
**2016 USRDS ANNUAL DATA REPORT:
Epidemiology of Kidney Disease
in the United States**

Volume 1: CKD in the United States

Introduction to Volume 1: CKD in the United States

Introduction

Chronic kidney disease (CKD) has continued to receive more attention, primarily since the consensus definition and staging classification of CKD was first published by the National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI). Federal agencies have also done much to raise awareness of CKD as a significant public health problem. The USRDS Annual Data Report (ADR) first included a chapter addressing CKD in 2002, and expanded this to a multi-chapter CKD volume in 2008. In 2002, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) launched a 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.

The Centers for Disease Control and Prevention (CDC) supports a CKD initiative with the CKD Surveillance Program as its major component; since 2007, this project has reported on many aspects of this important chronic condition.

A nexus between common non-communicable diseases (NCDs), such as diabetes mellitus, hypertension, obesity, and CKD is well recognized. Over the last decade, the relationship between acute kidney injury (AKI) and CKD has received greater attention. During the 2011 High-Level Meeting of the United Nations General Assembly on Prevention and Control of NCDs, it was recognized that, similar to other chronic NCDs “...pose a major health burden for many countries and that these diseases share common risk factors and can benefit from common responses to non-communicable diseases” (United Nations, 2011). The Meeting concluded, however, that CKD could be addressed as a complication of the four main NCDs highlighted by the World Health Organization: cardiovascular disease, cancer, chronic lung diseases,

and diabetes mellitus. At present, the national NCD public health programs of many countries do not specifically include CKD as a public health priority. It is imperative that CKD continue to be recognized as an NCD in its own right, and directly addressed in national programs to combat NCDs around the world. CKD is common, and is associated with high morbidity, mortality, and cost, yet is readily identifiable by simple testing of blood and urine. Timely recognition and treatment has the potential to delay progression of the disease and reduce complications.

While the number of new patients with end-stage renal disease (ESRD) appears to be stabilizing in the United States, the need to further reduce both the incidence and prevalence of this devastating complication of kidney disease cannot be overemphasized. The key to success is undoubtedly in the realm of prevention and optimal management of CKD in order to slow progression, with the goal of completely avoiding ESRD. Large observational studies have shown that even mild to moderate reductions in kidney function and small quantities of albumin in the urine are associated with high rates of all-cause mortality and cardiovascular mortality in particular. CKD has therefore been appropriately recognized as a ‘cardiovascular risk equivalent’.

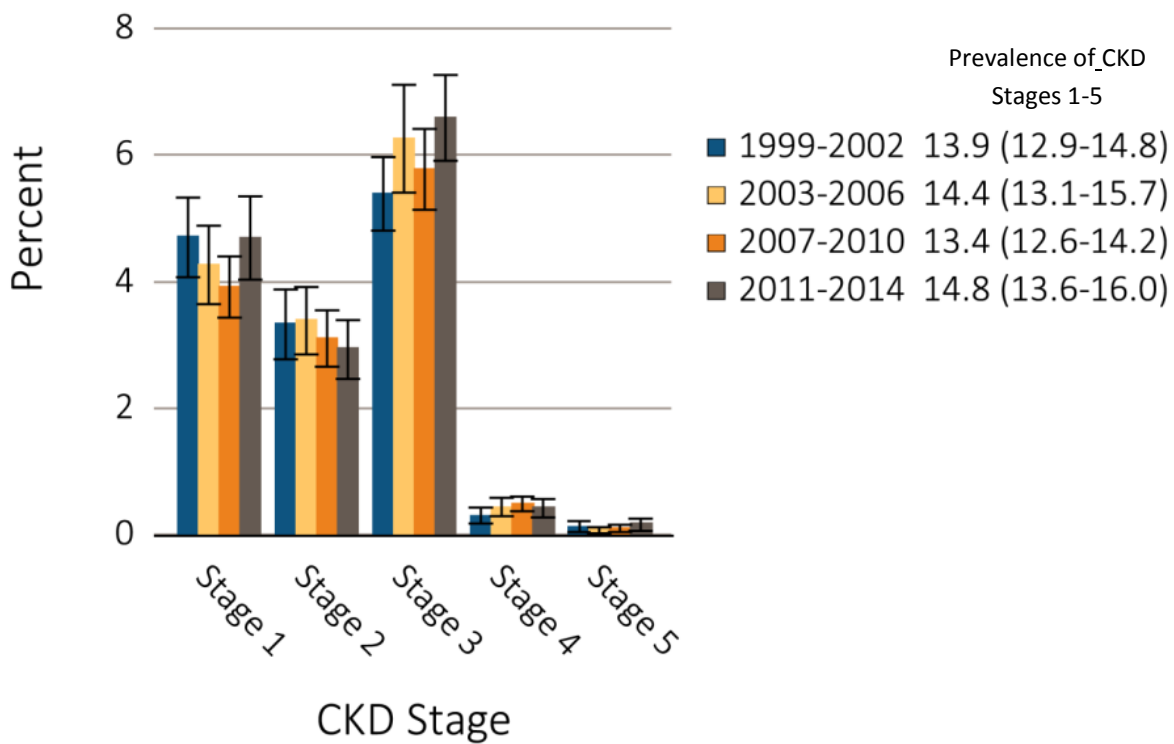
Volume 1 of the 2016 USRDS ADR provides key statistics on CKD in the United States. Volume 1 includes the following chapters: *CKD in the General Population* (Chapter 1); *Identification and Care of Patients With CKD* (Chapter 2); *Morbidity and Mortality in Patients with CKD* (Chapter 3); *Cardiovascular Disease in Patients with CKD* (Chapter 4); *Acute Kidney Injury* (Chapter 5); *Medicare Expenditures for Persons with CKD* (Chapter 6); *Medicare Part D Prescription Drug Coverage in Patients with CKD* (Chapter 7); and *Transition of Care in Chronic Kidney Disease* (Chapter 8).

Chapter 1: CKD in the General Population

As for many other conditions, the National Health and Nutrition Examination Survey (NHANES) has been a valuable resource for estimation of the prevalence of CKD in the United States. NHANES data are released biennially; we primarily report trends based on four 4-year time periods within the last 16 years—1999–2002, 2003–2006, 2007–2010, and 2011–2014. Chapter 1 uses these data to describe CKD in the U.S. general (non-institutionalized) population of people aged 20 and older. We find that CKD is more common than diabetes mellitus in the United States; an estimated 14.8% of adults have CKD by most recent estimates, compared to 12.3% with diabetes mellitus. It has been argued that this may well be an overestimate

of CKD prevalence, as it is based on single point estimates of serum creatinine and urine albumin available in the NHANES survey, while the consensus clinical definition of CKD requires the demonstration of persistent abnormality over at least a three-month period. However, for public health surveillance of CKD, a single measurement in stable, ambulatory individuals appears to be a satisfactory compromise, as implementation of two or more measurements is likely not practical on a large scale, in a national study such as NHANES. As shown in Figure i.1, the overall prevalence of CKD increased from 12% to 14% between 1988–1994 and 1999–2004, and the most recent estimate is 14.8% in 2011–2014, with CKD stage 3 being the most prevalent stage.

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

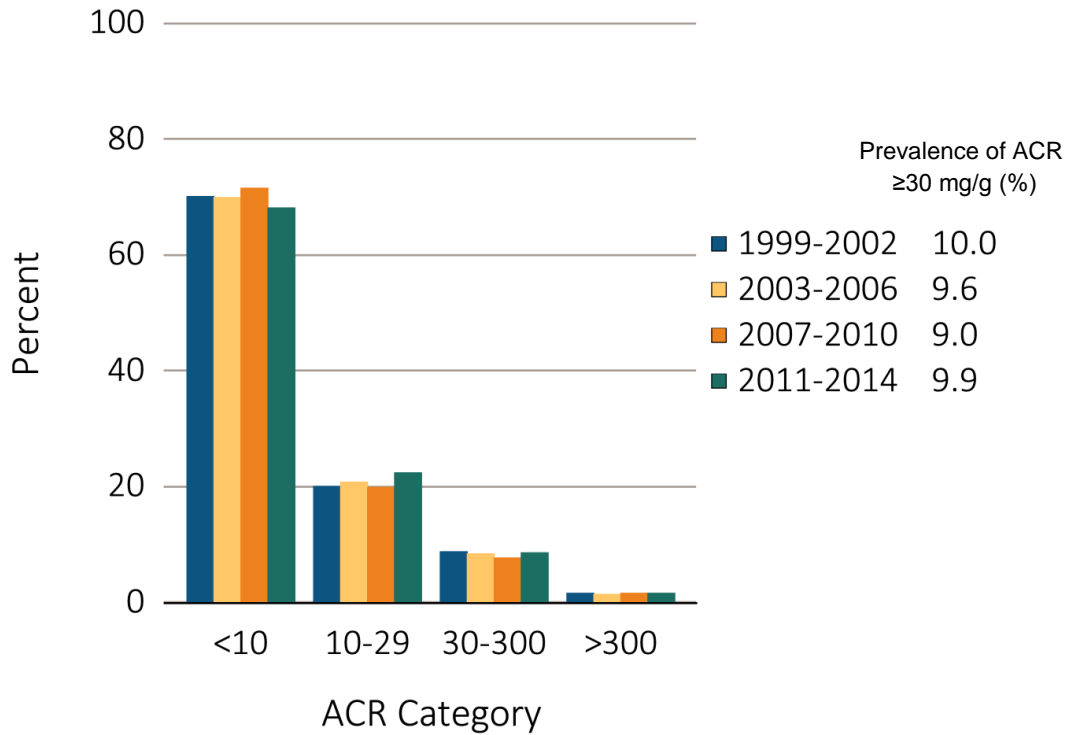


Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2002, 2003-2006, 2007-2010 & 2011–2014 participants aged 20 & older. Whisker lines indicate 95% confidence intervals. Abbreviation: CKD, chronic kidney disease. This graphic is adapted from Figure 1.1.

The most recent KDIGO guidelines emphasize the importance of albuminuria in individuals with CKD.

Figure i.2 displays urine albumin/creatinine ratio (ACR) among NHANES participants.

vol 1 Figure i.2 Urine albumin/creatinine ratio (ACR) distribution among NHANES participants, 1999-2014



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. This graphic is adapted from Figure 1.3.

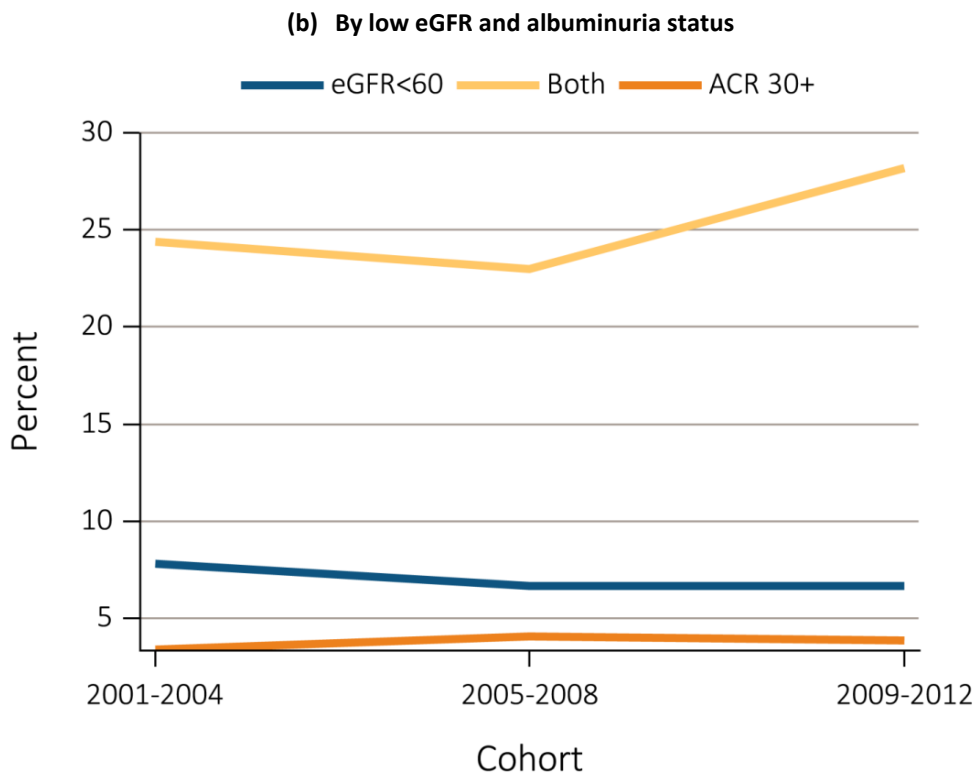
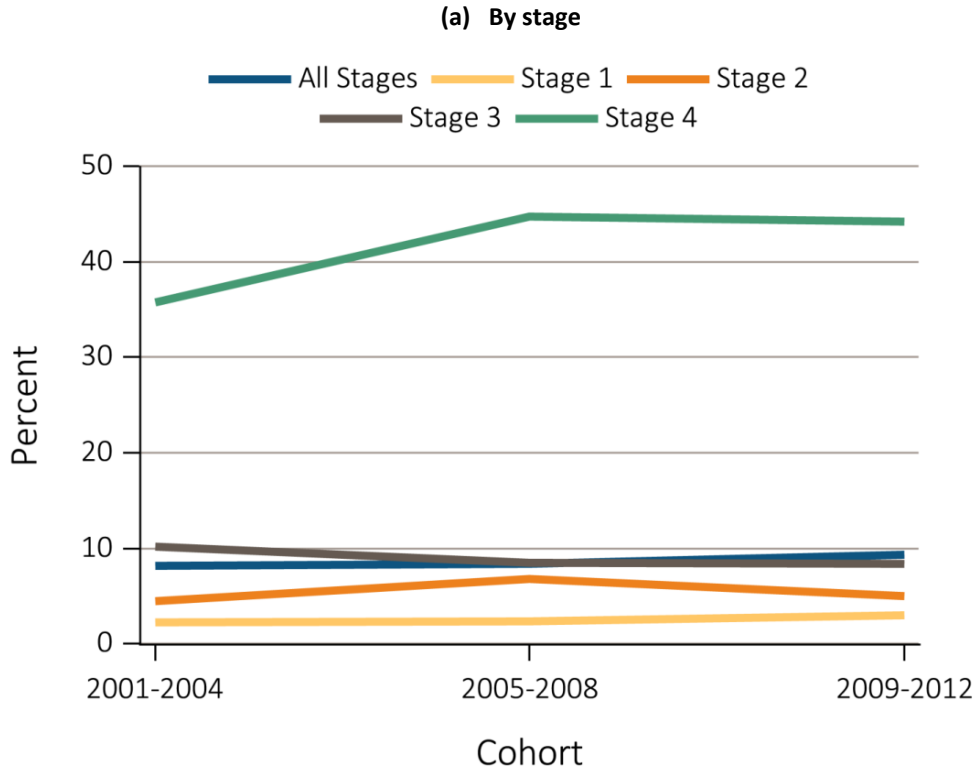
There has been little change over time in the distribution patterns of individuals with ACR of 30-300 mg/g or ACR >300 mg/g. However, examination of the groups with ACR <30 mg/g, shows a decrease in the proportion of individuals with ACR <10 and an increase in the proportion of individuals with ACR of 10 to <30 mg/g, over the four periods. This has important mortality implications, as increased rates of all-cause mortality have been seen at ACR at low as 10 mg/g.

Aging as a risk factor for CKD has emerged as important theme in recent years. Other important and clinically relevant risk factors that should prompt

screening for the presence of CKD include the presence of diabetes mellitus, hypertension, cardiovascular disease, obesity, or metabolic syndrome, a family history of ESRD or CKD, and a history of AKI.

CKD is a notoriously silent disease, and patient awareness remains very low at less than 10% for those with Stages 1-3 CKD (Figure i.3a and b). Not surprisingly, awareness is higher among those with Stage 4 CKD, by which time patients often experience overt symptoms, and among those with both albuminuria and lower eGFR than with either abnormality alone.

vol 1 Figure i.3 NHANES participants with CKD aware of their kidney disease, 2001-2012



Data Source: National Health and Nutrition Examination Survey (NHANES), 2001-2012 participants aged 20 & older. Abbreviations: CKD, chronic kidney disease. This graphic is adapted from Figure 1.16.

Chapter 2: Identification and Care of Patients with CKD

Epidemiological evaluations of the identification and care of patients with chronic kidney disease (CKD) are a significant challenge. While NHANES continues to serve as a rich source of information for estimating the prevalence of CKD and analyzing risk factors, it does not contain health system derived data, such as claims data from Medicare or other health plans or health systems. For this year's chapter, we have utilized several health care datasets, including the general Medicare 5% sample, with an average of 1.2 million patients each year, Clinformatics™ Data Mart data (drawn from the commercial plans of a large U.S. national health insurance company), with information on about nine million lives per year, and national health system-derived data from the U.S. Department of Veterans Affairs (VA). 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 in Medicare managed care programs are not included due to the absence of billing claims. The Clinformatics™ Data Mart data provides insight into a younger, employed population and their

dependent children. Like Medicare data, it contains information in the form of diagnosis and procedure codes on claims. The Clinformatics™ dataset also includes information on pediatric age groups, although for the analyses in this chapter only adult patients aged 22-64 years are included. Finally, the VA dataset includes diagnosis and procedure codes, as well as fairly complete biochemical results data. This allows comparison of the prevalence of CKD based on diagnosis codes versus biochemical data.

Throughout this chapter, the term “recognized CKD” is used when patients are identified based on the presence of a relevant diagnosis code in Medicare, Clinformatics™, or VA data, meaning that either a provider or billing coder in the health care system recognized the presence of CKD. As such, prevalence of recognized CKD may not necessarily reflect true disease prevalence, and any observed trend may not necessarily reflect true change in disease prevalence, but rather change in awareness or recognition of CKD, or indeed in billing practices, in general.

Table i.1 presents demographic and comorbidity characteristics of individuals in the Medicare 5% sample (aged 65 and older) and the Clinformatics™ dataset.

vol 1 Table i.1 Demographic characteristics of all patients, among Medicare (aged 65+ years) and Clinformatics™ (all ages) patients, 2014

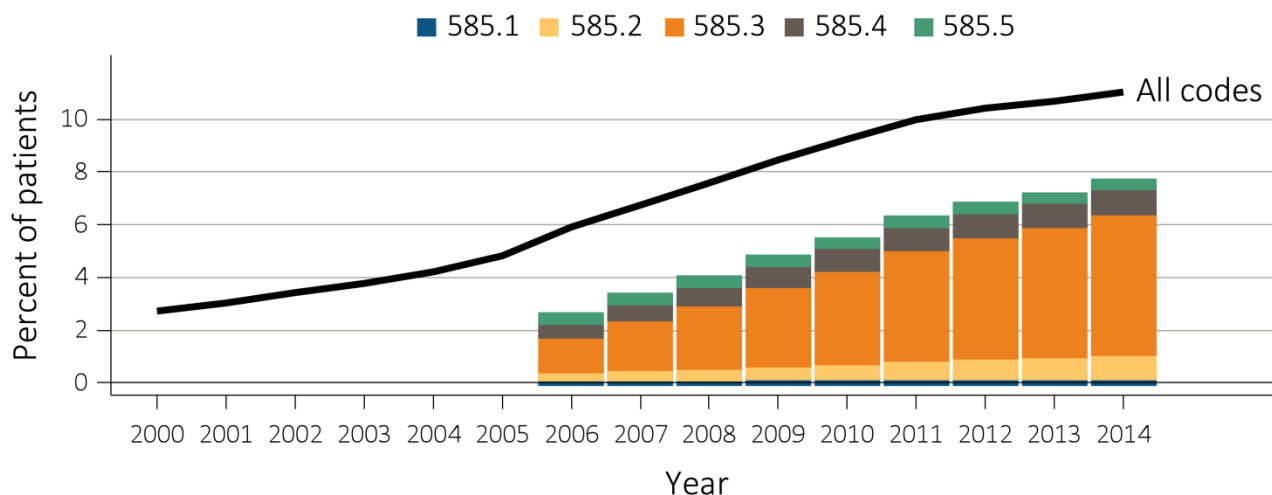
	<i>Medicare 5%</i>		<i>Clinformatics™</i>	
	Sample count	(%)	Sample count	(%)
All	1,276,732	100%	6,445,818	100%
Age				
<4	-	-	281,307	4.4
5-9	-	-	412,438	6.4
10-13	-	-	357,248	5.5
14-17	-	-	373,678	5.8
18-21	-	-	367,539	5.7
22-30	-	-	798,922	12.4
31-40	-	-	1,043,124	16.2
41-50	-	-	1,131,850	17.6
51-65	-	-	1,444,158	22.4
65-74	712,995	55.9	179,303	2.8
75-84	392,923	30.8	39,673	0.6
85+	170,814	13.4	16,578	0.3
Sex				
Male	554,559	43.4	3,279,378	50.9
Female	722,173	56.6	3,165,945	49.1
Race/Ethnicity				
White	1,095,736	85.8	4,469,440	69.7
Black/African American	96,565	7.6	556,682	8.7
Native American	5,407	0.4		
Asian	24,606	1.9	334,804	5.2
Hispanic	-	-	707,399	11.0
Other	42,846	3.4		
Unknown/Missing	11,572	0.9	341,121	5.3
Comorbidity				
DM	302,155	23.7	281,945	4.4
HTN	753,286	59.0	663,987	10.3
CVD	497,773	39.0	286,632	4.5

Data Source: Special analyses, Medicare 5% sample (aged 65 and older) and Clinformatics™ (all ages) alive & eligible for all of 2014. Abbreviations: CKD, chronic kidney disease; CVD, cardiovascular disease; DM, diabetes mellitus; HTN, hypertension. 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. - No available data. This table is adapted from Table 2.1.

The mean age of the Medicare patients was 75.9 years, and the mean age of Clinformatics™ patients was 52.3 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 have diagnoses of hypertension and diabetes, respectively. In comparison, only 10.3% and 4.4% of the total Clinformatics™ population have diagnoses of hypertension and diabetes, respectively.

Figure i.4 shows the trend from 2000-2014 in prevalence of recognized CKD overall and by CKD

vol 1 Figure i.4 Trends in prevalence of recognized CKD, overall and by CKD stage, among Medicare patients (aged 65+ years), 2000-2014



Data Source: Special analyses, Medicare 5% sample. Known CKD stages presented as bars; curve showing “All codes” includes known CKD stages (codes 585.1-585.5) and the CKD-stage unspecified codes (585.9, and remaining non-585 CKD codes). Note: In previous years, this graph reported 585.9 codes as a component of the stacked bars. Abbreviation: CKD, chronic kidney disease. This graphic is adapted from Figure 2.1.

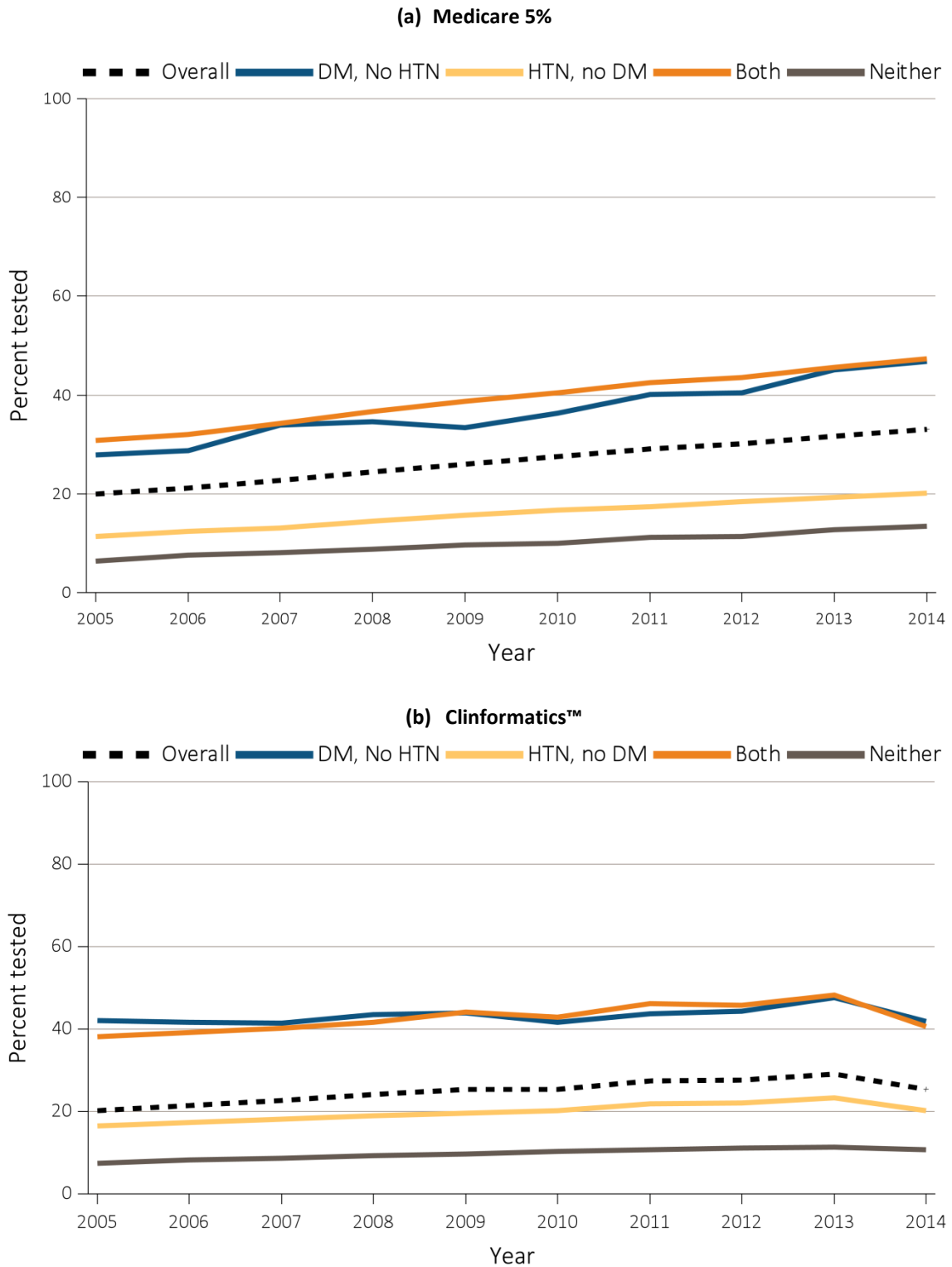
Urine albumin testing is important for monitoring patients with diabetes mellitus, and the recent Kidney Disease: Improving Global Outcomes (KDIGO) guidelines on CKD evaluation and management emphasize the importance of testing CKD patients for the presence of albuminuria in addition to estimated glomerular filtration rate (eGFR) for risk stratification purposes. Because urine albumin testing must be ordered separately from standard blood tests (as opposed to serum creatinine, which is usually

stage-specific code in the Medicare 5% sample. It shows that the prevalence of recognized CKD has steadily risen each year.

This diagnosis claims-based estimate likely underestimates the true prevalence of CKD in enrollees using Medicare-reimbursed health care services (especially when compared to the high rate of CKD estimated from NHANES), but has high specificity, identifying the individuals likely to have an accurate diagnosis.

included as part of a standard panel of tests), urine albumin testing may better represent intent to assess kidney disease. As shown in Figure i.5, among patients with a diagnosis of CKD, patterns of testing revealed somewhat higher rates of urine testing, to patients without CKD. For example, in 2014, among patients with a diagnosis of CKD and both diabetes and hypertension, urine albumin testing was performed for 48% in the Medicare population and 43% in the Clinformatics™ population.

vol 1 Figure i.5 Trends in percent of patients with testing of urine albumin in (a) Medicare 5% (aged 65+ years) & (b) Clinformatics™ (aged 22-64 years) patients with a diagnosis of CKD by year, 2005-2014



Data Source: Special analyses, Medicare 5% sample (aged 65 and older) with Part A & B coverage in the prior year and Clinformatics™ population (aged 22-64 years). Tests tracked during each year. Abbreviations: CKD, chronic kidney disease; DM, diabetes mellitus; HTN, hypertension. This graphic is adapted from Figure 2.3.

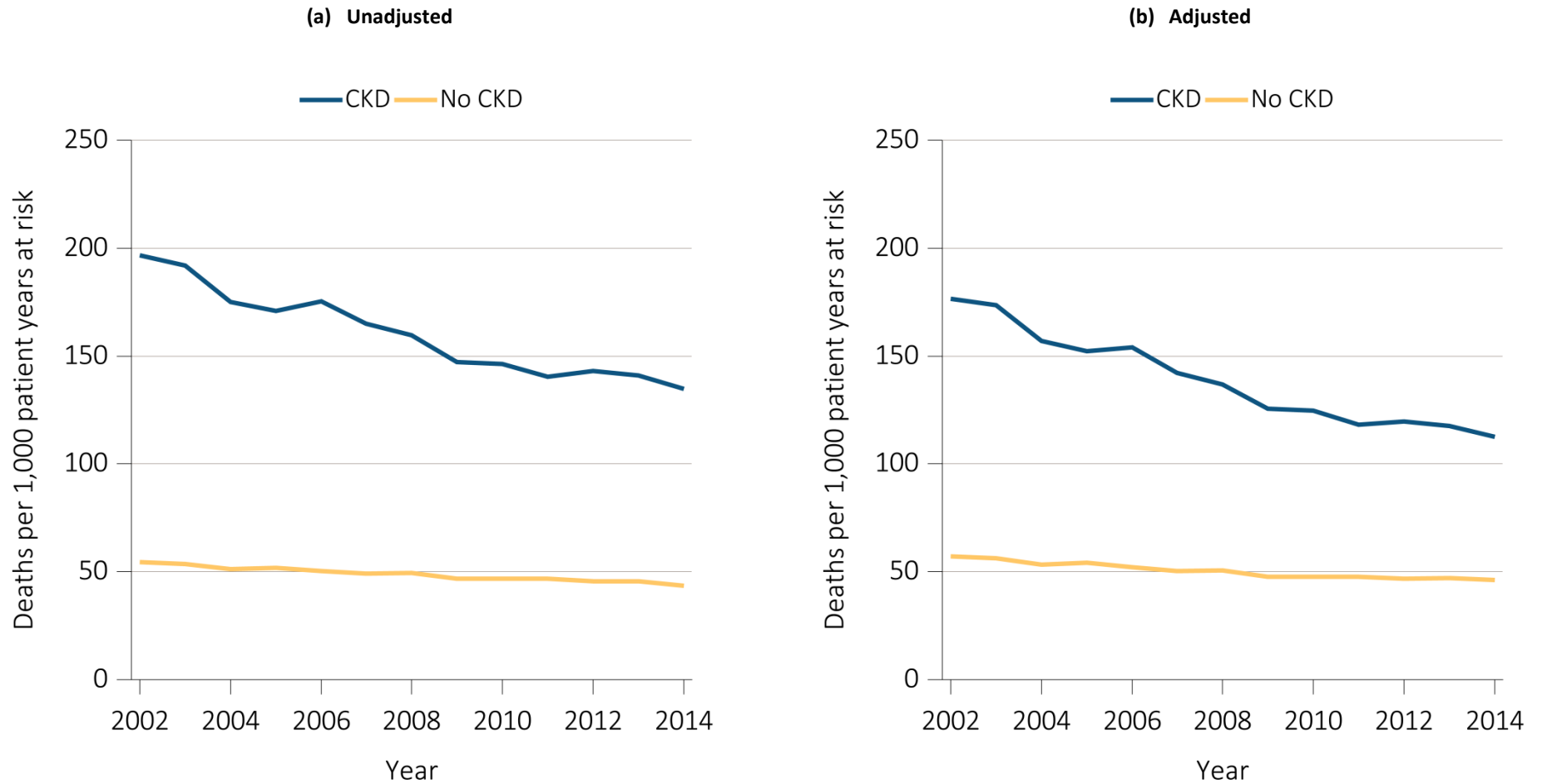
Chapter 3: Morbidity and Mortality in Patients with CKD

In this chapter we evaluate the morbidity and mortality of patients with chronic kidney disease (CKD). All 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, 9th revision, clinical modification) diagnosis codes from Medicare claims. As with many chronic conditions, patient mortality in those with CKD is of paramount importance as a major outcome.

Adjusted mortality rates were higher for Medicare patients with CKD than those without, and rates

increase with CKD stage, a finding consistent with studies using biochemical measures to define CKD (e.g. serum creatinine with validated equations to eGFR). Trends in the mortality rates for Medicare patients aged 66 and older are shown in Figure i.6. Unadjusted mortality in CKD patients has decreased by 31.5% since 2002, from 197 deaths per 1,000 patient years to 135 deaths in 2014. For those without CKD, the unadjusted rate decreased from 55 deaths per 1,000 patient years in 2002 to 44 deaths in 2014, a reduction of 20.0%. When adjusted for age, race, and sex, the 2014 mortality rate for CKD patients reduced considerably, to 113 deaths per 1,000 patient years at risk (ref:2013). Among those without CKD, adjustment for these factors resulted in a slightly higher mortality rate of 47 deaths per 1,000, as compared to the unadjusted rate of 44.

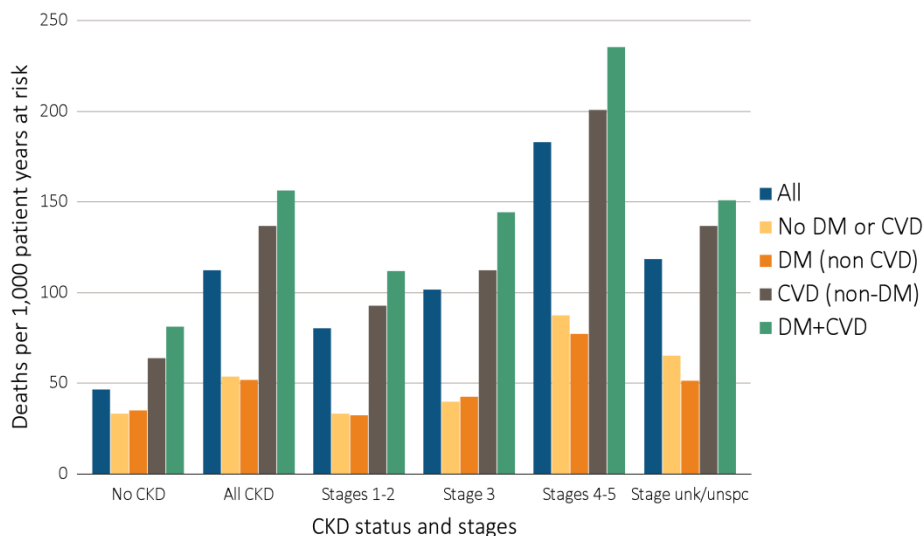
vol 1 Figure i.6 Unadjusted and adjusted all-cause mortality rates (per 1,000 patient years at risk) for Medicare patients aged 66 and older, by CKD status and year, 2002-2014



Data source: Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race. Reference population 2013 patients. Abbreviation: CKD, chronic kidney disease. This graphic is adapted from Figure 3.1.

The co-occurrences of DM and CVD with CKD multiply a patient’s risk of death (Figure i.7)

vol 1 Figure i.7 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, 2014

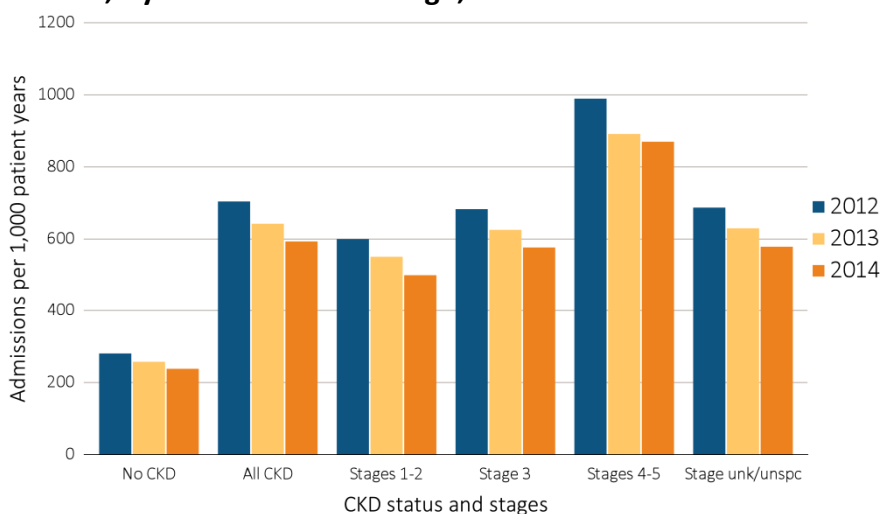


Data source: Medicare 5% sample. January 1, 2014 point prevalent patients aged 66 and older. Adjusted for age/sex/race. Reference population all patients, 2014. Abbreviations: CKD, chronic kidney disease; CVD, cardiovascular disease; DM, diabetes mellitus; unk/unspc, CKD stage unidentified. This graphic is adapted from Figure 3.6.

Rates of all-cause hospitalizations in 2014 increased with disease severity, from 492 admissions per 1,000 patient years for those in Stages 1 and 2, to 569 for

Stage 3, and 864 for Stages 4 and 5; notably, these were uniformly lower than those that occurred in 2012 and 2013 (see Figure i.8).

vol 1 Figure i.8 Adjusted all-cause hospitalization rates (per 1,000 patient years at risk) for Medicare patients aged 66 and older, by CKD status and stage, 2012-2014

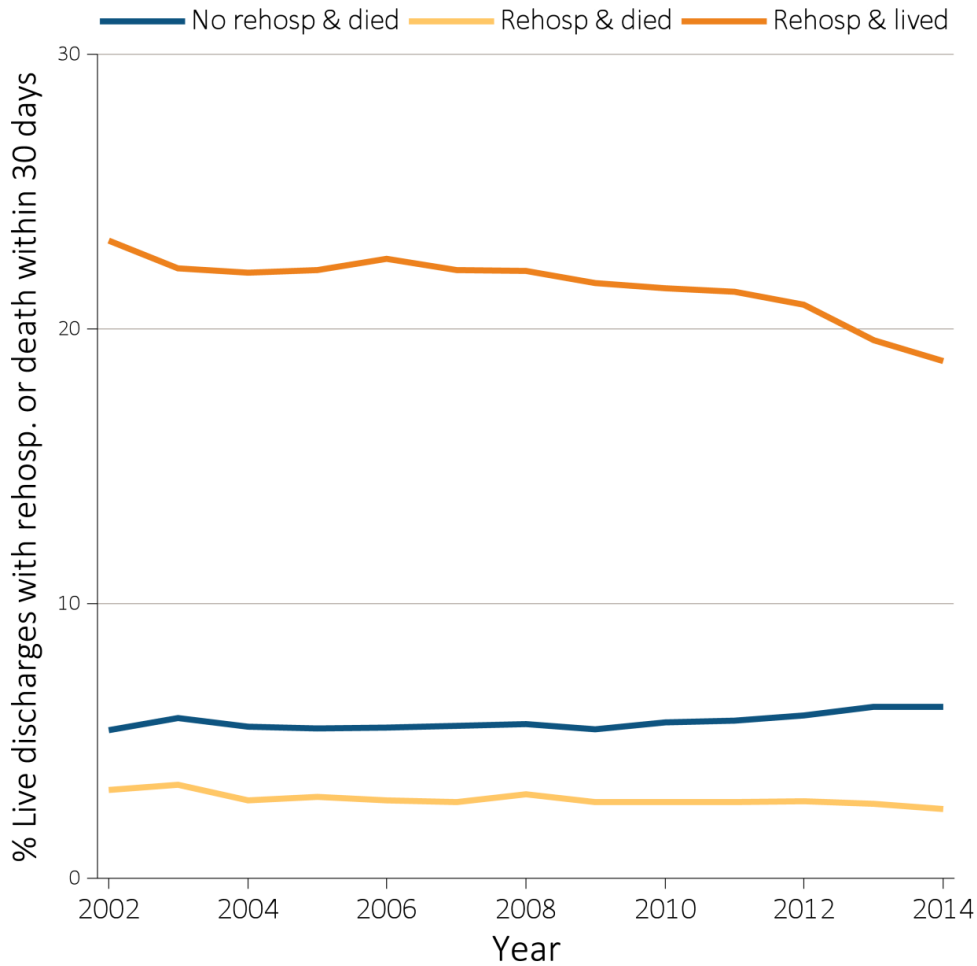


Data source: Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race. Reference population all patients, 2014. See Table A for CKD stage definitions. Abbreviations: CKD, chronic kidney disease; unk/unspc, CKD stage unidentified. This graphic is adapted from Figure 3.8.

Reducing the rate of patient readmission to a hospital within 30 days of discharge from their original hospitalization is a quality assurance goal for

many healthcare systems, including the Medicare program. The trend for adjusted readmissions from 2002-2014 is shown in Figure i.9.

vol 1 Figure i.9 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, 2002-2014

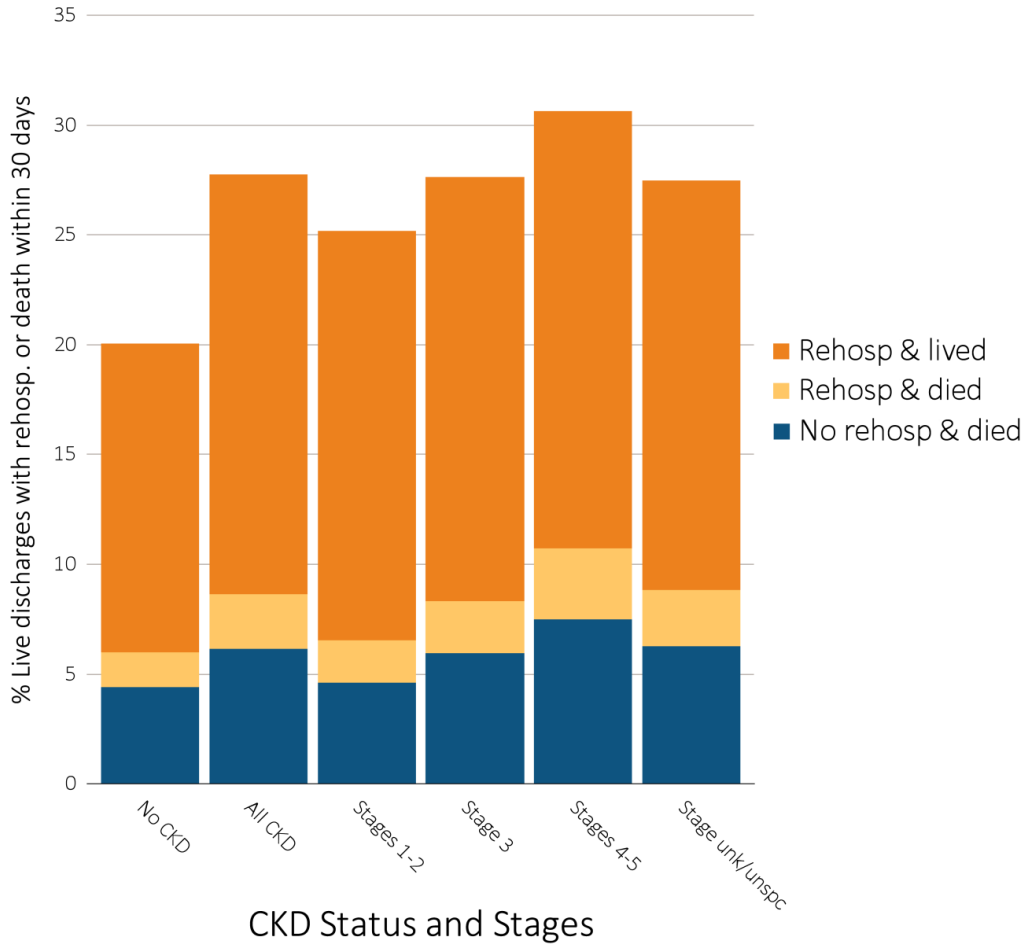


Data source: Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older with CKD (defined during the prior year), discharged alive from an all-cause index hospitalization between January 1 and December 1 of the reported year. Adjusted for age/sex/race. Reference population 2014. Abbreviations: CKD, chronic kidney disease; Rehosp, rehospitalized. This graphic is adapted from Figure 3.16.

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, those with CKD had a higher proportion of live discharges linked to a rehospitalization or death.

vol 1 Figure i.10 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, 2014



Data source: Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 and older, discharged alive from an all-cause index hospitalization between January 1, 2014, and December 1, 2014, unadjusted. Abbreviations: CKD, chronic kidney disease; Rehosp, rehospitalized; unk/unspc, CKD stage unidentified. This graphic is adapted from Figure 3.17.

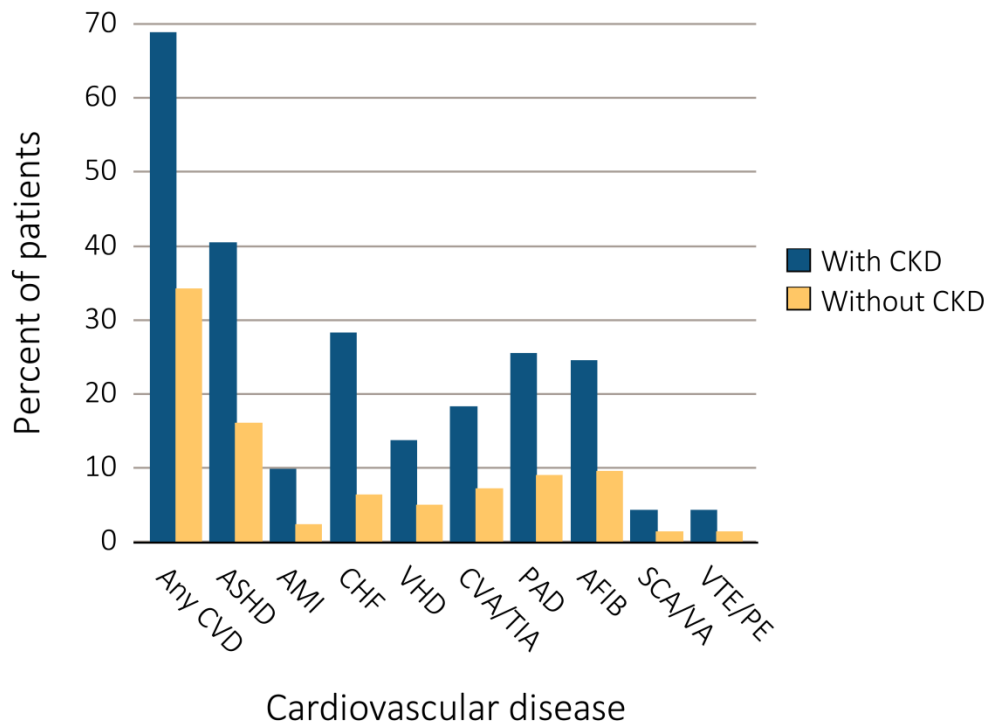
Chapter 4: Cardiovascular Disease in Patients with CKD

Chapter 4 explores cardiovascular disease as an important comorbidity for patients with CKD. CKD patients are at high-risk for cardiovascular disease, and the presence of CKD often complicates cardiovascular disease treatment and prognosis. In this chapter, we review recent trends in the prevalence and outcomes of cardiovascular disease in CKD patients and compare these to outcomes of

cardiovascular disease in patients without CKD, focusing on the high-risk, elderly Medicare population. Their CKD and cardiovascular disease diagnoses were obtained from billing claims from the Medicare 5% sample. The overall study cohort for 2014 includes 1,241,019 patients, of whom 138,176 have CKD.

Indeed, as shown in Figure i.11, the prevalence of any cardiovascular diseases of different types is double among those with CKD compared to those without (68.8% versus 34.1%). Part of this differential is due to the older age of CKD patients.

vol 1 Figure i.11 Prevalence of cardiovascular diseases in patients with or without CKD, 2014



Data Source: Special analyses, Medicare 5% sample. Abbreviations: AFIB, atrial fibrillation; AMI, acute myocardial infarction; ASHD, atherosclerotic heart disease; CHF, congestive heart failure; CKD, chronic kidney disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; CVD, cardiovascular disease; PAD, peripheral arterial disease; SCA/VA, sudden cardiac arrest and ventricular arrhythmias; VHD, valvular heart disease; VTE/PE, venous thromboembolism and pulmonary embolism. This graphic is adapted from Figure 4.1.

It is of note that atherosclerotic heart disease (ASHD) is the most frequent cardiovascular disease linked to CKD; its prevalence in CKD patients aged 66 years and older exceeds 40% in 2013.

The presence of CKD worsens the short- and long-term prognosis for cardiovascular disease and many interventions, as shown in Figure i.12.

vol 1 Figure i.12 Survival of patients with a prevalent cardiovascular disease, by CKD status, 2013-2014

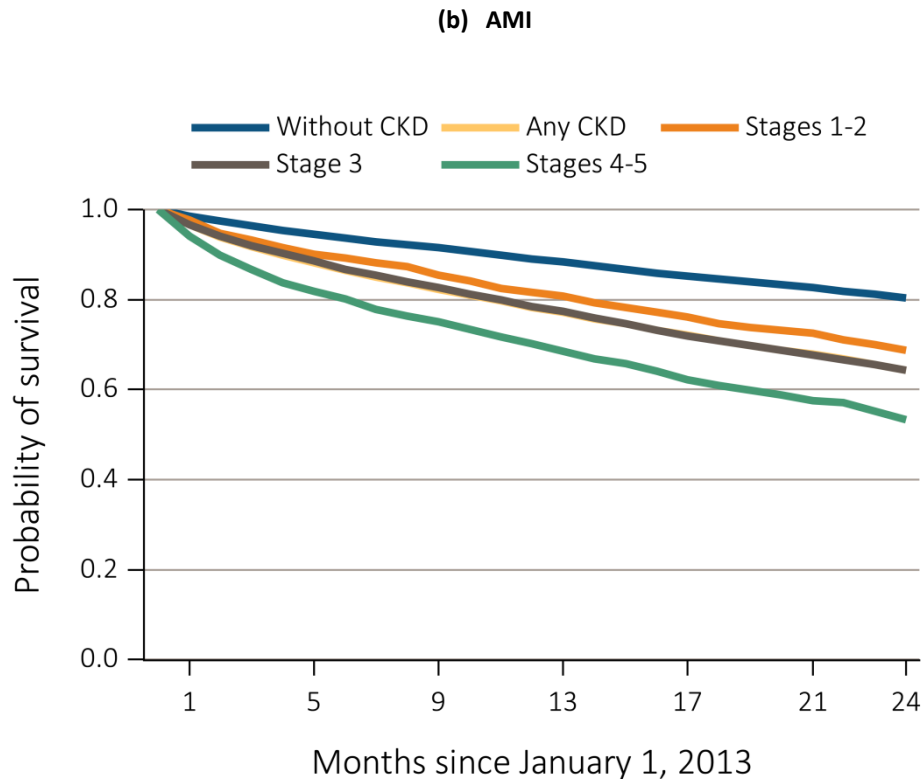
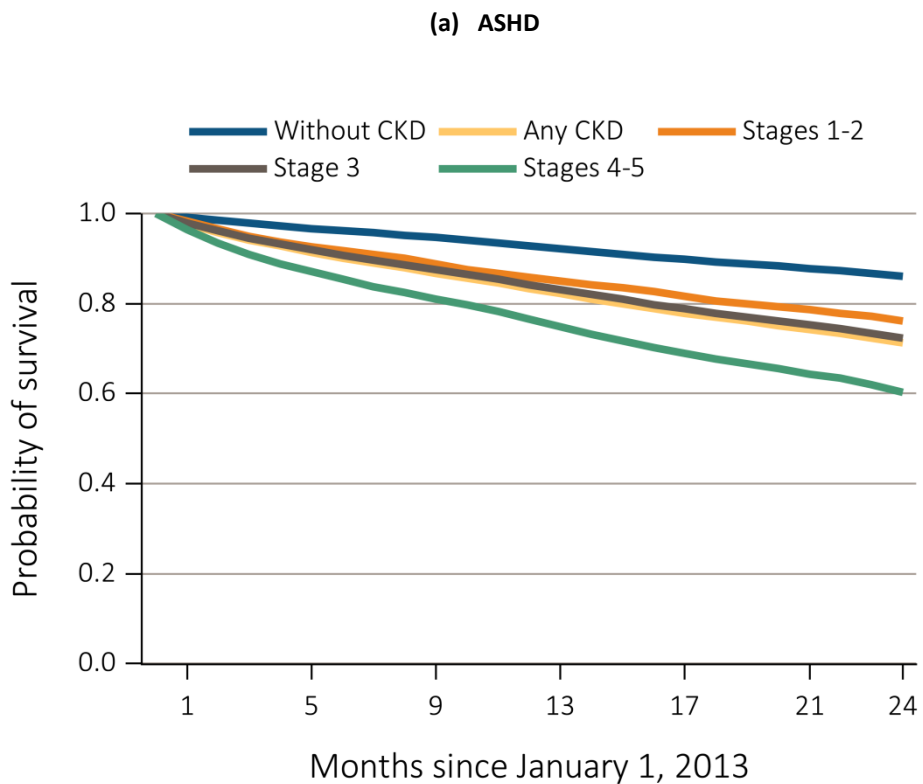


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vol 1 Figure i.12 Survival of patients with a prevalent cardiovascular disease, by CKD status, 2013-2014 (continued)

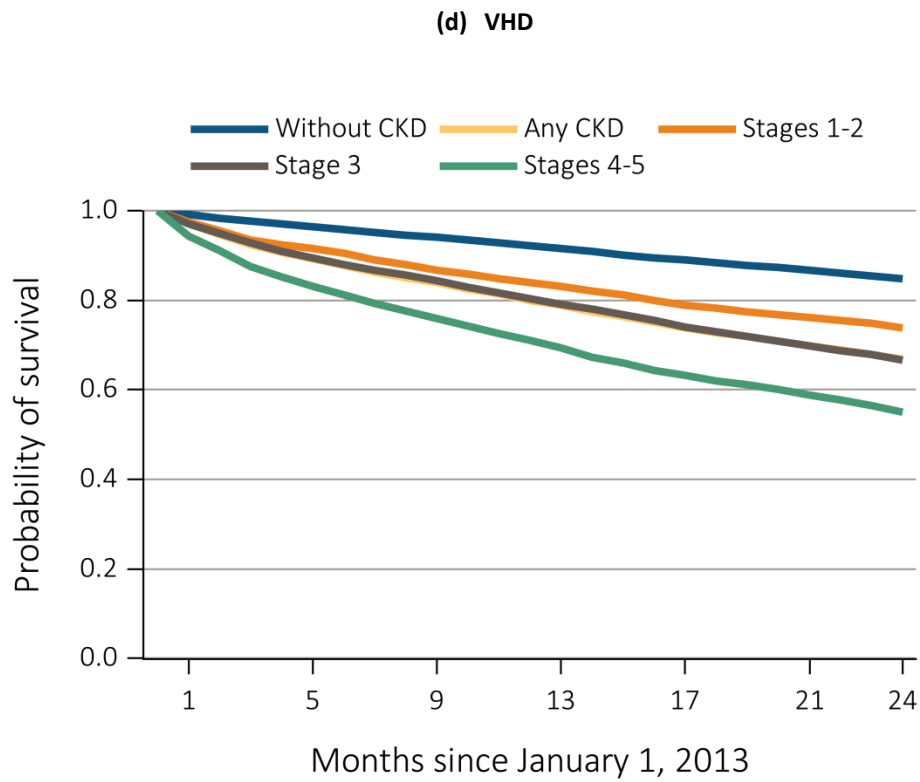
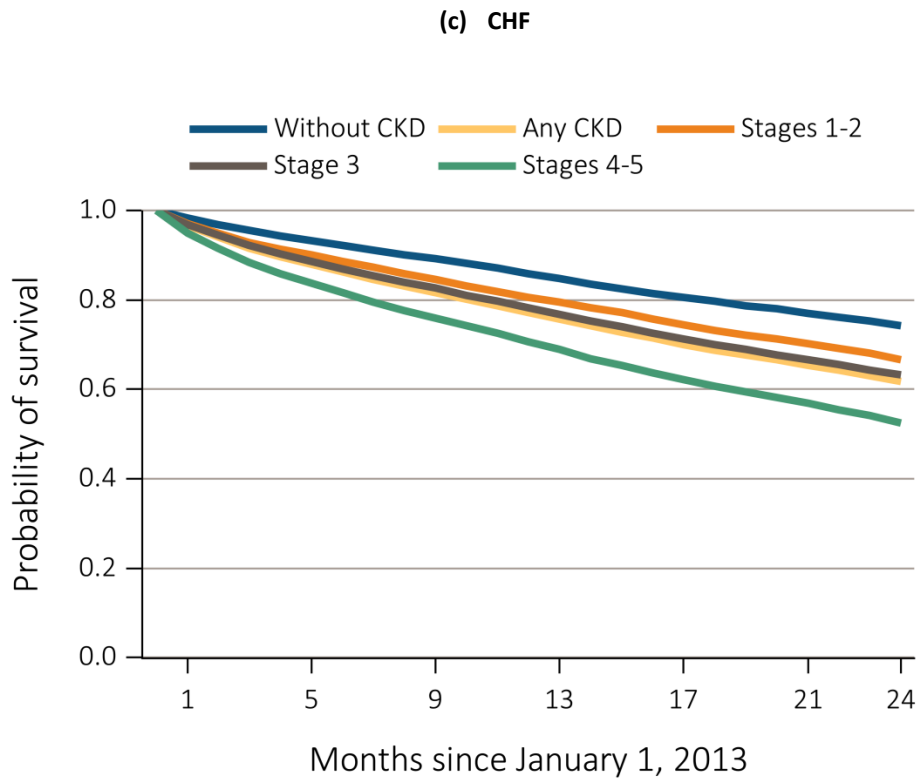


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vol 1 Figure i.12 Survival of patients with a prevalent cardiovascular disease, by CKD status, 2013-2014 (continued)

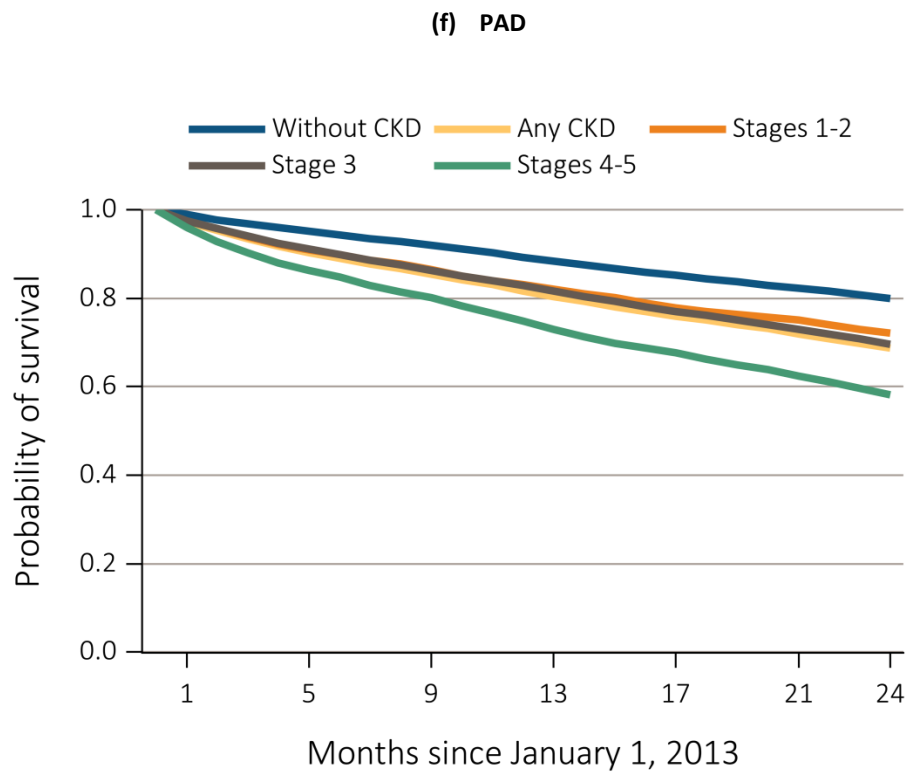
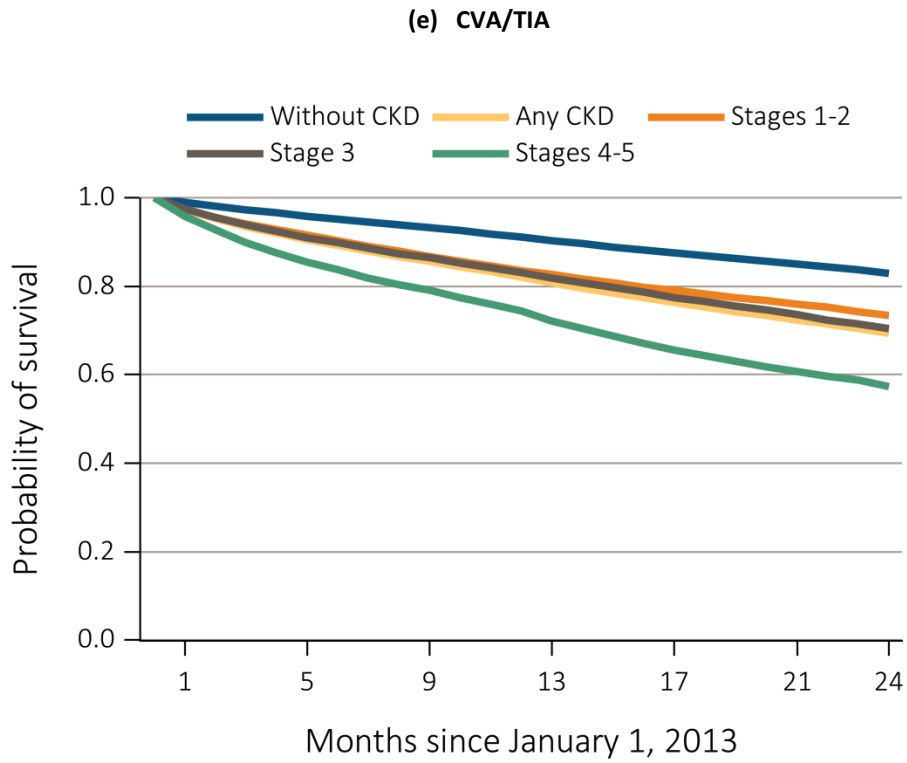


Figure i.12 continued on next page.

vol 1 Figure i.12 Survival of patients with a prevalent cardiovascular disease, by CKD status, 2013-2014 (continued)

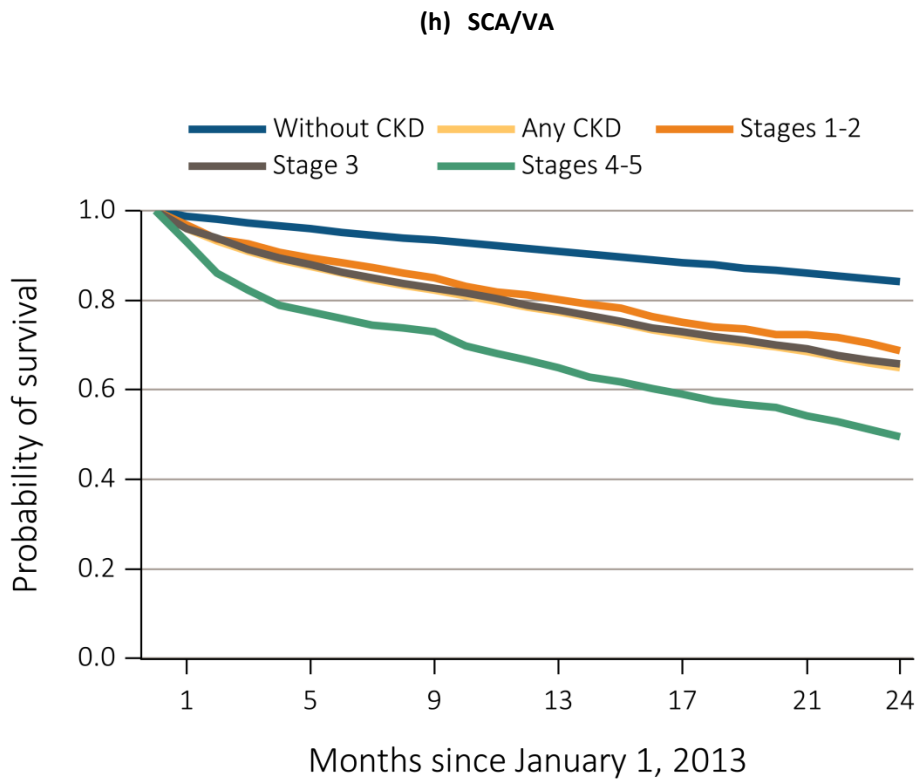
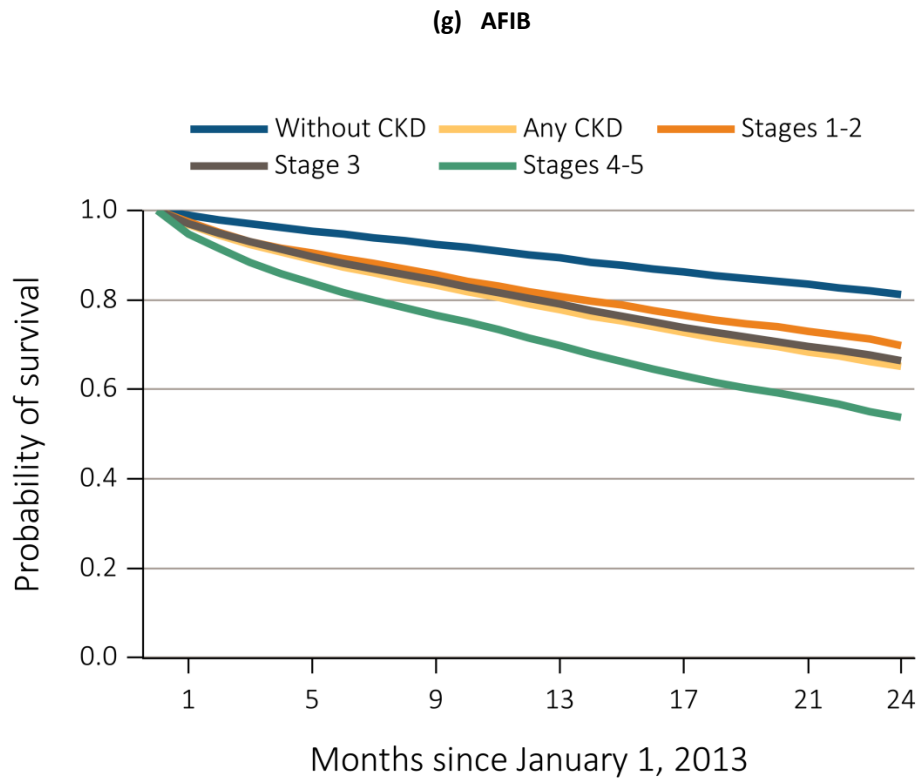
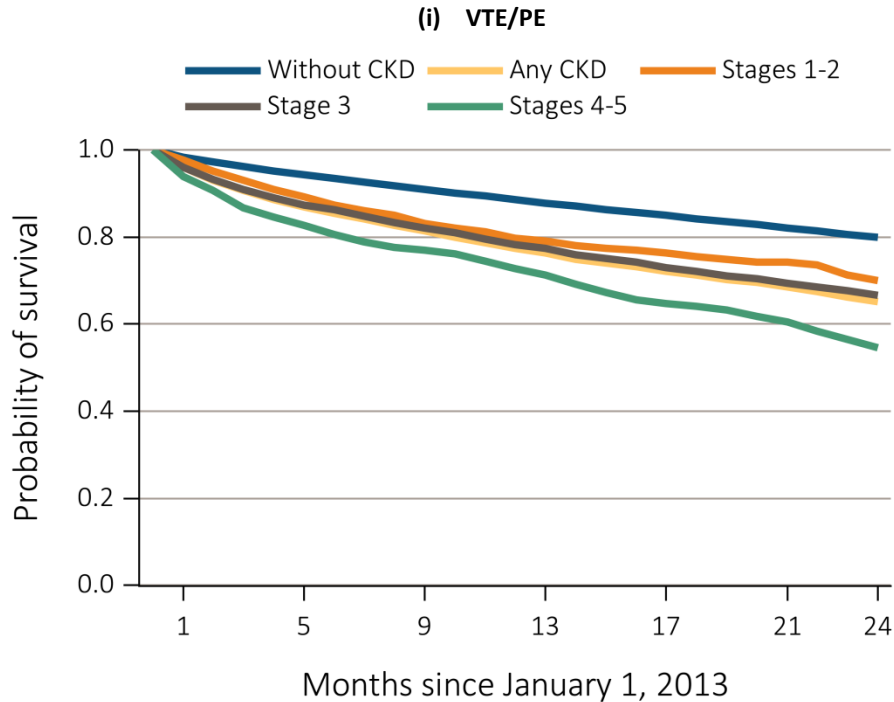


Figure i.12 continued on next page.

vol 1 Figure i.12 Survival of patients with a prevalent cardiovascular disease, by CKD status, 2013-2014 (continued)



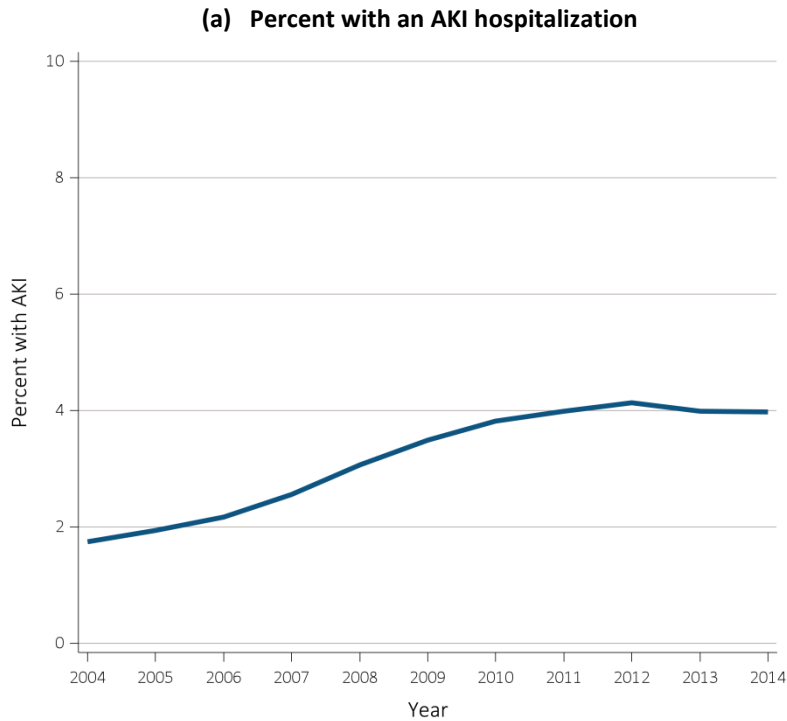
Data Source: Special analyses, Medicare 5% sample. Patients aged 66 and older, alive, without end-stage renal disease, and residing in the United States on 12/31/2012, with fee-for-service coverage for the entire calendar year. Abbreviations: AFIB, atrial fibrillation; AMI, acute myocardial infarction; ASHD, atherosclerotic heart disease; CHF, congestive heart failure; CKD, chronic kidney disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; PAD, peripheral arterial disease; SCA/VA, sudden cardiac arrest and ventricular arrhythmias; VHD, valvular heart disease; VTE/PE venous thromboembolism and pulmonary embolism. graphic is adapted from Figure 4.2.

Chapter 5: Acute Kidney Injury

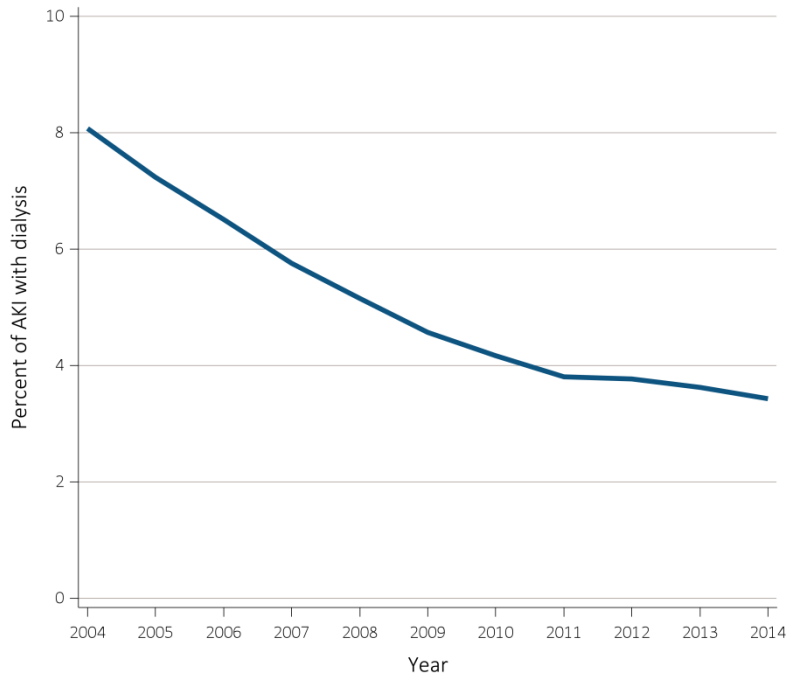
Acute kidney injury (AKI) is now recognized as a major risk factor for the development of chronic kidney disease (CKD). Studies have demonstrated significantly increased long-term risk of CKD and ESRD following AKI, even after initial recovery of renal function. Furthermore, this relationship is bi-directional and CKD patients are at substantially greater 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, in addition to the Medicare 5% sample, we utilized two additional data sources: the United Health Group's Clinformatics DataMart (Optum) dataset and national health system derived data from the U.S. Department of Veterans Affairs (VA). In contrast to Medicare and Optum, VA data contains clinical data which can be used to apply serum creatinine-based criteria to identify episodes of

AKI. We present some data from the VA population to illustrate the potential gap between AKI episodes that are identified by administrative coding versus clinical data. As shown in Figure i.13, the percentage of patients with an AKI hospitalization in the Medicare fee-for-service population has risen over the past decade but appears to have plateaued around 4.0% since 2011. The proportion of AKI patients requiring dialysis has declined over the same period, but also appears to be leveling off since 2011. Figure i.14 reveals very similar trends in the Optum population, although the percentage of patients with an AKI hospitalization is far lower overall in this younger patient population (0.2% in 2014). Taken together, these findings suggest that 'code creep' for AKI is indeed occurring: 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 fairly stable.

vol 1 Figure i.13 Percent of Medicare patients aged 66+ (a) with at least one AKI hospitalization, and (b) percent among those with an AKI hospitalization that required dialysis, by year, 2004-2014

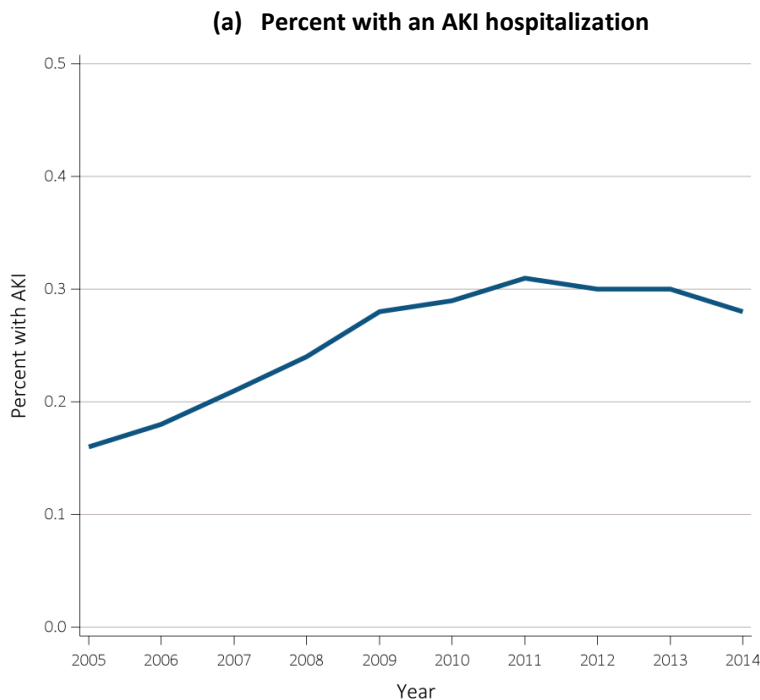


(b) Percent of patients requiring dialysis among those with a first AKI hospitalization

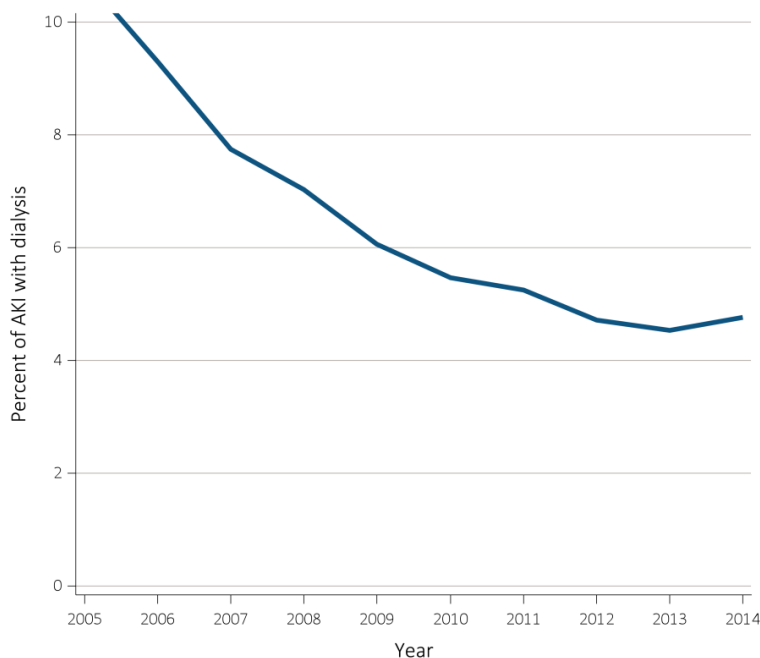


Data Source: Special analyses, Medicare 5% sample. (a) Percent with an AKI hospitalization among all Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, no ESRD by first service date from Medical Evidence form, and were alive on January 1 of year shown. (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 period of the AKI inpatient claim. Abbreviations: AKI, acute kidney injury; ESRD, end-stage renal disease. This graphic is adapted from Figure 5.1.

vol 1 Figure i.14 Percent of Clinformatics™ patients aged 22+ (a) with at least one AKI hospitalization, and (b) percent among those with an AKI hospitalization that required dialysis, by year, 2005-2014



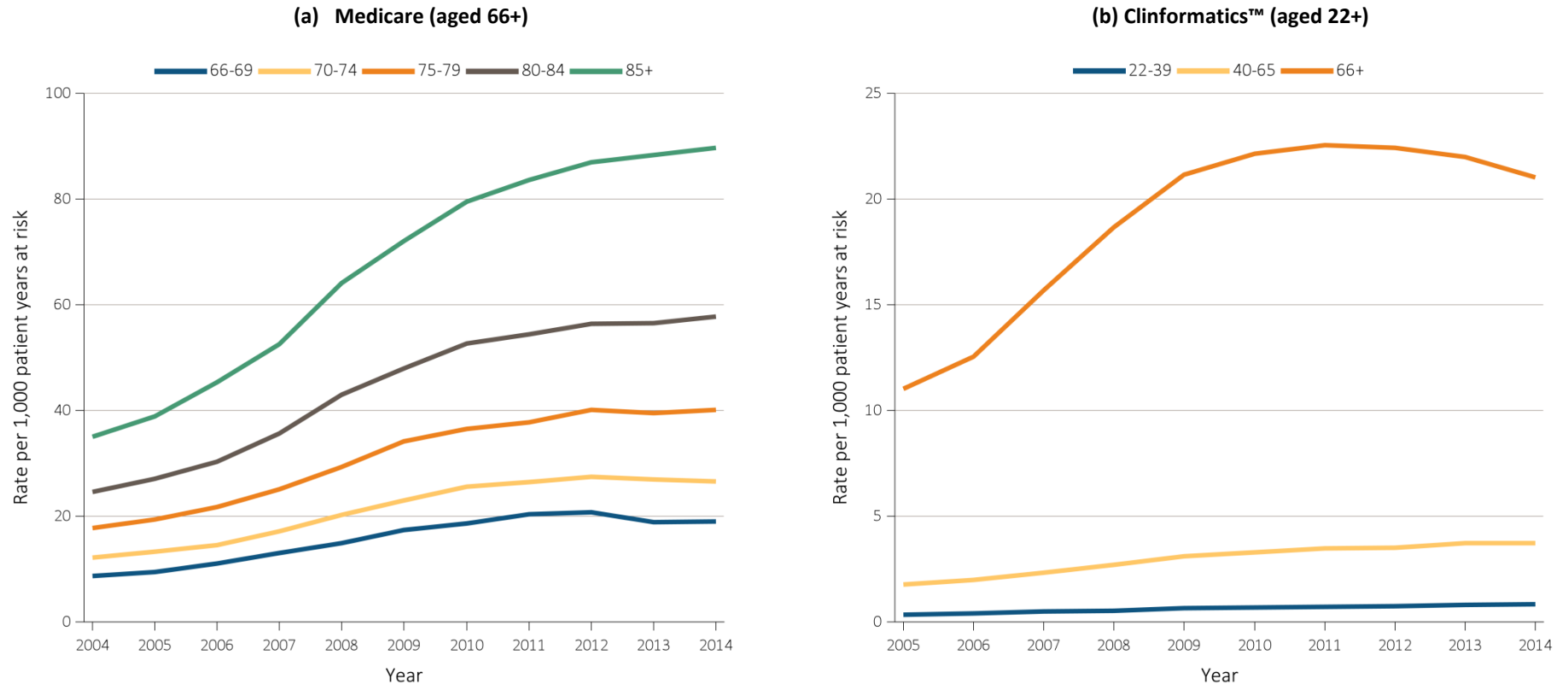
(b) Percent of patients requiring dialysis among those with a first AKI hospitalization



Data Source: Special analyses, Clinformatics™. (a) Percent with an AKI hospitalization among all 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, 2014. (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 period of the AKI inpatient claim. Abbreviations: AKI, acute kidney injury; ESRD, end-stage renal disease. This graphic is adapted from Figure 5.2.

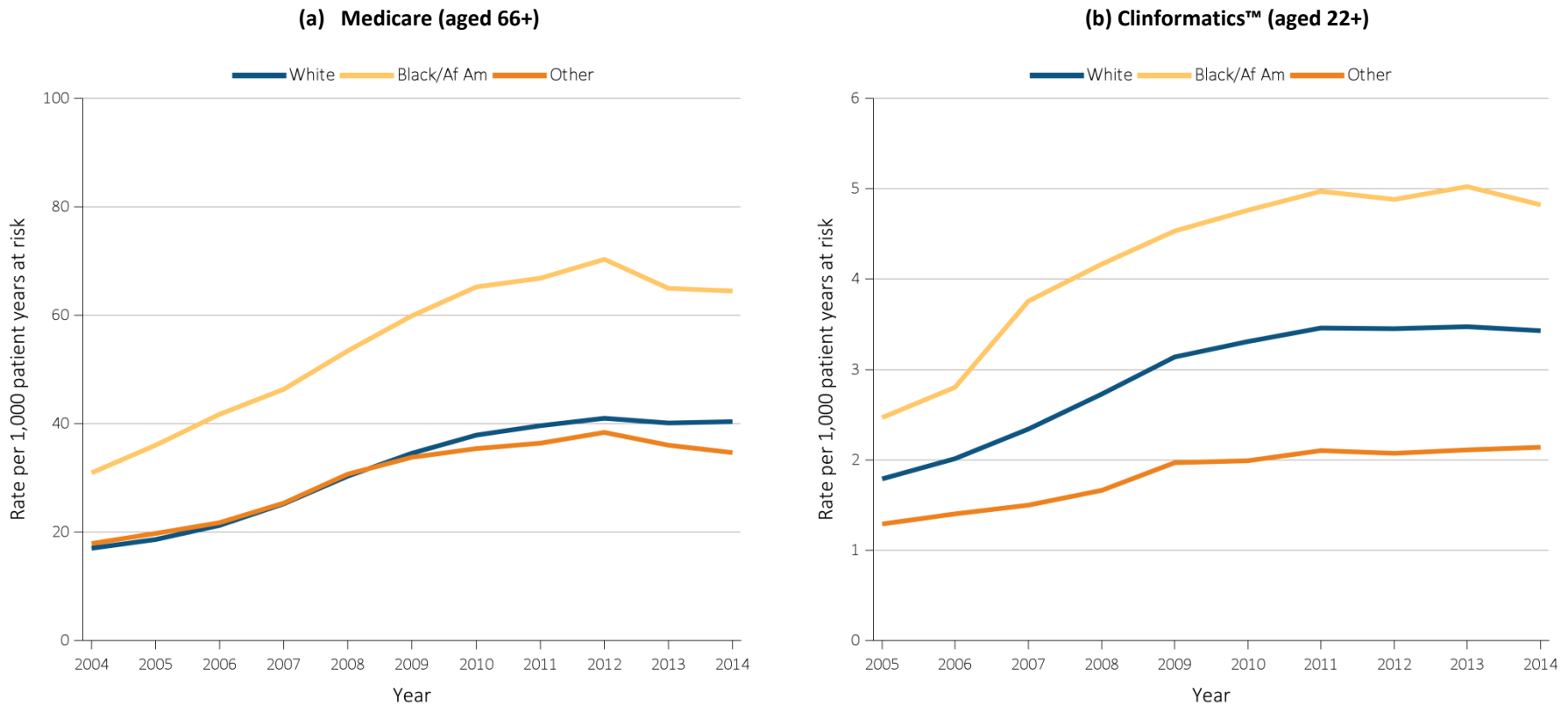
Figures i.15 and i.16 highlight differences in rate of first hospitalization with AKI by age and by race over time, in Medicare and Optum population.

vol 1 Figure i.15 Unadjusted rates of first hospitalization with AKI, per 1,000 patient-years at risk, by age and year, 2004-2014



Data Source: Special analyses, Medicare 5% sample and Clinformatics™. (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 Part A & B participation, or switch to Medicare Advantage program. (b) All patient-years at risk for 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. Abbreviation: AKI, acute kidney injury; ESRD, end-stage renal disease. This graphic is adapted from Figure 5.3.

vol 1 Figure 1.16 Unadjusted rates of first hospitalization with AKI, per 1,000 patient-years at risk, by race and year, 2004-2014

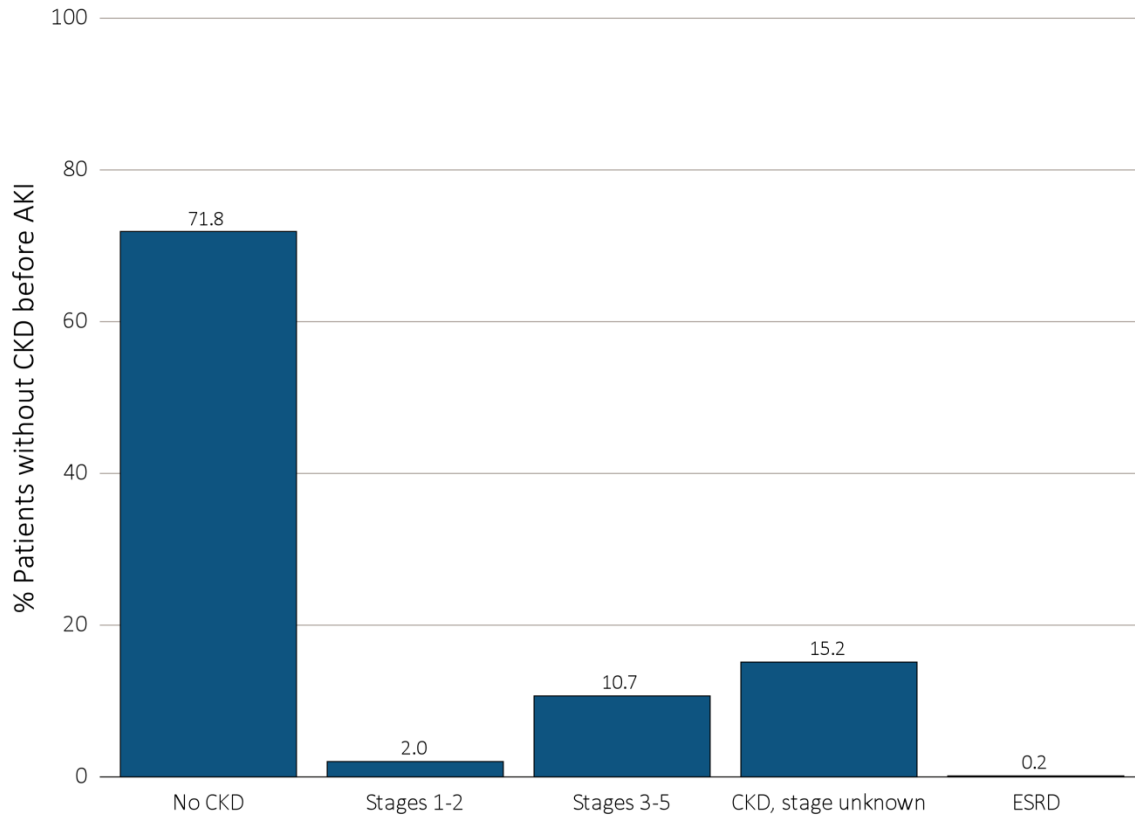


Data Source: Special analyses, Medicare 5% sample and Clinformatics™. (a) All patient-years at risk for Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, no ESRD by first service date from Medical Evidence form, and were alive on January 1 of year shown. Censored at death, ESRD, end of Medicare Part A & B participation, or switch to Medicare Advantage program. (b) All patient-years at risk for 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: Af Am, African American; AKI, acute kidney injury; ESRD, end-stage renal disease. This graphic is adapted from Figure 5.4.

CKD status changes significantly in the year following an AKI hospitalization, as shown in Figure i.17. Among Medicare patients without baseline CKD,

nearly 30% are reclassified as having some degree of CKD, including 0.20% being declared ESRD.

vol 1 Figure i.17 Renal status one year following discharge from AKI hospitalization in 2012-2013, among surviving Medicare patients aged 66+ without kidney disease prior to AKI hospitalization, by CKD stage and ESRD status



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, were discharged alive from a first AKI hospitalization in 2012 or 2013, 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. This graphic is adapted from Figure 5.12.

Chapter 6: Medicare Expenditures for Persons with CKD

When examining AKI in the VA system using serum creatinine-based criteria, fewer than 50% of identified cases had an associated diagnosis of AKI during their hospitalization. For Medicare patients aged 66 years and older with an AKI hospitalization in 2012, the cumulative probability of a recurrent AKI hospitalization within one year was 35%. For Optum patients aged 22 years and older, the probability of recurrent AKI hospitalization was 18%. Overall, 16% of Medicare patients and 17% of Optum patients had a nephrology visit within six months of live discharge from an AKI hospitalization. Among Medicare patients aged 66 years and older with a first AKI hospitalization, the in-hospital mortality rate in 2013 was 9.0% (or 13.9% when including discharge to hospice). Less than half of all patients were discharged to their home, while 30% were discharged to an institution such as a rehabilitation or skilled nursing facility.

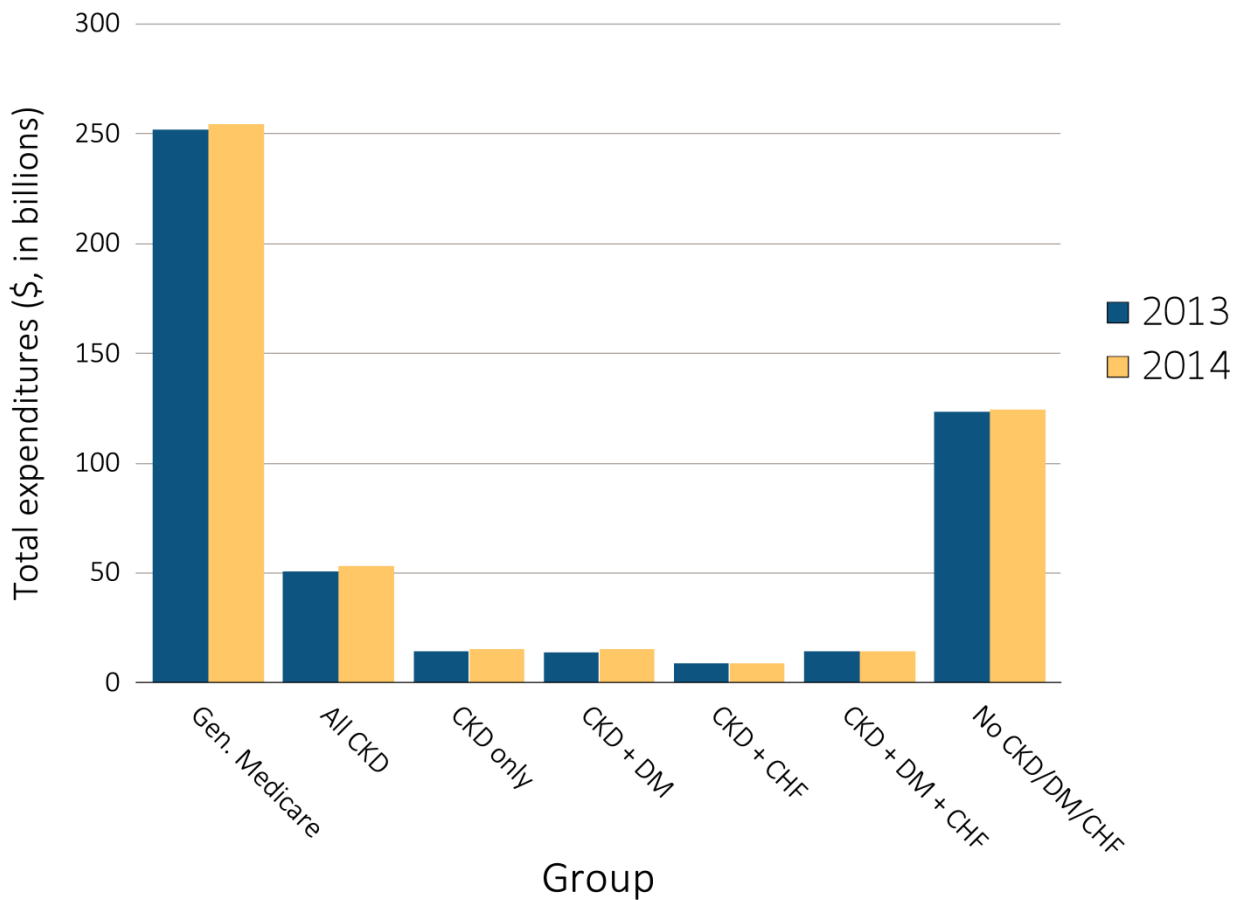
Determining the economic impact of chronic kidney disease (CKD) on a health care system is challenging for a variety of reasons described in this chapter, but primarily due to under recognition of CKD in health systems and reliance on diagnosis codes for its identification.

Medicare spending for beneficiaries aged 65 and older who have Chronic Kidney Disease (CKD) exceeded \$50 billion in 2014, representing 20% of all Medicare spending in this age group (Figure i.18). Medicare spending for beneficiaries with CKD who were younger than age 65 exceeded \$8 billion in 2014, representing 44% of spending in this age group.

Examining Medicare costs reinforces CKD's reputation as a cost multiplier. For example, Medicare beneficiaries with recognized CKD, who represented 10% of the point prevalent aged Medicare population, accounted for 20% of total expenditures (see Tables i.18 and i.19 for the aged 65 and older and under-65 populations, respectively).

Among the general Medicare population aged 65 and older, total spending for Parts A, B, and D rose by \$3 billion to \$254 billion between 2013 and 2014. Total spending rose by \$2.2 billion to \$52.8 billion among CKD patients (Figure i.18). 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).

vol 1 Figure i.18 Overall Medicare Parts A, B, and D fee-for-service spending for beneficiaries aged 65 and older, by CKD, DM, CHF, and year, 2013 & 2014



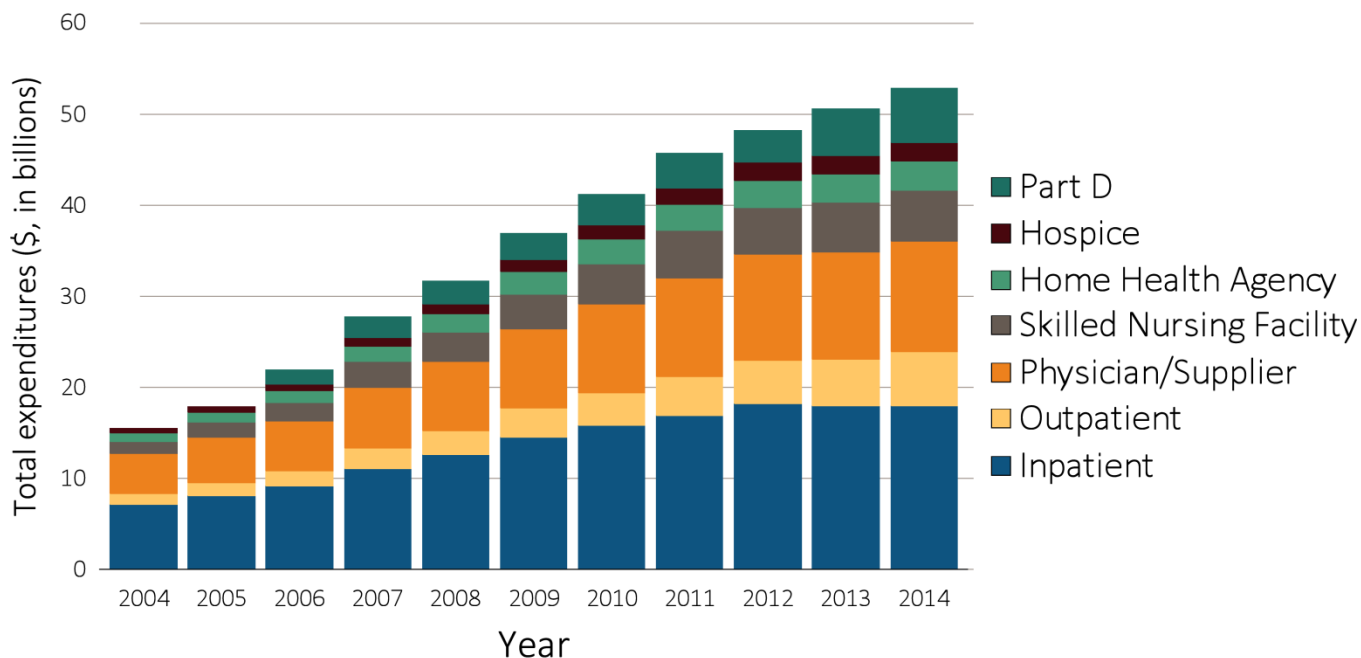
Data source: Medicare 5% sample. Abbreviations: CKD, chronic kidney disease; CHF, congestive heart failure, DM, diabetes mellitus. This graphic is adapted from Figure 6.1.

Over time, the costs for Medicare beneficiaries aged 65 and older with recognized CKD have accounted for an increasing share of Medicare expenditures, expanding from 4.2% in 1995 to 7.7% in 2003, and 20.8% in 2014.

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 Medicare expenditures required to

provide inpatient care was 34% in 2014, while outpatient costs were predictably lower at 11%. Physician/supplier service costs amounted to 23% in 2014, while those for skilled nursing facility care reached 11% (Figure i.19). In the Medicare non-CKD population, these expenditure percentages were 29% to provide inpatient care, 14% for outpatient, 28% for Physician/supplier services, and 8% those for skilled nursing facility care.

vol 1 Figure i.19 Trends in total Medicare Parts A, B, and D fee-for-service spending for CKD patients aged 65 and older, by claim type, 2004-2014



Data source: Medicare 5% sample. Part D data was initiated since 2006. This graphic is adapted from Figure 6.3.

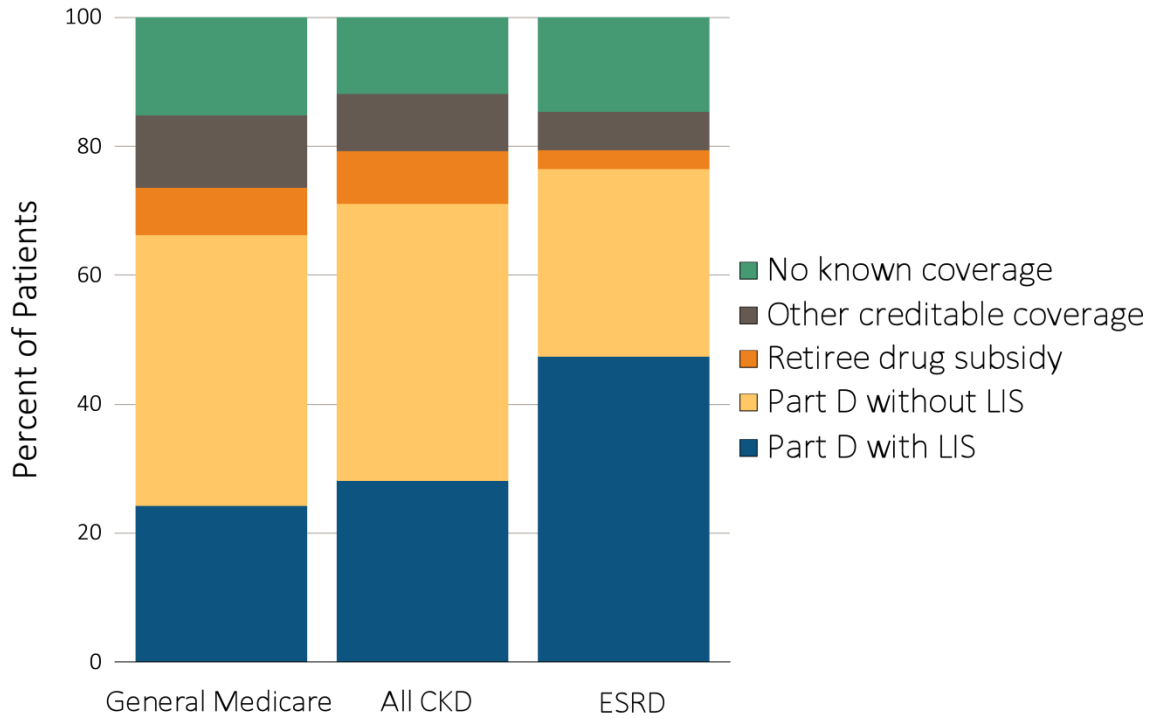
Chapter 7: Medicare Part D Prescription Drug Coverage in Patients With CKD

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 prescription drug plan (PDP) or through a Medicare Advantage (MA) managed care plan, which provides medical as well as prescription benefits. Chronic Kidney Disease (CKD) patients have the option to enroll in an MA plan; ESRD patients, in

contrast, are precluded from entering an MA plan if they are not already enrolled in one when they reach ESRD.

The percentage of CKD patients with Part D coverage increased from 59 % to 71% between 2011 and 2014. In 2014, the proportion of CKD patients with no known coverage was 12%, lower than the 15% seen in the general Medicare population. In 2014, 40% of CKD patients enrolled in Part D qualified for the LIS, compared with 37% of general Medicare beneficiaries and 62% of ESRD patients (Figure i.20).

vol 1 Figure i.20 Sources of prescription drug coverage in Medicare enrollees, by population, 2014



Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; LIS, Medicare Low-income Subsidy; Part D, Medicare prescription drug coverage benefit. This graphic is adapted from Figure 7.1.

Part D spending for identified CKD patients rose 26% and 65% for general Medicare and ESRD patients, respectively (Table i.2). from \$5.2 billion in 2011 to \$7.7 billion in 2014—an increase of 49%, compared to the lesser cost growth of

vol 1 Table i.2 Total estimated Medicare Part D spending for enrollees (in billions), 2011-2014

	General Medicare	All CKD	All ESRD
2011	40.1	5.2	1.6
2012	35.7	4.8	2.0
2013	45.7	6.8	2.3
2014	50.5	7.7	2.7

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. ESRD totals include all Part D claims for Medicare ESRD patients with Medicare Part D stand-alone prescription drug plans. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; Part D, Medicare prescription drug coverage benefit. This table is adapted from Table 7.4.

The top 15 drug classes are ranked based on the percentage of beneficiaries with at least one claim for a drug. The list is led by cardiovascular therapies (statins, beta blockers, and diuretics). Over one third

of CKD patients received opioid agonists, proton-pump inhibitors antidepressants, angiotensin-converting enzyme inhibitors, or dihydropyridines (Table i.3).

vol 1 Table i.3 Top 15 drug classes received by Part D-enrolled CKD patients, by percent of patients 2014

Rank	Drug class	Percent of patients
1	HMG-CoA Reductase Inhibitors (statins)	59%
2	β-Adrenergic Blocking Agents	57%
3	Opiate Agonists	46%
4	Loop Diuretics	39%
5	Proton-pump Inhibitors	38%
6	Antidepressants	35%
7	Angiotensin-Converting Enzyme Inhibitors	34%
8	Dihydropyridines	33%
9	Quinolones	27%
10	Thyroid Agents	25%
11	Angiotensin II Receptor Antagonists	24%
12	Anticonvulsants, Miscellaneous	23%
13	Adrenals	21%
14	Replacement Preparations	20%
15	Insulins	20%

Data source: Medicare Part D claims. CKD patients with Medicare Part D stand-alone prescription drug plans in the Medicare 5% sample. Part D spending represents the sum of the Medicare covered amount and the Low-income Subsidy amount. This table is adapted from Table 7.6.

Chapter 8: Transition of Care in Chronic Kidney Disease (TC-CKD)

The Transition of Care in Chronic Kidney Disease (TC-CKD) Special Study Center examines the transition of care to renal replacement therapy, i.e., dialysis or transplantation, in patients with very-late-stage non-dialysis dependent (NDD) CKD. The main

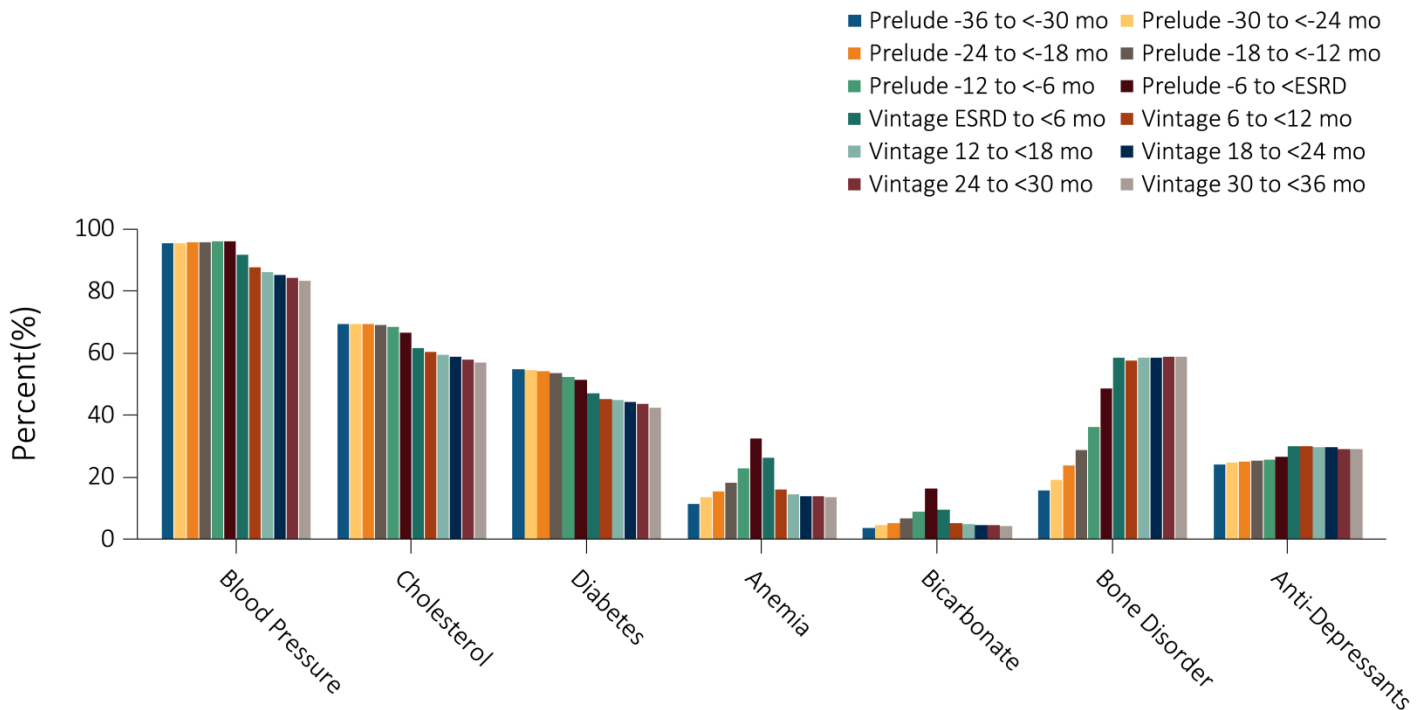
databases used in these analyses are created from the linkage between the national USRDS data and two large longitudinal databases of NDD-CKD patients, i.e., the national (entire U.S.) Veterans Affairs (VA) database, and the regional (Southern California) Kaiser Permanente (KP-SC) database.

Patterns of medication use before, during and after transition to ESRD are examined. As shown in Figure

i.21, over 90% of patients were on blood pressure lowering medications prior to ESRD transition, and this high medication rate persisted during and throughout post-transition period. Diabetes medications were given to 50% of all veterans prior to ESRD transition, but this rate declined to 40% in Year 1 of the vintage. Phosphorus binders were rarely prescribed during the prelude to ESRD, but a major

surge is observed in the final six months of the prelude and immediately prior to transition to ESRD, followed by a substantial rise during the vintage period. Anti-depressants show a rather constant prescription pattern independent of transition to ESRD, in that almost 30% of veterans received these medications during both prelude and vintage, although some upwards trends is observed after transition to ESRD.

vol 1 Figure i.21 Prescribed medication to incident ESRD veterans who transitioned to ESRD during 10/1/2007-3/31/2014, with data up to -36 months prior to transition (prelude) and up to +36 months after transition (vintage) (data were abstracted from 68,435 veterans)



Data source: VHA Administrative data, CMS Medicare Inpatient and Outpatient data. Abbreviations: ESRD, end-stage renal disease; mo, month. This graphic is adapted from Figure 8.5.

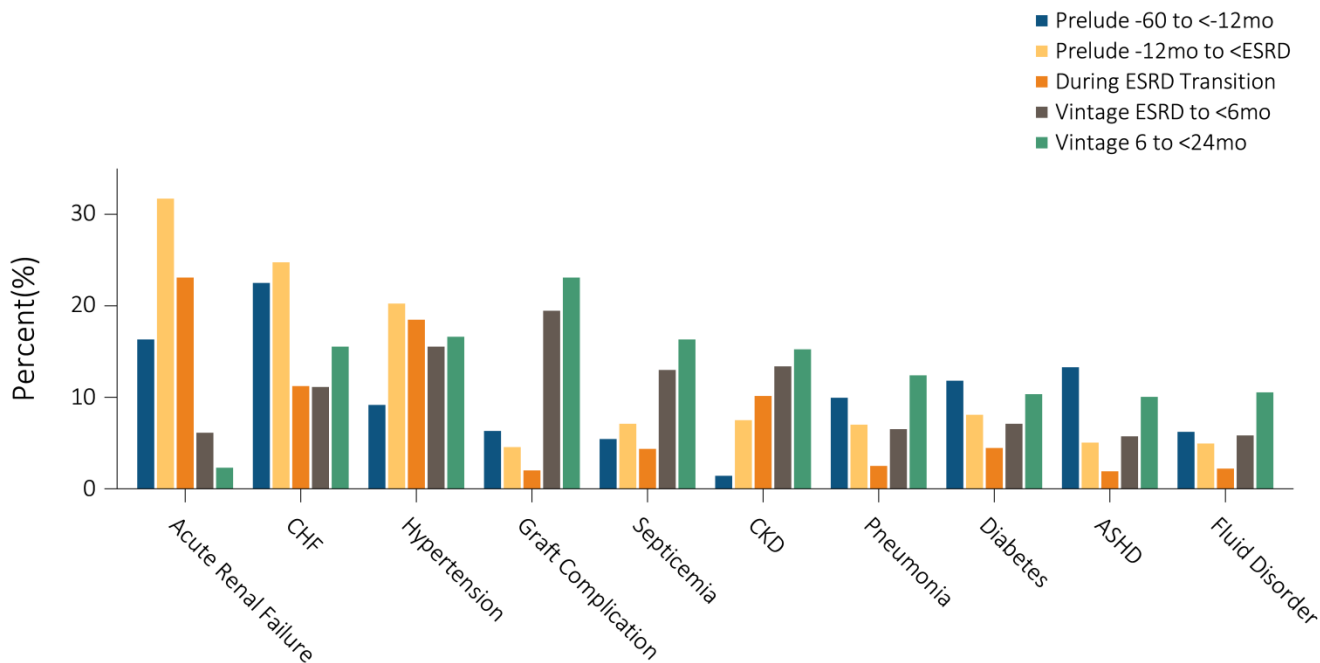
Cause-specific hospitalization events were also analyzed. Figure i.22 shows the top 20 causes of hospitalization among 74,382 veterans who transitioned to ESRD over the 6.5-year period (10/2007-3/2014) with at least one hospitalization event from -5 years prelude to +2 years vintage surrounding the transition intercept. Of the top 20 causes of hospitalization, notably septicemia-related hospital events increased dramatically after ESRD

transition. The most common causes of hospital admission that also consisted of the ESRD transition day included acute renal failure, hypertension, CHF, and CKD.

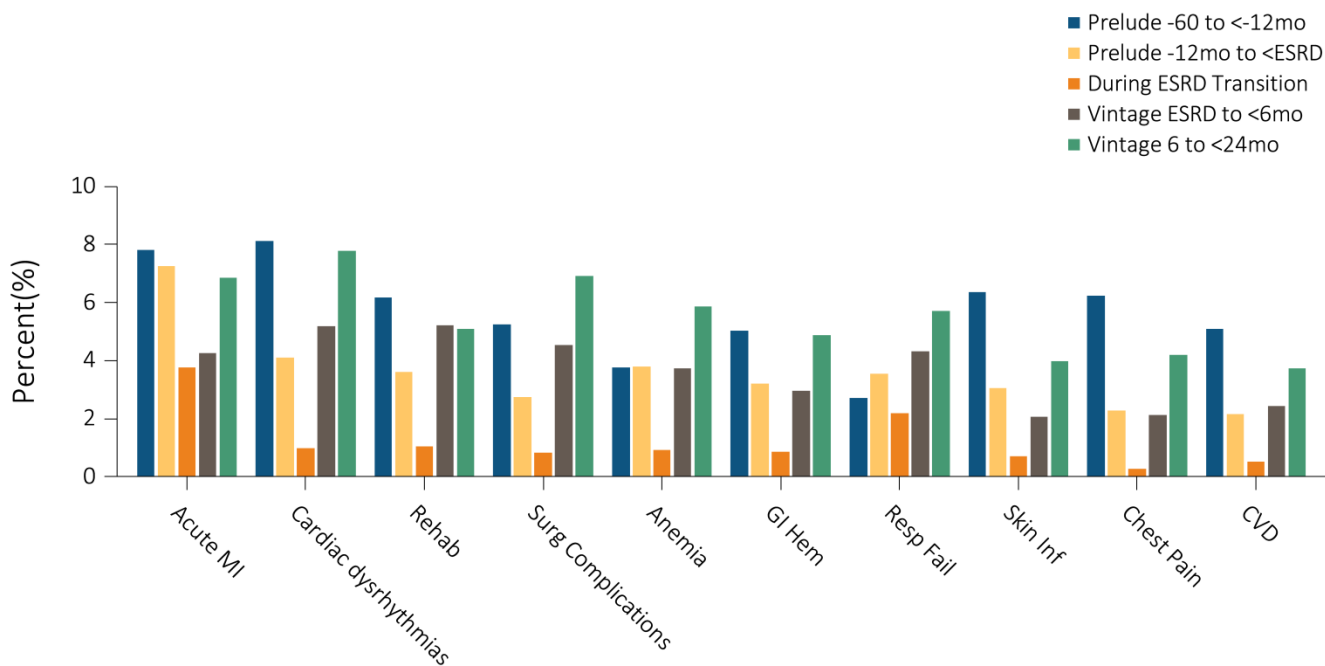
Figure i.23 shows the pre-ESRD trend in serum phosphorus in 24,765 veterans who eventually transitioned to ESRD over 20 calendar quarters or 5 years. Serum phosphorus increased from 4 to above 5.5 mg/dL immediately prior to transition to ESRD.

vol 1 Figure i.22 Top 20 causes of hospitalizations in 74,382 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) Causes 1-10



(b) Causes 11-20

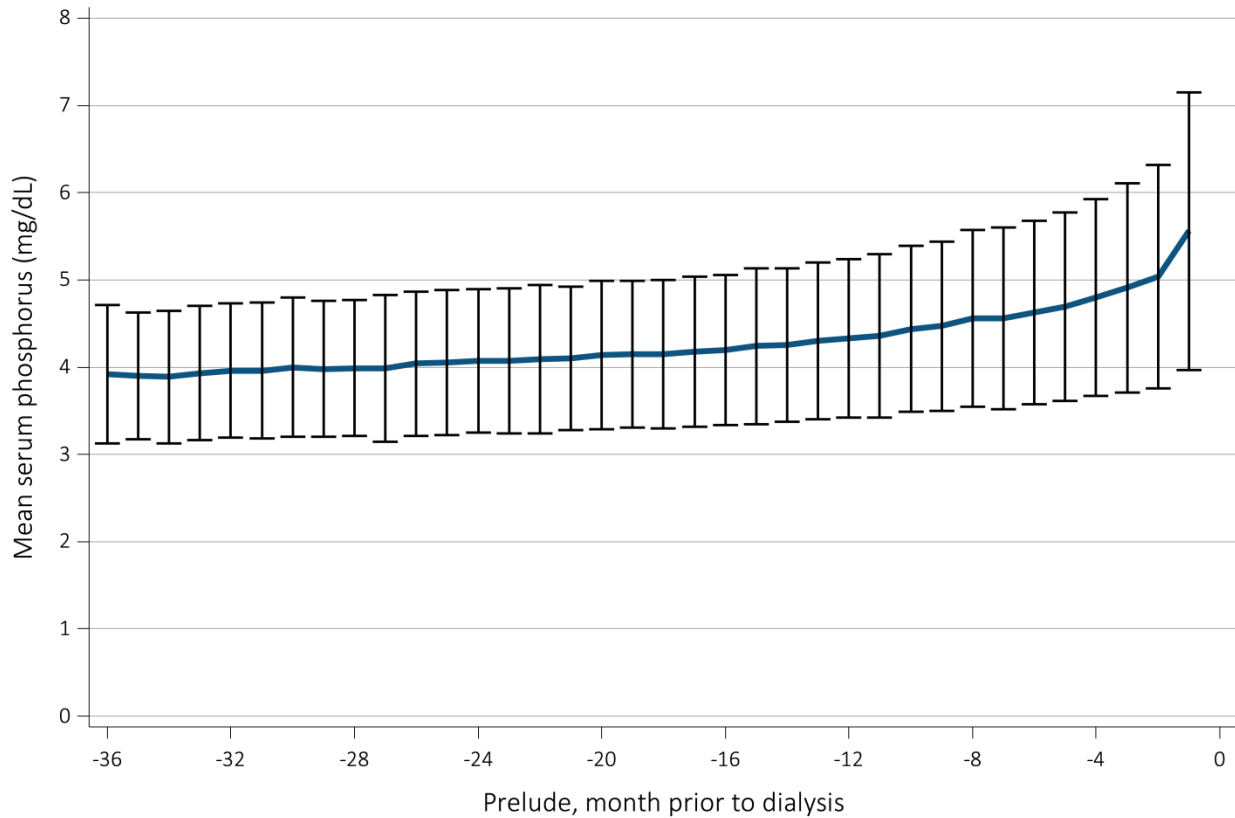


Data source: VHA Administrative data, USRDS ESRD Database, CMS Medicare Inpatient and Outpatient data. Abbreviations: ASHD, atherosclerotic heart disease; CHF, congestive heart failure; CKD, chronic kidney disease; CVD, acute cerebrovascular disease; ESRD, end-stage renal disease; GI Hem, gastrointestinal hemorrhage; MI, myocardial infarction; mo, month; Resp Fail, respiratory failure; Skin Inf, skin infection; surg, surgical. This graphic is adapted from Figure 8.8.

Figure i.23 shows the pre-ESRD trend in averaged serum phosphorus in 24,765 veterans who transitioned to ESRD over 36 months or 3 years.

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

vol 1 Figure i.23 Trend in serum phosphorus level during the prelude (pre-ESRD) time over 36 months in 24,765 veterans who transitioned to ESRD during 10/1/2007-3/31/2014



Data source: VHA Administrative data. Abbreviations: ESRD, end-stage renal disease; mg/dL, milligrams per deciliter. This graphic is adapted from Figure 8.11.

Chapter 1: CKD in the General Population

- Overall prevalence of CKD (Stages 1-5) in the U.S. adult general population was 14.8% in 2011-2014. CKD Stage 3 is the most prevalent (NHANES: Figure 1.2 and Table 1.2).
- Roughly 40% of individuals with CKD also have diabetes, 32% have hypertension, and 40% have self-reported cardiovascular disease (Table 1.2).
- The prevalence of urinary ACR >10 in the general U.S. population is 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 have urinary ACR 10-29 mg/g, which although below the threshold for albuminuria, has been shown to have prognostic significance (Figure 1.4).
- Age is best correlate of low eGFR (eGFR <60 ml/min/1.73m²), while hypertension is the greatest predictor of albuminuria (Figures 1.10 & 1.11).
- In a comparison of four cohorts of NHANES participants (1999-2002, 2003-2006, 2007-2010, and 2011-2014), increases over time were seen in the percentage of individuals at target blood pressure of <140/90 (Figure 1.12) and percentage with normal cholesterol levels (Figure 1.13).
- Minimal change over time was seen in the amount of self-reported physical activity (Figure 1.14).
- Following a 1999-2002 initial increase in the percentage of diabetics with glycosylated hemoglobin <7%, these fell steadily over the last three time periods (Figure 1.15 & Table 1.3).
- Comparing these same NHANES cohorts, little improvement has been seen in the percentage of individuals with CKD who are aware of their disease, especially in Stages 1 to 3 CKD. A small increase in disease awareness has been seen in individuals with Stage 4 CKD (Figure 1.16).
- 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 1.17).
- Life expectancy becomes progressively shorter with greater severity of CKD in all age groups, and is shorter for individuals with both albuminuria and low eGFR than for individuals with either albuminuria or low eGFR alone (Figure 1.18).

Introduction

This chapter presents representative cross-sectional estimates of chronic kidney disease (CKD) prevalence in the United States (U.S.), through analysis of data from the National Health and Nutrition Examination Survey (NHANES; CDC 2015a). Administered by the Centers for Disease Control and Prevention (CDC), 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 in the general U.S. population. NHANES data are released biennially; we primarily report trends based on four 4-year time 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.

Utilizing data from the Behavioral Risk Factors Surveillance System (BRFSS; CDC 2015b), this year we also present the 2012 and 2014 prevalence of self-reported kidney disease by geographic region. Also administered by the CDC, the BRFSS 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, weights are applied to allow generation of estimates considered to be representative of the U.S. population. In the survey, each participant is asked a simple question pertaining to kidney disease “(Ever told) you have kidney disease?” In contrast to the NHANES data, with this data source contains participants’ residence information, to allow some

assessment of geographic distributions of self-reported kidney disease.

As the NHANES database does not contain diagnostic information, we developed criteria to identify individuals who potentially have CKD based upon the KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (KDIGO, 2012). First, we evaluate kidney function by eGFR as calculated using the CKD-EPI creatinine equation (Levey et al., 2009). Individuals with eGFR <60 ml/min/1.73m² are considered to have reduced kidney function. Secondly, we use the ACR to assess urinary albumin excretion, and consider four categories: <10 mg/g, 10-<30 mg/g, 30-300 mg/g, and >300 mg/g. Lastly, we consider a composite measure of both eGFR and ACR, classifying individuals as CKD if they have either an eGFR <60 ml/min/1.73m² or ACR ≥30 mg/g. Staging of kidney disease follows the Kidney Disease Outcomes and Quality Improvement (KDOQI) CKD guidelines (NKF, 2002).

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

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

The biochemical data available in NHANES are used to evaluate kidney function through estimated glomerular filtration rate (eGFR), and kidney damage through urinary albumin excretion as estimated by urine albumin/creatinine ratio (ACR). Consistent with the assessment of the prevalence of other medical conditions in this national survey, both measures are based on laboratory specimens collected at a single point in time. In clinical practice, diagnosis of CKD typically requires multiple assessments of kidney function and urine albumin (or total protein) over weeks or months. In this case we must instead 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 than

would be the case if measures of eGFR and urine albumin/creatinine ratio (ACR) were repeated over time to fulfill the KDIGO criteria of ‘persistence for 3 months or longer’ for the clinical diagnosis of CKD, due to fluctuations in eGFR or ACR.

In contrast, all other chapters in this ADR volume identify the presence of CKD and its related stages based on ICD-9-CM (International Classification of Diseases, 9th revision, clinical modification) diagnosis codes. These classifications are more likely to miss the earlier stages of CKD. The NHANES data allows us to distinguish individuals within Stage 1 (eGFR >90 with ACR >30) and Stage 2 (eGFR >60 with ACR >30).

By providing NHANES data demonstrating level of kidney function and the related comorbidities of DM, HTN, and CVD in the general population, this chapter sets the stage for Chapter 2 of Volume 1, *Identification and Care of Patients with CKD*. There we discuss CKD as recognized in the health care system via analysis of Medicare claims, OPTUM, and Veterans Affairs data, providing information on morbidity, interventions, and costs.

Methods

Two nationally representative data sources were used in this chapter: NHANES (1999-2014) and BRFSS (2012, 2014).

The National Health and Nutrition Examination Survey (NHANES) is a sample of about 5,000 individuals per year from the U.S. civilian, noninstitutionalized population. Respondents answer survey questions and receive a medical examination including blood and urine samples tested for various biochemical markers, including serum creatinine and urine albumin. All tables and figures in this chapter use NHANES data except for Figure 1.17.

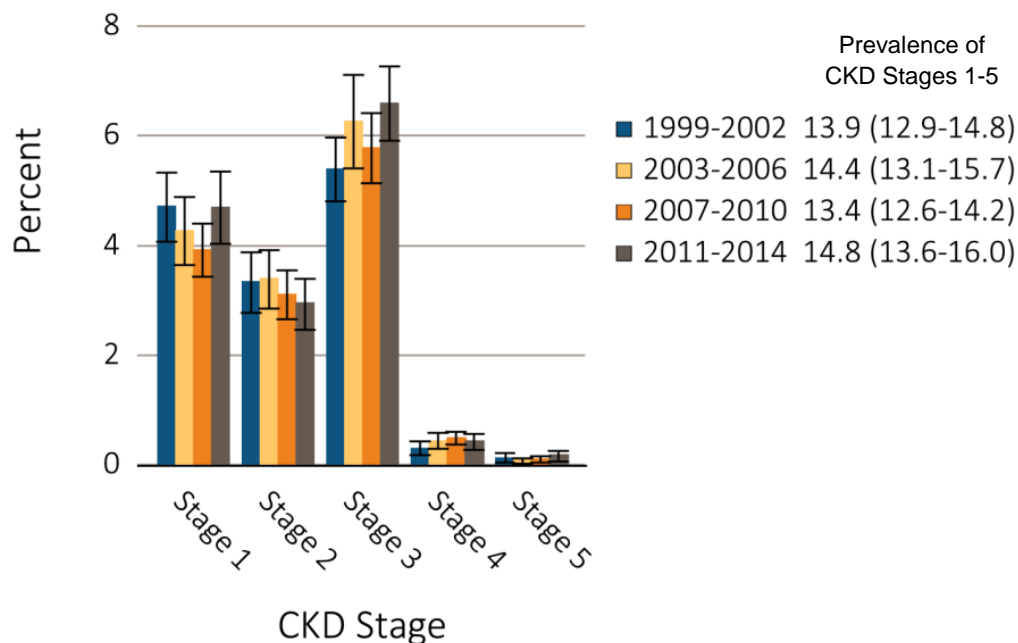
Figure 1.17 uses data from the Behavioral Risk Factor Surveillance System (BRFSS) to show estimates of self-reported kidney disease in smaller geographic regions. These data are also a sample of the U.S. general population, but respondents are asked survey questions during a phone interview, and there is no medical examination. However, the sample size is larger, allowing precise estimation for U.S. states.

A full explanation of these data and an explanation of the analytical methods used to generate the figures and tables in this chapter can be found in the *CKD Analytical Methods* chapter.

Prevalence of CKD

The prevalence of CKD in the United States over four periods from 1999 to 2014 is shown in Figure 1.1. This illustrates that the largest increase occurred in Stage 3 CKD, which rose from 5.4% to 6.6% over the four time 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.

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

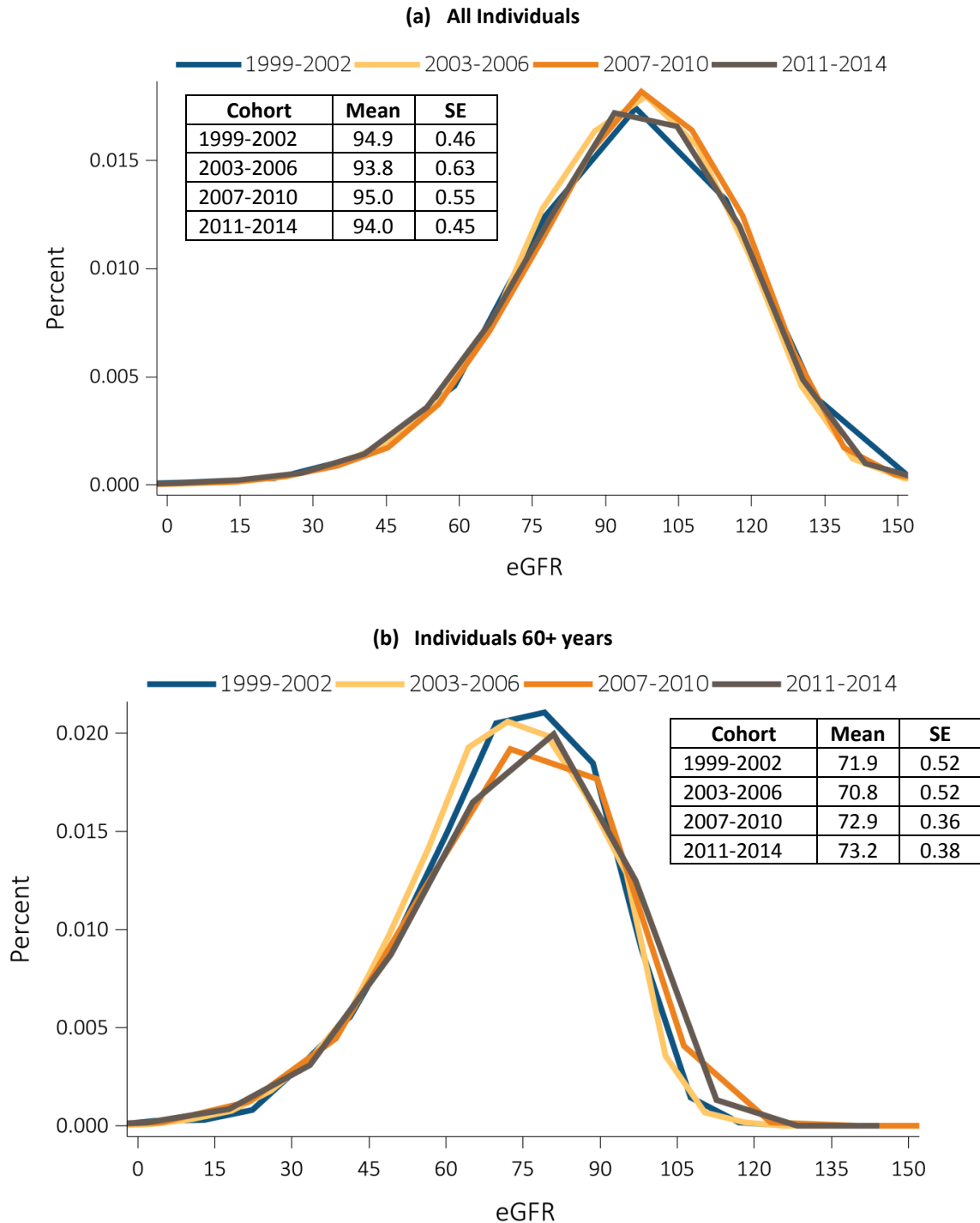


Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2002, 2003-2006, 2007-2010 & 2011-2014 participants aged 20 & older. Whisker lines indicate 95% confidence intervals. Abbreviation: CKD, chronic kidney disease.

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

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 full sample (Figure 1.2b).

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

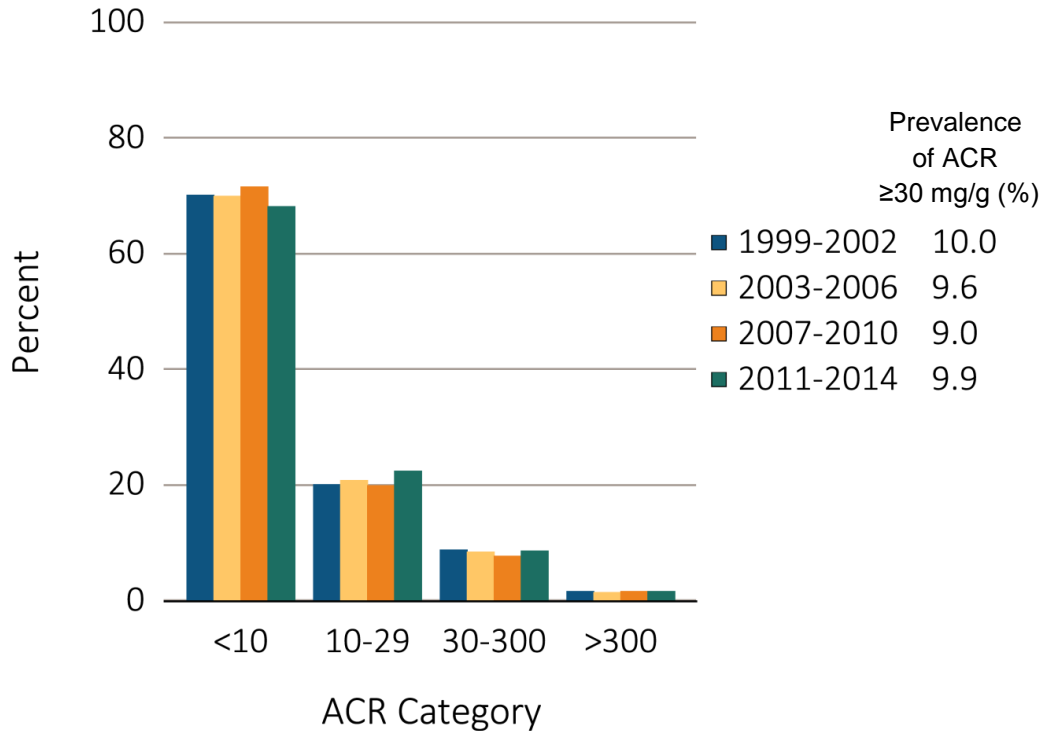


Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2014 participants aged 20 & older. Single-sample estimates of eGFR; eGFR calculated using the CKD-EPI equation. Abbreviations: eGFR, estimated glomerular filtration rate; SE, standard error. Accounts for change in serum creatinine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

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

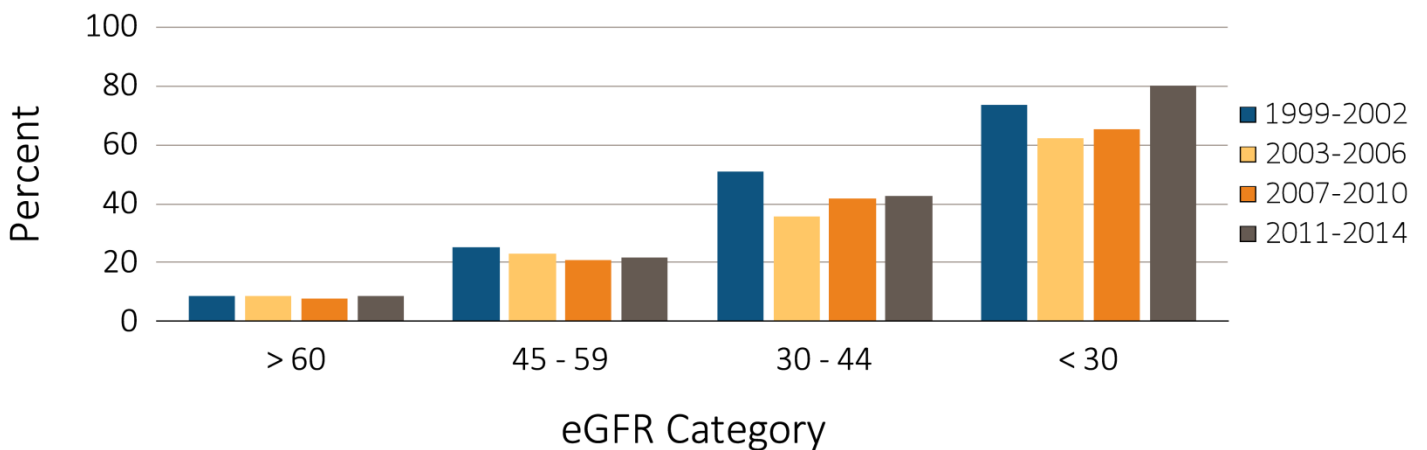
increase in the proportion of individuals with ACR of 10 to <30 mg/g, over the four periods. This has important mortality implications, as increased rates of all-cause mortality have been seen with ACR values as low as 10 mg/g (versus 5 mg/g: HR = 1.20, 95% CI: 1.15-1.26; Matsushita, 2010).

vol 1 Figure 1.3 Urine albumin/creatinine ratio (ACR) distribution among NHANES participants, 1999-2014



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.

vol 1 Figure 1.4 Percentage of NHANES (1999-2014) participants with ACR >30 mg/g, by eGFR category



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 was 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. For persons with Stage 4 CKD

(eGFR <30 ml/min/1.73m²), over half had evidence of albuminuria.

Over the four time periods there was an overall rise in the percentage of individuals in the three higher-risk KDIGO categories, increasing from 13.9% of 1999-2002 participants to approximately 15% in 2011-2014 (see Table 1.1b). Although the prevalence fluctuated over the four periods, it increased from 13.5% to 14.9% between the two most recent cohorts.

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

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

				Albuminuria categories		
				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
GFR categories (ml/min/1.73 m ²)	G1	Normal to high	≥ 90	54.7	4.3	0.4
	G2	Mildly decreased	60-89	30.4	2.6	0.3
	G3a	Mildly to moderately decreased	45-59	3.9	0.9	0.2
	G3b	Moderately to severely decreased	30-44	1.0	0.5	0.2
	G4	Severely decreased	15-29	0.1	0.1	0.2
	G5	Kidney failure	< 15	<0.001	0.001	0.01

(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	13.9 {	14.5 {	13.5 {	14.9 {				
High risk					10.4	10.6	9.6	10.8
Very high risk					2.2	2.7	2.5	2.6
Very high risk	1.3	1.2	1.4	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 ≥60 ml/min/1.73 m² and ACR <30 mg/g; moderately high risk: eGFR 45-59 ml/min/1.73 m² or eGFR ≥60 ml/min/1.73 m² and ACR 30-300 mg/g; high risk: eGFR 30-44 ml/min/1.73 m² or eGFR 45-59 ml/min/1.73 m² and ACR 30-300 mg/g or eGFR ≥60 ml/min/1.73 m² and ACR >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 ≥60 ml/min/1.73 m² and ACR >300 mg/g.

Comorbidity, Risk Factors, Treatment, and Control

Many studies have shown that older age, diabetes, hypertension, cardiovascular disease, and higher body mass index (≥ 30 kg/m²; 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 ≥ 30 mg/g confirms a higher estimated prevalence in the presence of each of these risk factors, although with a smaller increase for BMI ≥ 30 kg/m² (Table 1.2). Other observations of interest include that CKD more prevalent in women and those over 60 years of age and DM is the most common comorbid risk factor for CKD. Ethnic and racial comparisons show that non-Hispanic Blacks have higher rates of ACR > 30

but lower rates of eGFR < 60 as compared to non-Hispanic Whites.

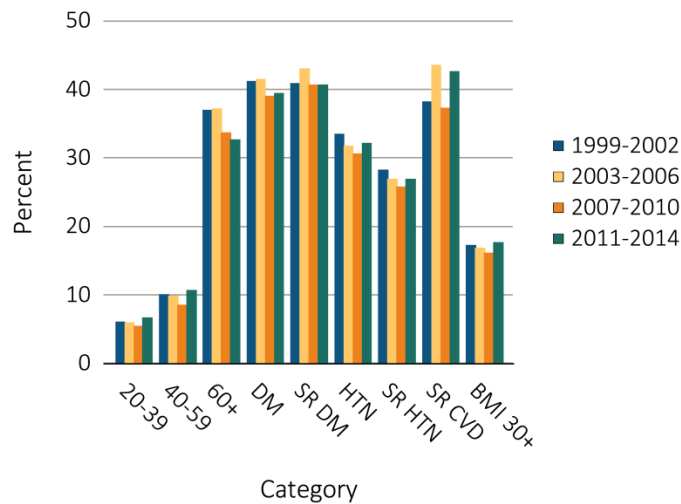
Occurrences of eGFR > 60 ml/min/1.73 m² and ACR ≥ 30 mg/g for adult NHANES participants are shown in Table 1.2. When CKD was defined as either eGFR < 60 or ACR ≥ 30 , prevalence estimates varied over time, with an overall rise from 13.9% to 14.8% (Figure 1.5). The largest relative increase in prevalence was seen 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% over the four periods, with the largest relative increase (1.7-fold) seen in those aged 40-59. Prevalence for ACR ≥ 30 remained steady over this period, between 9-10%.

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

	All CKD				eGFR <60 ml/min/1.73m ²				ACR ≥30 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
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	8.2	7.0	8.5
Sex												
Male	12.0	12.6	11.7	13.0	4.8	5.7	5.2	6.4	9.1	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	8.5	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

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 ≥130/≥80 for those with diabetes or CKD, otherwise BP ≥140/≥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.

vol 1 Figure 1.5 Prevalence of CKD by age & risk factor among NHANES participants, 1999-2014

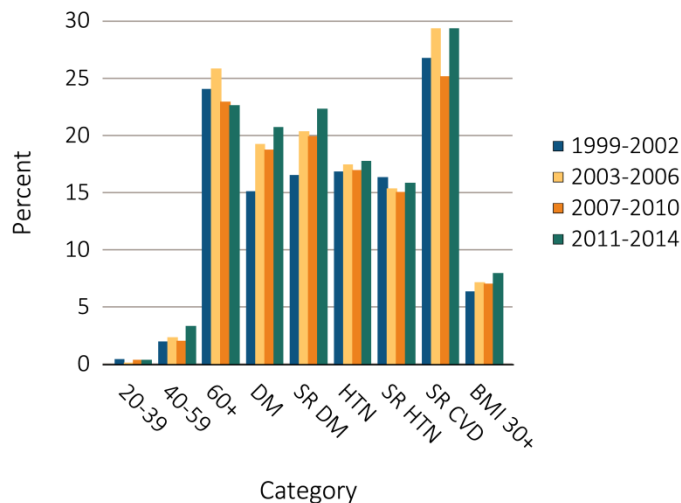


Data Source: National Health and Nutrition Examination Survey (NHANES), 1999–2014 participants age 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation. Diabetes defined as HbA1c >7 percent, self-reported, or currently taking glucose-lowering medications. Hypertension defined as BP ≥130/≥80 for those with diabetes or CKD, otherwise BP ≥140/≥90, or taking medication for hypertension. 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-reported.

Figure 1.6 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 cohort of 2003-2006 participants, 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 time 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.

vol 1 Figure 1.6 NHANES participants with eGFR <60 ml/min/1.73 m², by age & risk factor, 1999-2014

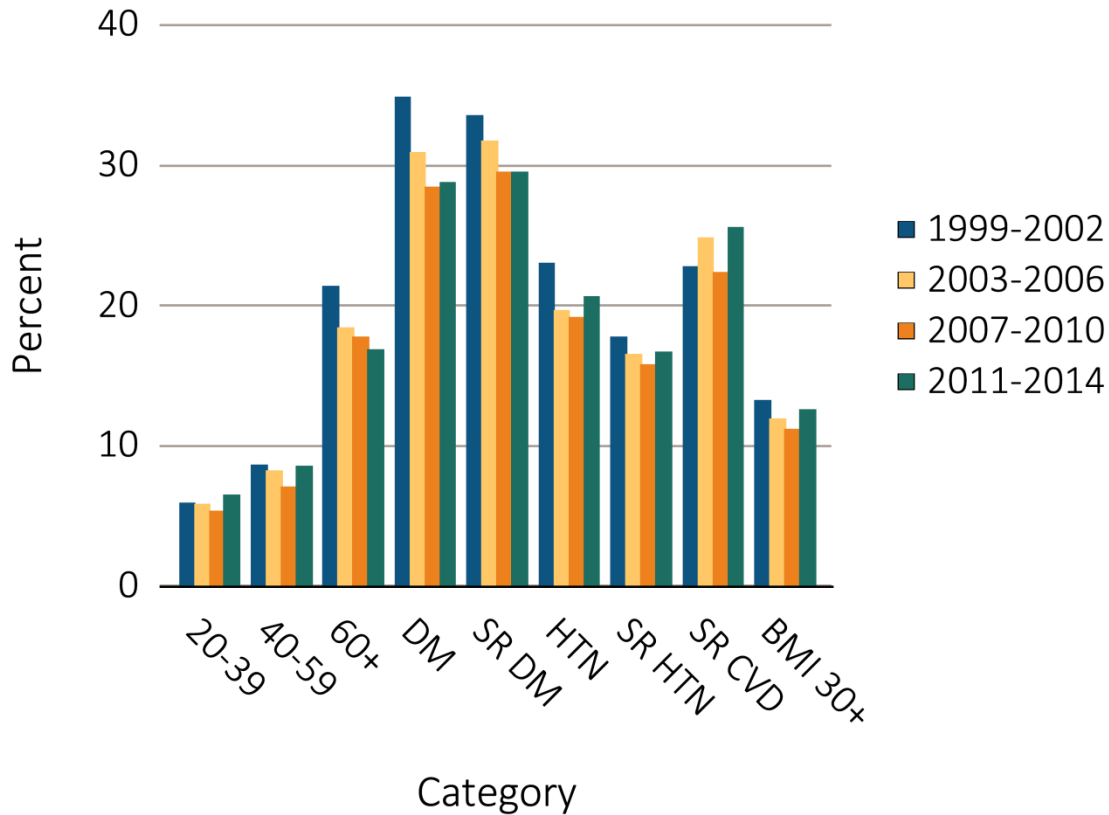


Data Source: National Health and Nutrition Examination Survey (NHANES), 1999–2002, 2003–2006, 2007–2010, & 2011–2014 participants age 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation. Diabetes defined as HbA1c >7 percent, self-reported (SR), or currently taking glucose-lowering medications. Hypertension defined as BP ≥130/≥80 for those with diabetes or CKD, otherwise BP ≥140/≥90, or taking medication for hypertension. Abbreviations: ACR, urine albumin/creatinine ratio; BMI, body mass index; CVD, cardiovascular disease; DM, diabetes mellitus; eGFR, estimated glomerular filtration rate; HTN, hypertension; SR, self-reported.

The prevalence of ACR ≥ 30 mg/g decreased over the three time periods among individuals with DM, self-reported DM, HTN, self-reported HTN, and

higher BMI (Figure 1.7). Prevalence was higher in the older age groups, but less markedly than for eGFR < 60 .

vol 1 Figure 1.7 NHANES participants with urine albumin/creatinine ratio ≥ 30 mg/g, by age & risk factor, 1999-2014

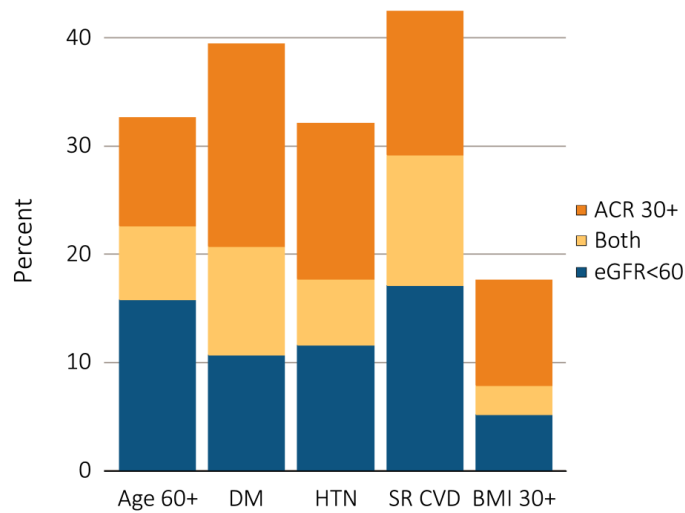


Data source: National Health and Nutrition Examination Survey (NHANES), 1999–2002, 2003–2006, 2007–2010 & 2011–2014 participants age 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation. Diabetes defined as HbA1c > 7 percent, self-reported (SR), or currently taking 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. 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.

Figure 1.8 displays the prevalence of CKD markers (eGFR < 60 ml/min/1.73 m² and ACR ≥ 30 mg/g) among adult NHANES 2011–2014 participants—specifically those aged 60 years and older, and those of all ages who have 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, HTN,

and higher BMI, at 20.7%, 17.7% and 9.9%, respectively. An ACR ≥ 30 was most common in those with DM, at 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 ≥ 30 was most common with SR CVD, at 12.1%, followed by DM, those aged 60 years and older, with HTN, and with higher BMI, at 10.0%, 6.8%, 6.1%, and 2.7%, respectively.

vol 1 Figure 1.8 Distribution of markers of CKD in NHANES participants with diabetes, hypertension, self-reported cardiovascular disease, & obesity, 2011–2014

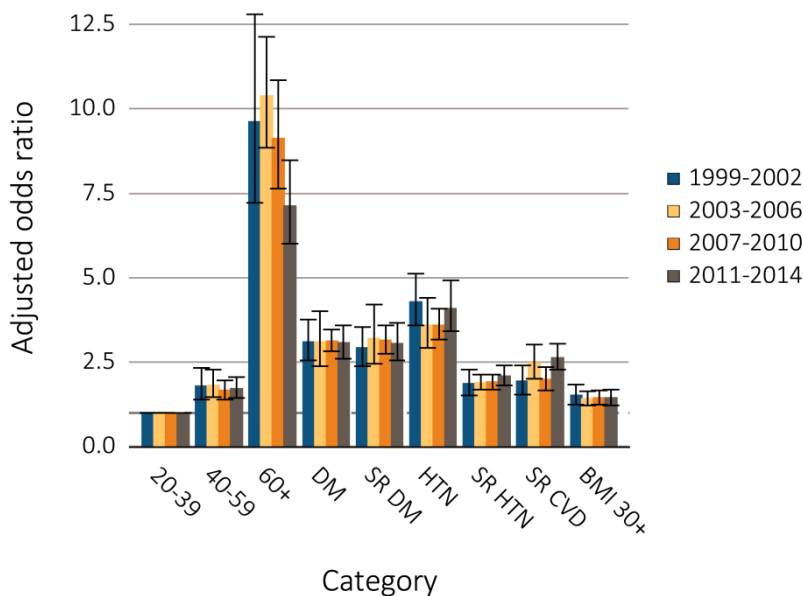


Data Source: National Health and Nutrition Examination Survey (NHANES), 2011–2014 participants age 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation. Abbreviations: ACR, urine albumin/creatinine ratio; BMI, body mass index; CKD, chronic kidney disease; SR CVD,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

Figures 1.9–1.11 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 ≥ 30 mg/g.

vol 1 Figure 1.9 Adjusted odds ratios of CKD in NHANES participants by risk factor, 1999–2014



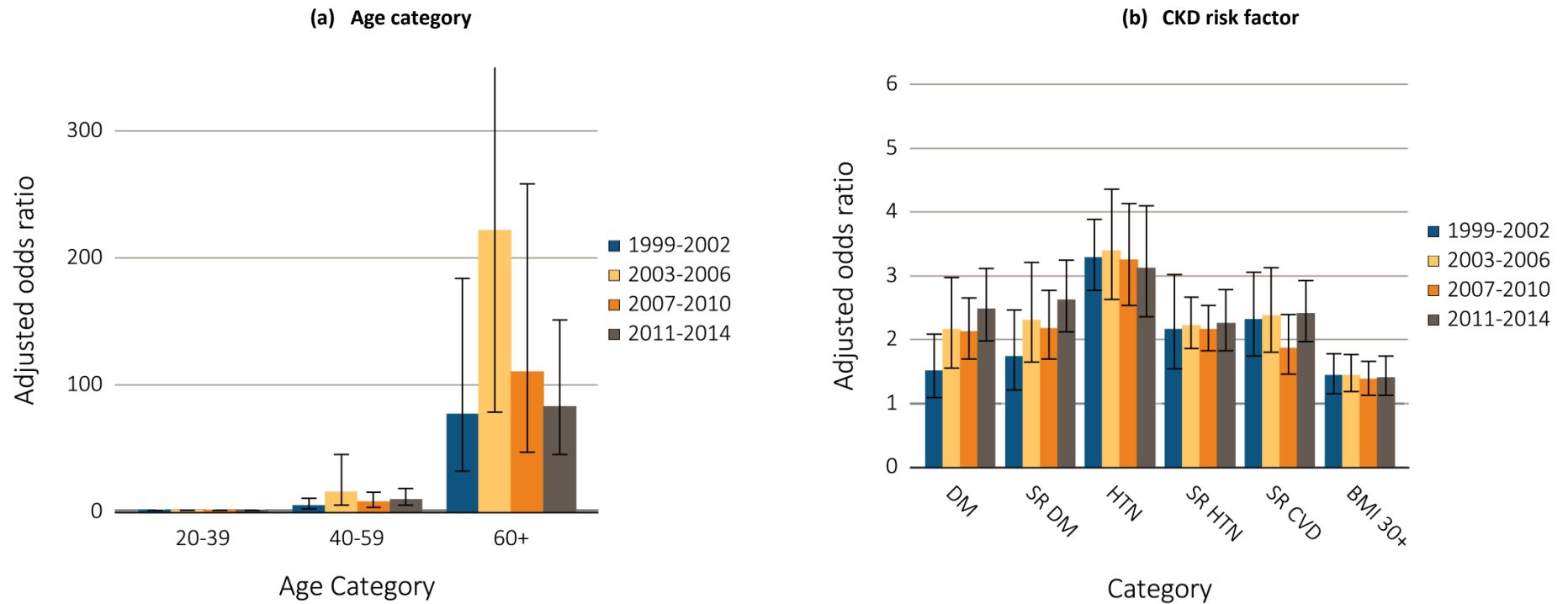
Data Source: National Health and Nutrition Examination Survey (NHANES), 1999–2002, 2003–2006, 2007–2010 & 2011–2014 participants age 20 & older; single-sample estimates of eGFR & ACR. Adj: age, sex, & race; eGFR calculated using the CKD-EPI equation. Whisker lines indicate 95% confidence intervals. Abbreviations: 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.

Adjusted odds ratios for eGFR <60 ml/min/1.73 m² or ACR ≥30 mg/g (Figure 1.9) 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, respectively. Age was the strongest factor associated with CKD, followed by HTN, DM and CVD; these comorbidities had about one third of the effect size as did age.

For eGFR <60 alone (Figure 1.10), adjusted odds ratios followed a similar pattern, except for DM and SR DM, where the odds increased

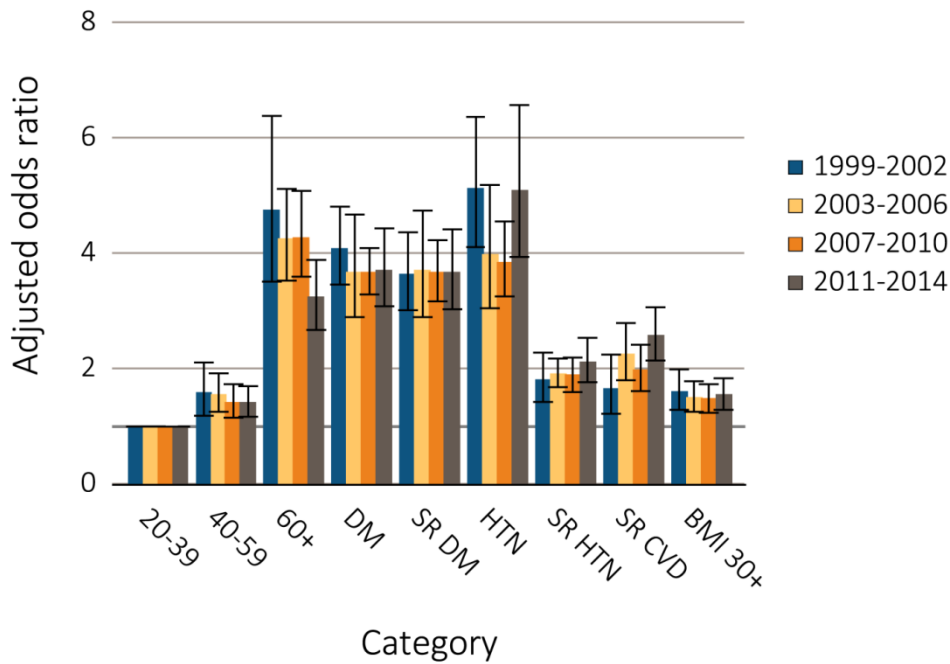
from 1.6 to approximately 2.5 in both groups. Also, eGFR <60 showed a very strong association with age, with adjusted odds ratios in the 100 range. For ACR ≥30 alone (Figure 1.11), a substantial decline in the adjusted odds ratio is seen among both those with DM (from 4.08 to 3.69) and aged 60 or older (from 4.74 to 3.23), while a substantial increase in the adjusted odds ratio is seen for those self-reporting CVD (from 1.65 to 2.57).

vol 1 Figure 1.10 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 1.11 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.

Treatment of CKD

Table 1.3 presents awareness of hypertension, treatment of CKD-contributing conditions, and control of HTN, hyperlipidemia, and DM in NHANES adult participants with eGFR <60 ml/min/1.73 m² or ACR ≥ 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

the same time frame. The proportion of hypertensive individuals, who were aware, treated, and disease controlled rose steadily from approximately 8% in the early cohorts to 28% in 2011-2014. In the subgroup with DM, glycemic control over time showed little improvement with 57.1% uncontrolled in 2011-2014. No improvement was seen in activity level or smoking status.

vol 1 Table 1.3 Awareness, treatment, & measures of control of CKD risk factors, percent of NHANES participants, 1999-2014

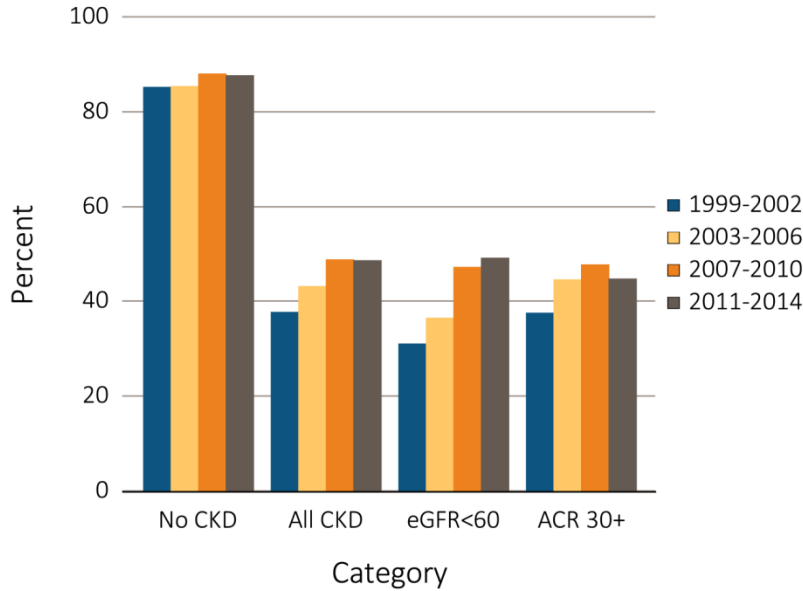
	All CKD					eGFR <60 ml/min/1.73m ²					ACR ≥30 mg/g				
	1999-2002	2003-2006	2007-2010	2011-2014	Trend p-value	1999-2002	2003-2006	2007-2010	2011-2014	Trend p-value	1999-2002	2003-2006	2007-2010	2011-2014	Trend p-value
Hypertension, by current hypertensive status^a															
Non-hypertensive status	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 (measured/treated)	73.1	74.2	73.2	73.9		85.2	85.4	84.4	83.0		70.3	69.7	68.9	71.5	
Control of hypertension among hypertensive patients^b															
Unaware	64.3	25.4	19.5	22.6	<0.001	58.1	21.0	17.0	13.1	<0.001	67.7	26.8	24.7	23.0	<0.001
Aware, not treated	5.6	8.4	9.7	5.8		3.2	5.2	2.5	4.3		6.6	10.3	8.2	12.6	
Aware, treated, uncontrolled	22.1	46.6	42.3	43.8		26.6	51.4	45.5	45.8		21.1	46.3	44.9	43.9	
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	<0.001	40.7	56.6	62.6	64.3	<0.001	44.9	52.8	58.2	61.3	<0.001
200–239 (borderline high)	35.3	27.5	26.3	24.1		37.0	25.8	23.5	22.0		34.2	27.7	27.2	24.8	
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	
Physical Activity															
Vigorous	22.4	20.8	20.6	23.3	0.47	14.0	14.8	13.0	16.9	0.55	24.2	22.9	23.5	24.7	0.65
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	0.93	7.4	8.7	8.4	9.1	0.38	20.4	20.1	18.7	18.6	0.87
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	
Control of diabetes among patients with diabetes^d															
Glycohemoglobin <7% (controlled)	32.8	51.1	46.9	42.9	0.20	45.6	62.5	55.9	49.3	0.57	28.8	45.3	40.1	36.8	0.37
Glycohemoglobin 7% or higher (uncontrolled)	67.2	48.9	53.1	57.1		54.4	37.5	44.1	50.7		71.2	54.7	59.9	63.2	

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 ≥130/≥80 for those with CKD and diabetes; otherwise ≥140/≥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 1.12-1.15, 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 eGFR

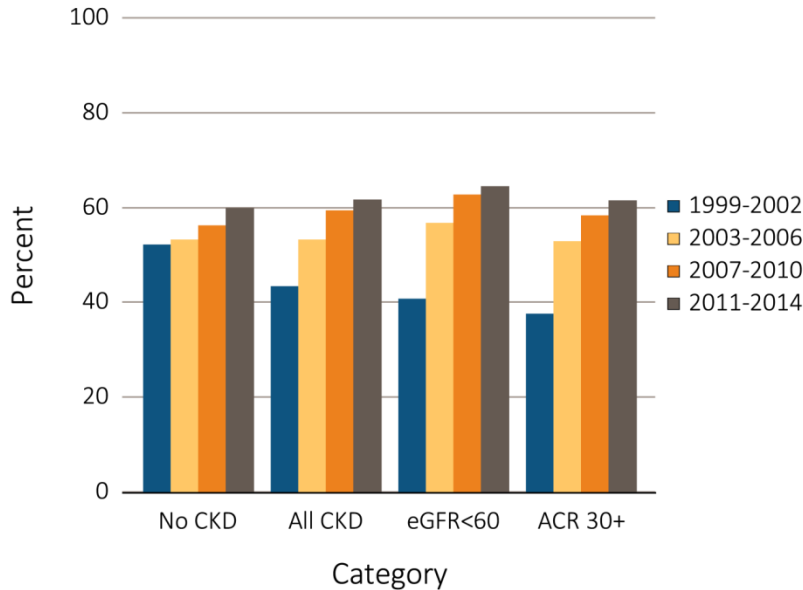
or ACR level was used as the criteria. These figures include estimates for individuals without CKD for comparison.

vol 1 Figure 1.12 NHANES participants at target blood pressure, 1999-2014



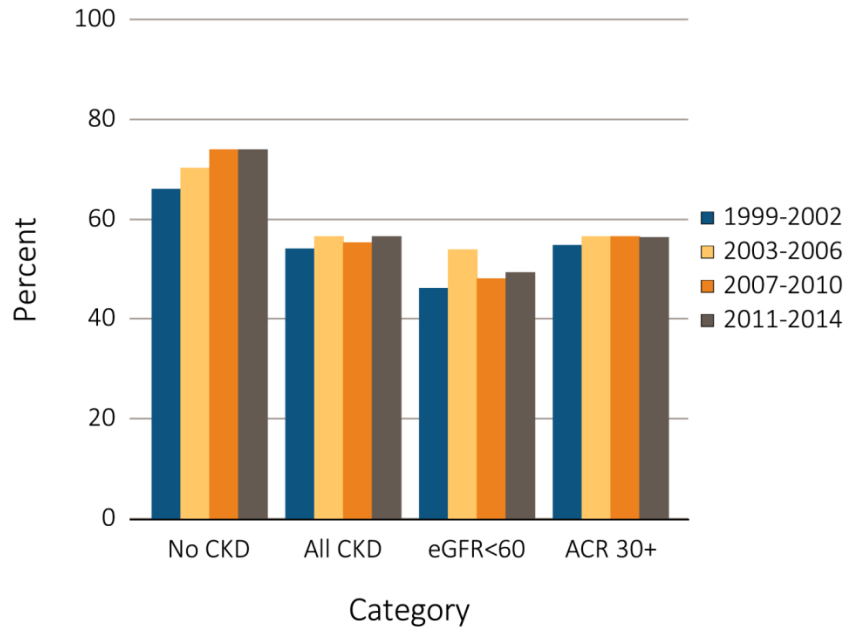
Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2002, 2003-2006, 2007-2010 & 2011–2014 participants aged 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation. Figure represents all hypertensive participants including those who were 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 1.13 NHANES participants within cholesterol normal range, 1999-2014



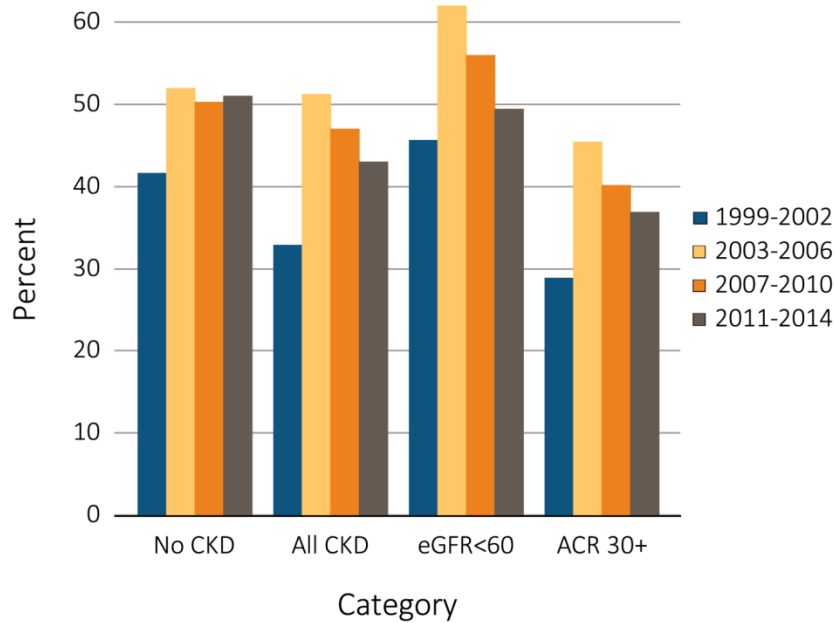
Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2002, 2003-2006, 2007-2010 & 2011–2014 participants aged 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation. Abbreviations: ACR, urine albumin/creatinine ratio; CKD, chronic kidney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

vol 1 Figure 1.14 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.

vol 1 Figure 1.15 Diabetic NHANES participants with glycosylated hemoglobin <7%, 1999-2014



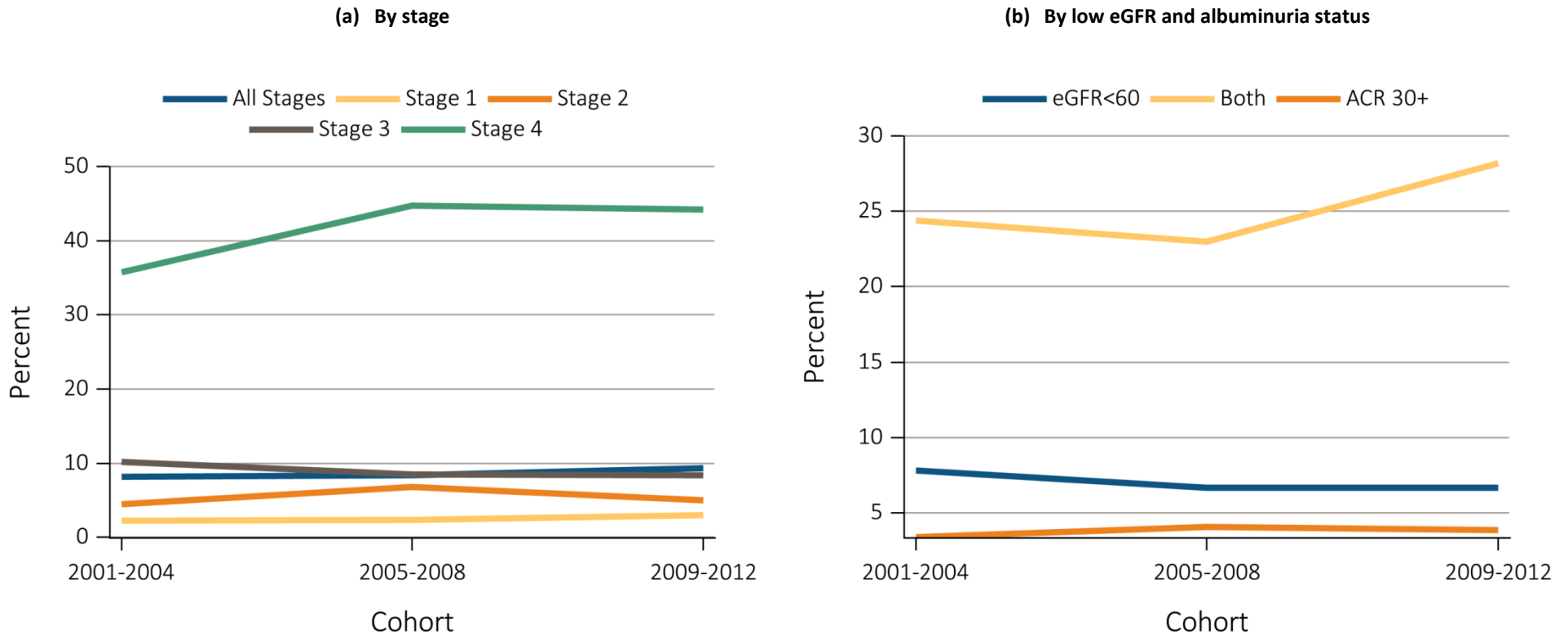
Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2002, 2003-2006, 2007-2010 & 2011-2014 participants aged 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation. Abbreviations: ACR, urine albumin/creatinine ratio; CKD, chronic kidney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

CKD Awareness

Among the individuals that were classified by laboratory measurements as having CKD, the percent of those individuals being aware of their kidney disease has remained low over the years from 2001-2012 (Figure 1.16). There is some suggestion of an improvement among

individuals with Stage 4 CKD between 2001-2004 and 2005-2008, although this did not persist in the 2009-2012 cohort. Note that 4-year cohorts are examined in this graphic. Awareness data is not presented for Stage 5 CKD due to 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 1.16 NHANES participants with CKD aware of their kidney disease, 2001-2012



Data Source: National Health and Nutrition Examination Survey (NHANES), 2001-2012 participants aged 20 & older. Abbreviations: CKD, chronic kidney disease.

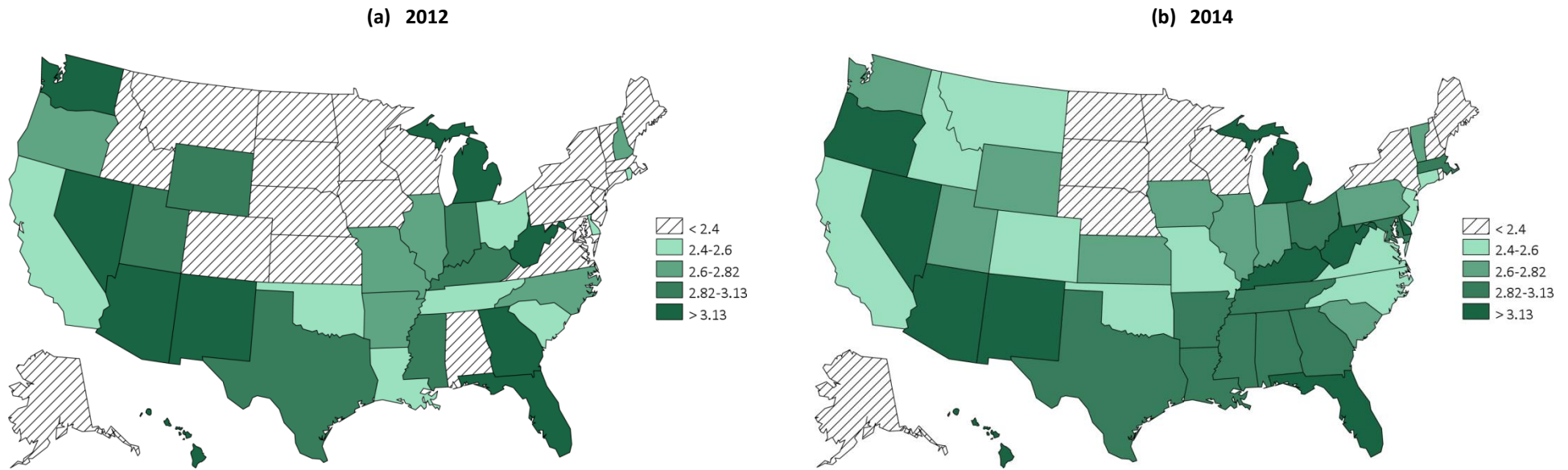
Figure 1.17 displays the state-specific proportion of individuals who reported being told they had ‘kidney disease’ based on the 2012 and 2014 BRFSS sample. The overall national means were very low at 2.7% and 2.8%, respectively. Also at 2.8%, the NHANES prevalence of self-reported kidney disease (‘weak or failing kidneys’) 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 who indicated that they had been informed that they had kidney disease in both years included Hawaii, Arizona, Florida, New Mexico, Michigan, West Virginia, and Nevada. Conversely,

the states with the lowest proportion reporting 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. 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 higher actual prevalence of the disease, greater awareness among those who have the condition, or a combination of both.

vol 1 Figure 1.17 Estimated prevalence of self-reported kidney disease by state (%), BRFSS participants ages 18 and older, 2012 (N=471,107) & 2014 (N=464,617)



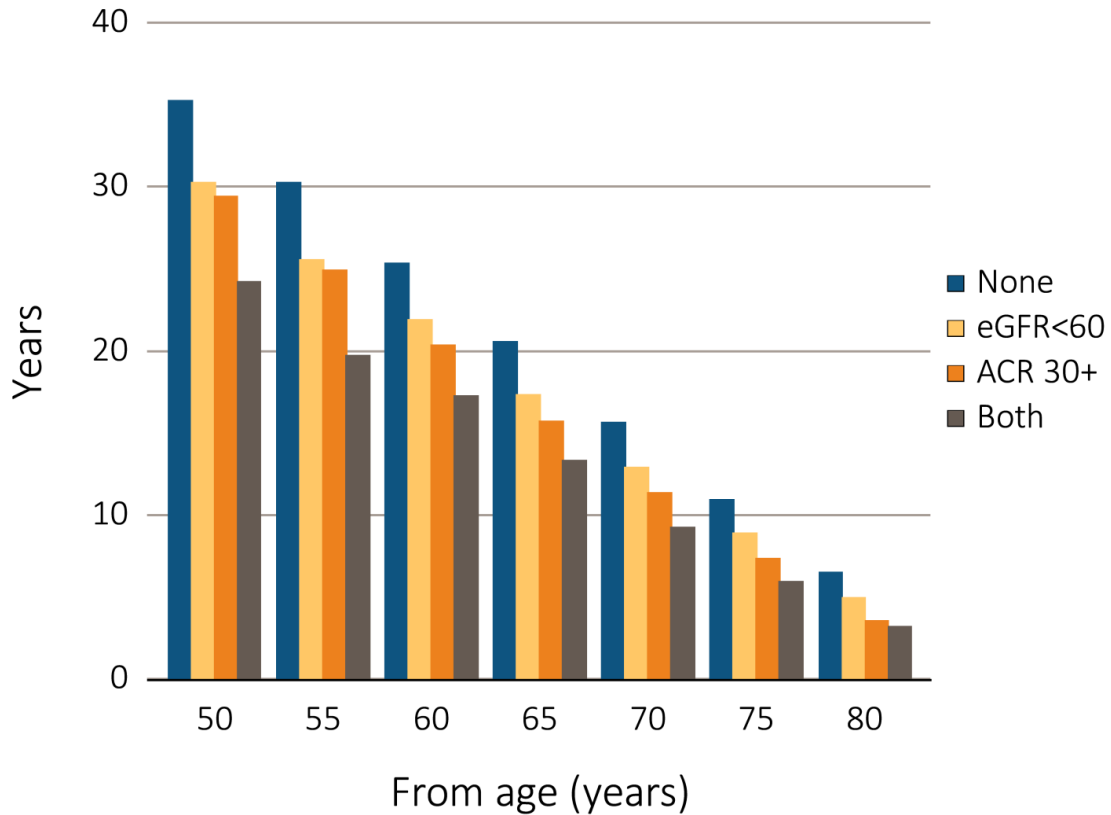
Data source: Behavioral Risk Factors Surveillance System (BRFSS), 2012 participants aged 18 & older.

Life Expectancy

Figure 1.18 shows life expectancy estimates for adult NHANES 1999–2011 participants with single-sample estimates of GFR and ACR. At age 50, estimated life expectancy for subjects with normal range eGFR and ACR was 35.2 years. The reduction in life expectancy associated with eGFR <60 ml/min/1.73 m² was five

years, or 14.2% of the 35.2 years. Participants with ACR ≥30 mg/g had a reduction in estimated life expectancy of 5.8 years (16.5%); this became an 11 year reduction (31.3%) for those with both conditions. When life expectancy was calculated from successively older starting points, absolute reductions declined and percentage reductions remained similar.

vol 1 Figure 1.18 Life expectancy of NHANES participants with or without CKD, 1999–2011



NHANES 1999–2011 participants age 20 & older. Single-sample estimates of eGFR & ACR; eGFR calculated using the CKD-EPI equation.

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Chapter 2: Identification and Care of Patients With CKD

- Over half of patients from the Medicare 5% sample (restricted to age 65 and older) have a diagnosis of chronic kidney disease (CKD), cardiovascular disease, or diabetes, while 18% have two or more of these conditions. Within a younger population (restricted to ages 22-64 years) derived from the Clinformatics™ Data Mart, 8.4% have at least one of the conditions, while 1.1% have two or more of the conditions (Table 2.2.b).
- In the Medicare 5% sample, 11.0% of patients were diagnosed with CKD in 2014, as opposed to less than 1% of patients in the Clinformatics™ population (aged 22-64) (Table 2.3).
- The total population with recognized CKD from the Medicare 5% sample has grown steadily, from 2.7% in 2000 to 11.0% in 2014. (Figure 2.1).
- Of patients in the Medicare 5% sample diagnosed with CKD Stage 3 in 2009, 2% had progressed to ESRD and 42% had died by 2014. In the Medicare population without identified CKD, progression to ESRD and death was 0.12% and 22%, respectively (Table 2.5).
- Urine albumin testing is recommended for monitoring patients with diabetes mellitus. Among patients with diabetes in the Medicare population, with or without a diagnosis of CKD, claims data indicate that testing for urine albumin has been steadily rising over time though it is still done in less than half of such patients (24.8% in 2005 and 39.1% in 2014). For example, urine albumin testing was performed in 48% of patients with a diagnosis of CKD and both diabetes and hypertension, in 2014. Patterns were similar, but with somewhat lower rates of testing in the Clinformatics™ population (Figures 2.2 and 2.3).
- Among Medicare patients with diagnosed CKD in 2013, patients who saw a nephrologist were more likely to be tested for urine albumin in 2014 (51%) than those who saw a primary care physician but not a nephrologist (24%) (Figure 2.4).

Introduction

Epidemiological evaluations of the identification and care of patients with chronic kidney disease (CKD) are a significant challenge, as most large administrative health care datasets lack the biochemical data (serum creatinine and urine albumin or urine total protein) required to definitively identify the disease. The National Health and Nutrition Examination Survey (NHANES), a nationally representative survey dataset contains the necessary biochemical information, as shown in Chapter 1, to estimate the prevalence of CKD in the general population. However, the cross-sectional nature of

NHANES and the relatively small sample of patients (compared to large administrative datasets) limits the precision of estimated prevalence; evaluation of long-term outcomes, adverse events, and quality of care delivered to patients with CKD, as well as the ability to conduct analyses on subsets of patients. In addition, the NHANES survey only includes a single measure of serum creatinine and urine albumin. KDIGO guidelines state that two abnormal measures over at least 90 days are necessary to definitively determine CKD. While NHANES-based calculations likely overestimate the prevalence of CKD in the United States, this is the best source of such information at the present time.

Methods

For this year's chapter, we have utilized several health care datasets, including the general Medicare 5% sample, with an average of 1.2 million patients each year, Clinformatics™ Data Mart data (drawn from the commercial plans of a large U.S. national health insurance company), with information on about 9 million lives per year, and national health system-derived data from the U.S. Department of Veterans Affairs (VA). 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 in Medicare managed care programs are not included due to the absence of billing claims. The Clinformatics™ Data Mart data provides insight into a younger, employed population and their dependent children. Like Medicare data, it contains information in the form of diagnosis and procedure codes on claims. The Clinformatics™ dataset also includes information on pediatric age groups, although for the analyses in this chapter only adult patients (ages 22-64 years) are included. Finally, the VA dataset includes diagnosis and procedure codes, as well as fairly complete biochemical results data. This allows comparison of the prevalence of CKD based on diagnosis codes versus biochemical data.

Throughout this chapter, the term “recognized CKD” is used when patients are identified based on the presence of a relevant diagnosis code in Medicare,

Clinformatics™, or VA data, meaning that either a provider or billing coder in the health care system recognized the presence of CKD. As such, prevalence of recognized CKD may not necessarily reflect true disease prevalence, and any observed trend may not necessarily reflect true change in disease prevalence, but rather change in awareness or recognition of CKD, or indeed in billing practices, in general. 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 diabetes (250.4x) and hypertension (403.9x), and some of which are more kidney-disease specific, such as glomerular disease (583.x). In 2005, 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 in 2007 and 68% in 2014. Total CKD coding continues to grow, suggesting growing recognition of CKD over time. Studies have shown that diagnosis codes for CKD generally have excellent specificity (>90%), though their sensitivity is low (Grams et al., 2011). Table A lists the CKD-related ICD-9-CM codes used in this chapter. Details of these data sources are described in the [Data Sources](#) section of the *CKD Analytical Methods* chapter.

See [Chapter 2](#) of the *CKD Analytical Methods* chapter for an explanation of analytical methods used to generate the study cohorts, figures, and tables in this chapter.

Table A. 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 is 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.

Prevalence of Recognized CKD

Table 2.1 presents demographic and comorbidity characteristics of individuals in the Medicare 5% sample (aged 65 and older) and the Clinformatics™ dataset. The mean age of the Medicare patients was 75.9 years, and the mean age of Clinformatics™ patients was 52.3 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 have diagnoses of hypertension and diabetes, respectively. In comparison, only 10.3% and 4.4% of the total Clinformatics™ population have diagnoses of hypertension and diabetes, respectively.

vol 1 Table 2.1 Demographic characteristics of all patients, among Medicare (aged 65+ years) and Clinformatics™ (all ages) patients, 2014

	Medicare 5%		Clinformatics™	
	Sample count	(%)	Sample count	(%)
All	1,276,732	100%	6,445,818	100%
Age				
<4	-	-	281,307	4.4
5-9	-	-	412,438	6.4
10-13	-	-	357,248	5.5
14-17	-	-	373,678	5.8
18-21	-	-	367,539	5.7
22-30	-	-	798,922	12.4
31-40	-	-	1,043,124	16.2
41-50	-	-	1,131,850	17.6
51-65	-	-	1,444,158	22.4
65-74	712,995	55.9	179,303	2.8
75-84	392,923	30.8	39,673	0.6
85+	170,814	13.4	16,578	0.3
Sex				
Male	554,559	43.4	3,279,378	50.9
Female	722,173	56.6	3,165,945	49.1
Race/Ethnicity				
White	1,095,736	85.8	4,469,440	69.7
Black/African American	96,565	7.6	556,682	8.7
Native American	5,407	0.4		
Asian	24,606	1.9	334,804	5.2
Hispanic	-	-	707,399	11.0
Other	42,846	3.4		
Unknown/Missing	11,572	0.9	341,121	5.3
Comorbidity				
DM	302,155	23.7	281,945	4.4
HTN	753,286	59.0	663,987	10.3
CVD	497,773	39.0	286,632	4.5

Data Source: Special analyses, Medicare 5% sample (aged 65 and older) and Clinformatics™ (all ages) alive & eligible for all of 2014. Abbreviations: CKD, chronic kidney disease; CVD, cardiovascular disease; DM, diabetes mellitus; HTN, hypertension. 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. - No available data.

Table 2.2 provides the prevalence of recognized CKD, diabetes, and cardiovascular comorbid conditions among patients in the Medicare population (aged 65 and older) and the adult Clinformatics™ population aged 22 through 64 years of age (younger patients were excluded as these comorbidities would

be rare in them). Over half of the Medicare population has at least one of these comorbid conditions, and 18% have two or more. As expected, prevalence was much lower in the Clinformatics™ population: approximately 8.4% had at least one of these comorbid conditions, and 1.1% had two or more.

vol 1 Table 2.2 Prevalence of coded comorbid conditions (CKD, CVD & DM), (a) total & (b) one or more, among Medicare (aged 65+ years) and Clinformatics™ (aged 22-64 years) patients, 2014

	(a) Any diagnosis of CKD, CVD, or DM			
	Medicare 5%		Clinformatics™	
	Sample count	%	Sample count	%
	1,276,732	100%	4,418,054	100%
Total CKD	141,001	11.0	40,774	0.9
Total CVD	497,773	39.0	213,093	4.8
Total DM	302,155	23.7	234,456	5.3

	(b) Combinations of CKD, CVD, or DM diagnoses			
	Medicare 5%		Clinformatics™	
	Sample count	%	Sample count	%
	1,276,732	100%	4,418,054	100%
Only CKD	23,811	1.9	19,758	0.4
Only CVD	282,930	22.2	169,514	3.8
Only DM	117,872	9.2	186,038	4.2
CKD & DM, no CVD	18,506	1.4	10,455	0.2
CKD & CVD, no DM	49,066	3.8	5,616	0.1
DM & CVD, no CKD	116,159	9.1	33,018	0.7
CKD & CVD & DM	49,618	3.9	4,945	0.1
No CKD, no CVD, no DM	618,770	48.5	3,988,710	90.3

Data Source: Special analyses, Medicare 5% sample (aged 65 and older) and Clinformatics™ (aged 22-64) alive & eligible for all of 2014. 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.

Table 2.3 presents the prevalence of recognized CKD in the Medicare population. Of Medicare patients aged 65 and older, 11.0% have a recognized (i.e., coded diagnosis of) CKD. The prevalence of recognized CKD increases with age, from 7.5% at ages 65–74 to 18.9% at age 85 and older. Males have slightly higher prevalence than females. The prevalence among Blacks/African Americans (hereafter, Blacks) (16.0%) is roughly 50% higher than Whites, while Asians and Native Americans have a prevalence

slightly higher than Whites. Results from the adjusted analyses confirm greater odds of recognized CKD in older patients, Blacks, and those with diabetes, hypertension, or cardiovascular disease. The prevalence of recognized CKD in the Clinformatics™ population is substantially lower, driven by the lower prevalence among younger patients. Among patients of comparable age to the Medicare population, the prevalence is still lower possibly reflecting a healthier, employed population in the Clinformatics™ dataset.

vol 1 Table 2.3 Prevalence of CKD, by demographic characteristics and comorbidities, among Medicare 5% sample (aged 65+ years) and Clinformatics™ (all ages) patients, 2014

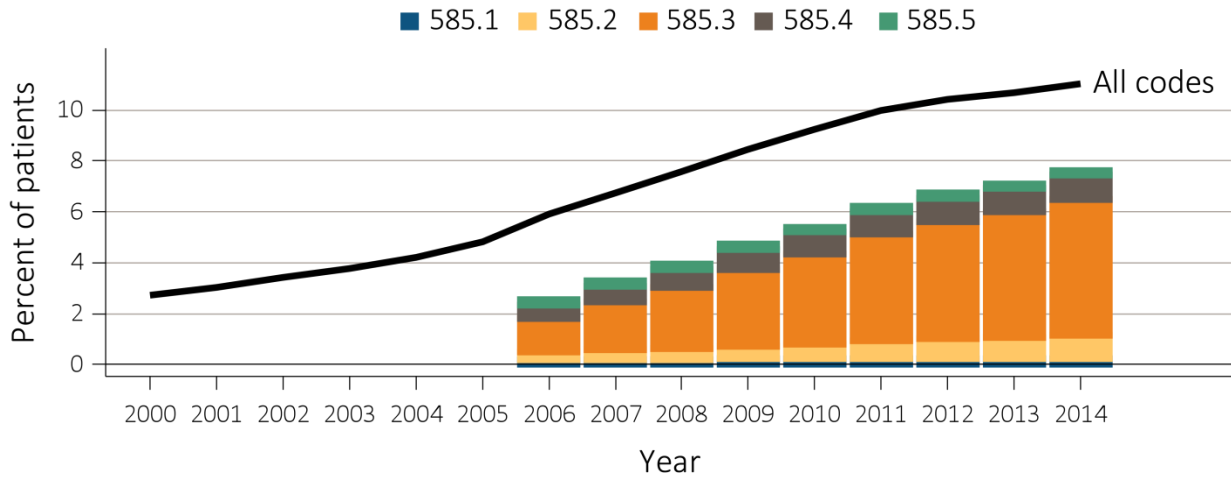
	Prevalence of CKD	
	Medicare 5%	Clinformatics™
Overall	11.0	0.9
Age		
< 4	-	0.3
5-9	-	0.1
10-13	-	0.1
14-17	-	0.1
18-21	-	0.2
22-30	-	0.2
31-40	-	0.4
41-50	-	0.8
51-65	-	1.8
65-74	7.5	4.4
75-84	14.1	9.6
85+	18.9	13.2
Sex		
Male	12.1	1.0
Female	10.2	0.8
Race/Ethnicity		
White	10.7	0.9
Black/African American	16.0	1.2
Native American	11.7	-
Asian	11.7	0.5
Hispanic	-	0.8
Other/Unknown	9.8	0.8
Comorbidity		
DM – Yes	22.5	7.8
DM – No	7.5	0.6
HTN – Yes	17.2	5.8
HTN – No	2.1	0.3
CVD – Yes	19.8	6.5
CVD – No	5.4	0.6

Data Source: Special analyses, Medicare 5% sample (aged 65 and older) and Clinformatics™ (aged 22-64) alive & eligible for all of 2014. Abbreviations: CKD, chronic kidney disease; CVD, cardiovascular disease; DM, diabetes mellitus; HTN, hypertension. 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. - No available data.

Figure 2.1 shows the trend from 2000-2014 in prevalence of recognized CKD overall and by CKD stage-specific code in the Medicare 5% sample. It

shows that the prevalence of recognized CKD has steadily risen each year.

vol 1 Figure 2.1 Trends in prevalence of recognized CKD, overall and by CKD stage, among Medicare patients (aged 65+ years), 2000-2014



Data Source: Special analyses, Medicare 5% sample. Known CKD stages presented as bars; curve showing “All codes” includes known CKD stages (codes 585.1-585.5) and the CKD-stage unspecified codes (585.9, and remaining non-585 CKD codes). Note: In previous years, this graph reported 585.9 codes as a component of the stacked bars. Abbreviation: CKD, chronic kidney disease.

Table 2.4 compares the prevalence of CKD in the NHANES, Medicare and VA populations among patients aged 65 and older, stratified by demographic characteristics and comorbid conditions, in order to highlight issues with identification of CKD across various types of data. For the VA population, information is presented on prevalence of CKD both based on diagnosis codes, as well as on available laboratory data documenting at least one serum creatinine result corresponding to an eGFR <60 ml/min/1.73m². Across all datasets, the prevalence of CKD increased with older age. However, the absolute prevalence of CKD was highest in the NHANES data, intermediate in the VA data (eGFR-based), and the lowest when based on diagnosis codes alone in Medicare claims or VA data. The NHANES, by design, includes measurement of kidney function in all participants, thus providing the closest estimate of the

true prevalence of CKD, though overestimation is possible given its reliance on a single measurement. NHANES also does not represent people living in long-term care facilities, while many of those residents have Medicare insurance and are included in claims data. In contrast, the prevalence of recognized CKD based on diagnosis codes in either Medicare or VA data is lowest due to under-recognition and under-coding of the condition, with better capture of more advanced cases of CKD. Finally, eGFR-based CKD prevalence in the VA population while based on laboratory data, is dependent on the frequency of testing in the health care system, which is in turn based on clinical indication (i.e., not performed in all patients) and is likely an underestimate of the true prevalence in the population served by the VA health system.

vol 1 Table 2.4 Percent of patients with CKD by demographic characteristics, among individuals (aged 65+ years) overall and with DM, or HTN, in NHANES (2011-2014), Medicare 5% sample (2014) and VA (2014) datasets

	Overall				DM (with or without HTN)				HTN (No DM)			
	NHANES		Medicare		VA		NHANES		Medicare		VA	
	CKD eGFR	CKD code	CKD code	CKD eGFR	CKD eGFR	CKD code	CKD code	CKD eGFR	CKD eGFR	CKD code	CKD code	CKD eGFR
Age												
65-74	28.1	7.5	3.1	14.3	46.0	18.4	7.2	23.8	32.1	8.7	4.6	17.2
75-79	46.0	14.1	4.2	26.0	57.4	25.9	10.3	40.3	44.1	14.8	7.5	32.8
80+	61.8	18.9	5.2	35.7	80.1	30.8	13.1	53.3	63.6	20.9	11.9	49.5
Race												
White	38.6	10.7	3.6	22.9	55.2	22.0	8.3	33.1	44.1	12.8	6.7	29.1
Black/African American	45.0	16.0	7.6	22.6	63.5	26.8	13.2	31.4	40.6	16.8	10.5	26.5
Native American	-	11.7	3.4	17.9	-	23.1	7.9	27.9	-	12.3	5.5	21.7
Asian	-	11.7	4.2	14.8	-	20.8	10.6	25.7	-	12.8	8.1	22.1
Other/Unknown	37.8	9.7	2.3	19.1	50.5	21.1	7.8	33.6	39.5	11.2	6.7	31.1
Sex												
Male	37.3	12.1	3.9	22.5	49.8	24.3	9.0	32.8	41.4	15.0	7.2	28.8
Female	40.3	10.2	2.1	18.9	61.1	21.1	6.8	34.8	44.7	11.8	5.0	31.0
All	38.6	11.0	3.8	22.4	55.3	22.5	8.9	32.8	43.3	13.1	7.2	28.9

Data Source: Special analyses, Medicare 5% sample aged 65 and older alive & eligible for all of 2014. NHANES 2011-2014 participants aged 65 and older, and VA aged 65 and older alive & eligible for all of 2014. The numerator for CKD by ICD-9 diagnosis codes included at least one inpatient ICD-9 diagnosis or two outpatient diagnosis codes in 2014; the numerator for CKD based on eGFR<60 ml/min/1.73m² for the VA data included anyone with at least one outpatient serum creatinine available in 2014; 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 2014. Abbreviations: CKD, chronic kidney disease; DM, diabetes mellitus; HTN, hypertension; VA, Veterans Affairs. - No available data.

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

Table 2.5 shows CKD stage, ESRD, or death in 2013-2014 for a cohort of patients based on CKD diagnosis in 2009. The percentage of all Medicare patients from 2009 who died by the end of 2014 (i.e., after 5 years) was

23.7%, and the percentage alive with ESRD was 0.3%. In comparison, patients with a CKD diagnosis in 2009 were even more likely to have these outcomes. Among patients with no CKD in 2009, 22% had died by 2014, while 0.1% were still alive with ESRD. Among patients with any CKD in 2009, 43% had died and 2% were alive with ESRD in 2014.

vol 1 Table 2.5 Change in CKD status from 2009 to 2014, among Medicare patients (aged 65+ years) alive and without ESRD in 2009

		2013-2014 Status												
		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	
2009 Status	No CKD Diagnosis	row %	56.8	0.2	0.8	4.1	0.5	0.1	3.6	0.1	0.1	21.6	12.1	1,112,300
	CKD Stage 1	row %	18.5	5.1	4.0	15.0	2.6	0.6	6.4	1.1	1.4	36.2	9.2	2,620
	CKD Stage 2	row %	15.2	1.0	9.9	20.5	2.6	0.5	6.0	0.8	0.9	33.9	8.8	6,150
	CKD Stage 3	row %	8.3	0.4	1.8	27.1	5.8	0.6	4.1	1.9	2.1	40.1	7.9	36,419
	CKD Stage 4	row %	2.6	0.2	0.5	8.1	11.4	1.5	2.0	7.5	9.4	51.1	5.8	9,657
	CKD Stage 5	row %	7.1	0.4	0.7	6.8	3.0	1.5	3.8	8.0	10.7	52.5	5.6	2,581
	CKD Stage-unspecified	row %	19.6	0.5	1.5	10.5	2.4	0.4	10.9	0.7	0.9	45.0	7.8	45,246
	Any CKD	row %	13.4	0.6	2.0	16.8	4.5	0.6	7.0	2.0	2.4	43.1	7.7	102,673
	Total	row %	53.1	0.2	0.9	5.2	0.9	0.2	3.9	0.2	0.3	23.4	11.7	
	Total N	645,589	2,809	10,786	63,087	10,287	2,001	46,862	3,385	3,757	284,435	141,975	1,214,973	

Data Source: Special analyses, Medicare 5% sample. Patients alive & eligible for all of 2009. Death and ESRD status were examined yearly between 2010-2014, and were carried forward if present. Among patients without death or ESRD by 2014, the last CKD diagnosis claim was used; if not available, then the last CKD diagnosis claim from 2013 was used. Lost to follow-up represents the patients who were not enrolled in Medicare Part A and Part B in 2013 or 2014. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease.

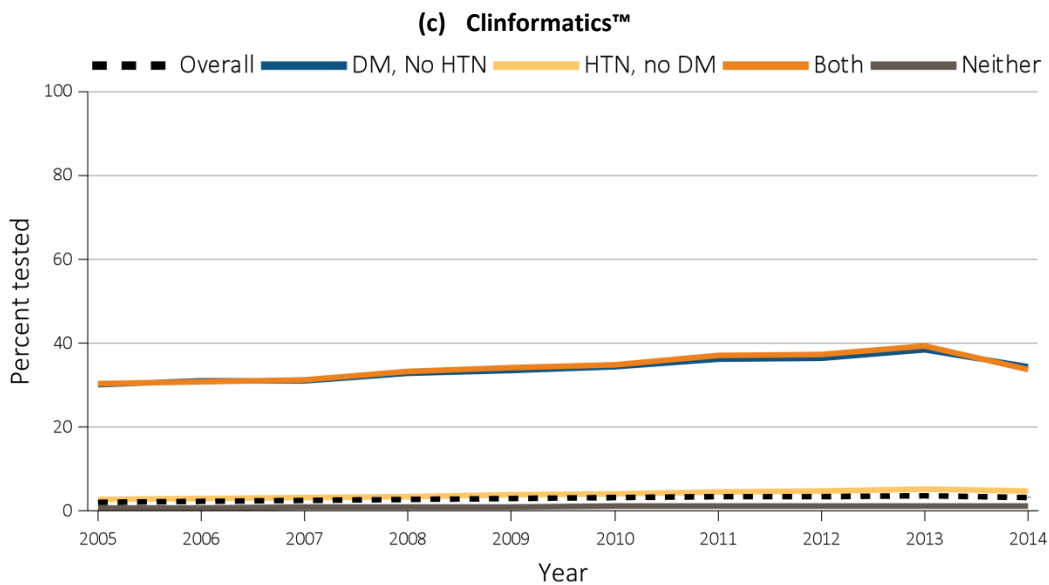
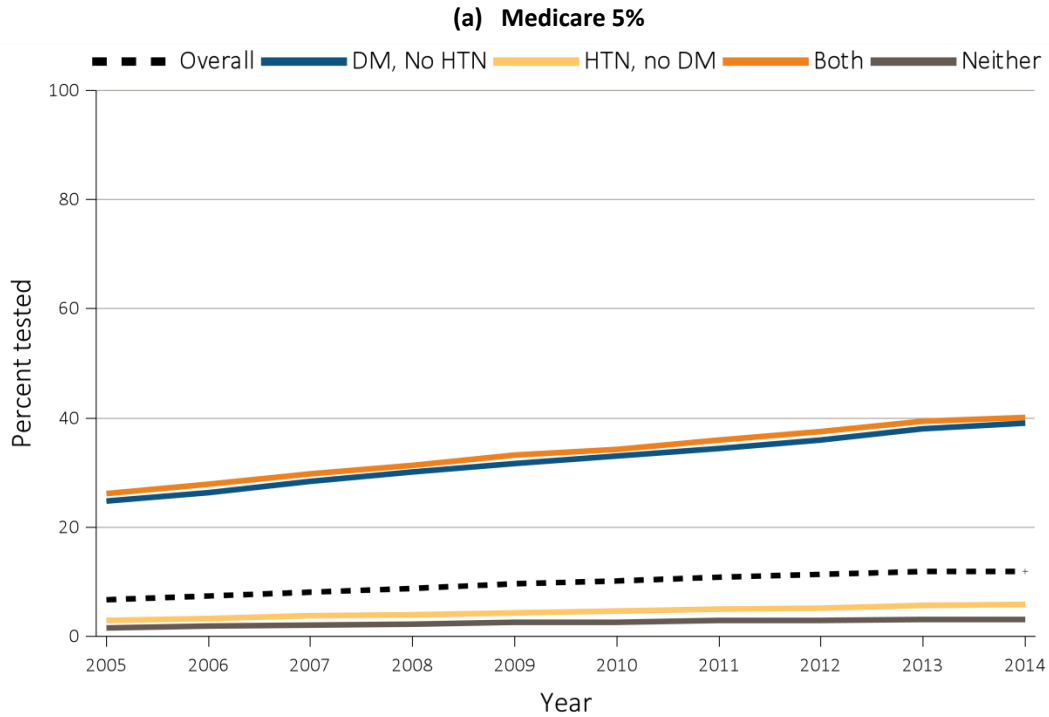
Laboratory Testing of Patients With and Without CKD

Assessing the care of patients at high risk for kidney disease has long been a focus of the USRDS, and is now part of the Healthy People 2020 goals developed by the Department of Health and Human Services (see the *Healthy People 2020* chapter in Volume 2). Although there are no recommendations to screen asymptomatic patients not at high risk for CKD, individuals at risk for CKD (most notably those with diabetes mellitus) should be screened periodically for kidney disease, and those with CKD should be monitored for progression of disease. Urine albumin is a valuable laboratory marker to detect signs of kidney damage, as well as to evaluate for progression of kidney damage. Urine testing for albumin in patients with diabetes has been recommended for some time by the American Diabetes Association (ADA). 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 glomerular filtration rate (based on estimating equations incorporating serum creatinine values),

emphasizing that this test is needed to understand patients' kidney disease status and risk of death and progression to end-stage renal disease (ESRD) (Matsushita et al., 2010; Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group, 2012).

As shown in Figure 2.2, 12% of Medicare patients without diagnosed CKD received urine albumin testing in 2014, while 4.3% of the adult patients (aged 22 to 64 years) in the Clinformatics™ dataset without diagnosed CKD received a urine albumin test. Among Medicare patients, 39% with diabetes alone had urine albumin testing, compared to 6% of patients with hypertension alone. Having both diabetes and hypertension is known to increase the likelihood of developing CKD: among these patients (Medicare beneficiaries without a CKD diagnosis), 40% had urine albumin testing in 2014. Similar patterns were seen in the Clinformatics™ population in 2014: 35% of patients with diabetes alone had urine albumin testing, compared to 6% with hypertension alone, and 36% with both diabetes and hypertension. Because urine albumin testing must be ordered separately from standard blood tests (as opposed to serum creatinine, which is usually included as part of a standard panel of tests), urine albumin testing may better represent intent to assess kidney disease.

vol 1 Figure 2.2 Trends in percent of patients with testing of urine albumin (a) in Medicare 5% sample (aged 65+ years) & (b) Clinformatics™ (aged 22-64 years) patients without a diagnosis of CKD by year, 2005-2014

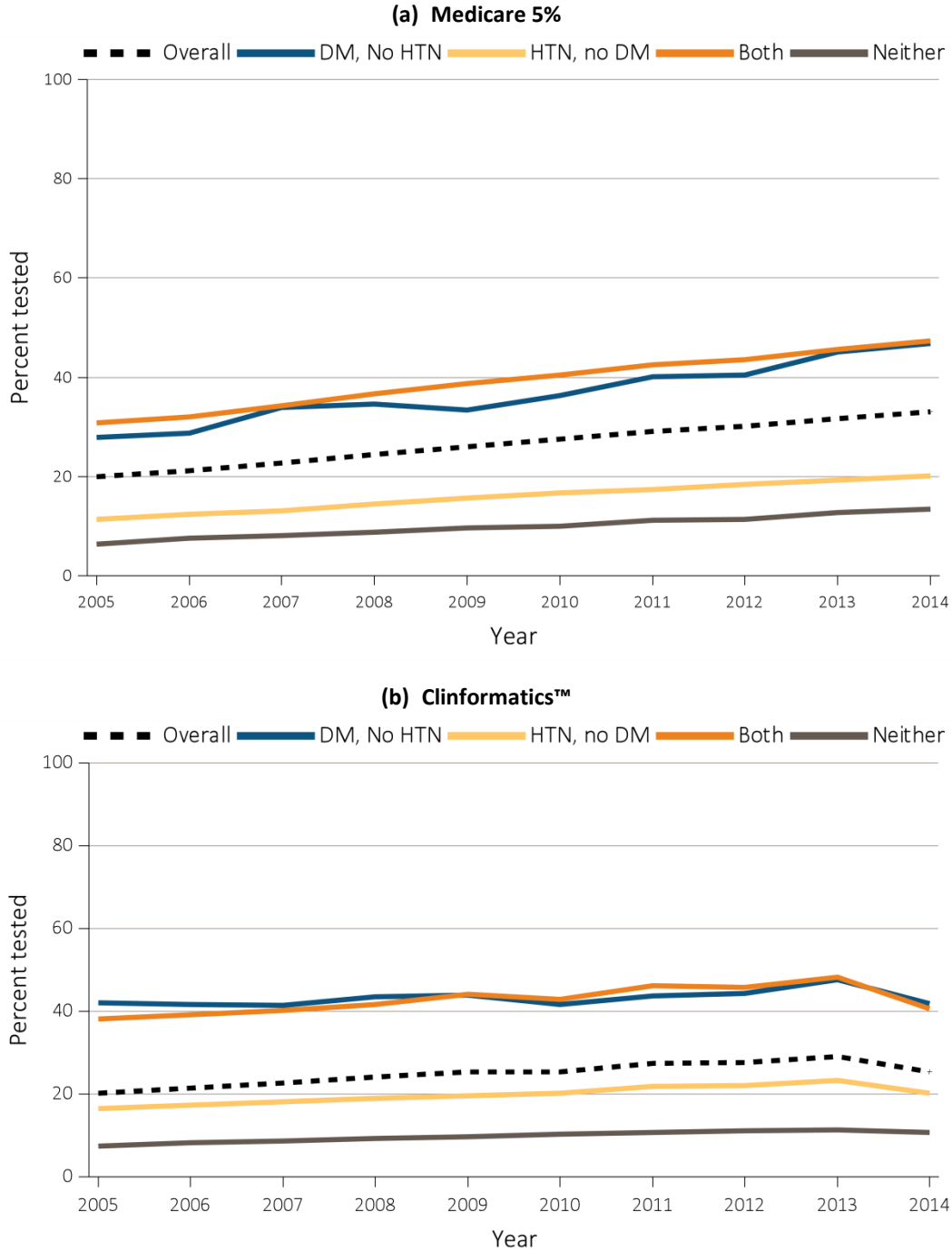


Data Source: Special analyses, Medicare 5% sample aged 65 and older with Part A & B coverage in the prior year and Clinformatics™ patients aged 22-64 years. Tests tracked during each year. Abbreviations: CKD, chronic kidney disease; DM, diabetes mellitus; HTN, hypertension.

As shown in Figure 2.3, among patients with a diagnosis of CKD, patterns of testing were similar, though at somewhat higher rates, to patients without CKD. For example, in 2014, among patients with a

diagnosis of CKD and both diabetes and hypertension, urine albumin testing was performed for 48% in the Medicare population and 43% in the Clinformatics™ population.

vol 1 Figure 2.3 Trends in percent of patients with testing of urine albumin in (a) Medicare 5% (aged 65+ years) & (b) Clinformatics™ (aged 22-64 years) patients with a diagnosis of CKD by year, 2005-2014



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

Physician Visits After a CKD Diagnosis

Table 2.6 indicates the proportion of patients with at least one visit to a primary care physician, cardiologist, or nephrologist in 2014, among those with a CKD diagnosis in 2013. Patients with any CKD diagnosis were far more likely to visit a primary care physician or cardiologist than a nephrologist. This may relate in part to the fact that most guidelines (including the KDIGO CKD guidelines) indicate the need for referral to nephrology only for advanced CKD (CKD Stage 4; i.e., once the estimated glomerular filtration rate (eGFR) falls to under 30 ml/min/1.73 m²), unless there are other concerns such as rapid

progression of disease. Indeed, fewer than one-third of patients with any CKD claim in 2013 were seen by a nephrologist over the subsequent year. However, nearly half with CKD Stage 3 and roughly two-thirds with CKD Stage 4 or higher visited a nephrologist in 2014. Whether the involvement of a nephrologist improves outcomes, and at what stage of CKD, is a matter of ongoing interest. Overall, the patterns of physician visits varied little across demographic categories. A notable exception is that patients 85 and older with CKD Stage 3 or higher were as likely as younger patients to visit a cardiologist, but less likely than younger patients to visit a nephrologist.

vol 1 Table 2.6 Percent of patients with a physician visit in 2014 after a CKD diagnosis in 2013, among Medicare 5% patients (aged 65+ years)

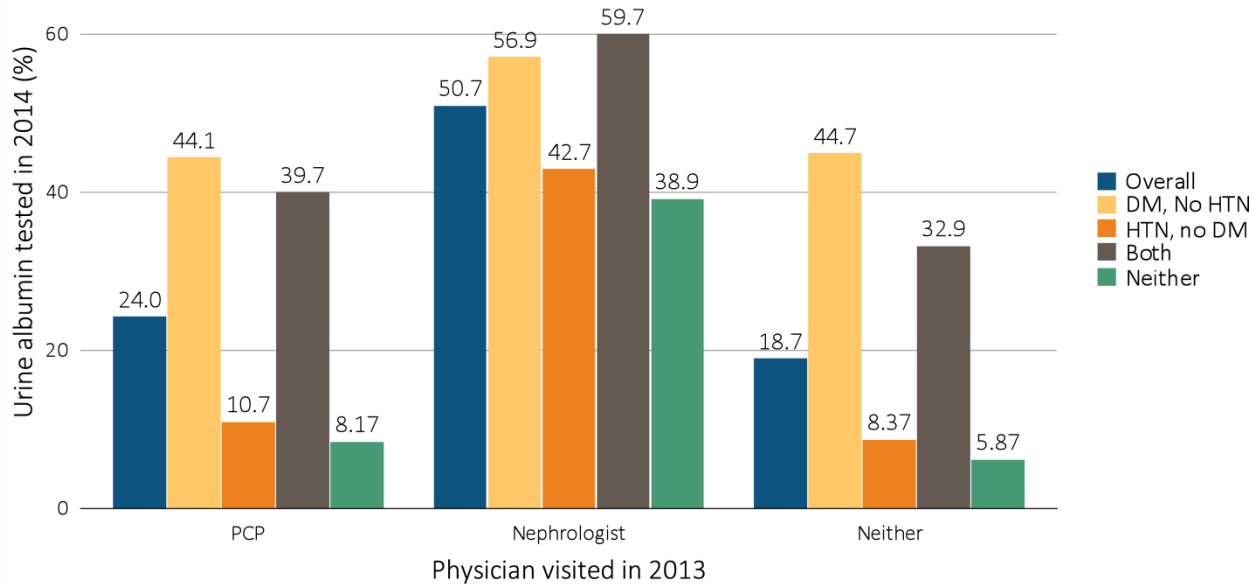
	Any CKD diagnosis			CKD diagnosis code of 585.3 (Stage 3)			CKD diagnosis code of 585.4 (Stage 4) or higher		
	Primary care	Cardiologist	Nephrologist	Primary care	Cardiologist	Nephrologist	Primary care	Cardiologist	Nephrologist
Age									
65-74	88.8	54.3	31.6	89.2	53.7	53.0	80.5	48.1	70.5
75-84	92.1	63.2	30.7	92.1	61.9	46.6	84.3	54.8	68.4
85+	93.6	64.3	24.0	93.3	62.9	34.1	86.7	53.7	55.0
Sex									
Male	91.1	59.8	28.9	91.5	59.1	45.7	83.7	52.5	66.1
Female	91.1	59.8	35.5	90.9	59.1	52.5	83.2	50.9	66.8
Race									
White	89.5	53.0	28.9	88.9	53.2	45.6	82.0	46.6	66.0
Black/African American	91.5	56.5	28.9	91.6	55.3	44.6	84.6	49.1	64.6
Asian	91.2	59.7	30.4	91.3	59.1	48.9	83.6	52.6	67.1
Other	90.5	62.4	30.5	91.0	62.6	48.7	82.2	54.9	68.0
Overall	91.0	59.4	29.9	91.3	58.7	46.7	90.0	63.0	66.1

Data Source: Special analyses, Medicare 5% sample aged 65 and older alive & eligible for all of 2013. CKD diagnosis is at date of first CKD claim in 2013; claims for physician visits were searched during the 12 months following that date. CKD diagnosis code of 585.4 or higher represents CKD Stages 4-5. Abbreviation: CKD, chronic kidney disease.

Figure 2.4 presents the proportion of patients with CKD (based on diagnostic code) who were tested for urine albumin in 2014, according to whether they saw a primary care physician or nephrologist in 2013. 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 patients without diabetes mellitus. The smaller difference in being tested for urine albumin across provider type among diabetic patients relates to the wide promulgation of guidelines directed at primary care physicians, such as those from the ADA, for routine renal function assessment in diabetics.

vol 1 Figure 2.4 Percent of Medicare 5% CKD patients (age 65+), with urine albumin testing in the following year (2014), by comorbidity and type of physician visit in 2013



Data Source: Special analyses, Medicare 5% sample aged 65 and older alive & eligible for all of 2014, with a CKD diagnosis claim and a physician visit in 2013. 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.

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Notes

Chapter 3: Morbidity and Mortality in Patients With CKD

MORTALITY

- When adjusted for sex, age, and race, the 2014 mortality rates for Medicare patients with CKD of 111.2 per 1,000 patient years, remained more than double that of those without, at 45.2 per 1,000 patient years. These rates increased with CKD severity, and the gap has narrowed between CKD and Non-CKD patients from 2002-2014 (Table 3.1, reference year 2014).
- Male patients without CKD experienced higher mortality rates of 50.8 per 1,000 patient years than did females, at 41.1 per 1,000. This relative difference was somewhat less among those with CKD, with a mortality rate of 122.7 per 1,000 patient years for males and 103.6 per 1,000 for females (Table 1 and Figure 3.4, reference year 2014).
- When adjusted for sex and age, a comparison of 2014 Medicare patients with CKD showed higher rates of mortality for those of White race at 113.1 per 1,000 patient years, than for Blacks/African Americans at 110.6 per 1,000. This racial difference contrasts to that seen in ESRD dialysis patients, where Whites have significantly higher mortality than Blacks (Table 1 and Figure 3.5).

HOSPITALIZATION

- A notable decrease in hospitalization rates occurred from 2013 to 2014; even after adjustment, admissions decreased by 7.4% for CKD patients and by 7.5% for those without CKD (Figure 3.7).
- Not surprisingly, older patients exhibited greater rates of hospitalization than did the younger age cohorts after adjustment for sex and race. In the CKD group, those over 85 years of age had 735.2 admissions per 1,000 patient years. This was 43.7% higher than the 511.5 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 686.78 per 1,000 patient years than did Whites, with 582.06 per 1,000, and those of other races at 512.48 per 1,000; disparity increased with disease severity (Figure 3.14).

REHOSPITALIZATION

- Rates of rehospitalization for CKD patients were higher at 21.4% than the 15.3% for those without CKD (Table 3.3).
- For Medicare patients without CKD, males exhibited a higher rehospitalization rate than did females, with age and race adjusted percentages of 16.4 and 14.7 (Table 3.3).

Introduction

In this chapter we evaluate the morbidity and mortality of patients with chronic kidney disease (CKD). All 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, 9th

revision, clinical modification) diagnosis codes from Medicare claims. We then report patients' hospitalizations, services, and deaths for the calendar year following entry. For example, the rates reported for 2014 were based on events in 2014 for patients with and without CKD in 2013. We initially present results on mortality, then focus on hospitalizations, and 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).

Adjusted mortality rates were higher for Medicare patients with CKD than for those without, and rates increased with advancing CKD stage, a finding consistent with studies using biochemical measures to define CKD¹. The co-occurrence of diabetes mellitus (DM) and cardiovascular disease (CVD) with CKD increased 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. Clearly, early detection and active treatment are important considerations in reducing morbidity and mortality in the CKD population.

As with mortality, hospitalization rates in the CKD population increased with advancing stages of CKD, for both overall and cause-specific admissions. When data were adjusted for age, race, and sex, CKD patients overall were hospitalized at a rate of 0.59 admissions per patient year—0.49 for those in Stages 1-2, 0.57 for Stage 3, and 0.86 for Stages 4-5 (0.57 where stage was not specified; see Table A for ICD-9-CM definitions). 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 increased in the presence of underlying comorbidities, such as DM and CVD.

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. Rates of rehospitalization for CKD patients were higher than

those for patients without diagnosed CKD. In 2014, 21.4% of patients with CKD were readmitted within 30 days, compared to only 15.3% of those without CKD. These rates have not changed significantly in the past decade, which is of major concern.

In Volume 1, Chapter 2, *Identification and Care of Patients with Chronic Kidney Disease*, we analyzed diagnosis codes from Medicare claims to document the increasing recognition of CKD. The ascertainment of CKD cases through claims data has increased in recent years, likely resulting in decreased estimates of average disease severity, as influenced by the early disease stage of those identified most recently. Thus, changes in mortality and hospitalization rates over time should be interpreted with some caution.

Methods

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

¹ Serum creatinine with validated equations to estimate glomerular filtration rate; Matsushita et al., 2010

See the section on *Chapter 3* in the *CKD Analytical Methods* chapter for an explanation of analytical methods used to generate the study cohorts, figures, and tables in this chapter.

Mortality Rates

As with many chronic conditions, patient mortality in those 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 prior 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, as differences are apparent.

For patients with CKD, the unadjusted mortality rate was 134.8 per 1,000 patient years; this decreased to 111.2 per 1,000 after adjusting for age, sex and race (Reference population: 2014). 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 both higher unadjusted and adjusted mortality rates than did Black patients. This contrasts to the trend for those receiving dialysis, where Whites have much higher mortality rates.

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, 2014

	Unadjusted		Adjusted	
	No CKD	All CKD	No CKD	All CKD
All	43.5	134.8	45.2	111.2
Age				
66–69	15.0	62.7	14.7	60.5
70–74	20.8	76.4	20.6	75.5
75–84	43.8	116.7	43.9	114.8
85+	137.4	247.6	138.3	247.2
Sex				
Male	44.0	139.6	50.8	122.7
Female	43.2	130.4	41.1	103.6
Race				
White	44.3	138.8	45.5	113.1
Black/African American	43.5	120.3	48.8	110.6
Other	32.1	102.0	36.1	82.9

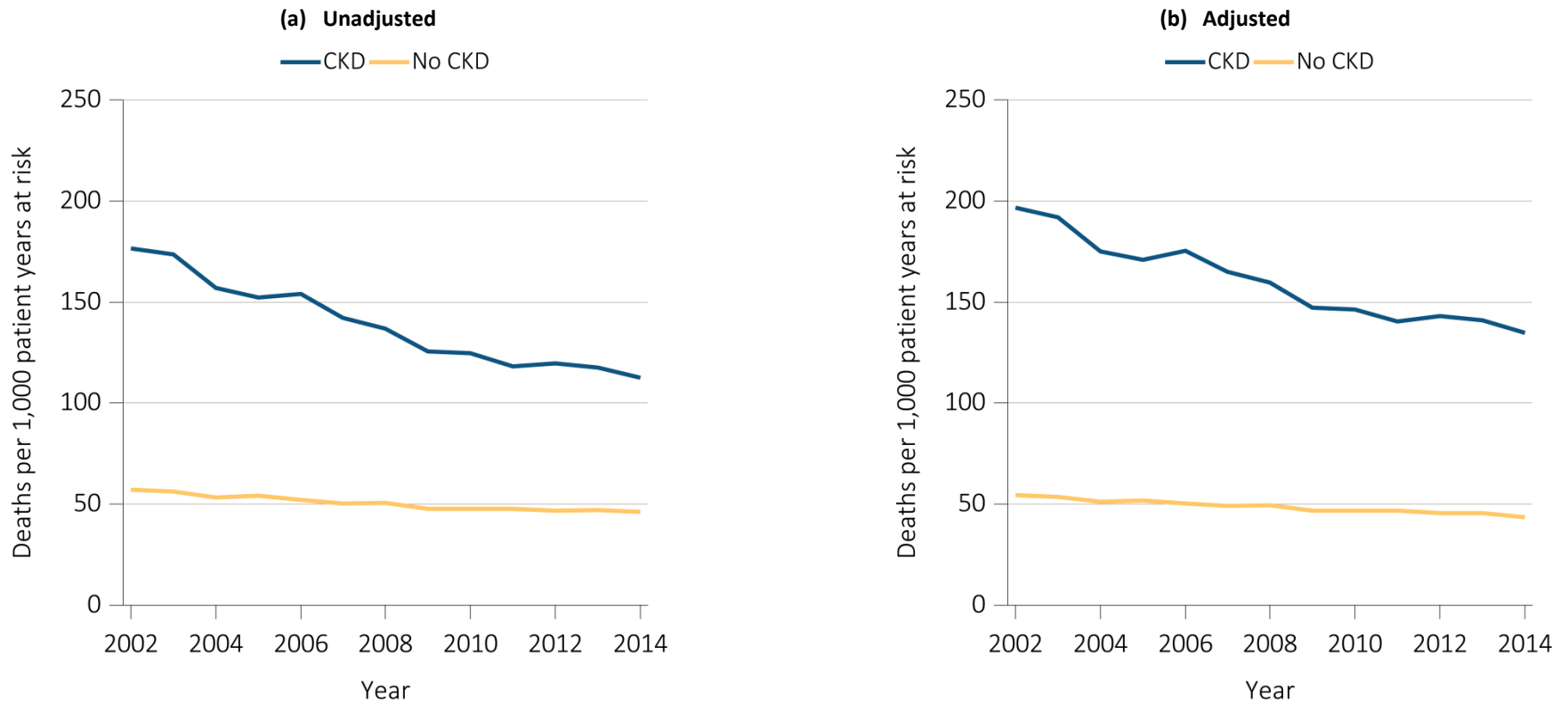
Data source: Medicare 5% sample. January 1, 2014 point prevalent patients aged 66 and older. Adjusted for age/sex/race. Reference population all patients, 2014. Abbreviation: CKD, chronic kidney disease.

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 31.5% since 2002, from 197 deaths per 1,000 patient years to 135 deaths in 2014. For those without CKD, the unadjusted rate decreased from 55 deaths per 1,000 patient years in 2002 to 44 deaths in 2014, a reduction of 20.0%.

When adjusted for age, race, and sex, the 2014 mortality rate for CKD patients reduced considerably, to 113 deaths per 1,000 patient years at risk

(Reference population: 2013). Among those without CKD, adjustment for these factors resulted in a slightly higher mortality rate of 47 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 with the CKD and no-CKD cohorts. In 2014, the mean age of patients with CKD was 76.4 years, compared to 70.1 years for those without, and 71.5 years for the sample as a whole.

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, 2002-2014

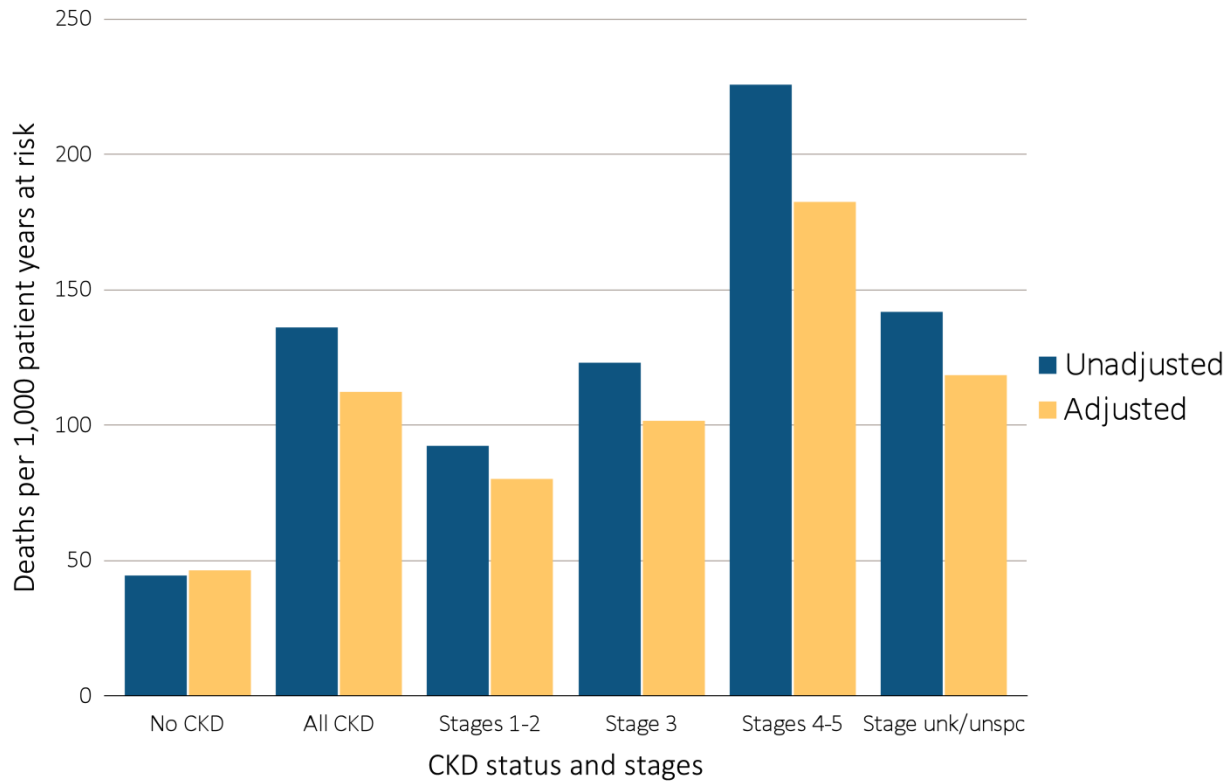


Data source: Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race. Reference population 2013 patients. Abbreviation: CKD, chronic kidney disease.

As expected, unadjusted mortality rates increased with progressing stage of CKD, as shown in Figure 3.2. These rose progressively, from 92 deaths per 1,000 patient years for those in Stages 1 and 2, to 122 for Stage 3, and 225 for Stages 4 and 5 (without ESRD; stages identified by the ICD-9-CM codes, see Table A). Those without an identified CKD stage or with a diagnosis other than from the 585 code series had an

unadjusted mortality rate falling between that of Stage 3 and Stages 4-5, at 141 deaths per 1,000 patient years at risk. After adjustment, death rates for Stages 1-2 and Stage 3 were 79 and 101 deaths per 1,000 patient years. The adjusted rate for Stages 4-5 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, 2014



Data source: Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race. Reference population all patients, 2014. See Table A for CKD stage definitions. Abbreviations: CKD, chronic kidney disease; unk/unspc, CKD stage unidentified.

Table A. 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, 403.9xm & others

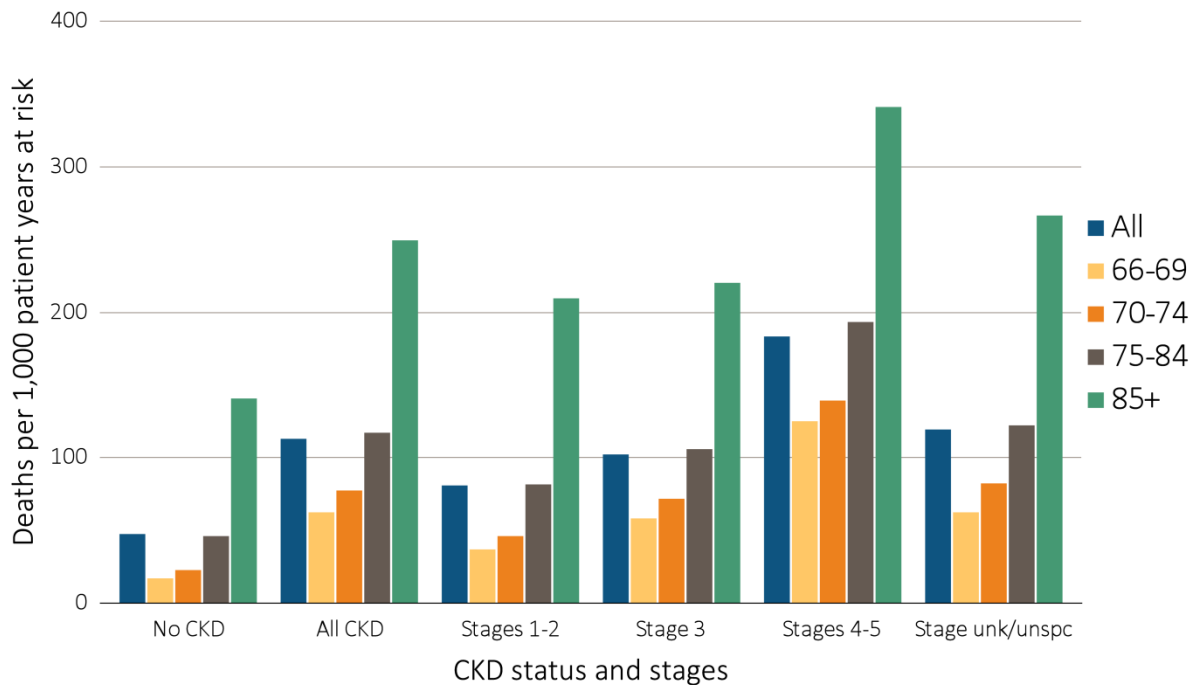
^a For analyses in this chapter, CKD stage estimates require at least one occurrence of a stage-specific code, and the last available CKD stage in a given year is used.

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

Adjusted mortality rates for 2014 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 61 deaths per 1,000 patient years at

risk, while those aged 75-84 had nearly double that, at 115 deaths. As also might be expected, patients aged 85 and older experienced the highest rates of mortality, with 248 deaths per 1,000 patient years.

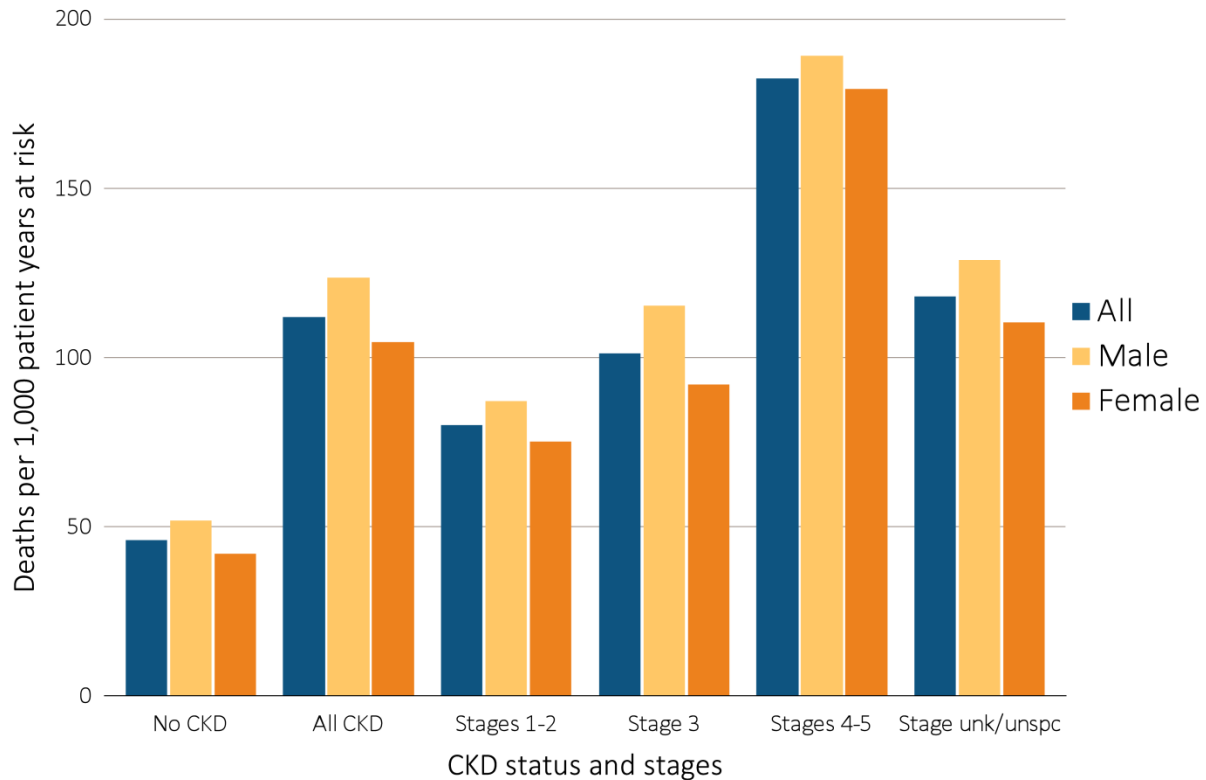
vol 1 Figure 3.3 Adjusted all-cause mortality rates (per 1,000 patient years at risk) for Medicare patients aged 66 and older, by age, CKD status, and stage, 2014



Data source: Medicare 5% sample. January 1, 2014 point prevalent patients aged 66 and older. Adjusted for age/sex/race. Reference population all patients, 2014. Abbreviations: CKD, chronic kidney disease; unk/unspc, CKD stage unidentified.

A comparison of adjusted 2014 mortality rates by sex is shown in Figure 3.4. The rates for males were higher than for females in all stages.

vol 1 Figure 3.4 Adjusted all-cause mortality rates (per 1,000 patient years at risk) for Medicare patients aged 66 and older, by sex, CKD status, and stage, 2014

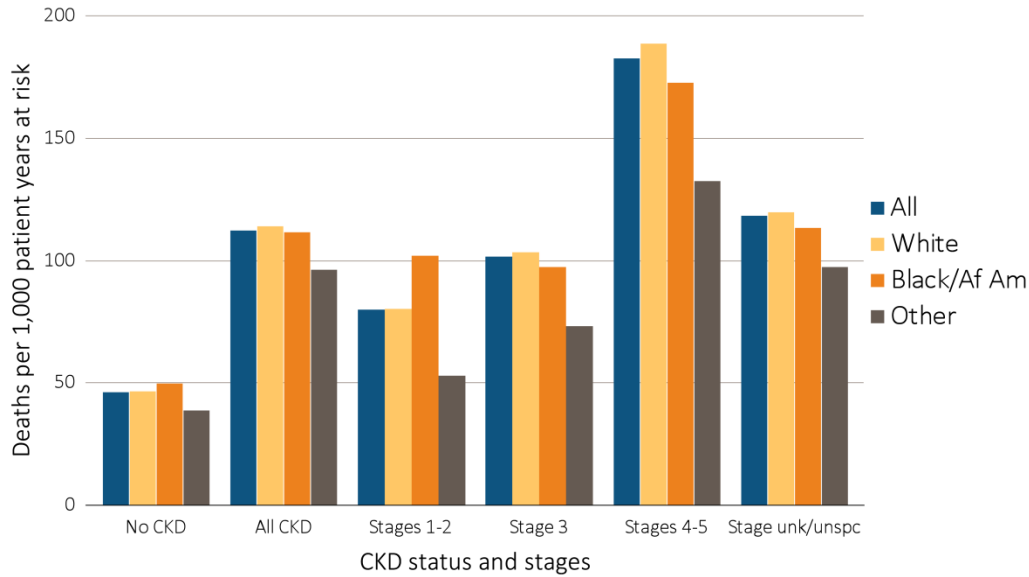


Data source: Medicare 5% sample. January 1, 2014 point prevalent patients aged 66 and older. Adjusted for age/sex/race. Reference population all patients, 2014. Abbreviations: CKD, chronic kidney disease; unk/unspc, CKD stage unidentified.

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. Black rates were lower than Whites in all stages except for 1-2; the mortality rates for Whites were higher than Blacks in Stages 3,

and 4-5. For Whites the adjusted rates were 80 per 1,000 patient years at risk for Stages 1-2, with 103 per 1,000, and 188 per 1,000 for Stages 3 and 4-5, respectively. The Black patient groups showed adjusted rates of 101 deaths per 1,000 patient years at risk in Stages 1-2, with 97 per 1,000 and 172 per 1,000 in Stages 3 and 4-5.

vol 1 Figure 3.5 Adjusted all-cause mortality rates (per 1,000 patient years at risk) for Medicare patients aged 66 and older, by race, CKD status, and stage, 2014

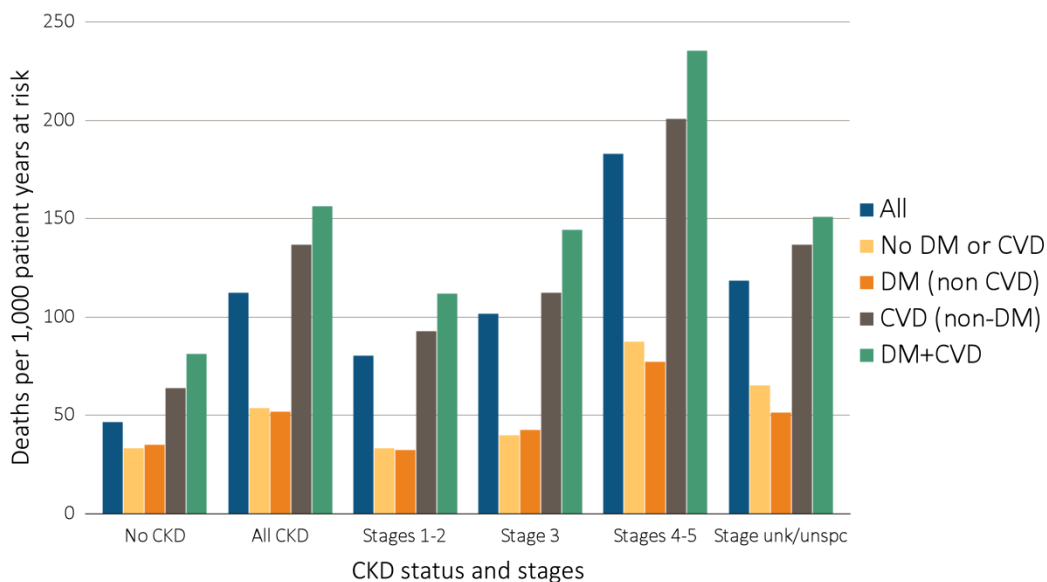


Data source: Medicare 5% sample. January 1, 2014 point prevalent patients aged 66 and older. Adjusted for age/sex/race. Reference population all patients, 2014. Abbreviations: Af Am, African American; CKD, chronic kidney disease; unk/unspc, CKD stage unidentified.

Adjusted rates of mortality were observed to increase 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 of these patients. In 2014, those with CKD but without DM or CVD had an adjusted

mortality rate of 53 deaths per 1,000 patient years at risk, while those with both DM and CVD experienced triple that rate, at 156 deaths per 1,000 patient years. Diabetes alone, however, did not increase mortality risk among persons with CKD (52 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, 2014



Data source: Medicare 5% sample. January 1, 2014 point prevalent patients aged 66 and older. Adjusted for age/sex/race. Reference population all patients, 2014. Abbreviations: CKD, chronic kidney disease; CVD, cardiovascular disease; DM, diabetes mellitus; unk/unspc, CKD stage unidentified.

Hospitalization Rates

Table 3.2 shows all-cause hospitalization rates in 2014 for older Medicare patients, by whether they had recognized CKD during 2013. The unadjusted rate for those with CKD was 617 hospitalizations per 1,000 patient years at risk, compared to a much lower rate of 230 for patients without CKD. Encouragingly, these 2014 admission rates for CKD patients showed a reduction from the unadjusted 2013 levels of 656 per 1,000 for those with CKD and 245 per 1,000 with no-CKD. Across all demographic characteristics, the 2014 unadjusted hospitalization rate for patients with CKD

was two to three times the corresponding rate for patients without CKD. Once adjustment was made for age, race, and sex, the hospitalization rate for patients with CKD of 586 per 1,000 patient years at risk was 150.4% greater than for those without CKD, at 234 per 1,000. As with mortality, the adjusted hospitalization rate increased with age for all patients. In contrast to the mortality findings, however, women with CKD had higher adjusted hospitalization rates of 598 per 1,000 patient years at risk than did men, at 578 per 1,000, whereas women without CKD had lower adjusted hospitalization rates of 232 per 1000 than did men at 237.

vol 1 Table 3.2 Unadjusted and adjusted all-cause hospitalization rates (per 1,000 patient years at risk) for Medicare patients aged 66 and older, by CKD status, 2014

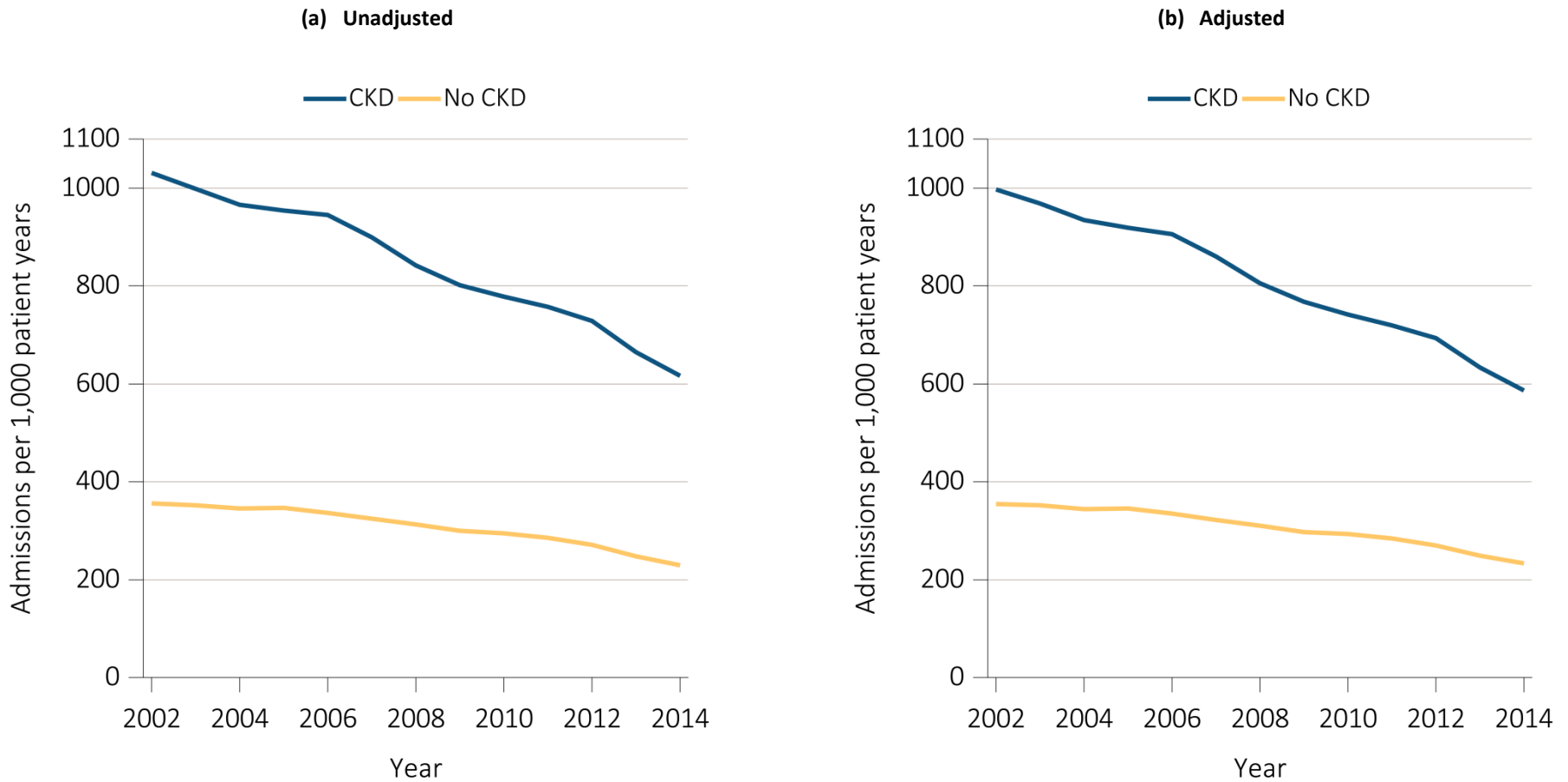
	Unadjusted		Adjusted	
	No CKD	All CKD	No CKD	All CKD
All	229.3	616.3	233.1	586.0
Age				
66–69	141.5	514.8	142.1	511.5
70–74	181.1	540.3	180.8	541.4
75–84	262.5	615.1	262.4	613.1
85+	404.8	732.6	408.1	735.2
Sex				
Male	221.2	603.3	236.4	577.3
Female	235.2	628.1	231.4	597.3
Race				
White	231.6	611.1	234.1	582.1
Black/African American	246.3	700.0	258.3	686.8
Other	174.3	541.3	186.7	512.5

Data source: Medicare 5% sample. January 1, 2014 point prevalent Medicare patients, aged 66 and older. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Reference population all patients, 2014. Abbreviations: CKD, chronic kidney disease.

Figure 3.7 presents the trends in hospitalization rates for Medicare patients over the past 13 years. The overall trends between adjusted and unadjusted rates, CKD and no-CKD, 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

notable decrease in hospitalization rates occurred from 2013 to 2014; even after adjustment the CKD group decreased by 17.6%, from 634 to 586 per 1,000 patient years at risk for the CKD group, and by 5.6%, from 248 to 234 per 1,000 for the no-CKD group.

vol 1 Figure 3.7 Unadjusted and adjusted all-cause hospitalization rates (per 1,000 patient years at risk) for Medicare patients aged 66 and older, by CKD status and year, 2002-2014

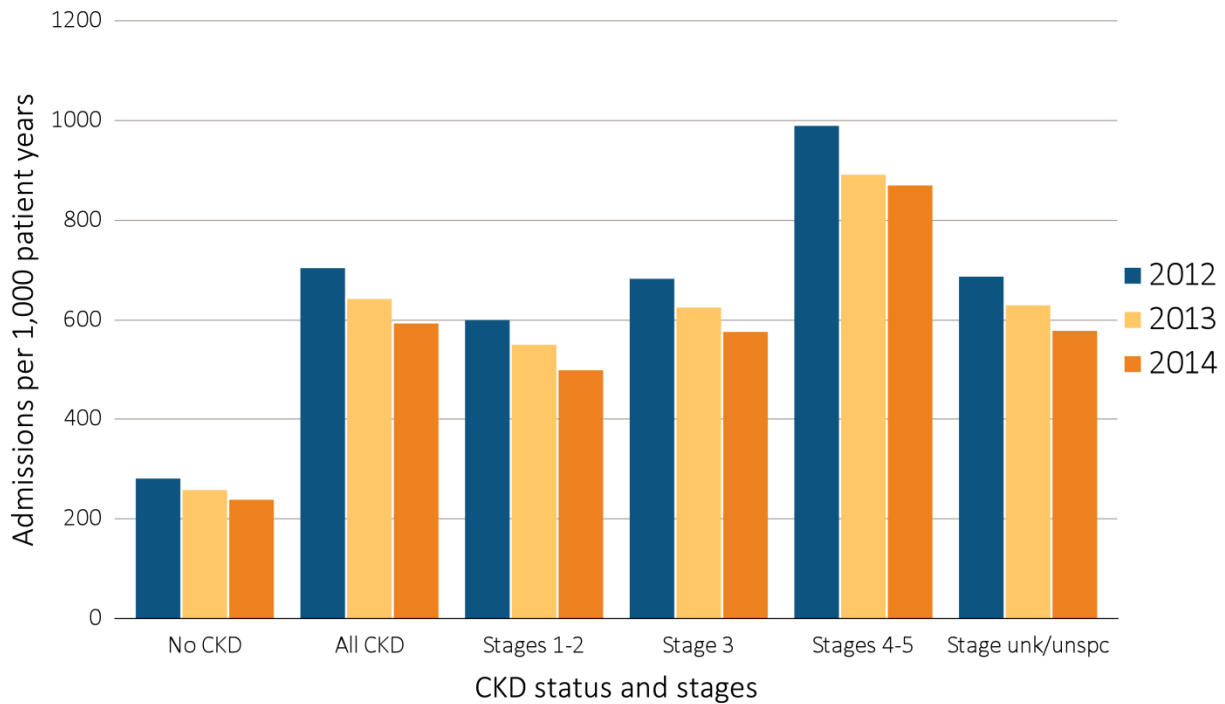


Data source: Medicare 5% sample. January 1 of each reported year point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race. Reference population 2014 patients. Abbreviations: CKD, chronic kidney disease.

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 hospitalization rates resulting from CVD (23.0% of all-cause admissions), infection (20.9%), and all other cause categories (56.1%). As the covariates in the adjusted model no longer include comorbidities and prior year hospitalizations, the adjusted rates may vary noticeably from results presented prior to the 2014 ADR.

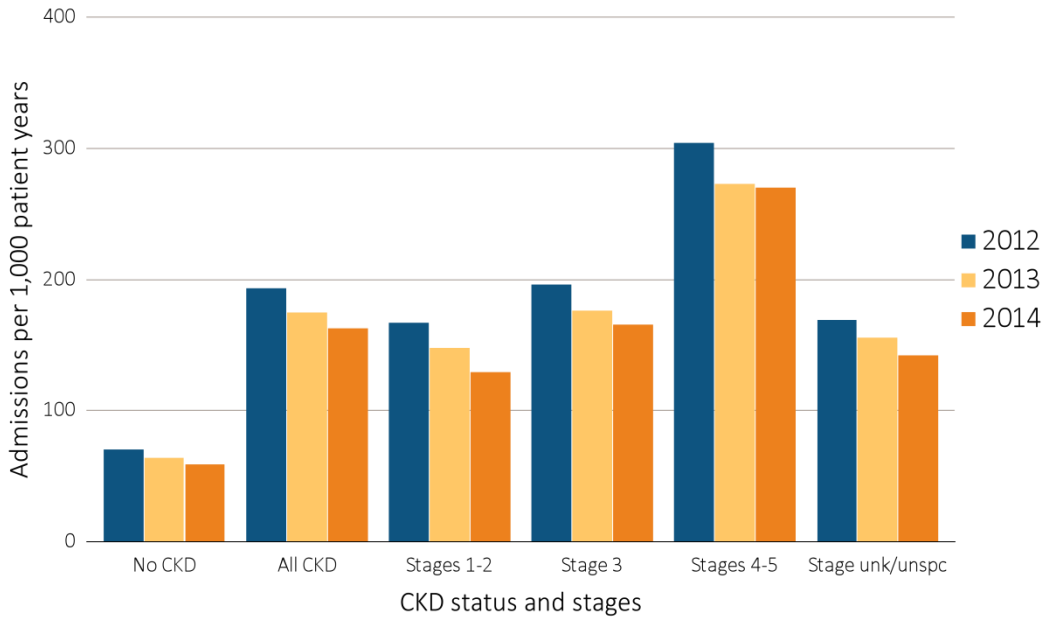
Rates of all-cause hospitalizations in 2014 increased with disease severity, from 492 admissions per 1,000 patient years for those in Stages 1 and 2, to 569 for Stage 3, and 864 for Stages 4 and 5; these were uniformly lower than those that occurred in 2012 and 2013 (see Figure 3.8). The pattern of increase for hospitalizations resulting from a primary diagnosis of CVD was similar, with rates rising from 128 admissions per 1,000 patient years for CKD Stages 1 and 2, to 164 for Stage 3, and 268 for Stages 4 and 5 (see Figure 3.9).

vol 1 Figure 3.8 Adjusted all-cause hospitalization rates (per 1,000 patient years at risk) for Medicare patients aged 66 and older, by CKD status and stage, 2012-2014



Data source: Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race. Reference population all patients, 2014. See Table A for CKD stage definitions. 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 patients aged 66 and older, by CKD status and stage, 2012-2014

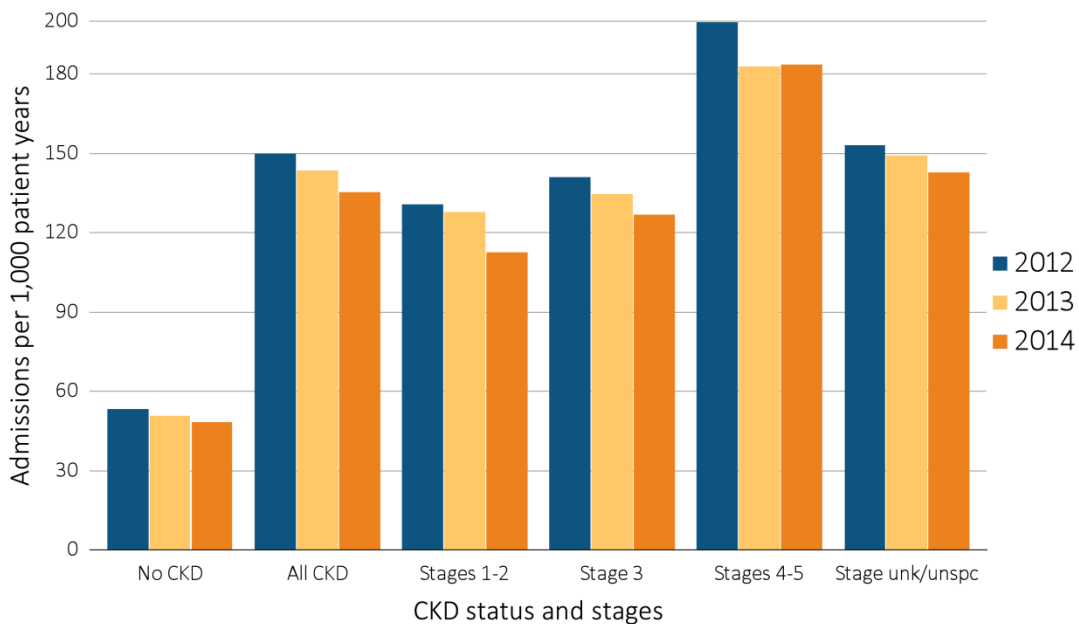


Data source: Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Reference population all patients, 2014. See Table A for CKD stage definitions. Abbreviations: CKD, chronic 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

across all areas decreased from 2012 to 2014, with a small exception for Stages 4 to 5 in 2013 to 2014.

vol 1 Figure 3.10 Adjusted rates of hospitalization for infection (per 1,000 patient years at risk) for Medicare patients aged 66 and older, by CKD status and stage, 2012-2014

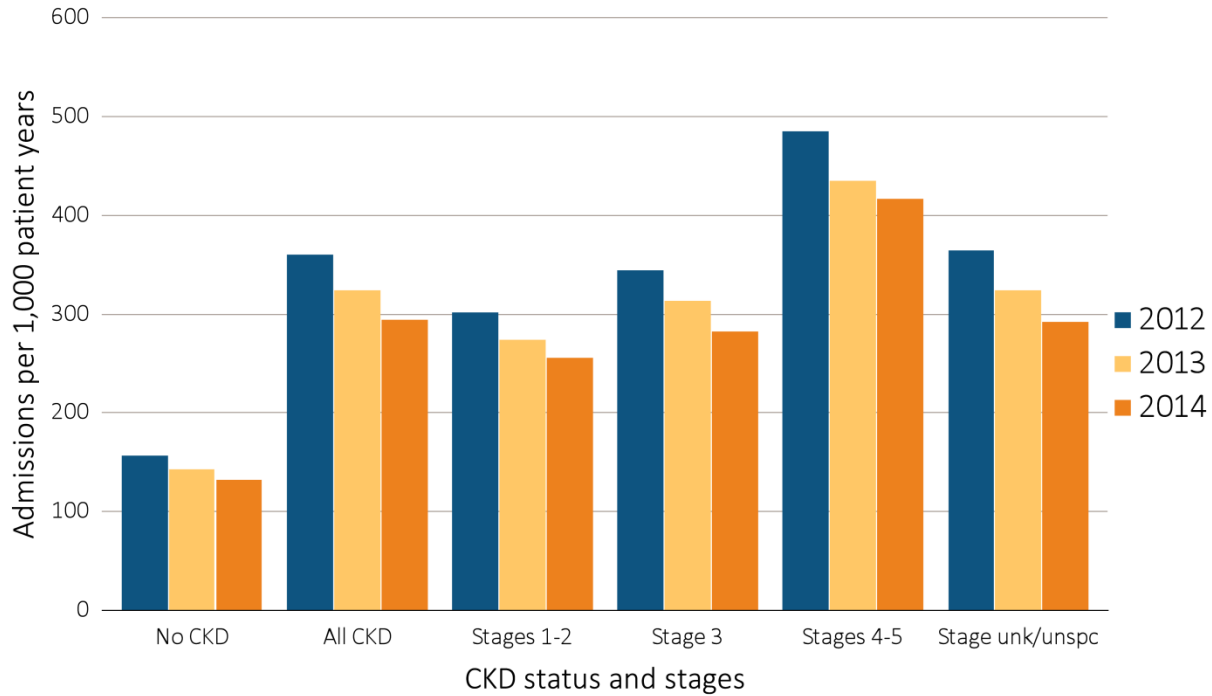


Data source: Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Reference population all patients, 2014. See Table A for CKD stage definitions. Abbreviations: CKD, chronic 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 rates steadily decreasing from 2012 to 2014.

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 patients aged 66 and older, by CKD status and stage, 2012-2014

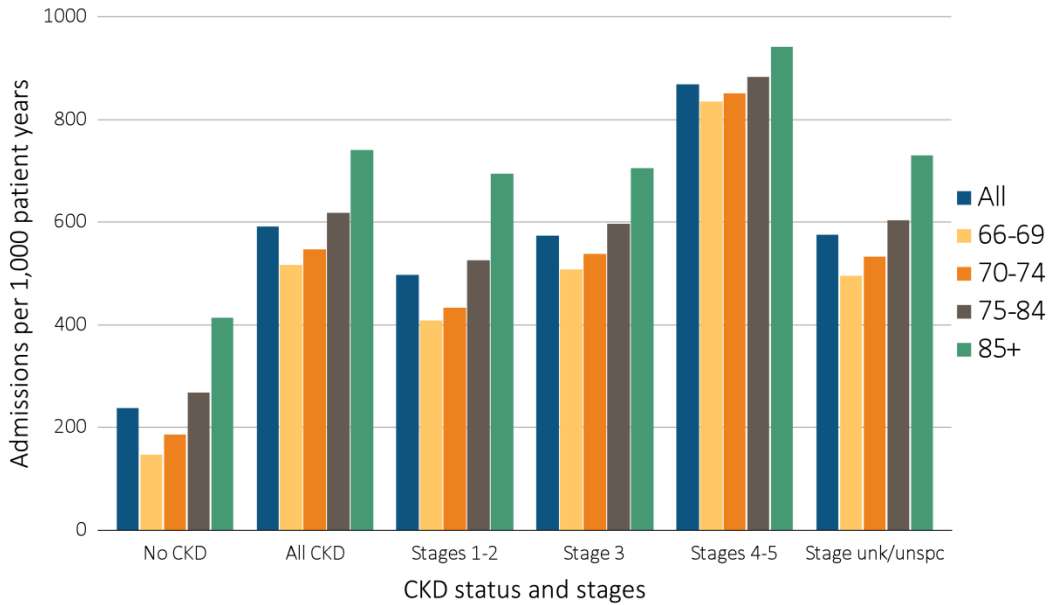


Data source: Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Reference population all patients, 2014. See Table A for CKD stage definitions. Abbreviations: CKD, chronic 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 patients exhibit higher rates of hospitalization than did the younger age cohorts.

vol 1 Figure 3.12 Adjusted all-cause hospitalization rates (per 1,000 patient years at risk) for Medicare patients aged 66 and older, by age, CKD status, and stage, 2014

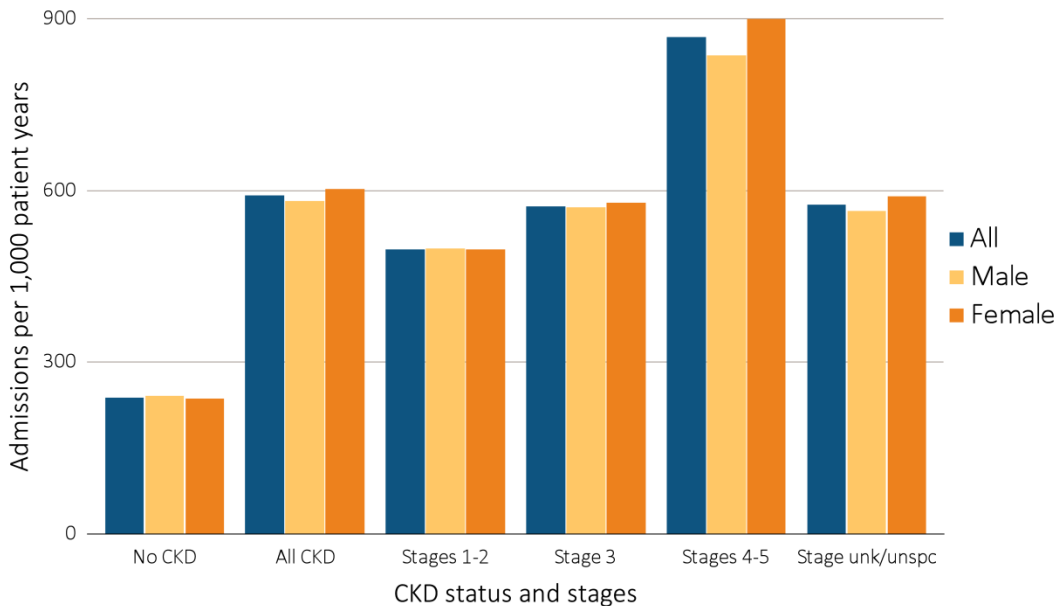


Data source: Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Reference population all patients, 2014. See Table A for CKD stage definitions. Abbreviations: CKD, chronic kidney disease; unk/unspc, CKD stage unidentified.

A comparison of adjusted 2014 all-cause hospitalization rates by CKD group and sex is shown

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

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, 2014

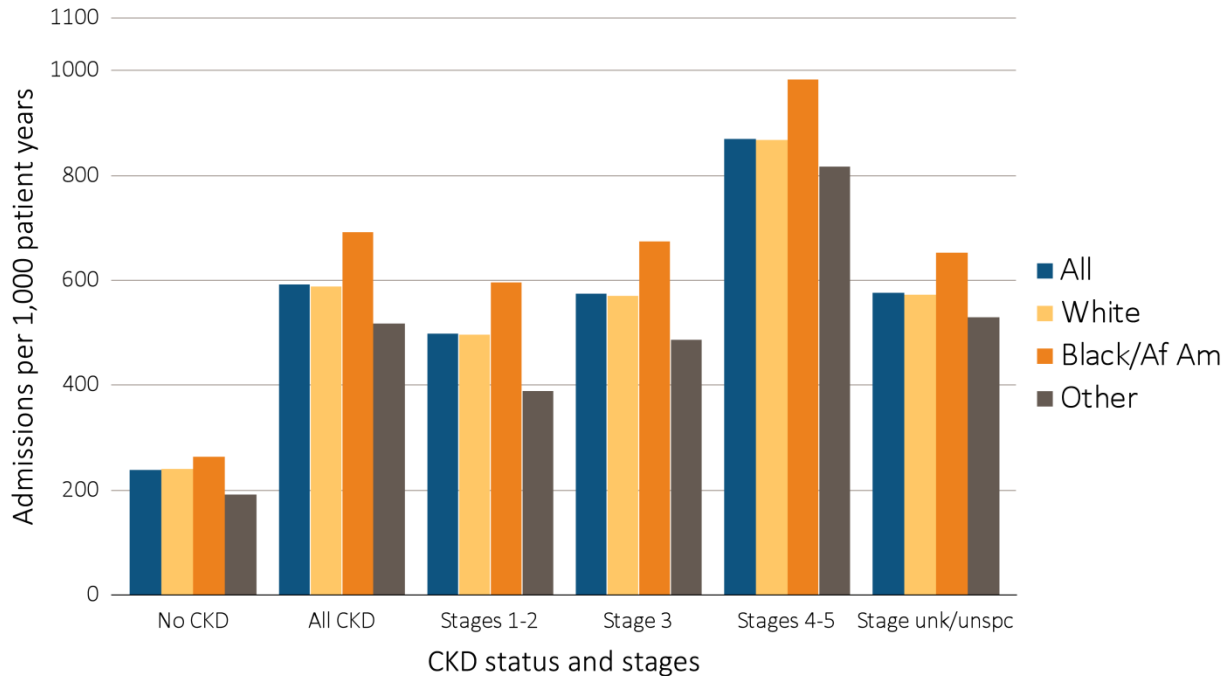


Data source: Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Reference population all patients, 2014. See Table A for CKD stage definitions. Abbreviations: CKD, chronic kidney disease; unk/unspc, CKD stage unidentified.

Racial differences in hospitalization were notable. In both the no-CKD and CKD populations, Black patients were hospitalized more frequently than those of other races. In 2014, Black patients in the CKD group showed higher rates than did Whites or those of other races (687 per 1,000 patient years vs. 583 and 513, respectively; Figure 3.14). This disparity decreased

with disease severity, with rates for Black patients 20.1% higher than Whites in Stages 1-2 (591 vs 492), 18.4% higher in Stage 3 (669 vs 565) and 13.4% higher in Stages 4-5 (976 vs 861). Patients of other races experienced the lowest rates of hospitalization in all disease stages.

vol 1 Figure 3.14 Adjusted all-cause hospitalization rates (per 1,000 patient years at risk) for Medicare patients aged 66 and older, by race, CKD status, and stage, 2014

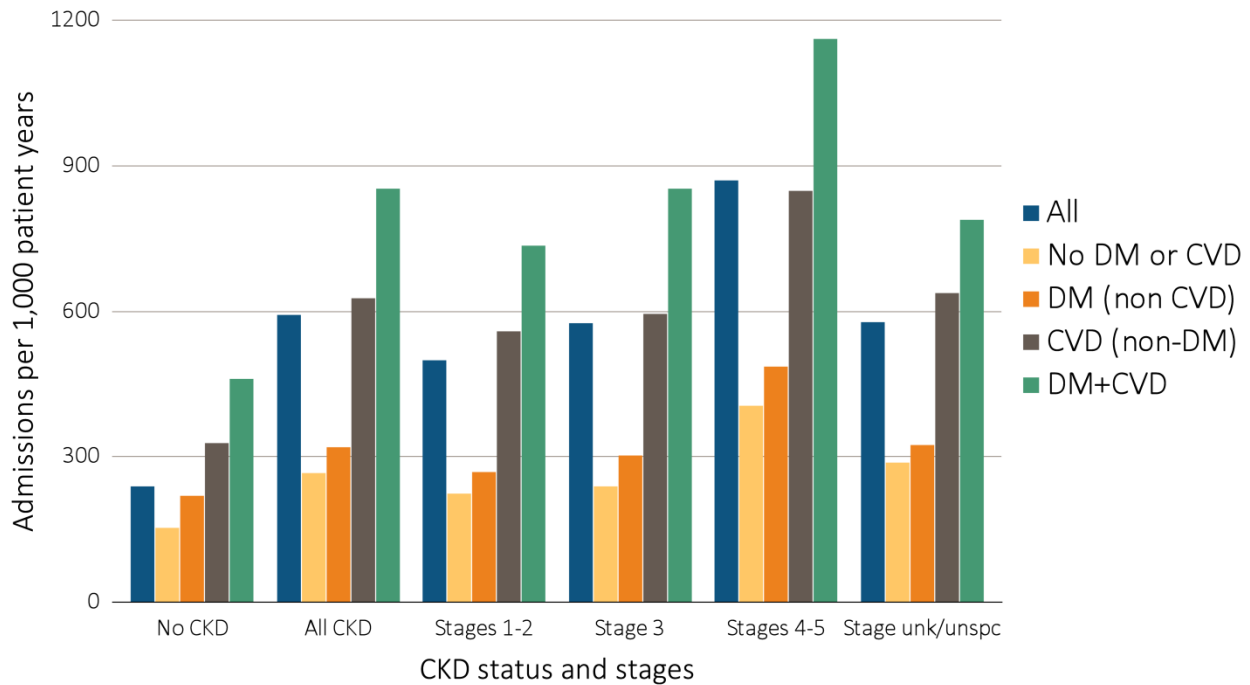


Data source: Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Reference population all patients, 2014. See Table A for CKD stage definitions. Abbreviations: Af Am, African American; CKD, chronic kidney disease; unk/unspsc, CKD stage unidentified.

Adjusted rates of all-cause hospitalization increased in the presence of DM and CVD for 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 no DM or CVD, 215 per 1,000 for patients with DM only, 323 per 1,000 for those with CVD only, and 455 per 1,000 for patients with both DM and CVD. In 2014, admissions per 1,000 patient years increased from 260 for CKD

patients without DM or CVD, to 314 for those with only DM and 621 with only CVD, to a high of 846 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 1,156 admissions per 1,000 patient years, compared to only 398 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, 2014



Data source: Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 and older. Adjusted for age/sex/race; rates by one factor are adjusted for the others. Reference population all patients, 2014. See Table A for CKD stage definitions. Abbreviations: CKD, chronic kidney disease; CVD, cardiovascular disease; DM, diabetes mellitus; unk/unspc, CKD stage unidentified.

Rehospitalization

Reducing the rate of patient readmission to a hospital 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 2014 Medicare population among those with and without recognized CKD, by CKD stage, 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 15.3% for those without CKD and 21.4% for those with CKD (see Table 3.3). These rates represent a slight decrease from 2013 levels. Rehospitalization rates increased slightly with stage of CKD, from 20.3% in Stages 1-2 to 22.9% in Stages 4-5.

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, 2014

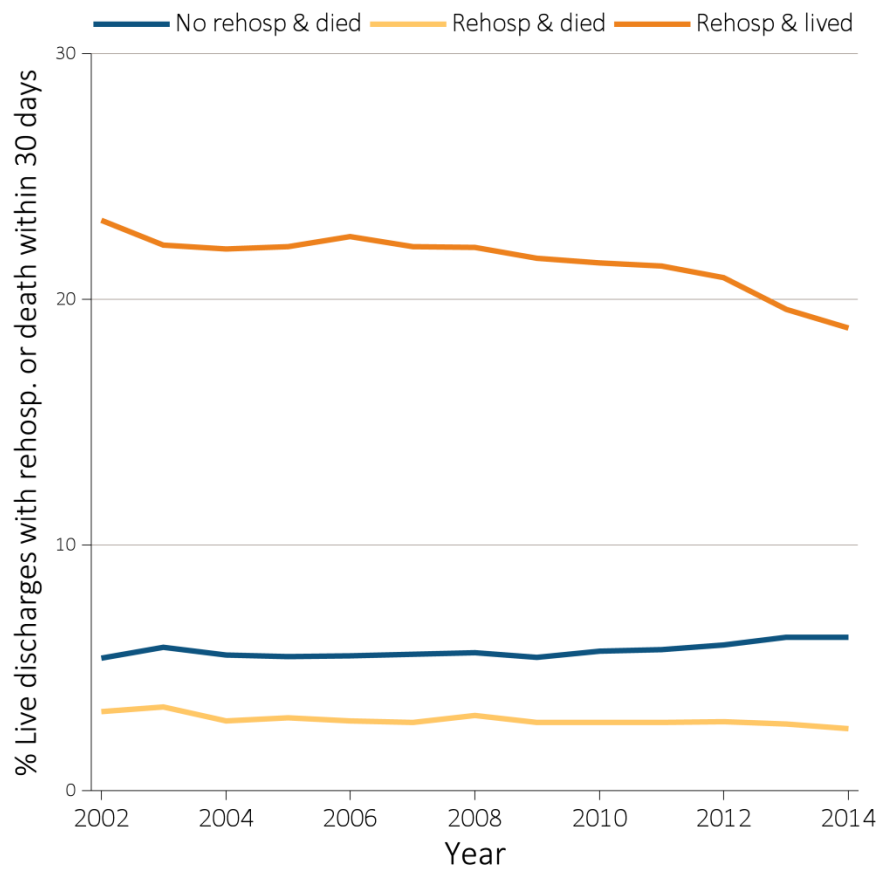
	No CKD (%)	All CKD (%)	Stages 1-2 (%)	Stage 3 (%)	Stages 4-5 (%)	Stage Unknown /unspecified (%)
All	15.3	21.4	20.3	21.4	22.9	20.9
Age						
66-69	14.8	23.4	24.7	23.1	23.8	23.3
70-74	15.0	22.1	19.5	22.4	25.2	21.4
75-84	15.8	21.6	20.8	21.8	23.2	21.0
85+	15.3	19.8	17.8	19.8	21.4	19.6
Sex						
Male	16.4	21.7	22.0	21.7	22.7	21.5
Female	14.7	21.0	18.8	21.2	23.1	20.5
Race						
White	15.2	20.8	19.6	20.9	22.0	20.6
Black/African American	17.7	24.6	24.4	25.1	26.7	22.7
Other	14.8	22.4	20.5	21.7	26.0	22.6
Rehospitalization						
No rehospitalization & died	4.5	6.3	4.8	6.1	7.6	6.4
Rehospitalization & died	1.6	2.5	1.9	2.4	3.2	2.6
Rehospitalization & lived	13.7	18.8	18.4	19.0	19.7	18.4

Data source: Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 and older, discharged alive from an all-cause index hospitalization between January 1, 2014, and December 1, 2014; unadjusted. See Table A for CKD stage definitions. Abbreviations: CKD, chronic kidney disease.

The trend for adjusted readmissions from 2002-2014 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 22.6% in 2006 to 18.8% in 2014, a decrease of

3.7% over the 13-year period. While any reductions are encouraging, the proportion of patients who were rehospitalized and subsequently died within 30 days of the initial discharge has not changed significantly—reducing by only 0.8% from 2013 levels. Of note, the rate of patients who were not rehospitalized but died within 30 days of the initial discharge has increased somewhat, by 0.9% since 2009.

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, 2002-2014

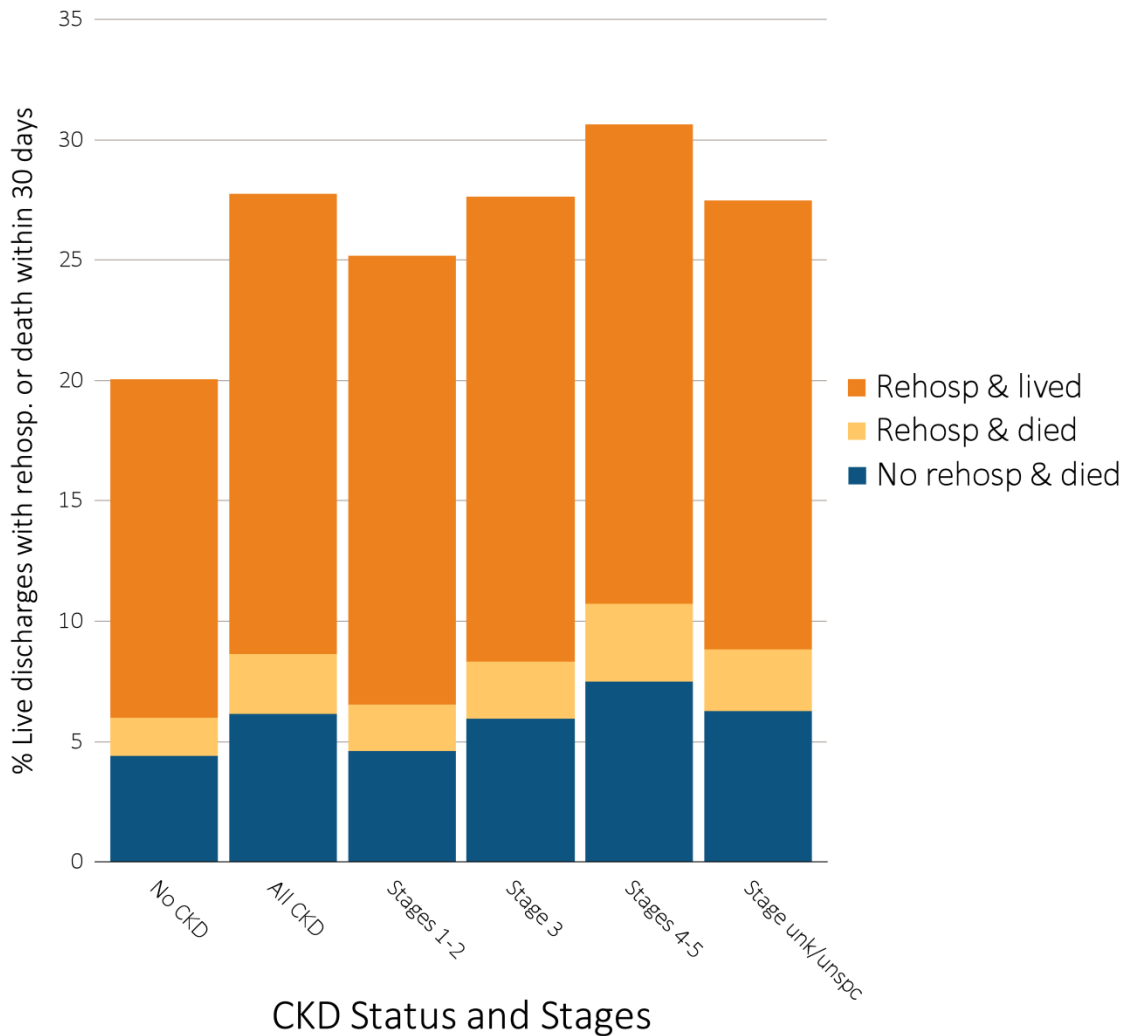


Data source: Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older with CKD (defined during the prior year), discharged alive from an all-cause index hospitalization between January 1 and December 1 of the reported year. Adjusted for age/sex/race. Reference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

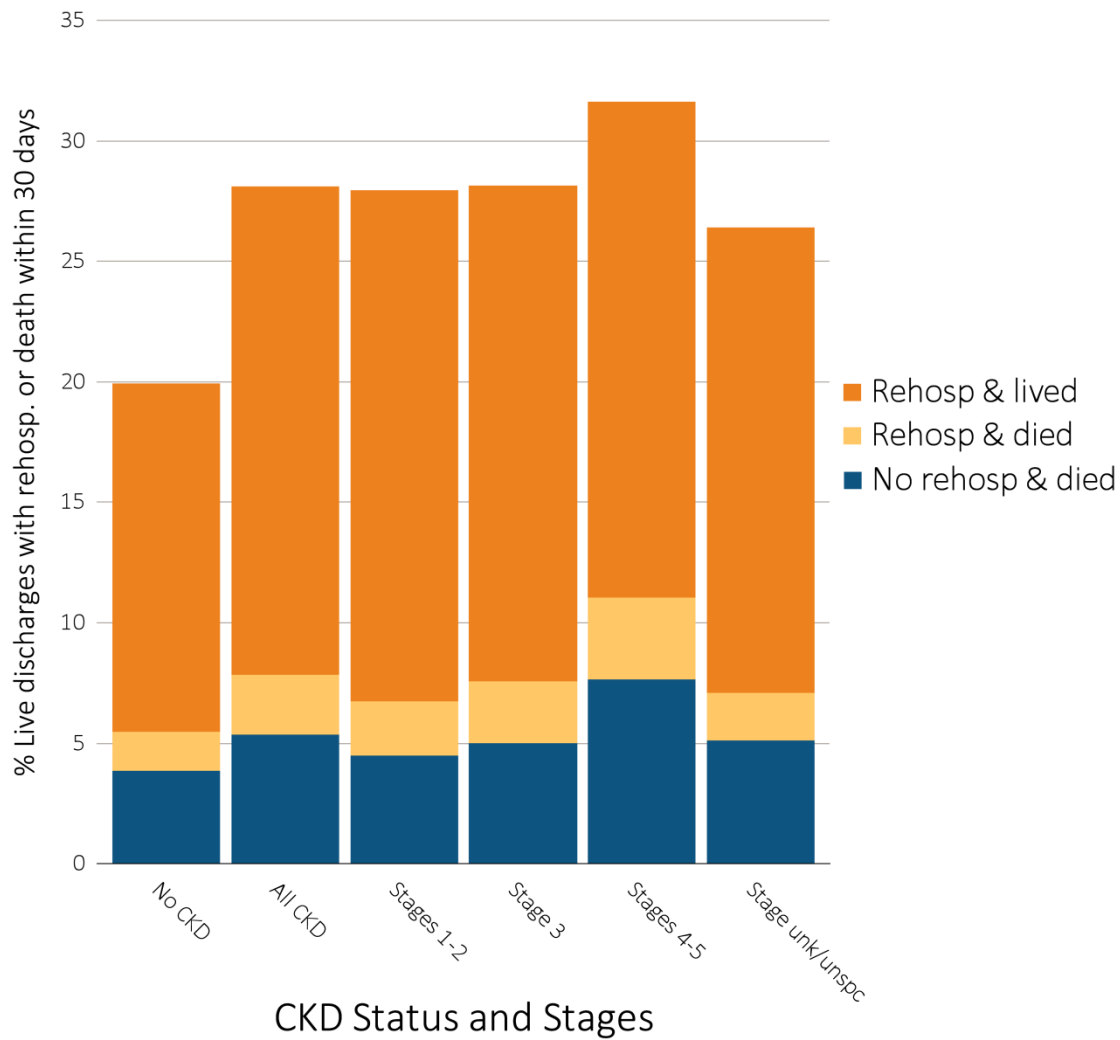


Data source: Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 and older, discharged alive from an all-cause index hospitalization between January 1, 2014, and December 1, 2014, unadjusted. Abbreviations: CKD, chronic kidney disease; Rehosp, rehospitalized; unk/unspc, CKD stage unidentified.

Figure 3.18 shows the death and rehospitalization percentages for older Medicare patients who were discharged alive from a CVD index hospitalization; 20.0% of patients with CKD and 14.2% 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, 2014

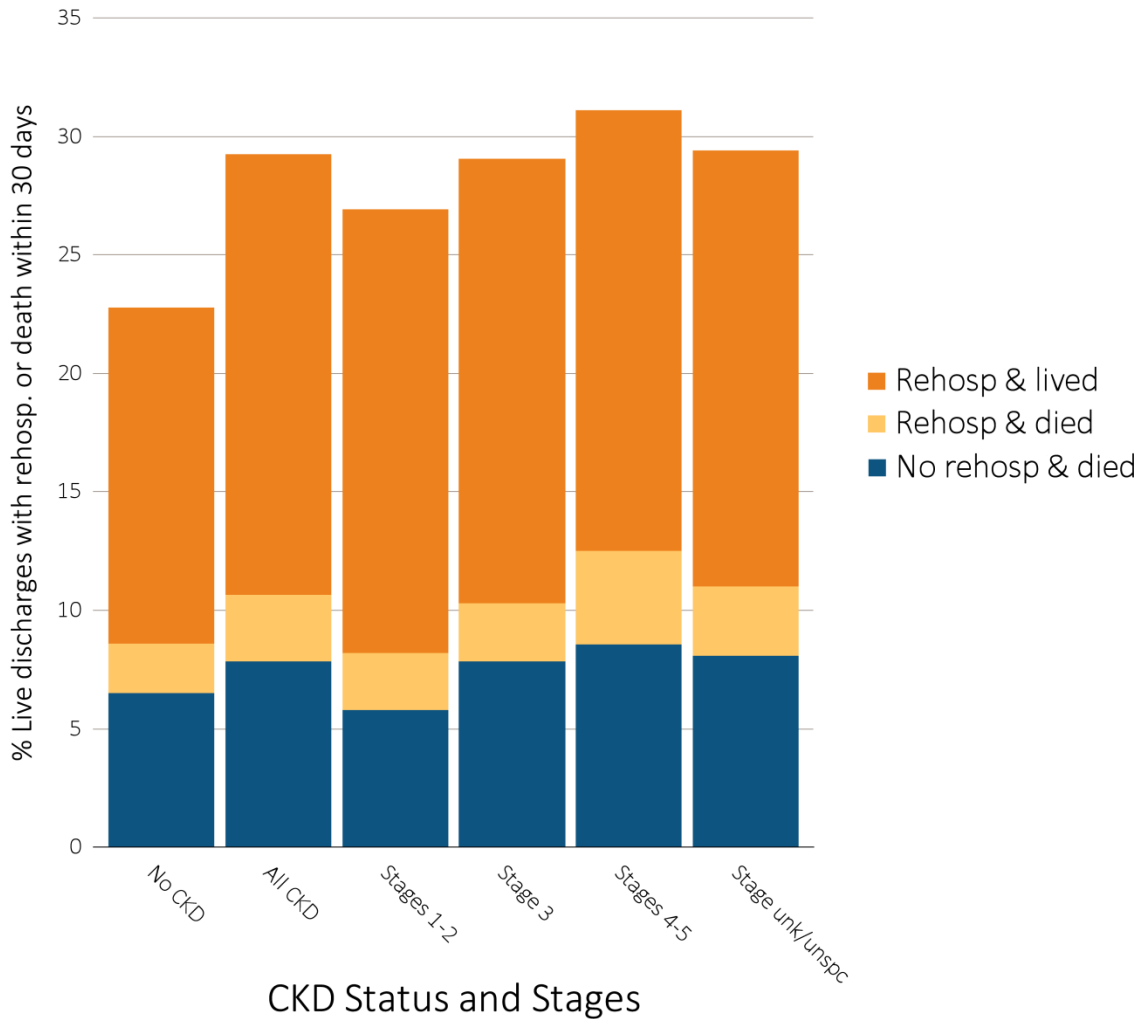


Data source: Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 and older, discharged alive from an all-cause index hospitalization between January 1, 2014, and December 1, 2014; unadjusted. Abbreviations: CKD, chronic kidney disease; Rehosp, rehospitalized; unk/unspc, CKD stage unidentified.

Of all patients without CKD who experienced an infection-related admission, 13.9% required rehospitalization (see Figure 3.19). Of these patients, 2.1% died following rehospitalization, and 6.6% of patients were not rehospitalized and later died. In the

CKD group, 18.3% of patients were subsequently rehospitalized and lived within 30 days of the initial discharge, and an additional 2.8% died following rehospitalization; 8.0% of patients were not rehospitalized, and 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, 2014

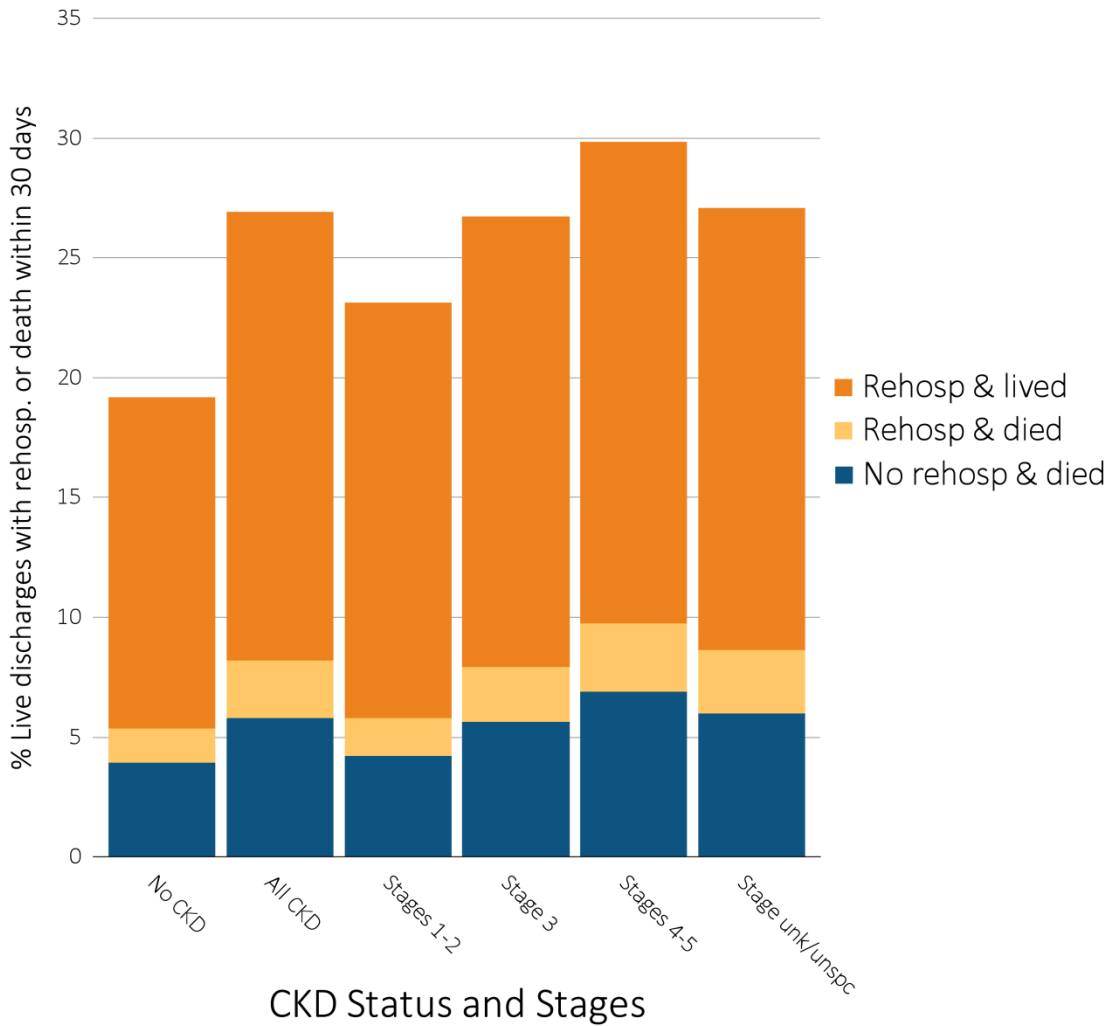


Data source: Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 and older, discharged alive from an all-cause index hospitalization between January 1, 2014, and December 1, 2014, unadjusted. Abbreviations: CKD, chronic kidney disease; Rehosped, rehospitalized; unk/unspc, CKD stage unidentified.

Figure 3.20 shows the death and rehospitalization percentages for Medicare patients aged 66 and older who were discharged alive from index hospitalization for all causes other than CVD and infection. The patterns of these percentages were similar to those for all-cause index hospitalizations. For the CKD group,

patients who were not rehospitalized but died, rehospitalized and died, or rehospitalized and lived were 5.9%, 2.4%, and 18.4%. In the no-CKD group, these percentages were somewhat lower at 4.1%, 1.4%, and 13.5%.

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, 2014

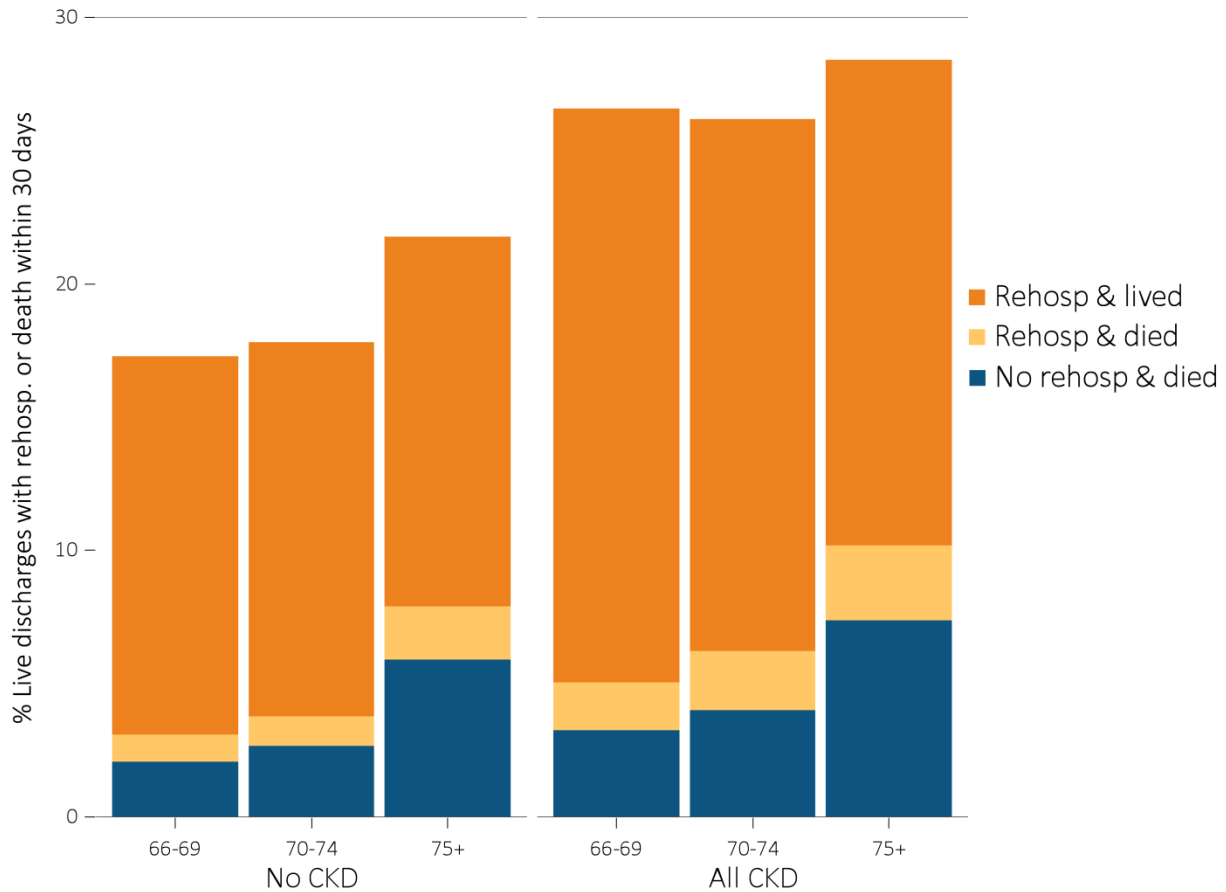


Data Source: Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 and older, discharged alive from an all-cause index hospitalization between January 1, 2014, and December 1, 2014; unadjusted. Abbreviations: CKD, chronic kidney disease; Rehosp, rehospitalized; unk/unspc, CKD stage unidentified.

Figure 3.21 illustrates a comparison by age group of the percentages of Medicare patients who were re-hospitalized or died within 30 days of discharge from an all-cause, index hospitalization, among those with CKD and those without. Rates of rehospitalization with survival in patients with CKD decreased with age across all stages of CKD in the Medicare population.

These findings were likely influenced by the competing risk of death in older age groups. 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, 2014

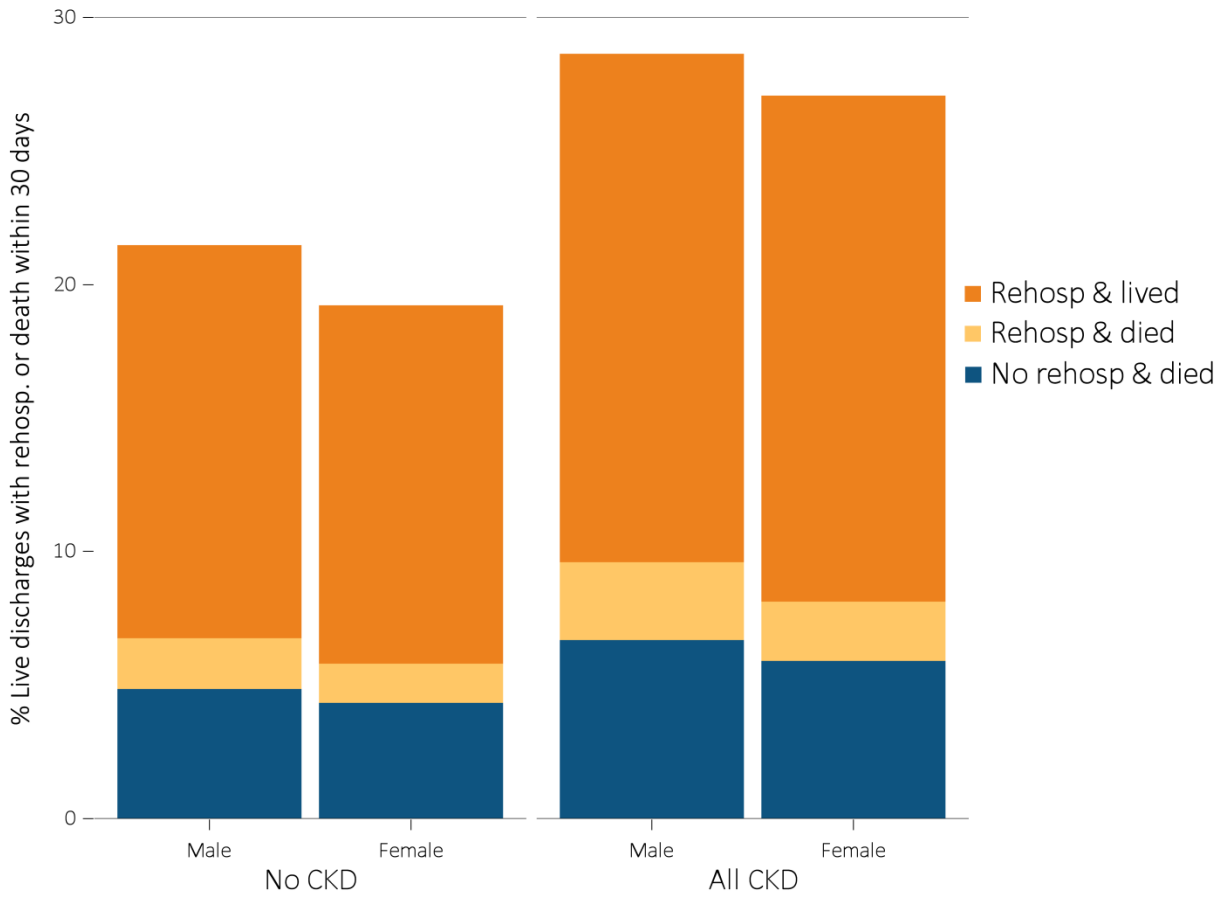


Data source: Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 and older, discharged alive from an all-cause index hospitalization between January 1, 2014, and December 1, 2014; unadjusted. Abbreviations: CKD, chronic kidney disease; Rehospi, rehospitalized.

Figure 3.22 compares the rates of all-cause hospitalization rates by sex. Male patients exhibited higher rates than did females in all outcome categories. Specifically, 6.8% of males 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 categories showed 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, 2014

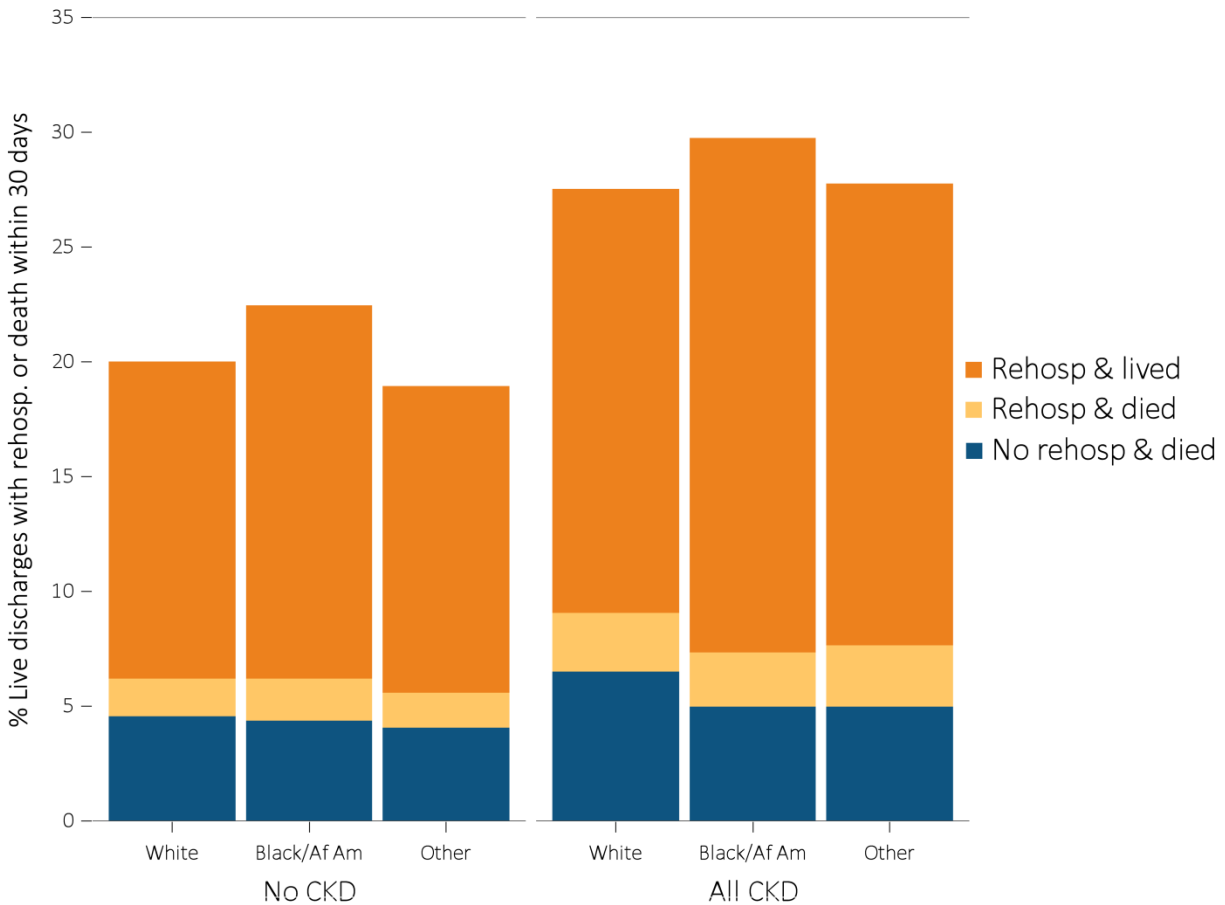


Data source: Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 and older, discharged alive from an all-cause index hospitalization between January 1, 2014, and December 1, 2014; unadjusted. Abbreviations: CKD, chronic kidney disease; Rehosp, rehospitalized.

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 (16.0%) than did both Whites (13.6%) and patients of other races (13.1%). For patients with CKD, Blacks survived

rehospitalization at 22.1%, Whites at 18.2%, and those of other races at 19.8%. Whites with or without CKD experienced the highest rates of death without rehospitalization (4.7% for no-CKD, 6.6% with CKD); more CKD patients of other races were observed to have died following their rehospitalization (2.7%).

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, 2014



Data Source: Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 and older, discharged alive from an all-cause index hospitalization between January 1, 2014, and December 1, 2014; unadjusted. Abbreviations: Af Am, African American; CKD, chronic kidney disease; Rehosp, rehospitalized.

This chapter focused on mortality and morbidity in Medicare patients with and without CKD. 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. In future iterations of the ADR, we will also examine data on morbidity and mortality in the CKD population from additional non-Medicare data sources.

References

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- Matsushita K, van der Velde M, Astor BC, Woodward M, Levey AS, de Jong PE, Coresh J, Gansevoort RT. Association of estimated glomerular filtration rate and albuminuria with all-cause and cardiovascular mortality in general population cohorts: a collaborative meta-analysis. *Lancet* 2010;375(9731):2073–81.

Chapter 4: Cardiovascular Disease in Patients With CKD

- The prevalence of cardiovascular disease is 68.8% among patients aged 66 and older who have CKD, compared to 34.1% among those who do not have CKD (Table 4.1).
- The presence of CKD worsens the short- and long-term prognosis for many common cardiovascular diseases. The two-year survival of prevalent AMI patients without a diagnosis of CKD is 80%, compared to 69% for CKD Stage 1-2 patients and 53% for CKD Stage 4-5 patients (Figure 4.2).
- Over a two-year period, Medicare patients with both congestive heart failure and CKD have an adjusted survival probability of 76.0%, compared with 89.3% for those with CKD alone (Figure 4.5).
- Atrial fibrillation is common among Medicare patients with CKD (24.5%). The prevalence of atrial fibrillation is higher for males, those with more advanced stages of CKD, older persons, and is higher in the presence of hypertension, and congestive heart failure. Nearly half of CKD patients with congestive heart failure have a diagnosis of atrial fibrillation (Table 4.2).

Introduction

Cardiovascular disease remains the leading cause of death in most developed countries including the United States (Centers for Disease Control and Prevention. National Center for Health Statistics, 2015) and accounts for approximately 41% of the deaths among those on dialysis (see [Volume 2, Chapter 9: Cardiovascular Disease in Patients with ESRD](#)). Death from cardiovascular disease is far more common in patients with chronic kidney disease (CKD) than progression to end-stage renal disease (ESRD) (Gargiulo et al., 2015). CKD has been recognized as an independent risk factor for cardiovascular disease and has now been recognized as a coronary disease risk equivalent (Briasoulis and Bakris, 2013), similar to diabetes mellitus, suggesting that the risk of CKD is equivalent to individuals who have established coronary disease. The complex relationship between cardiovascular disease and kidney disease is thought to be due to shared traditional risk factors (e.g., diabetes mellitus, hypertension, physical inactivity, left ventricular hypertrophy, smoking, family history,

and dyslipidemia), as well as the influence of non-traditional risk factors in the presence of CKD (e.g., endothelial dysfunction, vascular medial hyperplasia, sclerosis and calcification, volume overload, abnormalities in mineral metabolism, anemia, malnutrition, inflammation, oxidative stress, and autonomic imbalance). The cardio-renal syndrome continues to pose both a diagnostic and therapeutic challenge for those with heart failure (Husain-Syed et al., 2015). Thus, cardiovascular disease is an important comorbidity among patients with CKD.

In this chapter, we review recent trends in the prevalence and outcomes of cardiovascular disease in CKD patients and compare these to outcomes of cardiovascular disease in patients without CKD, focusing on the high-risk, elderly Medicare population. Their CKD and cardiovascular disease diagnoses were obtained from billing claims from the Medicare 5% sample. The overall study cohort for 2014 includes 1,241,019 patients, of whom 138,176 have CKD.

Methods

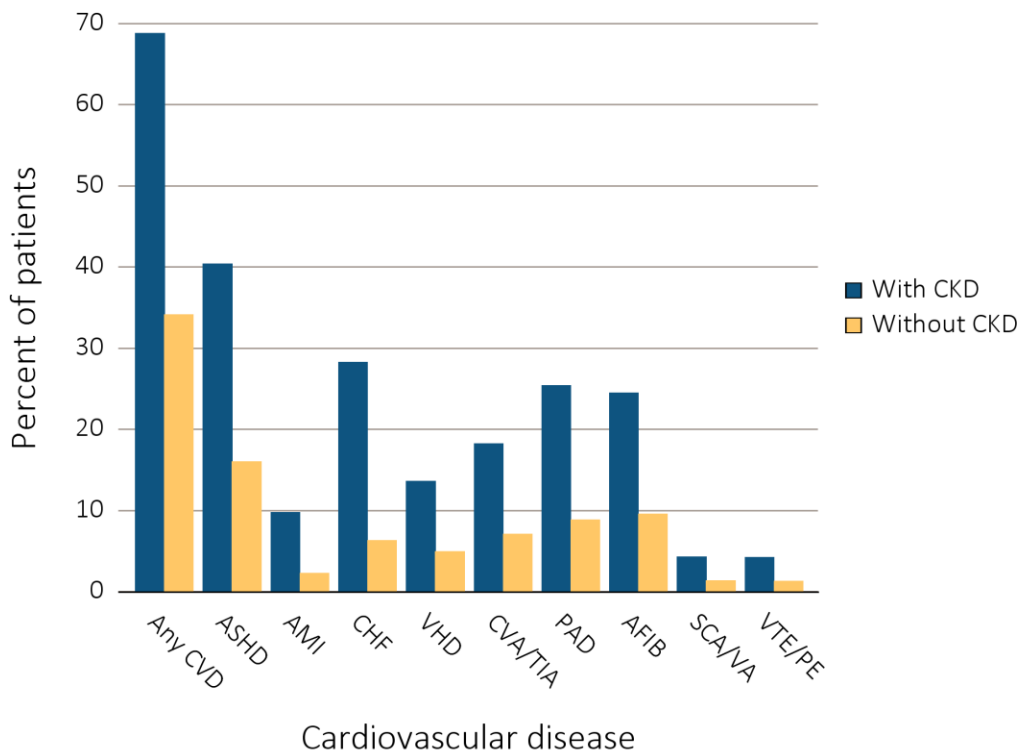
This chapter uses data from the Medicare 5% sample’s fee-for-service patients aged 66 and older, alive, without end-stage renal disease, and residing in the United States on 12/31/2014 with fee-for-service coverage for the entire calendar year. See the section on [Chapter 4](#) in the *CKD Analytical Methods* chapter for an explanation of analytical methods used to generate the study cohorts, figures, and tables in this chapter.

Cardiovascular Disease Prevalence and Outcomes in CKD

As shown in Figure 4.1, elderly CKD patients have a greater burden of cardiovascular disease than do their counterparts without a diagnosis of CKD for a wide

range of conditions. Stable atherosclerotic heart disease (ASHD), acute myocardial infarction (AMI), congestive heart failure (CHF), valvular heart disease (VHD), stroke (cerebrovascular accident/transient ischemic attack, CVA/TIA), peripheral arterial disease (PAD), atrial fibrillation (AFIB), sudden cardiac arrest and ventricular arrhythmias (SCA/VA), and venous thromboembolism and pulmonary embolism (VTE/PE) are all more common in CKD patients aged 66 and older when compared to those without CKD. Indeed, the prevalence of any cardiovascular disease is double among those with CKD compared to those without (68.8% versus 34.1%). Part of this differential is due to the older age of CKD patients (see [Volume 1, Chapter 2: Identification and Care of Patients With CKD](#)). The prevalence of both CKD and CVD increases with age.

vol 1 Figure 4.1 Prevalence of cardiovascular diseases in patients with or without CKD, 2014



Data Source: Special analyses, Medicare 5% sample. Abbreviations: AFIB, atrial fibrillation; AMI, acute myocardial infarction; ASHD, atherosclerotic heart disease; CHF, congestive heart failure; CKD, chronic kidney disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; CVD, cardiovascular disease; 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 also generally increases with age and presence of CKD (Table 4.1). The relationship with race, ethnicity, and sex is less straightforward. Major procedures utilized for the treatment of cardiovascular disease are more common among CKD patients, including percutaneous

coronary intervention (PCI), coronary artery bypass grafting (CABG), the 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) cardiovascular procedures, (%) by CKD status, age, race, & sex, 2014

		(a) Cardiovascular comorbidities									
		# Patients	% Patients								
			Overall	66-69	70-74	75-84	85+	White	Blk/Af Am	Other	Male
Any CVD											
Without CKD	1,102,843	34.1	20.3	28.8	41.2	54.4	35.0	30.4	25.3	37.4	31.6
Any CKD	138,176	68.8	55.6	61.4	70.3	79.1	69.8	64.7	61.8	72.4	65.5
Atherosclerotic heart disease (ASHD)											
Without CKD	1,102,843	16.0	9.9	14.3	19.7	22.5	16.5	12.9	12.2	21.3	11.9
Any CKD	138,176	40.3	32.1	36.7	42.6	44.0	41.4	33.9	36.5	47.9	33.4
Acute myocardial infarction (AMI)											
Without CKD	1,102,843	2.2	1.5	1.9	2.6	3.2	2.3	1.8	1.4	2.9	1.7
Any CKD	138,176	9.8	8.7	9.0	9.9	10.7	10.1	8.3	7.9	11.7	8.0
Congestive heart failure (CHF)											
Without CKD	1,102,843	6.2	3.0	4.3	7.3	13.7	6.3	7.3	4.5	6.4	6.1
Any CKD	138,176	28.2	20.7	22.2	27.7	37.4	28.3	30.4	23.0	28.8	27.7
Valvular heart disease (VHD)											
Without CKD	1,102,843	4.9	2.4	3.7	6.3	8.8	5.2	3.3	3.4	4.7	5.0
Any CKD	138,176	13.6	8.2	10.0	14.1	18.1	14.2	10.3	10.4	13.6	13.5
Cerebrovascular accident/transient ischemic attack (CVA/TIA)											
Without CKD	1,102,843	7.1	3.8	5.7	9.0	11.8	7.1	7.7	5.4	7.1	7.1
Any CKD	138,176	18.2	13.8	15.4	19.0	21.3	18.1	20.4	15.5	18.5	17.9
Peripheral artery disease (PAD)											
Without CKD	1,102,843	8.8	4.2	6.4	10.5	18.6	8.9	9.6	6.6	8.9	8.8
Any CKD	138,176	25.3	18.6	21.6	25.6	31.2	25.6	24.7	22.2	26.7	24.1
Atrial fibrillation (AFIB)											
Without CKD	1,102,843	9.5	4.0	6.7	12.3	19.1	10.2	4.8	5.1	10.7	8.6
Any CKD	138,176	24.5	14.1	17.8	25.6	33.1	26.3	15.0	16.0	27.0	22.2
Cardiac arrest and ventricular arrhythmias (SCA/VA)											
Without CKD	1,102,843	1.3	0.9	1.2	1.6	1.6	1.4	1.1	0.8	1.8	1.0
Any CKD	138,176	4.2	3.6	4.1	4.6	4.1	4.3	4.4	3.0	5.8	2.8
Venous thromboembolism and pulmonary embolism (VTE/PE)											
Without CKD	1,102,843	1.2	0.8	1.0	1.5	1.9	1.3	1.5	0.7	1.2	1.3
Any CKD	138,176	4.2	3.9	3.8	4.2	4.5	4.1	5.4	3.0	4.0	4.3

Table 4.1 continued on next page.

vol 1 Table 4.1 Prevalence of (a) cardiovascular comorbidities & (b) cardiovascular procedures, (%) by CKD status, age, race, & sex, 2014 (continued)

	# Patients	(b) Cardiovascular procedures									
		% Patients					White	Blk/Af Am	Other	Male	Female
Overall	66-69	70-74	75-84	85+							
Revascularization – percutaneous coronary interventions (PCI)											
Without CKD	176,023	2.0	3.0	2.3	1.8	1.2	2.0	1.5	2.0	2.0	2.0
Any CKD	55,737	3.1	4.6	4.0	3.1	1.9	3.1	2.6	3.2	3.3	2.9
Revascularization – coronary artery bypass graft (CABG)											
Without CKD	176,023	1.1	1.7	1.4	1.1	0.2	1.1	0.8	1.2	1.4	0.7
Any CKD	55,737	1.7	2.9	2.5	1.9	0.5	1.8	1.0	1.8	2.2	1.1
Implantable cardioverter defibrillators & cardiac resynchronization therapy with defibrillator (ICD/CRT-D)											
Without CKD	68,844	0.5	0.8	0.8	0.6	0.2	0.5	0.4	0.4	0.8	0.3
Any CKD	38,963	0.8	1.3	1.3	0.9	0.3	0.7	0.9	0.8	1.2	0.4
Carotid artery stenting and carotid artery endarterectomy (CAS/CEA)											
Without CKD	272,967	0.6	0.7	0.7	0.6	0.2	0.6	0.3	0.3	0.6	0.5
Any CKD	76,849	0.8	1.0	1.2	0.9	0.4	0.9	0.4	0.5	1.0	0.6

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 12/31/2014 with fee-for-service coverage for the entire calendar year. Abbreviations: AFIB, atrial fibrillation; AMI, acute myocardial infarction; ASHD, atherosclerotic heart disease; Blk/Af Am, Black African American; CABG, coronary artery bypass grafting; CAS/CEA, carotid artery stenting and carotid endarterectomy; CHF, congestive heart failure; CKD, chronic kidney disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; CVD, cardiovascular disease; 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 are Medicare enrollees aged 66+ by CKD status. (b) The denominators for overall prevalence of PCI and CABG are Medicare enrollees aged 66+ with ASHD by CKD status. The denominators for overall prevalence of ICD/CRT-D are Medicare enrollees aged 66+ with CHF by CKD status. The denominators for overall prevalence of CAS/CEA are Medicare enrollees aged 66+ with ASHD, CVA/TIA, or PAD by CKD status.

The presence of CKD also worsens the short- and long-term prognosis for many of these common cardiovascular diseases. Figures 4.2.a through 4.2.i and Figures 4.3.a through 4.3.d illustrate survival in patients with cardiovascular disease and undergoing cardiovascular procedures, respectively, stratified by the presence of CKD and its severity. In general, CKD patients have worse survival across all of the conditions reported, with late stages of CKD associated with the worst outcomes. This pattern also

is true in patients who undergo common major procedures for the treatment of cardiovascular diseases. For example, the two-year survival of AMI patients without a diagnosis of CKD is 80%, compared to 69% for CKD Stage 1-2 patients and 53% for CKD Stage 4-5 patients. All of these analyses are unadjusted for age. Older age is also associated with higher mortality and thus would attenuate the unadjusted findings presented here.

vol 1 Figure 4.2 Survival of patients with a prevalent cardiovascular disease, by CKD status, 2013-2014

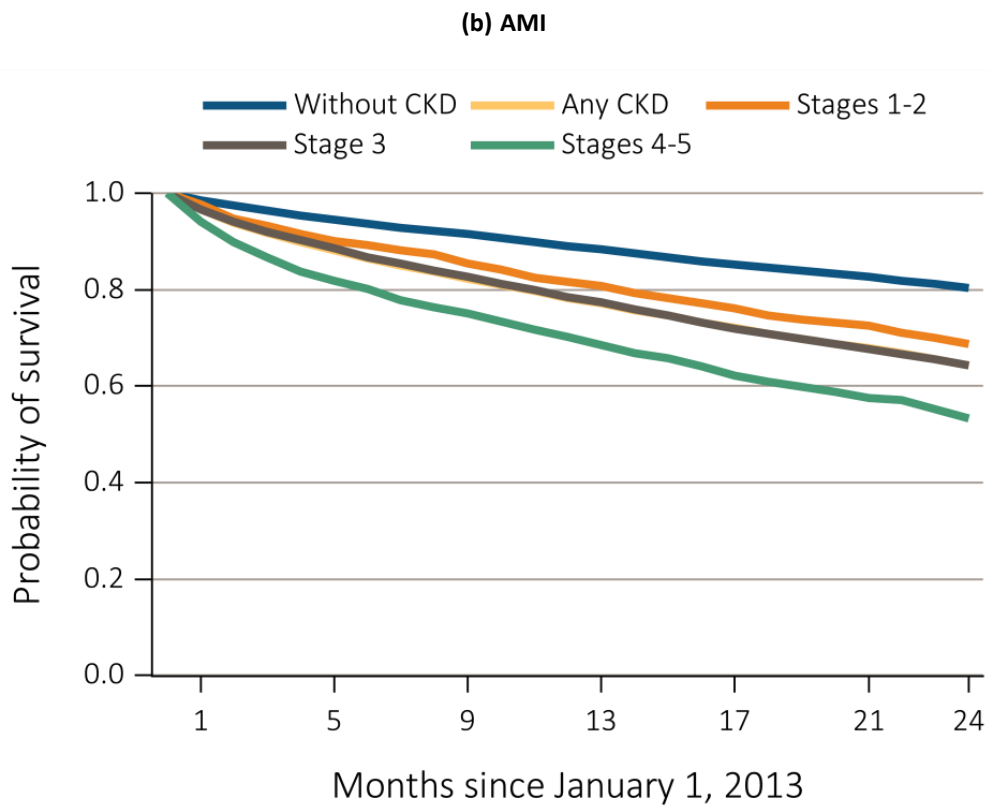
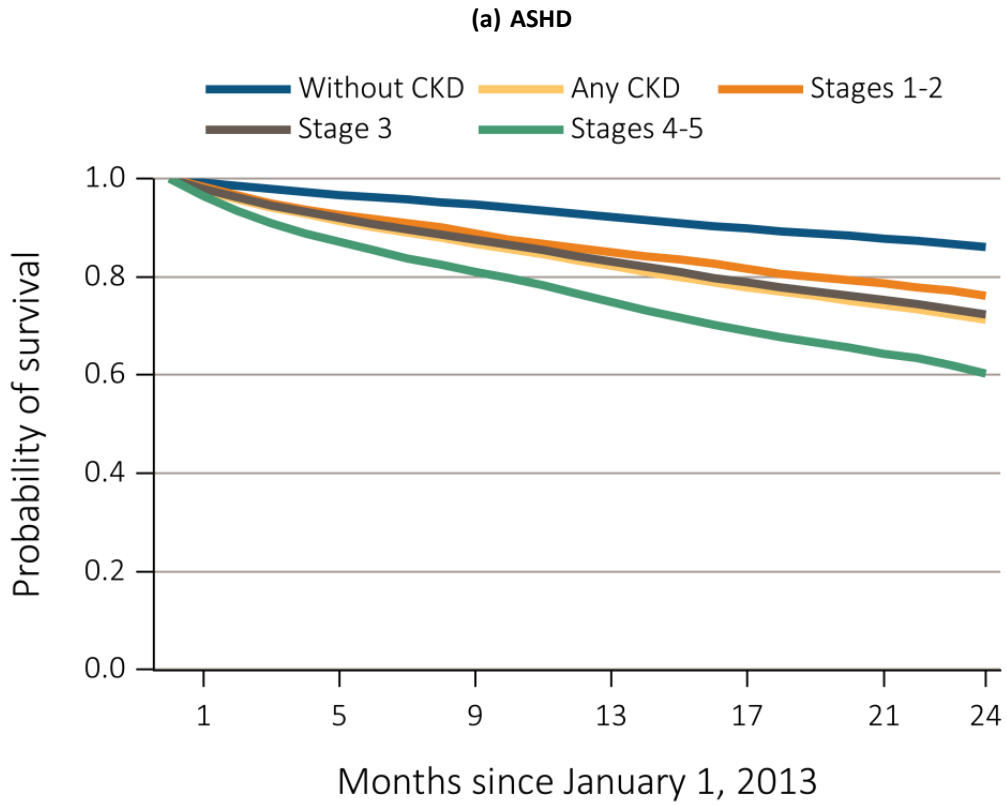


Figure 4.2 continued on next page.

vol 1 Figure 4.2 Survival of patients with a prevalent cardiovascular disease, by CKD status, 2013-2014
(continued)

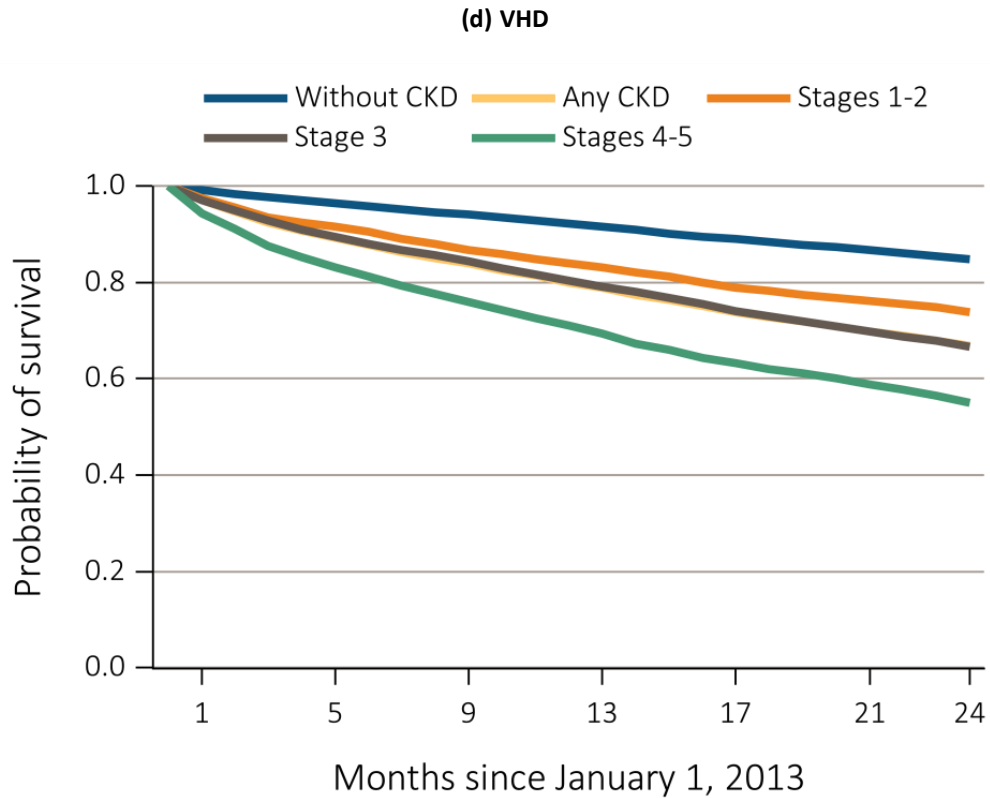
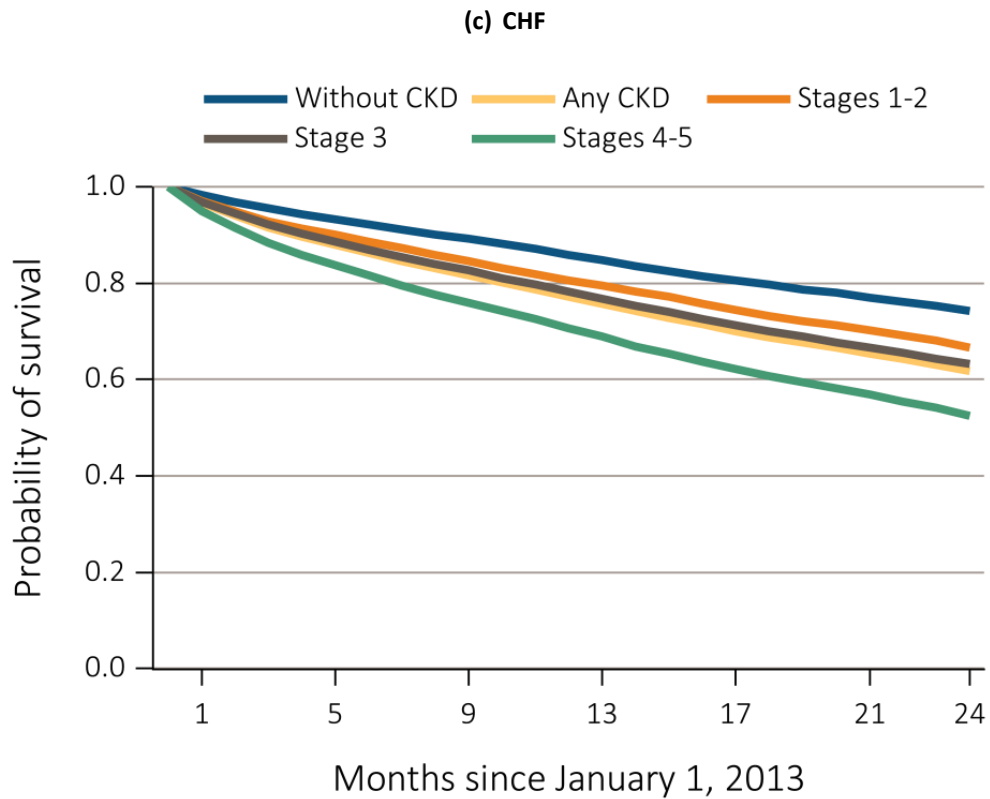


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vol 1 Figure 4.2 Survival of patients with a prevalent cardiovascular disease, by CKD status, 2013-2014
(continued)

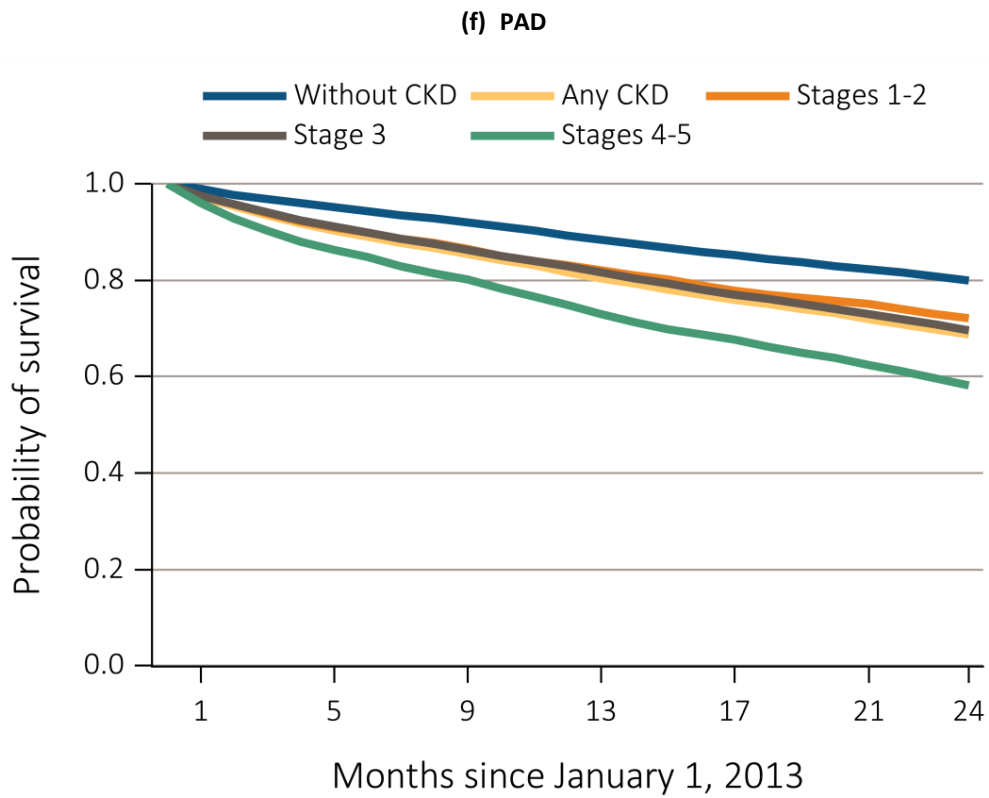
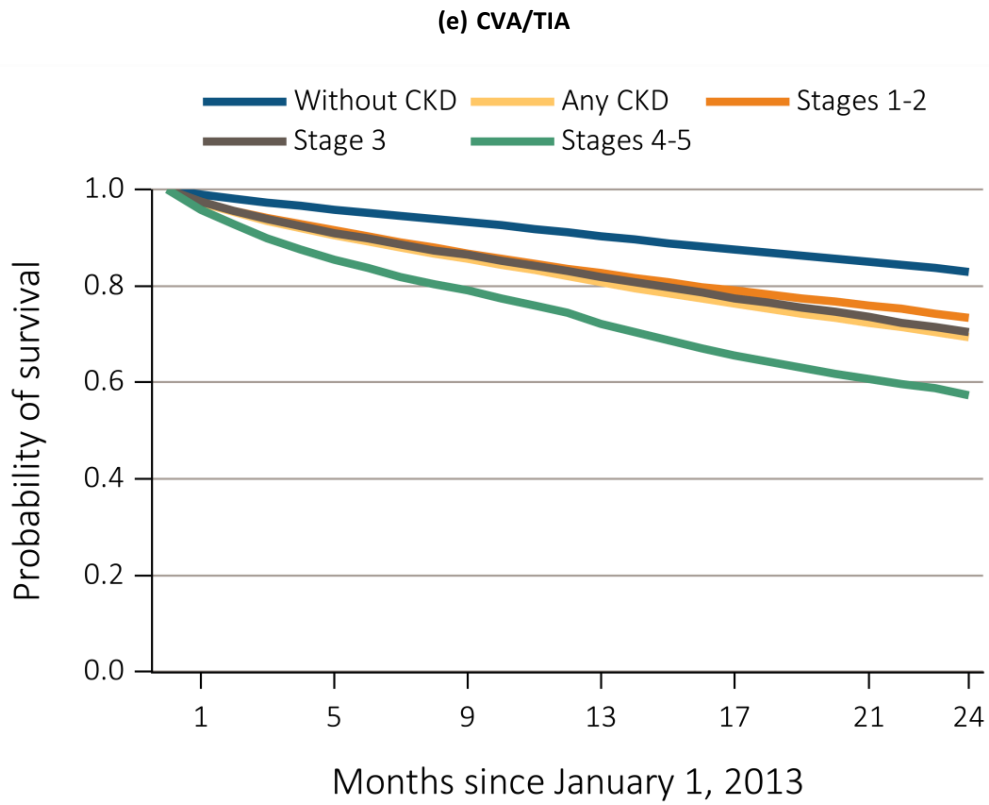


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vol 1 Figure 4.2 Survival of patients with a prevalent cardiovascular disease, by CKD status, 2013-2014
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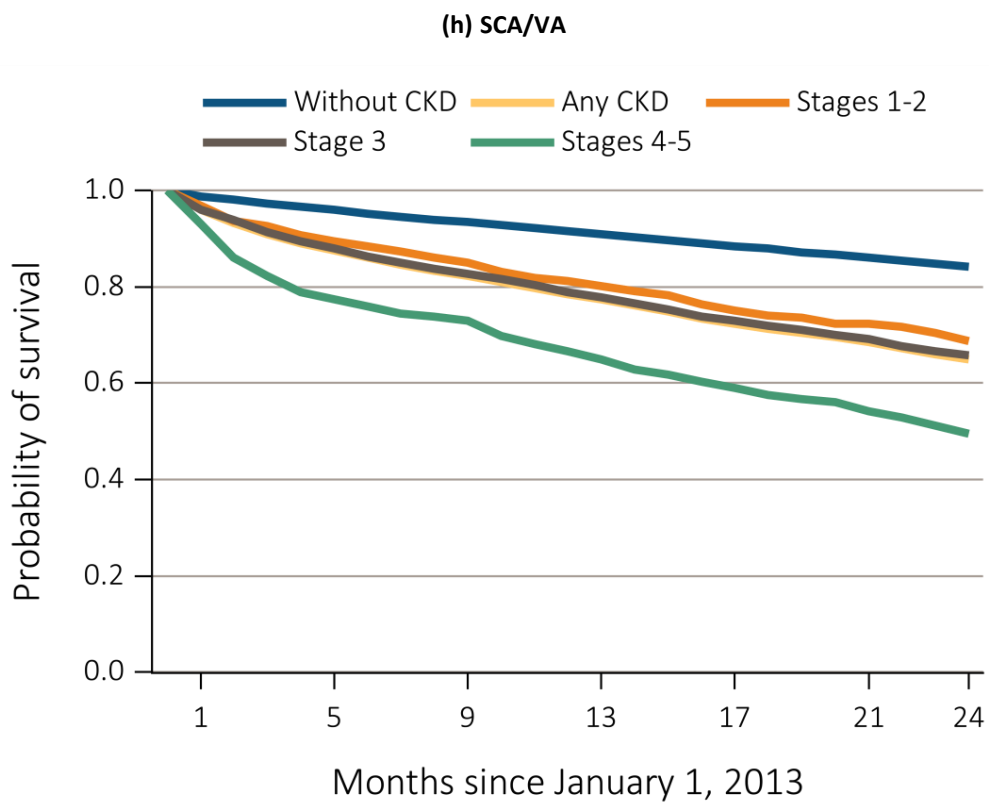
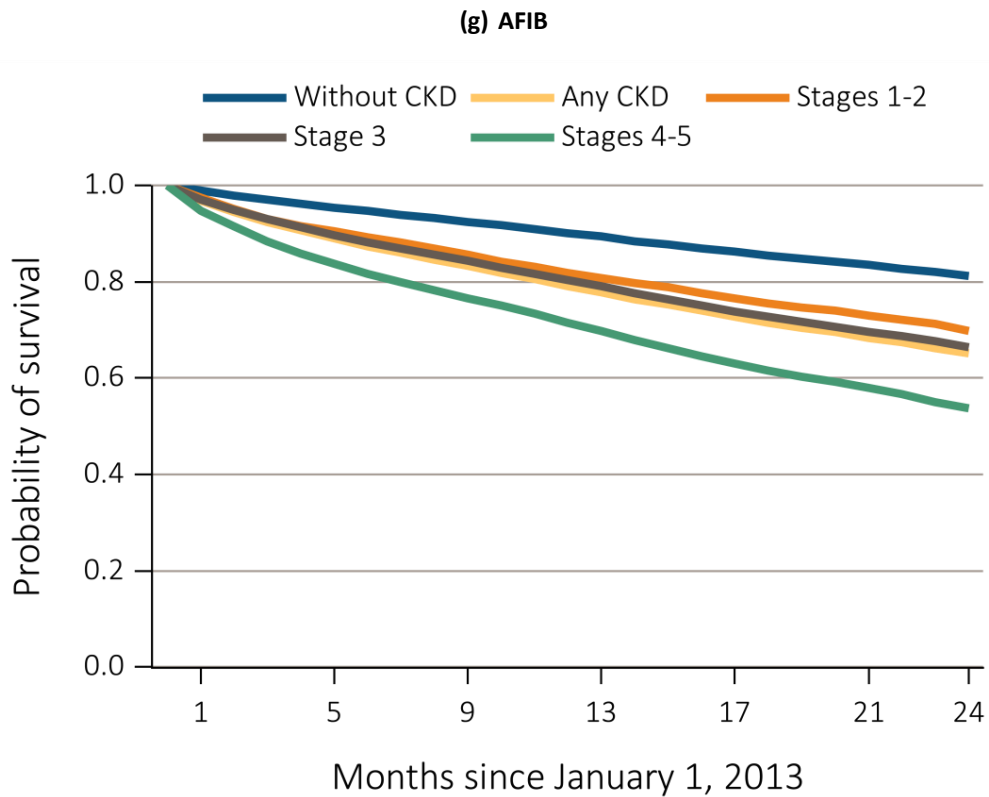
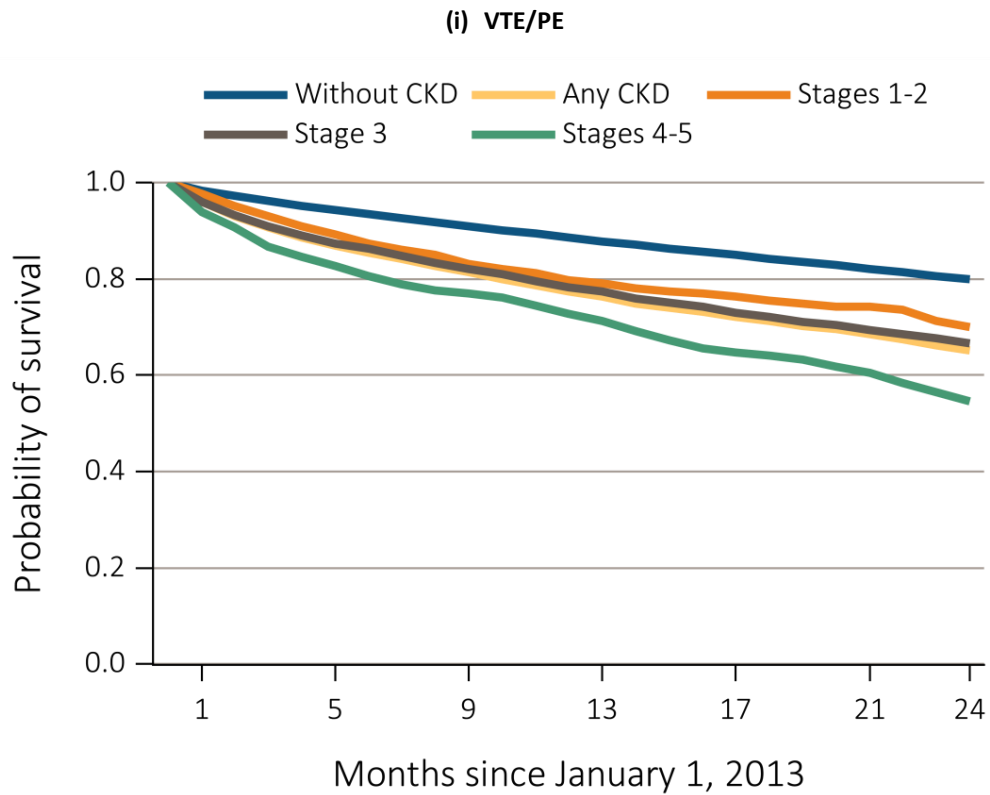


Figure 4.2 continued on next page.

vol 1 Figure 4.2 Survival of patients with a prevalent cardiovascular disease, by CKD status, 2013-2014
(continued)



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 12/31/2012, with fee-for-service coverage for the entire calendar year. Abbreviations: AFIB, atrial fibrillation; AMI, acute myocardial infarction; ASHD, atherosclerotic heart disease; CHF, congestive heart failure; CKD, chronic kidney disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; PAD, peripheral arterial disease; SCA/VA, sudden cardiac arrest and ventricular arrhythmias; VHD, valvular heart disease; VTE/PE venous thromboembolism and pulmonary embolism.

vol 1 Figure 4.3 Survival of patients with a cardiovascular procedure, by CKD status, 2012-2014

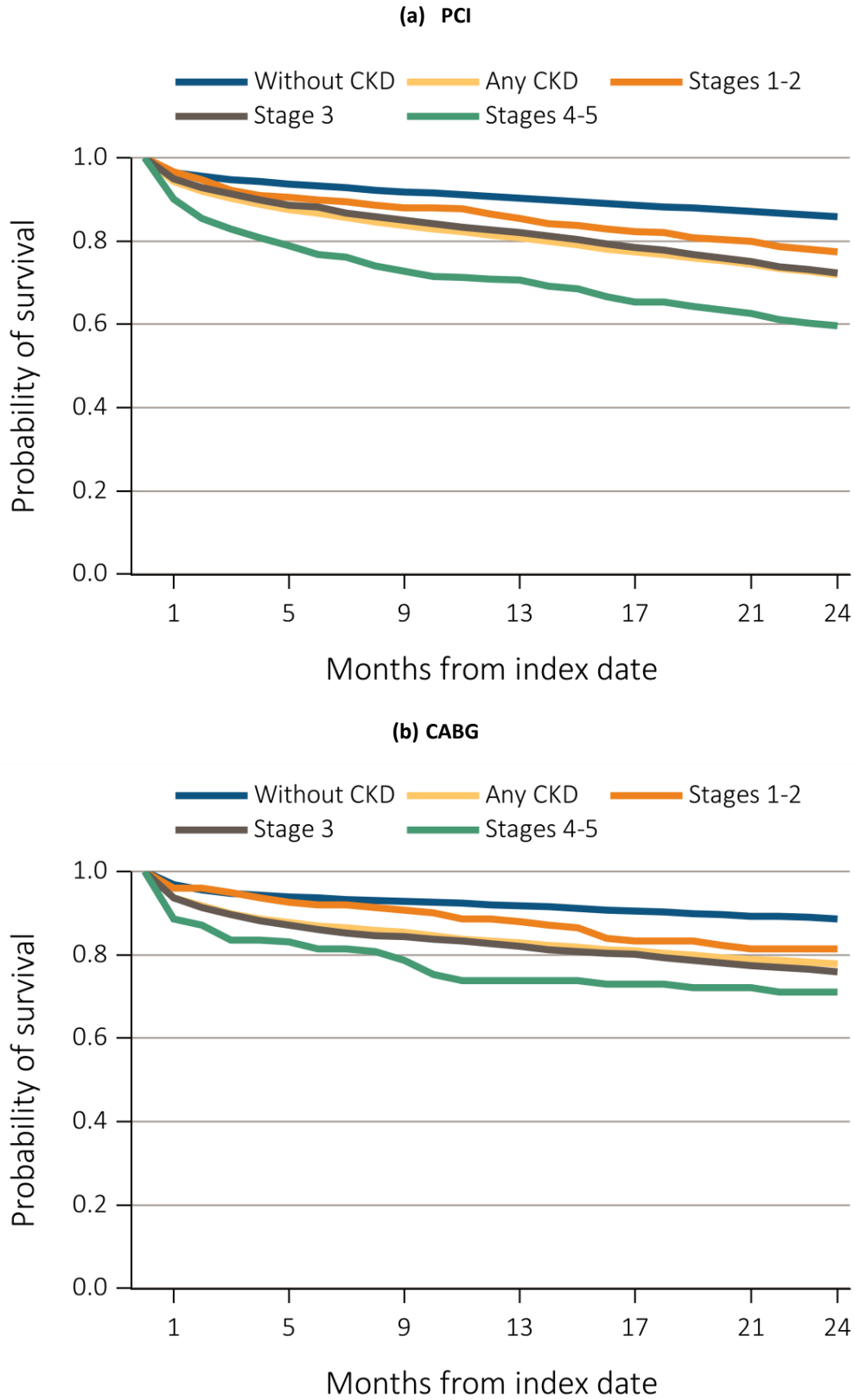
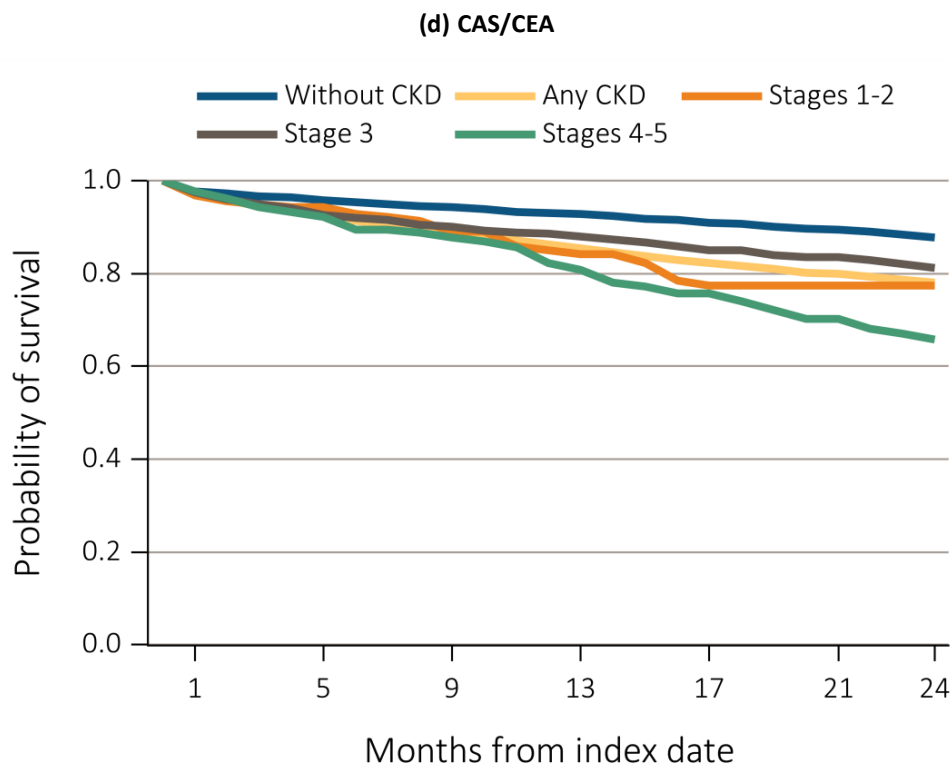
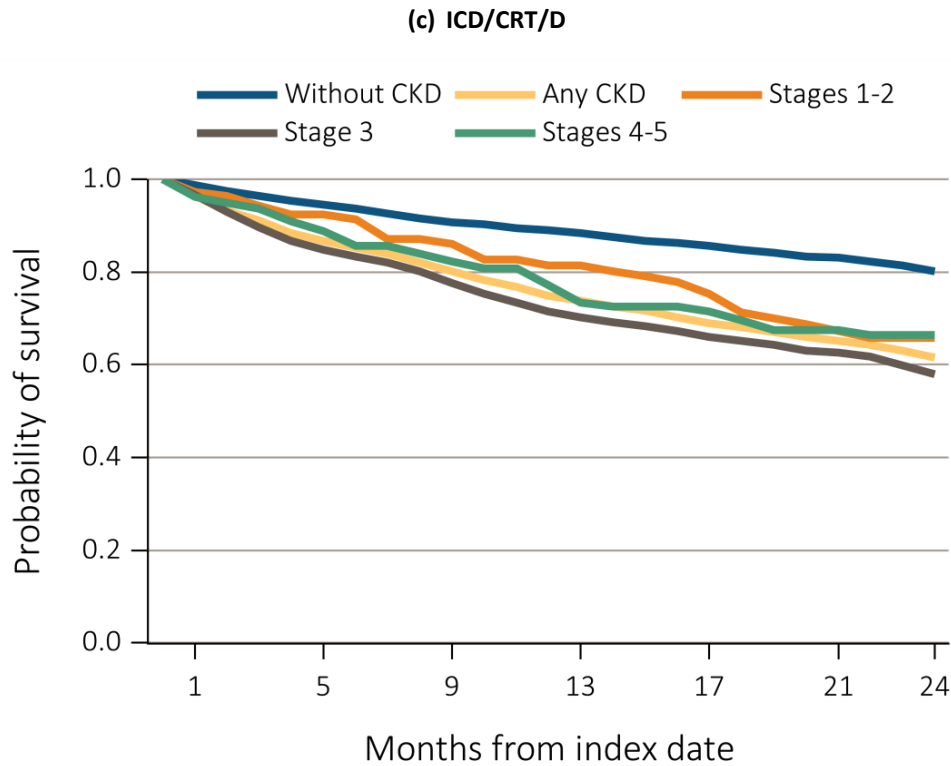


Figure 4.3 continued on next page.

vol 1 Figure 4.3 Survival of patients with a cardiovascular procedure, by CKD status, 2012-2014 (continued)



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 is the date of the first condition/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.

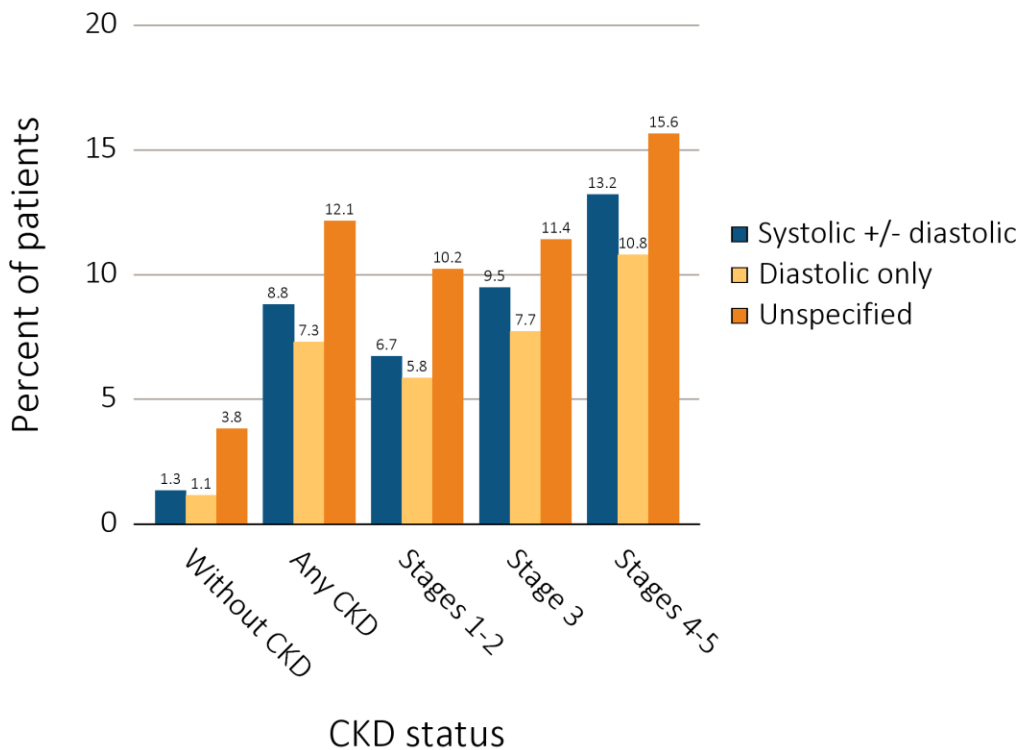
Congestive Heart Failure and Chronic Kidney Disease

Congestive heart failure (CHF) is among the more frequently diagnosed cardiovascular diseases among CKD patients. In 2014, the prevalence of CHF 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, key characteristics of CHF in CKD patients are further examined in Figure 4.4 after stratifying CHF based on systolic dysfunction (i.e., heart failure with decreased ejection fraction), diastolic dysfunction (i.e., heart failure with preserved ejection fraction), or

unspecified. For ease of reporting and for consistency with clinical approaches for categorizing the disease, systolic CHF includes patients with systolic dysfunction regardless of the presence of concomitant diastolic dysfunction. Patients with isolated diastolic CHF are treated separately since long-term risk assessments and treatments vary for this group.

The relative proportion of patients with systolic CHF is slightly higher than diastolic CHF in CKD patients, and increases with greater severity of CKD (e.g., Stages 1-2 vs. Stage 3 vs. Stages 4-5), although the vast majority of patients have unspecified CHF in all instances (Figure 4.4).

vol 1 Figure 4.4 Heart failure in patients with or without CKD, 2014

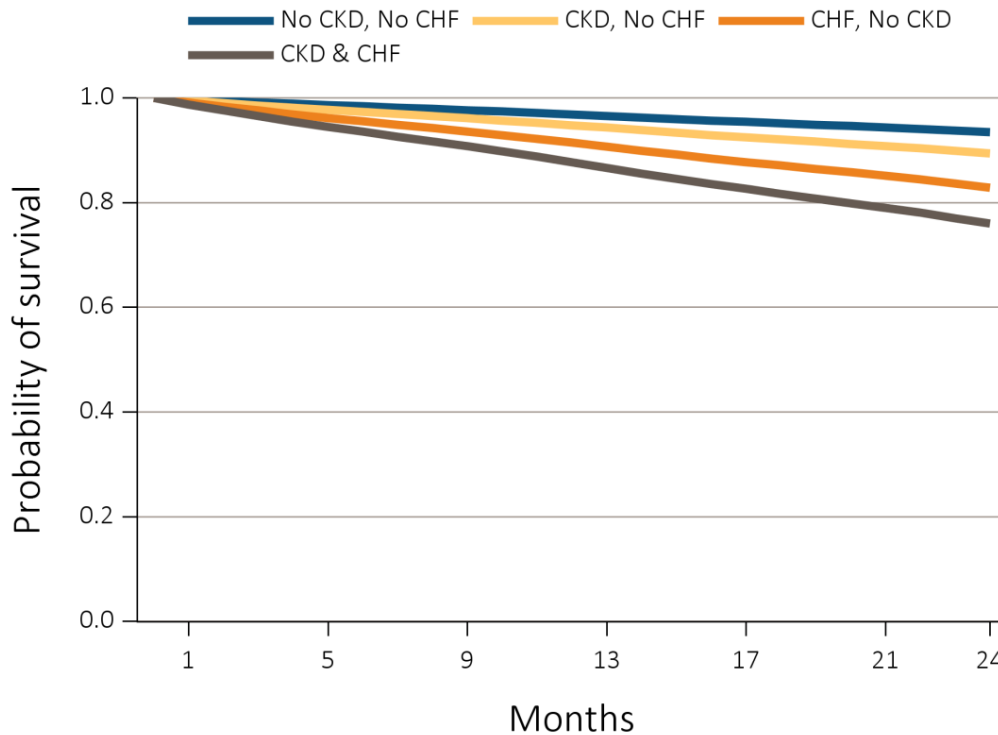


Data Source: Special analyses, Medicare 5% sample. Patients aged 66 and older, alive, without end-stage renal disease, and residing in the United States on 12/31/2014 with fee-for-service coverage for the entire calendar year. Abbreviation: CKD, chronic kidney disease.

The presence of CHF worsens survival among patients with and without CKD (Figure 4.5), but to a greater extent among those with CKD (p-value for interaction <0.0001). Over a two-year period, patients

with both CHF and CKD have an adjusted survival probability of 76.0%, as compared with 82.9% for those with CHF alone, 89.3% for those with CKD alone, and 93.4% for those without CHF or CKD.

vol 1 Figure 4.5 Adjusted survival of patients by CKD and CHF status, 2013-2014



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 12/31/2012 with fee-for-service coverage for the entire calendar year. Survival is adjusted for age, sex, race, diabetic status, and hypertension status. Abbreviations: CKD, chronic kidney disease; CHF, congestive heart failure.

Atrial Fibrillation and Chronic Kidney Disease

Atrial fibrillation 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 atrial fibrillation among CKD patients is high as well; it is present in approximately one-quarter of the population. The prevalence of atrial

fibrillation rises with more advanced stages of CKD, age, male sex, hypertension, and congestive heart failure (Table 4.2). In patients with CKD, the presence of congestive heart failure raises the prevalence of atrial fibrillation to nearly half of all patients. Patients with atrial fibrillation and CKD have an increased risk of stroke and bleeding, making the use of oral anticoagulants challenging, as demonstrated by recent reports.

vol 1 Table 4.2 Prevalence of AFIB by stage of CKD, age, race, sex, diabetic status, hypertension status, and CHF status, 2014

	Stage of CKD				Total
	Stages 1-2	Stage 3	Stages 4-5	Unknown stage	All CKD stages
N	14,364	67,122	13,746	42,944	138,176
AFIB (Overall)	20.9	25.0	27.9	23.7	24.5
Age					
66-69	11.8	14.4	17.8	13.8	14.1
70-74	15.8	18.2	20.6	17.4	17.8
75-84	22.0	26.1	28.8	25.0	25.6
85+	32.2	33.1	34.2	32.9	33.1
Sex					
Male	23.5	27.9	30.1	25.9	27.0
Female	18.4	22.4	26.1	21.7	22.2
Race					
White	22.7	26.8	30.4	25.4	26.3
Black/African American	13.4	15.4	17.5	13.9	15.0
Other	13.2	16.1	19.6	15.6	16.0
Comorbidity					
Non-diabetes	20.3	25.1	28.3	23.7	24.4
Diabetes	21.5	24.9	27.7	23.7	24.5
Non-hypertension	11.0	14.8	17.8	11.7	13.2
Hypertension	21.8	25.7	28.4	25.3	25.5
No Heart Failure (CHF)	12.7	14.7	14.4	14.9	14.5
Heart Failure (CHF)	48.9	50.9	48.6	49.0	49.9

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 12/31/2014 with fee-for-service coverage for the entire calendar year. Abbreviations: AFIB, atrial fibrillation; CHF, congestive heart failure; CKD, chronic kidney disease.

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Chapter 5: Acute Kidney Injury

- In 2014, the percent of Medicare fee-for-service beneficiaries experiencing a hospitalization complicated by AKI was 4.0%, and this appears to have plateaued since 2011 (Figure 5.1). A similar trend was observed in the Clinformatics™ population, among whom 0.3% had an AKI hospitalization in 2014 (Figure 5.2). Unadjusted rates of AKI hospitalization also seem to have plateaued since 2011 in both the Medicare and Clinformatics™ populations (Figure 5.3).
- When examining AKI among patients in the VA system using serum creatinine-based criteria, fewer than 50% of identified cases had an associated diagnosis of AKI during their hospitalization (Table 5.2).
- For Medicare patients aged 66 years and older with an AKI hospitalization in 2012, the cumulative probability of a recurrent AKI hospitalization within one year was 35% (Figure 5.6.a). For Clinformatics™ patients aged 22 years and older, the probability of recurrent AKI hospitalization was 23% (Figure 5.7.a).
- Overall, 16% of Medicare patients and 17% of Clinformatics™ patients had a nephrology visit within 6 months of live discharge from an AKI hospitalization (Figure 5.9).
- Among Medicare patients aged 66 years and older with a first AKI hospitalization, the in-hospital mortality rate in 2013 was 9.0% (or 13.9% when including discharge to hospice). Less than half of all patients were discharged to their home, while 30.4% were discharged to an institution such as a rehabilitation or skilled nursing facility (Figure 5.13).

Introduction

Acute kidney injury (AKI) is now recognized as a major risk factor for the development of chronic kidney disease (CKD). The clearest example of this relationship is seen in cases of severe dialysis-requiring AKI where patients fail to recover renal 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 renal disease burden resulting from AKI, as studies have demonstrated significantly increased long-term risk of CKD and ESRD following AKI, even after initial recovery of renal function. Furthermore, this relationship is bidirectional and 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, in addition to the Medicare 5% sample, we utilized two additional data sources: the 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 Clinformatics™ administrative data do not contain clinical or biochemical data with which to identify an AKI episode using consensus criteria based on changes in serum creatinine or urinary output. In these data sources, episodes of AKI are identified using ICD-9-CM (International Classification of Diseases, Ninth 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 addition, time 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/recognition of AKI) increase the likelihood of administrative coding for AKI. Thus, a rising incidence of AKI may represent a true increase in AKI cases, an increased likelihood to

code for AKI, or a combination of both factors. In addition, a lower threshold for coding for AKI would lead to identification of less severe episodes and an apparent decrease in the rate of associated adverse outcomes. For this chapter, we identified and included all hospitalizations during which a diagnosis of AKI was coded, referring to these as AKI hospitalizations; even if AKI was not the primary diagnosis. In contrast to Medicare and Clinformatics™, VA data contains clinical data that can be used to apply serum creatinine-based criteria to identify episodes of AKI. We present some data from the VA population to illustrate the potential gap between AKI episodes that are identified by administrative coding versus clinical data.

We begin this chapter by exploring trends in hospitalizations complicated by AKI and describing characteristics of these patients, including age, sex, race, and comorbidity status. For this chapter, 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. While coded AKI increased between 2004 and 2011, this trend appears to have leveled off since then in both the Medicare and Clinformatics™ populations. Rates of AKI per 1,000 patient-years at risk increased with increasing age. Patients with diabetes and CKD had higher rates than patients with either comorbidity alone; patients with CKD alone had higher risk of hospitalization than those with diabetes alone.

Next, we explore outcomes and follow-up care after an AKI hospitalization. Among Medicare patients aged 66 years and older, 35% had a recurrent AKI hospitalization by one year, and 47% had a recurrent AKI hospitalization within two years. For Clinformatics™ patients aged 22 years and older, the corresponding proportions were 18% and 26%, respectively. These findings highlight the at-risk nature of this population and support published recommendations for post-AKI follow-up nephrology care. However, in 2013 only 16% of Medicare patients and 17% of Clinformatics™ patients with AKI were

seen by a nephrologist within six months of hospital discharge.

As noted above, AKI plays an important role in CKD development and progression. Among Medicare patients without pre-existing CKD who experienced an AKI hospitalization, nearly 30% were reclassified as having some degree of CKD in the subsequent year.

Lastly, we explore patient disposition following an AKI hospitalization. Among patients not admitted from a nursing facility, 48% of Medicare patients suffering an AKI hospitalization returned directly to their homes, while 30% were institutionalized in a skilled nursing facility. By comparison, among hospitalized Medicare patients without an AKI episode, 68% returned home and 23% were institutionalized. These outcomes highlight the significant morbidity associated with AKI.

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 source than in previous years. This has coincided with a decrease in AKI hospitalizations since 2013 and we cannot rule out that this is an artifact of the differing source for the Medicare 5% data files, so caution should be used in drawing conclusions regarding trends. 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.

New this year, we present figures and s from the commercial insurance plan of a large national U.S. health insurance company as included in the Clinformatics™ Data Mart from OptumInsight. These data represent mainly working-age people and their minor dependents, in contrast to the Medicare data. See Table 2.1 in [Volume 1, Chapter 2: Identification and Care of Patients With CKD](#) for demographic characteristics of the Clinformatics™ population (all ages) and Tables 2.2 (ages 22–64) and 2.3 (all ages) for the prevalence of CKD and related conditions. This

chapter presents results for patients aged 22 and older. Additionally, Table 5.1 of this chapter uses data from all patients hospitalized within a VA hospital during fiscal year 2014 to show AKI 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 identified AKI episodes do not include the KDIGO criteria related to urine output.

Each of these three datasets has interactions between sex and age that are important to keep in mind when looking at differences in AKI by sex, since age is a major risk factor for AKI. Within both Clinformatics™ and the VA, women are younger on average than men. In Clinformatics™, 55% of women are between the ages of 22 and 39, compared to only 18.4 percent 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. On the other hand, women in the Medicare 5% sample are older, on average, than men. Women had a mean age of 76.8 years while the mean age for men was 75.2 years. A higher proportion of women vs. men were aged 85 and older; 20.2% of women compared to 13.3% of men.

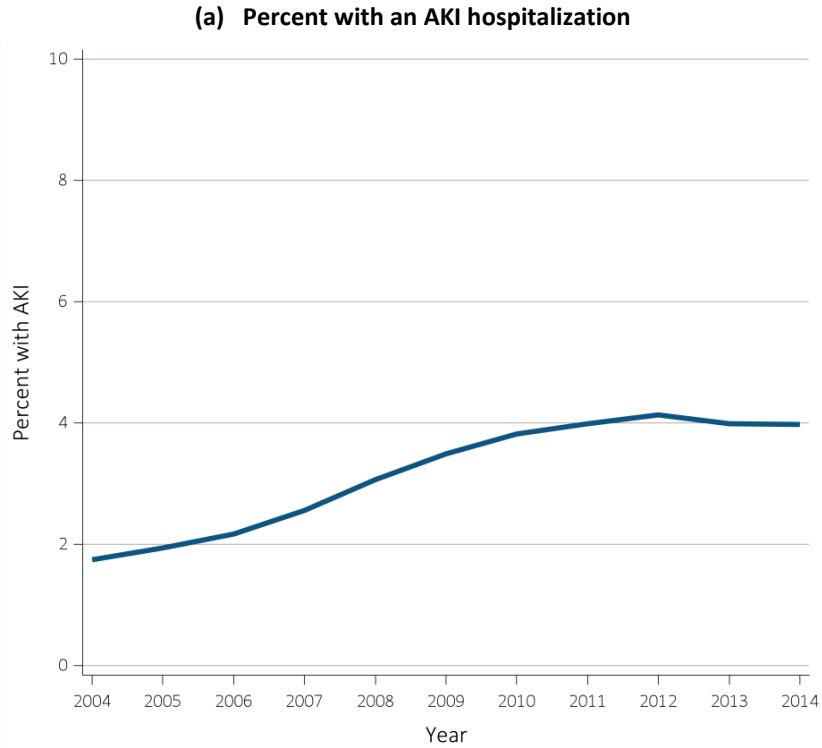
Note that all the figures except Figure 5.13 include all beneficiaries meeting the specified inclusion criteria. In Figure 5.13, those beneficiaries who were admitted from a long-term care facility to the

inpatient setting where the AKI hospitalization occurred are excluded. Therefore, the category of institution in this figure includes only those newly admitted following a hospitalization. See the section on [Chapter 5](#) in the *CKD Analytical Methods* chapter for an explanation of analytical methods used to generate the study cohorts, figures, and tables in this chapter.

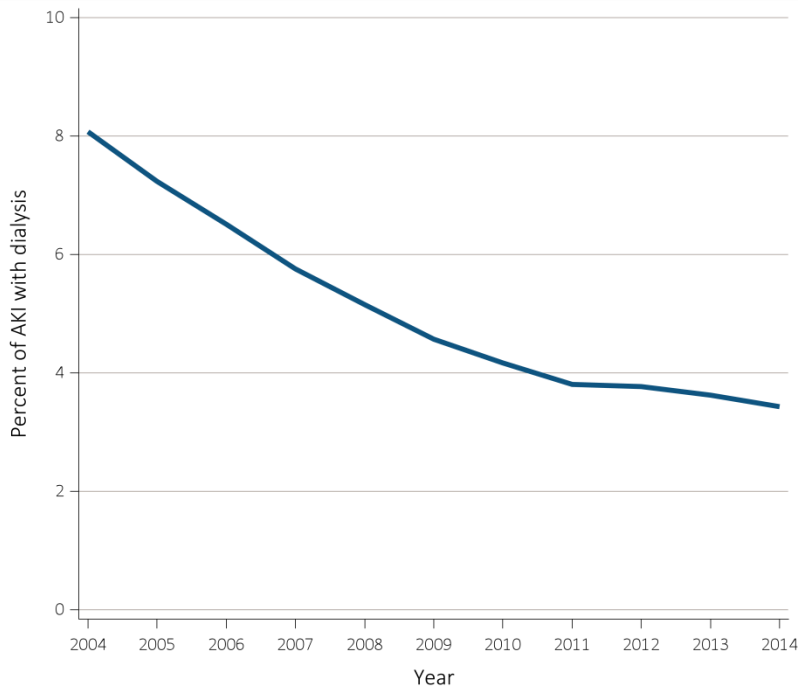
Characteristics of Patients With Acute Kidney Injury

As shown in Figure 5.1, the percentage of patients with an AKI hospitalization (where AKI was one of the diagnoses but not necessarily the admitting diagnosis) in the Medicare fee-for-service population has risen over the past decade but appears to have plateaued around 4.0% since 2011. The proportion of AKI patients requiring dialysis has declined over the same period, but also appears to be leveling off since 2011. Figure 5.2 reveals very similar trends in the Clinformatics™ population, although the percentage of patients with an AKI hospitalization is far lower overall in this younger patient population (0.3% in 2014). Taken together, these findings suggest that an increased likelihood to code for AKI is indeed occurring: 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 fairly 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 that required dialysis, by year, 2004-2014

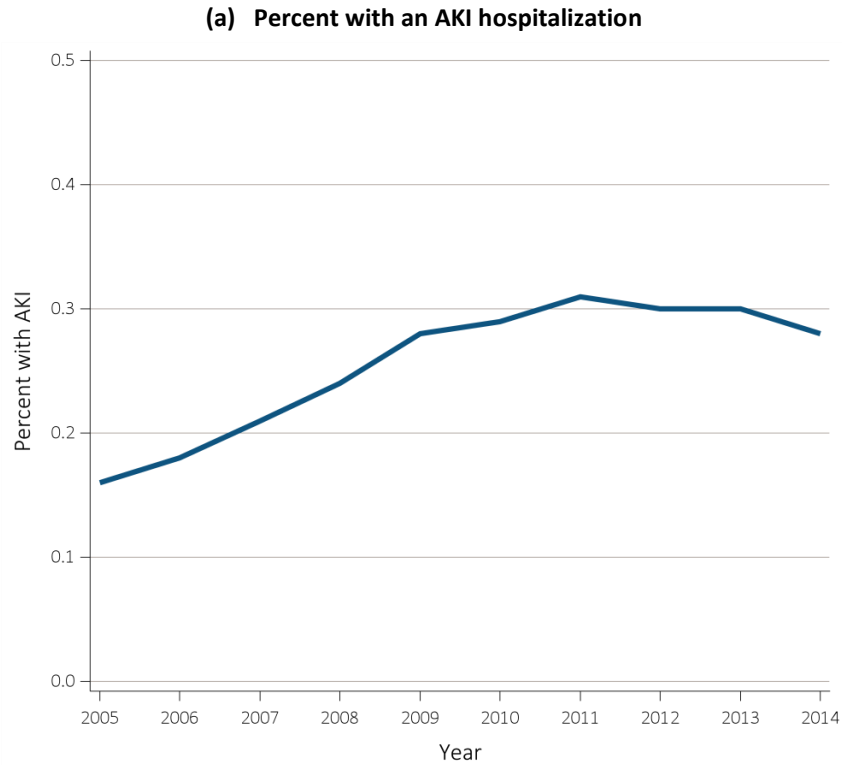


(b) Percent of patients requiring dialysis among those with a first AKI hospitalization

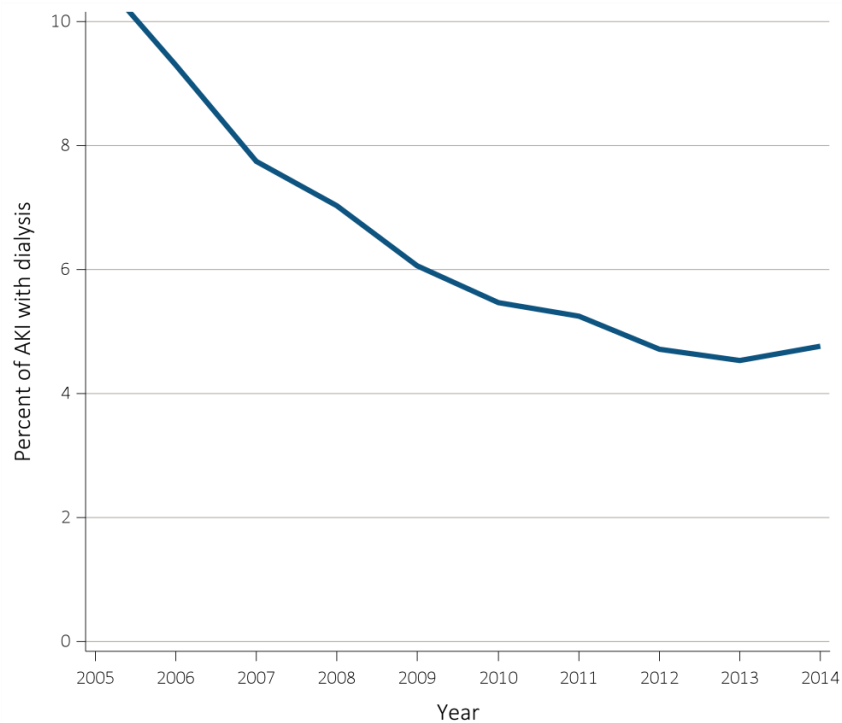


Data Source: Special analyses, Medicare 5% sample. (a) Percent with an AKI hospitalization among all Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, no ESRD by first service date from Medical Evidence form, and were alive on January 1 of year shown. (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 period of the AKI inpatient claim. Abbreviations: AKI, acute kidney injury; ESRD, end-stage renal disease.

vol 1 Figure 5.2 Percent of Clinformatics™ patients aged 22+ (a) with at least one AKI hospitalization, and (b) percent among those with an AKI hospitalization that required dialysis, by year, 2005-2014



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



Data Source: Special analyses, Clinformatics™. (a) Percent with an AKI hospitalization among all 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, 2014. (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 period 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 Clinformatics™ patients with AKI in 2014. AKI occurs commonly in older adults, and the incidence rises with age. In the fee-for-service Medicare population, patients aged 80 years and older comprise 54% of all patients with an AKI hospitalization. Diabetes

mellitus 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 Clinformatics™ population, about 36% of patients with an AKI hospitalization had either diabetes, CKD, or both.

vol 1 Table 5.1 Characteristics of Medicare and Clinformatics™ patients with at least one hospitalization, by age, sex, race, CKD, DM, and presence of AKI, 2014

	Medicare (aged 66+)						Clinformatics™ (aged 22+)					
	Total		Without AKI		With AKI		Total		Without AKI		With AKI	
	N	%	N	%	N	%	N	%	N	%	N	%
Total	231,894	100.0	178,747	100.0	53,147	100.0	307,333	100.0	287,415	100.0	19,918	100.0
Age												
22-39	—	—	—	—	—	—	132,848	43.2	130,828	45.5	2,020	10.1
40-65	—	—	—	—	—	—	145,567	47.4	132,606	46.1	12,961	65.1
65+	—	—	—	—	—	—	28,918	9.4	23,981	8.3	4,937	24.8
66-69	36,228	15.6	29,906	16.7	6,322	11.9	—	—	—	—	—	—
70-74	45,009	19.4	36,484	20.4	8,525	16.0	—	—	—	—	—	—
75-79	43,280	18.7	33,753	18.9	9,527	17.9	—	—	—	—	—	—
80-84	41,067	17.7	30,863	17.3	10,204	19.2	—	—	—	—	—	—
85+	66,310	28.6	47,741	26.7	18,569	34.9	—	—	—	—	—	—
Sex												
Male	98,054	42.3	72,345	40.5	25,709	48.4	105,505	34.3	92,960	32.3	12,545	63.0
Female	133,840	57.7	106,402	59.5	27,438	51.6	201,828	65.7	194,455	67.7	7,373	37.0
Race												
White	201,739	87.0	157,510	88.1	44,229	83.2	217,342	70.7	202,931	70.6	14,411	72.4
Black/African American	18,668	8.1	12,579	7.0	6,089	11.5	30,300	9.9	27,663	9.6	2,637	13.2
Native American	1,193	0.5	930	0.5	263	0.5	—	—	—	—	—	—
Hispanic	—	—	—	—	—	—	30,723	10.0	29,198	10.2	1,525	7.7
Asian	3,128	1.4	2,262	1.3	866	1.6	13,276	4.3	12,885	4.5	391	2.0
Other	7,166	3.1	5,466	3.1	1,700	3.2	15,692	5.1	14,738	5.1	954	4.8
Pre-existing comorbidities												
No DM or CKD, prior year	137,612	59.3	115,052	64.4	22,560	42.5	272,983	88.8	260,248	90.6	12,735	63.9
DM no CKD, prior year	49,165	21.2	38,030	21.3	11,135	21.0	24,720	8.0	20,937	7.3	3,783	19.0
CKD no DM, prior year	21,423	9.2	13,103	7.3	8,320	15.7	5,194	1.7	3,650	1.3	1,544	7.8
Both CKD & DM, prior year	23,694	10.2	12,562	7.0	11,132	21.0	4,436	1.4	2,580	0.9	1,856	9.3

Data Source: Special analyses, Medicare 5% sample and Clinformatics™. 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, 2014. 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, 2014. 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.

Table 5.2 presents characteristics of patients with an AKI hospitalization in the VA system. Here, AKI is defined using serum creatinine-based criteria according to the KDIGO guideline (Table A). Similar to the Medicare population, nearly 57% of VA patients with AKI have either diabetes, CKD, or both. Of note,

only 49% of patients meeting criteria for AKI were actually given a diagnosis of AKI during their hospital stay. This percentage increased with AKI severity, ranging from 45% of stage 1 AKI hospitalizations to 70% of stage 3 AKI hospitalizations.

Table A. KDIGO definition and staging of acute kidney injury

Definition of AKI:

An increase in serum creatinine (SCR) by ≥ 0.3 mg/dL (≥ 26.5 μ 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 μ mol/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 (≥ 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: 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 2014

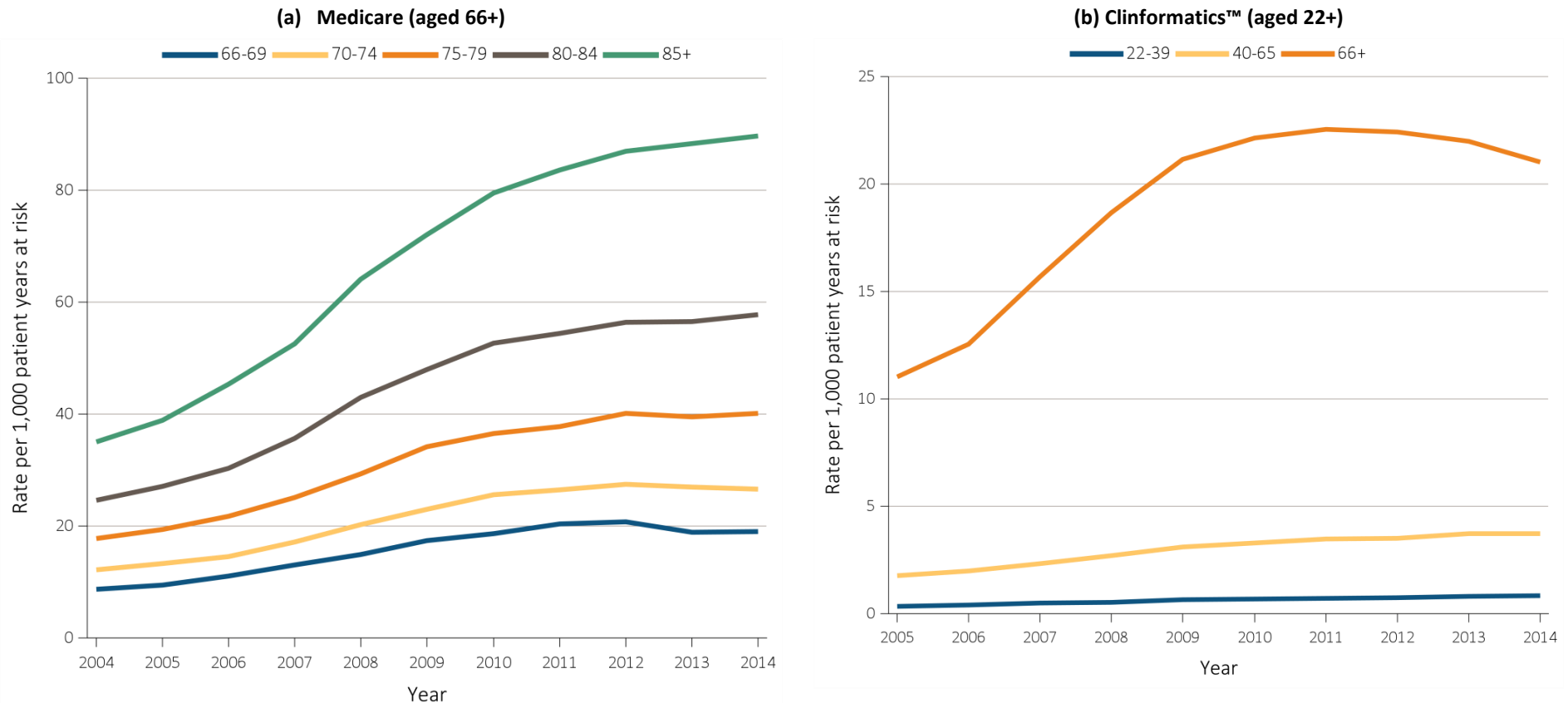
	Total	No AKI	Any Stage AKI	Stage 1	Stage 2	Stage 3
Total, N	319,969	242,834	77,135	64,566	2,673	9,896
Diagnosis of AKI, %	15.6	5.0	48.8	45.3	53.9	70.0
Age, %						
22-39	3.9	4.8	1.3	1.3	2.0	1.0
40-59	19.0	20.6	14.1	13.5	19.9	16.7
60-65	17.7	17.6	18.0	17.6	22.9	19.5
66-69	19.6	19.5	20.2	20.1	21.0	20.1
70-74	13.2	12.9	14.4	14.5	12.1	13.9
75-79	7.6	7.2	8.8	8.9	7.0	8.3
80-84	7.9	7.3	9.7	9.9	6.8	9.3
85+	10.9	10.1	13.5	14.1	8.2	11.2
Sex, %						
Male	94.3	93.5	96.8	96.8	95.1	97.1
Female	5.7	6.5	3.2	3.2	4.9	2.9
Race, %						
White	69.6	70.4	66.8	68.1	69.3	57.4
Black/African American	19.1	18.0	22.5	21.6	18.6	30.0
Native American	0.6	0.7	0.5	0.5	0.6	0.5
Hispanic	6.1	6.2	5.6	5.3	7.0	6.7
Asian	0.8	0.8	0.8	0.8	0.6	1.2
Other/Not known	3.8	3.8	3.8	3.7	4.0	4.3
Diabetes and CKD, %						
No DM or CKD	58.1	62.8	43.4	44.8	65.5	27.8
DM no CKD	24.7	23.5	28.7	30.5	31.4	16.1
CKD no DM	8.7	7.8	11.8	10.3	1.3	24.6
Both CKD & DM	8.4	6.0	16.2	14.4	1.8	31.5

Data Source: Special analyses, Veterans Affairs data. Patients aged 22 and older with at least one hospitalization in fiscal year 2014. AKI defined by serum creatinine criteria as in KDIGO (2012), see Table A for details. 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; ESRD, end-stage renal disease, FY, federal fiscal year (October 1, 2013 to September 30, 2014).

Rates of AKI are strongly influenced by age, as shown in Figure 5.3. Among fee-for-service Medicare patients in 2014, the rate of AKI for those ages 66–69 is 19.1 per 1,000 patient years, increasing to 26.7, 40.2, 57.8, and 89.7 respectively, for ages 70–74, 75–79, 80–84, and 85 years and older. Between 2003 and 2012, unadjusted rates of AKI increased across all age ranges. Data from 2013 and 2014 show a plateau or slight decrease in AKI rates. In the Medicare population, the overall unadjusted rate of

AKI decreased from a peak of 43.0 per 1,000 patient years in 2012 to 41.8 per 1,000 patient years in 2014. Among Clinformatics™ patients, the overall AKI rate peaked at 3.3 per 1,000 patient years in 2011 and was 3.3 per 1,000 patient years in 2014. Among Clinformatics™ patients aged 66 and older, the 2011 rate was 22.5 per 1,000 patient-years and fell to 21.0 per 1,000 patient-years in 2014.

vol 1 Figure 5.3 Unadjusted rates of first hospitalization with AKI, per 1,000 patient-years at risk, by age and year, 2004-2014

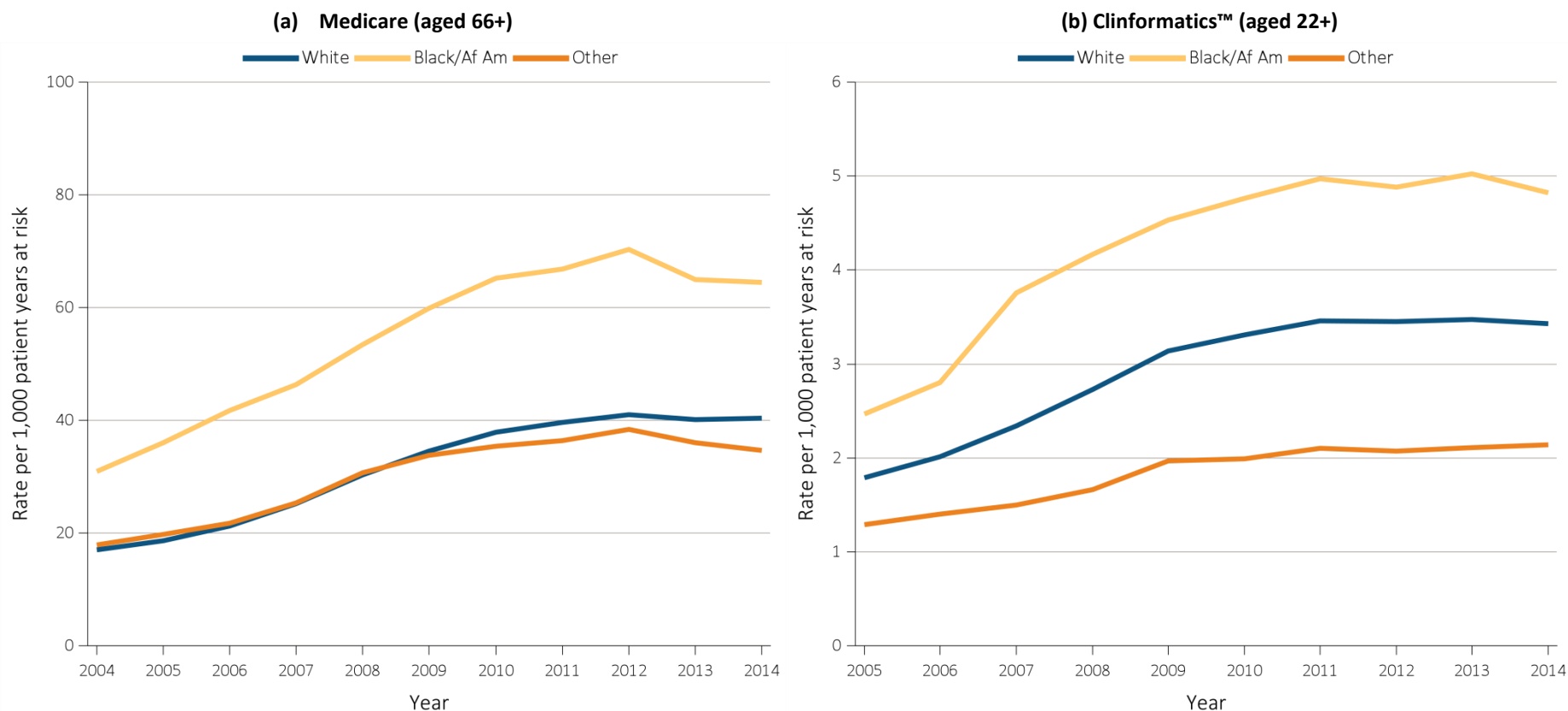


Data Source: Special analyses, Medicare 5% sample and Clinformatics™. (a) Age as of January 1 of specified year. All patient-years at risk for Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, no ESRD by first service date from Medical Evidence form, and were alive on January 1 of year shown. Censored at death, ESRD, end of Medicare Part A & B participation, or switch to Medicare Advantage program. (b) All patient-years at risk for 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. Abbreviation: AKI, acute kidney injury; ESRD, end-stage renal disease.

Figure 5.4 highlights differences in rates of AKI by race. In 2014, among fee-for-service Medicare patients aged 66 and older, the incidence rate was 64.5 per 1,000 patient years at risk in Blacks compared to 40.3 and 34.7, respectively, in Whites and individuals of other races. A similar relationship was observed in the Clinformatics™ population, albeit at much lower rates: 4.8, 3.4, and 2.1 per 1,000 patient years at risk in Blacks, Whites and individuals of other races, respectively. Rates have been flat

in the Clinformatics™ population since 2011, while in the Medicare population there has been a slight decrease since 2012. This decrease in AKI rates was noted in all race groups and was most pronounced in Blacks and individuals of other races, who had relative decreases (8.3% and 9.9%) between 2012 and 2014 respectively, compared to a 1.5% decrease among Whites.

vol 1 Figure 5.4 Unadjusted rates of first hospitalization with AKI, per 1,000 patient-years at risk, by race and year, 2004-2014



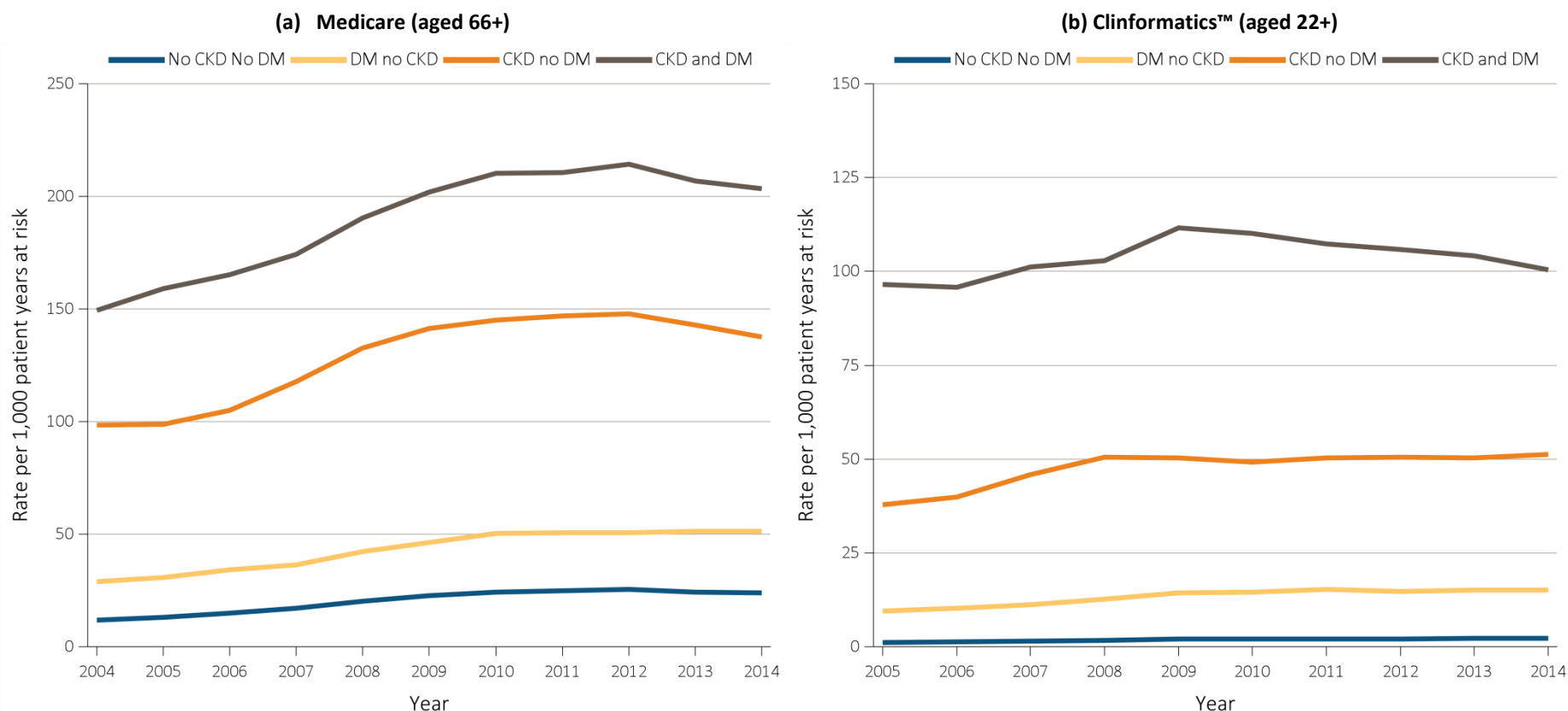
Data Source: Special analyses, Medicare 5% sample and Clinformatics™. (a) All patient-years at risk for Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, no ESRD by first service date from Medical Evidence form, and were alive on January 1 of year shown. Censored at death, ESRD, end of Medicare Part A & B participation, or switch to Medicare Advantage program. (b) All patient-years at risk for 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: Af Am, African American; AKI, acute kidney injury; ESRD, end-stage renal disease.

As shown in Figure 5.5, incidence rates for AKI also vary substantially by underlying comorbidity. In 2014, Medicare patients with diabetes and no known CKD had an AKI incidence rate of 51.2 per 1,000 patient years compared to 24.0 per 1,000 patient years in non-diabetic, non-CKD patients. Non-diabetic patients with CKD experienced an AKI incidence rate of 137.7 per 1,000 patient years, while the rate in patients with both diabetes and CKD was 203.4 per 1,000 patient years. That is, about 20% of

Medicare patients with both CKD and diabetes will experience a hospitalization with AKI in a given year.

Similar relationships were seen in the Clinformatics™ population, with patients with both CKD and diabetes experiencing the highest rates of AKI hospitalization at 100.5 per 1,000 patient years. However, the overall rates were much lower, presumably reflecting the younger age range.

vol 1 Figure 5.5 Unadjusted rates of first hospitalization with AKI, per 1,000 patient-years at risk, by CKD, DM, and year, 2004-2014



Data Source: Special analyses, Medicare 5% sample and 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 Part A & B participation, or switch to Medicare Advantage program. (b) All patient-years at risk for 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. Abbreviations: AKI, acute kidney injury; CKD, chronic kidney disease; DM, diabetes mellitus; ESRD, end-stage renal disease.

Hospitalization Associated With Acute Kidney Injury

Figures 5.6 and 5.7 show the probability of a recurrent AKI hospitalization after live discharge following an AKI hospitalization. Among Medicare patients aged 66 and older, in 2012 the overall probability of a recurrent AKI event is 0.35 in the next 12 months and 0.47 by 24 months, as shown in 5.6.a. Among Clinformatics™ patients, these probabilities are 0.18 and 0.26, respectively. In contrast to first episodes, the rate of recurrent AKI is relatively similar across age groups in the fee-for-service Medicare population (5.6.b); however, interpretation of this finding is limited due to the effect of death censoring, which is higher in older age groups.

In both the Medicare and 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 diabetes or CKD is associated with an increased probability for recurrent AKI compared to having neither (Figures 5.6.d and 5.7.d). The highest probability for recurrent AKI is seen in patients with both diabetes and CKD, reaching 0.58 by 24 months among Medicare patients and 0.45 among Clinformatics™ patients. In contrast, Medicare patients with neither comorbidity have a cumulative probability for recurrent AKI hospitalization of 0.31 by 24 months, while their Clinformatics™ counterparts have a probability of 0.22 by 24 months.

vol 1 Figure 5.6 Cumulative probability of a recurrent AKI hospitalization within two years of live discharge from first AKI hospitalization in 2012 for Medicare patients aged 66+, (a) overall, (b) by age, (c) by race, and (d) by CKD and DM

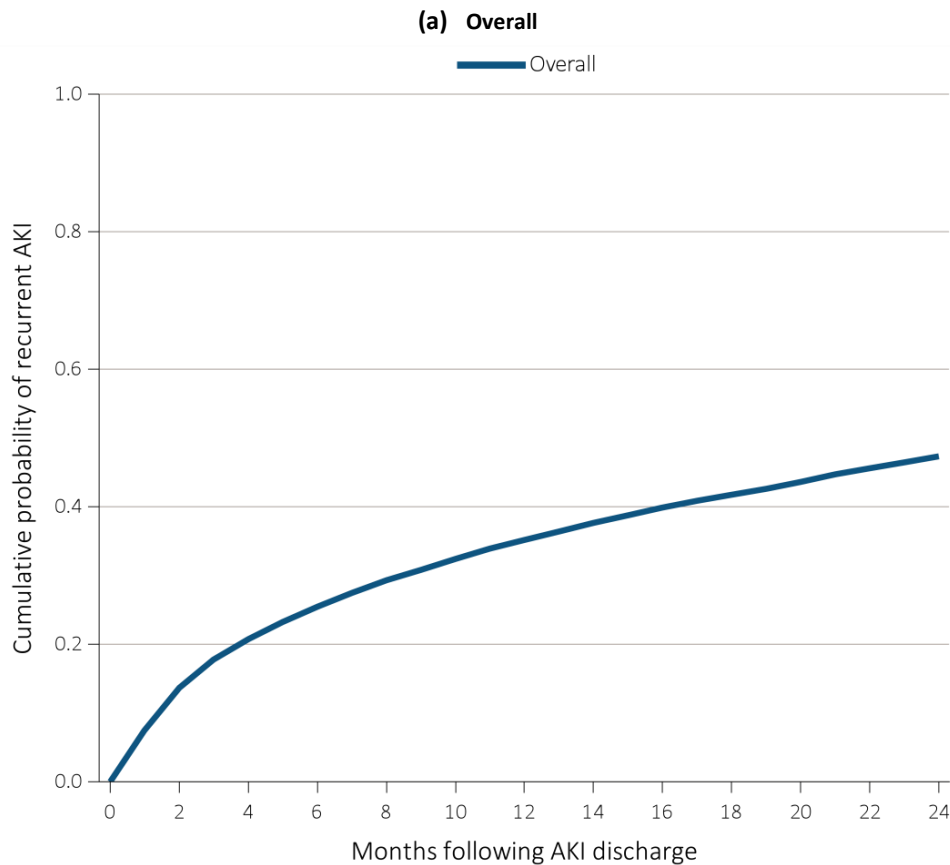


Figure 5.6 continued on next page.

vol 1 Figure 5.6 Cumulative probability of a recurrent AKI hospitalization within two years of live discharge from first AKI hospitalization in 2012 for Medicare patients aged 66+, (a) overall, (b) by age, (c) by race, and (d) by CKD and DM (continued)

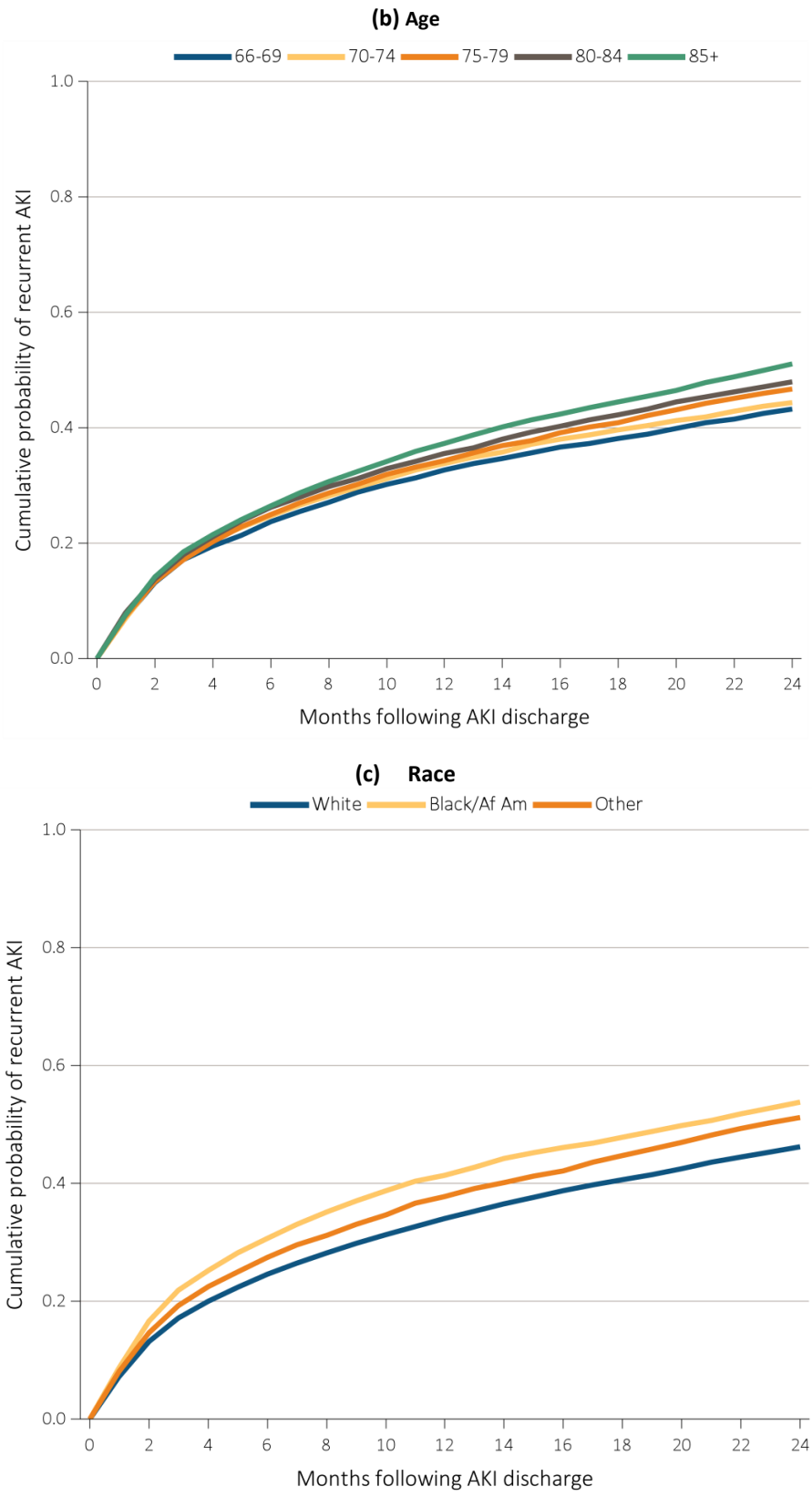
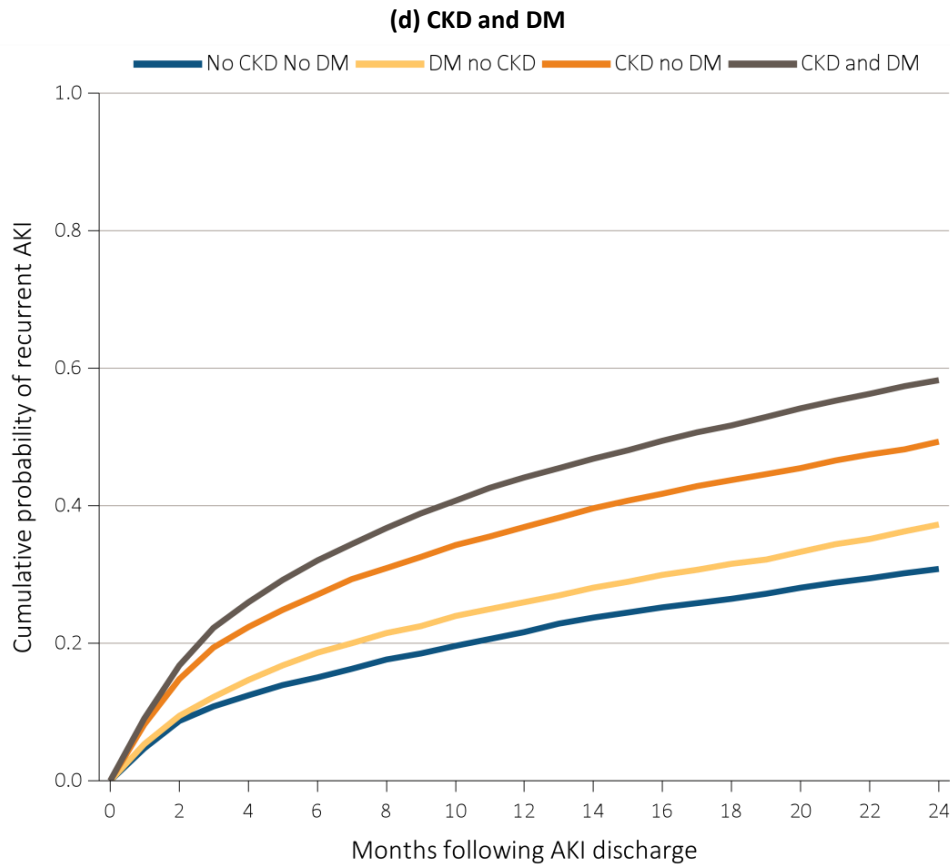


Figure 5.6 continued on next page.

vol 1 Figure 5.6 Cumulative probability of a recurrent AKI hospitalization within two years of live discharge from first AKI hospitalization in 2012 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, 2012. 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 1/1/2012, and were discharged alive from an AKI hospitalization in 2012. Censored at death, ESRD, end of Medicare Part 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 2012 for Clinformatics™ patients aged 22+, (a) overall, (b) by age, (c) by race, and (d) by CKD and DM

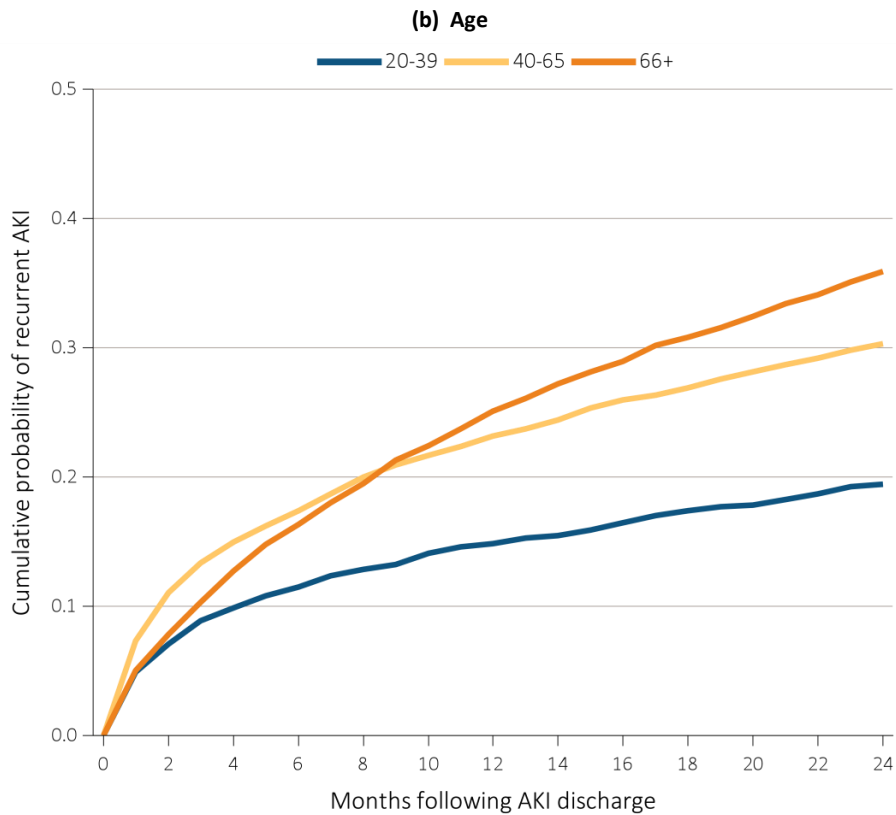
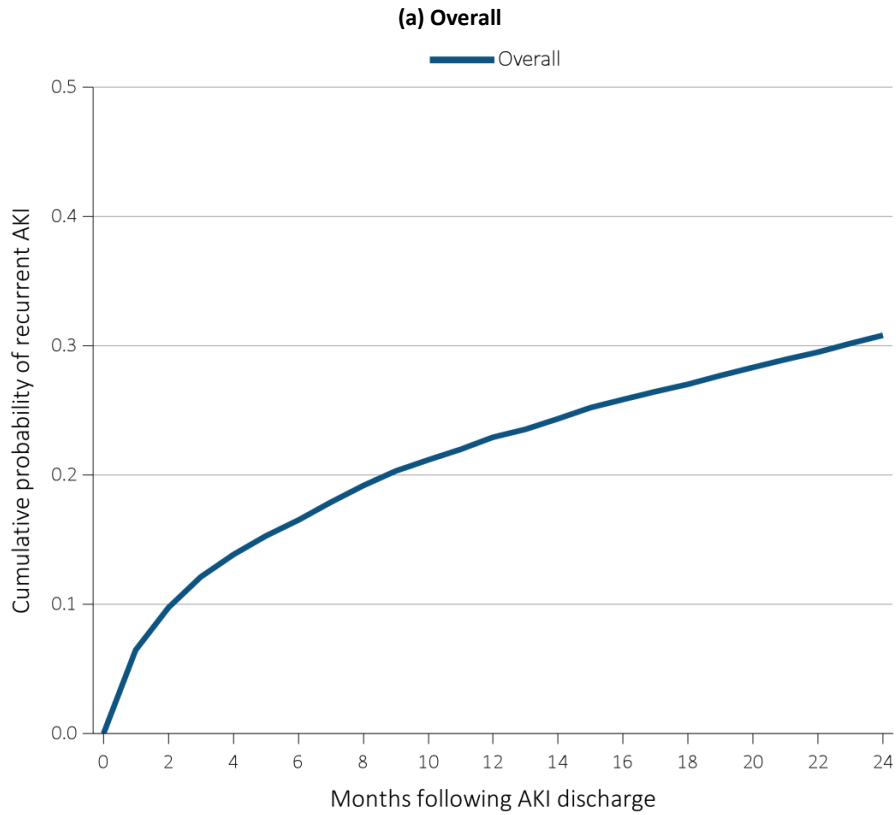
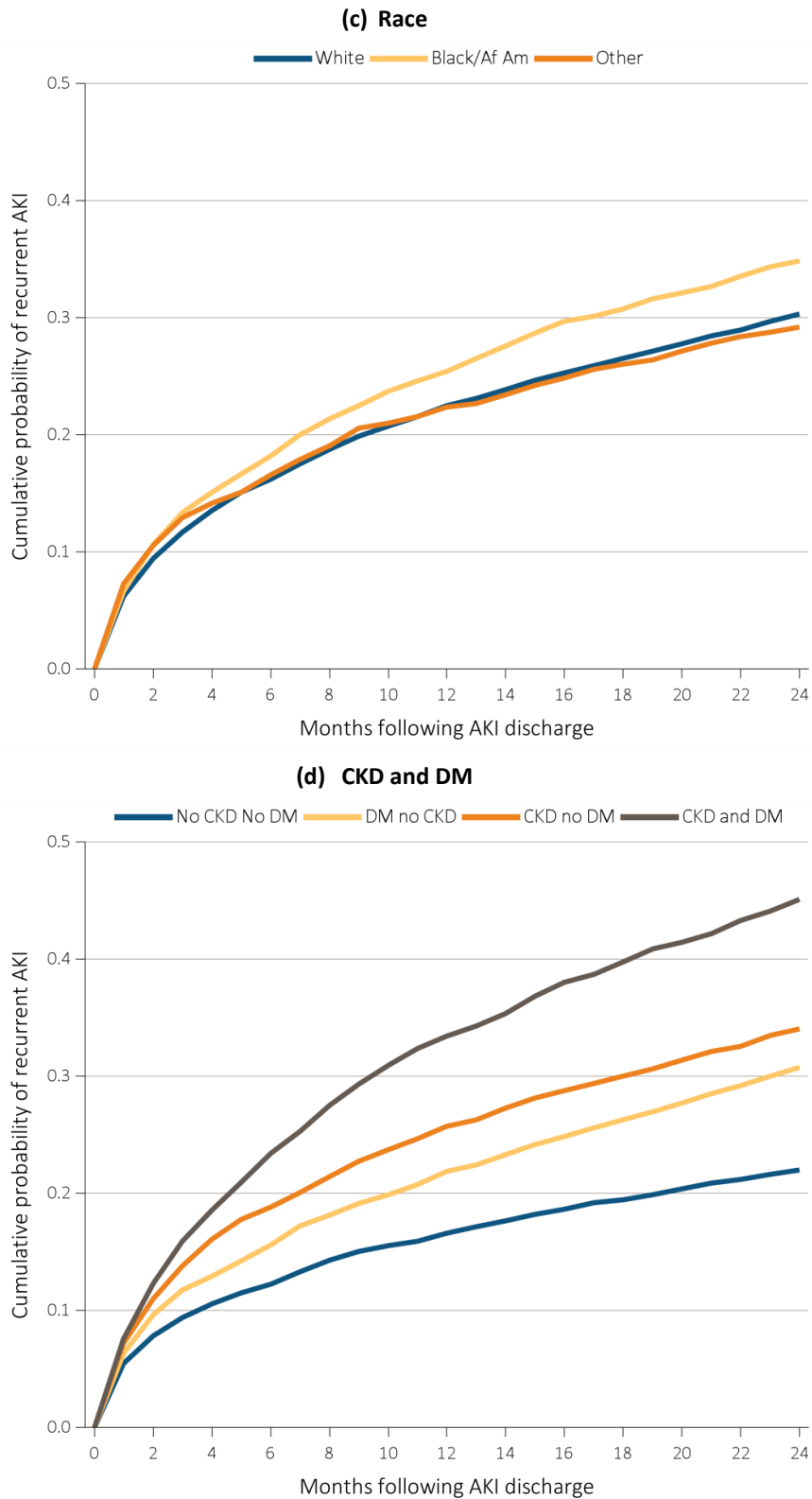


Figure 5.7 continued on next page.

vol 1 Figure 5.7 Cumulative probability of a recurrent AKI hospitalization within two years of live discharge from first AKI hospitalization in 2012 for Clinformatics™ patients aged 22+, (a) overall, (b) by age, (c) by race, and (d) by CKD and DM (continued)



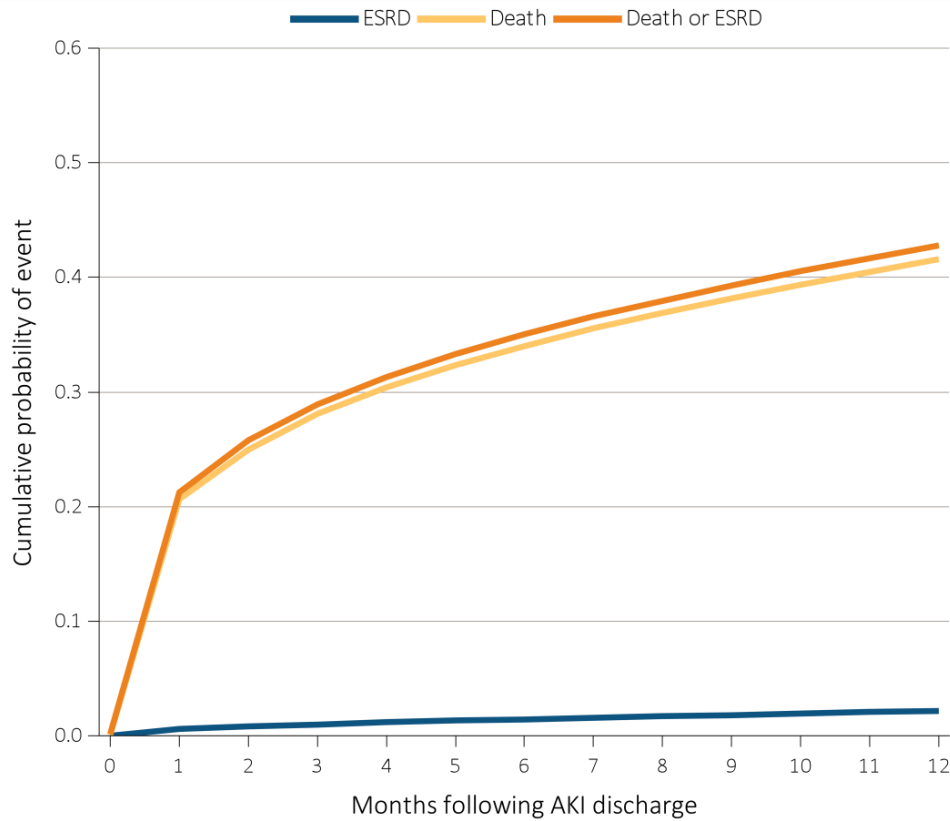
Data Source: Special analyses, Clinformatics™. Age as of January, 2012. Clinformatics™ commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD on January 1, 2012, and were discharged alive from an AKI hospitalization in 2012. Censored at death, ESRD diagnosis, or plan disenrollment. Abbreviations: AKI, acute kidney injury; CKD, chronic kidney disease; DM, diabetes mellitus; ESRD, end-stage renal disease.

Patient Care and Outcomes

Poor short-term outcomes for AKI, including hospital mortality, are well-recognized. Figure 5.8 shows that survivors of an AKI hospitalization (those discharged alive) continue to face significant risk for

adverse outcomes following discharge. Among survivors of an AKI hospitalization in 2012-2013, the overall probability of developing ESRD in the following year is about 2% in the Medicare fee-for-service population aged 66 and older. In this same time frame, the probability of death is nearly 42%.

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 2012-2013 for Medicare patients aged 66+



Data Source: Special analyses, Medicare 5% sample. 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 2012 or 2013. All models censored at the end of Medicare Part A & B participation, switch to Medicare Advantage program, or 365 days after AKI discharge. Model for ESRD also is censored at death. Model for death is not censored at the start of ESRD. Abbreviations: AKI, acute kidney injury; ESRD, end-stage renal disease.

In 2013, 16% of Medicare patients discharged alive from an AKI hospitalization had outpatient nephrology follow-up within the next six months, while 17% of 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 without diabetes, 19% and 26% were seen by a nephrologist within six months following discharge in the Medicare and Clinformatics™ populations, respectively. For patients with both CKD and diabetes, these

proportions rose to 25% and 36%, respectively. In contrast, just 3% of Medicare and 8% of Clinformatics™ AKI patients without diabetes or CKD were seen by a nephrologist by six months following AKI hospitalization.

Trends over the past decade show a slight decrease in post-AKI hospitalization nephrology follow-up in both the Medicare and Clinformatics™ populations. This may once again reflect code creep: milder cases of AKI are being captured by diagnosis, but these may be 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, by CKD, DM, 2004-2013

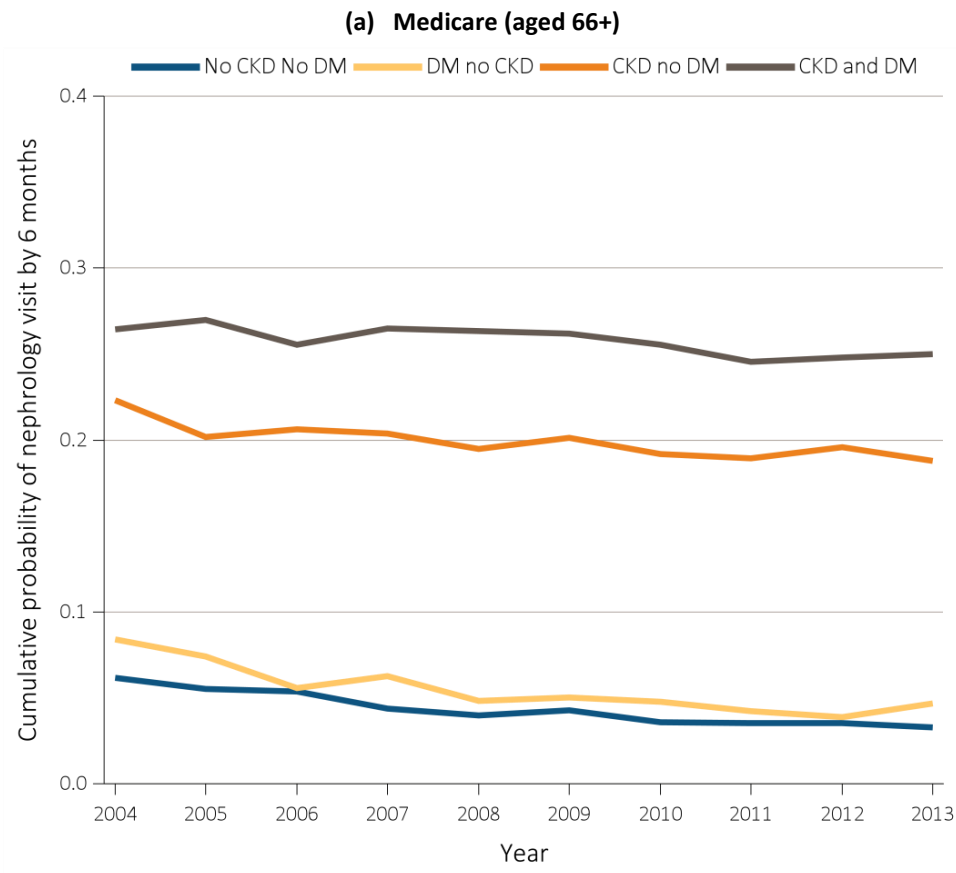
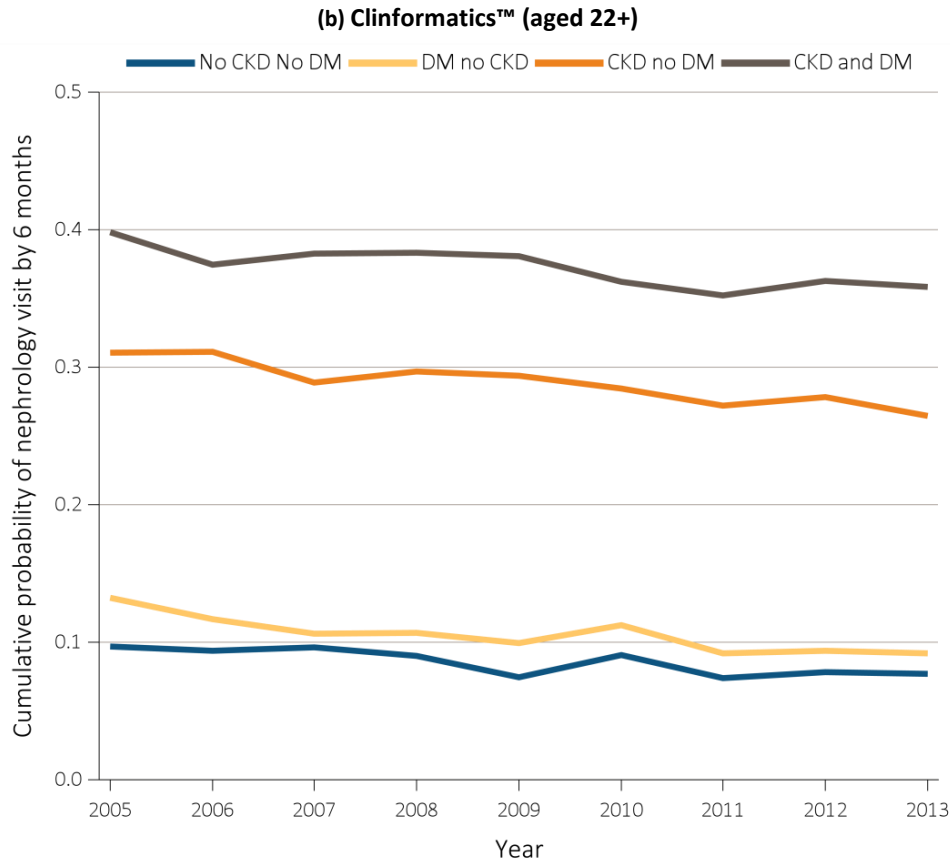


Figure 5.9 continued on next page.

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, by CKD, DM, 2004-2013 (continued)

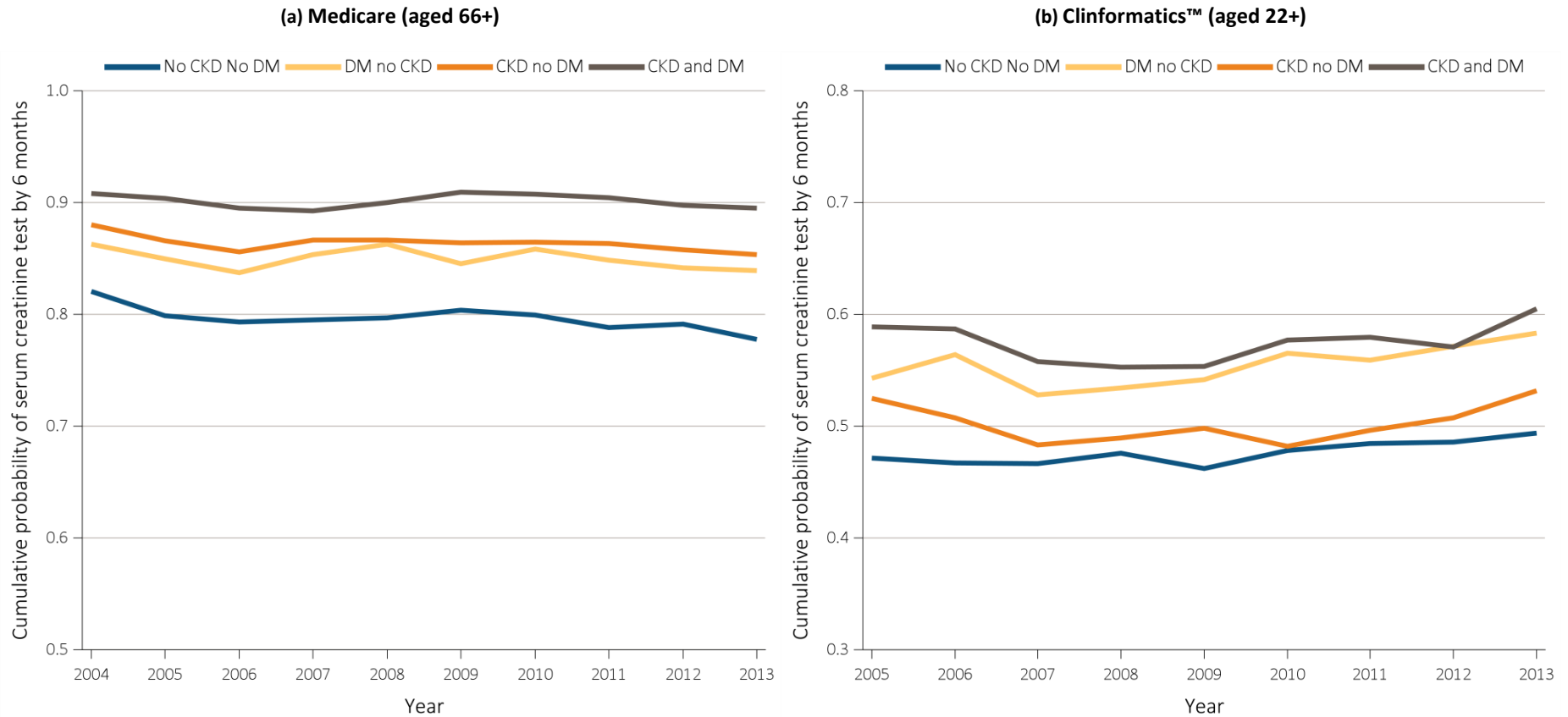


Data Source: Special analyses, Medicare 5% sample and Clinformatics™. (a) Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, no ESRD by first service date from Medical Evidence form on January 1 of year shown and were discharged alive from a first AKI hospitalization during the year. Censored at death, ESRD, end of Medicare Part 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) 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.

While not all patients with an AKI hospitalization will require formal nephrology follow-up, arguably most (if not all) should have some follow-up biochemical renal assessment. Figures 5.10 and 5.11 show the probability of serum creatinine and urine albumin testing within six months following live discharge from a hospitalization with AKI diagnosis. Of those patients with AKI in 2013, 85% had a follow-up creatinine test billed to Medicare by six months after hospitalization discharge, while 15% had urine albumin testing billed by this point. Among Clinformatics™ patients, 54% had serum creatinine

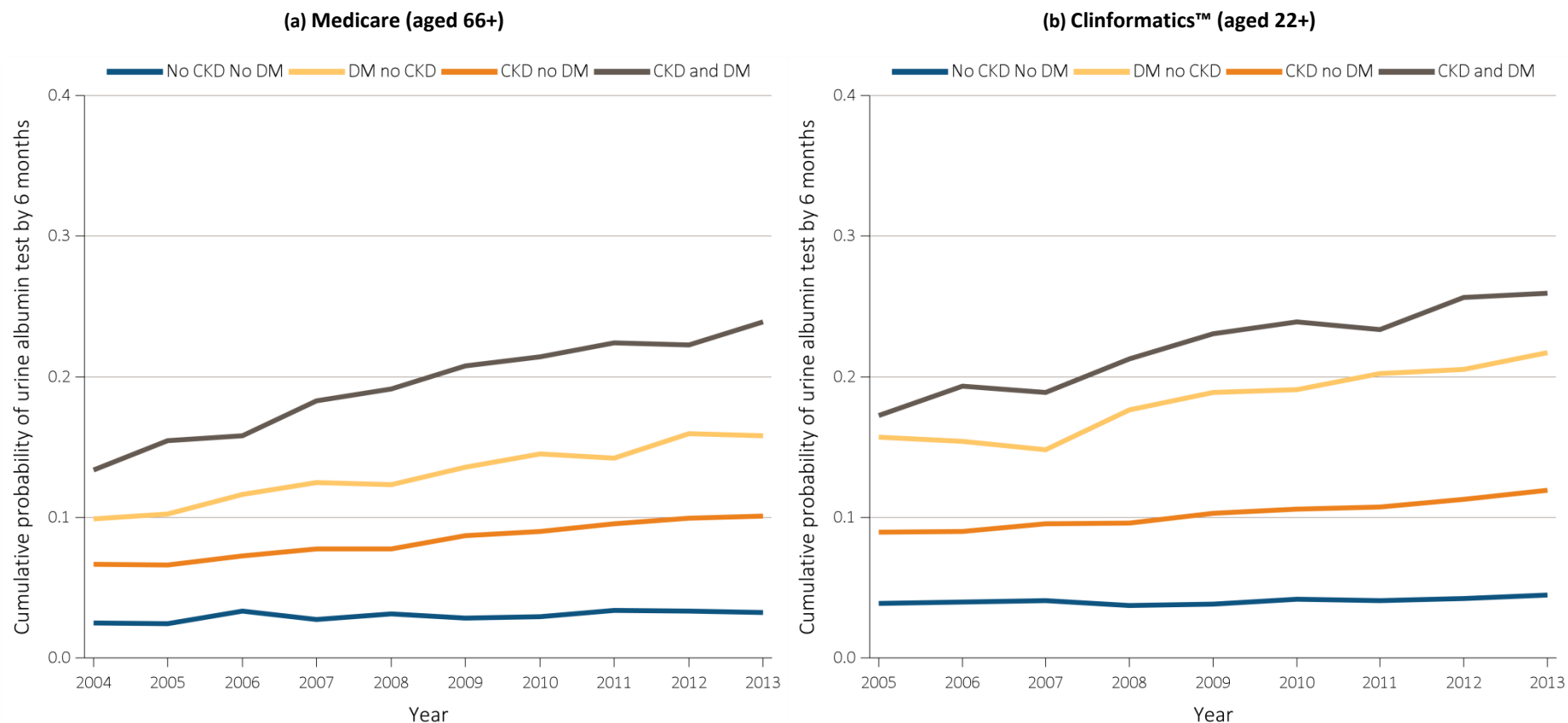
testing and 14% had urine albumin testing. In both the Medicare and Clinformatics™ populations, rates of serum creatinine testing by six months varied by diabetes and CKD status. Among Medicare beneficiaries, this ranged from 78% in patients with neither comorbidity to 89% in patients with both. Greater variation by comorbidity was seen in the probability of urine albumin testing; among Clinformatics™ patients, albumin testing occurred in 4% of patients without pre-existing CKD or diabetes, compared to 26% in patients with both.

vol 1 Figure 5.10 Cumulative probability of a claim for a serum creatinine test within six months of live discharge from first AKI hospitalization by CKD, DM, 2004-2014



Data Source: Special analyses, Medicare 5% sample and 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 in year shown. Censored at death, ESRD, end of Medicare Part A & B participation, or switch to Medicare Advantage program. (b) 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 diagnosis, or plan disenrollment. In both panels, date of first serum creatinine test following AKI discharge is from inpatient and outpatient claims with Healthcare Common Procedure Coding System (HCPCS) codes of 80048, 80050, 80053, 80069, or 82565. Abbreviations: AKI, acute kidney injury; CKD, chronic kidney disease; DM, diabetes mellitus; ESRD, end-stage renal disease.

vol 1 Figure 5.11 Cumulative probability of a claim for an urine albumin test within six months of live discharge from first AKI hospitalization by CKD, DM, 2004-2014



Data Source: Special analyses, Medicare 5% sample and Clinformatics™. (a) Medicare patients aged 66 and older who had both Medicare Parts A and 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 in 2013. Censored at death, ESRD, end of Medicare Part A & B participation, or switch to Medicare Advantage program. (b) 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 diagnosis, or plan disenrollment. In both panels, date of first urine albumin test following AKI discharge is from inpatient and outpatient claims with Healthcare Common Procedure Coding System (HCPCS) codes of 82042, 82043, 82044, or 84156. Abbreviations: AKI, acute kidney injury; CKD, chronic kidney disease; DM, diabetes mellitus; ESRD, end-stage renal disease.

Changes in CKD Status After Acute Kidney Injury

CKD status changes significantly in the year following an AKI hospitalization, as shown in Figure

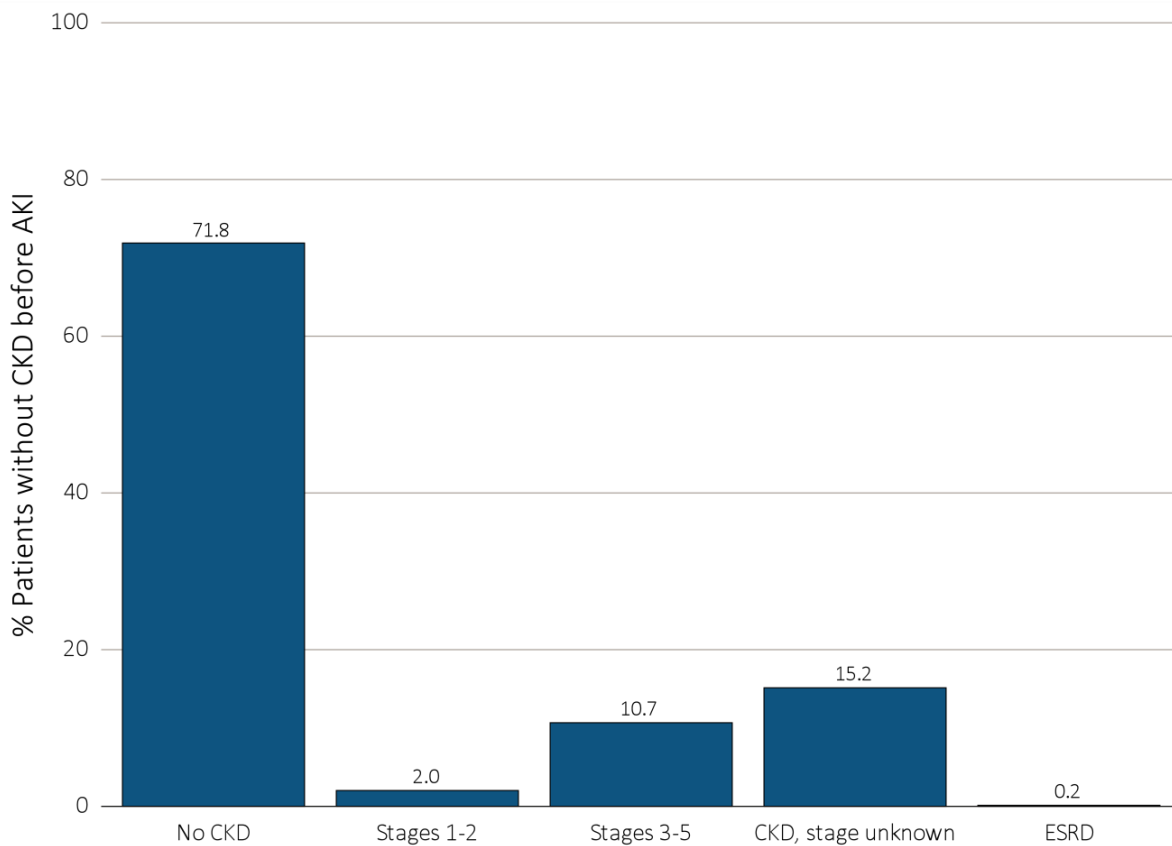
5.12. Among Medicare patients without baseline CKD, nearly 30% are reclassified as having some degree of CKD, including 0.2% being declared ESRD. Table B shows the ICD-9-CM diagnosis codes used to define stages of chronic kidney disease for Figure 5.12.

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 is 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 5.12 Renal status one year following discharge from AKI hospitalization in 2012-2013, among surviving Medicare patients aged 66+ without kidney disease prior to AKI hospitalization, by CKD stage and ESRD status

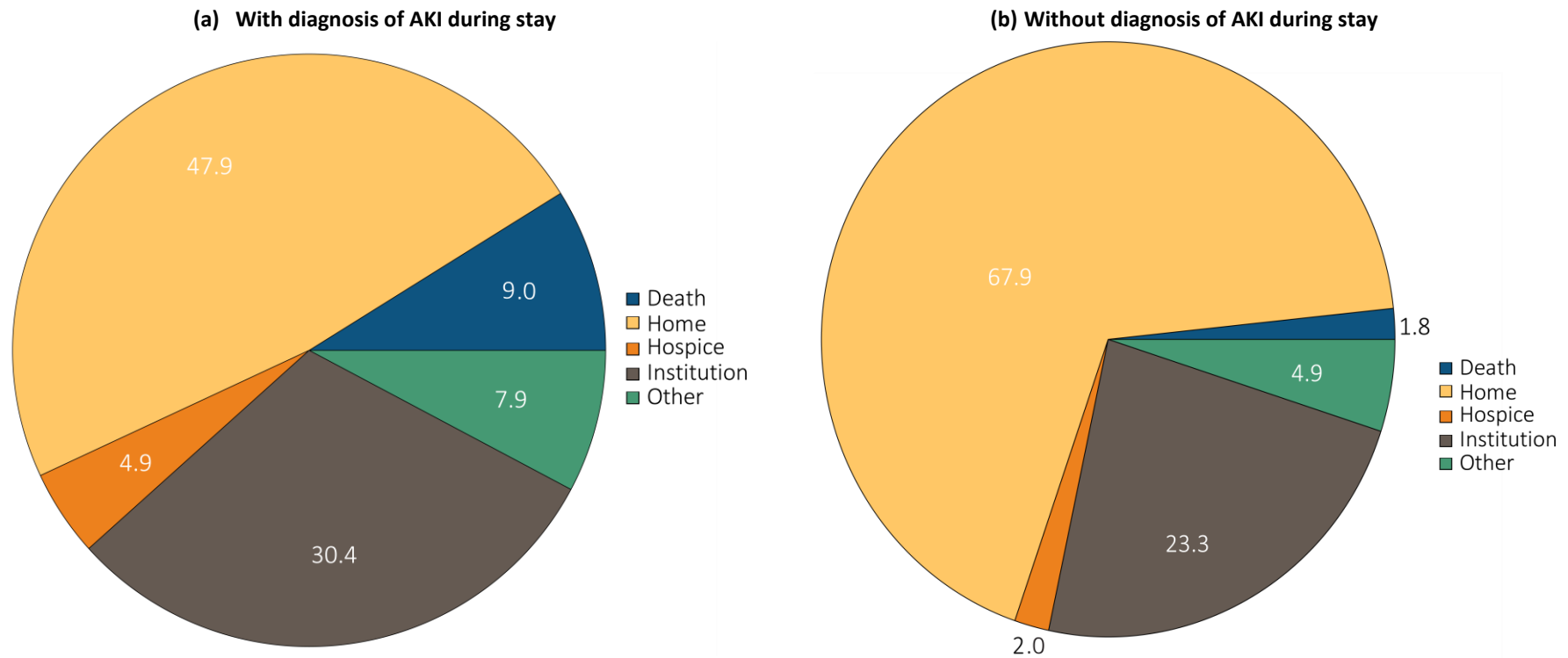


Data Source: Special analyses, Medicare 5% sample. Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, did not have ESRD, were discharged alive from a first AKI hospitalization in 2012 or 2013, and did not have any claims with a diagnosis of CKD in the 365 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.

In Figure 5.13, we examine the status and disposition for Medicare AKI patients once they are discharged from the hospital. After excluding patients admitted from a skilled nursing facility (n=1,997, leaving a total of 51,150 AKI discharges), among AKI patients aged 66 and older in 2014, fewer than 48% were discharged directly to their home. Mortality (including discharge to hospice) was 13.9%, while 30.4% of patients were

discharged to institutions including short-term skilled nursing facility stays, rehabilitation hospitals, or long-term care facilities. By comparison, among hospitalized Medicare patients without a diagnosis of AKI (excluding those admitted from a skilled nursing facility, n= 3,315, leaving a total of 172,802 discharges), nearly 68% returned home and 23.3% are discharged to institutions.

vol 1 Figure 5.13 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, 2014



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 1/1/2014, had a first hospitalization in 2014, 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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Notes

Chapter 6:

Medicare Expenditures for Persons With CKD

- Medicare spending for beneficiaries aged 65 and older who have Chronic Kidney Disease (CKD) exceeded \$50 billion in 2014, 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 exceeded \$8 billion in 2014, representing 44% of spending in this age group (Table 6.2).
- Beneficiaries aged 65 and older with diagnoses of CKD, diabetes, or congestive heart failure accounted for two-thirds of the growth in Medicare spending between 2013 and 2014 (\$2 billion of the total \$3 billion; Figure 6.1).
- Over 70% of total Medicare spending for beneficiaries with CKD who were aged 65 and older was incurred by those who also had diabetes, congestive heart failure, or both (Table 6.1).
- Spending per patient year was more than twice as high for those with all three chronic conditions of CKD, diabetes, and congestive heart failure (\$38,561) than for beneficiaries with only CKD (\$15,673; Table 6.1).
- In 2014, spending for Black/African-American beneficiaries with CKD exceeded that for those of White race by 14.6%, an increase from the 12.9% disparity observed in 2013 (Table 6.3).

Introduction

Determining the economic impact of CKD on a health care system is challenging. As noted in this 2016 Annual Data Report (ADR), Volume 1, Chapters [1](#), [2](#), and [3](#), under-recognition of CKD affects estimates of CKD-related expenditures in several ways:

- Biochemical measures of renal function and urine testing for proteinuria support the most definitive criteria, but health plan datasets, including Medicare's, rarely contain this information on a reliable or large scale.
- Even when health care data contain complete laboratory results, CKD is substantially under-identified as many persons with underlying CKD are not tested for the condition.
- Identification of persons with CKD using ICD-9-CM (International Classification of Diseases, 9th Revision, Clinical Modification) diagnosis codes will underestimate total CKD expenditures, as formal diagnoses of CKD are

not commonly documented early in the disease process.

- Assuming that under-identification is most common in the earliest and least costly cases, estimates of cost per patient year (PPY) based on diagnoses of CKD found in claims are likely to be biased upwards. To the extent that under-identification is not constant over time, caution needs to be exercised in the interpretation of trend data.

Future efforts to increase CKD identification may also bias estimates of CKD-related health system costs. For example, if the true total number of cases (and therefore true costs) in the population is constant, greater identification of CKD over time might give the appearance of increased total expenditures related to CKD, as the number of identified cases grows.

As alluded to above, greater identification will likely have the opposite effect on trends in PPY expenditures, as the newly identified cases are likely to be less severe. In addition, it is not possible to

accurately attribute health care expenditures solely to kidney disease; the costs of CKD are influenced by its interactive nature and associations with conditions, such as diabetes mellitus (DM), hypertension (HTN), and cardiovascular diseases (CVD) such as coronary artery disease, cerebrovascular disease, peripheral arterial disease, and congestive heart failure (CHF).

The use of Medicare billing data to accurately describe total Medicare expenditures is becoming increasingly problematic. Medicare pays for service to persons in managed care plans (“Medicare Advantage”) on a monthly capitated basis, thus specific billing data are not available for all beneficiaries. In recent years, enrollment in Medicare managed care plans has accelerated, possibly due to the enhanced Part D prescription drug coverage in these plans. The percent of Medicare beneficiaries enrolled in managed care increased from 13% in 2004 to 30% in 2014 (Kaiser, 2016), thus, while this chapter’s analyses include the majority of Medicare beneficiaries with CKD, data for a significant percentage are potentially missing.

Methods

This chapter uses data from the Medicare 5% sample for fee-for-service 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.

The methodology we employed to calculate costs related to CKD (excluding end-stage renal disease [ESRD]) utilizes ICD-9-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) in 2014. 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, costs are defined as Medicare expenditures rather than true economic costs, using claims from Medicare Parts A, B, and D as based on the 5% Medicare sample for calendar year 2014. In addition to reporting on the population aged 65 and older, this year we add information on beneficiaries younger than 65 who generally were Medicare-eligible due to disability.

See the *CKD Analytical Methods* chapter for a further explanation of analytical methods used to generate the figures and tables in this chapter.

Spending for CKD and Related Chronic Comorbidities

Examining Medicare costs reinforces CKD’s reputation as a cost multiplier. Beneficiaries with recognized CKD, who represented 10% of the point prevalent aged Medicare population, accounted for 20% of total expenditures (see Tables 6.1 and 6.2 for the aged 65 and older and under-65 populations, respectively). We examined 2014 costs in relation to beneficiaries’ CKD stage, age, sex, race, and concurrent disease, focusing on DM and CHF. These conditions, in addition to CKD, represent some of the costliest chronic disease populations for Medicare. CHF, for example, affects 9% of beneficiaries in the fee-for-service Medicare population, but accounts for 21% 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 costs were 101% higher for those with CKD only versus those with no CKD, DM, or CHF (\$15,673 vs \$7,812). Costs for those with CKD and DM were 54% higher than those with DM only. Similarly, expenditures for those with CKD and CHF were 47% higher than those with CHF alone. For beneficiaries with CKD, CHF, and DM, costs were 44% higher than for those with only CHF and DM. Overall, people with diagnoses of CKD, DM, and/or CHF accounted for one-third of the Medicare aged 65 and older population, but over half of total programmatic costs.

vol 1 Table 6.1 Prevalent Medicare fee-for-service patient counts and spending for beneficiaries aged 65 and older, by DM, CHF, and/or CKD, 2014

	U.S. Medicare Population	Total Costs (millions, U.S. \$)	PPPY Costs (U.S. \$)	Population (%)	Costs (%)
All	24,496,020	\$254,356	\$10,803	100.00	100.00
With CHF or CKD or DM	8,140,540	\$130,220	\$17,013	33.23	51.20
CKD only (- DM & CHF)	1,023,220	\$15,109	\$15,673	4.18	5.94
DM only (- CHF & CKD)	4,093,320	\$47,846	\$12,116	16.71	18.81
CHF only (- DM & CKD)	893,760	\$16,955	\$20,733	3.65	6.67
CKD and DM only (- CHF)	847,220	\$14,856	\$18,610	3.46	5.84
CKD and CHF only (- DM)	340,300	\$8,829	\$30,395	1.39	3.47
DM and CHF only (- CKD)	515,500	\$12,599	\$26,758	2.10	4.95
CKD and CHF and DM	427,220	\$14,025	\$38,561	1.74	5.51
No CKD or DM or CHF	16,355,480	\$124,136	\$7,812	66.77	48.80
All CKD (+/- DM & CHF)	2,637,960	\$52,819	\$21,857	10.77	20.77
All DM (+/- CKD & CHF)	5,883,260	\$89,327	\$16,003	24.02	35.12
All CHF (+/- DM & CKD)	2,176,780	\$52,409	\$26,975	8.89	20.60
CKD and DM (+/- CHF)	1,274,440	\$28,882	\$24,854	5.20	11.36
CKD and CHF (+/- DM)	767,520	\$22,854	\$34,935	3.13	8.99
DM and CHF (+/- CKD)	942,720	\$26,625	\$31,902	3.85	10.47

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

For the under age 65 Medicare population, one-fourth had one or more of CKD, DM, and/or CHF,

accounting for 44% of spending for this group (Table 6.2).

vol 1 Table 6.2 Prevalent Medicare fee-for-service patient counts and spending for beneficiaries younger than age 65, by DM, CHF, and/or CKD, 2014

	U.S. Medicare Population	Total Costs (millions, U.S. \$)	PPPY Costs (U.S. \$)	Population (%)	Costs (%)
All	5,121,280	\$61,479	\$12,524	100.00	100.00
With CHF or CKD or DM	1,322,060	\$26,830	\$21,479	25.82	43.64
CKD only (- DM & CHF)	101,280	\$2,199	\$23,125	1.98	3.58
DM only (- CHF & CKD)	837,480	\$13,531	\$16,882	16.35	22.01
CHF only (- DM & CKD)	102,740	\$2,292	\$23,678	2.01	3.73
CKD and DM only (- CHF)	115,440	\$3,022	\$28,325	2.25	4.92
CKD and CHF only (- DM)	22,120	\$743	\$37,972	0.43	1.21
DM and CHF only (- CKD)	89,400	\$2,774	\$33,358	1.75	4.51
CKD and CHF and DM	53,600	\$2,269	\$49,049	1.05	3.69
No CKD or DM or CHF	3,799,220	\$34,649	\$9,468	74.19	56.36
All CKD (+/- DM & CHF)	292,440	\$8,232	\$30,764	5.71	13.39
All DM (+/- CKD & CHF)	1,095,920	\$21,596	\$20,813	21.40	35.13
All CHF (+/- DM & CKD)	267,860	\$8,078	\$32,865	5.23	13.14
CKD and DM (+/- CHF)	169,040	\$5,291	\$34,592	3.30	8.61
CKD and CHF (+/- DM)	75,720	\$3,011	\$45,757	1.48	4.90
DM and CHF (+/- CKD)	143,000	\$5,043	\$38,966	2.79	8.20

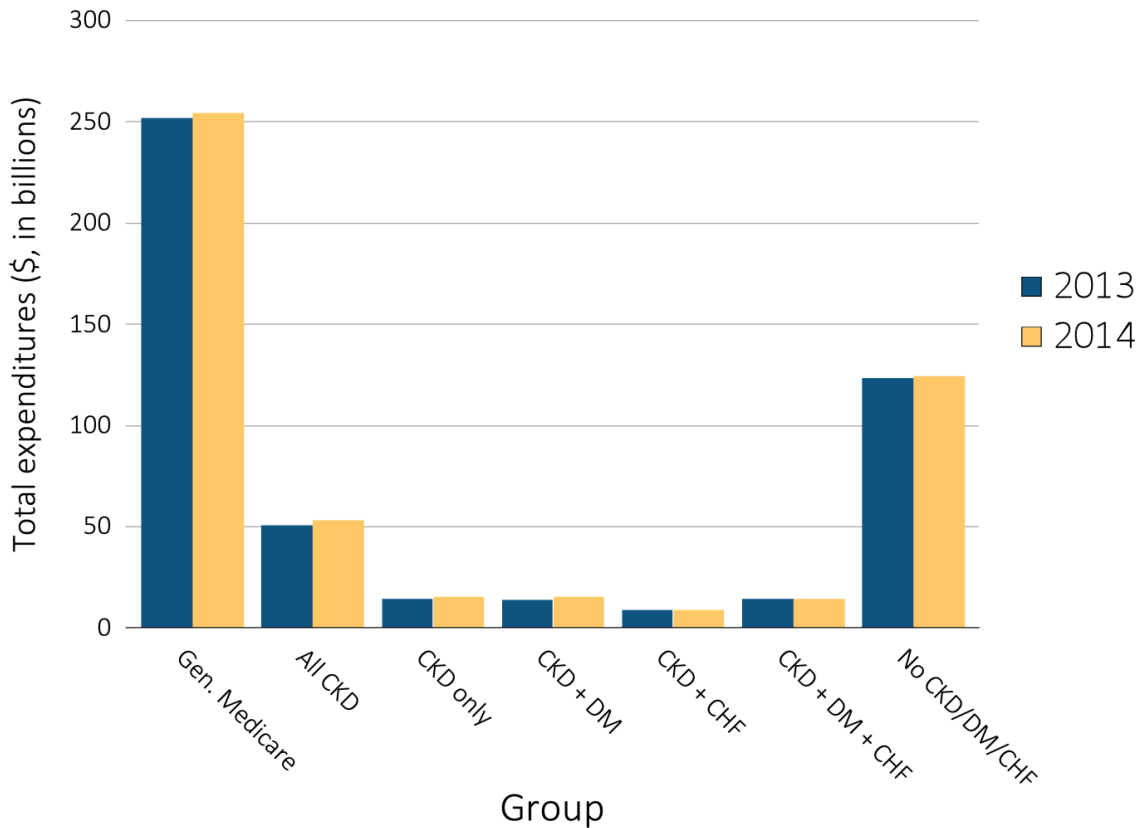
Data Source: Medicare 5% sample. Abbreviations: CKD, chronic kidney disease; CHF, congestive heart failure; DM, diabetes mellitus; PPPY, per patient per year costs.

Spending for CKD by Stage and Patient Characteristics

Among the general Medicare population aged 65 and older, total spending for Parts A, B, and D rose by \$3 billion to \$254 billion between 2013 and 2014. Total spending rose by \$2.2 billion to \$52.8 billion among CKD patients (Figure 6.1). Therefore, spending growth among CKD patients accounted for most of the costs increase in Medicare expenditures during this year. Further, Medicare expenditures were higher for

beneficiaries with CKD than beneficiaries with ESRD (\$52.8 billion vs. \$30.9 billion; see Volume 2, Chapter 11, *Medicare Expenditures for Persons with ESRD*). Costs for beneficiaries with CKD now represent 20.8% 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 ADR Volume 1, Figure 2.2 and Table 6.3).

vol 1 Figure 6.1 Overall Medicare Parts A, B, and D fee-for-service spending for beneficiaries aged 65 and older, by CKD, DM, CHF, and year, 2013 & 2014



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

Table 6.3 presents overall per person per year (PPPY) costs of Parts A, B, and D services for beneficiaries with CKD (but not ESRD), by stage of CKD (see Table A for definitions). In 2014, PPPY costs reached \$21,857 for Medicare CKD patients aged 65 and older, a slight decrease from 2013 (\$22,000). This decreased spending was observed in CKD Stages 1-2 and 3, while the costs in Stages 4-5 increased slightly from 2013 to 2014. During this period, the distribution of identified patient years also shifted towards the less severe and less costly stages. In 2014, costs for

beneficiaries with Stages 4-5 CKD (\$28,541) were 49.6% greater than for beneficiaries with Stages 1-2 CKD (\$19,075). Although the number of beneficiaries with unknown/unspecified CKD stage decreased slightly, it still accounted for one-third of all cases of CKD. The PPPY costs for unknown/unspecified were similar to those in the overall CKD population. Spending for Black/African-American beneficiaries with CKD exceeded that for Whites by 14.6%, an increase over the 12.9% disparity observed in 2013.

vol 1 Table 6.3 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, race, and year, 2013 & 2014

	2013					2014				
	Any CKD	Stages 1-2	Stage 3	Stages 4-5	Unk/Unspc	Any CKD	Stages 1-2	Stage 3	Stages 4-5	Unk/Unspc
Patient years at risk	2,300,185	227,240	1,023,212	229,794	819,940	2,416,542	248,264	1,125,979	227,522	814,776
All patients	\$22,000	\$19,926	\$21,339	\$27,580	\$21,836	\$21,857	\$19,075	\$21,176	\$28,541	\$21,781
Age										
65-69	\$21,054	\$17,013	\$20,891	\$31,048	\$20,387	\$20,672	\$17,301	\$20,399	\$30,169	\$20,085
70-74	\$20,374	\$17,545	\$19,566	\$26,823	\$20,707	\$20,365	\$17,440	\$19,957	\$28,312	\$20,172
75-79	\$21,537	\$20,037	\$20,904	\$26,564	\$21,431	\$21,432	\$17,389	\$20,857	\$28,836	\$21,647
80-84	\$22,464	\$21,296	\$21,549	\$27,563	\$22,444	\$22,104	\$20,458	\$21,127	\$27,564	\$22,344
85+	\$23,819	\$23,691	\$23,167	\$27,319	\$23,463	\$23,874	\$23,123	\$22,823	\$28,472	\$23,899
Sex										
Male	\$21,638	\$19,849	\$21,312	\$26,960	\$21,147	\$21,452	\$18,868	\$20,993	\$28,061	\$21,143
Female	\$22,322	\$19,999	\$21,363	\$28,077	\$22,449	\$22,223	\$19,270	\$21,342	\$28,932	\$22,355
Race										
White	\$21,633	\$19,686	\$21,007	\$26,698	\$21,573	\$21,473	\$18,852	\$20,855	\$27,764	\$21,412
Black/African American	\$24,413	\$20,839	\$23,358	\$32,551	\$23,901	\$24,604	\$21,039	\$23,593	\$32,269	\$24,415
Other	\$22,811	\$21,014	\$22,578	\$28,088	\$22,154	\$22,370	\$18,451	\$21,525	\$30,563	\$22,734

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

Table A. 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, 403.9xm & 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 & with no ESRD 2728 form or other indication of end-stage renal disease (ESRD) are considered to have code 585.5.

In Table 6.4, PPPY costs are shown for beneficiaries with both CKD and DM. Among the 2014 Medicare beneficiaries with these two conditions, PPPY costs for

Blacks were \$27,980—14.9% greater than the \$24,347 incurred for Whites.

vol 1 Table 6.4 Per person per year Medicare Parts A, B, and D fee-for-service spending for CKD patients with DM, aged 65 and older, by CKD stage, age, sex, race, and year, 2013 & 2014

	2013					2014				
	Any CKD	Stages 1-2	Stage 3	Stages 4-5	Unk/Unspc	Any CKD	Stages 1-2	Stage 3	Stages 4-5	Unk/Unspc
Patient years at risk	1,100,789	110,908	499,895	120,672	369,313	1,162,039	120,068	549,905	119,511	372,555
All patients	\$25,034	\$22,468	\$24,557	\$31,639	\$24,291	\$24,854	\$21,482	\$24,369	\$32,330	\$24,260
Age										
65-69	\$24,665	\$19,831	\$24,646	\$35,220	\$23,439	\$23,970	\$19,346	\$24,496	\$32,826	\$22,667
70-74	\$23,240	\$20,547	\$22,850	\$29,726	\$22,727	\$23,569	\$20,210	\$23,218	\$32,770	\$22,743
75-79	\$24,517	\$22,397	\$23,965	\$30,320	\$24,064	\$24,376	\$19,584	\$24,146	\$31,704	\$24,090
80-84	\$25,544	\$25,411	\$24,708	\$31,886	\$24,506	\$25,214	\$24,877	\$24,083	\$30,914	\$25,039
85+	\$27,560	\$25,850	\$27,130	\$32,040	\$26,846	\$27,346	\$25,921	\$26,190	\$33,411	\$26,959
Sex										
Male	\$24,105	\$21,913	\$23,976	\$30,246	\$23,131	\$23,899	\$21,157	\$23,721	\$31,034	\$23,008
Female	\$25,928	\$23,030	\$25,133	\$32,765	\$25,413	\$25,790	\$21,821	\$25,020	\$33,379	\$25,490
Race										
White	\$24,670	\$22,102	\$24,217	\$30,861	\$24,093	\$24,347	\$21,196	\$23,886	\$31,216	\$23,900
Black/African American	\$27,073	\$23,419	\$26,339	\$35,701	\$25,747	\$27,980	\$22,991	\$27,077	\$37,360	\$27,201
Other	\$25,242	\$23,934	\$25,170	\$30,824	\$23,930	\$24,832	\$21,589	\$25,023	\$32,828	\$23,314

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

Table 6.5 shows PPPY costs for beneficiaries with CKD and concurrent CHF. In 2014, PPPY costs for Black beneficiaries with both conditions reached

\$40,381—18.8% higher than the \$34,003 PPPY cost for their White counterparts.

vol 1 Table 6.5 Per person per year Medicare Parts A, B, and D fee-for-service spending for CKD patients with CHF, aged 65 and older, by CKD stage, age, sex, race, and year, 2013 & 2014

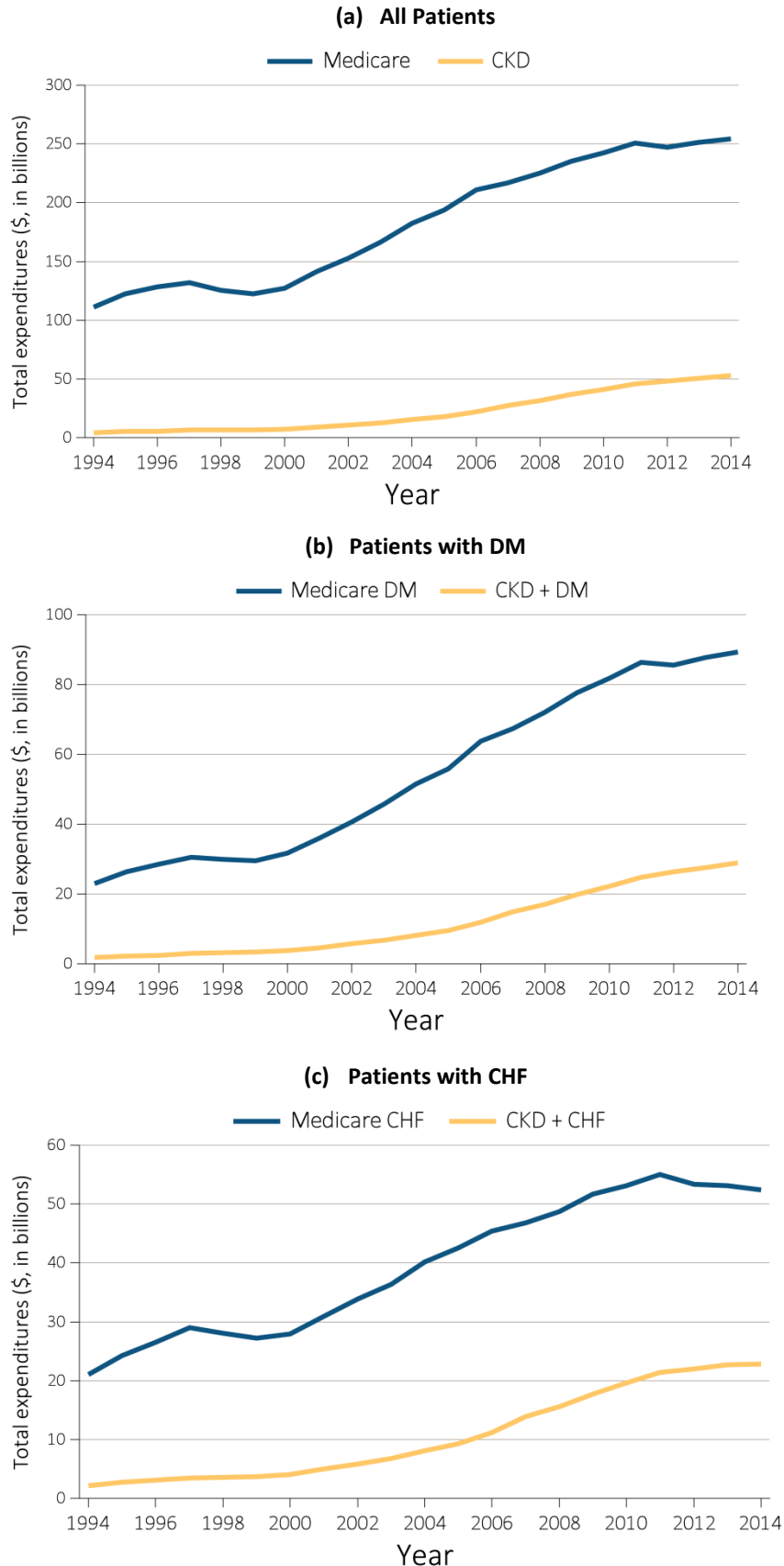
	2013					2014				
	Any CKD	Stages 1-2	Stage 3	Stages 4-5	Unk/Unspc	Any CKD	Stages 1-2	Stage 3	Stages 4-5	Unk/Unspc
Patient years at risk	650,103	55,549	289,311	85,624	219,619	654,178	55,376	307,849	83,484	207,469
All patients	\$34,876	\$34,247	\$34,704	\$39,045	\$33,638	\$34,935	\$32,433	\$34,544	\$40,904	\$33,783
Age										
65-69	\$39,632	\$35,199	\$39,416	\$50,130	\$37,742	\$38,821	\$35,443	\$38,226	\$48,717	\$37,075
70-74	\$36,251	\$34,125	\$36,037	\$39,043	\$36,113	\$35,832	\$29,128	\$35,852	\$42,876	\$35,328
75-79	\$35,995	\$35,625	\$35,685	\$39,639	\$35,082	\$36,241	\$31,037	\$35,947	\$43,423	\$35,355
80-84	\$34,416	\$34,794	\$33,919	\$38,352	\$33,374	\$34,054	\$34,510	\$33,344	\$39,060	\$32,937
85+	\$32,255	\$32,551	\$32,368	\$36,069	\$30,537	\$33,015	\$32,744	\$32,641	\$37,718	\$31,589
Sex										
Male	\$33,763	\$33,639	\$34,184	\$38,429	\$31,491	\$34,071	\$31,914	\$33,843	\$39,830	\$32,802
Female	\$35,875	\$34,810	\$35,197	\$39,531	\$35,504	\$35,715	\$32,932	\$35,216	\$41,766	\$34,616
Race										
White	\$34,182	\$33,238	\$34,148	\$37,803	\$33,103	\$34,003	\$31,565	\$33,765	\$39,763	\$32,753
Black/African American	\$38,725	\$37,758	\$37,761	\$45,665	\$36,847	\$40,381	\$36,094	\$39,766	\$46,374	\$39,611
Other	\$37,325	\$40,393	\$37,004	\$40,186	\$35,604	\$38,027	\$35,999	\$36,121	\$44,233	\$38,915

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

Over time, the costs for Medicare beneficiaries aged 65 and older with recognized CKD have accounted for an increasing share of Medicare expenditures, expanding from 4.2% in 1995 to 7.7% in 2003, and 20.8% in 2014. 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*. Persons aged 65 and older with CKD accounted for 1.7%, 3.8%, and 11.1% of the Medicare population in 1995, 2003, and 2014.

Figure 6.2 presents total expenditures on Part A, B, and D services for Medicare fee-for-service beneficiaries with CKD and other conditions. In 2014, expenditure for CKD patients was \$52.8 billion, accounting for 20.8% of the total spending for all Medicare beneficiaries. Costs for beneficiaries with CKD and concurrent DM amounted to \$28.9 billion in 2014, or 32.3% of total Medicare spending on DM. Spending on CHF in the Medicare population was \$52.4 billion in 2014. Of this, \$22.9 billion (43.6%) was spent on the CKD patient population with CHF.

vol 1 Figure 6.2 Overall Medicare Parts A, B, and D fee-for-service spending for general Medicare population aged 65 and older and for those with CKD, by year, 1994-2014

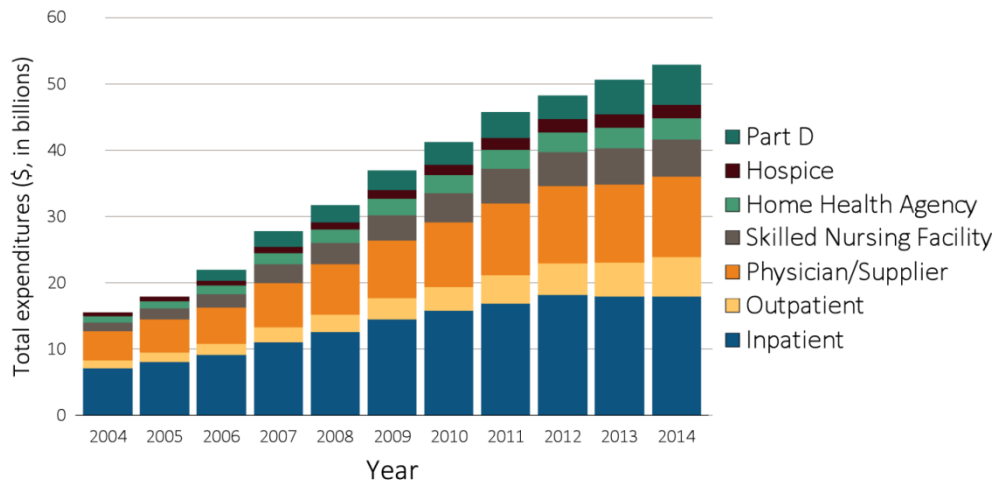


Data Source: Medicare 5% sample. Abbreviations: CKD, chronic kidney disease; CHF, congestive heart failure.

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 Medicare expenditures required to provide inpatient care was 34% in 2014, while outpatient costs were predictably lower at 11%. Physician/supplier service costs amounted to 23% in

2014, while those for skilled nursing facility care reached 11% (Figure 6.3). In the Medicare non-CKD population, these expenditure percentages were 29% to provide inpatient care, 14% for outpatient, 28% for Physician/supplier services, and 8% those for skilled nursing facility care.

vol 1 Figure 6.3 Trends in total Medicare Parts A, B, and D fee-for-service spending for CKD patients aged 65 and older, by claim type, 2004-2014

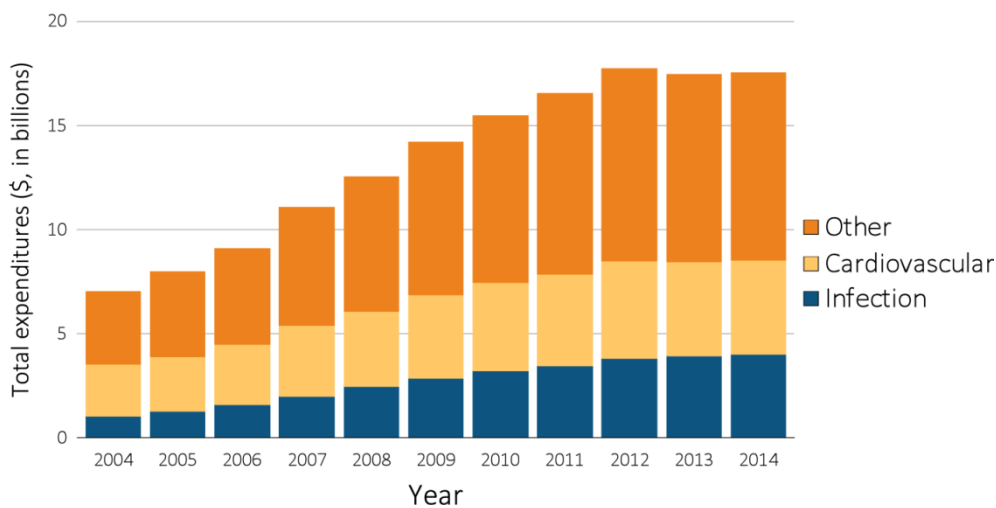


Data source: Medicare 5% sample. Part D data was initiated since 2006.

Hospitalization costs accounted for a large proportion of spending for CKD. Of the 2014 inpatient hospitalization spending for those with CKD, 49%

resulted from admissions to treat infections (23%) and cardiovascular conditions (26%; Figure 6.4).

vol 1 Figure 6.4 Total Medicare fee-for-service inpatient spending for CKD patients aged 65 and older, by cause of hospitalization, 2004-2014

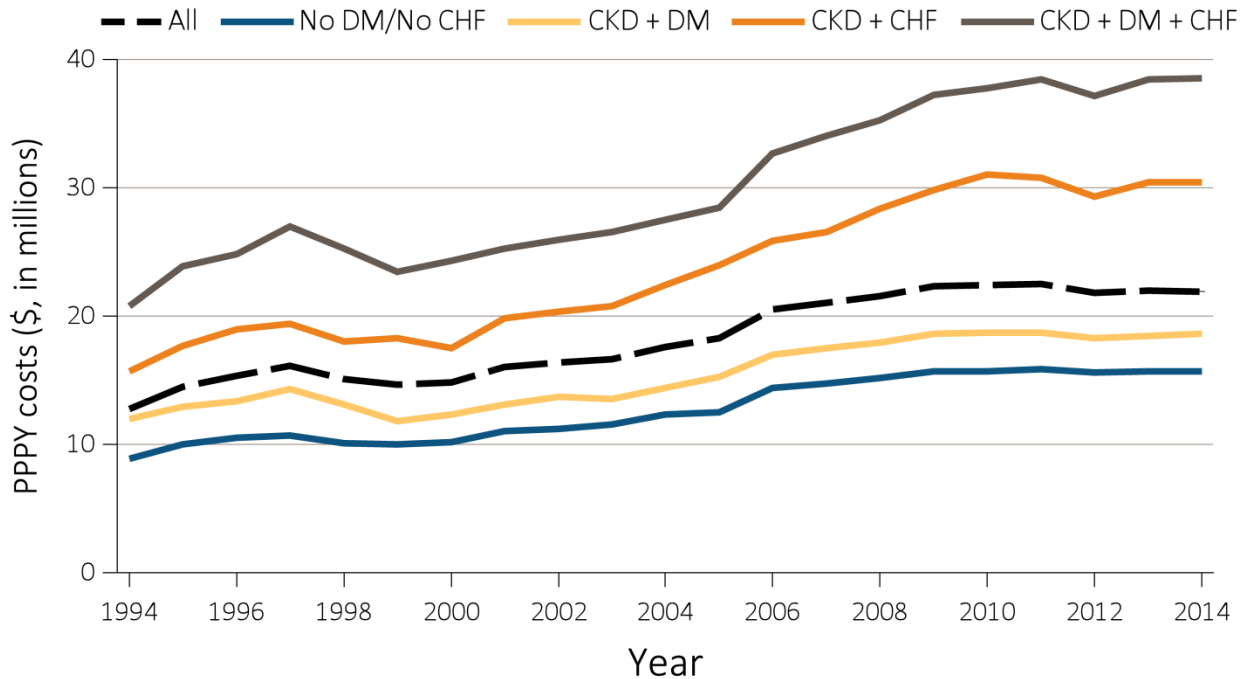


Data source: Medicare 5% sample. Part D data was initiated since 2006.

Figure 6.5 illustrates PPPY costs for Medicare CKD patients aged 65 and older by the presence of DM and CHF. In 2014, PPPY costs for CKD patients varied greatly by the presence of these comorbidities. CKD patients without DM and CHF cost \$15,672 per person

per year. Those with DM in addition to CKD averaged \$18,609 PPPY, and beneficiaries with CKD and CHF cost \$30,395; expenditures for those with all three conditions reached \$38,561 PPPY in 2014.

vol 1 Figure 6.5 Per person per year Medicare Parts A, B, and D fee-for-service spending for the CKD patients aged 65 and older, by DM, CHF, and year, 1994-2014



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

Conclusion

The analysis of Medicare expenses for beneficiaries with CKD indicates avenues for potential cost savings, enduring racial cost disparities, and the effect of cost containment efforts in this population. Potential savings 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 CHF. Beneficiaries with CKD, DM, and CHF, alone or in combination, account for the vast majority of spending growth in the entire aged 65 or older Medicare non-ESRD population. In the Medicare CKD population, Black beneficiaries continue to exhibit higher costs in all disease categories as compared to Whites and those of other races. Finally, a large portion of CKD hospitalization costs occur for infection or cardiovascular causes.

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).

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Notes

Chapter 7: Medicare Part D Prescription Drug Coverage in Patients With CKD

- Approximately 71% of chronic kidney disease (CKD) patients are enrolled in Medicare Part D, including both the stand-alone and Medicare Advantage plans. The Part D enrollment rate for this group is slightly higher than in the general Medicare population (66%), but lower than for the ESRD population (77%; Figure 7.1).
- As compared to Whites (22%), higher proportions of Asian (70%) and Black/ African American (52%) CKD patients qualify for Part D coverage with the Low-income Subsidy (LIS; Figure 7.3).
- The percentage of beneficiaries who receive the LIS is higher for CKD patients across all age and race categories than among the general Medicare population (Figures 7.2 and 7.3).
- In 2014, per patient per year (PPPY) Medicare Part D spending for CKD patients was 50% higher than for general Medicare beneficiaries, at \$4,198 as compared to \$2,806 (Figure 7.5a).
- Total Medicare spending for Part D-covered medications in 2014 was more than twice as high for CKD patients with the LIS (\$7,352) than for those without (\$3,262). Patient out-of-pocket costs represented only a 1% share of these total expenditures, as compared to 29% in each of the non-LIS populations (Figure 7.5b).
- Prescriptions for HMG-CoA Reductase Inhibitors (statins) and β -Adrenergic Blocking Agents (β blockers) were each filled by more than 50% of the CKD patient group during 2014, and over one third had at least one claim for opiate agonists, loop diuretics, proton-pump inhibitors, antidepressants, or angiotensin-converting enzyme inhibitors (ACEIs). By drug class, the Medicare Part D program spent the greatest amount on insulins, followed by antineoplastic agents (Tables 7.6 and 7.7).

Introduction

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 prescription drug plan (PDP) or through a Medicare Advantage (MA) managed care plan, which provides medical as well as prescription benefits. CKD patients have the option to enroll in an MA plan; end-stage renal disease (ESRD) patients, in contrast, are precluded from entering an MA plan if they are not already enrolled in one when they reach ESRD. Enrollment data are available for beneficiaries with both types of plans, however actual spending data are only available for beneficiaries in stand-alone plans. In 2014, 45% of general Medicare beneficiaries were enrolled in a stand-alone Medicare Part D PDP, while

23% received coverage through an MA plan (Kaiser, 2016).

Before 2006, Medicare beneficiaries obtained drug coverage through various avenues—insurance 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. After 2006, the majority of Medicare enrollees obtained Part D coverage.

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 are charged higher premiums once they do enroll. Consequently, 66% of general Medicare beneficiaries, 71% of CKD patients, and 77% of ESRD patients were enrolled in Part D in 2014. Other Medicare-enrolled CKD patients choose to

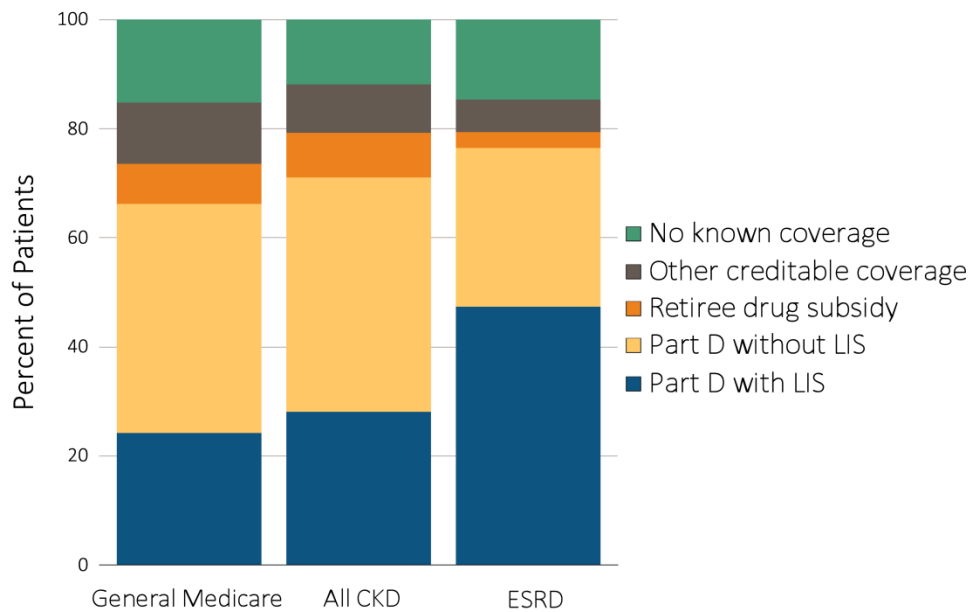
obtain outpatient medication benefits through retiree drug subsidy plans or other creditable coverage such as employer group health plans, other private coverage, or Veterans Administration benefits. Some enrollees remain uninsured and pay out-of-pocket for their outpatient prescription medications.

Between 2011 and 2014, the percentage of CKD patients with Part D coverage increased from 59% to 71%. In 2014, the proportion of CKD patients with no known coverage was 12%, lower than the 15% seen in the general Medicare population.

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 Part D coverage was expanded to include benzodiazepines with no restrictions, and barbiturates when prescribed for specific indications.

Before the Medicare Part D program began, beneficiaries dually-enrolled in Medicare and Medicaid received prescription benefits under state Medicaid programs. The Part D program offers a substantial Low-income Subsidy (LIS) benefit to enrollees with limited assets and income, including those who are 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”). In 2014, 40% of CKD patients enrolled in Part D qualified for the LIS, compared with 37% of general Medicare beneficiaries and 62% of ESRD patients (see Figure 7.1). Among Medicare Part D enrollees with CKD, 81% of Asian beneficiaries received the LIS, compared to 67% of Blacks/African Americans and 32% of Whites. Part D spending for identified CKD patients, which represents the sum of the Medicare covered amount and the Low-income Subsidy amount, rose from \$5.2 billion in 2011 to \$7.7 billion in 2014—an increase of 49%, compared to the lesser cost growth of 26% and 65% for general Medicare and ESRD patients.

vol 1 Figure 7.1 Sources of prescription drug coverage in Medicare enrollees, by population, 2014



Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; LIS, Medicare Low-income Subsidy; Part D, Medicare prescription drug coverage benefit.

Out-of-pocket (OOP) Part D costs for CKD patients were higher than for general Medicare beneficiaries, at \$624 versus \$438 per person per year (PPPY) in 2014. However, the out-of-pocket share of total expenditures borne by CKD patients was slightly lower than that experienced by the general Medicare population due to a higher rate of LIS coverage for this group.

Under the Affordable Care Act, the coverage gap (“donut” hole) in the Part D benefit will be phased out by 2020. As part of the phase-out, pharmaceutical manufacturers have provided a 50% discount to non-LIS beneficiaries on the price of brand-name drugs purchased while in the coverage gap, and the Part D plans have paid an additional 2.5% of brand-name costs in the gap. Plans also have paid 28% of the cost of generics purchased by non-LIS beneficiaries in the coverage gap.

Part D Coverage Plans

The Centers for Medicare and Medicaid Services provide prescription drug plans (PDPs) with guidance on structuring a “standard” Part D PDP. The upper portion of Table 7.1 shows the standard benefit design for PDPs in 2009 and 2014. In 2014, for example,

beneficiaries shared costs with the PDP (as co-insurance or copayments) until the combined total reached \$2,850 during the initial coverage period. After reaching this level, beneficiaries went into the coverage gap, or “donut hole,” where they paid 100% of costs.

In 2011 the government began providing non-LIS recipients reaching the coverage gap with more assistance each year. In 2014, beneficiaries received a 50% discount on brand name drugs from manufacturers plus 2.5% coverage from their Part D plans, and plans paid 28% of generic drug costs in the gap. Beneficiaries who paid a yearly out-of-pocket drug cost of \$4,550 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.

vol 1 Table 7.1 Medicare Part D parameters for defined standard benefit, 2009 & 2014

	2009	2014
Deductible		
After the deductible is met, the beneficiary pays 25% of total prescription costs up to the initial coverage limit.	\$295.00	\$310.00
Initial coverage limit		
The coverage gap (“donut hole”) begins at this point.	\$2,700.00	\$2,850.00
The beneficiary pays 100% of their prescription costs up to the out-of-pocket threshold		
Out-of-pocket threshold		
The total out-of-pocket costs including the “donut hole”	\$4,350.00	\$4,550.00
Total covered Part D prescription out-of-pocket spending		
(including the coverage gap). Catastrophic coverage begins after this point.	\$6,153.75	\$6,455.00
Catastrophic coverage benefit		
Generic/preferred multi-source drug	\$2.40	^a \$2.55
Other drugs	\$6.00	^a \$6.35
		^a plus a 52.50% brand name medication discount
2014 Example:		
\$310 (deductible)	\$295.00	\$310
+(((\$2850-\$310)*25%)(initial coverage)	\$601.25	\$635.00
+(((\$6455-\$2850)*100%)(coverage gap)	\$3,453.75	\$3,605.00
Total	\$4,350.00	\$4,550.00
(maximum out-of-pocket costs prior to catastrophic coverage, excluding plan premium)		

^aThe catastrophic coverage amount is the greater of 5% of medication cost or the values shown in the chart above. In 2014, beneficiaries were charged \$2.55 for those generic or preferred multisource drugs with a retail price less than \$51 and 5% for those with a retail price over \$51. For brand name drugs, beneficiaries paid \$6.35 for those drugs with a retail price less than \$127 and 5% for those with a retail price over \$127. Table adapted from <http://www.q1medicare.com/PartD-The-2014-Medicare-Part-D-Outlook.php>.

The proportion of beneficiaries that enrolled in Medicare Part D rose between 2011 and 2014 among general Medicare beneficiaries, patients with CKD, and those with ESRD (Table 7.2). In each year,

enrollment was slightly higher for those with CKD than in the general Medicare population; enrollment has been highest for beneficiaries with ESRD.

vol 1 Table 7.2 General Medicare, CKD, & ESRD patients enrolled in Part D (%)

	General Medicare	All CKD	All ESRD
2011	55.7	59.3	69.9
2012	57.6	60.5	71.7
2013	65.7	69.3	75.2
2014	66.3	71.1	76.5

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

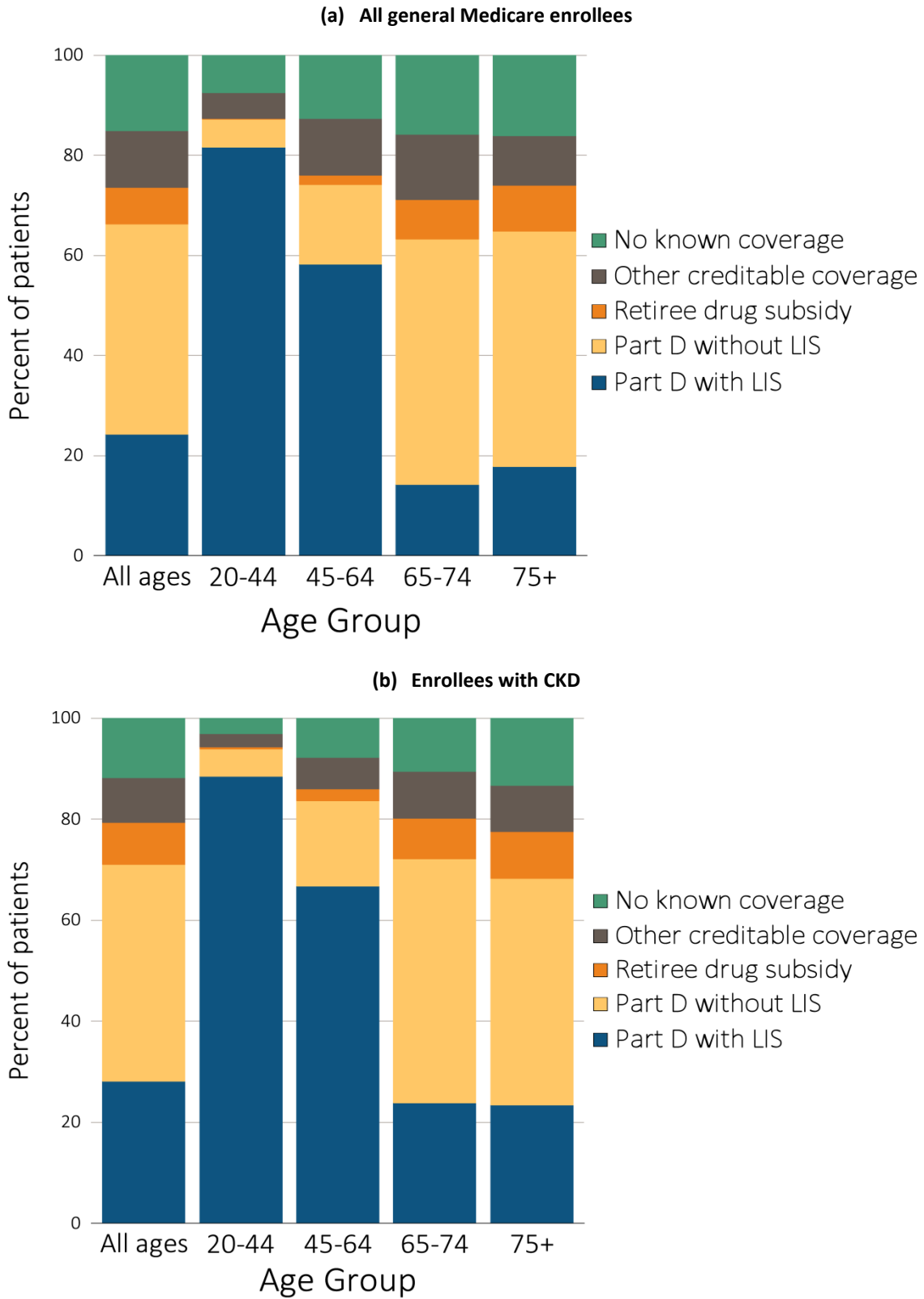
Part D Enrollment Patterns

Approximately 71% of CKD patients enrolled in Medicare Part D (including both stand-alone and MA plans) in 2014, slightly higher than Part D enrollment by those in the general Medicare population (66%) and lower than enrollment by those in the ESRD population (77%). Compared to beneficiaries in the general population, however, a higher percentage of CKD patients qualified for the LIS (Figure 7.1).

Among both general Medicare beneficiaries and those with CKD, the percentage of beneficiaries

enrolled in Part D generally declines with age. In the 75+ age group, similar proportions of general Medicare and CKD patients were enrolled in Part D, at 65–68%. The proportion of beneficiaries with LIS declined with age in both populations with the exception of general Medicare population aged 75 and older, but CKD patients in all age categories were more likely to receive this subsidy (Figure 7.2). Eighty-nine percent of CKD patients aged 20–44 received the LIS in 2014.

vol 1 Figure 7.2 Sources of prescription drug coverage in Medicare enrollees, by age, 2014

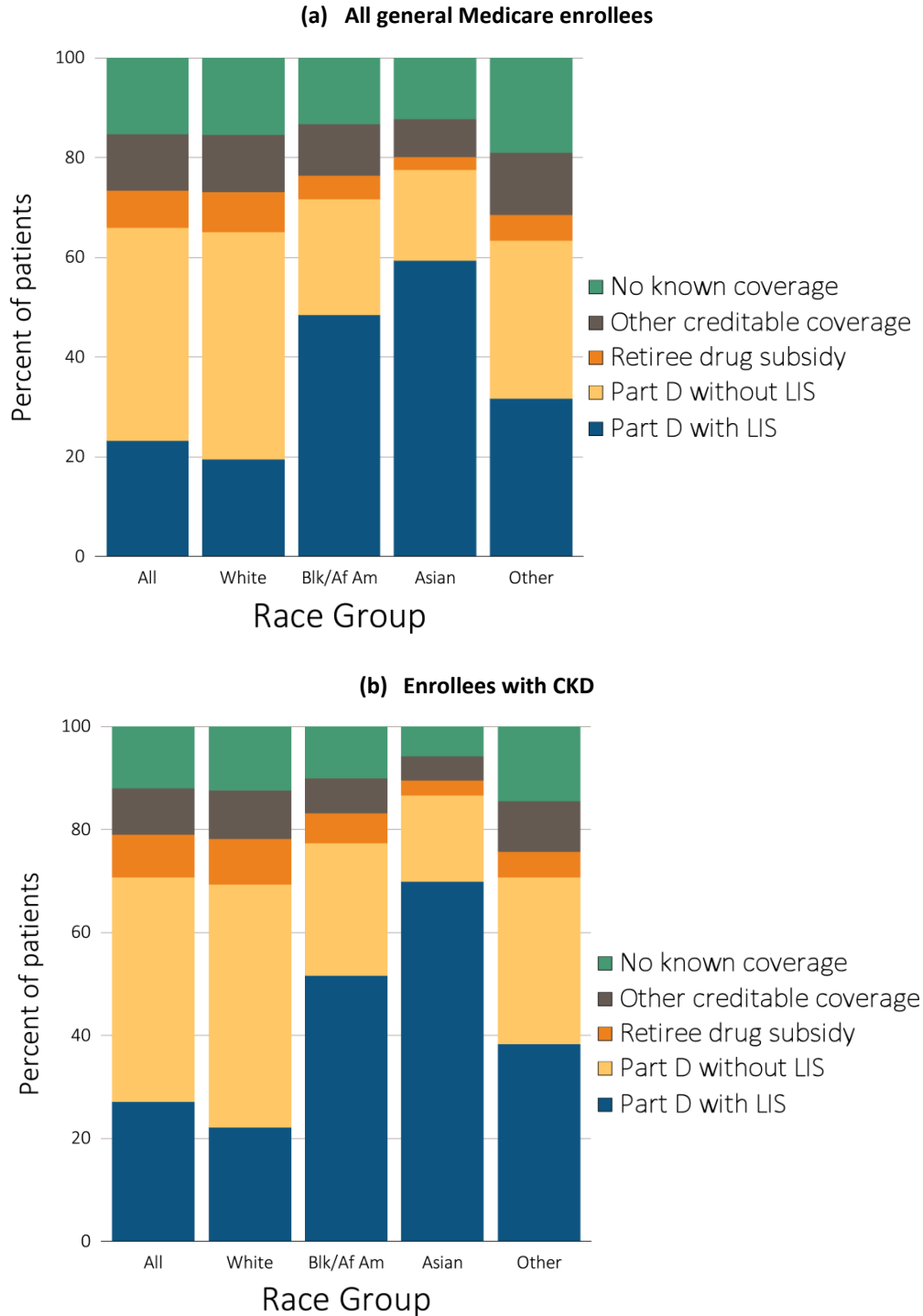


Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: CKD, chronic kidney disease; LIS, Medicare low income subsidy; Part D, Medicare prescription drug coverage benefit.

Patterns of coverage by race were similar in the both the general Medicare population and for beneficiaries with CKD (Figure 7.3). Compared to Whites, a higher portion of Asian and Black

beneficiaries had Part D coverage with the LIS. Across all races, the percentage of beneficiaries with the LIS was higher for CKD patients than among the entire general Medicare group

vol 1 Figure 7.3 Sources of prescription drug coverage in Medicare enrollees, by race, 2014



Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: Blk/Af Am, Black/African American; CKD, chronic kidney disease; LIS, Medicare Low-income Subsidy; Part D, Medicare prescription drug coverage benefit.

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

vol 1 Table 7.3 Medicare Part D enrollees (%) with the Low-income Subsidy, by age & race, 2014

	General Medicare	All CKD
	Part D with Low-income Subsidy	Part D with Low-income Subsidy
White		
All ages	30.0	31.9
20-44	92.9	94.0
45-64	76.0	77.1
65-74	17.2	26.4
75+	21.5	27.1
Black/African American		
All ages	67.6	66.7
20-44	95.3	94.1
45-64	85.7	84.7
65-74	49.0	56.4
75+	57.9	63.6
Asian		
All ages	76.5	80.6
20-44	91.9	100.0
45-64	85.1	85.9
65-74	68.4	74.3
75+	80.1	82.3
Other races		
All ages	50.1	54.3
20-44	92.8	90.5
45-64	79.2	83.7
65-74	34.4	40.8
75+	47.5	54.7

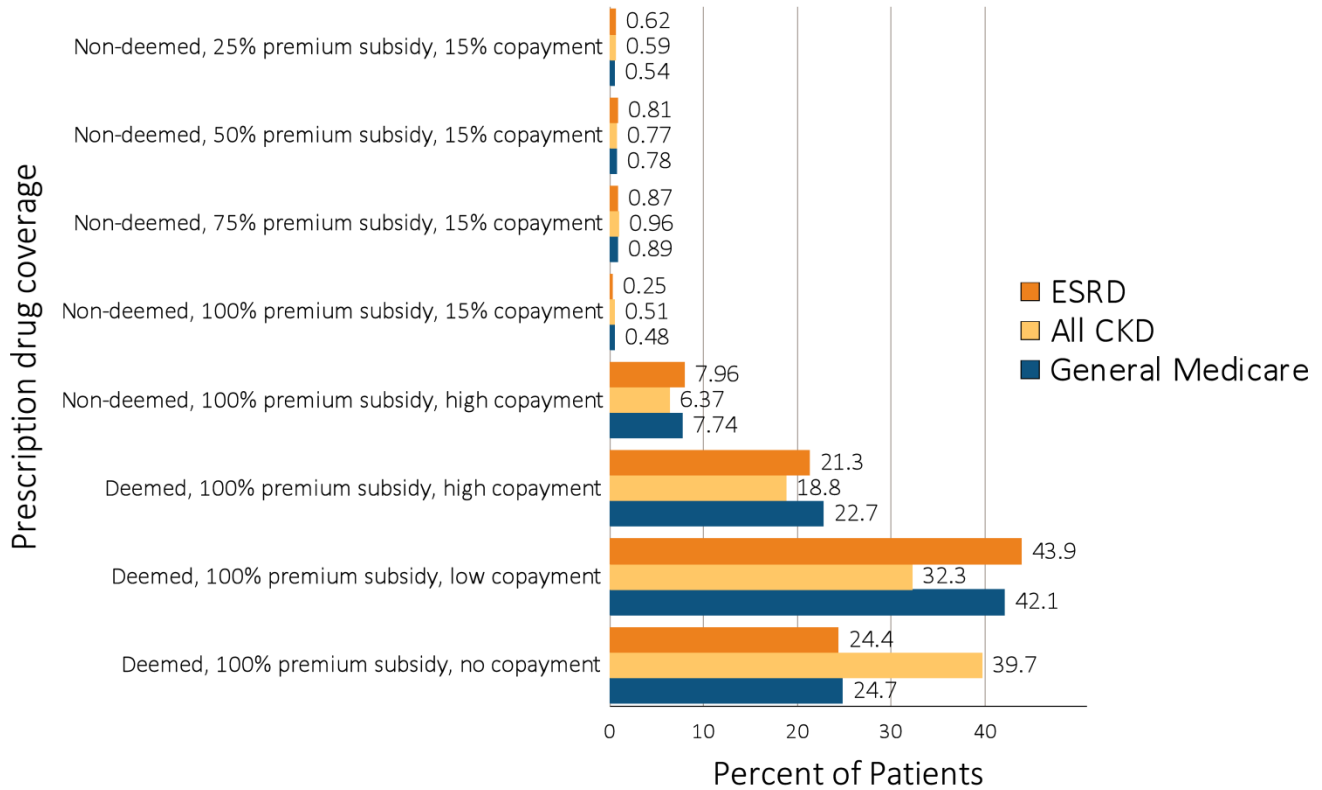
Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: CKD, chronic kidney disease; Part D, Medicare prescription drug coverage benefit.

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 Low-income 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.

The distribution of Part D enrollees receiving the LIS across benefit categories (premium subsidy, copayment) is described in Figure 7.4. The largest group of LIS recipients who had CKD were eligible for a full premium subsidy: 18.8% had a high copay, 32.3% had a low copay, and 39.7% had no copay.

vol 1 Figure 7.4 Distribution of Low-income Subsidy categories in Part D general Medicare, CKD, & ESRD patients, 2014



Data source: Medicare 5% sample. Point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; Part D, Medicare prescription drug coverage benefit.

Spending Under Stand-alone Part D Plans

In 2014, total Part D spending reached \$50.5 billion. Expenditures for beneficiaries with CKD or ESRD were \$10.4 billion—about 21% of total Part D prescription drug spending. Data over a four-year period shows a

consistent trend of increasing costs, by \$3.6 billion between 2011 and 2014 (Table 7.4). ESRD costs were \$2.7 billion in 2014, but did not include drugs paid for under the ESRD prospective payment system (e.g. ESAs, IV vitamin D, and iron) or those medications billed to Medicare Part B (e.g. immunosuppressants).

vol 1 Table 7.4 Total estimated Medicare Part D spending for enrollees (in billions), 2011-2014

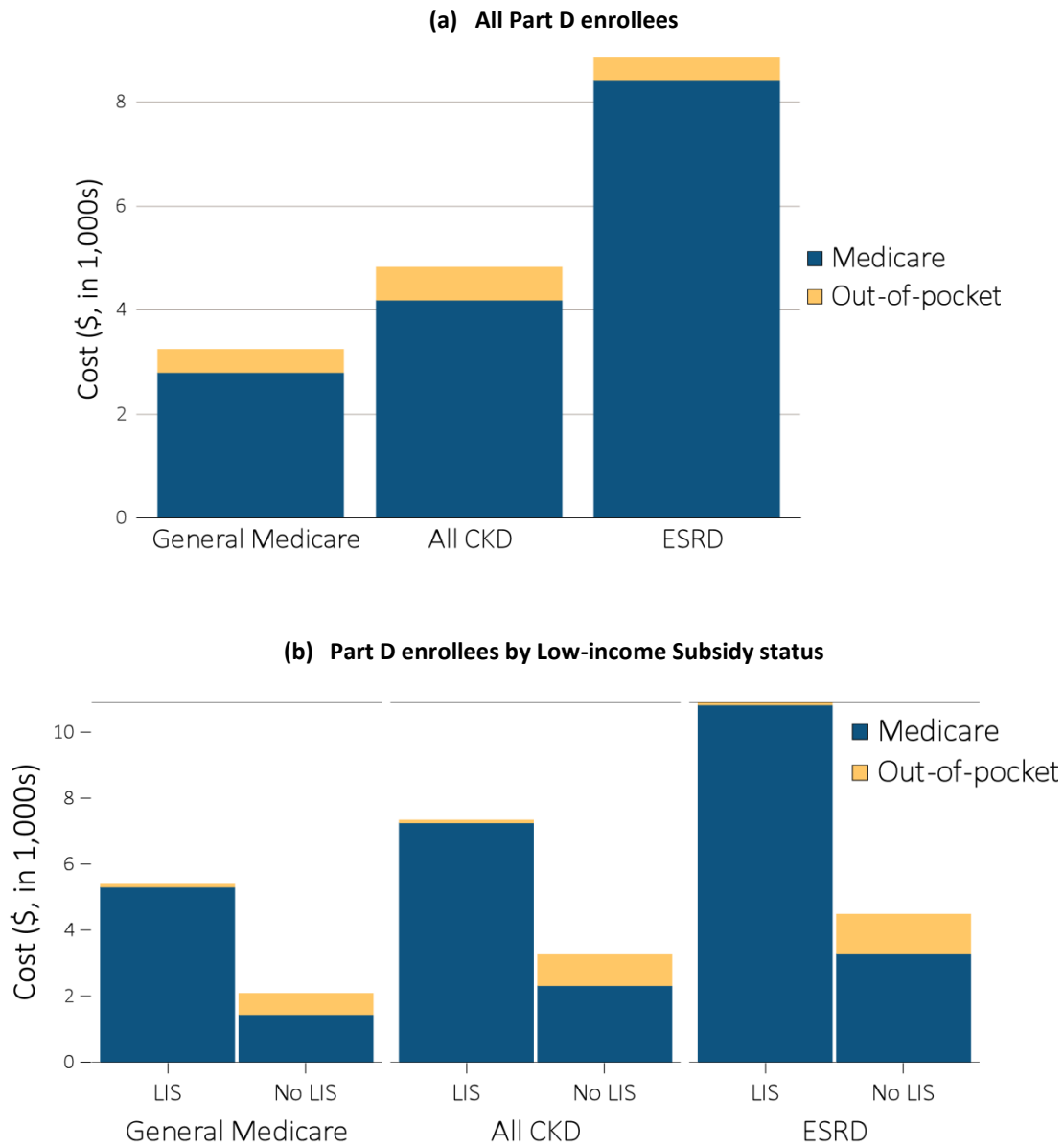
	General Medicare	All CKD	All ESRD
2011	40.1	5.2	1.6
2012	35.7	4.8	2.0
2013	45.7	6.8	2.3
2014	50.5	7.7	2.7

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. ESRD totals include all Part D claims for Medicare ESRD patients with Medicare Part D stand-alone prescription drug plans. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; Part D, Medicare prescription drug coverage benefit.

In 2014, PPPY Part D spending for CKD patients was 50% higher than for general Medicare beneficiaries, at \$4,198 compared to \$2,806. Out-of-pocket costs were 42% higher for beneficiaries with CKD than among the general Medicare population. Due to the much higher proportion of LIS in the ESRD population, out-of-pocket costs represented a smaller share of total spending (5%) than in the other two groups (13 % for CKD, and 14% for general Medicare; Figure 7.5a).

Total spending for Part D-covered medications in 2014 was more than twice as high for beneficiaries with the LIS than for those without (Figure 7.5b). In the LIS population, however, out-of-pocket costs represented only 1% of these total expenditures, compared to 27-30% in each of the non-LIS populations.

vol 1 Figure 7.5 Per person per year Medicare Part D spending & out-of-pocket costs for enrollees, 2014



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. ESRD totals include all Part D claims for Medicare ESRD patients with Medicare Part D stand-alone prescription drug plans. Costs are per person per year for calendar year 2014. Medicare Part D spending is the sum of the Medicare covered amount and the Low-income Subsidy amount. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; Part D, Medicare prescription drug coverage benefit.

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

Total PPPY Medicare Part D spending varied widely between those with and without the LIS (Table 7.5), excluding patient obligations. Overall, expenditures were highest in both categories for beneficiaries with ESRD. Total PPPY Medicare-paid Part D costs for LIS and non-LIS recipients varied from \$5,302 and \$1,447 PPPY in the general Medicare population to \$7,249 and \$2,318 among patients with CKD, and to \$10,826

and \$3,286 among those with ESRD. By race, PPPY spending was highest for Whites in the general Medicare and CKD LIS populations, but highest for Blacks and Asians in the general Medicare and CKD non-LIS populations, respectively. In each of the three populations, spending was highest in the age 45-64 category, regardless of LIS status.

vol 1 Table 7.5 Per person per year Part D spending (\$) for enrollees, by Low-income Subsidy status, 2014

	General Medicare		All CKD		All ESRD	
	Part D with Low-income Subsidy	Part D remaining enrollees	Part D with Low-income Subsidy	Part D remaining enrollees	Part D with Low-income Subsidy	Part D remaining enrollees
Age						
All	5,302	1,447	7,249	2,318	10,826	3,286
20-44	5,255	2,060	10,655	3,074	11,386	2,640
45-64	7,115	3,122	10,928	4,156	11,783	3,859
65-74	4,572	1,386	7,343	2,801	9,728	3,474
75+	4,030	1,329	5,426	1,952	7,826	2,643
Sex						
Male	5,310	1,556	7,694	2,476	10,925	3,349
Female	5,296	1,367	6,978	2,161	10,718	3,190
Race						
White	5,510	1,446	7,506	2,302	10,510	3,318
Black	4,881	1,513	6,563	2,344	11,325	3,167
Asian	4,858	1,278	7,339	2,750	11,105	3,369
Other race	4,728	1,396	6,708	2,745	7,956	3,319

Data source: Medicare Part D claims. All Medicare patients with Medicare Part D stand-alone prescription drug plans. CKD determined from claims. ESRD patients with Medicare Part D stand-alone prescription drug plans. Costs are per person per year for calendar year 2014. Medicare Part D PPPY is the sum of the Medicare covered amount and the Low-income Subsidy 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 2014. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; Part D, Medicare prescription drug coverage benefit.

Prescription Drug Classes

Ranking of the top 15 prescription drug classes used by patients is based on the percentage of beneficiaries with at least one claim for a drug. The list is led by cardiovascular therapies (statins, beta blockers, and

diuretics). Over one third of CKD patients received opioid agonists, proton-pump inhibitors antidepressants, angiotensin-converting enzyme inhibitors, or dihydropyridines (Table 7.6).

vol 1 Table 7.6 Top 15 drug classes received by Part D-enrolled CKD patients, by percent of patients 2014

Rank	Drug class	Percent of patients
1	HMG-CoA Reductase Inhibitors (statins)	59%
2	β-Adrenergic Blocking Agents	57%
3	Opiate Agonists	46%
4	Loop Diuretics	39%
5	Proton-pump Inhibitors	38%
6	Antidepressants	35%
7	Angiotensin-Converting Enzyme Inhibitors	34%
8	Dihydropyridines	33%
9	Quinolones	27%
10	Thyroid Agents	25%
11	Angiotensin II Receptor Antagonists	24%
12	Anticonvulsants, Miscellaneous	23%
13	Adrenals	21%
14	Replacement Preparations	20%
15	Insulins	20%

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

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

Insulins ranked first in total Medicare drug expenditures for CKD patients, followed closely by antineoplastic agents. These two drug classes

accounted for 13% and 10% of total Medicare Part D spending, respectively

vol 1 Table 7.7 Top 15 drug classes received by Part D-enrolled CKD patients, by Medicare Part D spending, 2014

Rank	Drug class	Medicare Part D spending (\$ in millions)	Percent of total Medicare Part D spending
1	Insulins	\$1,017.81	13%
2	Antineoplastic Agents	\$758.01	10%
3	Antipsychotics	\$288.85	4%
4	Proton-pump Inhibitors	\$252.85	3%
5	Dipeptidyl Peptidase IV (DDP-4) Inhibitors	\$240.78	3%
6	Corticosteroids	\$225.37	3%
7	HMG-CoA Reductase Inhibitors (statins)	\$223.01	3%
8	Antiretrovirals	\$209.87	3%
9	HCV antivirals	\$206.89	3%
10	Opiate Agonists	\$200.95	3%
11	Anticoagulants	\$181.25	2%
12	Anticonvulsants, Miscellaneous	\$178.52	2%
13	Antimuscarinics/Antispasmodics	\$169.03	2%
14	Antidepressants	\$167.42	2%
15	Angiotensin II Receptor Antagonists	\$155.01	2%

Data source: Medicare Part D claims. CKD patients with Medicare Part D stand-alone prescription drug plans in the Medicare 5% sample. Part D spending represents the sum of the Medicare covered amount and the Low-income Subsidy amount.

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The Henry J. Kaiser Family Foundation. *Medicare Indicators: Prescription Drug Plans*. Website. Retrieved June, 27, 2016 from <http://kff.org/state-category/medicare/prescription-drug-plans/enrollment-prescription-drug-plans-medicare/>

Notes

Chapter 8:

Transition of Care in Chronic Kidney Disease

- Over 20% of all 85,505 United States (U.S.) veterans who transitioned to end-stage renal disease (ESRD) over a 6.5-year period (10/2007-3/2014) received antidepressant medications prior to transition, or during the “prelude” period. After transition to ESRD (“vintage” period) the antidepressant prescription rate increased to almost 30%.
- Phosphorus binders (lanthanum, sevelamer, and calcium acetate) were rarely prescribed during the prelude period prior to ESRD transition, while a major surge was observed in the final six months of the prelude, followed by a substantial rise during the dialysis vintage period.
- Among the comorbid conditions of 74,382 veterans who transitioned to ESRD with at least one identified comorbidity, congestive heart failure (CHF), diabetes mellitus (DM), and chronic obstructive pulmonary disease (COPD) were each present in over half of the sample. Over a quarter of all veteran patients had a diagnosis of cancer (CA), and 32% had a prior myocardial infarction (MI).
- Among the 74,382 veterans who had at least one hospitalization event during their transition to ESRD, the most common causes of admission included acute kidney injury (AKI), hypertension (HTN), congestive heart failure (CHF), and chronic kidney disease (CKD). Septicemia-related hospital admissions increased dramatically after ESRD transition.
- CHF 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 after ESRD transition (vintage period).
- AKI was the leading cause for hospitalizations that included the transition to ESRD event, i.e., the first hemodialysis treatment.
- Prelude trend analyses provided important information about changes in clinical and laboratory measures over time during the several years prior to transition to ESRD, including measured serum phosphorus in 20 quarters (five years) prelude in the 24,765 veterans who eventually transitioned to ESRD; values gradually increased from 4.0 mg/dL to above 5.5 mg/dL immediately prior to transition.

Introduction

The Transition of Care in Chronic Kidney Disease (TC-CKD) Special Study Center examines the transition of care to renal replacement therapy (i.e., dialysis or transplantation) in patients with very-late-stage 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 the linkage between the national USRDS data and two large longitudinal databases of NDD-CKD patients—

the national Veterans Affairs (VA) database and the regional (Southern California) Kaiser Permanente (KP-SC) database. These linkages allowed us to identify all VA and all KP-SC patients who have transitioned to ESRD from the index point in time onwards. Each of these linked databases includes thousands of NDD-CKD patients who have transitioned to ESRD each year, in whom historical data for up to -5 (minus five) years prior to ESRD (the so-called “prelude” period) and up to +2 (plus two) years after ESRD transition (the so-called early “vintage” period) were examined.

In the first phase of this Special Study operation, we examined the recent national VA and KP-SC cohorts of incident ESRD patients. We 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 preliminary, 4-year pre- and post-ESRD data of approximately 52,000 incident ESRD veterans who transitioned to ESRD between 10/1/2007 and 9/30/2011 were presented in our 2014 and 2015 Annual Data Report (ADR) chapters. In this 2016 ADR, we present 6.5-year pre- and post-ESRD data on approximately 85,000 incident ESRD veterans who transitioned between 10/1/2007 and 3/31/2014. For these incident patients we also include additional data from the first two years of the post-ESRD (vintage) period and the 5-year prelude (pre-ESRD) data, along with additional data from the USRDS. Similar analyses are also presented for the KP-SC patient cohort.

As stated in the original goals of this Special Study Center, we continue to test the hypotheses that a pre-ESRD (prelude) data-driven individualized approach to the transition of care into ESRD in very-late-stage NDD-CKD is associated with more favorable outcomes, particularly if the decision is based on pre-ESRD factors such as clinical and laboratory variables, including the CKD progression rate, comorbid conditions during prelude period, and demographics. In subsequent years we also plan to develop and validate scoring systems 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 approximately 22 million veterans in the U.S.; nine million are enrolled in the Veterans Health Administration (VHA), including almost six million who receive their healthcare in one of the VHA facilities. During the 2013 fiscal year there were 86.4 million outpatient visits and 694,700 inpatient admissions at Veterans Affairs (VA) healthcare facilities.¹

Whereas currently some 90% of the U.S. veteran population is male, it is estimated that by 2040 approximately 18% will be female. Minority veterans

comprised about 22% of the total veterans' population in 2014. Most minority veterans were those of Black or African American race (12% of all veterans), and Hispanics or Latinos of any race comprised approximately 7% of all veterans²

The VHA facility network consists of 150 hospitals, along with 820 community-based outpatient clinics, 300 veterans' centers, and some 70 dialysis centers that are primarily hospital based³. Services provided by the VA department and VHA facilities include comprehensive medical care, life insurance, disability compensation, home loans, educational benefits, pensions, and vocational rehabilitation training.

MANAGEMENT OF ESRD IN THE VHA

The VHA provides comprehensive medical care for patients with kidney disease, including acute kidney injury (AKI) and all stages of CKD. Management of kidney disease that does not require dialysis or transplantation is typically provided by VA personnel at one of the nationwide VHA facilities, or outsourced to local private providers in cases where the VHA cannot provide adequate care, for reasons such as prohibitive distance or lack of adequate resources.

Any veteran who develops ESRD is eligible to receive kidney replacement therapy from the VHA. Dialysis care is a covered benefit under VA's Medical Benefits Package for veterans enrolled in the VA, irrespective of their service connectedness⁴. For patients requiring in-center dialysis treatment, the VHA provides dialysis both through units maintained and operated by individual VA facilities, (hence usually hospital based dialysis centers), or by outsourcing dialysis services to private dialysis providers. This may happen in cases where the distance from a VA facility is prohibitive for thrice-weekly dialysis, when there is a lack of home dialysis resources or expertise, or when the capacity of the VA facility-operated dialysis unit is exceeded. There are currently 71 VA facilities nationwide that maintain and operate a primarily in-house (in-center) dialysis center⁵. Most of the hospital-based dialysis units provide both chronic outpatient and acute inpatient dialysis treatments in the same location. In the USRDS ADR census these were usually classified under the category of "hospital based" facilities.

Although approximately 90% of the ESRD veterans receive dialysis treatment in non-VHA facilities, including large dialysis chains, the transition data of these and other outsourced dialysis veterans and in particular their prelude and early vintage analyses and other data are also included in this chapter (see below). Hence, our transition-of-care data for veterans with ESRD are exceptionally inclusive and comprehensive.

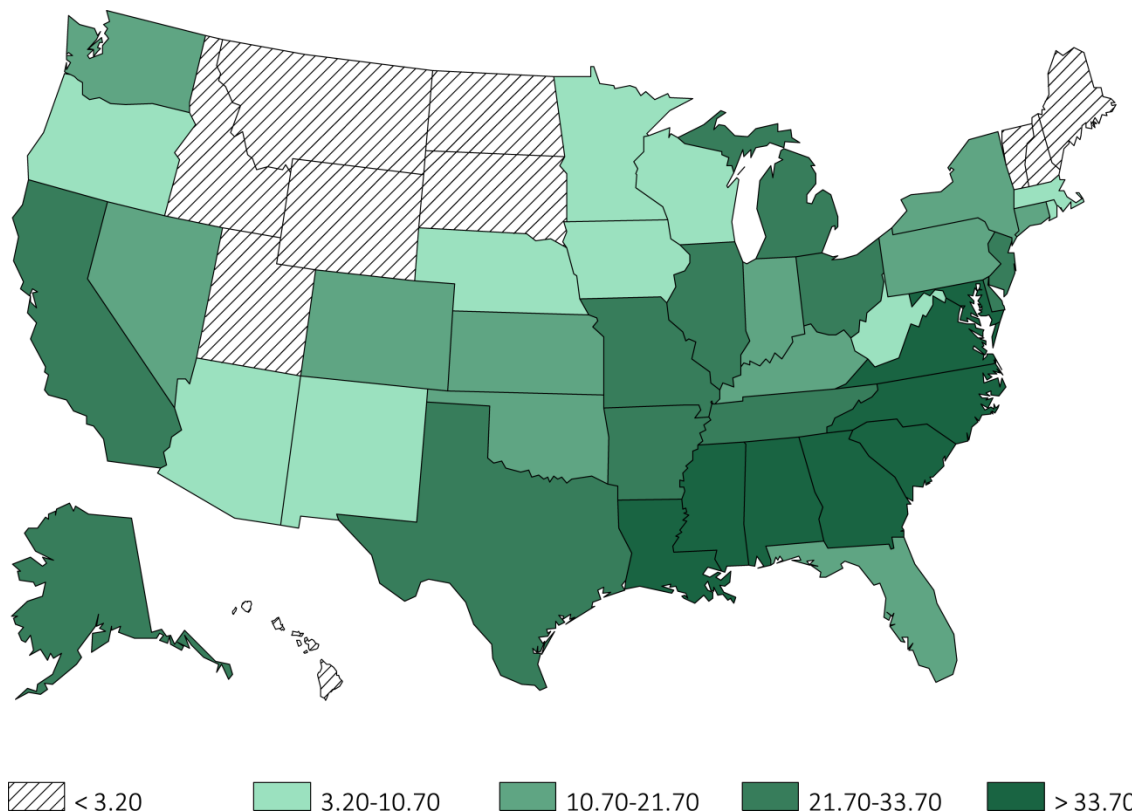
HIGHLIGHTS OF THE INCIDENT ESRD VETERANS POPULATION BETWEEN 10/1/2007 AND 3/31/2014

Between 10/1/2007 and 3/31/2014 (over 6.5 fiscal years) 85,505 veterans transitioned to ESRD. The mean \pm SD age was 70.1 \pm 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 (31%).

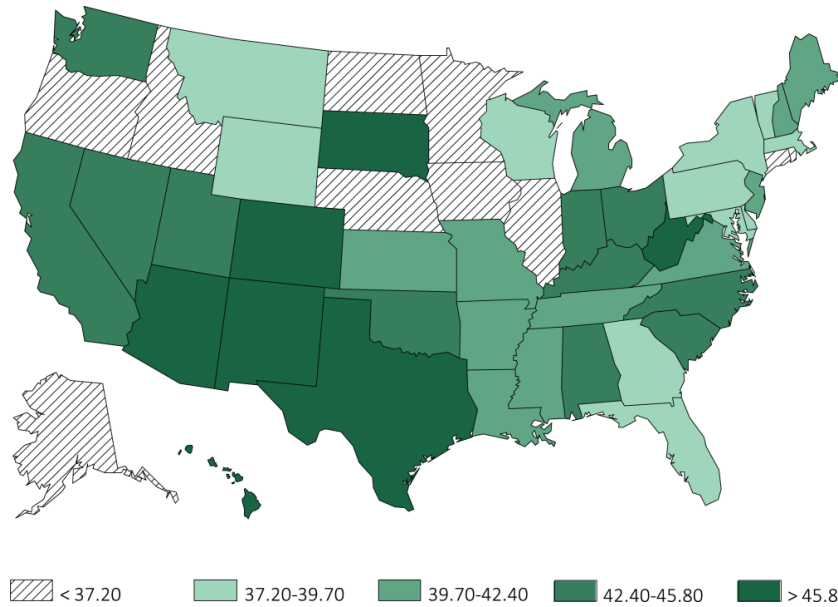
Across the nation, the proportion of Black incident ESRD veterans varied by state and region. Southern states such as Alabama, Georgia, Louisiana, Mississippi, and Washington D.C. had the highest proportion of Black veterans who transitioned to ESRD. Northeastern and northwestern states had lower proportions of Black veterans transitioning to ESRD (Figure 8.1). Furthermore, the distribution of patients with ESRD due to DM varied across the nation. 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 8.2).

vol 1 Figure 8.1 Distribution of Black incident ESRD veterans (%) among 85,505 incident ESRD veterans across states and territories of the United States, 10/1/2007-3/31/2014



Data source: VHA Administrative data, USRDS ESRD Database, CMS Medicare Inpatient and Outpatient data. States and territories of the United States of America.

vol 1 Figure 8.2 Distribution of diabetes (%) as the cause of ESRD among 85,505 incident ESRD veterans across states and territories of the United States, 10/1/2007-3/31/2014



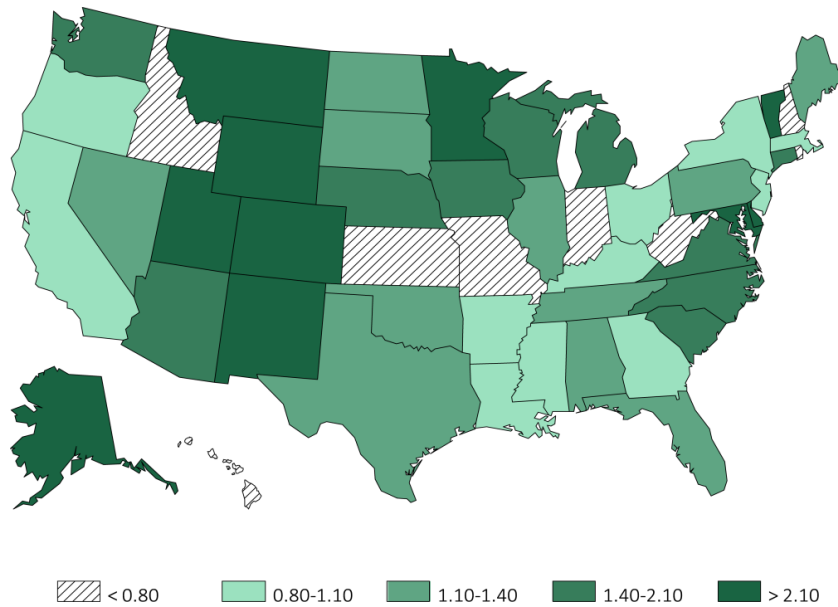
Data source: VHA Administrative data, USRDS ESRD Database. States and territories of the United States of America.

PREEMPTIVE KIDNEY TRANSPLANTATION AMONG VETERANS ACROSS THE NATION

Figure 8.3 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 (n=1133 preemptive transplantations over 6.5 years in the entire nation). The states with the highest preemptive kidney transplant rates among veterans (>2.1%) were Alaska, Colorado, Delaware, Maryland, Minnesota, Montana, New Mexico, Utah, Vermont, and Wyoming.

vol 1 Figure 8.3 Distribution of preemptive kidney transplant rates among 85,505 incident ESRD veterans across states and territories of the United States, 10/1/2007-3/31/2014



Data source: VHA Administrative data, USRDS ESRD Database. States and territories of the United States of America.

ESRD RATES AMONG VETERANS

As reported in previous ADR chapters on Transition of Care in CKD, during each year of the 6.5-year observation period, approximately 13,000 veterans transitioned to ESRD, with an average rate of ESRD transition of 1,096 veterans per month across the entire nation. In this report we have calculated the ESRD incident rates for veterans in each calendar year (Jan 1-Dec 31), instead of fiscal year (Oct 1-Sep 30). The U.S. Census data were accessed to obtain the Veteran population data using the Census Fact Finder site⁶.

We then calculated counts of all veterans in each year and per age strata. The USRDS incidence rates for ESRD among U.S. adults were obtained from the 2015 Standard Analysis Files (SAFs) databases for comparison. For the six calendar years between 2008 and 2013, the crude ESRD incident rates among veterans were 603.3, 633.4, 616.9, 594.5, 606.2, and 635.3 per million veterans, respectively. Given the ESRD incident rates of 488.0, 499.3, 498.3, 484.7, 488.1, and 485.9 per million per the USRDS

population, the calculated crude rate ratio of ESRD incidence among veterans compared to the U.S. general population is 1.24, 1.27, 1.24, 1.23, 1.24, and 1.31 for calendar years 2008 through 2013, respectively, suggesting that the ESRD is 23% to 31% more likely to occur among veterans than the general U.S. population.

However, the VA population is considerably older than the general U.S. population. Indeed, on an age specific and age adjusted basis, the VA rate of ESRD is 25 to 40 percent lower than the U.S. rate of ESRD. This lower-than-expected adjusted risk occurs despite the fact that the VA population is predominantly male. The remarkably low adjusted rate of ESRD among VA patients, despite higher crude ESRD incidence rates, is vastly unexplained. Is it because the VA 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 into military service, in that healthier subjects were 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 2008-2013 across 5 age strata of 18-34, 35-54, 55-64, 65-74, and 75+ years

(a) Age Strata: 18-34 years

Calendar Year	2008	2009	2010	2011	2012	2013
Incident ESRD veterans	77	73	75	74	56	69
All veterans	1,714,845	1,670,511	1,748,592	1,769,261	1,818,258	1,627,662
ESRD rate in veterans, PM	45	44	43	42	31	42
Incident ESRD in U.S.	5,523	5,745	5,556	5,484	5,611	5,462
U.S. Population	71,037,035	71,579,121	71,065,713	71,959,476	72,729,412	73,376,887
ESRD rate in the U.S., PM	78	80	78	76	77	74
ESRD rate ratio (Vet: US)*	0.58	0.54	0.55	0.55	0.40	0.57

(b) Age Strata: 35-45 years

Calendar Year	2008	2009	2010	2011	2012	2013
Incident ESRD veterans	1,374	1,378	1,227	1,124	1,163	987
All veterans	5,934,593	5,723,322	5,569,185	5,388,915	5,268,038	4,717,736
ESRD rate in veterans, PM	232	241	220	209	221	209
Incident ESRD in U.S.	25,998	26,659	26,023	25,784	25,938	25,836
U.S. Population	87,002,075	86,590,351	85,649,162	85,058,778	84,466,794	83,909,036
ESRD rate in the U.S., PM	299	308	304	303	307	308
ESRD rate ratio (Vet: US)*	0.77	0.78	0.73	0.69	0.72	0.68

(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 2008-2013 across 5 age strata of 18-34, 35-54, 55-64, 65-74, and 75+ years (continued)

(c) Age Strata: 55-64 years

Calendar Year	2008	2009	2010	2011	2012	2013
Incident ESRD veterans	3,214	3,413	3,256	3,152	2,977	2,633
All veterans	5,717,733	5,448,504	5,345,088	5,084,023	4,573,643	3,974,914
ESRD rate in veterans, PM	562	626	609	620	651	662
Incident ESRD in U.S.	26,034	27,140	27,652	27,601	28,701	28,478
U.S. Population	33,669,357	34,868,475	36,779,047	38,074,477	38,586,011	39,311,771
ESRD rate in the U.S., PM	773	778	752	725	744	724
ESRD rate ratio (Vet: US)*	0.73	0.80	0.81	0.86	0.88	0.91

(d) Age Strata: 65-74 years

Calendar Year	2008	2009	2010	2011	2012	2013
Incident ESRD veterans	3,091	3,283	3,187	3,205	3,599	3,889
All veterans	4,148,773	4,152,473	4,299,538	4,418,566	4,787,653	4,715,285
ESRD rate in veterans, PM	745	791	741	725	752	825
Incident ESRD in U.S.	26,074	27,245	27,874	27,147	28,372	29,714
U.S. Population	20,098,221	20,781,497	21,856,930	22,488,128	23,998,113	25,216,766
ESRD rate in the U.S., PM	1,297	1,311	1,275	1,207	1,182	1,178
ESRD rate ratio (Vet: US)*	0.57	0.60	0.58	0.60	0.64	0.70

(e) Age Strata: 75+ years

Calendar Year	2008	2009	2010	2011	2012	2013
Incident ESRD veterans	5,773	5,695	5,703	5,200	5,074	4,865
All veterans	4,908,768	4,859,564	4,835,674	4,797,662	4,783,273	4,552,989
ESRD rate in veterans, PM	1,176	1,172	1,179	1,084	1,061	1,069
Incident ESRD in U.S.	28,854	29,389	29,475	28,597	27,993	27,757
U.S. Population	18,671,803	18,846,651	18,620,282	18,881,385	19,145,631	19,487,308
ESRD rate in the U.S., PM	1,545	1,559	1,583	1,515	1,462	1,424
ESRD rate ratio (Vet: US)*	0.76	0.75	0.75	0.72	0.73	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.

FIRST THREE MONTHS AFTER TRANSITION TO ESRD

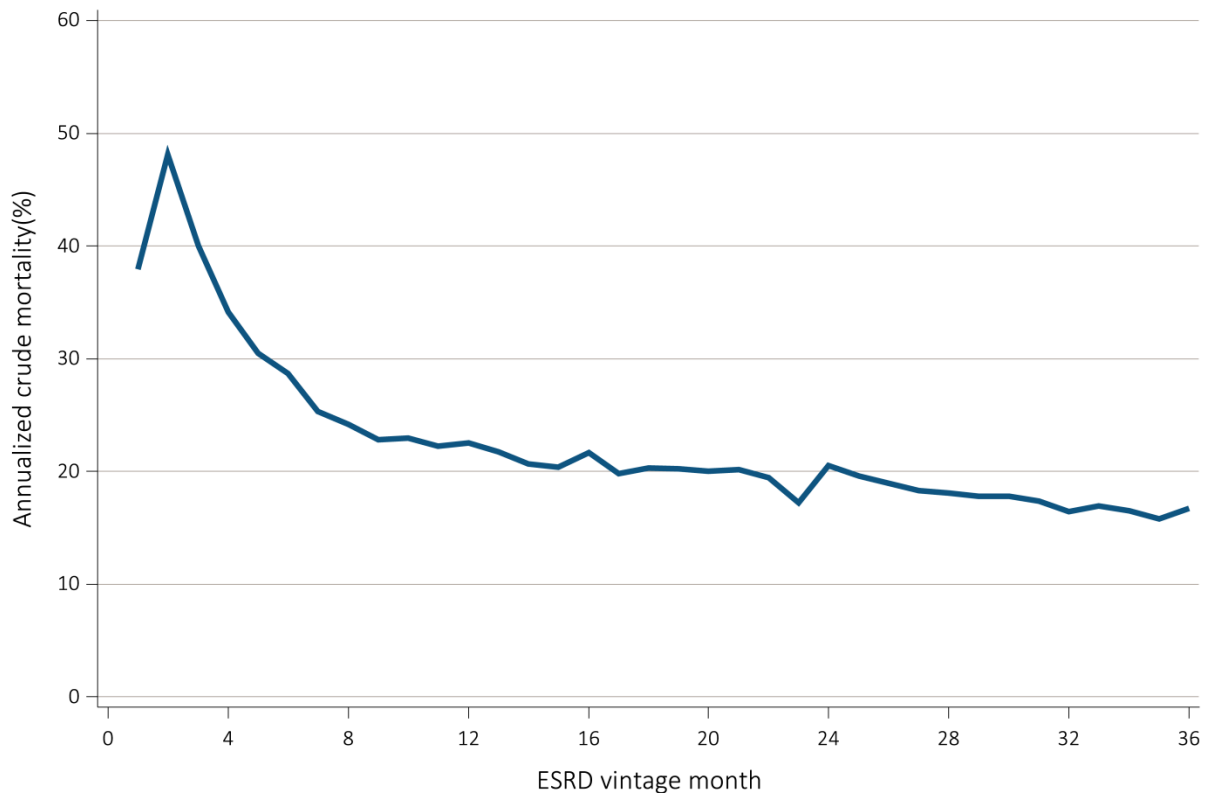
The status of incident ESRD veterans during the first three months upon transition to ESRD (10/1/2007-3/31/2014) is shown in Table 8.2. At ESRD service initiation, 81.4% and 6.1% of 85,505 veterans received in-center hemodialysis or peritoneal dialysis, respectively. After 90 days of ESRD service, 91.0% and 7.7% of all veterans receiving any dialysis treatment utilized in-center hemodialysis or peritoneal dialysis

(n=72,128 veterans). There were 1.3 % (n=1133) registered preemptive kidney transplant recipients at ESRD service initiation. During the first three months of the transition to ESRD, 10.0% (n=8,562) died, 1.5% (n=1272) received a kidney transplant, and 3.6% (n=3,064) recovered from ESRD and stopped dialysis therapy. As shown in Figure 8.4, the crude annualized mortality rate among incident ESRD veterans was exceptionally high during the initial months after ESRD transition, and reflects the similar early excess mortality that is seen in the general ESRD population.

vol 1 Table 8.2. Status of 85,505 incident ESRD veterans on Day 1 and Day 90 after transition to ESRD, 10/1/2007-3/31/2014

Modality	Day 1		Day 90	
	Frequency	%	Frequency	%
Hemodialysis	69,625	81.4	65,636	76.8
Home Hemodialysis	571	0.7	587	0.7
Peritoneal Dialysis	5,187	6.1	5,562	6.5
Uncertain Dialysis	8,989	10.5	343	0.4
Transplant	1,133	1.3	1,272	1.5
Discontinued Dialysis			388	0.5
Death			8562	10.0
Lost to Follow-up			81	0.1
Recovered kidney Function			3,074	3.6
Total	85,505	100	85,505	100

Data source: VHA Administrative data, USRDS ESRD Database, CMS Medicare Inpatient and Outpatient data . *Uncertain groups have no known dialysis modality, **n for outcomes is cumulative for subsequent periods after Day 1.

vol 1 Figure 8.4 Annualized unadjusted mortality of incident ESRD veterans who transitioned to ESRD during 10/1/2007-3/31/2014 and who were followed for up to 36 months (N=85,505)

Data source: VHA Administrative data, USRDS ESRD Database, CMS Medicare Inpatient and Outpatient data. Abbreviations: ESRD, end-stage renal disease.

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 VA 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 [EPO] 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 8.5, 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 8.6a, where it is shown that RAAS inhibitors and loop diuretics were prescribed to over two-thirds of veterans during the prelude time, while the use of thiazides and potassium sparing and loop diuretics dropped dramatically after transition to ESRD.

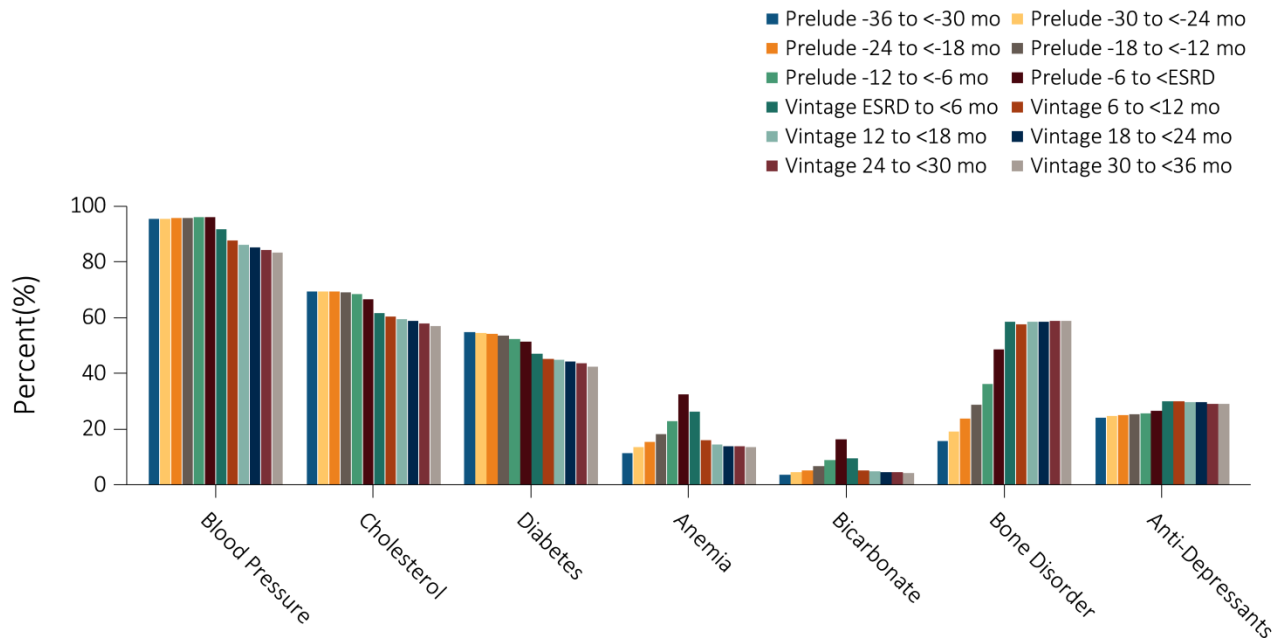
Similarly decreasing trends in the post-transition period were seen for cholesterol lowering drugs and diabetic medications (Figure 8.5). The decrease in diabetic medication prescriptions appears to be driven by a drop in prescribing oral hypoglycemics in the

post transition period (Figure 8.6b). 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 8.6c, 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 (EPO and iron) and bicarbonate medications had a modest surge in prescription

during ESRD transition and then rapidly declined post-transition (Figures 8.5 and 8.6b). However, it should be noted that data on EPO, iron, and active vitamin D medication use in the vintage period after the transition to ESRD were affected by these medications being administered in commercial dialysis clinics, and were therefore probably not well-captured by either the CMS or VA databases. Finally, approximately 22% of veterans received an antidepressant prescription during the prelude period. Antidepressant prescriptions slightly increased as patients approached ESRD transition, while rates increased approximately 3-5% to almost 30% of all veterans in the post-transition period.

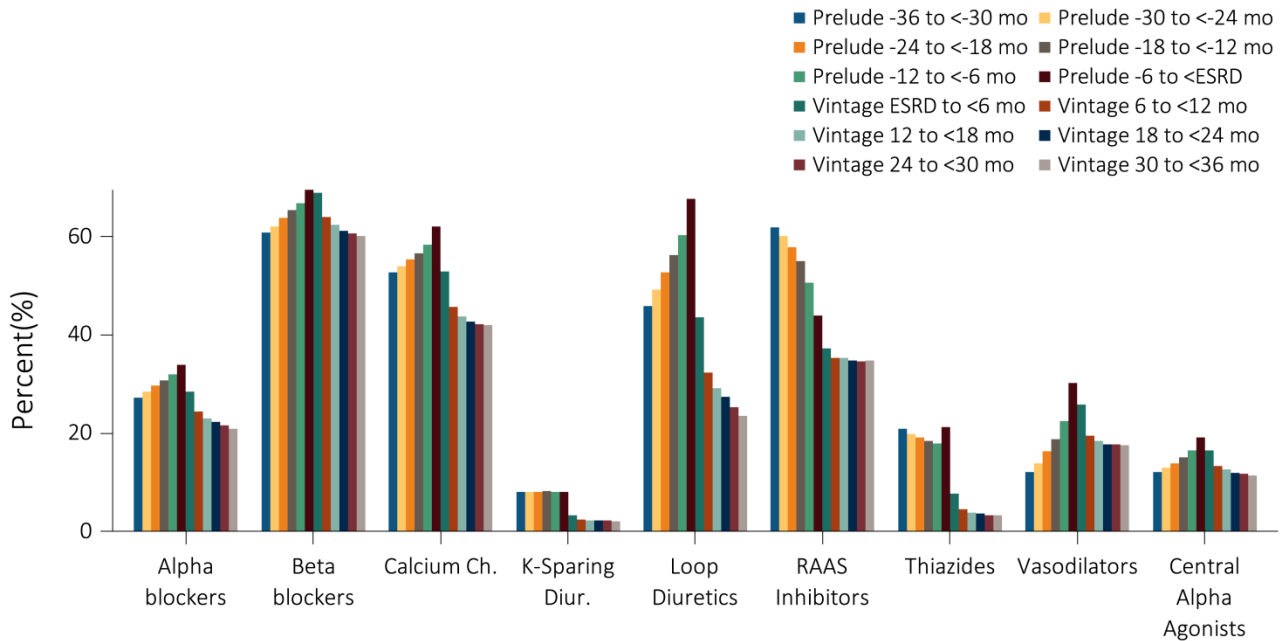
vol 1 Figure 8.5 Prescribed medication to incident ESRD veterans who transitioned to ESRD during 10/1/2007-3/31/2014, with data up to -36 months prior to transition (prelude) and up to +36 months after transition (vintage) (data were abstracted from 68,435 veterans)



Data source: VHA Administrative data, CMS Medicare Inpatient and Outpatient data. Abbreviations: ESRD, end-stage renal disease; mo, month.

vol 1 Figure 8.6 Granular Prescribed Medication Data for incident ESRD veterans who transitioned to ESRD during 10/1/2007-3/31/2014, with data up to -36 months prior to transition (prelude) and up to +36 months after transition (vintage) (data were abstracted from 68,435 veterans)

(a) Medications 1-9



(b) Medications 10-15

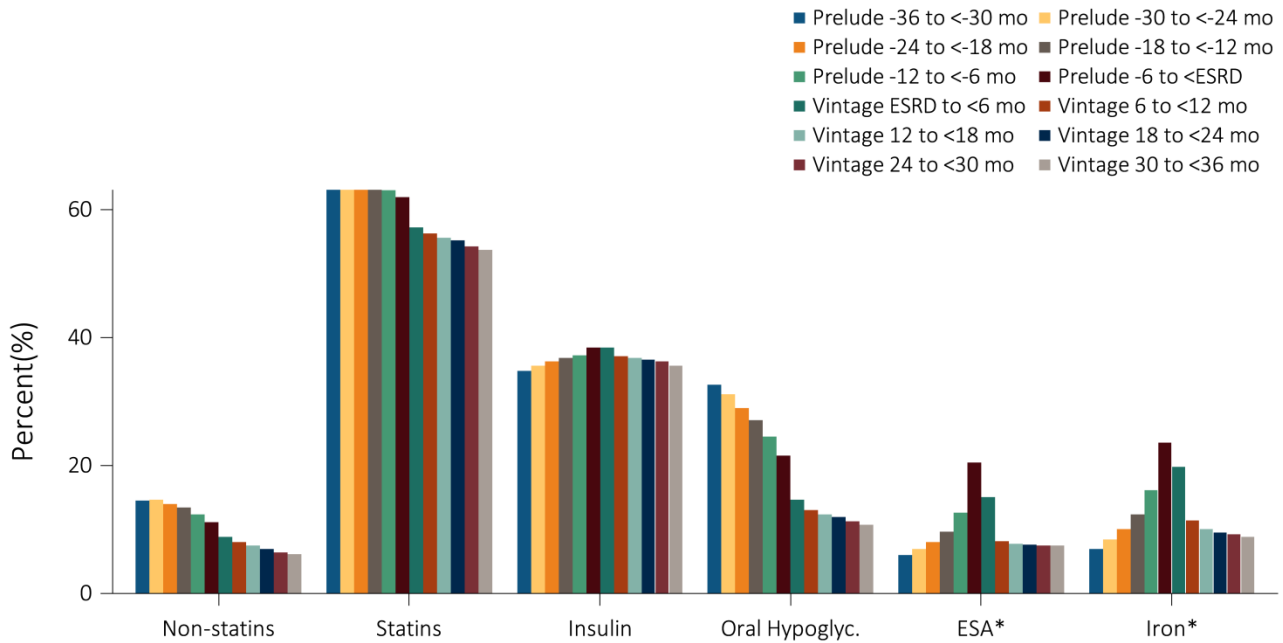
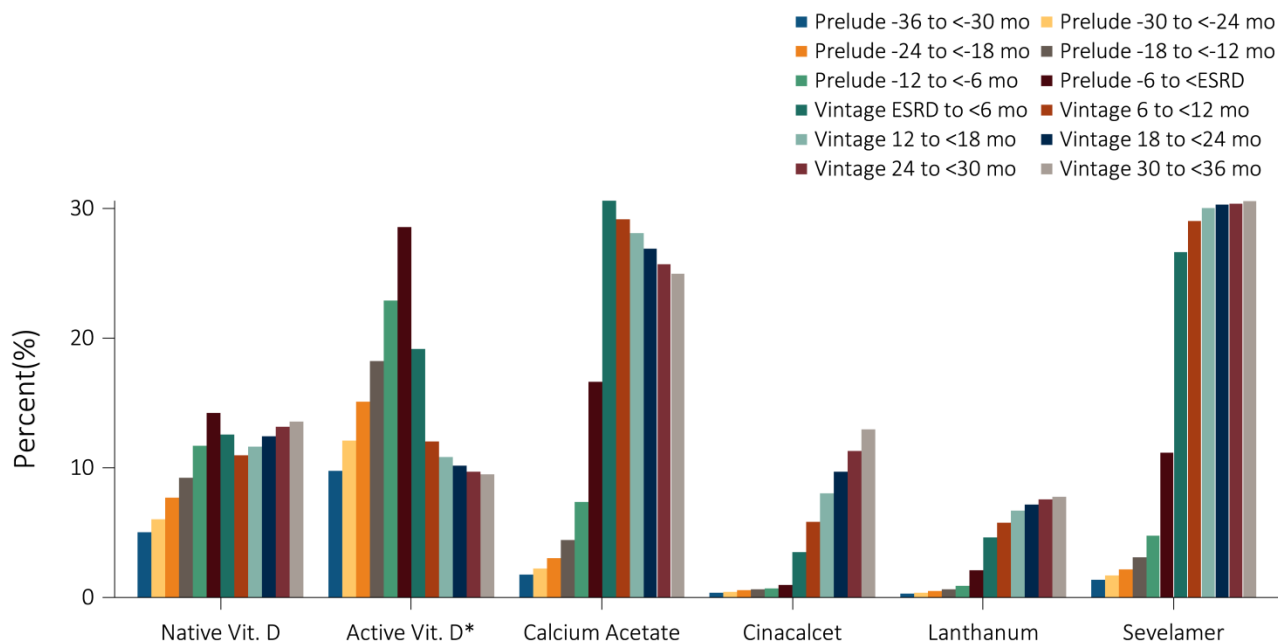


Figure 8.6 continued on next page.

vol 1 Figure 8.6 Granular Prescribed Medication Data for incident ESRD veterans who transitioned to ESRD during 10/1/2007-3/31/2014, with data up to -36 months prior to transition (prelude) and up to +36 months after transition (vintage) (data were abstracted from 68,435 veterans) (continued)

(c) Medications 16-21



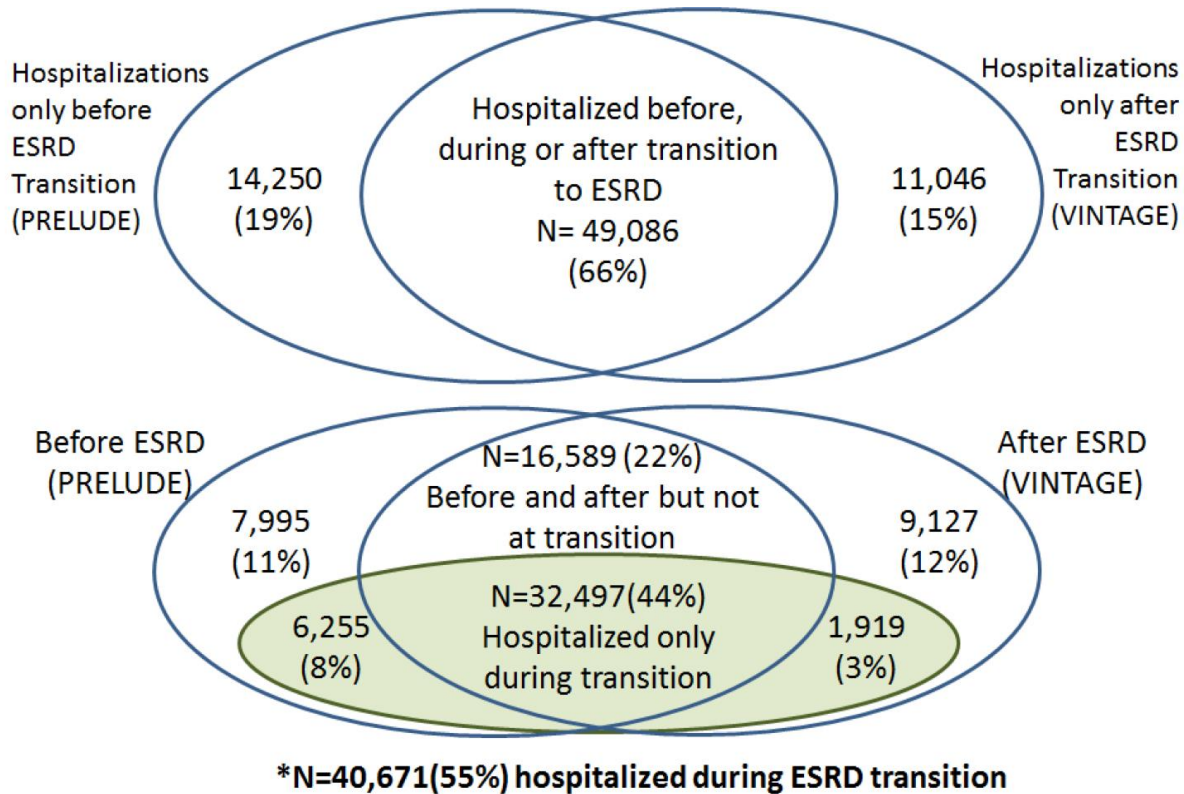
Data source: VHA Administrative data, CMS Medicare Inpatient and Outpatient data. *Data on EPO, iron and active vitamin D medication use in the vintage period were affected by these medications being administered in commercial HD units and were therefore probably not well-captured by either CMS or VA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

HOSPITALIZATION PATTERN DURING TRANSITION TO ESRD

Data on hospitalizations for the 85,505 veterans who transitioned to ESRD over 6.5 years (10/2007-3/2014) were collected from both inpatient and outpatient visits from VA, CMS Medicare, and USRDS data sources. There were 74,382 patients, or 87% of all 85,505 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). Figure 8.7 shows a Venn diagram of these hospitalization counts: 14,250(19%) veterans

were hospitalized only before but not after, and 11,046 (15%) veterans were hospitalized only after but not before the transition to ESRD. Over 66% of the population ever hospitalized during this period were hospitalized both before and after transition to ESRD (N=49,086). There were 40,671 veterans (55%) who experienced the transition to ESRD while they were in the hospital, including 32,497 veterans (44%) who were hospitalized before, after, and during ESRD transition.

vol 1 Figure 8.7 Hospitalization events in 74,382 incident ESRD veterans who transitioned to ESRD during 10/1/2007-3/31/2014

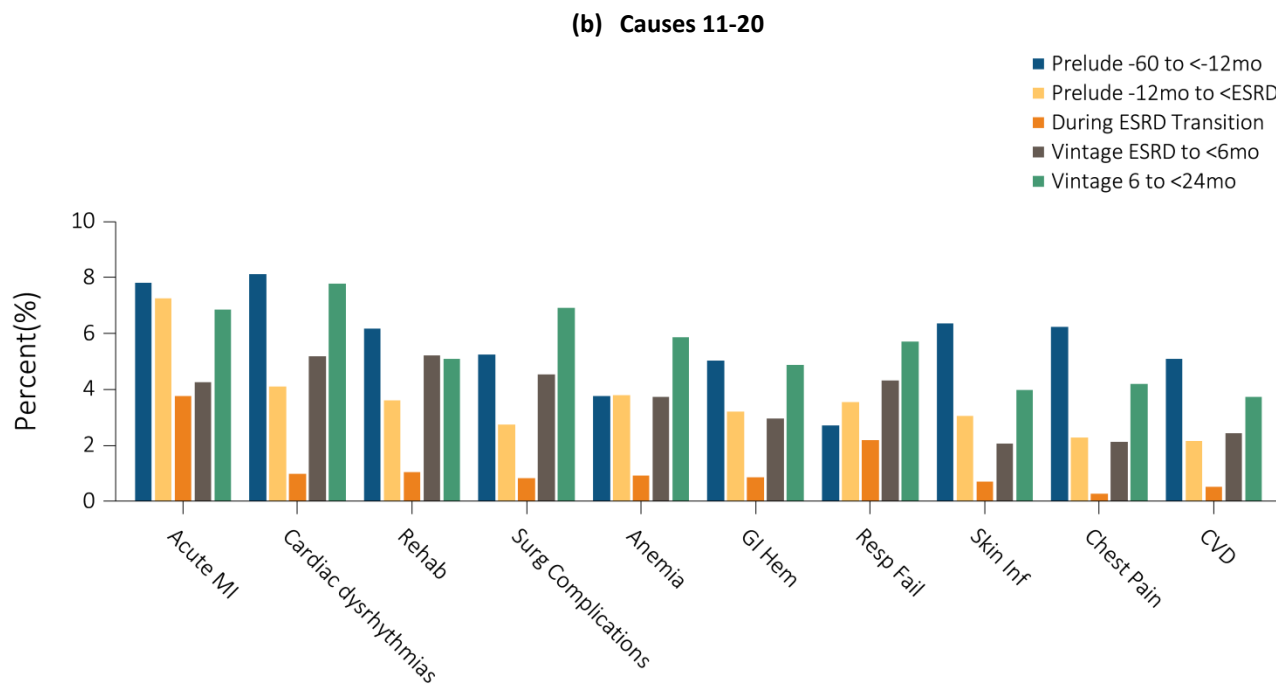
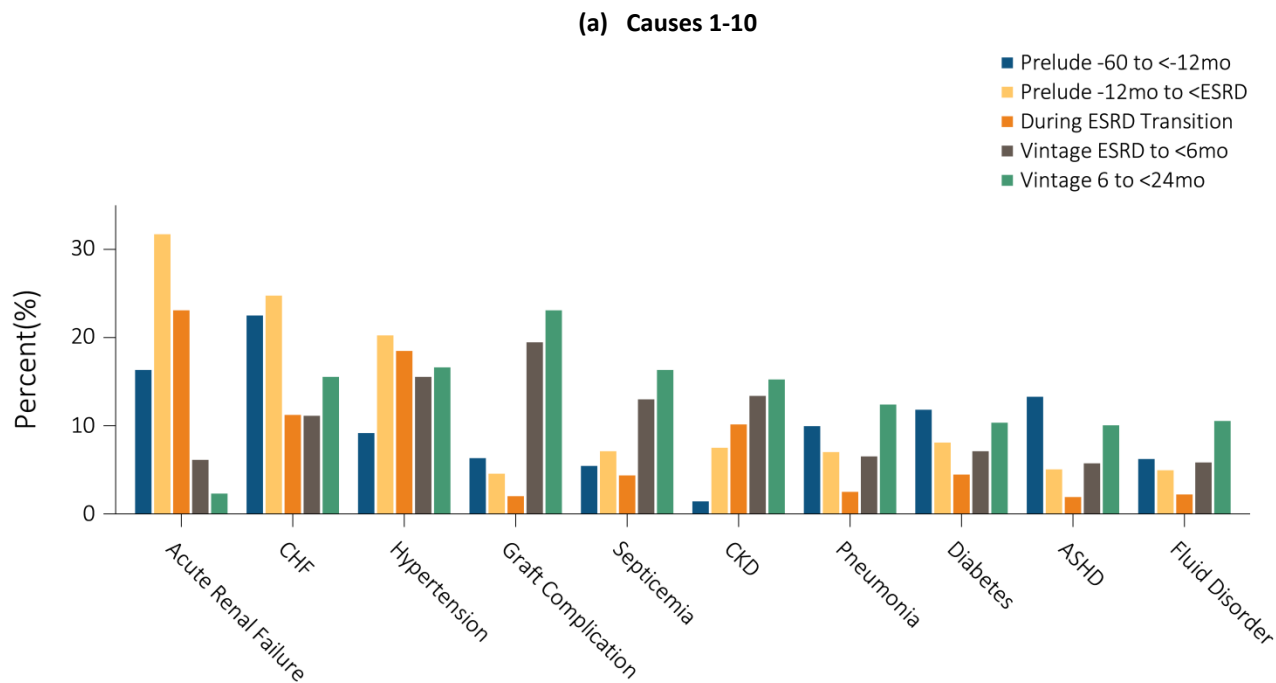


Data source: VHA Administrative data, USRDS ESRD Database, CMS Medicare Inpatient and Outpatient data. *Unique patients with an event during transition and before or after transition to ESRD. Data ranging from -60 months prior to transition (prelude) to +24 months after transition (vintage), Upper Venn diagram: Three major hospitalization categories; Lower Venn diagram: Focus of hospital events during transition to ESRD with shaded area showing patients whose transition to ESRD occurred in the hospital (n=40,671). Abbreviations: ESRD, end-stage renal disease.

Cause-specific hospitalization events were also analyzed based on the primary diagnosis. Figure 8.8 shows the top 20 causes of hospitalization among 74,382 veterans who transitioned to ESRD over the 6.5-year period (10/2007-3/2014), 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, including two prelude periods (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), two vintage categories (the first six months of ESRD, and thereafter, where the admission day was after transition to ESRD), and finally the fifth group consisting of the hospitalization that included the ESRD initiation event or preemptive kidney

transplantation, i.e., any hospitalization that began in the prelude and ended in the vintage. The top 20 causes of hospitalization included acute kidney injury, congestive heart failure (CHF), HTN, dialysis access complications (graft complication), septicemia, chronic kidney disease (CKD), pneumonia, diabetes, atherosclerotic heart disease (ASHD), fluid overload (fluid disorder), acute myocardial infarction (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, septicemia-related hospital events increased dramatically after ESRD transition. The most common causes of hospital admission that also consisted of the ESRD transition day included acute kidney injury, HTN, CHF, and CKD.

vol 1 Figure 8.8 Top 20 causes of hospitalizations in 74,382 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).



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

Hospitalization events during each of the five aforementioned periods are ranked in Table 8.3. Congestive heart failure (CHF) and acute kidney injury were the most common reasons for hospital admission prior to ESRD transition, whereas dialysis

access complications were the most common cause after ESRD transition. For hospitalizations that included the ESRD transition events, acute kidney injury (AKI) was the leading cause.

vol 1 Table 8.3. Ranking of the top 20 causes of hospitalization in 74,382 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)

Reason	Whole Cohort	Prelude -60 mo. to <-12 mo.	Prelude -12 mo. to <ESRD	During ESRD Transition	Vintage ESRD to <6 mo.	Vintage 6 mo. to <24 mo.
Acute Renal Failure	1	2	1	1	8	
CHF	2	1	2	3	5	4
Hypertension	3	6	3	2	2	2
Graft Complication	4	12	11	11	1	1
Septicemia	5	14	7	6	4	3
CKD	6		6	4	3	5
Pneumonia	7	5	8	8	7	6
Diabetes	8	4	4	5	6	8
ASHD	9	3	9	12	10	9
Fluid Disorder	10	13	10	10	9	7
Acute MI	11	8	5	7	15	12
Cardiac dysrhythmias	12	7	12	14	12	10
Rehab	13	11	14	13	11	15
Surgical Complications	14	15	19	17	13	11
Anemia	15		13	15	16	13
GI Hem	16	17	16	16	18	16
Respiratory Fail	17		15	9	14	14
Skin Infection	18	9	17	18		
Chest Pain	19	10				19
CVD	20	16				
COPD		18			18	
Urinary Tract Infection		20		19		
Osteoarthritis						
Aortic; peripheral; and visceral			19			
Heart valve disorders			20			
Other circulatory disease				17	17	
Other nervous system disorders					20	

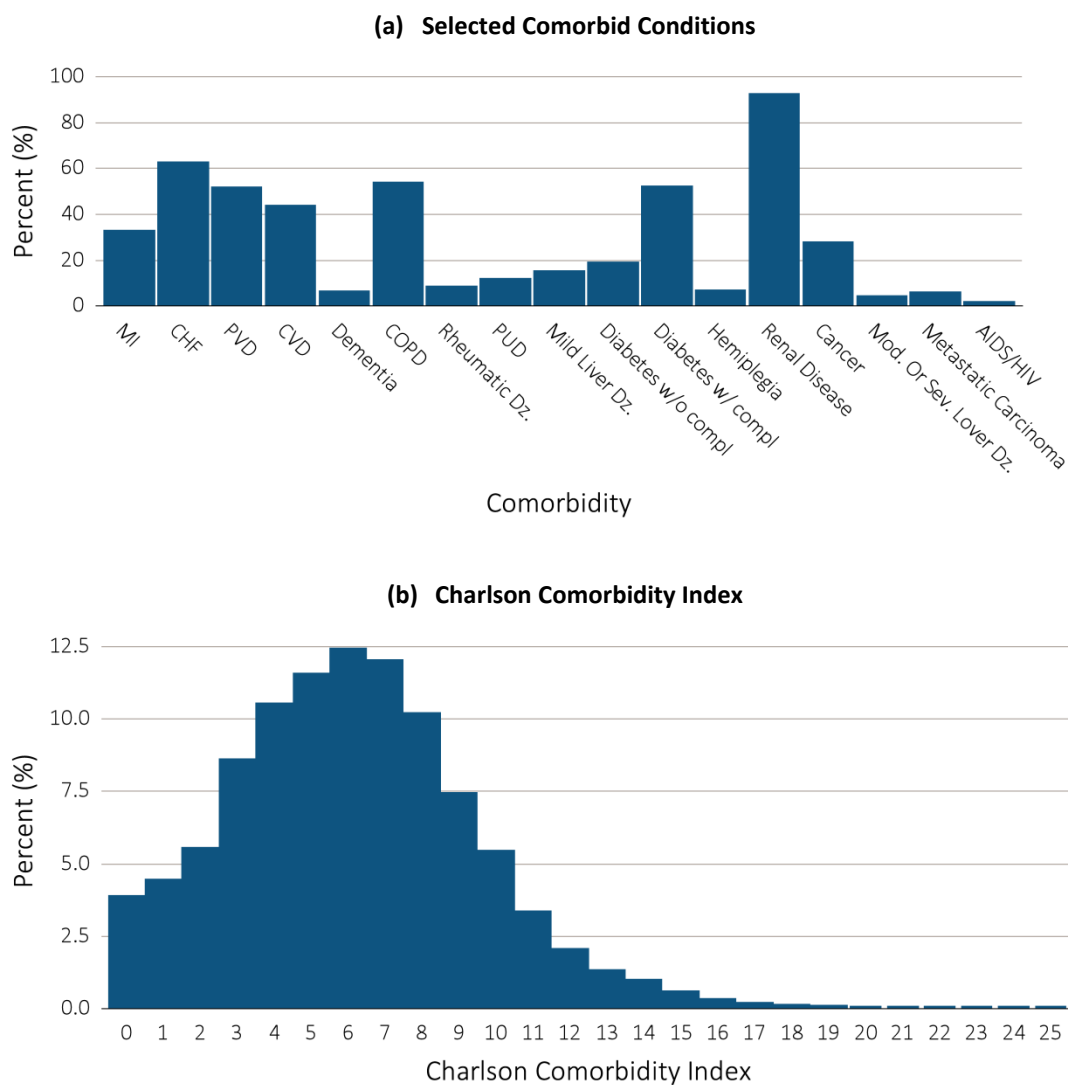
Data source: VHA Administrative data, USRDS ESRD Database, CMS Medicare Inpatient and Outpatient data. Abbreviations: ASHD, atherosclerotic heart disease; CHF, congestive heart failure; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CVD, acute cerebrovascular disease; ESRD, end-stage renal disease; GI Hem, gastrointestinal hemorrhage; MI, myocardial infarction; mo, month.

Comorbid Conditions upon Transition to ESRD

Data related to comorbid conditions were obtained from multiple VA and CMS sources, and were based on ICD-9 diagnoses. After merging data from all sources, 82,598 veterans (96.6%) were identified as being diagnosed with at least one comorbid condition in the prelude period. Figure 8.9 (upper panel) shows the most common comorbidities among these veterans prior to transition to ESRD; the comorbidity list is restricted to those used for the calculation of

Charlson Comorbidity Index (Deyo method), as shown in Figure 8.9 (lower panel). The calculation of the Charlson Comorbidity Index excluded renal disease from the score [See the Kaiser Permanente-Southern California Section of this chapter for Charlson Comorbidity Index equation and score calculation used]. In addition to renal disease, CHF, diabetes, chronic obstructive pulmonary disease, and peripheral vascular disease were present in over half of the veterans. Of note, almost a quarter of all patients had a prior diagnosis of cancer and over 30% had a prior myocardial infarction.

vol 1 Figure 8.9 Selected comorbid conditions (a) for calculation of the Charlson Comorbidity Index (b) prior to transition to ESRD in 82,598 incident ESRD veterans



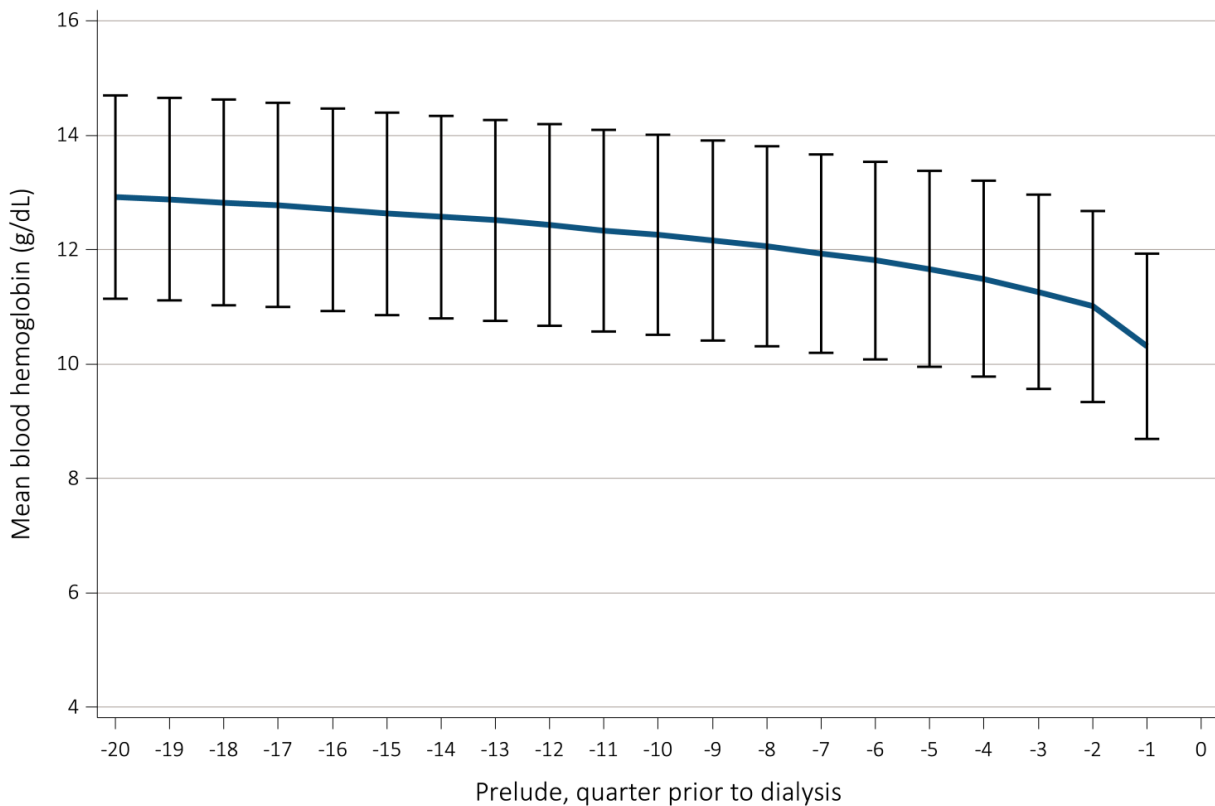
Data source: VHA Administrative data, CMS Medicare Inpatient and Outpatient data. Abbreviations: CHF, congestive heart failure; compl, complications; COPD, chronic obstructive pulmonary disease; CVD, cerebrovascular disease; Dz, disease; ESRD, end-stage renal disease; MI, myocardial infarction; Mod, moderate; PVD, peripheral vascular disease; PUD, peptic ulcer disease; Set, Severe.

Trends during Prelude Period (Prior to ESRD Transition)

Selected prelude (pre-ESRD) trends in laboratory data for up to 5 years prior to transition are shown below. Figure 8.10 shows the pre-ESRD trend in

average blood hemoglobin in 47,854 veterans who transitioned to ESRD over 20 calendar quarters, or 5 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 8.10 Trend in blood hemoglobin level during the prelude (pre-ESRD) time over 20 calendar quarters in 47,854 veterans who later transitioned to ESRD during 10/1/2007 -3/31/2014.

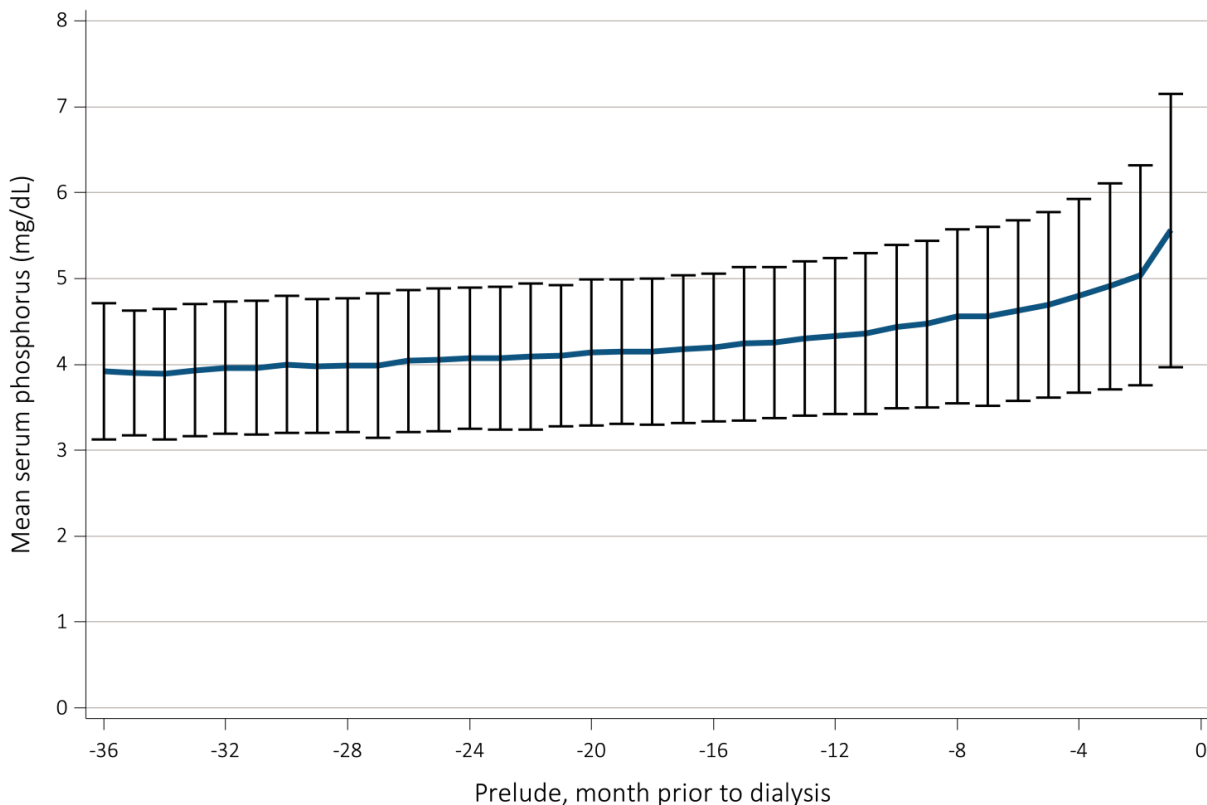


Data source: VHA Administrative data. Abbreviations: ESRD, end-stage renal disease; g/dL, grams per deciliter.

Figure 8.11 shows the pre-ESRD trend in averaged serum phosphorus in 24,765 veterans who transitioned to ESRD over 36 months or 3 years.

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

vol 1 Figure 8.11 Trend in serum phosphorus level during the prelude (pre-ESRD) time over 36 months in 24,765 veterans who transitioned to ESRD during 10/1/2007-3/31/2014.

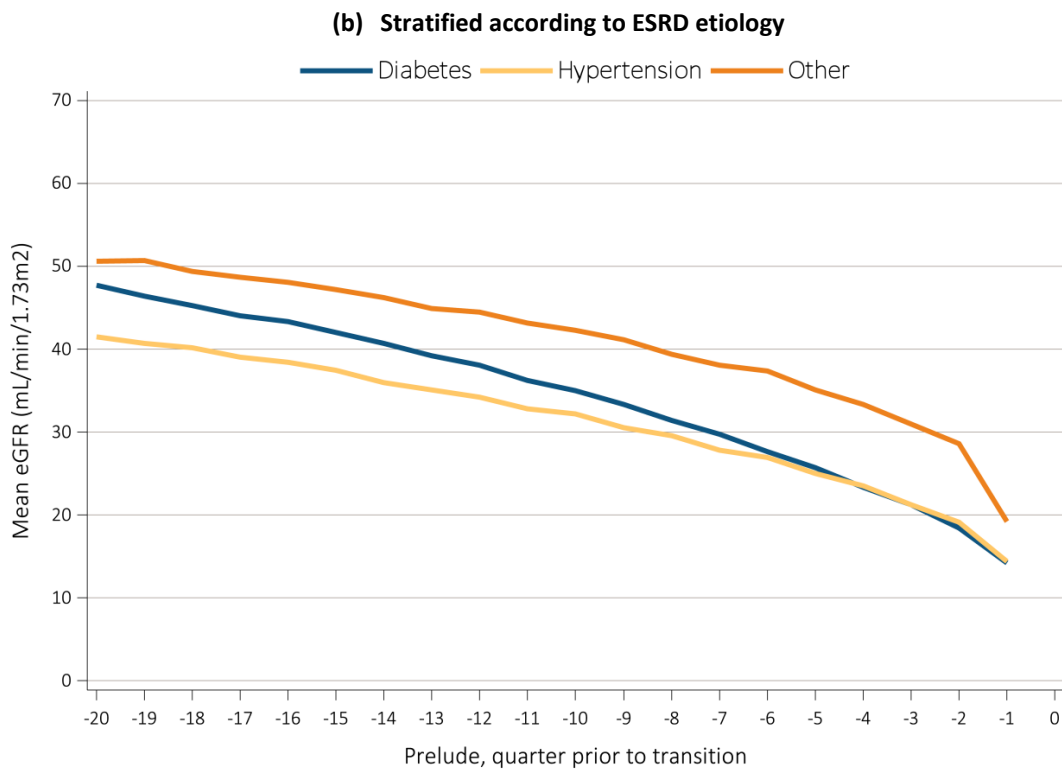
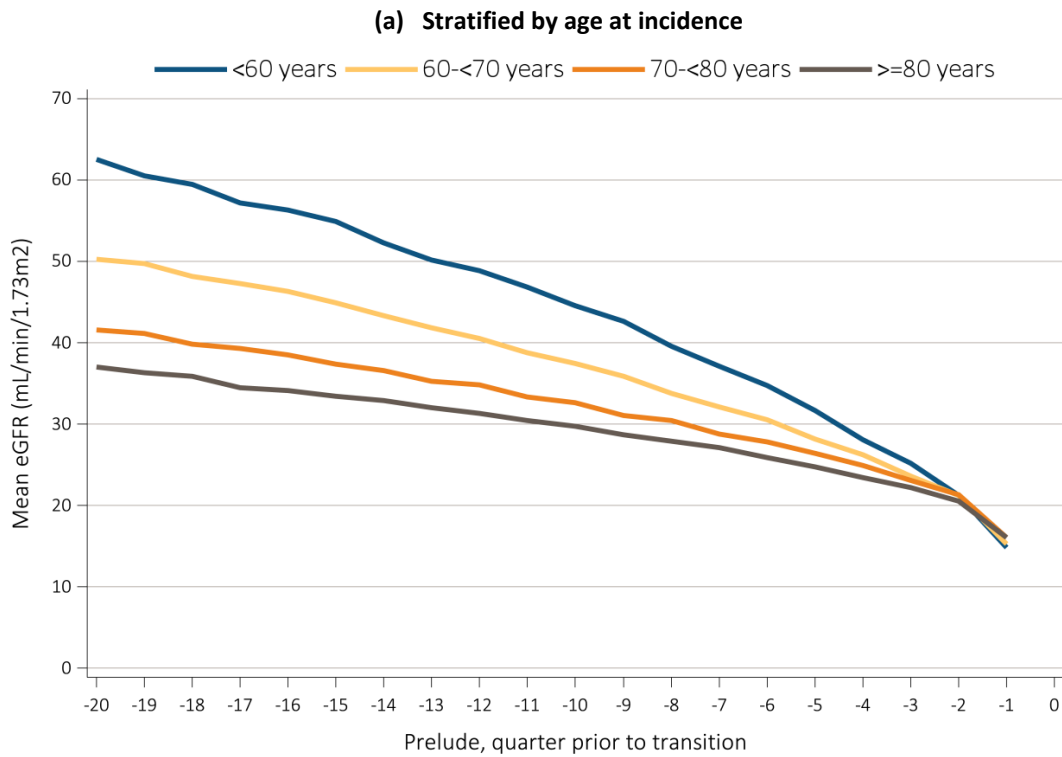


Data source: VHA Administrative data. Abbreviations: ESRD, end-stage renal disease; mg/dL, milligrams per deciliter.

Figure 8.12 shows the pre-ESRD trends in average eGFR calculated by the CKD-EPI creatinine equation for 49,871 veterans who transitioned to ESRD over 20 calendar quarters (5 years), stratified by age and cause of ESRD. Panel a shows that CKD patients who

transition at an older age have slower rate of progression than younger patients. Panel b suggests that those with diabetes as a cause of ESRD have a faster CKD progression.

vol 1 Figure 8.12 Trends in eGFR during the prelude (pre-ESRD) time over 20 calendar quarters in 49,871 veterans who transitioned to ESRD during 10/1/2007-9/31/2011.

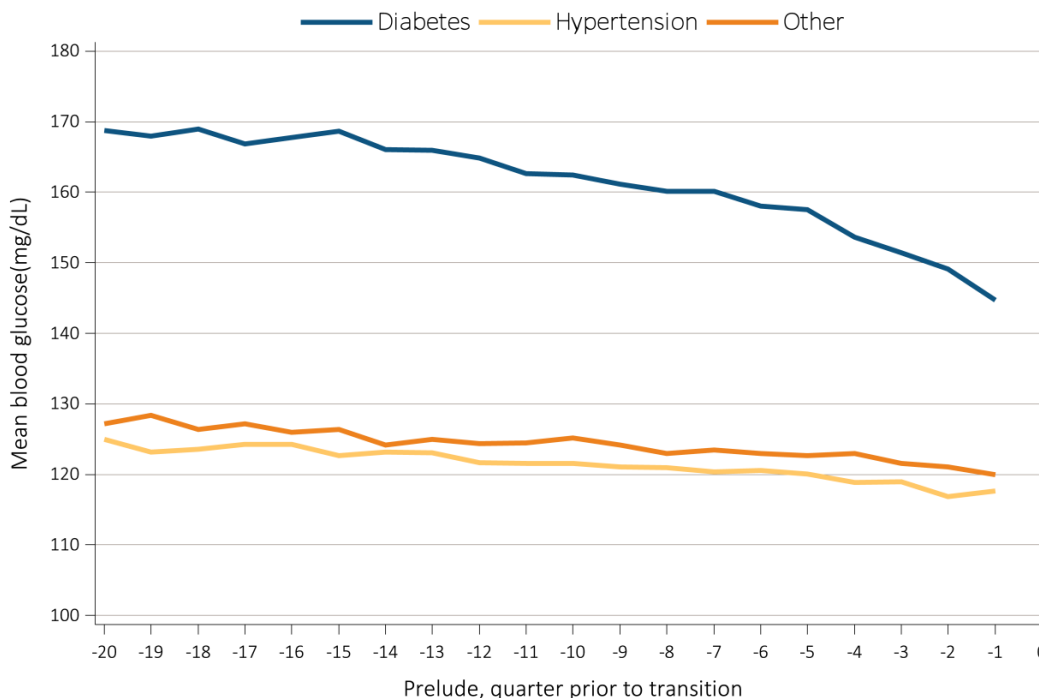


Data source: VHA Administrative data, USRDS ESRD Database. Abbreviations: eGFR; estimated glomerular filtration rate ;ESRD, end-stage renal disease; mL/min/1.73m2, milliliter per minute per 1.73 meters squared.

Figure 8.13 shows the pre-ESRD trend in glucose level by ESRD-reason for 49,608 veterans who transitioned to ESRD over 20 calendar quarters, or 5 years. Patients whose ESRD was due to diabetes

appeared to exhibit a gradual fall in serum glucose over time, as their CKD progressed to ESRD. Blood glucose levels did not change among patients whose ESRD was not due to diabetes.

vol 1 Figure 8.13 Trend in blood glucose level during the prelude (pre-ESRD) time over 20 calendar quarters in 49,608 veterans who transitioned to ESRD during 10/1/2007-3/31/2014.



Data source: VHA Administrative data, USRDS ESRD Database. Abbreviations: ESRD, end-stage renal disease; mg/dL, milligrams per deciliter.

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 Los Angeles and Orange Counties combined, with >17 million people) and is the fifteenth largest economy in the world. In addition to substantial socioeconomic diversity, SC has remarkable racial/ethnic diversity (38% Hispanics, 9% non-Hispanic Asians, and 8% non-Hispanic

Blacks). Kaiser Permanente of Southern California (KP-SC) is an integrated health care system that provides comprehensive health services for approximately four million residents of Southern California. KP-SC is the largest Kaiser Permanente (KP) region. Table 8.4 shows the demographic characteristics of the KP-SC member population compared to the 2010 US census and California populations. Proportion of males to females as well as distribution by age appears similar to both US census and California specific populations. Proportion of Hispanic patients matches that of the California specific total population. KP-SC has a larger proportion of non-Hispanic Black and a smaller proportion of Asian patients in comparison to the California total population.

vol 1 Table 8.4. Demographic characteristics of the Kaiser Permanente Southern California member population compared to the 2010 US census and California populations

	KPSC* (%)	US census 2010 (%)	California 2010 (%)
Sex			
Male	48.2	49.2	49.7
Female	51.8	50.8	50.3
Age			
Under 5 years	5.7	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	11.4
Ethnicity			
Hispanic	37.2	16.3	37.6
Non-Hispanic	52.9	83.7	62.4
Unknown	9.9		
Race			
White	47.1	74.8	61.6
Black	9.7	13.6	7.2
Native American Indian and Alaska	0.4	1.7	1.9
Asian	8.9	5.6	14.9
Others	6.9		18.9
Unknown	27.1		

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

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 claims⁷. Patients' demographic information—including 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, which mainly relies on four KP systems: Operational Data Store (ODS), HealthConnect (HC), Enhanced Prenatal Services

System (PSS), and Membership Extract Enrollment Management (MXEM). 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 from 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 California State Death Master Files, California State Multiple Cause of Death Master Files (MCOF), 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).

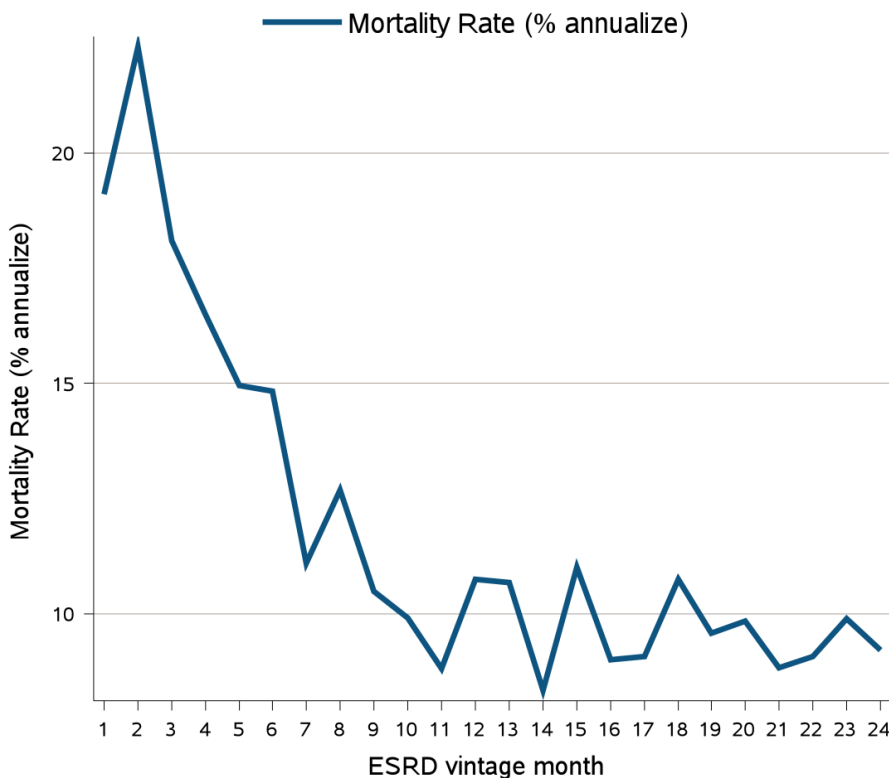
Over the seven years between 01/01/2007 and 12/31/2013, a total of 8,038 KP-SC members transitioned to ESRD. They were 62.5 ± 14.7 years old (mean \pm SD) and included 4,664 (58.0%) men and 3,374 (42.0%) women. Race/ethnic groups included non-Hispanic whites (2403, 29.9%), Blacks (1703, 21.2%), Asians (816, 10.2%), Hispanics (2866, 35.7%), and those of other race (250, 3.1%). According to SCPMG Renal program records, the cause of ESRD was diabetes in 4,189 (50.4%) patients and HTN in 1,488 (18.5%). At transition to ESRD, 6,806(84.6%) started on in-center HD, 1,030 (12.8%) started on PD (CAPD and CCPD), and 23 (0.3%) started on home hemodialysis. Among 6,829 patients starting on HD at transition, arteriovenous (AV) fistula was used in 2,428 (35.7%) and AV graft was used in 231 (3.4%)

patients for initial dialysis access. Pre-emptive transplant occurred in 156 (1.9%) at transition. During the first three months, 392 (4.9%) of all incident ESRD patients died.

OUTCOMES OF KAISER PERMANENTE SOUTHERN CALIFORNIA PATIENTS WHO TRANSITIONED TO ESRD

The annualized mortality rates among the 8,038 incident dialysis patients over the first 24 months of the vintage are depicted in Figure 8.14. 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.

vol 1 Figure 8.14 Annualized unadjusted mortality rate of the 8,038 incident ESRD patients who transitioned to ESRD during 1/1/2007-12/31/2013 who were followed for up to 24 months (N=8,038)



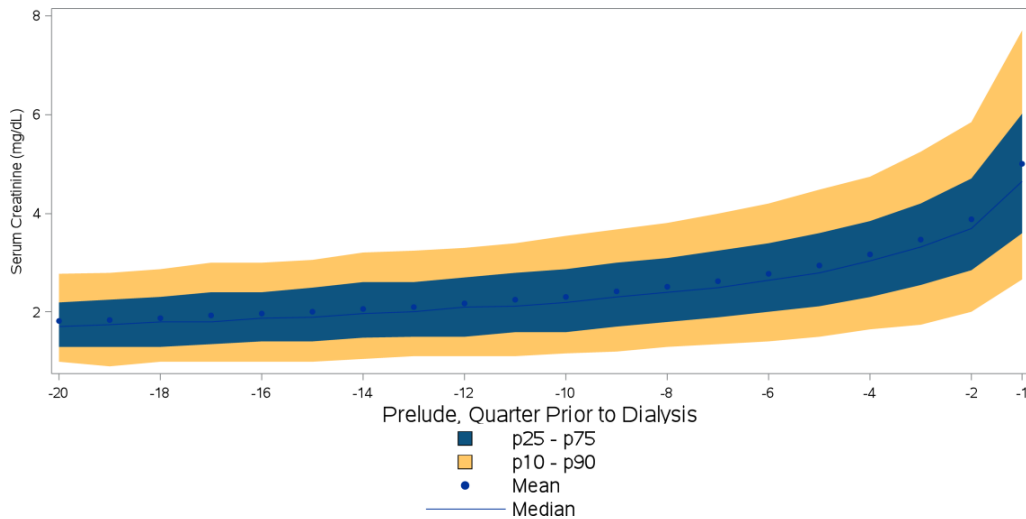
Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: ESRD, end-stage renal disease.

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

These data were extracted from the KP-SC Laboratory database which tracks inpatient and outpatient laboratory orders and results, spanning

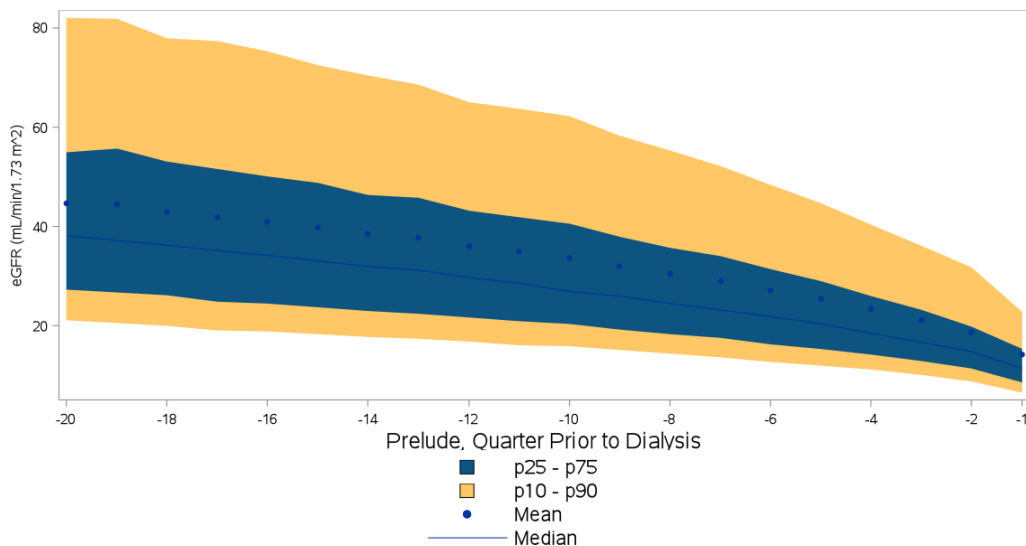
over 20 years. Figures 8.15 and 8.16 show prelude variables (including serum creatinine and eGFR) averaged by 91 day quarters (n=20 quarters) among the 7,885 patients who transitioned to dialysis. Age-stratified eGFR trend over 20 quarters shows that older CKD patients had a slower progression rate than younger patients (Figure 8.17).

vol 1 Figure 8.15 Trend in serum creatinine level during the prelude (pre-ESRD) period over 20 calendar quarters among 7,885 patients who transitioned to dialysis during 1/1/2007-12/31/2013



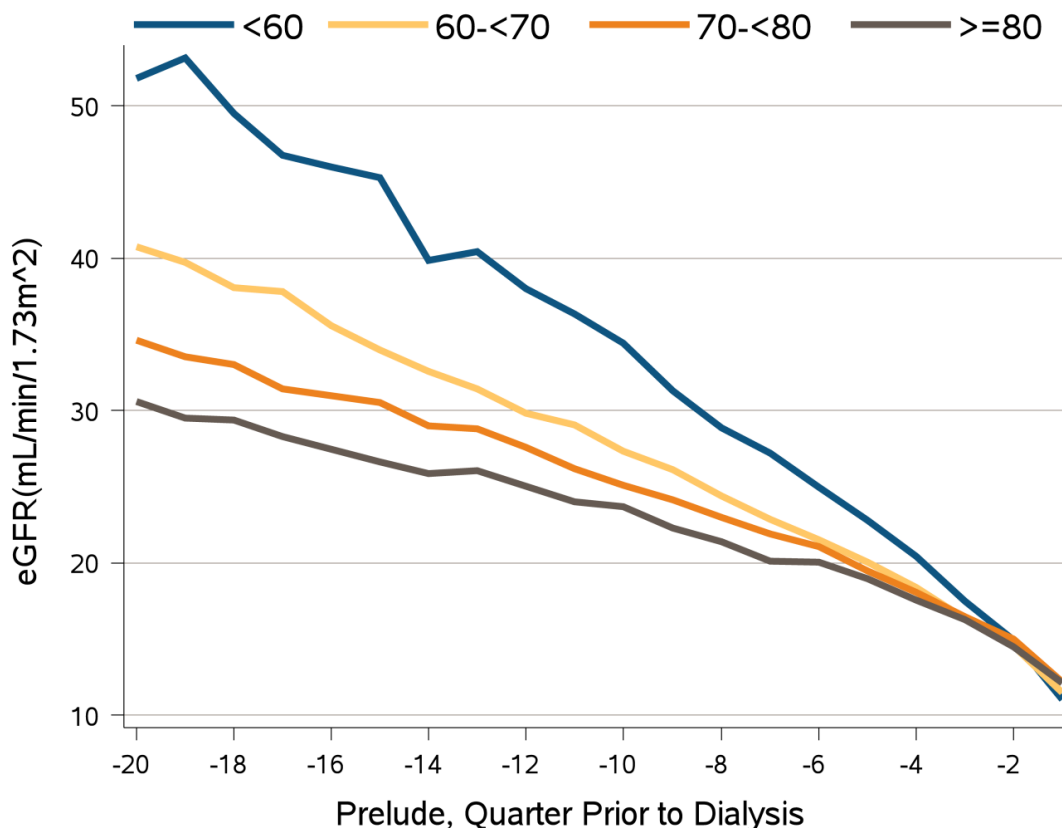
Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: ESRD, end-stage renal disease; mg/dL, milligrams per deciliter; p, percentile.

vol 1 Figure 8.16 Trend in eGFR during the prelude (pre-ESRD) period over 20 calendar quarters among 7,885 patients who transitioned to dialysis during 1/1/2007-12/31/2013



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

vol 1 Figure 8.17 Age-at-incidence stratified trends in eGFR during the prelude (pre-ESRD) period over 20 calendar quarters among 7,885 patients who transitioned to dialysis during 1/1/2007-12/31/2013

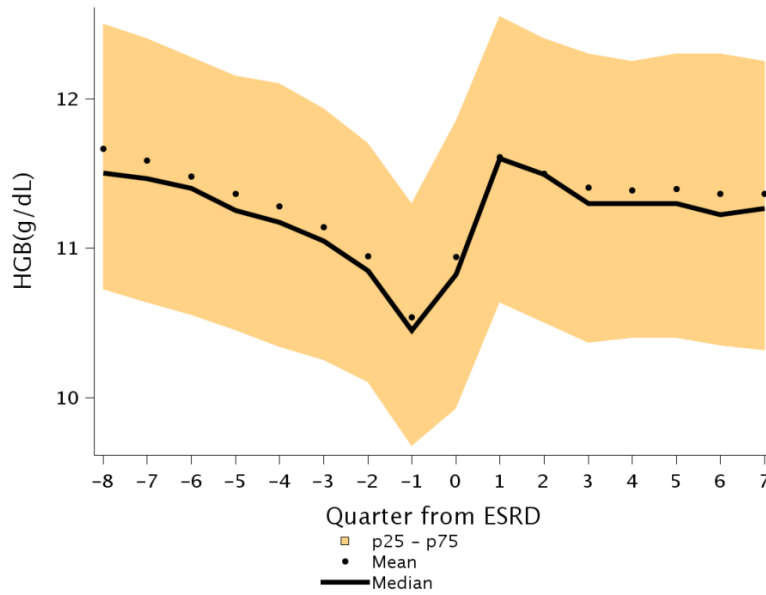


Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: eGFR; estimated glomerular filtration rate ;ESRD, end-stage renal disease; mL/min/1.73m², milliliter per minute per 1.73 meters squared.

Among the 8,038 patients who transitioned to ESRD, the next set of figures show selected KP-SC laboratory data for hemoglobin, HbA_{1c}, phosphorus, parathyroid hormone (PTH) and albumin levels during the prelude (pre-ESRD) and vintage (post-ESRD) periods over eight prelude (quarters -8 to -1) and eight vintage (quarters 0 to +7) calendar quarters (see Figure 8.18, 8.19, 8.20, 8.21 and 8.22 respectively).

Mean hemoglobin gradually decreased from 11.66 g/dL to a nadir of 10.54 g/dL in the prelude period of progression from CKD to ESRD. Immediately after transition to ESRD, a slight increase in mean hemoglobin to 10.94 g/dL was observed in the first quarter (quarter 0), followed by a rise to a peak of 11.60 g/dL in the second quarter (quarter 1). Subsequent mean hemoglobin in vintage quarter 3 and later appeared fairly stable (Figure 8.18).

vol 1 Figure 8.18 Trend in hemoglobin levels (g/dL) over 8 calendar quarters each in the prelude (pre-ESRD) and vintage (post-ESRD) periods among 8,038 patients who transitioned to ESRD during 1/1/2007-12/31/2013

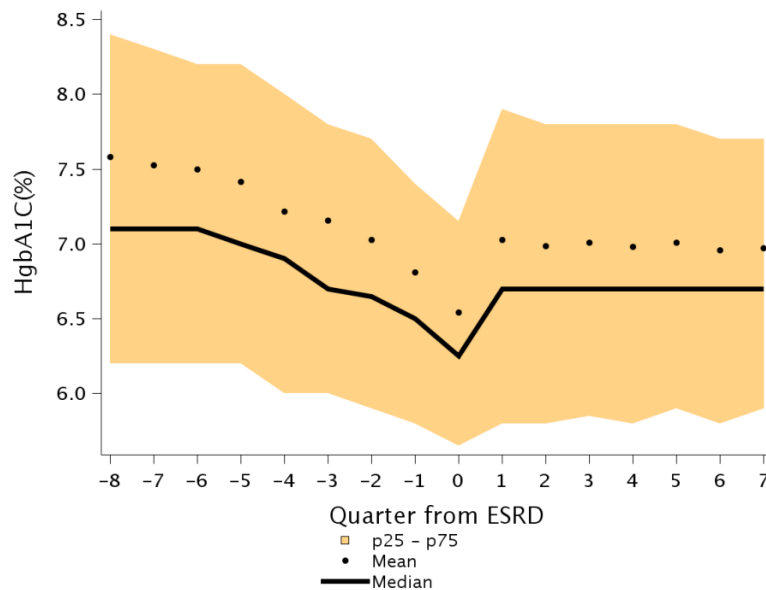


Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: ESRD, end-stage renal disease; g/dL, grams per deciliter; p, percentile.

In Figure 8.19, mean HbA1c levels dropped from 7.58% to 6.81% in the prelude period, then slightly decreased even further from 6.81% to 6.54% immediately after transition to ESRD. In the second

quarter post transition, mean HbA1c levels rose to 7.03% and remained fairly stable afterwards in the vintage period.

vol 1 Figure 8.19 Trend in HgbA1C levels (% of total Hgb) over 8 calendar quarters each in the prelude (pre-ESRD) and vintage (post-ESRD) periods among 8,038 patients who transitioned to ESRD during 1/1/2007-12/31/2013

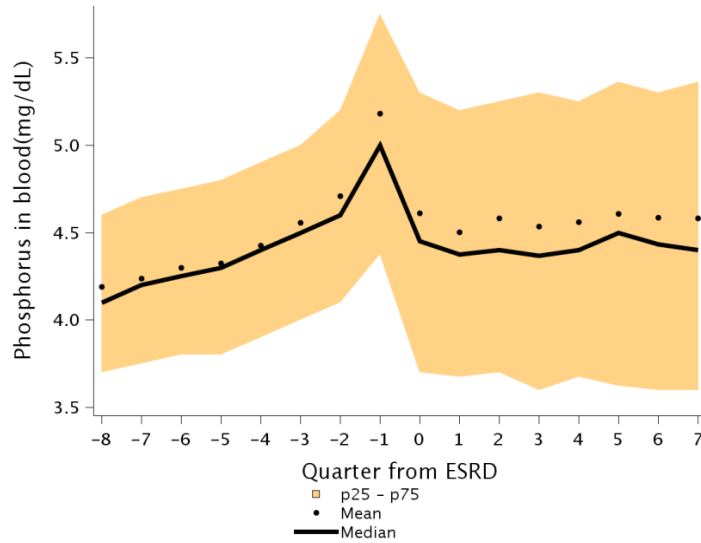


Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: HbA1C, hemoglobin A1C; Hb, hemoglobin; ESRD, end-stage renal disease ; p, percentile.

Mean phosphorus increased in the prelude period from 4.19 mg/dL to 5.18 mg/dL (Figure 8.20). Immediately after transition to ESRD, mean

phosphorus decreased from 5.18 mg/dL to 4.61 mg/dL and remained fairly stable in the vintage period.

vol 1 Figure 8.20 Trend in phosphorus levels (mg/dL) over 8 calendar quarters each in the prelude (pre-ESRD) and vintage (post-ESRD) periods among 8,038 patients who transitioned to ESRD during 1/1/2007-12/31/2013

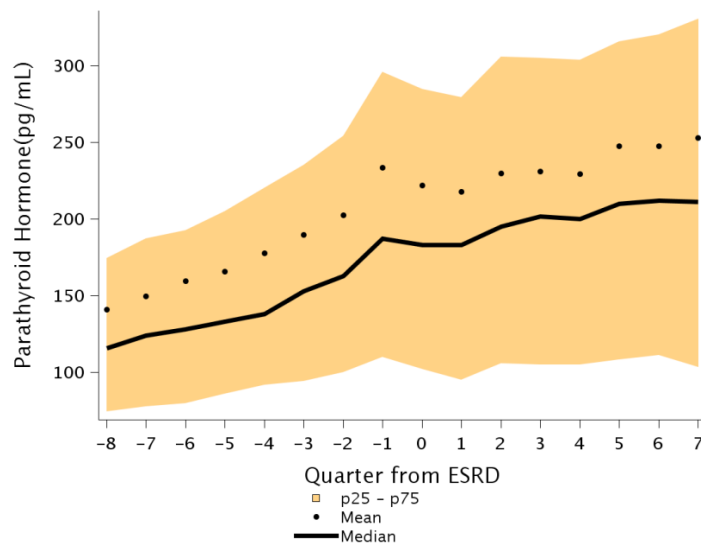


Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: ESRD, end-stage renal disease; mg/dL, milligrams per deciliter; p, percentile.

Figure 8.21 shows mean parathyroid hormone (PTH) steadily increasing over the prelude and vintage periods from 141.18 pg/mL to 252.84 pg/mL. Transition

to ESRD did not appear to modify the increase trajectory of PTH over time.

vol 1 Figure 8.21 Trend in PTH levels (pg/mL) over 8 calendar quarters each in the prelude (pre-ESRD) and vintage (post-ESRD) periods among 8,038 patients who transitioned to ESRD during 1/1/2007-12/31/2013

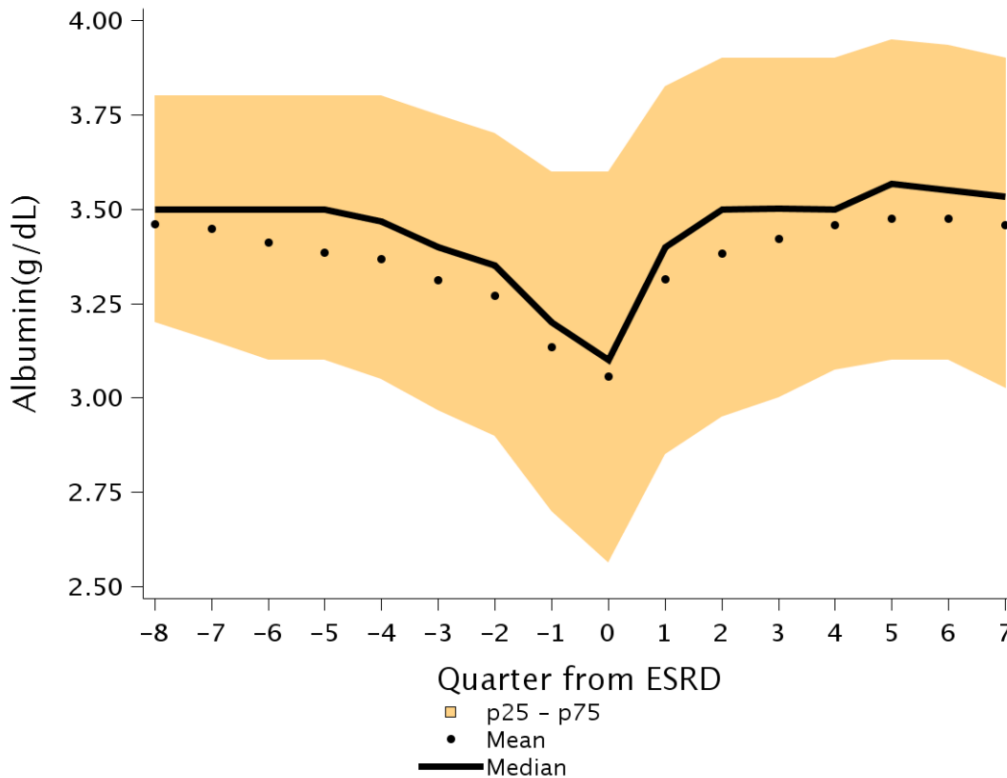


Data source: Kaiser Permanente Southern California Electronic Health Records. Abbreviations: PTH, parathyroid hormone; ESRD, end-stage renal disease; pg/dL, picograms per deciliter; p, percentile.

Mean albumin dropped from 3.46 g/dL to 3.06 g/dL over the prelude period and until the first quarter post transition to ESRD, but increased to 3.31 g/dL in the

second vintage quarter and subsequently remained stable over the following vintage period (Figure 8.22).

vol 1 Figure 8.22 Trend in albumin levels (g/dL) over 8 calendar quarters each in the prelude (pre-ESRD) and vintage (post-ESRD) periods among 8,038 patients who transitioned to ESRD during 1/1/2007-12/31/2013



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

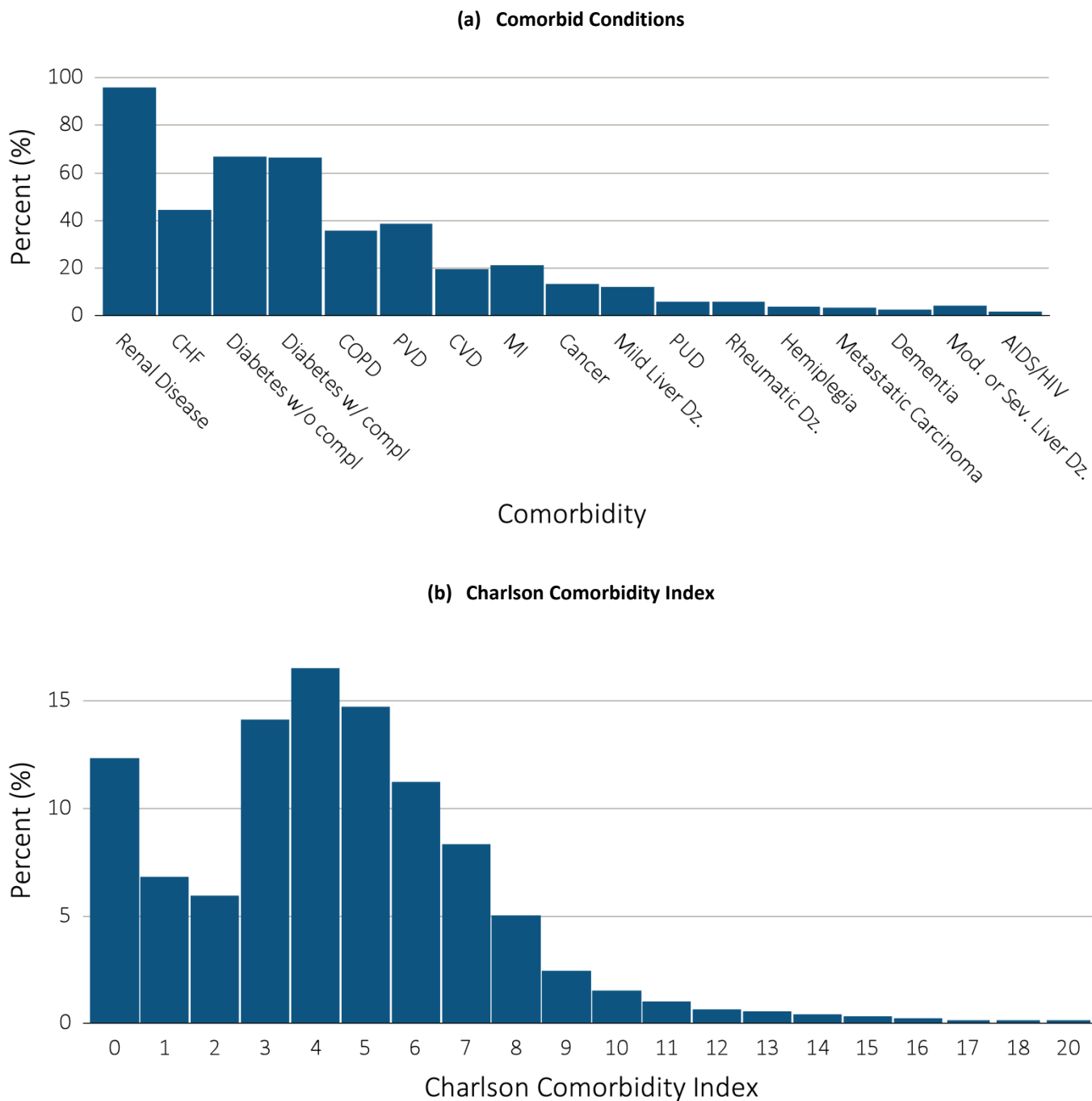
TC-CKD COMORBIDITY DATA PRIOR TO ESRD TRANSITION AT KAISER PERMANENTE SOUTHERN CALIFORNIA

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 comorbidities were determined by ICD-9-CM documentation in records from inpatient or outpatient settings in the three years prior to transition to ESRD. A macro originally developed at Manitoba Centre for Health Policy (MCHP) website was used to estimate Charlson Comorbidity Index (CCI) scores (see Figure 8.23). A revised, weighted

Charlson Comorbidity Index (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

vol 1 Figure 8.23 Selected comorbid conditions for calculation of the Charlson Comorbidity Index prior to transition to ESRD 8,038 incident ESRD patients



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.

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Volume 1: CKD Analytical Methods

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Introduction

In this chapter we describe the data sources, preparation and management, variable definition, and analytic methods used to produce the statistics presented in Volume 1 of the 2016 USRDS Annual Data Report (ADR), which focuses on chronic kidney disease (CKD) prior to end-stage renal disease (ESRD). Datasets and methods used for ESRD analyses are described in the ESRD Analytic Methods chapter of Volume 2.

Data Sources

The USRDS uses several data sources to describe pre-ESRD kidney disease in the United States (U.S.), through obtaining data on diagnoses, demographic characteristics, health care procedures, prescription drug plan participation, and filled prescriptions. Data on the non-institutionalized, general population were obtained 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 health care systems were used: the standard Centers for Medicare and Medicaid Services (CMS) Medicare 5% sample, the Clinformatics™ Data Mart Database of people with commercial health insurance plans as obtained from OptumInsight, and the Veterans Administration.

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.. NHANES III was conducted in two phases between 1988 and 1994. In 1999, NHANES became a continuous, annual survey to provide for regular estimates, with the release of public-use data files every two years. Both NHANES III and NHANES 1999–2014 were nationally-representative, cross-sectional surveys with a complex, stratified, multi-stage probability cluster sampling design that included the selection of primary sampling units (counties),

household segments within the counties, and sample persons from selected households (Johnson et al., 2013). Survey participants were interviewed in their homes and/or received standardized medical examinations in mobile examination centers. Both sets of surveys over-sampled African Americans, Mexican Americans, and individuals aged 60 or older 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 land-line subscribers, cell phone users were included in the sample frame. A question regarding kidney health was added in 2012—specifically, respondents were 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%).

CLINFORMATICS™ DATA MART DATABASE (OPTUMINSIGHT, EDEN PRAIRIE, MN)

The Clinformatics™ Data Mart data provides paid medical and prescription claims and enrollment information for national participants in commercial insurance plans of a large U.S. managed care health insurance company. The data is purchased from OptumInsight, and participants are enrolled in both a medical and a prescription plan.

The Clinformatics™ data license requires that 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 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 m.1 for specific code values. We present Clinformatics™ data from 2005 through 2014 in the 2016 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 used the Date of Death (DOD) view of the data; detailed geographic

and socio-economic data were not available in the files, but date of death was included. The other available data views do not contain death date. Enrollment and member information, such as year of birth, gender, race/ethnicity, state of residence, and plan participation, are contained in the MEMBER and MEMBER_DETAIL data tables. A summarized facility detail record for each inpatient episode occurring in an acute care hospitalization or skilled nursing facility setting is contained in the inpatient CONFINEMENT data table, while all services for both inpatient and outpatient care are located in the MEDICAL claims data table.

vol 1 Table m.1 ICD-9-CM diagnosis, CPT procedure, and DRG codes used to define ESRD in the Clinformatics™ and VA datasets throughout Volume 1 of the ADR

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
CPT Procedure codes		90935, 90937, 90940, 90945, 90947, 90951-90970, 90989, 90993, 90997, 90999; codes from earlier years: 90918-90925
DRG Codes	Prior to FY2007:	302,512
	FY2007-present:	652,008

Abbreviations: CPT, current procedural terminology, DRG, diagnosis related group, FY, fiscal year (10/1/06 to 9/30/07), ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification.

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

Date of death information is provided as month and year only and not a specific date. 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. The Clinformatics™ Data Mart is augmented with data from the Social Security Death Master File (SSDMF). In November of 2011, however, 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).

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 for reimbursement by health care providers. CMS and its contractors produce the 5% data sets by selecting all final action claims for Medicare beneficiaries whose CMS Health Insurance Claims (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 has the effect of creating a built-in longitudinal panel dataset. 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 2016 ADR includes all claims for care occurring up to December 31, 2014, that were submitted and processed by June of 2015.

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 were divided into two groups based on the type of healthcare provider—institutional or physician/supplier. Institutional claims were 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 received 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) were received in one set for durable medical equipment (DME) and another for all other Part B covered services (BCARRIER). For each of these, we received 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 received files on beneficiary information and claims, 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 final action claims for prescription drugs submitted by pharmacies on behalf of the Part D beneficiary. This data set contains details about the drug (name, days supplied, dose, strength, quantity, etc.) and payment amounts.

In addition to these beneficiary and beneficiary-prescription fill level datasets, we also received files containing data about the Part D plan, prescribers, and pharmacies. For the 2016 ADR, we used the Plan Characteristics file (PLAN_CHAR) and premium (PREMIUM) files to report on the coverage gap and distribution of premiums.

VETERANS ADMINISTRATION HEALTH CARE DATA

The 2016 ADR is the first year we present data on kidney disease from the Veterans Administration's health care system. Data is primarily from the Corporate Data Warehouse (CDW) supplemented by 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 VA's electronic medical record and the analyses in the 2016 ADR are based on a cohort created by the VINCI data manager on June 24, 2016. Our basic cohort is defined as all patients with at least one outpatient encounter (a record in the VISIT table in the OUTPAT domain) during calendar year 2014. Age, gender, race, and date of death are taken from the PATIENT.PATIENT table and race was supplemented with data from the PATSUB.PATIENTTRACE table. Ethnicity was from PATSUB.PATIENTETHNICITY.

In the CDW, various types of inpatient care provided by the VA 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 admission 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 MEDICALSERVICE variable to have one of the following values: medicine, surgery, psychiatric, spinal cord injury, intermediate medicine, or neurology. Additionally, the Specialty variable must also have a value related to the type of care provided in short-term hospitals¹.

Serum creatinine laboratory test results were 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 were 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.) were dropped, as were those with values less than 0.4 mg/dL or greater than 15.0 mg/dL for the CKD analyses (20.0 mg/dL for the acute kidney injury analyses).

¹ Contact usrds@usrds.org to request a detailed listing of all SPECIALTY variable values.

ESRD MEDICAL EVIDENCE FORM

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 on ESRD, we searched the USRDS ESRD databases for the beneficiaries in the Medicare 5% files. The date of ESRD was determined from the ESRD Medical Evidence form (CMS 2728), the official form for registering ESRD patients, which must be submitted by dialysis or transplant providers within 45 days of ESRD initiation. First service date for ESRD is reported on this form, and for analyses in this Volume was used as the date when ESRD began. See Volume 2 for additional information on how the Medical Evidence form was used in analyses of ESRD patients.

ESRD DEATH NOTIFICATION FORM

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 supplemented 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, this form must be submitted by dialysis or transplant providers 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. Table m.2 shows the categories included in the original data files. For the Medicare 5% files and 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 could not identify Native Americans in the Clinformatics™ data. The NHANES, BRFSS, and VA data report two variables, one with race categories and a second designating Hispanic ethnicity. These categories are combined for some analyses due to small sample sizes in some data sets.

vol 1 Table m.2 Race and ethnicity categories reported in the data sources of Volume 1 of the ADR

Race/Ethnicity Variables	NHANES	BRFSS	Medicare 5% data	Clinformatics™ Data Mart	Veterans Administration
Separate variable for Hispanic?	X	X			X
Race Variable Categories					
White	X	X	X	X	X
Black/African American	X	X	X	X	X
Hispanic	Separate	Separate	X	X	Separate
Native American	X	X	X		X
Asian	X	X	X	X	X
Pacific Islander/Native Hawaiian	X	X			X
Other	X	X	X		X
Unknown/missing/refused	X	X	X	X	X

General Methods for Health Insurance Claim Data Files

For the purpose of analysis, several restrictions were applied to the claims data files to create a sample cohort. The specific restrictions used for each figure and table are detailed in the chapter-specific sections. 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 dataset was to reimburse health care 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 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) to 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 were often limited to beneficiaries that were enrolled in both Parts A and B and were not enrolled in a Medicare Advantage plan (Part C). In the 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 data sets, the cohort was limited to patients who met these plan participation requirement on a certain date, such as January 1 of the reported year. In other cases the sample may have been limited to beneficiaries meeting those enrollment requirements during entire calendar year.

In most analyses that were limited to patients with a certain disease or disorder, such as CKD, Medicare beneficiaries must have been 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 Clinformatics™ patients must have been enrolled in their plan for that time. This ensures that each patient has 12 months of claims from which to determine the presence of the disorder. The outcome under analysis was then determined from claims in the year following the entry period (‘year two’). Prevalence analyses, however, were not subject to this requirement and used 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 were restricted to beneficiaries that were age-eligible for Medicare and, therefore, aged 65 and older. Beneficiaries under the age of 65 may have qualified for Medicare on the basis of 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 for this Volume included 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 were excluded. The 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 did 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 censored a patient at the start of ESRD, as well as at death, or change in plan enrollment (for Medicare beneficiaries, the disenrollment from Parts A and B of Medicare, or switch to a Medicare Advantage plan and for Clinformatics™ patients, the end of plan participation as reported by the ELIGEND variable. The start of ESRD was 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 starting in 2004 for Clinformatics™ plan members.

Identification of Major Comorbidities

According to a previously validated method for using Medicare claims to identify diabetic patients (Herbert et al., 1999), a patient is considered diabetic if, within a one-year observation period, he or she had a qualifying ICD-9-CM diagnosis code of diabetes

mellitus (DM) on one or more Part A institutional claims (inpatient, skilled nursing facility, or home health agency), or two or more institutional outpatient claims and/or Part B physician/supplier claims. This algorithm—one inpatient claim, or two outpatient claims with specified diagnosis codes—was 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 was also applied to the claim data in the Clinformatics™ Data Mart with the inpatient/outpatient determination made by determining if the service date fell within an inpatient confinement defined by the admission and discharge dates. Tables m.3 and m.4 list these conditions and the ICD-9-CM diagnostic codes used to define them. Additionally, the overall grouping of cardiovascular disease (CVD) included patients with at least one of these individual conditions: atherosclerotic heart disease, 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 m.3 ICD-9-CM diagnosis codes used to define chronic kidney disease in the health insurance claim data files throughout Volume 1 of the ADR

Condition name	ICD-9-CM codes
Chronic kidney disease	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
Staging of chronic kidney disease	
Stage 1	585.1
Stage 2	585.2
Stage 3	585.3
Stage 4	585.4
Stage 5	585.5 or 585.6 with no CMS 2728 form
Stage unknown or unspecified	Patient has no claims with codes 585.1-585.6 but has: 016.0; 095.4; 189.0,189.9; 223.0; 236.91; 250.4; 271.4; 274.1; 283.11; 403; 404; 440.1; 442.1; 477.3; 572.4; 581-584; 585.9; 586-588; 591; 642.1; 646.2; 753.12-753.19; 753.2; 794.4

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

vol 1 Table m.4 ICD-9-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
Anemia	280-285
Atherosclerotic heart disease (ASHD)	410-414; V45.81; V45.82
Cancer	140-172; 174-208; 230-231; 233-234
Cardiac, other	420-424; 429; 785.0-785.3; V42.2; V43.3
Cerebrovascular accident (CVA) / transient ischemic attack (TIA)	430-438
Chronic obstructive pulmonary disorder (COPD)	491-494; 496; 510
Congestive heart failure (CHF)	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
Diabetes mellitus (DM)	250; 357.2; 362.0; 366.41
Dysrhythmia	426-427; V45.0; V53.3
Gastrointestinal bleeding disorders (GI)	456.0-456.2; 530.7; 531-534; 569.84-569.85; 578
Hypertension (HTN)	362.11; 401-405; 437.2
Liver disease	570-571; 572.1, 572.4; 573.1-573.3; V42.7
Peripheral vascular disease (PVD)	440-444; 447; 451-453; 557

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

Chapter 1: CKD in the General Population

Analyses in this chapter used 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). NHANES III was fielded in 1988-1994; starting in 1999 and continuing to the present, 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 the NHANES continuous cycle years 1999-2002, 2003-2006, 2005-2006, 2007-2010, and 2011-2014. The

statistical software package SAS[®], version 9.3, was used to analyze all NHANES data, incorporating the sampling weights and survey design through its survey procedures.

In this chapter, age was defined as the participant's age at the time of the household interview, categorized into the following age groups: 20-39, 40-59, 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 was based on the 2012 guidelines from the Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group (KDIGO, 2013)

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, which was 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 used the urine albumin

creatinine ratio (ACR) to measure albuminuria, but did not have information regarding the other markers of kidney damage. Also, the NHANES only included a single measurement of both serum creatinine (sCR, used to generate eGFR) and ACR, so we could not address the three-month persistence criteria for defining CKD.

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:

$$eGFR = 141 * \min\left(\frac{sCR}{\kappa}, 1\right)^\alpha * \max\left(\frac{sCR}{\kappa}, 1\right)^{-1.209} * 0.993^{AGE} * 1.018 * F * 1.159 * B$$

where:

sCR = serum creatinine in mg/dL

κ = 0.7 if female, 0.9 if male

α = -0.329 if female, -0.411 if male

F = 1 if female, 0 if male

B = 1 if Black/African American, 0 otherwise

AGE is measured in years

The ACR is the ratio of urinary albumin (mg/L) to urinary creatinine (mg/dL). Based on an NCHS suggestion, the urine creatinine value was adjusted to NHANES 2007-2008 (CDC, 2009).

Staging of CKD was first introduced by the National Kidney Foundation’s Kidney Disease Outcomes and Quality Improvement Guidelines in 2002 (NKF, 2002). Following these guidelines, we defined stages of CKD in this chapter as:

- Stage 1: ACR \geq 30 and eGFR \geq 90
- Stage 2: ACR \geq 30 and 60 \leq eGFR <90
- Stage 3: 30 \leq eGFR <60
- Stage 4: 15 \leq eGFR <60
- Stage 5: eGFR <15

Participants with diabetes mellitus (DM) included 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 A_{1c} (HbA_{1c}; glycohemoglobin) \geq 7%. Participants with self-reported diabetes mellitus (SR DM) were those who reported having been told by a doctor that they have diabetes or sugar diabetes (other than during pregnancy). In NHANES 2005–2012, participants answering “borderline” were classified as non-diabetic, to agree with NHANES III coding. Control of DM is assessed as an HbA_{1c} less than 7%.

Patients with hypertension (HTN) were 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) was 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 were classified as aware of their HTN if they reported 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 $\leq 140/\leq 90$ ($\leq 130/\leq 80$ for CKD or SR DM).

Participants who self-reported any of the following diseases were considered to have self-reported cardiovascular disease (SR CVD): angina, myocardial infarction, stroke, coronary heart disease, or congestive heart failure. Hyperlipidemia was measured in the medical examination. We assessed whether total cholesterol fell into one of three categories: <200 (desirable), 200–239 (borderline high), and ≥ 240 (high). Individuals were classified as current smokers if they gave an affirmative answer to the question “Do you now smoke cigarettes?” and former smokers if they responded negatively to the previous question, but affirmatively to the question “Have you smoked at least 100 cigarettes in your life?”

Adjusted odds ratios in Figures 1.9-1.11 were calculated using logistic regression, incorporating the sampling weight and survey design. Each figure displays the results of seven logistic models. The model for age included age (20-39/40-59/60+), 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) included age (20-39/40-59/60+), sex (male/female), race (White/Black/other) and presence of the risk factor shown (yes vs. no). Ninety-five percent confidence intervals are displayed.

Figure 1.17 tabulates responses to the 2012 and 2014 Behavioral Risk Factor Surveillance System question, “Has a doctor, nurse, or other health professional ever told you have kidney disease?” by U.S. state.

Figure 1.18 shows the expected remaining lifetime of patients with and without CKD given survival to various ages. Life expectancy was calculated from publicly available, mortality-linked NHANES data from 1999-2010, with follow-up through 2013.

Chapter 2: Identification and Care of Patients with CKD

All of the analyses in the *Prevalence of Recognized CKD and Longitudinal Change in CKD Status and Outcomes, Based on Diagnosis Codes* sections of this chapter included point prevalent patients who survived all of the reported year (2014 for most of the figures and tables) and did not have or develop ESRD during 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. Clinformatics™ analyses additionally required the plan member be enrolled the entire reported year, while the age range of included members varied by table, with Tables 2.1 and 2.3 including all ages and the remaining tables and figures including adults age 22-64. 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) and the Clinformatics™ dataset. Comorbidities included are 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, atherosclerotic heart disease, congestive heart failure, dysrhythmia or other cardiac comorbidities. Each comorbidity is defined by medical claims (at least one inpatient or two outpatient 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 m.3 and m.4 for a list of ICD-9-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 22-64 in the Clinformatics™ dataset. 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.

Table 2.3 shows the unadjusted prevalence of diagnosed CKD by age, sex (male/female), race (White/Black/Native American/Asian/Hispanic [Clinformatics™ only]/other), and comorbidity in 2014. Comorbidities included were DM, HTN and CVD. Figure 2.1 illustrates the prevalence of CKD over time in the fee-for-service, age-eligible Medicare population—overall (any code) and by CKD stage-specific codes.

Table 2.4 shows the percent of patients with CKD by demographic characteristics, among patients overall, those with DM (with or without HTN), and those with HTN without DM, in the NHANES (2011-2014, see the section *Chapter 1: CKD in the General Population* in this chapter for methods), the Medicare 5% sample (2014), and the VA (2014). NHANES data included the 2011-2014 survey years and were restricted to participants aged 65 or older. CKD was determined by $eGFR < 60 \text{ ml/min/1.73m}^2$ for the NHANES data, by ICD-9-CM diagnosis code in the Medicare 5% sample, and by both methods in the VA data.

Table 2.5 shows progression of kidney disease by CKD stage, end-stage renal disease (ESRD), or death in 2013-2014 for the fee-for-service, age-eligible Medicare population in 2009. The analysis cohort required patients to be alive and eligible for Medicare Parts A and B with no HMO coverage for all of 2009. Death and ESRD status were examined yearly between 2010 and 2014, and carried forward if present. In the 2016 ADR, the ESRD and death information are combined to create the three categories of ESRD-Alive, ESRD-Death, and Death without ESRD. For patients without death or ESRD by 2014 the last CKD diagnosis claim in 2014 was used; if this was not available, the last CKD diagnosis claim from 2013 was

used. Lost to follow-up status represents the patients who were not enrolled in Medicare Part A and B during 2013 or 2014 and who had no indication of death or ESRD.

Figures 2.2–2.3 show statistics on laboratory testing for serum creatinine and urine albumin among various patient populations and by patient characteristics. 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 had Medicare Parts A and B coverage, no Part C participation (Medicare Advantage plans), no ESRD, and have been alive for all of year one through to January 1 of year two. Additionally, the sample was limited to patients residing in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. First urinary microalbumin measurement was 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. Likewise, first serum creatinine measurement was defined as the first claim with a HCPCS code of 80047, 80048, 80049, 80050, 80053, 80054, 80069, or 82565.

Figures 2.3 and 2.4 show the proportion of patients tested across time, from 2000-2013 for patients with (Figure 2.4) and without (Figure 2.3) CKD. Figures 2.5 and 2.6 show the adjusted prevalence of testing in 2013 for those with (Figure 2.6) and without (Figure 2.5) CKD, by comorbidity status: (1) the patient has neither DM nor HTN; (2) the patient has HTN but not DM; (3) the patient has DM but not HTN; and (4) the patient has both DM and HTN. Adjustments were made for age (65-<75/75-<85/85+), sex (male/female), and race (White/Black/Native American/Asian/Hispanic/other/unknown).

Table 2.6 examined physician visits in the year after a diagnosis of CKD. Similar to the laboratory testing, the sample included patients who were alive, without ESRD, did not have a Medicare Advantage plan, and had both Parts A and B coverage for all of 2012. The date of the earliest CKD claim (any CKD or Stage 3/4/5 [585.3–585.6]) in 2012 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 and 11. Cardiologist visits were defined based on specialty code 06, and nephrology visits were defined based on specialty code 36.

Table 2.7 presented the proportion of patients in the fee-for-service, age-eligible Medicare population in 2013 with CKD (based on diagnostic code), who were tested for urine albumin or serum creatinine in 2013, according to whether they saw a primary care physician or nephrologist in 2012. The analysis cohort required patients to be alive and eligible for all of 2013 with a CKD diagnosis claim in 2012.

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, not in a Medicare Advantage plan (Part C) and covered by Parts A and B 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 these criteria and be aged 66 or older on January 1 of the following year (year two). Mortality and hospitalization were then determined from January 2 to December 31 of year two. Analyses were also 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 Medicare Parts A or B, switch to a Medicare Advantage plan (Part C), or December 31 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 the ESRD Death Notification form CMS 2746, and the Social Security Death Master file. Figure 3.1 shows time trends in unadjusted and adjusted all-cause mortality by CKD status from 2002 to 2014, and Figure 3.2 shows rates for 2014 by CKD status and stage.

Unadjusted mortality was calculated as the number of deaths divided by the number of patient-years at risk, and expressed as “per 1,000 patient years.” Adjusted mortality was based on a Cox regression model and adjusted for age (66-<70/70-<75/75-<85/85+ years), race (White/Black or African American/other), and sex. This modified set of adjustment covariates has been used 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 2013 were used as the reference cohort for Figure 3.1, while all patients in 2014 formed the reference cohort for Table 3.1 and Figures 3.2, 3.3, 3.4, 3.5 and 3.6.

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 overlapping claims (two claims covering the same time frame), consecutive claims (one claim’s admission date on the day following the previous claim’s discharge date), transfers (patient discharge status of 02 on the claim), and interim claims (claim sequence number, the third digit of the ‘type of bill’ code, of 2, 3, or 4). In these 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).

Unadjusted admission rates were calculated as the number of hospitalizations divided by the number of patient years at risk, and expressed as “per 1,000 patient years.” Adjusted admission rates in this chapter included the following variables as adjustments: age (66-<70/70-<74/75-<85/85+), race (White/Black/other), and sex (male/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. Adjusted rates reflected the distribution of a reference cohort, specified below in the discussion of the respective 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, 3.8, and 3.12-3.15 show adjusted all-cause admission rates for fee-for-service

Medicare patients aged 66 and older. Table 3.2 also shows the unadjusted rates. As mentioned above, diabetes and cardiovascular disease were ascertained in 2013 for the analysis of hospital admissions in 2014, as described in the *Identification of Major Comorbidities* section of this chapter. All patients must have been 66 years or older, not have had ESRD on 1/1/2014, had Medicare Parts A and B coverage for all of 2013 and on 1/1/2014, and were not participating in a Medicare Advantage plan from 1/1/2013 through 1/1/2014. Rates presented by one factor were adjusted for the others. The reference cohort included Medicare patients in 2014, aged 66 and older.

vol 1 Table m.5 ICD-9-CM diagnosis codes used to define cause of hospitalization

Hospitalization cause	Primary claim diagnosis for hospital stay, ICD-9-CM codes
Cardiovascular hospitalizations	276.6; 394-398; 401-405; 410-438; 440-459
Infectious hospitalizations	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; 572.0-572.1; 573.1-573.3; 575.0-575.12; 590; 595.1-595.4; 597; 598.0; 599.0; 601; 604; 607.1-607.2; 608.0, 608.4; 611.0; 614-616.1, 616.3, 616.4, 616.8; 670; 680-686; 706.0; 711; 730.0-730.3, 730.8-730.9; 790.7, 790.8; 996.6; 998.5; 999.3
Other causes of hospitalization	All codes except those included in Cardiovascular or Infectious above.

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

Figures 3.9-3.11 show adjusted, cause-specific admission rates by CKD status and stage. Cause-specific rates reflect hospital admissions for the purpose of the specified condition—cardiovascular or infectious—and were identified using the principal ICD-9-CM diagnosis code on the claim. Code values are shown in Table m.5. The ‘other cause’ of hospitalization is a residual category consisting of all hospitalizations other than cardiovascular or infectious.

REHOSPITALIZATION

Analyses of rehospitalization focused on the 30 days following discharge from a hospitalization in year two, the year reported in the figure. As in all the analyses in this chapter, comorbidities, including CKD, were 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 was identified; the latter date (12/1) was a cutoff to allow a 30-day follow-up period after discharge to evaluate rehospitalization. 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 rehospitalization for the entire 30 day period, so results are presented as percentages. Since death and rehospitalization are competing risks, the outcome is presented as: (1) the percent of hospital discharges that had the patient both return to the hospital and die within 30 days, (2) the percent with the patient rehospitalized within 30 days but alive on day 30, and (3) the percent where the patient died within 30 days without a rehospitalization. Table 3.3 shows the unadjusted percentage rehospitalized (both alive and dead on day 30) for age, sex, and race groups, plus the composite death and rehospitalization outcome described above by CKD status and stage. Figure 3.16 shows the adjusted percentages for the three-part rehospitalization and death outcome across time from 2002 to 2014. Live hospital discharges from January 1 to December 1 of each year are included. Rates were adjusted for age, sex, and race using direct adjustment, with a reference group of discharges in

2014. Figure 3.17 shows results for 2014 for 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, Figure 3.23 by race group, and Figure 3.15 for cardiovascular-related hospitalization instead of all-cause. Figure 3.14 displays annual trends in rates of rehospitalization and/or death within 30 days after hospital discharge among CKD patients.

Chapter 4: Cardiovascular Disease in Patients with CKD

This chapter describes the prevalence of cardiovascular comorbidities and selected cardiovascular procedures in fee-for-service, age-eligible Medicare enrollees. Cardiovascular comorbidities included atherosclerotic heart disease (ASHD), acute myocardial infarction (AMI), congestive heart failure (CHF), valvular heart disease (VHD), cerebrovascular accident/transient ischemic attack (CVA/TIA), peripheral arterial disease (PAD), atrial fibrillation (AFIB), sudden cardiac arrest and ventricular arrhythmias (SCA/VA), and venous thromboembolism and pulmonary embolism (VTE/PE). The 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 m.6. The presence of CKD, CKD staging, and comorbidities such as diabetes mellitus (DM) and hypertension (HTN) are also defined as described in the *Identification of Major Comorbidities* section of this chapter and Tables m.3 and m.4.

vol 1 Table m.6 ICD-9-CM diagnosis codes used to define cardiovascular disorders in Volume 1, Chapter 4 of the ADR

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

Source: ICD-9-CM, *International Classification of Diseases, Ninth Revision, Clinical Modification*. Diagnosis codes can have up to five digits with a decimal point between the 3rd and 4th digit. Codes listed with three digits include all existing 4th and 5th digits, and those listed with four digits include all existing 5th digits. Peripheral arterial disease is defined as having a diagnosis and/or a procedure.

Cardiovascular procedures included percutaneous coronary interventions (PCI), coronary artery bypass grafting (CABG), the placement of implantable cardioverter defibrillators (ICD) and cardiac resynchronization devices with defibrillators (CRT-D), and carotid artery stenting 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 m.7 shows the codes and type of claims used to identify each procedure.

vol 1 Table m.7 Procedure codes (ICD-9-CM and HCPCS) & claims files used to define cardiovascular procedures in Volume 1, Chapter 4 of the ADR

Peripheral arterial disease (PAD)**ICD-9-CM Procedure codes:**

Claims files searched: IP, OP, SN
 Values: 39.25, 39.26, 39.29; 84.0, 84.1, 84.91

HCPCS codes:

Claims files searched: PB, OP-revenue
 Values: 24900, 24920, 25900, 25905, 25920, 25927, 27295, 27590, 27591, 27592, 27598, 27880, 27881, 27882, 27888, 27889, 28800, 28805, 34900, 35131, 35132, 35141, 35142, 35151, 35152, 34051, 34151, 34201, 34203, 34800–34834, 35081–35103, 35331, 35341, 35351, 35355, 35361, 35363, 35371, 35372, 35381, 35450, 35452, 35454, 35456, 35459, 35470, 35471, 35472, 35473, 35474, 35480, 35481, 35482, 35483, 35485, 35490, 35491, 35492, 35493, 35495, 35521, 35531, 35533, 35541, 35546, 35548, 35549, 35551, 35556, 35558, 35563, 35565, 35566, 35571, 35583, 35585, 35587, 35621, 35623, 35646, 35647, 35651,

Percutaneous coronary interventions (PCI)**ICD-9-CM Procedure codes:**

Claims files searched: IP, OP, SN
 Values: 00.66; 36.01, 36.02, 36.05, 36.06, 36.07

HCPCS codes:

Claims files searched: PB, OP-revenue
 Values: 92980-92982, 92984, 92995-92996, G0290, G0291

Coronary artery bypass graft (CABG)**ICD-9-CM Procedure codes:**

Claims files searched: IP
 Values: 36.1

Implantable cardioverter defibrillators & cardiac resynchronization therapy with defibrillator (ICD/CRT-D)**ICD-9-CM Procedure codes:**

Claims files searched: IP, OP, SN
 Values: 00.51; 37.94

Carotid artery stenting and carotid endarterectomy (CAS/CEA)**ICD-9-CM Procedure codes:**

Claims files searched: IP, OP, SN
 Values: 00.61, 00.62, 00.63, 00.64, 00.65; 17.53, 17.54, 38.11, 38.12, 38.31, 38.32, 38.41, 38.42; 39.74

HCPCS codes:

Claims files searched: PB, OP-revenue
 Values: 37215; 37216

Source: ICD-9-CM, International Classification of Diseases, Ninth 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. 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, resided in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, did not have ESRD on December 31, 2014, and who were continuously enrolled in Medicare Parts A and B and not enrolled in a Medicare Advantage plan (Part C) for all of 2014. Cardiovascular conditions, CKD, and CKD staging were determined from claims in 2014.

Table 4.1 presents the prevalence data shown in Figure 4.1 by age, race, sex, and CKD status (Panel a), and presents data on cardiovascular procedures performed in 2014 (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 were out of cohort members with ASHD, the percent with ICD/CRT-D was out of cohort members with CHF, and the percent with CAS/CEA was out of the cohort members with ASHD, CVA or PAD.

Figures 4.2 and 4.3 present the unadjusted, two-year survival of patients with cardiovascular conditions (Figure 4.2) or cardiovascular procedures (Figure 4.3). The methods for calculating these figures have changed for this 2016 ADR; conditions are assessed in a baseline year (2012), the origin for survival time is January 1 of the following year (1/1/2013), and there is no attempt to isolate incident diagnoses, so all the diagnosis codes listed for CHF in Table m.6 are used to define CHF for Figure 4.2. Methods for the procedures in Figure 4.3 are the same as in past years.

To form the study cohort for each condition in Figure 4.2, Medicare claims from 2012 were searched for the diagnoses (and procedure codes for PAD) specified in Tables m.6 and m.7. To be retained in the analysis cohort, the patient must have been alive without ESRD and aged 66 or older on 1/1/2013, and resided in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, was enrolled in Medicare Parts A and B, and not enrolled in a Medicare Advantage plan (Part C) for all of 2012. Patients were then followed from 1/1/2013 until the

earliest of date of death, ESRD diagnosis, or December 31, 2014. The Kaplan-Meier method was used to estimate survival.

To form the study cohort for each procedure in Figure 4.3, Medicare claims from 1/1/2011 through 12/31/2014 were searched for the procedure codes specified in Tables m.7, and the date of the first claim with a specified code was considered the index date. To be retained in the analysis cohort, the patient must have been aged 66 or older on the index date, resided in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, was enrolled in Medicare Parts A and B, and not enrolled in a Medicare Advantage plan (Part C). 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, three years after the index date, ESRD diagnosis, or December 31, 2014. The Kaplan-Meier method was used to estimate survival.

CONGESTIVE HEART FAILURE AND CHRONIC KIDNEY DISEASE

The type of heart failure for the calendar year was determined by frequency of diagnoses and a hierarchy. The presence of systolic (428.2x or 428.4), diastolic (428.3x) and unspecified (all other CHF diagnosis codes in Table m.6) diagnoses was determined by searching all reported diagnoses on all claims for a given calendar day. Each day was counted as systolic if there were any systolic diagnoses, as diastolic if there were no systolic diagnoses but at least one diastolic diagnosis, and as unspecified if there were no systolic or diastolic diagnoses but at least one unspecified diagnosis. The number of days with systolic, diastolic, and unspecified diagnoses was then summed for the calendar year. The patient’s type of heart failure for the year was then determined by a hierarchy similar to that applied for each calendar day: if the patient had any systolic heart failure and no diastolic-only heart failure, he/she was classified as systolic heart failure; if the patient had diastolic heart failure and no systolic, he/she was classified as diastolic heart failure; and if

the patient had only unspecified heart failure, he/she was classified as unspecified heart failure. When a patient had both systolic and diastolic-only diagnosis days during the year, he/she was assigned to the heart failure type that was most frequent during the year.

Figure 4.4 shows the distribution of heart failure type by CKD status in 2014. The study cohort included Medicare enrollees who were alive, aged 66 and older, resided in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, who did not have ESRD on December 31, 2014, and who were continuously enrolled in Medicare Parts A and B and not enrolled in a Medicare Advantage plan (Part C) for all of 2014. 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 heart failure type within that CKD status or stage group.

Figure 4.5 presents the adjusted, two-year survival of patients with and without CKD and CHF. 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 CHF and CKD status. CHF, CKD, DM and HTN statuses were determined from claims for 2012; the study cohort included Medicare enrollees who were alive and aged 66 or older on December 31, 2012, resided in 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 2012. Patients with ESRD on or before December 31, 2012 were excluded. Follow-up began on 1/1/2013 and continued until death or 12/31/2014. Type of heart failure was determined by the same procedure as the previous figures using claims from 2012. Codes used to define DM and HTN can be found in Table m.4 of this chapter. Age was defined as of 12/31/2012. Since the interaction between CHF status and CKD status was significant in the Cox model, adjusted survival curves were created for the four combination groups of CHF status and CKD status (No CKD and no CHF, CKD and no CHF, CHF and no CKD, and CKD and CHF). The survival curves were adjusted for the other significant factors in the model listed above.

ATRIAL FIBRILLATION AND CHRONIC KIDNEY DISEASE

Table 4.2 presents the prevalence of AFIB by CKD stage, age, race, sex, diabetic status, hypertension status, and heart failure (CHF) status for 2013. The cohort was the same used for Figure 4.1.

Chapter 5: Acute Kidney Injury

For the 2016 ADR, three sources of data were used for the AKI chapter: the Medicare 5% sample, Clinformatics™ Data Mart, and the Veterans Administration Healthcare data. Both the Medicare and Clinformatics™ datasets contain only diagnosis code information on AKI, and 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 Veterans Administration data sets contain serum creatinine measurements for both routine outpatient visits and inpatient stays, allowing the KDIGO consensus definition of AKI to be calculated (although the data do not contain urine output measurements), and AKI episodes to be classified by stage (KDIGO 2012). Diagnosis codes are also available in the VA data. As in prior years, this chapter only examined AKI as identified during an inpatient hospital stay.

In the Clinformatics™ data set, inpatient stays were identified by a non-missing confinement ID variable (CONF_ID) in the MEDICAL claims data table. We identified more patients with at least one or more inpatient stays from the MEDICAL claims data table than were contained in the CONFINEMENT data table, so the MEDICAL claims data table was used. Admission and discharge dates are not available in the MEDICAL claims data table and must be generated. Since the combination of patient ID (PATID) and confinement ID uniquely identified a hospitalization in the CONFINEMENT data table, 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 for CONF_ID observations that were not in the CONFINEMENT data table. Review of inpatient stays that were included in the CONFINEMENT data table verified that this process created

appropriate dates. A second disadvantage of using the MEDICAL claims data table is that each inpatient claim only contains three ICD-9-CM procedure codes, as compared to the five procedure codes per claim in the CONFINEMENT data table. This may result in a systematic underestimation of dialysis-requiring AKI for all years of Clinformatics™ data.

Dialysis during the hospitalization with AKI was defined using diagnosis, procedure, and revenue center codes (for Medicare 5% sample). 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-9-CM procedure codes 39.95 and 54.98, and Medicare revenue center codes 0800–0809. 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 (ICD-9-CM procedure codes 39.95 and 54.98) and outpatient procedures (HCPCS codes 90935, 90937, 90945, and 90947) in the MEDICAL claims data table that were performed between the admission and discharge dates of the inpatient stay. Similarly, the Veterans Administration data was searched for dialysis procedures during the time frame of the inpatient stay. Patients with ESRD prior to the inpatient stay were not counted as having AKI.

CHARACTERISTICS OF PATIENTS WITH AKI

The cohort used for Figures 5.1, 5.3a, 5.4a, 5.5a and Table 5.1 (Medicare) included all patients alive, aged 66 or older, enrolled in Medicare Parts A and B, not enrolled in a Medicare Advantage (Part C) program, and without ESRD on January 1 of the reported year. The Clinformatics™ cohort for Figures 5.2, 5.3b, 5.4b, 5.5b and Table 5.1 (Clinformatics™) included all patients 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 m.3 and m.4, using claims from a one-year entry period (year one, the calendar year *before* the year in which hospitalization was assessed for AKI) and then assessed hospitalization in the following year (year two, the year reported in the figures and tables). While a patient can have more than one

hospitalization with AKI during a given calendar year, the figures and table in this section counted only the first AKI hospitalization per patient, per year. Each calendar year formed a separate cohort; so a patient can have a “first” AKI hospitalization in multiple years. This process was used for both Medicare and Clinformatics™ data sets.

Figures 5.1 and 5.2 show the same statistics but for Medicare (Figure 5.1) and the Clinformatics™ (Figure 5.2) data sets. 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 each year. 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 that received a dialysis procedure during that hospitalization. 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 used 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 Clinformatics™.

Table 5.2 shows data from the Veterans Administration Health system. Data is from fiscal year 2014 (October 1, 2013 through September 30, 2014) as retrieved from the Corporate Data Warehouse. Short-term hospital stays were isolated from the INPAT.INPATIENT for discharges within the fiscal year. (see Veterans Administration Health Care 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) mean SCR of all outpatient measurements done at least seven days prior to admission up to 365 days prior to admission; (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; (3) if no outpatient SCR values were available, the first

inpatient SCR was assigned as the baseline SCR. Patients without at least one inpatient SCR were excluded from the analysis. SCR 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 AKI or no AKI. Table m.8 shows the criteria for AKI from the KDIGO guidelines.

vol 1 Table m.8. KDIGO definition and staging of acute kidney injury

Definition of AKI:		
An increase in serum creatinine (SCR) by ≥ 0.3 mg/dL (≥ 26.5 μ 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 μ mol/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 (≥ 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 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 the increase to 1.5 times baseline within seven days. A person's first SCR measurement on the day of admission is compared to their baseline to determine if that SCR is 0.3 mg/dL or 1.5 times higher. If so, the patient is said to have AKI. If not, the second SCR measurement is examined to see if its date is 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 a SCR measure is more than 48 hours from admission, it is compared to all previous SCR measurement that occurred within 48 hours of its measurement, rather than the patient's baseline. For example, if a patient with a baseline SCR of 0.8 mg/dL is admitted on January 1 and has a first SCR of 0.8 mg/dL, then one on January 2nd measuring 0.7 mg/dL, another on January 4th of 0.9 mg/dL and then 1.5 on January 5th, the January 5th measurement is compared

to the January 4th and determined to have AKI, but it would not be compared to the ones on January 1st or 2nd or the baseline for the 0.3 mg/dL increase condition. Similarly for the seven day increase to 1.5 times baseline, 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.

One the patient is determined to have experienced an AKI based on SCR changes, the hospitalization as a whole is used to assign the stage of AKI. The highest SCR during the hospitalization is compared to the baseline. If the difference is greater than 3 times the baseline, or the highest SCR is greater than 4.0 mg/dL or renal replacement therapy was used during the stay, that hospitalization is classified as Stage 3. If the AKI episode is not Stage 3 and the difference between the maximum SCR and baseline is more than 2 times baseline but less than 3, the hospitalization is classified as Stage 2. If the AKI episode is not Stage 2

or 3, it is Stage 1, an increase of at least 0.3 mg/dL but less than 2 times baseline.

Figures 5.3-5.5 used the entire analysis cohort as the denominator to calculate rates of first AKI per 1,000 patient years at risk for Medicare (Panel A) and Clinformatics™ (Panel B) beneficiaries. Only the first hospitalization with AKI for a patient was counted as an event, and years at risk were calculated for each patient as the time (total days divided by 365.25) between January 1 of the reported year (year two) to the earliest date of hospitalization with AKI, 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. A Cox proportional hazard model with no covariates, stratified by the variable of interest, was used to estimate survival, and the rate was calculated as $-\log(\text{survival})$ and multiplied by 1,000 to generate the rate per 1000 patient years at risk.

HOSPITALIZATION 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 Clinformatics™ (Figure 5.7) beneficiaries. The sample for this figure began with the 2012 cohort as used in 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 1/1/2012. The first hospitalization with AKI in 2012 was identified. Age was as of 1/1/2012, 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 m.3 and m.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 2012 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. To increase the precision of these estimates, we created the cohort for this figure to include patients with a first hospitalization with AKI in 2012 or 2013. Patients were alive, aged 66 or older, without ESRD, with 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 were 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 Parts A or B, 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 Parts A or B, switch to a Medicare Advantage program, or 365 days following discharge.

Figures 5.9-5.11 present physician visits and laboratory tests within the first six months after a live discharge from a hospitalization with AKI. For Figure 5.9, claims were searched for services provided by nephrologists for 180 days following the discharge date of the hospitalization with AKI. In the Medicare data, nephrology visits were a provider specialty code 36, while in the Clinformatics™ data they were identified by a provider category code for nephrologist (PROVCAT 0597-0604). Figures 5.10 and 5.11 show time-to-first-claim for specified laboratory tests. A first serum creatinine measurement was defined as the first claim with a Healthcare Common Procedure Coding System (HCPCS) code of 80047, 80048, 80049, 80050, 80053, 80054, 80069, or 82565. Likewise, first urinary microalbumin measurement was defined as the first claim with an HCPCS code of 82042, 82043, 82044, or

84156. Time to visit or lab test began on the date of discharge listed on the claim for the hospitalization with AKI, and continued until the earlier of the visit or test, 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 or lab test defined as (1-survival).

Figure 5.12 shows the renal status after one year for Medicare patients discharged alive from their first hospitalization with AKI. To increase the precision of the estimates, we created the cohort for this figure from patients with a first hospitalization with AKI in 2012 or 2013. Patients were alive, aged 66 or older, without ESRD, with 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 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 claim closest to 365 days after discharge and ESRD by first service date on the ESRD Medical Evidence form.

Figure 5.13 shows discharge status following a Medicare patient's first hospitalization in 2014. Panel A shows patients whose hospitalization contained an AKI episode while Panel B shows those whose hospital stay did not. The cohort included all patients who experienced a hospitalization during 2014 and 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, 2014. 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) were excluded. Patients with a 'patient discharge status' code of 01 (routine discharge to home) or 06 (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: Medicare Expenditures for CKD

The cohort used for this chapter continued the methodology introduced in the 2010 ADR, which 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 2014 (year two) included all costs incurred by patients with a CKD diagnosis in 2012 (year one). Prior to the 2010 ADR, patients newly diagnosed with CKD during year two were also included in the total.

The same general Medicare point prevalent cohort was used to create all the tables and figures in this chapter. Each year's cohort included patients aged 65 and older (except for Table 6.2 which includes only those under age 65) who were alive and without ESRD on January 1 of the reported year (year two). Cohort members were continuously enrolled in Medicare Parts A and B and not enrolled in a Medicare Advantage plan (Part C) for all of year one (the one-year entry period prior to the year in which costs were assessed). Costs were 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 Parts A or B, switch to a Medicare Advantage program, or December 31 of year two. Dividing the total cost amount by the patient years at risk yielded the per person per year (PPPY) costs. Since these total costs and number of patients were based on the 5% Medicare files, counts and

expenditures were multiplied by 20 to represent 100% of Medicare fee-for-service Parts A, B, and D expenditures for age-eligible patients who were continuously enrolled in Parts A and B and not enrolled in a Medicare Advantage plan for all of the previous year (year one).

Claims can be submitted for episodes of care that span calendar years. The expenditures for these claims are spilt across calendar years based on the fraction of the claim's total days that occurred in the reported year. For example, if a claim began on December 29, 2013, and ended on January 7, 2014, it spanned 10 days, with three days in 2013 and seven days in 2014. Seventy percent of that claim's total expenditure amount would be added to total expenditures for 2014 and 30% to total expenditures for 2013.

The disease conditions of CKD, congestive heart failure (CHF), diabetes mellitus (DM), and the stage of CKD are determined from the claims in the year prior to the reported year (year one) with the algorithm described in the *Identification of Major Comorbidities* section of this chapter, using the diagnosis codes listed in Tables m.3 and m.4. Age was determined as of December 31 of year one. Race and sex were provided by the Master Beneficiary Summary File. The cause of hospitalization presented in Figure 6.4 was determined using the same methods as in Chapter 3, using the codes displayed in Table m.5.

Chapter 7: Medicare Part D Prescription Drug Coverage in Patients with CKD

This chapter describes the participation in the Medicare Part D program by Medicare beneficiaries overall, and by those with CKD and ESRD. CKD was determined as described in the *Identification of Major Comorbidities* section of this chapter and Table m.3, using claims from a one-year entry period (year one, the calendar year before the year in which Part D utilization was assessed). Part D utilization was assessed in the following year (year two, the year reported in the figures and tables), while ESRD was determined by the date of first ESRD service. In this Part D 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.

In this chapter, beneficiaries must have been enrolled in 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 Parts A and B 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 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, 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 related to amyotrophic lateral sclerosis, and thus should not be viewed as representative of the U.S. general population under age 65.

For comparison, several figures and tables also include the ESRD population. Patients were selected from the USRDS ESRD database who had Medicare as either their primary or secondary payer, and had ESRD for at least 90 days by January 1 of the analysis year (year two). See the ESRD Methods chapter for more information on the USRDS ESRD database.

Figures 7.1-7.3 summarize the prescription drug insurance coverage for Medicare beneficiaries by source, comparing General Medicare, CKD, and ESRD populations and by showing results by age and race categories. The sources of coverage across the calendar year were combined into mutually exclusive and exhaustive categories in a hierarchical manner. Enrollment in a Part D plan was 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 “o1” through “o8.” For beneficiaries not enrolled in a Part D plan, there were several options for non-Medicare prescription drug coverage as reported to the Medicare program. A beneficiary was 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 employer-sponsored prescription drug plan that qualified for Part D’s retiree drug subsidy. If the patient was not in a Part D plan or employer-sponsored plan, they were classified as “Other Creditable Coverage” if the Creditable Coverage Switch has 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 later enroll in Part D. If a beneficiary met none of the situations described above, he or she was classified as “No Known Coverage.” Figure 7.1 presents the distribution of this categorical variable for the General Medicare, CKD, and ESRD cohorts described above.

Table 7.1 is an adaptation of data presented in the 2014 Medicare Outlook section of the www.qimedicare.com web site, and has no analyses. Table 7.2 shows the percent of beneficiaries with Part D coverage for the past three years in the General Medicare, CKD, and ESRD cohorts. A beneficiary was considered enrolled in Part D if at least one month’s Part D Plan Contract Number had the first digit of “E,” “H,” “R”, or “S.” Figure 7.2 shows the categories of prescription drug coverage (described above for Figure 7.1) by age groups (20-44/45-64/65-74/75+) for General Medicare (Panel A) and CKD (Panel B), while

Figure 7.3 shows it by race groups (White/Black or African American/Asian/Other).

Table 7.3 was 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 Figures 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 was 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, CKD, and ESRD cohorts.

The next several tables and figures 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 was paid by the Part D low-income subsidy (LIS Amount) and the net amount that the Part D plan paid for the PDE (Covered Part D Plan Paid Amount). Table 7.4 shows the total Medicare Part D benefit expenditures for the General Medicare, CKD, and ESRD cohorts (defined above) for beneficiaries enrolled in stand-alone Part D plans (i.e., spending for Medicare Advantage prescription drug plans was 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 7.5a shows Medicare spending and patient out-of-pocket amounts per patient per year for the General Medicare, CKD, and ESRD cohorts, again for only those who were in stand-alone Part D plans. Out of pocket cost was the sum of the amounts paid by the patient without being reimbursed by a third party (Patient Payment Amount) which included all copayments, coinsurance, deductible, or other patient payment amounts, and the amount of any payment made by other third-party payers that reduced the beneficiary’s liability for the PDE (Other True Out-of-Pocket Amount). Two examples of this were payments by qualified state pharmacy assistance programs or charities. Figure 7.5b breaks out these costs by whether the patient received any low income

subsidies. Table 7.5 stratifies these costs by age, sex, and race.

All drugs in the PDE file were matched to a therapeutic category according to the American Hospital Formulary Service classification system. The cohort for Tables 7.6 and 7.7 was limited to those in the CKD cohort who have 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 on each drug class and its percentage of total Part D costs. Table 7.6 shows the top 15 drug classes ranked by the highest percent of CKD patients with at least 1 prescription filled in that class. 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 on each drug class for CKD patients with stand-alone Part D plans and the next column shows that drug class' cost as a percentage of all Medicare Part D costs for these patients.

Reference Tables: CKD

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 age-eligible (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 (Part C) 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, congestive heart failure (CHF), and diabetes mellitus (DM) and the stage of CKD were determined from the 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 m.3 and m.4. Counts were multiplied by 20 to represent 100% of the Medicare population meeting the cohort definition.

Reference Tables B.7–B.10 are 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 is defined as an estimated glomerular filtration rate (eGFR) less than 60 ml/min/1.73m² (which identifies Stages 3 and 4) or 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 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, DM was defined as in Chapter 1, and eGFR and ACR as described for Table B.8. Table B.10 presents results for CHF, 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?"

Tables K.1–5 present estimates of per-person 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 include 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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Notes