

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'.

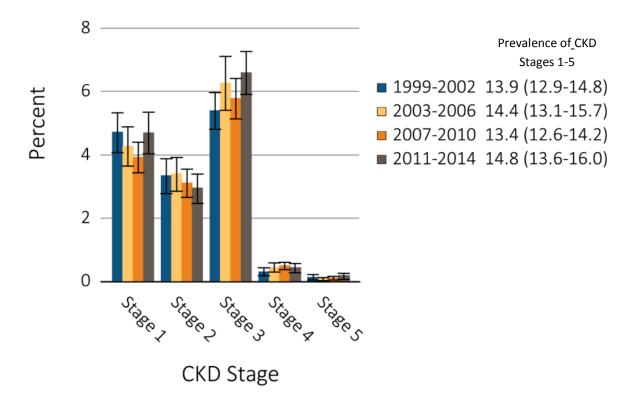
Volume 1 of the 2016 USRDS ADR provides key statistics on CKD in the United States. Volume 1 includes the following chapters: CKD in the General Population (Chapter 1); Identification and Care of Patients With CKD (Chapter 2); Morbidity and Mortality in Patients with CKD (Chapter 3); Cardiovascular Disease 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).

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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.

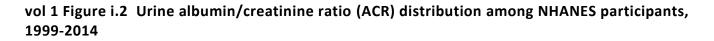


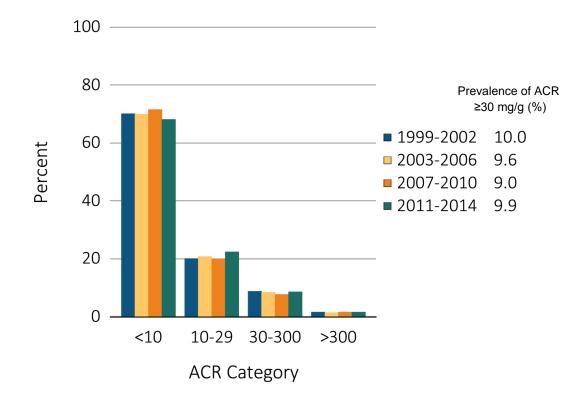


Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2002, 2003-2006, 2007-2010 & 2011–2014 participants aged 20 & older. Whisker lines indicate 95% confidence intervals. Abbreviation: CKD, chronic kidney disease. This graphic is adapted from Figure 1.1.

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

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





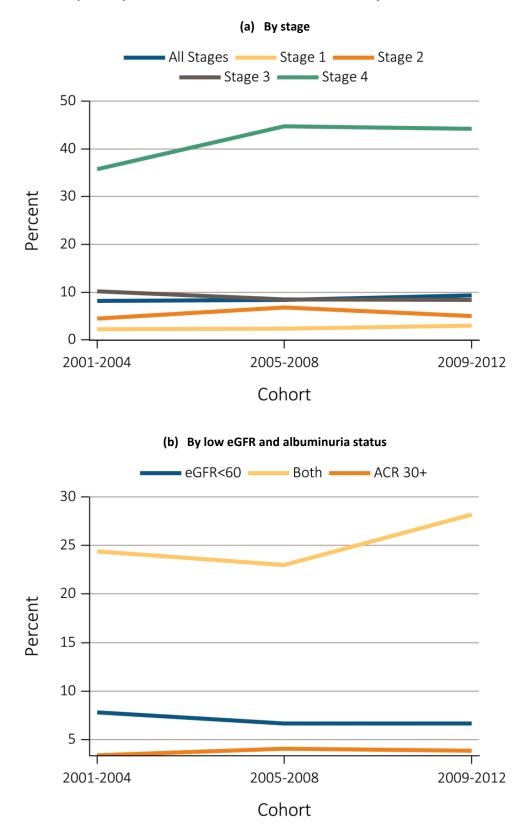
Data Source: National Health and Nutrition Examination Survey (NHANES), 1999-2014 participants aged 20 & older. Single-sample estimates of ACR. Abbreviation: ACR, urine albumin (mg)/creatinine (g) ratio. This graphic is adapted from Figure 1.3.

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.

	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

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

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.

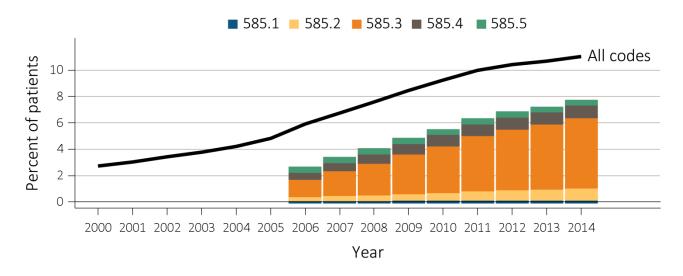
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The mean age of the Medicare patients was 75.9 years, and the mean age of Clinformatics[™] patients was 52.3 years. The high prevalence of comorbid conditions in the Medicare 5% sample reflects the older age of these patients. For example, 59% and 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

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

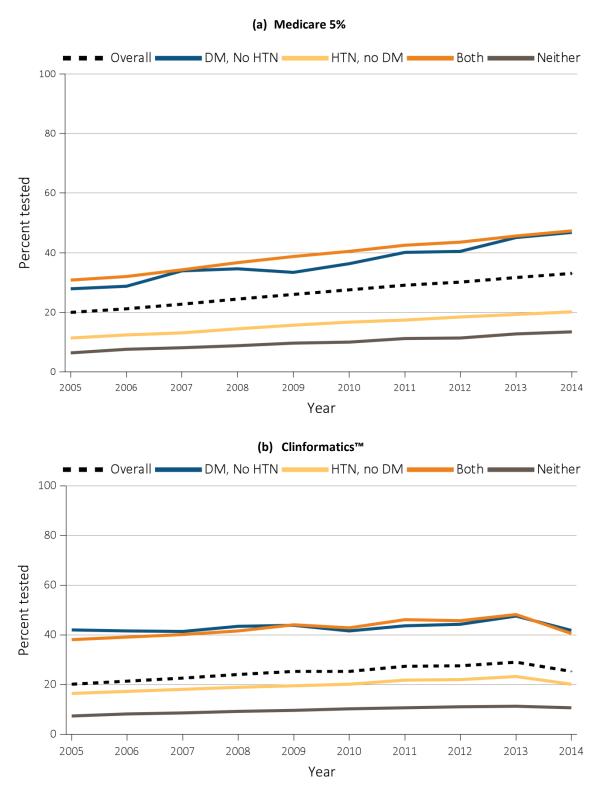
This diagnosis claims-based estimate likely underestimates the true prevalence of CKD in enrollees using Medicare-reimbursed health care services (especially when compared to the high rate of CKD estimated from NHANES), but has high specificity, identifying the individuals likely to have an accurate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



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 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.

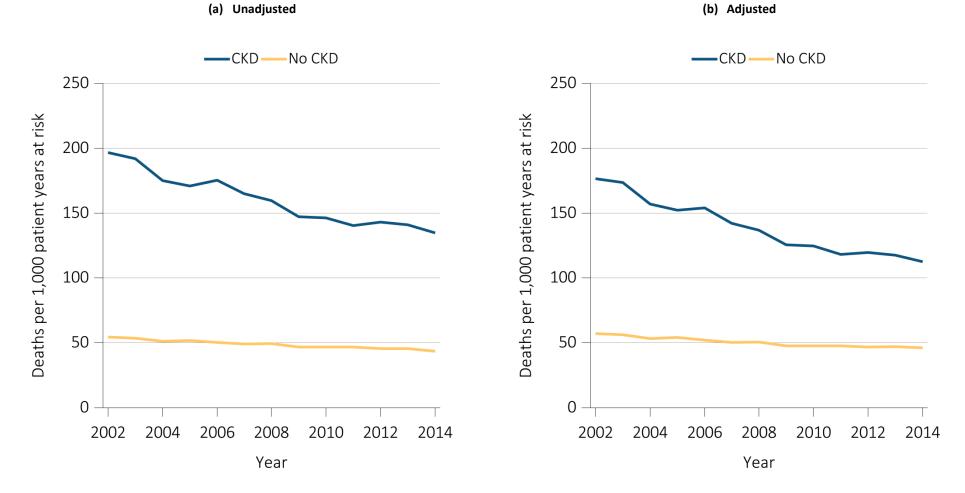
Chapter 3: Morbidity and Mortality in Patients with CKD

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

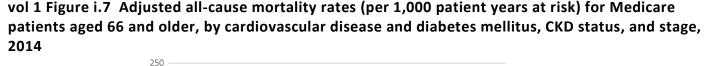
increase with CKD stage, a finding consistent with studies using biochemical measures to define CKD (e.g. serum creatinine with validated equations to eGFR). Trends in the mortality rates for Medicare patients aged 66 and older are shown in Figure i.6. Unadjusted mortality in CKD patients has decreased 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.

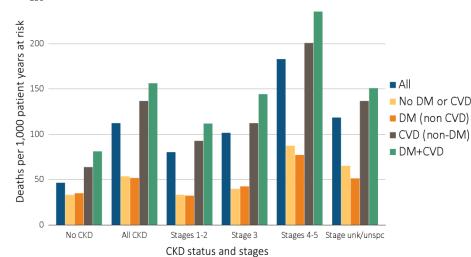
vol 1 Figure i.6 Unadjusted and adjusted all-cause mortality rates (per 1,000 patient years at risk) for Medicare patients aged 66 and older, by CKD status and year, 2002-2014



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)

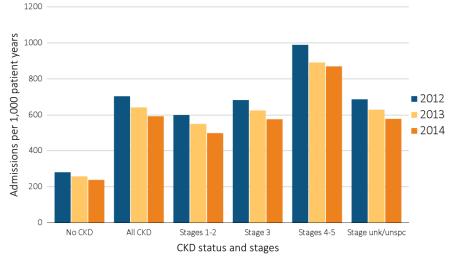




Data source: Medicare 5% sample. January 1, 2014 point prevalent patients aged 66 and older. Adjusted for age/sex/race. Reference population all patients, 2014. Abbreviations: CKD, chronic kidney disease; CVD, cardiovascular disease; DM, diabetes mellitus; unk/unspc, CKD stage unidentified. This graphic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

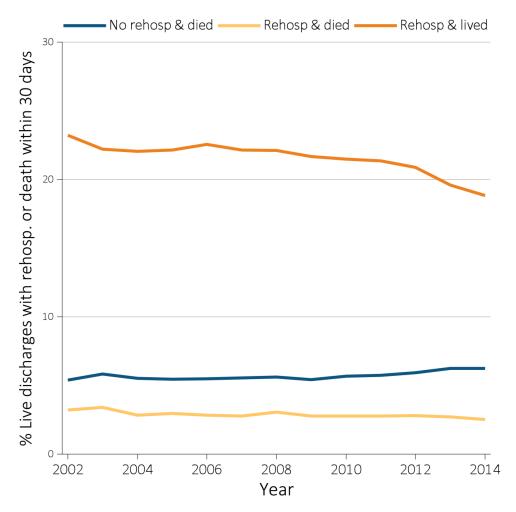
vol 1 Figure i.8 Adjusted all-cause hospitalization rates (per 1,000 patient years at risk) for Medicare patients aged 66 and older, by CKD status and stage, 2012-2014



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

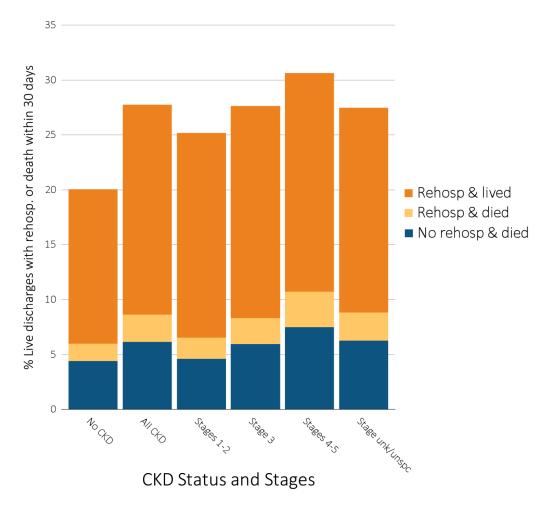


Data source: Medicare 5% sample. January 1 of each reported year, point prevalent Medicare patients aged 66 and older with CKD (defined during the prior year), discharged alive from an all-cause index hospitalization between January 1 and December 1 of the reported year. Adjusted for age/sex/race. Reference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

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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

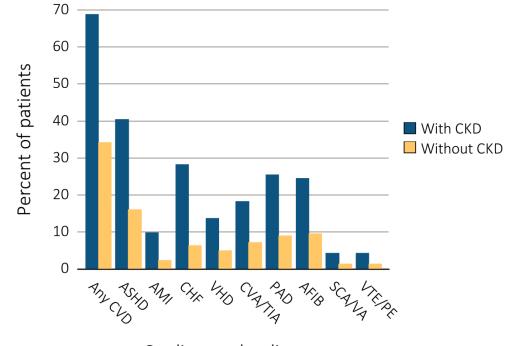


Data source: Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 and older, discharged alive from an all-cause index hospitalization between January 1, 2014, and December 1, 2014, unadjusted. Abbreviations: CKD, chronic kidney disease; Rehosp, rehospitalized; unk/unspc, CKD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

Cardiovascular disease

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 longterm 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

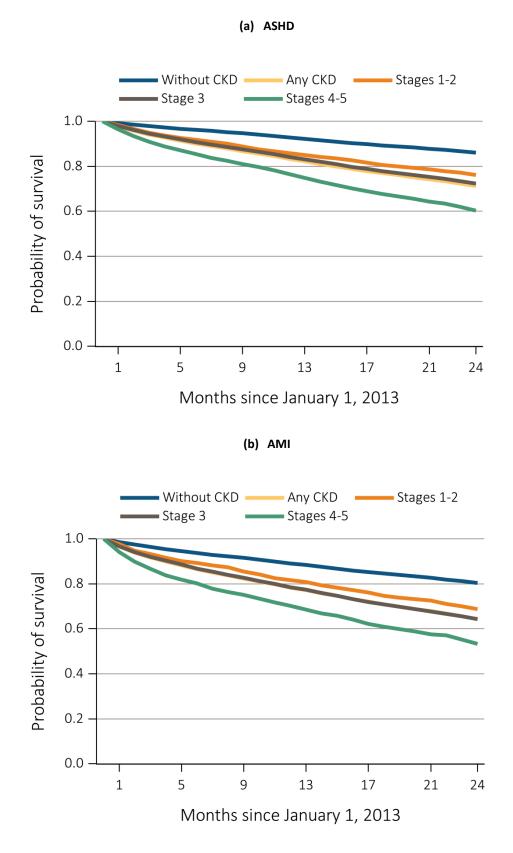


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vol 1 Figure i.12 Survival of patients with a prevalent cardiovascular disease, by CKD status, 2013-2014 (continued)

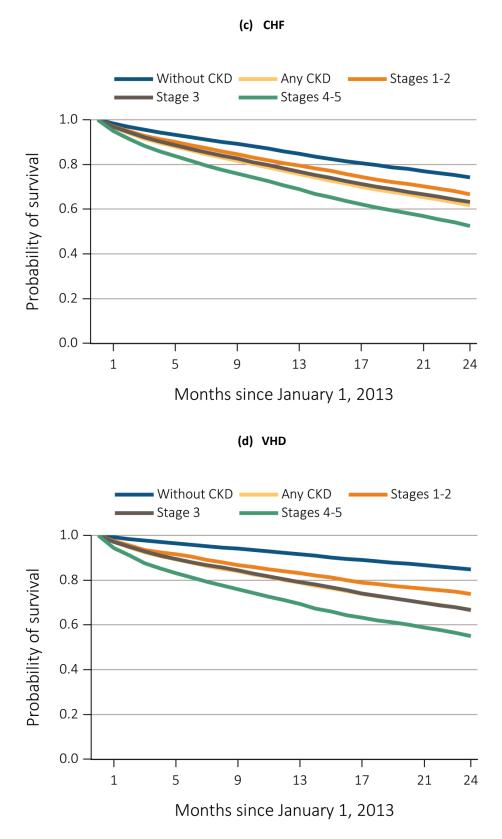


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vol 1 Figure i.12 Survival of patients with a prevalent cardiovascular disease, by CKD status, 2013-2014 (continued)

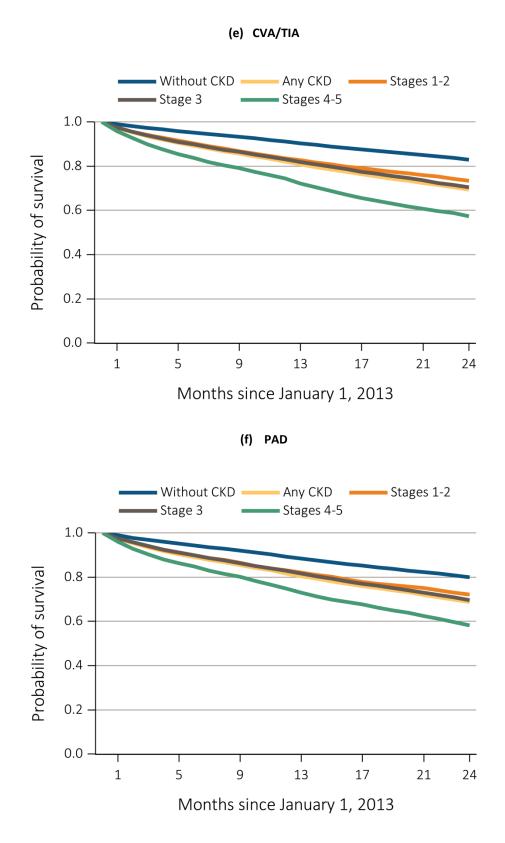


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vol 1 Figure i.12 Survival of patients with a prevalent cardiovascular disease, by CKD status, 2013-2014 (continued)

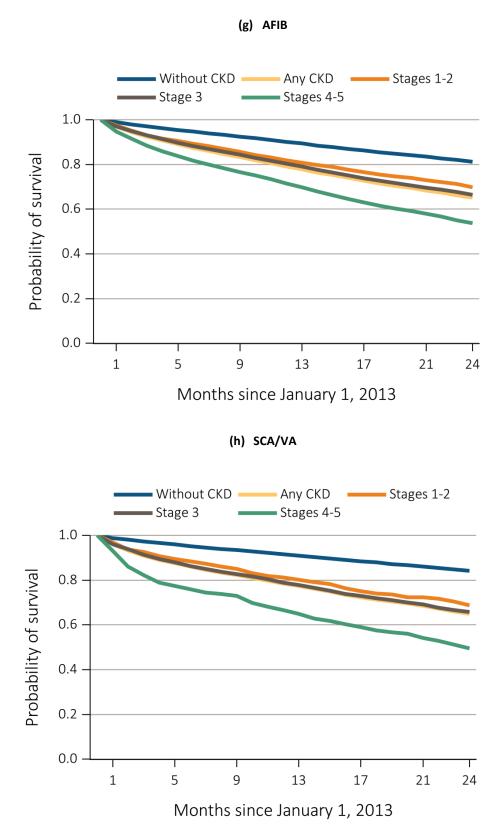
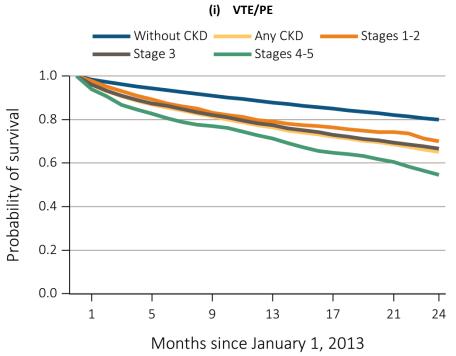


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vol 1 Figure i.12 Survival of patients with a prevalent cardiovascular disease, by CKD status, 2013-2014 (continued)



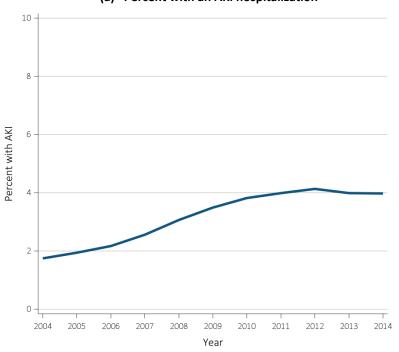
Data Source: Special analyses, Medicare 5% sample. Patients aged 66 and older, alive, without end-stage renal disease, and residing in the United States on 12/31/2012, with fee-for-service coverage for the entire calendar year. Abbreviations: AFIB, atrial fibrillation; AMI, acute myocardial infarction; 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

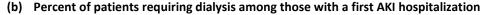
Acute kidney injury (AKI) is now recognized as a major risk factor for the development of chronic kidney disease (CKD). Studies have demonstrated significantly increased long-term risk of CKD and ESRD following AKI, even after initial recovery of renal function. Furthermore, this relationship is bidirectional 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

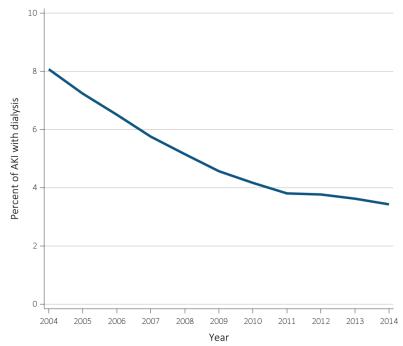
AKI. We present some data from the VA population to illustrate the potential gap between AKI episodes that are identified by administrative coding versus clinical data. As shown in Figure i.13, the percentage of patients with an AKI hospitalization in the Medicare fee-for-service population has risen 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



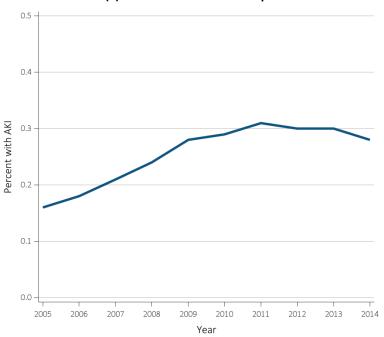
(a) Percent with an AKI hospitalization



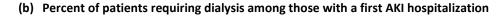


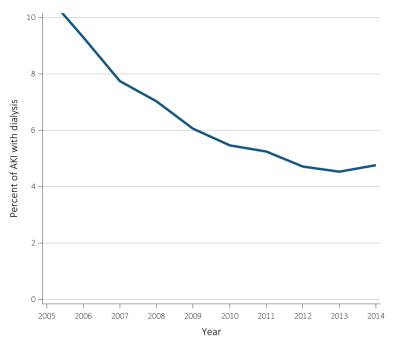
Data Source: Special analyses, Medicare 5% sample. (a) Percent with an AKI hospitalization among all Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, no ESRD by first service date from Medical Evidence form, and were alive on January 1 of year shown. (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



(a) Percent with an AKI hospitalization

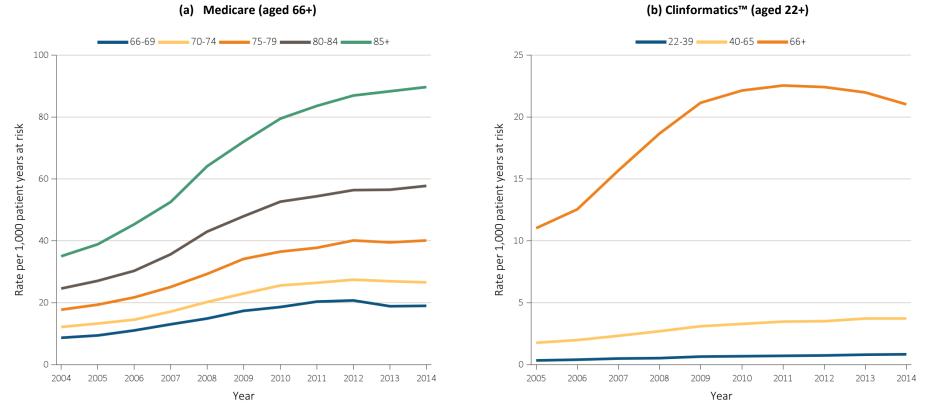




Data Source: Special analyses, Clinformatics[™]. (a) Percent with an AKI hospitalization among all Clinformatics[™] commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD, and were alive on January 1, 2014. (b) Percent of patients receiving dialysis 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.

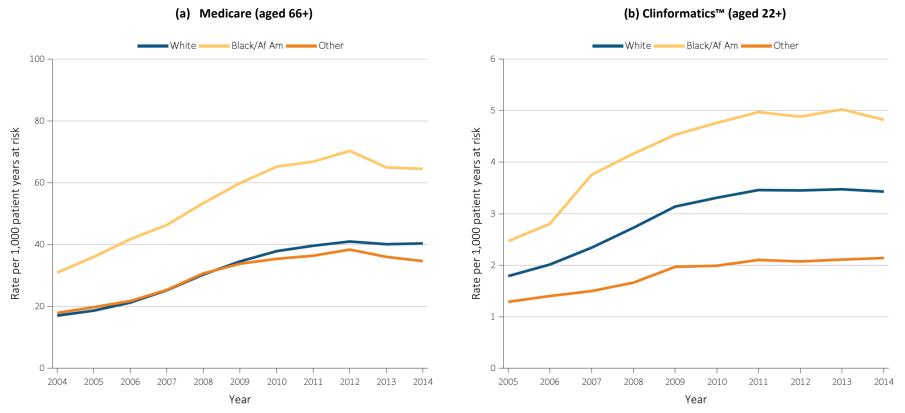
Figures i.15 and i.16 highlight differences in rate of first hospitalization with AKI by age and by race over time, in Medicare and Optum population.





Data Source: Special analyses, Medicare 5% sample and Clinformatics^m. (a) Age as of January 1 of specified year. All patient-years at risk for Medicare patients aged 66 and older who had both Medicare Parts A & B, no Medicare Advantage plan, no ESRD by first service date from Medical Evidence form, and were alive on January 1 of year shown. Censored at death, ESRD, end of Medicare Part A & B participation, or switch to Medicare Advantage program. (b) All patient-years at risk for Clinformatics^m commercial insurance patients aged 22 and older who were enrolled in the plan, did not have diagnoses of ESRD, and were alive on January of year shown. Abbreviation: AKI, acute kidney injury; ESRD, end-stage renal disease. This graphic is adapted from Figure 5.3.

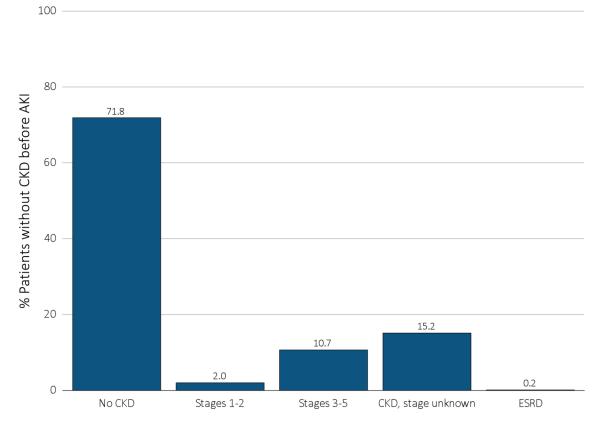
vol 1 Figure 1.16 Unadjusted rates of first hospitalization with AKI, per 1,000 patient-years at risk, by race and year, 2004-2014



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

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 22years 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.

Chapter 6: Medicare Expenditures for Persons with CKD

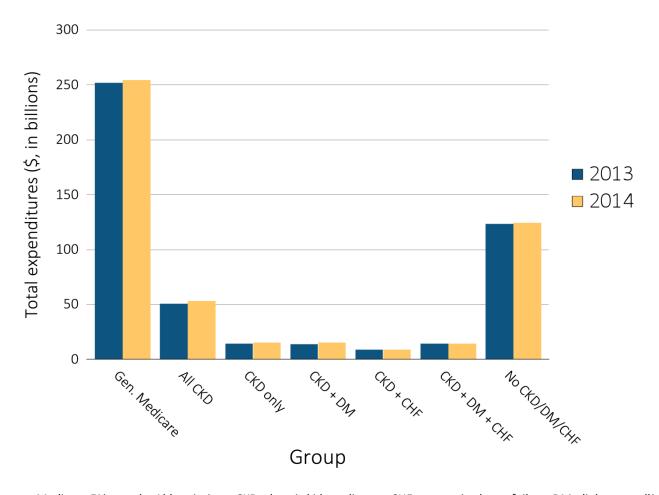
Determining the economic impact of chronic kidney disease (CKD) on a health care system is challenging for a variety of reasons described in this chapter, but primarily due to under recognition of CKD in health systems and reliance on diagnosis codes for its identification.

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).

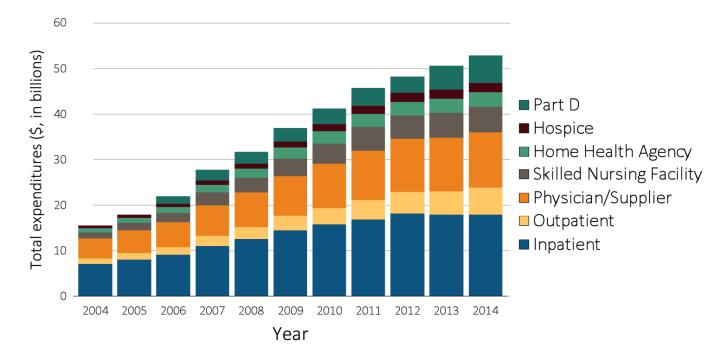
vol 1 Figure i.18 Overall Medicare Parts A, B, and D fee-for-service spending for beneficiaries aged 65 and older, by CKD, DM, CHF, and year, 2013 & 2014



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.



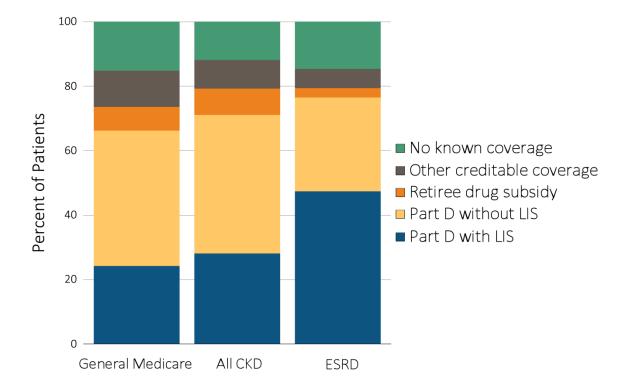
vol 1 Figure i.19 Trends in total Medicare Parts A, B, and D fee-for-service spending for CKD patients aged 65 and older, by claim type, 2004-2014

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 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, respectively (Table i.2).

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, protonpump inhibitors antidepressants, angiotensinconverting 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.

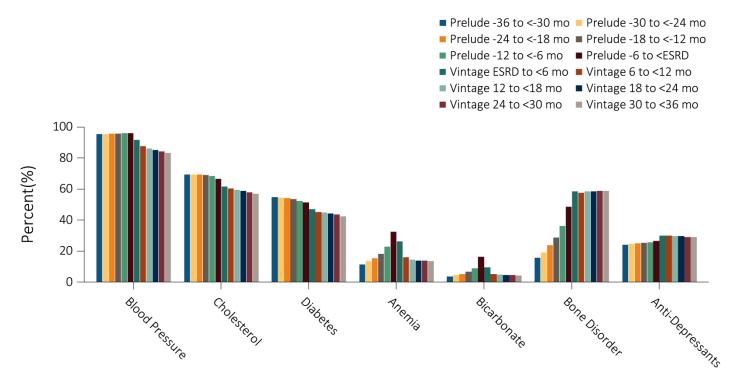
Chapter 8: Transition of Care in Chronic Kidney Disease (TC-CKD)

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-latestage 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. Antidepressants 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.

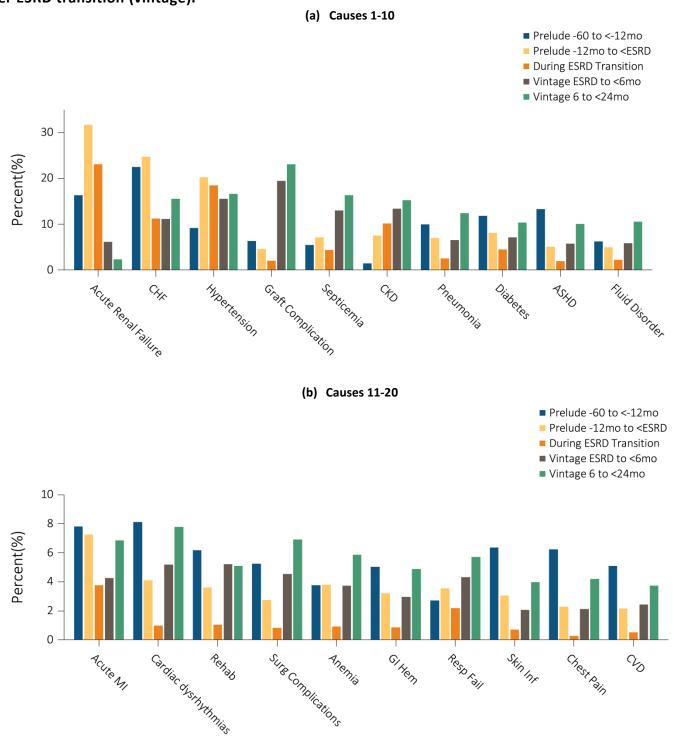
vol 1 Figure i.21 Prescribed medication to incident ESRD veterans who transitioned to ESRD during 10/1/2007-3/31/2014, with data up to -36 months prior to transition (prelude) and up to +36 months after transition (vintage) (data were abstracted from 68,435 veterans)



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.

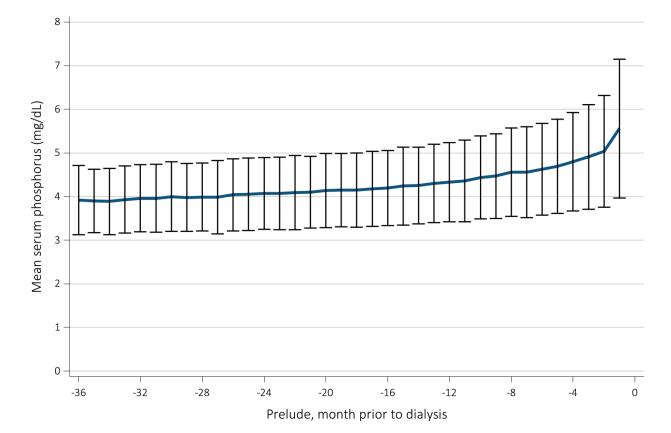
Cause-specific hospitalization events were also analyzed. Figure i.22 shows the top 20 causes of hospitalization among 74,382 veterans who transitioned to ESRD over the 6.5-year period (10/2007-3/2014) with at least one hospitalization event from -5 years prelude to +2 years vintage surrounding the transition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



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