

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

Volume 2: ESRD in the United States



Introduction to Volume 2: ESRD in the United States

Introduction

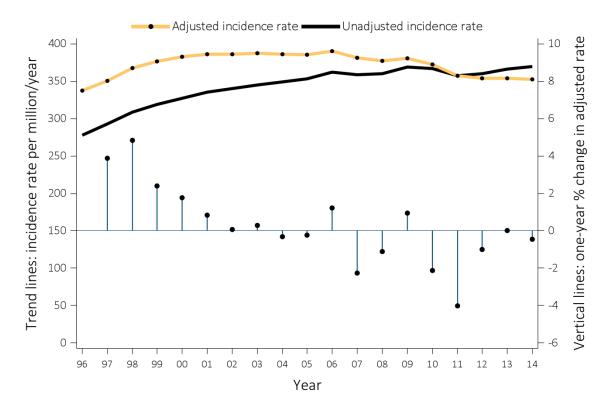
Volume 2 of the USRDS Annual Data Report (ADR) offers a detailed descriptive epidemiology of end-stage renal disease (ESRD) in the United States. Registration in the U.S. national ESRD database legally requires the completion of the ESRD Medical Evidence form (CMS 2728). This documentation of new ESRD patients must be submitted to the Centers for Medicare & Medicaid Services (CMS) within 45 days of onset of renal replacement therapy (RRT).

Data collection for many national projects administered by the CMS has been transitioning from paper-based data entry to a fully web-based system. These projects include data to create core metrics and measures, such as the assessment and reporting of provider performance through Dialysis Facility Reports (DFR) and Dialysis Facility Compare (DFC), as well as the Quality Incentive Program (QIP), which ties provider achievement of selected quality targets to Medicare reimbursement. This web-based system is known as the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb). For Volume 2 of the USRDS ADR, the Coordinating Center has previously relied on data from Medicare claims for its analyses; however, since the 2014 ADR, data from CROWNWeb is being included incrementally in several chapters.

Volume 2 of the 2016 USRDS ADR provides key statistics on ESRD in the United States and includes the following chapters: <u>Incidence, Prevalence, Patient</u> <u>Characteristics, and Treatment Modalities</u> (Chapter 1); <u>Healthy People 2020</u> (Chapter 2); <u>Clinical Indicators</u> <u>and Preventive Care</u> (Chapter 3); <u>Vascular Access</u> (Chapter 4); <u>Hospitalization</u> (Chapter 5); <u>Mortality</u> (Chapter 6); <u>Transplantation</u> (Chapter 7); <u>ESRD</u> <u>Among Children, Adolescents, and Young Adults</u> (Chapter 8); <u>Cardiovascular Disease in Patients With</u> <u>ESRD</u> (Chapter 9); <u>Dialysis Providers</u> (Chapter 10); <u>Medicare Expenditures for Persons With ESRD</u> (Chapter 11); <u>Part D Prescription Drug Coverage in</u> <u>Patients with ESRD</u> (Chapter 12); <u>International</u> <u>Comparisons</u> (Chapter 13); <u>USRDS Special Study Center</u> on End-of-life Care for Patients With ESRD (Chapter 14).

Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities

There were 120,688 newly reported cases of ESRD in 2014; the crude (unadjusted) incidence rate was 370 per million/year, representing a slight increase (1.1%) compared to 2013 (not shown, see Table 1.11 in Volume <u>2: Chapter 1</u>). Adjusted incidence rate rose sharply in the 1980s and 1990s, but leveled off in the early 2000s, and has declined slightly since its peak in 2006 (Figure i.1). The rate of incident ESRD is roughly 3-fold higher for Black/African Americans than for other races, and approximately 1.4-fold higher for Hispanics versus non-Hispanics. Notably, there has been a rather dramatic decline in ESRD incidence in the Native American population. vol 2 Figure i.1 Trends in the unadjusted and adjusted* incidence rates (per million/year) of ESRD (trend lines; scale on right), and annual percent (%) change in the adjusted* incidence rate of ESRD (vertical lines; scale on left) in the U.S. population, 1996-2014

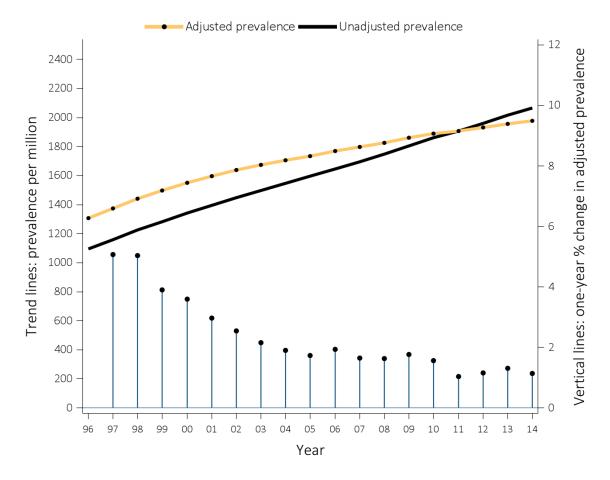


Data Source: Reference Table A.2(2) and special analyses, USRDS ESRD Database. *Adjusted for age, sex, race, and ethnicity. The standard population was the U.S. population in 2011. Abbreviation: ESRD, end-stage renal disease. This graphic is adapted from Figure 1.1.

Despite relative stability in ESRD incidence over the last 3 years, at the end of 2014, there were 678,383 prevalent dialysis and transplant patients receiving treatment for ESRD — a 3.5% increase from 2013. The number of ESRD prevalent cases continues to rise by about 21,000 cases per year, as does the adjusted prevalence (Figure i.2). Because the incidence of ESRD has plateaued, the ongoing rise in prevalence can be attributed to the decline in the mortality rate among ESRD patients.

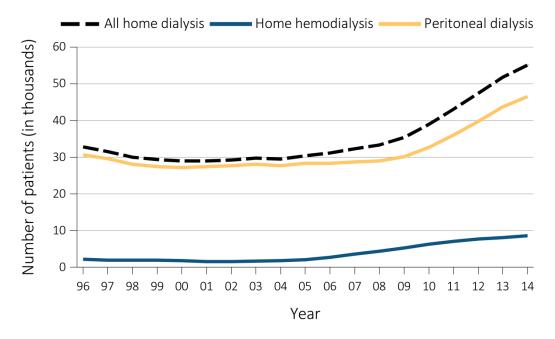
Among prevalent ESRD cases, the use of home dialysis (peritoneal dialysis or home hemodialysis; Figure i.3) continues to show a rising trend.

vol 2 Figure i.2 Trends in the unadjusted and adjusted* ESRD prevalence (per million) (trend lines; scale on left), and annual percent (%) change in adjusted* prevalence of ESRD (vertical lines; scale on right), in the U.S. population, 1996-2014



Data Source: Reference Table B.2(2) and special analyses, USRDS ESRD Database. *Adjusted for age, sex, race, and ethnicity. The standard population was the U.S. population in 2011. Abbreviation: ESRD, end-stage renal disease. This graphic is adapted from Figure 1.10.

vol 2 Figure i.3 Trends in number of prevalent ESRD cases (in thousands) using home dialysis, by type of therapy, in the United States, 1996-2014



Data Source: Reference Table D.1. December 31 prevalent ESRD patients; Peritoneal dialysis consists of CAPD and CCPD only. Abbreviations: CAPD, continuous ambulatory peritoneal dialysis; CCPD, continuous cycler peritoneal dialysis; ESRD, end-stage renal disease. This graphic is adapted from Figure 1.19.

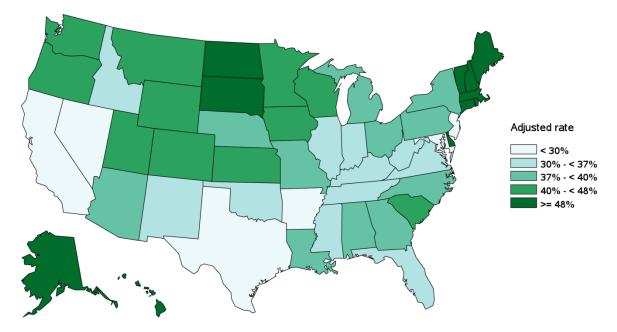
Wide geographic variations by Health Service Area and Dialysis Networks were notable with respect to incidence, prevalence, home dialysis use, eGFR, hemoglobin values at start, and duration of pre-ESRD care prior to ESRD. Nationally, 24% of patients starting ESRD therapy in 2014 were reported on the CMS 2728 form as not having received nephrology care prior to ESRD onset. This reflects little change from 2013. An additional 13% had unknown duration of pre-ESRD nephrology care.

Chapter 2: Healthy People 2020

We present data for 10 Healthy People 2020 (HP2020) Objectives, spanning 19 total indicators overall, stratified by race, gender, and age group. In 2014, 12 of 19 indicators met HP2020 goals, and most of the remaining objectives continue to show improvement. We include maps for some of the indicators to illustrate geographic variation. Specifically, we present state-level comparison maps for HP2020 objectives CKD-10 (proportion of chronic kidney disease (CKD) patients receiving care from a nephrologist at least 12 months before the start of RRT) and CKD-13.1 (proportion of patients receiving a kidney transplant within three years of end-stage renal disease; not shown, see Figure 2.2 in Volume 2: <u>Chapter 2</u>). More than 80% of states achieved the HP2020 target for CKD-10, while just over 20% achieved the target for CKD-13.1. For both these objectives there was significant geographic variation, with percentages varying between states by greater

than 50% from the lowest to highest quintiles. For HP2020 objectives relating to vascular access, we present data from CROWNWeb. Until 2013, USRDS annual data reports had relied on data from the clinical performance measures project, which only collected information through 2007. Using CROWNWeb, we continue to present data from 2012 and 2014 for HP2020 objectives CKD 11-1 (proportion of adult hemodialysis patients who use an arteriovenous (AV) fistula as the primary mode of vascular access) and CKD 11-2 (proportion of adult hemodialysis patients who use a catheter as the only mode of vascular access). In 2014, we continued to observe an increasing trend in proportion of patients using AV fistulas, reaching 63.9% overall; notably, this trend was observed across nearly all subgroups. In 2014, we continued to observe a trend towards decreasing all-cause mortality among prevalent dialysis patients. The total death rate fell to 172.8 deaths per 1,000 patient years, decreasing more than 25% from 233.7 deaths per 1,000 patient years in 2001.

vol 2 Figure i.4 HP2020 CKD-10 Geographic distribution of the adjusted proportion of chronic kidney disease patients receiving care from a nephrologist at least 12 months before the start of renal replacement therapy, by state, in the U.S. population, 2013: Target 29.8%

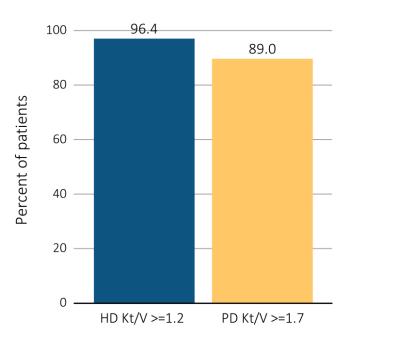


Data Source: Special analyses, USRDS ESRD Database. Incident hemodialysis patients with a valid ESRD Medical Evidence CMS 2728 form; nephrologist care determined from Medical Evidence form. Adjusted for age, sex, and race. Abbreviations: CDC, Centers for Disease Control and Prevention; CKD, chronic kidney disease; ESRD, end-stage renal disease. This graphic is adapted from Figure 2.1.

Chapter 3: Clinical Indicators and Preventive Care

Given the high morbidity and mortality of the ESRD population receiving dialysis, quality improvement has long been a priority. Owing to recent availability of data from CROWNWeb, national trends in serum calcium, phosphorus, ferritin, and transferrin saturation levels are reported in the ADR, providing a more representative view of Kt/V (Figure i.5.a) and Hgb levels (Figure i.5.b) for the dialysis population than was previously possible, as it includes data from both Medicare and non-Medicare insured patients. Figure i.5.a shows that achievement of dialysis adequacy targets for hemodialysis is nearly universal, with 96.4% of patients obtaining a single pool Kt/V \geq 1.2 (for more information about Kt/V see the *Glossary* in the ADR Appendices). Achievement of the dialysis adequacy target for peritoneal dialysis (a weekly Kt/V \ge 1.7) is somewhat lower, at 89.0% (Figure i.5.a). As of December 2015, the majority (63.3%) of hemodialysis patients in December 2015 had Hgb levels between 10-12 g/dL, while 14.7% had Hgb \geq 12 g/dL, 6.8% had Hgb less than 9 g/dL, and 15.2% had Hgb between 9-10g/dL, with the mean Hgb being 10.8/dL). About 2% of patients receiving either dialysis modality had calcium levels >10.2 mg/dL (Figure i.5.c). Avoidance of this threshold is currently being utilized as a quality indicator in CMS programs such as Dialysis Facility Compare and the Quality Incentive Program given concerns about associations between hypercalcemia and vascular calcifications or cardiovascular events. The percent of patients with hypercalcemia for both modalities has declined compared to December 2014.

vol 2 Figure i.5 ESRD clinical indicators: (a) percentage of prevalent hemodialysis and peritoneal dialysis patients meeting clinical care guidelines for dialysis adequacy by modality, (b) percent distribution of Hgb levels among prevalent hemodialysis and peritoneal dialysis patients; and (c) percentage of dialysis patients with serum calcium >10.2 mg/dL by modality, CROWNWeb data, December 2015

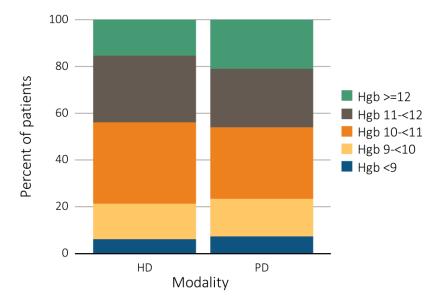


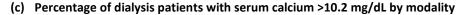
(a) Percentage of prevalent hemodialysis and peritoneal dialysis patients meeting clinical care guidelines for dialysis adequacy by modality

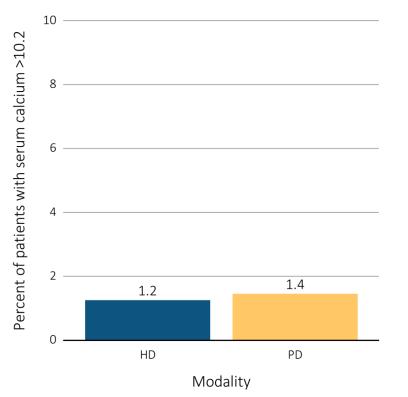
Figure i.5 continued on next page.

vol 2 Figure i.5 ESRD clinical indicators: CROWNWeb data, December 2015 (continued)

(b) Percent distribution of Hgb levels among prevalent hemodialysis and peritoneal dialysis patients







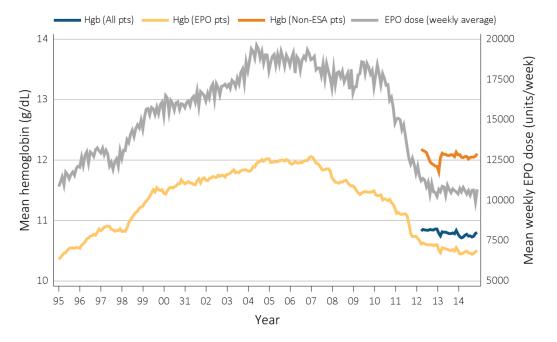
Data Source: Special analyses, USRDS ESRD Database. Results shown are for laboratory values reported to CROWNWeb for December 2015, restricted to patients as follows: (a) dialysis patients initiating treatment for ESRD at least 1 year prior to December 1, 2015, and who were alive through December 31, 2015; (b) dialysis patients initiating treatment for ESRD at least 90 days prior to December 1, 2015, who were \geq 18 years old as of December 1, 2015, and who were alive through December 31, 2015; and (c) hemodialysis and peritoneal dialysis patients initiating treatment for ESRD at least 9, 2015; who were \geq 18 years old as of December 31, 2015. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease; HD, hemodialysis; Hgb, hemoglobin; Kt/V, see Glossary; PD, peritoneal dialysis. This graphic is adapted from Figure 3.1.

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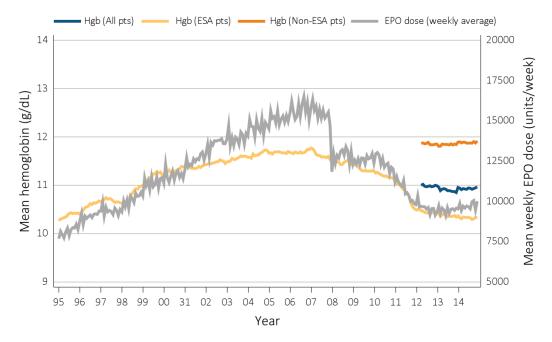
From December 2013 to December 2014, EPO doses increased by 1.5% in hemodialysis patients and 4.5% in peritoneal dialysis patients. In 2014, average monthly

EPO doses were approximately 10,524 units/week and 9,716 units/week for hemodialysis and peritoneal dialysis patients, respectively (Figures i.6 and i.7).

vol 2 Figure i.6 Anemia measures among adult hemodialysis patients on dialysis ≥90 days: mean monthly Hgb level and mean weekly EPO dose (averaged over a month), Medicare claims, 1995-2014



Data Source: Special analyses, USRDS ESRD Database. Mean monthly Hgb level among ESA-treated adult hemodialysis patients on dialysis \geq 90 days (1995 through 2014) or mean monthly Hgb level among all adult hemodialysis patients (April 2012 to December 2014 only) who, within the given month had a Hgb claim (only the first reported Hgb value in a month was used) and were on dialysis \geq 90 days; analyses were restricted to patients \geq 18 years old at the start of the month. Mean weekly EPO (epoetin alfa) dose is shown for hemodialysis patients within a given month who had an EPO claim, were on dialysis \geq 90 days, and were \geq 18 years old at the start of the month. EPO dose is expressed as mean EPO units per week averaged over all EPO claims within a given month. Abbreviations: EPO, erythropoietin; ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin. This graphic is adapted from Figure 3.2.

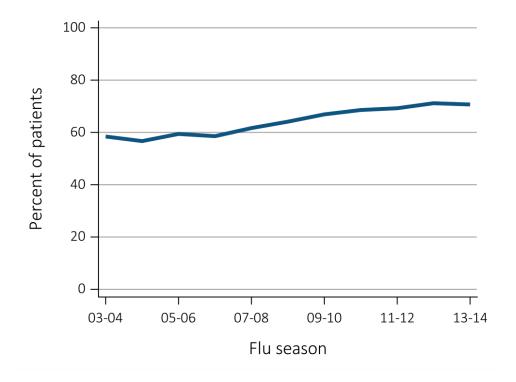


vol 2 Figure i.7 Anemia measures among adult peritoneal dialysis patients on dialysis ≥90 days: mean monthly Hgb level and mean weekly EPO dose (averaged over a month), Medicare claims, 1995-2014

Data Source: Special analyses, USRDS ESRD Database. Mean monthly Hgb level among ESA-treated adult peritoneal dialysis patients on dialysis \geq 90 days (1995 through 2014) or mean monthly Hgb level among all adult peritoneal patients (April 2012 to December 2014 only) who, within the given month had a Hgb claim (only the first reported Hgb value in a month was used) and were on dialysis \geq 90 days; analyses were restricted to patients \geq 18 years old at the start of the month. Mean weekly EPO (epoetin alfa) dose is shown for peritoneal patients within a given month who had an EPO claim, were on dialysis \geq 90 days, and were \geq 18 years old at the start of the month. EPO dose is expressed as mean EPO units per week averaged over all EPO claims within a given month. Abbreviations: EPO, erythropoietin; ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin. This graphic is adapted from Figure 3.8.

Approximately 71% of patients received an influenza vaccination in the 2013-2014 flu season, still below the Healthy People 2020 (HP2020) target of 90%. Although stable over the last two seasons, the percent vaccinated has increased from 58.4% a decade prior (Figure i.8).

vol 2 Figure i.8 Percentage of ESRD patients with a claim for seasonal influenza vaccination (August 1-April 30 of subsequent year), overall, Medicare data, 2003-2014

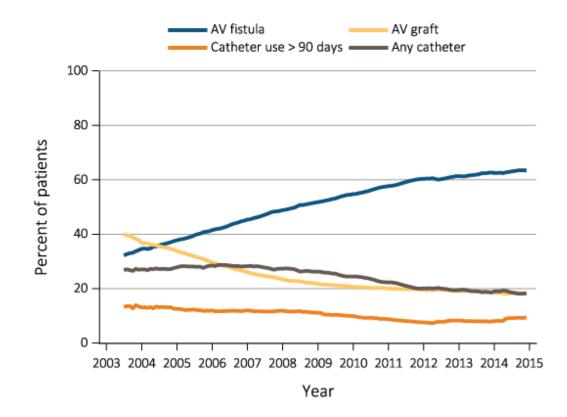


Data Source: Special analyses, USRDS ESRD Database. ESRD patients initiating treatment for ESRD at least 90 days before seasonal period: August 1-April 30 for influenza. Abbreviation: ESRD, end-stage renal disease. This graphic is adapted from Figure 3.19.

Chapter 4: Vascular Access

New since 2015, this chapter outlines the patterns of vascular access for incident and prevalent hemodialysis patients in the United States.

Figure i.9 displays trends in vascular access use among prevalent hemodialysis patients from 2003-2014. There has been a large rise in AV fistula use and AV fistula placement since 2003, with use increasing from 32% to 63%. In contrast, AV graft use has decreased from 40% to 18% over the same time period. Catheter use has also declined, albeit not as dramatically, decreasing from 27% to 18%. In 2014, only 9% of prevalent hemodialysis patients had been using a catheter for >90 days.

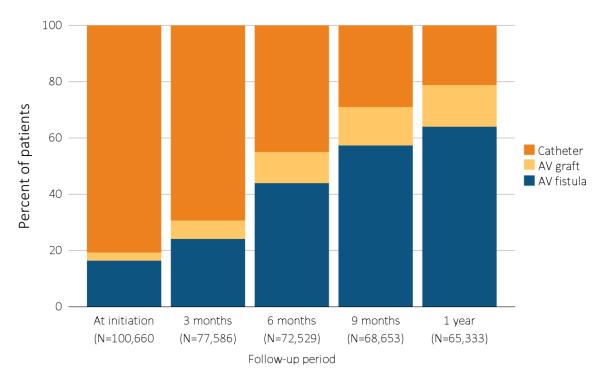


vol 2 Figure i.9 Trends in vascular access type use among ESRD prevalent patients, 2003-2014

Data Source: Special analyses, USRDS ESRD Database and Fistula First data. Fistula First data reported from July 2003 through April 2012, CROWNWeb data are reported from June 2012 through December 2014. Abbreviations: AV, arteriovenous; CROWNWeb, Consolidated Renal Operations in a Web-enabled Network; ESRD, end-stage renal disease. This graphic is adapted from Figure 4.6.

Figure i.10 shows cross-sectional data from both the Medical Evidence form (CMS 2728) (for vascular access information at initiation) and CROWNWeb (for follow-up data with respect to vascular access in use at 3, 6, and 9 months, and 1 year). At 90 days, most hemodialysis patients were still using a catheter, highlighting the importance of ongoing efforts to improve pre-dialysis access planning. The percentage

of patients using an AV fistula exclusively at the end of 1 year on dialysis was 65%, up from 17% at initiation of hemodialysis. The proportion of patients with an AV graft for vascular access was 3% at initiation, and 15% at 1 year. Thus, at 1 year, 80% of patients were using either an AV fistula or AV graft without the presence of a catheter. vol 2 Figure i.10 Change in type of vascular access during the first year of dialysis among patients starting ESRD via hemodialysis in 2014 quarterly: type of vascular access in use (cross-sectional), ESRD Medical Evidence form (CMS 2728) and CROWNWeb, 2014-2015

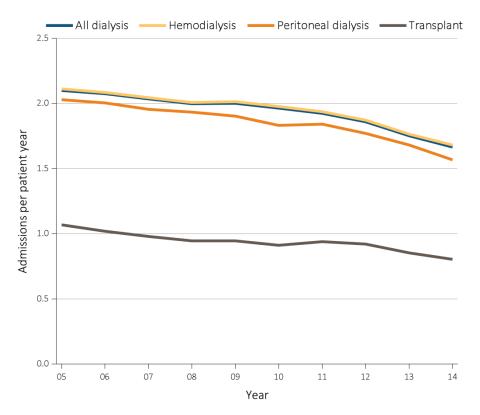


Data Source: Special analyses, USRDS ESRD Database. Data from January 1, 2014 to December 31, 2014: (a) Medical Evidence form (CMS 2728) at initiation and CROWNWeb for subsequent time periods. (b) ESRD patients initiating hemodialysis (N =102,367). Patients with a maturing AV fistula / AV graft with a catheter in place were classified as having a catheter. The apparent decrease in AV fistula and AV graft use at 1 month is related to missing data due to the different data sources used for incident and prevalent patients. Abbreviations: AV, arteriovenous; CMS, Centers for Medicare & Medicaid; CROWNWeb, Consolidated Renal Operations in a Web-enabled Network; ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis. This graphic is adapted from Figure 4.7.

Chapter 5: Hospitalization

On average, ESRD patients are admitted to the hospital nearly twice a year. About 30% of those have an unplanned rehospitalization within the 30 days following discharge. Hospitalization represents a significant societal and financial burden, accounting for approximately 40% of total Medicare expenditures for dialysis patients. Over the past decade, the frequency of hospital admissions and resulting number of hospital days for ESRD patients have declined gradually, but fairly consistently. In 2014, the adjusted rate of admission for hemodialysis patients decreased to 1.7 per patient year as compared to 2.1 in 2005, a reduction of 19.0% (Figure i.11). During that same period, admission rates for peritoneal dialysis patients fell by about 23.8%, to 1.6 in 2014 from 2.1 in 2005. For transplant patients this reduced by 27.2%, to 0.8 in 2014 from 1.1 in 2005.

vol 2 Figure i.11 Adjusted hospitalization rates for ESRD patients, by treatment modality, 2005-2014

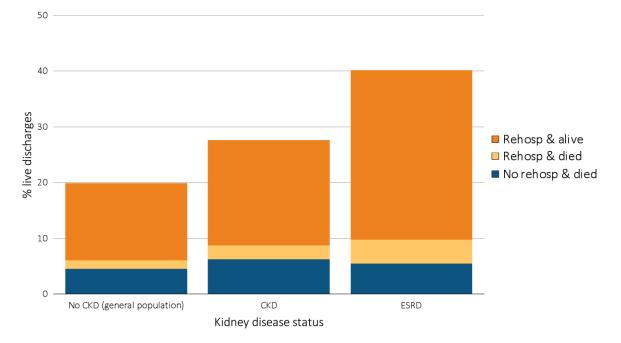


Data Source: Reference Tables G.1, G.3, G.4, G.5, G.6, G.8, G.9, G.10, and special analyses, USRDS ESRD Database. Period prevalent ESRD patients; adjusted for age, sex, race, primary cause of kidney failure & their two-way interactions; reference population, ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease. This graphic is adapted from Figure 5.1.

Rehospitalization has also been recognized as an important indicator of both morbidity and quality of life. It is also often costly, particularly among the ESRD patients being treated in dialysis facilities. In this chapter, rehospitalization/readmission is defined as a hospital admission occurring within 30 days of a hospital discharge, excluding ER visits and those for rehabilitation purposes. Hospital readmissions with associated death were more common among patients with CKD or ESRD than in the general population. Patients with CKD and ESRD experienced rehospitalization rates of 21.4% and 34.6%, respectively, as compared to only 15.3% of older Medicare beneficiaries without a diagnosis of kidney disease (Figure i.12). This held true for the combined outcomes of post-discharge death and/or rehospitalization—experienced by 27.6% of CKD patients and 40.1% of those with ESRD, versus only 19.8% of patients without diagnosed kidney disease.

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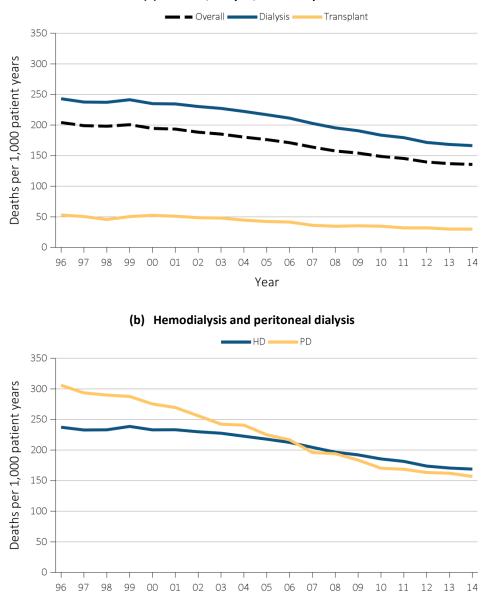
vol 2 Figure i.12 Proportion of patients aged 66 & older discharged alive from the hospital who were either rehospitalized or died within 30 days of discharge, by kidney disease status, 2014



Data Source: Special analyses, USRDS ESRD Database and Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 & older on December 31, 2013. For general Medicare: January 1, 2014 point prevalent, Medicare patients aged 66 & older, discharged alive from an all-cause index hospitalization between January 1, 2014, and December 1, 2014, unadjusted. CKD determined using claims for 2013. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; rehosp, rehospitalization. This graphic is adapted from Figure 5.6.

Chapter 6: Mortality

Increasing lifespan among ESRD patients is likely the main reason for continued growth in the prevalent ESRD population. Overall mortality rates among ESRD (dialysis and transplant) patients continue to decline, with steeper declines in more recent years. In 2014, adjusted mortality rates for ESRD, dialysis, and transplant patients, were 136, 166, and 30, per 1,000 patient-years, respectively (Figure i.13). By dialysis modality, mortality rates were 169 for hemodialysis patients and 157 for peritoneal dialysis patients, per 1,000 patient-years. Since 1996, crude mortality rates have decreased by 26% for dialysis patients and have increased by 2% for transplant recipients over the same period. However, when accounting for changes in population characteristics, adjusted mortality rates continue to decrease for dialysis and transplant patients, falling by 32% and 44%, respectively. vol 2 Figure i.13 Adjusted all-cause mortality (deaths per 1,000 patient-years) by treatment modality (a) overall, dialysis, and transplant, and (b) hemodialysis and peritoneal dialysis, for period-prevalent patients, 1996-2014

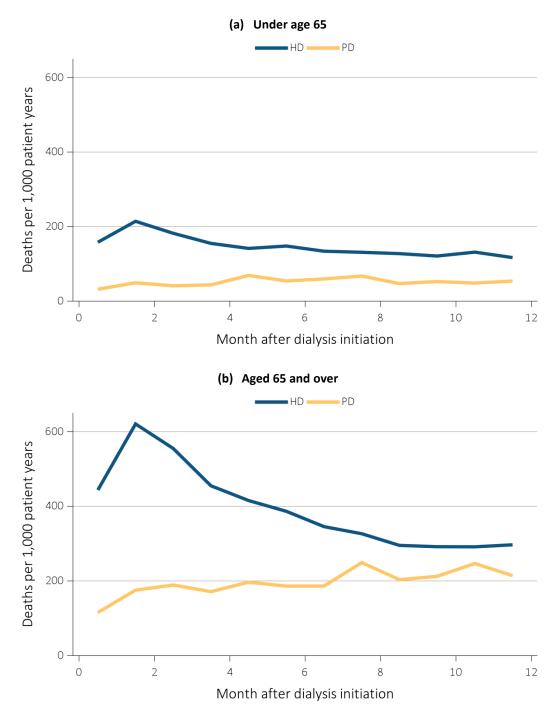


(a) Overall, dialysis, and transplant

Data Source: Reference Tables H.2_adj, H4_adj, H.8_adj, H.9_adj, and H.10_adj; and special analyses, USRDS ESRD Database. Adjusted for age, sex, race, ethnicity, primary diagnosis and vintage. Reference population: period prevalent ESRD patients, 2011. Abbreviations: HD, hemodialysis; PD, peritoneal dialysis. This graphic is adapted from Figure 6.1.

Year

The conundrum of high mortality in the first year of dialysis remains. Patterns of mortality during the first year of dialysis differ substantially by modality. For hemodialysis patients, reported mortality is highest in month 2, but declines thereafter; this effect is more pronounced for patients aged 65 and over (Figure i.14). In contrast, mortality rises slightly over the course of the year for peritoneal dialysis patients. vol 2 Figure i.14 Adjusted mortality (deaths per 1,000 patient-years) by treatment modality and number of months after treatment initiation among ESRD patients (a) under age 65 and (b) aged 65 and over, 2013



Data Source: Special analyses, USRDS ESRD Database. Adjusted (age, race, sex, ethnicity, and primary diagnosis) mortality among 2013 incident ESRD patients during the first year of therapy. Reference population: incident ESRD patients, 2011. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis. This graphic is adapted from Figure 6.3.

The relationship between race and mortality differs considerably by age among dialysis patients. White dialysis patients younger than age 22 have mortality rates comparable to Black patients, but experience higher mortality than Blacks at older ages.

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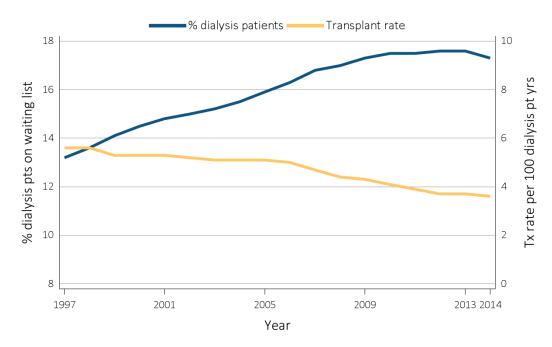
Dialysis patients continue to have substantially higher mortality, and fewer expected remaining life years, compared to the general population and Medicare populations with cancer, diabetes, or cardiovascular disease. However, the relative and absolute decline in mortality for dialysis patients in the past 15 years has been greater than for Medicare patients in these other diagnostic categories.

Chapter 7: Transplantation

During the year 2014, 17,914 kidney transplants, including 17,205 kidney-alone and 709 kidney plus at least one additional organ, were performed in the United States. Of these transplants, 5,574 were identified as coming from living donors and 12,328 from deceased donors. As of December 31, 2014, the kidney transplant waiting list increased by 3% over the previous year to 88,231 candidates (dialysis patients only), 83% of whom were awaiting their first kidney transplant. Fifty-seven percent (50,692) of wait-listed candidates were in active status and 43% (37,539) were inactive. With less than 18,000 kidney transplants performed in 2014, the active waiting list was 2.8 times larger than the supply of donor kidneys, which presents a continuing challenge. An additional 15,498 (15%) patients not yet on dialysis were on the waiting list as of December 31, 2014.

The unadjusted transplant rate per 100 dialysis patient years has been falling, while the percentage of prevalent dialysis patients wait-listed for a kidney has risen, though it appears to have plateaued in recent years (Figure i.15).

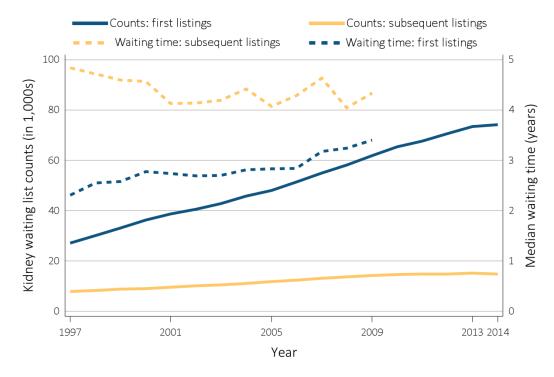
vol 2 Figure i.15 Percentage of dialysis patients wait-listed and unadjusted kidney transplant rates, 1997-2014



Data Source: Reference Tables E.4 and E.9. Percentage of dialysis patients on the kidney waiting list is for all dialysis patients. Unadjusted transplant rates are for all dialysis patients. Abbreviations: Tx, transplant; pt yrs, patient years. This graphic is adapted from Figure 7.1.

The unadjusted transplant rate per 100 dialysis patient years has been falling, while the probable contributing causes include growing prevalent dialysis population, longer survival of ESRD patients on dialysis, and the growing imbalance between donor supply and demand, which in turn leads to longer kidney transplant waiting times. Waiting list counts and median waiting time to transplantation continue to grow for first-time listings. (Figure i.16).

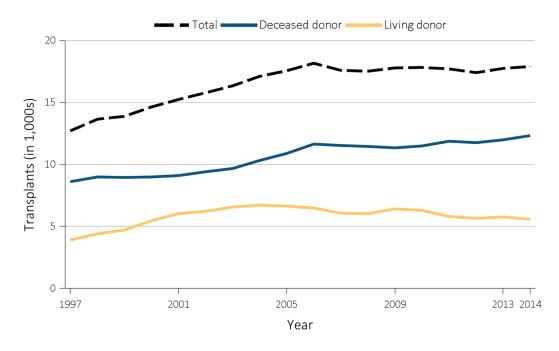
vol 2 Figure i.16 Number of patients wait-listed for kidney transplant, 1997-2014, and median waiting time, 1997-2009



Data Source: Reference Tables E.2 and E.3. Waiting list counts include all candidates listed for a kidney transplant on December 31 of each year. Median waiting time is calculated for all candidates enrolled on the waiting list in a given year. This graphic is adapted from Figure 7.2.

The total number of kidney transplants has leveled off over the past decade (Figure i.17). During this period, a modest rise in deceased donor kidney transplants has been balanced by a small decrease in living donor transplants.

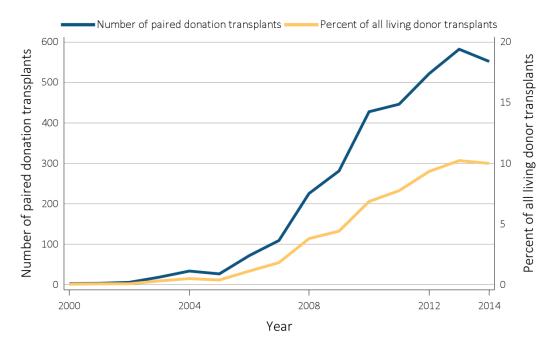




Data Source: Reference Tables E.8, E.8.2, and E.8.3. Counts of all transplants by year. This graphic is adapted from Figure 7.3.

A relatively recent initiative aimed at increasing the availability of living donor transplants is the process of kidney paired donation (KPD). This typically applies when an otherwise willing potential living donor is incompatible with the recipient. In its simplest form, two living donors who are incompatible with their respective recipients perform an exchange whereby the donation goes to each other's compatible recipient. More complex chains involving exchanges among three or more recipient-donor pairs are possible and have been performed. The counts of KPD transplants has risen sharply in recent years, with 552 performed in 2014, representing 10% of living donor transplants that year (Figure i.18).

vol 2 Figure i.18 Number of paired donation transplants and percent of all living donor transplants, 2000-2014



Data Source: Data are obtained from the Organ Procurement and Transplantation Network (OPTN). Paired donation transplant counts and percent of all living donor transplants. This graphic is adapted from Figure 7.15.

Since 2010, Blacks have surpassed Whites in deceased donation rates (not shown, see Figure 7.18.b Donation rates by race in <u>Volume 2</u>, <u>Chapter 7</u>). The rate of deceased donors per 1,000 deaths among Blacks nearly doubled from 1999 to 2014. Notably, Asian or Pacific Islanders have had the highest donation rate, and Native Americans have had the lowest donation rates since 1999.

During 1997-2013, kidney transplant patients experienced improved health outcomes, with decreases in deaths and all-cause graft failure at one year posttransplantation. Among the recipients of deceased donor kidney transplants, the probability of all-cause graft failure in the first year following transplant decreased from 14% in 1997 to 8% in 2013, while the probability of death decreased from 6% in 1997 to 4% in 2013. Similarly, among those who received living donor kidney transplants, the probability of all-cause graft failure in the first year following transplant decreased from 7% in 1997 to 3% in 2013, while probability of death decreased from 3% to 1% over the same period.

Improvements in patient survival probabilities have persisted for most of the five- and ten-year outcomes (not shown, see Tables 7.3 and 7.4 in <u>Volume 2</u>, <u>Chapter 7</u>).

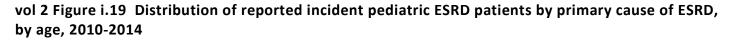
Chapter 8: ESRD Among Children, Adolescents, and Young Adults

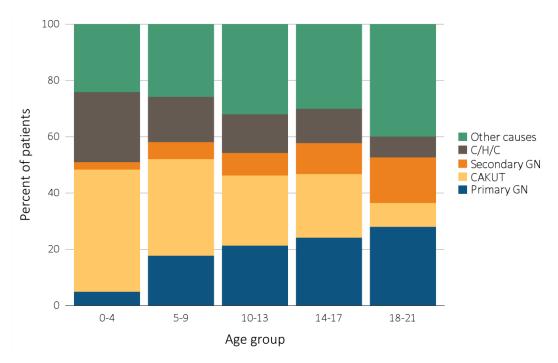
A greatly expanded chapter on pediatric ESRD (renamed this year to ESRD Among Children, Adolescents, and Young Adults to emphasize its scope) is a notable feature since the 2015 ADR. ESRD affects children of all ages. The majority of this population will depend on renal replacement therapies over many decades. Consequently, children with incident ESRD often traverse the entire ESRD modality continuum of hemodialysis, peritoneal dialysis, and transplantation. Children with ESRD are subject to frequent hospitalizations and have a risk of mortality far exceeding the general pediatric population in the United States. They are quite different in disease etiology, transplant opportunities, morbidity and mortality when compared to adults with ESRD. Since 2015, The chapter includes information about vascular access in children as this can have far reaching implications into adulthood. Also, since 2015, this chapter also includes a section on young adults, providing an opportunity to improve our understanding of the issues surrounding "transitional" ages and outcomes in these patients.

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The leading causes of ESRD in children during 2010-2014 are as follows: primary glomerular disease (25.3%), CAKUT [congenital anomalies of the kidney and urinary tract] (24.1%), cystic/hereditary/congenital disorders (14.3%), and secondary glomerular disease (12.4%) (not shown, see Table 8.1 in <u>Volume 2, Chapter 8</u>). The most common individual diagnoses associated with pediatric ESRD include renal hypoplasia/dysplasia (N=728), congenital obstructive uropathies (N=541), focal glomerular sclerosis (N=901), and systemic lupus

erythematosus (N=489). In children with ESRD, sickle cell nephropathy, human immunodeficiency virus (HIV) nephropathy, and systemic lupus erythematosus are more common among Blacks compared with other racial groups. Figure i.19 shows the distribution of the most common causes of ESRD by age and by year (2010-2014) of onset of ESRD. CAKUT and Congenital/Hereditary/Cystic disorders cause more ESRD in young children, and primary and secondary glomerulonephritis and other etiologies become more common with advancing age.



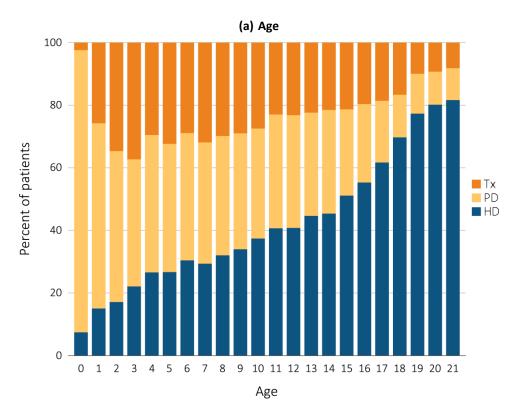


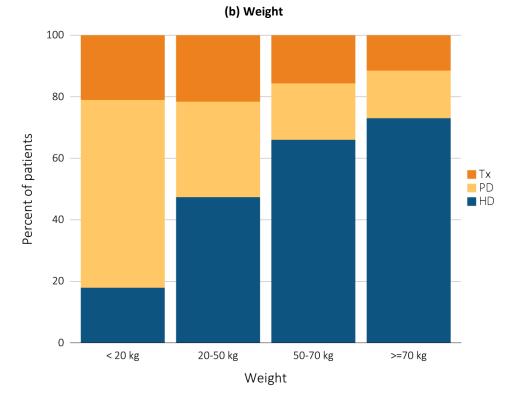
Data Source: Special analyses, USRDS ESRD Database. Abbreviations: CAKUT, congenital anomalies of the kidney and urinary tract; C/H/C, cystic/hereditary/congenital diseases; GN, glomerulonephritis. This graphic is adapted from Figure 8.3.

In 2014, a total of 1,398 children had new onset ESRD, which was 6% less than in 2013. By the end of 2014, the point prevalence of children with ESRD was 9,721, which represented a 1.6% decrease from the previous year. Prevalence measures do not account for the large number of pediatric patients who have aged into adulthood. Approximately half of the pediatric ESRD population (50.4%) initiated renal replacement by hemodialysis, 420 (30.0%) by peritoneal dialysis, and 271 (19.4%) received kidney transplant as their first modality. Peritoneal dialysis is the most common initial ESRD treatment modality for children aged 9 years and younger (Figure i.20.a). Hemodialysis becomes the most common initial modality at patient aged 9.5 years and older. Similarly, initial ESRD treatment modality is associated with patient weight. Peritoneal dialysis is most commonly the initial modality in small children weighing less than 20 kg. Hemodialysis is the least common initiating modality in small children and increases in frequency with increasing patient weight (Figure i.20.b)

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vol 2 Figure i.20 Cross-sectional trends in pediatric ESRD modality at initiation, by patient (a) age and (b) weight, 1996-2014





Data Source: Special analyses, USRDS ESRD Database. Includes incident ESRD patients in the years 1996-2014. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant. This graphic is adapted from Figure 8.2.

Overall, 36.0% of children received a kidney transplant within the first year of ESRD care during 2010-2014. A total of 1,321 children were wait-listed for a kidney transplant in 2014, including 896 patients listed for the first time and 425 patients listed for repeat transplant. A total of 1,018 children received a kidney transplant in 2014. Since 1997, there has been a decrease in the median waiting time for those listed for their first transplant with a flattening of the curve in 2005, which coincides with the change in the Organ Procurement and Transplantation Network (OPTN) organ allocation policy. The median waiting time for patients receiving their first kidney transplant has ranged between 150-220 days. Over the same time period, children receiving a repeat transplant have, on average, been on the waiting list at least 3-4 times longer than those awaiting their first transplant. The median waiting time to transplant for incident patients on dialysis has been improving over time. In 2002, the median waiting time peaked at 1.83 years and began to decline, with the most dramatic improvement occurring after 2005 (not shown, see Figure 8.15.a in Volume 2, Chapter 8), which coincides with the change in the OPTN organ allocation policy. Since 2005, the median waiting time for incident dialysis patients has continued to decrease and was at its lowest in 2013 at 1.04 years. Since 2007, the waiting times for incident patients on dialysis have been similar for hemodialysis and peritoneal dialysis. In 2013, the median waiting time to transplant for hemodialysis patients was 1.01 years, and for peritoneal dialysis patients it was 1.06 years.

Kidney grafts in pediatric transplant recipients were most commonly from living donors prior to 2005. There has been a decline in the number of pediatric patients receiving living donor kidneys since 2009. In 2014, living donors accounted for 40.0% of kidney transplants, which is a 2.1% decrease from 2013 and a 21% decrease since 2009.

Over time, transplant has become the most common prevalent ESRD treatment modality in children. Of the 9,721 children and adolescents between the ages of o and 21 years with prevalent ESRD as of December 31, 2014, kidney transplant was the most common modality (6,825[70.2%]), followed by hemodialysis (1,745 [18.0%]) and peritoneal dialysis (1,122 [11.5%]). Over 80% of prevalent children ages 5 to 13 have a kidney transplant.

As a result of improvements in the care of pediatric patients with ESRD and kidney transplants, a larger percentage of these children are surviving into adulthood. The transition of these patients into adulthood represents a truly unique process and has resulted in the development of specific transition programs to improve health care for these individuals. Since the 2015 USRDS ADR, we continue to include a section in the pediatric chapter highlighting the young adult age group (defined in the USRDS as 22-29 years of age) that classically encompasses the transitional age groups. Despite their young age, cardiovascular disease remains the leading cause of mortality in this cohort, similar to older patients with ESRD.

Chapter 9: Cardiovascular Disease in ESRD Patients

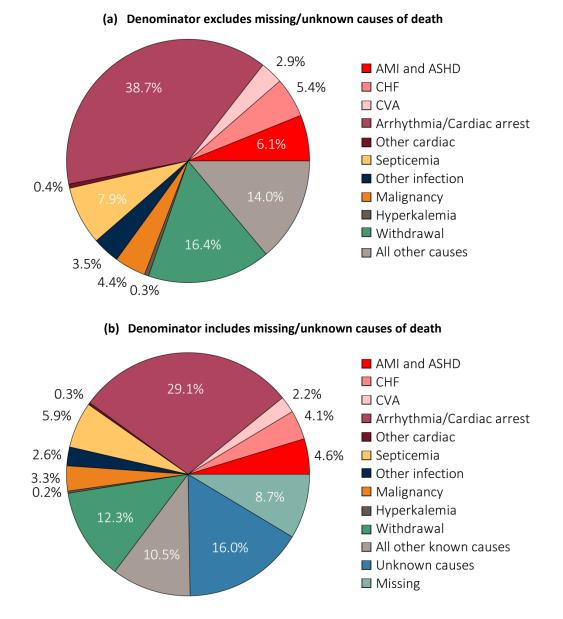
This chapter was reintroduced in the 2015 ADR, as the USRDS special study dealing with cardiovascular disease in CKD/ESRD ended at the beginning of 2014. Patients with ESRD are among the highest risk populations for a number of cardiovascular diseases, and cardiovascular diseases are a major cause of death in ESRD patients. Cardiovascular disease is a significant comorbidity for patients along the entire spectrum of CKD and ESRD. Presence of ESRD often complicates disease management and treatment, as it can influence both medical and procedural options, thereby adversely affecting a patient's prognosis. In this chapter, we focus on reporting the prevalence and outcomes of ESRD patients with diagnosed major cardiovascular conditions, stratifying by type of RRT received (hemodialysis, peritoneal dialysis, and kidney transplantation). For individual cardiovascular conditions, we compare the survival of patients with and without the condition. Given its role as the primary health care payer for ESRD patients, our analyses are based mostly on data from the national Medicare population.

Figure i.21 presents both the proportion of known causes of death and the proportion of total deaths among ESRD patients. As shown in Figure i.21.a,

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cardiovascular diseases are a major cause of death in ESRD patients, contributing to more than half of all deaths with known causes. The category of arrhythmias and cardiac arrest alone is responsible for 38.7% of the deaths, excluding those with missing/unknown causes of death. Figure i.21.b provides an alternate analysis in which deaths with unknown and missing causes are included in the denominator and appear as separate categories. As shown in Figure i.21.b, the categories of arrhythmias and cardiac arrest, congestive heart failure (CHF), acute myocardial infarction (AMI), and atherosclerotic heart disease (ASHD) are responsible for over one-third of the total deaths. A significant proportion (24.7%) of the deaths is due to unknown causes or missing cause of death. We speculate that unidentified cardiovascular conditions may well be the true underlying causes of death in this category.

vol 2 Figure i.21 Causes of death in ESRD patients, 2012-2014

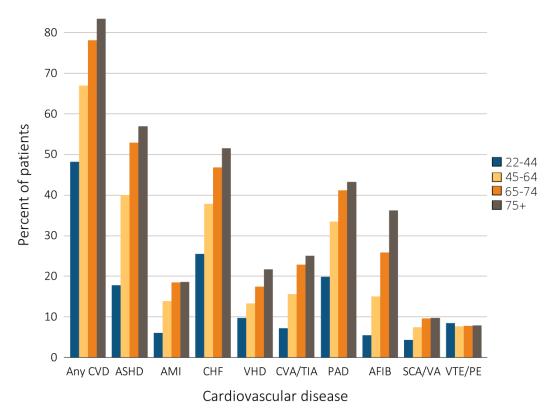


Data Source: Special analysis using Reference Table H.12. (a) Denominator includes other causes of death and excludes missing/unknown causes of death (24.7% of patients have unknown or missing causes of death). (b) Denominator includes other known causes, unknown causes of death, and records that are missing the cause of death. Unknown causes include records from the CMS 2746 ESRD death notification form that specifically designate an unknown cause of death. Missing includes records in the ESRD database that are missing the CMS 2746, or have the form but are missing or have recording errors in the primary cause of death field. Abbreviations: ASHD, atherosclerotic heart disease; AMI, acute myocardial infarction; CHF, congestive heart failure; CVA, cerebrovascular accident. This graphic is adapted from Figure 9.1.

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ESRD patients have a high burden of cardiovascular disease across a wide range of conditions (Figure i.22). Not surprisingly, older ESRD patients tend to have a higher prevalence of cardiovascular conditions (not shown, see Figure 9.3 in <u>Volume 2, Chapter 9</u>). It is notable, however, that the prevalence of these conditions is high even among those 22-44 years of age (48.2%), although a much higher prevalence is observed among those 45 years or older (66.9% to 83.4%). ASHD is the most common condition, with its prevalence exceeding 50% in ESRD patients aged 65 years and older, followed by CHF, PAD, AFIB, CVA/TIA, and VHD. The presence of VTE/PE did not vary as much by age.

vol 2 Figure i.22 Prevalence of cardiovascular diseases in adult ESRD patients, by age, 2014

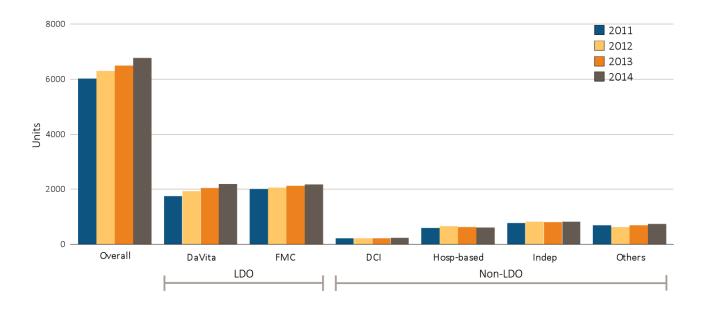


Data Source: Special analyses, USRDS ESRD Database. Point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older, with Medicare as primary payer on January 1, 2014, who are continuously enrolled in Medicare Parts A and B from January, 1, 2013 to December 31, 2013, and ESRD service date is at least 90 days prior to January 1, 2014. Abbreviations: AFIB, atrial fibrillation; AMI, acute myocardial infarction; ASHD, atherosclerotic heart disease; CHF, congestive heart failure; 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 9.3.

Chapter 10: Dialysis Providers

At the end of 2014, there were 6,757 dialysis units (Figure i.23) and 460,675 dialysis patients (not shown, see Figure 10.2 in <u>Volume 2</u>, <u>Chapter 10</u>) in the United States. Together the two large dialysis organizations (LDOs), DaVita, and Fresenius, treated 317,587 of these patients (69%) in 4,362 dialysis units (65%). Nationwide, 748 dialysis units were added during the four-year period from 2011 to 2014, with Fresenius and DaVita accounting for 609 (81%) of the new units. For the 2016 ADR, we have avoided use of any formal classification system of dialysis providers, given the disproportionate size of the two largest dialysis providers, the heterogeneity in dialysis provider ownership type, and the evolving nature of mergers and acquisitions in the provider community. Nationwide, 608 dialysis units were added during the four-year period from 2010 to 2013, with most belonging to the LDOs; DaVita experienced the largest growth of all provider types in both facilities and patients. Small dialysis organizations experienced declines in the numbers of patients and units over the same period. Nearly 90% of all dialysis patients in 2013 received hemodialysis; hospital-based providers had the highest proportion of peritoneal dialysis patients at 21%, which is more than double the national average.

vol 2 Figure i.23 Dialysis unit counts, by unit affiliation, 2011–2014



Data source: Special analyses, USRDS ESRD Database. Abbreviations: DCI, Dialysis Clinic, Inc.; FMC, Fresenius; Hosp-based, hospitalbased dialysis centers; Indep, independent dialysis providers; Others, other dialysis organizations. Note: the number of dialysis units in 2011 has been updated for DaVita from 1,681 as reported in the 2015 ADR to 1,745; and from 750 in 2015 to 686 currently for Others. This graphic is adapted from Figure 10.1.

Table i.1 provides the standardized mortality ratio for a sample set of dialysis providers for 2014. This example is designed to provide a simpler and more direct comparison of a given provider type to other providers and to the national value in a single year.

Affiliation	All (National average)	White	Black/African American	Asian	Native American	Hispanic
Overall	1.00 (0.99-1.01)	1.12 (1.11-1.13)	0.85 (0.84-0.86)	0.70 (0.68-0.72)	0.86 (0.81-0.91)	0.79 (0.77-0.80)
LDOs						
DaVita	1.02 (1.01-1.03)	1.14 (1.13-1.16)	0.85 (0.83-0.86)	0.71 (0.67-0.75)	0.82 (0.74-0.90)	0.79 (0.77-0.81)
Fresenius	0.98 (0.97-0.99)	1.10 (1.09-1.12)	0.81 (0.79-0.82)	0.77 (0.73-0.82)	0.88 (0.76-1.00)	0.79 (0.77-0.81)
DCI	0.92 (0.89-0.95)	1.06 (1.01-1.10)	0.78 (0.73-0.82)	0.66 (0.51-0.84)	0.70 (0.54-0.90)	0.77 (0.66-0.89)
Hospital-based	0.94 (0.91-0.97)	1.04 (1.00-1.08)	0.86 (0.80-0.91)	0.69 (0.58-0.81)	0.72 (0.58-0.89)	0.71 (0.63-0.79)
Independent	1.03 (1.01-1.04)	1.14 (1.11-1.16)	0.90 (0.87-0.93)	0.70 (0.65-0.75)	0.92 (0.81-1.03)	0.82 (0.78-0.85)
Others	1.02 (1.00-1.04)	1.12 (1.09-1.14)	0.87 (0.84-0.90)	0.75 (0.70-0.80)	1.27 (1.05-1.54)	0.81 (0.78-0.85)

vol 2 Table i.1 All-cause Standardized Mortality Ratio, by unit affiliation, 2014

Data source: Special analyses, USRDS ESRD Database. Period prevalent dialysis patients; 95% confidence intervals are shown in parentheses. The overall measure is adjusted for patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence, and population death rates. The race-specific measures are adjusted for all the above characteristics except patient race. The Hispanic-specific measure is adjusted for all the above characteristics. DCI, Dialysis Clinic, Inc.; LDO, large dialysis organizations; Others, other dialysis organizations. This table is adapted from Table 10.2.

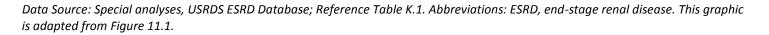
Dialysis providers of all types continued to experience declining Standardized Mortality Ratios between 2011 and 2014. However, all types of providers experienced relatively flat change trends in Standardized Hospitalization Ratios between 2011 and 2014.

Chapter 11: Medicare Expenditures for Persons With ESRD

The Medicare program for the elderly was enacted in 1965. Seven years later, in 1972, Medicare eligibility was extended both to disabled persons aged 18 to 64 and to persons with irreversible kidney failure who required dialysis or transplantation. On January 1, 2011, CMS implemented the ESRD Prospective Payment System (PPS). This program bundled Medicare's payment for renal dialysis services together with separately billable ESRD-related supplies (primarily erythropoiesis stimulating agents (ESAs), vitamin D, and iron) into a single, per treatment payment amount. The bundle payment supports up to three dialysis treatments per individual per week, with additional treatments covered on the basis of medical necessity. The reimbursement to facilities is the same regardless of dialysis modality, but is adjusted for case-mix, geographic area health care wages, and small facility size. This chapter presents recent patterns and longer-term trends in both total Medicare spending and spending by type of service. Data from 2014 is featured, which is the fourth full year under the expanded, bundled PPS.

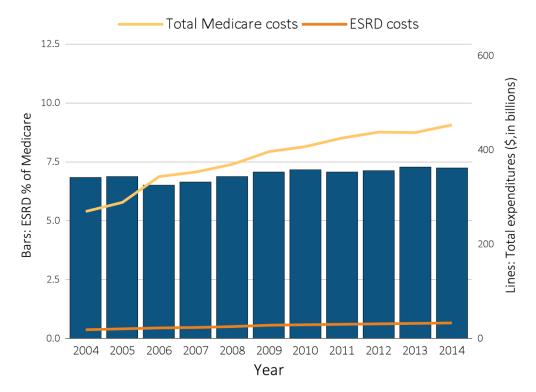
Figure i.24 displays Medicare's total annual paid claims for period prevalent ESRD patients from 2004-2014. These costs represent about three-quarters of all spending for the care of U.S. ESRD patients. Medicare fee-for-service ESRD spending rose by 3.3% from 2013 to 2014, marking the fourth year of modest growth relative to historical trends, and following the implementation of the bundled payment system. The Medicare patient obligation amount has also grown over the years in proportion to these paid claims. Patient obligations may be paid by the patient, by a secondary insurer, or may be uncollected. Overall, the patient obligation represented 14.8% of the total Medicare Allowable Payments in 2014.

vol 2 Figure i.24 Trends in ESRD expenditures, 2004-2014



As illustrated in Figure i.25, total Medicare fee-forservice spending in the general Medicare population increased by 3.8% in 2014 to \$453.6 billion; \$32.8 billion in spending for ESRD patients accounted for 7.2% of the overall Medicare paid claims costs in the fee-for-service system.



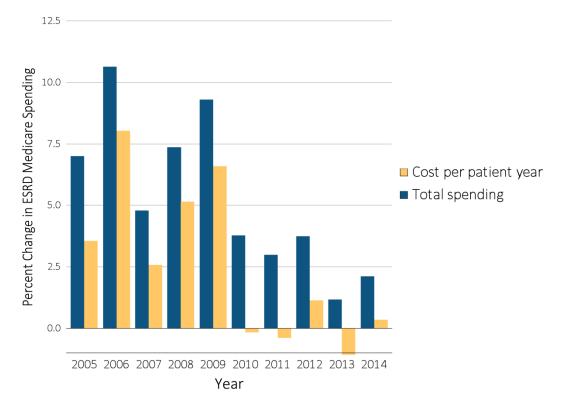


Data Source: Special analyses, Total ESRD costs obtained from USRDS ESRD Database; Reference Table K.1. Total Medicare expenditures obtained from Trustees Report, Table II.B1 https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/TrusteesReports.html. Abbreviations: ESRD, end-stage renal disease. This graphic is adapted from Figure 11.2.

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For the fifth consecutive year, the annual increase in total Medicare ESRD spending for beneficiaries with primary payer status was less than 4%. In 2014, total Medicare paid claims for ESRD services and supplies increased by 2.1% to \$30.5 billion (Figure i.26; for total and specific values see Reference Table K.4). In 2014, ESRD per patient per year (PPPY) spending increased by 0.3%. Given that these expenditures decreased or increased only minimally from 2009 to 2013, the growth in total ESRD costs during these years is almost entirely attributable to growth in the number of covered beneficiaries.

vol 2 Figure i.26 Annual percent change in Medicare ESRD spending, 2004-2014

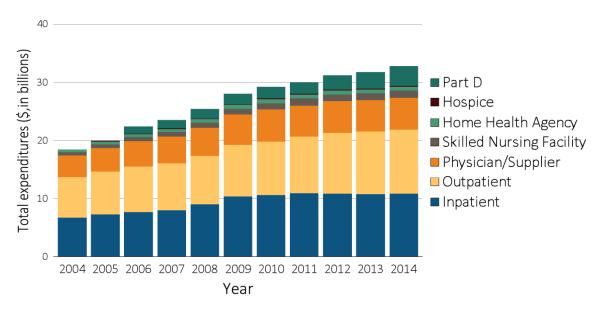


Data Source: Special analyses, USRDS ESRD Database; Reference Table K.4. Total Medicare ESRD costs from claims data; includes all claims with Medicare as primary payer only. Abbreviations: ESRD, end-stage renal disease. This graphic is adapted from Figure 11.4.

Total Medicare fee-for-service spending for ESRD patients is reported by type of service in Figure i.27. Compared to 2013, the costs of Part D claims and skilled nursing facility care in 2014 grew at the fastest rates of 21.0% and 5.5%, respectively. The increase in Part D (prescription drug) expenditures is consistent with drug cost trends nationally. All other categories of spending rose by less than 3%. The smallest share of Medicare spending for ESRD patients was for hospice care. It should be noted, however, that prior to 2013 hospice care had been experiencing one of the highest rates of growth of any category; this spending declined by 6.3% in 2014.

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vol 2 Figure i.27 Trends in total Medicare fee-for-service spending for ESRD, by type of service, 2004-2014



Data Source: Special analyses, USRDS ESRD Database; Reference Table K.1. Total Medicare costs from claims data. Abbreviations: ESRD, end-stage renal disease. This graphic is adapted from Figure 11.5.

Chapter 12: Part D Prescription Drug Coverage in Patients With ESRD

The share of beneficiaries with ESRD that enrolled in Part D increased annually between 2011 and 2014 (Table i.2). Total enrollment was higher in the dialysis population than in the general Medicare population, but the growth between 2011 and 2014 was somewhat slower among beneficiaries on dialysis. Both the level and trend in Part D enrollment among beneficiaries with transplants mirrored that in the general Medicare population.

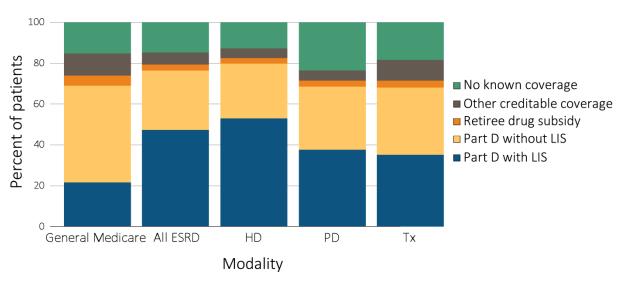
	General Medicare	All ESRD	Hemodialysis	Peritoneal dialysis	Transplant
2011	60	70	74	62	59
2012	62	72	76	64	62
2013	67	75	79	67	66
2014	69	77	80	69	68

vol 2 Table i.2 General Medicare & ESRD patients enrolled in Part D (%)

Data source: 2011-2014 Medicare data, point prevalent Medicare enrollees alive on January 1. Medicare data: general Medicare, 5% Medicare sample (ESRD, hemodialysis, peritoneal dialysis, and transplant, 100% ESRD population). Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage. This table is adapted from Table 12.2.

More hemodialysis, peritoneal dialysis, and transplant patients with Part D receive the Lowincome Subsidy (LIS) — 66%, 55%, and 52%, compared to 31% of the general Medicare population. About 15% of ESRD beneficiaries have no identified prescription drug coverage. By modality, peritoneal dialysis and transplant patients are least likely to have known coverage (see Figure i.28).





Data source: Special analyses, 2014 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; LIS, Low-income Subsidy; Part D, Medicare Part D prescription drug coverage; PD, peritoneal dialysis; Tx, kidney transplant. This graphic is adapted from Figure 12.1.

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Total Part D spending for beneficiaries with ESRD increased by 65% from \$1.64 billion in 2011 to \$2.71 billion in 2014 (Table i.3). These amounts do not include costs of medications subsumed under the ESRD prospective payment system (e.g. ESAs, IV vitamin D, and iron) or billed to Medicare Part B (e.g. immunosuppressants). Between 2011 and 2014, total estimated Part D spending increased by 63%, 91%, and 63% for hemodialysis, peritoneal dialysis, and kidney transplant patients. These rates of increase far outpaced the 26% spending growth that occurred in the general Medicare population.

	General Medicare	All ESRD	Hemodialysis	Peritoneal dialysis	Transplant
2011	45.96	1.64	1.29	0.09	0.21
2012	40.08	2.00	1.59	0.12	0.23
2013	52.08	2.27	1.79	0.14	0.27
2014	58.07	2.71	2.10	0.17	0.35

Data source: 2011-2014 Medicare data, period prevalent Medicare enrollees alive on January 1, excluding those in Medicare Advantage Part D plans and Medicare secondary payer, using as-treated model (see ESRD Methods chapter for analytical methods). Part D spending represents the sum of the Medicare covered amount and the Low- income Subsidy amount. This table is adapted from Table 12.4.

By ESRD modality, hemodialysis patients had the highest PPPY Medicare Part D spending at \$9,089, compared to \$8,188 for peritoneal dialysis, and \$6,284 for transplant patients. PPPY Part D spending was three times greater for beneficiaries with ESRD (\$8,420) than for general Medicare beneficiaries (\$2,830). As a proportion of total costs, however, outof-pocket costs were lower for beneficiaries with ESRD

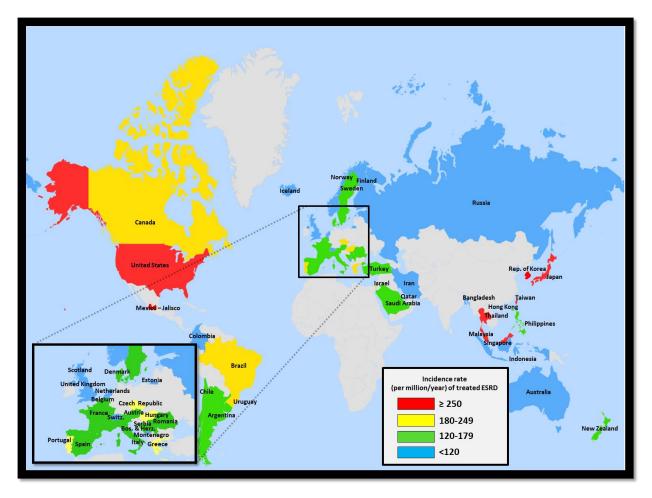
Chapter 13: International Comparisons

This chapter examines international trends in treatment of ESRD. The number of countries and regions represented in this year's ADR has increased to 60 (from 57 in last year's ADR, and 54 countries in the 2014 ADR), with the addition of Morocco, Montenegro, and Sri Lanka.

This work is made possible through the substantial efforts of many individuals from all participating countries in collecting and contributing data for this international collaboration. The information provided is meant to serve as a resource for the worldwide ESRD community to inform health care policies, patient care, and application of resources, while stimulating meaningful research for improving ESRD patient care. The comparisons presented are intended to increase awareness of the international trends, representing 4%, 7%, and 8% of PPPY costs for hemodialysis, peritoneal dialysis, and transplant patients, compared to 13% in the general Medicare population (not shown, see Figure 12.5a in <u>Volume 2</u>, <u>Chapter 12</u>). A higher proportion of beneficiaries with ESRD receive the LIS relative to the general Medicare population, which substantially reduces out-of-pocket obligations.

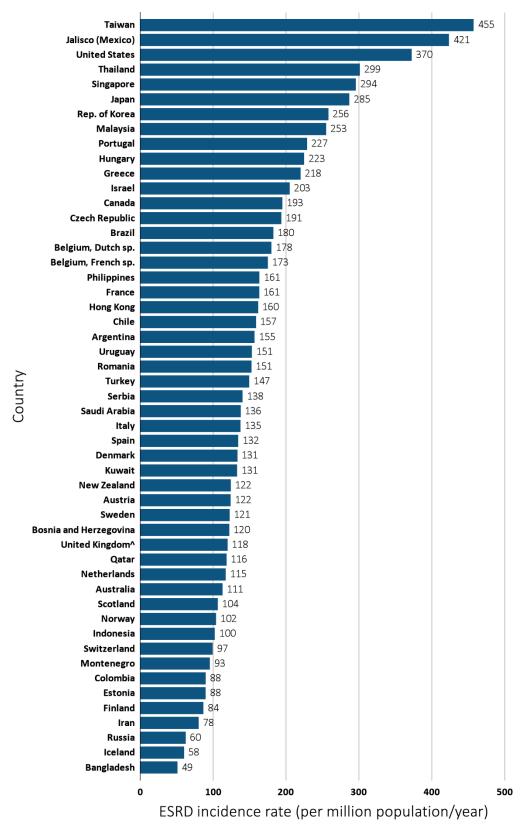
similarities, and differences in key ESRD treatment measures. Data collection methods vary considerably across countries, and therefore direct comparisons should be made with caution. Data reflect "treated ESRD". Unrecognized ESRD or poor access to RRT may result in reported ESRD incidence that substantially underestimates the true incidence of irreversible kidney failure. Furthermore, in some countries where RRT is widely available, true ESRD incidence also may be underestimated because some patients decline dialysis or transplantation.

Significant geographic variation is observed with respect to the incidence and prevalence of ESRD by country (Figures i.29, i.30, i.31, i.32). Taiwan had the highest incidence and prevalence of ESRD. The United States was ranked among the top three countries for both highest ESRD incidence and prevalence. Notably, males have a higher incidence of ESRD than females in all countries reporting data to the USRDS. vol 2 Figure i.29 Geographic variations in the incidence rate of treated ESRD (per million population/year), by country, 2014

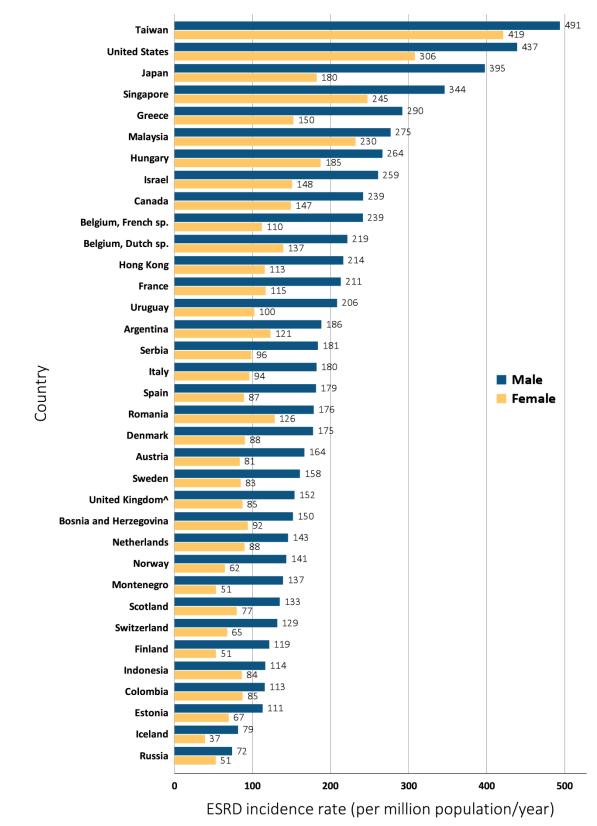


Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. All rates are unadjusted. ^United Kingdom: England, Wales, Northern Ireland (Scotland data reported separately). Data for Italy include 6 regions. Data for Indonesia represent the West Java region. Data for France include 22 regions. Data for Spain include 18 of 19 regions. Data for Canada excludes Quebec. Japan includes dialysis patients only. Abbreviation: ESRD, end-stage renal disease. This graphic is adapted from Figure 13.1.

vol 2 Figure i.30 Incidence rate of treated ESRD (per million population/year), by country, 2014



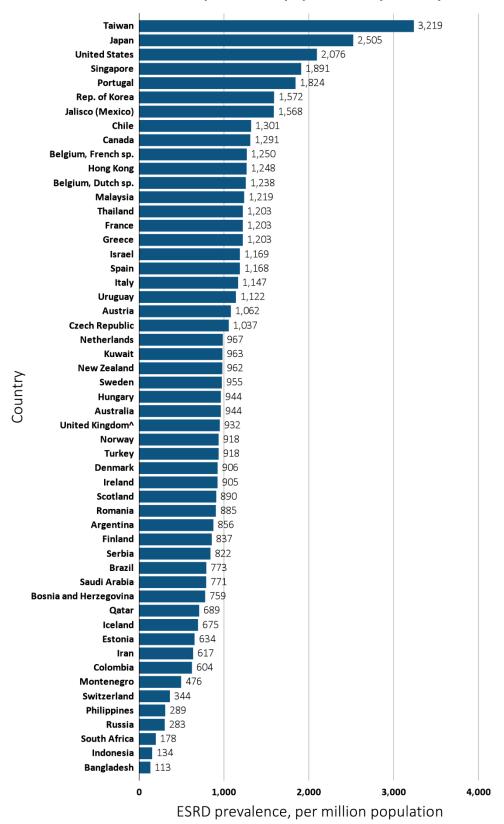
Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. All rates are unadjusted. ^United Kingdom: England, Wales, Northern Ireland (Scotland data reported separately). Data for Italy include 6 regions. Data for Indonesia represent the West Java region. Data for France include 22 regions. Data for Spain include 18 of 19 regions. Data for Canada excludes Quebec. Japan includes dialysis patients only. Abbreviations: ESRD, end-stage renal disease; sp., speaking. This graphic is adapted from Figure 13.2.



vol 2 Figure i.31 Incidence rate of treated ESRD (per million population/year), by sex and country, 2014

Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. ^United Kingdom: England, Wales, Northern Ireland (Scotland data reported separately). Data for Spain include 18 of 19 regions. Data for France include 22 regions. Data for Indonesia represent the West Java region. Data for Italy represent 6 regions. Data for Canada excludes Quebec. Japan includes dialysis patients only. Abbreviations: ESRD, end-stage renal disease; sp., speaking. This graphic is adapted from Figure 13.8.

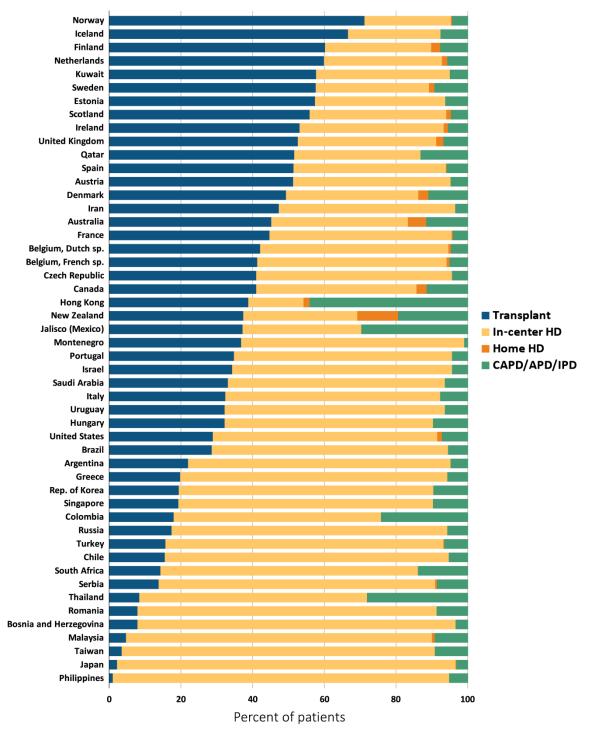
vol 2 Figure i.32 Prevalence of treated ESRD per million population, by country, 2014



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. ^United Kingdom: England, Wales, Northern Ireland (Scotland data reported separately). The prevalence is unadjusted and reflects prevalence at the end of 2014. Switzerland includes dialysis patients only. Data for Indonesia represent the West Java region. Data for Spain include 18 of 19 regions. Data for France include 22 regions. Data for Italy includes 6 regions. Data for Canada excludes Quebec. Abbreviations: ESRD, end-stage renal disease; sp., speaking. This graphic is adapted from Figure 13.9.

Significant variation was also observed with respect to the type of RRT used by ESRD patients across countries (Figure i.33), and the rate of kidney transplantation as a treatment modality.

vol 2 Figure i.33 Percent distribution of type of renal replacement therapy modality used by ESRD patients, by country, in 2014



Data source: Special analyses, USRDS ESRD Database. Denominator is calculated as the sum of patients receiving HD, PD, Home HD, or treated with a functioning transplant; does not include patients with other/unknown modality. Data for Spain include 18 of 19 regions. Data for France include 22 regions. Data for Italy include 6 regions. Data for Canada excludes Quebec. Abbreviations: CAPD, continuous ambulatory peritoneal dialysis; APD, automated peritoneal dialysis; IPD, intermittent peritoneal dialysis; ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; sp., speaking. This graphic is adapted from Figure 13.12.

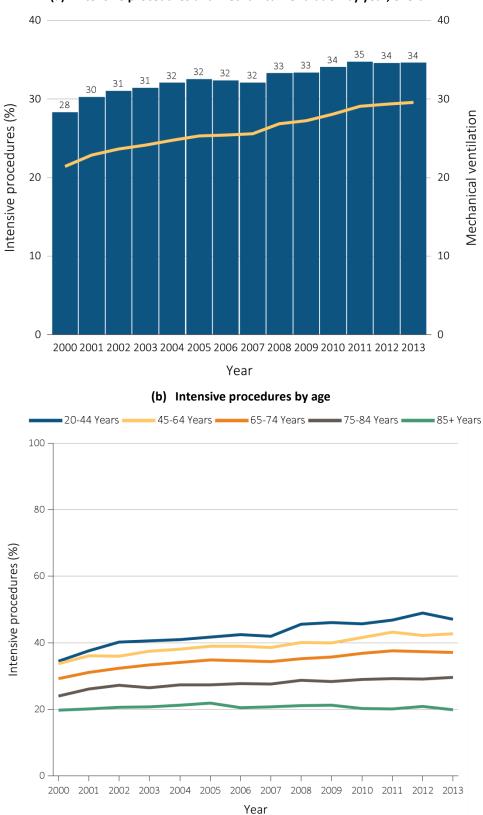
Chapter 14: USRDS Special Study Center on Palliative and End-of-Life Care

The limited survival of many patients with ESRD and their very high levels of disability, frailty, and functional impairment provide a strong rationale for efforts to integrate a more palliative and patientcentered approach to their care. The overarching goal of the USRDS Special Study Center (SSC) on Palliative and End-of-Life Care is to provide the nephrology community with innovative, rigorous, and nationally representative information about a domain of ESRD care for which little information is currently available to guide policy and practice.

Chapter 14 includes information on treatment practices, patterns of health care utilization, and costs at the end of life among decedents with ESRD over the 14-year period from 2000 through 2013. New to this year's chapter is information on nursing facility use during the last year of life. Key findings include an upward trend over this time period in the percentage of Medicare beneficiaries with ESRD admitted to an intensive or coronary care unit and the percentage who received an intensive procedure in the last 90 days of life; an upward trend in the percentage of patients who received care in a nursing facility during the last year of life; an upward trend in the percentage of patients who discontinued dialysis before death, though with a downward trend in the last two years; an upward trend in the percentage of patients who were receiving hospice at the time of death; and a downward trend in the percentage of patients dying in the hospital. Receipt of hospice services occurred less than a week before death in most cases, was closely tied to dialysis discontinuation — with the most marked increases in hospice use occurring among those who discontinued dialysis before death — and was associated with lower costs during the last days and weeks of life.

The percentage of Medicare beneficiaries with ESRD receiving an intensive procedure to prolong life during the last 90 days of life increased from 27% to 35% (Figure i.34). The percentage of Medicare beneficiaries with ESRD receiving hospice care at the time of death increased from 11% to 25% (Figure i.35). Most patients receive hospice services only after discontinuing dialysis treatments. From 2004-2012, hospice use prior to death increased from 59% to 80% among patients who discontinued dialysis treatments, but from only 5% to 7% among those who did not (not shown, see Figure 14.7 in Volume 2, Chapter 14).

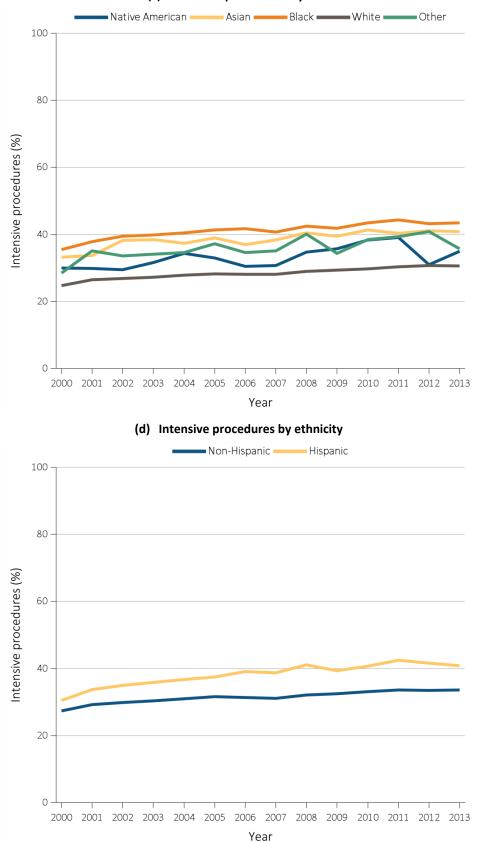
vol 2 Figure i.34 Intensive procedures during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2013



(a) Intensive procedures and mechanical ventilation by year, overall

Figure i.34 continued on next page.

vol 2 Figure i.34 Intensive procedures during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2013 (continued)



(c) Intensive procedures by race

Figure i.34 continued on next page.

vol 2 Figure i.34 Intensive procedures during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2013 (continued)

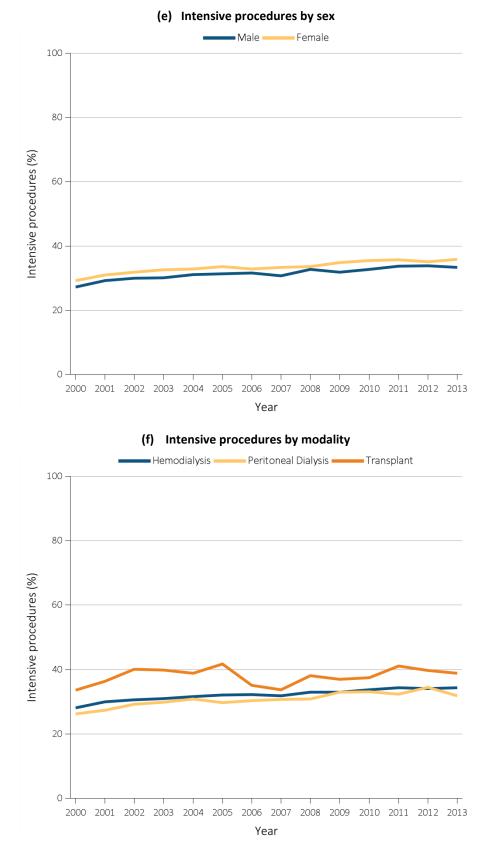
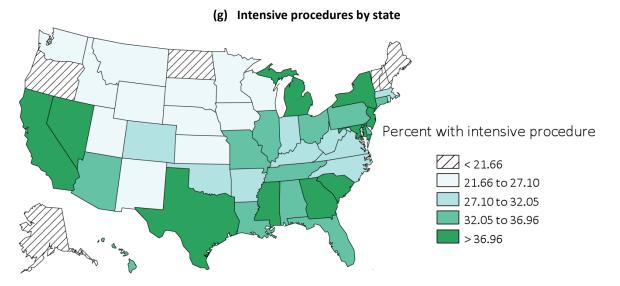


Figure i.34 continued on next page.

vol 2 Figure i.34 Intensive procedures during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2013 (continued)



Data Source: Special analyses, USRDS ESRD Database. Denominator population is all decedents with Medicare Parts A and B throughout the last 90 days of life. Intensive procedures were identified by ICD-9 procedure code search of Medicare Institutional claims from short- and long-stay hospitals. The yellow line in panel (a) denotes the percentage of patients who were intubated or received mechanical ventilation. This graphic is adapted from Figure 14.4.

vol 2 Figure i.35 Hospice utilization at the time of death among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, modality, and whether dialysis was discontinued, 2000-2013

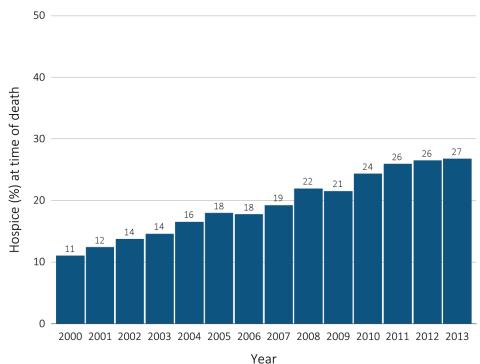
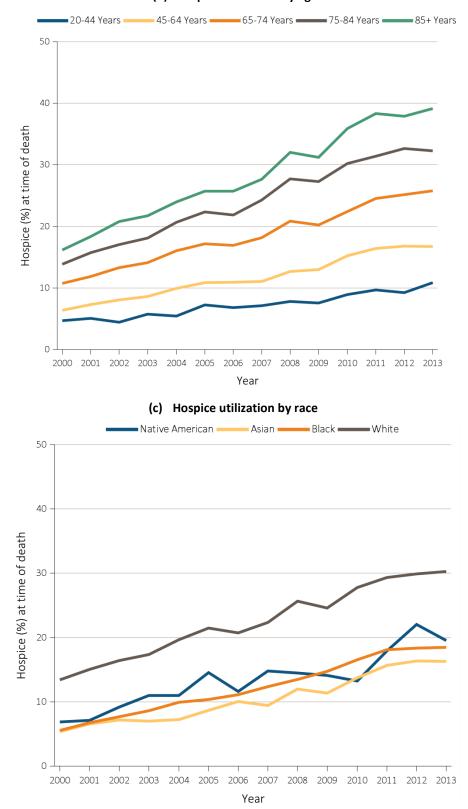




Figure i.35 continued on next page.

vol 2 Figure i.35 Hospice utilization at the time of death among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, modality, and whether dialysis was discontinued, 2000-2013 *(continued)*



(b) Hospice utilization by age

Figure i.35 continued on next page.

vol 2 Figure i.35 Hospice utilization at the time of death among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, modality, and whether dialysis was discontinued, 2000-2013 *(continued)*

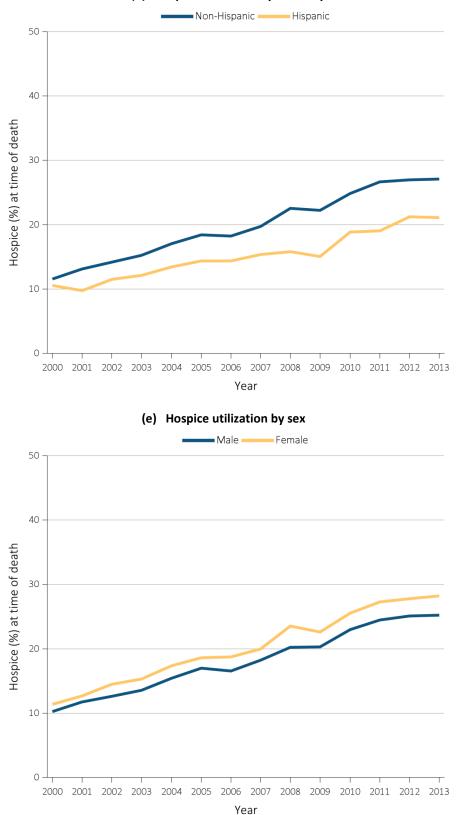
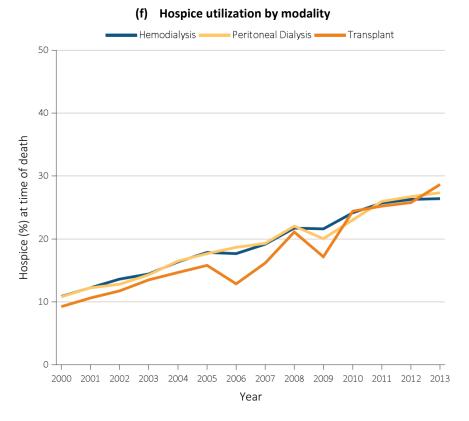




Figure i.35 continued on next page.

vol 2 Figure i.35 Hospice utilization at the time of death among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, modality, and whether dialysis was discontinued, 2000-2013 *(continued)*



(g) Hospice utilization by whether patients discontinued dialysis before death

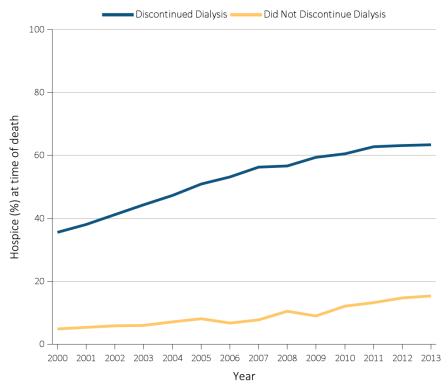
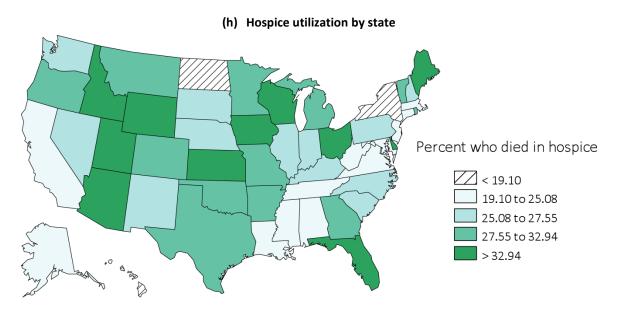


Figure i.35 continued on next page.

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vol 2 Figure i.35 Hospice utilization at the time of death among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, modality, and whether dialysis was discontinued, 2000-2013 *(continued)*



Data Source: Special Analyses, USRDS ESRD Database. Denominator population is all decedents with Medicare Parts A and B throughout the last 90 days of life. Receipt of hospice care at the time of death was defined as having a claim in the Hospice SAF on or after the date of death or Discharge Status from hospice=40, 41, or 42. This graphic is adapted from Figure 14.8.



Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities

Incidence

- The number of incident (newly reported) ESRD cases in 2014 was 120,688; the unadjusted (crude) incidence rate was 370 per million/year (Table 1.1). Since 2011, both the number of incident cases and the unadjusted incidence rate have begun rising again (Figure 1.1).
- The age-gender-race-ethnicity adjusted incidence rate of ESRD in the United States rose sharply in the 1990s, leveled off in the early 2000s, and has declined slightly since its peak in 2006 (Figure 1.1).
- In 2014, the adjusted ESRD incidence rate ratios for Blacks/African Americans, Native Americans, and Asians/Pacific Islanders, compared with Whites, were 3.1, 1.2, and 1.2, respectively; the rate ratio for Hispanics versus non-Hispanics was 1.3 (Figures 1.5 and 1.6).

Prevalence

- On December 31, 2014, there were 678,383 prevalent cases of ESRD; the unadjusted prevalence (crude proportion) was 2,067 per million in the U.S. population (Table 1.3).
- While the number of ESRD incident cases plateaued in 2010, the number of ESRD prevalent cases continues to rise by about 21,000 cases per year (Figure 1.11).
- Compared to Whites, ESRD prevalence in 2014 was about 3.7 times greater in Blacks, 1.4 times greater in Native Americans, and 1.5 times greater in Asians (Figure 1.14).

Treatment modalities

- In 2014, 87.9% of all incident cases began renal replacement therapy with hemodialysis, 9.3% started with peritoneal dialysis, and 2.6% received a pre-emptive kidney transplant (Figure 1.2).
- On December 31, 2014, 63.1% of all prevalent ESRD cases were receiving hemodialysis therapy, 6.9% were being treated with peritoneal dialysis, and 29.6% had a functioning kidney transplant (Figure 1.11). Among hemodialysis cases, 88.0% used in-center hemodialysis, and 1.8% used home hemodialysis (Figure 1.19).

Characteristics of incident ESRD cases

- Up to 38% of incident ESRD cases in 2014 received little or no pre-ESRD nephrology care (Table 1.7).
- Mean eGFR at initiation of dialysis in 2014 was 10.2 ml/min/1.73m². The percent of incident ESRD cases starting with eGFR at ≥10 ml/min/1.73 m² rose from 13% in 1996 to 43% in 2010, but had decreased to 39% in 2014 (Table 1.22).

Introduction

The focus of this chapter is the incidence and prevalence of end-stage renal disease (ESRD) in the U.S. population. It should be noted that the terms ESRD incidence and prevalence, as used throughout the ADR, refer to treated cases of ESRD, i.e., patients started *or* currently on renal replacement therapy (dialysis or transplantation); they do not refer exclusively to disease occurrence (biological constructs). Although ESRD is often equated with treatment (i.e., renal replacement therapy with dialysis or transplantation) and usually commences in Stage 5 CKD (GFR <15 ml/min), it should be noted

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that some patients with eGFR <15 may not receive (or choose to forego) dialysis or transplantation. In addition, there are a number of "ESRD treated" patients on renal replacement therapy who are initiated on dialysis at an eGFR greater than 15. In short, the definition of ESRD incidence and prevalence used throughout the USRDS is a treatment-based definition, not a purely physiological or biological construct. Thus, although the terms "incident ESRD" and "prevalent ESRD" are used throughout this chapter, they should always be interpreted as "treated ESRD."

Incidence refers to the occurrence or detection of new (incident) cases of a disease during a given period. In this chapter, ESRD incidence is expressed as a count (number of incident cases in one year) and as a rate (number of incident cases in one year, divided by person-years at risk, which is approximated by the mid-year census for the population in that year). Incidence rates are expressed as per million population per year. They are used to describe the occurrence or burden of new cases of ESRD in the population, to identify risk factors for ESRD in etiologic studies, and to evaluate the impact of interventions for reducing ESRD risk in primaryprevention studies.

Prevalence refers to the presence of existing (prevalent) cases of a disease at a point in time (point prevalence) or during a specific period (period prevalence). In this chapter, ESRD (point) prevalence is expressed as a count (number of prevalent cases) and as a proportion (number of prevalent cases, divided by the size of the population from which those cases were identified). ESRD prevalences at the end of each year are expressed per million population. It should be noted that ESRD prevalence depends on both the incidence rate of ESRD and the duration of the disease from the start of renal replacement therapy to death.

Both incidence rates and prevalences in this chapter are presented without adjustment for other factors (i.e., crude measures) and with adjustment for age, gender, and race by using a method known as "standardization." This method involves stratification of the population by those three variables and calculation of a weighted average of stratum-specific rates or prevalences, where the weights are the numbers of persons in strata of a "standard population," which, since the 2014 ADR, has been the U.S. population in 2011. Each standardized (adjusted) incidence rate or prevalence for a specific group or year is interpreted as the expected (crude) rate or prevalence if that group or year had exhibited the agegender-race distribution of the standard population. Since we are not adjusting for other major ESRD risk factors such as diabetes, hypertension, or cardiovascular disease, interpreting comparisons of incidence rates or prevalences between groups or years should be done with caution.

PRIMARY CAUSE OF ESRD: A CAUTIONARY NOTE

The "primary cause of renal failure," as assessed by individual physicians and reported on the CMS 2728 form, has been used for many years in nephrology to compare populations and assess temporal trends. In the ADR, it allows us to estimate the ESRD incidence rate and prevalence for different subtypes of chronic kidney disease, i.e., those with the primary cause listed as diabetes, hypertension, glomerulonephritis, or cystic kidney disease. It should be noted, however, that this approach is not the same as stratifying on comorbidity status. For example, in this chapter we are not estimating adjusted incidence rates of ESRD among diabetics and non-diabetics because we do not have data on laboratory-based diabetes status in the total U.S. population by strata of age, gender, and race. In Reference Table A.11, however, incidence rates of ESRD are estimated for self-reported diabetics in the U.S. population. Those estimates should be interpreted with caution as many persons with diabetes either do not report their condition or are not aware that they have diabetes.

Another issue is that the reliability of clinicianassigned "primary-cause" of ESRD has not been well established. Because causation for some diagnoses cannot be definitively established on the basis of clinical judgment or testing, and because many patients arrive at ESRD without benefit of prior nephrology care, establishing the validity of these etiologic subtypes of ESRD remains a challenge. In diabetics with CKD, for example, kidney biopsies are rarely performed. Moreover, though authorities such as <u>KDIGO</u> provide guidance for assigning a diagnosis of diabetic CKD (diabetes as the primary cause), it is likely in reality that this judgment is quite variable among nephrologists completing the CMS 2728 form.

Methods

This chapter uses data from the Centers for Medicare & Medicaid Services (CMS). Findings were primarily drawn from special analyses based on the USRDS ESRD Database. See the section on <u>Chapter 1</u> in the *ESRD Analytical Methods* chapter for a more detailed description of the analytical methods used to generate the study cohorts, figures, and tables in this chapter.

Incidence of ESRD: Counts, Rates, and Trends

OVERALL INCIDENCE COUNTS AND RATE

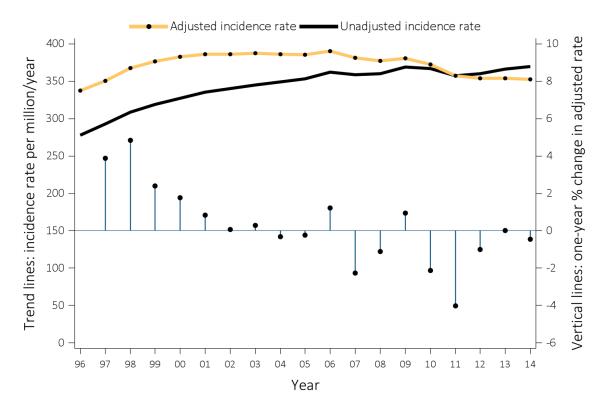
The number of incident (newly reported) ESRD cases in 2014 was 120,688 (Table 1.1 and Figure 1.2). The unadjusted (crude) incidence rate in 2014 was 370 per million/year. After a year-by-year rise in the number of incident ESRD cases over two decades from 1980 through 2000, the increase leveled off between 2001 and 2012, but rose again in 2013 and 2014. Table 1.1 and Figure 1.1 provide the unadjusted and age-gender-raceadjusted incidence rates of ESRD each year from 1996 through 2014. While the unadjusted and adjusted rates are the same in 2011 because the standard population is the 2011 U.S. population, the trends for these two rates are different. The unadjusted ESRD incidence rate approximates the change in the incident count (the numerator of the unadjusted rate); it increased steadily from 1996 through 2006, then remained relatively stable until 2011, and has increased again since 2011. The implication of this trend is that the burden of kidney failure in the United States — with respect to the expected impact on health-care utilization and costs — continues to increase.

In contrast, the adjusted ESRD incidence rate increased from 1996 through 2000, leveled off through 2006, then declined slightly in most years through 2014 (the exceptions are 2009 and 2013; Table 1.1). The specific implication of this recent downward trend is more difficult to interpret, as suggested above, but it likely reflects improvements in the prevention of ESRD. Thus, even though the population is aging and the prevalence of obesity and diabetes are increasing, which probably accounts for the increasing number of incident ESRD cases and the increasing unadjusted incidence rate, the recent decline in the adjusted rate may reflect successful efforts to prevent or postpone kidney failure in the United States. vol 2 Table 1.1 Trends in annual number of ESRD incident cases, unadjusted and adjusted* incidence rates (per million/year) of ESRD, and annual percent change, in the U.S. population, 1996-2014

-	Incide	ent count	Unadjuste	d rate	Adjusted rate		
Year	No. cases	% Change from previous year	Unadjusted rate (per million/year)	% Change from previous year	Adjusted rate (per million/year)	% Change from previous year	
1996	77,018	n/a	278	n/a	328	n/a	
1997	82,116	6.6	293	5.3	343	4.4	
1998	87,353	6.4	308	5.3	360	4.8	
1999	91,431	4.7	319	3.4	368	2.4	
2000	94,662	3.5	327	2.5	374	1.5	
2001	98,005	3.5	336	2.6	380	1.8	
2002	100,233	2.3	340	1.3	381	0.1	
2003	102,770	2.5	345	1.5	382	0.3	
2004	104,560	1.7	349	1.2	382	-0.1	
2005	106,662	2.0	353	1.2	382	0.0	
2006	110,342	3.5	362	2.5	387	1.4	
2007	110,381	0.0	359	-0.9	379	-2.1	
2008	111,899	1.4	360	0.3	375	-1.0	
2009	115,508	3.2	369	2.5	379	1.1	
2010	115,920	0.4	367	-0.6	372	-2.0	
2011	113,796	-1.8	358	-2.5	358	-3.8	
2012	115,602	1.6	360	0.7	355	-0.8	
2013	118,119	2.2	366	1.7	355	0.2	
2014	120,688	2.2	370	1.1	354	-0.3	

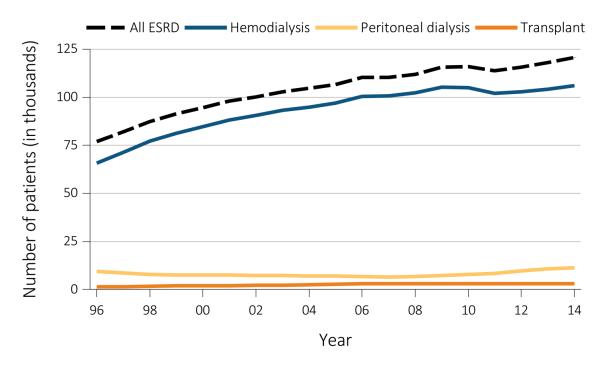
Data Source: Reference Tables A.1, A.2, A2.2 and special analyses, USRDS ESRD Database. *Adjusted for age, sex, and race. Abbreviations: ESRD, end-stage renal disease; n/a, not applicable.

vol 2 Figure 1.1 Trends in the unadjusted and adjusted* incidence rates (per million/year) of ESRD (trend lines; scale on right), and annual percent (%) change in the adjusted* incidence rate of ESRD (vertical lines; scale on left) in the U.S. population, 1996-2014



Data Source: Reference Table A.2.2 and special analyses, USRDS ESRD Database. *Adjusted for age, sex, race, and ethnicity. The standard population was the U.S. population in 2011. Abbreviation: ESRD, end-stage renal disease.

Among incident ESRD cases in 2014, 87.9% used hemodialysis, 9.3% used peritoneal dialysis, and 2.6% received a pre-emptive kidney transplant (Figure 1.2). The size of the incident hemodialysis population is now 25% larger than in 2000. The size of the incident peritoneal dialysis population is now 50% larger than in 2000. The size of the pre-emptive transplant population is now 63.2% larger than in 2000. By comparison, the U.S. population is also 13% larger than in 2000. vol 2 Figure 1.2 Trends in the annual number of ESRD incident cases (in thousands), by modality, in the U.S. population, 1996-2014



Data Source: Reference Table D1. Abbreviation: ESRD, end-stage renal disease.

INCIDENCE RATE: BY REGION

Variation in ESRD incidence rates among the 18 ESRD Networks remains substantial (Table 1.2). Adjusting for differences in age, sex, and race, the lowest rate was 250 per million/year in Network 1 (CT, MA, ME, NH, RI, VT), while the rate in Network 14 (TX) was 73% higher at 432 per million/year. Much of the high incidence in Texas and Southern California is due to the high numbers of Hispanics in these States. Hispanics account for 38% of the populations in Texas and California, compared to 18% nationwide. Renal replacement therapy (RRT) modality use by region, also presented in Table 1.2., is discussed in the section *Modality of Renal Replacement Therapy: Incident ESRD Cases* later in this chapter. vol 2 Table 1.2 Unadjusted and adjusted* incidence rates of ESRD (per million/year) and annual number of ESRD incident cases, by modality (hemodialysis, peritoneal dialysis, transplantation) and ESRD Network, in the U.S. population, 2014

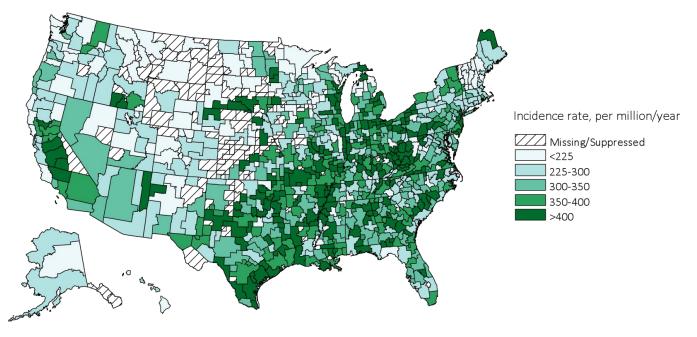
		Total ESRD			Hemodialysis		Peritoneal dialysis		Transplant	
Network	States** in Network	No. of cases	Adjusted incidence rate (per million/year)	Unadjusted incidence rate (per million/year)	No. of cases	% of network	No. of cases	% of network	No. of cases	% of network
14	ТХ	10585	432	391	9451	89.3	922	8.7	183	1.7
18	S. CA	9396	430	386	8396	89.4	857	9.1	129	1.4
3	NJ, PR	5451	395	429	3524	91.4	236	6.1	89	2.3
9	IN, KY, OH	9293	390	410	8213	88.4	835	9.0	202	2.2
10	IL	5217	384	403	4517	86.6	536	10.3	143	2.7
13	AR, LA, OK	4982	383	431	4402	88.4	488	9.8	90	1.8
8	AL, MS, TN	6567	364	455	5701	86.8	757	11.5	100	1.5
4	DE, PA	5368	352	390	4730	88.1	471	8.8	159	3.0
5	MD, DC, VA, WV	7045	343	418	6289	89.3	560	7.9	177	2.5
11	MI, MN, ND, SD, WI	7517	343	330	6624	88.1	561	7.5	310	4.1
17	N. CA, HI, GU, AS	5871	341	350	4732	83.7	781	13.8	135	2.4
12	IA, KS, MO, NE	4428	336	316	3768	85.1	522	11.8	131	3.0
2	NY	7352	334	370	6772	92.1	332	4.5	245	3.3
6	NC, SC, GA	10359	326	415	8970	86.6	1176	11.4	204	2.0
7	FL	7890	319	395	6994	88.6	723	9.2	150	1.9
15	AZ, CO, NV, NM, UT, WY	5682	297	275	4852	85.4	608	10.7	216	3.8
16	AK, ID, MT, OR, WA	3599	268	248	3075	85.4	410	11.4	109	3.0
1	CT, MA, ME, NH, RI, VT	3751	250	255	3238	86.3	340	9.1	172	4.6
	All networks	120688	354	370	104248	87.9	11115	9.4	2944	2.5

Data Source: Reference Table A.11 and special analyses, USRDS ESRD Database. *Adjusted for age, sex, and race. The standard population was the U.S. population in 2011. Listed from highest to lowest adjusted rate per million/year. **Includes 50 states, Washington, D.C. (DC), Puerto Rico (PR), Guam (GU), and American Samoa (AS). Northern and Southern California (CA) split into Networks 17 and 18. Abbreviations: Af Am, African American; ESRD, end-stage renal disease; Hisp, Hispanic; N Am, Native American.

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Across 677 Health Service Areas in 2014, the adjusted incidence rate of ESRD ranged from 83 per million/year to 4,172 per million/year (interquartile range: 264 to 406 per million/year) (Figure 1.3). Although specific geographic patterns are difficult to identify based on these HSA-level data without further geospatial analyses, the rates were generally highest in parts of the Ohio and Mississippi River valleys, the Southeast, Texas, and California, and lowest in parts of New England, the Northwest, and certain Upper Midwest and Rocky Mountain states.

vol 2 Figure 1.3 Map of the adjusted* incidence rate (per million/year) of ESRD, by Health Service Area, in the U.S. population, 2014

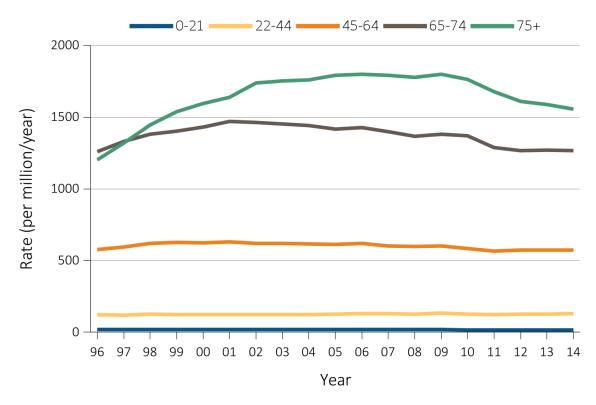


Data Source: Special analyses, USRDS ESRD Database. *Adjusted for age, sex, and race. The standard population was the U.S. population in 2011. Values for cells with 10 or fewer patients are suppressed. Abbreviation: ESRD, end-stage renal disease.

INCIDENCE RATE: BY AGE

Across age groups, adjusted ESRD incidence rates have been generally stable or fallen for a decade or more (Figure 1.4). Pronounced declines have been seen recently among those aged 65 and over: among ages 65-74, the ESRD incidence rate is the lowest since 1997; and among ages 75 and over, the rate is the lowest since 2000.



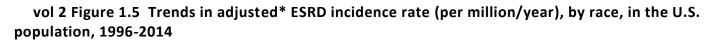


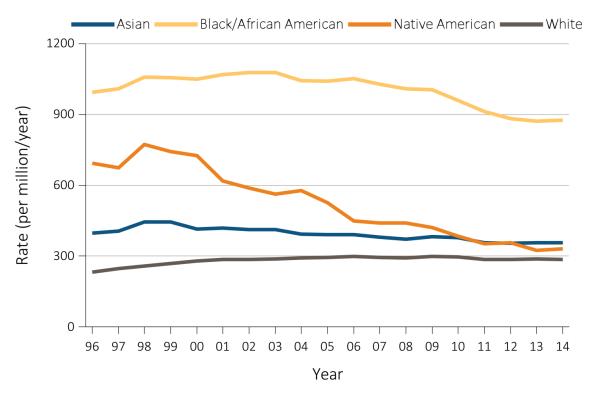
Data Source: Reference Table A.2.2 and special analyses, USRDS ESRD Database. *Adjusted for sex and race. The standard population was the U.S. population in 2011. Abbreviation: ESRD, end-stage renal disease.

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INCIDENCE RATE: BY RACE AND ETHNICITY

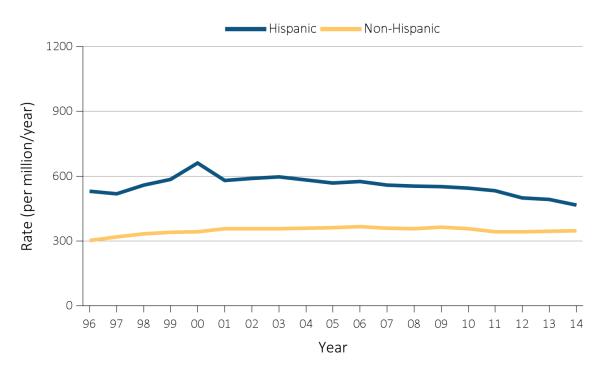
The adjusted ESRD incidence rates for Blacks/African Americans (hereafter, Blacks), Native Americans, and Asians have declined over the nearly 20-year period shown in Figure 1.5. The decline has been greatest (over 2-fold) among Native Americans. Over the same period, the rate initially rose among Whites but has been generally stable since around 2000. The ratio of adjusted incidence rates for Blacks versus Whites decreased from 3.8 in 2000 to 3.1 in 2014. Similarly, the ratio of incidence rates for Asians versus Whites decreased from 1.5 to 1.2 during the same period; and the ratio of incidence rates for Native Americans versus Whites decreased from 2.6 to 1.2.





Data Source: Reference Table A.2.2 and special analyses, USRDS ESRD Database. *Adjusted for age and sex. The standard population was the U.S. population in 2011. Abbreviations: Af Am, African American; ESRD, end-stage renal disease.

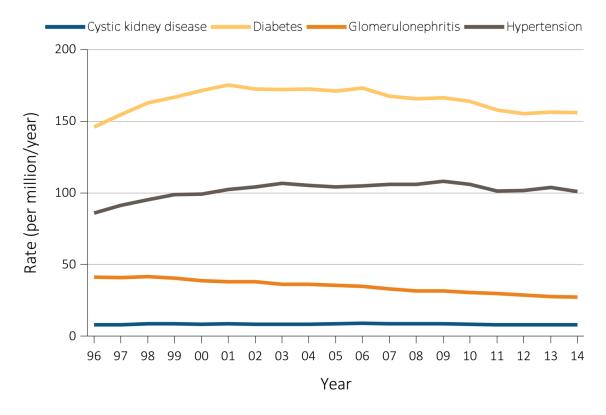
Among both Hispanic and non-Hispanic populations, the adjusted ESRD incidence rates have been stable or somewhat declining since 2001 (Figure 1.6). Although the absolute difference in adjusted rates between the two ethnic groups has declined since 2000, the ESRD incidence rate in 2014 remained nearly 35% higher among Hispanics than non-Hispanics. vol 2 Figure 1.6 Trends in adjusted* ESRD incidence rate (per million/year), by Hispanic ethnicity, in the U.S. population, 1996-2014



*Data Source: Reference Tables A.2.2. *Adjusted for age, sex, and race. The standard population was the U.S. population in 2011. Abbreviation: ESRD, end-stage renal disease.*

INCIDENCE RATE: BY PRIMARY CAUSE OF ESRD

The adjusted incidence rate of ESRD with diabetes listed as the primary cause plateaued in 2001 and has declined in most subsequent years, with the lowest rate in 2013 (Figure 1.7). The rate with ESRD due to hypertension plateaued in 2003 and has been stable since then. The rate due to glomerulonephritis has fallen steadily since the 1990s, while the rate due to cystic disease has remained stable. Whether these trends reflect a true changing etiology of ESRD or a changing labeling of primary cause is not clear (see the section titled *Primary cause of ESRD: A cautionary note* in this chapter). vol 2 Figure 1.7 Trends in adjusted* ESRD incidence rate (per million/year), by primary cause of ESRD, in the U.S. population, 1996-2014



Data Source: Reference Table A.2(2) and special analyses, USRDS ESRD Database. *Adjusted for age, sex and race. The standard population was the U.S. population in 2011. Abbreviation: ESRD, end-stage renal disease.

DIABETES AS PRIMARY CAUSE OF ESRD, BY PATIENT CHARACTERISTICS

While the gender-race adjusted incidence rate of ESRD is highest for those aged 75 and older (Figure 1.4), the sex-adjusted rate of ESRD due to diabetes is highest for ages 65-74 in Whites, Blacks, and Hispanics (Figures 1.8.a-c), presumably because type 2 diabetes tends to occur before age 75 (contrast with Figure 1.9). The adjusted incidence rate of ESRD due to diabetes is, as expected, substantially higher for ages 65 and older than for younger age groups. Rates have been generally stable or slightly increased among individuals aged 20-44 years, but have declined in older age groups.

Sex-adjusted incidence rates of ESRD due to diabetes were several-fold higher in Blacks within each age category compared to Whites, though they are generally declining more quickly in Blacks than in Whites. Diabetes is 60% more common among Blacks than among Whites

(http://www.cdc.gov/diabetes/statistics/prev/national /figbyrace.htm). These racial differences are generally similar to those seen for overall ESRD incidence rates. Among Hispanics, the incidence rates of ESRD due to diabetes compared to Whites are similar for ages 22-44 years, but much higher for ages 44 and over. Across age categories, incidence rates in Hispanics are lower than in Blacks. vol 2 Figure 1.8 Trends in the sex-adjusted incidence rate (per million/year) of ESRD due to diabetes as the primary cause, by age and race (a & b), and by age and ethnicity (c), in the U.S. population, 1996-2014

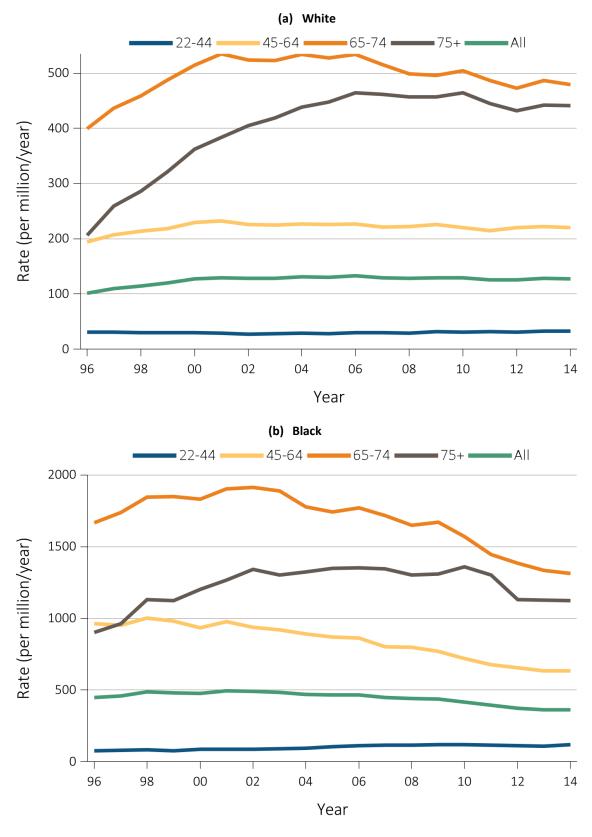
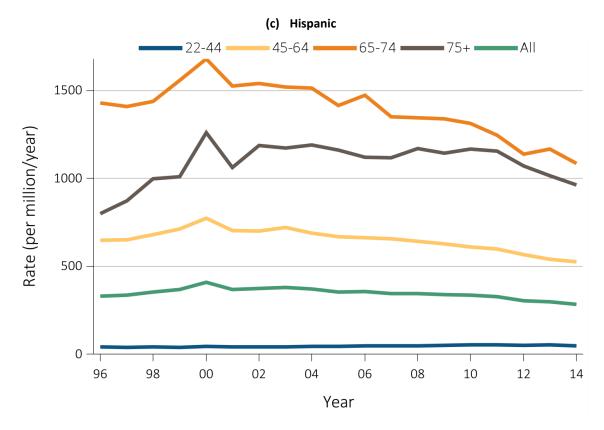


Figure 1.8 continued on next page.

vol 2 Figure 1.8 Trends in the sex-adjusted incidence rate (per million/year) of ESRD due to diabetes as the primary cause, by age and race (a & b), and by age and ethnicity (c), in the U.S. population, 1996-2014 (continued)



Data Source: Special analyses, USRDS ESRD Database. *Adjusted for sex. The standard population was the U.S. population in 2011. Abbreviations: ESRD, end-stage renal disease.

HYPERTENSION AS PRIMARY CAUSE OF ESRD, BY PATIENT CHARACTERISTICS

The sex-adjusted incidence rate of ESRD with hypertension listed as the primary cause has remained higher among older age categories (Figures 1.9.a-c). In contrast to incidence rates of ESRD with diabetes listed as the primary cause, these rates remain substantially higher at age 75 and older than at 65-74 years of age.

Within each age category, the incidence rate of ESRD with hypertension listed as the primary cause is

dramatically higher among Blacks than among Whites or Hispanics. Compared to Whites in each age category, incident rates among Blacks in 2014 were 8.9-fold higher at ages 22-44, 6.7-fold higher at ages 45-64, 4.4-fold higher at ages 65-74, and 2.7-fold higher at age 75 and over. Part of the higher rates of hypertensive ESRD among Blacks could be due to ascertainment bias among nephrologists. Although hypertension is almost universal among all ESRD patients, it is generally believed that nephrologists are more likely to ascribe it as the causative factor for Blacks than for Whites. vol 2 Figure 1.9 Trends in the sex-adjusted incidence rate (per million/year) of ESRD due to hypertension as the primary cause, by (a & b) age and race, and by (c) age and ethnicity, in the U.S. population, 1996-2014

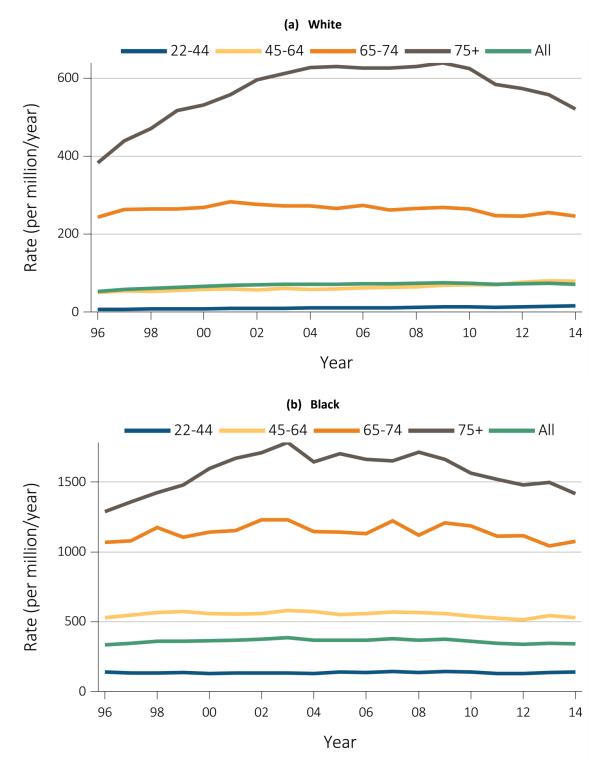
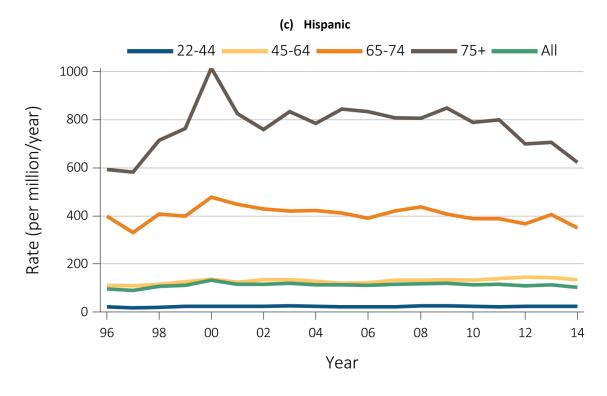


Figure 1.9 continued on next page.

vol 2 Figure 1.9 Trends in the sex-adjusted incidence rate (per million/year) of ESRD due to hypertension as the primary cause, by (a & b) age and race, and by (c) age and ethnicity, in the U.S. population, 1996-2014 (continued)



Data Source: Special analyses, USRDS ESRD Database. *Adjusted for sex. The standard population was the U.S. population in 2011. Abbreviation: ESRD, end-stage renal disease.

Prevalence of ESRD: Counts, Prevalence, and Trends

OVERALL PREVALENCE

On December 31, 2014, there were 678,383 prevalent cases of ESRD in the United States, an increase of 3.5% over 2013 and an increase of 74% since 2000 (Table 1.3 and Figure 1.11). The unadjusted ESRD prevalence reached 2,067 per million (~0.21%), an increase of 2.6% over 2013 and an increase of 54.1% since 2000 (Table 1.3).

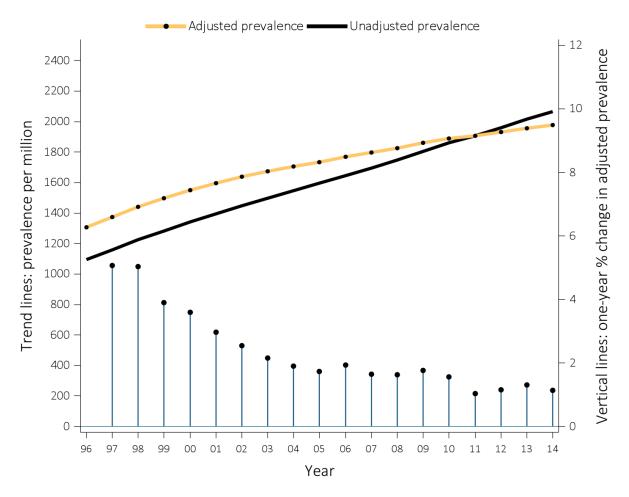
As shown in Table 1.3 and Figure 1.10, both unadjusted (crude) and adjusted prevalence of ESRD increased steadily between 1996 and 2014. In general, however, the absolute and proportional yearly changes were a little greater for the unadjusted prevalence than for the adjusted prevalence, especially after 2000 (Table 1.3). The increasing prevalent count and unadjusted prevalence reflect the need for more resources to manage ESRD in the U.S. population as demonstrated in *Chapter 11: Medicare Expenditures for* Persons With ESRD. Because prevalence reflects both the incidence and course of the disease (see explanation in the Introduction), these ESRD prevalence trends reflect not only the increasing number of incident cases (Table 1.1), but also longer survival among ESRD patients, which is encouraging news regarding efforts to manage kidney failure in the United States. This interpretation is demonstrated by the fact that the adjusted ESRD prevalence has continued to increase while the adjusted ESRD incidence rate has declined in recent years (Table 1.1).

vol 2 Table 1.3 Trends in annual number of ESRD prevalent cases, unadjusted and adjusted* prevalence (per million) of ESRD, and annual percent change, in the U.S. population, 1996-2014

	Prevale	ent count	Unadjusted	prevalence	Adjusted prevalence		
Year	No. cases	% Change from previous year	Unadjusted (per million)	% Change from previous year	Adjusted (per million)	% Change from previous year	
1996	303,311	n/a	1,095	n/a	1,283	n/a	
1997	326,067	7.5	1,159	5.8	1,348	5.1	
1998	348,578	6.9	1,225	5.7	1,415	5.0	
1999	369,375	6.0	1,283	4.8	1,471	4.0	
2000	390,158	5.6	1,341	4.5	1,524	3.6	
2001	409,963	5.1	1,396	4.1	1,572	3.2	
2002	429,172	4.7	1,449	3.8	1,614	2.7	
2003	447,667	4.3	1,499	3.4	1,651	2.3	
2004	466,013	4.1	1,547	3.2	1,685	2.1	
2005	484,935	4.1	1,595	3.1	1,717	1.9	
2006	505,715	4.3	1,647	3.3	1,753	2.1	
2007	525,866	4.0	1,696	3.0	1,785	1.8	
2008	546,918	4.0	1,748	3.0	1,817	1.8	
2009	569,547	4.1	1,805	3.3	1,852	1.9	
2010	591,776	3.9	1,860	3.1	1,884	1.8	
2011	611,456	3.3	1,908	2.6	1,908	1.2	
2012	632,806	3.5	1,960	2.7	1,934	1.4	
2013	655,435	3.6	2,015	2.8	1,964	1.5	
2014	678,383	3.5	2,067	2.6	1,990	1.3	

Data Source: Reference Tables B.1, B.2, B2(2) and special analyses, USRDS ESRD Database. *Adjusted for age, sex, and race. Abbreviations: ESRD, end-stage renal disease; n/a, not applicable.

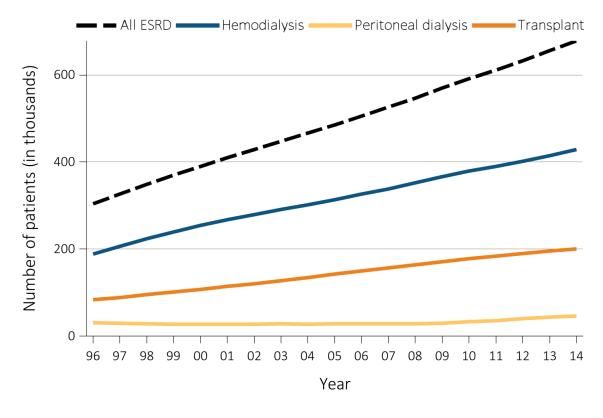
vol 2 Figure 1.10 Trends in the unadjusted and adjusted* ESRD prevalence (per million) (trend lines; scale on left), and annual percent (%) change in adjusted* prevalence of ESRD (vertical lines; scale on right), in the U.S. population, 1996-2014



Data Source: Reference Table B.2(2) and special analyses, USRDS ESRD Database. *Adjusted for age, sex, race, and ethnicity. The standard population was the U.S. population in 2011. Abbreviation: ESRD, end-stage renal disease.

Among prevalent ESRD cases on December 31, 2014, 63.1% used hemodialysis, 6.9% used peritoneal dialysis, and 29.6% had a functioning kidney transplant (Figure 1.11). The size of the prevalent hemodialysis population is now 69% larger than in 2000 (Figure 1.11). The size of the prevalent peritoneal dialysis population is now 71% larger than in 2000. The size of the transplant population is now 87% larger than in 2000.

vol 2 Figure 1.11 Trends in the number of ESRD prevalent cases (in thousands) by modality, in the U.S. population, 1996-2014



Data Source: Reference Table D.1. Abbreviation: ESRD, end-stage renal disease.

PREVALENCE: BY REGION

Among the 18 ESRD Networks, the age-sex-raceadjusted prevalence of ESRD ranged from 2,339 per million in Network 8 (AL, MS, TN) to 1,419 per million in Network 16 (AK, ID, MT, OR, WA) (Table 1.4). RRT modality use by region, also presented in Table 1.4., is discussed in the *Modality of Renal Replacement Therapy: Incident ESRD Cases* section later in this chapter.

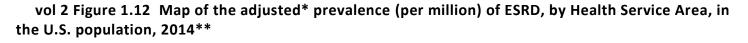
vol 2 Table 1.4 Unadjusted and adjusted* prevalence of ESRD (per million) and annual number of ESRD prevalent cases, by modality (hemodialysis, peritoneal dialysis, and transplantation) and ESRD Network, in the U.S. population, 2014

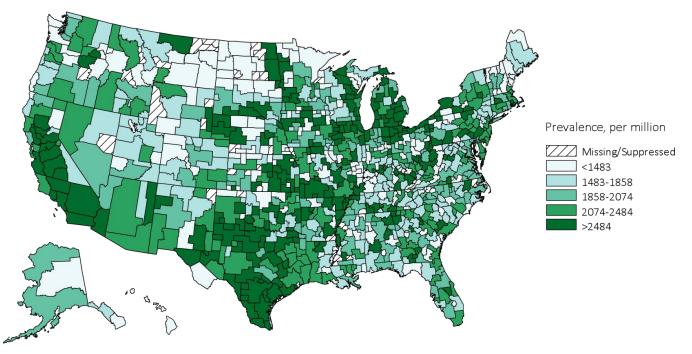
		Total ESRD			Hemodialysis		Peritoneal dialysis		Transplant	
Network	States** in network	No. of cases	Adjusted prevalence (per million)	Unadjusted prevalence (per million)	No. of cases	% of network	No. of cases	% of network	No. of cases	% of network
8	AL, MS, TN	35140	2339	2428	23808	67.8	2802	8.0	8410	23.9
6	NC, SC, GA	59380	2260	2365	40533	68.3	4917	8.3	13774	23.2
5	MD, DC, VA, WV	39245	2231	2317	25003	63.7	2400	6.1	11700	29.8
10	IL	30102	2228	2317	18301	60.8	1917	6.4	9758	32.4
18	S. CA	55698	2177	2274	37558	67.4	4343	7.8	13661	24.5
14	ТХ	59670	2116	2187	41281	69.2	3926	6.6	14208	23.8
17	N. CA, HI, GU, AS	36668	2112	2195	21879	61.3	3077	8.6	10650	29.8
3	NJ, PR	27205	2103	2184	12712	64.2	877	4.4	6163	31.1
13	AR, LA, OK	24766	2075	2141	16609	67.1	2045	8.3	6015	24.3
2	NY	42624	2047	2119	28040	65.8	1528	3.6	12982	30.5
4	DE, PA	29182	2039	2116	17832	61.1	1843	6.3	9421	32.3
9	IN, KY, OH	46204	1962	2032	28985	62.7	3401	7.4	13561	29.4
7	FL	40258	1926	1997	25976	64.5	2914	7.2	11211	27.8
11	MI, MN, ND, SD, WI	44363	1867	1941	24774	55.8	2434	5.5	17025	38.4
12	IA, KS, MO, NE	24584	1695	1750	13625	55.4	1980	8.1	8893	36.2
15	AZ, CO, NV, NM, UT, WY	34342	1581	1653	20092	58.5	2522	7.3	11596	33.8
1	CT, MA, ME, NH, RI, VT	23127	1498	1560	12563	54.3	1394	6.0	9116	39.4
16	AK, ID, MT, OR, WA	21512	1419	1474	11648	54.1	1801	8.4	7975	37.1
	All networks	678383	1990	2067	421219	63.3	46121	6.9	196119	29.5

Data Source: Special analyses, USRDS ESRD Database. *Adjusted for age, sex, and race. The standard population was the U.S. population in 2011. Listed from lowest to highest prevalence per million. **Includes 50 states, Washington, D.C. (DC), Puerto Rico (PR), Guam (GU), and American Samoa (AS). Northern and Southern California (CA) split into Networks 17 and 18. Abbreviations: Af Am, African American; ESRD, end-stage renal disease; Hisp, Hispanic; N Am, Native American.

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Across 786 Health Service Areas, the adjusted prevalence of ESRD in 2014 ranged from 339 per million to 7,134 per million (interquartile range: 1,545 to 2,501 per million) (Figure 1.12). Although specific geographic patterns are difficult to identify without further geospatial analyses, examples of high ESRD prevalence in 2014 include parts of the Ohio and Mississippi River valleys, Michigan, northern Illinois and parts of Wisconsin along Lake Michigan, Texas, and California. Lower prevalence was observed in northern New England, the Northwest, and certain Upper Midwest and Rocky Mountain regions. These patterns are roughly similar to patterns of ESRD incidence shown earlier in this chapter in Figure 1.3.

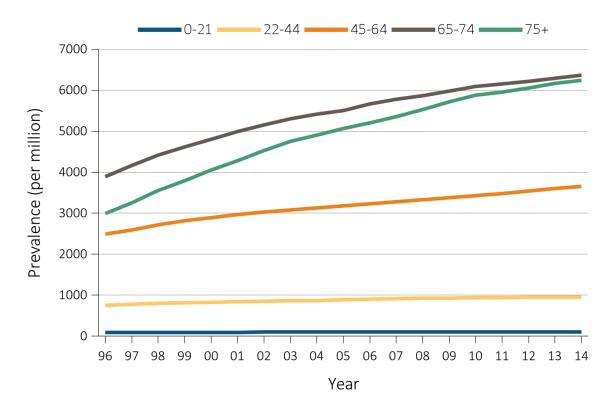




Data Source: Special analyses, USRDS ESRD Database. *Adjusted for age, sex, and race. The standard population was the U.S. population in 2011. **Three Health Service Areas were suppressed because the ratio of unadjusted rate to adjusted rate or adjusted rate to unadjusted rate was greater than 3. Values for cells with 10 or fewer patients are suppressed. Abbreviation: ESRD, end-stage renal disease.

PREVALENCE: BY AGE

Across age groups, adjusted ESRD prevalence has risen over time, with steeper increases among older age groups (Figure 1.13). These increases over time contrast with the ongoing declines in adjusted ESRD incidence rate across age groups (Figure 1.4), and thus are likely due to longer survival among ESRD patients as well as the fact that patients who are in one age group at incidence necessarily age into older age groups. Among the age groups, ESRD prevalence per million is highest at 65-74 years. Although those aged 75 and older have the highest ESRD incidence rate, lower prevalence per million is presumably due to higher mortality among ESRD patients in this age group. vol 2 Figure 1.13 Trends in the adjusted* prevalence (per million) of ESRD, by age group, in the U.S. population, 1996-2014



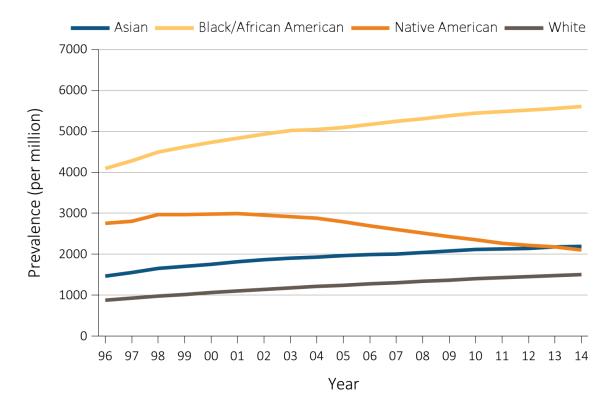
Data Source: Reference Table B.2(2) and special analyses, USRDS ESRD Database. *Point prevalence on December 31 of each year. Adjusted for sex and race. The standard population was the U.S. population in 2011. Abbreviations: ESRD, end-stage renal disease.

PREVALENCE: BY RACE AND ETHNICITY

The adjusted prevalence of ESRD continues to rise among Whites, Blacks, and Asian Americans (Figure 1.14). However, the remarkable decline in incidence rates among Native Americans has resulted in a decline in the prevalence of ESRD in this population over the past decade, from a peak of 2,991 in 2001 to 2,101 in 2014, a 50% decline. In 2014, the prevalence per million was 5,605 among Blacks, 2,101 among Native Americans, 2,198 among Asians, and 1,507 among Whites (Figure 1.14). The prevalence of ESRD remains much higher in Blacks than in other racial groups, at nearly 2.6-fold higher than Native Americans and Asians, and nearly 3.7-fold higher than Whites.

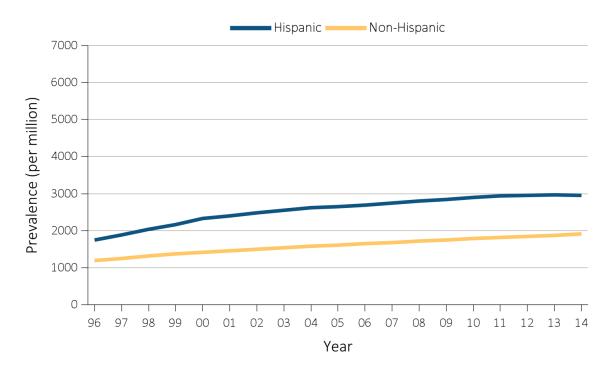
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vol 2 Figure 1.14 Trends in adjusted* prevalence (per million) of ESRD, by race, in the U.S. population, 1996-2014



Data Source: Reference Table B.2(2) and special analyses, USRDS ESRD Database. *Point prevalence on December 31 of each year. Adjusted for age and sex. The standard population was the U.S. population in 2011. Abbreviations: Af Am, African American; ESRD, end-stage renal disease.

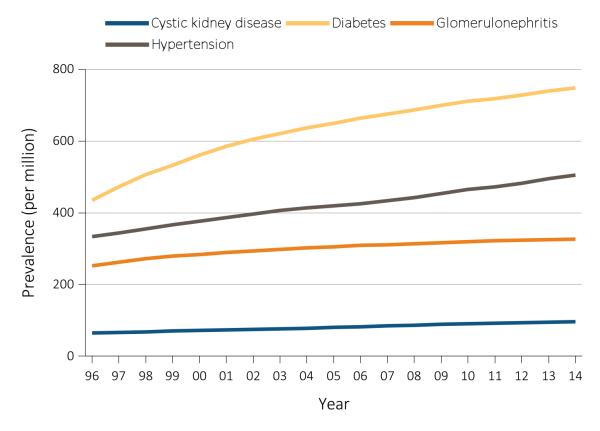
The adjusted ESRD prevalence has continued to rise for both non-Hispanics and Hispanics, though it may be plateauing among Hispanics since 2011 (Figure 1.15). In 2014, the adjusted prevalence was 1,912 per million among non-Hispanics and nearly 58% higher, at 2,958 per million, among Hispanics. vol 2 Figure 1.15 Trends in the adjusted* prevalence (per million) of ESRD, by Hispanic ethnicity, in the U.S. population, 1996-2014



Data Source: Reference Tables B.1, B.2(2). *Point prevalence on December 31 of each year. Adjusted for age, sex, and race. The standard population was the U.S. population in 2011. Abbreviation: ESRD, end-stage renal disease.

PREVALENCE: BY PRIMARY CAUSE OF ESRD

The prevalence of ESRD with diabetes, hypertension, glomerulonephritis, or cystic kidney disease listed as the primary cause has continued to rise since 1996 (Figure 1.16), despite the recent stabilization of incidence rates. For diabetes as the primary cause, the increase in adjusted prevalence has been more gradual over the last 12 years than it had been previously. vol 2 Figure 1.16 Trends in adjusted* prevalence (per million) of ESRD, by primary cause of ESRD, in the U.S. population, 1996-2014



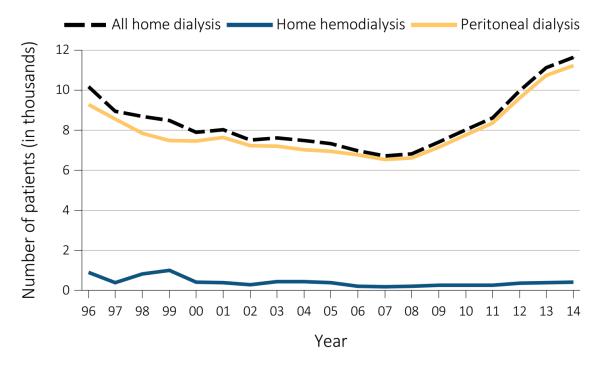
Data Source: Reference Table B.2(2) and special analyses, USRDS ESRD Database. *Point prevalence on December 31 of each year. Adjusted for age, sex, and race. The standard population was the U.S. population in 2011. Abbreviation: ESRD, end-stage renal disease.

Modality of Renal Replacement Therapy: Incident ESRD Cases

TRENDS IN INCIDENT COUNTS: BY RRT MODALITY

Use of home dialysis among incident ESRD patients has increased notably in recent years (Figure 1.17). Home dialysis use overall in 2014 was 73% higher

than at its nadir in 2007. Use of peritoneal dialysis and home hemodialysis in 2014 were 72% and 120% higher, respectively, than in 2007. Despite the large relative rise in home hemodialysis, its overall use among incident ESRD patients is low, as only 3.4% of home dialysis patients were treated with hemodialysis in 2014. Peritoneal dialysis remains the dominant form of home dialysis. vol 2 Figure 1.17 Trends in the number of incident ESRD cases (in thousands) using home dialysis, by type of therapy, in the U.S. population, 1996-2014



Data Source: Reference Table D.1. Abbreviations: ESRD, end-stage renal disease.

RRT MODALITY USE: BY PATIENT CHARACTERISTICS

Use of peritoneal dialysis and pre-emptive kidney transplants were markedly more common in younger groups and were somewhat less common among Black or Hispanic patients (Table 1.5). Use of peritoneal dialysis and pre-emptive kidney transplants were more common among patients with glomerular or cystic kidney disease, versus diabetes or hypertension, as the primary cause of ESRD. This difference may be attributed in part to age, as both glomerular and cystic kidney disease are more common in younger patients.

	Total	HD			PD)	Tr	ans	plant
	Total	n	%	_	n	%	n		%
Age									
0-21	1,413	722	51.1		420	29.7	27	1	19.2
22-44	13,630	10,926	80.2		1,976	14.5	72	8	5.3
45-64	46,674	40,437	86.6		4,742	10.2	1,4	95	3.2
65-74	30,945	27,887	90.1		2,506	8.1	55	2	1.8
75+	27,773	26,125	94.1		1,592	5.7	56	5	0.2
Sex									
Male	69,968	61,612	88.1		6,580	9.4	1,7	76	2.5
Female	50,467	44,485	88.1		4,656	9.2	1,3	26	2.6
Race									
White	80,560	70,312	87.3		7,861	9.8	2,3	87	3.0
Black/African American	31,894	29,115	91.3		2,484	7.8	29	5	0.9
Asian	6,067	5,087	83.8		753	12.4	22	7	3.7
Native American	1,097	997	90.9		67	6.1	33	3	3.0
Other/Unknown	817	586	71.7		71	8.7	16	0	19.0
Ethnicity									
Hispanic	17,459	15,614	89.4		1,566	9.0	27	9	1.6
Non-Hispanic	102,976	90,483	87.9		9,670	9.4	2,8	23	2.7
Primary Cause of ESRD									
Diabetes	53,525	48,311	90.3		4,774	8.9	44	0	0.8
Hypertension	34,087	30,857	90.5		2,950	8.7	28	0	0.8
Glomerulonephritis	9,038	6,991	77.4		1,495	16.5	55	2	6.1
Cystic Kidney	2,543	1,536	60.4		537	21.1	47	0	18.5
Other/Unknown	21,242	18,402	86.6		1,480	7.0	1,3	50	6.4
Total	120,435	106,097	88.1	_	11,236	9.3	3,1)2	2.6

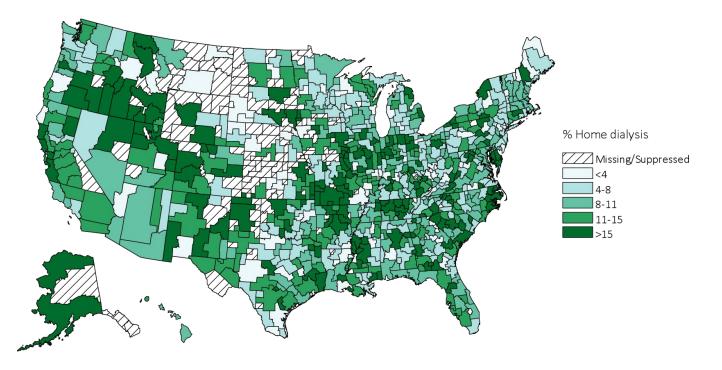
vol 2 Table 1.5 Number and percentage of incident cases of hemodialysis, peritoneal dialysis, and transplantation by age, sex, race, ethnicity, and primary cause of ESRD, in the U.S. population, 2014

Data Source: Special analyses, USRDS ESRD Database. The numbers in this table exclude "Other PD" and "Uncertain Dialysis." Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis.

RRT MODALITY USE: BY REGION

Among incident ESRD cases, hemodialysis was the predominant modality in all networks, ranging from 85.1% in Network 12 (IA, KS, MO, NE) to 92.1% in Network 2 (NY) (Table 1.2). Use of peritoneal dialyses varied over 2-fold, from to 4.5% in Network 2 (Table 1.2) to 13.8% in Network 17 (Table 1.2). Pre-emptive kidney transplantation remained an uncommon initial RRT modality (2.5% overall), although its use ranged over 3-fold from 1.4% in Network 18 to 4.6% in Network 1.

The proportion of incident dialysis cases using home dialysis varied substantially across 677 Health Services Areas, ranging from o% to 55% (interquartile range: 6.5% to 14.3%) (Figure 1.18). Geographic patterns are not apparent, supporting the likelihood that differences in home dialysis use are largely driven by differences among individual dialysis centers or groups of centers, rather than by large-scale regional effects. vol 2 Figure 1.18 Map of the percentage of incident dialysis cases using home dialysis (peritoneal dialysis or home hemodialysis), by Health Service Area, 2014



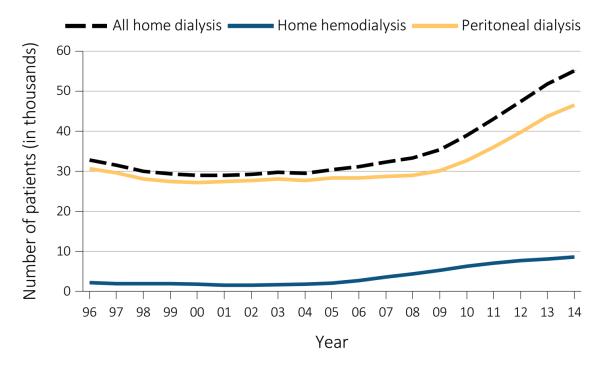
Data Source: Special analyses, USRDS ESRD Database. Values for cells with 10 or fewer patients are suppressed.

Modality of Renal Replacement Therapy: Prevalent ESRD Cases

TRENDS IN PREVALENT COUNTS: BY RRT MODALITY

The use of home dialysis (peritoneal dialysis or home hemodialysis) among prevalent ESRD cases has

increased appreciably in recent years (Figure 1.19), mirroring patterns shown for incident dialysis cases (Figure 1.17). Home dialysis accounted for 11.6% of all prevalent dialysis patients in 2014, up from a low of 8.7% in 2008. Among home dialysis cases, the proportion using hemodialysis was over 2.5-fold higher in 2014 (15.6%) than in 2000 (6.2%). vol 2 Figure 1.19 Trends in number of prevalent ESRD cases (in thousands) using home dialysis, by type of therapy, in the United States, 1996-2014



Data Source: Reference Table D.1. December 31 prevalent ESRD patients. Peritoneal dialysis consists of CAPD and CCPD only. Abbreviations: CAPD, continuous ambulatory peritoneal dialysis; CCPD, continuous cycler peritoneal dialysis; ESRD, end-stage renal disease.

RRT MODALITY USE: BY PATIENT CHARACTERISTICS

Distributions of modality use by patient characteristics generally mirror those for incident patients. Uses of peritoneal dialysis and kidney transplant were more common among patients who were younger, White, non-Hispanic, and with glomerular disease or cystic kidney disease as the primary cause of ESRD (Table 1.6).

	Tatal	HD		PD)	Transp	lant
	Total	n	%	n	%	n	%
Age							
0-21	9,783	1,783	18.2	1,131	11.6	6,869	70.2
22-44	101,298	50,922	50.3	8,797	8.7	41,579	41.0
45-64	298,786	177,690	59.5	20,609	6.9	100,487	33.6
65-74	157,089	106,869	68.0	9,943	6.3	40,277	25.6
75+	109,043	91,294	83.7	6,054	5.6	11,695	10.7
Sex							
Male	389,372	243,883	62.6	25,658	6.6	119,831	30.8
Female	286,562	184,637	64.4	20,873	7.3	81,052	28.3
Race							
White	414,472	240,919	58.1	30,680	7.4	142,873	34.5
Black/African American	208,419	156,716	75.2	11,697	5.6	40,006	19.2
Asian	38,644	23,463	60.7	3,472	9.0	11,709	30.3
Native American	7,325	5,099	69.6	432	5.9	1,794	24.5
Other/Unknown	7,139	2,361	33.1	253	3.5	4,525	63.4
Ethnicity							
Hispanic	115,330	78,135	67.7	7,190	6.2	30,005	26.0
Non-Hispanic	560,669	350,423	62.5	39,344	7.0	170,902	30.5
Primary Cause of ESRD							
Diabetes	255,896	193,487	75.6	17,078	6.7	45,331	17.7
Hypertension	170,487	125,422	73.6	12,377	7.3	32,688	19.2
Glomerulonephritis	108,406	44,073	40.7	8,440	7.8	55,893	51.6
Cystic Kidney	31,794	9,850	31.0	2,064	6.5	19,880	62.5
Other/Unknown	109,416	55,726	50.9	6,575	6.0	47,115	43.2
Total	675,999	428,558	63.4	46,534	6.9	200,907	29.7

vol 2 Table 1.6 Percentage of prevalent cases of in-center hemodialysis, home hemodialysis, peritoneal dialysis, and transplant by age, sex, race, ethnicity, and primary ESRD diagnosis, in the United States, 2014

Data Source: Special analyses, USRDS ESRD Database. The numbers in this table exclude "Other PD" and "Uncertain Dialysis." Abbreviation: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis.

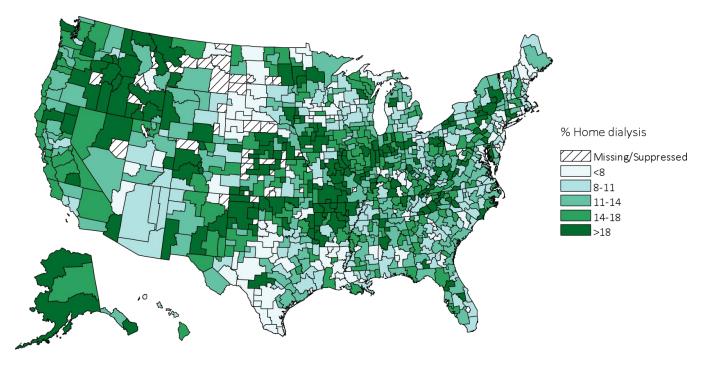
RRT MODALITY USE: BY REGION

As observed for incident dialysis cases, RRT modality use among prevalent ESRD cases varied substantially by region. Use ranged between networks from 54% to 69% for hemodialysis, from 4% to 9% for peritoneal dialysis, and from 23% to 39% for transplantation (Table 1.4). The percent on hemodialysis was generally higher and the percent with a transplant was generally lower in networks with higher prevalence of ESRD.

Across 763 Health Service Areas in 2014, the percent of prevalent dialysis cases using home dialysis ranged from 0% to 83% (interquartile range: 9.5% to 17.2%) (Figure 1.20). Health Service Areas with home dialysis use ranging from low to high were found in most regions of the country.

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vol 2 Figure 1.20 Map of the percentage of prevalent dialysis cases using home dialysis, by Health Service Area, 2014



Data Source: Special analyses, USRDS ESRD Database. Values for cells with 10 or fewer patients are suppressed.

Patient and Treatment Characteristics at ESRD Onset

PRE-ESRD CARE

In 2014, 24% of patients starting ESRD therapy in 2014 were reported on the CMS 2728 form as not having received nephrology care prior to ESRD onset (Table 1.7). This reflects little change from 25% in 2013. An additional 13% had unknown duration of pre-ESRD nephrology care. Because treatment characteristics (e.g., erythropoiesis-stimulating agent [ESA] use and dietary care) for this group were similar to those for no pre-ESRD nephrology care, one may assume that up to 38% of new ESRD cases received little or no pre-ESRD nephrology care (Table 1.7.a).

Several differences are notable in the distributions of pre-ESRD nephrology care by patient characteristics. Young patients (o-21 years) were most likely (43%), and adults aged 22-64 years were least likely (28%), to have had longer duration (12 months or more) of pre-ESRD nephrology care. Blacks were slightly less likely to have had pre-ESRD care than were other racial groups, and Hispanics were less likely to have had pre-ESRD care than were non-Hispanics.

ESRD patients with a primary etiologic diagnosis of cystic kidney disease or, to a lesser extent, glomerulonephritis were more likely to have had pre-ESRD nephrology care than were patients with a diagnosis of diabetes or hypertension. Having no nephrology care was most common for patients with hypertension as the primary cause of ESRD. One could surmise that some patients initially presenting at or near dialysis facilities might be assigned this diagnosis in the absence of evidence of other possible etiologies.

Patients receiving longer pre-ESRD nephrology care were relatively more likely to use an ESA before ESRD, receive dietary care before ESRD, and start dialysis with an arteriovenous fistula (AV) fistula, rather than a central venous catheter (Table 1.7.b). Patients receiving longer pre-ESRD nephrology care were less likely to start dialysis at either very low eGFR levels (<5 ml/min/1.73m²) or very high (\geq 15 ml/min/1.73m²) eGFR levels. vol 2 Table 1.7 Distribution (%) of the reported duration of pre-ESRD nephrology care, by (a) demographic and (b) clinical characteristics, among incident ESRD cases in the U.S. population, 2014

) Demograph			pre-ESRD ne	nhrology	care
	No. of cases	>12 mo.	6-12 mo.	0-6 mo.	None	Unknowr
Total	116290	30.6	18.6	13.2	24.2	13.4
Age						
0-21	1523	43.1	13.8	15.1	22.1	5.9
22-44	13513	27.4	17.8	13.1	29.1	12.5
45-64	44653	28.1	18.8	13.6	26	13.3
65-74	29745	32.8	18.9	12.9	21.8	13.5
75+	26856	33.1	18.5	12.7	21.3	14.2
Sex						
Female	49041	30.8	18.6	13.4	23.6	13.5
Male	67249	30.5	18.5	13	24.6	13.3
Race						
Native American	1158	27.6	18.6	18.4	26.2	9.1
Asian	6029	30.5	19.5	15	21.7	13.2
Black/African American	31252	26.2	18.4	12.7	26.8	15.6
White	77843	32.4	18.5	13.1	23.3	12.6
Other/Unknown	*	*	*	12.5	12.5	50
Ethnicity						
Non-Hispanic	99715	31.8	18.6	13	23.4	13.1
Hispanic	16575	23.3	18.5	14	29	15.1
Primary Diagnosis						
Diabetes	53642	31.4	20.6	13.7	21	13.3
Hypertension	34226	27.4	17.9	13.1	25.6	15.9
Glomerulonephritis	9151	38.8	17.8	12.6	22.7	8
Cystic kidney	2573	58.3	16.3	8.6	9.6	7.2
Other/Unknown	16698	25.8	13.9	12.8	34.5	12.4

Table 1.7 continued on next page.

vol 2 Table 1.7 Distribution (%) of the reported duration of pre-ESRD nephrology care, by (a) demographic and (b) clinical characteristics, among incident ESRD cases in the U.S. population, 2014 (continued)

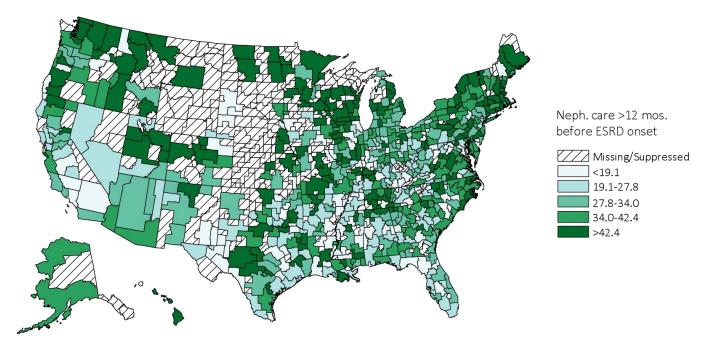
			Duration o	f pre-ESRD N	ephrology C	Care
Total	No. of cases	>12 mo.	6-12 mo.	0-6 mo.	None	Unknown
Dietary care						
No	106987	28.7	17.9	12.5	26.2	14.5
Yes	9303	52.6	25.5	20.7	0.8	0.4
ESA use						
No	99400	26.7	17.5	12.5	27.8	15.5
Yes	16890	53.7	25.1	17.2	3	1
eGFR at RRT start						
<5	16366	25.3	16.4	11.3	33.8	13.1
5-<10	54384	32.4	19.3	13.1	22.8	12.5
10-<15	31461	32.4	19.2	14.1	20.8	13.4
>=15	13967	26.1	16.7	13.7	25.9	17.4
Vascular Access						
AV fistula	17253	55.1	24	9.5	3.8	7.5
AV graft	2965	43.1	24.3	13.6	9.7	9.2
CVC with maturing fistula/graft	19087	30.7	21.9	14.6	20.9	11.8
CVC only	63052	19	14.8	13.8	35	17.4
Other/Unknown	13933	49.8	23.1	12.7	7.9	5.7

(b) Clinical characteristics (% within row)

Data Source: Special analyses, USRDS ESRD Database. Population only includes incident cases with CMS form 2728. *Count ≤ 10 . eGFR calculated using the CKD-EPI equation (CKD-EPI eGFR (ml/min/1.73 m²) for those aged ≥ 18 years and the Schwartz equation for those aged <18 years. Abbreviations: AV, arteriovenous; CKD-EPI, chronic kidney disease epidemiology calculation; CVC, central venous catheter; eGFR, estimated glomerular filtration rate; ESA, erythropoiesis-stimulating agents; ESRD, end-stage renal disease; RRT, renal replacement therapy.

The proportion of incident ESRD cases in 2014 with >12 months of pre-ESRD nephrology care was 31% in the United States; it varied substantially across 677 Health Services Areas, ranging from a low of 0% to a high of 83% (interquartile range: 24% to 43%) (Figure 1.21). Health Service Areas with the greatest

proportions of patients with >12 months of pre-ESRD care were clustered in the Northeast, Upper Midwest, and Northwest, where over 40% of patients were under a nephrologists care for >12 months prior to ESRD. vol 2 Figure 1.21 Percent of incident cases who had received >12 months of pre-ESRD nephrology care, by Health Service Area, 2014

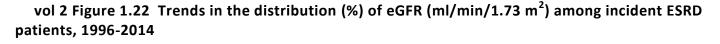


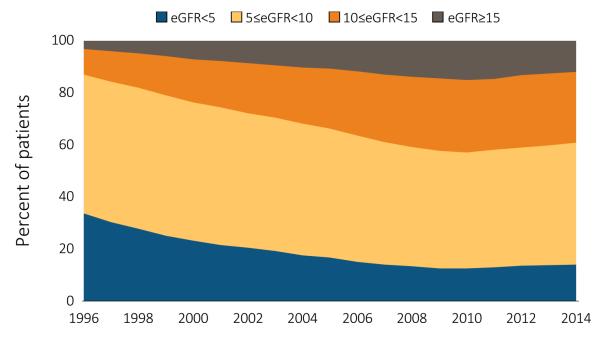
Data Source: Special analyses, USRDS ESRD Database. Population only includes incident cases with CMS form 2728. Values for cells with 10 or fewer patients are suppressed. Abbreviations: ESRD, end-stage renal disease; Neph., nephrology.

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EGFR AT ESRD ONSET

Figure 1.22 shows that the percentage of incident ESRD cases who were started on renal replacement therapy at higher eGFR levels increased steadily from 1996 until 2010, but has been stable or decreased slightly from 2010 to 2014. For example, the percent of incident ESRD cases starting with eGFR at ≥ 10 ml/min/1.73 m² rose from 13% in 1996 to 43% in 2010, but decreased to 39% in 2014. The percent of incident ESRD cases who started therapy at eGFR <5 ml/min/1.73 m² decreased from 34% in 1996 to 13% in 2010, and was 14% in 2014.





Data Source: Special analyses, USRDS ESRD Database. Population only includes incident cases with CMS form 2728. eGFR calculated using the CKD-EPI equation (CKD-EPI eGFR ($ml/min/1.73 m^2$) for those aged ≥ 18 and the Schwartz equation for those aged < 18. Abbreviations: CKD-EPI; chronic kidney disease epidemiology calculation; eGFR, estimated glomerular filtration rate; ESRD, end-stage renal disease.

Mean eGFR at ESRD start was higher among young patients (0-21 years), males, Whites, non-Hispanics, or those with diabetes as the primary cause of ESRD (Table 1.8). Mean eGFR at ESRD start in 2013 varied substantially by Health Service Area (Figure 1.23). For

example, Health Service Areas with higher average eGFRs at initiation of ESRD clustered in the North and Midwest regions, and Health Service Areas with lower average eGFRs at ESRD start clustered in the South.

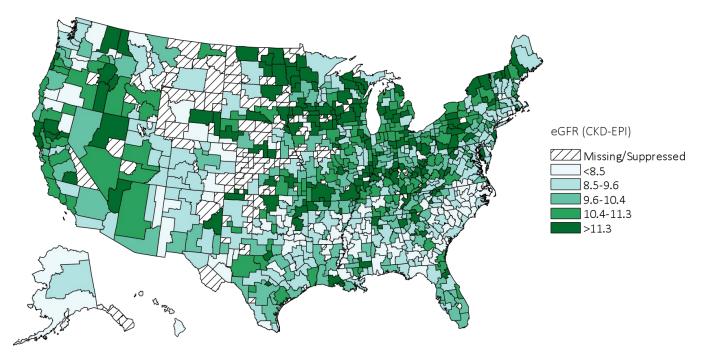
		Nutr	ition	Anem	ia	Lipi	ds	Diabetes
	eGFR (mL/min / 1.73 m ²)	Serum albumin (g/dL)	Dietary care (%)	Hemoglobin (g/dL)	ESA use (%)	Total cholester ol (mg/dL)	LDL (mg/dL)	HbA1c (%)
Age								
0-21	13.41	3.4	37.5	9.7	27.7	177	106.9	5.27
22-44	9.49	3.3	7.5	9.4	10.3	172	102.2	7.03
45-64	9.97	3.2	7.7	9.4	12.0	159	90.9	6.87
65-74	10.31	3.2	7.9	9.5	14.9	149	83.0	6.68
75+	10.44	3.2	6.8	9.6	16.2	143	77.5	6.43
Sex								
Male	10.48	3.2	8.0	9.6	12.5	148	84.0	6.71
Female	9.71	3.2	7.6	9.4	15.5	165	92.9	6.78
Race								
White	10.43	3.2	8.2	9.6	13.9	152	85.3	6.73
Black/African American	9.72	3.2	6.4	9.2	12.4	160	92.7	6.71
Native American	9.36	2.9	6.6	9.3	13.7	146	77.1	7.18
Asian	8.94	3.3	10.8	9.4	18.6	164	91.5	6.74
Ethnicity								
Hispanic	9.61	3.2	7.4	9.4	12.0	156	89.1	6.80
Non-Hispanic	10.24	3.2	7.9	9.5	14.1	155	87.2	6.73
Primary Cause of ESRD								
Diabetes	10.35	3.1	7.5	9.4	15.3	154	86.6	7.09
Hypertension	9.67	3.3	6.1	9.6	12.2	154	87.1	6.17
Glomerulonephritis	9.19	3.3	11.2	9.6	18.0	171	99.3	5.93
Cystic Kidney	9.35	3.8	15.0	10.3	16.1	161	88.1	5.68
Total	10.15	3.2	7.9	9.5	13.7	155	87.5	6.74

vol 2 Table 1.8 Distributions of laboratory values (mean) and treatment characteristics (%), by age, sex, race, ethnicity, and primary cause of ESRD, among incident ESRD cases, 2014

Data Source: Special analyses, USRDS ESRD Database. Abbreviations: eGFR, estimated glomerular filtration rate; ESA, erythropoiesisstimulating agents; ESRD, end-stage renal disease; HbA1c, glycosylated hemoglobin; LDL, low-density lipoprotein.

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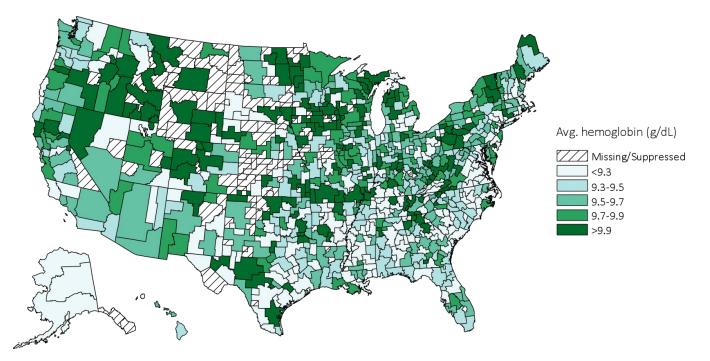
vol 2 Figure 1.23 Map of mean eGFR at initiation of renal replacement therapy, by Health Service Area, 2014



Data Source: Special analyses, USRDS ESRD Database. Population only includes incident cases with CMS form 2728. eGFR calculated using the CKD-EPI equation (CKD-EPI eGFR ($ml/min/1.73 m^2$) for those aged ≥ 18 and the Schwartz equation for those aged <18. Values for cells with 10 or fewer patients are suppressed. Abbreviations: eGFR, estimated glomerular filtration rate; CKD-EPI, chronic kidney disease epidemiology calculation.

ANEMIA AT ESRD ONSET

The overall mean hemoglobin level at ESRD onset in 2014 was 9.5 g/dL. Incident ESRD cases with cystic kidney disease as the primary cause had higher mean hemoglobin levels at ESRD onset than did other ESRD cases (Table 1.9). Figure 1.24 shows the distribution of mean hemoglobin levels by Health Service Area across the United States. There appear to be large Health Service Areas with higher average hemoglobin levels in the western half of the United States, especially in the Rocky Mountain areas, with smaller areas with higher hemoglobin at start of ESRD across the rest of the country. vol 2 Figure 1.24 Map of average hemoglobin level at initiation of renal replacement therapy, by Health Service Area, 2014



Data Source: Special analyses, USRDS ESRD Database. Population only includes incident cases with CMS form 2728. Values for cells with 10 or fewer patients are suppressed. Abbreviation: ESRD, end-stage renal disease.

VARIATION IN TREATMENT CHARACTERISTICS BY ESRD NETWORK

Geographic variation in pre-ESRD care is also evident by ESRD Network. Most pronounced was over 2-fold variation in the percentage of incident ESRD cases with pre-ESRD nephrology care >12 months, ranging from 47% in Network 1 to 20% in Network 18. Mean eGFR at ESRD start ranged from 8.9 ml/min/1.73m² in Network 6 to 10.7 ml/min/1.73m² in Network 11. Mean hemoglobin at dialysis start ranged from 9.4 to 9.8 g/dL across the 18 Networks (Table 1.9). At the ESRD Network level, regional variation in eGFR at initiation does not seem to be associated with regional variation in length of time with pre-ESRD nephrology care (Table 1.9).

vol 2 Table 1.9 Distribution of duration of pre-ESRD nephrology care, hemoglobin level, and eGFR, by ESRD Network, among incident ESRD cases, 2014

		I	Duration of p	ore-ESRD nep	ohrology c	are		Mean
Network	States* in network			(% in row)			Mean eGFR	Hgb
		>12 months	6-12 months	0-6 months	None	Unknown	(ml/min/1.73 m ²)	(g/dL
18	S. CA	19.6	16.3	16.8	24.4	23.0	10.3	9.6
14	ТХ	25.0	18.4	14.6	29.0	12.9	9.4	9.5
10	IL	25.8	16.7	13.4	22.2	21.9	10.2	9.5
5	MD, DC, VA, WV	26.4	20.8	13.9	25.4	13.5	9.6	9.4
7	FL	26.5	17.7	12.9	27.0	15.9	10.0	9.4
3	NJ, PR	27.4	19.6	9.9	35.3	7.7	9.6	9.5
13	AR, LA, OK	28.3	18.5	11.7	26.4	15.1	9.5	9.5
9	IN, KY, OH	30.3	20.6	11.7	20.6	16.8	10.6	9.5
8	AL, MS, TN	30.5	18.9	12.6	26.1	11.9	9.1	9.3
17	N. CA, HI, GUAM, AS	30.7	20.7	14.8	21.3	12.5	10.1	9.5
15	AZ, CO, NV, NM, UT, WY	32.2	18.1	16.2	22.5	11.0	10.4	9.7
2	NY	32.7	17.3	11.8	23.6	14.6	9.3	9.3
6	NC, SC, GA	33.8	19.0	12.6	23.1	11.4	8.9	9.4
12	IA, KS, MO, NE	35.4	17.9	12.2	24.8	9.8	10.5	9.8
4	DE, PA	36.0	19.2	13.7	21.0	10.1	10.1	9.6
11	MI, MN, ND, SD, WI	39.4	16.8	11.7	22.4	9.7	10.7	9.5
16	AK, ID, MT, OR, WA	43.5	19.3	14.6	18.6	4.1	10.1	9.7
1	CT, MA, ME, NH, RI, VT	47.1	19.6	10.2	15.3	7.8	9.2	9.6
	All networks	30.6	18.6	13.2	24.2	13.4	9.8	9.5

Data Source: Special analyses, USRDS ESRD Database. Population only includes incident cases with CMS form 2728. eGFR calculated using the CKD-EPI equation (CKD-EPI eGFR (ml/min/1.73 m^2) for those aged \geq 18 years and the Schwartz equation for those aged <18 years. Listed from lowest to highest by >12 months duration of pre-ESRD nephrology care. *Includes 50 states, Washington, D.C. (DC), Puerto Rico (PR), Guam (GU), and American Samoa (AS). Northern and Southern California (CA) split into Networks 17 and 18. Abbreviations: ESRD, end-stage renal disease; eGFR, estimated glomerular filtration rate; CKD-EPI, chronic kidney disease epidemiology calculation; Hgb, hemoglobin.



Chapter 2: Healthy People 2020

- In this chapter we examine data for ten Healthy People 2020 (HP2020) Objectives (nine for CKD and one for diabetes), spanning 19 total indicators. As in previous ADRs, we present data overall and stratified by race, sex, and age groups.
- In 2014, 12 of 19 indicators met HP2020 goals, with most of the remaining objectives continuing to show improvement.
- We present state-level comparison maps for HP2020 objectives CKD-10 (proportion of ESRD patients receiving care from a nephrologist at least 12 months before the start of renal replacement therapy) and CKD-13.1 (proportion of patients receiving a kidney transplant within three years of end-stage renal disease; Figures 2.1 and 2.2). More than 80% of states achieved the HP2020 target for CKD-10, while just over 20% achieved the target for CKD-13.1. For both these objectives there was significant geographic variation, with percentages varying between states by greater than 50% from the lowest to highest quintiles.
- For HP2020 objectives relating to vascular access, we present data from CROWNWeb examining HP2020 objectives CKD 11-1 (proportion of adult hemodialysis patients who use arteriovenous fistulas as the primary mode of vascular access) and CKD 11-2 (proportion of adult hemodialysis patients who use catheters as the only mode of vascular access; Tables 2.9 and 2.10). In 2014, we continued to observe an increasing trend in proportion of patients using arteriovenous fistulas, reaching 63.9% overall; notably, this trend was observed across nearly all subgroups.
- In 2014, we continued to observe a trend towards decreasing all-cause mortality among prevalent dialysis patients. The total death rate fell to 172.8 deaths per 1,000 patient years, a more than 25% decrease from 233.7 deaths per 1,000 patient years seen in 2001.

Introduction

For more than three decades, the Healthy People initiative has served as the nation's agenda for health promotion and disease prevention. Coordinated by the United States (U.S.) Department of Health and Human Services, the initiative provides a vision and strategy for improving the health of all Americans by setting priorities, identifying baseline data and 10-year targets for specific objectives, monitoring outcomes, and evaluating progress. Since its inaugural iteration in 1980, in each decade the program has released updated plans that reflect emerging health priorities and that have helped to align health promotion resources, strategies, and research.

Healthy People 2020 (HP2020) was launched on December 2, 2010. It represents the fourth-generation plan, and encompasses more than 1,000 health objectives organized into 42 different topic areas. Built on the success of the three previous initiatives, HP2020 seeks to achieve the following overarching goals:

- to assist all Americans in attaining highquality, longer lives free of preventable disease, disability, injury, and premature death;
- to achieve health equity, eliminate disparities, and improve the health of all groups;
- to create social and physical environments that promote good health for all, and
- to promote quality of life, healthy development, and healthy behaviors across all life stages (HP2020, 2010).

One of the key priorities of the HP2020 initiative is to "reduce new cases of chronic kidney disease (CKD)

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and its complications, disability, death, and economic costs." The development of CKD and its progression to end-stage renal disease (ESRD) is a major source of diminished quality of life in the U.S., and is responsible for significant premature mortality. For patients with this condition, the HP2020 CKD objectives were designed to reduce the long-term burden of kidney disease, increase lifespan, improve quality of life, and to eliminate related health care disparities. To accomplish these goals the HP2020 program developed 14 objectives related to CKD, encompassing 24 total indicators with targets designed to evaluate the program's success. Herein, we provide data for nine of these objectives, as well as information on urine albumin testing in non-CKD patients diagnosed with diabetes mellitus (DM). These nine objectives were measured through 19 total indicators.

Overall, encouraging trends were noted for nearly all nine objectives, with 11 out of 19 indicators meeting or exceeding their improvement targets. With respect to the provision of recommended care, indicators related to the proportion of patients with both DM and CKD receiving recommended medical evaluations have surpassed their targets and continue to improve. Nearly all indicators related to reductions in mortality among ESRD patients have exceeded their targets. However, the data also demonstrate that several indicators continued to fall short of their targets. The rates of new cases of ESRD (CKD Objective 8) and the rate of ESRD among patients with DM (CKD Objective 9.1) remained above target, although some subgroups have achieved the target. Of note, several transplantrelated objectives remained short of their HP2020 goals, including transplant wait-listing of dialysis patients (CKD Objective 12), death rate among patients with a functioning kidney transplant (CKD Objective 14.4), and the proportion of patients receiving a kidney transplant within three years of ESRD (CKD Objective 13.1).

It is important to highlight that one of the four overarching goals of HP2020 is to eliminate health care disparities. While much of the data showed promising trends relevant to this goal, progress overall has not always translated into reduced differences across subgroups. To facilitate comparisons, data is presented overall and by racial, ethnic, sex, and age subgroups. In many cases, while an objective may have been met by the overall population, one or more subgroups may have fallen well short. Primarily, however, trends were similar across different subgroups.

Below, the detailed findings and trends for each of the 10 objectives (with 19 total indicators) are presented separately. Additional information on the HP2020 program objectives can be found at www.healthypeople.gov.

Methods

This chapter uses multiple data sources including data from the Centers for Medicare & Medicaid Services (CMS), the Organ Procurement and Transplantation Network (OPTN), the Centers for Disease Control and Prevention (CDC), and the United States Census. Details of data sources are described in the Data Sources section of the ESRD Analytical Methods chapter.

See the Analytical Methods Used in the ESRD Volume section of the ESRD Analytical Methods chapter for an explanation of analytical methods used to generate the figures and tables in this chapter.

CHAPTER 2: HEALTHY PEOPLE 2020

Recommended Care

In recent years, acute kidney injury (AKI) has become established as an important risk factor for the subsequent development, or worsening, of CKD. Unfortunately, the published literature suggests that the rate of post-AKI renal follow-up is quite low. This objective aims to promote improved renal follow-up within six months after an episode of AKI. Post-AKI follow-up allows for early identification of CKD development, and provides an opportunity to institute renoprotective measures early in the course of evolving disease. Over the past decade, there has been a steady increase in the percentage of Medicare patients with AKI receiving follow-up renal evaluation. In 2014, 16.4% of patients aged 65 and older who were hospitalized for AKI had a follow-up renal evaluation during the next six months (see Table 2.1). This is the fourth consecutive year that the HP2020 goal of 12.2% has been achieved.

	2001 (%)	2002 (%)	2003 (%)	2004 (%)	2005 (%)	2006 (%)	2007 (%)	2008 (%)	2009 (%)	2010 (%)	2011 (%)	2012 (%)	2013 (%)	2014 (%)
All	2.4	3.1	4.5	8.4	9.0	10.4	11.2	10.5	11.5	11.8	12.7	12.8	15.9	16.4
Race/Ethnicity														
American Indian or Alaska Native	0.0	0.0	2.9	16.7	4.8	13.2	12.0	15.2	6.9	11.0	16.7	9.5	9.2	11.0
Asian	3.8	2.0	4.6	8.1	12.3	19.1	15.0	11.5	16.4	15.5	16.1	14.7	22.6	26.5
Black/African American	2.9	2.5	4.0	7.9	9.8	9.0	11.1	10.2	12.2	11.3	12.0	13.2	15.6	17.0
White	2.3	3.2	4.5	8.3	8.8	10.5	11.1	10.4	11.2	11.8	12.5	12.5	15.6	15.9
Hispanic or Latino	1.4	6.6	7.1	12.9	12.2	10.3	11.9	15.7	13.2	13.0	17.1	16.0	23.1	22.5
Sex														
Male	2.8	3.5	4.6	8.8	9.9	11.2	12.6	11.9	12.5	12.8	13.9	13.9	17.4	17.6
Female	2.0	2.8	4.3	8.0	8.3	9.7	10.0	9.3	10.5	11.0	11.6	11.8	14.6	15.3
Age														
65-74	3.7	4.2	6.2	11.6	12.8	14.6	16.1	14.8	16.0	16.4	17.5	17.2	20.8	21.2
75-84	2.0	3.2	4.2	8.5	8.6	10.4	11.1	10.8	11.3	12.3	13.3	13.0	16.7	17.4
85+	0.8	1.1	2.2	3.1	4.4	5.1	5.1	5.0	6.4	6.0	6.3	6.9	8.8	8.6

vol 2 Table 2.1 HP2020 CKD-3 Increase the proportion of hospital patients who incurred acute kidney injury who have follow-up renal evaluation in 6 months post discharge: Target 12.2%

Data Source: Special analyses, Medicare 5 percent sample. Medicare patients aged 65 & older with a hospitalized AKI event in a given year. Abbreviation: CKD, chronic kidney disease.

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The proportion of patients receiving post-AKI renal evaluation decreased with older age. Among patients aged 65-74, 21.2% received follow-up evaluation. This declined to 17.4% in patients aged 75-84, and only 8.6% of those aged 85 and older received such care. In addition, men were more likely to receive follow-up renal evaluation as compared with women, and a slightly higher proportion of Blacks/African Americans had post-AKI follow-up compared to Whites.

Over the past decade, there has been steady annual improvement in the proportion of patients with diagnosed DM who received an annual urine albumin measurement reaching 46.2% in 2014 and once again meeting the HP2020 target (see Table 2.2).

	2001 (%)	2002 (%)	2003 (%)	2004 (%)	2005 (%)	2006 (%)	2007 (%)	2008 (%)	2009 (%)	2010 (%)	2011 (%)	2012 (%)	2013 (%)	2014 (%)
All	15.3	18.1	21.2	25.5	28.5	31.0	33.3	35.3	36.9	38.6	40.5	42.3	44.9	46.2
Race/Ethnicity														
American														
Indian or	11.4	12.1	13.1	15.5	18.9	20.1	20.9	21.2	24.1	23.0	24.5	24.1	27.1	27.8
Alaska Native														
Asian	16.8	20.6	23.9	28.9	30.5	33.4	34.9	37.3	39.5	41.7	43.8	47.3	49.4	50.4
Black/African	13.1	15.6	18.5	23.5	26.4	29.0	31.5	33.3	35.3	36.9	39.0	40.5	43.0	43.9
American														
White	15.5	18.5	21.6	25.7	28.7	31.2	33.5	35.5	37.1	38.6	40.6	42.3	44.9	46.3
Hispanic or Latino	15.3	17.8	20.7	25.5	29.6	31.3	33.2	35.1	37.5	40.2	42.3	44.3	47.8	48.7
Sex														
Male	15.9	18.8	21.9	26.5	29.4	32.0	34.5	36.4	37.9	39.5	41.6	43.3	46.1	47.4
Female	14.8	17.6	20.7	24.7	27.8	30.2	32.4	34.4	36.2	37.7	39.6	41.5	44.0	45.2
Age														
65-74	18.2	21.2	24.7	29.4	32.6	35.1	37.7	39.9	41.8	43.3	45.3	47.2	49.6	50.7
75-84	13.7	16.7	19.6	23.8	26.8	29.6	31.8	33.7	35.3	37.1	39.1	41.0	44.4	45.8
85+	7.2	9.0	10.9	13.9	16.1	18.1	20.5	22.2	23.5	25.0	26.7	28.0	31.4	32.6

vol 2 Table 2.2 HP2020 D-12 Increase the proportion of persons with diagnosed diabetes who obtain an annual urinary microalbumin measurement: Target 37.0%

Data Source: Special analyses, Medicare 5 percent sample. Medicare patients with diabetes mellitus, aged 65 & older. Abbreviation: D, diabetes mellitus.

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The trend of increasing urine albumin measurements was seen in all age groups, and in both men and women. However, the proportion of patients with DM who had urine albumin measurements declined with age, falling from 50.7% in the 65-74 age group to 32.6% in patients older than 85 years. Proportions were relatively similar when examined by race, with the exception of American Indians or Alaska Natives. While this group had a low rate of 27.8%, testing in this population may have been underreported, as services rendered through the Indian Health Service (HIS) are not in claims reported to the Medicare system. This IHS reporting only affects data based on Medicare billing, however. Outcomes such as incidence rates, mortality rates and transplant rates are fully reported in the CROWNWEB system, thus, such differences between American Indians or Alaska Natives and the other racial groups will not be due to under reporting.

HP2020 CKD Objective 4.1 examines the proportion of patients with CKD who receive recommended medical testing, including for serum creatinine, urine albumin, and lipids. In the Medicare population aged 65 and older, 33.8% of CKD patients underwent serum creatinine, lipid, and urine albumin testing in 2014, surpassing the HP2020 goal of 28.3% for the fifth consecutive year.

As observed with other measures of recommended testing, the proportion of patients tested declined with rising age; testing occurred in 41.9%, 34.5%, and 19.0% of individuals in the 65-74, 75-84, and 85 years and older age groups. As compared to females, a higher proportion of males had recommended testing. When examining race and ethnicity, Asians had the highest proportion of recommended testing, followed by Hispanic or Latino patients. American Indians or Alaska Natives had the lowest proportion, although once again this may be related to lack of data capture from the IHS.

	2001 (%)	2002 (%)	2003 (%)	2004 (%)	2005 (%)	2006 (%)	2007 (%)	2008 (%)	2009 (%)	2010 (%)	2011 (%)	2012 (%)	2013 (%)	2014 (%)
All	7.3	9.1	10.6	19.8	22.1	23.4	25.7	26.7	28.1	29.0	30.2	31.1	33.0	33.8
Race/Ethnicity														
American														
Indian or	8.2	6.0	7.0	13.7	19.2	15.8	16.9	16.7	18.3	20.4	21.0	18.4	23.2	22.1
Alaska Native														
Asian	8.4	14.4	14.1	27.5	27.9	32.5	35.3	34.1	37.5	36.9	39.5	41.2	43.8	45.0
Black/African	6.6	8.7	10.1	20.8	22.8	24.4	26.7	27.8	30.1	30.6	32.3	33.1	34.9	35.4
American	0.0		2012	2010			_0.7	_//0	0012	0010		00.1	0.110	0011
White	7.1	8.8	10.4	19.3	21.6	22.9	25.1	26.3	27.4	28.3	29.4	30.3	32.1	32.8
Hispanic or Latino	13.1	17.3	17.7	26.8	30.4	31.1	33.0	32.1	36.0	36.7	38.9	41.3	44.1	44.8
Sex														
Male	7.5	9.3	11.3	21.1	23.4	24.5	27.1	28.4	29.6	30.6	32.0	33.0	35.0	35.7
Female	7.0	8.9	10.0	18.6	20.9	22.4	24.3	25.2	26.7	27.6	28.6	29.5	31.3	31.9
Age														
65-74	10.3	12.6	14.2	26.1	29.2	31.4	33.9	35.1	36.7	37.7	38.9	39.9	41.4	41.9
75-84	6.2	8.0	9.8	18.5	20.8	22.6	24.9	26.2	27.7	28.9	30.3	31.2	33.6	34.5
85+	2.3	3.1	4.0	8.2	10.0	10.1	12.1	13.1	14.0	14.8	16.2	17.0	18.6	19.0

vol 2 Table 2.3 HP2020 CKD-4.1 Increase the proportion of persons with chronic kidney disease who receive medical evaluation with serum creatinine, lipids, and microalbuminuria: Target 28.3%

Data Source: Special analyses, Medicare 5 percent sample. Medicare patients aged 65 & older with CKD. Abbreviation: CKD, chronic kidney disease.

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Patients with both CKD and type 1 or type 2 diabetes require comprehensive laboratory monitoring to assess for development of complications. The glycosylated hemoglobin (HgbA1c) test provides an assessment of blood glucose control over prolonged periods of time, while diabetic retinopathy can be detected through regular eye examinations. In the 2014 diabetic CKD population aged 65 and older, 29.9% of patients received serum creatinine, urine albumin, HgbA1c, and lipid testing, as well as an eye examination (see Table 2.4). This exceeded the HP2020 goal of 25.3% for the fifth consecutive year.

Similar to the percentages seen for HP2020 CKD Objective 4.1, the proportion of patients tested declined with rising age; testing occurred in 32.5%, 31.0%, and 20.7% of individuals in the 65-74, 75-84, and 85 years and older age groups. When examining race and ethnicity, American Indians or Alaska Natives had the lowest proportion, although once again this may be related to lack of data capture from the IHS.

vol 2 Table 2.4 HP2020 CKD-4.2 Increase the proportion of persons with type 1 or type 2 diabetes and chronic kidney disease who receive medical evaluation with serum creatinine, microalbuminuria, A1c, lipids, and eye examinations: Target 25.3%

	2001 (%)	2002 (%)	2003 (%)	2004 (%)	2005 (%)	2006 (%)	2007 (%)	2008 (%)	2009 (%)	2010 (%)	2011 (%)	2012 (%)	2013 (%)	2014 (%)
All	9.0	10.4	12.1	18.4	20.0	21.1	23.0	23.7	25.1	26.5	26.9	27.6	29.8	29.9
Race/Ethnicity														
American														
Indian or Alaska Native	7.3	3.1	5.7	5.6	15.8	12.5	10.2	10.9	10.9	15.1	14.2	11.2	16.4	17.0
Asian	8.3	12.4	12.8	25.0	21.8	26.1	26.7	25.3	27.1	29.5	30.8	32.4	36.9	34.3
Black/African American	6.7	7.2	9.9	16.3	17.9	18.8	19.7	21.1	22.4	23.8	25.1	25.3	27.1	26.7
White	9.4	11.0	12.5	18.6	20.3	21.4	23.4	24.2	25.6	27.0	27.1	27.9	29.9	30.2
Hispanic or Latino	10.4	11.8	11.8	20.4	20.3	19.8	22.1	21.7	24.6	24.0	26.5	25.2	29.7	29.7
Sex														
Male	9.3	10.6	12.4	18.8	20.3	21.4	23.5	23.7	25.6	26.7	27.3	27.8	30.2	30.3
Female	8.7	10.3	11.8	18.0	19.7	20.9	22.5	23.6	24.7	26.2	26.6	27.5	29.4	29.5
Age														
65-74	10.9	12.3	14.3	22.0	23.4	24.6	26.6	27.2	28.5	30.0	30.1	30.7	32.6	32.5
75-84	8.1	9.9	11.6	16.9	18.9	20.7	22.6	23.3	25.2	26.7	27.4	28.4	30.8	31.0
85+	4.0	4.2	4.9	9.5	11.5	11.3	13.0	14.2	15.5	16.6	17.7	18.3	20.4	20.7

Data Source: Special analyses, Medicare 5 percent sample. Medicare patients aged 65 & older with CKD & diabetes mellitus. Abbreviations: CKD, chronic kidney disease; A1c, glycosylated hemoglobin.

Incidence of End-stage Renal Disease

Since 2006, the rate of new cases of ESRD has been slowly declining, although at 358.2 new cases per million population (PMP) it still remains above the target rate of 344.3. As shown in Table 2.5, substantial variation in the incidence of ESRD across race and ethnicity remains a persistent challenge. Consistent with previous years, higher rates of incident ESRD were seen among Blacks (906.5 new cases per million) and Native Hawaiians/Pacific Islanders (2,512.1 new cases per million) as compared to Whites (288.2 new cases per million) and Asians (321.2 new cases per million). The most substantial decrease was observed among Blacks, where incidence decreased to 906.5 new cases per million from 932.3 new cases per million in 2013, although levels remain far in excess of the target.

It should be noted that the extraordinarily high rates among Native Hawaiians and Pacific Islanders may have been due in part to differential race reporting between the Census Bureau and the ESRD Medical Evidence Report forms (CMS 2728; ME) data collections. Although in the Census one-half of Native Hawaiians and Pacific Islanders self-identified as of multiple races, only 7% did so in the ME. The rate of incident ESRD among Hispanics (491.3 per million) was approximately 35% greater than among non-Hispanics (360.1 per million). This represents an approximately 10% narrowing of the gap from 2013.

Rates across the sexes remained fairly stable, with 453.9 new cases PMP among men and 279.6 cases per million among women, a gap of nearly 62%. This represents an overall gap increase as compared to 2001 levels, when males had a rate only 45% higher than females.

Kidney Failure Due to Diabetes

Overall there has been a decline in the rate of kidney failure due to diabetes (DM) over the past decade. However, the trend appears to have flattened over the past four years, and in 2014 the rate of 158.9 PMP remained above the HP2020 target of 150.6.

The rates varied widely by race, and were markedly higher in Blacks as compared to Whites (391.6 versus 133.6 per million). However, it is notable that the rates in Blacks have decreased by 21.1% since 2005, compared to nearly unchanged rates in Whites. The extraordinarily high rates among Native Hawaiians and Pacific Islanders may have been due in part to differential race reporting between the Census Bureau and the ESRD Medical Evidence Report forms (CMS 2728; ME) data collections. In 2014, males continued to have a higher rate of diabetic kidney failure than did females, at 196.5 compared with 127.0 PMP. In recent years this difference has widened, as the rate in females has been decreasing while that of males has been relatively flat.

	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
All	387.7	388.4	388.7	388.2	390.9	398.6	390.9	386.5	389.4	381.7	365.5	359.4	359.6	358.2
Race														
American Indian or Alaska Native	709.2	671.9	623.2	634.1	608.9	526.5	540.1	544.4	528.5	489.1	457.8	465.1	413.2	405.4
Asian	319.4	312.8	305.3	282.7	337.4	355.7	357.9	355.8	365.3	354.7	346.9	337.3	333.8	321.2
Native Hawaiian														
or Pacific	3432.2	3551.6	3554.6	3762.6	2897.8	2848.4	2400.4	2205.3	2431.2	2608.0	2369.2	2548.4	2581.3	2512.1
Islander~														
Black/African American	1125.8	1133.1	1132.5	1094.2	1103.2	1114.0	1091.7	1073.2	1072.0	1032.0	991.8	947.5	932.3	906.5
White	292.1	293.2	293.9	298.8	302.2	312.0	306.7	304.1	307.5	304.2	291.0	287.0	288.0	288.2
Two or more						145.8	147.8	158.6	145.1	140.9	114.2	13.3		2.3
races	•	•	•	•	•	145.0	147.0	150.0	143.1	140.5	117.2	15.5	•	2.5
Ethnicity														
Hispanic/Latino	642.4	651.1	653.6	629.3	608.3	610.0	593.0	588.6	584.7	577.9	566.2	531.3	522.9	491.3
Non-Hispanic	372.1	372.3	373.0	374.0	376.7	382.2	375.6	372.1	376.8	369.6	354.2	354.4	357.3	360.1
Non-Hispanic														
Black/African	1141.9	1151.0	1149.2	1107.5	1118.5	1131.1	1110.7	1091.8	1091.8	1052.6	1012.2	970.5	957.5	934.4
American														
Non-Hispanic White	268.6	267.5	267.4	273.4	275.4	281.1	275.6	271.9	275.1	270.7	256.9	256.1	257.4	260.4
Sex														
Male	463.5	469.7	469.3	477.0	483.1	493.9	486.5	483.6	488.5	480.4	463.5	469.7	469.3	477.0
Female	327.0	323.6	324.6	317.1		322.1	314.7	308.9	310.2		327.0	323.6	324.6	317.1
Age	02/10	01010	01.10	01/12	01/10		01		0101		02/10	01010	01.00	01/11
<18	11.5	11.9	12.0	12.6	12.5	11.5	12.3	12.3	12.0	11.6	11.7	11.6	11.4	10.8
0-4	8.8	7.8	9.3	10.8	9.9	8.9	12.5	12.5	12.0	11.0	11.7	11.0	11.4	10.8
5-11	0.0 7.5	8.9	9.5 7.6	8.0	9.9 7.8	6.6	7.0	7.8	7.2	7.2	6.9	7.5	7.7	7.1
12-17	18.3	8.9 18.7	-	8.0 19.5		19.3	7.0 19.6	7.8 19.2	18.5			16.6	15.9	
		-	19.5		19.9			-		17.1	17.6			15.3
18-44	112.3	111.7	110.9	112.3	117.0	120.8	119.3	118.6	122.2		115.1	113.7	_	118.9
18-24	43.6	41.7	41.7	39.8	42.3	43.4	42.9	41.4	40.5	39.7	39.5	36.0	37.1	34.4
25-44	136.4	136.2					146.1	145.7				140.9	142.0	148.5
45-64	614.8	604.9								574.7		556.0		552.6
45-54	389.0	387.7		387.7		402.3		386.1		373.1		368.8		382.8
55-64	840.7			811.8							739.7		729.2	
65+													1456.9	
65-74	1437.7	1427.1	1408.5	1398.8	1383.9	1413.6	1378.3	1350.7	1357.9	1351.4	1269.0	1236.3	1241.6	1225.1
75-84	1760.4	1856.6	1848.4	1846.9	1891.6	1914.1	1877.1	1853.3	1864.2	1859.7	1785.7	1696.5	1694.5	1647.2
85+	1261.5	1342.2	1408.6	1427.1	1462.7	1478.9	1508.4	1522.4	1548.2	1477.0	1363.0	1309.6	1235.1	1196.2

vol 2 Table 2.5 HP2020 CKD-8 Reduce the rate of new cases of end-stage renal disease (ESRD): Target 344.3 new cases per million population

Data Source: Special analyses, USRDS ESRD Database and CDC Bridged Race Intercensal Estimates Dataset, Incident ESRD patients. Rates adjusted for: overall, age/sex/race; rates by age adjusted for sex/race; rates by sex adjusted for age/race; rates by race/ethnicity adjusted for age/sex. Reference: 2012 patients. "." Zero values in this cell. ~Estimate shown is imprecise due to small sample size and may be unstable over time. Abbreviations: CDC, Centers for Disease Control and Prevention; CKD, chronic kidney disease; ESRD, end-stage renal disease.

	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
All	177.8	174.9	174.2	174.0	173.8	177.3	171.4	168.7	169.3	166.7	159.7	157.6	158.8	158.9
Race														
American Indian or Alaska Native	526.0	494.3	469.6	478.2	430.0	367.7	379.6	390.0	382.6	347.6	321.3	322.6	298.6	288.6
Asian	151.6	142.3	139.8	128.8	159.6	177.2	173.0	180.1	180.4	172.3	173.1	169.9	172.1	168.4
Native Hawaiian or Pacific Islander~	2196.7	1990.6	2003.8	2301.3	1692.7	1740.0	1499.4	1330.4	1528.7	1643.2	1447.7	1518.4	1662.9	1607
Black/African American	525.7	519.7	511.3	496.1			477.8	473.2	470.8	455.7	435.6	411.0	400.4	391.6
White	133.3	131.9	132.3	134.3	135.0	139.6	136.2	133.9	135.0	134.3	129.2	129.7	132.5	133.6
Two or more races		•				73.5	80.4	78.0	75.9	69.3	58.4	6.2	•	*
Ethnicity														
Hispanic/Latino	410.0	411.0	412.1	398.9	378.5	376.8	366.6	366.6	358.9	355.2	346.5	323.2	316.7	299.8
Non-Hispanic	164.3	161.4	160.7	161.5	161.4	163.9	158.5	156.0	157.5	154.9	148.2	147.5	149.3	150.7
Non-Hispanic														
Black/African	532.6	526.9	517.7	501.6	503.5	508.9	485.8	480.9	479.3	464.4	443.8	420.5	410.1	402.8
American Non-Hispanic White	114.5	112.1	111.7	114.1	114.2	116.4	112.9	109.2	110.3	109.1	103.5	105.6	108.6	110.6
Sex														
Male	194.2	194.8	194.8	200.2	201.5	206.5	202.0	200.4	202.8	200.4	193.4	190.8	194.3	196.5
Female	163.8	158.1	156.9	152.1	150.5	152.6	145.7	142.2	141.3	138.3	131.3	129.3	128.7	127.0
Age														
<18	0.1	0.1	*	0.1	0.1	*	*	*	*	0.1	*	0.1	0.1	0.1
0-4	*	*	*	*	*	*	*	*	*	*	*	*	*	0.4
5-11		*			*			*				*		
12-17	*	*	*	*	0.2	*	*	*	*	*	*	*	*	
18-44	33.6	32.7	33.4	34.3	35.1	38.3	37.8	37.6	39.8	39.6	39.7	38.1	39.2	41.6
18-24	3.6	2.9	2.9	2.1	3.1	3.2	2.7	2.4	2.6	2.5	2.2	2.5	2.6	1.9
25-44	44.0	43.1	44.1	45.5	46.3	50.5	50.1	49.9	52.9	52.5	52.8	50.6	52.0	55.5
45-64	343.5	333.1	328.7	323.3	321.9	323.2	309.7	307.8	306.4	294.7	281.7	283.8	280.9	279.6
45-54	191.0	188.5	186.7	184.7	182.1	189.2	178.8	178.2	179.9	175.3	173.5	175.1	181.8	181.7
55-64	495.9	477.7	470.7	461.9	461.7	457.2	440.6	437.4	432.8	414.1	389.8	392.5	380.0	377.5
65+	679.8	690.3	684.3	691.3	694.0	706.5	690.9	673.5	672.8	678.9	647.0	616.0	627.4	619.8
65-74	749.1	736.2	729.1	723.1	711.2	725.3	697.4	677.2	674.3	668.2	631.7	612.1	620.0	609.6
75-84	650.9	683.8	676.0	694.0	713.4	722.3	716.8	699.5	699.6	719.4	691.2	646.6	664.3	658.8
85+	275.2	297.4	319.8	345.7	328.9	359.8	366.8	376.3	389.5	381.6	358.0	349.2	331.9	332.5

vol 2 Table 2.6 HP2020 CKD-9.1 Reduce kidney failure (or end-stage renal disease, ESRD) due to diabetes: Target 150.6 per million population

Data Source: Special analyses, USRDS ESRD Database and CDC Bridged Race Intercensal Estimates Dataset, Incident ESRD patients. Adjusted for age/sex/race; reference: 2012. "." Zero values in this cell. *Values for cells with 10 or fewer patients are suppressed. ~Estimate shown is imprecise due to small sample size and may be unstable over time. Abbreviations: CDC, Centers for Disease Control and Prevention; CKD, chronic kidney disease; ESRD, end-stage renal disease.

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In 2014 the adjusted rate of kidney failure due to DM was 2,282 PMP (adjustment by age, sex, and race; see Table 2.7). While this represents the fifth consecutive year that the rate was below the HP2020 target of 2,380.5, it was notable that the overall rate had somewhat leveled off over the past several years. 2014 rates varied among races, and remained highest in Blacks with DM at 3,531 per million in 2014, compared to 2033 per million in their White counterparts. However, the rate in Blacks with diabetes has steadily improved—the 2014 rate represents a 21.1% overall decrease from 2007.

Nephrologist Care

At 35.0%, the proportion of CKD patients in 2014 receiving care from a nephrologist at least 12 months before the start of renal replacement therapy exceeded the HP2020 goal of 29.8%, and reflected an approximately 10% increase from the 25.7% seen in 2005 (Table 2.8). Percentages by ethnicity were lowest among Hispanics and Latinos, at 27.0%. Variations by race continued to be observed, with Whites (36.7%) and Asians (35.5%) having a greater proportion than Blacks (30.8%) and Native Hawaiians and Pacific Islanders (32.3%). While overall percentages have increased, the gap between lowest and highest has remained fairly consistent, increasing slightly from a 5.2% difference in 2005 to 5.9% in 2014. Even broader variation was observed by age, with the proportions ranging from 29.3% among those aged 18-44 to 42.7% among those under age 18. In contrast to the differences seen by race and age, percentages of pre-ESRD nephrologist care were similar by sex, at 34.7% among males and 35.3% among females.

vol 2 Table 2.7 HP2020 CKD-9.2 Reduce kidney failure (or end-stage renal disease, ESRD) due to diabetes among persons with diabetes: Target 2,380.5 per million population

	2007	2008	2009	2010	2011	2012	2013	2014
All	2616	2486	2401	2344	2271	2260	2289	2282
Race								
American Indian or Alaska Native	2559	2926	2931	2594	2246	2286	2029	1729
Asian	2067	2185	2207	2106	2070	2159	2303	2268
Native Hawaiian or Pacific Islander~								
Black/African American	4476	4335	4242	3978	3820	3696	3569	3531
White	2276	2138	2047	2025	1971	1979	2029	2033
Two or more races	610	553	517	484	463	49	*	*
Ethnicity								
Hispanic/Latino	3313	3177	2960	2898	2900	2799	2786	2666
Non-Hispanic	2518	2391	2321	2261	2179	2172	2205	2210
Non-Hispanic Black/African American	4686	4528	4473	4191	4057	3901	3757	3738
Non-Hispanic White	2049	1899	1822	1799	1729	1759	1821	1841
Sex								
Male	2927	2744	2621	2541	2521	2534	2598	2594
Female	2327	2235	2177	2139	2019	1987	1983	1966
Age								
<18	*	*	30	35	*	38	42	66
0-4								
5-11	*					*		*
12-17	*	*	*	*	*	*	*	*
18-44	1613	1531	1507	1461	1557	1511	1557	1700
18-24	341	268	285	290	334	294	285	214
25-44	1748	1677	1642	1578	1665	1646	1709	1885
45-64	2377	2257	2195	2134	2068	2111	2120	2122
45-54	2005	1846	1854	1864	1875	1883	1954	1953
55-64	2643	2571	2436	2308	2179	2252	2219	2219
65+	3101	2939	2800	2720	2574	2503	2551	2476
65-74	3186	2990	2894	2771	2619	2559	2616	2535
75-84	3351	3156	2934	2873	2799	2717	2848	2741
85+	1946	2073	1976	2073	1765	1696	1505	1502

Data Source: Special analyses, USRDS ESRD Database and CDC Bridged Race Intercensal Estimates Dataset, Incident ESRD patients. Adjusted for age/sex/race; Ref: 2012. National Health Interview Survey 2006–2015 used to estimate diabetes mellitus prevalence. "." Zero values in this cell; *Values for cells with 10 or fewer patients are suppressed. Abbreviations: CDC, Centers for Disease Control and Prevention; CKD, chronic kidney disease; ESRD, end-stage renal disease; Ref, reference.

vol 2 Table 2.8 HP2020 CKD-10 Increase the proportion of chronic kidney disease patients receiving care from a nephrologist at least 12 months before the start of renal replacement therapy: Target 29.8%

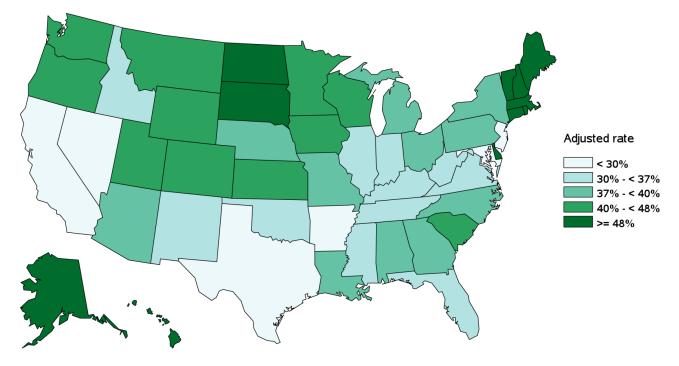
	2005 (%)	2006 (%)	2007 (%)	2008 (%)	2009 (%)	2010 (%)	2011 (%)	2012 (%)	2013 (%)	2014 (%)
All	25.7	26.4	27.3	28.6	28.6	29.5	31.0	33.1	34.2	35.0
Race										
American Indian or Alaska Native	25.2	27.3	26.0	27.9	26.8	23.8	27.6	30.4	30.2	30.4
Asian	25.8	23.9	26.5	27.5	29.1	29.7	31.4	31.8	35.4	35.5
Native Hawaiian or Pacific Islander	23.5	25.1	24.0	22.5	23.9	25.3	26.9	27.3	29.9	32.3
Black/African American	22.1	23.2	24.0	24.7	24.9	25.5	27.2	29.6	30.2	30.8
White	27.3	27.9	28.8	30.3	30.1	31.3	32.7	34.7	35.9	36.7
Two or more races	22.9	22.7	24.6	29.1	28.5	31.7	31.5	31.0	*	*
Ethnicity										
Hispanic/Latino	20.0	21.2	21.2	22.2	22.5	23.6	25.0	25.6	27.0	27.0
Non-Hispanic	26.6	27.2	28.2	29.6	29.5	30.5	32.1	34.4	35.4	36.3
Non-Hispanic Black/African American	22.1	23.2	24.0	24.7	25.0	25.6	27.2	29.7	30.3	30.9
Non-Hispanic White	28.8	29.4	30.5	32.2	32.0	33.2	34.7	37.0	38.2	39.2
Sex										
Male	26.1	26.5	27.3	28.3	28.3	29.6	30.7	33.1	34.1	34.7
Female	25.3	26.4	27.3	28.8	28.8	29.5	31.3	33.0	34.3	35.3
Age										
<18	39.6	35.6	34.6	39.0	38.8	36.5	44.1	40.8	46.5	42.7
0-4	24.0	20.6	25.0	25.9	22.7	22.3	25.4	27.8	28.3	24.7
5-11	49.5	47.9	40.9	51.2	47.6	47.1	59.1	51.7	57.9	52.4
12-17	41.6	36.3	36.2	39.4	41.5	38.1	46.3	42.1	49.6	47.1
18-44	23.2	22.9	23.5	24.3	23.9	24.2	25.6	27.8	27.6	29.3
18-24	24.2	23.0	24.5	23.9	24.4	25.2	27.2	26.5	27.2	30.1
25-44	23.1	22.9	23.4	24.4	23.8	24.1	25.4	27.9	27.6	29.3
45-64	25.7	26.1	26.6	27.3	27.4	27.9	29.4	31.1	32.1	32.3
45-54	24.0	24.9	25.5	25.2	25.8	26.2	28.4	29.5	30.6	31.2
55-64	26.8	26.9	27.4	28.6	28.4	29.0	30.1	32.1	33.1	33.0
65+	26.2	27.5	28.6	30.5	30.5	32.0	33.4	35.8	37.3	38.3
65-74	27.1	28.4	28.9	30.6	30.7	32.1	33.4	35.6	36.7	38.0
75-84	25.9	27.3	28.9	31.2	30.9	32.7	33.9	36.6	38.4	38.9
85+	22.9	24.1	26.7	27.5	28.3	29.7	31.5	33.9	36.3	37.8

Data Source: Special analyses, USRDS ESRD Database. Incident patients with a valid ESRD Medical Evidence CMS 2728 form; nephrologist care determined from Medical Evidence form. Abbreviations: CMS, Centers for Medicare and Medicaid Services; CKD, chronic kidney disease; ESRD, end-stage renal disease.

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Substantial geographic variation was also observed in the proportion of chronic kidney disease patients receiving care from a nephrologist at least 12 months before the start of renal replacement therapy (Figure 2.1). While more than 80% of U.S. states met or exceeded the HP2020 target of 29.8% in 2014, percentages varied by over 50% from the lowest quintile to the highest quintile. In general, the highest percentages of patients receiving this care were observed in the North Atlantic and Northern Plains regions, with the lowest occurring in the Mid-South and Southern Plains states.

vol 2 Figure 2.1 HP2020 CKD-10 Geographic distribution of the adjusted proportion of chronic kidney disease patients receiving care from a nephrologist at least 12 months before the start of renal replacement therapy, by state, in the U.S. population, 2014: Target 29.8%



Data Source: Special analyses, USRDS ESRD Database. Incident hemodialysis patients with a valid ESRD Medical Evidence CMS 2728 form; nephrologist care determined from Medical Evidence form. Adjusted for age, sex, and race. Abbreviations: CDC, Centers for Disease Control and Prevention; CKD, chronic kidney disease; ESRD, end-stage renal disease.

Vascular Access

In the 2015 ADR we introduced data from CROWNWeb, a dialysis data reporting system launched in 2012. Prior to the 2015 ADR, data regarding vascular access was derived from the ESRD Clinical Performance Measures (CPM) Project, which only collected this information through 2007. Vascular access is an important aspect of hemodialysis care, and arteriovenous (AV) fistulas are considered and are established as the primary access of choice. The HP2020 CKD Objective 11.1 examines the use of AV fistulas among prevalent hemodialysis patients (see Table 2.9).

In 2014, 63.9% of prevalent adult hemodialysis patients were using an AV fistula as their primary access, more than double the proportion reported in ESRD CPM data for 2000 (29.9%) and well above the last available ESRD CPM data from 2007 (49.6%; USRDS, 2012). This overall prevalence exceeded the previous HP2020 target of 50.6%, although comparisons should be made with caution as this target was derived from a different data source (ESRD CPM). Importantly, the trend of increasing AV fistula usage was observed across all race and ethnicity groups, in both males and females, and across all age groups. The only subgroup that fell just below the HP2020 target was that of patients aged 85 years and older, of whom 49.6% used AV fistulas as their primary access.

In comparison to AV fistulas, reliance on hemodialysis catheters as primary vascular access is associated with increased morbidity and mortality. HP2020 CKD objective 11.2 aims to reduce the proportion of hemodialysis patients that are dependent on catheters. Data for this objective was also obtained from CROWNWeb and thus interpretation of target achievement may be limited, as the former HP2020 target was derived from a different data source (ESRD CPM Project).

In 2014, 16.3% of prevalent adult hemodialysis patients were using catheters as the primary mode of access. This reversed the decrease seen between 2012 and 2013, and represents a 12.4% increase compared to 2013 (Table 2.10). However, this remains a significant improvement compared to the most recent data from the ESRD CPM Project which showed that 27.7% of hemodialysis patients were using a catheter in 2007. Consistent with the percentages seen for HP2020 CKD Objective 11.1, the only subgroup that did not meet the HP2020 target was that of patients aged 85 years and older, of whom 27.0% used catheters as their primary access.

vol 2 Table 2.9 HP2020 CKD-11.1: Increase the proportion of adult hemodialysis patients who use arteriovenous fistulas as the primary mode of vascular access: Previous data source target 50.6%

	2012	2013	2014
All	62.1	63.5	63.9
Race			
American Indian or Alaska Native	72.2	75.0	75.5
Asian	67.0	68.3	68.5
Native Hawaiian or Pacific Islander	65.4	68.4	68.7
Black/African American	57.4	58.7	59.1
White	64.4	65.9	66.2
Two or more races	69.8	69.8	71.0
Ethnicity			
Hispanic/Latino	67.8	68.7	69.0
Non-Hispanic	60.8	62.3	62.8
Non-Hispanic Black/African American	57.3	58.6	59.2
Non-Hispanic White	62.9	64.6	65.0
Sex			
Male	68.4	69.5	69.7
Female	54.0	55.8	56.4
Age			
18-44	66.0	66.8	67.2
18-24	65.2	67.0	68.3
25-44	66.1	66.8	67.:
45-64	64.0	65.4	65.8
45-54	65.7	66.9	67.5
55-64	62.7	64.3	64.6
65+	57.9	59.7	60.2
65-74	60.0	61.7	62.2
75-84	56.6	58.2	59.0
85+	46.9	49.5	49.6

Data Source: Special analyses, CROWNWeb. Prevalent hemodialysis patients with a valid ESRD Medical Evidence CMS 2728 form, vascular access type determined from CROWNWeb. Abbreviations: CMS, Centers for Medicare and Medicaid Services; CKD, chronic kidney disease; ESRD, end-stage renal disease.

vol 2 Table 2.10 HP2020 CKD-11.2: Reduce the proportion of adult hemodialysis patients who use catheters
as the only mode of vascular access: Previous data source target 26.1%

	2012	2013	2014
All	15.1	14.5	16.3
Race			
American Indian or Alaska Native	12.3	11.4	12.6
Asian	13.1	12.7	13.5
Native Hawaiian or Pacific Islander	14.3	14.1	14.5
Black/African American	14.3	13.7	15.2
White	16.0	15.3	17.3
Two or more races	9.6	9.2	8.1
Ethnicity			
Hispanic/Latino	13.1	12.8	14.6
Non-Hispanic	15.6	14.9	16.6
Non-Hispanic Black/African American	14.3	13.6	15.2
Non-Hispanic White	17.3	16.4	18.5
Sex			
Male	13.2	12.8	14.5
Female	17.6	16.7	18.5
Age			
18-44	14.4	13.8	15.5
18-24	17.3	15.7	16.7
25-44	14.1	13.6	15.3
45-64	14.0	13.4	15.1
45-54	13.3	12.7	14.3
55-64	14.6	13.9	15.6
65+	16.8	16.2	18.0
65-74	15.2	14.6	16.8
75-84	17.6	16.9	18.3
85+	26.6	25.2	27.0

Data Source: Special analyses, CROWNWeb. Prevalent hemodialysis patients with a valid ESRD Medical Evidence CMS 2728 form, vascular access type determined from CROWNWeb. Abbreviations: CMS, Centers for Medicare and Medicaid Services; CKD, chronic kidney disease; ESRD, end-stage renal disease.

Programs such as HP2020 and the Fistula First Initiative continue to work to increase the use of fistulas, and to promote early placement prior to initiation of ESRD therapy. In 2014, 35.7% of incident hemodialysis patients had a maturing arteriovenous fistula or were using one as their primary vascular access. This represents a 4.0% decrease from 2013, but remains a 14.4% increase from 2005, above the HP2020 target of 34.5% (see Table 2.11). This marks the fourth consecutive year that the target for this objective was met.

In 2014, the proportions of arteriovenous fistula use or maturing fistula did not meet the HP2020 target among males (32.0%), Hispanics (33.0%), Native Hawaiian or Pacific Islanders (34.0%), and Blacks (34.3%). By age group, patients aged 65-74 had the highest proportion at 37.4%, compared to 27.3% in patients aged 18-24 and 32.4% in patients aged 25-44. The proportion was also below the HP2020 target among patients aged 85 or older (29.4%).

Transplantation

The proportion of ESRD patients younger than age 70 who were wait-listed or received a kidney transplant from a deceased donor within one year of initiating dialysis therapy slightly decreased between 2013 (17.5%) and 2014 (17.1%; Table 2.12). Across race categories, the target was only exceeded by Asians (30.8%) and non-Hispanic Whites (18.6%). Additionally, males (18.3%) were much closer to the target than females (15.6%). Groups furthest from the target included American Indians or Alaska Natives (9.0%), those aged 65-69 (11.7%), and Blacks (14.3%). Gaps between groups with the highest and lowest percentages have remained fairly stable, showing only minor decreases over time.

At 13.7%, the proportion of 2011 patients younger than age 70 who received a kidney transplant within three years of starting ESRD therapy remained well below the HP2020 target of 19.7% (see Table 2.13). This continues the slow but consistent decrease observed since 1998, when 20.0% of patients received a transplant within three years of initiating ESRD therapy.

Rates were lowest among American Indians and Alaska Natives (6.4%) and Blacks (7.2%) and were highest among Whites (16.8%) and Asians (17.0%). At 14.2%, males were slightly more likely to receive a transplant as compared to females at 12.9%. The percentage of patients receiving transplants decreased with age, from 74.2% in pediatric patients to 7.9% among those aged 65-69. vol 2 Table 2.11 HP2020 CKD-11.3 Increase the proportion of adult hemodialysis patients who use arteriovenous fistulas or have a maturing fistula as the primary mode of vascular access at the start of renal replacement therapy: Target 34.5%

	2005 (%)	2006 (%)	2007 (%)	2008 (%)	2009 (%)	2010 (%)	2011 (%)	2012 (%)	2013 (%)	2014 (%)
All	31.2	32.0	31.7	31.2	32.3	33.8	35.1	36.6	37.2	35.7
Race										
American Indian or Alaska Native	36.3	39.0	37.7	41.2	41.5	41.1	40.4	40.7	42.5	40.2
Asian	35.9	37.6	35.1	35.9	35.5	37.3	37.0	37.9	41.4	38.3
Native Hawaiian or Pacific Islander	41.0	34.5	35.3	32.9	32.4	32.6	36.0	37.4	40.1	34.0
Black/African American	28.5	29.4	29.9	29.2	30.6	32.1	34.0	35.8	35.7	34.3
White	32.0	32.8	32.2	31.7	32.7	34.2	35.3	36.8	37.4	36.1
Two or more races	25.9	36.4	33.2	28.5	35.4	37.9	39.0	44.7	*	*
Ethnicity										
Hispanic/Latino	31.5	32.4	29.9	29.7	31.0	32.7	33.4	34.1	34.8	33.0
Non-Hispanic	31.2	32.0	32.0	31.5	32.5	34.0	35.4	37.0	37.6	36.2
Non-Hispanic Black/African American	28.4	29.3	29.8	29.2	30.6	32.0	33.9	35.8	35.7	34.3
Non-Hispanic White	32.1	32.9	32.8	32.3	33.2	34.8	36.0	37.6	38.3	37.1
Sex										
Male	35.0	35.2	34.9	33.9	34.9	36.3	37.8	39.0	32.7	32.0
Female	26.4	28.0	27.6	27.7	28.9	30.4	31.4	33.3	39.2	37.8
Age										
18-44	29.5	29.5	28.1	27.4	29.2	30.8	31.6	32.2	34.4	32.8
18-24	26.0	22.6	20.8	20.9	22.6	23.4	24.8	25.5	27.4	27.3
25-44	29.9	30.2	28.9	28.1	29.8	31.5	32.3	32.9	33.3	32.4
45-64	33.3	33.4	32.6	32.5	33.1	34.3	35.8	37.6	37.7	36.2
45-54	32.4	33.1	32.3	32.1	32.8	33.9	35.8	36.9	37.2	35.8
55-64	33.9	33.6	32.9	32.7	33.4	34.5	35.8	38.0	38.0	36.4
65+	30.0	31.6	31.8	31.1	32.4	34.1	35.2	36.7	37.7	36.1
65-74	31.8	33.6	34.1	33.0	34.3	35.9	37.0	38.8	39.2	37.4
75-84	29.5	30.7	30.7	30.9	32.0	33.9	35.0	36.1	37.8	36.3
85+	23.8	25.2	25.4	24.3	25.4	26.8	28.5	29.1	30.1	29.4

Data Source: Special analyses, USRDS ESRD Database. Incident hemodialysis patients aged 18 & older. Abbreviation: CKD, chronic kidney disease.

vol 2 Table 2.12 HP2020 CKD-12 Increase the proportion of dialysis patients waitlisted and/or receiving a kidney transplant from a deceased donor within 1 year of end-stage renal disease (ESRD) start (among patients under 70 years of age): Target 18.4% of dialysis patients

	2000 (%)	2001 (%)	2002 (%)	2003 (%)	2004 (%)	2005 (%)	2006 (%)	2007 (%)	2008 (%)	2009 (%)	2010 (%)	2011 (%)	2012 (%)	2013 (%)	2014 (%)
All	15.2	14.5	14.4	14.5	15.3	15.9	16.9	17.0	16.8	17.1	16.8	17.4	17.4	17.5	17.1
Race															
American Indian	13.0	9.5	10.1	9.5	10.2	10.9	10.3	11.5	10.6	11.4	11.4	11.1	12.2	12.1	9.0
or Alaska Native			-												
Asian	26.9	28.7	27.9	28.4	32.2	28.2	31.3	30.7	31.1	31.9	31.6	32.7	31.9	33.0	30.8
Native Hawaiian or Pacific	17.6	17.2	18.5	19.6	18.1	16.3	15.0	14.7	14.1	14.8	15.0	14.5	16.5	18.1	15.4
Islander	17.0	17.2	10.5	19.0	10.1	10.5	15.0	14.7	14.1	14.0	15.0	14.5	10.5	10.1	13.4
Black/African		40 5	10.0	40 5	11.0	12.0	42.4	42.2	42.2	12.0	12.0				44.2
American	11.1	10.5	10.6	10.5	11.6	12.0	13.1	13.3	13.2	13.8	13.8	14.4	14.7	14.7	14.3
White	17.0	16.2	16.1	16.3	16.7	17.6	18.5	18.5	18.2	18.2	17.7	18.3	18.3	18.3	18.1
Two or more						14.2	19.4	13.7	23.4	23.9	22.9	18.0	*	*	*
races Ethnicity															
Hispanic/Latino	12.9	12.6	13.1	13.7	14.4	15.9	17.7	17.8	17.6	18.1	17.4	18.4	17.7	17.7	16.4
Non-Hispanic	15.5	14.7	14.6	14.6	15.4	15.8	16.7	16.7	16.6	16.8	16.6	17.1	17.2	17.3	17.1
Non-Hispanic	15.5	14.7	14.0	14.0	13.4	15.0	10.7	10.7	10.0	10.0	10.0	17.1	17.2	17.5	17.1
Black/African	11.2	10.4	10.6	10.5	11.5	11.9	13.0	13.2	13.2	13.8	13.8	14.4	14.7	14.6	14.3
American															
Non-Hispanic	18.0	17.0	16.8	16.7	17.2	18.1	18.7	18.8	18.3	18.2	17.8	18.2	18.4	18.5	18.6
White	10.0	17.0	10.0	10.7	17.2	10.1	10.7	10.0	10.5	10.2	17.0	10.2	10.1	10.5	10.0
Sex															
Male	16.4	15.2	15.6	15.5	16.4	16.9	17.9	17.8	17.5	18.0	17.6	18.2	18.4	18.3	18.3
Female	13.4	13.3	12.6	12.9	13.6	14.3	15.3	15.7	15.7	15.7	15.7	16.2	16.2	16.6	15.6
Age	44.0	40.4	40.0	40.0	45 5	52.0	50 F	56.0	co 7	50.0	56.4		56.0		50.4
<18	41.3	40.1	40.8	49.8	45.5	53.9	59.5	56.9	60.7	58.8	56.1	54.4	56.8	57.0	59.1
0-4 5-11	23.5	26.7 48.8	31.1 44.4	43.6 50.0	32.7 51.1	35.4 64.2	43.0 64.3	36.7 66.5	42.7 69.1	46.2 65.3	40.2 58.8	35.7 61.6	34.2 63.2	34.7 67.9	31.6
12-17	40.6 47.3	48.8 39.8	44.4 41.6	50.0 51.5	47.4	54.2 54.9	63.3	60.5	63.9	61.1	58.8 61.7	59.5	64.2	67.9 62.1	71.1 67.8
18-44	26.3	25.1	24.4	23.6	25.2	25.0	26.3	25.7	25.4	25.7	25.0	26.7	25.5	26.2	25.9
18-24	30.8	29.1	30.3	23.0	33.2	23.0	32.5	32.4	29.9	32.5	32.1	32.3	33.1	36.1	36.0
25-44	26.0	29.1	23.8	23.1	24.5	28.0	25.7	25.1	25.0	25.1	24.3	26.1	24.8	25.2	25.0
45-64	14.1	13.4	13.3	13.5	14.1	14.6	15.6	15.8	15.5	15.8	15.6	16.2	16.6	16.3	15.7
45-54	18.2	17.3	17.0	16.6	16.8	16.9	18.3	18.5	17.3	18.2	17.8	18.4	18.8	18.5	17.9
55-64	11.1	10.5	10.6	11.4	12.1	13.1	13.8	14.0	14.3	14.1	14.2	14.7	15.2	14.9	14.3
65+	5.0	5.3	6.0	6.2	7.5	8.0	9.0	9.3	9.9	10.9	10.9	10.7	10.8	11.7	11.7
65-69	5.0	5.3	6.0	6.2	7.5	8.0	9.0	9.3	9.9	10.9	10.9	10.7	10.8	11.7	11.7

Data Source: Special analyses, USRDS ESRD Database. Incident ESRD patients younger than age 70. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease.

vol 2 Table 2.13 HP2020 CKD-13.1 Increase the proportion of patients receiving a kidney transplant within 3 years of end-stage renal disease (ESRD): Target 19.7%

	1998 (%)	1999 (%)	2000 (%)	2001 (%)	2002 (%)	2003 (%)	2004 (%)	2005 (%)	2006 (%)	2007 (%)	2008 (%)	2009 (%)	2010 (%)	2011 (%)
All	20.0	19.4	19.1	18.4	18.4	18.1	18.3	17.7	17.1	16.5	15.6	14.6	14.0	13.7
Race														
American														
Indian or	11.3	10.2	15.5	8.6	11.6	8.7	9.3	8.8	10.2	10.0	6.9	7.2	7.3	6.4
Alaska Native														
Asian	19.0	18.1	18.6	18.9	21.2	21.7	20.5	18.6	18.9	17.6	17.9	16.7	17.4	17.0
Native														
Hawaiian or	12.1	12.9	8.3	12.7	12.4	11.8	12.6	9.9	9.7	10.5	10.9	8.4	7.4	8.0
Pacific Islander														
Black/African	9.8	9.5	9.8	8.8	9.6	9.2	10.0	9.6	9.0	9.0	8.6	7.7	7.6	7.2
American														
White _	26.2	25.2	24.6	23.8	23.3	22.9	22.7	22.1	21.4	20.6	19.3	18.1	17.1	16.8
Two or more races								16.4	16.4	14.4	17.6	17.3	15.0	17.4
Ethnicity														
Hispanic/Latino	16.5	14.8	15.2	14.6	14.5	14.7	14.9	15.0	14.7	13.9	12.8	11.8	11.3	11.4
Non-Hispanic	20.1	19.7	19.4	18.7	18.8	18.4	18.6	18.0	17.3	16.8	15.9	14.9	14.3	13.9
Non-Hispanic														
Black/African	9.7	9.4	9.8	8.8	9.5	9.2	9.9	9.5	8.9	8.9	8.6	7.7	7.6	7.2
American														
Non-Hispanic	28.3	27.8	26.9	26.3	25.9	25.3	25.0	24.4	23.7	23.0	21.7	20.4	19.4	19.0
White	20.5	27.0	20.9	20.5	25.9	25.5	25.0	24.4	25.7	25.0	21.7	20.4	19.4	19.0
Sex														
Male	22.0	21.1	20.5	19.8	20.0	19.7	19.6	19.1	18.5	17.4	16.2	15.2	14.4	14.2
Female	17.6	17.4	17.3	16.6	16.3	16.1	16.5	15.8	15.3	15.3	14.8	13.7	13.4	12.9
Age														
<18	72.1	74.3	71.8	71.9	73.2	77.4	75.5	76.2	78.0	78.4	76.5	77.9	73.8	74.2
0-4	73.2	80.3	74.3	73.8	76.6	80.5	77.5	74.0	77.5	75.5	68.8	76.0	70.1	68.6
5-11	77.1	76.2	73.2	80.9	78.3	81.7	82.9	81.9	82.1	87.1	85.6	83.1	79.3	85.2
12-17	69.2	71.7	70.6	66.9	69.6	74.7	71.7	74.7	76.8	76.2	75.8	76.8	73.0	72.2
18-44	33.6	32.6	31.3	30.2	29.9	28.8	29.2	27.7	26.6	25.2	23.8	22.4	21.7	21.3
18-24	44.3	42.6	43.6	42.4	39.9	42.1	41.8	40.3	37.1	35.1	33.1	33.9	34.0	30.2
25-44	32.4	31.5	30.0	28.8	28.7	27.3	27.9	26.2	25.4	24.1	22.7	21.2	20.4	20.2
45-64	16.3	15.7	15.9	15.3	15.1	15.0	15.1	14.9	14.5	14.0	13.2	12.3	11.8	11.5
45-54	21.0	20.1	20.2	19.5	18.4	18.4	18.5	17.5	17.1	16.9	15.5	14.8	13.8	13.3
55-64	12.5	12.1	12.4	11.9	12.5	12.4	12.6	13.1	12.6	12.0	11.6	10.6	10.5	10.3
CE -														
65+	5.3	6.0	6.2	6.5	7.4	7.7	8.1	7.9	8.4	8.3	8.2	7.9	8.0	7.9

Data Source: Special analyses, USRDS ESRD Database. Incident ESRD patients younger than age 70. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease.

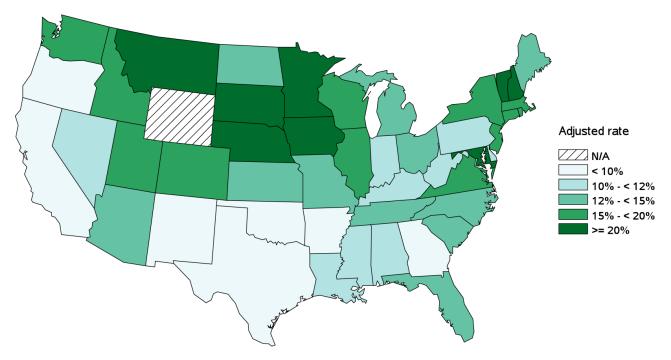
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Geographic variation in the proportion of patients receiving a kidney transplant within three years of ESRD was also observed (Figure 2.2). In 2011, just over 20% of U.S. states met or exceeded the HP2020 target of 19.7%; these were almost exclusively located in the North Atlantic and Northern Plains regions. States with the lowest percentages were generally observed throughout the South and in the West.

The percentage of patients receiving a preemptive transplant at the start of ESRD remained stable at

3.7% in 2014, consistent with the previous six years (see Table 2.14). Not surprisingly, preemptive transplants were most common in pediatric patients, reaching 31.6% among those aged five to 11.
Proportions were slightly higher among females at 3.8%, as compared to males at 3.5%. Broad variation was observed by race, however, ranging from 1.0% among Blacks to 4.2% among Whites.

vol 2 Figure 2.2 HP2020 CKD-13.1 Geographic distribution of the adjusted proportion of patients receiving a kidney transplant within 3 years of end-stage renal disease (ESRD), by state, in the U.S. population, 2011: Target 19.7%



Data Source: Special analyses, USRDS ESRD Database. Incident ESRD patients younger than age 70. Adjusted for age, sex, and race. Alaska, Hawaii, and Wyoming are not reported due to small sample size. Abbreviation: CKD, chronic kidney disease.

	2001 (%)	2002 (%)	2003 (%)	2004 (%)	2005 (%)	2006 (%)	2007 (%)	2008 (%)	2009 (%)	2010 (%)	2011 (%)	2012 (%)	2013 (%)	2014 (%)
All	3.3	3.3	3.4	3.7	3.8	4.0	4.0	3.9	3.7	3.8	3.8	3.6	3.6	3.7
Race														
American														
Indian or	*	*	1.5	*	*	1.4	*	*	1.6	*	1.6	1.3	1.2	1.3
Alaska Native														
Asian	2.0	2.9	2.6	2.5	2.8	3.0	3.1	3.5	3.1	3.4	3.8	3.2	4.5	3.9
Native														
Hawaiian or	*	*	*	*	*	1.5	1.9	2.7	1.9	1.2	*	*	*	1.2
Pacific Islander														
Black/African	0.6	0.7	0.7	0.8	0.9	1.0	1.1	1.1	1.1	1.2	1.2	1.0	1.1	1.0
American														
White -	4.2	4.2	4.1	4.6	4.9	5.1	5.2	5.0	4.7	4.7	4.8	4.5	4.3	4.2
Two or more						*	*	*	*	*	*	*	*	*
races						4		4	4			4	4.	
Ethnicity														
Hispanic/Latino	1.4	1.4	1.5	1.8	1.9	2.3	2.1	2.1	2.1	2.2	2.3	2.2	2.2	2.0
Non-Hispanic	3.2	3.3	3.3	3.6	3.9	4.0	4.1	3.9	3.7	3.8	3.9	3.5	3.6	3.5
Non-Hispanic														
Black/African American	0.6	0.7	0.7	0.8	0.9	1.0	1.1	1.1	1.1	1.2	1.2	1.0	1.1	1.0
Non-Hispanic														
White	4.8	4.9	4.9	5.4	5.8	6.1	6.3	6.0	5.5	5.6	5.7	5.3	5.2	5.0
Sex														
Male	3.5	3.4	3.5	3.6	3.9	4.2	4.1	3.8	3.7	3.8	3.8	3.5	3.4	3.5
Female	3.1	3.2	3.2	3.7	3.8	3.9	3.8	4.0	3.7	3.8	3.8	3.7	3.9	3.8
Age	5.1	5.2	5.2	5.7	5.0	5.5	5.0	-1.0	5.7	5.0	5.0	5.7	5.5	5.0
<18	20.6	19.3	21.0	19.4	23.0	23.4	20.6	20.1	24.3	22.0	23.5	23.7	23.6	22.4
0-4	18.3	13.6	19.2	19.4	16.3	17.0	18.9	11.2	18.0	14.7	18.1	17.2	17.6	13.8
5-11	22.1	26.9	29.0	20.8	27.9	31.3	29.9	30.3	32.6	30.5	28.4	29.5	31.8	31.6
12-17	20.8	17.2	18.0	18.9	23.3	22.6	17.7	19.5	23.4	21.3	23.8	24.2	22.5	22.2
18-44	5.9	5.9	5.5	6.0	5.8	6.2	5.9	5.9	5.6	5.4	5.8	5.4	5.3	5.7
18-24	8.8	8.7	9.0	9.0	8.9	10.0	8.0	8.4	8.5	8.6	8.9	8.6	5.5 7.6	10.1
25-44			5.2				5.7		5.3		5.5			
	5.6	5.6		5.7	5.4	5.8		5.7		5.1		5.1	5.1	5.3
45-64	2.7	2.7	2.8	3.1	3.3	3.5	3.6	3.4	3.2	3.4	3.3	3.1	3.1	3.2
45-54	3.7	3.7	3.8	4.0 2.5	4.2	4.3	4.6	4.2	4.0	4.3	4.0	3.7	3.7	3.8
55-64	1.9	2.0	2.1	2.5	2.7	2.9	3.0	2.9	2.7	2.9	2.9	2.7	2.8	2.9
65+	0.8	0.9	1.2	1.3	1.6	2.0	1.8	2.0	1.9	2.1	2.3	2.2	2.4	2.2
65-69	0.8	0.9	1.2	1.3	1.6	2.0	1.8	2.0	1.9	2.1	2.3	2.2	2.4	2.2

vol 2 Table 2.14 HP2020 CKD-13.2 Increase the proportion of patients who receive a preemptive transplant at the start of end-stage renal disease (ESRD): No applicable target

Data Source: Special analyses, USRDS ESRD Database. Incident ESRD patients younger than age 70. *Values for cells with 10 or fewer patients are suppressed. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease.

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Mortality

As demonstrated in Table 2.15, the total death rate among prevalent patients on dialysis has fallen by more than 25%, from 233.7 deaths per 1,000 patient years in 2001 to 172.8 in 2014, exceeding the HP2020 target of 190.0 for the fifth consecutive year. Mortality was slightly lower among males at 171.0 deaths per 1,000 patient years, compared to females, at 175.0 deaths.

Since 2001, significant reductions in rates were observed across all age groups, with the largest reduction—approximately 25% fewer deaths—for patients younger than 18 years in 2014 (32.3 deaths per 1,000 patient years) compared with 2001 (43.1 deaths). Overall rates were highest among patients aged 65 and older, at 259.0 deaths per 1,000 patient years.

With respect to race, rates among Whites were highest and continue to exceed the target at 206.3 deaths per 1,000 patient years. Rates were lowest among Native Hawaiians and Pacific Islanders (124.5 deaths per 1,000 patient years), Asians (124.9 deaths per 1,000), and Hispanics (126.6 per 1,000).

Since its peak in 2003 at 391.2 deaths per 1,000 patient years at risk, the rate of mortality among dialysis patients in the first three months after initiation has fallen by more than 22%, to 321.0 in 2014. For the third year in a row the rate was below the HP2020 target of 328.7 deaths (see Table 2.16). Whites remain the only racial group that exceeded the target rate at 376.7 deaths per 1,000. Rates were lowest among Native Hawaiians and Pacific Islanders (129.9 deaths per 1,000) and American Indians and Alaska Natives (148.0 deaths per 1,000), as well as among those with Hispanic or Latino ethnicity (179.4 deaths per 1,000). Males had lower rates than females, at 313.6 deaths per 1,000 patient years compared to 331.1 deaths per 1,000. Mortality rates were highest among those aged 85 years or older, at 860.6 deaths per 1,000 patient years.

vol 2 Table 2.15 HP2020 CKD-14.1 Reduce the total number of deaths for persons on dialysis: Target 190.0 deaths per 1,000 patient years

	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
All	233.7	231.5	229.8	226.1	222.0	217.6	208.9	201.6	196.4	189.5	185.7	178.2	174.6	172.8
Race														
American														
Indian or	203.0	195.1	189.0	183.2	177.9	171.5	163.1	167.6	170.6	152.1	146.5	144.7	143.6	150.5
Alaska Native														
Asian	170.6	156.7	167.6	159.8	163.6	153.6	150.6	138.1	139.6	130.6	133.7	128.4	123.5	124.9
Native														
Hawaiian or	162.8	178.2	168.3	165.2	151.5	160.6	160.6	146.9	153.0	148.6	135.6	133.7	119.0	124.5
Pacific Islander														
Black/African	185.4	181.9	182.0	181.3	176.7	171.1	164.5	158.0	153.5	145.9	141.2	136.2	133.9	132.2
American					-									
White	277.3	276.2	272.9	266.9	262.9	258.5	247.5	239.4	232.6	226.5	223.1	213.6	209.2	206.3
Two or more					156.2	163.9	145.9	151.1	146.9	136.2	129.4	121.5	122.3	138.4
races								-			-			
Ethnicity														
Hispanic/Latino	176.3	173.4	172.6	167.7	165.2	158.2	147.8	141.9	141.1	133.0	131.5	131.6	127.0	126.6
Non-Hispanic	237.2	237.7	237.9	235.4	231.5	228.1	220.1	212.9	207.1	200.6	196.6	188.0	184.7	182.6
Non-Hispanic														
Black/African	185.9	182.2	182.2	181.4	176.9	171.5	164.9	158.3	154.0	146.3	141.5	135.9	133.8	132.3
American														
Non-Hispanic	301.6	301.6	299.0	294.3	290.2	288.3	278.7	271.7	264.2	259.9	257.5	246.5	242.3	238.9
White														
Sex														
Male	227.2	224.8	225.0	222.0	217.8	213.5	205.8	199.1	195.9	188.1	184.7	177.5	172.5	171.0
Female	240.9	239.1	235.4	230.8	226.9	222.5	212.7	204.7	197.1	191.2	186.8	179.1	177.2	175.0
Age														
<18	43.1	40.6	48.0	39.9	41.5	38.6	34.3	34.9	39.6	35.3	25.1	32.1	30.0	32.3
0-4	164.9	96.6	109.1	81.8	87.5	98.0	79.3	97.5	98.8	72.4	43.5	62.5	71.2	64.8
5-11	39.5	*	66.9	45.6	36.4	*	*	39.9	44.8	41.9	*	*	*	37.7
12-17	17.3	35.0	28.9	29.0	33.2	27.7	23.3	15.5	19.2	20.6	15.7	18.9	*	15.7
18-44	89.8	91.2	88.2	84.8	83.1	80.1	76.2	71.1	70.4	63.8	61.7	60.0	58.3	57.7
18-24	48.2	45.7	53.8	54.2	50.5	49.6	48.4	44.5	40.3	37.2	38.0	33.5	33.9	32.3
25-44	93.2	95.0	91.1	87.3	85.8	82.6	78.5	73.3	72.9	66.0	63.6	62.0	60.2	59.5
45-64	175.4	170.6	172.1	168.5	161.9	160.4	151.6	145.2	141.6	135.8	132.9	127.4	123.0	122.4
45-54	146.1	140.4	139.5	137.6	134.1	131.7	125.8	117.5	114.0	107.5	106.1	98.6	96.9	95.3
55-64	200.3	195.8	198.8	193.3	183.4	182.3	170.9	165.6	161.6	155.8	151.2	146.8	140.3	140.3
65+	351.1	347.8	341.8	337.3	334.6	326.6	316.2	306.9	297.6	288.4	282.6	269.6	264.1	259.0
65-74	289.3	285.8	279.7	274.2	270.3	258.8	248.6	243.0	237.6	228.3	222.3	213.1	210.7	207.6
75-84	407.1		389.8	385.9	381.4	375.0	361.5	350.0	336.4	326.8	320.7	304.6	298.3	292.4
85+	566.5		551.4			520.6	514.9	489.0	469.1		454.8	436.7	425.8	418.4
1001	500.5	500.0	551.4	JJ2.J	525.0	520.0	514.3	409.0	409.1	4,00.7	404.0	430.7	423.0	410.4

Data Source: Special analyses, USRDS ESRD Database. Period prevalent dialysis patients. *Values for cells with 10 or fewer patients are suppressed. Abbreviation: CKD, chronic kidney disease.

vol 2 Table 2.16 HP2020 CKD-14.2 Reduce the number of deaths in dialysis patients within the first 3 months of initiation of renal replacement therapy: Target 328.7 deaths per 1,000 patient years at risk

	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
All	385.2	385.0	391.2	388.0	384.4	379.5	370.0	368.5	360.6	360.8	341.8	324.5	321.2	321.0
Race														
American Indian or Alaska Native	186.4	148.0	198.0	212.0	218.8	171.2	176.5	248.3	172.1	157.1	158.4	227.4	206.6	148.0
Asian	234.2	228.6	236.9	234.5	254.7	217.2	244.6	198.5	216.9	216.0	178.6	194.2	188.1	202.4
Native Hawaiian or Pacific Islander	212.5	184.0	186.0	181.9	177.6	216.9	171.4	156.3	198.1	160.7	181.1	115.8	156.7	129.9
Black/African American	277.7	269.5	283.2	278.1	279.7	271.5	256.5	258.4	250.4	247.0	230.6	213.2	222.7	225.4
White	452.9	458.5	461.2	455.7	447.0	444.2	436.7	435.4	427.3	429.1	410.3	388.9	378.7	376.7
Two or more races					316.6	285.4	276.7	290.2	204.8	265.7	256.0	*	*	*
Ethnicity														
Hispanic/Latino	253.3	233.7	248.7	232.6	248.1	222.6	222.7	214.5	205.5	207.9	205.9	196.4	187.0	179.4
Non-Hispanic	402.1	405.8	410.5	409.0	402.4	400.6	391.6	390.3	383.0	384.6	364.5	344.4	342.9	342.5
Non-Hispanic Black/African American	278.6	269.4	283.6	279.2	279.4	271.3	258.3	258.9	250.9	247.8	232.0	211.8	223.0	226.5
Non-Hispanic White	488.5	502.7	503.1	500.9	489.9	496.6	487.2	491.3	484.0	487.9	467.3	441.7	430.8	428.3
Sex														
Male	386.1	378.8	390.2	387.4	378.5	375.3	371.8	369.0	365.5	357.7	340.9	320.0	319.9	313.6
Female	384.3	392.2	392.4	388.8	391.7	384.8	367.8	367.7	354.2	364.7	343.1	330.6	323.1	331.1
Age														
<18	*	*	*	60.5	*	*	*	*	*	*	*	*	*	*
0-4	*	*	*	*	*	*	*		*	*	*	*	*	*
5-11	*	*	•	*	*	•	*	*	*	•	*	*	*	•
12-17	*	*	*	*	*	*		*	*	*	*	*	*	
18-44	102.0	104.0	106.9	107.7	106.8		100.9	100.7	107.1	94.1	91.7	71.7	78.4	71.9
18-24	71.1	49.5	65.5	77.5	62.2	92.8	67.3	57.0	46.3	65.7	56.4	*	52.1	41.4
25-44	105.2	109.8	111.3	110.8	111.5	106.2	104.5	105.3	113.2	97.0	95.6	76.3	81.1	74.7
45-64	219.1	212.9	224.2	216.4	221.2	212.8	202.3	212.0	209.0	211.1	196.0	187.7	189.8	186.6
45-54	163.9	166.3	169.1	172.1	176.9	161.3	156.0	173.0	160.9	164.8	154.5	142.2	140.6	139.3
55-64	260.2	247.8	264.9	248.4	252.2	249.3	233.9	238.0	240.7	240.4	222.6	215.7	220.6	215.8
65+	595.4	594.9	601.0	601.8	593.7	592.2	585.3	573.4	558.5	555.8	533.4	511.1	497.6	500.6
65-74	449.2	448.7	434.0		438.0	425.7	420.0	422.9	413.3	407.6	386.8	377.9	371.4	372.3
75-84	698.0	694.6	703.7					641.0	634.2	646.2	616.7	589.1	571.5	592.1
85+	1056.1	995.2	10/6.1	1027.6	1012.2	1020.9	991.4	1002.4	935.9	905.5	908.4	870.5	880.0	860.6

Data Source: Special analyses, USRDS ESRD Database. Incident dialysis patients, unadjusted. "." Zero values in this cell; *Values for cells with 10 or fewer patients are suppressed. Abbreviation: CKD, chronic kidney disease.

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Since 2001, the overall rate of cardiovascular death among those on dialysis has fallen by approximately 44%. In 2014, for the fifth consecutive year, the HP2020 goal of 80.9 cardiovascular deaths per 1,000 patient years at risk was met, with a rate of 67.2 (see Table 2.17). Though both exceeded the target, rates were lower among females (65.6 deaths per 1,000) as compared with males (68.5 deaths). Rates were lowest among Blacks (53.4 deaths per 1,000) and Asians (55.0 deaths). Cardiovascular death continued to be highest among Whites, at 78.1 deaths per 1,000 patient years. Since 2001, large reductions in rates by age have been observed, with the largest reduction—approximately 47.8% fewer deaths— for patients older than 65 years in 2014 (94.6 deaths per 1,000 patient years), compared with 2001 (181.1 deaths per 1,000).

The total death rate for patients with a functioning transplant has slowly declined since 2001, although in 2014, at 32.2 deaths per 1,000 patient years at risk, it still remained slightly above the HP2020 target of 29.3 (Table 2.18). Consistent with previous trends, males experienced higher rates of 34.2 deaths per 1,000 patient years, as compared with females at 29.1 deaths per 1,000. Rates were lowest among Asians (21.0 per 1,000) and highest among Whites (33.7 per 1,000) and American Indians and Alaska Natives (33.3 per 1,000). Death rates for patients with functioning transplants were highest among those aged 65 and older, at 74.3 deaths per 1,000 patient years compared with those aged 45-64, at 24.5, and those aged 18-44, at 7.6.

vol 2 Table 2.17 HP2020 CKD-14.3 Reduce the number of cardiovascular deaths for persons on dialysis: Target 80.9 deaths per 1,000 patient years at risk

	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
All	119.5	116.0	113.4	108.6	102.2	96.2	90.7	86.0	83.3	80.4	77.2	74.7	71.8	67.2
Race														
American														
Indian or	103.4	93.1	89.5	85.4	77.0	73.2	68.8	61.2	69.2	62.9	58.5	57.1	56.7	58.4
Alaska Native														
Asian	96.4	86.5	93.0	83.0	84.6	70.6	69.0	66.1	67.2	60.9	62.4	58.7	56.7	55.0
Native														
Hawaiian or	102.2	110.6	103.4	90.6	77.9	88.8	80.5	72.5	80.3	79.5	67.0	66.5	62.7	59.2
Pacific Islander														
Black/African	91.1	89.0	87.3	85.6	81.4	77.5	72.6	69.6	66.9	63.3	59.9	59.3	57.2	53.4
American							, 2.0			05.5		55.5		
White only	143.4	139.1	135.5	128.8	120.3	112.5	106.1	99.9	96.5	94.3	91.2	87.5	83.9	78.1
Two or more					71.2	73.3	66.8	70.2	64.5	68.1	59.7	52.2	50.6	60.1
races					, 1.2	75.5	00.0	70.2	04.5	00.1	55.7	52.2	50.0	00.1
Ethnicity														
Hispanic/Latino	94.6	90.3	86.4	83.2	80.7	73.2	67.6	65.1	65.4	62.0	60.2	59.8	58.7	57.9
Non-Hispanic	120.7	118.6	117.2	112.7	105.8	100.3	95.0	89.9	86.8	84.1	80.7	77.9	74.7	69.3
Non-Hispanic														
Black/African	91.3	89.0	87.5	85.6	81.3	77.6	72.7	69.7	67.0	63.4	60.0	59.2	57.2	53.5
American														
Non-Hispanic	155.2	151.3	148.3	141.4	131.4	124.1	118.2	111.4	107.1	105.7	102.7	98.5	93.9	86.2
White	135.2	191.9	140.5	1-1	191.4	124.1	110.2	111.4	107.1	105.7	102.7	50.5	55.5	00.2
Sex														
Male	118.7	115.3	113.6	109.5	102.7	97.1	91.7	87.6	85.5	82.2	78.9	76.7	73.5	68.5
Female	120.4	116.8	113.2	107.5	101.5	95.1	89.6	84.0	80.5	78.2	75.1	72.2	69.7	65.6
Age														
<18	14.9	11.9	9.2	12.2	17.7	17.5	9.1	10.2	17.5	*	*	10.7	*	13.1
0-4	*	*	*	*	*	*	*	*	49.4	*	*	*	*	*
5-11	*	*	*	*	*	*	*	*	*		*		*	*
12-17	*	*	*	*	18.2	13.8	*	*	*	*	*	*	*	*
18-44	41.1	41.6	39.9	39.0	38.1	35.7	33.1	31.1	31.4	29.6	27.2	27.5	26.5	25.2
18-24	20.5	20.2	25.3	25.3	24.7	19.1	18.4	15.9	18.3	19.7	18.8	14.0	15.1	11.8
25-44	42.8	43.4	41.1	40.2	39.2	37.1	34.2	32.4	32.5	30.4	27.8	28.6	27.4	26.2
45-64	90.1	86.8	85.0	81.5	76.1	73.8	68.6	65.5	63.9	61.1	59.3	57.4	55.5	53.0
45-54	73.2	69.9	67.1	64.4	61.5	60.1	56.9	53.4	52.1	47.9	48.5	45.3	44.2	42.7
55-64	104.5	101.0	99.7	95.2	87.5	84.2	77.3	74.4	72.4	70.4	66.7	65.6	63.0	59.9
65+	181.1	174.9	170.1	162.2	152.5	141.4	134.6	127.0	121.7	118.0	113.0	108.2	103.1	94.6
65-74	151.3	145.0	140.1	134.4	125.4	115.8	109.3	105.2	102.1	97.4	93.8	90.3	87.1	80.4
75-84	208.6	199.0	193.4	183.5	173.3	158.7	152.6	140.9	132.9	131.4	125.0	118.2	113.7	104.5
85+	282.9	283.2	270.8	249.2	229.6	219.2	204.4	191.8	183.2	176.0	123.0	165.0	149.7	136.5
	202.5	203.2	2,0.0	273.2	225.0	213.2	207.7	1,110	105.2	1,0.0	107.7	105.0	173.7	130.5

Data Source: Special analyses, USRDS ESRD Database. Period prevalent dialysis patients; unadjusted. *Values for cells with 10 or fewer patients are suppressed. Abbreviation: CKD, chronic kidney disease.

	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
All	33.4	31.5	32.8	31.3	32.2	31.3	31.0	29.7	31.1	31.0	31.0	31.5	31.3	32.2
Race														
American Indian or Alaska Native	39.2	37.1	41.0	39.9	38.9	43.8	36.7	37.6	54.5	45.7	43.0	43.9	34.1	33.3
Asian	20.4	20.8	18.2	20.5	21.7	18.9	24.3	18.8	17.0	16.7	21.8	22.3	18.3	21.0
Native Hawaiian or Pacific Islander	*	24.8	*	19.1	24.4	15.8	13.0	16.8	24.8	16.6	17.9	20.0	25.5	22.9
Black/African American	37.4	35.3	36.5	33.2	34.5	33.7	30.0	30.7	30.1	30.1	30.3	30.2	30.2	30.2
White	33.2	31.4	32.9	31.6	32.3	31.6	32.0	30.2	32.1	32.2	31.9	32.5	32.5	33.7
Two or more races					23.1	20.5	15.2	23.0	22.4	22.4	23.6	25.9	31.3	25.0
Ethnicity														
Hispanic/Latino	24.1	22.6	21.6	20.8	24.5	24.9	21.5	22.5	22.8	23.0	22.3	22.5	24.3	23.0
Non-Hispanic	28.8	28.0	30.9	29.6	30.1	29.5	30.2	28.9	30.3	31.0	31.6	32.7	32.6	34.0
Non-Hispanic														
Black/African American	37.8	35.6	36.4	33.4	35.0	34.0	30.1	30.9	30.0	30.4	30.4	30.5	30.2	30.5
Non-Hispanic White	34.3	32.4	34.4	33.2	33.3	32.5	33.7	31.6	33.9	33.8	33.9	34.6	34.4	36.1
Sex														
Male	35.8	33.1	34.0	33.5	34.6	33.2	33.0	31.3	32.6	33.1	33.1	33.5	32.9	34.2
Female	29.7	29.3	31.2	28.1	28.6	28.7	28.0	27.4	28.9	27.8	28.0	28.5	29.0	29.1
Age														
<18	4.8	7.9	6.7	3.5	7.2	3.8	*	2.9	3.4	6.7	2.8	3.1	*	*
0-4	*	*	*	*	*	*	*	*	*	*	*	*	*	*
5-11	*	*	*	*	*	*	*	*	*	*	*	*	*	*
12-17	*	6.8	6.1	*	7.5	*	*	*	*	6.0	*	*	*	*
18-44	14.8	14.0	12.5	11.9	12.0	11.4	10.5	9.6	9.9	8.9	8.0	7.9	7.4	7.6
18-24	9.4	4.6	4.8	6.4	7.3	8.3	5.9	6.0	6.4	6.4	4.3	4.9	4.7	3.7
25-44	15.3	14.9	13.3	12.4	12.5	11.8	11.1	10.0	10.4	9.2	8.5	8.2	7.8	8.1
45-64	38.7	34.7	35.8	32.6	33.3	31.6	29.8	28.4	28.1	27.4	27.5	25.7	25.2	24.5
45-54	30.1	27.3	26.6	24.0	25.5	24.4	22.0	21.4	21.7	19.2	18.5	16.5	16.5	15.8
55-64	51.1	44.8	47.7	43.0	42.3	39.6	38.0	35.6	34.4	35.0	35.5	33.7	32.6	31.8
65+	90.4	85.7	89.9	86.2	83.1	79.1	79.5	72.4	75.8	74.5	72.8	75.7	72.7	74.3
65-74	84.8	80.1	81.5	78.0	76.2	69.8	70.7	63.1	65.8	64.6	61.9	63.7	60.5	62.6
75-84	134.4	127.5	148.4	136.8	122.0	129.0	121.2	115.7	119.9	113.5	114.7	118.7	116.5	113.2
85+	163.3	120.6	106.0	176.3	173.1	137.0	209.4	129.5	150.3	193.1	160.8	214.2	179.8	195.9

vol 2 Table 2.18 HP2020 CKD-14.4 Reduce the total number of deaths for persons with a functioning kidney transplant: Target 29.3 deaths per 1,000 patient years at risk

Data Source: Special analyses, USRDS ESRD Database. Period prevalent transplant patients, unadjusted. *Values for cells with 10 or fewer patients are suppressed. Abbreviation: CKD, chronic kidney disease.

CHAPTER 2: HEALTHY PEOPLE 2020

Continuing to meet the HP2020 target of 4.5 deaths per 1,000 patients for the seventh year in a row, the rate of cardiovascular mortality among transplant patients has fallen by 55% since 2001, to the observed 2.5 deaths per 1,000 in 2014 (see Table 2.19). Rates were lowest among Asians at 1.3 deaths per 1,000, and Hispanics or Latinos at 1.5 per 1,000. Blacks continued to have the highest rates among race categories, at 2.8 deaths per 1,000. Also consistent with prior trends, rates were lower among females (2.0 deaths per 1,000) compared with males (2.8 per 1,000), although both remained below the HP2020 target.

vol 2 Table 2.19 HP2020 CKD-14.5 Reduce the number of cardiovascular deaths in persons with a functioning kidney transplant: Target 4.5 deaths per 1,000 patient years at risk

	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
All	5.6	5.1	5.2	5.6	5.5	5.2	5.1	4.1	4.2	4.3	3.5	3.3	3.0	2.5
Race														
American Indian or	*	0.2	*	*	*	*	*	*	*	*	*	*	C A	*
Alaska Native		9.3		4	4			4	4				6.4	
Asian	*	3.6	*	2.6	2.4	3.6	3.7	*	*	1.8	2.1	2.2	1.4	1.3
Native Hawaiian or	*	*	*	*	*	*	*	*	*	*		*	*	*
Pacific Islander											•			
Black/African	6.7	5.8	6.1	6.1	6.0	5.9	5.4	5.0	5.0	5.0	4.1	3.9	3.4	2.8
American													• •	- <i>.</i>
White	5.5	5.0	5.2	5.7	5.5	5.2	5.2	4.0	4.1	4.3	3.4	3.3	2.9	2.4
Two or more races					*	4.7	*	*	4.0	*	*	*	*	*
Ethnicity														
Hispanic/Latino	3.9	5.1	4.0	3.9	4.0	4.4	3.2	3.3	3.2	2.7	2.9	2.0	2.3	1.5
Non-Hispanic	5.4	4.9	5.4	5.3	5.4	5.1	5.2	4.1	4.3	4.6	3.6	3.6	3.2	2.7
Non-Hispanic														
Black/African	6.9	5.8	6.0	6.1	6.1	6.0	5.5	5.0	5.0	4.9	4.1	4.0	3.4	2.9
American														
Non-Hispanic White	5.7	4.9	5.4	6.0	5.7	5.3	5.5	4.2	4.3	4.6	3.5	3.5	3.0	2.6
Sex														
Male	6.2	5.5	5.5	6.2	5.9	5.6	5.8	4.6	4.2	4.8	3.9	3.4	3.3	2.8
Female	4.8	4.5	4.8	4.8	5.0	4.8	4.2	3.4	4.2	3.5	2.8	3.2	2.4	2.0
Age														
<18	*	*	*		*	*	*	*		*		*		*
0-4	*						*			*				
5-11	*	•	*			•	•		•	•	•	•		
12-17	*	*	*		*	*	*	*		*		*		*
18-44	2.5	2.5	2.3	2.3	2.2	2.0	2.0	1.7	1.4	1.4	1.0	1.1	1.2	0.7
18-24	*	*	*	*	*	*	*	*	*	*	*	*	*	*
25-44	2.6	2.7	2.5	2.5	2.3	2.1	2.1	1.8	1.5	1.5	1.0	1.2	1.3	0.8
45-64	6.8	5.7	5.8	6.1	5.8	5.7	5.2	4.2	4.0	4.1	3.3	2.8	2.6	2.1
45-54	6.4	4.3	4.6	5.1	4.5	4.3	4.4	3.2	3.2	2.8	2.2	2.0	1.9	1.3
55-64	7.4	7.7	7.4	7.3	7.3	7.2	6.0	5.2	4.7	5.2	4.4	3.6	3.2	2.8
65+	13.7	12.5	13.0	14.0	13.6	11.7	12.0	8.6	9.7	9.3	7.4	7.3	5.8	5.0
65-74	13.3	11.4	11.5	13.2	13.0	10.0	10.6	8.0	8.4	8.8	6.9	6.2	5.2	4.3
75-84	15.9	20.7	23.9	19.2	16.0	21.7	19.1	11.5	16.0	11.4	8.8	11.6	8.4	7.8
85+	*	*		*	*		*	*	*	*	*	*	*	*

Data Source: Special analyses, USRDS ESRD Database. Period prevalent transplant patients, unadjusted. "." Zero values in this cell; *Values for cells with 10 or fewer patients are suppressed. Abbreviation: CKD, chronic kidney disease.

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Healthy People 2020. *About Healthy People*. Website. ©2010-2014. Retrieved October 4, 2015 from <u>http://www.healthypeople.gov/2020/about/default.</u> <u>aspx .</u> U.S. Renal Data System, USRDS 2013 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2013. Notes



Chapter 3: Clinical Indicators and Preventive Care

Anemia

- The majority (63.3%) of hemodialysis patients in December 2015 had Hgb levels between 10-12 g/dL, while 14.7% had Hgb ≥12 g/dL, 6.8% had Hgb less than 9 g/dL, and 15.2% had Hgb between 9-10g/dL, with the mean Hgb being 10.8/dL (Figure 3.1.b).
- The majority (55.6%) of peritoneal dialysis patients in December 2015 had Hgb levels between 10-12 g/dL, while 20.3% had Hgb ≥12 g/dL, 8.0% had Hgb less than 9 g/dL, and 16.1% had Hgb between 9-10 g/dL, with the mean Hgb being 10.9 g/dL (Figure 3.1.b).
- From December 2013 to December 2014, EPO doses increased by 1.5% in hemodialysis patients and 4.5% in peritoneal dialysis patients in the United States. In 2014, average monthly EPO doses were approximately 10,524 units/week and 9,716 units/week for hemodialysis and peritoneal dialysis patients, respectively (Figures 3.2.a and 3.8.a).
- Little change was seen in IV iron use (60.6% to 61.2%) and IV iron dose (296.4 mg to 295.6 mg) from 2013 to 2014 in U.S. hemodialysis patients (Figure 3.4).
- Little change was seen in IV iron use (23.8% to 24.7%) and IV iron dose (194.3 mg to 195.5 mg) from 2013 to 2014 in U.S. peritoneal dialysis patients (Figure 3.10).
- Serum ferritin levels have fluctuated slightly in all dialysis patients from 2013 to 2015, with 54.8% of hemodialysis patients and 39.2% of peritoneal dialysis patients having serum ferritin levels >800 ng/mL in December 2015 (Figures 3.6 and 3.12).

Mineral and Bone Disorder

- In December 2015, 58.5% of hemodialysis and 56.5% of peritoneal dialysis patients had calcium levels within a typical laboratory reference range (8.4-9.5 mg/dL). About 2% of patients receiving either dialysis modality had calcium levels >10.2 mg/dL, whereas 17.7% of hemodialysis patients and 23.4% of peritoneal dialysis patients had calcium levels <8.4 mg/dL (Figures 3.14 and 3.15).
- In December 2015, 65.5% of hemodialysis patients and 69.4% of peritoneal dialysis patients had serum phosphorus levels >4.5 mg/dL (Figures 3.16 and 3.17).

Preventive Care

- In 2014, only 32.8% of ESRD patients with diabetes received comprehensive diabetes monitoring (defined as at least one HbA1c test, one lipid test, and one dilated eye exam). This is a decline from 36.4% in 2010 (Figure 3.18).
- 70.7% of patients received an influenza vaccination in the 2013-2014 flu season, which is still below the Healthy People 2020 (HP2020) target of 90%. Although stable over the last two seasons, the percent vaccinated has increased from 58.4% a decade prior (Figure 3.19.a).

Introduction

Given the high morbidity and mortality of individuals in the end-stage renal disease (ESRD) population on dialysis, initiatives aimed at quality improvement have long been a priority. Notable efforts from the Centers for Medicare & Medicaid Services (CMS) include assessment and reporting of provider performance through Dialysis Facility Reports (DFR) and Dialysis Facility Compare (DFC) (www.dialysisdata.org), as well as the Quality Incentive Program (QIP), which ties Medicare reimbursement to achievement of selected quality targets. Data collection for these projects has

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undergone a transition from paper-based data entry to web-based or electronic data entry and the data collection system is known as the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb). This system, which was implemented nationally in May 2012, allows for monthly submission of selected laboratory and clinical data from facilities for patients under their care; however, the system is still evolving and not all data are fully captured. This year, CROWNWeb data are used in this chapter for analyses on dialysis adequacy, bone and mineral disorders, and selected anemia measures.

Methods

This chapter uses data from the Centers for Medicare & Medicaid Services (CMS). Details of the data source are described in the <u>Data Sources</u> section of the *ESRD Analytical Methods* chapter.

See the section on <u>Chapter 3</u> in the *ESRD Analytical Methods* chapter for a detailed explanation of analytical methods used to generate the study cohorts, figures, and tables in this chapter.

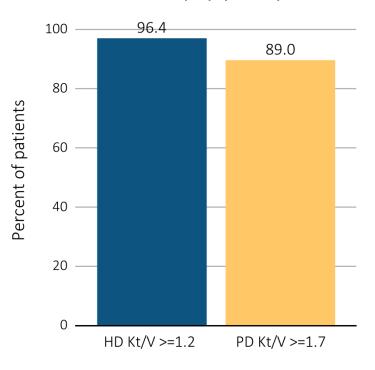
Clinical Indicators

In Figure 3.1, we present CROWNWeb data from December 2015 on a selection of clinical indicators relating to dialysis adequacy, achieved hemoglobin (Hgb) level, and hypercalcemia. Figure 3.1.a shows that achievement of dialysis adequacy targets for hemodialysis is nearly universal, with 96.4% of patients obtaining a single pool Kt/V \geq 1.2 (for more information about Kt/V see the *Glossary*). Achievement of the dialysis adequacy target for peritoneal dialysis (a weekly Kt/V \geq 1.7) is somewhat lower, at 89.0% (Figure 3.1.a).

Views on anemia treatment with erythropoiesisstimulating agents (ESAs) have evolved in recent years, as safety concerns emerged from controlled clinical trials with CKD patients who experienced greater risks of death, serious adverse cardiovascular reactions, and stroke when administered ESAs to target a hemoglobin level of greater than 11 g/dL. The results of these trials led the FDA in 2011 to recommend reducing or interrupting the dose of ESA when a patient's hemoglobin level approaches or exceeds 11 g/dL. Current guidelines do not specify an appropriate lower limit. This has resulted in generally lower Hgb levels among dialysis patients. Using CROWNWeb data, Figure 3.1.b presents a more representative view of Hgb levels for the dialysis population than was previously possible, as it includes data from both Medicare and non-Medicare insured patients. Among hemodialysis patients (both ESAtreated and non-treated), the majority (63.3%) have Hgb levels in the range of 10-12 g/dL, with 14.7% having Hgb ≥ 12 g/dL in December 2015. The pattern is similar with peritoneal dialysis patients, though a somewhat higher percentage (20.3%) have Hgb ≥12 g/dL. Later in this chapter, Medicare claims (updated through 2014) are utilized for the anemia analyses in order to provide information on time trends. In addition, CROWNWeb data are used to describe iron indices (ferritin and transferrin saturation).

In Figure 3.1.c we present CROWNWeb data on the percentage of dialysis patients having serum calcium levels >10.2 mg/dL as of December 2015, and calculated as a three-month rolling average, which is similar to methods utilized by the QIP. The rationale for this measure is to encourage avoidance of hypercalcemia given its associations with vascular calcifications and cardiovascular events. The percent of patients with hypercalcemia for both modalities has declined compared to December 2014. Later in the chapter, we present additional CROWNWeb data on trends in serum calcium and phosphorus levels.

vol 2 Figure 3.1 ESRD clinical indicators: (a) percentage of prevalent hemodialysis and peritoneal dialysis patients meeting clinical care guidelines for dialysis adequacy by modality, (b) percent distribution of Hgb levels among prevalent hemodialysis and peritoneal dialysis patients; and (c) percentage of dialysis patients with serum calcium >10.2 mg/dL by modality, CROWNWeb data, December 2015



(a) Percentage of prevalent hemodialysis and peritoneal dialysis patients meeting clinical care guidelines for dialysis adequacy by modality

(b) Percent distribution of Hgb levels among prevalent hemodialysis and peritoneal dialysis patients

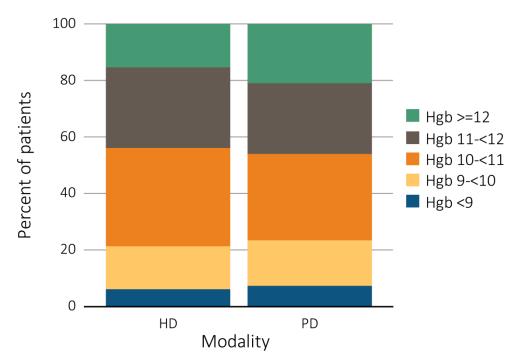
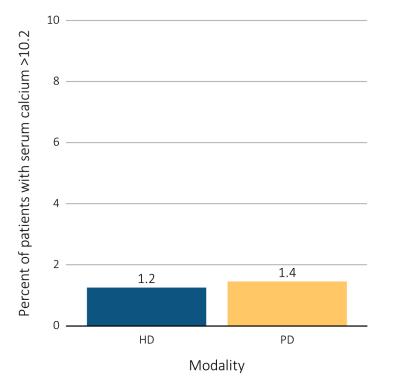


Figure 3.1 continued on next page.

vol 2 Figure 3.1 ESRD clinical indicators: (a) percentage of prevalent hemodialysis and peritoneal dialysis patients meeting clinical care guidelines for dialysis adequacy by modality, (b) percent distribution of Hgb levels among prevalent hemodialysis and peritoneal dialysis patients; and (c) percentage of dialysis patients with serum calcium >10.2 mg/dL by modality, CROWNWeb data, December 2015 (continued)



(c) Percentage of dialysis patients with serum calcium >10.2 mg/dL by modality

Data Source: Special analyses, USRDS ESRD Database. Results shown are for laboratory values reported to CROWNWeb for December 2015, restricted to patients as follows: (a) dialysis patients initiating treatment for ESRD at least 1 year prior to December 1, 2015, and who were alive through December 31, 2015; (b) dialysis patients initiating treatment for ESRD at least 90 days prior to December 1, 2015, who were ≥ 18 years old as of December 1, 2015, and who were alive through December alives patients initiating treatment for ESRD at least 90 days prior to December 1, 2015, who were ≥ 18 years old as of December 1, 2015, and who were alive through December 31, 2015; and (c) hemodialysis and peritoneal dialysis patients initiating treatment for ESRD at least 90 days prior to December 1, 2015, who were ≥ 18 years old as of December 1, 2015, and who were alive through December 31, 2015. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease; HD, hemodialysis; Hgb, hemoglobin; Kt/V, see Glossary; PD, peritoneal dialysis.

Anemia Treatment by Modality

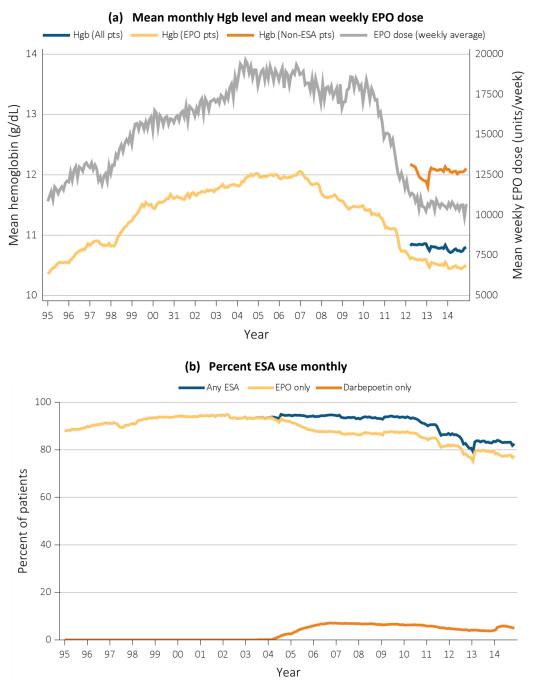
In this section, long-term trends in Hgb levels, ESA use, erythropoietin (EPO) dose, intravenous (IV) iron use, IV iron dose, levels of iron stores, and red blood cell transfusion rates are described through the year 2014 by dialysis modality in CMS claims data. Monthly mean IV iron doses are now provided for years 2005 to 2014 based on CMS claims data. Prior to 2012, to meet CMS billing requirements, Hgb values were only reported by dialysis providers when filing a claim for patients receiving an ESA during the given month. Consequently, Hgb values based on CMS claims data prior to 2012 were restricted to ESA-treated patients. Beginning in 2012, CMS required reporting of Hgb values for all patients, regardless of whether they received an ESA. This allows a comparison of Hgb values for ESA-treated patients to non-ESA treated patients and compared to all patients based upon CMS claims data beginning in April 2012.

HGB LEVELS, ESA USE, AND EPO DOSE IN HEMODIALYSIS PATIENTS

Claims data indicate that mean Hgb levels have declined substantially since they peaked near 12.0 g/dL in 2007 in ESA-treated hemodialysis patients (Figure 3.2.a). During 2011, the mean Hgb level for ESA-treated hemodialysis patients declined by 0.5 g/dL from 11.2 g/dL to 10.7 g/dL. Since then, Hgb levels have continued to slowly decline to a mean monthly Hgb of 10.5g/dL in 2014 among *ESA-treated* hemodialysis patients on dialysis \geq 90 days. Mean monthly Hgb values in 2014 were 10.8 g/dL for *all* hemodialysis patients on dialysis \geq 90 days and 12.1 g/dL for non-ESA treated patients. Similarly, analyses of CROWNWeb data have indicated a similar mean Hgb level of 10.8 g/dL for *all* hemodialysis patients in December 2014.

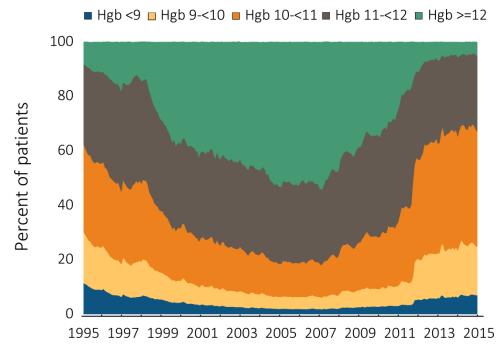
Typically, 82%-84% of hemodialysis patients on dialysis for \geq 90 days had a claim for ESA use during any single month in 2014 (Figure 3.2.b). In most months of 2014, approximately 78% of hemodialysis patients on dialysis ≥90 days received EPO and around 5% received darbepoetin. Between December 2006 and December 2014, mean weekly EPO doses (averaged over a month) have declined 44% in hemodialysis patients. Mean weekly EPO doses in 2014 were very similar to those in 2013 (Figure 3.2.a), with the mean weekly EPO dose (averaged over a month) being relatively stable throughout 2014. The mean EPO dose for hemodialysis patients on dialysis ≥ 90 days, when calculated for the prevalent cross-section of these patients in each month of 2014, and then averaged across 12 months, indicated an average weekly EPO dose of 10,524 ± 70.5 units/week in 2014.

vol 2 Figure 3.2 Anemia measures among adult hemodialysis patients on dialysis ≥90 days: (a) mean monthly Hgb level and mean weekly EPO dose (averaged over a month), and (b) percent ESA use monthly, Medicare claims, 1995-2014



Data Source: Special analyses, USRDS ESRD Database. (a) Mean monthly Hgb level among ESA-treated adult hemodialysis patients on dialysis \geq 90 days (1995 through 2014) or mean monthly Hgb level among all adult hemodialysis patients (April 2012 to December 2014 only) who, within the given month had a Hgb claim (only the first reported Hgb value in a month was used) and were on dialysis \geq 90 days; analyses were restricted to patients \geq 18 years old at the start of the month. Mean weekly EPO (epoetin alfa) dose is shown for hemodialysis patients within a given month who had an EPO claim, were on dialysis \geq 90 days, and were \geq 18 years old at the start of the month. EPO dose is expressed as mean EPO units per week averaged over all EPO claims within a given month. (b) Monthly ESA use in all hemodialysis patients who were \geq 18 years old at the start of the month and were on dialysis \geq 90 days. "EPO only" use is defined as receiving EPO but not darbepoetin; "Darbepoetin only" use is defined as receiving darbepoetin but not EPO. "Any ESA" use is defined as receiving either or both EPO and Darbepoetin. Abbreviations: EPO, erythropoietin; ESA, erythropoiesisstimulating agents; Hgb, hemoglobin. Between 2007 and 2014, a large shift has occurred in the percentage of ESA-treated adult hemodialysis patients in the highest versus lowest categories of Hgb levels (Figure 3.3). The percentage with Hgb <10 g/dL increased from 7% in 2007 to 25% in 2014 among ESAtreated patients on dialysis \geq 90 days, while the percentage with Hgb \geq 12 g/dL has declined 10-fold from 49.6% in 2007 to 4.8% in 2014. Among all (both ESA treated and non-ESA treated) hemodialysis patients on dialysis ≥90 days in December 2014, 6% had Hgb <9 g/dL, 15% had Hgb of 9 to <10 g/dL, 65% had Hgb between 10-12 g/dL, and 14% had Hgb ≥12 g/dL.

vol 2 Figure 3.3 Distribution of monthly Hgb (g/dL) levels in ESA-treated adult hemodialysis patients on dialysis ≥90 days, Medicare claims, 1995-2014



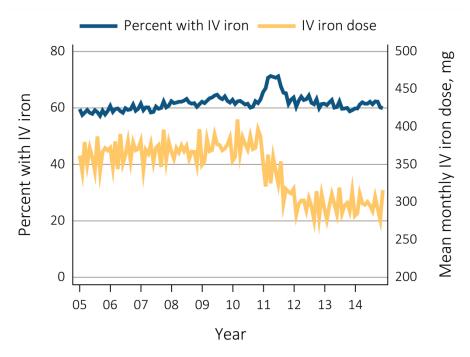
Data Source: Special analyses, USRDS ESRD Database. Distribution among hemodialysis patients within a given month who had claims for Hgb level and ESA use, were on dialysis \geq 90 days and \geq 18 years old at the start of the month. Abbreviations: ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

IV IRON USE, IV IRON DOSE, AND MEASURES OF IRON STORES IN HEMODIALYSIS PATIENTS

Trends in IV iron use for hemodialysis patients from 2005 to 2014 are shown in Figure 3.4. IV iron use increased sharply from 60.1% in August 2010 to 71.3% by April 2011, which may have been in response to the start of the CMS bundled Prospective Payment System (PPS) for dialysis services in January 2011. However, since July 2011, IV iron use has declined steadily to 59.9% by December 2014, which is what it was prior to the start of the bundled PPS in 2011. The trend in mean monthly IV iron dose is provided for 2005 through 2014, as calculated among patients with an IV iron dose claim during the month. The average mean monthly IV iron dose per year rose from 362 mg in 2005 to 378 mg in 2010. However, coincident with the 2011 implementation of the PPS, IV iron doses declined from an average mean monthly IV iron dose of 332 mg in 2011, to 297 mg in 2012, and to 296 mg in 2013 and 2014. Thus, since 2011, both IV iron use and the average monthly IV iron dose have declined in the United States among hemodialysis patients.

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vol 2 Figure 3.4 Monthly percent IV iron use and mean monthly IV iron dose in adult hemodialysis patients on dialysis ≥90 days, Medicare claims, 2005-2014

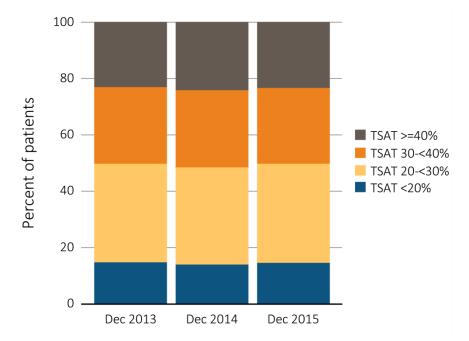


Data Source: Special analyses, USRDS ESRD Database. Monthly IV iron use is among hemodialysis patients on dialysis \geq 90 days and \geq 18 years old at the start of the given month. Mean IV iron dose was calculated as the average number of mg of IV iron given to all such patients during a month, among patients receiving iron during the month. Abbreviation: IV, intravenous.

The iron store measures, transferrin saturation (TSAT) and serum ferritin, are now reported by U.S. dialysis units as part of CROWNWeb data collection. Reporting of these measures to CROWNWeb has increased over time. For example, serum ferritin was reported for N=296,869 hemodialysis patients in 2013 versus N=354,937 hemodialysis patients in 2015. Typically, reporting of TSAT levels in hemodialysis patients has been 20%-30% lower than for serum ferritin levels. Due to the changes in reporting of data from facilities over time, the trends noted below should be interpreted cautiously.

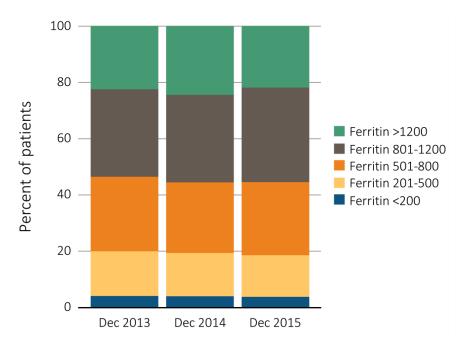
The distributions of TSAT (Figure 3.5) and serum ferritin (Figure 3.6) levels among hemodialysis

patients on dialysis ≥90 days did not differ appreciably during 2013-2015. Averaged across this time period, 15.1% of patients had a TSAT <20%, with 34.9%, 27.2%, and 22.9% of patients having TSAT levels of 20% to <30%, 30% to <40%, and ≥40%, respectively. The percentage of patients with TSAT <20% remained relatively stable varying from 14.6% to 15.4%. During 2013-2015, on average, 4.6% of patients had serum ferritin ≤200 ng/mL, with 15.4%, 25.9%, 31.9%, and 22.3% of patients having serum ferritin levels of 201-500, 501-800, 801-1200, and >1200 ng/mL, respectively. The mean serum ferritin level increased slightly from 893 to 901 ng/mL from December 2013 to December 2015. vol 2 Figure 3.5 Distribution of TSAT levels (%) in adult hemodialysis patients on dialysis for at least 90 days, CROWNWeb data, December 2013, 2014, and 2015



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for December 2013, December 2014, and December 2015. Dialysis patients on treatment for ESRD at least 90 days before the time of measurement of TSAT level for that year, \geq 18 years old as of December 1 of that year and who were alive through December 31 of that year. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; TSAT, transferrin saturation.

vol 2 Figure 3.6 Distribution of the most recent value of serum ferritin (ng/mL) level taken between October and December in adult hemodialysis patients on dialysis for at least 90 days, CROWNWeb data, 2013-2015

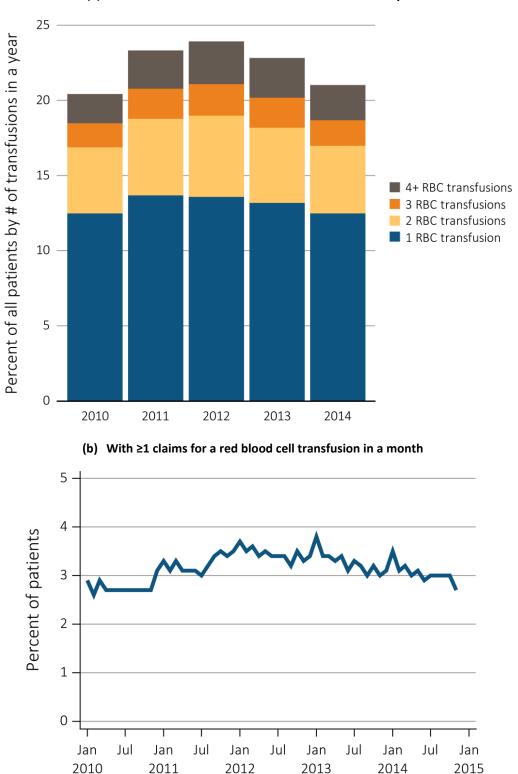


Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for October to December for years 2013, 2014, and 2015. Dialysis patients initiating treatment for ESRD at least 90 days before the time of measurement of serum ferritin for that year, \geq 18 years old as of December 1 of that year and who were alive through December 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

RED BLOOD CELL TRANSFUSIONS IN HEMODIALYSIS PATIENTS

The distribution of the number of red blood cell transfusions received by hemodialysis patients, by year, is shown in Figure 3.7.a, from 2010 through 2014, based on CMS claims data. The results shown are for all adults (≥18 years old) receiving at least one hemodialysis treatment during a given year, and represent the entire hemodialysis patient population. However, because some individuals did not receive hemodialysis therapy for the entire year, these results should be interpreted cautiously. The results indicate that 20.3% of hemodialysis patients received ≥1 red blood cell transfusion in year 2010, which increased to approximately 23.8% of patients in 2012, and decreased to 20.9% of hemodialysis patients in 2014. Across this five-year time period, typically 13%-14% of patients received one red blood cell transfusion per year, 4%-5% received two red blood cell transfusions per year, 1.6%-2.1% received 3 transfusions per year, and 2%-3% received ≥ 4 red blood cell transfusions per year. Sensitivity analyses demonstrated that the percentage of hemodialysis patients receiving ≥1 red blood cell transfusion in a year was slightly higher when including any patient who received at least one hemodialysis treatment during the year, compared to analyses of patients who underwent hemodialysis for at least 30, 90, or 180 days within the indicated year.

Trends in the percentage of hemodialysis patients with ≥ 1 red blood cell transfusions within a month, from 2010-2014, are shown in Figure 3.7.b. Overall, the percent of hemodialysis patients receiving ≥ 1 red blood cell transfusions in a month has gradually declined from 3.6% in the first quarter of 2012 to 3.0% by the third quarter of 2014. From January to November 2014, on average, 3.1% of White patients had ≥ 1 red blood cell transfusions in a month compared to 3.0% of Black patients and 2.5% of patients of Other/Unknown race. Note that since these differences were small, only the overall trend line is shown in Figure 3.7.b. vol 2 Figure 3.7 Percentage of all adult hemodialysis patients (a) by number of red blood cell transfusions received in a year, and (b) with ≥1 claims for a red blood cell transfusion in a month, from Medicare claims data, 2010-2014



(a) Number of red blood cell transfusions received in a year

Data Source: Special analyses, USRDS ESRD Database. The percentage of hemodialysis patients \geq 18 years old at the start of the month with \geq 1 red blood cell transfusion claims in a given month among hemodialysis patients having a claim for at least one dialysis session during the month. Abbreviation: RBC, red blood cell.

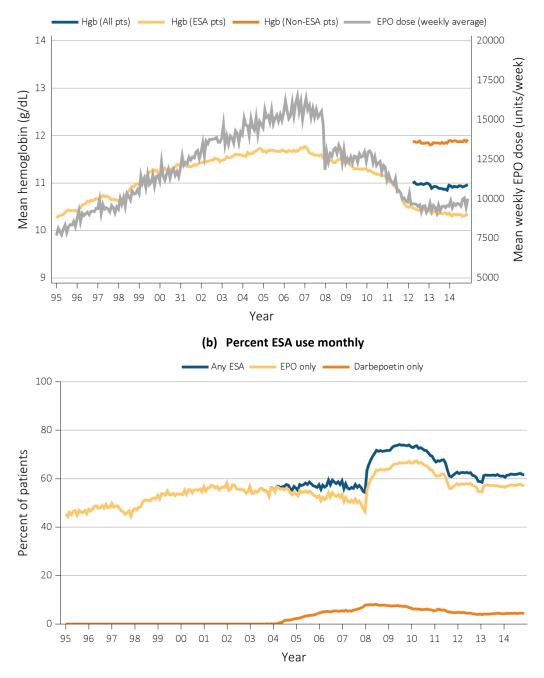
HGB LEVELS, ESA USE, AND EPO DOSE IN PERITONEAL DIALYSIS PATIENTS

Claims data indicate that mean Hgb levels have declined substantially in ESA-treated peritoneal dialysis patients since peaking near 11.8 g/dL in January 2007 (Figure 3.8.a). During 2011, the mean Hgb level for ESA-treated peritoneal dialysis patients declined 0.6 g/dL from 11.1 g/dL to 10.5 g/dL. This was a larger decline, with a lower achieved mean Hgb level than that seen for ESA-treated hemodialysis patients during 2011. Since then, Hgb levels have continued to decline to a mean monthly Hgb of 10.3 g/dL in 2014 among ESA-treated peritoneal dialysis patients on dialysis ≥90 days. In contrast, mean monthly Hgb values of 10.9 g/dL were seen for all peritoneal dialysis patients on dialysis ≥90 days and 11.9 g/dL for non-ESA treated patients in 2014. Similarly, analyses of CROWNWeb data have indicated a similar mean Hgb level of 11.0 g/dL for all peritoneal dialysis patients on December 31, 2014.

The percentage of peritoneal dialysis patients on dialysis ≥90 days with an ESA claim during any single

month was stable at 61%-62%% during 2014 (Figure 3.8.b). In most months of 2014, approximately 57% of peritoneal dialysis patients on dialysis ≥90 days received EPO and 4% received darbepoetin. Mean weekly EPO dose (averaged over a month) in peritoneal dialysis patients declined approximately 24% from December 2008 to December 2014 (Figure 3.8.a). Mean weekly EPO dose was on average 2.7% higher in 2014 than in 2013 among peritoneal dialysis patients on dialysis ≥90 days. The mean weekly EPO dose (averaged over a month) was relatively stable throughout 2014. The mean EPO dose for peritoneal dialysis patients on dialysis ≥90 days, when calculated for the prevalent cross-section of these patients in each month of 2014, and then averaged across the 12 months in 2014, indicated an average weekly EPO dose of $9,716 \pm 63$ units/week in 2014. The rapid, large decline in mean weekly EPO dose (Figure 3.8.a) and rise in percent ESA use seen at the start of 2008 (Figure 3.8.b) is under further investigation since this change also coincides with a change in the reporting codes for EPO-related claims submission at that time.

vol 2 Figure 3.8 Anemia measures among adult peritoneal dialysis patients on dialysis ≥90 days: (a) mean monthly Hgb level and mean weekly EPO dose (averaged over a month), and (b) percent ESA use monthly, Medicare claims, 1995-2014



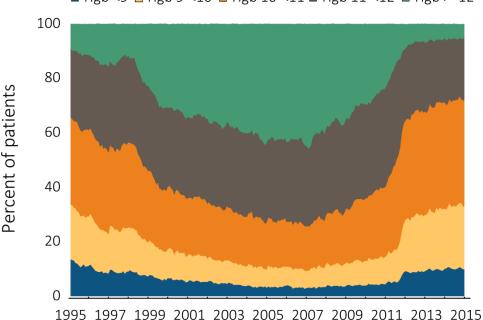
(a) Mean monthly Hgb level and mean weekly EPO dose

Data Source: Special analyses, USRDS ESRD Database. (a) Mean monthly Hgb level among ESA-treated adult peritoneal dialysis patients on dialysis \geq 90 days (1995 through 2014) or mean monthly Hgb level among all adult peritoneal patients (April 2012 to December 2014 only) who, within the given month had a Hgb claim (only the first reported Hgb value in a month was used) and were on dialysis \geq 90 days; analyses were restricted to patients \geq 18 years old at the start of the month. Mean weekly EPO (epoetin alfa) dose is shown for peritoneal patients within a given month who had an EPO claim, were on dialysis \geq 90 days, and were \geq 18 years old at the start of the month. EPO dose is expressed as mean EPO units per week averaged over all EPO claims within a given month. (b) Monthly ESA use in all peritoneal dialysis patients who were \geq 18 years old at the start of the month and were on dialysis \geq 90 days. "EPO only" use is defined as receiving EPO but not darbepoetin; "Darbepoetin only" use is defined as receiving either or both EPO and Darbepoetin. Abbreviations: EPO, erythropoietin; ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

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Between 2007 and 2014, a large shift occurred in the percentage of ESA-treated adult peritoneal dialysis patients in the highest versus lowest Hgb concentration categories (Figure 3.9). Among ESAtreated patients on dialysis \geq 90 days, the percentage with Hgb <10 g/dL increased from 11% in 2007 to 33% in 2014, while the percentage with Hgb \geq 12 g/dL declined from 41.4% in 2007 to 5.5% in 2014. Among all (both ESA treated and non-ESA treated) peritoneal dialysis patients on dialysis \geq 90 days in December 2014, 7.2% had Hgb <9 g/dL, 16.1% had Hgb of 9 to <10 g/dL, 54.6% had Hgb between 10-12 g/dL, and 22.1% had Hgb \geq 12 g/dL.

vol 2 Figure 3.9 Distribution of monthly Hgb (g/dL) levels in ESA-treated adult (≥18 years old) peritoneal dialysis patients on dialysis ≥90 days, Medicare claims, 1995-2014



■ Hgb <9 ■ Hgb 9-<10 ■ Hgb 10-<11 ■ Hgb 11-<12 ■ Hgb >=12

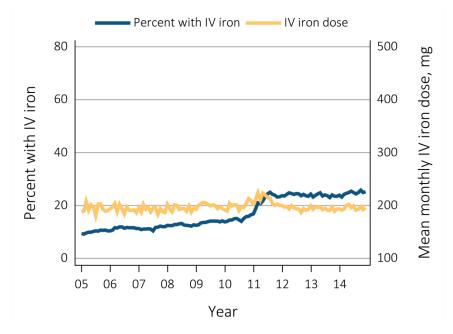
Data Source: Special analyses, USRDS ESRD Database. Distribution of Hgb levels among peritoneal dialysis patients within a given month who had claims for Hgb level and ESA use, were on dialysis \geq 90 days and \geq 18 years old at the start of the month. Abbreviations: ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

IV IRON USE, IV IRON DOSE, AND MEASURES OF IRON STORES IN PERITONEAL DIALYSIS PATIENTS

Trends in IV iron use are shown from 2005 through 2014 for peritoneal dialysis patients (Figure 3.10). IV iron use increased sharply from 14.0% in August 2010 to 25.0% by August 2011, which may have been in response to the start of the CMS bundled PPS for dialysis services in January 2011. As of the final quarter of 2014, IV iron use among peritoneal dialysis patients on dialysis \geq 90 days has remained higher at 25.3%.

The mean monthly IV iron dose per year steadily rose from 194 mg in 2005 to 211 mg in 2011. However, coincident with the 2011 implementation of the new CMS Prospective Payment System, IV iron doses have declined to an average mean monthly IV iron dose of 194-196 mg in years 2012-2014. Thus, since 2011, IV iron use in the United States has increased, while the average monthly IV iron dose among patients given iron has declined among peritoneal dialysis patients on dialysis \geq 90 days.

vol 2 Figure 3.10 Monthly IV iron use and mean monthly IV iron dose in adult peritoneal dialysis patients on dialysis ≥90 days, Medicare claims, 2005-2014



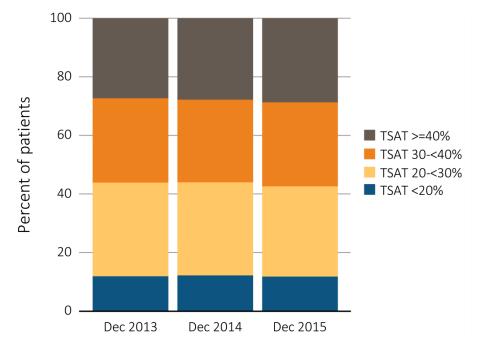
Data Source: Special analyses, USRDS ESRD Database. Monthly IV iron use is among peritoneal dialysis patients on dialysis \geq 90 days and \geq 18 years old at the start of the given month. Mean IV iron dose was calculated as the average number of mg of IV iron given to all such patients during a month, among patients receiving iron during the month. Abbreviation: IV, intravenous.

As mentioned previously, reporting of the iron store measures, transferrin saturation (TSAT) and serum ferritin, has gradually increased over time. For example, when based upon the most recent serum ferritin value reported in the prior three months, serum ferritin was reported for N=29,803 peritoneal dialysis patients in 2013 versus N=39,042 peritoneal dialysis patients in 2015. Due to the changes in facility data reporting over time, the trends noted below should be interpreted cautiously.

Across the three end-of-year cross-sections shown in Figure 3.11 for TSAT and in Figure 3.12 for ferritin, the distribution of TSAT and serum ferritin levels among peritoneal dialysis patients on dialysis \geq 90 days did not differ appreciably. Averaged across the three years, 12.6% of patients had a TSAT<20%, with 31.5%, 28.6%, and 27.3% of patients having TSAT levels of 20% to <30%, 30% to <40%, and \geq 40%, respectively. Across the 2013-2015 time period, on average, 13.0% of patients had a serum ferritin \leq 200 ng/mL, with 25.3%, 23.7%, 22.4%, and 15.7% of patients having serum ferritin levels of 201-500, 501-800, 801-1200, and >1200 ng/mL, respectively. The mean serum ferritin level slightly increased from 718 to 735 ng/mL during the December 2013 to December 2015 cross-section.

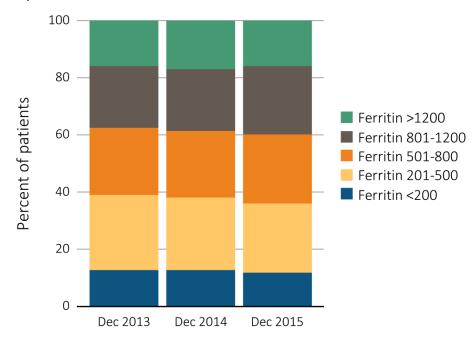
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vol 2 Figure 3.11 Distribution of TSAT levels (%) in adult peritoneal dialysis patients on dialysis for at least 90 days, CROWNWeb data, December 2013, 2014, and 2015



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for October to December for years 2013, 2014, and 2015. Dialysis patients on treatment for ESRD at least 90 days at the time of measurement of TSAT level for that year, \geq 18 years old as of December 1 of that year, and who were alive through December 31 of that year. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; TSAT, transferrin saturation.

vol 2 Figure 3.12 Distribution of the most recent serum ferritin (ng/mL) level taken between October and December in adult peritoneal dialysis patients on dialysis for at least 90 days, CROWNWeb data, December 2013, 2014, and 2015

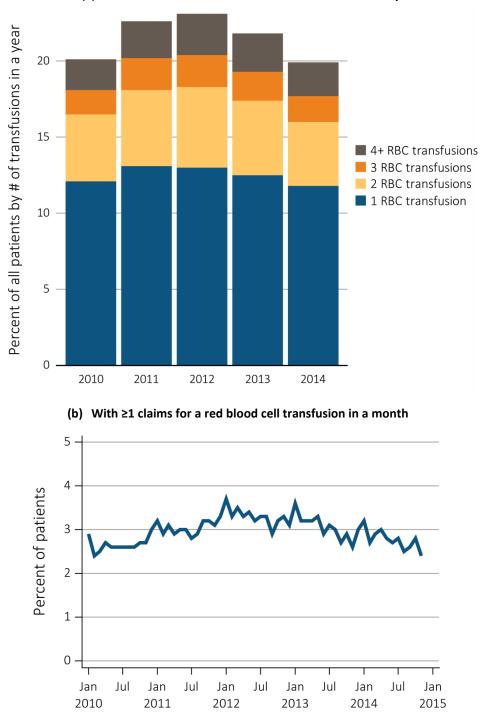


Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for October to December for years 2013, 2014, and 2015. Dialysis patients on treatment for ESRD at least 90 days at the time of measurement of serum ferritin for that year, \geq 18 years old as of December 1 of that year, and who were alive through December 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

RED BLOOD CELL TRANSFUSIONS IN PERITONEAL DIALYSIS PATIENTS

The distribution of the number of red blood cell transfusions received by peritoneal dialysis patients, by year, is shown in Figure 3.13.a, during 2010 through 2014. The results shown are for all adults (\geq 18 years old) receiving at least one peritoneal dialysis treatment during a given year. However, because some individuals did not receive peritoneal therapy for the entire year, these results should be interpreted cautiously. The results indicate that 20.0% of peritoneal dialysis patients received \geq 1 red blood cell transfusions in 2010, which increased to approximately 23% of patients in 2011 and 2012, 21.7% in 2013, and declined to 19.8% of peritoneal dialysis patients in 2014. Across this five-year time period, typically 12%-13% of peritoneal dialysis patients received 1 red blood cell transfusion per year, 4%-5% received 2 red blood cell transfusions per year, 2% received 3 transfusions per year, and 2%-3% received ≥ 4 red blood cell transfusions per year.

Trends in the percentage of peritoneal dialysis patients with one or more red blood cell transfusions within a month, during 2010-2014, are shown in Figure 3.13.b. Overall the percent of peritoneal dialysis patients receiving \geq 1 red blood cell transfusions in a month has gradually declined from 3.5% in the first quarter of 2012 to 2.6% by the third quarter of 2014. From January to November 2014, on average, 2.7% of White patients had \geq 1 red blood cell transfusions in a month compared to 3.0% of Black patients and 2.4% of patients of Other/Unknown race. Note that since these differences were small, only the overall trend line is shown in Figure 3.13.b. vol 2 Figure 3.13 Percentage of all adult peritoneal dialysis patients (a) by number of red blood cell transfusions received in a year, and (b) with ≥1 claims for a red blood cell transfusion in a month, from Medicare claims data, 2010-2014



(a) Number of red blood cell transfusions received in a year

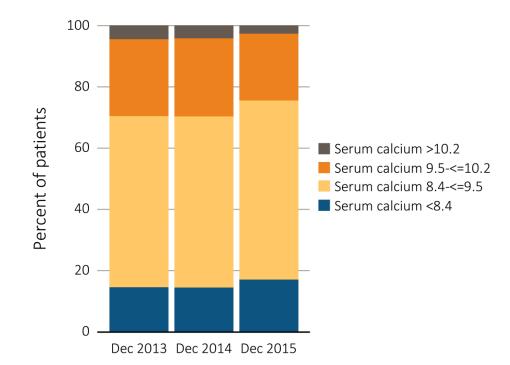
Data Source: Special analyses, USRDS ESRD Database. The percentage of peritoneal dialysis patients with \geq 1 red blood cell transfusion claims in a given month was among peritoneal dialysis patients having a claim for at least one dialysis session during the month, and who were \geq 18 years old at the start of the month. Abbreviation: RBC, red blood cell.

Mineral and Bone Disorder

Evidence from basic scientific and epidemiological studies supports the role of abnormalities in markers of mineral and bone metabolism in the pathogenesis of vascular calcifications and cardiovascular disease. which is a major cause of increased hospital admissions and mortality in the ESRD population. Specifically, elevated levels of calcium and phosphorus have been associated with increased cardiovascular events and mortality. Very low calcium and phosphorus levels have also been associated with poor outcomes; while low calcium and phosphorus levels may reflect, in part, poor nutritional status, the possibility of inappropriate treatment should also be considered in these patients. Based on these observations, current Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guidelines (KDIGO, 2009) suggest maintaining calcium and phosphorus levels in the laboratory reference range among patients on chronic dialysis.

CALCIUM

The distributions of calcium levels (based on the value in the month of December for the calendar year) among adult hemodialysis and peritoneal dialysis patients are shown in Figures 3.14 and 3.15. Between 2013 and 2015, no substantial change in calcium distribution was observed. The majority of patients (hemodialysis: 58.5%, peritoneal dialysis: 56.5%) in 2015 had calcium levels within the usual normal reference range (8.4-9.5 mg/dL), while a very small percentage (hemodialysis: 1.9%, peritoneal dialysis: 2.2%) had calcium levels >10.2 mg/dL, a cut point that reflects the quality measure that is currently included in the QIP and DFC programs. The prevalence of very low calcium levels (<8.4 mg/dL) was much higher in patients on peritoneal dialysis vs. hemodialysis (23.4% vs 17.7% in December 2015), likely due in large part to differences in dialytic treatment and serum albumin levels.

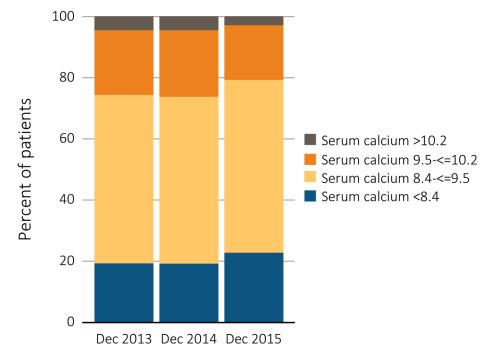




Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for October to December for years 2013, 2014, and 2015. Dialysis patients on treatment for ESRD at least 1 year at the time of measurement of serum calcium for that year, \geq 18 years old as of December 1 of that year and who were alive through December 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

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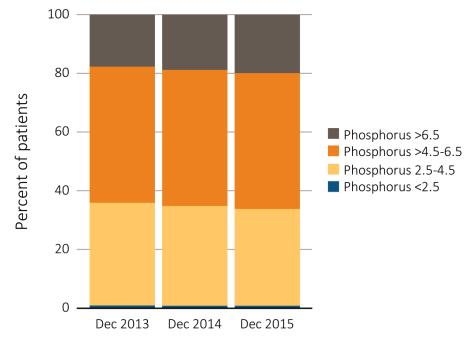
vol 2 Figure 3.15 Distribution of serum calcium levels in adult peritoneal dialysis patients on dialysis for at least 1 year, CROWNWeb data, December 2013, 2014, and 2015



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for October to December for years 2013, 2014, and 2015. Dialysis patients on treatment for ESRD at least 1 year at the time of measurement of serum calcium for that year, ≥18 years old as of December 1 of that year and who were alive through December 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

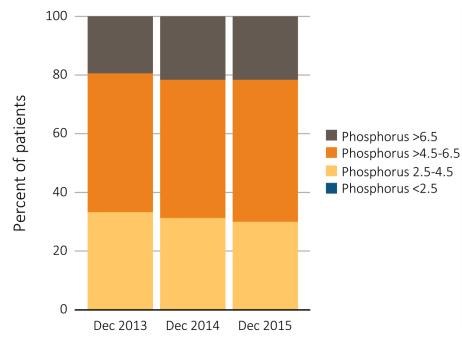
Phosphorus

The distributions of serum phosphorus levels among adult hemodialysis and peritoneal dialysis patients are shown in Figures 3.16 and 3.17. Between 2013 and 2015, a slight increase in mean serum phosphorus was observed both in hemodialysis and peritoneal dialysis patients (hemodialysis: from 5.2 to 5.3 mg/dL; peritoneal dialysis: from 5.3 to 5.5 mg/dL). KDIGO guidelines recommend maintaining phosphorus levels within the laboratory reference range (typically between 2.5 and 4.5 mg/dL). Among hemodialysis patients in December 2015, approximately two-thirds (65.5%) had serum phosphorus >4.5 mg/dL. This percentage was even higher among patients on peritoneal dialysis (69.4%), indicating a clear opportunity for improvement. Prior studies have shown that patients having low serum phosphorus levels (<2.5 mg/dL) have elevated mortality risk and have a high likelihood of malnutrition. In CROWNWeb data, in cross-sections in 2013 to 2015, a small percentage of patients had serum phosphorus levels <2.5 mg/dL (1.4%-1.5% of hemodialysis patients and 0.6%-0.7% of peritoneal dialysis patients). vol 2 Figure 3.16 Distribution of serum phosphorus (%) levels in adult hemodialysis patients on dialysis for at least 1 year, CROWNWeb data, December 2013, 2014, and 2015



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for December 2013, December 2014, and December 2015. Dialysis patients on treatment for ESRD at least 1 year at the time of measurement of serum phosphorus for that year, ≥18 years old as of December 1 of that year and who were alive through December 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

vol 2 Figure 3.17 Distribution of serum phosphorus (%) levels in adult peritoneal dialysis patients on dialysis for at least 1 year, CROWNWEB data, December 2013, 2014, and 2015



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for December 2013, December 2014, and December 2015. Dialysis patients on treatment for ESRD at least 1 year at the time of measurement of serum phosphorus for that year, ≥18 years old as of December 1 of that year and who were alive through December 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

Preventive Care

DIABETES MELLITUS

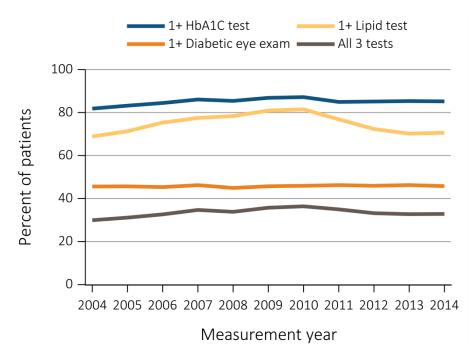
Recommendations for glycemic and lipid monitoring, treatment, and target levels in diabetic patients with ESRD are controversial. The role of regular dilated eye exams and timely treatment in preventing vision loss is, however, well-established.

From 2003 to 2010, Medicare claims show a steady increase in the percentage of ESRD patients with diabetes receiving at least one glycosylated hemoglobin (HbA1c) test and at least one lipid test per year (87.2% with at least one HbA1c test and 81.5% with at least one lipid test in 2009) (Figure 3.18). The National Committee for Quality Assurance Comprehensive Diabetes Care data also show an increase in testing over this time period in the privately insured population with diabetes (89% with at least one HbAic test and 85% with at least one lipid test in 2009) and in the Medicare population with diabetes (90% with at least one HbA1c test and 87% with at least one lipid test in 2009) compared to the data presented in this report (National Committee for Quality Assurance, 2010). In 2011, there was a slight decrease in the percentage of patients with diabetes receiving at least one HbAic test per year and a more substantial decrease in the percentage of patients

receiving at least one lipid test per year, though rates of testing have plateaued in more recent years (Figure 3.18). The decrease in HbA1c testing may reflect an increasing awareness of the limitations of HbA1c as an indicator of average glycemia in patients with ESRD. National Committee for Quality Assurance Comprehensive Diabetes Care data show a leveling off, but do not demonstrate similar decreases in HbA1c or low-density lipoprotein (LDL) cholesterol testing rates since 2010 in the privately insured, Medicaid, or Medicare populations with diabetes (National Committee for Quality Assurance, 2014). The reason for the apparent decrease in lipid testing rates in the Medicare ESRD population with diabetes is unclear, but may possibly be related to the publication of two reports demonstrating a lack of effect of statin therapy on fatal and nonfatal cardiovascular outcomes in patients undergoing hemodialysis (Wanner et al., 2005; Fellstrom et al., 2009).

The percentage of patients with annual dilated eye exams has remained low but constant over the past decade (approximately 46%, which is lower than the Healthy People 2020 target of 58.7%), with a similar pattern for the performance of all three tests (approximately 33% in the most recent year). There remains a substantial opportunity for quality improvement.

vol 2 Figure 3.18 Diabetes-related care among ESRD patients with diabetes mellitus aged 18-75 years, Medicare claims, 2004-2014



Data Source: Special analyses, USRDS ESRD Database. Point prevalent Medicare ESRD patients aged 18 to 75 years with a diagnosis claim for diabetes mellitus in the previous year and diabetes-related care in the measurement year. Abbreviations: ESRD, end-stage renal disease; HbA1c, glycosylated hemoglobin.

VACCINATION

Yearly influenza vaccination is recommended for all ESRD patients. Seasonal influenza vaccination is defined here more broadly than the typical October through March influenza season, and covers the period of August 1 through April 30 to account for early or later vaccinations. Based on Medicare claims data, the percentage of ESRD patients receiving influenza vaccination has slowly improved over the past decade, rising from 58.4% in the 2003-2004 season to 70.7% in the 2013-2014 season, though it appears to have plateaued over the last two seasons (Figure 3.19.a). However, it remains below the Healthy People 2020 (HP2020) target of 90%. The percentage of patients vaccinated is highest in older age groups, with only 44.0% of ESRD patients aged 0-21 years vaccinated in the 2013-2014 season (Figure 3.19.b). The percentage of patients vaccinated is similar in the most recent years across race/ethnicity, though slightly lower among Blacks at 68.6% in the 2013-2014

season (Figure 3.19.c). By modality, hemodialysis patients were vaccinated at the highest frequency (75.5% in the most current data), compared with 73.2% in peritoneal dialysis patients, and 53.9% in kidney transplant patients (Figure 3.19.d). The higher percentage of vaccination in hemodialysis patients may relate to the greater frequency of medical contact, providing more opportunities for vaccination. The percentage vaccinated may also be lower in transplant patients in part because vaccination is often delayed for several months after a new transplant due to concerns about an ineffective immune response or the possibility of triggering an acute rejection episode. The percentages vaccinated reported here may be underestimates, as they are derived from claims, which may not completely capture all vaccination events. Future analyses for the ADR will utilize CROWNWeb data, which should provide more complete information on vaccination, including status for other recommended vaccinations, such as for pneumococcus and hepatitis B.

vol 2 Figure 3.19 Percentage of ESRD patients with a claim for seasonal influenza vaccination (August 1-April 30 of subsequent year), (a) overall, (b) by age, (c) by race/ethnicity, and (d) by modality, Medicare data, 2003-2014

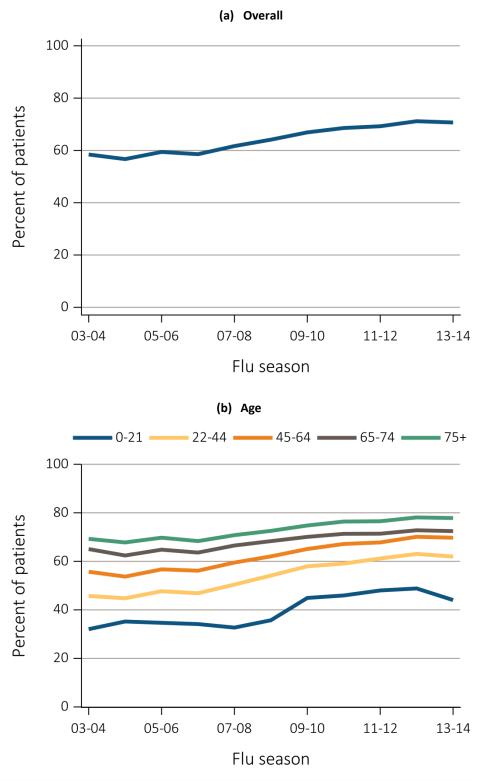
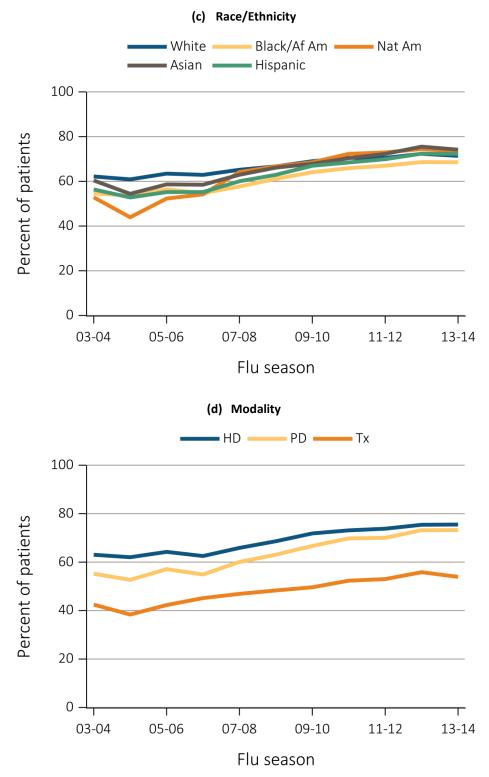


Figure 3.19 continued on next page.

vol 2 Figure 3.19 Percentage of ESRD patients with a claim for seasonal influenza vaccination (August 1-April 30 of subsequent year), (a) overall, (b) by age, (c) by race/ethnicity, and (d) by modality, Medicare data, 2003-2014 (continued)



Data Source: Special analyses, USRDS ESRD Database. ESRD patients initiating treatment for ESRD at least 90 days before seasonal period: August 1-April 30 for influenza. Abbreviations: Af Am, African American; ESRD, end-stage renal disease; HD, hemodialysis; Nat Am, Native American; PD, peritoneal dialysis; Tx, transplant.

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Chapter 4: Vascular Access

- 80.3% of patients were using a catheter at hemodialysis initiation in 2014, which has changed little since 2005 (Figure 4.1).
- At 90 days after initiation of dialysis, 68.3% of hemodialysis patients were still using a catheter in 2014 (Figure 4.7.a).
- AV fistula use at hemodialysis initiation rose from 12% to 16.9% over the period 2005-2014 (Figure 4.1).
- The percentage of patients at hemodialysis initiation using an AV fistula or with a maturing AV fistula increased from 28.9% to 33.8%, over the same period (Figure 4.1).
- The percentage of patients using an AV fistula exclusively at the end of one year on hemodialysis was 65%, up from 17% at initiation (Figure 4.7.a).
- The proportion of patients with an AV graft for vascular access was 3% at hemodialysis initiation, and 15% at 1 year after initiation (Figure 4.7.a).
- At 1 year after hemodialysis initiation, 80% of patients were using either an AV fistula or AV graft without the presence of a catheter (Figure 4.7.a).
- By December 2014, 63.4 % of prevalent dialysis patients were using an AV fistula (Figure 4.6).
- In 2014, 33.8% of AV fistulas placed failed to be in use following placement, with a median of 114 days to first AV fistula use (Table 4.7).
- The percent of AV fistula that successfully matured was higher with younger age; similarly, the median time to first AV fistula use was somewhat shorter with younger age (Table 4.7).

Introduction

Clinical practice guidelines recommend an autogenous arteriovenous (AV) fistula as the preferred vascular access for hemodialysis (National Kidney Foundation, 2006). A recent systematic review of 62 cohort studies with 586,337 patients evaluated the association between type of vascular access and risk of mortality, infection, and major cardiovascular events. While recognizing the risk of selection bias inherent in observational studies, it concluded that central venous catheters (hereafter, catheter[s]) were associated with the highest risk of death, infection, and cardiovascular events, compared with other types of vascular access, and that patients who had a usable AV fistula were at the lowest risks for these events (Ravani et al., 2013). The international Dialysis Outcomes and Practice Patterns Study (DOPPS) highlighted the fact that U.S. dialysis practices with respect to vascular access lagged behind other industrialized countries of the world (Pisoni et al., 2002; Goodkin et al., 2010; Robinson et al., 2010). In large part, these international comparisons served as impetus for implementation of the Fistula First Breakthrough Initiative (FFBI) by the Centers for Medicare & Medicaid (CMS) (Vassalotti et al., 2012). A steady increase in AV fistula placement efforts followed in the United States over the next decade, such that the proportion of prevalent hemodialysis patients using an AV fistula rose from 32% in 2003 to 63% by 2014.

A robust debate continues as to whether an AV fistula should remain the access of first choice in every dialysis patient. Although an AV fistula continues to

be considered the optimal type of vascular access in many patients owing to its potential for durability and lower risk of infection and intervention to ensure patency, the focus has shifted somewhat toward creating the most appropriate access for the individual patient, based upon the clinical situation, patient characteristics, life expectancy, patient preference, and other factors. Whether this approach will indeed prove superior can only be determined by further detailed, prospective studies, and/or clinical trials.

A landmark clinical trial where maturation of an AV fistula was a secondary outcome, revealed the high prevalence of failure of newly placed fistulas ever coming to use (Dember et al., 2008). This topic is of great interest to the nephrology community (Riella, et al., 2013) and led to the NIDDK funded Hemodialysis Fistula Maturation Study (Dember et al., 2014) designed to study this phenomenon further. Between primary surgical failures and maturation failures, 33.8% of AV fistula placements in the United States are unsuccessful (Table 4.7). The many potential factors underlying this phenomenon need to be rigorously evaluated so that primary surgical success rates and subsequent optimal maturation of the AV fistula can be ensured. In this regard, greater emphasis on AV fistula placement during surgical training may need to be prioritized in the United States (Saran et al., 2008; Goodkin et al., 2010). A number of other factors, including patient motivation for access placement, timeliness of referral for nephrology care and vascular access placement, likely impact successful AV fistula placement—suggesting that a systematic, multilevel approach is required for ensuring optimal vascular access for every hemodialysis patient (Huber, 2015).

Interventional nephrology has gained prominence in the United States over the last decade or so, introducing a new class of specialists involved with vascular access procedures to a field previously dominated primarily by surgeons and interventional radiologists trained in vascular access procedures. The impact of this phenomenon on patient outcomes has yet to be systematically studied. In addition, technological advances, such as bioengineered vessels, continue to be studied, and have the potential to influence future vascular access practice and patient outcomes. All of the above considerations make it imperative to comprehensively and carefully track vascular access placements, related practices, and outcomes. In addition to patient characteristics, other factors such as technological advances, improved surgical and medical treatments, use of specific medications, payment reform and bundling, and improved predialysis care can impact vascular access practice patterns and outcomes. Despite the emphasis on improving AV fistula success rates, at the time of their initial dialysis, 80% of patients are still using a catheter. Well-coordinated pre-dialysis care during the critical transition period to ESRD may be the key to future improvements in this suboptimal practice pattern.

This chapter describes patterns of vascular access use among incident and prevalent dialysis patients by patient characteristics and geographic region over the last decade. In addition, we explore variation in timeto-first-use of AV fistula after placement as a surrogate of AV fistula maturation across the country. Additional information describing vascular access use by dialysis providers is provided in <u>Chapter 10: Dialysis</u> <u>Providers</u> in Volume 2 of this Annual Data Report.

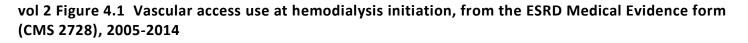
Methods

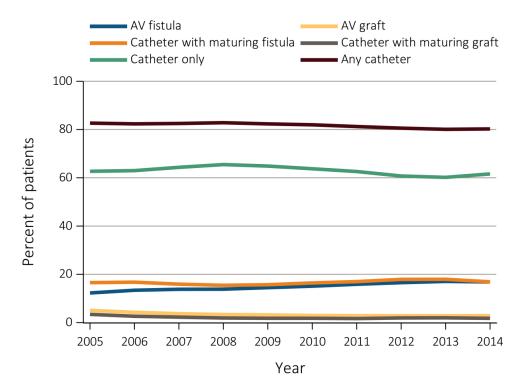
This chapter uses data from the Centers for Medicare & Medicaid Services (CMS). Details of the data source are described in the <u>Data Sources</u> section of the ESRD Analytical Methods chapter.

See the section on <u>Chapter 4</u> in the ESRD Analytical Methods chapter for an explanation of analytical methods used to generate the study cohorts, figures, and tables in this chapter.

Vascular Access Use at Initiation of Hemodialysis

A total of 80.3% of patients were using a catheter at hemodialysis initiation in 2014, which has changed little since 2005. Figure 4.1 shows that, in 2014, 61.6% of hemodialysis patients incident to ESRD had neither an AV fistula nor AV graft in place (or maturing) at their first outpatient hemodialysis session. This peaked at 65.4% in 2008, and has been relatively stable near 60% since around 2012. Over the last seven years, there has been a relatively small absolute increase in AV fistula use at hemodialysis initiation, rising from 12.3% in 2005 to 16.9% in 2014. Over the same period, the percentage of patients with either an AV fistula or a maturing AV fistula has increased from 28.9% to 33.8%.





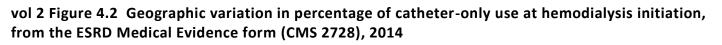
Data Source: Special analyses, USRDS ESRD Database. ESRD patients initiating hemodialysis in 2005-2014. Abbreviations: AV, arteriovenous; CMS, Centers for Medicare & Medicaid; ESRD, end-stage renal disease.

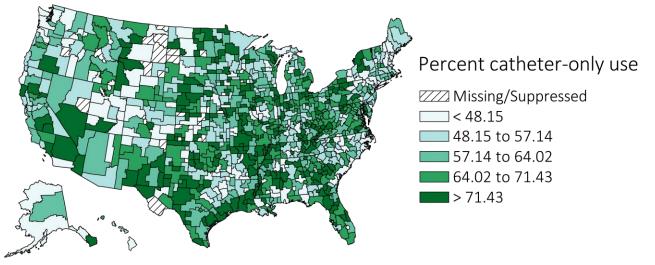
Table 4.1 shows dialysis access use at hemodialysis initiation stratified by patient characteristics. The o-21 year old age group had the highest percentage of catheter use at hemodialysis initiation (92.3%) and lowest percentage of AV fistula use (6.6%). Many of these patients were children who received a renal transplant relatively quickly, with hemodialysis serving as a bridge to transplantation, and those in the youngest age categories, who, being small, may have presented surgical challenges in creating an AVF fistula. The 65-74 year age group had the highest percentage of patients with AV fistula use at hemodialysis initiation (18.4%) with slightly lower levels of 17.1% and 16.6% AV fistula use seen for individuals \geq 75 years old and 45-64 years old, respectively. Patients of Hispanic ethnicity displayed the lowest proportion with AV fistula being used (11.7%) at hemodialysis initiation and the highest catheter alone use (69.5%). Blacks/African Americans (hereafter, Blacks) displayed the highest proportion of AV graft use at hemodialysis initiation (4.2%) compared with 1.9% to 3% for individuals of other races or of Hispanic ethnicity. Those with cystic kidney disease had higher rates of AV fistula use at hemodialysis initiation (42.8%), perhaps related to younger age at disease detection, slower progression of underlying CKD, earlier referral, and relatively preserved vasculature. vol 2 Table 4.1 Vascular access used at hemodialysis initiation by patient characteristics from the ESRD Medical Evidence form (CMS 2728), 2014

	AV fistula	AV graft	Catheter with maturing fistula	Catheter with maturing graft	Catheter only
All	16.9	2.9	16.9	1.8	61.6
Age					
0-21	6.6	0.7	10.8	0.4	81.4
22-44	13.9	1.9	17.1	1.5	65.7
45-64	16.6	2.7	18.2	1.6	60.8
65-74	18.4	3.1	17.0	1.8	59.7
75+	17.1	3.4	14.8	2.1	62.6
Sex					
Male	18.4	2.2	17.5	1.5	60.4
Female	14.8	3.8	16.1	2.2	63.2
Race/Ethnicity					
Hispanic	11.7	1.8	15.6	1.4	69.5
Non-Hispanic					
White NH	17.7	2.4	16.6	1.6	61.7
Black/African American NH	15.3	4.2	17.6	2.3	60.6
Native American NH	15.6	1.9	23.0	0.8	58.7
Asian NH	19.6	3.0	16.9	1.9	58.6
Primary Cause of ESRD					
Diabetes	17.6	3.1	19.4	1.9	58.1
Hypertension	17.1	3.0	16.1	1.8	61.9
Glomerulonephritis	18.4	2.4	15.4	1.4	62.3
Cystic Kidney	42.8	4.6	14.1	1.2	37.3
Other Urologic	14.7	2.4	14.0	1.6	67.3
Other Cause	9.3	1.9	10.6	1.4	76.8
Unknown/Missing	11.7	2.5	12.5	1.4	72.0
Comorbidities					
Diabetes	16.8	2.9	18.4	1.9	60.0
Congestive heart failure	12.9	2.5	17.6	2.0	65.0
Atherosclerotic heart disease	16.8	3.2	18.6	2.1	59.4
Cerebrovascular disease	14.7	3.5	18.2	2.4	61.1
Peripheral vascular disease	15.3	2.7	18.7	2.1	61.2
Hypertension	17.4	3.0	17.3	1.8	60.5
Other cardiac disease	14.0	2.5	16.2	1.7	65.6

Data Source: Special analyses, USRDS ESRD Database. Abbreviations: AV, arteriovenous; CMS, Centers for Medicare & Medicaid; ESRD, end-stage renal disease; NH, non-Hispanic.

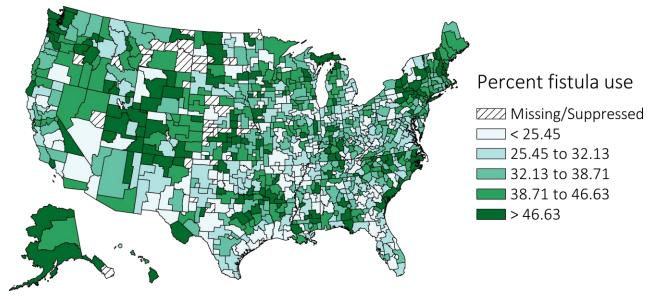
Figures 4.2 and 4.3 illustrate the geographic variation in catheter use alone and AV fistula use, respectively, at hemodialysis initiation by Health Service Area. Considerable variation is seen in both of these categorizations, even within individual states. New England, the Northwest, and parts of the East coast tend to have a lower percentage of catheter use and a higher percentage of AV fistula use at initiation. Some of the Central and Western mountain states appear to have a higher incidence of AV fistula use.





Data Source: Special analyses, USRDS ESRD Database. Abbreviations: CMS, Centers for Medicare & Medicaid; ESRD, endstage renal disease.

vol 2 Figure 4.3 Geographic variation in percentage of AV fistula use at hemodialysis initiation, from the ESRD Medical Evidence form (CMS 2728), 2014



Data Source: Special analyses, USRDS ESRD Database. Abbreviations: AV, arteriovenous; CMS, Centers for Medicare & Medicaid; ESRD, end-stage renal disease.

Vascular Access Use Among Prevalent Hemodialysis Patients

Table 4.2 shows patterns of access use among prevalent hemodialysis patients (those with ESRD for ≥90 days). By December 2014, 63.1% of prevalent hemodialysis patients were using an AV fistula. In general, demographic variation was similar to the patterns observed among incident patients. Among prevalent hemodialysis patients, the 0-21 year old age group displays the highest catheter use, while the 4564 year old age group had the lowest catheter use. Black/African Americans displayed the lowest AV fistula utilization but highest utilization of an AV graft. Highest catheter use was reported for White, non-Hispanic hemodialysis patients. When examined among individuals by primary cause of ESRD, those with cystic kidney disease maintained the highest fistula usage, although the differences in vascular access use between patients with different etiologies were smaller compared with what was observed in patients new to dialysis (Table 4.1).

vol 2 Table 4.2 Distribution of type of vascular access in use among prevalent hemodialysis patients in 2014, from CROWNWeb data, December 2014

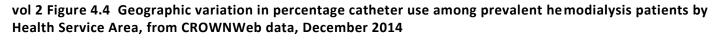
	AV fistula	AV graft	Catheter
All	63.1	18.1	18.8
Age			
0-21	49.6	6.2	44.2
22-44	65.3	15.2	19.4
45-64	64.8	17.4	17.8
65-74	62.5	18.8	18.7
75+	59.4	20.4	20.1
Sex			
Male	69.1	14.0	16.9
Female	55.4	23.4	21.2
Race/Ethnicity			
Hispanic	68.0	15.2	16.8
Non-Hispanic			
White NH	64.9	13.7	21.4
Black/ African American NH	57.7	24.9	17.4
Native American NH	75.1	10.8	14.1
Asian NH	67.5	16.3	16.2
Primary Cause of ESRD			
Diabetes	63.4	17.9	18.7
Hypertension	62.5	19.0	18.5
Glomerulonephritis	65.3	17.9	16.8
Cystic Kidney	70.1	16.7	13.2
Other Urologic	61.6	17.7	20.7
Other Cause	58.1	16.8	25.2
Unknown/Missing	62.8	17.6	19.7

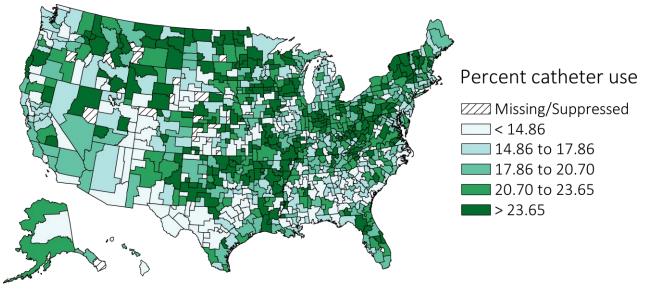
Data Source: Special analyses, USRDS ESRD Database. CROWNWeb data, catheter = any catheter use; fistula and graft use shown are without the use of a catheter. Abbreviations: AV, arteriovenous; CROWNWeb, Consolidated Renal Operations in a Web-enabled Network; CROWNWeb, Consolidated Renal Operations in a Web-enabled Network; CROWNWeb, consolidated Renal Operations in a Web-enabled Network; ESRD, end-stage renal disease; NH, non-Hispanic.

CHAPTER 4: VASCULAR ACCESS

Figure 4.4, shows the geographic variation in proportion of patients using a catheter among prevalent hemodialysis patients in the United States in 2014. Significant variation was observed across the country. Clusters of high catheter utilization are evident in parts of Montana and upper Idaho (in contrast to the Pacific Northwest), in southern Missouri, two-thirds of Arkansas and Oklahoma, and along the Appalachian Mountain range from northeastern upstate New York through parts of Pennsylvania and West Virginia, to the eastern portion of Tennessee.

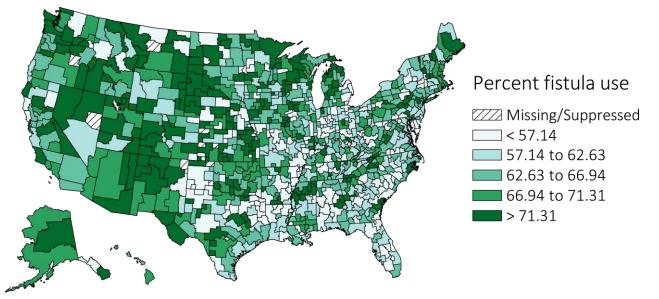
Figure 4.5 shows variation in fistula use among prevalent hemodialysis patients in the United States in 2014. While there are pockets where there is greater than 71% utilization of AV fistula among prevalent hemodialysis patients throughout the country, higher fistula use is more apparent in the western half of the country.





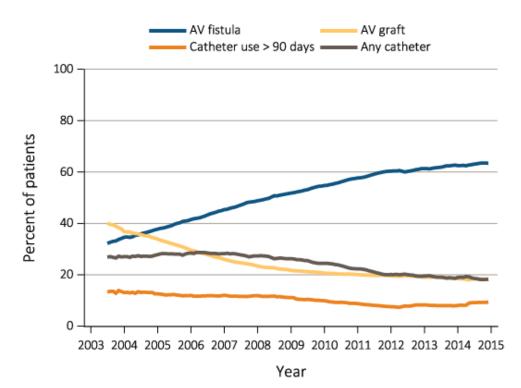
Data Source: Special analyses, USRDS ESRD Database. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-enabled Network.

vol 2 Figure 4.5 Geographic variation in percentage AV fistula use among prevalent hemodialysis patients by Health Service Area, from CROWNWeb data, December 2014



Data Source: Special analyses, USRDS ESRD Database. Abbreviations: AV, arteriovenous; CROWNWeb, Consolidated Renal Operations in a Webenabled Network.

Figure 4.6 displays trends in vascular access use among prevalent hemodialysis patients from 2003-2014. There has been a large rise in AV fistula use since 2003, with use increasing from 32% to 63% of patients. In contrast, AV graft use has decreased from 40% to 18% over the same period. Catheter use has also declined, albeit not as dramatically, decreasing from 27% to 18%. In 2014, only 9% of prevalent hemodialysis patients had been using a catheter for >90 days.



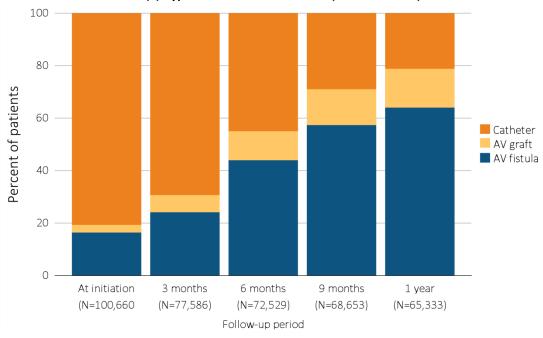
vol 2 Figure 4.6 Trends in vascular access type use among ESRD prevalent patients, 2003-2014

Data Source: Special analyses, USRDS ESRD Database and Fistula First data. Fistula First data reported from July 2003 through April 2012, CROWNWeb data are reported from June 2012 through December 2014. Abbreviations: AV, arteriovenous; CROWNWeb, Consolidated Renal Operations in a Web-enabled Network; ESRD, end-stage renal disease.

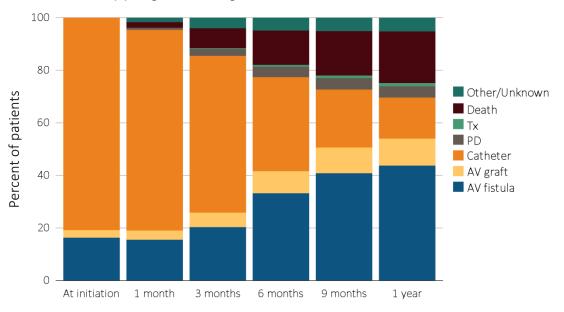
Change in Type of Vascular Access During the First Year of Dialysis

Figure 4.7.a shows cross-sectional data from both the CMS Medical Evidence form (CMS 2728) (for vascular access information at initiation) and CROWNWeb (for follow-up data with respect to vascular access in use at 3, 6, 9 months and 1 year). At 90 days, most hemodialysis patients were still using a catheter, highlighting the importance of ongoing efforts to improve pre-dialysis access planning. The percentage of patients using an AV fistula exclusively at the end of 1 year on dialysis was 65%, up from 17% seen at hemodialysis initiation. The proportion of patients with an AV graft for vascular access was 3% at initiation, and 15% at 1 year. Thus, at 1 year, 80% of patients were using either an AV fistula or AV graft without the presence of a catheter.

Figure 4.7.b displays one-year longitudinal changes in vascular access use and other outcomes in the cohort of patients who initiated ESRD via hemodialysis in 2014. In the incident ESRD hemodialysis cohort, 80.3% of patients initiated hemodialysis using a central venous catheter. After 12 months, 44.3% were using an AV fistula, 10.3% were using an AV graft, 13.6% were dialyzing with a catheter only, 2.0% were dialyzing with a catheter but had AV access in place, 1.2% were living with a kidney transplant, 4.3% were receiving peritoneal dialysis, 19.6% had died, and 4.7% were classified as other/unknown. vol 2 Figure 4.7 Change in type of vascular access during the first year of dialysis among patients starting ESRD via hemodialysis in 2014 quarterly: (a) type of vascular access in use (cross-sectional), and (b) longitudinal changes in vascular access use and other outcomes, ESRD Medical Evidence form (CMS 2728) and CROWNWeb, 2014-2015



(a) Type of vascular access in use (cross-sectional)



(b) Longitudinal changes in vascular access use and other outcomes

Data Source: Special analyses, USRDS ESRD Database. Data from January 1, 2014 to December 31, 2014: (a) Medical Evidence form (CMS 2728) at initiation and CROWNWeb for subsequent time periods. (b) ESRD patients initiating hemodialysis (N =102,367). Patients with a maturing AV fistula / AV graft with a catheter in place were classified as having a catheter. The apparent decrease in AV fistula and AV graft use at 1 month is related to missing data due to the different data sources used for incident and prevalent patients. Abbreviations: AV, arteriovenous; CMS, Centers for Medicare & Medicaid; CROWNWeb, Consolidated Renal Operations in a Web-enabled Network; ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis.

Tables 4.3 through 4.5 show cross-sectional distributions of vascular access use at several time points during the first year of hemodialysis therapy, stratified by age, race, and sex. Catheter use was most common at initiation and at the end of one year in the o-21 year old age group for reasons discussed earlier (e.g., higher transplant rates, anatomical challenges). AV graft use was higher in the 75+ age group both at initiation and at the end of one year. At 1 year, catheter use of approximately 20% is seen in all age groups, except the o-21 year old cohort, indicating that barriers still remain in establishing surgical access, even after one year. Black patients have the highest proportion of AV graft use, both at initiation and at 1 year. At 1 year, 20.0% of Black patients were using an AV graft compared to 13.0% of Asians and 12.5% of Whites. Females have a higher proportion of AV graft use and males a higher proportion of AV fistula use both at initiation and at 1 year. At 1 year, catheter use was highest in patients of other/unknown race and females. For most adult patients, an AV fistula prevalence of 60% or higher is achieved by 1 year on hemodialysis. At 1 year, the highest proportions of AV fistula were seen among males, those of Native American or Asian race, and the lowest AV fistula proportion was observed among African Americans.

vol 2 Table 4.3 Cross-sectional distributions of vascular access use, quarterly during the first year of hemodialysis, among patients new to hemodialysis in 2014, by age group, from the ESRD Medical Evidence form (CMS 2728) and CROWNWeb, 2014-2015

A	A			Time		
Age	Access type	At initiation	3 months	6 months	9 months	1 year
0-21	AV fistula	6.7	12.1	32.7	40.5	47.0
	AV graft	0.7	0.8	1.7	3.8	3.9
	Catheter	92.6	87.1	65.6	55.6	49.1
22-44	AV fistula	13.9	21.5	44.3	58.6	66.3
	AV graft	1.9	4.5	7.6	10.0	10.6
	Catheter	84.3	74.0	48.1	31.4	23.1
45-64	AV fistula	16.7	24.7	45.5	59.7	66.7
	AV graft	2.8	5.7	9.6	11.9	13.0
	Catheter	80.5	69.6	44.9	28.4	20.4
65-74	AV fistula	18.6	26.5	45.7	58.8	65.2
	AV graft	3.1	6.6	11.4	14.1	15.4
	Catheter	78.3	66.9	42.9	27.1	19.4
75+	AV fistula	17.2	24.3	41.8	53.9	59.9
	AV graft	3.5	9.0	15.0	18.1	19.4
	Catheter	79.4	66.7	43.2	28.1	20.7

Data Source: Special analyses, USRDS ESRD Database. Medical Evidence form (CMS 2728) at initiation and CROWNWeb for subsequent time periods. Abbreviations: AV, arteriovenous; CMS, Centers for Medicare & Medicaid; CROWNWeb, Consolidated Renal Operations in a Web-enabled Network; ESRD, end-stage renal disease.

				Time		
Race	Access type	At initiation	3 months	6 months	9 months	1 year
Native American	AV fistula	16.0	25.9	53.9	67.8	75.0
	AV graft	2.0	4.0	6.9	8.3	9.4
	Catheter	82.0	70.0	39.2	23.9	15.6
Asian	AV fistula	19.3	27.1	49.4	62.5	69.7
	AV graft	2.9	6.7	10.3	12.2	13.0
	Catheter	77.8	66.2	40.3	25.3	17.3
Black/African American	AV fistula	15.3	21.6	39.4	52.0	58.5
	AV graft	4.2	9.2	15.0	18.3	20.0
	Catheter	80.5	69.2	45.6	29.6	21.5
White	AV fistula	17.5	25.8	46.3	60.1	66.9
	AV graft	2.4	5.4	9.4	11.7	12.5
	Catheter	80.1	68.7	44.3	28.2	20.6
Other/Unknown	AV fistula	14.9	21.5	42.9	62.5	66.7
	AV graft	4.2	6.0	10.7	11.0	10.3
	Catheter	81.0	72.5	46.3	26.5	23.1

vol 2 Table 4.4 Cross-sectional distributions of vascular access use, quarterly during the first year of hemodialysis among patients new to hemodialysis in 2014, by race, from the ESRD Medical Evidence form (CMS-2728) and CROWNWeb, 2014-2015

Data Source: Special analyses, USRDS ESRD Database. Medical Evidence form (CMS 2728) at initiation and CROWNWeb for subsequent time periods. Abbreviations: AV, arteriovenous; CMS, Centers for Medicare & Medicaid; CROWNWeb, Consolidated Renal Operations in a Web-enabled Network; ESRD, end-stage renal disease.

vol 2 Table 4.5 Cross-sectional distributions of vascular access use, quarterly during the first year of hemodialysis among patients new to hemodialysis in 2014, by sex, from the ESRD Medical Evidence form (CMS 2728) and CROWNWeb, 2014-2015

Sex		Time						
	Access type	At initiation	3 months	6 months	9 months	1 year		
Male	AV fistula	18.4	27.9	50.4	64.2	70.9		
	AV graft	2.2	5.1	8.6	10.6	11.4		
	Catheter	79.3	66.9	41.1	25.2	17.7		
Female	AV fistula	14.9	20.2	36.5	49.3	55.9		
	AV graft	3.8	8.5	14.5	17.9	19.5		
	Catheter	81.2	71.2	49.0	32.9	24.6		

Data Source: Special analyses, USRDS ESRD Database. Medical Evidence form (CMS 2728) at initiation and CROWNWeb for subsequent time periods. Abbreviations: AV, arteriovenous; CMS, Centers for Medicare & Medicaid; CROWNWeb, Consolidated Renal Operations in a Web-enabled Network; ESRD, end-stage renal disease.

Predictors of AV Fistula Use at Hemodialysis Initiation

Programs such as Fistula First and Fistula First Catheter Last were created to inform and educate the medical community on the higher morbidity, mortality, and costs associated with catheter use, while encouraging greater AV fistula use. Although AV fistula use has increased greatly in prevalent patients, improvement in AV fistula use at initiation continues to lag behind. Many reasons can be postulated for these trends, such as access to primary and/or nephrology care, disparities in health-care access, difficulty in AV fistula maturation in certain patient groups, such as the elderly diabetic or those with limited transportation or financial incentives, and the wide variety of health care providers with differing expertise in creating AV fistula for dialysis patients. The following figures and tables examine associations between clinical and patient characteristics and

successful surgical access use (AV fistula as well as AV fistula/AV graft use) at initiation of hemodialysis.

Table 4.6 examines patient characteristics as well as factors such as length of pre-ESRD care and ESRD networks. Asians have the highest odds of AV fistula use at hemodialysis initiation, while both Asians and Blacks have the highest odds of a surgical access (AV fistula or AV graft) in use at hemodialysis initiation, with females less likely to be using an AV fistula/AV graft at initiation. ESRD Network 16 (Northwest Renal Network) displays the highest odds of patients using an AV fistula at initiation as well as higher odds of AV fistula or AV graft use at hemodialysis initiation. Patients with ESRD secondary to diabetes are less likely to use an AV fistula or AV graft at hemodialysis initiation compared with patients for whom the primary cause of ESRD was not diabetes. This model has somewhat different findings from other published models, such as that by Zarkowsky, et al. (2015), as it adjusts for different covariates.

vol 2 Table 4.6 Odds ratios and 95% confidence intervals from logistic regression models of (a) AV fistula use at hemodialysis initiation, and (b) AV fistula or graft use at hemodialysis initiation, from the ESRD Medical Evidence form (CMS 2728), 2014

	AV fistu	la use at ini	tiation	AV fistula d	or graft use a	t initiatio	
	95% confidence				95% confiden		
	Odds ratio	inte	rval	Odds	inte	erval	
Predictors		Lower	Upper	ratio	Lower	Upper	
Predictors		bound	bound		bound	bound	
Pre-ESRD nephrology care							
0 months	0.05	0.05	0.06	0.06	0.06	0.07	
>0 -<6 months	0.28	0.26	0.29	0.29	0.28	0.31	
6-12 months	0.59	0.56	0.62	0.60	0.57	0.62	
>12 months	Ref.			Ref.			
Unknown	0.20	0.18	0.21	0.20	0.19	0.21	
Age							
0-21	0.31	0.23	0.42	0.28	0.21	0.38	
22-44	0.89	0.84	0.96	0.84	0.79	0.90	
45-64	Ref			Ref			
65-74	1.01	0.97	1.06	1.04	0.99	1.08	
75+	0.89	0.85	0.93	0.95	0.91	0.99	
Sex							
Female	0.74	0.72	0.77	0.85	0.83	0.88	
Male	Ref			Ref			
Race							
Hispanic	0.77	0.69	0.86	0.76	0.69	0.84	
Non-Hispanic							
White NH	Ref			Ref			
Black/African American NH	0.97	0.93	1.01	1.13	1.09	1.18	
Native American NH	0.81	0.68	0.98	0.82	0.69	0.98	
Asian NH	1.03	0.95	1.12	1.03	0.95	1.11	
Other/Unknown NH	0.82	0.58	1.15	0.96	0.70	1.31	
Diabetes as cause of ESRD	0.96	0.93	0.99	0.98	0.95	1.01	
Facility census						-	
< 20	Ref			Ref			
20-50	0.94	0.91	0.98	0.93	0.89	0.96	
51-100	0.75	0.70	0.81	0.71	0.66	0.77	
101-200	0.36	0.24	0.54	0.47	0.34	0.66	
>200	1.17	0.85	1.61	1.38	1.03	1.84	
ESRD network							
1 (vs. average network)	1.13	1.04	1.23	1.11	1.02	1.20	
2 (vs. average network)	1.08	1.01	1.16	1.07	1.01	1.14	
3 (vs. average network)	0.84	0.78	0.92	0.87	0.80	0.94	
4 (vs. average network)	0.97	0.89	1.04	1.01	0.94	1.08	
5 (vs. average network)	0.99	0.92	1.04	0.93	0.87	1.00	
6 (vs. average network)	1.02	0.96	1.00	1.01	0.96	1.00	
7 (vs. average network)	0.68	0.63	0.73	0.69	0.64	0.74	
8 (vs. average network)	0.95	0.88	1.02	0.96	0.89	1.03	
9 (vs. average network)	0.98	0.92	1.04	0.97	0.92	1.03	
10 (vs. average network)	0.91	0.83	0.99	0.92	0.85	1.00	
11 (vs. average network)	1.01	0.95	1.08	0.98	0.92	1.00	
12 (vs. average network)	0.86	0.78	0.94	0.86	0.79	0.94	
13 (vs. average network)	1.08	1.00	1.17	1.03	0.95	1.11	
14 (vs. average network)	0.73	0.69	0.78	0.78	0.73	0.83	
15 (vs. average network)	1.24	1.15	1.34	1.16	1.08	1.25	
16 (vs. average network)	1.24	1.30	1.54	1.44	1.33	1.56	
17 (vs. average network)	1.42	1.18	1.34	1.44	1.33	1.50	
18 (vs. average network)	1.28	1.18	1.38	1.30	1.27	1.47	

Data Source: Special analyses, USRDS ESRD Database. For more on ESRD networks, see <u>http://www.cms.gov/About-CMS/Agency-</u> <u>Information/RegionalOffices/RegionalMap.html</u>. Abbreviations: AV, arteriovenous; CMS, Centers for Medicare & Medicaid; ESRD, end-stage renal disease.

Fistula Maturation

Timely fistula maturation is an area of central interest for the dialysis community. While AV fistula utilization among prevalent hemodialysis patients has improved (Figure 4.6), the proportion of patients using a dialysis catheter at incidence of ESRD remains high (Figure 4.1). Limiting catheter exposure time is critical, as prolonged catheter use is often associated with bacteremia, sepsis, thrombosis, and central venous stenoses (Morsy et al., 1998), which limits future access survival, as well as poor long-term patient outcomes (Pisoni et al., 2009). "Observational data indicate catheter use is associated with higher mortality risk, compared to other access types, potentially through the greater risk for sepsis and as a source of inflammation due to the 'foreign body' in the bloodstream effect, biofilm formation and other mechanisms, which may cause persistent adverse outcomes even after catheter removal" (Foley et al., 2004). While AV grafts are ready for use sooner and more reliably, they require more procedures to assure their long-term patency. They are associated with a higher frequency of other complications that can significantly impact mortality and morbidity, including dialysis access-associated ischemia (also known as "distal hypoperfusion ischemic syndrome" or "steal syndrome") and infections (Churchill et al., 1992; Stevenson, 2002; Ravani, 2013), adding significant risk with this choice of conduit. These complications can also have a significant impact on quality of life as well. Furthermore, the premature use of an AV graft may limit access options in the future (National Kidney Foundation, 2006) — a significant concern for those with longer life expectancy. At the present time, it is unclear whether prolonged AV fistula maturation time, and the risks associated with prolonged catheter exposure should warrant prioritizing AV graft placement in certain patient populations such as the elderly. Conversion from a catheter to permanent access of either type has been shown to be associated with better patient outcomes (Bradbury et al., 2009).

In an effort to better understand which patients experience longer maturation times, data on

prevalent hemodialysis patients was examined, as these patients are more likely to experience use of their AV fistula as soon as it is reasonable to do so. Fistula placement was identified through inpatient, outpatient, and physician/supplier Medicare claims using the following ICD-9 procedure codes: 36818, 36819, 36820, 36821 and 36825. Subsequent first use of the placed fistula was determined by finding evidence of fistula use in CROWNWeb data through the end of 2015. If the fistula was indicated as being used in CROWNWeb following its placement (and prior to any subsequent fistula placements), the fistula was considered to have successfully matured for use. If CROWNWeb data did not indicate the fistula was used following placement, the fistula was assumed to have failed to mature. In order to be included in the analyses patients were required to have vascular access use data in CROWNWeb following the fistula placement. Time to maturation was determined using the date of fistula placement in claims data, and the date of first use in CROWNWeb data through the end of 2015, given that the exact time of fistula maturity is currently not determinable exclusively from CROWNWeb data. The percentage of fistula placements that failed was calculated as the number of failed placements over the total number of placements in 2014 among patients with vascular access use data in CROWNWeb. Patients who died following the fistula placement were included in the analysis.

In 2014, 33.8% of AV fistulas placed failed to be in use following placement, with a median of 114 days to first AV fistula use (Table 4.7), among those that were used. Younger patients tended toward higher maturation rates, with patients over age 75 displaying higher failure rates than the overall rate; the oldest patients had the longest median time to first AVF use (117 days) and the youngest patients had the shortest median time to first AVF use (108 days). Males had a higher maturation rate compared to females, and with a shorter time to first use. AV fistula placement failure rates among Native Americans and Asians were lower than the overall rate, while Blacks experienced higher failure rates. vol 2 Table 4.7 Distribution of number of days between AV fistula placement and first successful use*, overall and by patient characteristics, for new AV fistulas created in 2014 (excludes patients not yet ESRD when fistula was placed), from Medicare claims and CROWNWeb, 2014-2015

	Total AV	Percentage	Number of days between AV fistula placemen and first use				
	fistula placements	of failed placements	Average	Median	25 th percentile	75 th percentile	
Overall	31,720	33.8	136	114	78	171	
Age							
0-21	142	26.8	157	108	79	175	
22-44	3,612	29.7	133	110	73	165	
45-64	11,978	32.1	136	113	75	171	
65-74	8,757	34.6	139	116	80	174	
75+	7,231	37.7	136	117	81	169	
Race							
Hispanic	1,641	26.8	132	108	75	162	
Non-Hispanic							
White NH	17,885	33.4	137	115	79	171	
Black/African American NH	10,336	36.3	137	114	74	175	
Native American NH	384	29.9	128	118	76	158	
Asian NH	1,076	28.6	130	110	75	162	
Other/Unknown NH	398	28.4	141	116	74	184	
Sex							
Male	17,962	29.6	130	110	76	162	
Female	13,758	39.2	147	124	81	187	
Primary Cause of ESRD							
Diabetes	14,679	34.0	138	116	78	174	
Hypertension	9,609	34.1	134	114	78	168	
Glomerulonephritis	2,816	31.9	131	107	71	162	
Cystic kidney	530	28.7	135	113	71	170	
Other urologic	482	34.0	131	111	73	157	
Other cause	2,676	35.1	135	113	76	169	
Unknown cause	928	32.0	147	117	77	185	

Data Source: Special analyses, USRDS ESRD Database. *With follow-up through the end of 2014; date of first use was the date the given access was first reported in CROWNWeb to be in use in a particular patient. Abbreviations: AV, arteriovenous; CROWNWeb, Consolidated Renal Operations in a Web-enabled Network; ESRD, end-stage renal disease.

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Notes



Chapter 5: Hospitalization

- On average, ESRD patients are admitted to the hospital nearly twice a year. About 30% of those have an unplanned rehospitalization within the 30 days following discharge.
- Hospitalization represents a significant societal and financial burden, accounting for approximately 40% of total Medicare expenditures for dialysis patients.
- Over the past decade, the frequency of hospital admissions and resulting number of hospital days for ESRD patients have declined gradually, but fairly consistently. In 2014, the adjusted rate of admission for hemodialysis (HD) patients decreased to 1.7 days per patient year (PPY) as compared to 2.1 in 2005, a reduction of 19.0%. During that same period, admission rates for peritoneal dialysis (PD) patients fell by about 23.8%, to 1.6 in 2014 from 2.1 in 2005. For transplant patients this reduced by 27.2% to 0.8 days in 2014, from 1.1 in 2005 (Figure 5.1).
- During this same decade, hemodialysis patient hospitalizations due to cardiovascular events or for vascular access infection fell by 32.6 % and 71.4% (Table 5.1).
- In 2013-2014, some patient groups exhibited a higher risk of hospitalization, both overall and for most causespecific diagnoses. There was inconsistent variation by age. Hospitalization rates were 17% higher for females than for males. Whites were hospitalized more often than those of other races by approximately 33% and Blacks by approximately 31%. Persons with diabetes were 10% more likely to be hospitalized than the overall patient average (Table 5.1).
- Patients with CKD and ESRD experienced rehospitalization rates of 21.4% and 34.6%, as compared to only 15.3% of the older Medicare beneficiaries without a diagnosis of kidney disease (Figure 5.6).
- Among hemodialysis patients prevalent in 2014, 36.6% of discharges from a hospitalization for any cause were followed by a rehospitalization within 30 days (Figure 5.7a).

Introduction

Admissions and readmissions to the hospital represent major burdens for patients with end-stage renal disease (ESRD). On average, ESRD patients are admitted to the hospital nearly twice a year, and about 30% have an unplanned rehospitalization within the 30 days following discharge (CMS, 2014). Given the disruption of everyday life stemming from dialysis treatment, hospital admissions and readmissions additionally compromise patients' well-being and quality of life and are associated with adverse clinical outcomes. Furthermore, inpatient treatment represents a significant societal and financial burden, accounting for approximately 40% of total Medicare expenditures for dialysis patients (CMS, 2014). Clinical studies conducted in a broad range of settings have demonstrated that both improved health care and care coordination may reduce rates of unplanned or non-elective hospitalization and rehospitalization; some studies have suggested that a sizable portion of such readmissions may be preventable. Hence, monitoring trends in hospitalization and rehospitalization is a key to ensuring that quality of care is maintained, potential problems are identified, and cost-effective health care is provided. Informed care providers can respond with targeted strategies to prevent or minimize inappropriate admissions and reduce the incidence of rehospitalization.

2016 USRDS ANNUAL DATA REPORT | VOLUME 2 - ESRD IN THE UNITED STATES

Methods

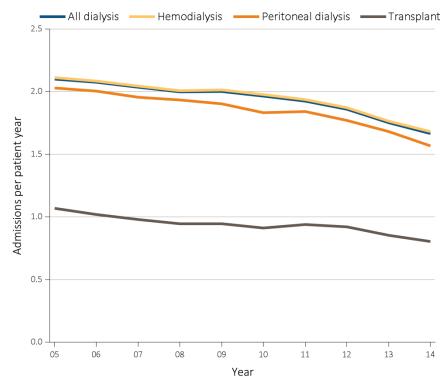
The findings presented in this chapter were drawn from multiple data sources, including the Centers for Medicare & Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the United States Census. Details of these are described in the *Data Sources* section of the *ESRD Analytical Methods*_chapter.

See the Analytical Methods Used section of the ESRD Analytical Methods chapter for an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter.

Trends in Hospitalization Rates

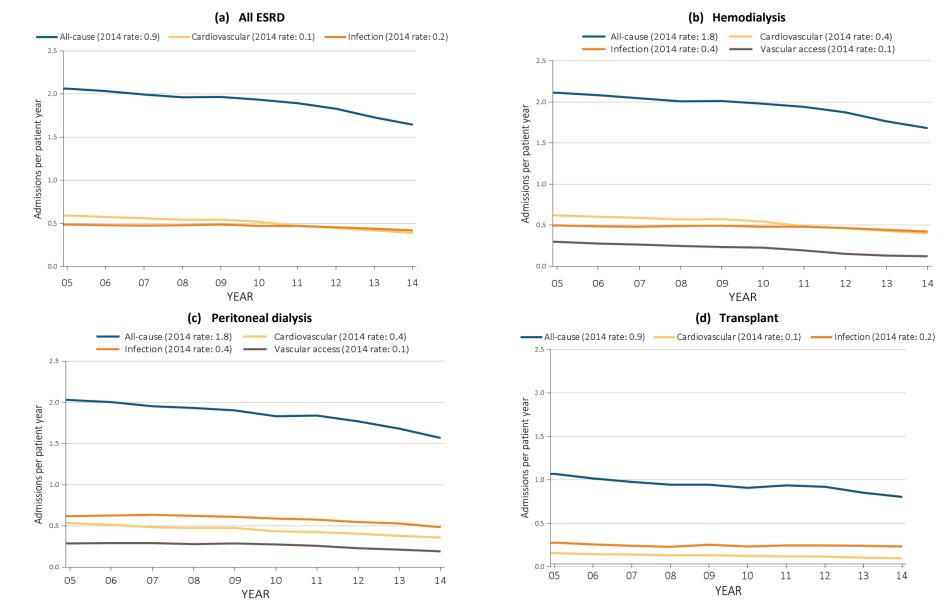
Over the past decade, the frequency of hospital admissions and resulting number of hospital days for ESRD patients have declined gradually, but fairly consistently. As shown in Figure 5.1, in 2014 the adjusted rate of admission for hemodialysis (HD) patients decreased to 1.7 per patient year (PPY) as compared to 2.1 in 2005, a reduction of 19.0%. During that same period, rates for peritoneal dialysis (PD) patients fell by about 23.8%, from 2.1 in 2005 to 1.6 in 2014; rates for transplant patients reduced by 27.2%, from 1.1 to 0.8.

vol 2 Figure 5.1 Adjusted hospitalization rates for ESRD patients, by treatment modality, 2005-2014



Data Source: Reference Tables G.1, G.3, G.4, G.5, G.6, G.8, G.9, G.10, and special analyses, USRDS ESRD Database. Period prevalent ESRD patients; adjusted for age, sex, race, primary cause of kidney failure & their two-way interactions; reference population, ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease.

In recent years, the Annual Data Report (ADR) has highlighted cause-specific hospitalization as an important morbidity surveillance issue. Between 2005 and 2014, rates of hospitalizations due to any cause among ESRD patients declined from 2.07 to 1.64 per patient year (PPY). The 8.7% overall decline in hospitalizations due to infection was more pronounced among patients on PD (23.8%) and those with a transplant (11.5%), as compared to HD patients (10.6%; see Figure 5.2). These improvements likely reflect, at least in part, targeted interventions to prevent and reduce infection rates, especially among PD and transplant patients. Hospital admissions resulting from other causes have also decreased over the same period (e.g., a 61.3% decrease in hospitalizations was observed for vascular access procedures).



vol 2 Figure 5.2 Adjusted all-cause & cause-specific hospitalization rates for ESRD patients, by treatment modality, 2005-2014

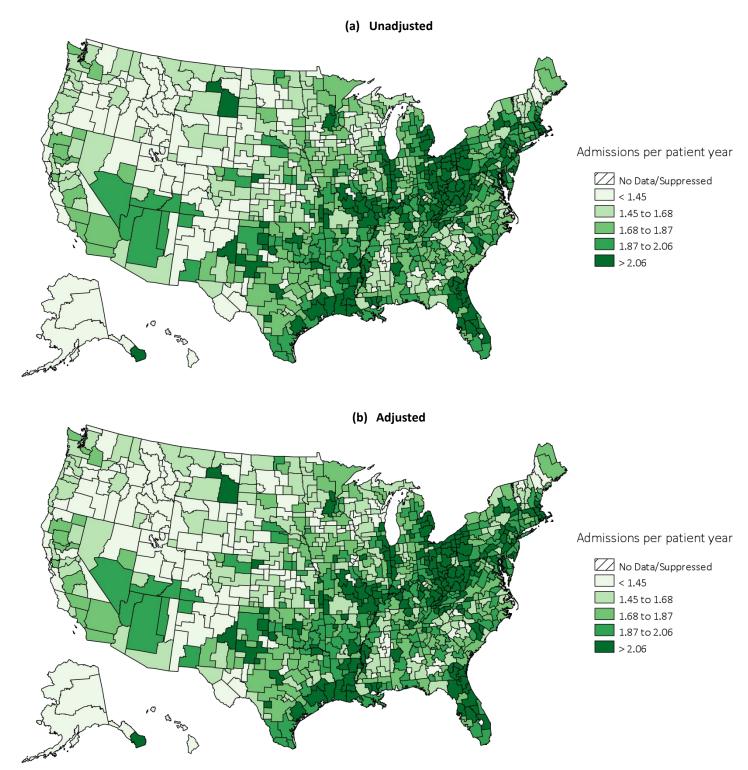
Data Source: Reference Tables G.1, G.3, G.4, G.5, and special analyses, USRDS ESRD Database. Period prevalent ESRD patients; adjusted for age, sex, race, primary cause of kidney failure & their two-way interactions; reference population ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease.

All-cause hospitalization rates among adult HD patients decreased by 18.3% from 2005 to 2014 (see Table 5.1). Hospitalizations due to cardiovascular events and those for vascular access infection fell by 32.6% and 71.4%, respectively. Patient groups with a higher risk of overall hospitalization included those aged 22–44 years or 75 years and older, females, those of White or Black/African American race. Patients who had diabetes as their primary cause of kidney failure had a higher risk of hospitalization both overall and for most cause-specific diagnoses.

While the overall trends of decreasing hospitalization rates are encouraging, it is plausible that these global and cause-specific declines were influenced at least in part by changes in clinical care practices, and policies that emphasize greater utilization of ambulatory care services.

The 2014 unadjusted hospitalization rate of ESRD ranged across 805 U.S. Health Service Areas (HSAs) from a low of 1.57*10⁻⁷ PPY to a high of 2.28 PPY (interquartile range: 0.7944 PPY; Figure 5.3a). The rates were generally highest in parts of the Ohio, southern Texas, and Florida and lowest in Alaska and certain Upper Midwest and Rocky Mountain states. The adjusted hospitalization rate of ESRD in 2014 ranged across the HSAs, from a low of 0.60 PPY to a high of 3.25 (interquartile range: 0.4601 PPY; Figure 5.3b). The rates were generally highest in parts of the Northeast, Florida, and Ohio and lowest in certain Upper Midwest and Rocky Mountain states.

vol 2 Figure 5.3 Map of the hospitalization rates of ESRD, by Health Service Area, in the U.S. population, 2014



Data Source: Reference Tables G.1, G.3, G.4, G.5, and special analyses, USRDS ESRD Database. Period prevalent ESRD patients; adjusted for age, sex, race, & primary cause of kidney failure; reference population ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease.

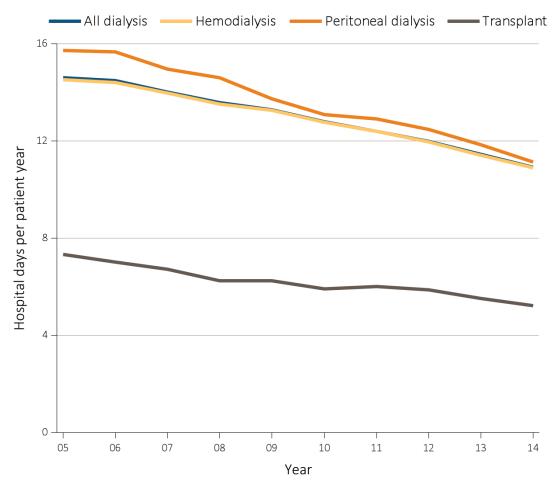
vol 2 Table 5.1 Rates of all-cause & cause-specific hospitalization per patient year for adult hemodialysis patients, 2005-2014

	A	I	Cardiova	ascular	Infectio	n (any)	Vascular infect	
	Unadjusted	Adjusted	Unadjusted	Adjusted	Unadjusted	Adjusted	Unadjusted	Adjusted
2005-2006	2.12	2.13	0.63	0.63	0.50	0.50	0.14	0.14
2007-2008	2.06	2.06	0.60	0.60	0.49	0.49	0.12	0.12
2009-2000	2.02	2.02	0.57	0.57	0.49	0.49	0.11	0.11
2011-2012	1.93	1.93	0.49	0.49	0.48	0.48	0.07	0.07
2013-2014	1.74	1.74	0.43	0.43	0.44	0.44	0.04	0.04
2013-2014								
Age								
22-44	1.73	1.89	0.35	0.36	0.41	0.44	0.06	0.06
45-64	1.68	1.68	0.40	0.40	0.41	0.41	0.05	0.05
65-74	1.78	1.76	0.46	0.45	0.45	0.44	0.04	0.04
75+	1.81	1.80	0.48	0.47	0.49	0.48	0.04	0.04
Sex								
Male	1.61	1.62	0.40	0.40	0.41	0.41	0.04	0.04
Female	1.91	1.90	0.46	0.45	0.48	0.48	0.05	0.05
Race								
White	1.79	1.78	0.43	0.43	0.47	0.47	0.04	0.04
Black/African	1.73	1.76	0.43	0.44	0.40	0.41	0.05	0.05
American	1.75	1.70	0.43	0.44	0.40	0.41	0.05	0.05
Other race	1.37	1.34	0.33	0.33	0.48	0.37	0.04	0.04
Ethnicity								
Hispanic	1.60	1.69	0.38	0.38	0.42	0.42	0.04	0.04
Non-Hispanic	1.77	1.78	0.44	0.44	0.44	0.44	0.05	0.05
Cause of Renal								
Failure								
Diabetes	1.90	1.92	0.46	0.46	0.48	0.48	0.04	0.05
Hypertension	1.62	1.62	0.44	0.43	0.39	0.39	0.04	0.04
Glomerulonephritis	1.47	1.49	0.35	0.37	0.37	0.38	0.05	0.04
Other	1.66	1.68	0.35	0.37	0.45	0.46	0.05	0.05

Data Source: Reference Tables G.3, G.13, and special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients aged 22 & older; adjusted for age, sex, race, ethnicity, primary cause of kidney failure & their two-way interactions. Rates by one factor adjusted for the remaining three; reference population, hemodialysis patients, 2011. See Vol. 2, ESRD Analytical Methods for principal ICD-9-CM diagnosis codes included in each cause of hospitalization category.

Hospital Days

Continuing a downward trend observed since 2005, the number of total hospital days PPY among all dialysis patients has decreased from 14.7 to 10.9 (Figure 5.4). From 2005 to 2014, hospital days PPY decreased to 10.9 for HD patients, 11.1 for PD patients, and to 5.2 days for those with a functioning kidney transplant.



vol 2 Figure 5.4 Adjusted hospital days for ESRD patients, by treatment modality, 2005-2014

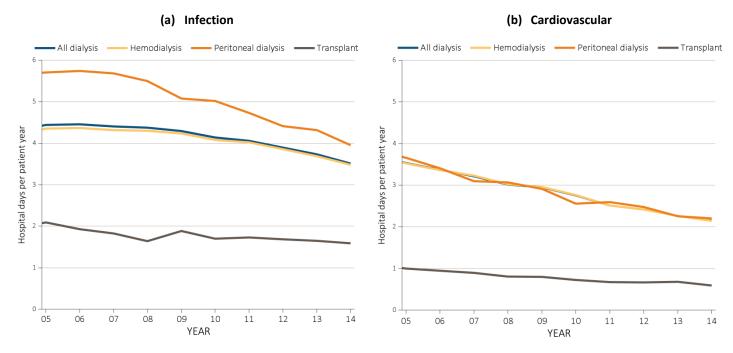
Data Source: Reference Tables G.1, G.3, G.4, G.5, G.6, G.8, G.9, G.10, and special analyses, USRDS ESRD Database. Period prevalent ESRD patients; adjusted for age, sex, race, primary cause of kidney failure & their two-way interactions; reference population: ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease.

With patient-specific adjustment, the number of infection-related hospital days PPY decreased by 16.3% for HD patients, 30.1% for patients on PD, and 18.0% for patients with a kidney transplant. The number of inpatient days for cardiovascular hospitalization reduced by 42.0% for all dialysis patients, and by 46.8% for those with a transplant.

Even after adjustment, the number of hospital days due to infections and cardiovascular events for

patients on dialysis were more than twice that of those with a transplant. For HD and PD patients in 2014, infection-related hospital days were 3.5 and 4.0 PPY, respectively, compared to 1.6 PPY for those with a transplant. Among patients with a cardiovascular admission, hospital days were 2.1 and 2.2 PPY for HD and PD patients, as compared to 0.6 PPY for those with a transplant.

vol 2 Figure 5.5 Adjusted hospital days for infection & cardiovascular causes, for ESRD patients by their treatment modality, 2005-2014

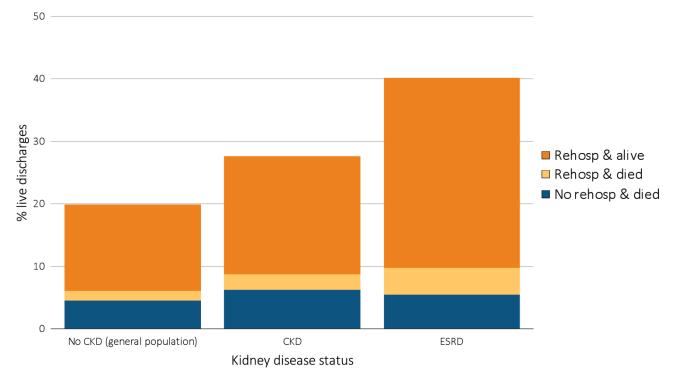


Data Source: Special analyses, USRDS ESRD Database. Period prevalent ESRD patients, adjusted for age, sex, race, primary cause of kidney failure & their two-way interactions; reference population: ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease.

Rehospitalization

Readmissions following a hospital discharge are an important predictor of subsequent adverse clinical events, both in the general and ESRD populations. Among dialysis patients, rehospitalizations are associated with increased morbidity and mortality, and reduced quality of life. Recurrent hospitalizations also pose a significant societal and financial burden, particularly for ESRD patients.

In this chapter rehospitalization/readmission is defined as a hospital admission occurring within 30 days of a hospital discharge, excluding ER visits and those for rehabilitation purposes. Hospital readmissions with associated death were more common among patients with chronic kidney disease (CKD) or ESRD than in the general population. Patients with CKD and ESRD experienced rehospitalization rates of 21.4% and 34.6%, respectively as compared to only 15.3% of older Medicare beneficiaries without a diagnosis of kidney disease (Figure 5.6). This held true for the combined outcomes of post-discharge death and/or rehospitalization—experienced by 27.6% of CKD patients and 40.1% of those with ESRD, versus only 19.8% of patients without diagnosed kidney disease.

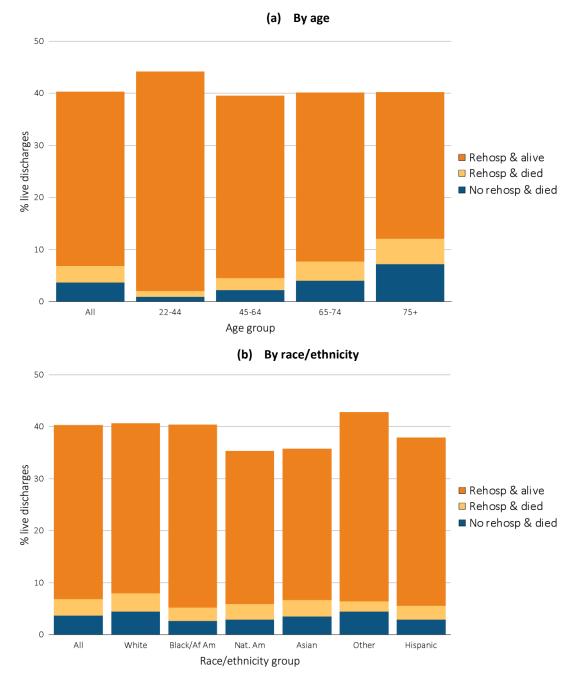


vol 2 Figure 5.6 Proportion of patients aged 66 & older discharged alive from the hospital who were either rehospitalized or died within 30 days of discharge, by kidney disease status, 2014

Data Source: Special analyses, USRDS ESRD Database and Medicare 5% sample. January 1, 2014 point prevalent Medicare patients aged 66 & older on December 31, 2013. For general Medicare: January 1, 2014 point prevalent, Medicare patients aged 66 & older, discharged alive from an all-cause index hospitalization between January 1, 2014, and December 1, 2014, unadjusted. CKD determined using claims for 2013. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; rehosp, rehospitalization.

Among HD patients prevalent in 2014, 36.6% of discharges from a hospitalization for any cause were followed by a rehospitalization within 30 days (see Figure 5.7a). For older patients, rehospitalization rates decreased as mortality increased, illustrating these competing risks, as death precluded the outcome of readmission. Rates of post-discharge death without rehospitalization, for example, were highest in patients aged 75 years and older, at 7.2%, while these patients had the lowest rehospitalization rates, at 33%.

vol 2 Figure 5.7 Proportion of hemodialysis patients discharged alive from the hospital who either were rehospitalized or died within 30 days of discharge, by demographic characteristics, 2014



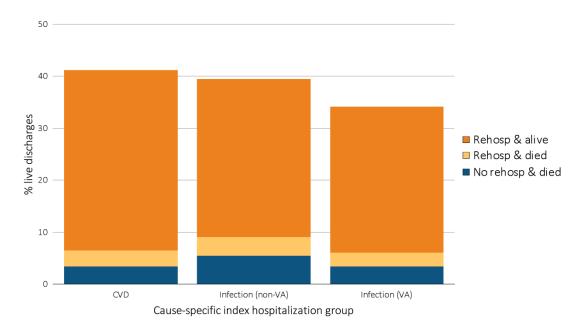
Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients, all ages, 2014; unadjusted. Includes live hospital discharges from January 1 to December 1, 2014. Cause-specific hospitalizations are defined by principal ICD-9-CM codes. See Vol. 2, ESRD Analytical Methods for principal ICD-9-CM diagnosis codes included in each cause of hospitalization category. Abbreviations: Af Am, African American; ESRD, end-stage renal disease; Nat Am, Native American; Other, other or unidentified race; rehosp, rehospitalization.

CHAPTER 5: HOSPITALIZATION

The highest rates of rehospitalization with survival occurred for adults aged 22 to 44 years—42.0% of their discharges were followed by a readmission within 30 days. For the two combined outcomes of either survival or death, the highest rates were again seen among patients aged 20–44 years, at 43.1%. The rate of survival following rehospitalization exceeded the two combined death outcomes for all age groups (33.5% vs. 6.8%), even in patients aged 75 and older, at 28.1% and 12.0%, respectively. These data illustrate that the observed, elevated rehospitalization rates among younger versus older groups were not fully due to the competing risk of mortality in the aged.

We examined the proportion of HD patients discharged alive who were either rehospitalized or died within 30 days of discharge by their race & ethnicity; the highest rates were observed among the aggregate Other race group (36.3% for rehospitalized and lived vs. 38.3% for rehospitalized with the combined outcomes of either survival or death), followed by Blacks (35.1% vs. 37.7%). The lowest such rates occurred among Asians, of whom 29.1% were rehospitalized and lived, and 32.2% were rehospitalized with the combined outcomes of either survival or death. The highest rate of post-discharge death occurred among White HD patients at 3.6%, possibly influenced by the older average age among White HD patients.

For HD patients, the all-cause rehospitalization rate in 2014 was 37.0% (Figure 5.7a). For index hospitalizations due to cardiovascular, infection, and vascular access infections, patients' rehospitalization rates were 37.7, 34.0, and 30.6%, respectively (see Figure 5.8).



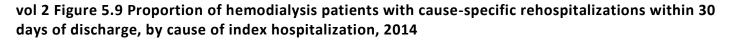
vol 2 Figure 5.8 Proportion of hemodialysis patients discharged alive that either were rehospitalized or died within 30 days of discharge, by cause of index hospitalization, 2014

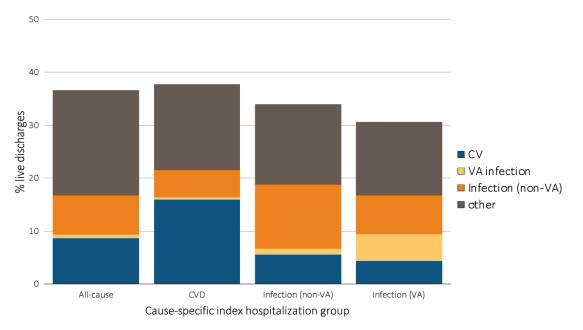
Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients, all ages, 2014, unadjusted. Includes live hospital discharges from January 1 to December 1, 2014. Cause-specific hospitalizations are defined by principal ICD-9-CM codes. See Vol. 2, ESRD Analytical Methods for principal ICD-9-CM diagnosis codes included in each cause of hospitalization category. Abbreviations: CVD, cardiovascular disease; ESRD, end-stage renal disease; rehosp, rehospitalization; VA, vascular access.

Figure 5.9 illustrates that rehospitalization in the 30 days following a hospital discharge does not always result from a similar diagnostic cause as the index hospitalization.

During 2014, of those admitted for treatment of cardiovascular issues and then soon rehospitalized, nearly half (42.5%) were admitted to treat the same or another cardiovascular condition. However, this pattern differed for those initially hospitalized to address vascular access infection (16.7%), and other types of infection (35.6%).The proportion of causespecific readmission among those with an all-cause index hospitalization were also fairly low—only 23.7% returned for additional cardiovascular treatment, 1.8% for vascular access infection, and 20.3% to address other types of infection.

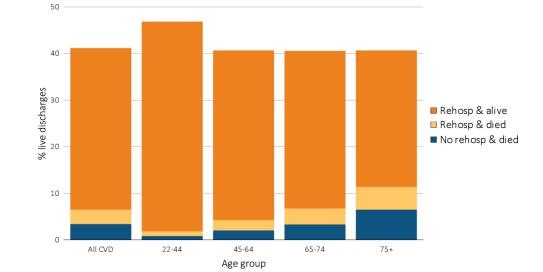
The patterns of rehospitalization following an unrelated index hospitalization suggest the development of new conditions or complications of the original condition. These differences might in part be attributed to the nature of chronic conditions that typically do not resolve (i.e. cardiovascular disease) versus acute conditions that are expected to resolve (i.e. infection).





Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients, all ages, 2014, unadjusted. Includes live hospital discharges from January 1 to December 1, 2014. Cause-specific hospitalizations are defined by principal ICD-9-CM codes. See Vol. 2, ESRD Analytical Methods for principal ICD-9-CM diagnosis codes included in each cause of hospitalization category. Abbreviations: CVD, cardiovascular disease; ESRD, end-stage renal disease; rehosp, rehospitalization; VA, vascular access.

Rehospitalization rates following discharge from a cardiovascular index hospitalization were slightly higher among younger adults, compared with all other age groups in which rehospitalization rates appear similar. For those aged 22–44, for example, 46.0% of such discharges were followed by a rehospitalization within 30 days (Figure 5.10). In general, these rates mirrored those for all-cause index hospitalizations as seen in Figure 5.6, although the rates in Figure 5.9 for those aged 22-44 were slightly higher.

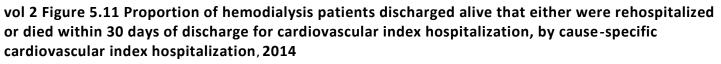


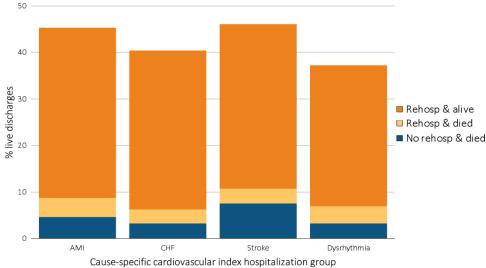
vol 2 Figure 5.10 Proportion of hemodialysis patients discharged alive that either were rehospitalized or died within 30 days of discharge for cardiovascular index hospitalization, by age, 2014

Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients, all ages, 2014, unadjusted. Patients less than age 22 are not represented as a group due to insufficient sample size. Includes live hospital discharges from January 1 to December 1, 2014. Cause-specific hospitalizations are defined by principal ICD-9-CM codes. See Vol. 2, ESRD Analytical Methods for principal ICD-9-CM diagnosis codes included in each cause of hospitalization category. Abbreviations: CVD, cardiovascular disease; ESRD, end-stage renal disease; rehosp, rehospitalization.

For cardiovascular index hospitalizations (Figure 5.11), rehospitalization occurred most frequently following discharge from treatment of acute myocardial infarction (AMI) and stroke, at 40.6 and

38.5%, respectively. The lowest rates occurred following discharge after dysrhythmia, at 33.9%. When not rehospitalized, stroke patients had the highest post-discharge mortality rate at 7.6%.





Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients, all ages, 2014, unadjusted. Includes live hospital discharges from January 1 to December 1, 2014. Cause-specific hospitalizations are defined by principal ICD-9-CM codes. See Vol. 2, ESRD Analytical Methods for principal ICD-9-CM diagnosis codes included in each cause of hospitalization category. Abbreviations: AMI, acute myocardial infarction; CHF, congestive heart failure; ESRD, end-stage renal disease; rehosp, rehospitalization.

As comorbid cardiovascular disease and its complications have a critical interaction with kidney disease of all types, this 2016 ADR features two chapters specifically addressing these issues— Volume1, Chapter 4 *Cardiovascular Disease in Patients with CKD*, and Volume 2, Chapter 9, *Cardiovascular Disease in Patients with ESRD*.

References

Center for Medicare and Medicaid Services (2014, June). Report for the Standardized Readmission Ratio. Retrieved October 23, 2015, from <u>https://www.cms.gov/Medicare/Quality-</u> <u>Initiatives-Patient-Assessment-</u> <u>Instruments/ESRDQIP/Downloads/MeasureMetho</u> <u>dologyReportfortheProposedSRRMeasure.pdf</u>



Chapter 6: Mortality

- In 2014, adjusted mortality rates for ESRD, dialysis, and transplant patients, were 136, 166, and 30, per 1,000 patient-years, respectively. By dialysis modality, mortality rates were 169 for hemodialysis patients and 157 for peritoneal dialysis patients, per 1,000 patient-years (Figure 6.1).
- Since 1996, crude mortality rates have decreased by 26% for dialysis patients and have increased by 2% for transplant recipients over the same period. However, when accounting for changes in population characteristics, adjusted mortality rates continue to decrease for dialysis and transplant patients, falling by 32% and 44%, respectively (Figure 6.1).
- Patterns of mortality during the first year of dialysis differ substantially by modality. For hemodialysis patients, reported mortality is highest in month 2, but declines thereafter; this effect is more pronounced for patients aged 65 and over. In contrast, mortality rises slightly over the course of the year for peritoneal dialysis patients (Figure 6.3).
- The relationship between race and mortality differs considerably by age among dialysis patients. White dialysis patients younger than age 22 have mortality rates comparable to Black/African American patients, but experience higher mortality than Blacks at older ages (Figure 6.1.a).
- Dialysis patients continue to have substantially higher mortality, and fewer expected remaining life years, compared to the general population and Medicare populations with cancer, diabetes, or cardiovascular disease. However, the relative and absolute decline in mortality for dialysis patients in the past 15 years has been greater than for Medicare patients in these other diagnostic categories (Tables 6.4 and 6.5, Figure 6.5).
- The decline in mortality shown in this chapter has important implications for both patients and resource allocation. Increasing lifespan among ESRD patients is likely the main reason for continued growth in the prevalent ESRD population.

Introduction

Mortality analyses in this chapter are based on both end-stage renal disease (ESRD) data and general population data. ESRD data are from the USRDS ESRD Database. General population data are based on the Medicare 5% standard analytical files and U.S. Census mortality data. Note that universal reporting of ESRD patient deaths to the Centers for Medicare & Medicaid (CMS) is required via CMS form 2746 as a condition of coverage for dialysis units and transplant centers. In addition, mortality ascertainment is augmented by Social Security Death Master File data to the extent allowed by regulation (which differs by state). For analyses in this chapter, the term "incident" refers to patients new to ESRD, while "prevalent" refers to patients receiving ESRD treatment on a specific date, and "period prevalent" includes patients treated for ESRD over a particular period of time. Modality is assigned as of the earliest date within the range used in the analysis, without use of the 6o-day stable modality rule (i.e., the requirement of 6o days on a modality for change in modality assignment) or the 90-day rule for outcomes (the attribution of outcomes to the previous modality, for up to 90 days after a change in modality).

Methods

The findings in this chapter are based on data from multiple data sources, including the Centers for Medicare & Medicaid Services (CMS), the Organ Procurement and Transplantation Network (OPTN), the Centers for Disease Control and Prevention (CDC), the U.S. Census, and the National Vital Statistics Report. For details about these data sources, see the <u>Data Sources</u> section of the *ESRD Analytical Methods* chapter.

See the section on <u>Chapter 6</u> in *the ESRD Analytical Methods* chapter for an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter.

Mortality Among ESRD Patients, Overall, and by Modality

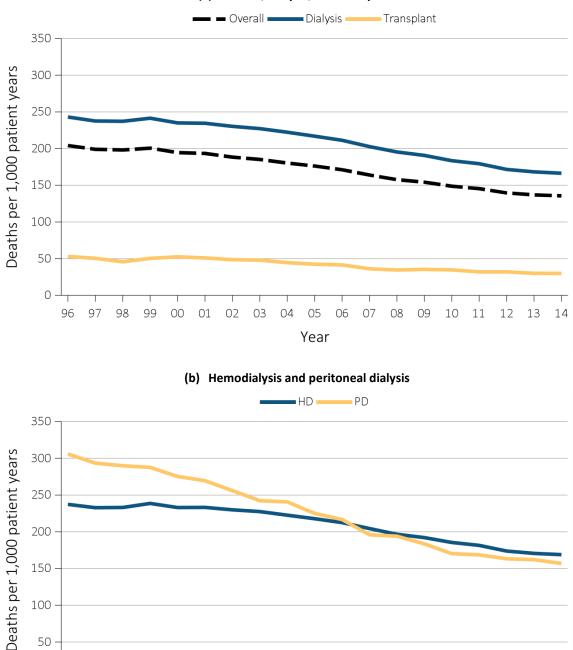
Overall mortality rates among ESRD (dialysis and transplant) patients continue to decline, with steeper reductions observed during more recent years. Between 1996 and 2014, the crude death rate (not shown) for the ESRD population decreased by 26%, from 186 to 137 per 1,000 patient-years, while the adjusted death rate (Figure 6.1.a) decreased by 34%. (Note that the reference population for each adjusted rate is described within the footnote of each table or figure: e.g., for Figure 6.1, the reference population consists of period prevalent ESRD patients in 2011). The crude death rate for the dialysis population decreased by 26%, while the adjusted death rate decreased by 32%. The crude death rate for the transplant population increased by 2%, while the adjusted death rate decreased by 44%.

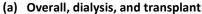
The differences between the crude and adjusted rates largely reflect changes in the age distribution of the ESRD population. Death rates for dialysis and transplant patients have decreased by over 30% between 1996 and 2014 within most age groups, and the adjusted rate reflects this decrease. The crude rate is affected by both this decrease and by the fact that the ESRD population is older in 2014 than in 1996, which offsets this effect. For example, patients over the age of 65 comprised 42% of the dialysis population in 1996 and 45% in 2014; among transplant recipients, these numbers were 8% and 26%, respectively. Thus, the very large change in age among transplant patients has masked overall improvements in mortality.

The adjusted mortality rate decreased by 9% from 1996 to 2003, and by 25% from 2004 to 2014 for the ESRD population (Figure 6.1.a). The trend was similar for dialysis (hemodialysis and peritoneal dialysis) patients, with the adjusted mortality rate decreasing by 7% from 1996 to 2003 and by 25% from 2004 to 2014 (Figure 6.1.b). Among transplant patients, mortality decreased by 9% from 1996 to 2003 and by 33% from 2004 to 2014. Since 1996, the net reduction in mortality was 34% for all ESRD patients, including 32% for dialysis patients and 44% for transplant patients.

Among hemodialysis patients, the adjusted mortality rate decreased by 4% from 1996 to 2003 and by 24% from 2004 to 2014. Among peritoneal dialysis patients, the mortality rate decreased by 21% from 1996 to 2003 and by 35% from 2004 to 2014 (Figure 6.1.b). The net reductions in mortality from 1996 to 2014 were 29% for hemodialysis patients and 49% for peritoneal dialysis patients.

Adjusted mortality rates in 2014 were 136, 166, and 30 per 1,000 patient-years for ESRD, dialysis, and transplant patients, respectively. By dialysis modality, mortality rates were 169 for hemodialysis patients and 157 for peritoneal dialysis patients per 1,000 patientyears. vol 2 Figure 6.1 Adjusted all-cause mortality (deaths per 1,000 patient-years) by treatment modality (a) overall, dialysis, and transplant, and (b) hemodialysis and peritoneal dialysis, for period-prevalent patients, 1996-2014





Data Source: Reference Tables H.2_adj, H4_adj, H.8_adj, H.9_adj, and H.10_adj; and special analyses, USRDS ESRD Database. Adjusted for age, sex, race, ethnicity, primary diagnosis and vintage. Reference population: period prevalent ESRD patients, 2011. Abbreviations: HD, hemodialysis; PD, peritoneal dialysis.

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Mortality by Duration of Dialysis, Including Trends Over Time

Among hemodialysis patients, from 1996-2011 the average death rate was highest during the first year following dialysis initiation, then dropped to its lowest point during the second year, and then tended to rise for more than 5 years thereafter (Figure 6.2.a). Mortality rates among these patients tended to be higher after 5 years than between 2-5 years on dialysis. Death rate patterns by time-since-dialysis-initiation have been fairly similar over calendar time (comparing cohorts based on calendar year of initiation of treatment).

Among peritoneal dialysis patients, mortality rates generally increased over the first five years after starting dialysis (Figure 6.2.b). As with hemodialysis patients, peritoneal dialysis patient mortality rates tended to be higher after 5 years than between 2-5 years on dialysis. Death rate patterns by time-sincedialysis-initiation have also been fairly similar over time for peritoneal dialysis patients.

vol 2 Figure 6.2 Adjusted all-cause mortality (deaths per 1,000 patient-years) by treatment modality, cohort (year of ESRD onset), and number of years after start of dialysis among incident (a) hemodialysis patients and (b) peritoneal dialysis patients, 1996, 2001, 2006, and 2011

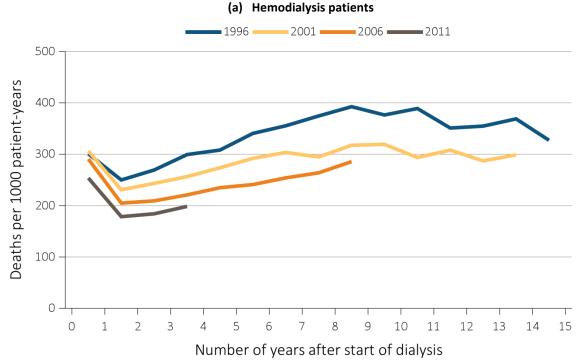
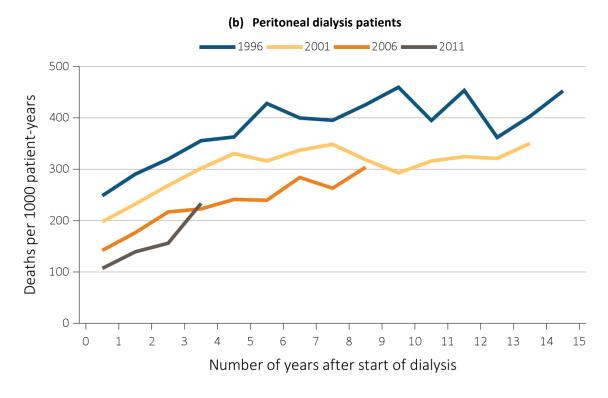


Figure 6.2 continued on next page.

vol 2 Figure 6.2 Adjusted all-cause mortality (deaths per 1,000 patient-years) by treatment modality, cohort (year of ESRD onset), and number of years after start of dialysis among incident (a) hemodialysis patients and (b) peritoneal dialysis patients, 1996, 2001, 2006, and 2011 *(continued)*



Data Source: Special analyses, USRDS ESRD Database. Adjusted for age, sex, race, and primary diagnosis. Ref: period prevalent ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease.

Mortality During the First Year of ESRD

Among patients starting hemodialysis in 2012, reported all-cause mortality peaked at 382 deaths per 1,000 patient-years in month 2, and decreased thereafter to 189 per 1,000 patient-years in month 12. The decrease in mortality for HD patients during the first year was sharper for patients aged 65 and over (Figure 6.3); this pattern is similar to that previously found by Robinson et al. (2014). Among patients under the age of 65, mortality dropped from 214 deaths per 1,000 patient-years in month 2 to 117 in month 12. Among patients aged 65 and over, mortality dropped from 620 deaths per 1,000 patient-years in month 2 to 297 in month 12. Note that the steep rise in hemodialysis mortality rates between months 1 and 2 may reflect data reporting issues; e.g., some patients who die soon after starting dialysis related to ESRD might not be registered as having ESRD on CMS 2728, and therefore, would not be included in the CMS

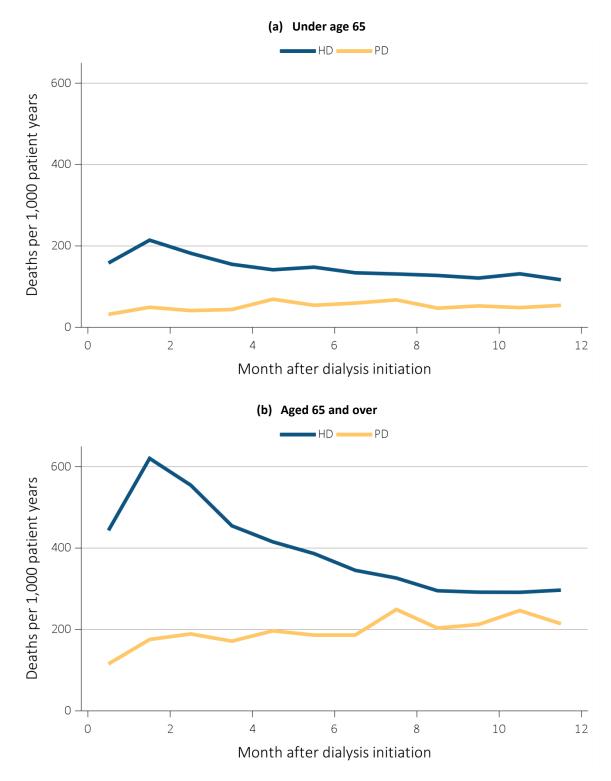
database (Foley et al., 2014). The extent to which this occurs is currently unknown.

Among patients with peritoneal dialysis as the initial renal replacement modality, mortality does not peak early, but instead tends to increase gradually during the first year on dialysis. Mortality at month 12 among these patients was 119 per 1,000 patient-years. Among peritoneal dialysis patients under the age of 65, mortality increased from 32 deaths per 1,000 patient-years in month 1 to 54 in month 12. Among patients aged 65 and over, mortality increased from 115 deaths per 1,000 patient-years in month 1 to 214 in month 12. Peritoneal dialysis patients may not experience an early peak in mortality, in part, because patients beginning ESRD via peritoneal dialysis are a highly selected group, in many cases being younger, healthier, and having undergone substantial pre-ESRD planning.

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Post-transplant mortality among the <2% of patients who initiate ESRD treatment with a kidney transplant peaks in month 4, followed by a generally decreasing trend for the remainder of the first year (not shown).

vol 2 Figure 6.3 Adjusted mortality (deaths per 1000 patient-years) by treatment modality and number of months after treatment initiation among ESRD patients (a) under age 65 and (b) aged 65 and over, 2013



Data Source: Special analyses, USRDS ESRD Database. Adjusted (age, race, sex, ethnicity, and primary diagnosis) mortality among 2013 incident ESRD patients during the first year of therapy. Reference population: incident ESRD patients, 2011. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis.

Mortality by Age and Race

Mortality rates among ESRD patients increases with age, as expected. Mortality rates differ by race, but this difference is not constant within age groups or by modality (Table 6.1.a). For example, White patients on dialysis had comparable mortality rates to Black/African American (hereafter, Black) patients among those aged o-22 years old, but higher mortality than Blacks at older ages. Mortality rates tended to be similar between White and Black transplant patients over the age of 45. It should be noted that these analyses underestimate the survival advantage of Blacks compared to non-Hispanic Whites. As demonstrated by Yan et al. (2013), Hispanics have mortality rates similar to other non-White ethnic groups and inclusion of them in the White calculation underestimates the high mortality rates among non-Hispanic Whites on dialysis.

Among dialysis and transplant patients, males aged o-44 years tended to have lower adjusted mortality than females, but higher adjusted mortality at ages 65 and over (Table 6.1.b).

(a) Age and race									
Age	Race	Race ESRD							
0-21	White	10	33	4					
	Black/African American	18	35	6					
	Other	8	26	4					
22-44	White	33	64	9					
	Black/African American	43	54	11					
	Other	20	37	4					
45-64	White	108	155	35					
	Black/African American	98	112	34					
	Other	77	102	20					
65-74	White	209	249	80					
	Black/African American	171	185	79					
	Other	139	161	59					
75+	White	357	377	136					
	Black/African American	270	276	143					
	Other	233	240	111					

vol 2 Table 6.1 Adjusted all-cause mortality (deaths per 1,000 patient-years) (a) by age and race, and (b) by age and sex, among ESRD patients, 2014

	(b) Age and sex											
Age	Sex	ESRD	Dialysis	Transplant								
0-21	Male	9	31	3								
	Female	12	36	4								
22-44	Male	34	56	9								
	Female	39	66	10								
45-64	Male	105	141	36								
	Female	107	144	31								
65-74	Male	205	245	83								
	Female	196	224	74								
75+	Male	357	379	140								
	Female	330	342	129								

*/*1 \

Data Source: Special analyses, USRDS ESRD Database. (a) Adjusted (race and primary diagnosis) all-cause mortality among 2014 period prevalent patients. (b) Adjusted (sex and primary diagnosis) all-cause mortality among 2014 period prevalent patients. Reference population: period prevalent ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease.

Cause-Specific Mortality Rates

The largest category of known cause-specific mortality for dialysis patients is death due to cardiovascular disease (CVD), which comprises 41% of the deaths and 54% of the deaths with known causes. The cause of death information (based on CMS 2746) is missing or unknown for 24% of dialysis patients and 73% of transplant patients.

	Cause-specific mortality								
	CVD	Infection	Other cause	Missing cause					
Modality									
ESRD	39%	8%	25%	28%					
Dialysis	41%	8%	26%	24%					
Transplant	9%	5%	13%	73%					

vol 2 Table 6.2 Unadjusted percentages of deaths due to cardiovascular disease (CVD), infection, other specified causes, and with missing data, by modality among ESRD patients, 2013

Data Source: Special analyses, USRDS ESRD Database. All-cause mortality among 2012 prevalent patients. Reference population: period prevalent ESRD patients, 2011. Abbreviations: CVD, cardiovascular disease; ESRD, end-stage renal disease.

Survival Probabilities for ESRD Patients

Survival has improved between the 2001 and 2009 incident ESRD cohorts for all modalities. For example, five-year survival rose from 36% to 42% among hemodialysis patients, from 39% to 51% among peritoneal dialysis patients, from 66% to 76% among deceased donor transplant patients, and from 76% to 85% among living donor transplant patients. Adjusted survival was consistently higher in the transplant population than in dialysis patients, and among living donor transplant recipients than deceased donor recipients.

Despite improvements in survival on dialysis over the years, adjusted survival for hemodialysis patients who were incident in 2009 is only 56% at three years after ESRD onset (Table 6.3). For peritoneal dialysis patients, adjusted survival is 67% at three years. For deceased-donor and living-donor recipients, three-year survival is 84% and 91% respectively.

Average three-year survival among an age- and sexmatched general population is considerably higher. The general population matched to hemodialysis patients' age and sex distribution has a 92% three-year survival, and the general population matched to peritoneal dialysis patients' age and sex distribution has a 94% three-year survival. For the age and sex distribution among both deceased-donor and livingdonor recipients, the matched three-year survival in the general population was 98% (calculated using the Social Security Administration "Period Life Table 2013").

	3 months	12 months	24 months	36 months	60 months
Hemodialysis					
2001	91.0	74.8	61.4	50.8	35.6
2003	91.0	74.8	61.8	51.4	36.5
2005	91.2	75.4	62.7	52.9	38.5
2007	91.5	76.3	64.1	54.6	39.9
2009	91.7	77.4	65.6	56.1	41.5
Peritoneal dialysis					
2001	95.5	82.1	67.3	55.4	39.4
2003	96.3	83.9	69.0	57.7	42.9
2005	96.4	85.6	72.3	61.6	45.7
2007	96.9	87.5	74.8	64.6	49.0
2009	97.3	87.8	76.5	66.5	51.4
Deceased-donor transplant					
2001	94.9	89.4	83.2	77.8	66.1
2003	95.7	90.0	84.6	79.5	69.2
2005	95.6	89.9	85.1	80.5	71.3
2007	96.7	92.3	88.1	83.7	73.3
2009	96.8	92.3	88.5	84.3	75.7
Living donor transplant					
2001	97.3	93.6	89.6	85.5	76.0
2003	98.1	95.6	91.9	87.8	79.3
2005	98.2	95.3	92.0	88.7	81.0
2007	99.1	97.2	94.8	91.9	85.1
2009	98.9	97.1	94.5	91.4	84.6

vol 2 Table 6.3 Adjusted survival (%) by treatment modality and incident cohort year (year of ESRD onset)

Data Source: Reference Tables I.1_adj-I.36_adj. Adjusted survival probabilities, from day one, in the ESRD population. Reference population: incident ESRD patients, 2011. Adjusted for age, sex, race, Hispanic ethnicity, and primary diagnosis. Abbreviation: ESRD, end-stage renal disease.

Expected Remaining Lifetime: Comparison of ESRD Patients to the General U.S. Population

The differences in expected remaining lifetime between the ESRD and general populations are striking (Table 6.4). Dialysis patients younger than 80 years old are expected to live less than one-third as long as their counterparts without ESRD, and dialysis patients aged 80 years and older are expected to live around one-half as long as their counterparts without ESRD. Transplant patients fare considerably better, with expected remaining lifetimes for people under the age of 75 estimated at 68% to 85% of expected lifetimes in the general population.

			ral U.S.				
	Dia	lysis	Tran	splant	population, 2013		
Age	Male	Female	Male	Female	Male	Female	
0-14	22.6	23.3	60.1	59.8	70.7	75.4	
15-19	21.6	19.0	47.9	48.5	59.7	64.4	
20-24	18.5	16.4	43.4	44.2	55	59.5	
25-29	16.2	14.3	39.2	40.2	50.3	54.6	
30-34	14.3	13.0	35.1	36.4	45.7	49.7	
35-39	12.6	11.6	31.0	32.8	41	45	
40-44	11.0	10.4	27.2	28.9	36.4	40.3	
45-49	9.2	8.9	23.4	25.2	31.9	35.6	
50-54	7.9	7.8	19.9	21.7	27.7	31.1	
55-59	6.6	6.6	16.7	18.3	23.7	26.8	
60-64	5.5	5.7	13.8	15.3	19.8	22.6	
65-69	4.5	4.8	11.4	12.6	16.2	18.5	
70-74	3.8	4.0	9.5	10.4	12.8	14.7	
75-79	3.2	3.5	7.7 ^a	8.7 ^a	9.8	11.3	
80-84	2.6	2.9			7.1	8.4	
85+	2.2	2.4			3.7	4.4	

vol 2 Table 6.4 Expected remaining lifetime (years) by age, sex, and treatment modality of prevalent dialysis patients and transplant patients, and the general U.S. population, 2013

Data Source: Reference Table H.13; special analyses, USRDS ESRD Database; and National Vital Statistics Report. "Table 7. Life expectancy at selected ages, by race, Hispanic origin, race for non-Hispanic population, and sex: United States, 2013 (2016)." Expected remaining lifetimes (years) of the general U.S. population and of period prevalent dialysis and transplant patients. ^aCell values combine ages 75+. Abbreviation: ESRD, end-stage renal disease.

Mortality Rates: Comparisons of ESRD Patients to the Broader Medicare Population

COMPARISON TO THE GENERAL MEDICARE POPULATION

The population of people without ESRD but still covered by Medicare under the age of 65 tends to be non-representative of the general population under the age of 65. For this reason, Table 6.5 focuses on comparisons between the ESRD population and the general Medicare population using age groups starting at age 65, where the Medicare population is expected to be much more representative. Dialysis patients over the age of 75 years experienced mortality rates 3.8 times higher for males and 4.0 times higher for females, compared with males and females in the general Medicare population (Table 6.5). Among kidney transplant patients, mortality rates were 2.5-2.9 times higher than for the general Medicare population aged 65-74, and 1.3-1.5 times higher at age 75 and older.

Age	Sex	Dialysis	alysis Transplant All Medicare Cancer Diabetes		CHF	CVA/TIA	AMI		
65-74	Male	228	64	26	75	41	106	71	92
	Female	215	53	18	67	31	102	59	97
75+	Male	345	119	91	139	110	236	168	206
	Female	324	119	82	134	101	220	150	205

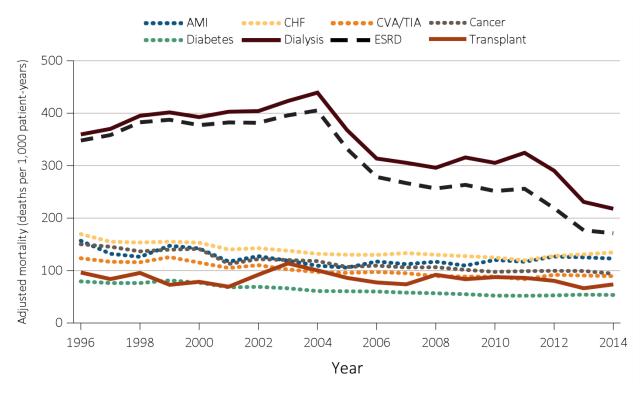
vol 2 Table 6.5 Adjusted mortality (deaths per 1,000 patient-years) by age, sex, treatment modality, and comorbidity among ESRD patients and the general Medicare population, 2013-2014

Data Source: Special analyses, USRDS ESRD Database and Medicare 5% sample. Adjusted for race. Medicare data limited to patients with at least one month of Medicare eligibility in 2013. Reference population: Medicare patients, 2014. Abbreviations: AMI, acute myocardial infarction; CHF, congestive heart failure; CMS, Centers for Medicare & Medicaid; CVA/TIA, cerebrovascular accident/transient ischemic attack; ESRD, end-stage renal disease.

COMPARISON TO COMORBIDITY-SPECIFIC MEDICARE PATIENTS

From 1996 to 2014, adjusted mortality among ESRD patients aged 65 years and older declined by 51%, from 348 to 171 per 1,000 patient-years (Figure 6.4). Among dialysis patients, adjusted mortality fell 39%, from 360 to 218. Among transplant patients, adjusted mortality fell 24%, from 96 to 74. The decline in mortality for dialysis patients was greater than for other major diagnostic groups, including cancer, diabetes, congestive heart failure (CHF), cerebrovascular accident/transient ischemic attack (CVA/TIA), and acute myocardial infarction (AMI). Adjusted mortality fell 37% for patients with cancer and 33% for patients with diabetes, but somewhat less for cardiovascular conditions, at 21% for heart failure, 28% for CVA/TIA, and 22% for AMI.

In 2014, mortality rates among dialysis patients aged 65 years and older ranged from 1.6 times higher than mortality rates among heart failure patients to 4.1 times higher than mortality rates among patients with diabetes. For transplant patients aged 65 and older, the mortality rate was within the range of mortality rates for Medicare patients with the other listed conditions. vol 2 Figure 6.4 Adjusted mortality (deaths per 1,000 patient-years) by calendar year, treatment modality, and comorbidity among ESRD patients and comorbidity-specific Medicare populations aged 65 & older, 1996-2014



Data Source: Special analyses, USRDS ESRD Database and Medicare 5% sample. Unadjusted and adjusted (sex and race) mortality rates starting with the January 1 point prevalent sample in the ESRD and general populations, aged 65 and older (per 1,000 patient-years at risk). Reference population: period prevalent ESRD patients, 2012. Abbreviations: AMI, acute myocardial infarction; CHF, congestive heart failure; CVA/TIA, cerebrovascular accident/transient ischemic attack; ESRD, end-stage renal disease.

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Notes



Chapter 7: Transplantation

- 17,914 kidney transplants were performed in the United States in 2014 (17,205 were kidney-alone) (Figure 7.3).
- Less than one-third of kidneys transplanted in 2014 were from living donors (Figure 7.3).
- From 2013 to 2014, the cumulative number of recipients with a functioning kidney transplant increased 2.9% to a total of 200,907 (Figure 7.4).
- On December 31, 2014, the kidney transplant waiting list had 88,231 candidates (dialysis patients only) with 50,692 active candidates. 83% of all candidates were awaiting their first transplant (Figure 7.2).
- Among candidates newly wait-listed for either a first-time or repeat kidney-alone transplant (living or deceased donor) in 2009, the median waiting time to transplant was 3.5 years (Figure 7.2). The waiting time among newly wait-listed candidates varies greatly by region of the country, from a low of 0.8 years in Utah to a high of 5.6 years in Mississippi (Reference Table E.2.2).
- The number of deceased kidney donors has risen from 6,231 in 2003 to 8,385 in 2014.
- The rate of donation among deceased Blacks/African Americans more than doubled from the year 2000 (4 donations/1,000 deaths) to 2014 (8 donations/1,000 deaths) (Figure 7.18.b).
- 16% of kidneys recovered from deceased donors were discarded in 2014, which has been stable since 2010.
- The counts of KPD transplants has risen sharply in recent years, with 552 performed in 2014, representing 10% of living donor transplants that year (Figure 7.15).
- In 2013, the probability of one-year graft survival was 92% and 97% for deceased and living donor kidney transplant recipients, respectively (Tables 7.3 and 7.4).
- The probability of patient survival within one year post-transplant was 96% and 99% in deceased and living donor kidney transplant recipients, respectively, in 2013 (Tables 7.3 and 7.4).
- Since 1997, the probabilities of graft survival and patient survival have steadily improved among recipients of both living and deceased donor kidney transplants (Tables 7.3 and 7.4).
- The one-year graft survival and patient survival advantage experienced by living donor transplant recipients persists at five and ten years post-transplant (Table 7.4).

Introduction

Kidney transplantation is the renal replacement therapy of choice for a majority of patients with endstage renal disease (ESRD). Successful kidney transplantation is associated with improved survival, improved quality of life, and health care cost savings when compared to dialysis. This chapter reports on the trends of the kidney transplant waiting list, kidney transplants performed over the years, and the health outcomes of those who have received a transplant. In addition, to further enhance our understanding of the donor pool, this year we report the trends and epidemiology of deceased kidney donations among deaths of all causes and traumatic deaths over the years.

Notably, there was a major overhaul of the kidney allocation system (KAS) that took effect on December 4, 2014, with the purpose of reducing discards of potentially usable donor kidneys, decreasing access disparities, and decreasing unrealized life-years from the available organ supply. Some of the substantial

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changes included: (1) a move to the more refined donor quality metric, the Kidney Donor Profile Index (KDPI) in place of the previous categories of standard criteria or extended criteria donors; (2) the calculation of an Expected Post-Transplant Survival (EPTS) score for all adult kidney candidates with preferential allocation of donor kidneys with the best KDPI scores of 20% or less to candidates with the best EPTS scores of 20% or less; (3) increased priority for sensitized candidates through a sliding scale point system based on calculated panel reactive antibodies (PRA); and (4) inclusion of pre-waiting list dialysis time in a candidate's waiting time (Organ Procurement and Transplantation Network [OPTN], Health Resources and Services Administration, U.S. Department of Health & Human Services, 2015). As this year's chapter only includes data through the end of 2014, we do not yet examine the potential effects of the new allocation policy. However, OPTN reports that the KAS has resulted in a bolus of transplants in highly sensitized patients and those with more than a decade of dialysis, with similar 6-month graft survival (Stewart et al., 2016). Not surprisingly, kidneys are being shipped over greater distances and the occurrence of delayed graft function has increased. The full impact of the allocation policy will be an increasing focus of this chapter in future Annual Data Reports.

Methods

This chapter uses multiple data sources including data from the Centers for Medicare & Medicaid Services (CMS), OPTN, the Centers for Disease Control and Prevention (CDC), and the U.S. Census. Details of data sources are described in the <u>Data</u> <u>Sources</u> section of the *ESRD Analytical Methods* chapter.

See the section on <u>Chapter 7</u> in the *ESRD Analytical Methods* chapter for an explanation of analytical methods used to generate the figures and tables in this chapter.

Overview

During the year 2014, 17,914 kidney transplants, including 17,205 kidney-alone and 709 kidney plus at least one additional organ, were performed in the United States. Of these transplants, 5,574 were identified as coming from living donors and 12,328 from deceased donors. Overall, there were 145 (1%) more kidney transplants in the United States in 2014 than in 2013. Although the number of kidney transplants has, in general, remained stable since 2005, ranging from a high of 18,166 in 2006, to a low of 17,405 in 2012, the cumulative number of recipients living with a functioning kidney transplant continues to grow, reaching 200,907 in 2014, a 2.9% increase over 2013.

As of December 31, 2014, the kidney transplant waiting list increased by 3% over the previous year to 88,231 candidates (dialysis patients only), 83% of which were awaiting their first kidney transplant. Fifty-seven percent (50,692) of wait-listed candidates were in active status and 43% (37,539) were inactive. With less than 18,000 kidney transplants performed in 2014, the active waiting list was 2.8 times larger than the supply of donor kidneys, which presents a continuing challenge. An additional 15,498 (15%) of patients not yet on dialysis were on the waiting list as of December 31, 2014.

Among incident ESRD patients who started their dialysis in 2013, 12% were added to the waiting list or received a deceased or living donor transplant within one year of ESRD initiation. Among candidates newly wait-listed for either a first-time or repeat kidneyalone transplant in 2009, the median waiting time to transplant (deceased or living donor) was 3.5 years, i.e., 50% of patients had received a transplant within 3.5 years after being wait-listed for a transplant.

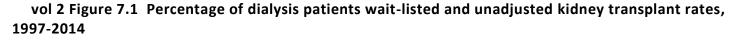
The probability of one-year graft survival for deceased donor kidney transplant recipients in 2013 was 92%, unchanged from 2012. Analyzing the separate components of graft failure, the probability of either returning to dialysis or undergoing repeat transplantation was 5%, while that of death was 4%. The probability of one-year graft survival for living donor transplant recipients was 97%. Analyzing the separate components of graft failure, the probability of either returning to dialysis or undergoing repeat transplantation was 2% and that of death was 1%.

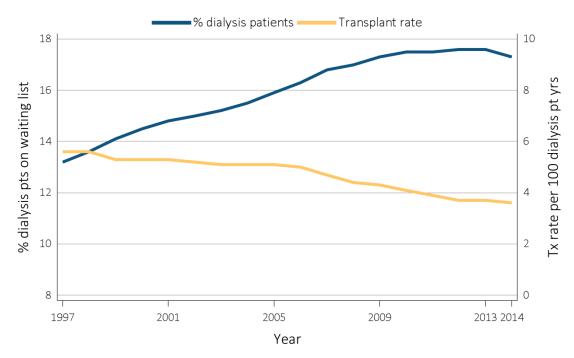
For recipients of deceased donor transplants in 2009, the probability of five-year graft survival remained unchanged from the prior year at 73%. Five-

year graft survival for living donor transplant

The unadjusted transplant rate per 100 dialysis patient years has been falling, while the percentage of prevalent dialysis patients wait-listed for a kidney has risen, though it appears to have plateaued in recent years (Figure 7.1). Probable contributing causes include a higher prevalent dialysis population, longer survival of ESRD patients on dialysis, and the growing imbalance between donor supply and demand, which in turn leads to longer kidney transplant waiting times. Waiting list counts and median waiting time to transplantation continue to grow for first-time listings (Figure 7.2). The number of candidates on the waiting list for repeat kidney transplant has plateaued at approximately 14,700 over the last five years, accounting for about 17% of the total wait-listed candidates. The median waiting time to transplantation (deceased or living donor) for firsttime listings was 3.4 years in 2009, 11 months shorter than that for candidates listed for repeat transplants. Table 7.1 presents median waiting times over time,

recipients also remained unchanged at 85%. stratified by blood type and PRA at time of listing. Patients with blood types B and O have the longest waiting times. As expected, patients with higher PRA tend to have longer waiting times, although waiting times have been dropping over time in those with the highest levels of sensitization (PRA of 80% or greater). In addition to variations in waiting time as a function of blood type and level of sensitization, there are also large regional differences (Reference Table E.2.2). Two states (Louisiana and Mississippi) have waiting times in excess of five years. Eleven states have waiting times less than two years with the lowest times in Utah (0.8 years), Maine (1.2 years), and Iowa (1.3 years). The total number of kidney transplants has leveled off over the past decade (Figure 7.3). During this period, a modest rise in deceased donor kidney transplants has been balanced by a small decrease in living donor transplants. As noted above, the total number of recipients with functioning kidney transplants continues to grow (Figure 7.4).

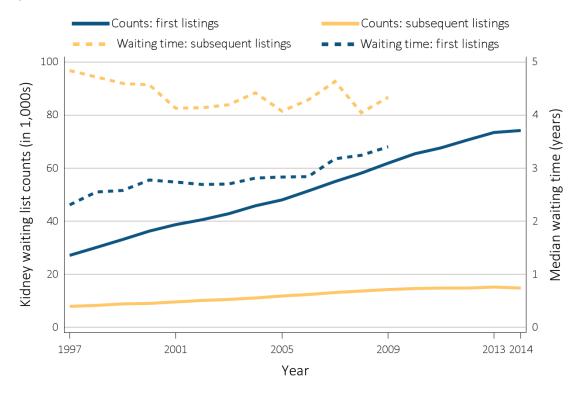




Data Source: Reference Tables E.4 and E.9. Percentage of dialysis patients on the kidney waiting list is for all dialysis patients. Unadjusted transplant rates are for all dialysis patients. Abbreviations: Tx, transplant; pt yrs, patient years.

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vol 2 Figure 7.2 Number of patients wait-listed for kidney transplant, 1997-2014, and median waiting time, 1997-2009



Data Source: Reference Tables E.2 and E.3. Waiting list counts include all candidates listed for a kidney transplant on December 31 of each year. Median waiting time is calculated for all candidates enrolled on the waiting list in a given year.

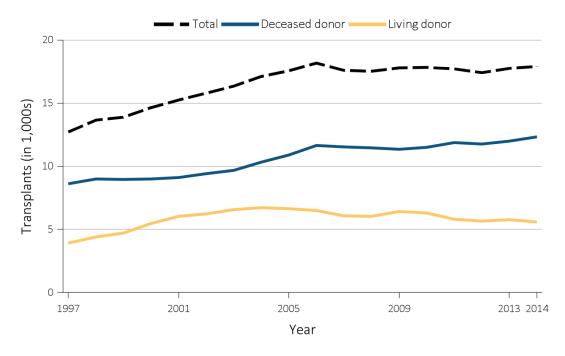
Blood type	PRA	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Blood type A	PRA = 0	1.0	1.1	1.1	1.4	1.2	1.3	1.3	1.3	1.2	1.4	1.8	1.8	2.0
	0 < PRA =< 20%	1.7	2.0	2.0	2.0	2.1	2.1	2.1	2.0	1.6	1.7	2.1	2.7	3.1
	20% < PRA =< 80%	3.3	3.1	2.9	2.8	3.0	3.2	2.6	2.8	2.9	3.0	2.8	2.5	3.0
	80% < PRA < 100%	6.2	5.2	6.4	5.6	4.6	4.7	5.1	5.1	3.9	3.8	4.9	3.2	3.4
Blood type B	PRA = 0	2.1	2.7	2.7	3.2	2.9	2.8	3.2	2.5	2.8	3.2	3.3	3.4	3.6
	0 < PRA =< 20%	3.6	3.7	4.1	4.2	4.0	4.1	3.4	3.3	3.8	3.9	3.7	4.4	5.2
	20% < PRA =< 80%	4.9	5.7	5.0	5.3	6.0	5.5	4.9	5.6	5.4	5.2	5.0	4.9	4.4
	80% < PRA < 100%	16.6	7.8	7.6	11.7	8.8	10.0	8.2	7.9	7.0	8.6	7.0	۸	۸
Blood type AB	PRA = 0	0.5	0.7	0.7	0.8	0.8	0.8	0.9	1.0	0.7	0.8	1.0	0.9	1.2
	0 < PRA =< 20%	0.9	1.1	1.1	1.0	1.3	1.3	1.4	1.1	1.1	1.0	1.1	1.8	2.6
	20% < PRA =< 80%	2.3	2.1	2.5	2.5	2.2	2.0	1.5	2.2	1.8	1.7	2.3	1.8	1.9
	80% < PRA < 100%	^	4.1	6.3	4.1	5.2	2.8	2.7	3.5	4.3	2.9	3.2	3.4	3.4
Blood type O	PRA = 0	2.0	2.2	2.3	2.4	2.4	2.4	2.4	2.7	2.8	2.9	3.6	3.7	3.8
	0 < PRA =< 20%	3.2	3.1	3.3	3.5	3.5	3.6	3.3	3.4	3.4	3.3	3.9	5.1	۸
	20% < PRA =< 80%	4.8	4.8	4.8	4.8	4.9	4.5	4.2	4.5	4.3	4.2	4.2	4.7	4.4
	80% < PRA < 100%	5.0	6.6	6.0	6.6	6.5	6.2	5.8	5.9	6.0	5.0	6.9	4.8	4.1

vol 2 Table 7.1 Median waiting time (in year) for kidney transplant, by blood type and PRA, 1997-2009

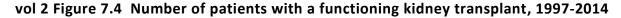
Data Source: Special analyses, USRDS ESRD Database. Abbreviation: PRA, panel reactive antibodies. ^ Value is missing since the estimated survival probability has not reached 50% and the corresponding data for that group were not sufficient to estimate median waiting time.

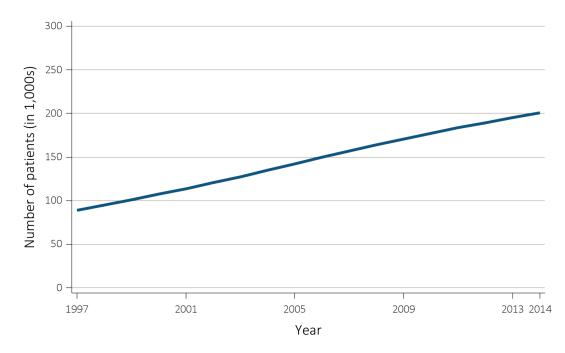
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Data Source: Reference Tables E.8, E.8(2), and E.8(3). Counts of all transplants by year.

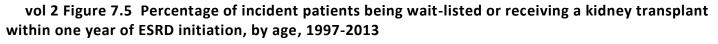


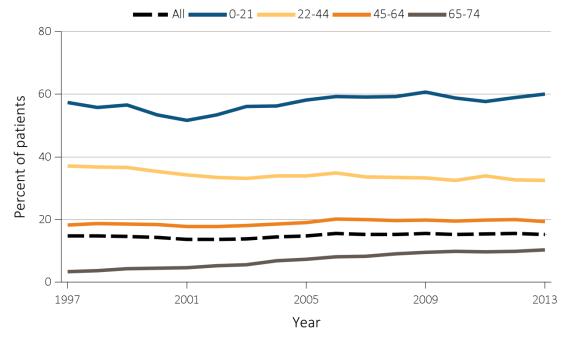


Data Source: Reference Table D.9. Prevalent counts of patients with a functioning kidney transplant as of December 31 of each year.

Kidney Transplant Waiting List

The percentage of patients wait-listed or receiving a transplant in their first ESRD-year has declined for those between the ages of 22 and 44 years, but has increased steadily since 2001 among those patients aged 0-21 years (Figure 7.5). There has been a consistent increase over time in the percentage of patients aged 65-74 years being wait-listed or receiving a kidney transplant within one year of ESRD initiation. However, older patients continue to comprise a minority of those being wait-listed or transplanted within one year of ESRD initiation.



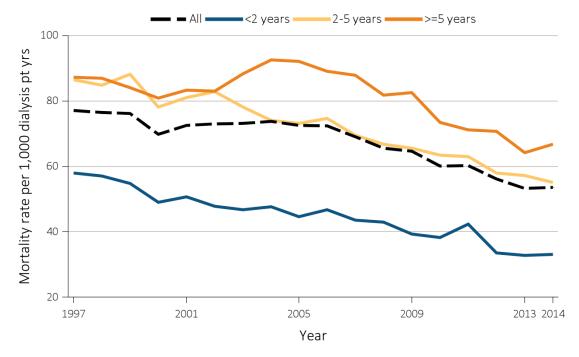


Data Source: Reference Table E.5(2). Waiting list or transplantation among incident ESRD patients by age (0-74 years). Abbreviation: ESRD, end-stage renal disease.

There has been a 27% relative decline in the overall mortality rate for dialysis patients on the kidney transplant waiting list since 2004, likely reflecting

similar trends observed in the overall dialysis population (Figure 7.6).

vol 2 Figure 7.6 Annual mortality rates for dialysis patients on the kidney transplant waiting list by time on the list, 1997-2014



Data Source: Reference Table H.6. Annual mortality rates of dialysis patients on the kidney transplant waiting list per 1,000 dialysis patient years at risk, by patient vintage. Abbreviation: pt yrs, patient years.

Transplant Counts and Rates

The overall number of annual kidney transplants has remained relatively stable since 2005, ranging from a high of 18,166 in 2006, to a low of 17,405 in 2012. However, as the dialysis population has expanded, the annual transplant rate among these dialysis patients has seen a continuous decline (Table 7.2). During 2005-2014, this trend was more pronounced in those aged 22-44 and 45-64 years. This decline is noticeable in both males and females, and across all racial groups and causes of ESRD. In subsequent sections, counts and rates of transplants are presented separately for deceased versus living donor sources as the trends differ substantially for certain subgroups. Most notably, transplant rates for ages 0-21 years have declined for living donor sources over the last decade but increased for deceased donor sources, resulting in overall stable transplant rates in recent years.

2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
36.2	37	31.6	31.9	34.4	32.5	31.1	31.9	31	32.1
11.3	11	10.2	9.3	9.3	8.7	8.3	8.1	7.8	7.7
6.0	6.0	5.6	5.3	5.1	5.0	4.7	4.4	4.4	4.3
2.6	2.7	2.5	2.6	2.6	2.6	2.6	2.5	2.5	2.4
0.3	0.3	0.4	0.3	0.4	0.4	0.4	0.4	0.3	0.4
5.6	5.6	5.2	4.9	4.7	4.5	4.3	4.0	4.0	3.9
4.5	4.3	4.1	3.9	3.9	3.7	3.5	3.3	3.3	3.2
6.2	6.0	5.6	5.2	5.1	4.7	4.5	4.4	4.3	4.1
3.3	3.3	3.1	2.9	3.0	3.0	2.9	2.6	2.5	2.5
3.3	4.0	3.0	3.6	3.7	2.9	3.0	2.5	2.3	2.7
5.6	5.4	4.8	5.0	4.7	4.6	4.3	4.2	4.3	4.2
3.4	3.2	3.1	2.9	2.8	2.6	2.5	2.3	2.3	2.2
3.2	3.2	3.1	3.0	2.9	2.8	2.6	2.6	2.5	2.5
9.8	10.1	9.1	8.8	8.7	8.8	8.3	7.9	7.8	7.6
5.1	5.0	4.7	4.4	4.3	4.1	3.9	3.7	3.7	3.6
	36.2 11.3 6.0 2.6 0.3 5.6 4.5 6.2 3.3 3.3 5.6 3.4 3.2 9.8	36.2 37 11.3 11 6.0 6.0 2.6 2.7 0.3 0.3 5.6 5.6 4.5 4.3 6.2 6.0 3.3 3.3 3.3 4.0 5.6 5.4 3.4 3.2 3.2 3.2 9.8 10.1	36.2 37 31.6 11.3 11 10.2 6.0 6.0 5.6 2.6 2.7 2.5 0.3 0.3 0.4	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	36.2 37 31.6 31.9 34.4 32.5 31.1 31.9 11.3 11 10.2 9.3 9.3 8.7 8.3 8.1 6.0 6.0 5.6 5.3 5.1 5.0 4.7 4.4 2.6 2.7 2.5 2.6 2.6 2.6 2.6 2.5 0.3 0.3 0.4 0.3 0.4 0.4 0.4 0.4 7.6 5.6 5.2 4.9 4.7 4.5 4.3 4.0 4.5 4.3 4.1 3.9 3.9 3.7 3.5 3.3 7.6 5.6 5.2 5.1 4.7 4.5 4.3 4.0 4.5 4.3 4.1 3.9 3.9 3.7 3.5 3.3 7.6 5.6 5.2 5.1 4.7 4.5 4.4 3.3 3.3 3.1 2.9 3.0 3.0 2.9 2.6 3.3 4.0 3.0 3.6 3.7 2.9 3.0 2.5 5.6 5.4 4.8 5.0 4.7 4.6 4.3 4.2 3.4 3.2 3.1 2.9 2.8 2.6 2.5 2.3 3.4 3.2 3.1 3.0 2.9 2.8 2.6 2.5 2.3 3.2 3.1 3.0 2.9 2.8 2.6 2.6 2.6 9.8 10.1 9.1 8.8 8.7 8.8	36.2 37 31.6 31.9 34.4 32.5 31.1 31.9 31 11.3 11 10.2 9.3 9.3 8.7 8.3 8.1 7.8 6.0 6.0 5.6 5.3 5.1 5.0 4.7 4.4 4.4 2.6 2.7 2.5 2.6 2.6 2.6 2.6 2.5 2.5 0.3 0.3 0.4 0.3 0.4 0.4 0.4 0.4 0.4 2.6 5.6 5.2 4.9 4.7 4.5 4.3 4.0 4.0 4.5 4.3 4.1 3.9 3.9 3.7 3.5 3.3 3.3 3.3 3.1 2.9 3.0 3.0 2.9 2.6 2.5 3.3 3.3 3.1 2.9 3.0 3.0 2.9 2.6 2.5 3.3 4.0 3.0 3.6 3.7 2.9 3.0 2.5 2.3 5.6 5.4 4.8 5.0 4.7 4.6 4.3 4.2 4.3 3.4 3.2 3.1 2.9 2.8 2.6 2.5 2.3 2.3 3.4 3.2 3.1 3.0 2.9 2.8 2.6 2.6 2.5 9.8 10.1 9.1 8.8 8.7 8.8 8.3 7.9 7.8

vol 2 Table 7.2 Unadjusted kidney transplant rates, all donor types, by age, sex, race, and primary cause of ESRD, per 100 dialysis patient years, 2005-2014

Data Source: Reference Table E.9. Abbreviation: ESRD, end-stage renal disease.

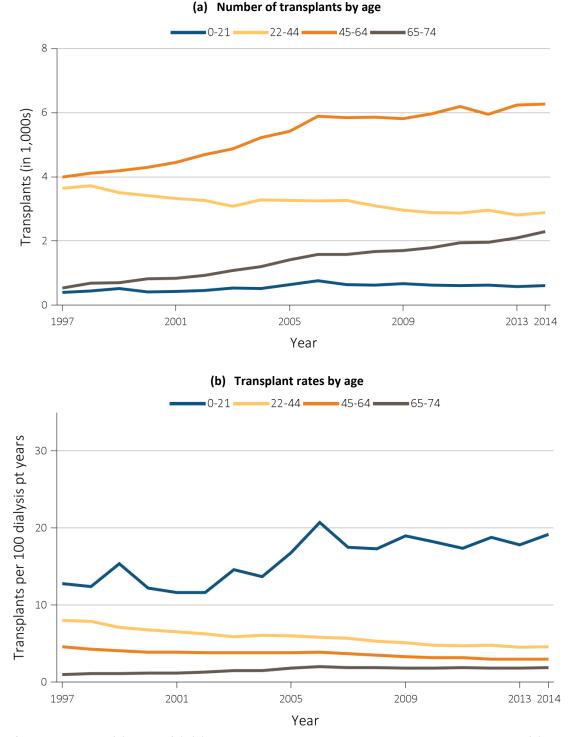
COUNTS AND RATES OF DECEASED DONOR TRANSPLANTS

The overall number of deceased donor transplants has leveled off since 2007 (Figure 7.3). In this section, we review trends in counts and rates of deceased donor transplants by age, sex, race, and primary cause of ESRD (Figures 7.7-7.10). As a general trend, while there are often increased transplant numbers (counts), there are decreased transplant rates, likely due to stagnation in the numbers of both deceased donor and living donor kidneys available for transplant coupled with a growing waiting list.

For patients aged 45-64 and 65-74 years, the number of deceased donor transplant recipients has continued to increase throughout the past two decades, although less markedly since 2006. The counts were highest for recipients aged 45-64 years, reaching 6,265 in 2014 (Figure 7.7.a, Number of transplants by age). In contrast, during this same time period, the number of deceased donor transplant recipients has decreased steadily to 2,886 for those aged 22-44 years.

Counts and rates of deceased donor transplantation per 100 dialysis patient years are presented in Figure 7.7 by age categories without statistical adjustment. The patterns for deceased donor transplant counts in Figure 7.7.a versus rates in 7.7.b look very different, as the number of dialysis patients varies, and increases markedly with age. Due to the small denominator for children on dialysis, and the pediatric allocation priority for kidneys from deceased donors under the age of 35 years, deceased donor transplant rates are highest in children (<22 years old); their rates increased in 2005-2007, stabilizing thereafter. While there has been a reduction in deceased donor kidney transplantation rates for those aged 22-44 and 45-64 years, the rates for those aged 65-74 years have stabilized at low levels.

vol 2 Figure 7.7 Number of deceased donor transplants and unadjusted transplant rates among deceased donor kidney recipients, by recipient age, 1997-2014



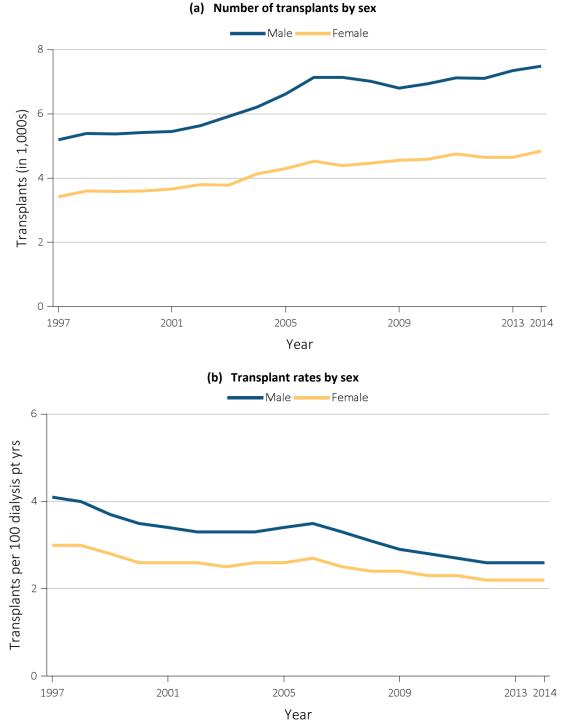
Data Source: Reference Tables E.8(2) and E.9(2). (a) Deceased donor kidney transplant counts by recipient age. (b) Unadjusted deceased donor kidney transplant rates by recipient age. Abbreviation: pt, patient.

The trends for counts of deceased donor transplants by year are similar for males and females, rising over the past decade, with some leveling off after 2006 (Figure 7.8.a, Number of transplants by sex). Males received substantially more transplants than females. This difference seems to be largely explained by the fact that males account for more than 60% of wait-listed candidates.

The rates of deceased donor kidney transplantation during 1997-2014 declined for both male and female

dialysis patients (Figure 7.8.b, Transplant rates by sex), although there has been some leveling off in the last year. This decline is explained partly by the growing number of dialysis patients. The difference in transplantation rates between males and females has been narrowing in recent years.

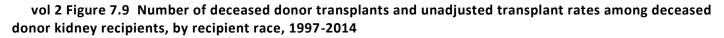
vol 2 Figure 7.8 Number of deceased donor transplants and unadjusted transplant rates among deceased donor kidney recipients, by recipient sex, 1997-2014

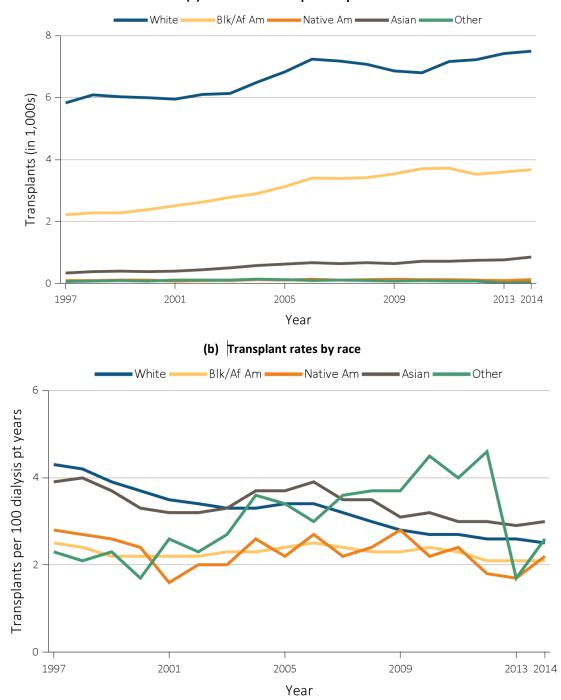


Data Source: Reference Tables E.8(2) and E.9(2). (a) Deceased donor kidney transplant counts by recipient sex. (b) Unadjusted deceased donor kidney transplant rates by recipient sex. Abbreviation: pt yrs, patient years.

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Among Whites and Blacks/African Americans (hereafter, Blacks), the number of deceased donor transplants has grown substantially over the past decade, with smaller increases for Asians, and small decreases for Native American and Other races (Figure 7.9.a, Number of transplants by race). Since 1996, deceased donor transplant rates for White dialysis patients have been declining. Since 2003, deceased donor transplant rates for Asians have been higher than for Whites (Figure 7.9.b, Transplant rates by race). The rates of deceased donor transplants for Blacks and Native Americans continue to remain low compared to Whites.





(a) Number of transplants by race

Data Source: Reference Tables E.8(2) and E.9(2). (a) Deceased donor kidney transplant counts by recipient race. (b) Unadjusted deceased donor kidney transplant rates by recipient race. Abbreviations: Blk/Af Am, Black/African American; Native Am, Native American; pt, patient.

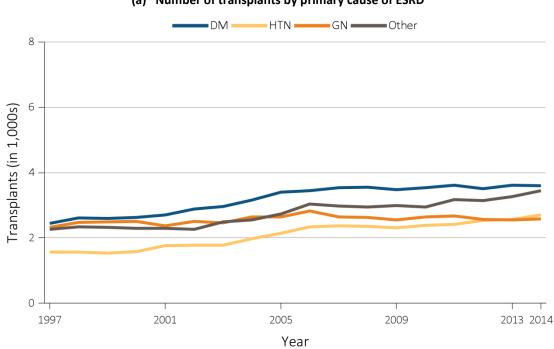
CHAPTER 7: TRANSPLANTATION

The largest growth in deceased donor transplantation numbers has been among recipients with diabetes or hypertension (Figure 7.10.a, Number of transplants by primary cause). This growth is not surprising, as diabetes was the most common disease among the major causes of ESRD.

The rates of deceased donor transplants for all diagnosis groups have been declining since 2006 (Figure 7.10.b, Transplant rates by primary cause of ESRD).

Transplant rates among dialysis patients with glomerular disease exceeded those for any other causes, followed by the Other causes category (including cystic disease). Deceased donor transplant rates for candidates with ESRD attributed to hypertension and diabetes are similar to each other, but were lower than those observed for the glomerulonephritis and Other categories. This rank order is likely explained in part by differences in the suitability for transplantation of patients with these diagnoses as the primary cause of ESRD.

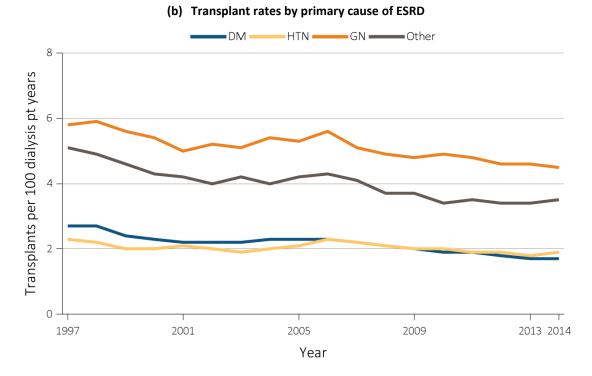
vol 2 Figure 7.10 Number of deceased donor transplants and unadjusted transplant rates among deceased donor kidney recipients, by recipient primary cause of ESRD, 1997-2014



(a) Number of transplants by primary cause of ESRD

Figure 7.10 continued on next page.

vol 2 Figure 7.10 Number of deceased donor transplants and unadjusted transplant rates among deceased donor kidney recipients, by recipient primary cause of ESRD, 1997-2014 (continued)



Data Source: Reference Tables E.8(2) and E.9(2). (a) Deceased donor kidney transplant counts by recipient primary cause of ESRD. (b) Unadjusted deceased donor kidney transplant rates by recipient primary cause of ESRD. Abbreviations: DM, diabetes mellitus; ESRD, end-stage renal disease; GN, glomerulonephritis; HTN, hypertension; pt, patient.

COUNTS AND RATES OF LIVING DONOR TRANSPLANTS

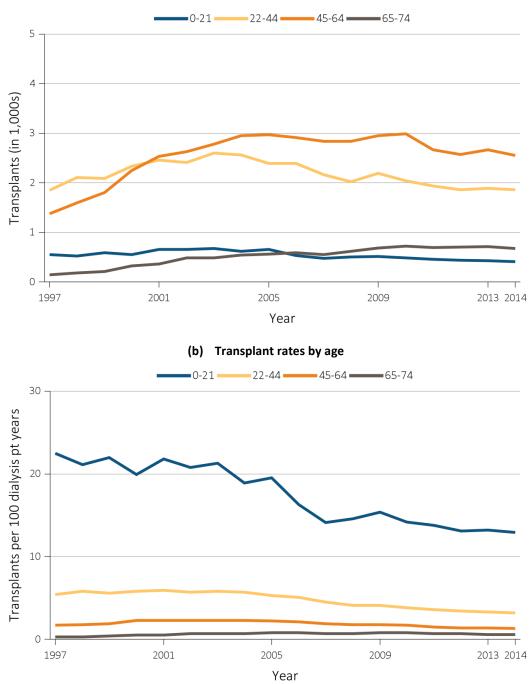
Though annual living donor kidney transplant counts rose steadily for adult recipients between 1996 and 2004, there has since been a steady but modest decline. In this section, we review trends in annual counts and rates of living donor kidney transplants by age, sex, race, and primary cause of ESRD (Figures 7.11-7.14).

Counts for living donor transplants for those aged 22-44 years decreased from 2,603 in 2003 to 1,861 in 2014. The number of living donor transplants for the group aged 45-64 years has shown a more recent decline, falling from 2,993 in 2010 to 2,549 in 2014 (Figure 7.11.a, Number of transplants by age). While

transplant counts for those over 65 years old increased between 1997 and 2010, they have subsequently remained relatively stable, at close to 800 per year.

Kidney transplantation rates from living donors per 100 dialysis patient years show that younger age groups have substantially higher annual rates (Figure 7.11.b, Transplant rates by age). However, there was a steep decline in these rates for the 0-21 year old group starting in 2003, with recent trends more static. Among adults, the 22-44 year old group has the highest living donor transplantation rate, although it too is declining. Only the very low rates for ages 65-74 years have remained stable over the past decade.

vol 2 Figure 7.11 Number of living donor transplants and unadjusted transplant rates among living donor kidney recipients, by recipient age, 1997-2014

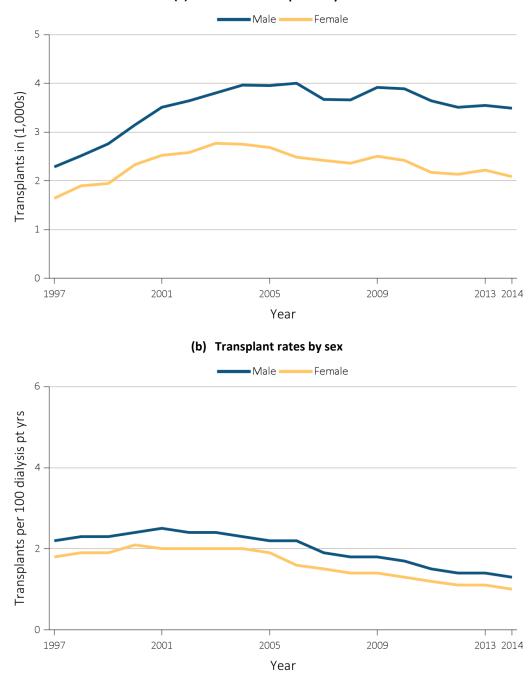


(a) Number of transplants by age

Data Source: Reference Tables E.8(3) and E.9(3). (a) Living donor kidney transplant counts by recipient age. (b) Unadjusted living donor kidney transplant rates by recipient age. Abbreviation: pt, patient.

The annual counts of living donor kidney transplantation show consistently higher numbers of male, compared to female, recipients (Figure 7.12.a, Number of transplants by sex). However, since 2009, living donor kidney transplant counts have decreased for both males and females. While the living donor transplant rates continue to remain higher for males than for females, the difference is relatively small (Figure 7.12.b, Transplant rates by sex).

vol 2 Figure 7.12 Number of living donor transplants and unadjusted transplant rates among living donor kidney recipients, by recipient sex, 1997-2014

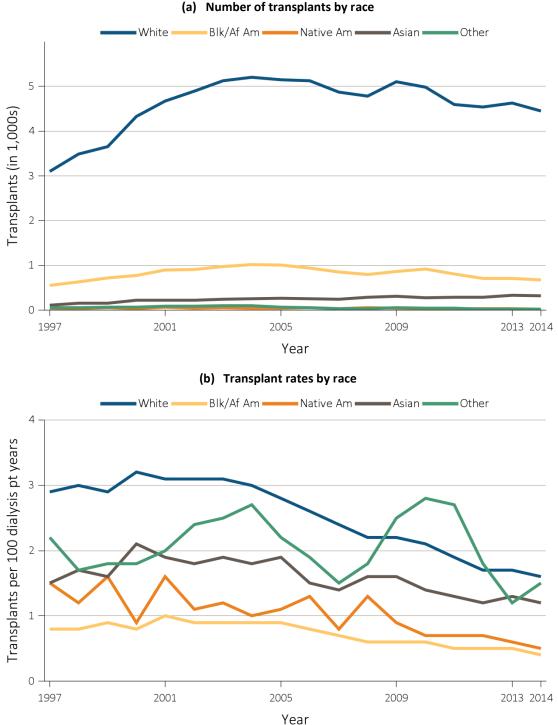


(a) Number of transplants by sex

Data Source: Reference Tables E.8(3) and E.9(3). (a) Living donor kidney transplant counts by recipient sex. (b) Unadjusted living donor kidney transplant rates by recipient sex. Abbreviation: pt yrs, patient years.

Consistent with the overall trend, living donor kidney transplant counts steadily increased until 2004 for all races (Figure 7.13.a, Number of transplants by race). Since then, the annual number of living donor kidney transplants has decreased for Whites and Blacks, while the counts for Asians have shown a small increase. Living donor transplant rates for Whites are the highest among all race groups, while rates among Native Americans are the lowest (Figure 7.13.b, Transplant rates by race), while the rate for Other races is quite variable by year. From 2013 to 2014, living donor transplant rates have declined slightly among all race groups except for Other among whom the transplant rate has increased.

vol 2 Figure 7.13 Number of living donor transplants and unadjusted transplant rates among living donor kidney recipients, by recipient race, 1997-2014



Data Source: Reference Tables E.8(3) and E.9(3). (a) Living donor kidney transplant counts by recipient race. (b) Unadjusted living donor kidney transplant rates by recipient race. Abbreviations: Blk/Af Am, Black/African American; Native Am, Native American; pt, patient.

The ranking of living donor kidney transplantation counts by primary cause of ESRD has remained the same over the past decade, from highest to lowest

frequency: other, glomerulonephritis, diabetes, and hypertension (Figure 7.14.a, Number of transplants by primary cause of ESRD). This trend contrasts with the

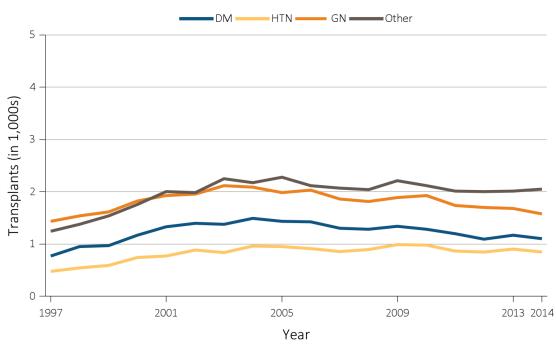
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pattern among deceased donor recipients (Figure 7.10.a, Number of transplants by primary cause), where the numbers with ESRD caused by diabetes mellitus and hypertension have grown steadily in comparison to other causes.

The rates of living donor transplantation for all diagnosis groups have been declining over the past

decade (Figure 7.14.b, Transplant rates by primary cause of ESRD). Similar to the rates of deceased donor transplants, the rates of living donor transplants among patients with glomerular disease exceed those for any other causes, followed by other causes (including cystic disease), and are lowest for those with hypertension and diabetes.

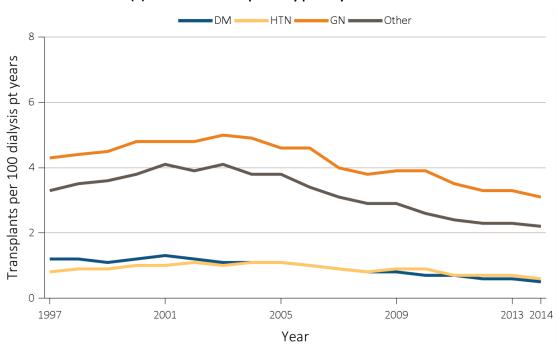
vol 2 Figure 7.14 Number of living donor transplants and unadjusted transplant rates among living donor kidney recipients, by recipient primary cause of ESRD, 1997-2014



(a) Number of transplants by primary cause of ESRD

Figure 7.14 continued on next page.

vol 2 Figure 7.14 Number of living donor transplants and unadjusted transplant rates among living donor kidney recipients, by recipient primary cause of ESRD, 1997-2014 (continued)

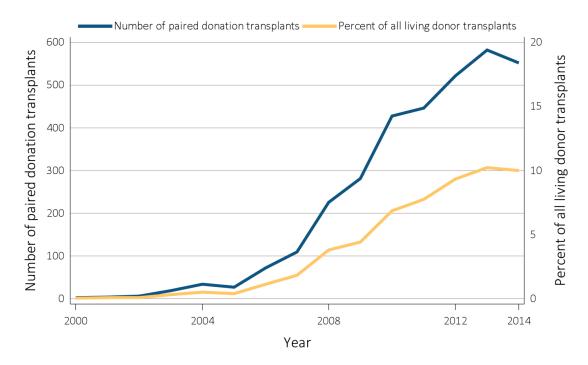


(b) Number of transplants by primary cause of ESRD

Data Source: Reference Tables E.8(3) and E.9(3). (a) Living donor kidney transplant counts by recipient primary cause of ESRD. (b) Unadjusted living donor kidney transplant rates by recipient primary cause of ESRD. Abbreviations: DM, diabetes mellitus; ESRD, endstage renal disease; GN, glomerulonephritis; HTN, hypertension; pt, patient.

A relatively recent initiative aimed at increasing the availability of living donor transplants is the process of kidney paired donation (KPD). This typically applies when an otherwise willing potential living donor is incompatible with the recipient. In its simplest form, two living donors who are incompatible with their respective recipients perform an exchange whereby the donation goes to each other's compatible recipient. More complex chains involving exchanges among three or more recipient-donor pairs are possible and have been performed. The counts of KPD transplants have risen sharply in recent years, with 552 performed in 2014, representing 10% of living donor transplants that year (Figure 7.15).

vol 2 Figure 7.15 Number of paired donation transplants and percent of all living donor transplants, 2000-2014

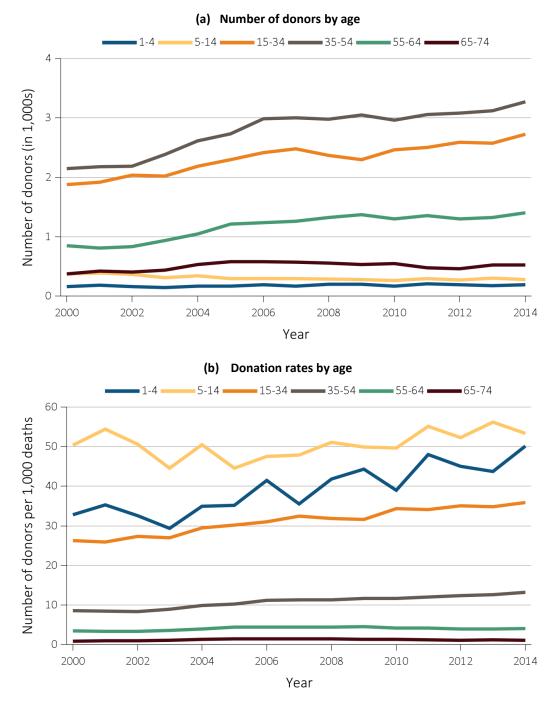


Data Source: Data are obtained from the Organ Procurement and Transplantation Network (OPTN). Paired donation transplant counts and percent of all living donor transplants.

Deceased Donation Counts and Rates among All-cause Deaths

The number of deceased donors, aged 1-74 years, with at least one kidney retrieved has been increasing from 6,231 in 2003 to 8,385 in 2014 (Figure 7.16.a, Number of donors by age).

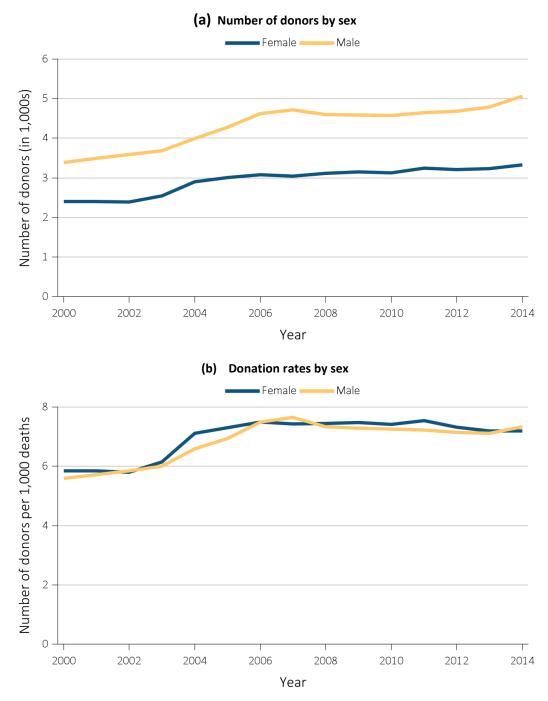
Since 2002, the number of donors among those aged 1-4, 5-14, and 65-74 years has been relatively stable, but the number of donors among those aged 15-64 years has been increasing slowly. Donors aged 35-54 years have been the leading source of kidney donations during the past 15 years, with donors aged 15-34 years being the second highest source, and those aged 55-64 years being the third highest. Annual donation rates were calculated as the number of deceased donors from whom at least one kidney was retrieved per 1,000 deaths in the U.S. population (Centers for Disease Control and Prevention, 2016). The overall donation rates ranged from 5.7 per 1,000 deaths in 2000 to 7.3 per 1,000 deaths in 2014. Donation rates among those aged younger than 55 years have increased from 14 per 1,000 deaths in 2003 to 20 per 1,000 deaths in 2014 (Figure 7.16.b, Donation rates by age). The highest donation rates were among those aged 1-4 (rising from 33 per 1,000 deaths in 2000 to 50 per 1,000 deaths in 2014) and 5-14 years (rising slightly from 50 per 1,000 deaths in 2000 to 53 per 1,000 deaths in 2014). vol 2 Figure 7.16 Number of deceased kidney donors and unadjusted kidney donation rates, by donor age, 2000-2014



Data Source: Data on the annual number of deaths in the U.S. population are obtained from the Centers for Disease Control and Prevention; the deceased donor data are obtained from the Organ Procurement and Transplantation Network (OPTN). Deceased donor kidney donation counts and rates by donor age.

Deceased kidney donor counts of males have been consistently around 1.5 times greater than those of females (Figure 7.17.a Number of donors by sex), but the donation rates are similar between males and females (Figure 7.17.b Donation rates by sex). Both groups have demonstrated an increase in the donor numbers and rates after 2003, but have been stable since 2008.

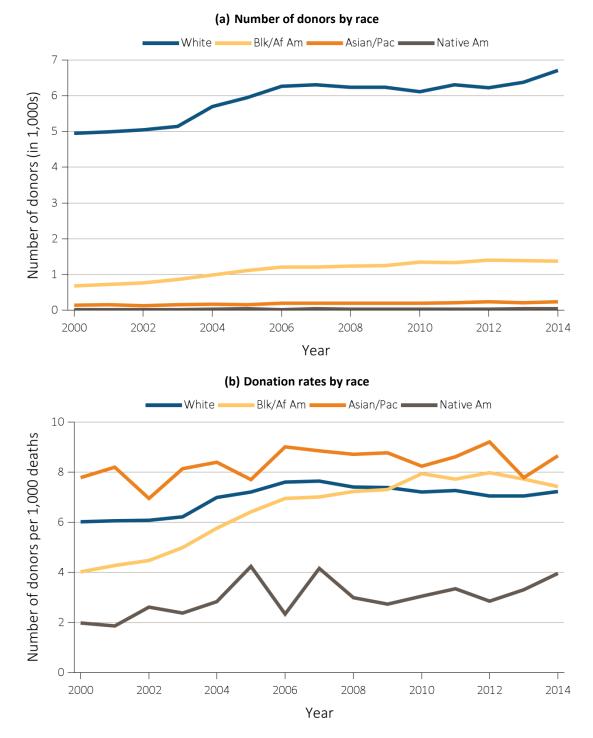
vol 2 Figure 7.17 Number of deceased kidney donors and unadjusted kidney donation rates, by donor sex, 2000-2014



Data Source: Data on the annual number of deaths in the U.S. population are obtained from the Centers for Disease Control and Prevention; the deceased donor data are obtained from the Organ Procurement and Transplantation Network (OPTN). Deceased donor kidney donation counts and rates by donor sex.

Whites have contributed the most to the number of deceased donors each year during 2000-2014 (Figure 7.18.a Number of donors by race), but Blacks have surpassed Whites in donation rates since 2009 (Figure 7.18.b Donation rates by race). The rate of deceased donors per 1,000 deaths among Blacks almost doubled from 2000 to 2014. Since 2000, Asian or Pacific Islanders have had the highest donation rate, and Native Americans have had the lowest donation rates.

vol 2 Figure 7.18 Number of deceased kidney donors and unadjusted kidney donation rates, by donor race, 2000-2014



Data Source: The U.S. death population data are obtained from the Centers for Disease Control and Prevention; the deceased donor data are obtained from the Organ Procurement and Transplantation Network (OPTN). Deceased donor kidney donation counts and rates by donor race. Abbreviations: Asian/Pac, Asian/Pacific Islander; Blk/Af Am, Black/African American; Native Am, Native American.

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In 2014, among 16,404 kidneys that were recovered from deceased donors, 2,703 (16%) were discarded due to various reasons. During 2010-2014, the percent of kidneys discarded has ranged between 16%-17% (OPTN, 2015).

Deceased Donation Counts and Rates Among Traumatic Deaths

In this new section, counts and rates of deceased donations are presented focusing on donors with traumatic causes of death (motor vehicle accident, suicide, or homicide). Such cases represent a common source of donation, as they may be less likely to have other underlying health issues that would preclude use of the organs. The number of such donors, aged 1-74 years, with at least one kidney retrieved, has been relatively steady since 2006, with 2,449 donations in 2014 (which represents 29% of all deceased donations). As expected, due to the underlying cause of death, donors in the age range of 15-54 years are overrepresented, with only small numbers of donors in the other age categories (Figure 7.19.a, Number of donors by age).

Annual donation rates were calculated as the number of deceased donors with a traumatic cause of death from whom at least one kidney was retrieved per 1,000 deaths (with cause being motor vehicle accident, suicide, or homicide) in the U.S. population (Centers for Disease Control and Prevention, 2016). In 2014, overall donation rates among those with traumatic deaths (28.5 per 1,000 deaths) were 4.1 times as high as donation rates among those with death from any cause (7.3 per 1,000 deaths). Donation rates for traumatic deaths were highest among those aged 5-34 years (47 per 1,000 deaths, Figure 7.19.b, Donation rates by age).

vol 2 Figure 7.19 Number of deceased kidney donors and unadjusted kidney donation rates, for traumatic deaths, by donor age, 2000-2014

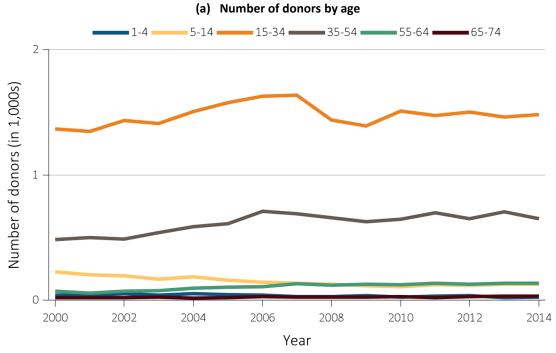
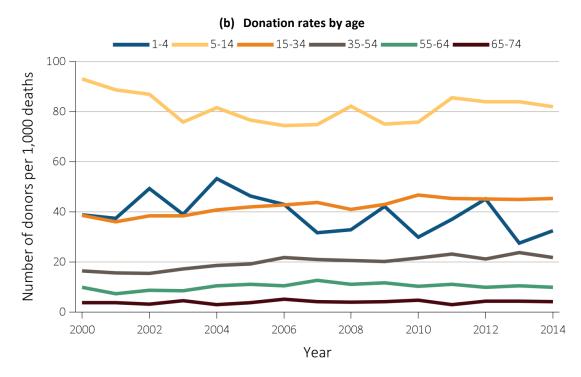


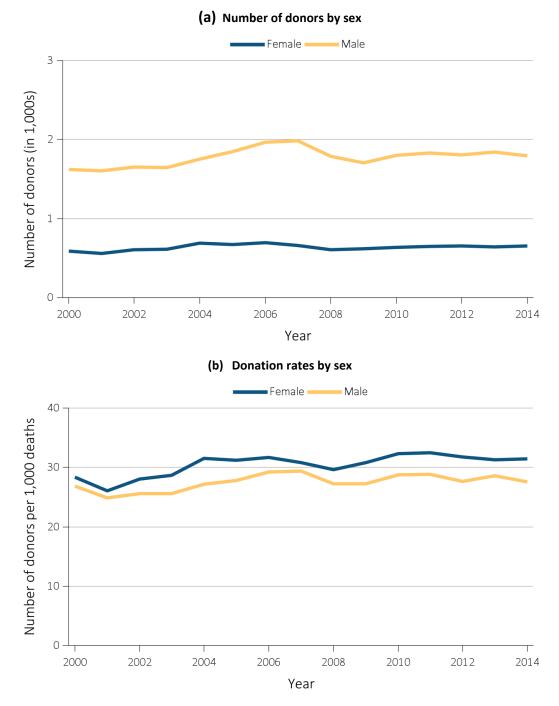
Figure 7.19 continued on next page.

vol 2 Figure 7.19 Number of deceased kidney donors and unadjusted kidney donation rates, for traumatic deaths, by donor age, 2000-2014 (continued)



Data Source: Data on the annual number of deaths in the U.S. population are obtained from the Centers for Disease Control and Prevention; the deceased donor data are obtained from the Organ Procurement and Transplantation Network (OPTN). Deceased donor kidney donation counts and rates by donor age.

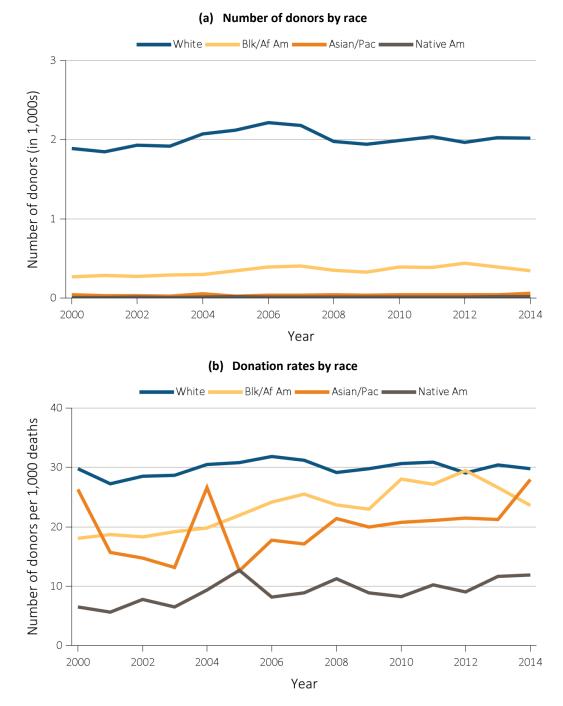
While deceased kidney donor counts of males have been consistently around double those of females (Figure 7.20.a Number of donors by sex), male and female donation rates are similar (Figure 7.20.b Donation rates by sex). Both counts and rates of kidney donation among males and females with traumatic deaths have been stable for the last several years. vol 2 Figure 7.20 Number of deceased kidney donors and unadjusted kidney donation rates, for traumatic deaths, by donor sex, 2000-2014



Data Source: Data on the annual number of deaths in the U.S. population are obtained from the Centers for Disease Control and Prevention; the deceased donor data are obtained from the Organ Procurement and Transplantation Network (OPTN). Deceased donor kidney donation counts and rates by donor sex.

Whites have contributed the most to the number of deceased donors each year during 2000-2014 (Figure 7.21.a Number of donors by race), although rates of donation in the most recent years have been similar across Whites, Blacks, and Asian or Pacific Islanders (Figure 7.21.b Donation rates by race).

vol 2 Figure 7.21 Number of deceased kidney donors and unadjusted kidney donation rates, for traumatic deaths, by donor race, 2000-2014



Data Source: The U.S. death population data are obtained from the Centers for Disease Control and Prevention; the deceased donor data are obtained from the Organ Procurement and Transplantation Network (OPTN). Deceased donor kidney donation counts and rates by donor race. Abbreviations: Asian/Pac, Asian/Pacific Islander; Blk/Af Am, Black/African American; Native Am, Native American.

Transplant Outcomes

There has been a progressive improvement in outcomes of kidney transplant recipients in the last few years. In this section, we review the trends in probability of all-cause graft failure, probability of returning to dialysis or retransplantation, and probability of death at one, five, and ten years posttransplant. All-cause graft failure is defined as any graft failure, including death with graft function as a graft failure. The probability of return to dialysis or retransplantation represents death-censored graft failure.

During 1997-2013, kidney transplant patients experienced improved health outcomes, with decreases in deaths and all-cause graft failure at one year post-transplantation. Among the recipients of deceased donor kidney transplants, the probability of all-cause graft failure in the first year following transplant decreased from 14% in 1997 to 8% in 2013, while the probability of death decreased from 6% in 1997 to 4% in 2013. Similarly, among those who received living donor kidney transplants, the probability of all-cause graft failure in the first year following transplant decreased from 7% in 1997 to 3% in 2013, while probability of death decreased from 3% to 1% over the same period.

Improvements in patient and graft survival probabilities have persisted for most of the five- and ten-year outcomes as well. Among deceased donor kidney transplant recipients, the probability of allcause graft failure by the fifth year improved, dropping from 34% in 1997 to 27% in 2009, and by the tenth year post-transplant it also decreased from 58% in 1997 to 53% in 2004. Probability of death by the fifth year post-transplant improved by dropping from 19% in 1997 to 16% in 2009, and for tenth year post transplant improved by decreasing from 39% in 1997 to 37% in 2004. Similarly, for living donor kidney transplant recipients, the probability of all-cause graft failure by the fifth year decreased from 22% in 1997 to 15% in 2009, while in the tenth year it decreased from 43% in 1997 to 38% in 2004. The probability for death by fifth year post-transplant also improved by falling from 11% in 1997 to 8% in 2009, while in the tenth year it decreased from 24% in 1997 to 22% in 2004. Overall, the outcomes have been consistently more advantageous in living donor kidney transplant recipients in comparison to deceased donor transplant recipients (Tables 7.3 and 7.4).

	One y	ear post-tran	splant	Five ye	ears post-trar	nsplant	Ten ye	all- cause return to dialysis or repeat graft return to dialysis or repeat ailure transplant 57.9% 41.0% 56.4% 40.3% 56.3% 39.2% 56.7% 38.6% 55.2% 36.7% 53.5% 35.8% 54.4% 35.8%			
Year	Prob. of all- cause graft failure	Prob. of return to dialysis or repeat transplant	Prob. of death	Prob. of all- cause graft failure	Prob. of return to dialysis or repeat transplant	Prob. of death	Prob. of all- cause graft failure	return to dialysis or	Prob. of death		
1997	13.9%	8.1%	6.1%	34.2%	23.4%	19.2%	57.9%	41.0%	39.3%		
1998	13.5%	8.3%	5.5%	33.2%	23.5%	18.2%	56.4%	40.3%	38.0%		
1999	14.3%	8.4%	5.9%	33.4%	22.7%	18.8%	56.3%	39.2%	38.2%		
2000	13.7%	7.9%	6.4%	34.0%	22.7%	19.7%	56.7%	38.6%	39.2%		
2001	12.7%	7.6%	5.7%	32.9%	21.1%	19.8%	55.2%	36.7%	38.6%		
2002	12.7%	7.8%	5.6%	32.5%	21.8%	18.8%	53.5%	35.8%	37.1%		
2003	12.4%	7.3%	5.6%	31.7%	20.3%	18.4%	54.4%	35.8%	37.6%		
2004	11.8%	7.1%	5.4%	31.2%	20.5%	18.3%	53.1%	35.4%	36.7%		
2005	11.5%	6.9%	6.0%	29.9%	19.1%	17.8%					
2006	10.8%	6.6%	5.1%	29.3%	18.7%	17.1%					
2007	9.8%	5.9%	4.6%	28.2%	17.7%	16.9%					
2008	9.6%	6.0%	4.5%	26.8%	16.1%	16.3%					
2009	9.4%	5.6%	4.9%	26.8%	16.3%	16.1%					
2010	8.8%	5.4%	4.4%								
2011	7.3%	4.3%	3.9%								
2012	7.8%	4.8%	3.8%								
2013	7.7%	4.8%	3.5%								

vol 2 Table 7.3 Trends in 1-, 5-, & 10-year deceased donor kidney transplant outcomes, 1997-2013

Data Source: Reference Tables F.2, F.14, I.26; F.5, F.17, I.29; F.6, F.18, I.30. Outcomes among recipients of a first-time deceased donor kidney transplant; unadjusted. Abbreviation: Prob., probability.

vol 2 Table 7.4 Trends in 1-, 5-, & 10-year living donor kidney transplant outcomes, 1997-2013

	One	year post-trai	nsplant	Five ye	ears post-trar	nsplant	Ten ye	ars post-trar	splant
Year	Prob. of all- cause graft failure	Prob. of return to dialysis or repeat transplant	Prob. of death	Prob. of all- cause graft failure	Prob. of return to dialysis or repeat transplant	Prob. of death	Prob. of all- cause graft failure	Prob. of return to dialysis or repeat transplant	Prob. of death
1997	6.7%	4.8%	2.7%	22.1%	15.7%	10.5%	43.1%	31.0%	24.3%
1998	5.9%	4.3%	2.3%	20.7%	14.5%	10.1%	42.1%	30.4%	23.3%
1999	6.0%	4.2%	2.1%	20.8%	14.6%	9.5%	41.0%	28.9%	22.5%
2000	6.5%	4.4%	2.6%	21.7%	14.7%	10.5%	41.9%	28.9%	23.7%
2001	6.1%	4.0%	2.5%	21.2%	14.2%	10.2%	41.0%	27.6%	23.7%
2002	5.7%	3.8%	2.4%	20.3%	13.5%	10.2%	39.7%	26.1%	24.4%
2003	5.5%	4.0%	1.8%	20.1%	13.8%	9.4%	39.3%	26.0%	23.0%
2004	5.2%	3.6%	2.1%	18.8%	12.7%	8.8%	38.3%	24.7%	22.4%
2005	5.4%	3.7%	2.0%	18.7%	12.7%	8.8%			
2006	4.5%	3.1%	1.7%	16.8%	11.2%	8.0%			
2007	3.8%	2.5%	1.3%	16.6%	10.6%	7.9%			
2008	4.3%	2.9%	1.6%	15.4%	10.1%	7.4%			
2009	4.0%	2.7%	1.3%	15.1%	9.3%	7.6%			
2010	3.7%	2.4%	1.4%						
2011	3.5%	2.0%	1.8%						
2012	3.5%	2.1%	1.4%						
2013	2.6%	1.5%	1.2%						

Data Source: Reference Tables F.8, F.20, I.32; F.11, F.23, I.35; F.12, F.24, I.36. Outcomes among recipients of a first-time living donor kidney transplant; unadjusted. Abbreviation: Prob., probability.

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Chapter 8: ESRD Among Children, Adolescents, and Young Adults

- The number of children beginning end-stage renal disease (ESRD) care decreased by 6% in 2014, totaling 1,398 (Figure 8.1.a).
- 9,721 children were being treated for ESRD on December 31, 2014 (Figure 8.1.b).
- Peritoneal dialysis is the most common initial ESRD treatment modality in children younger than 9 years and those who weigh less than 20 kg (Figure 8.2).
- The most common initial ESRD treatment modality among children overall continues to be hemodialysis (50.4%) (Figure 8.1.a). However, among the prevalent pediatric population, 70% are living with a functioning kidney transplant.
- Since 2006, 81% of incident pediatric ESRD patients have started hemodialysis with a central venous catheter without a maturing fistula or graft (Figure 8.11.a).
- 36% of children received a kidney transplant within the first year of ESRD care during 2010-2014 (Table 8.1).
- The total number of children wait-listed for kidney transplant was 1,321 in 2014 (Figure 8.13.b).
- Since 2006, deceased donor transplants have become more common in children than living donor transplants (Figure 8.13.c).
- All-cause hospitalization rates increased 24.4%, totaling 2 per patient year among children with incident ESRD (Figure 8.4.b).
- The five-year patient survival probability was 0.90 for children initiating ESRD care between 2005-2009 (Figure 8.10.b).
- The five-year patient survival probability was 0.80 for young adults (ages 22-29) initiating ESRD care between 2005-2009 (Figure 8.19).

Introduction

Pediatric end-stage renal disease (ESRD) affects children of all ages. The majority of these children will depend on renal replacement therapies over many decades. Consequently, children with incident ESRD often traverse the entire ESRD modality continuum of hemodialysis, peritoneal dialysis, and transplantation. These children are subjected to frequent hospitalizations and have a risk of mortality far exceeding that of the general pediatric population in the United States. Children with ESRD are quite different in disease etiology, transplant opportunities, morbidity, and mortality when compared to adults with ESRD. Consequently, this chapter of the Annual Data Report (ADR) focuses on pediatric ESRD. This chapter also includes a section on young adults in order to improve our understanding of the issues surrounding transitions and outcomes in these patients.

Methods

This chapter uses multiple data sources, including data from the Centers for Medicare & Medicaid Services (CMS), the Organ Procurement and Transplantation Network (OPTN), the Centers for Disease Control and Prevention (CDC), and the U.S.

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Census. Details of these data sources are described in the <u>Data Sources</u> section of the *ESRD Analytical Methods* chapter.

The categories of ESRD etiology have been updated this year to include the widely accepted Congenital Anomalies of the Kidney and Urinary Tract (CAKUT). In addition, with this 2016 pediatric chapter the ICD-9 codes included for cardiovascular hospitalization were reorganized to reflect the spectrum of cardiovascular diseases in children and exclude diagnoses such as hypertension, hemorrhage NOS, and esophageal varices. More details are provided in the *ESRD Analytical Methods* chapter.

See the section on <u>Chapter 8</u> in the *ESRD Analytical Methods* chapter for an explanation of analytical methods used to generate the study cohorts, figures, and tables in this chapter.

Epidemiology of End-Stage Renal Disease

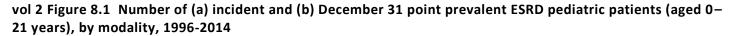
in Children

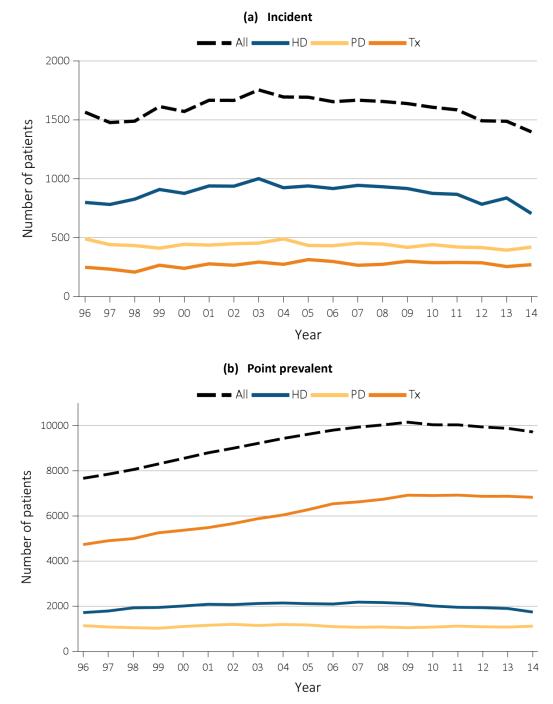
The incidence of ESRD in children has been decreasing annually in the United States between 2008 and 2014 (Figure 8.1.a). In 2014, a total of 1,398 children had new onset ESRD, which was 6% less than in 2013. By age, the number of incident cases ranged from a low of 152 in the 5-9 age group to 555 in the 18-21 age group. Children ages 18-21 years old account for 40% of the incident pediatric ESRD population. In terms of rates, incidence ranges from 6.8 per million for the 5-9 age group to 30.6 per million in the 18-21 age group. Similarly, as of December 31, 2014, the point prevalence of children with ESRD was 9,721, which represents a 1.6% decrease from the previous year (Figure 8.1.b). Prevalence counts do not account for the large number of pediatric patients who have aged into adulthood.

Incidence and Prevalence by ESRD Modality

From the earliest reporting year, in aggregate, children have initiated ESRD therapy with hemodialysis more frequently than peritoneal dialysis or transplantation. Data from 2014 demonstrate the same pattern with 705 (50.4%) initiating with hemodialysis, 420 (30.0%) peritoneal dialysis, and 271 (19.4%) transplant (Figure 8.1.a). This equates to an incidence rate per million per year (per million/year) of 7.5 in hemodialysis, 4.4 in peritoneal dialysis, 2.3 in transplant, and total ESRD incidence of 14.2 per million children per year.

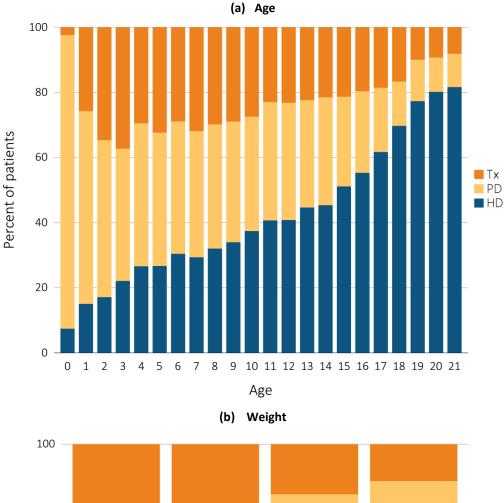
When examined by age, peritoneal dialysis is the most common initial ESRD treatment modality for children aged 9 years and younger (Figure 8.2.a). Hemodialysis becomes the most common initial modality for patients aged 9.5 years and older. Similarly, initial ESRD treatment modality is associated with patient weight. Peritoneal dialysis is most commonly the initial modality in small children weighing less than 20 kilograms (kg). Hemodialysis is the least common initiating modality in small children and increases in frequency with increasing patient weight (Figure 8.2.b). Kidney transplantation accounts for less than 40% of initial modality across all pediatric ages and weights but is the predominant prevalent ESRD treatment modality used in children. Of the 9,721 children and adolescents between the ages of o and 21 years with prevalent ESRD as of December 31, 2014, kidney transplant was the most common modality (6,825[70.2%]), followed by hemodialysis (1,745 [18.0%]) and peritoneal dialysis (1,122 [11.5%]) (Figure 8.1.b). Over 80% of prevalent children ages 5-13 have a kidney transplant. This equates to a point prevalence per million population of 18.5 for hemodialysis, 11.7 for peritoneal dialysis, and 69.8 for transplant.

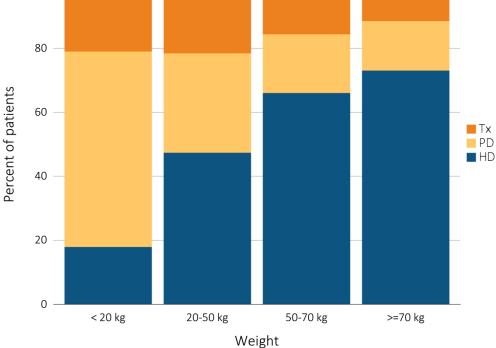




Data Source: Special analyses, USRDS ESRD Database. Peritoneal dialysis consists of continuous ambulatory peritoneal dialysis and continuous cycling peritoneal dialysis. All consists of hemodialysis, peritoneal dialysis, uncertain dialysis, and transplant. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

vol 2 Figure 8.2 Cross-sectional trends in pediatric ESRD modality at initiation, by patient (a) age and (b) weight, 1996-2014





Data Source: Special analyses, USRDS ESRD Database. Includes incident ESRD patients in the years 1996-2014. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

CHAPTER 8: ESRD AMONG CHILDREN, ADOLESCENTS, AND YOUNG ADULTS

Etiology

The underlying etiologies of ESRD are generated from the ESRD Medical Evidence form (CMS 2728) and summarized in Table 8.1. Patients have been classified using the updated format (see the section on <u>Chapter 8</u> in *ESRD Analytical Methods* chapter for details). The leading causes of ESRD in children during 2010-2014 are as follows: primary glomerular disease (25.3%), CAKUT (congenital anomalies of the kidney and urinary tract) (24.1%),

cystic/hereditary/congenital disorders (14.3%), and secondary glomerular disease (12.4%). The most common individual diagnoses associated with pediatric ESRD include renal hypoplasia/dysplasia (N=728), congenital obstructive uropathies (N=541), focal glomerular sclerosis (N=901), and systemic lupus erythematosus (N=489).

Figure 8.3 shows the distribution of the most common causes of ESRD by age and by year of onset of ESRD. CAKUT and congenital/hereditary/cystic disorders cause more ESRD in young children and primary and secondary glomerulonephritis and other etiologies become more common with advancing age. The distribution of ESRD etiology by age and year of onset of ESRD were consistent between incident years 2005-2009 and 2010-2014.

vol 2 Table 8.1 Distribution of reported incident pediatric ESRD patients by primary cause of ESRD (aged 0-21 years), and by demographic characteristics, 2005-2009 (period A) and 2010-2014 (period B)

		otal ients	% Inc	ident		dian ge	% N	lales	% White		Afr	lack/ ican rican	n % Other		% Transplant first year		% Died first year	
Primary disease groups	А	В	А	В	А	В	А	В	А	В	А	В	А	В	А	В	А	В
All ESRD, (reference)	8307	7570	100	100	16	16	56.6	56.4	65.4	66.0	25.3	24.1	9.3	9.9	37.4	36.0	3.6	2.7
Diabetes	103	93	1.4	1.4	20	20	43.7	40.9	52.4	40.9	42.7	54.8	4.9	4.3	14.6	10.8	8.7	5.4
Diabetes with renal manifestations Type 2	45	45	0.6	0.7	20	20	40	42.2	53.3	42.2	40	53.3	6.7	4.4	11.1	8.9	8.9	6.7
Diabetes with renal manifestations Type 1	58	48	0.8	0.7	20	20	46.6	39.6	51.7	39.6	44.8	56.3	3.4	4.2	17.2	12.5	8.6	4.2
Primary glomerular disease	1977	1702	26.4	25.3	18	18	55.5	55	61.3	64.3	32.1	28	6.6	7.7	32.2	30	1.6	1.6
Glomerulonephritis (GN) (histologically not examined)	398	303	5.3	4.5	19	19	63.3	59.7	67.8	69.3	24.4	20.1	7.8	10.6	23.4	20.5	2.5	1.3
Focal glomerulosclerosis, focal sclerosing GN	1018	901	13.6	13.4	17	17	55	55.8	52.2	58.8	42.9	35.7	4.9	5.4	35.4	29.1	1.7	1.8
Membranous nephropathy	50	36	0.7	0.5	18	19	50	69.4	54	52.8	40	41.7	6	5.6	28	44.4	0	0
Membranoproliferative GN type 1, diffuse MPGN	92	86	1.2	1.3	17	17	44.6	45.3	75	67.4	16.3	22.1	8.7	10.5	45.7	43	0	2.3
Dense deposit disease, MPGN type 2	31	28	0.4	0.4	16	15	51.6	50	100	75	0	10.7	0	14.3	32.3	7.1	3.2	0
IgA nephropathy, Berger's disease (proven by immunofluorescence)	212	204	2.8	3	19	19	63.7	59.8	72.2	77	17.5	10.3	10.4	12.7	35.8	40.7	0	2
IgM nephropathy (proven by immunofluorescence)	15	16	0.2	0.2	19	19	53.3	62.5	66.7	68.8	26.7	25	6.7	6.3	26.7	18.8	0	0
With lesion of rapidly progressive GN	61	54	0.8	0.8	16	16	37.7	20.4	72.1	74.1	13.1	20.4	14.8	5.6	11.5	27.8	1.6	1.9
Other proliferative GN	100	74	1.3	1.1	16	17	38	41.9	76	66.2	17	27	7	6.8	30	41.9	2	1.4
CAKUT	1694	1620	22.6	24.1	12	11	69.3	69.6	77.6	74.4	16.4	19.1	6	6.4	49.8	49.6	2.6	1.8
Congenital obstruction of ureteropelvic junction	54	50	0.7	0.7	13	15	79.6	74	72.2	72	22.2	22	5.6	6	44.4	46	1.9	2
Congenital obstruction of uretrovesical junction	56	50	0.7	0.7	14	14	85.7	82	76.8	72	21.4	18	1.8	10	50	44	0	2
Other Congenital obstructive uropathy	515	541	6.9	8	12	11	82.1	82.1	73.8	71	20.8	23.1	5.4	5.9	44.1	49.5	2.7	0.7
Renal hypoplasia, dysplasia, oligonephronia	753	728	10	10.8	10	10	62.7	61	77.6	75.3	15.8	18	6.6	6.7	51.4	50.1	3.1	2.3
Prune belly syndrome	92	77	1.2	1.1	8	5	97.8	98.7	80.4	63.6	17.4	29.9	2.2	6.5	57.6	46.8	2.2	1.3
Chronic pyelonephritis, reflux nephropathy	224	174	3	2.6	16	17	43.8	48.9	87.1	87.9	5.4	6.3	7.6	5.7	55.4	51.1	1.8	2.9
Secondary glomerular disease/Vasculitis	1081	834	14.4	12.4	18	18	31.9	27.6	51.2	54.3	40.9	39.1	7.9	6.6	12.8	13.8	6.9	3
Lupus erythematosus, (SLE nephritis)	649	489	8.7	7.3	19	19	20.5	19	38.8	38.2	50.8	54	10.3	7.8	6.5	4.9	8.3	2.9
Henoch-Schonlein syndrome	30	30	0.4	0.4	17	14	56.7	53.3	93.3	83.3	3.3	10	3.3	6.7	43.3	40	0	3.3
Hemolytic uremic syndrome	154	109	2.1	1.6	8	11	46.8	34.9	79.2	80.7	16.9	12.8	3.9	6.4	29.9	40.4	4.5	0.9
Polyarteritis and other vasculitis	41	44	0.5	0.7	15	15	48.8	25	63.4	86.4	24.4	9.1	12.2	4.5	12.2	22.7	0	2.3
Wegeners granulomatosis	59	59	0.8	0.9	16	17	44.1	47.5	84.7	76.3	11.9	16.9	3.4	6.8	28.8	16.9	0	1.7
Goodpasture syndrome	50	53	0.7	0.8	20	19	46	39.6	88	98.1	8	0	4	1.9	12	17	2	3.8
Secondary GN, other	26	18	0.3	0.3	18	19	65.4	27.8	76.9	77.8	19.2	16.7	3.8	5.6	26.9	33.3	7.7	0
AIDS nephropathy	63	26	0.8	0.4	19	20	54	57.7	11.1	3.8	87.3	96.2	1.6	0	1.6	0	15.9	15.4

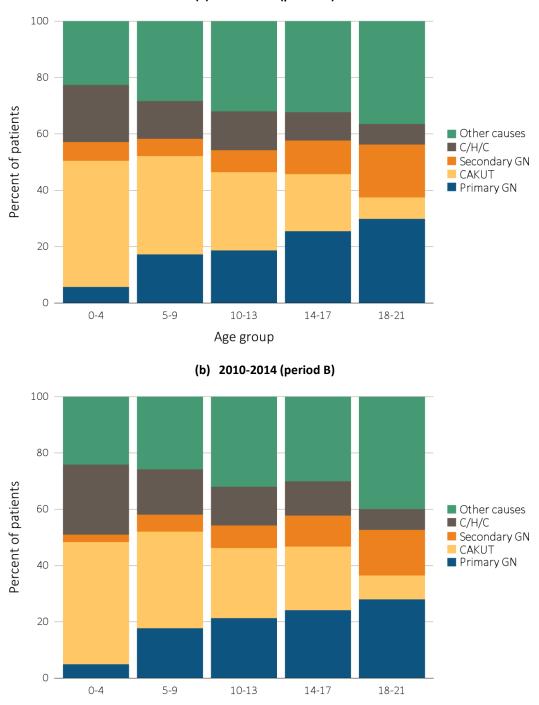
Table 8.1 continued on next page.

vol 2 Table 8.1 Distribution of reported incident pediatric ESRD patients by primary cause of ESRD (aged 0-21 years), and by demographic characteristics, 2005-2009 (period A) and 2010-2014 (period B) *(continued)*

		ents	% Inc	ident		dian ge	% Males		% V	/hite	% Black/ African American		% Other race		% Transplant first year		% Died first year	
Primary disease groups	А	В	А	В	А	В	Α	В	А	В	А	В	А	В	А	В	Α	В
Interstitial nephritis/Pyelonephritis	338	281	4.5	4.2	17	16	54.7	55.2	76.9	76.9	18.3	14.2	4.7	8.9	29.3	31	6.8	8.2
Nephropathy caused by other agents	47	39	0.6	0.6	17	15	53.2	56.4	87.2	82.1	12.8	7.7	0	10.3	40.4	30.8	17	5.1
Nephrolithiasis	21	16	0.3	0.2	18	14	42.9	25	85.7	81.3	9.5	12.5	4.8	6.3	57.1	68.8	0	12.5
Chronic interstitial nephritis	80	73	1.1	1.1	17	17	60	53.4	76.3	76.7	20	13.7	3.8	9.6	50	45.2	2.5	4.1
Tubular necrosis (no recovery)	167	138	2.2	2.1	15	14	55.1	57.2	75.4	75.4	18.6	15.9	6	8.7	15.6	18.1	7.2	10.9
Hypertensive/Large vessel disease	16	15	0.2	0.2	14	14	56.3	53.3	81.3	86.7	6.3	13.3	12.5	0	43.8	26.7	6.3	0
Cystic/Hereditary/Congenital diseases	910	959	12.1	14.3	14	13	58.8	59.2	78.2	76.9	16.9	15.8	4.8	7.3	54.4	47	4	3.3
Polycystic kidneys, adult type (dominant)	49	48	0.7	0.7	19	18	44.9	45.8	77.6	79.2	20.4	18.8	2	2.1	44.9	43.8	2	2.1
Polycystic, infantile (recessive)	141	152	1.9	2.3	7	1	52.5	46.1	80.1	75.7	16.3	17.1	3.5	7.2	48.9	40.1	12.1	6.6
Medullary cystic disease, including nephronophthisis	102	115	1.4	1.7	13	12	38.2	46.1	87.3	80.9	5.9	11.3	6.9	7.8	71.6	67.8	0	1.7
Hereditary nephritis, Alport syndrome	185	165	2.5	2.5	17	17	86.5	85.5	69.7	78.2	23.8	15.2	6.5	6.7	50.3	48.5	0	0
Cystinosis	68	43	0.9	0.6	13	12	47.1	60.5	95.6	83.7	4.4	11.6	0	4.7	79.4	67.4	0	0
Primary oxalosis	19	16	0.3	0.2	6	7	52.6	81.3	78.9	75	10.5	0	10.5	25	63.2	56.3	5.3	6.3
Congenital nephrotic syndrome	123	138	1.6	2.1	2	3	56.9	52.2	80.5	81.2	14.6	12.3	4.9	6.5	58.5	39.1	5.7	3.6
Drash syndrome, mesangial sclerosis	18	31	0.2	0.5	1	1	61.1	48.4	77.8	80.6	16.7	16.1	5.6	3.2	44.4	25.8	5.6	3.2
Other (congenital malformation syndromes)	168	222	2.2	3.3	15	13	56	62.2	84.5	77.9	10.1	12.2	5.4	9.9	52.4	46.8	2.4	4.5
Sickle cell disease/anemia	26	19	0.3	0.3	19	20	69.2	68.4	7.7	0	88.5	100	3.8	0	11.5	15.8	19.2	10.5
Neoplasms/Tumors	50	51	0.7	0.8	8	10	46	45.1	70	76.5	18	13.7	12	9.8	16	21.6	28	9.8
Renal tumor	37	41	0.5	0.6	5	5	45.9	41.5	67.6	73.2	21.6	17.1	10.8	9.8	16.2	22	21.6	9.8
Transplant complications	148	84	2	1.2	16	17	55.4	56	77	69	14.9	21.4	8.1	9.5	46.6	26.2	14.2	14.3
Other transplant complication	94	73	1.3	1.1	15	16	56.4	56.2	76.6	68.5	16	23.3	7.4	8.2	37.2	23.3	20.2	15.1
Kidney transplant complication	48	*	0.6	0.1	16	19	56.3	50	77.1	83.3	14.6	0	8.3	16.7	62.5	50	0	0
Miscellaneous conditions	812	849	10.8	12.6	19	19	62.4	60.1	60.5	60.4	33.7	32.2	5.8	7.4	30.4	24.3	3.4	2.7
Acquired obstructive uropathy	54	42	0.7	0.6	17	16	77.8	69	75.9	78.6	18.5	14.3	5.6	7.1	40.7	35.7	0	0
Unspecified with renal failure	495	517	6.6	7.7	20	20	62.4	63.1	50.1	50.1	45.1	44.9	4.8	5	17.8	11.8	2	2.9
Traumatic or surgical loss of kidney(s)	15	11	0.2	0.2	9	12	66.7	54.5	80	54.5	13.3	18.2	6.7	27.3	53.3	9.1	13.3	18.2
Other renal disorders	244	272	3.3	4	15	14	59.4	52.9	76.6	77.9	15.6	11.8	7.8	10.3	52.9	46	5.3	2.2
Etiology uncertain	942	714	12.6	10.6	16	16	58	55.5	68.9	69	18	17.1	13.1	13.9	34.7	33.1	1.6	1.4
Missing	236	368	3.1	5.5	14	15	64.8	62	9.7	36.7	4.7	12.5	85.6	50.8	94.9	73.1	0.8	2.4

Data Source: Special analyses, USRDS ESRD Database. Abbreviations: AIDS, acquired-immune deficiency syndrome; CAKUT, congenital anomalies of the kidney and urinary tract; congenital obstructive uropathy, combination of congenital ureteropelvic junction obstruction, congenital uretrovesical junction obstruction, and other congenital anomalies; ESRD, end-stage renal disease; GN glomerulonephritis; IgA immunoglobulin A; IgM, immunoglobulin M; incl., including; MPGN, membranoproliferative glomerulonephritis; SBE, sub-acute bacterial endocarditis. Diagnoses with 10 or fewer total patients for year categories are suppressed.

vol 2 Figure 8.3 Distribution of reported incident pediatric ESRD patients by primary cause of ESRD, by age (a) 2005-2009 (period A) and (b) 2010-2014 (period B)



(a) 2005-2009 (period A)

Data Source: Special analyses, USRDS ESRD Database. Abbreviations: CAKUT, congenital anomalies of the kidney and urinary tract; C/H/C, cystic/hereditary/congenital disease; ESRD, end-stage renal disease; GN, glomerulonephritis.

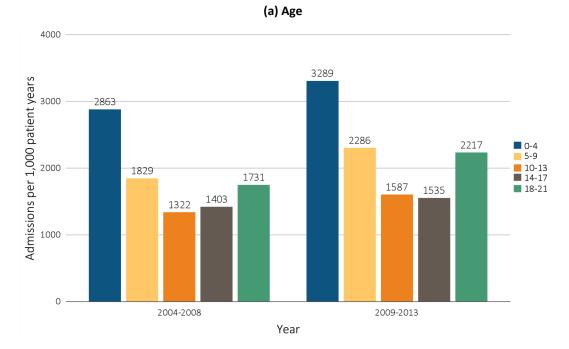
Age group

Hospitalizations in Children With Incident ESRD

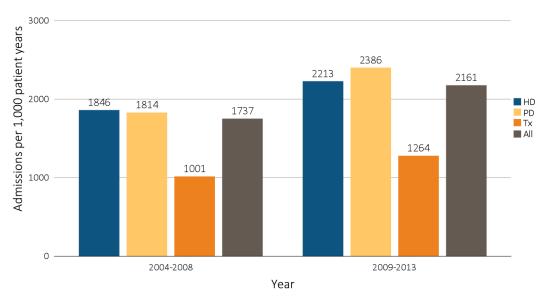
The one-year adjusted all-cause hospitalization rates by age (Figure 8.4.a) from 2004-2008 and 2009-2013 were highest in the youngest segment of children with incident ESRD (o-4 years of age). The rates of hospitalization rose in each incident age group during the 2009-2013 time frame compared with the prior four-year period. The one-year adjusted all-cause hospitalization rates in all incident children on renal replacement therapy (Figure 8.4.b) rose 24.4% from 1,737 to 2,161 admissions per 1,000 patient years. The one-year adjusted all-cause hospitalization rates rose

for all modalities in incident patients as follows: hemodialysis by 19.9%, peritoneal dialysis by 31.5%, and transplant by 26.3% from one period to the next.

vol 2 Figure 8.4 One-year adjusted all-cause hospitalization rates in incident pediatric patients (aged 0-21 years), by (a) age and (b) modality, 2004-2008 and 2009-2013



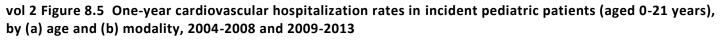


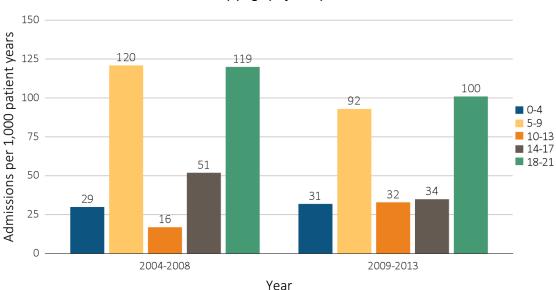


Data Source: Special analyses, USRDS ESRD Database. Includes incident pediatric ESRD patients in the years 2004-2013, surviving the first 90 days after ESRD initiation and followed from day 90. Adjusted for sex, race, primary cause of ESRD, and Hispanic ethnicity. Reference population: incident ESRD patients aged 0-21, 2010-2011. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

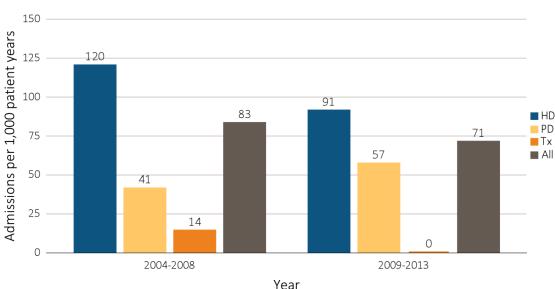
While accounting for a minority of hospitalizations in children with incident ESRD, we report the cardiovascular disease and infection associated hospitalizations for consistency with previous ADR pediatric chapters and to align with two leading causes of ESRD associated mortality in children. Using

the newly defined cardiovascular diagnosis codes (for definition of terms, see the section on <u>Chapter 8</u> in the *ESRD Analytical Methods* chapter), cardiovascular hospitalizations are substantially different in frequency with the increased precision in case definition. In total, the one-year cardiovascular hospitalization rates per 1,000 patient-years for children less than 22 years of age with incident ESRD was 85 from 2004-2008 and 71 from 2009-2013 (Figure 8.5.b). The highest rates of cardiovascular hospitalizations in incident patients were observed in children aged 5-9 and 18-21 years (Figure 8.5.a) and in children treated with hemodialysis (Figure 8.5.b).





(a) Age (adjusted)



(b) Modality (unadjusted)

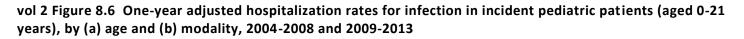
Data Source: Special analyses, USRDS ESRD Database. Includes incident pediatric ESRD patients in the years 2004-2013, surviving the first 90 days after ESRD initiation and followed from day 90. Reference population: incident ESRD patients aged 0-21, 2010-2011. (a) Adjusted for sex, race, primary cause of ESRD, and Hispanic ethnicity. (b) Unadjusted. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

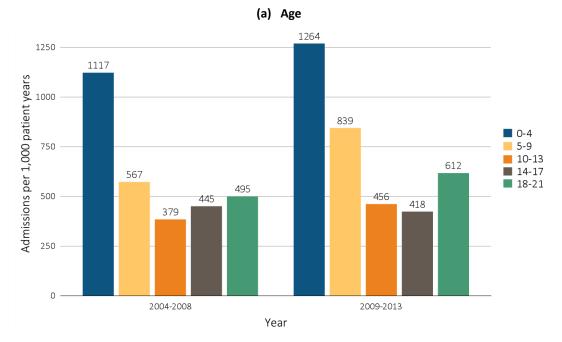
The overall rate of hospitalization for infection was 650 admissions per 1,000 patient years during 2009-2013,

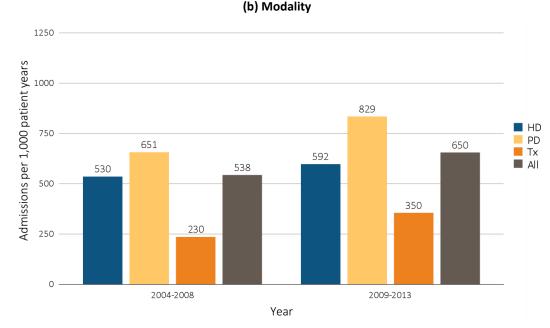
which is 20.8% higher than during 2004-2008 (Figure 8.6.b). The rates of infection-related hospitalizations

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rose by 13.2% in children aged 0-4 years, 48.0% in those aged 5-9 years, 20.3% in those aged 10-13 years, and 23.6% in those aged 18-21 years (Figure 8.6.a). Children between 14-17 years of age represented the only improvement in infection-related hospitalizations, decreasing 6.1% during the most recent time period (2009-2013) compared with 2004-2008. In examining modality, children on peritoneal dialysis had the highest rate of infection-related hospitalizations during 2004-2008 and 2009-2013 (Figure 8.6.b). However, during this time period there was an increase in infection-related hospitalization rates in each modality of renal replacement therapy (hemodialysis 11.7%, peritoneal dialysis 27.3%, transplantation 52.2%).





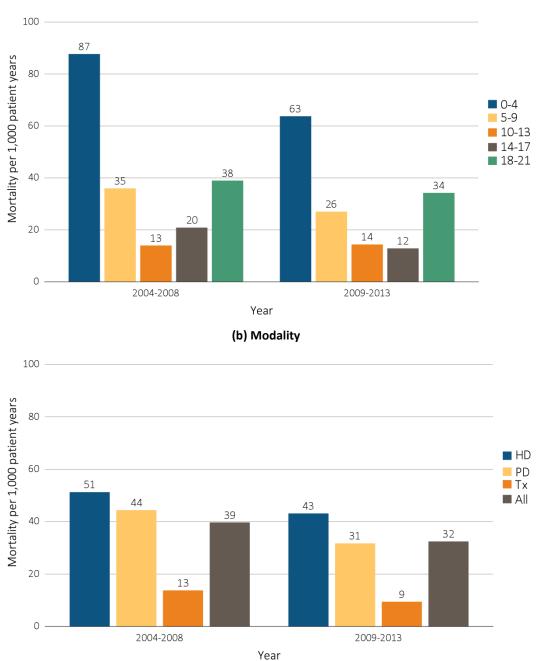


Data Source: Special analyses, USRDS ESRD Database. Includes incident pediatric ESRD patients in the years 2004-2013, surviving the first 90 days after ESRD initiation and followed from day 90. Adjusted for sex, race, primary cause of ESRD, and Hispanic ethnicity. Reference population: incident ESRD patients aged 0-21, 2010-2011. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

Mortality

During 2009-2013, the one-year adjusted all-cause mortality rate was 32 per 1,000 patient years, which represents a decrease of 17.9% from the 39 per 1,000 patient years rate in 2004-2008 (Figure 8.7.b). The adjusted one-year all-cause mortality rates decreased in all age categories except for those aged 10-13 years (Figure 8.7.a). Adjusted one-year all-cause mortality rates by modality from 2004-2008 and 2009-2013 show decreases of 15.7% among hemodialysis patients, 29.5% among peritoneal dialysis patients, and 30.8% among transplant patients (Figure 8.7.b). Transplant-associated mortality continues to remain low.

vol 2 Figure 8.7 One-year adjusted all-cause mortality rates in incident pediatric patients with ESRD (aged 0-21 years), by (a) age and (b) modality, 2004-2008 and 2009-2013

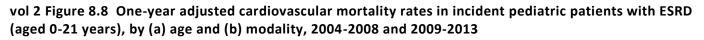


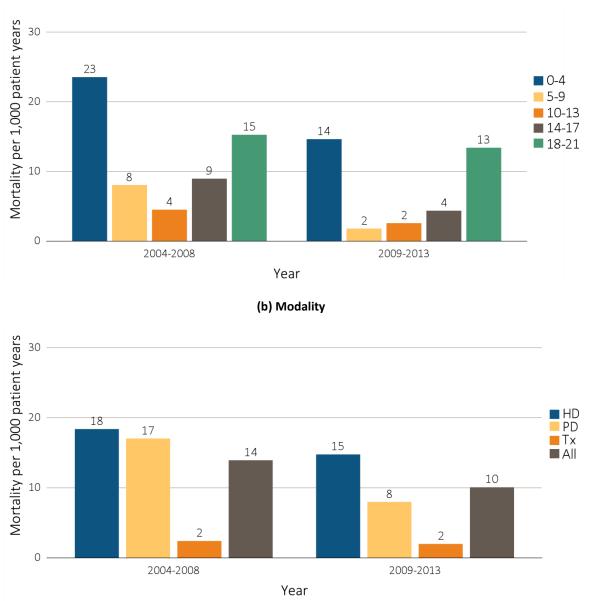
Data Source: Special analyses, USRDS ESRD Database. Incident dialysis and transplant patients defined at the onset of dialysis or the day of transplant without the 60-day rule; followed to December 31, 2014. Adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD. Reference population: incident ESRD patients aged 0-21, 2010-2011. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

(a) Age

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During 2009-2013, the one-year adjusted cardiovascular mortality rate was 10 per 1,000 patient years, which was a decrease of 28.6% from the 2004-2008 period (Figure 8.8.b). The adjusted one-year cardiovascular mortality rate decreased across all age groups: 0-4 years by 39.1%, 5-9 years by 75%, 10-13 years by 50%, 14-17 years by 55.6%, and 18-21 years by 13.3% (Figure 8.8.a). Compared to other pediatric age groups, children aged o-4 years continued to have the highest adjusted one-year cardiovascular mortality. Examining adjusted one-year cardiovascular mortality across the periods 2004-2008 and 2009-2013 by modality, the rate decreased by 16.7% in hemodialysis, 52.9% in peritoneal dialysis, and was unchanged and quite low in transplant patients (Figure 8.8.b).

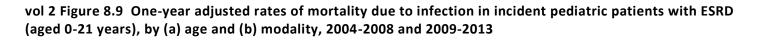


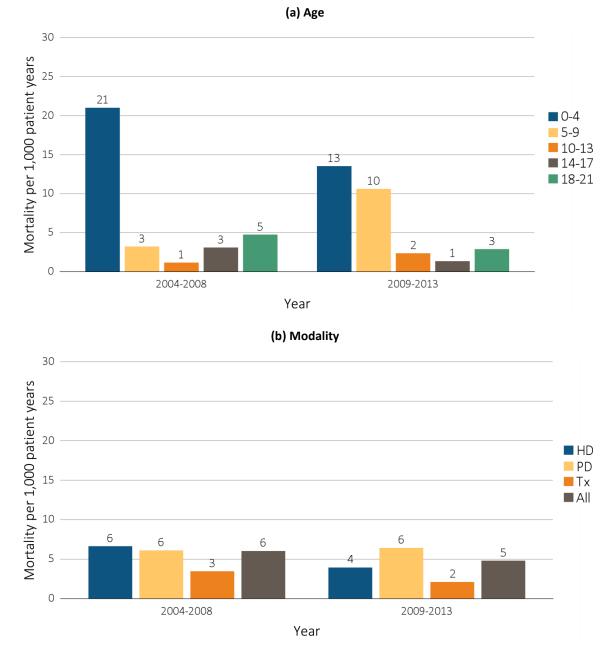


Data Source: Special analyses, USRDS ESRD Database. Incident dialysis and transplant patients defined at the onset of dialysis or the day of transplant without the 60-day rule; followed to December 31, 2014. Adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD. Reference population: incident ESRD patients aged 0-21, 2010-2011. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

(a) Age

During 2009-2013, the one-year adjusted infectionrelated mortality rate decreased from 6 to 5 per 1,000 patient years when compared to the 2004-2008 period (Figure 8.9.b). The adjusted one-year infection-related mortality rate decreased in those aged 0-4 years by 38.1% (Figure 8.9.a). There was a rise in the rate of infection-related mortality in children aged 5-9 years, but the overall rates remained low in the remaining groups. Those o-4 years of age continued to have the highest adjusted one-year infection-related mortality rate. By modality, the one-year infection-related mortality rate ranges from 2 to 6 per 1,000 patient years in children with incident ESRD during 2009-2013 (Figure 8.9.b). Overall cardiovascular mortality rates continue to exceed infection-related mortality rates in children with ESRD.



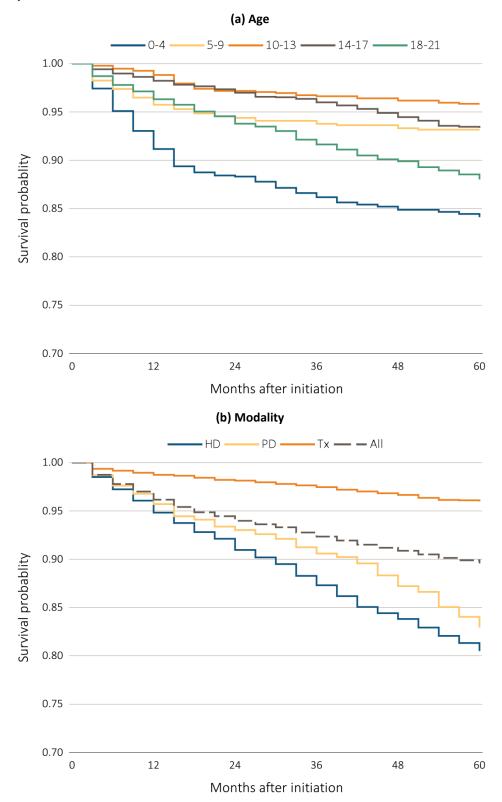


Data Source: Special analyses, USRDS ESRD Database. Incident dialysis and transplant patients defined at the onset of dialysis or the day of transplant without the 60-day rule; followed to December 31, 2014. Adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD. Reference population: incident ESRD patients aged 0-21, 2010-2011. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

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For patients beginning ESRD therapy during 2005-2009, the probability of five-year survival was 0.90 (Figure 8.10.b). The probability of surviving five years by age was 0.84 for ages 0-4, 0.93 for ages 5-9, 0.96 for ages 10-13, 0.93 for ages 14-17, and 0.88 for ages 18-21 years (Figure 8.10.a). Mortality is most common in the initial year of ESRD care for children o-4 years of age. Patients initiating ESRD care with transplantation had the highest probability of surviving five years, with a probability of 0.96, as compared to 0.81 with hemodialysis, and 0.83 with peritoneal dialysis (Figure 8.10.b).

vol 2 Figure 8.10 Adjusted five-year survival in incident pediatric patients (aged 0-21 years) from day 1, by (a) age and (b) modality, 2005-2009



Data Source: Special analyses, USRDS ESRD Database. Incident dialysis and transplant patients defined at the onset of dialysis or the day of transplant without the 60-day rule; followed to December 31, 2014. Adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD. Reference population: incident ESRD patients aged 0-21, 2010-2011. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

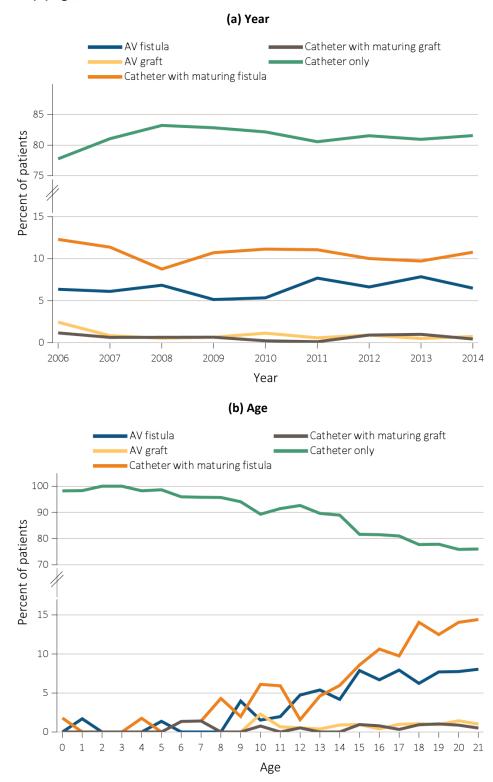
Vascular Access

The decisions and approach to vascular access in ESRD patients impact both immediate and future patient outcomes. Due to the potential short- and long-term consequences that central venous catheter (hereafter, catheter) use can have on future access, and because many pediatric patients will require multiple forms of vascular access during their lifetime, vascular access decisions are particularly important in pediatric patients. In this section, we will describe the vascular access practices in incident and prevalent hemodialysis patients. Vascular access in pediatric ESRD patients is approached differently than vascular access in adult ESRD patients due to factors such as anatomical differences, transplant waiting times, and transplant rates. The technical challenge of accessing vessels in small children and an expected short waiting time until a kidney transplant becomes

available may influence the vascular access experience in children with ESRD. Since 2006, approximately 81% of incident pediatric ESRD patients have started hemodialysis with a catheter (ranging from 77.8% to 83.2%) (Figure 8.11.a). The initiation of hemodialysis with a catheter is observed in the majority of children and adolescents between the ages of 0 and 21 years (Figure 8.11.b). Beginning at age 8 years of age, catheters with a maturing fistula and fistula alone become increasingly more common with advancing age of hemodialysis initiation.

The trends in initial vascular access remain stable despite concerted efforts, such as the Fistula First Breakthrough Initiative, to increase the utilization of arteriovenous (AV) fistulas in pediatric patients. The explanation for this dichotomy may stem from an expected short waiting time for children on the transplant list.

vol 2 Figure 8.11 Vascular access type at initiation of incident pediatric hemodialysis patients (aged 0-21 years) by (a) year and (b) age, 2006-2014

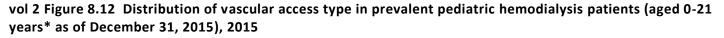


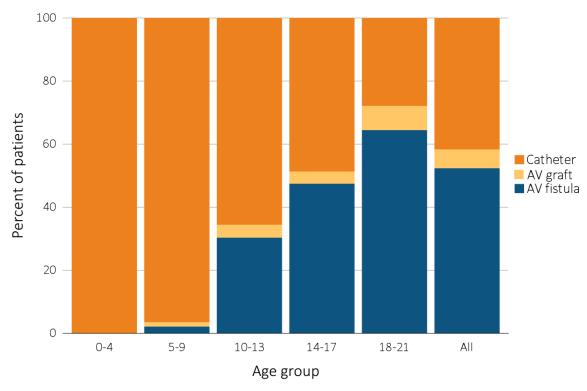
Data Source: Special analyses, USRDS ESRD Database. ESRD patients initiating hemodialysis in 2006-2014. Abbreviations: AV, arteriovenous; ESRD, end-stage renal disease.

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When vascular access is examined in prevalent hemodialysis patients, there are higher rates of AV fistula and AV graft utilization in children aged 10-13 (35%), 14-17 (52%), and 18-21 (73%) than in children under age 10. (Figure 8.12).

A cross-sectional analysis of point prevalent ESRD patients aged 0-21 years in December 2015 shows that 58.9% of patients had AV fistula or AV graft as their type of vascular access (Figure 8.12). Age continues to strongly predict the type of vascular access in use. There is a stepwise increase in the utilization of AV fistula or AV graft for vascular access that parallels the increase in patient age, with the highest rates in older children, including 51.9% for those aged 14-17 and 72.7% for those aged 18-21 years. Also, when examining race and etiology of ESRD (figures not shown), there were subtle differences in vascular access in the prevalent patients in unadjusted analysis. Blacks/African Americans (hereafter, Blacks) had a higher proportion of AV graft use (8.8%) when compared to other races (white 4.3%, and other 5.7%). Whites and Blacks had lower use of central venous catheters only when compared to other races (41.7%, 39.7%, vs. 44.3%, respectively). Overall, patients with primary and secondary glomerulonephritis as the etiology of ESRD had a higher proportion of surgical access in place (AV fistula 57% or graft 21%) when compared to all other etiologies (AV fistula 51% or graft 5%) in unadjusted analysis.





Data Source: Special analyses, USRDS ESRD Database. Hemodialysis patients initiating treatment for ESRD at least 90 days prior to December 1, 2015, *who were <22 years old as December 1, 2015, and who were alive through December 31, 2015; Catheter = any catheter use; fistula and graft use shown are without the use of a catheter. Abbreviations: AV, arteriovenous; ESRD, end-stage renal disease.

Trends in Pediatric Kidney Transplantation

Overall, 36.0% of children received a kidney transplant within the first year of ESRD care during 2010-2014 (Table 8.1), including 37.5% of children with weight greater than 10 kg. In 2014 the rate of transplants was 32.1 per 100 dialysis patient years, which has remained stable since 2007 (Figure 8.13.a).

A total of 1,321 children were wait-listed for a kidney transplant in 2014, including 896 patients listed for the first time and 425 patients listed for repeat transplant. The number of patients awaiting a kidney transplant has ranged from 1,233 to 1,391 since 2004 (Figure 8.13.b). Since 1997, there has been a decrease in the median waiting time for those listed for their first transplant with a flattening of the curve in 2005, which coincides with the change in the OPTN organ allocation policy. The median waiting time for patients receiving their first kidney transplant has ranged between 150-220 days. Over the same time period, children receiving a repeat transplant have, on average, been on the waiting list at least 3-4 times longer than those awaiting their first transplant.

A total of 1,018 children received a kidney transplant in 2014 (Figure 8.13.c). Kidney grafts in pediatric transplant recipients were most commonly from living donors prior to 2005. There has been a decline in the number of pediatric patients receiving living donor kidneys since 2009. In 2014, living donors accounted for 40.0% of kidney transplants, which is a 2.1% decrease from 2013 and a 21% decrease since 2009.

vol 2 Figure 8.13 Trends in pediatric transplantation (aged 0-21 years), by (a) ESRD incident and kidney transplant rates, (b) pediatric patient transplant counts and kidney transplant waiting list times, and (c) kidney transplant counts, (d) kidney transplant counts, patients 0-17 years, (e) kidney transplant counts, patients 18-21 years, 1996-2014

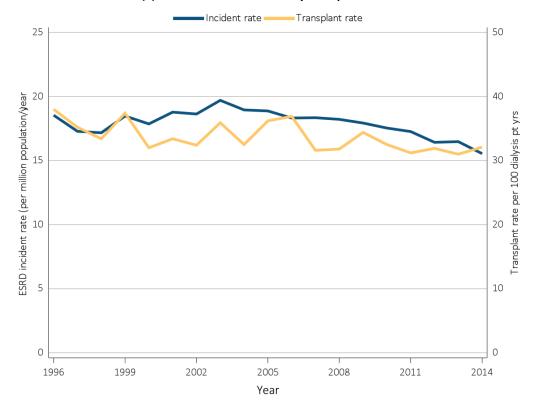




Figure 8.13 continued on next page.

vol 2 Figure 8.13 Trends in pediatric transplantation (aged 0-21 years), by (a) ESRD incident and kidney transplant rates, (b) pediatric patient transplant counts and kidney transplant waiting list times, and (c) kidney transplant counts, (d) kidney transplant counts, patients 0-17 years, (e) kidney transplant counts, patients 18-21 years, 1996-2014 (continued)

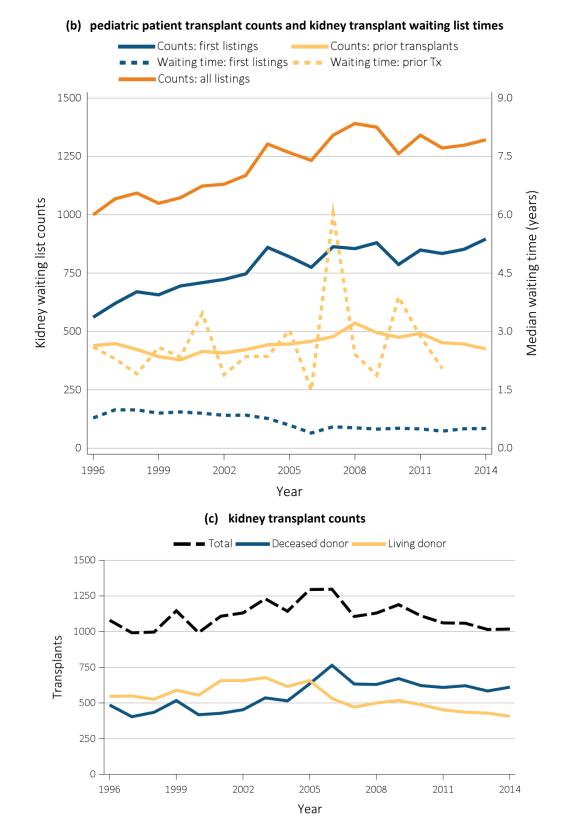
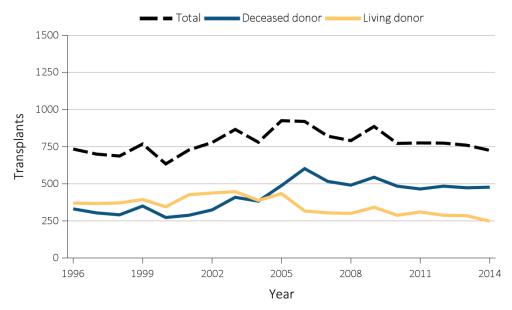


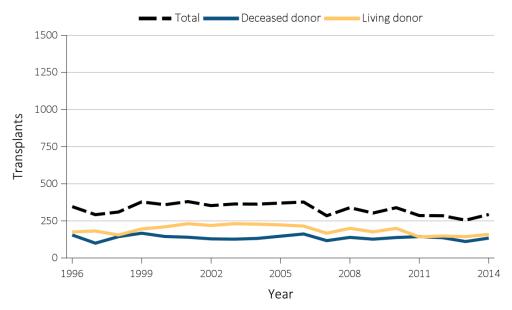
Figure 8.13 continued on next page.

vol 2 Figure 8.13 Trends in pediatric transplantation (aged 0-21 years), by (a) ESRD incident and kidney transplant rates, (b) pediatric patient transplant counts and kidney transplant waiting list times, and (c) kidney transplant counts, (d) kidney transplant counts, patients 0-17 years, (e) kidney transplant counts, patients 18-21 years, 1996-2014 (continued)



(d) kidney transplant counts, patients 0-17 years

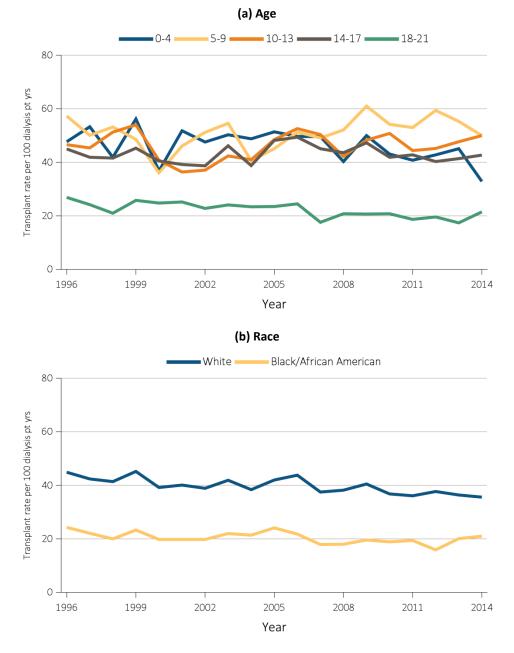




Data Source: (a) Reference Tables A1, E9, and M1. The rate of ESRD per million among the U.S. population aged 0-21 years and the rate of transplantation in dialysis patients aged 0-21 years at the time of transplant, 1996–2014. (b) Special analyses, USRDS ESRD Database. The waiting list count provides the number of pediatric candidates aged 0-21 years on the Organ Procurement and Transplantation Network kidney transplant waiting list on December 31 of each year for first and subsequent kidney alone or kidney plus pancreas transplantation. Candidates listed at more than one center on December 31 are counted only once. There are no data available for median waiting list time for patients with prior transplants listed after 2012. (c)(d)(e) Reference Tables E8, E8(2), E8(3). This figure represents kidney alone and kidney plus pancreas transplant counts for all pediatric candidates. Abbreviations: ESRD, end-stage renal disease; pt, patient; Tx, transplant; yrs, years.

Overall, the transplant rates in each of the age groups have remained stable during 1996-2014. In 2014, patients 5-9 and 10-13 years old had the highest rates of transplantation at 50.0 transplants per 100 dialysis patient years and those 18-21 years old had the lowest transplant rate at 21.5 transplants per 100 dialysis patient years (Figure 8.14.a). In 2014, males with ESRD were transplanted at a higher rate than females with ESRD, 34.3 versus 30.2 per 100 dialysis patient years, respectively. The transplant rate remains lower in Black dialysis patients compared with White dialysis patients (21.0 vs 35.6 per 100 dialysis patient years) (Figure 8.14.b). Analyses for Native and Asian Americans were excluded due to the low number of transplants.

vol 2 Figure 8.14 Annual rates of live and deceased donor transplants in pediatric dialysis patients (aged 0-21 years), by (a) age and (b) race, 1996-2014



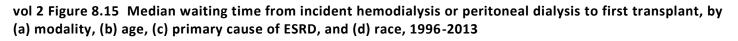
Data Source: Special analyses, USRDS ESRD Database. Includes transplant year between 1996–2014. Abbreviations: ESRD, end-stage renal disease; pt, patient; yrs, years.

The median waiting time to transplant for incident patients on dialysis has been improving over time. In 2002, the median waiting time peaked at 1.83 years and began to decline, with the most dramatic improvement occurring after 2005 (Figure 8.15.a), which coincides with the change in the OPTN organ allocation policy. Since 2005, the median waiting time for incident dialysis patients has continued to

decrease and was at its lowest in 2013 at 1.04 years. Since 2007, the waiting times for incident patients on dialysis have been similar for hemodialysis and peritoneal dialysis. In 2013, the median waiting time to transplant for hemodialysis patients was 1.01 years, and for peritoneal dialysis patients it was 1.06 years.

Kidney transplant waiting times vary by age and ESRD etiology. In patients younger than 18 years old, who were given priority on the waiting list, the median time for incident dialysis to transplant has been improving from 1996 to 2013 in all age groups, with the exception of those o-4 years old (Figure 8.15.b). Children aged o-4 years have had stable waiting times, which may reflect the surgical complexities in this age group. Since 1996, patients aged 18-21 years old have shown the largest improvement with waiting times. In 2013, the median waiting time for children o-4 years old surpassed that of patients 18-21 years old. Patients with secondary glomerulonephritis as the cause of their ESRD had the longest median waiting time to first transplant, with a median of 1.32 years in 2013 (Figure 8.15.c).

In 1996, White patients were on the waiting list on average 35% shorter than Black patients awaiting a transplant (Figure 8.15.d). Since then, the average time on the transplant list has improved significantly for all patients, and the gap between races has narrowed substantially. Consequently, median waiting times are now similar between groups (Whites 1.00 and Blacks 1.05 years). With the resolution of the waiting time gap between Black and White pediatric ESRD patients, improving the transplant disparity observed in dialysis dependent Black children may be addressed through efforts to improve the listing rate in these children.



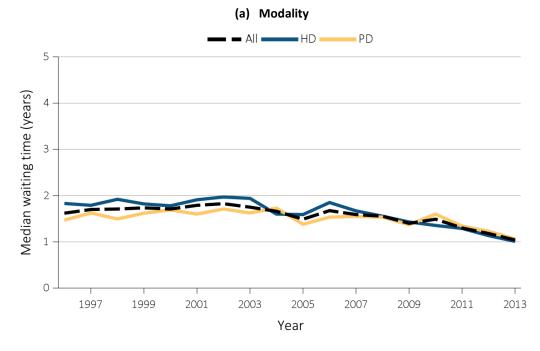


Figure 8.15 continued on next page.

vol 2 Figure 8.15 Median waiting time from incident hemodialysis or peritoneal dialysis to first transplant, by (a) modality, (b) age, (c) primary cause of ESRD, and (d) race, 1996-2013 (continued)

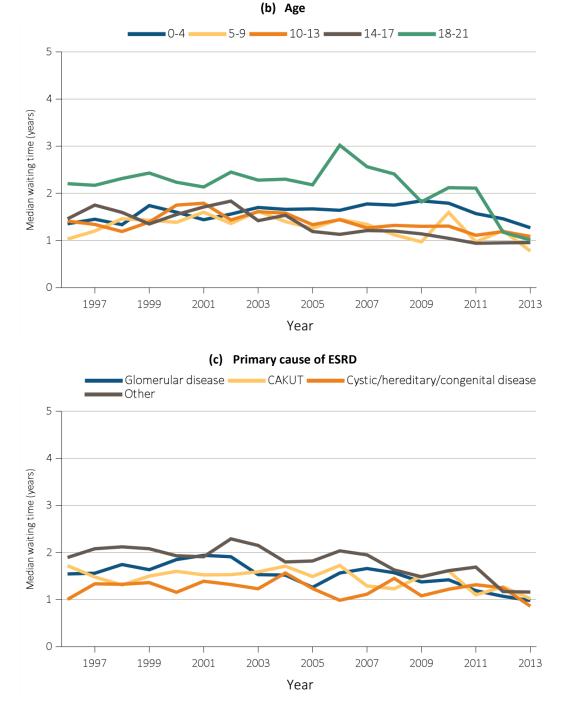
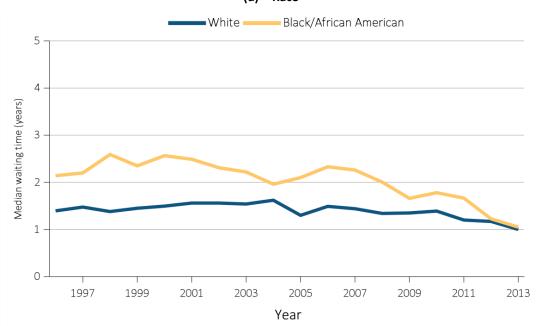


Figure 8.15 continued on next page.

vol 2 Figure 8.15 Median waiting time from incident hemodialysis or peritoneal dialysis to first transplant, by (a) modality, (b) age, (c) primary cause of ESRD, and (d) race, 1996-2013 *(continued)*



Data Source: Special analyses, USRDS ESRD Database. Incident dialysis and transplant patients defined at the onset of dialysis or the day of transplant with the 60-day rule. Includes pediatric patients (aged 0-21 years) starting initiation of HD or PD in 1996-2013 and having the first transplant before 12/31/2015. Abbreviations: CAKUT, congenital anomalies of the kidney and urinary tract; ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis.

Table 8.2 displays the ten-year kidney transplant outcomes. The ten-year outcomes improved with decreasing probability of all-cause graft loss and death for both deceased and living kidney transplants. Recipients of living donor kidneys have lower probability of returning to dialysis or retransplantation (0.42 in 2004), when compared to recipients of deceased donor kidneys (0.55 in 2004). The probability of death was higher for recipients of living donor kidney transplants than for deceased donor transplants until 2004, when the probability of death dropped to 0.06 for living donor recipients versus 0.08 for deceased donor recipients. The tenyear outcomes show significantly better all-cause graft failure outcomes for patients receiving living donor kidney transplants (0.45 in 2004) when compared to deceased donor kidney transplants (0.58 in 2004).

		Adjusted ten-year outcomes											
		Deceased		Living									
Year	All-cause graft failure	Return to dialysis or retransplant	Death	All-cause graft failure	Return to dialysis or retransplant	Death							
1996	0.62	0.58	0.11	0.51	0.49	0.15							
1997	0.61	0.56	0.13	0.50	0.47	0.16							
1998	0.57	0.54	0.10	0.50	0.47	0.10							
1999	0.58	0.55	0.11	0.51	0.48	0.14							
2000	0.57	0.54	0.10	0.52	0.49	0.16							
2001	0.56	0.53	0.11	0.49	0.46	0.14							
2002	0.50	0.47	0.06	0.43	0.41	0.15							
2003	0.53	0.49	0.11	0.44	0.41	0.12							
2004	0.58	0.55	0.08	0.45	0.42	0.06							

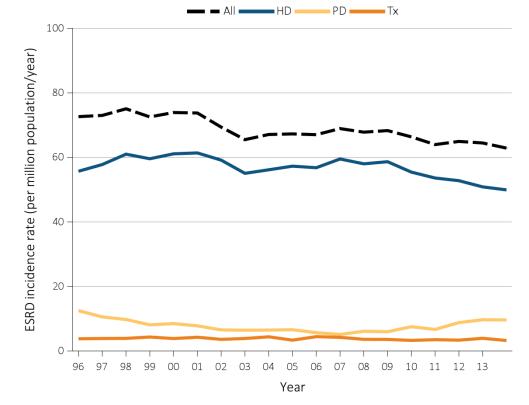
vol 2 Table 8.2 Adjusted ten-year outcomes for kidney transplants in pediatric patients (aged 0-21 years), by donor type and year, 1996-2004

Data Source: Deceased: Reference Tables F6, F18, I30. Live: Reference Tables F12, F24, I36. Probabilities for all-cause graft failure and return to dialysis or repeat transplant are adjusted for age, sex, race, primary cause of ESRD, and first versus subsequent transplant. All-cause graft failure includes repeat transplant, return to dialysis, and death. The death outcome is not censored at graft failure, and includes deaths that occur after repeat transplant or return to dialysis. Probabilities of death are adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD. The reference population for all-cause graft failure and return to dialysis or repeat transplantation is all pediatric patients receiving a kidney alone transplant in 2011. The reference population for death is incident pediatric ESRD patients in 2011. Abbreviation: ESRD, end-stage renal disease.

Young Adults

As a result of improvements in the care of pediatric patients with ESRD, a larger percentage of these children are surviving into adulthood. The transition of these patients into adulthood represents a truly unique process and has resulted in the development of specific transition programs to improve health care for these individuals. In the USRDS ADR, the young adult age group is defined as those 22-29 years old. Cardiovascular disease remains the leading cause of mortality in this cohort, similar to children and older adults with ESRD. This section highlights the young adult population focusing on modality and the cardiovascular disease trends in this population.

The overall incident rate of ESRD in the young adult cohort has been slowly decreasing (Figure 8.16). In 1996, the rate was 72.6 per million/year in the young adult census population, while in 2014 the ESRD incident rate was 62.9 per million/year. In 2014, the rates of incident hemodialysis, peritoneal dialysis, and transplant were 49.9, 9.6, and 3.3 patients per million/year, respectively. Since 2008, there has been a trend in increased utilization of peritoneal dialysis as the incident ESRD modality. The point prevalence of young adults with ESRD (figure not shown) was 445.2 patients per million population in 2014. The use of ESRD modality within this 2014 point prevalent population included 206.1 hemodialysis, 43.4 peritoneal dialysis, and 194.3 transplant patients per million population, respectively.

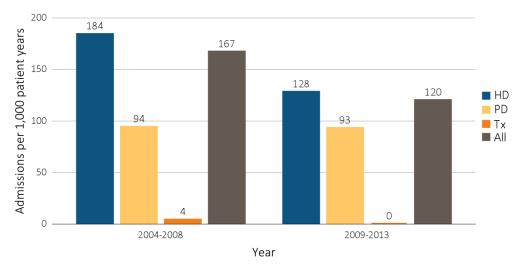


vol 2 Figure 8.16 Trends in incident rates of ESRD in young adults (aged 22-29 years), by modality, 1996-2014

Data Source: Special analyses, USRDS ESRD Database. Peritoneal dialysis consists of continuous ambulatory peritoneal dialysis and continuous cycling peritoneal dialysis. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

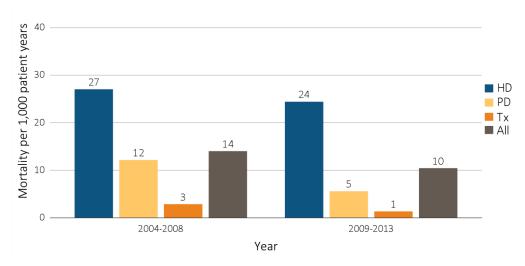
Cardiovascular health has been improving in the young adult ESRD population. The overall cardiovascular hospitalization rate during 2009-2013 was 124 admissions per 1,000 patient years, which is lower than the rate during 2004-2008 (Figure 8.17). The rate of cardiovascular hospitalizations remained highest in those on hemodialysis compared with other ESRD modalities. However, there was a 31.1% decline in cardiovascular hospitalization rates in hemodialysis patients in the most recent reporting years. Between 2009-2014, the one-year adjusted cardiovascular mortality was 10 per 1,000 patient years, which was a decrease of 28.6% from the 2004-2008 period (Figure 8.18). The adjusted one-year cardiovascular mortality rate decreased across all modalities.

vol 2 Figure 8.17 One-year unadjusted cardiovascular hospitalization rates in young adults with incident ESRD (aged 22-29 years), by modality, 2004-2008 and 2009-2013



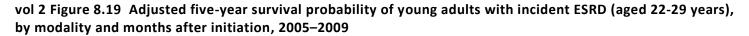
Data Source: Special analyses, USRDS ESRD Database. Includes incident pediatric ESRD patients in the years 2004-2013, surviving the first 90 days after ESRD initiation and followed from day 90. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

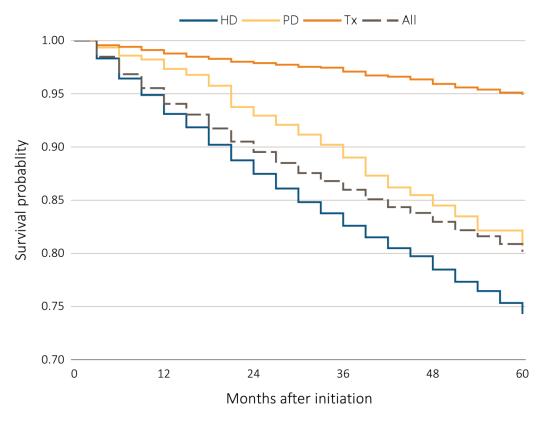
vol 2 Figure 8.18 One-year adjusted cardiovascular mortality rates in young adults with incident ESRD (aged 22-29 years), by modality, 2004-2008 and 2009-2013



Data Source: Special analyses, USRDS ESRD Database. Incident dialysis and transplant patients defined at the onset of dialysis or the day of transplant without the 60-day rule; followed to December 31, 2014. Adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD. Reference population: incident ESRD patients aged 22-29, 2010-2011. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

For young adults beginning ESRD therapy during the period 2005-2009, the probability of five-year survival was 0.80, which is lower than the 0.90 fiveyear survival in patients aged 0-21 years (Figure 8.19). Young adult transplant patients had the highest probability of surviving five years with 0.95, as compared to 0.74 in hemodialysis patients, and 0.81 in peritoneal dialysis patients.





Data Source: Special analyses, USRDS ESRD Database. Incident dialysis and transplant patients defined at the onset of dialysis or the day of transplant without the 60-day rule; followed to December 31, 2014. Adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD. Reference population: incident ESRD patients aged 22-29, 2010-2011. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.



Chapter 9: Cardiovascular Disease in Patients With ESRD

- Cardiovascular disease is common in adult ESRD patients, with atherosclerotic heart disease and congestive heart failure being the most common conditions (Table 9.1).
- Cardiovascular diseases are the leading cause of death in ESRD patients (Figure 9.1).
- Sudden death/cardiac arrhythmias account for almost 30% of all deaths in the Medicare ESRD population (Figure 9.1).
- Even relatively young ESRD patients (aged 22-44 and 45-64 years) experience significant cardiovascular morbidity (Figure 9.3).
- The presence of cardiovascular diseases worsens both short and long-term survival in adult ESRD patients (Figure 9.4).

Introduction

Patients with end-stage renal disease (ESRD) are among the highest risk populations for a number of cardiovascular diseases, and cardiovascular diseases are a major cause of death in ESRD patients. Presence of ESRD also often complicates disease management of cardiovascular disease, as it can influence both medical and procedural options, thereby adversely affecting a patient's prognosis. In this chapter, we focus on reporting the prevalence and outcomes of adult ESRD patients with diagnosed major cardiovascular conditions, stratifying by type of renal replacement therapy being received (hemodialysis, peritoneal dialysis, or kidney transplantation). For individual conditions, we compare the survival of ESRD patients with and without cardiovascular diseases. Given its role as the primary health care payer for ESRD patients, our analyses are based mostly on data from the national Medicare population.

Methods

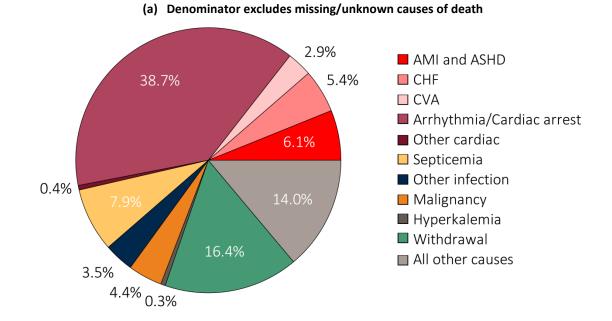
This chapter uses data from the Centers for Medicare & Medicaid Services (CMS). Findings were primarily drawn from special analyses based on the USRDS ESRD Database. Details of the data source are described in the <u>Data Sources</u> section of the *ESRD Analytical Methods* chapter.

See the section on <u>Chapter 9</u> in the *ESRD Analytical Methods* chapter for a detailed explanation of analytical methods used to generate the study cohorts, figures, and tables in this chapter.

Cardiovascular Disease Prevalence and Outcomes in ESRD Patients

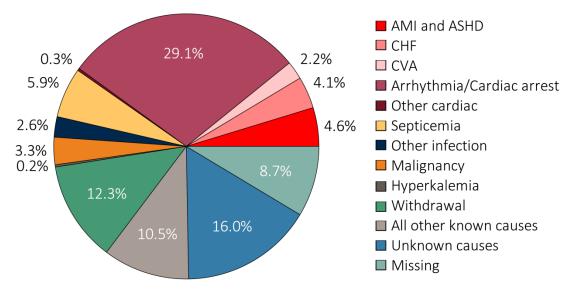
Figure 9.1 presents both the proportion of known causes of death and the proportion of total deaths among ESRD patients. As shown in Figure 9.1.a, cardiovascular diseases are a major cause of death in ESRD patients, contributing to more than half of all deaths with known causes. The category of arrhythmias and cardiac arrest alone is responsible for 38.7% of the deaths. Figure 9.1.b provides an alternate analysis in which deaths with unknown and missing causes are included in the denominator, and appear as separate categories. As shown in Figure 9.1.b, the categories of arrhythmias and cardiac arrest, congestive heart failure (CHF), acute myocardial infarction (AMI) and atherosclerotic heart disease (ASHD) are responsible for over one-third of the total deaths. A significant proportion (24.7%) of the deaths

is due to unknown causes or missing cause of death. We speculate that unidentified cardiovascular conditions may well be the true underlying causes of death in this category.



vol 2 Figure 9.1 Causes of death in ESRD patients, 2012-2014

(b) Denominator includes missing/unknown causes of death

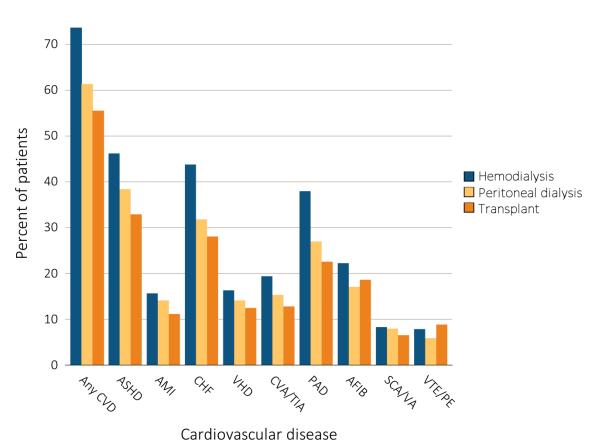


Data Source: Special analysis using Reference Table H12. (a) Denominator includes other causes of death and excludes missing/unknown causes of death (24.7% of patients have unknown or missing causes of death). (b) Denominator includes other known causes, unknown causes of death, and records that are missing the cause of death. Unknown causes include records from the CMS 2746 ESRD death notification form that specifically designate an unknown cause of death. Missing includes records in the ESRD database that are missing the CMS 2746, or have the form but are missing or have recording errors in the primary cause of death field. Abbreviations: ASHD, atherosclerotic heart disease; AMI, acute myocardial infarction; CHF, congestive heart failure; CVA, cerebrovascular accident.

CHAPTER 9: CARDIOVASCULAR DISEASE IN PATIENTS WITH ESRD

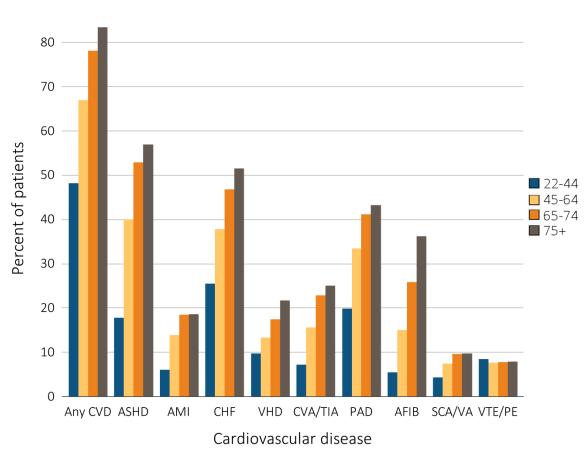
ESRD patients have a high burden of cardiovascular disease across a wide range of conditions (Figure 9.2). Stable ASHD and CHF are the two major leading cardiovascular diseases present in adult ESRD patients. However, acute myocardial infarction (AMI), valvular heart disease (VHD), cerebrovascular accident/transient 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) are also common. VTE/PE are presented for the first time in this chapter, and while lower than other cardiovascular diseases, its presence is nontrivial. In general, the prevalence of these cardiovascular diseases is highest among ESRD patients who receive hemodialysis (73.6%) followed by peritoneal dialysis (61.3%) and those with a kidney transplant (55.4%).

vol 2 Figure 9.2 Prevalence of cardiovascular diseases in adult ESRD patients, by treatment modality, 2014



Data Source: Special analyses, USRDS ESRD Database. Point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older, with Medicare as primary payer on January 1, 2014, who are continuously enrolled in Medicare Parts A and B from January, 1, 2013 to December 31, 2013, and ESRD service date is at least 90 days prior to January 1, 2014. Abbreviations: AFIB, atrial fibrillation; AMI, acute myocardial infarction; ASHD, atherosclerotic heart disease; CHF, congestive heart failure; 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.

Not surprisingly, older ESRD patients tend to have a higher prevalence of cardiovascular conditions (Figure 9.3). It is notable, however, that the prevalence of these conditions is high even among those 22-44 years of age (48.2%), although a much higher prevalence is observed among those 45 years or older (66.9% to 83.4%). ASHD is the most common condition, with its prevalence exceeding 50% in ESRD patients aged 65 years and older, followed by CHF, PAD, AFIB, CVA/TIA, and VHD. The presence of VTE/PE did not vary as much by age.



vol 2 Figure 9.3 Prevalence of cardiovascular diseases in adult ESRD patients, by age, 2014

Data Source: Special analyses, USRDS ESRD Database. Point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older, with Medicare as primary payer on January 1, 2014, who are continuously enrolled in Medicare Parts A and B from January, 1, 2013 to December 31, 2013, and ESRD service date is at least 90 days prior to January 1, 2014. Abbreviations: AFIB, atrial fibrillation; AMI, acute myocardial infarction; ASHD, atherosclerotic heart disease; CHF, congestive heart failure; 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 relationships between age, race or ethnicity, and sex with the prevalence of cardiovascular diseases in adult ESRD patients are displayed in Table 9.1. As noted earlier, advancing age is associated with higher prevalence of cardiovascular conditions. However, the relationships with race or ethnicity and sex are less definitive. The prevalence of major procedures for treating cardiovascular disease in ESRD patients is also reported in Table 9.1, including percutaneous coronary intervention (PCI), coronary artery bypass grafting (CABG), placement of implantable cardioverter defibrillators (ICD) and cardiac resynchronization therapy with defibrillator (CRT-D) devices, and carotid artery stenting (CAS) and carotid endarterectomy (CEA). The prevalence of CAS/CEA is low in ESRD patients relative to other major procedures.

	(a) Cardiovascular Comorbidities										
		% Patients									
	# Patients	Overall	22-44	45-64	65-74	75+	White	Blk/Af Am	Other	Male	Female
Atherosclerotic heart dise	ease (ASHD)										
Hemodialysis	191,559	46.2	18.9	41.4	54.1	57.4	50.8	40.3	44.0	46.8	45.4
Peritoneal dialysis	15,225	38.3	16.1	34.9	49.4	53.8	41.8	31.6	32.3	43.4	32.8
Transplant	14,918	32.9	8.9	28.1	42.6	49.4	35.8	26.0	30.3	35.5	28.9
Acute myocardial infarcti	on (AMI)										
Hemodialysis	191,559	15.6	6.4	14.2	18.8	18.7	17.4	13.5	14.7	16.0	15.2
Peritoneal dialysis	15,225	14.1	5.4	13.4	18.2	18.8	15.8	11.2	9.2	15.9	12.2
Transplant	14,918	11.1	3.3	9.9	14.6	15.0	12.2	8.6	10.2	11.7	10.2
Congestive heart failure (CHF)										
Hemodialysis	191,559	43.8	27.8	39.7	48.4	52.4	45.1	42.8	38.5	42.0	45.9
Peritoneal dialysis	15,225	31.7	19.6	29.5	38.0	40.7	32.1	32.4	25.5	33.4	29.9
Transplant	14,918	28.1	10.3	22.1	36.3	44.9	29.3	25.9	24.0	28.2	27.9
Valvular heart disease (V	HD)										
Hemodialysis	191,559	16.3	10.4	13.7	17.6	21.6	17.6	14.9	14.2	15.4	17.4
Peritoneal dialysis	15,225	14.1	8.7	12.3	16.1	21.2	14.9	12.9	11.3	14.3	14.0
Transplant	14,918	12.5	4.7	8.7	16.4	22.4	13.5	10.4	9.9	11.9	13.3
Cerebrovascular accident/	transient ischemic atta	ack (CVA/T	IA)								
Hemodialysis	191,559	19.4	7.6	16.2	23.5	25.2	19.6	19.5	15.9	17.7	21.4
Peritoneal dialysis	15,225	15.3	6.7	12.7	21.0	22.1	16.5	13.5	10.5	15.2	15.4
Transplant	14,918	12.8	3.2	10.2	16.5	21.8	13.6	11.1	10.9	12.2	13.8
Peripheral artery disease	(PAD)										
Hemodialysis	191,559	37.9	21.7	35.3	42.9	44.1	39.9	36.3	31.5	37.9	38.0
Peritoneal dialysis	15,225	26.9	13.2	24.9	33.8	35.8	29.8	22.0	18.7	28.9	24.8
Transplant	14,918	22.6	9.4	19.3	28.6	32.1	23.9	20.5	16.9	23.7	20.8
Atrial fibrillation (AFIB)											
Hemodialysis	191,559	22.2	5.9	15.6	25.9	36.1	26.5	17.0	19.5	22.8	21.5
Peritoneal dialysis	15,225	17.0	3.9	11.1	23.6	35.6	20.0	10.4	14.4	20.3	13.4
Transplant	14,918	18.6	2.3	11.6	26.3	38.0	21.2	12.5	15.7	19.7	16.8
Cardiac arrest and ventric	cular arrhythmias (SC	A/VA)									
Hemodialysis	191,559	8.3	4.5	7.6	9.6	9.6	8.4	8.3	7.2	8.9	7.5
Peritoneal dialysis	15,225	7.9	4.0	7.0	10.1	11.1	8.4	7.6	4.8	9.2	6.6
Transplant	14,918	6.5	2.9	4.7	8.9	9.9	6.9	5.9	4.2	7.2	5.4
Venous thromboembolis	m and pulmonary em	bolism (V									
Hemodialysis	191,559	7.8	8.8	7.7	7.7	7.7	7.1	9.2	5.3	7.2	8.7
Peritoneal dialysis	15,225	5.8	7.2	5.4	5.7	5.6	5.5	7.2	2.8	5.3	6.4
Transplant	14,918	8.8	6.3	7.6	10.2	11.9	9.0	9.2	5.6	8.4	9.5

vol 2 Table 9.1 Prevalence of (a) cardiovascular comorbidities & (b) cardiovascular procedures in adult ESRD patients, (%) by treatment modality, age, race, & sex, 2014

Table 9.1 continued on next page.

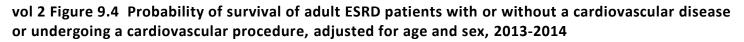
		(b) (Cardiova	ascular F	Procedur	es					
	% Patients										
	# Patients	Overall	22-44	45-64	65-74	75+	White	Blk/Af Am	Other	Male	Female
Revascularization – percu	taneous coronary int	ervention	s (PCI)								
Hemodialysis	88,440	4.9	4.0	5.7	5.4	3.6	5.1	4.5	5.5	5.0	4.8
Peritoneal dialysis	5,836	6.9	7.6	7.6	6.6	5.8	7.1	6.2	5.9	7.2	6.4
Transplant	4,905	4.2	4.8	5.0	3.9	3.5	4.2	3.6	6.3	4.3	4.1
Revascularization - coron	ary artery bypass gra	ft (CABG)									
Hemodialysis	88,440	1.6	1.8	2.3	1.7	0.7	1.7	1.4	2.4	1.9	1.2
Peritoneal dialysis	5,836	3.4	3.5	4.1	3.6	1.9	3.4	3.3	3.4	3.6	3.1
Transplant	4,905	1.5	1.1	2.0	1.2	1.2	1.6	0.7	3.1	1.7	1.0
Implantable cardioverter	defibrillators & cardi	ac resyncl	nronizati	on thera	py with d	efibrilla	tor device	es (ICD/CF	T-D)		
Hemodialysis	83,841	0.7	0.7	0.7	0.8	0.5	0.7	0.7	0.7	0.9	0.5
Peritoneal dialysis	4,828	0.8	0.6	0.8	0.9	0.9	1.1	0.4	0.0	0.9	0.7
Transplant	4,187	0.7	0.5	1.0	0.5	0.6	0.6	0.9	0.9	0.9	0.5
Carotid artery stenting an	d carotid artery end	arterector	ny (CAS/	CEA)							
Hemodialysis	120,105	0.4	0.1	0.3	0.5	0.4	0.5	0.2	0.2	0.3	0.4
Peritoneal dialysis	7,759	0.7	0.0	0.3	1.1	1.0	0.8	0.3	0.2	0.7	0.7
Transplant	6,603	0.4	0.3	0.2	0.4	0.7	0.5	0.1	0.0	0.3	0.6

vol 2 Table 9.1 Prevalence of (a) cardiovascular comorbidities & (b) cardiovascular procedures in adult ESRD patients, (%) by treatment modality, age, race, & sex, 2014 (continued)

Data Source: Special analyses, USRDS ESRD Database. Point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older, with Medicare as primary payer on January 1, 2014, who are continuously enrolled in Medicare Parts A and B from January, 1, 2013 to December 31, 2013, and ESRD service date is at least 90 days prior to January 1, 2014. (a) The denominators for all cardiovascular comorbidities are patients described above by modality.(b) The denominators for PCI and CABG are patients with ASHD by modality. The denominator for ICD/CRT-D is patients with CHF by modality. The denominator for CAS/CEA is patients with ASHD, CVA/TIA, or PAD by modality. Abbreviations: AFIB, atrial fibrillation; AMI, acute myocardial infarction; ASHD, atherosclerotic heart disease; Af Am, African American; Blk, black; CABG, coronary artery bypass grafting; CAS/CEA, carotid artery stenting and carotid artery endarterectomy; CHF, congestive heart failure; 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; VTE/PE, venous thromboembolism and pulmonary embolism.

The presence of cardiovascular diseases is known to decrease short- and long-term survival for ESRD patients. For example, in a classic study from the USRDS by Herzog et al. in 1998, one-year mortality after AMI approached 60% in patients on long-term dialysis. Figures 9.4.a through 9.4.m illustrate two-year survival curves in adult ESRD patients with and without individual cardiovascular diseases.

In general, ESRD patients have lower survival when cardiovascular disease conditions are present. A pattern of lower survival is observed in patients who undergo PCI, ICD/CRT-D placement, and CAS/CEA, but survival appears similar between patients who undergo CABG procedures and those who do not. The ESRD patients who undergo these procedures are being compared both with those who have any cardiovascular conditions but do not undergo these procedures and those without any cardiovascular conditions. These descriptive results in the adult ESRD population require careful interpretation. For example, the survival differences across therapies may be the consequence of confounding-by-indication due to selection of patients for the various procedures. Careful comparative effectiveness research with appropriate statistical methods would be necessary to evaluate whether these procedures improve or worsen patient prognoses among similar/equivalent patient groups comparing those that undergo the procedure versus those that do not.



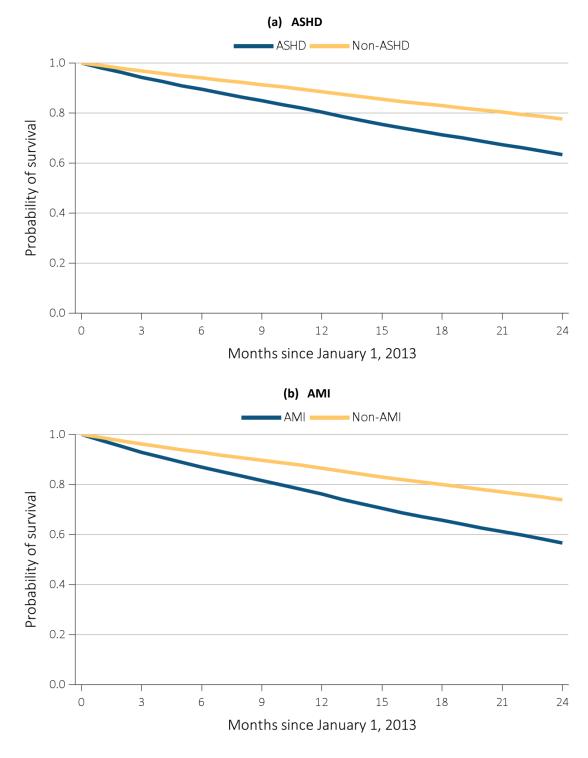


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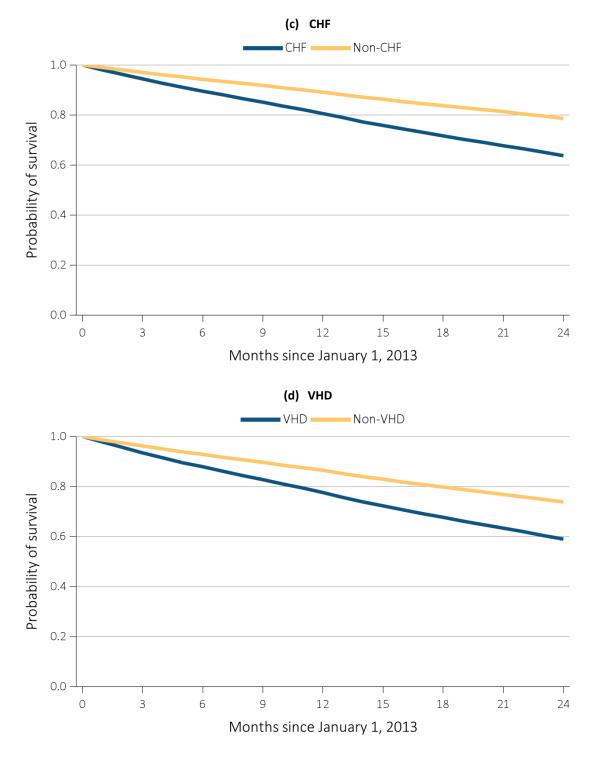


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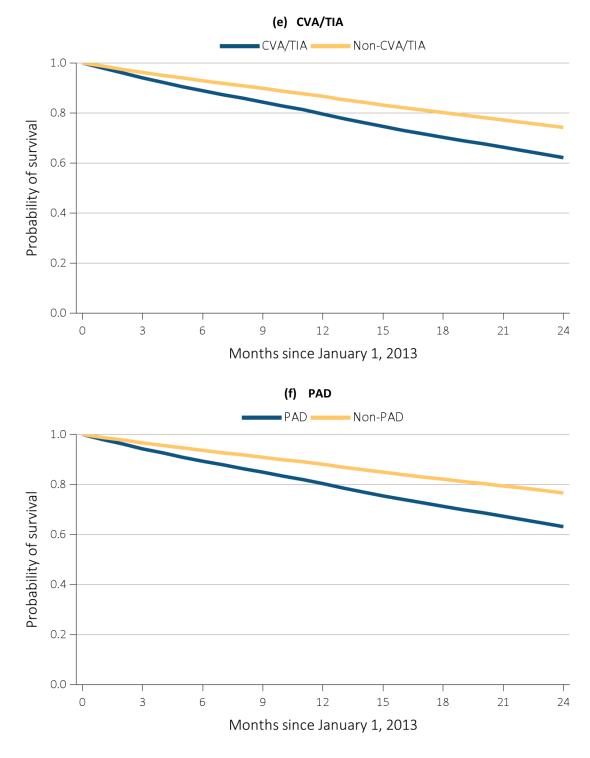


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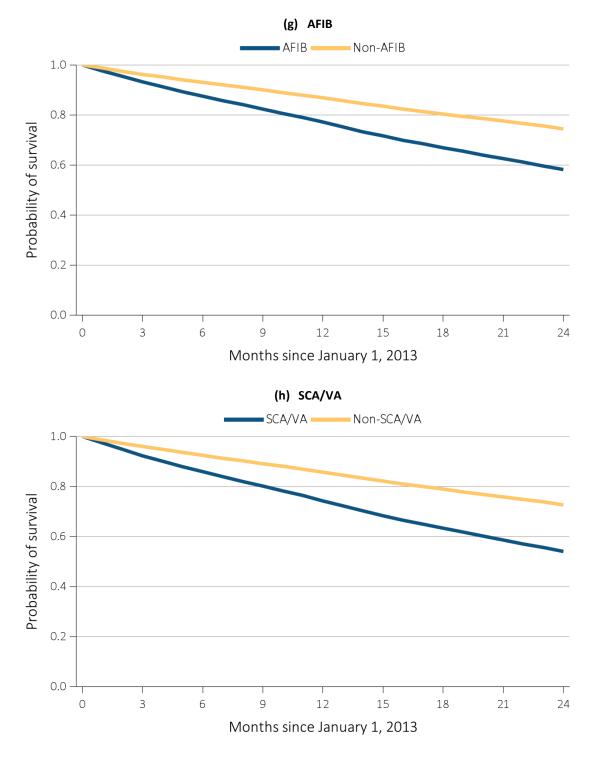


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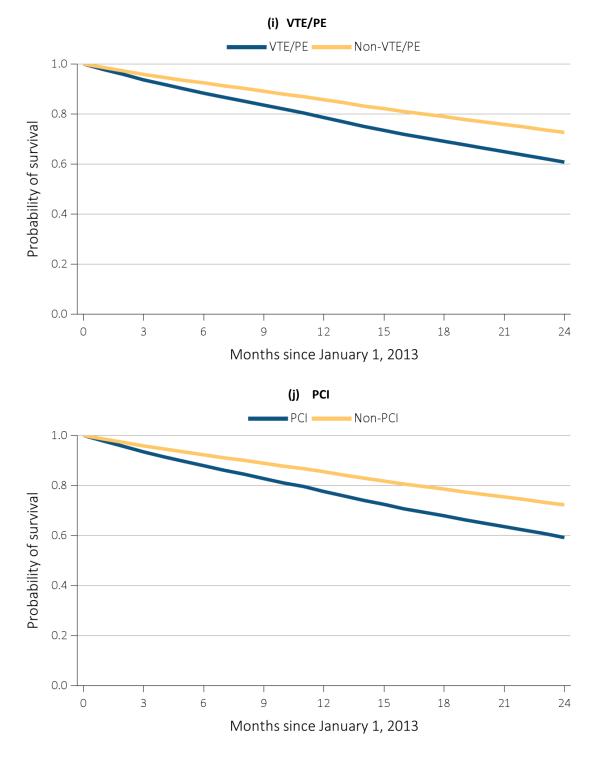


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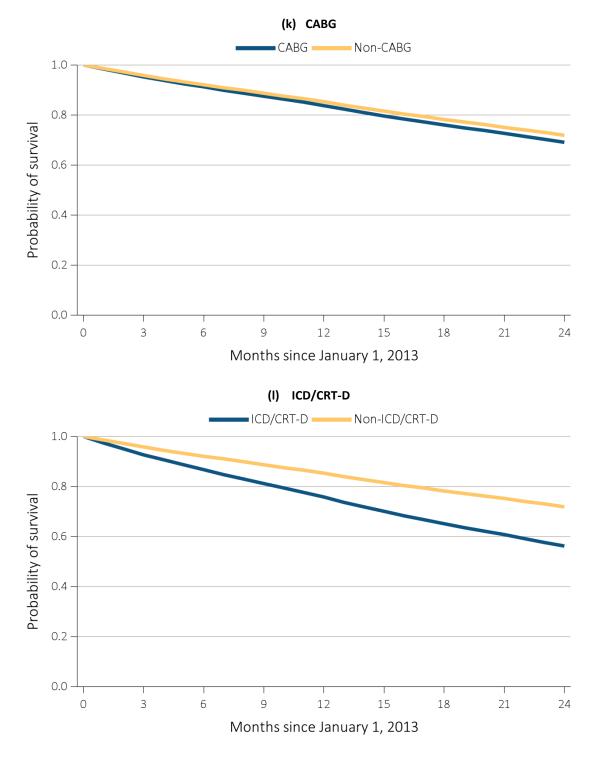
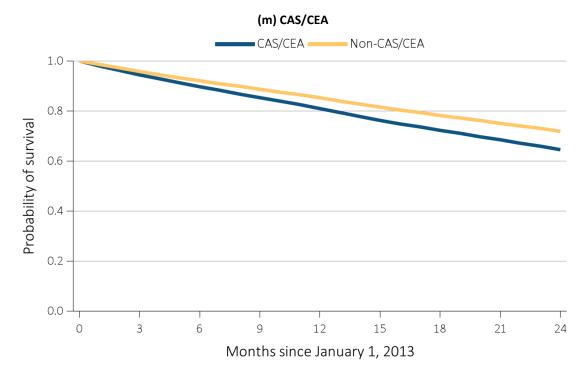


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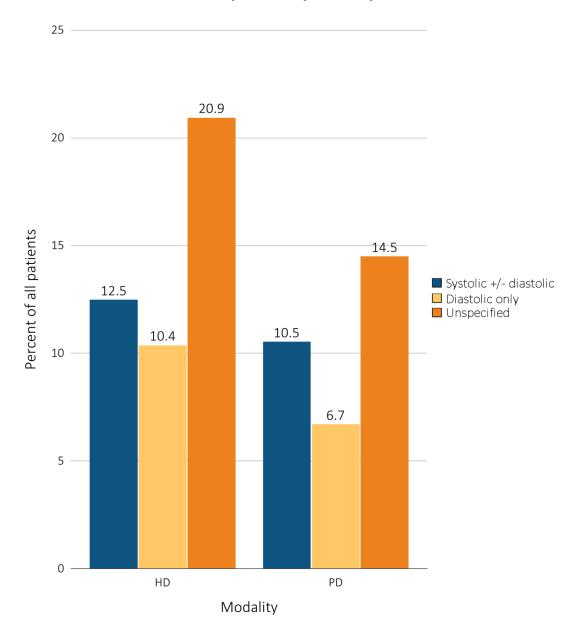


Data Source: Special analyses, USRDS ESRD Database. Point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older, with Medicare as primary payer on January 1, 2012, who are continuously enrolled in Medicare Parts A and B from January, 1, 2011 to December 31, 2011, and whose first ESRD service date is at least 90 days prior to January 1, 2012, and survived past 2012. Abbreviations: AFIB, atrial fibrillation; AMI, acute myocardial infarction; ASHD, atherosclerotic heart disease; CABG, coronary artery bypass grafting; CAS/CEA, carotid artery stunting and carotid artery endarterectomy; CHF, congestive heart failure; CVA/TIA, cerebrovascular accident/transient ischemic attack; 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.

Congestive Heart Failure Among ESRD Patients

Congestive heart failure (CHF) is a highly prevalent cardiovascular disease among ESRD patients. Presence of CHF adds further complexity to fluid management in ESRD patients, especially given the absence of renal function and clinical challenges with volume status assessment. CHF in ESRD patients is further examined in Figure 9.5 by stratifying CHF according to systolic dysfunction (i.e., heart failure with decreased ejection fraction), diastolic dysfunction (i.e., heart failure with preserved ejection fraction), or unspecified cardiac dysfunction. (Note: For ease of reporting and consistency in studying clinical approaches, systolic CHF includes all patients with systolic dysfunction, regardless of the presence of concomitant diastolic dysfunction. Patients with isolated diastolic CHF are analyzed separately since treatments and prognoses are markedly different for this group.)

Among adult ESRD patients, the largest percent of patients have unspecified CHF and the relative proportion of patients with systolic CHF is slightly higher than diastolic CHF (Figure 9.5). This pattern is true for both hemodialysis and peritoneal dialysis patients. The percentage of patients experiencing each type of heart failure is slightly higher among hemodialysis patients compared to peritoneal dialysis patients. As we identified categories of systolic dysfunction and diastolic dysfunction through ICD-9-CM diagnosis codes, the findings should be considered cautiously without further clinical data available given the limitations of these codes.





Data Source: Special analyses, USRDS ESRD Database. Point prevalent hemodialysis and peritoneal dialysis patients aged 22 and older, with Medicare as primary payer on January 1, 2014, who are continuously enrolled in Medicare Parts A and B from January, 1, 2013 to December 31, 2013, and ESRD service date is at least 90 days prior to January 1, 2014. Abbreviations: HD, hemodialysis; PD, peritoneal dialysis.

Summary

This chapter provides an overview of cardiovascular diseases among adult ESRD patients, using administrative claims data from Medicare. The relationship between cardiovascular disease and kidney disease is complex and bidirectional, and close attention to cardiovascular disease is vital to the care of these patients. The high prevalence of AMI, ASHD, CHF and sudden death/cardiac arrhythmias should draw more attention of researchers and clinicians. Improving outcomes in this complex patient population remains challenging, and the presence of ESRD should not detract health care practitioners from delivering the high quality cardiovascular care that they deserve.

CHAPTER 9: CARDIOVASCULAR DISEASE IN PATIENTS WITH ESRD

References

Herbert PL, Geiss LS, Tierney EF, Engelgau MM, Yawn BP, McBean AM. Identifying persons with diabetes using Medicare claims data. *Am J Med Qual* 1999;14(6):270-277. Herzog CA, Ma JZ, Collins AJ. Poor long-term survival after acute myocardial infarction among patients on long-term dialysis. *N Engl J Med* 1998;339(12):799-805.

Notes



Chapter 10: Dialysis Providers

- In 2014 the two largest dialysis organizations, Fresenius and DaVita, collectively treated 69% of patients in 65% of all dialysis units (Figure 10.2).
- Nearly 90% of all dialysis patients in 2014 received hemodialysis; Hospital-based providers treated the highest proportion of peritoneal dialysis (PD) patients at 21%, more than double the PD national average of 10% (Figure 10.3).
- Overall, dialysis providers of all types experienced a 12% decline in Standardized Mortality Ratios (SMR) between 2011 and 2014, while Standardized Hospitalization Ratios (SHR) essentially did not change in the same period (Tables 10.1 and 10.3).
- To highlight the complex differences between the demographic groups, beginning with the 2015 Annual Data Report (ADR) we have included sex-, race-, and ethnicity-specific breakdowns of patient outcomes for home-based dialysis modality, hemodialysis (HD) vascular access types, and kidney transplant waitlist participation, (Tables 10.4 and 10.5).
- In this 2016 ADR, we no longer classify dialysis providers solely according to number of dialysis facilities under their ownership. This is in recognition of the fact that the two major chains are disproportionately large, and that mergers and acquisitions have resulted in a constantly evolving landscape of the dialysis provider community. We also no longer describe the group of relatively smaller, for-profit dialysis providers as Small Dialysis Organizations. We now collectively refer to this heterogeneous group as Other Dialysis Organizations, or Others.

Introduction

This chapter focuses on the provider organizations dedicated to delivering care to dialysis patients. Particularly during the last two decades, there has been continued growth in the for-profit Large Dialysis Organizations (LDOs). Two LDOs in particular, Fresenius Medical Care (Fresenius) and DaVita Healthcare Partners, Inc. (DaVita), now dominate as providers of dialysis services in the United States (U.S.), with nearly two-thirds of facilities; their industry dominance is also growing on an international level. In contrast, there has been little to no growth in the provision of dialysis services by all other dialysis organizations that include not-for-profit organizations such as Dialysis Clinics, Inc. (DCI), Independent, or Hospital-based dialysis facilities, and all Other smaller for-profit dialysis organizations. For the 2016 ADR, we have avoided any formal classification of dialysis providers solely by size, given the disproportionate size of the two largest dialysis

providers, the heterogeneity in their ownership type, and the evolving nature of mergers and acquisitions in the provider community.

This chapter begins with a description of growth in dialysis facilities by the type of provider organization, followed by updated coverage of three key areas of clinical practice related to care of patients on dialysis. These include (i) choice of dialysis modality, (ii) patterns of vascular access type for both incident and prevalent dialysis patients, and (iii) the proportion of patients younger than age 70 who are wait-listed for kidney transplantation. We conclude the chapter with an analysis of standardized mortality and hospitalization ratios (SMRs and SHRs) by provider 'type', namely, LDOs, DCI, Independent and Hospitalbased providers, and Others.

In the 2015 ADR, we introduced a new approach used to calculate and present the standardized measures of major dialysis clinical outcomes. This methodology constituted a departure from previous

ADRs, but was designed to facilitate comparison of the SMR and the SHR across years. We computed these measures without adjusting for calendar years. Consequently, the measures are no longer standardized to a national norm annually, but instead are compared with the aggregated national population across the entire reporting period (i.e., four years). This method facilitates identification of short-term-change trends in the standardized measures, and enables comparisons of these measures from different types of providers across calendar years within the reporting period. To emphasize the variation in some key clinical practices at the level of the individual dialysis facilities, we also display facility-level variation in choice of dialysis modality, vascular access type, and wait-listing for a kidney transplant.

Methods

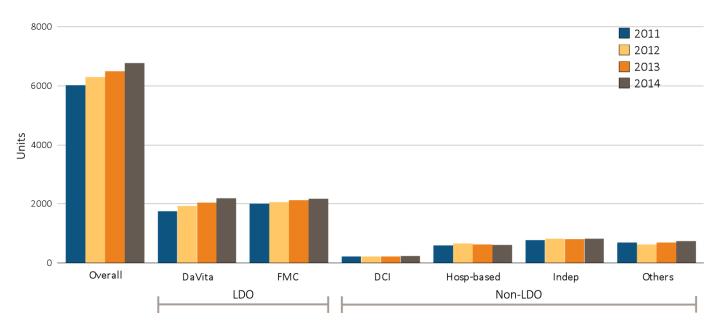
This chapter uses multiple data sources including data from the Centers for Medicare & Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the United States Census. Details of data sources are described in the Data Sources section of the *ESRD Analytical Methods* chapter.

See the *ESRD Analytical Methods* chapter for an explanation of the methods used to generate figures and tables in this chapter.

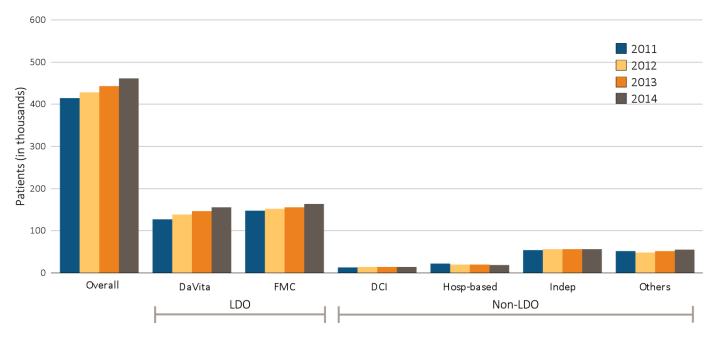
Provider Growth

At the end of 2014, there were 6,757 dialysis units (Figure 10.1) and 460,675 dialysis patients (Figure 10.2) in the U.S. Together the two LDOs, DaVita and Fresenius, treated 317,587 of these patients (69%) in 4,362 dialysis units (65%). DCI treated 14,287 (3%) patients in 230 (3%) units, Independent and Hospitalbased providers treated 55,768 (12%) and 18,350 (4%) patients, respectively, in 814 (12%) and 611 (9%) units, and all Other provider organizations collectively treated 54,683 patients (12%) in 740 units (11%). Nationwide, 748 dialysis units were added during the four-year period from 2011 to 2014, with most affiliated with the LDOs; DaVita experienced the largest growth in both facilities and patients. Fresenius and DaVita accounted for 609 (81%) of the new units.

vol 2 Figure 10.1 Dialysis unit counts, by unit affiliation, 2011–2014



Data source: Special analyses, USRDS ESRD Database. Abbreviations: DCI, Dialysis Clinic, Inc.; FMC, Fresenius; Hosp-based, hospitalbased dialysis centers; Indep, independent dialysis providers; Others, other dialysis organizations. Note: the number of dialysis units in 2011 has been updated for DaVita from 1681 as reported in the 2015 ADR to 1745; and from 750 in 2015 to 686 currently for Others.



vol 2 Figure 10.2 Dialysis patient counts, by unit affiliation, 2011–2014

Data source: Special analyses, USRDS ESRD Database. Abbreviations: DCI, Dialysis Clinic, Inc.; FMC, Fresenius; Hosp-based, hospitalbased dialysis centers; Indep, independent dialysis providers; Others, other dialysis organizations.

Key Dialysis Clinical Practices

CHOICE OF DIALYSIS MODALITY

In 2014, nearly 90% of all dialysis patients received in-center hemodialysis, a pattern consistently observed across most providers. The panels of figure 10.3 show the proportion of patients engaging in home dialysis therapies, by provider type. While the majority of provider types utilized in-center HD as the dominant modality, Hospital-based providers had the lowest proportion of patients on HD at 77% and the highest proportion of PD patients at 21%, more than double the national average. Nationwide, the prevalence of PD increased from 9% in 2011 to 10% in 2014. The largest increase in uptake of PD appeared to be among patients of Asian descent, from12% to 14%; this was particularly true for Hospital-based facilities, with growth from29% to 39%. This trend may in part be due to lower rates of obesity or greater acceptance of PD by this patient subgroup, and requires further investigation. For additional information on trends in the modality of dialysis see Volume 2, Chapter 1, *Incidence, Prevalence, Patient Characteristics, and Modalities.*

Home dialysis therapies have been associated with greater patient independence and improved quality of life. Younger, more educated patients and those with fewer comorbid conditions and greater access to care tend to adopt these treatments more frequently, making comparisons of survival between in-center and home dialysis fraught with a high degree of confounding-by-indication. Home hemodialysis remains uncommon in all racial and ethnic groups and types of facilities, representing fewer than 2% of all ESRD patients in 2014.

vol 2 Figure 10.3 Prevalence of home-based dialysis modality, by unit affiliation, 2011–2014

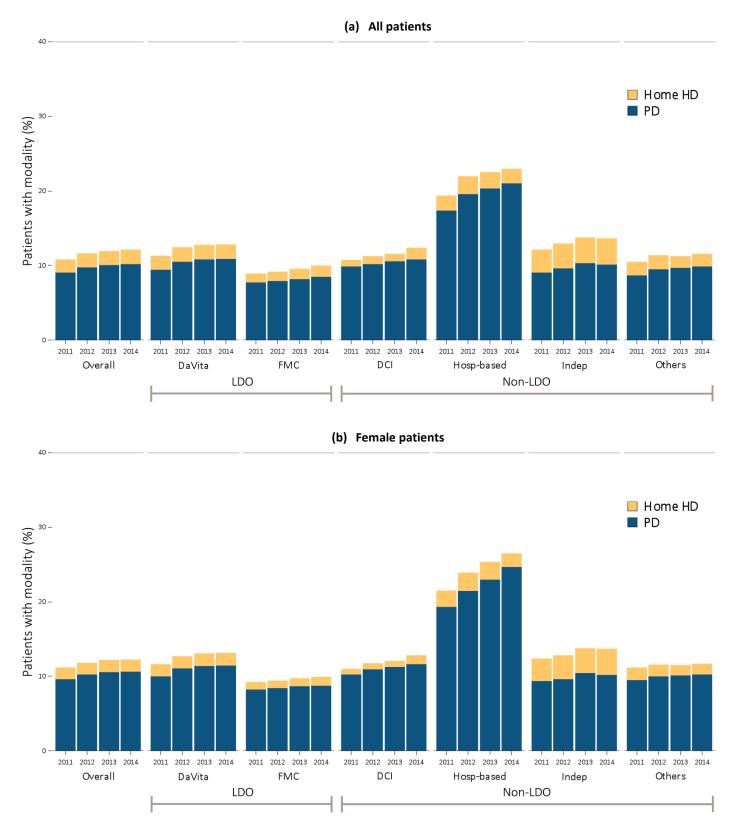


Figure 10.3 continued on next page.

vol 2 Figure 10.3 Prevalence of home-based dialysis modality, by unit affiliation, 2011–2014 (continued)

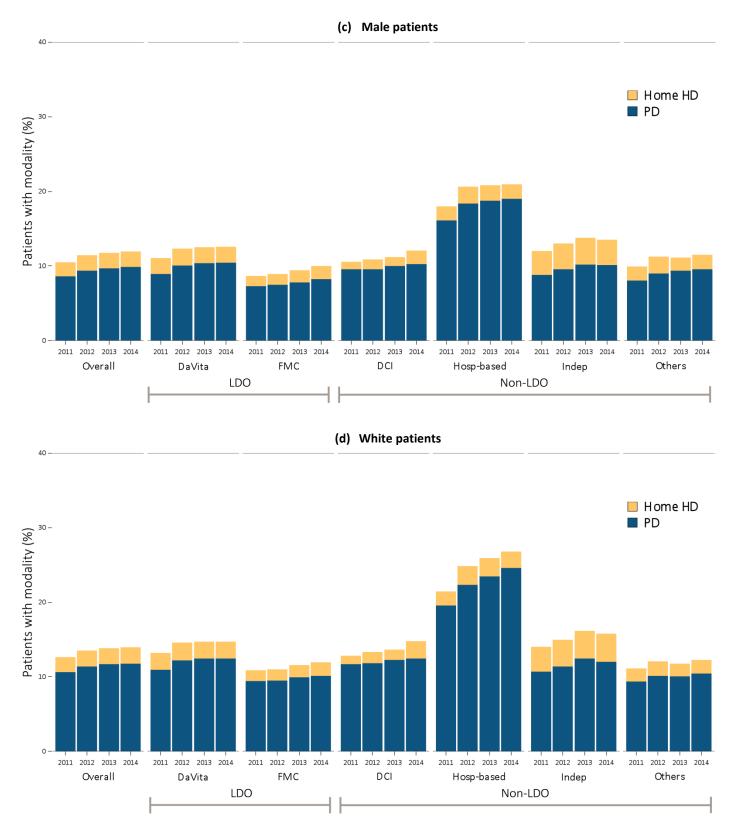


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vol 2 Figure 10.3 Prevalence of home-based dialysis modality, by unit affiliation, 2011–2014 (continued)

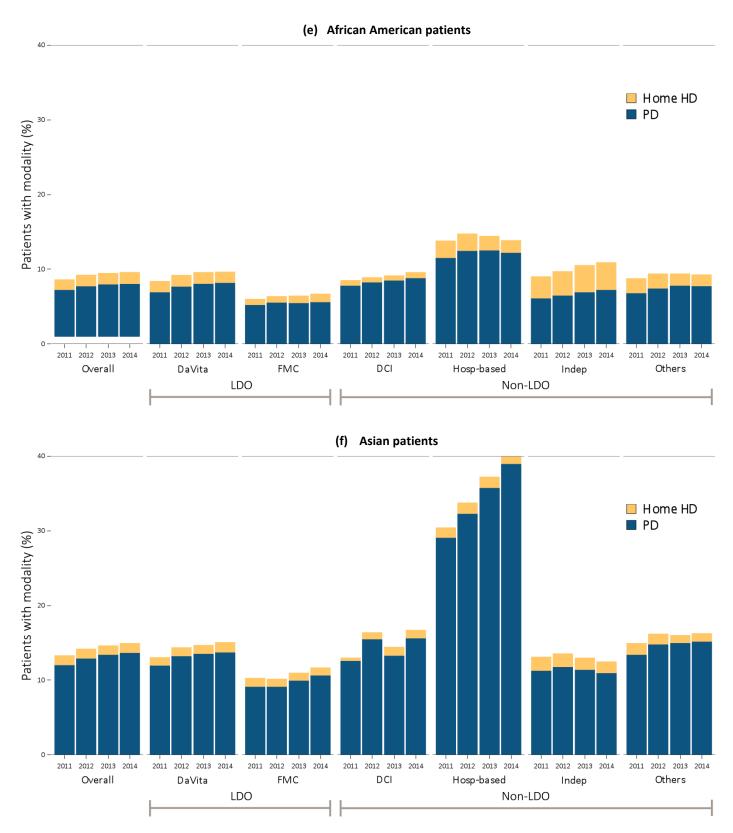
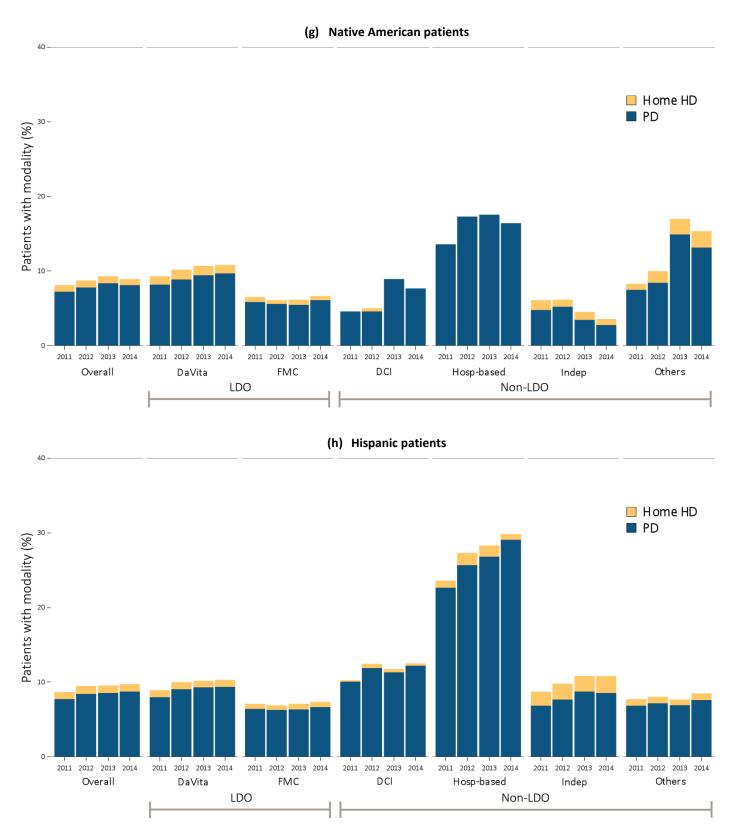


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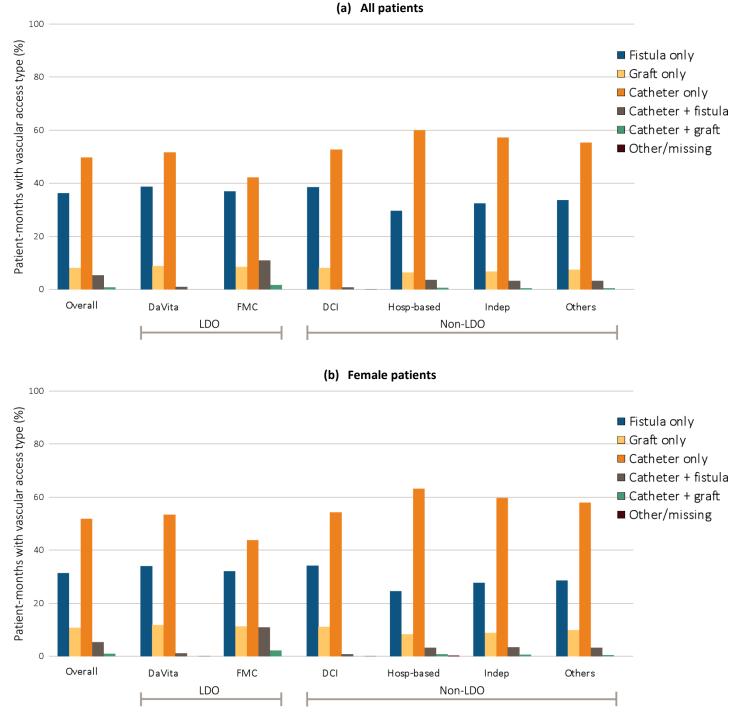
vol 2 Figure 10.3 Prevalence of home-based dialysis modality, by unit affiliation, 2011–2014 *(continued)*



Data source: Special analyses, USRDS ESRD Database. Abbreviations: HD, hemodialysis; Hosp-based, hospital-based dialysis centers; Indep, independent dialysis providers; LDO, large dialysis organizations; PD, peritoneal dialysis; Others, other dialysis organizations.

Type of Vascular Access

In 2014, 62% of prevalent HD patients in the U.S. received their treatment via an arteriovenous (AV) fistula and 17% via an indwelling catheter (Figures 10.5 a-h). Fistula use was highest among LDOs at 62%; catheter use was highest among Hospital-based providers, at 27%. During their first 30 days of ESRD, most incident patients (56%) received dialysis via a catheter. Of the dialysis organizations, DaVita had the highest proportion of incident patients with a fistula alone (39%), compared with the 38% in DCI, 37% in Fresenius, 30% of Hospital-based, 32% of Independents, and 34% of all Others (Figure 10.4a). The by-provider distributions of vascular access types for both incident and prevalent patients are presented by sex, race, and ethnicity in Figures 10.4a–h and 10.5a–h.



vol 2 Figure 10.4 Prevalence of vascular access types among incident hemodialysis patients, by unit affiliation, 2014

Figure 10.4 continued on next page.

vol 2 Figure 10.4 Prevalence of vascular access types among incident hemodialysis patients, by unit affiliation, 2014 *(continued)*

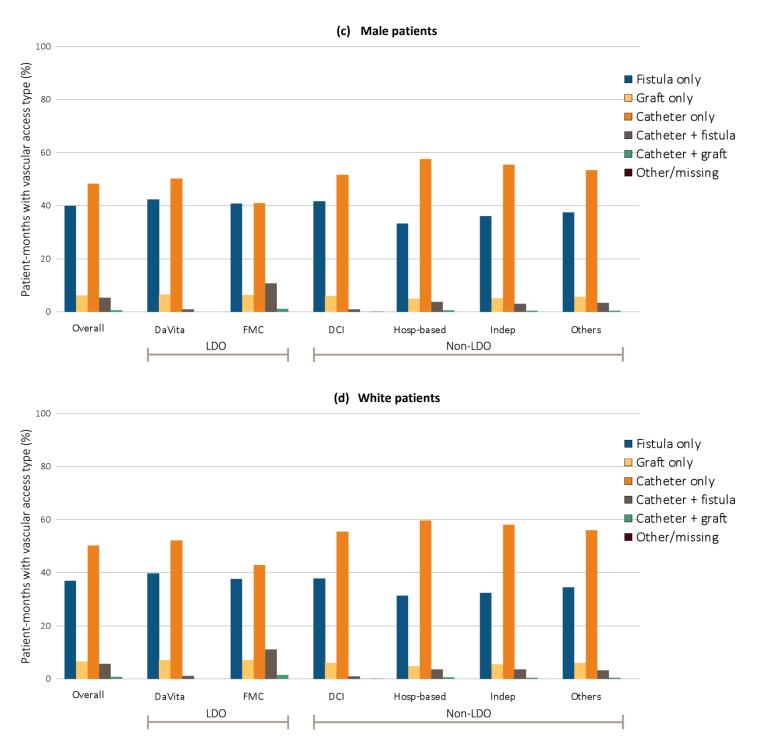


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vol 2 Figure 10.4 Prevalence of vascular access types among incident hemodialysis patients, by unit affiliation, 2014 *(continued)*

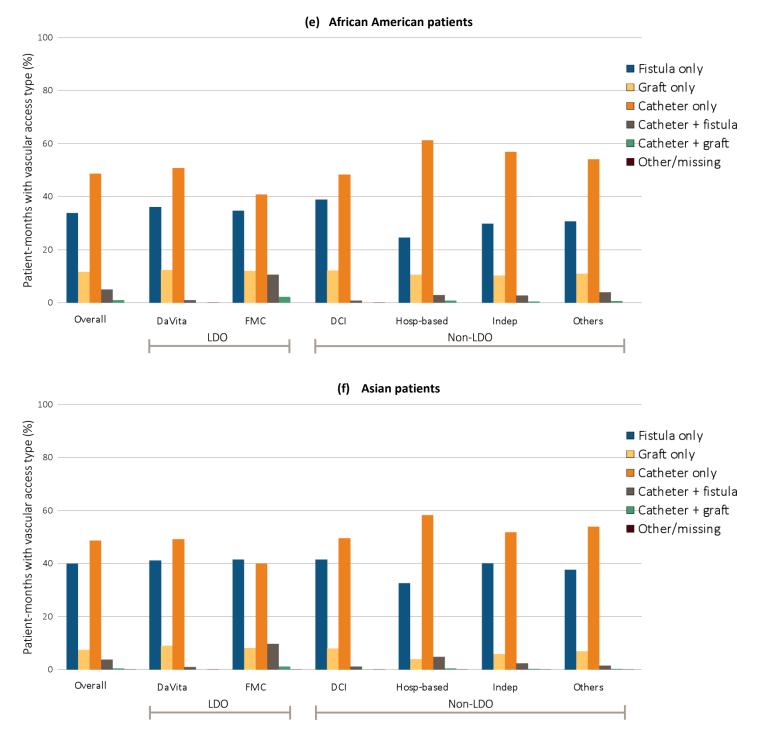
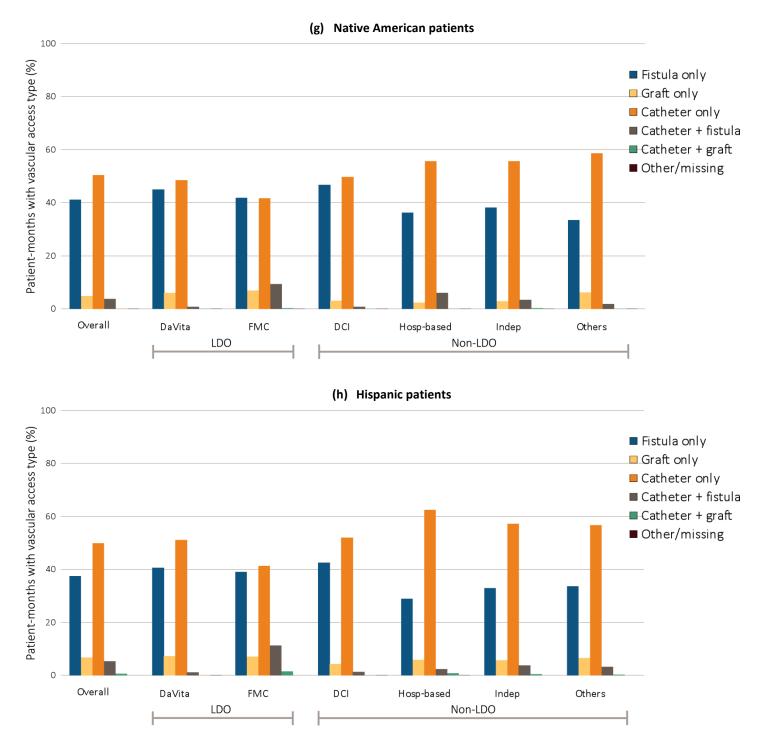
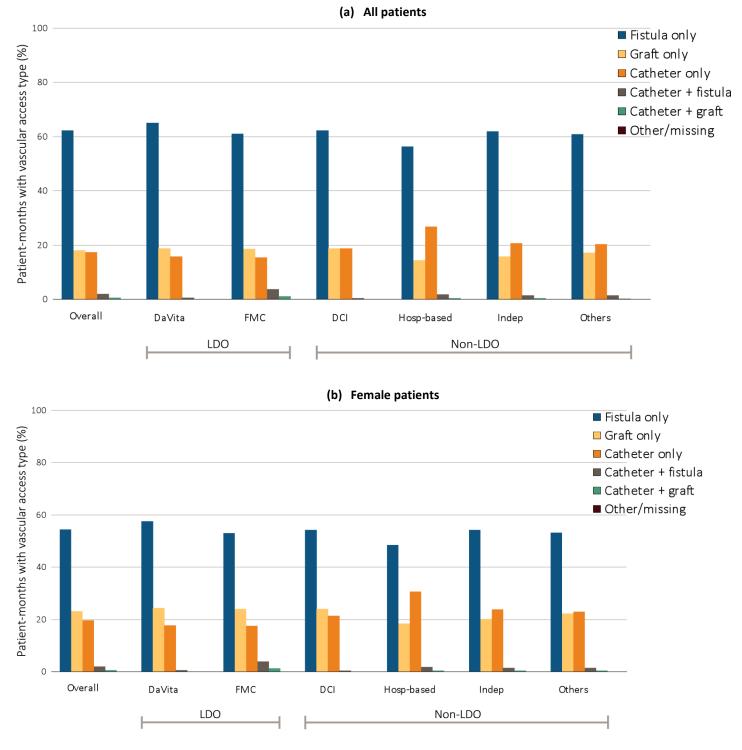


Figure 10.4 continued on next page.

vol 2 Figure 10.4 Prevalence of vascular access types among incident hemodialysis patients, by unit affiliation, 2014 *(continued)*



Data source: Special analyses, USRDS ESRD Database. Abbreviations: Hosp-based, hospital-based dialysis centers; Indep, independent dialysis providers; LDO, large dialysis organizations; Others, other dialysis organizations.



vol 2 Figure 10.5 Prevalence of vascular access types among prevalent hemodialysis patients, by unit affiliation, 2014

Figure 10.5 continued on next page.

vol 2 Figure 10.5 Prevalence of vascular access types among prevalent hemodialysis patients, by unit affiliation, 2014 *(continued)*

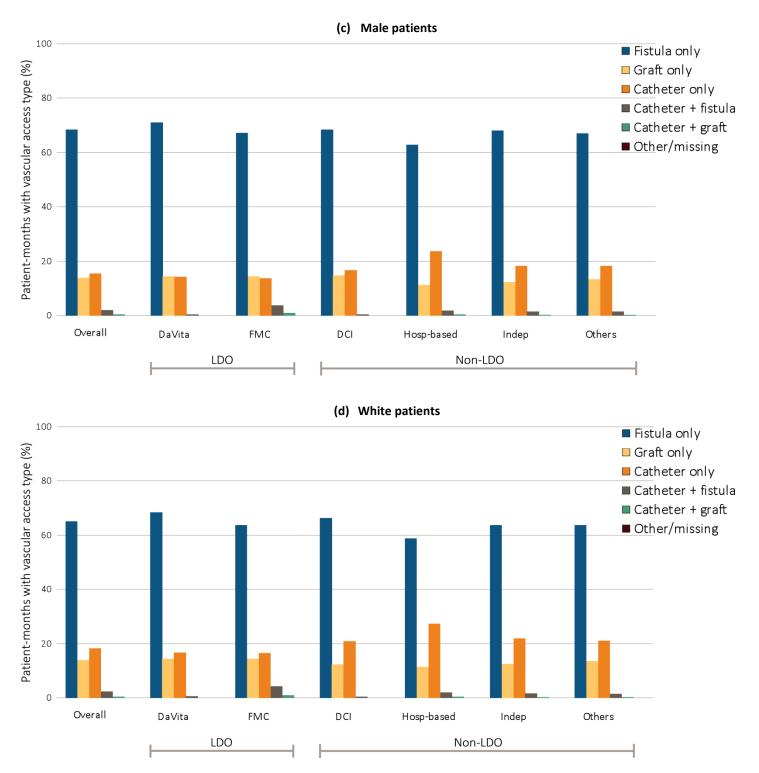


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vol 2 Figure 10.5 Prevalence of vascular access types among prevalent hemodialysis patients, by unit affiliation, 2014 *(continued)*

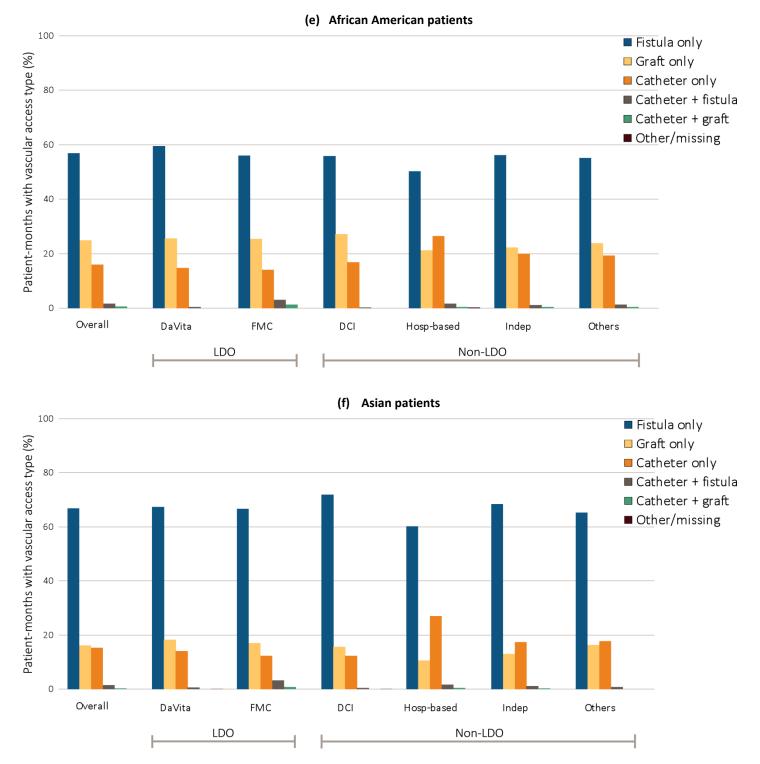
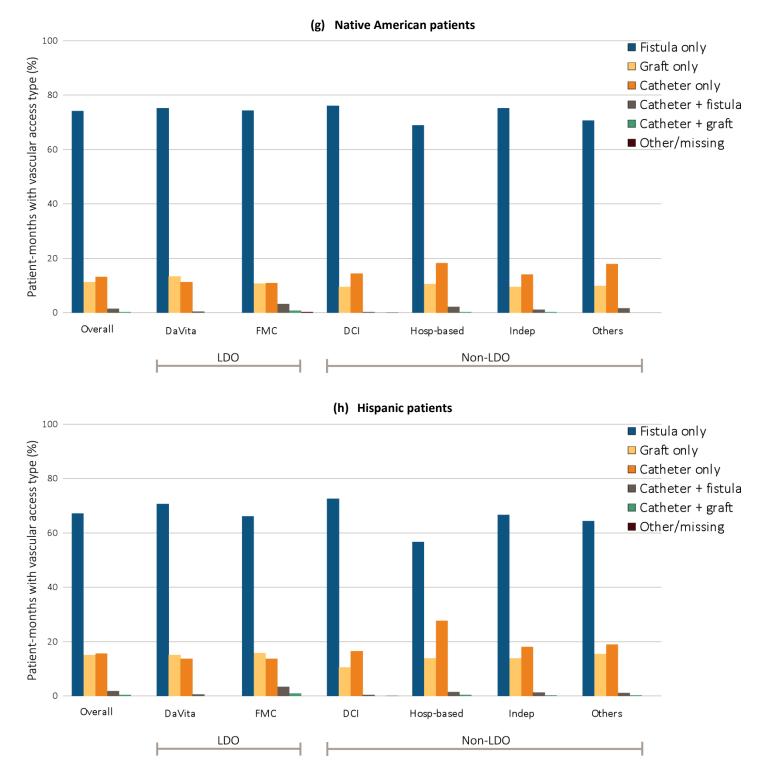


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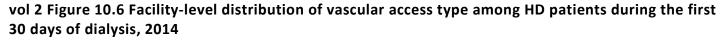
vol 2 Figure 10.5 Prevalence of vascular access types among prevalent hemodialysis patients, by unit affiliation, 2014 (continued)

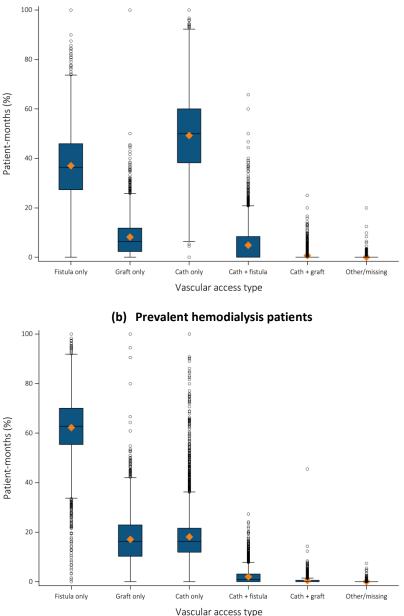


Data source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients. Abbreviations: Hosp-based, hospitalbased dialysis centers; Indep, independent dialysis providers; LDO, large dialysis organizations; Others, other dialysis organizations.

CHAPTER 10: DIALYSIS PROVIDERS

In 2014, although catheter alone was the most common vascular access type among patients in their first 30 days of dialysis (Figure 10.6a), considerable variation was observed with respect to the long-term distribution of the types in use at dialysis facilities. More than three-quarters of facilities successfully achieved the use of an AV fistula in the majority of their prevalent patients (Figure 10.6b). More than 15% of facilities achieved at least 70% fistula prevalence, with the top 5% of facilities in the nation achieving AV fistula use in more than 90% of their patients. Conversely, 5% of facilities had 30% or fewer of their prevalent patients using a fistula.





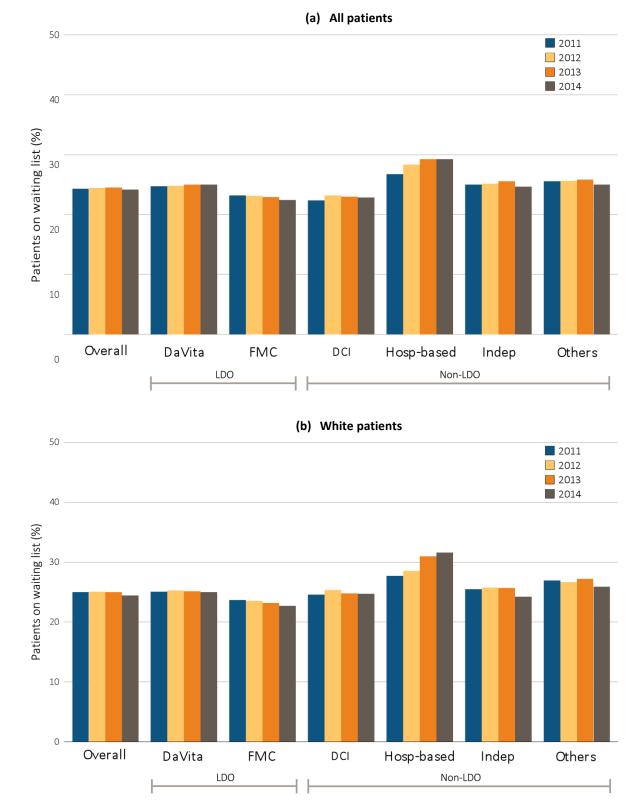
(a) Incident hemodialysis patients

Data source: Special analyses, USRDS ESRD Database. The orange diamonds represent the average facility-level rate of each type of vascular access. The bars within each box represent the median. The boxes represent the interquartile range. The vertical lines are capped at the 5th and 95th percentile of these facility-level rates. Abbreviation: Cath, catheter.

Wait-listing for Kidney Transplantation

Kidney transplantation is the modality of choice for most individuals with ESRD, and is associated with the highest quality of life and survival. Nationally, the percentage of patients on a kidney transplant waiting list remained fairly consistent between 2011 and 2014, with 24% of patients younger than age 70 on a waiting list (Figure 10.7a). We limited this measure to patients younger than age 70 in order to be comparable to the *Healthy People 2020* goals (see Volume. 2, Chapter 2, *Healthy People 2020*). Hospital-based dialysis providers had the highest rates of wait-listed patients in 2014, at 29%.

The overall percentages of patients on a kidney transplant waiting list in 2014 varied substantially by race and ethnicity, ranging from 18% among Native American patients to 35% among Asian patients. Within all racial and ethnic groups except Asian patients, Hospital-based facilities again had the highest percentages of patients on a transplant waiting list; for Asian patients those receiving treatment at DCI facilities were most likely to be on a transplant waiting list.



vol 2 Figure 10.7 Percentage of patients younger than 70 on a kidney transplant waiting list, by unit affiliation, 2011–2014

Figure 10.7 continued on next page.

vol 2 Figure 10.7 Percentage of patients younger than 70 on a kidney transplant waiting list, by unit affiliation, 2011–2014 (continued)

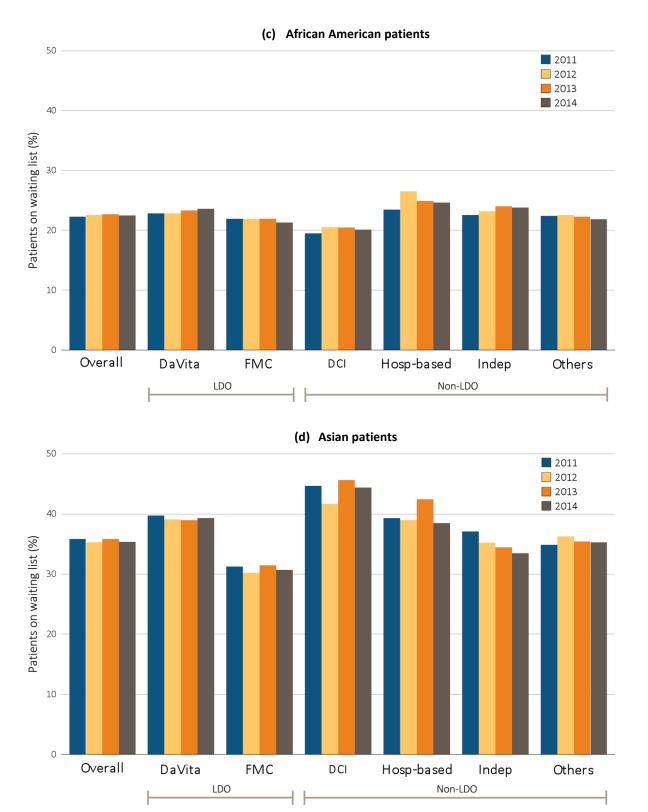
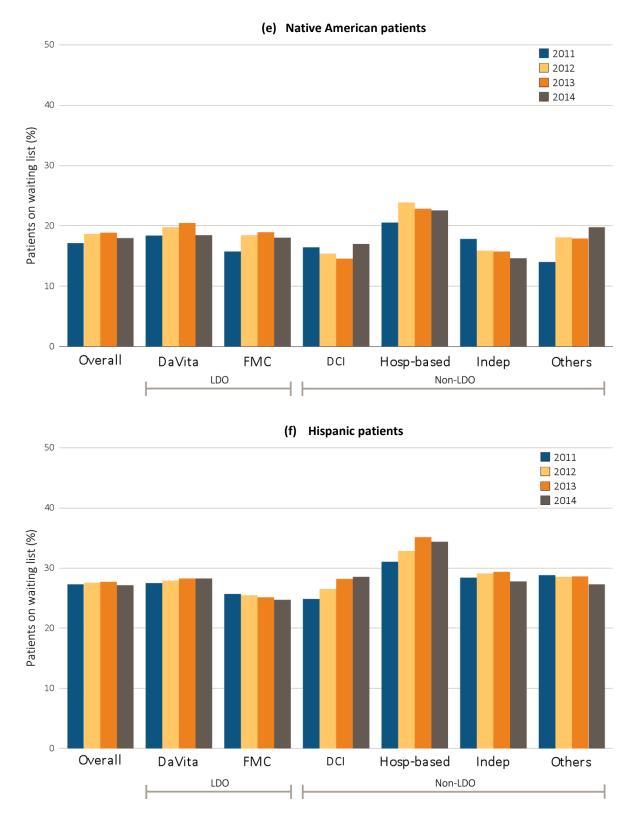


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vol 2 Figure 10.7 Percentage of patients younger than 70 on a kidney transplant waiting list, by unit affiliation, 2011–2014 (continued)



Data source: Special analyses, USRDS ESRD Database. Dialysis patients younger than 70 years on December 31. Abbreviations: Hospbased, hospital-based dialysis centers; Indep, independent dialysis providers; LDO, large dialysis organizations; Others, other dialysis organizations.

Standardized Measures of Clinical Outcomes

Standardized measures of the major clinical outcomes include the Standardized Mortality Ratio (SMR) and the Standardized Hospitalization Ratio (SHR). These measures were designed to compare the risk-adjusted mortality and hospitalization rates of each provider or organization to the overall mortality and hospitalization of all U.S. dialysis patients. Specifically, the SMR and SHR are calculated as the ratio of two numbers: the numerator ("observed") is the actual number of events for the patients of a provider or organization over the specified period, and the denominator ("expected") is the number of events that would have been expected to occur for the same patients if they received care during the same reporting period from a provider or organization conforming to the national norm (e.g., 2011–2014). The degree to which the provider's SMR or SHR varies from 1.00 is the degree to which it exceeds (>1.00) or is less than (<1.00) the national rates for patients with

the same characteristics as those in that provider. For example, an SMR=1.10 would indicate that the provider's death rates exceed national death rates by 10%.

STANDARDIZED MORTALITY RATIOS

All provider types experienced substantial declines in SMRs between 2011 and 2014 (Table 10.1). During this time, Hispanic patients experienced smaller decreases in SMR compared with the overall population. For Hispanic patients, SMR fell 7% overall in the 4-year period, compared with 12% for all patients.

Compared with the overall dialysis population, the decrease in SMR between 2011 and 2014 was of greater magnitude in the White, Black/African American, and Native American cohorts (Table 10.1). Among Black patients, overall SMR decreased significantly for provider types, by 12%. Asian patients experienced an average decrease in SMR of 9%.

	Affiliati	tandardized	2011	2012	2013	2014
	Overall		1.08 (1.07-1.09)	1.00 (0.99-1.00)	0.98 (0.98-0.99)	0.96 (0.95-0.96
	LDO	DaVita	1.09 (1.08-1.10)	0.99 (0.98-1.01)	1.00 (0.99-1.01)	0.97 (0.96-0.98
		Fresenius	1.08 (1.07-1.10)	1.00 (0.99-1.01)	0.98 (0.97-0.99)	0.94 (0.93-0.95
All patients	DCI	Tresenius	0.99 (0.96-1.03)	0.95 (0.92-0.98)	0.92 (0.89-0.96)	0.88 (0.85-0.91
An putients	Hospital-based		1.03 (1.00-1.06)	0.96 (0.92-0.98)	0.97 (0.94-1.00)	0.90 (0.87-0.93
	Independent		1.11 (1.09-1.13)	1.02 (1.01-1.04)	1.00 (0.98-1.01)	0.98 (0.97-1.00
	Others		1.10 (1.08-1.12)	1.02 (1.00-1.04)	1.00 (0.98-1.01)	0.97 (0.96-0.99
	Overall		1.20 (1.19-1.21)	1.11 (1.10-1.12)	1.11 (1.10-1.12)	1.07 (1.06-1.08
	LDO	DaVita	1.22 (1.20-1.24)	1.11 (1.10-1.12)	1.12 (1.11-1.13)	1.09 (1.08-1.12
		Fresenius	1.21 (1.19-1.22)	1.11 (1.10-1.13)	1.10 (1.09-1.12)	1.06 (1.04-1.07
White	DCI	TTESETTUS	1.15 (1.10-1.20)	1.11 (1.06-1.16)	1.07 (1.03-1.12)	1.01 (0.97-1.06
patients	Hospital-based		1.13 (1.09-1.17)	1.04 (1.00-1.08)	1.11 (1.07-1.15)	1.00 (0.96-1.04
	Independent		1.13 (1.09-1.17)	1.14 (1.12-1.16)	1.12 (1.10-1.15)	1.09 (1.07-1.11
	Others		1.22 (1.19-1.24)	1.14 (1.12-1.10)	1.12 (1.10-1.13)	1.07 (1.05-1.09
	Overall		0.93 (0.92-0.94)	0.85 (0.84-0.86)	0.83 (0.82-0.84)	0.81 (0.80-0.82
	LDO	DaVita	0.92 (0.92-0.94)	0.83 (0.84-0.80)	0.84 (0.83-0.86)	0.81 (0.80-0.82
Divel / African	LDO		0.92 (0.90-0.94)			-
Black/African		Fresenius		0.84 (0.82-0.86)	0.82 (0.80-0.83)	0.77 (0.76-0.79
American	DCI		0.81 (0.76-0.86)	0.76 (0.72-0.81)	0.76 (0.72-0.81)	0.74 (0.70-0.79
patients	Hospital-based		0.93 (0.88-0.99)	0.93 (0.88-0.99)	0.81 (0.76-0.86)	0.82 (0.77-0.87
	Independent		0.99 (0.96-1.02)	0.88 (0.85-0.91)	0.83 (0.80-0.86)	0.86 (0.83-0.89
	Others		0.97 (0.94-1.01)	0.90 (0.87-0.93)	0.83 (0.81-0.86)	0.83 (0.81-0.86
	Overall	5 . Y	0.74 (0.72-0.77)	0.69 (0.66-0.71)	0.65 (0.63-0.67)	0.65 (0.64-0.67
	LDO	DaVita -	0.82 (0.77-0.87)	0.74 (0.70-0.78)	0.65 (0.61-0.68)	0.67 (0.63-0.7)
Asian		Fresenius	0.74 (0.70-0.78)	0.68 (0.65-0.72)	0.66 (0.62-0.70)	0.72 (0.68-0.7
patients	DCI		0.59 (0.44-0.78)	0.70 (0.53-0.90)	0.58 (0.44-0.75)	0.61 (0.47-0.79
	Hospital-based		0.82 (0.71-0.94)	0.59 (0.50-0.70)	0.65 (0.55-0.77)	0.65 (0.55-0.7
	Independent		0.76 (0.70-0.83)	0.76 (0.70-0.82)	0.70 (0.65-0.75)	0.65 (0.61-0.70
	Others		0.82 (0.75-0.89)	0.71 (0.65-0.77)	0.71 (0.66-0.76)	0.70 (0.66-0.7)
	Overall		0.93 (0.88-0.99)	0.87 (0.82-0.93)	0.80 (0.75-0.85)	0.82 (0.77-0.87
	LDO	DaVita	0.89 (0.80-0.98)	0.81 (0.73-0.90)	0.72 (0.65-0.81)	0.78 (0.70-0.80
Native		Fresenius	1.15 (1.02-1.29)	1.13 (1.00-1.26)	0.80 (0.69-0.92)	0.83 (0.73-0.95
American	DCI		0.80 (0.60-1.05)	0.75 (0.57-0.97)	0.79 (0.61-1.02)	0.67 (0.51-0.86
patients	Hospital-based		0.88 (0.70-1.08)	0.79 (0.64-0.97)	0.76 (0.61-0.94)	0.69 (0.55-0.8
	Independent		1.04 (0.90-1.21)	0.70 (0.61-0.81)	0.84 (0.74-0.96)	0.87 (0.77-0.98
	Others		0.64 (0.52-0.77)	1.24 (1.01-1.51)	0.92 (0.72-1.16)	1.21 (0.99-1.46
	Overall		0.82 (0.80-0.83)	0.79 (0.78-0.80)	0.76 (0.75-0.77)	0.75 (0.74-0.7
	LDO	DaVita	0.80 (0.77-0.82)	0.76 (0.73-0.78)	0.76 (0.74-0.78)	0.75 (0.73-0.7
Hispanis		Fresenius	0.84 (0.81-0.86)	0.79 (0.77-0.81)	0.74 (0.72-0.77)	0.75 (0.73-0.7
Hispanic nationts	DCI		0.69 (0.58-0.82)	0.82 (0.70-0.95)	0.80 (0.68-0.93)	0.73 (0.63-0.84
patients	Hospital-based		0.88 (0.80-0.96)	0.78 (0.71-0.86)	0.71 (0.63-0.78)	0.68 (0.61-0.75
	Independent		0.84 (0.80-0.88)	0.89 (0.86-0.93)	0.86 (0.82-0.90)	0.78 (0.75-0.81
	Others		0.88 (0.84-0.92)	0.82 (0.79-0.86)	0.81 (0.77-0.84)	0.77 (0.74-0.80

Data source: Special analyses, USRDS ESRD Database. Period prevalent dialysis patients; 95% confidence intervals are shown in parentheses. The overall measure is adjusted for patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence, and population death rates. The race-specific measures are adjusted for all the above characteristics except patient race. The Hispanic-specific measure is adjusted for all the above characteristics concept patient ethnicity. Abbreviations: DCI, Dialysis Clinic, Inc.; LDO, large dialysis organizations; Others, other dialysis organizations.

Table 10.1 presents data with which to compare a dialysis unit's performance on the SMR across multiple years. Table 10.2 provides an alternate perspective for 2014 only. This second example is

designed to provide a simpler and more direct comparison of a given provider type to other providers and to the national value in a single year.

Affiliation	All (National Average)	White	Black/African American	Asian	Native American	Hispanic
Overall	1.00 (0.99-1.01)	1.12 (1.11-1.13)	0.85 (0.84-0.86)	0.70 (0.68-0.72)	0.86 (0.81-0.91)	0.79 (0.77-0.80)
LDOs						
DaVita	1.02 (1.01-1.03)	1.14 (1.13-1.16)	0.85 (0.83-0.86)	0.71 (0.67-0.75)	0.82 (0.74-0.90)	0.79 (0.77-0.81)
Fresenius	0.98 (0.97-0.99)	1.10 (1.09-1.12)	0.81 (0.79-0.82)	0.77 (0.73-0.82)	0.88 (0.76-1.00)	0.79 (0.77-0.81)
DCI	0.92 (0.89-0.95)	1.06 (1.01-1.10)	0.78 (0.73-0.82)	0.66 (0.51-0.84)	0.70 (0.54-0.90)	0.77 (0.66-0.89)
Hospital-based	0.94 (0.91-0.97)	1.04 (1.00-1.08)	0.86 (0.80-0.91)	0.69 (0.58-0.81)	0.72 (0.58-0.89)	0.71 (0.63-0.79)
Independent	1.03 (1.01-1.04)	1.14 (1.11-1.16)	0.90 (0.87-0.93)	0.70 (0.65-0.75)	0.92 (0.81-1.03)	0.82 (0.78-0.85)
Others	1.02 (1.00-1.04)	1.12 (1.09-1.14)	0.87 (0.84-0.90)	0.75 (0.70-0.80)	1.27 (1.05-1.54)	0.81 (0.78-0.85)

vol 2 Table 10.2 All-cause Standardized Mortality Ratio, by unit affiliation, 2014

Data source: Special analyses, USRDS ESRD Database. Period prevalent dialysis patients; 95% confidence intervals are shown in parentheses. The overall measure is adjusted for patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence, and population death rates. The race-specific measures are adjusted for all the above characteristics except patient race. The Hispanic-specific measure is adjusted for all the above characteristics. DCI, Dialysis Clinic, Inc.; LDO, large dialysis organizations; Others, other dialysis organizations.

Standardized Hospitalization Ratios

All types of providers experienced relatively flat change trends in SHRs between 2011 and 2014 (Table 10.3). Hospital-based dialysis providers exhibited the lowest SHR, at 0.92. In 2014 only, units owned by DaVita had the highest SHRs at 1.03 (Table 10.4). For patients overall, the SHRs remained the same at 1.00 between 2011 and 2014. Patients of White and Black race experienced SHR to a similar degree as those in the overall population (Table 10.3).

CHAPTER 10: DIALYSIS PROVIDERS

	Affiliati	on	2011	2012	2013	2014
	Overall		1.00 (1.00-1.00)	0.99 (0.99-1.00)	1.01 (1.00-1.01)	1.00 (1.00-1.00
	LDO	DaVita	0.99 (0.99-1.00)	0.99 (0.99-0.99)	1.03 (1.02-1.03)	1.03 (1.03-1.03
		Fresenius	0.98 (0.98-0.99)	0.97 (0.97-0.98)	0.99 (0.99-0.99)	0.96 (0.96-0.9
All patients	DCI		0.92 (0.91-0.93)	0.88 (0.88-0.89)	0.93 (0.92-0.93)	0.93 (0.92-0.94
	Hospital-based		0.95 (0.94-0.95)	0.97 (0.97-0.98)	0.92 (0.92-0.93)	0.92 (0.92-0.9
	Independent		1.03 (1.03-1.04)	1.04 (1.03-1.04)	1.00 (0.99-1.00)	0.99 (0.98-0.9
	Others		1.01 (1.01-1.02)	1.00 (0.99-1.00)	0.99 (0.98-0.99)	1.01 (1.00-1.0
	Overall		1.01 (1.01-1.01)	1.02 (1.01-1.02)	1.03 (1.03-1.03)	1.02 (1.02-1.0
	LDO	DaVita	1.02 (1.02-1.03)	1.02 (1.01-1.02)	1.05 (1.05-1.05)	1.05 (1.05-1.0
14/6:40		Fresenius	1.01 (1.01-1.02)	1.01 (1.00-1.01)	1.03 (1.03-1.03)	0.99 (0.99-1.0
White	DCI		0.97 (0.96-0.98)	0.95 (0.94-0.96)	0.97 (0.96-0.98)	0.99 (0.98-1.0
patients	Hospital-based		0.90 (0.89-0.91)	0.94 (0.93-0.95)	0.93 (0.92-0.94)	0.91 (0.90-0.9
	Independent		1.03 (1.03-1.04)	1.05 (1.05-1.06)	1.01 (1.01-1.02)	0.99 (0.98-0.9
	Others		0.99 (0.99-1.00)	0.99 (0.99-1.00)	1.01 (1.00-1.01)	1.02 (1.01-1.0
	Overall		1.01 (1.00-1.01)	1.00 (1.00-1.00)	1.00 (1.00-1.00)	1.00 (1.00-1.0
	LDO	DaVita	0.99 (0.98-0.99)	0.99 (0.99-1.00)	1.02 (1.02-1.03)	1.04 (1.03-1.0
Black/African		Fresenius	0.96 (0.96-0.96)	0.96 (0.96-0.96)	0.96 (0.95-0.96)	0.93 (0.93-0.9
American	DCI		0.87 (0.86-0.89)	0.84 (0.83-0.86)	0.91 (0.90-0.92)	0.91 (0.90-0.9
patients	Hospital-based		1.10 (1.08-1.11)	1.13 (1.11-1.14)	0.97 (0.96-0.98)	0.99 (0.98-1.0
	Independent		1.07 (1.06-1.07)	1.05 (1.05-1.06)	1.02 (1.01-1.02)	1.03 (1.02-1.0
	Others		1.10 (1.09-1.11)	1.05 (1.04-1.06)	0.99 (0.99-1.00)	1.02 (1.02-1.0
	Overall		0.76 (0.75-0.77)	0.72 (0.72-0.73)	0.75 (0.75-0.76)	0.76 (0.75-0.7
	LDO	DaVita	0.71 (0.70-0.72)	0.71 (0.70-0.72)	0.74 (0.73-0.75)	0.74 (0.73-0.7
		Fresenius	0.75 (0.74-0.77)	0.70 (0.69-0.71)	0.78 (0.77-0.79)	0.73 (0.72-0.7
Asian	DCI		1.07 (1.01-1.12)	0.74 (0.69-0.79)	0.69 (0.65-0.74)	0.68 (0.64-0.7
patients	Hospital-based		0.58 (0.55-0.61)	0.58 (0.55-0.62)	0.68 (0.65-0.71)	0.60 (0.57-0.6
	Independent		0.86 (0.85-0.88)	0.80 (0.79-0.82)	0.76 (0.75-0.78)	0.82 (0.81-0.8
	Others		0.72 (0.70-0.74)	0.66 (0.65-0.68)	0.67 (0.66-0.68)	0.71 (0.70-0.7
	Overall		0.80 (0.78-0.81)	0.73 (0.71-0.74)	0.78 (0.77-0.79)	0.75 (0.74-0.7
	LDO	DaVita	0.77 (0.75-0.79)	0.71 (0.69-0.73)	0.83 (0.82-0.85)	0.71 (0.69-0.7
Native		Fresenius	0.96 (0.93-0.98)	0.74 (0.71-0.76)	0.73 (0.71-0.75)	0.84 (0.82-0.8
American	DCI		0.69 (0.65-0.74)	0.47 (0.43-0.52)	0.72 (0.68-0.76)	0.48 (0.44-0.5
patients	Hospital-based		0.90 (0.86-0.94)	0.84 (0.81-0.89)	0.89 (0.85-0.93)	0.95 (0.91-0.9
•	Independent		0.69 (0.66-0.72)	0.66 (0.64-0.69)	0.70 (0.67-0.72)	0.64 (0.61-0.6
	Others		0.60 (0.58-0.63)	0.86 (0.81-0.91)	0.78 (0.74-0.82)	0.91 (0.86-0.9
	Overall		0.89 (0.88-0.89)	0.89 (0.89-0.89)	0.89 (0.88-0.89)	0.90 (0.90-0.9
	LDO	DaVita	0.88 (0.87-0.88)	0.87 (0.86-0.87)	0.90 (0.90-0.91)	0.90 (0.90-0.9
		Fresenius	0.84 (0.83-0.85)	0.86 (0.85-0.87)	0.84 (0.83-0.84)	0.83 (0.82-0.8
Hispanic	DCI	i i cocinuo	0.84 (0.81-0.87)	0.85 (0.82-0.88)	0.83 (0.80-0.86)	0.97 (0.94-1.0
patients	Hospital-based		0.85 (0.83-0.88)	0.87 (0.85-0.89)	0.82 (0.80-0.80)	1.00 (0.98-1.0
	Independent		1.05 (1.04-1.06)	1.00 (0.99-1.01)	0.96 (0.96-0.97)	0.97 (0.96-0.9
	Others		0.83 (0.82-0.84)	0.83 (0.82-0.84)	0.85 (0.84-0.86)	0.89 (0.88-0.9)

Data source: Special analyses, USRDS ESRD Database. Period prevalent dialysis patients with Medicare as primary payer; 95% confidence intervals are shown in parentheses. Adjusted for patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, and body mass index (BMI) at incidence. The race-specific measures are adjusted for all the above characteristics except patient ethnicity. Abbreviations: DCI, Dialysis Clinic, Inc.; LDO, large dialysis organizations; Others, other dialysis organizations.

Similar to the SMR presentation, Table 10.4 displays the 2014-only SHR, which is constructed to provide a simpler and more direct comparison of a given provider type to the national value in a given year, versus comparing a provider type's performance on the SHR across years, as Table 10.3 is designed to facilitate.

vol 2 Table 10.4 All-cause standardized hospitalization ratio, by unit affiliation, 2014

Affiliation	All (National Average)	White	Black/African American	Asian	Native American	Hispanic
Overall	1.00 (1.00-1.00)	1.02 (1.02-1.02)	1.00 (1.00-1.01)	0.76 (0.75-0.77)	0.75 (0.74-0.77)	0.91 (0.90-0.91)
LDO						
DaVita	1.03 (1.03-1.03)	1.05 (1.05-1.05)	1.04 (1.03-1.04)	0.74 (0.73-0.76)	0.71 (0.69-0.73)	0.91 (0.90-0.92)
Fresenius	0.96 (0.96-0.96)	0.99 (0.99-0.99)	0.93 (0.93-0.94)	0.73 (0.72-0.74)	0.85 (0.82-0.87)	0.83 (0.83-0.84)
DCI	0.93 (0.93-0.94)	0.99 (0.98-1.00)	0.91 (0.90-0.92)	0.68 (0.64-0.72)	0.48 (0.44-0.52)	0.97 (0.94-1.00)
Hospital- based	0.93 (0.92-0.93)	0.91 (0.90-0.92)	1.00 (0.98-1.01)	0.61 (0.57-0.64)	0.95 (0.91-1.00)	1.01 (0.98-1.03)
Independent	0.99 (0.98-0.99)	0.99 (0.98-0.99)	1.03 (1.02-1.03)	0.83 (0.81-0.84)	0.64 (0.61-0.66)	0.98 (0.97-0.99)
Others	1.01 (1.00-1.01)	1.02 (1.01-1.02)	1.02 (1.02-1.03)	0.72 (0.70-0.73)	0.91 (0.86-0.96)	0.89 (0.88-0.90)

Data source: Special analyses, USRDS ESRD Database. Period prevalent dialysis patients with Medicare as primary payer; 95% confidence intervals are shown in parentheses. Adjusted for patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, and body mass index (BMI) at incidence. The race-specific measures are adjusted for all the above characteristics except patient race. The Hispanic-specific measure is adjusted for all the above characteristics except patient race. In the Hispanic ethnicity. Abbreviations: DCI, Dialysis Clinic, Inc.; LDO, large dialysis organizations; Others, other dialysis organizations.

References

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Notes



Chapter 11:

Medicare Expenditures for Persons With ESRD

- Between 2013 and 2014 Medicare fee-for-service spending for beneficiaries with end-stage renal disease (ESRD) rose by 3.3%, from 31.8 billion to 32.8 billion, accounting for 7.2% of the overall Medicare paid claims costs (Figure 11.2). This marks the fourth year of modest growth relative to historical trends, and follows the 2011 implementation of the bundled payment system.
- In keeping with the increase in global expenditures for ESRD patients, total fee-for-service spending in the general Medicare population increased by 3.8% in 2014, to \$453.6 billion (Figure 11.2).
- In 2014, ESRD spending per patient per year (PPPY) increased by 0.3% (Figure 11.4). Given that ESRD PPPY spending either decreased or increased only slightly from 2009 to 2014, the rise in Medicare expenditures for beneficiaries with ESRD during these years is almost entirely attributable to growth in the number of covered lives.
- For hemodialysis (HD) care, both total and PPPY spending were nearly flat between 2013 (\$25.5 billion and \$87,482; Figure 11.7) and 2014 (\$26.1 billion and \$87.638, Figure 11.8). During this period, total peritoneal dialysis (PD) spending grew by 8.8%, as the share of patients receiving PD continued to rise. PD PPPY spending remained consistent between 2013 and 2014, however, and PD remained less costly on a per patient basis than HD. Finally, total and PPPY transplant spending has also increased by 3.6%. Total spending for transplant patients increased from \$2.9 billion to \$3.1 billion, and per capita spending increased from \$27,325 to \$32,586.

Introduction

The Medicare program for the elderly was enacted in 1965. Seven years later, in 1972, Medicare eligibility was extended both to disabled persons aged 18 to 64 and to persons with irreversible kidney failure who required dialysis or transplantation. When Medicare eligibility was first extended to beneficiaries with ESRD, only about 10,000 were receiving dialysis (Rettig, 2011); this patient group grew to 399,455 by 2014. Even though the ESRD population remained at less than 1% of the total Medicare population, it has accounted for about 7% of Medicare fee-for-service spending in recent years (Figure 11.2).

On January 1, 2011, The Centers for Medicare and Medicaid Services (CMS) implemented the ESRD Prospective Payment System (PPS). This program bundled Medicare's payment for renal dialysis services together with separately billable ESRD-related supplies (primarily erythropoiesis stimulating agents (ESAs), vitamin D, and iron) into a single, per treatment payment amount. The bundle payment supports up to three dialysis treatments per individual per week, with additional treatments covered on the basis of medical necessity. The reimbursement to facilities is the same regardless of dialysis modality, but is adjusted for case-mix, geographic area health care wages, and facility size. Early research linked the PPS with substantial declines in the utilization of expensive injectable medications and increased use of in-home PD by generally healthier patients (Hirth et al., 2013; Civic Impulse, 2013).

Most of the savings from these changes have accrued to dialysis facilities, as CMS initially set the bundled payment rate at 98% of what spending would have been under the costlier utilization patterns observed prior to the PPS. In the American Taxpayer Relief Act of 2012, Congress authorized CMS to "re-

base" the PPS bundled payment rate by an inflationadjusted decrease of 9%. Re-basing the bundled payment rate would transfer the savings from dialysis facilities to Medicare and, ultimately, to taxpayers. Before the bundled payment rate reduction could be fully implemented, however, the Protecting Access to Medicare Act of 2014 required that it be phased in by limiting annual adjustments to the bundled payment rate. That legislation also delayed CMS's plans to include more oral medications (primarily phosphate binders) in the bundle in 2016, to no sooner than 2024.

This chapter presents recent patterns and longerterm trends in both total Medicare spending and spending by type of service. Data from 2014 is featured, the fourth full year under the expanded, bundled PPS.¹

Methods

This chapter uses multiple data sources, including data from the Centers for Medicare & Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the United States Census. Details of data sources are described in the *Data Sources* section of the *ESRD Analytical Methods* chapter.

Aggregate costs of ESRD presented in this report include only those ESRD beneficiaries covered by original Medicare (fee-for-service) for their Medicare Parts A and B benefits. Medicare expenditures can be calculated from the claims submitted for payment for health care provided to these individuals, but not for those enrolled in Medicare Advantage (managed care) plans. The Medicare program pays for services provided through Medicare Advantage plans on a riskadjusted, per-capita basis, and not by specific claims for services. Methods of estimating Medicare expenditures for Medicare Advantage beneficiaries with ESRD will be explored for future ADRs.

Only a subset of ESRD patients is eligible to participate in a Medicare Advantage plan. If a person becomes eligible for Medicare solely due to ESRD, they are generally not permitted to enroll in a Medicare Advantage plan and must use fee-for-service Medicare. Current Medicare beneficiaries who develop ESRD are allowed to remain in their Medicare Advantage plan, but with few exceptions, cannot switch to a Medicare Advantage plan if they were enrolled in fee-for-service Medicare at the time of ESRD onset.

Those who become newly entitled to Medicare due to ESRD and require dialysis experience a threemonth waiting period before Medicare coverage begins; an exception is for those initiating home dialysis training, where coverage may start as early as the first month of dialysis. If the new ESRD patient has private insurance through an employer or union, there are rules governing what Medicare will pay. During the first 30 months after the start of Medicare eligibility due to ESRD, the private insurance will be considered the primary payer of ESRD services. Medicare acts as the secondary payer and may reimburse some services not covered by the private insurance carrier. At month 31 the roles are reversed, and Medicare becomes the primary payer with the private insurance designated the secondary payer. Medicare becomes primary at any time if the person loses private coverage.

Additionally, Medicare eligibility based solely on ESRD ends for those ESRD patients who receive a kidney transplant or discontinue dialysis. Medicare coverage ends 12 months after the last dialysis treatment and 36 months after a successful transplant. However, if a transplant recipient also qualifies for disability or is over the age of 65 then Medicare entitlement will continue. If a transplant fails and the recipient returns to dialysis, Medicare eligibility is reinstated.

In this chapter, data from both the Medicare Enrollment Database (EDB) and dialysis claims information are used to categorize payer status as Medicare primary payer (MPP), Medicare secondary payer (MSP), or non-Medicare. Non-Medicare patients

¹ The reader may find information on Medicare Health Maintenance Organizations (HMO; managed care), and private insurer spending through 2011 in the 2013 Annual Data Report (USRDS, 2013).

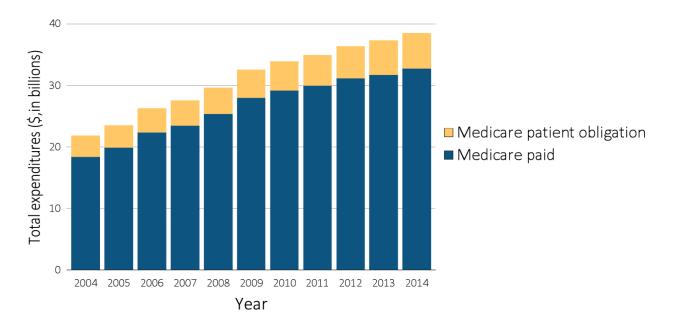
in the EDB include those who are pre- or post-Medicare entitlement, such as patients in the initial three-month waiting period.

A more accurate picture of total ESRD-related costs would take into account more than just expenditures by the Medicare program. It would include expenses such as those incurred by private insurance carriers when Medicare is the secondary payer, costs during the waiting period for initial Medicare coverage, and as provided by insurance carriers of people living with a functioning kidney transplant following the termination of Medicare coverage. It would also include the beneficiaries' portion of the cost-sharing with Medicare, including the Parts B and D premiums of those enrolled in Medicare solely due to ESRD, the beneficiary's deductible, and their co-insurance amounts for ESRD services. In 2014, the Part A and Part B deductibles were \$1,216 and \$147, respectively; the Part B premium was \$104.90 per month. Finally, indirect costs of care such as patient and care-giver

travel time and care-giver support for home dialysis would also be included in a comprehensive measure of costs associated with ESRD.

Overall & per Person per Year Costs of ESRD

Figure 11.1 displays Medicare's total annual paid claims for period prevalent ESRD patients from 2004-2014. These costs represent about three quarters of all spending for the care of U.S. ESRD patients (USRDS, 2013). Medicare fee-for-service ESRD spending rose by 3.3% from 2013 to 2014, marking the fourth year of modest growth relative to historical trends, and following the implementation of the bundled payment system. The Medicare patient obligation amount has also grown over the years in proportion to these paid claims. Patient obligations may be paid by the patient, by a secondary insurer, or may be uncollected. Overall, the patient obligation represented 14.8% of the total Medicare Allowable Payments in 2014.

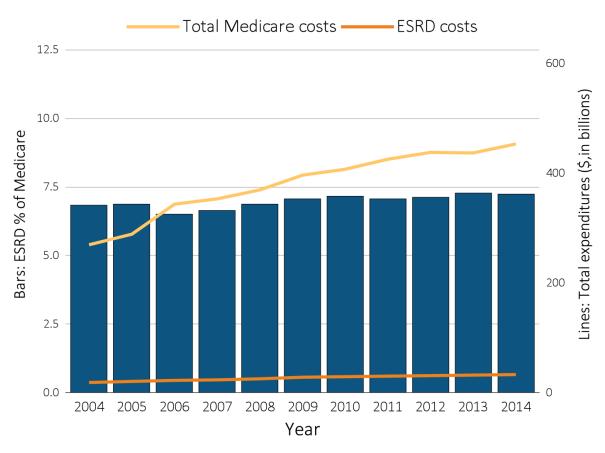




Data Source: USRDS ESRD Database; Reference Table K.1. Abbreviation: ESRD, end-stage renal disease.

As illustrated in Figure 11.2, total Medicare fee-forservice spending in the general Medicare population increased by 3.8% in 2014 to \$453.6 billion; the spending for ESRD patients of \$32.8 billion accounted for 7.2% of the overall Medicare paid claims costs in the fee-for-service system. Note that Medicare Advantage plans (private managed care) represented a larger share of general Medicare spending than did

ESRD. The share of all Medicare enrollees in these plans rose from 13% in 2004 to 30% in 2014 (Kaiser, 2016), while restrictions on new Medicare enrollment by beneficiaries with ESRD limited that growth in the ESRD population. This implies that the increasing fraction of Medicare fee-for-service spending accounted for by ESRD patients reflects both the growth in ESRD spending and the gradual shift away from fee-for-service in the general Medicare population.



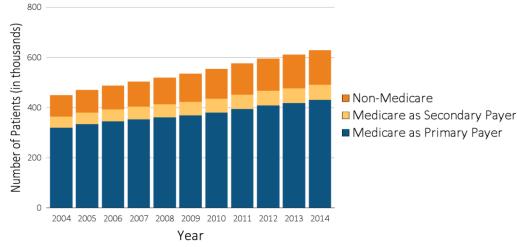
vol 2 Figure 11.2 Trends in costs of the Medicare & ESRD programs, 2004-2014

Data Source: Total ESRD costs obtained from USRDS ESRD Database; Reference Table K.1. Total Medicare expenditures obtained from Trustees Report, Table II.B1 <u>https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/TrusteesReports.html</u>. Abbreviation: ESRD, end-stage renal disease.

Funding Sources for the ESRD Population

Figure 11.3 illustrates the annual number of prevalent ESRD patients by their Medicare status. Data from the Medicare Enrollment Database (EDB) and dialysis claims information were used to categorize payer status as Medicare primary payer (MPP), Medicare secondary payer (MSP), or nonMedicare. Non-Medicare patients in the EDB included those who were pre- or post-Medicare entitlement. The number of ESRD patients with MPP grew by 3.1 % from 2013 (418,454) to 2014 (431,323). The MSP ESRD population increased by 1.6% from 2013 (59,717) to 2014 (60,643), while the non-Medicare ESRD population rose 2.6 %, to 136,948.





Data Source: USRDS ESRD Database. December 31 point prevalent ESRD patients. Abbreviation: ESRD, end-stage renal disease.

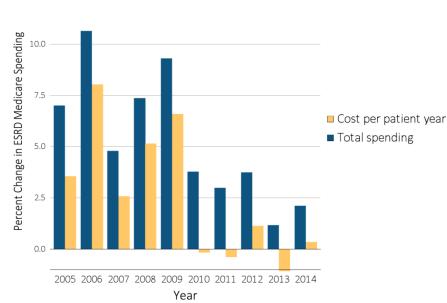
Figure 11.4 displays the annual percent change in Medicare ESRD fee-for-service spending for all ESRD patients for whom Medicare is the primary payer. Part D costs are included in these measures. However, as Part D is a voluntary component of the Medicare program, some recipients do not participate or have an alternate source of pharmaceutical coverage (e.g., from an employer) and would not have medication claims represented in the Part D records.

For the fifth consecutive year, the annual increase in total Medicare ESRD spending for beneficiaries

12.5

with primary payer status was less than 4%. In 2014, total Medicare paid claims for ESRD services and supplies increased by 2.1% to \$30.5 billion (see Figure 11.4; for total and specific values see Ref. Table K.4).

In 2014, ESRD PPPY spending increased by 0.3%. Given that these expenditures decreased or increased only minimally from 2009 to 2013, the growth in total ESRD costs during these years is almost entirely attributable to growth in the number of covered beneficiaries.



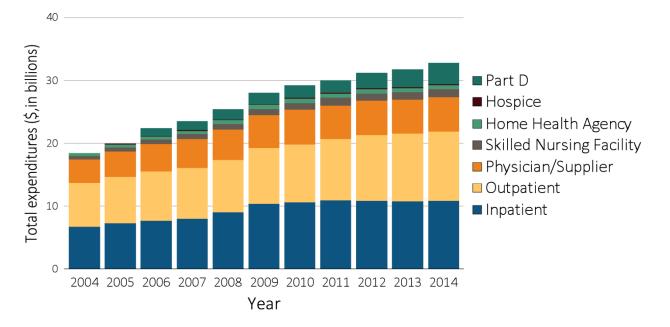
Data Source: USRDS ESRD Database; Reference Table K.4. Total Medicare ESRD costs from claims data; includes all claims with Medicare as primary payer only. Abbreviation: ESRD, end-stage renal disease.

vol 2 Figure 11.4 Annual percent change in Medicare ESRD spending, 2004-2014

Total Medicare fee-for-service spending for ESRD patients is reported by type of service in Figure 11.5. Compared to 2013, the costs of Part D claims and skilled nursing facility care in 2014 grew at the fastest rates of 21.0% and 5.5%, respectively. The increase in Part D (prescription drug) expenditures is consistent with drug cost trends nationally (CMS, 2016).All other

categories of spending rose by less than 3%. The smallest share of Medicare spending for ESRD patients was for hospice care. It should be noted, however, that prior to 2013 hospice care had been experiencing one of the highest rates of growth of any category; this spending declined by 6.3% in 2014.

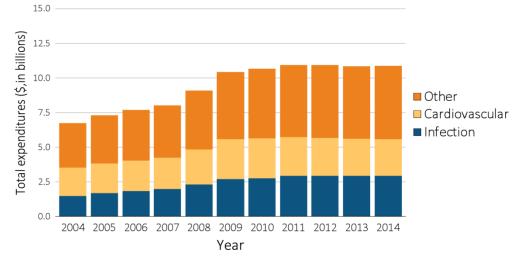




Data Source: USRDS ESRD Database; Reference Table K.1. Total Medicare costs from claims data. Abbreviation: ESRD, end-stage renal disease.

Of 2014 spending on inpatient hospitalization for those with ESRD, 27.1% resulted from admissions to treat infections and 24.5% for those to treat cardiovascular conditions (Figure 11.6).

vol 2 Figure 11.6: Total Medicare fee-for-service inpatient spending by cause of hospitalization, 2004-2014

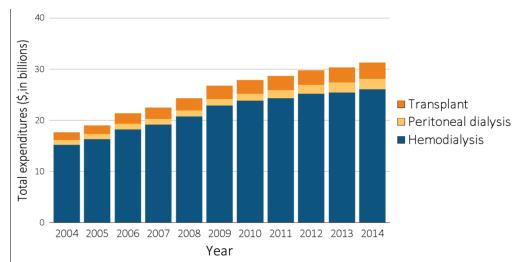


Data Source: USRDS ESRD Database. Total Medicare costs from claims data. Abbreviation: ESRD, end-stage renal disease. Unknown hospitalization cost (<0.01%) was combined with 'Other'.

ESRD Spending by Modality

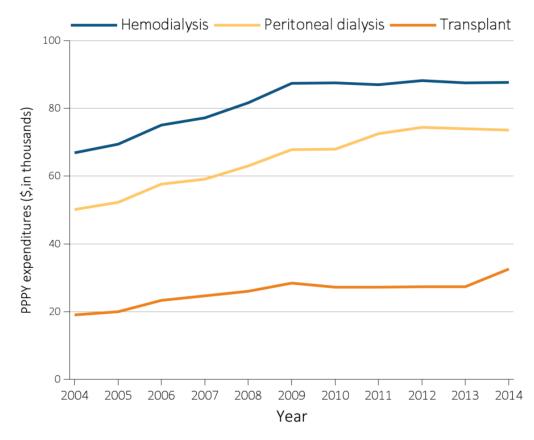
For patients receiving hemodialysis, both total and PPPY fee-for-service spending were nearly flat between 2013 and 2014 (Figures 11.7 and 11.8; total spending includes costs for beneficiaries with Medicare as either primary or secondary payer, and PPPY includes only beneficiaries with Medicare as primary payer). Peritoneal dialysis total spending increased by 8.0% between 2013 and 2014, as the share of patients receiving PD continued to rise. PD growth on a PPPY basis declined slightly between 2013 and 2014 (-0.6%), however, and PD remained less costly on a per patient basis in 2014 (\$73,612) than HD (\$87,638). Finally, transplant spending in 2014 increased from 2013 levels by 28.3% in total and 19.3% PPPY. In 2014 the PPPY cost for transplant patients, \$32,586, remained far lower than spending for either dialysis modality.

vol 2 Figure 11.7 Total Medicare ESRD expenditures, by modality, 2004-2014



Data Source: USRDS ESRD Database. Total Medicare costs from claims data for period prevalent ESRD patients. Abbreviation: ESRD, end-stage renal disease.





Data Source: USRDS ESRD Database; Reference Tables K.7, K.8, & K.9.Period prevalent ESRD patients; includes all claims with Medicare as primary payer only. Abbreviation: ESRD, end-stage renal disease.

Conclusion

While Medicare expenditures for beneficiaries with ESRD continued to grow through 2014 and accounted for a disproportionate share of overall Medicare spending, costs on a per patient year basis have changed only modestly in recent years. Therefore, the overall growth primarily reflects an increase in the number of patients and treated-patient years. Total inpatient spending grew rapidly from 2004 until 2009, followed by slower growth from 2009 until 2011, and has remained quite stable since 2011.

CHAPTER 11: MEDICARE EXPENDITURES FOR PERSONS WITH ESRD

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Notes



Chapter 12: Part D Prescription Drug Coverage in Patients With ESRD

- In this year's Annual Data Report (ADR) we focus on beneficiary data from 2014. The per patient per year (PPPY) Medicare Part D spending for those with end-stage renal disease (ESRD) (\$8,420) was three times higher than for the population of all general Medicare beneficiaries (\$2,830). Hemodialysis (HD) patients had the highest PPPY Medicare Part D spending, at \$9,089, compared to \$8,188 and \$6,284 for those receiving peritoneal dialysis and kidney transplant (Figure 12.5a).
- Among beneficiaries with Part D enrollment, a higher proportion of those treated with HD (66%), peritoneal dialysis (PD; 55%), and kidney transplant (52%) receive the Low-income Subsidy (LIS) than in the overall general Medicare population (31%; Figure 12.1).
- Across general Medicare and ESRD populations, PPPY Part D spending was 2.8-3.7 times greater for beneficiaries with LIS benefits than for those without. This difference reflects both higher utilization among those with LIS benefits and the higher share of spending covered by Medicare for LIS beneficiaries (Figure 12.5b).
- LIS beneficiaries' out-of-pocket costs represented only 1% of total Part D expenditures, compared to 27-30% in the non-LIS populations (Figure 12.5b).
- Phosphate-binding agents, β-adrenergic blocking agents, and opiate agonists were each prescribed to more than half of dialysis patients during 2014, and over one third of dialysis patients had at least one claim for HMG-CoA Reductase Inhibitors, dihydropyridines, and proton-pump inhibitors. Phosphate-binding agents ranked first in Medicare Part D spending, followed by cinacalcet, and insulins (Tables 12.6a and 12.6b).

Introduction

2016 will mark ten years of operation for the Medicare Part D prescription drug benefit. Over that time period, Part D has become an important component of Medicare as whole. Given the clinical and socioeconomic status of the ESRD population, this benefit has been particularly significant. Before this program began on January 1, 2006, some Medicare beneficiaries were able to obtain drug coverage through various private insurance plans, state Medicaid programs, or the Department of Veterans Affairs. Others received partial support through pharmaceutical-assistance programs or free samples available from their physicians. However, many beneficiaries with ESRD did not have reliable coverage, and incurred substantial out-of-pocket expenses for their medications. Given that very few ESRD beneficiaries are enrolled in Medicare Advantage plans that provide both medical and prescription coverage, most obtain Part D benefits through a stand-alone prescription drug plan (PDP).

Enrollment in Part D is not mandatory; non-Part D Medicare enrollees may choose to obtain outpatient medication benefits through other creditable coverage sources that provide benefits equivalent to or better than Part D. These include employer group health plans, retiree health plans, Veterans Administration benefits, and state kidney programs. Those without an alternative source of coverage pay for their prescriptions out-of-pocket. The proportion of Medicare-covered beneficiaries with ESRD who have no known source of drug coverage is highest in the PD and transplant populations. Given that more of these

patients are employed (relative to HD patients), it is likely that some have sources of prescription drug coverage not currently tracked by Medicare.

Beneficiaries dually-enrolled in Medicare and Medicaid are automatically eligible for Part D under the Low-income Subsidy (LIS) benefit. Non-Medicaid eligible beneficiaries can also qualify for the LIS based on limited assets and income. 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 coverage gap ("donut hole"). The LIS also provides assistance for the premiums, deductibles, and co-payments of the Medicare Part D program. Some Medicare enrollees are automatically deemed eligible for LIS and do not need to file an application (referred to as "deemed LIS beneficiaries"). Such beneficiaries include persons dually eligible for both Medicaid and Medicare, those receiving supplemental security income, and those participating in Medicare savings programs (e.g., Qualified Medicare Beneficiaries (QMB) and Qualified Individuals (QI)). Other Medicare beneficiaries with limited incomes and resources who do not automatically qualify for LIS (non-deemed beneficiaries) can apply for the LIS and have their eligibility determined by their state Medicaid agency or the Social Security Administration.

In 2014, 62% of Medicare-covered beneficiaries with ESRD enrolled in Part D received the LIS benefit, compared to 31% of the general Medicare Part D population. By modality, 66%, 55%, and 52% of enrolled HD, PD, and transplant patients qualified for the LIS. By race, White dialysis patients were the least likely to qualify for LIS benefits.

Phosphate-removing agents comprise the most common Part D medication class taken by dialysis patients (by percentage of beneficiaries with at least one prescription filled), while cardiovascular agents (β -adrenergic blocking agents, HMG-CoA reductase inhibitors, and dihydropyridines) account for three of the top five. The list of medications by total Medicare Part D spending¹ is topped by phosphate-removing agents and and cinacalcet.

In 2014, total estimated Medicare Part D expenditures for ESRD and general Medicare Part D enrollees were \$2.7 billion and \$58.1 billion. Between 2011 and 2014, total Part D spending increased by 63% and 91% for HD and PD patients, compared to 26% for general Medicare beneficiaries; for transplant patients, total Part D spending rose by 63%. In 2014, regardless of LIS status, Medicare Part D spending for HD, PD, and transplant patients averaged \$9,089, \$8,188, and \$6,284 PPPY, compared to only \$2,830 for general Medicare beneficiaries. Out-of-pocket Part D costs for beneficiaries with ESRD were slightly higher than for general Medicare beneficiaries, at \$441 versus \$423.

The Medicare Part D program functions in concert with Medicare Part B. Part B covers medications administered in physician offices, including some of those administered during hemodialysis (e.g. intravenous antibiotics that are not associated with dialysis-related infections), and most immunosuppressant medications required following a kidney transplant. Immunosuppression coverage continues as long as the transplant recipient maintains Medicare eligibility. Entitlement may end three years post-transplant or be continued due to disability or age. Beneficiaries whose kidney transplant is not covered by Medicare, but who become Medicare-eligible due to age or disability can enroll in and receive their immunosuppressant medications through Part D. Prescription drugs not covered for beneficiaries under Part B may be covered by Part D, depending upon whether the drug is included on the plan formulary. Until January 2011, costs of erythropoietin stimulating agents, IV vitamin D, iron, and antibiotic agents administered during dialysis were separately reimbursable under Medicare Part B. Since 2011, coverage for these products has been included in the monthly bundled payment to dialysis providers. Part B costs are thus not displayed

¹ In this chapter, Medicare Part D spending represents the sum of the Medicare covered amount and the Low- income Subsidy amount.

CHAPTER 12: PART D PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH ESRD

in chapter figures, as they have been in previous ADRs.

Part D Coverage Plans

CMS provides participating prescription drug plans (PDPs) with guidance on structuring a "standard" Part D PDP. The upper portion of Table 12.1 illustrates the standard benefit design for PDPs in 2009 and 2014. In 2014, for example, beneficiaries shared costs with the PDP through co-insurance or copayments until the combined total during the initial coverage period reached \$2,850. After reaching this threshold, beneficiaries entered a coverage gap, or "donut hole," where they were then required to pay 100% of their prescription costs.

In each year since 2010, the U.S. government has been providing increasing assistance to those reaching this coverage gap. In 2014, beneficiaries received a 52.5% discount on brand name medications from drug manufacturers, and Part D plans paid 28% of generic drug costs for those in the gap (Q1 Medicare, 2014). Beneficiaries who reached annual out-of-pocket drug costs of \$4,550 entered the catastrophic coverage phase, in which they then paid only a small copayment for any additional prescriptions until the end of that year (Table 12.1).

PDPs have the latitude to structure their plans differently from the example presented, but companies offering non-standard plans must demonstrate that their coverage is at least actuarially equivalent to the standard plan. Many have developed plans featuring 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 (Table 12.1; Q1 Medicare, 2014).

vol 2 Table 12.1 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	\$2.40	°\$2.55
Generic/preferred multi-source drug	\$6.00	²\$6.35
Other drugs		^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 <u>http://www.q1medicare.com/PartD-The-2014-Medicare-Part-D-Outlook.php</u>.

CHAPTER 12: PART D PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH ESRD

The share of beneficiaries with ESRD that enrolled in Part D increased annually between 2011 and 2014 (Table 12.2). Total enrollment was higher in the dialysis population, than in the general Medicare population, but the growth between 2011 and 2014 was somewhat slower among beneficiaries on dialysis. Both the level and trend in enrollment among beneficiaries with transplants mirrored that in the general Medicare population.

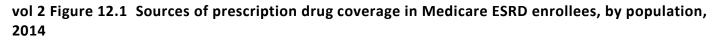
vol 2 Table 12.2 General Medicare & ESRD patients enrolled in Part D (%)

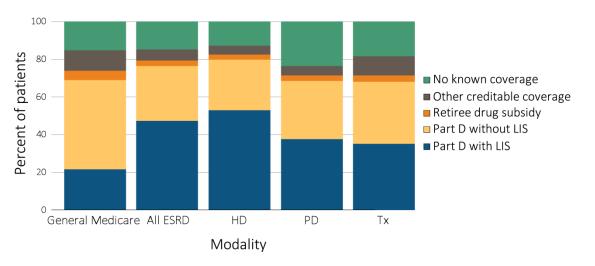
	General Medicare	All ESRD	Hemodialysis	Peritoneal dialysis	Transplant
2011	60	70	74	62	59
2012	62	72	76	64	62
2013	67	75	79	67	66
2014	69	77	80	69	68

Data source: 2011-2014 Medicare data, point prevalent Medicare enrollees alive on January 1. Medicare data: general Medicare, 5% Medicare sample (ESRD, hemodialysis, peritoneal dialysis, and transplant, 100% ESRD population). Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage.

Part D Enrollment Patterns

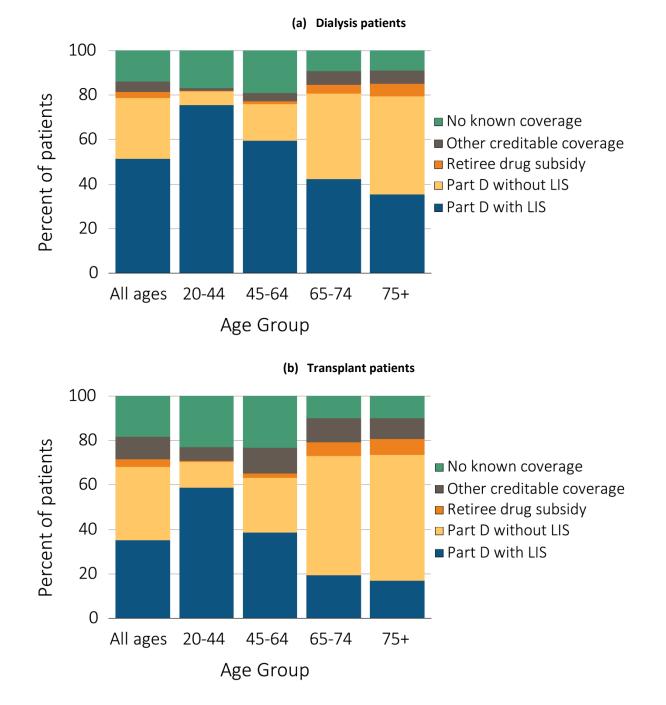
In 2014, 69% of the general Medicare population enrolled in a Medicare Part D prescription drug plan. Medicare-covered beneficiaries with ESRD exceed the Part D enrollment rate of the general Medicare population, with 77% participation. Enrollment varies by renal replacement modality: 80% of HD, 69% of PD, and 68% of kidney transplant patients enrolled in Part D. More HD, PD, and transplant patients with Part D receive the LIS—66%, 55%, and 52%, compared to 31% of the general Medicare population. About 15% of ESRD beneficiaries have no identified prescription drug coverage. By modality, PD and transplant patients are least likely to have known coverage (see Figure 12.1).





Data source: 2014 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; LIS, Low-income Subsidy; Part D, Medicare Part D prescription drug coverage; PD, peritoneal dialysis; Tx, kidney transplant.

Beneficiaries with ESRD obtain prescription drug coverage from a variety of sources, and the sources vary widely by age (Figure 12.2). Total enrollment from any known source varied modestly across age groups. However, receipt of the LIS decreased substantially with age in both populations. Finally, in each age category transplant patients are markedly less likely than those on dialysis to receive the LIS benefit.

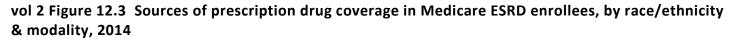


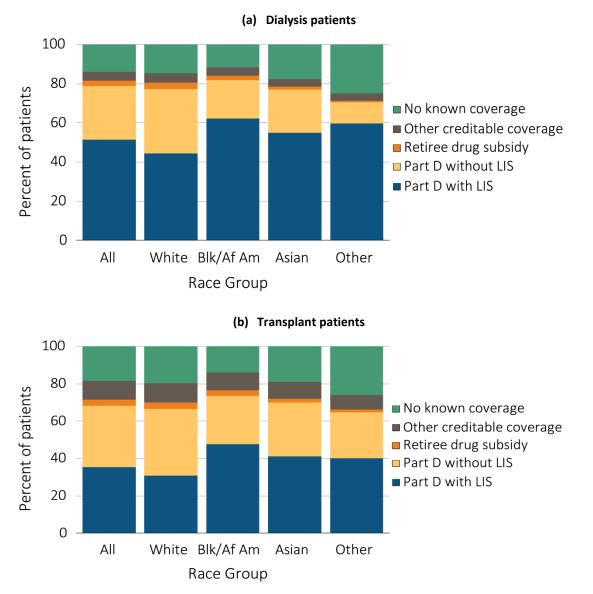
vol 2 Figure 12.2 Sources of prescription drug coverage in Medicare ESRD enrollees, by age & modality, 2014

Data source: 2014 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: ESRD, end-stage renal disease; LIS, Low-income Subsidy; Part D, Medicare Part D prescription drug coverage.

CHAPTER 12: PART D PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH ESRD

Overall, approximately 79% of dialysis patients were enrolled in Part D. A higher percentage of dialysis patients who identified as Black/African American enrolled in Part D (82%) compared to those who identified as White (77%) or Asian (77%; Figure 12.3a). Seventy-six percent of Blacks and 71% of Asians with Part D coverage qualified for the LIS benefit, compared to 58% of Whites; Blacks were the least likely to have no known prescription drug coverage. Sixty-eight percent of transplant patients enrolled in Part D. By race, 67% of Whites, 74% of Blacks, and 70% of Asian transplant patients enrolled. A larger share of Black (65%) and Asian (59%) transplant patients with Part D coverage have the LIS, compared to 46% of White transplant patients (Figure 12.3b).



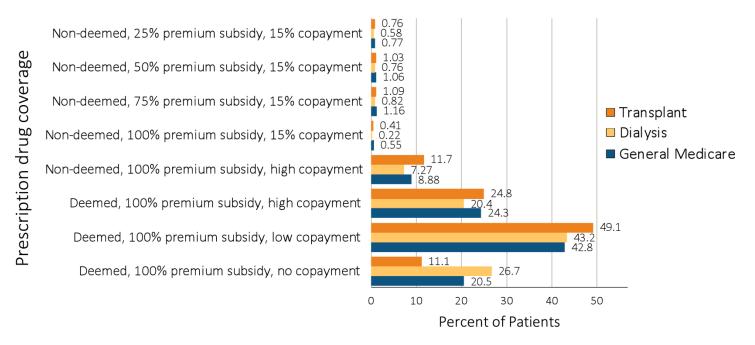


Data source: 2014 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: Blk/Af Am, Black or African American; ESRD, end-stage renal disease; LIS, Low-income Subsidy; Part D, Medicare Part D prescription drug coverage.

In 2014, 90% of dialysis patients with Part D LIS coverage were deemed LIS beneficiaries, compared to

85% and 88% of transplant and general Medicare beneficiaries (Figure 12.4).

vol 2 Figure 12.4 Distribution of Low-income Subsidy categories in Part D general Medicare & ESRD patients, 2014



Data source: 2014 Medicare data, point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage.

CHAPTER 12: PART D PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH ESRD

Within each racial category, the share of general Medicare beneficiaries who receive the LIS decreases with age but increases among those aged 75 and older (see Table 12.3). This increase in receipt of the LIS

among the oldest beneficiaries is not seen in the ESRD population, except among Asians (note that samples of Asian patients by age category are relatively small).

	General Medicare	All ESRD	Hemodialysis	Peritoneal dialysis	Transplant
White					
All ages	24.7	54.4	58.8	48.1	46.4
20-44	88.2	88.1	91.6	88.3	82.3
45-64	51.7	70.3	76.1	64.4	57.1
65-74	14.7	39.7	48.6	24.7	21.3
75+	19.0	34.1	37.5	17.5	18.0
Black/Africa	n				
American All ages	57.9	74.4	76.3	71.2	64.9
20-44	92.8	92.3	94.3	90.3	85.9
45-64	74.5	80.4	82.8	74.6	69.2
65-74	42.2	59.5	63.7	40.6	40.3
75+	49.7	59.5	61.2	36.1	39.1
Asian					
All ages	64.1	68.7	73.2	57.1	58.8
20-44	89.8	87.0	89.5	83.7	83.1
45-64	65.4	73.5	78.3	58.9	66.0
65-74	55.5	58.3	65.2	40.6	45.3
75+	71.3	66.9	70.7	54.0	41.2
Other race					
All ages	37.8	78.6	85.3	78.8	62.2
20-44	88.5	91.2	95.9	96.5	76.4
45-64	56.3	83.2	89.0	82.8	67.9
65-74	25.9	67.9	77.2	54.0	48.8
75+	38.1	66.5	75.0	37.5	40.4

Data source: 2014 Medicare data, point prevalent Medicare enrollees alive on January 1, 2014. Abbreviations: ESRD, end-stage renal disease; LIS, Low-income Subsidy; Part D, Medicare Part D prescription drug coverage.

Spending Under Stand-alone Part D Plans

In recent years, total Part D spending for beneficiaries with ESRD increased by 65%, from \$1.64 billion in 2011 to \$2.71 billion in 2014 (Table 12.4). These amounts do not include costs of medications subsumed under the ESRD prospective payment system (e.g. ESAs, IV vitamin D, and iron) or billed to Medicare Part B (e.g. immunosuppressants). Between 2011 and 2014, total estimated Part D spending increased by 63%, 91%, and 63% for HD, PD, and kidney transplant patients. These rates of increase far outpaced the 26% spending growth that occurred in the general Medicare population.

	General Medicare	All ESRD	Hemodialysis	Peritoneal dialysis	Transplant
2011	45.96	1.64	1.29	0.09	0.21
2012	40.08	2.00	1.59	0.12	0.23
2013	52.08	2.27	1.79	0.14	0.27
2014	58.07	2.71	2.10	0.17	0.35

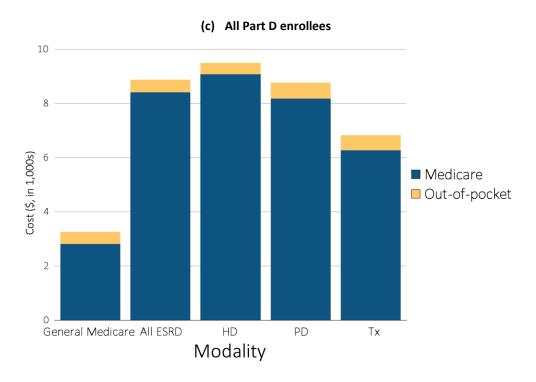
vol 2 Table 12.4 Total estimated Medicare Part D s	pending for enrollees	in billions. 2011-2014
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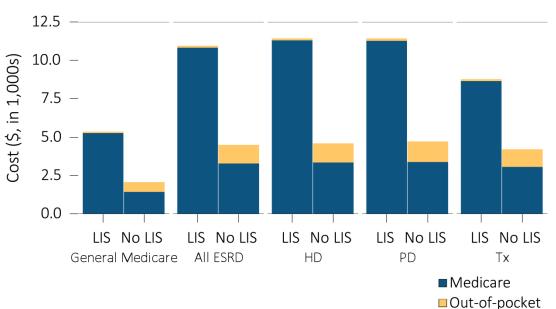
Data source: 2011-2014 Medicare data, period prevalent Medicare enrollees alive on January 1, excluding those in Medicare Advantage Part D plans and Medicare secondary payer, using as-treated model (see ESRD Methods chapter for analytical methods). Part D spending represents the sum of the Medicare covered amount and the Low- income Subsidy amount.

By ESRD modality, HD patients had the highest PPPY Medicare Part D spending at \$9,089, compared to \$8,188 for those with PD and \$6,284 for transplant patients. PPPY Part D spending was three times greater for beneficiaries with ESRD (\$8,420) than for general Medicare beneficiaries (\$2,830). As a proportion of total costs, however, out-of-pocket costs were lower for beneficiaries with ESRD, representing 4%, 7%, and 8% percent of PPPY costs for HD, PD, and transplant patients, compared to 13% in the general Medicare population (Figure 12.5a). A higher proportion of beneficiaries with ESRD received the LIS relative to the general Medicare population, which substantially reduced out-of-pocket obligations.

Across general Medicare and ESRD populations, PPPY Part D spending was 2.8-3.7 times greater for beneficiaries with LIS benefits than for those without. In the LIS population, however, out-of-pocket costs represented only 1% of total expenditures, compared to 27-30% among general Medicare and ESRD populations that did not receive the subsidy. PPPY Part D spending was 2.1 and 2.3 times greater for beneficiaries with ESRD than for general Medicare beneficiaries in the LIS and non-LIS populations (Figure 12.5b).

vol 2 Figure 12.5 Per person per year Medicare Part D spending & out-of-pocket costs for enrollees, 2014





(d) Part D enrollees by Low-income Subsidy status

Data source: 2014 Medicare data, period prevalent Medicare enrollees alive on January 1, 2014, excluding those in Medicare Advantage Part D plans and Medicare secondary payer, using as-treated model (see ESRD Methods chapter for analytical methods). Part D spending represents the sum of the Medicare covered amount and the Low- income Subsidy amount.

Total PPPY Medicare Part D spending varied by age, sex, and race (Table 12.5). Generally, younger beneficiaries aged 20-44 or 45-64, had

higher costs than older patients. Medicare Part D spending varied only modestly by sex and race.

vol 2 Table 12.5 Per person per year Part D spending (\$) for enrollees, by Low-income Subsidy status, 2014

	General Medicare		licare All ESRD		Hemod	Hemodialysis		Peritoneal dialysis		Transplant	
	Part D with LIS	Part D without LIS									
Age											
All	5,265	1,437	10,826	3,286	11,323	3,358	11,287	3,402	8,655	3,080	
20-44	5,341	2,104	11,386	2,640	12,908	3,464	11,564	2,780	6,902	1,551	
45-64	6,861	2,163	11,783	3,859	12,310	4,075	11,595	3,727	9,529	3,272	
65-74	4,457	1,371	9,728	3,474	9,957	3,560	9,434	3,577	9,016	3,274	
75+	4,026	1,331	7,826	2,643	8,075	2,653	7,021	2,877	6,905	2,632	
Sex											
Male	5,283	1,542	10,925	3,349	11,411	3,361	11,608	3,420	8,853	3,291	
Female	5,253	1,358	10,718	3,190	11,228	3,354	10,987	3,373	8,394	2,753	
Race											
White	5,461	1,436	10,510	3,318	11,056	3,405	11,416	3,487	8,499	3,084	
Black/African American	5,133	1,512	11,325	3,167	11,745	3,204	10,875	2,914	8,884	3,105	
Asian	4,523	1,220	11,105	3,369	11,523	3,537	12,539	3,523	9,086	2,996	
Other race	4,617	1,365	7,956	3,319	7,713	3,764	10,034	3,699	8,381	2,765	

Data source: 2014 Medicare data, period prevalent Medicare enrollees alive on January 1, 2014, excluding those in Medicare Advantage Part D plans and Medicare secondary payer, using as-treated model (see ESRD Methods chapter for analytical methods). Part D spending represents the sum of the Medicare covered amount and the Low- income Subsidy amount.

Prescription Drug Classes

The top 15 drug classes used by this population are ranked based on the percentage of beneficiaries with at least one claim for a drug within the class. Phosphate-binding agents were the most frequently prescribed Part D medication class in dialysis patients during 2014, and first as well in terms of Medicare Part D spending. Meanwhile, more than half of dialysis patients had at least one claim for β -adrenergic blocking agents and opiate agonists (Table 12.6). Cinacalcet and insulin were the second and third most costly classes of medications. Together, phosphatebinding agents and cinacalcet accounted for more than 50% of Part D spending (Table 12.7).

vol 2 Table 12.6 Top 15 drug classes received by Part D-enrolled dialysis patients, by percent of patients,
2014

Rank	Drug class	Percent of patients
1	Phosphate-binding Agents	72%
2	β-Adrenergic Blocking Agents	66%
3	Opiate Agonists	54%
4	HMG-CoA Reductase Inhibitors	47%
5	Dihydropyridines	46%
6	Proton-pump Inhibitors	42%
7	Insulins	32%
8	Cinacalcet	30%
9	Antidepressants	30%
10	Anticonvulsants	27%
11	Angiotensin-Converting Enzyme Inhibitors	27%
12	Direct Vasodilators	24%
13	Quinolones	22%
14	Central α-Agonists	19%
15	Platelet-aggregation Inhibitors	18%

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

Rank	Drug class	Medicare Part D spending (\$ in millions)	Percent of total Medicare Part D spending
1	Phosphate-binding Agents	\$840.53	37.0%
2	Cinacalcet	\$479.86	21.1%
3	Insulins	\$160.58	7.1%
4	HIV Antiretrovirals	\$72.73	3.2%
5	Nucleosides and Nucleotides	\$60.02	2.6%
6	Antineoplastic Agents	\$52.79	2.3%
7	Proton-pump Inhibitors	\$41.02	1.8%
8	HCV antivirals	\$37.50	1.7%
9	Opiate Agonists	\$30.54	1.3%
10	Vasodilating Agents	\$24.95	1.1%
11	Vasodilating Agents	\$22.57	1.0%
12	Anticonvulsants	\$21.25	0.9%
13	HMG-CoA Reductase Inhibitors	\$21.10	0.9%
14	Antipsychotics	\$20.14	0.9%
15	Corticosteroids	\$20.09	0.9%

Vol 2 Table 12.7 Top 15 drug classes received by Part D-enrolled dialysis patients, by spending, 2014

Data source: Medicare Part D claims. Dialysis 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.

References

Q1 Medicare. *The 2014 Medicare Part D Prescription Drug Program.* Website. Retrieved August 30, 2015 from <u>http://www.q1medicare.com/PartD-The-2014-Medicare-</u> <u>Part-D-Outlook.php</u>



Chapter 13: International Comparisons

- Taiwan, the Jalisco region of Mexico, and the U.S. continue to report the highest incidence of treated ESRD, at 455, 421, and 370 patients per million general population (PMP), as they have done for the past decade (Fig. 13.2).
- The greatest proportionate increases in the incidence of treated ESRD over the interval from 2001/02 to 2013/14 (Reference Table N.1) were reported for Thailand (1009%), Bangladesh (643%), Russia (291%), the Philippines (190%), Malaysia (162%), the Republic of Korea (101%), and the Jalisco region of Mexico (93%).
- Incidence rates of treated ESRD have remained relatively stable since 2001/02 in most high-income countries, and have declined by between 3 and 14% in Austria, Denmark, Iceland, Finland, Sweden, and Scotland (Ref. Table N.1).
- In 2014, diabetes mellitus was reported as the primary cause of ESRD for greater than 50% of incident treated ESRD patients in Singapore, Malaysia, and the Jalisco region of Mexico, but for less than 20% of incident ESRD patients in the Netherlands, Dutch-speaking Belgium, Norway, Estonia, Romania, and Iceland (Figure 13.4).
- The greatest increases in diabetes-related ESRD incidence rates from 2001/02 to 2013/14 have occurred in Thailand, Russia, the Philippines, Malaysia, the Republic of Korea, and the Jalisco region of Mexico, where rates have more than doubled over this time period (Reference Table N.2).
- The highest prevalence of treated ESRD in 2014 was reported for Taiwan, Japan, and the U.S. (3219, 2505, and 2076 PMP respectively, Figure 13.9).
- From 2001 to 2014 the prevalence of treated ESRD steadily increased in all countries with reported data. The largest proportionate increases in ESRD prevalence were in the Philippines, Thailand, and the Jalisco region of Mexico, ranging from 343% to 1092% (Reference Table N.4).
- Use of the different renal replacement therapies varies considerably across countries (Figure 13.12). Dialysis is the predominant therapeutic approach for treatment of ESRD in the majority of countries. In the majority of countries, in-center hemodialysis (HD) is utilized for greater than 80% of dialysis provision (Figure 13.15 and Reference Table N.7). The highest utilization of peritoneal dialysis (PD) among dialysis patients in 2014 was seen in Hong Kong (72%), the Jalisco region of Mexico (47%), Thailand (30%), New Zealand (31%), and Colombia (29%).
- In 2014, the percentage of ESRD patients living with a kidney transplant ranged from less than10% in some Asian and eastern European countries to 50–75% in the Nordic countries (Denmark, Finland, Iceland, Norway, and Sweden), Estonia, the Netherlands, the U.K. (including Scotland), Spain, Austria, and Qatar (Figure 13.12).
- In 2014, the highest rates of kidney transplantation were reported for the Jalisco region of Mexico, the Netherlands, Spain, and the U.S., with 56–60 kidney transplants PMP (Figure 13.16a). When expressed relative to the size of the prevalent dialysis population, the highest rates of kidney transplantation per 1000 dialysis patients occurred in Norway (205 per 1000), the Netherlands (154 per 1000), Finland (133 per 1000), and Scotland (126 per 1000), with 22% of countries indicating less than 20 kidney transplants per 1000 dialysis patients (Figure 13.16b).

Introduction

This chapter examines international trends in treatment of end-stage renal disease (ESRD). The number of countries and regions represented in this year's Annual Data Report has increased to 60 from 57 in last year's ADR, with the addition of Morocco, Montenegro, and Sri Lanka.

This work is made possible through the substantial efforts of many individuals from all participating

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countries in collecting and contributing data for this international collaboration. We sincerely thank all of the registries and providers for their efforts, and have included a list of participants at the end of this chapter to further acknowledge their contributions. The information we provide is intended to serve as a resource for the worldwide ESRD community, to inform health care policies, patient care, and application of resources, while stimulating meaningful research for improving ESRD patient care.

The comparisons we present are intended to increase awareness of the international trends, similarities, and differences in key ESRD treatment measures. Data collection methods vary considerably across countries, therefore direct comparisons should be made with caution. Data reflect "treated ESRD". The degree of unrecognized diagnosis of ESRD or reduced access to renal replacement therapy (RRT) varies across countries. In countries where the latter are more common, reported ESRD incidence may substantially underestimate the true incidence of irreversible kidney failure. Furthermore, in some countries where RRT is widely available, true ESRD incidence may be underestimated because some patients decline dialysis or transplantation. The term "conservative kidney management" has been used to describe patients who choose to forego or postpone RRT while continuing active medical care by nephrologists and other providers (Robinson et al, 2016).

We welcome any suggestions to further improve the content of this chapter for the benefit of the international community, and invite all renal registries to participate in this data collection and collaboration in the future. There are many countries not yet represented, therefore efforts to increase international engagement and enhance this chapter's content will continue to be a focus of our work.

Methods

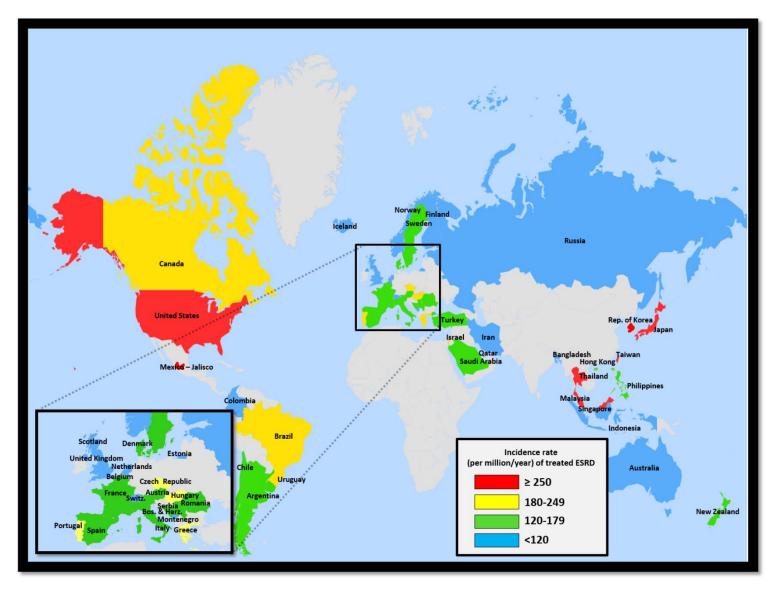
The findings presented in this chapter are drawn from each country's response to the USRDS request for information on patients receiving renal replacement therapy, as recorded on our *international data-collection form* provided to participants.

Data tables formerly presented in the content of this chapter are now located in *Reference Table N*. Please also see the ESRD Analytical Methods chapter in the ESRD volume for an explanation of analytical methods used to generate the figures in this chapter.

Incidence of Treated ESRD

In 2014, reported incidence rates of treated ESRD varied greatly across countries (see Figures 13.1 and 13.2). Taiwan, the Jalisco region of Mexico, and the U.S. reported the highest incidence of treated ESRD, at 455, 421, and 370 individuals per million general population (PMP), respectively. The next highest rates, ranging from 203–299 PMP, were reported for Thailand, Singapore, Japan, the Republic of Korea, Malaysia, Portugal, Hungary, Greece, and Israel. The lowest treated ESRD incidence rates, ranging from 49 to 97 PMP, were reported by Bangladesh, Russia, Iceland, Iran, Finland, Estonia, Colombia, Montenegro, and Switzerland.

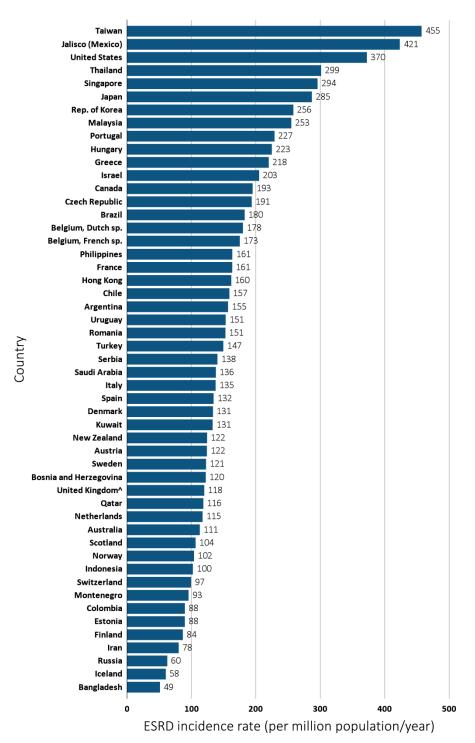
Trends in the incidence of treated ESRD also varied greatly across countries, as shown in Figure 13.3. In addition, we evaluated the percent change in averaged ESRD incidence rates in 2013/14 versus that in 2001/02 (Reference Table N.1). The greatest increases in the incidence of treated ESRD were reported for Thailand (1009%), Bangladesh (643%), Russia (291%), the Philippines (190%), Malaysia (162%), the Republic of Korea (101%), and the Jalisco region of Mexico (93%). In contrast, the averaged ESRD incidence in 2013/14 was 3-14% lower than that in 2001/02 in Austria, Denmark, Iceland, Finland, Sweden, and Scotland. The incidence of treated ESRD was relatively stable in nearly half of all countries, displaying an overall increase of 2% to 30% when comparing the rate in 2013/14 to that of 2001/02. The U.S. displayed one of the more stable ESRD incidence rates over this time period, with an overall 9% increase from 2001/02 to that in 2013/14. Most of this change occurred prior to 2006, with little change in U.S. ESRD incidence rates since 2006.



vol 2 Figure 13.1 Geographic variations in the incidence rate of treated ESRD (per million population/year), by country, 2014

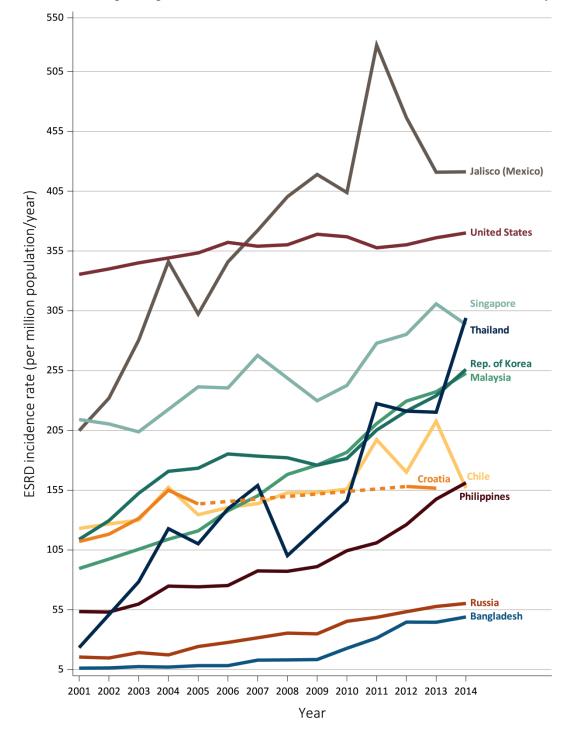
Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. All rates are unadjusted. ^United Kingdom: England, Wales, Northern Ireland (Scotland data reported separately). Data for Italy include 6 regions. Data for Indonesia represent the West Java region. Data for France include 22 regions. Data for Spain include 18 of 19 regions. Data for Canada excludes Quebec. Japan includes dialysis patients only. Abbreviation: ESRD, end-stage renal disease.

vol 2 Figure 13.2 Incidence rate of treated ESRD (per million population/year), by country, 2014



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. All rates are unadjusted. ^United Kingdom: England, Wales, Northern Ireland (Scotland data reported separately). Data for Italy include 6 regions. Data for Indonesia represent the West Java region. Data for France include 22 regions. Data for Spain include 18 of 19 regions. Data for Canada excludes Quebec. Japan includes dialysis patients only. Abbreviations: ESRD, end-stage renal disease; sp., speaking.

vol 2 Figure 13.3 Trends in the incidence rate of treated ESRD (per million population/year), by country, 2001-2014

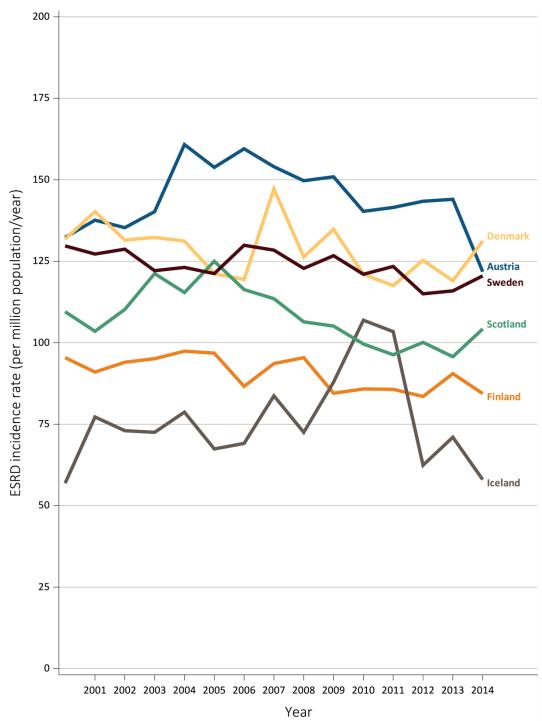


a) Ten countries having the highest % rise in ESRD incidence rate in 2001/02 versus that in 2013/14, plus the U.S.

Data source: Special analyses, USRDS ESRD Database. All rates are unadjusted. Data for Croatia are missing from 2006-2011, 2014, indicated by the dashed line. Data for U.S. are shown for comparison purposes. Abbreviation: ESRD, end-stage renal disease.

Figure 13.3 continued on next page.

vol 2 Figure 13.3 Trends in the incidence rate of treated ESRD (per million population/year), by country, 2001-2014 (continued)



b) Six countries having the largest % decline in ESRD incidence rate: 2013/14 versus that in 2001/02

Data source: Special analyses, USRDS ESRD Database. All rates are unadjusted. Only six countries had a decrease in incidence from 2001/02-2013/14. Abbreviation: ESRD, end-stage renal disease.

CHAPTER 13: INTERNATIONAL COMPARISONS

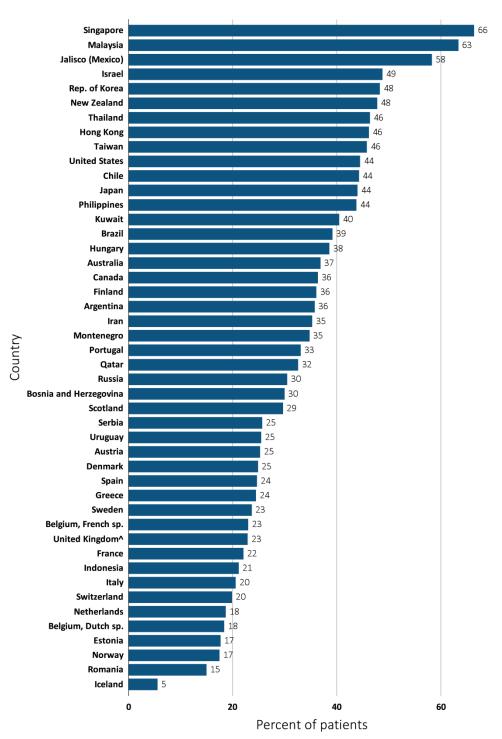
DIABETES AS PRIMARY CAUSE OF END-STAGE RENAL DISEASE IN INCIDENT PATIENTS

Data on the incidence of treated ESRD with a primary cause of diabetes mellitus (DM)—a key contributor to the global burden of ESRD-were provided by nearly 72% of the countries participating in this report. In 2014, Singapore, Malaysia, and the Jalisco region of Mexico reported the highest proportions of patients with new ESRD due to DM, at 66%, 63%, and 58% (Figure 13.4). Furthermore, DM was the primary cause of new ESRD for at least 40% of patients in Israel, the Republic of Korea, New Zealand, Thailand, Hong Kong, Taiwan, U.S., Chile, Japan, the Philippines, and Kuwait. In contrast, in 2014, DM was the primary cause of ESRD for less than 20% of new ESRD patients in Italy, Switzerland, the Netherlands, Belgium (Dutch-speaking), Estonia, Norway, Romania, and Iceland.

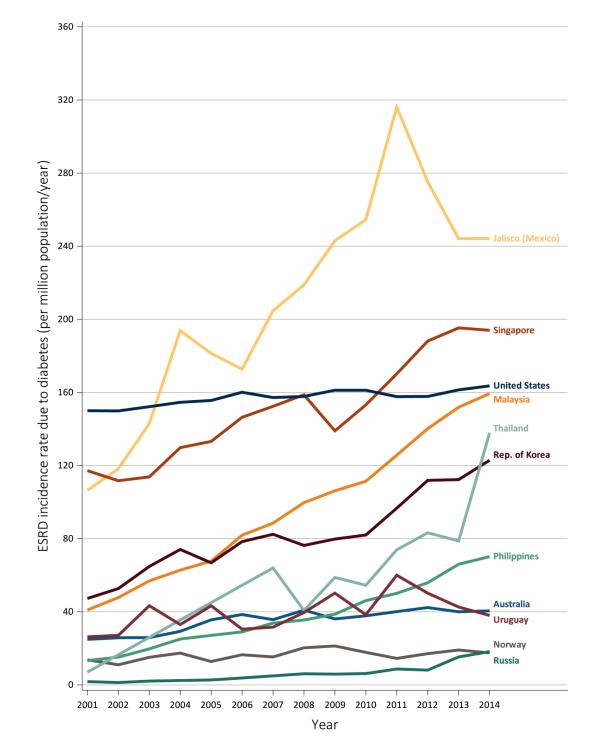
Twenty-three countries have provided rates of ESRD due to DM for the entire time period from 2001 to 2014. These data indicate an overall rise in the rate of treated ESRD due to DM in most, but not all areas (Reference Table N.2). In some countries this increase has been especially large (Figure 13.5), such as in Thailand, Russia, the Philippines, Malaysia, the Republic of Korea, and the Jalisco region of Mexico. In these countries, the rates of treated ESRD incidence due to DM have more than doubled between 2001 and 2014. Among the countries shown, the Jalisco region of Mexico had the highest rate in 2014, at nearly 244 new ESRD patients PMP having diabetes as primary ESRD cause. It is conceivable that determination of primary ESRD cause may have altered in some countries over this reporting period, and thus have potentially contributed to observed changes in the percentage of incident patients with DM as cause of ESRD. However, we currently have no information regarding the extent of this possibility for any of the countries.

The relationship of percent change in overall treated ESRD incidence with change in treated incidence due to DM is shown in Figure 13.6. Data represent 27 countries across three international regions, from 2001-2014. In each international region, although not in all countries, a positive relationship is seen between the percent change in treated ESRD incidence and percent change in treated ESRD incidence due to DM. Overall, the largest increases in treated ESRD incidence due to DM were seen in the region consisting of Asia and Russia, and were associated with the largest rises in overall ESRD incidence from 2001-2014. In contrast, six countries showed a decline in ESRD due to DM from 2001-2014, with five of these countries also showing declines in overall treated ESRD incidence (Austria, Iceland, Finland, Denmark, Sweden, and the Dutch-speaking region of Belgium}. It is noteworthy that this relationship differs considerably across countries, whereby in some the percent change in treated ESRD incidence is of similar magnitude to the percent change in treated ESRD incidence due to DM, while in others this positive relationship is of a much lower equivalence. Thus, the contribution of treated ESRD incidence due to DM to the overall treated ESRD incidence varies substantially.

vol 2 Figure 13.4 Percentage of incident ESRD patients with diabetes as the primary cause of ESRD, by country, 2014



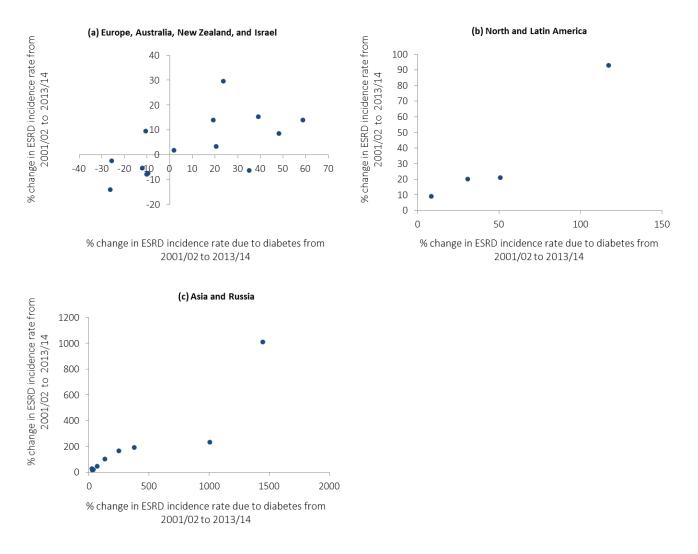
Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. ^United Kingdom: England, Wales, Northern Ireland (Scotland data reported separately). Data for Spain include 18 of 19 regions. Data for France include 22 regions. Data for Indonesia represent the West Java region. Data for Italy includes 6 regions. Data for Canada excludes Quebec. Abbreviations: ESRD, end-stage renal disease; sp., speaking.



vol 2 Figure 13.5 Trends in the incidence rate of treated ESRD due to diabetes (per million population/year), by country, 2001-2014

Data source: Special analyses, USRDS ESRD Database. Ten countries having the highest % rise in 2013/14 versus that in 2001/02, plus the U.S. Data presented only for countries from which relevant information was available. Abbreviation: ESRD, end-stage renal disease.

vol 2 Figure 13.6 Country correlation of the percent change in ESRD incidence with the percent change in ESRD incidence due to diabetes, by region, 2001-2014



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. United Kingdom: England, Wales, Northern Ireland (Scotland data reported separately). Countries listed in order of lowest to highest % change in ESRD incidence due to diabetes in each panel (a) Europe and Israel: (< 3%) Iceland, Austria, Finland, Belgium (Dutch-speaking), Denmark, Sweden, Belgium (French-speaking), (> 20%) the Netherlands, New Zealand, Greece, Scotland, Israel, Norway, Australia; (b) North and Latin America: United States, Canada, Uruguay, Jalisco (Mexico); (c) Asia and Russia: (27%-135%) Hong Kong, Japan, Taiwan, Singapore, Rep. of Korea, (>251%) Malaysia, Philippines, Russia, and Thailand. Abbreviation: ESRD, end-stage renal disease.

CHAPTER 13: INTERNATIONAL COMPARISONS

INCIDENCE OF TREATED END-STAGE RENAL DISEASE BY AGE GROUP AND SEX

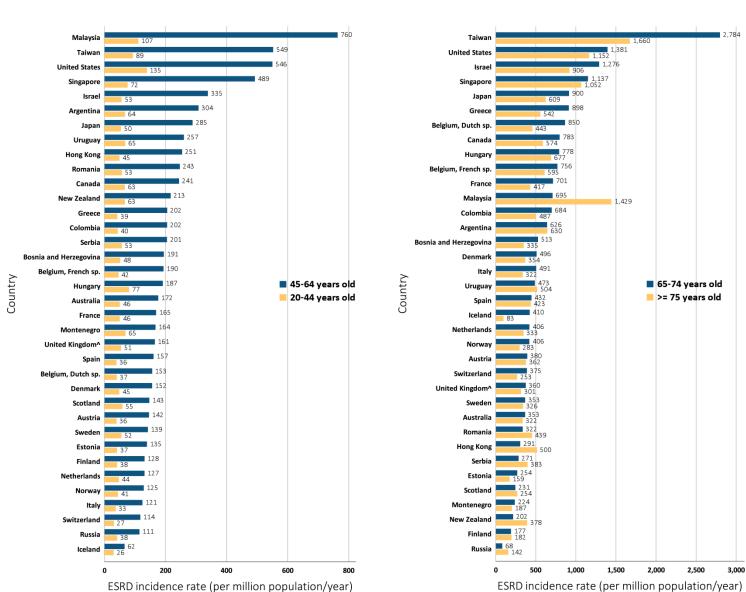
The incidence of treated ESRD in 2014 is shown by age group in Figure 13.7. In the majority of countries, treated ESRD incidence was highest among patients aged 75 years or older. The highest rates in this age group were reported for Taiwan, with 2784 PMP/year. This was twice the next highest rate as reported for the U.S., at 1381 PMP/year, followed by Israel and Singapore, at 1276 and 1137 PMP/year. However, the oldest cohort did not display the highest incidence in all countries. In Hong Kong, Malaysia, New Zealand, Serbia, Romania, and Russia the incidence of treated ESRD was 20-50% lower in the population aged 75 years or older, as compared to those aged 65-74 years. The highest rate in younger adults (aged 20-44 years) was reported in the U.S. (135 PMP/year) and in Malaysia (107 PMP/year), where 2014 rates were more than twice that of most other countries with available data.

Trends in the incidence of treated ESRD by age group are provided in Reference Table N.3, as the percent change for years 2013/14 versus 2005/06 in the 29 countries for which these data have been contributed. It is noteworthy that both in the U.S. and in nearly half of the 29 countries, an overall decline in the treated ESRD incidence rate was seen among persons aged 75 years or older, and in 22 of the 29 countries a corresponding decline was seen in the 65-74 age group. These latter trends are especially meaningful, since in many countries nearly half of all new ESRD patients are 65 years or older.

Comparisons of the incidence of treated ESRD by sex are shown in Figure 13.8. In every country the rate is substantially higher for males than for females. ESRD incidence was at least two times higher for males in Austria, Uruguay, Spain, Iceland, Frenchspeaking Belgium, Japan, Norway, Finland, and Montenegro, and was 1.2 to 1.9 times higher for males in most other countries.

The considerably lower ESRD incidence for females in nearly all countries shown in Figure 13.8 is consistent with the recent paper by Hecking et al (2014), who observed considerably fewer women than men being treated with hemodialysis for ESRD in 12 of the countries participating in the Dialysis Outcomes and Practice Patterns Study (DOPPS) from 2002-2012. In conjunction with the prior findings by Hecking et al (2014), the sex differences in incidence rates from all countries shown in this report support investigation of the broader question of which factors are responsible for the differential ESRD incidence in males versus females.

vol 2 Figure 13.7 Incidence rate of treated ESRD (per million population/year), by age group and country, 2014

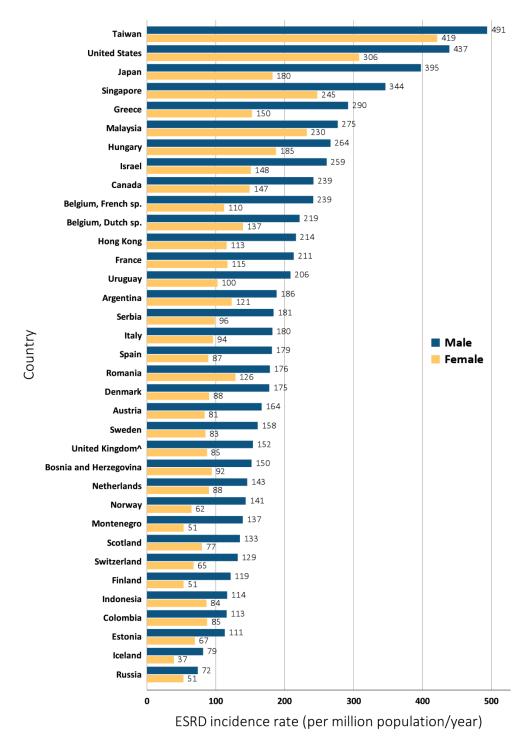


Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. ^United Kingdom: England, Wales, Northern Ireland (Scotland data reported separately). Data for Spain include 18 of 19 regions. Data for Italy include 6 regions. Data for France include 22 regions. Data for Canada excludes Quebec. Japan includes dialysis patients only. For graph (a), data for Spain include patients 15-64 years old, and data for the United States include patients 22-64 years old. Abbreviations: ESRD, end-stage renal disease; sp., speaking.

(a) 20-44 and 45-64 years old

(b) 65-74 and >75 years old

vol 2 Figure 13.8 Incidence rate of treated ESRD (per million population/year), by sex and country, 2014



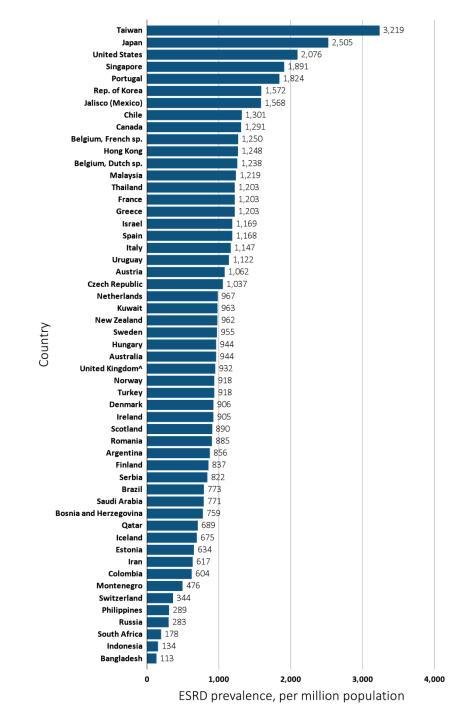
Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. ^United Kingdom: England, Wales, Northern Ireland (Scotland data reported separately). Data for Spain include 18 of 19 regions. Data for France include 22 regions. Data for Indonesia represent the West Java region. Data for Italy represent 6 regions. Data for Canada excludes Quebec. Japan includes dialysis patients only. Abbreviations: ESRD, end-stage renal disease; sp., speaking.

Prevalence of End-stage Renal Disease

In 2014, a total of 2,217,350 patients were treated for ESRD in all reporting countries. The number was by far the highest in the U.S., with 662,048 treated patients accounting for 30% of the total (Reference Table N.4b), followed by Japan and Brazil with approximate cohorts of 318,000 and 157,000 prevalent ESRD patients. The Republic of Korea, Taiwan, Thailand, Turkey, France, Spain, and the United Kingdom reported between 50,000 to 81,000 treated ESRD patients in 2014, with all other countries indicating smaller populations, with approximately 18,000 treated ESRD patients in the median country.

In 2014, ESRD prevalence varied nearly 30-fold across represented countries (see Figure 13.9 and Reference Table N.4a). Treated ESRD prevalence was highest, ranging from 1568 to 3219 PMP, in the Asian countries of Taiwan, Japan, Singapore, and the Republic of Korea, as well as in the U.S., Portugal, and the Jalisco region of Mexico. In nearly 30% of countries, prevalence ranged from 1,000 to 1,300 PMP, while approximately 40% reported 600 to 1000 prevalent ESRD patients PMP. These included many countries in Western, Central, and Eastern Europe, Australia, and New Zealand, the South American countries of Argentina, Brazil, and Colombia, and the Middle Eastern nations of Iran, Qatar, and Saudi Arabia. The lowest rates were reported in Bangladesh, Indonesia, South Africa, Russia, the Philippines, Switzerland, and Montenegro, where ESRD prevalence ranged from 113 to 476 PMP.

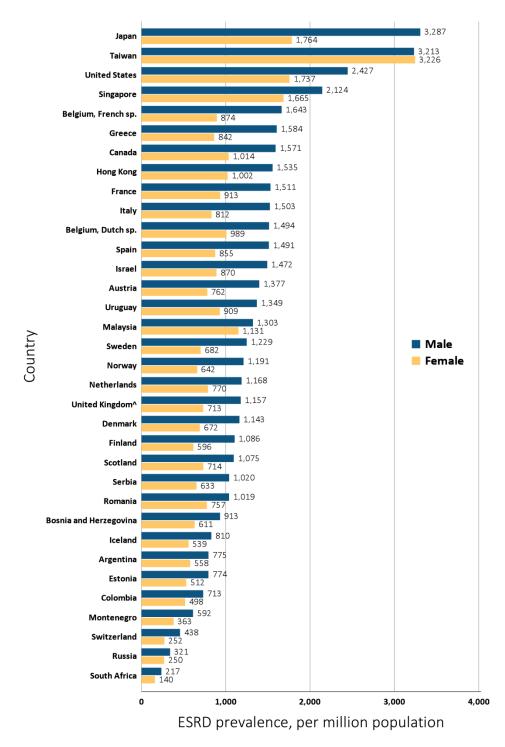
Although ESRD incidence rates have been quite level or decreasing in many countries during recent years, ESRD prevalence PMP has steadily increased in all 32 countries that provided data from 2001 to 2013 and/or 2014 (Reference Table N.4a and Figure 13.11). Over this time period, the median increase in ESRD prevalence was 48%, varying from 18% to 1092% in rise.. These trends are indicative of the increasing worldwide need for additional dialysis and kidney transplantation services to meet the health needs of individuals with ESRD. The largest proportionate increases in ESRD prevalence between 2001/02 and 2013/14 were observed in the Philippines, Thailand, and Jalisco region of Mexico, ranging from 343 to 1092%, followed by rises of 106% to 245% in Israel, Republic of Korea, Malaysia, and Russia. In the U.S., ESRD prevalence increased 43% overall from 2001/02 to 2013/14, with a nearly constant annual increase of 3.2%.



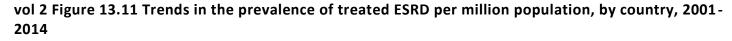
vol 2 Figure 13.9 Prevalence of treated ESRD per million population, by country, 2014

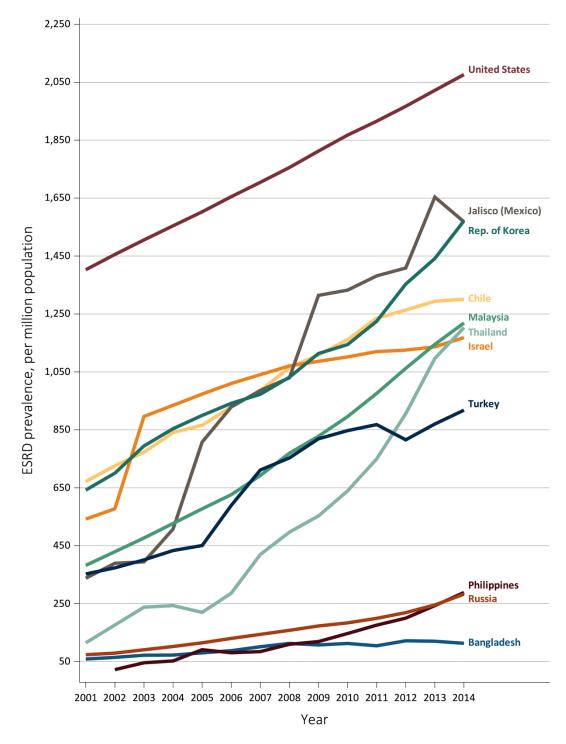
Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. ^United Kingdom: England, Wales, Northern Ireland (Scotland data reported separately). The prevalence is unadjusted and reflects prevalence at the end of 2014. Switzerland includes dialysis patients only. Data for Indonesia represent the West Java region. Data for Spain include 18 of 19 regions. Data for France include 22 regions. Data for Italy includes 6 regions. Data for Canada excludes Quebec. Abbreviations: ESRD, end-stage renal disease; sp., speaking.

vol 2 Figure 13.10 Prevalence of treated ESRD per million population, by sex and country, 2014



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. ^United Kingdom: England, Wales, Northern Ireland (Scotland data reported separately). Switzerland includes dialysis patients only. Data for Spain include 18 of 19 regions. Data for France include 22 regions. Data for Italy include 6 regions. Data for Canada excludes Quebec. Abbreviations: ESRD, end-stage renal disease; sp., speaking.



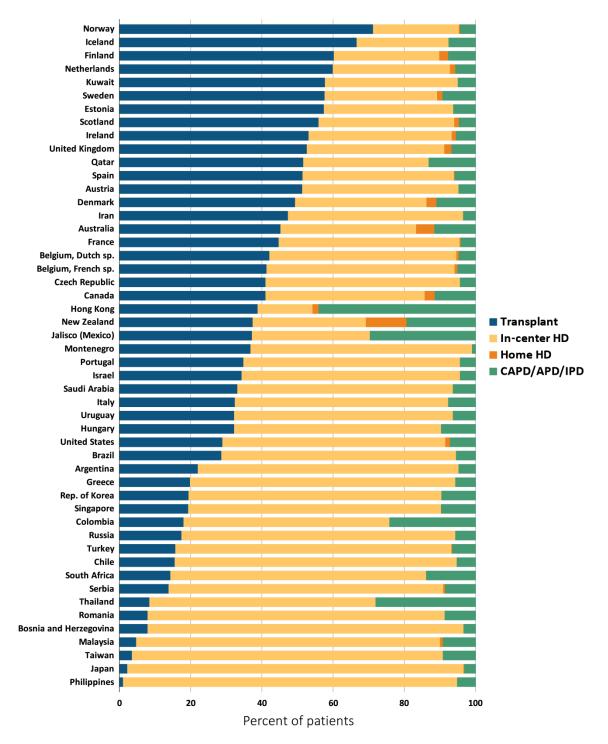


Data source: Special analyses, USRDS ESRD Database. Ten countries having the highest % rise in ESRD prevalence: 2013/14 versus that in 2001/02, plus the U.S. ESRD prevalence is unadjusted. Israel includes dialysis patients only from 2001-2002. U.S. is shown for comparison purposes. Abbreviation: ESRD, end-stage renal disease.

Variations in Use of Different Renal Replacement Therapies for ESRD

In-center hemodialysis, home hemodialysis, peritoneal dialysis, and kidney transplantation serve as the different forms of renal replacement therapy (RRT) for persons with ESRD. As shown in Figure13.12, the proportionate use of the different RRT forms differs considerably across countries. Dialysis is the most commonly utilized therapeutic approach for treatment of ESRD in the majority of countries, followed by kidney transplantation. Kidney transplantation is the renal replacement therapy (RRT) often viewed by many eligible ESRD patients as their first choice due to substantially higher quality of life and longer median survival as compared with dialysis therapy. In 2014, transplantation use for patients with ESRD ranged from less than 10% in some Asian and eastern European countries to 50–75% transplant use in the Nordic countries (Denmark, Finland, Iceland, Norway, and Sweden), Estonia, the Netherlands, United Kingdom (including Scotland), Spain, Austria, and Qatar. A striking observation is that the countries with the highest proportion of kidney transplants among ESRD patients also tend to have lower treated ESRD incidence rates of approximately 80 to 130 PMP/year, as shown in Figure 13.2 and Reference Table N.1. Additional information regarding trends in the percent of ESRD patients living with a kidney transplant since 2001 is provided by country in Reference Table N.9.

vol 2 Figure 13.12 Percent distribution of type of renal replacement therapy modality used by ESRD patients, by country, in 2014

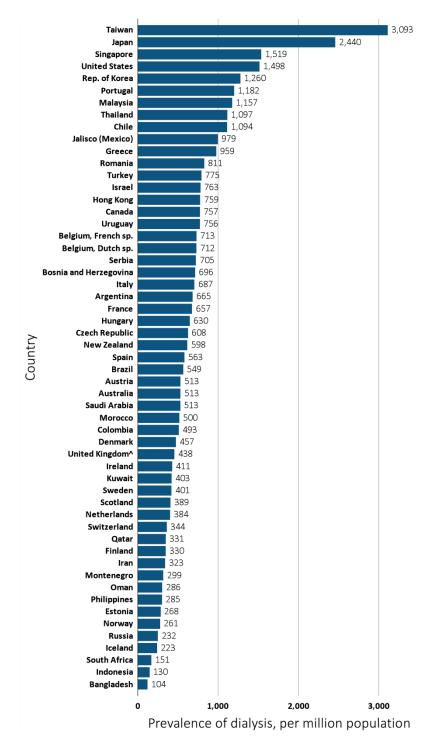


Data source: Special analyses, USRDS ESRD Database. Denominator is calculated as the sum of patients receiving HD, PD, Home HD, or treated with a functioning transplant; does not include patients with other/unknown modality. Data for Spain include 18 of 19 regions. Data for France include 22 regions. Data for Italy include 6 regions. Data for Canada excludes Quebec. Abbreviations: CAPD, continuous ambulatory peritoneal dialysis; APD, automated peritoneal dialysis; IPD, intermittent peritoneal dialysis; ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; sp., speaking

Dialysis Therapy for ESRD

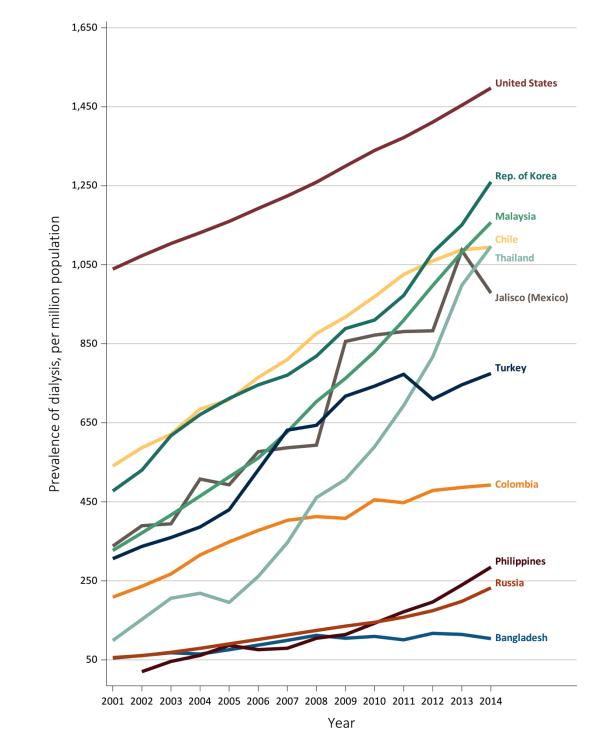
In 2014, the number of ESRD patients receiving dialysis PMP varied nearly 30-fold across countries, from 104 to 151 per million population in Bangladesh, Indonesia, and South Africa to 2440 to 3093 in Japan and Taiwan (Figure 13.13). Some countries have experienced very large rises in the prevalence of dialysis since 2001/02, with an approximately 1200% and 960% increase in the Philippines and Thailand, respectively, and a 180% to 270% rise in Russia, Malaysia, and the Jalisco region of Mexico (Reference Table N.6). Furthermore, the prevalence of dialysis has increased 238% in Romania from 2005 to 2014. However, a plateauing or decline in the prevalence of patients receiving dialysis has been seen in nearly a quarter of all countries during the last five years (Reference Table N.5). These countries include Denmark, Sweden, Iceland, Finland, Norway, the Netherlands, Scotland, Spain, Italy, Austria, Hungary, Oman, and Bangladesh-most of which also tend to have a higher percent use of kidney transplantation, as noted in the prior section.

Hemodialysis (HD) continues to be the most common form of dialysis therapy in nearly all countries (Figure 13.15). In nearly three-fourths of reporting countries, at least 80% of chronic dialysis patients were receiving in-center HD in 2014. However, in 2014, PD was used by 72% of dialysis patients in Hong Kong, and 47% in the Jalisco region of Mexico (Figure 13.15, Reference Table N.7b). Furthermore, 29%-31% PD use was reported in Colombia, New Zealand, and Thailand, with 16% to 27% seen in Australia, Canada, Denmark, Finland, Iceland, Qatar, South Africa, and Sweden. Since 2006, an overall trend of increasing PD use as a percentage of all chronic dialysis has been seen in the countries of Argentina, Bangladesh, Chile, Spain, Taiwan, Thailand, the U.S., and Uruguay (Ref. Table N.7b). In contrast, PD use has declined over this same time period in countries such as Belgium, Bosnia and Herzegovina, Colombia, Croatia, Denmark, Finland, France, Greece, Hong Kong, Israel, Jalisco (Mexico), Republic of Korea, the Netherlands, New Zealand, Norway, Romania, Russia, Scotland, Singapore, Turkey, and the United Kingdom. In 2014, home HD therapy was provided to 9.4% and 18.3% of dialysis patients in Australia and New Zealand. Home HD was also used by 3.0 to 6.0% of dialysis patients in Canada, Denmark, Finland, the Netherlands, Sweden, the United Kingdom, and Scotland. However, in all other countries, home HD was either not provided, or was used by fewer than 3% of dialysis patients.



vol 2 Figure 13.13 Prevalence of dialysis per million population, by country, 2014

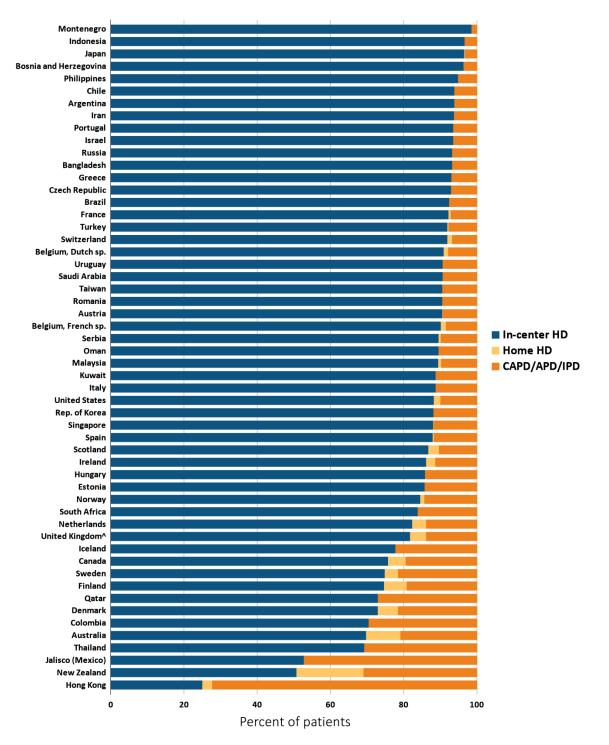
Data source: Special analyses, USRDS ESRD Database. ESRD prevalence is unadjusted and reflects prevalence at the end of 2014. United Kingdom: England, Wales, Northern Ireland (Scotland data reported separately). Data for Indonesia represent the West Java region. Data for Spain include 18 of 19 regions. Data for France include 22 regions. Data for Italy include 6 regions. Data for Canada excludes Quebec. Abbreviation: sp., speaking.



vol 2 Figure 13.14 Trends in the prevalence of dialysis per million population, by country, 2001-2014

Data source: Special analyses, USRDS ESRD Database. Ten countries having the highest % rise in dialysis prevalence: 2013/14 versus that in 2001/02, plus the U.S. The prevalence is unadjusted and reflects prevalence of dialysis at the end of each year. Abbreviation: ESRD, end-stage renal disease.

vol 2 Figure 13.15 Distribution of the percentage of prevalent dialysis patients using in-center HD, home HD, or peritoneal dialysis (CAPD/APD/IPD), 2014



Data source: Special analyses, USRDS ESRD Database. Denominator is calculated as the sum of patients receiving HD, PD, Home HD; does not include patients with other/unknown modality. ^United Kingdom: England, Wales, & Northern Ireland (Scotland data reported separately). Data for Spain include 18 of 19 regions. Data for France include 22 regions. Data for Italy include 6 regions. Data for Canada excludes Quebec. Abbreviations: CAPD, continuous ambulatory peritoneal dialysis; APD, automated peritoneal dialysis; IPD, intermittent peritoneal dialysis.

Kidney Transplantation

Kidney transplantation rates vary greatly across countries, which may reflect not only geographic variations in ESRD incidence and prevalence but also differences in national health care systems, infrastructure for transplantation services, organ availability, degree of genetic homogeneity or heterogeneity within a country's population, and cultural beliefs. Kidney transplantation rates when expressed per million population (PMP) serve to standardize rates according to the size of a country's population and thus, to some extent account for the potential kidney donor pool size (Figure 13.16a). However, it is also of interest to understand transplantation rates in relationship to the size of the population in need. Towards this purpose, we also display kidney transplantation rates per 1000 dialysis patients in a country (Figure 13.16b). Such a comparison indicates that the relative rates by country differ considerably between the two metrics. For example, the U.S. ranks fourth in the world in terms of transplants per million population. However, the U.S. is 33rd in the world in transplants per 1000 dialysis patients (among 49 countries), partially due to the high numbers of U.S. dialysis patients.

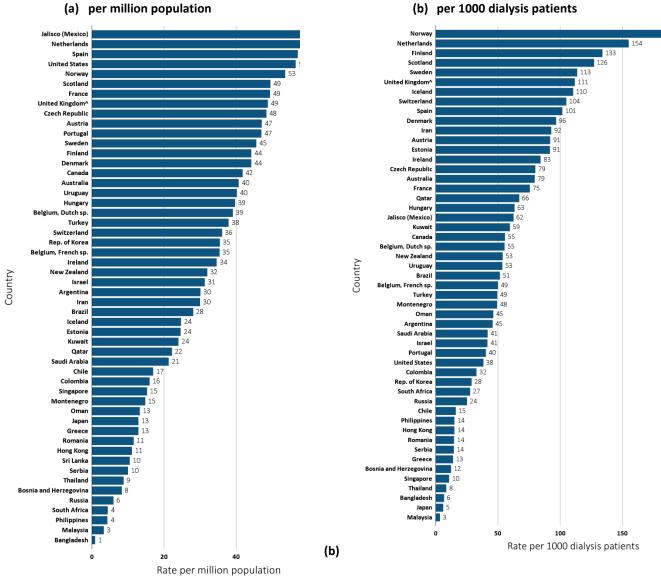
Kidney transplant rates varied greater than 30-fold across countries when expressed PMP, from one to 60 PMP in 2014 (Figure 13.16a). The highest rates were reported in the Jalisco region of Mexico, the Netherlands, Spain, and the U.S., with 56–60 kidney transplants PMP. Transplant rates ranged from 30–53 PMP for 44% percent of countries, 11–28 for 26% of countries, and 1–10 kidney transplants for the remaining 22%. Countries reporting the lowest rates of kidney transplantation, at 1-4 PMP, included Bangladesh, Malaysia, the Philippines, and South Africa.

Kidney transplant rates as expressed per 1000 dialysis patients also varied greatly across countries, from 3 to 205 in 2014 (Figure 13.16b). The highest rates per 1000 dialysis patients occurred in Norway (205), the Netherlands (154), Finland (133), and Scotland (126). Furthermore, transplant rates of 101 to 113 per 1000 dialysis patients were reported in Sweden, the United Kingdom (excluding Scotland), Iceland, Switzerland, and Spain. One-third of countries reported rates of 50 to 99 per 1000 dialysis patients, 24% had rates of 20-49 per 1000, and the remaining 24% of countries reported rates of less than 20 in 2014. The lowest rates of three to eight transplants per 1000 dialysis patients were reported by the countries of Malaysia, Japan, Bangladesh, and Thailand. During 2104 in the U.S., 38 kidney transplants were performed per 1000 dialysis patients.

Since 2001, some countries have shown a substantial increase in kidney transplant rates PMP (Ref. Table N.8, Figure 13.17). When comparing transplant rates in 2013/14 to 2001/02, Turkey, Croatia, Iceland, Bangladesh, Thailand, Russia, the Netherlands, the Republic of Korea, Scotland, and Uruguay, have demonstrated the largest increases (62% to 417%). Additionally, kidney transplantation rates PMP were 28-46% higher in the Czech Republic, Israel, Australia, Denmark, and Sweden in 2013/14 versus that in 2001/02 in these countries.

vol 2 Figure 13.16 Kidney transplantation rate, by country, 2014

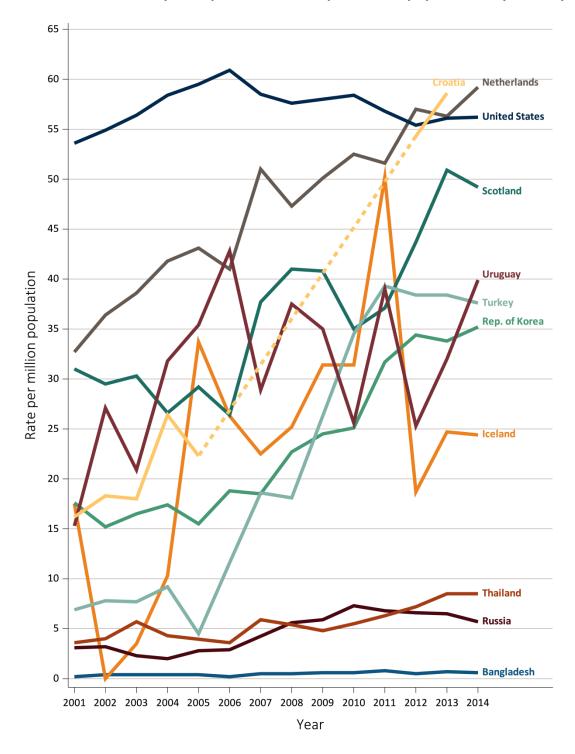
(a)



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. All rates are unadjusted. ^United Kingdom: England, Wales, & Northern Ireland (Scotland data reported separately). Data for France include 22 regions. Data for Sri Lanka is from 7 government hospitals. Data for Spain include all regions. Data for Canada excludes Quebec. Abbreviation: sp., speaking.

(b) per 1000 dialysis patients





Data source: Special analyses, USRDS ESRD Database. Ten countries having the highest % rise in kidney transplantation rate: 2013/14 versus that in 2001/02, plus the U.S. All rates are unadjusted. Data for Croatia are missing from 2006-2011, 2014. Abbreviations: ESRD, end-stage renal disease.

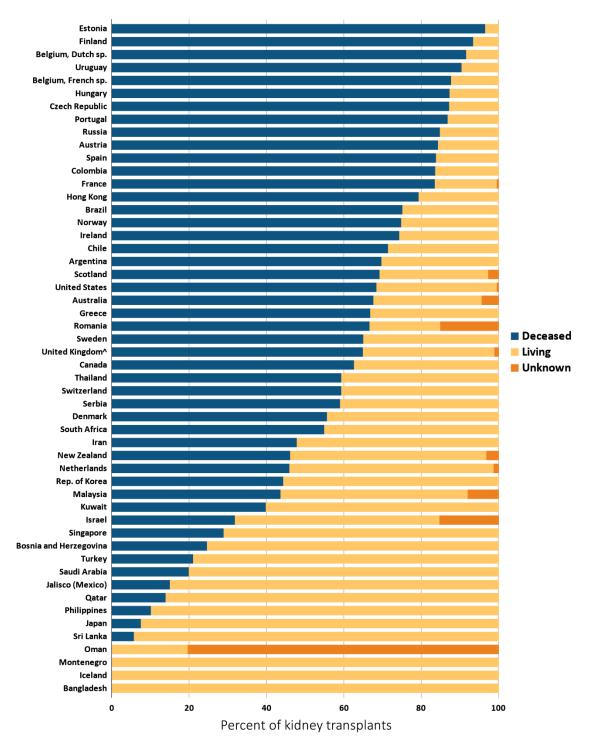
CHAPTER 13: INTERNATIONAL COMPARISONS

Large international differences also are seen in the types of kidney donors, ranging from 80%-100% living donor kidney transplants in Bangladesh, Montenegro, Sri Lanka, Japan, the Philippines, Qatar, the Jalisco region of Mexico, Saudi Arabia, and Turkey, to only 5% in Estonia (Figure 13.18). In approximately 60% of countries, donation from deceased individuals was the predominant form of kidney donation during 2014.

In 2014, Norway, Portugal, and the U.S. reported the highest prevalence of ESRD patients living with a kidney transplant per million population, at 630 to 657 PMP (Figure 13.19 and Ref. Table N.9). Thirty-five percent of countries indicated 400 to 599 prevalent ESRD patients PMP living with a kidney transplant, while the remaining 56% of countries were nearly evenly divided between having less than 200, or 200-399 PMP. However, as noted earlier in this chapter, countries having a high prevalence of ESRD patients living with a kidney transplant PMP may not necessarily have a high fraction of ESRD patients living with a kidney transplant (e.g., see section on *Variations in Use of Different Renal Replacement Therapies for ESRD*). In comparisons of data from 2013/14 to 2001/02, the prevalence of ESRD patients living with a kidney transplant PMP has increased in every country with available data, rising from 52% to 372% in approximately one-half of all countries, and by 13%-50% in the remaining nations (Reference Table N.9). The largest increases during this period of 148% to 372% in the prevalence of ESRD patients living with a kidney transplant PMP were seen in Russia, Croatia, Uruguay, Turkey and Thailand.

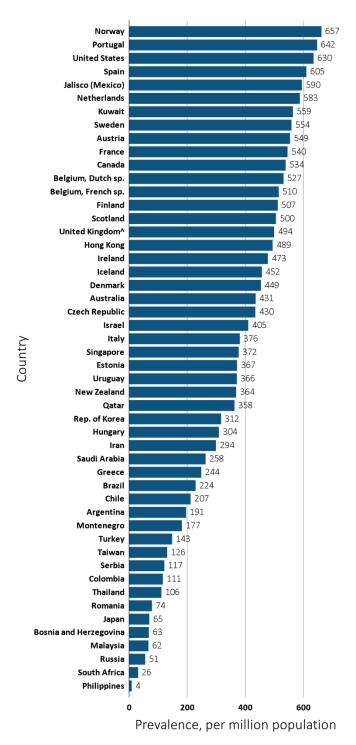
The percentage of all ESRD patients living with a kidney transplant has remained relatively constant in most countries from 2001-2014 (Reference Table N.10). However, some countries have demonstrated a continuing increase, particularly in Denmark, Iceland, the Netherlands, Scotland, Sweden, and the United Kingdom, which have 50%-67% of their ESRD patients living with a kidney transplant. Furthermore, Uruguay and Turkey also have shown notable increases in the percent of ESRD patients living with a kidney transplant. In contrast, Malaysia, Singapore, the Philippines, and Chile have shown a decline.

vol 2 Figure 13.18 Distribution of the percentage of kidney transplantations by kidney donor type and country, 2014



Data source: Special analyses, USRDS ESRD Database. Denominator is calculated as the sum of deceased, living donor, and unknown transplants. AUnited Kingdom: England, Wales, & Northern Ireland (Scotland data reported separately). Data for France include 22 regions. Data for Sri Lanka is from 7 government hospitals. Data from Canada excludes Quebec. Abbreviation: ESRD, end-stage renal disease.

vol 2 Figure 13.19 Prevalence of treated ESRD patients with a functioning kidney transplant, per million population, by country, 2014



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. The prevalence is unadjusted. ^United Kingdom: England, Wales, & Northern Ireland (Scotland data reported separately). Data for Spain include 18 of 19 regions. Data for France include 22 regions. Data for Italy includes 6 regions. Data for Canada excludes Quebec. Abbreviations: ESRD, end-stage renal disease; sp., speaking.

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Acknowledgements

We would like to greatly thank the following contributors:

Australia and New Zealand	Kylie Hurst		
Austria	Reinhard Kramar		
Argentina	Dr. Sergio Miguel Marinovich, Coordinator Argentina Chronic Dialysis Registry		
Bangladesh	Harun Ur Rashid, Nazrul Islam		
Belgium, Dutch-speaking	Bart De Moor, Frans Schroven, and Johan De Meester		
Belgium, French-speaking	Jean-Marin des Grottes and Frederic Collart		
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Finland	Patrik Finne and Carola Grönhagen-Riska		
France	Mathilde Lassalle and Cécile Couchoud		
Greece	Nikolaos Afentakis		
Hong Kong	C.B. Leung and Stanley Lo		
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Sweden	Karl Goran Prütz, Maria Stendahl, Marie Evans									
Switzerland	Patrice Ambühl, Rebecca Winzeler									
Taiwan	Hung-Chun Chen, Mai-Szu Wu, Chih-Cheng Hsu, and Jer-Ming Chang									
Turkey	Kearkiat Praditpornsilpa MD, MS, Chairman, Thailand Renal Replacement Therapy Registry Nephrology Society of Thailand, Division of Nephrology, Department of Medicine, Chulalongkorn University, Anan Chuasuwan, M.D., Kidney Center, Department of Medicine, Bhumibol Adulyadej Hospital (Thailand), Prof. Dr. Gultekin Suleymanlar, Prof. Dr. Nurhan Seyahi, Prof. Dr. Kenan Ateş									

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United Kingdom	Anna Casula and Dr. Fergus Caskey
Uruguay	María Carlota González-Bedat on behalf of the Uruguayan Dialysis Registry, Francisco González-Martínez on behalf of the Registry of Renal Transplantation of Uruguay

Notes



Chapter 14: End-of-life Care for Patients With End-Stage Renal Disease: 2000-2013

- Between 2000 and 2013:
 - The percentage of Medicare beneficiaries with ESRD admitted to an intensive or coronary care unit during the last 90 days of life increased from 50% to 63% (Figure 3.a).
 - The percentage of Medicare beneficiaries with ESRD receiving an intensive procedure during the last 90 days of life increased from 28% to 34% (Figure 4.a).
 - The percentage of Medicare beneficiaries with ESRD who died in the hospital decreased from 49% to 39% (Figure 5.a).
 - The percentage of patients with ESRD who received care in a nursing facility (skilled nursing or nursing home) during the last year of life increased from 37% to 46% Figure 6.a).
 - The percentage of patients who discontinued maintenance dialysis treatments before death increased from 20% to 24% (Figure 7.a).
 - The percentage of Medicare beneficiaries with ESRD receiving hospice care at the time of death increased from 11% to 27% (Figure 8.a).
- Most patients receive hospice services only after discontinuing dialysis treatments. From 2004-2013, hospice use prior to death based on the CMS Death Notification form increased from 59% to 82% among patients who discontinued dialysis treatments, and from 5% to 8% among those who did not.
- Median per person costs under Medicare Parts A and B in 2013 were \$119,937 over the last year of life, \$20,731 over the last 30 days of life, and \$8,180 over the last 7 days of life.
- Costs during the final weeks of life were progressively lower for ESRD patients referred earlier to hospice. Median per person Medicare costs during the last 7 days of life ranged from \$1,553 for those referred to hospice more than 2 weeks before death to \$11,036 for those not referred until the last 2 days of life (Figures 9.a & 9.b).

Introduction

In this chapter, we update information included in Chapter 14 of the 2015 Annual Data Report (ADR) on treatment practices, patterns of health care utilization, and costs at the end of life to include the 14-year period from 2000 through 2013 among decedents with ESRD. New to this year's chapter is information on nursing facility use during the last year of life. Nursing facilities provide a variety of care services. Skilled nursing facilities (SNF) provide skilled nursing or medical care and rehabilitation following hospitalization. Nursing homes provide custodial care for patients who are no longer able to live independently. Medicare beneficiaries can receive up to 100 days of care in a SNF after hospitalizations lasting three or more days. Frequent use of nursing facilities (i.e. SNFs and/or nursing homes) near the end life not only implies a large burden of disability in the population, but may have implications for the delivery of end-of-life care to patients with end-stage renal disease (ESRD). Frequent transitions in the site of care can be burdensome to patients and may increase fragmentation of care. These concerns may be especially relevant to patients with ESRD for whom admission to a nursing facility may also entail transitioning to a new dialysis facility.

This chapter is divided into the following six sections: (1) Characteristics of Decedents With ESRD; (2) Patterns of Inpatient Utilization During the Last 90 Days of Life Among Medicare Beneficiaries With ESRD; (3) Nursing Facility Utilization During the Last Year of Life; (4) Patterns of Dialysis Discontinuation Before Death; (5) Patterns of Hospice Utilization Before Death; and (6) End-of-life Costs for Services Under Medicare Parts A and B.

Methods

Data supporting these analyses were derived from the 2016 version of the public-use Standard Analysis Files (SAFs) supplied by the USRDS Coordinating Center at the University of Michigan, specifically the Patients file, the MEDEVID file, the RXHIST file, the PAYHIST file, the Death file, and linked Medicare Institutional and Physician/Supplier claims. We also include information from the Minimum Patient Dataset for patients with ESRD.

Because complete information on Medicare utilization and costs are only available for patients with fee-for-service Medicare Parts A and B, analyses that rely on these measures were restricted to patients with Medicare Parts A and B as the primary payer throughout the relevant time period whose care was not covered by a health maintenance organization (HMO). We used the PAYHIST file to track primary payer for each patient over time, and to identify denominator populations of fee-for-service Medicare beneficiaries with Medicare Parts A and B as primary payer throughout time periods relevant to each analysis (e.g., last 90 days of life). Because Medicare Parts A and B were listed as the primary payer for a minority of patients aged 19 years or younger at the time of death, we do not report stratified results for this age group. With the exception of analyses of nursing facility utilization in the last year of life, these younger patients are included in the denominator for all calculations.

We used the Patients file to ascertain information on age at death, sex, race, and ethnicity. Each patient's most recent ESRD treatment modality before death was ascertained from the RXHIST file. We used Medicare Institutional claims to ascertain dates of hospital admission (which included admissions to short- and long-stay hospitals), dates of hospice utilization (HCFASAF=H), and receipt of hospice care at the time of death (HCFASAF=H on or after the date of death or Discharge Status from hospice=40, 41, or 42). Episodes of ICU utilization were captured using intensive and coronary care unit revenue center codes in Medicare Institutional claims (020x and 021x). We used an ICD-9 procedure code search of Medicare Institutional claims to capture intensive procedures occurring during hospital admissions. These procedures included intubation and mechanical ventilation (ICD-9 codes 96.04, 96.05, 96.7x), tracheostomy (ICD-9 codes 31.1, 31.21, 31.29), gastrostomy tube insertion (ICD-9 codes 43.2, 43.11, 43.19, 43.2, 44.32), enteral or parenteral nutrition (ICD-9 codes 96.6 and 99.15), and cardiopulmonary resuscitation (CPR, ICD-9 codes 99.60, 99.63) (Barnato et al., 2009).

To characterize nursing facility use in the last year of life, we restricted the cohort to patients who were at least 20 years of age at the time of death, had been treated for ESRD for at least one year, and had continuous Medicare Parts A & B coverage during the last year of life. We ascertained nursing facility use using Medicare claims - HCFASAF=N in Part A claims or PLCSRV=31-33 in Part B claims. To determine the number of days patients received care in a nursing facility in the last year of life, we assigned each day in the patient's last year of life to their location of care, based on Medicare claims (Wei, 2014; Intrator, 2011). We first used Part A claims, assigning hospital days, followed by nursing facility days, hospice days, and home health days, in this order. Next, using Part B claims, we then assigned, in order, home health days, nursing facility days, and assisted living facility days. Next, we assigned any days with an unknown location of care to the nursing facility, if: (1) the interval between 2 consecutive nursing facility claims was ≤90 days with no claims in between and with at least one claim being a Part B claim, (2) the interval between a nursing facility Part B claim and another institutional claim (hospital, hospice or assisted living) was \leq_{31} days and there were no claims in between, or (3) the interval between a nursing facility Part B claim and death was ≤31 days and there were no claims in between. When the start or end of a nursing facility

claim fell on the same day as the start or end of another claim, (e.g. hospital discharge occurring on the same day as a nursing facility admission), we assigned the overlap day to a nursing facility stay. To verify the accuracy of this approach, we used admission and discharge information from the Minimum Dataset, a national registry of nursing home patients, which was available to us only for patients who were admitted to a nursing home between 2000 and 2010 (Centers for Medicare & Medicaid, 2012). We found that the claims-based approach described above underestimated total days in a nursing facility by an average of 3 days compared with registry data.

The Centers for Medicare & Medicaid Services (CMS) Death Notification form (CMS 2746) reports provider responses to questions about whether renal replacement therapy was discontinued before death, the date of the last dialysis treatment before death for patients who discontinued treatment, and whether the patient was receiving hospice care prior to death. Analyses based on the CMS Death Notification form were conducted among those with complete information for the relevant data element. Analyses of hospice use and date of last dialysis treatment from the Death Notification form are available for most decedents from 2004 onward. Information on treatment discontinuation before death was available throughout the period of study. Analyses of discontinuation were restricted to patients for whom dialysis was listed as the most recent modality. While most measures of hospice utilization at the end of life reported in this chapter were obtained from Medicare claims, these are supplemented with information on place of death, hospice utilization, and date of last dialysis treatment from the Death Notification form. These two sources do not agree perfectly, in part, because there are differences in how each measure is defined, in the denominator populations with complete information for each measure, and in the time periods and methods of ascertainment.

Costs for Medicare Part A and B services were calculated using payments to Medicare recorded in both Institutional (CLM_AMT) and Physician Supplier (PMTAMT) claims. Patients for whom Medicare Parts A and B were listed as the primary payer in the PAYHIST file but had zero or negative costs during the last year of life (or last 30 days of life when calculating costs over shorter time periods before death) were excluded from cost analyses. Medicare Part A payments for hospital stays were calculated by adding the CLM_AMT to the pass-through payments for each stay (PER DIEM*CVR DCNT). Costs for hospital and skilled nursing facility admissions spanning the time period of interest (e.g., 90 days before death) were pro-rated. Cost calculations do not include Medicare Part D costs, Medicaid costs, Medicare copayments, or other health care costs for Medicare beneficiaries.

Analyses reported in Chapter 14 of the 2015 ADR were restricted to decedents with a first ESRD service date in 1995 or later. We have removed this restriction in the current chapter. This change combined with updates to the source data from USRDS has resulted in small changes to results reported in Chapter 14 of the 2015 ADR for earlier time periods.

Characteristics of Decedents With ESRD

We identified a total of 1,201,415 patients listed in the USRDS Database who died between calendar years 2000 and 2013. The mean age (± standard deviation) of decedents was 68.5 (±13.7) years (Table 14.1). Patients aged 45-64 years comprised the largest group of decedents (28.6%) and more than 80% of decedents were between the ages of 45 and 84 years of age at the time of death. Overall, 67.1% of decedents were White, 27.4% were Black/African American (hereafter, Black), 3.3% were Asian, 1.1% were Native American, 1.0% were of Other race and 10.7% were of Hispanic ethnicity. Overall 54.4% of patients were male. The most recent modality prior to death was hemodialysis in 88.5% of patients, peritoneal dialysis in 5.5%, and transplant in 5.2% (0.8% were missing information on modality). During 2000-2013, the mean age of decedents rose from 67.5 (±13.7) years to 69.2 (±13.2) years, and the percentage of patients aged 85 years and older at the time of death increased from 8.4% to 12.9%. There was little change in racial, ethnic, and gender composition over time. The percentage of decedents with peritoneal dialysis as their most recent modality decreased over time until 2007, increasing slightly since this time. The percentage of decedents who had received a kidney transplant has increased over time. The percentage of patients A and B as primary payer during the last 90 days of life ranged from a low of 66.6% in 2013 and a high of 75.0% in 2003.

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Total
n	72,814	76,865	79,489	82,382	84,057	85,792	87,500	87,526	88,329	89,855	90,563	91,775	91,781	92,687	1,201,415
%	6.1	6.4	6.6	6.9	7.0	7.1	7.3	7.3	7.4	7.5	7.5	7.6	7.6	7.7	100
Age (meen)	67.5	67.6	67.8	67.9	68.1	68.3	68.5	68.6	68.8	68.7	69.0	69.1	69.2	69.2	68.5
Age (mean)	(13.7)	(13.8)	(13.8)	(13.8)	(13.7)	(13.8)	(13.8)	(13.8)	(13.6)	(13.7)	(13.5)	(13.4)	(13.4)	(13.2)	(13.7)
Age Category															
0-19	0.2	0.2	0.2	0.2	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
20-44	6.4	6.3	6.1	5.7	5.6	5.4	5.1	5.1	4.8	4.8	4.4	4.3	4.2	4.0	5.1
45-64	27.9	28.3	28.1	28.7	28.8	28.6	29.1	28.7	28.7	29.0	28.9	28.8	28.3	28.0	28.6
65-74	28.6	27.9	27.5	27.0	26.7	26.2	25.7	25.9	26.3	26.5	26.6	26.9	27.7	28.5	27.0
75-84	28.5	28.7	28.8	28.8	28.9	29.0	28.6	28.5	27.9	27.4	27.3	27.0	26.7	26.6	28.0
≥85	8.4	8.7	9.4	9.7	10.0	10.7	11.3	11.8	12.1	12.2	12.7	13.0	13.1	12.9	11.2
Race															
Native American	1.2	1.1	1.1	1.1	1.1	1.2	1.1	1.1	1.1	1.1	1.1	1.0	1.0	0.9	1.1
Asian	2.8	2.8	2.9	3.0	3.0	3.2	3.2	3.4	3.3	3.5	3.5	3.7	3.7	3.7	3.3
Black/African American	28.1	28.3	28.0	28.1	28.4	28.0	27.7	27.4	27.3	27.1	26.7	26.4	26.1	26.0	27.4
White	66.0	65.9	66.2	65.8	65.5	66.3	67.1	67.2	67.4	67.5	68.0	68.2	68.7	69.1	67.1
Unknown	0.2	0.1	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.1	0.1
Other	1.7	1.7	1.7	1.8	1.8	1.2	0.9	0.8	0.8	0.7	0.6	0.6	0.4	0.2	1.0
Hispanic															
No	72.9	76.4	79.1	80.6	81.9	82.9	83.8	84.6	84.8	84.8	85.0	84.9	84.5	84.6	82.4
Yes	8.6	9.2	9.5	10.0	10.2	10.5	10.6	10.6	10.9	11.3	11.4	11.9	11.9	11.7	10.7
Unknown	15.4	11.8	9.2	7.2	5.8	4.7	3.8	3.2	2.6	2.3	2.0	1.7	1.6	1.4	4.9
Missing	3.2	2.6	2.2	2.2	2.1	1.9	1.8	1.6	1.6	1.6	1.6	1.6	2.1	2.2	2.0
Sex															
Male	47.8	47.6	47.5	46.9	46.3	46.0	45.8	45.3	44.9	44.3	44.2	43.8	43.6	45.4	45.6
Female	52.2	52.4	52.5	53.2	53.7	54.0	54.2	54.7	55.1	55.7	55.8	56.2	56.4	54.5	54.4
Last Treatment Modality															
Hemodialysis	86.7	87.4	88.2	88.5	88.7	88.8	89.0	89.3	89.1	89.1	89.0	88.4	87.9	88.1	88.5
Peritoneal Dialysis	7.7	7.1	6.5	6.0	5.8	5.3	5.1	4.7	4.7	4.5	4.5	4.8	5.2	5.7	5.5
Transplant	4.7	4.7	4.5	4.7	4.7	5.0	5.0	5.2	5.2	5.5	5.6	5.8	6.1	6.1	5.2
Missing	1.0	0.9	0.8	0.8	0.8	0.9	0.9	0.9	1.0	1.0	0.9	0.9	0.8	0.1	0.8
Medicare Parts A&B as															
primary payer during last															
90 days of life															
Yes	73.4	73.4	74.4	75.0	74.9	74.3	73.2	71.5	69.6	68.8	68.1	67.7	67.5	66.6	71.2

vol 2 Table 14.1 Characteristics of decedents with ESRD by death year, 2000-2013

Data Source: Special analyses, USRDS ESRD Database. Denominator is all decedents. Abbreviation: ESRD, end-stage renal disease.

Inpatient Utilization During the Last 90 Days of Life Among Medicare Beneficiaries With ESRD

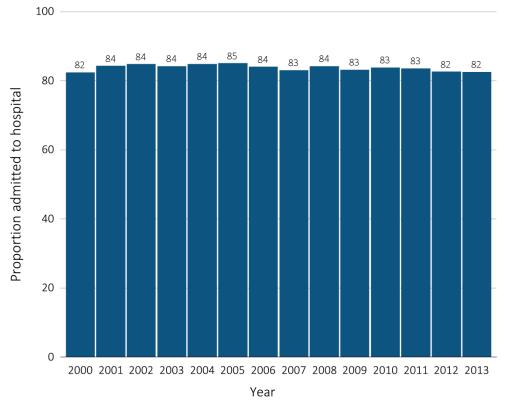
In this section, we describe the following measures of inpatient utilization during the last 90 days of life among fee-for-service Medicare beneficiaries with ESRD from 2000-2013: (1) hospital admission; (2) days spent in the hospital; (3) ICU admission; (4) receipt of intensive procedures; and (5) inpatient deaths.

HOSPITAL ADMISSION

Overall, 83.4% of patients were hospitalized during the last 90 days of life (Figure 14.1). The percentage of patients admitted to the hospital was highest for those aged 75-84 years (84.7%) and lowest for those aged 45-64 years (81.2%). Hospital admission was most common in Blacks (84.3%) and least common in Asians (80.6%), was more common in Hispanics vs. non-Hispanics (84.6% vs. 83.6%), in women vs. men (85.8% vs. 81.4%), and in those whose most recent modality was hemodialysis vs. peritoneal dialysis vs. transplant (83.7% vs. 82.0% vs. 78.3%). The proportion of patients admitted to the hospital during the last 90 days of life either remained the same or decreased slightly in all subgroups examined.

Overall, 27.0% of decedents were admitted to and/or discharged from the hospital within 3 days of death. The percentage of patients admitted or discharged within 3 days of death did not vary greatly by age, race, ethnicity, gender, or most recent modality. Over time, the frequency of these potentially burdensome transitions increased slightly from 26.4% in 2000 to 27.6% in 2013.

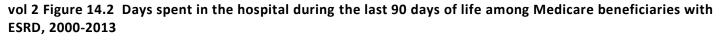
vol 2 Figure 14.1 Hospital admission during the last 90 days of life among Medicare beneficiaries with ESRD, 2000-2013

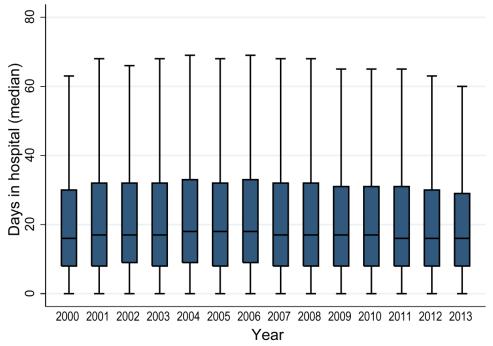


Data Source: Special analyses, USRDS ESRD Database. Denominator is all decedents with Medicare Parts A and B throughout the last 90 days of life. Includes hospital stays in both short- and long-stay hospitals. Abbreviation: ESRD, end-stage renal disease.

DAYS SPENT IN THE HOSPITAL

Patients with Medicare Parts A and B who were admitted to the hospital at least once during the last 90 days of life had a median of 2 admissions during this time frame (interquartile range [IQR], 1, 3) and 27.7% had 3 or more admissions. The percentage of patients admitted to the hospital and the median number of admissions were stable over time and similar in all subgroups. Those admitted to the hospital during the last 90 days of life spent a median of 17 days in the hospital (IQR, 8, 31) (Figure 14.2). The median number of days spent in the hospital during the last 90 days of life changed very little from 2000 through 2013.



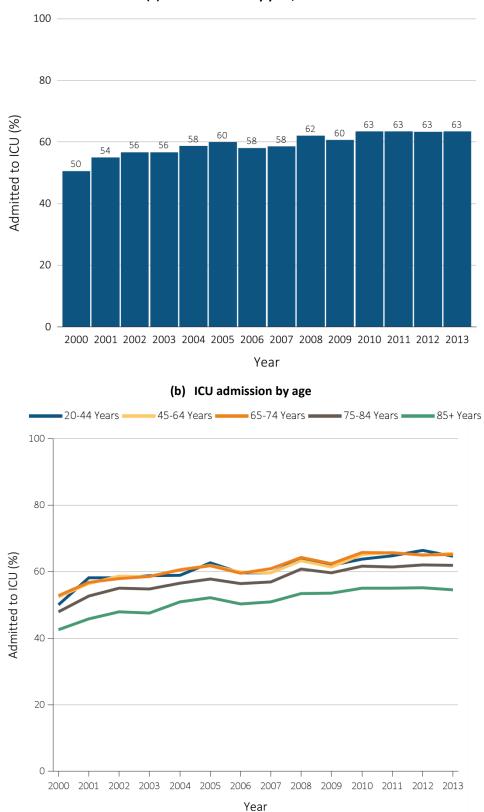


Data Source: Special analyses, USRDS ESRD Database. Denominator is all decedents with Medicare Parts A and B throughout the last 90 days of life who were admitted to the hospital at least once. Includes hospital stays in both short- and long-stay hospitals. Explanation of box plot: The lower border of the box is the first quartile and the upper border is the third quartile of the distribution, the length of the box is the interquartile range and the line in the middle of the box is the median value. The whiskers (vertical lines above and below each box) extend from the lowest value of the distribution that is \geq the first quartile plus 1.5 times the interquartile range at the bottom to the highest value of the distribution: ESRD, end-stage renal disease.

ICU ADMISSION

Overall, 59.0% of patients were admitted to an ICU during the last 90 days of life (Figure 14.3). The percentage admitted to the ICU was highest for those aged 65-74 years (61.3%) and lowest for those aged 85 years and older (51.7%), was highest for Asians (62.6%) and lowest for patients of Other race (46.9%), was higher for Hispanics vs. non-Hispanics (63.6% vs. 58.9%), was slightly higher for women vs. men (60.5% vs. 57.7%), and was similar in patients whose most recent modality was hemodialysis vs. peritoneal dialysis vs. transplant (59.2% vs. 57.4% vs. 57.2%). Over time, the percentage of patients admitted to the ICU during the last 90 days of life increased from 50.1% in 2000 to 62.9% in 2013. There was an increase in the percentage of patients admitted to the ICU over time among all subgroups examined. The percentage of patients admitted to an ICU in the last three months of life ranged from 28.9% to 71.9% across states in the continental United States. More intensive use of ICU was found in the Southern tier of states.

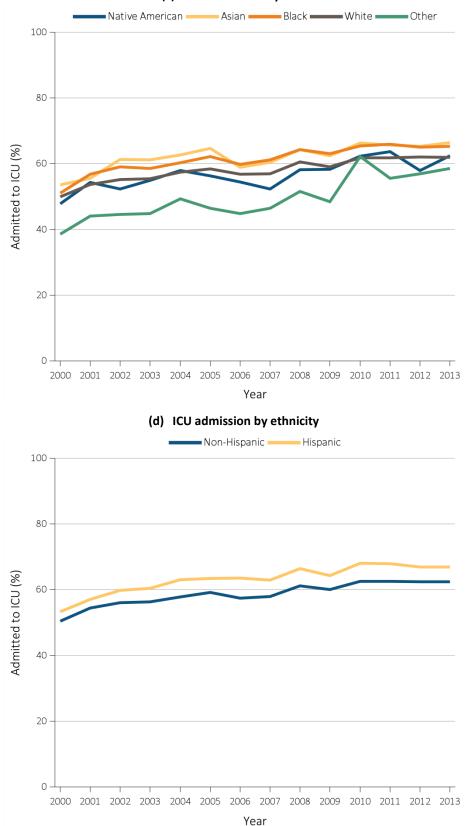
vol 2 Figure 14.3 ICU admission during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2013



(a) ICU admission by year, overall

Figure 14.3 continued on next page.

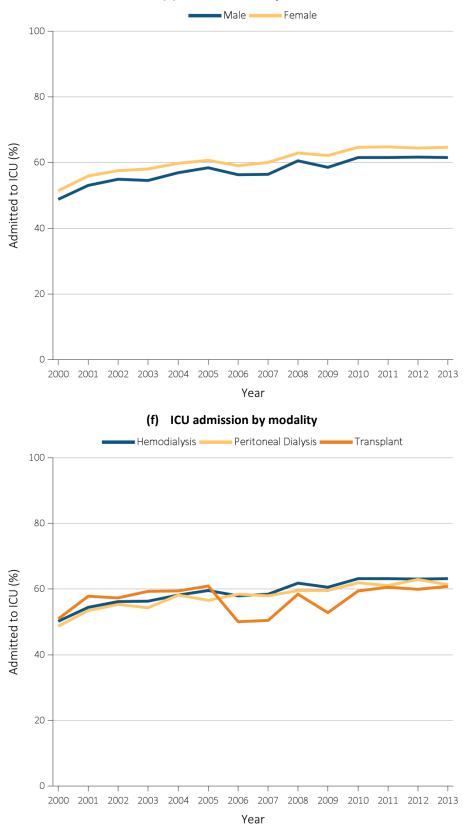
vol 2 Figure 14.3 ICU admission during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2013 (continued)



(c) ICU admission by race

Figure 14.3 continued on next page.

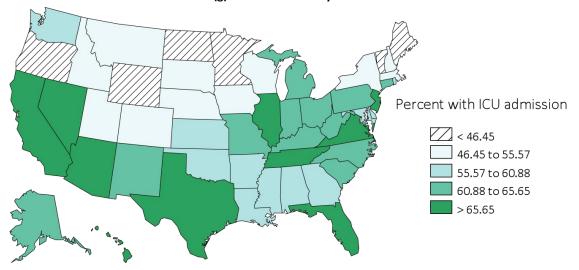
vol 2 Figure 14.3 ICU admission during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2013 (continued)



(e) ICU admission by sex

Figure 14.3 continued on next page.

vol 2 Figure 14.3 ICU admission during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2013 (continued)



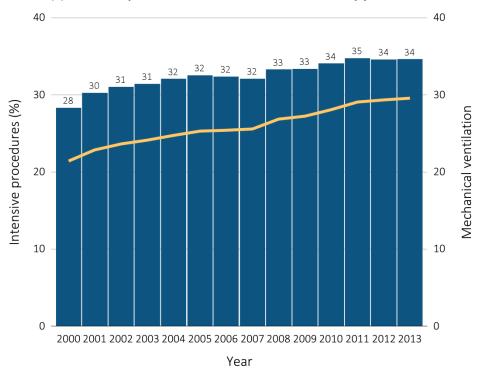
(g) ICU admission by state

Data Source: Special analyses, USRDS ESRD Database. Denominator is all decedents with Medicare Parts A and B throughout the last 90 days of life. ICU admission was identified using ICU revenue center codes in Medicare Institutional claims. Abbreviations: ESRD, end-stage renal disease; ICU, Intensive care unit.

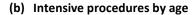
INTENSIVE PROCEDURES

A total of 32.4% of decedents had an inpatient intensive procedure during the last 90 days of life and 26.0% of patients were intubated or received mechanical ventilation (Figure 14.4). The percentage of patients receiving intensive procedures during the last 90 days of life was highest for those aged 20-44 years (42.5%) and lowest for those aged 85 years and older (20.7%), was highest for Blacks (41.2%) and lowest for Whites (28.5%), was higher for Hispanics vs. non-Hispanics (38.4% vs. 31.6%), was slightly higher for women vs. men (33.4% vs. 31.5%), and was higher for those with transplant vs. hemodialysis vs. peritoneal dialysis as the most recent modality (38.0% vs. 32.2% vs. 30.5%). Over time, the percentage of patients who received an intensive procedure increased from 28.2% in 2000 to 34.4% in 2013. The percentage of patients who were intubated or received mechanical ventilation during the last 90 days of life increased from 21.4% to 29.6% over the same time period. The percentage of patients receiving an intensive procedure increased over time for most subgroups examined. The percentage of patients who received an intensive procedure during the last 90 days of life ranged from 14.6% to 46.4% across states in the continental United States. Use of intensive procedures roughly paralleled ICU use by region. Higher rates were found in the Southern tier of States.

vol 2 Figure 14.4 Intensive procedures during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2013



(a) Intensive procedures and mechanical ventilation by year, overall



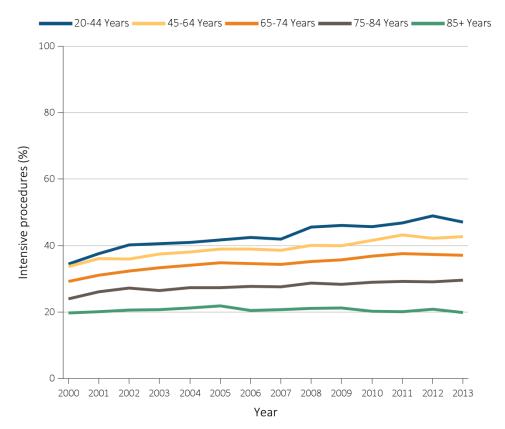
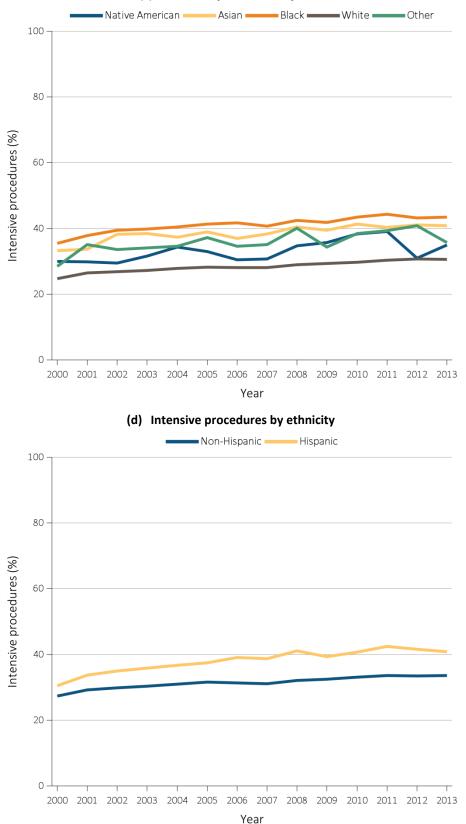


Figure 14.4 continued on next page.

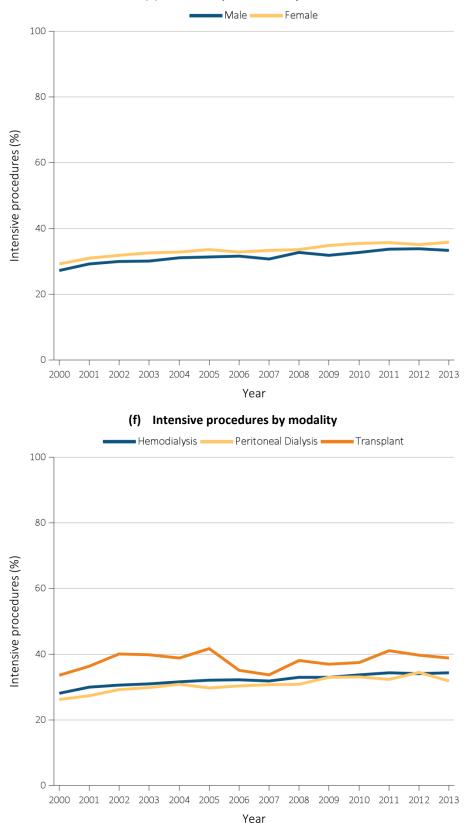
vol 2 Figure 14.4 Intensive procedures during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2013 (continued)



(c) Intensive procedures by race

Figure 14.4 continued on next page.

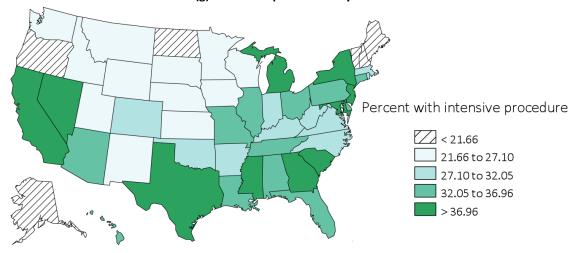
vol 2 Figure 14.4 Intensive procedures during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2013 (continued)



(e) Intensive procedures by sex

Figure 14.4 continued on next page.

vol 2 Figure 14.4 Intensive procedures during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2013 (continued)



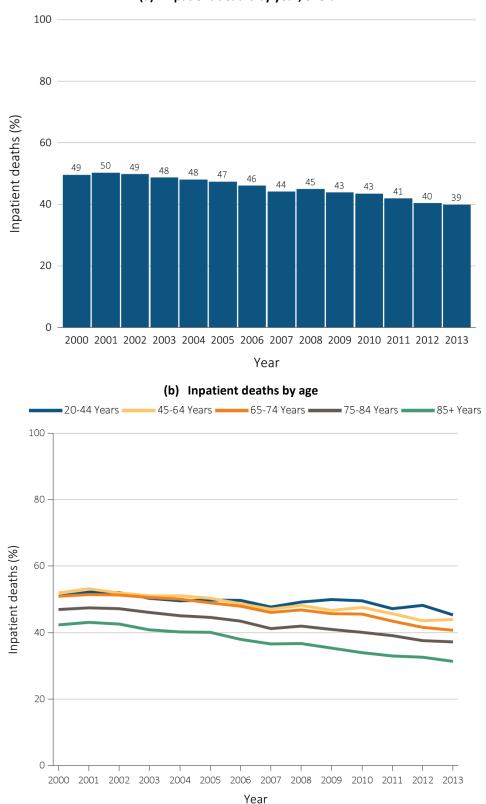
(g) Intensive procedures by state

Data Source: Special analyses, USRDS ESRD Database. Denominator population is all decedents with Medicare Parts A and B throughout the last 90 days of life. Intensive procedures were identified by ICD-9 procedure code search of Medicare Institutional claims from short- and long-stay hospitals. The yellow line in panel (a) denotes the percentage of patients who were intubated or received mechanical ventilation. Abbreviation: ESRD, end-stage renal disease.

INPATIENT DEATHS

Based on Medicare Institutional claims, 45.1% of patients died in the hospital during 2000-2013 (Figure 14.5). The proportion of inpatient deaths was highest for those aged 20-44 years (49.5%) and lowest for those aged 85 years and older (37.0%). Death in the hospital was most common in those of Other race (53.2%) and least common in Whites (42.9%), was more common in Hispanics vs. non-Hispanics (50.5% vs. 44.1%), was more common in women vs. men (46.8% vs. 43.7%), and was more common in patients whose most recent modality was transplant vs. peritoneal dialysis vs. hemodialysis (49.3% vs. 48.5% vs. 44.7%). Over time, the percentage of inpatient deaths decreased from 49.2% in 2000 to 39.4% in 2013; the percentage of inpatient deaths decreased over time for most subgroups examined. When we used information from the CMS Death Notification form, 63.2% of decedents for whom this information was available were reported to have died in the hospital, declining from 68.5% in 2000 to 59.0% in 2013. The sensitivity and specificity of the CMS Death Notification form for detecting inpatient deaths based on Medicare claims were 93% and 63%, respectively, among patients with complete information from both sources.

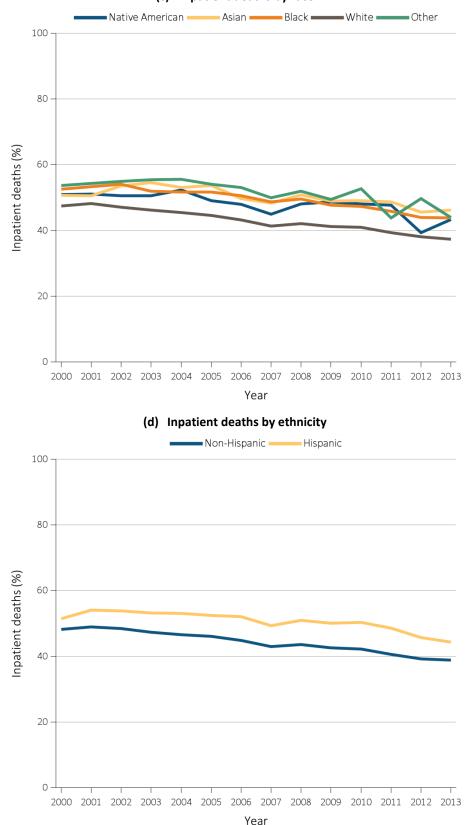
vol 2 Figure 14.5 Inpatient deaths among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2013



(a) Inpatient deaths by year, overall

Figure 14.5 continued on next page.

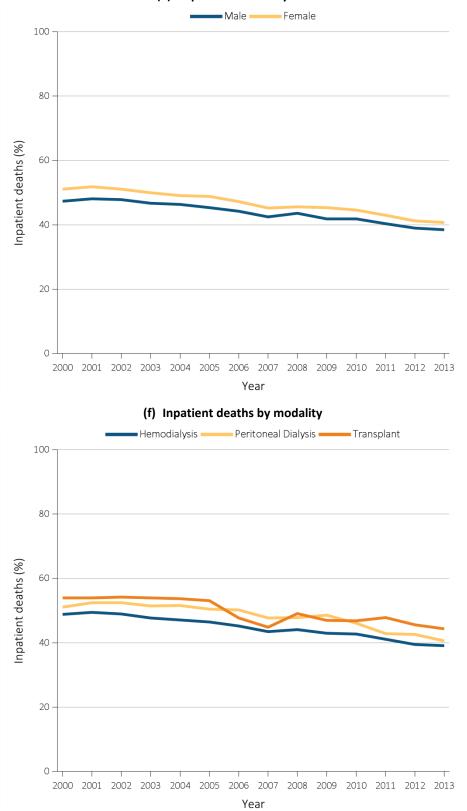
vol 2 Figure 14.5 Inpatient deaths among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2013 (continued)



(c) Inpatient deaths by race

Figure 14.5 continued on next page.

vol 2 Figure 14.5 Inpatient deaths among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2013 (continued)



(e) Inpatient deaths by sex

Data Source: Special Analyses, USRDS ESRD Database. Denominator population is all decedents with Medicare Parts A and B throughout the last 90 days of life. Includes deaths occurring in short- and long-stay hospitals. Abbreviation: ESRD, end-stage renal disease.

Nursing Facility Utilization in the Last Year of Life

We identified a total of 257,022 patients who received care in a nursing facility (i.e., SNF and/or nursing home) in the last year of life (Table 14.2). The average age of decedents who received care in a nursing facility during the last year of life was 71 ±12 years and the median ESRD vintage was 4 (IQR 2, 6) years (Figure 14.6). The characteristics of decedents with ESRD who received care in a nursing facility during in the last year of life did not change substantially between 2000 and 2013.

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Total
N	13,818	14,780	16,026	16,999	18,223	18,683	18,722	18,313	18,996	19,122	19,704	20,918	21,026	21,692	257,022
Age, mean (std)	70.5(11.9)	70.5(12.1)	70.8(12.0)	71.0(12.0)	70.9(12.0)	71.3(12.0)	71.3(12.1)	71.4(12.1)	71.7(12.0)	71.5(12.1)	71.5(12.0)	71.6(11.9)	71.5(12.1)	71.4(12.0)	71.3(12.0
/intage of ESRD, year, mean (std)	4(4)	5(4)	5(4)	5(4)	5(4)	5(4)	5(4)	5(4)	5(4)	5(4)	5(5)	6(5)	6(5)	6(5)	5(4)
/intage of ESRD, year, median (q1,q3)	3(2,6)	3(2,6)	4(2,6)	4(2,6)	4(2,6)	4(2,6)	4(2,6)	4(2,6)	4(2,6)	4(2,7)	4(2,7)	4(2,7)	4(2,7)	4(3,8)	4(2,6)
Age Category															
20-44	3.5	3.6	3.3	3.0	3.1	2.8	2.8	2.7	2.5	2.3	2.3	2.1	2.3	2.2	2.7
45-64	22.3	22.7	22.1	23.0	22.9	22.6	23.5	22.9	22.6	23.8	24.3	24.0	24.9	24.3	23.4
65-74	32.4	31.4	30.9	29.6	29.8	29.0	28.3	28.9	28.9	28.9	28.9	29.4	28.6	30.1	29.5
75-84	32.7	33.0	33.7	34.1	34.0	34.4	33.2	33.0	32.7	31.4	31.0	30.6	30.4	29.6	32.3
>=85	9.1	9.4	10.1	10.3	10.2	11.1	12.2	12.5	13.2	13.5	13.5	13.9	13.9	13.8	12.1
Race															
Native American	1.4	1.0	1.3	1.1	1.1	1.1	1.1	1.1	1.1	1.0	1.0	1.1	1.0	1.0	1.1
Asian	1.9	1.9	1.9	2.2	2.0	2.1	2.3	2.3	2.4	2.5	2.5	2.6	2.8	2.9	2.3
Black/African American	29.6	29.9	29.3	29.1	30.0	29.1	29.6	29.5	28.3	28.9	28.3	28.3	28.4	27.7	28.9
White	66.5	66.3	66.5	66.7	66.0	67.1	66.7	66.8	67.7	67.2	67.8	67.5	67.5	68.2	67.1
Unknown	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0
Other	0.6	0.8	0.9	0.9	0.8	0.5	0.3	0.3	0.4	0.4	0.3	0.4	0.3	0.2	0.5
lispanic															
Missing on Hispanic	0.4	0.5	0.4	0.3	0.3	0.4	0.3	0.2	0.4	0.4	0.4	0.4	0.5	0.5	0.4
Hispanic	8.0	8.5	8.5	8.9	8.6	9.2	8.9	9.0	8.9	9.6	9.3	9.9	10.7	10.8	9.3
Non-Hispanic	81.0	84.7	87.1	88.4	89.2	89.0	89.8	90.1	90.0	89.4	89.7	89.1	88.4	88.4	88.4
Unknown	10.7	6.3	4.0	2.4	1.8	1.5	0.9	0.7	0.8	0.7	0.6	0.6	0.4	0.3	2.0
ex*															
Male	46.0	46.7	46.6	47.0	48.7	48.9	49.3	50.0	50.3	51.4	51.5	51.7	51.7	51.6	49.6
Female	54.0	53.3	53.4	53.0	51.3	51.1	50.6	50.0	49.7	48.6	48.5	48.3	48.3	48.4	50.4
ast Treatment Modality															
Missing on modality	9.7	10.7	11.6	11.1	11.8	12.3	13.1	12.4	16.2	14.5	15.2	15.5	16.0	16.6	13.6
Hemodialysis	82.0	82.0	82.0	82.4	81.8	81.8	81.1	82.1	78.1	79.7	78.8	77.9	76.9	76.1	80.0
Peritoneal dialysis	5.4	4.1	3.6	3.4	3.2	2.7	2.8	2.5	2.3	2.0	2.1	2.4	2.5	2.6	2.9
Transplant	2.9	3.2	2.9	3.1	3.2	3.1	3.1	3.1	3.4	3.7	3.9	4.1	4.6	4.7	3.6
Dual eligibility															
Missing on dual eligibility	10.1	10.2	10.7	10.1	9.8	9.5	9.1	9.0	9.4	9.4	9.8	9.3	9.8	4.7	9.3
Dual eligibility	53.6	54.0	53.5	54.5	53.5	53.0	53.8	54.1	54.0	53.6	54.0	53.6	53.0	56.0	53.9
Non-dual eligibility	36.3	35.7	35.8	35.4	36.7	37.6	37.1	36.9	36.6	37.0	36.2	37.1	37.2	39.3	36.9
Aedicare Parts A&B as primary payer luring last 365 days of life															
Yes Data Source: Special analyses, USRDS ES	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

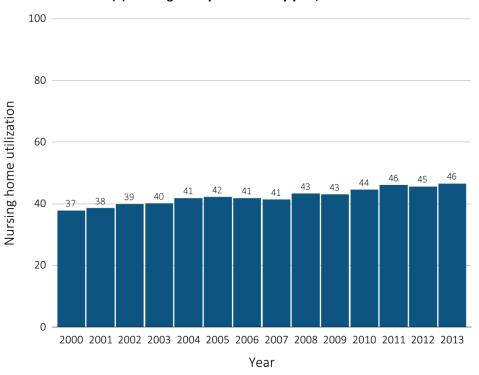
end-stage renal disease.

Overall, 42.0% of patients with ESRD received care in a nursing facility during the last year of life, increasing from 37.4% in 2000 to 46.1% in 2013. Nursing facility care at the end of life increased among all age groups between 2000 and 2013, with the highest use among the oldest age group, those aged 85 and older (57.2%). Women were more likely than men to receive nursing facility care at the end of life (46.1% vs. 38.3%). Whites were more likely to receive nursing facility care at the end of life compared to Blacks, Asians, and those of Other race (43.5% vs. 40.4% vs. 33.5% vs. 23.0%), and non-Hispanics were more likely to receive nursing facility care than Hispanics (43.2% vs. 34.1%). There were marked differences in receipt of nursing facility care at the end of life by modality, with the highest percentage among patients receiving hemodialysis (43.0%), followed by transplant recipients (27.8%), followed by those receiving peritoneal dialysis (22.3%). Notably, patients receiving peritoneal dialysis were the only group for whom nursing facility care at the end of life decreased over time, from 25.8% in 2000 to 23.6% in 2013.

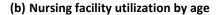
An increase over time in the percentage of patients receiving nursing facility care at the end of life was accompanied by an increase in the total number of days spent in a nursing facility at the end of life. Overall, those admitted to a nursing facility in the last year of life spent a median of 54 days (IQR 18, 162) in a nursing

facility, increasing from 43 days (IQR 14, 144) in 2000 to 57 days (IQR 20, 166) in 2013. The median number of nursing facility days covered by Medicare Part A claims, which is part of the postacute hospitalization SNF benefit, was 30 (IQR 8, 75). Median number of nursing facility days increased over time for all age groups except for those aged 85 years and older. Among this age group, the median number of days spent in a nursing facility during the last year of life decreased from 71 days (IQR 19, 228) to 63 days (IQR 23, 194) between 2000 and 2013. Consequently, by 2013 there were only modest differences across age groups in the number of days spent in a nursing facility during the last year of life. There were large differences in the median number of days spent in a nursing facility by race. Asians (59 days [IQR 16, 204]) and Blacks (64 days [IQR 20, 195]) had the highest median number of nursing facility days, whereas Whites had shorter median nursing facility days (50 days [IQR 17, 147]). Median nursing facility days also differed substantially by modality, with hemodialysis patients spending the longest median number of days in a nursing facility (56 days [IQR 19, 169]), as compared with transplant recipients (31 days (IQR 11, 84)) and peritoneal dialysis patients (25 days [IQR 8, 77]).

vol 2 Figure 14.6 Nursing facility utilization in the last year of life among decedents overall, and by age, race, ethnicity, sex, and modality, 2000-2013



(a) Nursing facility utilization by year, overall



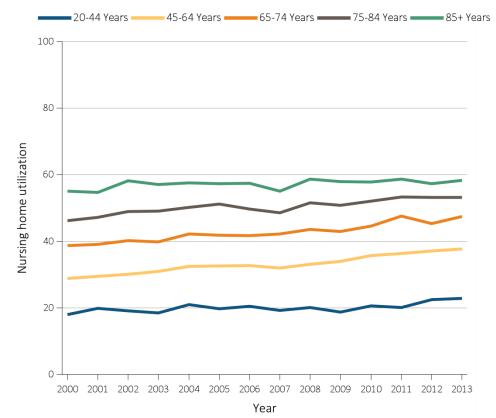
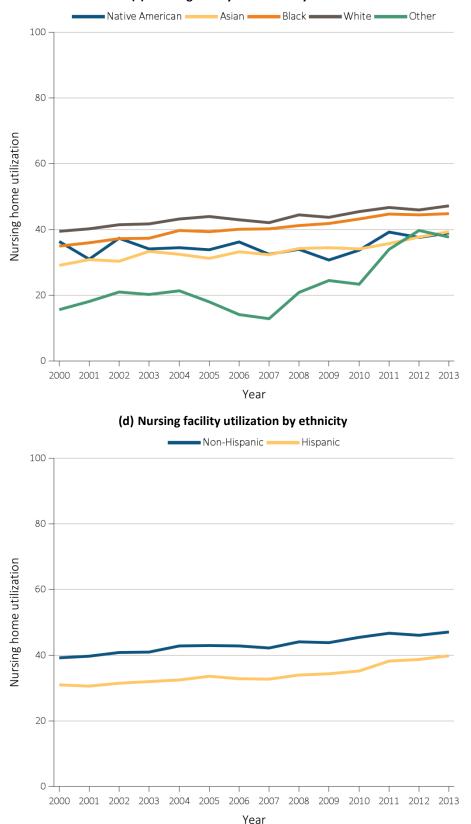


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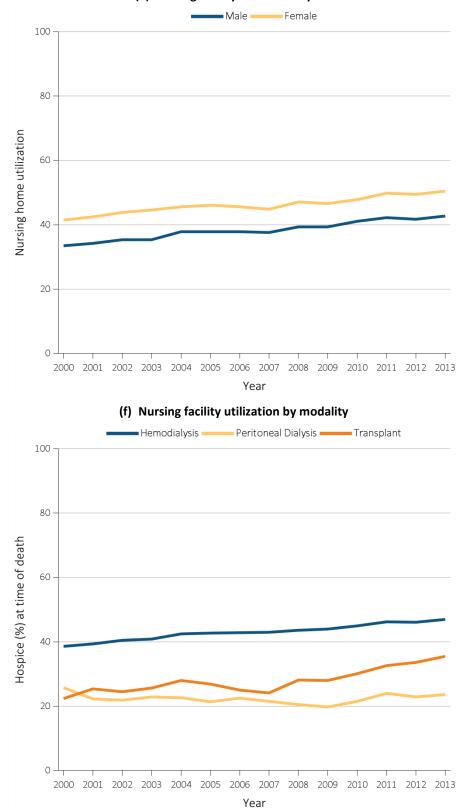
vol 2 Figure 14.6 Nursing facility utilization in the last year of life among decedents overall, and by age, race, ethnicity, sex, and modality, 2000-2013 (continued)



(c) Nursing facility utilization by race

Figure 14.6 continued on next page.

vol 2 Figure 14.6 Nursing facility utilization in the last year of life among decedents overall, and by age, race, ethnicity, sex, and modality, 2000-2013 (continued)



(e) Nursing facility utilization by sex

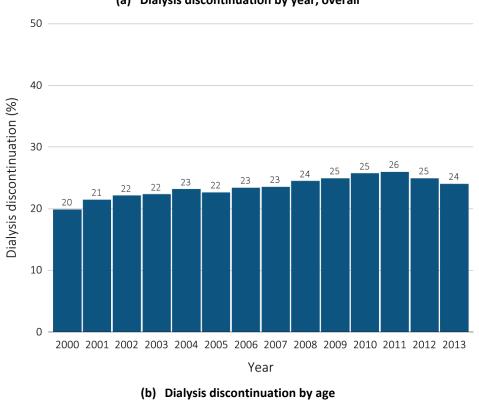
Data Source: Special analyses, USRDS ESRD Database. Denominator population is all decedents admitted to a nursing home during the last year of life. Abbreviation: ESRD, end-stage renal disease.

Dialysis Discontinuation Before Death

Overall, 23.4% of patients with either hemodialysis or peritoneal dialysis listed as their most recent modality were reported to have discontinued dialysis treatments before death on the CMS Death Notification Form (Figure 14.7). The frequency of dialysis discontinuation before death was highest for patients aged 85 years and older (34.1%) and lowest for those aged 20-44 years (11.2%), was highest for Whites (27.6%) and lowest for patients of Other race (10.6%), was higher for non-Hispanics vs. Hispanics (22.3% vs. 17.9%), was higher for women vs. men (24.0% vs. 22.0%), and for those whose most recent modality was hemodialysis vs. peritoneal dialysis (23.4% vs. 22.3%). The median time from discontinuation to death as reported on the CMS Death Notification form was 6 days (IQR, 3, 12 days). This interval was slightly

shorter for those treated with peritoneal dialysis (4 days, IQR, 2, 8 days) vs. hemodialysis (7 days, IQR, 3, 12 days), and slightly longer for those who received hospice (7 days, IQR, 4, 13 days) vs. those who did not (4 days, IQR, 2, 8 days). Over time, there was an upward trend in the percentage of decedents who discontinued dialysis before death from 19.6% in 2000 to 25.8% in 2011, with a slight decrease more recently to 23.8% in 2013. The percentage of decedents who discontinued dialysis generally increased over time for most subgroups examined over this time period. The percentage of patients who discontinued dialysis before death ranged from 12.7% to 47.6% across states in the continental United States. The lowest rates of discontinuation occurred in the Southern tier of states, roughly paralleling higher rates of intensive procedures and ICU use at the end of life.

vol 2 Figure 14.7 Dialysis discontinuation before death among decedents overall, and by age, race, ethnicity, sex, and modality, 2000-2013



(a) Dialysis discontinuation by year, overall

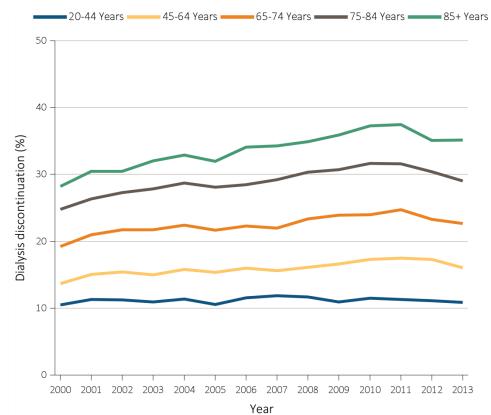
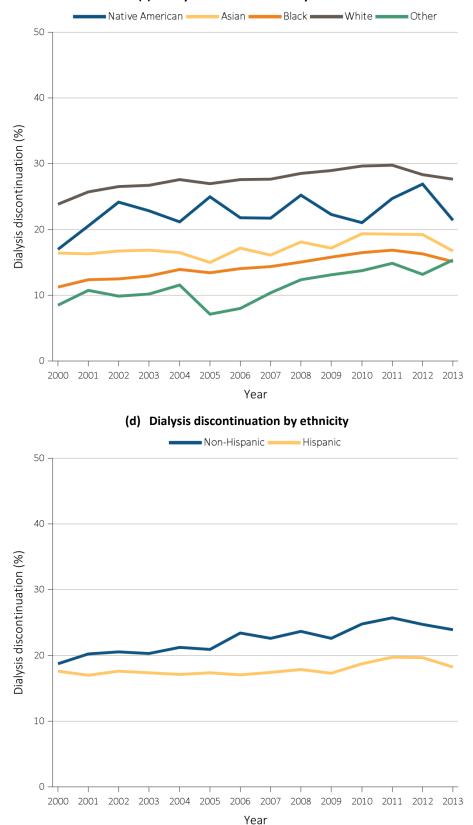


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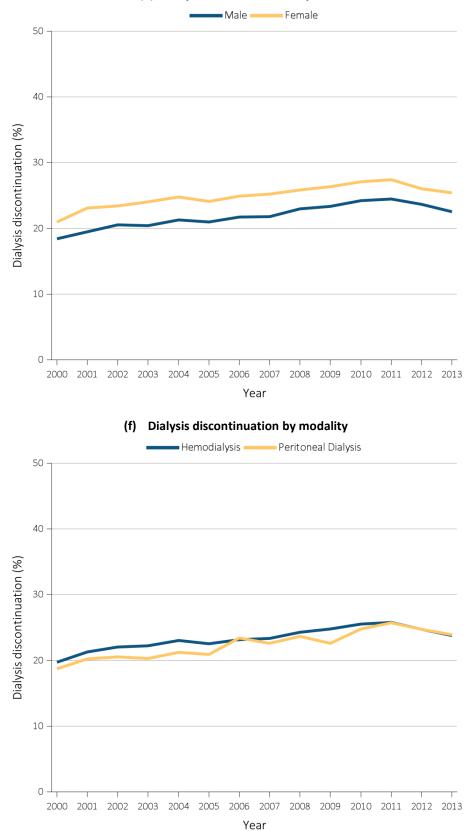
vol 2 Figure 14.7 Dialysis discontinuation before death among decedents overall, and by age, race, ethnicity, sex, and modality, 2000-2013 (continued)



(c) Dialysis discontinuation by race

Figure 14.7 continued on next page.

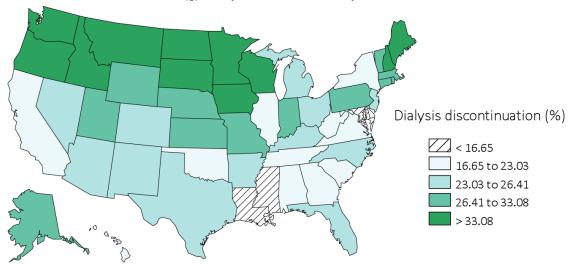
vol 2 Figure 14.7 Dialysis discontinuation before death among decedents overall, and by age, race, ethnicity, sex, and modality, 2000-2013 (continued)



(e) Dialysis discontinuation by sex

Figure 14.7 continued on next page.

vol 2 Figure 14.7 Dialysis discontinuation before death among decedents overall, and by age, race, ethnicity, sex, and modality, 2000-2013 (continued)



(g) Dialysis discontinuation by state

Data Source: Special analyses, USRDS ESRD Database. Denominator population is all patients with complete data on dialysis discontinuation from the CMS ESRD Death Notification form (CMS 2746). Abbreviation: ESRD, end-stage renal disease.

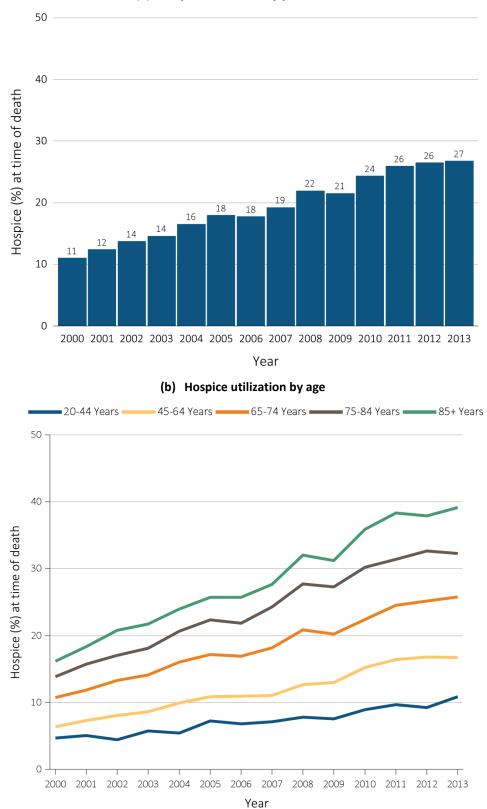
Patterns of Hospice Utilization Before Death

Overall, 19.2% of patients with Medicare Parts A and B as primary payer were receiving hospice at the time of death based on Medicare Institutional claims (Figure 14.8). Use of hospice services was highest for patients aged 85 years and older (29.4%) and lowest for those aged 20-44 years (7.0%), was highest for Whites (22.7%) and lowest for those of Other race (7.7%), was higher for non-Hispanics vs. Hispanics (20.2% vs. 15.5%), was higher for women vs. men (20.2% vs. 18.4%), and was higher for those whose most recent modality was hemodialysis vs. peritoneal dialysis vs. transplant (19.3% vs. 18.6% vs. 18.3%). The percentage of patients receiving hospice services at the time of death based on Medicare claims differed markedly according to whether patients did or did not discontinue dialysis based on the CMS Death Notification form (53.2 % vs. 9.1%), most likely reflecting both the intertwined nature of these two treatment decisions and financial and regulatory barriers to concurrent receipt of dialysis and hospice services for many patients with ESRD (Murray et al., 2006). The percentage of patients receiving hospice services at the time of death increased from 10.8% in

2000 to 26.6% in 2013; hospice utilization increased over time for most subgroups. Hospice use at the time of death ranged from 14.7% to 39.8% across states in the continental United States, although regional patterns of hospice use did not correspond with those of other markers of healthcare intensity such as use of intensive procedures, ICU admission and dialysis discontinuation. Overall, 21.1% of patients with Medicare Parts A and B as primary payer had an institutional claim for hospice in the last 90 days of life. Among these, the median interval between the first claim for hospice within this time frame and death was 5 days (IQR, 2, 13 days) and 39.6% of patients had their first claim for hospice \leq 3 days before death.

Figure 14.8 shows trends in receipt of hospice care at the time of death based on Medicare claims. In a separate analysis using information on hospice use from the CMS Death Notification form, 24.0% of decedents for whom this information was available were reported to have received hospice care before death (data available only from 2004-2013). The sensitivity and specificity of the CMS Death Notification form for detecting hospice at the time of death based on Medicare claims were 83% and 92%, respectively, among patients with complete

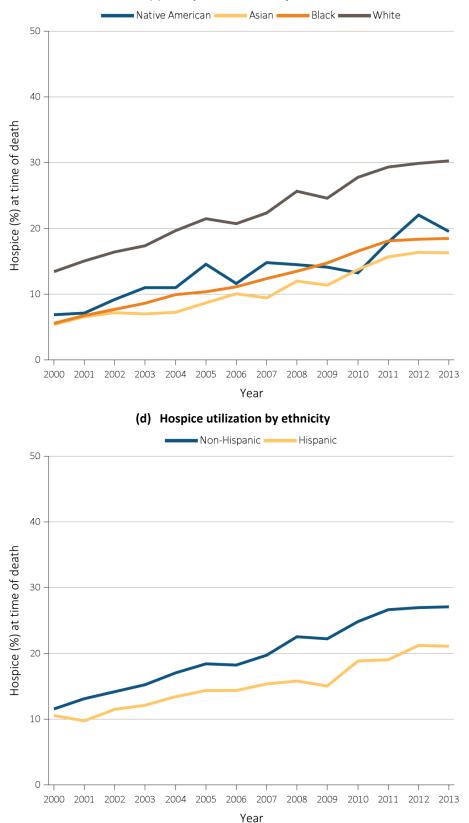
information from both sources. As for claims-based analyses, the percentage of patients who received hospice care before death based on the CMS Death Notification form was highly correlated with dialysis discontinuation before death: 74.3% of those who had discontinued dialysis before death received hospice as compared with 6.7% of those who had not discontinued dialysis. From 2004-2013, the percentage of patients who received hospice care prior to death based on the CMS Death Notification form increased from 17.5% to 27.5% in the overall population for whom this was reported, from 59.3% to 81.5% for those who discontinued dialysis treatments before death, and from 5.4% to 7.8% for those who did not. vol 2 Figure 14.8 Hospice utilization at the time of death among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, modality, and whether dialysis was discontinued, 2000-2013



(a) Hospice utilization by year, overall

Figure 14.8 continued on next page.

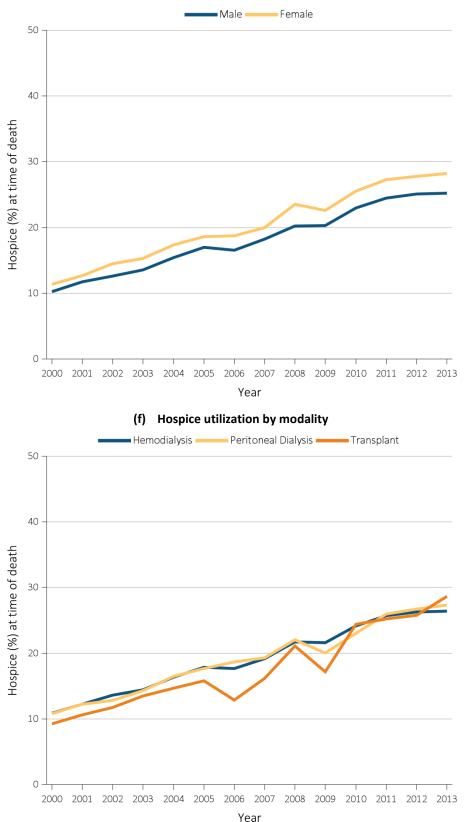
vol 2 Figure 14.8 Hospice utilization at the time of death among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, modality, and whether dialysis was discontinued, 2000-2013 (continued)



(c) Hospice utilization by race

Figure 14.8 continued on next page.

vol 2 Figure 14.8 Hospice utilization at the time of death among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, modality, and whether dialysis was discontinued, 2000-2013 (continued)

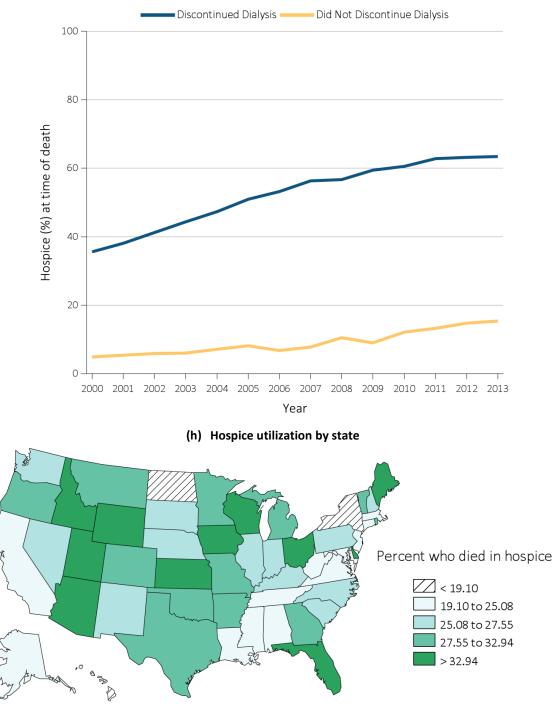


(e) Hospice utilization by sex

Figure 14.8 continued on next page.

vol 2 Figure 14.8 Hospice utilization at the time of death among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, modality, and whether dialysis was discontinued, 2000-2013 (continued)

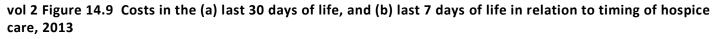
(g) Hospice utilization by whether patients discontinued dialysis before death



Data Source: Special analyses, USRDS ESRD Database. Denominator population is all decedents with Medicare Parts A and B throughout the last 90 days of life. Receipt of hospice care at the time of death was defined as having a claim in the Hospice SAF on or after the date of death or Discharge Status from hospice=40, 41, or 42. Abbreviation: ESRD, end-stage renal disease.

End-of-life Costs for Services Under Medicare Parts A and B

For ESRD patients who died in 2013, median per person costs under Medicare Parts A and B were \$119,937 (IQR \$ 77,216, \$ 181,469) over the last year of life, \$20,731 (IQR, \$9,944, \$36,147) over the last 30 days of life, and \$8,180 (IQR, \$ 1,893, \$ 15,403) over the last 7 days of life (Figure 14.9). Median costs over the last 30 days of life were progressively lower for patients with a longer time interval between the first claim for hospice and death, ranging from \$8,351 for those referred to hospice more than 2 weeks before death (IQR, \$5,514, \$16,285) to \$24,405 for those first referred to hospice 2 days or less before death (IQR, \$15,906, \$37,238), as compared with the referent group without a claim for hospice during the last 90 days of life (\$22,000; IQR, \$10,675, \$39,119). Median costs during the last 7 days of life were also lower for those referred earlier to hospice, ranging from \$1,553 (IQR, \$1,199, \$2,842) for those referred more than 2 weeks before death to \$11,036 (IQR, \$5,486, \$15,645) for those not referred until the last 2 days of life, as compared with the referent group without a claim for hospice during the last 90 days of life (\$10,441; IQR, \$2,455, \$17,330).



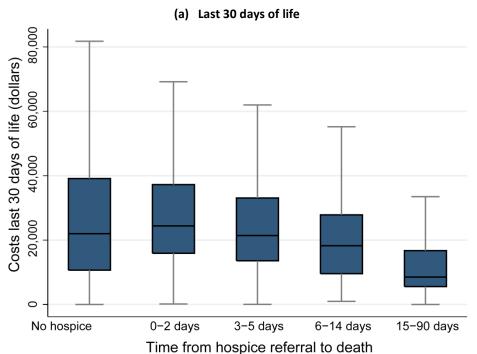
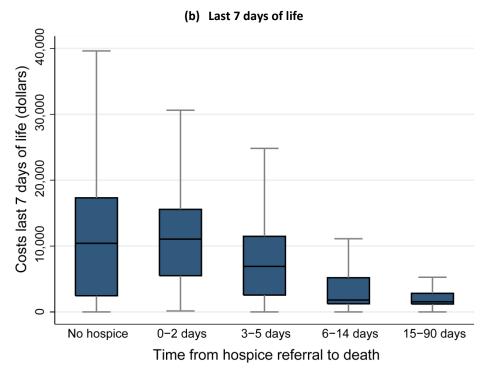


Figure 14.9 continued on next page.

vol 2 Figure 14.9 Costs in the (a) last 30 days of life, and (b) last 7 days of life in relation to timing of hospice care, 2013 *(continued)*



Data Source: Special analyses, USRDS ESRD Database. Denominator population is all decedents with Medicare Parts A and B throughout the last 90 days of life exclusive of those patients without any costs during the last 30 days of life and those with negative costs. Date of the first claim in the Hospice SAF (HCFASAF=H) within the last 90 days of life is taken as the date of first receipt of hospice services. Timing of hospice referral in relation to death was categorized as 0-2 days, 3-5 days 6-14 days, and 15-90 days). Explanation of box plot: the lower border of the box is the first quartile and the upper border is the third quartile of the distribution, the length of the box is the interquartile range, and the line in the middle of the box is the median value. The whiskers extend from the lowest value of the distribution that is \geq the first quartile minus 1.5 times the interquartile range at the bottom to the highest value of the distribution that is \leq the third quartile plus 1.5 times the interquartile range at the top. Values outside this range (outliers) are not plotted.

Summary

From 2000-2013, there were marked increases in the intensity of inpatient care during the final months of life for patients with ESRD. Over the same time period, there was a decline in inpatient deaths, an increase in nursing home utilization, an increase in dialysis discontinuation and an increase in hospice utilization. Receipt of hospice services occurred less than a week before death in most cases, was closely tied to dialysis discontinuation, and was associated with lower costs during the last days and weeks of life.

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VOLUME 2: ESRD ANALYTICAL METHODS

Introduction

In the ESRD Analytical Methods chapter, we present details on the United States Renal Data System (USRDS) database, its standardized working datasets and specialized code definitions, and the common data processing practices applied to the data used in the production of this Annual Data Report (ADR). We also describe the statistical methods used in the ADR. The Researcher's Guide to the USRDS Database, available through <u>www.usrds.org</u>, provides additional information about the database and standard analysis files (SAFs). For this ADR, data are reported through December 31, 2014. Some of the outcomes referred to depend on ascertainment of Medicare Claims data, for which careful construction of appropriate denominators based on Medicare as primary payer eligibility are required, and will be indicated by "\$".

Data Sources

The USRDS maintains a relational database of diagnostic and demographic characteristics of endstage renal disease (ESRD) patients, including information on the incidence, prevalence, morbidity, and mortality of this population, as well as biochemical lab results, dialysis and other institutional claims^{\$}, physician/supplier services^{\$}, treatment histories (useful for modality determination), and payer histories (essential for determining denominators for Medicare Claims data as shown below), hospitalization^{\$} and modality events, and details regarding providers. As the ESRD population are typically Medicare beneficiaries (although not always Medicare as primary payer), the main data source for this database is the Centers for Medicare & Medicaid Services (CMS).

HISTORY OF CMS DATA COLLECTION

This section traces the history of data collection for ESRD patients, and discusses the systems that have evolved to house the data. Detailed discussions about the data and analytical methods that are used in each chapter are found in the section titled *Analytical Methods Used in the ESRD Volume*.

In October 1972, by Public Law 92-603, which expanded the Social Security Act (U.S. Government

Publishing Office, 1972), ESRD patients were included as beneficiaries in the Medicare Program. With the provision of insurance coverage for ESRD care now instituted, a means of collecting and utilizing data about that care was sought. The government made efforts to contract out a project to implement a national data collection system, or ESRD registry, between 1974 and 1977, but the effort was not successful. Meanwhile, Medicare expenditures and the number of ESRD beneficiaries began to grow significantly, and both government and the renal community became more concerned with the development of such a national registry (Blagg et al., 1989).

In accordance with the Privacy Act of 1974, which established a formal Systems of Records (SOR) for the protection of collected personal information such as name and Social Security number, a SOR was created for the ESRD program titled the End Stage Renal Disease (ESRD) Program Management and Medical Information System (PMMIS) — SOR system number 09-70-0520 (CMS SOR). This progress toward a data collection system, along with the 1975 and 1976 legislative amendments to the Social Security Act expanding Medicare coverage to ESRD patients, furthered the push for the development of a national ESRD Registry.

In 1977, the Health Care Financing Administration (HCFA), an agency that oversaw Medicare's financing (later renamed the Centers for Medicare & Medicaid Services (CMS)), was established under the department of Health Education and Welfare (HEW), which was renamed Health and Human Services (HHS) in 1979. CMS handles payment and administrative functions for all Medicare recipients on a regional (e.g., state) level. Originally, this was done through contracted intermediaries (Part A services) and carriers (Part B services). In recent years, the Parts A and B bill processing function has been combined into Medicare Administrative Contractors (MACs). Furthermore, CMS contracts with 18 regional ESRD Network offices that perform research and data collection activities, assure quality of medical care, and adjudicate patient grievances.

In June of 1978, Public Law 95-292 addressed the need for significant improvements to ensure costeffective quality of care in the ESRD program. This

finally led to the development of a comprehensive Medicare-based data system for the ESRD program within the HCFA (Rettig and Levinsky, 1991; CMS Fact Sheet, 2012). Thus, the original data storage system was created and it was known by the same name as the official SOR title, the ESRD Program Management and Medical Information System (PMMIS). It was established to provide medical and cost information for ESRD program analysis, policy development, and epidemiologic research (CMS Fact Sheet, 2012).

The PMMIS gathered information on Medicare ESRD patients and Medicare-approved ESRD hospitalbased and independent dialysis facilities. Data were compiled via Medicare claims and data forms that were collected through the Medicare intermediaries. The forms included the Medical Evidence form (CMS 2728), the Death Notification form (CMS 2746), and the Facility Survey form (CMS 2744). Other files maintained in the system included the Patient Identification File, the Transplant File, the Transplant Follow-up File, the Quarterly Dialysis File, and the Hospital Inpatient Stay Record File. There was no mandatory compliance for data collection, so early data is quite incomplete. In 1981, reporting on the incidence of ESRD was mandated as a requirement for Medicare Entitlement and a new Medical Evidence form was introduced. Since that time, there has been continuous improvement in the completeness of the data (CMS Fact Sheet, 2012). The PMMIS was maintained on HCFA computers, and was a batchoriented Model 204 (M204 IBM Mainframe) data system.

Initially, HCFA was required to submit an annual report to Congress on the ESRD program and three reports were published (HCFA 1979, 1980, 1982). Due to the burden for HCFA of compiling many related reports, Congress rescinded the requirement for a separate report and the agency was permitted to include the ESRD program in its annual report on the whole Medicare program (CMS, Fact Sheet, 2012). This level of reporting did not, however, adequately meet the needs of the renal community for reliable data collection and reporting on outcomes and quality of care. Throughout the 1980s, efforts continued to create a comprehensive ESRD registry with reporting beyond that which the PMMIS provided. This need was recognized politically as well as among researchers, and in the Omnibus Budget Reconciliation Act of 1986, Congress called for HHS to establish a "national end-stage renal disease registry". An interagency committee was formed between HHS and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and a Request for Proposal was shortly thereafter issued for the development of the United States Renal Data System (USRDS) to establish a complete ESRD Registry, which was to be built upon and surpass the HCFA data collected by the PMMIS. The contract was awarded by NIDDK in May 1988 to the Urban Institute, with a subcontract to the University of Michigan, and the first USRDS Annual Data Report on the ESRD population was released in 1989.

The specific data systems utilized by CMS to manage the ESRD database have evolved over the years as technology has changed and the need for improvements was identified. In 1995, CMS transitioned from the way data were stored in the original PMMIS, replacing its Medicare ESRD Support Subsystem (MESS) with an enhanced online M204 data system known as the Renal Beneficiary and Utilization System (REBUS). Also in 1995, non-Medicare patients began to be included in the database as the ESRD Medical Evidence Report form (CMS 2728) was again revised and made mandatory for all ESRD patients.

In 2003, the REBUS database was converted into an Oracle relational database known as the Renal Management Information System (REMIS), and the Standard Information Management System (SIMS) database of the ESRD networks was also established.

REMIS calculates Medicare ESRD coverage periods for renal patients and includes operational interfaces to the SIMS Central Repository and the Medicare Enrollment Database (EDB). REMIS also includes sophisticated data quality problem resolution support (CMS REMIS, 2012).

SIMS collected the CMS Medical Evidence, Death Notification, and Facility Survey forms mentioned above, and also included information to track patient movement in and out of ESRD facilities, and their transitions from one treatment modality to another. With the integration of the SIMS events data into the USRDS Database, it became possible to better track

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patients beyond the initiation of treatment. The SIMS events data, along with the mandate for the Medical Evidence form beginning in 1995, allowed for inclusion of patients for whom there previously were no data on initial modality or death. SIMS was replaced by CROWNWeb in 2012.

CROWNWEB AND STANDARD INFORMATION MANAGEMENT SYSTEM DATABASE

CROWNWeb is a web-based data collection system that captures clinical and administrative data from Medicare-certified dialysis facilities for all ESRD patients, and allows authorized users to securely submit, update, and verify data provided to Medicare. This system was rolled out nationally in May 2012. In addition to replacing the patient tracking functionality of SIMS, CROWNWeb also collects new data to support calculation of clinical measures (e.g., Kt/V, hemoglobin, and calcium), and integrates these data with the REMIS system.

Thus, the USRDS Database contains demographic, diagnostic, and treatment history information for all patients with ESRD, regardless of whether they are Medicare beneficiaries. The data are updated on a regular basis using the Medicare EDB, ESRD Medical Evidence and Death Notification Report forms (CMS 2728 and 2746), Medicare Institutional and Carrier claims, and the Organ Procurement and Transplantation Network (OPTN) transplant database. CMS has also established data-integrity rules to ensure accurate identification of patients in the CMS databases.

CMS MEDICARE ENROLLMENT DATABASE

The Medicare EDB is the designated repository of all Medicare beneficiary enrollment and entitlement data, including current and historical information on beneficiary residence, Medicare as secondary payer (MSP) and employer group health plan (EGHP) status, and Health Insurance Claim/Beneficiary Identification Code cross-referencing.

ESRD MEDICAL EVIDENCE FORM (CMS 2728)

The CMS ESRD Medical Evidence Report form (CMS 2728) is used to register patients at the onset of ESRD, and must be submitted by dialysis facilities or transplant centers within 45 days of treatment initiation. The form establishes Medicare eligibility for individuals previously not Medicare beneficiaries, reclassifies previously eligible beneficiaries as ESRD patients, and provides demographic and diagnostic information on all new ESRD patients regardless of Medicare entitlement. The CMS, USRDS, and renal research communities rely on the form to ascertain patient demographics, primary cause of ESRD, comorbidities, and biochemical test results at the time of ESRD initiation.

Prior to 1995, providers were required to file the Medical Evidence form only for Medicare-eligible patients. Since the 1995 revision, however, providers are required to complete the form for all new ESRD patients regardless of Medicare eligibility status. The 1995 revised form included new fields for comorbid conditions, employment status, expanded race categories, ethnicity, and biochemical data at ESRD initiation.

The third major revision of the Medical Evidence form in May 2005 remedied several shortcomings of the 1995 form and its earlier versions. It includes new data collection methods and new variables. It allows users to specify whether the Medicare registration is initial (new ESRD patient), re-entitlement (reinstating Medicare entitlement after a lapse due to no claims being filed for 12 or more months or a functioning graft for 36 or more months), or supplemental (updating missing or incorrect information). This clarifies the intended use of the form without recourse to the "First Regular Dialysis Start Date," and helps chronicle the historical sequence of multiple forms for the same patient. Data fields for nephrologist care, dietitian care, and access type were added, with their respective time intervals relative to ESRD onset. Data on the laboratory values hematocrit, creatinine clearance, BUN, and urea clearance are no longer collected. Added laboratory values are HbAic and lipid profiles (total cholesterol, low-density lipoprotein, high-density lipoprotein, and triglycerides). Additional fields relate to whether patients were informed of transplant options, and if not, why not, and donor type. The Medical Evidence form is the only source of information about the cause of a patient's ESRD. Because the list of diseases has been revised, the USRDS stores the codes from each version so that detail is not lost through conversion of one set of codes to another.

Only one Medical Evidence form is expected for each ESRD patient for the entire ESRD treatment period; however, multiple forms may be filed for patients whose insurance eligibility changes due to therapy changes. For example, transplant patients with functioning grafts after three years lose Medicare benefits if ESRD was the sole qualification for Medicare eligibility. If such a patient experiences graft failure and returns to dialysis, a second Medical Evidence Report must be filed to reestablish Medicare eligibility. Dialysis patients who discontinue dialysis for more than 12 months also lose Medicare ESRD benefits. If such a patient returns to dialysis or undergoes kidney transplant, a second Medical Evidence form must be filed to reestablish Medicare eligibility.

Both the 2005 and 1995 versions of the CMS 2728 form are provided in the USRDS Core SAF dataset and are available in the USRDS Researcher's Guide, Appendix D: Data Collection Forms on the USRDS website: <u>www.usrds.org/research.aspx</u>.

ESRD DEATH NOTIFICATION FORM (CMS 2746)

The ESRD Death Notification form (CMS 2746) is used to report the death of ESRD patients. According to CMS policy, this form must be submitted by dialysis or transplant providers within 30 days of a patient's death, and provides the date and causes of death (primary and secondary), reasons for discontinuation of renal replacement therapy, if applicable, and evidence of hospice care prior to death. It is the primary source of death information for CMS and the USRDS, identifying more than 90% of deaths. The USRDS also utilizes several supplemental data sources for ascertaining death (see the Death Date Determination section below for more details). The USRDS has not used the National Death Index due to the prohibitive cost of obtaining this for the U.S. dialysis population.

ANNUAL FACILITY SURVEY (CMS 2744)

In addition to the CMS ESRD databases, independent ESRD patient counts are available from the CMS Annual Facility Survey (AFS) (CMS 2744). Every facility approved by Medicare to provide services to ESRD patients must provide the information requested in the AFS. It is also the facility's responsibility to provide patient and treatment counts to their local ESRD Network upon termination of operations. Facilities certified as only providing inpatient services are not requested to complete a survey. The AFS reports the counts of patients being treated at the end of the year, new ESRD patients starting treatment during the year, and patients who die during the year. Both Medicare and non-Medicare end-of-year patients are counted. While AFS files do not carry patient-specific demographic and diagnosis data, they provide independent patient counts used to complement the CMS patient-specific records. In addition, CMS 2744 includes facility level information such as ownership, services offered, number of stations, and detailed staffing data. Starting with the 2005 AFS, CMS stopped posting data from these surveys on the Internet. Beginning with the 2007 ADR, the USRDS extracted the relevant facility survey data directly from the SIMS database. Beginning in 2012, when SIMS was replaced by CROWNWeb, the USRDS received the facility survey data directly from CROWNWeb.

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK DATABASE

In the early 1980s, CMS began collecting data on all Medicare kidney transplants in the PMMIS data system. In 1984, the National Organ Transplant Act established the Organ Procurement and Transplant Network (OPTN) to collect data and maintain a registry for organ matching and transplantation. The United Network for Organ Sharing (UNOS) was awarded the OPTN contract in 1988 to provide a national system for allocating donor organs and to maintain a centralized data depository for organ transplants. OPTN also began collecting data on all transplants. The OPTN and CMS collection efforts were consolidated in 1994 and only OPTN continued to collect data on transplant donors and recipients. In addition to these sources, transplants are also identified from Medical Evidence forms that indicate transplant as the initial modality, from CROWNWeb transplant events, and from institutional inpatient claims.

CMS STANDARD ANALYTICAL FILES

The CMS ESRD SAFs contain data from final action claims submitted by Medicare beneficiaries, in which all adjustments have been resolved. For Part A

- Inpatient
- Outpatient
- Skilled Nursing Facility
- Home Health Agency
- Hospice

For Part-B Physician/Supplier, the USRDS uses the following 100% SAF claims:

- Physician/Supplier
- Durable Medical Equipment

CMS SAFs are updated each quarter through June of the following year, when the annual files are finalized. Datasets for the current year are created six months into the year and updated quarterly until finalized at 18 months, after which files are frozen and will not include late arriving claims. The data lag behind assessments of death and graft loss by about nine months. Annual files are thus approximately 98% complete. The USRDS 2015 SAF includes all claims up to December 31, 2013. Patient-specific demographic and diagnosis information, however, includes data as recent as June 2015. The 2016 ADR includes claims up to December 31, 2014.

CMS PRESCRIPTION DRUG EVENT FILE

In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), amending the Social Security Act by adding Part D under Title XVIII. With this new Part D coverage, health plans must submit a summary record called the prescription drug event (PDE) record to CMS whenever a Medicare beneficiary fills a prescription. Each drug is identified by a National Drug Code (NDC). The record also contains prescription dosage information, drug costs above and below the out-of-pocket threshold, other true out-ofpocket (TrOOP) amounts, plan paid amounts, and low-income cost sharing subsidy amounts. The USRDS 2016 ADR includes 2006-2014 PDE data.

CMS 5% STANDARD ANALYTICAL FILES

The CMS 5% general Medicare SAFs are a random sample of 5% of the entire Medicare population, and contain billing data from final action claims submitted

for Medicare beneficiaries in which all adjustments have been resolved. CMS and its contractors produce the Medicare 5% datasets by selecting all final action claims for Medicare beneficiaries whose CMS Health Insurance Claim (HIC) number ends in 05, 20, 45, 70, or 95. These five two-digit pairs were randomly selected to create a sample containing 5% of the total number of Medicare beneficiaries (Merriman and Asper, 2007). 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 data files until death or a change in the HIC number. Since 2012, the USRDS has received the Master Beneficiary Summary File (formerly the Denominator file), containing demographic information on each beneficiary in the sample, as well as dates of enrollment in the various Medicare programs (Hospital Insurance [Part A], Supplemental Medical Insurance [Part B], Medicare Advantage managed care plans [Part C], and Prescription Drug Benefit [Part D]). Institutional claims for beneficiaries in the Medicare 5% sample are received in five files, which are based on type of medical service: inpatient, outpatient, home health agency, hospice, and skilled nursing facility. Physician and Supplier claims (also referred to as Carrier Claims) are comprised of one file for durable medical equipment and another file for all other Part B covered services. These files collectively are referred to as the Medicare 5% files in the ADR. The 5% files are used to conduct studies on Healthy People 2020 objectives, comparing preventive care and other non-ESRD disease treatments in general Medicare and ESRD patients. The 5% files are also used to construct CKD, diabetes, and congestive heart disease cohorts based on billing data. The total Medicare 5% sample is used to develop total Medicare cost and utilization data for comparison purposes.

CMS DIALYSIS FACILITY COMPARE DATA

The USRDS uses the CMS Dialysis Facility Compare data to define corporation name and ownership type for each renal facility. Prior to the 2003 ADR, similar data were extracted from the Independent Renal Facility Cost Report (CMS 265-94).

CDC NATIONAL SURVEILLANCE DATA

During 1993-1997 and 1999-2002, the Centers for Disease Control and Prevention (CDC) used its survey

National Surveillance of Dialysis-Associated Diseases in the United States to collect information from dialysis facilities on patient and staff counts, membrane types, reuse practices, water treatment methods, therapy types, vascular access use, antibiotic use, hepatitis vaccination and conversion rates (for both staff and patients), as well as the incidence of HIV, AIDS, and tuberculosis. None of the information is patient-specific. Because the CDC terminated this program in 2003, the last surveillance report is for 2002 data. The CDC did not conduct a survey in 1998.

UNITED STATES CENSUS

The U.S. population data are from the 2000 and 2010 U.S. Census, and also incorporate CDC postcensal and intercensal population estimates. The data and methods for these estimates are available at

http://www.cdc.gov/nchs/nvss/bridged_race.htm. Both intercensal and postcensal estimate datasets are available at

http://www.cdc.gov/nchs/nvss/bridged_race/data_do cumentation.htm. USRDS summarizes the data with different race categories at state and national levels.

Database Definitions

ESRD is defined as chronic renal failure requiring renal replacement treatment — dialysis or transplant — to sustain life. It is not the same as acute renal failure, from which patients are expected to recover within weeks or months. A Medical Evidence Report form must be completed immediately by renal providers for all ESRD patients to register them in the CMS ESRD database and to apply for Medicare eligibility if they were not previously eligible.

IDENTIFYING ESRD PATIENTS

A person is identified as having ESRD when a physician certifies the disease on the Medical Evidence form, or when there is other evidence of chronic dialysis that meets the criteria of ESRD or eligibility for a kidney transplant. The identification of ESRD patients does not rely on International Classification of Diseases (ICD)-9 or ICD-10 codes for ESRD (ICD-9 code: 585.6; ICD-10 code: N18.6) or dependence on dialysis (ICD-10 code: Z99.2).

Patients with acute kidney failure who are on dialysis for days or weeks, but who subsequently

recover kidney function, are excluded from the database if their Medical Evidence forms have not been submitted. Patients who die soon after kidney failure without receiving dialysis are sometimes omitted.

FIRST ESRD SERVICE DATE

The ESRD first service date is the single most important data element in the USRDS Database, and each patient must, at a minimum, have a valid first service date. This date is used to determine the incident year of each patient and the first year in which the patient is counted as prevalent.

In most cases, the first service date is derived by identifying the earliest date of any of the following potential indicators:

- The start of dialysis for chronic kidney failure as reported on the Medical Evidence form
- The first CROWNWeb event
- A kidney transplant as reported on a CMS or OPTN transplant form, a Medical Evidence form, or a hospital inpatient claim
- The first Medicare dialysis claim

There are two exceptions to the first ESRD service date determination:

- If the CROWNWeb event and Medical Evidence form agree (within 30 days of each other) and are more than 90 days after the first Medicare dialysis claim, and, if there is no transplant event between the first dialysis claim and the earlier of either the CROWNWeb event date or Medical Evidence form date, then first service date is defined as the earlier of the CROWNWeb event date or the Medical Evidence form date.
- If the Medical Evidence form date is one year earlier than the first CROWNWeb event date, and if the first claim date or first transplant date agrees with the first CROWNWeb event date, then the CROWNWeb first event date is used as the first service date.

DEATH DATE DETERMINATION

After the ESRD first service date, the date of death is the most critical piece of information in the ESRD database. Death dates are obtained from several sources, including the CMS Medicare EDB, CMS forms 2746 and 2728, the OPTN transplant follow-up form, CROWNWeb database, inpatient claims, and, where allowed by regulation, the Social Security Death Master File. Because multiple sources report death information for the same patient, one patient may have several reported dates. For these patients, the death date is based on the hierarchy order below, with lower numbers having a higher priority:

- 1. CMS 2746 Death Notification form
- 2. CMS Enrollment Database
- 3. CROWNWeb Events
- 4. OPTN Transplant data
- 5. CMS 2728 Medical Evidence form
- 6. CMS Institutional Claims
- 7. CMS Patient List

TRANSPLANT DATES

The CMS and OPTN transplant data files overlap for 1988-1993, and transplants can also be identified from Medical Evidence forms that indicate transplant as the initial modality, from CROWNWeb transplant events, and from institutional inpatient claims. To resolve any conflicts among these sources, and create a complete list of unique transplant events, the USRDS has adopted the following procedure:

- Before 1988, all transplant events found in CMS PMMIS/REBUS/REMIS Transplant Files are used.
- After 1994, all transplant events found in OPTN Files are used.
- Between 1988 and 1993, all transplant events found in OPTN Files are used, and additional transplant events from the CMS PMMIS/REBUS/REMIS Transplant File are used only if they occur at least 30 days before or after a previously accepted transplant event.
- Additionally, transplant events associated with reported incident transplant patients from the Medical Evidence Report are used if they occur at least 30 days before or after a previously accepted transplant event. Transplant events found in CMS inpatient claims records are also included as transplants found in the CROWNWeb patient events data.

Each transplant event found in the Transplant File of the USRDS Core SAF dataset is thus a unique event derived from the OPTN database, the CMS Transplant database, Medical Evidence Report records, CROWNWeb patient events, or Institutional Claims Files.

GRAFT FAILURE

We assume a graft failure date reported in the OPTN transplant follow-up or REMIS identification file is correct unless death or a new transplant occurs before this date. A graft failure date may not be recorded in either file, however. In this case, we use the earliest of the following events:

- Date of death
- Date of subsequent transplant
- Date of return to regular dialysis, indicated by a continuous period of dialysis billing records covering a minimum of 60 days with at least 22 reported treatments
- Date of return to dialysis reported on the Medical Evidence form, or the date of graft nephrectomy from the OPTN follow-up record or a Medicare claim

MEDICARE AND NON-MEDICARE PATIENTS

Beneficiaries who are enrolled in Medicare due to their age are representative of the U.S. population aged 65 and older, as 98% are eligible for Medicare. Those who are younger than 65 tend to have more serious health conditions than the U.S. population their age, since they are entitled to Medicare due to disability or ESRD.

Most ESRD patients under age 65 are eligible to apply for Medicare as their primary insurance payer at the start of their third month following the start of ESRD treatment. Some, however, may not immediately enroll in Medicare if they have private insurance such as employer group health plans (EGHPs). For a person with private insurance, that insurance is the primary payer for the first 30 months of ESRD treatment, after which Medicare becomes primary. The patient may choose to enroll in Medicare at the start of ESRD or may wait to enroll until the 30month coordination of coverage period is completed. These patients will have first service dates established by Medical Evidence forms or CROWNWeb events, but have no dialysis claims or hospitalization events in the CMS claims database. In the REMIS database, all non-Medicare ESRD patients are assigned a code of 'ZZ' in the two-character Beneficiary Identification

Code field. All ESRD patients, regardless of their Medicare Eligibility status, are included in the CROWNWeb system.

The USRDS recognizes that these non-Medicare (ZZ) patients are true ESRD patients and should be included in patient counts for incidence, prevalence, and treatment modality, as well as mortality and transplant rate calculations. Calculations of hospitalization statistics, or possibly of any outcomes derived from Medicare claims including outpatient claims or in any other setting (i.e., any specific diagnostic or therapeutic code), however, should not include these patients because of the small number of claims available in the first 30-33 months after their first ESRD service. It is important to understand that only a fraction of the patients on the USRDS files fulfill Medicare primary criteria at any given time. For this reason, constructing a denominator cohort using the PAYHIST file, as discussed in the Payers (Essential to establish proper denominators for Medicare Claims defined outcomes, including hospitalizations) section below, is suggested.

INTEGRATION OF THE CROWNWEB AND CMS CLAIMS DATABASES

The USRDS uses all available data to create a treatment history for each patient in the database, including all modality events, their duration, and the renal providers involved in each patient's care. The treatment history data can be found in the public SAFs RXHIST (detailed treatment history) and RXHIST60 (condensed treatment history with 60-day stable modality rule applied; see 60-day Stable Modality Rule: Treatment History section below). More information about RXHIST and RXHIST60 data files can be found in the Researcher's Guide to the USRDS Database. This history can be used to identify incident and prevalent cohorts and determines censoring points and outcomes for observational studies. The CROWNWeb event database is the primary source of the modality sequence file, and the dialysis claims are used as a way of confirming placements and resolving problem cases. As described in previous sections, we use all available sources to determine first service dates, deaths, transplants, and graft failures. For patients who either do not appear in the CROWNWeb events file or for whom the only

event is "New ESRD Patient," and patients who have transfer-out gaps, the Medicare dialysis claim file is used. For "Transfer Out" and "Transfer Out for a Transplant" events followed by large gaps (seven days or more), claims falling in gaps are included, with the exception that no claims data are included if the "Transfer Out for a Transplant" event has a corresponding transplant/transplant failure event that occurred within (before or after) 30 days. Claims data are also included for the periods after "Transplant Failure" events and "Discontinued Dialysis" modality if the periods are longer than seven days. Because the claims data capture the modality "Center Self-Hemodialysis" more accurately than the CROWNWeb data, this claims-based designation overrides other dialysis modalities from CROWNWeb. Any CROWNWeb dialysis event that falls into a "Center Self-Hemodialysis" period as determined by claims is recoded as "Center Self-Hemodialysis."

Events that are implausible are removed. These include events that occur before a patient's first service date, those falling between "Transplant" and "Transplant Failure," and "Transfer Out for a Transplant" events that occur 60 days or less after the corresponding "Transplant," and events occurring after "Death."

LOST-TO-FOLLOW-UP METHODOLOGY

Gaps frequently exist in the CROWNWeb and billing data upon which modality periods are based. The USRDS assumes that a modality continues until death or the next modality-determining event. A patient with a functioning transplant is assumed to maintain it unless a new CROWNWeb event, claim event, or death date is encountered in the data. A dialysis modality, in contrast, is assumed to continue for only 365 days from the date of the last claim, in the absence of a new CROWNWeb event, a transplant date, a death date, or dialysis claims. After this period, the patient is declared lost-to-follow-up, until the occurrence of a new CROWNWeb event, dialysis claim, or transplant event.

Patients are considered lost-to-follow-up beginning 365 days after a "Transplant Failure" event or "Discontinued Dialysis" modality with no subsequent events. Patients for whom the only event is a first service date, and who do not exist in any other files were also treated as lost-to-follow-up, beginning one year after the first service date. A number of events can result in a lack of dialysis data and eventual reclassification of a patient as lost-to-follow-up:

- The patient may have recovered renal function (RRF) and no longer have ESRD. Unlike in prior ADRs, which required that to be classified as having RRF the recovery had to occur within 180 days of the first service date and persist for at least 90 days, starting with the 2016 ADR, every indication of RRF is considered valid.
- The patient may no longer reside in the United States.
- The patient's death may not have been reported to the Social Security Administration or to CMS.

60-DAY STABLE MODALITY RULE: TREATMENT HISTORY

The 6o-day stable modality rule requires that a modality continue for at least 6o days before it is considered a primary or switched modality. The rule is used to construct a second modality sequence, or treatment history, for each patient and assigns the patient a modality only if it is a stable or established modality. The hospitalization statistics shown by modality and the vascular access analyses in the ADR use the 6o-day rule to define a stable modality. Most of the other data reported in the ADR do not apply this rule.

90-DAY RULE: OUTCOMES ANALYSES

This rule defines each patient's start date for data analyses as day 91 of ESRD and is used primarily to calculate hospitalization rates.

SERUM ALBUMIN DATA

The Medical Evidence form reports patient albumin levels along with the test's lower limit, which indicates the testing method: bromcresol purple or bromcresol green, with lower limits of 3.2 and 3.5 g/dL, respectively. For all figures in the ADRs that present serum albumin data from the Medical Evidence form, the USRDS ESRD Database includes only those incident patients with both an albumin value and an albumin lower limit of 3.2 or 3.5 g/dL.

MODALITIES

USRDS and CMS have worked extensively on methods of categorizing patients by ESRD treatment modality. The initial modality for a patient is determined using an algorithm based on a hierarchy of data sources. The hierarchy of sources is evaluated in the following order: CROWNWeb data, Medical Evidence form, claims data, and transplant data. The modality indicated in the CROWNWeb and Medical Evidence form may be temporary, as patients often change to a new modality during the first 90 days of treatment, and it can be difficult to track modality during this time. Patients aged 65 and older have Medicare claims in the first 90 days that contain revenue codes designating modality. Patients younger than 65 and in EGHPs or Medicare risk programs, however, have no such early claims. Thus, modality may not be determined until Medicare becomes the primary payer at day 91 or, for EGHP patients, at 30-33 months after the ESRD first service date. These limitations influence our ability to determine a patient's modality at any one point in time.

Of note are patients categorized as having an unstable modality (i.e., on a modality for fewer than 60 consecutive days) in the first 90 days of treatment. Because these patients tend to have higher death and hospitalization rates, interpretations of modalityspecific outcome data including them should be viewed with caution. These patients are not recognized as being either stable hemodialysis (HD) or stable peritoneal dialysis (PD) patients in analyses of patients with stable modality (e.g., hospitalization rates in the ADR). When the 60-day stable modality rule is used, these patients are included in the "all ESRD" category, which provides a more complete view of outcomes with the least biasing of the data.

As mentioned earlier, a new modality/event recovered renal function (RRF) — was introduced in the 2007 ADR. Prior to the 2016 ADR, this event could be established only if it occurred within the first 180 days following the first service date, and if the RRF period persisted for at least 90 days. Starting with the 2016 ADR, every indication of a RRF is now considered valid. The RRF event is similar to the lost-to-follow-up event in that such patients will not be included in the prevalent populations for outcomes analyses. However, as with lost-to-follow-up events, we retain

these patients in the modality sequence so that subsequent renal failure episodes can be tracked closely and in a timely manner.

ESRD treatment modalities may be categorized in different ways within the analyses in each chapter; these are defined in the chapter-specific analytical methods sections that follow this section.

PAYERS (ESSENTIAL TO ESTABLISH PROPER DENOMINATORS FOR MEDICARE CLAIMS DEFINED OUTCOMES, INCLUDING HOSPITALIZATIONS)

Information on payers is obtained from the Medicare EDB. We also examine Medicare outpatient claims to identify patients for whom the EDB does not indicate Medicare as primary payer (MPP), but who have at least three consecutive months of dialysis treatment covered by Medicare; these patients are also designated as having MPP coverage. From these two data sources we construct a Payer Sequence file to provide payer history, and, beginning with the 2003 ADR, we use this file to identify Medicare eligibility status and other payers. The construction of this file is similar to that of the Treatment History file. Payer status is maintained for each ESRD patient from the ESRD first service date until death or December 31, 2014.

Payer status information prior to the start of ESRD (ESRD first service date) is available from the backcasted Payer Sequence file. The Payer Sequence file is similar to the standard ESRD Payer Service file, except that the pre-ESRD Payer Sequence file begins at the first evidence of Medicare enrollment from the Enrollment Database, rather than first ESRD service date, as is the case with the ESRD Payer Sequence. The pre-ESRD payer sequence ends the day before the first ESRD service date.

Constructing denominators based on payer history is essential for proper ascertainment of studies assessing Medicare claims defined outcomes, which is any outcome using a specific diagnostic or procedure code, such as ICD, current procedure and terminology (CPT), or HCPCS (Healthcare Common Procedure Coding System) codes. Only a minority of dialysis patients have Medicare primary payer status when they start dialysis (and thus would not be included in claims-defined outcomes), which increases to about 60% of patients after several months after the start of dialysis. Prior ADRs and some medical journal articles have suggested using the 90-day after dialysis start rule to assume Medicare primary payer eligibility, but this is only a guideline. Both the percent of patients with Medicare coverage at incidence and the average time from initiation of dialysis to Medicare coverage for those not covered at incidence have changed over time (as shown in Figure 4ii, Incident patient distribution by first modality & payer, in the 2010 ADR, <u>https://www.usrds.org/2010/pdf/V2_04.pdf</u>, page 281). Because of this, using actual payer status and dates, as described above, is much more precise and is the recommended method.

Payer data are used to categorize a patient as MPP (established in the SAF PAYHIST), Medicare as secondary payer (MSP) with EGHP, MSP non-EGHP, Medicare Advantage (Medicare + Choice), Medicare or Medicaid, or a combination of payers (see the <u>Researcher's Guide to the USRDS Database</u> for more information) during a given period of time.

PRIMARY CAUSE OF RENAL FAILURE

Information on the primary cause of renal failure is obtained directly from the Medical Evidence form (CMS 2728). For the ADR, we use eight categories with corresponding International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes as follows:

- Diabetes: 250.00, 250.01, 250.40, 250.41
- Hypertension: 401.0, 401.1, 401.9, 403.0, 403.1, 403.9, 403.91, 404.0, 404.1, 404.9, 440.1, 593.81, and 593.83
- Glomerulonephritis: 283.1, 283.11, 287.0, 443.1, 446.0, 446.2, 446.21, 446.29, 446.4, 580.0, 580.4, 580.9, 581.1, 581.8, 581.9, 582.0, 582.1, 582.9, 583.1, 583.2, 583.21, 583.22, 583.4, 583.81, 583.82, 583.9, 583.91, 583.92, 695.4, 710fhc.0, and 710.1
- Cystic kidney: 583.9, 753.1, 753.13, 753.14, and 753.16
- Other urologic: 223.0, 223.9, 274.1, 590.0, 591.0, 592.0, 592.9, 599.0, and 599.6
- Other cause: 016.0, 042.0, 042.9, 043.9, 044.9, 135.0, 189.0, 189.1, 189.9, 202.8, 202.83, 202.85, 202.86, 203.0, 203.08,239.50, 239.51, 239.52, 270.0, 271.8, 272.7, 273.3, 274.1, 274.11, 275.4, 275.49, 277.3, 282.6, 282.61, 282.62, 282.63, 282.69, 282.83, 282.86, 287.3, 446.6, 572.4, 580.89, 582.89, 583.0, 583.6, 583.7, 583.89, 584.5, 587.0, 591.8, 590.9, 593.89, 593.9,

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599.0, 639.3, 646.2, 714.0, 728.89, 753.0, 753.2, 753.21, 753.22, 753.29, 753.3, 753.39, 756.7, 756.71, 759.5, 759.8, 759.89, 866.0, 965.4, 965.9, 977.8, 982.8, 984.9, 996.8, 996.81, 996.82, 996.83, 996.84, 996.85, 996.86, 996.87, and 996.89

- Unknown cause: 239.5, 428.0, 500.0, 582.0, 586.0, 489.9, 589.0, 589.1, 589.9, 592.1, 593.1, 799.9, 799.99, 888.88, 899.9, 999.99, 999.9, and ICD-9-CM codes not covered by the lists of codes above
- Missing cause: no ICD-9-CM code listed

RACE AND ETHNICITY

Data on patient race and ethnicity are obtained from the Medical Evidence form, the CMS Medicare Enrollment Database, the REMIS patient identification file, and the CROWNWeb patient roster. Because they are addressed in separate questions on the Medical Evidence form, patients can be assigned a racial category and an ethnic category independently. Patient ethnicity became a required field on the 1995 revised Medical Evidence form, but because the form did not go into effect until midway through 1995, data for 1995 are incomplete. Therefore, information on Hispanic patients is presented starting in 1996. The non-Hispanic category includes all non-Hispanics and patients with unknown ethnicity. Because of the small number of ESRD patients of some races, as well as how race is categorized in the U.S. Census data, we concentrate on White, Black/African American, Native American (including Alaskan Native), and Asian (including Pacific Islander) populations. Data on patients of other races will be presented as their numbers increase. The race and ethnicity categorization presented in each chapter remains consistent with that of the specific data sources used.

The data sources for race are (from high priority to low):

- The CROWNWeb patient list
- The Medical Evidence (2728) form,
- The REMIS patient lists
- The Medicare Enrollment Database.

The race categories in each source are regrouped to USRDS race categories. See Table m.1 for the race categories in each source. If information is missing from the CROWNWeb patient list, then the other three sources are checked in the order above to supply race information.

USRDS race categories	CROWNWeb patient list	Medical Evidence form	REMIS	Medicare Enrollment Database
White	White; Mid-East Arabian	White; Mid-East Arabian	White; Mid-East Arabian	White
Black/African American	Black	Black	Black	Black
Native American	American Indian/ Alaska Native	American Indian/ Alaska Native	American Indian/ Alaska Native	Native American
Asian	Asian; Pacific Islander; Indian Sub- Continent	Asian; Pacific Islander; Indian Sub-Continent	Asian; Pacific Islander; Indian Sub- Continent	Asian
Unknown	Unknown; Missing	Unknown; Missing	Unknown; Missing	Unknown; Missing
Other	Other/Multiracial	Other/Multiracial	Other/Multiracial	Other/Multiracial

The data sources for ethnicity are (from high priority to low):

- 1. Medical Evidence form
- 2. CROWNWeb Patient list
- 3. Clinical Performance Measures (CPM)
- 4. Medicare Enrollment Database

Similar to the race categorization, if information is missing from the CROWNWeb patient list, then the other three sources are checked in the order above to fill in ethnicity information.

Analytical Methods Used in the ESRD Volume

Data sources are indicated in the footnotes of each table and figure in Volume 2: End-Stage Renal Disease (ESRD) in the United States. Additional information on these sources is also available in the *Data Sources* section above. Methodology used for the figures and tables in Volume 2 is described below in the corresponding chapter or ESRD Reference Table Methods section. When figure or table data come directly from a particular Reference Table, please refer to the appropriate *ESRD Reference Table Methods section* for additional detail.

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

INCIDENCE OF ESRD: COUNTS, RATES, AND TRENDS

Because data are available only for patients whose ESRD therapy is reported to CMS, we qualify the term "incidence" as "incidence of reported ESRD." Some ESRD registries use the term "acceptance into ESRD therapy." We believe, however, that "incidence of reported ESRD therapy" is more precise, because "acceptance" implies that remaining patients are rejected, when they may simply not be identified as ESRD cases or may not be reported to CMS.

Rate adjustments in this chapter are as follows: overall rates (including those in the maps) are adjusted for age, sex, and race; rates by age are adjusted for sex and race; rates by race or ethnicity are adjusted for age and sex; and rates by primary cause of ESRD are adjusted for age, sex, and race. Direct adjustment, as described in the *Statistical Methods* section of the chapter, was used. Census data rate is now based on intercensal estimates; for details, see the section on the *United States Census* in the Data Sources section of this chapter.

For Figures 1.4-1.7, incident cases and incidence rates are taken directly from Reference Table A. More specifically, cases come from A.1 and rates come from A.2(2) and A.2(3). For details on the methods used, refer to the section for *Reference Table A: Incidence* and the section for *Statistical Methods* used for rate calculations. Figure 1.17 reports the home dialysis patient distribution by therapy type and among incident populations.

For all maps by Health Service Area (HSA), data were suppressed for HSAs with 10 or fewer cases.

PREVALENCE OF ESRD: COUNTS, PREVALENCE, AND TRENDS

Here and throughout the ADR, the USRDS generally reports point prevalence as of December 31, while period prevalence is reported for a calendar year. Annual period prevalent data thus consist both of patients who have the disease at the end of the year and those who have the disease during the year and die before the year's end. Because the USRDS treats successful transplantation as a therapy rather than as a "recovery" from ESRD, patients with a functioning transplant are counted as prevalent patients.

Because data are available only for patients whose ESRD therapy is reported to CMS, we qualify the terms prevalence as prevalence of reported ESRD. Beginning with the 1992 ADR, lost-to-follow-up patients are not included in the point prevalent counts; they are, however, reported in Table B.1 of the Reference Tables.

Prevalence adjustments in this chapter are as follows: overall prevalence (including those in the maps) is adjusted for age, sex, and race; prevalence by age is adjusted for sex and race; prevalence by race or ethnicity is adjusted for age and sex; and prevalence by primary cause of ESRD is adjusted for age, sex, and race. Direct adjustment, as described in the *Statistical Methods* section of the chapter, was used. Census data rate and prevalence calculations are now based on intercensal estimates; for details, see the section on the *United States Census* in the Data Sources section of this chapter.

Data for Figures 1.13-1.16 come directly from Reference Table B. Specifically, prevalent cases correspond to those found in B.1 and prevalence corresponds to that found B.2.2 and B.2.3. For details on the methods used, refer to the sections for *Reference Table B: Prevalence* and the section for *Statistical Methods* for rate calculations. Figure 1.19 reports the home dialysis patient distribution, by therapy type and among point prevalent populations.

For all maps by Health Service Area (HSA), data were suppressed for HSAs with 10 or fewer cases.

MODALITY OF RENAL REPLACEMENT THERAPY

Modality figures and the associated Reference Tables describe the treatment modalities of all known ESRD patients, both Medicare and non-Medicare, who are not classified as lost-to-follow-up or as having RRF. Treatment History Files RXHIST and RXHIST60 are used to determine modality. Unless noted otherwise, incident and point prevalent cohorts without the 60-day stable modality rule are used in the analyses. Treatment modalities are defined as follows:

- Center HD: HD treatment received at a dialysis center
- Center self-HD: HD administered by the patient at a dialysis center; a category usually combined with center HD
- Home hemodialysis: HD administered by the patient at home; cannot always be reliably identified in the database
- CAPD (continuous ambulatory peritoneal dialysis): usually combined with CCPD and other PD
- CCPD (continuous cycling peritoneal dialysis): usually combined with CAPD and other PD
- Peritoneal dialysis (PD): analyses typically consist of CAPD, CCPD and intermittent peritoneal dialysis (IPD)
- Other peritoneal dialysis: primarily IPD, a small category except among very young children; usually combined with CAPD and CCPD to form PD category
- Uncertain dialysis: a period in which the dialysis type is unknown or multiple modalities occur but do not last 60 days; usually combined with unknown dialysis to form an other/unknown dialysis category
- Unknown dialysis: a period in which the dialysis modality is not known (e.g., when dialysis sessions are performed in a hospital); usually combined with uncertain dialysis to form an other/unknown dialysis category

- Renal transplantation: a functioning graft from either a living donor (a blood relative or other living person) or a deceased donor
- Death: a category not appearing in the year-end modality tables, which report only living patients, but used as an outcome (e.g., in tables showing living patients followed for a period of time for their modality treatment history)

Facilities began submitting patient data via CROWNWeb beginning in 2012. This information was previously submitted by facilities via the ESRD Networks. The new method of data input and submission may lead to unanticipated changes in trends beginning in 2012.

PATIENT AND TREATMENT CHARACTERISTICS AT ESRD ONSET

For Tables 1.4, 1.5, and 1.6, and Figures 1.21, 1.22, 1.23, and 1.24, laboratory values and treatment characteristics were derived from questions on the Medical Evidence form. All eGFR values are calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation from data acquired from the Medical Evidence form.

CHAPTER 2: HEALTHY PEOPLE 2020

OBJECTIVE CKD-3: INCREASE THE PROPORTION OF HOSPITAL PATIENTS WHO INCURRED ACUTE KIDNEY INJURY^S WHO HAVE FOLLOW-UP RENAL EVALUATION IN 6 MONTHS POST-DISCHARGE

Data for this objective include all patients in the Medicare 5% sample who are aged 65 and older and who have either a hospital-associated acute kidney injury (AKI) event or a primary discharge diagnosis of an AKI in the given year (2001-2014). Because this is a Medicare defined event, a Medicare Primary cohort is required. Hospitalized AKI is defined by the presence of ICD-9-CM diagnosis code 584 in any field of the inpatient claims, and renal evaluation is identified by a microalbumin test. Patients are followed from the discharge date to the earliest date of death, ESRD, end of Medicare coverage, or six months after the discharge date. Current procedure and terminology (CPT) codes for urinary microalbumin measurement are identified from Healthcare Effectiveness Data and Information Set (HEDIS) 2008 specifications (HEDIS 2008, a National Committee for Quality Assurance

(NCQA) program, is used to monitor the performance of managed health care plans), and include 82042, 82043, 82044, and 84156.

OBJECTIVE D-12: INCREASE THE PROPORTION OF PERSONS WITH DIAGNOSED DIABETES WHO OBTAIN AN ANNUAL URINE ALBUMIN MEASUREMENT^S

The cohort includes general Medicare patients diagnosed with diabetes mellitus (DM) in each year, continuously enrolled in Medicare Parts A and B during the whole year, and aged 65 or older at the beginning of the year. CPT codes for urinary microalbumin measurement are those used in Objective CKD-3, above. Testing is tracked during each year. Diabetes is defined by a qualifying ICD-9-CM diagnosis code of 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 physician/supplier claims within a one-year observation period. Qualifying ICD-9-CM codes for DM are as follows: 250.XX, 357.2, 362.0X, and 366.41.

OBJECTIVE CKD-4.1: INCREASE THE PROPORTION OF PERSONS WITH CHRONIC KIDNEY DISEASE WHO RECEIVE MEDICAL EVALUATION WITH SERUM CREATININE, LIPIDS, AND URINE ALBUMIN^S

The cohort here is similar to that used for Objective D-12, but includes all CKD patients. Testing is tracked during each year. Patients are excluded if they are enrolled in a managed care program (HMO), acquire Medicare as secondary payer, are diagnosed with ESRD during the year, have a missing date of birth, or do not live in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. Racial and ethnic categories are mutually exclusive. Methods of defining CKD are described in the CKD Analytical Methods chapter of Volume 1: Chronic Kidney Disease (CKD) in the United States. Serum creatinine is identified through CPT codes 80047-80050, 80053-80054, 80069, and 82565, while lipid testing is identified through CPT codes 80061, 82465, 82470, 83695, 83705, 83715-83721, 84478, 83700, 83701, and 83704. CPT codes for urinary microalbumin measurement are the same as those used for Objective CKD-3 above.

OBJECTIVE CKD-4.2: INCREASE THE PROPORTION OF PERSONS WITH TYPE 1 OR TYPE 2 DIABETES AND CHRONIC KIDNEY DISEASE WHO RECEIVE MEDICAL EVALUATION WITH SERUM CREATININE, URINE ALBUMIN, HGBA1C, LIPIDS, AND EYE EXAMINATIONS^{\$}

Methods and codes used to determine rates of HbA1c testing and eye examinations are taken from HEDIS 2008 specifications. CPT codes 83036 and 83037 are used to identify HbA1c testing. Codes used to identify diabetic eye examinations are as follows: CPT codes, 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92226, 92230, 92235, 92240, 92250, 92260, 67101, 67105, 67107, 67108, 67110, 67112, 67141, 67145, 67208, 67210, 67218, 67227, 67228, 67028, 67030, 67031, 67036, 67038, 67039, 67041, 67042, 67043, 67113, 67121, 67221, 67228, S0625, S0620, S0621, and S3000; ICD-9-CM procedure codes, 14.1-14.5, 14.9, 95.02, 95.03, 95.04, 95.11, 95.12, and 95.16; and ICD-9-CM diagnosis code V72.0. The cohort is similar to that used for Objective CKD-4.1, but includes all diabetic CKD patients. Methods of defining DM are described in the CKD Analytical Methods chapter Volume 1: Chronic Kidney Disease (CKD) in the United States.

OBJECTIVE CKD-8: REDUCE THE RATE OF NEW CASES OF END-STAGE RENAL DISEASE

Incident rates are calculated using the methods described for Chapter 1. Overall rates are adjusted by age, sex, and race; rates by age are adjusted for sex and race; rates by sex are adjusted for age and race; and rates by race and ethnicity are adjusted by age and sex.

OBJECTIVE CKD-9.1: REDUCE KIDNEY FAILURE DUE TO DIABETES

Rates of kidney failure due to DM are also calculated using the methods described for Chapter 1, and adjustments are the same as those described for Objective CKD-8, above.

OBJECTIVE CKD-9.2: REDUCE KIDNEY FAILURE DUE TO DIABETES AMONG PERSONS WITH DIABETES

This table uses data from the National Health Interview Survey; all ages are included. Three-year data are used to estimate the prevalence of DM in the middle year, and the size of the population with DM is based on U.S. Census data. The incident rate per million of ESRD caused by DM is calculated as the number of incident ESRD patients with a primary cause of ESRD of DM, divided by the size of the population with DM in that group.

OBJECTIVES CKD-10: INCREASE THE PROPORTION OF CHRONIC KIDNEY DISEASE PATIENTS RECEIVING CARE FROM A NEPHROLOGIST AT LEAST **12** MONTHS BEFORE THE START OF RENAL REPLACEMENT THERAPY **& CKD-11.3:** INCREASE THE PROPORTION OF ADULT HEMODIALYSIS PATIENTS WHO USE ARTERIOVENOUS FISTULAS OR HAVE A MATURING FISTULA AS THE PRIMARY MODE OF VASCULAR ACCESS AT THE START OF RENAL REPLACEMENT THERAPY

These tables use data from the newest version of the Medical Evidence form. The cohorts include incident HD patients, with CKD-11.3 limited to those aged 18 and older at initiation who have a known vascular access at that time. CKD-10 includes only patients for whom it is known whether they saw a nephrologist prior to initiation.

OBJECTIVES CKD-11.1: INCREASE THE PROPORTION OF ADULT HEMODIALYSIS PATIENTS WHO USE AN ARTERIOVENOUS FISTULA AS THE PRIMARY MODE OF VASCULAR ACCESS & **CKD-11.2: DECREASE THE** PROPORTION OF ADULT HEMODIALYSIS PATIENTS WHO USE CATHETERS AS THE ONLY MODE OF VASCULAR ACCESS

These tables use data from CROWNWeb. The cohort includes prevalent HD patients from 2012 to 2014 who are aged 18 and older. Access type represents the last access type used in the year, according to CROWNWeb data.

OBJECTIVE CKD-12: INCREASE THE PROPORTION OF DIALYSIS PATIENTS WAIT-LISTED AND/OR RECEIVING A DECEASED DONOR KIDNEY TRANSPLANT WITHIN 1 YEAR OF END-STAGE RENAL DISEASE START (AMONG PATIENTS UNDER **70** YEARS OF AGE)

The cohort includes patients from 2000-2014 who are younger than age 70 at the initiation of ESRD. Percentages are calculated as the number of patients placed on the deceased donor organ waiting list or receiving a deceased donor transplant within one year of initiation, divided by the number of patients without a living donor available (i.e., patients receiving a living donor transplant are excluded), and are estimated using the Kaplan-Meier methodology.

OBJECTIVE CKD-13.1: INCREASE THE PROPORTION OF PATIENTS RECEIVING A KIDNEY TRANSPLANT WITHIN **3** YEARS OF END-STAGE RENAL DISEASE

The cohort includes patients from 1998-2011 who are younger than age 70 at the initiation of ESRD. Patients are followed from ESRD certification to transplant, censoring at death or three years after the initiation of ESRD. Percentages are calculated using the Kaplan-Meier methodology.

OBJECTIVE CKD-13.2: INCREASE THE PROPORTION OF PATIENTS WHO RECEIVE A PRE-EMPTIVE TRANSPLANT AT THE START OF END-STAGE RENAL DISEASE

The cohort includes patients from 2001-2014 who are younger than age 70 at the initiation of ESRD. Preemptive transplants are those in which ESRD initiation date is the date of transplant. Percentages are calculated as 100 (N/D), where N=the number of preemptive transplants in the year and D=the number of ESRD patients in the year.

OBJECTIVES CKD-14.1: REDUCE THE TOTAL DEATH RATE FOR PERSONS ON DIALYSIS & CKD-14.3: REDUCE THE CARDIOVASCULAR DEATH RATE FOR PERSONS ON DIALYSIS

Cohorts for these tables include period prevalent dialysis patients in each calendar year, 2001-2014, whose first ESRD service date is at least 90 days prior to the beginning of the year (point prevalent patients on January 1) or who reach day 91 of ESRD treatment during the year (incident patients). We exclude patients with unknown age or sex and those with an age calculated to be less than zero, as well as patients who are not residents of the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. Age is calculated on January 1, and race is defined from the Medical Evidence form. Cardiovascular mortality is defined using codes from past and current Death Notification forms: 01, 02, 03, 04, 1, 2, 3, 4, 23, 25, 26, 27, 28, 29, 30, 31, 32, 36, and 37. Patients are followed from January 1 (for point prevalent dialysis patients) or day 91 of ESRD (for incident dialysis patients) until death, transplant, or December 31 of the year. Rates are estimated as the number of patients who die from any cause (Objective 14.1) and who die from cardiovascular disease (Objective 14.3) in each year, per 1,000 patient years at risk.

OBJECTIVE CKD-14.2: REDUCE THE DEATH RATE IN DIALYSIS PATIENTS WITHIN THE FIRST **3** MONTHS OF INITIATION OF RENAL REPLACEMENT THERAPY

Cohorts here include incident dialysis patients in each calendar year, 2001-2014. In addition to applying the same exclusion criteria described for Objectives 14.1 and 14.3, we further exclude patients with recovered kidney function. Age is calculated on the first ESRD service date. Patients are followed from the first service date until death, transplant, or 90 days after ESRD. Rates are estimated as the number of patients who die from any cause per 1,000 patient years at risk.

OBJECTIVES CKD-14.4: REDUCE THE TOTAL DEATH RATE FOR PERSONS WITH A FUNCTIONING KIDNEY TRANSPLANT & CKD-14.5: REDUCE THE CARDIOVASCULAR DEATH RATE IN PERSONS WITH A FUNCTIONING TRANSPLANT

Patient cohorts here include period prevalent transplant patients, 2001-2014, whose first ESRD service date is at least 90 days prior to the beginning of the year (point prevalent patients on January 1) or who reach day 91 of ESRD treatment (incident patients). Exclusion criteria are the same as those described for Objectives 14.1 and 14.3. Patients are followed from January 1 (for point prevalent dialysis patients) or day 91 of ESRD (for incident dialysis patients) until death or December 31 of the year. Rates are estimated as the number of patients who die from any cause (Objective 14.4) and who die from cardiovascular disease (Objective 14.5) in each year, per 1,000 patient years at risk.

CHAPTER 3: CLINICAL INDICATORS AND PREVENTIVE CARE

CLINICAL INDICATORS

In Figure 3.1, all data are obtained from CROWNWeb clinical extracts for December 2015. The adequacy (Kt/V) analyses are restricted to patients at least 18 years old as of December 1, 2015. Patients must have been alive as of December 31, 2015, and must have had ESRD for at least one year as of the time of the measurement. If multiple measurements were available for a patient, the last one in the month was used. In Figure 3.1.b, all adult (aged 18 and older) patients who are on dialysis for at least 90 days as of December 1, 2015, and alive as of December 31, 2015, are included. If multiple hemoglobin measurements were available for a patient, the last one in the month was used. The categorical distribution of hemoglobin is shown for both HD and PD patients. In Figure 3.1.c, the hypercalcemia measure was calculated as a 3month rolling average for both HD and PD patients, who were alive as of December 31, 2015, and had ESRD for at least 90 days as of the time of measurement of an uncorrected serum calcium value.

ANEMIA TREATMENT BY MODALITY^{\$}

All of the findings in this section are based on Medicare claims data. Efforts have been made for the figures and tables to be as fully representative as possible of the U.S. dialysis patient population represented by CMS claims data, resulting in substantially larger sample sizes in some of the tables associated with this anemia section as compared with the 2015 ADR. The modality of the patient in each month is determined from the primary modality that is indicated on the claims file associated with each claim for hemoglobin, iron dose, and epoetin alfa (EPO) dose variables in the given month. For transfusion analyses, patients were assigned to HD or PD if having at least one claim for HD or PD therapy, respectively, in that month. There were very few patients having dual modality use within the same month.

Calculation of hemoglobin levels are shown in Figures 3.2, 3.3, 3.8, and 3.9. Hemoglobin values were based upon the first reported claim in each month for HD patients (Figures 3.2, 3.3) or for PD patients (Figure 3.8, 3.9). When hemoglobin levels were not available in claims data, hematocrit values, if available, were divided by 3 to serve as a proxy estimate. Patients were excluded in a given month if the hemoglobin level (or hemoglobin values estimated from hematocrit values) was <5 g/dL or >20 g/dL. Results are shown for erythropoiesis-stimulating agent (ESA)treated patients in Figures 3.2, 3.3, 3.8, and 3.9, in which case analyses were restricted to patients who: (1) within the indicated month had a claim for ESA use and a claim for either hemoglobin or hematocrit level, and (2) at the start of the month, were on dialysis for 90 days or more and were aged 18 or older. In Figures 3.2 and 3.8, hemoglobin levels are also provided for all patients, and the same restrictions were used as

described in statement 2 above, but not limited to patients with an ESA claim within the given month in 2012. In addition, hemoglobin levels for patients not on any ESA drugs in a month were also shown for HD patients (Figure 3.2) and PD patients (Figure 3.8).

Calculation of mean EPO dose levels is shown in Figures 3.2 and 3.8. Mean monthly EPO dose is provided for HD patients in Figure 3.2 and for PD patients in Figure 3.8. Mean monthly EPO dose is shown for patients who within a given month had an EPO claim, were on dialysis for 90 days or longer, and were 18 years and older at the start of the month. EPO dose is expressed as mean EPO units per week, averaged over all EPO claims within a given month. Patients were excluded from these calculations for a given month if their monthly average EPO dose was either less than 250 units per week (resulting in 0.4% being excluded) or if their monthly average EPO dose was greater than 400,000 units per week; these criteria resulted in <0.001% of patients being excluded. Monthly ESA use for HD patients is shown in Figure 3.2.b and for PD patients in Figure 3.8.b. Monthly "EPO only" use (EPO and not Darbopoetin), "Darbopoetin only" use (Darbopoetin and not EPO), and "Any ESA" use (either or both EPO and Darbopoetin) are calculated among patients who are on dialysis for at least 90 days and 18 years or older at the start of the given month. Calculation of intravenous iron use is shown in Figures 3.4 and 3.10. Intravenous iron use and IV iron dose for HD patients is presented in Figure 3.4 and for PD patients in Figure 3.10. Monthly intravenous iron use was among patients on dialysis for 90 days or longer and 18 years or older at the start of the given month. Mean IV iron dose was calculated as the average dose of IV iron (iron sucrose and ferrous gluconate) a patient received, among patients receiving iron during the month. This analysis was restricted to only those patients who had more than 6 sessions but less than or equal to 18 sessions in a month. The permissible range of values considered for sucrose and ferrous gluconate are (50-1800 mg) and (12.5-1800 mg), respectively.

Categorical distribution of iron store measures, transferrin saturation (TSAT) and serum ferritin for December 2013, December 2014, and December 2015, using CROWNWeb data are shown in Figures 3.5 and

3.6, respectively, for HD patients. For PD patients, iron store measures, TSAT and serum ferritin are shown in Figures 3.11 and 3.12, respectively. For Figure 3.5, dialysis patients on treatment for ESRD at least 90 days at the time of measurement of TSAT value for that year, \geq 18 years old as of December 1 of that year and who were alive through December 31 of that year are included in the study. For each year, the latest non-missing TSAT value during October-December was used. Similar analyses were done for PD patients.

Figure 3.6 analyses include dialysis patients who were treated for ESRD for at least 90 days at the time of measurement of serum ferritin for that year, who were \geq 18 years old as of December 1 of that year, and who were alive through December 31 of that year. For each year, the latest non-missing serum ferritin value during October-December, a 3-month time period, was used. Similar analyses were done for PD patients.

Percentage of all HD patients according to the number of red blood cell transfusions in a year is shown in Figure 3.7.a, which was calculated from Medicare claims data for years 2010-2014. Here, the denominator included all patients having a claim for at least one dialysis session during the month and who were 18 years or older at the start of the month, and the numerator consisted of the total number of claims for transfusions a patient had in a year. The modality of the first treatment in the year determines the modality of the patient for that year. Similarly, Figure 3.13.a, shows the distribution of the number of red blood cell transfusions received by PD patients, by year.

Calculations of the percentage of dialysis patients with one or more claims for a red blood cell transfusion in a given month from 2010-2014 are shown in Figures 3.7.b (HD patients) and 3.13.b (PD patients). For this calculation, the numerator consisted of dialysis patients with one or more red blood cell transfusion claims in a given month (the transfusion claims were identified using the codes as listed in Table m.2); the denominator included all patients having a claim for at least one dialysis session during the month and who were 18 years or older at the start of the month.

Code	Code Type	Code Description	
36430	СРТ	Transfusion, blood or blood components	
P9010	HCPCS	Blood (whole), for transfusion, per unit	
P9011	HCPCS	Blood, split unit	
P9016	HCPCS	Red blood cells, leukocytes reduced, each unit	
P9021	HCPCS	Red blood cells, each unit	
P9022	HCPCS	Red blood cells, washed, each unit	
P9038	HCPCS	Red blood cells, irradiated, each unit	
P9039	HCPCS	Red blood cells, deglycerolized, each unit	
P9040	HCPCS	Red blood cells, leukocytes reduced, irradiated, each unit	
P9051	HCPCS	Whole blood or red blood cells, leukocytes reduced, CMV-negative, each unit	
P9054	HCPCS	Whole blood or red blood cells, leukocytes reduced, frozen, deglycerol, washed, each unit	
P9056	HCPCS	Whole blood, leukocytes reduced, irradiated, each unit	
P9057	HCPCS	Red blood cells, frozen/deglycerolized/washed, leukocytes reduced, irradiated, each unit	
P9058	HCPCS	Red blood cells, leukocytes reduced, CMV-negative, irradiated, each unit	
99.03	ICD-9	Other transfusion of whole blood; transfusion: blood NOS, hemodilution, NOS	
99.04	ICD-9	Transfusion of packed cells	

vol 2 Table m.2 Transfusion codes used in defining a red blood cell transfusion

Data Source: USRDS ESRD Database. Abbreviations: CMV, cytomegalovirus; CPT, Current procedure and terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-9, International Classification of Diseases, Ninth Revision; NOS, nitrous oxide synthase.

MINERAL AND BONE DISORDER

Distributions of calcium levels for HD and PD patients for December 2013, December 2014, and December 2015, using CROWNWeb data are shown in in Figures 3.14 and 3.15. Figure 3.14 analyses include HD patients on treatment for ESRD at least 1 year at the time of measurement of serum calcium value for that year, who were ≥18 years old as of December 1 of that year, and who were alive through December 31 of that year. Similar analyses were done for PD patients in Figure 3.15.

Distributions of phosphorus levels for HD and PD patients for December 2013, December 2014, and December 2015, using CROWNWeb data are shown in in Figures 3.16 and 3.17. For Figure 3.16, analyses include HD patients on treatment for ESRD for at least 1 year at the time of measurement of serum phosphorus value for that year, who were ≥18 years old as of December 1 of that year, and who were alive through December 31 of that year. Similar analyses were done for PD patients in Figure 3.17.

PREVENTIVE CARE^{\$}

Figure 3.18 presents data on diabetic preventive care. The ESRD population includes patients initiating therapy at least 90 days prior to January 1 of the first year of each study period and with DM in the first year. Testing is tracked in the second year of each study period, and tests are at least 30 days apart. ESRD patients without Medicare inpatient/outpatient and physician/supplier coverage during the entire study period are omitted, as are general Medicare patients enrolled in an HMO or diagnosed with ESRD during the study period. Also omitted are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories; who have a missing date of birth; who do not survive the entire reporting period; who have ESRD for fewer than 90 days prior to the start of the reporting interval; or who are lost to

follow-up during the study period. Age is calculated at the end of the study period.

Patients are defined as having DM either through medical claims (one inpatient/home health/skilled nursing facility claim, or two outpatient or physician/supplier claims), or through a listing of DM on the Medical Evidence form as the primary cause of ESRD or as a comorbid condition. ICD-9-CM diagnosis codes used to define DM are 250.xx, 357.2, 362.0x, and 366.41. Methods and codes used to determine rates of HgbA1c testing and eye examinations are taken from HEDIS 2008 specifications. CPT codes 83036 and 83037 are used to identify HgbAic testing. Codes used to identify diabetic eye examinations are as follows: CPT codes, 67028, 67030, 67031, 67036, 67038, 67039, 67040, 67041, 67042, 67043, 67101, 67105, 67107, 67108, 67110, 67112, "67113, 67121, 67141, 67145, 67208, 67210, 67218, 67220, 67221, 67227, 67228, 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92226, 92230, 92235, 92240, 92250, 92260, S0620, S0621, S0625, S3000; ICD-9-CM procedure codes, 14.1-14.5, 14.9, 95.02, 95.03, 95.04, 95.11, 95.12, and 95.16; and ICD-9-CM diagnosis code V72.0. Lipid testing is identified through CPT codes 80061, 82465, 82470, 83695, 83700, 83701, 83704, 83705, 83715, 83716, 83717, 83718, 83719, 83720, 83721, 84478. Comprehensive diabetic care includes at least one HgbAic test, at least one lipids test, and at least one eye exam. HgbAic and lipid tests should occur at least 30 days apart.

Figure 3.19 (a-d) presents data on influenza vaccinations for prevalent ESRD patients by overall claims, age, race/ethnicity, and modality. The cohort for influenza vaccinations includes all ESRD patients initiating therapy at least 90 days prior to August 1 of the first year of the study period and alive on April 30 of the second year. Patients without Medicare inpatient/outpatient and physician/supplier coverage during the study period are omitted, as are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. Also omitted are those who have a missing date of birth; who have ESRD for fewer than 90 days prior to the start of the study period; or who are lost-to-follow-up during the study period. Age is calculated at the end of the study period. Influenza vaccinations are tracked between August 1 of the first year and April 30 of the

second year in the study period. Influenza vaccinations are identified by CPT codes 90724, 90657, 90658, 90659, and 90660, and Healthcare Common Procedure Coding System (HCPCS) code Gooo8.

CHAPTER 4: VASCULAR ACCESS

VASCULAR ACCESS USE AT INITIATION OF HEMODIALYSIS

Data for Figures 4.1-4.3 and Table 4.1 are obtained from the Medical Evidence form (CMS 2728); data are restricted to the most recent version. Patients with missing vascular access data are excluded. Figure 4.1 presents data for patients who began hemodialysis during 2005-2014. Table 4.1 and Figures 4.2-4.3 present data for patients beginning dialysis in 2014. Age is calculated as of the date regular chronic dialysis began.

Figures 4.2 and 4.3 show the geographic variation in percentage of catheter-only use and percentage of AV fistula use, respectively, at hemodialysis initiation in 2014. Figures 4.2-4.3 exclude patients not living in the 50 states or the District of Columbia.

VASCULAR ACCESS USE AMONG PREVALENT HEMODIALYSIS PATIENTS

Vascular access use among prevalent patients is described in Table 4.2 and Figures 4.4-4.6.

For Table 4.2, CROWNWeb data is used to obtain vascular access use for December 2014. Catheter use implied any catheter use, whereas, arteriovenous (AV) fistula and AV graft use shown are without the use of a central venous catheter.

Figures 4.4 and 4.5 show geographic variation in percentage of catheter-only and percentage of AV fistula use, respectively, among prevalent hemodialysis patients by Health Service Area using CROWNWeb data from December 2014. These figures exclude patients not living in the 50 states or the District of Columbia.

Figure 4.6 presents data as reported from Fistula First from July 2003 to April 2012 and CROWNWeb data from June 2012 to December 2014. May 2012 was not included in the analysis to denote the breakpoint between the two sources. This figure shows prevalence of the vascular type used and for June 2012 to December 2014. The denominator is obtained from the treatment history file, limited to hemodialysis patients who are non-transplanted and are alive at the end of each month. The numerator is obtained from vascular access extract files in CROWNWeb. Access type at vascular access initiation includes data obtained from the Medical Evidence form for patients beginning dialysis between January 1, 2013 and December 31, 2014; vascular access data for all other time points are obtained from CROWNWeb. There is a 15-day lookback and 15-day look-forward time period to determine vascular access.

CHANGE IN TYPE OF VASCULAR ACCESS DURING THE FIRST YEAR OF DIALYSIS

Figure 4.7.a and Tables 4.3-4.5 include a crosssection of patients (who were incident in 2014) alive at each time point. They use data from January 1, 2014 to December 31, 2014, using the Medical Evidence form (CMS 2728) at initiation and CROWNWeb for subsequent time periods. Data are restricted to the most recent version of the CMS 2728. Patients with missing vascular access data are excluded.

Figure 4.7.b follows the same set of patients from dialysis initiation to 1 year after initiation, so each time point has the same number of patients. (N =102,367). As with Figure 4.7a, Figure 4.7b uses the Medical Evidence form (CMS 2728) to find access type at initiation and CROWNWeb for subsequent time periods. Patients with a maturing AV fistula/AV graft with a catheter in place were classified as having a catheter. The apparent decrease in AV fistula and AV graft use at 1 month is related to missing data due to the different data sources used for incident and prevalent patients.

PREDICTORS OF AV FISTULA USE AT HEMODIALYSIS INITIATION

Table 4.6 presents two models of the odds of AV fistula use at initiation and AV fistula or AV graft use at initiation using vascular access type data at initiation (as well as demographic and facility information) from Medical Evidence form (CMS 2728). Demographic variables included gender, age, race/ethnicity, pre-ESRD nephrology care, diabetes as cause of ESRD, facility census, and ESRD network. Two multiple logistic regression models were used to create this table.

FISTULA MATURATION

Table 4.7 includes patients with a fistula placed at any point between January 1, 2014 and December 31, 2014 who are already on ESRD at time of placement. Fistula placement was identified through inpatient, outpatient, and physician/supplier Medicare claims using the following HCPCS codes: 36818, 36819, 36820, 36821 and 36825. Subsequent first use of the placed fistula was determined by finding evidence of fistula use in CROWNWeb through the end of 2015. If the fistula was indicated to be used in CROWNWeb following the placement (and prior to any later fistula placements), the fistula was considered to have successfully matured for use. If CROWNWeb did not indicate the fistula was used following placement, the fistula was assumed to have failed to mature. In order to be included in the analyses, patients were required to have vascular access use data in CROWNWeb following the fistula placement. Time to maturation was determined using the date of fistula placement and the date of first use in CROWNWeb, given that the exact time of "fistula maturity" is currently not determinable from CROWNWeb. Patients that died following the fistula placement were also included in the analysis.

CHAPTER 5: HOSPITALIZATION^{\$}

INCLUSION AND EXCLUSION OF SUBJECTS

Methods used to examine hospitalization in prevalent patients generally echo those used for the tables in Reference Table G: Morbidity and Hospitalization^{\$} (described below). Inclusion and exclusion criteria are generally the same, as are the methods for counting hospital admissions and days, and defining the follow-up time at risk. One difference is the exclusion in Reference Table G of patients of races that are unknown or other than White, Black/African American, Native American, or Asian, however, these patients are included in the Chapter 5 figures. Included patients have Medicare as primary payer, with Part A coverage at the start of follow-up, and without HMO coverage. Rates include total admissions or hospital days during the time at risk, divided by patient years at risk. The period at risk begins at the later date of either January 1 or day 91 of ESRD, and censoring occurs at death, end of Medicare

Part A coverage, or December 31, in addition to other censoring criteria that vary by modality as described below. Since a currently hospitalized patient is not at risk for admission, hospital days are subtracted from the time at risk for hospital admissions. Additionally, rehospitalization rates include the percentage of live hospital discharges that are followed by a subsequent hospital admission within 30 days. Hospitalization data do not exclude inpatient stays for the purpose of rehabilitation therapy.

STATISTICAL MODELS

Inpatient institutional claims are used for the analyses, and methods for cleaning claims follow those described for Reference Table G. Adjusted rates are calculated using the model-based adjustment method on the observed category-specific rates. Predicted rates are calculated with a Poisson model, and adjusted rates are then computed with the direct adjustment method and a reference cohort. This method is described further in the discussion of Reference *Table G: Morbidity and Hospitalization^{\$}*, and in the *Statistical Methods* section later in this chapter.

TRENDS IN HOSPITALIZATION RATES

Methods in Figures 5.1-5.3 follow those for Reference *Table G: Morbidity and Hospitalization*^{\$}. Figure 5.1 presents adjusted rates of total hospital admissions and days per patient year. Prevalent ESRD patients are included, and rates are adjusted for age, sex, race, primary cause of ESRD, and their two-way interactions with the 2011 ESRD cohort used as the reference.

Figure 5.2 shows the admission rates since 2005 for period prevalent ESRD patients. Included patients have Medicare as primary payer and are residents of the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories. Patients with AIDS as a primary or secondary cause of death are excluded, as are patients with missing age or sex information. Rates are adjusted for age, sex, race, and primary cause of ESRD, and their two-way interactions using the model-based adjustment method. The reference cohort includes period prevalent ESRD patients in 2011. New dialysis access codes for PD patients appeared in late 1998. For PD patients, dialysis access hospitalizations are those defined as "pure" inpatient

vascular/dialysis access events, as described for Tables G.11-G.15. For HD patients, vascular access hospitalizations include "pure" inpatient vascular access events, and vascular access for HD patients excludes codes specific to PD catheters (996.56, 996.68, and V56.2). Principal ICD-9-CM diagnosis codes are used to identify cardiovascular and infection admissions. The cardiovascular category consists of codes 276.6, 394-398.99, 401-405, 410-420, 421.9, 422.90, 422.99, 423-438, and 440-459, while infection is indicated by codes 001-139, 254.1, 320-326, 331.81, 372-372.39, 373.0-373.2, 382-382.4, 383, 386.33, 386.35, 388.60, 390-393, 421-421.1, 422.0, 422.91-422.93, 460-466, 472-474.0, 475-476.1, 478.21-478.24, 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, 566-567.9, 569.5, 572-572.1, 573.1-573.3, 575-575.12, 590-590.9, 595-595.4, 597-597.89, 598.0, 599.0, 601-601.9, 604-604.9, 607.1, 607.2, 608.0, 608.4, 611.0, 614-616.1, 616.3-616.4, 616.8, 670, 680-686.9, 706.0, 711-711.9, 730-730.3, 730.8-730.9, 790.7-790.8, 996.60-996.69, 997.62, 998.5, and 999.3.

Figure 5.3 presents unadjusted and adjusted rates of total hospital admissions per patient year by Health Service Area in 2014. Prevalent ESRD patients are included, and rates are adjusted for age, sex, race, and primary cause of ESRD with the 2011 ESRD cohort used as the reference.

Table 5.1 presents unadjusted and adjusted admission rates among adult (aged 22 and older) period prevalent HD patients. Principal ICD-9-CM diagnosis codes are used to identify cause-specific admissions: codes for cardiovascular and infectious admissions are listed in the discussion of Figure 5.2, while codes for vascular access infection are listed in Table m.5 in the section describing the methods for Reference Table G: Morbidity and Hospitalization^{\$}. Rates are adjusted for age, sex, race, primary ESRD diagnosis, and their two-way interactions; values presented by one factor are adjusted for the other three. For adjusted rates, HD patients in 2011 are used as the reference cohort. Values by age, sex, race, and primary cause of ESRD are shown for 2012-2013 prevalent HD patients.

HOSPITALIZATION DAYS

Figure 5.4 shows adjusted hospital day rates by treatment modality among prevalent ESRD patients.

Again, rates are adjusted for age, sex, race, primary cause of ESRD, their two-way interactions with ESRD patients in 2011 used as the reference cohort. Treatment modalities are listed in the discussion of Figure 5.2.

Figure 5.5 shows adjusted infectious and cardiovascular hospital day rates among prevalent ESRD patients. Again, rates are adjusted for age, sex, race, primary cause of ESRD, their two-way interactions with ESRD patients in 2011 used as the reference cohort. Principal ICD-9-CM codes for cardiovascular and infection hospitalizations are listed in the discussion of Figure 5.2.

REHOSPITALIZATION RATES

Figures 5.6-5.11 show rates of rehospitalization and/or death among prevalent HD patients of all ages, 30 days after hospital discharge. Live hospital discharges from January 1 to December 1 of the year are identified as index hospitalizations; the latter date provides a 30-day period following the latest discharge to evaluate rehospitalization. The units of analyses include hospital discharges rather than patients. Hospitalization data exclude transfers. Discharges with a same-day admission to long-term care or a critical access hospital are excluded. For HD patients in Figures 5.6-5.11, discharges with a transplant, loss to follow-up, or end of payer status before day 30 after discharge are excluded. For ESRD patients in Figure 5.6, the same exclusions apply except as related to transplant; discharges from transplant patients are excluded if they occur after 2 years and 11 months following the most recent transplant to ensure that complete claims are available during the 30-day postdischarge period.

Figure 5.6 shows overall percentages of discharges with 30-day rehospitalization and/or death in the general Medicare, CKD, and ESRD populations. Data include point prevalent Medicare patients on December 31, 2013, who are aged 66 and older. Patients are grouped by younger or older than age 66 so they have at least one year of CKD or ESRD care. For general Medicare patients with and without CKD, CKD is defined during 2013, and patients remain who are without ESRD, with continuous enrollment in Medicare Parts A and B, and without HMO coverage. Live hospital discharges from January 1 to December 1, 2014 are included.

Figures 5.6-5.8 and 5.10-5.11 indicate the percentage of discharges with readmission and/or death within 30 days after discharge. The groups indicate status at day 30 after discharge from the index hospitalization, and do not consider events after day 30. Figures 5.6-5.7 include all-cause index hospitalizations, while in Figure 5.8, categories of cause-specific admissions are based on principal ICD-9-CM diagnosis codes of the index hospitalization. Codes for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 5.2; vascular access infection codes are 996.62 and 999.31. Figures 5.10-5.11 include the codes for discharges from cardiovascular hospitalizations listed for Figure 5.2, and Figure 5.11 includes the codes for acute myocardial infarction (AMI), congestive heart failure (CHF), stroke and dysrhythmia. ICD-9 CM codes for AMI: 410.x0 and 410.x1; CHF: 398.91, 402.x1, 404.x1, 404.x3. 425, and 428; stroke: 430-434; and dysrhythmia: 426-427. Figure 5.9 indicates the percentage of hospital discharges followed by a 30-day rehospitalization by cause-specific groups for both the index hospitalization and the rehospitalization. Categories of cause-specific rehospitalization also include non-vascular access infections, defined by infection codes excluding 996.62 and 999.31, and other, defined by codes other than cardiovascular and infectious.

CHAPTER 6: MORTALITY

Unless otherwise specified, patient cohorts underlying the analyses presented in Chapter 6 include Medicare and non-Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories.

MORTALITY AMONG ESRD PATIENTS, OVERALL, AND BY MODALITY

Figure 6.1 shows trends in mortality rates by modality among incident ESRD patients during 1996-2013. Modalities include ESRD, dialysis, HD, CAPD/CCPD, and first transplant; results aggregating across modalities are also presented. Patients are classified by year based on date of ESRD onset. Dialysis patients are followed from ESRD onset (i.e., day one) censored at the earliest of date of transplant,

loss to follow-up, 90 days after recovery of native renal function, or December 31, 2013. Transplant patients begin follow-up at the date of transplant and are censored on December 31, 2013. Adjusted mortality rates for each period after first treatment are computed separately by taking an appropriate weighted average of Cox-regression based predicted rates. The adjustment is made through model-based direct standardization, and is described later in the *Statistical Methods* section of this chapter. The Cox proportional hazard model serves as the basis for the predicted rates, adjusted for age, sex, race, and primary cause of ESRD. The reference population consists of 2011 period prevalent ESRD patients.

MORTALITY BY DURATION OF DIALYSIS, INCLUDING TRENDS OVER TIME

Figure 6.2 shows adjusted all-cause mortality among incident patients by year after incidence. The rates are based on the predicted cumulative hazard for patients in the reference dataset from an adjusted Cox model on survival based on incident patients in 2012, adjusted to period prevalent patients in 2011.

MORTALITY DURING THE FIRST YEAR OF ESRD

Figure 6.3 displays adjusted mortality for incident patients in the first year by modality. Patients are followed from ESRD onset (day one; as reflected by first service date) up to one year, and censored at loss to follow-up, transplant, or 90 days after recovery of kidney function. The analyses are conducted separately for dialysis patients under the age of 65 (6.3.a) and aged 65 and over (6.3.b). Note that patients with unknown age, sex, or primary cause of ESRD are excluded from the analysis. Rates are adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD, with the 2011 incident ESRD patients serving as the reference population. The adjustment method is similar to that used for Figure 6.2.

MORTALITY BY AGE AND RACE

Table 6.1 shows the death rates for different race and age (6.1.a) and sex and age (6.1.b) categories among period prevalent transplant and dialysis patients in 2012. Adjusted death rates within each category are determined by calculating the weighted average across the sex, diagnosis, and race categories. Weighting is calculated according to the age, race, sex, and diagnosis category prevalence within the 2011 period prevalent reference data.

CAUSE-SPECIFIC MORTALITY RATES

Table 6.2 shows cause-specific mortality percentages by modality. Cardiovascular disease causes of death included: pericarditis (including cardiac tamponade), acute myocardial infarction, cardiac (other than pericarditis or myocardial infarction), cerebrovascular (including spontaneous subdural hematoma), atherosclerotic heart disease, cardiomyopathy, cardiac arrhythmia, cardiac arrest (cause unknown), valvular heart disease, pulmonary edema due to exogenous fluid, congestive heart failure, cerebrovascular accident including intracranial hemorrhage, and ischemic brain damage/anoxic encephalopathy. Infectious causes of death included: septicemia due to internal vascular access, septicemia due to vascular access catheter, septicemia due to peripheral vascular disease (gangrene), septicemia (other), peritoneal access infectious complication (bacterial or fungal), peritonitis (complication of peritoneal dialysis), central nervous system infection (brain abscess, meningitis, encephalitis, etc.), pulmonary infection (bacterial, fungal, or other), viral infection (CMV), viral infection (other, excepting hepatitis), tuberculosis, A.I.D.S., infections (other), cardiac infection (endocarditis), pulmonary infection (pneumonia, influenza), abdominal infection (peritonitis [not complication of PD], perforated bowel, diverticular disease, gallbladder), hepatitis B, hepatitis C, other viral hepatitis, genitourinary infection (urinary tract infection, pyelonephritis, renal abscess), or fungal peritonitis.

SURVIVAL PROBABILITIES FOR ESRD PATIENTS

Table 6.3 presents adjusted three-month, one-year, two-year, three-year, and five-year survival by modality. Data are obtained from Reference Table I: Patient Survival.

In the discussion for Table 6.3, we conducted an analysis in order to estimate three-year survival in the general population, matching on the age and sex distribution in specific ESRD populations. We used the 2013 life table from the Social Security Administration to obtain three-year survival at each year of age for males and for females. These data were matched by year of age at incidence for all ESRD patients, hemodialysis patients, peritoneal dialysis patients, deceased-donor kidney recipients, and living-donor kidney recipients in 2009. The mean three-year survival was calculated for this age- and sex-matched group and reported in Chapter 6.

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

Table 6.4 presents expected remaining lifetimes in years for the 2012 general U.S. population, and for 2013 prevalent dialysis and transplant patients. For period prevalent ESRD patients in 2013, expected lifetimes are calculated using the death rates from a generalized linear model with 16 age groups, assuming a constant mortality rate within each age group. The method for calculating expected remaining lifetimes is described in the *Statistical Methods* section at the end of this chapter. Data for the general population are obtained from the National Vital Statistics Report, Table 7, "Life expectancy at selected ages, by race, Hispanic origin, race for non-Hispanic population, and sex: United States, 2012" (CDC, 2012).

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

Table 6.5 shows adjusted all-cause mortality in the ESRD and general Medicare populations (over the age of 65) using the Medicare 5% sample. Each prevalent sample is defined by the Medicare Part A and B beneficiaries available on December 31 of the preceding year. Follow-up for ESRD patents is from January 1 to December 31 of each year. For general Medicare patients, follow-up is from January 1 to December 31 of each year, censored at ESRD and at the end of Medicare entitlement or switching to managed care (Medicare Advantage). Adjusted mortality is adjusted for age, sex, and race, with 2014 ESRD patients serving as the reference population.

Figure 6.4 presents both unadjusted and adjusted all-cause mortality in the ESRD, dialysis, transplant, and among general Medicare patients from the 5% sample with cancer, DM, CHF, cerebrovascular accident/transient ischemic attack (CVA/TIA), and AMI. Patients can be in more than one comorbidity category. All cohorts are defined on December 31 of

the preceding year, and include patients aged 65 and older. Adjustment methods and follow-up are as defined for Table 6.5, except the reference population is 2012 ESRD patients.

CHAPTER 7: TRANSPLANTATION

OVERVIEW

Figures 7.1-7.4 present an overview of trends in kidney transplantation.

Figure 7.1 juxtaposes the percentage of dialysis patients wait-listed for a kidney transplant with the falling rate of transplantation in dialysis patients at all ages, 1997-2014. The data source is Reference Tables E.4 and E.9.

Figure 7.2 shows the number of ESRD-certified candidates on the OPTN kidney transplant waiting list on December 31 of each year during 1997-2014, for first and subsequent kidney-alone or kidney plus other organ transplants. Figure 7.2 also shows the median waiting time from wait-listing to kidney transplantation for candidates for kidney-alone transplants (i.e., the time by which 50% of these candidates had received a kidney transplant). Candidates listed at more than one transplant center on December 31 are counted only once. Median waiting time is calculated for all candidates enrolled on the waiting list in each given year during 1997-2009. The data source is Reference Tables E.2 and E.3.

Table 7.1 shows the median waiting time from waitlisting to kidney transplantation for candidates for kidney-alone transplants, by blood types and panel reactive antibodies (PRA), during 1997-2009. The same methods used to calculate the median waiting time in Figure 7.2 are used for Table 7.1.

Figure 7.3 presents the number of transplants by donor type during 1997-2014. The data source is Reference Tables E.8, E.8(2), and E.8(3).

Figure 7.4 shows the cumulative number of functioning kidney-alone and kidney-pancreas transplants as of December 31 of each year during 1997-2014. The data source is Reference Table D.9.

KIDNEY TRANSPLANT WAITING LIST

Figure 7.5 shows the percentage of patients waitlisted or receiving a deceased or living donor kidney-

alone or kidney plus other organ transplant within one year of ESRD initiation, stratified by age, during 1997-2013. The data source is Reference Table E.5(2).

Figure 7.6 shows the annual mortality rates of dialysis patients who were wait-listed for a kidneyalone or kidney plus other organ transplant, per 1,000 dialysis patient years at risk, by time since listing, during 1997-2014. The data source is Reference Table H.6.

TRANSPLANT COUNTS AND RATES

Table 7.2 shows the unadjusted kidney transplant rates of all donor types, by age, sex, race, and primary cause of ESRD, per 100 dialysis patient years, during 2005-2014. The data source is Reference Table E.9.

Figures 7.7-7.10 illustrate the counts and unadjusted rates of deceased kidney-alone and simultaneous kidney-pancreas transplants by age, sex, race, and recipient primary cause of ESRD, during 1997-2014. The data source is Reference Tables E.8(2) and E.9(2).

Figures 7.11-7.14 portray the counts and unadjusted rates of living donor kidney-alone and simultaneous kidney-pancreas transplants by age, sex, race, and primary cause of ESRD, during 1997-2014. The data source is Reference Tables E.8(3) and E.9(3).

Figure 7.15 shows the number of kidney paired donation transplants and percent of all living donor transplants during 2012-2014. The denominator is any kidney-alone or kidney plus at least one other organ transplant from a living donor. A kidney paired donation transplant is defined as any living donor kidney transplant for which the donor type (as reported on the OPTN Living Donor Registration form) was coded as "non-biological, unrelated: paired donation." Data are obtained from OPTN.

DECEASED DONATION COUNTS AND RATES AMONG ALL-CAUSE DEATHS

Figures 7.16-7.18 show the counts and unadjusted rates of deceased donor donation among all deaths within the U.S. population younger than 75 years old, by age, sex, and race, during 2000-2014. Donors had at least one kidney recovered. Data on the deceased donors are obtained from OPTN, and data on the annual number of deaths in the U.S. population are obtained from the Centers for Disease Control and Prevention.

DECEASED DONATION COUNTS AND RATES AMONG TRAUMATIC DEATHS

Figures 7.19-7.21 show the counts and unadjusted rates of deceased donation among traumatic deaths within the U.S. population younger than 75 years old, by age, sex, and race, during 2000-2014. Traumatic deaths include motor vehicle accident, suicide, or homicide. Donors had at least one kidney recovered. Data on the deceased donors are obtained from OPTN, and data on the annual number of deaths in the U.S. population are obtained from the Centers for Disease Control and Prevention.

TRANSPLANT OUTCOMES

Table 7.3 shows one-, five-, and ten-year graft and patient outcomes for recipients who received a first kidney transplant from a deceased donor during 1997-2013. Data sources for one-, five-, and ten-year trends are Reference Tables F.2, F.14, I.26; F.5, F.17, I.29; and F.6, F.18, I.30, respectively.

Table 7.4 shows one-, five-, and ten-year graft and patient outcomes for recipients who received a first kidney transplant from a living donor during 1997-2013. Data sources for one-, five-, and ten-year trends are Reference Tables F.8, F.20, I.32; F.11, F.23, I.35; and F.12, F.24, I.36, respectively.

In both Tables 7.3 and 7.4, data are reported as unadjusted probabilities of each outcome, computed using Kaplan-Meier methods. All-cause graft failure is defined as any graft failure, including repeat transplantation, return to dialysis, and death. Death outcome is not censored at graft failure repeat transplantation, or return to dialysis.

CHAPTER 8: ESRD AMONG CHILDREN, Adolescents, and Young Adults

Information on pediatric patients is a subset of ESRD patient data reported in other chapters of the ADR; methods used for most figures are therefore the same as those described in the related chapter discussions.

After reviewing the height and weight of patients aged o-4 years old from 1996-2014, from the Medical

Evidence form and CROWNWeb data, a data cleaning process was deemed necessary for this chapter. There were 217 patients with unreasonable height and weight values, which we considered to be adults mistaken as pediatric patients. These patients have been excluded from all special analyses in this chapter.

INCIDENCE AND PREVALENCE

Methods for this section should refer to the discussion of methods for *Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment* Modalities. Data sources are the same with the exception of the data cleaning mentioned above.

ETIOLOGY

The underlying etiologies of ESRD are generated from the ESRD Medical Evidence Form (CMS 2728). New primary disease groups CAKUT (congenital anomalies of the kidney and urinary tract) and transplant complications are created and some of the diseases are regrouped based on clinical review this year. Diseases such as scleroderma, nephropathy due to heroin abuse and related drugs, analgesic abuse, radiation nephritis, lead nephropathy, gouty nephropathy, acute interstitial nephritis, urolithiasis, Other disorders of calcium metabolism, tuberous sclerosis, Fabry's disease, sickle cell trait and other sickle cell (HbS/Hb other), urinary tract tumor, lymphoma of kidneys, multiple myeloma, other immunoproliferative neoplasms, amyloidosis, postpartum renal failure, hepatorenal syndrome are suppressed from Table 8.1 due to 10 or fewer total pediatric patients for year categories.

HOSPITALIZATION^{\$}

Figures 8.4-8.6 present adjusted admission rates in the first year of ESRD, by age, and modality, for 2004-2008 and 2009-2013 incident patients younger than age 22. The patients are divided into five age groups (ages 0-4, 5-9, 10-13, 14-17, and 18-21) or three modality groups (HD, PD, and transplant). Since in-center hemodialysis patients who are younger than 65 and not disabled cannot bill for hospitalizations until 90 days after ESRD initiation, the 90-day rule is applied. Patients are required to survive the first 90 days after initiation, and are followed for admissions for up to one year after day 90. Data cleaning and counting of admissions and time at risk for admissions generally follow methods described for Reference Table G: Morbidity and Hospitalization. Censoring occurs at death, loss to follow-up, end of payer status, December 31, 2014, or at one year. Censoring also occurs three days prior to transplant for dialysis patients, and three years after the transplant date for transplant patients. Rates are adjusted for sex, race, Hispanic ethnicity, and primary cause of ESRD. Adjusted rates are calculated with a model-based adjustment method and an interval Poisson model. The reference includes incident ESRD patients aged o-21 years in 2010-2011. Principal ICD-9-CM diagnosis codes used for infectious hospitalizations are listed in the discussion of Figure 5.2. Changes are made this year for the cardiovascular hospitalization codes in order to reflect the appropriate events considered for children. The cardiovascular category consists of principal ICD-9-CM diagnosis codes 390, 391, 394-398.99, 402, 404, 404.01, 404.03, 404.91, 410-414, 414.00-414.02, 414.05-414.07, 414.8, 414.9, 414.14, 416, 420-429.9, 430-438, 440-449, 459, 525.8, 745, 746.0-746.9, 779.89, V43.3.

MORTALITY AND SURVIVAL

Figures 8.7-8.9 present adjusted all-cause and cause-specific mortality in the first year of ESRD, by age and modality, for 2004-2008 and 2009-2013 incident patients younger than 22 years old. The patients are divided into five age groups (ages 0-4, 5-9, 10-13, 14-17, and 18-21) or three modality groups (HD, PD, and transplant). Dialysis patients are followed from the day of ESRD onset until December 31, 2014, and censored at loss to follow-up, transplantation, or recovered renal function. Transplant patients who receive a first transplant in a calendar year are followed from the transplant date to December 31, 2014. Rates by age are adjusted for sex, race, Hispanic ethnicity, and primary cause of ESRD; rates by modality are adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD. Incident ESRD patients who were younger than 22 years in 2010-2011 are used as the reference cohort. Cardiovascular mortality is defined using codes from past and current Death Notification forms: 01, 02, 03, 04, 1, 2, 3, 4, 23, 25, 26, 27, 28, 29, 30, 32, 36, and 61; infection mortality is defined using codes from past and current Death Notification forms: 10, 11, 12, 13, 33, 34, 45, 46, 47, 48,

49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 62, 63, 64, 65, 70, 71,74.

Figure 8.10 presents five-year survival rates for 2005-2009 incident ESRD patients aged 0-21 years, by age, modality, and ethnicity. The patients are divided into five age groups (age 0-4, 5-9, 10-13, 14-17, and 18-21) or three modality groups (HD, PD, and transplant). Dialysis patients are followed from the day of ESRD onset until December 31, 2014, and censored at loss to follow-up, transplantation, or recovered kidney function. Transplant patients who receive a first transplant in a calendar year are followed from the transplant date until December 31, 2014. Probabilities by age are adjusted for sex, race, Hispanic ethnicity, and primary cause of ESRD; probabilities by modality are adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD. The reference population consists of 2010-2011 incident pediatric ESRD patients.

VASCULAR ACCESS

Data for Figure 8.11 and Figure 8.12 are obtained from the Medical Evidence form; data are restricted to the most recent version. Figures 8.11 also include data from CROWNWeb. Patients with missing vascular access data are excluded. Figure 8.10 present data for pediatric patients who began dialysis during 2006-2014; age is calculated as of the date regular chronic dialysis began. In Figure 8.11, all HD pediatric patients who had ESRD at least 90 days at the time vascular access was reported were included. Patients must have been alive as of December 31, 2015.

TRANSPLANTATION

Figure 8.13 presents an overview of the transplant population among children and adolescents.

Figure 8.13.a shows the rate of ESRD among those aged o-21 years in the U.S. population, and the rate of transplantation in dialysis patients aged o-21 at transplant during 1996- 2014. Pre-emptive transplant patients were included in both the numerator and the denominator.

Figure 8.13.b shows the number of ESRD-certified candidates o-21 years old on the OPTN kidney transplant waiting list on December 31 of each year, and the median waiting time from wait-listing to kidney transplantation for new candidates (i.e., the

time by which 50% of newly wait-listed candidates had received a kidney transplant). Candidates listed at more than one center on December 31 are counted only once. Median waiting time is reported for patients listed in each given year.

Figure 8.13.c-8.13.e present counts for all transplant recipients 0-21 years old, by donor type, and by patient age group 0-17 years vs. 18-21 years.

Figure 8.14 presents transplant rates per 100 dialysis patient years among dialysis patients (0-21 years old). Figure 8.14.a presents rates by age group. Figure 8.14.b presents rates by race. Asian and Native American groups were not displayed, however, because of the fluctuation due to small populations. Rates were calculated among dialysis patient years in that specific subgroup.

Figure 8.15 shows the median waiting time from initiation of HD or PD in incident pediatric ESRD patients (0-21 years old) to first transplant. Patient age in Figure 8.15.b was defined as the age at initiation of HD or PD. Incident dialysis and transplant patients are defined at the onset of dialysis or the day of transplant using the 60-day rule. Figure 8.15.b includes pediatric patients (0-21 years old) starting initiation of HD or PD in 1996-2013, and having the first transplant before 12/31/2015.

Table 8.2 presents patient adjusted ten-year outcomes for pediatric recipients (ages 0-21) who received a kidney transplant from a deceased or living donor. Death outcome probabilities are calculated among first-time transplants. Data are reported as adjusted probabilities of each outcome, and are computed using Cox proportional hazards models. The death outcome is not censored at graft failure, and includes deaths that occur after repeat transplantation or return to dialysis. These probabilities are adjusted as described below.

For the all-cause graft failure analyses, data are reported as adjusted probabilities of each outcome, and are computed using Cox proportional hazards models. Probabilities are adjusted for age, sex, race, primary cause of ESRD, and first versus subsequent transplant, and standardized to 2011 patient characteristics. All-cause graft failure includes retransplant, return to dialysis, and death.

VOLUME 2: ESRD ANALYTICAL METHODS

For the probability of death analyses, the Cox model and the model-based adjustment method are used for adjusted probabilities. The adjusted survival probability for a cohort is based on expected survival probability for the cohort and the reference population. The survival/conditional probabilities are modeled separately for each period: 0-90 days, 91 days to one year, one year to two years, two years to three years, three years to five years, and five years to ten years. The expected survival probabilities for 90 days, one year, two years, and so on are calculated based on the survival/conditional survival probabilities. We fit one model for each cohort to obtain adjusted probabilities overall and for age, sex, race, and primary cause of ESRD. The reference population consists of 2011 incident ESRD patients. The death outcome is not censored at graft failure, and includes deaths that occur after re-transplant or return to dialysis.

YOUNG ADULTS

Analytical methods in the young adult section are similar to the pediatric section. The reference population consists of 2010-2011 incident young adult ESRD patients who were 22-29 years old.

CHAPTER 9: CARDIOVASCULAR DISEASE^{\$}

This chapter describes the prevalence of cardiovascular comorbidities and selected cardiovascular procedures in fee-for-service, eligible Medicare enrollees. According to a previously validated method for using Medicare claims to identify diabetic patients, a patient is considered diabetic if within a one-year observation period, he or she: (1) had a qualifying ICD-9-CM diagnosis code of DM on one or more Part A institutional claims (inpatient, skilled nursing facility, or home health agency), or (2) had two or more institutional outpatient claims and/or Part B physician/supplier claims (Herbert et al., 1999). Using the same approach, we identified patients with comorbid conditions related to cardiovascular diseases using ICD-9-CM diagnosis codes over a oneyear observation period. In contrast to these diagnoses, procedures were identified when one procedure code appeared for the patient during the observation period.

Cardiovascular comorbidities include 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 algorithm above is used to define these cardiovascular conditions using the ICD-9-CM code values in Table m.3.

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; 424-425,427-428; 430- 438; 440-444; 447; 452-453; 557; V42.1, V45.81, V45.82	
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	

vol 2 Table m.3 ICD-9-CM diagnosis codes used to define cardiovascular disorders in the USRDS ADR, Volume 2, Chapter 9

Data 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 include percutaneous coronary interventions (PCI), coronary artery bypass grafting (CABG), the placement of implantable cardioverter defibrillators (ICD) and cardiac resynchronization devices with defibrillators (CRT-D), and carotid artery stenting (CAS) and carotid artery endarterectomy (CEA). Procedures require only one claim with the procedure code. The presence of PAD is determined by the diagnosis or a claim for a procedure. Table m.4 shows the codes and type of claims used to identify each procedure.

vol 2 Table m.4 Procedure codes (ICD-9-CM and HCPCS) & claims files used to define cardiovascular procedures in the USRDS ADR, Volume 2, Chapter 9

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, 35133 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, 35473, 35474, 35480, 35481, 35482, 35483, 35485, 35490, 35491, 35493, 35495, 35561, 35531, 35533, 35541, 35546, 35548, 35549, 35553, 35566, 35558, 35563, 35565, 35566, 35571, 35583, 35587, 35623, 35623, 35646, 35647, 35651, 35654, 35656, 35661, 35663, 35665, 35661, 35671
Percutaneous coronary interventions (Pe	CI)
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 8	a 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 stunting and carotid arter	y 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

Data Source: ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification. 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. Abbreviations: HCPCS, Healthcare Common Procedure Coding System, IP, inpatient, OP, outpatient services during inpatient stay, SN, skilled nursing facility, PB, physician and supplier services covered by Part B, OP-revenue, outpatient revenue claims during inpatient stay.

CARDIOVASCULAR DISEASE PREVALENCE AND OUTCOMES IN ESRD PATIENTS^{\$}

Figure 9.1 shows the causes of death in prevalent dialysis patients during 2012-2014. The data source is a special analysis using the data in Reference Table H.12. There are two versions of the pie chart presented in parts (a) and (b) of Figure 9.1. In (a), the percentages shown in the pie chart are among known causes of death; the denominator excludes missing/unknown causes of death. In (b), the percentages shown in the pie chart are among all deaths; the denominator includes missing/unknown causes of death. Unknown causes of death include records from the CMS 2746 ESRD Death Notification form that specifically designate an unknown cause of death. Deaths with missing causes include records in the ESRD database that are missing the CMS 2746 ESRD Death Notification form, or have the form but are missing or have recording errors in the primary cause of death field.

Table 9.1 displays the prevalence of cardiovascular comorbidities and procedures, by modality, age, race and gender, among ESRD patients in 2014. The cohort includes point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older with Medicare as primary payer on January 1, 2014, who are continuously enrolled in Medicare Parts A and B from January, 1, 2013 to December 31, 2013, and whose ESRD service date is at least 90 days prior to January 1, 2014. We exclude patients with unknown age, gender, or race and those with an age calculated to be less than zero or greater than 110. The denominators for the cardiovascular procedures were not "all patients in the cohort," which was the denominator for the prevalence statistics for cardiovascular comorbidities. The percent with PCI or CABG 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 cohort members with ASHD, CVA/TIA, or PAD.

Figures 9.2 and 9.3 show the percentage of patients who had cardiovascular comorbidities, by modality and age, respectively, among adult ESRD patients in 2014. The cohort is the same one used for Table 9.1.

Figure 9.4 illustrates the adjusted survival of patients, by cardiovascular diagnosis or procedure.

The cohort includes point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older with Medicare as primary payer on January 1, 2012, who are continuously enrolled in Medicare Parts A and B from January, 1, 2011 to December 31, 2011, whose first ESRD service date is at least 90 days prior to January 1, 2012, and who survived past 2012. Patients with CHF, PAD, and CVA/TIA are those whose Medicare claims indicated the diagnosis or procedure in 2012 or Medical Evidence forms reported the comorbidities during ten years before the first ESRD service date. Patients with ASHD, AMI, VHD, AFIB, SCA/VA, VTE/PE, PCI, CABG, ICD/CRT-D, or CAS/CEA are those whose Medicare claims indicate the diagnosis or procedure in 2012. Patients are followed from January 1, 2013, until the earliest date of death, modality change, transplant, loss to follow-up, recovery of renal function, or December 31, 2014. The adjusted probability of survival was calculated using the results of a Cox model, in which significant factors included age group and sex.

CONGESTIVE HEART FAILURE AMONG ESRD PATIENTS^{\$}

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.3) 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 9.5 shows the distribution of heart failure type by modality in 2014 for the same study cohort as in Table 9.1, except that patients who received a transplant were excluded. The denominators were the total numbers of patients for each modality, and the numerators were the numbers of patients with the given heart failure type within that modality.

CHAPTER 10: PROVIDERS

The methods and data sources used to identify dialysis facilities are the same as those used in Reference Table J. Please refer to the section on *Reference Table J: Providers*, found later in this document, for detailed methods and data source description.

A facility's hospital-based or freestanding status is determined from the third and fourth digits of the provider number assigned to each unit by CMS. A facility's profit status is determined through the ownership type field on the CMS survey (for years prior to 2001) or the profit status field of the DFC database (2001 to the present).

PROVIDER GROWTH

Figures 10.1 and 10.2 show the counts of units and patients for all provider types from the 2011-2014 Annual Facility Survey.

CHOICE OF DIALYSIS MODALITY

Figure 10.3 presents the percentage of patients who are being treated by PD and home HD by provider type and patient characteristics.

TYPE OF VASCULAR ACCESS

Figures 10.4 and 10.5 present the percentage of patient-months in 2014 during which a hemodialysis patient had a particular type of access: catheter, fistula, graft, or other/missing type for incident and prevalent HD patients, respectively. Both sets of figures show the percentages for all patients and are stratified by patient characteristics (gender and race).

Figure 10.6 describes the facility level distribution of percentage of patient-months in each of the above vascular access types for 2014 incident and prevalent HD patients, respectively.

WAIT-LISTING FOR KIDNEY TRANSPLANTATION

Figure 10.7 shows the percentage of dialysis patients on the kidney transplant waiting list in 2011, 2012, 2013, and 2014, all patients and stratified by patient characteristics (gender and race). This set of figures measures wait-listing only among patients younger than age 70, because transplantation occurs much less frequently in people aged 70 and older.

STANDARDIZED MEASURES OF CLINICAL OUTCOMES

Tables 10.1 and 10.4 compare mortality and hospitalization among dialysis provider types and chains, using standardized mortality ratios (SMRs) and standardized hospitalization ratios (SHRs). Both measures are estimated using a two-stage Cox proportional hazards model (described in the *Statistical Methods* section below). SMR and SHR calculations include all 2011, 2012, 2013, and 2014 period prevalent dialysis patients; SHR calculations include only dialysis patients with Medicare as primary payer.

ADJUSTMENT

Both SMRs and SHRs are adjusted for patient age, race, ethnicity, sex, DM, duration of ESRD, nursing home status, patient comorbidities at incidence, and body mass index (BMI) at incidence. The SMR is additionally adjusted for race-specific population death rates.

To facilitate comparison of the SMR and SHR across years, Table 10.1 (SMR) and Table 10.3 (SHR) report these measures with the year adjustment removed from the model. That is, the measures do not compare outcomes for each year to the national norm for that year, but rather compare each year to the national averages over the entire reporting period combined (e.g., four years). Because all years are reported relative to the same standard, values can be compared across years, facilitating identification of short-term trends over time. Tables 10.2 (SMR) and 10.4 (SHR) present one-year versions of the respective measures.

CONFIDENCE INTERVALS

Given the large number of observations that go into the SMR and SHR models, we choose to

approximate rather than directly calculate the 95% confidence intervals for the respective measures. This approach gains efficiency with minimal loss of precision. In particular, the exact 95% confidence intervals are derived by applying the Wilson-Hilferty Approximation (Wilson and Hilferty, 1931), which approximates chi-square percentiles using percentiles of the standard normal distribution (Breslow and Day, 1987).

PATIENT PLACEMENT

We identified each patient's dialysis provider at each point in time using data from a combination of Medicare-paid dialysis claims, the Medical Evidence form (CMS 2728), and paid dialysis claims. Starting with day 91 after onset of ESRD, we attribute a patient to a facility according to the following rules. A patient is attributed to a facility once the patient has been treated there for 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility. In particular, a patient is attributed to their current facility on day 91 of ESRD if that facility had treated him or her for at least 60 days. If on day 91, the facility had treated a patient for fewer than 60 days, we wait until the patient reaches day 60 of treatment at that facility before attributing the patient to the new facility. When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we do not attribute that patient to any facility. Patients were censored upon receiving a transplant. Patients who withdrew from dialysis or recovered renal function remained assigned to their treatment facility for 60 days after withdrawal or recovery. If a period of one year passed with neither paid dialysis claims nor CROWNWeb/SIMS information to indicate that a patient was receiving dialysis treatment, we considered the patient lost to follow-up and did not include that patient in the analysis from that point forward. When dialysis claims or other evidence of dialysis reappeared, the patient was included in the analysis again starting after 60 days of continuous therapy at a single facility.

CHAPTER 11: MEDICARE EXPENDITURES FOR PERSONS WITH ESRD^{\$}

OVERALL & PER PERSON PER YEAR COSTS OF ESRD

For the 2016 ADR, reported costs of ESRD include only those ESRD beneficiaries covered by Original Medicare (fee-for-service) for their Medicare Part A and B benefits. Medicare expenditures can be calculated from the claims submitted for payment for health care provided to these individuals, but not for those enrolled in Medicare Advantage (managed care) plans. The Medicare program pays for services provided through Medicare Advantage plans on a riskadjusted, per-capita basis, and not by specific claims for services. Methods of estimating Medicare expenditures for Medicare Advantage beneficiaries with ESRD will be explored in future ADRs.

Figure 11.1 displays Medicare paid amounts for period prevalent ESRD patients from 2004-2014, as well as patient obligations, which were estimated as the difference between Medicare allowable and Medicare paid amounts. Patient obligations may be paid by the patient, by a secondary insurer, or may be uncollected.

In Figure 11.2, total Medicare costs from each year were abstracted from the Medicare Trustees Report, Table B.1, which is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/TrusteesReports.html. Part C costs were deducted to show the fee-for-service Medicare costs.

FUNDING SOURCES FOR THE ESRD POPULATION

Figure 11.3 presents point prevalence of Medicare as primary payer, Medicare as secondary payer, and non-Medicare ESRD patients by year using the USRDS database.

Figure 11.4 describes the percent change in ESRD Medicare spending in total and per patient year, including claims with Medicare as primary payer only. Medicare spending was abstracted from Reference Table K.4.

Figure 11.5 shows the total ESRD Medicare fee-forservice expenditures by type of service, which was taken from Reference Table K.1. The analysis includes period prevalent patients, specifically, all ESRD patients with at least one Medicare claim.

Figure 11.6 presents total Medicare fee-for-service inpatient spending by cause of hospitalization during 2004-2014.

ESRD SPENDING BY MODALITY

Figure 11.7 describes total Medicare ESRD expenditures by modality. Medicare costs are from claims data.

Figure 11.8 shows the total Medicare ESRD expenditures per person per year by modality. The analysis includes period prevalent ESRD patients, and is restricted to patients with Medicare as primary payer only. Data sources are Reference Tables K.7, K.8, and K.9.

CHAPTER 12: PRESCRIPTION DRUG COVERAGE IN PATIENTS WITH ESRD^{\$}

In figures and tables regarding enrollment and utilization of Medicare Part D, we analyze data on cohorts of Medicare enrollees in 2011-2014 based on 100% of the ESRD population receiving hemodialysis, receiving peritoneal dialysis, or with a functioning kidney transplant, along with cohorts of Medicare enrollees in 2011-2014 based on the Medicare 5% sample (general Medicare enrollees). For general Medicare enrollees, we require continuous enrollment in Medicare Parts A and B during the previous calendar year, and Medicare enrollment in January of the index year. For hemodialysis, peritoneal dialysis, and kidney transplant cohorts, we identify all point prevalent patients alive and enrolled in Medicare on January 1 of the index year, with ESRD onset at least 90 days earlier; treatment modality is identified on January 1. Several tables and figures in this chapter are limited to beneficiaries who were enrolled in Part D plans for at least one month of the analysis year. See the following section for more information on Part D enrollment classification.

PART D COVERAGE PLANS

Table 12.2 reports the proportion of Medicare beneficiaries enrolled in Part D.

PART D ENROLLMENT PATTERNS

In Figures 12.1-12.3, the type of prescription drug coverage is defined sequentially. That is, we first classify patients as "Part D with low-income subsidy (LIS)," if there exists at least one calendar month in 2014 with Part D enrollment and receipt of LIS. In patients without one such month, we classify remaining patients as "Part D without LIS," if there exists at least one calendar month with Part D enrollment. In patients without one such month, we classify remaining patients as "retiree drug subsidy," if there exists at least one calendar month with employer receipt of the subsidy. In patients without one such month, we classify remaining patients as "other creditable coverage," if there exists at least one calendar month with enrollment in military, government employee, or employer group health plans. And we classify all remaining patients as "no known coverage." For Figure 12.4 and Table 12.3, we classify Part D enrollees as LIS recipients if there exists at least one calendar month in 2014 with receipt of the LIS.

SPENDING UNDER STAND-ALONE PART D PLANS

Part D costs for ESRD patients are based on Part D enrollees with traditional Medicare (Parts A and B), using the period prevalent, as-treated model. ESRD patients in Medicare Advantage Part D plans and Medicare secondary payer are excluded. In an astreated model, patients are first classified by their modality at entry into the analysis, and retain that classification until a modality change. When a change is encountered in the data, the beginning modality is censored at the change date plus 60 days, and a new observation with the new modality is created. The first 60 days after a change are attributed to the previous modality to account for any carryover effects. Some figures also include the general Medicare population (not enrolled in a Medicare Advantage Part D plan) based on the Medicare 5% sample. Costs in Tables 12.4, 12.5, and 12.7, and Figure 12.5 are presented as the total Part D spending, estimated as the Medicare covered amount plus the LIS amount. Out-of-pocket cost is estimated as patient pay amount plus the True Out-of-Pocket Costs (TrOOP) amount. Per person per year (PPPY) costs are calculated as dividing the total cost amount by the patient years at risk. Person years

at risk are calculated for the ESRD and general populations separately. For ESRD patients, person years at risk is calculated as subtracting the start date (the latest of Part D coverage start date, date of developing ESRD, and January 1 of the year) from the end date (the earliest of Part D coverage end date, death, and December 31 of the year). For general population, person years at risk is calculated as subtracting the start date (the later of Part D coverage start date and January 1 of the year) from the end date (the earliest of Part D coverage end date, date of developing ESRD, death, and December 31 of the year).

PRESCRIPTION DRUG CLASSES

Tables 12.6.and 12.7 list the top 15 drug classes used among Part D-enrolled dialysis patients by percentage of patients with any prescription filled and Medicare Part D spending. Part D covered prescriptions are grouped by their therapeutic purposes using the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification System.

CHAPTER 13: INTERNATIONAL COMPARISONS

DATA COLLECTION

Each country was provided a data-collection form spreadsheet (Microsoft Excel) to complete for years 2010 through 2014. Countries were asked to report patient count data for each year, if available, for the entire population, by sex (male, female), or by five different age categories (0-19, 20-44, 45-64, 65-74, 75+) for: (1) the country's or region's general population; (2) patients new to ESRD during the year; (3) patients new to ESRD during the year among new ESRD patients for whom diabetes was the primary cause of ESRD; (4) the point-prevalent count of ESRD patients living on December 31 of the given year; (5) total number of patients with a functioning kidney transplant on December 31 of the given year; (6) total number of kidney transplants performed during the year, by type of kidney transplant (deceased, living donor, other donor); and (7) the number of dialysis patients, HD patients, CAPD/APD/ IPD patients, and home HD patients on December 31 of the indicated year. Prevalence was reported for all patients at the end of the calendar year (December 31, 2014), except where otherwise noted. Data for the United States is

taken directly from the following Reference Tables: *M: Census Populations; A: Incidence; B: Prevalence; D: Treatment Modalities; and E: Transplantation Process.* Data provided by Argentina may be supplemented by Marinovich et al., 2016.

DATA LOADING AND CLEANING

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

INCIDENCE RATE OF TREATED ESRD

The incidence rate for Figures 13.1, 13.2, 13.7, and 13.8 was calculated as the number of patients new to ESRD during the year divided by the total population for that year, multiplied by one million. For agespecific and sex-specific categories, the incidence rate was calculated as the count in each category divided by the total population in the respective category, multiplied by one million. Figures 13.3.a presents the countries with the highest percent increase in incidence rate and 13.3.b presents the countries with the largest percent decline in incidence rate from 2001/2002-2013/2014. The percent change in incidence rate was calculated as the percent difference between the average incidence rates in 2014 and 2013 and the averages in 2001 and 2002.

DIABETES AS PRIMARY CAUSE OF ESRD IN INCIDENT PATIENTS

Ascertainment of primary ESRD cause may have changed over the reporting period in some countries and thus potentially contributed to observed changes in the percentage of patients with diabetes as cause of ESRD in incident patients. Figure 13.4 presents the percentage of incident ESRD patients with diabetes as the primary cause. The denominator is the total number of patients new to ESRD. Figure 13.5 presents the 10 countries with the highest percent increase from 2001/2002-2013/2014. The percent change in incidence of treated ESRD due to diabetes was calculated as the percent difference between the average incidence of treated ESRD due to diabetes in 2014 and 2013 and the averages in 2001 and 2002.

PREVALENCE OF ESRD

The prevalence for Figures 13.9 and 13.10 was calculated as the total number of ESRD patients receiving renal replacement therapy divided by the total population for that year, multiplied by one million. For age-specific and sex-specific categories, the prevalence was calculated as the count in each category divided by the total population in the respective category, multiplied by one million. Figure 13.11 presents the 10 countries with the highest percent increase in prevalence of ESRD from 2001/2002-2013/2014. The percent change in prevalence of ESRD was calculated as the percent difference between the average prevalence of ESRD in 2014 and 2013 and the averages in 2001 and 2002. Figure 13.12 presents the type of renal replacement therapy modality. The denominator is calculated as the sum of patients receiving HD, PD, home HD, or kidney transplantation.

PREVALENCE OF DIALYSIS

The prevalence for Figure 13.13 was the total number of ESRD patients on dialysis divided by the total population for that year, multiplied by one million. Figure 13.14 presents the 10 countries with the highest percent increase in prevalence of dialysis from 2001/2002-2013/2014. The percent change in prevalence of dialysis was calculated as the percent difference between the average prevalence of dialysis in 2014 and 2013 and the averages in 2001 and 2002. Figure 13.15 presents the percent distribution of the type of renal replacement therapy modality. The denominator is calculated as the sum of patients receiving HD, PD, home HD, and does not include patients with other/unknown modality.

KIDNEY TRANSPLANT

The kidney transplant rate is shown two ways: the transplant rate in Figure 13.16.a is calculated as the total number of kidney transplants divided by the population total, multiplied by one million; the rate in figure 13.16.b is calculated as the total number of kidney transplants divided by the prevalent number of dialysis patients, multiplied by 1000. Figure 13.17 presents the 10 countries with the highest percent increase in the kidney transplantation rate from 2001/2002-2013/2014. The percent change in kidney

transplantation rate was calculated as the percent difference between the average transplantation rates in 2014 and 2013 and the averages in 2001 and 2002. Figure 13.18 presents the percentage of kidney donor type (deceased, living, unknown). The denominator is calculated as the sum of deceased, living, and unknown donor. The prevalence in Figure 13.19 is calculated as the total number of patients with a functioning kidney transplant divided by the total population for that year, multiplied by one million.

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

CHAPTER 14: USRDS SPECIAL STUDY CENTER ON END-OF-LIFE CARE FOR PATIENTS WITH ESRD

Methods for the creation of the figures and tables in Chapter 14 are described within the chapter itself.

ESRD Reference Table Methods

REFERENCE TABLE A: INCIDENCE

The data sources for both incidence and prevalence patients are CROWNWeb, OPTN, ESRD Medical Evidence form (CMS 2728), and Medicare billing records. Incidence refers to the new cases of ESRD during a given time period. Incidence is expressed as a rate (number/million population/year). Prevalence refers to all patients receiving ESRD treatment at a particular time (December 31) and is expressed as a proportion (number/million population). A patient is considered incident at the time of first transplantation or first regular dialysis for chronic renal failure. A patient is considered prevalent if he/she is known to be receiving dialysis treatment or to have a functioning kidney transplant. Both incidence and prevalence rates are adjusted to a reference population using the direct method: this means the adjusted rate assumes a constant reference population, thus permitting meaningful comparison across years.

The 2016 ESRD Reference Tables present parallel sets of counts and rates for incidence (Table A) and December 31 point prevalence (Table B) from 1996 to 2014. Reference Table B also presents annual period prevalent counts and counts of lost-to-follow-up patients who lack any evidence of payment activity in the Medicare database for one year. Because the U.S.

population figures (shown in Reference Table M) used in the ADR include only residents of the 50 states and the District of Columbia, tables focus on patients from these areas. Exceptions are Tables A.1, A.6, A.8, and A.10, all of which present data specific to patients in Puerto Rico and the U.S. territories, or include these patients in the patient population. For incident patients, age is computed as of the beginning of ESRD therapy, while for prevalent patients, age is calculated as of December 31. Tables A.3 and B.3 are adjusted by the CDC diabetes population.

Rates in Reference Tables A.2, A.9, and A.11 are adjusted for age, sex, race, and ethnicity with the 2011 national population as reference.

Due to the lag time until reports of ESRD counts are complete, the data in these Reference Tables should be considered preliminary for 2014. The prevalence or incidence counts for a given year may change at a later date, in addition to this lag time, other factors contribute to uncertainty about the counts: for example, patients with recovered renal function, patients who die before chronic treatment is fully established; incident patients who stop chronic dialysis and then restart are counted as prevalent; incident patients who have a modality change, i.e., return to dialysis after a failed transplant, are not counted as incident ESRD patients.

REFERENCE TABLE B: PREVALENCE

Reference Table B focuses on patients in the 50 states and the District of Columbia, with the exception of Tables B.1, B.6, B.8, and B.10. Rates in Table B.2, B.9, and B.11 are adjusted for age, sex, race, and ethnicity with the 2011 national population as reference.

REFERENCE TABLE C: PATIENT CHARACTERISTICS

Data in Reference Table C are based on information collected with 2005 Medical Evidence forms (CMS 2728). The full title of the form is "End-Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration".

Each table in this section shows population characteristics by age, gender, race, ethnicity, and primary diagnosis. Mid-East/Arabian race and Indian Subcontinent race were dropped from the 2005 form; therefore, Mid-East/Arabian and Indian Subcontinent are removed from the race group. Hispanic, nonspecific ethnicity is also dropped from the 2005 form, but the category is retained since some records still provide this information. Data shown are based on the incident population with a completed Medical Evidence form within the given year range.

Table C.1 contains data on biochemical markers (item 19 in CMS 2728) from 2006-2014. Glycosylated hemoglobin (HbA1c), total cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglycerides are added to the Medical Evidence form introduced in 2005. Blood urea nitrogen (BUN) is dropped from the 2005 form; therefore, BUN data are not shown in Table C.1.

Table C.2 shows patient prior and current employment status (item 16 in CMS 2728) from 2006-2014. Employment status is collected currently and for six months prior to renal failure. There are eight employment categories for both current and prior employment status and only one should be selected for each. If the patient is under 6 years old, the employment status questions are left blank. For patients under 14, we leave six employment statuses (employed full time, employed part time, homemaker, retired due to age/preference, retired (disability), and medical leave of absence) blank. Only student and unemployed data are shown for patients under 14.

Table C.3 shows patient insurance coverage (items 11 and 12 in CMS 2728) from 2006-2014. There are eight categories of insurance coverage in item 12 — Medicare, Medicaid, Employer Group Health Insurance, DVA, Medicare Advantage, Other, and None — plus an additional category in item 11 applying for ESRD Medicare coverage.

Table C.4 presents patient comorbidity from 2009-2014 (item 17 in CMS 2728). A single patient could have multiple comorbidities.

Table C.5 describes the frequency and duration of prescribed therapy for hemodialysis patients (item 23 in CMS 2728) from 2009-2014.

Table C.6 presents distribution of patients on dialysis treatment receiving or not receiving transplant options (item 26 and 27 in CMS 2728) from 2009-2014. Patients who are not informed of transplant options have additional data for the reason for not being informed (item 27). A single patient could have multiple reasons for not getting informed.

Table C.7-C.10 describes care received prior to ESRD therapy (item 18 in CMS 2728) from 2010-2014. Table C.7 shows data for pre-ESRD nephrology care. Table C.8 shows data for pre-ESRD dietician care. Table C.9 shows data for vascular access at initiation of renal replacement therapy. If arteriovenous (AV) fistula access was not used, whether a maturing AV fistula or graft is present was further assessed. Table C.10 shows data for erythropoiesis stimulating agent (ESA) use prior to ESRD therapy.

Table C.11 presents primary dialysis setting at initiation of renal replacement therapy (item 22 in CMS 2728). Three primary dialysis settings are home, dialysis facility/center and skilled nursing facility/long-term care facility.

REFERENCE TABLE D: TREATMENT MODALITIES

Reference Table D is divided into four parts. The first, Tables D.1-D.11 and D.15-D.16, provides counts and percentages — by demographics, geographic location, and treatment modality — of incident and prevalent patients alive at the end of each year. Age is computed as of the start of ESRD for incident patients and as of December 31 for point prevalent patients.

The second part, Table D.12 shows modality at day 90 and at two years after first service for all incident patients from 2010 to 2012. The 90-day rule is used to exclude patients who die during the first 90 days of ESRD, and age is computed as of the first ESRD service date.

The third part, Tables D.13-D.14, presents counts of prevalent patients alive at the end of each year, by ESRD exposure time and modality. Table D.13 shows counts by the number of years of ESRD, while Table D.14 presents counts by the number of years on the end-of-year treatment modality. For the duration of ESRD exposure, zero should be read as less than one year, one year as at least one full year but less than two, and so on.

The fourth part, Tables D.17-D.24, presents counts of incident and prevalent patients alive at the end of selected years (i.e., 2006, 2010, 2014), by demographic characteristics, payer category, and treatment modality. Again, age is computed as of the start of ESRD for incident patients and as of December 31 for point prevalent patients. The payer categories are:

- Medicare Fee for Service (FFS) (i.e., Medicare as primary payer)
- Medicare/Medicaid (i.e., dually eligible)
- MSP (i.e., Medicare as secondary payer): EGHP and non-EGHP
- HMO (i.e., Medicare Advantage or Medicare+Choice plans)
- Other and unknown payers

A detailed discussion of payer categories can be found in the *Database Definitions* section of this chapter.

REFERENCE TABLE E: TRANSPLANTATION PROCESS

Reference Tables E.1-E.5 present data regarding the kidney transplant waiting list. Table E.1 presents counts of ESRD-certified candidates added to the waiting list for a kidney or kidney-pancreas transplant during the given year, by demographics, primary diagnosis, transplant number, active status, blood type, and panel reactive antibody (PRA) level. Patients listed at multiple transplant centers are counted only once. Table E.2 presents waiting times, defined as the median time in days from first listing to transplant among patients listed for a kidney-alone transplant, and is estimated with the Kaplan-Meier method. Patients listed at multiple centers are counted from the time of the first listing. The data are censored at the loss-of-follow-up, death, or the "end-of-study" (which is 2014 for the 2016 Reference Table). Given that the median waiting time for most subgroups of patients is between three to five years, the value cannot be estimated reliably without at least five years of follow-up. As a result, the 2016 Table E.2 only shows data up to year 2009. Table E.2 reports data by demographics, primary diagnosis, blood type, PRA level, and first or subsequent transplant. Table E.2.2 reports data by state/territory and Table E.2.3 reports data by renal network. Table E.3 presents counts of ESRD-certified patients on the waiting list at any transplant center on December 31 of the given year, regardless of when the first listing occurred, by demographics, primary diagnosis, transplant number, blood type, PRA level, and time on the list. Table E.4 includes point prevalent dialysis patients wait-listed

for a kidney on December 31 of the given year. Table E.4 reports data by demographics and primary diagnosis. E.4.2 reports data by state/territory and Table E.4.3 reports data by renal network. Table E.5 presents the percentage of patients either wait-listed or receiving a kidney transplant within one year of ESRD initiation, using the Kaplan-Meier method. Patients receiving a deceased donor kidney transplant are included in Tables E.5, E.5.3, and E.5.4, and patients receiving a deceased or live donor kidney transplant are included in Tables E.5.2, E.5.5, and E.5.6. Tables E.5 and E.5.2 report data by demographics, primary diagnosis; Tables E.5.3 and E.5.5 report data by state/territory; and Tables E.5.4 and E.5.6 report data by renal network. Note that residents of the 50 states, the District of Columbia, Puerto Rico, and U.S. territories are all included in these tables.

Tables E.6-E.8 present renal transplant counts by various combinations of factors. All kidney transplants, including kidney-alone and kidney plus at least one other organ, are included unless specified in the footnote, and all counts include non-Medicare patients. Table E.6 presents transplant counts by donor type. Table E.7 shows transplant counts for recipients whose age is younger than 22 years, by demographics, donor type, transplant number, and blood type. Table E.8 illustrates the distribution of recipients by donor type. Each E.8 table subsets transplant counts by demographics, primary diagnosis, blood type, transplant number, and PRA level, determined from the OPTN Recipient Histocompatibility form, and shows a crosstabulation of recipients and donors in terms of cytomegalovirus antibody status, hepatitis C antibody status, and Epstein-Barr virus antibody status at the time of transplantation. A recipient/donor is considered positive for any of these antibodies if any applicable OPTN data source indicates positive. Unknown status is applied when no applicable data fields indicate "positive" or "negative." Table E.8 reports data for all donor types. Table E.8.2 reports data for deceased donors. Cold ischemia time (in hours) is reported for deceased donor transplants only, and is taken from the OPTN Transplant Recipient Registration form. Table E.8.3 reports data for living donors, and donor relation is reported for living donor transplants only.

Table E.9 presents transplant rates per 100 dialysis patient years by donor type. Table E.9 reports data for all donor types. Table E.9.2 reports data for decease donors and Table E.9.3 reports data for living donors. All HD patients, PD (CAPD/CCPD) patients, and patients on an unknown form of dialysis are included, as are all non-Medicare dialysis patients. A patient's dialysis days are counted from the beginning of the specified year, or from day one of ESRD dialysis therapy if treatment begins within the specified year, until transplant, death, or the end of the year, whichever comes first. Dialysis time for patients returning to dialysis from transplant is counted. Transplant rates are calculated as the number of transplants, including kidney-alone and kidney plus at least one other organ, divided by the total number of dialysis patient years for each year.

REFERENCE TABLE F: TRANSPLANTATION: OUTCOMES

Reference Table F: Transplantation presents probabilities of graft survival and graft failure necessitating dialysis or repeat transplantation, by donor type, age, sex, race, ethnicity, primary cause of ESRD, and first versus subsequent transplant. Data are presented for outcomes at 90 days, one year, two years, three years, five years, and ten years posttransplant. The probabilities are expressed as percentages varying from 0 to 100 (rather than as probabilities varying from 0 to 1). This section seeks to address two major issues: the probability of graft survival at various times post-transplant, and the probability that a recipient will return to dialysis or require repeat transplantation at various times posttransplant. Recipients are followed from the transplant date to graft failure, death, or the end of the follow-up period (December 31, 2014). In the analysis of graft survival, death is considered a graft failure. In the analysis of graft failure necessitating dialysis or repeat transplantation, patients are followed until graft failure (excluding death), and patient follow-up is censored at death. To produce a standard patient cohort, patients with unknown age or sex are omitted. Unknown age is defined as a missing age at transplant, or an age calculated to be less than zero or greater than 100 years. Transplant patients for whom the donor type is recorded as other or unknown are excluded. Patients are also excluded if

their first ESRD service date is prior to 1977. Residents of the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories are included in these tables.

Unadjusted survival probabilities are estimated using the Kaplan-Meier method, while the Cox proportional hazards model is used for adjusted probabilities. Probabilities are adjusted for age, sex, race, primary cause of ESRD, and first versus subsequent transplant, and standardized to 2011 recipient characteristics.

REFERENCE TABLE G: MORBIDITY AND HOSPITALIZATION⁸

Reference Table G presents adjusted total admission and hospital day rates, by year, 2003-2014. The model-based adjustment method used in these tables is discussed later in this section and in the *Statistical Methods* section at the end of this chapter.

Because hospitalization data for non-Medicare patients may be incomplete, analyses in this section include only patients with Medicare as their primary payer. Hospitalization data are obtained from institutional inpatient claims. As in Chapter 5, hospitalization data in Reference Table G do not exclude inpatient stays for the purpose of rehabilitation therapy.

Tables G.1-G.15 include dialysis and transplant patients who are on their modality for at least 60 days, reaching day 91 of ESRD by the end of the year, and residing in the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories. Excluded are patients with AIDS as a primary or secondary cause of death; patients with missing values for age, sex, or race; and patients of races that are unknown or other than White, Black/African American, Native American, or Asian. Age is determined on January 1 of each year. Patients are also classified according to their primary cause of ESRD, in which the "other" category includes patients with missing data or causes other than DM, hypertension, or glomerulonephritis.

Patients are classified by modality at the beginning of the year:

• All dialysis: patients on HD, CAPD/CCPD, or dialysis of an unknown type, as well as those on more than one modality in the past 60 days

- Hemodialysis: patients on HD for at least 60 days as of the start of the period at risk
- CAPD/CCPD: patients on CAPD/CCPD for at least 60 days as of the start of the period at risk
- Transplant: patients with a functioning transplant, and who received the transplant less than three years prior to the start of the period at risk
- All-ESRD: all patients

To limit the contribution of patient years at risk from patients who do not have Medicare coverage but do have Medicare as a secondary payer or HMO coverage, and who therefore have incomplete hospitalization data, cohorts include only patients with Medicare Part A and B coverage at the start of follow-up. The follow-up period is censored when a patient's payer status changes to no longer having Medicare Part A and B coverage or Medicare as a primary payer.

For patients in the all-dialysis, HD, and PD categories, the period at risk for all hospitalization analyses is from January 1 or day 91 of ESRD until the earliest of death, three days prior to transplant, end of Medicare Part A and B coverage, or December 31. Modality change is considered a censoring event only in the case of a change from dialysis to transplant. For dialysis patients in the all-ESRD category, in contrast, the analysis period is censored only at death, end of Medicare Part A and B coverage, or December 31 of the given year; a modality change is not used as a censoring event. For transplant patients in the all-ESRD and transplant categories, the period is censored at the earliest of death, three years after the transplant date, end of Medicare Part A and B coverage, or December 31 of the given year. Censoring of transplant patients at three years following the transplant is necessary because Medicare eligibility may be lost and hospitalization data may be incomplete for these patients.

Time at risk is calculated differently for hospital days and total admissions. Since a hospitalized patient remains at risk for additional hospital days, rates for hospital days include hospital days in the time at risk value. Since a currently hospitalized patient is not, however, at risk for new admissions, hospital days for each year are subtracted from the time at risk for total admissions. In the case of a hospitalization in which

admission occurs the same day as discharge, zero days are subtracted from the time at risk for total admissions. When hospitalizations span the start of the analysis period, only the days within the period are subtracted from the time at risk for total admissions.

All admissions and hospital days during the analysis period are included, respectively, in the total admissions and hospital days for each year. An admission for a hospitalization that occurs before and spans the start of the analysis period is excluded from the total admissions for that period, and only the hospitalization days within the period are counted in the total days for hospital day rates. The minimum length of stay is one day, and hospitalizations with an admission and discharge on the same day, as well as those with a discharge the day after admission, are both counted as one day.

As in previous ADRs, all overlapping and only certain adjacent hospitalizations are combined, due to the fact that many adjacent claims may actually be legitimate separate hospitalizations. Specifically, hospitalizations with an admission on the same day or the day after a previous discharge are combined only when there is a discharge transfer code or indication of an interim claim. In the case of two hospitalizations combined into one, the principal diagnosis and procedure codes are retained from the first of the two hospitalizations, with the combined hospitalization extending from the first admission date to the last discharge date.

The methodology for computing adjusted total admission and hospital day rates uses the modelbased adjustment method (discussed in the section on *Statistical Methods*). Predicted rates for each subgroup combination of age, sex, race, primary cause of ESRD, and year are obtained using a model with the Poisson assumption. For prevalent patient cohorts, this model uses data from the current and previous two years, with respective weights of 1, ¹/₄, and ¹/₈ Adjusted rates are then calculated using the direct adjustment method, with all 2011 ESRD patients as the reference cohort.

Tables G.11-G.15 show inpatient utilization in the period prevalent ESRD patients. Methods — including modality definitions, inclusion criteria, data cleaning, follow-up time definitions, and rate calculations generally follow those described for the total admission rates in Tables G.1-G.5, but some differences do exist. While patients of races other than White, Black/African American, Native American, or Asian are excluded from G.1-G.5, they are included in G.11-G.15, except where rates are given by race. Rates are unadjusted and reflect total admissions per 100 patient years for 2006-2008, 2009-2011, and 2012-2014 (pooled) prevalent patients. While the rates for all causes are computed similarly to the unadjusted rates in G.1-G.5, the other nine cause-specific categories only include admissions for specific diseases. Vascular access and PD access hospitalizations are those classified as "pure" inpatient vascular/dialysis access events. Such access events are defined as admissions with a specified ICD-9-CM principal diagnosis code, or an ICD-9-CM principal procedure code in conjunction with a certain diagnosis-related group (DRG) code. Codes are listed in Table m.5. If an admission does not qualify as vascular/dialysis access, it is classified by the principal diagnosis code into one of eight other mutually exclusive groups. Categories and ICD-9-CM codes are as follows: circulatory diseases, 390-459; digestive diseases, 520-579; genitourinary diseases, 580-629; endocrine and metabolic diseases, 240-279; respiratory diseases, 460-519; infectious diseases, 001-139; and cancer, 140-172, 174-208, 230-231, and 233-234. Hospitalizations that do not fall under any of these categories are counted under all others.

vol 2 Table m.5 DRG & ICD-9-CM codes for vascular access & peritoneal dialysis access variables

DRG codes^a: prior to October 1, 2007

112 Percutaneous cardiovascular procedure

120 Other circulatory system OR procedure

315 Other kidney and urinary tract OR procedure

442 Other OR procedure for injuries with complication

443 Other OR procedure for injuries without complication

478 Other vascular procedure with complication

479 Other vascular procedure without complication

DRG codes^a: after September 30, 2007

252 Other vascular procedures with Major complicating conditions (MCC)

264 Other circulatory system O.R. procedures

673 Other kidney & urinary tract procedures with MCC

674 Other kidney & urinary tract procedures with CC

675 Other kidney & urinary tract procedures without CC/MCC

907 Other O.R. procedures for injuries with MCC

908 Other O.R. procedures for injuries with CC

909 Other O.R. procedures for injuries without CC/Medicare

ICD-9-CM procedure codes^a

38.95 Venous catheterization for renal dialysis

39.27 Arteriovenostomy for renal dialysis

39.42 Revision of arteriovenous shunt for renal dialysis

39.43 Removal of arteriovenous shunt for renal dialysis

39.93 Placement of vessel-to-vessel cannula

39.94 Replacement of vessel-to-vessel cannula

86.07 Placement of totally implantable vascular access device

ICD-9-CM diagnosis codes^b

996.1 Mechanical complication of vascular device, implant, graft

996.56 Mechanical complication

due to peritoneal dialysis catheter

996.62 Infectious complication of vascular device, implant, graft

996.68 Infectious complication due to peritoneal dialysis catheter

996.73 Other complication due to renal dialysis device, implant, graft

999.31 Infection due to central venous catheter

V56.1 Fitting and adjustment of extracorporeal dialysis catheter

V56.2 Fitting and adjustment of peritoneal dialysis catheter

^a DRG and procedure codes are used in conjunction to define inpatient pure vascular access events (both must be present). ^b The presence of any of these diagnosis codes as the "Principal Diagnosis Code" is sufficient to define an inpatient pure vascular access or peritoneal dialysis access event.

Tables G.1.1-G.5.1 present adjusted rates similar to those shown in G.1-G.5, but include more patient subgroups. Additionally, Tables G.1.2-G.5.2 display the counts of the total admissions, patient years at risk, and total patients that are used to calculate the total admission rates.

REFERENCE TABLE H: MORTALITY AND CAUSES OF DEATH

Cohorts for Reference Table H include both Medicare and non-Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories. The 60-day stable modality rule and 90-day rule are not applied to tables in Table H.

The cohorts in Tables H.1-H.12 are comprised of period prevalent patients, including those alive on January 1 and those incidents during a calendar year. All patients are followed from either January 1 (for those alive on January 1) or from the date of onset of ESRD (for those patients incident in a calendar year). Follow-up is censored at loss to follow-up, date of transplant (for dialysis patients), 90 days after recovery of function, or December 31 of the year. Age is defined at the beginning of follow-up. In calculating adjusted mortality, beginning in 1996, we have adjusted for and reported five race groups (White, Black/African American, Native American, Asian, and Other), as well as adjusted for ethnicity (Hispanics and non-Hispanics).

Tables H.1, H.2, and H.2.1 present mortality data for all ESRD patients. Total deaths are presented in Table H.1. Overall unadjusted and adjusted annual mortality rates by age, sex, race/ethnicity, primary cause of ESRD, and years of ESRD treatment are presented in Table H.2. Category-specific unadjusted mortality rates are calculated as total patient deaths divided by total follow-up time. Adjusted rates are computed by an appropriately weighted average of predicted category-specific rates, with the predicted rates based on generalized linear models. Such methods, akin to direct standardization, are described in the Statistical Methods section later in this chapter. Overall mortality rates are adjusted for age, sex, race, primary cause of ESRD, and years of ESRD treatment, while rates for each individual category are adjusted for the other four factors. The reference population includes 2011 prevalent ESRD patients. Table H.2.1 presents unadjusted mortality rates by age, sex, race, and primary cause of ESRD for 2013 prevalent ESRD patients; rates are again smoothed using a generalized linear model.

The same methods are used for Tables H.3, H.4, and H.4.1 (dialysis); H.5 (dialysis patients, never on

transplant waiting list); H.6 (dialysis patients on transplant waiting list); H.7 (dialysis patients, returned to dialysis from transplant); H.8 and H.8.1 (HD); H.9 and H.9.1 (CAPD/CCPD); and H.10 and H.10.1 (transplant).

For Table H.13, general U.S. population life expectancy, the data source is Table 7 in the National Vital Statistics Report (NVSR), Deaths: Final Data for 2012. The methodology used is different from previous years: the expected remaining lifetime reported for a five year age range is the mean of the values for the starting age and the ending age. For example, the value reported for the 15-19 year old age group is the average of the values at the exact ages 15 and 20. For the age group 0-14 years old, the number reported is the mean of the values for the exact ages of 0, 1, 5, 10 and 15. Similarly, the life expectancy of the 85+ age group is the mean of the values for the exact ages of 85, 90, 95, and 100.

REFERENCE TABLE I: PATIENT SURVIVAL

Reference Table I presents patient survival probabilities, based on incident cohorts. All causes of death are included, as are all non-Medicare patients and patients living in the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories. Patients are excluded if sex is unknown, or if age is unknown. All new ESRD patients with a first ESRD service date between January 1, 1996 and December 31, 2012, are included in the analysis. These patients are followed from day one (ESRD onset) until death, loss to follow-up, or December 31, 2013. For dialysis patients, both HD and PD, follow-up is also censored at recovery of native renal function and at receipt of a kidney transplant. Unadjusted patient survival probabilities are estimated using the Kaplan-Meier method, while adjusted survival is computed through model-based direct standardization using Cox regression. Incident 2011 ESRD patients served as the reference population for both overall and subgroupspecific adjusted survival.

REFERENCE TABLE J: PROVIDERS

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

CDC National Surveillance of Dialysis-Associated Diseases in the United States (1996-2002, excluding 1998, when the CDC did not conduct a survey). The CDC discontinued the National Surveillance of Dialysis-Associated Diseases after 2002.

In Reference Table J, we define a chain-affiliated unit as a freestanding dialysis unit owned or operated by a corporation at the end of a year. The category of "Others" includes all organizations meeting our definition of a chain but not owned by DaVita, Fresenius Medical Care (Fresenius), or Dialysis Clinic, Inc. (DCI).

A facility's hospital-based or freestanding status is determined from the third and fourth digits of the provider number assigned to each facility by CMS. A facility's profit status is determined through the ownership type field on the ESRD Facility Survey (1996-2001 and 2014) or the profit status field of the DFC database (2001-2013).

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

Table J.1 shows counts of the facilities by year for 1996 through 2014 by type of facility. Also, the number of patients in these facilities is shown. These facilities are the source for all tables reported in this section.

REFERENCE TABLE K: MEDICARE CLAIMS DATA^{\$}

Cost information in Reference Table K is derived from ESRD Medicare inpatient, outpatient, skilled nursing facility, hospice, home health, physician/supplier, durable medical equipment, and Part D claims data in the CMS SAFs, which are created annually six months after the end of each calendar year. A small number of pre-ESRD records are included in cases where a patient had a transplant within 30 days of their first service date; claims are checked for the previous 30 days to include any cost records associated with the transplant. Claims data are obtained for all patient identification numbers in the USRDS ESRD Database. Each type of claim is processed separately, with their data collapsed into the type categories that can be seen in K.1, K.4, K.a, K.b, and K.b.1-53. The individual types of claims are then set together and patient demographic data are added.

PAYER FILE\$

The payer sequence (available in the file PAYHIST) is similar in concept to the USRDS treatment history. Payer status is tracked for each ESRD patient from the first ESRD service date until death or the end of the study period. Data from the Medicare Enrollment Database and dialysis claims information are used to categorize payer status as Medicare primary payer (MPP), Medicare secondary payer (MSP), or non-Medicare. The claims database contains data only for MPP and MSP patients, so economic analyses are restricted to these categories. In addition, as it is impossible to determine the complete cost of care for ESRD patients with MS coverage, analyses of costs per person per year exclude patients during the periods when they have this coverage.

PAYMENT INFORMATION

The economic analyses for this section focus on the claim payment amount, which is the amount of the payment made from the Medicare Trust Fund for the services covered by the claim record. These analyses also include the pass-through per diem amount, which applies to inpatient claims and reimburses the provider for capital-related costs, direct medical education costs, and an estimate of organ acquisition costs (\$25,000 in 2016).

Model 1: As-treated actuarial model

Tables K.5-K.9, K.a, K.b, and K.b.1-53 are all processed by primary payer and model 1 modality. Model 1 modality is derived from the patient treatment history, and combines the treatment modality into an overall model: hemodialysis, CAPD/CCPD, other, transplant, and unknown. The category "other" includes cases in which the dialysis modality is not HD, CAPD, or CCPD, while the transplant category includes patients who have a functioning graft at the start of the period, or who receive a transplant during the period.

In an as-treated model patients are first classified by their modality at entry into the analysis, and retain that classification until a modality change. When a change is encountered in the data, the initial modality is censored, and a new observation with the new modality is created. Under this method, aggregation of Medicare payments is done on an as-treated basis,

attributing all payments for a particular claim to the patient's modality at the time of the claim.

Model 2: Categorical calendar year model

This model, described in the Health Care Financing Administration (now CMS) research report on ESRD (1993-1995), is used for Reference Tables K.10-K.13. With this method, patients are classified into four mutually exclusive treatment groups:

- Dialysis: ESRD patients who are on dialysis for the entire calendar year, or for that part of the year in which they are alive and have ESRD
- Transplant: ESRD patients receiving a kidney transplant during the calendar year
- Functioning graft: ESRD patients with a functioning graft for the entire calendar year, or for that part of the year in which they are alive and have ESRD
- Graft failure: ESRD patients who have had a transplant, but return to dialysis due to loss of graft function during the calendar year; patients with a graft failure and a transplant in the same calendar year are classified in the transplant category

Changes in 2016

1. Change to the definition of pre-ESRD versus ESRD

A change to what claims should be considered ESRD versus pre-ESRD has caused a significant change to the number of cost records included this year. In the previous year, only claims that started on or after first service date were included in ESRD. In 2016, that was changed. Now, if a claim overlaps a first service date, that claim is considered ESRD. This is most noticeable in Reference Tables K.1, K.4, K.a, K.b, and K.b.1-53, where cost types have the following categories:

In Inpatient Institutional claims:

- Medical DRG
- Surgical DRG
- Non-TX pass-through
- In Physician/Supplier claims:
- E&M nephrologist IP
- E&M non-nephrologist IP
- Inpatient dialysis

2. Change to Time at Risk

There was a change to time at risk calculations for Reference Tables K.5-K.13, K.a, K.b, and K.b.1-53 that can result in a smaller time at risk for some patients.

For 2016, time at risk was calculated by taking the latest date from:

- First of the year
- First service date
- Start of modality
- Start of primary payer history range
- And the earliest date from:
- End of the year
- Death date
- End of modality
- End of primary payer history range

Prior to the 2016 ADR, the start and end dates of a primary payer date range were not included in the algorithm.

3. Change to what cost records are included

There is another significant change in methodology this year that can result in lower costs reported than in the previous year for the same modality, payer, and time frame. Prior to the 2016 ADR, time at risk was calculated and either displayed on the worksheet, or used in calculating the sheet's average cost per time at risk. While that is still true in 2016, only cost records that overlap the same time frame as time at risk are included.

For example, if a patient's time at risk as a primary payer and dialysis patient was March 3-October 5, only claims records that overlap that same time period are included. If the patient had 10 different cost records for that year, and one of them was January 1-March 2, that cost would not be included.

REFERENCE TABLE L: VASCULAR ACCESS^{\$}

Within Reference Table L, Tables L.1-L.6 include period prevalent HD patients with Medicare as primary payer. Placements are identified from inpatient, outpatient, and physician-supplier Medicare claims, and rates represent the total number of events divided by the time at risk and are converted to be in

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terms of patient years. Time at risk is defined as the time between the first day of a given year and end of follow-up in the given year. Follow-up is censored at death, change in modality, change in payer status, or the end of the prevalent year.

Tables L.7-L.8 include point prevalent PD patients with Medicare as primary payer. Complications are obtained from inpatient Medicare claims during the time at risk in the prevalent year. Table L.7 shows the count of PD patients who experienced a complication in the prevalent year. Table L.8 show the percentages of PD patients who had at least one event in the given complication category (sepsis, peritonitis, infection) in the prevalent year. Follow-up on these patients is censored at death, a change in modality, a change in payer status, a claim for HD vascular access placement, or at the end of the prevalent year.

REFERENCE TABLE M: CENSUS POPULATIONS

Reference Table M.1 includes the U.S. resident population on July 1 by year, age, gender and race for years 1996-2014. The data sources are U.S. Census, intercensal, and postcensal population estimates from the CDC Bridged-Race Population Database. U.S. population data are used to calculate incidence and prevalence rates. The total U.S. population in 2011 is used as the reference population for analysis, which is adjusted for age, sex, and race or ethnicity in ADR chapters or other Reference Tables. The rates per million population are calculated based on the population of the corresponding year.

REFERENCE TABLE N: INTERNATIONAL COMPARISONS

This section presents trends, similarities, and differences in incidence, prevalence, treatment modality, and transplantation of treated end-stage renal disease (ESRD) in different countries. Data collection methods vary considerably across countries, and therefore direct comparisons should be made with caution.

Each country was provided a data-collection form spreadsheet (Microsoft Excel) to complete for years 2010 through 2014. Countries were asked to report patient count data for each year, if available, for the entire population, by sex (male, female), or by five different age categories (0-19, 20-44, 45-64, 65-74, 75+) for: (1) the country's or region's general population; (2) patients new to ESRD during the year; (3) patients new to ESRD during the year among new ESRD patients for whom diabetes was the primary cause of ESRD; (4) the point-prevalent count of ESRD patients living on December 31 of the given year; (5) total number of patients with a functioning kidney transplant on December 31 of the given year; (6) total number of kidney transplants performed during the year, by type of kidney transplant (deceased, living donor, other donor); and (7) the number of dialysis patients, HD patients, CAPD/APD/ IPD patients, and home HD patients on December 31 of the indicated year. Data for the United States is pulled from the following Reference Tables: M: Census Populations; A: Incidence; B: Prevalence; D: Treatment Modalities; and E: Transplantation: Process. Data for years before 2008 are pulled from historical files.

Prevalence was reported for all patients at the end of the calendar year (December 31), except where otherwise noted. The percent change is defined as the percent difference between the average incidence rates in 2013 and 2014 and the averages in 2001 and 2002, except in N.3. In N.3, the percent change is defined as the percent difference between the average incidence rates in 2013 and 2014 and the averages in 2005 and 2006 since more countries had incidence by age group starting in 2005.

Tables N.1-N.3 present trends in the incidence of ESRD patients in different countries. Incidence was calculated as the count of patients who start any form of renal replacement therapy during the year divided by the total population for that year, and then multiplied by one million. Table N.1 shows the trends in the incidence of treated ESRD patients, 2001-2014. Table N.2 shows the trends in the incidence of treated ESRD patients due to diabetes, 2001-2014. N.1 uses total incident patient count, and the count for N.2 is a subset of total incident patients whose failure is due to diabetic nephropathy. Table N.3 shows the changes in the incidence of treated ESRD by five age groups, 0-19, 20-44, 45-64, 65-74, and 75+. Age-specific incidence was calculated as the count in each age category divided by the total population in the respective category, multiplied by one million.

Tables N.4-N.5 present the prevalence of ESRD in different countries, 2001-2014. Prevalence was

calculated as the point prevalent count divided by the total population for that year, multiplied by one million. Table N.4.a shows the number of ESRD patients receiving some form of renal replacement therapy (dialysis and kidney transplantation). Table N.4.b shows the prevalent ESRD patient counts. Table N.5 specifically presents 2014 ESRD prevalence in different countries, by five age groups, 0-19, 20-44, 45-64, 65-74, and 75+.

Tables N.6-N.7 present dialysis therapy for ESRD, 2001-2014. Table N.6 shows trends in the unadjusted prevalence of patients receiving dialysis. Table N.7 shows the distribution of different modality use in prevalent dialysis patients, including percentage of incenter hemodialysis (N.7.a), percentage of CAPD/APD/IPD (N.7.b), and percentage of home hemodialysis (N.7.c). The denominator is calculated as the sum of patients receiving HD, PD, or home HD, and does not include patients with other/unknown modality.

Tables N.8-N.10 present data regarding kidney transplantation in different countries, 2001-2014. Table N.8 calculates the unadjusted kidney transplantation rate for each country. The kidney transplantation rate is defined as the total number of kidney transplants (sum of deceased, living donor, and unknown donor) divided by the total population for that year, multiplied by one million. Table N.9 shows the unadjusted prevalence of treated ESRD patients with a functioning kidney transplant. Table N.10 shows the percent of treated ESRD patients living with a functioning kidney transplant. The denominator is the prevalent number of patients receiving renal replacement therapy.

Statistical Methods

METHODS FOR CALCULATING RATES

The calculation of observed rates is straightforward, with some rates based on counts and others on follow-up time. The ESRD incident rate in 2014, for example, is the observed incident count divided by the 2014 population size and, if the unit is per million population, multiplied by one million. The 2014 death rate for prevalent ESRD patients is the number of deaths in 2014 divided by the total followup time (patient years) in 2014 of the 2014 prevalent patients, and, if the unit is per thousand patient years, multiplied by one thousand. Standard errors of estimated rates are based on the assumption of the data; the observed count has a Poisson or binomial distribution. The count-based rate describes the proportion having the "event," and the time-based rate tells how often the "event" occurs.

MODEL-BASED RATES

Some patient groups may be very small, and their observed rates are, therefore, unstable. If follow-up time is considered, the hazard of an event may change over time. A model-based method can improve the stability of these estimates and incorporate changes of hazard over time. In this ADR, for example, we have used the generalized linear model with log link and Poisson distribution to estimate prevalent patient mortality rates for Reference Table H.

MEASUREMENT UNIT FOR RATES

Both observed and model-based rates are calculated per unit of population (i.e., per 1,000 patients) or per unit of follow-up time (i.e., per 1,000 patient years). Calculating rates per unit of follow-up time can account for varying lengths of follow-up among patients. Patient years are calculated as the total number of years, or fractions of a year, of followup time for a group of patients.

Take, for example, a calculation of 2014 first hospitalization rates for two groups of patients, all receiving dialysis therapy on January 1, 2014. Group A consists of three patients: patient 1 had a first hospitalization on March 31, 2014; patient 2 was hospitalized on June 30, 2014; and patient 3 was on dialysis through December 31, 2014, with no hospitalizations. Group B also has three patients: patient 4 was first hospitalized on December 31, 2014; patient 5 was hospitalized on September 30, 2014; and patient 6 was on HD the entire year, with no hospitalizations through December 31, 2014.

Patients 1 to 6 contribute 0.25, 0.5, 1.0, 1.0, 0.75, and 1.0 patient years at risk, respectively. The first hospitalization rate per thousand patients is 667 for both groups in 2014. But the first hospitalization rate per thousand patient years at risk is 1,143 for Group A and 727 for Group B (calculated as [2 total events / 1.75 total patient years at risk] x 1,000 for Group A and [2 total events / 2.75 patient years at risk] x 1,000 for Group B). The resulting rate is lower for Group B because of the longer total follow-up time.

Rates per unit of population may be influenced by the proportion of patients who are followed for only a fraction of a year. The event rate per unit of population is likely to be lower, for example, in a group of patients followed for only one month until censoring than in a group whose patients are each followed for up to a full year. Rates per unit of followup time at risk, in contrast, count only the actual time that a patient is at risk for the event.

METHODS FOR ADJUSTING RATES

Because each cohort contains a different patient mix, observed event rates may not be comparable across cohorts. Adjusted analyses make results comparable by reporting rates that would have arisen had each cohort contained patients with the same distribution of confounders — such as age, sex, race, and primary cause of ESRD — as the reference population.

DIRECT ADJUSTMENT

There are several rate-adjustment methods, but only the direct method allows rates to be compared (Pickle & White, 1995). Here the adjusted rate is derived by applying the observed category-specific rates to a single standard population (i.e., the rate is a weighted average of the observed category-specific rates, using as weights the proportion of each category in the reference population). Categories are defined by the adjusting variables. For example, if a rate is adjusted for race and sex and there are three race groups (White, Black/African American, and Other) and two sex groups, there are six categories: White males, White females, Black/African American males, Black/African American females, males of other races, and females of other races.

Suppose we try to compare state-level incidence rates in 2014 after removing the difference caused by race. To do this, we need to calculate the incidence rate, adjusted for race, for each state. Because racial distributions in each state are quite different, we use as reference the national population — here, the population at the end of 2014 — with five race groups (White, Black/African American, Native American, Asian, and Other).

Assuming the incidence rate of state A in 2014 is 173 per million population, and the race-specific rates and race distribution of the national populations are as shown in Table m.6 below, the adjusted incidence rate of state A with the national population as reference is $(153 \times 75.1\%) + (250 \times 12.3\%) + (303 \times 0.9\%) + (174 \times$ $3.6\%) + (220 \times 8\%) = 158.73$ per million population. This means that if state A had the same racial distribution as the entire country, its incidence rate would be 158.73 instead of 173. If state B had an adjusted incidence rate of 205, we could say that state B had a higher incidence rate than state A if they both had the same racial distribution as the whole country.

vol 2 Table m.6 Example of adjusted incident rate calculation

	Incidence rate of state A	National population (%)
White	153	75.1
Black/African American	250	12.3
Native American	303	0.9
Asian	174	3.6
Other	220	8.0

This method is used to produce some adjusted incidence and prevalence rates in *Chapter 1: Incidence*, *Prevalence*, *Patient Characteristics*, and *Treatment Modalities*; *Chapter 3: Clinical Indicators and Preventive Care*; and *Reference Table A: Incidence* and *Reference Table B: Prevalence*, as well as in the modelbased adjustment method.

MODEL-BASED ADJUSTMENT

Under some circumstances, there are disadvantages to the direct adjustment method. Suppose we are calculating mortality rates for a set of groups, and adjusting for potential confounding variables. If one category in a group has only a few patients or deaths, its estimated category-specific mortality rate will be unstable, likely making the adjusted rate unstable as well. In addition, if one includes a category with no patients, the method is not valid for calculating an adjusted mortality rate for the group. An attractive alternative is a model-based

approach, in which we find a good model to calculate category-specific estimated rates for each group, and then calculate direct adjusted rates using these estimates with a given reference population. This method can also be extended to adjustments with continuous adjusting variables (Liu et al., 2006). As in previous ADRs, standard errors of the adjusted rates are calculated using a bootstrap approach. In general, the bootstrap approach works well, but is time consuming. Convergence problems occur in a few bootstrap replications and such cases are ignored in the calculation. In this ADR, we use model-based adjustments to calculate adjusted mortality rates, adjusted hospitalization rates, and state-level adjusted incidence and prevalence rates using the Poisson model and some other rates, as described in the text on the individual figures.

SURVIVAL PROBABILITIES AND MORTALITY RATES

UNADJUSTED SURVIVAL PROBABILITIES

In this ADR, unadjusted survival probabilities are calculated using the Kaplan-Meier method, and corresponding standard errors are calculated with Greenwood's formula (Kalbfleisch & Prentice, 2002). Survival probabilities in *Reference Table I: Patient Survival* are expressed as percentages from o to 100. The mortality/event rate in the period of (o,t) is calculated by [-ln(Survival at time t)]. This event rate will be the same as that estimated by event time divided by follow-up time after adjustment of the unit, if the event rate is a constant over time.

SURVIVAL PROBABILITY WITH COMPETING RISKS

When competing risks exist, the estimate of the cumulative incidence function of a specific cause may be biased if the other competing risks are ignored. If we have K competing risks, the cumulative incidence function of cause k, k=1, 2, ..., K, at time t, $I_k(t)$, is defined as the probability of failing from cause k before time t (including time t), $Prob(T \le t, D = k)$. Then

$$I_k(t) = \int_0^t \lambda_k(s) S(s) ds$$

where $\lambda_k(s)$ is the hazard of event from cause k at time s and S(s) is the survival probability at time s (the probability of no event happening). If we have failing

time $t_1, t_2, ..., t_m$, the cumulative incidence function of cause k at time t is estimated by

$$I_k(t) = \sum \hat{\lambda}_{\kappa}(t_j) \hat{S}(t_j-1)$$

where $\hat{\lambda}_{\kappa}(t_j)=D_{kj}/n_j$, $\hat{S}(t_j-1)$ is the Kaplan-Meier estimate of survival at time t_j-1 , D_{kj} is the number of patients failing from cause k at time t_j , and n_j is the number of patients at risk at prior time t_j (Putter et al., 2007).

ADJUSTED SURVIVAL PROBABILITIES

Adjusted survival probabilities are reported in Reference Table I: Patient Survival, with age, sex, race, Hispanic ethnicity, and primary cause of ESRD used as adjusting risk factors. The model-based adjustment method is used, with survival probabilities/conditional survival probabilities predicted from the Cox regression model (Kalbfleisch & Prentice; 1980, 2002). This process yields estimates of probabilities that would have arisen in each year if the patients had had the same attributes as the reference population. Since the probabilities in each table are adjusted to the same reference set of patient attributes, any remaining differences among cohorts and years are due to factors other than age, sex, race, Hispanic ethnicity, and primary cause of ESRD. The adjusted mortality rates for incident cohorts are calculated using similar methods as discussed in the methods section on Reference Table H: Mortality and Causes of Death.

GENERALIZED LINEAR MODELS

GENERALIZED LINEAR MODEL FOR MORTALITY RATES

We use the generalized linear model with log link and Poisson distribution to calculate mortality and first transplant rates for prevalent patients. While rates are reported for a year, data from the previous two years with different weights are also used to improve the stability of the estimates.

The generalized linear model is fitted in SAS using PROC GLIMMIX . Models used to calculate adjusted rates incorporated age (categorical), ethnicity, race, sex, diabetes status (unless stratified by diabetes) and year, and all the two-way interaction terms (not between race and ethnicity). Models in the "_adj" worksheets also adjusted for vintage and all the twoway interaction terms (but, not between race and ethnicity).

For tables with mortality rates for both intersecting and marginal groups, we have used a single model to calculate all rates in each table. The marginal rates are simply the weighted averages of the estimated, crossclassified rates, with cell-specific patient years as weights. Standard errors for the estimated rates were obtained using the bootstrap method.

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

GENERALIZED LINEAR MODEL FOR HOSPITALIZATION RATES

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

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

STANDARDIZED MORTALITY RATIOS

The standardized mortality ratio (SMR) compares the mortality of a group of patients relative to a specific norm, or reference, after adjusting for some important risk factors. For example, the dialysis chainlevel SMR is used to compare mortality in prevalent dialysis patients — after adjusting for age, race, ethnicity, sex, DM, duration of ESRD, nursing home status, patient comorbidities at incidence, and BMI at incidence in each dialysis chain. Qualitatively, the degree to which the facility's SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the national death rates for patients with the same characteristics as those in the facility. For example, an SMR=1.10 would indicate that the facility's death rates typically exceed national death rates by 10% (e.g., 22 deaths observed where 20 were expected,

according to the facility's patient mix). Similarly, an SMR=0.95 would indicate that the facility's death rates are typically 5% below the national death rates (e.g., 19 observed versus 20 expected deaths). An SMR=1.00 would indicate that the facility's death rates equal the national death rates, on average. Note that if multiple years are included in fitting the model, the interpretation of the SMR for a particular year is different depending on whether calendar year is included in the model. If calendar year is included as an adjustment, the SMR for a particular year compares facility outcomes to the national average rates for that particular year. On the other hand, if calendar year is not included, the comparison is to the national rates over the entire period included in fitting the model.

METHOD OF SMR CALCULATION

The SMR is designed to reflect the number of deaths for the patients at a facility, relative to the number of deaths that would be expected based on overall national rates and the characteristics of the patients at that facility. Specifically, the SMR is calculated as the ratio of two numbers; the numerator ("observed") is the actual number of deaths, excluding deaths due to abused drugs and accidents unrelated to treatment, over a specified time period. The denominator ("expected") is the number of deaths that would be expected if patients at that facility died at the national rate for patients with similar characteristics. The expected mortality is calculated from a Cox model (Cox, 1972; SAS Institute Inc., 2004; Kalbfleisch and Prentice, 2002; Collett, 1994). The model used is fit in two stages. The Stage I model is a Cox model stratified by facility and adjusted for patient characteristics. This model allows the baseline survival probabilities to vary between strata (facilities), and assumes that the regression coefficients are the same across all strata. Stratification by facility at this stage avoids biases in estimating regression coefficients that can occur if the covariate distributions vary substantially across centers. The results of this analysis are estimates of the regression coefficients in the Cox model and these provide an estimate of the relative risk for each patient. This is based on a linear predictor that arises from the Cox model, and is then used as an offset in the Stage II model, which is unstratified and includes

an adjustment for the race-specific age-adjusted state population death rates.

STANDARDIZED HOSPITALIZATION RATIOS^{\$}

The Standardized Hospitalization Ratios (SHR) for Admissions is designed to reflect the number of hospital admissions for the patients at a dialysis facility, relative to the number of hospital admissions that would be expected based on overall national rates and the characteristics of the patients at that facility. Numerically, the SHR is calculated as the ratio of two numbers: the numerator ("observed") is the actual number of hospital admissions for the patients in a facility over a specified time period, and the denominator ("expected") is the number of hospital admissions that would have been expected for the same patients if they were in a facility conforming to the national norm.

The denominator of the SHR stems from a proportional rates model (Lawless and Nadeau, 1995; Lin et al., 2000; Kalbfleisch and Prentice, 2002). This is the recurrent event analog of the well-known proportional hazards or Cox model (Cox, 1972; Kalbfleisch and Prentice, 2002). To accommodate large-scale data, we adopt a model with piecewise constant baseline rates (e.g., Cook and Lawless, 2007) and the computational methodology developed in Liu, Schaubel, and Kalbfleisch (2012). The modeling process has two stages. At Stage I, a stratified model is fitted to the national data with piecewise-constant baseline rates, stratification by facility and adjusting for age, sex, DM, duration of ESRD, nursing home status, comorbidities at incidence, BMI at incidence, and calendar year. The baseline rate function is assumed to be a step function with break points at 6 months, 1 year, 2 years, 3 years, and 5 years since the onset of dialysis. This model allows the baseline hospitalization rates to vary between strata (facilities), but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated. The stratification on facilities is important in this phase to avoid bias due to possible confounding between covariates and facility effects. At Stage II, the relative risk estimates from the first stage are used to create offsets, and an unstratified model is fitted to obtain estimates of an overall baseline rate function.

EXPECTED REMAINING LIFETIMES

The expected remaining lifetime for a patient group is the average of the remaining life expectancies for the patients in that group. Some patients will live longer than, and some will live less than, the average. Although the average cannot be known until all patients in the cohort have died, the expected remaining lifetime can be projected by assuming that patients in the cohort will die at the same rates as those observed among groups of recently prevalent ESRD patients.

For a subgroup of ESRD patients of a particular age, the expected remaining lifetime is calculated using a survival function, estimated for the group. Let S(A)denote the survival function of patients at age A. Among patients alive at age A, the probability of surviving X more years is S(X|A) = S(A+X)/S(A). For a given starting age A, the expected remaining lifetime is then equal to the area under the curve of S(X|A)plotted versus X. Because few patients live beyond 100, this area is truncated at the upper age limit A + X =100.

HALF-LIVES (MEDIAN TIME)

CONDITIONAL HALF-LIFE

The conditional half-life is conditional on having survived a given period of length T_o without the event, the point at which 50% of patients who survived the given period remain alive. In other words, it is the median remaining lifetime conditional on surviving a given period T_o .

The conditional half-life is estimated using the Kaplan-Meier method if the median survival time falls in the duration of follow-up. Otherwise, the conditional half-life is estimated as the following:

Estimate the survival probabilities $S(t_o)$ and $S(t_1)$ using the Kaplan-Meier method from the data available, where $t_o < t_1$ and T_1 is within the follow-up

$$\mu = \frac{t_1 - t_o}{(\ln[S(t_o)] - \ln[S(t_1)])},$$

the estimate of the conditional half-life = $\mu \cdot \ln(2)$.

This method can be used only when the hazard is a constant after t_0 and t_1 is chosen to be big enough to obtain a stable estimate of $ln(S(t_0))-ln(S(t_1))$.

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MAPPING METHODS

Throughout the ADR, data in maps and graphs are unadjusted unless otherwise noted. Because of area size and limitations in the mapping software, data for Puerto Rico and the U.S. territories are not included in the maps.

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