

2017 USRDS Annual Data Report: Executive Summary

Kidney Disease – a Major Public Health Problem: End-Stage Renal Disease Treated by Dialysis or Transplantation is the Tip of the Iceberg!

This year marks the 28th publication of the Annual Data Report (ADR), a central and ever-evolving component of the United States Renal Data System (USRDS). The USRDS has developed into an internationally utilized resource—a world-class, comprehensive data system that supports high quality surveillance of kidney disease through a patient care, policy, and public health centered mission.

Why should we care about the trends and current state of kidney disease in the US? Research has established these as a disease continuum that holds great cost to both the individual and society. The key to success lies undoubtedly in the realm of prevention and optimal management of CKD in order to slow progression, with the goal of completely avoiding development of ESRD. This, for the most part, is an unmet challenge of the community focused on management of advanced kidney disease or ESRD.

A nexus clearly exists between kidney disease and common non-communicable diseases (NCDs), such as diabetes mellitus, hypertension, and obesity. It is therefore imperative that CKD (including ESRD) continues to be recognized as a major NCD, together with the obesity-metabolic syndrome-diabetes complex, hypertension and cardiovascular diseases, mental health disorders, cancer, and pulmonary diseases.

The onset of end-stage renal disease (ESRD) is easily identified when defined by the use of renal replacement therapies. In contrast, CKD is often silent or under-recognized and awareness in the general population is very low, even though it is readily identifiable through simple testing of blood and urine. Increasing awareness to promote timely recognition and treatment has the potential to delay progression of the disease and reduce its complications.

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 United States Renal Data System (USRDS), the largest and most comprehensive national, ESRD and CKD surveillance system. The initial USRDS Annual Data Reports (ADR) offered a detailed descriptive epidemiology of ESRD. 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 this 2017 ADR, we seek 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 for AKI patients who are dialysis dependent to outpatient dialysis units.

The two current USRDS special studies investigate the transition of care from CKD to ESRD and palliative 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 the healthcare providers involved in care of patients with kidney disease – nephrologists, transplantation specialists, and general physicians. This report is also of value for health care 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.

Newer Considerations for the 2017 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. In the 2017 ADR, we addressed the challenge of converting our data and analyses from ICD-9-CM diagnosis and procedure codes to the newly introduced ICD-10-CM. This will allow us to provide continuity with the data trends and analyses presented in previous ADRs. Our CKD and ESRD Analytical Methods chapters include a detailed comparison 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 experience of all Americans who live with kidney disease. A large proportion of our information represents Medicare beneficiaries, who are not a nationally representative group. Thus, each year we strive to find ways to provide a more wholly inclusive report. This year we include two new data sources that expand our basis of comparison.

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

In 2017, we further characterized 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. Wherever 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 2017 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, this year we have increased the number of geospatial analyses and national maps.

DATA SOURCES AND ANALYTICAL METHODS

Originally, the ADR was the product of a standalone database on the diagnoses and demographic characteristics of ESRD patients, along with biochemical data, dialysis claims, and information on treatment and payer histories, hospitalization events, deaths, physician/supplier services, and providers. The findings presented in the current 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 Microsoft Excel and PowerPoint files containing the data and graphics for the figures and tables are available on the <u>USRDS website</u>.

SUMMARY OF DATA SOURCES

The USRDS uses numerous data sources to describe kidney disease in the U.S. These data are collected in various methods by different sources, each with its own strengths and limitations. Comparisons between chapters and volumes of the ADR should be made in this context.

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 claimsbased and enrollment data obtained from the Centers for Medicare and 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 are a random sample of 5% of the entire Medicare population. Medicare ESRD Claims Standard Analysis Files (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 crossreferencing.

Others 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). This 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 begun in 2012. It captures clinical and administrative data from Medicare-certified dialysis facilities for all ESRD patients. This system was implemented nationally in May 2012. 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 also referred to the USRDS Infographic at USRDS.org for an overview of key highlights. The following paragraphs represent only an outline of some of the salient findings reported in the 2017 ADR. More detailed commentary and the USRDS Special Studies reports are presented within the individual chapters of the ADR.

CKD

Volume 1 of the 2017 USRDS ADR provides an analysis of 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 reports on Transition of Care in Chronic *Kidney Disease (Chapters 8 & 9).*

Through these topics 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 to define and understand 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 the need for interventions before reaching the often-irreversible need for renal replacement therapy.

CHAPTER 1: CKD IN THE GENERAL POPULATION

We continue to provide estimates of CKD prevalence in the general population of the United States based on NHANES data, and using the KDIGO definition of CKD based on single point estimate of eGFR or albuminuria. The prevalence of Stages 1-4 CKD, while relatively stable at 14.8%, implies that an estimated 30 million American adults have CKD. The prevalence of self-reported CKD is very low in the U.S. general population, as indicated in a large representative telephone-based survey (BRFSS). Reports ranged from 1.8% in Virginia to 4.0% in Arizona. Given the overall prevalence of CKD in the U.S. population of about 14%, these numbers are consistent with limited awareness of CKD among those who have the condition (Figure 1.14). Based on trends observed in the NHANES cohorts, little improvement has been seen in the percentage of individuals with CKD who are aware of their disease, especially among those in Stages 1 to 3. A small increase in disease awareness is now being observed seen in individuals with Stage 4 CKD (Figure 1.13).

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 - CKD, cardiovascular disease (CVD), or diabetes mellitus (DM), while 18.5% had two or more of these conditions. Within a younger population derived from the Optum Clinformatics[™] Data Mart (ages 22-64 years), 9.9% had at least one of the three conditions, and 1.3% had two or more of these conditions. As indicated by diagnosis claims from the VHA, 15.4% of patients had at least one of the three conditions, while 2.7% had at least two. (Table 2.2.b). In the Medicare 5% sample and VHA data, 11.7% and 9.7% of patients had a diagnosis of CKD in 2015, as opposed to only 1.1% of patients in the Optum Clinformatics[™] population (Table 2.4). Of those in the 2010 Medicare 5% sample who had a diagnosis of CKD Stage 3, by 2015, 3.5% had progressed to ESRD and 40.3% had died. For these Medicare patients without identified CKD, progressions to ESRD and death by 2015 were 0.2% and 21.3% (Table 2.5).

CHAPTER 3: MORBIDITY AND MORTALITY IN PATIENTS WITH CKD

In 2015, Medicare patients with CKD experienced a mortality rate of 109.7 per 1,000 patient-years. When adjusted for sex, age, and race, the rate remained more than double the 45.6 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 2003-2015. Among patients with CKD, a decrease in hospitalization rates occurred from 2014 to 2015; even after adjustment the Medicare CKD group decreased by 2.1%, from 595 to 583 per 1,000 patient-years at risk, and by 1.7%, from 237 to 233 per 1,000 for the no-CKD group. In contrast, during the same period an increase in hospitalization rates occurred for Optum ClinformaticsTM beneficiaries; even after adjustment the CKD group increased by 3.9%, from 174 to 181 per 1,000 patient-years at risk. At 21.5%, rates of rehospitalization for CKD patients were higher than the 15.5% for those without CKD.

CHAPTER 4: CARDIOVASCULAR DISEASE IN PATIENTS WITH CKD

CKD patients are more than twice as likely to have CVD compared to non-CKD Medicare patients (CVD prevalence 66% versus 32%, respectively). Heart failure (HF) prevalence increases dramatically with CKD severity; nearly 40% of patients with Stages 4-5 CKD carried a diagnosis of HF in 2015. Atrial fibrillation (AF) is common among Medicare patients with CKD, affecting about 25% of this population. The prevalence of AF is higher among males, older persons, and patients with hypertension (HTN), advanced stages of CKD, and HF.

CHAPTER 5: ACUTE KIDNEY INJURY

In 2015, the percent of Medicare fee-for-service beneficiaries experiencing a hospitalization complicated by Acute Kidney Injury (AKI) was 4.0%; this appears to have plateaued since 2011. A similar trend was observed in the Clinformatics[™] population, among whom 0.3% had an AKI hospitalization in 2015. In 2013, Medicare patients aged 66 years and older who were hospitalized for AKI had a 35% cumulative probability of a recurrent AKI hospitalization within one year. For Clinformatics[™] patients aged 22 years and older, the probability of recurrent AKI hospitalization was 23%. Among the older Medicare patients, 28% were given an initial diagnosis of CKD in the year following an AKI hospitalization. In the Clinformatics[™] population, 19% of patients with an AKI hospitalization were newly classified as having CKD in the subsequent year.

CHAPTER 6: HEALTHCARE EXPENDITURES FOR PERSONS WITH **CKD**

Medicare spending for all beneficiaries who have CKD (10% of total) exceeded \$64 billion in 2015 (20% of spending; Tables 6.1 and 6.3). When adding the \$34 billion of spending for beneficiaries with ESRD (volume, 2 Figure 9.2), total Medicare spending for beneficiaries with kidney disease was nearly \$100 billion. 60% of Medicare beneficiaries aged 65 and older with CKD also had DM, HF or both, and accounted for over 70% of total Medicare spending for beneficiaries with CKD (Table 6.1). Growth in total CKD spending has primarily been driven by growth in the number of identified cases, particularly in the earlier stages (CKD 1-3).

CHAPTER 7: MEDICARE PART D PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH CKD

In 2015, per patient per year (PPPY) spending on prescriptions for CKD patients was 1.5 times higher than general beneficiaries in those patients with stand-alone Part D plans (\$4,547 vs. \$2,971), 1.7 times higher in those with Medicare Advantage plans (2,914, vs. 1,760) and 4.5 times higher in those with commercial coverage (\$4,398 vs. \$971; Figure 7.5.a). By drug class, the greatest medication expenditures by Medicare Part D were for antidiabetic agents (\$1,685.4 millions), followed by antineoplastic agents (\$994.6 millions), antivirals (\$643.5 millions), and lipidlowering agents (\$437.5 million, Tables 7.7.a). Importantly, nearly 44.5% of Medicare CKD patients had at least one filled prescription for opioid agonists, ranging from 57.0% in Mississippi to 22.6% in Hawaii.

ESRD

Volume 2 of the ADR provides key statistics on 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); Hospitalization (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 current progress on the kidney disease objectives outlined in the Healthy People 2020 program.

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

In 2015, 124,111 new cases of end stage renal disease (ESRD) were reported with a total of nearly 500,000 patients receiving dialysis treatment and well over 200,000 living with a kidney transplant. Despite the 6.1% decline in the age-sex-race-adjusted incidence rate of ESRD between 2009 and 2015, the annual number of incident cases has increased by 7.5% during the same period, due to the aging and growing size of the U.S. population. Native Hawaiians and Pacific Islanders have a very high incidence rate. Although the age-sex-adjusted ESRD incidence rate in this patient population declined by 17% from 2000 to 2015, in 2015 it was nearly three times greater than for African Americans and more than six times greater than for whites. In contrast to adjusted incidence-rate trends between 2000 and 2015, the adjusted prevalence of ESRD increased in every racial group, except Native Americans, due primarily to declining mortality rates among ESRD patients.

CHAPTER 2: CLINICAL INDICATORS AND PREVENTIVE CARE:

In 2016, 97% of patients undergoing HD and 89% of patients undergoing peritoneal dialysis (PD) achieved targets for HD adequacy. Since 2011, the percentages of HD and PD patients having hemoglobin levels within a target range of 10-12 g/dL have improved with more judicious use of erythropoietin. Since implementation of the CMS ESRD Quality Incentive Program, the percentage of ESRD patients with hypercalcemia(calcium >10.2 mg/dL) has declined.

CHAPTER 3: VASCULAR ACCESS:

Arteriovenous fistula (AV) use at HD initiation rose from 12% to 17% over the period 2005-2015 (Figure 3.1). The percentage of patients using an AV fistula or with a maturing AV fistula at HD initiation increased from 28.9% to 33.4% over the same period (Figure 3.1). Seventeen percent of patients used an AV fistula exclusively at dialysis initiation. This increased to 65% by the end of one year on HD, and to 72% at the end of two years (Figure 3.7.a).

CHAPTER 4: HOSPITALIZATION:

Over the past decade, the frequency of hospital admissions and resulting number of hospital days for ESRD patients have declined gradually and consistently. In 2015, the adjusted rates of admission for HD patients and for PD patients decreased to 1.7 per patient year (PPY) as compared to 2.1 in 2006, a reduction of 19.0%. During that same period, admission rates for transplant patients reduced by 20.0%, to 0.8 days in 2015 from 1.0 in 2006. During this same decade, HD patient hospitalizations due to cardiovascular events and for vascular access infections fell by 23.3% and 8.3%. Patients with CKD and ESRD experienced rehospitalization rates of 21.4% and 35.2%, as compared to only 15.4% for older Medicare beneficiaries without a diagnosis of kidney disease.

CHAPTER 5: MORTALITY:

Between 2001 and 2015, adjusted mortality rates decreased by 28% for dialysis patients. The net reductions in mortality from 2001 to 2015 were 27% for HD patients and 41% for PD patients (Figure 5.1). Patterns of mortality during the first year of dialysis differ substantially by modality. For HD patients, reported mortality is highest in month 2, but declines thereafter; this effect is more pronounced for patients aged 65 and over. In contrast, mortality for PD patients is relatively low initially but rises slightly over the course of the year (Figure 5.3). Dialysis patients continue to have substantially higher mortality compared to the general population and Medicare populations with cancer, diabetes, or cardiovascular disease. However, the relative and absolute decline in mortality for dialysis patients in the past 15 years has

been greater than for Medicare patients in these other diagnostic categories (Tables 5.5).

CHAPTER 6: TRANSPLANTATION:

On December 31, 2015, the kidney transplant waiting list had 83,978 candidates on dialysis, 52,703 (62.8%) of whom were active. Eighty-four percent of all candidates were awaiting their first transplant (Figure 6.1). Among 2010 candidates newly wait-listed for either a first time or repeat kidney-alone transplant (living or deceased donor), the median waiting time to transplant was 3.9 years (Figure 6.4). This waiting time varied greatly by region of the country, from a low of 1.2 years in Utah to a high of 5.2 years in Georgia (Reference Table E.2.2). For the first time, a decrease in kidney transplant waiting list by 2.3 percent is observed. This is likely a result of recent changes in kidney allocation system. Since 1998, the probabilities of graft survival and patient survival have steadily improved among recipients of both living and deceased donor kidney transplants (Tables 6.4 and 6.5). In 2014, the probabilities of one-year graft survival were 93% and 97% for deceased and living donor kidney transplant recipients, respectively (Tables 6.4 and 6.5).

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

The one-year ESRD patient mortality among the o-4 year age group has declined approximately 41.6% over the past decade. As of December 31, 2015, the point prevalence of children and adolescents, o to 21 years of age, with ESRD was 9,672, or 99.5 per million population. There an additional, 10,251 adult survivors of childhood onset ESRD contributing to the 2015 point prevalence of ESRD in adults. The number of children and adolescents beginning ESRD care is steadily decreasing from a high of 17.5 per million in 2004 to 13.7 per million population in 2015, representing a decrease of 21.7%.

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

CVD is prevalent in a majority of dialysis patients (70% of HD patients and 57% of PD patients), with HF, CAD, and PAD being the three most common

cardiovascular diagnoses in the dialysis population. All CVD diagnoses are associated with decreased survival in ESRD, with acute myocardial infarction (AMI) and sudden cardiac arrest/ventricular arrhythmia being most closely associated with 2-year mortality. Given the many challenges of pharmacotherapy in advanced kidney disease, potentially beneficial cardiovascular drugs are often not prescribed to ESRD patients. In 2015, only about two-thirds of dialysis or transplant patients with AMI received beta-blockers. Among ESRD patients with HF, fewer than half-received angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs). Only about one-third of dialysis patients with AF were treated with warfarin for stroke prevention.

CHAPTER 9: HEALTHCARE EXPENDITURES FOR PERSONS WITH **ESRD**:

Between 2014 and 2015 Medicare fee-for-service spending for beneficiaries with ESRD rose by 2.4%, from \$33.1 billion to \$33.9 billion, accounting for 7.1% of the overall Medicare paid claims costs, a figure that has remained stable since 2004 (Figure 9.2). This marks the fourth year of modest growth relative to historical trends. In 2015, ESRD spending per patient per year (PPPY) increased by 1.1% (Figure 9.4). Given that ESRD PPPY spending either decreased or increased only slightly from 2009 to 2015, the rise in Medicare expenditures for beneficiaries with ESRD during these years is almost entirely attributable to growth in the number of covered lives. For HD care, both total and PPPY spending were nearly flat between 2014 (\$26.2 billion and \$88,750; Figures 9.7 and 9.8) and 2015 (\$26.7 billion and \$88.195). During this period, total PD spending grew by 4.7%, as the share of patients receiving PD continued to rise. PD PPPY spending rose 1.6% from 2014 to 2015, however, and PD remained less costly on a per patient basis than HD.

CHAPTER 10: PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH ESRD:

By modality, dialysis patients had a higher PPPY spending on prescriptions than transplant patients in patients enrolled in stand-alone Part D plans (HD\$12,589; PD: \$11,828; Transplant: \$8,038), while dialysis patients had a lower PPPY spending on prescription than transplant patients in those with Medicare Advantage plans (\$5,596 vs. \$9,181) and those with commercial coverage (\$7,794 vs. \$ 10,199; Figure 10.5a-c). Ion-removing agents (mostly Kayexalate), cinacalcet, antidiabetic agents, antivirals, and immunosuppressive agents were the most costly prescriptions for ESRD patients (Tables 10.7). Importantly, approximately 50.3% of Medicare ESRD patients used opioid agonists, ranging from 38.1% in New York to 59.2% in Alabama (Figure 10.7).

CHAPTER 11: INTERNATIONAL COMPARISONS:

The number of countries and regions represented in this year's International Comparisons Chapter increased to 73, with the addition of Albania, Brunei (Darussalam), Bulgaria, Egypt, Kazakhstan, Latvia, Lithuania, the Republic of Macedonia, and Peru. In 2015, nearly 2.5 million patients were treated for ESRD across all reporting countries. Treated ESRD prevalence, per million population (PMP), varied nearly 30-fold across represented countries, with the three highest rates of 3,317 PMP (Taiwan), 2,529 PMP (Japan), and 2,138 PMP (United Stated); the lowest reported rates were 119 - 211 PMP in Bangladesh, Ukraine, South Africa, Indonesia, and Kazakhstan. (Figure 11.9). In-center HD is the most commonly utilized therapeutic approach for treatment of ESRD in the majority of countries. However, transplantation was the primary renal replacement therapy - used for 51-72% of ESRD patients - in the Nordic countries (Denmark, Finland, Iceland, Norway, and Sweden) and in Estonia, Latvia, the Netherlands, Switzerland, the U.K. (including Scotland), Spain, Austria, and Qatar. (Figure 11.12)

HEALTHY PEOPLE 2020:

Within every age group, the death rate of dialysis patients was 17% - 55% lower in 2015 than in 2006. (CKD-14.1). Within every age group of adult HD patients, fistula use is 1-3 percentage points higher in 2015 than in 2012. (CKD-11.1). Within every age group except o-4 year-olds (20% growth) and 25-44 year-olds (1% growth), the rate of new cases of ESRD per million population is 1-21% lower than in 2006. (CKD-9.1).



Chapter 1: CKD in the General Population

- This year we introduce an examination of the socioeconomic factors of health insurance status, income, and education level among individuals with chronic kidney disease (CKD; Table 1.3).
- Overall prevalence of CKD (Stages 1-5) in the United States (U.S.) adult general population was 14.8% in 2011-2014. CKD Stage 3 (6.6%) was the most prevalent (Figure 1.2 and Table 1.2).
- Roughly, 40% of individuals with CKD also had diabetes (DM), 32% had hypertension (HTN), and 40% had self-reported cardiovascular disease (SR CVD; Table 1.2).
- In the general U.S. population, the prevalence of a urinary albumin-to-creatinine ratio (ACR) with >10mg/g of creatinine was 32%, including 8.5% with ACR 30–300 mg/g and 1.4% with ACR >300 mg/g (Figure 1.4).
- Approximately 20% of individuals had urinary ACR 10-29 mg/g, which although below the threshold for albuminuria, has shown evidence of prognostic significance (Figure 1.4).
- Age was the best correlate of low estimated glomerular filtration rate (eGFR; <60 ml/min/1.73m²), while HTN was the greatest predictor of albuminuria (Figures 1.7 & 1.8).
- In a comparison of four cohorts of NHANES participants (1999-2002, 2003-2006, 2007-2010, and 2011-2014), the percentage of individuals at target blood pressure of <140/90 (Figure 1.10) and the percentage with normal cholesterol levels (Figure 1.11) increased over time.
- Only minimal changes in self-reported physical activity occurred over time (Figure 1.9).
- Following a 1999-2002 initial increase in the percentage of diabetics with glycosylated hemoglobin <7%, this rate fell steadily over the subsequent three time periods (Figure 1.12 & Table 1.5).
- Comparing these same four NHANES cohorts, there was little improvement in the percentage of individuals with CKD who were aware of their disease, especially among those in Stages 1 to 3. Individuals with Stage 4 CKD reported a small increase in disease awareness (Figure 1.13).
- The prevalence of self-reported CKD was very low in the U.S. general population, as indicated in a large representative telephone-based survey (BRFSS). Reports ranged from 1.8% in Virginia to 4.0% in Arizona. Given the overall prevalence of CKD in the U.S. population of about 14%, these numbers are consistent with limited awareness of CKD among those who have the condition (Figure 1.14).

Introduction

This chapter presents representative crosssectional estimates of CKD prevalence in the U.S., through analysis of data from the National Health and Nutrition Examination Survey (NHANES; CDC, 2015a) and from the Behavioral Risk Factors Surveillance System (BRFSS; CDC, 2015b), both administered by the Centers for Disease Control and Prevention (CDC). Both surveys use a stratified probability sampling design to select participants, rather than a simple random sample.

The NHANES program of studies combines interviews and physical examinations, creating a valuable source of information for assessing disease prevalence overall and in at-risk groups. This sample is representative of the civilian, non-institutionalized U.S. population, with oversampling of certain population subgroups to increase the reliability and precision of health status indicator estimates for these groups.

The NHANES data are collected and released biennially; therefore, we primarily report trends based on four, four-year periods within the last 16 years— 1999-2002, 2003-2006, 2007-2010, and 2011-2014. These years include all data from the beginning of the "continuous" NHANES data collection. In previous Annual Data Reports (ADRs) NHANES III (1988-1994) data were also included; we refer readers to the past ADRs for this information. New data available for this year's ADR is limited to the 2013-2014 information on CKD, which became available in February of 2017.

The Behavioral Risk Factors Surveillance System (BRFSS; CDC, 2015b), is a system of health-related telephone surveys that collect state-level data of U.S. residents regarding their health-related risk behaviors, chronic health conditions, and use of preventive services. Similar to the NHANES survey methodology, the data is weighted to allow generation of estimates considered representative of the U.S. population. In the survey, each participant is asked, "(Ever told) you have kidney disease?". In contrast to the NHANES, this data source contains participants' residence information and allows an assessment of the geographic distribution of self-reported kidney disease. As BRFSS conducts annual data collection, we present analyses of data from the past four years, including the newest data gathered in 2015.

Defining Chronic Kidney Disease

While the definition of CKD as initially proposed by K/DOQI (NKF, 2002) and subsequently by KDIGO (KDIGO, 2012) has well served the renal community, it is pertinent to discuss its application to public health surveillance of kidney disease, as opposed to clinical practice. The definition requires that a measured eGFR abnormality or evidence of kidney damage (e.g., albuminuria), or both, be present for a minimum of three months. In examining survey data from random samples of the general population (e.g., NHANES) or available data within health systems (e.g., the national Veterans Affairs Health System, or others), repeat laboratory values are either not available, or repeat testing is conducted based on clinical indication. Therefore, as repeated measures are not available for a large number of individuals in these cohorts, using such data to determine rates of CKD is subject to biasby-indication.

While it is possible that a second data point from repeat testing may result in lower estimates of prevalence of kidney disease than those calculated from single values, it is equally possible that the values obtained in these two settings under stable conditions are acceptable for purposes of public health surveillance. This is especially likely given that the variability of repeat serum creatinine measurements in individuals is based on a number of factors (diet, physical activity, state of hydration, etc.) and also because the potential fluctuations in urine albumin excretion can be influenced by posture, exercise, early morning specimen vs. random urine specimen, etc. Furthermore, and especially at higher levels of kidney function (GFR \geq 60 ml/min/1.73m²), the estimating equations currently in use are known to be increasingly imprecise, and have not been validated for use in the very elderly, in those with poor muscle mass, or at the extremes of body size.

Given the considerations above, although the potential for imprecise prevalence estimates from a single serum creatinine or urine albumin measurement is real, an estimate for CKD prevalence based on just two readings may also result in underor over-estimates. Therefore on balance, and for public health purposes alone, when samples have been obtained in a stable, community-based setting such as the NHANES survey, we believe that the estimate based on a single random sample from the noninstitutionalized population is sufficient and realistic at the population level. Further, NHANES does not collect data on the institutionalized populations who are mostly elderly and likely to skew the overall prevalence estimate.

With the above caveat, we used the KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (KDIGO, 2012) to identify CKD. Our working definition differs from that of KDIGO in that data available in NHANES are not longitudinal in nature, and therefore

CHAPTER 1: CKD IN THE GENERAL POPULATION

information on the persistence of poor kidney function for three months is not available.

In clinical practice, diagnosis of CKD typically requires multiple assessments of kidney function and urine albumin (or total protein) over weeks or months. Instead, we rely on a single, cross-sectional sample available for all participants in the four cohorts to estimate the prevalence of CKD in the U.S. adult population, and to determine CKD trends over time. Thus, the estimates of CKD reported in this chapter may be higher (or lower) than would be the case if measures of eGFR and ACR were repeated over time to fulfill the KDIGO criteria of 'persistence for three months or longer' for the clinical diagnosis of CKD.

Consistent with the assessment of the prevalence of other medical conditions in NHANES, both eGFR and ACR measures are based on laboratory specimens collected at a single point in time. We evaluated kidney function by eGFR as calculated using the CKD-EPI creatinine equation (Levey et al., 2009).

Individuals with eGFR <60 ml/min/1.73m² were considered to have reduced kidney function. In addition, we used the ACR to assess urinary albumin excretion, and considered four categories: <10 mg/g, 10-<30 mg/g, 30-300 mg/g, and >300 mg/g. We then created a composite measure of both eGFR and ACR, classifying individuals as CKD if they had either an eGFR <60 ml/min/1.73m² or ACR \geq 30 mg/g. Staging of kidney disease follows the Kidney Disease Outcomes and Quality Improvement (KDOQI) CKD guidelines (Table A; NKF, 2002).

It is important to note that estimates presented in this chapter may differ from those published by the Centers for Disease Control Chronic Kidney Disease (CDC CKD) Surveillance project. This is because the CDC CKD Surveillance project has historically employed the Modification of Diet in Renal Disease (MDRD) formula (Levey et al., 1999) to calculate eGFR. Currently, though, the project is transitioning to use of the CKD-EPI creatinine equation.

CKD Stage	Description	GFR (ml/min/1.73 m²)
1	Kidney damage with normal or Υ GFR	> 90
2	Kidney damage with mild \downarrow in GFR	60-89
3	Moderate \downarrow in GFR	30-59
4	Severe \downarrow in GFR	15-29
5	Kidney failure	< 15 (or dialysis)

Table A Kidney Disease Outcomes and Quality Improvement (KDOOI) CKD Staging Guidelines

In contrast, all other chapters in this ADR volume identify the presence of CKD and its related stages based on ICD-9-CM and ICD-10-CM (International Classification of Diseases, Ninth and Tenth revisions, clinical modification) diagnosis codes. These classification systems are more likely to underreport the initial stages of CKD, as care providers often do not document formal diagnoses of CKD early in the disease process, or may have not yet clinically identified CKD. In addition, because of the asymptomatic nature of much of CKD, many individuals with early stage CKD will not have sought medical care. NHANES data allows us to distinguish individuals within Stage 1 (eGFR >90 with ACR >30) and Stage 2 (eGFR 60-89 with ACR >30).

By examining level of kidney function and the related comorbidities of DM, HTN, and CVD in the general population, this chapter sets the stage for Volume 1, Chapter 2, Identification and Care of Patients with CKD. There we discuss CKD as recognized in the health care system via analysis of Medicare claims, OPTUM Clinformatics[™], and Veterans Health Administration (VHA) data, providing information on morbidity, interventions, and costs.

Methods

Two nationally representative data sources are included in the analyses for this chapter: NHANES (1999-2014) and BRFSS (2012-2015).

The National Health and Nutrition Examination Survey (NHANES) is a sample of about 5,000 individuals per year drawn from the U.S. civilian, noninstitutionalized population. Respondents answer survey questions, receive a medical examination, and provide blood and urine samples that are tested for various biochemical markers, including serum creatinine and urine albumin. Except for Figure 1.14, all tables and figures in this chapter are based on NHANES data.

Figure 1.14 employs data from the Behavioral Risk Factor Surveillance System (BRFSS) to illustrate the geographic distribution by state of self-reported kidney disease. These data are also a sample of the U.S. general population, but respondents answer survey questions during a phone interview, and there is no medical examination. However, the sample size is larger and data includes residence information, allowing precise estimation for U.S. states.

A full explanation of these data is included in the *Data Sources* section of the *CKD Analytical Methods*

chapter. See the Chapter 1, <u>CKD Analytical Methods</u> section of the <u>CKD Analytical Methods</u> chapter for an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter. Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available to download from the <u>USRDS</u> <u>website</u>.

Prevalence of CKD

Figure 1.1 presents the U.S. prevalence of CKD, over four periods from 1999 to 2014. The largest increase occurred in Stage 3 CKD, which rose from 5.4% to 6.6% over the four periods. The percent of individuals in Stages 1 and 2 decreased from 1999-2010; Stage 2 continued to decrease but Stage 1 reverted to initial levels in the most recent time frame. The trend in increasing prevalence for Stages 3-5 (non-ESRD) was statistically significant (OR=1.06 per each more recent cohort, p=0.01), although some of the increase is explained by age (OR=1.03, p=0.25). The U.S. population experienced a population age shift during the included years, primarily resulting from an influx of the "baby boomer" population aging into retirement. Because of the large effect of age on CKD prevalence, higher rates are understandable.

vol 1 Figure 1.1 Prevalence of CKD by stage among NHANES participants, 1999-2014



Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2002, 2003-2006, 2007-2010 & 2011–2014 participants aged 20 & older. Whisker lines indicate 95% confidence intervals. Abbreviation: CKD, chronic kidney disease.

Figure 1.2 provides the density distributions of eGFR in NHANES 1999-2002, 2003-2006, 2007-2010, and 2011-2014. Overall, minimal population changes have been observed over the entire period. We also examined these densities among individuals over the CHAPTER 1: CKD IN THE GENERAL POPULATION

age of 60 years, as this group experiences the highest prevalence of CKD. The average eGFR for the individuals over 60 years was approximately 25 ml/min/1.72m², lower than for the complete sample (Figure 1.2.b).

vol 1 Figure 1.2 eGFR distribution among NHANES participants, 1999-2014



(a) All Individuals

(b) Individuals 60+ years



Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2014 participants aged 20 & older. Single-sample estimates of eGFR; eGFR calculated using the CKD-EPI equation. Abbreviations: eGFR, estimated glomerular filtration rate; SE, standard error. Accounts for change in serum creatinine assays.

Figure 1.3, with corresponding findings for ACR, shows little change over time in the distribution patterns of individuals with ACR >300 mg/g. However, comparison of the groups with ACR 10-29 mg/g and 30-300 shows a slight increase, with a corresponding

decrease in the proportions of individuals with either ACR <10 mg/g, over the four periods. This has important mortality implications, as increased rates of all-cause mortality have occurred with ACR values as low as 10 mg/g (Matsushita, 2010).





Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2014 participants aged 20 & older. Single-sample estimates of ACR. Abbreviation: ACR, urine albumin (mg)/creatinine (g) ratio.





Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2014 participants aged 20 & older. Single-sample estimates of eGFR. Abbreviation: ACR, urine albumin (mg)/creatinine (g) ratio; eGFR, estimated glomerular filtration rate.

When assessing the joint distribution of eGFR and ACR, we observed higher prevalence of albuminuria with lower kidney function. For example, in the 2011 to 2014 NHANES sample, 6.5% of persons with normal kidney function (>90 eGFR ml/min/1.73m²) had some evidence of albuminuria (Table 1.1). This rose to 9.4%

among individuals with an eGFR of 60-90, 22.2% for those with an eGFR of 45-59, and 46.7% for those with an eGFR of 30-44. Of individuals with Stage 4 CKD (eGFR <30 ml/min/1.73m²), over half had evidence of albuminuria.

vol 1 Table 1.1 Percentage of NHANES 2011-2014 participants, in the various CKD (eGFR and albuminuria) risk categories (KDIGO 2012)

				A	Ibuminuria categor	ies
				A1	A2	A3
				Normal to mildly increased	Moderately increased	Severely increased
				<30 mg/g <3 mg/mmol	30-300 mg/g 3-30 mg/mmol	>300 mg/g >30 mg/mmol
(G1	Normal to high	≥90	54.7	4.3	0.4
ies m²)	G2	Mildly decreased	60-89	30.4	2.6	0.3
GFR categories nl/min/1.73 m	G3a	Mildly to moderately decreased	45-59	3.9	0.9	0.2
GFR cate; (ml/min/1	G3b	Moderately to severely decreased	30-44	1.0	0.5	0.2
J D D	G4	Severely decreased	15-29	0.1	0.1	0.2
)	G5	Kidney failure	<15	<0.001	0.001	0.01

(a) Percentage in each category (2011-2014)

(b) Summary of prevalence in each risk category, by cohort (1999-2014)

	1999-2002	2003-2006	2007-2010	2011-2014
Low risk	86.1	85.5	86.5	85.1
Moderately high risk	^{10.4}	^{10.6}	^{9.6}	$\int^{10.8}$
High risk	13.9 - 2.2	14.5 - 2.7	13.5 - 2.5	14.9 - 2.6
Very high risk	L 1.3	L _{1.2}	L 1.4	L _{1.5}

Data source: National Health and Nutrition Examination Survey (NHANES), 1999-2002, 2003-2006, 2007-2010 & 2011–2014 participants aged 20 and older. Single-sample estimates of eGFR and ACR; eGFR calculated using the CKD-EPI equation. Abbreviations: ACR, urine albumin/creatinine ratio; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; GFR, glomerular filtration rate; KDIGO, Kidney Disease: Improving Global Outcomes CKD Work Group. Low risk: eGFR \geq 60 ml/min/1.73 m² and ACR <30 mg/g; moderately high risk: eGFR 45-59 ml/min/1.73 m² or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g; high risk: eGFR <30 ml/min/1.73 m² or eGFR 30-44 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g; very high risk: eGFR <30 ml/min/1.73 m² or eGFR 30-44 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g; very high risk: eGFR <30 ml/min/1.73 m² or eGFR 30-44 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g; very high risk: eGFR <30 ml/min/1.73 m² or eGFR 30-44 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR \geq 60 ml/min/1.73 m² and ACR <60 ml/min/1.73 m²

ACR >300 mg/g.

Demographic Characteristics and Biological Risk Factors for CKD

Many studies have shown that older age, diabetes mellitus (DM), hypertension (HTN), cardiovascular disease (CVD), and higher body mass index $(\geq_{30} \text{ kg/m}^2; \text{BMI})$ are associated with CKD. Data showing the percentage of adult NHANES participants with either eGFR <60 ml/min/1.73 m² or an ACR \ge 30 mg/g confirmed a higher estimated prevalence in the presence of each of these risk factors, although with a smaller increase in relation to BMI \geq 30 kg/m² (Table 1.2). Other observations of interest include that CKD was more prevalent in women and those over 60 years of age, and that DM was the most common comorbid risk factor for CKD. Ethnic and racial comparisons showed that non-Hispanic Blacks had a higher prevalence of ACR >30 but lower prevalence of eGFR, <60 as compared to non-Hispanic Whites.

Occurrences of eGFR <60 ml/min/1.73 m² and ACR \ge 30 mg/g for adult NHANES participants are shown in Table 1.2. When CKD was defined as either eGFR <60 or ACR \ge 30, prevalence estimates varied over time, with an overall rise from 13.9% to 14.8% (Figure 1.5). The largest relative increase in prevalence occurred among those with SR CVD, where estimates rose from 38.2% in 1999-2002 to 42.6% in 2011-2014. The prevalence of eGFR <60 rose from 5.8 to 7.2% (p=0.01) over the four periods, with the largest relative increase (1.7-fold) seen in those aged 40–59 (p=0.04). Prevalence for ACR \ge 30 remained steady over this period, between 9-10%. Table 1.2 shows that CKD defined by an eGFR <60 was much more prevalent in individuals aged 60 and older. Low eGFR was present in this age group for over 25.0% of the 2003-2006 participant cohort, compared to 0.1% of individuals aged 20 to 39 years and 2.3% of those aged 40 to 59 years. The prevalence of low eGFR also rose in all other comorbidity categories over these periods, especially for DM (15.1% to 20.7%). The prevalence of eGFR <60 increased for both sexes and for all races, although more so for non-Hispanic whites (6.6% to 8.5%), as shown in Table 1.2.

The prevalence of ACR \geq 30 mg/g decreased over the four periods among individuals with DM, SR DM, HTN, SR HTN, and higher BMI. Prevalence was higher in the older age groups, but less markedly than for eGFR <60.

		All	СКД		е	GFR	eGFR <60 ml/min/1.73m ²				ACR ≥	30 mg/g	
	1999-	2003-	2007-	2011-	199	99-	2003-	2007-	2011-	199	9- 2003-	2007-	2011-
	2002	2006	2010	2014	200)2	2006	2010	2014	200	2 2006	2010	2014
Age													
20-39	6.0	5.9	5.4	6.6	0.	4	0.1	0.3	0.3				
40-59	10.0	9.8	8.5	10.6	1.	9	2.3	2.0	3.3	5.9	5.8	5.3	6.4
60+	36.9	37.1	33.6	32.6	24	.0	25.8	22.9	22.6	8.6	5 8.2	7.0	8.5
Sex													
Male	12.0	12.6	11.7	13.0	4.	8	5.7	5.2	6.4	9.2	8.9	8.4	8.8
Female	15.6	16.1	15.0	16.5	6.	8	7.8	7.5	7.9	10.	9 10.2	9.4	10.9
Race/Ethnicity													
Non-Hispanic White	13.9	14.3	13.8	15.2	6.	6	7.9	7.5	8.5	9.3	8 8.5	8.4	9.0
Non-Hispanic Black/African American	15.1	15.8	14.8	16.9	5.	3	5.2	5.8	6.2	12.	7 13.0	11.2	13.5
Mexican American	11.6	11.6	11.8	12.5	1.	4	1.6	2.3	2.5	10.	4 10.9	10.5	11.2
Other Hispanic	13.8	15.5	11.4	12.8	3.	6	3.5	3.3	4.3	11.	7 13.3	9.5	10.5
Other Non-Hispanic	14.0	16.2	10.6	12.8	3.	9	4.2	3.1	4.3	12.	1 13.5	9.1	10.3
Risk Factor													
Diabetes	41.2	41.5	39.0	39.4	15	.1	19.2	18.7	20.7	34.	8 30.9	28.4	28.7
Self-reported diabetes	40.8	43.0	40.6	40.6	16	.5	20.3	19.9	22.3	33.	5 31.7	29.5	29.5
Hypertension	33.4	31.7	30.6	32.1	16	.8	17.4	16.9	17.7	23.	0 19.6	19.1	20.6
Self-reported hypertension	28.2	26.9	25.7	26.9	16	.3	15.3	15.0	15.8	17.	7 16.5	15.7	16.6
Self-reported cardiovascular disease	38.2	43.5	37.2	42.6	26	.7	29.3	25.1	29.3	22.	7 24.8	22.3	25.5
Obesity (BMI >30)	17.2	16.8	16.1	17.6	6.	3	7.1	7.0	7.9	13.	2 11.9	11.1	12.5
All	13.9	14.4	13.4	14.8	5.	8	6.8	6.4	7.2	10.	1 9.6	8.9	9.9

vol 1 Table 1.2 Prevalence (%) of CKD in NHANES population within age, sex, race/ethnicity, & risk factor categories, 1999-2014

Data source: National Health and Nutrition Examination Survey (NHANES), 1999-2002, 2003-2006, 2007-2010 & 2011-2014 participants age 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation. Diabetes defined as HbA1c >7 percent, self-reported (SR), or currently taking glucose-lowering medications. Hypertension defined as BP \geq 130/ \geq 80 for those with diabetes or CKD, otherwise BP \geq 140/ \geq 90, or taking medication for hypertension. Values in Figure 1.12 cannot be directly compared to those in Table 1.3 due to different survey cohorts. The table represents NHANES participants who are classified as hypertensive (measured/treated) but some of those are at target blood pressure. Abbreviations: ACR, urine albumin/creatinine ratio; BMI, body mass index; BP, blood pressure, CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate.

Figure 1.5 displays the prevalence of CKD markers (eGFR <60 ml/min/1.73 m² and ACR \ge 30 mg/g) among adult NHANES 2011–2014 participants—specifically those aged 60 years and older, and those of all ages who had the comorbid conditions of DM, HTN, SR CVD, and higher BMI. The prevalence of eGFR <60 was highest among those aged 60 years or older (22.6%) and those with SR CVD (29.2%), followed by those with DM (20.7%), HTN (17.7%), and higher BMI

(9.9%). An ACR \geq 30 was most common in those with DM (28.7%), followed by those with SR CVD (25.4%), with HTN (20.5%), aged 60 or older (16.8%), and of higher BMI (12.4%). The presence of both eGFR <60 and ACR \geq 30 was most common with SR CVD, at 12.1%, followed by DM at 10.0%, those aged 60 years and older (6.8%), with HTN (6.1%), and with higher BMI (2.7%).



vol 1 Figure 1.5 Distribution of markers of CKD in NHANES participants with diabetes, hypertension, self-reported cardiovascular disease, & obesity, 2011–2014

Data Source: National Health and Nutrition Examination Survey (NHANES), 2011–2014 participants age 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation. Abbreviations: ACR, urine albumin/creatinine ratio; BMI, body mass index; CKD, chronic kidney disease; SR CVD, self-reported cardiovascular disease; eGFR, estimated glomerular filtration rate; HTN, hypertension.

CHAPTER 1: CKD IN THE GENERAL POPULATION

Figures 1.6-1.8 illustrate the odds ratios for presence of CKD for each of the common comorbid conditions. Analyses were adjusted for age, sex, and race. As consistent with the remainder of this chapter, presence of CKD was indicated by either eGFR <60 ml/min/1.73 m² or ACR \ge 30 mg/g.





Data Source: National Health and Nutrition Examination Survey (NHANES), 1999–2002, 2003-2006, 2007-2010 & 2011–2014 participants age 20 & older; single-sample estimates of eGFR & ACR. Adj: age, sex, & race; eGFR calculated using the CKD-EPI equation. Whisker lines indicate 95% confidence intervals. Abbreviations: ACR, urine albumin/creatinine ratio; BMI, body mass index; CKD, chronic kidney disease; CVD, cardiovascular disease; DM, diabetes mellitus; eGFR, estimated glomerular filtration rate; HTN, hypertension; SR, self-report.

Adjusted odds ratios for presence of CKD (Figure 1.6) were generally lower in NHANES 2003-2006, 2007–2010, and 2011-2014 participants than during 1999–2002. This was true for each risk factor except SR HTN and SR CVD, where adjusted odds ratios rose from 1.86 to 2.09 and 1.93 to 2.63 over these periods. Age had the strongest association with CKD, followed by HTN, DM, and CVD; these comorbidities contributed about one third of the effect size as did age. For eGFR <60 alone (Figure 1.7), adjusted odds ratios followed a similar pattern, except for DM and SR DM, where the odds increased from 1.6 to approximately 2.5 in both groups. Also, eGFR <60 showed a very strong association with age, with adjusted odds ratios in the 100 range. For ACR \geq 30 alone (Figure 1.8), a substantial decline in the adjusted odds ratio was seen among both those with DM (from 4.08 to 3.69) and aged 60 or older (from 4.74 to 3.23), while a substantial increase in the adjusted odds ratio was seen for those with SR CVD (from 1.65 to 2.57). vol 1 Figure 1.7 Adjusted odds ratios of eGFR <60 ml/min/1.73m² in NHANES participants, by age & risk factor, 1999-2014



Data Source: National Health and Nutrition Examination Survey (NHANES), 1999–2002, 2003-2006, 2007-2010 & 2011–2014 participants age 20 & older; single-sample estimates of eGFR & ACR. Adj: age, sex, & race; eGFR calculated using the CKD-EPI equation. Whisker lines indicate 95% confidence intervals. Abbreviations: ACR, urine albumin/creatinine ratio; BMI, body mass index; CKD, chronic kidney disease; CVD, cardiovascular disease; DM, diabetes mellitus; eGFR, estimated glomerular filtration rate; HTN, hypertension; SR, self-report.



vol 1 Figure 1.8 Adjusted odds ratios of urine albumin/creatinine ratio ≥30 mg/g in NHANES participants, by age & risk factor, 1999-2014

Data Source: National Health and Nutrition Examination Survey (NHANES), 1999–2002, 2003-2006, 2007-2010 & 2011–2014 participants age 20 & older; single-sample estimates of eGFR & ACR. Adjusted: age, sex, & race; eGFR calculated using the CKD-EPI equation. Whisker lines indicate 95% confidence intervals. Abbreviations: ACR, urine albumin/creatinine ratio; BMI, body mass index; CKD, chronic kidney disease; CVD, cardiovascular disease; DM, diabetes mellitus; eGFR, estimated glomerular filtration rate; HTN, hypertension; SR, self-report.

Socioeconomic Factors and CKD

New to this year's ADR we begin to examine the socioeconomic factors of health insurance status, income, and education level among individuals with CKD (Table 1.3). The overall proportion with health care coverage remained steady between approximately 86-90%. The highest coverage was seem among individuals with eGFR <60, who were typically older in age. The highest percentage of individuals had a combination of government provided health insurance (mainly Medicare) and private insurance coverages.

Income levels for these cohorts appear to have risen over time; approximately 22% of individuals with CKD reported an income of \$75,000 or more in 2011-2014. Comparatively, the U.S. median income fluctuated across the same period, decreasing from \$57,909 in 1999 to \$56,716 in 2015, with the lowest income of \$52,666 reported in 2012 (U.S. Census Bureau). Education levels also rose over time, especially among those with eGFR <60. The percentage of individuals with less than high school education decreased from 37.0% in 1999-2003 to 21.3% from 2011-2014, while the group with at least some college increased from 36.9% to 56.5% over the same period.

These trends are similar to those of the general U.S. population. The National Center for Education Statistics reports that adjusted high school graduation rates increased from 79% in 2010/2011 to 83% percent in 2014/2015. Rates were highest overall among those of White and Asian race, and lowest for Blacks and American Indians. In addition, college enrollment rose from 35% in 2000 to 40% in 2015. Overall college enrollment rates were higher for females as compared to males.

	All CKD			eGF	eGFR <60 ml/min/1.73m ²				ACR ≥3	80 mg/g		
	1999- 2002	2003- 2006	2007- 2010	2011- 2014	1999- 2002	2003- 2006	2007- 2010	2011- 2014	1999- 2002	2003- 2006	2007- 2010	2011- 2014
Health Insurance Status												
Not Insured	11.4	10.1	11.4	13.8	3.9	3.3	4.2	3.9	14.7	13.2	14.8	18.9
Insured	88.6	89.9	88.6	86.2	96.1	96.7	95.8	96.1	85.3	86.8	85.2	81.1
Private Only	37.2	30.0	30.6	30.8	22.5	16.8	18.7	22.9	42.2	36.2	35.9	33.4
Medicare Only	17.4	17.4	15.6	15.9	23.8	23.9	20.9	23.0	16.2	14.4	13.3	12.3
Other Government Only	4.9	5.9	5.1	6.9	2.6	2.3	3.0	5.5	5.8	7.8	6.2	8.7
Private and any Government	21.7	26.8	28.6	22.9	36.6	41.1	44.0	34.2	14.6	19.3	21.1	17.1
Other/Unknown	7.4	9.8	8.7	9.7	10.6	12.6	9.2	10.5	6.5	9.1	8.7	9.6
Income												
Less than \$10,000	14.5	7.5	6.8	8.0	13.8	6.1	4.6	5.9	16.3	8.2	8.3	9.4
\$10,000 – \$24,999	29.7	28.0	23.9	24.5	31.8	31.8	26.0	25.4	29.8	27.8	24.2	25.2
\$25,000 – \$44,999	18.8	23.2	23.4	19.8	22.6	24.7	24.3	21.2	17.2	21.0	22.6	19.3
\$45,000 – \$74,999	15.3	20.8	18.1	18.9	13.4	19.8	19.5	19.7	14.8	21.0	16.7	17.8
\$75,000 or more	11.4	14.2	20.1	22.6	8.4	10.9	16.6	22.2	11.5	15.6	20.8	21.1
Missing	10.2	6.3	7.7	6.6	10.0	6.7	9.0	5.5	10.2	6.4	7.5	7.2
Education												
< High School	33.4	26.2	27.1	22.4	37.0	27.8	26.6	21.3	32.8	26.3	29.2	23.8
High School Graduate/GED	25.6	27.1	26.9	22.3	26.1	30.6	27.5	22.2	26.3	25.0	26.3	23.5
At least some College	41.0	46.7	46.0	55.3	36.9	41.4	45.9	56.5	40.9	48.6	44.5	52.7

vol 1 Table 1.3 Socioeconomic factors among individuals with CKD, percent of NHANES participants, 1999-2014

Data Source: National Health and Nutrition Examination Survey (NHANES), 1999–2002, 2003-2006, 2007-2010 & 2011–2014 participants age 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation. Abbreviations: ACR, urine albumin/creatinine ratio; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate.

CHAPTER 1: CKD IN THE GENERAL POPULATION

Health Risk Behaviors

Historically, health risk behaviors for CKD have received less emphasis than have the contributing biological risk factors. Table 1.4 examines self-reported activity level, smoking status, amount of sleep, and types of diet. Little change has occurred in activity level across these cohorts, with almost half of individuals with CKD reporting a sedentary life-style. This is in contrast to individuals without CKD who have shown an increase in the percentage reporting physical activity (Figure 1.9).

A moderate decrease in the percentage of individuals reporting current smoking was seen across the cohorts, primarily in the individuals with eGFR <60. The percentage of current smokers increased among those with albuminuria. Reported amount of sleep was lowest for those with albuminuria, while a higher percentage of those with eGFR <60 reported more than nine hours of sleep per night. A very low percentage of individuals in all cohorts reported following a special diet. The most common type reported by these participants was a "diabetic diet", although the percentage endorsing this decreased slightly over time.

		All	CKD		eGF	⁻ R <60 ml	/min/1.7	3m ²		ACR ≥3	80 mg/g	
	1999-	2003-	2007-	2011-	1999-	2003-	2007-	2011-	1999-	2003-	2007-	2011-
	2002	2006	2010	2014	2002	2006	2010	2014	2002	2006	2010	2014
Physical Activity												
Vigorous	22.4	20.8	20.6	23.3	14.0	14.8	13.0	16.9	24.2	22.9	23.5	24.7
Moderate	31.5	35.7	34.6	33.1	32.0	39.0	35.0	33.9	30.5	33.6	32.9	31.6
Sedentary	46.1	43.5	44.8	43.6	53.9	46.2	52.0	49.2	45.3	43.5	43.6	43.7
Smoking												
Current	16.6	16.2	15.0	15.0	7.4	8.7	8.4	9.1	20.4	20.1	18.7	18.6
Former	31.6	31.8	31.6	33.3	39.2	38.1	39.0	39.8	28.7	29.3	28.9	30.6
Never	51.8	52.0	53.4	51.7	53.4	53.2	52.6	51.1	50.9	50.6	52.5	50.8
Amount of Sleep												
Less than 6 hours	-	15.2	15.5	13.5	-	8.9	12.6	12.4	-	18.8	17.6	14.6
6 hours	-	21.9	21.5	20.5	-	21.5	19.2	18.1	-	23.7	22.8	22.3
7-8 hours	-	55.4	53.2	54.9	-	60.8	55.4	53.0	-	51.3	51.2	54.8
9 hours or more	-	7.6	9.8	11.1	-	8.8	12.8	16.5	-	6.2	8.4	8.3
Self-Reported Special Diet												
Low fat/Low cholesterol	-	3.5	2.8	2.4	-	3.8	3.3	2.8	-	2.9	2.5	2.1
Low salt/Low sodium	-	2.5	3.5	3.6	-	3.1	4.7	5.3	-	2.6	3.6	3.1
Sugar free/Low sugar	-	2.0	1.1	0.4	-	2.5	1.5	0.3	-	1.6	1.1	0.5
Diabetic diet	-	6.6	5.2	5.1	-	6.8	5.4	6.9	-	7.4	5.2	5.5
Renal diet	-	-	0.3	0.6	-	-	0.7	1.2	-	-	0.5	0.8

Data Source: National Health and Nutrition Examination Survey (NHANES), 1999–2002, 2003-2006, 2007-2010 & 2011–2014 participants age 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation. Abbreviations: ACR, urine albumin/creatinine ratio; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate.



vol 1 Figure 1.9 NHANES participants physically active, 1999-2014

Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2002, 2003-2006, 2007-2010 & 2011–2014 participants aged 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation. Abbreviations: ACR, urine albumin/creatinine ratio; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate.

Treatment/Control of CKD

Table 1.5 presents reported awareness of HTN, treatment of CKD-contributing conditions, and control of HTN, hyperlipidemia, and DM in the NHANES adult participants with eGFR <60 ml/min/1.73 m² or ACR \geq 30 mg/g. While the 73-74% prevalence of HTN among CKD patients was similar in the four periods, the proportion of participants unaware of their HTN fell from 64.3% to 22.6% in those years. The proportion of hypertensive individuals who were aware, treated, and diseasecontrolled rose steadily from approximately 8% in the early cohorts to 28% in 2011-2014. In the subgroup with DM, glycemic control showed little improvement over time, with 57.1% remaining uncontrolled in 2011-2014. Participants reported no improvements in activity level or smoking status.

vol 1 Table 1.5 Awareness, treatment, & measures of control of CKD risk factors, percentage of NHANES participants, 1999-2014

			All CK	D		е	GFR <6	60 ml/n	nin/1.7	3m²		AC	CR ≥30	mg/g	
	1999-	2003-	2007-	2011-	Trend	1999-	2003-	2007-		Trend	1999-	2003-	2007-	2011-	Trend
Unertension by surrout by series	2002	2006	2010	2014	p-value	2002	2006	2010	2014	p-value	2002	2006	2010	2014	p-value
Hypertension, by current hyperte															
Non-hypertensive status	26.9	25.8	26.8	26.1	0.87	14.8	14.6	15.6	17.0	0.20	29.7	30.3	31.1	28.6	0.75
Hypertensive	73.1	74.2	73.2	73.9	0.07	85.2	85.4	84.4	83.0	0.20	70.3	69.7	68.9	71.5	0.75
Control of hypertension among hy	perten	sive pa	tients ^b												
Unaware	64.3	25.4	19.5	22.6		58.1	21.0	17.0	13.1		67.7	26.8	24.7	23.0	
Aware, not treated	5.6	8.4	9.7	5.8	.0.001	3.2	5.2	2.5	4.3	.0.001	6.6	10.3	8.2	12.6	.0.001
Aware, treated, uncontrolled	22.1	46.6	42.3	43.8	<0.001	26.6	51.4	45.5	45.8	<0.001	21.1	46.3	44.9	43.9	<0.001
Aware, treated, controlled	8.0	19.6	28.5	27.8		12.1	22.4	35.0	36.8		4.7	16.5	22.1	20.5	
Total cholesterol ^c															
<200 (desirable)	43.2	53.1	59.2	61.6		40.7	56.6	62.6	64.3		44.9	52.8	58.2	61.3	
200–239 (borderline high)	35.3	27.5	26.3	24.1	<0.001	37.0	25.8	23.5	22.0	<0.001	34.2	27.7	27.2	24.8	<0.001
240+ (high)	21.5	19.4	14.5	14.4		22.3	17.6	13.9	13.7		20.9	19.5	14.6	13.9	
Control of diabetes among patien	ts with	diabete	es ^d												
Glycohemoglobin <7% (controlled)	32.8	51.1	46.9	42.9		45.6	62.5	55.9	49.3		28.8	45.3	40.1	36.8	
Glycohemoglobin 7% or higher (uncontrolled)	67.2	48.9	53.1	57.1	0.20	54.4	37.5	44.1	50.7	0.57	71.2	54.7	59.9	63.2	0.37

Data Source: National Health and Nutrition Examination Survey (NHANES), 1999–2002, 2003-2006, 2007-2010 & 2011–2014 participants age 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation. Abbreviations: ACR, urine albumin/creatinine ratio; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate. a. Hypertension defined as blood pressure \geq 130/ \geq 80 for those with CKD and diabetes; otherwise \geq 140/ \geq 90, or self-reported treatment for hypertension.

b. Awareness and treatment are self-reported. Control defined as <130/<80 for those with CKD and diabetes; otherwise <140/<90. c. Total cholesterol classified according to Adult Treatment Panel III blood cholesterol guidelines (ATP III). d. Glycohemoglobin classified according to American Diabetes Association guidelines.

As illustrated by Figures 1.10-1.12, over the periods of 1999–2002, 2003-2006, 2007-2010, & 2011–2014, improvements in the management of HTN and cholesterol were observed, regardless of whether the criterion was eGFR, or ACR level. For comparison, these figures include estimates for individuals without CKD.



vol 1 Figure 1.10 NHANES participants at target blood pressure, 1999-2014

Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2002, 2003-2006, 2007-2010 & 2011–2014 participants aged 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation. Figure represents all hypertensive participants including those who were at target blood pressure, probably due to medication. Abbreviations: ACR, urine albumin/creatinine ratio; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate.



vol 1 Figure 1.11 NHANES participants within cholesterol normal range, 1999-2014

Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2002, 2003-2006, 2007-2010 & 2011–2014 participants aged 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation. Abbreviations: ACR, urine albumin/creatinine ratio; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate.



vol 1 Figure 1.12 Diabetic NHANES participants with glycosylated hemoglobin <7%, 1999-2014

Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2002, 2003-2006, 2007-2010 & 2011–2014 participants aged 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation. Abbreviations: ACR, urine albumin/creatinine ratio; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate.

CKD Awareness

Among the individuals who were classified by laboratory measurements as having CKD, the percentage who were aware of their kidney disease remained low from 1999-2014 (Figure 1.13). There was some suggestion of an improvement among individuals with Stage 4 CKD between 2003-2006 and 2007-2010, although this did not persist in the 2011-2014 cohort (note that this graphic is based on fouryear cohorts). We do not present awareness data for those in Stage 5 CKD because of a very small sample size. When examined by eGFR <60 vs. ACR >30, awareness was markedly higher for individuals who had both conditions.



vol 1 Figure 1.13 NHANES participants with CKD aware of their kidney disease, 1999-2014

Figure 1.13 continued on next page.





Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2014 participants aged 20 & older. Abbreviations: CKD, chronic kidney disease.

Figure 1.14 displays the state-specific proportions of individuals who reported being told they had 'kidney disease', based on the 2012 and 2014 BRFSS sample. The overall national averages were very low, at 2.7% in 2012 and 2.8% in 2014. The NHANES prevalence of self-reported kidney disease ('weak or failing kidneys') of 2.8% matches this national estimate from the BRFSS survey, suggesting poor identification or awareness of kidney disease in the general population.

States with the highest proportion of participants in both years who indicated that they had been informed that they had kidney disease included Hawaii, Arizona, Florida, New Mexico, Michigan, West Virginia, and Nevada. Conversely, the states with the lowest proportion of BRFSS participants reporting awareness of kidney disease included Wisconsin, North Dakota, and Minnesota. These differences could reflect varying prevalence of kidney disease by state, or variations in survey participants' awareness of the condition, if present. The true underlying prevalence of kidney disease by individual U.S. state is unknown. Therefore, it is presently unclear whether higher prevalence of 'self-reported kidney disease' reflects actual higher prevalence of the disease, greater awareness among those who have the condition, or a combination of both.



vol 1 Figure 1.14 Estimated prevalence of self-reported kidney disease by state, BRFSS participants ages 18 and older

Data source: Behavioral Risk Factors Surveillance System (BRFSS), 2012 participants aged 18 & older. 2012 (N=471,107), 2013 (N=491,777), 2014 (N=464,617), and 2015 (N=441,460).

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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 18.5% had two or more of these conditions. Within a younger population derived from the Optum Clinformatics™ Data Mart (ages 22-64 years), 9.9% had at least one of the three conditions, and 1.3% had two or more. As indicated by diagnosis claims and biochemical data from the Department of Veterans Affairs (VA), 15.4% of patients had at least one of the three conditions, while 2.7% had at least two. (Table 2.2.b).
- In the Medicare 5% sample and VA data, 11.7% and 9.7% of patients had a diagnosis of CKD in 2015, as opposed to only 1.1% of patients in the Optum Clinformatics[™] population (Table 2.4).
- The proportion of patients with recognized CKD in the Medicare 5% sample has grown steadily, from 2.7% in 2000 to 11.7% in 2015 (Figure 2.2).
- Of those in the 2010 Medicare 5% sample who had a diagnosis of CKD Stage 3, by 2015 3.5% had progressed to endstage renal disease (ESRD) and 40.3% had died. For these Medicare patients without identified CKD, progressions to ESRD and death by 2015 were 0.2% and 21.3% (Table 2.5).
- 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 still conducted for less than half of these patients—40.5% in 2015, up from 24.8% in 2005. In 2015, urine albumin testing was performed in 48.6% 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 2014, patients who saw a nephrologist were roughly twice as likely to have a claim for urine albumin testing in 2015 (53.1%) than those who saw only a primary care physician (25.4%; Figure 2.5).

Introduction

Epidemiological evaluations of the identification and care of patients with CKD are a significant challenge, as unlike ESRD, no single data source contains all the information necessary to definitively identify CKD-related care practices in the United States (U.S.) population. Furthermore, most large administrative health care datasets lack the biochemical data (serum creatinine and urine albumin or urine total protein) required per KDIGO guidelines for definitive identification of CKD.

As presented in Volume 1, Chapter 1, <u>*CKD* in the</u> <u>*General Population*</u>, The National Health and Nutrition Examination Survey (NHANES) is a nationally representative survey that contains the biochemical information with which to estimate the prevalence of CKD in the U.S. However, NHANES is constrained by its cross-sectional nature, a relatively small sample size, and lack of geographic detail. This limits precision in estimating prevalence, in evaluating long-term outcomes, adverse events, and quality of care delivered, and in the ability to conduct analyses by geography or on subsets of patients.

In addition, the NHANES includes only a single measure of serum creatinine and urine albumin for each patient. Per KDIGO guidelines, two abnormal measures over at least 90 days are necessary to definitively diagnose CKD. Because NHANES-based calculations rely on laboratory measures at a single

time point, they may overestimate the national prevalence of CKD. Regardless, NHANES is generally considered the best available source of such information at the present time.

To provide a more comprehensive picture of the identification and care of CKD throughout the nation, in this chapter we compliment NHANES with the examination of health care data in large and diverse administrative health care datasets—the Medicare 5% sample, and data from the Optum ClinformaticsTM Data Mart and from the U.S. Veterans Health Administration (VHA).

We first present the prevalence of CKD in these health system populations as recognized through diagnosis claims—both for the overall disease state and with the comorbidities of DM and HTN. This was achieved through comparison of rates in the NHANES, Medicare 5% sample, Optum Clinformatics[™], and VHA populations among cohorts of patients aged 22-64, or 65 and older. These were stratified by demographic characteristics in order to highlight issues with identification of CKD across these various types of data.

We next examined longitudinal changes in CKD status and general outcomes for patients at high risk for kidney disease, through presenting trends in laboratory screening and monitoring of patients with and without CKD. Finally, we assessed the spectrum and impact of follow-up care received by newly diagnosed CKD patients.

Methods

For this year's chapter we utilized several large health care datasets. The general Medicare 5% sample includes an average of 1.2 million patients each year. The Optum Clinformatics[™] Data Mart cohort was drawn from the commercial plans of a large U.S. national health insurance company, and holds information on about nine million lives per year. The national health system-derived data from the U.S. Veterans Health Administration (VHA) represents more than six million veterans.

Analyses using the Medicare 5% dataset are restricted to patients aged 65 and older and are limited to those persons with both Part A and Part B fee-for-service coverage. Persons covered by Medicare managed care programs are not included in this source because of the absence of billing claims. The Optum Clinformatics[™] Data Mart data provides insight into a younger, employed population and their dependent children. Like Medicare data, it contains diagnosis and procedure codes as found on claims. The Optum Clinformatics[™] dataset also includes information on pediatric age groups, although for some analyses in this chapter only adult patients (ages 22-64 years) are included. Finally, the VHA dataset includes both diagnosis and procedure codes and more complete biochemical test data. This allowed us to estimate the prevalence of CKD as indicated by diagnoses codes combined with serum creatinine blood and urine test results, wherever available.

Throughout this chapter, the term 'recognized CKD' is used when patients are identified based on the presence of a relevant diagnosis code in Medicare, Optum Clinformatics[™], or VHA data. This implies that either a provider or billing coder in the health care system recognized the presence of CKD. As such, prevalence of 'recognized CKD' likely underestimates true disease prevalence. An observed trend may not necessarily indicate a true change in disease prevalence, but rather a change in clinical awareness or recognition of CKD, or indeed, evolving billing practice. Studies have shown that diagnosis codes for CKD generally have excellent specificity (>90%), though their sensitivity is low (Grams et al., 2011).

To identify the recognized CKD population we included a variety of ICD-9-CM diagnosis codes, some of which are sub-codes under related comorbidities such as DM (250.4x) and HTN (403.9x), and other conditions that are kidney-disease specific, such as glomerular disease (583.x). In 2006, new CKD stage-specific codes (585.x) were introduced, providing an opportunity to track trends in the severity of CKD over time. Since their introduction, the CKD stage-specific codes have been increasingly utilized, accounting for 49% of all CKD diagnostic documentation in 2007 and 68% in 2015.

Beginning on October 1, 2015, the new ICD-10-CM coding system was implemented, and its related diagnosis codes were then utilized to identify CKD stages and comorbid conditions. Table A lists the

CHAPTER 2: IDENTIFICATION AND CARE OF PATIENTS WITH CKD

CKD-related ICD-9-CM and ICD-10-CM codes used in this chapter.

Details of this data are described in the <u>Data</u> <u>Sources</u> section of the <u>CKD Analytical Methods</u> chapter. See the <u>CKD Analytical Methods</u> section of the <u>CKD</u> <u>Analytical Methods</u> chapter for an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter. Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available to download from the <u>USRDS website</u>.

Table A. ICD-9-CM and ICD-10-CM codes for Chronic Kidney Disease (CKD) stages

ICD-9-CM code ^a	ICD-10-CM code ^a	Stage
585.1	N18.1	CKD, Stage 1
585.2	N18.2	CKD, Stage 2 (mild)
585.3	N18.3	CKD, Stage 3 (moderate)
585.4	N18.4	CKD, Stage 4 (severe)
585.5	N18.5	CKD, Stage 5 (excludes 585.6: Stage 5, requiring chronic dialysis ^b)
CKD Stage-unspecified	CKD Stage-unspecified	For these analyses, identified by multiple codes including 585.9, 250.4x,
		403.9x & others for ICD-9-CM and A18.xx, E08.xx, E11.xx and other for ICD-
		10-CM.

^aFor analyses in this chapter, CKD stage estimates require at least one occurrence of a stage-specific code, and the last available CKD stage in a given year is used.

^bIn USRDS analyses, patients with ICD-9-CM code 585.6 or ICD-10-CM code N18.6 & with no ESRD 2728 form or other indication of end-stage renal disease (ESRD) are considered to have code 585.5 or N18.5

Patient Characteristics across Datasets

Table 2.1 presents demographic and comorbidity characteristics of individuals in the Medicare 5% sample (aged 65 and older), the Optum Clinformatics[™] dataset (all ages) and in data from the VHA. The mean age of Medicare patients was 74.6 years, of Optum Clinformatics[™] patients was 35.6 years, and for U.S. Veterans was 62.4 years. The high prevalence of comorbid conditions in the Medicare 5% sample reflects the older age of these patients. For example, 59% and 24% of the Medicare sample had diagnoses of HTN or DM. In comparison, only 10.3% and 4.4% of the total Optum Clinformatics[™] population had diagnoses of HTN or DM. In VHA data these proportions were 25.5% (HTN) and 16.9% (DM).

	Medica	re 5%	Optum Clinf	ormatics™	Veterans	Affairs
	Sample count	Percent (%)	Sample count	Percent (%)	Sample count	Percent (%)
All	1,278,406	100	6,775,263	100	6,400,280	100
Age						
<4	-	-	291,291	4.3	-	-
5-9	-	-	425,618	6.3	-	-
10-13	-	-	374,647	5.5	307	0.0
14-17	-	-	392,928	5.8	1,743	0.03
18-21	-	-	389,255	5.7	13,710	0.2
22-30	-	-	845,536	12.5	302,812	4.7
31-40	-	-	1,101,661	16.3	606,039	9.5
41-50	-	-	1,174,557	17.3	621,290	9.7
51-64	-	-	1,533,367	22.6	1,461,005	22.8
65-74	726,401	56.8	189,645	2.8	1,939,838	30.3
75-84	385,426	30.1	39,506	0.6	860,366	13.4
85+	166,579	13.0	17,252	0.2	593,226	9.3
Sex						
Male	558,868	43.7	3,325,386	49.1	5,725,195	89.5
Female	719,538	56.3	3,449,026	50.9	675,085	10.6
Race/Ethnicity						
White	1,095,386	85.7	4,600,023	68.6	4,501,016	70.3
Black/African American	95,611	7.5	574,327	8.6	987,346	15.4
Native American	5,611	0.4			47,887	0.8
Asian	24,078	1.9	367,328	5.5	65,184	1.0
Hispanic	42,505	3.3	817,247	12.2	-	-
Other	15,215	1.2	-	-	798,906	12.5
Unknown/Missing	-	-	341,536	5.1		-
Comorbidity						
Diabetes mellitus	301,337	23.6	281,945	4.4	1,080,974	16.9
Hypertension	752,521	58.9	663,987	10.3	1,629,982	25.5
Cardiovascular disease	495,362	38.8	286,632	4.5	847,785	13.3

vol 1 Table 2.1 Demographic characteristics of all patients, among Medicare (aged 65+ years), Optum Clinformatics[™] (all ages) and Veterans Affairs *(all ages) patients, 2015

Data Source: Special analyses, Medicare 5% sample (aged 65 and older), Optum Clinformatics™ (all ages) and Veterans Affairs (all ages) alive & eligible for all of 2015. Abbreviation: CKD, chronic kidney disease. CVD is defined as presence of any of the following comorbidities: cerebrovascular accident, peripheral vascular disease, atherosclerotic heart disease, heart failure, dysrhythmia or other cardiac comorbidities. - No available data.

Table 2.2 provides the prevalence of recognized CKD, DM, and cardiovascular comorbid conditions among patients aged 65 and older in the Medicare population, for Optum Clinformatics[™] adults aged 22 through 64 years, and for VHA patients aged 22 to 64. Younger Optum Clinformatics[™] patients were excluded as these comorbidities are rare in this population. Of Medicare patients aged 65 and older, recognized (i.e., coded diagnosis of) CKD was observed in 11.7%. Over half of the Medicare cohort (51.2%) had at least one of these comorbid conditions, 18.5% had two or more, and 4.1% had all three. As expected, the prevalence of recognized CKD in the Optum Clinformatics[™] population was substantially lower, driven by the lower prevalence among younger patients. Approximately 9.9% of this cohort had at least one of these comorbid conditions, and 1.3% had two or more.

vol 1 Table 2.2 Prevalence of comorbid conditions by diagnosis codes (CKD, CVD, & DM), (a) total & (b) one or more, among Medicare (aged 65+ years), Optum Clinformatics™ (aged 22-64 years) and Veterans Affairs (aged 22-64 years) patients, 2015

		(a) Any dia	gnosis of CKD, CVD, or D	м		
	Medicare S	5%	Clinformati	CS™	Veterans Af	fairs
	Sample count	%	Sample count	%	Sample count	%
All	1,278,406	100	4,655,121	100	2,991,146	100
Total CKD	149,461	11.7	53,554	1.1	100,107	3.3
Total CVD	495,362	38.7	228,843	4.9	151,426	5.1
Total DM	301,337	23.6	249,315	5.3	297,246	9.9

(b) Combinations of CKD, CVD, or DM diagnoses

	Medicare	e 5%	Clinformat	tics™	Veterans Affa	airs
	Sample count	%	Sample count	%	Sample count	%
All	1,278,406	100	4,655,121	100	2,991,146	100
Only CKD	26,658	2.1	26,985	0.6	57,170	1.9
Only CVD	278,913	21.8	177,814	3.8	94,266	3.2
Only DM	116,250	9.1	194,651	4.2	226,166	7.6
CKD & DM, no CVD	19,715	1.5	11,730	0.2	23,479	0.8
CKD & CVD, no DM	51,077	4.0	8,095	0.2	9,559	0.3
DM & CVD, no CKD	113,361	8.9	36,190	0.8	37,702	1.3
CKD & CVD & DM	52,011	4.1	6,744	0.1	9,899	0.3
At least one comorbidity	660,344	51.6	462,209	9.9	458,241	15.4
At least two comorbidities	237,238	18.6	62,759	1.3	80,639	2.7
No CKD, no CVD, no DM	620,421	48.5	4,192,912	90.1	2,532,905	84.7

Data Source: Special analyses, Medicare 5% sample (aged 65 and older), Optum Clinformatics[™] (aged 22-64) and Veterans Affairs (ages 22-64 years) alive & eligible for all of 2015. Abbreviations: CKD, chronic kidney disease; CVD, cardiovascular disease; DM, diabetes mellitus. CVD is defined as presence of any of the following comorbidities: cerebrovascular accident, peripheral vascular disease, atherosclerotic heart disease, congestive heart failure, dysrhythmia or other cardiac comorbidities. CKD in the VA is defined as anyone with at least one inpatient ICD-9 or ICD-10 diagnosis or two outpatient diagnosis codes in 2015 or

eGFR<60 ml/min/1.73m² based on at least one outpatient serum creatinine available in 2015; eGFR was calculated using the CKD-EPI formula; if more than one value was available, the last one in the year was used. The denominator included everyone with at least one outpatient visit in 2015.

Comparison of CKD Prevalence across Datasets

Table 2.3 compares the prevalence of CKD in the NHANES, Medicare 5% sample, Optum Clinformatics[™], and VHA populations among patients aged 65 and older. We stratified by demographic characteristics in order to highlight issues with identification of CKD in the varying types of data. Across all datasets, the prevalence of CKD increased with older age. Variance between the data sources,

however, can somewhat be explained by the nature of their measurements and specific populations.

The absolute prevalence of CKD was highest in the NHANES data, intermediate in the VHA data (eGFR-based), and lowest when based on diagnosis codes alone in Medicare claims, Optum Clinformatics[™], or VHA data.

The NHANES, by design, includes laboratory measurement of kidney function in all participants, thus providing the closest estimate of the true prevalence of CKD. Overestimation is possible,

however, because it relies on a single measurement. NHANES also does not represent people living in long-term care facilities—many of those residents have Medicare insurance and were represented in the Medicare 5% sample.

The prevalence of recognized CKD based on diagnosis codes was lowest due to under-recognition and likely under-coding of the condition, particularly in its earlier stages, with more accurate capture of advanced cases of CKD.

For the VHA population, CKD prevalence is presented based on diagnosis codes and available laboratory data documenting at least one serum creatinine result corresponding to an eGFR <60 ml/min/1.73m². Blood and urine assays are initiated by clinical indication and not performed in all patients, and thus likely underestimate the true prevalence in the population served by the VHA health system.

The overall CKD prevalence, and CKD prevalence by gender and race/ethnicity varies substantially depending on the method of CKD ascertainment: survey (NHANES), vs. claim-based (Medicare and Optum ClinformaticsTM), vs. claim and lab based data (VHA data).

vol 1 Table 2.3 Percent of patients with CKD by demographic characteristics, among individuals aged 65+ years in NHANES (2011-2015), Optum Clinformatics[™] (2015), Medicare 5% sample (2015), and Veterans Affairs (2015) datasets

	Survey-based	Claim-b	ased	Claim and lab-based
-	NHANES	Optum Clinformatics [™]	Medicare	VA
	CKD (eGFR)	CKD (Code)	CKD (Code)	CKD (Code or eGFR)
All	38.6	1.0	11.7	23.8
Age				
65-74	28.1	5.1	8.0	15.4
75-79	46.0	11.2	15.0	26.4
80+	61.8	16.0	20.3	36.3
Race				
White	38.6	1.2	11.4	23.2
Black/African American	45.0	0.9	16.5	18.9
Native American	-		12.6	19.1
Asian	-	1.1	12.1	16.4
Other/Unknown	37.8	1.3	9.9	18.0
Sex				
Male	37.3	0.6	12.9	23.2
Female	40.3	1.0	10.8	18.9

Data Source: Special analyses, Medicare 5% sample aged 65 and older alive & eligible for all of 2015. NHANES 2011-2015 participants aged 65 and older, and VA aged 65 and older alive & eligible for all of 2015. CKD in the VA is defined as anyone with at least one inpatient ICD-9 or ICD-10 diagnosis or two outpatient diagnosis codes in 2015 or eGFR<60 ml/min/1.73m² based on at least one outpatient serum creatinine available in 2015; eGFR was calculated using the CKD-EPI formula; if more than one value was available, the last one in the year was used. The denominator included everyone with at least one outpatient visit in 2015. Abbreviations: CKD, chronic kidney disease; VA, Veterans Affairs. - No available data.
CHAPTER 2: IDENTIFICATION AND CARE OF PATIENTS WITH CKD

Table 2.4 presents the prevalence of recognized CKD by demographic characteristics and comorbidities in the Medicare, Optum Clinformatics[™] and the VHA populations, overall and with DM or HTN. The prevalence of recognized CKD increased with age in all three datasets, and from 8% at ages 65– 74 to 20.3% at age 85 and older in the Medicare data. Males had slightly higher prevalence than females in the Medicare and Optum Clinformatics[™] datasets, but there was substantially higher prevalence in women than men in the VHA dataset. The prevalence of CKD among Blacks/African Americans was higher than Whites in the Medicare and Optum Clinformatics[™] datasets, but lower in the VHA dataset. Results from adjusted analyses of the Medicare dataset (data not shown) confirm greater odds of recognized CKD in older patients, Blacks, and those with DM, HTN, or cardiovascular disease. Among Optum Clinformatics[™] patients of comparable age to the Medicare population, the prevalence remained lower, possibly reflecting a healthier, employed population. As expected, the prevalence of recognized CKD was higher in both datasets among those with a diagnosis of DM or HTN, and particularly so in the younger patients in the Optum Clinformatics[™] dataset. vol 1 Table 2.4 Prevalence of CKD, by demographic characteristics and comorbidities, among Medicare 5% sample (aged 65+ years), Optum Clinformatics™ (all ages), and Veterans Affairs (all ages) patients overall, and with diabetes mellitus or hypertension, 2015

		All			Diabetes mellitus r without hypert		Hypertension (without diabetes mellitus)			
	Medicare 5%	Optum Clinformatics [™]	Veterans Affairs	Medicare 5%	Optum Clinformatics [™]	Veterans Affairs	Medicare 5%	Optum Clinformatics [™]	Veterans Affairs	
Overall	11.7	1.1	9.7	23.8	8.7	23.4	13.7	4.8	21.8	
Age										
< 4	-	0.3	0	-		0	-	26.7	0	
5-9	-	0.1	0	-		-	-	28	-	
10-13	-	0.1	0	-	0.8	-	-	16.7	-	
14-17	-	0.1	0	-	1	0	-	9.7	0	
18-21	-	0.2	0	-	2.3	0	-	7.1	-	
22-30	-	0.3	0.2	-	3.8	0.9	-	4.3	1.4	
31-40	-	0.6	0.5	-	4.5	1.5	-	3.4	2.4	
41-50	-	1	1.7	-	5.7	4.4	-	3.3	4.9	
51-64	-	2.2	5.9	-	8.6	12.9	-	4.3	11.8	
65-74	8	5.1	15.4	19.3	14.6	26	9.3	7.3	23.8	
75-84	15	11.2	29.4	27.5	24	45.5	15.4	14	43.2	
85+	20.3	16	38.9	32.9	30.5	59.3	22	21.9	58.7	
Sex										
Male	12.9	1.2	4.7	25.6	9.6	18.2	15.8	5.3	16.9	
Female	10.8	0.9	14.9	22.2	7.7	28.6	12.3	4.3	26.7	
Race/Ethnicity										
White	11.4	1.1	15.4	23.4	8.9	29.4	13.5	4.9	27.6	
Black/African American	16.5	1.3	11.2	27.6	9.2	23.9	17.3	5	21.7	
Native American	12.6	-	9.4	23.2	-	22.1	12.7	-	20.9	
Asian	12.1	0.6	6.8	23.9	6.6	20.7	12.8	4.6	20	
Hispanic	-	1	-	21.5	8.3	-	11.8	4.4	-	
Other/Unknown	9.9	1	8.8	19.34	8.4	28.2	9.3	4.9	27.1	

Data Source: Special analyses, Medicare 5% sample (aged 65 and older), Optum Clinformatics^m data (all ages) and the Veterans Affairs data (all ages) alive & eligible for all of 2015. Abbreviation: CKD, chronic kidney disease. CKD in the VA is defined as anyone with at least one inpatient ICD-9 or ICD-10 diagnosis or two outpatient diagnosis codes in 2015 or eGFR<60 ml/min/1.73m² based on at least one outpatient serum creatinine available in 2015; eGFR was calculated using the CKD-EPI formula; if more than one value was available, the last one in the year was used. The denominator included everyone with at least one outpatient visit in 2015. - No available data.-- data suppressed

CHAPTER 2: IDENTIFICATION AND CARE OF PATIENTS WITH CKD

Figure 2.1 presents maps displaying the prevalence of recognized CKD by state, in the Medicare 5% sample and the Optum Clinformatics[™] dataset. Variation in prevalence across states was more than two-fold in both datasets.

vol 1 Figure 2.1 Prevalence of CKD among Medicare 5% sample (aged 65+ years) and Optum Clinformatics™ (all ages) patients, 2015



Data Source: Special analyses, Medicare 5% sample (aged 65 and older) and Optum Clinformatics™ data (all ages) alive & eligible for all of 2015.

Figure 2.2 shows the 2000-2015 Medicare trend in prevalence of recognized CKD overall and by CKD stage-specific code. The prevalence of recognized CKD

has steadily risen each year, accompanied by a comparable increase in the percentage of patients with a stage-specific CKD diagnosis code.





Data Source: Special analyses, Medicare 5% sample. Known CKD stages presented as bars; curve showing "All codes" includes known CKD stages (ICD-9 codes 585.1-585.5 or ICD-10 codes N18.1-N18.5) and the CKD-stage unspecified codes (ICD-9 code 585.9, ICD-10 code N18.9 and remaining non-stage specific CKD codes). For years 2000-2015, ICD-9 codes are used to identify CKD; additionally, starting October 1, 2015, ICD-10 codes are used to identify CKD. Note: In previous years, this graph reported 585.9 codes as a component of the stacked bars. Abbreviation: CKD, chronic kidney disease.

CHAPTER 2: IDENTIFICATION AND CARE OF PATIENTS WITH CKD

Longitudinal Change in CKD Status and Outcomes, Based on Diagnosis Codes

Table 2.5 shows patient status of CKD stage, ESRD, or death in 2014-2015 for those who had a CKD diagnosis in 2010. Among patients with

no CKD in 2010, 21.4% had died after five years, while 0.2% had reached ESRD and 0.1% were alive with ESRD by the end of 2015. In comparison, patients with a CKD diagnosis in 2010 were much more likely to have these outcomes. Among CKD patients, by 2015 43% had died, 4% had reached ESRD, and 1.8% were alive with ESRD.

		2014-2015 Status (row %)												
		No CKD Diagnosis	CKD Stage 1	CKD Stage 2	CKD Stage 3	CKD Stage 4	CKD Stage 5	CKD Stage- unspecified	ESRD alive	ESRD death	Death without ESRD	Lost to follow-up	Total N	
	No CKD Diagnosis	55.6	0.2	0.8	4.0	0.5	0.1	4.1	0.1	0.1	21.3	13.2	1,110,468	
	Any CKD	12.7	0.5	2.0	16.9	4.2	0.5	7.9	1.8	2.2	42.7	8.6	112,830	
	CKD Stage 1	16.5	5.7	4.2	15.1	2.0	0.3	7.4	0.9	1.7	36.8	9.6	2,603	
2010	CKD Stage 2	15.2	0.9	9.2	18.8	2.2	0.3	7.2	0.6	0.9	34.6	10	7,186	
Status	CKD Stage 3	8.1	0.3	1.8	26.6	5.2	0.6	5.1	1.6	1.9	40.3	8.5	43,530	
	CKD Stage 4	2.7	0.2	0.4	7.8	11.6	1.4	2.4	7.2	8.9	50.9	6.4	10,257	
	CKD Stage 5	5.9	0.4	0.7	6.6	2.5	1.7	3.6	8.2	11	53.3	6.2	2,594	
	CKD Stage Unspecified	19.1	0.4	1.5	10.1	2.1	0.3	12.0	0.6	0.7	44.1	9.1	46,660	
	Total	51.6	0.2	0.9	5.2	0.8	0.1	4.4	0.3	0.3	23.3	12.8		
	Total N	631,759	2,599	10,784	63,709	9,758	1,686	54,378	3,253	3,733	285,004	156,635	1,223,298	

vol 1 Table 2.5 Change in CKD status from 2010 to 2015, among Medicare patients (aged 65+ years) alive and without ESRD in 2010

Data Source: Special analyses, Medicare 5% sample. Patients alive & eligible for all of 2009. Death and ESRD status were examined yearly between 2010-2015, and were carried forward if present. Among patients without death or ESRD by 2015, the last CKD diagnosis claim was used; if not available, then the last CKD diagnosis claim from 2014 was used. Lost to follow-up represents the patients who were not enrolled in Medicare Part A and Part B in 2014 or 2015. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease.

Laboratory Testing of Patients with and Without CKD

Assessing the care of patients at high risk for kidney disease has long been a focus of the USRDS, and is part of the Healthy People 2020 goals developed by the Department of Health and Human Services (see the <u>Healthy People 2020</u> chapter). There are no recommendations to screen asymptomatic patients, but individuals at high risk for CKD, most notably those with DM, should be screened periodically for kidney disease; those with CKD should be monitored for progression of disease.

Urine albumin is a valuable laboratory marker used to detect signs of kidney damage and to evaluate for disease progression. Serum creatinine measurement is usually included as part of a standard panel of blood tests, but urine albumin testing must be ordered separately. For this reason urine albumin testing may better represent intent to assess kidney disease.

The American Diabetes Association (ADA) recommends urine testing for albumin in patients with DM. The 2012 Kidney Disease Improving Global Outcomes (KDIGO) guidelines on CKD evaluation and management recommend risk stratification of CKD patients using both the urine albumin/creatinine ratio and the estimated eGFR (based on estimating equations incorporating serum creatinine values). They emphasized that these tests are needed to understand patients' kidney disease status and risks of death and progression to ESRD (Matsushita et al., 2010; KDIGO CKD Work Group, 2012).

As shown in Figure 2.3, 12.3% of Medicare patients without diagnosed CKD received urine albumin testing in 2015, while 3.6% of Optum Clinformatics[™] patients aged 22 to 64 years without diagnosed CKD received a urine albumin test (assessment of urine protein was also included in these percentages, representing approximately 20% of the testing performed). Among Medicare patients, 40.5% with DM alone had urine albumin testing, compared to 6.3% of patients with HTN alone.

Having both DM and HTN is known to increase the likelihood of developing CKD. Among Medicare beneficiaries without a CKD diagnosis, 41.5% had urine albumin testing in 2015. Similar patterns were seen in the Optum Clinformatics[™] population—37.7% of patients with DM alone in 2015 had urine albumin testing, compared to 5.6% with HTN alone, and 38.9% with both DM and HTN.

vol 1 Figure 2.3 Trends in percent of patients with testing of urine albumin (a) in Medicare 5% sample (aged 65+ years), & (b) Optum Clinformatics[™] (aged 22-64 years) patients without a diagnosis of CKD, by year from 2005 to 2015



Data Source: Special analyses, Medicare 5% sample aged 65 and older with Part A & B coverage in the prior year and Optum Clinformatics™ patients aged 22-64 years. Tests tracked during each year. Abbreviations: CKD, chronic kidney disease; DM, diabetes mellitus; HTN, hypertension.

As shown in Figure 2.4, patients with a diagnosis of CKD received testing at similar, though somewhat higher rates, to patients without CKD. In 2015, among patients with the combined diagnoses of CKD, DM,

and HTN, urine albumin testing was performed for 48.6% of the Medicare and 47% of the Optum Clinformatics[™] cohorts.

vol 1 Figure 2.4 Trends in percent of patients with testing of urine albumin in (a) Medicare 5% (aged 65+ years), & (b) Optum Clinformatics™ (aged 22-64 years) patients *with* a diagnosis of CKD, by year from 2005-2015





Data Source: Special analyses, Medicare 5% sample (aged 65 and older) with Part A & B coverage in the prior year and Optum Clinformatics™ population (aged 22-64 years). Tests tracked during each year. Abbreviations: CKD, chronic kidney disease; DM, diabetes mellitus; HTN, hypertension.

CHAPTER 2: IDENTIFICATION AND CARE OF PATIENTS WITH CKD

Physician Visits after a CKD Diagnosis

Table 2.6 indicates the percentage of patients with a CKD diagnosis in 2014 who had at least one visit to a primary care physician, cardiologist, or nephrologist in 2015. Patients with any CKD diagnosis were far more likely to visit a primary care physician or a cardiologist than a nephrologist. This may relate to the fact that most guidelines, including KDIGO CKD, indicate the need for referral to nephrology only for those with advanced, Stage 4 CKD (see Table A), unless there are other concerns such as rapid progression of disease. Indeed, fewer than one-third of patients with any CKD claim in 2014 were seen by a nephrologist in the subsequent year. However, nearly half with CKD Stage 3 and roughly two-thirds with CKD Stage 4 or higher visited a nephrologist in 2015. Whether the involvement of a nephrologist improves outcomes, and at what stage of CKD, is a matter of ongoing research interest.

Overall, the patterns of physician visits varied little across demographic categories. A notable exception was that patients aged 85 and older with CKD Stage 3 or higher were as likely as younger patients to visit a cardiologist, but less likely to visit a nephrologist.

		Any CKD diagnosis			CKD diagnosis code of 585.3 (Stage 3)			CKD diagnosis code of 585.4 (Stage 4) or 585.5 (Stage 5)			
	Primary care	Cardiologist	Nephrologist	Primary care	Cardiologist	Nephrologist	Primary care	Cardiologist	Nephrologist		
Overall	89.6	56.2	28.6	92.7	60.1	47.1	92.2	65.2	68.8		
Age											
65-74	86.9	50.6	29.8	90.9	55.3	53.5	81.8	49.0	73.6		
75-84	91.0	60.4	29.7	93.4	63.0	47.1	85.8	55.3	70.8		
85+	93.0	62.5	23.1	94.4	64.1	34.1	88.5	55.7	57.4		
Sex											
Male	89.7	56.3	27.6	92.9	60.6	46.1	85.1	53.5	68.9		
Female	90.3	57.7	34.5	92.1	59.5	53.2	84.7	51.6	70.4		
Race											
White	88.4	51.2	27.8	90.5	53.9	45.6	84.8	48.7	66.2		
Black/African American	90.3	53.4	27.8	93.0	56.4	44.8	85.5	49.9	67.6		
Other	89.0	59.1	29.1	92.4	64.0	49.3	84.5	56.3	70.5		

vol 1 Table 2.6 Percent of patients with a physician visit in 2015 after a CKD diagnosis in 2014, among Medicare 5% patients (aged 65+ years)

Data Source: Special analyses, Medicare 5 sample aged 65 and older alive & eligible for all of 2014. CKD diagnosis is at date of first CKD claim in 2014; claims for physician visits were searched during the 12 months following that date. ICD-9 CKD diagnosis code of 585.4 or higher represents CKD Stages 4-5. Abbreviation: CKD, chronic kidney disease.

Figure 2.5 illustrates the proportion of patients with CKD in 2014 who were tested for urine albumin in 2015, according to whether they saw a primary care physician or nephrologist in 2014. Patients who saw a nephrologist were more likely to be tested for urine albumin than those who saw only a primary care physician. This difference was greatest for those without DM. Diabetic patients showed a smaller difference in testing for urine albumin across provider type. This finding relates to the wide dissemination of guidelines for routine renal function assessment in diabetics that are directed at primary care physicians by organizations such as the American Diabetes Association.



vol 1 Figure 2.5 Percent of CKD patients in 2014 with physician visit (nephrologist, primary care provider, both, and neither), with laboratory testing in the following year (2015), by comorbidity

Data Source: Special analyses, Medicare 5% sample aged 65 and older alive & eligible for all of 2015, with a CKD diagnosis claim based on ICD-9 diagnostic codes and a physician visit in 2014. Patient visits with both PCP and nephrologists are classified as nephrologist. Abbreviations: CKD, chronic kidney disease; DM, diabetes mellitus; HTN, hypertension; PCP, primary care physician.

References

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Chapter 3:

Morbidity and Mortality in Patients with CKD

• In this 2017 Annual Data Report (ADR) we introduce analysis of a new dataset. To provide a more comprehensive examination of morbidity patterns, we now compliment the Medicare 5% sample with information from the Optum Clinformatics[™] Data Mart, including beneficiaries of a large commercial insurance provider. This allows us to further examine trends with respect to rates of hospitalization for all-cause and cause-specific reasons.

MORTALITY

- In 2015, Medicare patients with CKD experienced a mortality rate of 109.7 per 1,000 patient-years. When adjusted for sex, age, and race, the rate remained more than double the 45.6 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 2003-2015 (Table 3.1 and Figure 3.1).
- Male patients without CKD experienced higher mortality rates of 51.5 per 1,000 patient-years than did females, at 41.3. This relative difference was similar among those with CKD, with a mortality rate of 120.2 per 1,000 patient-years for males and 102.6 for females (Table 3.1 and Figure 3.4).
- In a comparison adjusted for sex and age, 2015 Medicare patients with CKD showed lower rates of mortality for those of White race at 110.5 per 1,000 patient-years, than for Blacks/African Americans at 114.5 per 1,000. This racial difference contrasts to that seen specifically in Stages 4 to 5 patients, where Whites had substantially higher mortality than Blacks (Figure 3.5).

HOSPITALIZATION

- Among patients with CKD, a decrease in hospitalization rates occurred from 2014 to 2015; even after adjustment the Medicare CKD group decreased by 2.1%, from 595 to 583 per 1,000 patient-years at risk, and by 1.7%, from 237 to 233 per 1,000 for the no-CKD group. In contrast, during the same period an increase in hospitalization rates occurred for Optum Clinformatics[™] beneficiaries; even after adjustment the CKD group increased by 3.9%, from 174 to 181 per 1,000 patient-years at risk (Figure 3.7).
- Not surprisingly, after adjustment for sex and race, rates of hospitalization in older patients were greater than for younger age cohorts. In the CKD group, those over 85 years of age had 752.2 admissions per 1,000 patient-years. This was 44.3% higher than the 521.1 per 1,000 rate of those aged 66 to 69 years (Figure 3.12).
- Racial differences in hospitalization rates were notable. Black patients with CKD had higher adjusted rates of hospitalization, 664.3 per 1,000 patient-years, than did Whites, with 580.3 per 1,000, and those of other races at 491.2; disparity increased with disease severity (Figure 3.14).

REHOSPITALIZATION

- At 21.5%, rates of rehospitalization for CKD patients were higher than the 15.5% for those without CKD (Table 3.3).
- In Medicare patients without CKD, males exhibited a higher rehospitalization rate than did females, with age and race adjusted percentages of 16.2 and 14.9 (Table 3.3).

Introduction

In Volume 1, Chapter 2, <u>Identification and Care of</u> <u>Patients with Chronic Kidney Disease</u>, we analyzed diagnosis codes from Medicare and Optum Clinformatics[™] claims to document the increasing recognition of CKD. The ascertainment of CKD cases through claims data has improved in recent years. This has likely resulted in decreased estimates of average disease severity, as influenced by the early

disease stage of those identified most recently. Thus, recent changes in mortality- and hospitalization-rate trends should be interpreted in this context.

In this chapter we evaluate the morbidity and mortality of patients with and without chronic kidney disease (CKD). We begin by examining mortality as it interacts with the patient characteristics of CKD severity, age, sex, race, and the common comorbid conditions of diabetes mellitus (DM) and cardiovascular disease (CVD). The co-occurrence of DM and CVD with CKD increase a patient's risk of death. This is clinically significant, as cardiovascular risk factors are relatively undertreated in CKD patients in the United States (U.S.). We illustrate this in Volume 1, Chapter 1, CKD in the General Population, through data on disease awareness, treatment, and control of risk factors from the population-level National Health and Nutrition Examination Survey (NHANES) cohorts.

We then similarly focus on patients' hospitalizations—for all-causes, and separately for CVD, infection, and other cause-related admissions. It has been established for over a decade that rates of hospitalization for CVD and infection also rise with CKD stage (Go et al., 2004). In general, and not surprisingly, rates of hospitalizations among CKD patients also increase in the presence of underlying comorbidities, such as DM and CVD. While hospitalization rates have been decreasing over time, the underlying causes for this decline and the lessons learned from these data trends require both further research and the application of enhanced quality improvement efforts.

We end with an examination of patient readmission to the hospital within 30 days of discharge from their first hospitalization of the calendar year (referred to as the index hospitalization). Hospital readmissions are a key quality indicator for the Medicare program. In an attempt to lower the rate of readmission, the Medicare Hospital Readmission Reduction Program was instituted as part of the Patient Protection and Affordable Care Act (CMS, 2010), to reduce Medicare payments to hospitals with excess readmissions. Patients with CKD are rehospitalized more frequently than those without diagnosed CKD. These rates have not changed significantly in the past decade, which is of major concern.

Clearly, early detection and active treatment are important considerations in reducing morbidity and mortality in the CKD population. In future iterations of the ADR, we will also examine additional non-Medicare data sources for Emergency Department visits in the CKD population.

Methods

As in previous years, we use data from the Medicare 5% sample's fee-for-service patients aged 66 and older. Roughly 98% of Americans aged 65 and older qualify for Medicare, and as a result, analysis of Medicare data is representative of this demographic. However, as Medicare data for those under 65 is skewed towards the sickest of patients in that age group, we do not include Medicare patients under 65 in the analyses for this Chapter.

All Medicare analysis samples were limited to patients aged 66 and older who were continuously enrolled in Medicare. Employing a one-year entry period allowed us to identify CKD and other medical conditions using ICD-9-CM (International Classification of Diseases, Ninth Revision, Clinical Modification) and ICD-10-CM (International Classification of Diseases, Tenth Revision, Clinical Modification) diagnosis codes as available from Medicare.

This year, in addition to the Medicare 5% sample, for analyses of hospitalization rates we utilized one additional data source: the Optum Clinformatics[™] Data Mart dataset available from OptumInsight, and representing claims from a large U.S. national health insurance company. In contrast to the Medicare data, the Optum Clinformatics[™] Data Mart dataset represents primarily working-age people and their minor dependents. We limited inclusion to patients aged 22 and older who were continuously enrolled in the Optum Clinformatics[™]. Employing a one-year entry period again allowed us to identify CKD and other medical conditions using ICD-9-CM and ICD-10-CM diagnosis codes.

Optum Clinformatics[™] includes the date of death from the Social Security Death Master File. In November 2011, the Social Security office stopped

sourcing mortality dates from states, and now only includes dates obtained from other sources such as funeral homes and family members. This resulted in a 30% drop in reported dates of death. We considered this to be a limitation to the data, and chose not to include Optum Clinformatics[™] in the mortality analyses.

Details of this data are described in the <u>Data</u> <u>Sources</u> section of the <u>CKD Analytical Methods</u> chapter. See the <u>CKD Analytical Methods</u> section of the <u>CKD Analytical Methods</u> chapter for an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter. Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available to download from the <u>USRDS</u> <u>website</u>.

Mortality Rates

As with many chronic conditions, mortality in patients with CKD is of paramount importance as a major outcome. In Table 3.1 we present mortality rates for several demographic subgroups of patients, both unadjusted and adjusted for age, sex, and race. This year we again applied modified adjustment variables; in the 2014 ADR and in previous years, data was also adjusted for prior year hospitalization and disease comorbidities. We removed these covariates in the 2015 ADR as we believed that adjustment to this extent would result in artificially low mortality rates. This modification should be kept in mind when comparing adjusted rates with those in prior ADRs.

For patients with CKD, the unadjusted mortality rate in 2015 was 134.8 per 1,000 patient-years; this decreased to 109.7 per 1,000 after adjusting for age, sex, and race (standard population: 2015). As expected, mortality rates rose as age increased, particularly for the oldest cohort. In all cases, male patients had slightly higher mortality rates than did females, more so for those with CKD and when adjusted.

For patients with CKD, White patients had higher unadjusted mortality rates than did Blacks, but lower adjusted mortality rates, primarily due to the older age distribution among Whites as compared to Blacks.

	Unadj	usted	Adjusted		
	No CKD	All CKD	No CKD	All CKD	
All	43.8	134.8	45.6	109.7	
Age					
66–69	15.4	64.6	15.1	63.0	
70–74	21.3	70.6	21.1	68.7	
75–84	44.0	115.9	44.1	113.5	
85+	142.8	255.6	143.6	253.9	
Sex					
Male	44.5	138.4	51.5	120.2	
Female	43.3	131.5	41.3	102.6	
Race					
White	44.6	137.8	45.8	110.5	
Black/African American	43.8	125.9	49.4	114.5	
Other	31.4	105.3	36.5	88.3	

vol 1 Table 3.1 Unadjusted and adjusted all-cause mortality rates per 1,000 patient-years at risk for Medicare patients aged 66 and older, by CKD status, 2015

Data source: Medicare 5% sample. January 1, 2015 point prevalent patients aged 66 and older. Adjusted for age/sex/race. Standard population all patients, 2015. Abbreviation: CKD, chronic kidney disease.

Trends in the mortality rates for Medicare patients aged 66 and older are shown in Figure 3.1. Unadjusted mortality in CKD patients has decreased by 29.7% since 2003, from 192 deaths per 1,000 patient-years to 135 deaths in 2015. For those without CKD, the unadjusted rate decreased from 54 deaths per 1,000 patient-years in 2003 to 44 deaths in 2015, a reduction of 18.5%.

When adjusted for age, race, and sex, the 2015 mortality rate for CKD patients reduced considerably, to 111 deaths per 1,000 patient-years at risk (Figure 3.1.b; standard population: 2014). Among those without CKD, adjustment for these factors resulted in a slightly higher mortality rate of 46 deaths per 1,000, as compared to the unadjusted rate of 44. One major contributor to the discrepancy between adjusted and unadjusted death rates was the relative age difference between the CKD and no-CKD cohorts. In 2015, the mean age of patients with CKD was 78.9 years, compared to 75.4 years for those without, and 75.8 years for the sample as a whole. In 2006, CKD stagespecific coding was introduced. This may explain the increased mortality rate for the CKD group in 2006.

vol 1 Figure 3.1 Unadjusted and adjusted all-cause mortality rates per 1,000 patient-years at risk for Medicare patients aged 66 and older, by CKD status and year, 2003-2015



Figure 3.1 continued on next page.





Data source: Special analyses, Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older. 1.b adjusted for age/sex/race and 1.c adjusted for age/sex/race/comorbidities. Standard population Medicare 2014 patients. Abbreviation: CKD, chronic kidney disease.

Rates increased with advancing CKD stage, as shown in Figure 3.2, a finding consistent with studies using biochemical measures of serum creatinine with validated equations to estimate glomerular filtration rate to define CKD (Matsushita et al., 2010). As expected, unadjusted mortality rates rose progressively, from 94 deaths per 1,000 patient-years for those in Stages 1 or 2, to 121 for Stage 3, and 234 for Stages 4 or 5 (without ESRD; stages identified by the ICD-10-CM codes, see Table A). Those without an identified CKD stage or with a diagnosis other than from the N18 code series had an unadjusted mortality rate falling between that of Stage 3 and Stages 4 or 5, at 141 deaths per 1,000 patient-years at risk.

After adjustment, death rates for Stages 1 or 2 and Stage 3 were 82 and 97 deaths per 1,000 patient-years. The adjusted rate for Stages 4 or 5 was higher, at 182 deaths per 1,000. Those with an unspecified CKD stage had death rates at 118 per 1,000 patient-years.

vol 1 Figure 3.2 Unadjusted and adjusted all-cause mortality rates per 1,000 patient-years at risk for Medicare patients aged 66 and older, by CKD status and stage, 2015



Data source: Special analyses, Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race. Standard population Medicare 2015 patients. Abbreviations: CKD, chronic kidney disease; unk/unspc, CKD stage unidentified.

Table A. ICD-9-CM and ICD-10-CM codes for Chronic Kidney Disease (CKD) stages (introduced in 2006)

ICD-9-CM code ^a	ICD-10-CM code ^a	Stage
585.1	N18.1	CKD, Stage 1
585.2	N18.2	CKD, Stage 2 (mild)
585.3	N18.3	CKD, Stage 3 (moderate)
585.4	N18.4	CKD, Stage 4 (severe)
585.5	N18.5	CKD, Stage 5 (excludes 585.6: Stage 5, requiring chronic dialysis ^b)
CKD Stage unspecified	CKD Stage unspecified	For these analyses, identified by multiple codes including 585.9, 250.4x, 403.9xm & others

^a For analyses in this chapter, CKD stage estimates require at least one occurrence of a stage-specific code, and the last available CKD stage in a given year is used.

^b In USRDS analyses, patients with ICD-9-CM code 585.6 or ICD-10-CM code N18.6 & with no ESRD 2728 form or other indication of end-stage renal disease (ESRD) are considered to have code 585.5 or N18.5.

Adjusted mortality rates for 2015 are shown in Figure 3.3 by CKD status and age group. As expected, the mortality rates for older patient groups were higher. In the CKD group, those aged 66-69 years had a mortality rate of 63 deaths per 1,000 patient-years at risk, while those aged 75-84 had nearly double that, at 114 deaths. As also might be expected, patients aged 85 and older experienced the highest rates of mortality, with 254 deaths per 1,000 patient-years.





Data source: Special analyses, Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race. Standard population Medicare 2015 patients. Abbreviations: CKD, chronic kidney disease; unk/unspc, CKD stage unidentified.

A comparison of adjusted 2015 mortality rates by CKD group and sex is shown in Figure 3.4. The rates for males were higher than for females in all stages.





Data source: Special analyses, Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race. Standard population Medicare 2015 patients. Abbreviations: CKD, chronic kidney disease; unk/unspc, CKD stage unidentified.

Figure 3.5 illustrates mortality rates adjusted by race, CKD status, and stage. The rates for the CKD group were more than twice those of the no-CKD group for patients of all races. Variation by race was inconsistent across CKD stages. Rates were higher for Blacks than Whites in all Stages except for 4 to 5. For Whites the adjusted rates were 82 per 1,000 patientyears at risk for Stages 1 or 2, 98 per 1,000 for Stages 3, and 184 for Stages 4 to 5. The Black patient group showed adjusted rates of 91 deaths per 1,000 patientyears at risk in Stages 1 or 2, with 101 per 1,000 and 172 per 1,000 in Stages 3 and 4 to 5.





Data source: Special analyses, Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race. Standard population Medicare 2015 patients. Abbreviations: CKD, chronic kidney disease; unk/unspc, CKD stage unidentified.

Adjusted rates of mortality also increased with greater patient health complexity. Figure 3.6 presents mortality rates by the presence of two common comorbidities of CKD—DM and CVD. These comorbid conditions dramatically influenced the health outcomes. In 2015, those with CKD but without DM or CVD had an adjusted mortality rate of 50 deaths per 1,000 patient-years at risk, while those with both DM and CVD experienced triple that rate, at 146 deaths per 1,000 patient-years. Diabetes alone, however, did not increase mortality risk among persons with CKD, at 48 deaths per 1,000 patient-years at risk.

vol 1 Figure 3.6 Adjusted all-cause mortality rates per 1,000 patient-years at risk for Medicare patients aged 66 and older, by cardiovascular disease and diabetes mellitus, CKD status, and stage, 2015



Data source: Special analyses, Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race. Standard population Medicare 2015 patients. Abbreviations: CKD, chronic kidney disease; CVD, cardiovascular disease; DM, diabetes mellitus; unk/unspc, CKD stage unidentified.

Hospitalization Rates

Table 3.2 presents all-cause hospitalization rates in 2015 for older Medicare patients and younger Optum ClinformaticsTM patients, by whether they had recognized CKD during 2015. Among Medicare patients, the unadjusted rate for those with CKD was 614 hospitalizations per 1,000 patient-years at risk, compared to a much lower rate of 227 for patients without CKD. Among Optum ClinformaticsTM patients, the unadjusted rate for those with CKD was 214 hospitalizations per 1,000 patient-years at risk, compared to a much lower rate of 36 for patients without CKD.

Across all demographic characteristics, the 2015 unadjusted hospitalization rate for patients with CKD was more than twice the corresponding rate for patients without CKD. Once adjustment was made for age, race, and sex, the hospitalization rate for Medicare patients with CKD of 581 per 1,000 patientyears at risk was 151.2% greater than for those without CKD, at 231 per 1,000. The hospitalization rate for Optum Clinformatics[™] patients with CKD of 180 per 1,000 patient-years at risk was 400% greater than for those without CKD, at 36 per 1,000. As with mortality, the adjusted hospitalization rate increased with age for all patients, except those 40-65 years.

In contrast to the mortality findings, however, women with CKD had higher adjusted hospitalization rates of 592 per 1,000 patient-years at risk than did men, at 574 per 1,000. For Medicare recipients, women without CKD had lower adjusted hospitalization rates of 229 per 1000 than did men, at 235. For Optum Clinformatics[™] patients, women had higher unadjusted and adjusted hospitalization rates than men, in both the with and without CKD cohorts.

vol 1 Table 3.2 Unadjusted and adjusted all-cause hospitalization rates per 1,000 patient-years at risk
for Medicare and Optum Clinformatics [™] patients, by CKD status, 2015

		Medicare	e (aged 66+)		Optu	Optum Clinformatics [™] (aged 22+)				
	Unadjusted		Adjı	usted	Unad	Unadjusted				
	No	All	No	All	No	All	No	All		
	CKD	CKD	CKD	CKD	CKD	CKD	CKD	CKD		
All	226.8	613.8	231.0	581.1	35.8	214.1	35.9	179.8		
Age										
22-39	•	•	•	•	34.7	156.2	35.5	154.6		
40-65	•	•	•	•	32.8	186.1	32.8	186.4		
65+	•	•	•	•	102.7	342.0	100.9	343.3		
66–69	137.7	519.7	138.5	521.1	•	•	•			
70–74	179.8	516.7	179.5	519.9	•	•	•			
75–84	261.7	610.7	261.4	608.9	•	•	•			
85+	413.8	750.0	416.7	752.2	•	•	•			
Sex										
Male	219.1	603.4	234.8	573.5	25.5	202.0	25.6	161.5		
Female	232.6	623.4	228.8	591.8	46.3	230.3	46.4	197.2		
Race										
White	230.3	612.3	232.8	580.3	38.0	226.4	37.9	188.7		
Black/African American	237.4	677.9	250.2	664.3	28.6	225.5	38.6	194.8		
Other	163.9	520.0	179.6	491.2	38.6	165.2	29.0	147.4		

Data source: Medicare 5% sample and Optum ClinformaticsTM. January 1, 2015 point prevalent Medicare patients, aged 66 and older. Standard population all Medicare patients, 2015. Optum Clinformatics™ commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD, and were alive on January 1, 2015. Adjusted for age/sex/race; rates by one factor are adjusted for the others. No data available, cell intentionally left blank. Standard population all Optum ClinformaticsTM patients, 2015. Abbreviation: CKD, chronic kidney disease.

Figure 3.7 presents the trends in hospitalization rates for Medicare and Optum ClinformaticsTM patients over the past 13 years. The overall trend relationships between adjusted and unadjusted rates, CKD and no-CKD groups, were consistent with other data presented thus far.

After adjustment, the pattern of hospitalization rates across this time frame showed a gradual decline and less variability. A reduction in hospitalization rates occurred from 2014 to 2015. Even after adjustment the Medicare rates showed a decrease—by 2.1%, from 595 to 583 per 1,000 patient-years at risk for the CKD group, and by 1.7%, from 237 to 233 per 1,000 for the no-CKD group. Conversely, an increase in hospitalization rates occurred from 2014 to 2015 in the Optum Clinformatics[™] population. Even after adjustment this CKD group increased by 3.9%, from 174 to 181 per 1,000 patient-years at risk.

vol 1 Figure 3.7 Unadjusted and adjusted all-cause hospitalization rates per 1,000 patient-years at risk for Medicare and Optum Clinformatics[™] patients, by CKD status and year, 2003-2015



Figure 3.7 continued on next page.

vol 1 Figure 3.7 Unadjusted and adjusted all-cause hospitalization rates per 1,000 patient-years at risk for Medicare and Optum Clinformatics[™] patients, by CKD status and year, 2003-2015 (*continued*)



(c) Optum Clinformatics[™] - unadjusted

Data source: Medicare 5% sample and Optum Clinformatics[™]. January 1, 2015 point prevalent Medicare patients, aged 66 and older. Standard Medicare population all patients, 2014. Optum Clinformatics[™] commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD, and were alive on January 1, 2015. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Standard Optum Clinformatics[™] population all patients, 2014. Abbreviation: CKD, chronic kidney disease.

For patients with CKD, differences were observed in the rates of hospitalizations necessary to treat different comorbid conditions. Figure 3.8 shows the adjusted hospitalization rates for all causes. In Figures 3.9 through 3.11 we present Medicare hospitalization rates resulting from CVD (22.5% of all-cause admissions), infection (20.8%), and from a combination of all other cause categories (56.7%). For the Optum Clinformatics[™] population we also present hospitalization rates resulting from CVD (10.7% of all-cause admissions), infection (8.3.%), and all other cause categories (75.1%). As the covariates in the adjusted model no longer include comorbidities and prior year hospitalizations, the Medicare adjusted rates may vary noticeably from results presented prior to the 2014 ADR.

Rates of all-cause hospitalizations in 2015 increased with disease severity, from 474 admissions per 1,000

patient-years for Medicare patients in Stages 1 or 2, to 572 for Stage 3, and 866 for Stages 4 or 5. Rates also increased with severity for the Optum Clinformatics[™] cohort, from 201 admissions per 1,000 patient-years for those in Stages 1 or 2, to 322 for Stage 3, and 598 for Stages 4 or 5 (see Figure 3.8).

The pattern of increase for Medicare hospitalizations resulting from a primary diagnosis of

CVD was similar, with rates rising from 122 admissions per 1,000 patient-years for CKD Stages 1 or 2, to 164 for Stage 3, and 263 for Stages 4 or 5. Patients in the Optum Clinformatics[™] group experienced 24 admissions per 1,000 patient-years in Stages 1 or 2, increasing to 59 for Stage 3, and 119 for Stages 4 or 5 (see Figure 3.9).

vol 1 Figure 3.8 Adjusted all-cause hospitalization rates per 1,000 patient-years at risk for Medicare and Optum Clinformatics[™] patients aged 66 and older, by CKD status and stage, 2013-2015



Data source: Medicare 5% sample and Optum Clinformatics[™]. January 1, 2015 point prevalent Medicare patients, aged 66 and older. Standard Medicare population all patients, 2014. Optum Clinformatics[™] commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD, and were alive on January 1, 2015. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Standard population all Optum Clinformatics[™] patients, 2014. Abbreviations: CKD, chronic kidney disease unk/unspc, CKD stage unidentified. vol 1 Figure 3.9 Adjusted rates of hospitalization for cardiovascular disease per 1,000 patient-years at risk for Medicare and Optum Clinformatics[™] patients aged 66 and older, by CKD status and stage, 2013-2015



Data source: Medicare 5% sample and Optum Clinformatics[™]. January 1, 2015 point prevalent Medicare patients, aged 66 and older. Standard Medicare population all patients, 2014. Optum Clinformatics[™] commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD, and were alive on January 1, 2015. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Standard Optum Clinformatics[™] population all patients, 2014. Abbreviations: CKD, chronic kidney disease unk/unspc, CKD stage unidentified.

Adjusted rates of hospitalization for infection are shown by CKD status and stage in Figure 3.10. Rates in all subgroups decreased from 2013 to 2015, with a small exception for 2014 Medicare patients with Stages

4 or 5. Among Optum Clinformatics[™] patients, hospitalization rates did decrease from 2013 to 2015 in Stages 4 or 5.

vol 1 Figure 3.10 Adjusted rates of hospitalization for infection per 1,000 patient-years at risk for Medicare and Optum ClinformaticsTM patients aged 66 and older, by CKD status and stage, 2013-2015



(b) Optum Clinformatics[™] 200 180 Admissions per 1,000 patient years 150 120 2013 2014 2015 90 60 30 0 All CKD No CKD Stages 1-2 Stage 3 Stages 4-5 Stage unk/unspc

Data source: Medicare 5% sample and Optum Clinformatics[™]. January 1, 2015 point prevalent Medicare patients, aged 66 and older. Standard Medicare population all patients, 2014. Optum Clinformatics™ commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD, and were alive on January 1, 2015. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Standard population all Optum Clinformatics™ patients, 2014. Abbreviations: CKD, chronic kidney disease unk/unspc, CKD stage unidentified.

Figure 3.11 presents the adjusted rates of hospitalization resulting from all other health causes. The pattern was similar to that seen in Figure 3.8, with admission rates for Medicare patients steadily decreasing from 2013 to 2015.

vol 1 Figure 3.11 Adjusted rates of hospitalization for causes other than cardiovascular disease and infection per 1,000 patient-years at risk for Medicare and Optum Clinformatics[™] patients aged 66 and older, by CKD status and stage, 2013-2015



Data source: Medicare 5% sample and Optum ClinformaticsTM. January 1, 2015 point prevalent Medicare patients, aged 66 and older. Standard Medicare population all patients, 2014. Optum ClinformaticsTM commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD, and were alive on January 1, 2015. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Standard Optum ClinformaticsTM population all patients, 2014. Abbreviations: CKD, chronic kidney disease unk/unspc, CKD stage unidentified.

Demographic comparisons also highlight differences in all-cause hospitalization rates for CKD, as shown in Figures 3.12-3.14. In general, and consistent with mortality patterns, older Medicare patients exhibited higher rates of hospitalization than did the younger age cohorts, although the age effect was less pronounced for the CKD population than for the non CKD population.





Data source: Medicare 5% sample. January 1, 2015 point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Standard population all patients, 2015. Abbreviations: CKD, chronic kidney disease; unk/unspc, CKD stage unidentified.

A comparison of adjusted 2015 all-cause hospitalization rates by CKD group and sex is shown

in Figure 3.13. The rates for females in all stages of CKD were slightly higher than for males.

vol 1 Figure 3.13 Adjusted all-cause hospitalization rates per 1,000 patient-years at risk for Medicare patients aged 66 and older, by sex, CKD status, and stage, 2015



Data source: Medicare 5% sample. January 1, 2015 point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Standard population all patients, 2015. Abbreviations: CKD, chronic kidney disease; unk/unspc, CKD stage unidentified.

Racial differences in Medicare hospitalization rates were notable. In both the CKD and no-CKD populations, Black patients were hospitalized more frequently than those of Other races. In 2015, Black patients in the CKD group showed higher rates than did Whites or those of Other races, at 664 per 1,000 patient-years versus 580 for Whites and 491 for other patients (Figure 3.14). This disparity decreased with disease severity; rates for Black patients were 10.6% higher than Whites in Stages 1 or 2 (523 vs. 473), 9.4% higher in Stage 3 (627 vs. 573) and 18.6% higher in Stages 4 or 5 (1018 vs. 858). Patients of Other races experienced the lowest rates of hospitalization in all disease stages.





Data source: Medicare 5% sample. January 1, 2015 point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Standard population all patients, 2015. Abbreviations: Af Am, African American; CKD, chronic kidney disease; unk/unspc, CKD stage unidentified.

Adjusted rates of all-cause hospitalizations increased in the presence of DM and CVD for Medicare patients both with and without CKD (see Figure 3.15). In the no-CKD population, the adjusted hospitalization rates were 148 per 1,000 patient-years for those without DM or CVD, 207 per 1,000 for patients with DM only, 321 for those with CVD only, and 451 for patients with both DM and CVD.

In 2015, admissions per 1,000 patient-years for those with CKD increased from 255 for patients

without DM or CVD, to 309 for those with only DM and 617 with only CVD, to a high of 853 for CKD patients with both comorbidities. This additional disease burden was most striking for patients with Stage 4 or 5 CKD. Patients with both DM and CVD in addition to late-stage CKD had an all-cause hospitalization rate of 1,165 admissions per 1,000 patient-years, compared to only 370 for late-stage CKD patients without either comorbidity. vol 1 Figure 3.15 Adjusted all-cause hospitalization rates per 1,000 patient-years at risk for Medicare patients aged 66 and older, by cardiovascular disease and diabetes mellitus, CKD status, and stage, 2015



Data source: Medicare 5% sample. January 1, 2015 point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Standard population all patients, 2015. Abbreviations: CKD, chronic kidney disease; CVD, cardiovascular disease; DM, diabetes mellitus; unk/unspc, CKD stage unidentified.

Rehospitalization

Reducing the rate of patient readmission that occurs within 30 days of discharge from their original hospitalization is a quality assurance goal for many healthcare systems, including the Medicare program. Table 3.3 shows the distribution of unadjusted percentages of rehospitalization in the 2015 Medicare population among those with and without recognized CKD, by CKD stage, and stratified by age group, sex, and race. The unadjusted proportion of Medicare patients aged 66 and older who were readmitted to the hospital within 30 days of discharge from a first, all-cause hospitalization was 15.5% for those without CKD and 21.5% for those with CKD (see Table 3.3). These rates represent a slight increase from 2014 levels. Rehospitalization rates increased slightly with stage of CKD, from 20.3% in Stages 1 or 2 to 23.4% in Stages 4 or 5.

vol 1 Table 3.3 Unadjusted percentage of patients readmitted to the hospital within 30 days of discharge, among Medicare patients aged 66 and older who were discharged alive from an all-cause index hospitalization between January 1 and December 1, by CKD status and stage, 2015

						Stage
	No CKD (%)	All CKD (%)	Stages 1 or 2 (%)	Stage 3 (%)	Stages 4 or 5 (%)	5 Unknown /unspecified (%)
All	15.5	21.5	20.3	21.4	23.4	23.1
Age						
66-69	15.2	23.8	22.5	23.2	21.0	22.1
70-74	14.8	22.2	19.4	22.1	25.6	22.0
75-84	15.6	22.2	20.7	22.4	23.2	21.7
85+	15.8	20.3	19.9	20.1	22.0	20.0
Sex						
Male	16.2	21.7	21.2	21.8	23.5	20.9
Female	14.9	21.3	19.4	21.0	23.4	21.3
Race						
White	15.3	21.1	19.6	21.2	22.9	20.7
Black/African American	17.6	23.5	23.1	23.3	25.6	22.8
Other	15.5	22.8	23.8	21.1	24.6	24.2
Rehospitalization						
No rehospitalization & died	4.6	6.2	5.2	5.9	8.1	6.3
Rehospitalization & died	1.7	2.6	2.0	2.5	3.6	2.5
Rehospitalization & lived	13.7	18.8	18.2	18.9	19.7	18.5

Data source: Medicare 5% sample. January 1, 2015 point prevalent Medicare patients aged 66 and older, discharged alive from an all-cause index hospitalization between January 1, 2015, and December 1, 2015; unadjusted. Abbreviation: CKD, chronic kidney disease.

The adjusted trend for Medicare readmissions occurring from 2003-2015 is shown in Figure 3.16. Results may differ from those presented in previous edition ADRs, in part because the adjustment variables of disease comorbidity and prior year hospitalization are no longer applied in the model.

Specifically, the percentage of patients who were rehospitalized and lived within 30 days of their initial discharge declined from 22.5% in 2006 to 18.8% in 2015, a decrease of 16.4% over the 14-year period. While any reductions in readmission are encouraging, the proportion of patients who were rehospitalized and subsequently died within 30 days of the initial discharge has not changed significantly—it has increased by 4.0% from 2014. Of note, the rate of patients who were not rehospitalized but died within 30 days of the initial discharge has decreased somewhat, by 15.9% since 2014.

vol 1 Figure 3.16 Adjusted percentage of patients readmitted to the hospital within 30 days of discharge, among Medicare CKD patients aged 66 and older who were discharged alive from an all-cause index hospitalization between January 1 and December 1, by year, 2003-2015



Data source: Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older with CKD (defined during the prior year), discharged alive from an all-cause index hospitalization between January 1 and December 1 of the reported year. Adjusted for age/sex/race. Standard population 2014. Abbreviations: CKD, chronic kidney disease; Rehosp, rehospitalized.

Figure 3.17 presents the percentages of Medicare patients who were rehospitalized and/or died, with or without rehospitalization, within 30 days of discharge following an index hospitalization. Compared to those without a diagnosis of CKD, patients with CKD had a higher proportion of live discharges linked to a rehospitalization or death.

vol 1 Figure 3.17 Unadjusted percentage of patients readmitted to the hospital within 30 days of discharge, among Medicare patients aged 66 and older who were discharged alive from an all-cause index hospitalization between January 1 and December 1, by CKD status and stage, 2015



Data source: Medicare 5% sample. January 1, 2015 point prevalent Medicare patients aged 66 and older, discharged alive from an all-cause index hospitalization between January 1, 2015, and December 1, 2015, unadjusted. Abbreviations: CKD, chronic kidney disease; Rehosp, rehospitalized; unk/unspc, CKD stage unidentified.

Figure 3.18 shows the death and rehospitalization percentages for older Medicare patients who were discharged alive from a CVD-related index hospitalization; 18.3% of patients with CKD and 13.7% of those without required rehospitalization within 30 days. Otherwise, the magnitude and pattern of these readmission rates were similar to those for all-cause index hospitalizations.

vol 1 Figure 3.18 Unadjusted percentage of patients readmitted to the hospital within 30 days of discharge, among Medicare patients aged 66 and older who were discharged alive from a cardiovascular-related index hospitalization between January 1 and December 1, by CKD status and stage, 2015



Data source: Medicare 5% sample. January 1, 2015 point prevalent Medicare patients aged 66 and older, discharged alive from an CVD index hospitalization between January 1, 2015, and December 1, 2015; unadjusted. Abbreviations: CKD, chronic kidney disease; Rehosp, rehospitalized; unk/unspc, CKD stage unidentified.

Of all patients without CKD who experienced an infection-related admission, 16.2% required rehospitalization (see Figure 3.19). Of these, 2.6% died following rehospitalization, and 6.2% were not rehospitalized and later died. In the CKD group,

within 30 days of the initial discharge 20.0% of patients were subsequently rehospitalized and lived, an additional 3.3% died following rehospitalization, and 7.6% of patients were not rehospitalized but later died.

vol 1 Figure 3.19 Unadjusted percentage of patients readmitted to the hospital within 30 days of discharge, among Medicare patients aged 66 and older who were discharged alive from an infection-related index hospitalization between January 1 and December 1, by CKD status and stage, 2015



Data source: Medicare 5% sample. January 1, 2015 point prevalent Medicare patients aged 66 and older, discharged alive from an infection index hospitalization between January 1, 2015, and December 1, 2015, unadjusted. Abbreviations: CKD, chronic kidney disease; Rehosp, rehospitalized; unk/unspc, CKD stage unidentified.

Figure 3.20 shows the death and rehospitalization percentages for Medicare patients aged 66 and older who were discharged alive from an index hospitalization for all causes other than CVD and infection. The patterns of these percentages were similar to those for the entire group of index hospitalizations, for all-causes. For those with CKD, 6.0% of patients were not rehospitalized but died, 2.2% were rehospitalized and died, and 16.7% were rehospitalized and lived. In the no-CKD group, these percentages were somewhat lower, at 4.3%, 1.4%, and 12.2%.

vol 1 Figure 3.20 Unadjusted percentage of patients readmitted to the hospital within 30 days of discharge, among Medicare patients aged 66 and older who were discharged alive from a no-cardiovascular and no-infection-related index hospitalization between January 1 and December 1, by CKD status and stage, 2015



Data Source: Medicare 5% sample. January 1, 2015 point prevalent Medicare patients aged 66 and older, discharged alive from an no-cardiovascular and no-infection index hospitalization between January 1, 2015, and December 1, 2015; unadjusted. Abbreviations: CKD, chronic kidney disease; Rehosp, rehospitalized; unk/unspc, CKD stage unidentified.
CHAPTER 3: MORBIDITY AND MORTALITY IN PATIENTS WITH CKD

Figure 3.21 illustrates a comparison by age group and presence of CKD of the percentages of Medicare patients who were rehospitalized or died within 30 days of discharge from an all-cause, index hospitalization. In the Medicare population, rates of rehospitalization with survival decreased with increasing age across all stages of CKD. These findings were likely influenced by the competing risk of death in older age groups. Consistently, for both patients with and without CKD, the proportion returning to the hospital and dying within 30 days of discharge, or dying without rehospitalization, increased with older age.

vol 1 Figure 3.21 Unadjusted percentage of patients readmitted to the hospital within 30 days of discharge, among Medicare patients aged 66 and older who were discharged alive from an all-cause index hospitalization between January 1 and December 1, by age and CKD status, 2015



Data source: Medicare 5% sample. January 1, 2015 point prevalent Medicare patients aged 66 and older, discharged alive from an all-cause index hospitalization between January 1, 2015, and December 1, 2015; unadjusted. Abbreviations: CKD, chronic kidney disease; Rehosp, rehospitalized.

2017 USRDS ANNUAL DATA REPORT | VOLUME 1 - CKD IN THE UNITED STATES

Figure 3.22 compares the rates of all-cause hospitalization by sex. Male patients exhibited higher rates than did females in all outcome categories. Specifically, 6.8% of male CKD patients did not require rehospitalization but later died, 2.9% were rehospitalized and later died within 30 days of the initial discharge, and 18.8% were rehospitalized and lived. CKD patients in all subgroups experienced higher rates of rehospitalization than did those without CKD.

vol 1 Figure 3.22 Unadjusted percentage of patients readmitted to the hospital within 30 days of discharge, among Medicare patients aged 66 and older who were discharged alive from an all-cause index hospitalization between January 1 and December 1, by sex and CKD status, 2015



Data source: Medicare 5% sample. January 1, 2015 point prevalent Medicare patients aged 66 and older, discharged alive from an all-cause index hospitalization between January 1, 2015, and December 1, 2015; unadjusted. Abbreviations: CKD, chronic kidney disease; Rehosp, rehospitalized.

CHAPTER 3: MORBIDITY AND MORTALITY IN PATIENTS WITH CKD

Racial trends in post-discharge outcomes were mixed. As shown in Figure 3.23, for patients without CKD, those of Black race who were rehospitalized subsequently survived at greater rates (16.2%) than did both Whites (13.5%) and patients of Other races (13.9%). For patients with CKD, Blacks survived rehospitalization at 21.1%, Whites at 18.3%, and those of Other races at 20.1%. Whites with or without CKD experienced the highest rates of death without rehospitalization (4.7% for no-CKD, 6.5% with CKD); more CKD patients of Other races were observed to have died following their rehospitalization (2.4%).

vol 1 Figure 3.23 Unadjusted percentage of patients readmitted to the hospital within 30 days of discharge, among Medicare patients aged 66 and older who were discharged alive from an all-cause index hospitalization between January 1 and December 1, by race and CKD status, 2015



Data Source: Medicare 5% sample. January 1, 2015 point prevalent Medicare patients aged 66 and older, discharged alive from an all-cause index hospitalization between January 1, 2015, and December 1, 2015; unadjusted. Abbreviations: Af Am, African American; CKD, chronic kidney disease; Rehosp, rehospitalized.

2017 USRDS ANNUAL DATA REPORT | VOLUME 1 - CKD IN THE UNITED STATES

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Chapter 4:

Cardiovascular Disease in Patients with CKD

- The prevalence of cardiovascular disease (CVD) was 65.8% among patients aged 66 and older who had chronic kidney disease (CKD), compared to 31.9% among those who did not (Table 4. 1).
- The presence of CKD worsens the short- and long-term prognosis for many common cardiovascular diseases. The adjusted two-year survival of patients with acute myocardial infarction (AMI) and without a diagnosis of CKD was 81%, compared with 71% for CKD Stage 1-2 patients and 56% for Stage 4-5 patients (Figure 4.2).
- The presence of cardiovascular disease also worsens the 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 77.3%, compared to 89.9% for those with CKD alone (Figure 4.5).
- Atrial fibrillation (AF) was common among Medicare patients with CKD (24.6%). 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 61.7% of CKD patients with HF, despite the risk of hyperkalemia. Although direct oral anticoagulants have been less studied among patients with CKD, these drugs were prescribed to 25.0% of patients with AF and CKD, as compared with 27.8% of patients with AF and no CKD (Table 4.4).

Introduction

Cardiovascular disease (CVD) remains the leading cause of death in the United States (U.S.) and most other developed countries (CDC, 2015). It accounts for approximately 39% of deaths among those on dialysis (see Volume 2, Chapter 5, *Mortality*). Among patients with CKD, death from CVD is far more common than progression to end-stage renal disease (ESRD; Gargiulo et al., 2015).

CKD has been identified as an independent risk factor for CVD, and experts have argued that it should be recognized as a coronary disease risk equivalent (Briasoulis and Bakris, 2013, Sarnak et al. 2003), similar to diabetes mellitus (DM). The complex relationship between CVD and kidney disease is thought to be due to shared traditional risk factors, such as DM, HTN, physical inactivity, left ventricular hypertrophy, smoking, family history, and dyslipidemia.

Non-traditional risk factors exert an additional influence when in the presence of CKD—some

examples include endothelial dysfunction, vascular medial hyperplasia, sclerosis and calcification, volume overload, abnormalities in mineral metabolism, anemia, malnutrition, inflammation, oxidative stress, and autonomic imbalance. In cardiorenal syndrome, dysfunction in the heart or kidney may directly induce dysfunction in the other organ. In particular, this continues to pose both a diagnostic and therapeutic challenge for managing fluid status when treating those with HF (Husain-Syed et al., 2015). Thus, characterizing the epidemiology of cardiovascular comorbidities is a critical step toward improving morbidity and mortality in the CKD population.

In this chapter, we review recent trends in the prevalence and outcomes of cardiovascular disease in CKD patients and compare these to outcomes of CVD in patients without CKD, focusing on the high-risk, elderly Medicare population.

Methods

The findings presented in this chapter were drawn from data from the Medicare 5% sample's fee-forservice patients aged 66 and older. Those in the cohort were alive, without end-stage renal disease, and residing in the U.S. on 12/31/2015, with fee-forservice coverage for the entire calendar year of 2015. CKD and CVD diagnoses were obtained via billing claims from the Medicare 5% sample. The overall study cohort for 2015 included 1,249,076 patients, of whom 146,663 had CKD. Details of this data are described in the <u>Data Sources</u> section of the <u>CKD</u> <u>Analytical Methods</u> chapter.

See the <u>CKD Analytical Methods</u> section of the <u>CKD</u> <u>Analytical Methods</u> chapter for an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter. Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available to download from the <u>USRDS website</u>.

Cardiovascular Disease Prevalence and Outcomes in CKD

As shown in Figure 4.1, elderly CKD patients had a greater burden of cardiovascular disease than did their counterparts without a diagnosis of CKD. A wide range of conditions were more common in CKD patients aged 66 and older than in those without CKD, including stable coronary artery disease (CAD), acute myocardial infarction (AMI), heart failure (HF), valvular heart disease (VHD), stroke (cerebrovascular accident/transient ischemic attack, or 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). Indeed, the prevalence of these cardiovascular conditions was double among those with CKD compared to those without (65.8% versus 31.9%). Part of this differential results from the older age of CKD patients (see Volume 1, Chapter 2, Identification and Care of Patients with CKD).



vol 1 Figure 4.1 Prevalence of common cardiovascular diseases in patients with or without CKD, 2015

Data Source: Special analyses, Medicare 5% sample. Abbreviations: AF, atrial fibrillation; AMI, acute myocardial infarction; CAD, coronary artery disease; CKD, chronic kidney disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; CVD, cardiovascular disease; HF, heart failure; PAD, peripheral arterial disease; SCA/VA, sudden cardiac arrest and ventricular arrhythmias; VHD, valvular heart disease; VTE/PE, venous thromboembolism and pulmonary embolism.

The prevalence of these conditions generally increases with age and presence of CKD (Table 4.1). The relationships with race, ethnicity, and sex are less straightforward.

Major procedures performed for the treatment of CVD were more common among CKD patients,

including percutaneous coronary intervention (PCI), coronary artery bypass grafting (CABG), placement of implantable cardioverter defibrillators (ICD) and cardiac resynchronization (CRT) devices, and carotid artery stenting and carotid endarterectomy (CAS/CEA).

vol 1 Table 4.1 Prevalence of (a) cardiovascular comorbidities & (b) annual incidence of cardiovascular procedures, by CKD status, age, race, & sex, 2015

	# Patients					% Pa	atients				
		Overall	66-69	70-74	75-84	85+	White	Blk/Af Am	Other	Male	Female
Any CVD											
Without CKD	1,102,413	31.9	18.9	27.0	39.0	52.1	32.8	28.0	23.3	35.3	29.3
Any CKD	146,663	65.8	52.0	58.5	67.6	76.4	66.9	61.7	57.7	69.8	62.1
Coronary artery disease (CAD)											
Without CKD	1,102,413	15.6	9.6	13.9	19.4	22.4	16.1	12.3	11.7	20.8	11.6
Any CKD	146,663	39.4	30.9	35.8	41.6	43.6	40.5	33.3	34.8	47.0	32.3
Acute myocardial infarction (A	AMI)										
Without CKD	1,102,413	2.2	1.5	2.0	2.7	3.4	2.3	1.9	1.4	2.9	1.7
Any CKD	146,663	9.7	8.3	9.1	9.7	10.9	10.0	8.2	7.3	11.5	8.0
Heart failure (HF)											
Without CKD	1,102,413	6.1	3.0	4.3	7.2	13.6	6.2	6.9	4.2	6.4	5.9
Any CKD	146,663	27.6	20.0	21.7	27.2	37.1	27.9	29.3	21.8	28.2	27.2
Valvular heart disease (VHD)											
Without CKD	1,102,413	5.0	2.4	3.8	6.6	9.2	5.3	3.3	3.3	4.9	5.1
Any CKD	146,663	13.6	8.1	10.0	14.2	18.5	14.2	10.3	10.7	13.6	13.6
Cerebrovascular accident/trans	ient ischemic	attack (CVA/TI	4)							
Without CKD	1,102,413	6.9	3.7	5.6	8.9	11.7	7.0	7.5	5.2	6.9	6.9
Any CKD	146,663	17.5	12.7	15.0	18.6	20.5	17.5	18.6	15.4	17.7	17.3
Peripheral artery disease (PAI))										
Without CKD	1,102,413	9.1	4.3	6.7	11.0	19.1	9.2	9.7	6.5	9.3	8.9
Any CKD	146,663	24.9	17.5	20.6	25.5	31.6	25.3	24.4	20.9	26.5	23.5
Atrial fibrillation (AF)											
Without CKD	1,102,413	9.6	4.1	6.9	12.5	19.6	10.3	4.8	5.1	10.8	8.7
Any CKD	146,663	24.6	14.2	17.9	25.9	33.7	26.4	14.7	16.0	27.3	22.1
Cardiac arrest and ventricular	arrhythmias	(SCA/VA	4)								
Without CKD	1,102,413	1.3	0.9	1.3	1.7	1.7	1.4	1.1	0.8	1.9	1.0
Any CKD	146,663	4.2	3.5	4.0	4.6	4.2	4.3	4.4	2.8	5.7	2.8
Venous thromboembolism an	d pulmonary	embolis	sm (VTE	/PE)							
Without CKD	1,102,413	1.3	0.8	1.1	1.5	1.9	1.3	1.5	0.6	1.2	1.3
Any CKD	146,663	4.1	3.8	3.6	4.1	4.6	4.1	5.1	2.4	4.0	4.2

(a) Cardiovascular comorbidities

Table 4.1 continued on next page.

vol 1 Table 4.1 Prevalence of (a) cardiovascular comorbidities & (b) annual incidence of cardiovascular procedures, by CKD status, age, race, & sex, 2015 *(continued)*

	# Patients					% Pa	atients				
		Overall	66-69	70-74	75-84	85+	White	Blk/Af Am	Other	Male	Female
Revascularization – perc	utaneous coronary	/ interve	ntions	(PCI)							
Without CKD	171,640	1.6	2.3	1.8	1.4	1.0	1.6	1.4	1.5	1.6	1.6
Any CKD	57,788	2.4	3.0	2.9	2.5	1.7	2.4	2.2	2.2	2.5	2.1
Revascularization – coro	onary artery bypass	graft (C	ABG)								
Without CKD	171,640	1.1	1.6	1.4	1.1	0.3	1.1	0.5	1.1	1.3	0.7
Any CKD	57,788	1.6	2.9	2.4	1.8	0.4	1.7	1.2	1.8	2.1	1.0
Implantable cardioverte	er defibrillators & ca	ardiac re	synchr	onizatio	on thera	apy wi	th defib	rillator (ICD/CR	T-D)	
Without CKD	67,366	0.5	0.8	0.8	0.7	0.2	0.5	0.6	0.5	0.8	0.4
Any CKD	40,545	0.9	1.3	1.4	1.0	0.5	0.9	1.0	0.9	1.3	0.6
Carotid artery stenting a	and carotid artery e	endarter	ectomy	(CAS/O	CEA)						
Without CKD	269,224	0.6	0.7	0.7	0.7	0.3	0.6	0.4	0.5	0.6	0.5
Any CKD	79,790	0.7	0.9	1.1	0.8	0.4	0.8	0.4	0.5	0.9	0.6

(b) Cardiovascular procedures

Data Source: Special analyses, Medicare 5% sample. Patients aged 66 and older, alive, without end-stage renal disease, and residing in the United States on 12/31/2015 with fee-for-service coverage for the entire calendar year. Abbreviations: AF, atrial fibrillation; AMI, acute myocardial infarction; Blk/Af Am, Black African American; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CAS/CEA, carotid artery stenting and carotid endarterectomy; CKD, chronic kidney disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; CVD, cardiovascular disease; HF, heart failure; ICD/CRT-D, implantable cardioverter defibrillators/cardiac resynchronization therapy with defibrillator devices; PAD, peripheral arterial disease; PCI, percutaneous coronary interventions; SCA/VA, sudden cardiac arrest and ventricular arrhythmias; VHD, valvular heart disease; VTE/PE, venous thromboembolism and pulmonary embolism. (a) The denominators for overall prevalence of all cardiovascular comorbidities were Medicare enrollees aged 66+ by CKD status. (b) The denominators for overall prevalence of PCI and CABG were Medicare enrollees aged 66+ with CAD by CKD status. The denominators for overall prevalence of ICD/CRT-D were Medicare enrollees aged 66+ with Fby CKD status. The denominators for overall prevalence of CAS/CEA were Medicare enrollees aged 66+ with CAD, CVA/TIA, or PAD by CKD status.

The presence of CKD also worsens the short- and long-term prognosis for many common cardiovascular diseases and for patients who undergo cardiovascular procedures. Figures 4.2.a through 4.2.i and Table 4.2 illustrate survival among patients with CVD. Figures 4.3.a through 4.3.d and Table 4.3 illustrate survival among patients undergoing cardiovascular procedures. Results were stratified by the presence of CKD and its severity, and adjusted for age and sex. In general, CKD patients had a lower probability of survival for all of the conditions reported, with late stages of CKD being associated with the worst outcomes. For example, the adjusted two-year survival of AMI patients without a diagnosis of CKD was 81%, compared to 71% for CKD Stage 1-2 patients and 56% for CKD Stage 4-5 patients (see Table A for CKD stage definitions). This pattern also held for patients who underwent common major procedures for the treatment of CVD. The adjusted two-year survival of patients undergoing PCI without a diagnosis of CKD was 85%, compared to 76% for CKD Stage 1-2 patients and 64% for CKD Stage 4-5 patients.

ICD-9-CM code ^a	ICD-10-CM code ^a	Stage
585.1	N18.1	CKD, Stage 1
585.2	N18.2	CKD, Stage 2 (mild)
585.3	N18.3	CKD, Stage 3 (moderate)
585.4	N18.4	CKD, Stage 4 (severe)
585.5	N18.5	CKD, Stage 5 (excludes 585.6: Stage 5, requiring chronic dialysis ^b)
CKD Stage- unspecified	CKD Stage- unspecified	For these analyses, identified by multiple codes including 585.9, 250.4x, 403.9x & others for ICD-9-CM and A18.xx, E08.xx, E11.xx and others for ICD-10-CM.

Table A. ICD-9-CM and ICD-10-CM codes for Chronic Kidney Disease (CKD) stages

^a For analyses in this chapter, CKD stage estimates require at least one occurrence of a stage-specific code, and the last available CKD stage in a given year is used. ^b In USRDS analyses, patients with ICD-9-CM code 585.6 or ICD-10-CM code N18.6 & with no ESRD 2728 form or other indication of end-stage renal disease (ESRD) are considered to have code 585.5 or N18.5

vol 1 Figure 4.2 Probability of survival of patients with a prevalent cardiovascular disease, by CKD status, adjusted for age and sex, 2014-2015



Figure 4.2 continued on next page.

CHAPTER 4: CARDIOVASCULAR DISEASE IN PATIENTS WITH CKD





Figure 4.2 continued on next page.

2017 USRDS ANNUAL DATA REPORT | VOLUME 1 – CKD IN THE UNITED STATES

vol 1 Figure 4.2 Probability of survival of patients with a prevalent cardiovascular disease, by CKD status, adjusted for age and sex, 2014-2015 (continued)



(e) Cerebrovascular accident/transient ischemic attack (CVA/TIA)

Figure 4.2 continued on next page.

CHAPTER 4: CARDIOVASCULAR DISEASE IN PATIENTS WITH CKD

vol 1 Figure 4.2 Probability of survival of patients with a prevalent cardiovascular disease, by CKD status, adjusted for age and sex, 2014-2015 *(continued)*



Figure 4.2 continued on next page.

vol 1 Figure 4.2 Probability of survival of patients with a prevalent cardiovascular disease, by CKD status, adjusted for age and sex, 2014-2015 (continued)



(i) Venous thromboembolism and pulmonary embolism (VTE/PE)

Data Source: Special analyses, Medicare 5% sample. Patients aged 66 and older, alive, without end-stage renal disease, and residing in the United States on 12/31/2013, with fee-for-service coverage for the entire calendar year. Abbreviations: CKD, chronic kidney disease.

vol 1 Table 4.2 Two-year survival of patients with a prevalent cardiovascular disease, by CKD status, adjusted for age and sex, 2014-2015

_	CKD Status									
Cardiovascular Disease	No CKD (%)	СКD (%)	Stages 1 to 2 (%)	Stage 3 (%)	Stages 4 to 5 (%)					
CAD	87.3	76.4	80.9	77.4	67.4					
AMI	81.3	67.8	70.7	68.3	56.3					
HF	75.3	64.2	68.6	65.4	55.1					
VHD	86.1	72.2	76.2	72.9	61.3					
CVA/TIA	83.3	72.7	77.7	74.3	62.2					
PAD	81.2	72.0	75.8	73.4	61.7					
AF	82.8	69.6	74.4	70.8	59.6					
SCA/VA	84.9	68.5	73.2	68.7	55.1					
VTE/PE	81.3	68.8	70.2	71.3	58.0					

Data Source: Special analyses, Medicare 5% sample. Patients aged 66 and older, alive, without end-stage renal disease, and residing in the United States on 12/31/2013, with fee-for-service coverage for the entire calendar year. Abbreviations: AF, atrial fibrillation; AMI, acute myocardial infarction; CAD, coronary artery disease; CKD, chronic kidney disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; HF, heart failure; PAD, peripheral arterial disease; SCA/VA, sudden cardiac arrest and ventricular arrhythmias; VHD, valvular heart disease; VTE/PE, venous thromboembolism and pulmonary embolism.

CHAPTER 4: CARDIOVASCULAR DISEASE IN PATIENTS WITH CKD

vol 1 Figure 4.3 Probability of survival of patients with a cardiovascular procedure, by CKD status, adjusted for age and sex, 2013-2015

1.0 0.8 Probability of survival Without CKD 0.6 Any CKD Stages 1-2 Stage 3 0.4 Stages 4-5 0.2 0.0 Т 5 9 13 1 17 21 24 Months from index date

(a) Percutaneous coronary interventions (PCI)

(b) Coronary artery bypass grafting (CABG)



Figure 4.3 continued on next page.

2017 USRDS ANNUAL DATA REPORT | VOLUME 1 - CKD IN THE UNITED STATES

vol 1 Figure 4.3 Probability of survival of patients with a cardiovascular procedure, by CKD status, adjusted for age and sex, 2013-2015 (continued)

(c) Implantable cardioverter defibrillators/cardiac resynchronization therapy with defibrillator devices (ICD/CRT-D)



Data Source: Special analyses, Medicare 5% sample. Patients aged 66 and older, alive, without end-stage renal disease, and residing in the United States on the index date, which was the date of the first procedure claim, with fee-for-service coverage for the entire year prior to this date. Abbreviations: CKD, chronic kidney disease.

CHAPTER 4: CARDIOVASCULAR DISEASE IN PATIENTS WITH CKD

vol 1 Table 4.3 Two-year survival of patients with a cardiovascular procedure, by CKD status, adjusted for age and sex, 2013-2015

_	CKD Status										
Cardiovascular Procedure	No CKD (%)	CKD (%)	Stages 1 to 2 (%)	Stage 3 (%)	Stages 4 to 5 (%)						
PCI	85.3	74.7	76.3	76.1	63.7						
CABG	89.1	81.3	83.4	82.0	70.2						
ICD/CRT-D	78.9	64.4	64.1	64.4	57.9						
CAS/CEA	87.6	79.5	79.1	81.6	69.0						

Data Source: Special analyses, Medicare 5% sample. Patients aged 66 and older, alive, without end-stage renal disease, and residing in the United States on the index date, which was the date of the first procedure claim, with fee-for-service coverage for the entire year prior to this date. Abbreviations: CABG, coronary artery bypass grafting; CAS/CEA, carotid artery stenting and carotid endarterectomy; CKD, chronic kidney disease; ICD/CRT-D, implantable cardioverter defibrillators/cardiac resynchronization therapy with defibrillator devices; PCI, percutaneous coronary interventions.

Cardiovascular Disease and Pharmacological Treatments

For clinicians, pharmacological treatment of cardiovascular disorders in the CKD population is fraught with challenges given that many drugs are cleared by the kidneys. Patients with advanced renal dysfunction are often excluded from large clinical trials, so the risk-benefit ratios of their treatment with various medications are often unclear. Angiotensin converting enzyme inhibitors (ACEs) and angiotensin receptor blockers (ARBs) are mainstays of HF therapy and are frequently prescribed to CKD patients. In 2015, these drugs were prescribed to 61.5% of CKD patients, as compared with 55.1% of non-CKD patients who also had CVD. This difference may be explained in part by the fact that ACEs and ARBs are also used for their nephroprotective effects. Despite the potential clinical benefits, these drugs must be prescribed with caution in this population due to increased risk of hyperkalemia.

Warfarin dose adjustment can be more difficult among patients with CKD, and renal failure is a risk factor for bleeding while on warfarin therapy. Although direct oral anticoagulants have not been as well studied as warfarin among patients with CKD, these drugs were used quite frequently in this group, particularly for stroke prevention in the context of AF (Table 4.4). Aspirin is commonly recommended to those with cardiovascular diseases such as CAD and PAD, regardless of the patient's renal function. As it is most often purchased over the counter, however, prescribing rates for aspirin were low (<1%) for patients with all types of CVD; aspirin is omitted from Table 4.4.

vol 1 Table 4.4 Cardiovascular pharmacological treatments by (a) comorbidities and (b) procedures, by CKD status, 2015

(a) Cardiovascular comorbidities

				% Pa	atients		
	# Patients	Beta- blockers	Statins	P2Y ₁₂ inhibitors	Warfarin	Direct Oral Anticoagulants	ACEs/ ARBs
Any CVD							
Without CKD	239,800	57.1	63.0	16.6	15.2	9.8	55.1
Any CKD	66,354	68.0	68.0	20.7	18.3	10.9	61.5
Coronary artery dis	sease (CAD)						
Without CKD	116,846	68.1	75.7	26.3	11.7	7.9	60.5
Any CKD	39,684	76.1	75.8	28.8	17.5	10.7	63.8
Acute myocardial i	nfarction (AMI)						
Without CKD	16,545	77.6	78.2	39.8	14.1	9.9	65.2
Any CKD	9,666	83.5	79.0	39.7	19.1	12.3	65.4
Heart failure (HF)							
Without CKD	46,509	72.5	60.6	16.9	22.1	13.4	63.4
Any CKD	28,204	77.8	67.4	21.8	23.8	14.0	61.7
Valvular heart dise	ase (VHD)						
Without CKD	37,493	60.5	61.9	13.7	18.6	11.1	56.0
Any CKD	13,585	74.9	69.8	21.5	24.6	14.1	62.6
Cerebrovascular acc	cident/transient	ischemic atta	ck (CVA/TIA)				
Without CKD	52,488	51.3	68.1	25.0	12.8	8.0	55.6
Any CKD	17,830	67.4	73.1	30.0	16.8	10.9	62.1
Peripheral artery d	lisease (PAD)						
Without CKD	69,923	50.2	58.7	18.2	11.5	6.8	53.3
Any CKD	25,460	67.0	68.0	25.7	16.3	9.8	60.8
Atrial fibrillation (A	AF)						
Without CKD	71,368	69.4	57.8	8.9	40.8	27.8	53.2
Any CKD	24,507	76.4	65.4	14.9	40.7	25.0	58.9
Cardiac arrest and	ventricular arrh	ythmias (SCA	VA)				
Without CKD	9,951	73.6	64.2	17.0	16.7	12.5	60.9
Any CKD	4,205	82.0	70.9	25.4	26.0	15.2	65.1
Venous thromboer	mbolism and pu	Imonary emb	olism (VTE/	PE)			
Without CKD	9,580	44.4	49.2	6.9	57.7	23.9	46.0
Any CKD	4,137	60.9	58.6	11.9	54.5	23.4	55.5

Table 4.4 continued on next page.

vol 1 Table 4.4 Cardiovascular pharmacological treatments by (a) comorbidities and (b) procedures, (%) by CKD status, 2015 *(continued)*

				% Pa	tients		
	# Patients	Beta- blockers	Statins	P2Y ₁₂ inhibitors	Warfarin	Direct Oral Anticoagulants	ACEs/ ARBs
Revascularization	n – percutaneous	coronary inte	erventions (P	CI)			
Without CKD	1,738	90.0	91.3	95.4	10.1	7.5	75.5
Any CKD	899	93.2	89.2	96.6	13.3	11.6	73.6
Revascularization	n – coronary arter	y bypass graf	t (CABG)				
Without CKD	1,167	93.8	92.9	38.6	20.0	9.3	68.2
Any CKD	607	92.9	92.1	41.7	22.7	12.0	68.5
Implantable card	lioverter defibrilla	tors & cardia	c resynchron	ization therapy	y with defibril	lator (ICD/CRT-D)	
Without CKD	263	88.6	75.7	22.4	31.9	24.7	78.7
Any CKD	284	91.2	73.9	34.5	35.9	21.5	75.7
Carotid artery ste	enting and carotic	l artery endar	rterectomy (CAS/CEA)			
Without CKD	1,034	58.3	80.8	52.9	8.8	9.4	62.2
Any CKD	408	71.6	85.3	50.5	15.0	10.8	72.1

(b) Cardiovascular procedures

Data Source: Special analyses, Medicare 5% sample. Patients aged 66 and older, alive, without end-stage renal disease, and residing in the United States on 12/31/2015 with fee-for-service and Part D coverage for the entire calendar year. Abbreviations: ACEs/ARBs, Angiotensin converting enzyme inhibitors and angiotensin receptor blockers; AF, atrial fibrillation; AMI, acute myocardial infarction; CAD, coronary artery disease; CABG, coronary artery bypass grafting; CAS/CEA, carotid artery stenting and carotid endarterectomy; CKD, chronic kidney disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; CVD, cardiovascular disease; HF, heart failure; ICD/CRT-D, implantable cardioverter defibrillators/cardiac resynchronization therapy with defibrillator devices; PAD, peripheral arterial disease; PCI, percutaneous coronary interventions; SCA/VA, sudden cardiac arrest and ventricular arrhythmias; VHD, valvular heart disease; VTE/PE, venous thromboembolism and pulmonary embolism.

Heart Failure and CKD

Heart failure (HF) is among the more frequently diagnosed cardiovascular diseases in the CKD population. In 2015, the prevalence of HF in CKD patients aged 66 and older was close to 30%, compared to 6% among patients without CKD (Table 4.1). Given its importance in this population, we further examined key characteristics of HF in CKD patients after stratifying HF based on presence or absence of left ventricular systolic dysfunction (i.e., "systolic" heart failure with decreased ejection fraction, "diastolic" heart failure with preserved ejection fraction, or unspecified; Figure 4.4). For ease of reporting and consistency with clinical approaches for categorizing the disease, systolic HF includes patients with left ventricular systolic dysfunction, regardless of the presence of concomitant diastolic dysfunction. Patients with isolated diastolic HF were treated separately, since long-term risk assessments and treatments vary for this group.

All types of HF were more common among those with CKD than among non-CKD patients. The relative proportion of CKD patients with systolic HF was higher than with diastolic HF, and increased with greater severity of CKD Stage. The percentage of patients without CKD who had unspecified HF was slightly higher than for systolic or diastolic HF. For patients with CKD, the percentage with unspecified HF was slightly lower than with systolic HF (Figure 4.4).

2017 USRDS ANNUAL DATA REPORT | VOLUME 1 - CKD IN THE UNITED STATES



vol 1 Figure 4.4 Heart failure in patients with or without CKD, 2015

Data Source: Special analyses, Medicare 5% sample. Patients aged 66 and older, alive, without end-stage renal disease, and residing in the United States on 12/31/2015 with fee-for-service coverage for the entire calendar year. Abbreviation: CKD, chronic kidney disease.

The presence of HF reduced the probability of survival among patients both with and without CKD (Figure 4.5), but to a greater extent among those with CKD (p-value for interaction <0.0001). Over a twoyear period, patients with both HF and CKD had an adjusted survival probability of 77.3%, as compared to 84.3% for those with HF alone, 89.9% for those with CKD alone, and 93.6% for those without HF or CKD.

vol 1 Figure 4.5 Adjusted survival of patients by CKD and heart failure status, 2014-2015



Data Source: Special analyses, Medicare 5% sample. Patients aged 66 and older, alive, without end-stage renal disease, and residing in the United States on 12/31/2013 with fee-for-service coverage for the entire calendar year. Survival was adjusted for age, sex, race, diabetic status, and hypertension status. Abbreviations: CKD, chronic kidney disease.

CHAPTER 4: CARDIOVASCULAR DISEASE IN PATIENTS WITH CKD

Atrial Fibrillation and CKD

Atrial fibrillation (AF) is one of the most common arrhythmias seen in the general U.S. population, and is associated with significant morbidity and mortality. The prevalence of AF among CKD patients is also high, being present in approximately one-quarter of the population.

In 2015, the prevalence of AF increased with more advanced stages of CKD, age, male sex, white race, hypertension, and heart failure (Table 4.5). In patients with CKD, the presence of HF increased the prevalence of AF to about half of all patients. Patients with AF and CKD have an increased risk of stroke and bleeding, making the use of oral anticoagulants challenging, as demonstrated by recent reports. Warfarin was prescribed to 40.8% of patients without CKD and 40.7% of patients with CKD, while direct oral anticoagulants were prescribed to 27.8% of patients without CKD and 25.0% of patients with CKD (Table 4.4).

vol 1 Table 4.5 Prevalence of atrial fibrillation by stage of CKD, age, race, sex, and diabetic, hypertension, and heart failure status, 2015

			Stage	of CKD		Total
	No CKD	Stages 1-2	Stage 3	Stages 4-5	Unknown stage	All CKD stages
# Patients	1,102,413	16,008	75,595	13,951	41,109	146,663
Atrial fibrillation (Overall)	9.6	21.5	25.5	27.7	23.1	24.6
Age						
66-69	4.1	11.5	15.5	16.9	13.0	14.2
70-74	6.9	16.9	18.5	21.6	16.4	17.9
75-84	12.5	22.8	26.4	28.4	25.1	25.9
85+	19.6	32.5	34.0	33.6	33.6	33.7
Sex						
Male	10.8	24.3	28.6	30.6	25.1	27.3
Female	8.7	18.7	22.7	25.2	21.2	22.1
Race						
White	10.3	23.4	27.4	30.2	24.7	26.4
Black/African American	4.8	12.7	14.9	17.2	14.0	14.7
Other	5.1	13.6	16.8	17.6	15.2	16.0
Comorbidity						
No diabetes	8.8	20.7	25.0	27.8	22.9	24.2
Diabetes	12.9	22.2	26.1	27.5	23.5	25.1
No hypertension	3.9	11.9	15.5	16.3	11.1	13.3
Hypertension	14.2	22.5	26.4	28.3	25.0	25.8
No heart failure	7.3	13.4	14.9	14.5	14.4	14.5
Heart failure	44.6	49.5	52.1	48.2	50.8	51.0

Data Source: Special analyses, Medicare 5% sample. Patients aged 66 and older, alive, without end-stage renal disease, and residing in the United States on 12/31/2015 with fee-for-service coverage for the entire calendar year. Abbreviations: CKD, chronic kidney disease.

2017 USRDS ANNUAL DATA REPORT | VOLUME 1 - CKD IN THE UNITED STATES

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Chapter 5: Acute Kidney Injury

- In 2015, 4.3% of Medicare fee-for-service beneficiaries experienced a hospitalization complicated by Acute Kidney Injury (AKI); this appears to have plateaued since 2011 (Figure 5.1). The 2015 Optum Clinformatics[™] population showed a similar trend—0.3% had an AKI hospitalization (Figure 5.2).
- Among hospitalized veterans who did not have a prior diagnosis of AKI, 15% met KDIGO guidelines for AKI as defined using serum creatinine-based criteria (Table A). This included 13.4%, 0.5%, and 1.2% of patients with Stage 1, Stage 2, and Stage 3 AKI (Table 5.2).
- In 2013, Medicare patients aged 66 years and older who were hospitalized for AKI had a 35% cumulative probability of a recurrent AKI hospitalization within one year (Figure 5.6.a). For Optum Clinformatics[™] patients aged 22 years and older, the probability of recurrent AKI hospitalization was 23% (Figure 5.7.a).
- Among these older Medicare patients, 28% were given an initial diagnosis of CKD in the year following an AKI hospitalization (Figure 5.10.a). In the Optum Clinformatics[™] population, 19% of patients with an AKI hospitalization were newly classified as having CKD in the subsequent year (Figure 5.10.b).
- Among Medicare patients aged 66 years and older with a first AKI hospitalization in 2015, the in-hospital mortality rate was 8.7%, or 13.7% when including discharge to hospice. Comparable mortality rates for non-AKI hospitalizations were 2.1% and 4.2%. Less than half of all patients returned to their home on discharge, as compared to two-thirds of non-AKI patients, while 30.6% were discharged to an institution such as a rehabilitation or skilled nursing facility. About one-quarter of non-AKI patients are discharged to rehabilitation or skilled nursing facility.

Introduction

Acute kidney injury (AKI) is now recognized as a major risk factor for the development of chronic kidney disease (CKD). This is obvious in cases of severe, dialysis-requiring AKI where patients fail to recover kidney function. Indeed, acute tubular necrosis without recovery is the primary diagnosis for 2% to 3% of incident end-stage renal disease (ESRD) cases annually. Yet, this represents a small fraction of the kidney disease burden resulting from AKI.

Studies have demonstrated significantly increased long-term risk of CKD and ESRD following AKI, even after initial recovery of function (Heung, 2012). Furthermore, this relationship is bidirectional—CKD patients are at substantially higher risk of suffering an episode of AKI. As a result, AKI is frequently superimposed on CKD, and plays a key role in CKD progression.

This year we again present data from three sources: the Medicare 5% sample, the Optum Clinformatics[™] Data Mart dataset (from OptumInsight, representing claims from a large U.S. national health insurance company), and national data from the U.S. Department of Veterans Affairs (VA) health system. Medicare and Optum Clinformatics[™] administrative data do not contain clinical or biochemical data with which to identify an AKI episode using the consensus criteria based on changes in serum creatinine or urinary output. In these data sources, episodes of AKI were identified using ICD-9-CM and ICD-10-CM (International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification) diagnosis codes from claims. While this approach carries a high degree of specificity, an important limitation of this indirect method is poor sensitivity, generally <30%, and even lower for less severe cases of AKI. In particular, trends in AKI incidence must be interpreted with caution due to the possibility of "code creep", whereby non-clinical factors such as changing billing thresholds or increased awareness and recognition of AKI increase the likelihood of administrative coding for AKI. Thus, a rising incidence of AKI may represent a true increase

2017 USRDS ANNUAL DATA REPORT | VOLUME 1 - CKD IN THE UNITED STATES

in cases, an increased likelihood to code for AKI, or a combination of both factors. In addition, a lower threshold for coding would lead to identification of less severe episodes and an apparent decrease in the rate of associated adverse outcomes.

In contrast to Medicare and Optum Clinformatics[™], VA data contain clinical information to identify episodes of AKI through serum creatininebased criteria. We present some data from the VA population to illustrate the potential gap between AKI episodes identified by administrative coding versus clinical data.

We begin this chapter by exploring trends in hospitalizations that became complicated by AKI, and describing the characteristics of those patients. We refer to "AKI hospitalizations" as any hospitalization during which there was a diagnosis of AKI; the AKI diagnosis was not necessarily the primary or admitting diagnosis. We focus on hospitalizations because the occurrence of AKI exclusively in the community is uncommon and often unrecognized. Next, we explore the risk of re-hospitalization with recurrent AKI, and describe follow-up care after an episode. We end by examining the impact of AKI on outcomes, including subsequent CKD status and patient disposition after an AKI hospitalization.

Methods

Starting with the 2013 claim year, the USRDS Coordinating Center has received the Medicare 5% sample from the Medicare Chronic Conditions Warehouse, a different data source than in previous years. This has coincided with a subsequent decrease in AKI hospitalizations, and we cannot rule out that this is an artifact of the differing source of the Medicare 5% data files. Conclusions regarding trends should be made in this context.

For the Medicare data, we often present results for those aged 66 and older. This allows a full year of Medicare eligibility (ages 65-66) for us to assess the patient's CKD and diabetes mellitus (DM) status prior to the hospitalization within which AKI occurred.

In contrast to the Medicare data, we also present figures and tables from the commercial insurance

plans of a large national U.S. health insurance company, as included in the Optum Clinformatics[™] Data Mart from OptumInsight. These data represent mainly working-age people and their minor dependents.

We present results only for patients aged 22 and older. In Volume 1, Chapter 2, *Identification and Care of Patients with CKD* see Table 2.1 for demographic characteristics of the Optum Clinformatics[™] population (all ages) and Table 2.2 (ages 22-64) and Table 2.3 (all ages) for the prevalence of CKD and related conditions. Additionally, Table 5.2 of this chapter uses data from all patients hospitalized at a VA hospital during fiscal year 2015, to show AKI as defined by serum creatinine measurements and staged as outlined in the KDIGO clinical practice guideline for AKI (KDIGO, 2012). Note that urine output data was not available, so identification of AKI episodes did not include the KDIGO criteria related to urine output.

Age is a major risk factor for AKI. Each of the included datasets had interactions between sex and age that are important to keep in mind when comparing differences in AKI by sex. Within both Optum Clinformatics[™] and the VA, women were younger on average than men. In Optum Clinformatics[™], 56% of women were between the ages of 22 and 39, compared to only 19.4% of men. Among VA patients with at least one outpatient visit, 82% of men were aged 60 and older compared to only 46.6% of women. Conversely, women in the Medicare 5% sample were older, on average. Women had a mean age of 77.2 years while for men it was 75.5 years, and a higher proportion of women (20.4%) than men (13.2%) were aged 85 and older.

Note that the analyses for all figures except Figure 5.11 were based on all beneficiaries meeting the specified inclusion criteria. In Figure 5.11, we excluded those beneficiaries who were admitted from a longterm care facility to the inpatient setting where the AKI hospitalization occurred. Therefore, the category of institution in this figure includes only those newly admitted following a hospitalization.

Details of this data are described in the <u>Data</u> <u>Sources</u> section of the <u>CKD Analytical Methods</u>

CHAPTER 5: ACUTE KIDNEY INJURY

chapter. Also see the <u>CKD Analytical Methods</u> section of the <u>CKD Analytical Methods</u> chapter for an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter. Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available to download from the <u>USRDS</u> <u>website</u>.

Characteristics of Patients with Acute Kidney Injury

The percentage of Medicare fee-for-service patients with an AKI hospitalization has risen over the past decade, but appears to have plateaued near 4.0% since 2011 (Figure 5.1). Of note, the increase was mostly seen in patients who did not require an intensive care unit (ICU) stay during their hospitalization. Over the same period, the proportion of AKI patients requiring inpatient dialysis initially declined, but also appears to have become stable since 2011. Not surprisingly, a higher proportion of patients with an ICU stay had AKI requiring dialysis, compared to patients without an ICU stay. Figure 5.2 reveals very similar trends in the Optum Clinformatics[™] population, although the overall percentage of patients with an AKI hospitalization was far lower for these younger patients, at 0.3% in 2015. Taken together, these findings seem to support "code creep": while the threshold for defining (and thus coding for) AKI has decreased over the last 10 years, the threshold for dialysis initiation has likely remained stable.

vol 1 Figure 5.1 Percent of Medicare patients aged 66+ (a) with at least one AKI hospitalization, and (b) percent among those with an AKI hospitalization who required dialysis, and by whether an intensive care unit (ICU) stay was required, 2005-2015



(a) Percent of patients with an AKI hospitalization

Figure 5.1 continued on next page.

vol 1 Figure 5.1 Percent of Medicare patients aged 66+ (a) with at least one AKI hospitalization, and (b) percent among those with an AKI hospitalization who required dialysis, and by whether an intensive care unit (ICU) stay was required, 2005-2015 (continued).





Data Source: Special analyses, Medicare 5% sample. (a) Percent with an AKI hospitalization among all Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, no ESRD by first service date from Medical Evidence form, and were alive on January 1 of year shown. (b) Percent of patients receiving dialysis during their first AKI hospitalization among patients with a first AKI hospitalization. Dialysis is identified by a diagnosis or charge for dialysis on the AKI hospitalization inpatient claim or a physician/supplier (Part B) claim for dialysis during the time of the AKI inpatient claim. Abbreviations: AKI, acute kidney injury; ESRD, end-stage renal disease.

vol 1 Figure 5.2 Percent of Optum Clinformatics™ patients aged 22+ (a) with at least one AKI hospitalization, and (b) percent among those with an AKI hospitalization who required dialysis, by year, 2005-2015



(a) Percent of patients with an AKI hospitalization

Figure 5.2 continued on next page.

vol 1 Figure 5.2 Percent of Optum Clinformatics[™] patients aged 22+ (a) with at least one AKI hospitalization, and (b) percent among those with an AKI hospitalization who required dialysis, by year, 2005-2015 (continued)



(b) Percent of patients requiring dialysis, among those with a first AKI hospitalization

Data Source: Special analyses, Optum Clinformatics^M. (a) Percent with an AKI hospitalization among all Optum Clinformatics^M commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD, and were alive on January 1, 2015. (b) Percent of patients receiving dialysis during their first AKI hospitalization among patients with a first AKI hospitalization. Dialysis is identified by a diagnosis or charge for dialysis on the AKI hospitalization inpatient (confinement) claim or a medical claim for dialysis during the time of the AKI inpatient claim. Abbreviations: AKI, acute kidney injury; ESRD, end-stage renal disease.

Table 5.1 presents demographic and comorbidity characteristics of Medicare and Optum Clinformatics[™] patients with AKI in 2015. AKI occurs commonly in older adults, and the incidence rises with age. In the fee-for-service Medicare population, over half of all patients with an AKI hospitalization were aged 80 or older. In both the Medicare and Clinformatics[™] populations, a higher proportion of Black/African American patients had AKI compared to Whites or Asians. Diabetes and pre-existing CKD are recognized as two major risk factors for AKI; at least one of these risk factors was present in nearly 58% of Medicare patients with an AKI hospitalization and 21% of patients had both. Even in the younger Optum Clinformatics[™] population, about 34% of patients with an AKI hospitalization had either DM, CKD, or both. vol 1 Table 5.1 Characteristics of Medicare and Optum Clinformatics[™] patients with at least one hospitalization, by age, sex, race, CKD, DM, and presence of AKI, 2015

		Medi	care (Age	e 66+)		Optum Clinformatics™ (Age 22+)					
	Total	No A	AKI	Any	AKI	Total	No A	KI	Any	ΑΚΙ	
	Ν	Ν	%	N	%	N	Ν	%	N	%	
Total	232,082	176,482	76.0	55,600	24.0	317,719	294,930	92.8	22,789	7.2	
Age											
22-39	_	_	_	_	—	137,638	135,283	98.3	2,355	1.7	
40-65	—	—	—	—	—	151,583	136,433	90.0	15,150	10.0	
65+	—	—	—	—	—	28,498	23,214	81.5	5,284	18.5	
66-69	37,398	30,489	81.5	6,909	18.5	—	_	_	—	—	
70-74	45,068	35,980	79.8	9,088	20.2	_	_	_	—	_	
75-79	42,957	33,078	77.0	9,879	23.0	—	_	_	—	—	
80-84	40,215	29,779	74.1	10,436	26.0	—	_	_	—	—	
85+	66,444	47,156	71.0	19,288	29.0	—	_	_	—	—	
Sex											
Male	98,975	71,850	72.6	27,125	27.4	110,121	95,841	87.0	14,280	13.0	
Female	133,107	104,632	78.6	28,475	21.4	207,598	199,089	95.9	8,509	4.1	
Race & Ethnicity											
White	202,210	155,688	77.0	46,522	23.0	222,381	206,032	92.6	16,349	7.4	
Black/African American	18,353	12,053	65.7	6,300	34.3	32,099	29,071	90.6	3,028	9.4	
Native American	1,215	925	76.1	290	23.9	_	_	_	_	_	
Hispanic	_	_	_	_	_	34,526	32,532	94.2	1,994	5.8	
Asian	3,034	2,247	74.1	787	25.9	13,578	13,127	96.7	451	3.3	
Other	7,270	5,569	76.6	1,701	23.4	15,135	14,168	93.6	967	6.4	
Pre-existing comorbidities											
No DM or CKD, prior year	137,436	114,016	83.0	23,420	17.0	283,027	267,963	94.7	15,064	5.3	
DM no CKD, prior year	47,804	36,483	76.3	11,321	23.7	24,634	20,599	83.6	4,035	16.4	
CKD no DM, prior year	22,252	13,258	59.6	8,994	40.4	5,366	3,692	68.8	1,674	31.2	
Both CKD & DM, prior year	24,590	12,725	51.8	11,865	48.3	4,692	2,676	57.0	2,016	43.0	

Data Source: Special analyses, Medicare 5% sample and Optum Clinformatics^M. Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, no ESRD by first service date from Medical Evidence form, and were alive on January 1, 2015. Optum Clinformatics^M commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD, and were alive on January 1, 2015. Abbreviations: AKI, acute kidney injury; CKD, chronic kidney disease; DM, diabetes mellitus; ESRD, end-stage renal disease. —This category does not apply for this dataset.

CHAPTER 5: ACUTE KIDNEY INJURY

Table 5.2 presents characteristics of VA patients who had an AKI hospitalization. Here, AKI was defined using serum creatinine-based criteria per the KDIGO guidelines (Table A). For VA patients with diabetes, about 28.2% of them had AKI hospitalization as defined by KDIGO criteria. This percentage increased to 43.7% among CKD patients, and 54.4% among patients with both DM and CKD.

Table A. KDIGO definition and staging of Acute Kidney Injury

Definition of AKI:

An increase in serum creatinine (SCR) by ≥ 0.3 mg/dL ($\geq 26.5 \mu$ mol/l) within 48 hours; or an increase in SCR to ≥ 1.5 times baseline, which is known or presumed to have occurred within the prior 7 days; or urine volume <0.5 ml/kg/h for 6 hours.

Stage	Serum creatinine	Urine output
1	1.5–1.9 times baseline <u>OR ></u> 0.3 mg/dL (>26.5 μmol/l) increase	<0.5 ml/kg/h for 6-12 hours
2	2.0–2.9 times baseline	<0.5 ml/kg/h for <u>></u> 12 hours
3	3.0 times baseline <u>OR</u> increase in SCR to >4.0 mg/dL (\geq 353.6 µmol/l) <u>OR</u> initiation of renal replacement therapy <u>OR</u> , in patients <18 years, decrease in eGFR to <35 ml/min/1.73m ²	<0.3 ml/kg/h for <u>></u> 24 hours <u>OR</u> anuria for <u>></u> 12 hours

Adapted from KDIGO (2012). Abbreviations: AKI, acute kidney injury; eGFR, estimated glomerular filtration rate; SCR, serum creatinine.

vol 1 Table 5.2 Characteristics of Veterans Affairs patients aged 22+ with at least one hospitalization, by age, sex, race, CKD, DM, presence and stage of AKI, defined by serum creatinine, FY 2015

	Total	No Al	(Any Stag	e AKI	Stage	1	Stage	2	Stage	3ª
	Ν	Ν	%	Ν	%	Ν	%	Ν	%	Ν	%
Total	305,189	227,325	74.5	77,864	25.5	65,343	21.4	2,651	0.9	9,870	3.2
Diagnosis of AKI											
No	254,588	216,356	85.0	38,232	15.0	34,074	13.4	1,212	0.5	2,946	1.2
Yes	50,601	10,969	21.7	39,632	78.3	31,269	61.8	1,439	2.8	6,924	13.7
Age at this inpatient admission											
20-39	12,264	11,198	91.3	1,066	8.7	884	7.2	61	0.5	121	1
40-59	54,613	44,364	81.2	10,249	18.8	8,334	15.3	509	0.9	1,406	2.6
60-65	50,687	37,877	74.7	12,810	25.3	10,485	20.7	551	1.1	1,774	3.5
66-69	56,000	41,230	73.6	14,770	26.4	12,258	21.9	501	0.9	2,011	3.6
70-74	49,322	35,952	72.9	13,370	27.1	11,304	22.9	398	0.8	1,668	3.4
75-79	24,810	17,307	69.8	7,503	30.2	6,395	25.8	187	0.8	921	3.7
80-84	23,262	15,901	68.4	7,361	31.6	6,282	27.0	186	0.8	893	3.8
85+	34,231	23,496	68.6	10,735	31.4	9,401	27.5	258	0.8	1,076	3.1
Sex											
Male	287,706	212,346	73.8	75,360	26.2	63,260	22.0	2,508	0.9	9,592	3.3
Female	17,483	14,979	85.7	2,504	14.3	2,083	11.9	143	0.8	278	1.6
Race/ethnicity											
Non-Hispanic White	209,767	159,271	75.9	50,496	24.1	43,264	20.6	1,761	0.8	5,471	2.6
Non-Hispanic Black	58,349	40,597	69.6	17,752	30.4	14,244	24.4	515	0.9	2,993	5.1
American Indian/Alaska Native	1,598	1,238	77.5	360	22.5	292	18.3	9	0.6	59	3.7
Hispanic	18,730	13,677	73.0	5,053	27.0	4,053	21.6	227	1.2	773	4.1
Asian	2,365	1,792	75.8	573	24.2	461	19.5	17	0.7	95	4
Other/Unknown	14,380	10,750	74.8	3,630	25.2	3,029	21.1	122	0.8	479	3.3
Had CKD before admission											
No	267,428	208,873	78.1	58,555	21.9	50,740	19.0	2,555	1.0	5,260	2
Yes	37,761	18,452	48.9	19,309	51.1	14,603	38.7	96	0.3	4,610	12.2
Had hypertension before admission	on										
No	118,179	96,638	81.8	21,541	18.2	17,986	15.2	1,021	0.9	2,534	2.1
Yes	187,010	130,687	69.9	56,323	30.1	47,357	25.3	1,630	0.9	7,336	3.9
Had diabetes before admission											
No	201,945	159,424	78.9	42,521	21.1	35,607	17.6	1,785	0.9	5,129	2.5
Yes	103,244	67,901	65.8	35,343	34.2	29,736	28.8	866	0.8	4,741	4.6
Pre-admission CKD and diabetes s	status										
Neither	180,509	147,353	81.6	33,156	18.4	28,751	15.9	1,728	1.0	2,677	1.5
Diabetes only	79,518	57,072	71.8	22,446	28.2	20,041	25.2	827	1.0	1,578	2
CKD only	21,436	12,071	56.3	9,365	43.7	6,856	32.0	57	0.3	2,452	11.4
Diabetes & CKD	23,726	10,829	45.6	12,897	54.4	9,695	40.9	39	0.2	3,163	13.3

Data Source: Special analyses, Veterans Health Administration data. Patients aged 22 and older with at least one hospitalization in fiscal year 2015. AKI defined by serum creatinine criteria as in KDIGO (2012), see Table A for details. ^a Stage 3 includes those requiring dialysis. Diabetes and CKD determined by ICD-9-CM diagnosis codes. Excludes those with evidence of ESRD prior to admission by diagnosis and procedure codes. Abbreviations: AKI, acute kidney injury; CKD, chronic kidney disease; DM, diabetes mellitus; FY, federal fiscal year (October 1, 2014 to September 30, 2015).

CHAPTER 5: ACUTE KIDNEY INJURY

As shown in Figure 5.3, rates of AKI were strongly influenced by age. Among fee-for-service Medicare patients in 2015, the rate of AKI for those aged 66-69 was 26.8 per 1,000 patient years, increasing to 37.4, 55.4, 77.1, and 110.5 for those aged 70-74, 75-79, 80-84, and 85 years and older. Between 2005 and 2012, unadjusted rates of AKI increased for all age groups. Data from 2011 to 2015 showed a plateau or slight decrease in AKI rates for patients less than 80 years; rates continued to rise in older patients. Among Optum Clinformatics[™] patients, the overall group AKI rate increased over time, peaking at 4.2 per 1,000 patient years in 2015. For the subgroup aged 66 and older, the 2011 rate was 27.1 per 1,000 patient-years and remained somewhat stable at 26.6 per 1,000 in 2015.

vol 1 Figure 5.3 Unadjusted rates of hospitalization with AKI, per 1,000 patient-years at risk, by age, 2005-2015



Data Source: Special analyses, Medicare 5% sample and Optum Clinformatics^M. (a) Age as of January 1 of specified year. All patient-years at risk for Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, no ESRD by first service date from Medical Evidence form, and were alive on January 1 of year shown. Censored at death, ESRD, end of Medicare Parts A & B participation, or switch to Medicare Advantage program. (b) All patient-years at risk for Optum Clinformatics^M commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD, and were alive on January 1 of year shown. Abbreviation: AKI, acute kidney injury; ESRD, end-stage renal disease.

2017 USRDS ANNUAL DATA REPORT | VOLUME 1 - CKD IN THE UNITED STATES

Figure 5.4 highlights differences in AKI rates by race. In 2015, among fee-for-service Medicare patients aged 66 and older, the incidence rate for those of Black race was 90.2 per 1,000 patient-years at risk compared to 53.4 and 43.0, in Whites and individuals of other races. A similar

relationship was observed in the Optum Clinformatics[™] population, albeit at much lower rates: 6.1, 4.5, and 2.8 per 1,000 patient-years at risk in Blacks, Whites, and individuals of other races.

vol 1 Figure 5.4 Unadjusted rates of hospitalization with AKI, per 1,000 patient-years at risk, by race, 2005-2015



Data Source: Special analyses, Medicare 5% sample and Optum Clinformatics^M. (a) All patient-years at risk for Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, no ESRD by first service date from Medical Evidence form, and were alive on January 1 of year shown. Censored at death, ESRD, end of Medicare Parts A & B participation, or switch to Medicare Advantage program. (b) All patient-years at risk for Optum Clinformatics^M commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD, and were alive on January 1 of year shown. Abbreviations: Af Am, African American; AKI, acute kidney injury; ESRD, end-stage renal disease.

CHAPTER 5: ACUTE KIDNEY INJURY

As shown in Figure 5.5, incidence rates for AKI also varied substantially by underlying comorbidity. In 2015, Medicare patients with DM but no known CKD had an AKI incidence rate of 65.3 per 1,000 patient-years compared to 29.7 per 1,000 patient-years in non-diabetic, non-CKD patients. Non-diabetic patients with CKD experienced an AKI incidence rate of 179.3 per 1,000 patient-years, while the rate in patients with both DM and CKD was 281.4 per 1,000. That is, about 28% of Medicare patients with both CKD and DM experienced a hospitalization with AKI in each year.

The Optum Clinformatics[™] population showed similar relationships. Patients with both CKD and DM experienced the highest rates of AKI hospitalization at 142.1 per 1,000 patient-years. However, their overall rates were much lower, presumably reflecting the younger age range in this population.

vol 1 Figure 5.5 Unadjusted rates of hospitalization with AKI, per 1,000 patient-years at risk, by CKD and DM, 2005-2015



Data Source: Special analyses, Medicare 5% sample and Optum Clinformatics[™]. (a) All patient-years at risk for Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, no ESRD by first service date from Medical Evidence form, and were alive on January 1 of year shown. Censored at death, ESRD, end of Medicare Parts A & B participation, or switch to Medicare Advantage program. (b) All patient-years at risk for Optum Clinformatics[™] commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD, and were alive on January 1 of year shown. Abbreviations: AKI, acute kidney injury; CKD, chronic kidney disease; DM, diabetes mellitus; ESRD, end-stage renal disease.

Re-hospitalization Associated with Acute Kidney Injury

Figures 5.6 and 5.7 show the probability of a patient's recurrent AKI hospitalization after their live discharge from an initial AKI hospitalization. Among 2013 Medicare patients aged 66 and older the overall probability of a recurrent AKI event was 0.35 in the next 12 months and 0.48 by 24 months, as shown in Figure 5.6.a. Among Optum Clinformatics[™] patients, these probabilities were 0.23 and 0.31. In contrast to first episodes, the rate of recurrent AKI was relatively similar across age groups in the fee-for-service Medicare population (Figure 5.6.b). Interpretation of this finding is limited, however, because of the effect of death censoring, which was higher in older age groups.

In both the Medicare and Optum Clinformatics[™] populations, Blacks had a higher probability of recurrent AKI compared to Whites or individuals of

other races (Figures 5.6.c and 5.7.c). Similarly, having either DM or CKD was associated with an increased probability for recurrent AKI compared to having neither (see Figures 5.6.d and 5.7.d). The highest probability for recurrent AKI was for patients with both DM and CKD, reaching 0.59 by 24 months among Medicare patients and 0.45 among Optum Clinformatics[™] patients. In contrast, Medicare patients with neither comorbidity had a cumulative probability for recurrent AKI hospitalization of 0.30 by 24 months, while their Optum Clinformatics[™] counterparts had a probability of 0.21 by 24 months.

Siew et al. (2016) examined recurrent AKI for VA patients in 2003 and 2010 who survived their first AKI hospitalization (n=11,683). Of these, 8.5% had a second AKI episode within 30 days, 14.6% within 90 days, 19.5% within 180 days, and 25.3% with 12 months. AKI was defined according to KDIGO criteria using serum creatinine.

vol 1 Figure 5.6 Cumulative probability of a recurrent AKI hospitalization within two years of live discharge from first AKI hospitalization in 2013 for Medicare patients aged 66+, (a) overall, (b) by age, (c) by race, and (d) by CKD and DM



Figure 5.6 continued on next page.

vol 1 Figure 5.6 Cumulative probability of a recurrent AKI hospitalization within two years of live discharge from first AKI hospitalization in 2013 for Medicare patients aged 66+, (a) overall, (b) by age, (c) by race, and (d) by CKD and DM *(continued)*



Figure 5.6 continued on next page.

vol 1 Figure 5.6 Cumulative probability of a recurrent AKI hospitalization within two years of live discharge from first AKI hospitalization in 2013 for Medicare patients aged 66+, (a) overall, (b) by age, (c) by race, and (d) by CKD and DM *(continued)*



Data Source: Special analyses, Medicare 5% sample. Age on January 1, 2013. Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, no ESRD by first service date from Medical Evidence form on 1/1/2013, and were discharged alive from an AKI hospitalization in 2013. Censored at death, ESRD, end of Medicare Parts A & B participation, or switch to Medicare Advantage program. Abbreviations: AKI, acute kidney injury; CKD, chronic kidney disease; DM, diabetes mellitus; ESRD, end-stage renal disease.
vol 1 Figure 5.7 Cumulative probability of a recurrent AKI hospitalization within two years of live discharge from first AKI hospitalization in 2013 for Optum Clinformatics[™] patients aged 22+, (a) overall, (b) by age, (c) by race, and (d) by CKD and DM



Figure 5.7 continued on next page.

vol 1 Figure 5.7 Cumulative probability of a recurrent AKI hospitalization within two years of live discharge from first AKI hospitalization in 2013 for Optum Clinformatics[™] patients aged 22+, (a) overall, (b) by age, (c) by race, and (d) by CKD and DM *(continued)*



Data Source: Special analyses, Optum Clinformatics^M. Age as of January, 2013. Optum Clinformatics^M commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD on January 1, 2013, and were discharged alive from an AKI hospitalization in 2013. Censored at death, ESRD diagnosis, or plan disenrollment. Abbreviations: AKI, acute kidney injury; CKD, chronic kidney disease; DM, diabetes mellitus; ESRD, end-stage renal disease.

CHAPTER 5: ACUTE KIDNEY INJURY

Patient Care and Outcomes

Poor short-term outcomes for AKI, including hospital mortality, are well recognized. Figure 5.8 illustrates that survivors of an AKI hospitalization who were discharged alive continued to face significant risk for adverse outcomes. Among survivors of an AKI hospitalization in 2013-2014, the overall probability of developing ESRD in the following year was about 2% in the Medicare fee-for-service population aged 66 and older, and 5% in the Optum Clinformatics[™] population. In this same period, the probability of death was 41.3% and 7.3% in the Medicare and Optum Clinformatics[™] populations.

vol 1 Figure 5.8 Cumulative probability of death-censored ESRD, death, and the composite of death or ESRD within one year of live discharge from first AKI hospitalization occurring in 2013-2014



Data Source: Special analyses, Medicare 5% sample. (a) Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, no ESRD by first service date from Medical Evidence form, and were discharged alive from a first AKI hospitalization in 2013 or 2014. (b) All patient-years at risk for Optum Clinformatics[™] commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD, and were alive on January of year shown. All models censored at the end of Medicare Parts A & B participation, switch to Medicare Advantage program, or 365 days after AKI discharge. Model for ESRD also was censored at death. Model for death was not censored at the start of ESRD. Abbreviations: AKI, acute kidney injury; ESRD, end-stage renal disease.

In 2014, 16% of Medicare patients discharged alive from an AKI hospitalization had outpatient nephrology follow-up within the next six months, while 17% of Optum Clinformatics[™] patients had follow-up over the same period. As shown in Figure 5.9, follow-up rates varied by comorbidity. Among patients with AKI superimposed on pre-existing CKD, but without DM, 19% of Medicare and 24% of Optum Clinformatics[™] patients were seen by a nephrologist within six months following discharge. For patients with both CKD and DM, these proportions rose to 25% and 32. In contrast, just 3% of Medicare and 6% of Optum Clinformatics[™] AKI patients without DM or CKD were seen by a nephrologist by six months following an AKI hospitalization.

Trends over the past decade showed a slight decrease in post-AKI hospitalization nephrology follow-up for both the Medicare and Optum Clinformatics[™] populations. This may once again reflect code creep: the milder cases of AKI captured by diagnosis may have been the least likely to require nephrology referral.

vol 1 Figure 5.9 Cumulative probability of a claim for an outpatient nephrology visit within six months of live discharge from first AKI hospitalization, overall and by CKD, DM, 2005-2014



Data Source: Special analyses, Medicare 5% sample and Optum Clinformatics[™]. (a) Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, no ESRD by first service date from Medical Evidence form on January 1 of year shown and were discharged alive from a first AKI hospitalization during the year. Censored at death, ESRD, end of Medicare Parts A & B participation, or switch to Medicare Advantage program. Physician visits are from physician/supplier claims with provider specialty codes for nephrology (39) and claim source indicating an outpatient setting. (b) Optum Clinformatics[™] commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD, and were discharged alive from an AKI hospitalization in the year shown. Censored at death, ESRD, or plan disenrollment. Provider specialty of "nephrologist" used to identify nephrology visits. Abbreviations: AKI, acute kidney injury; CKD, chronic kidney disease; DM, diabetes mellitus; ESRD, end-stage renal disease.

CHAPTER 5: ACUTE KIDNEY INJURY

Changes in CKD Status after Acute Kidney Injury

CKD status changed significantly in the year following an AKI hospitalization, as shown in Figure 5.10. Among Medicare patients without baseline CKD, nearly 28% were reclassified as having some degree of CKD, including 0.2% being declared ESRD. In the Optum Clinformatics[™] population, about 19% of patients with an AKI hospitalization were newly classified as having CKD in the subsequent year, and 2.2% were given a diagnosis of ESRD. Although the percent of patients with ESRD was markedly higher in the younger Optum Clinformatics[™] population as compared to Medicare patients, it is important to note that these were proportions of surviving patients only. Table B shows the ICD-9-CM diagnosis codes used to define stages of CKD for Figure 5.10.

Table B. ICD-9-CM codes for Chronic Kidney Disease (CKD) stages

ICD-9-CM code ^a	Stage
585.1	CKD, Stage 1
585.2	CKD, Stage 2 (mild)
585.3	CKD, Stage 3 (moderate)
585.4	CKD, Stage 4 (severe)
585.5	CKD, Stage 5 (excludes 585.6: Stage 5, requiring chronic dialysis ^b)
CKD Stage-unspecified	For these analyses, identified by multiple codes including 585.9, 250.4x, 403.9x & others

^a For analyses in this chapter, CKD stage estimates require at least one occurrence of a stage-specific code, and the last available CKD stage in a given year was used. ^b In USRDS analyses, patients with ICD-9-CM code 585.6 & with no ESRD 2728 form or other indication of end-stage renal disease (ESRD) are considered to have code 585.5.

vol 1 Figure 5.10 Renal status one year following discharge from AKI hospitalization in 2013-2014, among surviving patients without kidney disease prior to AKI hospitalization, by CKD stage and ESRD status



Data Source: Special analyses, Medicare 5% sample. (a) Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, did not have ESRD, were discharged alive from a first AKI hospitalization in 2013 or 2014, and did not have any claims with a diagnosis of CKD in the 365 days prior to the AKI. (b) Optum Clinformatics™ commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD, and were discharged alive from an AKI hospitalization in 2013 or 2014, and did not have any claims with a diagnosis of CKD in the 365 days prior to the AKI. Renal status after AKI determined from claims between discharge from AKI hospitalization and 365 days after discharge. Stage determined by 585.x claim closest to 365 days after discharge; ESRD by first service date on Medical Evidence form. Abbreviations: AKI, acute kidney injury; CKD, chronic kidney disease; ESRD, end-stage renal disease.

CHAPTER 5: ACUTE KIDNEY INJURY

In Figure 5.11, we examined the status and disposition of 2015 Medicare AKI patients once they were discharged from the hospital. We excluded patients admitted from a skilled nursing facility (SNF; n=1,890), leaving 53,710 AKI discharges. Among AKI patients aged 66 and older about 48% were discharged directly to their home. Mortality (including those discharged to hospice) was 13.7%, while 30.6% of patients were

discharged to institutions such as short-term SNFs, rehabilitation hospitals, or long-term care facilities. By comparison, among hospitalized Medicare patients without a diagnosis of AKI (excluding those admitted from a SNF, n= 2,979, leaving 170,626 discharges), 68% returned home and approximately 23% were discharged to institutions.

vol 1 Figure 5.11 Hospital discharge status of first hospitalization for Medicare patients aged 66+ (a) with diagnosis of AKI during stay, and (b) without diagnosis of AKI during stay, 2015



Data Source: Special analyses, Medicare 5% sample. Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, did not have ESRD on 1/1/2015, had a first hospitalization in 2015, and were not admitted to the acute care hospital from a skilled nursing facility. Institution includes short-term skilled nursing facilities, rehabilitation hospitals, and long-term care facilities. Home also includes patients receiving home health care services. Abbreviations: AKI, acute kidney injury; ESRD, end-stage renal disease.

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Chapter 6:

Healthcare Expenditures for Persons with CKD

- In this 2017 Annual Data Report (ADR), we introduce information from the Optum Clinformatics[™] DataMart for persons with Medicare Advantage and commercial managed care coverage. This will provide a more comprehensive examination of the financial costs necessary to provide care to beneficiaries with CKD.
- Medicare spending for all beneficiaries who had chronic kidney disease (CKD; 11% of total) exceeded \$64 billion in 2015 (Tables 6.1 and 6.3). When adding an extra \$34 billion of end-stage renal disease (ESRD) costs (Volume 2, Chapter 9, <u>Healthcare Expenditures for Persons with ESRD</u>, Figure 9.2), total Medicare spending on both CKD and ESRD was over \$98 billion.
- In 2015, Medicare spending for beneficiaries with CKD aged 65 and older exceeded \$55 billion, representing 20% of all Medicare spending in this age group (Figure 6.1).
- Medicare spending for beneficiaries with CKD who were younger than age 65 (6% of total) exceeded \$8 billion in 2015, representing 14% of total spending in this age group (Table 6.3).
- 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 the 2015 Medicare spending for beneficiaries aged 65 and older was for those who had diagnoses of CKD, diabetes mellitus (DM), or heart failure (HF; Figure 6.1).
- Over 70% of total Medicare spending for beneficiaries with CKD who were aged 65 and older was incurred by the 60% of these patients who also had DM, HF, or both (Table 6.1).
- Spending per patient-year for those with all three chronic conditions of CKD, DM, and HF was more than twice as high (\$39,395) than for beneficiaries with only CKD (\$15,930; Table 6.1).
- Per-person per-year spending for Medicare Advantage enrollees and those in the Optum Clinformatics[™] managed care was slightly lower, at 93% and 99% of the expenditures for fee-for-service Medicare (Table 6.6).
- For beneficiaries under age 65 who qualified for Medicare based on a disability rather than age, spending was somewhat higher in the Medicare Advantage program, both when averaged across all beneficiaries (12% higher) and among all those with CKD (6% higher; Table 6.3).
- In the fee-for-service Medicare CKD population, Black/African American beneficiaries continued to exhibit higher spending in all disease categories as compared to Whites and those of other races. However, Blacks with Medicare Advantage may have lower spending than do patients of other races.
- The analysis of expenses for beneficiaries with CKD indicates avenues for potential savings, and the effect of cost-containment efforts in this population. 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.

Introduction

Persons with CKD often have extensive healthcare needs and frequently face co-existing illnesses. This chapter assesses the overarching financial cost of caring for persons with CKD through comparison of expenditures in three payment systems. As in previous Annual Data Reports (ADR), the Medicare 5% sample was used to determine spending for Medicare fee-forservice (FFS) beneficiaries. In this chapter, we present recent patterns and longer-term trends in both total claims-based spending and spending by CKD status,

patient characteristics such as age, sex, and race, and DM and HF status.

In this 2017 ADR, we add comparable information from the Optum Clinformatics[™] DataMart for persons enrolled in Medicare Advantage and through a large commercial managed care organization. Growth in the percent of Medicare beneficiaries enrolled in managed care increased from 13% in 2004 to 31% in 2015 (Kaiser, 2017); 16.8 million individuals were enrolled in an Medicare Advantage plan in March 2015. Addition of this data makes our assessment of CKD spending significantly more comprehensive, particularly for the CKD population aged 65 and older. Similarly, the addition of commercial insurance data allows more complete assessment of CKD spending, particularly for those younger than age 65, as commercial insurance was the largest source of payment for this group.

While our analyses provide a sound and valid estimate of the costs of CKD to healthcare systems, when interpreting spending levels and trends in these claims data the impact of potential underidentification should be kept in mind. Unlike ESRD, where determination is straightforward due to the need for renal replacement services, CKD can be under-identified. There may be valid underrecognition that occurs when patients who have impaired renal function have not vet been tested. Claims-based under-identification can also occur when patients who have been tested and identified clinically do not have a CKD diagnosis listed on an insurance claim. Such under-identification makes the determination of the full economic impact of CKD on a healthcare system challenging.

Under-recognition of CKD can affect estimates of CKD-related expenditures in several ways. Identification of persons with CKD using ICD-9-CM and ICD-10-CM (International Classification of Diseases, Ninth and Tenth Revision, Clinical Modification) diagnosis codes will result in an underestimate of total CKD expenditures, as early in the disease process formal diagnoses of CKD are not commonly documented or may not even have been identified clinically. Assuming that underidentification occurs most often in the earliest and least costly patient cases, spending estimates per patient-year (PPY) calculated solely from the claimsbased diagnoses of CKD are likely to be biased upwards. To the extent that under-identification is not constant over time, interpretation of trend data for both total and PPY expenditures should be made in this context.

In addition, it is not possible to attribute healthcare expenditures solely to kidney disease with any accuracy; the costs of CKD are influenced by its interactive nature and associations with other chronic conditions such as DM and hypertension (HTN), and with cardiovascular diseases (CVD) such as coronary artery disease, cerebrovascular disease, peripheral arterial disease, and HF. In order to understand better the complexity of how these conditions contribute to costs, we often present and compare results for patients with varying combinations of CKD, DM, and HF.

Similar issues of CKD under-identification are also discussed in this 2017 ADR, Volume 1, Chapters 1 (*CKD* in the General Population), 2 (Identification and Care of Patients with CKD), and <u>3 (Morbidity and Mortality in Patients with CKD</u>).

Methods

This chapter uses data from three primary sources including beneficiaries of general Medicare, those enrolled in Medicare Advantage plans, and a cohort of individuals enrolled in a commercial managed care plan.

The Medicare 5% sample provides information on FFS beneficiaries aged 66 and older. Roughly 98% of Americans aged 65 and older qualify for Medicare, and as a result, analysis of Medicare data is representative of beneficiaries age 65 and older.

Medicare prescription drug coverage through Part D plans is also included in this chapter. Note that beneficiaries have many options to purchase prescription drugs, so the claims filled through the Part D plan may not represent all medications prescribed to Medicare beneficiaries.

In addition to reporting on the population aged 65 and older, beginning in 2014 we have added information on beneficiaries younger than 65 who generally were Medicare-eligible due to disability. The data from the Optum Clinformatics[™] DataMart is

CHAPTER 6: HEALTHCARE EXPENDITURES FOR PERSONS WITH CKD

presented for those both younger than 65, and 65 and older.

The Optum Clinformatics[™] DataMart includes a cohort of individuals with commercial managed care plans. Optum Clinformatics[™] data provides paid medical and prescription claims and enrollment information for national participants in the commercial managed care plans of a large U.S. health insurance company. The data was purchased from OptumInsight, and participants are enrolled in both a medical and a prescription plan.

The methodology we employed to calculate costs related to CKD (excluding ESRD) utilizes ICD-9-CM and ICD-10-CM diagnosis codes to define the point prevalent CKD cohort. We included only those beneficiaries classified as having CKD on January 1 of each given year, to avoid possible association with acute kidney injury (AKI). How to best integrate the costs of AKI patients into CKD calculations is a continuing area for research, due to the potential for transition from AKI to CKD.

In this chapter, we defined costs as insurance expenditures rather than true economic costs, using claims from Medicare Parts A, B, and D as based on the 5% Medicare sample for calendar years 1996-2015 and from 100% of the Optum Clinformatics[™] dataset for calendar years 2006-2015. To account for differences in pricing across health plans and provider contracts, Optum Clinformatics[™] applies standard pricing algorithms to claims data. These algorithms were designed to create standard prices that reflect <u>allowed payments</u> across all provider services.

Details of this data are described in the <u>Data</u> <u>Sources</u> section of the <u>CKD Analytical Methods</u> chapter. See the Chapter 6 section of <u>CKD Analytical</u> <u>Methods</u>, in the <u>CKD Analytical Methods</u> chapter for an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter. Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available to download from the <u>USRDS</u> <u>website</u>.

Spending for CKD and Related Chronic Comorbidities

BENEFICIARIES AGED 65 AND OLDER

FEE-FOR-SERVICE MEDICARE

Examining FFS Medicare spending reinforces CKD's reputation as a cost multiplier. Beneficiaries with recognized CKD represent 11% of the point prevalent aged Medicare population, yet accounted for 21% of total expenditures (Table 6.1).

We examined 2015 costs in relation to beneficiaries' CKD stage, age, sex, race, and concurrent disease, focusing on DM and HF. These conditions, in addition to CKD, represent some of the costliest chronic disease populations for Medicare. For example, HF affects 9% of beneficiaries in the FFS Medicare population, but accounts for 20% of expenditures. Thirty-five percent of overall expenditures were directed toward the 24% of beneficiaries with DM.

In those aged 65 and older, per-person per-year (PPPY) costs were 97% higher for patients with CKD only, versus those with no CKD, DM, or HF (\$15,930 vs \$8,074). Costs for those with CKD and DM were 54% higher than for those with DM only. Similarly, expenditures for those with CKD and HF were 45% higher than for those with HF alone. For beneficiaries with CKD, HF, and DM, costs were 44% higher than for those with only HF and DM. Overall, people with diagnoses of CKD, DM, and/or HF accounted for one-third of the Medicare aged 65 and older population, but over half of total programmatic costs.

	U.S. Medicare	Total Spending	PPPY	Population	Spending
	Population	(millions, U.S. \$)	(U.S. \$)	(%)	(%)
All	24,449,480	\$262,261	\$11,127	100.00	100.00
With HF or CKD or DM	8,106,280	\$133,562	\$17,506	33.16	50.93
CKD only (- DM & HF)	1,070,980	\$16,124	\$15,930	4.38	6.15
DM only (- HF & CKD)	4,003,460	\$48,143	\$12,432	16.37	18.36
HF only (- DM & CKD)	872,680	\$17,290	\$21,707	3.57	6.59
CKD and DM only (- HF)	886,240	\$15,993	\$19,109	3.63	6.10
CKD and HF only (- DM)	347,500	\$9,255	\$31,401	1.42	3.53
DM and HF only (- CKD)	495,060	\$12,343	\$27,397	2.03	4.71
CKD and HF and DM	430,360	\$14,413	\$39,395	1.76	5.50
No CKD or DM or HF	16,343,200	\$128,699	\$8,074	66.85	49.07
All CKD (+/- DM & HF)	2,735,080	\$55,785	\$22,228	11.19	21.27
All DM (+/- CKD & HF)	5,815,120	\$90,892	\$16,448	23.78	34.66
All HF (+/- DM & CKD)	2,145,600	\$53,302	\$27,941	8.78	20.32
CKD and DM (+/- HF)	1,316,600	\$30,406	\$25,280	5.39	11.59
CKD and HF (+/- DM)	777,860	\$23,668	\$35,828	3.18	9.03
DM and HF (+/- CKD)	925,420	\$26,756	\$32,774	3.79	10.20

vol 1 Table 6.1 Prevalent Medicare fee-for-service patient counts and spending for beneficiaries aged 65 and older, by diabetes, heart failure, and/or CKD, 2015

Data Source: Medicare 5% sample. Abbreviations: CKD, chronic kidney disease; HF, heart failure; DM, diabetes mellitus; PPPY, per-person per-year spending.

MEDICARE ADVANTAGE AND COMMERCIAL MANAGED CARE COVERAGE

CKD was also a cost multiplier for individuals 65 and older who were beneficiaries of Medicare Advantage or commercial managed care plans. The Medicare Advantage population was similar to FFS Medicare, with 10% having CKD and those with CKD accounting for 18% of spending. The managed care population had a lower prevalence of CKD (6%), but those with CKD also accounted for an outsize (12%) proportion of spending.

Per-person per-year spending in these populations was somewhat lower than that for FFS Medicare. In

this data set, Optum Clinformatics[™] Medicare Advantage spending was 93% of those receiving FFS Medicare, with managed care beneficiaries at 99%. Such differences can arise from plan effects (e.g., care management activities of Medicare Advantage plans) or patient selection (e.g., those over 65 with commercial coverage are often still employed, so may be younger and healthier than the typical Medicare FFS beneficiary). Spending for those with CKD was only about 80.3% (\$15,630 vs \$8,670) and 90.1% (\$17,615 vs \$9,267) higher than for those with no CKD, DM, or HF in the Medicare Advantage and managed care populations.

	М	edicare Advanta	age	Managed care				
	РРРҮ	Population	Spending	РРРҮ	Population	Spending		
	(U.S. \$)	(%)	(%)	(U.S. \$)	(%)	(%)		
All	\$11,191	100.00	100.00	\$11,146	100.00	100.00		
With HF or CKD or DM	\$17,253	29.81	45.29	\$17,100	24.19	36.80		
CKD only (- DM & HF)	\$15,630	4.14	5.71	\$17,615	2.75	4.37		
DM only (- HF & CKD)	\$13,612	15.54	18.88	\$13,675	14.76	17.99		
HF only (- DM & CKD)	\$20,916	2.69	4.84	\$21,260	2.16	4.07		
CKD and DM only (- HF)	\$19,226	3.73	6.32	\$21,008	2.32	4.32		
CKD and HF only (- DM)	\$27,505	1.02	2.34	\$30,363	0.55	1.44		
DM and HF only (- CKD)	\$27,223	1.47	3.41	\$27,612	1.00	2.43		
CKD and HF and DM	\$37,105	1.23	3.78	\$38,928	0.65	2.18		
No CKD or DM or HF	\$8,670	70.19	54.71	\$9,267	75.81	63.20		
All CKD (+/- DM & HF)	\$20,603	10.12	18.16	\$22,092	6.27	12.32		
All DM (+/- CKD & HF)	\$16,673	21.96	32.39	\$16,167	18.73	26.92		
All HF (+/- DM & CKD)	\$26,435	6.41	14.38	\$26,431	4.37	10.12		
CKD and DM (+/- HF)	\$23,459	4.96	10.10	\$24,841	2.97	6.50		
CKD and HF (+/- DM)	\$32,736	2.26	6.13	\$35,002	1.20	3.62		
DM and HF (+/- CKD)	\$31,658	2.70	7.19	\$32,012	1.65	4.61		

vol 1 Table 6.2 Prevalent Medicare Advantage and managed care spending for beneficiaries aged 65 and older, by diabetes, heart failure, and/or CKD, 2015

Data Source: Optum Clinformatics^M. Abbreviations: CKD, chronic kidney disease; HF, heart failure; DM, diabetes mellitus; PPPY, perperson per-year costs. Numbers of 'All' patients included in this table are 2,167,627 and 223,395 for Medicare Advantage and Commercial managed care respectively.

BENEFICIARIES YOUNGER THAN AGE 65

FEE-FOR-SERVICE MEDICARE

For the FFS Medicare population under age 65 only 6% had CKD, but those individuals accounted for 14%

of spending. One-fourth had one or more of CKD, DM, and/or HF, accounting for 43% of spending for this group (Table 6.3). Much of these expenditures, however, were for those who had DM, at 21% of the population and 35% of spending.

vol 1 Table 6.3 Prevalent Medicare fee-for-service patient counts and spending for beneficiaries younger	
than age 65, by diabetes, heart failure, and/or CKD, 2015	

	U.S. Medicare Population	Total Costs (millions, U.S. \$)	PPPY spending (U.S. \$)	Population (%)	Spending (%)	
All	4,967,060	\$62,093	\$13,025	100.00	100.00	
With HF or CKD or DM	1,278,300	\$26,984	\$22,311	25.74	43.46	
CKD only (- DM & HF)	99,680	\$2,236	\$23,803	2.01	3.60	
DM only (- HF & CKD)	808,920	\$13,605	\$17,551	16.29	21.91	
HF only (- DM & CKD)	99,140	\$2,295	\$24,701	2.00	3.70	
CKD and DM only (- HF)	113,500	\$3,078	\$29,119	2.29	4.96	
CKD and HF only (- DM)	21,600	\$775	\$40,786	0.44	1.25	
DM and HF only (- CKD)	83,280	\$2,673	\$34,484	1.68	4.30	
CKD and HF and DM	52,180	\$2,322	\$51,377	1.05	3.74	
No CKD or DM or HF	3,688,760	\$35,109	\$9,868	74.26	56.54	
All CKD (+/- DM & HF)	286,960	\$8,411	\$31,879	5.78	13.55	
All DM (+/- CKD & HF)	1,057,880	\$21,677	\$21,600	21.30	34.91	
All HF (+/- DM & CKD)	256,200	\$8,065	\$34,373	5.16	12.99	
CKD and DM (+/- HF)	165,680	\$5,399	\$35,785	3.34	8.70	
CKD and HF (+/- DM)	73,780	\$3,097	\$48,241	1.49	4.99	
DM and HF (+/- CKD)	135,460	\$4,995	\$40,705	2.73	8.04	

Data Source: Medicare 5% sample. Abbreviations: CKD, chronic kidney disease; HF, heart failure; DM, diabetes mellitus; PPPY, perperson per-year costs.

MEDICARE ADVANTAGE AND COMMERCIAL MANAGED

The under age 65 Medicare Advantage population was similar to the FFS Medicare population. Thirty percent of the Medicare Advantage beneficiaries had one or more of CKD, DM, and/or HF, accounting for 44% of spending for this group (Table 6.4). At only 6%, the managed care population under age 65 was much less likely to have CKD, DM, or HF (Table 6.4). For those under age 65 who qualified for Medicare based on a disability rather than age, spending was somewhat higher for beneficiaries in the Medicare Advantage program, both when averaged across all beneficiaries (42% higher) and among all with CKD (24% higher; Tables 6.3 and 6.4). Consistent with our other findings, average spending for those with CKD was considerably lower in the managed care population than in the Medicare FFS and Medicare Advantage populations.

	N	ledicare Advanta	age	Managed care				
	РРРҮ	Population	Spending	РРРҮ	Population	Spending		
	(U.S. \$)	(%)	(%)	(U.S. \$)	(%)	(%)		
All	\$18,503	100.00	100.00	\$5,279	100.00	100.00		
With HF or CKD or DM	\$27,572	29.77	43.92	\$13,208	6.37	15.62		
CKD only (- DM & HF)	\$29,476	2.04	3.23	\$16,206	0.55	1.66		
DM only (- HF & CKD)	\$22,035	19.20	22.77	\$11,029	5.02	10.30		
HF only (- DM & CKD)	\$32,499	2.09	3.59	\$20,752	0.30	1.14		
CKD and DM only (- HF)	\$34,673	2.99	5.54	\$22,361	0.32	1.33		
CKD and HF only (- DM)	\$53,785	0.44	1.23	\$40,815	0.03	0.21		
DM and HF only (- CKD)	\$39,620	1.91	3.97	\$28,588	0.11	0.56		
CKD and HF and DM	\$63,266	1.12	3.59	\$59,704	0.04	0.41		
No CKD or DM or HF	\$14,713	70.23	56.08	\$4,751	93.63	84.38		
All CKD (+/- DM & HF)	\$38,954	6.58	13.60	\$20,782	0.94	3.62		
All DM (+/- CKD & HF)	\$26,570	25.21	35.88	\$12,359	5.49	12.60		
All HF (+/- DM & CKD)	\$42,663	5.55	12.38	\$26,831	0.48	2.33		
CKD and DM (+/- HF)	\$42,169	4.10	9.14	\$26,253	0.36	1.75		
CKD and HF (+/- DM)	\$60,539	1.56	4.83	\$51,605	0.07	0.63		
DM and HF (+/- CKD)	\$48,183	3.02	7.56	\$36,721	0.15	0.97		

vol 1 Table 6.4 Prevalent Medicare Advantage and managed care fee-for-service spending for beneficiaries younger than age 65, by diabetes, heart failure, and/or CKD, 2015

Data Source: Optum Clinformatics™. Abbreviations: CKD, chronic kidney disease; HF, heart failure; DM, diabetes mellitus; PPPY, perperson per-year spending. Number of 'All' patients included in this table are 277,724 and 4,868,546 for Medicare Advantage and Managed care respectively.

Spending for CKD by Stage and Patient Characteristics

Among the FFS Medicare population aged 65 and older, between 2014 and 2015 total spending for Parts A, B, and D rose by \$7 billion, to \$262 billion. Total spending for CKD patients rose by \$2.8 billion, to \$55.8 billion (Figure 6.1). Therefore, spending growth among CKD patients accounted for over one third of the increase in Medicare expenditures during this year.

Further, Medicare expenditures were higher for beneficiaries with CKD than for beneficiaries with

ESRD (\$55.8 billion vs. \$33.9 billion; see Volume 2, Chapter 9, *Healthcare Expenditures for Persons with ESRD*). Expenditures for beneficiaries with CKD now represent 21.3% of all Medicare Parts A, B, and D non-ESRD spending.

Expenditures increased for all covered groups, but the highest growth rates occurred in those with only CKD and CKD with comorbid DM. The spending increase appears to be driven by a rise in the proportion of beneficiaries with recognized CKD (see Table 6.7 and Volume 1, Chapter 2, <u>Identification and</u> <u>Care of Patients with CKD</u>, Figure 2.2).

vol 1 Figure 6.1 Overall Medicare Parts A, B, and D fee-for-service spending for beneficiaries aged 65 and older, by CKD, diabetes, and heart failure, 2014 & 2015





Data source: Medicare 5% sample. Abbreviations: CKD, chronic kidney disease; HF, heart failure, DM, diabetes mellitus.

All CKD patients 65 and older required increased care as they progressed to later stages of disease (Figures 6.2.a-c; see Table A for CKD definitions). In the FFS Medicare population, PPPY expenditures in 2015 ranged from \$19,074 for those in Stages 1-2, to \$29,151 for those in Stages 4-5. In the Medicare Advantage population, expenditures increased from \$16,691 in Stages 1-2 to \$31,277 in Stages 4-5. The managed care population was similar, with expenditures of \$18,026 in Stages 1-2 to \$32,585 in Stages 4-5.

Group trends in PPPY spending from 2012-2015 were mixed (Figures 6.2.a-c). FFS Medicare saw PPPY expenditures increase 1.8% overall for individuals with any CKD, but the increase was most dramatic for those in Stages 4-5, rising by 6.2%. However, PPPY spending dropped 13% over this period for Medicare Advantage beneficiaries with CKD. Spending for managed care beneficiaries moved without clear patterns, but it should be noted that the Optum Clinformatics[™] population of managed care enrollees with CKD was relatively small (N=14,011 in 2015). Overall PPPY spending was slightly higher in 2015 than in 2012, but spending on beneficiaries in Stages 1-2 decreased by 6% while expenditures on beneficiaries in Stages 4-5 increased by 10%.

CHAPTER 6: HEALTHCARE EXPENDITURES FOR PERSONS WITH CKD

vol 1 Figure 6.2 Overall per-person per-year spending for beneficiaries aged 65 and older, by CKD stage, and year, 2012-2015



Figure 6.2 continued on next page.

vol 1 Figure 6.2 Overall per-person per-year spending for beneficiaries aged 65 and older, by CKD stage, and year, 2012-2015 (continued)



Data Source: Medicare 5% sample and Optum Clinformatics™. Abbreviations: CKD, chronic kidney disease; PPPY, per-person per-year.

ICD-9-CM code ^a	ICD-10-CM code ^a	Stage
585.1	N18.1	CKD, Stage 1
585.2	N18.2	CKD, Stage 2 (mild)
585.3	N18.3	CKD, Stage 3 (moderate)
585.4	N18.4	CKD, Stage 4 (severe)
585.5	N18.5	CKD, Stage 5 (excludes 585.6: Stage 5, requiring chronic dialysis ^b)
CKD Stage-unspecified	CKD Stage-unspecified	For these analyses, identified by multiple codes including 585.9, 250.4x, 403.9x & others for ICD-9-CM and A18.xx, E08.xx, E11.xx and others for ICD-10-CM.

Table A. ICD-9-CM and ICD-10-CM codes for Chronic Kidney Disease (CKD) stages

^a For analyses in this chapter, CKD stage estimates require at least one occurrence of a stage-specific code, and the last available CKD stage in a given year is used. ^b In USRDS analyses, patients with ICD-9-CM code 585.6 or ICD-10-CM code N18.6 & with no ESRD 2728 form or other indication of end-stage renal disease (ESRD) are considered to have code 585.5 or N18.5

CHAPTER 6: HEALTHCARE EXPENDITURES FOR PERSONS WITH CKD

Table 6.5 presents PPPY Medicare FFS spending for Parts A, B, and D services, for beneficiaries with CKD (but not ESRD), by stage of CKD. In 2015, PPPY costs reached \$22,228 for FFS Medicare CKD patients aged 65 and older, a slight increase from 2014 (\$21,942). This increased spending was observed in CKD Stages 3 and 4-5, while the costs in Stages 1-2 decreased slightly from 2014 to 2015. During this period, the distribution of identified patient years also shifted towards the less severe and less costly stages. In 2015, costs for beneficiaries with Stages 4-5 CKD (\$29,151) were 52.8% greater than for beneficiaries with Stages 1-2 CKD (\$19,074). Although the number of beneficiaries with unknown/unspecified CKD stage decreased slightly, this still accounted for one-third of all cases of CKD. The PPPY costs for those unknown/unspecified were similar to the overall CKD population.

Spending for Black beneficiaries with CKD exceeded that for Whites by 9.1%, a decrease over the 14.9% disparity observed in 2014. Per capita spending for Whites increased slightly while per capita spending for Blacks decreased slightly.

			2014					2015		
	Any CKD	Stages	Stage	Stages	Unk/	Any CKD	Stages	Stage	Stages	Unk/
		1-2	3	4-5	Unspc		1-2	3	4-5	Unspc
Patient years at risk	2,416,562	248,272	1,125,995	227,538	814,757	2,509,731	266,837	1,231,392	228,778	782,724
All patients	\$21,942	\$19,139	\$21,271	\$28,637	\$21,854	\$22,228	\$19,074	\$21,649	\$29,151	\$22,190
Age										
65-69	\$20,751	\$17,380	\$20,541	\$30,039	\$20,137	\$21,115	\$17,869	\$20,801	\$31,518	\$20,432
70-74	\$20,437	\$17,460	\$20,036	\$28,398	\$20,247	\$20,363	\$16,778	\$19,940	\$28,408	\$20,459
75-79	\$21,512	\$17,472	\$20,924	\$28,916	\$21,740	\$21,516	\$18,711	\$20,820	\$28,681	\$21,746
80-84	\$22,217	\$20,511	\$21,253	\$27,794	\$22,417	\$22,737	\$19,779	\$22,190	\$28,657	\$22,776
85+	\$23,957	\$23,214	\$22,907	\$28,587	\$23,967	\$24,600	\$22,760	\$23,673	\$29,170	\$24,882
Sex										
Male	\$21,542	\$18,916	\$21,099	\$28,166	\$21,221	\$21,928	\$18,499	\$21,589	\$29,200	\$21,662
Female	\$22,303	\$19,348	\$21,429	\$29,022	\$22,424	\$22,501	\$19,631	\$21,704	\$29,111	\$22,677
Race										
White	\$21,551	\$18,921	\$20,939	\$27,871	\$21,476	\$21,990	\$18,809	\$21,563	\$28,272	\$21,962
Black/African American	\$24,746	\$21,099	\$23,787	\$32,269	\$24,566	\$23,983	\$19,880	\$22,439	\$33,943	\$24,13
Other	\$22,457	\$18,470	\$21,625	\$30,737	\$22,811	\$22,492	\$20,878	\$21,520	\$30,138	\$22,185

vol 1 Table 6.5 Per-person-per year Medicare Parts A, B, and D fee-for-service spending for all CKD beneficiaries aged 65 and older, by CKD stage, age, sex, and race, 2014 & 2015

Table 6.6 presents overall PPPY spending for Medicare Advantage and managed care beneficiaries with CKD (but not ESRD) by stage of CKD (see Table A for definitions). In contrast to the FFS Medicare population, for these patients spending generally decreased with age and was lower for Blacks than Whites, by 26% for those covered by Medicare Advantage and 35% in the managed care population.

vol 1 Table 6.6 Per-person per-year Medicare Advantage and managed care spending for all CKD beneficiaries aged 65 and older, by CKD stage, age, sex, and race, 2015

		Medi	care Adva	ntage		Managed care						
	Any CKD	Stages	Stage	Stages	Unk/	Any CKD	Stages	Stage	Stages	Unk/		
	-	1-2	3	4-5	Unspc		1-2	3	4-5	Unspc		
Patient	219,259	20,495	95,087	14,940	88,737	14,011	1,362	5,689	885	6,075		
years at risk												
All patients	\$20,603	\$16,691	\$18,693	\$31,277	\$21,829	\$22,092	\$18,026	\$20,361	\$32,585	\$23,181		
Age												
65-69	\$23,527	\$17,190	\$21 <i>,</i> 886	\$44,084	\$24,137	\$24,336	\$17,469	\$22 <i>,</i> 059	\$46,513	\$25,893		
70-74	\$21,985	\$17,372	\$19,741	\$39,711	\$23,206	\$22,982	\$17,434	\$21,171	\$36,387	\$24,639		
75-79	\$21,877	\$16,864	\$20,030	\$36,906	\$22,773	\$21,245	\$18,328	\$19,516	\$32,263	\$21,899		
80-84	\$19,893	\$16,195	\$18,033	\$28,614	\$21,269	\$21,046	\$22,427	\$19,681	\$28,361	\$21,024		
85+	\$16,823	\$15,424	\$15,522	\$19,491	\$18,104	\$17,723	\$15,833	\$17,728	\$20,386	\$17,265		
Sex												
Male	\$21,368	\$16,838	\$19,439	\$33,226	\$22,607	\$22,401	\$18,668	\$20,884	\$33,259	\$23,275		
Female	\$19,958	\$16,563	\$18,082	\$29,777	\$21,143	\$21,520	\$17,010	\$19,634	\$30,595	\$22,941		
Race												
White	\$20,675	\$17,205	\$18,746	\$28,785	\$22,259	\$22,051	\$18,662	\$20,563	\$31,447	\$22,840		
Black/Africa n American	\$15,316	\$9,883	\$13,756	\$30,632	\$15,671	\$14,326	\$9,709	\$13,809	\$16,624	\$15,869		
Other	\$21,058	\$16,534	\$19,134	\$36,471	\$21,648	\$22,955	\$17,167	\$20,220	\$37,534	\$25,162		

Data Source: Optum Clinformatics™. Abbreviations: CKD, chronic kidney disease; Unk/unspc, CKD stage unknown or unspecified.

CHAPTER 6: HEALTHCARE EXPENDITURES FOR PERSONS WITH CKD

Tables 6.7 and 6.8 present PPPY spending for beneficiaries with both CKD and DM. These tables show similar results as in the overall CKC population. Among the 2015 FFS Medicare beneficiaries with these two conditions, PPPY spending for Blacks was \$27,016—7.9% greater than the \$25,033 incurred for Whites. Yet, spending by Medicare Advantage was 29% lower for Blacks than Whites and 39% lower for the managed care population.

vol 1 Table 6.7 Per-person per-year Medicare Parts A, B, and D fee-for-service spending for CKD patients with diabetes, aged 65 and older, by CKD stage, age, sex, and race, 2014 & 2015

			2014			2015						
	Any CKD	Stages	Stage	Stages	Unk/	Any CKD	Stages	Stage	Stages	Unk/		
	-	1-2	3	4-5	Unspc		1-2	3	4-5	Unspc		
Patient years at risk	1,162,063	120,091	549,920	119,516	372,537	1,202,782	128,814	594,220	121,161	358,588		
All patients	\$24,967	\$21,570	\$24,500	\$32,440	\$24,354	\$25,280	\$21,797	\$24,884	\$32,981	\$24,585		
Age												
65-69	\$24,083	\$19,437	\$24,709	\$32,609	\$22,750	\$24,540	\$20,290	\$24,791	\$35,626	\$22,878		
70-74	\$23 <i>,</i> 657	\$20,235	\$23,321	\$32,854	\$22,836	\$23,494	\$19,302	\$23,080	\$32,525	\$23,234		
75-79	\$24,488	\$19,732	\$24,237	\$31,863	\$24,205	\$24,861	\$22,062	\$24,094	\$32,501	\$24,692		
80-84	\$25,378	\$24,944	\$24,261	\$31,261	\$25,138	\$26,032	\$22,450	\$25,815	\$32,439	\$25,194		
85+	\$27,438	\$26,046	\$26,286	\$33,507	\$27,039	\$27,854	\$27,396	\$27,078	\$32,502	\$27,318		
Sex												
Male	\$24,023	\$21,210	\$23,884	\$31,141	\$23,101	\$24,469	\$20,952	\$24,242	\$33,138	\$23,506		
Female	\$25,892	\$21,945	\$25,119	\$33,493	\$25,586	\$26,091	\$22,709	\$25,536	\$32,850	\$25,676		
Race												
White	\$24,447	\$21,301	\$23,990	\$31,348	\$23,983	\$25,033	\$21,259	\$24,937	\$31,991	\$24,264		
Black/African American	\$28,184	\$23,038	\$27,392	\$37,347	\$27,386	\$27,016	\$23,370	\$25,170	\$37,048	\$27,042		
Other	\$24,914	\$21,601	\$25,129	\$32,986	\$23,376	\$24,927	\$24,014	\$23,732	\$34,155	\$24,011		

Data source: Medicare 5% sample. Abbreviations: CKD, chronic kidney disease; Unk/unspc, CKD stage unknown or unspecified.

		Medio	are Adva	ntage		Managed care					
	Any CKD	Stages	Stage Stages		Unk/	Any CKD	Stages	Stage	Stages	Unk/	
	-	1-2	3	4-5	Unspc	-	1-2	3	4-5	Unspc	
Patient years at risk	107,428	9,995	43,494	7,767	46,172	6,635	639	2,654	463	2,879	
All patients	\$23,459	\$19,036	\$22,041	\$37,182	\$23,520	\$24,841	\$20,492	\$22,766	\$40,557	\$25,317	
Age											
65-69	\$26,544	\$19,241	\$25 <i>,</i> 468	\$47,871	\$26,425	\$26,569	\$20,232	\$24,953	\$57 <i>,</i> 489	\$25,754	
70-74	\$24,704	\$20,200	\$23,189	\$46,334	\$24,195	\$26,149	\$20,599	\$23 <i>,</i> 648	\$34,882	\$28,886	
75-79	\$24,210	\$19,675	\$23,096	\$40,660	\$23,647	\$25,107	\$21,032	\$21,791	\$43,039	\$26,212	
80-84	\$21,876	\$17,292	\$20,196	\$31,204	\$22,715	\$21,687	\$20,809	\$19,994	\$32,716	\$21,318	
85+	\$19,103	\$17,144	\$18,085	\$22,900	\$19,679	\$18,985	\$20,578	\$19,382	\$18,487	\$18,494	
Sex											
Male	\$23,726	\$18,819	\$22,148	\$39,575	\$23 <i>,</i> 959	\$24,446	\$20,642	\$23,026	\$37,771	\$24,757	
Female	\$23,213	\$19,248	\$21,942	\$35,321	\$23,111	\$25,342	\$20,305	\$22,399	\$42,098	\$26,236	
Race											
White	\$23,863	\$20,115	\$22,348	\$34,321	\$24,408	\$25,208	\$21,737	\$23,826	\$37,791	\$25,244	
Black/African American	\$16,837	\$10,561	\$16,427	\$34,072	\$15,804	\$15,377	\$9,056	\$13,847	\$29,197	\$16,665	
Other	\$23,558	\$18,545	\$22,138	\$42,299	\$22,931	\$24,750	\$18,664	\$20,564	\$48,899	\$26,600	

vol 1 Table 6.8 Per-person per-year Medicare Advantage and managed care spending for CKD patients with diabetes, aged 65 and older, by CKD stage, age, sex, and race, 2015

Data Source: Optum Clinformatics™. Abbreviations: CKD, chronic kidney disease; Unk/unspc, CKD stage unknown or unspecified.

Tables 6.9 and 6.10 present PPPY spending for beneficiaries with CKD and concurrent HF. The presence of HF greatly increased the costs of care for persons with CKD. Persons with both CKD and HF cost 61% more (\$35,826) than the average CKD patient (\$22,228). These results were consistent with those seen in the previous tables. In 2015, FFS Medicare

PPPY expenditures for Black beneficiaries with both conditions reached \$39,417—12.0% higher than the \$35,188 PPPY for their White counterparts. In contrast to FFS Medicare, Black Medicare Advantage beneficiaries required 21% less spending than did their White counterparts, and Black managed care beneficiaries 27% less.

			2014			2015					
	Any CKD	Stages	Stage	Stages	Unk/	Any CKD	Stages	Stage	Stages	Unk/	
		1-2	3	4-5	Unspc		1-2	3	4-5	Unspc	
Patient years at risk	654,204	55,380	307,873	83,501	207,451	660,606	57,097	330,479	83,409	189,622	
All patients	\$35,089	\$32,559	\$34,707	\$41,078	\$33,920	\$35 <i>,</i> 828	\$33,808	\$35,519	\$41,364	\$34,540	
Age											
65-69	\$38,964	\$35,468	\$38,564	\$48,415	\$37,139	\$39,623	\$36,226	\$39,094	\$50,216	\$37,389	
70-74	\$35,963	\$29,170	\$35,946	\$43,186	\$35,479	\$36,739	\$31,040	\$36,867	\$42,396	\$36,129	
75-79	\$36,424	\$31,296	\$36,130	\$43 <i>,</i> 382	\$35,605	\$36,501	\$35,705	\$35,884	\$42,059	\$35,505	
80-84	\$34,257	\$34,638	\$33,533	\$39,513	\$33,075	\$35,416	\$33,497	\$35,522	\$39,841	\$33,786	
85+	\$33,136	\$32,880	\$32,752	\$37,922	\$31,686	\$33,936	\$33,324	\$33,469	\$38,722	\$32,654	
Sex											
Male	\$34,250	\$32,001	\$34,025	\$40,137	\$32,947	\$34,930	\$32,710	\$34,640	\$41,134	\$33,565	
Female	\$35,846	\$33,096	\$35,360	\$41,834	\$34,747	\$36,682	\$34,895	\$36,387	\$41,556	\$35,451	
Race											
White	\$34,139	\$31,708	\$33,906	\$39,922	\$32,868	\$35,188	\$32,972	\$35,058	\$39,893	\$34,087	
Black/Africa n American	\$40,636	\$36,146	\$40,085	\$46,446	\$39,937	\$39,417	\$34 <i>,</i> 856	\$38,612	\$48,199	\$37,335	
Other	\$38,247	\$36,062	\$36,300	\$44,948	\$39,040	\$38,654	\$43,218	\$36,990	\$45,342	\$36,434	

vol 1 Table 6.9 Per-person per-year Medicare Parts A, B, and D fee-for-service spending for CKD patients with heart failure, aged 65 and older, by CKD stage, age, sex, race, and year, 2014 & 2015

Data source: Medicare 5% sample. Abbreviations: CKD, chronic kidney disease; Unk/unspc, CKD stage unknown or unspecified.

vol 1 Table 6.10 Per-person per-year Medicare Advantage and managed care spending for CKD patients with heart failure, aged 65 and older, by CKD stage, age, sex, and race, 2015

	Medicare Advantage					Managed care					
—	Any	Stages	Stage	Stages	Unk/		Any	Stages	Stage	Stages	
	CKD	1-2	3	4-5	Unspc		CKD	1-2	3	4-5	
Patient years	48,871	3,174	19,734	4,511	21,452		2,690	163	1,136	258	
at risk All patients	\$32,736	\$29,232	\$30,743	\$43,293	\$32,942	,	\$35,002	\$38,649	\$31,856	\$44,486	
Age											
65-69	\$44,743	\$37,331	\$42,551	\$63,593	\$44,291	0	\$49,769	\$44,473	\$49,095	\$88,857	
70-74	\$39,263	\$34,410	\$36,482	\$53,006	\$40,104	6	\$39,502	\$35,685	\$33,810	\$45,028	
75-79	\$36,693	\$30,348	\$34,727	\$55,871	\$35,681	0	\$34,234	\$56,697	\$27,289	\$48,370	
80-84	\$31,036	\$26,279	\$29,781	\$42,645	\$30,439	0	\$30,377	\$35,981	\$27,208	\$37,293	
85+	\$22,865	\$21,992	\$21,782	\$25,391	\$23,468		\$21,646	\$21,051	\$22,002	\$21,908	
Sex											
Male	\$33,430	\$29,907	\$31,443	\$44,242	\$33,698	0	\$34,497	\$41,971	\$31,942	\$48,441	
Female	\$32,103	\$28,621	\$30,082	\$42,488	\$32,264	0	\$35,950	\$32,429	\$31,858	\$39,303	
Race											
White	\$31,967	\$29,231	\$29,922	\$39,984	\$32,672	0	\$33,237	\$36,180	\$29,610	\$41,622	
Black/African American	\$25,266	\$13,455	\$26,010	n/a	\$23,104	Q T	\$24,231	\$31,264	\$29,097	n/a	
Other	\$35,124	\$30,102	\$33,213	\$51,387	\$34,282	C .	\$42,126	\$46 <i>,</i> 988	\$40,216	\$55,446	

Data Source: Optum Clinformatics™. n/a: data not shown due to limited number of patients. Abbreviations: CKD, chronic kidney disease; Unk/unspc, CKD stage unknown or unspecified.

Over time FFS Medicare beneficiaries aged 65 and older with recognized CKD have accounted for an increasing share of Medicare expenditures, expanding from 5.8% in 2000 to 14.1% in 2008, and 21.3% in 2015. Much of this growth was due to the increased ascertainment of CKD as shown in Volume 1, Chapter 2, *Identification and Care of Patients with CKD*, Figure 2.2. Persons aged 65 and older with CKD accounted for 2.1%, 8.8%, and 12.3% of the FFS Medicare population in 2000, 2008, and 2015. Figure 6.3 presents total expenditures on Parts A, B, and D services for Medicare FFS beneficiaries with CKD, DM, and HF. In 2015, expenditures for CKD patients reached \$55.8 billion, accounting for 21.2% of the total spending for all FFS Medicare beneficiaries. Care of beneficiaries with CKD and concurrent DM required \$30.4 billion in 2015, or 33.4% of the total FFS Medicare spending on DM. Spending on HF in the FFS Medicare population was \$53.3 billion in 2015. Of this, \$23.7 billion (44.4%) was spent on the CKD patient population with HF.

CHAPTER 6: HEALTHCARE EXPENDITURES FOR PERSONS WITH CKD

vol 1 Figure 6.3 Overall Medicare Parts A, B, and D fee-for-service spending for general Medicare population aged 65 and older and for those with CKD, 1996-2015



Figure 6.3 continued on next page.

vol 1 Figure 6.3 Overall Medicare Parts A, B, and D fee-for-service spending for general Medicare population aged 65 and older and for those with CKD, 1996-2015 (continued)



Data Source: Medicare 5% sample. Abbreviation: CKD, chronic kidney disease.

Most spending for CKD patients was incurred for inpatient and outpatient care, physician/supplier services, and care in skilled nursing facilities. The proportion of total FFS Medicare expenditures required to provide inpatient care was 33% in 2015, while outpatient costs were predictably lower at 11%. Physician/supplier service costs amounted to 23% in 2015, while those for skilled nursing facility care reached 10% (Figure 6.4). In the Medicare non-CKD population, these expenditure percentages were 29% to provide inpatient care, 15% for outpatient, 28% for physician/supplier services, and 8% those for skilled nursing facility care (not shown).





Data source: Medicare 5% sample. Part D data occurring since 2006.

Hospitalization costs accounted for a large proportion of spending for CKD. Of the 2015 inpatient hospitalization spending for those with CKD, 22% resulted from admissions to treat infections, and 26% from cardiovascular conditions, with the remaining 52% resulting from all other causes (Figure 6.5).





Data source: Medicare 5% sample. Part D data occurring since 2006.

Figure 6.6 illustrates PPPY costs for CKD patients aged 65 and older by the presence of DM and HF. In 2015, PPPY costs for CKD patients varied greatly by the presence of these comorbidities. CKD patients without DM and HF required \$15,930 PPPY from FFS Medicare. Those with DM in addition to CKD averaged \$19,109 PPPY, and beneficiaries with both CKD and HF cost \$31,401. Expenditures for those with all three conditions reached \$39,395 PPPY in 2015 for FFS Medicare. Spending was also higher as comorbidities increased in the Medicare Advantage and managed care populations.





Figure 6.6 continued on next page.

vol 1 Figure 6.6 Per-person per-year Medicare, Medicare advantage, and managed care spending for CKD patients aged 65 and older, by diabetes and heart failure, 2006-2015 (continued)



Data Source: Medicare 5% sample and Optum Clinformatics[™]. Abbreviations: CKD, chronic kidney disease; DM, diabetes mellitus; HF, heart failure; PPPY, per person per year. Due to the inconsistent data, PPPY costs for Medicare Advantage in 2006 are suppressed.

References

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Chapter 7:

Prescription Drug Coverage in Patients with CKD

- In this 2017 Annual Data Report (ADR) we introduce two new chapter features:
 - To provide a more comprehensive examination of Medicare Part D enrollment patterns and spending under stand-alone prescription drug plans, we now compliment the Medicare 5% sample with information from the Optum Clinformatics[™] DataMart for persons with Medicare Advantage and commercial managed care coverage.
 - Of the top 15 drug classes used by CKD patients, this year we specifically investigate geospatial, medication use patterns of the analgesic classes of nonsteroidal anti-inflammatory agents (NSAIDs) and opioids.
- Approximately 71.9% of chronic kidney disease (CKD) patients enrolled in Medicare Part D in 2015, 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 (67.1%; Figure 7.1).
- 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 7.2 and 7.3).
- As compared to Whites (29.7%), much higher proportions of Asian (77.6%) and Black/ African American (64.2%) CKD Part D beneficiaries qualified for the LIS (Figure 7.3).
- For 2015 patients with stand-alone Part D plans, per patient per year (PPPY) spending on prescriptions was 1.5 times higher for Medicare patients with CKD than for general beneficiaries (\$4,547 vs. \$2,971). Spending for CKD patients with Medicare Advantage plans was 1.7 times higher (\$2,914, vs. \$1,760), and 4.5 times higher in those with managed care coverage (\$4,398 vs. \$971; Figure 7.5.a).
- Total PPPY Medicare spending for Part D-covered medications in 2015 was more than twice as high for CKD patients with the LIS (\$8,145) than for those without (\$2,658). Patient out-of-pocket costs for LIS patients represented only a 1.3-1.4% share of these total expenditures, as compared to 26.2-28.1% in each of the non-LIS populations (Figure 7.5.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 2015 (Table 7.6). CKD patients with Medicare Advantage and managed care coverage showed similar patterns of use for these drug classes.
- By drug class, the greatest medication expenditures for patients with CKD were for antidiabetic agents, followed by antineoplastic agents, antivirals, and lipid-lowering agents (Table 7.7).
- In the United States (U.S.), the overall proportion of CKD patients using prescription non-steroidal antiinflammatory agents (NSAIDs) was 14.7%, and ranged from 19.6% in Alabama to 7.9% in North Dakota.
- Approximately 44.5% of Medicare CKD patients had at least one filled prescription for opioid agonists, ranging from 57.0% in Mississippi to 22.6% in Hawaii.

Introduction

Pharmaceutical therapy serves as a critical part of CKD treatment to control and reduce complications and delay disease progression. This chapter assesses prescription drug coverage, prescription drug-related costs, and patterns of prescription drug use for CKD patients in three health systems. In the 2016 ADR (USRDS, 2016), the Medicare 5% sample was used to describe Part D enrollment patterns in Medicare beneficiaries and Medicare Part D spending under stand-alone prescription drug plans (PDPs). For this year's chapter we have added information on prescription drug use and associated costs from the Optum Clinformatics[™] DataMart (obtained from OptumInsight) for persons with Medicare Advantage and commercial managed care coverage.

In 2015, 45% of general Medicare beneficiaries enrolled in a stand-alone PDP, while 24% received coverage through a Medicare Advantage plan (Kaiser, 2017); adding information for Medicare Advantage beneficiaries thus makes our assessment of prescription drug use in CKD more complete. Additionally, Optum Clinformatics[™] data for beneficiaries with managed care complements our report by providing insight into a younger and employed population.

In the 2016 ADR, we reported the cost and utilization rate of the top 15 drug classes used by CKD patients. Beginning this year, we will annually select a drug class to investigate medication use patterns in detail. Given that pain is a common symptom in CKD patients, we will begin with analgesics, particularly focusing on prescription nonsteroidal antiinflammatory agents (NSAIDs) and opioid analgesics.

A parallel examination of prescription drug use and associated costs in patients with ESRD can be found in Volume 2, Chapter 10, <u>Prescription Drug Coverage in</u> <u>Patients with ESRD</u>.

Methods

In this chapter, we examine the Medicare 5% sample data to describe Part D enrollment and prescription utilization for Medicare beneficiaries. Enrollment data are available for both traditional Medicare (fee-for-service) enrollees and Medicare Advantage enrollees; however, actual claim data and spending data are only available for beneficiaries with traditional Medicare. Thus, our past estimations for Part D enrollment applied to all Medicare beneficiaries, but the reporting of prescription utilization and associated costs applied only to the sub-group of Medicare fee-for-services Part D enrollees. We have now introduced Optum Clinformatics[™] data to augment our assessment of prescription utilization and associated costs for both the Medicare Advantage population and a commercially insured, managed care population.

Details of this data are described in the <u>Data</u> <u>Sources</u> section of the <u>CKD Analytical Methods</u> chapter. See the Chapter 6 section of <u>CKD Analytical</u> <u>Methods</u>, in the <u>CKD Analytical Methods</u> chapter for an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter. Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available to download from the <u>USRDS</u> <u>website</u>.

To be included in analyses specific to the Medicare 5% population, eligible beneficiaries must have been enrolled in traditional Medicare for all of the one-year entry period (year one, the calendar year before the year reported in the figures and tables), and be alive, without ESRD, and enrolled in Medicare on January 1 of the reported year (year two). These criteria were necessary to enable CKD identification, as diagnosis codes were not available for patients before they became eligible for fee-for-service Medicare. CKD patients were identified via having a minimum of one inpatient and/or two outpatient CKD diagnoses claims in year one. We assessed Part D enrollment and prescription utilization for year two. The Medicare Part D drug event file provided data to evaluate prescription utilization; it contains records of all prescriptions filled by the beneficiaries under Medicare Part D.

For beneficiaries selected from the Optum Clinformatics[™] data, to create comparable results we applied the same eligibility algorithm as for the Medicare population. Beneficiaries were required to

CHAPTER 7: PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH CKD

be in the Optum Clinformatics[™] dataset throughout year one, be alive, without ESRD, and covered by either a Medicare Advantage plan or a commercial managed care plan on January 1 of year two. Those with Medicare Advantage at the beginning of year two were classified as the Medicare Advantage population; otherwise, they were classified as the managed care population. All of beneficiaries in the Optum Clinformatics[™] dataset had prescription drug coverage.

In this chapter, we define spending as plan payments. For example, Medicare Part D spending is the sum of Medicare net payment and the Lowincome Supplement (LIS) amount. Patients' obligations are the sum of the deductible and copayment.

Medicare Part D Coverage Plans

The optional Medicare Part D prescription drug benefit has been available to all beneficiaries since 2006. Part D benefits can be managed through a stand-alone PDP or through a Medicare Advantage plan. Most Medicare Advantage plans offer prescription drug coverage (Medicare Advantage prescription drug plan, MA-PD). CKD patients have the option to enroll in a Medicare Advantage plan; end-stage renal disease (ESRD) patients, in contrast, are precluded from entering a Medicare Advantage plan if they are not already enrolled in one when they reach ESRD.

Before 2006, Medicare beneficiaries obtained drug coverage through various avenues—plans, state Medicaid programs, pharmaceutical assistance programs, or samples received from physicians. Those with none of these options paid for their medications out-of-pocket. Beneficiaries with low income who were dually enrolled in Medicare and Medicaid received prescription benefits under state Medicaid programs.

After 2006, the majority of Medicare enrollees obtained Part D coverage. The Part D program offers a substantial Low-income Subsidy (LIS) benefit to enrollees with limited assets and income, including those dually enrolled. The LIS provides full or partial waivers for many out-of-pocket cost-sharing requirements, including premiums, deductibles, and copayments, and provides full or partial coverage during the Part D coverage gap (commonly referred to as the "donut hole").

Besides Medicare Part D plans (PDP and MA-PD), Medicare beneficiaries can choose instead to obtain outpatient medication benefits through retiree drug subsidy plans or other creditable coverage such as employer group health plans, other private coverage, or Veterans Health Administration (VHA) benefits. Some enrollees remain uninsured and pay out-ofpocket for their outpatient prescription medications. The premiums for Part D coverage are partially subsidized. Beneficiaries who delay voluntary enrollment yet lack other creditable coverage at least equivalent to Part D pay higher premiums once they do enroll.

In 2015, approximately 71.9% of CKD patients enrolled in Medicare Part D (including both standalone and Medicare Advantage plans). This rate was slightly higher than Part D enrollment by those in the general Medicare population (67.1%, Figure 7.1). Compared to beneficiaries in the general population, a higher percentage of CKD patients qualified for the LIS (26.4% vs. 23.1%). The proportion of CKD patients with no known coverage was 11.0%, lower than the 14.1% of the general Medicare population who did not have coverage.



vol 1 Figure 7.1 Sources of prescription drug coverage in Medicare enrollees, by population, 2015

Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1, 2015. Abbreviations: CKD, chronic kidney disease; LIS, Medicare Low-income Subsidy; Part D, Medicare prescription drug coverage benefit.

The proportion of beneficiaries that enrolled in Medicare Part D rose between 2011 and 2015, among both general Medicare beneficiaries and patients with CKD (Table 7.1). In each year, enrollment was slightly higher for those with CKD than in the general Medicare population.

dicare and CKD patients enrolled in Part D						
	General Medicare (%)	All CKD (%)				
2011	55.7	59.3				
2012	57.6	60.5				
2013	65.7	69.3				
2014	66.3	71.1				
2015	67.1	71.9				

vol 1 Table 7.1 General Medicare and CKD patients enrolled in Part D

Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1. Abbreviations: CKD, chronic kidney disease; Part D, Medicare prescription drug coverage benefit.

The Centers for Medicare and Medicaid Services (CMS) provide prescription drug plans (PDPs) with guidance on structuring a 'standard" Part D PDP. The upper portion of Table 7.2 shows the standard benefit design for PDPs in 2010 and 2015. In 2015, for example, beneficiaries shared costs with the PDP as co-insurance or copayments, until the combined total during the initial coverage period reached \$2,960.

After reaching this level, beneficiaries entered the coverage gap ("donut hole") where they paid 100% of prescription costs. Under the original Affordable Care Act, the coverage gap in the Part D benefit will be phased out by 2020.

As part of the phase-out, the government began providing non-LIS recipients reaching the coverage

CHAPTER 7: PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH CKD

gap with increasing assistance each year. In 2015, beneficiaries received a 50% discount on brand name drugs from manufacturers plus 5% coverage from their Part D plans; plans also paid 35% of generic drug costs in the gap. Beneficiaries who had paid yearly out-ofpocket drug costs of \$4,700 reached the catastrophic coverage phase, in which they then had only a small copayment for their drugs until the end of the year.

PDPs have the latitude to structure their plans differently than the model presented here; companies offering non-standard plans must show that their coverage is at least actuarially equivalent to the standard plan. Many have developed plans with no deductibles or with drug copayments instead of the 25% co-insurance, and some plans provide generic and/or brand name drug coverage during the coverage gap.

Part D does not cover all medications prescribed to Medicare enrollees. Several drug categories—such as over-the-counter medications, anorexia and weight loss or gain medications, prescription vitamins (except for prenatal vitamins), and cough and cold medications are excluded from the Part D program formulary. This creates a lack of support for some drugs commonly prescribed to treat CKD, including oral iron, ergocalciferol, and cholecalciferol. In January 2013, Medicare expanded Part D coverage to include benzodiazepines without restriction, and barbiturates when prescribed for specific indications.

Medicare Part D Enrollment Patterns

Among both general Medicare beneficiaries and those with CKD, the percentage of beneficiaries enrolled in Part D generally declined with age. In the 75+ age group, similar proportions of general Medicare and CKD patients were enrolled in Part D, at 65.9% and 69.2% (Figure 7.2). The proportion of beneficiaries with LIS declined with age in both populations, with the exception of general Medicare population aged 75 and older. CKD patients in all age categories were more likely to receive this subsidy.

vol 1 Table 7.2 Medicare Part D parameters for defined standard benefit, 2010 & 2015

		2010	2015	
Deductible		\$310	\$320	
	net, the beneficiary pays 25% of total the initial coverage limit.			
Initial coverage limit		\$2,830	\$2,960	
The coverage gap ("don	ut hole") begins at this point.			
The beneficiary pays 100 the out-of-pocket thresh	0% of their prescription costs up to hold			
Out-of-pocket threshold		\$4,550 \$4,700		
The total out-of-pocket	costs including the "donut hole"			
Total covered Part D prescr	iption out-of-pocket spending	\$6,440.00	\$6,680.00	
Catastrophic coverage b coverage gap).	egins after this point (including the			
Catastrophic coverage bene	efit	\$2.50	*\$2.65	
Generic/preferred multi-	source drug	\$6.30	*\$6.60	
Other drugs			plus a 55% brand-name medication discount	
2015 Example:				
\$320	(deductible)	\$310.00	\$320	
+((\$2960-\$320)*25%)	(initial coverage)	\$630.00	\$660.00	
+((\$6680-\$2960)*100%)	(coverage gap)	\$3,610.00	\$3,720.00	
Total		\$4,550.00	\$4,700.00	
(maximum out-of-pocke excluding plan premium	t costs prior to catastrophic coverage,)			

*The catastrophic coverage amount is the greater of 5% of medication cost or the values shown in the chart above. In 2015, beneficiaries were charged \$2.65 for those generic or preferred multisource drugs with a retail price less than \$53 and 5% for those with a retail price over \$53. For brand name drugs, beneficiaries paid \$6.6 for those drugs with a retail price less than \$132 and 5% for those with a retail price over \$132. Table adapted from http://www.q1medicare.com/PartD-The-2015-Medicare-Part-D-Outlook.php.

CHAPTER 7: PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH CKD

vol 1 Figure 7.2 Sources of prescription drug coverage in Medicare enrollees, by age, 2015



(a) All general Medicare enrollees





Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1, 2015. Abbreviations: CKD, chronic kidney disease; LIS, Medicare Low-income Subsidy; Part D, Medicare prescription drug coverage benefit.

Patterns of coverage by race were similar for both general Medicare beneficiaries and for those with CKD (Figure 7.3). Among Medicare Part D enrollees with CKD, 77.6% of Asian beneficiaries received the LIS,

compared to 64.2% of Blacks, and 29.7% of Whites. Across all races, the percentage of beneficiaries with the LIS was higher for CKD patients than their general Medicare counterparts.



(a) All general Medicare enrollees

vol 1 Figure 7.3 Sources of prescription drug coverage in Medicare enrollees, by race, 2015



(b) Enrollees with CKD

Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1, 2015. Abbreviations: Blk/Af Am, Black/African American; CKD, chronic kidney disease; LIS, Medicare Low-income Subsidy; Part D, Medicare prescription drug coverage benefit.
	General Medicare (%)	All CKD (%)
	Part D with	Part D with
	Low-income Subsidy	Low-income Subsidy
White		
All ages	28.3	29.7
20-44	92.5	94.4
45-64	75.5	76.6
65-74	15.9	24.4
75+	20.0	24.8
Black/African American		
All ages	65.5	64.2
20-44	95.0	95.6
45-64	85.3	85.0
65-74	46.5	54.4
75+	55.5	60.1
Asian		
All ages	72.6	77.6
20-44	92.7	100.0
45-64	84.2	84.3
65-74	63.6	71.7
75+	76.2	79.0
Other races		
All ages	47.2	49.2
20-44	93.4	88.2
45-64	79.5	79.3
65-74	31.4	38.9
75+	43.6	48.5

vol 1 Table 7.3 Medicare Part D enrollees with the Low-income Subsidy, by age & race, 2015

Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1, 2015. Abbreviations: CKD, chronic kidney disease; Part D, Medicare prescription drug coverage benefit.

Table 7.3 reports the percentage of general Medicare and CKD enrollees who were eligible for the LIS, stratified by both age and race.

Several categories of Medicare beneficiaries automatically qualify for LIS and Part D benefits, and are considered to be 'deemed'. These individuals include full-benefit Medicare/Medicaid dual eligible individuals, partial dual eligible individuals, Qualified Medicare Beneficiaries (QMB-only), Specified Lowincome Medicare Beneficiaries (SLMB-only), Qualifying Individuals (QI), and people who receive Supplemental Security Income (SSI) benefits but not Medicaid. Other Medicare beneficiaries with limited incomes and resources who do not automatically qualify for LIS (non-deemed) can apply for LIS and have their eligibility determined by their State Medicaid agency or the Social Security Administration.

Figure 7.4 illustrates the distribution of Part D enrollees receiving the LIS across the benefit categories of premium subsidy and copayment. The largest group of LIS recipients who had CKD was eligible for a full premium subsidy—20.6% had a high copay, 30.2% had a low copay, and 39.8% had no copay.

vol 1 Figure 7.4 Distribution of Low-income Subsidy categories in Part D general Medicare and CKD patients, 2015



Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1, 2015. Abbreviations: CKD, chronic kidney disease; Part D, Medicare prescription drug coverage benefit.

Spending for Prescriptions

In 2015, total Medicare Part D spending for fee-forservice beneficiaries reached \$54.2 billion. This figure represents the sum of the Medicare covered amount and the LIS amount. Spending for beneficiaries with CKD was \$8.7 billion—about 16.1% of total Part D spending. Data over a five-year period shows a consistent trend of increasing costs; between 2011 and 2015 spending rose by 35.3% for general Medicare patients (14.1 billion) and 68.8% for Medicare CKD patients (\$3.6 billion; Table 7.4). This increase mirrors increase of CKD ascertainment in the same period.

vol 1 Table 7.4 Total estimated Medicare Part D spending for fee-for-service beneficiaries (in billions), 2011-2015

	General Medicare	All CKD
2011	40.1	5.2
2012	35.7	4.8
2013	45.7	6.8
2014	50.5	7.7
2015	54.2	8.7

Data source: Medicare Part D claims. Medicare totals include Part D claims for Part D enrollees with traditional Medicare (Parts A & B). CKD totals include Medicare CKD patients, as determined from claims. Abbreviations: CKD, chronic kidney disease; Part D, Medicare prescription drug coverage benefit.

CHAPTER 7: PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH CKD

Figure 7.5.a illustrates PPPY spending and patient out-of-pocket costs by type of coverage. In 2015, PPPY spending for CKD beneficiaries was 1.5, 1.7, and 4.5 times higher than for general beneficiaries of the Medicare Part D, Medicare Advantage, and managed care cohorts. Similar to patterns of spending, out-ofpocket costs for CKD patients were 1.5, 1.5, and 3.0 times higher than for general populations with Medicare Part D, Medicare Advantage, and managed care coverage. Out-of-pocket costs represented a larger share of total spending in the CKD and general Medicare Advantage cohorts (19.3% and 17.9%) and the general managed care cohort (18.6%) than in the CKD (12.6%) and general Medicare Part D (13.0%) groups and the CKD managed care cohort (13.3%).

Per patient per year spending for general and CKD Medicare Part D enrollees was further stratified by their LIS status (Figure 7.5.b). Total 2015 spending for Part D-covered medications was more than twice as high for beneficiaries with the LIS than for those without, regardless the presence of CKD. In the LIS populations, however, out-of-pocket costs represented only 1.3-1.4% of these total expenditures, compared to 26.2-28.1% in each of the non-LIS populations.

vol 1 Figure 7.5 Per patient per year & out-of-pocket costs (in \$1,000s) for enrollees, 2015



(a) All enrollees by type of insurance and modality



(b) Medicare Part D enrollees by Low-income Subsidy status

Data source: Medicare Part D claims and Optum Clinformatics^M claims. Medicare totals include Part D claims for Part D enrollees with traditional Medicare (Parts A & B). CKD totals include Medicare CKD patients as determined from claims. Costs are per person per year for calendar year 2015. Medicare total is the sum of Medicare net payment plus Low-income Supplement amount. Abbreviations: Gen., general enrollees; CKD, chronic kidney disease; Medicare adv., Medicare Advantage plans.

Total PPPY spending for prescriptions (excluding patient obligations) varied widely by coverage (Table 7.5). Overall, expenditures for beneficiaries with CKD were higher than in the general populations. Total PPPY prescription spending was highest in Medicare Part D beneficiaries with LIS for both the general and CKD populations (\$5,788 and \$8,145). For the general population cohorts spending was lowest in managed care (\$971), and for the CKD cohorts was lowest in Medicare Part D without LIS (\$2,658).

By race, PPPY spending was highest for Whites in populations covered by Medicare Part D with LIS and

managed care, but highest for Blacks in populations covered by Medicare Advantage plans and the CKD population covered by Medicare Part D without LIS. In each of the populations, spending was highest in the age 45-64 category, except for the general population covered by managed care and the CKD Medicare Advantage cohort.

As there are differences between the Medicare and Optum Clinformatics[™] beneficiary populations and in their methods of reporting costs, however, these results should be interpreted in those contexts.

	Medicare Part D with LIS, General	Medicare Part D with LIS, CKD	Medicare Part D without LIS, General	Medicare Part D without LIS, CKD	Medicare Advantage, General	Medicare Advantage, CKD	Managed care, General	Managed care, CKD
Age								
All	5,788	8,145	1,598	2,658	1,760	2,914	971	4,398
20-44	5,613	10,613	2,636	3,020	4,847	9,465	538	2,639
45-64	7,872	12,647	3,790	5,959	4,887	7,564	1,289	4,726
65-74	4,966	8,217	1,527	3,138	1,490	3,367	2,048	5,379
75+	4,146	5,802	1,450	2,212	1,348	2,206	2,725	3,824
Sex								
Male	5,877	8,816	1,749	2,891	1,740	2,828	945	4,651
Female	5,727	7,733	1,488	2,427	1,774	2,989	997	4,056
Race								
White	5,988	8,237	1,587	2,586	1,794	2,840	1,004	4,484
Black/African American	5,590	7,947	1,811	3,054	2,567	3,864	916	4,189
Asian	4,710	7,467	1,360	2,380	1,855	3,713	554	3,188
Other race	4,861	7,081	1,723	4,525	NA	NA	NA	NA

vol 1 Table 7.5 Per patient per year spending (\$) for enrollees, 2015

Data source: Medicare Part D claims and Optum Clinformatics™ claims. CKD determined from claims. Costs are per person per year for calendar year 2015. Medicare PPPY is the sum of Medicare net payment and the Low-income Supplement amount. LIS status is determined from the Part D enrollment. A person is classified as LIS if they are eligible for the LIS for at least one month during 2015. Abbreviations: CKD, chronic kidney disease; Part D, Medicare prescription drug coverage benefit.

Prescription Drug Classes

Ranking of the top 15 prescription drug classes used by CKD patients is based on the percentage of beneficiaries with at least one claim for a medication in that class during 2015. The proportion of patients using each drug class was somewhat lower for Medicare Advantage and managed care enrollees in the Optum Clinformatics[™] database than for

CHAPTER 7: PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH CKD

those having Medicare Part D. These differences could arise from plan effects such as coverage or care management activities, or from patient selection in the younger and healthier Optum ClinformaticsTM cohort. The most commonly used drug classes were similar between the different cohorts. The list was led by lipid-lowering agents, antibacterials, reninangiotensin-aldosterone system inhibitors, β -adrenergic blocking agents (Beta Blockers), analgesics, and antipyretics (Table 7.6).

vol 1 Table 7.6 Top 15 drug classes received by CKD cohorts in different health plans, by percent of patients, 2015

	Medicare Part D		Medicare Advantage		Managed Care	
Rank	C Drug class	%	Drug class	%	Drug class	%
1	Lipid-lowering agents	63.6	Lipid-lowering agents	53.4	Renin-angiotensin-aldosterone system inhibitors	51.4
2	Antibacterials	60.5	Renin-angiotensin-aldosterone system inhibitors	51.1	Antibacterials	49.5
3	Renin-angiotensin-aldosterone system inhibitors	58.1	Antibacterials	44.8	Lipid-lowering agents	48.0
4	β-adrenergic blocking agents	56.0	β-adrenergic blocking agents	42.9	Analgesics and antipyretics	41.7
5	Analgesics and antipyretics	49.4	Analgesics and antipyretics	37.9	β-adrenergic blocking agents	33.4
6	Diuretics	48.5	Diuretics	36.2	Antidiabetic agents	32.8
7	Antiulcer agents and acid suppressants	42.4	Calcium-channel blocking agents	32.5	Calcium-channel blocking agents	26.8
8	Calcium-channel blocking agents	39.1	Antidiabetic agents	31.6	Diuretics	25.8
9	Antidiabetic agents	36.9	Antiulcer agents and acid suppressants	30.3	Psychotherapeutic agents	23.1
10	Psychotherapeutic agents	36.8	Psychotherapeutic agents	26.4	Diabetic consumables*	21.8
11	Antithrombotic agents	31.4	Diabetic consumables*	22.7	Antiulcer agents and acid suppressants	21.2
12	Anticonvulsants	26.0	Antithrombotic agents	21.8	Adrenals	18.8
13	Thyroid and antithyroid agents	25.8	Thyroid and antithyroid agents	19.8	Anxiolytics, sedatives, and hypnotics	18.2
14	Anxiolytics, sedatives, and hypnotics	24.2	Anticonvulsants	18.3	Anticonvulsants	15.1
15	Adrenals	21.9	Vaccines	17.4	Thyroid and antithyroid agents	14.8

Data source: Medicare Part D claims and Optum Clinformatics™ claims. CKD patients with Medicare Part D stand-alone prescription drug plans in the Medicare 5% sample. Diabetic Consumables refers to blood glucose test strips, blood glucose meters/sensors, lancets, needles, pen needles etc.

For the CKD Medicare Part D cohort, antidiabetic agents required the greatest spending, at 19.4% of the total for this group. For the Medicare Advantage and managed care cohorts, antidiabetic agents accounted for 17.7% and 21.9% of total spending. Other costly medications include antineoplastic agents, antivirals, and lipid-lowering agents.

For an examination of the prevalence of cardiovascular agent use in Medicare beneficiaries, see Volume 1, Chapter 4, <u>Cardiovascular Disease in</u> <u>Patients with CKD</u>. This chapter includes comparisons by cardiovascular comorbidities, procedures, and CKD status.

vol 1 Table 7.7 Top 15 drug classes received by different CKD cohorts (Medicare Part D/Medicare Advantage programs/managed care health plans), by spending, 2015

Rank	Drug class	Spending (\$ in millions)	Percent of total spending (%)		
1	Antidiabetic agents	1,685.4	19.4		
2	Antineoplastic agents	994.6	11.4		
3	Antivirals	643.5	7.4		
4	Lipid-lowering agents	437.5	5.0		
5	Psychotherapeutic agents	386.7	4.4		
6	Antithrombotic agents	283.2	3.3		
7	Analgesics and antipyretics	262.3	3.0		
8	Anti-inflammatory agents	255.0	2.9		
9	Antiulcer agents and acid	246.8	2.8		
10	Anticonvulsants	231.1	2.7		
11	Disease-modifying antirheumatic agents	177.8	2.0		
12	Anticholinergic agents	174.5	2.0		
13	Antibacterials	154.0	1.8		
14	Vasodilating agents (respiratory tract)	150.9	1.7		
15	Central nervous system agents, miscellaneous	148.4	1.7		

(a) Medicare Part D

Table 7.7 continued on next page.

vol 1 Table 7.7 Top 15 drug classes received by different CKD cohorts (Medicare Part D/ Medicare Advantage programs/managed care health plans), by spending, 2015 (*continued*)

Rank	Drug class	Spending (\$ in millions)	Percent of total spending
1	Antidiabetic agents	109.2	17.7
2	Antineoplastic agents	63.3	10.3
3	Lipid-lowering agents	46.7	7.6
4	Antivirals	32.9	5.3
5	Diabetes consumables*	30.1	4.9
6	Psychotherapeutic agents	23.8	3.9
7	Antithrombotic agents	23.0	3.7
8	Analgesics and antipyretics	18.8	3.0
9	Anti-inflammatory agents	18.7	3.0
10	Renin-angiotensin-aldosterone system inhibitors	15.9	2.6
11	Antiulcer agents and acid	15.3	2.5
12	Anticonvulsants	14.8	2.4
13	Anticholinergic agents	11.9	1.9
14	Calcium-channel blocking agents	10.0	1.6
15	β-adrenergic blocking agents	9.4	1.5

(b) Medicare Advantage

(c) Managed care

Rank	Drug class	Spending (\$ in millions)	Percent of total spending
1	Antidiabetic agents	49.1	21.9
2	Antineoplastic agents	32.5	14.5
3	Antivirals	18.4	8.2
4	Lipid-lowering agents	13.4	6.0
5	Disease-modifying antirheumatic agents	8.7	3.9
6	Analgesics and antipyretics	7.9	3.5
7	Antithrombotic agents	6.8	3.1
8	Psychotherapeutic agents	6.5	2.9
9	Diabetic consumables*	6.2	2.8
10	Renin-angiotensin-aldosterone system inhibitors	4.3	1.9
11	Anti-inflammatory agents	3.7	1.6
12	Anticonvulsants	3.6	1.6
13	Antibacterials	3.3	1.5
14	Immunosuppressive agents	3.1	1.4
15	Immunomodulatory agents	2.8	1.3

Data source: Medicare Part D claims and Optum Clinformatics™ claims. CKD patients with Medicare Part D stand-alone prescription drug plans in the Medicare 5% sample. Medicare Part D spending represents the sum of the Medicare covered amount and the Lowincome Subsidy amount. Diabetic Consumables refers to blood glucose test strips, blood glucose meters/sensors, lancets, needles, pen needles etc.

Medications for Pain Management

Non-steroidal anti-inflammatory drugs (NSAIDs) and opioid analgesics are two of the primary drug classes used for pain management. Figures 7.6 and 7.7 display the state-specific proportion of CKD Medicare Part D beneficiaries who were prescribed NSAIDs or opioid analgesics in 2015.

Nationally, 14.7% of these patients used prescription NSAIDs at some time during the year. The Southern region demonstrated the highest proportion of use, including Alabama, Mississippi, Louisiana, and Oklahoma. As NSAIDs are widely available over-the-counter, however, these findings likely underestimate the proportions of actual NSAID use.

The national proportion of patients using opioid analgesics was higher, at 44.5%. Greatest by-state use occurred in the Mountain region (Montana, Idaho, and Utah) and the South Central region (Mississippi, Oklahoma, Arkansas, Alabama, Tennessee, and Louisiana). More than half of patients with CKD in these states had received opioid analgesics at some point in 2015. Medication use varies by CKD stage, so results may reflect differences in pain management strategies by state.

vol 1 Figure 7.6 Estimated utilization rate of prescription NSAIDs, by state, Medicare CKD Patients, 2015



Data source: Medicare Part D claims. CKD patients with Medicare Part D stand-alone prescription drug plans in the Medicare 5% sample. Abbreviations: NSAIDs, nonsteroidal anti-inflammatory agents. NSAIDs filled under Medicare Part D represent a fraction of actual NSAID use.

CHAPTER 7: PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH CKD

vol 1 Figure 7.7 Estimated utilization rate of opioid analgesics, by state, Medicare CKD Patients, 2015



Data source: Medicare Part D claims. CKD patients with Medicare Part D stand-alone prescription drug plans in the Medicare 5% sample.

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Notes



Chapter 8: Transition of Care in Chronic Kidney Disease

- In every age group, from 18-34 to 75 years and older, incidence rates for Department of Veterans Affairs (VA) patients were 20% to 40% lower than in the United States (U.S.) in general. Because VA patients are disproportionately male and non-white, the relative advantage to VA patients is even greater.
- Mortality rates continued to be highest in the first several months upon transition to dialysis, among both the 100,000 U.S. Veterans and 9,000 members of Kaiser Permanente of Southern California who transitioned to end-stage renal disease (ESRD) between 2007 and 2015.
- Over 20% of the more than 100,000 U.S. Veterans who transitioned to ESRD over a 7.5-year period (10/2007-3/2015) received antidepressant medications prior to transition (prelude period). After transition to ESRD (vintage period), the antidepressant prescription rate increased to almost 30%. Among these Veterans, the prevalence of depression and post-traumatic stress disorder exhibited an upward trend over nine consecutive years (2007-2015).
- Among the 90,676 Veterans who transitioned to ESRD with at least one documented comorbidity, 64% had congestive heart failure (CHF), 53% had diabetes mellitus (DM) with complications, and 55% had chronic obstructive pulmonary disease (COPD). Over a quarter of all these Veteran patients had a diagnosis of cancer (CA), and 33% had a prior myocardial infarction (MI).
- Among the 50,786 Veterans who transitioned to ESRD as an inpatient during a hospitalization, the most common primary admission diagnoses (causes) included 23% for acute kidney injury (AKI), 18% for hypertension (HTN), 11% for CHF, and 9% for chronic kidney disease (CKD). Septicemia-related hospital admissions also increased dramatically after ESRD transition.
- Congestive heart failure and AKI were the most common reasons for hospital admission prior to ESRD transition (prelude period), whereas dialysis access complications were the most common cause for hospitalization after ESRD transition (vintage period).
- Prelude trend analyses provided important information about changes in clinical and laboratory measures during the several years prior to transition to ESRD. For the 29,362 Veterans who transitioned to ESRD, measured serum phosphorus in the 36 months (3 years) prelude gradually increased from 4.0 mg/dL to above 5.5 mg/dL immediately prior to transition. After transition to dialysis, serum phosphorus levels dropped to below 5 mg/dL.
- The secular trends observed over nine consecutive years (2007-2015) suggest changes in practice patterns for Veterans with advanced CKD, resulting in lower blood hemoglobin (<9 g/dL) and lower eGFR values (<7 ml/min/1.73m²) in the finals days prior to transitioning to ESRD.

Introduction

The Transition of Care in Chronic Kidney Disease (TC-CKD) Special Study Center examines the transition of care to renal replacement therapy (RRT; i.e., dialysis or transplantation) in patients with verylate-stage (advanced) non-dialysis dependent (NDD) CKD. These are often people with an estimated glomerular filtration rate (eGFR) <25 ml/min/1.73 m². The primary databases used in these analyses were created from a linkage between the national USRDS data and two large longitudinal databases of NDD-CKD patients—the national Veterans Health Administration (VHA) database and the regional (Southern California) Kaiser Permanente (KP-SC) database. These linkages have allowed us to identify nearly all VHA and KP-SC patients who have transitioned to ESRD from the index point, 2007,

onwards. Each of these linked databases includes thousands of NDD-CKD patients who transitioned to ESRD each year, in whom historical data were examined from up to -5 (minus five) years prior to ESRD ("prelude" period) to +2 (plus two) years after ESRD transition (early "vintage" period).

In this USRDS Special Study operation, we have examined the recent national VHA and KP-SC cohorts of incident ESRD patients. We have provided pre-ESRD (prelude) data on all available ESRD transitions since 10/1/2007 among Veterans, and since 1/1/2007 among KP-SC patients. Analyses that examined 4-year (10/1/2007-9/30/2011) pre- and post-ESRD data of approximately 52,000 incident ESRD Veterans who transitioned to ESRD were presented in 2014 and 2015 Annual Data Report (ADR) chapters. In our 2016 ADR chapter, we presented 6.5-year (10/1/2007-3/31/2014) and 7-year (01/01/2007-12/31/2013) transition-to-ESRD data on approximately 85,000 incident ESRD Veterans across the entire nation and 8,038 KP-SC members in Southern California. In this 2017 ADR, we present 7.5year pre- and post-ESRD data on more than 100,000 incident ESRD Veterans who transitioned between 10/1/2007 and 3/31/2015. In this year's chapter, we feature, for the first time, several secular trends among pre-ESRD Veterans over nine calendar years, i.e., 2007 through 2015. As in the previous years, this chapter also includes KP-SC data over eight years (01/01/2007-12/31/2014), which includes 9,260 KP-SC members who transitioned to ESRD in Southern California.

As stated in the original goals of this Special Study Center, we have continued to test the hypotheses that a pre-ESRD (prelude) data-driven personalized approach to the transition of care into ESRD in verylate-stage NDD-CKD is associated with more favorable outcomes. We believe this is particularly true if decisions are based on pre-ESRD factors such as clinical and laboratory variables, including the CKD progression rate, comorbid conditions during prelude period, and demographics. We have published some of these concepts and data in the form of abstracts and 12 peer-reviewed manuscripts over the past two years.¹⁻¹² We have also developed and validated a scoring system derived from these pre-ESRD data to better ascertain the extent to which timing, preparation, and modality of ESRD may be associated with better outcomes.

The Veterans Health Administration

There are more than 20 million Veterans in the U.S.; approximately nine million are enrolled in the Veterans Health Administration (VHA), including approximately six million who receive their healthcare in one of the VHA facilities. Whereas approximately 90% of the U.S. Veteran population is presently male, it is estimated that in the next decade the proportion of females will rise to 18-20%.13-14 Minority Veterans currently comprise about 22% of the overall Veteran population, among whom the majority are of Black or African American race (12% of all Veterans) and Hispanic or Latino ethnicity (7% of all Veterans).¹⁵⁻¹⁶ Each year approximately 13,000 Veterans transition to RRT, mostly in the form of maintenance dialysis treatment.¹⁷ Among the more than 6,000 dialysis units nationwide, there are currently approximately 70 VHA dialysis centers.¹⁷ Given this number of VHA dialysis centers and their limited capacity, only 10% of all incident dialysis Veterans initiate treatment in a VHA center.¹⁷ Although almost 90% of the ESRD Veterans receive dialysis treatment in non-VHA facilities, including large dialysis organizations, the transition data of these and other outsourced Veterans and in particular, their prelude and early vintage analyses and other data, are also included in this chapter. Hence, our transition-of-care data for more than 100,000 (N=102,477) Veterans with ESRD are inclusive and comprehensive.

ESRD RATES AMONG VETERANS

As reported in previous ADR chapters on Transition of Care in CKD, on average 13,664 Veterans transitioned to ESRD each year over the period of 2007-2015, with an average national ESRD transition rate of 1,139 Veterans per month (see below for additional data and analyses on secular trend data). In this report, we have also calculated the ESRD incident rates for Veterans in each calendar year (January 1-December 31), instead of federal government fiscal year (October 1-September 30). The most updated U.S. Census data were accessed to obtain annual Veteran population data using the Census Fact Finder site.⁶

We calculated the counts of all Veterans in each year and per age strata (Table 8.1). The USRDS incidence rates for ESRD among U.S. adults were obtained from the 2016 Standard Analysis Files (SAFs)

for comparison. For the seven full calendar years between 2008 and 2014, the crude ESRD incident rates among Veterans were 635.3, 664.1, 646.5, 620.9, 635.6, 669.8, and 665.0 per million Veterans. Given the ESRD incident rates of 488.1, 499.6, 495.7, 482.4, 485.5, 484.7, and 492.0 per million per the general U.S. population (PMP), the calculated crude rate ratios of ESRD incidence among Veterans compared to the U.S. general population were 1.30, 1.33, 1.30, 1.29, 1.31, 1.38, and 1.35 for calendar years 2008 through 2014, suggesting that ESRD is 29-38% more likely to occur among Veterans than in the general U.S. population.

It is important to note, however, that the VHA population is considerably older than the general U.S. population. Hence, as stated in our 2016 ADR chapter,

on an age-specific and age-adjusted basis, the VHA rate of ESRD is 25-40% lower than the U.S. rate of ESRD. This lower-than-expected adjusted risk occurs despite the fact that the VHA population is predominantly male and disproportionately nonwhite. The remarkably lower adjusted rate of ESRD among VHA patients, despite higher crude ESRD incidence rates, is currently unexplained. Is it because the VHA provides an integrated health care system with better care to CKD patients, including Blacks, in whom higher CKD burden is well known? Is it because there is a selection bias of persons entering into military service, through healthier persons or those without preexisting kidney disease being selected to serve? Further research may shed some light on this issue.

vol 1 Table 8.1. Rates and ratio of incident ESRD Veterans among the veteran population and the U.S. adult population for calendar years 2008-2014 across five age strata of 18-34, 35-54, 55-64, 65-74, and 75+ years

(a) 18-34 years							
	2008	2009	2010	2011	2012	2013	2014
Incident ESRD Veterans	84	83	81	81	69	84	89
All Veterans	1,704,278	1,660,932	1,743,846	1,759,591	1,825,854	1,625,853	1,656,336
ESRD rate in Veterans, PM	49	50	46	46	38	52	54
Incident ESRD in U.S.	5,532	5,758	5,564	5,497	5,607	5,491	5,619
U.S. Population	71,037,035	71,579,121	71,981,752	72,914,022	73,727,483	74,436,376	74,980,662
ESRD rate in the U.S., PM	78	80	77	75	76	74	75
ESRD rate ratio (Vet: U.S.)*	0.63	0.62	0.60	0.61	0.50	0.70	0.72

(Table 8.1 continued on next page)

vol 1 Table 8.1. Rates and ratio of incident ESRD Veterans among the veteran population and the U.S. adult population for calendar years 2008-2014 across five age strata of 18-34, 35-54, 55-64, 65-74, and 75+ years *(continued)*

(b) 35-54 years

	2008	2009	2010	2011	2012	2013	2014
Incident ESRD Veterans	1,442	1,446	1,277	1,177	1,226	1,051	1,060
All Veterans	5,942,549	5,725,846	5,558,510	5,386,065	5,265,255	4,720,849	4,583,813
ESRD rate in Veterans, PM	243	253	230	219	233	223	231
Incident ESRD in U.S.	25,998	26,691	26,014	25,814	25,962	25,975	26,516
U.S. Population	87,002,075	86,590,351	85,977,283	85,433,299	84,892,906	84,384,863	83,971,984
ESRD rate in the U.S., PM	299	308	303	302	306	308	316
ESRD rate ratio (Vet: U.S.)*	0.81	0.82	0.76	0.72	0.76	0.72	0.73

(c) 55-64 years

	2008	2009	2010	2011	2012	2013	2014
Incident ESRD Veterans	3,342	3,511	3,357	3,247	3,084	2,769	2,610
All Veterans	5,718,302	5,441,739	5,340,529	5,085,647	4,564,636	3,976,482	3,640,087
ESRD rate in Veterans, PM	584	645	629	638	676	696	717
Incident ESRD in U.S.	26,043	27,163	27,661	27,635	28,743	28,598	29,344
U.S. Population	33,669,357	34,868,475	36,785,628	38,090,424	38,614,954	39,343,044	40,077,581
ESRD rate in the U.S., PM	773	779	752	726	744	727	732
ESRD rate ratio (Vet: U.S.)*	0.76	0.83	0.84	0.88	0.91	0.96	0.98

(d) 65-74 years

	2008	2009	2010	2011	2012	2013	2014
Incident ESRD Veterans	3,201	3,405	3,319	3,317	3,759	4,081	4,286
All Veterans	4,148,572	4,152,331	4,294,221	4,420,436	4,798,175	4,720,849	4,891,968
ESRD rate in Veterans, PM	772	820	773	750	783	864	876
Incident ESRD in U.S.	26,073	27,251	27,885	27,169	28,399	29,805	31,188
U.S. Population	20,098,221	20,781,497	21,857,563	22,495,852	24,010,384	25,228,428	26,398,290
ESRD rate in the U.S., PM	1,297	1,311	1,276	1,208	1,183	1,181	1,181
ESRD rate ratio (Vet: U.S.)*	0.59	0.63	0.61	0.62	0.66	0.73	0.74

(Table 8.1 continued on next page)

vol 1 Table 8.1. Rates and ratio of incident ESRD Veterans among the veteran population and the U.S. adult population for calendar years 2008-2014 across five age strata of 18-34, 35-54, 55-64, 65-74, and 75+ years *(continued)*

(e) 75 years or older								
	2008	2009	2010	2011	2012	2013	2014	
Incident ESRD Veterans	6,178	6,053	6,045	5,502	5,356	5,135	4,750	
All Veterans	4,911,012	4,851,671	4,839,173	4,806,688	4,776,945	4,544,552	4,468,254	
ESRD rate in Veterans, PM	1,258	1,248	1,249	1,145	1,121	1,130	1,063	
Incident ESRD in U.S.	28,849	29,384	29,466	28,605	28,001	27,849	28,011	
U.S. Population	18,671,803	18,846,651	18,621,790	18,870,776	19,154,525	19,494,613	19,844,921	
ESRD rate in the U.S., PM	1,545	1,559	1,582	1,516	1,462	1,429	1,411	
ESRD rate ratio (Vet: U.S.)*	0.81	0.80	0.79	0.76	0.77	0.79	0.75	

Data source: VHA Administrative data, USRDS ESRD Database, CMS Medicare Inpatient and Outpatient data, U.S. Census Bureau; data derived from U.S. veteran incident dialysis patients. *Veterans to U.S. rate ratios. Abbreviations: ESRD, end-stage renal disease; PM, per million; Vet, Veterans.

HIGHLIGHTS OF THE INCIDENT ESRD VETERANS POPULATION BETWEEN 10/1/2007 AND 3/31/2015

Between 10/1/2007 and 3/31/2015 (over 7.5 fiscal years), 102,477 Veterans transitioned to ESRD. The mean ± standard deviation age was 70.2 ±12.0 years, and included 25% patients of Black race and 6% of Hispanic ethnicity. The main causes of ESRD were DM (42%) or HTN (32%).

Across the nation, the distribution of patients with ESRD due to DM varied. Primarily, southwestern states, such as Texas, New Mexico, and Arizona had a higher proportion of patients with ESRD due to DM, while northern states such as Alaska, Oregon, Idaho, and North Dakota had lower proportions of ESRD due to DM (Figure 8.1).

vol 1 Figure 8.1. Distribution of diabetes (%) as the cause of ESRD among 102,477 incident ESRD Veterans across states and territories of the United States, 10/1/2007-3/31/2015



States and territories of the United States of America.

Out of 102,477 Veterans, there were 1,355 preemptive transplantations over 7.5 years in the entire nation. As in the general ESRD population, preemptive transplantation is fairly rare. Figure 8.2 shows the proportions of preemptive kidney transplantation in each state and territory of the U.S. The rates were calculated based on the number of preemptive transplants divided by the total number of the incident ESRD Veterans in that state or territory. The states with the highest preemptive kidney transplant rates among Veterans (>2.2%) were Alaska, Colorado, Delaware, Minnesota, Montana, Nebraska, New Mexico, Utah, Vermont, and Wyoming.





States and territories of the United States of America

NINE-YEAR SECULAR TRENDS AMONG Veterans who Transitioned to ESRD

Baseline characteristics of 102,477 incident ESRD Veterans were summarized by calendar year at transition to ESRD, and are shown in Table 8.2. Data were presented as mean ± standard deviation (SD) or median (interquartile range, IQR) for continuous variables, and percentages for categorical variables. Changes may occur in demographics, practice patterns, and clinical measures over a period of several years. In this year's TC-CKD chapter, we examine some of these secular trends.

In addition to renal disease, congestive heart failure (CHF), DM, and chronic obstructive

pulmonary disease (COPD) were present in over half of the Veterans. Of note, almost a quarter of all patients had a prior diagnosis of cancer (CA) and over 30% had a prior myocardial infarction (MI). The median (IQR) Charlson Comorbidity Index (CCI) score was 5 (3, 7), and 10% had a CCI of 10 or greater.

Among Veterans who transitioned to ESRD between 10/1/2007 and 3/31/2015, the mean age remained steady over time. The prevalence of Veterans who were Black, divorced, and had mild liver disease increased over time; however, the median CCI was the same each year. The percentage of Veterans who had ischemic heart disease decreased over time compared to earlier years of transition to ESRD. vol 1 Table 8.2. Baseline characteristics of 102,477 incident ESRD Veterans who transitioned to ESRD between 10/1/2007 and 3/31/2015 according to incidence year at transition to ESRD

	Incidence Year									
	Total	2007	2008	2009	2010	2011	2012	2013	2014	2015
N	102477	3575	14247	14498	14080	13326	13495	13122	12797	3337
Age (years)	70.2±12.0	69.7±12.1	70.1±12.2	70.0±12.2	70.4±12.1	70.3±12.1	70.2±11.9	70.4±11.7	70.1±11.8	70.3±11.6
Female (%)	7	6	6	7	6	7	7	7	7	8
Race (%)										
White	71	73	72	71	72	71	71	69	69	68
Black/African American	25	24	24	25	24	25	25	26	27	27
American Indian or Alaska Native	0.87	0.73	0.90	0.90	0.82	0.83	0.92	0.85	0.95	0.81
Asian	1.09	1.17	1.12	1.10	0.90	0.98	1.11	1.19	1.16	1.41
Native Hawaiian or Pacific Islander	0.07	0.03	0.05	0.08	0.08	0.06	0.05	0.09	0.07	0.21
Other or Multiracial	2.06	1.90	2.16	1.65	1.81	2.11	2.19	2.58	2.09	1.71
Unknown	0.02	0	0.02	0.02	0.02	0.02	0.05	0	0.01	0
Ethnicity (%)										
Hispanic	6	7	6	6	7	7	7	6	7	6
Non-Hispanic	3	3	4	3	3	3	4	4	4	4
Unknown	0.02	0	0.01	0.03	0.01	0	0.04	0.01	0.01	0
Non-Hispanic White	65	67	66	66	66	65	65	64	63	63
Non-Hispanic Black/African-American	25	23	24	25	24	25	25	26	27	27
Marital Status (%)										
Single	8	7	7	8	7	8	8	8	9	8
Married	61	63	62	62	62	61	62	61	60	60
Divorced	21	19	19	20	20	21	21	22	22	23
Widowed	10	11	12	11	11	10	10	9	8	9
Charlson comorbidity index	5 (3,7)	5 (3,7)	5 (3,7)	5 (3,7)	5 (3,7)	5 (3,7)	5 (3,7)	5 (3,7)	5 (3,7)	5 (3,7)

Table 8.2 continued on next page.

vol 1 Table 8.2. Baseline characteristics of 102,477 incident ESRD Veterans who transitioned to ESRD between 10/1/2007 and 3/31/2015 according to incidence year at transition to ESRD (continued)

	Incidence Year									
-	Total	2007	2008	2009	2010	2011	2012	2013	2014	2015
Comorbidity (%)										
Myocardial infarction	33	32	33	34	34	33	34	34	32	30
Congestive heart failure	64	63	64	64	65	64	64	65	63	59
Peripheral vascular disease	53	53	53	53	54	53	53	53	52	51
Dementia	6	6	6	6	6	6	6	6	5	4
Cerebrovascular disease	45	43	45	46	47	46	45	46	44	43
Chronic obstructive pulmonary disease	55	51	53	54	55	55	56	56	55	54
Connective tissue/Rheumatic disease	9	8	8	9	9	9	9	9	9	9
Peptic ulcer disease	12	10	12	12	12	12	11	12	12	10
Mild liver disease	16	14	14	15	16	16	17	17	18	18
Moderate/Severe liver disease	4	3	3	3	4	4	3	4	4	5
Diabetes without complications	19	20	20	19	19	18	18	18	18	19
Diabetes with complications	53	51	50	52	53	53	54	55	56	55
Cancer	27	26	26	27	28	27	26	27	27	28
Metastatic cancer	6	5	6	5	6	6	6	6	5	6
Hemiplegia	6	6	6	6	6	6	6	6	6	7
HIV/AIDS	1.0	0.8	1.1	1.0	0.9	1.1	1.0	1.0	1.2	1.1
Anemia	80	77	79	80	81	80	80	81	82	78
Atrial fibrillation	27	25	27	27	28	27	27	27	27	26
Depression	29	24	25	27	28	29	31	31	33	33
Hyperlipidemia	83	80	80	82	83	84	84	85	85	84
Ischemic heart disease	67	67	67	68	68	67	66	67	65	62
Post-traumatic stress disorder	7	4	5	6	7	7	8	9	10	10
Initial dialysis modality (%)										
Hemodialysis	81	83	82	83	81	81	80	80	80	80
Home hemodialysis	0.51	0.53	0.51	0.37	0.46	0.50	0.64	0.52	0.57	0.72
Peritoneal dialysis	6	5	5	5	6	6	7	7	7	7

Although the mean age remained steady over time, Figure 8.3 shows secular trends and changes in age groups across nine years (2007 through 2015) among the 102,477 Veterans who transitioned to ESRD during 10/1/2007-3/31/2015. During this period, the proportion of ESRD-transitioning Veterans decreased in the 40 - <60 year-old age group, but increased in the 60 - <80 year-old age group. Whereas the prevalence of Veterans in the <40 year-old age group remained steady, there was no clear trend among those older than 80 years.





Age group

Figure 8.4 shows the secular trends in dialysis modality on the first day of transition to ESRD, across nine incidence years, for 102,477 Veterans who transitioned to ESRD during 10/1/2007-3/31/2015. There was an increasing trend in peritoneal dialysis (PD) treatment as the initial modality, except for a decrease in 2015. This was likely due to seasonal variation effect, given that the 2015 data are limited to the first three months of that year. There also appears to be a slight downward trend in the prevalence of preemptive transplant cases, but there was no clear trend in home hemodialysis (HD) use.

vol 1 Figure 8.4. Secular trends in modality on the first day of transition to ESRD, stratified by incidence year in 102,477 Veterans who transitioned to ESRD during 10/1/2007-3/31/2015.



The drop in the prevalence of incident peritoneal dialysis patients in 2015 may have been influenced by the possibility of seasonal variation. Data for 2015 represent only the winter season, which includes months January to March.

Figure 8.5.a shows the secular trends in the pre-ESRD eGFR calculated by the CKD-EPI creatinine equation, for 25,035 Veterans who transitioned to ESRD during 10/1/2007-3/31/2015, and whose eGFR in the final 31 days of the prelude period was available. Over time, there was an upward trend in the proportion of patients with a last-31-day eGFR <7 ml/min/1.73m2, but a downward trend in the group with eGFR \geq 13 ml/min/1.73m². These secular trends may reflect changes in practice patterns towards deferred dialysis initiation in Veterans with advanced CKD.

Out of 102,477 patients, there were 55,814 patients who initiated dialysis during a hospitalization; of these, 11,520 and 5,528 had a listed primary cause of hospitalization as AKI and CHF. Figures 8.5.b and 8.5.c illustrate pre-ESRD secular trends of the last 31-day prelude eGFR among patients hospitalized by AKI or CHF at time of transition. Compared to all Veterans (Figure 8.5.a), a greater percentage of Veterans who were hospitalized due to AKI during transition to ESRD (Figure 8.5.b) started dialysis at lower eGFR levels of <7 mL/min/1.73m2. Conversely, a greater percentage of Veterans hospitalized due to CHF during transition to ESRD had a higher last 31day prelude eGFR level of ≥ 13 mL/min/1.73 m² (Figure 8.5.c). More analyses are needed to examine such practice pattern alterations over time, including across age and comorbid conditions.

vol 1 Figure 8.5 Secular trends in eGFR in the last 31 days of the prelude (pre-ESRD) time stratified by incidence year in 25,035 Veterans who transitioned to ESRD during 10/1/2007-3/31/2015.





(b) Veterans hospitalized by AKI at time of transition

Fig. 8.5 continued on next page.

vol 1 Figure 8.5 Secular trends in eGFR in the last 31 days of the prelude (pre-ESRD) time stratified by incidence year in 2,775 Veterans who were hospitalized during transition to ESRD due to acute kidney injury and who transitioned to ESRD during 10/1/2007-3/31/2015 (continued).



(c) Veterans hospitalized by CHF at time of transition

Figure 8.6 shows the secular trends in comorbidities over nine years for 90,676 Veterans who transitioned to ESRD during 10/1/2007-3/31/2015. Data related to comorbid conditions were obtained from multiple VHA and CMS sources, and were based on ICD-9 diagnostic codes. A total of 90,676 Veterans (88.4%) were identified from all sources as being diagnosed with at least one comorbid condition in the prelude period. Five selected comorbid conditions are shown in Figure 8.6. The prevalence of CHF remained steady, except for a slight drop in 2015. There were substantial upward trends in the frequency of depression and post-traumatic stress disorder, while a less substantial upward trend for diabetes was noticeable.

vol 1 Figure 8.6. Secular trends in comorbidities during the prelude (pre-ESRD) time stratified by calendar year in 90,676 Veterans who transitioned to ESRD during 10/1/2007-3/31/2015.



Abbreviations: CHF, Congestive Heart Failure; and PTSD, Post-Traumatic Stress Disorder

Figure 8.7 shows the pre-ESRD secular trends in last 31-day hemoglobin measurement during the prelude period in 23,333 Veterans who transitioned to ESRD during 10/1/2007-3/31/2015. Low hemoglobin levels <9 g/dL immediately prior to transition exhibited a remarkable upward trend, whereas there was a downward trend for hemoglobin levels of 10- <11 and \geq 11 g/dL. There was no clear trend in the group with a hemoglobin level of 9- <10 g/dL.

vol 1 Figure 8.7. Secular trends in hemoglobin in the last 31 days of the prelude (pre-ESRD) time stratified by incidence year in 23,333 Veterans who transitioned to ESRD during 10/1/2007-3/31/2015.



Figure 8.8 shows the secular trends in mortality according to days after transition to ESRD, stratified by calendar year for 102,477 Veterans who transitioned to ESRD during 10/1/2007-3/31/2015. The mortality incidence in the first 30 days after transition to ESRD

remained consistent among Veterans over the 9-year period. In the first 60, 90 and 365 days after transition to ESRD, there were slight spikes in mortality in years 2008 and 2015.





Figure 8.9 shows the secular trends in "recoveredkidney-function" status after transition to ESRD. These were patients who did not need to continue dialysis therapy after having started maintenance dialysis. The analysis was stratified by the number of days after ESRD transition, for 102,477 Veterans who transitioned to ESRD during 10/1/2007-3/31/2015. Among Veterans on dialysis, at 30, 60, and 90 days after dialysis initiation downward trends in recovered function were observed from 2013 through 2015. A less remarkable downward trend can be seen among Veterans on dialysis 365 days after transition to ESRD.

vol 1 Figure 8.9. Secular trends in "recovered-kidney-function" according to days after transition to ESRD stratified by incidence year in 102,477 Veterans who transitioned to ESRD during 10/1/2007-3/31/2015.



Data for 365 days after transition to ESRD in years 2014 and 2015 were not shown given incomplete longitudinal data.

FIRST THREE MONTHS AFTER TRANSITION TO ESRD

The status of incident ESRD Veterans during the first three months after transition to ESRD (10/1/2007-3/31/2015) is shown in Table 8.3. At ESRD service initiation, 81.0% and 6.2% of 102,477 Veterans received in-center HD or PD. Nearly the same number of Veterans continued to receive in-center HD or PD in the first 30 and 60 days after transition to ESRD, with a slight decrease of in-center HD use in the latter period. After 90 days of ESRD service, 90.9% and 7.9% of all Veterans receiving any dialysis treatment utilized in-center HD or PD (n=86,137 Veterans).

There were 1.3% (n=1,355) registered preemptive kidney transplant recipients at ESRD service initiation. Over the next 30 and 60 days after transition to ESRD, the percentage of kidney transplants remained steady at 1.4% (n=1,405 and n=1,474), but the percentage of deaths doubled from 3.1% (n=3,148) to 7.0% (n=7,135). During the first three months of the transition to ESRD, 10.1% (n=10,324) died, 1.5% (n=1,542) received a kidney transplant, and 3.8% (n=3,877) recovered from ESRD and stopped dialysis therapy. As shown in Figure 8.10, the crude annualized mortality rate among incident ESRD Veterans was higher during the initial months after ESRD transition, across all strata, including those hospitalized for AKI, CHF, or other causes, and those not hospitalized during transition to ESRD. The peaks in annualized mortality rates at about three months reflect the similar early excess mortality that is seen in the general ESRD population. Of note, the highest peak in annualized mortality rate in the early months after ESRD transition was seen in Veterans who were hospitalized due to CHF during transition to ESRD.

vol 1 Table 8.3. Status of 102,477 incident ESRD Veterans on Day 1, Day 30, Day 60, and Day 90 after transition to ESRD, 10/1/2007-3/31/2015

	Day 1		Day 30		Day 60		Day 90	
Modality	Frequency	%	Frequency	%	Frequency	%	Frequency	%
Hemodialysis	82985	81.0	82994	81.0	82835	80.8	78299	76.4
Home Hemodialysis	527	0.5	527	0.5	526	0.5	591	0.6
Peritoneal Dialysis	6353	6.2	6354	6.2	6352	6.2	6793	6.6
Uncertain Dialysis*	11257	11.0	6653	6.5	805	0.8	454	0.4
Transplant	1355	1.3	1405	1.4	1474	1.4	1542	1.5
Discontinued Dialysis			367	0.4	512	0.5	494	0.5
Death			3148	3.1	7135	7.0	10324	10.1
Lost to Follow-up			34	0.03	73	0.1	103	0.1
Recovered Function			995	1.0	2765	2.7	3877	3.8
Total	102477	100	102477	100	102477	100	102477	100

Data source: VHA Administrative data, USRDS ESRD Database, CMS Medicare Inpatient and Outpatient data. *Uncertain groups have no known dialysis modality.

vol 1 Figure 8.10. Annualized unadjusted mortality of incident ESRD Veterans who transitioned to ESRD during 10/1/2007-3/31/2015 and who were followed for up to 36 months, stratified according to cause of hospitalization during transition to ESRD (N=89,527).



*Abbreviations: ESRD, end-stage renal disease; hosp., hospitalization; AKI, acute kidney injury; CHF, congestive heart failure; and trans., transition.

DATA BEFORE, DURING, AND AFTER TRANSITION TO ESRD

In the section below, we illustrate the unique aspect of this Special Study Center cohort in the examination of the changes in medication prescriptions, cause of hospitalizations, and laboratory measurements throughout the transition period, including before (prelude), during, and after (vintage) transition. A deeper understanding of these changes can guide the personalized approach to transition of care into ESRD, and help produce outcomes that are more favorable for ESRD patients.

PRESCRIBED MEDICATIONS UPON TRANSITION TO ESRD

The Veteran ESRD population utilizes a number of medications, and the patterns of medication use vary before (prelude), during, and after (vintage) transition to ESRD. Both VHA prescription records and CMS Medicare Part D prescription records were used to describe medication use in 6-month intervals before (up to -3 years prelude), during, and after (up to +3 years vintage) ESRD transition. Seven groups of medications were analyzed, including (1) medication used for blood pressure management (alpha blockers, beta blockers, calcium channel blockers, potassium sparing diuretics, loop diuretics, RAAS inhibitors, thiazide diuretics, vasodilators, and central alpha agonists), (2) cholesterol lowering medications (statins and non-statin lipid lowering drugs), (3) diabetes medications (insulin and oral hypoglycemics), (4) anemia medications (erythropoietin stimulating agents [ESA] and iron), (5) mineral and bone disorder medications (native vitamin D, active vitamin D, calcium acetate, cinacalcet, lanthanum, sevelamer), (6) bicarbonate medication, and (7) antidepressants.

As shown in Figure 8.11, over 90% of patients were prescribed blood pressure lowering medications in the last three years of the prelude period prior to ESRD transition, and this persisted at a slightly lower rate during and throughout the post-transition or vintage period. More granular data on trends in blood pressure medication type are presented in Figure 8.12.a, where it is shown that RAAS inhibitors and loop diuretics were prescribed to over half of Veterans during the prelude time, while the use of thiazides, potassium sparing, and loop diuretics dropped dramatically after transition to ESRD.

Similarly, decreasing trends in the post-transition period were seen for cholesterol lowering drugs and diabetic medications (Figure 8.11). The decrease in diabetic medication prescriptions appears to be driven

by a drop in prescribing oral hypoglycemics in the post-transition period (Figure 8.12.b). Mineral and bone disorder medications (including phosphorous binders) were prescribed at a low rate during the prelude to ESRD, but a major surge was observed in the final prelude months immediately prior to transition to ESRD, followed by a substantial rise during the vintage period. More granular data on trends in mineral and bone disorder medication type are presented in Figure 8.12.c, which shows large surges in prescription of lanthanum and sevelamer after transition to ESRD, and that the calcimimetic agent cinacalcet was mostly prescribed in the vintage, but not prelude period.

Both anemia (ESA and iron) and bicarbonate medications had a modest surge in prescription during ESRD transition, and then rapidly declined post-transition (Figures 8.11 and 8.12.b). However, it should be noted that data on ESA, iron, and active vitamin D medication use in the vintage period after the transition to ESRD do not include these medications being administered in commercial dialysis clinics, and were therefore likely not wellcaptured by either the CMS or VHA databases. Finally, approximately 22% of Veterans received an antidepressant prescription during the prelude period. Antidepressant prescriptions increased slightly as patients approached ESRD transition, while rates increased approximately 3-5% to almost 30% of all Veterans in the post-transition period.

vol 1 Figure 8.11. Prescribed medication to incident ESRD Veterans who transitioned to ESRD during 10/1/2007-3/31/2015, with data up to -36 months prior to transition (prelude) and up to +36 months after transition (vintage; data were abstracted from 84,004 Veterans)



Abbreviations: ESRD, end-stage renal disease; mo, month.

vol 1 Figure 8.12. Granular prescribed medication data for incident ESRD Veterans who transitioned to ESRD during 10/1/2007-3/31/2015, with data up to -36 months prior to transition (prelude) and up to +36 months after transition (vintage; data were abstracted from 84,004 Veterans)



(b) Prescribed medications 10-15 60 Prescription drug period Prelude -36 to <-30 mo</p> Prelude -30 to <-24 mo</p> 40 Prelude -24 to <-18 mo</p> Percent (%) Prelude -18 to <-12 mo</p> Prelude -12 to <-6 mo</p> ■ Prelude -6 to <ESRD ■ Vintage ESRD to <6 mo ■ Vintage 6 to <12 mo Vintage 12 to <18 mo</p> 20 Vintage 18 to <24 mo</p> Vintage 24 to <30 mo</p> Vintage 30 to <36 mo</p> 0 Non-statins Statins Insulin Oral ESA* Iron* hypoglyc.

Figure 8.12 continued on next page.

172

vol 1 Figure 8.12. Granular prescribed medication data for incident ESRD Veterans who transitioned to ESRD during 10/1/2007-3/31/2015, with data up to -36 months prior to transition (prelude) and up to +36 months after transition (vintage) (data were abstracted from 84,004 Veterans) (continued)



*Data on EPO, iron and active vitamin D medication use in the vintage period were affected by these medications being administered in commercial HD units, and therefore, were probably not well-captured by either CMS or VHA databases. Abbreviations: ESRD, end-stage renal disease; mo, month; Ch, channel; diur, diuretics; Hypoglyc, hypoglycemics; ESA, erythropoietin stimulating agents; and Vit, vitamin.

HOSPITALIZATION PATTERN DURING TRANSITION TO ESRD

Data on hospitalizations for the 102,477 Veterans who transitioned to ESRD over 7.5 years (10/2007-3/2015) were collected from both inpatient and outpatient visits from VHA, CMS, and USRDS data sources. There were 89,552 patients, or 87% of all 102,477 ESRD transitioning Veterans, who were hospitalized at least once during a period of -5 years prior to (prelude) and +2 years after transition to ESRD (vintage). Table 8.4 shows a distribution of these hospitalization counts—77,709 (86%) were hospitalized during the prelude period, which includes Veterans who were hospitalized (1) only before, and (2) both before and after, transition to ESRD; and 12,453 (14%) were hospitalized only after but not before transition to ESRD. Among the Veterans who were hospitalized during the prelude period, 63% (n=48,414) were also hospitalized during transition to ESRD. Finally, of the Veterans who were hospitalized during the prelude and transition to ESRD periods, 40,690 (84%) were also hospitalized after the transition to ESRD.

vol 1 Table 8.4. Hospitalization events in 89,552 incident ESRD Veterans who transitioned to ESRD during 10/1/2007-3/31/2015

Hospitalized Prelude?	Hospitalized at time of ESRD?	Hospitalized after ESRD?				
		Yes				
	Yes*	N=40,690 (84%)				
	N=48,414 (63%)	No				
Yes		N=7,724 (16%)				
N=77,709 (86%)		Yes				
	No	N=9,111 (32%)				
	N=28,685 (37%)	No				
		N=19,574 (68%)				
		Yes				
	Yes**	N=2,372 (100%)				
	N=2,372 (19%)	No				
Νο		N=0 (0%)				
N=12,453 (14%)		Yes				
	No	N=10,081 (100%)				
	N=10,081 (81%)	No				
		N=0 (0%)				

Data source: VHA Administrative data, USRDS ESRD Database, CMS Medicare patient and Outpatient data. Data ranging from -60 months prior to transition (prelude) to +24 months after transition (vintage). *Among Veterans who were hospitalized during the transition to ESRD, included were hospitalizations that occurred (1) only during, and (2) both during and before, transition to ESRD. **Veterans who were hospitalized during the transition to the first day of dialysis treatment. Abbreviations: ESRD, end-stage renal disease.

Cause-specific hospitalization events were also analyzed based on the primary diagnosis. Figure 8.13 shows the top 20 causes of hospitalization among 89,552 Veterans who transitioned to ESRD over the 7.5-year period (10/2007-3/2015), and who had at least one hospitalization event from -5 years prelude to +2 years vintage surrounding the transition intercept. These hospitalizations were then divided into five temporal categories. The two prelude periods consisted of the final 12 months of prelude, and the time prior to these 12 months, where the patient discharge day was considered as prior to the transition to ESRD. The two vintage categories were the first six months of ESRD, and thereafter, where the admission day was after transition to ESRD. The fifth time group consisted of the hospitalization that included the ESRD initiation event or preemptive kidney

transplantation—any hospitalization that began in the prelude and ended in the vintage.

The top 20 causes of hospitalization included AKI, CHF, HTN, dialysis access complications (graft complication), septicemia, CKD, pneumonia, DM, atherosclerotic heart disease (ASHD), fluid overload (fluid disorder), acute MI, cardiac arrhythmias, rehabilitation, surgery (surgical complication), anemia, gastrointestinal (GI) hemorrhage, respiratory failure, skin infection (skin inf.), chest pain, and cerebrovascular disease (CVD). Of note, septicemiarelated hospital events increased dramatically after ESRD transition. The most common causes of hospital admission that also included the ESRD transition day were AKI, HTN, CHF, and CKD.

vol 1 Figure 8.13. Top 20 causes of hospitalizations in 89,552 incident ESRD Veterans who were hospitalized at least once during the 60 months prior to ESRD transition (prelude) up to 24 months after ESRD transition (vintage).

(a) Top causes of hospitalizations 1-10





Abbreviations: ASHD, atherosclerotic heart disease; CHF, congestive heart failure; CKD, chronic kidney disease; CVD, acute cerebrovascular disease; ESRD, end-stage renal disease; GI Hem, gastrointestinal hemorrhage; MI, myocardial infarction; mo, month; Resp Fail, respiratory failure; Skin Inf, skin infection; Rehab, rehabilitation; and surg, surgical.

Hospitalization events during each of the five aforementioned periods are ranked in Table 8.5. Congestive heart failure (CHF) and acute kidney injury were the most common primary reasons for hospital admission prior to ESRD transition (prelude period), whereas dialysis access complications were the most common cause after ESRD transition (vintage period). For hospitalizations that included the ESRD transition events, acute kidney injury (AKI) was the leading cause.

vol 1 Table 8.5. Ranking of the top 20 causes of hospitalization in 89,552 incident ESRD Veterans who were hospitalized at least once during the period of -60 months prior to transition (prelude) to +24 months after transition (vintage)

Cause of hospitalization	Whole cohort	Prelude 60 months to 12 <-12 months	Prelude 2 months to <esrd< th=""><th>During ESRD Transition</th><th>Vintage ESRD to <6 months</th><th>Vintage 6 months to <24 months</th></esrd<>	During ESRD Transition	Vintage ESRD to <6 months	Vintage 6 months to <24 months
Acute renal failure	1	2	1	1	8	
Congestive heart failure	2	1	2	3	4	3
Hypertension	3	6	3	2	2	5
Graft complication	4	12	11	11	1	1
Septicemia	5	14	5	5	3	2
Pneumonia	6	5	8	8	7	4
Diabetes	7	4	4	6	6	6
Atherosclerotic heart disease	8	3	9	12	15	11
Acute myocardial infarction	9	8	6	7	13	8
Fluid disorder	10	13	10	10	10	7
Cardiac dysrhythmias	11	7	12	14	11	10
Chronic kidney disease	12		7	4	5	15
Rehabilitation	13	10	15	13	9	12
Surgical complications	14	15	19	16	12	9
Gastrointestinal hemorrhage	15	16	16	15	16	14
Respiratory failure	16		14	9	14	13
Skin infection	17	9	17	18		18
Chest pain	18	11				16
Acute cerebrovascular disease	19	17			19	17
Anemia	20		13	17	20	
Chronic obstructive pulmonary		18	18			20
Urinary tract infection		19	20		18	
Osteoarthritis		20				
Other circulatory disease					17	19
Cancer of kidney and renal pelvis				19		
Aortic; peripheral; and visceral artery aneurysms				20		

Data source: VHA Administrative data, USRDS ESRD Database, CMS Medicare Inpatient and Outpatient data.

TRENDS DURING PRELUDE PERIOD (PRIOR TO ESRD TRANSITION)

Selected prelude (pre-ESRD) trends in laboratory data for up to five years prior to transition are shown below. Figure 8.14 shows the pre-ESRD trend in average blood hemoglobin in 55,329 Veterans who transitioned to ESRD over 20 quarters, or five years. Mean blood hemoglobin dropped from 13 g/dL to below 11 g/dL over the prelude period of progression from CKD to ESRD.

vol 1 Figure 8.14. Trend in blood hemoglobin level during the prelude (pre-ESRD) time over 20 quarters in 55,329 Veterans who later transitioned to ESRD during 10/1/2007-3/31/2015.



Figure 8.15 shows the pre-ESRD trend in averaged serum phosphorus in 29,362 Veterans who transitioned to ESRD over 36 months or three years.

Serum phosphorus increased from 4 to above 5.5 mg/dL immediately prior to transition to ESRD.

vol 1 Figure 8.15. Trend in serum phosphorus level during the prelude (pre-ESRD) time over 36 months in 29,362 Veterans who transitioned to ESRD during 10/1/2007-3/31/2015.



Figure 8.16 shows the pre-ESRD trends in average eGFR calculated by the CKD-EPI creatinine equation over 20 quarters (five years) for 57,615 Veterans who transitioned to ESRD, stratified by age and cause of ESRD. Figure 8.16.a shows that CKD patients who

transitioned at an older age had a slower rate of progression than younger patients. Figure 8.16.b suggests that those with DM as a cause of ESRD had a faster CKD progression.

vol 1 Figure 8.16. Trends in eGFR during the prelude (pre-ESRD) time over 20 quarters in 57,615 Veterans who transitioned to ESRD during 10/1/2007-9/31/2015. (a) Stratified by age at incidence,(b) Stratified according to ESRD etiology



(a) Prelude eGFR stratified by age at incidence



(b) Prelude eGFR stratified according to ESRD etiology

Figure 8.17 shows the pre-ESRD trend in glucose level by ESRD reason for 57,267 Veterans who transitioned to ESRD over 20 quarters, or five years. Patients whose ESRD was due to DM appeared to exhibit a gradual fall in serum glucose levels over time, as their CKD progressed to ESRD. Blood glucose levels did not change among patients whose ESRD was not due to DM.





COMPARING LABORATORY TRENDS DURING PRELUDE (PRIOR TO ESRD TRANSITION) AND VINTAGE PERIODS (AFTER ESRD TRANSITION)

The changes in clinical and laboratory values that occur when a patient with non-dialysis dependent CKD transitions to RRT are not well understood. Hence, in this year's TC-CKD chapter, we have compared trends in select relevant measures between the prelude and vintage periods. Figure 8.18 shows the pre- and post-ESRD trends in average blood hemoglobin levels in Veterans who transitioned to ESRD during 10/1/2007-3/31/2015 over (a) 20 and four quarters (N=58,281), respectively, and (b) over eight quarters each (N=54,526). In Figure 8.18.a, mean blood hemoglobin dropped from 13 g/dL to almost 10 g/dL over the prelude period (-20 quarters), then increased from above 10 g/dL to less than 12 g/dL over the vintage period (+4 quarters). Figure 8.18.b shows that blood hemoglobin dropped from 12 g/dL to almost 10 g/dL to almost 10 g/dL over the prelude period (-8 quarters), and then increased from above 10 g/dL to a steady level below 12 g/dL over the vintage period (+8 quarters).

vol 1 Figure 8.18. Pre- and post-ESRD trends in average blood hemoglobin levels in Veterans who transitioned to ESRD during 10/1/2007-3/31/2015 over (a) 20 and 4 quarters (N=58,281), and (b) 8 quarters each (N=54,526).





Figure 8.19 shows the pre- and post-ESRD trends in average sodium levels in Veterans who transitioned to ESRD during 10/1/2007-3/31/2015 over (a) 20 and 4 quarters (N=60,372), and 8 quarters each (N=56,729), respectively. Figure 8.19.a shows that mean sodium levels remained relatively steady at around 139 g/dL over the prelude period (-20 quarters), and then dropped to 138 g/dL in the vintage period (+4

quarters). In Figure 8.19.b, mean sodium levels remained at a steady average above 139 g/dL over the prelude period (-8 quarters) and then dropped to a steady average of 138 g/dL over the vintage period (+8 quarters).
CHAPTER 8: TRANSITION OF CARE IN CHRONIC KIDNEY DSEASE

vol 1 Figure 8.19. Pre- and post-ESRD trends in average sodium levels in Veterans who transitioned to ESRD during 10/1/2007-3/31/2015 over (a) 20 and 4 quarters (N=60,372) and (b) 8 quarters each (N=56,729).





(b) Average sodium levels during transition, -8 to +8 quarters

Figure 8.20 shows the pre- and post-ESRD trends in average albumin levels in Veterans who transitioned to ESRD during 10/1/2007-3/31/2015 over (a) 20 and 4 quarters (N=57,277), respectively, and (b) 8 quarters each (N=53,634), respectively. In Figure 8.20.a, mean albumin levels declined from 3.8 g/dL to less than 3.4 g/dL over the prelude period (-20 quarters), and then increased to almost 3.6 g/dL in the vintage

period (+4 quarters). Figure 8.20.b shows that mean albumin levels decreased from 3.6 g/dL to less than 3.4 g/dL over the prelude period (-8 quarters), and then returned to a starting pre-ESRD level of 3.6 g/dL over the vintage period (+8 quarters).

vol 1 Figure 8.20. Pre- and post-ESRD trends in average albumin levels in Veterans who transitioned to ESRD during 10/1/2007-3/31/2015 over (a) 20 and 4 quarters (N=57,277) and (b) 8 quarters each (N=53,634).





Figure 8.21 shows the pre- and post-ESRD trends in average white blood cells counts (an indirect surrogate of inflammatory conditions) in Veterans who transitioned to ESRD during 10/1/2007-3/31/2015 over (a) 20 and 4 quarters (N=58,322), and (b) 8 quarters each (N=54,811). In Figure 8.21.a, mean white blood cell levels remained consistent at 7.5 $103/\mu$ L, but increased to 8.0 $103/\mu$ L over the 20 quarters prior to

transition to ESRD, and then returned to pre-ESRD levels over the 4 quarters after transition to ESRD. Figure 8.21.b shows that mean white blood cells levels remained steady at 7.5 103/ μ L, but increased to 8.0 103/ μ L over the 8 quarters prior to transition to ESRD, and then returned to slightly lower than pre-ESRD levels over the 8 quarters after transition to ESRD. vol 1 Figure 8.21. Pre- and post-ESRD trends in average white blood cells levels in Veterans who transitioned to ESRD during 10/1/2007-3/31/2015 over (a) 20 and 4 quarters (N=58,322) and (b) 8 quarters each (N=54,811).







(b) Average white blood cells levels during transition, -8 to +8 quarters

Vol 1 Figure 8.22. Pre- and post-ESRD trends in blood glucose levels by ESRD-reason for (a) 60,103 Veterans who transitioned to ESRD during 10/1/2007-3/31/2015 over 20 and 4 quarters, and (b) 56,455 Veterans who transitioned to ESRD during 10/1/2007-3/31/2015 over 8 quarters in each period.





Figure 8.23 shows the pre- and post-ESRD trends in averaged serum phosphorus in 33,739 Veterans who transitioned to ESRD during 10/1/2007 to 3/31/2015 over 36 months or three years and 12 months or one

year. Serum phosphorus increased from 4.0 to above 5.5 mg/dL immediately prior to transition to ESRD, and decreased to a steady level below 5.0 mg/dL after transition to ESRD.

CHAPTER 8: TRANSITION OF CARE IN CHRONIC KIDNEY DSEASE

vol 1 Figure 8.23. Trend in mean serum phosphorus level during the prelude (pre-ESRD) and vintage (post-ESRD) times over 36 and 12 months, in 33,739 Veterans who transitioned to ESRD during 10/1/2007-3/31/2015.



Figure 8.24 shows the trends in prescribed phosphorus binders, mean serum phosphorus level, and mean serum calcium level for incident ESRD Veterans who transitioned to ESRD during 10/1/2007-3/31/2015 (N=84,004; N=37,789; and N=60,007), with data up to -36 months prior to transition (prelude) and up to +36 months after transition (vintage). The use of phosphorus binders starts to increase rapidly about a year before transition to ESRD and continues to climb for up to a year after transition. Concurrently, as the use of phosphorous binders increases surrounding the time of transition, serum phosphorus levels decrease and serum calcium levels rise.

Vol 1 Figure 8.24. Trends in prescribed phosphorus binders, mean serum phosphorus level and mean serum calcium level for incident ESRD Veterans who transitioned to ESRD during 10/1/2007-3/31/2015 (N=84,004; N=37,789; and N=60,007), with data up to -36 months prior to transition (prelude) and up to +36 months after transition (vintage).



Each unit on the x-axis represents a 6-month interval. Negative signs represent time prior to transition to dialysis, and positive signs represent time after transition to dialysis. Abbreviations: phos, phosphorus.

Data from Kaiser Permanente of Southern California

California is the most populous (38 million) and racially/ethnically diverse U.S. state. Southern California (SC) is the most populous mega-region of California with 23 million people (60% of California's population), and bears four of the nation's 50 most populated cities (Los Angeles, San Diego, Fresno, and Long Beach). It encompasses the Los Angeles Metropolitan region, including the >17 million people in Los Angeles and Orange Counties combined, and is the fifteenth largest economy in the world. In addition to substantial socioeconomic diversity, SC has remarkable racial/ethnic diversity that is reflective among the Kaiser Permanente Southern California member population.

Kaiser Permanente Southern California (KP-SC), the largest Kaiser Permanente region, is an integrated health care system that provides comprehensive health services for over 4.2 million members. Table 8.6 displays demographic characteristics of the KP-SC member population compared to the 2010 U.S. census and California populations. The KP-SC member population, like the California-specific total population, has greater racial/ethnic diversity as compared to the nation. The proportion of Hispanic patients at KP-SC matches that of the Californiaspecific total population. KP-SC also has a larger proportion of non-Hispanic Black, and a smaller proportion of non-Hispanic Asian patients than the California-specific total population. The proportion of males to females and distribution by age appears similar to both the U.S. census and California populations.

	KPSC (%)	U.S. census 2010 (%)	California 2010 (%)
Sex			
Male	48.2	49.2	49.7
Female	51.8	50.8	50.3
Age			
Under 5 years	5.8	6.5	6.8
5-17 years	19.1	17.5	18.6
18 to 24 years	8.7	9.9	10.5
25 to 44 years	26.1	26.6	28.2
45 to 64 years	28.2	26.4	24.9
65 years and over	12.1	13.0	11.4
Ethnicity			
Hispanic	37.6	16.3	37.6
Non-Hispanic	53.0	83.7	62.4
Unknown	9.4	۸	٨
Race			
White	47.7	76.2	40.1
Black/African American	9.8	14.6	5.8
American Indian/Alaska Native	0.4	0.9	0.4
Asian	9.1	5.6	12.8
Native Hawaiian/Pacific Islander	1.0	0.2	0.3
Other/Multirace	5.1	2.5	2.8
Unknown	26.3	۸	۸

vol 1 Table 8.6. Demographic characteristics of the Kaiser Permanente Southern California member population compared to the 2010 U.S. census and California populations

Data source: Kaiser Permanente Southern California Electronic Health Records, U.S. Census Bureau. Active KPSC Members (all medical centers) on June 30, 2010. Abbreviations: KPSC, Kaiser Permanente Southern California; US, United States. ^Data not available.

CHAPTER 8: TRANSITION OF CARE IN CHRONIC KIDNEY DSEASE

TRANSITION TO ESRD IN KAISER PERMANENTE OF SOUTHERN CALIFORNIA

The Kaiser Permanente transition to ESRD (TC-CKD) database is maintained by the KP-SC Renal Business Group, in which all members undergoing dialysis or transplantation were tracked through the health system's Renal Program, and regularly reconciled with internal dialysis unit census and outside claims. Patients' demographic informationincluding race, ethnicity, sex, and zip code-were linked to the KP-SC Membership and Benefit Research Data Warehouse created by the Research and Evaluation (R&E) Department. This mainly relies on four KP systems: the Operational Data Store (ODS), HealthConnect (HC), the Enhanced Prenatal Services System (PSS), and the Membership Extract Enrollment Management (MXEM) files. Other data such as socioeconomic information (education and household income) were collected from the KP-SC Geocoding database created by the R&E Department, in which three sources, including the U.S. Census, Claritas (i.e. Nielsen) and American Community Survey (ACS) five-year summary were combined. Mortality data of the ESRD population were obtained from the KP-SC Mortality database, which combines multiple data sources, including the California State Death Master Files, California State Multiple Cause of Death Master Files (MCOD), Social Security Administration (SSA) Death Master Files, KP-SC Hospital and Emergency Room (ER) records, KP-SC Membership System, Perinatal Data Mart (PDM), and Outside Claims Processing System (OCPS).

Over the eight years between 01/01/2007 and 12/31/2014, 9,260 KP-SC members transitioned to ESRD, i.e. dialysis and transplant patients. Crude and adjusted incidence rates are shown in Table 8.7. KP-SC incidence rates were lower than the U.S. general population, likely due to several different factors. These include an earlier and more standardized comprehensive delivery of care for the CKD population, and a population that may have been comprised of a larger proportion of people who were healthier and employed. KP-SC members were 62.6 ± 14.6 years old (mean \pm SD) and included 5,382 (58.1%) men and 3,878 (41.9%) women. Race/ethnic groups included non-Hispanic whites (2,750, 29.7%), Blacks (1,936, 20.9%), Asians (939, 10.1%), Hispanics (3,356, 36.2%), American Indians or Alaska Natives (19, 0.2%), Native Hawaiians or Pacific Islanders (129, 1.4%) and those of other race (64, 0.7%). According to KP-SC Renal Program records, the cause of ESRD was DM in 4,870 (52.6%) patients and HTN in 1,694 (18.3%). At transition to ESRD, 7,771 (83.9%) started on in-center HD, 1,236 (13.3%) started on PD (continuous ambulatory PD and continuous cycling PD), and 27 (0.3%) started on home HD. Among 7,798 patients starting on HD at transition, arteriovenous (AV) fistula was used in 2,875 (36.9%) and AV graft was used in 269(3.4%) patients for initial dialysis access. Pre-emptive transplant occurred in 174 (1.9%) cases at transition. During the first three months, 455 (5.0%) of all incident dialysis patients died.

	Number of incident ESRD patients	Number of KP-SC members	Crude incidence/ 1,000,000 person years	Age-, Sex-adjusted incidence/1,000,000 person years
2007	1,122	3,183,804	352.4	379.9
2008	1,101	3,200,101	344.1	362.2
2009	1,233	3,216,209	383.4	397.9
2010	1,218	3,247,766	375.0	381.3
2011	1,124	3,387,552	331.8	336.0
2012	1,102	3,485,161	316.2	314.4
2013	1,139	3,551,617	320.7	310.9
2014	1,221	3,667,316	332.9	317.2

vol 1 Table 8.7. Crude and age- and sex-adjusted incidence rates among Kaiser Permanente Southern California members who transitioned to ESRD between 1/1/2007 and 12/31/2014

Data source: Kaiser Permanente Southern California Electronic Health Records, U.S. Census Bureau. The United States census 2010 was used as the standard population. Abbreviations: ESRD, end-stage renal disease; KP-SC, Kaiser Permanente Southern California.

OUTCOMES OF KAISER PERMANENTE SOUTHERN CALIFORNIA PATIENTS WHO TRANSITIONED TO ESRD

The annualized mortality rates among the 9,086 incident dialysis patients over the first 24 months of the vintage period are depicted in Figure 8.25. The higher mortality rates in the first several months bear resemblance to that observed among Veterans with incident ESRD and the U.S. ESRD population overall.

Among patients dying early (two months after ESRD transition), 38.3% were hospitalized for AKI six months prior to ESRD transition compared to 19.4% who survived at least 12 months. Congestive heart failure was a primary cause of hospitalization six months prior to ESRD transition among the 27.0% of patients who died at two months compared to 11.4% who were alive more than 12 months. Table 8.8 shows the comparison of hospitalizations for CHF and AKI.

vol 1 Figure 8.25. Annualized unadjusted mortality of the 9,086 incident dialysis patients who transitioned to ESRD during 1/1/2007-12/31/2014 and were followed for up to 24 months



Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: ESRD, end-stage renal disease.

vol 1 Table 8.8. Comparison of hospitalizations for congestive heart failure and acute kidney injury for incident dialysis patients who died at two months vs. alive more than 12 months after ESRD transition

	Patients died at two months (N=167)	Patients survived more than 12 months (N=7,864)	
-	N (%)	N (%)	
Primary cause of hospitalization in 6 months prior to ESRD transition			
Congestive heart failure	45 (27.0)	893 (11.4)	
Acute kidney injury	64 (38.3)	1529 (19.4)	
Hospitalization related diagnosis in 6 months prior to ESRD transition			
Congestive heart failure	95 (56.9)	2179 (27.7)	
Acute kidney injury	134 (80.2)	3155 (40.1)	

Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: ESRD, end-stage renal disease.

CHAPTER 8: TRANSITION OF CARE IN CHRONIC KIDNEY DSEASE

TC-CKD COMORBIDITY DATA PRIOR TO ESRD **TRANSITION AT KAISER PERMANENTE SOUTHERN CALIFORNIA**

The comorbidity data for the prelude period were created from the KP-SC utilization database, which stores comprehensive patient diagnosis and procedure information from 1981 to the present. Pre-existing co-morbidities were determined by ICD-9-CM documentation in records from inpatient or outpatient settings in the three years prior to transition to ESRD. Among the top five comorbid

conditions seen in Figure 8.26.a, more than 65% of the 9,086 incident dialysis patients at KP-SC had DM with or without complications. Over a third of the ESRD patients had peripheral vascular disease or myocardial infarction. Cancer affected 11% of the ESRD patients.

A macro originally developed at Manitoba Centre for Health Policy (MCHP) website was used to estimate Charlson Comorbidity Index (CCI) scores as shown in Figure 8.26.b. A revised, weighted CCI score that excluded renal disease was calculated according to the formula below:

CCI = 1* Myocardial Infarction + 1* Congestive Heart Failure + 1* Peripheral Vascular Disease + 1* Cerebrovascular Disease + 1* Dementia + 1* Chronic Pulmonary Disease + 1* Rheumatic Disease + 1* Peptic Ulcer Disease + 1* Mild Liver Disease + 1* Diabetes without chronic complications

 $+ 2^*$ Diabetes with chronic complications $+ 2^*$ Paraplegia or Hemiplegia $+ 2^*$ Any Cancer

+ 3* Moderate or Severe Liver Disease

+ 6* Metastatic Carcinoma + 6*AIDS/HIV

The mean CCI was 4.1 ± 2.1 and 0.4% had a CCI of 10 or greater. The mean weighted CCI was slightly

greater, 5.4 ± 2.6 , and 5.6% of the persons with weighted CCI had a CCI of 10 or greater.

vol 1 Figure 8.26 Selected (a) comorbid conditions for calculation of the (b) Charlson Comorbidity Index, prior to transition to ESRD in 9,086 incident dialysis patients during 1/1/2007-12/31/2014



(a) Comorbid conditions

Figure 8.26 continued on next page

vol 1 Figure 8.26 Selected (a) comorbid conditions for calculation of the (b) Charlson Comorbidity Index, prior to transition to ESRD in 9,086 incident dialysis patients during 1/1/2007-12/31/2014 *(continued)*



Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: CHF, congestive heart failure; compl, complications; COPD, chronic obstructive pulmonary disease; CVD, cerebrovascular disease; dz, disease; ESRD, end-stage renal disease; MI, myocardial infarction; Mod, moderate; PVD, peripheral vascular disease; PUD, peptic ulcer disease; sev, severe.

SEASONAL TREND AMONG KAISER PERMANENTE Southern California Incident Dialysis Patients who Transitioned to ESRD

The seasonal trend of the 9,086 incident dialysis patients who transitioned to ESRD is shown in Figure 8.27. A greater number of patients transitioned to ESRD in the winter months of January, February and March, compared to the rest of the year. The least number of incident dialysis patients were in the month of November, where less than 700 patients transitioned to ESRD.

vol 1 Figure 8.27 Seasonal trend among 9,086 incident dialysis patients who transitioned to ESRD during 1/1/2007-12/31/2014



Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: ESRD, end-stage renal disease; Jan, January; Feb, February; Mar, March; Apr, April; Jun, June; Jul, July; Aug, August; Sep, September; Oct, October; Nov, November; Dec, December.

PRELUDE AND VINTAGE LABORATORY TRENDS OF TC-CKD DATA IN KAISER PERMANENTE SOUTHERN CALIFORNIA

These data were extracted from the KP-SC Laboratory database that tracks inpatient and outpatient laboratory orders and results, spanning over 20 years. Figures 8.28 and 8.29 show prelude variables (including serum creatinine and eGFR) averaged by 91-day quarters (n=20 quarters) among the 9,086 patients who transitioned to dialysis. In the 90 days immediately prior to transition, serum creatinine levels remarkably increased and eGFR levels decreased. Furthermore, the age-stratified eGFR trend over 20 quarters shows that older CKD patients had a slower progression rate than younger patients (Figure 8.30). KP-SC started at lower eGFR rates, by about 10 mL/min/1.73m² for each age group compared to the VHA population, but showed a similar age-related eGFR trend.

vol 1 Figure 8.28 Trend in serum creatinine level during the prelude (pre-ESRD) period over 20 quarters among 9,086 patients who transitioned to dialysis during 1/1/2007-12/31/2014



Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: ESRD, end-stage renal disease; mg/dL, milligrams per deciliter; p, percentile.

vol 1 Figure 8.29 Trend in eGFR during the prelude (pre-ESRD) period over 20 quarters among 9,086 patients who transitioned to dialysis during 1/1/2007-12/31/2014



Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: eGFR; estimated glomerular filtration rate; ESRD, endstage renal disease; mL/min/1.73m², milliliter per minute per 1.73 meters squared; p, percentile.

vol Figure 8.30 Trends in eGFR during the prelude (pre-ESRD) period over 20 quarters among 9,086 patients who transitioned to dialysis during 1/1/2007-12/31/2014, stratified by age-at-incidence



Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: eGFR; estimated glomerular filtration rate; ESRD, endstage renal disease; mL/min/1.73m², milliliter per minute per 1.73 meters squared.

Among the 9,086 patients who transitioned to ESRD, the next set of figures show selected KP-SC laboratory data for hemoglobin, hemoglobin A1C, phosphorus, parathyroid hormone, and albumin levels during the prelude (pre-ESRD) and vintage (post-ESRD) periods over eight prelude (quarters -8 to -1) and eight vintage (quarters o to +7) quarters (see Figures 8.31, 8.32, 8.33, 8.34, and 8.35). Mean hemoglobin levels gradually decreased from 11.70 g/dL to a nadir of 10.63 g/dL in the prelude period of progression from CKD to ESRD. Immediately after transition to ESRD, a slight increase in mean hemoglobin to 11.26 g/dL was observed in the first quarter (quarter o), followed by a rise to a peak of 11.65 g/dL in the second quarter (quarter 1). Subsequent mean hemoglobin decreased in vintage quarter 3 and later appeared stable (Figure 8.31).

vol 1 Figure 8.31 Trend in hemoglobin levels (g/dL) over 8 quarters each in the prelude (pre-ESRD) and vintage (post-ESRD) periods among 9,086 patients who transitioned to dialysis during 1/1/2007-12/31/2014



Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: ESRD, end-stage renal disease; g/dL, grams per deciliter; p, percentile.

In Figure 8.32, mean hemoglobin A1C levels dropped from 7.58% to 6.83% in the prelude period, then slightly decreased even further from 6.83% to 6.59% immediately after transition to ESRD. In the second quarter, post transition (quarter 1), mean hemoglobin A1C levels rose to 7.06% and remained stable afterwards in the vintage period.

vol 1 Figure 8.32 Trend in hemoglobin A1C levels (%) over 8 quarters each in the prelude (pre-ESRD) and vintage (post-ESRD) periods among 9,086 patients who transitioned to dialysis during 1/1/2007-12/31/2014



Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: ESRD, end-stage renal disease; p, percentile.

Mean phosphorus levels increased in the prelude period from 4.18 mg/dL to 5.19 mg/dL (Figure 8.33). Immediately after transition to ESRD, mean phosphorus decreased from 5.19 mg/dL to 4.40 mg/dL. In the third quarter post transition (quarter 2), mean phosphorus increased to 4.59 and remained stable in the vintage period.

vol 1 Figure 8.33 Trend in phosphorus levels (mg/dL) over 8 quarters each in the prelude (pre-ESRD) and vintage (post-ESRD) periods among 9,086 patients who transitioned to dialysis during 1/1/2007-12/31/2014



Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: ESRD, end-stage renal disease; mg/dL, milligrams per deciliter; p, percentile.

Figure 8.34 shows mean parathyroid hormone levels steadily increasing over the prelude and vintage periods from 139.22 pg/mL to 240.29 pg/mL.

Transition to ESRD did not appear to modify the increased trajectory of parathyroid hormone over time.

vol 1 Figure 8.34 Trend in parathyroid hormone levels (pg/mL) over 8 quarters each in the prelude (pre-ESRD) and vintage (post-ESRD) periods among 9,086 patients who transitioned to dialysis during 1/1/2007-12/31/2014



Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: ESRD, end-stage renal disease; pg/dL, picograms per deciliter; p, percentile.

Mean albumin levels dropped from 3.50 g/dL to 3.30 g/dL over the prelude period. Immediately after transition to ESRD, mean albumin increased to

3.36 g/dL in the first quarter to 3.66 g/dL in the fourth quarter (quarter 3) of the vintage period, and subsequently remained stable (Figure 8.35).

vol 1 Figure 8.35 Trend in albumin levels (g/dL) over 8 quarters each in the prelude (pre-ESRD) and vintage (post-ESRD) periods among 9,086 patients who transitioned to dialysis during 1/1/2007-12/31/2014



Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: ESRD, end-stage renal disease; g/dL, grams per deciliter; p, percentile.

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Volume 1: CKD Analytical Methods

Contents

Volume 1: CKD Analytical Methods	213
Contents	213
Introduction	214
Data Sources	214
National Health and Nutrition Examination Survey	214
Behavioral Risk Factor Surveillance System	214
Optum Clinformatics™ Data Mart Database (OptumInsight, Eden Prairie, MN)	214
Centers for Medicare and Medicaid Services Medicare 5% Sample	216
Enrollment Data (Denominator File)	216
Medicare Parts A and B Claims Files	216
Medicare Part D Files	217
Veterans Health Administration (VHA) Data	217
ESRD Medical Evidence Form (CMS 2728)	218
ESRD Death Notification Form (CMS 2746)	218
Race and Ethnicity	218
General Methods for Health Insurance Claim Data Files	219
Plan Participation	219
Medicare Reason for Entitlement	219
ESRD	219
Identification of Major Comorbidities	220
Chapter 1: CKD in the General Population	223
Chapter 2: Identification and Care of Patients with CKD	227
Chapter 3: Morbidity and Mortality	228
Chapter 4: Cardiovascular Disease in Patients with CKD	231
Chapter 5: Acute Kidney Injury	236
Chapter 6: Healthcare Expenditures for Persons with CKD	240
Chapter 7: Prescription Drug Coverage in Patients with CKD	241
Reference Tables	244
References	246

Introduction

In this chapter, we describe the data sources, preparation and management, variable definitions, and analytical methods used to produce the statistics presented in Volume 1 of the 2017 USRDS Annual Data Report (ADR), which focuses on chronic kidney disease (CKD) prior to end-stage renal disease (ESRD). We outline the detail regarding the datasets and methods used for ESRD analyses in the *ESRD Analytical Methods* chapter of Volume 2.

Enhancements for the 2017 ADR included conversion of our data and analyses from ICD-9-CM diagnosis and procedure codes to the newly introduced ICD-10-CM, and expansion of our application of Optum Clinformatics[™] and Veterans Health Administration data. This CKD Methods chapter does not address Chapters 8 and 9 of Volume 1, which were the product of a Special Study Center. Relevant methods are included within those chapters.

Data Sources

The USRDS uses several data sources to describe pre-ESRD kidney disease in the U.S. These contain data regarding patient diagnoses, demographic characteristics, healthcare procedures, prescription drug plan participation, and filled prescriptions. Data on the non-institutionalized, general population are from the National Health and Nutrition Examination Survey (NHANES) and the Behavioral Risk Factor Surveillance System (BRFSS). For patients with CKD, acute kidney injury (AKI) and related comorbidities, data from three healthcare systems were used: the standard Centers for Medicare and Medicaid Services (CMS) Medicare 5% sample, the Optum Clinformatics[™] Data Mart Database of people with commercial health insurance and Medicare Advantage plans, and the Veterans Health Administration (VHA) beneficiary data.

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY

NHANES is a series of health examination surveys conducted by the National Center for Health Statistics (NCHS) of the U.S. Centers for Disease Control and Prevention (CDC). Begun in 1959, NHANES was designed to monitor the health and nutritional status of the non-institutionalized civilian population in the U.S. In 1999, NHANES became a continuous, annual survey to provide for more timely and regular estimates; public-use data files are released every two years.

NHANES 1999–2014 are nationally-representative, cross-sectional surveys with a complex, stratified, multi-stage probability cluster sampling design that includes the selection of primary sampling units (counties), household segments within the counties, and sample persons from selected households (Johnson et al., 2013). Survey participants are interviewed in their homes and/or receive standardized medical examinations in mobile examination centers. African Americans, Mexican Americans, and individuals aged 60 or older are oversampled to improve the estimates for these subgroups.

BEHAVIORAL RISK FACTOR SURVEILLANCE System

The BRFSS is a series of telephone-based surveys of health-related risk behaviors, chronic health conditions, and use of preventive services; BRFSS sampling is designed to provide state-specific estimates (CDC, 2015). Like NHANES, it is also conducted by the CDC through the NCHS. BRFSS began in 1984 with 15 states, and expanded nationwide in 1993. As of 2011, in addition to traditional landline subscribers, cell phone users are included in the sample frame. A question regarding kidney health was added starting in 2012—specifically, respondents are asked, "Has a doctor, nurse, or other health professional ever told you have kidney disease? Do NOT include kidney stones, bladder infection or incontinence (Incontinence is not being able to control urine flow)." Allowable responses were "yes", "no", and "not sure", with additional coding for "refused to answer" and "missing/not asked." Of the 475,687 respondents in 2012, only 202 respondents refused to answer (0.04%), three were missing, and 1,322 answered "not sure" (0.28%). Data from 2012-2015 are used in the 2017 ADR.

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 the commercial insurance plans and Medicare Advantage plans of a large U.S. managed-care health insurance company. Included plan members are enrolled in both a medical and a prescription plan, and the sample represents all areas of the country.

The USRDS purchased data from OptumInsight. With our data delivery in 2017, OptumInsight expanded the number of diagnosis and procedure codes in the MEDICAL claims table from eight (five diagnosis codes and three procedure codes) to 25. This provides us the potential to detect more disease conditions and procedures than in the 2016 ADR.

The Optum Clinformatics[™] data license requires that their data not be merged with any other data files, so we are unable to match these individuals with the USRDS ESRD databases to comprehensively identify ESRD patients. Therefore, we assign these individuals a first service date for ESRD as the earliest date of either the first claim with a diagnosis of ESRD, a procedure code for outpatient dialysis, or a diagnosis related group (DRG) code for a kidney transplant surgery. See Table 10.1 for specific code values. **VOLUME 1: CKD ANALYTICAL METHODS**

through 2015 in the 2017 ADR. To comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and prevent the re-identification of individuals in the database, certain combinations of sensitive data elements are not allowed. OptumInsight provides the data as different 'views', each containing a limited amount of sensitive data. For this report, we use the Date of Death (DOD) view—detailed geographic and socio-economic data are not available in the files, but date of death is included. The other available data views do not contain date of death. Enrollment and member information, such as year of birth, sex, race/ethnicity, state of residence, and plan participation are contained in the MEMBER and MEMBER_DETAIL data tables.

All services for both inpatient and outpatient care are located in the MEDICAL claims data table, with the confinement ID $(conf_id)$ variable indicating inpatient institutional claims. Combined with the admission and discharge dates from the inpatient institutional claims, we identify all inpatient medical services performed for the patient during that time.

We present Optum Clinformatics[™] data from 2005

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

vol 1 Table 10.1 ICD diagnosis, CPT procedure, and DRG codes used to define ESRD in the Optum Clinformatics[™] and VHA datasets throughout Volume 1 of the ADR

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

The MEMBER and MEMBER_DETAIL tables were processed to create an enrollment table by deleting observations with data inconsistencies, and combining enrollment periods with a non-coverage gap of less than one month. Enrollment observations were dropped if (1) the year of birth variable, *yrdob*, was missing or zero, (2) the year of the plan coverage effective date, *eligeff*, was before the year of birth, (3) the year of plan coverage effective date was after the year of the death date, (4) the coverage ending date, *eligend*, was the same as or earlier than the coverage start date, or (5) the member had more than one year of birth reported and these differ by more than one year.

Observations from MEMBER_DETAIL with overlapping enrollment periods (defined as *eligeff* through *eligend*) are combined into one. Observations where the gap between the end date (*eligend*) of the first period (i.e., observation) and the start (*eligeff*) of the second period is less than one month are also combined, as beneficiaries with brief coverage lapses do not present as significantly different than those with continuous coverage.

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

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

CENTERS FOR MEDICARE AND MEDICAID SERVICES MEDICARE 5% SAMPLE

These files contain billing data from final action claims on behalf of Medicare beneficiaries; all adjustments have been resolved, and submitted to Medicare by healthcare providers for reimbursement. CMS and its contractors produce the 5% datasets by selecting all final action claims for Medicare beneficiaries whose CMS Health Insurance Claim (HIC) number has the last two digits of 05, 20, 45, 70 or 95. These five two-digit pairs were randomly selected to create a sample containing five percent of the total number of Medicare beneficiaries (Merriman and Asper, 2007).

The sample design creates a built-in longitudinal panel dataset as well as a nationally representative, yearly cross-section sample. Once in the sample, a beneficiary will remain a part of all future-year data files until death or a change to their HIC number. Since 2015, the USRDS Coordinating Center has received the data files from the Medicare Chronic Conditions Warehouse contractor. The files, described below, are collectively referred to in the ADR as the Medicare 5% files. The 2017 ADR includes all claims for care occurring up to December 31, 2015, that were submitted and processed by June of 2016.

ENROLLMENT DATA (DENOMINATOR FILE)

Since 2015, we have received two data files from the Master Beneficiary Summary File—one for Medicare Parts A and B (MBSF_AB_SUMMARY; formerly called the Denominator file) and another for Part D (MBSF_D_CMPNTS). The files provide 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]).

MEDICARE PARTS A AND B CLAIMS FILES

Claims files for Medicare Parts A and B are divided into two groups based on the type of healthcare provider—institutional or non-institutional (physician/supplier and durable medical equipment). Institutional claims are divided into five sets of files based on the type of medical service: INPATIENT, OUTPATIENT, and HHA (home health agency), HOSPICE, and SNF (skilled nursing facility) care. For each type of medical service we receive six files corresponding to different parts of the claim: (*<type of service>_BASE_* CLAIMS_J (the base claim file), *<type of service>* _REVENUE_CENTER_J (revenue center file), *<type of service>_CONDITION_CODES* (condition code file), *<type* of service>_OCCURRNCE_CODE (occurrence code file),
<type of service>_SPAN_CODES (span code file), and <type
of service>_VALUE_CODES (value code file).

Physician and supplier claims (also referred to as carrier claims) are received in one set for durable medical equipment (DME) and another for all other Part B covered services (BCARRIER). For each of these, we receive two files corresponding to different parts of the claim (*<type of service>_*CLAIMS_J (the base claim file) and *<type of service>_*LINE_J (the line item file).

MEDICARE PART D FILES

For Part D, we receive files on beneficiary information and prescription drug events (records of each prescription fill and refill, similar to a claim), as well as information about plan characteristics and premiums. The MBSF_D_CMPNTS file, mentioned above, contains monthly enrollment information for Part D program participation, type of plan, creditable coverage, eligibility for cost sharing and low-income subsidies, and additional information. The Part D Events (PDE) file contains all events related to final action claims for prescription drugs submitted by pharmacies on behalf of the Part D beneficiary. This dataset contains details about the drug (name, days supplied, dose, strength, quantity, etc.) and payment amounts.

In addition to these beneficiary and beneficiaryprescription fill level datasets, we also received files containing data about the Part D plan, prescribers, and pharmacies. For the 2017 ADR, we used the Plan Characteristics file (PLAN_CHAR) and premium (PREMIUM) files to report on the coverage gap and distribution of premiums.

VETERANS HEALTH ADMINISTRATION (VHA) DATA

In 2016, we introduced data on kidney disease from the Veterans Health Administration's (VHA), and we update those analyses and present new tabulations for the 2017 ADR. Data are primarily from the VHA Corporate Data Warehouse (CDW) supplemented by

VOLUME 1: CKD ANALYTICAL METHODS

laboratory results from the Managerial Cost Accounting (MCA, formerly Decision Support System, DSS) National Data Extract LAR file. Data is accessed through and stored in the VA Informatics and Computing Infrastructure (VINCI). Data in the CDW is refreshed nightly from the VHA's electronic medical record, and the analyses in the 2017 ADR were based on a cohort created by the VINCI data manager on April 21, 2017. Our basic cohort was defined as all patients with at least one outpatient encounter (a record in the VISIT table in the OUTPAT domain) during calendar year 2015. Age, sex, race, and date of death were taken from the PATIENT.PATIENT table, and race was supplemented with data from the PATSUB.PATIENTRACE table. Ethnicity is from PATSUB.PATIENTETHNICITY.

In the CDW, various types of inpatient care provided by the VHA are included in the INPAT.INPATIENT table. These include the stays at short-term hospitals that are commonly thought of when referring to hospital care, but also admissions to rehabilitation hospitals, long-term care facilities, and the VA's Domiciliary Residential Rehabilitation Treatment Programs, among others. We identified short-term hospital stays by requiring the *medical_service* variable to have one of the following values: medicine, surgery, psychiatry, spinal cord injury, intermediate medicine, or neurology. Additionally, the *specialty* variable must also have had a value related to the type of care provided in shortterm hospitals¹.

Serum creatinine laboratory test results are obtained from the MCA_LAR file. The variable *dsslarno* denotes the type of laboratory test result in each observation; a value of '31' denotes serum creatinine. Lab results are categorized using the result date variable (*res_date*) rather than the order date, collection time, or date of the visit associated with the lab order. Records with text in the result field (such as COMMENT, CANC, PENDING, etc.) are dropped, as are those with values less than 0.4 mg/dL or greater than

¹ Contact <u>usrds@usrds.org</u> to request a detailed listing of all SPECIALTY variable values.

15.0 mg/dL for the CKD analyses (20.0 mg/dL for the AKI analyses).

ESRD MEDICAL EVIDENCE FORM (CMS 2728)

The analyses in this volume of the ADR often exclude patients with ESRD or censor time-dependent outcomes at the point when a patient reaches ESRD. To obtain this information, we search the USRDS ESRD databases for the beneficiaries in the Medicare 5% files. The date of ESRD is determined from the ESRD Medical Evidence form (CMS 2728), the official form for registering ESRD patients, that must be submitted by dialysis or transplant providers within 45 days of ESRD initiation. First service date for ESRD is reported on this form; for analyses in Volume 2 it is used as the date when ESRD began. See Volume 2, *ESRD Analytical Methods* for additional information on how the Medical Evidence form was used in analyses of ESRD patients.

ESRD DEATH NOTIFICATION FORM (CMS 2746)

The Master Beneficiary Summary File delivered with the Medicare 5% sample files contains the date of death as reported to Medicare. For this volume, we supplement this date of death for patients in the Medicare 5% file who experienced ESRD prior to death with information from the ESRD Death Notification form (CMS 2746; the official form for reporting the death of a patient with ESRD). According to CMS policy, dialysis or transplant providers must submit this form within 30 days of a patient's death.

Race and Ethnicity

Throughout the ADR, race and ethnicity categorizations are limited by what distinctions are available in the original data sources. The race variables for the CKD volume are different from those available in the ESRD volume, so we are unable to replicate the new race/ethnicity categories implemented in the 2017 ADR. Table 10.2 shows the categories included in the original data files. For the Medicare 5% files and Optum Clinformatics[™] Data Mart, we were unable to consider ethnicity as separate from race or to separate Pacific Islanders from other categories (Asian or Other). Additionally, we cannot identify Native Americans in the Optum Clinformatics[™] data. The NHANES, BRFSS, and VHA data report two variables, one with race categories, and a second designating Hispanic ethnicity. These categories are combined for some analyses due to the small sample sizes in some datasets.

Race/Ethnicity Variables	NHANES	BRFSS	Medicare 5% data	Clinformatics™ Data Mart	Veterans Health Administration
Separate variable for Hispanic?	Х	Х			Х
Race Variable Categories					
White	х	х	х	х	х
Black/African American	х	х	х	х	х
Hispanic	Separate	Separate	х	х	Separate
Native American	х	х	х		х
Asian	х	х	х	х	х
Pacific Islander/Native Hawaiian	х	х			х
Other	х	х	х		х
Unknown/missing/refused	х	х	х	х	х

vol 1 Table 10.2 Race and ethnicity variables in the Volume 1 data sources

VOLUME 1: CKD ANALYTICAL METHODS

General Methods for Health Insurance Claim Data Files

For the purpose of analysis, several restrictions are applied to the claims data files to create a sample cohort. The individual restrictions that are used for each figure and table are detailed in the chapterspecific sections of this chapter. The general rationale and explanation of these restrictions apply to all analyses with the health system data files and are detailed here. It is important to remember that the primary purpose of the data collection underlying these datasets is to reimburse healthcare providers for services performed for beneficiaries. Information that is not necessary to facilitate payment for services, such as results of lab tests, family medical history, or health behaviors such as smoking, generally is not available in the dataset.

PLAN PARTICIPATION

Medicare currently provides medical benefits through four programs commonly known by the part of Title XVIII of the Social Security Act that created them. Part A provides hospital insurance, Part B provides supplemental medical insurance (including physician services, durable medical equipment, ambulance, radiology, and laboratory services), Part C is for enrollment in managed care plans (which provide all part A and part B services), and Part D provides prescription drug coverage (CMS, 2014).

Part A coverage is free to beneficiaries, while the other parts can have premiums paid by the beneficiary and are optional. Beneficiaries are also allowed to switch between Original Medicare (fee-for-service) and Medicare Advantage plans (Part C) during open enrollment. Medicare Advantage plan providers are not paid through the claims submission process, therefore, there are no data in the Medicare 5% claims files for these patients.

Over the course of a year, people become newly eligible for Medicare (e.g., reach age 65) and enroll in the program, people die and therefore are not eligible during part of the year, and people drop their coverage. To create appropriate denominators for the statistics that are presented, samples are often limited to beneficiaries that are enrolled in both Parts A and B and are not enrolled in a Medicare Advantage plan (Part C). In the Optum Clinformatics[™] Data Mart, plan enrollment intervals are provided in the MEMBER_DETAIL table with a start date (*eligeff*) and an end date (*eligend*). In some analyses for both datasets, the cohort is limited to patients who meet these plan participation requirements on a certain date, such as January 1 of the reported year. In other cases the sample may have been limited to beneficiaries who meet those enrollment requirements during the entire calendar year.

In most analyses that are limited to patients with a certain disease or disorder, such as CKD, Medicare beneficiaries must be enrolled in Parts A and B and not Part C for the year prior to the reported year (the entry period or 'year one'), while Optum Clinformatics[™] patients must be enrolled in their plan for the year. This ensures that each patient has 12 months of claims from which to determine the presence of the disorder. The outcome under analysis is then determined from claims in the year following the entry period ('year two'). Prevalence analyses, however, are not subject to this requirement and use claims during the reported year (the typical year two) to determine the presence of the disorder.

MEDICARE REASON FOR ENTITLEMENT

In this volume, the majority of analyses are restricted to beneficiaries that were age-eligible for Medicare and, therefore, aged 65 and older. Beneficiaries under the age of 65 may qualify for Medicare based on disability (meeting requirements for one of the Social Security Administration's income support programs for disabled individuals) or diagnosis of ESRD (patients that are excluded from the CKD volume) and are not representative of the U.S. population of the same age. In contrast, 98% of the U.S. population aged 65 and older is eligible for Medicare (McBean, 2012). However, unlike the chapter-specific figures and tables, the Reference Tables that accompany this Volume include all adult (aged 20 or older), non-ESRD Medicare beneficiaries regardless of reason for entitlement.

ESRD

As the focus of this volume is on patients that do not have ESRD, Medicare patients under age 65 who were only eligible for Medicare due to ESRD are excluded. The Optum Clinformatics[™] Data Mart cannot be linked to the USRDS ESRD database due to

licensing restrictions, so the identification of ESRD patients is from diagnosis and procedure codes from claims. Most analyses for both data sources restrict the sample to beneficiaries/plan members that do not have ESRD, either as of a certain date or for the entire calendar year. Additionally, analyses of time-to-event outcomes (e.g., mortality, hospitalization, readmission, time to the performance of a laboratory test) often censor a patient at the start of ESRD. Censoring also often occurs at death, upon change in plan enrollment (for Medicare beneficiaries, the disenrollment from Parts A and B of Medicare orwhen switching to a Medicare Advantage plan, and for Optum Clinformatics[™] patients at the end of plan participation as reported by the *eligend* variable). The start of ESRD is the date of first service from the CMS 2728 form for Medicare patients and the date of the first claim with an ESRD diagnosis, outpatient dialysis procedure, or transplant hospitalization for Optum Clinformatics[™] plan members (starting in 2004 through the most recent year).

Identification of Major Comorbidities

We employ a previously validated method (Herbert et al., 1999) to identify diabetic patients through Medicare claims. A patient is considered diabetic if, within a one-year observation period, he or she had a qualifying ICD-9-CM or ICD-10-CM diagnosis code of diabetes mellitus (DM) on one or more Part A institutional claims (inpatient, skilled nursing facility, or home health agency), or on two or more institutional outpatient claims and/or Part B physician/supplier claims. This algorithm—one inpatient claim or two outpatient claims with specified diagnosis codes—is used to determine the presence of CKD and 13 other conditions commonly associated with CKD as risk factors, co-occurring conditions, or consequences of the disease. This same algorithm is also applied to the claim data in the Optum Clinformatics[™] Data Mart with the inpatient/outpatient determination made by determining if the service date fell within an inpatient confinement identified by the confinement ID (admission and discharge dates calculated from the first and last date of the claims with a specific confinement ID). Tables 10.3 and 10.4 list these conditions and the ICD-9-CM and ICD-10-CM diagnostic codes used to define them. Additionally, the overall grouping of cardiovascular disease (CVD) includes patients with at least one of these individual conditions: coronary artery disease (formerly called atherosclerotic heart disease), heart failure (HF; formerly called congestive heart failure), cerebrovascular accident/transient ischemic attack, peripheral vascular disease, dysrhythmias, or other cardiac conditions. Analyses within individual chapters also defined additional conditions using the same algorithmic structure, as described in the chapter-specific sections below.

vol 1 Table 10.3 ICD-9-CM and ICD-10-CM diagnosis codes used to define chronic kidney disease in the health insurance claim data files throughout Volume 1 of the ADR

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

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

vol 1 Table 10.4 ICD-9-CM and ICD-10-CM diagnosis codes used to define medical conditions in the health
insurance claim data files throughout Volume 1 of the ADR

Condition name	ICD-9-CM codes	ICD-10-CM codes
Anemia	280-285	D50.0-D64.9
Cancer	140-172; 174-208; 230-231; 233-234	C00.0-C43.9; C45.0-C75.9; C76.0-D03.9; D05.00-D09.9
Cardiac, other	420-424; 429; 785.0-785.3; V42.2; V43.3	A18.84; I23.0-I23.8; I25.10; I30.0-I39; I51.0- I52; I97.0-I97.191; M32.11; M32.12; R00.0; R00.2-R01.2; Z95.2-Z95.4
Cerebrovascular accident (CVA) / transient ischemic attack (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
Chronic obstructive pulmonary disorder (COPD)	491-494; 496; 510	J41.0-J47.9; J86.0; J86.9
Coronary artery disease (CAD)	410-414; V45.81; V45.82	112.00-122.9; 124.0-125.9; Z95.1; Z95.5; Z98.61
Diabetes mellitus (DM)	250; 357.2; 362.0; 366.41	E08.311-E08.36; E08.40; E08.42; E09.311- E09.36; E09.40; E09.42; E10.10-E13.9
Dysrhythmia	426-427; V45.0; V53.3	I44.0-I49.9; R00.1; Z45.0-Z45.09; Z95.0; Z95.810; Z95.818; Z95.9
Gastrointestinal bleeding disorders (GI)	456.0-456.2; 530.7; 531-534; 569.84- 569.85; 578	185.00-185.11; K22.6; K25.0-K28.9; K55.20; K55.21; K56.60; K92.0-K92.2
Heart failure (HF)	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 422; 425; 428; V42.1	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
Hypertension (HTN)	362.11; 401-405; 437.2	H35.031-H35.039, I10-I13.2, I15.0-I15.9, I67.4, N26.2
Liver disease	570-571;572.1, 572.4; 573.1-573.3; V42.7	B25.1; K70.0-K72.01; K73.0-K74.69; K77; Z48.23; Z94.4
Peripheral vascular disease (PVD)	440-444; 447; 451-453; 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-I82.91; K55.0; K55.1; K55.8; K55.9; M31.8; M31.9

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

The U.S. federal government changed from using the International Classification of Diseases, Ninth Revision (ICD-9) coding system to using the ICD-10 coding system at the start of fiscal year 2016, which was October 1, 2015. Therefore, there are 3 months of claims in calendar year 2015 that use the ICD-10-CM code frame. To identify the ICD-10 codes that indicated the chronic conditions previously identified by ICD-9 codes, we used the CMS General Equivalence Mapping (GEM) dataset. There is not a one-to-one match between ICD-9 and ICD-10 codes in the GEM, but rather a one-to-many match in both directions; an ICD-9 code can match to multiple ICD-10 codes and an ICD-10 code can match to multiple ICD-9 codes. We then looked at counts and percentages for each comorbidity for 2013, 2014, and 2015 to note any changes in the monthly pattern starting in October 2015.While the overall numbers reasonably matched the results from prior years, a detailed review of the ICD-10-CM codes will be performed in the coming year.

Chapter 1: CKD in the General Population

Analyses in this chapter use data collected through the NHANES, a nationally representative survey that combines interviews and medical examinations to assess the health of the U.S. non-institutionalized civilian population (Johnson et al., 2013). Starting in 1999-2000, the NHANES collects data continuously and releases public-use data files in two-year cycles. Data for this chapter represents participants 20 years and older in four clusters of NHANES continuous cycle years 1999-2002, 2003-2006, 2007–2010, and 2011-2014. The statistical software package SAS[®] was used to analyze all NHANES data, incorporating the sampling weights and survey design through its survey procedures.

In this chapter, age is defined as the participant's age at the time of the NHANES household interview, categorized into the following age groups: 20 to 39, 40 to 59, or 60 and older. Race and ethnicity are self-reported and categorized as non-Hispanic White, non-Hispanic African American, or other. The identification of CKD is based on the 2012 guidelines

VOLUME 1: CKD ANALYTICAL METHODS

from the Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group (KDIGO, 2013), which was implemented with the data available in NHANES. KDIGO defines CKD as "abnormalities of kidney structure or function, present for >3 months, with implications for health." Decreased glomerular filtration rate (GFR) is defined as GFR less than 60 ml/min/1.73 m², calculated using the Chronic Kidney Disease-Epidemiology Collaboration (CKD-EPI) estimated glomerular filtration rate (eGFR) equation (Levey et al., 2009). Markers of kidney damage include albuminuria, a history of kidney transplantation, and abnormalities as detected by histology or in urine sediment, electrolytes (due to tubular disorders), or structure (detected by imaging). With NHANES data we use the urine albumin creatinine ratio (uACR) to measure albuminuria, but there is no information regarding the other markers of kidney damage. Also, the NHANES only includes a single measurement of both serum creatinine (sCR, used to generate eGFR) and uACR, so we cannot address the three-month persistence criteria for defining CKD; the implications of this are discussed in detail in the chapter.

The eGFR (measured in ml/min/1.73 m²) was calculated using the CKD-EPI equation, based on the NCHS-recommended standardized creatinine values (Selvin et al., 2007).

The CKD-EPI equation is:

eGFR = 141 * min
$$\left(\frac{\text{sCR}}{\kappa}, 1\right)^{\alpha}$$
 * max $\left(\frac{\text{sCR}}{\kappa}, 1\right)^{-1.209}$ * 0.993^{AGE} * 1.018 * F * 1.159 * B

where:

sCR = serum creatinine in mg/dL

 $\kappa = 0.7$ if female, 0.9 if male

 α = -0.329 if female, -0.411 if male

F = 1 if female, o if male

B = 1 if Black/African American, o if otherwise

AGE is measured in yearsThe uACR is the ratio of urinary albumin (mg/L) to urinary creatinine (mg/dL). Based on an NCHS suggestion, the urine creatinine value is adjusted to NHANES 2007-2008 (CDC, 2009). Staging of CKD was first introduced in 2002 through the National Kidney Foundation's Kidney Disease Outcomes and Quality Improvement Guidelines (NKF, 2002). Following these guidelines, we define stages of CKD in this chapter as:

- Stage 1: ACR ≥30 and eGFR ≥90
- Stage 2: ACR ≥30 and 60 ≤ eGFR <90
- Stage 3: 30≤ eGFR <60
- Stage 4: 15≤ eGFR <60
- Stage 5: eGFR <15, not ESRD

NHANES respondents are also asked, "Have you ever been told by a doctor or other health professional that you had weak or failing kidneys? Do not include kidney stones, bladder infections, or incontinence." When a respondent endorses CKD as measured above, we call this question awareness of kidney disease. Those answering "yes" are aware of their CKD.

Participants with diabetes mellitus (DM) include those with any of the following: (1) an affirmative answer to the question *"Have you ever been told by a doctor or other health professional that you have diabetes or sugar diabetes (other than during pregnancy)?*", (2) an affirmative response to either *"are you now taking insulin?" or "are you now taking diabetic pills to lower your blood sugar?"*, or (3) hemoglobin Aic (HgbAic; glycohemoglobin) \geq 7%. Participants with self-reported diabetes mellitus (SR DM) are those who report having been told by a doctor that they have diabetes or sugar diabetes (other than during pregnancy). Participants answering "borderline" are classified as non-diabetic. Control of DM is assessed as a HgbAic less than 7%.

Patients with hypertension (HTN) are those with either (1) high blood pressure, defined as systolic blood pressure above 140 mmHg (>130 mmHg for those with CKD or SR DM) or diastolic blood pressure above 90 mmHg (>80 mmHg for those with CKD or SR DM) or (2) an affirmative answer to the question "Are you now taking prescribed medicine for high blood pressure?" Self-reported hypertension (SR HTN) is identified through an affirmative answer to the question "Have you ever been told by a doctor or other health professional that you had hypertension, also called high blood pressure?" Patients are classified as aware of their HTN if they report having been told they have high blood pressure, as treated for their HTN if they reported currently taking a prescription medication to control HTN, and as in control of their HTN if their blood pressure at time of medical examination was ≤140/≤90 (≤130/≤80 for CKD or SR DM).

Participants who self-reported any of the following diseases are considered to have self-reported cardiovascular disease (SR CVD): angina, myocardial infarction, stroke, coronary heart disease, or congestive heart failure. Hyperlipidemia is measured in the medical examination. We assess whether total cholesterol falls into one of three categories: <200 (desirable), 200–239 (borderline high), and \geq 240 (high). Individuals were classified as current smokers if they give an affirmative answer to the question "Do you now smoke cigarettes?" and former smokers if they respond negatively to the previous question, but affirmatively to the question "Have you smoked at least 100 cigarettes in your life?"

New to the 2017 ADR is the examination of CKD by socioeconomic variables and additional health-related behaviors. Three socioeconomic variables were added: health insurance status, annual family income, and education. First, health insurance as a yes/no variable is determined by the answer to the question, "Are you covered by health insurance or some kind of healthcare plan? [Include health insurance obtained through employment or purchased directly as well as government programs like Medicare and Medicaid that provide medical care or help pay medical bills]." The category private insurance is determined by a "yes" answer to "Are you covered by private insurance?" Medicare coverage is a "yes" answer to "Are you covered by Medicare?" Other government coverage is defined by a "yes" answer to having coverage through Medigap, Medicaid, State Child Health Insurance Program (SCHIP), military healthcare, Indian Health Service, or other government insurance. Answers to these questions are categorized as private only, Medicare only, other government insurance only, private and any government (Medicare or other government insurance), and other/unknown.

Income was total annual family income (*indfminc*) in the 1999-2006 NHANES, reported in ranges of \$5,000 increments up to a top range of "\$75,000 and over". In 2007-2008 the variable *indfmin2* contained annual family income with two additional categories on the upper end of the distribution—\$75,000 to \$99,999 and \$100,000 and over. We collapsed reported income levels into categories of less than \$10,000, \$10.000-\$24,999, \$25,000-\$44,999, \$45,000-\$74,999, and \$75,000 or more.

Education was derived from the question, "What is the highest grade or level of school you have completed or the highest degree you have received?" Valid answers are less than 9th grade, 9th-11th grade (including 12th grade with no diploma), high school grad/GED (general educational development) or equivalent, some college or AA (associate) degree, college graduate or above. We collapse these categories into less than high school, high school grad/GED, and at least some college.

Physical activity was defined using several questions from the NHANES survey. For the 1999-2006 and 2001-2002 NHANES, vigorous activity was defined as a yes answer to the question, "Over the past 30 days, did you do any vigorous activities for at least 10 minutes that caused heavy sweating, or large increases in breathing or heart rate? Some examples are running, lap swimming, aerobics classes or fast bicycling" while moderate activity is a yes answer to "Over the past 30 days, did you do any moderate activities for at least 10 minutes that caused only light sweating, or a slight to moderate increase in breathing or heart rate? Some examples are brisk walking, bicycling for pleasure, golf, and dancing". Starting with the 2007-2008 NHANES, different questions are asked about physical activity; separate questions ask about work (paid, unpaid, volunteer, house and yardwork), transportation (walking or using a bicycle) and recreational activities. The questions are phrased similarly to the previous NHANES questions but with reference to work and recreation. Vigorous activity in the ADR was defined as answering "yes" to either work or recreational vigorous activity, with moderate activity defined the same way. The final physical activity categorical variable was defined in a hierarchical manner; if a person reported both vigorous and moderate activity, they are classified as "vigorous" activity level.

Sedentary was defined as having neither vigorous nor moderate activity.

Sleep is another health behavior examined this year. Sleep amount was determined by the answer to the question, *"How much sleep do you usually get at night on weekdays or workdays?"* Valid answers were one to 11 or *"12 hours or more"*. A categorical variable was then made with ranges of less than six hours, six hours, seven to eight hours, and nine or more hours. Self-reported special diet was indicated by an answer of *"yes"* to the question, *"What kind of diet are you on? (Is it a weight loss or low calorie diet; low fat or cholesterol diet; low salt or sodium diet; sugar free or low sugar diet; low fiber diet; high fiber diet; diabetic diet; or another type of diet?).*

In the chapter, Figure 1.1 shows the weighted percentage of NHANES respondents with each stage of CKD, defined as above, for four time periods, 1999-2002, 2003-2006, 2007-2010, 2011-2014. The whisker bars show the 95% confidence interval around each estimate of the U.S. civilian, noninstitutionalized population fraction with each stage of kidney disease. The test for trends noted in the text is a logistic regression with appropriate accounting for survey design elements, including weights, with the four time periods forming a continuous variable with values 1 to 4 in order of calendar time. Figure 1.2, panel a shows the distribution of estimated eGFR for all NHANES respondents and Figure 1.2, panel b, shows the distribution for those aged 60 and over. These figures are box plots. The structure of the box is as follows:

vol 1 Figure 10.1 Interpretation of a box plot



Figure 1.3 shows the urine albumin creatinine ratio (uACR) for NHANES respondents in four categories: less than 10 mg/g, 10 to 29 mg/g, 30-300 mg/g (also known as microalbuminuria), and greater than 300 (macroalbuminuria) for the four periods used in Figure 1.1. Figure 1.4 shows the percent of NHANES respondents with uACR of 30 mg/g or higher by level of eGFR and time period. Table 1.1, panel a shows updated statistics for Figure 8 from Chapter 1: Definition and Classification of CKD of the KDIGO 2012 Clinical Practice Guideline for CKD Evaluation and Management (KDIGO, 2013) using data for 2011-2014. Panel b summarizes the results by the risk categories shown in panel a—low risk, moderately high risk, high risk and very high risk, over the four time periods.

Table 1.2 shows demographic variables (age, race, sex) and clinical risk factors and consequences of CKD (DM, SR DM, HTN, SR HTN, SR CVD, and obesity) by three definitions of CKD-the standard definition using eGFR and uACR (All CKD), using reduced eGFR alone (< 60 ml/min/1.73m²), and using the albuminuria criterion alone (uACR \geq 30mg/g). This table shows what percent of the group described by the row label has CKD, for example, 32.6% of those aged 60 or older in 2011-2014 had CKD by the eGFR and uACR criteria combined. The test for trends noted in the text is a logistic regression with appropriate accounting for survey design elements, including weights, with the four periods forming a continuous variable with values 1 to 4 in order of calendar time. The Figure 1.5 shows the prevalence of each measure of CKD, reduced eGFR only, elevated uACR only, or both reduced eGFR and elevated uACR, among each risk factor group. For example, 15.8% of those aged 60 or older met the reduced eGFR criterion only, 10% met the elevated uACR criterion only; and 6.8% had both reduced eGFR and elevated uACR.

Adjusted odds ratios in Figures 1.6-1.8 are calculated using logistic regression, incorporating the sampling weight and survey design. In Figures 1.6 and 1.8 we display the results of seven logistic models. Figure 1.7 splits the models into two panels with age in panel a, and the CKD risk factors in panel b. The model for age includes age (20 to 39/40 to 59/60 and older), sex (male/female) and race (White/Black/other). Models for the six other factors shown in the figure (DM, SR DM, HTN, SR HTN, SR CVD, and body mass index [BMI] greater than 30) include age (20 to 39/40 to 59/60 and older), sex (male/female), race (White/Black/other) and presence of the risk factor shown (yes vs. no). Ninety-five percent confidence intervals are displayed and results shown for the four periods.

Table 1.3 shows the distribution of three socioeconomic variables among those with CKD either the standard definition, reduced eGFR, or elevated uACR—for the four periods. The column percentages of not insured and insured add up to 100%, the types of insurance add up to the percentage insured, and the income and education categories each add to 100%. Table 1.4 shows the distribution of health risk behaviors in a manner similar to Table 1.3. Sleep amount and self-reported special diet are not available for the 1999-2002 period. Figure 1.9 shows the percent of NHANES respondents who are physically active (defined as moderate or vigorous activity) by CKD definition/components and the four periods.

Table 1.5 shows the distribution of several measures of awareness, treatment, and control for the CKD risk factors of HTN, high cholesterol, and DM. Again, these column percentages sum to 100% within each panel. Figure 1.10 shows the percent of NHANES respondents whose blood pressure at the medical exam was at the target level, by CKD definition/components and the four periods. Figure 1.11 shows the percentage with cholesterol levels within target range, and Figure 1.12 shows the percentage with HgbA1c within target range.

Figure 1.13 shows the percent of NHANES respondents that report having a health professional tell them they had kidney disease, which we define as being aware of their kidney disease, by the four periods. Figure 1.13, panel a shows this by stage and panel b by reduced eGFR, elevated uACR, and both. Figure 1.14 tabulates responses to the 2012-2015 Behavioral Risk Factor Surveillance System question, *"Has a doctor, nurse, or other health professional ever told you have kidney disease?"* by U.S. state for each of the past four years of available data.

VOLUME 1: CKD ANALYTICAL METHODS

Chapter 2: Identification and Care of Patients with CKD

All of the analyses in the chapter sections Patients Characteristics across Datasets, Comparison of CKD Prevalence across Datasets, and Longitudinal Change in CKD Status and Outcomes, Based on Diagnosis Codes, include point prevalent patients who survived all of the reported year (2015 for most of the figures and tables) and who did not have or develop ESRD during the reported year. Medicare analyses also required the beneficiary to be continuously enrolled in Medicare Parts A and B in the reported year, not enrolled in a Medicare Advantage plan (Part C), and aged 65 or older as of January 1 of the reported year. Optum Clinformatics[™] analyses additionally required the plan member to be enrolled for the entire reported year. The age range of members varied by table, with Tables 2.1 and 2.4 including all ages and the remaining tables and figures including adults aged 22 to 64. The sections Laboratory Testing of Patients with and Without CKD and Table 2.6 of Visits with a Physician after CKD Diagnosis include patients meeting the restrictions described above, for a one-year entry period (year one) before the reported year (year two) and on January 1 of year two. Patients were then censored in the analysis if they died, developed ESRD, switched to a Medicare Advantage plan (Part C), or disenrolled from Parts A and B during year two.

Table 2.1 presents demographic and comorbidity characteristics of individuals in the Medicare 5% sample (aged 65 and older), the Optum Clinformatics[™] dataset (all ages), and the VHA (all ages). Comorbidities included diabetes mellitus (DM), hypertension (HTN), and cardiovascular disease (CVD). CVD was defined as the presence of any of the following comorbidities: cerebrovascular accident, peripheral vascular disease, coronary artery disease (formerly called atherosclerotic heart disease), heart failure, dysrhythmia, or other cardiac comorbidities. Each comorbidity was defined by at least one inpatient or two outpatient medical claims during the reported year. Refer to the Identification of Major Comorbidities section of this chapter for the complete methodology used to identify these comorbidities, and Tables 10.3 and 10.4 for a list of ICD-9-CM and ICD-10-CM codes used.

Table 2.2 presents the prevalence of coded CKD, DM, and CVD in the fee-for-service, age-eligible Medicare population, and patients aged 22 to 64 in the Optum Clinformatics[™] and VHA datasets. Panel a shows the sample counts and percent of all patients with the condition, for each condition separately. Panel b shows the interaction between all three conditions, identifying those with all combinations of the conditions, plus the number and percentage who had at least one or at least two comorbidities.

Table 2.3 shows a comparison of the percent of patients with CKD by demographic characteristics, in different datasets. The survey-based NHANES data (see the section *Chapter 1: CKD in the General Population* in this chapter for methods), include the 2011-2014 survey years and are restricted to participants aged 65 or older. CKD is determined by eGFR<60 ml/min/1.73m². In the claim-based datasets of Optum Clinformatics[™] (2015) and the Medicare 5% sample (2015), CKD is determined by ICD-9-CM or ICD-10-CM diagnosis codes. In the claim and labbased VHA dataset (2105) patients are considered to have CKD via either a diagnosis or eGFR<60 ml/min/1.73m², as determined by routine blood testing for serum creatinine.

Table 2.4 shows the 2015 unadjusted prevalence of diagnosed CKD by age, sex (male/female), race (White/Black/Native American/Asian/Hispanic [Optum Clinformatics[™] only]/other), and comorbidity for the Medicare 5% sample, Optum Clinformatics[™], and the VHA. Comorbidities include DM with or without HTN and HTN without DM. Figure 2.1 has two map panels for (a) the Medicare 5% sample and (b) the Optum Clinformatics[™] dataset, showing the prevalence of diagnosed CKD across the U.S.

Figure 2.1 shows the 2015 distribution of CKD prevalence, among the Medicare 5% sample (aged 65+ years) and Optum Clinformatics[™] (all ages) patients in 2015, by states.

Figure 2.2 illustrates the prevalence of CKD over time in the fee-for-service, age-eligible Medicare population—overall (any code) and by CKD stagespecific codes.

Table 2.5 shows progression of kidney disease by CKD stage, end-stage renal disease (ESRD), or death in 2014-2015 for the fee-for-service, age-eligible

Medicare population of 2010. The analysis cohort required patients to be alive and eligible for Medicare Parts A and B with no HMO coverage for all of 2010. Death and ESRD status were examined yearly between 2011 and 2015, and carried forward if present. The ESRD and death information were combined to create three categories: ESRD-alive, ESRD-death, and Death without ESRD. For patients who did not progressto death or ESRD by 2015 the last CKD diagnosis claim in 2015 was used; if this was not available, the last CKD diagnosis claim from 2014 was used. Lost to follow-up status represents the patients who were not enrolled in Medicare Part A and B during 2014 or 2015 and who had no indication of death or ESRD.

Figures 2.3–2.4 show the proportion of patients tested for urine albumin from 2005-2015, for patients with (Figure 2.4) and without (Figure 2.3) CKD by the comorbidities of DM without HTN, HTN without DM, both DM and HTN, or neither. For these analyses, a one-year period was used to define comorbid conditions (year one) and laboratory testing was assessed in the following year (year two, the year reported in the figures). Patients must have been enrolled in their plan (for Medicare, Parts A and B coverage, and no Medicare Advantage plans), not have ESRD, and alive for all of year one through to January 1 of year two. Additionally, the sample is limited to patients residing in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. First urinary microalbumin measurement is defined as the first claim with a Healthcare Common Procedure Coding System (HCPCS, similar to the Current Procedural Terminology, CPT[°], system) code of 82042, 82043, 82044, or 84156. Panel a shows the Medicare 5% sample and panel b the Optum Clinformatics[™] data.

Table 2.6 examines physician visits in the year after a diagnosis of CKD. Similar to the laboratory testing, the sample includeed patients who were alive, without ESRD, did not have a Medicare Advantage plan, and had both Parts A and B coverage for all of 2014. The date of the earliest CKD claim (any CKD or Stage 3/4/5 [585.3–585.6, ICD-10 codes were not used in 2014]) in 2014 was used as the date of CKD diagnosis, and claims were then searched for services provided by primary care physicians, nephrologists, and cardiologists for the 365 days following that date. Primary care visits were defined based on a physician specialty code of 01, 08, or 11. Cardiologist visits were defined based on specialty code 06, and nephrology visits based on specialty code 36.

Figure 2.5 presents the proportion of CKD patients in the fee-for-service, age-eligible Medicare population in 2015 (based on diagnostic code) who were tested for urine albumin in 2015, according to whether they saw a primary care physician, a nephrologist, or neither in 2014. The analysis cohort required patients to be alive and eligible for all of 2015 with a CKD diagnosis claim in 2014.

Chapter 3: Morbidity and Mortality

The analyses in this chapter used a one-year entry period to determine disease conditions prior to hospitalization, referred to as 'year one'. Patients were required to be alive, aged 65 or older on January 1, without ESRD, enrolled in their plan (for Medicare, covered by Parts A and B with no Medicare Advantage plan (Part C)) for all of year one. Claims from year one were then searched for diagnoses as described in the Identification of Major Comorbidities section of this chapter. Additionally, patients must have met the above criteria and be aged 66 or older on January 1 of the following year (year two). We then determined patient mortality and/or hospitalization for the period January 2 to December 31 of year two. Analyses were limited to patients residing in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. The calculation of years at risk began on January 1 of year two, and was censored at the earliest of the date of death, start of ESRD, disenrollment from their plan (for Medicare, Parts A or B or a switch to a Medicare Advantage plan), or December 31 of year two. The analyses of Optum Clinformatics[™] data employed similar selection criteria, except patients must have been enrolled in their Optum Clinformatics[™] plan for all of year one and January 1 of year two.

MORTALITY

The date of death was provided by CMS in the Master Beneficiary Summary File. If the patient experienced ESRD prior to death, the date of death from the USRDS ESRD database was also used in the analysis; this date is found in the integrated data from
VOLUME 1: CKD ANALYTICAL METHODS

the ESRD Death Notification form CMS 2746. Figure 3.1 shows trends in unadjusted and adjusted all-cause mortality by CKD status from 2003 to 2015, and Figure 3.2 shows rates for 2015 by CKD status and stage. We calculated unadjusted mortality as the number of deaths divided by the number of patient-years at risk, and express this as "per 1,000 patient years." Adjusted mortality was based on a Cox regression model and adjusted for age (66 to less than 70, 70 to less than 75, 75 to less than 85, or 85 years and older), race (White, Black or African American, other), and sex. We have applied this modified set of adjustment covariates since the 2014 ADR—prior year hospitalization and comorbidities are no longer included. These differ from those used in the 2013 and older ADRs, therefore, differences between adjusted rates in the 2014-present ADRs and rates from the 2013 and older ADRs may be notable.

All patients in 2015 formed the reference cohort for Table 3.1 and Figures 3.1-3.6. Optum Clinformatics[™] data were not used in mortality analyses as the date of death determination is now limited to information from the Social Security Death Master file. Since 2012, the Social Security Administration no longer releases death dates derived from state sources. The number of deaths reported has dropped by over 30%, indicating artificially low mortality rates.

HOSPITALIZATION

For the hospitalization analysis, additional processing was performed on the inpatient claims data. A patient's inpatient claims were ordered by date and compared to identify 1) overlapping claims (two claims covering the same time frame), 2) consecutive claims (one claim's admission date on the day following the previous claim's discharge date), 3) transfers (patient discharge status of 02 on the claim), and 4) interim claims (claim sequence number, the third digit of the 'type of bill' code, of 2, 3, or 4). In such cases, the claims were consolidated into one claim, with dates, diagnoses, and procedures combined. Analyses excluded claims from non-acute care facilities such as rehabilitation hospitals (the last four digits of the provider number between 2500 and 3999, or the third digit of R or T).

We calculated unadjusted admission rates as the number of hospitalizations divided by the number of patient years at risk, and express this as "per 1,000 patient years." Adjusted admission rates in this chapter included the following variables as adjustments: age (66 to less than 70, 70 to less than 75, 75 to less than 85, or 85 years or older), race (White, Black, or other), and sex (male, or female). As with mortality, a different set of adjustment covariates were applied starting with the 2014 ADR, thus adjusted rates may differ substantially from the 2013 and older ADRs. A model-based adjustment method was used with a generalized linear model using a Poisson distribution and log link function. The sample included data from the current and previous two years, with respective weights of 1.0, 0.25 and 0.125 applied. Adjusted rates reflect the distribution of a reference cohort, as specified below in the discussion of the specific figures. With this method, the parameter estimates from the model were used to calculate an estimated admission rate for each patient in the reference cohort. Overall adjusted rates were then computed as the weighted average of these individual rates, using the time at risk of each patient in the reference cohort as the weight.

Table 3.2, and Figures 3.7 and 3.8 show adjusted allcause admission rates for fee-for-service Medicare patients aged 66 and older and Optum Clinformatics™ patients aged 22 and older. Table 3.2 also shows the unadjusted rates. As mentioned above, DM and CVD were ascertained in 2014 for the analysis of hospital admissions in 2015, as described in the Identification of Major Comorbidities section of this chapter. All Medicare patients in the cohort were 66 years or older (22 and older for Optum Clinformatics[™]), did not have ESRD on 1/1/2015, had Medicare Parts A and B coverage (for Optum Clinformatics[™], plan enrollment) for all of 2014, and did not participate in a Medicare Advantage plan from 1/1/2014 through 1/1/2015. Rates presented by one factor were adjusted for the others. The reference cohort for Medicare analyses included all 2015 Medicare patients aged 66 and older. The reference cohort for Optum Clinformatics[™] analyses includes all patients in 2015.

vol 1 Table 10.5 ICD-9-CM and ICD-10-CM diagnosis codes used to define cause of hospitalization

Cause of hospitalization	ICD-9-CM diagnosis codes	ICD-10-CM diagnosis codes
Cardiovascular diseases	276.6; 394-398; 401-405; 410- 438; 440-459	A18.84; 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-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
Infections	001-139; 254.1; 320-326; 331.81; 372.0-372.3; 373.0- 373.3;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- 575.12; 590; 595.1-595.4; 597; 598.0; 599.0; 601; 604; 607.1- 607.2; 608.0, 608.4; 611.0; 614- 616.1, 616.3, 616.4, 616.8; 670; 680-686; 706.0; 711; 730.0- 730.3, 730.8-730.9; 790.7, 790.8; 996.6; 998.5; 999.3	A00.0-A32.9; A35-B99.9; D86.0-D86.9; E32.1; E83.2; G00.0-G04.02;G04.2-G09; G14; G37.4; G92; G93.7; H00.011-H10.9; H16.251-H16.269; H32; H66.001-H66.43; H67.1-H67.9; H70.001-H70.93; H75.00-H75.83; H83.01-H83.09; H92.10-H92.13; H95.00-H95.199; I00-I02.9; I09.2; I32; I33.0; I39-I40.8; I41;I67.3; J00-J18.1; J18.8-J21.9; J31.0-J32.9; J35.01-J35.03; J36;J37.0; J37.1; J39.0-J39.2; J40; J41.1; J47.0-J47.9; J85.0-J85.2; J86.0-J92.9; J94.0-J94.9; J95.02; K04.6; K04.7; K11.3; K12.2; K35.2-K37; K50.014; K50.114; K50.814; K50.914; K51.014; K51.214; K51.314; K51.414; K51.514; K51.814; K51.914; K57.00; K57.01; K57.20; K57.21; K57.40; K57.41; K57.80; K57.81; K61.0-K61.4; K63.0; K65.0-K65.9; K67-K68.9; K71.0-K71.9; K75.0-K75.3; K75.81-K75.9; K76.4; K77; K81.0-K81.9; K90.81; L01.0-L08.9; L44.4; L70.2; L88; L92.8; L94.6; L98.0; L98.3; M00.00-M01.X9; M02.10-M02.19; M02.30-M02.89; M35.2; M46.20-M46.39; M86.00-M86.9; M90.80-M90.89; N10-N12; N13.6; N15.1; N15.9; N16; N28.84-N28.86; N30.0- N30.31; N30.80; N30.81; N34.0-N34.3; N35.111-N35.12; N37-N39.0; N41.0-N41.9; N45.1-N45.4; N47.6; N48.1-N48.29; N49.0-N49.9; N51; N61; N70.01-N74; N75.1; N76.0-N76.4; N77.1; N98.0; O85; O86.12; O86.81; O86.89; R09.1; R11.11; R78.81;T80.211A-T80.29A; T81.4XXA; T82.6XXA; T82.7XXA; T83.51xXA-T83.6XXA; T84.50XA-T84.7XXA; T85.71XA-T85.79XAT86.842; T87.40-T87.44; T88.0XXA
Other causes	All codes except those in cardiovascular or infection.	All codes except those in cardiovascular or infection.

Principle diagnosis for hospital stay

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

Figures 3.9-3.15 show adjusted, cause-specific admission rates by CKD status and stage for Medicare and Optum Clinformatics[™] patients. Cause-specific rates reflect hospital admissions for the purpose of treating the specified condition—cardiovascular or infectious—and are identified using the principal ICD-9-CM or ICD-10-CM diagnosis code on the claim. Code values are shown in Table 10.5. The 'other cause' of hospitalization is a residual category consisting of all hospitalizations other than those for cardiovascular or infectious conditions.

READMISSION

Analyses of readmissions focus on the 30 days following discharge from a hospitalization in year two,

the year reported in the figure. As for all the analyses in this chapter, comorbidities, including CKD, are defined during year one, the year prior to that reported in the figure. Each of a person's hospitalizations between January 1 and December 1 of year two were identified; the latter date (12/1) was chosen as a cutoff to allow a 30-day follow-up period after discharge to evaluate readmission. The unit of analysis was a hospital discharge rather than a patient. Hospital stays were excluded if the patient died before discharge, developed ESRD within 30 days of discharge, switched to a Medicare Advantage (Part C) plan or disenrolled from Parts A and B coverage within 30 days of discharge (unless the Parts A and B coverage loss was due to death). Due to the December 1 cutoff all patients were at risk of death or readmission for the entire 30 day period, so results are presented as percentages.

Since death and readmission are competing risks, the outcome was presented as: (1) the percent of hospital discharges where the patient both returned to the hospital and died within 30 days, (2) the percent where the patient was rehospitalized within 30 days but remained alive on day 30, and (3) the percent where the patient died within 30 days without a readmission. Table 3.3 shows the unadjusted percentage who were rehospitalized (both alive and dead on day 30) for age, sex, and race groups, plus the composite death and readmission outcome described above by CKD status and stage. Figure 3.16 adds a fourth category to the three described above for those who did not have a readmission and were still alive at day 30. It shows the adjusted percentages for the four readmission and death outcomes across time from 2003 to 2015. Live hospital discharges from January 1 to December 1 of each year were included. Rates were adjusted for age, sex, and race using direct adjustment, with a reference group of discharges in 2015. Figure 3.17 shows results for 2015 patients with and without CKD before the all-cause index hospitalization, while Figures 3.18-3.20 show this for cardiovascular, infection, and other cause-specific index hospitalizations. Figure 3.21 illustrates this by

age group, Figure 3.22 by sex, and Figure 3.23 by race group.

Chapter 4: Cardiovascular Disease in Patients with CKD

This chapter describes the prevalence of cardiovascular comorbidities and selected cardiovascular procedures in fee-for-service, ageeligible Medicare enrollees. Cardiovascular comorbidities include coronary artery disease (CAD; formerly referred to as atherosclerotic heart disease, ASHD), acute myocardial infarction (AMI), heart failure (HF; formerly congestive heart failure, CHF), valvular heart disease (VHD), cerebrovascular accident/transient ischemic attack (CVA/TIA), peripheral artery disease (PAD), atrial fibrillation (AFIB), sudden cardiac arrest and ventricular arrhythmias (SCA/VA), and venous thromboembolism and pulmonary embolism (VTE/PE). The same algorithm described in the Identification of Major Comorbidities section of this chapter (one inpatient or two outpatient claims with the specific diagnosis) was used to define these cardiovascular conditions. Code values are shown in Table 10.6. The presence of CKD, CKD staging, and comorbidities such as diabetes mellitus (DM) and hypertension (HTN) were also defined as described in the Identification of Major Comorbidities section of this chapter and Tables 10.3 and 10.4.

Condition	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	121.01-122.9; 125.2
Atrial fibrillation (AFIB)	427.3	148.0-148.92
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	112.00-122.9; 124.0-125.9; 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	150.20-150.23; i50.40-150.43
Diastolic only	428.3	150.30-150.33
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	146.2-147.0; 147.2; 149.01; 149.02; 149.3; 149.49
Valvular heart disease (VHD)	424	A18.84; I34.0-I39; M32.11
Venous thromboembolism and pulmonary embolism (VTE/PE)	452-453.9	181-182.91

vol 1 Table 10.6 ICD-9-CM and ICD-10-CM diagnosis codes used to define cardiovascular disorders in Volume 1, Chapter 4 of the ADR

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

Cardiovascular procedures include revascularization – percutaneous coronary interventions (PCI), revascularization – coronary artery bypass graft (CABG), the placement of implantable cardioverter defibrillators (ICD) and cardiac resynchronization therapy with defibrillator (CRT-D), and carotid artery stenting and carotid endarterectomy (CAS/CEA). Procedures required only one claim with the procedure code. The presence of PAD was determined by the diagnosis or a claim for a procedure. Table 10.7 shows the codes and type of claims used to identify each procedure

vol 1 Table 10.7 Procedure codes (ICD-9/10-CM and HCPCS) and claims files used to define cardiovascular procedures in Volume 1, Chapter 4

Data Sources (Claims files searched)	Values	
Peripheral arterial disease (PAD)		
ICD-9-CM Procedure codes (IP, OP, SN)	39.25, 39.26, 39.29; 84.0, 84.1, 84.91	
ICD-10-CM Procedure codes (IP, OP, SN)	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 (PB, OP-revenue)	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 (IP, OP, SN)	00.66; 36.01, 36.02, 36.05, 36.06, 36.07	
ICD-10-CM Procedure codes (IP, OP, SN)	02703ZZ; 02704ZZ; 02713ZZ; 02714ZZ; 02723ZZ; 02724ZZ; 02733ZZ; 02734ZZ	
HCPCS codes (PB, OP-revenue)	92980-92982, 92984, 92995-92996, G0290, G0291	
Coronary artery bypass graft (CABG)		
ICD-9-CM Procedure codes (IP)	36.1	
ICD-10-CM Procedure code (IP, OP, SN)	All of: 0210083-02100ZF; 0210483-02104ZF; 211088-021108C; 021208C; 021208W; 021209C; 021209W; 02120AC; 02120AW; 02120JC; 02120JW; 02120JKC; 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 xxxxxF, xxxxxA; 211088-02110ZC; 211488-02114ZC;	
Implantable cardioverter defibrillators	& cardiac resynchronization therapy with defibrillator (ICD/CRT-D)	
ICD-9-CM Procedure codes (IP, OP, SN)	00.51; 37.94	
ICD-10-CM Procedure code (IP, OP, SN)	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 arte	ery endarterectomy (CAS/CEA)	
ICD-9-CM Procedure codes (IP, OP, SN)	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 (IP, OP, SN)	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 0. 05RL07Z-05RV4KZ; 06R307Z-06R34KZ	
HCPCS codes (PB, OP-revenue)	37215, 37216	

Source: ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification; 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. 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

CARDIOVASCULAR DISEASE PREVALENCE AND OUTCOMES IN CKD

For Figure 4.1, the study cohort included Medicare enrollees who were alive, aged 66 and older, were residents of the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, did not have ESRD on December 31, 2015, and who were continuously enrolled in Medicare Parts A and B but not in a Medicare Advantage plan for all of 2015. Cardiovascular conditions, CKD, and CKD staging were determined from claims in 2015.

Table 4.1 presents the prevalence data shown in Figure 4.1 by age, race, sex, and CKD status (panel a), and data on cardiovascular procedures performed in 2015 (panel b). The cohort was the same as that used for Figure 4.1. However, the denominators for the cardiovascular procedures were not "all patients in the cohort", which was the denominator for the prevalence statistics. The percent with PCI or CABG in this table was only of the cohort members with CAD, the percent with ICD/CRT-D was of cohort members with HF, and the percent with CAS/CEA was of the cohort members with CAD, CVA, or PAD.

Figures 4.2 and 4.3 present the two-year survival of patients with cardiovascular conditions (Figure 4.2) or cardiovascular procedures (Figure 4.3) adjusted for age and sex. We again used the adjusted algorithm explained in the 2016 ADR. We assessed conditions in a baseline year (2013), the origin for survival time was January 1 of the following year (1/1/2014), and there was no attempt to isolate incident diagnoses. Procedures used the same algorithm as in the past.

To form the study cohort for each condition in Figure 4.2, we searched 2013 Medicare claims for the diagnoses (and procedure codes for PAD) specified in Tables 10.6 and 10.7. To be retained in the analysis cohort, the patient must have been alive without ESRD and aged 66 and older on 1/1/2014, residing in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, be enrolled in Medicare Parts A and B, but not enrolled in a Medicare Advantage plan for all of 2013. Patients were then followed from 1/1/2014 until the earliest of date of death, ESRD diagnosis, or December 31, 2015. The Kaplan-Meier method was used to estimate survival. Table 4.2 shows the numeric values for two-year survival for each condition by CKD status and stage.

To form the study cohort for each procedure in Figure 4.3, Medicare claims from 1/1/2012 through 12/31/2015 were searched for the procedure codes specified in Tables 10.7, and the date of the first claim with a specified code was considered as the index date. To be retained in the analysis cohort, the patient must have been aged 66 and older on the index date, reside in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, be enrolled in Medicare Parts A and B, and not enrolled in a Medicare Advantage plan. Patients with ESRD on or before the index date were excluded. Claims for the patient in the 365 days prior to the index date were then searched for a prior occurrence of the given condition/procedure, and these patients were excluded from the analysis. CKD status and stage were also determined from the patient's claims in the 365 days prior to the index date. Patients were then followed from the index date until the earliest of date of death, two years after the index date, ESRD diagnosis, or December 31, 2015. The Kaplan-Meier method was used to estimate survival. Table 4.3 shows the numeric values for two-year survival for each procedure by CKD status and stage.

CARDIOVASCULAR DISEASE AND PHARMACOLOGICAL TREATMENTS

New to the 2017 ADR, 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.

Creation of the cohort for Table 4.4 begins with the cohort described for Table 4.1 and then excludes patients who are not enrolled in a Part D prescription plan for all of the reported calendar year (2015). All drugs in the PDE file were matched to a therapeutic category according to the American Hospital Formulary Service Pharmacologic-Therapeutic Classification[®]. Claims for 2015 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

classes during 2015. The prescription must be part of the AFHS Classification group and have a generic name as specified in Table 10.8.

Drug class	AFHS classification	Generic drug name
Beta blockers	242400	<no restriction=""></no>
Statins	240608	<no restriction=""></no>
P2Y ₁₂ inhibitors	201218	prasugrel, ticagrelor, or clopidogre
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=""></no>

HEART FAILURE AND CHRONIC KIDNEY DISEASE

The type of heart failure (HF) for the calendar year was determined by frequency of diagnoses and a hierarchy. The presence of systolic (ICD-9: 428.2x, 428.4; ICD-10: I50.2, I50.4), diastolic (ICD-9:428.3x; ICD-10: I50.3) and unspecified diagnoses (all other HF diagnosis codes listed in Table 10.6) 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 predominant type of HF for the year was then determined by a hierarchy similar to that applied for each calendar day. If the patient had any systolic HF and no diastolic-only heart failure, he/she was classified as systolic heart failure; if the patient had diastolic HF 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 the HF type that was most frequent during the year.

Figure 4.4 shows the distribution of type by CKD status in 2015. The study cohort included Medicare

enrollees who were alive, aged 66 and older, were residents of the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, who did not have ESRD on December 31, 2015, and who were continuously enrolled in Medicare Parts A and B and not enrolled in a Medicare Advantage plan for all of 2015. The denominators were the total numbers of patients in each CKD status or stage group, and the numerators were the numbers of patients with the given HF type within that CKD status or stage group.

Figure 4.5 presents the adjusted, two-year survival of patients with and without CKD and HF. The adjusted probability of survival was calculated using the results of a Cox model, in which significant factors included age group, sex, race, diabetic (DM) status, hypertension (HTN) status, and a four-category variable summarizing HF and CKD status. We determined heart failure, CKD, DM, and HTN statuses from 2013 claims data. The study cohort included Medicare enrollees who were alive and aged 66 or older on December 31, 2013, residents of the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, were continuously enrolled in Medicare Parts A and B, and were not enrolled in a Medicare Advantage plan for all of 2013. Patients with ESRD on or before December 31, 2013 were excluded. Follow-up began on 1/1/2014, and continued until death or 12/31/2015. Type of HF was determined by the same procedure as the previous figures, using claims from 2013. Codes used to define DM and HTN are listed in Table 10.4 of this chapter. Age was defined as of

2017 USRDS ANNUAL DATA REPORT | VOLUME 1 – CKD IN THE UNITED STATES

12/31/2013. As the interaction between HF status and CKD status was significant in the Cox model, adjusted survival curves were created for the four combination groups of HF status and CKD status (no CKD and no HF, CKD and no HF, HF and no CKD, and CKD with HF). The survival curves were adjusted for the other significant factors in the model listed above.

ATRIAL FIBRILLATION AND CHRONIC KIDNEY DISEASE

Table 4.5 presents the prevalence of AFIB by CKD stage, age, race, sex, diabetic status, HTN status, and HF status for 2015. The cohort was the same used for Figure 4.1.

Chapter 5: Acute Kidney Injury

Three sources of data were used for the AKI chapter: the Medicare 5% sample, Optum Clinformatics[™] Data Mart, and the VHA data. Both the Medicare and Optum Clinformatics[™] datasets contain only diagnosis code information on AKI, but no laboratory measurements. For these two sources, a hospitalization with AKI was defined as an inpatient stay with any diagnosis code for AKI, not necessarily as the primary diagnosis. The VHA datasets contain serum creatinine measurements for both routine outpatient visits and inpatient stays, but not urine output measurements. This allowed calculation of the serum creatinine criteria of the KDIGO consensus definition of AKI, and episodes to be classified by stage (KDIGO 2012). Diagnosis codes are also available in the VHA data. As in prior ADRs, this chapter only examined AKI as identified during an inpatient hospital stay.

In the Optum ClinformaticsTM dataset, inpatient stays were identified by a non-missing confinement ID variable ($conf_id$) in the MEDICAL claims data table. Previously, we identified more patients with at least one or more inpatient stays from the MEDICAL claims data table than the CONFINEMENT data table, so we continued to use the MEDICAL claims data table. Admission and discharge dates are not available in the MEDICAL claims data table and must be generated. We created the admission date as the minimum "claim from" date (fst_dt) and the discharge date as the maximum "claim through" date (lst_dt) for all claims with a given *patid-conf_id* combination. Review of inpatient stays that were included in the CONFINEMENT data table verified that this process created appropriate dates.

Dialysis during the hospitalization with AKI is defined from the Medicare 5% sample using diagnosis, procedure, and revenue center codes. For the Medicare 5% sample, the inpatient claims file was searched for ICD-9-CM diagnosis codes V45.1, V56.0, and V56.1, ICD-10-CM diagnosis codes Z49.01, Z49.31, Z91.15, and Z99.2, ICD-9-CM procedure codes 39.95 and 54.98, ICD-10-CM procedure codes 5A1DooZ, 5A1D6oZ, and 3E1M39Z, and Medicare revenue center codes o800-o809. Additionally, physician and supplier claims were searched for HCPCS codes 90935, 90937, 90945, and 90947, with service dates that corresponded to the patient's inpatient stay. In the Clinformatics[™] Data Mart, we searched for both inpatient and outpatient dialysis procedures in the MEDICAL claims data table that were performed between the admission and discharge dates of the inpatient stay. Similarly, the VHA datasetwas searched for dialysis procedures during the time frame of the inpatient stay. Patients with ESRD prior to the inpatient stay were not considered to have AKI.

CHARACTERISTICS OF PATIENTS WITH AKI

The cohort for Figures 5.1, 5.3.a, 5.4.a, 5.5.a, and Table 5.1 (Medicare) included all patients who were alive, aged 66 or older, enrolled in Medicare Parts A and B, not enrolled in a Medicare Advantage program, and without ESRD on January 1 of the reported year. The Optum Clinformatics[™] cohort for Figures 5.2, 5.3.b, 5.4.b, 5.5.b, and Table 5.1 (Optum Clinformatics[™]) included all patients who were alive, aged 22 or older, enrolled in their plan, and without ESRD on January 1 of the reported year. The comorbidities of CKD and diabetes mellitus (DM) were determined as described in the Identification of Major Comorbidities section of this chapter (and Tables 10.3 and 10.4), using claims from a one-year entry period (year one, the calendar year before the year in which hospitalization was assessed for AKI). Hospitalization was then assessed in the following year (year two, the year reported in the figures and tables). Figures 5.1 and 5.2 and Table 5.1 show statistics on people who had at least one hospitalization with an AKI diagnosis anywhere on the claim. Information specific to the AKI hospitalization used the first AKI hospitalization in the calendar year. Each calendar

year formed a separate cohort, so that a patient can have a "first" AKI hospitalization in multiple years. This process was used for both the Medicare and Optum Clinformatics[™] datasets. For the 2017 ADR, Figures 5.3, 5.4, and 5.5 show the rate of all AKI hospitalizations, with an individual allowed to have more than one AKI during the calendar year. The denominator was the same as in previous years, with time at risk calculated for each person.

Figures 5.1 and 5.2 illustrate the same statistics, but for Medicare (Figure 5.1) and the Optum Clinformatics[™] (Figure 5.2) datasets. Each figure has two panels that employ different denominators. Panel a shows the fraction of the entire cohort (described in the previous paragraph) that had a hospitalization with a diagnosis of AKI (in any position on the claim) in each year, and by whether the hospitalization with the AKI diagnosis contained a stay in the ICU. Panel b, however, used the numerator of panel a as its denominator, showing the fraction of cohort patients with at least one hospitalization with AKI who received a dialysis procedure during that hospitalization, and whether that hospitalization contained a stay in the ICU. ICU stays were determined by revenue center codes falling between 0200 and 0204, or between 0207 and 0209. We could not determine ICU stays for Optum Clinformatics[™] beneficiaries.

Note that these percentages did not take into account each patient's individualized time at risk—for example, a patient who died in February was still included in the denominator for the entire year, even though he/she was not at risk of having an AKI hospitalization after February. These percentages answered the question, "What percent of people (meeting the cohort inclusion criteria in the previous paragraph) alive on January 1 experienced an AKI hospitalization during the year?" Table 5.1 also uses the total number of cohort patients with at least one hospitalization with AKI as the denominator, and presents the distribution of age, sex, race, DM, and CKD for those with AKI for Medicare and Optum Clinformatics[™].

Table 5.2 shows data from the VHA. Data are from fiscal year 2015 (October 1, 2014 through September 30, 2015) as retrieved from the Corporate Data Warehouse. Short-term hospital stays were isolated from the INPAT.INPATIENT table for discharges within the fiscal year (see Veterans Health Administration (VHA) Data earlier in this chapter). All outpatient serum creatinine (SCR) measurements within the 365 days prior to the admission date were obtained from the MCA (formerly DSS) national data extract of laboratory results (LAR file; dsslarno=31 and in_out="O"). SCR results containing text ("CANC", "N.A.", etc.) and those with values greater than 20.0 mg/dL or less than 0.4 mg/dL were set to missing. Each patient was assigned a baseline SCR by this hierarchy: (1) the mean of all outpatient SCR measurements collected between seven and 365 days prior to admission, or (2) if the patient had no outpatient SCR values before seven days prior to admission, they were assigned the outpatient SCR value within seven days of admission, using the one farthest from admission if more than one measure was available, or (3) if no outpatient SCR values were available within the year before the AKI hospitalization, the first inpatient SCR was assigned as the baseline SCR. Patients without at least one inpatient SCR measurement were excluded from the analysis. Serum creatinine measurements within the inpatient stay were then compared to the baseline SCR and each other, to identify episodes of AKI and to stage those episodes. We did not distinguish multiple episodes of AKI within one inpatient stay, only whether there was any or no AKI. Table 10.9 shows the criteria for AKI from the KDIGO guidelines.

vol 1 Table 10.9 KDIGO definition and staging of acute kidney injury

Definition of AKI:

An increase in serum creatinine (SCR) by ≥ 0.3 mg/dL ($\geq 26.5 \mu$ mol/I) within 48 hours; or an increase in SCR to ≥ 1.5 times baseline, which is known or presumed to have occurred within the prior seven days; or urine volume <0.5ml/kg/h for six hours.

AKI Stage	Serum creatinine	Urine output
1	1.5–1.9 times baseline <u>OR ></u> 0.3 mg/dL (>26.5 μmol/l) increase	<0.5 ml/kg/h for 6-12 hours
2	2.0–2.9 times baseline	0.5 ml/kg/h for ≥12 hours
3	3.0 times baseline <u>OR</u> increase in SCR to >4.0 mg/dL (\geq 353.6 μ mol/l) <u>OR</u> initiation of renal replacement therapy <u>OR</u> , in patients <18 years, decrease in eGFR to <35 ml/min/1.73m ²	<0.3 ml/kg/h for ≥24 hours <u>OR</u> anuria for ≥12 hours

Adapted from KDIGO (2012). Abbreviations: eGFR, estimated glomerular filtration rate; SCR, serum creatinine.

The consensus SCR criteria in the KDIGO guidelines contain two conditions to identify AKI. One is a rise by 0.3 mg/dL within 48 hours, and the second is an increase to 1.5 times baseline within seven days. A person's first SCR measurement on the day of admission was compared to their baseline to determine if that SCR is 0.3 mg/dL or 1.5 times higher. If so, the patient was said to have AKI. If not, the second SCR measurement was examined to determine if it was measured within two days of the admission, and if so, whether the second SCR is 0.3 mg/dL or 1.5 times higher than the baseline or the first inpatient measurement. This continues and when an SCR measure was more than 48 hours from admission, it was compared to all previous SCR measurement that occurred within 48 hours of its measurement, rather than to the patient's baseline.

For example, a patient with a baseline SCR of o.8 mg/dL is admitted. On January 1 they have a first inpatientSCR of o.8 mg/dL, then another on January 2nd measuring 0.7 mg/dL, another on January 4th of o.9 mg/dL, and then 1.5 mg/dL on January 5th. The January 5th measurement is compared to the January 4th, where it meets the criteria for AKI. It would not be compared to the measures of January 1st or 2nd, or the baseline for the 0.3 mg/dL increase condition. Similarly, for the increase to 1.5 times baseline over seven days, each SCR measurement is compared to all other SCR measurements within seven days of its date. If a patient experiences either the 48 hour increase or

the seven day increase he or she is said to have had a hospitalization with AKI.

Once the patient was determined to have experienced an AKI based on SCR changes, the hospitalization as a whole was used to assign the stage of AKI. The highest SCR during the hospitalization was compared to the baseline. If the difference was greater than three times the baseline, the highest SCR was greater than 4.0 mg/dL, or renal replacement therapy was used during the stay, that hospitalization was classified as Stage 3. If the AKI episode was not Stage 3 and the difference between the maximum SCR and baseline was more than two times baseline but less than three, the hospitalization was classified as Stage 2. If the AKI episode was not Stage 2 or 3, it was Stage 1, an increase of at least 0.3 mg/dL but less than two times baseline.

Figures 5.3-5.5 used the entire analysis cohort as the denominator to calculate rates of AKI per 1,000 patient years at risk for Medicare (panel a) and Optum Clinformatics[™] (panel b) beneficiaries. Each hospitalization with an AKI diagnosis (any position on the claim) for a patient was counted as an event, and years at risk were calculated for each patient as the time during the reported year (year two) censored at the development of ESRD, disenrollment from their plan (for Medicare, Parts A and B or a switch to a Medicare Advantage plan), death, or December 31 of year two. Age was as of January 1 of year two, while CKD and DM status were determined by claims in year one. For the 2017 ADR, a Poisson model was used to model the number of AKI events and the denominator was the sum of the time at risk of every cohort member.

REHOSPITALIZATION WITH AN AKI EPISODE

Figures 5.6 and 5.7 show the probability of having a second hospitalization with AKI within 24 months of the first hospitalization with AKI for Medicare (Figure 5.6) and Optum Clinformatics[™] (Figure 5.7) beneficiaries. The sample for this figure began with the 2013 cohort from the Characteristics of Patients with Acute Kidney Injury section above-alive, aged 66 or older, without ESRD, and enrolled in their plan (for Medicare, Parts A and B and no Medicare Advantage plan) on 1/1/2013. The first hospitalization with AKI in 2013 was identified. Age was as of 1/1/2013, and comorbidities were defined by searching claims one year prior to the AKI admission date (admission date-365 through one day before admission). Within this customized date range, CKD and DM status were defined according to the algorithm and codes described in the Identification of Major Comorbidities section and Tables 10.3 and 10.4 of this chapter. The final cohort for Figures 5.6 and 5.7 included only those patients with at least one hospitalization with AKI in 2013 who were discharged alive. Follow-up began on the date of discharge listed on the claim for the hospitalization with AKI, and continued until the earlier of a second hospitalization with AKI, death, ESRD, disenrollment from their plan (for Medicare, Parts A and B or a switch to a Medicare Advantage plan), or 730 days following the first AKI discharge. Kaplan Meier methods were used to estimate survival, with the cumulative probability of a recurrent hospitalization with AKI defined as (1-survival).

PATIENT CARE AND OUTCOMES

Figure 5.8 shows the outcomes of death or ESRD within one year of a live discharge from a hospitalization with AKI. For the 2017 ADR, we also present this data for the Optum Clinformatics[™] dataset. To increase the precision of these estimates, we created a cohort for this figure that included patients with a first hospitalization with AKI in 2013 or 2014. Patients were alive, aged 66 or older, without ESRD, enrolled in their plan (for Medicare, Parts A and B coverage, and with no Medicare Advantage plan

on January 1 of the year of their first hospitalization with AKI. Those who are discharged alive from their hospitalization with AKI were followed from the date of discharge until 365 days after discharge. For the models of time to ESRD and time to the composite end point of ESRD or death, the survival time was calculated from the date of discharge of the hospitalization with AKI to the earliest date of ESRD, death, disenrollment from their plan (for Medicare, Parts A or B or a switch to a Medicare Advantage program), or 365 days following discharge. Note that the mortality model in this year's ADR was not censored at the start of ESRD. For the mortality model, survival time was calculated from the date of discharge from the first hospitalization with AKI to the earliest of death, disenrollment from their plan (for Medicare, Parts A or B or a switch to a Medicare Advantage program), or 365 days following discharge.

Figures 5.9 presents the probability of a nephrology clinic visit within the first six months after a live discharge from a hospitalization with AKI. Claims were searched for services provided by nephrologists for 180 days following the discharge date of the hospitalization with AKI. In the Medicare data, visits with a nephrologist have the provider specialty code 36, while in the Optum Clinformatics[™] data they are identified by a provider category code for nephrologist (PROVCAT 0597-0604). Time to visit begins on the date of discharge listed on the claim for the hospitalization with AKI and continues until the earlier of the visit, death, ESRD, disenrollment from their plan (for Medicare, Parts A and B or a switch to a Medicare Advantage plan), or 180 days following the first AKI discharge. Kaplan Meier methods were used to estimate survival with the cumulative probability of a nephrology visit defined as (1-survival).

Figure 5.10 shows the renal status after one year for Medicare and Optum Clinformatics[™] patients discharged alive from their first hospitalization with AKI. To increase the precision of the estimates, we created a cohort for this figure of patients who had a first hospitalization with AKI in 2013 or 2014. Patients were alive, aged 66 or older, without ESRD, with plan coverage (for Medicare, Parts A and B coverage with no Medicare Advantage plan) on January 1 of the year of their hospitalization with AKI and did not have any claims with a diagnosis of CKD in the 365 days prior to

2017 USRDS ANNUAL DATA REPORT | VOLUME 1 – CKD IN THE UNITED STATES

that admission. Renal status after AKI was determined from claims occurring between discharge from the hospitalization with AKI and 365 days after discharge. CKD stage was determined by the 585.x or N18.x claim closest to 365 days after discharge, while ESRD determination used the first service date on the ESRD Medical Evidence form.

Figure 5.11 shows discharge status following a Medicare patient's first hospitalization in 2015. Panel a shows patients whose hospitalization contained an AKI episode while panel b shows those whose hospital stay did not. The cohort includes all patients who experienced a hospitalization during 2015 and are alive, aged 66 or older, enrolled in Medicare Parts A and B and not enrolled in a Medicare Advantage program, and without ESRD on January 1, 2015. For Medicare, patients admitted to an acute care hospital from a long-term care facility ('point of origin for admission,' previously named 'source of admission,' is 5) are excluded. Patients with a 'patient discharge status' code of oi (routine discharge to home) or o6 (discharged to home under care of a home health service organization in anticipation of covered skilled care) were identified as being discharged home. Those with a 'patient discharge status' of 50 (discharged to routine or continuous hospice at home) or 51 (transferred to an inpatient hospice program or facility) were identified as being discharged to hospice. Those identified as being discharged to an institution were those whose 'patient discharge status' was 03 (transferred to a Skilled Nursing Facility with Medicare certification in anticipation of skilled care), 62 (transferred to an inpatient rehabilitation facility including distinct part units of a hospital), or 63 (transferred to long term care hospital). Death was determined both by the date of death from the Master Beneficiary Summary File and the 'patient discharge status' of 20 (expired—this code is used only when the patient dies). 'Other' is a residual category that includes all discharges not identified by the previous categories.

Chapter 6: Healthcare Expenditures for Persons with CKD

This chapter used a cohort that continued the methodology introduced in the 2010 ADR, which we only tabulated CKD costs for patients with CKD

diagnoses (minimum of one inpatient and/or two outpatient) among their claims in the year prior to the reported year (year one). For example, the total costs of CKD for 2015 (year two) included all costs incurred by patients with a CKD diagnosis in 2014 (year one). Prior to the 2010 ADR, patients newly diagnosed with CKD during year two were also included in the total.

The same general point prevalent cohort was used to create all the Medicare tables and figures in this chapter, and a similar cohort was created for the Optum Clinformatics[™] tables and figures. Each year's cohorts included patients aged 65 and older who were alive and without ESRD on January 1 of the reported year (year two). Cohort members were continuously enrolled in their plan (for Medicare, Medicare Parts A and B and not enrolled in a Medicare Advantage plan) for all of year one (the one-year entry period prior to the year in which costs were assessed). Costs were then aggregated for the reported year (year two). Patient years at risk were calculated as the number of days (divided by 365.25) between January 1 of year two and the earliest of death, development of ESRD, disenrollment from their plan (for Medicare, Parts A or B or a switch to a Medicare Advantage program), or December 31 of year two. Per-person-per-year (PPPY) costs are produced by dividing the total cost amount by the number of patient years at risk. Since total costs and the numbers of patients for Medicare were based on the 5% Medicare files, we multiplied counts and expenditures by 20 in order to represent 100% of Medicare fee-for-service Parts A, B, and D expenditures. These were age-eligible patients who continuously enrolled in Parts A and B, and not enrolled in a Medicare Advantage plan, for all of the previous year (year one). The Optum Clinformatics™ data represents 100% of their beneficiaries, thus there was no need to weight the data to population totals.

New to the 2017 ADR, we are no longer attributing only a fraction of claims that span the calendar year to each year, but rather we place the entire payment for a claim spanning a calendar year in the year corresponding to the admission date.

The disease conditions of CKD, heart failure (HF), diabetes mellitus (DM), and the stage of CKD were determined from the claims in the year prior to the reported year (year one) using the algorithm described in the *Identification of Major Comorbidities* section of

this chapter and the diagnosis codes listed in Tables 10.3 and 10.4. Age was determined as of December 31 of year one. Table 6.1 shows the Medicare population aged 65 and older, total spending, per-patient, peryear spending, the fraction of the total Medicare population with the given disease conditions, and the fraction of total Medicare spending for the given disease conditions. Table 6.2 shows the Optum Clinformatics[™] data for members aged 65 and older covered by their commercial insurance and Medicare Advantage plans. For each plan type, the per-patient, per-year spending is shown, as is the fraction of the total plan members with each given condition and the fraction of total plan spending for each condition. Tables 6.3 and 6.4 show the same statistics for beneficiaries and members who were under the age of 65. Figure 6.1 shows the information in Table 6.1 graphically, along with the same information for the previous year.

Table 6.5 shows two years of per-person, per-year spending for any stage of CKD and by CKD stage for Medicare fee-for-service coverage, and Table 6.6 shows this for Optum Clinformatics[™] commercial insurance and Optum Clinformatics[™] Medicare Advantage plans. Costs and conditions were determined as in Tables 6.1, 6.2 and Figure 6.1 while race and sex were provided by the Master Beneficiary Summary File. Figure 6.2 displays this information graphically and for four years. Table 6.7 shows data similar to Table 6.5 but for those with CKD and DM. Table 6.8 shows the same statistics as Table 6.7 but for the Optum Clinformatics[™] Medicare Advantage and commercial insurance enrollees. Table 6.9 repeats Table 6.7, but for those with CKD and HF rather than DM. Table 6.10 presents the same results as Table 6.9, but for the Optum Clinformatics[™] Medicare Advantage and commercial insurance enrollees.

The focus of Figures 6.3 through 6.6 is expenditure trends. Figure 6.3 shows the spending on fee-forservice Parts A, B, and D for all Medicare patients and Medicare patients with CKD for all patients (panel a), patients with DM (panel b) and patients with HF (panel c). Figure 6.4 shows Medicare spending for feefor-service enrollees with CKD by the type of Medicare claim, which corresponds to the type of medical service delivered. The categories include inpatient institutional claims (billed by the hospital or other

facility), outpatient claims billed by facilities, physician/supplier claims (services from noninstitutional providers, mostly covered under Part B), skilled nursing facilities (Medicare covers short term stays for rehabilitation after medical procedures or surgery but not long-term care), home health agencies (another service provided following medical procedures or surgeries), hospice care, and Part D prescription drug claims. Figure 6.5 shows inpatient institutional costs by the cause of hospitalization, which was determined using the same methods as in Chapter 3, using the codes displayed in Table 10.5. Figure 6.6 shows per-person, per-year (PPPY) spending by a combination of chronic conditions. We included all patients regardless of condition-those without DM and HF, those with CKD and DM, CKD and HF, and those with all three (CKD, DM, and HF). Panel a shows Medicare fee-for-service spending, panel b shows Optum Clinformatics[™] commercial insurance plan members, and panel c shows Optum Clinformatics[™] Medicare Advantage spending.

Chapter 7: Prescription Drug Coverage in Patients with CKD

This chapter describes prescription drug coverage and usage. New for the 2017 ADR, it shows prescription drug utilization from the Optum Clinformatics[™] dataset for both those in Medicare Advantage plans and those in commercial plans as well as Medicare 5% sample beneficiaries. CKD was determined as described in the Identification of Major Comorbidities section of this chapter and Table 10.3, using claims from a one-year entry period (year one, the calendar year before the year in which prescription drug coverage participation and utilization was assessed). Prescription drug utilization and enrollment (for Part D coverage only) were assessed in the following year (year two, the year reported in the figures and tables), while ESRD was determined by the ESRD first service date. In this Prescription Drug Coverage chapter in Volume 1, both the General Medicare cohort and the CKD cohort had the same inclusion criteria, representing a change from the 2013 and earlier ADRs. This is also different from the sample used to describe General Medicare patients in Volume 2, Chapter 12, which does not apply restrictions based on year-one Medicare participation.

2017 USRDS ANNUAL DATA REPORT | VOLUME 1 - CKD IN THE UNITED STATES

In this chapter, beneficiaries must have been enrolled in their plan (for Medicare, Parts A and B and not enrolled in a Medicare Advantage plan) for all of year one and be alive, without ESRD, and enrolled in their plan on January 1 of year two. Note that those with a Medicare Advantage plan in January of year two were not specifically excluded; if a beneficiary was not in a Medicare Advantage plan for all of year one, but switched to Medicare Advantage for year two, they were still included in the analysis cohort. These criteria were necessary for the Medicare cohort to enable CKD identification, as diagnosis codes were only available for those with fee-for-service Medicare. In order to have an appropriate comparison for the CKD cohort, the same exclusion criteria were applied to the General Medicare group. Unlike the other chapters in Volume 1, this chapter includes all beneficiaries aged 20 years and older. For inclusion in the Medicare cohort, those under age 65 must have been eligible for Medicare through participation in federal disability programs (Social Security Disability Insurance or Supplemental Security Income) or their entitlement was related to amyotrophic lateral sclerosis, and thus should not be viewed as representative of the U.S. general population under age 65. On the other hand, the Optum Clinformatics[™] dataset represents those of prime working age in the country and is representative of the younger age groups.

Figures 7.1-7.3 summarize the prescription drug insurance coverage for Medicare beneficiaries by source, comparing the General Medicare and CKD 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 was 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 was enrolled in a Part D plan and received a low-income subsidy (LIS) in at least one month, he or she was classified as "Part D with LIS", and as "Part D without LIS" otherwise. The receipt of a low income subsidy was determined by the monthly Cost Sharing Group Code values "oı" through "o8."

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 were classified as "Retiree Drug Subsidy" if they were not enrolled in a Part D plan but had at least one month with a Part D Retiree Drug Subsidy Indicator value of "Y" (yes), indicating he or she was enrolled in an employersponsored prescription drug plan that qualified for Part D's retiree drug subsidy.

If the patient was not in a Part D plan or employersponsored 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 was at least as generous as the Part D benefit. This alternate coverage is known as creditable coverage because beneficiaries who maintain it do not have to pay a late enrollment penalty if they subsequently enroll in Part D. If a beneficiary meets none of the situations described above, he or she is classified as "No Known Coverage." Figure 7.1 presents the distribution of this categorical variable for the General Medicare and CKD cohorts described above.

Table 7.1 shows the percent of beneficiaries with Part D coverage for the past five years in the General Medicare and CKD cohorts. Table 7.2 is an adaptation of data presented in the 2015 Medicare Outlook section of the <u>www.qumedicare.com</u> web site, and has no analyses. Figure 7.2 shows the categories of prescription drug coverage (described above for Figure 7.1) by age groups (20 to 44, 45 to 64, 65 to 74, and 75 and older) for General Medicare (panel a) and CKD (panel b), while Figure 7.3 shows the coverage categories by race groups (White, Black or African American, Asian, Other.

Table 7.3 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 were determined as described for

VOLUME 1: CKD ANALYTICAL METHODS

Figure 7.1. Table 7.3 shows the percent of Part D enrollees with LIS within each race group ("all ages" row) and by age groups within the race group (also defined as above) for the General Medicare cohort and the CKD cohort. Figure 7.4 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 CKD cohorts.

Table 7.4 and Figure 7.5 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 7.4 shows the total Medicare Part D benefit expenditures for the General Medicare and CKD cohorts (defined above) for beneficiaries enrolled in stand-alone Part D plans (i.e., spending for Medicare Advantage prescription drug plans is not included). These cost numbers are, therefore, comparable to the statistics presented in Chapter 6, which show Medicare spending on Parts A and B benefits for those not in Medicare Advantage plans.

Figure 7.5, panel a shows spending and patient outof-pocket amounts per-person, per-year (PPPY) for the General Medicare members and CKD cohorts for those in fee-for-service Part D plans, Optum Clinformatics[™] Medicare Advantage plans, and Optum Clinformatics[™] commercial insurance plans. Out-of-pocket cost is the sum of the amounts the patient pays without being reimbursed by a third party (for fee-for-service Medicare, the Patient Payment Amount) which includes all copayments, coinsurance, deductible, or other patient payment amounts. For fee-for-service Medicare, this includes the amount of any payment made by other third-party payers that reduced the beneficiary's liability for the PDE or prescription claim (Other True Out-of-Pocket Amount). Two examples of this are payments by qualified state pharmacy assistance programs or charities. Panel b breaks out these costs by whether the patient received any low income subsidies. Table 7.5 shows PPPY spending by age, sex, and race for the General and CKD cohorts by fee-for-service Medicare with LIS, fee-for-service Medicare without LIS,

Optum Clinformatics[™] Medicare Advantage plans and Optum Clinformatics[™] commercial insurance plans.

All drugs in the PDE file and Optum Clinformatics[™] RX table were matched to a therapeutic category according to the American Hospital Formulary Service classification system. The Medicare cohort for Tables 7.6 and 7.7 was limited to those in the CKD cohort who had stand-alone Part D prescription drug coverage. Each therapeutic category was summarized and the percent of patients with CKD who filled at least one prescription for a drug in the given class was calculated, as well as the total amount spent by Medicare or the plans in the Optum Clinformatics[™] dataset on each drug class and its percentage of total prescription drug plan expenditures. Table 7.6 shows the top 15 drug classes ranked by the highest percent of CKD patients with at least one prescription filled in that class for fee-forservice Medicare, Optum Clinformatics[™], Medicare Advantage, and Optum Clinformatics[™] commercial insurance. Table 7.7 shows the top 15 drug classes ranked by spending. The column following the drug class name shows the total amount spent by Medicare (panel a), Optum Clinformatics[™] Medicare Advantage (panel b) and Optum Clinformatics[™] commercial insurance (panel c) on each drug class for CKD patients. The next column shows that drug class' cost as a percentage of all plan expenditures for these patients.

New in the 2017 ADR, this chapter has a special focus on analgesic drugs. Analgesics were identified as members of the AHFS classes 280804 - nonsteroidal anti-inflammatory agents (NSAIDs), 280808 - opiate agonists, and 280812 - opiate partial agonists. The cohort was the same as the Medicare cohort used in Tables 7.6 and 7.7; it excluded those with Medicare Advantage Part D plans as we are unable to identify CKD in those patients. Analgesic use in patients with CKD was defined as having filled or refilled at least one prescription of a drug in the drug classes listed above. The state of residence was from the Medicare Beneficiary Summary File. Figure 7.6 tabulates the use of NSAIDs (yes/no) by state, divides the states by quintiles, and shows the results in a map. Figure 7.7 does the same with the use of opiates.

Reference Tables

CKD REFERENCE TABLES

REFERENCE TABLE B: PREVALENCE

Reference Tables B.1–B.6 present estimated point prevalent (December 31) counts of the Medicare non-ESRD population, based on the 5% Medicare sample, for adults aged 20 and older rather than the ageeligible (aged 65 and older) cohort presented in Chapter 2. Each year's cohort included all patients alive and without ESRD, who were continuously enrolled in Medicare Parts A and B, and not enrolled in a Medicare Advantage program for the entire year. Age was calculated as of December 31 of the reported year. Race and sex were provided by the Master Beneficiary Summary File. The disease conditions of CKD, heart failure (HF), and diabetes mellitus (DM) and the stage of CKD were determined from claims in the reported year, using the methods described in the Identification of Major Comorbidities section of this chapter and the diagnosis codes listed in Tables 10.3 and 10.4. Counts were multiplied by 20 to represent 100% of the Medicare population meeting the cohort definition.

Reference Tables B.7-B.10 were based on NHANES data (see the NHANES methods description in the *Chapter 1: CKD in the General Population* section, above). For Table B.8, CKD was defined as an estimated glomerular filtration rate (eGFR) less than 60 ml/min/1.73m² (which identifies Stages 3 and 4) <u>or</u> urine albumin creatinine ratio (ACR) greater than 30 mg/g (which identifies Stages 1 and 2). eGFR was estimated from one serum creatinine measurement using the CKD-EPI equation (Levey et al., 2009).

The consensus definition of CKD requires two measurements of both eGFR and ACR meeting the criteria above within a three-month period, but only one measurement of each is available in NHANES. Therefore, the resulting numbers may overestimate the true number of CKD patients in the general U.S. population. CKD staging is as defined by the Kidney Disease Outcomes and Quality Improvement (KDOQI) CKD guidelines (NKF, 2002).

In Table B.9, diabetes mellitus (DM) was defined as in Chapter 1, and eGFR and ACR as described for Table B.8. Table B.10 presents results for heart failure (HF), which is self-reported in NHANES as an affirmative answer to, "Has a doctor or other health professional ever told you that you have congestive heart failure?"

REFERENCE TABLE K: MEDICARE EXPENDITURES

In Tables K.1–5 we present estimates of the perperson, per-year Parts A, B, and D Medicare expenditures for point prevalent (December 31) general Medicare patients, also derived from the 5% Medicare sample. Methods for these tables were the same as those described in the *Chapter 6: Medicare Expenditures for CKD* section of this document. The reference tables included all adult patients aged 20 and older, while the chapter presents these costs only for those age-eligible for Medicare (aged 65 or older).

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