chapter 9); *Prescription Drug Coverage in Patients with ESRD* (Chapter 10); *International Comparisons* (Chapter 11); and the USRDS Special Study Center report on *End-of-Life Care for Patients with ESRD* (Chapter 12). In addition, we also present a chapter on the Healthy People 2020 program, which assesses progress on the HP2020 kidney disease objectives.

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

The age-sex-race standardized incidence rate of end-stage renal disease (ESRD) in the United States rose sharply in the 1980s and 1990s, leveled off in early 2006, and has declined slightly since its peak in 2006 (Figure 1.1). In 2016, there were 124,675 newly reported cases of ESRD; the unadjusted (crude) incidence rate was 373.4 per million/year (Table 1.1). Since 2011, the crude rate had risen; however, the standardized rate appears to have plateaued (Figure 1.1). In 2016, the age-sex-standardized ESRD incidence rate ratio, compared with Whites, was 2.9 for Blacks/African Americans, 1.2 for American Indians/Alaska Natives, and 1.1 for Asians (Figure 1.5). All these represent reductions in the relative rate of ESRD for these populations compared to Whites over the past 16 years. The incidence rate ratio for Hispanics versus non-Hispanics was 1.3 (Figure 1.6). Based on 2013 data, the lifetime risk of being diagnosed with ESRD from birth was 4.0% in males and 2.9% in females. Among males, the lifetime risk ranged from a low of 3.4% in Whites to a high of 8.1% in Blacks/African Americans, while in females, it ranged from 2.3% in Whites to 6.8% in Blacks/African Americans. (Figure 1.7 and Table 1.3).

On December 31, 2016, there were 726,331 prevalent cases of ESRD; the crude prevalence was 2,160.7 per million in the U.S. population (Table 1.4). The number of prevalent ESRD cases has continued to rise by about 20,000 cases per year (Table 1.4). In contrast to the standardized incidence rate, the age-sex-race-

standardized prevalence of ESRD has continued to increase since 2006 (Tables 1.1 and 1.4).

In 2016, 35.4% of incident ESRD patients received little or no pre-ESRD nephrology care (Table 1.8.a). Mean eGFR at initiation of dialysis in 2016 was 9.7 ml/min/1.73 m² (Table 1.10), down from a peak of 10.4 in 2010. The percentage of incident ESRD cases starting with eGFR \geq 10 ml/min/1.73 m² rose from 12.9% in 1996 to 42.6% in 2010, but decreased to 38.6% in 2016 (Figure 1.19).

CHAPTER 2: CLINICAL INDICATORS AND PREVENTIVE CARE

In May 2017, the majority (64.5%) of hemodialysis (HD) patients had hemoglobin (Hgb) levels from 10 to <12 g/dL, while 14.5% had Hgb \geq 12 g/dL, 14.4% had Hgb from 9 to <10 g/dL, and 6.6% had Hgb <9 g/dL. The mean Hgb was 10.8 g/dL (Figure 2.1.b). The majority (56.1%) of peritoneal dialysis (PD) patients had Hgb levels from 10 to <12 g/dL, while 21.4% had Hgb \geq 12 g/dL, 15.2% had Hgb from 9 to <10 g/dL, and 7.3% had Hgb <9 g/dL. The mean Hgb was 10.9 g/dL (Figure 2.1.b). As of 2016, three different erythropoiesis-stimulating agents (ESAs) were prescribed to dialysis patients in the United States. December 2016 claims data indicated monthly use rates among HD patients on dialysis \geq 90 days of 34.4% for epoetin (EPO) alfa, 17.9% for darbepoetin, and 24.4% for pegylated EPO (PEG-EPO) beta. Twenty-two percent of HD patients were not using an ESA. Among PD patients, 31.2% were using EPO alfa, 13.0% darbepoetin, and 13.1% PEG-EPO, while 41.7% of PD patients were not using an ESA (Figures 2.2.d and 2.8.d.). For U.S. HD patients between 2015 and 2016, a small increase was seen in monthly percent intravenous (IV) iron use (60.0% to 61.8%), whereas, mean monthly IV iron dose declined slightly (from 294.1 mg to 291.8 mg; Figure 2.4). Similarly, for PD patients a small increase was also seen in monthly percent IV iron use (25.3% to 26.5%) and decline in mean monthly IV iron dose (from 196.2 mg to 190.9 mg; Figure 2.10). Serum ferritin levels increased slightly in all dialysis patients from 2015 to 2017. As of May 2017, 30.4% and 25.5% of HD patients had serum ferritin levels of 801-1200 and >1200 ng/mL. Among PD patients, 22.4% and 17.2% had serum ferritin levels of 801-1200 and >1200 ng/mL (Figures 2.6 and 2.12).

In May 2017, 60.5% of HD and 57.5% of PD patients had serum calcium levels within the range of 8.4-9.5 mg/dL. About 1.3% of HD patients and 1.9% of PD patients had serum calcium levels greater than 10.2 mg/dL, and 16.9% of HD patients and 23.1% of PD patients had serum calcium levels less than 8.4 mg/dL (Figures 2.14 and 2.15). Serum phosphorus levels were greater than 4.5 mg/dL among 66.1% of HD patients and 71.6% of PD patients (Figures 2.16 and 2.17).

In the 2015-2016 flu season, 71.3% of patients received an influenza vaccination. Although this rate has been stable over the last two years, the percent vaccinated has increased from 59.3% a decade earlier (Figure 2.19.a).

CHAPTER 3: VASCULAR ACCESS

In 2016, 80% of patients were using a catheter at hemodialysis (HD) initiation (Figure 3.1). At 90 days after the initiation of HD, 69% of patients were still using catheters (Figure 3.7.a). The percentage of patients using an arteriovenous (AV) fistula or with a maturing AV fistula at HD initiation increased from 28.9% to 33% over the same period (Figure 3.1). AV fistula use at HD initiation rose from 12% to 17% over the period 2005-2016 (Figure 3.1). AV fistula use increased to 64% by the end of one year on HD, and to 71% by the end of two years (Figure 3.7.a). The proportion of patients with an AV graft for vascular access was 3% at HD initiation, 15% at one year after initiation, and 17% at two years (Figure 3.7.a). At one year after HD initiation, 79% of patients were using either an AV fistula or AV graft without the presence of a catheter. By two years, this number rose to 88% (Figure 3.7.a). Of AV fistulas placed between June 2014 and May 2016, 39% failed to mature sufficiently for use in dialysis. Of those that did mature, the median time to first use was 108 days (Table 3.7). Patient demographic characteristics appear to contribute to success with AV fistula; at younger ages, the percent of AV fistulas that successfully mature is higher and the median time to first use is somewhat shorter (Table 3.7). Males had a higher AV fistula maturation rate compared to females, as well as shorter time to first use. Blacks were observed to have the highest AV fistula maturation failure rates.

CHAPTER 4: HOSPITALIZATIONS, READMISSIONS, EMERGENCY DEPARTMENT VISITS, AND OBSERVATION STAYS

End-stage renal disease (ESRD) patients continue to experience a relatively high frequency of hospitalization, although over the last decade the frequency of admissions has declined. Between 2007 and 2016, the adjusted hospital admission rate for dialysis patients declined from 2.0 to 1.7 per patient-year (PPY), a reduction of 15%. During that same period, the admission rate for transplant patients declined from 1.0 to 0.8 PPY, a 20% reduction (Figure 4.1). Hospitalization rates for hemodialysis (HD) patients were highest in their first year but fell considerably through the first three years of HD, whereas peritoneal dialysis (PD) patients generally experienced increasing hospitalization rates many years after dialysis initiation (Figure 4.3). All-cause hospitalization rates among adult HD patients decreased by 14.2% from 2007 to 2014 and remained stable in 2015-2016 (see Table 4.1). Hospitalizations due to cardiovascular events and those for vascular access infection fell by 18.9% and 54.6% from 2007 to 2016, respectively. Select patient groups continue to exhibit more frequent hospitalization. For 2015-2016, adjusted HD patient hospitalization rates were higher for those aged 22-44 years or 75 years and older, females, and those of non-Hispanic White or Black/African American race, and for those who had diabetes as their primary cause of kidney failure (Table 4.1).

The frequency of dialysis patient visits to the emergency department (ED) has increased over time. Between 2007 and 2016, unadjusted ED visit rates for HD patients increased from 2.6 to 3.0 PPY, while rates for peritoneal dialysis (PD) patients increased from 2.2 to 2.4 PPY, and rates for transplant patients increased from 1.3 to 1.4 PPY (Figure 4.14). Observation stays were relatively rare for ESRD patients, but approximately doubled in frequency from 2007-2016. Unadjusted rates of observation stays for HD patients increased from 0.16 to 0.38 PPY, while rates for PD patients increased from 0.12 to 0.25 PPY, and rates for transplant patients increased from 0.08 to 0.15 PPY (Figure 4.17).

Among ESRD patients in 2016, more than one in three live hospital discharges were followed by a readmission

within 30 days (35.4%), compared to 21.6% for patients with chronic kidney disease (CKD) and only 15.3% for older Medicare beneficiaries without a diagnosis of kidney disease (Figure 4.7). The frequency of 30-day readmissions among dialysis patients was stable from 2007-2011 at approximately 39%, fell somewhat in 2012-2013, and has remained at approximately 37% during 2014-2016. Readmissions for transplant patients were approximately 8 percentage points lower but followed a similar time trend (Figure 4.8).

CHAPTER 5: MORTALITY

The decline in mortality in the end-stage renal disease (ESRD) population has important implications for both patients and resource allocation. Increasing lifespan among ESRD patients is a primary reason for continued growth in the prevalent ESRD population. The relative decline in mortality for dialysis patients in the past 20 years has been similar to that of Medicare patients with cancer and diabetes, and greater than for Medicare patients with cerebrovascular disease or an acute myocardial infarction (Table 5.5, Figure 5.5). In 2016, adjusted mortality rates for ESRD, dialysis, and transplant patients were 134, 164, and 29 per 1,000 patient-years. By dialysis modality, mortality rates were 166 for hemodialysis (HD) patients and 154 for peritoneal dialysis (PD) patients, per 1,000 patient-years (Figure 5.1). Between 2001 and 2016, adjusted mortality rates decreased for dialysis patients by 29%. The net reductions in mortality from 2001 to 2016 were 28% for HD patients and 43% for PD patients (Figure 5.1). Between 2001 and 2016, unadjusted (crude) mortality rates decreased by 2% for transplant recipients. After accounting for changes in population characteristics (primarily increasing age), trends in post-transplant mortality were much more pronounced, with adjusted mortality rates decreasing by 40% (Figure 5.1). Patterns of mortality during the first year of dialysis differed substantially by modality. For HD patients, reported mortality was highest in month two, but declined thereafter; this effect was more pronounced for patients aged 65 and older. In contrast, mortality for PD patients was relatively low initially, but rose slightly over the course of the year (Figure 5.3). Dialysis patients over the age of 65 continued to have substantially higher mortality compared to the general population and Medicare

populations with cancer, diabetes, or cardiovascular disease.

CHAPTER 6: TRANSPLANTATION

In 2016, 20,161 kidney transplants were performed in the United States (19,301 were kidney-alone; Figure 6.6). Fewer than a third (28%) of kidneys transplanted in 2016 were from living donors (Figure 6.6). From 2015 to 2016, the cumulative number of recipients with a functioning kidney transplant increased by 3.4%, from 208,032 to a total of 215,061 (Figure 6.7). On December 31, 2016, the kidney transplant waiting list had 81,418 candidates on dialysis, 51,238 (62.9%) of whom were active. Eighty-five percent of all candidates were awaiting their first transplant (Figure 6.1). Among candidates newly wait-listed for either a first or repeat kidney-alone transplant (living or deceased-donor) during 2011, the median waiting time to transplant was 4.0 years (Figure 6.4). This waiting time varied greatly by region of the country, from a low of 1.4 years in Nebraska to a high of 5.1 years in Georgia (Reference Table E.2.2). The number of deceased kidney donors, aged 1-74 years, with at least one kidney retrieved increased by 62.7%, from 5,981 in 2001 to 9,732 in 2016 (Figure 6.19.a).

The rate of kidney donation from deceased Blacks/African Americans nearly doubled from 2002 to 2016, from 4.5 to 7.9 donations per 1,000 deaths (Figure 6.21.b). This rate overtook that of Whites in 2009. Asians consistently had the highest rate of deceased kidney donation during this time, at about 9 per 1,000 deaths. The number of kidney paired donation transplants has risen sharply since 2005, with 642 performed in 2016, which represented 11% of living-donor transplants that year. The rate plateaued during 2012-2014 but increased again in 2016 (Figure 6.18). Since 1999, the probabilities of graft survival have improved among recipients of both living and deceased-donor kidney transplants, over both the short-term (one-year survival) and long-term (five and ten-year survival) (Figure 6.25). In 2015, the probabilities of one-year graft survival were 93% for deceased and 98% for living-donor kidney transplant recipients (Figure 6.25). In 2015, the probabilities of patient survival within one-year post-transplant were 96% and 99% of deceased- and living-donor kidney

transplant recipients (Figure 2.6). The one-year graft-survival and patient-survival advantages experienced by living-donor transplant recipients persisted at five and ten years post-transplant (Figures 6.25 and 6.26).

CHAPTER 7: ESRD AMONG CHILDREN, ADOLESCENTS, AND YOUNG ADULTS

The number of children and adolescents beginning end-stage renal disease (ESRD) care is steadily decreasing from a high of 17.5 per million in 2004 to 13.8 per million population in 2016, representing a decrease of 21.1% (Figure 7.1.a). As of December 31, 2016, the point prevalence of children and adolescents, 0 to 21 years of age, with ESRD was 9,721, or 99.1 per million population (Figure 7.1.b). The one-year ESRD patient mortality decreased by 20.4% over the last decade, with the greatest improvement observed in the 0-4 year age group with a 35.0% decrease. (Figures 7.8.a and 7.8.b). Twenty percent of incident and 72% of prevalent children and adolescents with ESRD have kidney transplants, in 2016 (Figures 7.1.a and 7.1.b). Since 1978, a total of 19,441 survivors of childhood onset ESRD have transitioned into adulthood and 81% of these individuals were still alive as of December 31, 2016 (Figure 7.17).

CHAPTER 8: CARDIOVASCULAR DISEASE (CVD) IN PATIENTS WITH ESRD

Cardiovascular disease (CVD) is common in adult end-stage renal disease (ESRD) patients, with coronary artery disease (CAD) and heart failure (HF) being the most common conditions (Table 8.1). Even relatively young ESRD patients—those aged 22-44 and 45-64 years—are likely to suffer from cardiovascular disease (Figures 8.2.a and 8.2.b). The presence of cardiovascular disease is associated with both worse short- and long-term survival in adult ESRD patients (Figure 8.3). Only about two-thirds of dialysis or transplant patients with acute myocardial infarction (AMI) received beta-blocker medications. Similarly, among ESRD patients with HF, fewer than half received angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs). Although many ESRD patients with atrial fibrillation (AF) are at elevated risk of stroke, only about one-third of dialysis patients with AF were treated with warfarin (Table 8.3).

CHAPTER 9: HEALTHCARE EXPENDITURES FOR PERSONS WITH ESRD

Between 2015 and 2016, Medicare fee-for-service spending for beneficiaries with end-stage renal disease (ESRD) rose by 4.6%, from \$33.8 billion to \$35.4 billion, accounting for 7.2% of overall Medicare paid claims, a figure that has remained stable since 2004 (Figure 9.2). This marks the fifth year of modest growth relative to historical trends, and follows the 2011 implementation of the bundled payment system. When \$79 billion in expenditures for chronic kidney disease (CKD) are added, total Medicare expenditures for both CKD and ESRD are over \$114 billion, an increase of 16%. In 2016, ESRD spending per person per year (PPPY) increased by 2.5% (Figure 9.4). For the second year in a row, most of the increase in Medicare expenditures for beneficiaries with ESRD was attributable to higher PPPY spending, rather than growth in the number of covered lives. For hemodialysis (HD) care, both total and PPPY spending increased between 2015 (\$26.8 billion and \$88,782) and 2016 (\$28.0 billion and \$90,971) (Figures 9.7 and 9.8). During this period, total peritoneal dialysis (PD) spending grew by 5.7%, as the share of patients receiving PD continued to rise. However, while PPPY spending on PD rose 1.4% from 2015 to 2016, PD remained less costly on a per-patient basis than HD (Figures 9.7 and 9.8). Total and PPPY kidney transplant spending have increased by 4.6% and 2.1%. Total spending for transplant patients increased from \$3.3 billion to \$3.4 billion, and per capita spending increased from \$34,080 to \$34,780 (Figures 9.7 and 9.8). Total inpatient spending for patients with ESRD grew rapidly from 2004 until 2009, followed by slower growth from 2009 until 2011, remained quite stable from 2011 to 2015, but then increased by 5.3% in 2016 (Figure 9.5).

CHAPTER 10: PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH ESRD

In 2018, this chapter continues to report on analgesic use and updates the map of non-steroidal anti-inflammatory agents (NSAIDs) and opioid use in the United States using 2016 data. Further, because of increasing use of high-cost antivirals nationally, this year we investigate the spending and utilization rates

of antivirals, including prescription antiretrovirals, nucleosides and nucleotides, and protease inhibitors.

Among beneficiaries with Medicare Part D enrollment, a higher proportion of those treated with hemodialysis (HD; 65.5%), peritoneal dialysis (PD; 52.3%), and kidney transplant (50.3%) received the Low-income Subsidy (LIS) than did the general Medicare population (30.2%; Figure 10.1). In 2016, per patient per year (PPPY) Medicare Part D spending on prescriptions for end-stage renal disease (ESRD) patients with stand-alone Part D plans was 4.1 times higher than among the general Medicare population (\$13,310 vs. \$3,559; Figure 10.5.a). Of patients enrolled in stand-alone Part D plans, dialysis patients had a higher PPPY spending on prescriptions than did transplant patients (HD, \$14,922; PD, \$13,882; transplant, \$8,693; Figure 10.5.a). In both the general Medicare and ESRD populations, PPPY Part D spending was 2.8–3.6 times greater for beneficiaries with LIS benefits than for those without. This difference reflects both higher utilization among those with LIS benefits and the higher share of spending covered by Medicare for LIS beneficiaries. LIS beneficiaries' out-of-pocket costs represented only 0.6%–1.2% of total Part D expenditures, compared to 21.6–26.9% in the non-LIS populations (Figure 10.5.b). In 2016, ESRD patients were most frequently prescribed ion-removing agents, β -adrenergic blocking agents (beta blockers), antibacterials, analgesics, antipyretics, and lipid-lowering agents (Table 10.6). The highest costing medications for ESRD patients were ion-removing agents, cinacalcet, antidiabetic agents, antivirals, and immunosuppressive agents (Table 10.7). In the United States, the overall proportions of ESRD patients using prescription NSAIDs and opioids were 8.3% and 49.0%, respectively (Figures 10.6 and 10.7). In 2016, approximately 5.8%, 5.6%, and 24.1% of HD, PD, and transplant patients had at least one filled prescription antiviral; PPPY Medicare Part D spending among these users was \$918, \$844, and \$2,104, respectively (Figures 10.9 and 10.10).

CHAPTER 11: INTERNATIONAL COMPARISONS

This chapter now includes data received from 74 countries. In 2016, as seen over the past decade,

Taiwan, the United States, and the Jalisco region of Mexico reported the highest incidence of treated end-stage renal disease (ESRD), with rates of 493, 378, and 355 patients per million general population (PMP; Figure 11.2), respectively. Nearly 40% of countries had incidence rates of treated ESRD <120 patients PMP, with South Africa reporting the lowest incidence rate of 22 treated ESRD patients PMP in 2016. In 2016, large variation was seen across countries in whether diabetes mellitus (DM) was the primary cause of ESRD among incident treated ESRD patients, ranging from approximately 66% of incident treated ESRD patients in Malaysia, Singapore, and the Jalisco region of Mexico, to less than 16% in Norway, Latvia, and Romania (Figure 11.4.b). From 2003 to 2016, the Jalisco region of Mexico and Malaysia had the highest average yearly increases overall in the rates of ESRD incidence due to diabetes (Figure 11.5). In 2016, among young adults (aged 20–44 years), the United States reported the highest ESRD incidence rate at 134 PMP, followed by Malaysia at 111 PMP, with most countries having treated ESRD incidence rates <50 PMP in this young age group (Figure 11.7a). Large international variation exists in the use of the different renal replacement therapies (RRT; Figure 11.12). In approximately one-fourth of countries, 50%–70% of treated ESRD patients are living with a kidney transplant—particularly in northern European countries. In contrast, in approximately one-third of countries, less than 20% of treated ESRD patients are living with a kidney transplant. In most nations, in-center hemodialysis (HD) was the predominant RRT modality.

VOLUME 3, CHAPTER 1: HEALTHY PEOPLE 2020

In this chapter, we examine data for 10 Healthy People 2020 (HP2020) objectives spanning 19 total indicators for which the USRDS serves as the official data source. As in previous Annual Data Reports (ADR), we present data overall, and stratified by race, sex, and age groups to highlight any disparities in progress. In 2016, 11 of the 18 HP2020 indicators with specific targets met the established goals. Key areas where substantial improvement has been observed include mortality among dialysis patients and vascular access. Conversely, the incidence rates of end-stage renal disease (ESRD) overall, and ESRD due to

diabetes, remain above HP2020 targets. State-level comparison maps showed marked geographic variation for HP2020 Objectives CKD-10 (Proportion of ESRD patients receiving care from a nephrologist at least 12 months before the start of renal replacement therapy; Figure 1) and CKD-13.1 (Proportion of patients receiving a kidney transplant within three years of end-stage renal disease; Figure 2). Forty-eight states achieved the HP2020 target for CKD-10, while nine achieved the target for CKD-13.1. For HP2020 objectives relating to vascular access, we present data from CROWNWeb examining HP2020 Objectives CKD 11-1 (Proportion of adult hemodialysis patients who use arteriovenous fistulas as the primary mode of

vascular access; Table 9) and CKD 11-2 (Proportion of adult hemodialysis patients who use catheters as the only mode of vascular access; Table 10). In 2016, the overall proportion of prevalent patients using an arteriovenous fistula was 64.1%, and this appears to have plateaued since 2012. The all-cause mortality among prevalent dialysis patients in 2016 was 173.1 deaths per 1,000 patient-years (HP2020 objective CKD-14.1, Table 15). This rate represents a 16.8% decrease in the mortality rate since 2007. While this rate is lower than in 2015 (174.0 deaths per 1,000 patient-years), it is still higher than in 2014, when the rate was lower than it has ever been at 171.6 deaths per 1,000 patient-years.

Notes