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

Incidence

- In 2015, there were 124,114 newly reported cases of ESRD; the unadjusted (crude) incidence rate was 378 per million population (PMP; Table 1.1). Since 2011, both the number of incident cases and the unadjusted incidence rate have risen (Figure 1.1).
- The age-gender-race adjusted incidence rate of ESRD in the United States (U.S.) rose sharply in the 1980s and 1990s, leveled off in the early 2000s, and has declined slightly since its peak in 2006 (Figure 1.1).
- In 2015, the adjusted ESRD incidence rate ratios for Native Hawaiians/Pacific Islanders, Blacks/African Americans, American Indians/Alaska Natives, and Asians as compared with Whites were 8.4, 3.0, 1.2, and 1.0. All these represent reductions in relative risk of ESRD for these minorities compared to Whites over the past 15 years. The rate ratio for Hispanics versus non-Hispanics was 1.3 (Figures 1.5 and 1.6).

Prevalence

- On December 31, 2015, there were 703,243 prevalent cases of ESRD; the unadjusted prevalence was 2,128 per million in the U.S. population (PMP; Table 1.3).
- In contrast to incidence, the number of ESRD prevalent cases continued to rise by about 20,000 cases per year (Table 1.1).
- Compared to Whites, ESRD prevalence in 2015 was about 9.5 times greater in American Indians/Alaska Natives, 3.7 times greater in Blacks, 1.5 times greater in Native Hawaiians/Pacific Islanders, and 1.3 times greater in Asians (Figure 1.11).

Characteristics of incident ESRD cases

- In 2015, 36% of incident ESRD patients received little or no pre-ESRD nephrology care (Table 1.7).
- Mean eGFR at initiation of dialysis in 2015 was 9.8 ml/min/1.73 m^2, down from a peak of 10.4 in 2010. The percentage of incident ESRD cases starting with eGFR at ≥10 ml/min/1.73 m^2 rose from 13% in 1996 to 43% in 2010, but decreased to 39% in 2015 (Figure 1.18).

Treatment modalities

- In 2015, 87.3% of incident individuals began renal replacement therapy with hemodialysis (HD), 9.6% started with peritoneal dialysis (PD), and 2.5% received a preemptive kidney transplant (Figure 1.2).
- On December 31, 2015, 63% of all prevalent ESRD patients were receiving HD therapy, 7.0% were treated with PD, and 29.6% had a functioning kidney transplant (Figure 1.8). Among HD cases, 85.1% used in-center HD, and 1.8% used home HD (Figure 1.15).

Introduction

In this chapter, we describe the population of those individuals living with end-stage renal disease (ESRD) in the U.S., the numbers and relative rates of new and enduring cases, the sex, age, race, and ethnicity of those most often affected, the clinical precursors of their developing kidney disease, and the therapies used to treat it. This information creates the foundation from which to understand and interpret the current state and trends of ESRD as presented in the 2017 Annual Data Report (ADR).

The foci of this chapter are the incidence and prevalence of ESRD in the U.S. population. We report the absolute numbers of individuals affected, rates, and temporal trends. We examine the composition of this group specifically by their sex, age, race, and ethnicity. The population is also described in terms of geographic residence, listed primary cause of ESRD, the renal replacement therapy (RRT) chosen for treatment, and individual medical characteristics such as receipt of pre-ESRD care, and estimated glomerular filtration rate (eGFR) and prevalence and severity of anemia at onset of ESRD.

The definitions of ESRD incidence and prevalence used throughout the ADR are treatment-based, not purely physiological or biological constructs. These terms as used refer only to treated cases of ESRD, to patients starting or receiving dialysis or transplantation. Although a diagnosis of ESRD is often equated with RRT treatment, and usually commences in Stage 5 CKD (GFR <15 ml/min/1.73 m^2), many do not begin RRT until the eGFR is much lower than 15, and some never receive dialysis or transplantation. In addition, there are "ESRD treated" patients on RRT who were initiated on dialysis at an eGFR greater than 15. 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 cases of a disease during a given period. In this chapter, ESRD incidence is a count of the number of incident cases in one year or a rate calculated as the number of incident cases in one year divided by person-years at risk. Person-years at risk are approximated by the mid-year census for the population in that year. Incidence rates are expressed as per million population per year (PMP).

Prevalence refers to the presence of existing 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 a count of the number of prevalent cases, or a proportion of the 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 as PMP. ESRD prevalence in a population depends on both the incidence rate of ESRD and the duration of the disease from the start of RRT to death, or loss to follow-up.

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 these are described in the *Data Sources* section of the *ESRD Analytical Methods* chapter. Trends in overall incidence and prevalence are provided since 1980, when data were first available. Most adjusted data are provided since 2000, as race categories in the U.S. census were changed in that year.

Incidence rates and prevalences in this chapter are presented both without adjustment for other factors (i.e., as crude measures) and with adjustment for sex, age, 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. 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 or adjusted incidence rate or prevalence is interpreted as the expected (crude) rate or prevalence if that group or year had exhibited the age-gender-race distribution of the 2011 standard population. Because we are only adjusting for age, race, and sex the trends we see may be due to other variables such as differences in treatment and differences in case-mix.

See the section on Chapter 1 in the *Analytical Methods Used in the ESRD Volume* 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. Downloadable Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available on the USRDS website.

Primary cause of ESRD: A cautionary note

A caution in the interpretation of this chapter is that the reliability of clinician-assigned "primary-cause" of ESRD has not been well established. Because causation for some diagnoses cannot be, or are not definitively established through 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. For example, in diabetics with CKD (Yuan et al., 2017), confirmatory kidney biopsies are rarely performed, and published data suggest that assigned diagnoses for glomerular disease may be specific, but relatively insensitive (i.e. under-reported; Langenecker et al., 2000).

The reverse may be the case for diabetes mellitus (DM) or hypertension (HTN). For HTN in those of Black/African American race, for example, this may especially apply, as the APOL1 high-risk genotype and other emerging risk factors are recognized. For DM, often quoted as the leading "cause" of ESRD, authorities such as KDIGO provide guidance for assigning a diagnosis of diabetic CKD (DM as the primary cause). In reality, it is likely that this judgment is quite variable among nephrologists completing the CMS Medical Evidence form (CMS 2728). Single center studies suggest that DM as a "cause" of ESRD is over-reported on CMS 2728 compared to KDIGO criteria. It is likely that CMS 2728 data indicating primary cause of ESRD actually reflect ESRD patients who have DM, but not necessarily as the cause of their ESRD. This parallels reports of biopsy-confirmed diabetic nephropathy, although there is clear selection bias in patients who undergo biopsy.

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 trends. It may even have played a role in risk factor assessment for CKD screening, particularly in the primary roles of DM and HTN, in addition to NHANES and other cohorts. In the Annual Data Report (ADR), it allows us to estimate the ESRD incidence rate and prevalence for different subtypes of chronic kidney disease: those with the primary cause listed as DM, HTN, 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 laboratory-based data on DM status in the total U.S. population by strata of sex, age, and race. In Reference Table A.11, incidence rates of ESRD are estimated for self-reported DM in the U.S. population. As many persons with DM either do not report their condition or are not aware of it, those estimated should be viewed in that context.

Incidence of ESRD: Counts, Rates, and Trends

Overall Incidence Counts and Rate

In 2015, there were 124,114 incident cases of ESRD in the U.S., with an unadjusted incidence rate of 378 PMP. After a year-by-year rise in the number of incident ESRD cases from 1980 through 2000, the increase plateaued between 2001 and 2012, but rose again from 2013 to 2015. Table 1.1 and Figure 1.1 provide the annual counts and unadjusted and sex, age, and race adjusted incidence rates of ESRD from 1980 through 2015.

While the unadjusted and adjusted rates were the same in 2011 because the standard population was the 2011 U.S. population, the trends for these two rates were different. The unadjusted ESRD incidence rate increased steadily from 1980 through 2006, remained relatively stable until 2012, and has increased again since 2012. The implication of this recent trend is that the burden of kidney failure in the U.S.—with respect to the expected impact on health-care utilization and costs—continues to increase.

In contrast, the adjusted ESRD incidence rate increased from 1980 through 2001, leveled off through 2006, then has since declined slightly in most years (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. Our aging population and the rising prevalence of obesity and DM influence 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 U.S.

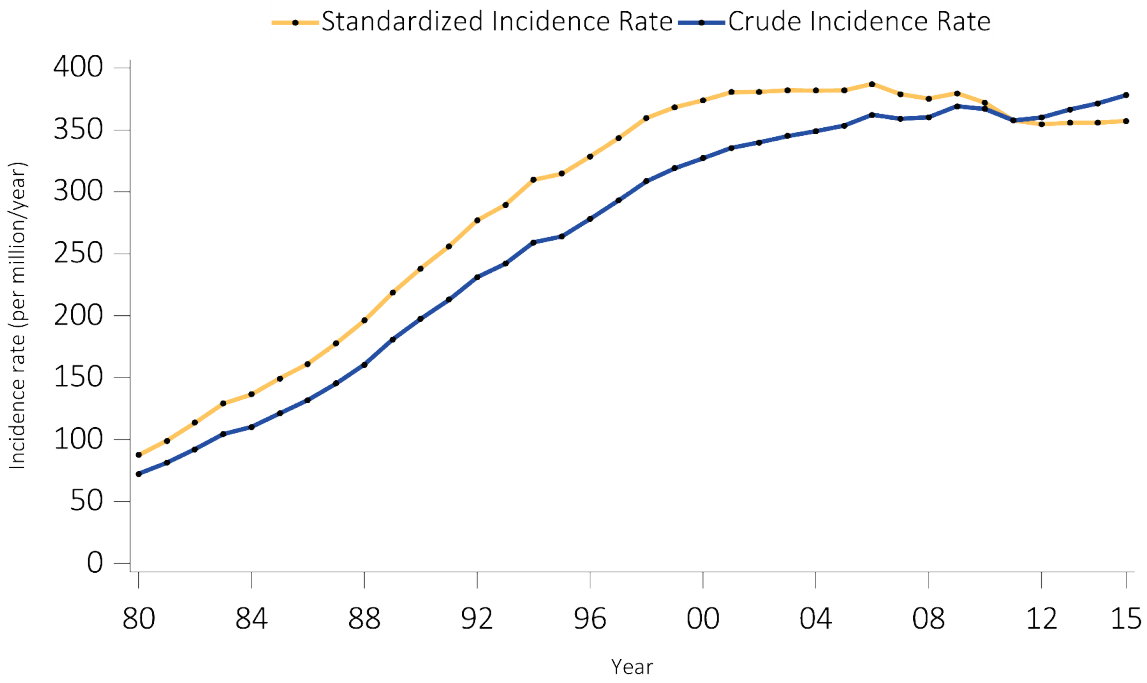
vol 2 Table 1.1 Trends in annual number of ESRD incident cases, unadjusted and adjusted incidence rates of ESRD, and annual percentage change in the U.S. population, 1980-2015

	Incident count		Unadjusted 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
1980	17,903	n/a	72	n/a	87	n/a
1981	20,039	11.9	81	12.3	99	13.4
1982	22,567	12.6	92	13.5	114	14.5
1983	25,774	14.2	104	13.1	129	13.7
1984	27,325	6.0	110	5.6	136	5.7
1985	30,214	10.6	121	9.9	149	9.5
1986	33,109	9.6	132	8.9	161	7.9
1987	36,604	10.6	145	10.1	178	10.2
1988	40,994	12.0	161	10.6	196	10.4
1989	46,304	13.0	181	12.6	219	11.5
1990	50,826	9.8	198	9.2	238	9.0
1991	55,388	9.0	213	7.7	256	7.5
1992	60,891	9.9	231	8.6	277	8.2
1993	64,488	5.9	242	4.7	290	4.5
1994	69,958	8.5	259	7.1	310	7.0
1995	72,199	3.2	264	1.8	315	1.6
1996	77,000	6.6	278	5.3	329	4.5
1997	82,120	6.6	293	5.3	343	4.4
1998	87,330	6.3	309	5.3	360	4.8
1999	91,409	4.7	319	3.4	368	2.4
2000	94,702	3.6	327	2.5	374	1.5
2001	97,966	3.4	336	2.6	380	1.7
2002	100,177	2.3	340	1.3	381	0.1
2003	102,599	2.4	345	1.5	382	0.3
2004	104,465	1.8	349	1.2	382	-0.1
2005	106,623	2.1	354	1.3	382	0.1
2006	110,327	3.5	362	2.5	387	1.4
2007	110,316	0.0	359	-0.9	379	-2.1
2008	111,843	1.4	360	0.4	375	-1.0
2009	115,497	3.3	369	2.5	380	1.2
2010	115,829	0.3	367	-0.6	372	-2.0
2011	113,735	-1.8	358	-2.5	358	-3.8
2012	115,437	1.5	360	0.7	355	-0.9
2013	118,160	2.4	367	1.8	356	0.3
2014	121,033	2.4	372	1.4	356	0.0
2015	124,114	2.5	378	1.8	357	0.4

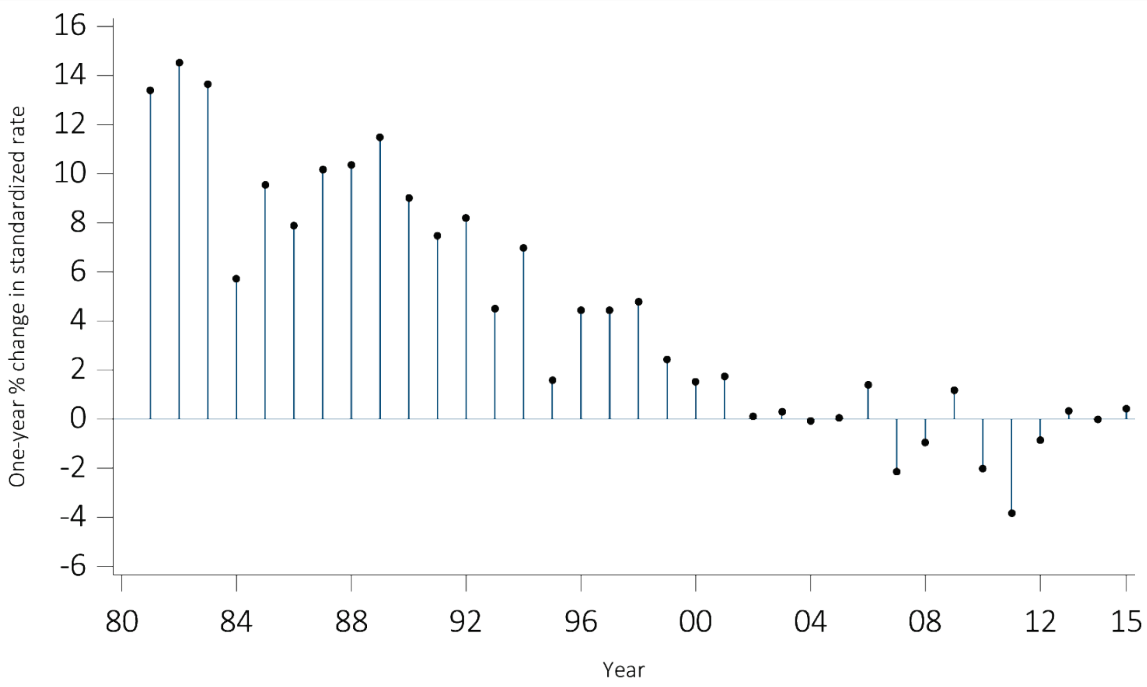
Data Source: Reference Tables A.1 and special analyses. The special analyses exclude U.S. Territories, unknown/other races. USRDS ESRD Database. Standardized for age, sex, and race. Abbreviations: ESRD, end-stage renal disease; n/a, not applicable.

vol 2 Figure 1.1 Trends in the (a) unadjusted and standardized incidence rates of ESRD, and (b) the annual percentage change in the standardized incidence rate of ESRD in the U.S. population, 1980-2015

(a) Incidence rate per million/year

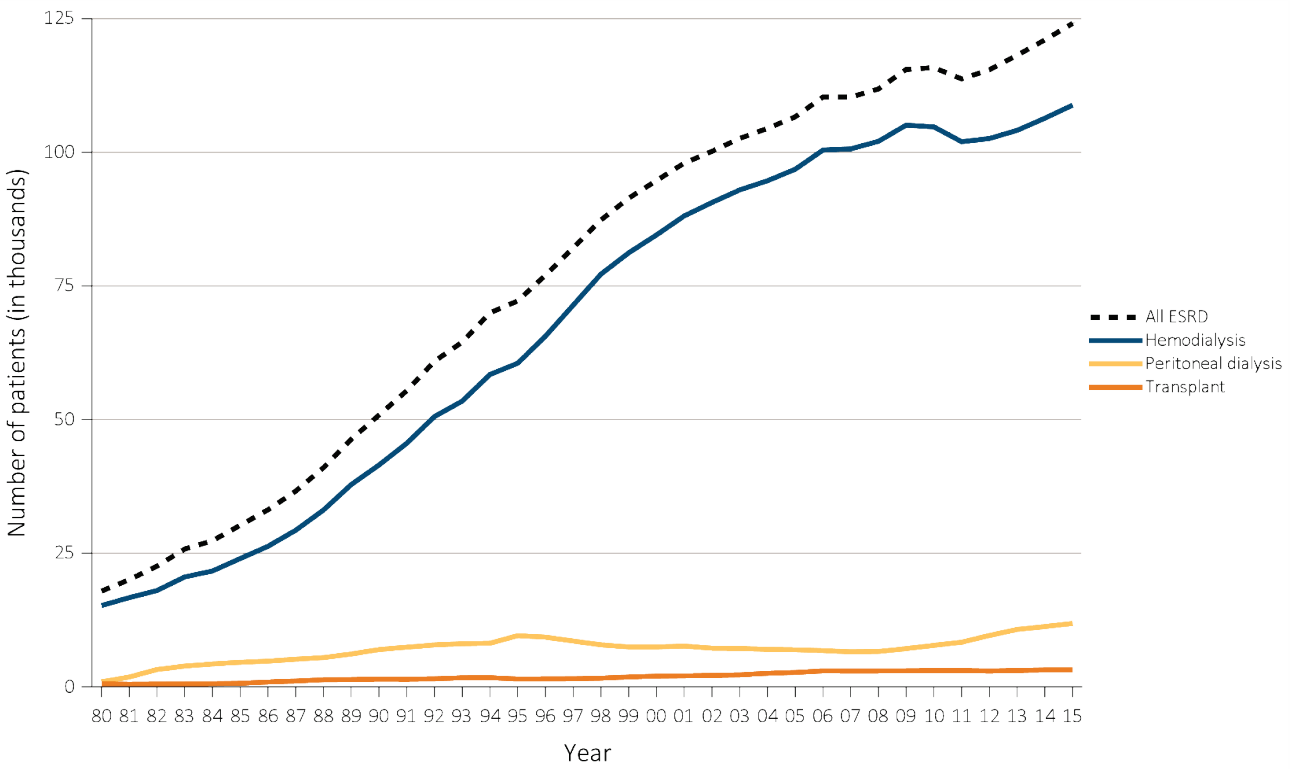


(b) One-year percentage change in standardized incidence rate



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

vol 2 Figure 1.2 Trends in the annual number of ESRD incident cases, by modality, in the U.S. population, 1980-2015



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 sex, age, and race, the rate was lowest at 254 PMP in Network 16 (AK, ID, MT, OR, and WA), and highest at 455 PMP in Network 14 (TX)—79% higher than Network 16. Much of the additional incidence in Texas and Southern California (Network 18) represents cases among Hispanics, of whom large numbers live in these States. Individuals who identify themselves as being ethnically Hispanic comprise 38% of the populations in both Texas and California, compared to 18% nationwide.

Renal replacement therapy (RRT) modality use by region is also presented in Table 1.2.; this is further discussed in the section *Modality of Renal Replacement Therapy: Incident ESRD Cases* later in this chapter.

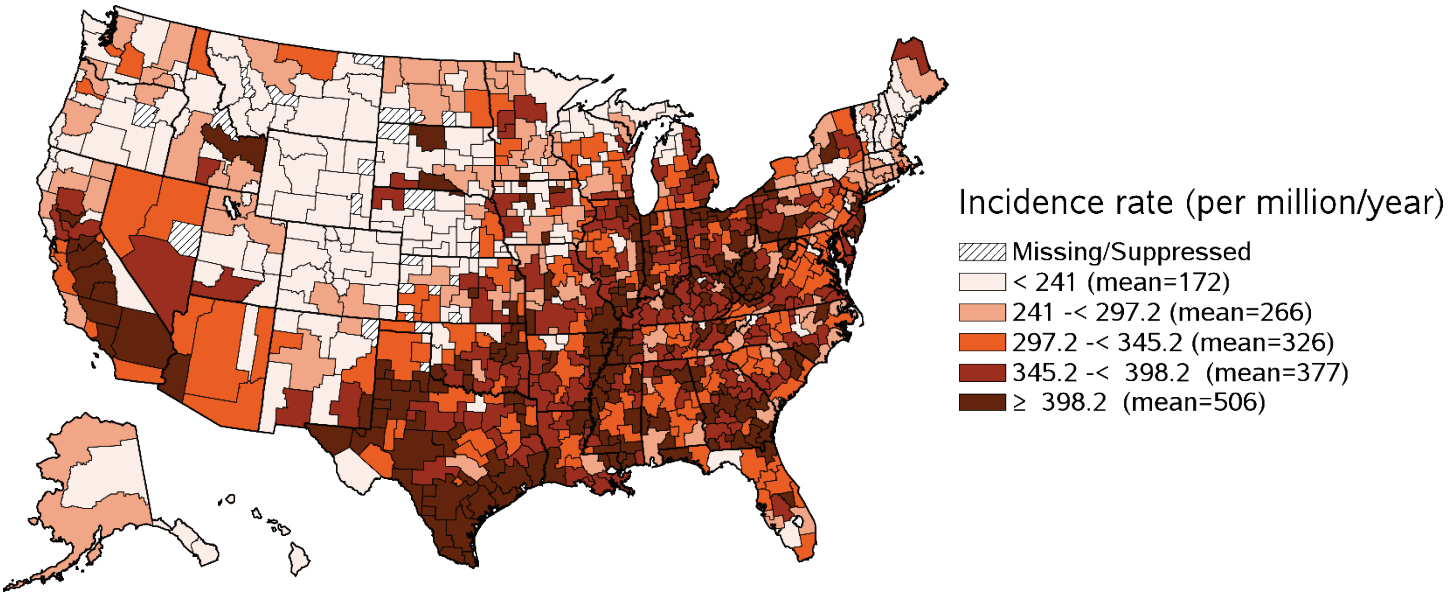
vol 2 Table 1.2 Unadjusted and adjusted incidence rates of ESRD and annual number of ESRD incident cases, overall and by modality and ESRD Network, in the U.S. population, 2015

		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	TX	11,472	455	415	10,318	89.9	896	7.8	237	2.1
18	Southern CA	9,480	419	384	8,365	88.2	925	9.8	182	1.9
13	AR, LA, OK	5,200	396	446	4,509	86.7	612	11.8	78	1.5
3	NJ, PR, VI	5,376	395	431	3,517	90.0	270	6.9	115	2.9
10	IL	5,387	391	414	4,647	86.3	585	10.9	130	2.4
9	IN, KY, OH	9,301	388	407	8,278	89.0	807	8.7	181	1.9
8	AL, MS, TN	6,688	368	461	5,809	86.9	782	11.7	88	1.3
12	IA, KS, MO, NE	4,640	349	329	3,919	84.5	587	12.7	127	2.7
17	Northern CA, HI, GU, AS, MP	6,144	347	356	4,914	83.5	842	14.3	124	2.1
4	DE, PA	5,326	342	386	4,737	88.9	439	8.2	128	2.4
11	MI, MN, ND, SD, WI	7,576	336	330	6,597	87.1	645	8.5	297	3.9
2	NY	7,548	336	377	6,953	92.1	359	4.8	229	3.0
6	NC, SC, GA	10,858	336	428	9,416	86.7	1,209	11.1	216	2.0
5	MD, DC, VA, WV	6,938	334	406	6,189	89.2	574	8.3	156	2.2
7	FL	8,310	327	405	7,379	88.8	758	9.1	150	1.8
15	AZ, CO, NV, NM, UT, WY	6,084	309	288	5,241	86.1	647	10.6	186	3.1
1	CT, MA, ME, NH, RI, VT	3,995	262	268	3,467	86.8	361	9.0	162	4.1
16	AK, ID, MT, OR, WA	3,500	254	237	2,943	84.1	446	12.7	108	3.1
All networks		124,114	354	376	107,198	87.8	11,744	9.6	2,894	2.4

*Data Source: Reference Table A.10, and special analyses, USRDS ESRD Database. The special analyses exclude U.S. Territories, unknown/other races. Standardized 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), American Samoa (AS), U.S. Virgin Islands, and Northern Mariana Islands. 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.*

Across 806 Health Service Areas (HSA) in 2011-2015, the adjusted incidence rate of ESRD ranged from 75 to 1731 PMP (interquartile range: 255 to 393 PMP; Figure 1.3). Without further geospatial analyses, specific geographic patterns based on these HSA-level data were difficult to identify. In general, the rates were highest in parts of the Ohio and Mississippi River valleys, sections of the southeastern U.S., Texas, and California, and lowest in areas of New England, the Northwest, and certain Upper Midwest and Rocky Mountain states.

vol 2 Figure 1.3 Map of the adjusted incidence rate of ESRD, by Health Service Area, in the U.S. population, 2011-2015

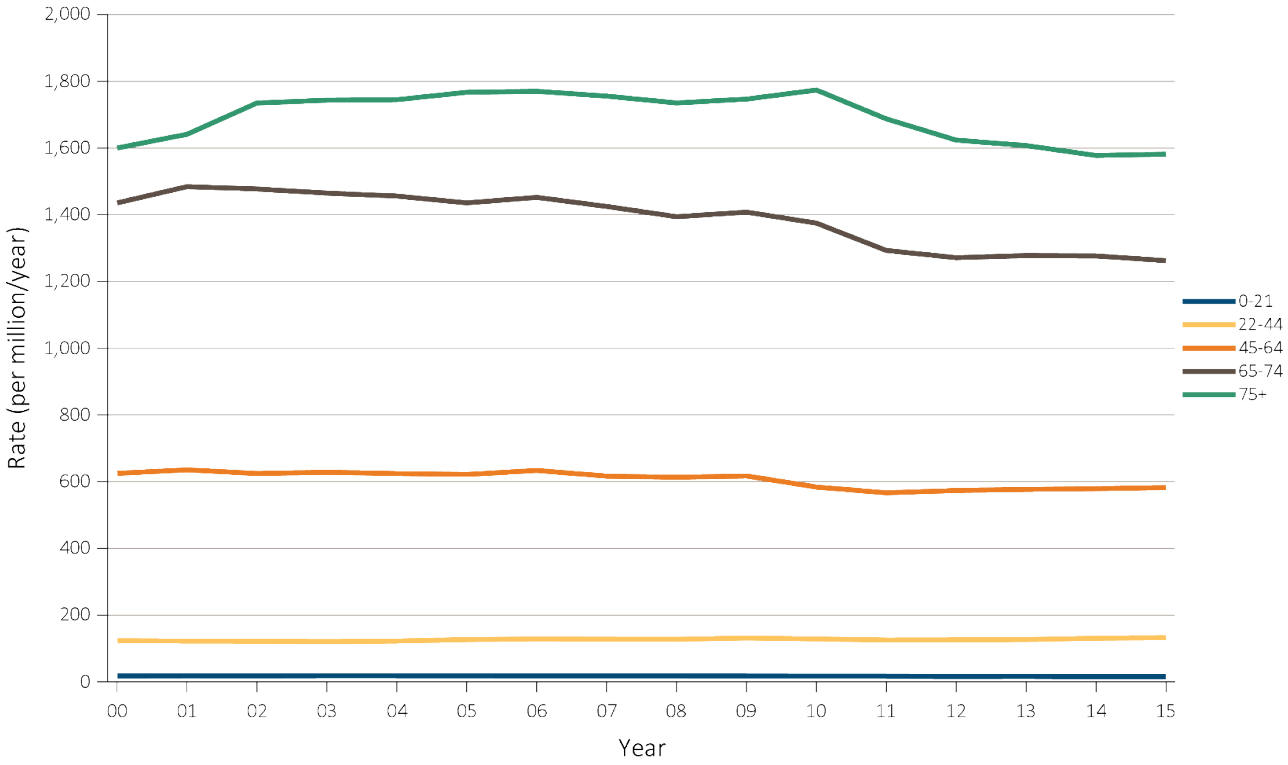


Data Source: Special analyses, USRDS ESRD Database. Standardized for age, sex, and race. The standard population was the U.S. population in 2011. Values for cells with 10 or fewer patients are suppressed. Abbreviation: ESRD, end-stage renal disease.

Incidence Rate: By Age

Across age groups, adjusted ESRD incidence rates either have been generally stable or have fallen for a decade or more (Figure 1.4). Recent pronounced declines have been observed for older patients. Among those aged 65-74 the ESRD incidence rate was lowest in 2015, and the lowest in 2014 for those aged 75 and older.

vol 2 Figure 1.4 Trends in adjusted ESRD incidence rate, by age group, in the U.S. population, 2000-2015



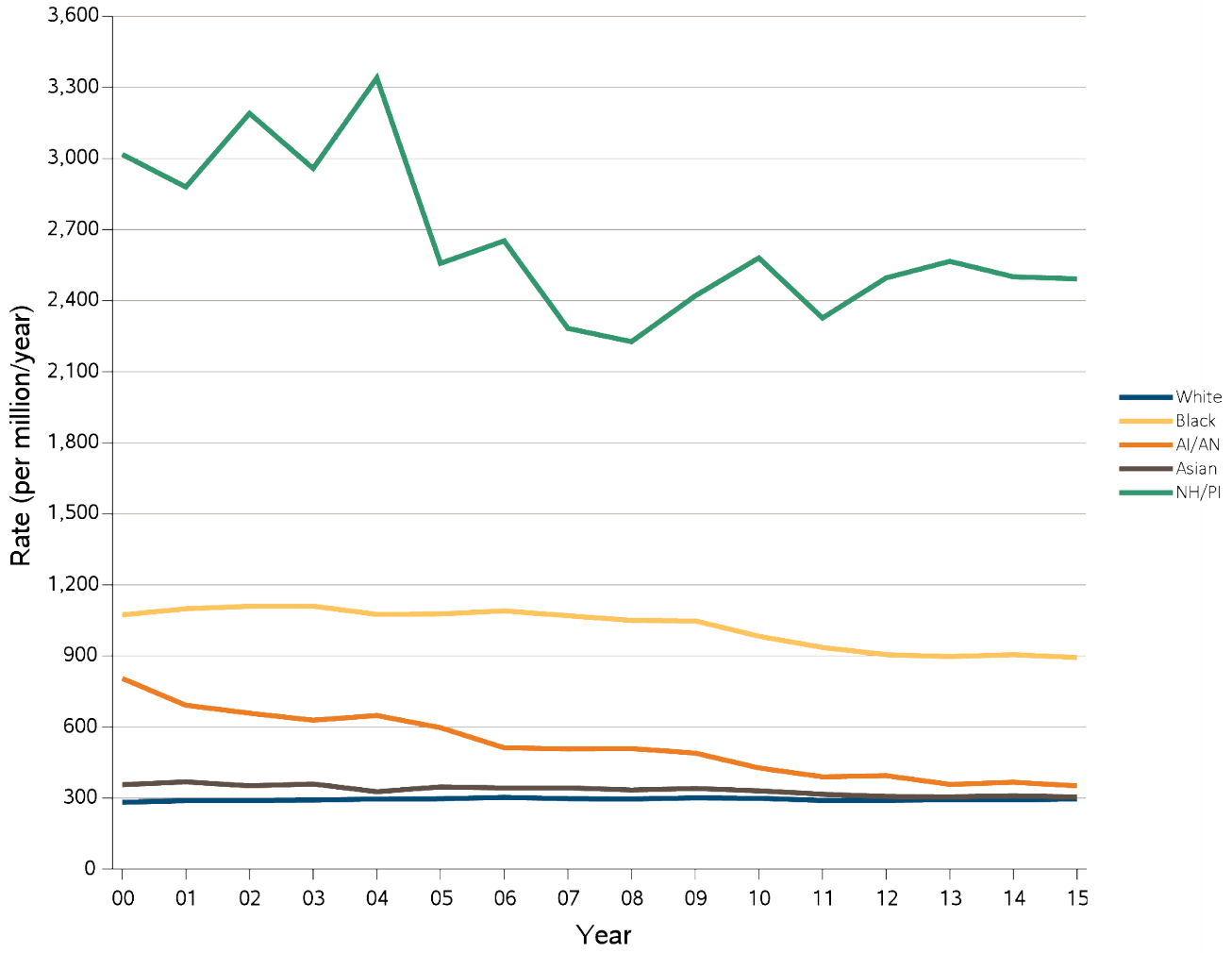
Data Source: Reference Table A.2(2) and special analyses, USRDS ESRD Database. Standardized for sex and race. The standard population was the U.S. population in 2011. Abbreviation: ESRD, end-stage renal disease.

Incidence Rate: By Race and Ethnicity

The adjusted ESRD incidence rate among Native Hawaiians/Pacific Islanders was many times higher than for other race groups; in 2015 this group had an adjusted incidence rate ratio versus Whites of 8.4 (Figure 1.5). As noted in the *Healthy People 2020* chapter, there is a significant difference between data contained in the U.S. Census and the USRDS ESRD Database regarding the reporting of multiple race status among Native Hawaiians/Pacific Islanders; this makes the ESRD rates for this racial group inconclusive.

The rate among Blacks was also much higher than for other groups, with a 2015 adjusted incidence rate ratio versus Whites of 3.0. The adjusted ESRD incidence rate among Whites has been generally stable since around 2000, but has declined in other race groups. The decline has been greatest, over 2-fold, among American Indians/Alaska Natives. The net result is that the excess risk of ESRD among minorities compared to Whites has decreased markedly. In the 15-year period from 2000 to 2015, the adjusted risk ratio for ESRD for African Americans has declined from 3.7 to 2.9, for American Indians/Alaska Natives from 2.8 to 1.5, and for Asians the excess risk no longer exists (1.4 in 2000 and 1.0 in 2015). These changes appear to represent a reduction in health inequalities, whether in the general population or the CKD population.

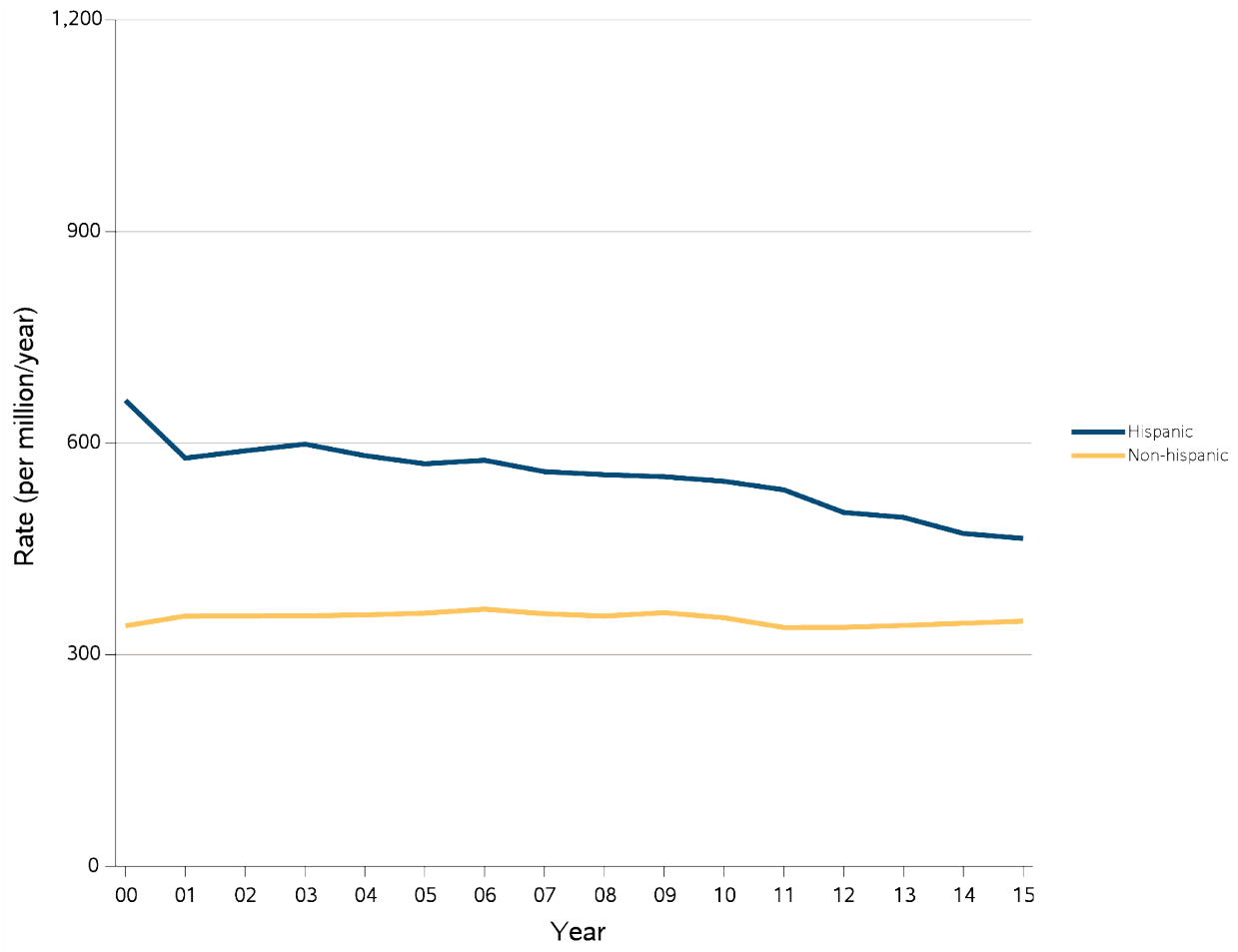
vol 2 Figure 1.5 Trends in adjusted ESRD incidence rate, by race, in the U.S. population, 2000-2015



Data Source: Reference Table A.2(2) and special analyses, USRDS ESRD Database. Standardized for age and sex. The standard population was the U.S. population in 2011. Abbreviations; AI/AN: Americans Indian/Alaska Native; NA/PI: Native Hawaiian/Pacific Islander; ESRD, end-stage renal disease.

Between 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 2015 remained nearly 34% higher among Hispanics than non-Hispanics.

vol 2 Figure 1.6 Trends in adjusted ESRD incidence rate, by Hispanic ethnicity, in the U.S. population, 2000-2015



Data Source: Reference Tables A.2(2). Standardized for age, sex, and race. 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, 2015, there were 703,243 prevalent cases of ESRD in the U.S.; this represents an increase of 3.4% since 2014, and of 80% since 2000 (Table 1.3 and Figure 1.8). The unadjusted ESRD prevalence reached 2,128 PMP, or 0.21% of the U.S. population. This was an increase of 2.4% since 2014 and of 58% since 2000 (Table 1.3).

As shown in Table 1.3 and Figure 1.7, both unadjusted and adjusted prevalence of ESRD increased steadily between 1980 and 2015. In general, however, the absolute and proportional yearly changes were a little greater for the unadjusted prevalence than for the adjusted, particularly after 2000 (Table 1.3). The increasing prevalent count and unadjusted prevalence indicate the need for additional resources to manage ESRD in the U.S. population, as demonstrated in Volume 2, Chapter 10: *Healthcare Expenditures for Persons with ESRD*.

Because prevalence reflects both the incidence and course of the disease, these ESRD prevalence trends could result from not only an increasing number of incident cases (Table 1.1), but also longer survival among ESRD patients. This interpretation is supported by the observation that the adjusted ESRD prevalence has continued to increase in recent years, while the adjusted incidence rate has declined (Table 1.1). This trend is encouraging regarding the success of efforts to treat kidney disease and kidney failure in the U.S.

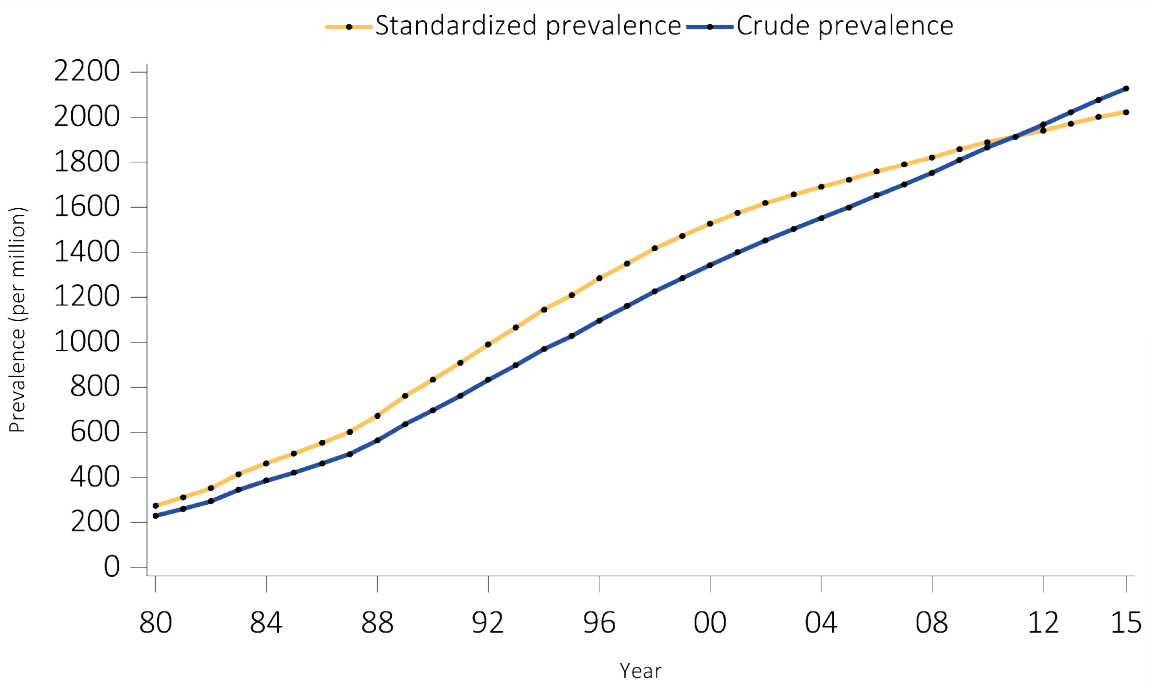
vol 2 Table 1.3 Trends in annual number of ESRD prevalent cases, unadjusted and adjusted of ESRD, and annual percentage change, in the U.S. population, 1980-2015

	Prevalent count		Unadjusted prevalence		Age-sex-race standardized	
Year	No. of cases	% change from previous year	Prevalence (per million year)	% change from previous year	Prevalence (per million year)	% change from previous year
1980	56,434	n/a	229.3	n/a	273.7	n/a
1981	64,252	13.9	260.3	13.5	311.6	13.8
1982	72,491	12.8	293.5	12.8	352.0	13.0
1983	85,570	18.0	344.8	17.5	414.7	17.8
1984	95,887	12.1	384.8	11.6	463.1	11.7
1985	105,423	9.9	421.1	9.4	505.9	9.2
1986	116,109	10.1	461.5	9.6	552.2	9.2
1987	127,468	9.8	503.9	9.2	601.9	9.0
1988	143,523	12.6	564.1	11.9	674.7	12.1
1989	162,662	13.3	636.2	12.8	760.9	12.8
1990	180,474	11.0	698.0	9.7	834.5	9.7
1991	199,548	10.6	762.8	9.3	909.6	9.0
1992	220,348	10.4	832.5	9.1	990.0	8.8
1993	240,557	9.2	898.6	7.9	1,065.8	7.7
1994	262,626	9.2	969.5	7.9	1,146.0	7.5
1995	281,557	7.2	1,027.1	5.9	1,209.0	5.5
1996	304,413	8.1	1,096.5	6.8	1,283.9	6.2
1997	326,185	7.2	1.160.2	5.8	1,349.0	5.1
1998	348,762	6.9	1.226.1	5.7	1,417.0	5.0
1999	369,623	6.0	1,284.9	4.8	1,473.2	4.0
2000	390,561	5.7	1,343.5	4.6	1,526.5	3.6
2001	410,502	5.1	1,399.1	4.1	1,575.2	3.2
2002	429,876	4.7	1,452.8	3.8	1,617.8	2.7
2003	448,514	4.3	1,503.2	3.5	1,655.6	2.3
2004	467,038	4.1	1,552.4	3.3	1,690.2	2.1
2005	485,905	4.0	1,600.2	3.1	1,722.5	1.9
2006	506,633	4.3	1,652.1	3.2	1,758.4	2.1
2007	526,709	4.0	1,701.3	3.0	1,789.5	1.8
2008	547,750	4.0	1,753.0	3.0	1,821.6	1.8
2009	570,416	4.1	1,810.2	3.3	1,857.3	2.0
2010	592,656	3.9	1,865.8	3.1	1,890.0	1.8
2011	612,417	3.3	1,914.1	2.6	1,913.9	1.3
2012	633,912	3.5	1,966.4	2.7	1,940.8	1.4
2013	656,856	3.6	2,022.1	2.8	1,971.5	1.6
2014	680,320	3.6	2,077.1	2.7	2,000.4	1.5
2015	703,243	3.4	2,127.6	2.4	2,023.6	1.2

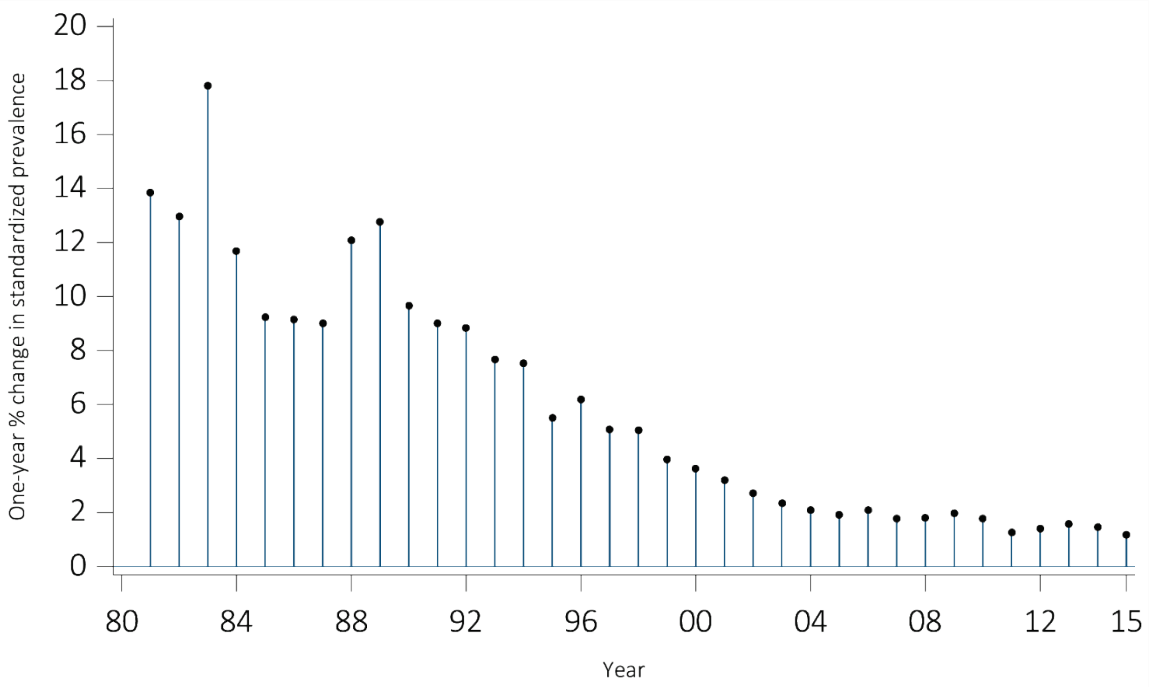
Data Source: Reference Tables B.1, B.2, B2(2) and special analyses, USRDS ESRD Database. The special analyses exclude U.S. Territories, unknown/other races. Standardized for age, sex, and race. Abbreviations: ESRD, end-stage renal disease; n/a, not applicable.

vol 2 Figure 1.7 Trends in the (a) unadjusted and standardized prevalence of ESRD, and (b) annual percentage change in the standardized prevalence of ESRD, in the U.S. population, 1980-2015

(a) Prevalence per million



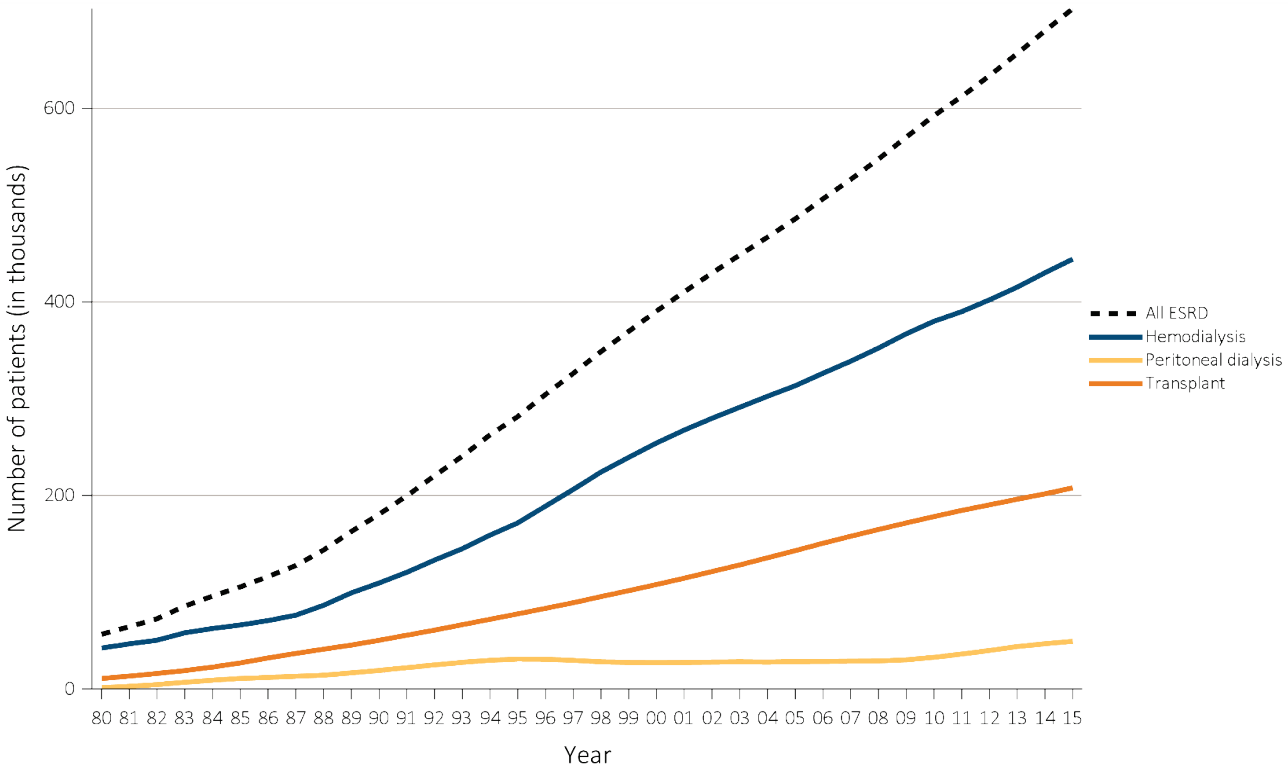
(b) One-year percentage change in standardized prevalence



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

Among prevalent ESRD cases on December 31, 2015, 63.2% used HD as their RRT, 7.0% used PD, and 29.6% had a functioning kidney transplant (Figure 1.8). The size of the prevalent HD population in 2015 was 74.8% larger than in 2000 (Figure 1.8), with the PD population reaching 81.8% larger. The size of the transplant population was 92.6% larger than in 2000.

vol 2 Figure 1.8 Trends in the number of ESRD prevalent cases, by modality, in the U.S. population, 1980-2015



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

Prevalence: By Region

Among the 18 ESRD Networks, the age-sex-race-adjusted prevalence of ESRD ranged from 2,375 PMP in Network 8 (AL, MS, and TN) to 1,437 PMP in Network 16 (AK, ID, MT, OR, and WA; Table 1.4). Renal replacement 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.

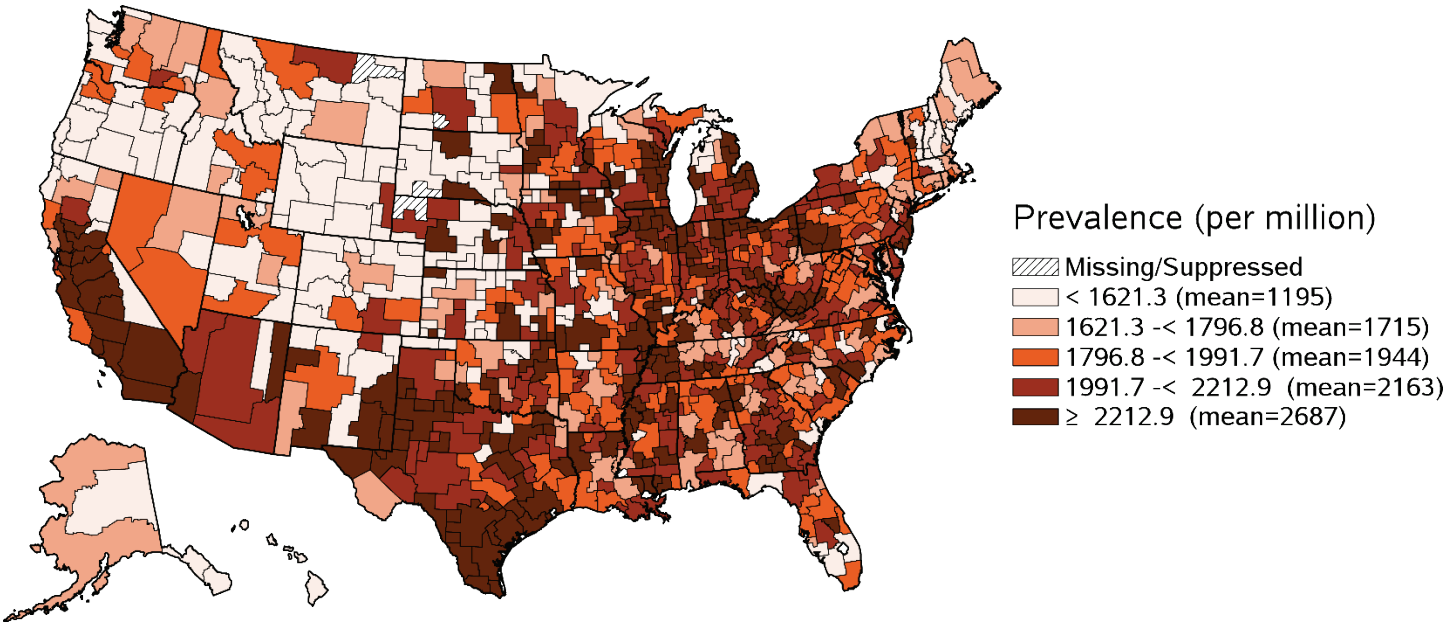
vol 2 Table 1.4 Unadjusted and adjusted* prevalence of ESRD and annual number of ESRD prevalent cases, by modality and ESRD Network, in the U.S. population, 2015

		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	36,231	2,375	2,493	24,557	67.8	2,954	8.2	8,639	23.8
6	NC, SC, GA	61,901	2,295	2,437	42,206	68.2	5,161	8.3	14,379	23.2
10	IL	31,186	2,284	2,405	19,036	61.0	2,112	6.8	9,960	31.9
5	MD, DC, VA, WV	40,283	2,244	2,366	25,508	63.3	2,540	6.3	12,118	30.1
18	Southern CA	58,464	2,233	2,370	39,367	67.3	4,583	7.8	14,433	24.7
14	TX	62,691	2,162	2,254	43,515	69.4	4,106	6.5	14,910	23.8
3	NJ, PR, VI	28,142	2,154	2,266	13,130	64.0	970	4.7	6,387	31.1
13	AR, LA, OK	25,861	2,146	2,261	17,373	67.2	2,236	8.6	6,174	23.9
2	NY	44,189	2,133	2,221	29,035	65.7	1,619	3.7	13,460	30.5
4	DE, PA	29,800	2,090	2,192	18,180	61.0	1,855	6.2	9,662	32.4
17	Northern CA, HI, GU, AS, MP	38,296	2,055	2,156	22,885	61.4	3,254	8.7	11,019	29.6
9	IN, KY, OH	47,341	1,986	2,077	29,914	63.2	3,557	7.5	13,710	29.0
7	FL	42,167	1,956	2,050	27,134	64.3	3,091	7.3	11,795	28.0
11	MI, MN, ND, SD, WI	45,422	1,883	1,980	25,329	55.8	2,608	5.7	17,384	38.3
12	IA, KS, MO, NE	25,378	1,726	1,799	14,057	55.4	2,138	8.4	9,119	35.9
15	AZ, CO, NV, NM, UT, WY	35,998	1,611	1,705	21,161	58.8	2,650	7.4	12,049	33.5
1	CT, MA, ME, NH, RI, VT	23,875	1,521	1,606	13,080	54.8	1,401	5.9	9,325	39.1
16	AK, ID, MT, OR, WA	22,340	1,437	1,508	12,060	54.0	1,935	8.7	8,287	37.1
All networks		703,243	2,026	2,129	437,527	63.3	48,770	7.1	202,810	29.4

*Data Source: Reference Table B.10 and special analyses, USRDS ESRD Database. The special analyses exclude U.S. Territories, unknown/other races. Standardized 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), American Samoa (AS), U.S. Virgin Islands, and Northern Mariana Islands. Northern and Southern California (CA) split into Networks 17 and 18. Unknown counties in California are grouped to Network*

Across 801 Health Service Areas, the adjusted prevalence of ESRD in 2011-2015 ranged from 400 PMP to 6546 PMP (interquartile range: 1,652 to 2,227 PMP; Figure 1.9). Although specific geographic patterns are difficult to identify without further geospatial analyses, examples of high ESRD prevalence in 2015 included 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.

vol 2 Figure 1.9 Map of the adjusted prevalence of ESRD, by Health Service Area, in the U.S. population, 2011-2015*

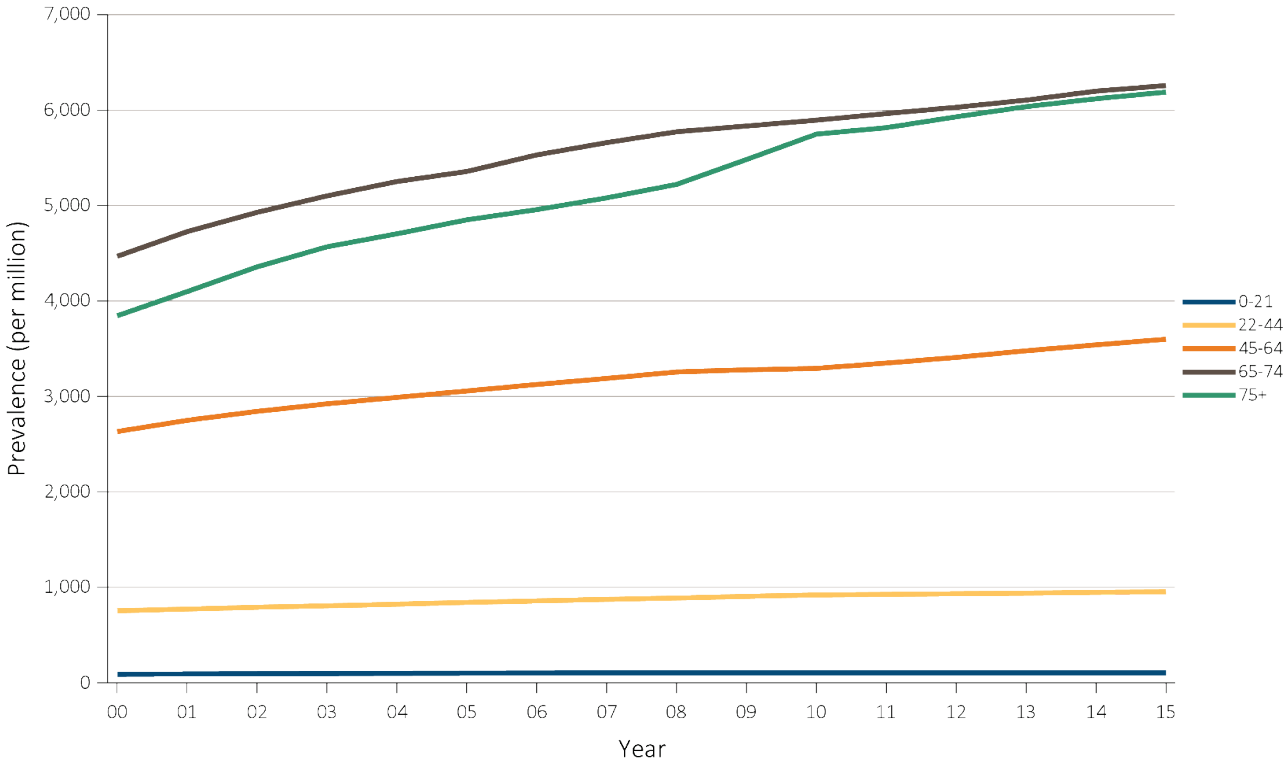


*Data Source: Special analyses, USRDS ESRD Database. Standardized for age, sex, and race. The standard population was the U.S. population in 2011. *Three Health Service Areas were suppressed because the ratio of unadjusted rate to adjusted rate or adjusted rate to unadjusted rate was greater than 3. 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 the older age groups (Figure 1.10). These increases contrast with the ongoing declines in adjusted ESRD incidence rate across age groups (Figure 1.4). This discrepancy likely results from both longer survival among ESRD patients and the expected progression of patients from one age group at incidence into other groups over time. Among the age groups, ESRD prevalence PMP was highest for the 65-74 years cohort. Although those aged 75 and older had the highest ESRD incidence rate, lower prevalence PMP was presumably due to higher mortality among these oldest ESRD patients.

vol 2 Figure 1.10 Trends in the adjusted prevalence of ESRD, by age group, in the U.S. population, 2000-2015



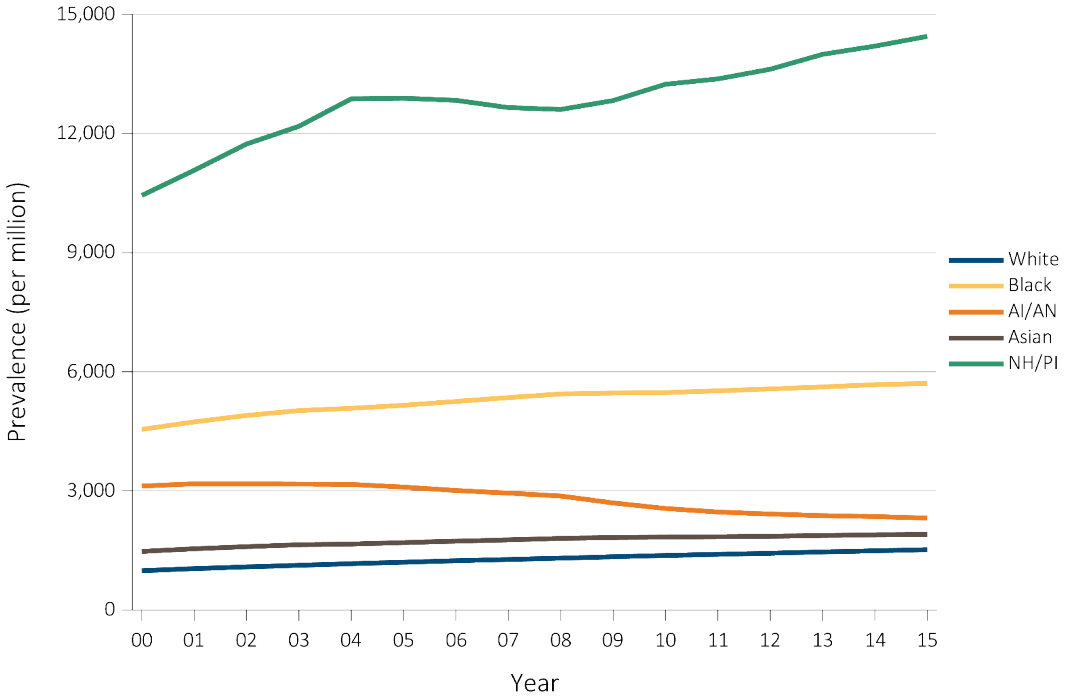
Data Source: Reference Table B.2(2) and special analyses, USRDS ESRD Database. Point prevalence on December 31 of each year. Standardized for sex and race. The standard population was the U.S. population in 2011. Abbreviations: ESRD, end-stage renal disease.

Prevalence: By Race and Ethnicity

In 2015, ESRD prevalence PMP was 14,448 among Native Hawaiians/Pacific Islanders, 5,705 among Blacks, 2,315 among American Indians/Alaska Natives, 1,905 among Asians, and 1,519 among Whites (Figure 1.11). The prevalence of ESRD for Native Hawaiians/Pacific Islanders was much higher than in other racial groups, by more than 9.5-fold as compared to Whites, nearly 7.6-fold higher than Asians, 6.2-fold higher than American Indians/Alaska Natives, and nearly 3.8-fold higher than Blacks.

The adjusted prevalence of ESRD continued to rise among Whites, Blacks, Native Hawaiians/Pacific Islanders, and Asians. However, the remarkable decline in incidence rates among American Indians/Alaska Natives has resulted in a 21% reduction in the prevalence of ESRD in this population over the past decade, from a peak of 3,017 in 2000 to 2,491 in 2015 (Figure 1.5).

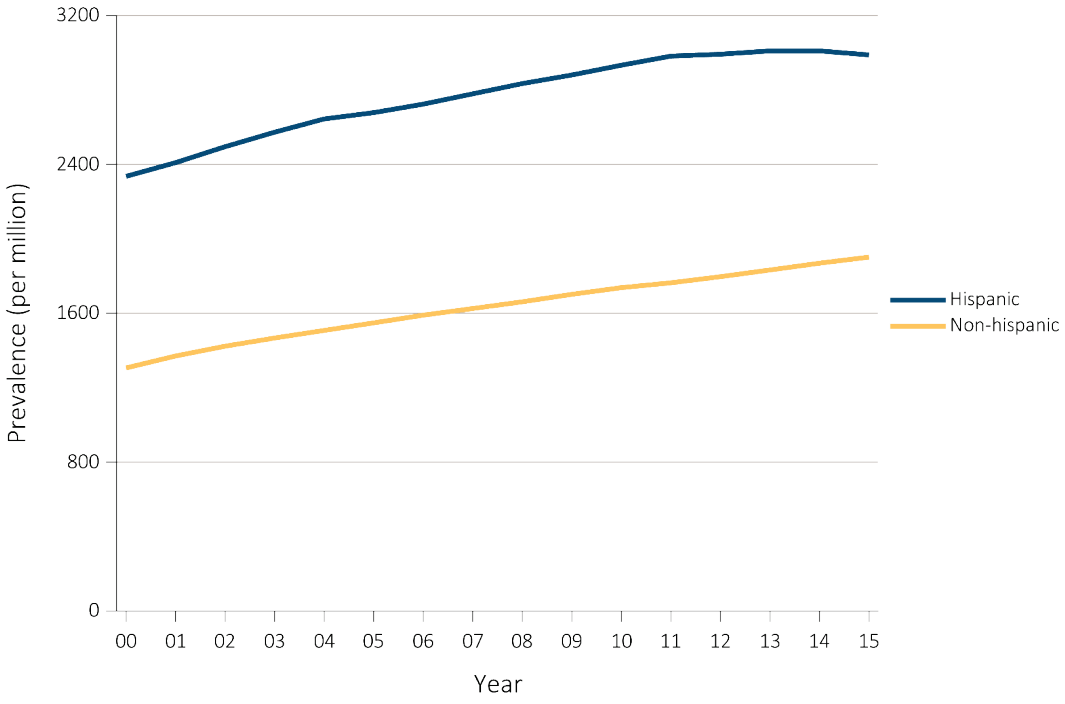
vol 2 Figure 1.11 Trends in adjusted prevalence of ESRD, by race, in the U.S. population, 2000-2015



Data Source: Reference Table B.2(2) and special analyses, USRDS ESRD Database. Point prevalence on December 31 of each year. Standardized for age and sex. The standard population was the U.S. population in 2011. Abbreviations NH/PI: Native Hawaiian/Pacific Islander; AI/AN: Americans Indian/Alaska Natives; ESRD, end-stage renal disease.

In 2015, the adjusted ESRD prevalence was 1,902 PMP among non-Hispanics, and nearly 57% higher, at 2,988 PMP, among Hispanics (Figure 1.12). The adjusted ESRD prevalence has risen for both non-Hispanics and Hispanics, though it shows signs of plateauing among Hispanics since 2011.

vol 2 Figure 1.12 Trends in the adjusted prevalence of ESRD, by Hispanic ethnicity, in the U.S. population, 2000-2015



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

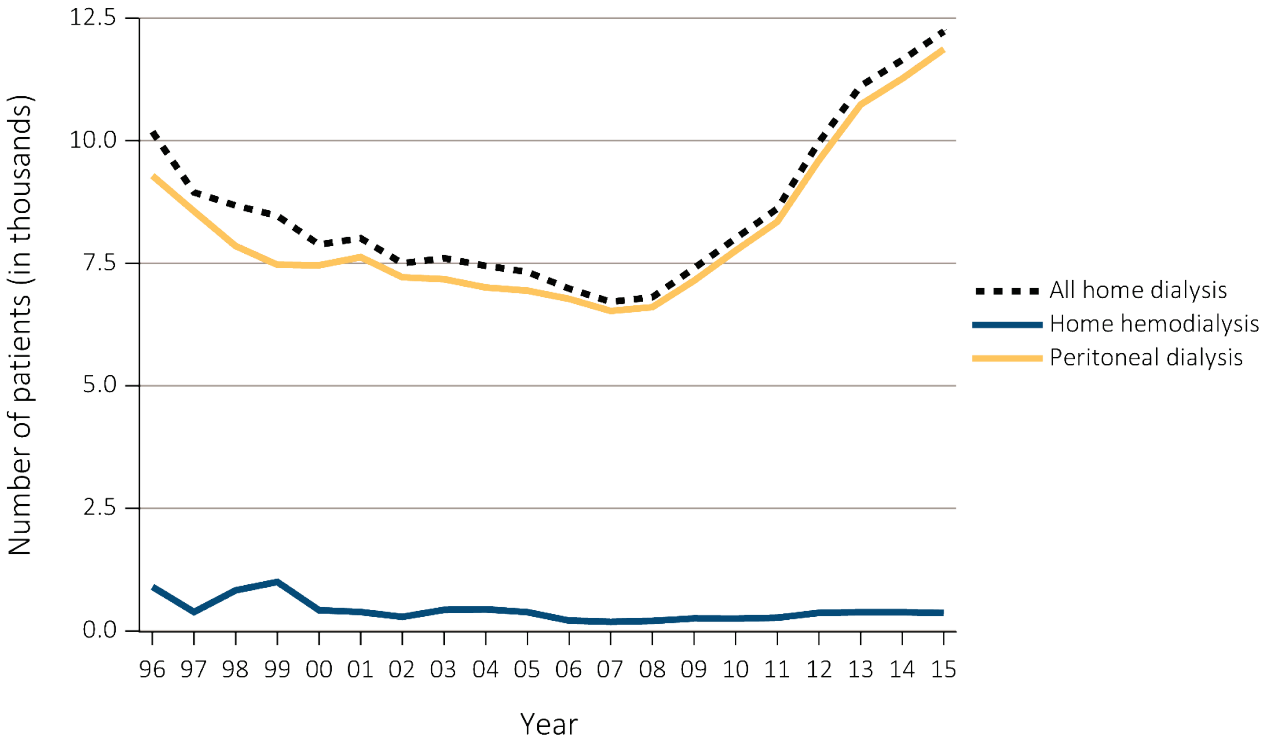
Modality of Renal Replacement Therapy: Incident ESRD Cases

As seen in Figure 1.2, among incident ESRD patients in 2015, 87.7% used HD as their RRT, 9.6% used PD, and 2.5% received a preemptive kidney transplant. Since 2000, the size of the incident HD population has increased by 29%. The size of the incident PD population has become 59% larger, and the preemptive transplant population 57% larger. By comparison, the U.S. population was 14% larger than in 2000.

Trends in Incident Counts: By Renal Replacement Therapy Modality

Use of home dialysis among incident ESRD patients has increased notably in recent years (Figure 1.13). Overall, home dialysis use in 2015 was 82% higher than at its least utilized point in 2007. In 2015, use of PD and home HD were 82% and 97% higher than in 2007. Peritoneal dialysis remained the dominant form of home dialysis. Despite the large relative rise in home HD, its overall use was only 3.5% among incident ESRD patients receiving home dialysis in 2015.

vol 2 Figure 1.13 Trends in the number of incident ESRD cases using home dialysis, by type of therapy, in the U.S. population, 1996-2015



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

Renal Replacement Therapy Modality Use: By Patient Characteristics

Use of PD and preemptive kidney transplants were markedly more common in younger groups, and were somewhat less common among Black or Hispanic patients (Table 1.5). Use of PD and preemptive kidney transplants were more common among patients with glomerular or cystic kidney disease as the primary cause of ESRD, versus DM or HTN. This difference is partially due to age, as both glomerular and cystic kidney disease are more common in younger patients.

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, 2015

	Total	HD		PD		Transplant	
		N	%	N	%	N	%
Age							
0-21	1,399	739	52.8	367	26.2	293	20.9
22-44	13,855	11,035	79.6	2,052	14.8	768	5.5
45-64	47,809	41,235	86.2	5,057	10.6	1,517	3.2
65-74	32,125	28,898	90.0	2,705	8.4	522	1.6
75+	28,644	26,919	94.0	1,683	5.9	42	0.1
Sex							
Male	71,984	63,256	87.9	6,839	9.5	1,889	2.6
Female	51,848	45,570	87.9	5,025	9.7	1,253	2.4
Race							
White	83,059	72,504	87.3	8,225	9.9	2,330	2.8
Black/African American	32,429	29,532	91.1	2,635	8.1	262	0.8
American Indian or Alaska Native	1,124	988	87.9	87	7.7	49	4.4
Asian	5,029	4,028	80.1	699	13.9	302	6.0
Native Hawaiian or Pacific Islander	1,466	1,298	88.5	158	10.8	10	0.7
Other or Multiracial	390	324	83.1	44	11.3	22	5.6
Unknown	335	152	45.4	16	4.8	167	49.9
Ethnicity							
Hispanic	18,151	16,201	89.3	1,649	9.1	301	1.7
Non-Hispanic	104,627	92,113	88.0	10,167	9.7	2,347	2.2
Unknown	1,054	512	48.6	48	4.6	494	46.9
Primary Cause of ESRD							
Diabetes	56,218	50,748	90.3	5,062	9.0	408	0.7
Hypertension	34,727	31,220	89.9	3,243	9.3	264	0.8
Glomerulonephritis	9,198	7,063	76.8	1,633	17.8	502	5.5
Cystic Kidney	2,833	1,764	62.3	596	21.0	473	16.7
Other/Unknown	20,856	18,031	86.5	1,330	6.4	1,495	7.2
Total	123,832	108,826	87.9	11,864	9.6	3,142	2.5

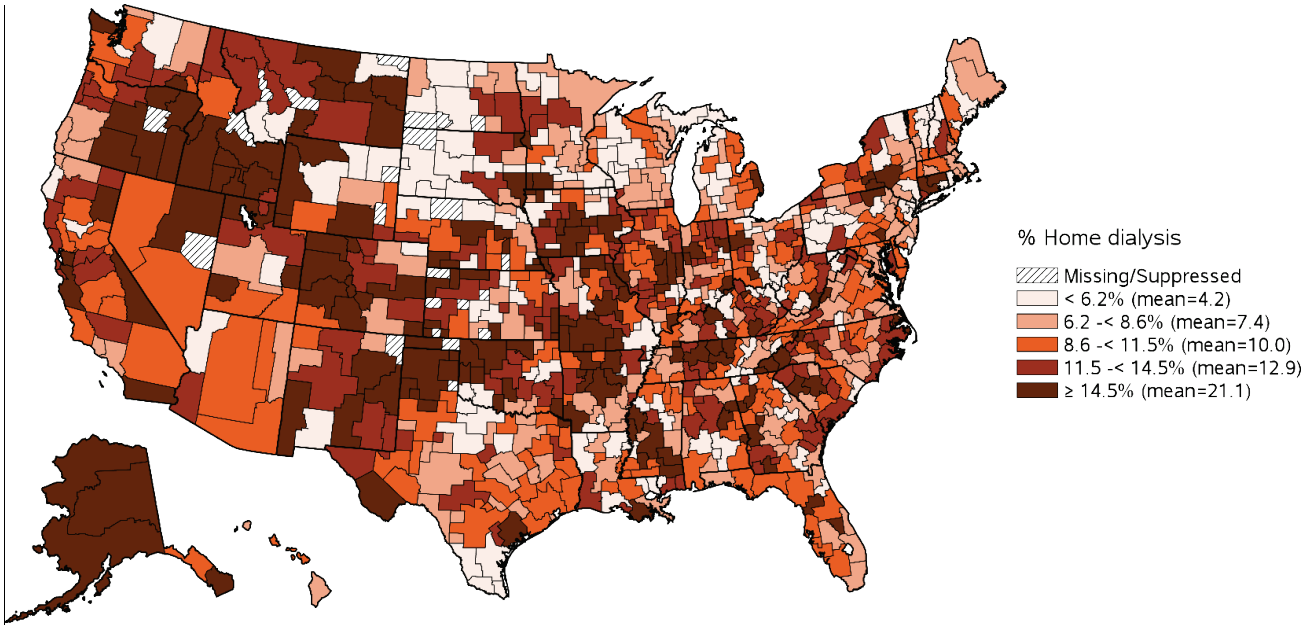
Data Source: Special analyses, USRDS ESRD Database. The numbers in this table exclude "Other PD" and "Uncertain Dialysis." Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis, including home hemodialysis and in center hemodialysis; PD, peritoneal dialysis.

Renal Replacement Therapy Modality Use: By Region

Among incident ESRD cases, HD was the predominant modality in all networks, ranging from 83.5% in Network 17 (N. CA, HI, GU, and AS) to 92.1% in Network 2 (NY; Table 1.2). Use of PD varied over 2-fold, from 4.8% in Network 2 (Table 1.2) to 14.3% in Network 17 (Table 1.2). Overall, preemptive kidney transplantation remained an uncommon initial RRT modality, at 2.5%, although its use ranged over 3-fold from 1.3% in Network 8 (IN, KY, and OH) to 4.1% in Network 1 (CT, MA, ME, NH, RI, and VT).

The proportion of incident dialysis patients using home dialysis varied substantially across 783 HSAs, ranging from 0% to 62% (interquartile range: 6.8% to 13.4%; Figure 1.14). Few geographic patterns were apparent, supporting the likelihood that differences in home dialysis use were largely driven by variations between individual dialysis centers or groups of centers, rather than by large-scale regional effects.

vol 2 Figure 1.14 Map of the percentage of incident dialysis cases using home dialysis (peritoneal dialysis or home hemodialysis), by Health Service Area, 2011-2015



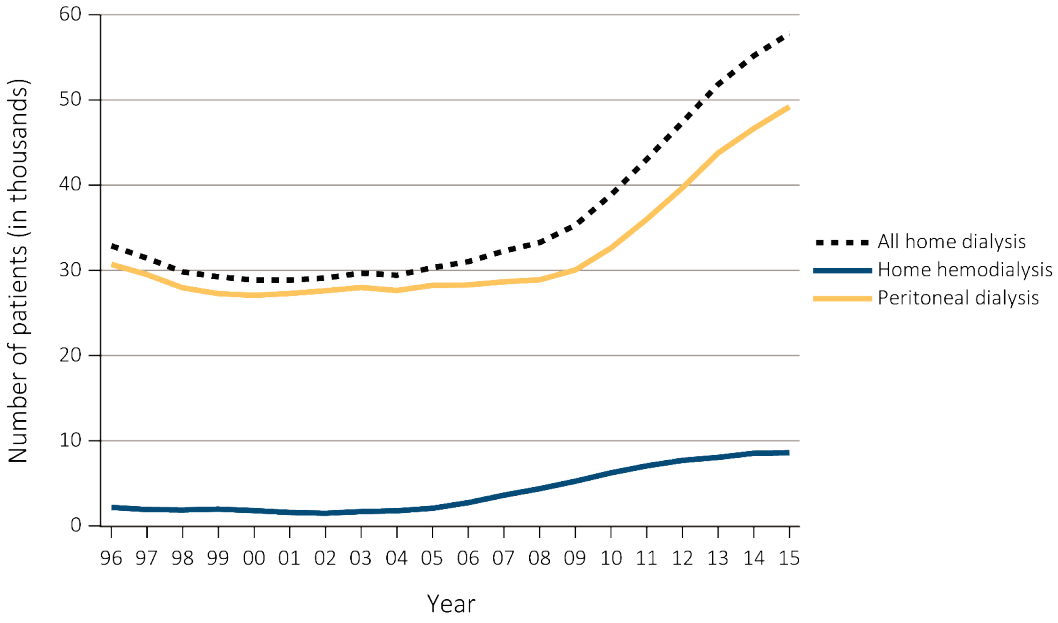
Data Source: Special analyses, USRDS ESRD Database. Values for cells with 10 or fewer patients are suppressed.

Modality of Renal Replacement Therapy: Prevalent ESRD Cases

Trends in Prevalent Counts: By Renal Replacement Therapy Modality

The use of home dialysis (PD or home HD) among prevalent ESRD patients has increased appreciably in recent years (Figure 1.15), mirroring patterns shown for incident dialysis (Figure 1.17). Home dialysis accounted for 8.6% of all prevalent dialysis patients in 2015, up from a low of 7.4% in 2008. In this group, the proportion using HD was over 2.5-fold higher in 2015 (16.3%) than in 2000 (6.1%).

vol 2 Figure 1.15 Trends in number of prevalent ESRD cases using home dialysis, by type of therapy, in the United States, 1996-2015



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.

Renal Replacement Therapy Modality Use: By Patient Characteristics

Distributions of the modality used, by patient characteristics, generally mirrored those for incident patients. Uses of PD 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 their ESRD (Table 1.6).

vol 2 Table 1.6 Percentage of prevalent cases of hemodialysis, peritoneal dialysis, and transplant by age, sex, race, ethnicity, and primary ESRD diagnosis, in the United States, 2015

	Total	Hemodialysis		Peritoneal dialysis		Transplant	
		N	%	N	%	N	%
Age							
0-21	9,738	1,775	18.2	1,008	10.4	6,955	71.4
22-44	102,744	51,188	49.8	9,072	8.8	42,484	41.3
45-64	308,616	184,098	59.7	21,791	7.1	102,727	33.3
65-74	166,679	112,875	67.7	10,899	6.5	42,905	25.7
75+	113,575	94,401	83.1	6,435	5.7	12,739	11.2
Sex							
Male	405,248	254,066	62.7	27,262	6.7	123,920	30.6
Female	296,046	190,240	64.3	21,941	7.4	83,865	28.3
Race							
White	430,569	251,259	58.4	32,543	7.6	146,767	34.1
Black/African American	215,299	160,990	74.8	12,304	5.7	42,005	19.5
American Indian or Alaska Native	7,497	5,228	69.7	421	5.6	1,848	24.6
Asian	32,968	18,927	57.4	3,104	9.4	10,937	33.2
Native Hawaiian or Pacific Islander	8,453	6,208	73.4	640	7.6	1,605	19.0
Other or Multiracial	3,333	1,176	35.3	142	4.3	2,015	60.5
Unknown	3,233	549	17.0	51	1.6	2,633	81.4
Ethnicity							
Hispanic	122,272	82,510	67.5	7,733	6.3	32,029	26.2
Non-Hispanic	561,794	359,578	64.0	41,248	7.3	160,968	28.7
Unknown	17,286	2,249	13.0	224	1.3	14,813	85.7
Primary Cause of ESRD							
Diabetes	267,956	203,295	75.9	18,294	6.8	46,367	17.3
Hypertension	178,875	130,537	73.0	13,459	7.5	34,879	19.5
Glomerulonephritis	112,235	44,897	40.0	8,785	7.8	58,553	52.2
Cystic Kidney	33,194	10,357	31.2	2,268	6.8	20,569	62.0
Other/Unknown	109,092	55,251	50.6	6,399	5.9	47,442	43.5
Total	701,352	444,337	63.4	49,205	7.0	207,810	29.6

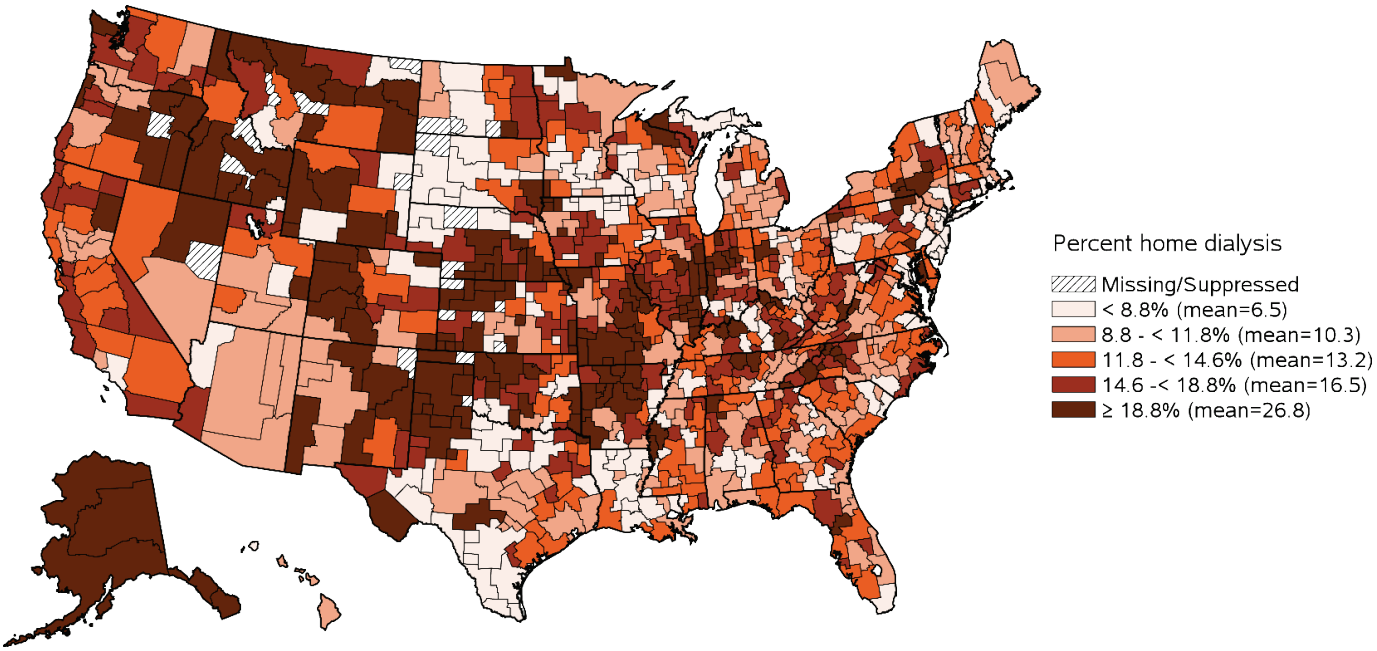
Data Source: Special analyses, USRDS ESRD Database. The numbers in this table exclude "Other PD" and "Uncertain Dialysis." Abbreviation: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis.

Renal Replacement Therapy Modality Use: By Region

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

Across 784 HSAs in 2011-2015, the percentage of prevalent patients using home dialysis ranged from 0% to 79% (interquartile range: 9.4% to 17.2%; Figure 1.16). Use of home dialysis varied considerably across the country; there were no apparent regional patterns of low versus high use of home HD in these HSAs.

vol 2 Figure 1.16 Map of the percentage of prevalent dialysis cases using home dialysis, by Health Service Area, 2011-2015



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 2015, 22% of patients starting ESRD therapy were reported on the CMS 2728 form as not having received nephrology care prior to ESRD onset (Table 1.7), a decrease of 2% from 2014. An additional 14% had an unknown duration of pre-ESRD nephrology care. Because treatment characteristics, such as erythropoiesis-stimulating agent (ESA) use and dietary care, for the unknown group were similar to those with no pre-ESRD nephrology care, one may assume that up to 36% of new ESRD cases received little or no pre-ESRD nephrology care (Table 1.7.a).

Several differences were notable in the distributions of pre-ESRD nephrology care by patient characteristics. The youngest patients 0-21 years old were most likely (44%), and adults aged 22-64 years were least likely to have had longer duration (12 months or more) of pre-ESRD nephrology care (27%-29%). 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 DM or HTN. Having no nephrology care was most common for patients with HTN as the primary cause of ESRD. One could surmise that some patients initially presenting with advanced CKD, approaching the need for dialysis, might be assigned the diagnosis of HTN in the absence of evidence of other possible etiologies.

Extensive pre-ESRD care was associated with greatly improved initial ESRD status. Over 50% of those patients with more than 12 months of nephrology care also received dietary care, received ESAs, and started dialysis with an arteriovenous (AV) fistula. The comparable rates for nephrology care of less than 6 months were 21% diet care, 17% ESA use, and 10% AV fistula. Patients receiving longer pre-ESRD nephrology care were less likely to start dialysis at either very low eGFR levels (<5 ml/min/1.73m^2) or very high (≥15 ml/min/1.73m^2) 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, 2015

(a) Demographic characteristics (% within row)

		Duration of pre-ESRD nephrology care				
	No. of cases	>12 months	6-12 months	0-6 months	None	Unknown
Total	119,580	30.9	19.3	13.4	22.4	14.0
Age						
0-21	1,449	44.1	14.7	14.1	20.5	6.5
22-44	13,573	27.4	18.3	13.9	28.3	12.2
45-64	45,701	28.9	19.4	13.6	23.9	14.1
65-74	31,082	32.6	19.9	13.0	20.1	14.3
75+	27,775	33.4	19.2	13.1	19.6	14.9
Sex						
Female	50,327	31.1	19.7	13.5	21.6	14.2
Male	69,253	30.8	19.0	13.3	22.9	13.9
Race						
American Indian/Alaska Native	1,123	31.3	20.6	13.5	23.8	10.8
Asian	4,850	33.1	20.2	14.8	18.6	13.3
Black/African American	31,580	27.1	19.0	13.4	24.5	16.0
White	80,581	32.4	19.4	13.2	21.7	13.4
Native Hawaiian/ Pacific Islander	1,440	28.1	19.2	14.4	27.2	11.1
Other/Unknown	*	50	17	*	*	33.4
Ethnicity						
Hispanic	17,158	24.0	19.0	14.4	27.0	15.7
Non-Hispanic	102,422	32.1	19.4	13.2	21.6	13.8
Primary Diagnosis						
Diabetes	56,369	31.6	21.4	13.6	19.5	13.8
Hypertension	34,821	28.0	18.6	13.7	23.3	16.4
Glomerulonephritis	9,336	40.0	18.1	12.0	21.6	8.3
Cystic kidney	2,873	57.2	18.1	9.1	9.2	6.5
Other/Unknown	16,181	24.9	14.7	13.2	33.1	14.1

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, 2015 *(continued)*

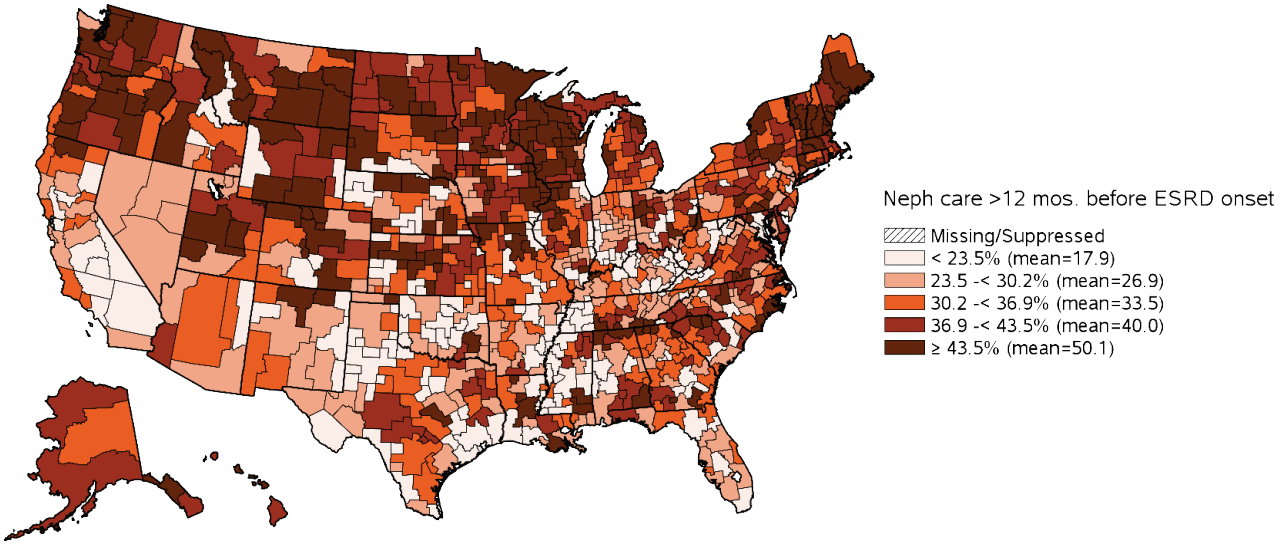
(b) Clinical characteristics (% within row)

		Duration of pre-ESRD nephrology care				
	No. of cases	**>12 mo.**	**6-12 mo.**	**0-6 mo.**	**None**	**Unknown**
Dietary care						
No	110,306	29.1	18.9	12.7	24.2	15.2
Yes	9,274	53.2	24.6	20.9	0.7	0.7
ESA use						
No	103,238	27.4	18.4	12.7	25.4	16.1
Yes	16,342	53.6	24.8	17.3	3.3	0.9
eGFR at RRT start						
<5	16,846	26.2	16.4	11.6	32.1	13.7
5-<10	56,028	33.2	20.1	13.4	20.3	13.0
10-<15	32,624	32.0	20.2	14.0	19.8	14.0
>=15	14,008	25.4	17.7	14.1	24.8	17.9
Vascular Access						
AV fistula	17,897	54.3	24.8	9.8	3.6	7.4
AV graft	3,147	42.5	26.3	13.6	8.5	9.0
CV catheter with maturing fistula/graft	19,078	32.8	21.7	14.4	18.2	12.8
CV catheter only	65,153	19.5	15.7	14.1	32.7	18.1
Other/Unknown	14,305	49.0	24.3	12.8	7.6	6.3

*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 m^2) for those aged ≥18 years and the Schwartz equation for those aged <18 years. Abbreviations: AV, arteriovenous; CKD-EPI, chronic kidney disease epidemiology calculation; CV, central venous; 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 2015 with greater than 12 months of pre-ESRD nephrology care varied substantially across 783 HSAs, ranging from a low of 2% to a high of 67% (interquartile range: 25% to 41%; Figure 1.17). Health Service Areas with the highest proportions of patients with more than 12 months of pre-ESRD care were clustered in the Northeast, Upper Midwest, and Northwest, where over 40% of patients were under a nephrologist's care for greater than 12 months prior to ESRD.

vol 2 Figure 1.17 Percentage of incident cases who had received >12 months of pre-ESRD nephrology care, by Health Service Area, 2011-2015

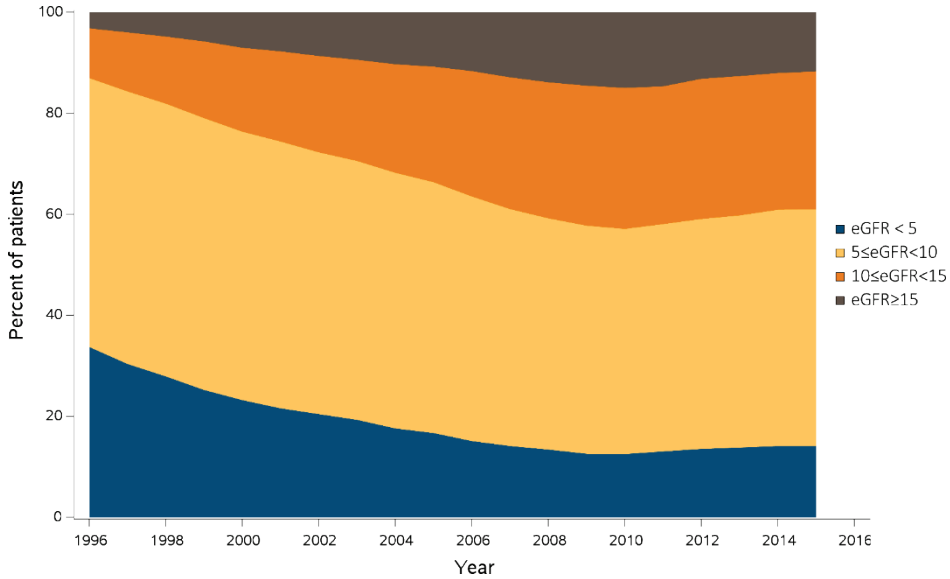


Data Source: Special analyses, USRDS ESRD Database. Population only includes incident cases with CMS form 2728. Values for cells with 10 or fewer patients are suppressed. Abbreviations: ESRD, end-stage renal disease; Neph., nephrology.

eGFR at ESRD onset

Figure 1.18 shows that the percentage of incident ESRD patients who initiated RRT at higher eGFR levels increased steadily from 1996 until 2010. Since 2010, eGFR at the start of dialysis has remained stable or has slightly declined. For example, the percentage 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 2015. The percentage who started therapy at eGFR <5 ml/min/1.73 m² decreased from 34% in 1996 to 13% in 2010, and then to 14% in 2015. This could reflect the influence of a number of publications questioning the advisability of early start dialysis.

vol 2 Figure 1.18 Trends in the distribution of eGFR (ml/min/1.73 m²) among incident ESRD patients, 1996-2015



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 m²) 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.

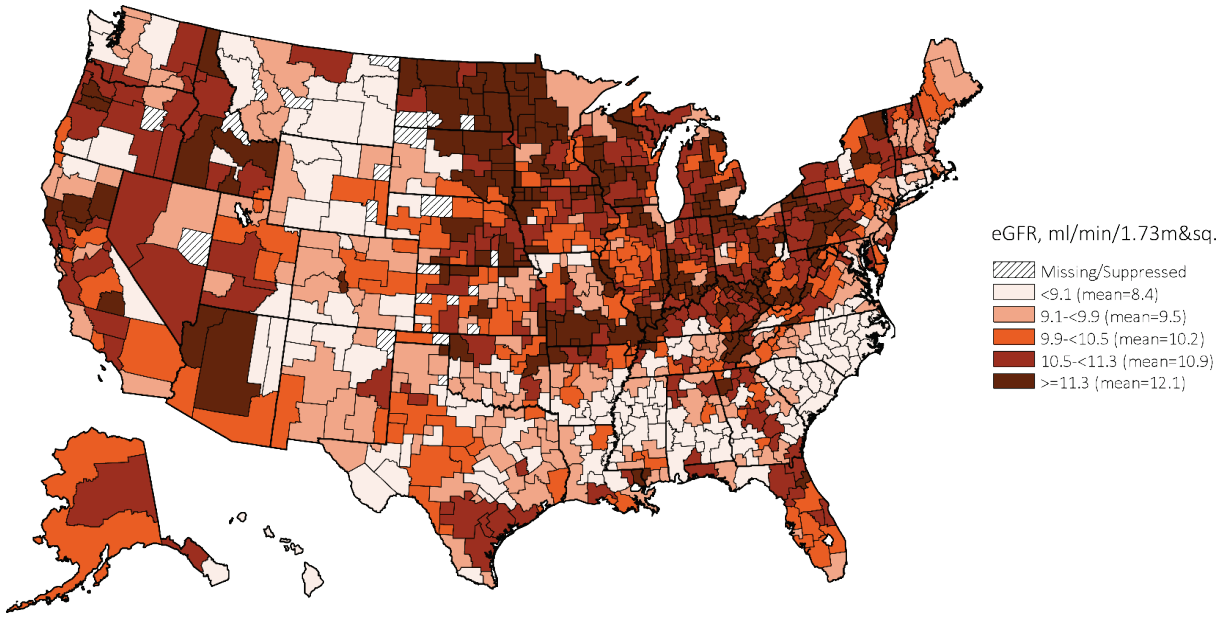
Mean eGFR at ESRD start was higher among young patients (0-21 years), males, Whites, non-Hispanics, and those with DM as their primary cause of ESRD (Table 1.8). Mean eGFR at ESRD start in 2013 varied substantially by HSA (Figure 1.19). For example, HSAs with higher average eGFRs at initiation of ESRD clustered in the North and Midwest regions, while those with lower averages clustered in the South.

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, 2015

		Nutrition		Anemia		Lipids		Diabetes
	eGFR (mL/min/1.73 m^2)	Serum albumin (g/dL)	Dietary care (%)	Hemoglobin (g/dL)	ESA use (%)	Total cholesterol (mg/dL)	LDL (mg/dL)	Hgb (%)
Age								
0-21	13.8	3.4	38.4	9.6	26.2	184.0	109.0	5.0
22-44	9.5	3.2	7.3	9.2	10.0	171.3	102.2	7.0
45-64	10.0	3.2	7.4	9.4	11.2	159.8	94.1	6.8
65-74	10.2	3.2	7.7	9.4	13.8	150.7	84.7	6.6
75+	10.4	3.2	6.6	9.5	15.4	141.2	77.3	6.4
Sex			0.0		0.0			
Male	10.4	3.2	7.8	9.5	11.7	149.3	86.3	6.7
Female	9.7	3.1	7.4	9.2	14.5	165.3	94.3	6.7
Race			0.0		0.0			
White	8.8	3.3	11.6	9.3	19.0	160.8	90.2	6.6
Black/African American	9.2	2.9	8.0	9.2	14.0	147.3	82.0	6.7
American Indian/Alaska Native	10.4	3.2	7.7	9.5	13.0	152.7	86.9	6.7
Asian	9.8	3.2	6.6	9.1	11.8	161.4	95.8	6.6
Native Hawaiian/Pacific Islander	8.3	3.2	9.9	9.3	16.0	155.6	87.6	6.8
Ethnicity			0.0		0.0			
Yes	9.6	3.1	7.5	9.2	11.3	156.1	88.5	6.8
No	10.2	3.2	7.6	9.4	13.3	155.4	89.6	6.7
Primary Cause of ESRD			0.0		0.0			
Diabetes	10.3	3.1	7.2	9.3	14.3	153.0	87.8	7.0
Hypertension	9.7	3.3	6.0	9.4	11.5	154.6	89.4	6.1
Glomerulonephritis	9.2	3.3	11.5	9.4	17.0	174.8	100.8	5.8
Cystic kidney	9.5	3.8	15.2	10.2	15.8	164.6	94.9	5.5
Total	10.1	3.2	7.6	9.4	12.9	155.5	89.5	6.7

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

vol 2 Figure 1.19 Map of mean eGFR at initiation of renal replacement therapy, by Health Service Area, 2011-2015

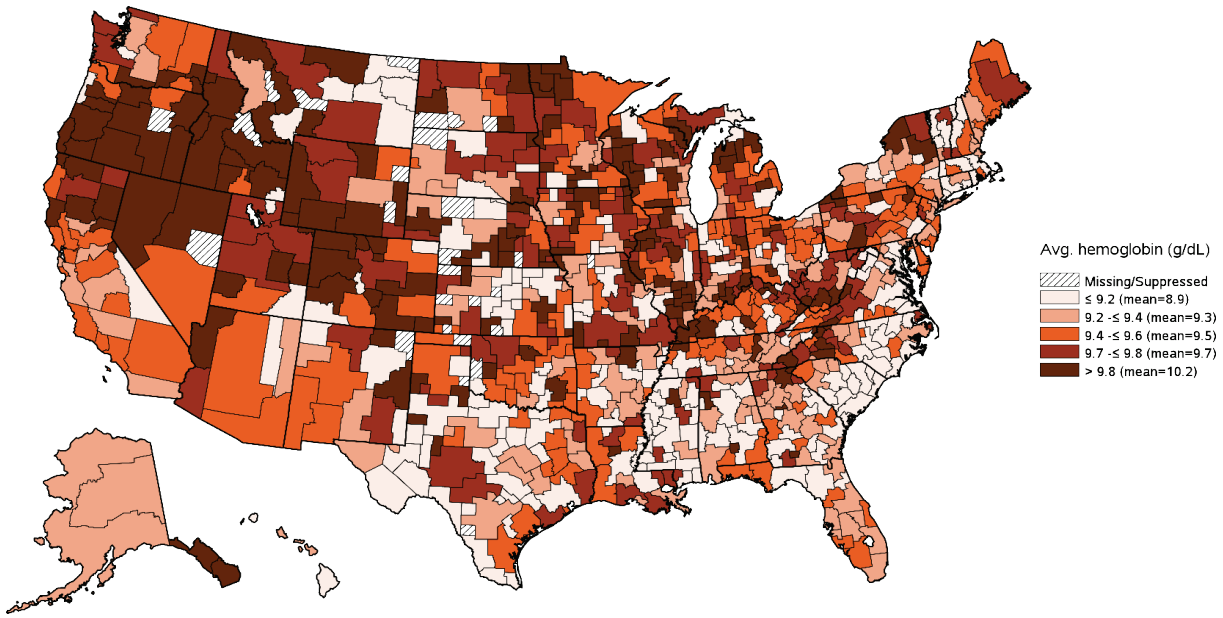


Data Source: Special analyses, USRDS ESRD Database. Population only includes incident cases with CMS form 2728. eGFR calculated using the CKD-EPI equation (CKD-EPI eGFR (ml/min/1.73 m²) for those aged ≥18 and the Schwartz equation for those aged <18. Values for cells with 10 or fewer patients are suppressed. Abbreviations: eGFR, estimated glomerular filtration rate; CKD-EPI, chronic kidney disease epidemiology calculation.

Anemia at ESRD onset

In 2015, the overall average hemoglobin (Hgb) level at ESRD onset was 9.4 g/dL. Incident ESRD patients with cystic kidney disease listed as the primary cause had higher mean Hgb levels at ESRD onset than did other groups (Table 1.9). Figure 1.20 shows the distribution of average Hgb levels by HSA across the U.S. Large HSAs with higher average Hgb levels were present in the western half of the U.S., especially in the Rocky Mountain region. Smaller areas of higher Hgb were evenly distributed throughout the rest of the country.

vol 2 Figure 1.20 Map of average hemoglobin level at initiation of renal replacement therapy, by Health Service Area, 2011-2015



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 was also evident by ESRD Network. Most pronounced was an over 2-fold variation in the percentage of incident ESRD patients with pre-ESRD nephrology care of greater than 12 months. This ranged from 47% in Network 1 (CT, MA, ME, NH, RI, and VT) to 21% in Network 18 (Southern CA). Mean eGFR at ESRD start ranged from 8.9 ml/min/1.73m² in Network 6 (NC, SC, and GA) to 10.7 ml/min/1.73m² in Network 11 (MI, MN, ND, SD, and WI). Mean Hgb at dialysis start ranged from 9.1 to 10.5 g/dL across the 18 Networks (Table 1.9). At the ESRD Network level, regional variation in eGFR at initiation did not seem to be associated with regional variation in length of 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, 2015

Network	States in network*	Duration of pre-ESRD nephrology care (% in row)					Mean eGFR (ml/min/1.73 m²)	Mean Hgb (g/dL)
		>12 months	6-12 months	0-6 months	None	Unknown		
18	Southern CA	21.1	17.5	17.5	22.3	21.5	10.3	9.5
14	TX	24.3	18.8	14.0	28.7	14.2	9.6	9.3
10	IL	25.7	17.9	15.5	19.0	22.0	10.2	9.3
5	FL	27.0	19.2	12.1	24.3	17.5	10.1	9.3
7	MD, DC, VA, WV	28.4	20.4	14.0	20.6	16.7	9.5	9.3
3	NJ, PR, VI	28.6	19.4	11.7	31.9	8.4	9.6	9.5
13	AR, LA, OK	28.8	19.3	10.8	25.8	15.2	9.3	9.5
9	AL, MS, TN	29.7	18.9	12.2	26.0	13.2	9.1	9.2
8	IN, KY, OH	30.1	21.7	12.3	17.9	18.1	10.7	9.4
17	Northern CA, HI, GU, AS, MP	31.9	22.6	14.8	19.4	11.3	9.8	9.4
15	AZ, CO, NV, NM, UT, WY	32.5	19.2	16.1	20.9	11.3	10.3	9.7
2	NY	32.7	17.5	11.4	22.2	16.2	9.3	9.2
6	NC, SC, GA	34.0	19.7	13.6	21.2	11.5	8.9	9.3
12	IA, KS, MO, NE	34.1	20.8	12.8	23.8	8.5	10.5	9.4
4	DE, PA	36.9	18.2	13.1	20.3	11.5	9.9	9.4
11	MI, MN, ND, SD, WI	40.6	17.8	12.5	20.0	9.1	10.5	9.5
16	AK, ID, MT, OR, WA	43.7	19.7	13.9	18.3	4.4	9.9	9.6
1	CT, MA, ME, NH, RI, VT	47.4	20.7	9.5	14.4	8.1	9.2	9.3
All networks		31.0	19.3	13.4	22.4	14.0	9.8	9.4

*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 m2) for those aged ≥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), American Samoa (AS), U.S. Virgin Islands, and Northern Mariana Islands. 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.*

References

Centers for Disease Control and Prevention (CDC) http://www.cdc.gov/diabetes/statistics/prev/national/figbyrace.htm

Langenecker JC, Coresh J, Klag MJ, Levey AS, Martin AA, Fink NE, Powe NR. Validation of comorbid conditions on the end-stage renal disease medical evidence report: the CHOICE study. Choices for Healthy Outcomes in Caring for ESRD. *J Am Soc Nephrol*. 2000 Mar;11(3):520-9. PubMed PMID: 10703676.

Yuan CM, Nee R, Ceckowski KA, Knight KR, Abbott KC. Diabetic nephropathy as the cause of end-stage kidney disease reported on the medical evidence form CMS2728 at a single center. *Clin Kidney J* 2017;10(2):257-262.

Chapter 2: Clinical Indicators and Preventive Care

Anemia

- In May 2016, the majority (64.7%) of hemodialysis (HD) patients had hemoglobin (Hgb) levels from 10 to <12 g/dL, while 13.6% had Hgb ≥12 g/dL, 14.9% had Hgb from 9 to <10 g/dL, and 6.8% had Hgb <9 g/dL. The mean Hgb was 10.8 g/dL (Figure 2.1.b).
- In May 2016, the majority (56.2%) of peritoneal dialysis (PD) patients had Hgb levels from 10 to <12 g/dL, while 20.3% had Hgb ≥12 g/dL, 16.0% had Hgb from 9 to <10 g/dL, and 7.5% had Hgb <9 g/dL. The mean Hgb was 10.9 g/dL (Figure 2.1.b).
- As of 2015, three different erythropoiesis-stimulating agents (ESAs) were prescribed to dialysis patients in the United States (U.S.). December 2015 claims data indicated monthly use rates among HD patients on dialysis ≥90 days of 42.6% for epoetin (EPO) alfa, 14.0% for darbepoetin, 20.5% for pegylated EPO (PEG-EPO) beta; 19.7% of these patients were not using an ESA. Among PD patients, 40.4% were using EPO alfa, 9.2% darbepoetin, 9.2% PEG-EPO, and 38.7% were not using an ESA (Figures 2.2.d and 2.8.d.).
- For U.S. HD patients in 2014 to 2015, little change was seen in the monthly percent intravenous (IV) iron use (61.2% to 60.0%) and mean monthly IV iron dose (295.6 mg to 294.0 mg; Figure 2.4). For PD patients little change was also seen in monthly percent IV iron use (24.7% to 25.3%) or mean monthly IV iron dose (195.5 mg to 196.2 mg; Figure 2.10).
- Serum ferritin levels increased slightly in all dialysis patients from 2014 to 2016. As of May 2016, 31.6% of HD patients had serum ferritin of 801-1200 and 21.9% had >1200 ng/mL. Among PD patients, 22.8% had serum ferritin of 801-1200 and 14.7% had >1200 ng/mL (Figures 2.6 and 2.12).

Serum Albumin

- In May 2016, 17.7% of HD and 42.8% of PD patients were hypoalbuminemic (<3.5 g/dl).

Mineral and Bone Disorders

- In May 2016, 59.5% of HD and 56.9% of PD patients had serum calcium levels within the range of 8.4-9.5 mg/dL. About 2% of patients receiving either dialysis modality had serum calcium levels greater than 10.2 mg/dL; 18.1% of HD patients and 23.9% of PD patients had calcium levels less than 8.4 mg/dL (Figures 2.14 and 2.15).
- In May 2016, 65.9% of HD patients and 70.1% of PD patients had serum phosphorus levels greater than 4.5 mg/dL (Figures 2.16 and 2.17).

Preventive Care

- In 2015, 86.5% of diabetic end-stage renal disease (ESRD) patients received at least one glycosylated hemoglobin (HbA1c) test, 71.8% a lipid test, and 46.9% a dilated eye exam. However, only 34.0% of diabetic ESRD patients received comprehensive diabetes monitoring that includes at least one of each of these tests. This was a decline from 36.4% comprehensive monitoring in 2010 (Figure 2.18).
- In the 2014-2015 flu season 72.2% of patients received an influenza vaccination. Although this rate had been stable over the last two years and the percent vaccinated has increased from 56.7% a decade earlier, the rate of flu vaccination was still below the Healthy People 2020 (HP2020) target of 90% (Figure 2.19.a).

Introduction

Given the high morbidity and mortality of individuals with ESRD who are receiving dialysis, initiatives aimed at quality improvement of renal replacement therapies (RRT) 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), as well as the Quality Incentive Program (QIP), which ties Medicare reimbursement to achievement of selected quality targets. Data collection for these projects has undergone a transition from paper-based data entry to web-based or electronic data entry using the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb). Implemented nationally in May 2012, this system allows facilities to submit monthly laboratory and clinical data for patients under their care. The system is still evolving, however, and data are select and not yet fully captured.

Methods

The findings presented in this chapter were drawn from data sources from the Centers for Medicare & Medicaid Services (CMS). Details of these 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 the analytical methods used to generate the study cohorts, figures, and tables in this chapter. Downloadable Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available on the USRDS website.

Clinical Indicators

In Figure 2.1, we present CROWNWeb data from May 2016 for a selection of clinical indicators relating to dialysis adequacy, achieved Hgb level, hypercalcemia, and serum albumin. Figure 2.1.a shows that achievement of dialysis adequacy targets for HD was nearly universal, with 96.7% of patients achieving a single pool Kt/V ≥1.2 (for more information about Kt/V see the Glossary). Achievement of the dialysis adequacy target for PD, a weekly Kt/V ≥1.7, was somewhat lower, at 88.9% (Figure 2.1.a).

Views on anemia treatment with ESAs have evolved in recent years, as safety concerns have emerged from controlled CKD clinical trials; study participants experienced greater risks of death, serious adverse cardiovascular reactions, and stroke when administered ESAs to achieve hemoglobin levels 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 approached or exceeded 11 g/dL. Current guidelines do not specify an appropriate lower limit, however, resulting in generally lower Hgb levels among dialysis patients.

CROWNWeb includes data from both Medicare and non-Medicare insured patients, and thus presents a more representative view of Hgb levels for the dialysis population than was previously possible through analyses based only upon claims data (Figure 2.1.b). In May 2016 the majority (64.7%) of both ESA-treated and non-treated HD patients had Hgb levels in the range of 10 to 12 g/dL, with 13.6% having Hgb ≥12 g/dL. The pattern was similar with PD patients, though a somewhat higher percentage (20.3%) had Hgb ≥12 g/dL. Later in this chapter, we utilize Medicare claims through 2015 in anemia trend analyses, and CROWNWeb data to describe the iron indices of ferritin and transferrin saturation (TSAT).

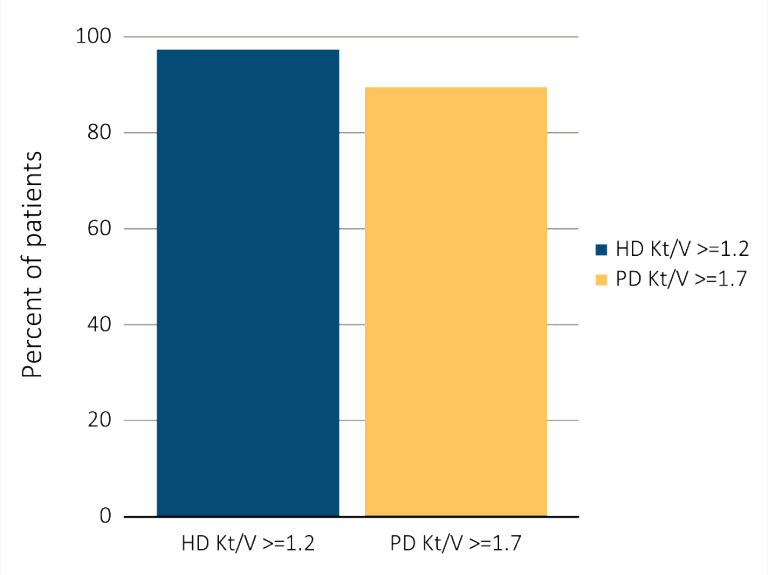
In Figure 2.1.c we present CROWNWeb data as of May 2016 on the percentage of dialysis patients having serum calcium levels >10.2 mg/dL. This was calculated as a three-month rolling average, similar to the methods utilized by the CMS ESRD Quality Incentive Program (QIP). The rationale for this quality measure is to encourage avoidance of hypercalcemia given its associations with vascular calcifications and cardiovascular events. For both modalities, the percent of patients with hypercalcemia has declined compared to May 2015. Later in the chapter, we present additional CROWNWeb data on trends in serum calcium and phosphorus levels.

Figure 2.1.d presents CROWNWeb data as of May 2016 on the distribution of serum albumin levels among dialysis patients. Although serum albumin has received much consideration as a potential quality measure and nutritional marker, several concerns

remain. These include its inconclusive link to nutritional status, as other factors, such as chronic inflammation or ongoing urinary protein loss can also lower serum albumin. In addition, it is unclear whether nutritional or other interventions can improve serum albumin levels. Nevertheless, given its importance as a prognostic marker and a strong association with mortality, we include national information on albumin levels. As of May 2016, 17.7% of HD and 42.8% of PD patients were hypoalbuminemic (<3.5 g/dl). The lower levels of serum albumin in PD patients compared to HD patients are thought to be in part due to peritoneal losses of protein.

vol 2 Figure 2.1 ESRD clinical indicator levels among prevalent hemodialysis versus peritoneal dialysis patients in CROWNWeb data, May 2016: (a) percentage of patients meeting clinical care guidelines for dialysis adequacy; (b) percent distribution of Hgb levels; (c) percentage of patients with serum calcium >10.2 mg/dL; (d) percent distribution of serum albumin levels.

(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

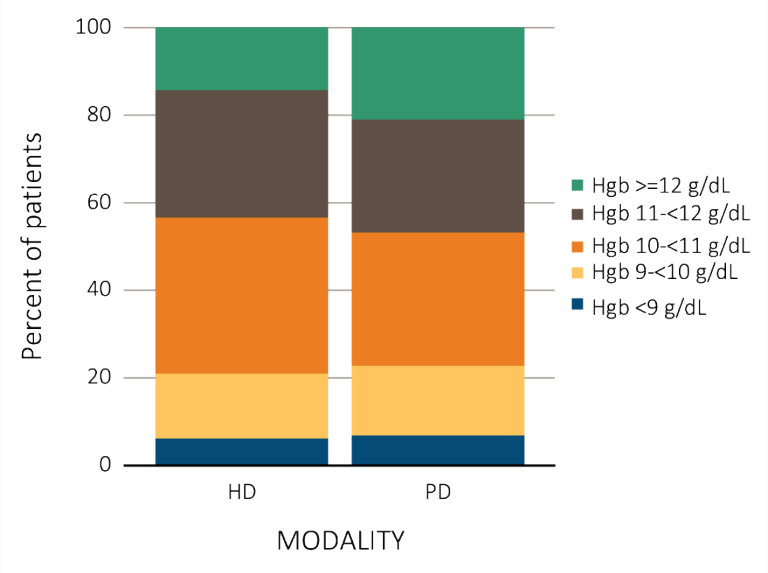
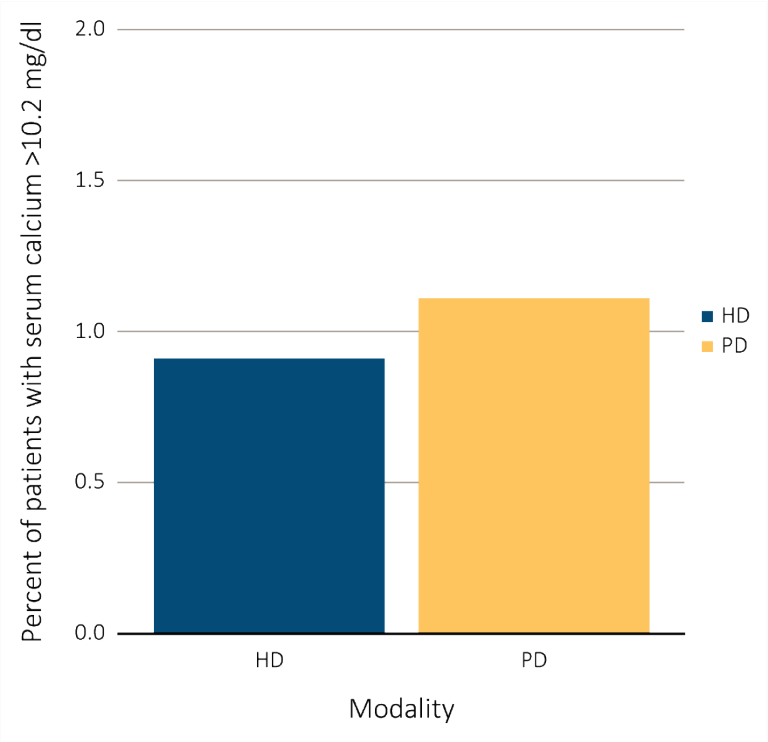


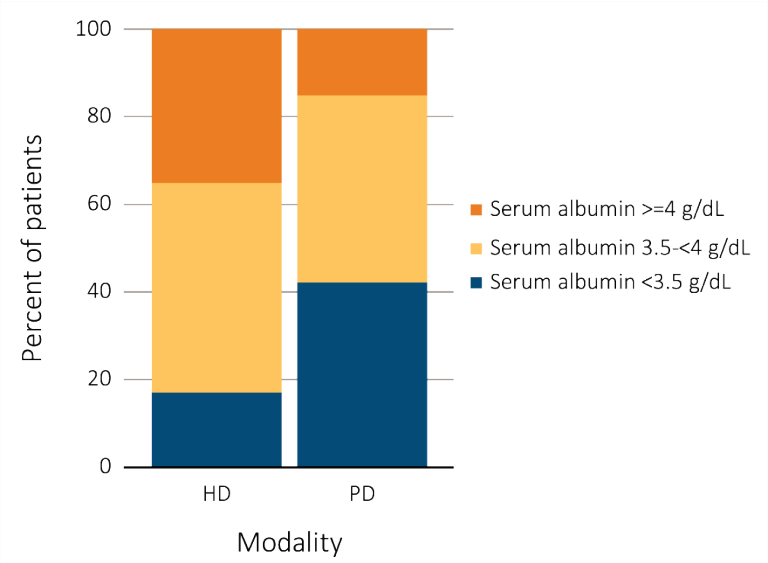
Figure 2.1 continued on next page.

vol 2 Figure 2.1 ESRD clinical indicator levels among prevalent hemodialysis versus peritoneal dialysis patients in CROWNWeb data, May 2016: (a) percentage of patients meeting clinical care guidelines for dialysis adequacy; (b) percent distribution of Hgb levels; (c) percentage of patients with serum calcium >10.2 mg/dL; (d) percent distribution of serum albumin levels *(continued)*

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



(d) Percent distribution of serum albumin 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 May 2016, restricted to patients as follows: (a) dialysis patients initiating treatment for ESRD at least 1 year prior to May 1, 2016, and who were alive through May 31, 2016; (b) dialysis patients initiating treatment for ESRD at least 90 days prior to May 1, 2016, who were ≥18 years old as of May 1, 2016, and who were alive through May 31, 2016; (c) hemodialysis and peritoneal dialysis patients initiating treatment for ESRD at least 90 days prior to May 1, 2016, who were ≥18 years old as of May 1, 2016, and who were alive through May 31, 2016; and (d) dialysis patients initiating treatment for ESRD at least 90 days prior to May 1, 2016, who were >=18 years old as of May 1, 2016, and who were alive through May 31, 2016. 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

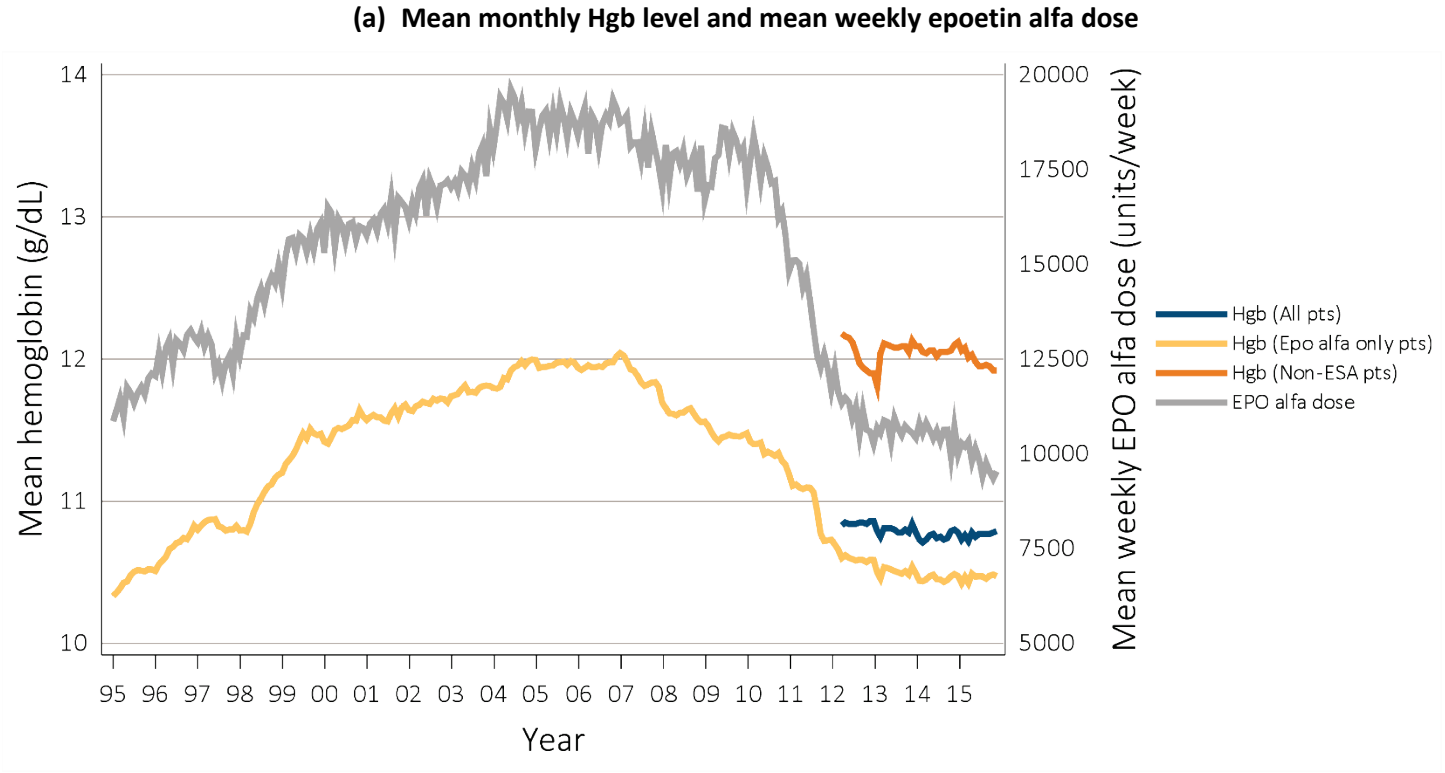
In this section, we describe long-term trends in Hgb levels, ESA use, ESA dose, IV iron use, IV iron dose, levels of iron stores, and red blood cell transfusion rates. We report analyses of CMS claims data by dialysis modality through 2015. Monthly mean IV iron doses are now provided for years 2005 to 2015. Prior to 2012, to meet CMS billing requirements, dialysis providers only reported Hgb values when filing a claim for patients who received an ESA during the given month. Consequently, Hgb values based on CMS claims data prior to 2012 were restricted to ESA-treated patients. Since April 2012, CMS required reporting of Hgb values for all patients, regardless of whether they received an ESA. This allows comparisons of Hgb values for ESA-treated patients to non-ESA treated patients, and to *all* patients.

Hgb Levels, ESA Use and Dose in Hemodialysis Patients

CMS data indicate that mean Hgb levels in ESA-treated HD patients have declined substantially since their 2007 peak near 12.0 g/dL (Figure 2.2.a). During 2011, mean Hgb level declined by 0.5 g/dL—from 11.2 g/dL to 10.7 g/dL. Since then, among ESA-treated HD patients on dialysis ≥90 days, Hgb levels have continued to slowly decline to a mean monthly level of 10.5 g/dL in 2015. Mean monthly Hgb values in 2015 were 10.8 g/dL for all HD patients on dialysis ≥90 days and 12.0 g/dL for non-ESA treated patients. Similarly, analyses of CROWNWeb data indicated a mean Hgb level of 10.8 g/dL for all HD patients in May 2015.

In 2015, 80%-83% of HD patients on dialysis for ≥90 days had a claim for ESA use during any single month (Figure 2.2.d). From December 2014 to December 2015, there was a large shift in the type of ESA prescribed to Medicare patients. In December 2014, 77.4% and 5% of patients were prescribed EPO alfa and darbepoetin, but by December 2015, 42.6%, 14.0%, and 20.5% were prescribed EPO alfa, darbepoetin, and PEG-EPO. Between December 2006 and December 2015, mean weekly EPO alfa doses (averaged over a month) declined by nearly 50% in HD patients. The mean weekly EPO alfa dose (averaged monthly) declined slightly from 2014 to 2015. When calculated for the prevalent cross-section of HD patients on dialysis ≥90 days, the mean monthly dose in 2015 (averaged across 12 months) indicated an average weekly EPO alfa dose of 9,849 ± 99.3 units.

vol 2 Figure 2.2 Anemia measures among adult hemodialysis patients on dialysis ≥90 days: (a) mean monthly Hgb level and mean weekly EPO alfa dose (averaged over a month), (b) mean monthly Hgb level and mean monthly darbepoetin dose, (c) mean monthly Hgb level and mean monthly PEG-EPO beta dose, and (d) percent ESA use monthly, Medicare claims, 1995-2015



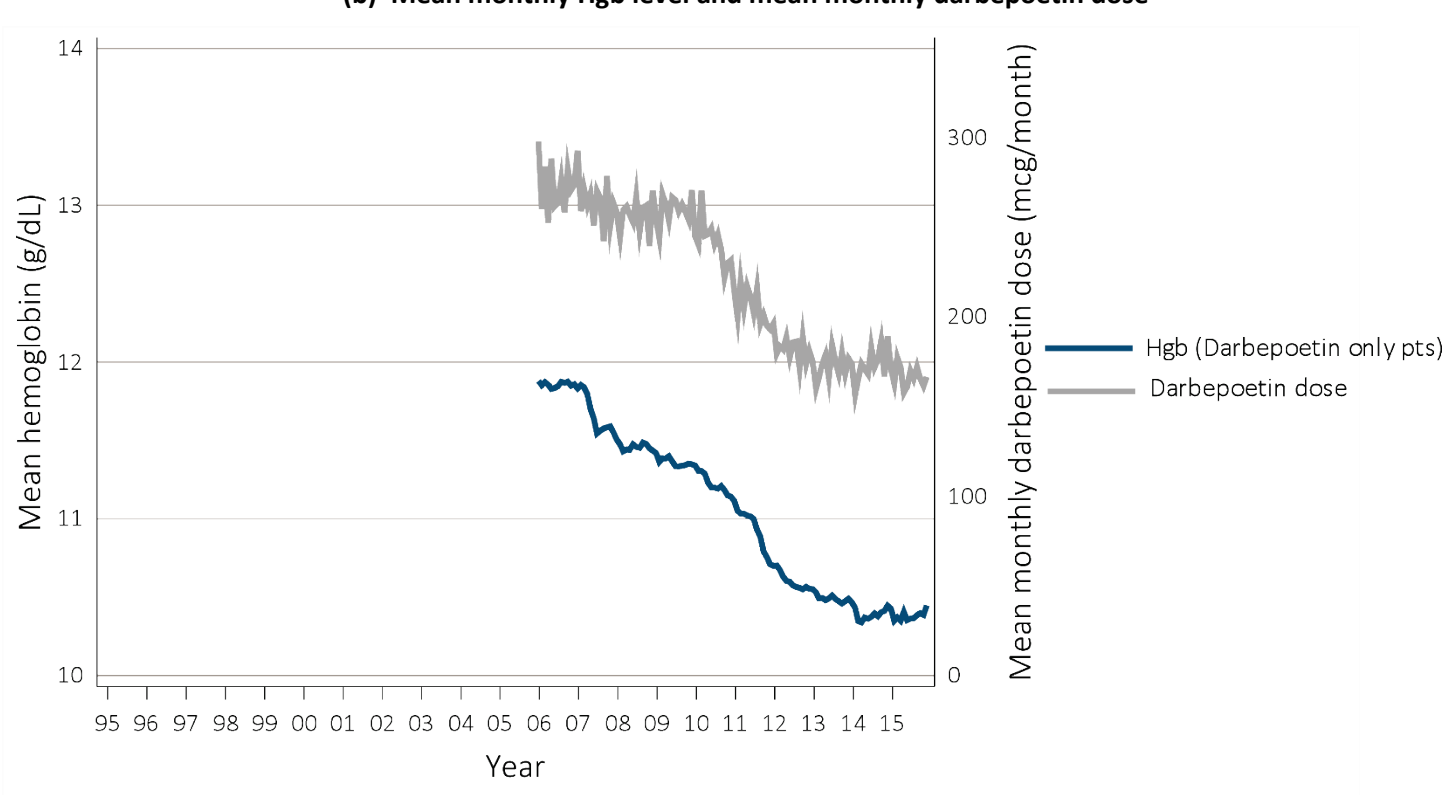
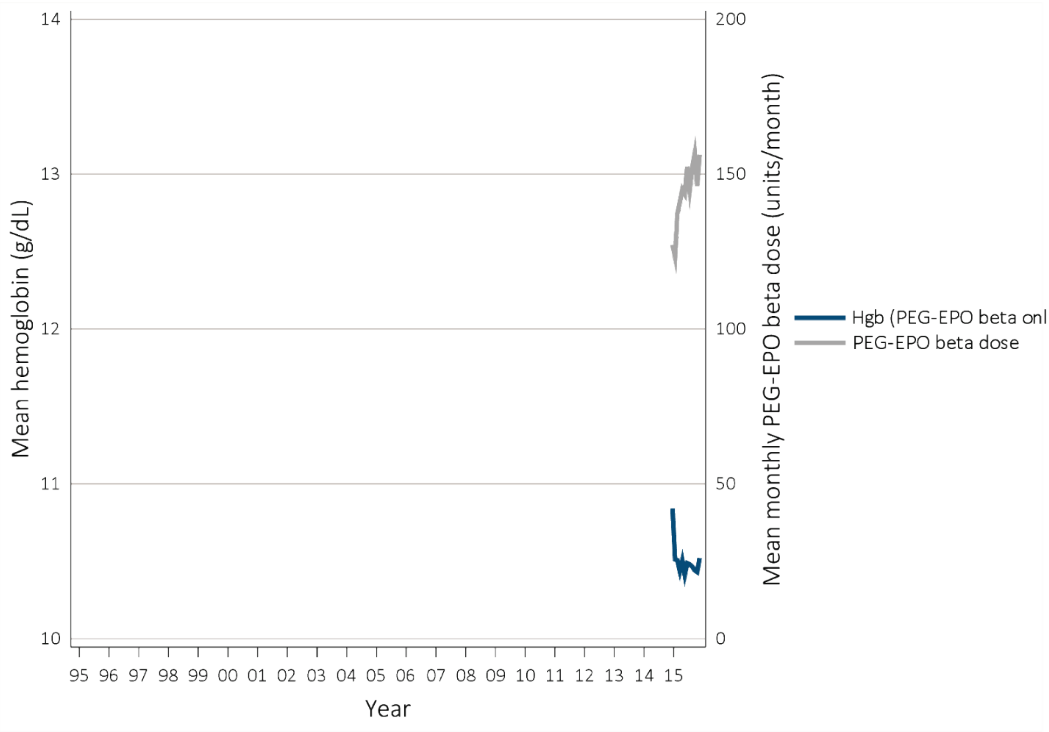


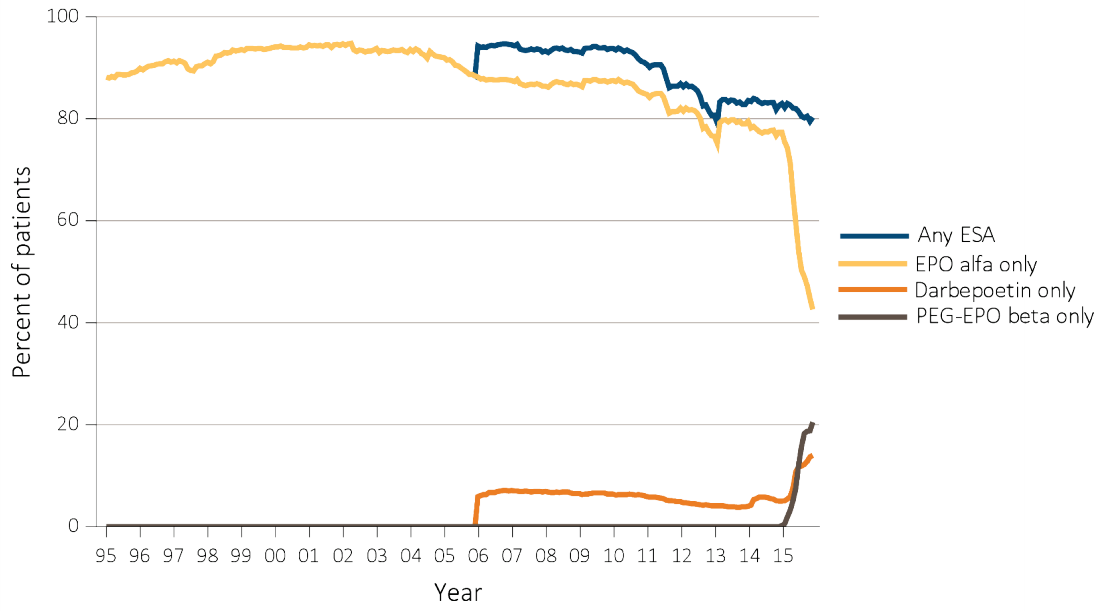
Figure 2.2 continued on next page.

vol 2 Figure 2.2 Anemia measures among adult hemodialysis patients on dialysis ≥90 days: (a) mean monthly Hgb level and mean weekly EPO alfa dose (averaged over a month), (b) mean monthly Hgb level and mean monthly darbepoetin dose, (c) mean monthly Hgb level and mean monthly PEG-EPO beta dose, and (d) percent ESA use monthly, Medicare claims, 1995-2015 *(continued)*

(c) Mean monthly Hgb level and mean monthly PEG-EPO beta dose



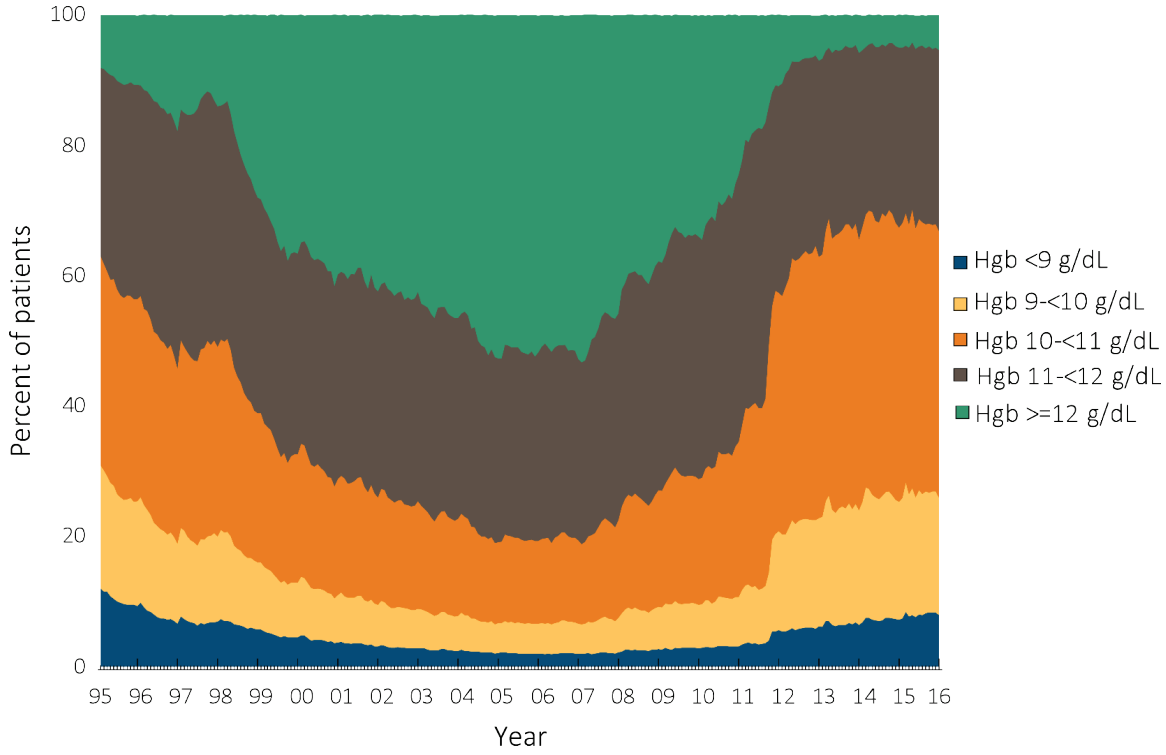
(d) Percent monthly ESA use



Data Source: Special analyses, USRDS ESRD Database. Mean monthly Hgb level among (a)EPO alfa- (b)darbepoetin (c)PEG-EPO beta patients on dialysis ≥ 90 days (1995-2015) or (a) mean monthly Hgb level among all adult hemodialysis patients (April 2012 to December 2015 only) who, within the given month had a Hgb claim (only 1st reported Hgb value in a month were used) and were on dialysis ≥ 90 days; analyses were restricted to patients ≥ 18 years old and who had been on dialysis ≥ 90 days at the start of the month. Average weekly (EPO alfa, Figure 2.2.a) or monthly (darbepoetin and PEG-EPO beta, Figures 2.2.b and c) doses are shown for hemodialysis patients who within a given month had a corresponding ESA claim. EPO alfa dose is expressed as mean EPO alfa units per week averaged over all of a patient's EPO alfa claims w/in a given month. Darbepoetin and PEG-EPO beta dose are expressed as mean units per month over all of a patient's corresponding Darbepoetin or PEG-EPO beta claims within a given month; (d) Monthly ESA use in all hemodialysis patients who were ≥ 18 years and on dialysis ≥ 90 days. Abbreviations: EPO alfa, erythropoietin alfa; PEG-EPO beta, pegylated erythropoetin beta; ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

Between 2007 and 2015, a large shift occurred in the percentage of ESA-treated adult HD patients in the highest versus lowest categories of Hgb level (Figure 2.3). Among ESA-treated patients on dialysis ≥90 days, the percentage with Hgb <10 g/dL increased from 7% in 2007 to 26% in 2015, while the percentage with Hgb ≥12 g/dL declined 10-fold from 48.5% in 2007 to 4.9% in 2015. For the group of all HD patients on dialysis ≥90 days in December 2015, 7% had Hgb <9 g/dL, 15% had Hgb of 9 to <10 g/dL, 64% had Hgb between 10-12 g/dL, and 14% had Hgb ≥12 g/dL.

vol 2 Figure 2.3 Distribution of monthly Hgb levels in ESA-treated adult hemodialysis patients on dialysis ≥90 days, Medicare claims, 1995-2015



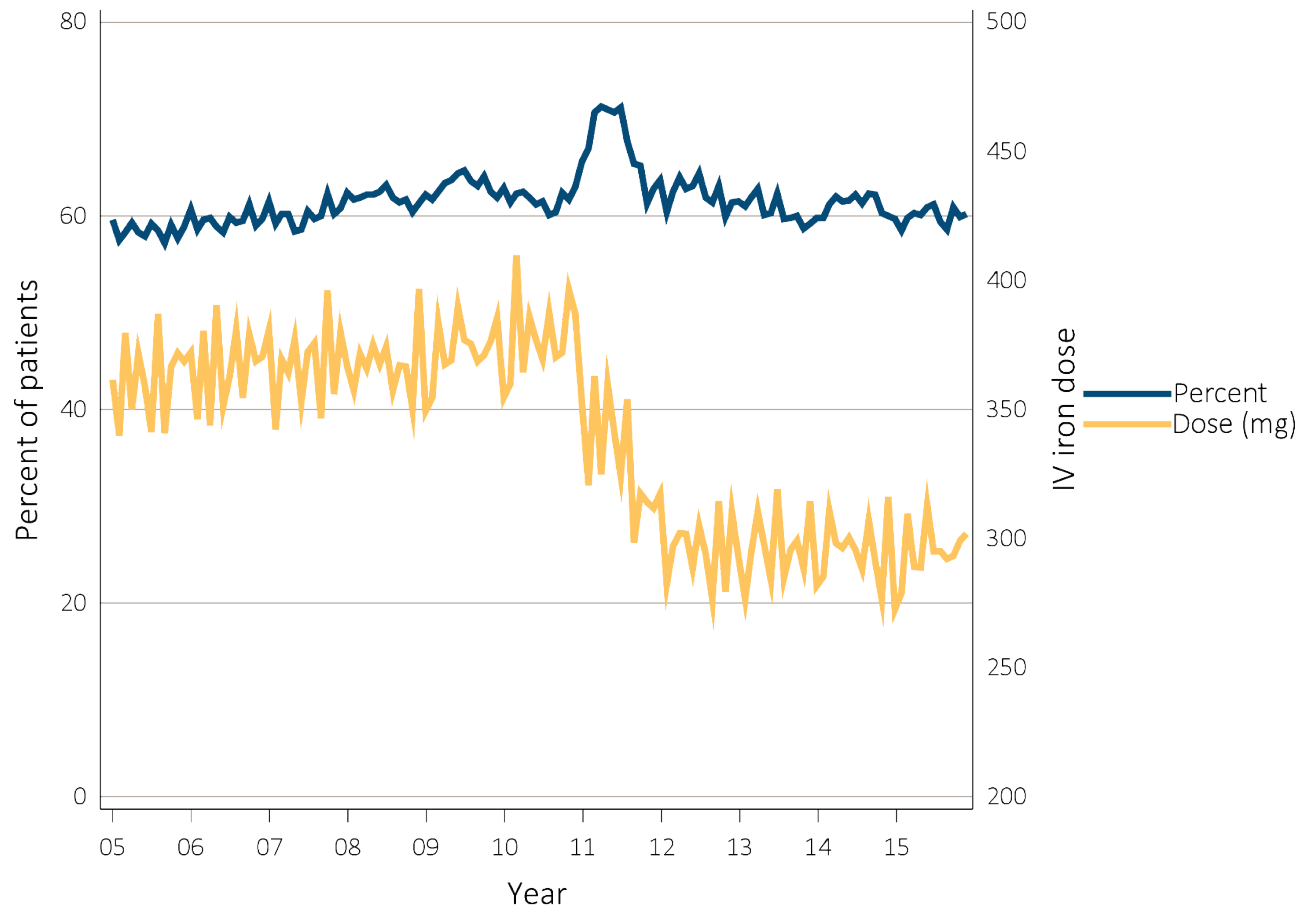
Data Source: Special analyses, USRDS ESRD Database. Distribution of monthly Hgb levels among hemodialysis patients within a given month who had claims for Hgb level and ESA use, were on dialysis ≥90 days and ≥18 years old at the start of the month. Abbreviations: ESA, erythropoiesis-stimulating agents;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

IV Iron Use, IV Iron Dose, and Measures of Iron Stores in Hemodialysis Patients

Trends in IV iron use for HD patients from 2005 to 2015 are shown in Figure 2.4. 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 introduction of the CMS bundled Prospective Payment System (PPS) for dialysis services that began in January 2011. However, since July 2011, IV iron use declined steadily to 60.2% by December 2015, similar to rates prior to the start of the bundled PPS in 2011.

The trend in mean monthly IV iron dose is provided for 2005 through 2015, as calculated among patients with an IV iron dose claim during the month. The average monthly dose rose from 362 mg in 2005 to 378 mg in 2010. However, coincident with the 2011 implementation of the PPS, mean monthly IV iron doses declined from 332 mg in 2011 to 297 mg in 2012, 296 mg in 2013 and 2014, and 294 mg in 2015. Thus, since 2011, both IV iron use and the average monthly IV iron dose have declined among HD patients in the U.S.

vol 2 Figure 2.4 Monthly percent IV iron use and mean monthly IV iron dose in adult hemodialysis patients on dialysis ≥90 days, Medicare claims, 2005-2015

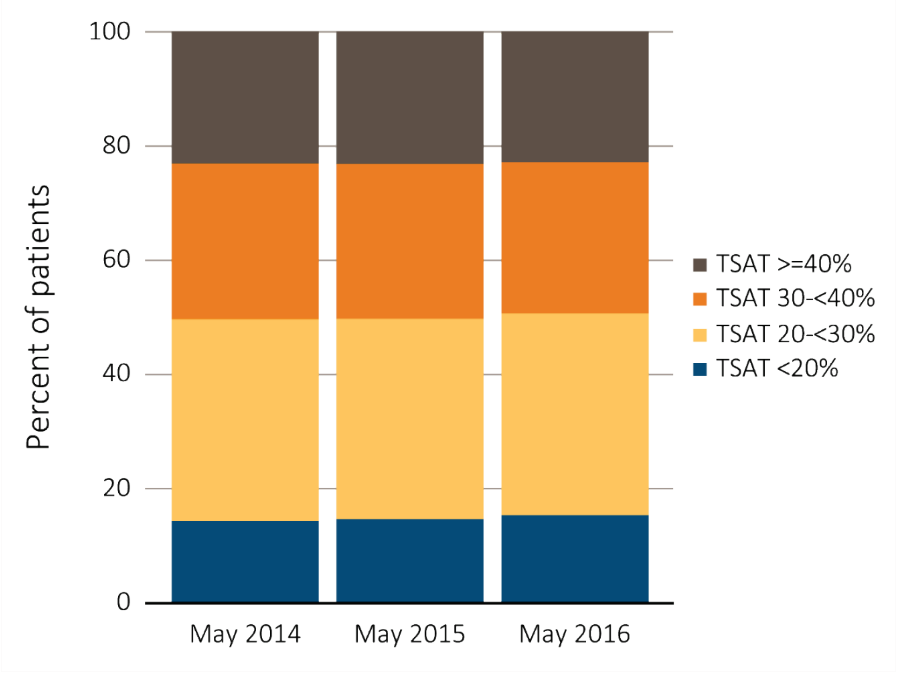


Data Source: Special analyses, USRDS ESRD Database. Monthly IV iron use is among hemodialysis patients on dialysis ≥90 days and ≥18 years old at the start of the given month. Mean IV iron dose was calculated as the average number of mg of IV iron given to all such patients during a month, among patients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

U.S. dialysis units now report iron store measures, TSAT, and serum ferritin as part of CROWNWeb data collection. Reporting of these measures to CROWNWeb has increased over time. For example, serum ferritin was reported for 380,548 HD patients in 2014 versus 421,272 HD patients in 2016. Typically, reporting of TSAT levels in HD patients has been 20%-30% lower than for serum ferritin levels. TSAT was reported for 421,272 patients in 2016, compared to only 380,548 patients in 2014. Due to the changes in facility data reporting over time, interpret the trends noted below in this context.

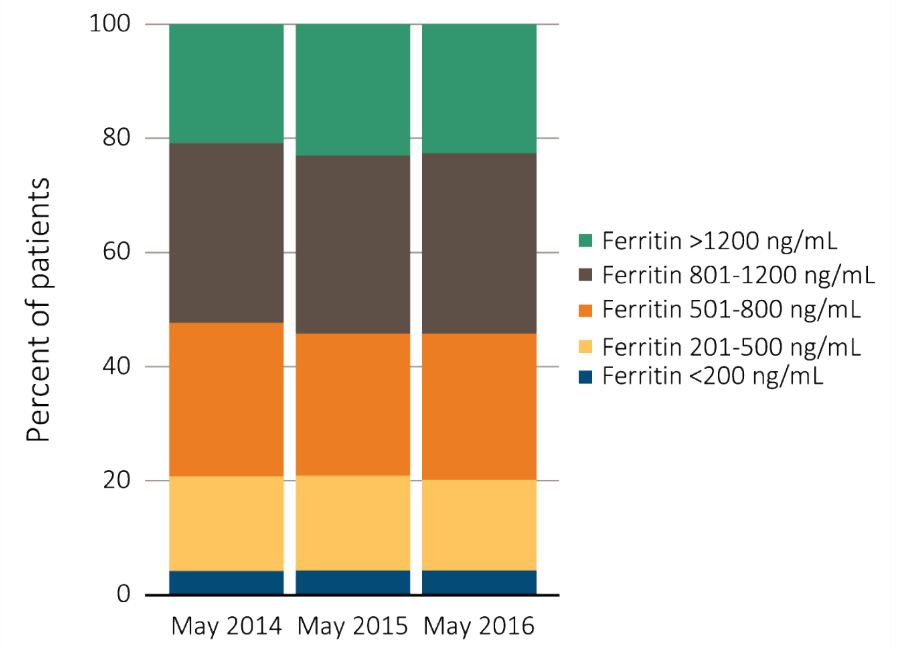
The distributions of TSAT (Figure 2.5) and serum ferritin (Figure 2.6) levels among HD patients on dialysis ≥90 days did not differ appreciably during 2014-2016. Averaged across this period, 15.4% of patients had a TSAT <20%, with 35.2%, 27.0%, and 22.4% of patients having TSAT levels of 20% to <30%, 30% to <40%, and ≥40%. The percentage of patients with TSAT <20% remained relatively stable, varying from 15.0% to 16.0%. During 2014-2016, on average 4.9% of patients had serum ferritin ≤200 ng/mL, with 16.4%, 25.8%, 31.4%, and 21.5% of patients having serum ferritin levels of 201-500, 501-800, 801-1200, and >1200 ng/mL. The mean serum ferritin level increased slightly, from 877 ng/mL in May 2014 to 896 in May 2016.

vol 2 Figure 2.5 Distribution of TSAT levels in adult hemodialysis patients on dialysis for at least 90 days, CROWNWeb data, May 2014, 2015, and 2016



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for May 2014, May 2015 and May 2016. Dialysis patients on treatment for ESRD at least 90 days before the time of measurement of TSAT level for that year, ≥18 years old as of May 1 of that year and who were alive through May 31 of that year. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; TSAT, transferrin saturation.

vol 2 Figure 2.6 Distribution of the most recent value of serum ferritin level taken between March and May in adult hemodialysis patients on dialysis for at least 90 days, CROWNWeb data, 2013-2016



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2014, 2015 and 2016. Dialysis patients initiating treatment for ESRD at least 90 days before the time of measurement of serum ferritin for that year, ≥18 years old as of May 1 of that year and who were alive through May 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 Medicare HD patients, by year from 2011 through 2015, is shown in Figure 2.7.a. The results represent the entire adult HD patient population (≥18 years old) receiving at least one HD treatment during a given year. However, because some individuals did not receive HD therapy for the entire year, interpretation should be made in this light. In 2011 23.2% of HD patients received ≥1 red blood cell transfusion. This decreased to approximately 22.8% of patients in 2013 and further to 19.0% in 2015. Across this five-year period, typically 12%-14% of patients received one red blood cell transfusion per year, 4%-5% received two, 1.5%-2% received three, and 2%-3% received four or more red blood cell transfusions per year.

Trends from 2010-2015 in the percentage of HD patients with one or more red blood cell transfusions within a month are shown in Figure 2.7.b. Overall, the rate gradually declined from 3.6% in the first quarter of 2013 to 2.7% by the third quarter of 2015. Red blood cell transfusion rates were approximately 2.5 fold higher for patients on dialysis <90 days at the start of the month, compared with patients on dialysis ≥90 days. From January to November 2015, an average of 2.9% of White patients had one or more red blood cell transfusions in a month compared to 2.8% of African American/Black patients and 2.2% of those of Other or Unknown race. Note that since these differences were small, only the overall trend line is shown in Figure 2.7.b.

vol 2 Figure 2.7 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, overall and by vintage, from Medicare claims, 2011-2015

(a) Percent of patients, by number of red blood cell transfusions received in a year

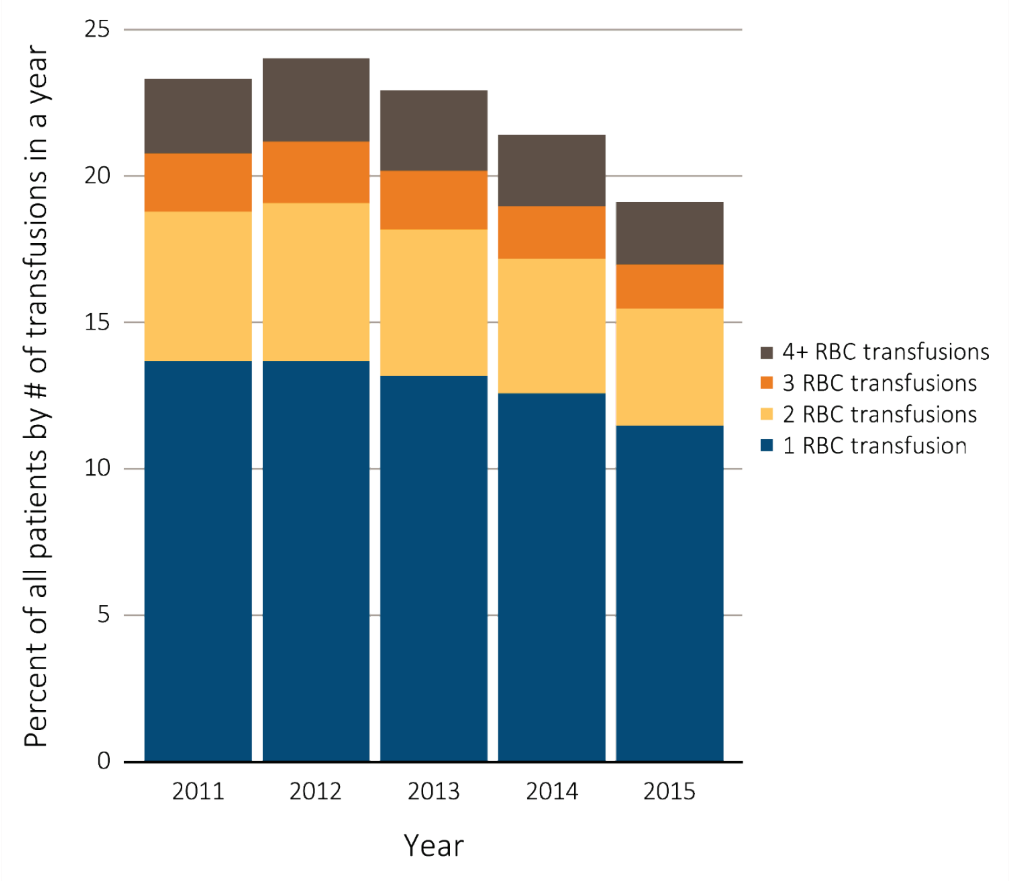
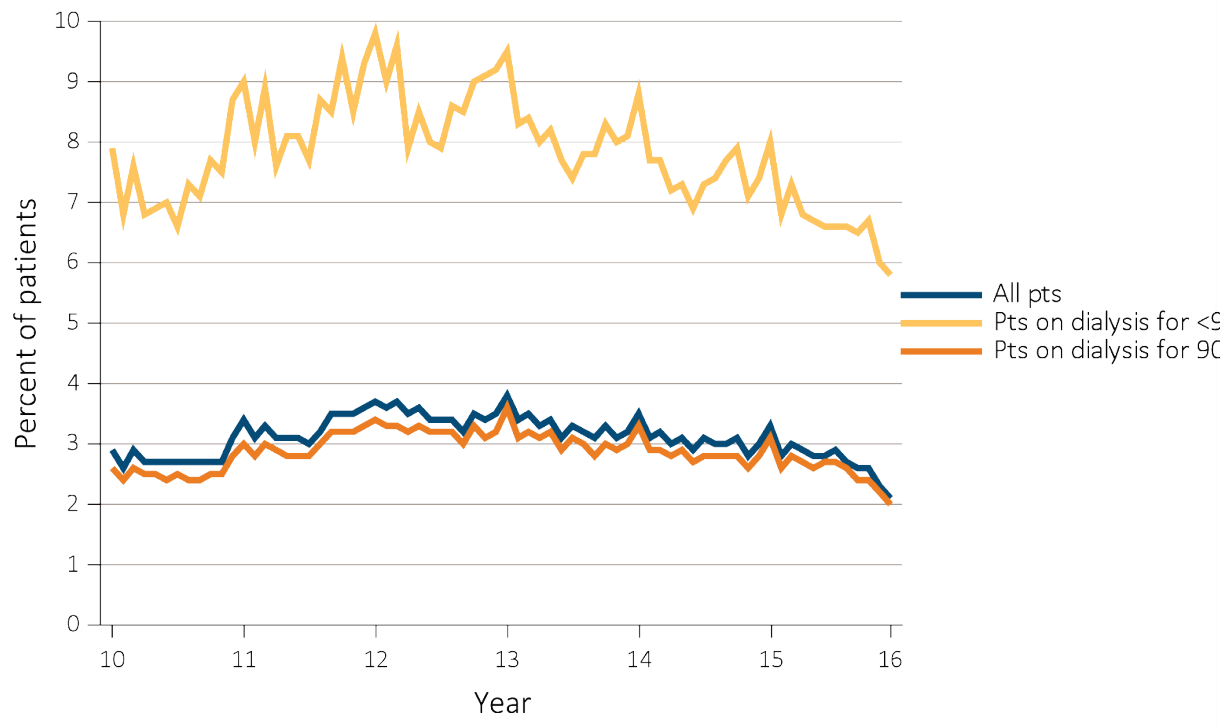


Figure 2.7 continued on next page.

vol 2 Figure 2.7 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, overall and by vintage, from Medicare claims, 2011-2015 (*continued)*

(b) Percent of all patients, patients on dialysis <90 days, or patients on dialysis ≥90 days, who had one or more claims for a red blood cell transfusion in a month



Data Source: Special analyses, USRDS ESRD Database. The percentage of hemodialysis patients ≥18 years old at the start of the month with ≥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. Additional analysis of RBC transfusion claims completed for patients on dialysis for < 90 days or ≥ 90 days. Abbreviation: RBC, red blood cell.

Hgb Levels, ESA Use, and Dose in Peritoneal Dialysis Patients

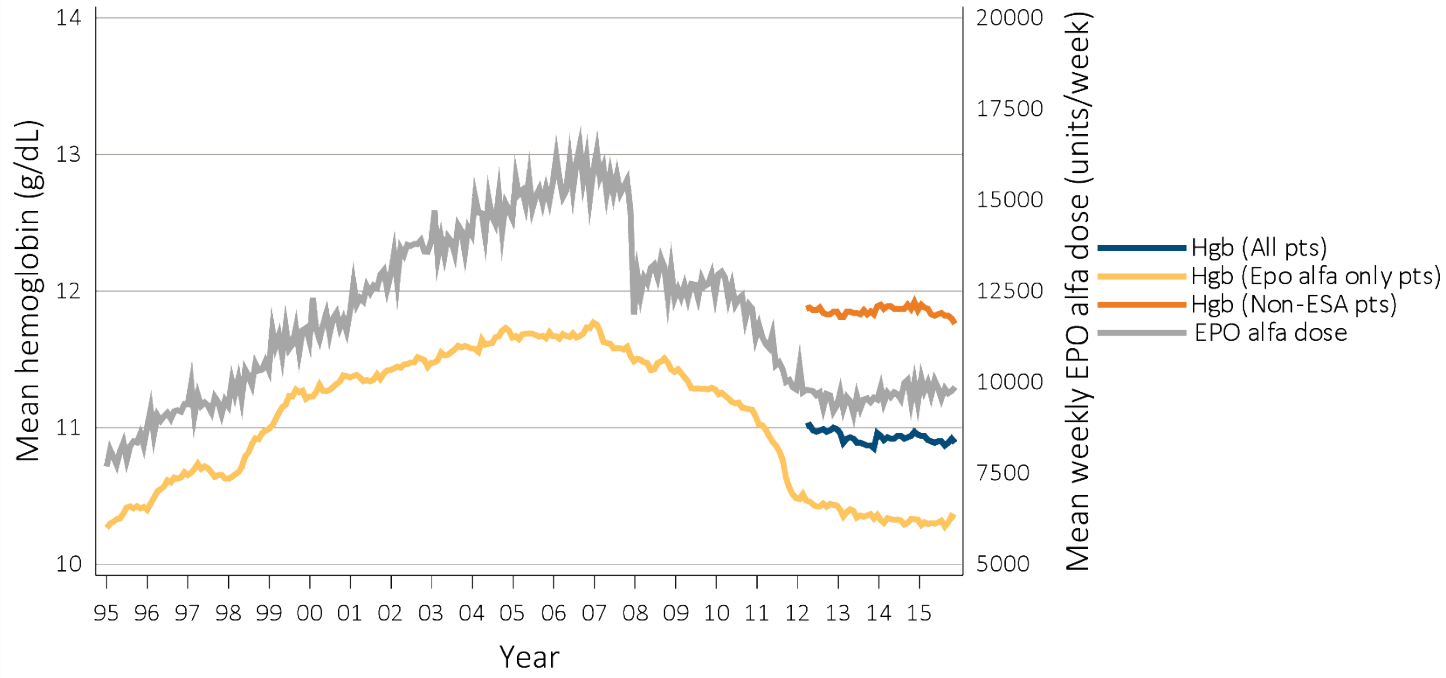
Claims data indicate that mean Hgb levels have declined substantially in ESA-treated PD patients since peaking near 11.8 g/dL in January 2007 (Figure 2.8.a). During 2011, patients' mean Hgb levels declined by 0.6 g/dL, from 11.1 g/dL to 10.5 g/dL. This was a larger decline, with a lower achieved mean Hgb level than that seen during 2011. Since then, levels have continued to decline to a mean monthly Hgb of 10.3 g/dL in 2015 among ESA-treated PD patients on dialysis ≥90 days. In contrast, in 2015, mean monthly Hgb values of 10.9 g/dL were seen for *all* PD patients on dialysis ≥90 days, and 11.8 g/dL for non-ESA treated patients. Analyses of CROWNWeb data have indicated a similar mean Hgb level of 10.9 g/dL for *all* PD patients in May 2016.

The percentage of PD patients on dialysis ≥90 days who had an ESA claim during any single month was stable during 2015, at 61%-64% (Figure 2.8.b). From December 2014 to December 2015, there was a large shift in the type of ESA prescribed to Medicare patients, with 57.1% and 4.5% prescribed EPO-alfa and darbepoetin in December 2014, to 40.4%, 9.2%, and 9.2% prescribed EPO alfa, darbeopoetin, and PEG-EPO beta in December 2015.

Among PD patients on dialysis ≥90 days, mean weekly EPO alfa dose was on average 0.8% higher in 2015 than in 2014, but was relatively stable throughout 2015. When calculated for the prevalent cross-section of PD patients on dialysis ≥90 days in each month of 2015, and then averaged across the 12 months in 2014, the mean weekly EPO alfa dose was 9,795 ± 57 units per week in 2015. The rapid, large decline (Figure 2.8.a) and rise in percent ESA use seen at the start of 2008 (Figure 2.8.b) may be related to a change in the reporting codes for EPO alfa-related claims submission at that time.

vol 2 Figure 2.8 Anemia measures among adult peritoneal dialysis patients on dialysis ≥90 days: (a) mean monthly Hgb level and mean weekly EPO alfa dose (averaged over a month), (b) mean monthly Hgb and mean monthly darbepoetin dose, and (c) percent ESA use monthly, Medicare claims, 1995-2015

(a) Mean monthly Hgb level and mean weekly epoetin alfa dose



(b) Mean monthly Hgb level and mean monthly darbepoetin dose

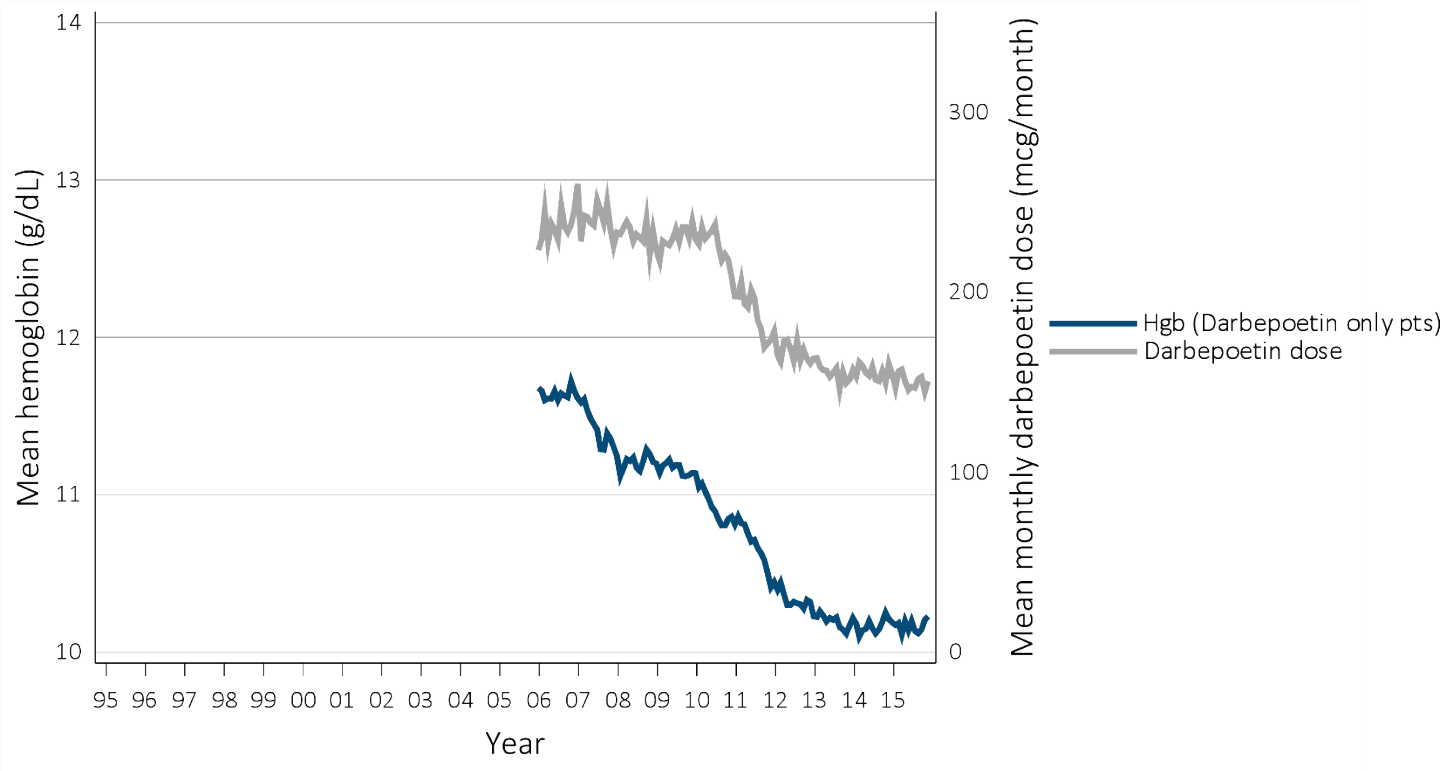
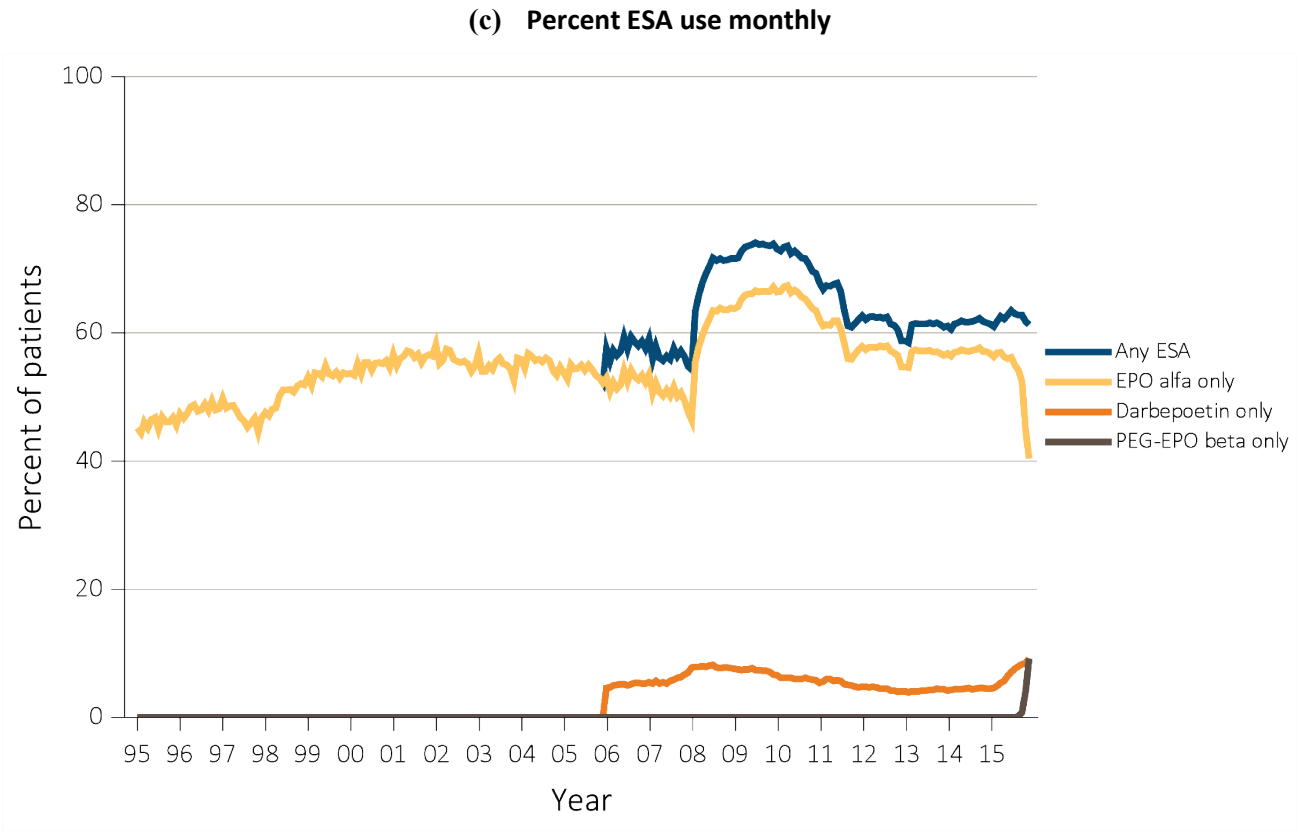


Figure 2.8 continued on next page.

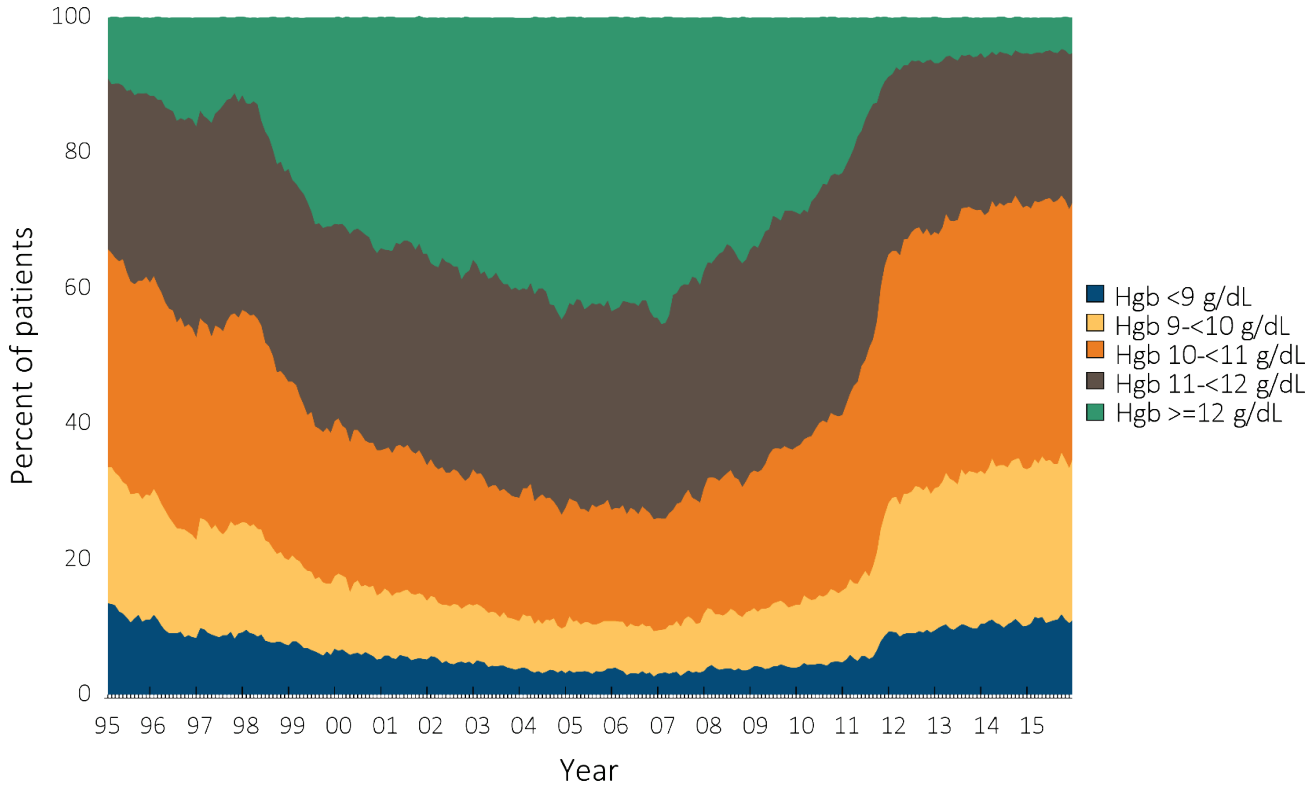
vol 2 Figure 2.8 Anemia measures among adult peritoneal dialysis patients on dialysis ≥90 days: (a) mean monthly Hgb level and mean weekly EPO alfa dose (averaged over a month), (b) mean monthly Hgb and mean monthly darbepoetin dose, and (c) percent ESA use monthly, Medicare claims, 1995-2015 *(continued)*



Data Source: Special analyses, USRDS ESRD Database. Mean monthly Hgb level among (a) EPO alfa- and (b) darbepoetin on dialysis ≥ 90 days (1995-2015) or (b) mean monthly Hgb level among all adult peritoneal dialysis patients (April 2012 to December 2015 only) who, within the given month, had a Hgb claim (only 1st reported Hgb value in a month were used) and were on dialysis ≥ 90 days; analyses were restricted to patients ≥ 18 years old and who had been on dialysis ≥ 90 days at the start of the month. Average weekly (EPO alfa, Figure 2.2.a) or monthly (darbepoetin, Figure 2.2.b) doses are shown for peritoneal dialysis patients who within a given month had a corresponding ESA claim. EPO alfa dose is expressed as mean EPO alfa units per week averaged over all a patient's EPO alfa claims within a given month. Darbepoetin dose is expressed as mean units per month over all of a patient's corresponding Darbepoetin claims within a given month. PEG-EPO beta dose and Hgb Figure excluded due to small numbers. (c) Monthly ESA use (EPO alfa, Darbepoetin, or PEG-EPO beta) in all hemodialysis patients who were ≥ 18 years and on dialysis ≥ 90 days. Abbreviations: EPO alfa, erythropoietin alfa; PEG-EPO beta, pegylated erythropoetin beta; ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

Between 2007 and 2014, a large shift occurred in the percentage of patients in the highest versus lowest Hgb concentration categories (Figure 2.9). Among ESA-treated adult patients on PD ≥90 days, the percentage with Hgb <10 g/dL increased from 11% in 2007 to 35% in 2015, while the percentage with Hgb ≥12 g/dL declined from 37.5% in December 2007 to 5.3% in December 2015. Among all PD patients on dialysis ≥90 days in December 2015, 7.6% had Hgb <9 g/dL, 16.7% had Hgb of 9 to <10 g/dL, 55.1% had Hgb between 10-12 g/dL, and 20.5% had Hgb ≥12 g/dL.

vol 2 Figure 2.9 Distribution of monthly Hgb levels in ESA-treated adult peritoneal dialysis patients on dialysis ≥90 days, Medicare claims, 1995-2015

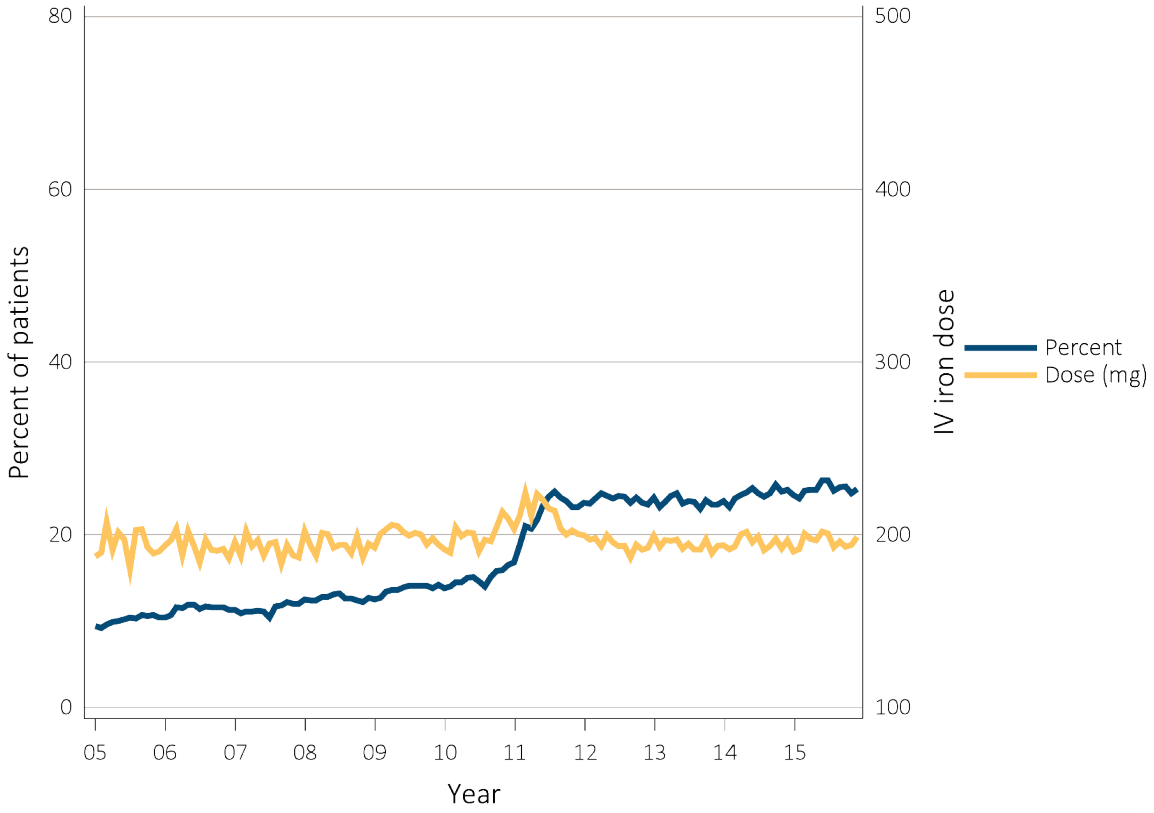


Data Source: Special analyses, USRDS ESRD Database. Distribution of Hgb levels among peritoneal dialysis patients within a given month who had claims for Hgb level and ESA use, were on dialysis ≥90 days and ≥18 years old at the start of the month. Abbreviations: ESA, erythropoiesis-stimulating agents;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

IV Iron Use, IV Iron Dose, and Measures of Iron Stores in Peritoneal Dialysis Patients

Trends in IV iron use by PD patients are shown from 2005 through 2015 (Figure 2.10). 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 prospective payment system (PPS) for dialysis services in January 2011. As of the final quarter of 2015, IV iron use among PD patients on dialysis ≥90 days remained higher, at 25.2%. The mean monthly IV iron dose rose steadily from 194 mg in 2005 to 211 mg in 2011. However, coincident with the 2011 implementation of the PPS, average mean monthly IV iron doses declined to 195-196 mg in years 2012-2015. Thus, since 2011, the rate of IV iron use in the U.S. has increased, while the average monthly IV iron dose among patients prescribed iron has declined.

vol 2 Figure 2.10 Monthly IV iron use and mean monthly IV iron dose in adult peritoneal dialysis patients on dialysis ≥90 days, Medicare claims, 2005-2015

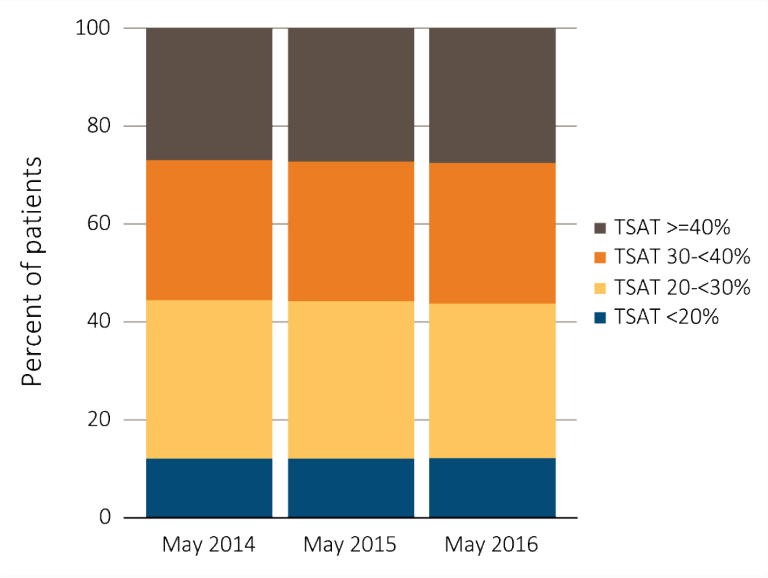


Data Source: Special analyses, USRDS ESRD Database. Monthly IV iron use is among peritoneal dialysis patients on dialysis ≥90 days and ≥18 years old at the start of the given month. Mean IV iron dose was calculated as the average number of mg of IV iron given to all such patients during a month, among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

As mentioned previously, reporting of iron store measures, TSAT, and serum ferritin has gradually increased over time. For example, when including the most recent value reported in the prior three months, serum ferritin was reported for 33,743 PD patients in 2014 versus 43,090 PD patients in 2016. TSAT was reported for 35,700 PD patients in 2014 compared to 44,153 PD patients in 2016.

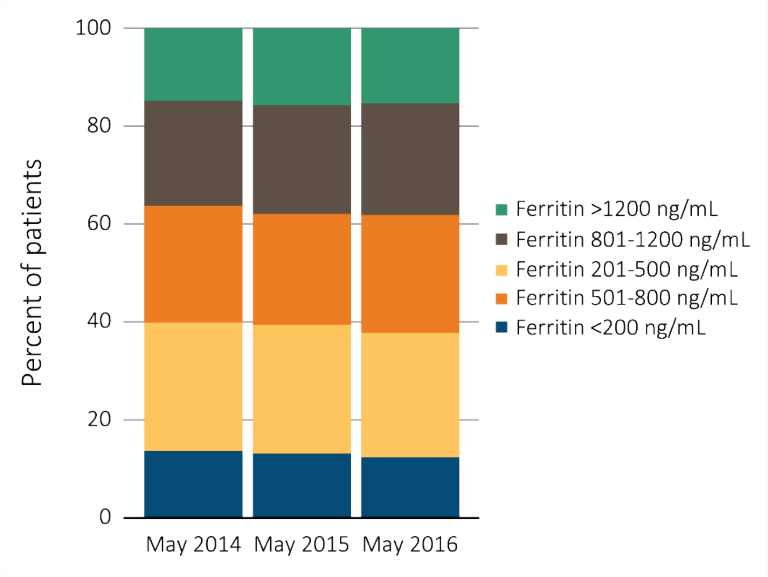
When interpreting the trends described below, it is helpful to bear in mind the changes in facility data reporting over time. Across the three mid-year cross-sections shown in Figures 2.11 and 2.12, the distribution of TSAT and serum ferritin levels among PD patients on dialysis ≥90 days did not differ appreciably. Averaged across the three years, 12.7% of patients had a TSAT<20%, with 32.1%, 28.6%, and 26.6% of patients having levels of 20% to <30%, 30% to <40%, and ≥40%. Across the 2014-2016 period, on average, 13.6% of patients had a serum ferritin ≤200 ng/mL, with 26.0%, 23.5%, 22.1%, and 14.7% of patients having levels of 201-500, 501-800, 801-1200, and >1200 ng/mL. The mean serum ferritin level increased slightly from 706 to 720 ng/mL during the May 2014 to May 2016 cross-section.

vol 2 Figure 2.11 Distribution of TSAT levels in adult peritoneal dialysis patients on dialysis for at least 90 days, CROWNWeb data, May 2014, 2015, and 2016



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2014, 2015 and 2016. Dialysis patients on treatment for ESRD at least 90 days at the time of measurement of TSAT level for that year, ≥18 years old as of May 1st of that year, and who were alive through May 31 of that year. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; TSAT, transferrin saturation.

vol 2 Figure 2.12 Distribution of the most recent serum ferritin level taken between March and May in adult peritoneal dialysis patients on dialysis for at least 90 days, CROWNWeb data, May 2014, 2015, and 2016



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2014, 2015 and 2016. Dialysis patients on treatment for ESRD at least 90 days at the time of measurement of serum ferritin for that year, ≥18 years old as of May 1 of that year, and who were alive through May 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

Red Blood Cell Transfusions in Peritoneal Dialysis Patients

Figure 2.13.a shows the distribution of the number of red blood cell transfusions received by PD patients from 2011 through 2015. The results are for those aged 18 years or older who received at least one PD treatment during a given year. However, because some individuals did not receive PD for the entire year, interpret results with this in mind.

In 2011, 22.6% of PD patients received one or more red blood cell transfusions. This increased to approximately 23% of patients in 2012, declined again to 21.7% in 2013, and to 19.8% of PD patients in 2014. In 2015, only 18% of PD patients received one or more red blood cell transfusions. Across this five-year period, typically 12%-13% of PD patients received one red blood cell transfusion per year, 4%-5% received two per year, 1.5%-2% received three, and 2%-3% received four or more.

Trends in the percentage of PD patients receiving one or more red blood cell transfusions within a month during 2010-2015 are shown in Figure 2.13.b. Overall the percent of PD patients receiving any red blood cell transfusions in a month has gradually declined from 3.3% in the first quarter of 2013 to 2.4% by the third quarter of 2015. When comparing red blood cell transfusion rates among incident versus prevalent PD patients, transfusion rates were only slightly higher for patients on PD <90 days at the start of the month compared with those on PD ≥90 days. From January to November 2015, on average 2.4% of White patients had one or more red blood cell transfusions in a month compared to 2.7% of Black patients and 2.0% of those of Other or Unknown race. Note that as these differences were small, only the overall trend line is shown in Figure 2.13.b.

vol 2 Figure 2.13 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 overall, within 90 days and after at least 90 days of first PD session, 2010-2015

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

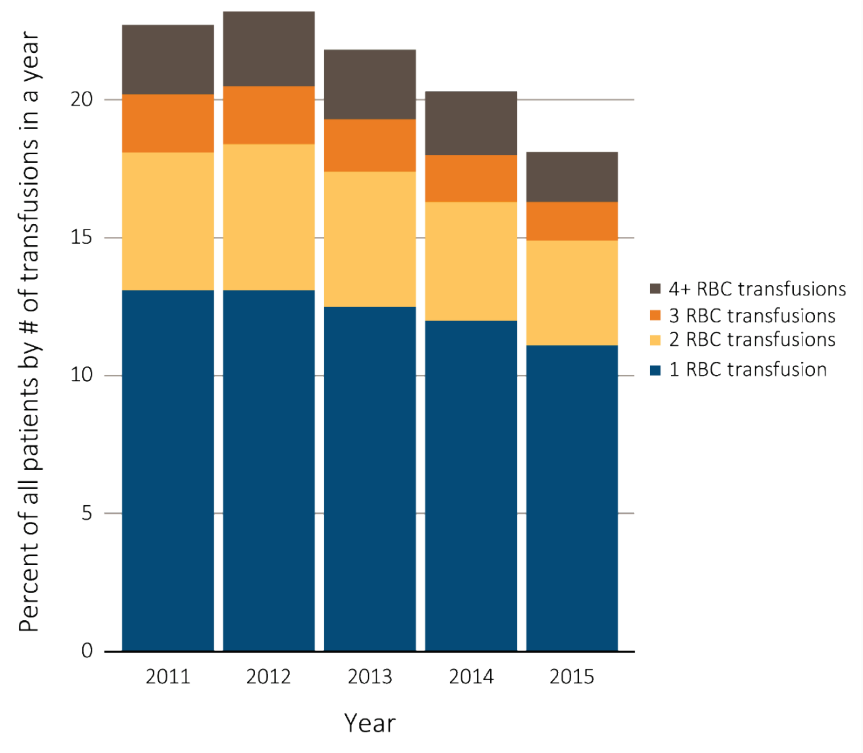
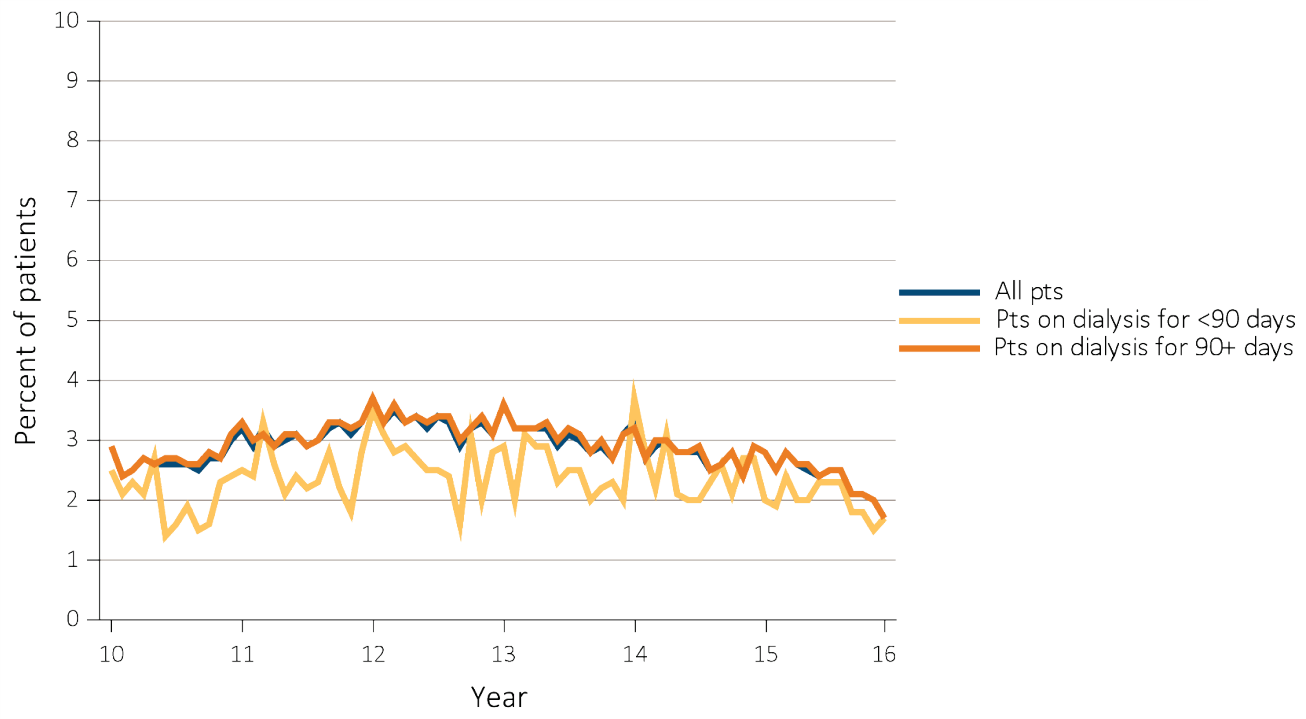


Figure 2.13 continued on next page.

vol 2 Figure 2.13 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 overall, within 90 days and after at least 90 days of first PD session, 2010-2015

(b) Percent of all patients, patients on dialysis <90 days, or patients on dialysis ≥ 90 days, who had ≥1 claim for a red blood cell transfusion in a month



Data Source: Special analyses, USRDS ESRD Database. The percentage of peritoneal dialysis patients with ≥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 ≥18 years old at the start of the month. Additional analysis of RBC transfusion claims completed for patients on dialysis for < 90 days or ≥ 90 days. Abbreviation: RBC, red blood cell.

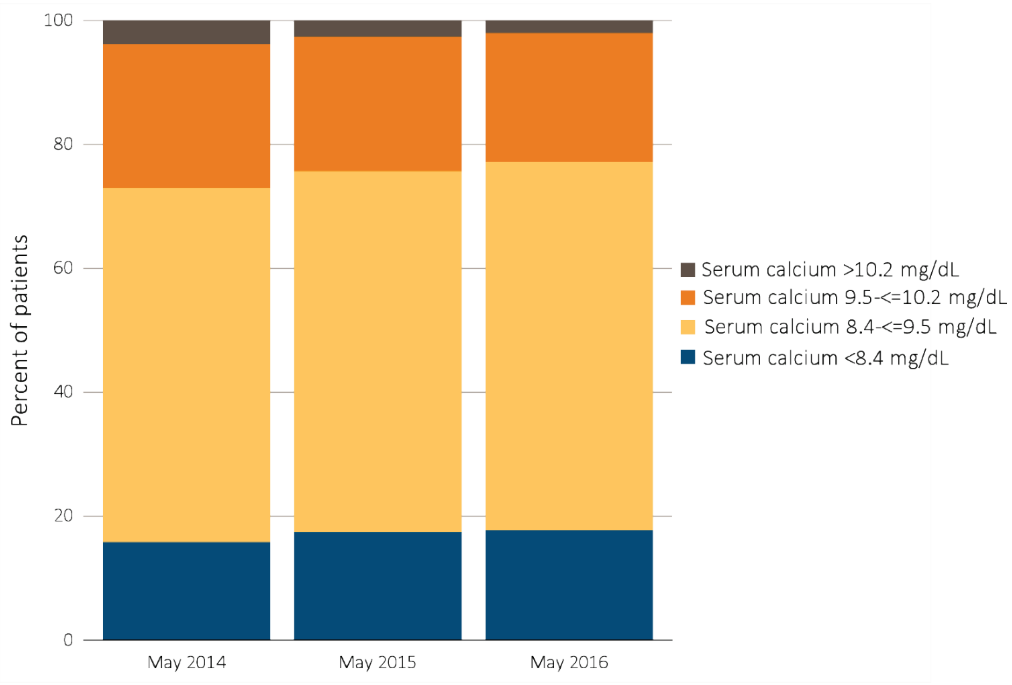
Mineral and Bone Disorders

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—major causes 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, it is also possible that they result from inappropriate treatment. Based on these observations, current Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guidelines (KDIGO, 2017: Chapter 4.1) suggest that chronic dialysis patients maintain serum calcium and phosphorus levels in the normal reference range.

Serum Calcium

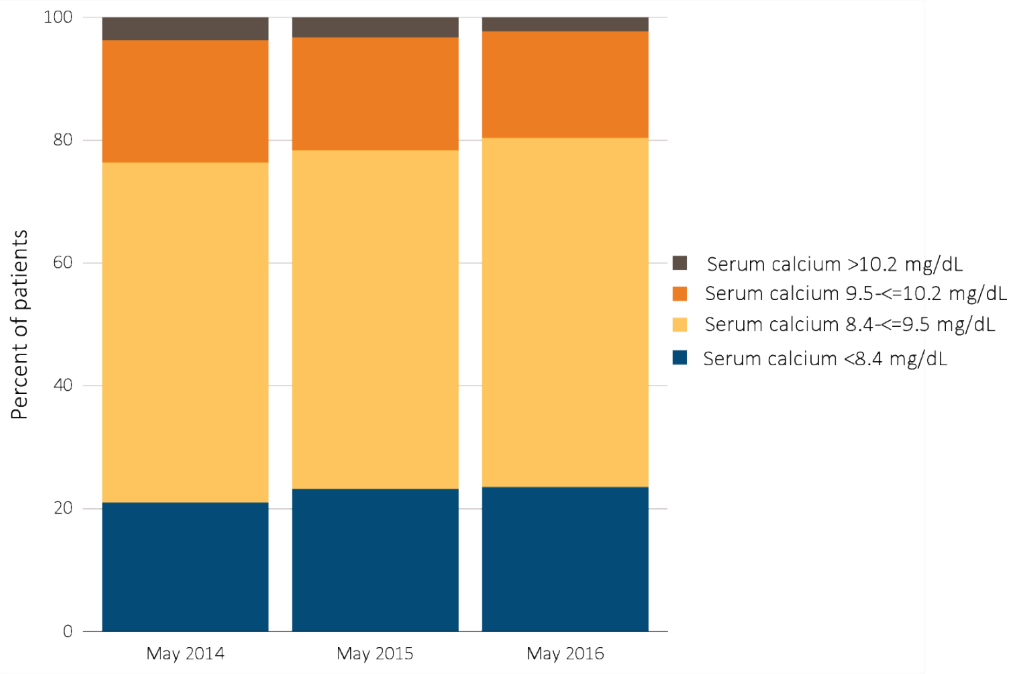
The distributions of serum calcium levels (based on the value in May of the indicated calendar year) among adult HD and PD patients are shown in Figures 2.14 and 2.15. Between 2014 and 2016, no substantial change was observed in serum calcium distribution. The majority of 2016 patients (HD: 59.5%, PD: 56.9%) had calcium levels within the usual normal reference range (8.4-9.5 mg/dL), while a very small percentage (HD: 1.7%, PD: 1.9%) had serum 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 May 2016 prevalence of very low calcium levels (<8.4 mg/dL) was higher in patients on PD, at 23.9%, than for HD at 18.1%, likely due to differences in serum albumin levels related to dialytic treatment.

vol 2 Figure 2.14 Distribution of serum calcium levels in adult hemodialysis patients on dialysis for at least 1 year, CROWNWeb data, May 2014, 2015, and 2016



Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2014, 2015 and 2016. 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 May 1 of that year and who were alive through May 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

vol 2 Figure 2.15 Distribution of serum calcium levels in adult peritoneal dialysis patients on dialysis for at least 1 year, CROWNWeb data, May 2014, 2015, and 2016

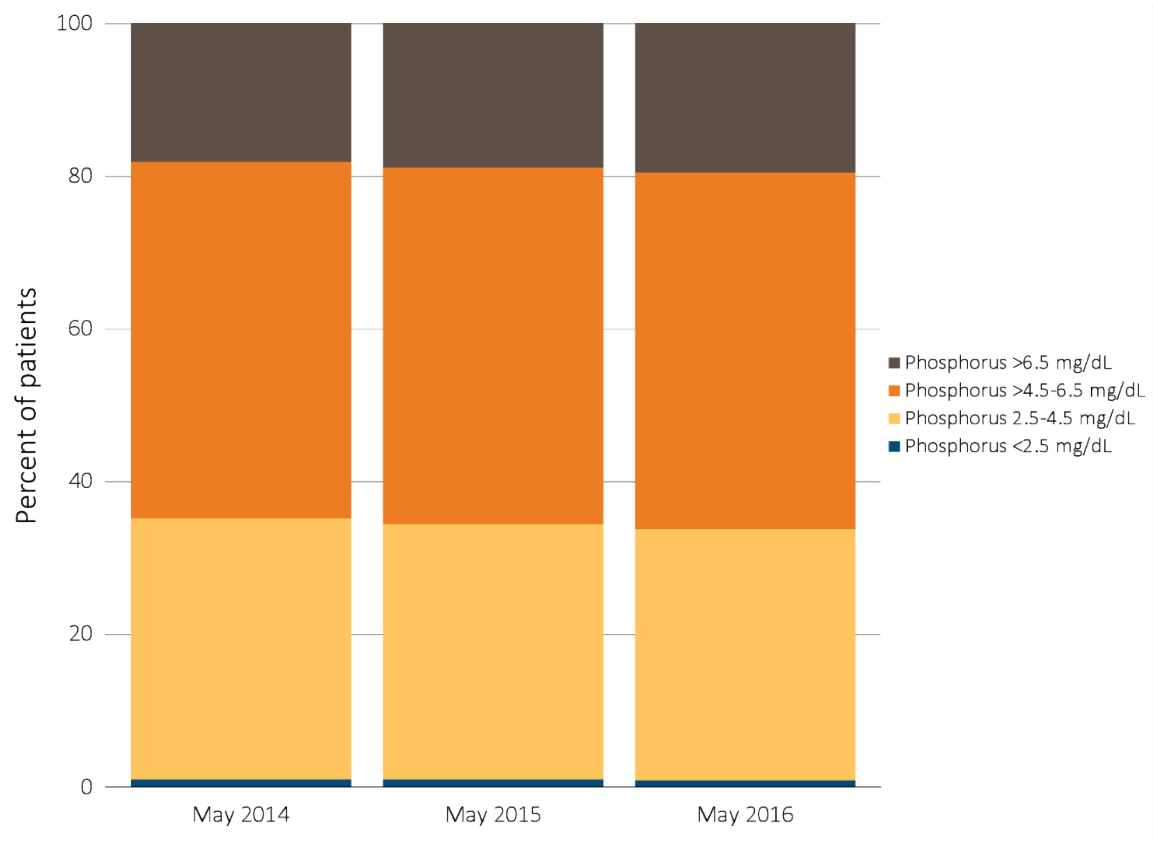


Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2014, 2015 and 2016. Dialysis patients on treatment for ESRD at least 1 year at the time of measurement of serum calcium for that year, ≥18 years old as of May 1 of that year and who were alive through May 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

Serum Phosphorus

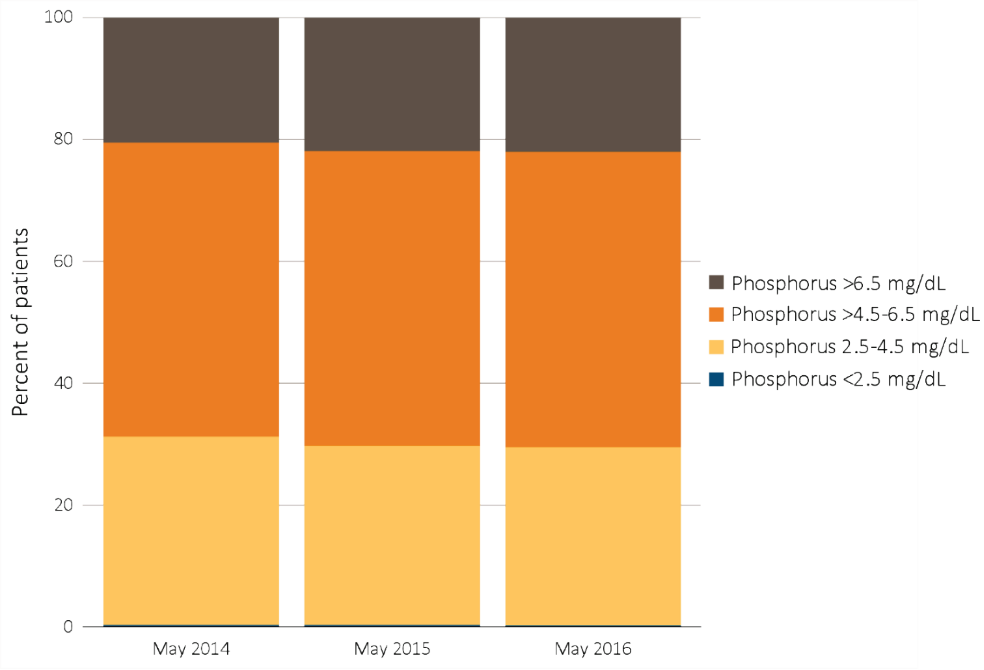
Figures 2.16 and 2.17 illustrate the distributions of serum phosphorus levels among adult HD and PD patients. Between 2014 and 2016, a slight increase in mean serum phosphorus was observed both in HD and PD patients (HD: from 5.2 to 5.3 mg/dL; PD: from 5.4 to 5.5 mg/dL). KDIGO guidelines (KDIGO, 2009) recommend maintaining phosphorus levels within the laboratory reference range, typically between 2.5 and 4.5 mg/dL. Among HD patients in May 2016, approximately two-thirds (65.9%) had serum phosphorus >4.5 mg/dL. This percentage was even higher among patients on PD (70.1%), indicating a clear opportunity for improvement in serum phosphorus control. Prior studies have shown that patients having low serum phosphorus levels (<2.5 mg/dL) have elevated mortality risk and a high likelihood of malnutrition. In cross-sectional 2014 to 2016 CROWNWeb data, only 1.3%-1.4% of HD patients and 0.6%-0.7% of PD patients had serum phosphorus levels of <2.5 mg/dL.

vol 2 Figure 2.16 Distribution of serum phosphorus levels in adult hemodialysis patients on dialysis for at least 1 year, CROWNWeb data, May 2014, 2015, and 2016



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for May 2014, May 2015, and May 2016. 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 May 1 of that year and who were alive through May 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

vol 2 Figure 2.17 Distribution of serum phosphorus levels in adult peritoneal dialysis patients on dialysis for at least 1 year, CROWNWEB data, May 2014, 2015, and 2016



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for May 2014, May 2015, and May 2016. 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 May 1 of that year and who were alive through May 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

Preventive Care

Diabetes Mellitus

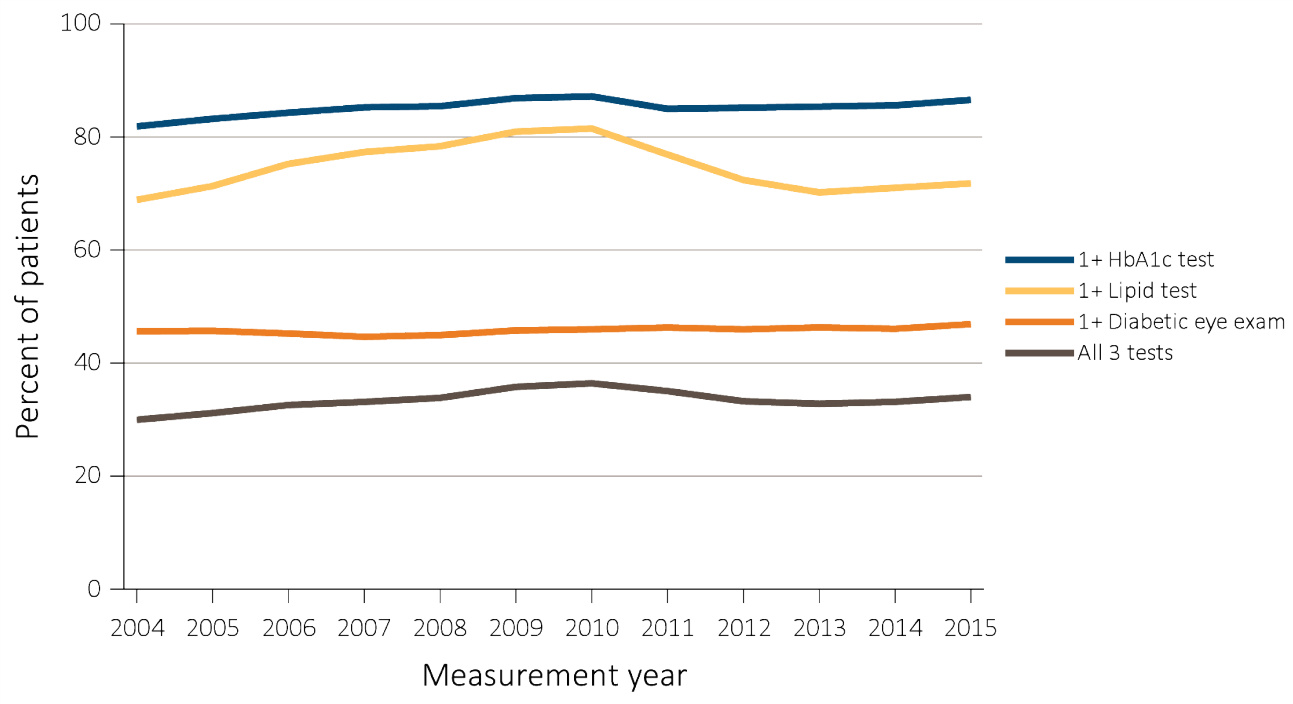
Recommendations for glycemic and lipid monitoring, treatment, and target levels in diabetic patients with ESRD are controversial. In preventing vision loss, however, the role of regular dilated eye exams and timely treatment is well established.

From 2004 to 2015, Medicare claims showed a slight increase in the percentage of ESRD patients with diabetes who received at least one glycosylated hemoglobin test (HbA1c; 81.9% in 2004 to 85.6% in 2015). The percentage of ESRD patients with diabetes who received at least one lipid test increased steadily from 2004 to 2010 (68.9% to 81.5%), decreased between 2010 and 2013 (81.5% to 71.2%), and since 2013 has remained stable at approximately 72% (71.8% in 2015; Figure 2.18). The National Committee for Quality Assurance Comprehensive Diabetes Care data also shows an increase in testing over this period in the privately insured population with diabetes—89-90% received at least one HbA1c test in 2015. In the Medicare population with diabetes, 93% received at least one HbA1c test in 2015. In 2014, 81-85% of privately insured people with diabetes received at least on LDL-C test and 89.0% of people in the Medicare population with diabetes received at least one LDL test. NCQA retired its LDL-C screening measure in 2015.

The decrease in HbA1c testing may reflect an increasing awareness of the limitations of HbA1c as an indicator of average glycemia in diabetic patients with ESRD. The reason for the decrease in lipid testing rates is unclear, but may have been influenced by relevant publications. Wanner et al. (2005) and Fellstrom et al. (2009) demonstrated a lack of effect of statin therapy on fatal and nonfatal cardiovascular outcomes in patients undergoing HD. In addition, the American College of Cardiology/American Heart Association introduced guidelines that recommended periodic, rather than annual lipid monitoring.

In 2015, 46.9% of patients had at least one diabetic eye exam, a low but constant rate over the past decade. This did not meet the *Healthy People 2020* target of 58.7%. A similar pattern exists for the patients receiving all three tests—approximately 34% in the most recent data year. Thus, there remains a substantial opportunity for quality improvement in preventive care for DM in this population.

vol 2 Figure 2.18 Diabetes-related care among ESRD patients with diabetes mellitus aged 18-75 years, Medicare claims, 2004-2015



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; diabetes-related care in the measurement year. Abbreviations: ESRD, end-stage renal disease; HbA1c, glycosylated hemoglobin.

Vaccination

It is recommended that all ESRD patients receive an annual influenza vaccination. To account for early or later vaccinations, we define seasonal influenza vaccination more broadly than the typical October through March influenza season by including the period of August 1 through April 30. Based on Medicare claims data, the percentage of ESRD patients receiving influenza vaccination has slowly improved over the past decade, rising from 56.7% in the 2004-2005 season to 72.2% in the 2014-2015 season (Figure 2.19.a). However, it remains below the *Healthy People 2020* target of 90%.

The percentage of patients vaccinated was highest in older age groups, with only 39.7% of ESRD patients aged 0-21 years receiving an influenza vaccine in the 2014-2015 season; this continued a downward trend seen since the 2012-2013 season (Figure 2.19.b). This trend may in part relate to the higher, and increasing, transplant rates in the age 0-21 years group, as vaccination rates are lower among transplant patients (Figure 2.19.e).

The percentage of patients vaccinated was similar in the most recent data years across both race and ethnicity groups, although slightly lower among Blacks at 71.0% in the 2014-2015 season (Figures 2.19.c and 2.19.d). By modality, HD patients were vaccinated at the highest frequency—78.1% in the most current data—compared with 77.2% of PD patients and 51.8% of kidney transplant patients (Figure 2.19.e). The percentage vaccinated may be lower in transplant patients in part because vaccination is often delayed for several months after a new transplant due to concerns regarding an ineffective immune response or the possibility of triggering an acute rejection episode. These percentages as reported may be underestimates, as they were derived from claims data that may not completely capture all vaccination events. Future Annual Data Reports will utilize CROWNWeb data that should provide information that is more complete, including status for other recommended vaccinations, such as for pneumococcus and hepatitis B.

vol 2 Figure 2.19 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 (d) by ethnicity, and (e) by ESRD treatment modality, Medicare data, 2003-2015

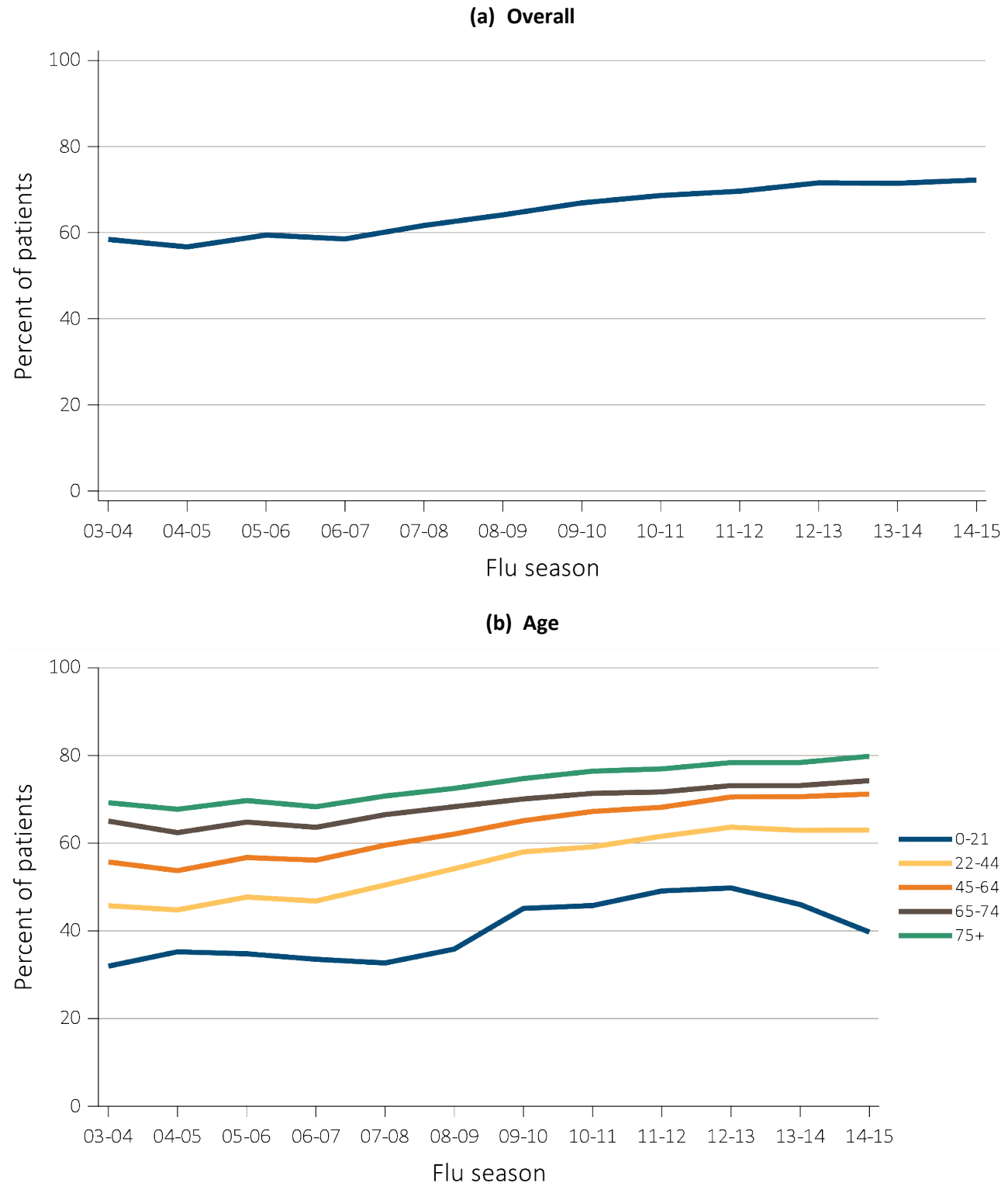
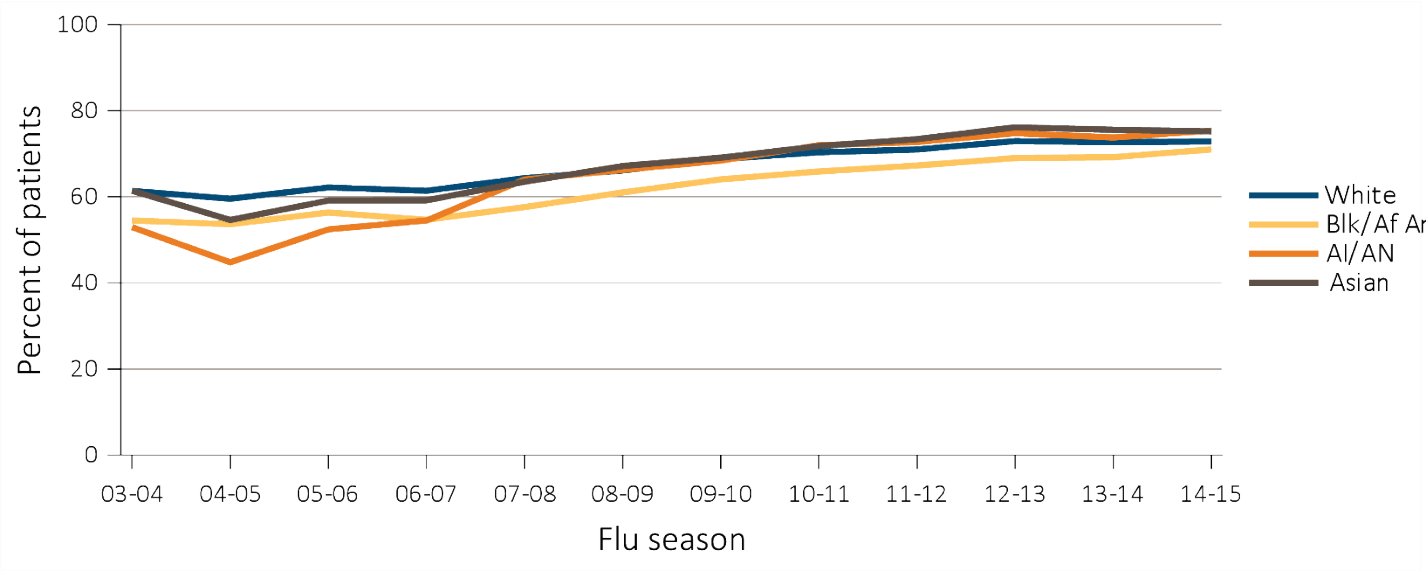


Figure 2.19 continued on next page.

vol 2 Figure 2.19 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 (d) by ethnicity, and (e) by ESRD treatment modality, Medicare data, 2003-2015 *(continued)*

(c) Race



(d) Ethnicity

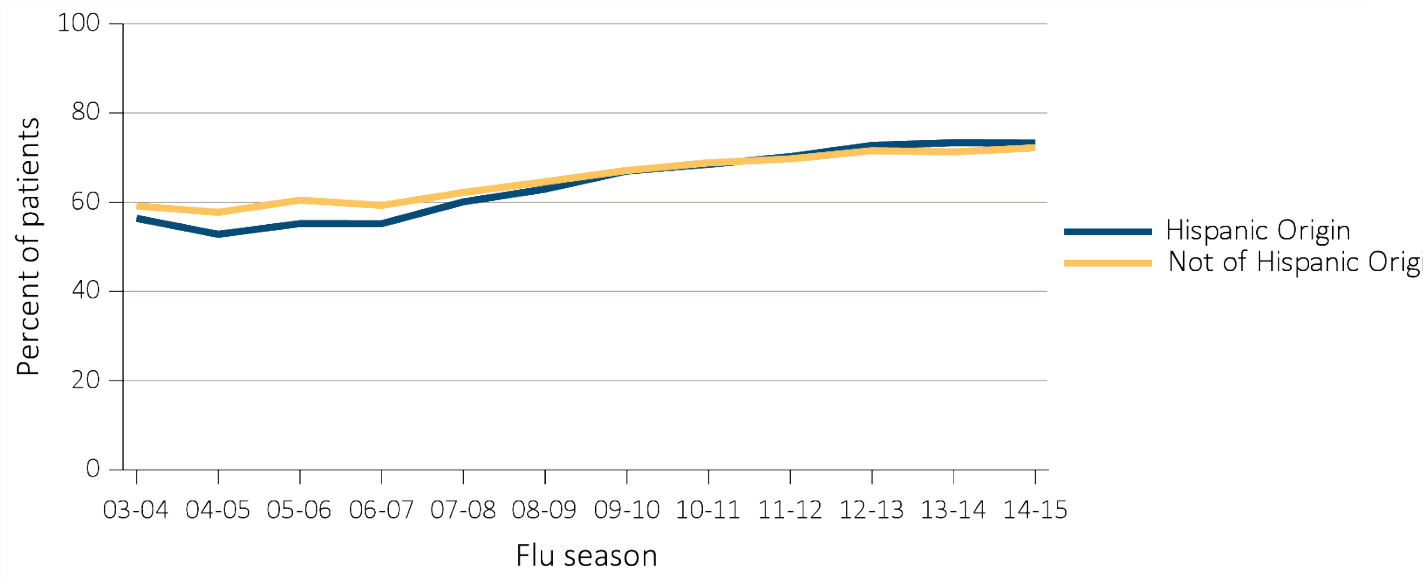
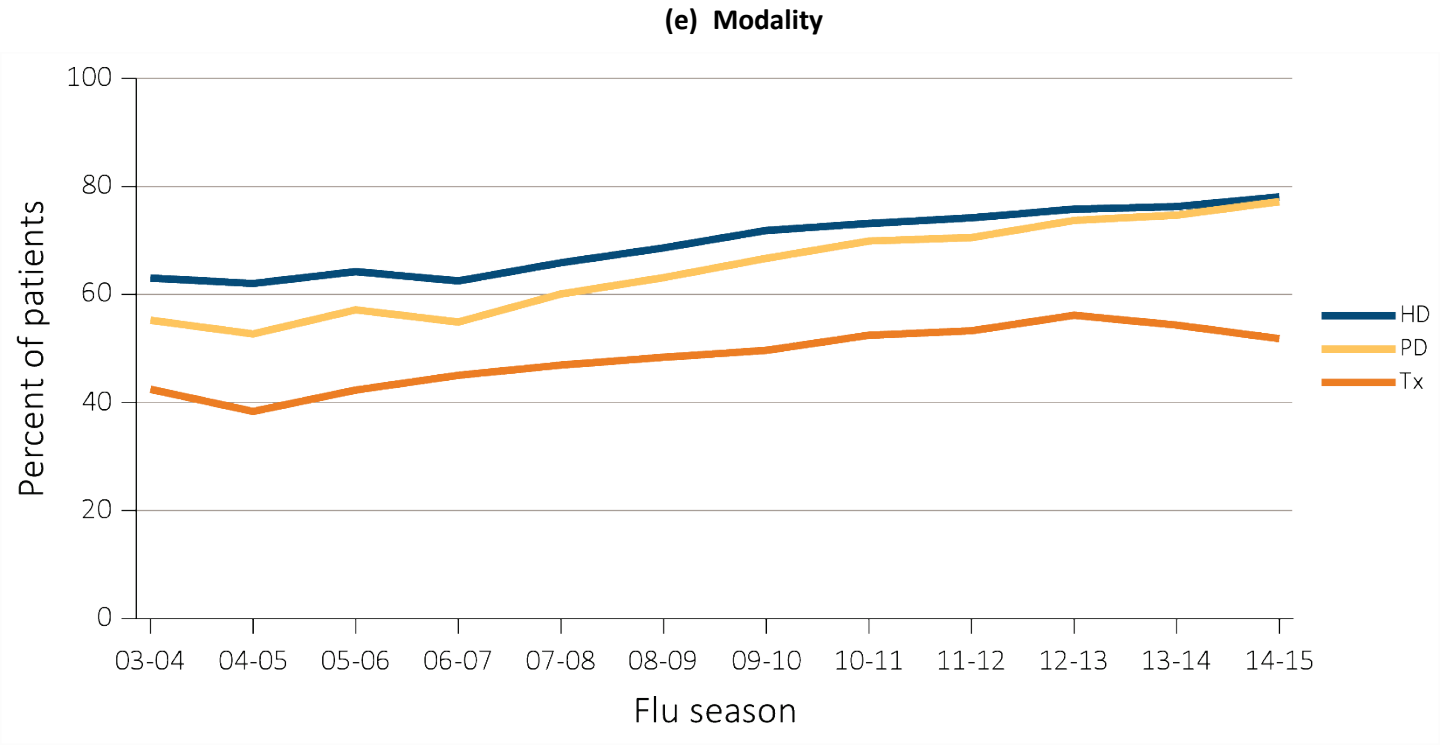


Figure 2.19 continued on next page.

vol 2 Figure 2.19 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 (d) by ethnicity, and (e) by ESRD treatment modality, Medicare data, 2003-2015 *(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. (c) Native Hawaiian/Pacific Islander, multiracial, and other/unknown races excluded due to small number of flu vaccination claims. Abbreviations: Af Am, African American; AI, American Indian; AN, Alaska Native; ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

References

Fellstrom BC, Jardine AG, Schmieder RE, Holdaas H, Bannister K, et al. Rosuvastatin and cardiovascular events in patients undergoing hemodialysis. *N Engl J Med* 2009;360(14):1395-1407.

Kidney Disease: Improving Global Outcomes (KDIGO). *KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD).* http://kdigo.org/wp-content/uploads/2017/02/2017-KDIGO-CKD-MBD-GL-Update.pdf. Published July 2017. Accessed October 4, 2017.

National Committee for Quality Assurance. Comprehensive diabetes care. In *The State of Health Care Quality* 2013;October:51-55. https://www.ncqa.org/Portals/0/Newsroom/SOHC/2013/SOHC-web_version_report.pdf. Accessed October 10, 2015.

Wanner C, Krane V, Marz W, Olschewski M, Mann JFE, et al. Atorvastatin in patients with type 2 diabetes mellitus undergoing hemodialysis. *N Engl J Med* 2005;353(3):238-248.

Chapter 3: Vascular Access

- In 2015, 80% of patients were using a catheter at hemodialysis (HD) initiation (Figure 3.1).
- At 90 days after the initiation of HD, 68.5% of patients were still using catheters. (Figure 3.7.a).
- Arteriovenous (AV) fistula use at HD initiation rose from 12% to 17% over the period 2005-2015 (Figure 3.1).
- The percentage of patients using an AV fistula or with a maturing AV fistula at HD initiation increased from 28.9% to 33.4% over the same period (Figure 3.1).
- Seventeen percent of patients used an AV fistula exclusively at dialysis initiation. This increased to 65% by the end of one year on HD, and to 72% by the end of two years (Figure 3.7.a).
- The proportion of patients with an AV graft for vascular access was 3% at HD initiation, 15% at one year after initiation, and 16% at two years (Figure 3.7.a).
- At one year after HD initiation, 80% of patients were using either an AV fistula or AV graft without the presence of a catheter. By two years, this number rose to 88% (Figure 3.7.a).
- By May 2016, 62.7 % of prevalent dialysis patients were using an AV fistula (Figure 3.6).
- Of AV fistulas placed between June 2014 and May 2015, 35.9% of failed to mature sufficiently for use in dialysis. Of those that did mature, the median time to first use was 111 days (Table 3.7).
- Patient age is a factor contributing to success with AV fistula; with younger age, the percent of AV fistulas that successfully matured was higher and the median time to first use was somewhat shorter (Table 3.7).

Introduction

Clinical practice guidelines recommend an autogenous arteriovenous (AV) fistula as the preferred vascular access for hemodialysis (HD; National Kidney Foundation, 2006). Central venous catheters (hereafter, catheter[s]) have been associated with the highest risks of death, infection, and cardiovascular events, compared to other types of vascular access. Patients with a usable AV fistula exhibit the lowest risks for these events (Ravani et al., 2013). Interestingly, recent data suggests that the comorbidities collinear with the catheter, rather than direct complications, may be partially responsible for this difference (Ravani et al., 2017; Brown et al., 2017).

The international Dialysis Outcomes and Practice Patterns Study (DOPPS) highlighted the fact that with respect to vascular access, dialysis practices in the United States (U.S.) lagged behind other industrialized countries (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). Over the next decade, a gradual but steady increase in AV fistula placement efforts followed in the U.S., such that the proportion of prevalent HD patients using an AV fistula rose from 32% in 2003 to 63% by 2014 (USRDS, 2016).

A robust debate continues as to whether an AV fistula should remain the access of first choice for every dialysis patient, with recent attention paid to the length of time and effort AV fistula creation can consume in certain higher risk populations (Lee et al., 2015; Hall et al., 2017). An AV fistula is considered optimal because of its potential for durability, lower risk of infection, and reduced need for intervention to ensure patency. However, recent focus has shifted somewhat toward tailoring the most appropriate access for individual patients, based upon their clinical situation, patient characteristics, life expectancy, preference, and other factors. Further

prospective studies and clinical trials will determine whether this approach will indeed prove superior.

A landmark clinical trial where maturation of an AV fistula was a secondary outcome revealed the high prevalence of failure of newly placed fistulas never coming to use (Dember et al., 2008). Between primary surgical failures and maturation failures, 33.8% of AV fistula placements in the U.S. are unsuccessful (USRDS, 2016). Rigorous evaluation of the many potential factors underlying this phenomenon is necessary to ensure primary surgical success and subsequent optimal maturation of the AV fistula. In this regard, patients may benefit should surgical training programs further emphasize skill in AV fistula placement (Saran et al., 2008; Goodkin et al., 2010).

Many additional factors likely influence successful AV fistula placement, including patient motivation for access placement, timeliness of referrals for nephrology care and placement, and institutional and payer support for pre-ESRD care and coordination of dialysis access placement and maintenance. These suggest that a systematic, multilevel approach is required for ensuring optimal vascular access for every HD patient (Huber, 2015).

The above considerations and other salient issues make it imperative to track carefully and comprehensively the current and future trends in vascular access placements, related practices, and outcomes. Despite the emphasis on improving AV fistula success rates, at the time of their initial dialysis 80.3% of patients used a catheter (USRDS, 2016). Well-coordinated pre-dialysis care during the critical transition period to ESRD may be the key to future improvements in this suboptimal practice pattern.

In this chapter, we describe 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 national variation in time-to-first-use of AV fistulas after placement, as a surrogate for AV fistula maturation.

Methods

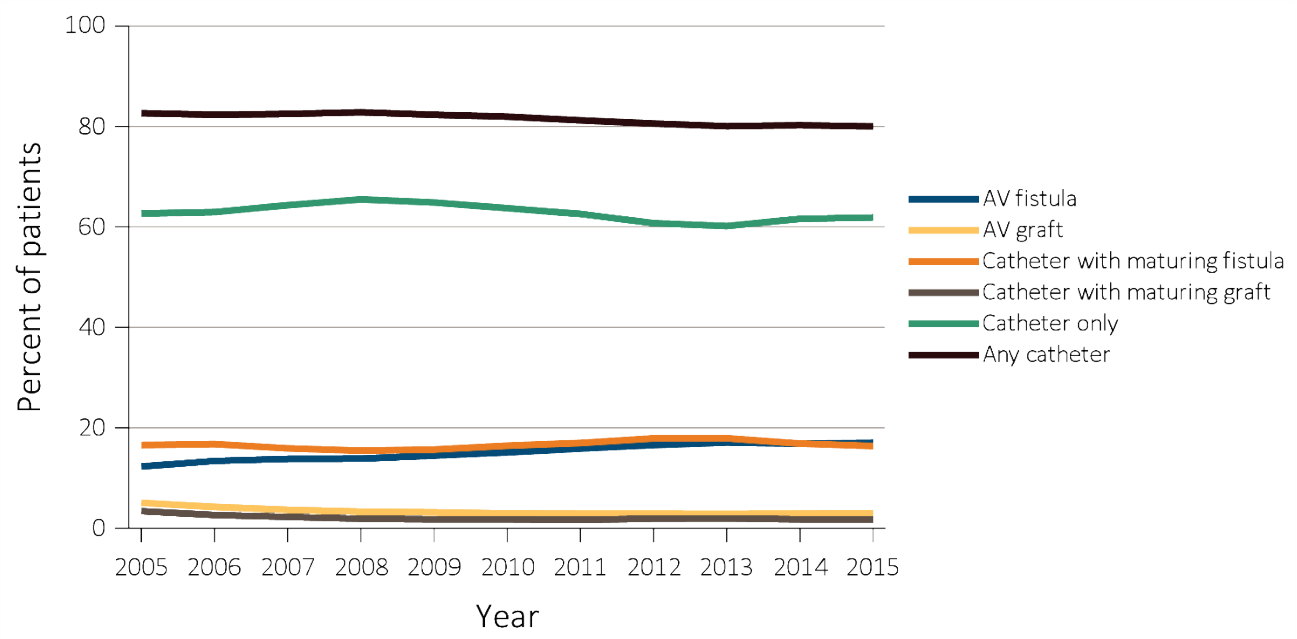
This chapter examines and reports data from the Centers for Medicare & Medicaid Services (CMS). Details of this data source are described in the *Data Sources* section of the *ESRD Analytical Methods* chapter.

See the Chapter 3 section of *Analytical Methods Used in the ESRD Volume* 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. Downloadable Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available on the USRDS website.

Vascular Access Use at Initiation of Hemodialysis

In 2015, 80% of patients were using a catheter at HD initiation, a rate that has changed only marginally since 2005. Figure 3.1 shows that in 2015, 61.9% of patients incident to ESRD had neither an AV fistula nor AV graft in place or maturing at their first outpatient HD session. This rate peaked at 65.5% in 2008, and has remained relatively stable since 2012 at near 60%. Over the last several years, there has been a relatively small absolute increase in AV fistula use at HD initiation, rising from 12.3% in 2005 to 17.0% in 2015. Over the same period, the percentage of patients with either an AV fistula or a maturing AV fistula increased from 28.9% to 33.4%.

vol 2 Figure 3.1 Vascular access use at hemodialysis initiation, from the ESRD Medical Evidence form (CMS 2728), 2005-2015



Data Source: Special analyses, USRDS ESRD Database. ESRD patients initiating hemodialysis in 2005-2015. Abbreviations: AV, arteriovenous; CMS, Centers for Medicare & Medicaid; ESRD, end-stage renal disease.

Table 3.1 shows dialysis access use at HD initiation, stratified by patient characteristics. The 0-21 year old age group had the highest percentage of catheter use at HD initiation (91.7%) and lowest percentage of AV fistula use (7.5%). Many of these patients were children who received a renal transplant relatively quickly, with HD serving as a bridge to transplantation, or those in the youngest age categories, who, being small, may have presented surgical challenges in creating an AV fistula. The 65-74 year age group had the highest percentage of patients with AV fistula use at HD initiation (18.7%), with slightly lower levels seen for individuals 75 years or older (17.0%) and those between 45-64 years (16.9%).

Patients of Hispanic ethnicity displayed both the lowest proportion of AV fistula use (14.8%) at HD initiation and the highest use of a catheter alone (65.2%). Blacks/African Americans displayed the highest proportion of AV graft use at HD initiation (4.5%) compared with 1.7% to 3.3% for individuals of other races or of Hispanic ethnicity.

Those with cystic kidney disease had higher rates of AV fistula use at HD initiation (40.2%), perhaps related to younger age at disease detection, slower progression of underlying CKD, earlier nephrology referral, more consistent pre-dialysis nephrology care, or relatively preserved vasculature.

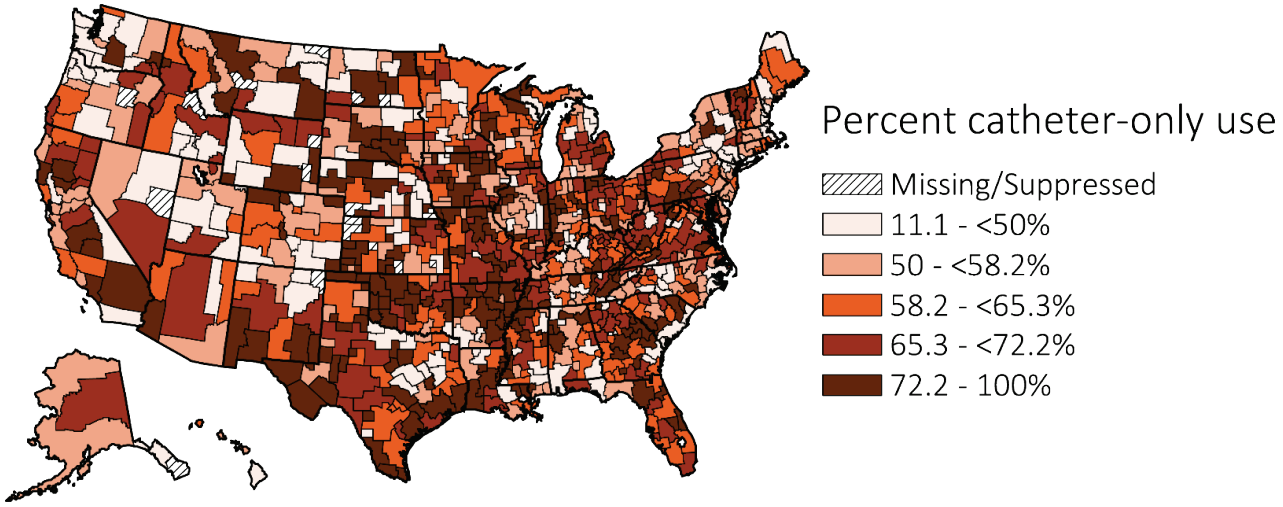
vol 2 Table 3.1 Vascular access used at hemodialysis initiation by patient characteristics from the ESRD Medical Evidence form (CMS 2728), 2015

	AV fistula	AV graft	Catheter with maturing fistula	Catheter with maturing graft	Catheter only
All	17.0	3.0	16.4	1.8	61.9
Age					
0-21	7.5	0.8	9.2	0.6	81.9
22-44	13.5	1.9	16.2	1.7	66.6
45-64	16.9	2.6	17.6	1.7	61.2
65-74	18.7	3.4	16.5	1.8	59.6
75+	17.0	3.5	14.6	1.9	62.9
Sex					
Male	18.7	2.2	16.9	1.4	60.7
Female	14.6	4.0	15.6	2.2	63.5
Race					
White	17.4	2.4	16.2	1.5	62.6
Black/African American	15.5	4.5	16.4	2.5	61.1
American Indian or Alaska Native	19.1	1.7	22.7	0.8	55.8
Asian	20.3	3.3	16.5	1.6	58.3
Native Hawaiian or Pacific Islander	17.1	2.5	18.9	1.4	60.0
Ethnicity					
Hispanic	14.8	2.0	16.8	1.3	65.2
Non-Hispanic	17.4	3.2	16.3	1.8	61.3
Race/Ethnicity					
Non-Hispanic White	18.1	2.5	16.1	1.5	61.8
Non-Hispanic Black/African American	15.4	4.5	16.4	2.5	61.1
Primary Cause of ESRD					
Diabetes	17.8	3.1	18.8	1.9	58.4
Hypertension	17.2	3.2	15.5	1.9	62.2
Glomerulonephritis	18.4	2.6	14.0	1.5	63.6
Cystic kidney	40.2	4.8	15.5	1.4	38.1
Other urologic	13.5	2.5	13.1	1.4	69.5
Other cause	8.8	2.1	10.4	1.3	77.3
Unknown/Missing	12.8	1.9	12.1	1.2	72.0
Comorbidities					
Diabetes	16.9	3.0	17.8	1.9	60.3
Congestive heart failure	12.9	2.6	17.2	1.9	65.4
Atherosclerotic heart disease	16.2	3.1	18.6	1.9	60.1
Cerebrovascular disease	14.7	3.5	17.0	2.7	62.0
Peripheral vascular disease	15.1	2.9	18.3	2.2	61.5
Hypertension	17.6	3.1	16.8	1.8	60.8
Other cardiac disease	13.7	2.6	16.5	1.8	65.3

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

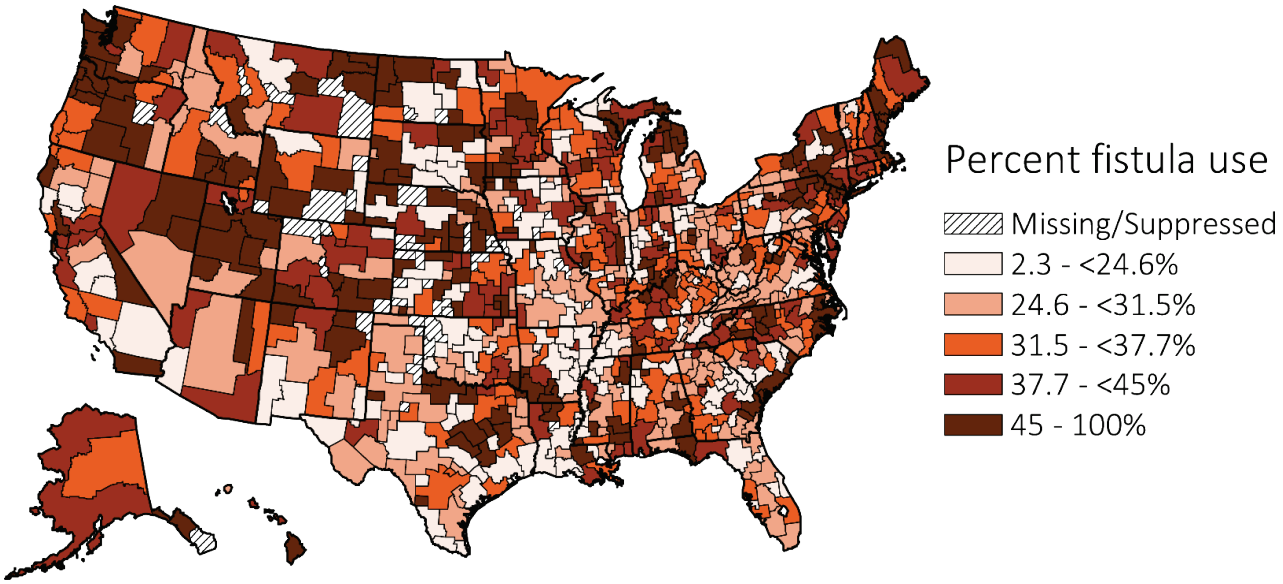
Figures 3.2 and 3.3 illustrate geographic variation by Health Service Area in the use of catheters alone or AV fistulas at HD initiation. Considerable variation occurred in both of these categorizations, even within individual states. New England, the Northwest, Utah, and parts of the East coast tended 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 also appeared to have a higher incidence of AV fistula use.

vol 2 Figure 3.2 Geographic variation in percentage of catheter-only use at hemodialysis initiation, from the ESRD Medical Evidence form (CMS 2728), 2015



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

vol 2 Figure 3.3 Geographic variation in percentage of AV fistula use at hemodialysis initiation, from the ESRD Medical Evidence form (CMS 2728), 2015



Special analyses, USRDS ESRD Database. AV fistula use includes not only AV fistulas, but also catheters with a maturing fistula. Abbreviations: AV, arteriovenous; CMS, Centers for Medicare & Medicaid; ESRD, end-stage renal disease.

Vascular Access Use among Prevalent Hemodialysis Patients

Table 3.2 shows patterns of access use among prevalent HD patients with ESRD for at least 90 days. By May 2016, 62.9% of these patients were using an AV fistula. In general, demographic variation was similar to the patterns observed for incident patients. Those in the 0-21 year old age group displayed the highest catheter use, while the 45-64 year group had the lowest use. Blacks displayed the lowest AV fistula utilization but highest of an AV graft. Whites and non-Hispanic patients reported the highest catheter use. When examined by primary cause of ESRD, individuals 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 that observed in patients incident to dialysis (Table 3.1).

vol 2 Table 3.2 Distribution of type of vascular access in use among prevalent hemodialysis patients in 2016, from CROWNWeb data, May 2016

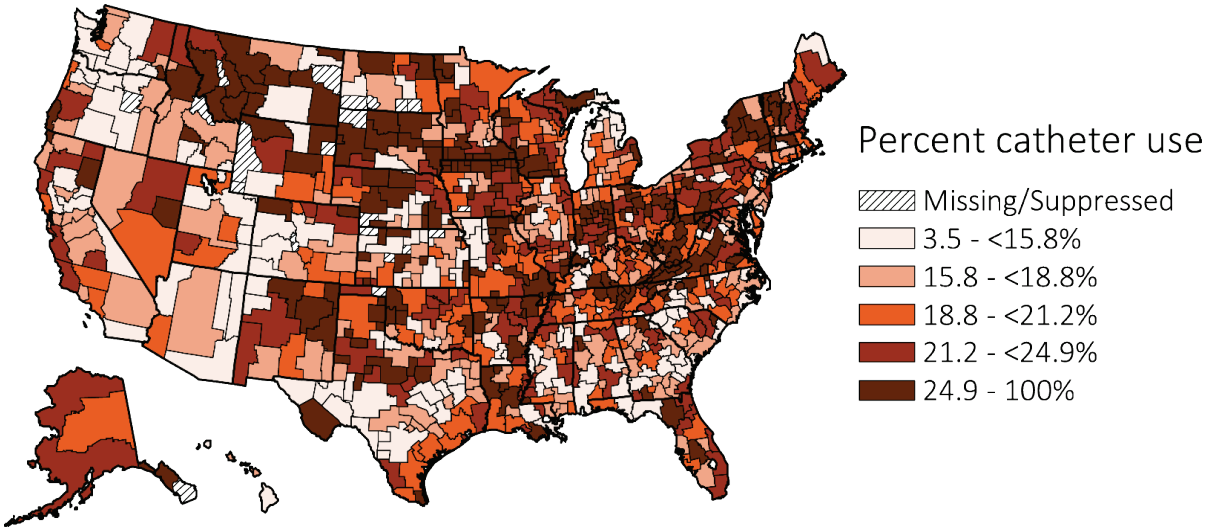
	AV fistula	AV graft	Catheter
All	62.9	17.7	19.4
Age			
0-21	45.6	5.7	48.6
22-44	64.5	14.8	20.7
45-64	64.9	16.8	18.4
65-74	62.3	18.5	19.1
75+	59.2	20.3	20.5
Sex			
Male	68.8	13.7	17.5
Female	55.2	23.0	21.9
Race			
White	65.6	13.8	20.6
Black/ African American	57.6	24.3	18.1
American Indian or Alaska Native	75.3	10.6	14.1
Asian	67.3	16.1	16.6
Native Hawaiian or Pacific Islander	67.3	15.3	17.4
Other or Multiracial	61.4	13.7	24.9
Ethnicity			
Hispanic	68.5	14.5	17.1
Non-Hispanic	61.7	18.4	19.9
Race/Ethnicity			
Non-Hispanic White	64.2	13.6	22.2
Non-Hispanic Black/African-American	57.6	24.4	18.0
Primary Cause of ESRD			
Diabetes	63.4	17.4	19.3
Hypertension	63.0	18.7	18.3
Glomerulonephritis	64.9	17.7	17.4
Cystic kidney	68.9	15.6	15.6
Other urologic	60.7	16.8	22.4
Other cause	56.5	16.6	26.9
Unknown/Missing	58.8	17.1	24.2

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; ESRD, end-stage renal disease.

Figure 3.4 presents geographic variation of the proportion of prevalent HD patients using a catheter in 2016. Rates varied widely across the country. Clusters of high catheter utilization were evident in parts of Montana and northern Idaho, 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. In contrast, the Pacific Northwest, parts of Georgia, and the mountainous portions of the Southwest exhibited lower catheter use.

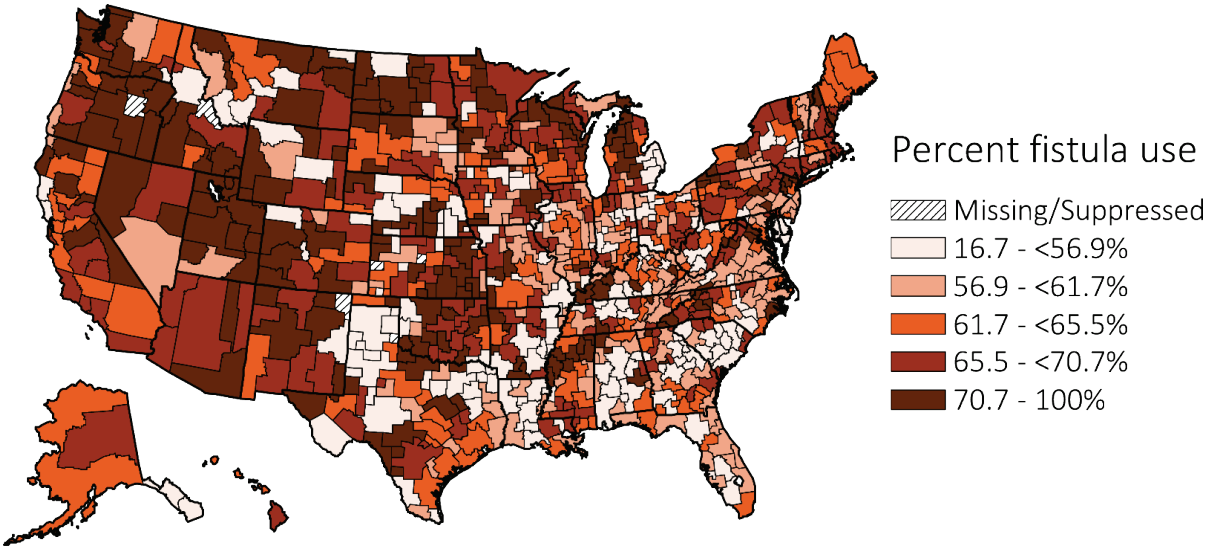
Figure 3.5 shows variation in AV fistula use among 2016 prevalent HD patients. While there were areas of greater than 70.8% utilization throughout the country, higher fistula use was most apparent in the western half. The deep South and the Texas Panhandle continued to have lower rates of fistula use.

vol 2 Figure 3.4 Geographic variation in percentage catheter use among prevalent hemodialysis patients by Health Service Area, from CROWNWeb data, May 2016



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

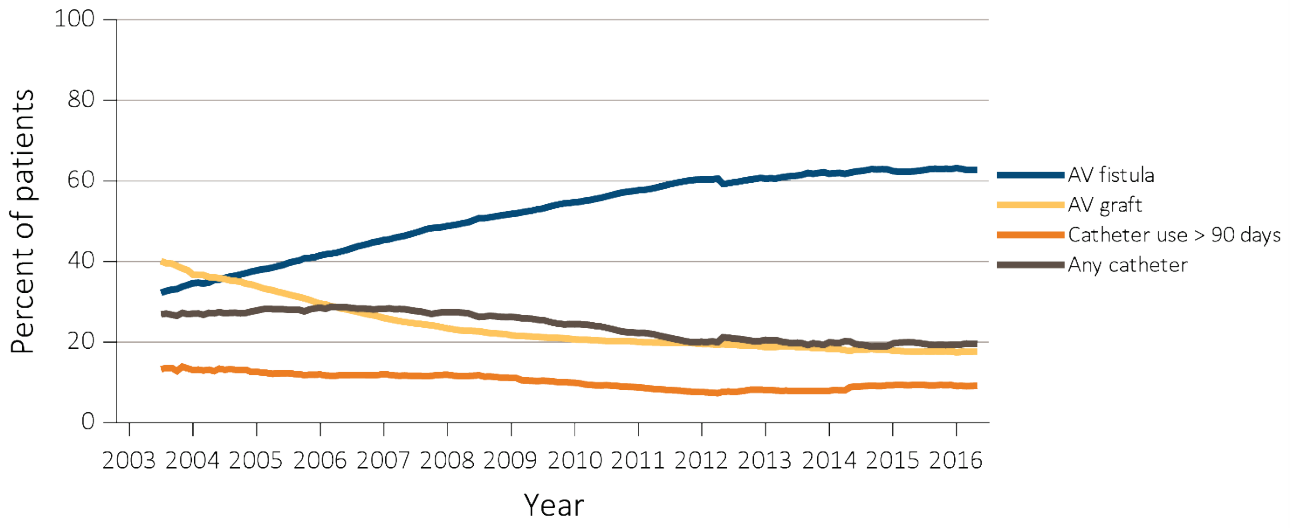
vol 2 Figure 3.5 Geographic variation in percentage AV fistula use among prevalent hemodialysis patients by Health Service Area, from CROWNWeb data, May 2016



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

Figure 3.6 displays trends in vascular access use among prevalent HD patients from 2003 to mid-2016. A large increase in AV fistula use has occurred since 2003, from 32% to 62.7% of patients; this has recently begun to plateau. In contrast, AV graft use has decreased from 40% to 17.6% over the same period. Catheter use has had a complementary decline, decreasing from 27% to 19.5%. In 2016, only 9.2% of prevalent HD patients had been using a catheter for greater than 90 days.

vol 2 Figure 3.6 Trends in vascular access type use among ESRD prevalent patients, 2003-2016



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 May 2016. Abbreviations: AV, arteriovenous; CROWNWeb, Consolidated Renal Operations in a Web-enabled Network; ESRD, end-stage renal disease.

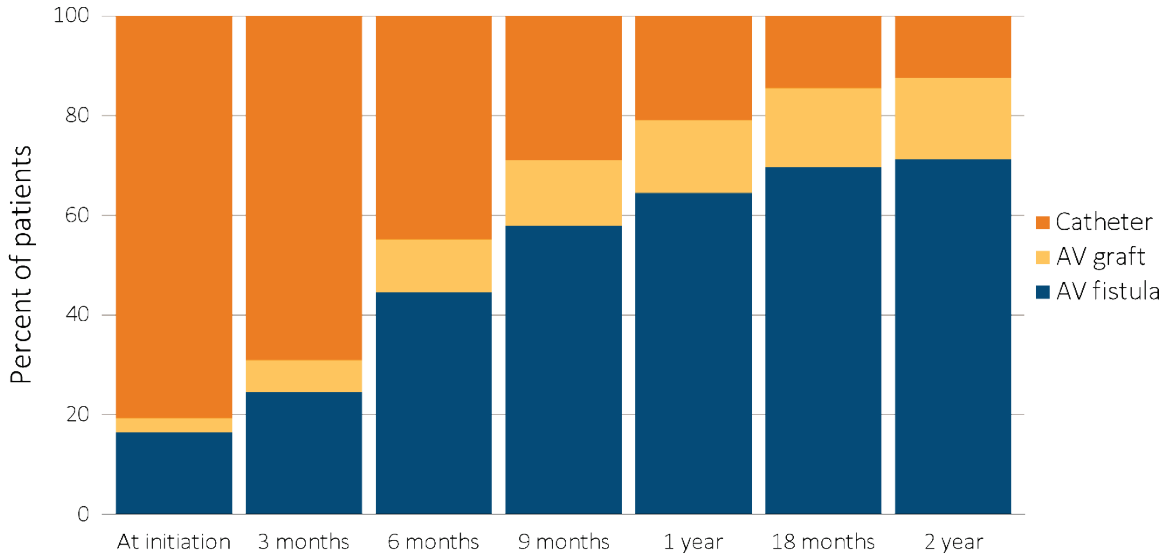
Change in Type of Vascular Access during the First Year of Dialysis

Figure 3.7.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 three, six, and nine months, and one year). At 90 days, the majority of HD patients were still using a catheter, highlighting the importance of ongoing efforts to improve access to pre-dialysis nephrology care and surgical access planning. Compared to 17% seen at HD initiation, the percentage of patients using an AV fistula exclusively at the end of one year on dialysis increased to 65%, and to 72% by the end of two years. The proportion of patients with an AV graft for vascular access was 3% at initiation, 15% at one year, and 16% at two years. Thus, at one year, 80% of patients were using either an AV fistula or AV graft without the presence of a catheter. At two years after HD initiation, this number rose to 88%.

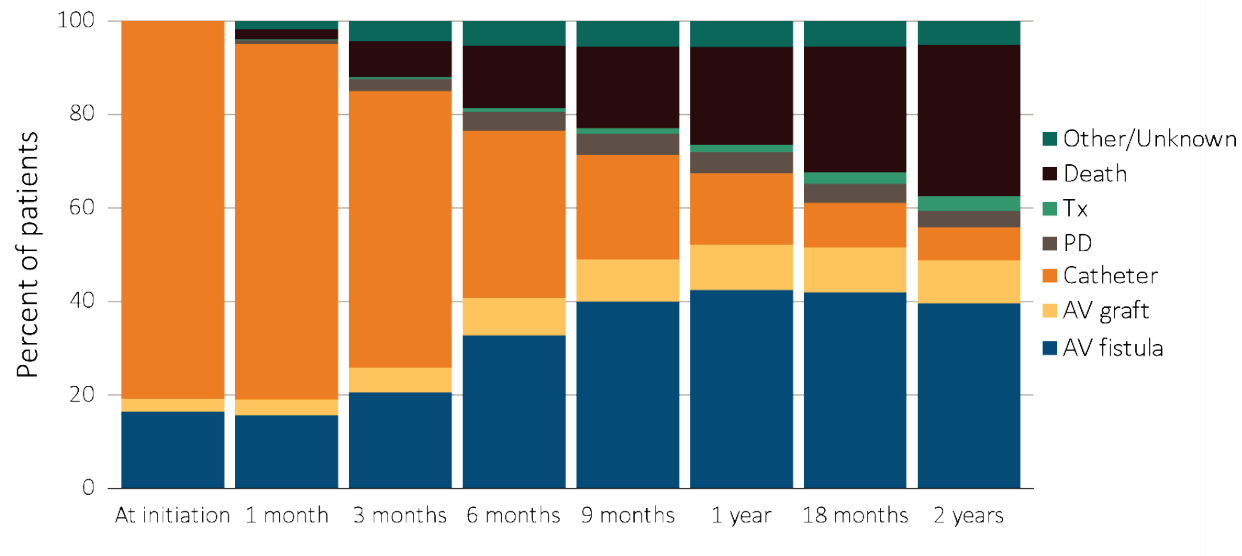
Figure 3.7.b displays one-year longitudinal changes in vascular access use and other outcomes in the cohort of patients who initiated ESRD via HD in 2013. In the incident ESRD HD cohort, 80.1% of patients initiated HD using a central venous catheter. After 12 months, 43.1% were using an AV fistula, 9.7% were using an AV graft, and 15.2% were dialyzing with a catheter only. Of this cohort, 1.7% were living with a kidney transplant, 4.5% were receiving peritoneal dialysis, 20.8% had died, and 4.9% were classified as having an Other/Unknown outcome. Thus, much of the percentage increase in fistula use can be attributed to higher mortality among catheter users.

vol 2 Figure 3.7 Change in type of vascular access during the first year of dialysis among patients starting ESRD via hemodialysis in 2013 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, 2013-2016

(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, 2013 to May 30, 2016: (a) Medical Evidence form (CMS 2728) at initiation and CROWNWeb for subsequent time periods. (b) ESRD patients initiating hemodialysis (N =101,453). Patients with a maturing AV fistula / AV graft with a catheter in place were classified as having a catheter. 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 3.3 through 3.5 show cross-sectional distributions of vascular access use at several time points during the first year of HD therapy, stratified by age, race, and sex. Catheter use was most common at initiation and at the end of one year in the 0-21 year old age group. Contributing influences discussed earlier include different pediatric nephrology practice patterns, higher transplant rates, or anatomical challenges. AV graft use was higher in the 75+ age group both at initiation and at the end of one year. At one year, approximately 20% of persons in all age groups, except the 0-21 year old cohort, used catheters. This indicates that barriers remain in establishing surgical access, even after one year of dialysis therapy. As noted above, much of the decrease in catheter use can be attributed to mortality effects.

Black patients had the lowest proportion of AV graft use at initiation, one year, and two years. At one year, 20.0% of Black patients were using an AV graft compared to 14.4% of Asians and 12.3% of Whites. At initiation, one year, and two years, females had a higher proportion of AV graft use and males a higher proportion of AV fistula use. At one year, catheter use was highest in patients of other or multiple races, and females. For most adult patients, an AV fistula prevalence of 60% or higher was achieved by one year of HD. At one year, males and those of American Indian /Alaska Native race has the highest proportions of AV fistula use; females and Blacks had the lowest AV fistula proportion.

vol 2 Table 3.3 Cross-sectional distributions of vascular access use, quarterly during the first two years of hemodialysis, among patients new to hemodialysis in 2013, by age group, from the ESRD Medical Evidence form (CMS 2728) and CROWNWeb, 2013-2016

Age	Access type	Time						
		At initiation	3 months	6 months	9 months	1 year	18 months	2 years
0-21	AV fistula	7.7	12.9	31.7	45.4	50.4	59.9	58.5
	AV graft	0.6	0.8	2.5	3.3	3.5	3.5	4.9
	Catheter	91.7	86.4	65.8	51.3	46.0	36.6	36.6
22-44	AV fistula	13.5	22.5	44.6	59.6	67.2	73.0	74.6
	AV graft	1.8	4.3	7.5	9.5	10.8	12.3	13.0
	Catheter	84.7	73.2	47.9	31.0	22.0	14.7	12.4
45-64	AV fistula	17.3	25.3	46.1	60.1	67.1	72.6	74.1
	AV graft	2.6	5.5	9.2	11.7	13.2	14.4	15.0
	Catheter	80.1	69.2	44.7	28.2	19.7	13.0	10.9
65-74	AV fistula	18.6	27.1	46.6	59.1	65.5	70.7	72.0
	AV graft	3.1	6.9	11.0	13.5	15.0	16.2	16.8
	Catheter	78.3	66.1	42.4	27.4	19.4	13.1	11.2
75+	AV fistula	17.3	24.9	43.6	56.1	61.6	66.0	67.5
	AV graft	3.5	8.5	14.0	16.9	18.5	19.6	19.8
	Catheter	79.2	66.6	42.4	27.0	20.0	14.5	12.6

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.

vol 2 Table 3.4 Cross-sectional distributions of vascular access use, quarterly during the first two years of hemodialysis among patients new to hemodialysis in 2013, by race, from the ESRD Medical Evidence form (CMS-2728) and CROWNWeb, 2013-2016

Race/Ethnicity	Access type	Time						
		At initiation	3 months	6 months	9 months	1 year	18 months	2 years
White	AV fistula	17.6	26.0	47.0	60.7	67.6	72.9	74.5
	AV graft	2.3	5.4	8.9	11.1	12.3	13.3	13.5
	Catheter	80.1	68.6	44.1	28.3	20.2	13.9	12.0
Black/African American	AV fistula	15.5	22.5	40.0	52.6	58.7	63.9	65.5
	AV graft	4.2	8.9	14.7	18.0	20.0	21.7	22.4
	Catheter	80.3	68.6	45.2	29.3	21.3	14.4	12.1
American Indian or Alaska Native	AV fistula	15.0	26.0	53.6	70.1	77.3	82.3	84.0
	AV graft	2.2	4.3	6.2	6.7	8.0	7.8	8.9
	Catheter	82.9	69.7	40.2	23.2	14.7	9.9	7.2
Asian	AV fistula	20.1	29.1	51.5	64.5	70.4	75.8	76.6
	AV graft	2.8	7.0	10.3	12.5	14.4	14.6	15.0
	Catheter	77.1	63.9	38.2	23.0	15.3	9.7	8.3
Native Hawaiian or Pacific Islander	AV fistula	18.6	28.5	48.8	61.3	69.7	77.1	77.2
	AV graft	2.3	4.5	6.1	9.2	10.2	11.2	13.3
	Catheter	79.0	67.1	45.1	29.5	20.1	11.7	9.5
Other or Multiracial	AV fistula	16.0	11.9	38.8	55.6	61.5	60.0	60.9
	AV graft	4.0	6.0	3.8	4.9	5.1	6.7	15.6
	Catheter	80.0	82.1	57.5	39.5	33.3	33.3	23.4
Hispanic	AV fistula	14.5	23.1	45.0	60.5	67.8	73.9	75.6
	AV graft	1.9	4.7	8.5	10.6	11.9	13.4	13.7
	Catheter	83.7	72.2	46.5	28.9	20.3	12.7	10.7
Non-Hispanic	AV fistula	17.6	25.5	45.2	58.1	64.5	69.6	71.0
	AV graft	3.0	6.7	11.0	13.6	15.2	16.4	17.0
	Catheter	79.4	67.7	43.8	28.3	20.3	14.1	12.0
Non-Hispanic White	AV fistula	18.5	26.9	47.6	60.7	67.4	72.4	74.0
	AV graft	2.4	5.6	9.1	11.2	12.4	13.2	13.5
	Catheter	79.1	67.5	43.4	28.0	20.1	14.4	12.5
Non-Hispanic Black/African American	AV fistula	15.5	22.4	40.0	52.6	58.7	63.9	65.5
	AV graft	4.2	9.0	14.8	18.1	20.0	21.7	22.5
	Catheter	80.3	68.5	45.2	29.3	21.3	14.4	12.0

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 3.5 Cross-sectional distributions of vascular access use, quarterly during the first two years of hemodialysis among patients new to hemodialysis in 2013, by sex, from the ESRD Medical Evidence form (CMS 2728) and CROWNWeb, 2013-2016

Sex	Access type	Time						
		At initiation	3 months	6 months	9 months	1 year	18 months	2 years
Male	AV fistula	18.7	28.5	50.9	65.0	71.4	76.3	77.7
	AV graft	2.1	4.9	8.0	9.9	11.0	11.9	12.3
	Catheter	79.2	66.7	41.1	25.2	17.6	11.8	10.0
Female	AV fistula	14.9	20.6	37.6	49.9	56.7	62.3	64.0
	AV graft	3.8	8.5	14.1	17.5	19.4	21.1	21.9
	Catheter	81.3	70.9	48.4	32.7	23.9	16.6	14.2

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 the rate of use at initiation continues to lag. There are many possible contributors to these trends, including access to primary and/or nephrology care, disparities in health-care access, difficulty with AV fistula maturation in specific patient groups such as elderly diabetics or those with limited transportation or financial incentives, and the wide variation in provider expertise in creating AV fistulas. The following figures and tables examine associations between clinical and patient characteristics and successful surgical access use, for both AV fistula and AV fistula/AV graft use, at initiation of HD.

Table 3.6 examines the influence of patient characteristics and factors such as length of pre-ESRD care and specific ESRD network of residence. At HD initiation, Asians had the highest odds of AV fistula use, while both Asians and Blacks had the highest odds of an AV fistula or AV graft surgical access in use. Females were less likely to be using an AV fistula/AV graft at initiation.

ESRD Network 16 (Alaska, Idaho, Montana, Oregon, and Washington) displayed the highest odds of patients using an AV fistula and higher odds of AV fistula or AV graft use at HD initiation. ESRD Networks 15 (Arizona, Colorado, Nevada, New Mexico, Utah, and Wyoming) and 17 (American Samoa, Guam, Mariana Islands, Hawaii, and Northern California) had outcomes approaching that of ESRD Network 16. Patients with ESRD secondary to diabetes were less likely to use an AV fistula or AV graft at HD initiation compared to patients for whom the primary cause of ESRD was not diabetes. Note that 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 3.6 Odds ratios and 95% confidence intervals from logistic regression models of AV fistula use at hemodialysis initiation, and AV fistula or graft use at hemodialysis initiation, from the CMS 2728, 2015

Predictors	AV fistula use at initiation			AV fistula or graft use at initiation		
	Odds ratio	95% confidence interval		Odds ratio	95% confidence interval	
		Lower bound	Upper bound		Lower bound	Upper bound
Pre-ESRD nephrology care						
0 months	0.06	0.05	0.06	0.07	0.06	0.07
>0 - <6 months	0.30	0.28	0.32	0.32	0.30	0.33
6 - 12 months	0.62	0.59	0.64	0.64	0.61	0.66
>12 months	Ref			Ref		
Unknown	0.19	0.18	0.20	0.19	0.18	0.21
Age 0-21	0.34	0.26	0.46	0.32	0.24	0.42
22-44	0.87	0.81	0.93	0.83	0.78	0.88
45-64	Ref			Ref		
65-74	1.03	0.99	1.08	1.08	1.04	1.13
75+	0.88	0.84	0.92	0.95	0.91	1.00
Sex Female	0.71	0.69	0.74	0.83	0.81	0.86
Male	Ref			Ref		
Race						
White	Ref			Ref		
Black/African American	0.99	0.94	1.03	1.18	1.13	1.22
American Indian or Alaska Native	0.97	0.81	1.15	0.94	0.79	1.12
Asian	1.09	1.00	1.19	1.12	1.02	1.22
Native Hawaiian or Pacific Islander	0.95	0.81	1.12	0.95	0.81	1.11
Other or Multiracial	0.97	0.70	1.33	0.97	0.71	1.31
Ethnicity Hispanic	0.98	0.93	1.04	0.97	0.92	1.02
Non-Hispanic	Ref			Ref		
Diabetes as cause of ESRD	0.97	0.94	1.01	0.98	0.95	1.01
Facility census < 20	Ref			Ref		
20-50	0.95	0.92	0.99	0.94	0.90	0.97
51-100	0.83	0.77	0.89	0.80	0.75	0.86
101-200	0.22	0.11	0.46	0.37	0.23	0.62
>200	0.21	0.10	0.44	0.16	0.08	0.33
ESRD network (vs. average network)						
1 CT, ME, MA, NH, RI, VT	1.20	1.10	1.29	1.19	1.10	1.28
2 NY	1.12	1.05	1.19	1.11	1.04	1.18
3 NJ, PR, VI	0.87	0.80	0.95	0.86	0.80	0.93
4 DE, PA	1.01	0.94	1.09	1.01	0.94	1.09
5 VA, WV, MD, DC	0.92	0.86	0.99	0.90	0.84	0.96
6 GA, NC, SC	1.02	0.96	1.08	0.97	0.92	1.03
7 FL	0.74	0.69	0.79	0.74	0.69	0.79
8 AL, MS, TN	1.00	0.93	1.08	1.04	0.98	1.12
9 IN, KY, OH	0.94	0.89	1.00	0.93	0.88	0.99
10 IL	0.90	0.83	0.98	0.97	0.90	1.05
11 MN, MI, ND, SD, WI	0.94	0.88	1.01	0.91	0.85	0.97
12 IA, KS, MO, NE	0.80	0.73	0.88	0.81	0.74	0.88
13 AR, LA, OK	1.04	0.96	1.13	0.99	0.92	1.07
14 TX	0.76	0.71	0.81	0.77	0.73	0.82
15 AZ, CO, NV, NM, UT, WY	1.26	1.17	1.35	1.21	1.13	1.30
16 AK, ID, MT, OR, WA	1.36	1.25	1.48	1.38	1.27	1.50
17 AS, GU, MP, HI, Northern CA	1.29	1.20	1.39	1.37	1.28	1.47
18 Southern CA	1.10	1.03	1.18	1.12	1.05	1.19

Data Source: Special analyses, USRDS ESRD Database. For more on ESRD networks, see http://www.cms.gov/About-CMS/Agency-Information/RegionalOffices/RegionalMap.html. Abbreviations: AV, arteriovenous; CMS, Centers for Medicare & Medicaid; CMS 2728, CMS ESRD Medical Evidence form2728; ESRD, end-stage renal disease.

Of AV fistulas placed between June 2014 and May 2015, 35.9% failed to mature sufficiently for use in dialysis. Of those that matured and were eventually used, the median time to first use was 111 days (Table 3.7). Younger patients tended toward higher maturation rates, with patients over age 75 displaying higher failure rates than the overall. Patients aged 65-74 had the longest median time to first AV fistula use (116 days) while patients aged 0-21 and 22-44 had the shortest (106 days). Males had a higher maturation rate compared to females, and a shorter time to first use. AV fistula placement failure rates were lower than the overall rate among American Indians/Alaska Natives, Native Hawaiians/Pacific Islanders, Asians, and those of Unknown race, while Blacks and those of Other/Multiracial race experienced higher failure rates.

Timely fistula maturation continues to be an area of central interest for the dialysis community. While AV fistula utilization among prevalent HD patients has improved (Figure 3.6), the proportion of patients using a dialysis catheter at incidence of ESRD remains stubbornly high (Figure 3.1). 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). Such complications limit future access patency and can result in poor long-term patient outcomes (Pisoni et al., 2009). Observational data suggest that central venous catheter use is associated with higher mortality (Powe et al., 1999). While the exact cause of this risk is difficult to discern, there is potentially greater risk for sepsis from the foreign body itself, from resulting biofilm or chronic thrombus formation, or other such mechanisms—some of which can persist after catheter removal.

While AV grafts are ready for use sooner and more reliably than fistulas, they require more procedures to assure their long-term patency. They are associated with a higher frequency of other complications that can significantly affect 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 to this choice of conduit. Furthermore, the premature placement of an AV graft may limit access options in the future (NKF, 2006)—a significant concern for those with longer life expectancy.

Currently 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. Recent studies, however, suggest a benefit in more liberal use of AV grafts in specific populations (Lee et al., 2015; Hall et al., 2017; Woo et al., 2017). Furthermore, conversion from a catheter to a permanent vascular access of either type has a demonstrated association with better patient outcomes (Bradbury et al., 2009).

vol 2 Table 3.7 Distribution of number of days between AV fistula placement and first successful use*, overall and by patient characteristics, for new AV fistulas created in 2014-2015 (excludes patients not yet ESRD when fistula was placed), from Medicare claims and CROWNWeb, 2014-2016

	Total AV fistula placements	Percentage of failed placements	Number of days between AV fistula placement and first use			
			Average	Median	25th percentile	75th percentile
Overall	43,530	35.9	132	111	75	166
Age						
0-21	167	29.3	137	106	75	159
22-44	5,011	31.5	130	106	69	162
45-64	16,284	34.0	131	109	73	167
65-74	12,297	36.7	136	116	79	169
75+	9,771	40.3	130	112	77	163
Race						
White	26,881	35.1	132	112	77	165
Black/African American	13,973	38.5	133	111	71	170
American Indian or Alaska Native	592	30.4	137	115	81	165
Asian	1,450	29.4	124	108	69	152
Native Hawaiian or Pacific Islander	458	31.9	131	110	72	180
Other or Multiracial	128	34.4	116	97	27	156
Unknown	27	29.6	167	143	54	228
Ethnicity						
Hispanic	6,211	31.4	128	108	75	158
Non-Hispanic	37,192	36.6	133	113	75	168
Race/Ethnicity						
Non-Hispanic White	20,937	36.2	133	113	78	167
Non-Hispanic Black/African American	13,776	38.4	133	111	71	170
Sex						
Male	24,495	34.8	113	104	71	144
Female	18,654	46.9	123	112	75	161
Primary Cause of ESRD						
Diabetes	20,308	36.0	135	113	77	169
Hypertension	13,312	36.1	131	111	75	164
Glomerulonephritis	3852	33.1	126	105	68	160
Cystic kidney	710	32	128	109	69	162
Other urologic	625	34.9	124	107	66	156
Other cause	3631	38.8	131	110	74	164
Unknown cause	1092	34.6	131	108	70	165

*Data Source: Special analyses, USRDS ESRD Database. *Fistulas places between June 1, 2014 and May 31, 2015, with follow-up through the June 2016; 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.*

References

Bradbury BD, Chen F, Furniss A, Pisoni RL, Keen M, Mapes D, Krishnan M. Conversion of vascular access type among incident hemodialysis patients: description and association with mortality. *Am J Kidney Dis* 2009;53(5):804-14.

Brown RS, Patibandla BK, Goldfarb-Rumyantzev AS. The survival benefit of "fistula first, catheter last" in hemodialysis is primarily due to patient factors. *J Am Soc Nephrol* 2017;28(2): 645-652.

Centers for Medicare & Medicaid (CMS). Regional map. http://www.cms.gov/About-CMS/Agency-Information/RegionalOffices/RegionalMap.html). Accessed September 16, 2016.

Churchill DN, Taylor DW, Cook RJ, LaPlante P, Barre P, Cartier P, Fay WP, Goldstein MB, Jindal K, Mandin H, et al. Canadian Hemodialysis Morbidity Study. *Am J Kidney Dis* 1992;19(3):214-34.

Dember LM, Beck GJ, Allon M, Delmez JA, Dixon BS, Greenberg A, Himmelfarb J, Vazquez MA, Gassman JJ, Greene T, Radeva MK, Braden GL, Ikizler TA, Rocco MV, Davidson IJ, Kaufman JS, Meyers CM, Kusek JW, Feldman HI, Dialysis Access Consortium Study G. Effect of clopidogrel on early failure of arteriovenous fistulas for hemodialysis: A randomized controlled trial. *JAMA* 2008;299(18):2164-2171.

Fistula First Breakthrough Initiative (FFBI) [database online]. www.fistulafirst.org. Accessed May 12, 2015, and no longer available in the public domain. Data publicly available on the Internet Archive, Wayback Machine. https://web.archive.org/web/20120930092044/http://www.fistulafirst.org/aboutfistulafirst/ffbidata.aspx Accessed September 29, 2015.

Goodkin DA, Pisoni RL, Locatelli F, Port FK, Saran R. Hemodialysis vascular access training and practices are key to improved access outcomes. *Am J Kidney Dis* 2010;56(6):1032-42.

Hall RK, Myers ER, Rosas SE, O'Hare AM, Colón-Emeric CS. Choice of hemodialysis access in older adults: a cost-effectiveness analysis. *Clin J Am Soc Nephrol* 2017;12(6): 947-954.

Huber TS. A call to action for pre-end-stage renal disease care. *JAMA Surg* 2015;150(5):449.

Lee T, Thamer M, Zhang Y, Zhang Q, Allon M. Outcomes of elderly patients after predialysis vascular access creation. *J Am Soc Nephrol* 2015;25(12): 3133-3140.

Morsy AH, Kulbaski M, Chen C, Isiklar H, Lumsden AB. Incidence and characteristics of patients with hand ischemia after a hemodialysis access procedure. *J Surg Res* 1998;74(1):8-10.

National Kidney Foundation (NKF). KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations, 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access. *Am J Kidney Dis* 2006 48 (Suppl 1): S1-S322.

Pisoni RL, Arrington CJ, Albert JM, Ethier J, Kimata N, Krishnan M, Rayner HC, Saito A, Sands JJ, Saran R, Gillespie B, Wolfe RA, Port FK. Facility hemodialysis vascular access use and mortality in countries participating in DOPPS: an instrumental variable analysis. *Am J Kidney Dis* 2009;53(3): 475-91.

Pisoni RL, Young EW, Dykstra DM, Greenwood RN, Hecking E, Gillespie B, Wolfe RA, Goodkin DA, Held PJ. Vascular access use in Europe and the United States: Results from the DOPPS. *Kidney Int* 2002;61:305-316.

Powe NR, Jaar B, Furth SL, Hermann J, Briggs W. Septicemia in dialysis patients: Incidence, risk factors, and prognosis. *Kidney Int* 1999;55: 1081–1090.

Ravani P, Palmer SC, Oliver MJ, Quinn RR, MacRae JM, Tai DJ, Pannu NI, Thomas C, Hemmelgarn BR, Craig JC, Manns B, Tonelli M, Strippoli GF, James MT. Associations between hemodialysis access type and clinical outcomes: a systematic review. *J Am Soc Nephrol* 2013 ;24(3):465-73.

Ravani P, Quinn R, Oliver M et al. Examining the association between hemodialysis access type and mortality: the role of access complications. *Clin J Am Soc Nephrol* 2017;12(6): 955-964.

Robinson BM, Port FK. Caring for dialysis patients: International insights from the Dialysis Outcomes and Practice Patterns Study (DOPPS). Identifying best practices and outcomes in the DOPPS. *Semin Dial* 2010;23(1):4-6.

Saran R, Elder SJ, Goodkin DA, Akiba T, Ethier J, Rayner HC, Saito A, Young EW, Gillespie BW, Merion RM, Pisoni RL. Enhanced training in vascular access creation predicts arteriovenous fistula placement and patency in hemodialysis patients: results from the Dialysis Outcomes and Practice Patterns Study. *Ann Surg* 2008;247(5): 885-91.

Stevenson KB, Hannah EL, Lowder CA, Adcox MJ, Davidson RL, Mallea MC, Narasimhan N, Wagnild JP. Epidemiology of hemodialysis vascular access infections from longitudinal infection surveillance data: predicting the impact of NKF-DOQI clinical practice guidelines for vascular access. *Am J Kidney Dis* 2002;39(3):549-555.

United States Renal Data System (USRDS). 2016 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2016.

Vassalotti JA, Jennings WC, Beathard GA, Neumann M, Caponi S, Fox CH, Spergel LM, Fistula First Breakthrough Initiative Community Education C. Fistula first breakthrough initiative: Targeting catheter last in fistula first. *Semin Dial* 2012;25(3):303-310.

Woo K, Gascue L, Goldman DP, Romley JA. Variations in outcomes of hemodialysis vascular access by race/ethnicity in the elderly. *Journal of Vascular Surgery* 2017;65(3): 783-792.e4.

Zarkowsky DS, Arhuidese IJ, Hicks CW, Canner JK, Qazi U, Obeid T, Schneider E, Abularrage CJ, Freischlag JA, Malas MB. Racial/ethnic disparities associated with initial hemodialysis access. *JAMA Surg* 2015;150(6):529-536.

Notes

Chapter 4: Hospitalization

- On average, end-stage renal disease (ESRD) patients are admitted to the hospital nearly twice a year. About 35% of ESRD patients who are discharged alive have a rehospitalization within the 30 days following discharge.
- Hospitalization represents a significant societal and financial burden, accounting for approximately 33% 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 and consistently. In 2015, the adjusted rates of admission for hemodialysis (HD) patients and for peritoneal dialysis (PD) patients decreased to 1.7 per patient year (PPY) as compared to 2.1 in 2006, a reduction of 19.0%. During that same period, admission rates for transplant patients reduced by 20.0%, to 0.8 days in 2015 from 1.0 in 2006 (Figure 4.1).
- During this same decade, HD patient hospitalizations due to cardiovascular events and for vascular access infections fell by 23.3% and 8.3% (Figure 4.2.b).
- During 2014-2015, some patient groups exhibited a higher risk of hospitalization when data was adjusted for age, sex, race, ethnicity, primary cause of kidney failure, and vintage, both overall and for most cause-specific diagnoses (Table 4.1).
- In general mortality rates increased with age. However, there was inconsistent variation in hospitalization rates by age, with relatively higher rates for the youngest and oldest age groups. The relatively high hospitalization rates for young patients were not due to kidney transplantation, which was excluded from these analyses.
- Hospitalization rates were 17.5% higher for females than for males, whereas males had higher mortality rates.
- Non-Hispanic White patients and Non-Hispanic Black/African American patients were hospitalized more often than those of other races.
- Persons with diabetes were 11.8% more likely to be hospitalized than the overall patient average.
- Patients with chronic kidney disease (CKD) and ESRD experienced rehospitalization rates of 21.4% and 35.2%, as compared to only 15.4% for older Medicare beneficiaries without a diagnosis of kidney disease (Figure 4.7).
- Among HD patients prevalent in 2015, 37.1% of discharges from a hospitalization for any cause were followed by a rehospitalization within 30 days (Figure 4.8.a).

Introduction

Admissions and readmissions to the hospital represent major burdens for patients with ESRD. On average, patients with ESRD are admitted to the hospital nearly twice a year, and about 35% have a rehospitalization within the 30 days following discharge. 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 33% of total Medicare expenditures for patients with ESRD (see Volume 2, Chapter 9, *Health Care Expenditures for Persons with ESRD*).

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 (Coleman et al. 2006; MedPAC 2007;

Rich et al. 1995; Stewart et al. 1999). 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.

Methods

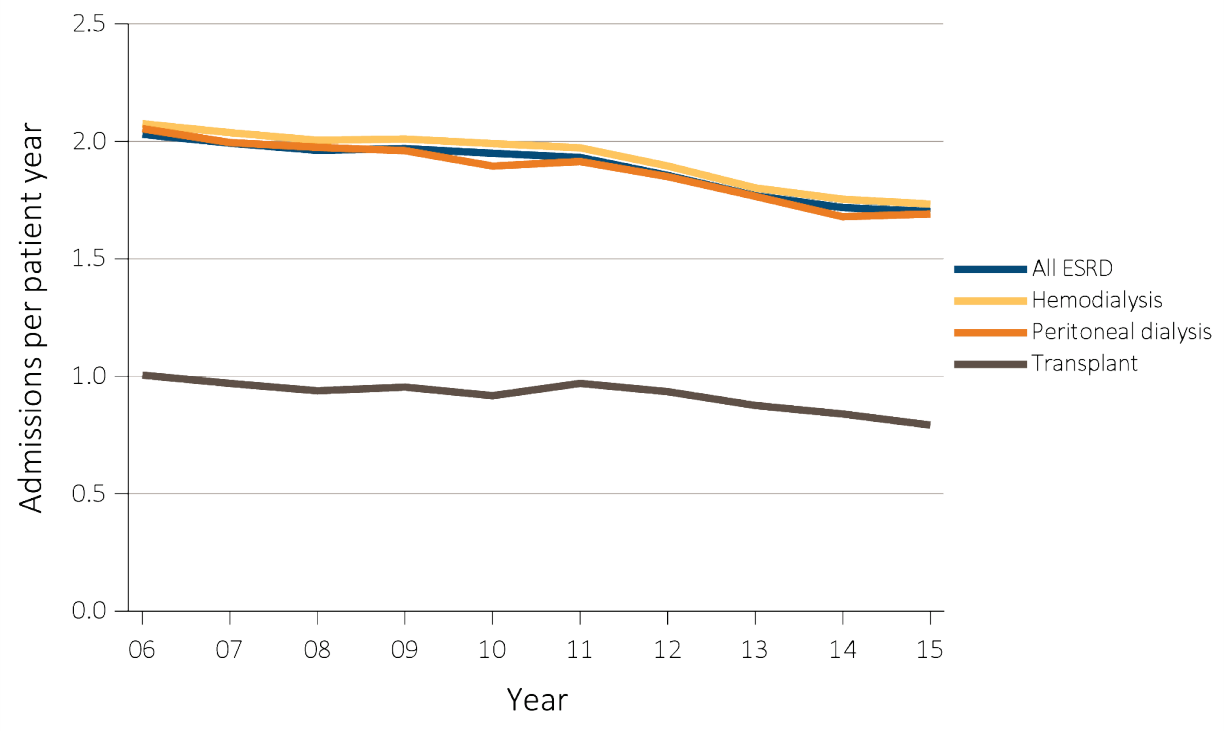
The findings presented in this chapter were drawn from data sources from the Centers for Medicare & Medicaid Services (CMS). Details of these are described in the *Data Sources* section of the *ESRD Analytical Methods* chapter.

See the *Analytical Methods Used in the ESRD Volume* section of the *ESRD Analytical Methods* chapter for an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter. Downloadable Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available on the USRDS website.

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 4.1, in 2015 the adjusted rates of admission for HD and PD patients decreased to 1.7 PPY as compared to 2.1 in 2006, a reduction of 19.0%. During that same period, admission rates for transplant patients reduced by 20.0%, to 0.8 PPY in 2015 from 1.0 in 2006.

vol 2 Figure 4.1 Adjusted hospitalization rates for ESRD patients, by treatment modality, 2006-2015



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; standard population: ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease.

The USRDS Annual Data Report (ADR) regularly highlights cause-specific hospitalization as an important morbidity surveillance issue, with a focus on hospitalizations resulting from infections and cardiovascular conditions. Hospitalizations for these causes have also declined over the 2006-2015 period (see Figure 4.2). The decline in hospitalizations due to infection was more pronounced among patients receiving PD (14.8%), as compared to HD (8.1%) and transplant patients (8.2%; see Figure 4.2). These improvements likely reflect, at least in part, targeted interventions to prevent and reduce infection rates, especially among PD patients.

vol 2 Figure 4.2 Adjusted all-cause & cause-specific hospitalization rates for ESRD patients, by treatment modality, 2006-2015

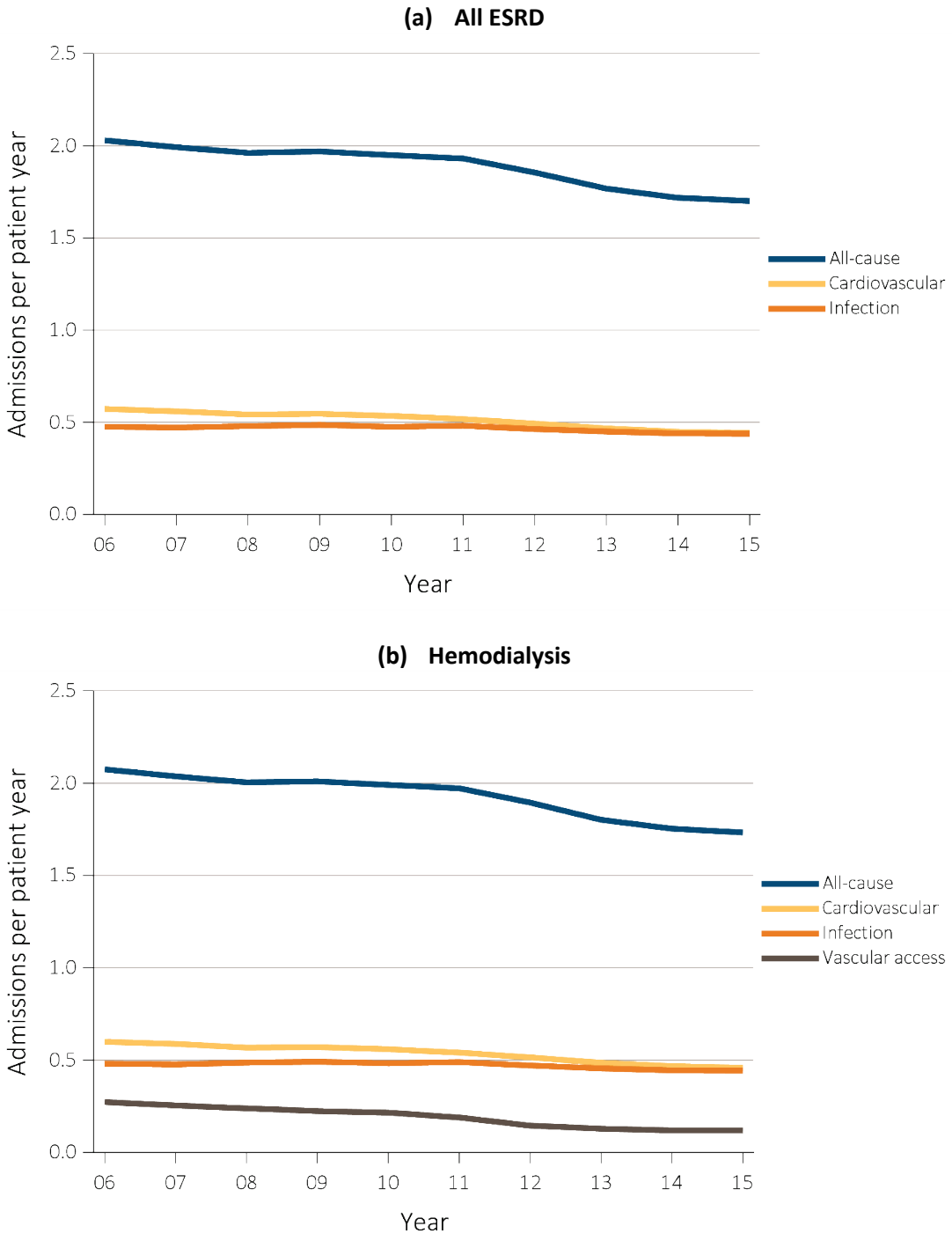
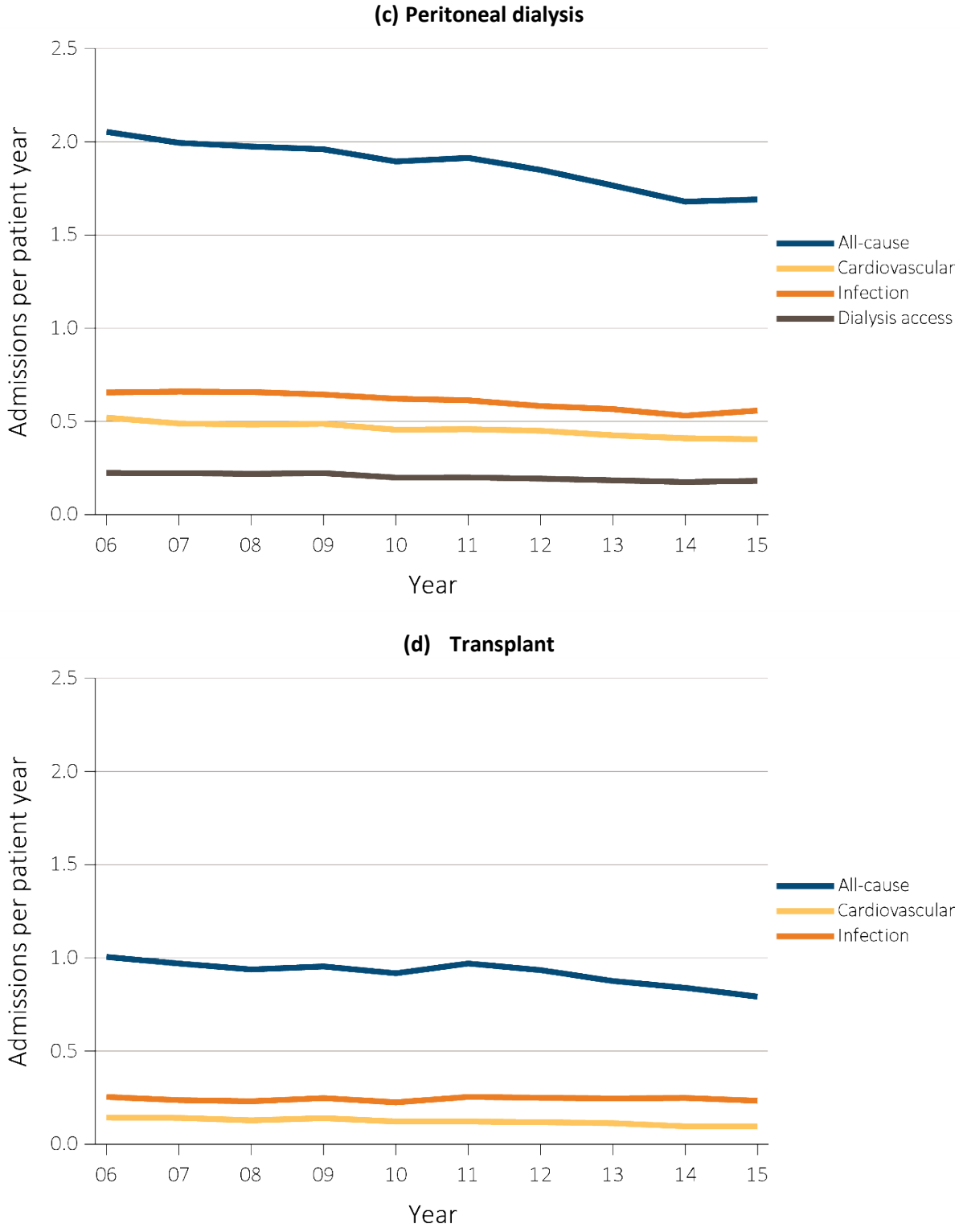


Figure 4.2 continued on next page.

vol 2 Figure 4.2 Adjusted all-cause & cause-specific hospitalization rates for ESRD patients, by treatment modality, 2006-2015 *(continued)*



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; standard population: ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease.

All-cause hospitalization rates among adult HD patients decreased by 14.9% from 2006 to 2015 (see Table 4.1). Hospitalizations due to cardiovascular events and those for vascular access infection fell by 22.0% and 53.7%. Patient groups with a higher risk of overall hospitalization included those aged 22–44 years or 75 years and older, females, and 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 all-cause 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.

vol 2 Table 4.1 Adjusted rates of all-cause & cause-specific hospitalization per patient year for adult hemodialysis patients, 2006-2015

	All	Cardiovascular	Any infection	Vascular access infection
2006-2007	2.04	0.59	0.48	0.25
2008-2009	2.01	0.57	0.49	0.22
2010-2011	1.97	0.54	0.49	0.19
2012-2013	1.80	0.49	0.45	0.13
2014-2015	1.73	0.46	0.44	0.12
2014-2015, by patient characteristics				
Age				
22-44	1.93	0.44	0.45	0.15
45-64	1.69	0.44	0.42	0.12
65-74	1.74	0.48	0.45	0.11
75+	1.79	0.49	0.49	0.11
Sex				
Male	1.58	0.43	0.41	0.10
Female	1.92	0.50	0.48	0.14
Race				
White	1.76	0.45	0.47	0.11
Black/African American	1.76	0.48	0.41	0.14
American Indian or Alaska Native	1.54	0.33	0.49	0.09
Asian	1.22	0.34	0.33	0.10
Native Hawaiian or Pacific Islander	1.19	0.34	0.34	0.08
Other or Multiracial	1.60	0.44	0.46	0.10
Ethnicity				
Hispanic	1.57	0.42	0.41	0.11
Non-Hispanic	1.76	0.47	0.45	0.12
Non-Hispanic White	1.86	0.48	0.50	0.11
Non-Hispanic Black/African American	1.74	0.48	0.41	0.13
Cause of Renal Failure				
Diabetes	1.96	0.50	0.50	0.13
Hypertension	1.60	0.46	0.38	0.11
Glomerulonephritis	1.47	0.39	0.38	0.11
Other cause	1.70	0.40	0.47	0.12
Vintage				
<1 year	1.79	0.47	0.49	0.13
1-<2 years	1.70	0.45	0.43	0.10
2-<5 years	1.71	0.47	0.42	0.10
5+ years	1.75	0.45	0.45	0.14

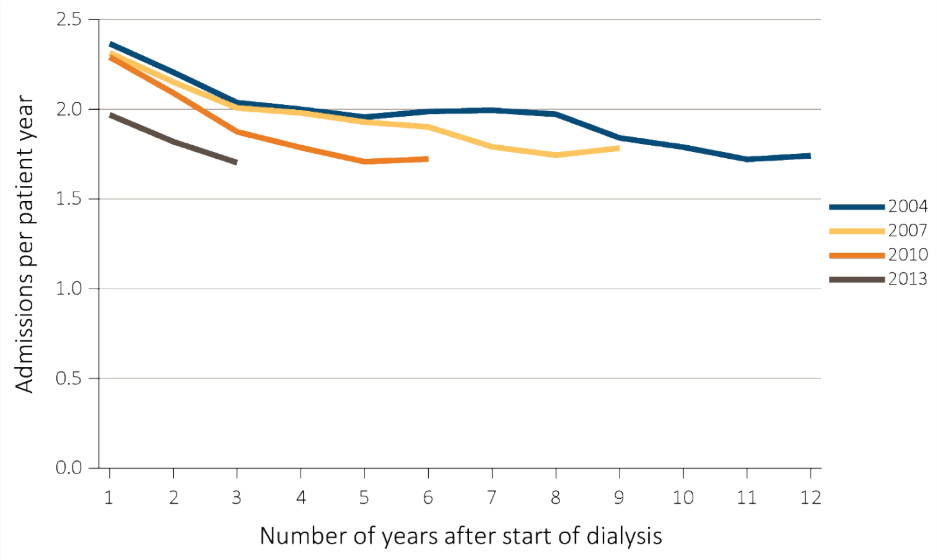
Data Source: Reference Tables G.3, G.13, and special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients aged 22 & older; adjusted for age, sex, race, ethnicity, primary cause of kidney failure, & their two-way interactions. Rates by one factor adjusted for the remaining three; standard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

For patients starting HD, hospitalization rates were highest in their first year but fell considerably through the first three years of HD, before stabilizing (Figure 4.3.a). More recent cohorts of incident HD patients consistently experienced lower hospitalization rates throughout their time on HD than did previous cohorts. Incident HD patients in 2013 had a relatively low hospitalization rate of 1.7 PPY during their first year of treatment, compared to the previous cohorts, who experienced hospitalization rates near 2.3 PPY in the first year of HD (Figure 4.3.a).

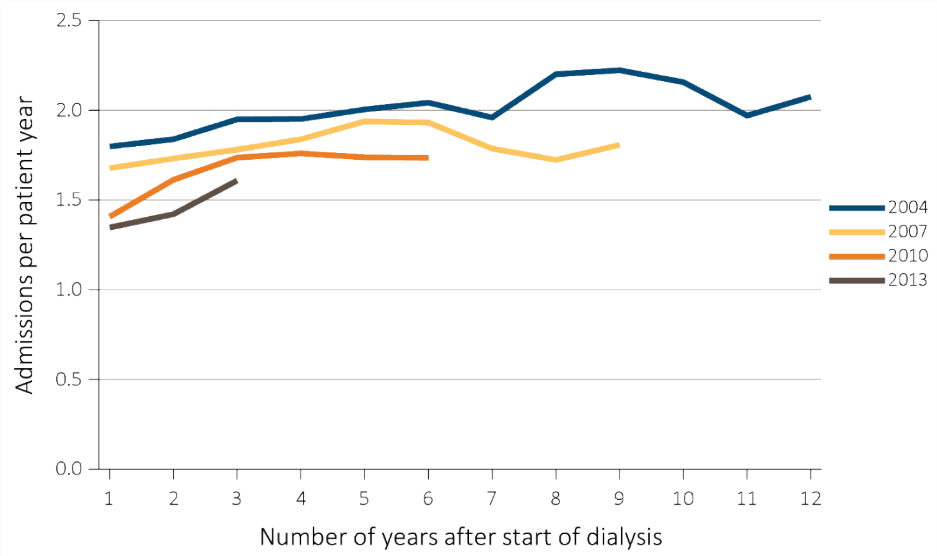
While patients on HD experienced falling hospitalization rates as they accumulated time on dialysis, PD patients saw rising hospitalization rates. However, recent cohorts of incident PD patients still had fewer hospitalizations overall than did the older cohorts. Incident PD patients in 2013 had 1.4 hospitalizations PPY, rising to 1.6 PPY by the third year of PD (Figure 4.3.b).

vol 2 Figure 4.3 Adjusted all-cause hospitalization rates by treatment modality and number of years after start of dialysis, for cohorts of incident patients in 2004, 2007, 2010, and 2013

(a) Hemodialysis patients



(b) Peritoneal dialysis patients

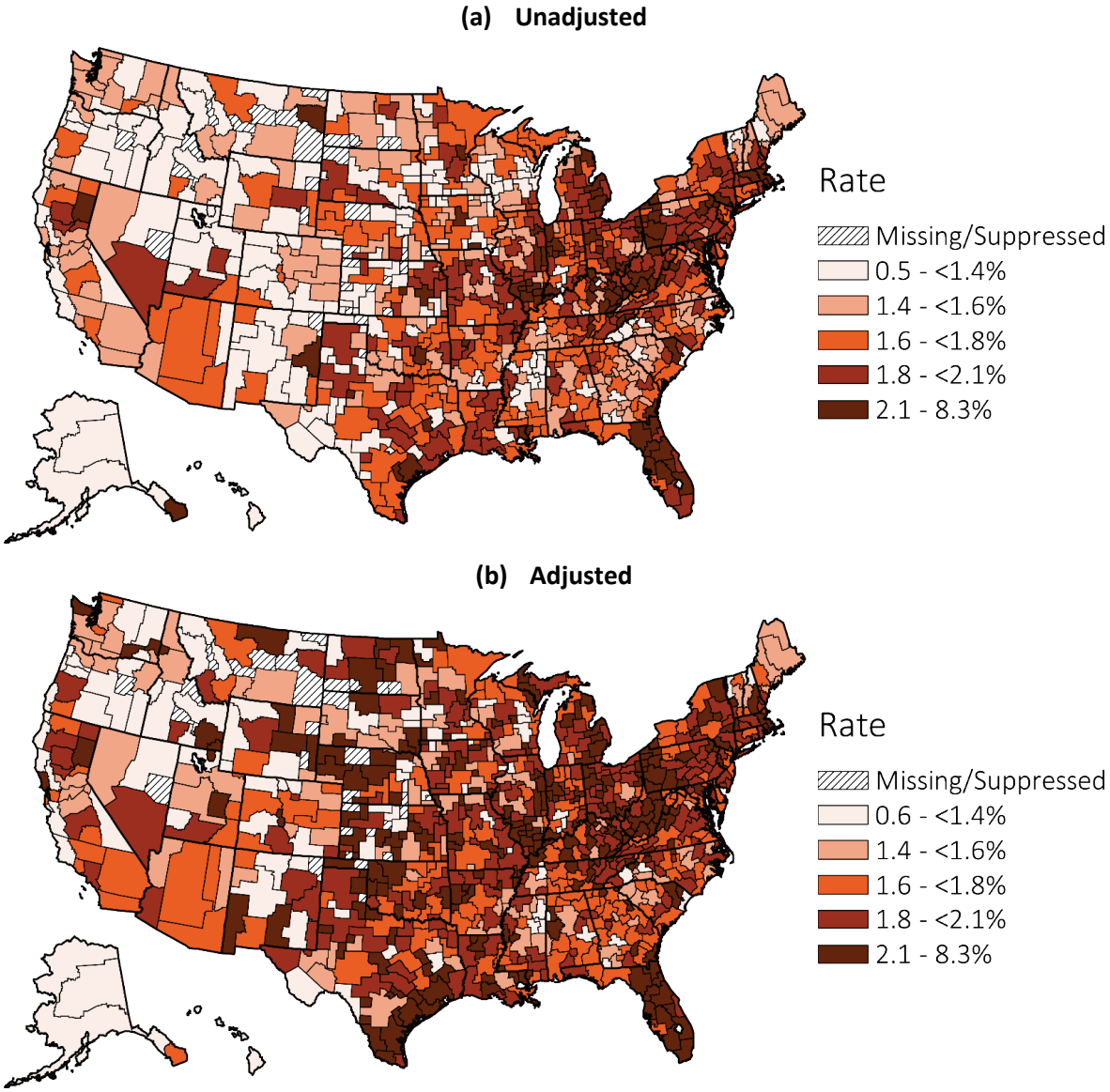


Data Source: Special analyses, USRDS ESRD Database. Period prevalent ESRD patients, adjusted for age, sex, race, ethnicity, primary cause of kidney failure; standard population: ESRD patients, 2011.

The 2014-2015 unadjusted hospitalization rates of patients with ESRD varied considerably across 805 U.S. Health Service Areas (HSAs), from a low of 0.49 PPY in Brookings and Kingsbury counties in South Dakota to a high of 3.20 PPY in McPherson county in Kansas (interquartile range: 0.44 PPY; Figure 4.4.a). The rates were generally highest in a wide band stretching from the Midwest through the Northeast.

It is also important to present these by-HAS rates adjusted for demographic characteristics. This allows for comparisons across HSAs without the effects of the demographic composition of different regions. After adjusting for age, sex, race, ethnicity, primary cause of kidney failure, and vintage, the adjusted hospitalization rates of patients with ESRD in 2014-2015 were more consistent across the HSAs, from a low of 0.56 PPY near Juneau and Sitka in Alaska to a high of 8.25 PPY in Harrison and Robertson counties in Kentucky (interquartile range: 0.54 PPY; Figure 4.4.b). While many differences in the unadjusted rates were attenuated after adjustment, the Rocky Mountain states continued to have generally lower hospitalization rates.

vol 2 Figure 4.4 Map of the hospitalization rates of ESRD, by Health Service Area, in the U.S. population, 2014-2015

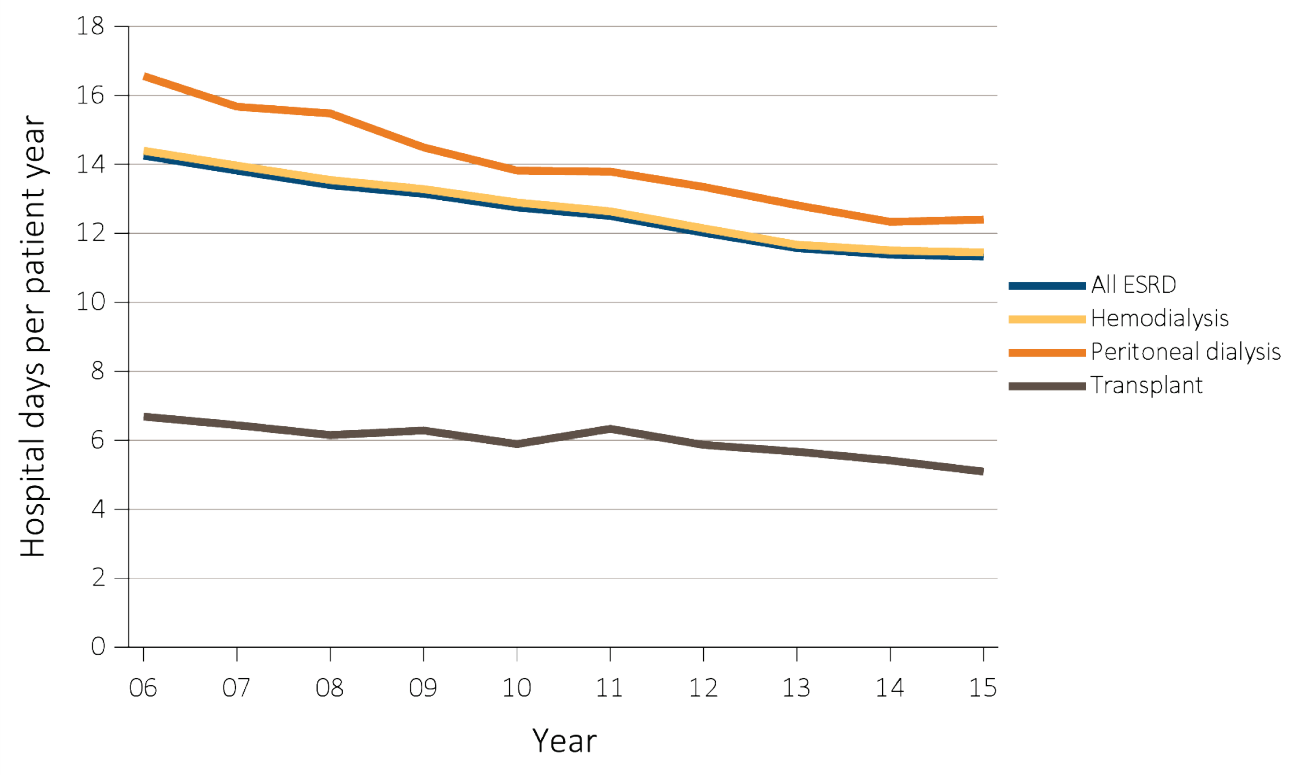


Data Source: Reference Tables G.1, G.3, G.4, G.5, and special analyses, USRDS ESRD Database. Period prevalent ESRD patients; adjusted for age, sex, race, & primary cause of kidney failure; standard population: ESRD patients, 2011. Values for HSAs with 10 or fewer patients are suppressed. Abbreviation: ESRD, end-stage renal disease.

Hospital Days

Continuing a downward trend observed since 2006, the number of total hospital days among all patients with ESRD has decreased from 14.3 PPY to 11.3 PPY (Figure 4.5). From 2006 to 2015, hospital days PPY decreased to 11.4 for HD patients, 12.4 for PD patients, and to 5.1 days for those with a functioning kidney transplant.

vol 2 Figure 4.5 Adjusted hospital days for ESRD patients, by treatment modality, 2006-2015



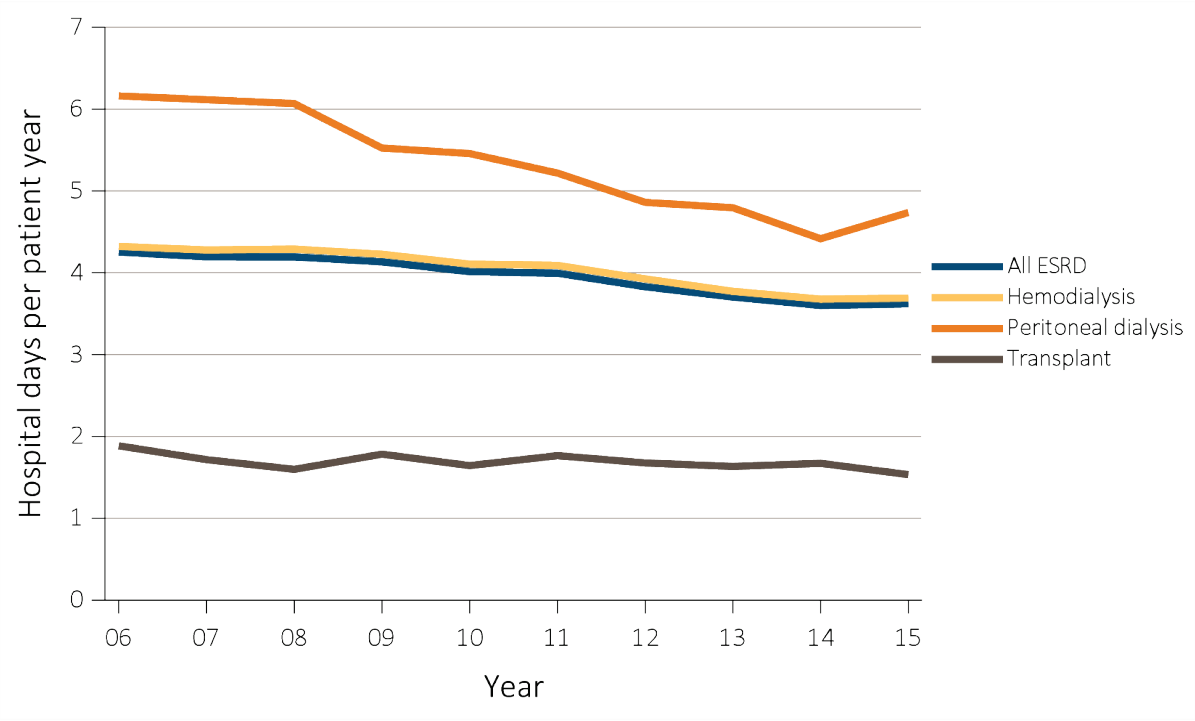
Data Source: Reference Tables G.1, G.3, G.4, G.5, G.6, G.8, G.9, G.10, and special analyses, USRDS ESRD Database. Period prevalent ESRD patients; adjusted for age, sex, race, primary cause of kidney failure, & their two-way interactions. standard population: ESRD patients, 2011. Abbreviation: ESRD, end-stage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

With adjustment for differences in patient characteristics, from 2006-2015 the number of infection-related hospital days decreased by 14.6% for HD patients, 23.1% for those on PD, and by 18.7% for patients with a kidney transplant (Figure 4.6). The number of inpatient days for cardiovascular hospitalization fell by 27.1% for all patients with ESRD, and by 38.2% for those with a transplant.

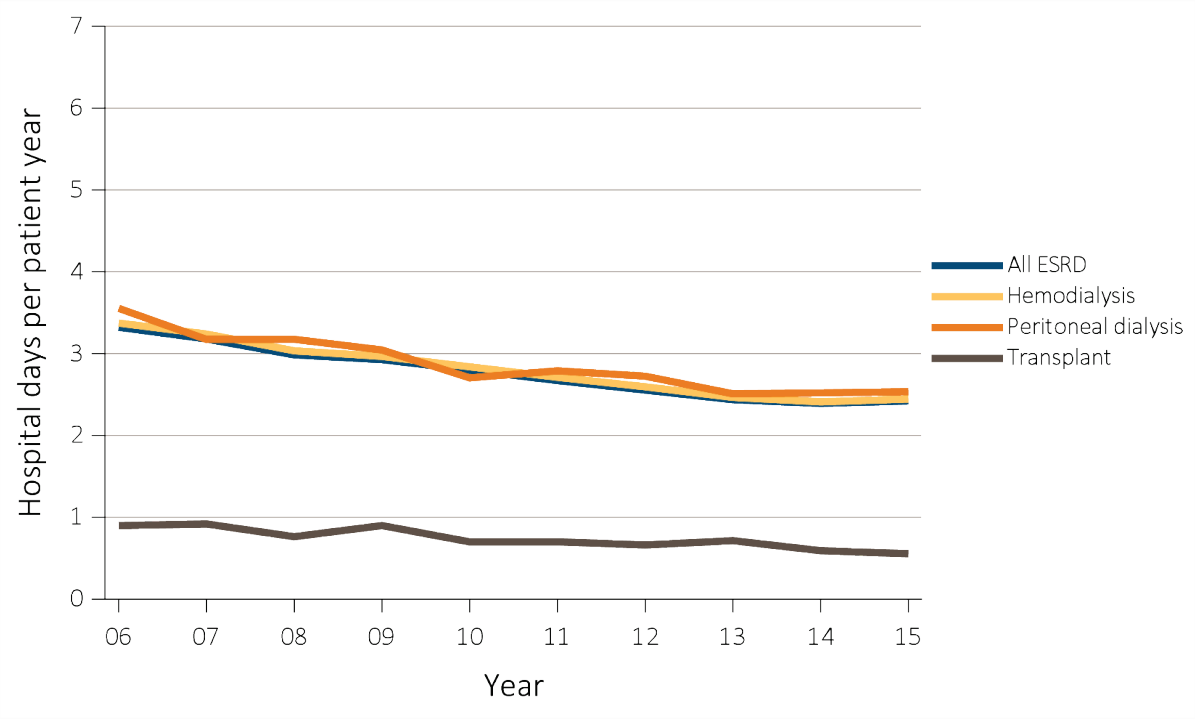
Even after adjustment, the number of hospital days due to infections and cardiovascular events for patients on dialysis were more than twice that of those with a transplant. For HD and PD patients in 2015, infection-related hospital days were 3.7 and 4.7 PPY, compared to 1.5 PPY for transplant recipients. Hospital days for cardiovascular admissions were approximately four times more frequent for patients on dialysis than for those with a transplant—2.4 and 2.5 PPY for HD and PD patients, as compared to 0.6 PPY for transplant recipients.

vol 2 Figure 4.6 Adjusted hospital days for infection & cardiovascular causes, for ESRD patients by their treatment modality, 2006-2015

(a) Infection



(b) Cardiovascular



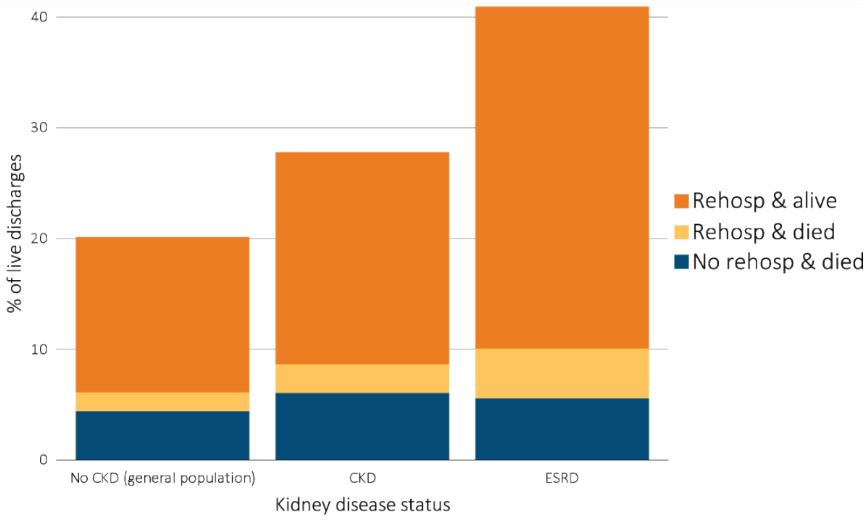
Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients, all ages, 2015; adjusted for age, sex, race, primary cause of kidney failure, & their two-way interactions. Includes live hospital discharges from January 1 to December 1, 2015. Cause-specific hospitalizations 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. 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 emergency room visits and those intended 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 35.2%, as compared to only 15.4% of older Medicare beneficiaries without a diagnosis of kidney disease (Figure 4.7). This held true for the combined outcomes of post-discharge death and/or rehospitalization—experienced by 27.6% of CKD patients and 41.0% of those with ESRD, versus only 20.0% of patients without diagnosed kidney disease.

vol 2 Figure 4.7 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, 2015



Data Source: Special analyses, USRDS ESRD Database and Medicare 5% sample. January 1, 2015 point prevalent Medicare patients aged 66 & older on December 31, 2013. For general Medicare: January 1, 2015 point prevalent, Medicare patients aged 66 & older, discharged alive from an all-cause index hospitalization between January 1, 2015, and December 1, 2014, unadjusted. CKD determined using claims for 2014. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; rehosp, rehospitalization.

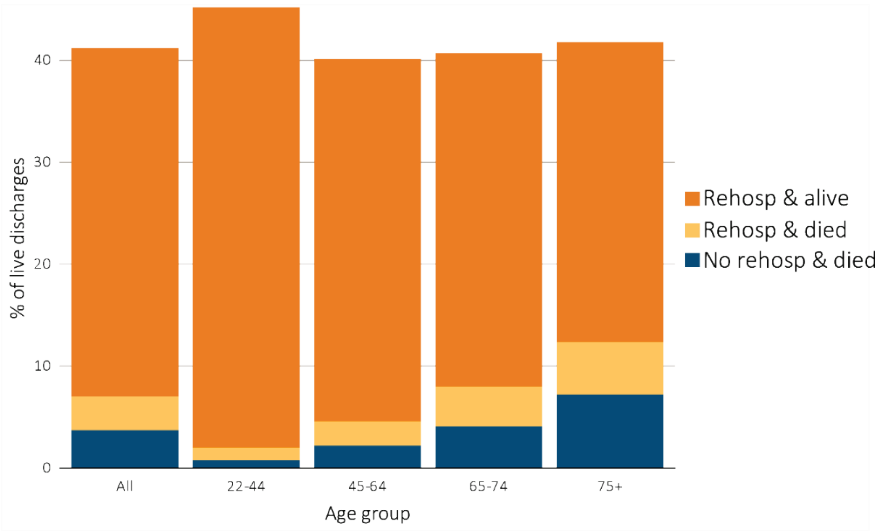
Among HD patients prevalent in 2015, 37.2% of discharges from a hospitalization for any cause were followed by a rehospitalization within 30 days (see Figure 4.8.a). For older patients, rehospitalization rates decreased as their mortality rates increased, illustrating these competing risks, as death precluded the outcome of readmission. Rates of post-discharge death without rehospitalization, for example, were highest in patients aged 75 years and older, at 7.4%, while these patients had the lowest rehospitalization rates, at 34.2%.

The highest rates of rehospitalization with survival occurred for adults aged 22 to 44 years—43.0% of their discharges were followed by a readmission within 30 days. For the two combined outcomes of rehospitalization followed by either survival or death, the highest rates were again seen among patients aged 20–44 years, at 44.2%. The rate of survival following rehospitalization exceeded the two combined death outcomes for all age groups (33.8% vs. 7.2%), even in patients aged 75 and older, at 29.1% and 12.5%. These data illustrate that the observed, elevated rehospitalization rates among younger versus older cohorts were not fully due to the competing risk of mortality in the aged.

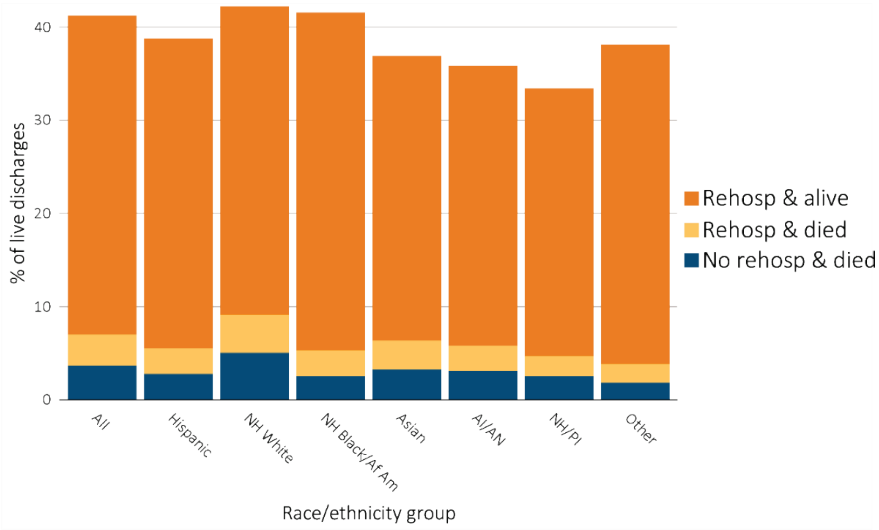
We examined the proportion of HD patients discharged alive who were either rehospitalized or died within 30 days of discharge, by their race and ethnicity (Figure 4.8.b). The highest rates were observed among Blacks—35.8% were rehospitalized and lived while 38.6% were rehospitalized with the combined outcomes of either survival or death. They were followed by the Other or Multiracial group (33.8% vs. 35.9%). The lowest such rates occurred among Native Hawaiians and Pacific Islanders, of whom 28.3% were rehospitalized and lived, and 30.5% were rehospitalized with the combined outcomes of either survival or death. The highest rate of post-discharge death occurred among Non-Hispanic White HD patients at 4.1%, possibly influenced by the older average age among this group.

vol 2 Figure 4.8 Proportion of hemodialysis patients discharged alive from the hospital who either were rehospitalized or died within 30 days of discharge, by demographic characteristics, 2015

(a) By age



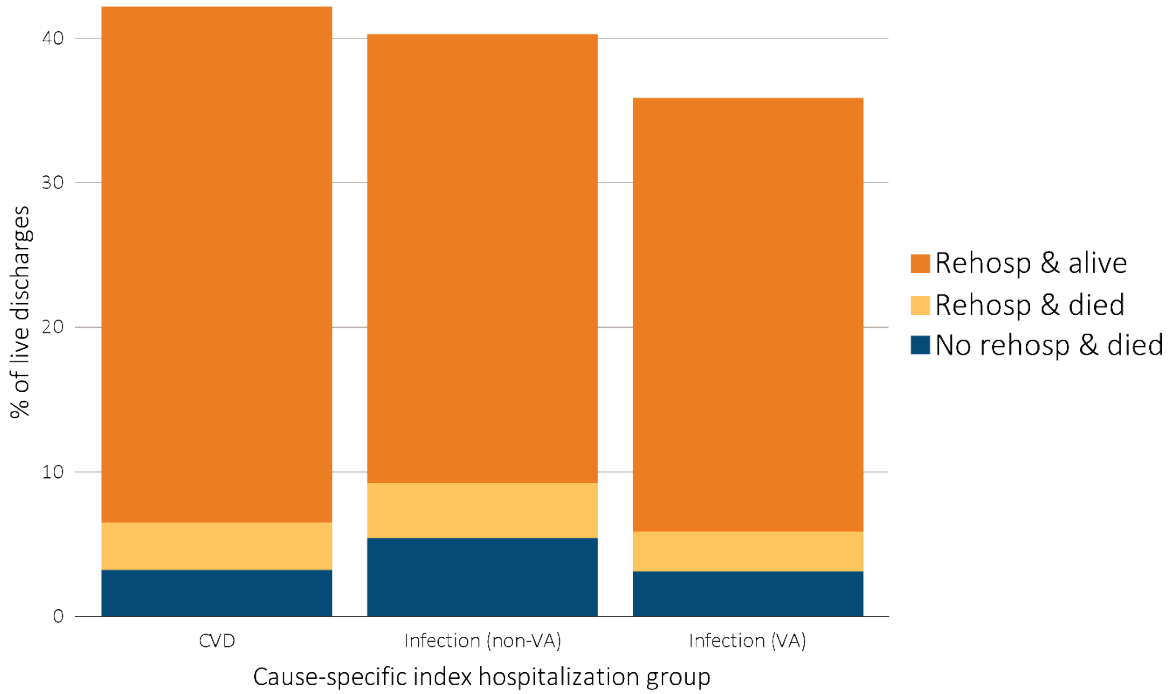
(b) By race/ethnicity



Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients, all ages, 2015, 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, 2015. 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. Af Am, African American; AI, American Indian; AN, Alaska Native; NH, Native Hawaiian; NH Black/Af Am, Non-Hispanic Black/African American; NH White, Non-Hispanic White; Other, other, multiracial, or unidentified race; PI, Pacific Islander; rehosp, rehospitalization.

For HD patients in 2015, the all-cause rehospitalization rate was 37.2% (Figure 4.8.a). For index hospitalizations due to cardiovascular conditions, infections, and vascular access infections, 38.8%, 34.5%, and 32.4% of these patients were rehospitalized within 30 days (see Figure 4.9).

vol 2 Figure 4.9 Proportion of hemodialysis patients discharged alive that either were rehospitalized or died within 30 days of discharge, by cause of index hospitalization, 2015



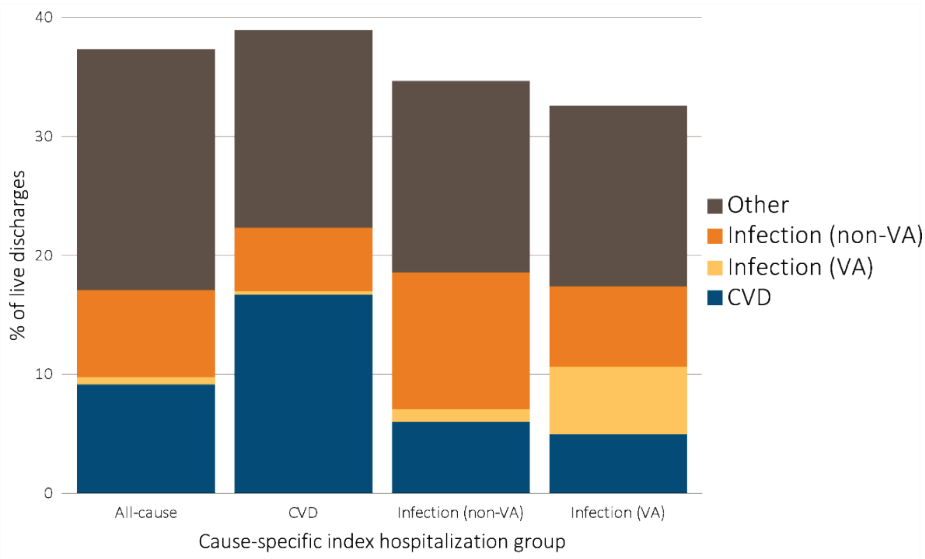
Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients, all ages, 2015, unadjusted. Includes live hospital discharges from January 1 to December 1, 2015. Cause-specific hospitalizations are defined by principal ICD-9-CM codes. See Vol. 2, ESRD Analytical Methods for principal ICD-9-CM diagnosis codes included in each cause of hospitalization category. Abbreviations: CVD, cardiovascular disease; rehosp, rehospitalization; VA, vascular access.

Figure 4.10 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 2015, of those admitted for treatment of cardiovascular issues and then soon rehospitalized, nearly half (43.5%) were admitted to treat the same or another cardiovascular condition. However, this pattern differed for those initially hospitalized to address vascular access infection (17.5%), and other types of infections (33.3%). The proportion of cause-specific readmission among those with all-cause index hospitalization were also fairly low—only 25.1% returned for additional cardiovascular treatment, 1.6% for vascular access infection, and 19.7% 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).

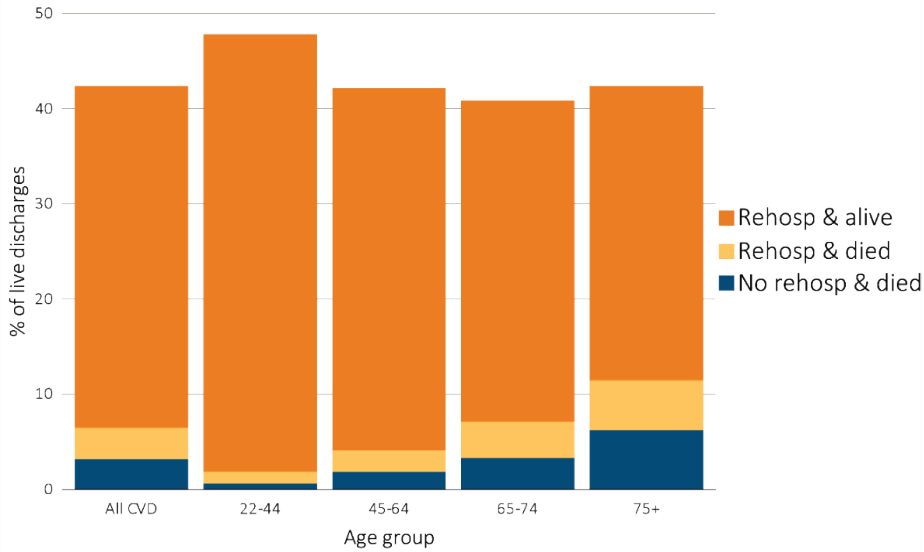
vol 2 Figure 4.10 Proportion of hemodialysis patients with cause-specific rehospitalizations within 30 days of discharge, by cause of index hospitalization, 2015



Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients, all ages, 2015, unadjusted. Includes live hospital discharges from January 1 to December 1, 2015. 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; VA, vascular access.

Rehospitalization rates following discharge from a cardiovascular index hospitalization were slightly higher among younger adults compared with all other age groups, for whom the rehospitalization rates appeared similar. For those aged 22–44, for example, 46.8% of such discharges were followed by a rehospitalization within 30 days (Figure 4.11). In general, these rates mirrored those for all-cause index hospitalizations as seen in Figure 4.8.a, although the rates in Figure 4.11 for those aged 22-44 were slightly higher.

vol 2 Figure 4.11 Proportion of hemodialysis patients discharged alive who were either rehospitalized or died within 30 days of discharge for cardiovascular index hospitalization, by age, 2015

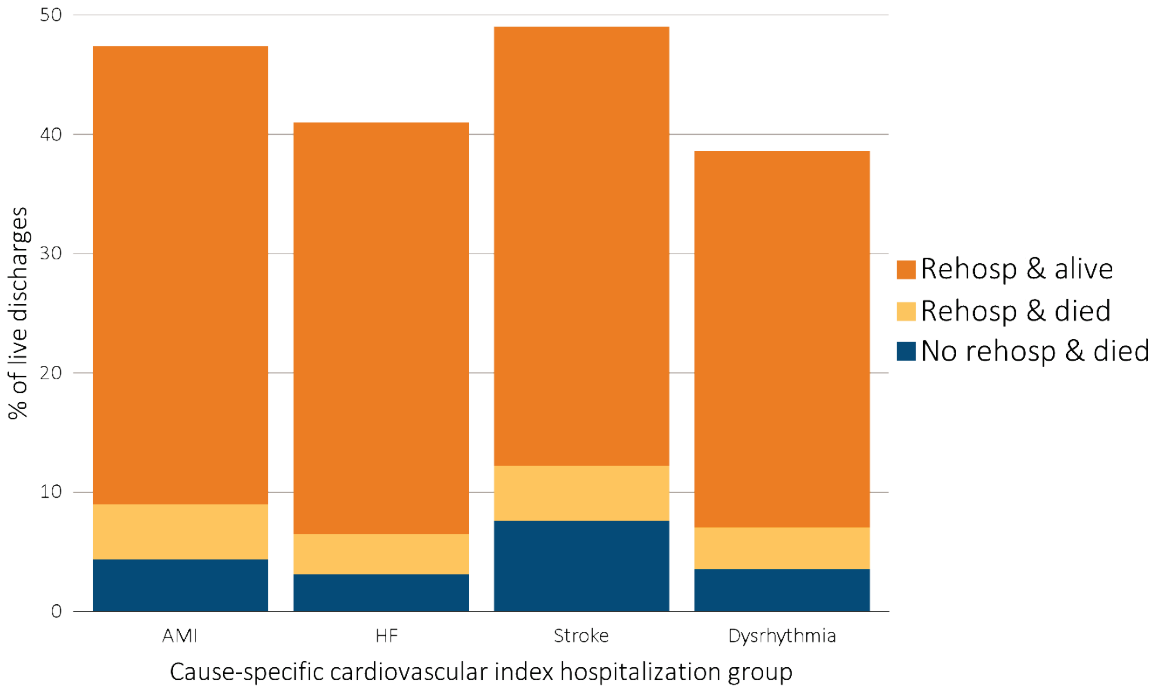


Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients, all ages, 2015, unadjusted. Patients less than age 22 are not represented as a group due to insufficient sample size. Includes live hospital discharges from January 1 to December 1, 2015. Cause-specific hospitalizations 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. Abbreviation: rehosp, rehospitalization.

In subgroups of cardiovascular index hospitalizations (Figure 4.12), rehospitalization occurred most frequently following discharge from treatment of acute myocardial infarction (AMI), at 42.6%, and stroke, at 41.0%. The lowest rates occurred following discharge after dysrhythmia, at 34.6%. When not rehospitalized, stroke patients had the highest post-discharge mortality rate of 7.8%.

As comorbid cardiovascular disease and its complications have a critical interaction with kidney disease of all types, this 2017 ADR features two chapters specifically addressing these issues—Volume 1, Chapter 4 *Cardiovascular Disease in Patients with CKD*, and Volume 2, Chapter 8, *Cardiovascular Disease in Patients with ESRD*.

vol 2 Figure 4.12 Proportion of hemodialysis patients discharged alive who were either rehospitalized or died within 30 days of discharge for cardiovascular index hospitalization, by cause-specific cardiovascular index hospitalization, 2015



Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients, all ages, 2015, unadjusted. Includes live hospital discharges from January 1 to December 1, 2015. 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; HF, heart failure; rehosp, rehospitalization.

References

Coleman EA, Parry C, Chalmers S, & Min SJ. The care transitions intervention: results of a randomized controlled trial. *Archives of Internal Medicine*. 2006, 166(17): 1822-1828.

Medicare Payment Advisory Commission (MedPAC). Report to Congress: Promoting Greater Efficiency in Medicare. http://www.medpac.gov/docs/default-source/reports/Jun07_EntireReport.pdf. Published June 2007. Accessed August 16, 2017.

Rich MW, Beckham V, Wittenberg C, Leven CL, Freedland KE, & Carney RM. A multidisciplinary intervention to prevent the readmission of elderly patients with congestive heart failure. *New England Journal of Medicine.* 1995, 333(18): 1190-1195.

Stewart S, Marley JE, & Horowitz JD. Effects of a multidisciplinary, home-based intervention on planned readmissions and survival among patients with chronic congestive heart failure: a randomised controlled study. *The Lancet. 1999*, 354(9184): 1077-1083.

Notes

Chapter 5: Mortality

- In 2015, adjusted mortality rates for ESRD, dialysis, and transplant patients were 136, 166, and 29 per 1,000 patient-years. By dialysis modality, mortality rates were 169 for hemodialysis (HD) patients and 159 for peritoneal dialysis (PD) patients, per 1,000 patient-years (Figure 5.1).
- Between 2001 and 2015, adjusted mortality rates decreased for dialysis patients by 28%. The net reductions in mortality from 2001 to 2015 were 27% for HD patients and 41% for PD patients (Figure 5.1).
- Between 2001 and 2015, unadjusted (crude) mortality rates decreased by 3% for transplant recipients. After accounting for changes in population characteristics (primarily increasing age), trends in post-transplant mortality were much more pronounced, with adjusted mortality rates decreasing by 40% (Figure 5.1).
- Patterns of mortality during the first year of dialysis differed substantially by modality. For HD patients, reported mortality was highest in month two, but declined thereafter; this effect was more pronounced for patients aged 65 and older. In contrast, mortality for PD patients was relatively low initially, but rose slightly over the course of the year (Figure 5.3).
- The relationship between race and mortality differed considerably by age among dialysis patients. White dialysis patients younger than age 22 had mortality rates comparable to Black/African American patients, but experienced higher mortality than did Blacks of older ages (Table 5.1.a).
- Dialysis patients continued to have substantially higher mortality compared to the general population and Medicare populations with cancer, diabetes, or cardiovascular disease. However, the relative and absolute declines in mortality for dialysis patients in the past 15 years havebeen greater than for Medicare patients in these other diagnostic categories (Tables 6.4 and 6.5, Figure 5.4).
- 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 primary reason for continued growth in the prevalent ESRD population.

Introduction

Kidney disease is among the 10 leading causes of premature mortality in the United States—persons with ESRD have a shortened life expectancy as compared to their peers without kidney disease. Examining trends related to death from this chronic condition is essential to guide and evaluate efforts in reducing the risk of death and increasing potential life span.

There are many points in the life cycle of kidney disease in which to make an impact. These include promoting healthy lifestyle habits, delaying disease progression and the resulting need to initiate renal replacement therapy for compromised individuals, and more widely applying the best practices known to prolong health and quality of life.

In this chapter we examine and highlight the variables that contribute to ESRD mortality. Common chronic comorbidities, particularly cardiovascular diseases, and acute conditions such as infections are linked to higher rates of death. Treatment modality also has an impact—transplant recipients have improved life expectancy as compared to those on dialysis. Increasing length of time on dialysis is also related to higher mortality rates. Regional differences in mortality rates vary substantially, and may indicate avenues for targeted intervention. Thus, attending to the trends and interrelationships between renal disease and mortality is an important component of reducing the public health burden of ESRD.

Methods

The findings presented 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. Details of these are described in the *Data Sources* section of the *ESRD Analytical Methods* chapter.

Mortality analyses in this chapter were based on both end-stage renal disease (ESRD) data and general population data. ESRD data were from the USRDS ESRD Database. General population data were 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 was augmented by Social Security Death Master File data to the extent allowed by regulation (which differs by state).

See the section on Chapter 5 in the *Analytical Methods Used in the ESRD Volume* 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. Note that the reference population for each adjusted rate is described within the footnote of each table or figure; e.g., for Figure 5.1, the reference population consists of period prevalent ESRD patients in 2011. Downloadable Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available on the USRDS website.

Mortality among ESRD Patients: Overall, and by Modality

Overall mortality rates among ESRD (dialysis and transplant) patients have consistently declined over the last 15 years, with rates levelling during recent years. Between 2001 and 2015, the unadjusted death rate (not shown) for the ESRD population decreased by 26%, from 187 to 138 per 1,000 patient-years, while the adjusted death rate (Figure 5.1.a) decreased by 28%. The unadjusted death rate for the dialysis population decreased by 26%, while the adjusted death rate decreased by 28%. The unadjusted death rate for the transplant population decreased by 3%, while the adjusted death rate decreased by 40%.

Differences between the unadjusted and adjusted rates largely reflect changes in the age distribution of the ESRD population. Death rates for dialysis and transplant patients decreased by over 30% between 2001 and 2015 within most age groups, and the adjusted rate reflects this decrease. The unadjusted rate was affected by both this decrease and by the fact that the ESRD population was older in 2015 than in 2001, which offsets the effect. For example, patients over the age of 65 comprised 44% of the dialysis population in 2001 and 46% in 2015; in the same years, transplant recipients received dialysis at 11% and 27%. Thus, the very large increase in age among transplant patients masked overall improvements in mortality.

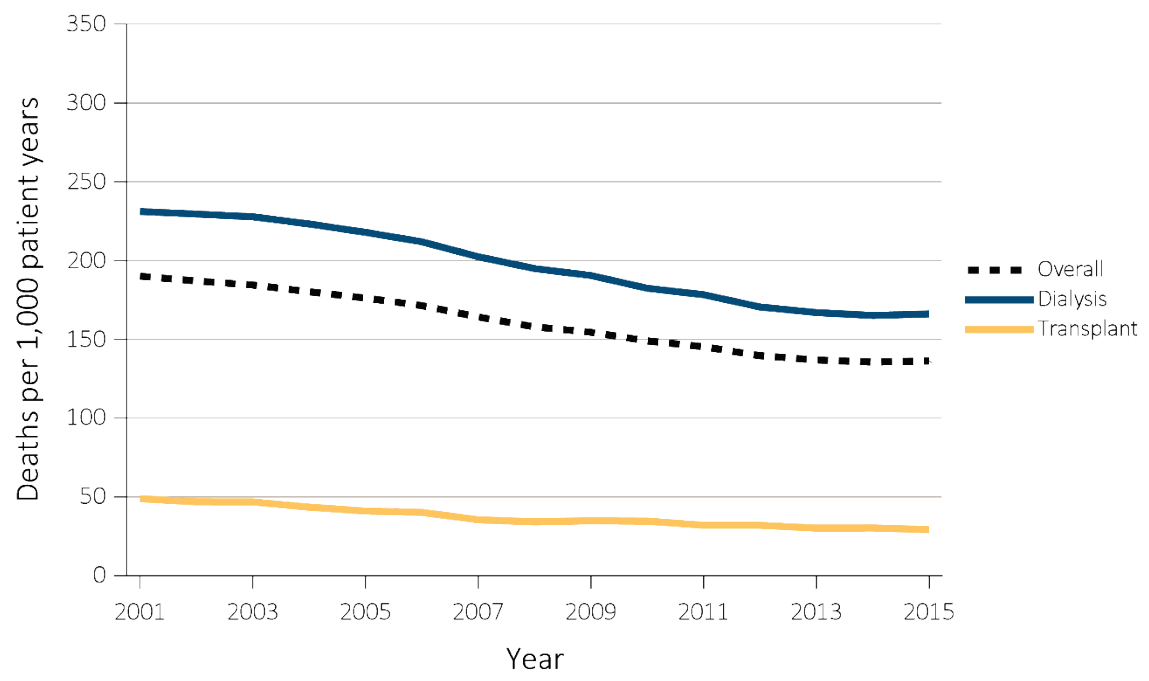
From 2001 to 2006, the adjusted mortality rate decreased by 10%, and by 17% from 2007 to 2015 for the ESRD population (Figure 5.1.a). The trend was similar for dialysis (HD and PD) patients, with the adjusted mortality rate decreasing by 8% from 2001 to 2006 and by 18% from 2007 to 2015 (Figure 5.1.b). Among transplant patients, adjusted mortality decreased by 18% from 2001 to 2006 and by 18% from 2007 to 2015.

Among HD patients, the adjusted mortality rate decreased by 7% from 2001 to 2006 and by 17% from 2007 to 2015. Among PD patients, the mortality rate decreased by 20% from 2001 to 2006 and by 19% from 2007 to 2015 (Figure 5.1.b). The net reductions in mortality from 2001 to 2015 were 27% for HD patients and 41% for PD patients.

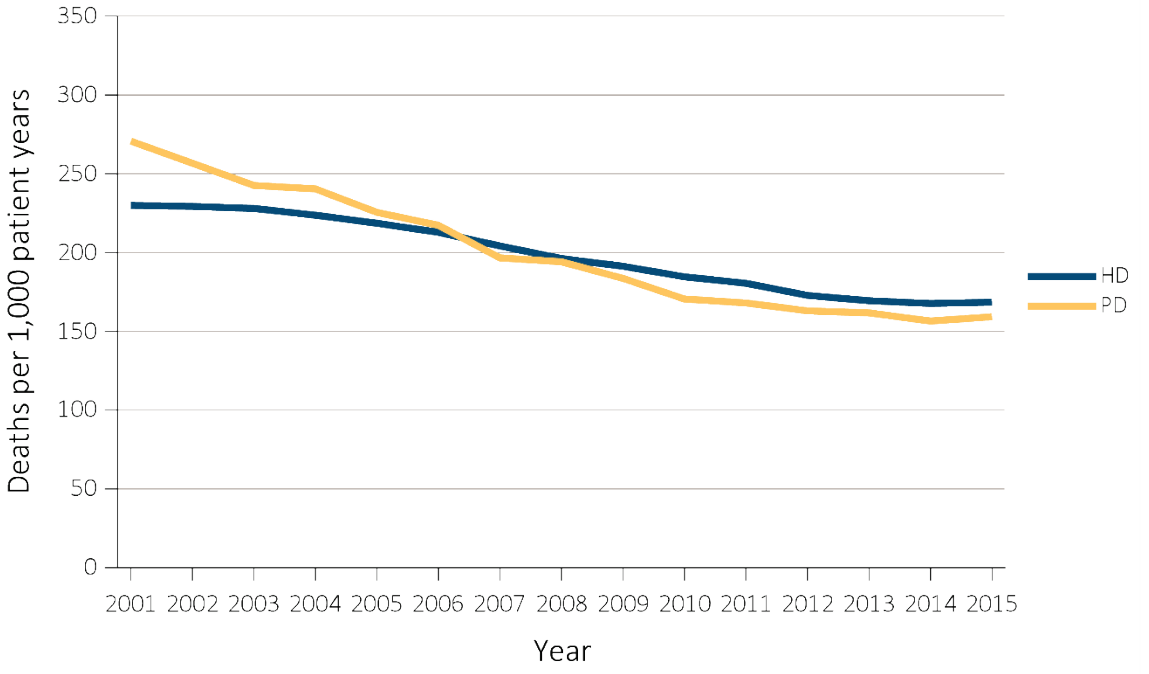
Adjusted mortality rates in 2015 were 136, 166, and 29 per 1,000 patient-years for ESRD, dialysis, and transplant patients. By dialysis modality, mortality rates were 169 per 1,000 patient-years for HD patients and 159 for PD patients.

vol 2 Figure 5.1 Adjusted all-cause mortality by treatment modality (a) overall, dialysis, and transplant, and (b) hemodialysis and peritoneal dialysis, for period-prevalent patients, 2001-2015

(a) Overall, dialysis, and transplant



(b) Hemodialysis and peritoneal dialysis



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.

Mortality by ESRD Network

There are geographic differences in mortality rates for each modality. Table 5.1 shows adjusted and unadjusted death rates within each of the 18 regional ESRD networks in the United States. The between-network variability was lower after adjustment for age, ethnicity, race, sex, diagnosis, and vintage, indicating that regional differences in these factors explain some, but not all of the between-region differences in mortality rates.

Variation in ESRD mortality rates among the 18 ESRD Networks remained substantial (Table 5.1). Adjusting for differences in age, sex, race, ethnicity, prognosis, and vintage, the rate was lowest at 124.2 per 1,000 patient-years at risk in Network 15 (AZ, CO, NV, NM, UT, and WY), and highest at 159.3 in Network 13 (AR, LA, and OK), 28% higher than Network 15.

vol 2 Table 5.1 Unadjusted and adjusted all-cause mortality by ESRD network and modality, 2013-2015

		Deaths per 1,000 patient-years							
		Total ESRD		Hemodialysis		Peritoneal dialysis		Transplant	
Network	States in Network	Adjusted	Unadjusted	Adjusted	Unadjusted	Adjusted	Unadjusted	Adjusted	Unadjusted
1	CT, MA, ME, NH, RI, VT	126.3	133.9	158.4	202.7	166.6	158.7	29.7	35.0
2	NY	128.1	130.3	157.9	177.1	133.4	121.7	27.2	29.2
3	NJ, PR	144.7	141.7	181.6	190.0	164.8	119.9	30.3	33.7
4	DE, PA	137.8	155.5	174.3	217.9	166.2	160.8	28.8	35.6
5	MD, DC, VA, WV	135.7	136.1	171.2	183.3	158.3	119.9	31.5	35.5
6	NC, SC, GA	141.1	135.2	173.2	170.6	165.2	128.0	29.5	30.9
7	FL	142.7	154.3	180.3	204.8	166.8	143.0	28.7	32.7
8	AL, MS, TN	151.2	149.0	184.7	187.8	182.0	141.1	35.0	37.2
9	IN, KY, OH	147.1	162.8	180.4	220.4	175.7	162.8	31.5	36.3
10	IL	133.5	135.7	170.6	189.2	168.4	151.7	27.2	29.8
11	MI, MN, ND, SD, WI	131.8	138.2	168.1	204.4	164.2	159.8	31.0	37.3
12	IA, KS, MO, NE	135.3	144.4	173.2	210.4	172.6	168.9	29.1	34.8
13	AR, LA, OK	159.3	156.1	199.3	199.5	171.0	138.5	33.6	38.3
14	TX	145.2	134.5	176.1	170.1	165.5	122.7	30.9	30.0
15	AZ, CO, NV, NM, UT, WY	124.2	125.9	159.1	175.5	149.0	137.5	28.7	33.1
16	AK, ID, MT, OR, WA	126.2	125.3	159.0	187.1	139.5	123.8	27.5	32.4
17	Northern CA, HI, GU, AS	124.6	118.4	156.7	161.3	136.8	106.8	24.2	25.8
18	Southern CA	128.4	122.6	155.8	160.1	133.1	96.4	25.9	26.1
	Overall	136.6	138.3	169.9	186.3	159.5	133.9	29.3	32.8

Data Source: Special analyses, USRDS ESRD Database. Adjusted (age, sex, race, ethnicity, vintage, and primary diagnosis) all-cause mortality among 2013-2015 period prevalent patients. Reference population: period prevalent ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease.

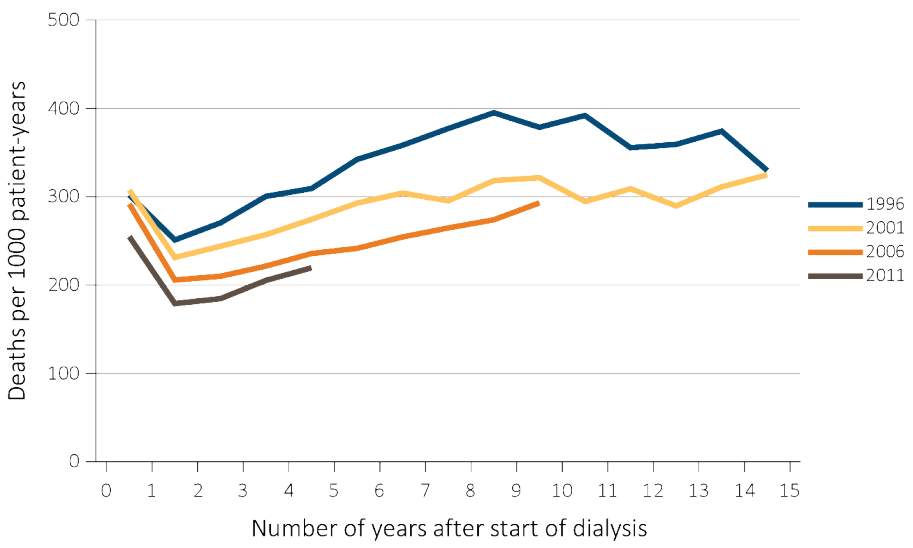
Mortality by Duration of Dialysis, Including Trends over Time

Among HD patients, from 1996-2011 the average death rate was highest during the first year following dialysis initiation, dropped to its lowest point during the second year, and tended to rise for more than five years thereafter (Figure 5.2.a). Mortality on HD tended to be higher after five years than between two to five years after dialysis initiation. Death rate patterns by time-since-dialysis-initiation have been similar over time, when comparing cohorts based on calendar year of treatment initiation.

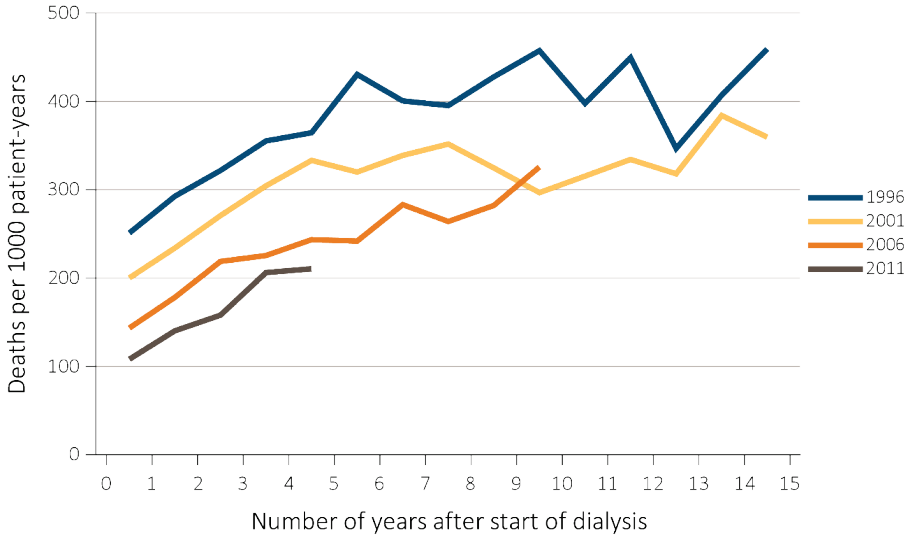
Among PD patients, mortality rates generally increased over the first five years after dialysis initiation (Figure 5.2.b). As with HD patients, PD patient mortality rates tended to be higher after five years than between two to five years on dialysis. Death rate patterns by time-since-dialysis-initiation have also been similar over time for PD patients.

vol 2 Figure 5.2 Adjusted all-cause mortality 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

(a) Hemodialysis patients



(b) Peritoneal dialysis patients



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 HD in 2014, the decrease in mortality during the first year was sharper for patients aged 65 and over (Figure 5.3); this pattern is similar to that previously reported by Robinson et al. (2014). Among patients under the age of 65, mortality dropped from 208 deaths per 1,000 patient-years in month 2 to 122 in month 12. Among patients aged 65 and over, mortality dropped from 644 deaths per 1,000 patient-years in month 2 to 310 in month 12. Note that the steep rise in HD mortality rates between months 1 and 2 may reflect data reporting issues. For example, some patients who die soon after starting dialysis related to ESRD might not be registered as having ESRD on CMS Form 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 PD as the initial renal replacement modality, mortality did not peak early, but instead tended to increase gradually during the first year on dialysis. Among PD patients under the age of 65, mortality increased from 37 deaths per 1,000 patient-years in month 1 to 71 in month 12. Among patients aged 65 and over, mortality increased from 152 deaths per 1,000 patient-years in month 1 to 215 in month 12. PD patients may not experience an early peak in mortality, in part, because patients beginning ESRD via PD are a highly selected group, in many cases being younger, healthier, and having undergone substantial pre-ESRD planning, most often associated with an elective start of dialysis. Post-transplant mortality among the less than 2% of patients who initiated ESRD treatment with a kidney transplant peaked in month 4, followed by a generally decreasing trend for the remainder of the first year (not shown).

vol 2 Figure 5.3 Adjusted mortality by treatment modality and number of months after treatment initiation among ESRD patients (a) under age 65 and (b) aged 65 and over, 2014

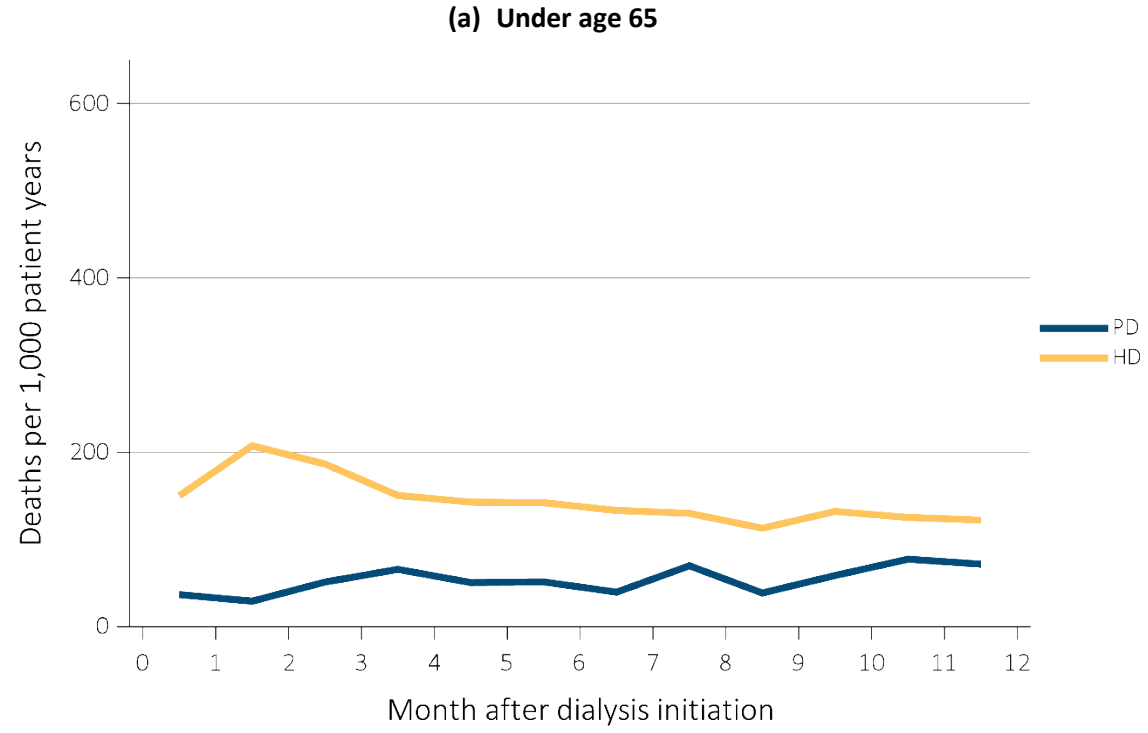
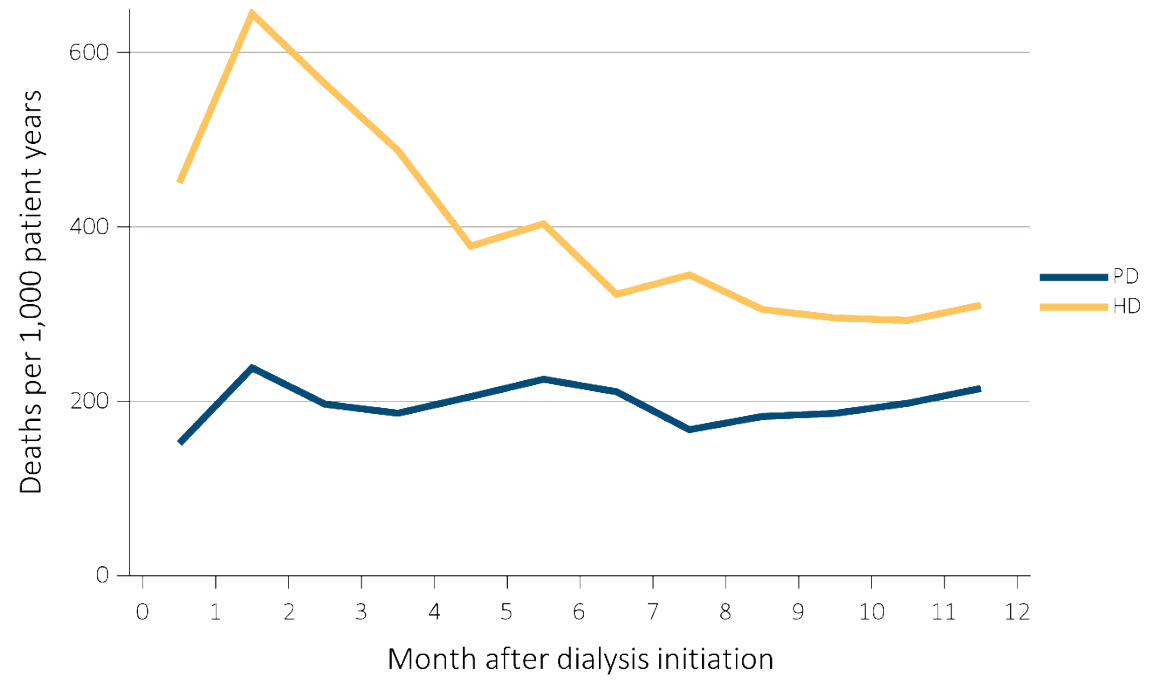


Figure 5.3 continued on next page.

vol 2 Figure 5.3 Adjusted mortality by treatment modality and number of months after treatment initiation among ESRD patients (a) under age 65 and (b) aged 65 and over, 2014 *(continued)*

(b) Aged 65 and older



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, Sex, and Race

Mortality rates among ESRD patients increase with age, as expected. Among dialysis and transplant patients, males aged 0-44 years tended to have lower adjusted mortality than females, but higher adjusted mortality at ages 65 and over (Table 5.2.b).

Mortality rates differed by race, but this difference was not constant within age groups or by modality (Table 5.2.a). For example, among patients aged 0-22 years, White patients on dialysis had comparable mortality rates to Blacks/African Americans. However, Black patients older than 22 years had a consistent survival advantage compared to Whites. In the case of transplant patients over the age of 45, mortality rates tended to be similar between Whites and Blacks. As demonstrated by Yan et al. (2013), Hispanics had mortality rates similar to other non-White race groups. Therefore, combining them with non-Hispanic Whites resulted in lowering the otherwise higher mortality rate observed among the non-Hispanic White population on dialysis.

vol 2 Table 5.2 Adjusted all-cause mortality (a) by age and race, and (b) by age and sex, among ESRD patients, 2015

(a) Age and race (deaths per 1,000 patient-years)

Age	Race	ESRD	Dialysis	Transplant
0-21	White	10	32	5
	Black/African American	18	37	6
	Other	8	23	6
22-44	White	33	64	10
	Black/African American	44	56	12
	Other	18	36	5
45-64	White	110	159	37
	Black/African American	100	115	37
	Other	74	103	22
65-74	White	211	253	86
	Black/African American	175	189	84
	Other	142	166	62
75+	White	358	379	141
	Black/African American	272	278	148
	Other	235	244	113

(b) Age and sex (deaths per 1,000 patient-years)

Age	Sex	ESRD	Dialysis	Transplant
0-21	Male	10	32	4
	Female	12	34	5
22-44	Male	34	57	10
	Female	39	67	11
45-64	Male	106	144	39
	Female	109	148	33
65-74	Male	208	249	88
	Female	198	227	79
75+	Male	359	382	147
	Female	330	344	131

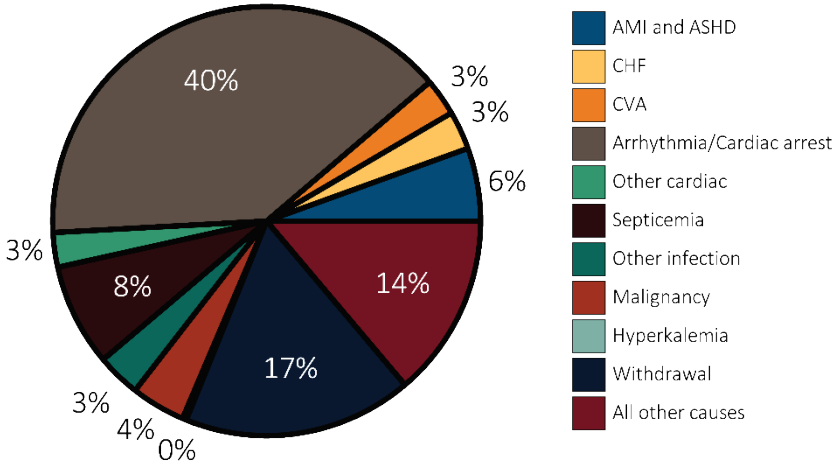
Data Source: Special analyses, USRDS ESRD Database. (a) Adjusted (race and primary diagnosis) all-cause mortality among 2015 period prevalent patients. (b) Adjusted (sex and primary diagnosis) all-cause mortality among 2015 period prevalent patients. Reference population: period prevalent ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease.

Cause-Specific Mortality Rates

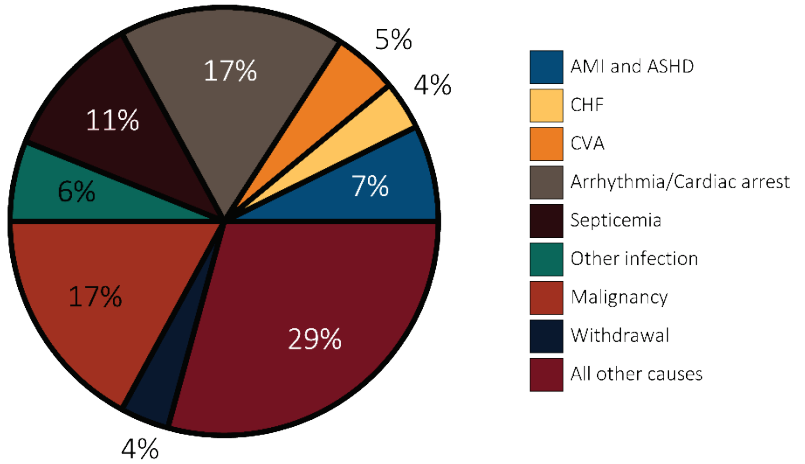
The largest category of known cause-specific mortality for dialysis patients is death due to cardiovascular disease. Arrhythmia and cardiac arrest comprised 40% of known causes of death among dialysis patients, and 17% of the known causes of death among transplant recipients. The cause of death information (based on CMS Form 2746) was missing or unknown for 26% of dialysis patients and 74% of transplant patients. Figures 6.4.a and 6.4.b show the distributions of deaths in 2014 including missing and unknown causes as categories, while Figures 6.4.c and 6.4.d show the distributions excluding deaths where the causes were missing or unknown. Cardiovascular causes—including arrhythmias, cardiac arrest, congestive heart failure (CHF), acute myocardial infarction (AMI), and atherosclerotic heart disease (ASHD)—were responsible for 48% of deaths among dialysis patients and 28% of deaths among transplant recipients. Given these rates, it is plausible that cardiovascular conditions (e.g., sudden cardiac death due to cardiac arrhythmia) may indeed have been the true underlying cause of death among many patients in the missing and unknown categories.

vol 2 Figure 5.4 Unadjusted percentages of deaths in 2014 by cause, with and without missing data, by modality among dialysis patients and transplant recipients

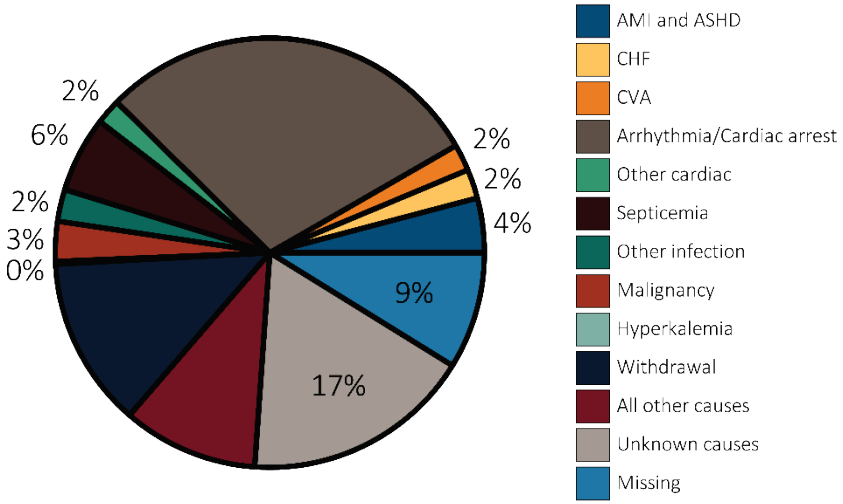
(a) Dialysis patients, denominator excludes missing/unknown causes of death



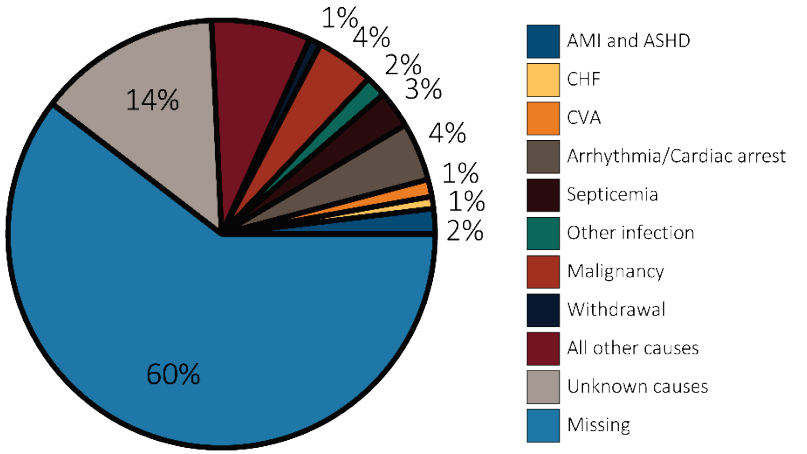
(b) Transplant patients, denominator excludes missing/unknown causes of death



(c) Dialysis patients, denominator includes missing/unknown causes of death



(d) Transplant recipients, denominator includes missing/unknown causes of death



Data Source: Special analysis using Reference table H.12_Dialysis and H.12_Tx. Mortality among 2014 prevalent patients. (a) Dialysis patients, denominator excludes missing/unknown causes of death. (b) Transplant recipients, denominator excludes missing/unknown causes of death. (c) Dialysis patients, denominator includes missing/unknown causes of death. (d) Transplant recipients, denominator includes missing/unknown causes of death. Abbreviations: ASHD, atherosclerotic heart disease; AMI, acute myocardial infarction; CHF, congestive heart failure; CVA, cerebrovascular accident.

Survival Probabilities for ESRD Patients

Survival has improved between the 2002 and 2010 incident ESRD cohorts for all modalities. For example, five-year survival rose from 36% to 42% among HD patients, from 42% to 52% among PD patients, from 69% to 76% among deceased donor transplant patients, and from 77% to 88% 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 HD patients who were incident in 2010 is only 57% at three years after ESRD onset (Table 5.3). For PD patients, adjusted survival is 68% at three years. For deceased-donor and living-donor recipients, three- year survival is 85% and 93% respectively.

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

vol 2 Table 5.3 Adjusted survival by treatment modality and incident cohort year (year of ESRD onset)

	3 months (%)	12 months (%)	24 months (%)	36 months (%)	60 months (%)
Hemodialysis					
2002	91.2	75.0	61.4	51.0	36.0
2004	91.1	75.2	62.3	52.1	37.5
2006	91.3	75.9	63.5	53.7	39.1
2008	91.6	76.9	64.9	55.2	40.6
2010	91.8	77.8	66.2	56.8	41.8
Peritoneal dialysis					
2002	95.8	82.8	68.2	56.9	41.5
2004	96.2	85.0	71.9	60.8	45.7
2006	97.0	86.7	74.0	62.7	47.5
2008	97.5	88.6	76.5	66.4	50.4
2010	97.4	89.3	77.8	67.6	51.7
Deceased-donor transplant					
2002	95.0	89.8	84.3	79.3	68.5
2004	96.2	90.5	85.4	79.7	69.7
2006	96.0	91.4	86.9	82.7	72.6
2008	96.8	92.7	88.5	84.4	74.4
2010	97.2	93.1	89.3	85.4	75.6
Living-donor transplant					
2002	97.5	94	89.8	85.9	77.4
2004	98.3	95.3	92.1	88.6	81.4
2006	98.7	96.3	93.7	90.8	83.6
2008	98.6	96.8	94.4	91.4	85.7
2010	99.2	97.5	95.8	93.0	87.6

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 were striking (Table 5.4). Dialysis patients younger than 80 years old were expected to live less than one-third as long as their counterparts without ESRD, and dialysis patients aged 85 years and older were expected to live around one-half as long as their counterparts without ESRD. Transplant patients fared considerably better, with expected remaining lifetimes for people under the age of 75 estimated at 68% to 84% of expected lifetimes in the general population.

vol 2 Table 5.4 Expected remaining lifetime (years) by age, sex, and treatment modality of prevalent dialysis patients and transplant patients, and the general U.S. population, 2014

	ESRD patients 2014				General U.S. population 2014	
	Dialysis		Transplant			
Age	Male	Female	Male	Female	Male	Female
0-14	23.8	23.1	59.3	60.3	70.7	75.4
15-19	21.8	19.1	47.6	48.7	59.7	64.4
20-24	18.8	16.1	43.4	44.5	55.0	59.5
25-29	16.2	14.1	39.4	40.7	50.3	54.6
30-34	14.1	12.6	35.1	36.6	45.7	49.7
35-39	12.6	11.5	31.1	33.0	41.0	45.0
40-44	11.0	10.3	27.2	28.9	36.5	40.3
45-49	9.3	8.8	23.3	25.2	32.0	35.6
50-54	7.9	7.7	19.9	21.8	27.7	31.1
55-59	6.6	6.6	16.7	18.4	23.7	26.8
60-64	5.5	5.7	13.9	15.4	19.9	22.6
65-69	4.6	4.8	11.4	12.7	16.2	18.6
70-74	3.8	4.0	9.4	10.3	12.8	14.8
75-79	3.2	3.5	7.6[a]	8.6[a]	9.8	11.4
80-84	2.6	2.9			7.1	8.4
85+	2.1	2.3			3.8	4.4

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 (2017)." Expected remaining lifetimes (years) of the general U.S. population and of period prevalent dialysis and transplant patients. [a]Cell 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 ESRD-free population eligible for Medicare coverage while under the age of 65 tends to be non-representative of the general population under the age of 65. For this reason, Table 5.6 focuses on comparisons between the ESRD population and the general Medicare population using age groups beginning at age 65, where the Medicare population is more representative. Male dialysis patients over the age of 75 years experienced mortality rates 3.7 times higher than their peers in the general Medicare population; the mortality rate for female dialysis patients was 3.8 times higher (Table 5.5). Among kidney transplant patients aged 65-74, mortality rates were 2.4-3.3 times higher than for the general Medicare population, and 1.3-1.4 times higher for those aged 75 and older.

vol 2 Table 5.5 Adjusted mortality (deaths per 1,000 patient-years) by age, sex, treatment modality, and comorbidity among ESRD patients and the general Medicare population, 2014

Age	Sex	Dialysis	Transplant	All Medicare	Cancer	Diabetes	CHF	CVA/TIA	AMI
65-74	Male	223	66	27	73	40	112	72	87
	Female	211	60	18	64	31	101	57	94
75+	Male	338	126	92	140	112	238	168	210
	Female	317	105	84	132	103	228	155	207

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 2014. 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.

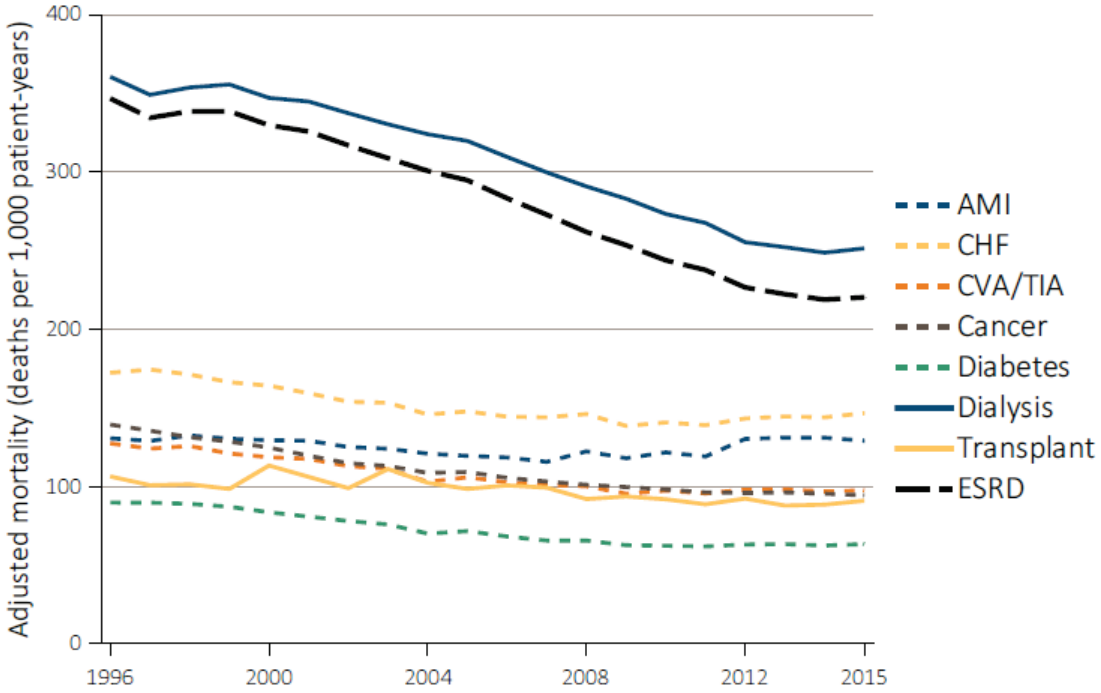
Comparison to Comorbidity-Specific Medicare Patients

From 1996 to 2015, adjusted mortality among ESRD patients aged 65 years and older declined by 36%, from 347 to 220 per 1,000 patient-years (Figure 5.5). Among dialysis patients, adjusted mortality fell 30%, from 361 to 251. Among transplant patients, adjusted mortality fell 15%, from 106 to 91. The decline in mortality for dialysis patients was greater than for heart failure (HF), cerebrovascular accident/transient ischemic attack (CVA/TIA), and acute myocardial infarction (AMI). Adjusted mortality fell 32% for patients with cancer and 29% for patients with diabetes mellitus (DM), but had a lower reduction for cardiovascular conditions, at 15% for HF, 24% for CVA/TIA, and 1% for AMI.

Note that in this year's Annual Data Report (ADR), Figure 5.4 was standardized based only on racial categories that were unaffected by the 2005 change in the CMS Form 2728. In prior ADRs, the trajectory of the standardized results was artificially affected in 2005 because the definitions of some racial categories (e.g. unknown, other) had changed in the new version of the data collection form.

In 2014, mortality rates among dialysis patients aged 65 years and older ranged from 1.7 times higher than for HF patients without kidney disease, to 4.0 times higher than patients with DM, but no ESRD. For transplant patients aged 65 and older, the mortality rate was within the same range as Medicare patients with the other listed conditions.

vol 2 Figure 5.5 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, 1996-2015



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.

References

Foley RN, Chen SC, Solid CA, Gilbertson DT, Collins AJ. Early mortality in patients starting dialysis appears to go unregistered. *Kidney Int* 2014;86(2):392-398.

National Center for Health Statistics. National Vital Statistics Reports. Table 7. Life expectancy at selected ages, by race, Hispanic origin, race for non-Hispanic population, and sex: United States, 2013. 2016;64(2):30. http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_02.pdf. Accessed September 13, 2016.

Robinson BM, Zhang J, Morgenstern H, Bradbury BD, Ng LJ, McCullough KP, Gillespie BW, Hakim R, Rayner H, Fort J, Akizawa T, Tentori F, Pisoni RL. Worldwide, mortality risk is high soon after initiation of hemodialysis. *Kidney Int* 2014; 85(1):158-65.

Social Security Administration. Period Life Table, 2013. Estimates from the 2016 Trustees Report. https://www.ssa.gov/oact/STATS/table4c6.html. Accessed September 9, 2016.

Yan G, Norris KC, Yu AJ, Ma JZ, Greene T, Yu W, Cheung AK. The relationship of age, race, and ethnicity with survival in dialysis patients. *Clin J Am Soc Nephrol* 2013;8(6):953-961.

Chapter 6: Transplantation

- In this 2017 Annual Data Report (ADR) we introduce a new chapter feature with data on outcomes following wait listing for patients, as a function of their age, blood type, and percent of panel reactive antibodies (PRA; Table 6.2).
- In addition, this year we highlight any relevant trends that may have resulted from the December 2014 changes to the kidney allocation system (KAS) policy. As this chapter only includes data through the end of 2015, we cannot yet fully evaluate the impact of the policy on longer-term outcomes.
- In 2015, 18,805 kidney transplants were performed in the United States (18,021 were kidney-alone; Figure 6.5).
- One-third of kidneys transplanted in 2015 were from living-donors (Figure 6.5).
- From 2014 to 2015, the cumulative number of recipients with a functioning kidney transplant increased by 3%, to a total of 207,810 (Figure 6.6)
- On December 31, 2015, the kidney transplant waiting list had 83,978 candidates on dialysis, 52,703 (62.8%) of whom were active. Eighty-four percent of all candidates were awaiting their first transplant (Figure 6.1).
- Among 2010 candidates newly wait-listed for either a first or repeat kidney-alone transplant (living or deceased-donor), the median waiting time to transplant was 3.9 years (Figure 6.4). This waiting time varied greatly by region of the country, from a low of 1.2 years in Utah to a high of 5.2 years in Georgia (Reference Table E.2.2).
- Unadjusted rates of kidney transplantation among dialysis patients had been declining since at least 2006 for candidates for both living and deceased-donors. These appear to have stabilized as of 2013, at about 2.0 per 100 dialysis patient years for recipients from deceased-donors and about 1.2 per 100 dialysis patient years for recipients from living-donors (Figure 6.7).
- The number of deceased kidney donors, aged 1-74 years, with at least one kidney retrieved increased from 5,895 in 2001 to 8,818 in 2015.
- The rate of kidney donation from deceased Blacks/African Americans almost doubled from 2001 to 2015, from 4.0 to 7.4 donations per 1,000 deaths (Figure 6.20.b). This rate overtook that of Whites in 2009, but Asians consistently had the highest rate of deceased kidney donation during this time, at about 8 per 1000 deaths.
- Since 1998, Whites have had the highest rate of living kidney donation, although this has been in steep decline along with all other races except Asians, who as of 2015 showed rates of living donation essentially equivalent to Whites (Figure 6.15.b).
- Seventeen percent of kidneys recovered from deceased-donors were discarded in 2015; this rate has been stable since 2010. The number of kidney paired donation transplants rose sharply in recent years, with 582 performed in 2015. This represented 10% of living-donor transplants that year, and the rate appears to have plateaued (Figure 6.17).
- Since 1998, the probabilities of graft survival and patient survival have steadily improved among recipients of both living and deceased-donor kidney transplants (Tables 6.4 and 6.5).
- In 2014, the probabilities of one-year graft survival were 93% for deceased and 97% for living-donor kidney transplant recipients (Tables 6.4 and 6.5).
- In 2014 the probabilities of patient survival within one year post-transplant were 96% and 99% of deceased- and living-donor kidney transplant recipients (Tables 6.4 and 6.5).
- The one-year graft-survival and patient-survival advantages experienced by living-donor transplant recipients persisted at five and ten years post-transplant (Tables 6.4 and 6.5).

Introduction

Kidney transplantation is the renal replacement therapy of choice for the majority of patients with end-stage 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. To enhance further our understanding of the donor pool, we report the trends and epidemiology of deceased kidney donations among deaths of all causes and traumatic deaths. In addition, this year we add data on outcomes following wait listing for patients as a function of age, blood type, and PRA (Table 6.2).

Recently, the Organ Procurement and Transplantation (OPTN) network conducted major revisions of the kidney allocation system (KAS). These changes took effect on December 4, 2014, with the objectives 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 KAS changes included:

(1) A move to a continuous, percentile based (lower is better) description of **donor** quality, the Kidney Donor Profile Index (KDPI; OPTN, 2016). This metric consists of ten donor factors, and replaces the previous binary categories of standard criteria or extended criteria donors that incorporated only four factors.

(2) For use in conjunction with the KDPI, the calculation of an Expected Post-Transplant Survival (EPTS) score for all adult kidney **recipient** candidates. The EPTS is based on four factors: age, time on dialysis, prior transplant of any organ, and presence of diabetes. This allows preferential allocation of donor kidneys with the best KDPI scores of 20% or less, to younger and healthier candidates with the best EPTS scores of 20% or less.

(3) Increased priority for sensitized candidates through a sliding scale point system based on their calculated panel reactive antibodies (PRA).

(4) The inclusion of pre-waiting list dialysis time in a candidate's waiting time (OPTN, 2015).

In this year's chapter, where relevant, we highlight any trend changes that may have resulted from the new policy. As this chapter only includes data through the end of 2015, we cannot yet fully evaluate the impact of the policy on longer-term outcomes, but this will be an ongoing focus in future ADRs.

Methods

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

See the section on Chapter 6 in the *Analytical Methods Used in the ESRD Volume* 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. Downloadable Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available on the USRDS website.

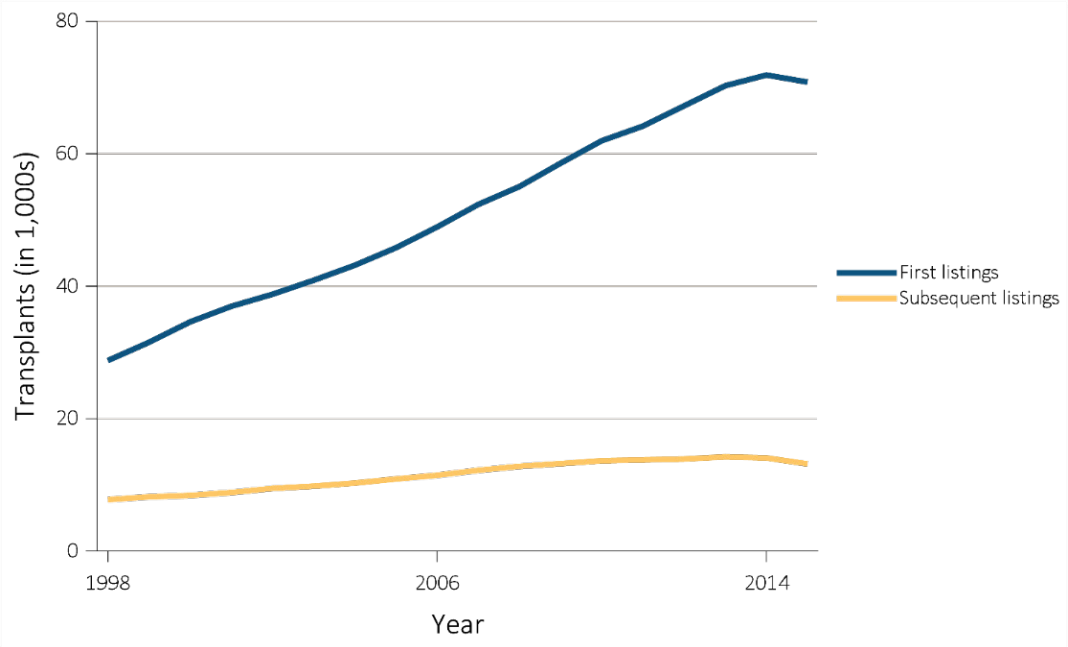
Kidney Transplant Waiting List

As of December 31, 2015, the kidney transplant waiting list decreased for the first time, by 2.3% over the previous year to 83,978 candidates (dialysis patients only), 84% of whom were awaiting their first kidney transplant (Figure 6.1). Notably, this decline was primarily driven by a reduction in the number of inactive wait-listed candidates to 31,275, a 5.6% reduction compared to the previous year (Reference Table E.3). This decrease almost certainly resulted from the new KAS policy changes. For patients already on dialysis at the time of listing, the KAS now ties the start of waiting time to date of dialysis initiation, regardless of when listing occurred. This thus reduced the incentive to list dialysis patients until they are actively ready for transplantation.

For those who meet glomerular filtration rate (GFR) criteria and are pre-dialysis, however, there is still an advantage to listing before dialysis initiation. Nevertheless, with less than 19,000 kidney transplants performed in the U.S. in 2015, the active waiting list remains nearly three times larger than the supply of donor kidneys, which presents a continuing challenge.

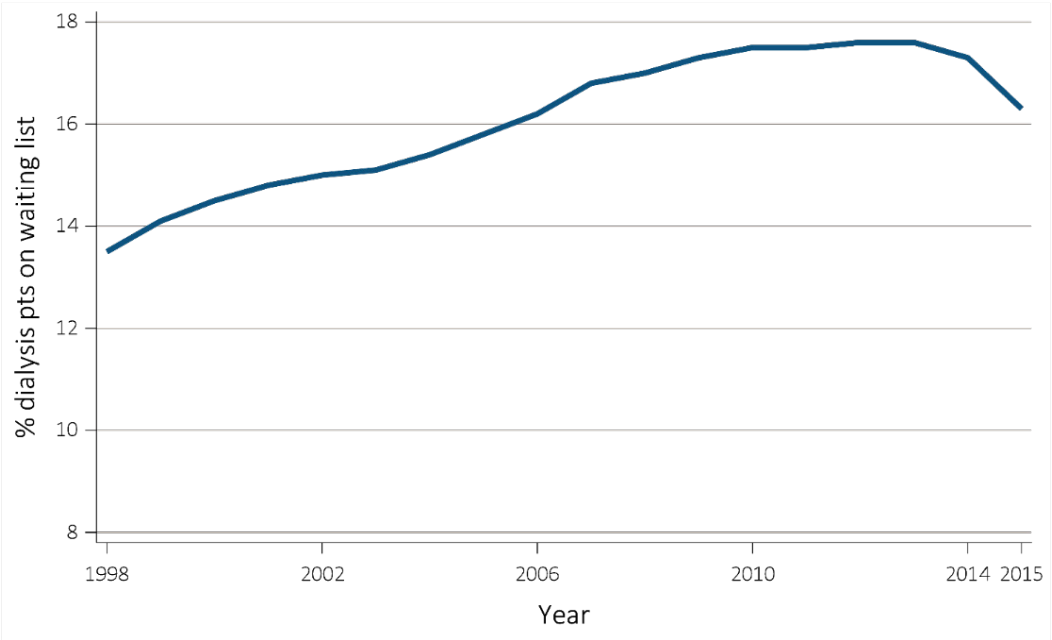
Like the above trends, the percentage of prevalent dialysis patients wait-listed for a kidney has also recently declined (Figure 6.2).

vol 2 Figure 6.1 Number of patients who were wait-listed for kidney transplant, 1998-2015



Data Source: Reference Table E.3. Number of patients wait-listed for kidney transplant. Waiting list counts include all candidates listed for a kidney transplant on December 31 of each year. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014.

vol 2 Figure 6.2 Percentage of dialysis patients who were wait-listed, 1998-2015

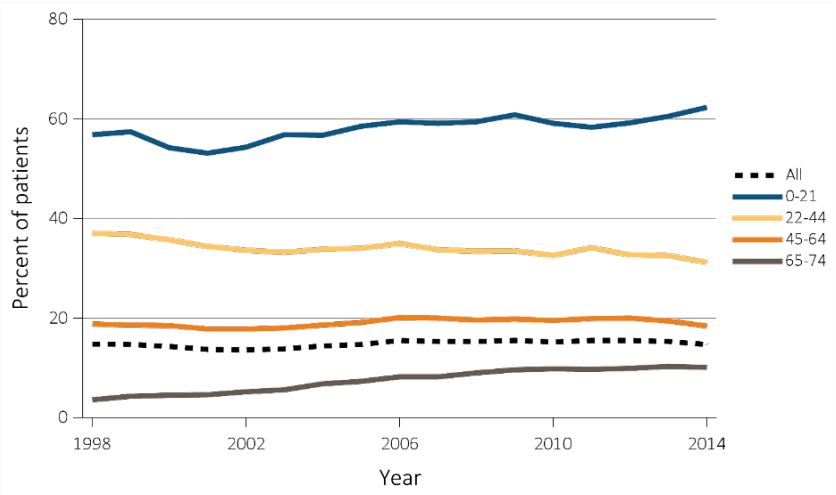


Data Source: Reference Table E.4. Percentage of dialysis patients on the kidney waiting list is for all dialysis patients. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. Abbreviation: pts, patients.

In 2014, 14.7% of incident ESRD patients who started dialysis that year joined a waiting list, or received a deceased or living-donor transplant within one year of ESRD initiation (Figure 6.3). Since 2001,

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 among those patients aged 0-21 years. 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 the minority of this group.

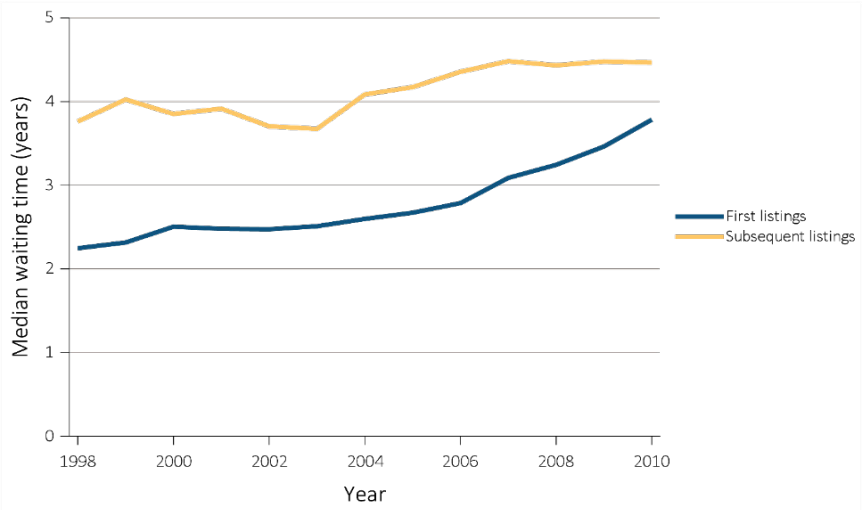
vol 2 Figure 6.3 Percentage of incident patients who were wait-listed or received a kidney transplant within one year of ESRD initiation, by age, 1998-2014



Data Source: Reference Table E.5(2). Waiting list or transplantation among incident ESRD patients by age (0-74 years). Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. Abbreviation: ESRD, end-stage renal disease.

Median waiting time to transplantation continues to increase for those listing for the first time (Figure 6.4). Among 2010 candidates newly wait-listed for either an initial or repeat kidney-alone transplant, the median waiting time (deceased or living-donor) was 3.9 years—50% of these patients received a transplant within 3.9 years after being wait-listed for a transplant. For first-time listings, the median 2010 waiting time to transplantation (deceased or living-donor) was 3.8 years, eight months shorter than that for candidates listed for repeat transplants.

vol 2 Figure 6.4 Median waiting time for kidney transplant, 1998-2010



Data Source: Reference Tables E.2. Median waiting time to kidney transplant. Median waiting time is calculated for all candidates enrolled on the waiting list in a given year.

Table 6.1 presents median waiting times, stratified by blood type and PRA sensitization at time of listing. Patients with blood types B and O had the longest wait. As expected, patients with higher PRA percentages tended to have longer waiting times; this duration has been decreasing for those with the highest levels of sensitization (PRA of 80% or greater).

vol 2 Table 6.1 Median waiting time (in years) for kidney transplant, by blood type and PRA, 1998-2010

Blood type	PRA	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Blood type A	PRA = 0	1.5	1.5	1.7	1.7	1.7	1.7	1.8	1.7	2.0	2.2	2.3	2.5	2.9
	0 < PRA =< 20%	1.6	1.6	1.8	2.2	2.2	1.9	1.9	2.0	1.8	2.2	2.6	2.5	2.5
	20% < PRA =< 80%	2.8	3.2	3.0	3.5	3.0	3.0	3.3	2.9	2.9	3.0	2.5	2.5	2.5
	80% < PRA < 98%	5.6	4.3	4.1	4.0	4.0	5.0	4.2	6.1	4.7	4.9	3.6	4.2	3.7
	98% =< PRA =< 100%	6.5	^	8.0	7.9	8.4	9.7	5.9	9.2	7.1	7.1	^	^	^
Blood type B	PRA = 0	3.3	3.6	3.9	3.6	3.6	3.5	3.4	3.4	4.0	3.9	4.0	4.1	4.8
	0 < PRA =< 20%	3.6	3.9	4.2	4.5	4.2	3.6	3.7	4.3	4.0	3.5	3.9	4.5	4.8
	20% < PRA =< 80%	4.6	4.4	5.3	7.5	5.6	6.2	7.4	5.5	5.5	5.0	5.2	5.2	3.7
	80% < PRA < 98%	4.4	7.0	^	11.9	^	7.5	11.5	6.6	^	6.4	6.6	6.6	^
	98% =< PRA =< 100%	^	^	^	10.0	^	^	^	^	^	^	^	^	5.9
Blood type AB	PRA = 0	0.8	0.9	1.0	1.1	1.1	1.2	1.3	1.1	1.2	1.5	1.4	1.6	2.0
	0 < PRA =< 20%	1.1	1.3	1.1	1.4	0.8	1.4	1.2	1.2	1.1	1.2	1.1	1.8	1.4
	20% < PRA =< 80%	1.8	3.1	3.0	2.1	2.9	2.5	2.9	3.6	2.7	3.2	2.1	2.6	1.4
	80% < PRA < 98%	4.6	4.3	4.9	7.1	1.8	3.7	^	2.7	2.0	4.1	7.0	5.8	3.2
	98% =< PRA =< 100%	1.9	6.2	13.5	3.0	^	4.6	^	2.1	^	^	6.4	6.6	^
Blood type O	PRA = 0	2.8	3.0	3.1	3.1	3.1	3.0	3.2	3.4	3.5	3.9	3.9	4.2	4.7
	0 < PRA =< 20%	3.5	3.2	3.6	3.7	3.7	3.4	3.6	3.7	3.2	3.8	4.1	3.8	4.7
	20% < PRA =< 80%	4.8	4.5	4.6	5.2	4.2	4.1	5.0	4.4	4.3	4.5	4.1	4.1	4.3
	80% < PRA < 98%	4.8	6.7	8.0	7.1	5.9	6.6	8.8	5.4	6.1	7.5	6.3	5.6	4.8
	98% =< PRA =< 100%	5.5	^	14.6	8.0	10.8	8.5	^	10.3	9.1	^	7.4	^	^

Data Source: Special analyses, USRDS ESRD Database. Abbreviation: PRA, panel reactive antibodies. ^ Value is blank since the estimated time to transplant probability had not reached 50% (median) at the end of the follow up, so the median waiting time could not be calculated.

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 E2.2). Two states, South Dakota and Georgia, have waiting times greater than five years. Seven states have waiting times of less than two years, with the lowest seen in Utah (1.2 years), Vermont (1.2 years), and Nebraska (1.5 years).

Table 6.2 displays outcomes within five years of follow-up for candidates who were first listed in 2010, as a function of their blood type, PRA, and age. Overall, among those not receiving a living-donor transplant, at five years 40% had received a deceased-donor transplant, slightly over a third had died or been removed from the waiting list, and nearly a quarter remained on the waiting list. Older patients were more likely to be removed from the waiting list or to die while waiting; the outcome of death was more likely than receipt of a deceased-donor transplant for most strata of patients aged 65 years or older. As expected, blood type also affected the outcomes. Finally, PRA appears to have had a minimal effect, possibly related to allocation policy initiatives aimed at improving access for sensitized patients.

vol 2 Table 6.2 Reported outcomes within five years since first listing in 2010, by blood type, PRA, and age

Patient characteristics			Number who received a living-donor transplant	Outcomes of patients who did not receive a living-donor transplant			
				Total number of patients	Received a deceased-donor transplant (%)	Still on waiting list (%)	Removed from waiting list at death or reason other than transplant (%)
Blood type	**PRA**	**Age**					
Blood type A	**PRA<20**	0-21	122	215	83	9	7
		22-44	585	1,245	54	21	25
		45-64	879	3,566	49	16	35
		65+	202	1,311	44	8	47
	PRA>=20	0-21	*	*	*	*	.
		22-44	38	97	55	16	29
		45-64	47	213	56	13	31
		65+	11	72	43	*	51
Blood type B	**PRA<20**	0-21	36	97	81	*	*
		22-44	204	647	34	38	28
		45-64	282	1,649	31	31	38
		65+	59	503	27	18	55
	PRA>=20	0-21	*	*	*	*	.
		22-44	15	37	30	35	35
		45-64	20	130	35	31	35
		65+	*	31	*	*	65
Blood type AB	**PRA>=0§**	0-21	14	29	79	*	*
		22-44	65	197	69	14	17
		45-64	100	452	61	11	29
		65+	16	163	56	*	39
Blood type O	**PRA<20**	0-21	142	396	77	11	12
		22-44	649	2,094	34	37	29
		45-64	975	5,326	32	30	38
		65+	258	1,752	29	17	54
	PRA>=20	0-21	*	18	61	*	*
		22-44	27	177	42	26	32
		45-64	47	345	37	26	37
		65+	*	103	23	18	58
All blood types			**4,812**	**20,874**	**40**	**23**	**37**

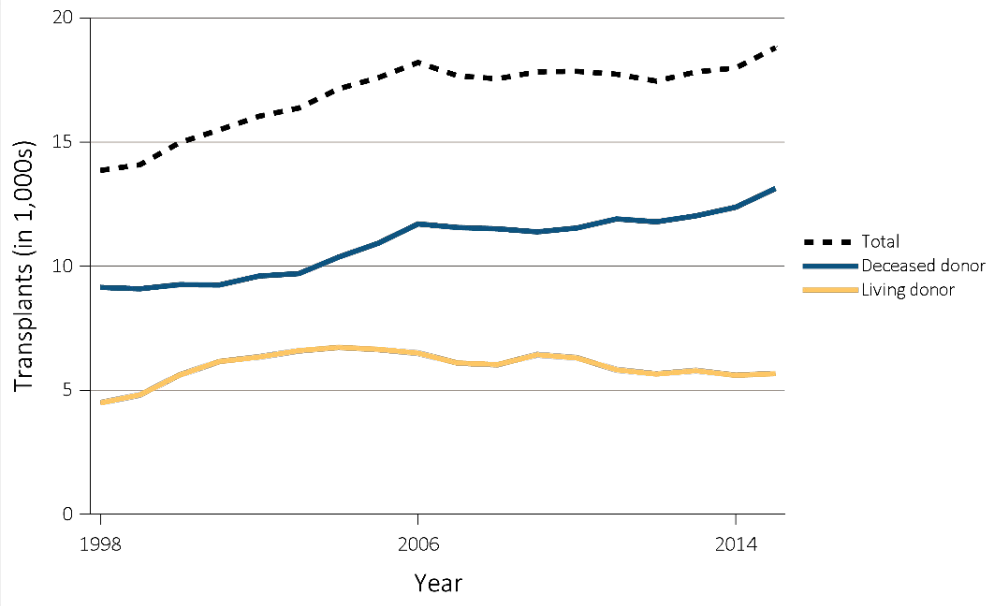
*Data Source: Special analyses, USRDS ESRD Database and the Organ Procurement and Transplantation Network (OPTN). Reported outcomes within five years since first listing in 2010, by blood type, PRA, and age. § PRA is not dichotomized due to small sample size. * Suppressed due to inadequate sample size. A dot (.) represents a zero value.*

Transplant Counts and Rates

During 2015, 18,805 kidney transplants were performed in the U.S., including 18,021 kidney-alone and 784 kidney plus at least one additional organ (Figure 6.5). Of these transplants, 5,672 were identified as originating from living-donors (30.2%) and 13,132 (69.8%) from deceased-donors. Overall, there were a record number of kidney transplants that year, with 815 (4.5%) more procedures occurring in 2015 than in 2014, and 596 (3.3%) more than during the previous peak in 2006.

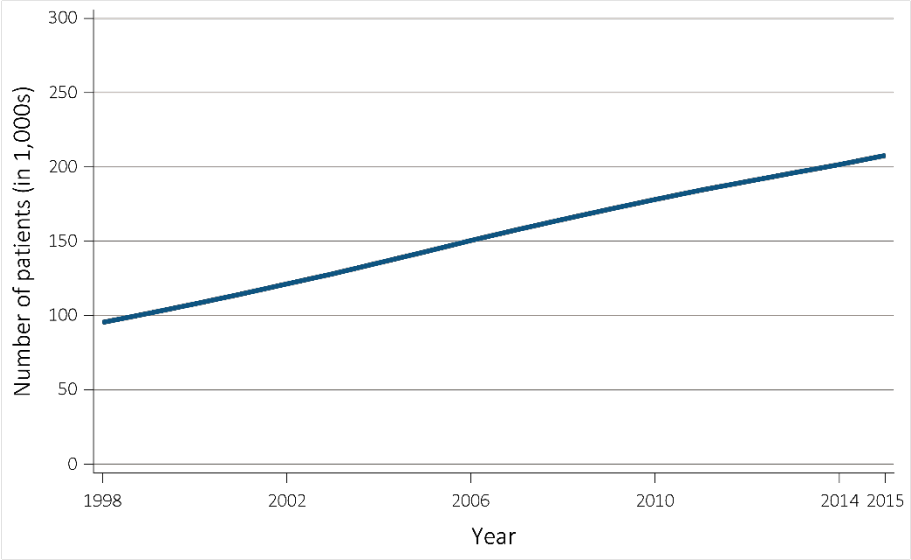
The cumulative number of recipients living with a functioning kidney transplant continues to grow, reaching 207,810 in 2015, a 3% increase over 2014 (Figure 6.6).

vol 2 Figure 6.5 Number of kidney transplants by donor type, 1998-2015



Data Source: Reference Tables E.8, E.8(2), and E.8(3). Number of kidney transplants by donor type. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014.

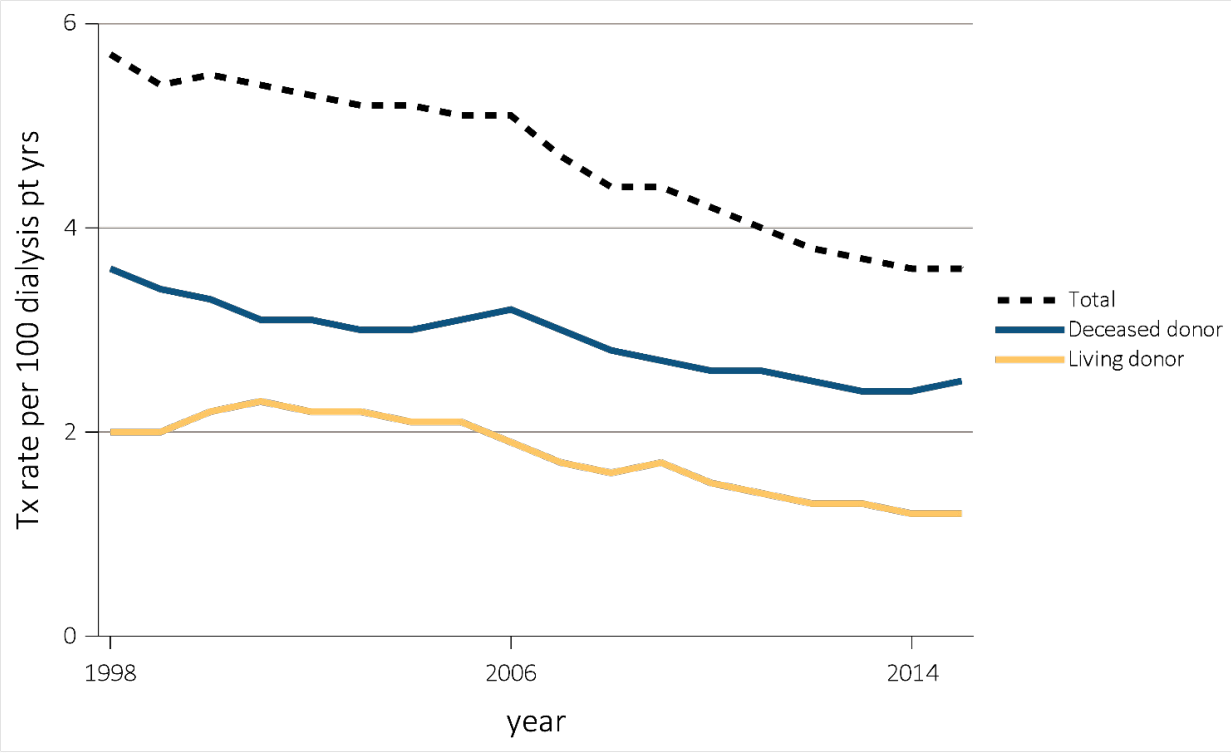
vol 2 Figure 6.6 Number of patients with a functioning kidney transplant, 1998-2015



Data Source: Reference Table D.9. Prevalent counts of patients with a functioning kidney transplant as of December 31 of each year. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014.

As the overall dialysis population expanded, the annual unadjusted transplant rate per 100 dialysis patient years saw a continuous decline, although it plateaued in 2015 (Figure 6.7). This plateau appeared to result from a small increase in the deceased-donor transplant rate in 2015, likely influenced by a relatively large increase in the deceased-donor transplant count that year.

vol 2 Figure 6.7 Unadjusted kidney transplant rates, by donor type, 1998-2015



Data Source: Reference Table E.9. Unadjusted transplant rates are for all dialysis patients. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. Abbreviations: pt yrs, patient years; tx, transplant.

In 2015, there was an increase in transplant rates among patients 22-44 years old, reversing the previous decade-long trend of decline (Table 6.3). Similarly, there was also an increase in transplant rates for Blacks in 2015, reversing a decline seen since 2010. The transplant rate for patients with diabetes mellitus (DM) continued to decline. In upcoming sections, we present counts and rates of transplants separately for deceased- versus living-donor sources, as trends differed substantially for certain subgroups. This particularly resulted from KAS policy changes that primarily influence deceased-donor transplants.

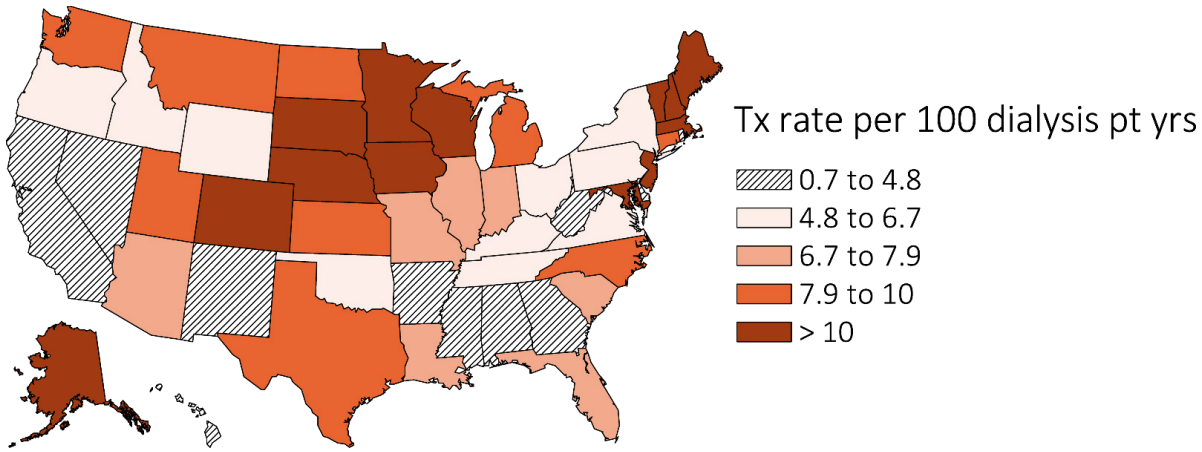
Rates of transplantation per 100 dialysis patient years are presented by geographic region in Figure 6.8, without statistical adjustment. The upper Midwest and New England demonstrated the highest transplant rates, with lower rates found in California, and areas of the Southwest and South. The wide regional variations may relate to geographic differences in organ availability and ESRD incidence (Mathur et al., 2010).

vol 2 Table 6.3 Unadjusted kidney transplant rates, all donor types, by age, sex, race, and primary cause of ESRD, per 100 dialysis patient years, 2006-2015

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Age										
0-21	38.6	32.7	33.1	35.3	33.6	32.2	32.9	32.2	33.1	34.7
22-44	10.9	10.1	9.3	9.2	8.6	8.3	8.1	7.9	7.8	9.3
45-64	5.9	5.6	5.3	5.1	4.9	4.7	4.4	4.4	4.2	4.2
65-74	2.7	2.6	2.6	2.6	2.6	2.6	2.5	2.5	2.5	2.2
75 and older	0.3	0.4	0.3	0.4	0.4	0.4	0.4	0.3	0.4	0.3
Sex										
Male	5.6	5.1	4.8	4.6	4.4	4.3	4.0	4.0	3.8	3.9
Female	4.3	4.0	3.8	3.8	3.7	3.5	3.3	3.3	3.2	3.3
Race										
White	6.0	5.5	5.2	5.0	4.7	4.5	4.3	4.3	4.1	4.0
Black/African American	3.3	3.1	2.9	3.0	3.0	2.9	2.6	2.6	2.5	2.8
American Indian/Alaska Native	3.9	2.9	3.6	3.7	2.9	3.0	2.5	2.2	2.7	3.2
Asian	5.9	5.3	5.5	5.1	5.1	4.8	4.7	4.8	4.7	5.2
Primary Cause of ESRD										
Diabetes	3.2	3.1	2.9	2.8	2.6	2.5	2.3	2.3	2.2	2.0
Hypertension	3.2	3.1	3.0	2.9	2.8	2.6	2.6	2.5	2.5	2.6
Glomerulonephritis	9.9	9.0	8.7	8.6	8.7	8.2	7.9	7.8	7.5	8.3
All	5.0	4.6	4.4	4.3	4.1	3.9	3.7	3.7	3.6	3.6

Data Source: Reference Table E.9. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. Abbreviation: ESRD, end-stage renal disease.

vol 2 Figure 6.8 Geographic distribution of unadjusted transplant rate by state, 2015



Data Source: Special analyses, USRDS ESRD Database. Geographic distribution of unadjusted transplant rate by state, 2015. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. Abbreviation: pt yrs; patient years; tx, transplant.

Counts and Rates of Deceased-Donor Transplants

As presented above in Figure 6.5, the overall number of deceased-donor transplants remained consistent between 2006 and 2011, and has increased steadily since 2012. In this section, we review detailed trends in counts and rates of deceased-donor transplants, by age, sex, race, and primary cause of ESRD (Figures 6.9-6.12).

Counts and rates of deceased-donor transplantation per 100 dialysis patient years are presented by age category in Figure 6.9, without statistical adjustment. Following a steady increase seen since before 1998, the counts were highest for recipients aged 45-64 years, reaching 6,322 in 2015 (Figure 6.9.a). In contrast, for those aged 22-44 years the number of deceased-donor transplants declined from 2006 to 2014, but increased sharply from 2,906 in 2014 to 3,915 in 2015. In 2015 there was a decline in transplant counts for those aged 65-74 years, reversing the previously rising trend.

These recent trend changes correlate temporally with the implementation of the new KAS policy in December 2014. As outlined in the Introduction, the quality assessment of deceased-donor organs was changed from a binary rating (extended criteria donor, ECD vs. standard criteria donor, SCD) to a continuous, percentile rating (lower is better) via the KDPI. In addition, the new policy gave priority for allocation of the highest quality kidneys (KDPI≤20) to younger, healthier candidates with the best EPTS, a key change. As these candidates also have equal access to other higher KDPI kidneys, they are effectively at a combined advantage in terms of overall access to deceased organs.

The patterns for deceased-donor transplant counts shown in Figure 6.9.a contrast with the rates shown in Figure 6.9.b, likely because the number of dialysis patients varies, increasing markedly with age. Due to the small denominator for children on dialysis, and the priority for allocating kidneys from deceased-donors under the age of 35 years to pediatric patients, deceased-donor transplant rates are highest in the <22 years category that includes children. The rates for this group increased in 2005-2007, then stabilized until 2013, and have since increased. There has been a slow reduction in deceased-donor kidney transplantation rates for those aged 45-64 and 65-74 years. The rate for those aged 22-44 years rose sharply in 2015, reflecting a 34.7% increase in counts that year.

vol 2 Figure 6.9 Number of deceased-donor transplants and unadjusted transplant rates among deceased-donor kidney recipients, by recipient age, 1998-2015

(a) Number of transplants by age

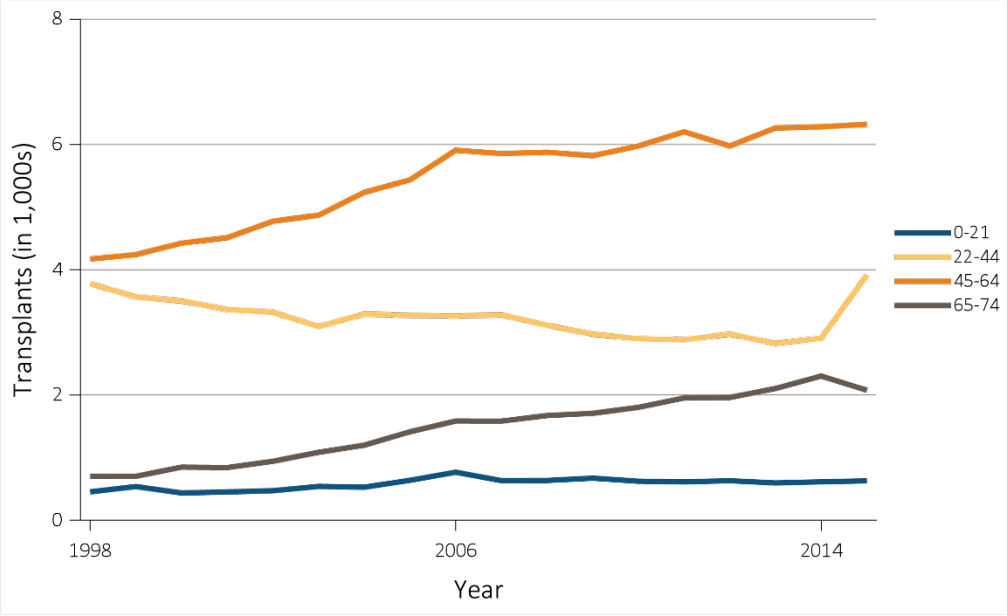
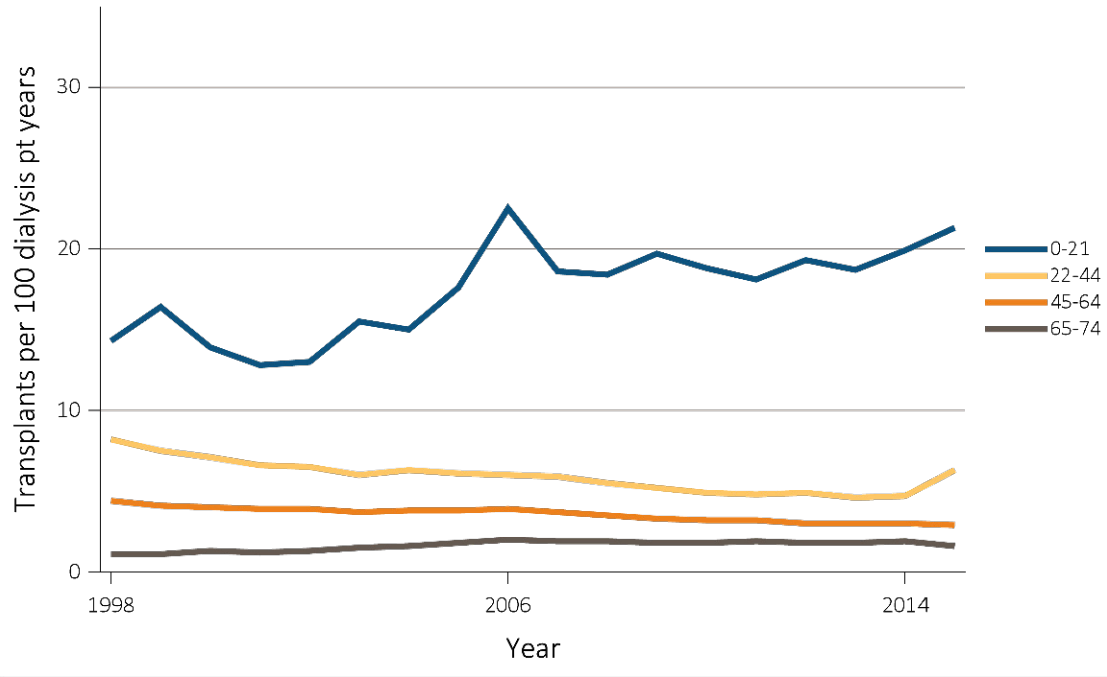


Figure 6.9 continued on next page.

vol 2 Figure 6.9 Number of deceased-donor transplants and unadjusted transplant rates among deceased-donor kidney recipients, by recipient age, 1998-2015 *(continued)*

(b) Transplant rates by age

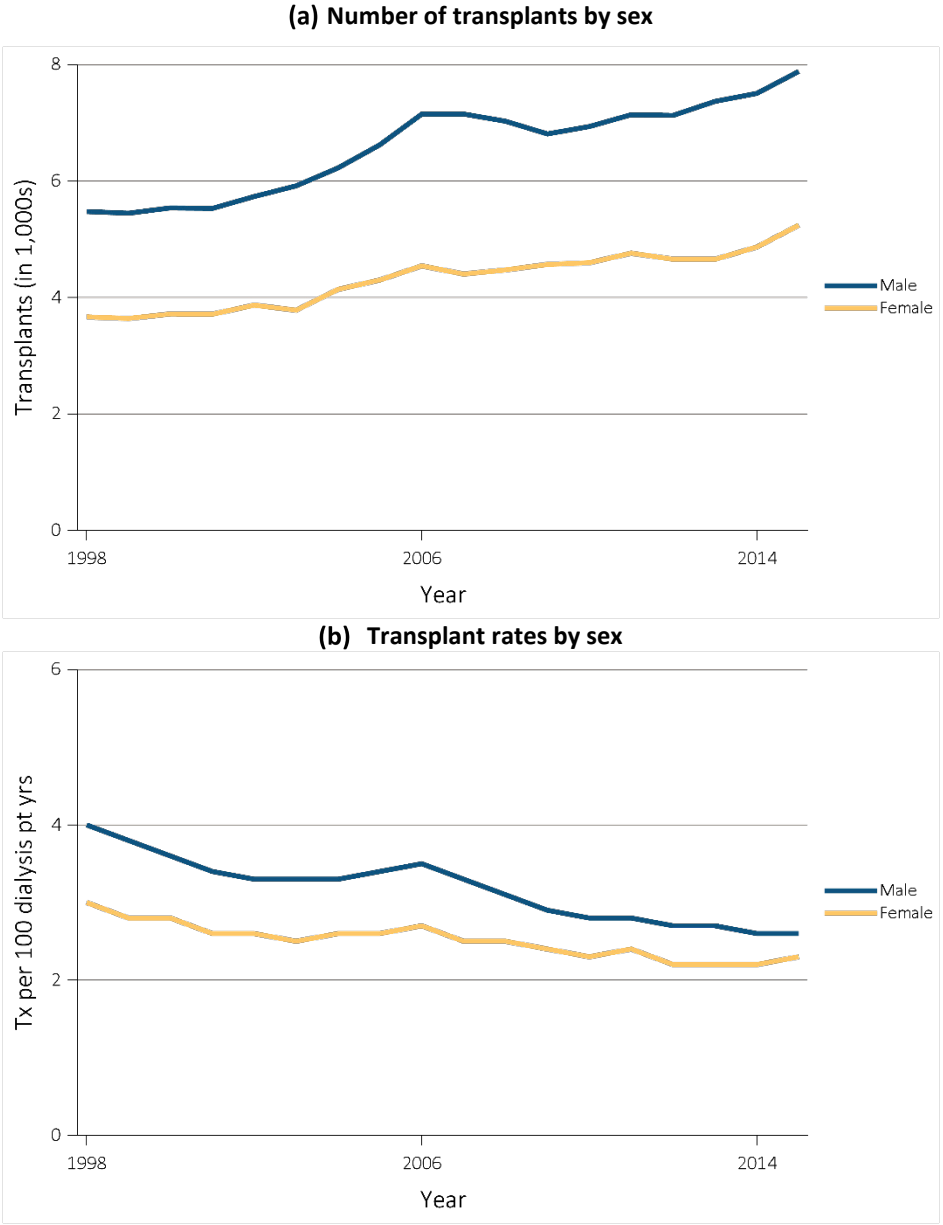


Data Source: Reference Tables E.8(2) and E.9(2). (a) Deceased donor kidney transplant counts by recipient age. (b) Unadjusted deceased-donor kidney transplant rates by recipient age. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. 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 and an increase seen again after 2013 (Figure 6.10.a). Males received substantially more deceased-donor transplants than did females, on average 52.9% more annually since 1998. This difference seems to be largely explained by the fact that males account for more than 60% of wait-listed candidates (Reference Table E.3).

The rates of deceased-donor kidney transplantation have generally declined since 2006 for both male and female dialysis patients (Figure 6.10.b), although they appear to have stabilized, with a slight increase among females in 2015. The latter finding may result from the additional prioritization of sensitized candidates in the new allocation policy. The difference in actual transplantation rates between males and females has been narrowing in recent years.

vol 2 Figure 6.10 Number of deceased-donor transplants and unadjusted transplant rates among deceased-donor kidney recipients, by recipient sex, 1998-2015

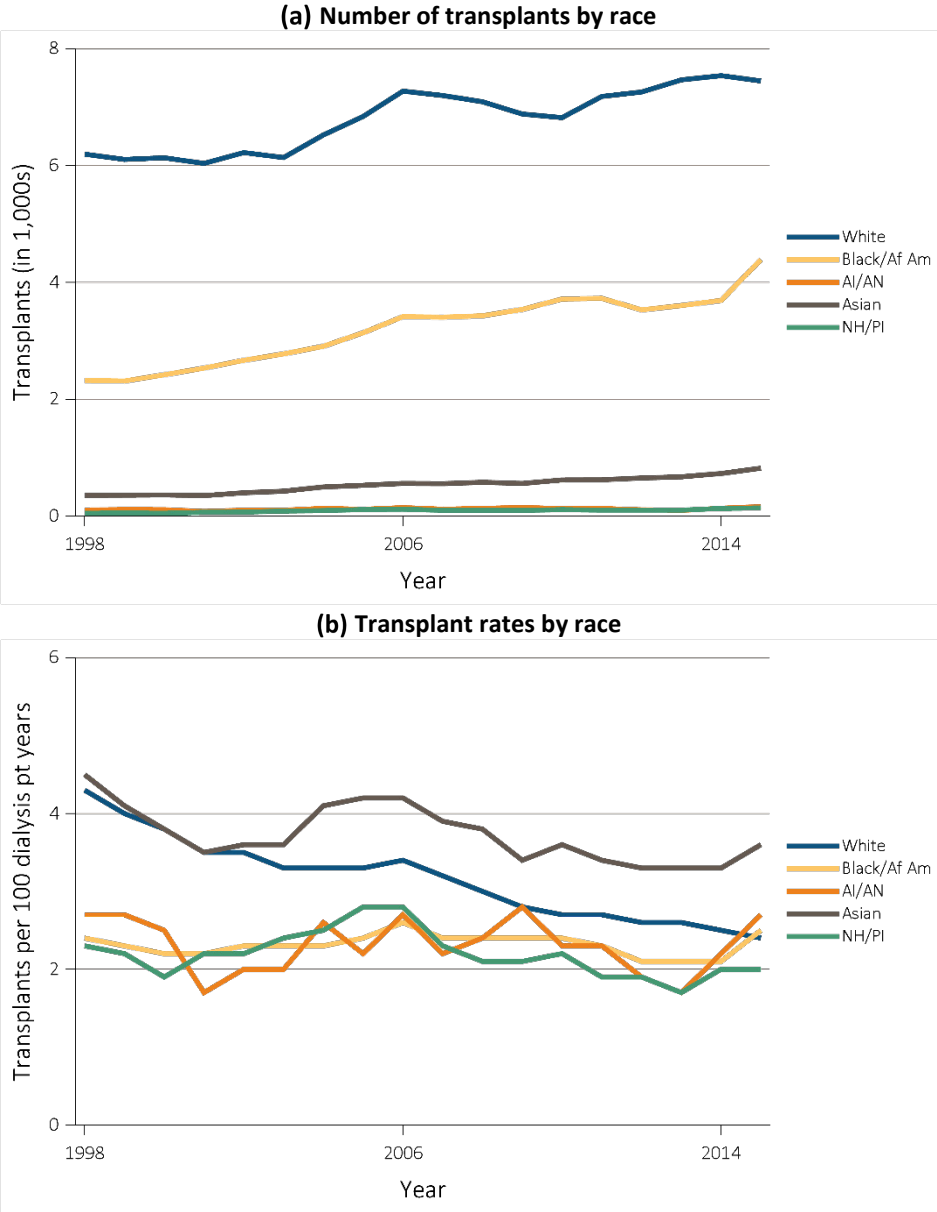


Data Source: Reference Tables E.8(2) and E.9(2). (a) Deceased donor kidney transplant counts by recipient sex. (b) Unadjusted deceased-donor kidney transplant rates by recipient sex. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. Abbreviation: pt yrs; patient years; tx, transplant.

For dialysis patients of White or Black race, the number of deceased-donor transplants has grown by 38.2% over the past 15 years, with a more modest increase observed for Asians (Figure 6.11.a).

Since 1998, deceased-donor transplant rates for White patients have been declining. Since 2002, deceased-donor transplant rates for Asians have been higher than for Whites (Figure 6.11.b). In 2015, the rates of deceased-donor transplants increased for Blacks, Asians, and American Indians/Alaska Natives; these are now similar to that of Whites. This recent convergence may be an impact of the new allocation policy, which dates the start of waiting list time to the initiation of dialysis, even if listing occurred after many years on dialysis. This may assist minorities and low-income persons, who often take longer to get waitlisted.

vol 2 Figure 6.11 Number of deceased-donor transplants and unadjusted transplant rates among deceased-donor kidney recipients, by recipient race, 1998-2015



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. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. Abbreviations: AI/AN, American Indian or Alaska Native; Black/Af Am, Black/African American; NH/PI, Native Hawaiian or Pacific Islander; pt, patient.

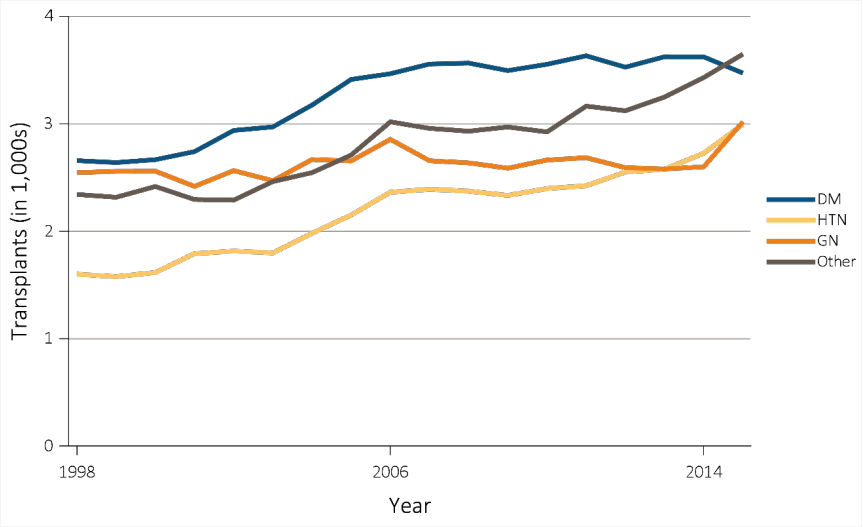
When considering transplant rates by primary cause of ESRD, the largest growth in deceased-donor transplantation numbers has been among recipients with DM or hypertension (HTN; Figure 6.12.a). This growth is not surprising, as DM has consistently been the most common disease among the major causes of ESRD.

Despite the increasing number of deceased-donor transplants over time, the rates of deceased-donor transplants for all diagnosis groups have been generally declining since 2006. In 2015, diabetics showed a sharp downturn, paired with a corresponding increase for all other causes of ESRD (Figure 6.12.b). Transplant rates among dialysis patients with glomerular disease were highest, followed by the Other causes category (including cystic disease). The lowest deceased-donor transplant rates occurred for candidates with ESRD attributed to HTN and DM; these were similar, but were lower than those observed for the glomerulonephritis and Other categories. This rank order is likely due in part to

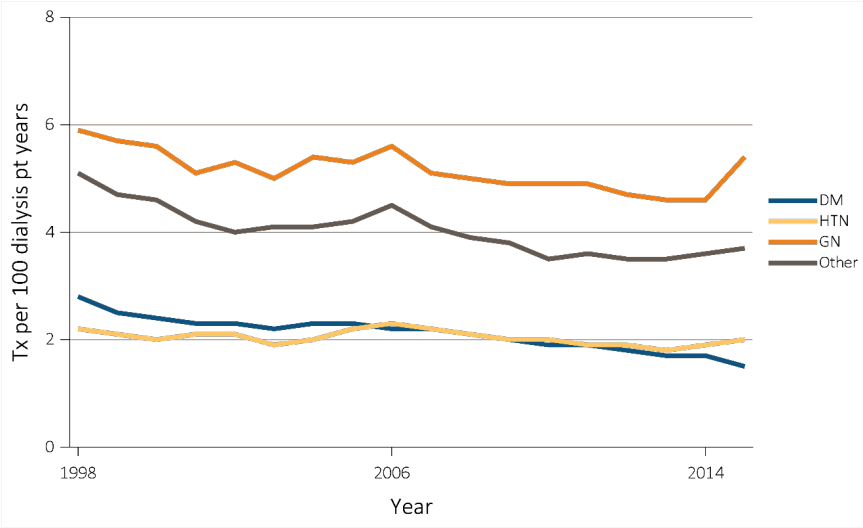
differences in the suitability for transplantation of the patients who have these diagnoses as their primary cause of ESRD. Differences in age and co-morbidities may contribute—the mean age in 2015 among those with ESRD attributed to DM was 55 years, versus 53 for HTN, 44 for glomerulonephritis and 46 for Other categories. The pattern change seen in 2015 likely reflects transplant advantages provided to healthier patients as part of the new allocation policy.

vol 2 Figure 6.12 Number of deceased-donor transplants and unadjusted transplant rates among deceased-donor kidney recipients, by recipient primary cause of ESRD, 1998-2015

(a) Number of transplants by primary cause of ESRD



(b) Transplant rates by primary cause of ESRD



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. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. Abbreviations: DM, DM mellitus; ESRD, end-stage renal disease; GN, glomerulonephritis; HTN, hypertension; pt, patient; tx, transplant.

Counts and Rates of Living-Donor Transplants

Since 2004 there has been an annual decline in living-donor kidney transplant counts, although this appears to have plateaued in recent years (Figure 6.5). In this section, we review detailed trends in annual counts and rates of living-donor kidney transplants, by age, sex, race, and primary cause of ESRD (Figures 6.13-6.16).

Counts of living-donor transplants for those aged 22-44 years decreased from 2,603 in 2003 to 1,809 in 2015. The number of living-donor transplants for the group aged 45-64 years has shown a more recent decline, falling from 2,994 in 2010 to 2,639 in 2015 (Figure 6.13.a). Transplant counts for those over 65 years have been steadily increasing.

Kidney transplantation rates from living-donors show that those in younger age groups have the highest annual rates per 100 dialysis patient years (Figure 6.13.b). However, beginning in 2003 there was a steep decline in rates for the 0-21 year-old group, likely related to the impact of the deceased-donor kidney allocation priority then given to that age group; recent trends have been 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 6.13 Number of living-donor transplants and unadjusted transplant rates among living-donor kidney recipients, by age, 1998-2015

(a) Number of transplants by age

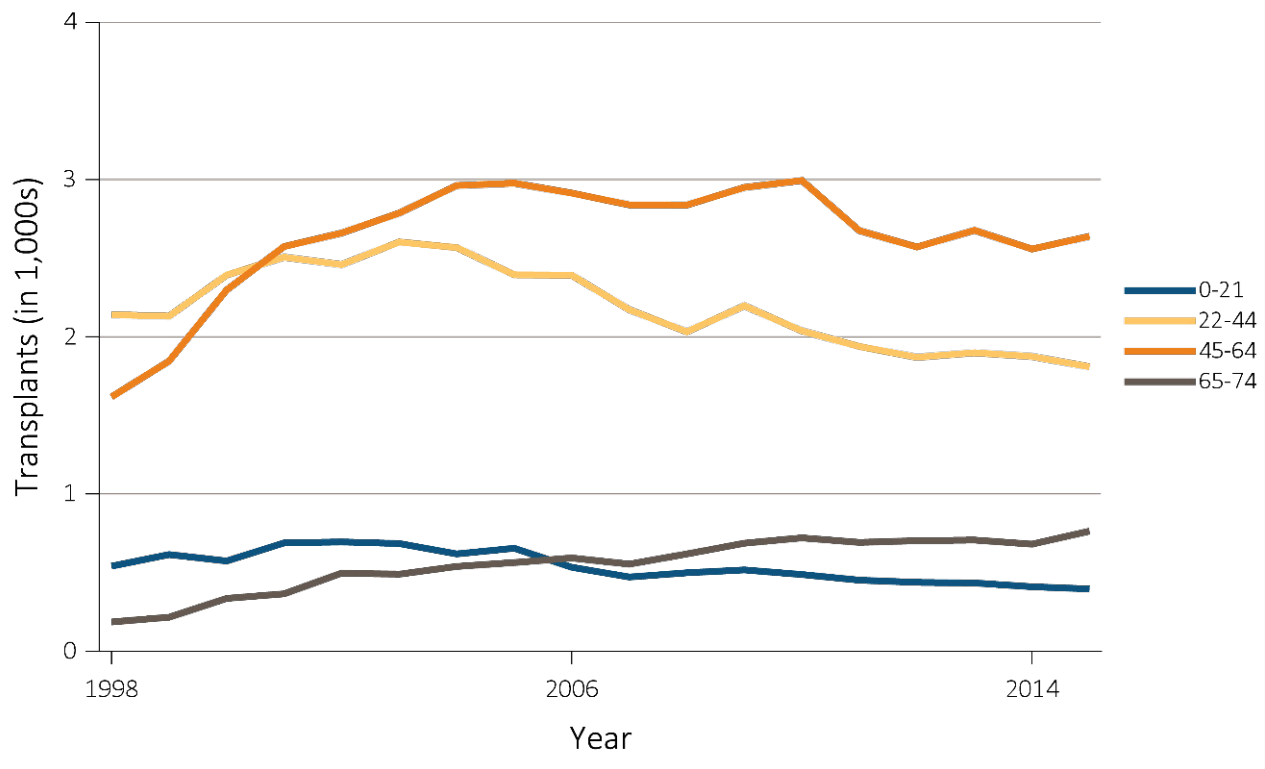
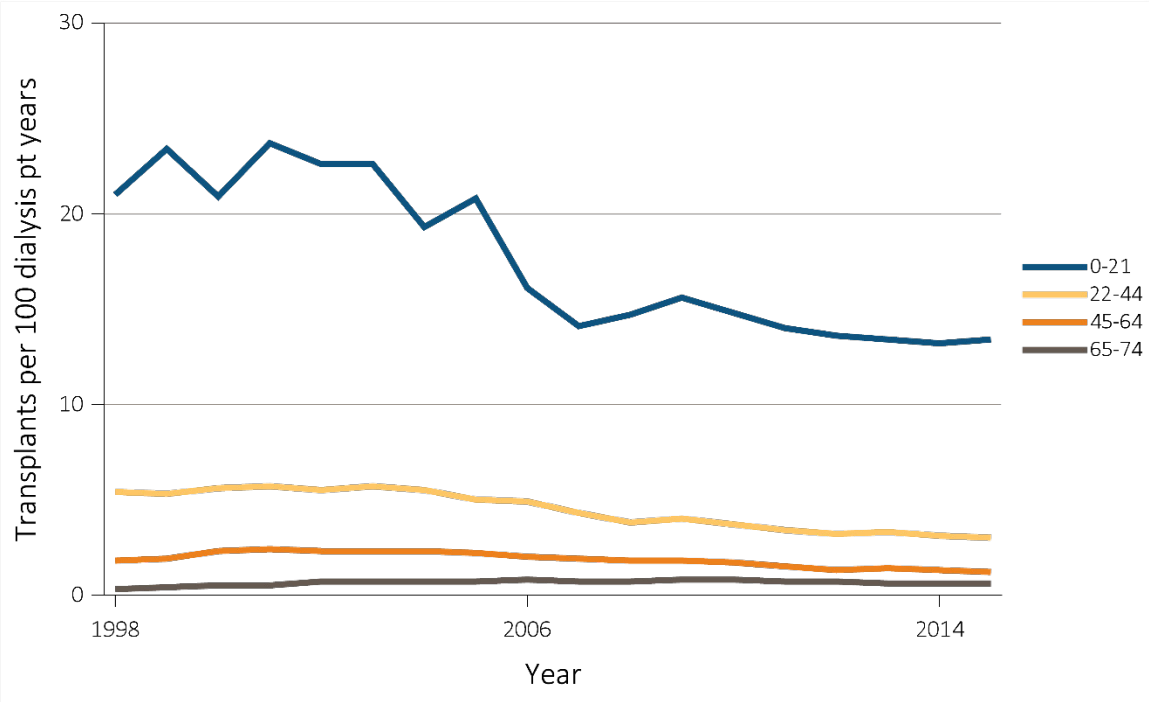


Figure 6.13 continued on next page.

vol 2 Figure 6.13 Number of living-donor transplants and unadjusted transplant rates among living-donor kidney recipients, by age, 1998-2015 *(continued)*

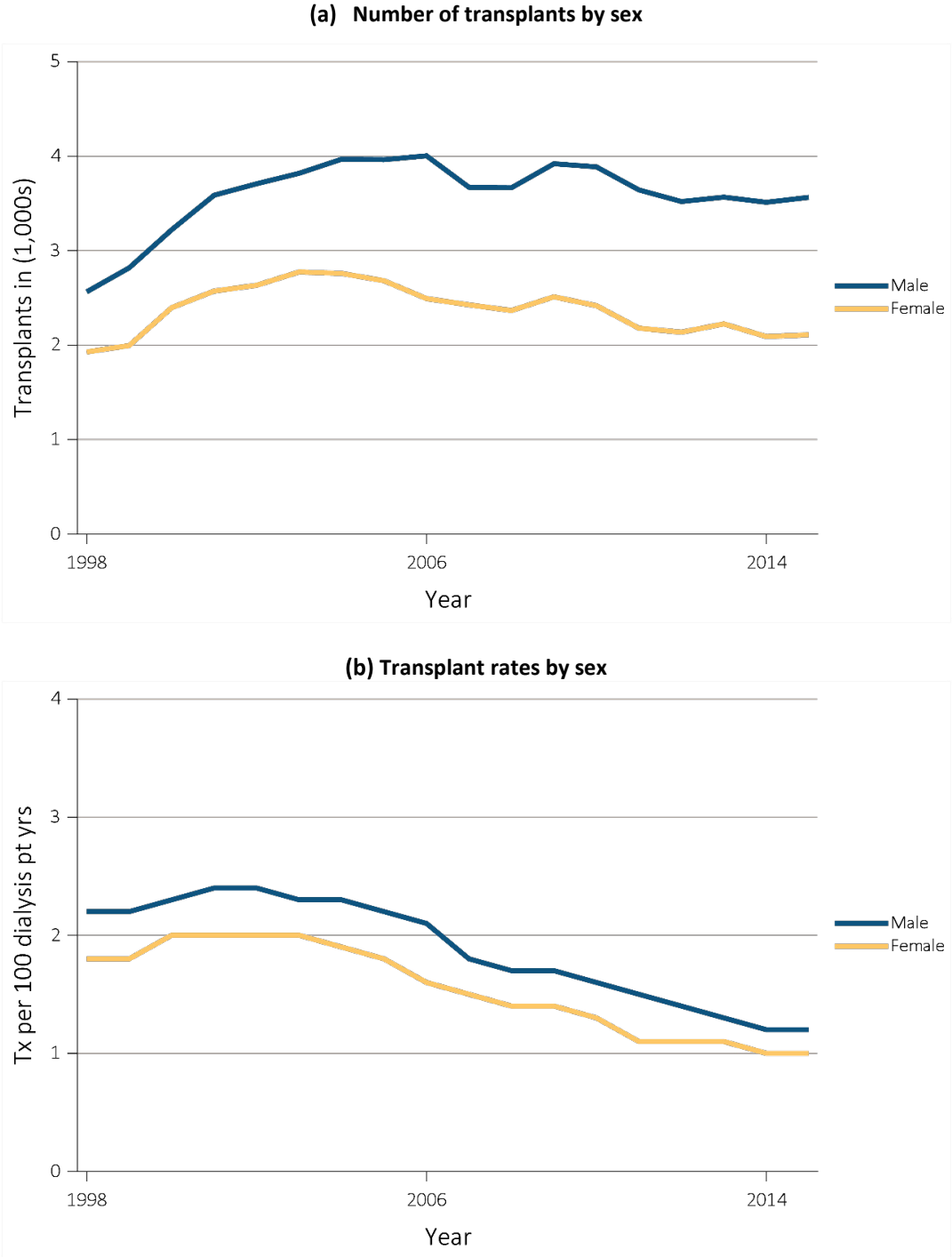
(b) Transplant rates by age



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. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. Abbreviation: pt, patient.

The annual counts of living-donor kidney transplantation by sex showed consistently higher numbers of male recipients (Figure 6.14.a). However, while the living-donor transplant rates continued to remain higher for males than for females, the difference was relatively small (Figure 6.14.b).

vol 2 Figure 6.14 Number of living-donor transplants and unadjusted transplant rates among living-donor kidney recipients, by recipient sex, 1998-2015

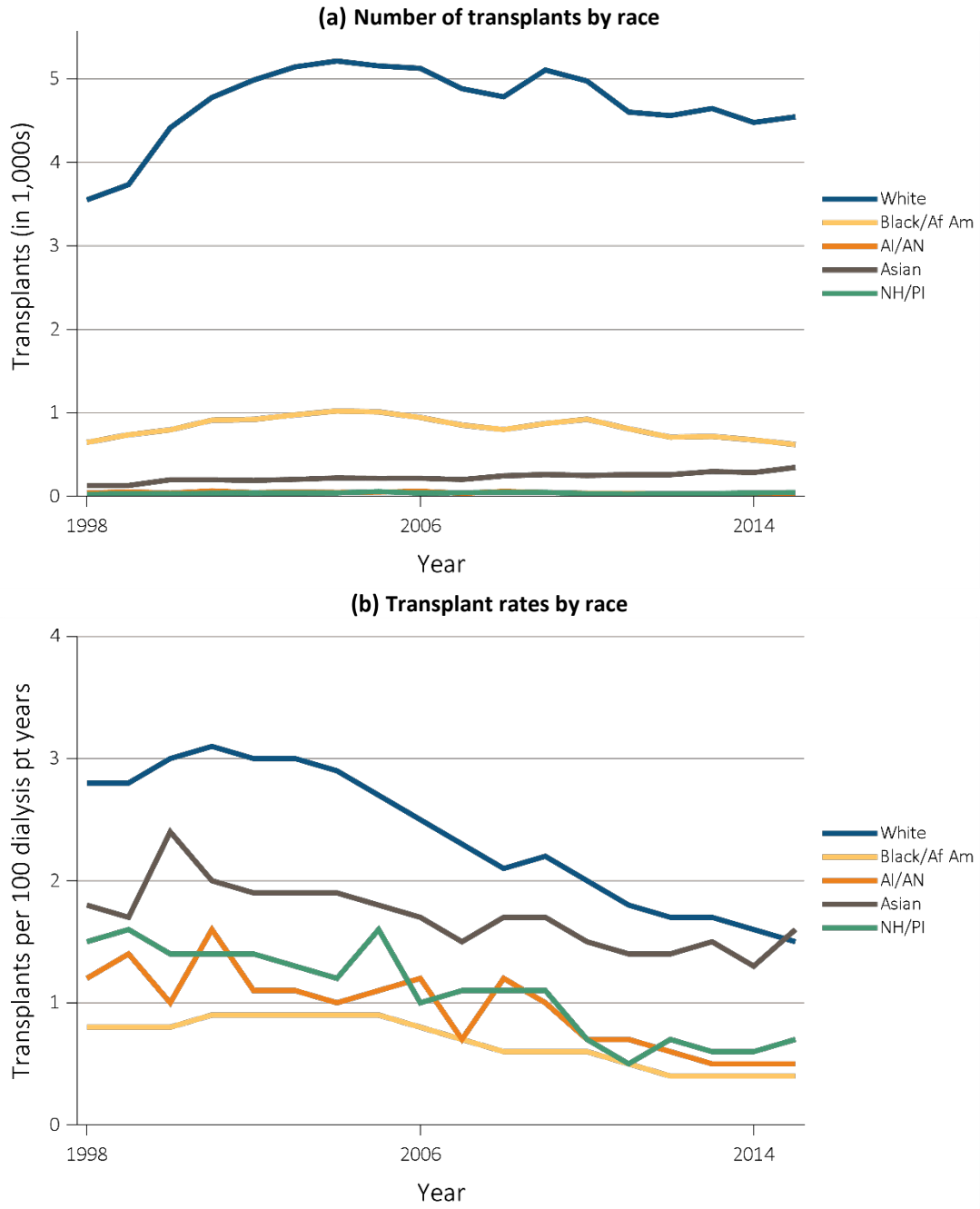


Data Source: Reference Tables E.8(3) and E.9(3). (a) Living-donor kidney transplant counts by recipient sex. (b) Unadjusted living-donor kidney transplant rates by recipient sex. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. Abbreviation: pt yrs, patient years; tx, transplant.

Consistent with the overall trend, living-donor kidney transplant counts steadily increased until 2004 for recipients of all races (Figure 6.15.a). 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 and Asians are higher than for the other race groups, while rates among Blacks have consistently been lowest (Figure 6.15.b). In 2015, living-donor transplant rates increased slightly among Asians and Native Hawaiians/Pacific Islanders.

vol 2 Figure 6.15 Number of living-donor transplants and unadjusted transplant rates among living-donor kidney recipients, by recipient race, 1998-2015



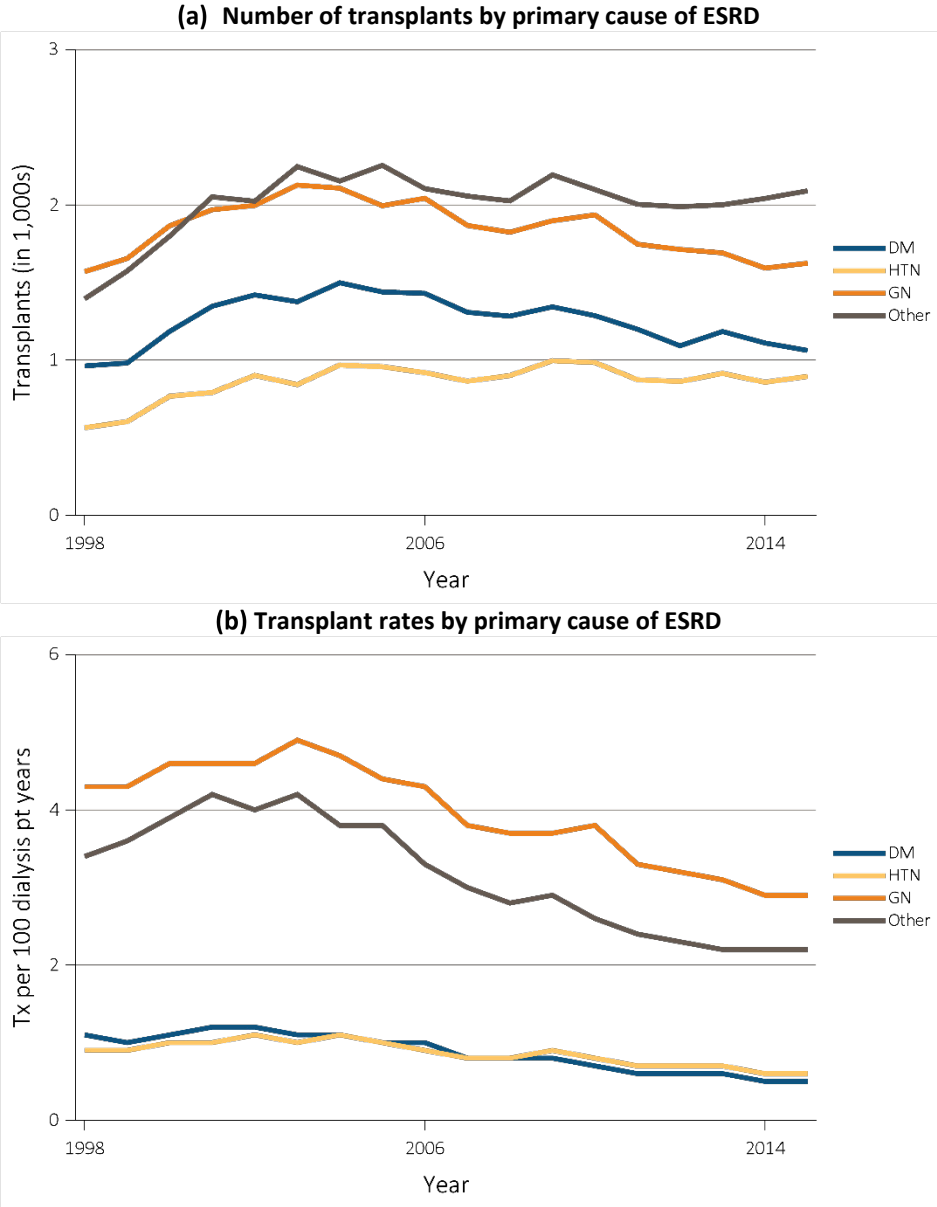
Data Source: Reference Tables E.8(3) and E.9(3). (a) Living-donor kidney transplant counts by recipient race. (b) Unadjusted living-donor kidney transplant rates by recipient race. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. Abbreviations: AI/AN, American Indian or Alaska Native; Black/Af Am, Black/African American; NH/PI, Native Hawaiian or Pacific Islander; pt, patient.

The ranking of living-donor kidney transplantation counts by primary cause of ESRD has remained consistent over the past decade. Rankings from highest to lowest frequency were the Other causes,

glomerulonephritis, DM, and HTN (Figure 6.16.a). This trend contrasts with the pattern among deceased-donor recipients (Figure 6.12.a), where the numbers with ESRD caused by DM and HTN 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 6.16.b). Like the rates of deceased-donor transplants, those from living-donors occur most often among patients with glomerular disease. In frequency, this is followed by Other causes (including cystic disease), with rates lowest for those with HTN and DM.

vol 2 Figure 6.16 Number of living-donor transplants and unadjusted transplant rates among living-donor kidney recipients, by recipient primary cause of ESRD, 1998-2015

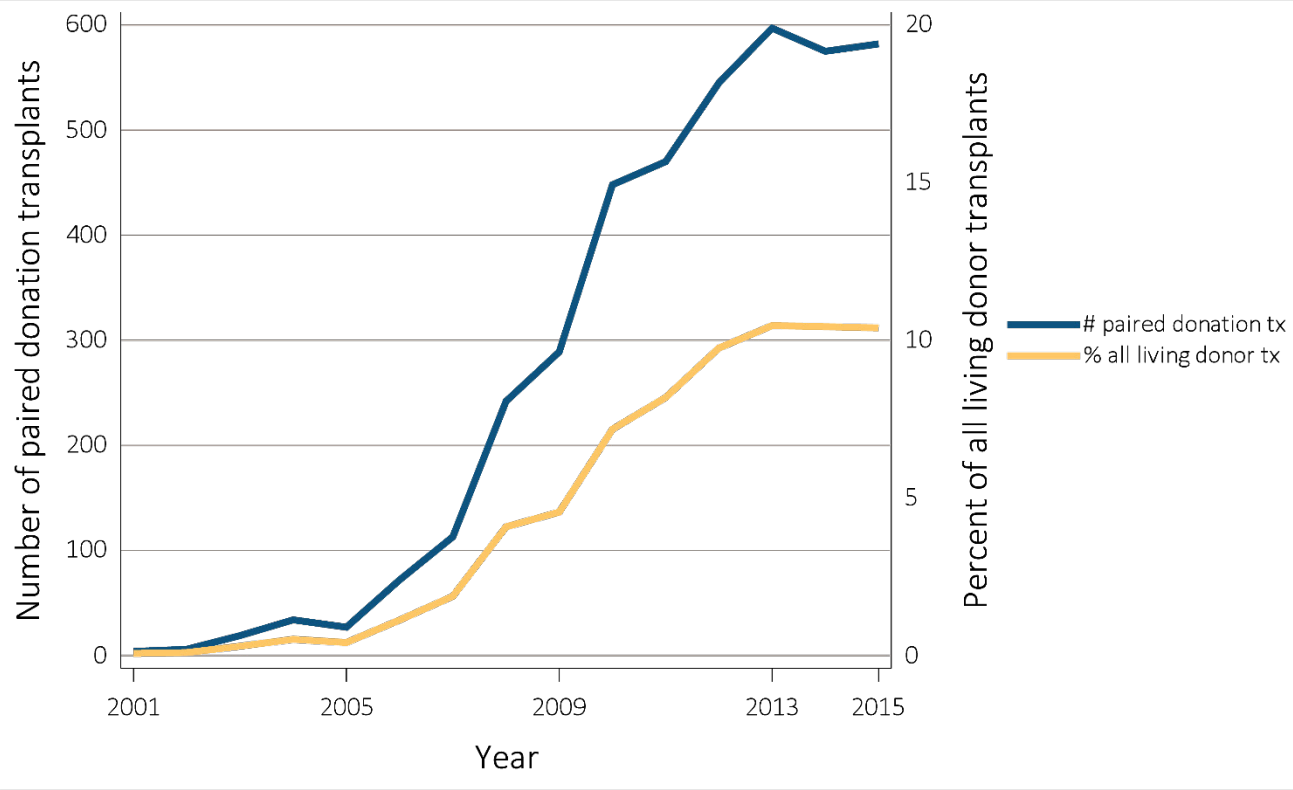


Data Source: Reference Tables E.8(3) and E.9(3). (a) Living-donor kidney transplant counts by recipient primary cause of ESRD. (b) Unadjusted living-donor kidney transplant rates by recipient primary cause of ESRD. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. Abbreviations: DM, DM mellitus; ESRD, end-stage renal disease; GN, glomerulonephritis; HTN, hypertension; pt, patient; Tx, transplant.

A relatively recent initiative aimed at increasing the availability of living-donor transplants is the process of kidney paired donation (KPD). This typically occurs when an otherwise willing potential living-donor is incompatible with their chosen recipient. In its simplest form, two living-donors who are incompatible with their respective recipients agree to an exchange whereby their donated organs go to each

other's compatible recipient. More complex chains involving exchanges among three or more recipient-donor pairs, have also occurred. Altruistic, undirected donors have also initiated complex chains. The counts of KPD transplants have risen sharply in recent years, though they appear to have plateaued since 2013 with 582 performed in 2015, representing 10% of living-donor transplants that year (Figure 6.17).

vol 2 Figure 6.17 Number of paired donation transplants and percent of all living-donor transplants, 2001-2015



Data Source: Data are obtained from the Organ Procurement and Transplantation Network (OPTN). Paired donation transplant counts and percent of all living-donor transplants. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. Abbreviation: tx, transplant.

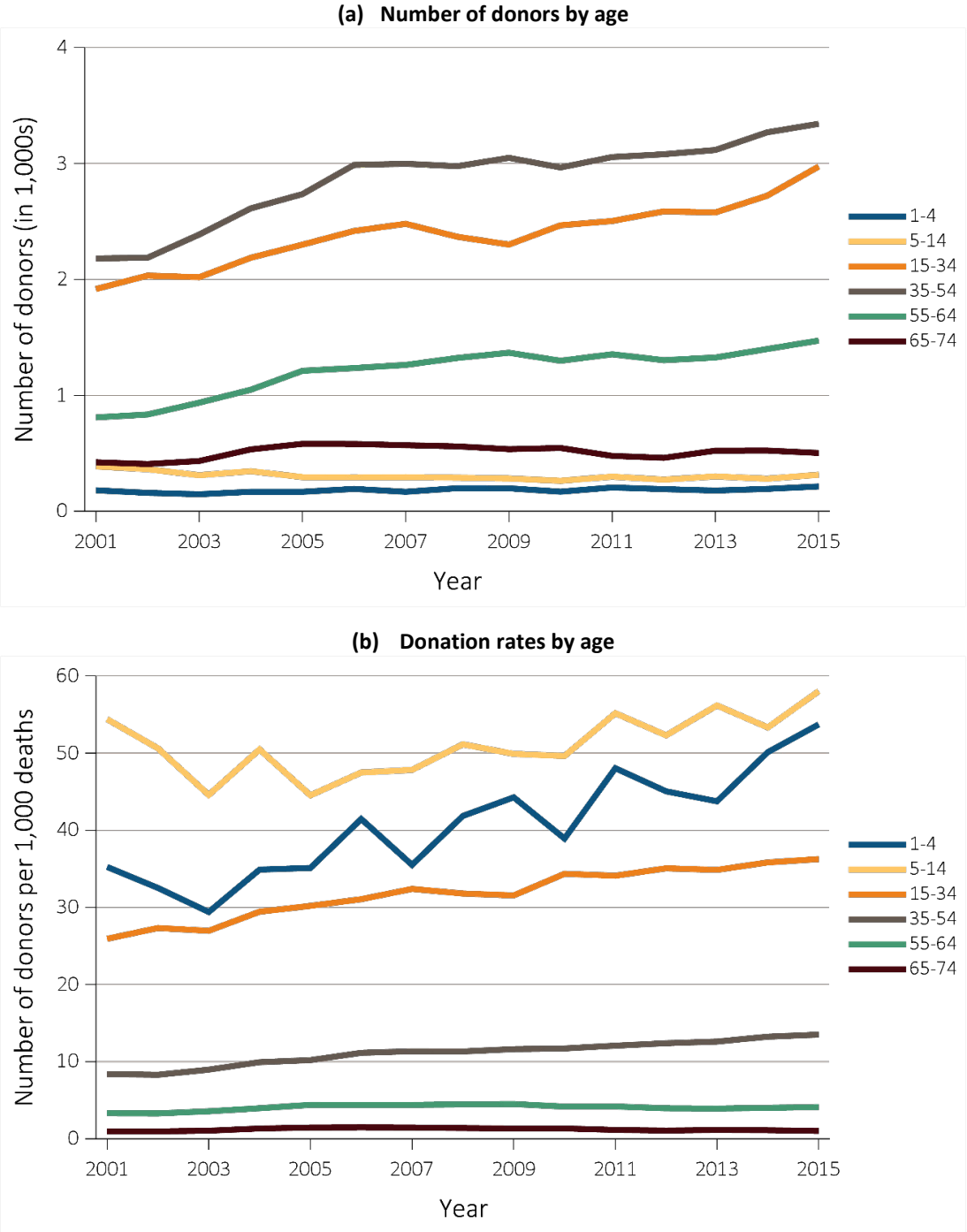
Deceased Donation Counts and Rates among All-cause Deaths

The number of deceased-donors, aged 1-74 years, with at least one kidney retrieved increased from 5,895 in 2001 to 8,818 in 2015 (Figure 6.18.a). We do not report on those aged 75 years and older because of the small number of deceased organ donations from this age group. In 2015, among the 17,303 kidneys that were recovered from deceased-donors, 2,938 (17%) were discarded for various reasons. During 2011-2015, the percentage of kidneys discarded ranged from 16%-17% (OPTN, 2016).

Since 2002, the number of donors among those aged 1-4, 5-14, and 65-74 years has been relatively stable, but the cohort of those aged 15-64 years has been increasing steadily, particularly over the last five years. Donors aged 35-54 years have been the leading source of kidney donations during the past 15 years, with persons aged 15-34 years being the second highest source, and those aged 55-64 years the third highest.

Annual donation rates are the number of deceased-donors with at least one retrieved kidney, per 1,000 deaths in the U.S. population (CDC, 2017). The overall donation rates ranged from 5.6 per 1,000 deaths in 2001 to 7.3 per 1,000 in 2015 (Figure 6.18.b). The highest donation rates were among those aged 5-14, reaching 58 per 1,000 deaths in 2015, followed by those 15-34 years, from whom donations rose from 26 per 1,000 deaths in 2001 to 36 per 1,000 in 2015.

vol 2 Figure 6.18 Number of deceased kidney donors and unadjusted kidney donation rates, by donor age, 2001-2015

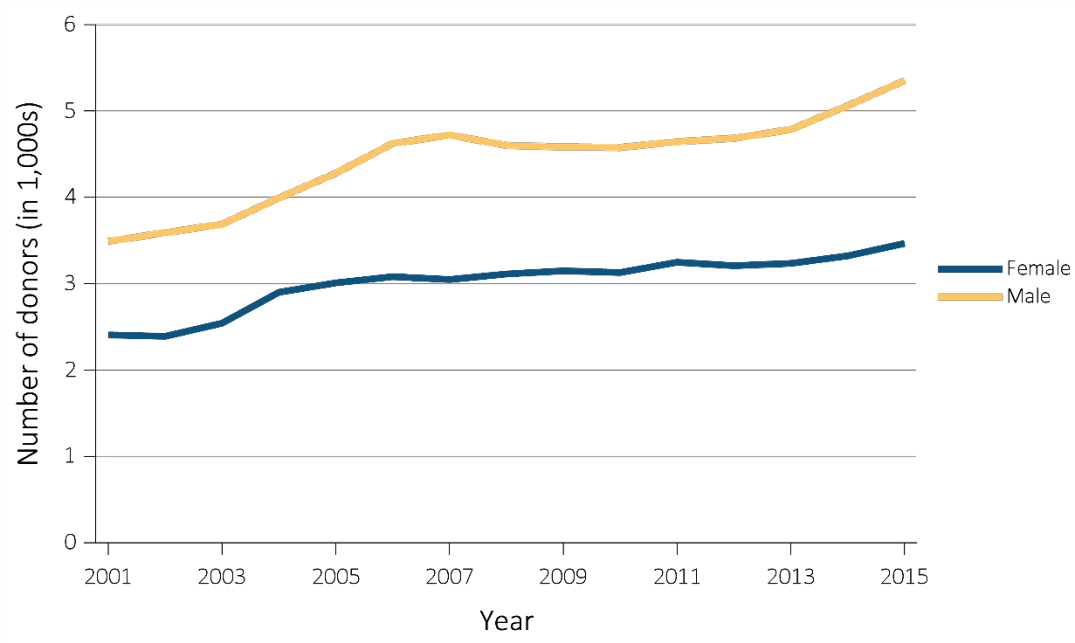


Data Source: Data on the annual number of deaths in the U.S. population are obtained from the Centers for Disease Control and Prevention; the deceased-donor data are obtained from the Organ Procurement and Transplantation Network (OPTN). Deceased-donor kidney donation counts and rates by donor age. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014.

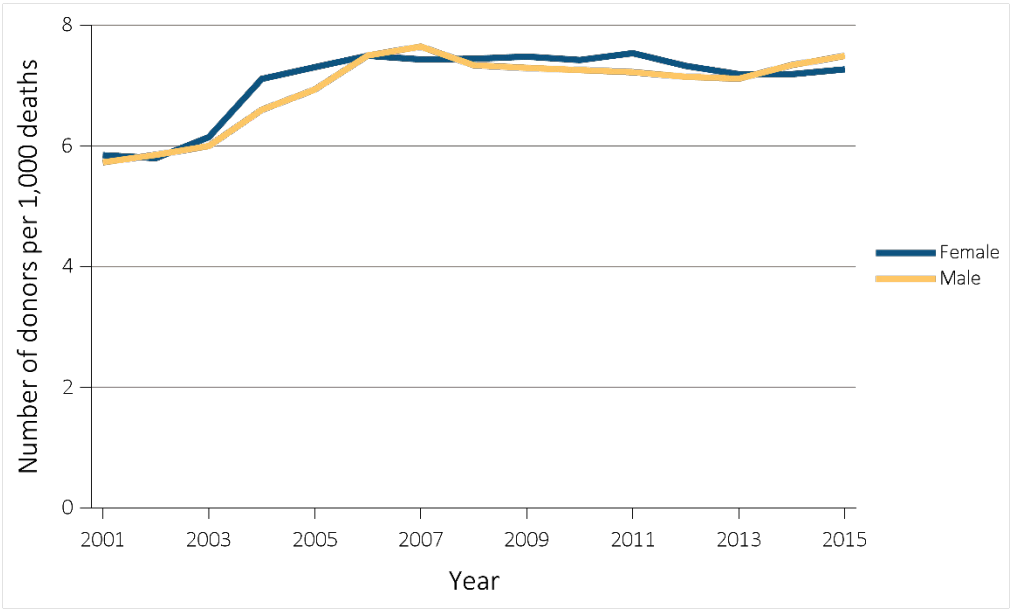
The number of deceased kidney donations by males has consistently been approximately 1.5 times greater than the number from females (Figure 6.19.a). However, the donation rates were similar between males and females (Figure 6.19.b). Both groups have demonstrated an increase in donor counts, particularly over the last two years, although rates have remained relatively stable.

vol 2 Figure 6.19 Number of deceased kidney donors and unadjusted kidney donation rates, by donor sex, 2001-2015

(a) Number of donors by sex



(b) Donation rates by sex



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. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014.

The number and rates of deceased organ donations has also varied by race. White persons have consistently accounted for the greatest absolute number of donations each year from 2001 to 2015 (Figure 6.20.a). The rate of deceased-donors per 1,000 deaths among Blacks has almost doubled during this period (Figure 6.20.b), however, with current donation rates being similar among Blacks, Whites, and Asians or Pacific Islanders.

vol 2 Figure 6.20 Number of deceased kidney donors and unadjusted kidney donation rates, by donor race, 2001-2015

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. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. Abbreviations: AI/AN, American Indian or Alaska Native; Asian/PI, Asian/Pacific Islander; Black/Af Am, Black/African American.

Deceased Donation Counts and Rates among Traumatic Deaths

In this section, we focus on donors who had a traumatic cause of death, such as a motor vehicle accident, suicide, or homicide. Such occurrences represent a common source of donation, as these individuals may be less likely to have underlying health issues that would preclude use of their organs. The number of such donors, aged 1-74 years, with at least one kidney retrieved, has been relatively steady since 2006 (Figure 6.21.a). There were 2,630 such donations in 2015, representing 20% of all deceased donations.

For this specific group, annual donation rates were calculated as the number of deceased-donors with a traumatic cause of death (motor vehicle accident, suicide, or homicide) from whom at least one kidney was retrieved, per 1,000 deaths in the U.S. population (CDC, 2017).

As expected due to the underlying cause of death, donors in the age range of 15-54 years were over-represented, with only small numbers from other age categories (Figure 6.21.a). Donation rates from traumatic deaths were highest among those aged 5-34 years (46 per 1,000 deaths, Figure 6.21.b). In 2015, overall organ donations from those with a traumatic death were 3.9 times the rate of those who died from any cause (28.6 versus 7.3 donations per 1,000 deaths).

vol 2 Figure 6.21 Number of deceased kidney donors and unadjusted kidney donation rates, for traumatic deaths, by donor age, 2001-2015

(a) Number of donors by age

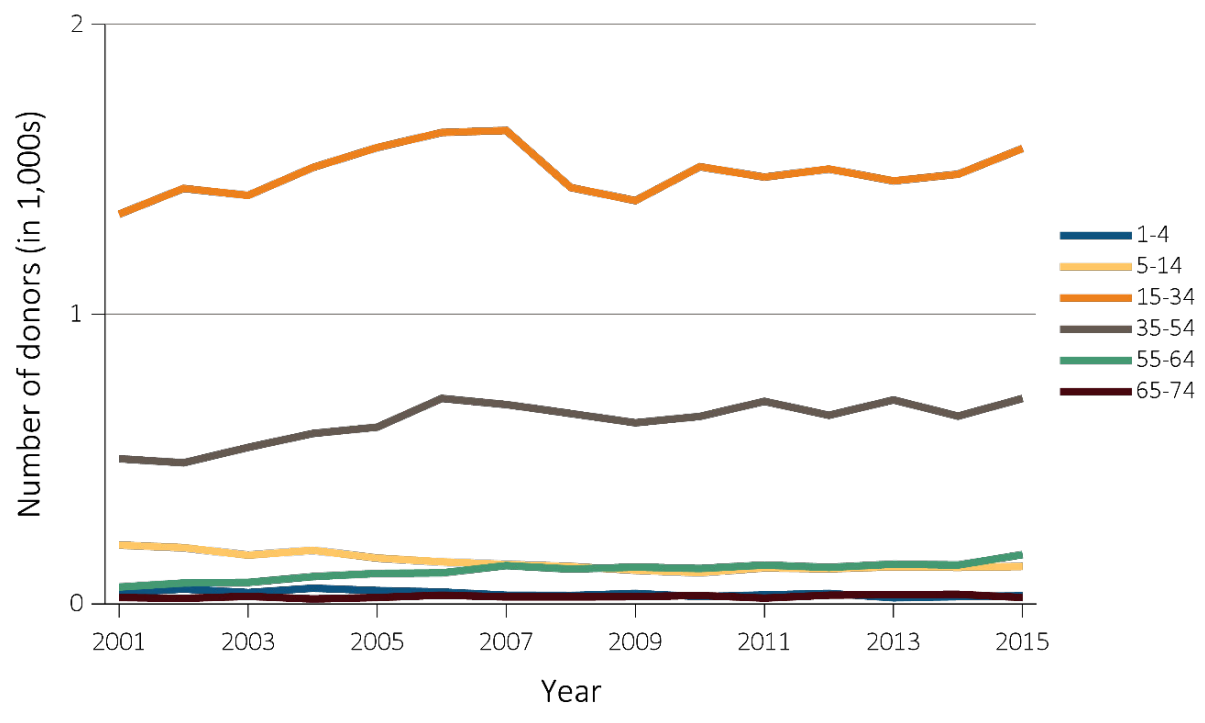
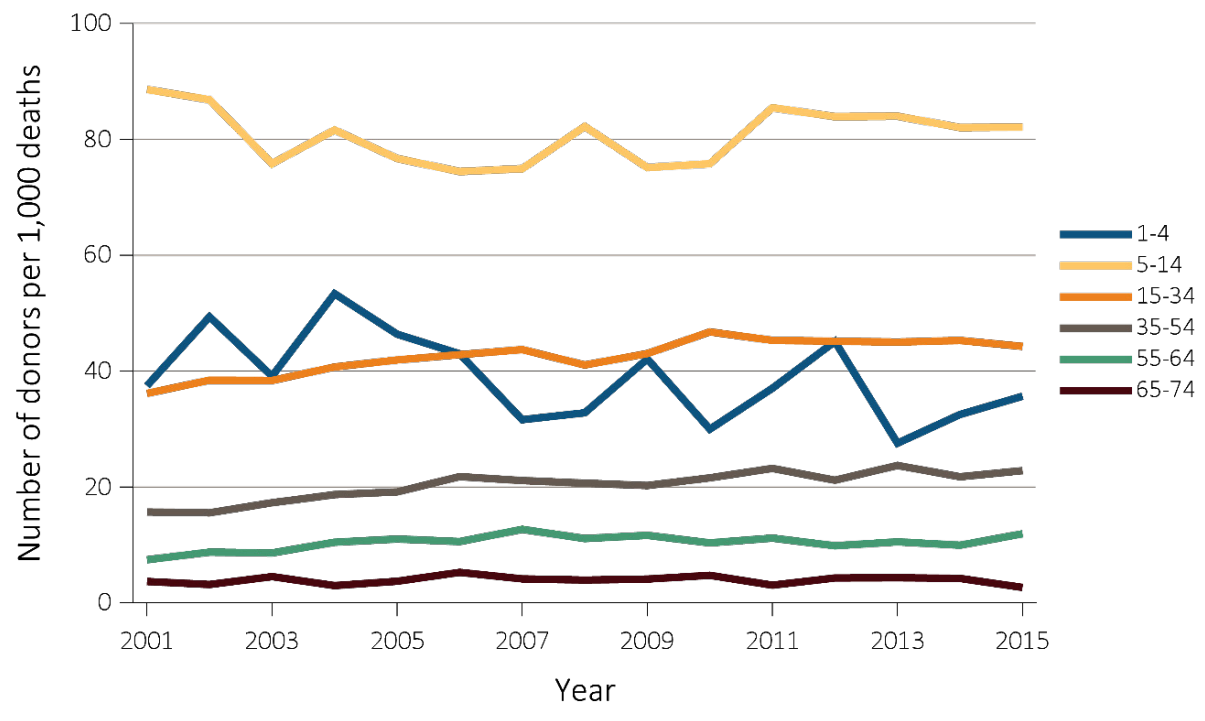


Figure 6.21 continued on next page.

vol 2 Figure 6.21 Number of deceased kidney donors and unadjusted kidney donation rates, for traumatic deaths, by donor age, 2001-2015 *(continued)*

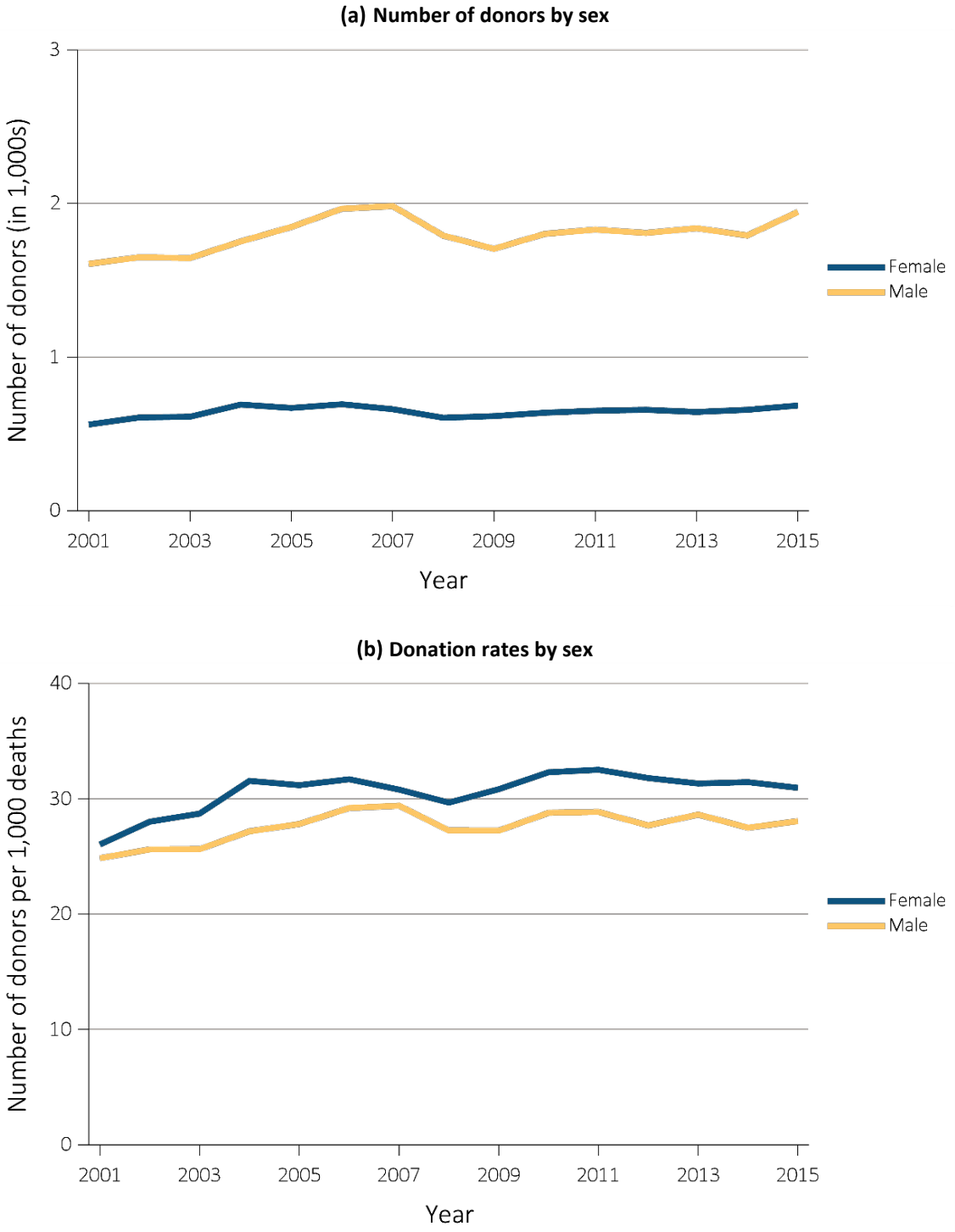
(b) Donation rates by age



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. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014.

Within this subgroup of donors, although counts for males have been consistently about double those of females (Figure 6.22.a) donation rates by sex were similar (Figure 6.22.b). Counts of donation among males with traumatic deaths increased slightly in 2015 but rates of kidney donation for both sexes in this group have been stable for the last several years.

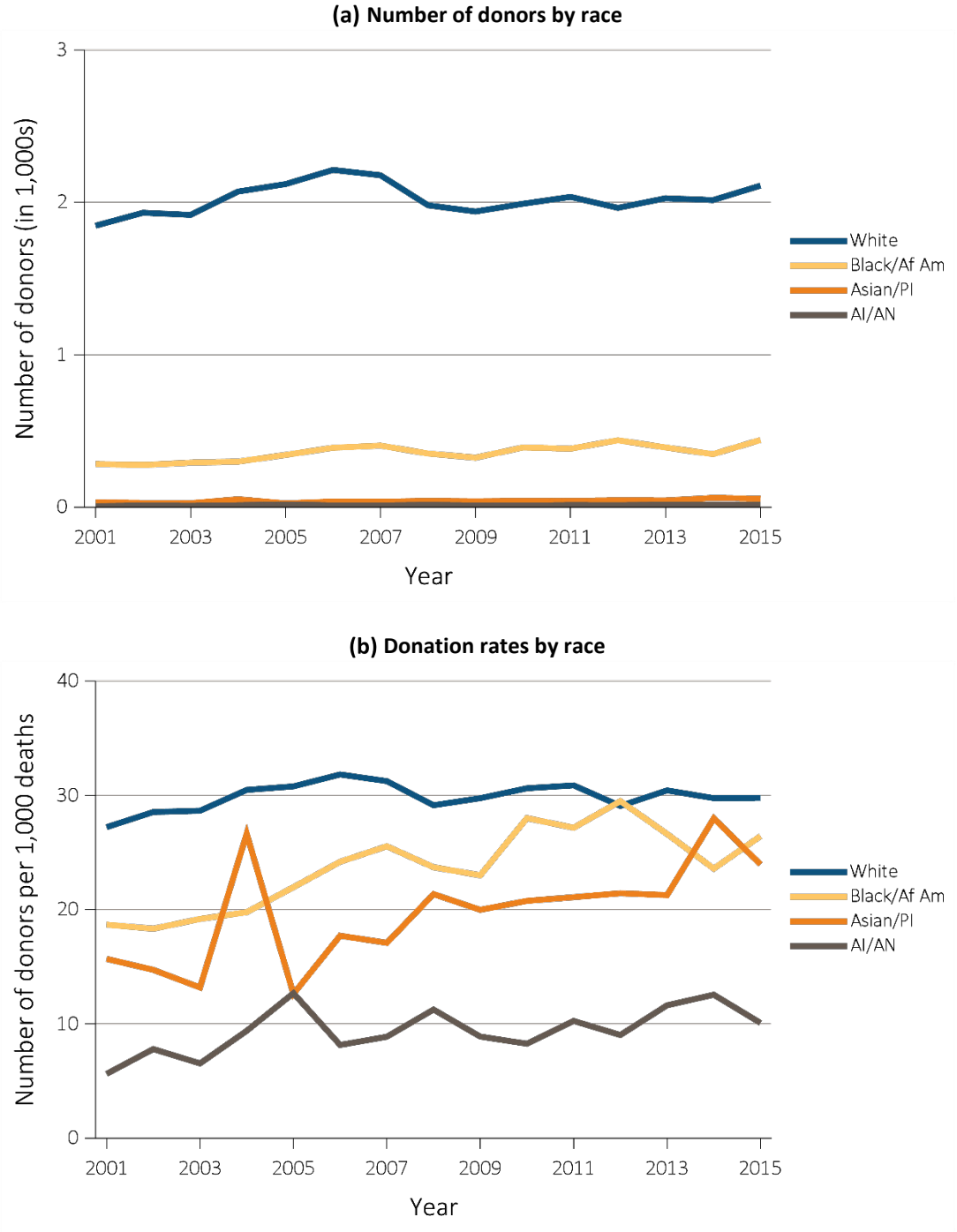
vol 2 Figure 6.22 Number of deceased kidney donors and unadjusted kidney donation rates, for traumatic deaths, by donor sex, 2001-2015



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. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014.

Whites have contributed most to the absolute number of traumatic deceased-donors each year from 2001-2015 (Figure 6.23.a). This was consistent with patterns of all-cause deceased donations and the U.S. racial/ethnic population distribution. Actual rates of donation in the most recent years, however, have been similar for Whites, Blacks, and Asians or Pacific Islanders (Figure 6.23.b).

vol 2 Figure 6.23 Number of deceased kidney donors and unadjusted kidney donation rates, for traumatic deaths, by donor race, 2001-2015



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. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014. Abbreviations: AI/AN, American Indian or Alaska Native; Asian/PI, Asian/Pacific Islander; Black/Af Am, Black/African American.

Transplant Outcomes

For more than a decade, there has been a progressive improvement in the health outcomes of kidney transplant recipients. In this section, we review trends in the probability of graft failures, probability of returning to dialysis or retransplantation, and the probability of death at one, five, and ten-years post-transplant. All-cause graft failure is defined as any failure of the transplanted organ, including death with a functioning kidney. The probability of an individual's need to return to dialysis or undergo retransplantation represents a death-censored graft failure.

During 1998-2014, kidney transplant patients experienced improved health outcomes, with decreases observed in deaths and all-cause graft failures at one year post-transplantation. Among the recipients of deceased-donor kidney transplants, the 2014 probability of one-year graft survival was 93%, slightly improved from 2013. The probability of all-cause graft failure in the first year following transplant decreased from 13% in 1998 to 7% in 2014, while the chance of death decreased from 6% in 1998 to 4% in 2014 (Table 6.4). In analysis of the separate outcomes of graft failure, the probability of either returning to dialysis or undergoing repeat transplantation was 4%, equal to that of death.

vol 2 Table 6.4 Trends in 1-, 5-, & 10-year deceased-donor kidney transplant outcomes, 1998-2014

	One year post-transplant			Five years post-transplant			Ten years post-transplant		
Year	Probability of all-cause graft failure (%)	Probability of return to dialysis or repeat transplant (%)	Probability of death (%)	Probability of all-cause graft failure (%)	Probability of return to dialysis or repeat transplant (%)	Probability of death (%)	Probability of all-cause graft failure (%)	Probability of return to dialysis or repeat transplant (%)	Probability of death (%)
1998	12.6	8.9	5.5	33.8	24.1	18.2	56.7	40.6	37.9
1999	13.2	8.8	5.9	33.6	23.0	18.8	56.3	39.3	38.1
2000	12.7	8.1	6.4	33.9	22.7	19.6	56.3	38.3	38.9
2001	12.2	8.0	5.7	33.1	21.3	19.7	55.3	36.7	38.5
2002	12.3	8.3	5.6	32.8	22.1	18.8	53.5	35.9	37.0
2003	11.8	7.3	5.6	31.7	20.3	18.4	54.4	35.7	37.6
2004	11.1	7.1	5.4	31.3	20.5	18.2	53.2	35.4	36.7
2005	11.2	6.9	6.0	29.9	19.0	17.8	52.4	33.4	36.5
2006	10.4	6.6	5.1	29.3	18.6	17.1			
2007	9.5	5.9	4.6	28.2	17.7	16.8			
2008	9.4	6.0	4.5	26.8	16.1	16.3			
2009	9.3	5.5	4.9	26.9	16.4	16.2			
2010	8.8	5.4	4.4	26.6	16.0	16.5			
2011	7.4	4.4	3.9						
2012	7.8	4.7	3.8						
2013	7.7	4.7	3.5						
2014	6.9	3.8	3.7						

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. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014.

Among those who received living-donor kidney transplants, the probability of one-year graft survival was even greater, at 98%. Like the deceased-donor group, the probability of all-cause graft failure in the first year following transplant decreased from 7% in 1998 to 3% in 2014, while probability of death decreased from 2% to 1% over the same period (Table 6.5). 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%.

vol 2 Table 6.5 Trends in 1-, 5-, & 10-year living-donor kidney transplant outcomes, 1998-2014

Year	One year post-transplant			Five years post-transplant			Ten years post-transplant		
	Probability of all-cause graft failure (%)	Probability of return to dialysis or repeat transplant (%)	Probability of death (%)	Probability of all-cause graft failure (%)	Probability of return to dialysis or repeat transplant (%)	Probability of death (%)	Probability of all-cause graft failure (%)	Probability of return to dialysis or repeat transplant (%)	Probability of death (%)
1998	6.5	4.8	2.3	21.3	15.0	10.1	42.4	30.8	23.2
1999	6.3	4.6	2.1	21.0	14.9	9.4	41.0	28.9	22.4
2000	7.0	5.0	2.6	22.3	15.2	10.6	42.1	29.2	23.7
2001	6.7	4.6	2.5	21.7	14.8	10.2	41.4	28.1	23.7
2002	6.3	4.4	2.4	20.8	14.1	10.2	39.9	26.4	24.3
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	24.6	22.4
2005	5.4	3.7	2.0	18.7	12.7	8.8	38.4	25.1	22.2
2006	4.5	3.1	1.7	16.8	11.2	8.0			
2007	3.8	2.5	1.4	16.7	10.5	7.9			
2008	4.3	2.9	1.6	15.4	10.1	7.4			
2009	4.1	2.8	1.3	15.2	9.4	7.6			
2010	3.7	2.4	1.4	15.3	9.6	7.3			
2011	3.5	2.0	1.8						
2012	3.5	2.1	1.5						
2013	2.6	1.5	1.2						
2014	3.0	1.9	1.4						

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. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014.

Improvements in patient and graft survival probabilities have persisted for most of the five- and ten-year outcomes as well. For 2010 recipients of deceased-donor transplants the probability of five-year graft survival remained unchanged from the prior year, at 73%. The probability of all-cause graft failure by the fifth year improved, dropping from 34% in 1998 to 27% in 2010. By the tenth-year post-transplant, it also decreased from 57% in 1998 to 52% in 2005 (Table 6.4). Probability of death by the fifth-year post-transplant improved by dropping from 18% in 1998 to 17% in 2010, and for tenth-year post transplant improved by decreasing from 38% in 1998 to 37% in 2005.

Similarly, for living-donor kidney transplant recipients, five-year graft survival for living-donor transplant recipients also remained unchanged at 85%. The probability of all-cause graft failure by the fifth year decreased from 21% in 1998 to 15% in 2010, while in the tenth year it decreased from 42% in 1998 to 38% in 2005 (Table 6.5). The probability of death by the fifth year post-transplant also improved, falling from 10% in 1998 to 7% in 2010; in the tenth year, it decreased from 23% in 1998 to 22% in 2005.

Overall, outcomes have been consistently more advantageous for living-donor kidney transplant recipients in comparison to deceased-donor transplant recipients. Dissemination of information on the advantages of living-donor kidney transplant is a valuable component of informed decision-making and transplant education, for both recipients and potential organ donors.

References

CDC: Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 2001-2015 on CDC WONDER Online Database, released 2016. Data are from the Multiple Cause of Death Files, 2001-2015, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. http://wonder.cdc.gov/ucd-icd10.html. Accessed June 15, 2017.

Mathur AK, Ashby VB, Sands RL, Wolfe RA. Geographic Variation in End-Stage Renal Disease Incidence and Access to Deceased Donor Kidney Transplantation. Am J Transplant 2010; 10:1069-1080.

OPTN: Organ Procurement and Transplantation Network, Health Resources and Services Administration, U.S. Department of Health & Human Services. The New Kidney Allocation System (KAS) Frequently Asked Questions https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf. Accessed June 15, 2017.

OPTN: Organ Procurement and Transplantation Network, Health Resources and Services Administration, U.S. Department of Health & Human Services. A Guide to Calculating and Interpreting the Kidney Donor Profile Index (KDPI). https://optn.transplant.hrsa.gov/media/1512/guide_to_calculating_interpreting_kdpi.pdf. Accessed July 19, 2016.

OPTN: Organ Procurement and Transplantation Network, Health Resources and Services Administration, U.S. Department of Health & Human Services. Kidney Donor Profile Index: A Guide for Clinicians. https://optn.transplant.hrsa.gov/resources/guidance/kidney-donor-profile-index-kdpi-guide-for-clinicians/ Accessed October 15, 2017.

Stewart DE, Kucheryavaya AY, Klassen DK, Turgeon NA, Formica RN, Aeder MI. Changes in Deceased Donor Kidney Transplantation 1 Year After KAS Implementation. *Am J Transplant* 2016; 16:1834–1847.

Chapter 7: ESRD among Children, Adolescents, and Young Adults

- The one-year end-stage renal disease (ESRD) patient mortality among the 0-4 year age group has declined approximately 41.6% over the past decade. (Figure 7.8). The transplantation rate did not account for changes during this time.
- The number of children and adolescents beginning ESRD care is steadily decreasing from a high of 17.5 per million in 2004 to 13.7 per million population in 2015, representing a decrease of 21.7% (Figure 7.1.a).
- As of December 31, 2015, the point prevalence of children and adolescents, 0 to 21 years of age, with ESRD was 9,672, or 99.5 per million population (Figure 7.1.b). An additional, 10,251 adult survivors of childhood onset ESRD contributed to the 2015 point prevalence of ESRD in adults.
- During 2011-2015, the proportion of missing, unknown, and unspecified etiologies of incident ESRD patients was particularly high among the 18-21 age group (27%; Table 7.2).

  Short stature is common in children and adolescents with incident ESRD; this affects the majority of the youngest patients between the ages of 0 and 4 years (52.7%).

Introduction

End-stage renal disease (ESRD) affects children of all ages. The majority of these children will depend on renal replacement therapies (RRT) over many decades. Consequently, children with ESRD often traverse the entire modality spectrum of hemodialysis (HD), peritoneal dialysis (PD), and transplantation. These children are at risk for growth failure, frequent hospitalizations, and significantly higher mortality than the general pediatric population. This chapter includes an evaluation of growth parameters in children with ESRD.

Children with ESRD are quite different in disease etiology, transplant opportunities, morbidity, and mortality than adults with ESRD. Consequently, this chapter of the Annual Data Report (ADR) focuses on pediatric ESRD. Additionally, we include a section on young adults in order to improve our understanding of the issues surrounding transitions and outcomes in this distinct population, wherein etiology and comorbidities are often more aligned with adolescents than older adults.

Methods

The findings presented in this chapter were drawn from multiple data sources, including 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. Census. Details of these are described in the *Data Sources* section of the *ESRD Analytical Methods* chapter.

See the section on Chapter 7 in the *Analytical Methods Used in the ESRD Volume* 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. Downloadable Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available on the USRDS website.

In this 2017 pediatric chapter, we align etiology classification with typical pediatric classifications, and report new results regarding growth status of children with ESRD. However, there are limitations in the reporting of trends in children 0 to 2 years old due to

the small total number of patients in this age group. These limitations drive the requirement to use larger age groupings for much of the chapter.

Epidemiology of End-stage Renal Disease in Children

The number of children and adolescents beginning ESRD care is steadily decreasing from a high of 17.5 per million population (PMP) in 2004 to 13.7 PMP in 2015—a decline of 21.7% (Figure 7.1.a). In 2015, the number and rate of these incident cases varied by age group; there were 211 cases in those aged 0-4 years, 117 aged 5-9, 163 aged 10-13, 336 aged 14-17, and 548 aged 18-21 years, for a total of 1,375 children with incident ESRD. Within these age-based cohorts, incidence rates in 2015 were 9.3 PMP per year for 0-4 year olds, 4.8 for 5-9 year olds, 8.6 for 10-13 year olds, 18.4 of those aged 14-17 years, and 29.8 PMP aged 18–21 years.

As of December 31, 2015, the point prevalence count of children, 0 to 21 years of age, with ESRD was 9,672, or 99.5 PMP (Figure 7.1.b). Overall, the prevalence of ESRD in children in the U.S. has been generally stable for the most recent decade.

Incidence and Prevalence by ESRD Modality

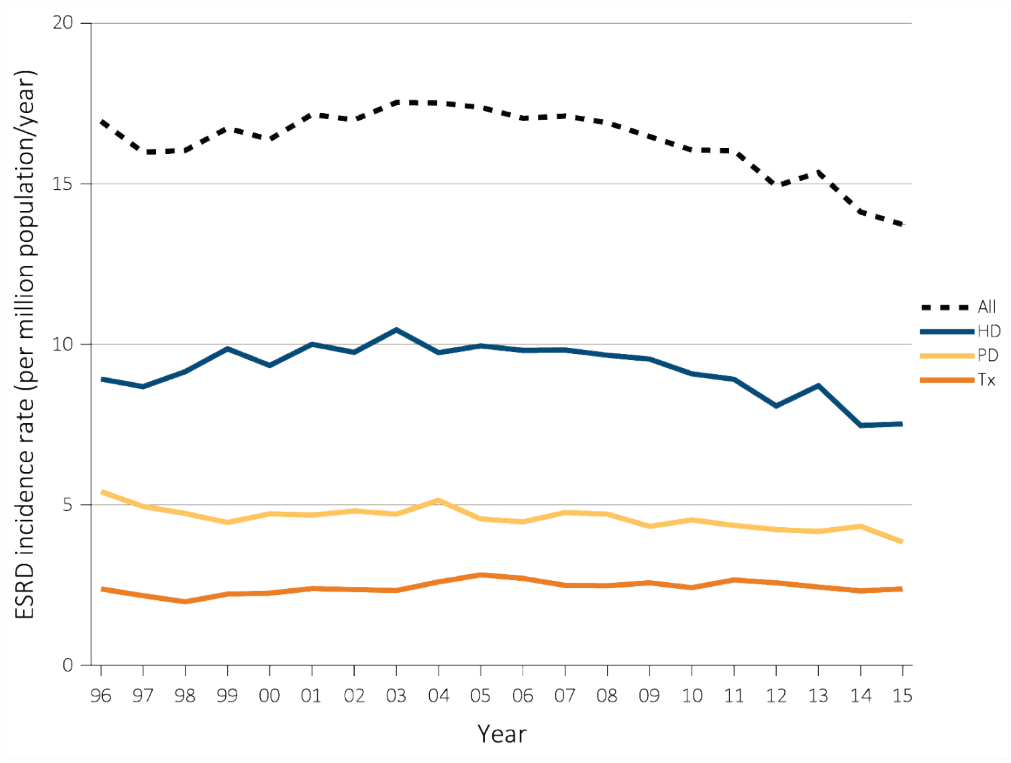
Over time, children have consistently initiated ESRD therapy with HD more frequently than PD or transplantation. Data from 2015 demonstrated this pattern, with 714 (51.9%) initiating with HD, 366 (26.6%) with PD, and 293 (21.3%) with transplant. This equates to an incidence rate of 7.5 with HD, 3.8 with PD, and 2.4 with transplant, PMP per year in 2015.

When examined by age, PD was the most common initial ESRD treatment modality for children aged 9 years and younger (Figure 7.2.a). Hemodialysis has become the most common initial modality for patients aged 10 years and older. Similar relationships are shown by patient weight, with PD most commonly prescribed as the initial modality in small children weighing less than 20 kilograms (kg), and initiation with HD becoming more common with increasing patient weight (Figure 7.2.b).

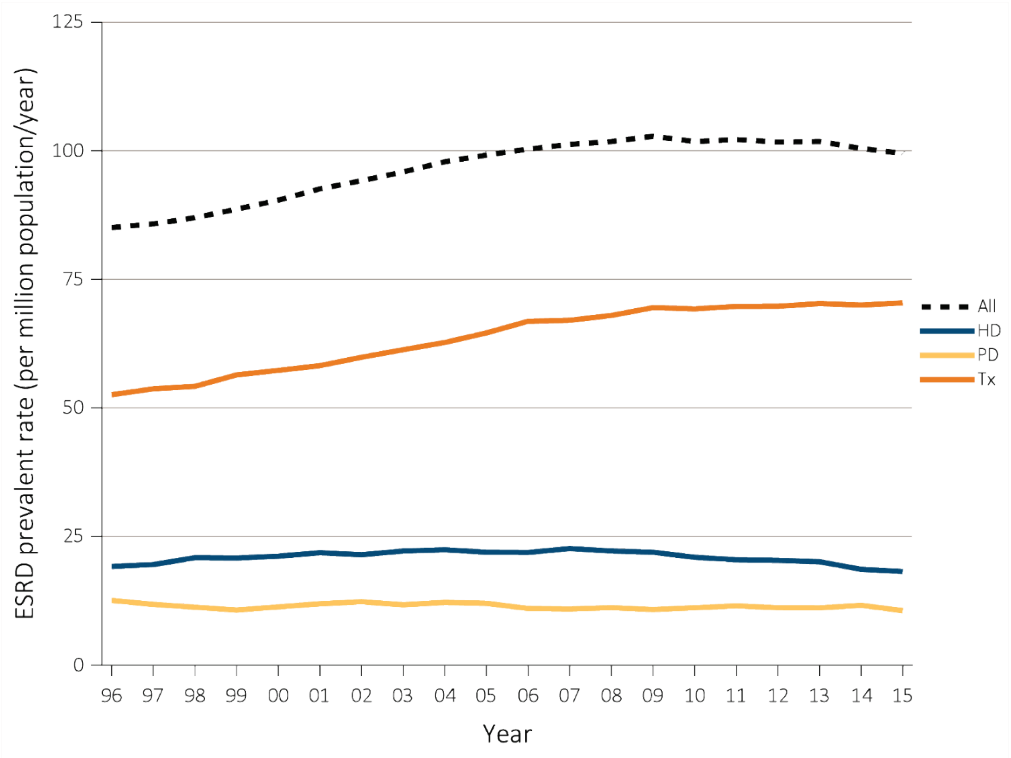
The modality at initiation varied greatly by race, with HD most commonly reported for those of African American/Black race (71.1%) compared to White (50.1%) and those of Other (43.0%) races (Figure 7.2.c). Kidney transplantation accounted for less than 40% of initial modality across all pediatric ages and weights, but was the predominant prevalent ESRD treatment modality used in children (Figure 7.1.b). Of the 9,672 children and adolescents under 22 years of age with prevalent ESRD as of December 31, 2015, kidney transplant was the most common ESRD modality (6,910, 71.4%), followed by HD (1,730, 17.9%) and PD (1,004, 10.4%;). This equates to a point prevalence PMP children of 18.2 for HD, 10.6 for PD, and 70.4 for transplant.

vol 2 Figure 7.1 (a) Incidence and, (b) December 31st point prevalence of ESRD among pediatric patients (aged 0–21 years), by modality, 1996-2015

(a) Incidence



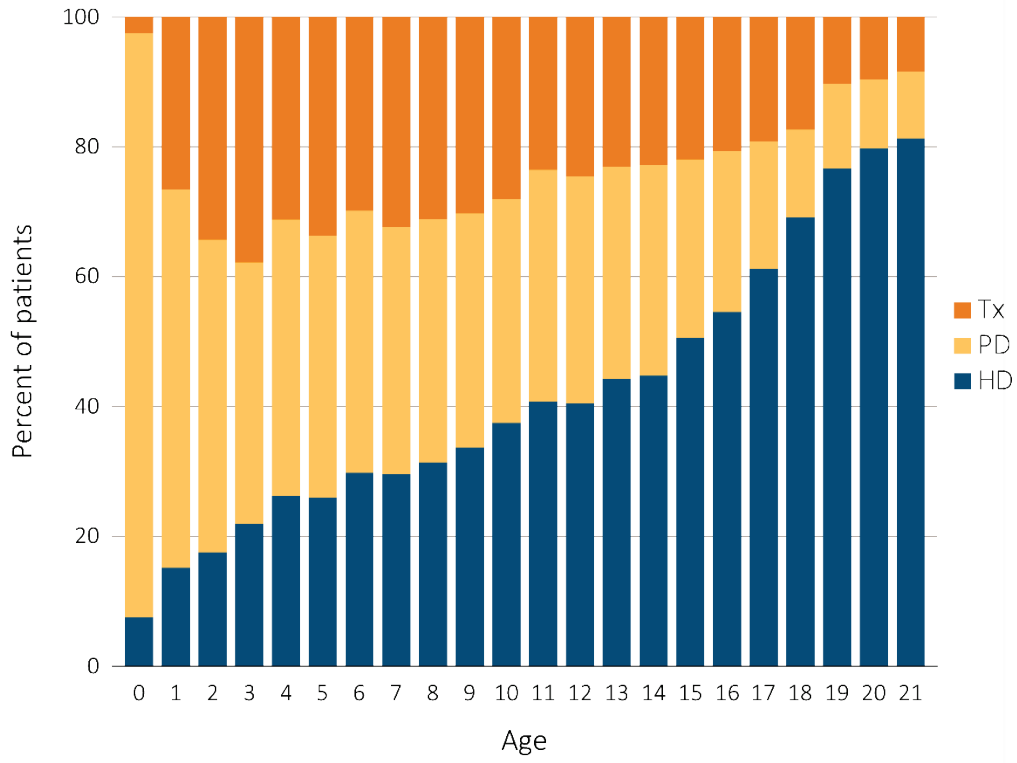
(b) Point prevalence



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 7.2 Cross-sectional trends in pediatric ESRD modality at initiation, by patient (a) age, (b) weight, and (c) race, 1996-2015

(a) Age



(b) Weight

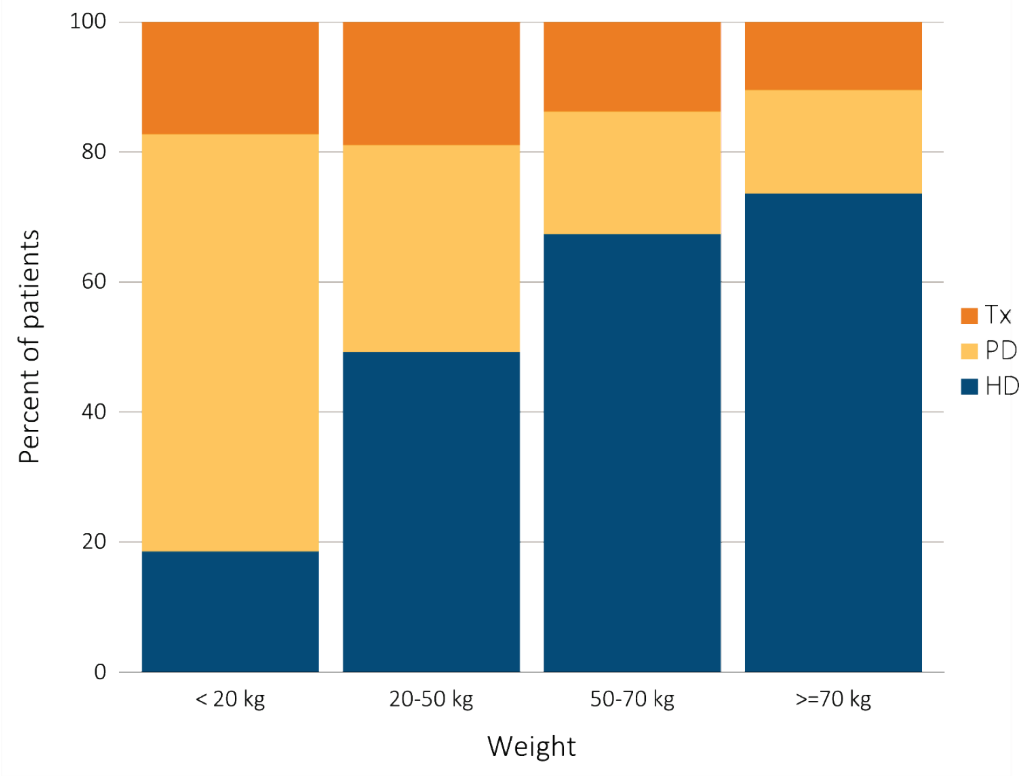
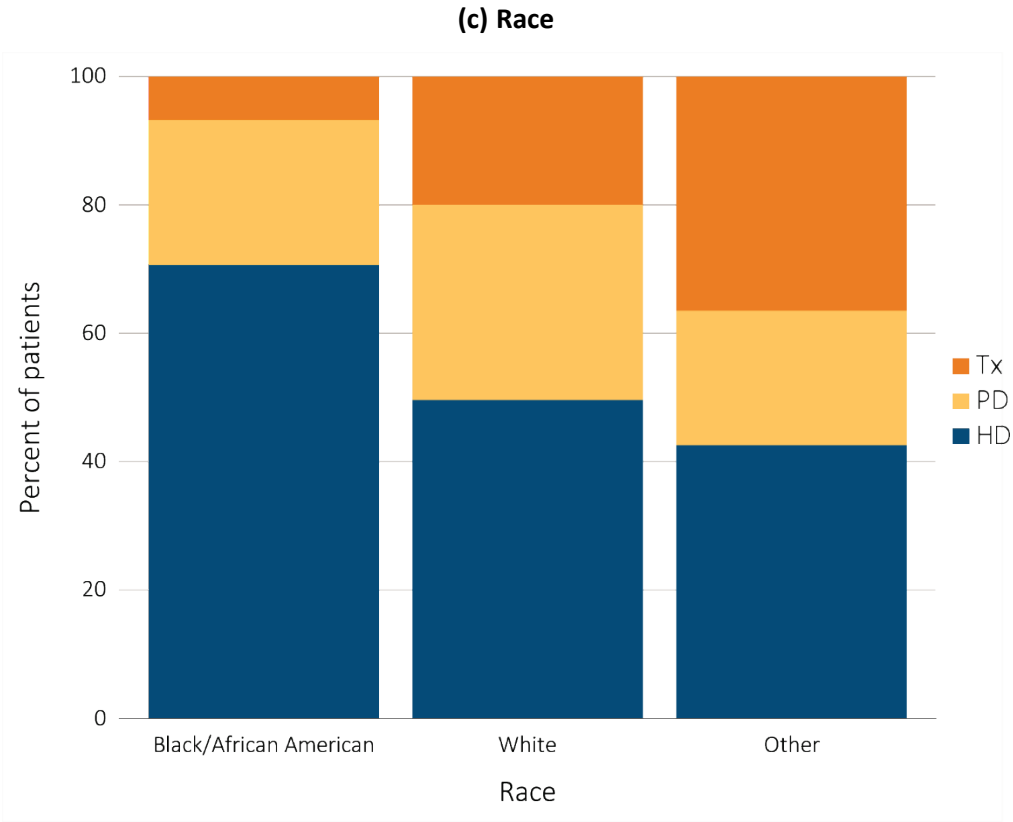


Figure 7.2 continued on next page.

vol 2 Figure 7.2 Cross-sectional trends in pediatric ESRD modality at initiation, by patient (a) age, (b) weight, and (c) race, 1996-2015 *(continued)*



Data Source: Special analyses, USRDS ESRD Database. Includes incident ESRD patients in 1996-2015. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

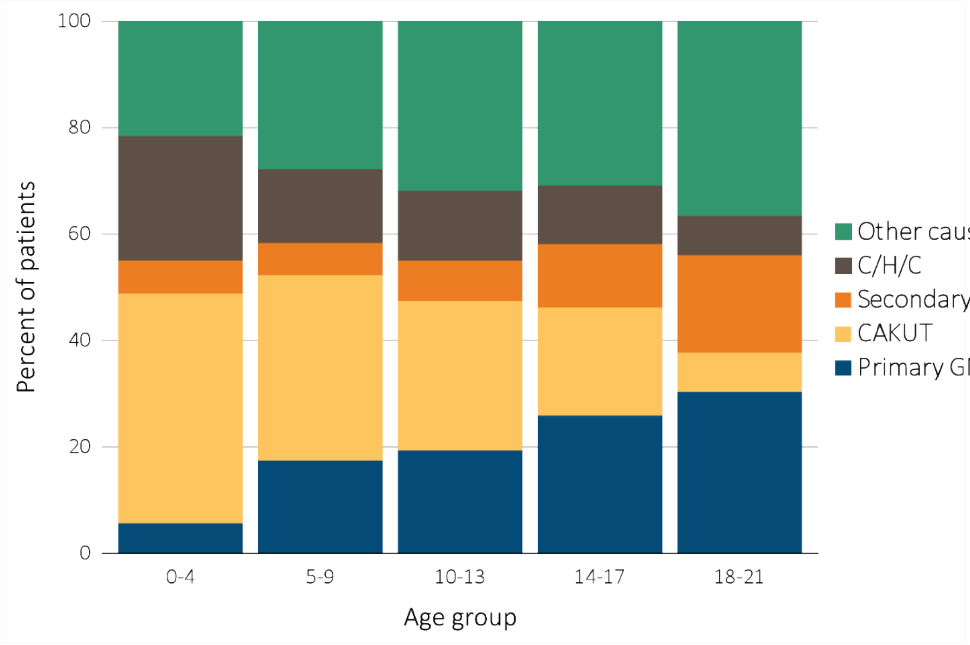
Etiology

The leading causes of ESRD in children during 2011-2015 were CAKUT (congenital anomalies of the kidney and urinary tract; 22%), primary glomerular disease (21.8%), cystic/hereditary/congenital disorders (12.5%), and secondary glomerular disease/vasculitis (10.7%). The most common individual diagnoses associated with pediatric ESRD included focal glomerulosclerosis (849, 11.6%), renal hypoplasia/dysplasia (737, 10%), congenital obstructive uropathies (712, 9.7%), and systemic lupus erythematosus (462, 6.3%).

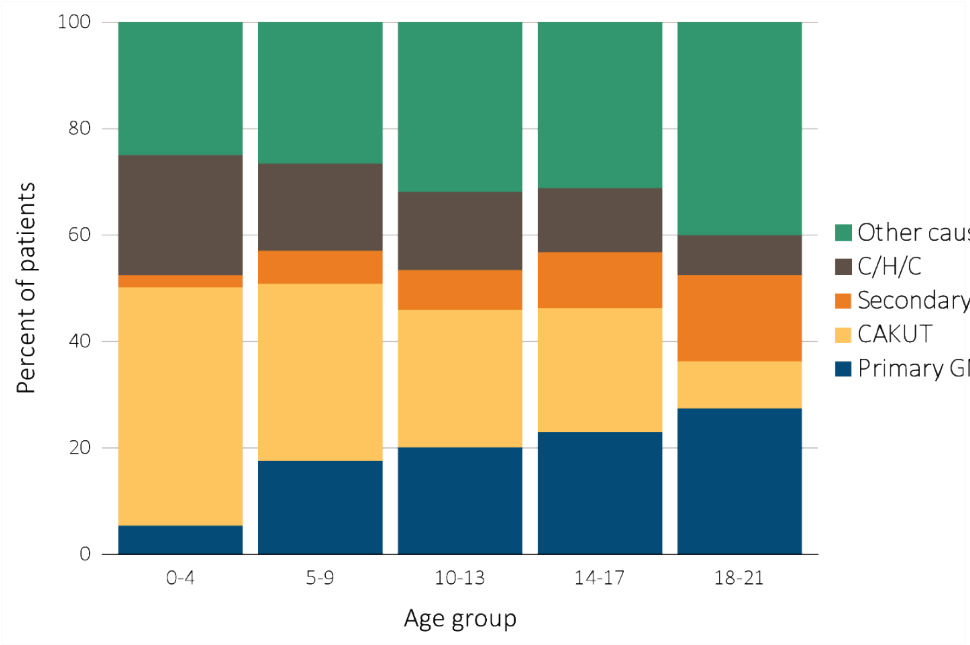
Figure 7.3 shows the distribution of the most common causes of ESRD by age and by year of onset of ESRD. CAKUT and congenital/hereditary/cystic disorders caused more ESRD in young children; primary and secondary glomerulonephritis and other etiologies became more common with advancing age. The distribution of ESRD etiology by age and year of onset of ESRD were consistent between incident years 2006-2010 and 2011-2015. The unspecified, uncertain, and missing reported ESRD etiologies accounted for over 1000 incident cases between 2011 and 2015 (20.6%) and represent an area for future quality improvement initiatives (Tables 7.1 and 7.2).

vol 2 Figure 7.3 Distribution of reported incident pediatric ESRD patients by primary cause of ESRD, by age in (a) 2006-2010 and (b) 2011-2015

(a) 2006-2010 (period A)



(b) 2011-2015 (period B)



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

vol 2 Table 7.1 Distribution of reported incident pediatric ESRD patients by primary cause of ESRD (aged 0-21 years), and by demographic characteristics

(a) 2006-2010 (period A)

Primary Disease Groups	Total Patients		Percent Incidence		Median Age		Percent Males		Percent White		Percent Black/ African American		Percent Other Race	
	A	B	A	B	A	B	A	B	A	B	A	B	A	B
All ESRD, (reference)	8221	7340	100	100	16	16	56.6	56.5	66	66.3	24.8	23.9	9.2	9.9
CAKUT	1662	1617	20.2	22	12	11	69.9	68.7	76.4	74.2	17.1	19.5	6.6	6.2
Congenital obstructive uropathies	721	712	8.8	9.7	11	11	83.4	82.4	74.1	69.9	20.7	24.4	5.3	5.6
Renal hypoplasia, dysplasia, oligonephronia	745	737	9.1	10	10	10	63.8	59.6	75.8	75.2	16.8	17.9	7.4	6.9
Chronic pyelonephritis, reflux nephropathy	196	168	2.4	2.3	16	17	43.9	50.6	86.7	88.1	5.1	6	8.2	6
Cystic/Hereditary/Congenital Diseases	954	921	11.6	12.5	14	13	58.8	59.3	79.1	76.9	15.9	15.9	4.9	7.3
Polycystic kidneys, adult type (dominant)	46	48	0.6	0.7	18	18	47.8	39.6	78.3	83.3	19.6	14.6	2.2	2.1
Polycystic, infantile (recessive)	145	151	1.8	2.1	4	1	47.6	49	77.2	79.5	19.3	13.2	3.4	7.3
Medullary cystic disease, including nephronophthisis	113	112	1.4	1.5	13	12	40.7	42.9	89.4	77.7	5.3	12.5	5.3	9.8
Hereditary nephritis, Alports syndrome	186	162	2.3	2.2	17	17	86.6	87.7	73.1	75.9	20.4	17.3	6.5	6.8
Cystinosis	59	40	0.7	0.5	13	11	49.2	62.5	96.6	82.5	3.4	12.5	0	5
Primary oxalosis	19	17	0.2	0.2	6	11	52.6	70.6	78.9	70.6	5.3	11.8	15.8	17.6
Congenital nephrotic syndrome	124	135	1.5	1.8	2	3	58.1	49.6	78.2	82.2	15.3	11.9	6.5	5.9
Drash syndrome, mesangial sclerosis	29	21	0.4	0.3	1	1	55.2	52.4	79.3	81	17.2	14.3	3.4	4.8
Other (congenital malformation syndromes)	204	208	2.5	2.8	14	13	58.3	63	84.8	76.9	9.8	13.9	5.4	9.1
Sickle cell disease/anemia	22	15	0.3	0.2	20	20	63.6	73.3	9.1	0	90.9	100	0	0
Primary Glomerular Disease	1985	1603	24.1	21.8	18	18	55.1	55.5	61.1	65.4	31.4	26.9	7.5	7.6
Glomerulonephritis (GN) (histologically not examined)	399	290	4.9	4.0	19	19	61.2	58.3	66.2	72.1	24.3	19.3	9.5	8.6
Focal glomerulosclerosis, focal sclerosing GN	1017	849	12.4	11.6	17	17	55	56.8	53.3	59.4	41.5	34.9	5.2	5.8
Membranous nephropathy	48	39	0.6	0.5	18	19	45.8	69.2	54.2	61.5	39.6	33.3	6.3	5.1
Membranoproliferative GN type 1, diffuse MPGN	105	70	1.3	1.0	17	17	43.8	45.7	66.7	75.7	21.9	14.3	11.4	10
Dense deposit disease, MPGN type 2	33	26	0.4	0.4	16	16	54.5	53.8	90.9	84.6	3	7.7	6.1	7.7
IgA nephropathy	208	187	2.5	2.5	19	18	65.4	58.8	73.6	74.9	14.9	10.2	11.5	15
IgM nephropathy	19	15	0.2	0.2	19	19	63.2	60	63.2	66.7	36.8	26.7	0	6.7
With lesion of rapidly progressive GN	64	47	0.8	0.6	15	16	32.8	27.7	71.9	72.3	15.6	17	12.5	10.6
Other proliferative GN	92	80	1.1	1.1	16	17	39.1	41.3	76.1	66.3	15.2	30	8.7	3.8

Table 7.1 continued on next page.

vol 2 Table 7.1 Distribution of reported incident pediatric ESRD patients by primary cause of ESRD (aged 0-21 years), and by demographic characteristics (con't)

(b) 2011-2015 (period B)

Primary Disease Groups	Total Patients		Percent Incidence		Median Age		Percent Males		Percent White		Percent Black/ African American		Percent Other Race	
	A	B	A	B	A	B	A	B	A	B	A	B	A	B
Secondary Glomerular Disease/Vasculitis	1045	788	12.7	10.7	18	19	31.3	28.2	53.4	54.3	39.4	39.2	7.2	6.5
Lupus erythematosus, (SLE nephritis)	613	462	7.5	6.3	19	19	19.9	19	39.6	38.7	50.9	53.7	9.5	7.6
Henoch-Schonlein (IgA Vasculitis)	36	27	0.4	0.4	17	13	58.3	48.1	88.9	85.2	5.6	7.4	5.6	7.4
Hemolytic uremic syndrome	147	100	1.8	1.4	9	11	46.3	37	81	81	15	14	4.1	5
Polyarteritis and other vasculitis	46	39	0.6	0.5	15	15	39.1	30.8	67.4	79.5	21.7	15.4	10.9	5.1
ANCA-associated vasculitis	59	69	0.7	0.9	16	17	45.8	44.9	86.4	75.4	11.9	17.4	1.7	7.2
Goodpastures syndrome	57	47	0.7	0.6	19	19	38.6	46.8	89.5	97.9	7	0	3.5	2.1
Secondary GN, other	28	16	0.3	0.2	18	19	60.7	37.5	78.6	68.8	17.9	25	3.6	6.3
AIDS nephropathy	52	20	0.6	0.3	20	21	55.8	50	7.7	0	92.3	100	0	0
Tubulointerstitial Diseases	279	206	3.4	2.8	16	17	59.9	56.3	75.6	75.2	17.9	17.5	6.5	7.3
Chronic interstitial nephritis	82	65	1	0.9	17	18	57.3	56.9	76.8	78.5	18.3	13.8	4.9	7.7
Tubular necrosis	176	118	2.1	1.6	16	14	61.9	53.4	77.3	73.7	15.9	18.6	6.8	7.6
Transplant Complications	150	87	1.8	1.2	16	16	55.3	62.1	74	66.7	17.3	25.3	8.7	8
Kidney transplant complication	54	*	0.7	0.1	16	18	61.1	57.1	74.1	71.4	20.4	0	5.6	28.6
Other transplant complication	89	77	1.1	1	16	16	52.8	62.3	74.2	66.2	16.9	27.3	9	6.5
Diabetes	108	83	1.3	1.1	20	20	43.5	39.8	56.5	37.3	38.9	56.6	4.6	6
Diabetes with renal manifestations Type 2	48	40	0.6	0.5	20	20	41.7	40	56.3	42.5	37.5	52.5	6.3	5
Diabetes with renal manifestations Type 1	60	43	0.7	0.6	20	20	45	39.5	56.7	32.6	40	60.5	3.3	7
Neoplasms/Tumors	48	46	0.6	0.6	9	9	50	39.1	70.8	80.4	18.8	10.9	10.4	8.7
Renal tumor	35	35	0.4	0.5	7	4	51.4	34.3	68.6	74.3	25.7	14.3	5.7	11.4
Hypertensive/Large Vessel Disease	15	17	0.2	0.2	14	18	73.3	58.8	80	94.1	13.3	5.9	6.7	0
Miscellaneous Conditions	856	964	10.4	13.1	19	18	60.4	61.2	63.1	62.7	31.2	29.6	5.7	7.8
Acquired obstructive uropathy	48	70	0.6	1	17	15	79.2	68.6	79.2	74.3	14.6	18.6	6.3	7.1
Nephrolithiasis	18	14	0.2	0.2	18	15	33.3	35.7	88.9	85.7	0	14.3	11.1	0
Unspecified with renal failure	495	505	6	6.9	20	20	62	65.1	51.5	51.1	44	43	4.4	5.9
Traumatic or surgical loss of kidney(s)	16	19	0.2	0.3	9	12	50	57.9	75	57.9	6.3	31.6	18.8	10.5
Other renal disorders	231	309	2.8	4.2	15	14	57.6	55.3	75.8	77.7	16.5	12	7.8	10.4
Nephropathy caused by other agents	45	39	0.5	0.5	18	15	55.6	51.3	91.1	71.8	6.7	20.5	2.2	7.7
Etiology Uncertain	824	514	10	7	16	16	58.3	50.8	75.1	70.8	18.7	19.3	6.2	9.9
Missing	295	494	3.6	6.7	14	15	61.7	60.1	14.2	43.5	6.1	10.9	79.7	45.5

Data Source: Special analyses, USRDS ESRD Database. Abbreviations: ANCA, anti-neutrophil cytoplasmic antibody; AIDS, acquired-immune deficiency syndrome; CAKUT, congenital anomalies of the kidney and urinary tract; congenital obstructive uropathy, combination of congenital ureteropelvic junction obstruction, congenital ureterovesical 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.

Table 7.2 Proportion of missing, unknown, and unspecified etiology of ESRD in children and adolescents, by age group.

	0-4	5-9	10-13	14-17	18-21	All
ESRD etiology missing, unknown, or unspecified	10.9%	14.4%	19.0%	19.3%	27.0%	20.6%

Data Source: Special analyses, USRDS ESRD Database.

Growth

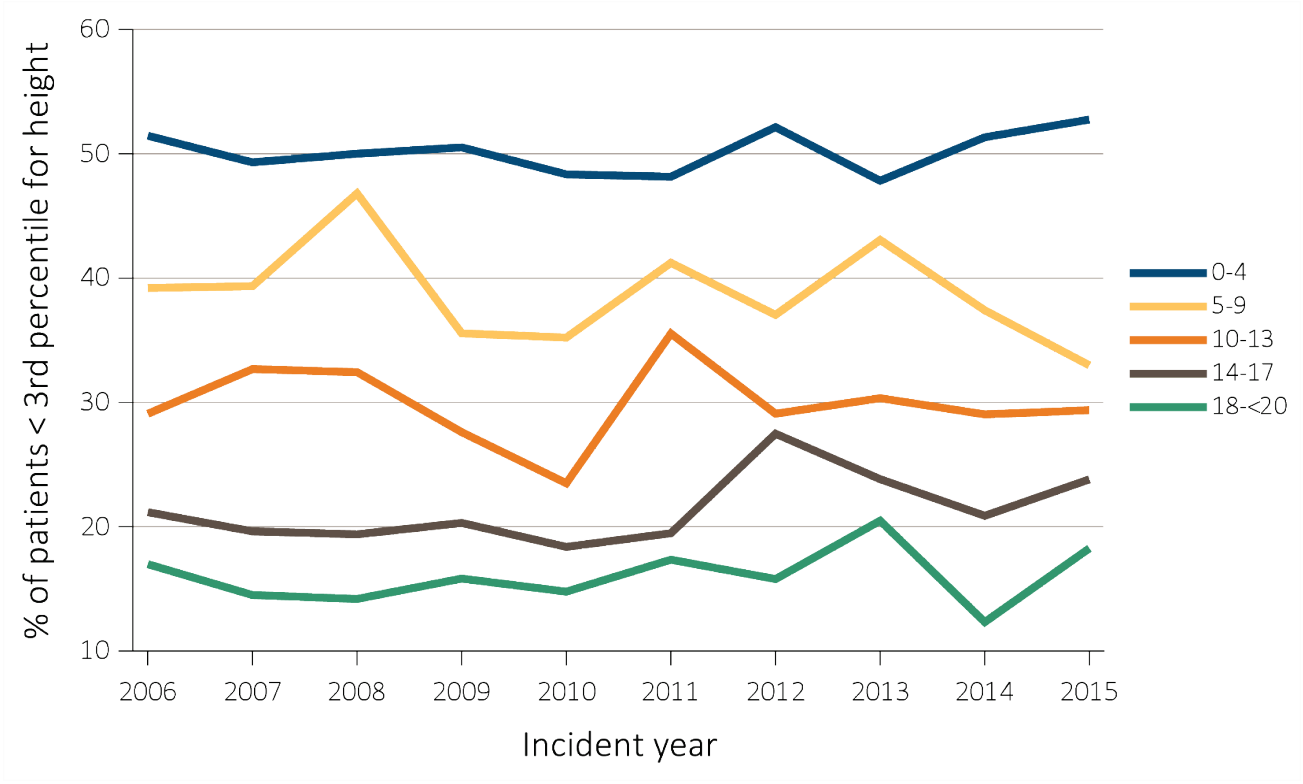
Children with chronic kidney disease and ESRD are at risk for growth impairment, requiring intensive intervention to optimize growth. In this 2017 ADR, we report growth parameters of short stature (defined as less than the third percentile for age) and body mass index (BMI) at incidence of ESRD.

Over the past 10 years, the 0-4 age group consistently had the highest proportion of children with short stature (Figure 7.4.a). The proportion of incident ESRD patients with short stature decreased in older age groups. In 2015, the percentage of incident ESRD patients with short stature was highest in the youngest patients, at 52.7% in the 0-4 age group, 33% in the 5-9 age group, 29.4% in the 10-13 age group, and 23.8% in the 14-17 age group. The prevalence of short stature in the incident pediatric ESRD population has not improved over the past 10 years.

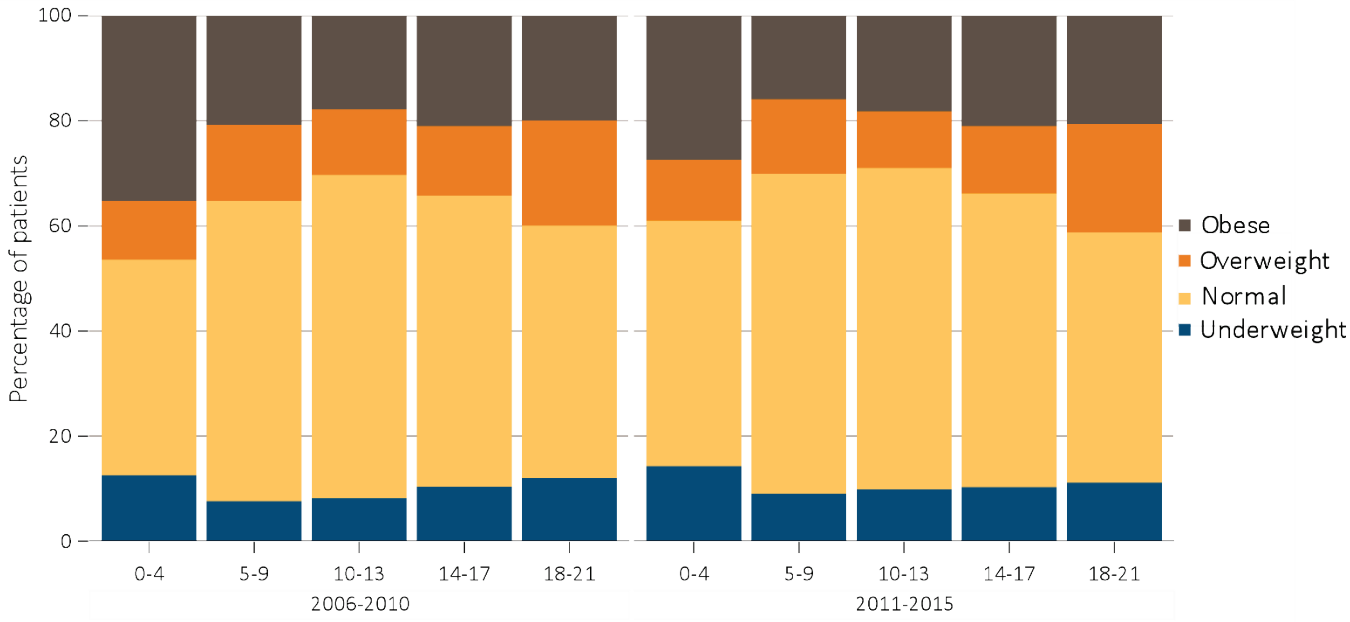
The youngest children with incident ESRD in the 2011-2015 period, those between 0-4 years of age, had the largest proportion of unhealthy weight status, including being underweight (14.8%) and obese (26.8%; Figure 7.4.b). In total, 55% of children aged 0-4 who were obese at ESRD initiation also had short stature, suggesting that nutritional support alone is insufficient to restore all patients to a normal stature.

vol 2 Figure 7.4 Growth status at the time of ESRD initiation by (a) Stature and (b) Body Mass Index (BMI)

(a) Stature



(b) BMI

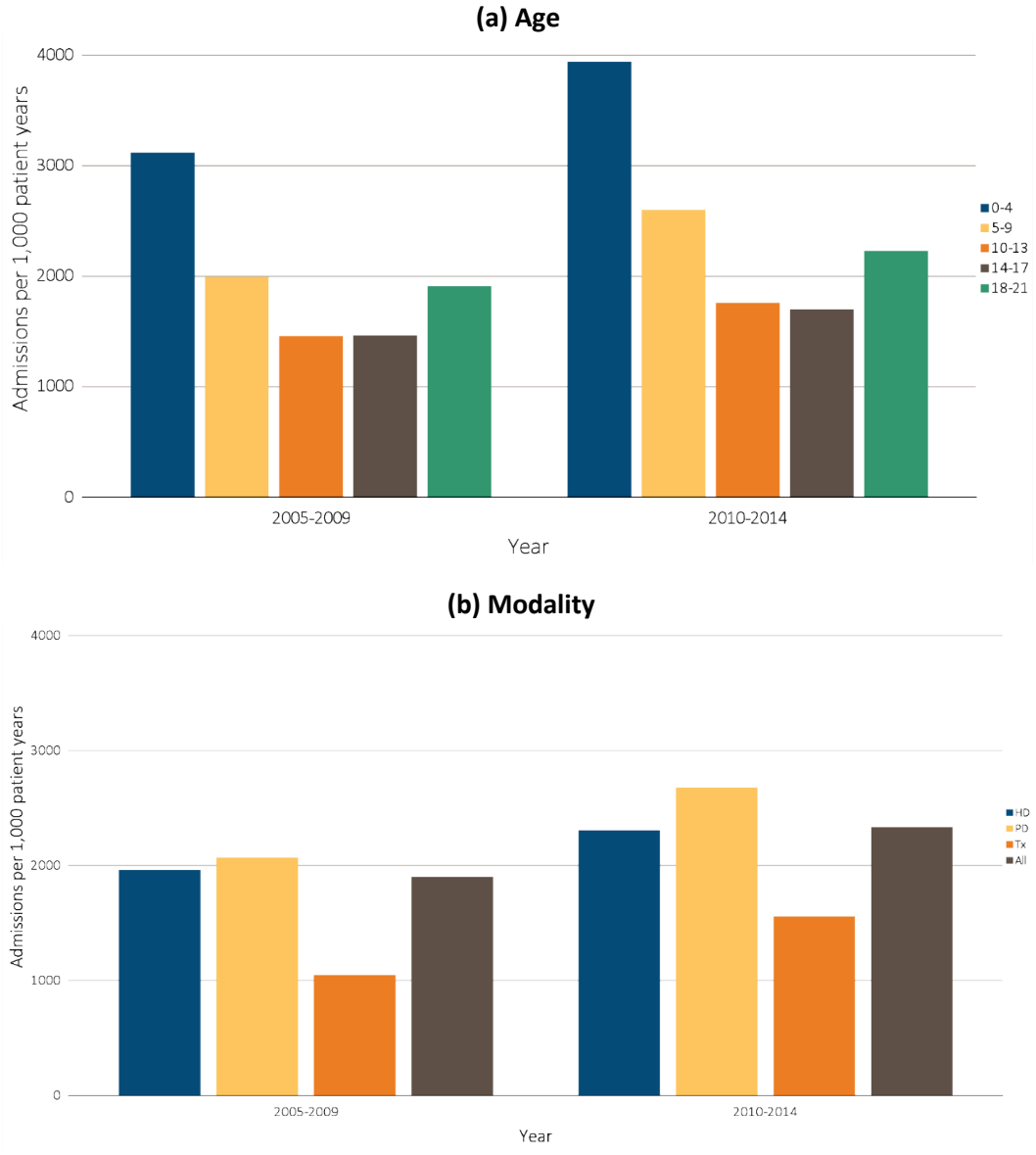


Data Source: Special analyses, USRDS ESRD Database. (a) Stature reported for age <21 per growth percentile guidelines. Percentiles for children greater or equal to 24 months of age and up to less than 20 years of age are calculated following Centers for Disease Control and Prevention (CDC) growth charts. Percentiles for children less than 24 months of age are calculated following World Health Organization (WHO) growth charts. Short stature is defined as height less than 3rd percentile for sex and age. (b) BMI categories are defined differently for patients younger than 18 (underweight: BMI < 5th percentile; Normal: 5th percentile ≤ BMI < 85th percentile; Overweight: 85th percentile ≤ BMI < 95th percentile; and obese: BMI ≥ 95th percentile) and patients 18 and older (underweight: BMI < 18.5; Normal: 18.5 ≤ BMI < 25 percentile; Overweight: 25 ≤ BMI < 30; and obese: BMI ≥ 30). Abbreviations: ESRD, end-stage renal disease; BMI, body mass index.

Hospitalizations in Children with Incident ESRD

The first ESRD-year adjusted all-cause hospitalization rates were highest in the youngest children, those 0-4 years of age (Figure 7.5.a). During the 2010-2014 reporting years, the rates of hospitalization rose overall from 1,885 to 2,318 admissions per 1,000 patient years. This increase in hospitalization rates was observed in every age group and for every RRT modality (Figure 7.5.b). While they account for a minority of hospitalizations in children with incident ESRD, we report the one-year hospitalizations associated with cardiovascular disease (CVD) and infection. This provides consistency with previous ADR pediatric chapters and aligns with two leading causes of ESRD-associated mortality in children. Other substantial causes of hospitalization in this population included hypertension (19.8%), complications of kidney transplant (8.6%), complications of dialysis, including access complications (7.2%), dehydration (2.9%), and hyperkalemia (2.4%).

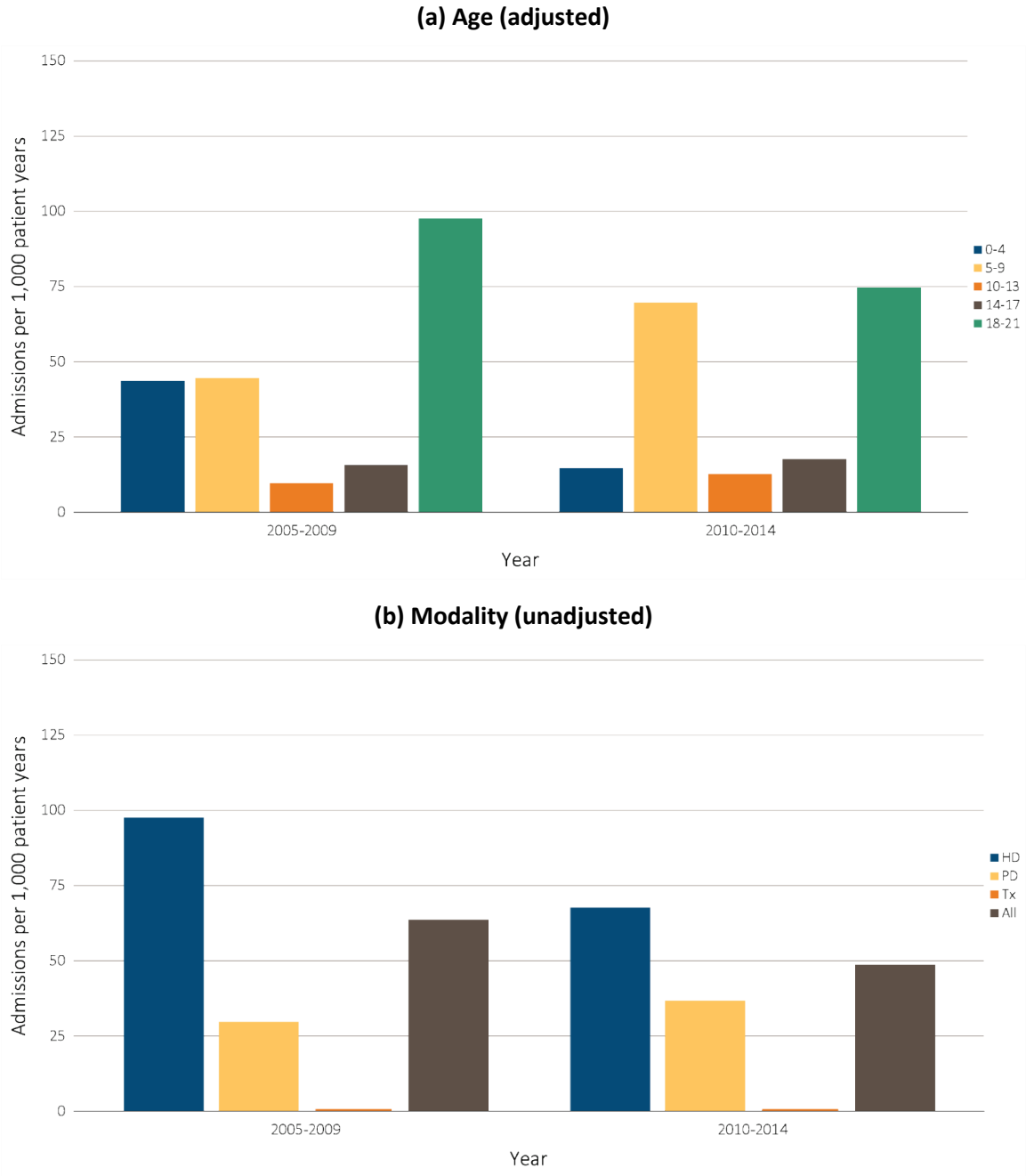
vol 2 Figure 7.5 One-year adjusted all-cause hospitalization rates in incident pediatric patients (aged 0-21 years), by (a) age and (b) modality, 2005-2009 and 2010-2014



Data Source: Special analyses, USRDS ESRD Database. Includes incident pediatric ESRD patients in the years 2005-2014, 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.

The first-year CVD hospitalization rates for children less than 22 years of age with incident ESRD were 63 per 1,000 patient-years from 2005-2009, and 48 from 2010-2014 (Figure 7.6.b). The highest rates of CVD hospitalizations in incident patients were observed in children aged 5-9 and 18-21 years (Figure 7.6.a) and in children treated with dialysis (Figure 7.6.b).

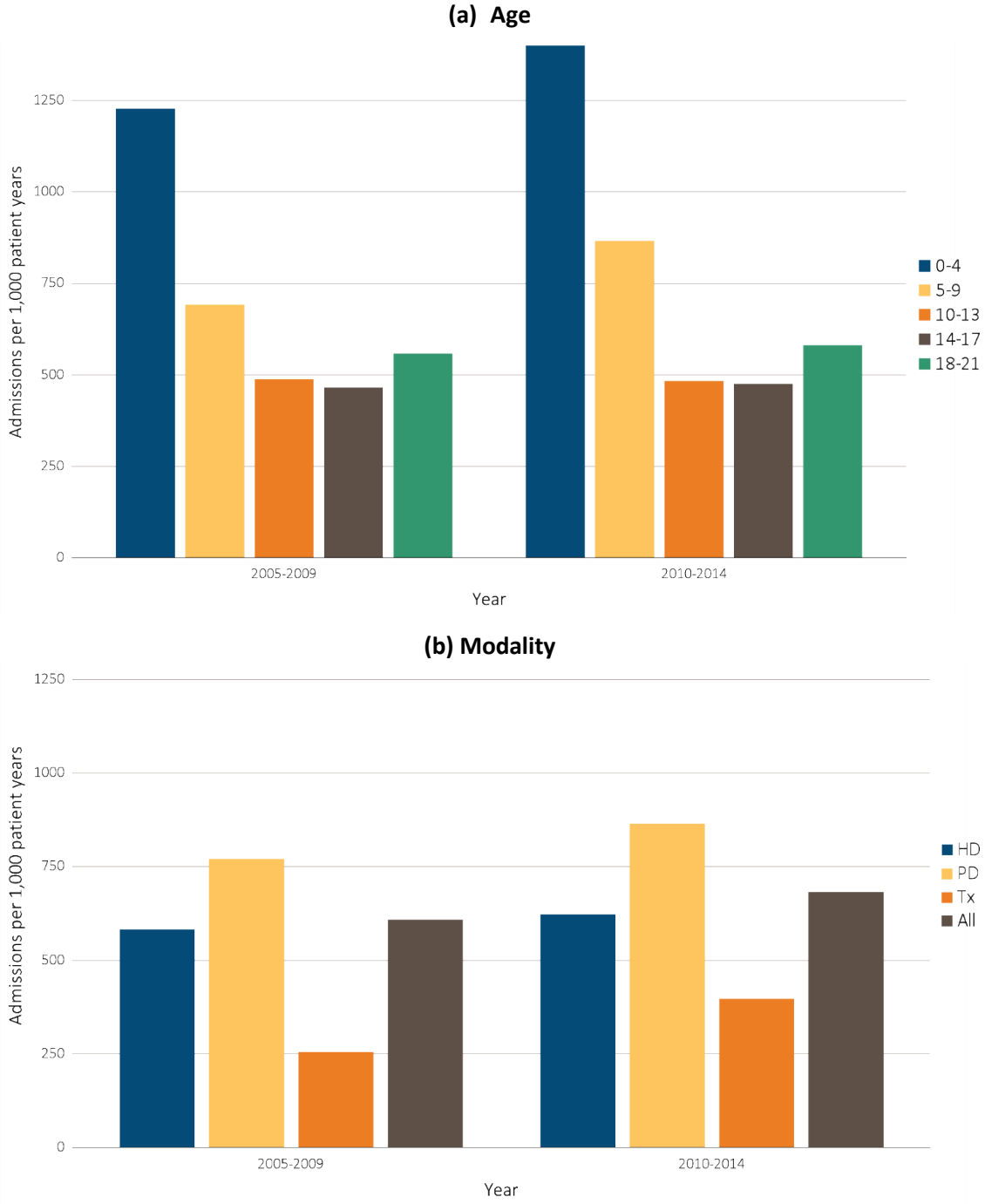
vol 2 Figure 7.6 One-year cardiovascular hospitalization rates in incident pediatric patients (aged 0-21 years), by (a) age and (b) modality 2005-2009 and 2010-2014



Data Source: Special analyses, USRDS ESRD Database. Includes incident pediatric ESRD patients in the years 2005-2014, 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 in the first year of ESRD care was 674 admissions per 1,000 patient years during 2010-2014, which was 11.8% higher than during 2005-2009 (Figure 7.7.b). These first year infection-related hospitalizations in children increased in every modality of RRT in the most recent 5-year reporting window, by 5.7% in HD, 13.1% in PD, and 56.2% in transplant patients. In examining between-modality statistics, children on PD and HD had higher rates of infection-related hospitalizations than did transplanted children (Figure 7.7.b).

vol 2 Figure 7.7 One-year adjusted hospitalization rates for infection in incident pediatric patients (aged 0-21 years), by (a) age and (b) modality, 2005-2009 and 2010-2014



Data Source: Special analyses, USRDS ESRD Database. Includes incident pediatric ESRD patients in the years 2005-2014, 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 2010-2014, the one-year adjusted all-cause mortality rate was 27 per 1,000 patient years, a decrease of 30.8% from the 39 per 1,000 patient years seen in 2005-2009 (Figure 7.8.b). Reduced mortality was reported in almost all age categories, with the greatest point estimate of reduced mortality by 41.6% in children age 0-4 years (Figure 7.8.a). The improvement in the one-year mortality in the 0-4 age group was mostly in the infants less than 2 years of age at onset of ESRD (age <2 years: 45% vs age 2 to <5: 32% reduction in mortality).

When comparing the 2005-2009 and 2010-2014 periods, adjusted one-year all-cause mortality rates by modality showed decreases of 27.5% among HD patients, 44.2% among PD patients, and 30.8% among transplant patients (Figure 7.8.b). Despite the overall improvement in the adjusted one-year all cause-mortality from 2010-2014, a difference in mortality by modality remained, with HD- and PD-associated one-year all-cause mortality rates 4.1 and 2.7 times higher than for transplant patients. Across all modalities, the five most common causes of death reported on the Death Notification Form were predominantly attributed to cardiac arrest cause unknown, withdrawal from dialysis, and sepsis for children aged 0 to 21 years. The youngest children had similar reported causes when compared with older children and adolescents.

Assessment of expected remaining lifetime based on age at ESRD incidence and modality is presented in Table 7.3, and compared with published general population estimates from the U.S. Social Security Administration.

vol 2 Figure 7.8 One-year adjusted all-cause mortality rates in incident pediatric patients with ESRD by (a) age with comparison to young adults (aged 0-29 years), and (b) modality (aged 0-21 years only), 2005-2009 and 2010-2014

(a) Age

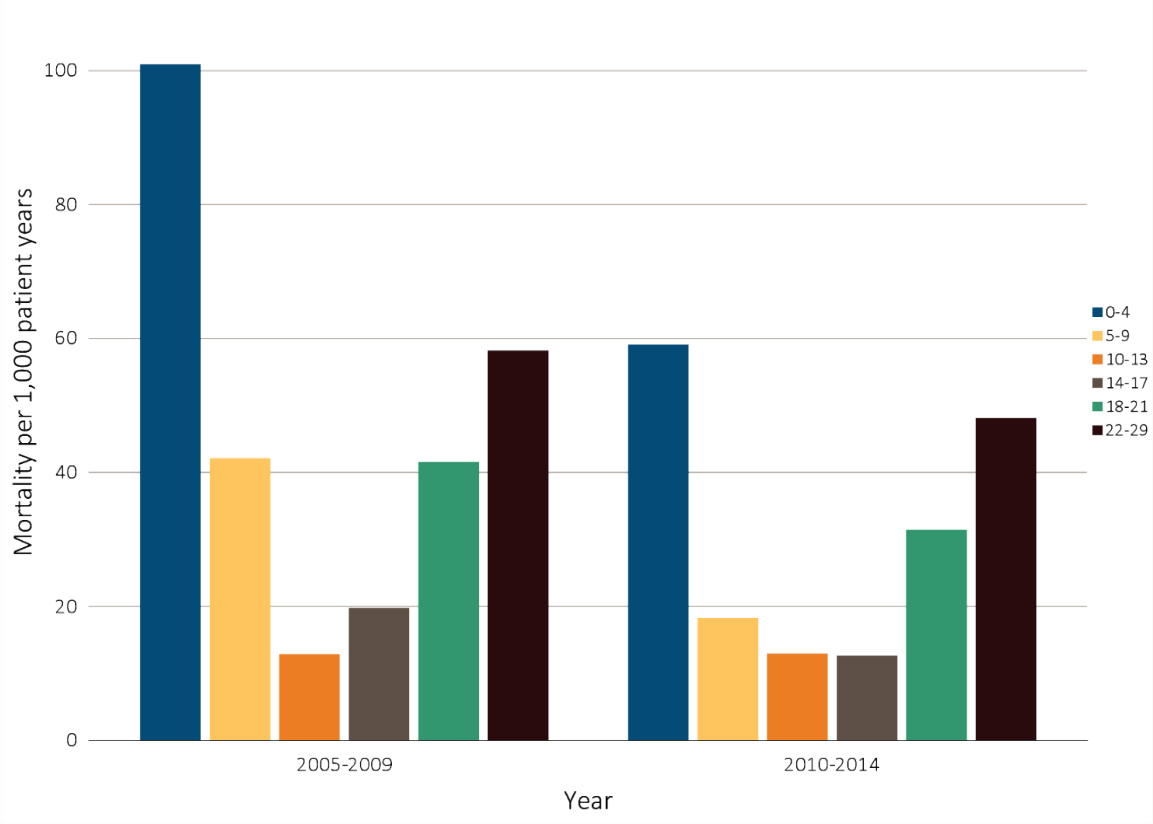
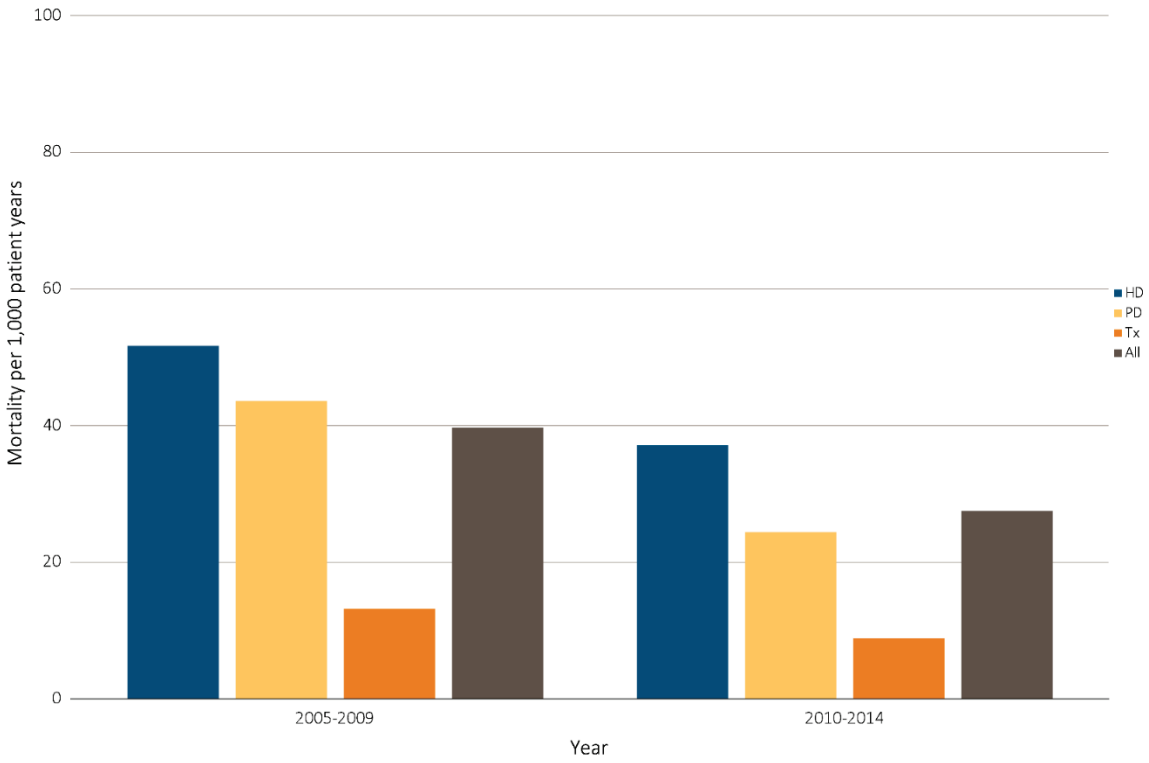


Figure 7.8 continued on next page.

vol 2 Figure 7.8 One-year adjusted all-cause mortality rates in incident pediatric patients with ESRD by (a) age with comparison to young adults (aged 0-29 years), and (b) modality (aged 0-21 years only), 2005-2009 and 2010-2014 *(continued)*

(b) Modality



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, 2015. 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.

Table 7.3 Expected remaining lifetime in years of prevalent patients by initial ESRD modality, 2014

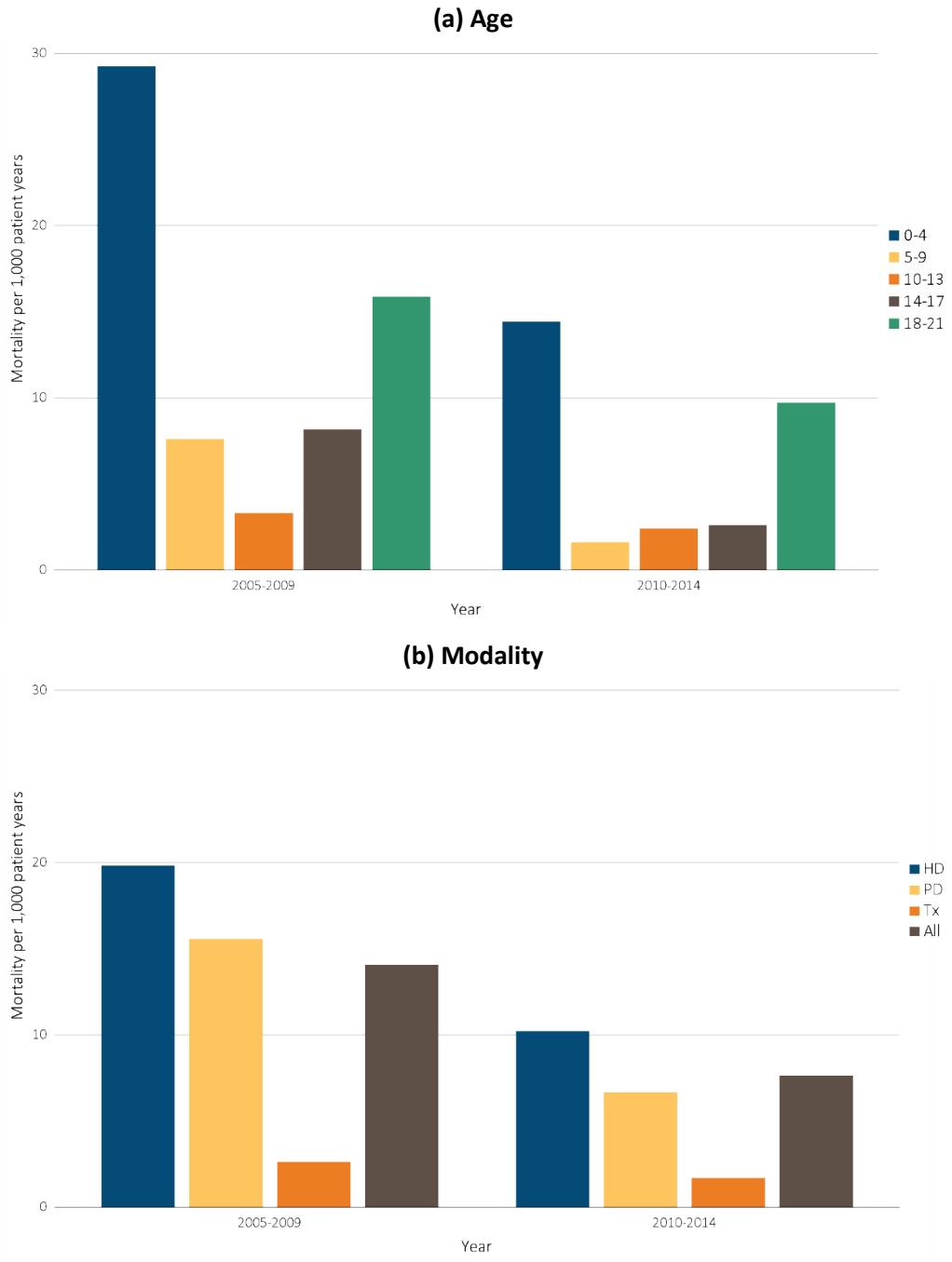
Age group	Dialysis patients	Transplant patients	General population
0-4	23.6	56.9	77.1
5-9	24.3	56.3	72.3
10-13	24.1	52.2	67.8
14-17	20.9	48.8	63.9
18-21	17.7	45.2	60.0
22-29	16.0	42.0	54.2

Data Source: Special analyses, USRDS ESRD Database, USA SSA (Social Security Administration) Period Life Table 2014. Includes period prevalent ESRD dialysis and transplant patients in 2014.

During 2010-2014, the one-year adjusted CVD mortality rate was eight per 1,000 patient years, a decrease of 42.9% from the 2005-2009 period (Figure 7.9.b). The adjusted one-year CVD mortality rate decreased across all age groups (Figure 7.9.a), but remained the highest in children aged 0-4 years.

When examining adjusted one-year CVD mortality across the periods from 2005-2009 and 2010-2014, mortality decreased in all ESRD treatment modality groups but continued to be highest in the dialysis groups, when compared to transplant (Figure 7.9.b).

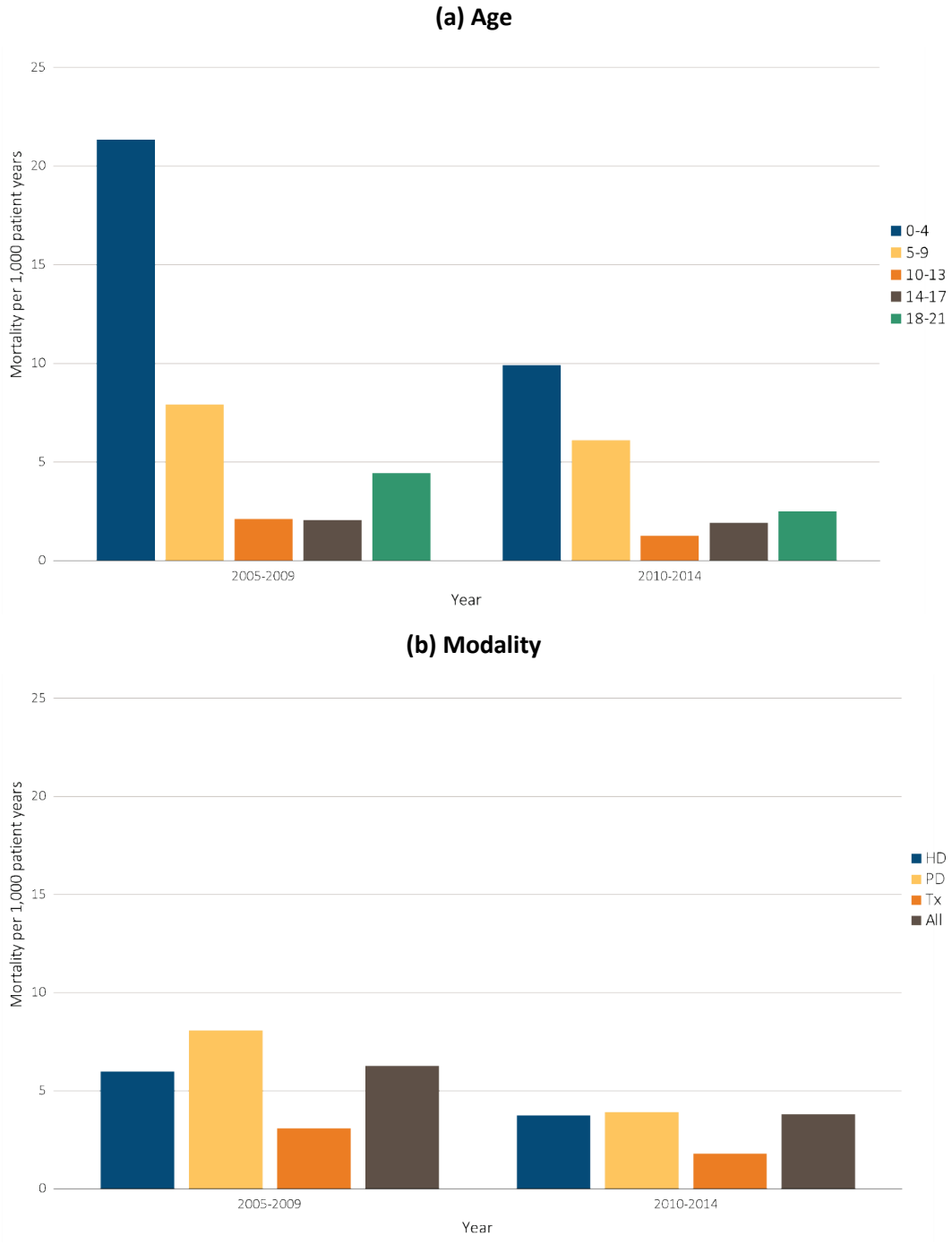
vol 2 Figure 7.9 One-year adjusted cardiovascular mortality rates in incident pediatric patients with ESRD (aged 0-21 years), by (a) age and (b) modality, 2005-2009 and 2010-2014



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, 2015. 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.

During 2010-2014, the one-year adjusted infection-related mortality rate decreased from six to four per 1,000 patient years when compared to the 2005-2009 period (Figure 7.10.b). This mortality rate decreased in those aged 0-4 years by 52.4% (Figure 7.10.a), but it continued to be higher than in other age groups. During 2010-2014 the by mortality rate was quite low, ranging from two to four per 1,000 patient years in children with incident ESRD (Figure 7.10.b).

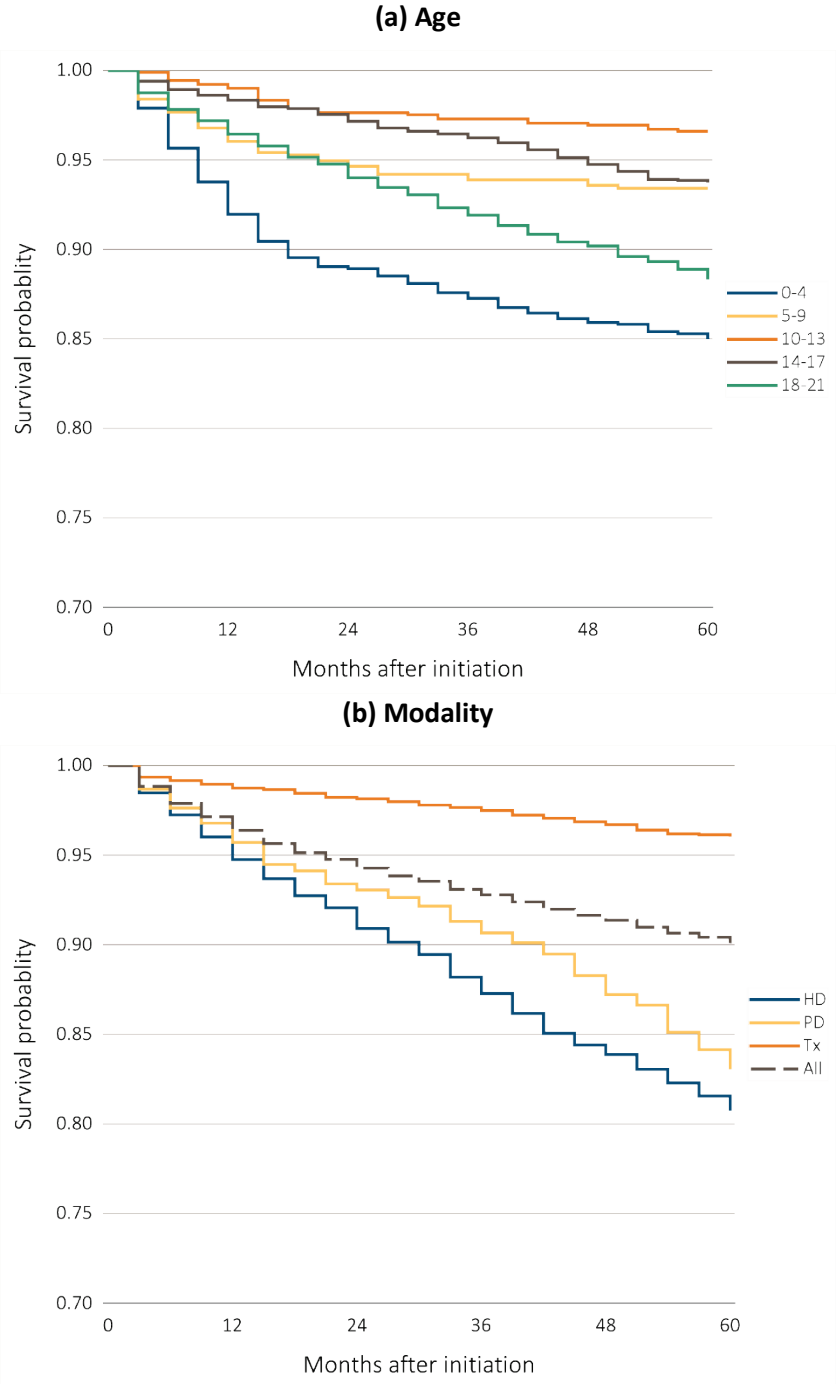
vol 2 Figure 7.10 One-year adjusted rates of mortality due to infection in incident pediatric patients with ESRD (aged 0-21 years), by (a) age and (b) modality, 2005-2009 and 2010-2014



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, 2015. 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.

For patients beginning ESRD therapy during 2006-2010, the probability of five-year survival was 0.90 (Figure 7.11.b). The probability of surviving five years by age was the worst for the youngest and oldest subsets, including 0.85 for ages 0-4 and 0.88 for ages 18-21 years (Figure 7.11.a). Patients initiating ESRD care with transplantation had the highest probability of surviving five years, at 0.96, as compared to 0.81 with HD, and 0.83 with PD (Figure 7.11.b).

vol 2 Figure 7.11 Adjusted five-year survival in incident pediatric patients (aged 0-21 years) from day 1, by (a) age and (b) modality, 2006-2010



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, 2015. 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 approach to vascular access in ESRD patients influences both immediate and future patient outcomes. Due to the 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 HD patients.

Vascular access in pediatric ESRD patients is approached differently than 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 HD with a catheter (ranging from 77.8% to 83.0%; Figure 7.12.a). The initiation of HD with a catheter was observed in the majority of children and adolescents between the ages of 0 and 21 years (Figure 7.12.b). Catheters with a maturing fistula and fistula alone became increasingly more common with advancing age of HD initiation, starting at age 8 years through adolescence.

These 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.

vol 2 Figure 7.12 Vascular access type at initiation of incident pediatric hemodialysis patients (aged 0-21 years) by (a) year and (b) age, 2006-2015

(a) Year

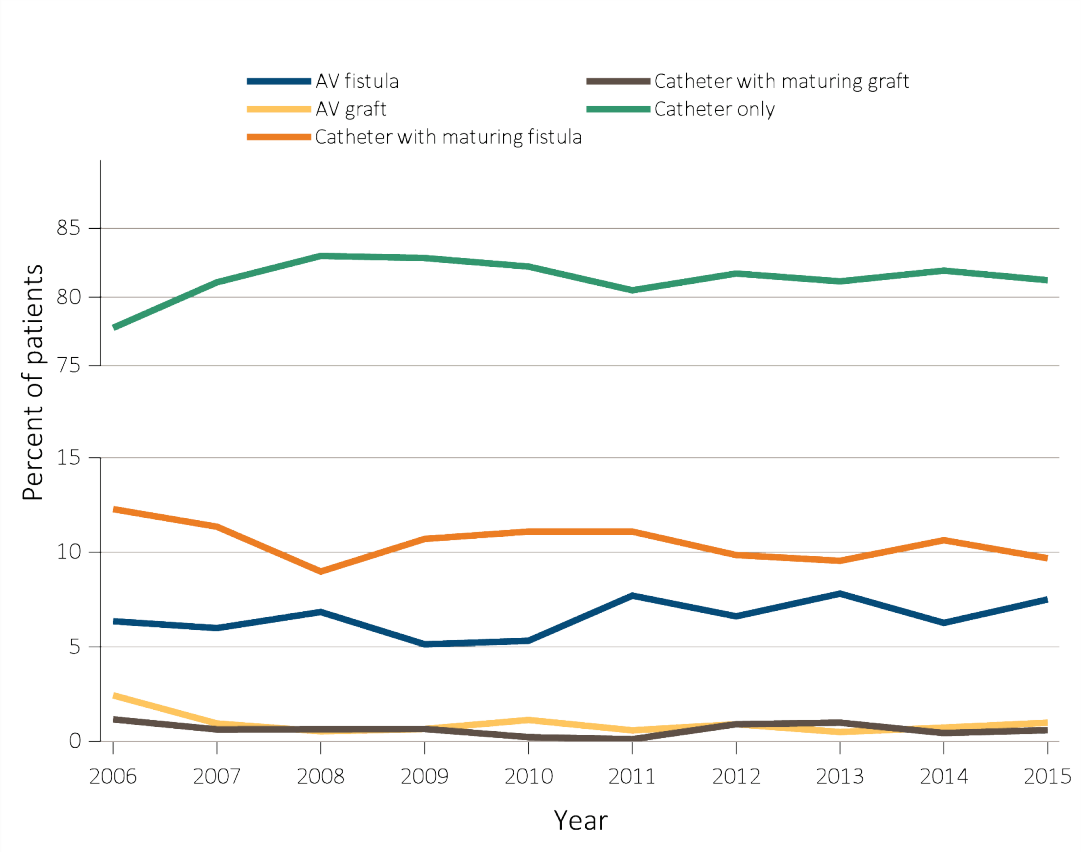
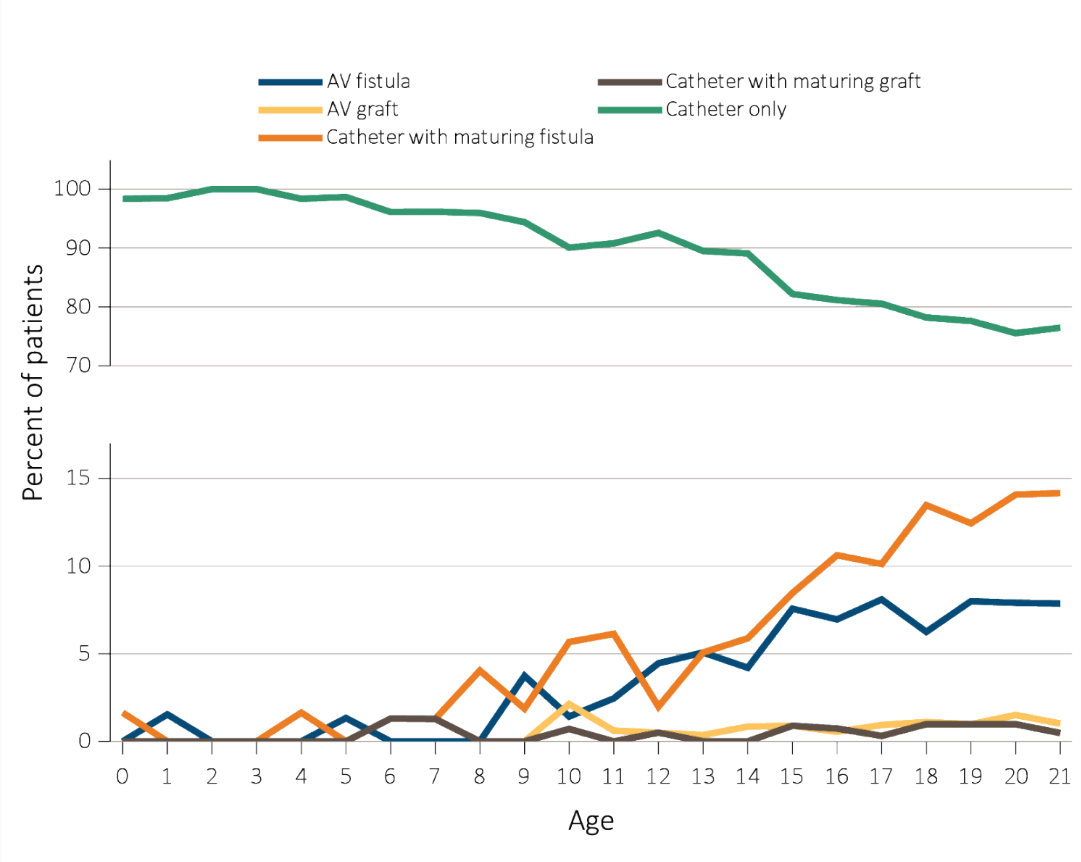


Figure 7.12 continued on next page.

vol 2 Figure 7.12 Vascular access type at initiation of incident pediatric hemodialysis patients (aged 0-21 years) by (a) year and (b) age, 2006-2015 *(continued)*

(b) Age



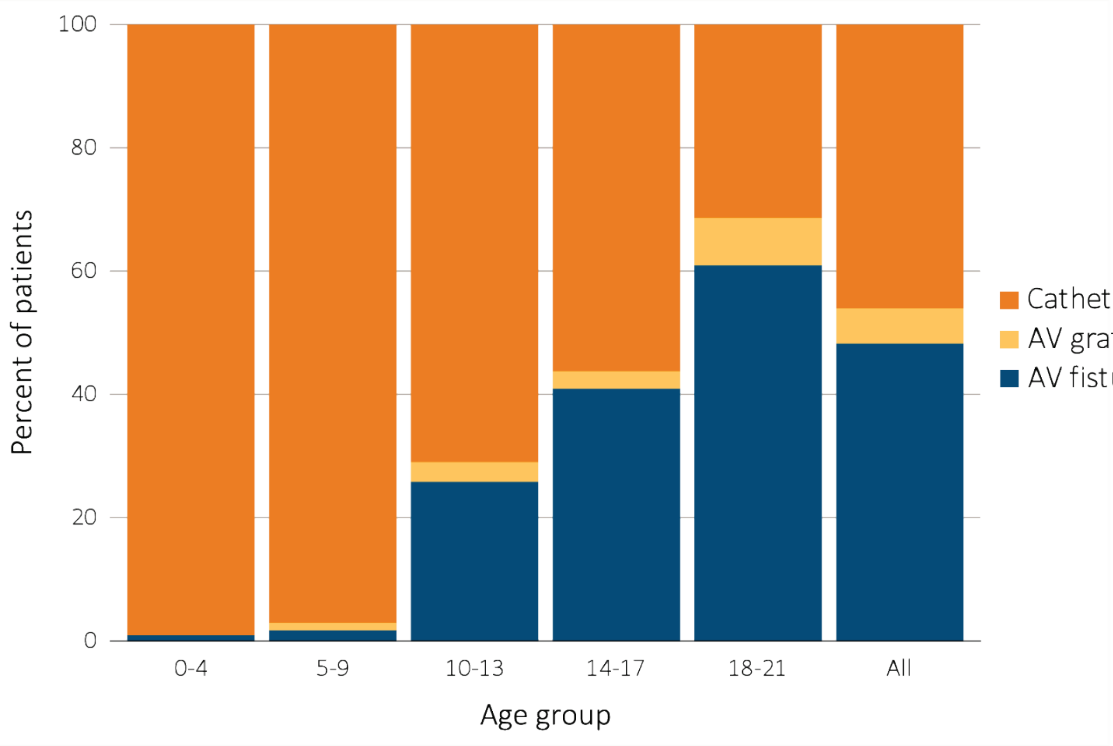
Data Source: Special analyses, USRDS ESRD Database. ESRD patients initiating hemodialysis in 2006-2015. Abbreviations: AV, arteriovenous; ESRD, end-stage renal disease.

When vascular access was examined in prevalent HD patients, there were higher rates of AV fistula and AV graft utilization in children aged 10-13 (29.6%), 14-17 (44.3%), and 18-21 (69.2%) than in children under age 10 (Figure 7.13).

A cross-sectional analysis of point prevalent ESRD patients aged 0-21 years in May 2016 showed that 54.5% of patients had an AV fistula or AV graft as their type of vascular access (Figure 7.13). Age strongly predicted the type of vascular access in use. There was a stepwise increase in the utilization of AV fistula or AV graft with increasing patient age, including 44.3% for those aged 14-17 and 69.2% for those aged 18-21 years.

When examining race and etiology of ESRD in age-adjusted analysis (figures not shown), there were subtle differences in vascular access in the prevalent patients. Blacks had a higher proportion of AV graft use (9.0%) when compared to other races (White 3.8%, and Other 6.0%). Whites and Blacks had similar use of catheters only when compared to Other races, at 45.3% and 45.8% compared to 43.8%. Overall, patients with primary glomerular disease as the etiology of ESRD had the highest proportion of surgical access in place (AV fistula 55.9% or graft 5.9%). In age-adjusted analysis, the highest rate of catheter use was in those with other etiologies of ESRD (51.4%).

vol 2 Figure 7.13 Distribution of vascular access type in prevalent pediatric hemodialysis patients (aged 0-21 years* as of May 31, 2016)



*Data Source: Special analyses, CROWNWeb clinical extracts for May 2016. Hemodialysis patients initiating treatment for ESRD at least 90 days prior to May 1, 2016, *who were <22 years old as of May 1, 2016, and who were alive through May 31, 2016; Catheter=any catheter use; fistula and graft use shown are without the use of a catheter. Abbreviations: AVF, arteriovenous fistula; AVG, arteriovenous graft; ESRD, end-stage renal disease*

Trends in Pediatric Kidney Transplantation

Overall, during 2010-2015, 36.0% of children received a kidney transplant within their first year of ESRD care (Table 7.1), including 37.5% of children with weight greater than 10 kg. In 2015 the rate of transplants was 33.6 per 100 dialysis patient years—a stable trend since 2007 (Figure 7.14.a).

In 2015, 1210 children were wait-listed for a kidney transplant, including 839 patients listed for the first time and 371 patients listed for repeat transplant. The number of patients awaiting a kidney transplant has ranged from 1179 to 1327 since 2004 (Figure 7.14.b). There has been a persistently low median waiting time for those listed for their first transplant over the most recent 10-year reporting period. Over this time, 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. See Figure 6.3 in Volume 2, Chapter 6, *Transplantation*, for trends from 1998-2014 in the percentage of incident patients aged 0-21 who were wait-listed or received a kidney transplant within one year of ESRD initiation.

In 2015, 1023 children received a kidney transplant (Figure 7.14.c). Prior to 2005, kidney grafts in pediatric transplant recipients were most commonly from living donors. There has been a decline, however, in the number of pediatric patients receiving living-donor kidneys since 2009. In 2015, living donors accounted for 38.6% of kidney transplants, an 11.2% decrease since 2009.

vol 2 Figure 7.14 Trends in pediatric transplantation (aged 0-21 years), by (a) ESRD incident and kidney transplant rates, (b) kidney transplant counts and waiting list times, (c) kidney transplant counts by donor type, (d) kidney transplant counts, patients 0-17 years, (e) and kidney transplant counts, patients 18-21 years

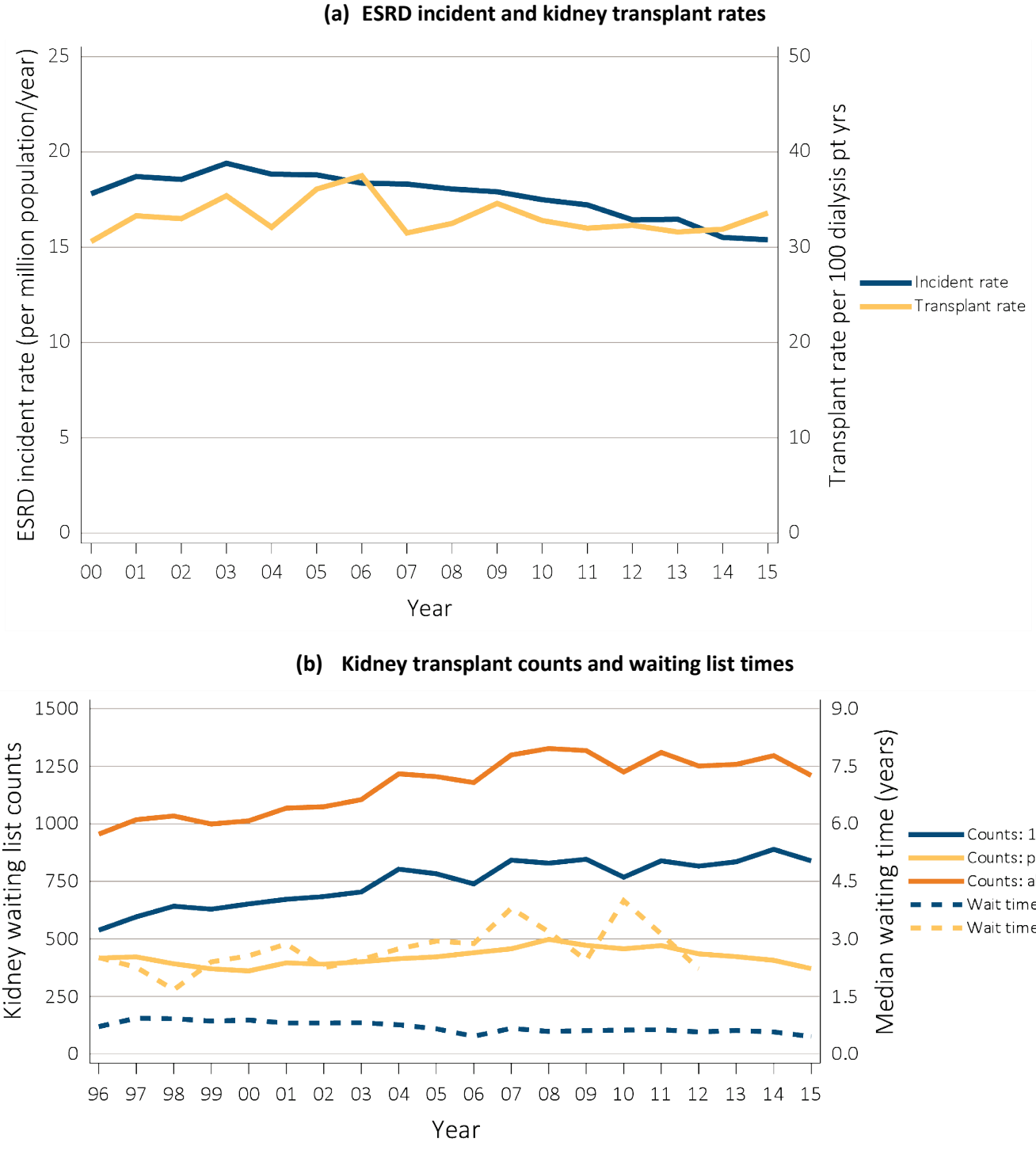
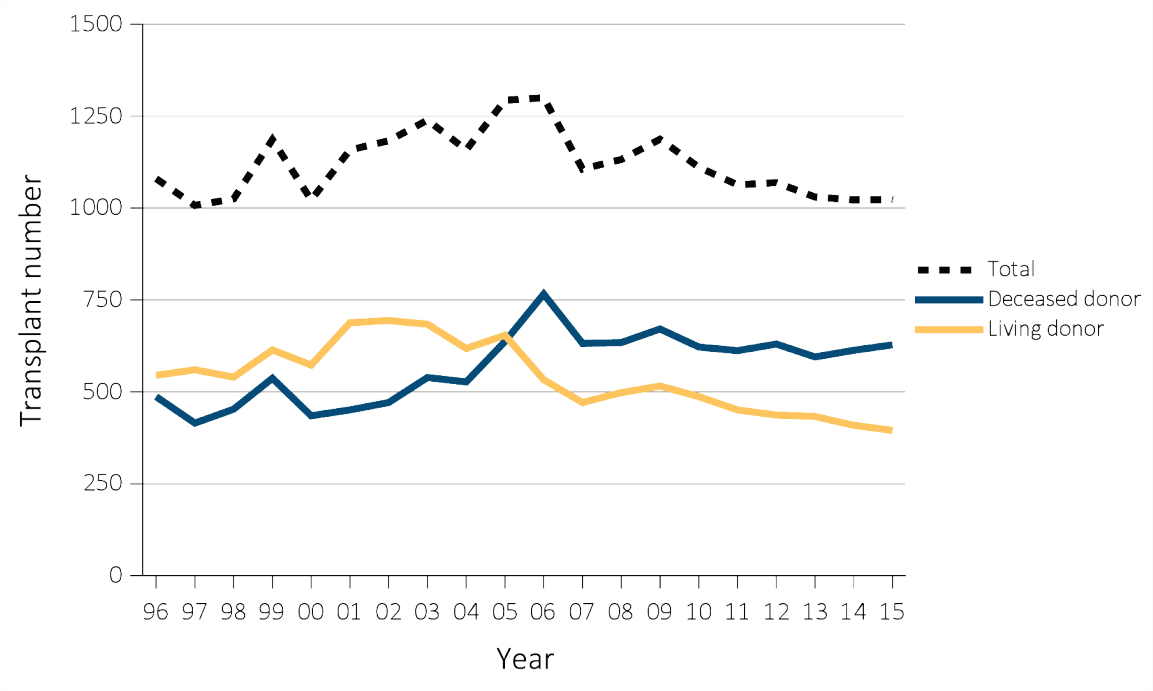


Figure 7.13 continued on next page.

vol 2 Figure 7.14 Trends in pediatric transplantation (aged 0-21 years), by (a) ESRD incident and kidney transplant rates, (b) kidney transplant counts and waiting list times, (c) kidney transplant counts by donor type, (d) kidney transplant counts, patients 0-17 years, (e) and kidney transplant counts, patients 18-21 years *(continued)*

(c) Kidney transplant counts by donor type



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

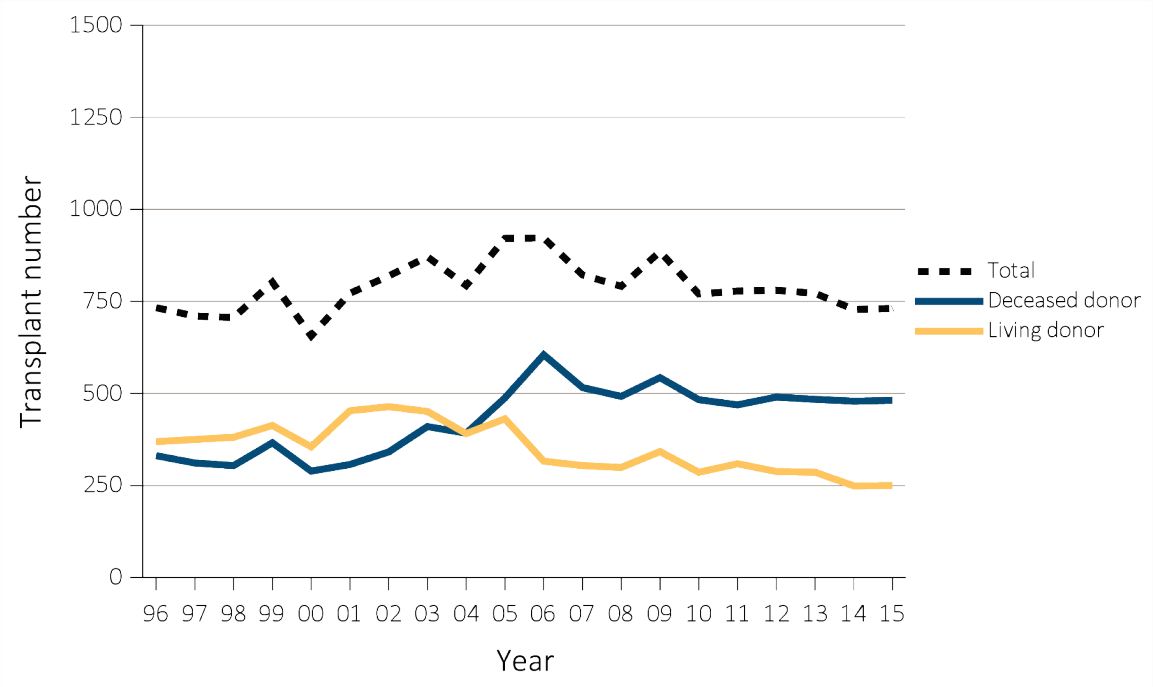
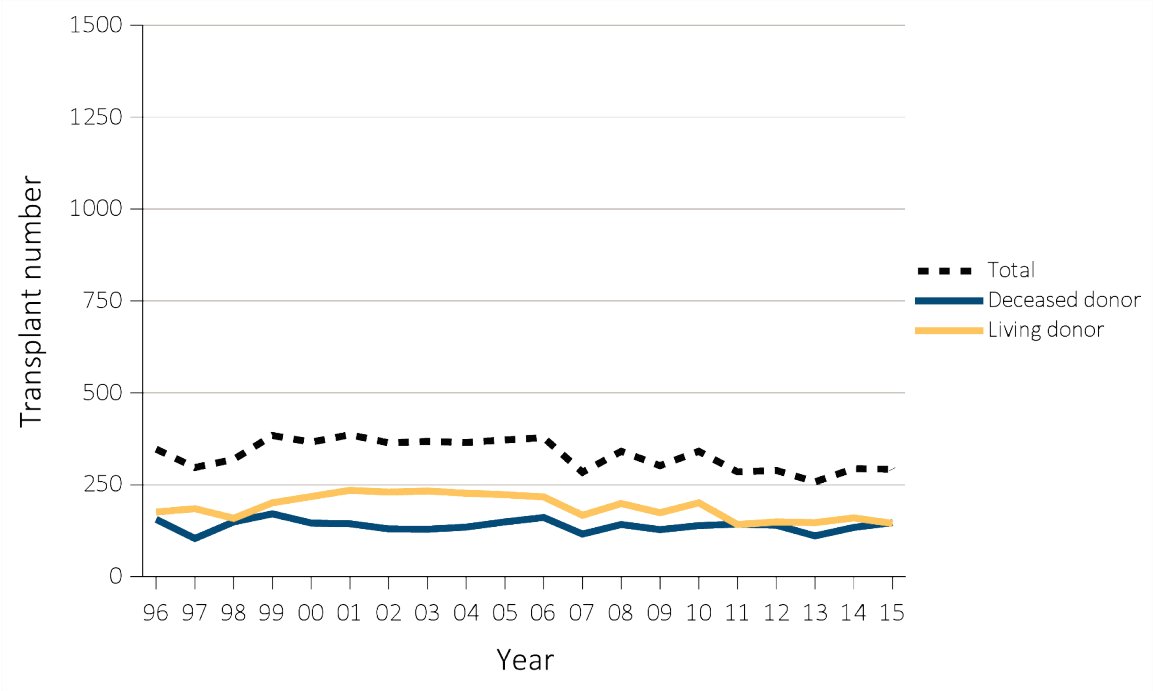


Figure 7.14 continued on next page.

vol 2 Figure 7.14 Trends in pediatric transplantation (aged 0-21 years), by (a) ESRD incident and kidney transplant rates, (b) kidney transplant counts and waiting list times, (c) kidney transplant counts by donor type, (d) kidney transplant counts, patients 0-17 years, (e) and kidney transplant counts, patients 18-21 years *(continued)*

(e) Kidney transplant counts, patients 18-21 years

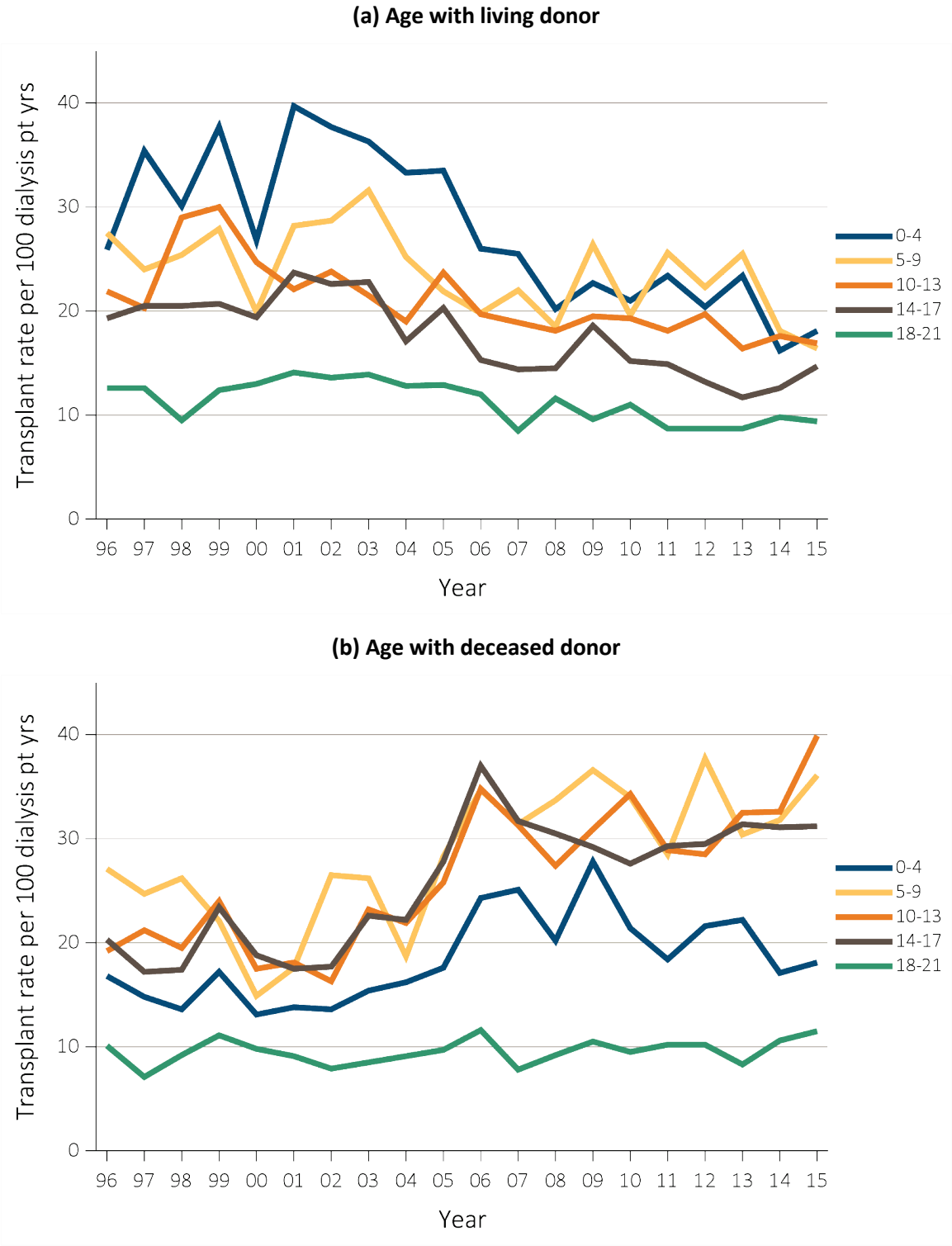


Data Source: (a) Reference Tables A1, E9, and M1. The rate of ESRD per million among the U.S. population aged 0-21 years and the rate of transplantation in dialysis patients aged 0-21 years at the time of transplant, 1996–2015. (b) Special analyses, USRDS ESRD Database. The waiting list count provides 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-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 1996-2015. In 2015, patients 5-9 and 10-13 years old had the highest rates of 52.5 and 56.8 transplants per 100 dialysis patient years, and those 18-21 years old had the lowest rate at 20.9 (Figure 7.15.a).

In 2015, males with ESRD were transplanted at a higher rate than females, at 37.7 versus 29.6 per 100 dialysis patient years. The transplant rate remained lower in Black dialysis patients compared with Whites, at 20.7 versus 36.9 per 100 dialysis patient years (Figure 7.15.b). Analyses for Native and Asian Americans were excluded due to the low number of transplants in these populations.

vol 2 Figure 7.15 Annual rates of living and deceased donor transplants in pediatric dialysis patients (aged 0-21 years), by (a) age and (b) race, 1996-2015



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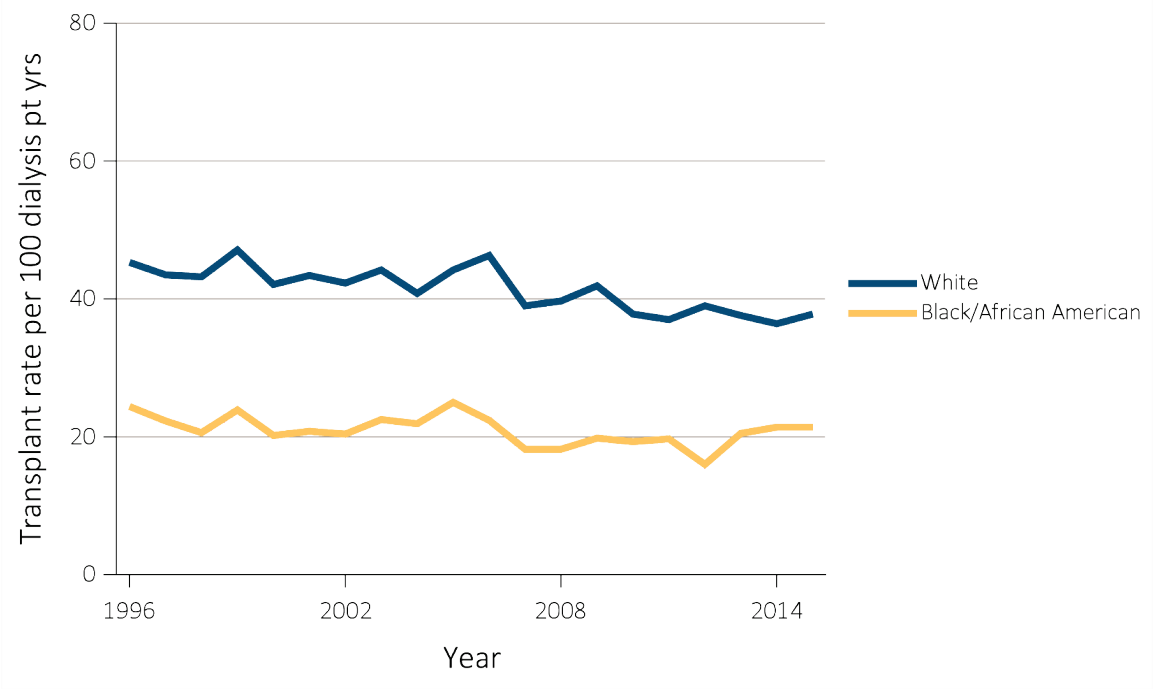
vol 2 Figure 7.15 Annual rates of living and deceased donor transplants in pediatric dialysis patients (aged 0-21 years), by (a) age and (b) race, 1996-2015

(c) Race



Data Source: Special analyses, USRDS ESRD Database. Includes transplant year between 1996–2015. Abbreviations: ESRD, end-stage renal disease; pt, patient; yrs, years.

The trend in median waiting time to transplant for incident patients on dialysis has been improving. In 2002, the median waiting time peaked at 22.1 months then began to decline, with the most dramatic improvement occurring after 2005 (Figure 7.16.a). This coincided with a 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 2014, at 11.2 months. Since 2007, the waiting times for incident patients on dialysis have been similar for HD and PD. In 2014, the median waiting time to transplant for HD patients was 11.1 months, and for PD patients was 11.7 months.

Kidney transplant waiting times varied by age and ESRD etiology. In patients younger than 18 years old, the median time from incident dialysis to transplant has been improving from 1996 to 2014 in most age groups. An exception was for those 0-4 years old (Figure 7.16.b). These youngest children have had stable waiting times, which may result from the surgical complexities in this age group. Since 1996, patients aged 18-21 years old have shown the largest improvement with waiting times. In 2014, the median waiting time for children 0-4 years old surpassed that of patients 18-21 years old. Patients with congenital anomalies of the kidney and urinary tract (CAKUT) as the cause of their ESRD had the longest median waiting time to first transplant, with a median of 13.7 months in 2014 (Figure 7.16.c).

In 1996, White patients were wait-listed for an average 35% shorter period than Blacks (Figure 7.16.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, most recent median waiting times were now similar between groups (Whites 10.8 and Blacks 13.5 months). 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.

The median transplant wait time for a deceased donor type has decreased steadily since 2010, such that the difference in waiting time between living and deceased donor organs was less than three months in 2014 (Figure 7.16.e).

Finally, Table 7.2 displays the ten-year kidney transplant outcomes. The ten-year outcomes remained stable in terms of all-cause graft failure and death for both deceased and living donor transplants.

vol 2 Figure 7.16 Median waiting time from incident hemodialysis or peritoneal dialysis to first transplant, by (a) modality, (b) age, (c) primary cause of ESRD, (d) race, and (e) donor type, 1996-2014

(a) Modality

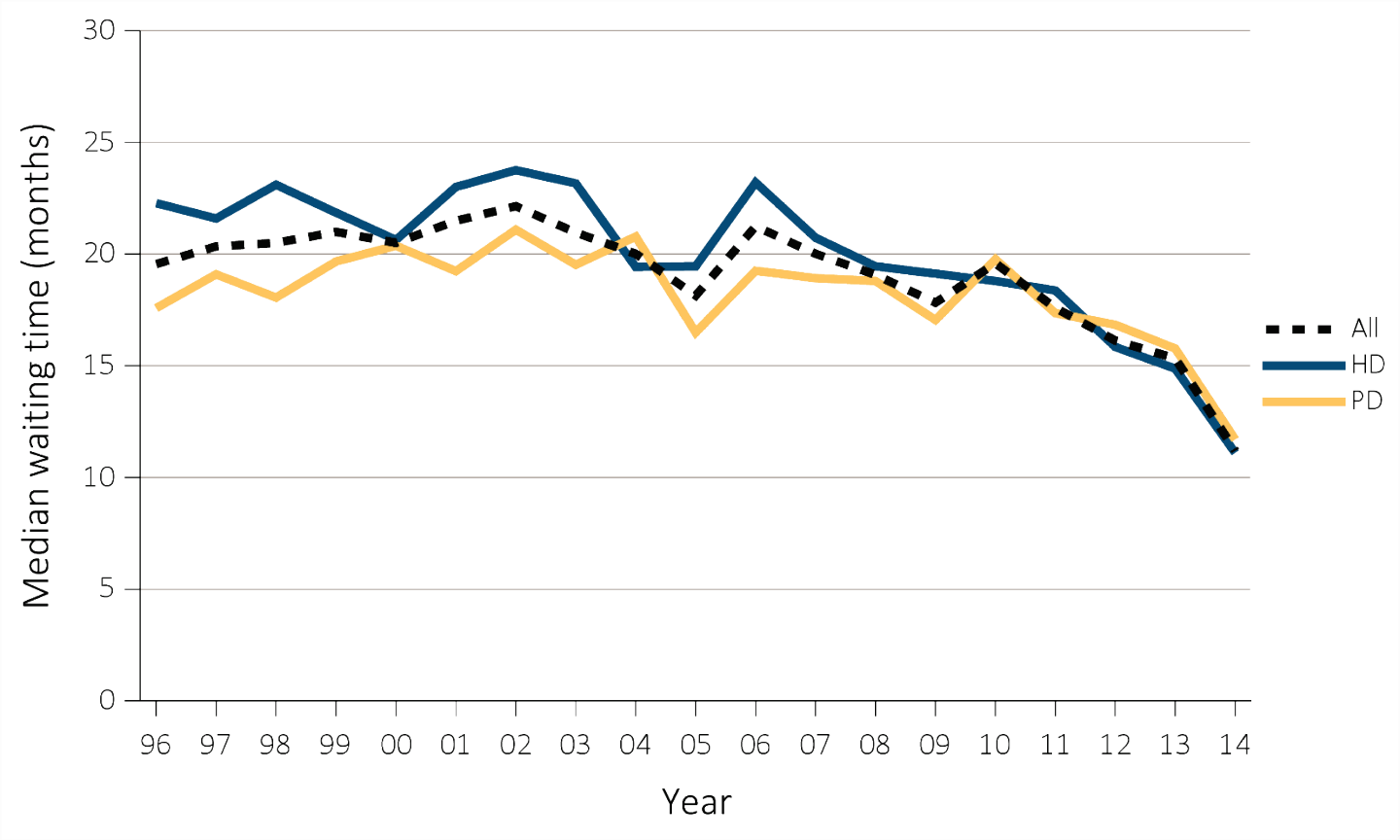
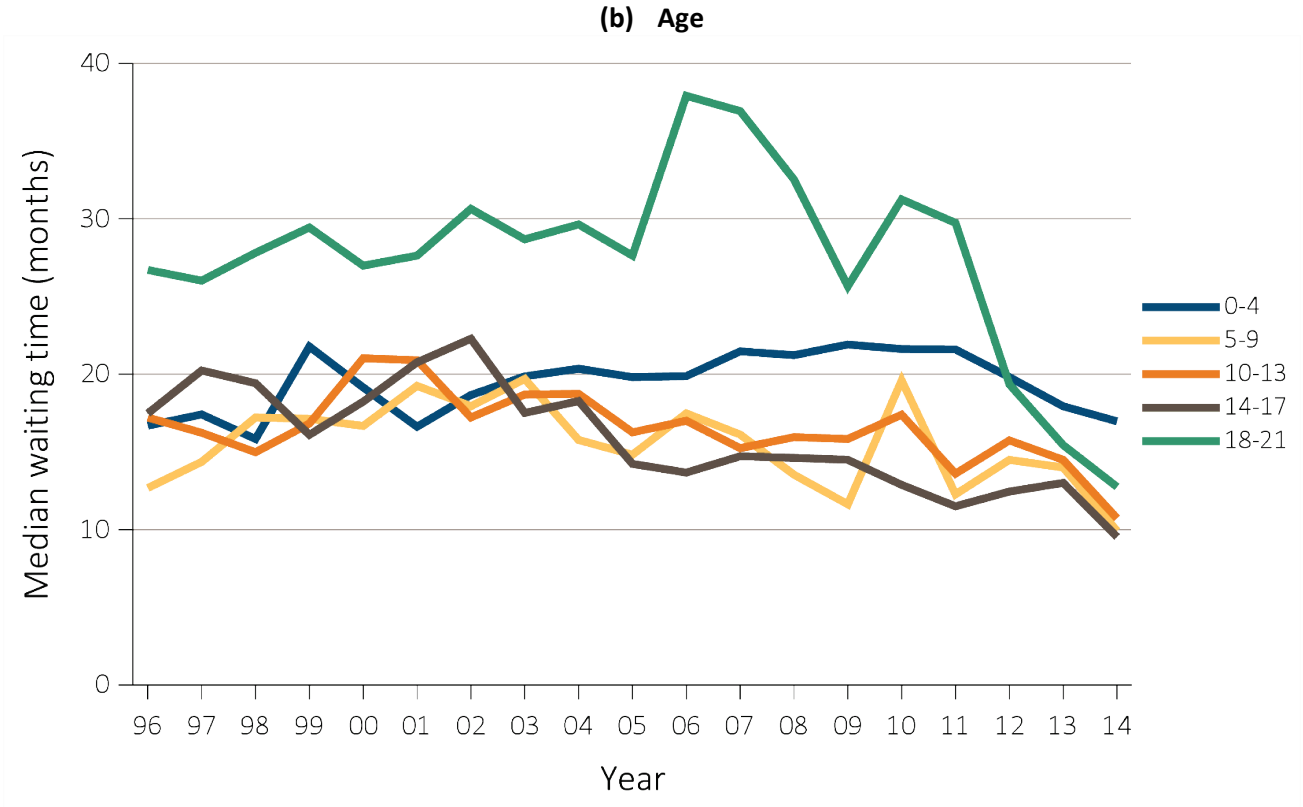


Figure 7.16 continued on next page.

vol 2 Figure 7.16 Median waiting time from incident hemodialysis or peritoneal dialysis to first transplant, by (a) modality, (b) age, (c) primary cause of ESRD, (d) race, and (e) donor type, 1996-2014 *(continued)*



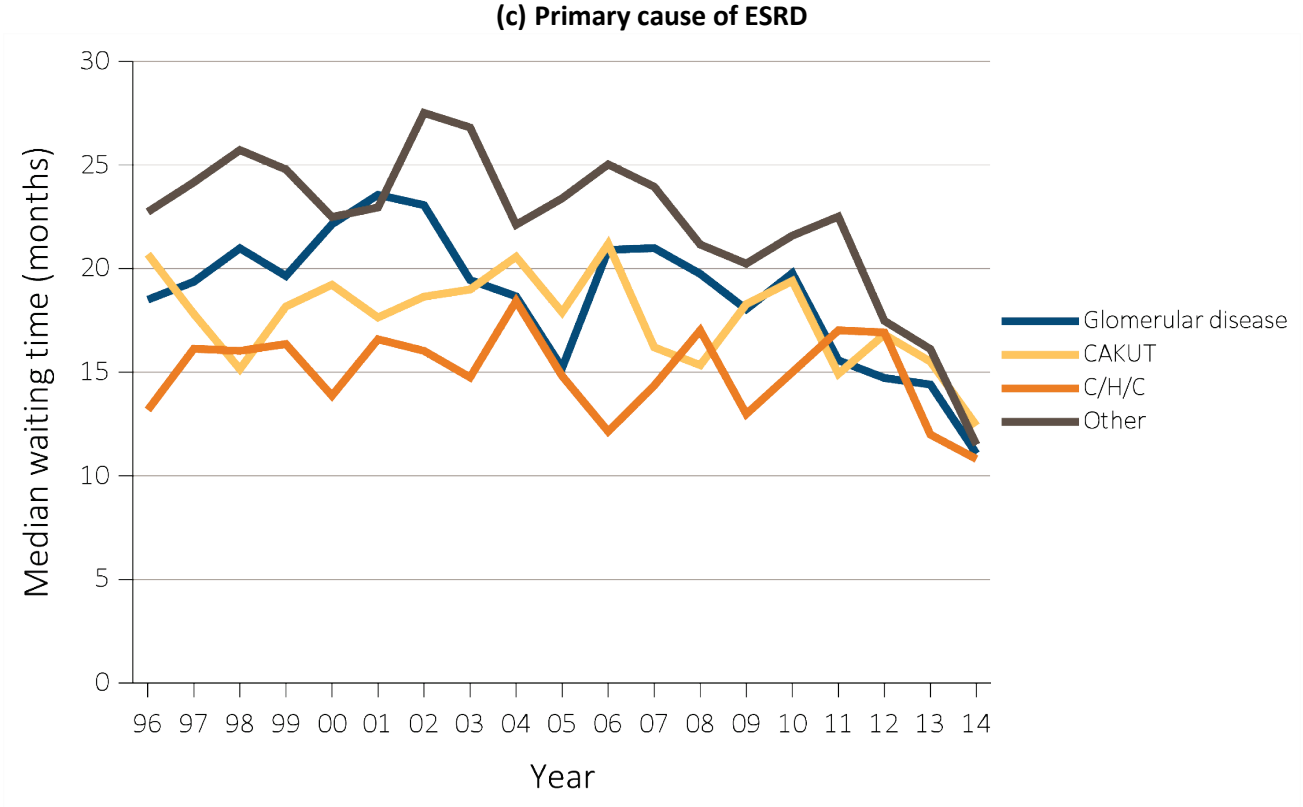
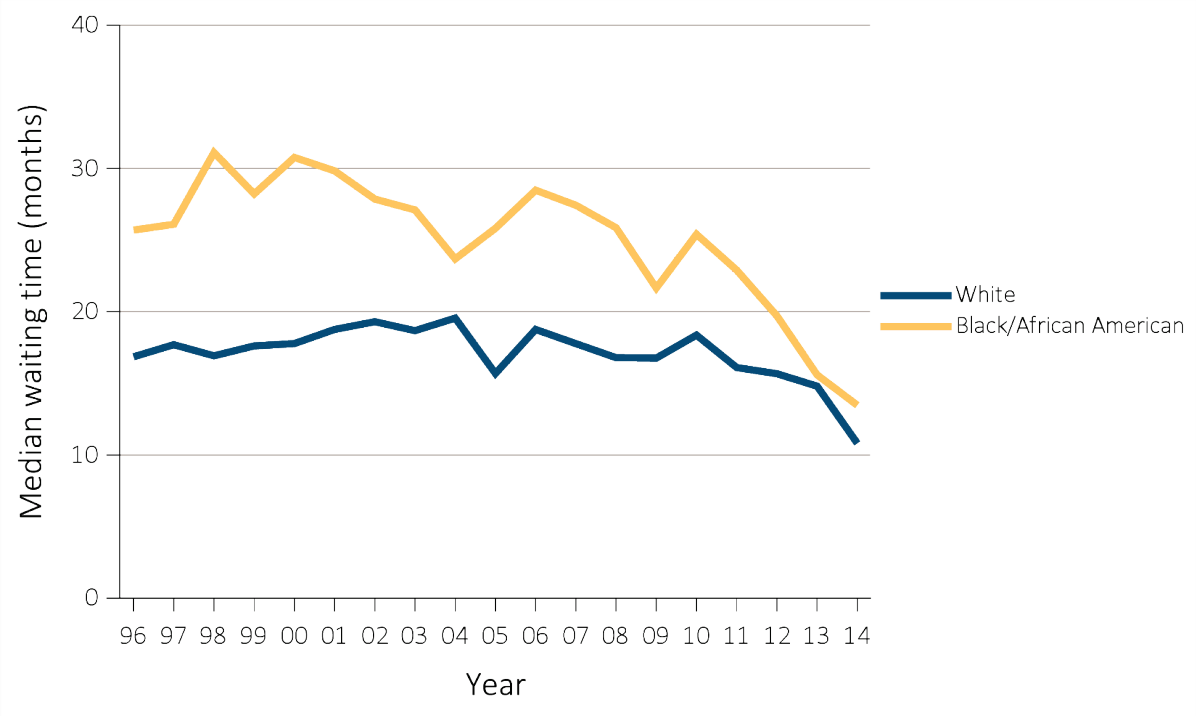


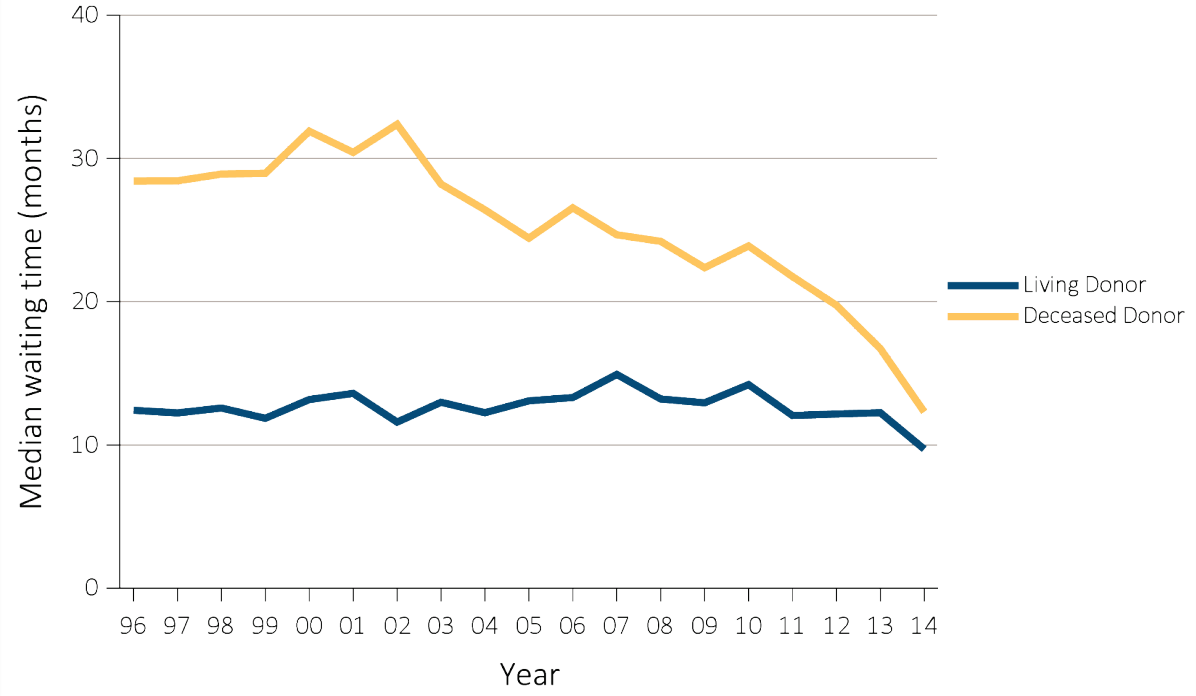
Figure 7.16 continued on next page.

vol 2 Figure 7.16 Median waiting time from incident hemodialysis or peritoneal dialysis to first transplant, by (a) modality, (b) age, (c) primary cause of ESRD, (d) race, and (e) donor type, 1996-2014 *(continued)*

(d) Race



(e) Donor type



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 1996-2014 and having the first transplant before 12/31/2015. Abbreviations: CAKUT, congenital anomalies of the kidney and urinary tract; C/H/C, Cystic/Hereditary/Congenital disease. ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis. Note that the percentage of unknown donor type is 1.32% in 1996, 1.11% in 1997, 0.44% in 1998, 0.54% in 1999, 0.22% in 2000, 0.10% in 2001, 0.30% in 2002, 0.10% in 2003, 0.10% in 2004, 0.23% in 2006, 0.14% in 2011, and 0% in 2005, 2007-2010, 2012-2014.

vol 2 Table 7.4 Adjusted ten-year outcomes for kidney transplants in pediatric patients (aged 0-21 years), by donor type and year, 1996-2005

	Adjusted ten-year outcomes (Probabilities)					
	Deceased			Living		
Year	All-cause graft failure	Return to dialysis or retransplant	Death	All-cause graft failure	Return to dialysis or retransplant	Death
1996	0.64	0.61	0.12	0.52	0.50	0.12
1997	0.62	0.58	0.13	0.50	0.47	0.16
1998	0.56	0.54	0.10	0.49	0.47	0.10
1999	0.58	0.55	0.10	0.50	0.48	0.14
2000	0.58	0.54	0.10	0.52	0.49	0.16
2001	0.56	0.53	0.11	0.49	0.47	0.14
2002	0.51	0.47	0.06	0.43	0.40	0.14
2003	0.53	0.50	0.11	0.43	0.40	0.12
2004	0.58	0.55	0.08	0.44	0.42	0.07
2005	0.54	0.51	0.09	0.49	0.46	0.12

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

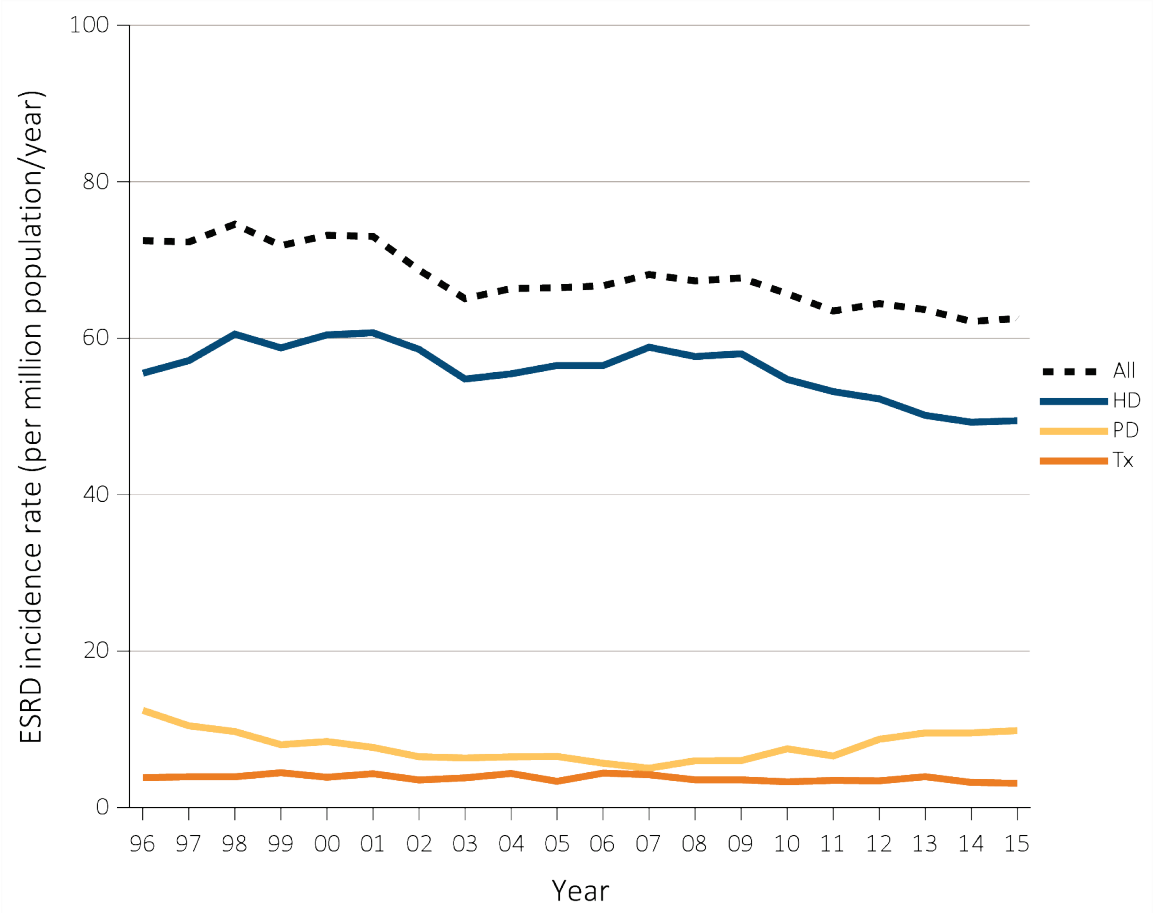
Because of improvements in the care of pediatric patients with ESRD, a larger percentage of these children are surviving into adulthood. The transition of these patients into adulthood represents a unique process; their specific needs have resulted in the development of transition programs to improve health care for these individuals. As of December 31, 2015, there were 10,251 young adult survivors of childhood onset ESRD in the U.S. These prevalent patients were dependent on HD (34.4%), PD (5.8%), and transplant (59.6%).

In addition to the survivor cohort, the young adult incident ESRD cohort includes individuals aged 22-29 years old at the time of ESRD onset. This section highlights the incident young adult population, focusing on modality and CVD trends.

The overall incident rate of ESRD in the young adult cohort has been slowly decreasing (Figure 7.17). In 1996, the rate was 72.5 PMP in the young adult census population, while by 2015 the ESRD incident rate had reduced to 62.5. In 2015, the rates of incident HD, PD, and transplant were 49.5, 9.8, and 3.1 patients PMP.

Since 2008, there has been a trend in increased utilization of PD as the incident ESRD modality. The point prevalence of young adults with ESRD (figure not shown) was 448.3 patients PMP in 2015. The use of ESRD modality within this 2015 point prevalent population included 204.1 HD, 44.8 PD, and 198.3 transplant patients PMP.

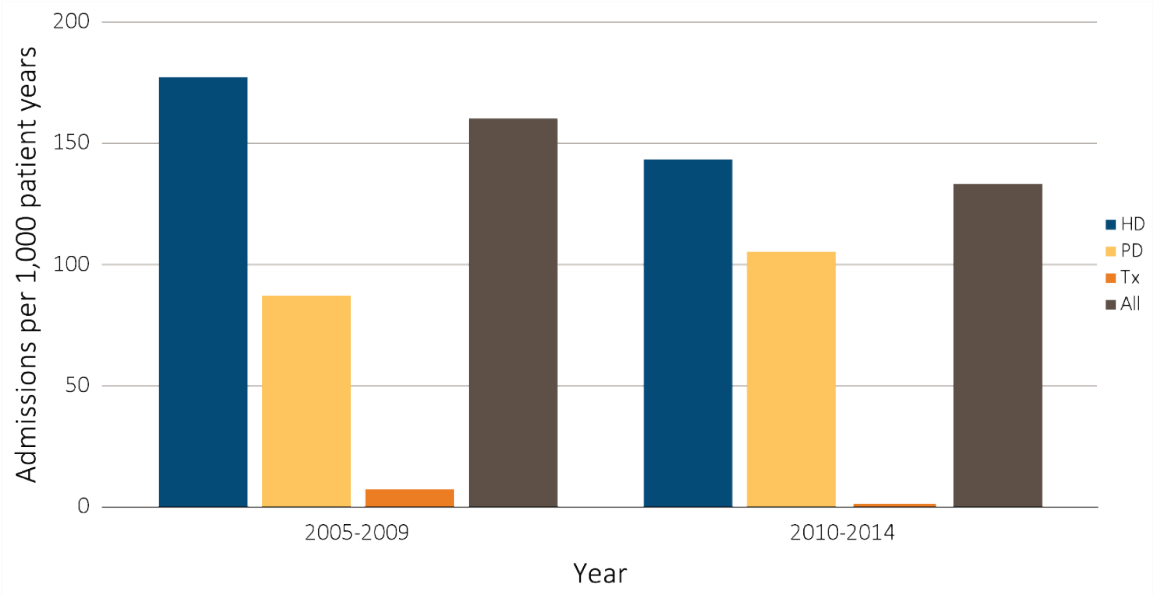
vol 2 Figure 7.17 Trends in incident rates of ESRD in young adults (aged 22-29 years), by modality, 1996-2015



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.

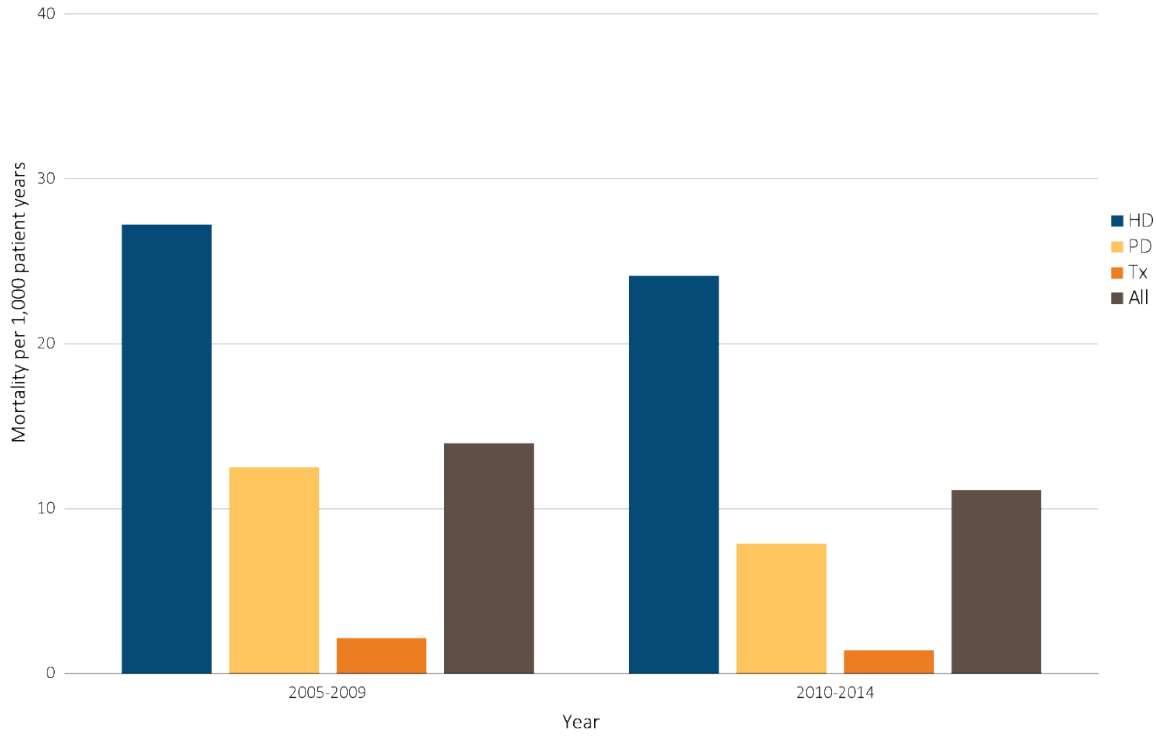
Cardiovascular health has been a major concern in the young adult ESRD population. The overall CVD hospitalization rate during 2010-2014 was 127 admissions per 1,000 patient years (Figure 7.18). The rate of CVD hospitalizations remained highest in those on HD compared with other ESRD modalities. However, there was a 19.5% decline in CVD hospitalization in HD patients in the most recent reporting years. Between 2010 and 2015, the one-year adjusted CVD mortality was 11 per 1,000 patient years, a decrease of 21.4% from the 2005-2009 period (Figure 7.19). The adjusted one-year CVD mortality rate decreased across all modalities.

vol 2 Figure 7.18 One-year unadjusted cardiovascular hospitalization rates in young adults with incident ESRD (aged 22-29 years), by modality, 2005-2009 and 2010-2014



Data Source: Special analyses, USRDS ESRD Database. Includes incident pediatric ESRD patients in the years 2005-2014, 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.

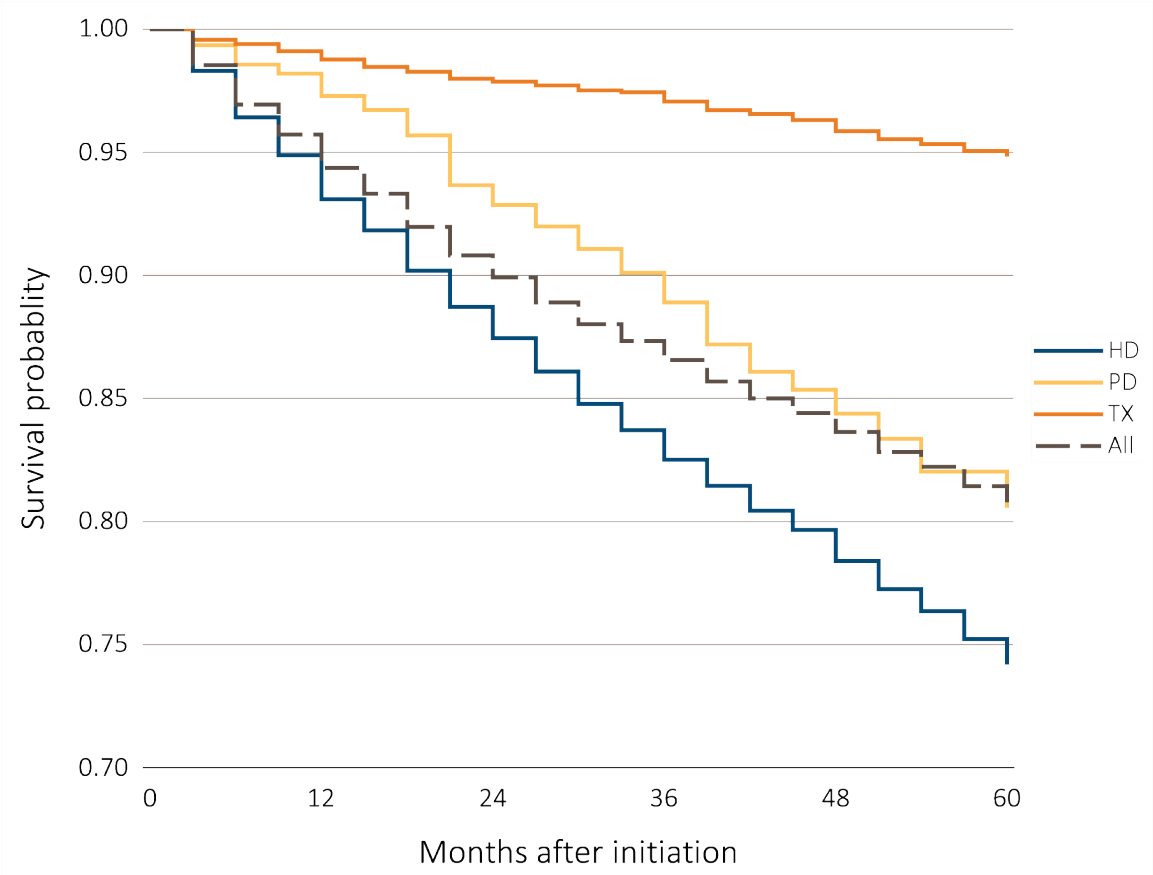
vol 2 Figure 7.19 One-year adjusted cardiovascular mortality rates in young adults with incident ESRD (aged 22-29 years), by modality, 2005-2009 and 2010-2014



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, 2015. 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.

One-year adjusted mortality rates for young adults initiating ESRD between 2010 and 2014 was 48 per 1,000 patient-years. (Figure 7.8.a). The probability of five-year survival was 0.81, which was lower than the 0.90 five-year survival in younger patients aged 0-21 years (Figure 7.20). Young adult transplant patients had the highest probability of surviving five years (0.95) compared to 0.74 seen in HD patients, and 0.81 in PD patients. (See Volume 2, Chapter 5, *Mortality* for adult survival statistics by age and modality)

vol 2 Figure 7.20 Adjusted five-year survival probability of young adults with incident ESRD (aged 22-29 years), by modality and months after initiation, 2006–2010



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, 2015. 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.

Notes

Chapter 8: Cardiovascular Disease in Patients with ESRD

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

Introduction

Patients with ESRD are among the highest risk populations for cardiovascular diseases (CVDs)—a major cause of death in ESRD patients. The relationship between CVD and kidney disease is complex and bidirectional, and close attention to CVD is vital to the care of these patients. The presence of ESRD often complicates disease management of CVD, as it can influence both medical and procedural options, thereby adversely affecting a patient's prognosis.

The high prevalence of AMI, CAD, HF, and sudden death/cardiac arrhythmias should draw more attention of kidney disease 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.

This chapter provides an overview of CVDs among adult ESRD patients, using administrative claims data from Medicare. We focus on reporting the prevalence and outcomes of diagnosed major cardiovascular conditions, stratifying by type of renal replacement therapy (RRT) being received—hemodialysis (HD), peritoneal dialysis (PD), 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 primarily on data from the national Medicare population.

Methods

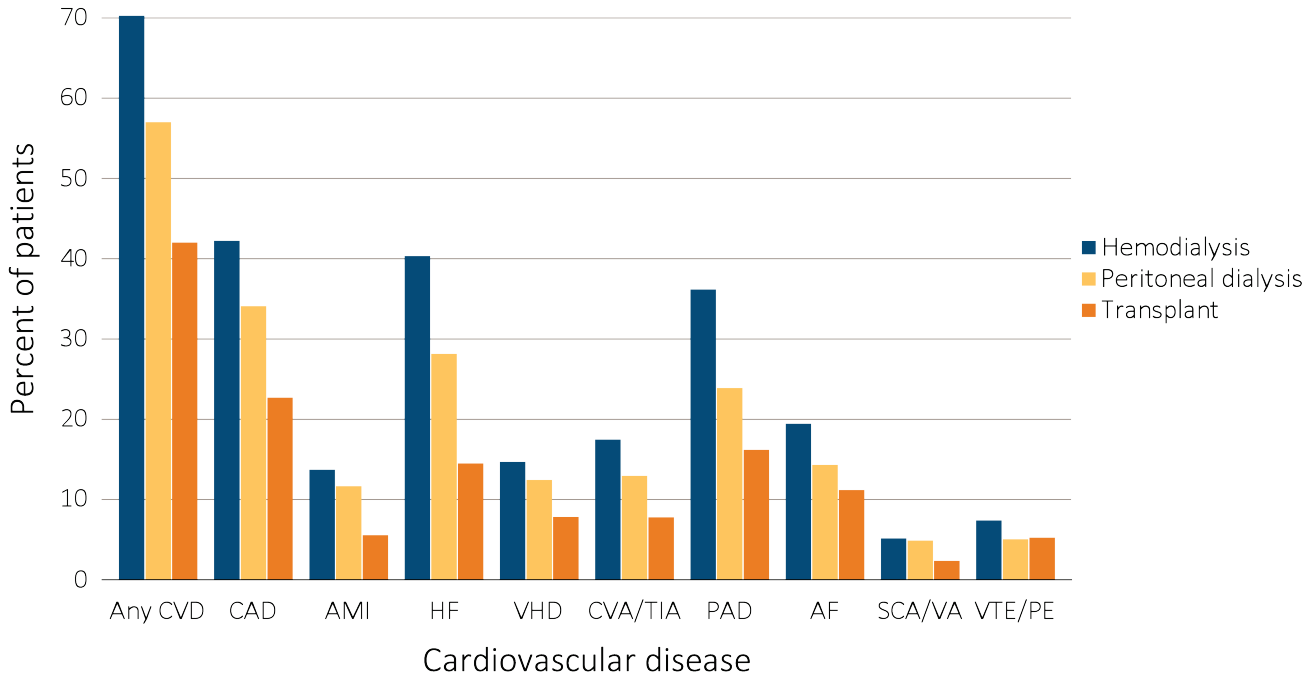
The findings presented in this chapter were drawn from data sources from the Centers for Medicare & Medicaid Services (CMS). Details of these are described in the *Data Sources* section of the *ESRD Analytical Methods* chapter.

See the section addressing Chapter 8 in the *Analytical Methods Used in the ESRD Volume* 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. Downloadable Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available on the USRDS website.

Cardiovascular Disease Prevalence in ESRD Patients

As expected from findings in previous Annual Data Reports (ADRs), in 2015 ESRD patients had a high burden of CVD across a wide range of conditions (Figure 8.1). Stable CAD and HF were the two major leading CVDs 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 (AF), sudden cardiac arrest and ventricular arrhythmias (SCA/VA), and venous thromboembolism and pulmonary embolism (VTE/PE) were also common. In general, the prevalence of these cardiovascular diseases was highest among ESRD patients who received HD (69.8%), followed by PD (56.6%), and those with kidney transplants (41.6%).

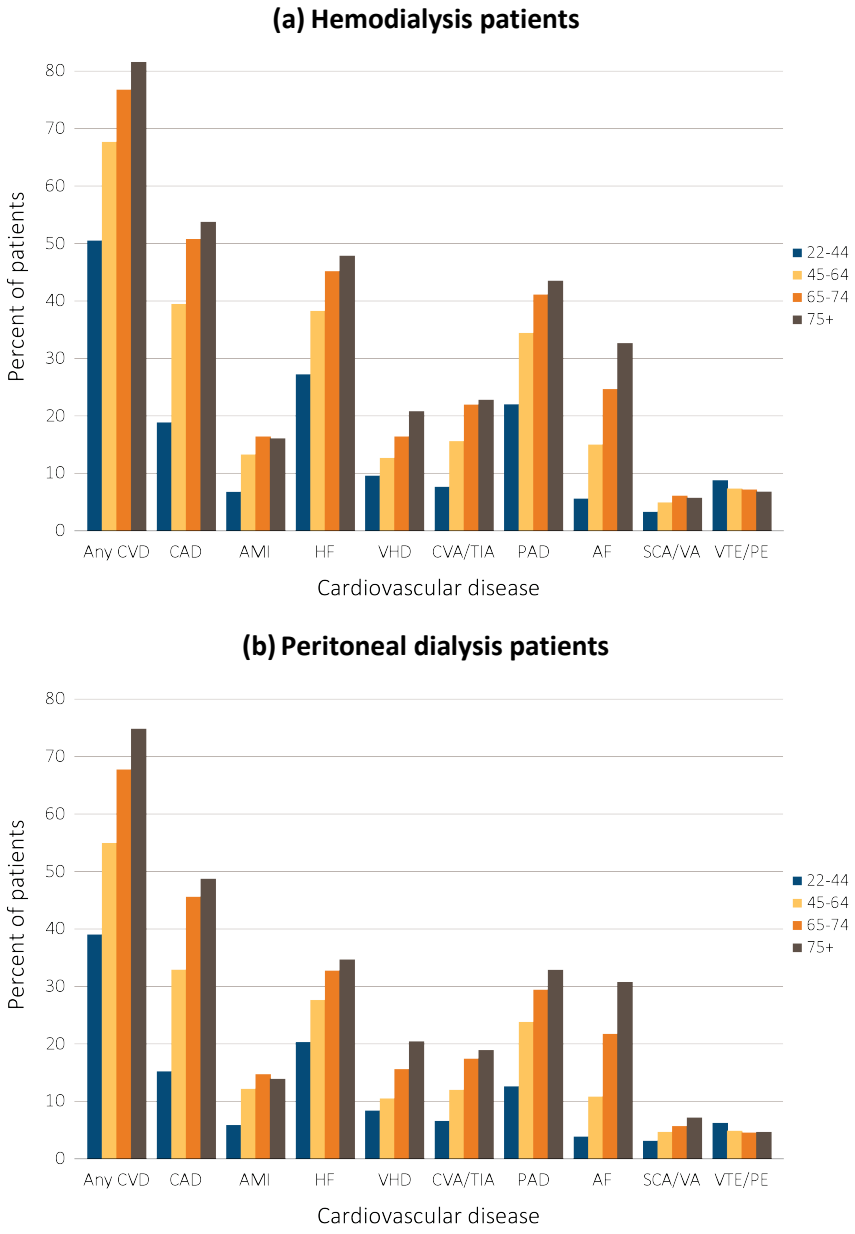
vol 2 Figure 8.1 Prevalence of cardiovascular diseases in adult ESRD patients, by treatment modality, 2015



Data Source: Special analyses, USRDS ESRD Database. Point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older, who are continuously enrolled in Medicare Parts A and B, and with Medicare as primary payer from January 1, 2015 to December 31, 2015, and ESRD service date is at least 90 days prior to January 1, 2015. Abbreviations: AF, atrial fibrillation; AMI, acute myocardial infarction; CAD, coronary artery disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; CVD, cardiovascular disease; HF, heart failure; PAD, peripheral arterial disease; SCA/VA, sudden cardiac arrest and ventricular arrhythmias; VHD, valvular heart disease; VTE/PE, venous thromboembolism and pulmonary embolism.

Peritoneal dialysis patients had a lower burden of certain cardiovascular conditions, including CAD, HF, and PAD, as compared to their HD counterparts. Not surprisingly, older ESRD patients tended to have a higher prevalence of cardiovascular conditions than did younger patients, whether they were receiving HD or PD (Figures 8.2.a and 8.2.b). It is notable that the prevalence of these conditions was high even among HD patients 22-44 years of age (50.1%), although a much higher prevalence was observed among those 45 years or older (67.2% to 81.1%). The same pattern was true for PD patients. Coronary artery disease was the most common condition, with a prevalence exceeding 50% in HD 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 for either HD or PD patients.

vol 2 Figure 8.2 Prevalence of cardiovascular diseases in adult ESRD patients, by age, 2015



Data Source: Special analyses, USRDS ESRD Database. Point prevalent hemodialysis and peritoneal dialysis patients aged 22 and older, who are continuously enrolled in Medicare Parts A and B, and with Medicare as primary payer from January 1, 2015 to December 31, 2015, and ESRD service date is at least 90 days prior to January 1, 2015. Abbreviations: AF, atrial fibrillation; AMI, acute myocardial infarction; CAD, coronary artery disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; CVD, cardiovascular disease; HD, hemodialysis; HF, heart failure; PAD, peripheral arterial disease; PD, peritoneal dialysis; SCA/VA, sudden cardiac arrest and ventricular arrhythmias; VHD, valvular heart disease; VTE/PE, venous thromboembolism and pulmonary embolism.

In Table 8.1, we present the relationships between age, race, and sex, and prevalent CVDs in adult ESRD patients. As noted earlier, advancing age was associated with higher prevalence of cardiovascular conditions. However, the relationships with race and sex were less definitive. The prevalence of major procedures for treating CVD in ESRD patients is also reported in Table 8.1, 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 was low in ESRD patients relative to other major procedures.

vol 2 Table 8.1 Prevalence of (a) cardiovascular comorbidities & (b) cardiovascular procedures in adult ESRD patients, by treatment modality, age, race, & sex, 2015

(a) Cardiovascular comorbidities

		Percentage of patients (%)												
	# Patients	Overall	22-44	45-64	65-74	75+	White	Black	AI/AN	Asian	NH/PI	Other	Male	Female
Any CVD														
Hemodialysis	216,384	69.8	50.1	67.2	76.3	81.1	72.2	67.6	61.2	66.4	61.8	65.4	68.2	72.0
Peritoneal dialysis	21,462	56.6	38.6	54.5	67.3	74.4	58.7	53.4	51.3	48.4	57.5	44.7	60.0	52.7
Transplant	72,535	41.6	18.4	37.5	54.8	65.8	42.8	39.4	40.9	34.5	36.7	36.7	43.6	38.6
Coronary artery disease (CAD)														
Hemodialysis	216,384	41.8	18.4	39.0	50.3	53.3	46.0	36.6	35.6	41.8	38.8	39.6	42.1	41.4
Peritoneal dialysis	21,462	33.7	14.8	32.5	45.2	48.3	36.8	27.6	29.0	29.7	30.7	26.3	38.7	27.8
Transplant	72,535	22.3	5.9	19.7	31.5	38.1	23.7	18.7	24.3	19.2	20.6	18.4	25.2	17.9
Acute myocardial infarction (AMI)														
Hemodialysis	216,384	13.3	6.3	12.8	16.0	15.6	14.9	11.4	11.5	11.9	13.4	10.5	13.4	13.2
Peritoneal dialysis	21,462	11.2	5.4	11.7	14.3	13.5	12.3	9.4	8.0	8.0	12.7	7.9	12.9	9.3
Transplant	72,535	5.1	1.9	4.8	6.8	7.9	5.5	4.2	6.1	3.3	5.6	3.6	5.8	4.2
Heart failure (HF)														
Hemodialysis	216,384	39.9	26.8	37.8	44.7	47.4	40.5	39.9	31.0	35.6	34.7	34.1	37.8	42.7
Peritoneal dialysis	21,462	27.7	19.9	27.2	32.3	34.2	27.6	29.1	26.9	21.8	28.5	23.7	29.5	25.7
Transplant	72,535	14.1	5.9	12.3	18.7	24.5	13.8	15.8	13.3	11.4	14.0	8.6	14.4	13.6
Valvular heart disease (VHD)														
Hemodialysis	216,384	14.3	9.2	12.2	16.0	20.4	15.5	13.0	9.9	14.0	11.1	14.4	13.1	15.8
Peritoneal dialysis	21,462	12.0	8.0	10.1	15.2	20.0	12.9	10.3	11.3	10.8	11.0	2.6	12.2	11.8
Transplant	72,535	7.4	2.5	5.5	10.7	16.1	7.9	6.4	3.8	6.2	5.6	6.0	7.1	7.8
Cerebrovascular accident/transient ischemic attack (CVA/TIA)														
Hemodialysis	216,384	17.1	7.2	15.2	21.5	22.4	17.4	17.1	10.8	15.4	14.5	13.1	15.4	19.2
Peritoneal dialysis	21,462	12.5	6.1	11.6	17.0	18.5	13.5	11.1	8.8	9.7	11.0	13.2	12.5	12.6
Transplant	72,535	7.3	2.2	5.8	10.8	14.1	7.6	7.0	6.1	5.5	5.4	5.6	7.2	7.5
Peripheral artery disease (PAD)														
Hemodialysis	216,384	35.7	21.6	34.0	40.7	43.1	37.7	34.1	30.9	29.0	27.3	31.8	35.4	36.1
Peritoneal dialysis	21,462	23.5	12.2	23.4	29.0	32.4	25.4	20.5	21.4	16.2	23.2	13.2	26.0	20.5
Transplant	72,535	15.8	6.3	14.5	20.7	25.3	16.1	15.5	18.4	11.5	13.0	17.3	17.1	13.8
Atrial fibrillation (AF)														
Hemodialysis	216,384	19.0	5.2	14.6	24.2	32.2	22.7	14.5	10.4	18.9	16.7	17.3	19.5	18.4
Peritoneal dialysis	21,462	13.9	3.4	10.4	21.3	30.3	16.1	9.0	9.2	12.9	15.8	5.3	16.5	10.8
Transplant	72,535	10.7	1.5	7.2	17.1	26.6	11.9	7.9	8.2	8.1	8.9	4.9	11.9	9.0
Cardiac arrest and ventricular arrhythmias (SCA/VA)														
Hemodialysis	216,384	4.7	2.9	4.5	5.7	5.3	4.8	4.9	3.3	3.3	3.2	3.4	5.2	4.2
Peritoneal dialysis	21,462	4.5	2.7	4.2	5.2	6.7	4.6	4.5	2.5	2.9	4.8	0.0	5.4	3.4
Transplant	72,535	1.9	0.7	1.6	2.7	3.7	1.9	2.1	1.7	1.3	1.2	1.7	2.1	1.6
Venous thromboembolism and pulmonary embolism (VTE/PE)														
Hemodialysis	216,384	7.0	8.3	6.9	6.8	6.4	6.3	8.2	4.2	4.5	4.3	6.3	6.3	7.9
Peritoneal dialysis	21,462	4.6	5.8	4.4	4.1	4.2	4.4	5.7	1.3	1.9	5.7	2.6	4.4	4.9
Transplant	72,535	4.8	3.4	4.5	5.8	6.5	4.7	5.8	3.8	2.0	3.3	3.8	4.9	4.8

Table 8.1 continued on next page.

vol 2 Table 8.1 Prevalence of (a) cardiovascular comorbidities & (b) cardiovascular procedures in adult ESRD patients, by treatment modality, age, race, & sex, 2015 *(continued)*

(b) Cardiovascular procedures

		Percentage of patients (%)												
	# Patients	Overall	22-44	45-64	65-74	75+	White	Blk/Af Am	AI/AN	Asian	NH/PI	Other	Male	Female
Revascularization – percutaneous coronary interventions (PCI)														
Hemodialysis	90,475	3.7	3.5	4.1	3.9	2.8	3.9	3.4	3.4	4.0	4.4	4.6	3.7	3.6
Peritoneal dialysis	7,224	5.5	5.1	6.8	4.5	4.1	5.9	4.1	4.3	6.4	2.9	*	5.3	5.7
Transplant	16,152	2.4	4.1	2.6	2.0	2.1	2.5	1.7	3.2	1.8	6.0	3.1	2.4	2.3
Revascularization – coronary artery bypass graft (CABG)														
Hemodialysis	90,475	1.8	2.0	2.4	1.8	0.7	1.9	1.5	2.6	1.9	2.5	2.0	2.1	1.4
Peritoneal dialysis	7,224	3.4	3.7	4.3	3.3	1.5	3.6	2.7	4.3	3.5	11.4	*	3.9	2.7
Transplant	16,152	1.3	0.8	1.6	1.3	0.8	1.4	1.3	1.6	1.1	0.0	3.1	1.5	1.1
Implantable cardioverter defibrillators & cardiac resynchronization therapy with defibrillator devices (ICD/CRT-D)														
Hemodialysis	86,319	0.8	0.7	0.9	0.9	0.6	0.8	0.7	0.7	1.0	0.6	0.8	1.0	0.6
Peritoneal dialysis	5,947	0.8	0.9	1.0	0.6	0.6	0.8	0.9	0.0	0.0	1.5	*	0.7	0.9
Transplant	10,206	0.6	0.3	0.8	0.6	0.5	0.6	0.7	1.0	0.3	1.5	0.0	0.7	0.4
Carotid artery stenting and carotid artery endarterectomy (CAS/CEA)														
Hemodialysis	127,063	0.4	0.1	0.3	0.5	0.5	0.5	0.2	0.2	0.1	0.4	0.5	0.4	0.4
Peritoneal dialysis	9,893	0.5	0.0	0.4	0.8	0.5	0.6	0.3	0.0	0.2	0.0	0.0	0.5	0.5
Transplant	23,416	0.3	0.0	0.2	0.5	0.3	0.4	0.2	0.4	0.6	0.7	0.0	0.3	0.3

*Data Source: Special analyses, USRDS ESRD Database. Point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older, who are continuously enrolled in Medicare Parts A and B, and with Medicare as primary payer from January 1, 2015 to December 31, 2015, and ESRD service date is at least 90 days prior to January 1, 2015. (a) The denominators for all cardiovascular comorbidities are patients described above by modality. (b) The denominators for PCI and CABG are patients with CAD by modality. The denominator for ICD/CRT-D is patients with HF by modality. The denominator for CAS/CEA is patients with CAD, CVA/TIA, or PAD by modality. *Values for cells with 10 or fewer patients are suppressed. Abbreviations: AF, atrial fibrillation; AI/AN, American Indian or Alaska Native; AMI, acute myocardial infarction; Blk/Af Am, Black African American; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CAS/CEA, carotid artery stenting and carotid artery endarterectomy; CVA/TIA, cerebrovascular accident/transient ischemic attack; CVD, cardiovascular disease; HF, heart failure; ICD/CRT-D, implantable cardioverter defibrillators/cardiac resynchronization therapy with defibrillator devices; NH/PI, Native Hawaiian or Pacific Islander; 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.*

The presence of CVDs 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 8.3.a through 8.3.i and Table 8.2 illustrate adjusted two-year survival in adult ESRD patients with and without individual CVDs. Figures 8.4.a through 8.4.d and Table 8.3 illustrate adjusted two-year survival in adult ESRD patients with and without completed cardiovascular procedures.

In general, ESRD patients have lower survival when CVD conditions are present. A pattern of lower survival was observed in those who underwent PCI, ICD/CRT-D placement (Figures 8.4.a and 8.4.c), and CAS/CEA (Figure 8.4.d), but survival appeared similar between patients who had CABG procedures, (Figure 8.4.b) and those who did not.

We compared the probability of survival of ESRD patients who underwent PCI and CABG with those who did not have these procedures, among patients with CAD (Figures 8.4.a and 8.4.b). The ESRD patients with HF who underwent ICD/CRT-D placement were compared with those who did not have this procedure (Figure 8.4.c). We also compared ESRD patients with CAD, CVA/TIA, or PAD who underwent CAS/CEA with those who did not have this procedure (Figure 8.4.d). These descriptive results in the adult ESRD population require careful interpretation. Comparative effectiveness research with appropriate statistical methods is necessary to evaluate whether these procedures improve or worsen patient prognoses.

vol 2 Figure 8.3 Probability of survival of adult ESRD patients with or without a cardiovascular disease, adjusted for age and sex, 2014-2015

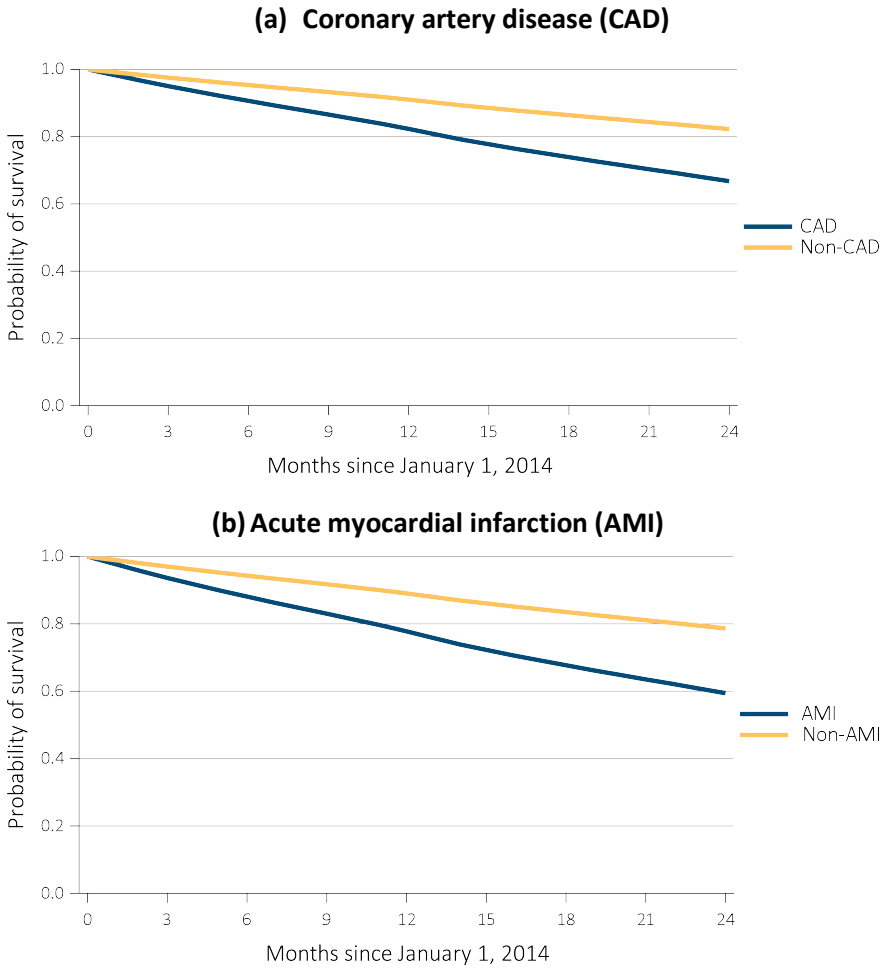


Figure 8.3 continued on next page.

vol 2 Figure 8.3 Probability of survival of adult ESRD patients with or without a cardiovascular disease, adjusted for age and sex, 2014-2015 *(continued)*

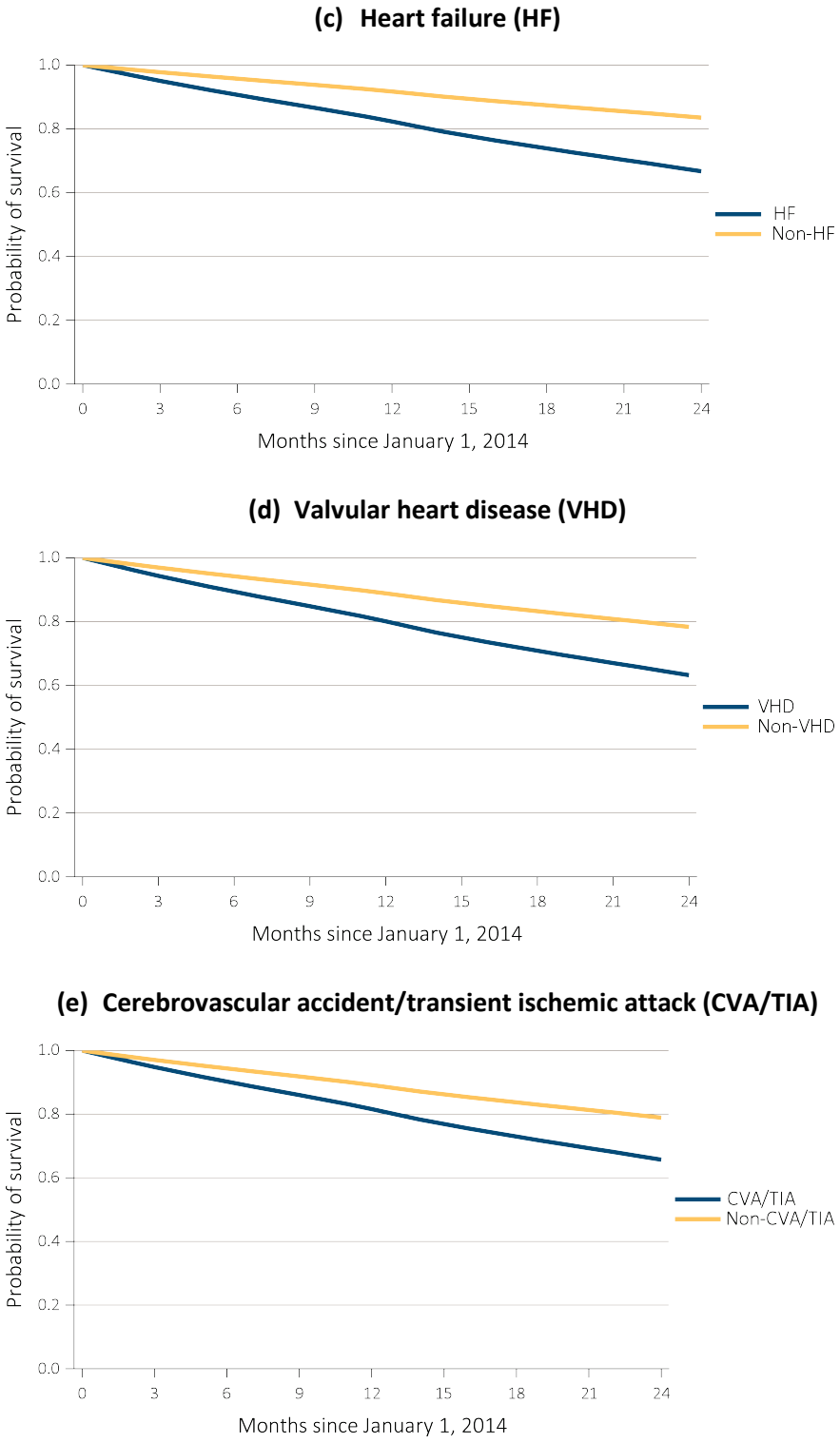


Figure 8.3 continued on next page.

vol 2 Figure 8.3 Probability of survival of adult ESRD patients with or without a cardiovascular disease, adjusted for age and sex, 2014-2015 *(continued)*

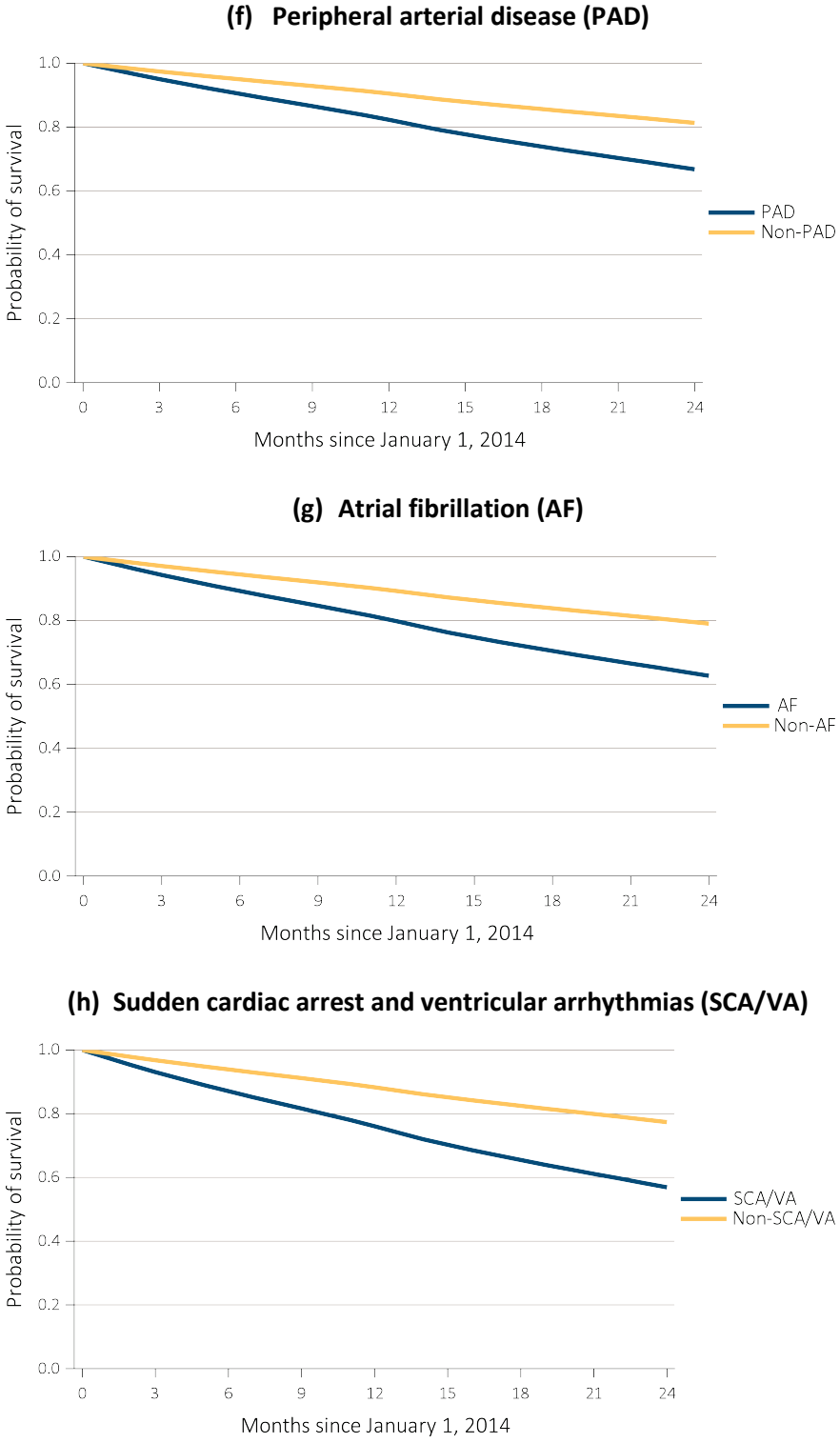
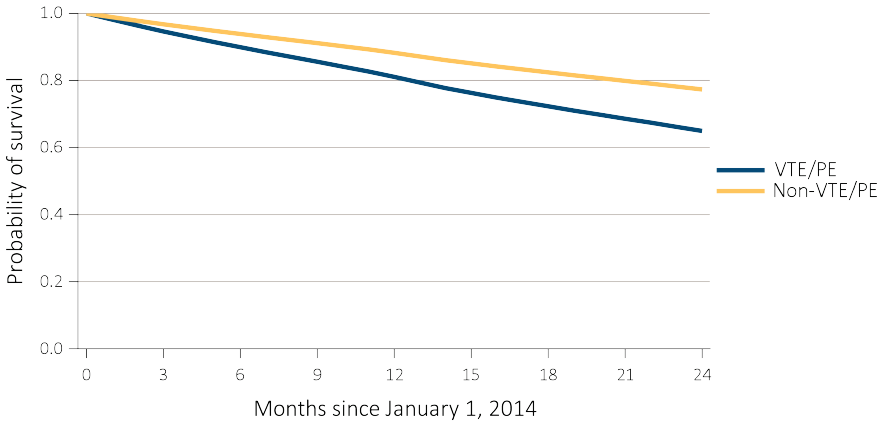


Figure 8.3 continued on next page.

vol 2 Figure 8.3 Probability of survival of adult ESRD patients with or without a cardiovascular disease, adjusted for age and sex, 2014-2015 *(continued)*

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



Data Source: Special analyses, USRDS ESRD Database. Point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older, who are continuously enrolled in Medicare Parts A and B, and with Medicare as primary payer from January 1, 2013 to December 31, 2013, and whose first ESRD service date is at least 90 days prior to January 1, 2013, and survived past 2013.

vol 2 Table 8.2 Two-year survival of adult ESRD patients with or without a cardiovascular disease, adjusted for age and sex, 2014-2015

	Presence of cardiovascular disease	
Cardiovascular disease	**Survival when present (%)**	**Survival when not present (%)**
CAD	66.8	82.3
AMI	59.4	78.6
HF	66.7	83.5
VHD	63.2	78.3
CVA/TIA	65.7	78.9
PAD	66.8	81.3
AF	62.7	79.0
SCA/VA	56.9	77.4
VTE/PE	65.0	77.3

Data Source: Special analyses, USRDS ESRD Database. Point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older, who are continuously enrolled in Medicare Parts A and B, and with Medicare as primary payer from January 1, 2013 to December 31, 2013, and whose first ESRD service date is at least 90 days prior to January 1, 2013, and survived past 2013. Abbreviations: AF, atrial fibrillation; AMI, acute myocardial infarction; CAD, coronary artery disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; HF, heart failure; PAD, peripheral arterial disease; SCA/VA, sudden cardiac arrest and ventricular arrhythmias; VHD, valvular heart disease; VTE/PE, venous thromboembolism and pulmonary embolism.

vol 2 Figure 8.4 Probability of survival of adult ESRD patients with or without a completed cardiovascular procedure, adjusted for age and sex, 2014-2015

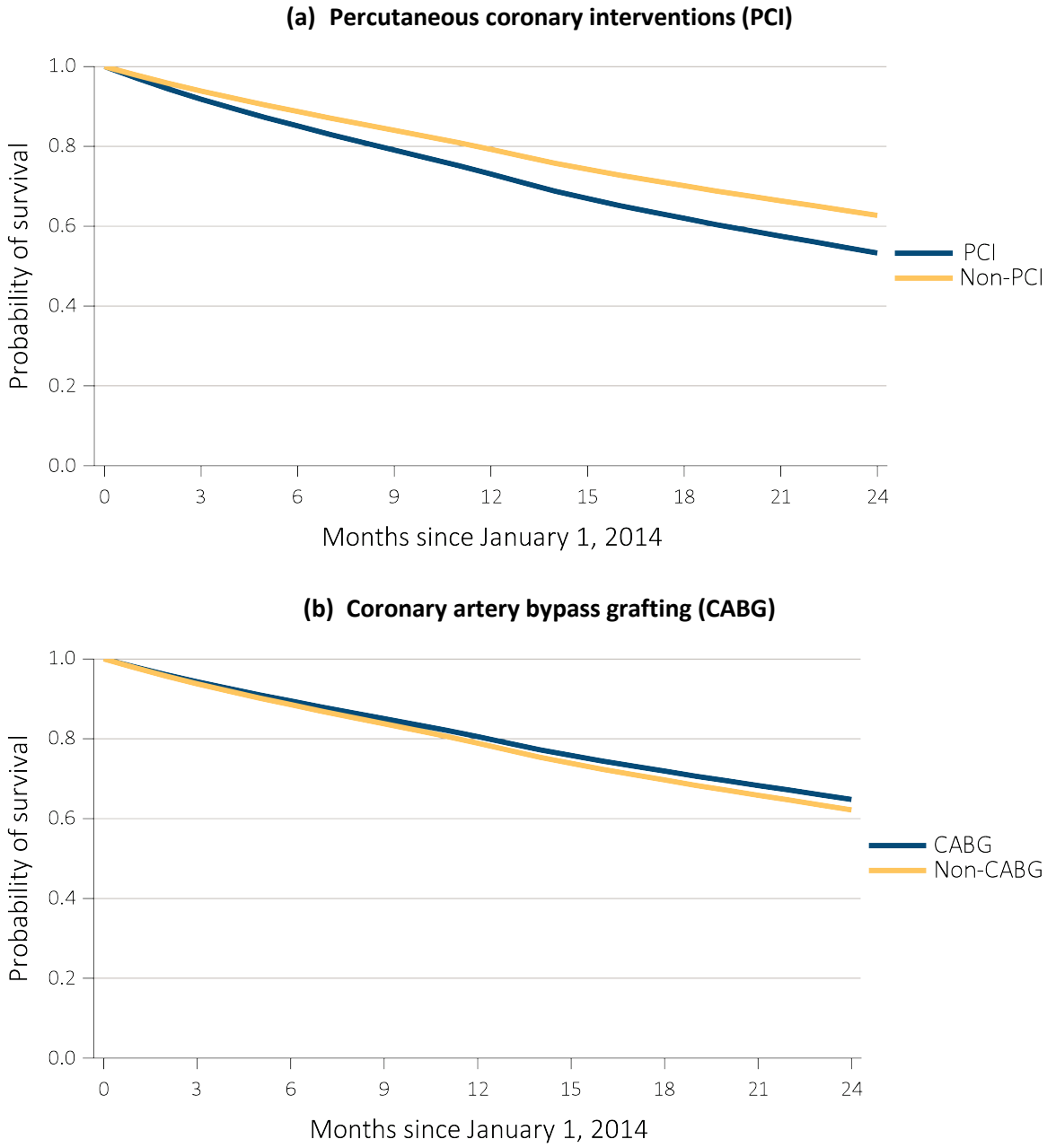
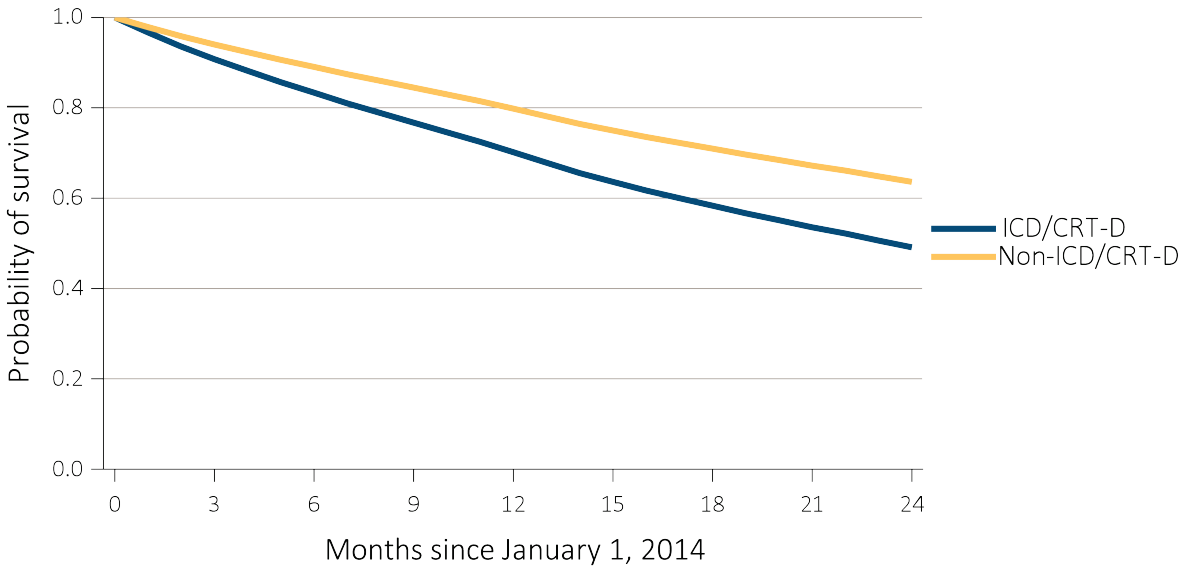


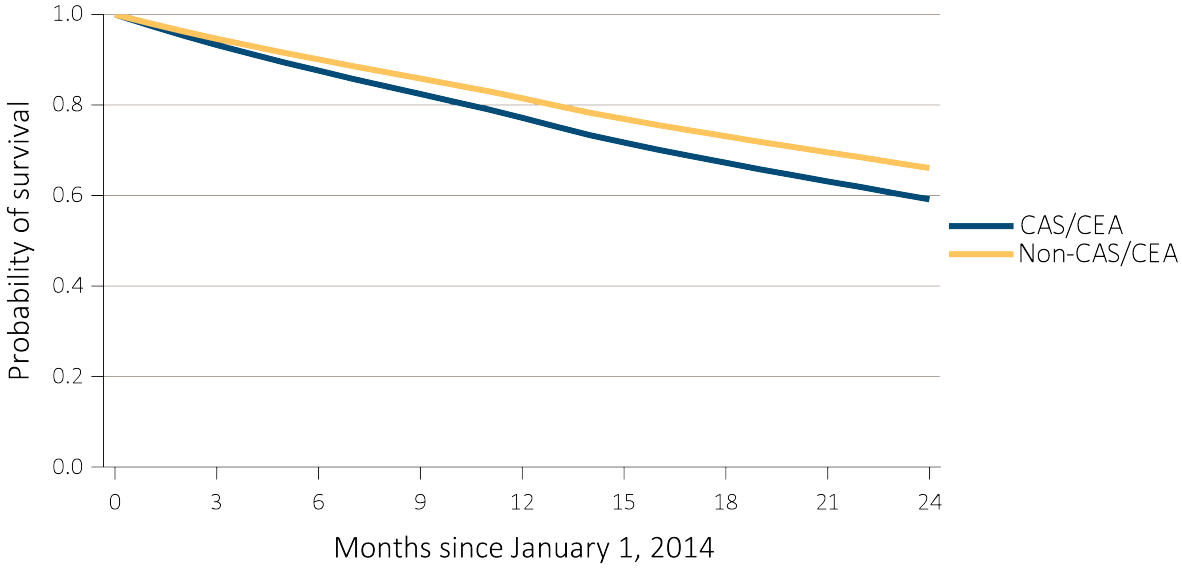
Figure 8.4 continued on next page.

vol 2 Figure 8.4 Probability of survival of adult ESRD patients with or without a completed cardiovascular procedure, adjusted for age and sex, 2014-2015 *(continued)*

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



(d) Carotid artery stenting and carotid endarterectomy (CAS/CEA)



Data Source: Special analyses, USRDS ESRD Database. Point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older, who are continuously enrolled in Medicare Parts A and B, and with Medicare as primary payer from January 1, 2013 to December 31, 2013, and whose first ESRD service date is at least 90 days prior to January 1, 2013, and survived past 2013.

vol 2 Table 8.3 Two-year survival of adult ESRD patients with or without a completed cardiovascular procedure, adjusted for age and sex, 2014-2015

	Presence of cardiovascular procedure	
Cardiovascular procedure	**Survival when present (%)**	**Survival when not present (%)**
PCI	53.3	62.7
CABG	64.8	62.2
ICD/CRT-D	49.1	63.6
CAS/CEA	59.2	66.1

Data Source: Special analyses, USRDS ESRD Database. Point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older, who are continuously enrolled in Medicare Parts A and B, and with Medicare as primary payer from January 1, 2013 to December 31, 2013, and whose first ESRD service date is at least 90 days prior to January 1, 2013, and survived past 2013. Abbreviations: CABG, coronary artery bypass grafting; CAS/CEA, carotid artery stunting and carotid artery endarterectomy; ICD/CRT-D, implantable cardioverter defibrillators/cardiac resynchronization therapy with defibrillator devices; PCI, percutaneous coronary interventions.

Cardiovascular Disease and Pharmacological Treatments

Medical therapy for CVD in the ESRD population is fraught with challenges. These patients are usually excluded from large clinical trials for conditions such as CAD, HF, and AF, and as a result, the risks and benefits of various medications in the ESRD population are often not well understood. Drug therapy may be limited by safety issues, such as risk of hyperkalemia with ACEI/ARB therapy, and intradialytic hypotension among HD patients. It is noteworthy that although administration of beta-blockers for AMI is a widely cited quality metric for cardiovascular care, only about two-thirds of dialysis or transplant patients with AMI received these drugs. Similarly, among ESRD patients with heart failure, less than half received ACEIs or ARBs.

Although many ESRD patients with AF are at elevated risk of stroke, only 33.9% of HD and 30.6% of PD patients with AF were treated with warfarin. One possible explanation for these relatively low rates is that ESRD patients on warfarin have a significantly increased risk of bleeding as compared to non-dialysis patients, and the benefit of warfarin in terms of stroke prevention has been called into question (Shah et al., 2014). Direct oral anticoagulants have not been well studied for stroke prevention in AF among ESRD patients, yet were nonetheless used in 5.7% of HD and 5.4% of PD patients. Patients purchase aspirin most commonly over the counter rather than by prescription, thus we could not be reliably assess aspirin use in this cohort.

vol 2 Table 8.4 Cardiovascular pharmacological treatments by (a) comorbidities and (b) procedures in adult ESRD patients, by modality, 2015

(a) Cardiovascular comorbidities

	# Patients	Percentage of patients (%)					
		Beta-blockers	Statins	$P2Y_{12}$ inhibitors	Warfarin	Direct Oral Anticoagulants	ACEIs/ ARBs
Any CVD							
Hemodialysis	151,130	60.2	46.6	19.7	13.6	2.0	36.4
Peritoneal dialysis	12,144	60.1	47.5	19.1	11.9	1.9	40.3
Transplant	30,158	58.2	52.5	13.5	15.0	4.8	33.0
Coronary artery disease (CAD)							
Hemodialysis	90,475	64.0	54.6	27.3	13.9	2.3	38.1
Peritoneal dialysis	7,224	62.7	54.8	27.4	11.6	1.9	40.8
Transplant	16,152	62.5	59.2	20.6	13.1	4.6	34.4
Acute myocardial infarction (AMI)							
Hemodialysis	28,770	68.5	60.0	36.4	15.5	2.6	42.0
Peritoneal dialysis	2,411	67.2	59.7	38.8	13.3	2.0	44.3
Transplant	3,723	67.7	63.2	30.6	16.4	5.9	37.5
Heart failure (HF)							
Hemodialysis	86,319	65.7	48.8	21.5	15.0	2.5	40.0
Peritoneal dialysis	5,947	65.7	49.0	21.1	13.1	2.3	43.6
Transplant	10,206	64.1	54.2	14.4	17.9	6.2	34.4
Valvular heart disease (VHD)							
Hemodialysis	30,888	63.3	47.7	21.5	18.8	2.8	38.7
Peritoneal dialysis	2,577	63.4	48.2	22.1	18.2	2.9	40.8
Transplant	5,365	60.2	52.4	13.0	19.8	6.3	33.3
Cerebrovascular accident/transient ischemic attack (CVA/TIA)							
Hemodialysis	36,896	63.4	55.7	27.3	14.7	2.4	39.2
Peritoneal dialysis	2,690	61.3	55.0	27.0	13.3	2.0	42.5
Transplant	5,328	58.9	58.0	21.1	15.3	5.2	34.5
Peripheral artery disease (PAD)							
Hemodialysis	77,324	59.8	49.3	24.3	14.2	2.1	36.0
Peritoneal dialysis	5,034	58.7	50.2	25.4	11.7	2.1	39.9
Transplant	11,431	58.9	53.9	17.9	13.9	4.4	34.5
Atrial fibrillation (AF)							
Hemodialysis	41,141	60.3	47.3	17.9	33.9	5.7	30.8
Peritoneal dialysis	2,979	59.2	46.5	16.9	30.6	5.4	34.4
Transplant	7,796	62.1	50.4	9.7	35.9	13.0	32.6
Cardiac arrest and ventricular arrhythmias (SCA/VA)							
Hemodialysis	10,245	67.1	50.1	24.6	20.9	3.5	38.0
Peritoneal dialysis	957	63.8	48.4	24.6	17.5	3.4	39.6
Transplant	1,400	66.2	55.0	17.3	22.3	7.8	35.2
Venous thromboembolism and pulmonary embolism (VTE/PE)							
Hemodialysis	15,078	58.5	42.8	18.2	39.9	5.2	33.5
Peritoneal dialysis	993	58.7	40.9	16.4	42.9	5.6	37.9
Transplant	3,497	56.0	48.0	8.3	48.2	11.1	30.9

Table 8.4 continued on next page.

vol 2 Table 8.4 Cardiovascular pharmacological treatments by (a) comorbidities and (b) procedures in adult ESRD patients, by modality, 2015 *(continued)*

(b) Cardiovascular procedures

	# Patients	Percentage of patients (%)					
		Beta-blockers	Statins	$P2Y_{12}$ inhibitors	Warfarin	Direct Oral Anticoagulants	ACEIs/ ARBs
Revascularization – percutaneous coronary interventions (PCI)							
Hemodialysis	3,353	75.1	72.4	78.0	12.0	2.0	50.3
Peritoneal dialysis	395	71.4	66.8	73.4	12.4	3.3	50.9
Transplant	384	75.0	74.5	75.5	11.7	7.0	41.9
Revascularization – coronary artery bypass graft (CABG)							
Hemodialysis	1,625	74.0	72.3	38.6	16.8	2.3	46.6
Peritoneal dialysis	248	72.2	73.0	35.9	16.1	3.6	46.8
Transplant	218	71.6	72.0	31.2	18.8	3.2	39.4
Implantable cardioverter defibrillators & cardiac resynchronization therapy with defibrillator (ICD/CRT-D)							
Hemodialysis	717	76.4	56.3	31.2	23.6	4.7	50.6
Peritoneal dialysis	49	77.6	53.1	36.7	16.3	4.1	59.2
Transplant	65	78.5	69.2	18.5	30.8	10.8	43.1
Carotid artery stenting and carotid artery endarterectomy (CAS/CEA)							
Hemodialysis	471	62.4	59.7	43.7	11.0	2.8	41.8
Peritoneal dialysis	51	66.7	66.7	41.2	13.7	2.0	43.1
Transplant	75	57.3	62.7	36.0	16.0	5.3	48.0

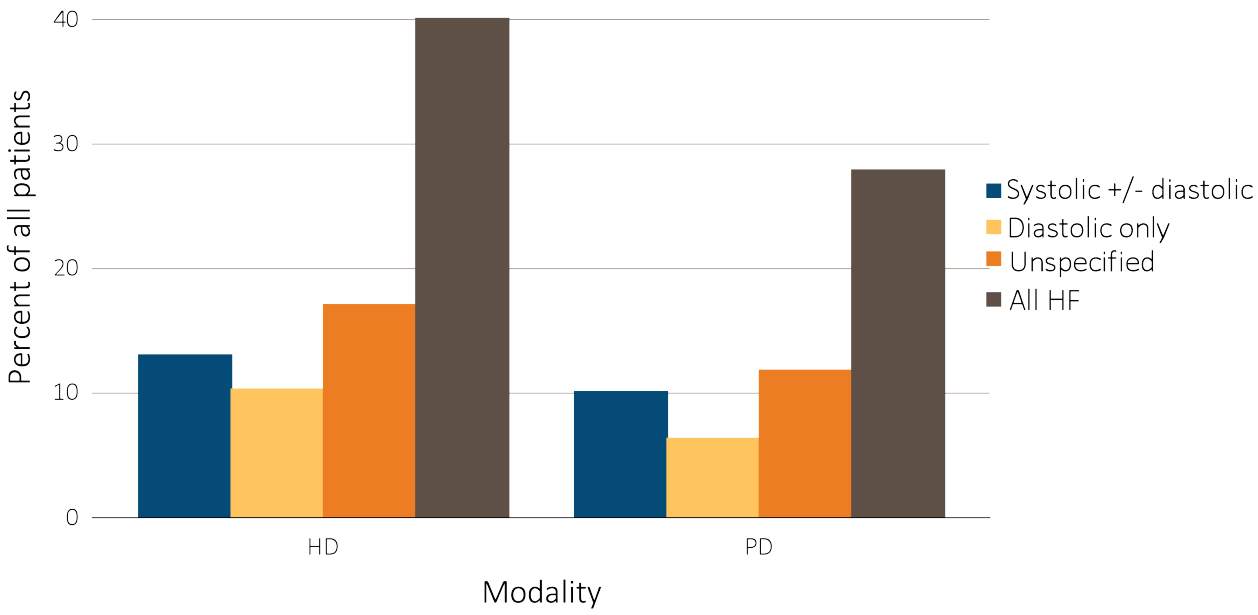
Data Source: Special analyses, USRDS ESRD Database. Point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older, who are continuously enrolled in Medicare Parts A, B, and D, and with Medicare as primary payer from January 1, 2015 to December 31, 2015, and ESRD service date is at least 90 days prior to January 1, 2015. Abbreviations: ACEIs/ARBs, Angiotensin converting enzyme inhibitors and angiotensin receptor blockers; AF, atrial fibrillation; AMI, acute myocardial infarction; CAD, coronary artery disease; CABG, coronary artery bypass grafting; CAS/CEA, carotid artery stenting and carotid endarterectomy; CVA/TIA, cerebrovascular accident/transient ischemic attack; CVD, cardiovascular disease; HF, heart failure; ICD/CRT-D, implantable cardioverter defibrillators/cardiac resynchronization therapy with defibrillator devices; PAD, peripheral arterial disease; PCI, percutaneous coronary interventions; SCA/VA, sudden cardiac arrest and ventricular arrhythmias; VHD, valvular heart disease; VTE/PE, venous thromboembolism and pulmonary embolism.

Heart Failure among ESRD Patients

Heart failure (HF) is a highly prevalent CVD among ESRD patients. Presence of HF adds further complexity to fluid management in ESRD patients, especially given the absence of renal function and clinical challenges with volume status assessment. Heart failure in ESRD patients is further examined in Figure 8.5 by stratifying HF according to left ventricular systolic dysfunction (i.e., heart failure with reduced ejection fraction), left ventricular diastolic dysfunction (i.e., heart failure with preserved ejection fraction), and unspecified cardiac dysfunction. Note that for ease of reporting and consistency in studying clinical approaches, we include in the systolic HF grouping all patients with systolic dysfunction, regardless of the presence of concomitant diastolic dysfunction. Patients with isolated diastolic HF were analyzed separately, since treatments and prognoses are markedly different for this group.

Among adult ESRD patients, the largest percentage of patients had unspecified HF, and the relative proportion of patients with systolic HF was slightly higher than diastolic HF (Figure 8.5). This pattern was true for both HD and PD patients. The percentage of patients experiencing each type of heart failure was slightly higher among HD patients compared to PD patients. We identified categories of systolic dysfunction and diastolic dysfunction through ICD-9-CM and ICD-10-CM diagnosis codes, which have limitations as sole source data. Thus, these findings should be considered cautiously in the absence of further, confirmatory clinical data.

vol 2 Figure 8.5 Heart failure in adult ESRD patients by modality, 2015



Data Source: Special analyses, USRDS ESRD Database. Point prevalent hemodialysis and peritoneal dialysis patients aged 22 and older, who are continuously enrolled in Medicare Parts A and B, and with Medicare as primary payer from January 1, 2015 to December 31, 2015, and ESRD service date is at least 90 days prior to January 1, 2015. Abbreviations: HD, hemodialysis; PD, peritoneal dialysis.

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.

Shah M, Avgil Tsadok M, Jackevicius CA, Essebag V, Eisenberg MJ, Rahme E, Humphries KH, Tu JV, Behlouli H, Guo H, Pilote L. Warfarin use and the risk for stroke and bleeding in patients with atrial fibrillation undergoing dialysis. *Circulation* 2014;129(11):1196-203.

Chapter 9: Healthcare Expenditures for Persons with ESRD

- Between 2014 and 2015, Medicare fee-for-service spending for beneficiaries with end-stage renal disease (ESRD) rose by 2.4%, from 33.1 billion to 33.9 billion, accounting for 7.1% of the overall Medicare paid claims costs, a figure that has remained stable since 2004 (Figure 9.2). This marks the fourth year of modest growth relative to historical trends, and follows the 2011 implementation of the bundled payment system.
- When adding an extra $64 billion of CKD costs (Volume 1, Chapter 6, *Healthcare Expenditures for Persons with CKD*, Tables 6.1 and 6.3), total Medicare spending on both CKD and ESRD is over $98 billion.
- In keeping with the increase in global expenditures for ESRD patients, total 2015 fee-for-service spending for the general Medicare population increased by 4.8%, to $475.3 billion (Figure 9.2).
- In 2015, ESRD spending per patient per year (PPPY) increased by 1.1% (Figure 9.4). Given that ESRD PPPY spending either decreased or increased only slightly from 2009 to 2015, the rise in Medicare expenditures for beneficiaries with ESRD during these years is almost entirely attributable to growth in the number of covered lives.
- For hemodialysis (HD) care, both total and PPPY spending were nearly flat between 2014 ($26.2 billion and $88,750; Figures 9.7 and 9.8) and 2015 ($26.7 billion and $88,195).
- During this period, total peritoneal dialysis (PD) spending grew by 4.7%, as the share of patients receiving PD continued to rise. Peritoneal dialysis PPPY spending rose 1.6% from 2014 to 2015, however, and PD remained less costly on a per patient basis than HD.
- Total and PPPY kidney transplant spending have increased by 3.0%. Total spending for transplant patients increased from $3.1 billion to $3.3 billion, and per capita spending increased from $33,078 to $34,084.
- Total inpatient spending grew rapidly from 2004 until 2009, followed by slower growth from 2009 until 2011; it has remained quite stable since 2011.

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 individuals were receiving dialysis (Rettig, 2011). By 2015, this patient group grew to 434,914. Even though the ESRD population remains 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 9.2).

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 inflation-adjusted decrease of 9%. Re-basing the bundled payment rate would have transferred 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 2015 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 longer-term trends in both total Medicare spending and spending by type of service. Data from 2015 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 these are described in the *Data Sources* section of the *ESRD Analytical Methods* chapter.

Aggregate costs of ESRD presented in this report include those ESRD beneficiaries covered by original Medicare (fee-for-service) for their Medicare Parts A, B, and D benefits. ESRD beneficiaries that are covered by the Medicare Advantage program managed care plans are also included in this report.

Medicare Parts A, B, and D 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 risk-adjusted, per-capita basis, and not by specific claims for services; these data are reported in Figures 9.1 and 9.3 only.

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 three-month waiting period before Medicare coverage begins; an exception is for those initiating home dialysis training or transplant, 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

[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).

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 re-instated.

In this chapter, we use data from both the Medicare Enrollment Database (EDB) and dialysis claims information to categorize payer status as Medicare primary payer (MPP), Medicare secondary payer (MSP), or non-Medicare. Non-Medicare patients in the EDB include those who are pre- or post-Medicare entitlement, such as patients in the initial three-month waiting period.

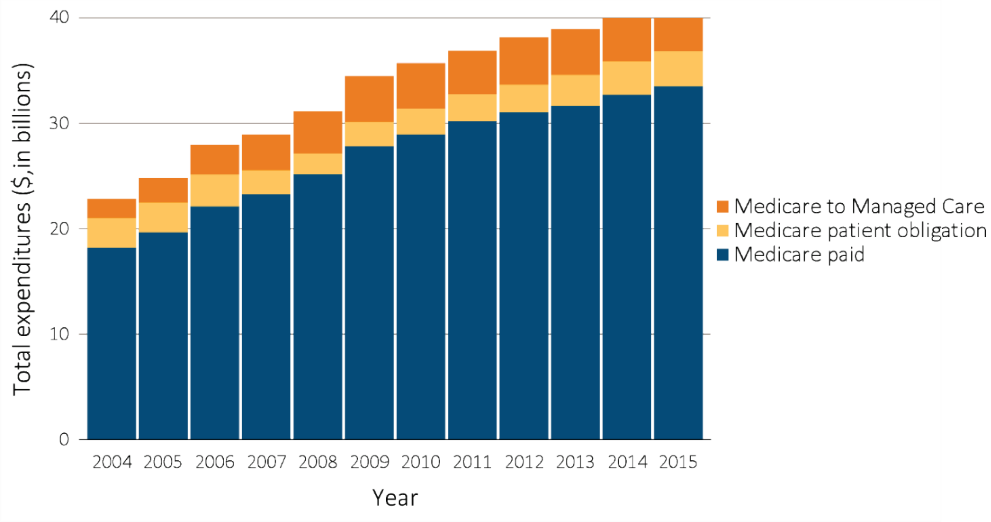
A more accurate picture of total ESRD-related costs would take into account more than just expenditures by the Medicare program. It would include expenses such as those incurred by private insurance carriers when Medicare is the secondary payer, costs during the waiting period for initial Medicare coverage, 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 2015, 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 caregiver travel time and care-giver support for home dialysis would also be included in a comprehensive measure of costs associated with ESRD.

See the *Analytical Methods Used in the ESRD Volume* 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. Downloadable Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available on the USRDS website.

Overall & per Person per Year Costs of ESRD

Figure 9.1 displays Medicare's total annual paid claims for period prevalent ESRD patients from 2004-2015. These costs represent about three quarters of all spending for the care of U.S. ESRD patients (USRDS, 2014). Medicare fee-for-service ESRD spending rose by 2.4% from 2014 to 2015, 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 8.9% of the total Medicare Allowable Payments in 2015. Medicare payments to managed care plans under the Medicare Advantage coverage option increased from 2004 to 2012 and then decreased to 2015, largely due to a reduction in the rates Medicare paid to managed care plans.

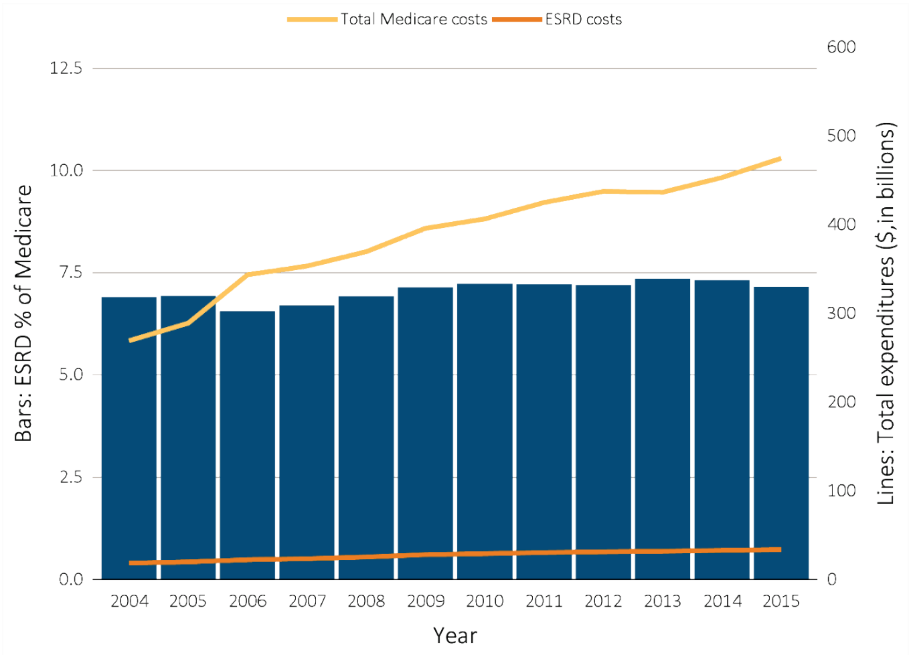
vol 2 Figure 9.1 Trends in ESRD expenditures, 2004-2015



Data Source: USRDS ESRD Database; Reference Table K.1. Abbreviation: ESRD, end-stage renal disease.

As illustrated in Figure 9.2, total Medicare fee-for-service spending in the general Medicare population increased by 4.8% in 2015 to $475.3 billion; the spending for ESRD patients of $33.8 billion accounted for 7.1% 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 24% in 2014 (Kaiser, 2017), 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 9.2 Trends in costs of the Medicare & ESRD programs, 2004-2015

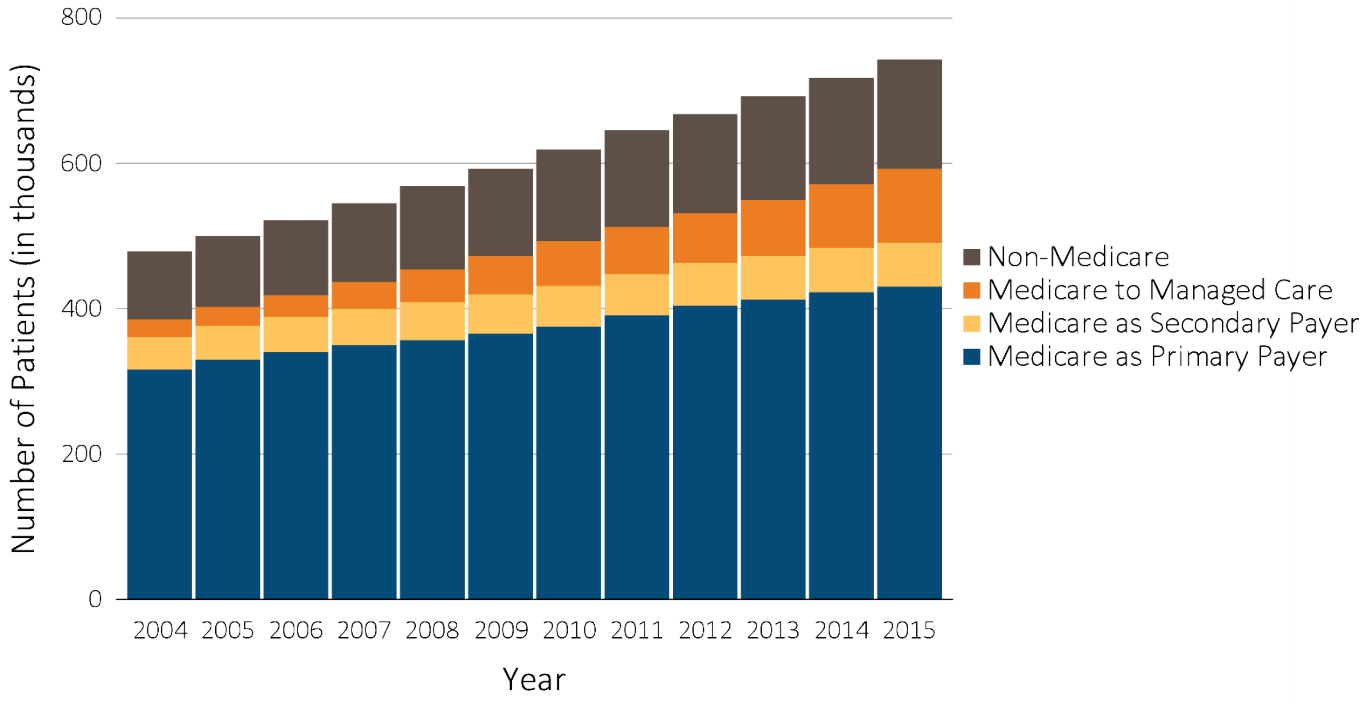


Data Source: Total ESRD costs obtained from USRDS ESRD Database; Reference Table K.1. Total Medicare expenditures obtained from Trustees Report, Table II.B1 https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/TrusteesReports.html. Abbreviation: ESRD,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

Funding Sources for the ESRD Population

Figure 9.3 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 as primary payer (MPP), Medicare as secondary payer (MSP), Medicare payments to Medicare Advantage managed care plans, or non-Medicare. Non-Medicare patients in the EDB included those who were pre- or post-Medicare entitlement. The number of ESRD patients with MPP grew by 1.7 % from 2014 (427,496) to 2015 (434,914).The MSP ESRD population decreased by 0.5% from 2014 (61,275) to 2015 (60,950), while the Medicare paid to managed care and non-Medicare ESRD population rose by 15.6% and 3.5%, to 101,348 and 141,367 respectively.

vol 2 Figure 9.3 Trends in numbers of point prevalent ESRD patients, 2004-2015



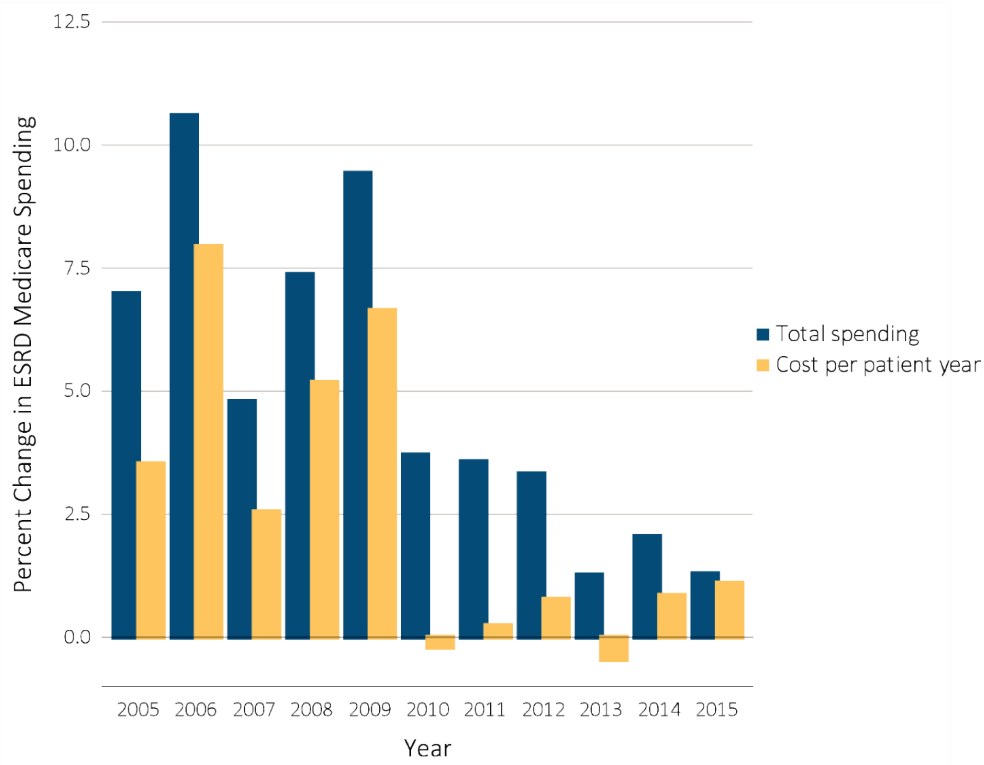
Data Source: USRDS ESRD Database. December 31 point prevalent ESRD patients. Abbreviation: ESRD, end-stage renal disease.

Figure 9.4 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 sixth consecutive year, the annual increase in total Medicare ESRD spending for beneficiaries with primary payer status was less than 5%. In 2015, total Medicare paid claims for ESRD services and supplies increased by 1.3% to $31.1 billion (see Figure 9.4; for total and specific values see Reference Table K.4).

In 2015, ESRD PPPY spending increased by 1.1%. Given that these expenditures decreased or increased only minimally from 2010 to 2015, the growth in total ESRD costs during these years is almost entirely attributable to growth in the number of covered beneficiaries.

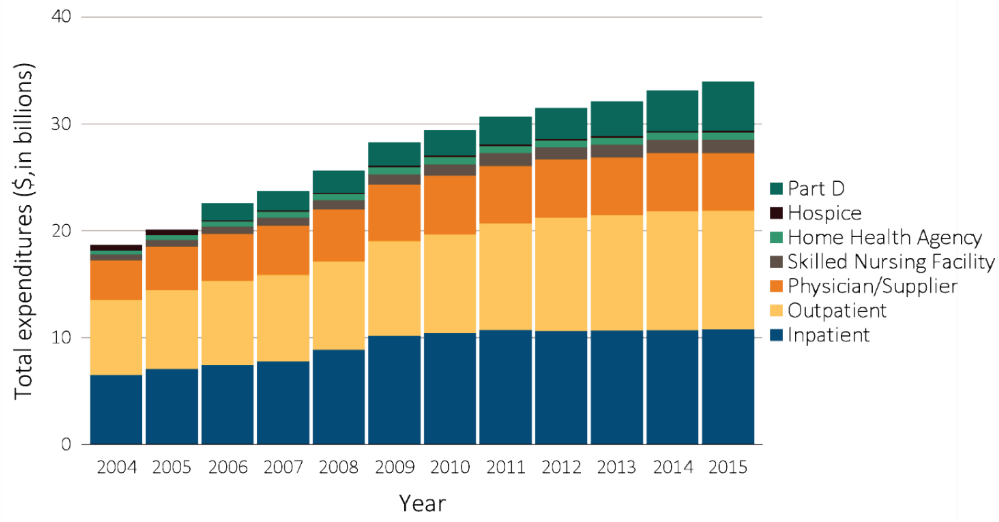
vol 2 Figure 9.4 Annual percent change in Medicare ESRD spending, 2004-2015



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.

Total Medicare fee-for-service spending for ESRD patients is reported by type of service in Figure 9.5. Compared to 2014, the costs of Part D claims in 2015 grew at the fastest rate of 23.5%. 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—this spending increased by 2.2% in 2015. It should be noted, however, that prior to 2013 hospice care had been experiencing one of the highest rates of growth of any category.

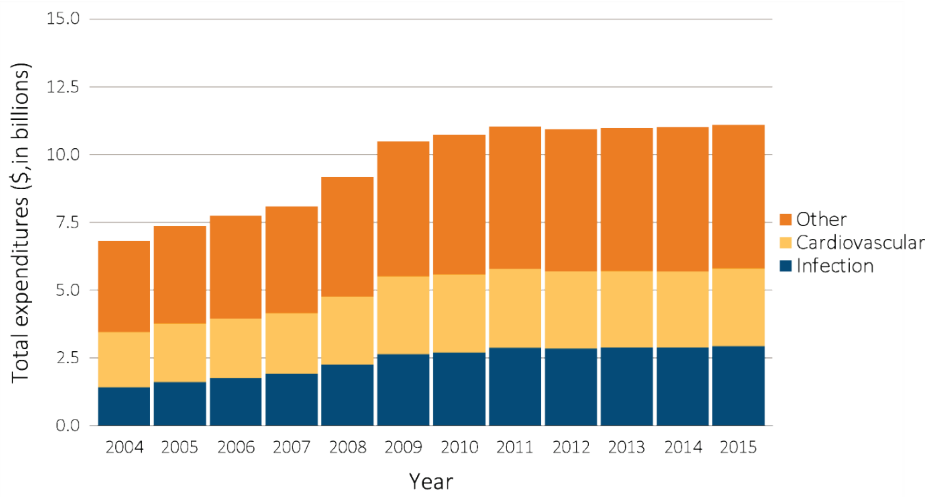
vol 2 Figure 9.5 Trends in total Medicare fee-for-service spending for ESRD, by type of service, 2004-2015



Data Source: USRDS ESRD Database; Reference Table K.1. Total Medicare costs from claims data. Abbreviation: ESRD, end-stage renal disease.

Of 2015 spending on inpatient hospitalization for those with ESRD, 27.4% resulted from admissions to treat infections and 26.0% for those to treat cardiovascular conditions (Figure 9.6). Total spending on hospitalizations has remained stable since 2009 due to decreasing hospitalization rates, which offset increasing costs of each hospitalization (see Volume 2, Chapter 4, *Hospitalization*).

vol 2 Figure 9.6 Total Medicare fee-for-service inpatient spending by cause of hospitalization, 2004-2015



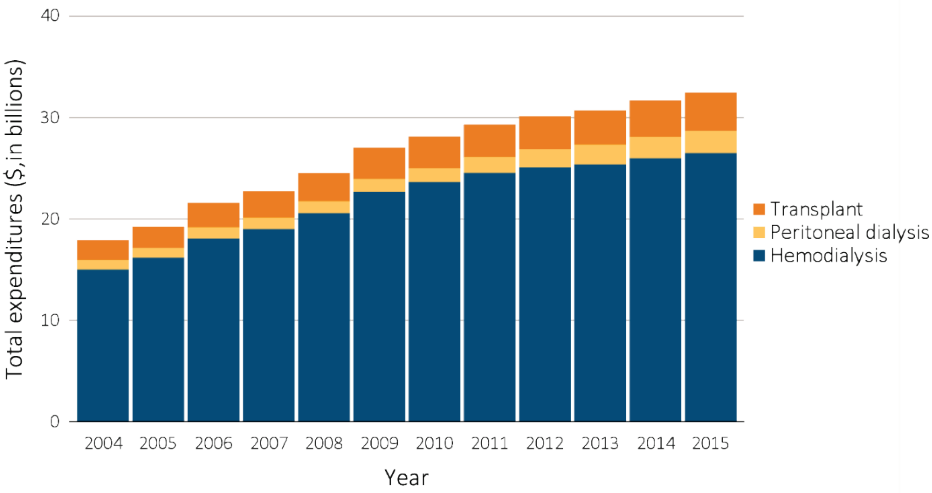
Data Source: USRDS ESRD Database. Total Medicare costs from claims data. Abbreviation: ESRD, end-stage renal disease. Unknown hospitalization cost (<0.01%) was combined with 'Other'.

ESRD Spending by Modality

For patients receiving hemodialysis (HD), both total and PPPY fee-for-service spending were nearly flat between 2014 and 2015 (Figures 9.7 and 9.8). Note that total spending includes costs for beneficiaries with Medicare as either primary or secondary payer, and PPPY amounts include only beneficiaries with Medicare as primary payer.

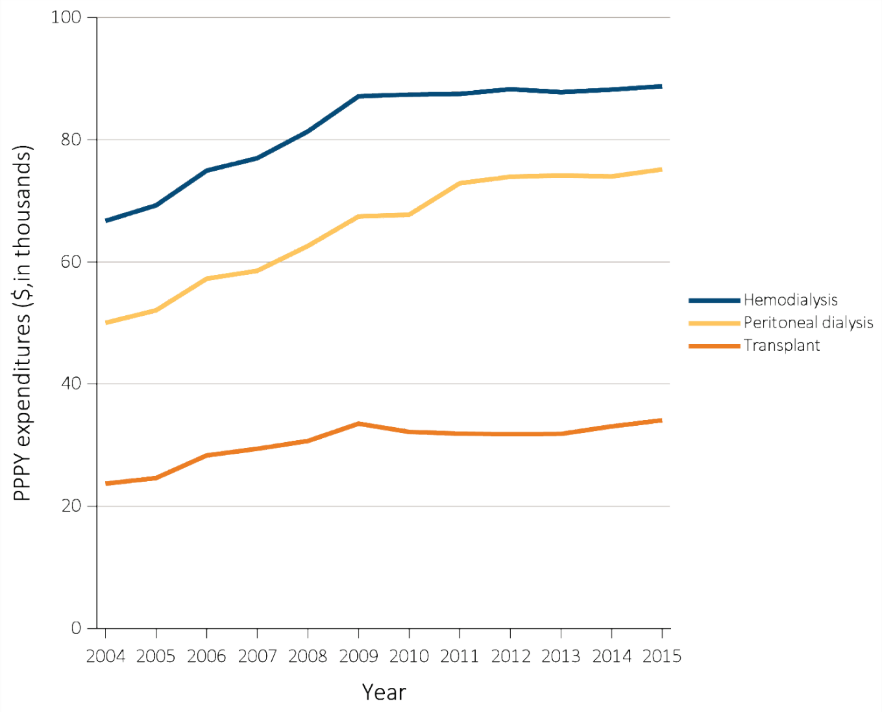
Between 2014 and 2015, peritoneal dialysis (PD) total spending increased by 4.7%, as the share of patients receiving PD continued to rise. PD growth on a PPPY basis increased slightly between 2014 and 2015 (1.6%), however, and it remained less costly on a per patient basis in 2015 ($75,140) than HD ($88,750). Finally, transplant spending in 2015 increased from 2014 levels by 5.7% in total and 3.0% in PPPY expenditures. In 2015 the PPPY cost for transplant patients, $34,084, remained far lower than spending for either dialysis modality.

vol 2 Figure 9.7 Total Medicare ESRD expenditures, by modality, 2004-2015



Data Source: USRDS ESRD Database. Total Medicare costs from claims data for period prevalent ESRD patients. Abbreviation: ESRD, end-stage renal disease.

vol 2 Figure 9.8 Total Medicare ESRD expenditures per person per year, by modality, 2004-2015



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.

References

American Taxpayer Relief Act of 2012, Pub. L. No. 112-240 § 632, 2313 Stat. 126.

Center for Medicare and Medicaid Services, *National Health Expenditures 2014 Highlights* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf. Accessed September 7, 2016.

Civic Impulse. 367; 113th Congress, Medicare Access to Rehabilitation Services Act of 2013: *A bill to amend title XVIII of the Social Security Act to repeal the Medicare outpatient rehabilitation therapy caps.* https://www.govtrack.us/congress/bills/113/s367 Accessed October 24, 2014.

Hirth RA, Turenne MN, Wheeler JR, Nahra TA, Sleeman KK, Zhang W, Messana JA. The initial impact of Medicare's new prospective payment system for kidney dialysis. *American Journal of Kidney Diseases* 2013, 62(4):662-669.

The Henry J. Kaiser Family Foundation (Kaiser). *Medicare indicators: Prescription drug plans: enrollment.* http://kff.org/state-category/medicare/prescription-drug-plans/enrollment-prescription-drug-plans-medicare/. Accessed July, 13, 2017.

The Henry J. Kaiser Family Foundation. *Medicare Advantage.* http://kff.org/medicare/fact-sheet/medicare-advantage/ Accessed August 16, 2016.

Rettig RA. Special Treatment—the Story of Medicare's ESRD Entitlement. *New England Journal of Medicine* 2011; 364:596-598.

United States 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.

United States Renal Data System. *2014 Annual Data Report: Epidemiology of Kidney Disease in the United States*. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2014.

Chapter 10: Prescription Drug Coverage in Patients with ESRD

- In this 2017 Annual Data Report (ADR) we introduce two new chapter features:
  - To provide a more comprehensive examination of prescription coverage and medication use in end-stage renal disease (ESRD) patients, we now add information from the Optum Clinformatics™ DataMart for persons with Medicare Advantage and commercial, managed care coverage.
  - Of the most common drug classes used by ESRD patients, this year we specifically investigate geospatial variation in analgesic use, including prescription nonsteroidal anti-inflammatory agents (NSAIDs) and opioids.
- Among beneficiaries with Medicare Part D enrollment, a higher proportion of those treated with hemodialysis (HD; 65.6%), peritoneal dialysis (PD; 53.2%), and kidney transplant (50.7%) received the Low-income Subsidy (LIS) than did the general Medicare population (30.7%; Figure 10.1).
- In 2015, per patient per year (PPPY) insurance spending on prescriptions for ESRD patients with stand-alone Part D plans was 3.8 times higher than the general Medicare population ($11,389 vs. $3,027). Prescription spending was also 3.3 times higher for these patients in Medicare Advantage plans ($6,139 vs. $1,836), and 11.8 times higher in managed care plans ($8,790 vs. $744; Figure 10.5.a-c).
- Of patients enrolled in stand-alone Part D plans, dialysis patients had a higher PPPY spending on prescriptions than did transplant patients (HD, $12,589; PD, $11,828; Transplant, $8,038). Conversely, dialysis patients had a lower PPPY spending on prescriptions than did transplant patients in Medicare Advantage plans ($5,596 vs. $9,181) and managed care coverage ($7,794 vs. $10,199; Figure 10.5.a-c).
- In both the general Medicare and ESRD populations, PPPY Part D spending was 2.7-3.7 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 10.5.b). LIS beneficiaries' out-of-pocket costs represented only 0.6-1.3% of total Part D expenditures, compared to 23.3-27.8% in the non-LIS populations (Figure 10.5.d).
- In 2015, ESRD patients were most frequently prescribed ion-removing agents, β-adrenergic blocking agents, antibacterials, analgesics, antipyretics, and lipid-lowering agents (Tables 10.6).
- Ion-removing agents, cinacalcet, antidiabetic agents, antivirals, and immunosuppressive agents had the highest total costs of medications prescribed to ESRD patients (Tables 10.7).
- In the United States (U.S.), 8.3% of ESRD patients used prescription, nonsteroidal anti-inflammatory agents (NSAIDs); geographic rates ranged from 3.1% in Vermont to 11.4% in California (Figure 10.6).
- Approximately 50.3% of Medicare ESRD patients used opioid agonists, ranging from 38.1% in New York to 59.2% in Alabama (Figure 10.7).

Introduction

Pharmaceutical therapy is an important component of ESRD treatment. The contribution of medications to positive health outcomes, combined with the clinical and socioeconomic status of ESRD patients, makes their prescription drug benefits particularly significant. This chapter assesses prescription drug coverage, prescription drug-related costs, and patterns of prescription drug use for ESRD

patients in several health systems. As in prior Annual Data Reports (ADR), Medicare Part D claims data from stand-alone prescription drug plans (PDPs) are used to describe Part D enrollment patterns and spending by Medicare beneficiaries.

In this year's chapter, we add comparable information on prescription drug use and associated costs from the Optum Clinformatics™ database for persons enrolled in Medicare Advantage, and through a large commercial, managed care insurance payer. These data promote a more complete assessment of prescription drug use in ESRD—in 2015, 45% of general Medicare beneficiaries were enrolled in a stand-alone PDP, while 24% received coverage through a Medicare Advantage plan (Kaiser, 2017). Additionally, Optum Clinformatics™ data for beneficiaries with managed care insurance provides insight into a younger and employed population, also enhancing our assessment of this topic.

In the 2016 ADR, we reported the spending and utilization rate of the top 15 drug classes used by ESRD patients. Beginning this year we will also annually select a different drug class for a more detailed investigation of medication use patterns. Given that pain is a common symptom experienced by ESRD patients, we begin with analgesics, focusing on prescription nonsteroidal anti-inflammatory agents (NSAIDs) and opioid analgesics.

A parallel examination of prescription drug use and associated costs in patients with CKD can be found in Volume 1, Chapter 7, *Prescription Drug Coverage in Patients with CKD*.

Methods

In this chapter, we traditionally examine Medicare data to describe Part D enrollment and prescription utilization for Medicare beneficiaries. Our cohort contained 100% of the ESRD population receiving HD, PD, or with a functioning kidney transplant. Enrollment data were available for both traditional Medicare (fee-for-service) enrollees and Medicare Advantage enrollees; however, actual claims and spending data were only available for beneficiaries of traditional Medicare. Thus, our past estimates for Part D enrollment applied to all Medicare beneficiaries, but the reporting of prescription utilization and associated costs applied only to Medicare fee-for-services Part D enrollees. We now introduce Optum Clinformatics™ data to augment and refine our assessment of prescription utilization and associated costs for both the Medicare Advantage population and a managed care population.

We included in our analyses the general Medicare beneficiaries who enrolled in both Medicare Parts A and B in the calendar year of interest. To create HD, PD, and kidney transplant cohorts, we identified all point prevalent and incident patients. Point prevalent cohorts included all patients alive and enrolled in Medicare on January 1 of the calendar year, with ESRD onset at least 90 days earlier; treatment modality was identified on January 1. Incident cohorts included all patients alive and enrolled in Medicare exactly 90 days after ESRD onset, between January 1 and December 31 of the index year; modality was identified on this date. We based Part D costs for ESRD patients on the 100 percent ESRD population, using the period prevalent, as-treated actuarial model (model 1, described in ESRD Reference Table K).

To create comparable results for beneficiaries selected from Optum Clinformatics™ data, we applied the same eligibility algorithm as for the Medicare population. Beneficiaries were required to be covered by either a Medicare Advantage plan or managed care insurance on January 1 of the calendar year of interest. Those with Medicare Advantage at the beginning of the year were classified as the Medicare Advantage population; otherwise, they were classified as the commercially insured, managed care population. Dialysis and transplant cohorts were identified by claims-based diagnosis codes; there was insufficient information in the datasets to distinguish HD and PD patients. All of beneficiaries in the Optum Clinformatics™ dataset had prescription drug coverage.

In this chapter, we defined insurance spending as plan payments. For example, we calculated Medicare Part D spending as the sum of the Medicare net payment and the Low-income Subsidy (LIS) amount, which reduces the out-of-pocket obligations of qualifying beneficiaries. Patients' obligations were defined as the sum of the deductible and co-payment.

Medicare Part D Coverage Plans

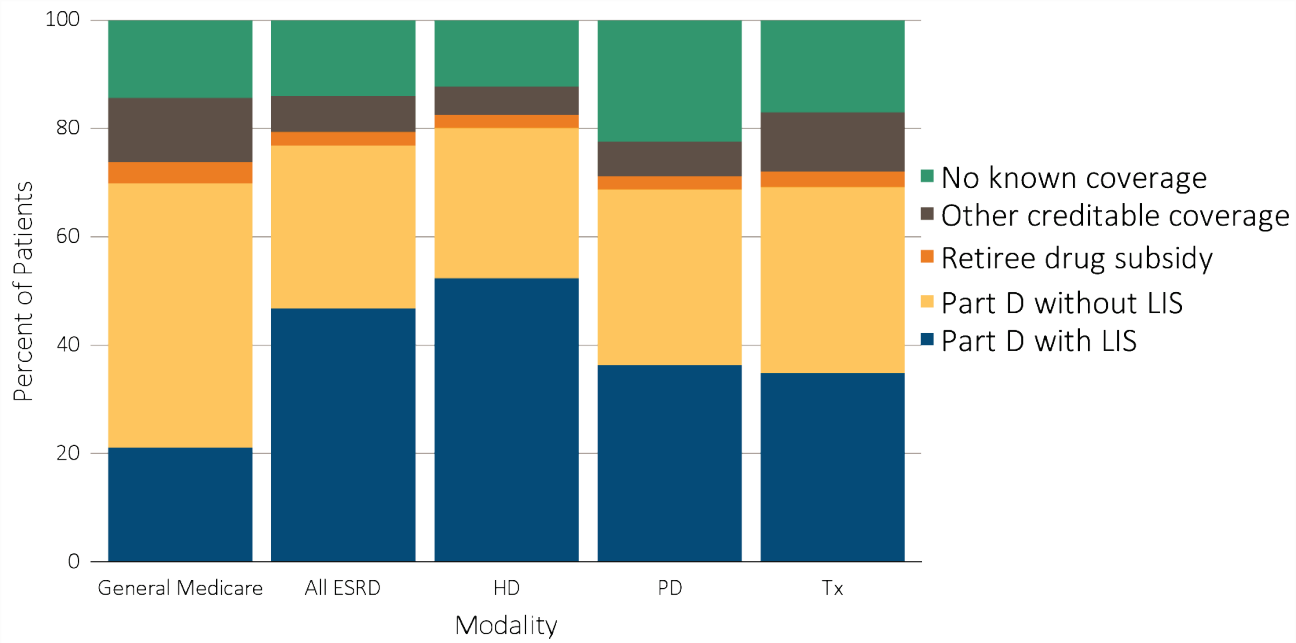
After more than a decade of availability, the Medicare Part D prescription drug benefit has become an integral component of Medicare coverage. Before this program began on January 1, 2006, some Medicare beneficiaries were able to obtain drug coverage through various private insurance plans, state Medicaid 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 (Medicare Advantage prescription drug plan, MA-PD), most obtain Part D benefits through a stand-alone PDP.

Enrollment in Part D is not mandatory. Non-Part D Medicare enrollees may 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 non-participants without an alternative source of coverage pay for their prescriptions out-of-pocket.

In 2015, 70.4% of the general Medicare population enrolled in a Medicare Part D prescription drug plan. Medicare-covered beneficiaries with ESRD exceeded the Part D enrollment rate of the general Medicare population, with 77.4% participation. The differences in benefit use between the ESRD and general Medicare cohorts extended to other areas. About 61.1% of Medicare beneficiaries with ESRD who enrolled in Part D received the LIS benefit, compared to only 30.7% of the general Medicare Part D population.

Other factors varied by renal replacement modality—80.7% of HD, 69.3% of PD, and 69.7% of kidney transplant patients enrolled in Part D (Figure 10.1). By modality, 65.6%, 53.2%, and 50.7% of enrolled HD, PD, and transplant patients qualified for the LIS. About 13.4% of ESRD beneficiaries had no identified prescription drug coverage, with PD and transplant patients most likely to have unknown coverage (Figure 10.1). Given that more of these patients were employed relative to those receiving HD, it is likely that some had sources of prescription drug coverage not currently tracked by Medicare.

vol 2 Figure 10.1 Sources of prescription drug coverage in Medicare ESRD enrollees, by population, 2015



Data source: 2015 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2015. 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.

The share of beneficiaries with ESRD who enrolled in Part D increased annually between 2011 and 2015 (Table 10.1). Total enrollment was higher in the dialysis population than in the general Medicare population, but the growth between 2011 and 2015 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 10.1 Percentage of general Medicare & ESRD patients enrolled in Part D

	General Medicare (%)	All ESRD (%)	Hemodialysis (%)	Peritoneal dialysis (%)	Transplant (%)
2011	60.1	69.4	73.3	61.2	59.0
2012	61.8	71.3	75.2	63.5	61.4
2013	67.2	75.2	78.9	67.2	66.0
2014	69.1	76.5	79.9	68.7	68.2
2015	70.4	77.4	80.7	69.3	69.7

Data source: 2011-2015 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.

The Centers for Medicare and Medicaid Services (CMS) provides participating prescription drug plans (PDPs) with guidance on structuring a "standard" Part D PDP. The upper portion of Table 10.2 illustrates the standard benefit design for PDPs in 2010 and 2015. In 2015, for example, beneficiaries shared costs with the PDP through co-insurance or co-payments until the combined total during the initial coverage period reached $2,960. After reaching this threshold, beneficiaries entered a coverage gap, or "donut hole," where they were then required to pay 100% of their prescription costs.

Under the Affordable Care Act, in each year since 2010 the U.S. government has been providing increasing assistance to those reaching this coverage gap. In 2015, beneficiaries received a 50% discount on brand name drugs from manufacturers plus 5% coverage from their Part D plans; plans also paid 35% of generic drug costs in the gap (Q1 Medicare, 2015). Beneficiaries who reached annual out-of-pocket drug costs of $4,700 entered the catastrophic coverage phase, in which they then paid only a small co-payment for any additional prescriptions until the end of that year (Table 10.2).

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 co-payments instead of the 25% co-insurance, and some plans provide generic and/or brand name drug coverage during the coverage gap (Table 10.2; Q1 Medicare, 2015).

vol 2 Table 10.2 Medicare Part D parameters for defined standard benefit, 2010 & 2015

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

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

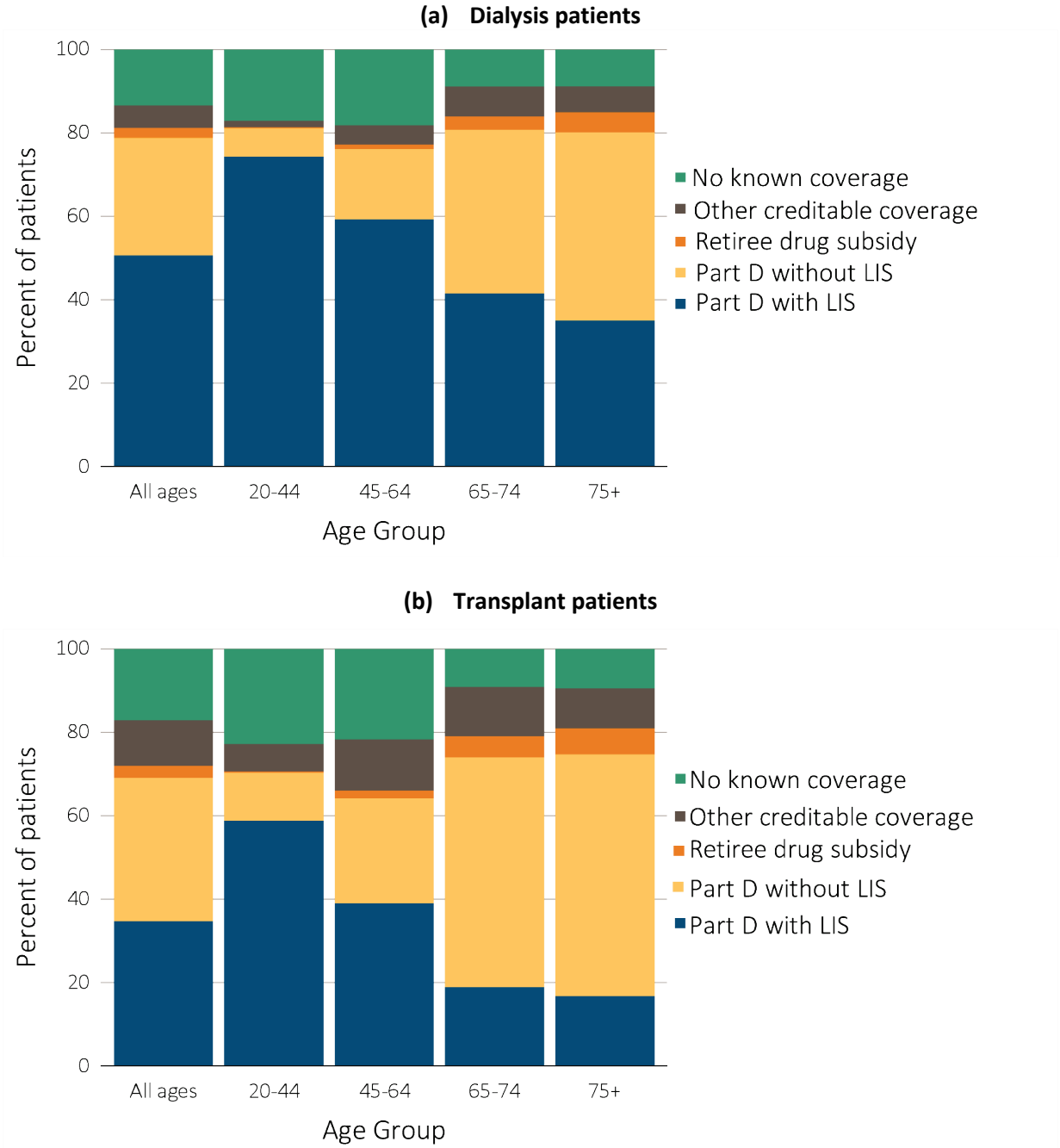
The Medicare Part D program functions in concert with Medicare Part B. Part B covers medications administered in physician offices, including some of those administered during HD (e.g. intravenous (IV) antibiotics that are not associated with dialysis-related infections), and most immunosuppressant medications 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 spending for these medications is displayed in ESRD Reference Table K.1,

but the cost of the bundled drugs are not broken out from the outpatient dialysis spending category.

Medicare Part D Enrollment Patterns

Beneficiaries with ESRD obtain prescription drug coverage from a variety of sources, and these vary widely by the beneficiary's age (Figure 10.2). 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 were markedly less likely than those on dialysis to receive the LIS benefit.

vol 2 Figure 10.2 Sources of prescription drug coverage in Medicare ESRD enrollees, by age & modality, 2015

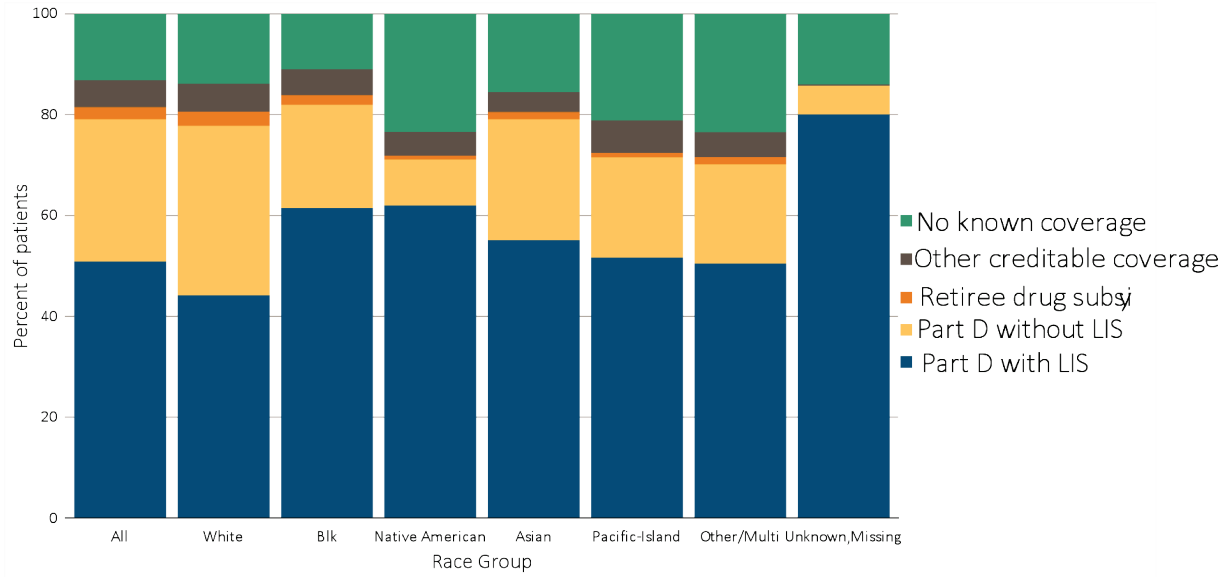


Data source: 2015 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2015. Abbreviations: ESRD, end-stage renal disease; LIS, Low-income Subsidy; Part D, Medicare Part D prescription drug coverage. ESRD patients aged under 20 were not presented.

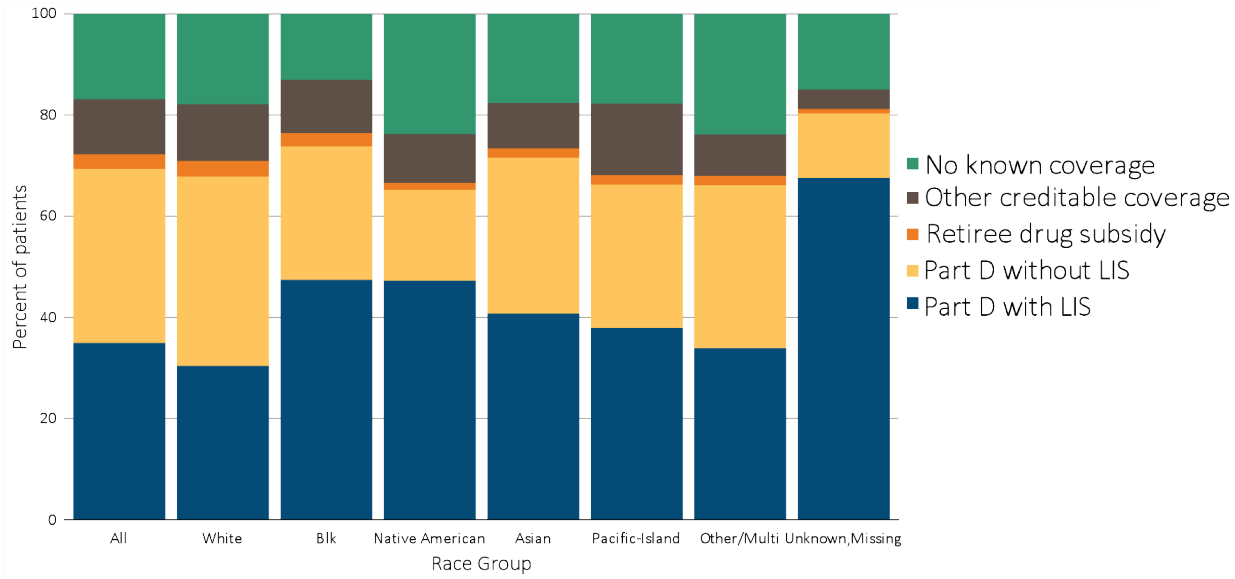
Overall, 79.5% of dialysis patients were enrolled in Part D. A higher percentage of dialysis patients who identified as Black/African American enrolled in Part D (82.4%) compared to those who identified as White (78.2%), Native American/Alaska Native (71.5%), or Asian (79.5%; Figure 10.3.a). About 87.2% of Native Americans/Alaska Natives, 75.2% of Blacks, and 69.8% of Asians with Part D coverage qualified for the LIS benefit, compared to 57.0% of Whites; Blacks were the least likely to have no known prescription drug coverage. About 69.7% of transplant patients enrolled in Part D. By race, 68.3% of White, 74.2% of Black, 65.7% of Native American/Alaska Native, and 72.0% of Asian transplant patients enrolled. A larger share of Native American/Alaska Native (72.6%), Black (64.4%) and Asian (57.2%) transplant patients with Part D coverage had the LIS, compared to 45.1% of White transplant patients (Figure 10.3.b).

vol 2 Figure 10.3 Sources of prescription drug coverage in Medicare ESRD enrollees, by race/ethnicity & modality, 2015

(a) Dialysis patients



(b) Transplant patients



Data source: 2015 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2015. 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.

Table 10.3 reports the percentage of general Medicare and ESRD enrollees who were eligible for the LIS, stratified by age and race. Please note that the numbers of Native American/Alaska Native, Hawaiian Native/Pacific Islander, Other/multiple race and Unknown/missing race beneficiaries in each age category are comparatively small.

vol 2 Table 10.3 Percentage of Medicare Part D enrollees with the Low-income Subsidy, by age & race, 2015

	General Medicare (%	All ESRD (%)	Hemodialysis (%)	Peritoneal dialysis (%)	Transplant (%)
White	N=1640171	N= 308137	N= 200447	N= 22761	N= 62861
All ages	24.2	53.6	58.2	46.8	45.1
20-44	88.2	87.5	90.7	87.5	81.9
45-64	52.0	70.1	75.9	63.6	57.1
65-74	14.5	39.1	48.0	24.3	20.9
75+	18.4	33.5	37.1	17.5	18.0
Black/African American	N=231027	N= 163167	N= 127716	N= 8407	N= 21580
All ages	57.2	73.6	75.6	69.0	64.4
20-44	92.8	92.2	93.8	89.3	87.5
45-64	74.8	80.3	82.7	73.3	69.8
65-74	41.6	58.5	62.8	40.2	39.2
75+	48.5	58.6	60.5	35.1	38.9
Native American/Alaska Native	N=8154	N= 4740	N= 3601	N= 267	N= 734
All ages	68.0	84.4	87.7	80.5	72.6
20-44	92.7	93.1	94.7	92.4	85.0
45-64	82.2	88.2	90.5	80.8	81.6
65-74	55.4	75.8	81.6	63.8	55.5
75+	56.7	75.1	80.3	54.5	54.7
Asian	N=50113	N= 20108	N= 13323	N= 1886	N= 4229
All ages	62.9	66.8	72.0	54.3	57.2
20-44	90.5	86.4	89.4	83.6	83.1
45-64	65.0	71.8	77.3	55.5	65.4
65-74	53.7	56.9	64.7	40.1	43.7
75+	70.7	65.8	70.0	50.4	41.5
Hawaiian Native/Pacific Islander	n/a	N= 4937	N= 3797	N= 386	N= 638
All ages	n/a	70.2	73.6	60.1	57.5
20-44	n/a	88.4	89.3	87.5	85.1
45-64	n/a	76.8	80.5	61.7	64.4
65-74	n/a	57.3	62.0	40.2	44.4
75+	n/a	62.1	65.3	56.3	29.4
Other/multiple race	N=37936	N= 1491	N= 619	N=66	N=694
All ages	30.5	61.2	72.4	69.7	51.6
20-44	85.5	81.4	88.7	83.3	75.0
45-64	45.1	67.4	82.4	88.9	53.8
65-74	21.1	47.5	59.5	33.3	39.9
75+	33.8	45.7	56.3	25.0	32.8
Unknown/missing	N=24737	N= 596	N=305	N=25	N=189
All ages	28.8	87.4	93.8	88.0	84.1
20-44	90.5	93.8	97.6	91.7	98.4
45-64	26.6	88.3	94.6	100.0	78.5
65-74	18.9	74.8	86.8	60.0	70.8
75+	79.8	85.0	83.3	.	90.0

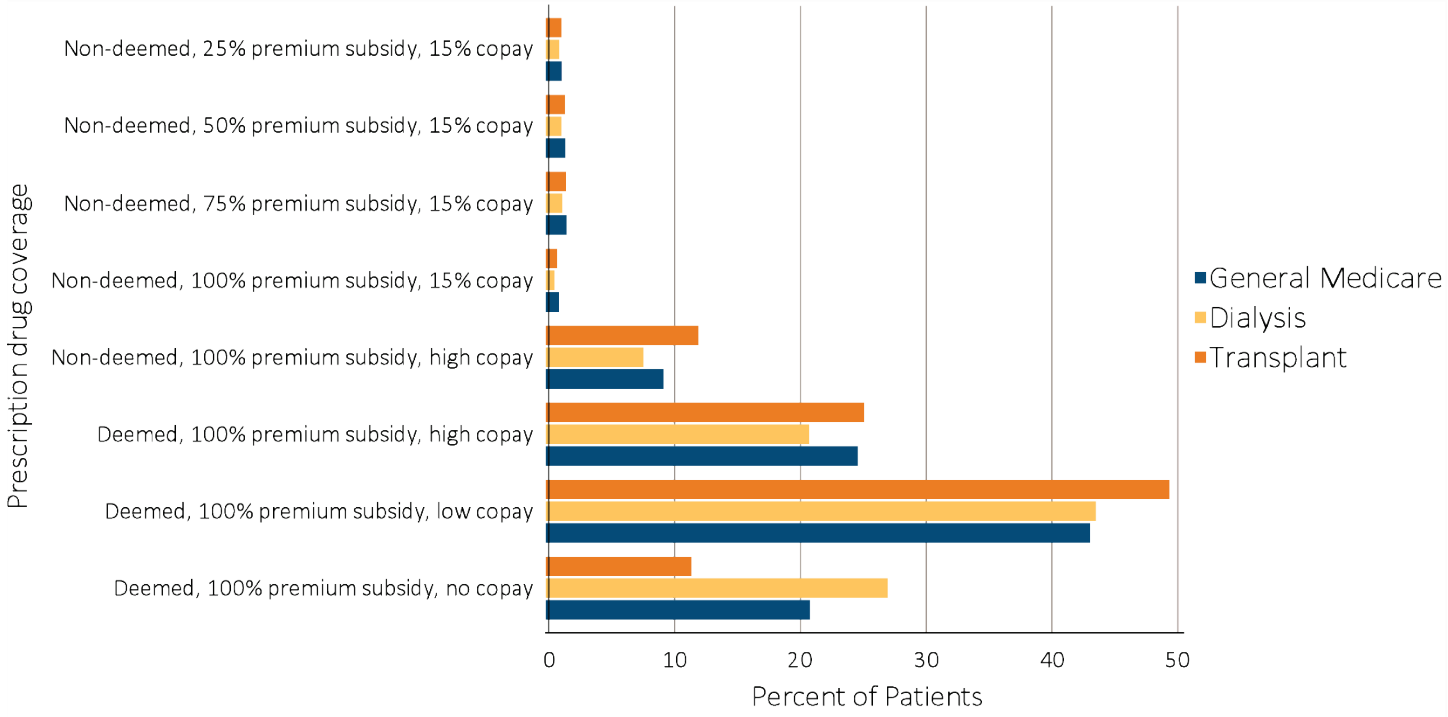
Data source: 2015 Medicare data, point prevalent Medicare enrollees alive on January 1, 2015. Abbreviations: ESRD, end-stage renal disease; LIS, Low-income Subsidy; Part D, Medicare Part D prescription drug coverage. ESRD patients aged under 20 were not presented

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 co-payments, 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 and Qualified Individuals). 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 2015, 90.4% of dialysis patients with Part D LIS coverage were deemed LIS beneficiaries, compared to 85.0% of transplant, and 87.6% of general Medicare beneficiaries (Figure 10.4).

vol 2 Figure 10.4 Distribution of Low-income Subsidy categories in Part D general Medicare & ESRD patients, 2015



Data source: 2015 Medicare data, point prevalent Medicare enrollees alive on January 1, 2015. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage.

Insurance Spending for Prescriptions

In recent years, total Part D spending for beneficiaries with ESRD increased by 81.7%, from $1.8 billion in 2011 to $3.2 billion in 2015 (Table 10.4). These amounts did 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). Medicare spending on outpatient dialysis, which included medications covered by the ESRD bundle, is presented in the USRDS ESRD reference table K.1. Between 2011 and 2015, total estimated Part D spending increased by 1.8, 2.2 and 1.8 times for HD, PD, and kidney transplant patients. These rates of increase far outpaced the 40% spending growth that occurred in the general Medicare population.

vol 2 Table 10.4 Total estimated Medicare Part D spending for enrollees, in billions, 2011-2015

	General Medicare ($)	All ESRD ($)	Hemodialysis ($)	Peritoneal Dialysis ($)	Transplant ($)
2011	46.0	1.8	1.4	0.1	0.2
2012	40.1	2.0	1.6	0.1	0.3
2013	52.1	2.3	1.8	0.1	0.3
2014	58.1	2.7	2.1	0.2	0.4
2015	63.4	3.2	2.5	0.2	0.5

Data source: 2011-2015 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 actuarial 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.

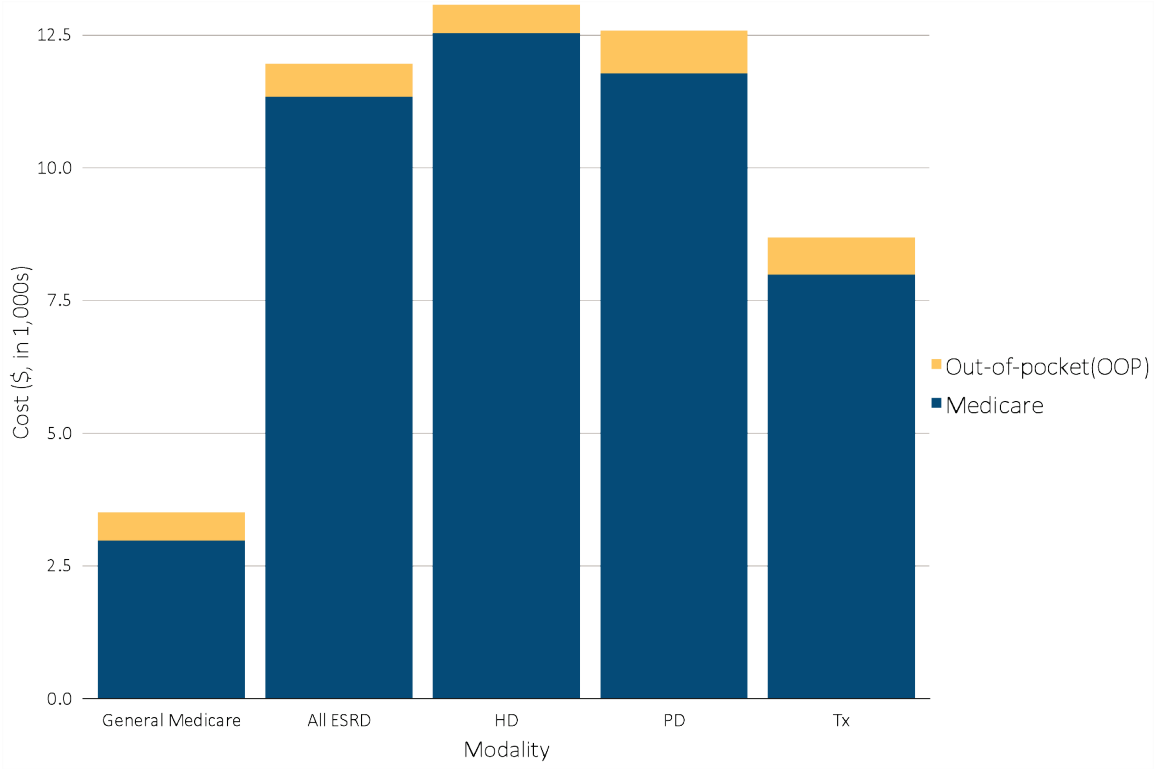
Per patient per year insurance spending was 3.8, 3.3 and 11.8 times greater for beneficiaries with ESRD than for general beneficiaries in the Medicare, Medicare Advantage, and managed care insurance populations. As a proportion of total costs, however, out-of-pocket costs were lower for beneficiaries with ESRD than all general beneficiaries (Medicare, 4.4% vs. 12.6%; Medicare Advantage, 12.0% vs. 18.8%; managed care, 7.9% vs. 19.0%). However, since total spending was so much higher for beneficiaries with ESRD, total out-of-pocket spending was still higher for beneficiaries with ESRD than the general population (Figures 10.5.a-c).

By modality, prescription spending was higher for dialysis patients than transplant patients in those covered by stand-alone Part D plans (HD,$12,589; PD, $11,828; Transplant, $8,038), while prescription spending was lower for dialysis patients than transplant patients in those with Medicare Advantage ($5,596 vs. $9,181) and managed care coverage ($7,794 vs. $10,199; Figures 10.5.a-c).

Across general Medicare and ESRD populations, PPPY Part D spending was 2.7-3.7 times greater for beneficiaries with LIS benefits than for those without. In the LIS population, however, out-of-pocket costs represented only 0.6-1.3% of total expenditures, compared to 23.3-27.8% among general Medicare and ESRD beneficiaries who did not receive the subsidy. PPPY Part D spending was 2.4 and 3.0 times greater for those with ESRD than for general Medicare beneficiaries in the LIS and non-LIS populations (Figure 10.5.d).

vol 2 Figure 10.5 Per person per year insurance & out-of-pocket costs for enrollees, 2015

(a) Medicare



(b) Medicare Advantage

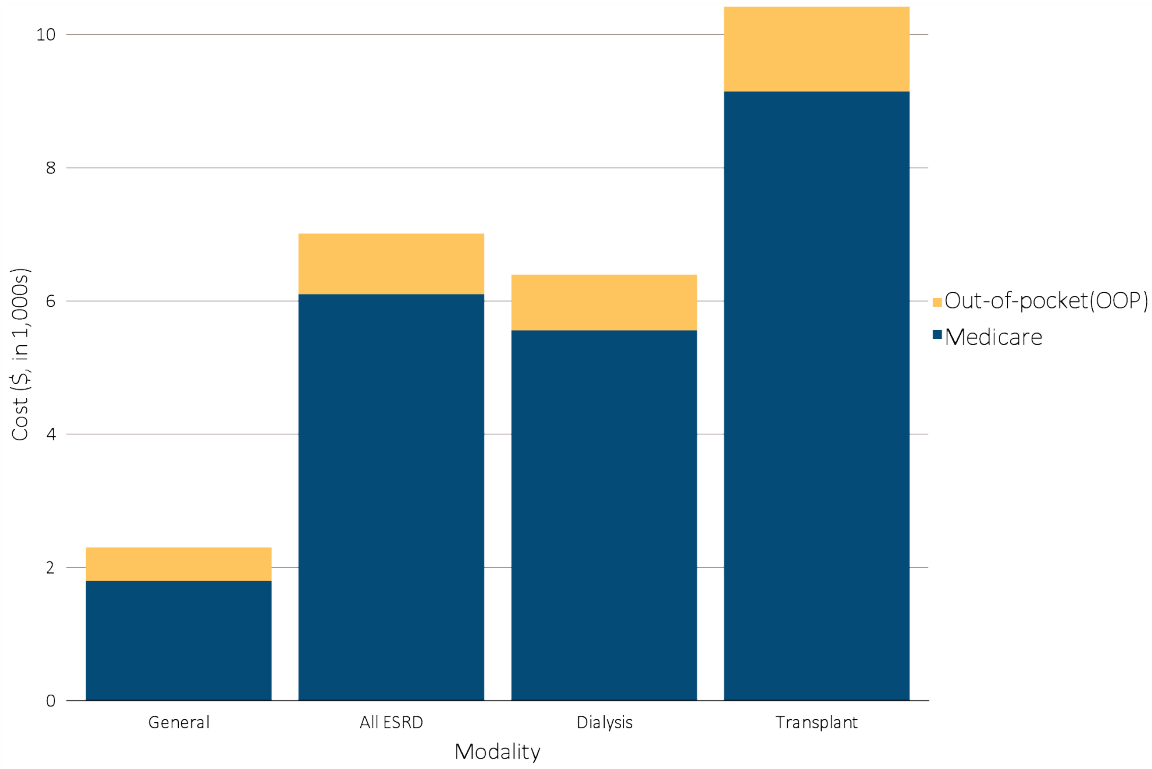
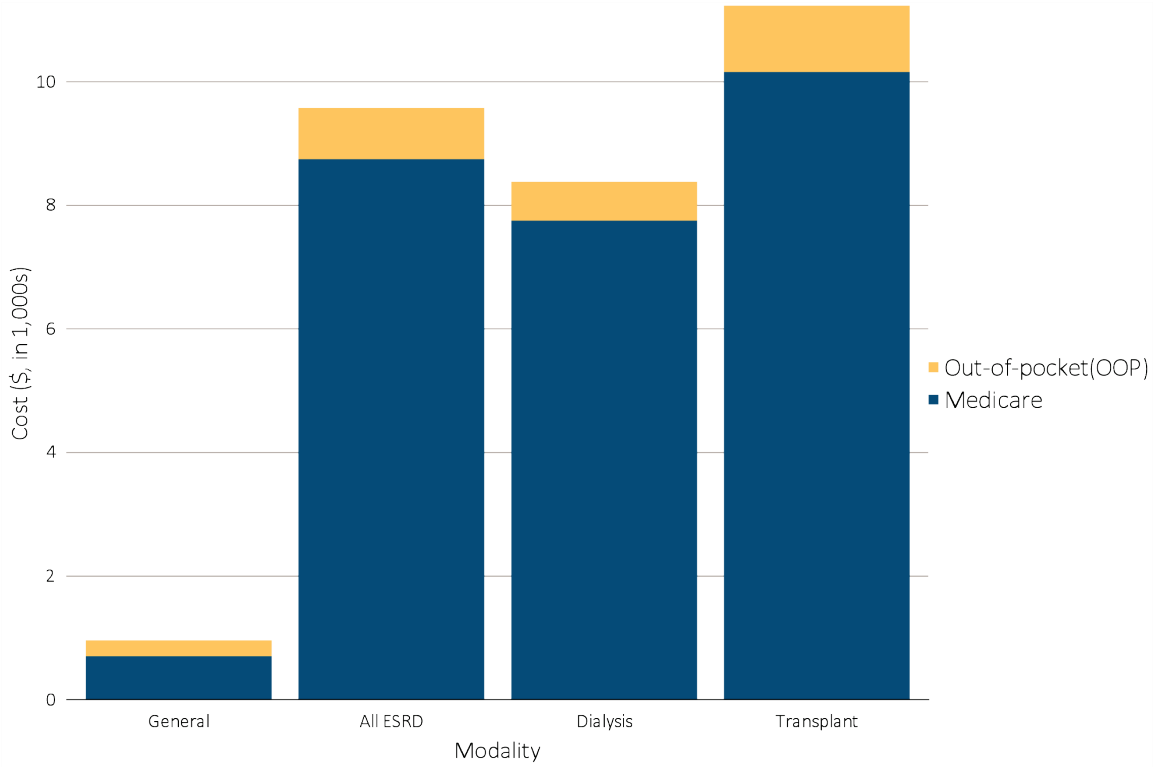


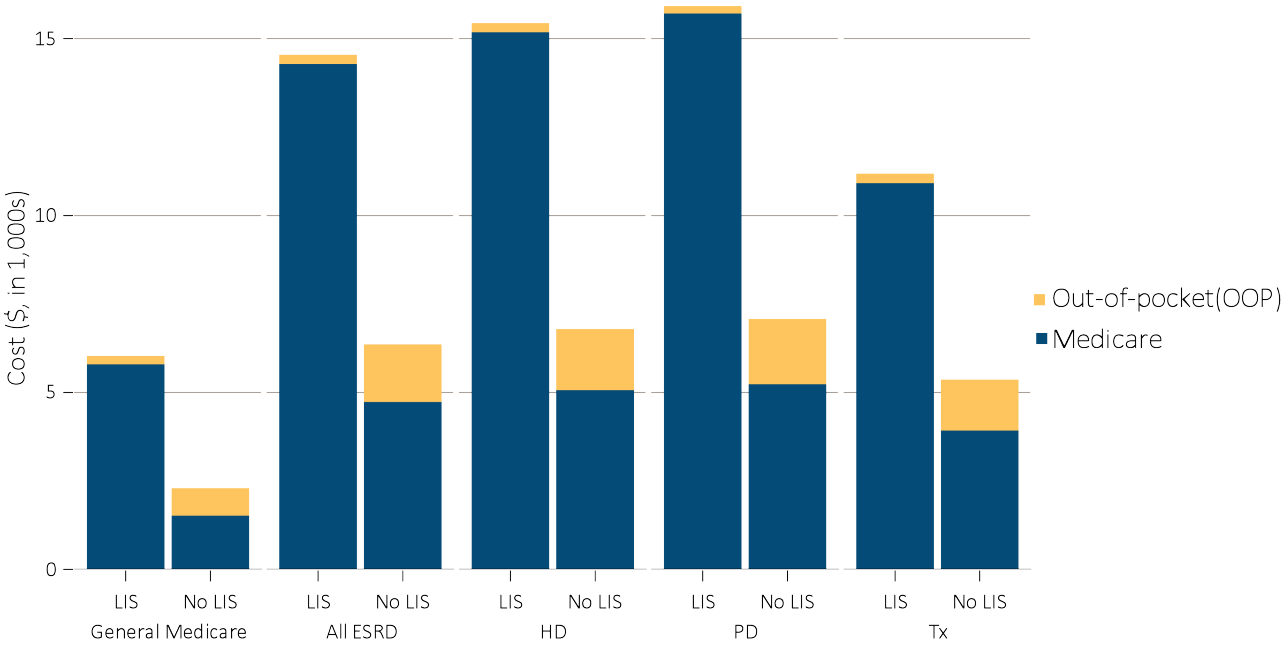
Figure 10.5 continued on next page.

vol 2 Figure 10.5 Per person per year insurance & out-of-pocket costs for enrollees, 2015 *(continued)*

(c) Managed care



(d) Medicare by Low-income Subsidy status



Data source: Medicare Part D claims and Optum Clinformatics™ claims. Medicare totals include Part D claims for Part D enrollees with traditional Medicare (Parts A & B)., Costs are per person per year for calendar year 2015, using as-treated actuarial 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 insurance spending for prescriptions (excluding patient obligations) varied by coverage, age, sex, and race (Table 7.5). Overall, spending for beneficiaries with ESRD was higher than in the general population. For both the general and ESRD cohorts, total PPPY prescription spending was highest in Medicare Part D with LIS ($5,877 and $14,364). Lowest spending for the general population cohorts occurred in managed care ($744), and for the ESRD cohorts in Medicare Part D without LIS ($4,812). Generally, younger beneficiaries aged 20-44 or 45-64, had higher costs than older patients. Insurance spending varied only modestly by sex. As there are differences between the Medicare and Optum Clinformatics™ beneficiary populations and in their methods of reporting costs, however, these results should be interpreted in those contexts.

vol 2 Table 10.5 Per person per year insurance spending for enrollees, 2015

(a) Medicare

	General ($)		All ESRD ($)		Hemodialysis ($)		Peritoneal dialysis ($)		Transplant ($)	
	Part D with LIS	Part D without LIS	Part D with LIS	Part D without LIS	Part D with LIS	Part D without LIS	Part D with LIS	Part D without LIS	Part D with LIS	Part D without LIS
Age										
All	5,877	1,600	14,364	4,812	15,263	5,146	15,791	5,311	10,995	4,006
20-44	5,839	2,510	14,574	4,670	16,584	5,994	16,000	5,091	9,433	3,027
45-64	7,909	2,934	15,623	5,675	16,549	5,944	16,321	5,720	12,027	4,856
65-74	4,965	1,514	12,993	4,947	13,605	5,472	13,572	5,640	10,645	3,928
75+	4,208	1,461	10,601	3,819	11,179	4,077	10,647	4,277	7,435	2,882
Sex										
Male	6,028	1,756	14,689	4,955	15,551	5,138	16,636	5,317	11,615	4,411
Female	5,771	1,484	13,997	4,596	14,945	5,159	15,030	5,302	10,172	3,384
Race										
White	6,029	1,586	13,941	4,732	15,107	5,167	16,183	5,343	10,351	3,813
Black/African American	6,090	1,873	15,068	5,061	15,612	5,082	15,053	5,119	12,463	4,931
Native American/Alaska Native	4,774	2,605	9,218	4,533	9,204	5,185	11,767	4,355	8,438	3,607
Asian	4,637	1,268	14,511	5,031	15,575	5,622	16,953	5,640	10,895	4,144
Native Hawaiian/Pacific-Islander	NA	NA	14,898	4,085	15,685	3,929	17,203	4,875	9,126	4,053
Other race	4,973	1,599	12,478	4,856	14,175	6,161	12,446	4,726	10,868	4,397
Unknown/missing	4,723	1,534	13,829	3,347	15,155	3,870	20,957	33,966	10,907	4,149

Data source: Medicare Part D claims and Optum Clinformatics™ claims. Costs are per person per year for calendar year 2015, using as-treated actuarial 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.

Table 10.5 continued on next page.

vol 2 Table 10.5 Per person per year insurance spending for enrollees, 2015 (*continued)*

(b) Medicare Advantage

	General ($)	All ESRD ($)	All Dialysis ($)	Transplant ($)
Age				
All	1,836	6,139	5,596	9,181
20-44	4,849	14,168	10,725	20,641
45-64	4,928	10,035	9,228	12,295
65-74	1,563	5,893	5,619	7,093
75+	1,421	4,125	4,050	5,387
Sex				
Male	1,836	5,932	5,186	9,915
Female	1,836	6,376	6,057	8,265
Race				
White	1,855	5,738	5,249	8,305
Black/African American	2,678	7,477	6,701	13,897
Asian	1,842	7,805	7,176	11,468
Unknown	1,689	5,590	5,321	6,756

(c) Managed care

	General ($)	All ESRD ($)	All Dialysis ($)	Transplant ($)
Age				
All	744	8,790	7,794	10,199
20-44	504	7,434	6,665	8,135
45-64	1,233	9,173	8,384	10,310
65-74	2,018	8,686	7,892	10,609
75+	2,711	5,792	5,466	8,616
Sex				
Male	738	9,147	8,206	10,540
Female	749	8,260	7,148	9,718
Race				
White	773	9,093	8,191	10,178
Black/African American	693	7,871	6,890	11,141
Asian	413	8,009	7,701	8,395
Unknown	764	8,909	7,051	10,592

Data source: Medicare Part D claims and Optum Clinformatics™ claims. Costs are per person per year for calendar year 2015, using as-treated actuarial 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

In this section we rank the top 15 drug classes used by ESRD patients based on the percentage of beneficiaries with at least one claim for a drug within the class during 2015. The proportion of patients using each drug class was somewhat lower for Medicare Advantage and managed care enrollees in the Clinformatics™ database than for those having Medicare Part D. These differences could arise from plan effects such as coverage or care management activities, or from patient selection in the younger and healthier Clinformatics™ cohort. ESRD patients in all insured populations commonly used ion-removing agents, β-adrenergic blocking agents, antibacterials, analgesics, and lipid-lowering agents. As expected, immunosuppressive agents were the most frequently prescribed medication class to transplant patients with Medicare Advantage and managed care coverage. The use proportion for this drug class for Medicare transplant recipients were underestimated, as only a fraction of immunosuppressive agents were covered through Part D (Table 10.6).

vol 2 Table 10.6 Top 15 drug classes received by ESRD cohorts in different health plans, by modality, 2015
(a) Medicare

	Hemodialysis		Peritoneal Dialysis		Transplant	
Rank	**Drug class**	**%**	**Drug class**	**%**	**Drug class**	**%**
1	Ion-removing agents	71.2	Ion-removing agents	61.7	Antibacterials	74.3
2	β-adrenergic blocking agents	63.7	β-adrenergic blocking agents	60.3	β-Adrenergic blocking agents	63.0
3	Antibacterials	58.7	Antibacterials	58.6	Antiulcer agents and acid suppressants	59.6
4	Analgesics and antipyretics	58.4	Analgesics and antipyretics	47.5	Lipid-lowering agents	56.6
5	Lipid-lowering agents	49.6	Lipid-lowering agents	47.3	Calcium-channel blocking agents	50.3
6	Calcium-channel blocking agents	47.7	Calcium-channel blocking agents	46.3	Analgesics and antipyretics	49.2
7	Antiulcer agents and acid suppressants	46.9	Renin-angiotensin-aldosterone system inhibitors	42.8	Adrenals	47.0
8	Renin-angiotensin-aldosterone system inhibitors	38.5	Antiulcer agents and acid suppressants	39.7	Antidiabetic agents	39.1
9	Antidiabetic agents	37.1	Antidiabetic agents	33.5	Renin-angiotensin-aldosterone system inhibitors	36.3
10	Hypotensive agents	32.5	Anti-infectives	33.5	Diuretics	33.5
11	Psychotherapeutic agents	31.7	Diuretics	32.7	Psychotherapeutic agents	25.3
12	Anticonvulsants	31.4	Hypotensive agents	27.2	Antivirals	24.8
13	Cinacalcet	30.9	Psychotherapeutic agents	27.2	Diabetic consumables	24.6
14	Antithrombotic agents	30.2	Cinacalcet	25.6	Anticonvulsants	22.3
15	Anxiolytics, sedatives, and hypnotics	26.8	Replacement preparations	25.1	Anti-infectives	20.4

Table 10.6 continued on next page.

vol 2 Table 10.6 Top 15 drug classes received by ESRD cohorts in different health plans, by modality, 2015 *(continued)*

(b) Medicare Advantage

	Dialysis		Transplant	
Rank	**Drug class**	**%**	**Drug class**	**%**
1	β-adrenergic blocking agents	44.8	Immunosuppressive agents	48.0
2	Lipid-lowering agents	41.0	Antibacterials	40.9
3	Analgesics and antipyretics	40.4	Adrenals	38.8
4	Antibacterials	40.2	β-adrenergic blocking agents	35.5
5	Ion-removing agents	37.2	Lipid-lowering agents	34.8
6	Calcium-channel Blocking agents	35.2	Antiulcer agents and acid suppressants	29.4
7	Antiulcer agents and acid suppressants	31.5	Calcium-channel Blocking agents	28.0
8	Antidiabetic agents	29.1	Analgesics and antipyretics	27.8
9	Diuretics	26.8	Renin-angiotensin-aldosterone system inhibitors	25.1
10	Renin-angiotensin-aldosterone system inhibitors	26.7	Antidiabetic agents	24.4
11	Diabetic consumables	24.8	Diabetic consumables	23.3
12	Antithrombotic agents	22.5	Diuretics	20.2
13	Hypotensive agents	22.0	Psychotherapeutic agents	15.6
14	Psychotherapeutic agents	21.9	Antithrombotic agents	14.5
15	Anticonvulsants	20.1	Anticonvulsants	13.9

(c) Managed care

	Dialysis		Transplant	
Rank	**Drug class**	**%**	**Drug class**	**%**
1	Ion-removing agents	44.0	Immunosuppressive agents	52.8
2	β-adrenergic blocking agents	42.6	Antibacterials	43.8
3	Analgesics and antipyretics	37.8	Adrenals	39.3
4	Antibacterials	36.6	β-adrenergic blocking agents	32.0
5	Calcium-channel Blocking agents	35.7	Lipid-lowering agents	30.2
6	Lipid-lowering agents	31.3	Calcium-channel Blocking agents	26.0
7	Renin-angiotensin-aldosterone system inhibitors	28.5	Renin-angiotensin-aldosterone system inhibitors	25.8
8	Antidiabetic agents	24.3	Analgesics and antipyretics	25.6
9	Diuretics	24.0	Antiulcer agents and acid suppressants	20.6
10	Hypotensive agents	22.9	Antidiabetic agents	15.3
11	Vitamin D	20.0	Diuretics	14.3
12	Antiulcer agents and acid suppressants	19.7	Vitamin D	13.1
13	Diabetic consumables	18.9	Diabetic consumables	13.0
14	Antithrombotic agents	14.9	Anxiolytics, sedatives, and hypnotics	11.9
15	Anxiolytics, sedatives, and hypnotics	14.5	Psychotherapeutic agents	11.7

Data source: Medicare Part D claims and Optum Clinformatics™ claims. Ion-removing agents include phosphate-binding agents, potassium-binding agents, etc. Hypotension agents include alpha-2-agonist and vasodilators. Diabetic consumables refer to blood glucose test strips, blood glucose meters/sensors, lancets, needles, pen needles, etc.

Ion-removing agents incurred the greatest costs for dialysis patients in all insured populations, at about 40% of total insurance spending. Antivirals ranked first for transplant patients with Medicare Part D, and immunosuppressive agents were highest for patients with Medicare Advantage and managed care coverage. Other costly medications and classes for treatment of ESRD included cinacalcet, antidiabetic agents, and antivirals (Table 10.7).

vol 2 Table 10.7 Top 15 drug classes received by different ESRD cohorts, by modality and insurance spending, 2015

(a) Medicare

	Hemodialysis			Peritoneal Dialysis			Transplant		
Rank	**Drug class**	**Costs**	**%**	**Drug class**	**Costs**	**%**	**Drug class**	**Costs**	**%**
1	Ion-removing agents	$1,005.1	40.7	Ion-removing agents	$83.3	41.7	Antivirals	$152.0	33.4
2	Cinacalcet	$546.0	22.1	Cinacalcet	$41.8	20.9	Antidiabetic agents	$76.2	16.8
3	Antidiabetic agents	$192.0	7.8	Antidiabetic agents	$20.2	10.1	Cinacalcet	$40.3	8.9
4	Antivirals	$135.3	5.5	Antivirals	$11.1	5.5	Immunosuppressive agents	$21.8	4.8
5	Antineoplastic agents	$57.8	2.3	Antineoplastic agents	$4.4	2.2	Antiulcer agents and acid suppressants	$11.9	2.6
6	Antiulcer agents and acid suppressants	$35.1	1.4	Lipid-lowering agents	$3.0	1.5	Lipid-lowering agents	$11.8	2.6
7	Analgesics and antipyretics	$32.2	1.3	Antiulcer agents and acid suppressants	$2.4	1.2	Adrenocortical Insufficiency	$8.5	1.9
8	Lipid-lowering agents	$31.9	1.3	Antibacterials	$2.1	1.1	Antibacterials	$7.7	1.7
9	Psychotherapeutic agents	$26.6	1.1	Analgesics and antipyretics	$1.6	0.8	Hematopoietic agents	$7.4	1.6
10	Vasodilating agents	$26.4	1.1	Serums	$1.5	0.8	Antineoplastic agents	$7.0	1.5
11	Antibacterials	$26.3	1.1	Pituitary	$1.5	0.8	Psychotherapeutic agents	$7.0	1.5
12	Anticonvulsants	$25.2	1.0	Vasodilating agents	$1.4	0.7	Serums	$6.4	1.4
13	Caloric agents	$23.7	1.0	Anticonvulsants	$1.4	0.7	Anticonvulsants	$6.2	1.4
14	Anti-inflammatory agents	$20.5	0.8	Psychotherapeutic agents	$1.3	0.6	Analgesics and antipyretics	$5.8	1.3
15	Antithrombotic agents	$15.2	0.6	β-adrenergic blocking agents	$1.1	0.6	Antithrombotic agents	$4.7	1.0

Table 10.7 continued on next page.

vol 2 Table 10.7 Top 15 drug classes received by different ESRD cohorts, by modality and insurance spending, 2015 *(continued)*

(b) Medicare Advantage

	Dialysis			Transplant		
Rank	**Drug class**	**Costs**	**%**	**Drug class**	**Costs**	**%**
1	Ion-removing agents	$13.9	27.4	Immunosuppressive agents	$5.2	34.8
2	Cinacalcet	$7.3	14.3	Antivirals	$2.8	19.0
3	Antidiabetic agents	$5.2	10.3	Antidiabetic agents	$1.3	8.8
4	Antineoplastic agents	$2.2	4.3	Cinacalcet	$1.3	8.4
5	Diabetic consumables	$1.9	3.7	Diabetic consumables	$0.5	3.5
6	Antivirals	$1.7	3.4	Ion-removing agents	$0.4	2.8
7	Lipid-lowering agents	$1.6	3.2	Lipid-lowering agents	$0.3	2.2
8	Vasodilating agents	$1.2	2.3	Antithrombotic agents	$0.2	1.3
9	Analgesics and antipyretics	$1.0	1.9	Antiulcer agents and acid	$0.2	1.3
10	Antiulcer agents and acid	$0.8	1.6	Antibacterials	$0.2	1.3
11	Calcium-channel Blocking agents	$0.7	1.5	Psychotherapeutic agents	$0.2	1.1
12	Psychotherapeutic agents	$0.7	1.5	Analgesics and antipyretics	$0.2	1.0
13	Anti-inflammatory agents	$0.7	1.4	Calcium-channel Blocking agents	$0.1	0.9
14	Antibacterials	$0.7	1.4	Serums	$0.1	0.9
15	Hypotensive agents	$0.7	1.4	β-adrenergic blocking agents	$0.1	0.8

(c) Managed care

	Dialysis			Transplant		
Rank	**Drug class**	**Costs**	**%**	**Drug class**	**Costs**	**%**
1	Ion-removing agents	$8.4	35.6	Immunosuppressive agents	$9.4	43.2
2	Cinacalcet	$3.2	13.7	Antivirals	$3.4	15.9
3	Antidiabetic agents	$2.4	10.3	Cinacalcet	$1.5	6.7
4	Antineoplastic agents	$1.2	5.0	Antidiabetic agents	$1.4	6.4
5	Antivirals	$1.1	4.8	Ion-removing agents	$1.0	4.4
6	Immunosuppressive agents	$0.7	3.0	Lipid-lowering agents	$0.4	2.1
7	Diabetic consumables	$0.5	2.2	Hematopoietic agents	$0.4	1.8
8	Lipid-lowering agents	$0.5	2.2	Antibacterials	$0.4	1.6
9	Antibacterials	$0.3	1.3	Diabetic consumables	$0.3	1.6
10	Vasodilating agents	$0.3	1.3	Antithrombotic agents	$0.2	1.0
11	Calcium-channel Blocking agents	$0.3	1.3	Pituitary	$0.2	1.0
12	Hypotensive agents	$0.3	1.2	β-adrenergic blocking agents	$0.2	0.8
13	Hematopoietic agents	$0.3	1.1	Calcium-channel Blocking agents	$0.2	0.7
14	Analgesics and antipyretics	$0.3	1.1	Antifungals	$0.2	0.7
15	β-adrenergic blocking agents	$0.3	1.1	Psychotherapeutic agents	$0.2	0.7

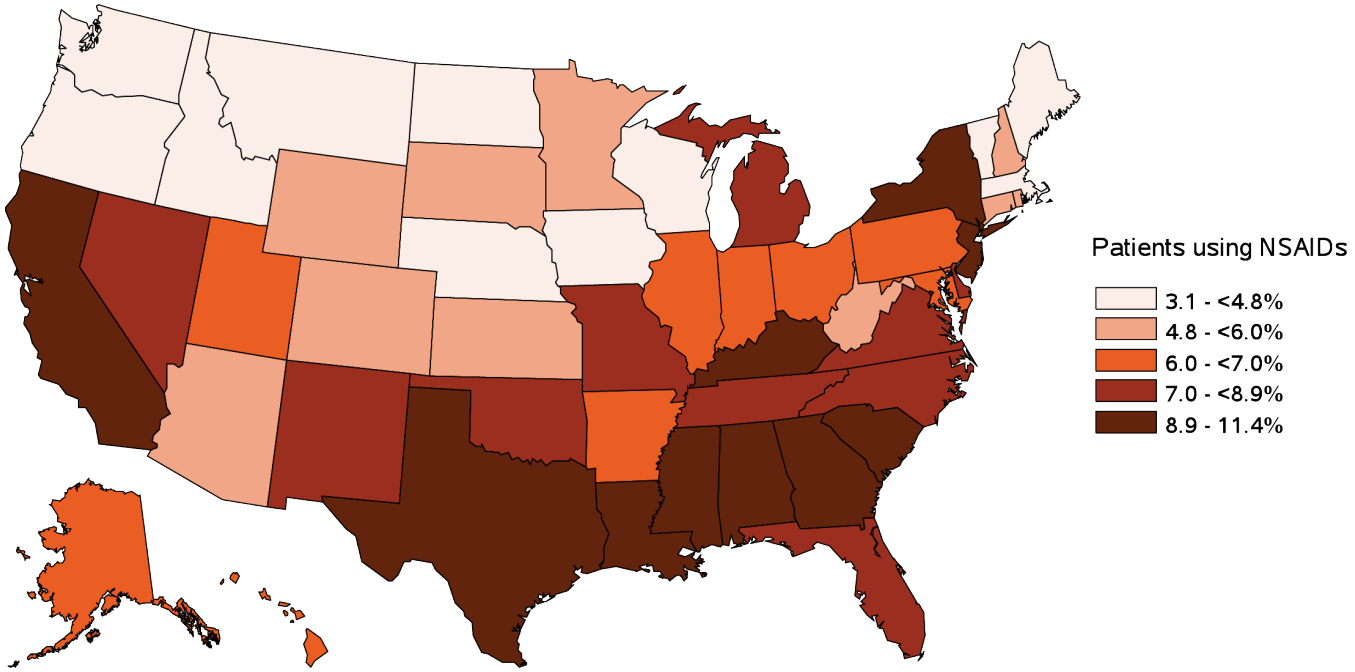
Data source: Medicare Part D claims and Optum Clinformatics™ claims. Part D spending represents the sum of the Medicare covered amount and the Low-income Subsidy amount. Ion-removing agents include phosphate-binding agents, potassium-binding agents, etc. Hypotension agents include alpha-2-agonists and vasodilators. Diabetic consumables refer to blood glucose test strips, blood glucose meters/sensors, lancets, needles, pen needles, etc.

Pain is a common symptom experienced by patients with ESRD (Murtagh et al, 2007). In this section, we examine two main drug classes used for pain management—nonsteroidal anti-inflammatory agents (NSAIDs) and opioid analgesics. The former are often obtained over the counter, therefore, any estimates based on prescription claims alone likely significantly underestimate their use. Each of these classes of agents has unique adverse effects that occur at higher frequency among ESRD patients (e.g., gastrointestinal bleeding, respiratory depression; Pham et al., 2009). Figure 10.6 and Figure 10.7 display the state-specific proportions of ESRD Medicare Part D patients prescribed NSAIDs and opioid analgesics in 2015.

The overall national proportion of prescription NSAID use was 8.3%. California, the District of Columbia, and southern states demonstrated the highest use. These rates are almost certainly an underestimate of actual use; however, as NSAIDs are more commonly purchased on a non-prescription, over-the-counter basis.

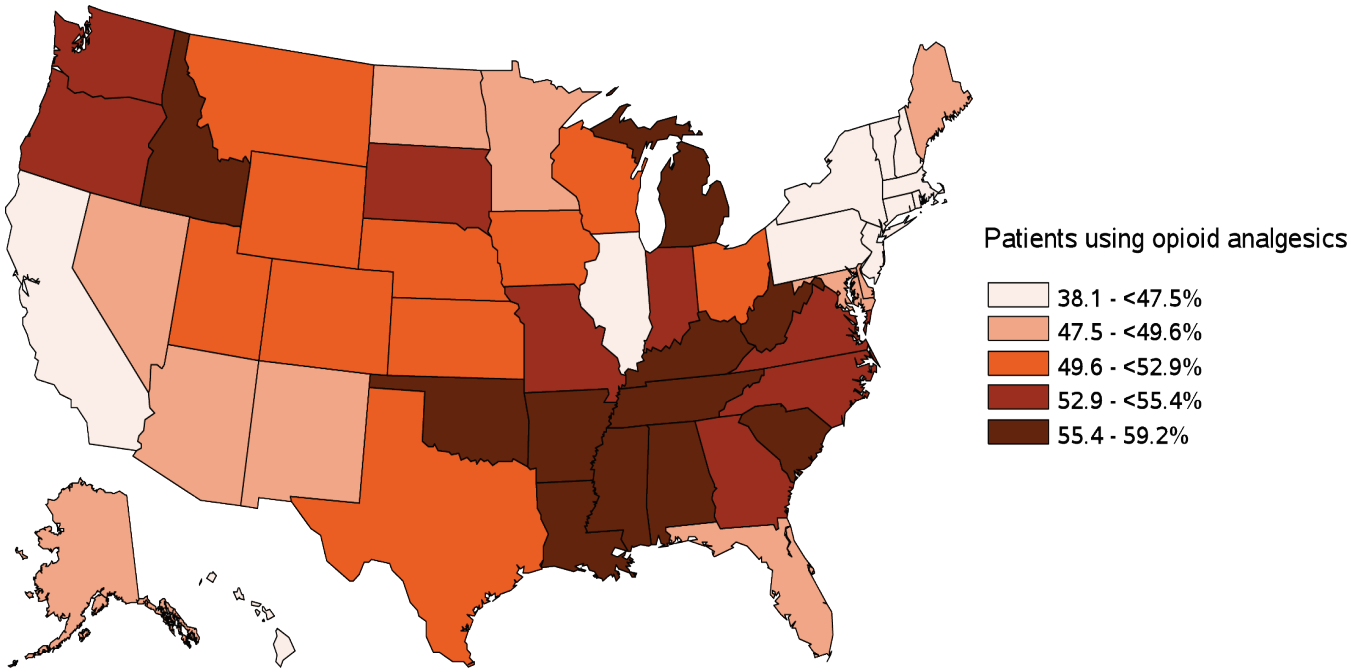
The proportion of patients using opioid analgesics was very high, at 50.3%. Use was greatest in the south central region (Alabama, Oklahoma, Louisiana, and Mississippi). These state differences could reflect varying prevalence of coexisting conditions, pain management practices, and preferences by state.

vol 2 Figure 10.6 Estimated utilization rate of prescription NSAIDs by state, Medicare ESRD Patients, 2015



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

vol 2 Figure 10.7 Estimated utilization rate of opioid analgesics by state, Medicare ESRD Patients, 2015



Data source: Medicare Part D claims. ESRD patients with Medicare Part D stand-alone prescription drug plans.

References

Murtagh FEM, Addington-Hall J, and Higginson IJ. The prevalence of symptoms in end-stage renal disease: a systematic review. *Advances in chronic kidney disease.* 2007;14(1): 82-99.

Pham PC, Toscano E, Pham PM, Pham PA, Pham SV, Pham PT. Pain management in patients with chronic kidney disease. *NDT plus*. 2009;2(2):111-8.

Q1 Medicare. *The 2015 Medicare Part D Prescription Drug Program.* http://www.q1medicare.com/PartD-The-2015-Medicare-Part-D-Outlook.php Accessed August 30, 2015.

Chapter 11: International Comparisons

- As they have done for the past decade, in 2015 Taiwan, the Jalisco region of Mexico, and the United States (U.S.) reported the highest incidence of treated ESRD, with rates of 476, 411, and 378 patients per million general population (PMP; Figure 11.2). Brunei, contributing to the chapter for the first time this year, also reported one of the highest global rates of treated ESRD incidence, at 393 patients PMP.
- The greatest proportionate increases in the incidence of treated ESRD over the interval from 2002/03 to 2014/15 (Reference Table N.1) were reported by Bangladesh (590%), Thailand (306%), Russia (246%), the Philippines (203%), Malaysia (154%), the Republic of Korea (92%), and the Jalisco region of Mexico (63%).
- Incidence rates of treated ESRD have remained relatively stable since 2002/03 in most high-income countries, and have declined by 2% to 10% in Austria, Finland, Sweden, Scotland, Denmark, and Iceland (Reference Table N.1). However, long-term trends are questionable because of year-to-year fluctuations.
- In 2015, countries identified diabetes mellitus (DM) as the primary cause of ESRD for greater than 50% of incident, treated ESRD patients in Singapore, Malaysia, the Jalisco region of Mexico, and Chile. Conversely, DM was listed as the primary cause for less than 20% of incident ESRD patients in the Netherlands, Indonesia, Switzerland, Italy (five regions), Norway, Russia, Latvia, Lithuania, Albania, and Romania (Figure 11.4).
- The greatest increases in diabetes-related ESRD incidence rates from 2002/03 to 2014/15 have occurred in Russia, the Philippines, Malaysia, and the Republic of Korea, where rates have more than doubled over this period (Reference Table N.2).
- Taiwan, Japan, and the U.S had the highest reported prevalence of treated ESRD in 2015, at 3317, 2529, and 2138 PMP (Figure 11.9).
- From 2002 to 2015, 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, and ranged from 299% to 785% (Reference Table N.4).
- Large international differences exist in the use of the different renal replacement therapies (RRT; Figure 11.12). In one-fourth of countries, 50-75% of treated ESRD patients are living with a kidney transplant—particularly in northern European countries. In contrast, less than 20% of treated ESRD patients are living with a kidney transplant in approximately one-third of countries. In most nations, in-center hemodialysis (HD) was the predominant RRT modality.
- In-center HD was the chosen modality for greater than 80% of dialysis provision in 82% of countries (Figure 11.15 and Reference Table N.7). The highest utilization of peritoneal dialysis (PD) in 2015 occurred in Hong Kong (70%), the Jalisco region of Mexico (51%), New Zealand (30%), Thailand (29%), Qatar (27%), and Colombia (27%).
- In 2015, the Jalisco region of Mexico, Spain, the U.S., and the Netherlands reported the highest rates of kidney transplantation, with 58-71 transplants PMP (Figure 11.16.a). When expressed relative to the size of the prevalent dialysis population, the highest rates of kidney transplantation per 1000 dialysis patients occurred in Norway (183 per 1000), the Netherlands, Latvia, Finland, and Scotland (from 119 to 151 per 1000). One-third of countries indicated less than 30 kidney transplants per 1000 dialysis patients (Figure 11.16.b).

Introduction

This chapter examines international trends in the treatment of end-stage renal disease (ESRD). The number of countries and regions represented in this year's Annual Data Report (ADR) increased to 73 in 2016, with the addition of Albania, Brunei (Darussalam), Bulgaria, Egypt, Kazakhstan, Latvia, Lithuania, the Republic of Macedonia, and Peru. Welcome to our newest contributors.

This work is made possible by the substantial efforts of many individuals from all participating countries, through collecting and contributing data for this international collaboration. We applaud and sincerely thank all of the registries for their dedicated efforts in providing their data for this effort. We acknowledge the specific contributors to this effort at the end of the chapter. We intend for the information in this chapter to serve as a resource for the worldwide ESRD community—to inform health care policies, patient care, and the application of resources while stimulating meaningful research for improving ESRD patient care.

Our goal is for the presented comparisons to increase awareness of the international trends, similarities, and differences in key ESRD treatment measures. Participating countries provide data through completion of a standardized survey form. Actual data collection methods vary considerably across countries, however, therefore any direct comparisons should be made within this context.

In some countries (e.g., U.S.), data are based in part upon claims submitted for billing purposes; such data tends to provide nearly 100% ascertainment of ESRD. However, countries using other data collection methods have also been very successful in identifying ESRD in their populations. In some registries, however, it may not be feasible to obtain 100% ascertainment of persons treated for ESRD or receiving chronic dialysis therapy.

In addition, we do not adjust these international comparisons for demographic differences. Most European countries, Japan, and other nations have rapidly aging populations. As ESRD rates tend to increase with older age, such nations are likely to report higher rates of ESRD as compared to those with younger populations. The descriptions in this international chapter are intended to characterize global ESRD treatment broadly. Thus whether a registry achieves 90%, 95%, or >99% ascertainment within their country, the key messages in this chapter remain very relevant. In 2018, we plan to include survey results further describing the international variability in ascertainment of ESRD capture across registries.

The degree of unrecognized diagnosis of ESRD and access to renal replacement therapy (RRT) also widely vary across countries. Where RRT access is limited, reported ESRD incidence and prevalence may substantially underestimate the true rates of irreversible kidney failure. Furthermore, in some countries where RRT is widely available, when patients decline dialysis or transplantation true ESRD incidence may be underestimated. The term "conservative kidney management" is 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). For these reasons, 'true ESRD incidence' may not be a meaningful concept. The information presented in this chapter reflects only treated cases of ESRD—patients started or currently on dialysis or transplantation. Thus, the data and trends reported represent "treated ESRD."

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. Feel free to contact us via email at USRDS@usrds.org –there are many countries not yet represented. 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 result from aggregate analyses each country's response to a request by the USRDS for a country's registry to complete a data collection form indicating various aspects of patients receiving RRT for ESRD. A copy of the Data Collection Form is available on the USRDS website.

Data tables formerly presented within the content of this chapter are now located in Reference Table N. See the *Analytical Methods Used in the ESRD Volume* section of the *ESRD Analytical Methods* chapter for an explanation of the analytical methods used to generate the study cohorts and figures in this chapter. Downloadable Microsoft Excel and PowerPoint files containing the data and graphics for these figures are available on the USRDS website.

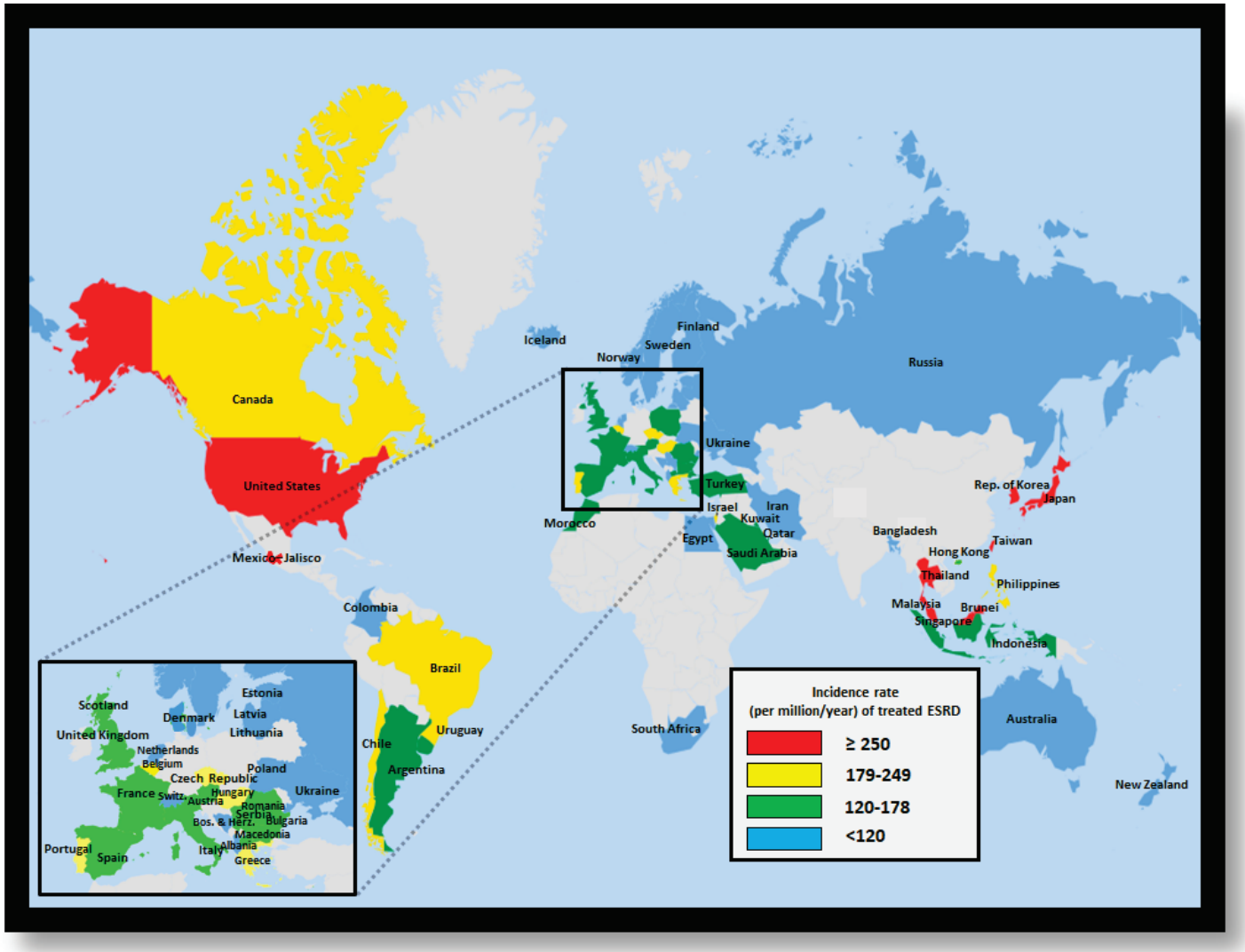
Incidence of Treated ESRD

In 2015, reported incidence rates of treated ESRD varied greatly across countries (see Figures 11.1 and 11.2). Taiwan, the Jalisco region of Mexico, Brunei, and the U.S. reported the highest incidence of treated ESRD, at 476, 411, 393, and 378 individuals per million general population (PMP). The next highest rates, ranging from 223–338 PMP were reported by Thailand, Singapore, Japan, the Republic of Korea, Malaysia, Greece, Portugal, the Czech Republic, and Hungary. The lowest treated ESRD incidence rates, ranging from 28 to 99 PMP, were reported by South Africa, Bangladesh, Russia, Iceland, Latvia, Albania, Estonia, Finland, and Norway.

Trends in the incidence of treated ESRD also varied greatly across countries, as shown in Figure 11.3, and Reference Table N.1. We evaluated the percentage change in averaged ESRD incidence rates in 2014/15 versus that in 2002/03. The greatest increases in the incidence of treated ESRD were reported for Bangladesh (590%), Thailand (306%), Russia (246%), the Philippines (203%), Malaysia (154%), the Republic of Korea (92%), and the Jalisco region of Mexico (63%). In contrast, the ESRD incidence in 2014/15 was 2-10% lower than that in 2002/03 in Austria, Finland, Sweden, Scotland, Denmark, and Iceland.

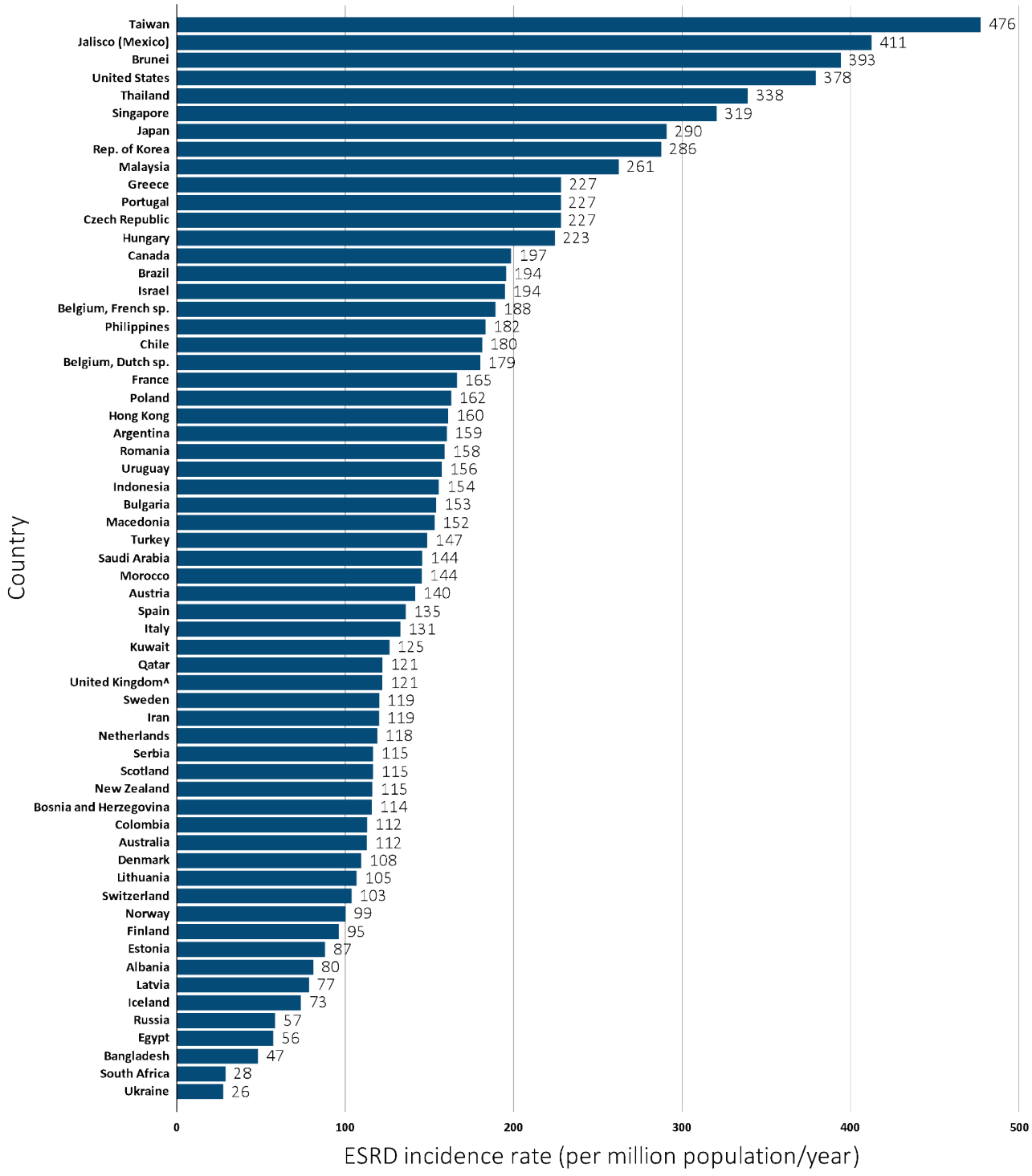
The incidence of treated ESRD was relatively stable in nearly half of all countries, displaying an overall increase of 1% to 31% when comparing the rates in 2014/15 with those in 2002/03. The U.S. displayed one of the more stable ESRD incidence rates over this period, with an overall 10% increase from 2002/03 to 2014/15. Most of this change occurred prior to 2006, with little change in U.S. incidence rates seen from 2006-2013, followed by a recent rise.

vol 2 Figure 11.1 Geographic variations in the incidence rate of treated ESRD (per million population/year), by country, 2015



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 five regions. Data for Indonesia represent the West Java region. Data for France exclude Martinique. Data for Canada excludes Quebec. Japan includes dialysis patients only. Abbreviation: ESRD, end-stage renal disease. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

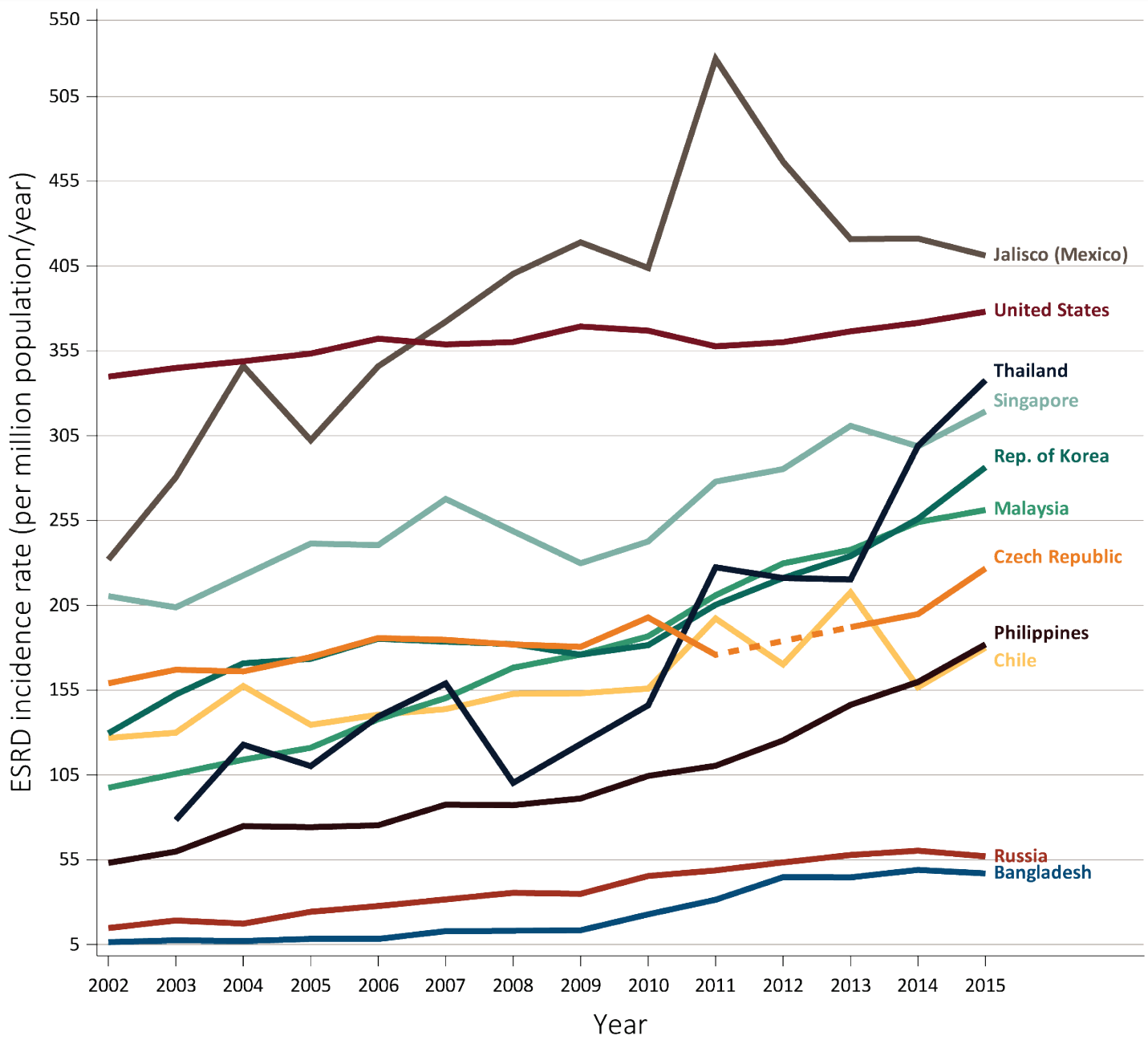
vol 2 Figure 11.2 Incidence rate of treated ESRD (per million population/year), by country, 2015



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 five regions. Data for Indonesia represent the West Java region. Data for France exclude Martinique. Data for Canada excludes Quebec. Japan includes dialysis patients only. Data for Latvia represents 80% of the country's population. Abbreviations: ESRD, end-stage renaldisease; sp., speaking. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

vol 2 Figure 11.3 Trends in the incidence rate of treated ESRD (per million population/year), by country, 2002-2015

(a) Ten countries having the highest percentage rise in ESRD incidence rate in 2002/03 versus that in 2014/15, plus the U.S.

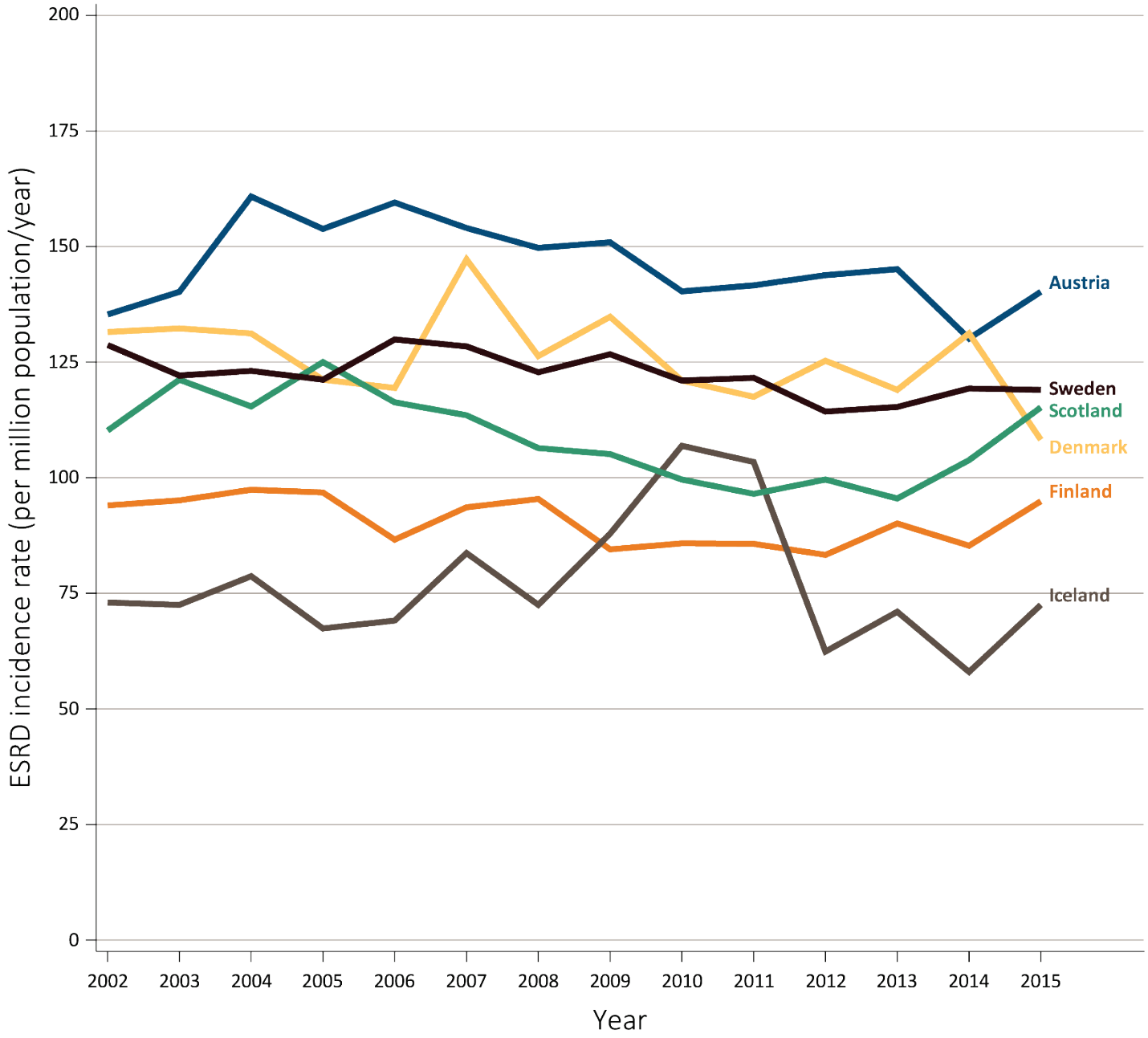


Data source: Special analyses, USRDS ESRD Database. All rates are unadjusted. Data for the Czech Republic are missing from 2012 indicated by the dashed line. Data for U.S. are shown for comparison purposes. Abbreviation: ESRD, end-stage renal disease. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

Figure 11.3 continued on next page.

vol 2 Figure 11.3 Trends in the incidence rate of treated ESRD (per million population/year), by country, 2002-2015 *(continued)*

(b) Six countries having the largest percentage decline in ESRD incidence rate: 2002/03 versus that in 2014/15



Data source: Special analyses, USRDS ESRD Database. All rates are unadjusted. Only six countries had a decrease in incidence from 2002/03-2014/15. Abbreviation: ESRD, end-stage renal disease. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

Diabetes as Primary Cause of End-stage Renal Disease in Incident Patients

In this section, we examine the relationship of diabetes mellitus (DM) to incidence of treated ESRD. We wish to note that other factors are related to ESRD incidence as a primary cause, including glomerulonephritis, other nephritis causes, hypertension, certain congenital disorders, immunological disorders, cancer, overuse of particular drugs, exposure to chemical nephrotoxic agents, and other environmental factors that may be particularly relevant in some regions.

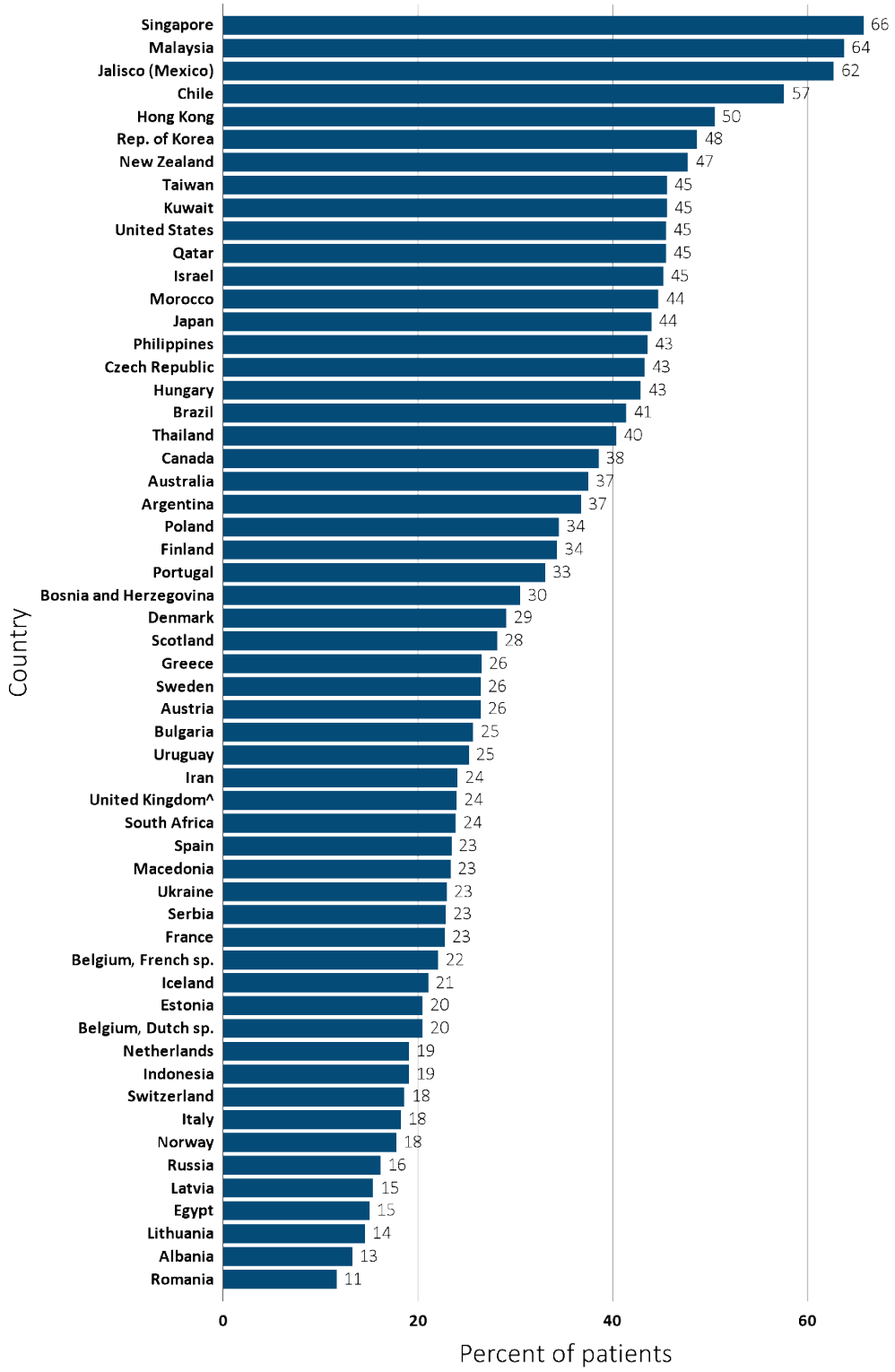
Nearly 77% of the countries participating in this report provided data on the incidence of treated ESRD with a primary cause of DM—a key contributor to the global burden of ESRD. In 2015, Singapore, Malaysia, the Jalisco region of Mexico, and Chile reported the highest proportions of patients with new ESRD due to DM, at 66%, 64%, 62%, and 57% (Figure 11.4).

Furthermore, DM was the primary cause of new ESRD for 40-50% of patients in Hong Kong, the Republic of Korea, New Zealand, Taiwan, Kuwait, the U.S., Qatar, Israel, Morocco, Japan, the Philippines, the Czech Republic, Hungary, Brazil, and Thailand. In contrast, in 2015, DM was the primary cause of ESRD for less than 20% of new ESRD patients in the Netherlands, Indonesia, Switzerland, Italy (five regions), Norway, Russia, Latvia, Egypt, Lithuania, Albania, and Romania.

Twenty-five countries provided incidence rates of ESRD due to DM for the entire period from 2002 to 2015. These data indicate an overall rise in the incidence of treated ESRD due to DM in most, but not all, of these nations (Reference Table N.2). In some countries, this increase has been especially large—from an 80-703% increase between 2002 and 2015 (Reference Table N.2, Figure 11.5). These included Russia, the Philippines, Malaysia, the Republic of Korea, the Jalisco region of Mexico, and Singapore. Furthermore, in Thailand the incidence of ESRD due to DM has more than doubled since 2007. Among the countries shown, the Jalisco region of Mexico had the highest incidence due to DM in 2015, at nearly 257 new ESRD patients PMP. It is conceivable that the practice of determining primary cause of ESRD may have altered in some countries over this reporting period, and thus methodology rather than true trends may have contributed to the observed changes. However, we currently have no information regarding the extent of this possibility for any of the countries.

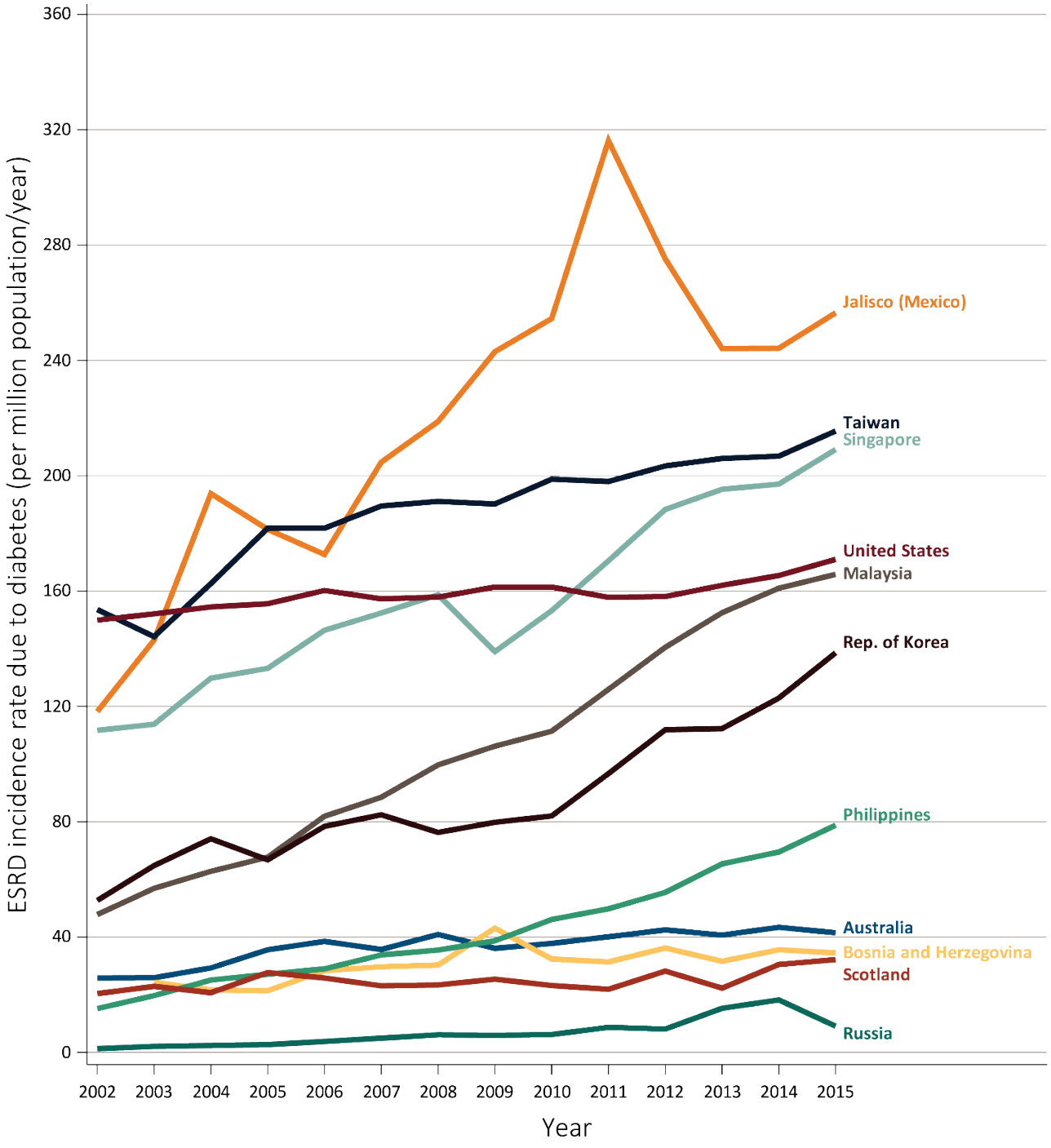
Figure 11.6 presents the relationship of percentage change in overall treated ESRD incidence to the change in treated incidence due to DM. Data represent 27 countries across three international regions, from 2002-2015. In each region, although not in all countries, a positive relationship was seen. Overall, from 2002-2015 the largest increases both in incidence due to DM and in overall ESRD incidence occurred in the region consisting of Asia and Russia. In contrast, five countries showed a decline in ESRD due to DM from 2002-2015, with four of these, Austria, Finland, Denmark, and Sweden, also reporting declines in overall treated ESRD incidence. It is noteworthy that this relationship differs considerably across countries, whereby in some nations the percentage change in treated ESRD incidence is of similar magnitude to the percentage 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 across countries.

vol 2 Figure 11.4 Percentage of incident ESRD patients with diabetes as the primary cause of ESRD, by country, 2015



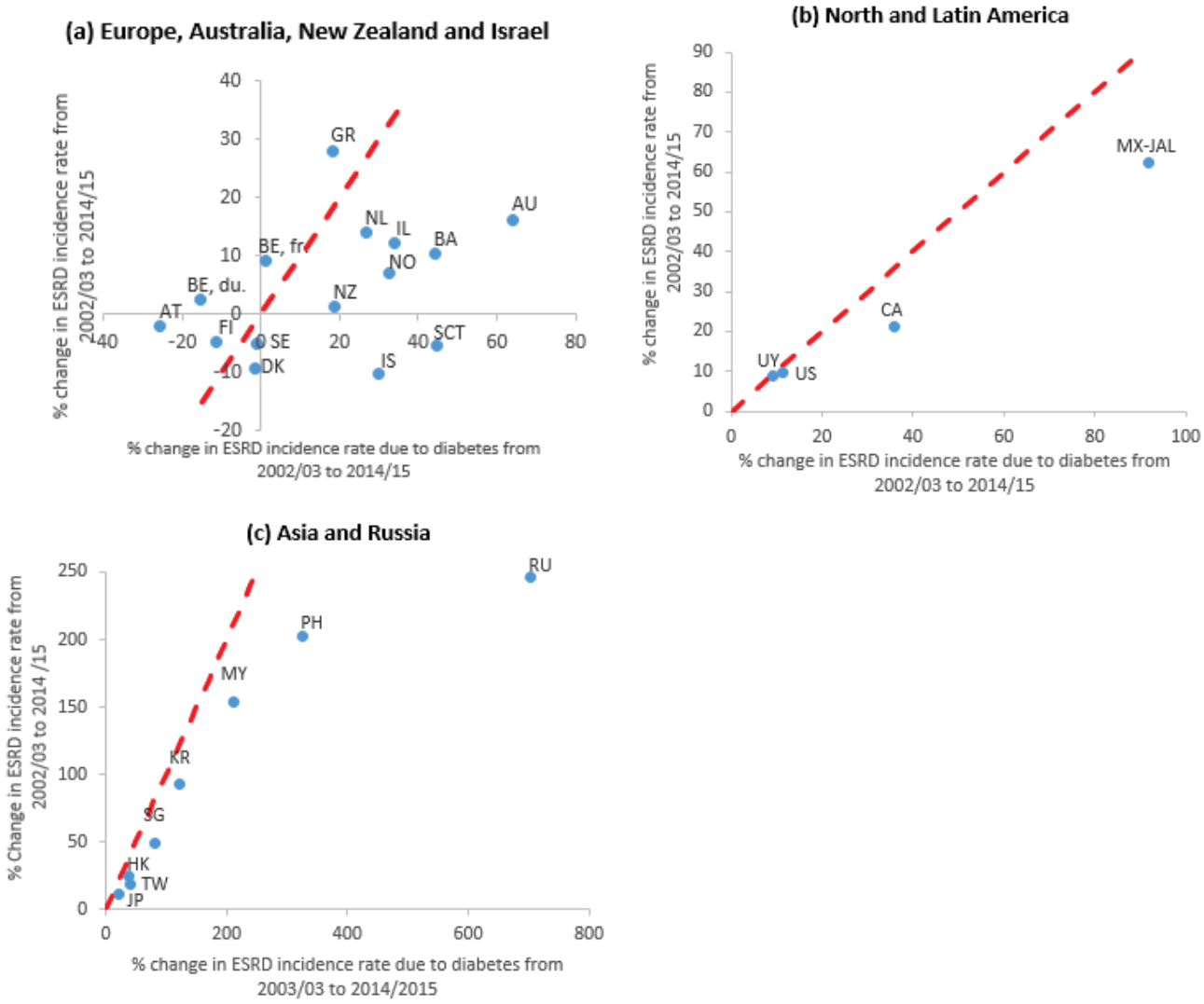
Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information were available. ^United Kingdom: England, Wales, Northern Ireland (Scotlanddata reported separately). Data for France exclude Martinique.Data for Indonesia represent the West Java region. Data for Italy includes five regions. Data for Canada excludes Quebec. Data for Latvia represents 80% of the country's population. Abbreviations: ESRD, end-stage renal disease; sp., speaking. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

vol 2 Figure 11.5 Trends in the incidence rate of treated ESRD due to diabetes (per million population/year), by country, 2002-2015



Data source: Special analyses, USRDS ESRD Database. Ten countries having the highest percentage rise in 2014/15 versus that in 2002/03, plus the U.S. Data presented only for countries from which relevant information were available. Abbreviation: ESRD, end-stage renal disease. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

vol 2 Figure 11.6 Correlation, by country, of the percentage change in ESRD incidence with the percentage change in ESRD incidence due to diabetes, from 2002-2015, with countries displayed by region



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. Reference line (in red) represents 1:1 ratio of percentage change in ESRD incidence rate due to diabetes and percentage change in ESRD incidence rate from 2002/03-2014/15. Countries listed in order of lowest to highest percentage change in ESRD incidence due to diabetes in each panel <u>(a) Europe, Australia, New Zealand, and Israel</u>: (1%-64%) Sweden (SE), Belgium (BE, French speaking), Denmark (DK), Finland (FI), Belgium (BE, Dutch Speaking) Greece (GR), New Zealand (NZ), Austria (AT), the Netherlands (NL), Iceland (IL), Norway (NO), Israel (IS), Bosnia and Herzegovina (BA), Scotland (SCT), Australia (AU).; <u>(b) North and Latin America: (9%-92%)</u> Uruguay (UY), United States (U.S.), Canada (CA), Jalisco (Mexico, MX-JAL); <u>(c) Asia and Russia:</u> (22%-703%) Japan (JP), Hong Kong (HK), Taiwan (TW), Singapore (SG), Rep. of Korea (KR), Malaysia (MY), Philippines (PH), Russia (RU). Abbreviation: ESRD, end-stage renal disease. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

Incidence of Treated ESRD Disease by Age Group and Sex

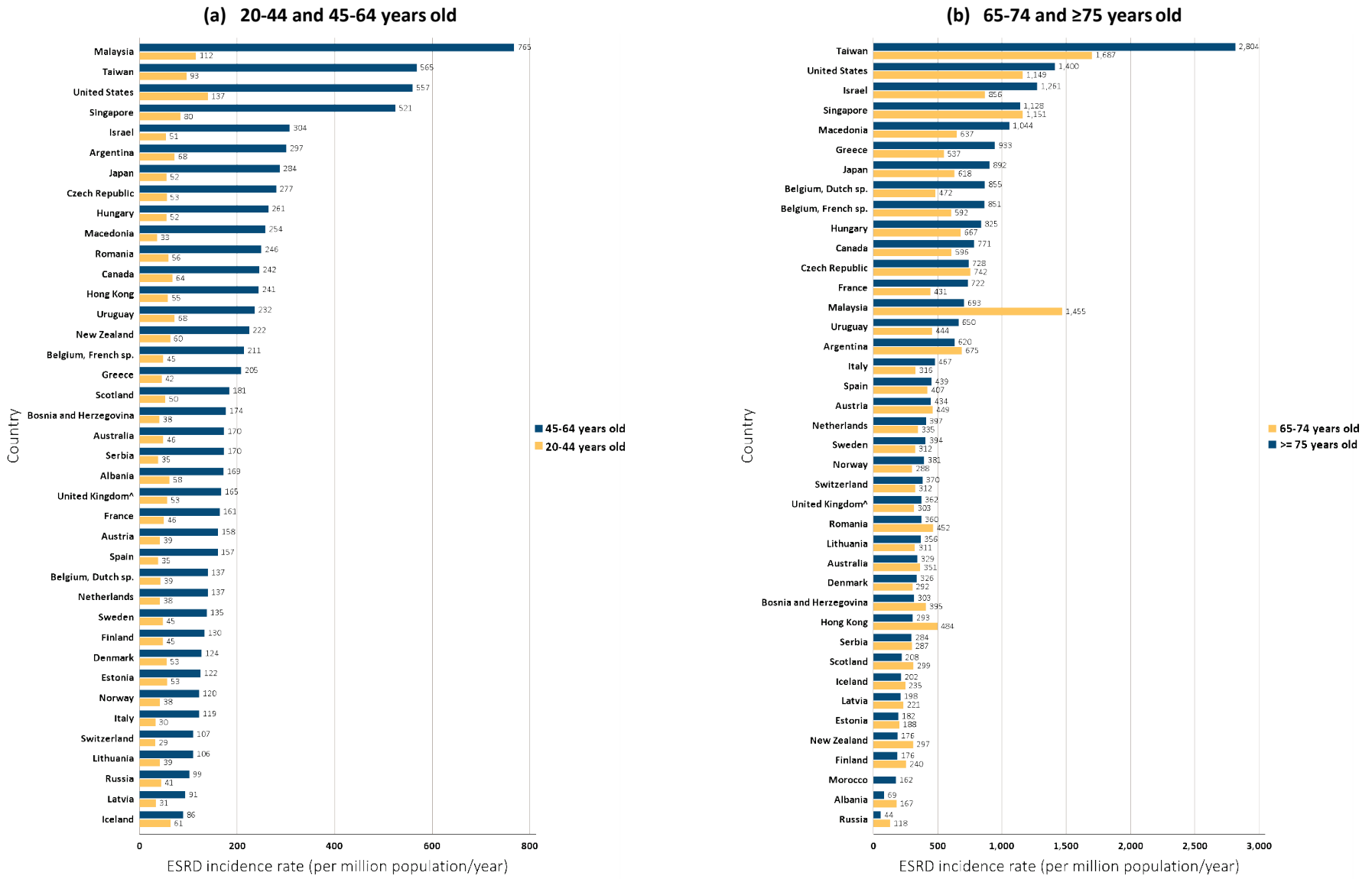
Figure 11.7 presents the 2015 incidence of treated ESRD by age group. Among countries having higher treated ESRD incidence, in most the rates were highest among patients aged 75 years or older. The highest rates in this age group occurred in Taiwan, with 2804 PMP/year. This was twice the next highest rate as reported for the U.S., of 1400 PMP/year, followed by Israel and Singapore, at 1261 and 1128. In contrast, among countries having lower rates, treated ESRD incidence often was concentrated among patients 65-74 yrs old. In Latvia, Iceland, Romania, Finland, Scotland, Hong Kong, New Zealand, Malaysia, Albania, and Russia, the incidence of treated ESRD was 11-91% lower in the population aged 75 years or older, as compared to those aged 65-74 years. In 2015, the U.S. reported the highest ESRD incidence rate in younger adults aged 20-44 years, at 137 PMP/year. In Malaysia, reported rates of PMP/year 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. These are expressed as the percentage change for years 2014/15 versus 2006/07, in the 29 countries for which these data have been contributed. It is noteworthy that both in the U.S. and nearly half of the 29 countries, an overall decline in the treated ESRD incidence rate was seen among persons aged 75 years or older. In 21 of the 29 countries, a corresponding decline was seen in the 65-74 year age group. These latter trends are especially meaningful, since in many countries nearly half of all new ESRD patients are 65 years or older. It is notable that in several countries ESRD incidence rates increased 23-65% from 2006/07 to 2014/15 in the youngest age group of 0-19 years of age, while showing declines or little change in the older age groups. This pattern was observed in Norway, Finland, Hong Kong, and Australia.

In Figure 11.8, we compare the incidence of treated ESRD by sex. In almost every country, the rate was substantially higher for males than for females, with the exception of Estonia and Colombia. ESRD incidence was at least two times higher for males in Italy (five regions), Greece, Lithuania, Spain, Japan, and Iceland, and was 1.1-1.9 times higher for males in most other countries. The ratios of male to female ESRD incidence in Estonia and Colombia were 0.86 and 0.91 respectively. In the U.S., males had a higher ESRD incidence rate, despite CKD being less prevalent among males than females, as reported in Volume 1, Chapter 1 of the ADR, *CKD in the General Population*.

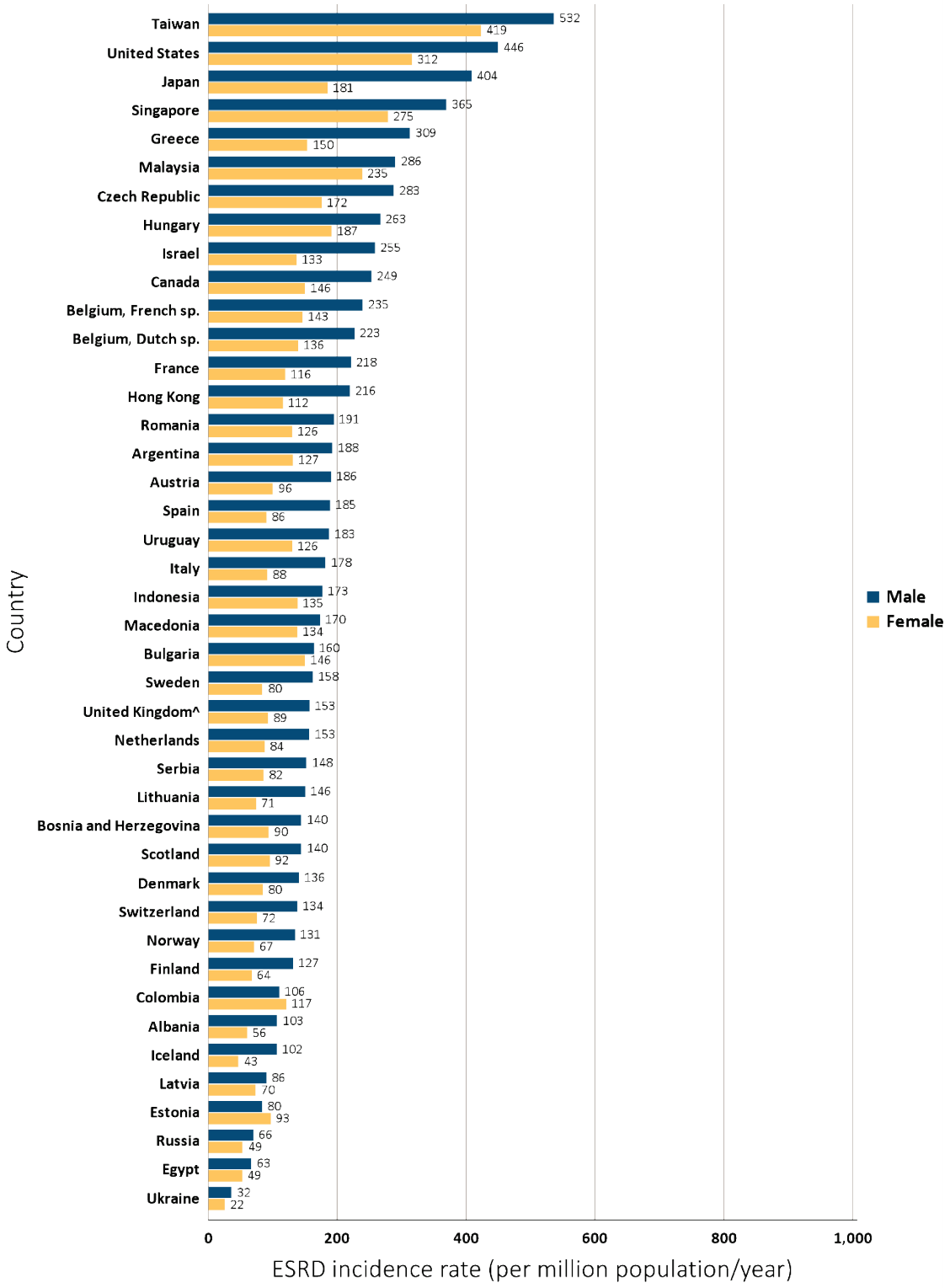
The considerably lower ESRD incidence for females in nearly all countries shown in Figure 11.8 is consistent with the recent paper by Hecking et al (2014), who observed considerably fewer women than men being treated with HD for ESRD in 12 of the countries participating in the Dialysis Outcomes and Practice Patterns Study (DOPPS) from 2002-2012. In conjunction with the prior findings by Hecking et al (2014), the sex differences in incidence rates from the great majority of 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. At this time, it is unknown whether the drivers of this sex difference are due to differences in biologic, environmental, or other factors.

vol 2 Figure 11.7 Incidence rate of treated ESRD (per million population/year), by age group and country, 2015



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 Italy include five regions. Data for France exclude Martinique. Data for Canada excludes Quebec. Japan includes dialysis patients only. Data for Latvia represents 80% of country's population. For graph (a), data for Spain include patients 15-64 years old, and data for the United States include patients 22-64 years old.(b) data for Morocco include patients 65 years old and older Abbreviations: ESRD, end-stage renal disease; sp., speaking. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

vol 2 Figure 11.8 Incidence rate of treated ESRD (per million population/year), by sex and country, 2015



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 France exclude Martinique. Data for Indonesia represent the West Java region. Data for Italy represent five regions. Data for Canada excludes Quebec. Japan includes dialysis patients only. Data for Latvia represents 80% of country's population. Abbreviations: ESRD, end-stage renal disease; sp., speaking. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

Prevalence of ESRD

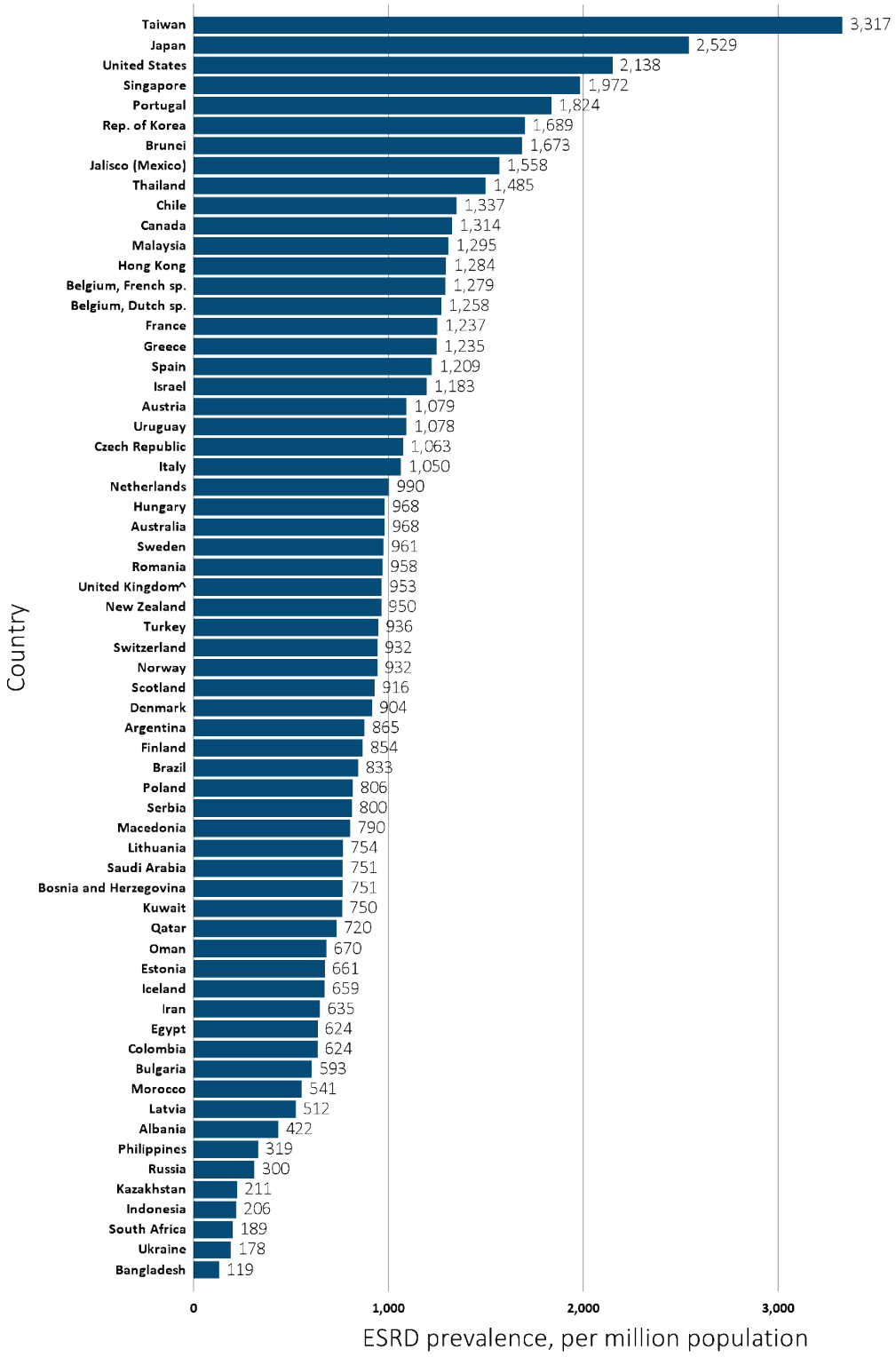
In 2015, 2,450,740 patients were treated for ESRD across all reporting countries. The number was by far the highest in the U.S., with 687,093 treated patients accounting for 28% of the total (Reference Table N.4.b), and followed by Japan and Brazil with approximate cohorts of 321,000 and 170,000 prevalent patients. The Republic of Korea, Taiwan, Thailand, Turkey, Egypt, France, Spain, the United Kingdom (U.K.), and Iran reported between 50,000 to 98,000 treated ESRD patients in 2015, while all other countries indicated smaller populations, with approximately 10,000 treated patients in the median country of South Africa.

In 2015, ESRD prevalence varied nearly 30-fold across represented countries (see Figure 11.9 and Reference Table N.4.a). Taiwan reported the highest treated ESRD prevalence of 3317 PMP, followed by Japan (2529 PMP), and the U.S. (2138 PMP). Singapore, Portugal, the Republic of Korea, Brunei, and the Jalisco region of Mexico also reported a very high prevalence, ranging from 1558-1972 PMP. In nearly 30% of countries, prevalence ranged from 1,000 to 1,500 PMP, while approximately 45% reported 600 to 999 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 Egypt, Iran, Kuwait, Oman, Qatar, and Saudi Arabia. Lowest prevalence rates ranging from 119 to 540 PMP were reported by Bangladesh, Ukraine, Indonesia, South Africa, Russia, the Philippines, Albania, Latvia, and Morocco.

Although ESRD incidence rates have been stable or decreasing in many countries during recent years, ESRD prevalence PMP has steadily increased in all 33 countries that provided data from 2002 to 2014 and/or 2015 (Reference Table N.4.a and Figure 11.11). Over this period, the median increase in ESRD prevalence was 47%, varying from 24% to 785% 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 2002/03 and 2014/15 were observed in the Philippines, Thailand, and the Jalisco region of Mexico, ranging from 299% to 785%, followed by rises of 118% to 242% in Russia, Malaysia, Turkey, Brazil, and Republic of Korea. In the U.S., ESRD prevalence increased 42% overall from 2002/03 to 2014/15, with a nearly constant annual increase of 3.6%.

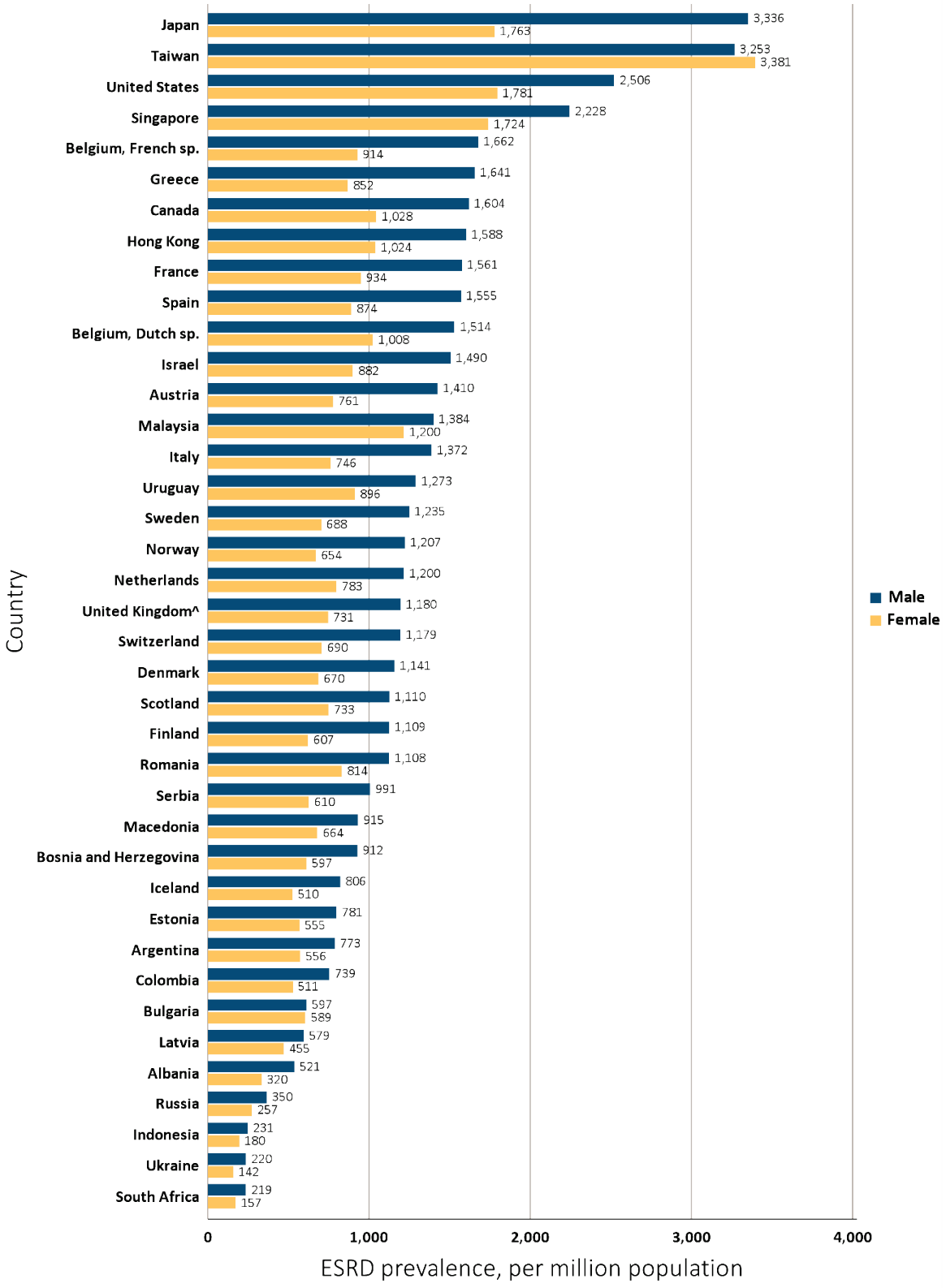
Similar to incidence of ESRD typically being higher among males than females in nearly every country, prevalence of ESRD PMP was higher for males than females in every country except in Taiwan (Figure 11.10).

vol 2 Figure 11.9 Prevalence of treated ESRD per million population, by country, 2015



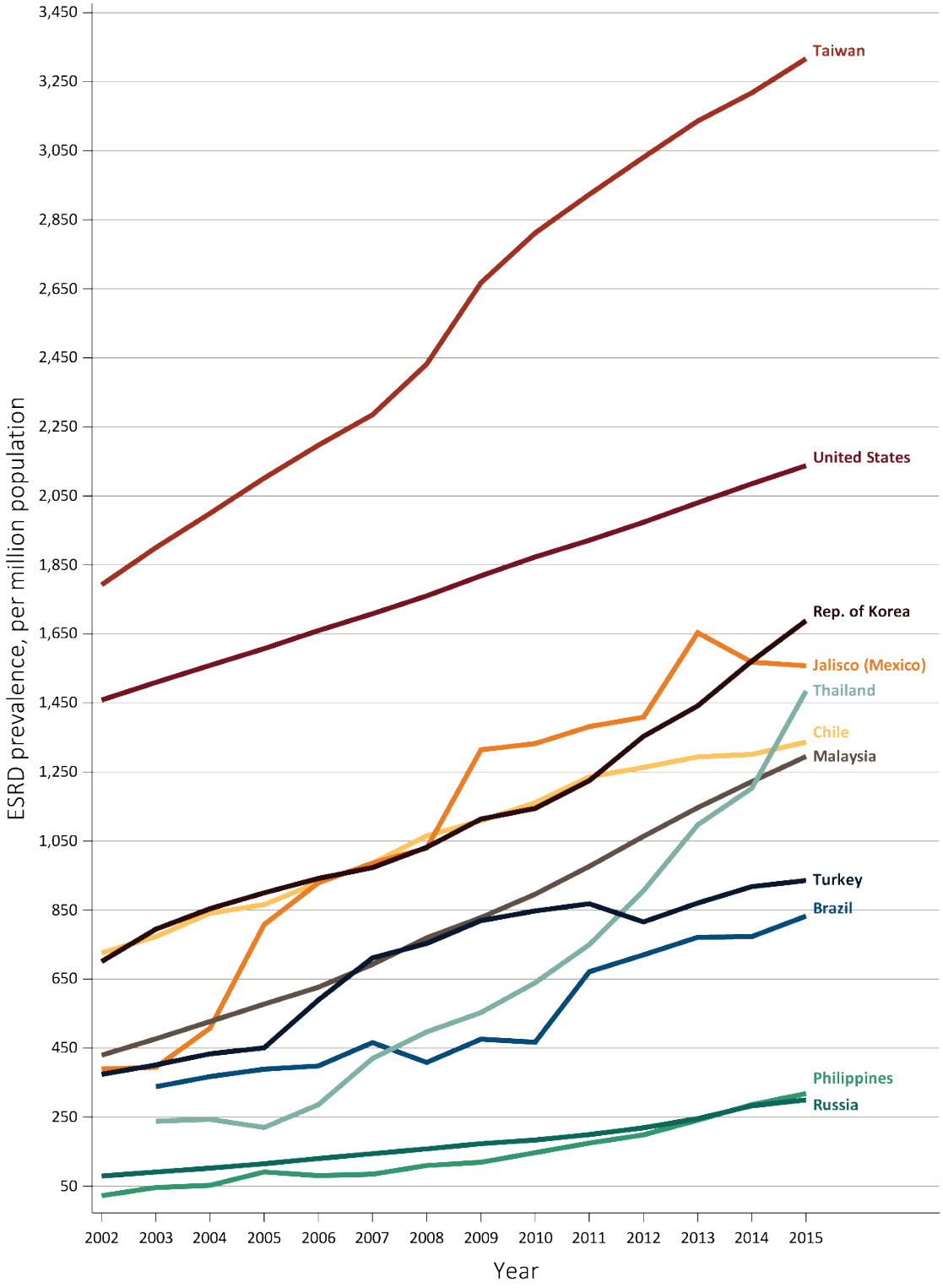
Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. ^United Kingdom: England, Wales, Northern Ireland (Scotland data reported separately). The prevalence is unadjusted and reflects prevalence at the end of 2015. Switzerland includes dialysis patients only. Data for Indonesia represent the West Java region. Data for France exclude Martinique. Data for Italy includes five regions. Data for Canada excludes Quebec. Data for Latvia represents 80% of country's population. Abbreviations: ESRD, end-stage renal disease; sp., speaking. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

vol 2 Figure 11.10 Prevalence of treated ESRD per million population, by sex and country, 2015



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 France exclude Martinique. Data for Italy include five regions. Data for Canada excludes Quebec. Data for Latvia represents 80% of country's population. Abbreviations: ESRD, end-stage renal disease; sp., speaking. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

vol 2 Figure 11.11 Trends in the prevalence of treated ESRD per million population, by country, 2002-2015



Data source: Special analyses, USRDS ESRD Database. Ten countries having the highest percentage rise in ESRD prevalence: 2014/15 versus that in 2002/03, plus the U.S. ESRD prevalence is unadjusted. U.S. is shown for comparison purposes. Abbreviation: ESRD, end-stage renal disease. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

Variations in Use of Different Renal Replacement Therapies for ESRD

In-center HD, home HD, PD, and kidney transplantation are the RRT options available for persons with ESRD. As shown in Figure 11.12, 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. Many eligible ESRD patients view kidney transplantation as their first choice due to substantially higher quality of life and longer median survival as compared with dialysis therapy.

In 2015, transplantation for patients with ESRD ranged from less than 10% in some Asian and eastern European countries to 51–72% in the Nordic countries of Denmark, Finland, Iceland, Norway, and Sweden, and in Estonia, Latvia, the Netherlands, Switzerland, the U.K. (including Scotland), Spain, Austria, and Qatar. Not surprisingly, countries with the highest proportion of kidney transplants among ESRD patients also tended to have lower treated ESRD incidence rates of approximately 70 (Iceland) to 140 (Austria) PMP/year (Figure 11.12 and Reference Table N.1). Additional information regarding trends since 2002 in the percentage of ESRD patients living with a kidney transplant is provided by country in Reference Table N.10. Hong Kong, the Jalisco region of Mexico, Iceland, and Norway had the lowest use of in-center HD (17% to 29%) to treat ESRD patients; this was achieved through a combination of greater use of kidney transplantation and/or home dialysis.

Dialysis Therapy for ESRD

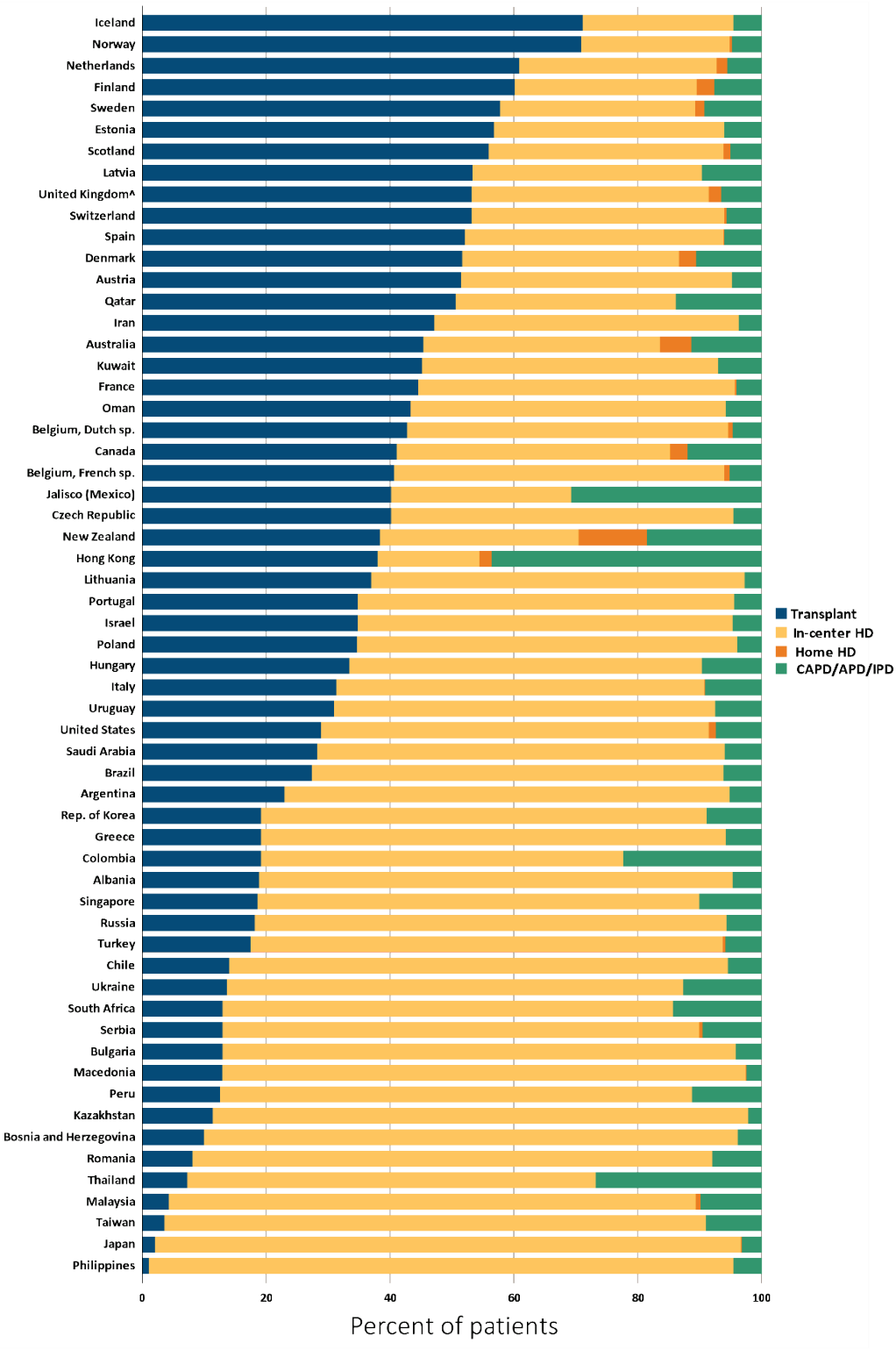
In 2015, the number of ESRD patients receiving dialysis PMP varied nearly 30-fold across countries, from 113 to 205 in Bangladesh, Ukraine, South Africa, Kazakhstan, Iceland, and Indonesia to 2464 to 3185 in Japan and Taiwan (Figure 11.13). Some countries have experienced very large rises in the prevalence of dialysis since 2002/03, with an approximately 802% and 499% increase in the Philippines and Thailand, and a rise ranging from 143% to 268% reported by Russia, Malaysia, and the Jalisco region of Mexico (Reference Table N.6).

However, during the last five years approximately 20% of all countries have seen a plateauing or decline in the prevalence of patients receiving dialysis (Reference Table N.6). These nations included Iceland, Denmark, Uruguay, Scotland, Sweden, the Netherlands, Bangladesh, Austria, Hungary, Italy, and Spain—most of which also tended to have a corresponding higher percentage use of kidney transplantation, as noted in the prior section.

Hemodialysis continues to be the most common form of dialysis therapy in nearly all countries (Figure 11.15). In nearly four-fifths of reporting countries, at least 80% of chronic dialysis patients were receiving in-center HD in 2015. However, in 2015, PD was used by 70% of dialysis patients in Hong Kong and by 51% in the Jalisco region of Mexico (Figure 11.15, Reference Table N.7.b).

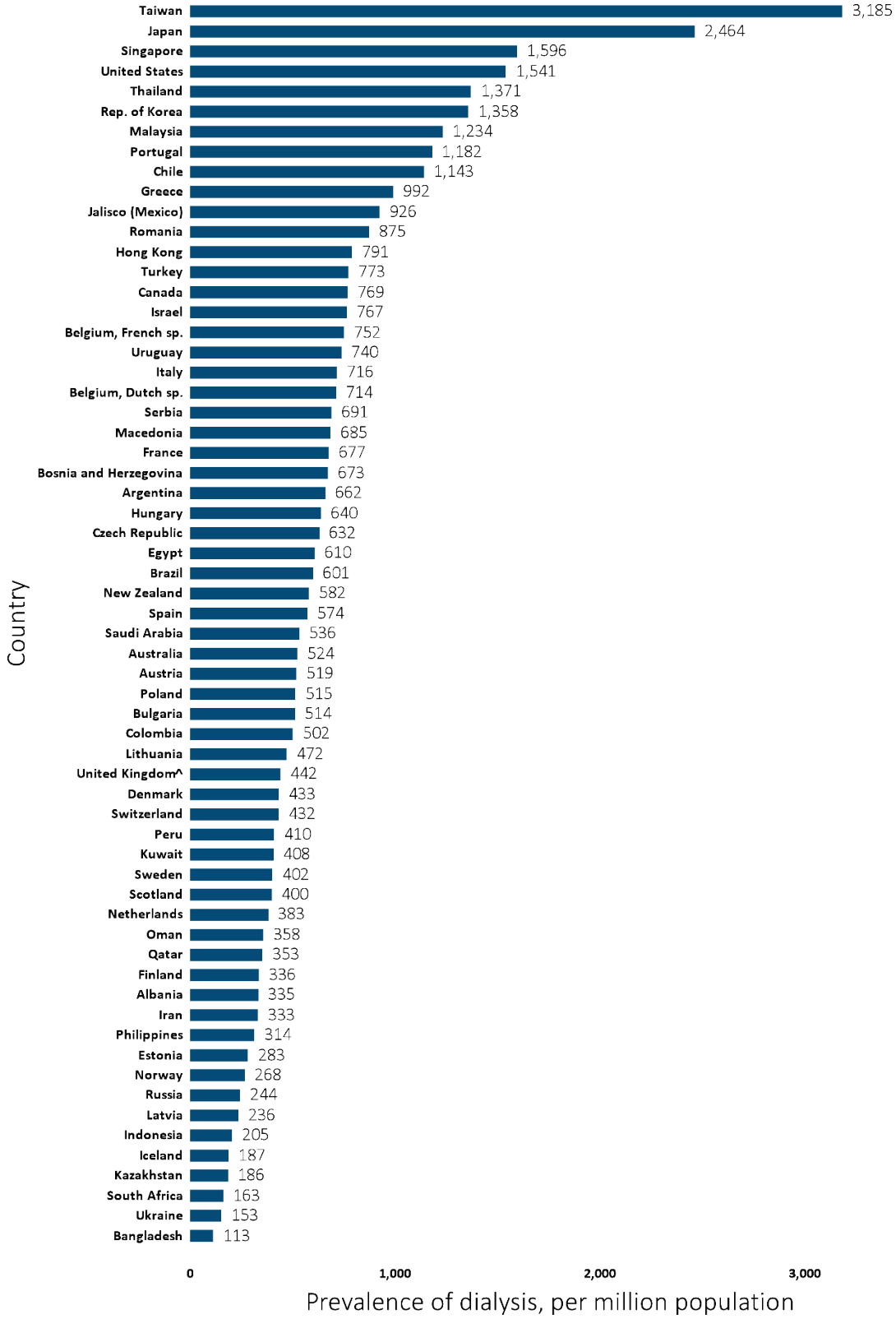
Furthermore, 27%-30% PD use was reported in New Zealand, Thailand, Qatar, and Colombia, with 16% to 21% PD use seen in South Africa, Finland, Canada, Latvia, Australia, Denmark, and Sweden. Since 2007, an overall trend of increasing PD use as a percentage of all chronic dialysis has been seen in the countries of Argentina, Bangladesh, Chile, Kuwait, Oman, Spain, Taiwan, Thailand, the U.S., and Uruguay (Reference Table N.7.b). In contrast, PD use has declined over this same time period in countries such as Belgium, Bosnia and Herzegovina, Brazil, Colombia, Croatia, Denmark, Finland, France, Greece, Hong Kong, Jalisco (Mexico), Republic of Korea, the Netherlands, New Zealand, Norway, Romania, Russia, Saudi Arabia, Scotland, Singapore, Turkey, and the U.K.. In 2015, home HD therapy was provided to 9.3% and 18.0% of dialysis patients in Australia and New Zealand. Home HD was also used by 2.5 to 7.2% of dialysis patients in Canada, Denmark, Finland, Hong Kong, the Netherlands, Sweden, the U.K., and Scotland. However, in all other countries, home HD was either not provided, or was used by fewer than 2.5% of dialysis patients.

vol 2 Figure 11.12 Percentage distribution of type of renal replacement therapy modality used by ESRD patients, by country, in 2015



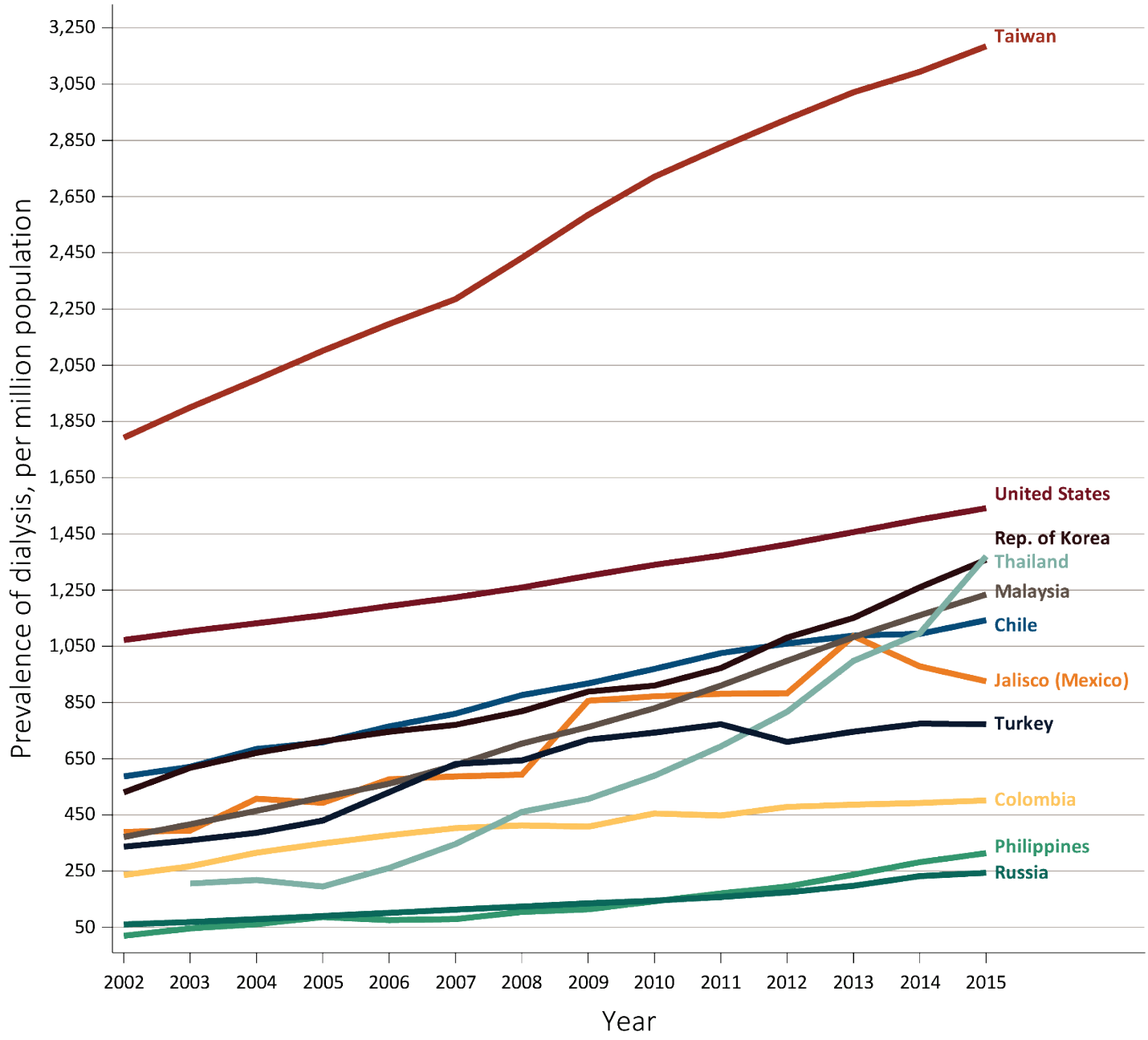
Data source: Special analyses, USRDS ESRD Database. Denominator is calculated as the sum of patients receiving HD, PD, Home HD, or treated with a functioning transplant; does not include patients with other/unknown modality. Data for France exclude Martinique. Data for Italy include five regions. Data for Canada excludes Quebec. Data for Latvia represents 80% of country's population; transplant data for Latvia is nationally representative. 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. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

vol 2 Figure 11.13 Prevalence of dialysis per million population, by country, 2015



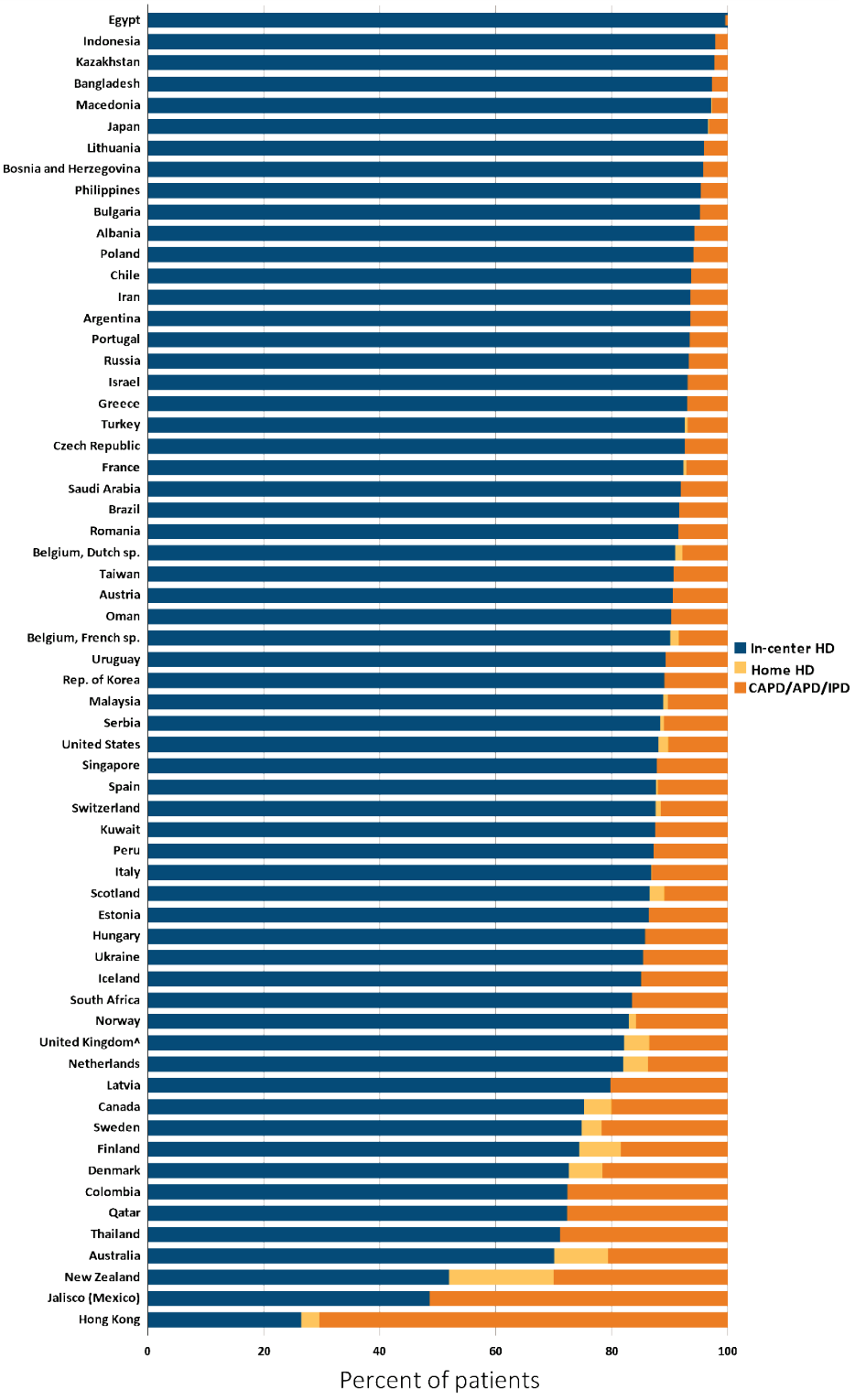
Data source: Special analyses, USRDS ESRD Database. ESRD prevalence is unadjusted and reflects prevalence at the end of 2015. United Kingdom: England, Wales, Northern Ireland (Scotland data reported separately). Data for Indonesia represent the West Java region. Data for France exclude Martinique. Data for Italy include five regions. Data for Canada excludes Quebec. Data for Latvia represents 80% of country's population. Abbreviation: sp., speaking. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

vol 2 Figure 11.14 Trends in the prevalence of dialysis per million population, by country, 2002-2015



Data source: Special analyses, USRDS ESRD Database. Ten countries having the highest percentage rise in dialysis prevalence: 2014/15 versus that in 2002/03, 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. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

vol 2 Figure 11.15 Distribution of the percentage of prevalent dialysis patients using in-center HD, home HD, or peritoneal dialysis (CAPD/APD/IPD), 2015



Data source: Special analyses, USRDS ESRD Database. Denominator was 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 France exclude Martinique. Data for Italy include five regions. Data for Canada excludes Quebec. Data for Latvia represents 80% of country's population. Abbreviations: CAPD, continuous ambulatory peritoneal dialysis; APD, automated peritoneal dialysis; IPD, intermittent peritoneal dialysis. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

Kidney Transplantation

International kidney transplantation rates vary greatly, 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 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 11.16.a).

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 11.16.b). Such a comparison indicates that the relative rates differ considerably between the two metrics. For example, the U.S. ranks third in the world in terms of transplants PMP, yet ranks 37th of 59 reporting countries in transplants per 1000 dialysis patients. This may be due, in part, to the high numbers of dialysis patients in the U.S.

Kidney transplant rates varied more than 30-fold across countries, from less than one to 71 PMP in 2015 (Figure 11.16.a). The highest rates were reported in the Jalisco region of Mexico, Spain, the U.S., and the Netherlands, with 58-71 kidney transplants PMP. Rates ranged from 29-52 kidney transplants PMP for 45% of countries, 11-27 transplants PMP for 23% of countries, and 1–10 PMP for the remaining 26%. Countries reporting the lowest rates of kidney transplantation, at 1-5 PMP, included Bangladesh, Ukraine, Malaysia, Morocco, the Philippines, and South Africa.

Kidney transplant rates when expressed per 1000 dialysis patients also varied greatly across countries, from three to 183 in 2015 (Figure 11.16.b). The highest rates per 1000 dialysis patients occurred in Norway (183), the Netherlands (151), Latvia (138), Finland (133), and Scotland (119). Transplant rates of 102 to 113 per 1000 dialysis patients were reported in Estonia, Sweden, Denmark, Spain (five regions), the U.K. (excluding Scotland), and Iceland. One-third of countries reported rates of 53 to 96 per 1000 dialysis patients, 22% had rates of 26-46, and the remaining 27% of countries reported rates of less than 24 transplants per 1000 dialysis patients in 2015. During 2015 in the U.S., 38 kidney transplants were performed per 1000 dialysis patients.

Since 2002, some countries have shown a substantial increase in kidney transplant rates PMP (Reference Table N.8, Figure 11.17). When comparing transplant rates in 2014/15 to 2002/03, Iceland, Turkey, the Republic of Korea, Russia, Thailand, Bangladesh, Scotland, the Netherlands, and Brazil demonstrated the largest increases of from 54% to 1203%. Additionally, during the same period, kidney transplantation rates PMP were 33-44% higher in Columbia, Singapore, Denmark, Australia, Uruguay, Finland, Bosnia and Herzegovina, and the Jalisco region of Mexico.

vol 2 Figure 11.16 Kidney transplantation rate, by country, 2015

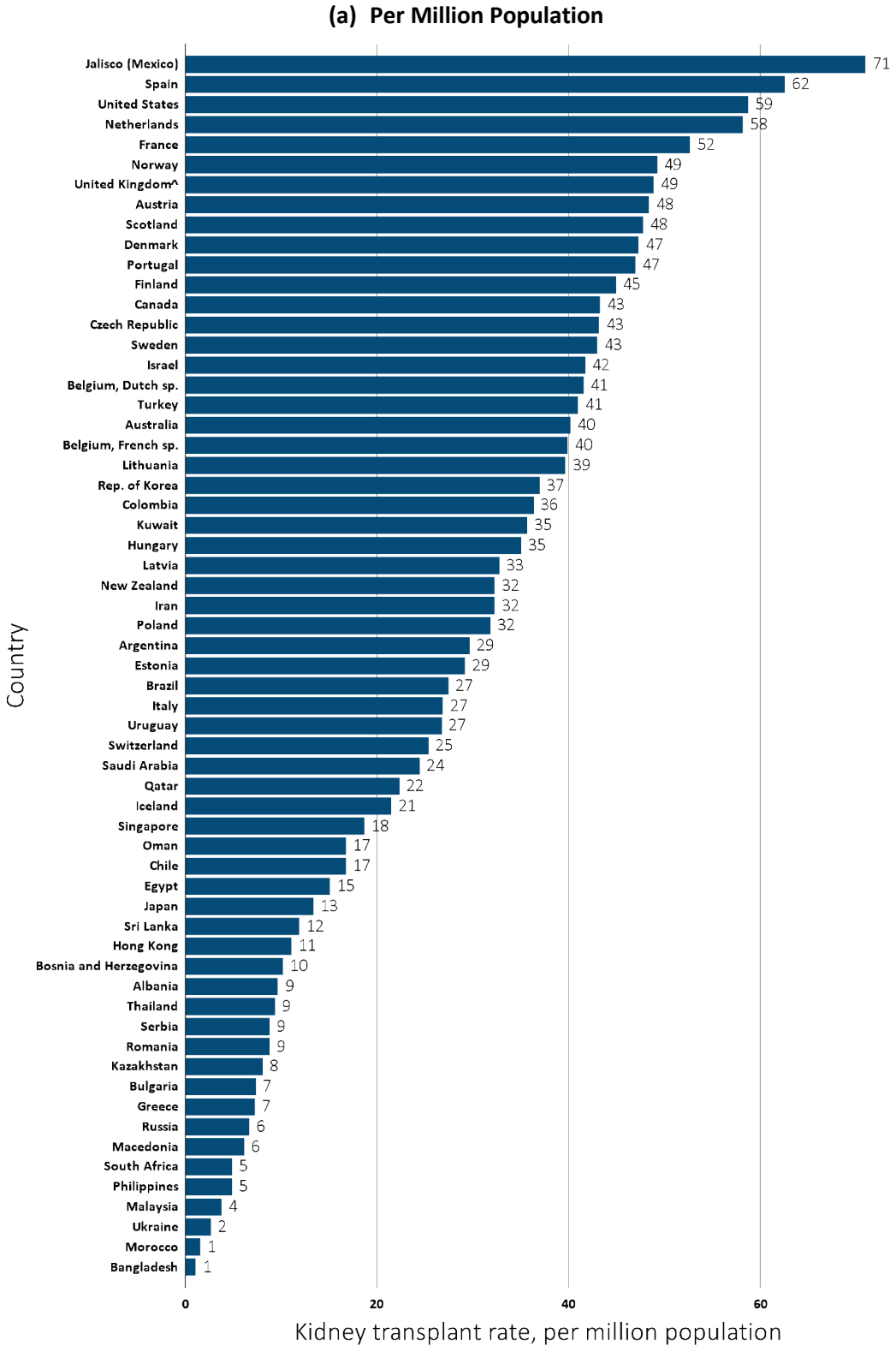
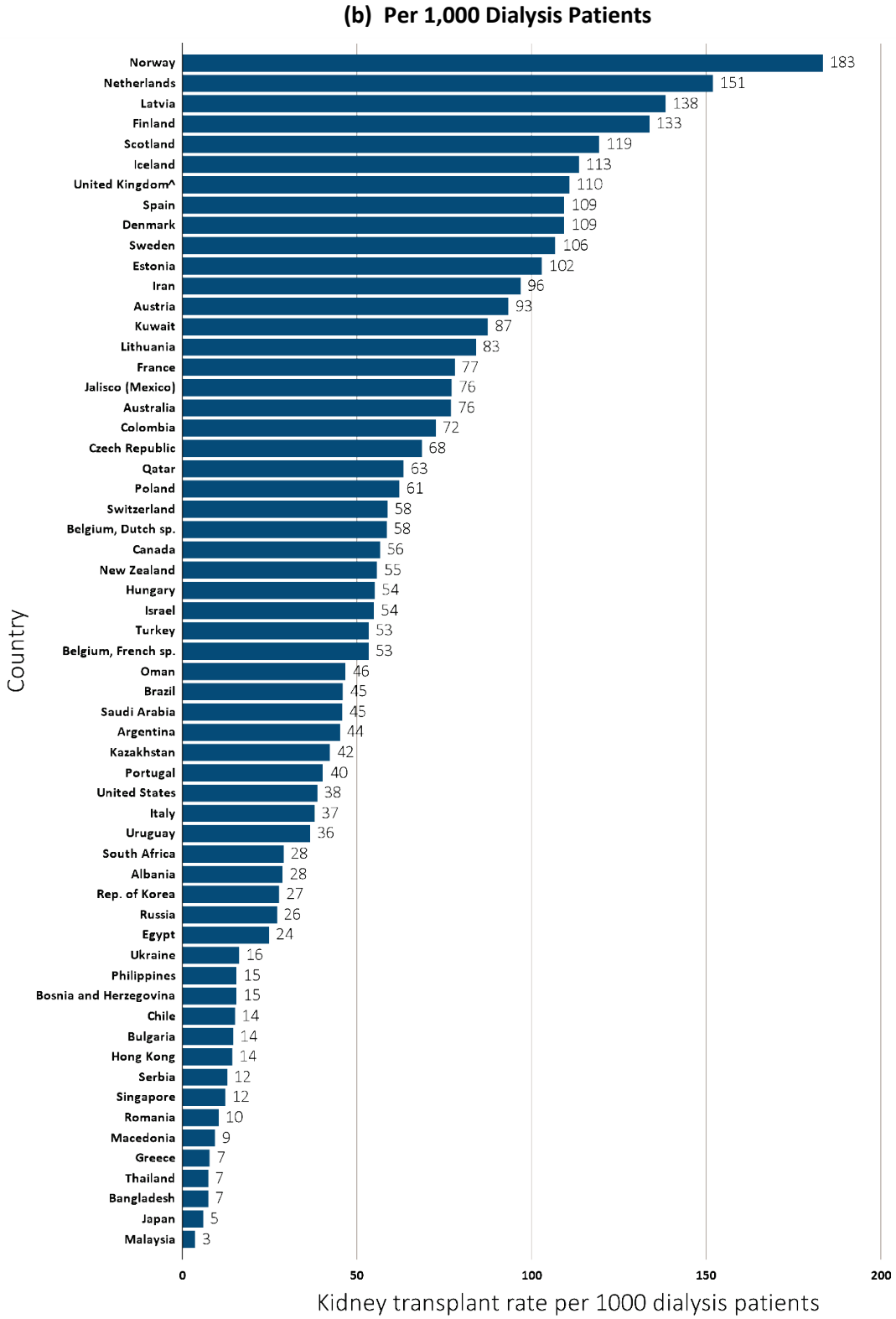


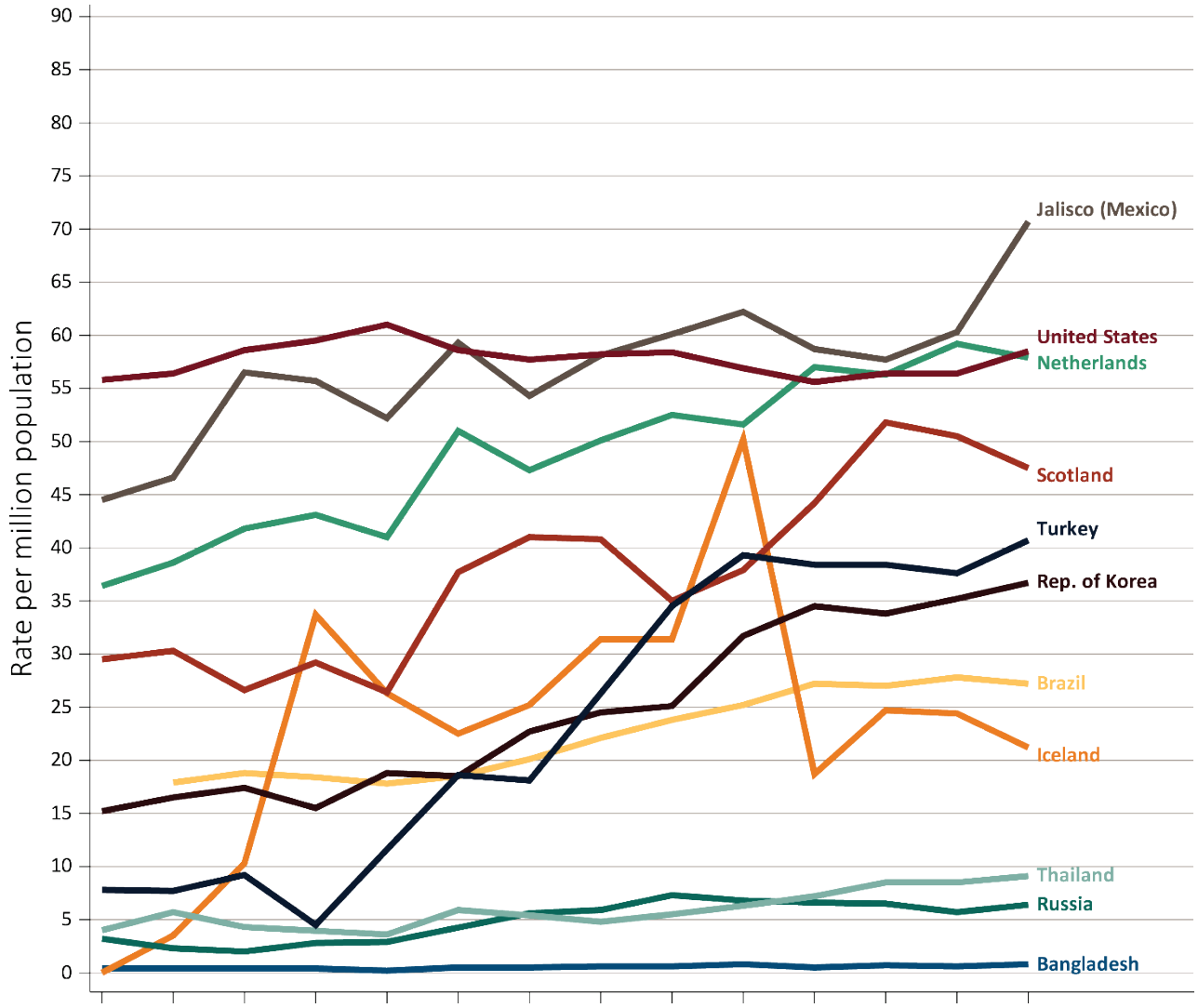
Figure11.16 continued on next page.

vol 2 Figure 11.16 Kidney transplantation rate, by country, 2015 *(continued)*



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 exclude Martinique. Data from Italy represent five regions. Data for Sri Lanka is from seven government hospitals. Data for Canada excludes Quebec. Abbreviation: sp., speaking. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

vol 2 Figure 11.17 Trends in kidney transplantation rates per million population, by country 2015



Data source: Special analyses, USRDS ESRD Database. Ten countries having the highest percentage rise in kidney transplantation rate: 2014/15 versus that in 2002/03, plus the U.S. All rates are unadjusted.Abbreviations: ESRD, end-stage renal disease. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

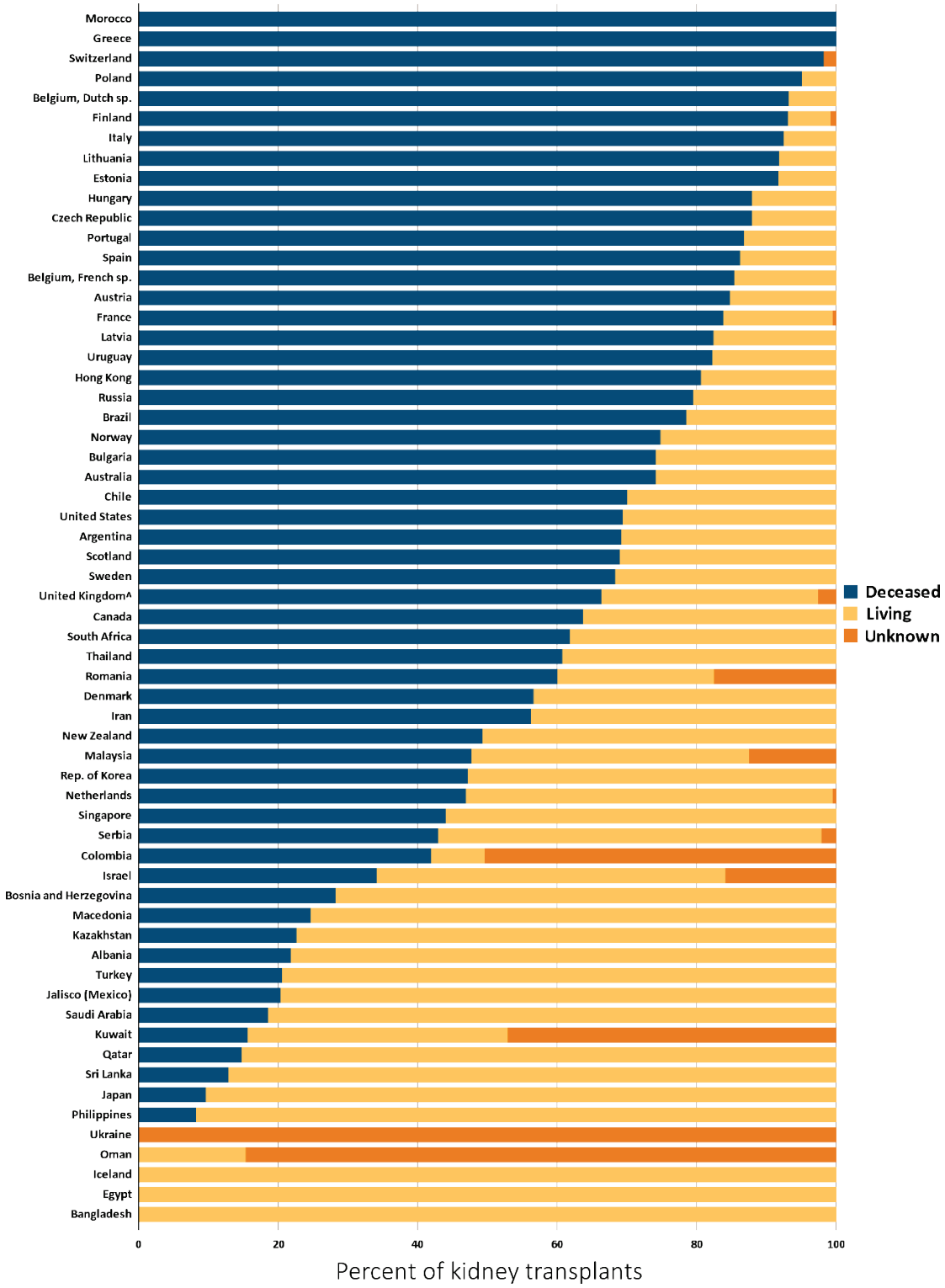
Large international differences were also seen in the types of kidney donors. Rates of living donor transplantation ranged from 80%-100% in Qatar, Turkey, Japan, the Philippines, Bangladesh, Iceland, Saudi Arabia, Sri Lanka, Egypt and the Jalisco region of Mexico, to 10% or lower in Poland, Belgium (Dutch), Finland, Italy, Lithuania, and Estonia (Figure 11.18). In nearly 60% of countries, donation from deceased individuals was the predominant form of kidney donation during 2015.

In 2015, Norway, the U.S., Portugal, Spain, and the Jalisco region of Mexico reported the highest prevalence of ESRD patients living with a kidney transplant, at 632 to 664 PMP (Figure 11.19 and Reference Table N.9). Twenty-nine percent of countries indicated 416 to 607 prevalent ESRD patients PMP living with a kidney transplant, while the remaining 61% of countries were nearly evenly divided between having less than 202, or 202-378 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.

In comparisons of data from 2014/15 to 2002/03, the prevalence of ESRD patients living with a kidney transplant PMP has increased in every country with available data, rising from 50% to 293% in approximately one-half of all countries, and by 4%-48% in the remaining nations (Reference Table N.9). Russia, Bosnia and Herzegovina, Uruguay, Thailand, and Turkey reported the largest increases during this period—from 162% to 293%.

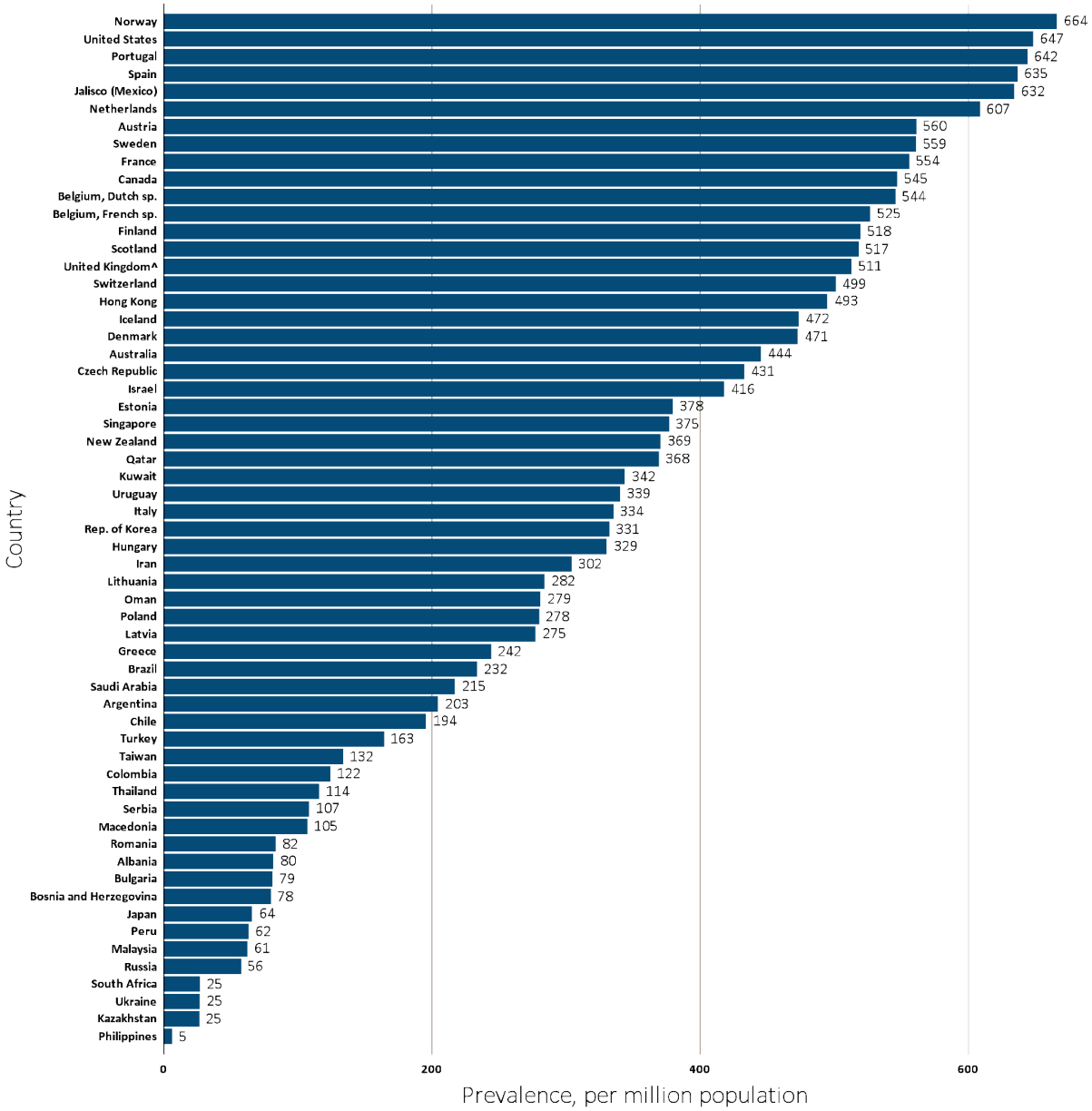
From 2002-2015 the percentage of all ESRD patients living with a kidney transplant remained relatively constant within most countries (Reference Table N.10). However, some nations have demonstrated a continuing increase, particularly in Denmark, Iceland, the Netherlands, Scotland, Sweden, the U.K., Bosnia and Herzegovina, Turkey, Argentina, Columbia, and Uruguay. In contrast, during this period the percentage of ESRD patients living with a kidney transplant declined substantially in Malaysia, Russia, and the Philippines.

vol 2 Figure 11.18 Distribution of the percentage of kidney transplantations by kidney donor type and country, 2015



Data source: Special analyses, USRDS ESRD Database. Denominator is calculated as the sum of deceased, living donor, and unknown transplants. ^United Kingdom: England, Wales, & Northern Ireland (Scotland data reported separately). Data for France exclude Martinique. Data from Canada excludes Quebec. Data from Italy represent five regions. Data from Sri Lanka is from seven government hospitals. Abbreviation: ESRD, end-stage renal disease. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

vol 2 Figure 11.19 Prevalence of treated ESRD patients with a functioning kidney transplant, per million population, by country, 2015



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 France exclude Martinique. Data for Italy includes five regions. Data for Canada excludes Quebec. Abbreviations: ESRD, end-stage renal disease; sp., speaking. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

References

Hecking M, Bieber BA, Ethier J, Kautzky-Willer A, Sunder-Plassmann G, et al. Sex-specific differences in hemodialysis prevalence and practices and the male-to-female mortality rate: The Dialysis Outcomes and Practice Patterns Study (DOPPS). *PLoS Med* 2014;11(10): e1001750.

Robinson BM, Akizawa T, Jager KJ, Kerr PG, Saran R, Pisoni RL. Factors affecting outcomes in patients reaching end-stage kidney disease worldwide: differences in access to renal replacement therapy, modality use, and haemodialysis practices. *Lancet*, 2016;388(10041):294–306.

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Notes

Chapter 12: End-of-life Care for Patients with End-Stage Renal Disease, 2000-2014

- This year we introduce information regarding patients' inpatient surgical procedures during their last 90 days of life, and an examination of the prevalence and content of advance directives among nursing home residents during the last year of life.
- Between 2000 and 2014:
    - The percentage of Medicare beneficiaries with end-stage renal disease (ESRD) admitted to an intensive or coronary care unit during the last 90 days of life increased from 50% to 62% (Figure 12.3).
    - The percentage of Medicare beneficiaries with ESRD who received an intensive procedure during the last 90 days of life increased from 28% to 34% (Figure 12.4).
    - The percentage of Medicare beneficiaries with ESRD who received an inpatient surgical procedure within the last 90 days of life decreased from 33% to 27% (Figure 12.5).
    - The percentage of Medicare beneficiaries with ESRD who died in the hospital decreased from 49% to 40% (Figure 12.6).
    - The percentage of Medicare beneficiaries with ESRD who received care in a skilled nursing facility (SNF) during the last 90 days of life increased from 24% to 32% (Figure 12.7).
    - The percentage of patients with ESRD who discontinued maintenance dialysis treatments before death increased from 20% in 2000 to 26% in 2011, then decreased to 24% in 2014 (Figure 12.8).
    - The percentage of Medicare beneficiaries with ESRD receiving hospice care at the time of death increased from 11% to 27% (Figure 12.9), with the most marked increases occurring among those who discontinued dialysis.
- The percentage of deceased ESRD nursing home residents who had an advance directive in the year before their death declined from 47% in 2000 to 41% in 2010 (Figure 12.10).
- Median 2014 per person costs under Medicare Parts A and B were $119,525 over the last year of life, $20,165 over the last 30 days of life, and $7,396 over the last seven days of life.

Introduction

In this chapter, we update information on treatment practices, inpatient, skilled nursing facility (SNF), and hospice utilization, and costs at the end of life among decedents with end-stage renal disease (ESRD). We provide new information on inpatient surgical procedures during the last 90 days of life and use of advance directives among nursing home residents. We present trends in all measures for the 15-year period from 2000 through 2014, with the exception of 2000-2010 trends in the prevalence and content of advance directives among patients with ESRD who resided in a nursing facility during the last year of life.

This chapter is divided into the following 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) skilled nursing facility utilization during the last 90 days of life, (4) patterns of dialysis discontinuation before death, (5) patterns of hospice utilization before death, (6) use of advance directives among nursing home residents, and (7) end-of-life costs for services under Medicare Parts A and B.

Methods

Data supporting analyses for this chapter were derived from the 2016 version of the public-use Standard Analysis Files (SAFs) supplied by the United States Renal Data System (USRDS) Coordinating Center at the University of Michigan. Specific SAFs included the Patients file, the MEDEVID file, the RXHIST file, the PAYHIST file, the Death file, the Residence file, and linked Medicare Institutional and Physician/Supplier claims. We used the Minimum Patient Dataset (available to us only for the years 2000 to 2010) to obtain advance directive information for patients with ESRD who resided in a nursing home during their last year of life.

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 for whom Medicare Parts A and B were the primary payers throughout the relevant period, and 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 beneficiaries with Medicare Parts A and B as primary payer throughout times 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. These younger patients are included in the denominator for all calculations except for those describing use of advance directives among nursing home residents.

We used the Patients file to obtain 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. Medicare Institutional claims were used to identify dates of short- and long-stay hospital admissions, dates of SNF admission (HCFASAF=S), 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 contained 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). Inpatient surgical procedures were ascertained using a previously published approach (Kwok et al., 2011).

The Centers for Medicare & Medicaid Services (CMS) Death Notification form (CMS 2746) reports provider responses to questions about whether renal replacement therapy (RRT) 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 2746 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 were 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 were supplemented with information from the CMS 2746 on place of death, hospice utilization, and date of last dialysis treatment. There was not perfect agreement between these two data sources due to differences in methods for hospice ascertainment, denominator populations, and periods studied.

We used the Minimum Dataset (MDS) for the years 2000 to 2010 to obtain advance directive information for patients with ESRD who resided in a nursing home during their last year of life. To characterize advance directive use, we identified patients with ESRD who

died between 2000 and 2010, and had an advance directive assessment recorded in the MDS during the last year of life. We restricted the cohort to patients 20 years of age or older at the time of death, who had been treated with dialysis or kidney transplantation for at least 90 days inclusive of the date of death, and had complete demographic information (N=334,607). We used the last available non-missing advance directive assessment to characterize the prevalence and content of advance directives. Respondents recorded whether there was documentation in the patient's medical record of a living will, a surrogate decision maker (durable power of attorney for health care), and one or more of the following treatment limitations: do not resuscitate (DNR), do not hospitalize (DNH), feeding restrictions, medication restrictions, and other treatment restrictions. We considered documentation of a living will, a surrogate decision maker, or a treatment limitation as an indication of an advance directive. We further categorized patients according to the presence or absence of a directive specifying the treatment limitations, and the presence or absence of a surrogate decision maker.

Costs for Medicare Part A and B services were calculated using the 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 who had zero or negative costs during the time frame of interest (e.g. last year, 90, or 30 days of life) 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 period of interest were pro-rated. Cost calculations did not include Medicare Part D costs, Medicaid costs, Medicare copayments, or other health care costs for Medicare beneficiaries.

Characteristics of Decedents with ESRD

We identified 1,297,656 patients listed in the USRDS Patients file who died between calendar years 2000 and 2014. The mean age (± standard deviation) of decedents was 68.6 (±13.6) years (Table 12.1). Patients aged 45-64 years comprised the largest group of decedents (28.5%) and more than 80% of decedents were between the ages of 45 and 84 at the time of death. Overall, 67.3% of decedents were White, 27.3% were Black/African American, 3.3% were Asian, 1.1% were Native American/Alaska Native, 1% were of other race, and 10.8% were of Hispanic ethnicity. Overall 54.7% of patients were male.

The most recent modality prior to death was hemodialysis (HD) in 88.3% of patients, peritoneal dialysis (PD) in 5.5%, and transplant in 5.3% (0.8% of patients were missing information on modality). During 2000-2014, the mean age of decedents rose from 67.5 (±13.7) years to 69.2 (±13.1) years, and the percentage of patients aged 85 years and older at the time of death increased from 8.4% to 12.6%. There was little change in racial, ethnic, and gender composition over time. The percentage of decedents with PD as their most recent modality decreased over time until 2007, increasing slightly thereafter. The percentage of decedents who had received a kidney transplant increased over time. The percentage of patients with Medicare Parts A and B as primary payer during the last 90 days of life ranged between a low of 63.8% in 2014 and a high of 75.0% in 2003.

vol 2 Table 12.1 Characteristics of decedents with ESRD by death year, 2000-2014

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	Total
n	72,803	76,882	79,501	82,432	84,109	85,835	87,539	87,569	88,379	89,894	90,620	91,831	91,847	92,794	95,621	1,297,656
%	5.6	5.9	6.1	6.4	6.5	6.6	6.7	6.7	6.8	6.9	7.0	7.1	7.1	7.2	7.4	
Age (mean)	67.48 (13.73)	67.57 (13.82)	67.83 (13.82)	67.93 (13.79)	68.12 (13.74)	68.31 (13.81)	68.45 (13.78)	68.61 (13.76)	68.75 (13.65)	68.73 (13.65)	69.02 (13.54)	69.13 (13.44)	69.20 (13.37)	69.24 (13.21)	69.22 (13.11)	68.55 (13.62)
Age Category																
0-19	0.17	0.15	0.15	0.18	0.15	0.16	0.14	0.1	0.12	0.11	0.13	0.08	0.09	0.08	0.08	0.12
20-44	6.43	6.29	6.14	5.73	5.56	5.41	5.15	5.08	4.78	4.77	4.35	4.26	4.16	3.97	3.96	5.01
45-64	27.94	28.29	28.07	28.68	28.75	28.62	29.08	28.70	28.72	29.04	28.92	28.78	28.32	28.05	27.92	28.53
65-74	28.60	27.92	27.49	26.96	26.65	26.15	25.73	25.86	26.33	26.46	26.59	26.87	27.67	28.45	28.96	27.10
75-84	28.50	28.65	28.76	28.77	28.90	28.99	28.62	28.51	27.93	27.38	27.27	27.01	26.67	26.58	26.53	27.89
≥85	8.36	8.70	9.39	9.69	9.99	10.67	11.28	11.75	12.12	12.24	12.74	13.00	13.08	12.87	12.56	11.34
Race																
Native American	1.23	1.11	1.14	1.12	1.11	1.16	1.08	1.08	1.14	1.14	1.06	1.04	1.02	0.92	0.95	1.08
Asian	2.79	2.81	2.87	3.01	3.03	3.20	3.24	3.39	3.27	3.45	3.50	3.66	3.67	3.66	3.89	3.32
Black/African American	28.15	28.30	27.95	28.14	28.37	28.04	27.67	27.45	27.33	27.13	26.72	26.38	26.15	26.03	25.91	27.26
White	65.95	65.91	66.16	65.78	65.53	66.26	67.07	67.26	67.41	67.52	68.05	68.25	68.67	69.07	68.92	67.26
Unknown	0.20	0.14	0.14	0.13	0.12	0.11	0.08	0.06	0.10	0.09	0.08	0.09	0.12	0.09	0.11	0.11
Other	1.68	1.74	1.75	1.82	1.84	1.24	0.86	0.76	0.75	0.67	0.59	0.57	0.36	0.23	0.23	0.97
Hispanic																
No	72.84	76.38	79.05	80.55	81.89	82.88	83.82	84.60	84.79	84.78	84.97	84.84	84.45	84.60	84.27	82.55
Yes	8.57	9.18	9.53	9.99	10.20	10.49	10.57	10.62	10.92	11.30	11.40	11.87	11.90	11.72	11.98	10.75
Unknown	15.43	11.80	9.18	7.24	5.79	4.74	3.79	3.22	2.62	2.33	2.04	1.71	1.57	1.45	1.33	4.67
Missing	3.16	2.64	2.25	2.23	2.11	1.89	1.82	1.57	1.67	1.59	1.58	1.57	2.08	2.23	2.42	2.03
Sex																
Female	47.83	47.55	47.47	46.87	46.28	45.94	45.77	45.30	44.86	44.27	44.18	43.83	43.61	43.72	43.35	45.28
Male	52.17	52.45	52.53	53.13	53.67	54.02	54.20	54.67	55.12	55.71	55.81	56.16	56.39	56.27	56.65	54.70
Missing	0.00	0.00	n/a	0.01	0.05	0.04	0.03	0.03	0.02	0.02	0.02	0.01	0.00	0.01	0.00	0.02
Last Treatment Modality																
Hemodialysis	86.77	87.4	88.2	88.46	88.65	88.76	88.92	89.2	89.08	89.02	88.92	88.33	87.79	88.00	87.24	88.33
Peritoneal Dialysis	7.61	7.04	6.44	6.02	5.82	5.32	5.07	4.74	4.72	4.46	4.5	4.83	5.24	5.64	6.08	5.52
Transplant	4.66	4.67	4.55	4.73	4.69	4.99	5.06	5.18	5.19	5.55	5.63	5.86	6.15	6.14	6.43	5.34
Missing	0.95	0.89	0.82	0.79	0.84	0.93	0.95	0.88	1.01	0.97	0.96	0.97	0.82	0.21	0.25	0.81
Medicare Parts A & B as ESRD Payer for Last 3-months of Life (Yes)	73.40	73.37	74.37	74.98	74.93	74.31	73.15	71.52	69.56	68.81	68.02	66.92	66.69	65.80	63.79	70.43

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

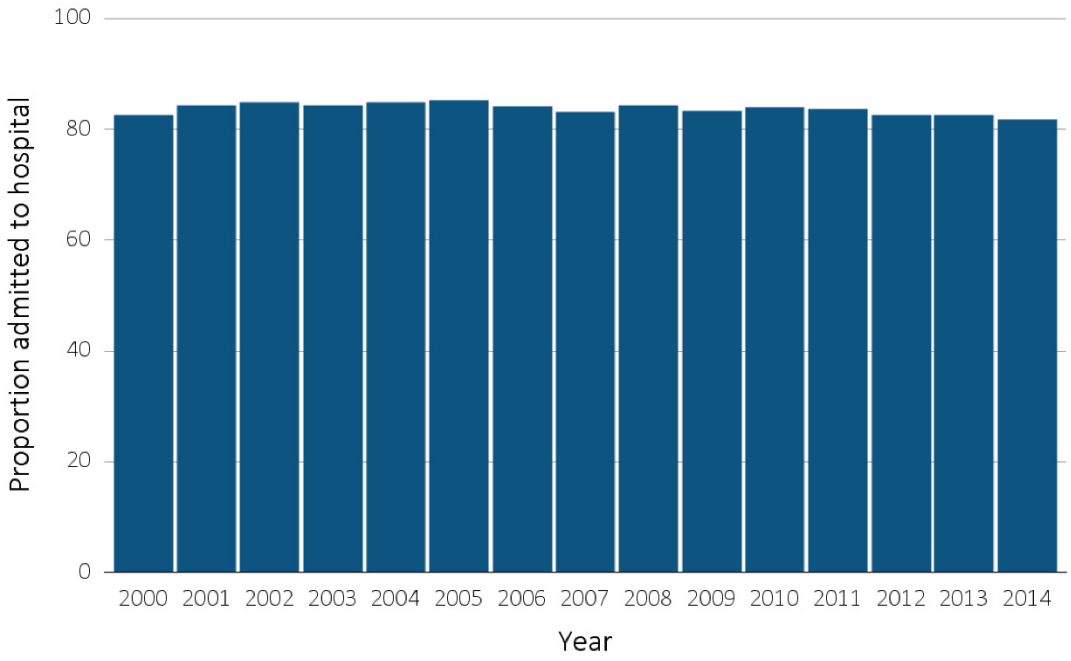
In this section, we describe the following measures of inpatient utilization during the last 90 days of life, among fee-for-service Medicare beneficiaries with ESRD from 2000-2014: (1) hospital admission, (2) days spent in the hospital, (3) ICU admission, (4) receipt of intensive procedures, (5) receipt of inpatient surgical procedures, and (6) inpatient deaths.

Hospital admission

Overall, 83.4% of patients were hospitalized during the last 90 days of life (Figure 12.1). The percentage of patients admitted to the hospital was highest for those aged 75-84 years (84.6%) and lowest for those aged 45-64 years (81.2%). Hospital admission was most common in Blacks (84.1%) and least common in Asians (80.7%), and was more common in Hispanics than non-Hispanics (84.4% vs. 83.5%). Females had more admissions than did males (85.6% vs. 81.2%), as did those whose most recent modality was HD rather than PD or transplant (83.6% vs. 81.8% 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, 27.1% of decedents were admitted to and/or discharged from the hospital within three days of death. These patients 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 26.3% in 2000 to 28.2% in 2014.

vol 2 Figure 12.1 Hospital admission during the last 90 days of life among Medicare beneficiaries with ESRD, 2000-2014

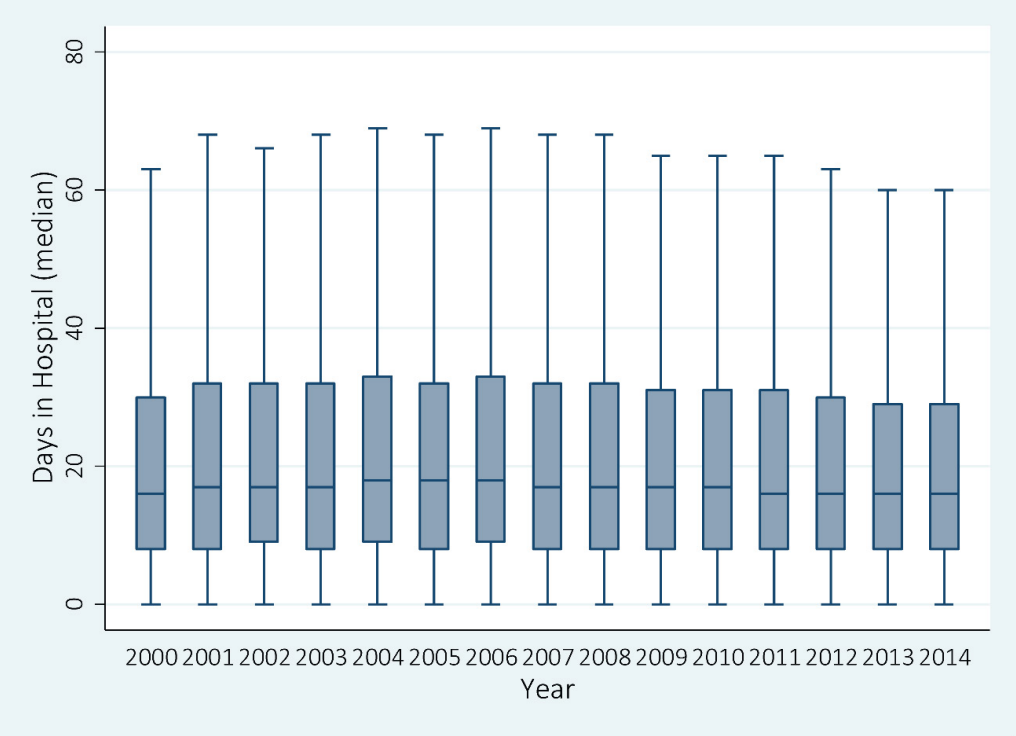


Data Source: Special analyses, USRDS ESRD Database. Denominator is all decedents with Medicare Parts A and B throughout the last 90 days of life. Includes hospital stays in both short- and long-stay hospitals. Abbreviation: ESRD, end-stage renal disease.

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 two admissions during this period (interquartile range [IQR], 1, 3) and 27.6% had three 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 had a median stay of 17 days (IQR, 8, 31; Figure 12.2). The median number of days spent in the hospital during the last 90 days of life changed very little over time.

vol 2 Figure 12.2 Days spent in the hospital during the last 90 days of life among Medicare beneficiaries with ESRD, 2000-2014



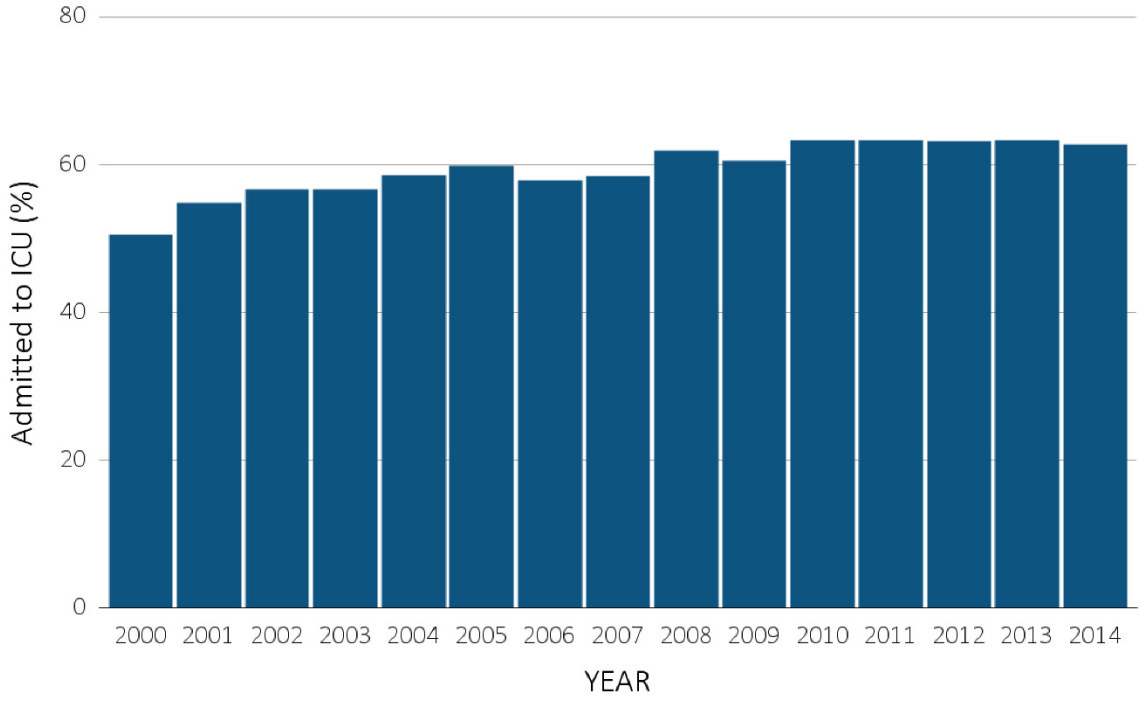
Data Source: Special Analyses, USRDS ESRD Database. Denominator is all decedents with Medicare Parts A and B throughout the last 90 days of life who were admitted to the hospital at least once. Includes hospital stays in both short- and long-stay hospitals. Explanation of box plot: The lower border of 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 ≥ the first quartile minus 1.5 times the interquartile range at the bottom to the highest value of the distribution that is ≤ the third quartile plus 1.5 times the interquartile range at the top. Values outside this range (outliers) are not plotted. Abbreviation: ESRD, end-stage renal disease.

ICU ADMISSION

Overall, 59.2% of patients were admitted to an ICU during the last 90 days of life (Figure 12.3). The percentage admitted to an ICU was highest among those aged 65-74 years (61.6%) and lowest for those aged 85 years and older (51.8%). ICU admission was highest for Asians (62.9%) and lowest for patients of Other race (47.2%), was higher for Hispanics than non-Hispanics (63.8% vs. 59.1%), was higher for females than males (60.7% vs. 57.9%), and was similar in patients whose most recent modality was HD rather than PD or transplant (59.4% vs. 57.8% vs. 57.5%). Over time, the percentage of patients admitted to the ICU during the last 90 days of life increased from 50.1% in 2000 to 62.4% in 2014. Over time and among all subgroups examined, there was an increase in the percentage of patients admitted to the ICU. The proportion of those admitted to an ICU in the last 90 days of life ranged from 33.3% to 70.9% across states in the continental United States (U.S.; Figure 12.3.g).

vol 2 Figure 12.3 ICU admission during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014

(a) ICU admission by year, overall



(b) ICU admission by age

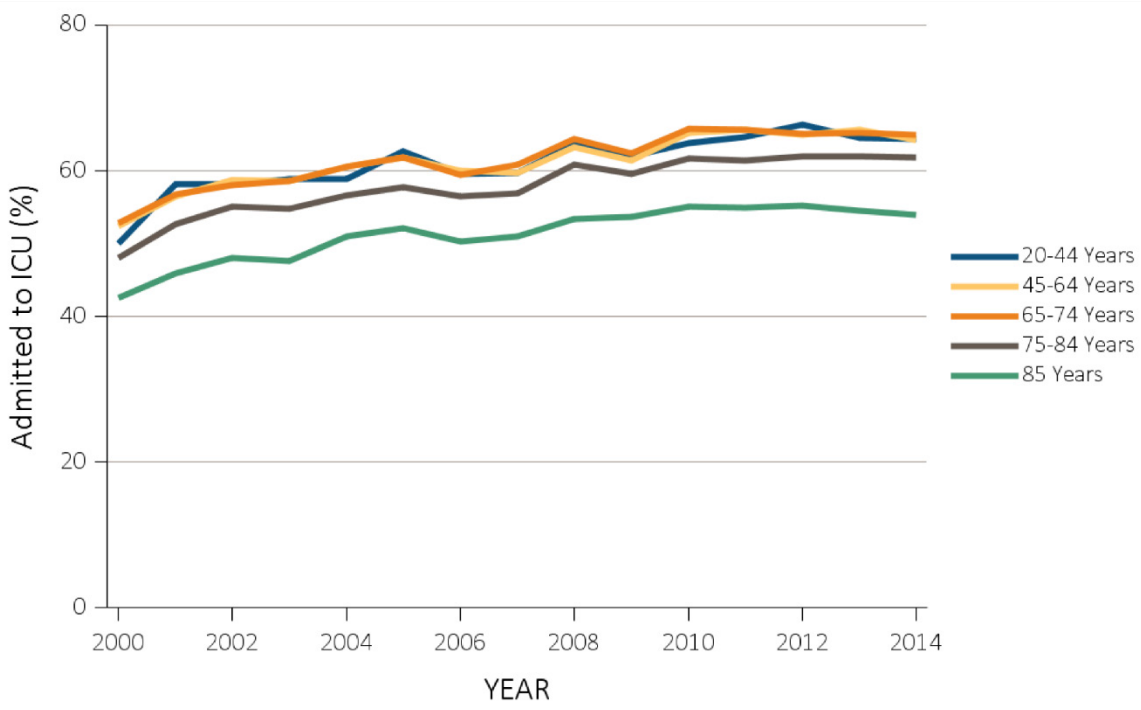
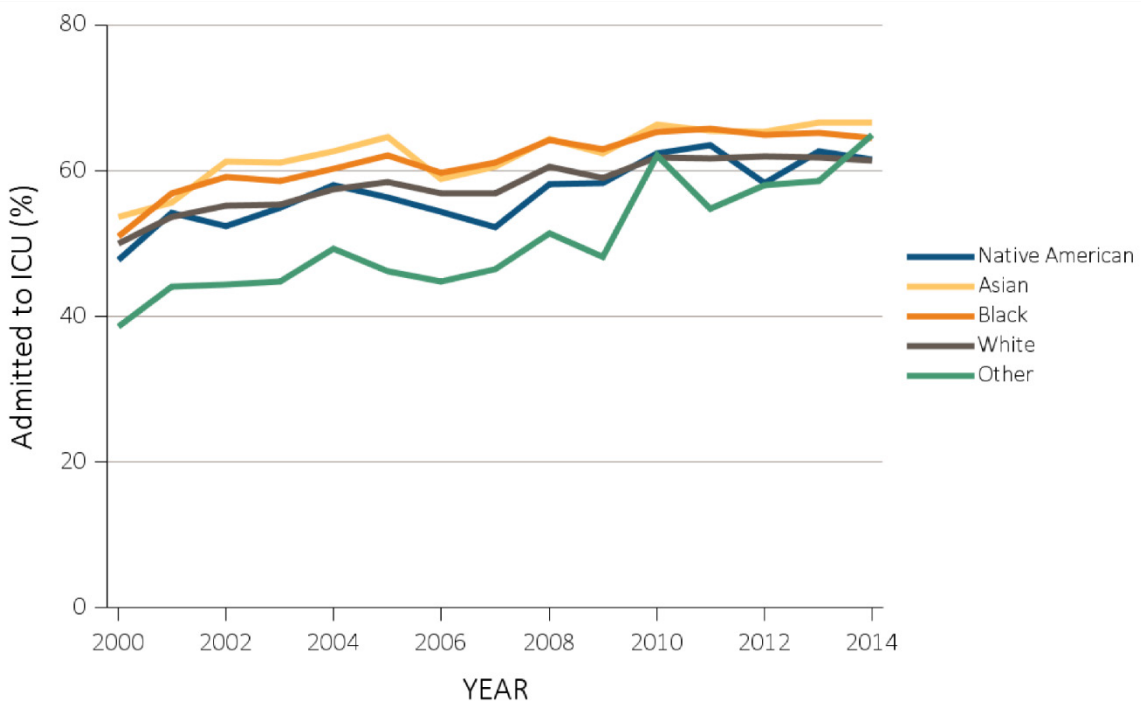


Figure 12.3 continued on next page.

vol 2 Figure 12.3 ICU admission during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014 *(continued)*

(c) ICU admission by race



(d) ICU admission by ethnicity

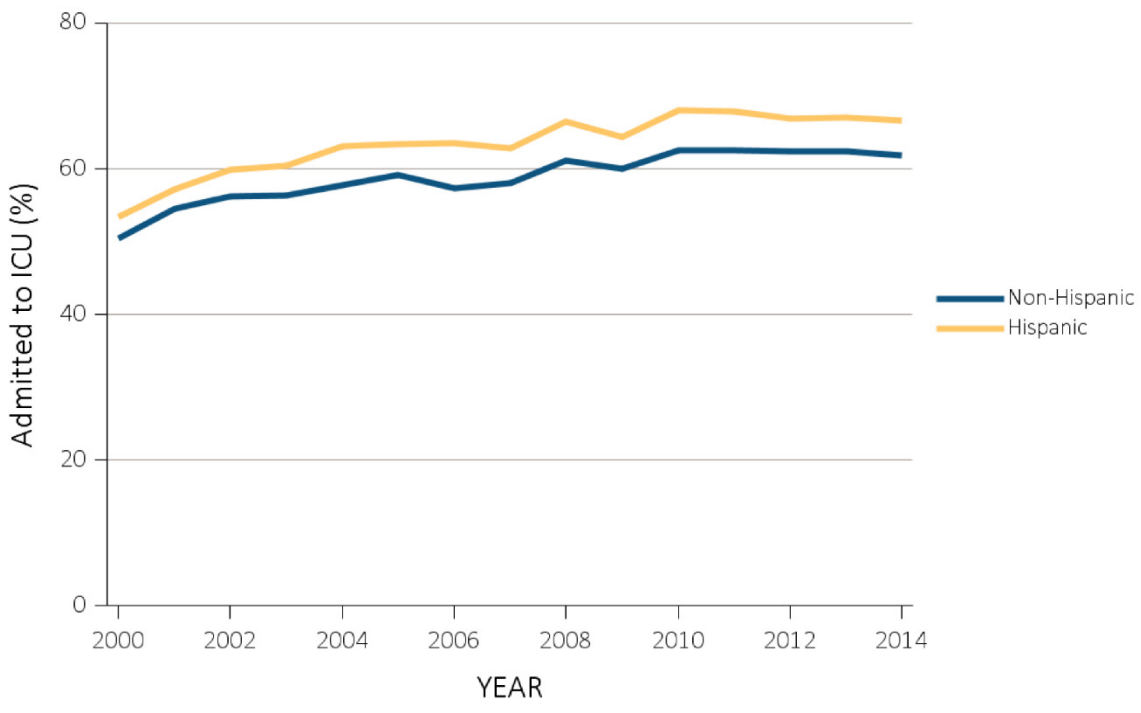
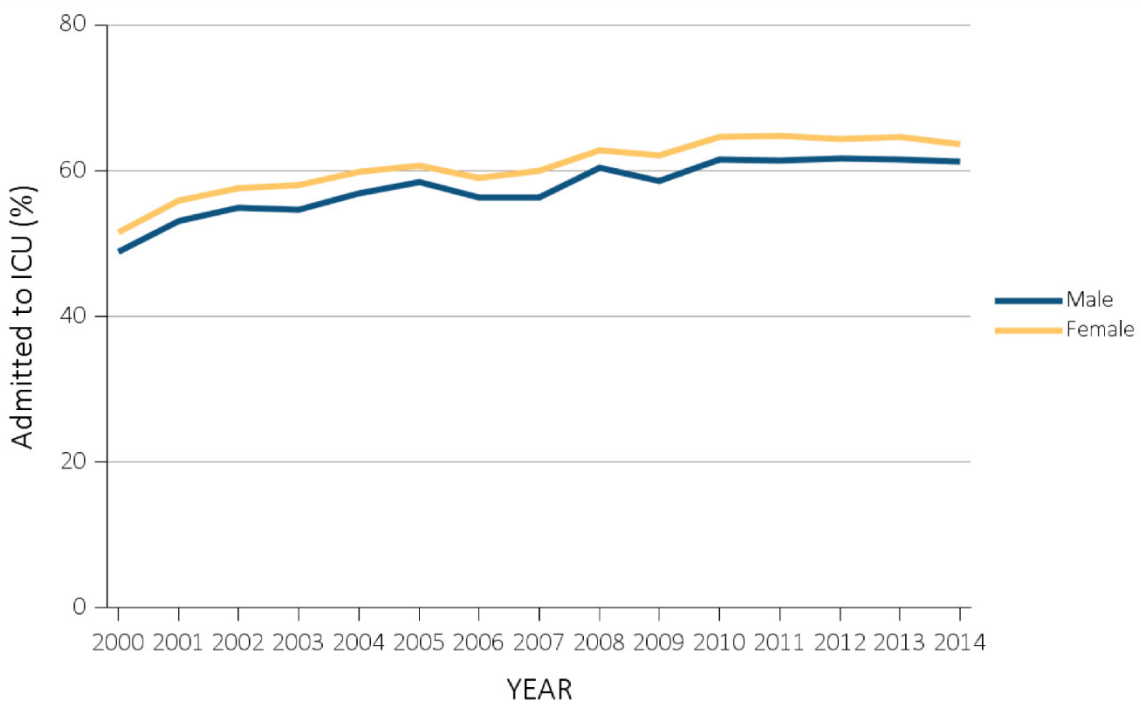


Figure 12.3 continued on next page.

vol 2 Figure 12.3 ICU admission during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014 *(continued)*

(e) ICU admission by sex



(f) ICU admission by modality

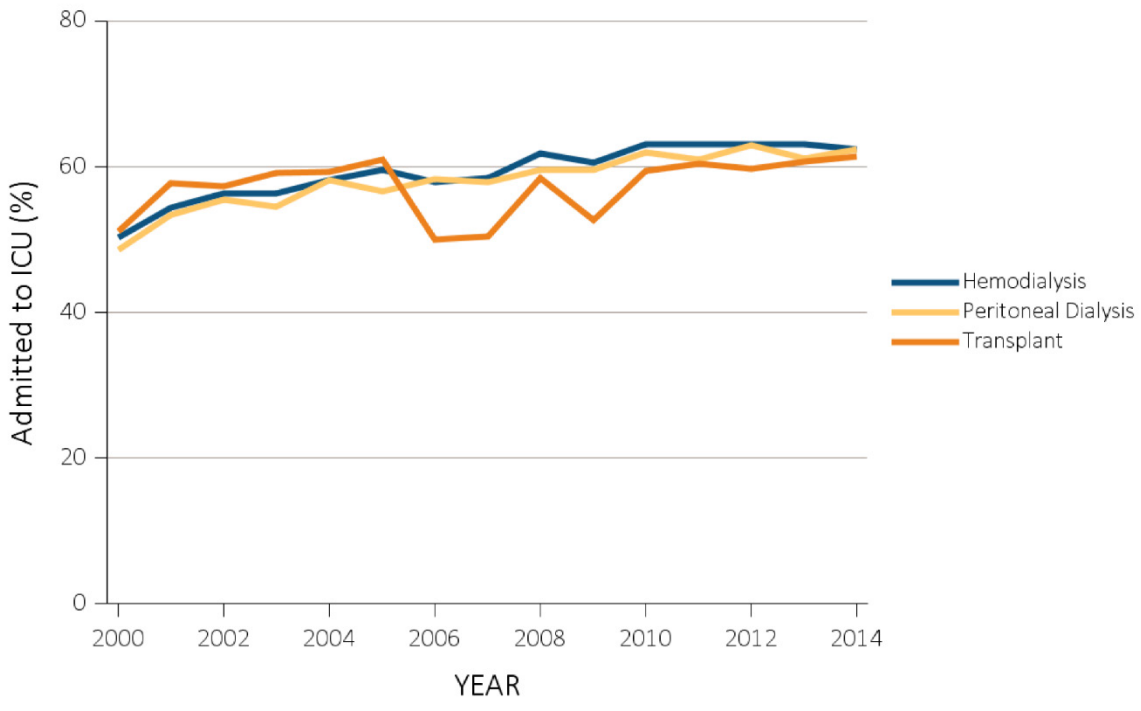
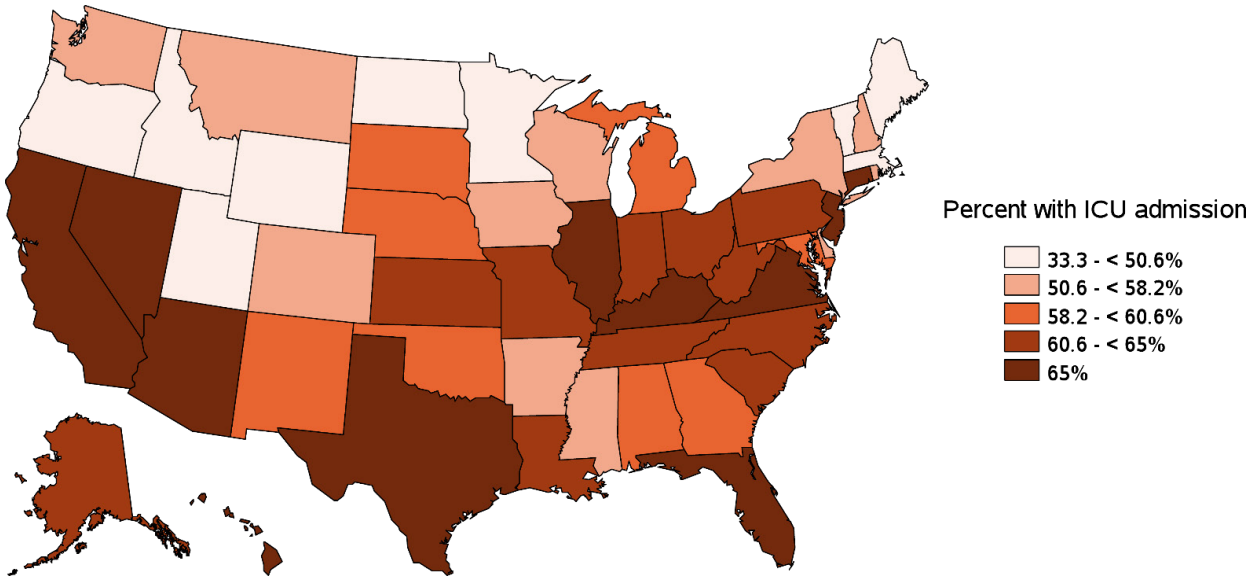


Figure 12.3 continued on next page.

vol 2 Figure 12.3 ICU admission during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014 *(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.

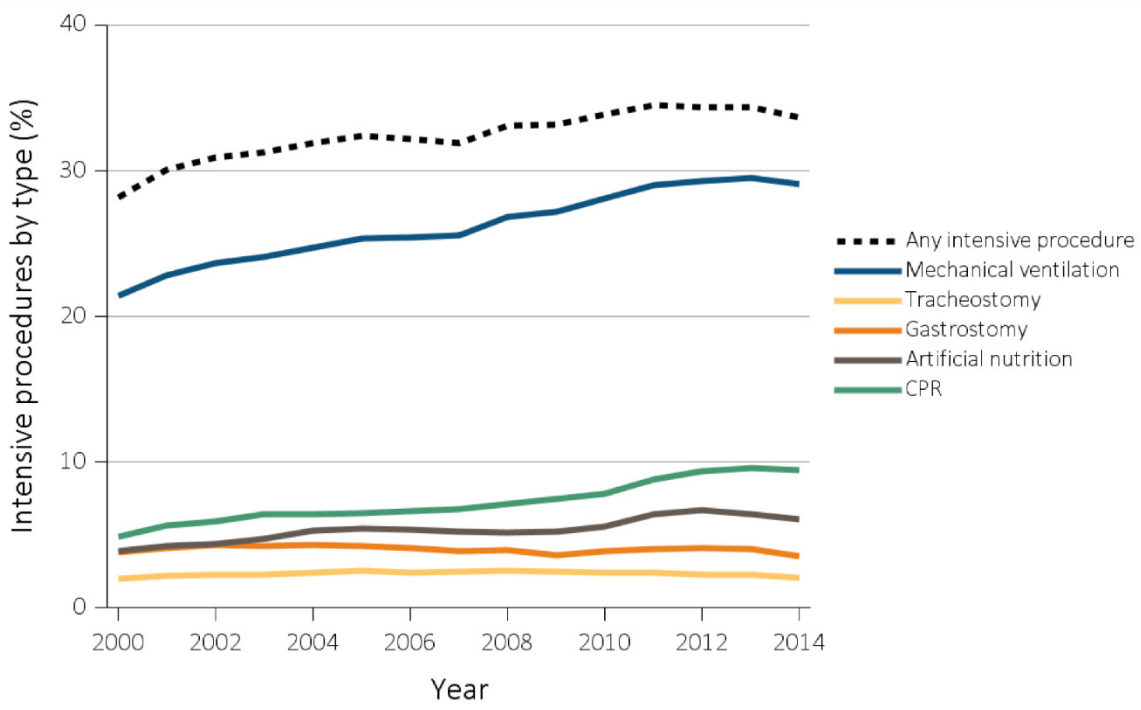
Intensive procedures

A total of 32.4% of decedents had an inpatient intensive procedure during the last 90 days of life; the most common procedure was intubation/mechanical ventilation (Figure 12.4). The percentage of patients receiving intensive procedures during the last 90 days of life was highest for those aged 20-44 years (42.7%) and lowest for those aged 85 years and older (20.6%). The rate of intensive procedures was highest for Blacks (41.2%) and lowest for Whites (28.6%), and was higher for Hispanics than non-Hispanics (38.5% vs. 31.7%). The percentage was also higher for females than males (33.5% vs. 31.6%), and was higher for those using transplant as their most recent modality rather than HD or PD (38.1% vs. 32.3% vs. 30.6%).

The percentage of patients who received an intensive procedure increased from 28.2% in 2000 to 33.7% in 2014. Those who were intubated, or who received mechanical ventilation during the last 90 days of life increased from 21.4% to 29.1% over the same period. The percentage of patients receiving an intensive procedure increased over time for most subgroups examined, and ranged from 12.0% to 44.3% across states in the continental U.S.

vol 2 Figure 12.4 Intensive procedures during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014

(a) Intensive procedures by sub-type and year, overall



(b) Intensive procedures by age

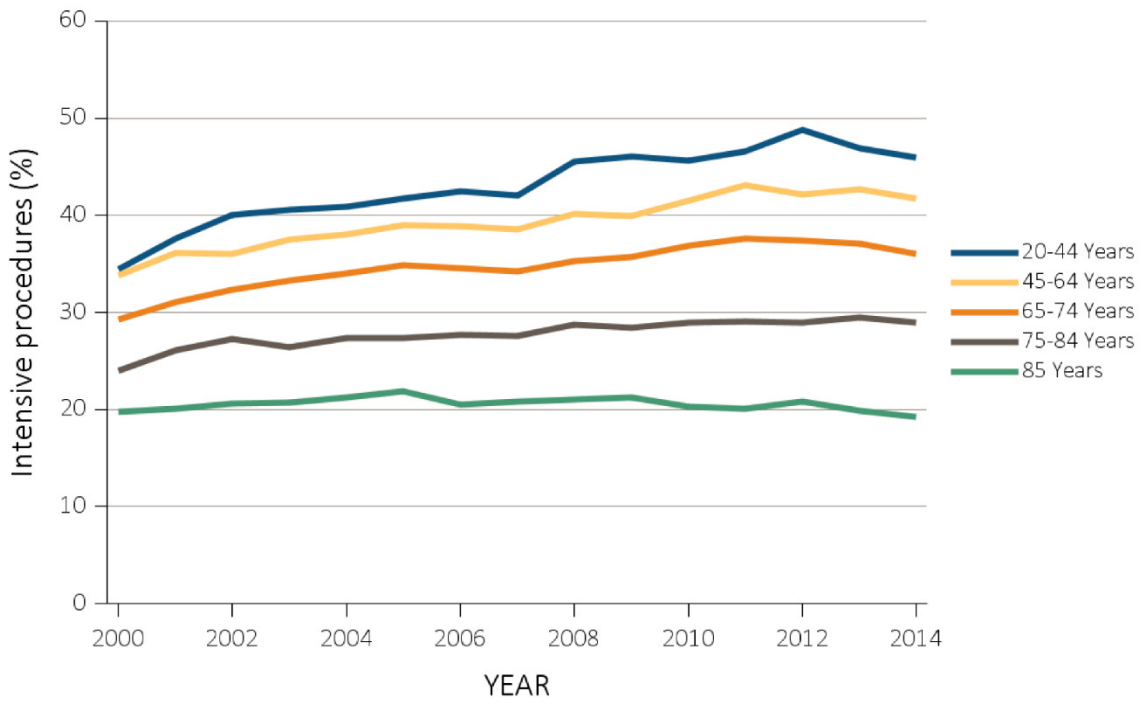
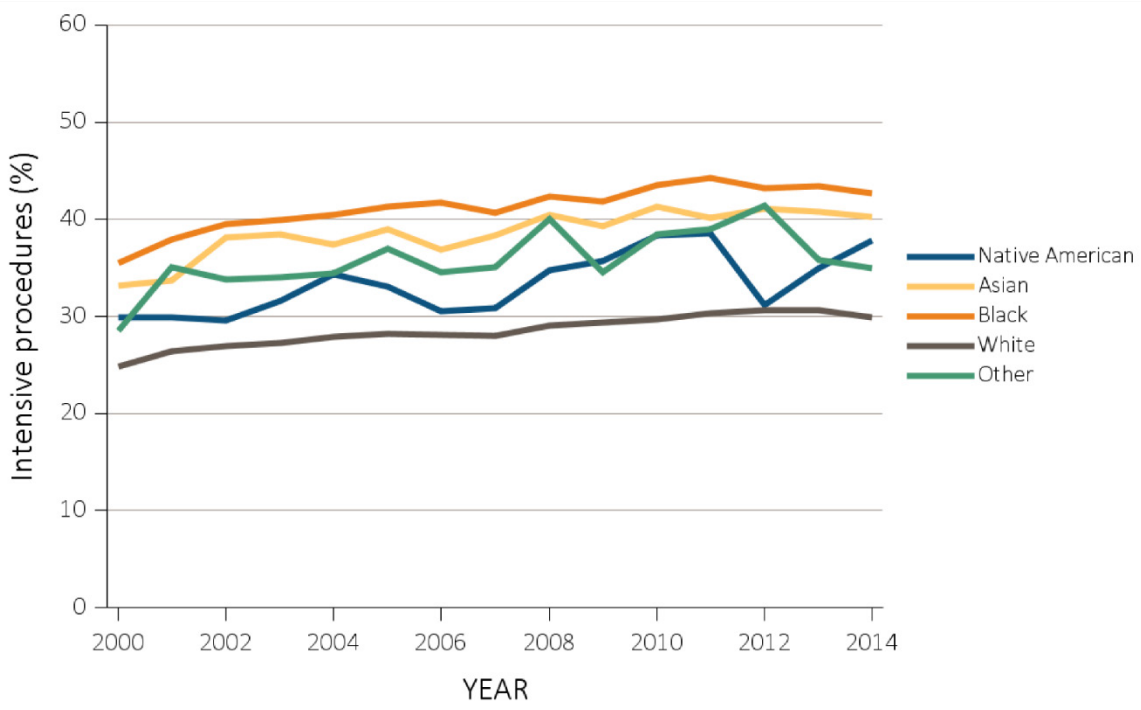


Figure 12.4 continued on next page.

vol 2 Figure 12.4 Intensive procedures during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014 *(continued)*

(c) Intensive procedures by race



(d) Intensive procedures by ethnicity

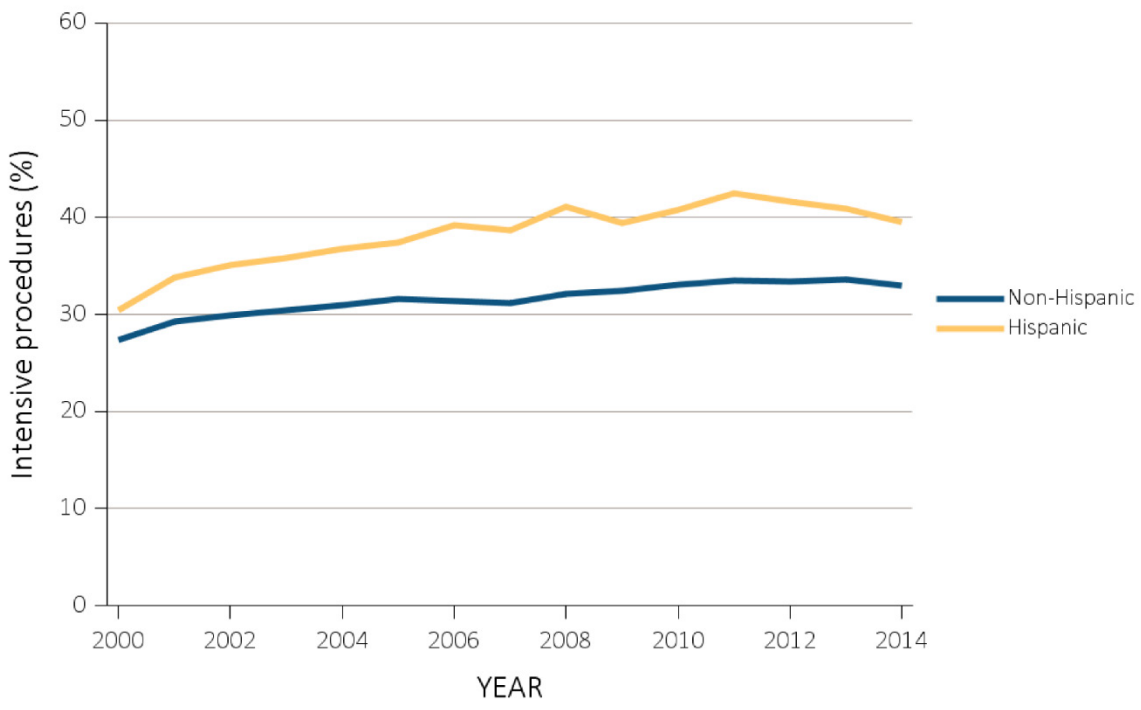
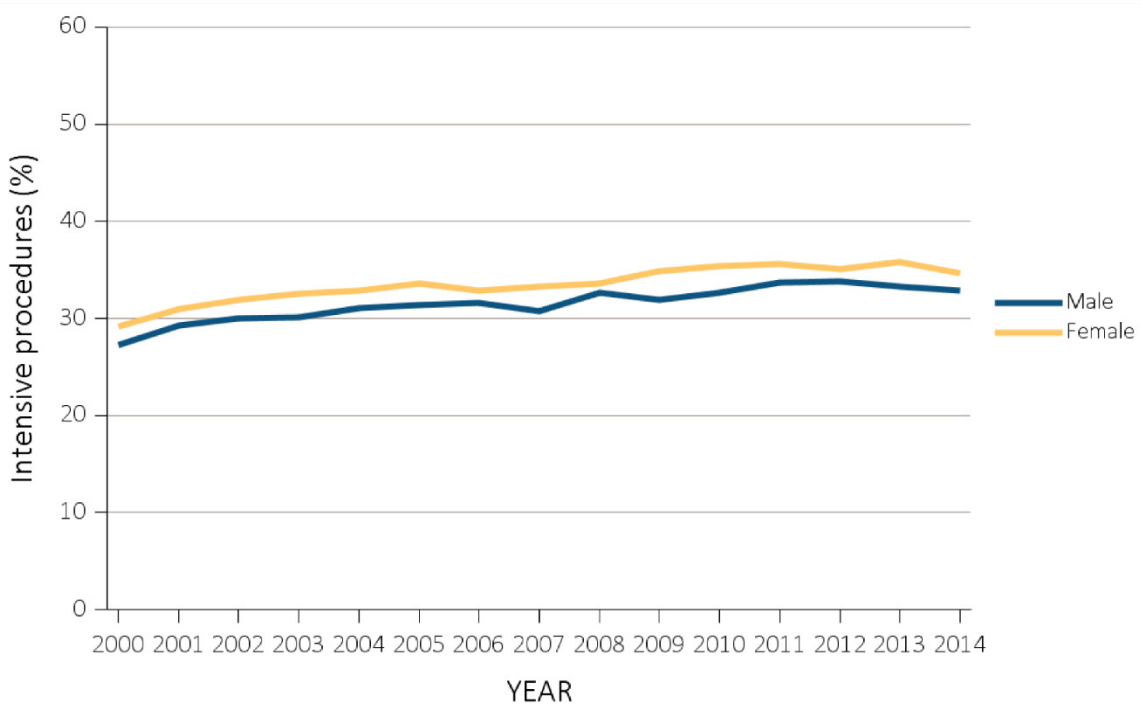


Figure 12.4 continued on next page.

vol 2 Figure 12.4 Intensive procedures during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014 *(continued)*

(e) Intensive procedures by sex



(f)Intensive procedures by modality

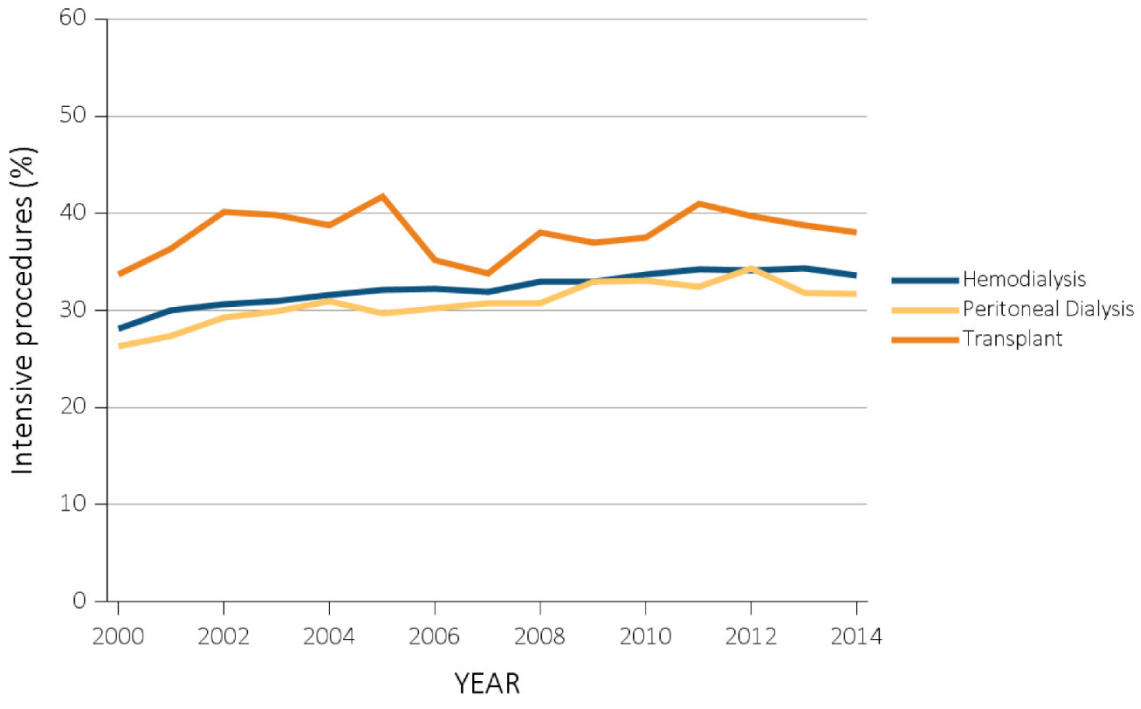
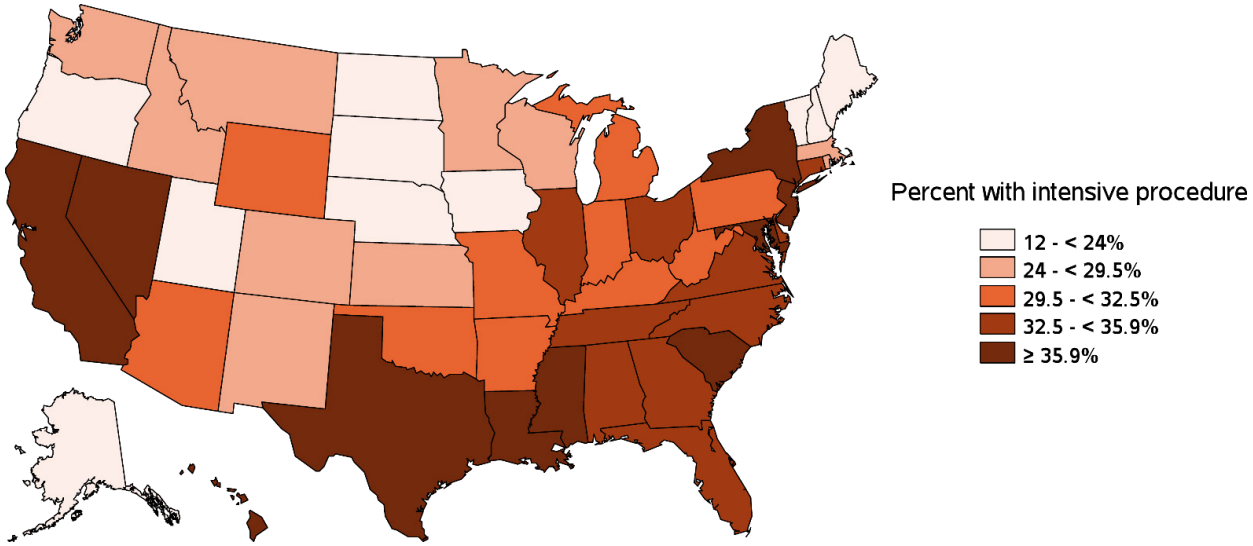


Figure 12.4 continued on next page.

vol 2 Figure 12.4 Intensive procedures during the last 90 days of life among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014 *(continued)*

(g) Intensive procedures by state



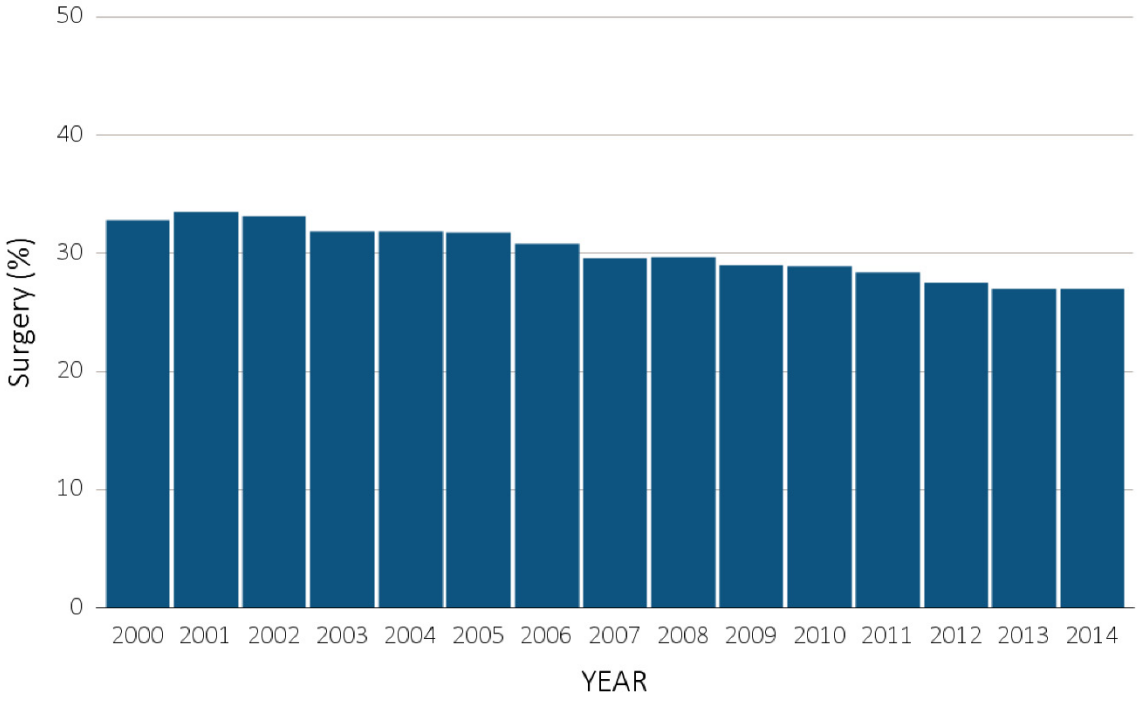
Data Source: Special analyses, USRDS ESRD Database. Denominator population is all decedents with Medicare Parts A and B throughout the last 90 days of life. Intensive procedures were identified by ICD-9 procedure code search of Medicare Institutional claims from short- and long-stay hospitals. The yellow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

Inpatient surgical procedures

Overall, 29.9% of patients received an inpatient surgical procedure during the last 90 days of life (Figure 12.5). The percentage was lowest for those aged 85 years and older (22.6%) and highest for those aged 45-64 years (32.3%). The rate of such procedures was highest for Blacks (33.1%) and lowest for Whites (28.6%), and higher for Hispanics vs. non-Hispanics (32.7% vs. 29.4%). Females had more procedures than males (30.7% vs. 29.2%), as did those receiving PD versus transplant versus HD (33.4% vs. 31.6% vs. 29.6%). The percentage of patients receiving an inpatient surgical procedure decreased from 32.5% in 2000 to 26.7% in 2014. Similar trends were present for most subgroups examined.

vol 2 Figure 12.5 Inpatient surgical procedures among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014

(a) Inpatient surgical procedures by year, overall



(b) Inpatient surgical procedures by age

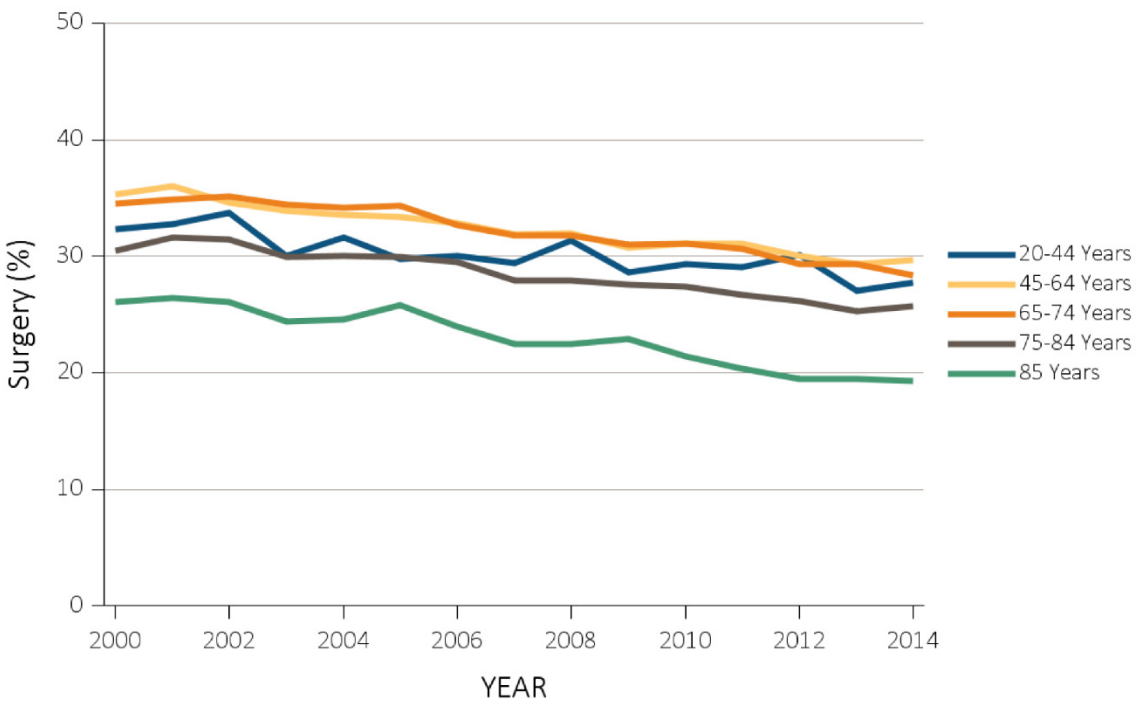
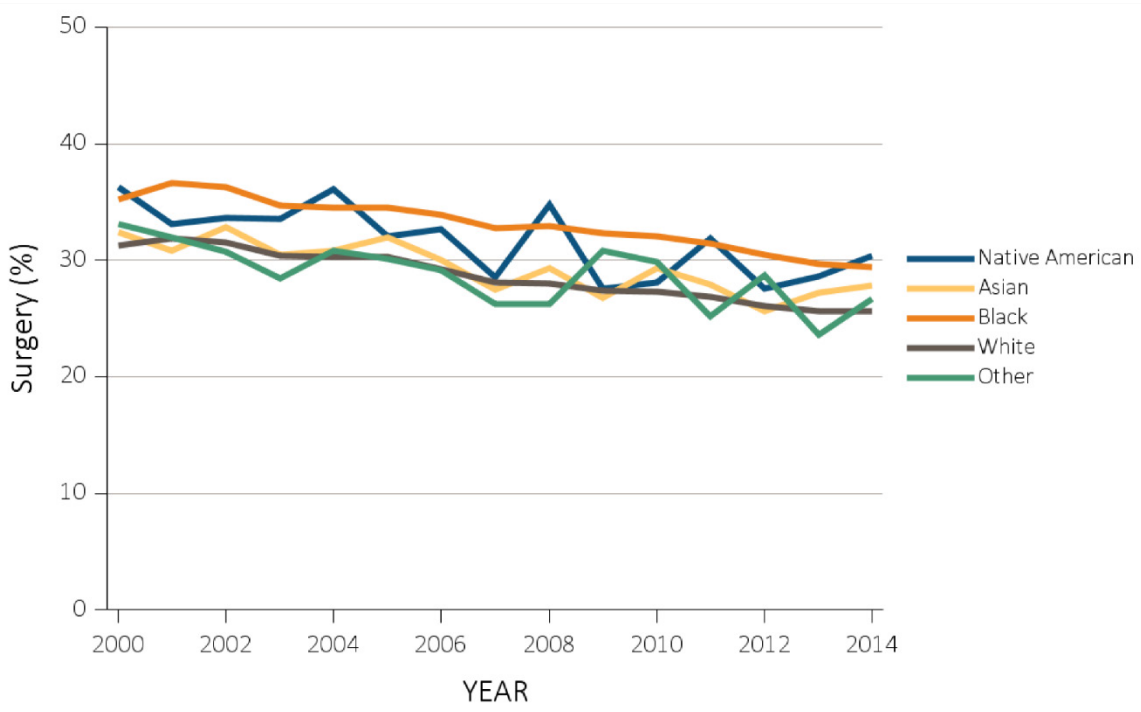


Figure 12.5 continued on next page.

vol 2 Figure 12.5 Inpatient surgical procedures among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014 *(continued)*

(c) Inpatient surgical procedures by race



(d) Inpatient surgical procedures by ethnicity

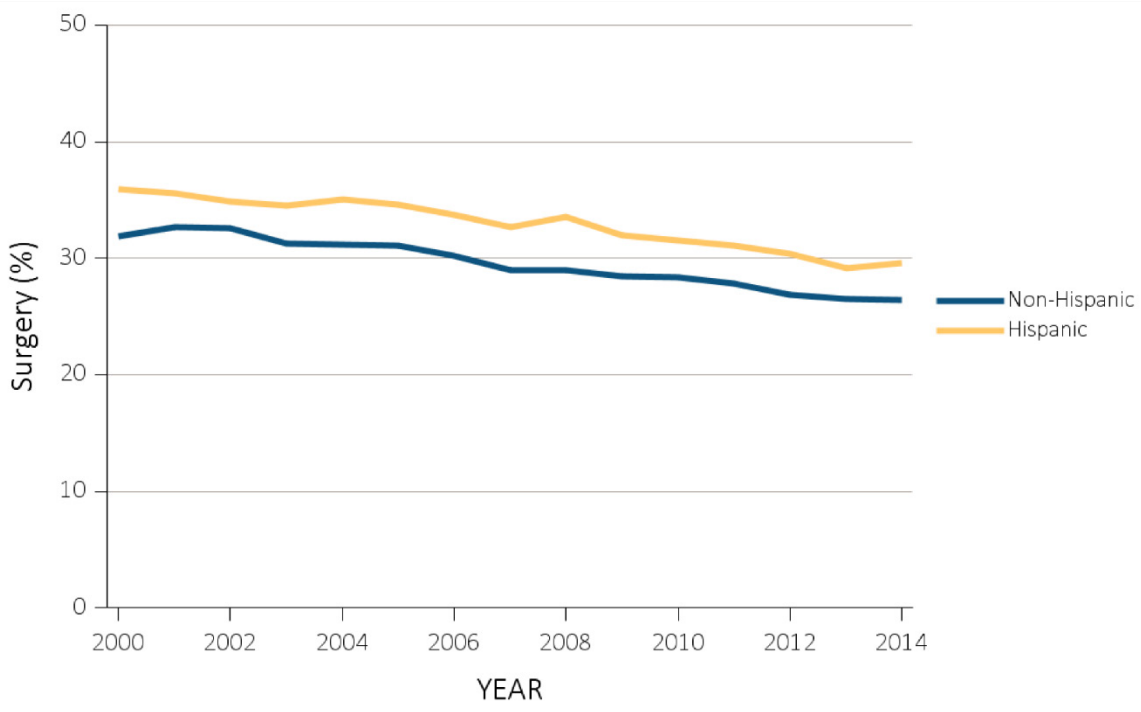
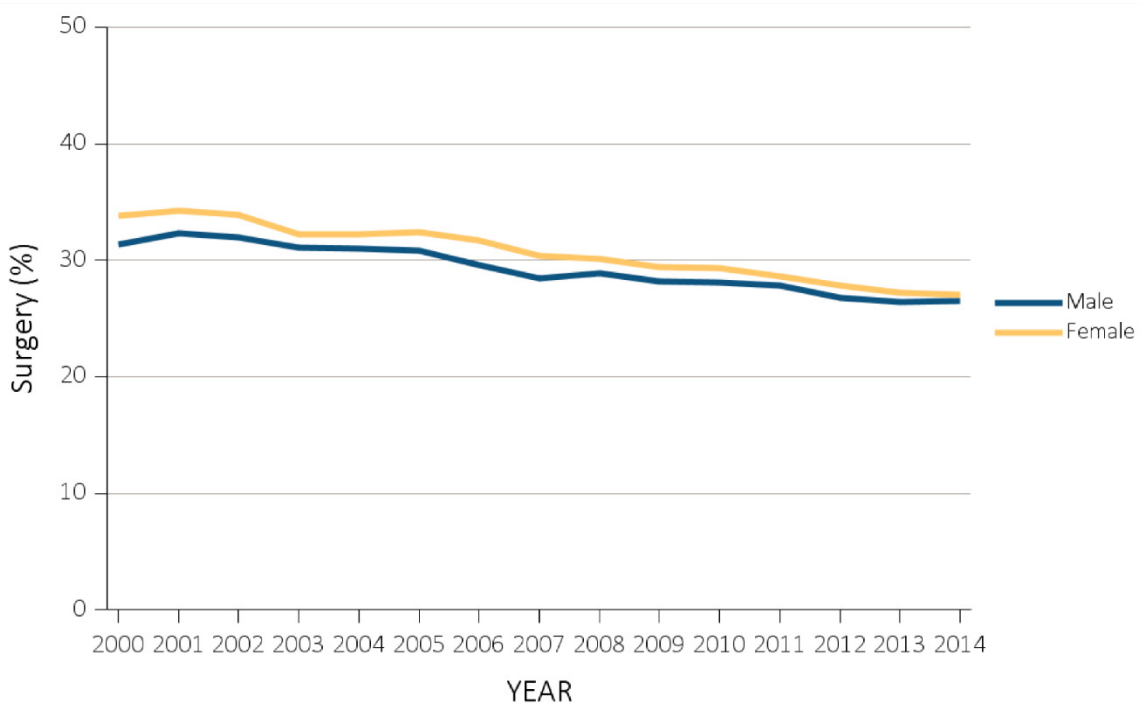


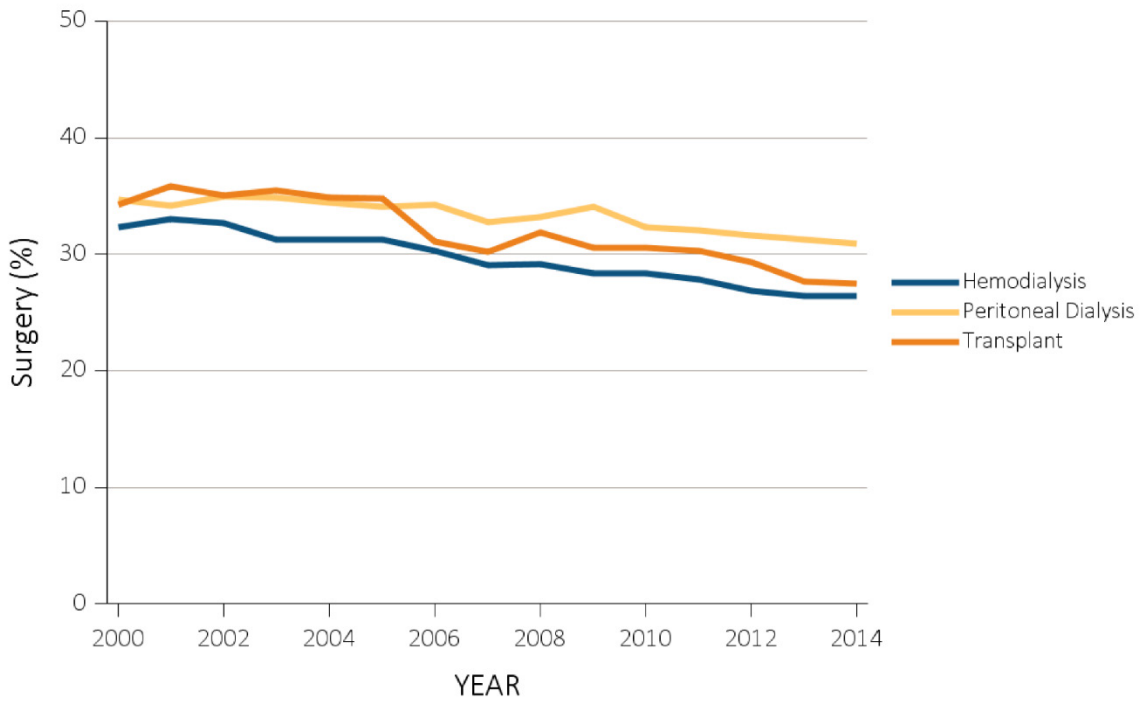
Figure 12.5 continued on next page.

vol 2 Figure 12.5 Inpatient surgical procedures among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014 *(continued)*

(e) Inpatient surgical procedures by sex



(f) Inpatient surgical procedures by modality



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. Inpatient surgical procedures identified by ICD-9 code search. Abbreviation: ESRD, end-stage renal disease.

Inpatient deaths

Based on Medicare Institutional claims, 44.7% of ESRD deaths occurred in the hospital during 2000-2014 (Figure 12.6). The proportion of inpatient deaths was highest for those aged 20-44 years (49.3%) and lowest for those aged 85 years and older (36.6%). Death in the hospital was most common for those of Other races (53.0%) and least common in Whites (42.6%), and was more common in Hispanics than non-Hispanics (50.1% vs. 43.8%). Inpatient death was also more common in females than males (46.4% vs. 43.3%), and in patients whose most recent modality was transplant rather than PD or HD (48.9% vs. 48.0% vs. 44.3%).

The percentage of inpatient deaths decreased from 49.2% in 2000 to 39.6% in 2014; a decline was present for most subgroups examined. When we instead used information from the CMS 2746, 62.6% of decedents for whom this information was available were reported to have died in the hospital, declining from 68.5% in 2000 to 58.4% in 2014. Among patients with complete information from both sources, the sensitivity and specificity of the CMS 2746 form for detecting inpatient deaths based on Medicare claims were 93% and 63%.

vol 2 Figure 12.6 Inpatient deaths among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014

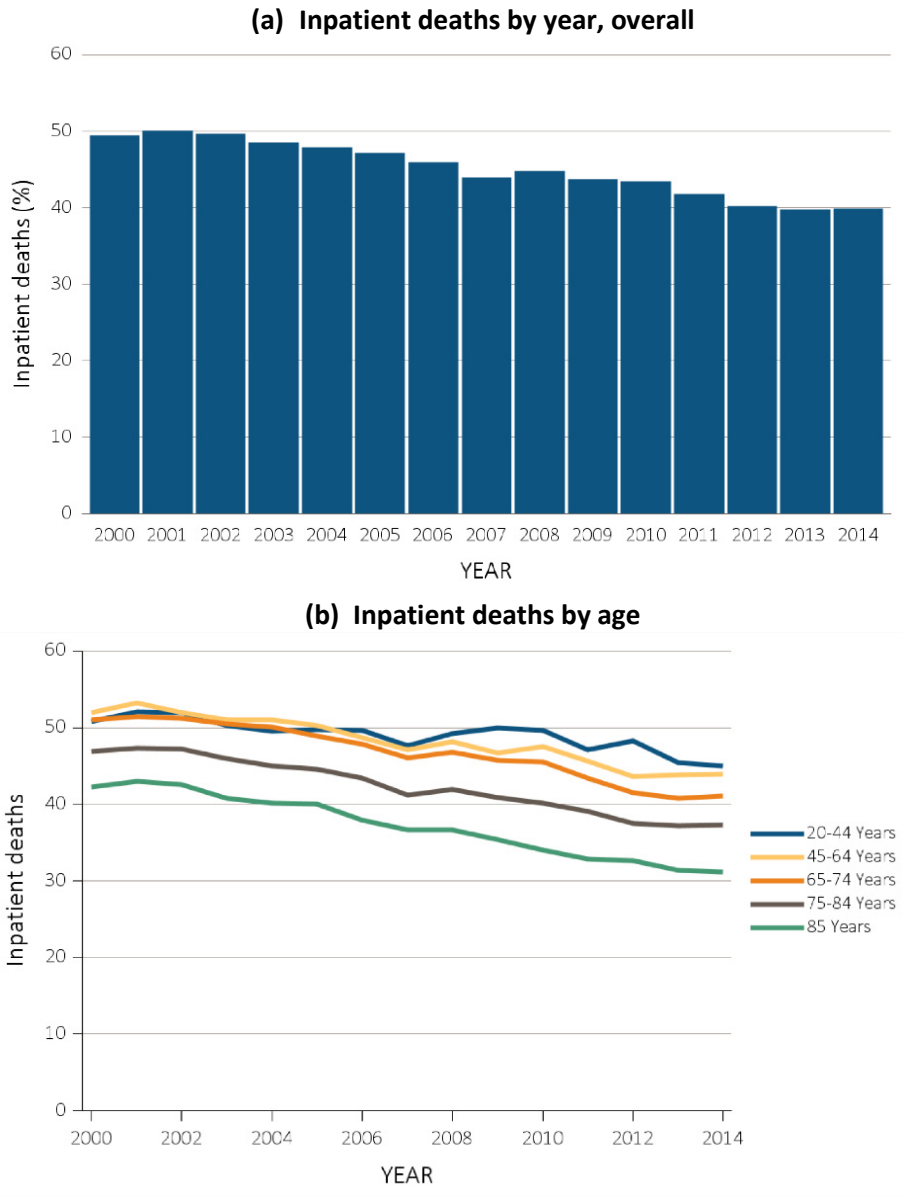
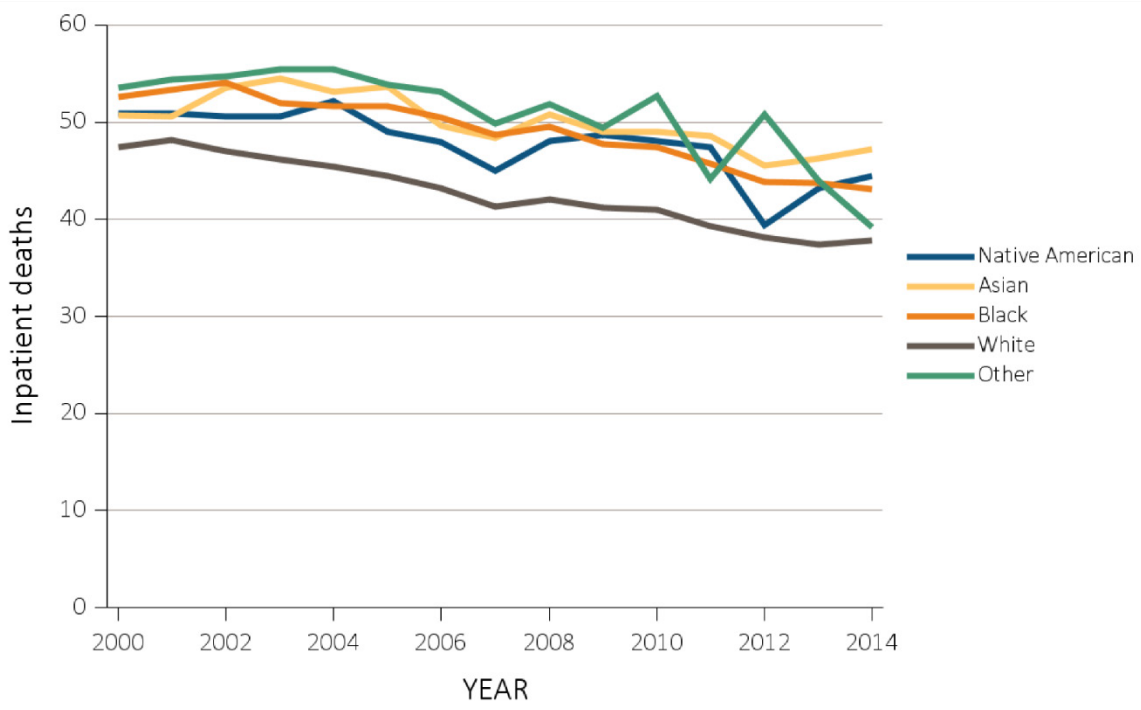


Figure 12.6 continued on next page.

vol 2 Figure 12.6 Inpatient deaths among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014 *(continued)*

(c) Inpatient deaths by race



(d) Inpatient deaths by ethnicity

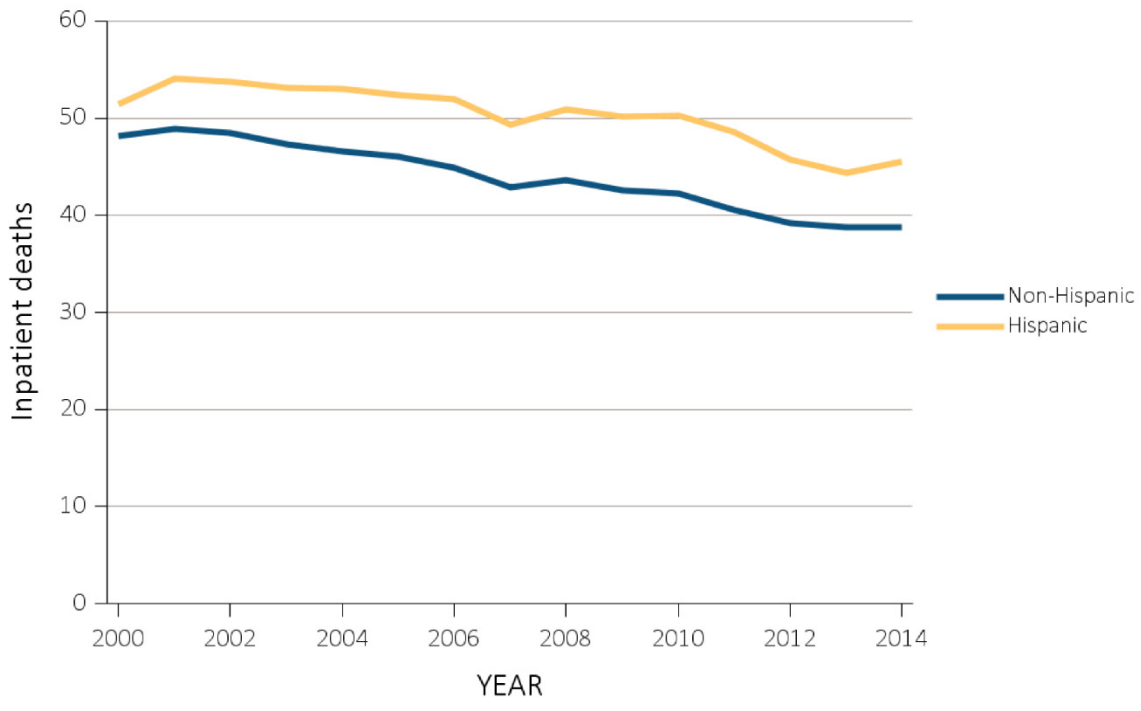
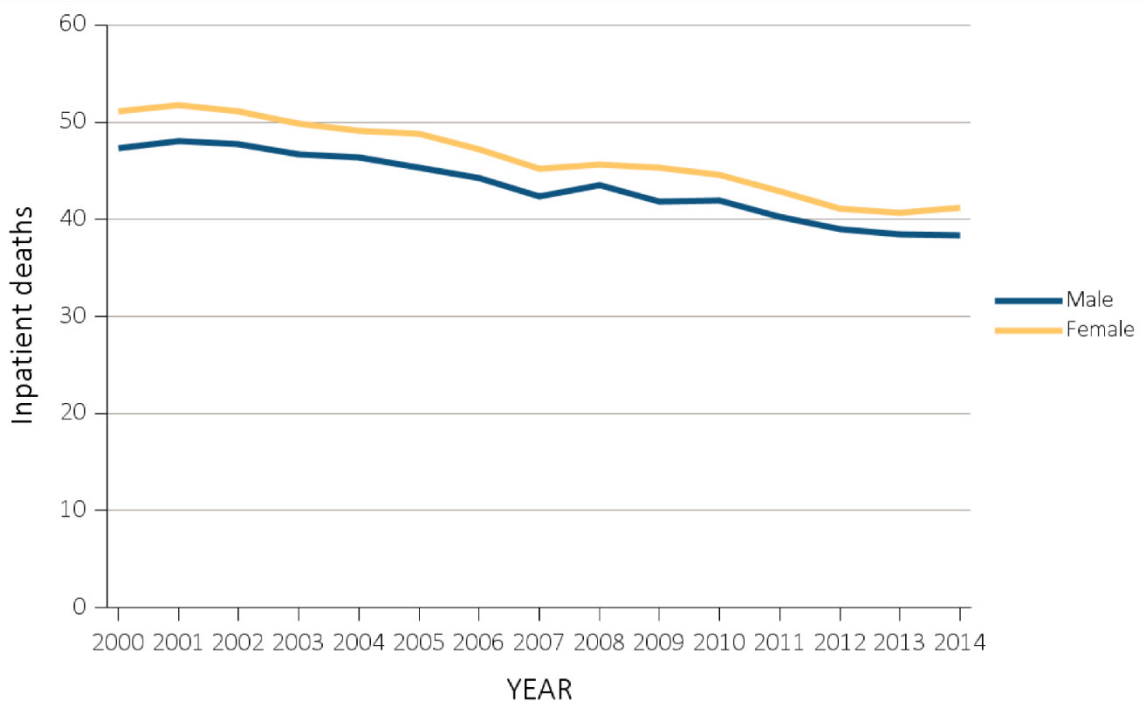


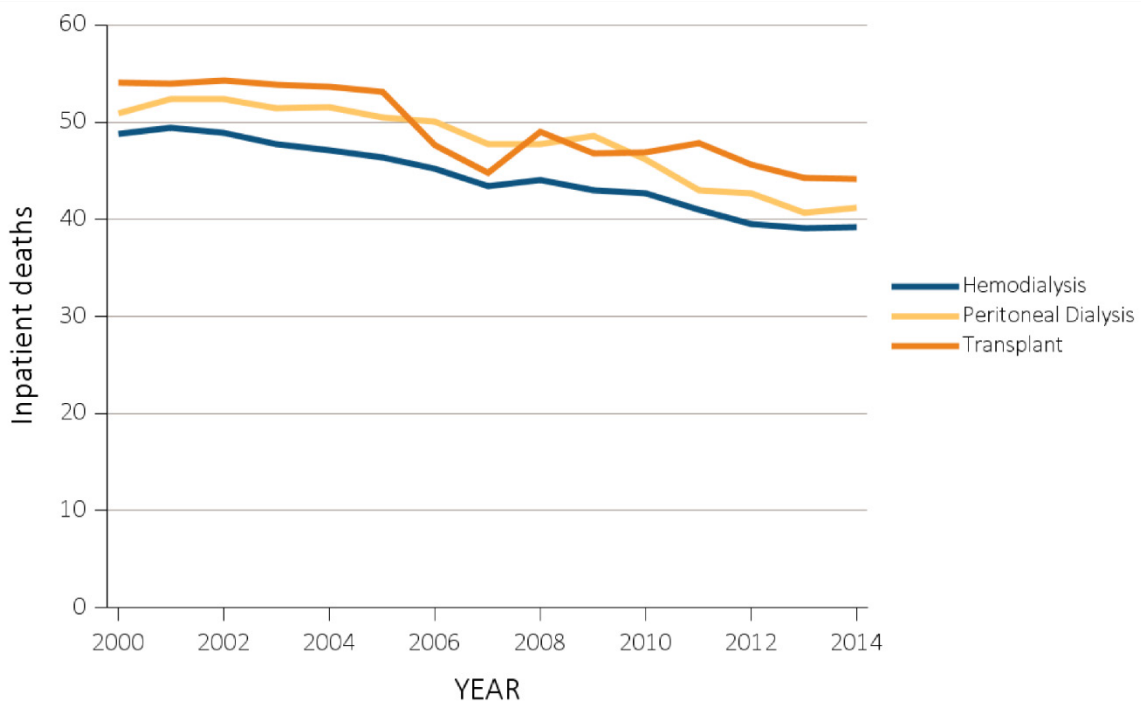
Figure 12.6 continued on next page.

vol 2 Figure 12.6 Inpatient deaths among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014 *(continued)*

(e) Inpatient deaths by sex



(f) Inpatient deaths by modality



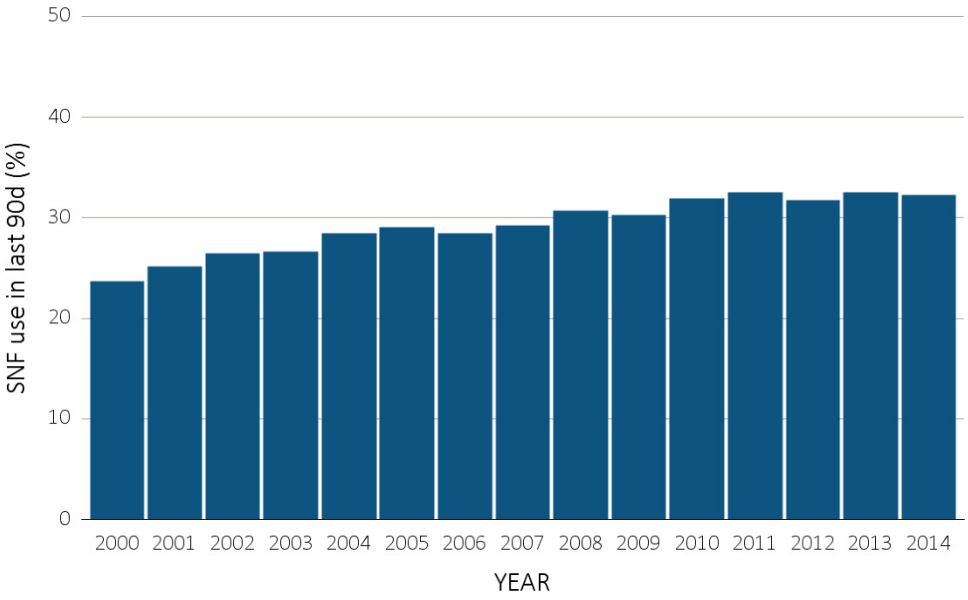
Data Source: Special Analyses, USRDS ESRD Database. Denominator population is all decedents with Medicare Parts A and B throughout the last 90 days of life. Includes deaths occurring in short- and long-stay hospitals. Abbreviation: ESRD, end-stage renal disease.

Skilled Nursing Facility Utilization

Overall, 29.1% of patients were admitted to a SNF during the last 90 days of life (Figure 12.7). Skilled nursing facility use was highest for those aged 85 years and older (39.9%) and lowest for those aged 20-44 years (10.4%). Use was highest for Whites (30.8%) and lowest for those of Other races (12.2%), and was lower for Hispanics than non-Hispanics (22.2% vs. 30.6%). Skilled nursing facility use was higher among females than males (31.5% vs. 27.1%), and for those whose most recent modality at the time of death was HD rather than transplant or PD (30.6% vs. 17.7% vs. 15.1%). The percentage of patients admitted to a SNF in the last 90 days of life increased from 23.5% in 2000 to 32.1% in 2014. A similar increase in SNF use was present for most subgroups examined.

vol 2 Figure 12.7 Skilled nursing facility utilization among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014

(a) Skilled nursing facility utilization by year, overall



(b) Skilled nursing facility utilization by age

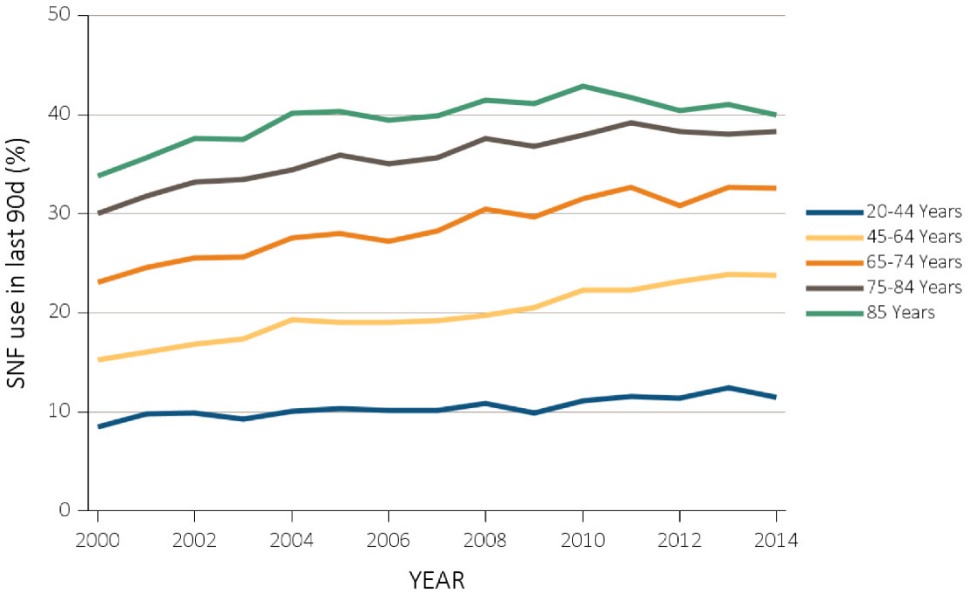
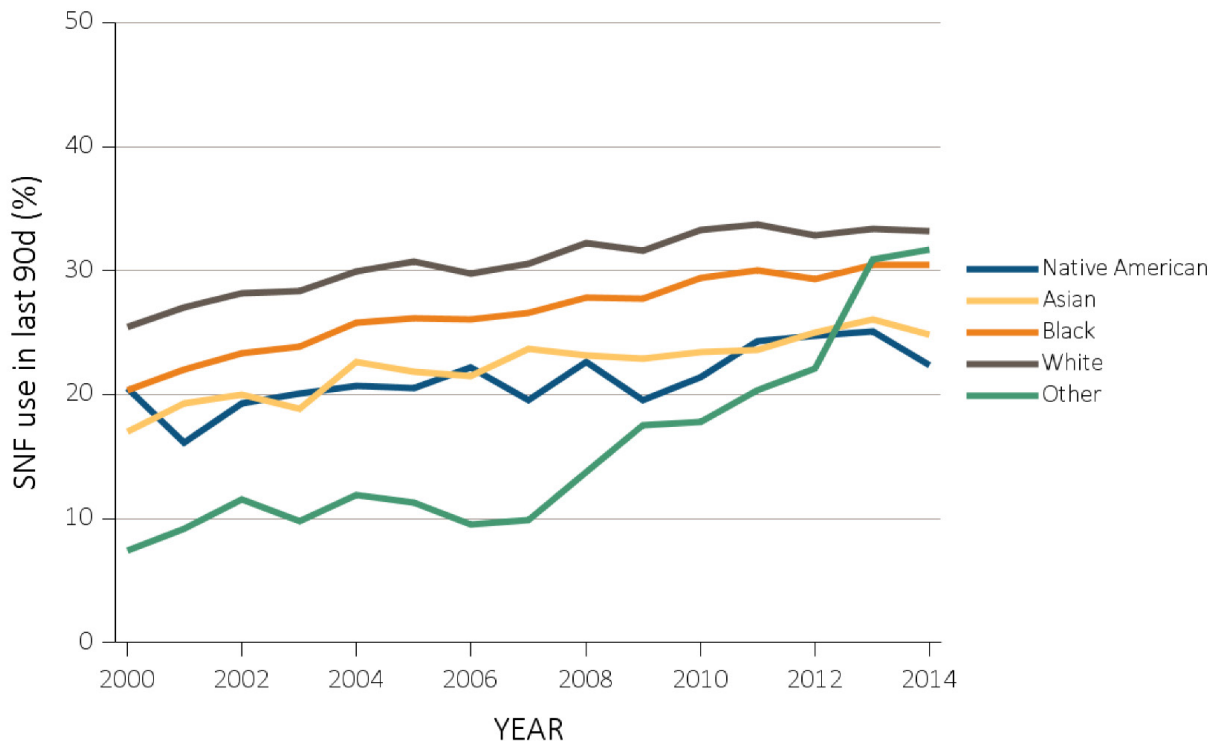


Figure 12.7 continued on next page.

vol 2 Figure 12.7 Skilled nursing facility utilization among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014 *(continued)*

(c) Skilled nursing facility utilization by race



(d) Skilled nursing facility utilization by ethnicity

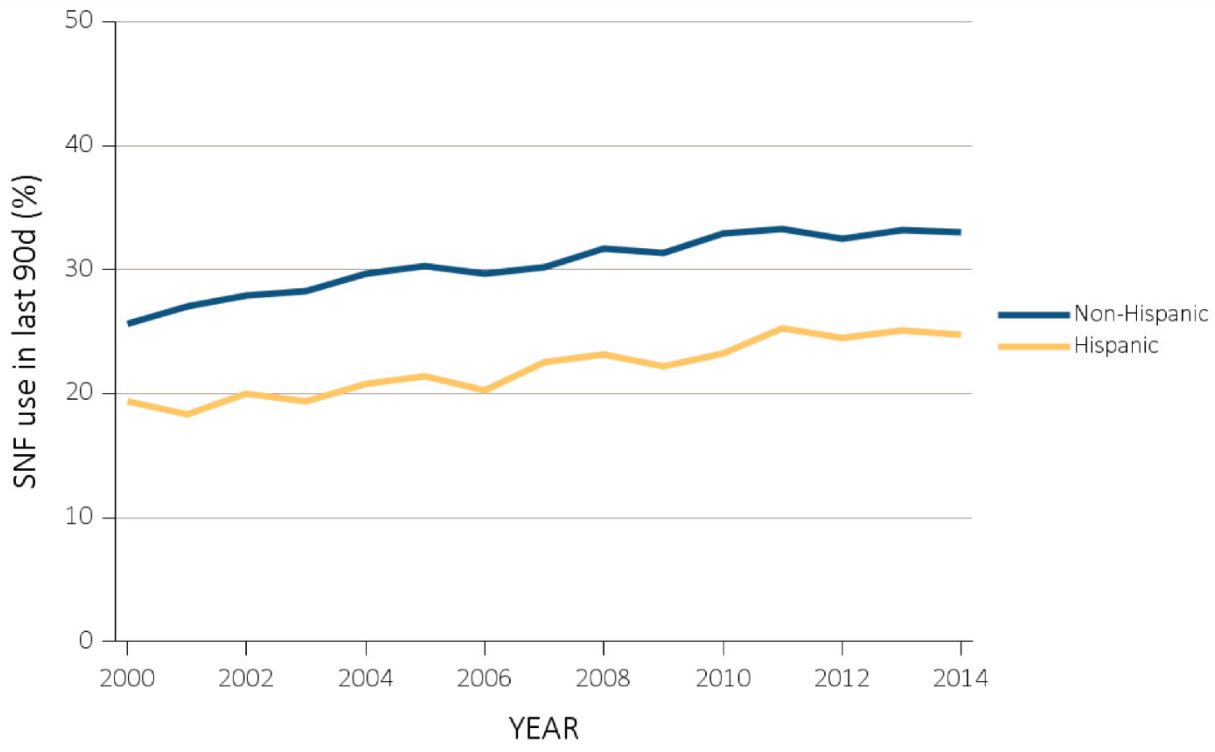
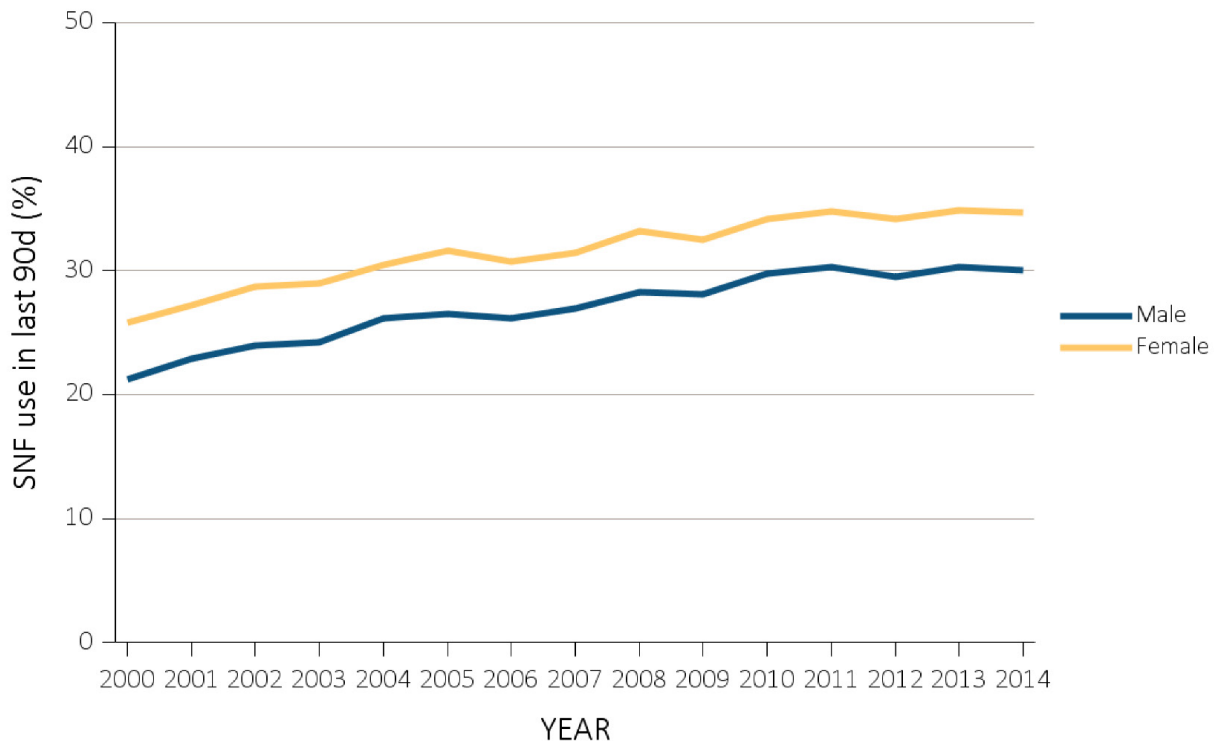


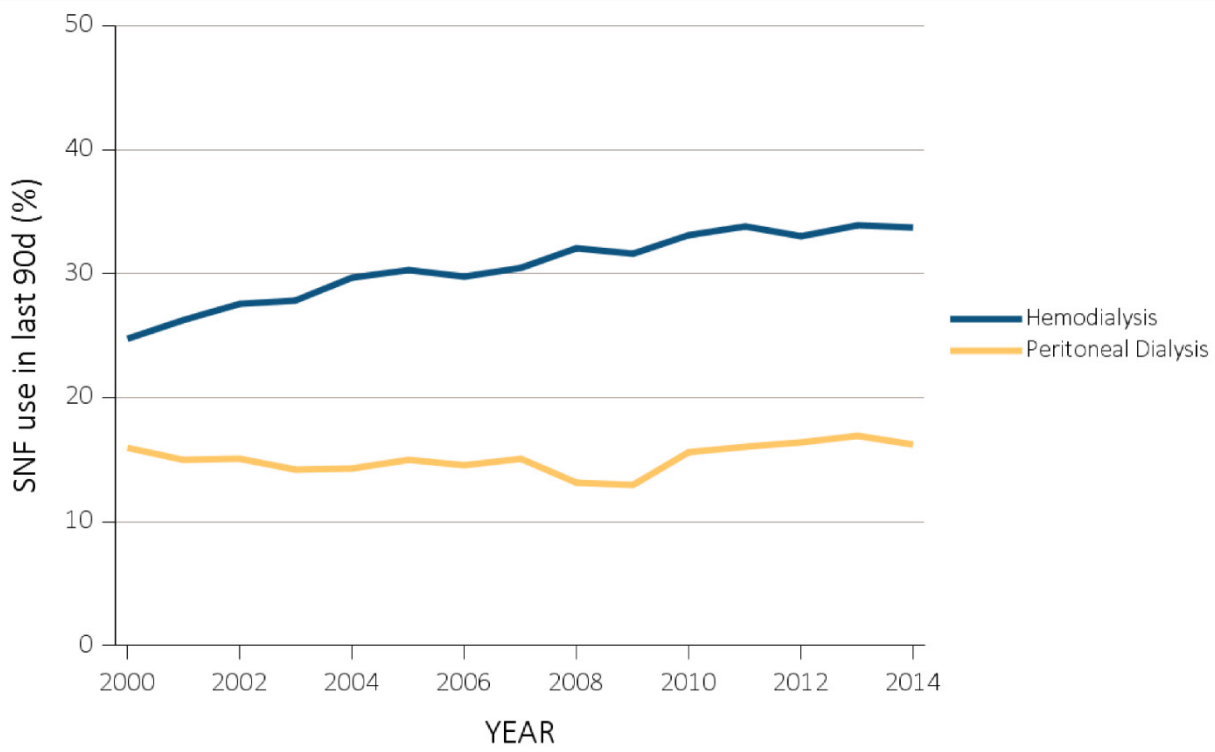
Figure 12.7 continued on next page.

vol 2 Figure 12.7 Skilled nursing facility utilization among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2014 *(continued)*

(e) Skilled nursing facility utilization by sex



(f) Skilled nursing facility utilization by modality



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. Abbreviation: ESRD, end-stage renal disease.

Dialysis Discontinuation before Death

Overall, 23.4% of patients with either HD or PD listed on the CMS 2746 as their most recent modality were reported to have discontinued dialysis treatments before death (Figure 12.8). The frequency of dialysis discontinuation before death was highest for patients aged 85 years and older (34.2%) and lowest for those aged 20-44 years (11.2%). Discontinuation was highest for Whites (27.6%), and lowest for patients of Other races (10.6%), and was higher for non-Hispanics than Hispanics (24.6% vs. 18.0%). Dialysis discontinuation before death was also higher for females than males (24.9% vs. 21.4%), and for those whose most recent modality was HD rather than PD (23.5% vs. 22.4%).

The median time from discontinuation of dialysis to death as reported on the CMS 2746 form was six days (IQR, 3, 12 days). This interval was slightly shorter for those treated with PD (four days, IQR, 2, eight days) than for those treated with HD (seven days, IQR, 4, 12 days), and slightly longer for those who received hospice (seven days, IQR, 4, 13 days) as compared to those who did not (four days, IQR, 2, eight days). The percentage who discontinued dialysis treatment before death increased from 19.6% in 2000 to 25.8% in 2011, decreasing thereafter to 23.8% in 2014. Trends in dialysis discontinuation were similar for most subgroups examined. There was wide geographical variation in discontinuation of dialysis, ranging from 4.4% to 42.2% across states in the continental U.S. This extensive range raises questions about the uniformity of reporting.

vol 2 Figure 12.8 Dialysis discontinuation before death among decedents overall, and by age, race, ethnicity, sex, and modality, 2000-2014

(a) Dialysis discontinuation by year, overall

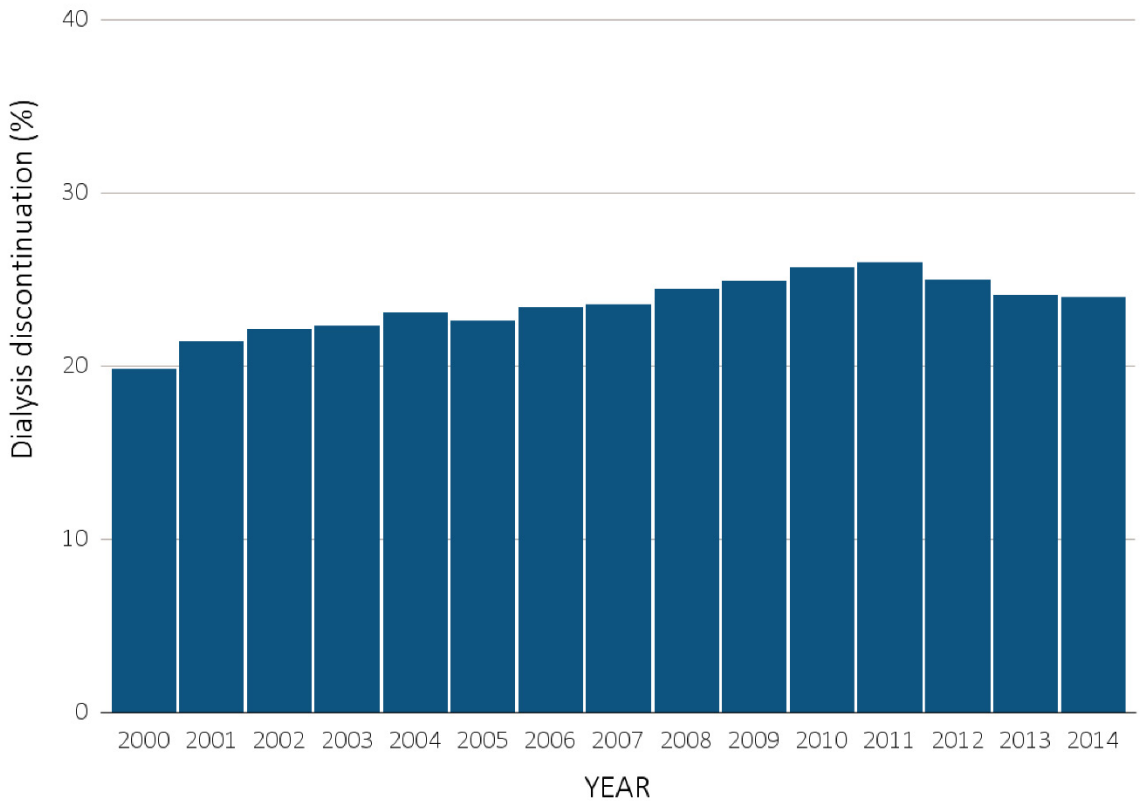
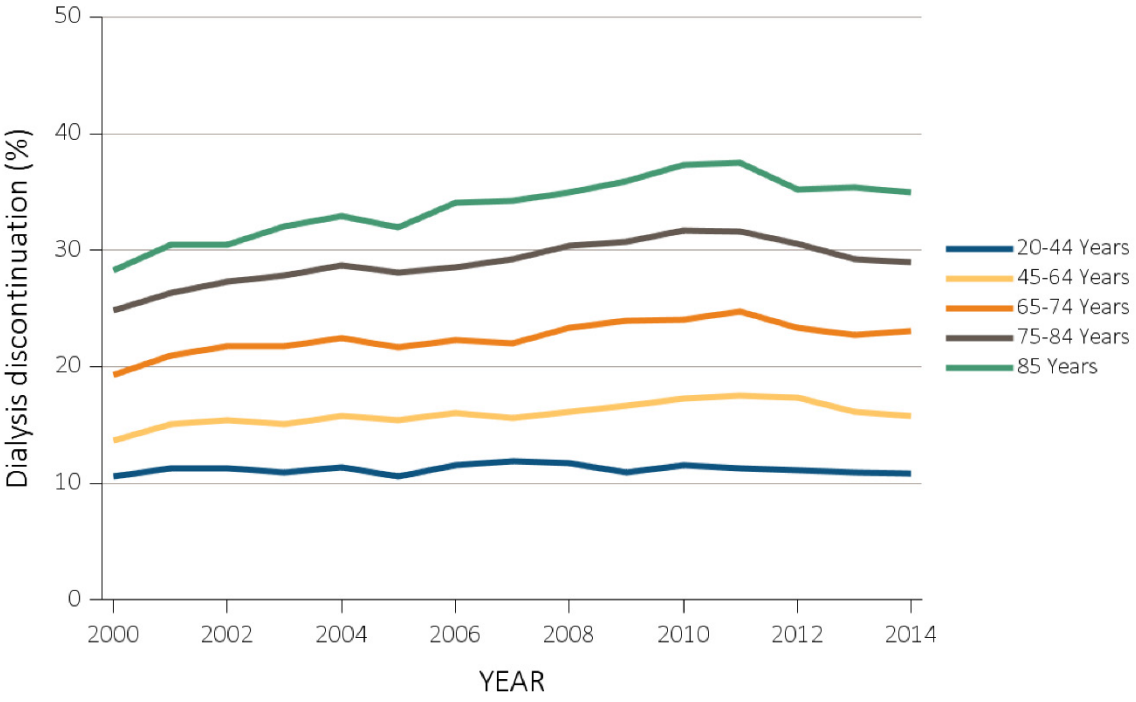


Figure 12.8 continued on next page.

vol 2 Figure 12.8 Dialysis discontinuation before death among decedents overall, and by age, race, ethnicity, sex, and modality, 2000-2014 *(continued)*

(b) Dialysis discontinuation by age



(c) Dialysis discontinuation by race

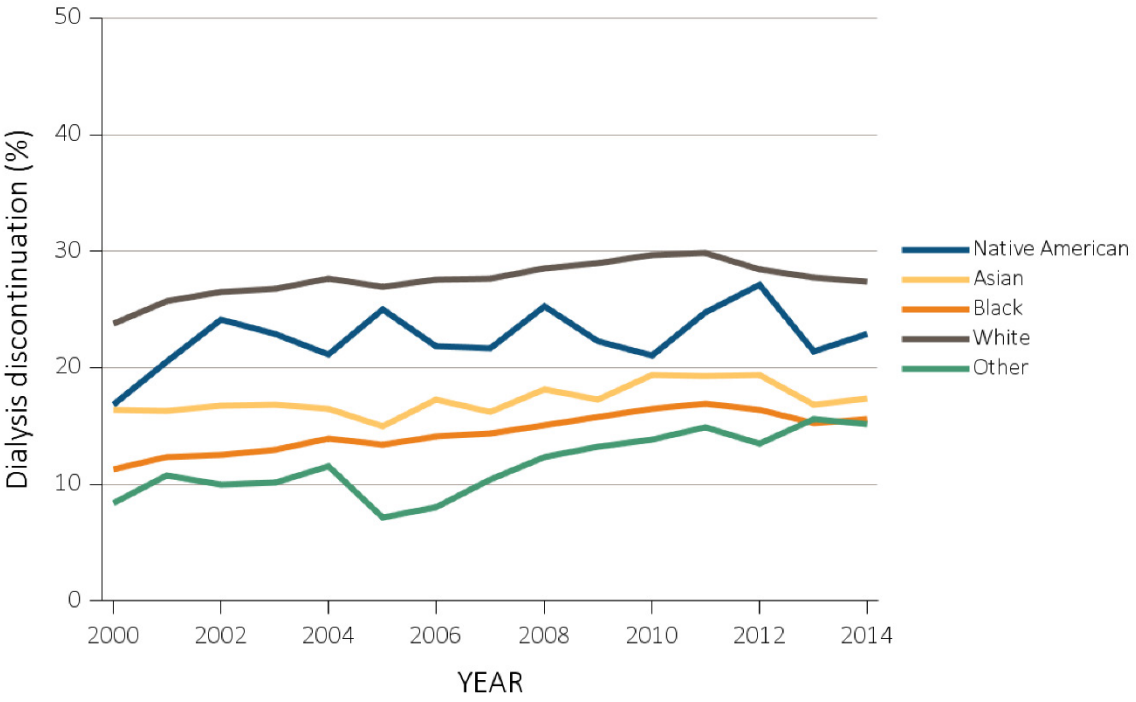
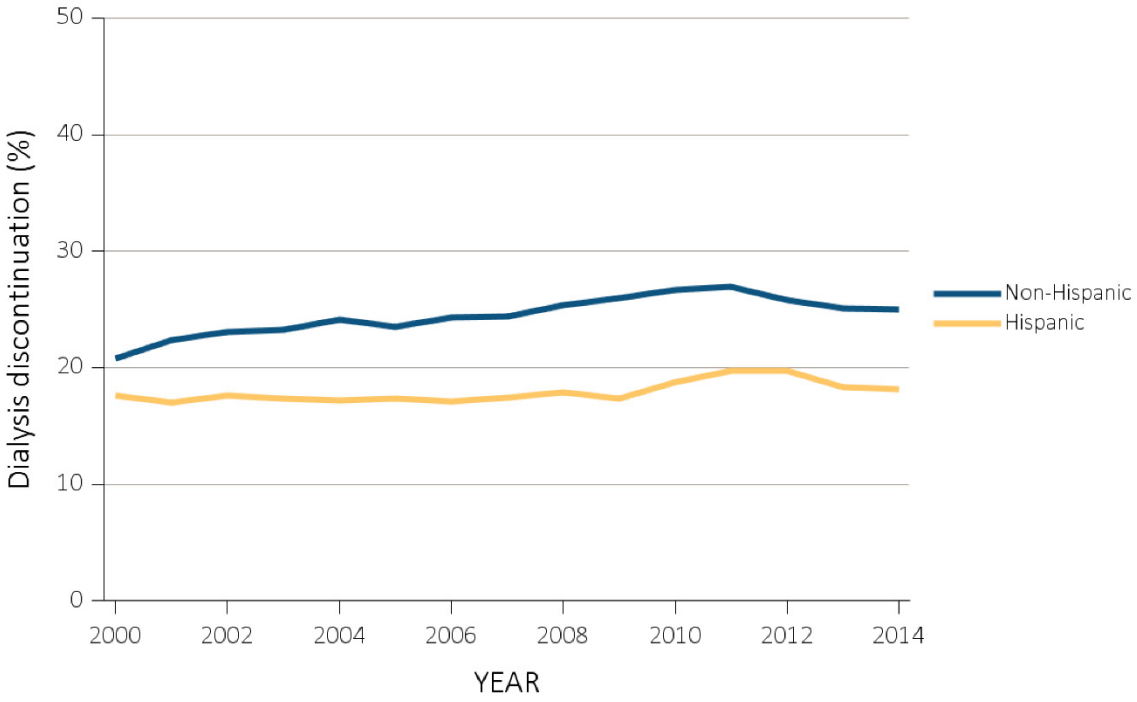


Figure 12.8 continued on next page.

vol 2 Figure 12.8 Dialysis discontinuation before death among decedents overall, and by age, race, ethnicity, sex, and modality, 2000-2014 *(continued)*

(d) Dialysis discontinuation by ethnicity



(e) Dialysis discontinuation by sex

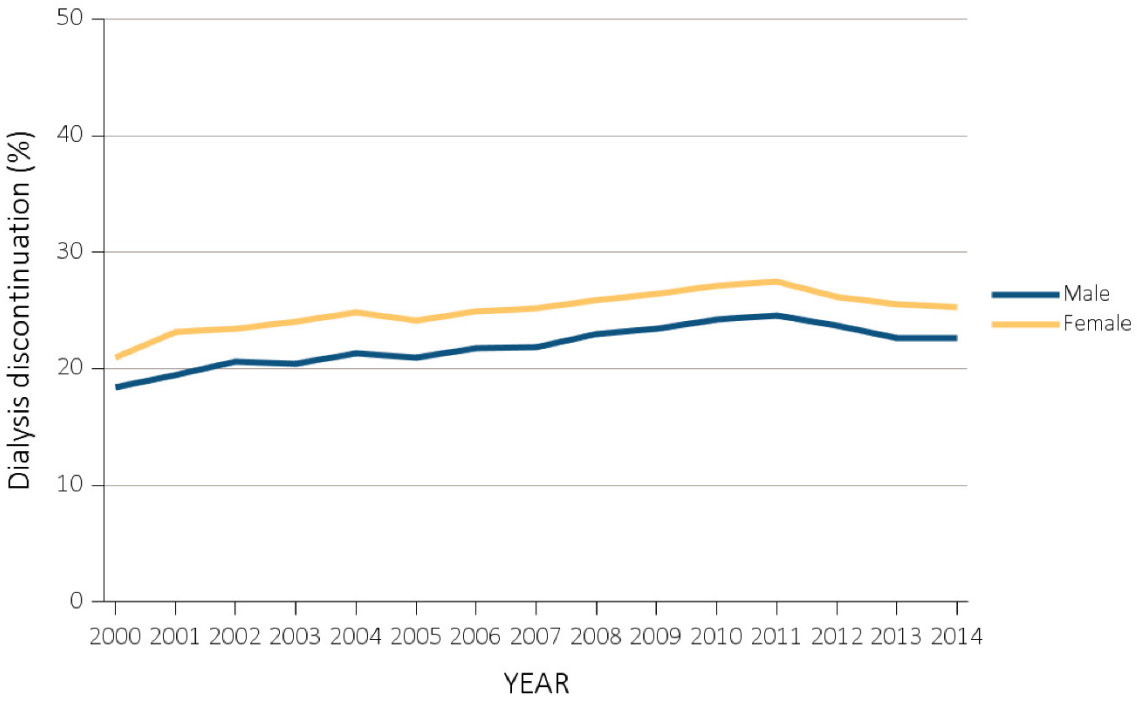
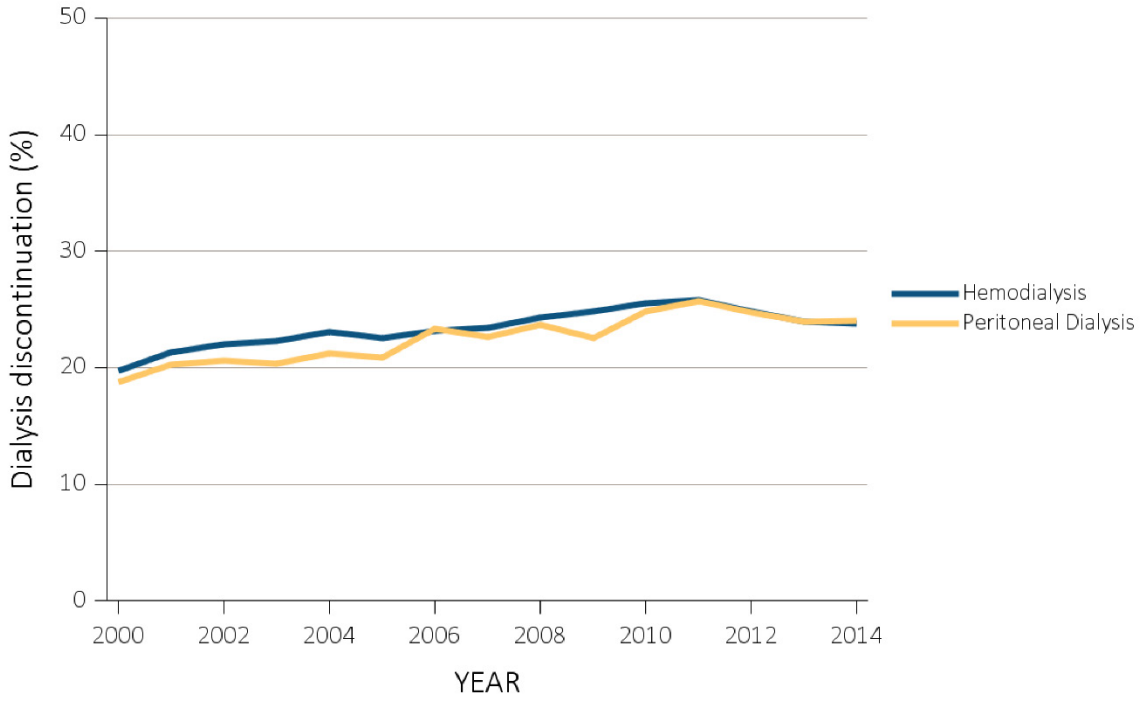


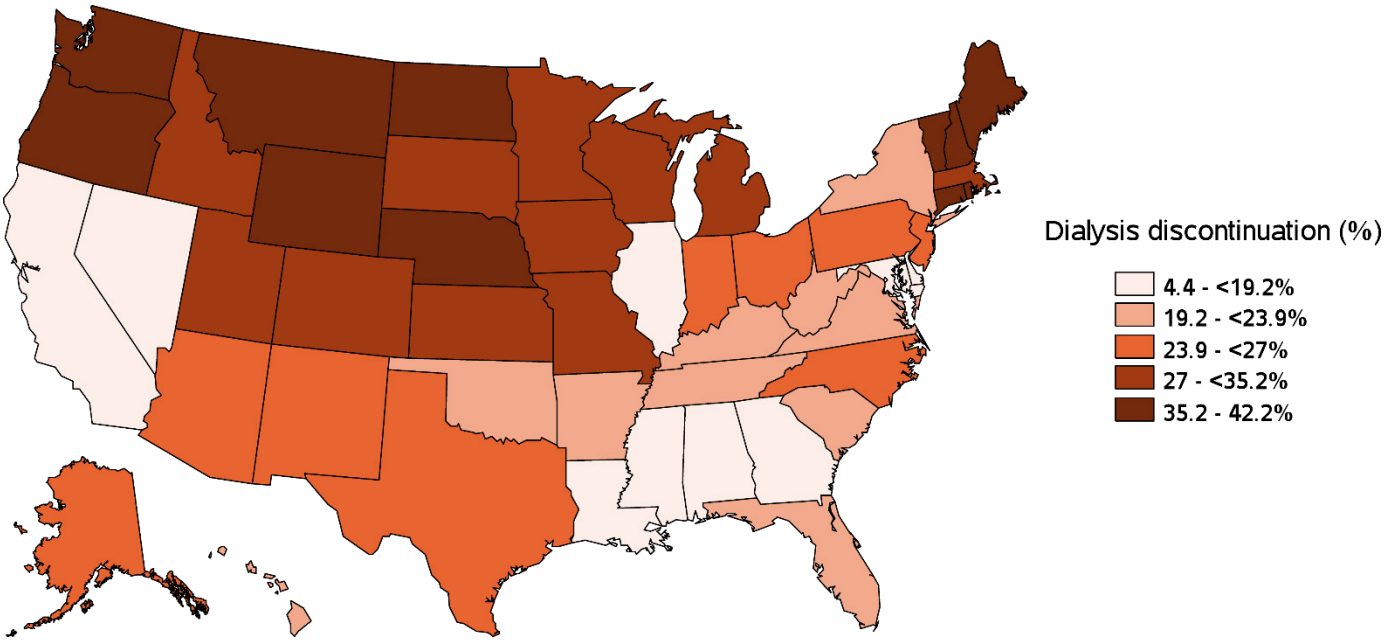
Figure 12.8 continued on next page.

vol 2 Figure 12.8 Dialysis discontinuation before death among decedents overall, and by age, race, ethnicity, sex, and modality, 2000-2014 *(continued)*

(f) Dialysis discontinuation by modality



(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.

vol 2 Table 12.2 Characteristics of patients with ESRD who resided in nursing home during the last year of life, 2000-2010

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	Total
n	23237	25789	27216	28743	30307	31205	33323	33518	33452	34480	33337	334607
Age, mean (std)	71.93 (11.32)	71.89 (11.45)	72.13 (11.50)	72.25 (11.45)	72.14 (11.59)	72.44 (11.54)	72.07 (11.90)	72.06 (11.96)	72.09 (11.87)	72.07 (11.85)	71.96 (11.86)	72.10 (11.69)
Age Category												
20-44	2.50	2.51	2.52	2.19	2.33	2.14	2.41	2.38	2.21	1.97	2.04	2.28
45-64	18.93	19.48	19.04	19.94	20.38	19.94	21.82	21.92	22.22	22.82	23.36	21.05
65-74	31.85	31.05	30.41	29.31	29.22	28.56	27.3	27.45	27.78	28.04	28.13	28.84
75-84	36.17	36.36	36.57	36.67	36.02	36.81	35.48	34.74	34.1	33.28	32.36	35.21
>=85	10.54	10.60	11.46	11.9	12.05	12.56	12.99	13.52	13.69	13.9	14.12	12.62
Vintage, mean (std)	0.96(1.57)	0.99(1.57)	1.01(1.61)	1.03(1.69)	1.04(1.70)	1.05(1.72)	1.08(1.75)	1.12(1.78)	1.18(1.83)	1.20(1.91)	1.22(1.91)	1.09(1.75)
Vintage Category												
<1yr	70.50	69.96	69.57	70	69.64	69.68	68.78	67.44	66.11	65.92	65.62	68.31
1-3yrs	17.78	17.65	18.17	17.09	17.02	17.02	17.41	18.12	18.76	18.21	18.26	17.79
>3yr	8.64	8.99	9.34	9.77	10.03	9.97	10.31	10.91	11.48	11.98	12.27	10.45
Missing	3.08	3.39	2.93	3.14	3.31	3.32	3.5	3.53	3.65	3.9	3.85	3.44
Race												
Native American	1.11	0.88	1.04	0.89	0.93	0.87	0.89	0.85	0.94	0.87	0.86	0.91
Asian	1.99	2.16	2.07	2.2	2.23	2.27	2.38	2.53	2.37	2.48	2.48	2.31
Black/African American	25.83	26.13	26	26.16	26.76	26.37	26.58	26.74	26.51	27	26.65	26.47
White	70.49	70.13	70.15	69.96	69.3	70.01	69.83	69.57	69.85	69.27	69.68	69.81
Other	0.59	0.71	0.75	0.79	0.77	0.47	0.32	0.3	0.34	0.37	0.33	0.5
Hispanic												
Non-Hispanic	77.28	80.59	83.25	84.33	85.71	86.36	87.41	87.73	88.04	88.26	88.46	85.61
Hispanic	6.53	6.65	6.92	7.23	7.05	7.68	7.38	7.81	7.93	7.93	8.09	7.44
Missing/Unknown	16.19	12.76	9.83	8.45	7.24	5.96	5.21	4.45	4.03	3.81	3.45	6.95
Sex												
Male	46.67	47.28	47.33	47.97	49.1	48.96	49.78	50.24	50.83	51.69	51.76	49.43
Female	53.33	52.72	52.67	52.03	50.9	51.04	50.22	49.76	49.17	48.31	48.24	50.57
Last Treatment Modality												
Hemodialysis	92.09	92.50	93.5	93.72	93.7	94.15	94.02	94.26	94.27	94.36	94.08	93.77
Peritoneal Dialysis	4.83	4.11	3.57	3.14	2.98	2.53	2.48	2.21	2.09	1.74	2.07	2.78
Transplant	2.08	2.27	1.99	2.24	2.46	2.39	2.55	2.77	2.87	3.21	3.11	2.58
Missing/Unknown	1.00	1.12	0.94	0.9	0.85	0.93	0.95	0.75	0.78	0.69	0.73	0.86
Impaired Decision Making												
No	63.72	63.93	63.69	63.52	63.18	63.81	64.74	64.92	64.64	64.06	66.31	64.28
Yes	36.28	36.07	36.31	36.48	36.82	36.19	35.24	34.64	34.86	35.52	33.27	35.54
Missing	N/A	N/A	N/A	N/A	N/A	0.01	0.02	0.44	0.5	0.43	0.41	0.18
Legal Guardian												
No	98.80	98.89	99.06	99.5	99.51	99.5	99.53	99.53	99.62	99.53	99.6	99.4
Yes	1.20	1.11	0.94	0.5	0.49	0.5	0.47	0.47	0.38	0.47	0.4	0.6

Data Source: Includes only patients with a record in the Minimum Data Set that was linked to USRDS between 2000 and 2010. Denominator population is patients with ESRD who died between 2000 and 2010, who were at least 20 years of age at the time of death, received treatment for ESRD for at least 90days, had an advance directive assessment recorded in the Minimum Dataset in the last year of life, and complete demographic information. Abbreviation: ESRD, end-stage renal disease.

Patterns of Hospice Utilization before Death

Overall, 19.7% 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 12.9). Use of hospice services was highest for patients aged 85 years and older (30.1%) and lowest for those aged 20-44 years (7.2%). Hospice use was highest for Whites (23.2%), lowest for those of Other races (7.8%), and higher for non-Hispanics than Hispanics (20.7% vs. 15.9%). Females were more likely to receive hospice than males (20.7% vs. 18.9%), as were those whose most recent modality was HD rather than PD or transplant (19.8% vs. 19.3% vs. 19.3%).

Based on Medicare claims, the percentage of patients receiving hospice services at the time of death differed markedly depending on whether the CMS 2746 form indicated that they did or did not discontinue dialysis (53.9 % vs. 9.5%). This likely reflects both the intertwined nature of these two treatment decisions, and the 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 26.8% in 2014. Hospice utilization increased over time for most subgroups, but an upward trend was far more pronounced for those who discontinued dialysis as compared with those who did not. Hospice use at the time of death ranged from 13.2% to 40.8% across states in the continental U.S.

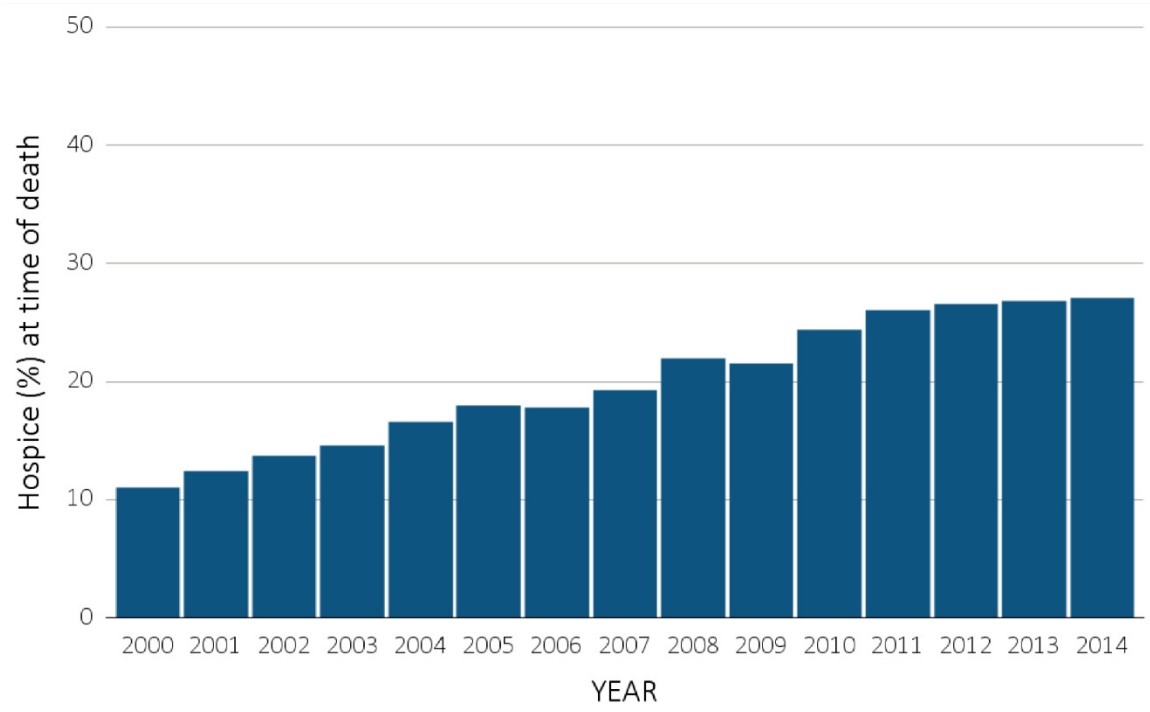
Overall, 21.6% of patients with Medicare Parts A and B as primary payer had an institutional claim for hospice in the last 90 days of life. Among these, the median interval between the first claim for hospice and death was five days (IQR, 2, 13 days), and 39.7% of patients had their first claim for hospice ≤ 3 days before death.

Figure 12.9 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 2746 form, 24.5% of decedents for whom this information was available were reported to have received hospice care before death (data were available only from 2004-2014). The sensitivity and specificity of the CMS 2746 form for detecting hospice at the time of death based on Medicare claims were 83% and 92%, 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 2746 form was highly correlated with dialysis discontinuation before death—75.2% of those who had discontinued dialysis before death received hospice as compared with 6.8% of those who had not.

From 2004-2014, the percentage of patients who received hospice care prior to death based on the CMS 2746 form increased from 17.5% to 28.1% in the overall population for whom this was reported, from 59.3% to 82.2% for the sub-group who discontinued dialysis treatments before death, and from 5.4% to 8.0% for the remaining patients who did not.

vol 2 Figure 12.9 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, 2000-2014

(a) Hospice utilization by year, overall



(b) Hospice utilization by age

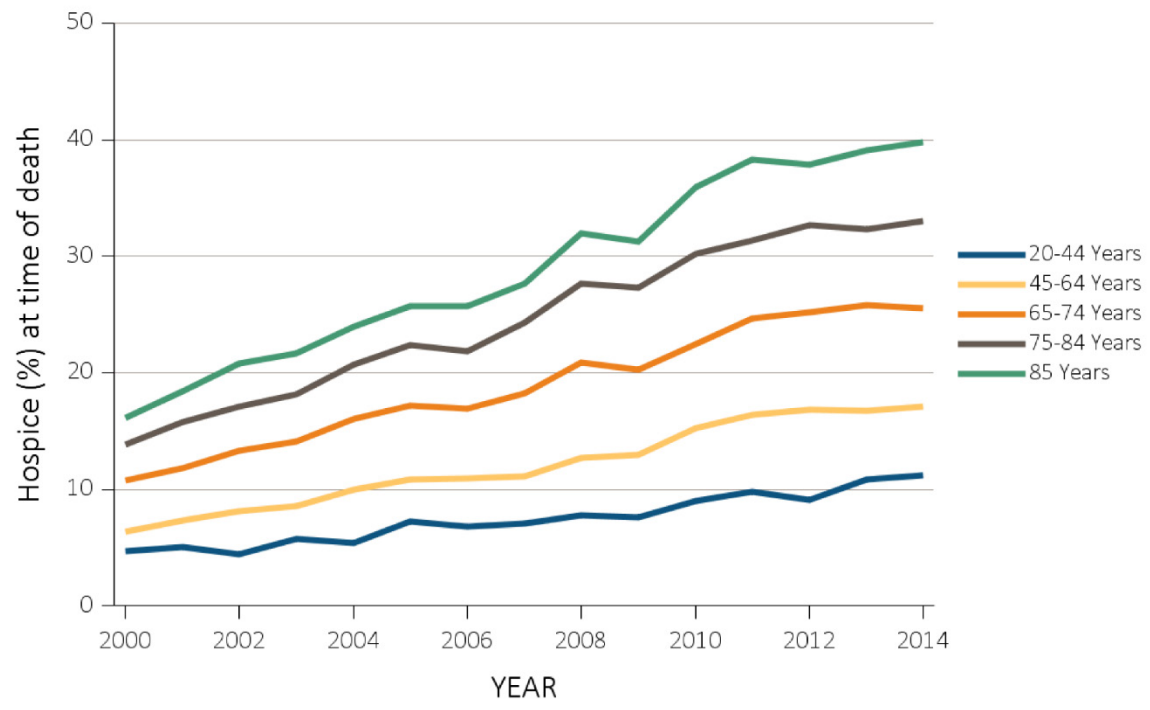
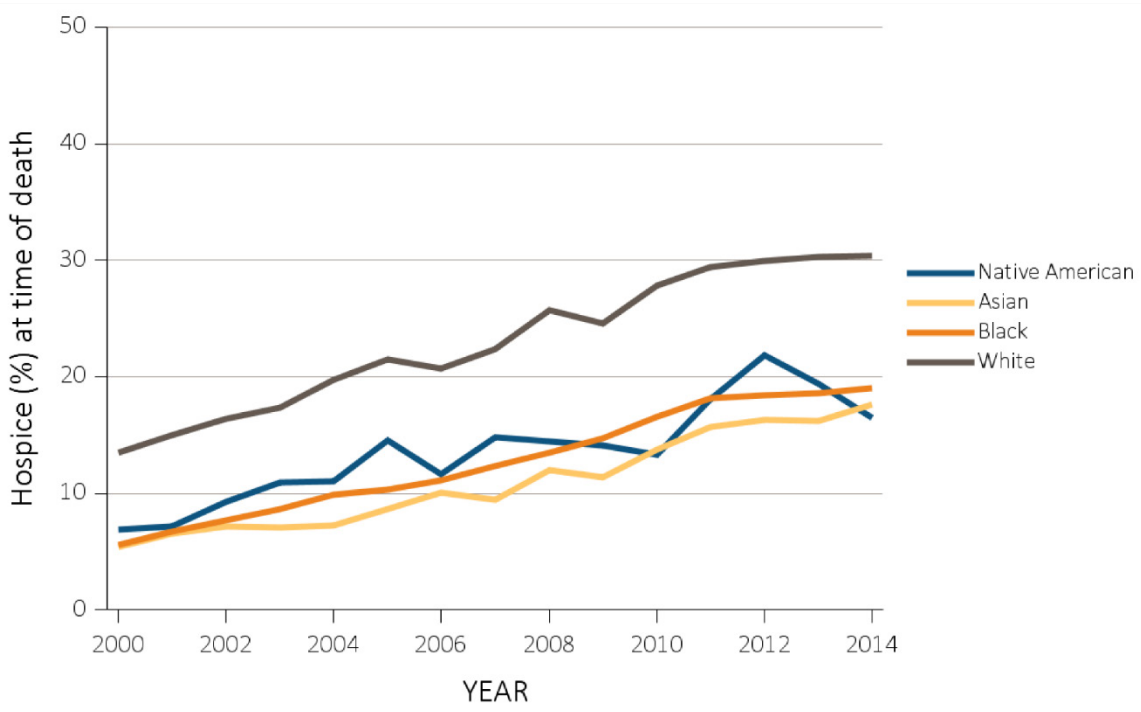


Figure 12.9 continued on next page.

vol 2 Figure 12.9 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, 2000-2014 *(continued)*

(c) Hospice utilization by race



(d) Hospice utilization by ethnicity

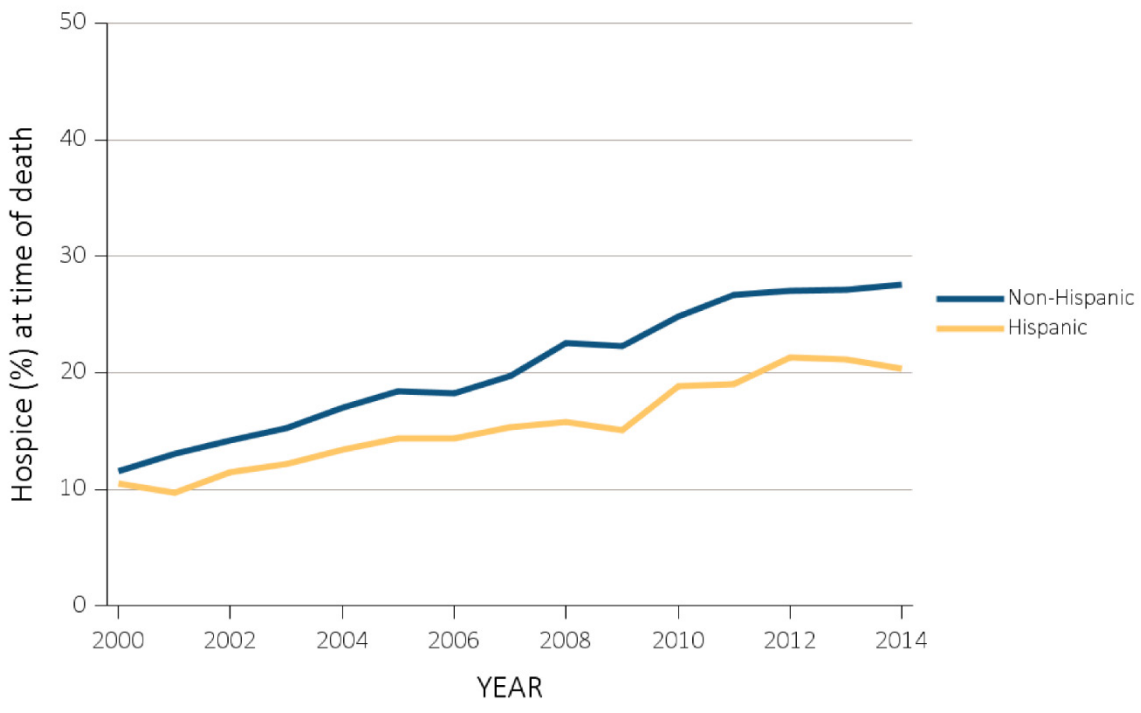
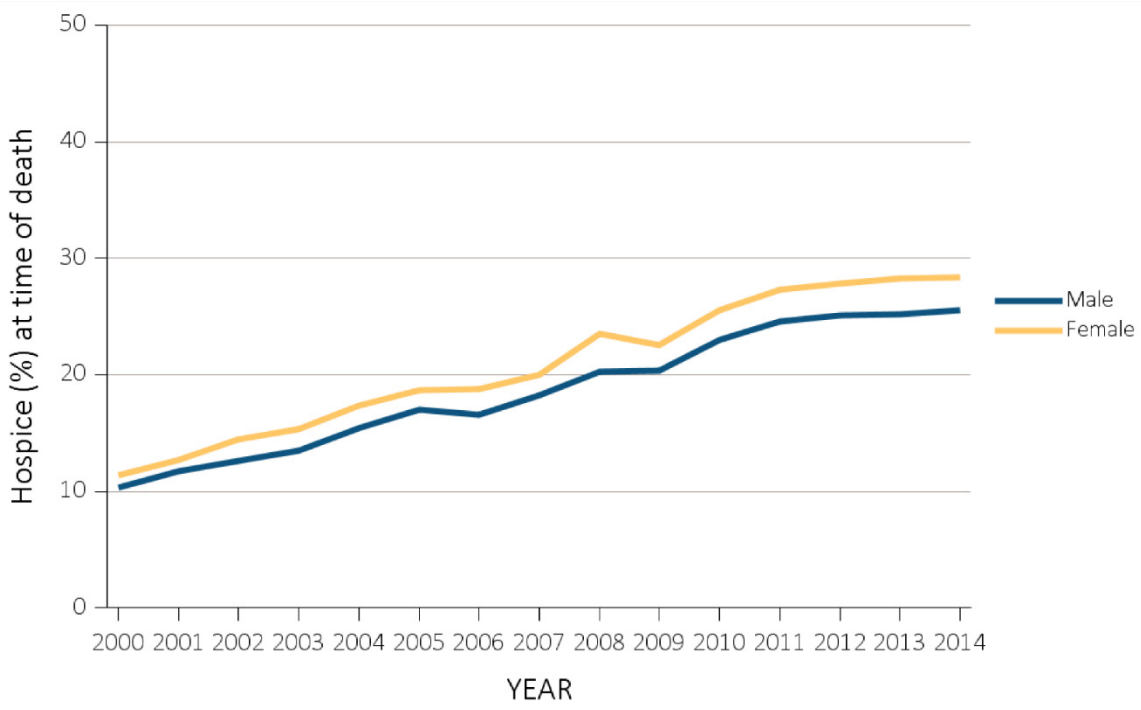


Figure 12.9 continued on next page.

vol 2 Figure 12.9 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, 2000-2014 *(continued)*

(e) Hospice utilization by sex



(f)Hospice utilization by modality

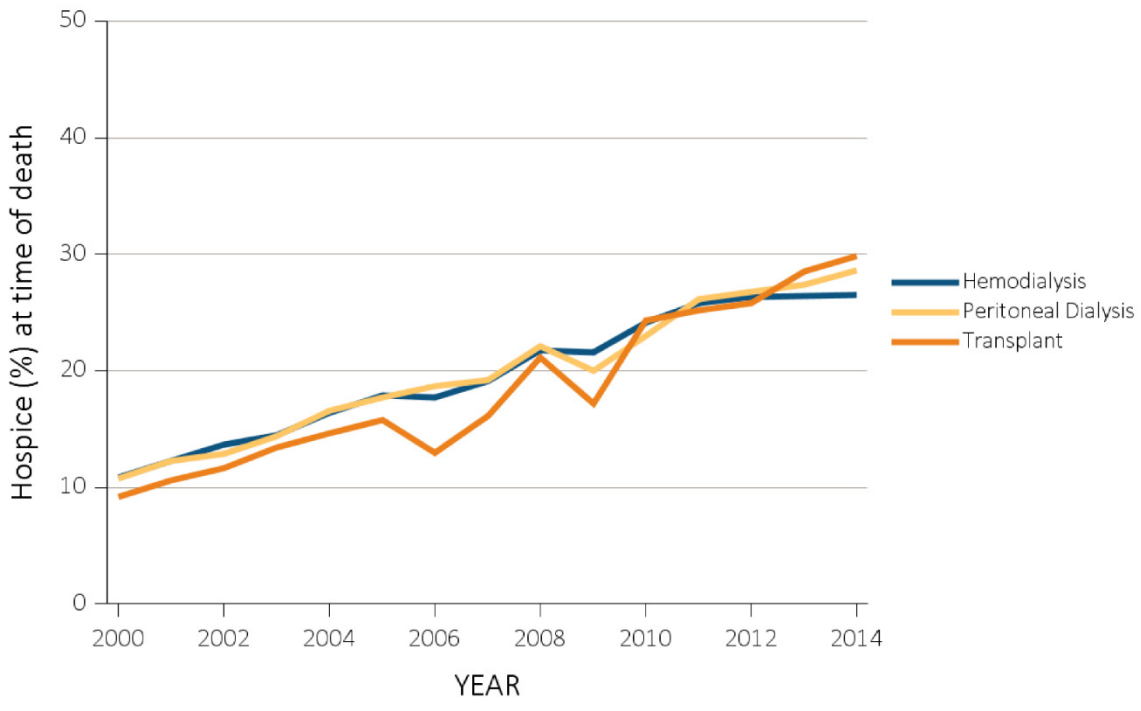
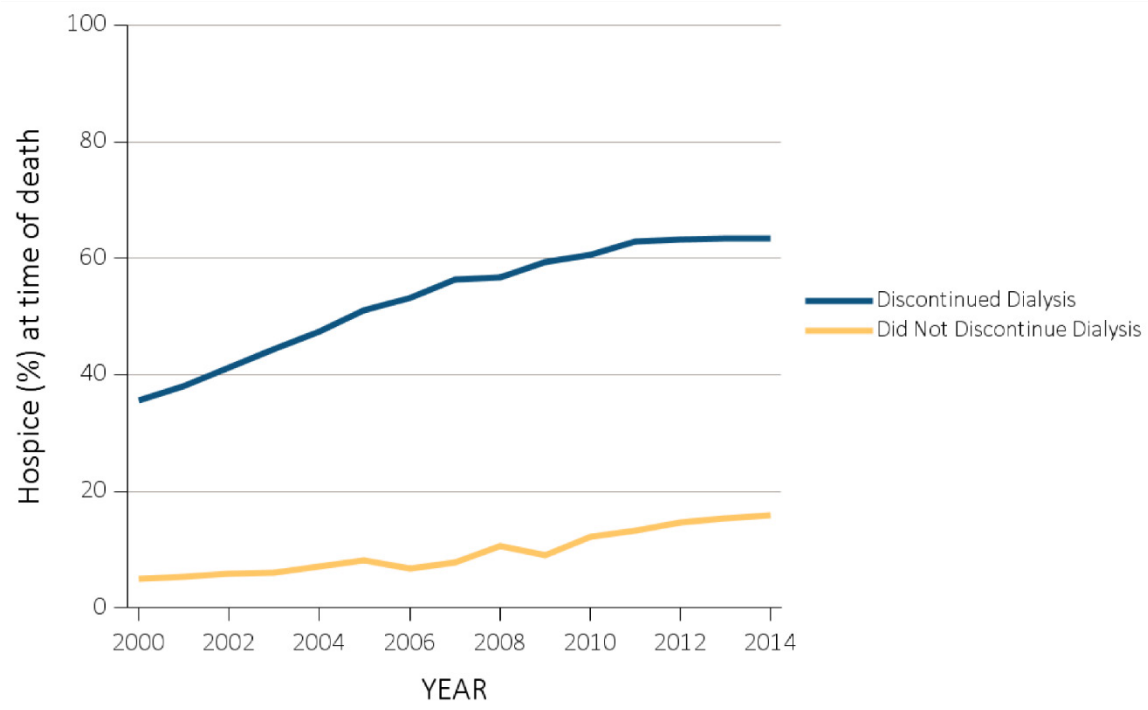


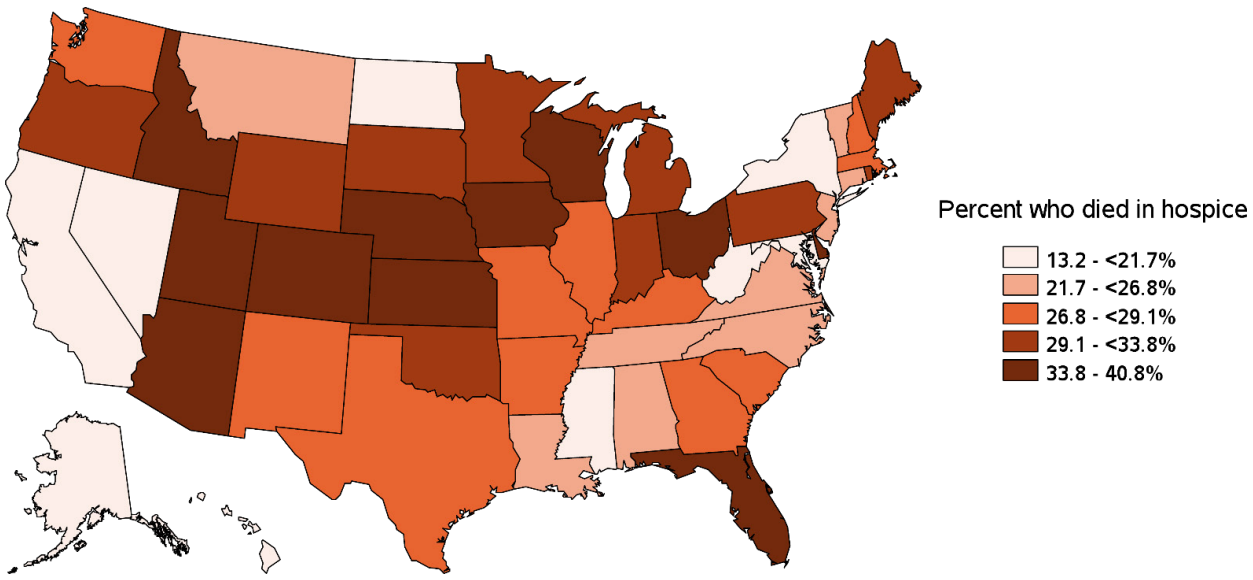
Figure 12.9 continued on next page.

vol 2 Figure 12.9 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, 2000-2014 *(continued)*

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



(h) Hospice Utilization 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. 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.

Advance Directives among ESRD Patients Residing in a Nursing Home in the Last Year of Life

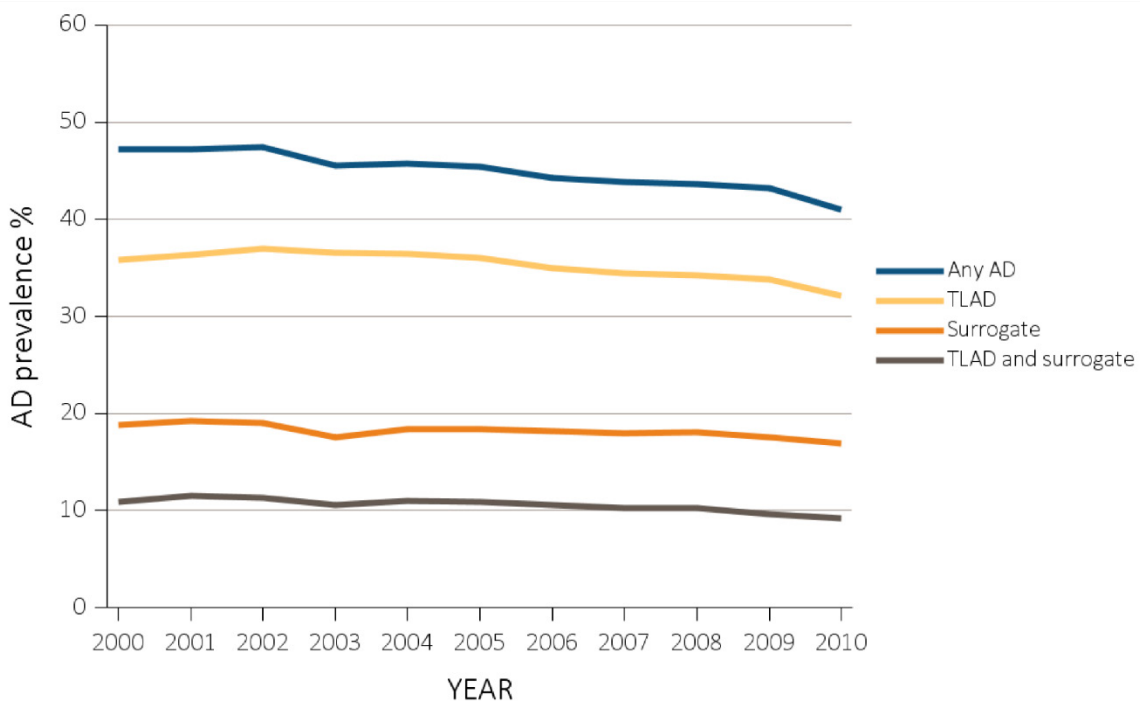
We identified 334,607 nursing home ESRD decedents who between 2000 and 2010 had an advance directive assessment recorded in the MDS in the last year of life (Table 12.2). The average age of decedents who received care in a nursing facility during the last year of life was 72 ±12 years, with a mean time since onset of ESRD of 1 ± 2 years. The most recent modality was HD in 94% of patients, with and PD and transplant each in only 3% of patients.

Overall, 36% of patients had impaired decision-making capacity as assessed by nursing home staff, and <1% had a legal guardian. From 2000 to 2010, mean time since dialysis initiation among decedents increased, as did the percentage of males, non-Whites, patients of Hispanic ethnicity, patients receiving HD (vs. other renal replacement modalities), and patients with impaired decision-making capacity. These rates are much lower than for nursing home decedents with other serious illnesses (Kurella et al., 2017).

The percentage of patients with any type of advance directive declined from 47% in 2000 to 41% in 2010 (Figure 12.10). Similarly, the percentage of patients with a treatment limiting advance directive decreased from 36% in 2000 to 32% in 2010, and the percentage with a surrogate decision maker declined from 19% in 2000 to 17% in 2010.The percentage of patients with both a treatment-limiting directive and a surrogate decision maker declined from 11% in 2000 to 9% in 2010.

vol 2 Figure 12.10 Advance directive prevalence before death among Nursing Home ESRD decedents with ESRD overall, and by age, race, ethnicity, sex, modality, vintage, and impaired decision making, 2000-2010

(a) Advance directive prevalence by year, overall



(b) Advance directive prevalence by age

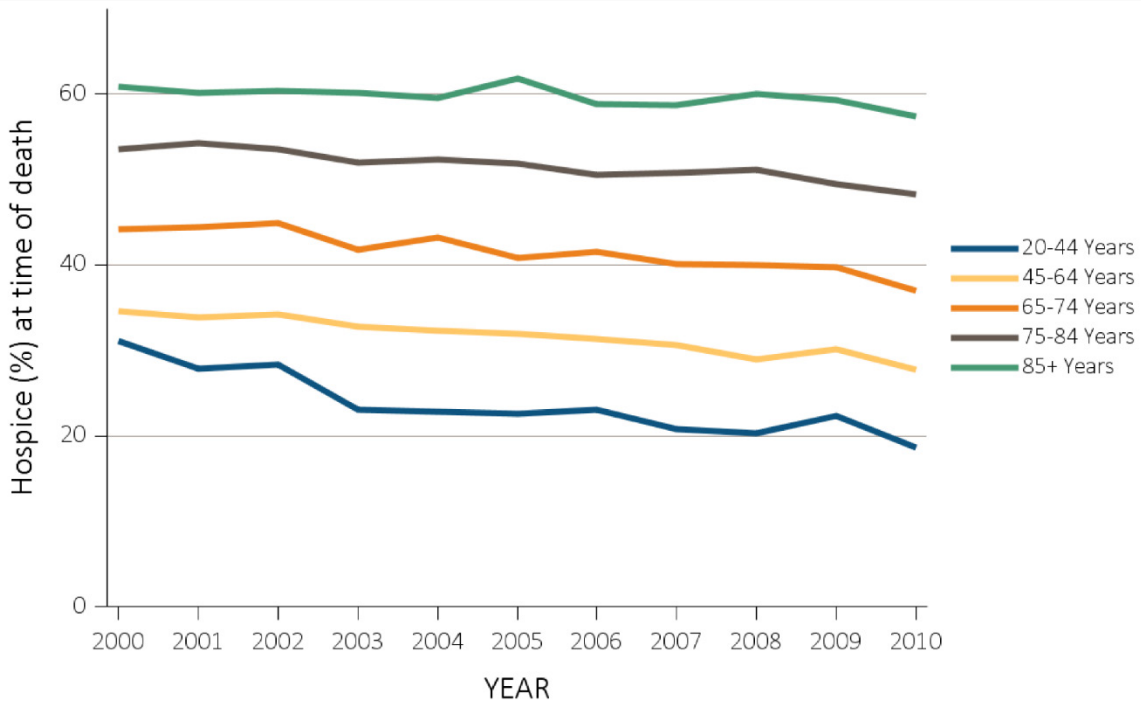
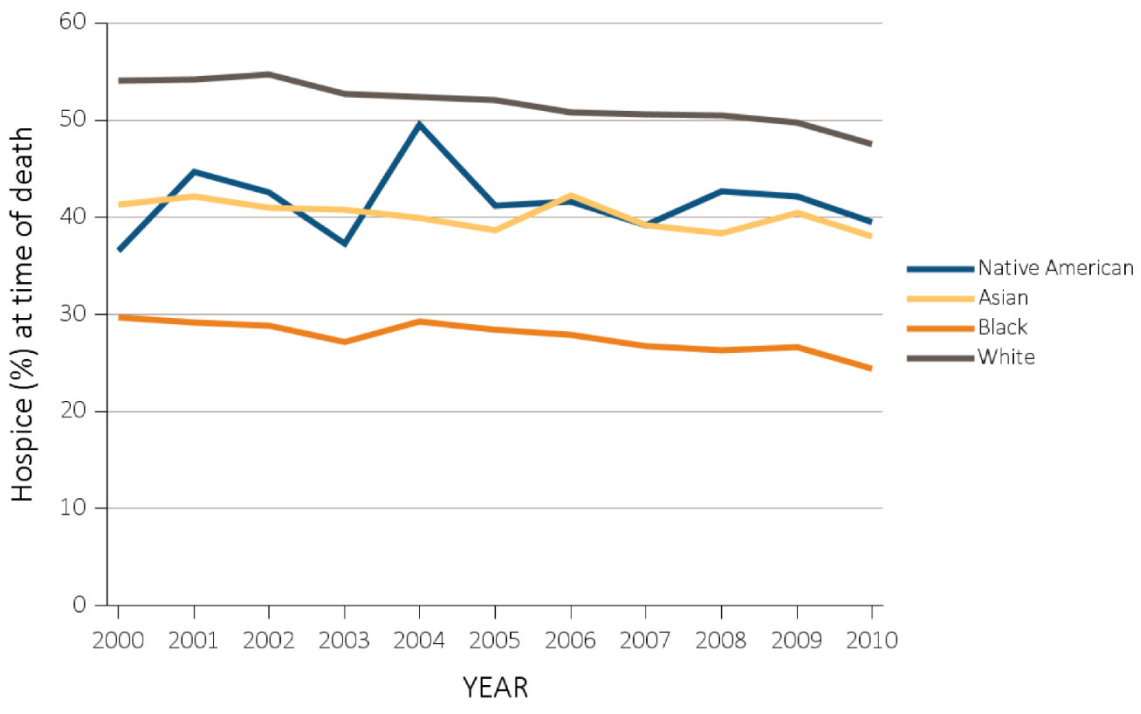


Figure 12.10 continued on next page.

vol 2 Figure 12.10 Advance directive prevalence before death among Nursing Home ESRD decedents overall, and by age, race, ethnicity, sex, modality, vintage, and impaired decision making, 2000-2010 *(continued)*

(c) Advance directive prevalence by race



(d) Advance directive prevalence by ethnicity

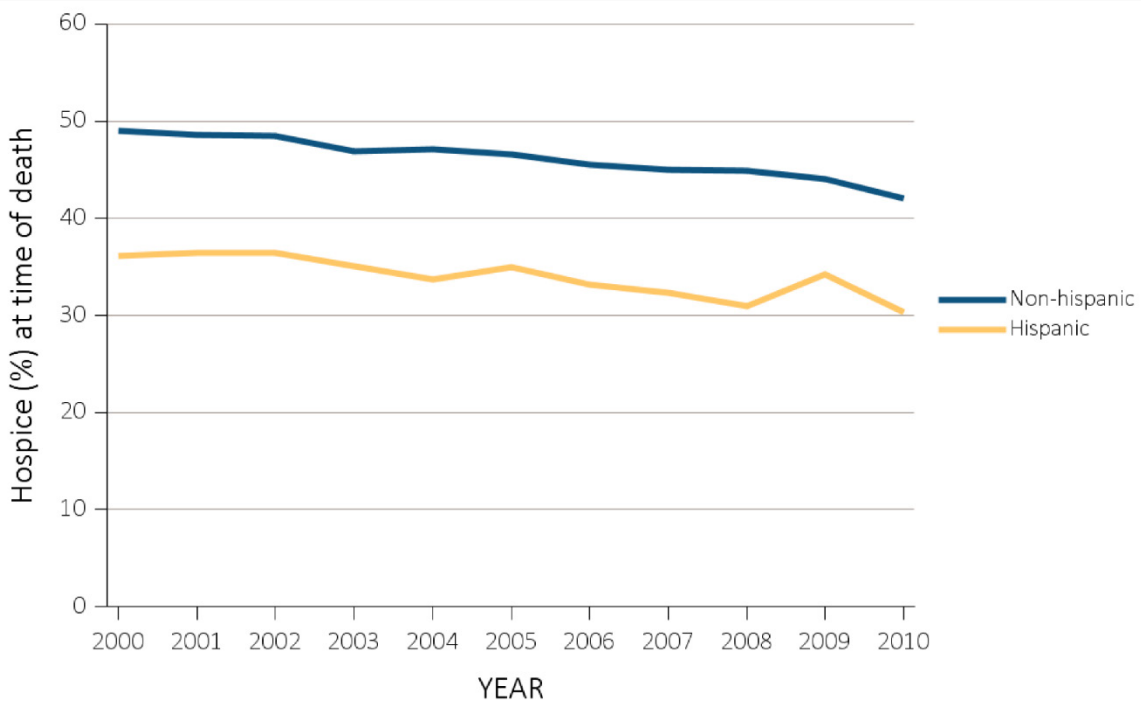
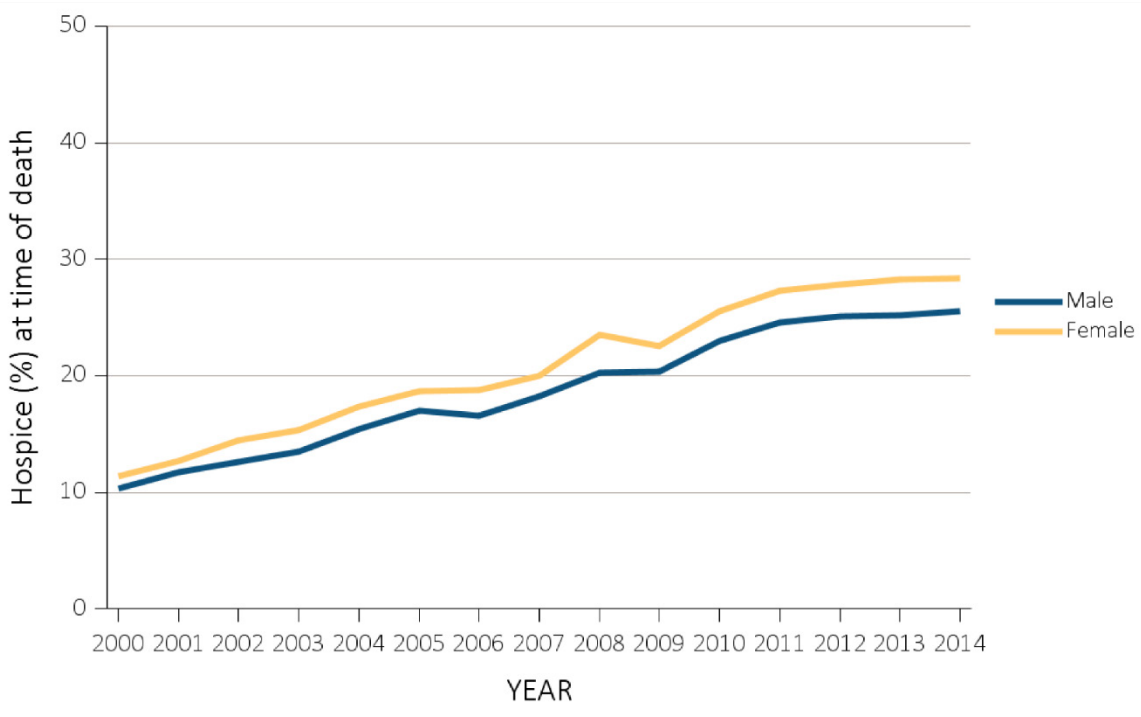


Figure 12.10 continued on next page.

vol 2 Figure 12.10 Advance directive prevalence before death among Nursing Home ESRD decedents overall, and by age, race, ethnicity, sex, modality, vintage, and impaired decision making, 2000-2010 *(continued)*

(e) Advance directive prevalence by sex



(f) Advance directive prevalence by modality

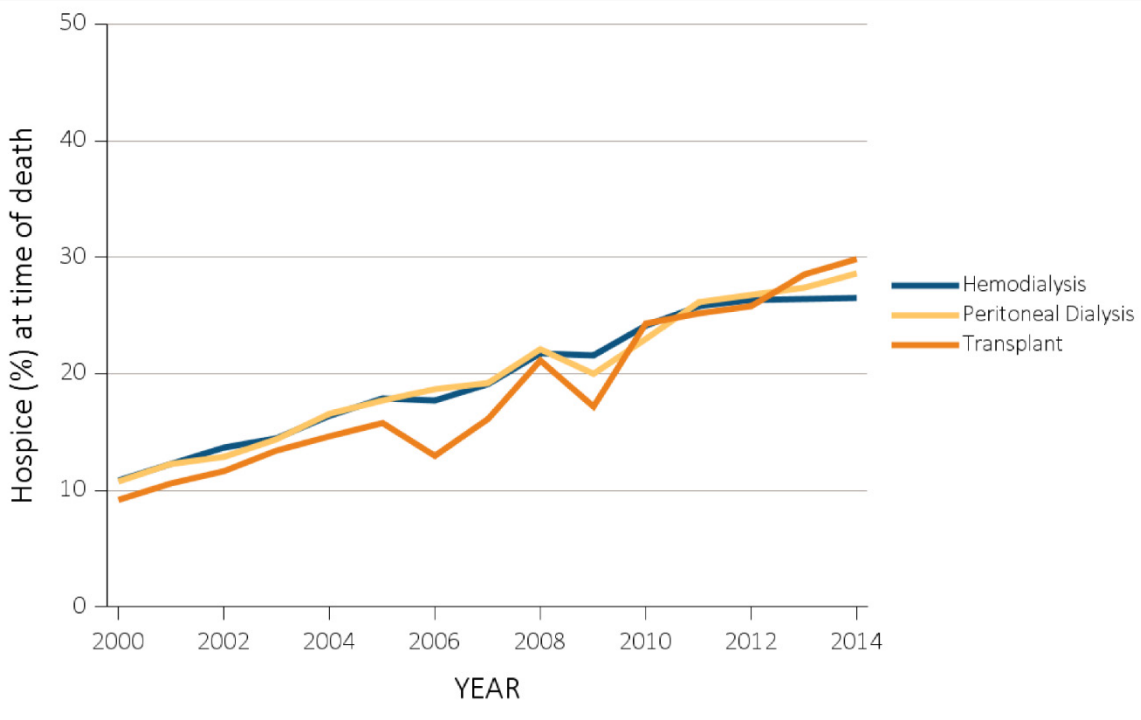
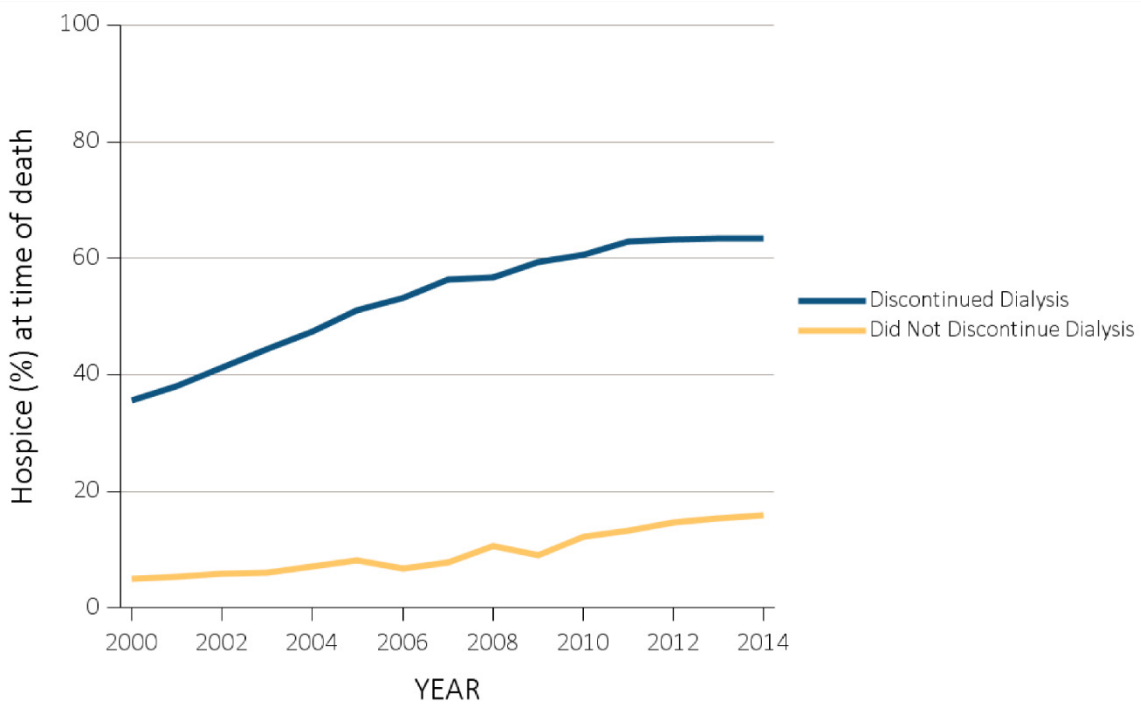


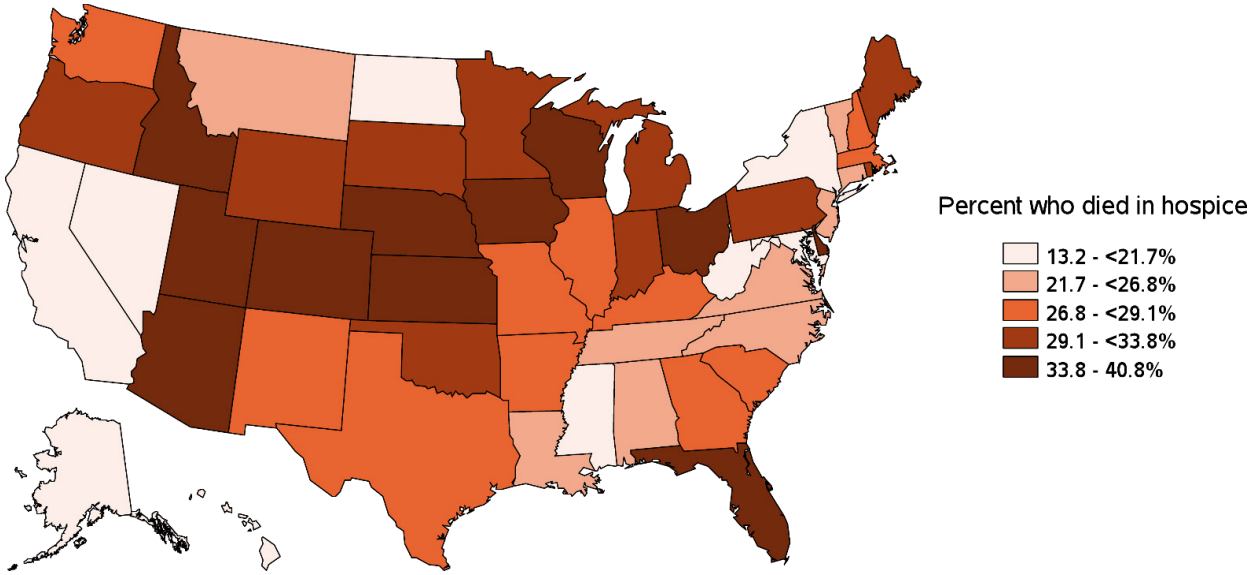
Figure 12.10 continued on next page.

vol 2 Figure 12.10 Advance directive prevalence before death among Nursing Home ESRD decedents overall, and by age, race, ethnicity, sex, modality, vintage, and impaired decision making, 2000-2010 *(continued)*

(g) Advance directive prevalence by vintage



(h) Advance directive prevalence by impaired decision making

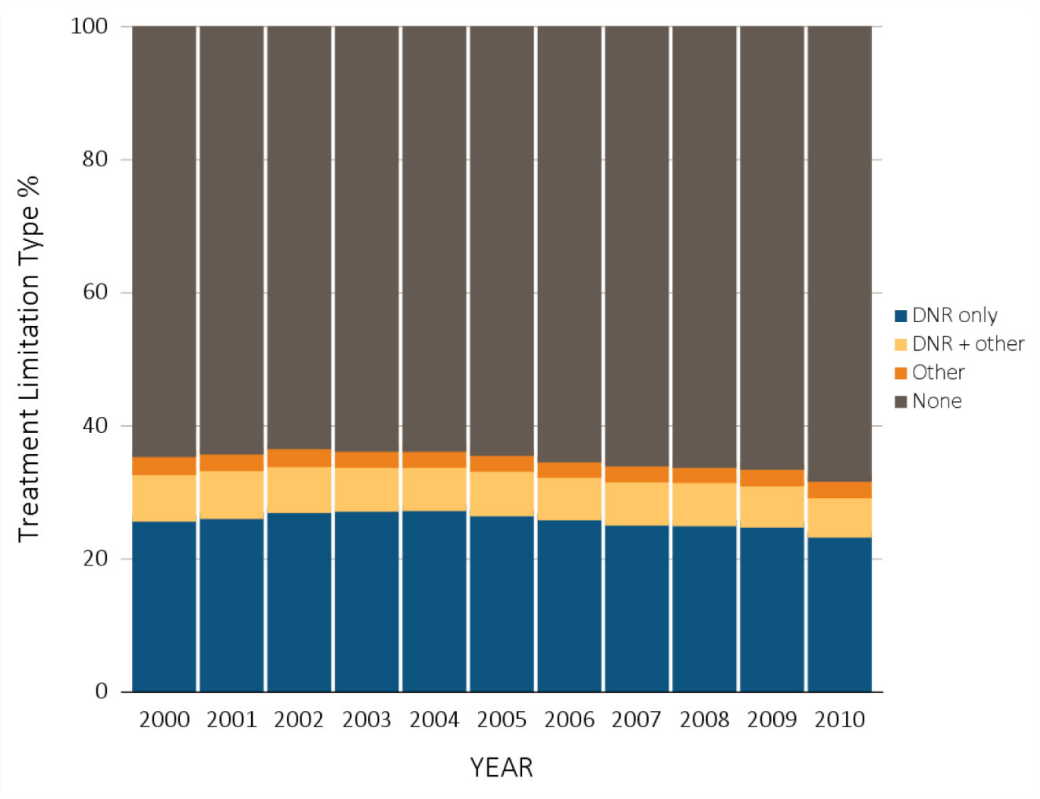


Data Source: Special Analyses, USRDS ESRD Database. Denominator population is all decedents with Medicare Parts A and B throughout the last 90 days of life. Receipt of hospice care at the time of death was defined as having a claim in the Hospice SAF on or after the date of death or Discharge Status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

In 2000, the prevalence of advance directives was lowest for those less than 45 years of age (31%) and highest for those aged ≥85 years (61%). The prevalence was also highest for Whites (54%), lowest for those of Other races (28%), and was lower for Hispanics than non-Hispanics (36% vs. 49%). Use of advance directives was similar for males and females, was lower for patients who had a kidney transplant or were receiving HD (46%-47%) than for those on PD (53%), and did not vary greatly by time since onset of ESRD. The prevalence of advance directives was higher for those with impaired decision-making capacity than those without (55% vs. 43%). The prevalence of advance directives declined from 2000 to 2010 for almost all sub-groups, with the most pronounced decrement occurring among patients younger than 45 years, those receiving PD, and those who started RRT within a year of death.

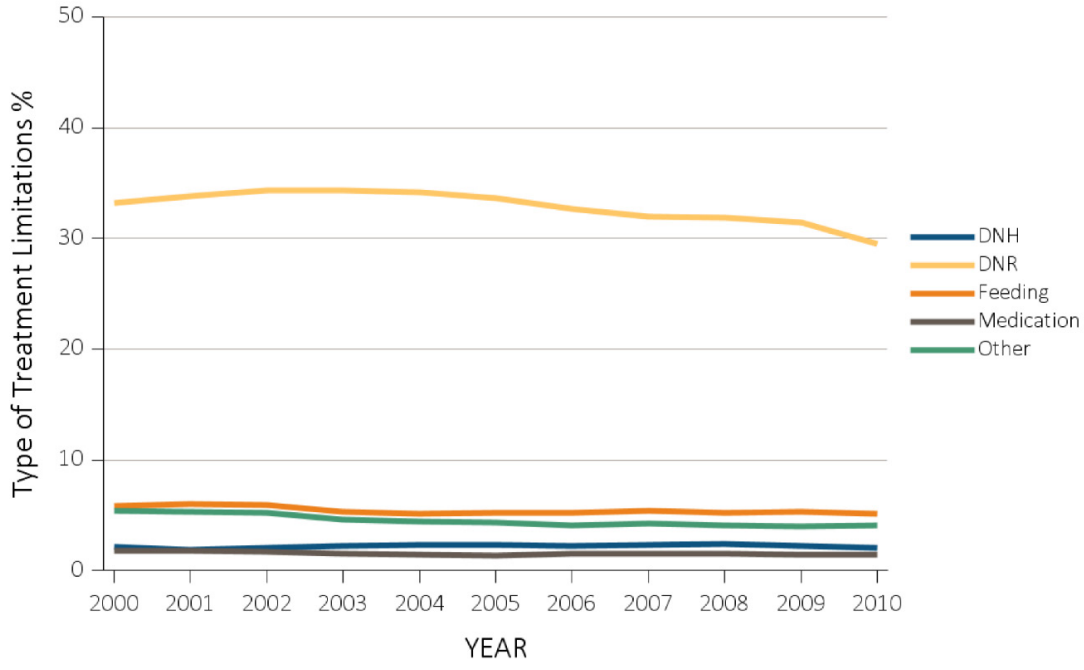
The percentage of patients with a treatment-limiting directive decreased from 36% in 2000 to 32% in 2010. Most of these patients had a do not resuscitate (DNR) order either alone, or in combination with other treatment limitations (Figure 12.11). The percentage of patients with a DNR declined slightly over time, whereas the percentage with other treatment limitations remained stable (Figure 12.12). Patients with impaired decision-making capacity had a higher prevalence of each advance directive component compared to patients without this impairment (Figure 12.13). Nevertheless, only 52% of patients with impaired decision-making capacity had an advance directive. Impaired decision-making capacity was more common among older patients, patients of Black or Asian race, and those who were receiving HD rather than PD or transplant. (Figure 12.14).

vol 2 Figure 12.11 Percent with treatment limitation in advance directives, 2000-2010



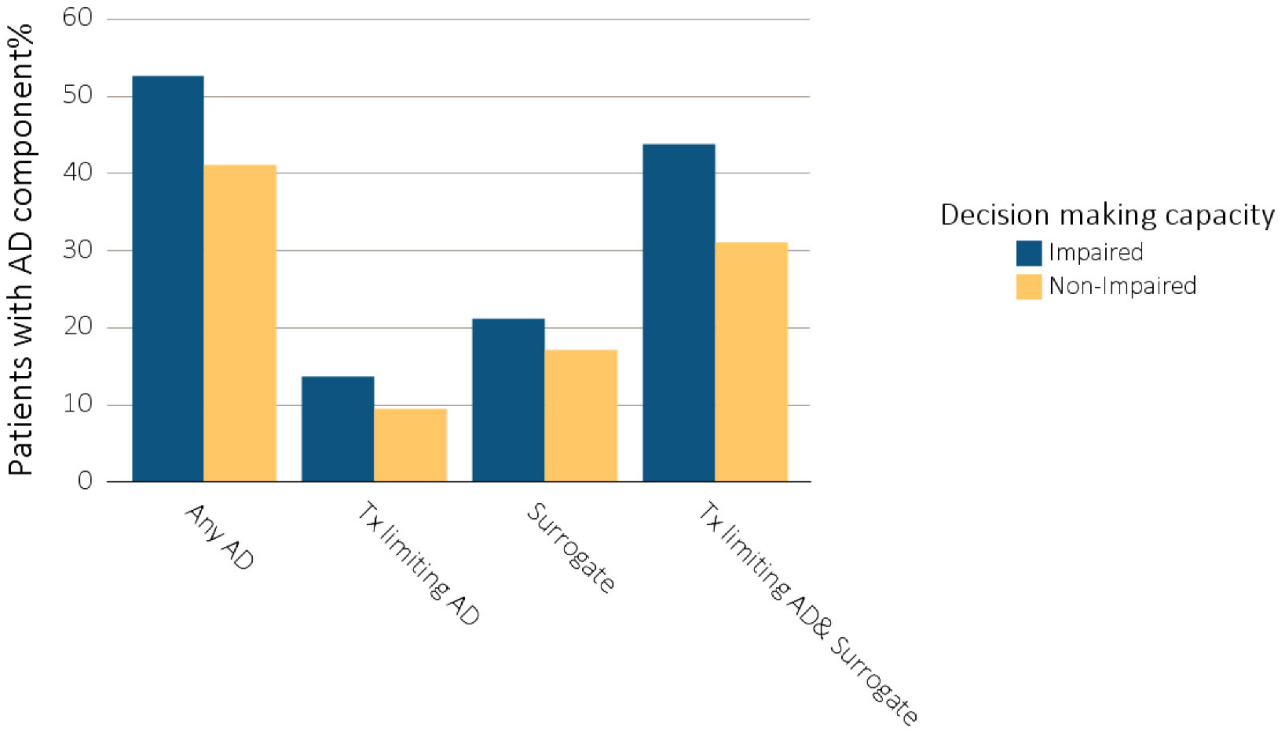
Data Source: Special Analyses, USRDS ESRD Database. Denominator population is all decedents with Medicare Parts A and B throughout the last 90 days of life. Receipt of hospice care at the time of death was defined as having a claim in the Hospice SAF on or after the date of death or Discharge Status from hospice=40, 41, or 42. Abbreviation: DNR, do not resuscitate; ESRD, end-stage renal disease.

vol 2 Figure 12.12 Type of treatment limitations listed in advance directives, 2000-2010



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: DNR, do not resuscitate; ESRD, end-stage renal disease.

vol 2 Figure 12.13 Prevalence of advance directive components, by decision-making status, 2000-2010



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.

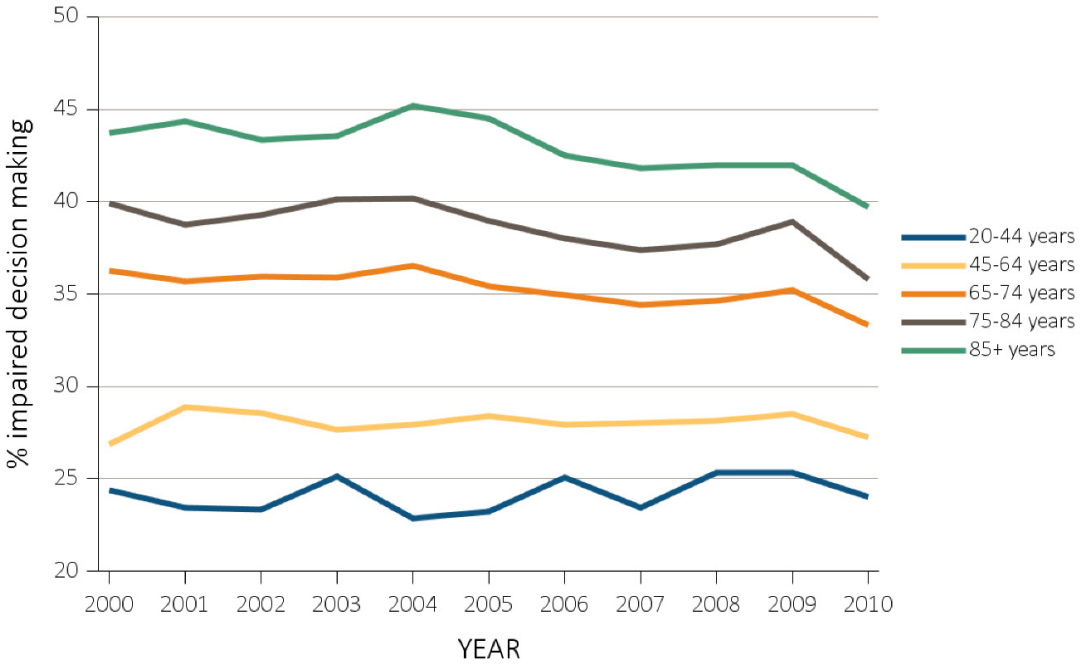
vol 2 Figure 12.14 Prevalence of impaired decision-making capacity, by patient characteristics

(a) Prevalence of impaired decision making capacity, by sex

Figure 12.14 continued on next page.

vol 2 Figure 12.14 Prevalence of impaired decision-making capacity, by patient characteristics *(continued)*

(b) Prevalence of impaired decision making capacity, by age at death



(c) Prevalence of impaired decision making capacity, by modality

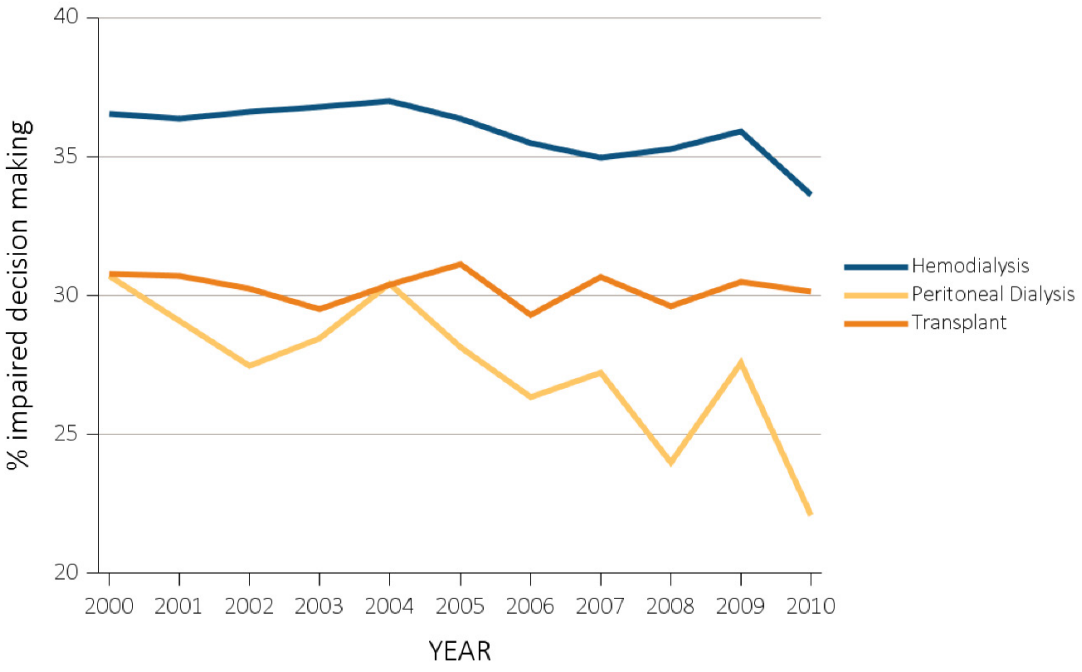
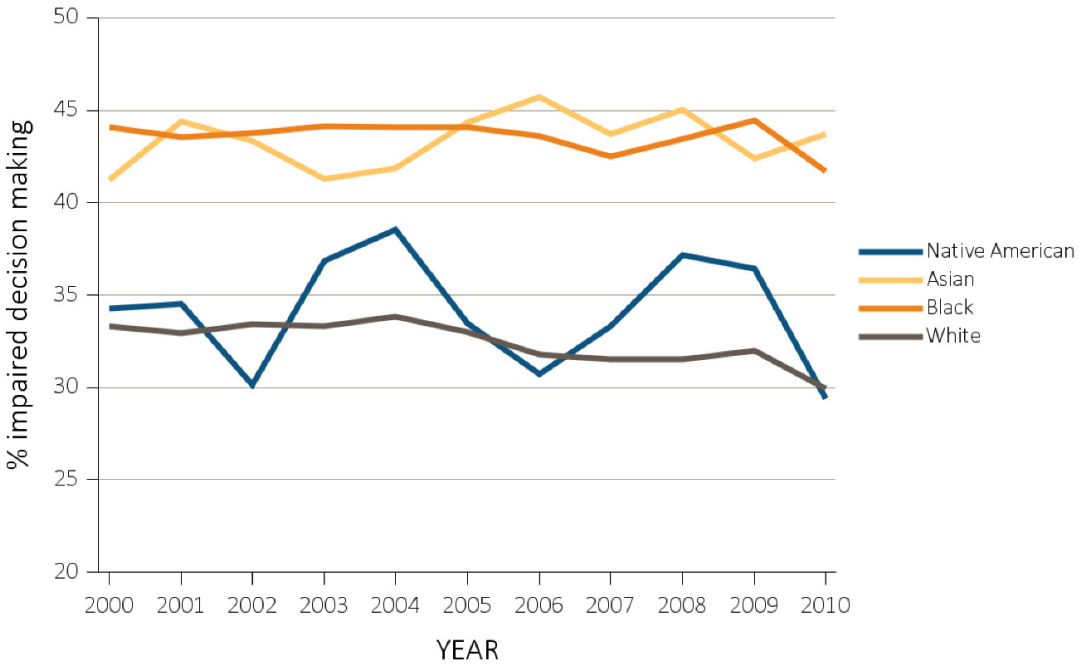


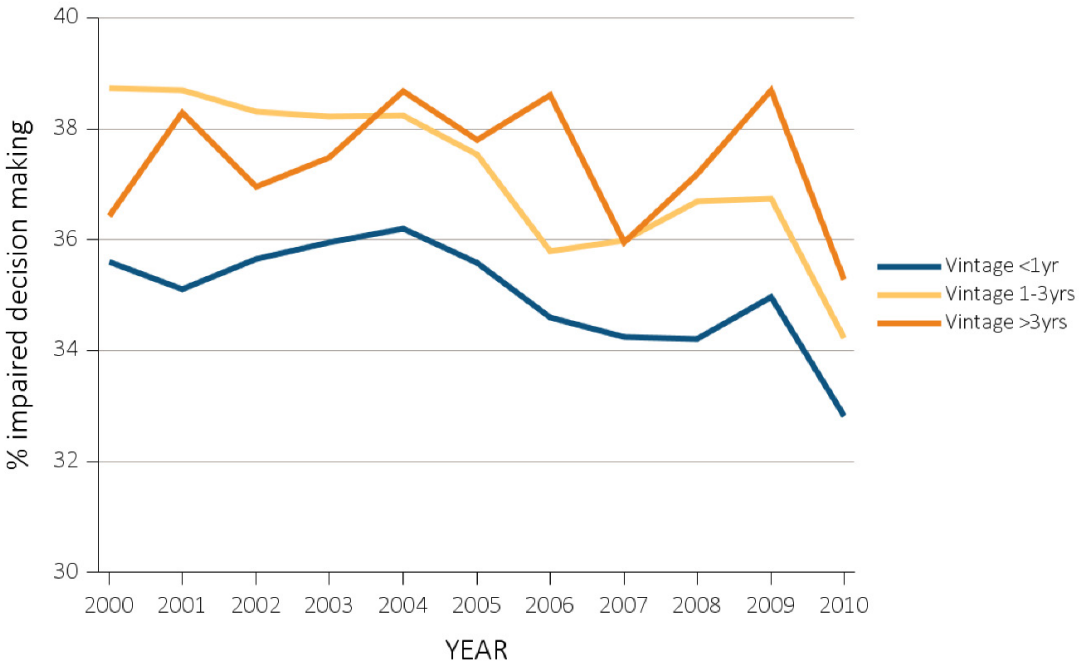
Figure 12.14 continued on next page.

vol 2 Figure 12.14 Prevalence of impaired decision-making capacity, by patient characteristics *(continued)*

(d) Prevalence of impaired decision making capacity, by race



(e) Prevalence of impaired decision making capacity, by vintage



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.

Costs in the Last Year, Month, and Week of Life

For ESRD patients who died in 2014, median per person costs under Medicare Parts A and B were $119,525 (IQR $75,886, $182,091) over the last year of life, $20,165 (IQR, $8,982, $35,555) over the last 30 days of life, and $7,396 (IQR, $1,723, $14,958 over the last seven days of life (Figure 12.15).

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. These costs ranged from $8,038 for those referred to hospice more than two weeks before death (IQR, $5,213, $16,125) to $23,847 for those first referred to hospice two days or less before death (IQR, $15,387, $37,811), as compared with the referent group without a claim for hospice during the last 90 days of life ($21,204; IQR, $9,292, $38,076).

Median costs during the last seven days of life were also lower for those referred earlier to hospice. These costs ranged from $1,424 (IQR, $1,166, $2,627) for those referred more than two weeks before death to $10,674 (IQR, $4,623, $15,266) for those not referred until the last two days of life, as compared with the referent group without a claim for hospice during the last 90 days of life ($9,617; IQR, $2,123, $16,793).

vol 2 Figure 12.15 Costs in the (a) last 30 days of life, and (b) last 7 days of life in relation to timing of hospice care, 2014

(a) Last 30 days of life

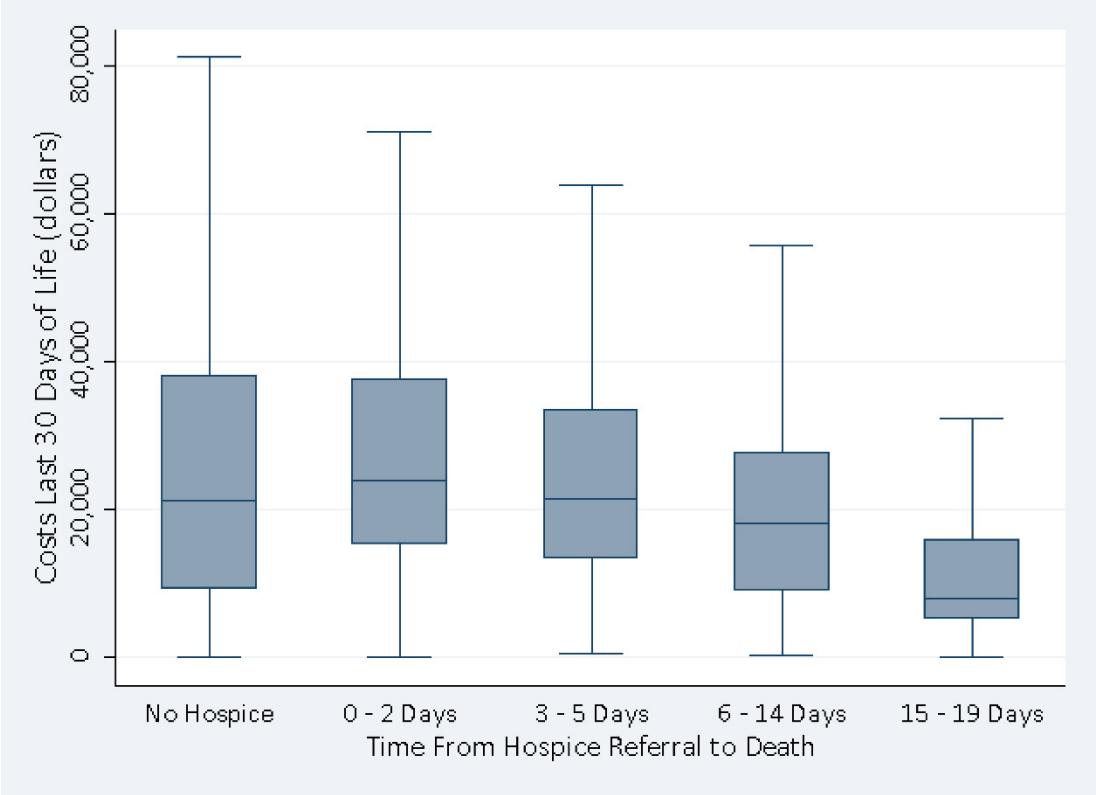
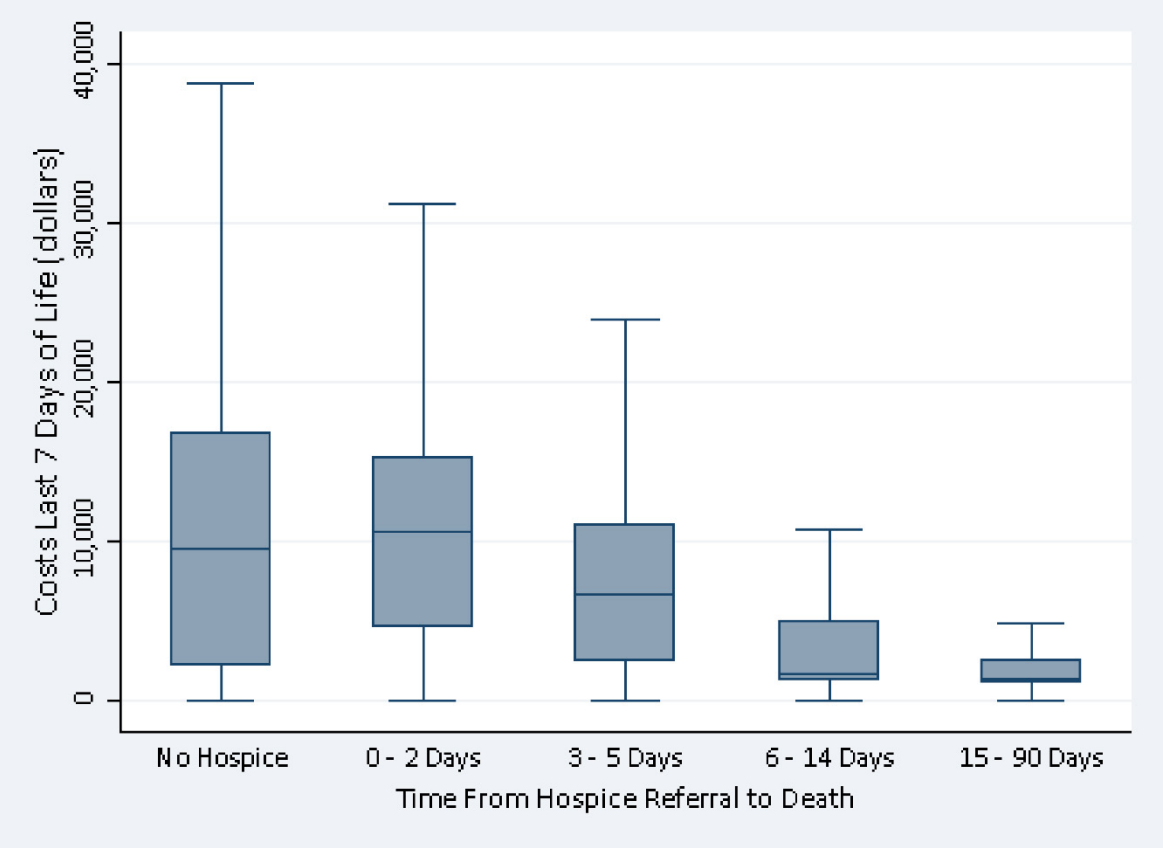


Figure 12.15 continued on next page.

vol 2 Figure 12.15 Costs in the (a) last 30 days of life, and (b) last 7 days of life in relation to timing of hospice care, 2014

(b) Last 7 days of life



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 ≥ the first quartile minus 1.5 times the interquartile range at the bottom to the highest value of the distribution that is ≤ the third quartile plus 1.5 times the interquartile range at the top. Values outside this range (outliers) are not plotted.

References

Barnato AE, Farrell MH, Chang CC, Lave JR, Roberts MS, Angus DC. Development and validation of hospital "end-of-life" treatment intensity measures. *Med Care* 2009;47(10):1098-1105.

Centers for Medicare & Medicaid, Minimum Data Set 3.0 Public Reports: MDS 3.0 Frequency Report. https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Minimum-Data-Set-3-0-Public-Reports/index.html. Page last updated: November 14, 2012. Accessed on June 15, 2016.

Kurella TM, Montez-Rath ME, Hall YN, Katz R, O'Hare AM. Advance Directives and End-of-Life Care among Nursing Home Residents Receiving Maintenance Dialysis. *Clin J Am Soc Nephrol* 2017; 12(3):435-442.

Kwok AC, Semel ME, Lipsitz SR, Bader AM, Barnato AE, Gawande AA, et al. The intensity and variation of surgical care at the end of life: a retrospective cohort study. Lancet. 2011;378(9800):1408-13.

Murray AM, Arko C, Chen SC, Gilbertson, DT and Moss, AH. Use of hospice in the United States dialysis population. *Clinical Journal of the American Society of Nephrology. 2006;*1(6):1248-1255.

USRDS
UNITED STATES RENAL DATA SYSTEM

Volume 2: ESRD Analytical Methods

Table of Contents

Introduction

The ESRD Analytical Methods chapter describes the data, analytical, and statistical methods for Volume 2 of the Annual Data Report (ADR). The *Researcher's Guide to the USRDS Database*, available through www.usrds.org, provides additional information about the database and standard analysis files (SAFs). For this ADR, we report on data through December 31, 2015. Some of the analyses depend on Medicare Claims data, therefore careful construction of appropriate denominators based on Medicare enrollment and primary payer status is required. These chapters and reference tables are marked with "[CLAIMS]" for easy identification. 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*.

Data Sources

The United States Renal Data System (USRDS) maintains a database of the medical and demographic characteristics of all end-stage renal disease (ESRD) patients who are Medicare beneficiaries. As the ESRD population is typically entitled to Medicare (although Medicare is not necessarily the primary payer), the primary data source for this database is the Centers for Medicare & Medicaid Services (CMS).

These data include information on ESRD incidence, prevalence, morbidity, mortality, and related biochemical laboratory results. Also incorporated are Medicare claims for care received in inpatient (IP), outpatient (OP, including dialysis), skilled nursing facility (SN), home health agency (HH), and hospice (HS) settings. This information is complemented by details of physician/supplier services (PS), treatment histories (useful for modality determination), and payer histories (essential for determining denominators for Medicare claims data as shown below), modality events, and provider characteristics.

History of CMS Data Collection

This section summarizes the history of federally organized data collection for U.S. ESRD patients.

In October 1972, ESRD patients became eligible for health insurance coverage through the Medicare Program (Public Law 92-603, expansion of the Social Security Act [U.S. Government Publishing Office, 1972]). Soon after, the development of computer systems to manage the data generated from the new ESRD program began.

In 1977, the Health Care Financing Administration (HCFA) was established to oversee Medicare's financing and claims processing. To organize and assure quality of medical care, collect data, and adjudicate patient grievances, HCFA created 18 regional ESRD Networks.

In June of 1978, Public Law 95-292 facilitated significant improvements to ensure cost-effective quality of care in the ESRD program. The ESRD Program Management and Medical Information System (PMMIS) was established to provide medical and cost information for ESRD program analysis, policy development, and epidemiologic research (Rettig and Levinsky, 1991; CMS Fact Sheet, 2012).

Data were compiled from Medicare claims and ESRD-specific data forms: the Medical Evidence form (CMS 2728), the Death Notification form (CMS 2746), and the Facility Survey form (CMS 2744). Initially 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 certification, and a new Medical Evidence form was introduced.

Throughout the 1980s, efforts continued to create a comprehensive ESRD registry with reporting beyond that which the PMMIS provided. The Omnibus Budget Reconciliation Act of 1986 called for the Department of Health and Human Services to establish a "national end-stage renal disease registry". A Request for Proposal was issued for the development of the United States Renal Data System (USRDS). The contract was awarded in May 1988 to the Urban Institute by NIDDK, with a subcontract to the University of Michigan, and the first USRDS Annual Data Report on the ESRD population was released in 1989.

In 1995, HCFA replaced its Medicare ESRD Support Subsystem with the Renal Beneficiary and Utilization System (REBUS). Also in 1995, non-Medicare patients were included in the database as the ESRD Medical Evidence form (CMS 2728) was made mandatory for all ESRD patients.

In 2001, HCFA was renamed the Centers for Medicare and Medicaid Services.

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.

SIMS collected the CMS Medical Evidence, Death Notification, and Facility Survey forms, and 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 patients beyond the initiation of treatment. SIMS was replaced by CROWNWeb in 2012.

CROWNWeb

The Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) is a web-based data collection system that captures clinical and administrative data from Medicare-certified dialysis facilities for all ESRD patients in the U.S. This system was implemented nationally in May 2012. In addition to replacing the existing 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.

CMS Medicare Enrollment Database (EDB)

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, employer group health plan 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 enrolled in Medicare, reclassifies existing 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 revised 1995 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 included new data collection methods and new variables. The revision allows users to specify whether the Medicare registration is initial (new ESRD patient), a 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 completed for the same patient. Data fields for nephrologist care, dietitian care, and access type were added, indicating their respective time intervals relative to ESRD onset. Data on the laboratory values hematocrit, creatinine clearance, BUN, and urea clearance were no longer collected. Added laboratory values were hemoglobin A1c (HgbA1c) and lipid profiles (total cholesterol, low-density lipoprotein, high-density lipoprotein, and triglycerides). Additional fields relate to whether patients have been informed of transplant options, and if not, why not, and discussed donor type.

Effective in October 2015, CMS updated the 2728 form with ICD-10-CM codes to reflect "primary cause of renal failure" (Field 15). ICD-10-CM codes provide more diagnoses and procedure detail as compared to those of ICD-9-CM, resulting in a better

understanding of the patient's health. In addition to updating the form, CMS implemented options of "<6 months" for Field 18, "Prior to ESRD therapy".

The Medical Evidence form is the only reliable group source of information about the cause of a patient's ESRD. Because the list of causal diseases has been revised, the USRDS stores the diagnosis codes from each version so that detail is not lost through conversion of one set of codes to another.

Most ESRD patients have only one Medical Evidence form completed during their entire ESRD treatment period. Multiple forms may be submitted, however, especially for transplant patients. Medicare entitlement for transplant patients with a functioning graft ends after three years 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.

All versions of the CMS 2728 form (2015, 2005 and 1995) 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: www.usrds.org/research.aspx.

ESRD Death Notification Form (CMS 2746)

The ESRD Death Notification form (CMS 2746) is used to report the death of an ESRD patient. According to CMS policy this form must be submitted by dialysis or transplant providers within 30 days of a patient's death. It 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 the USRDS ESRD database, 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 data due to the prohibitive cost of obtaining this for the entire 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 died during the year. Both Medicare and non-Medicare end-of-year patients are counted. While AFS files do not contain 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. Upon publication of 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. Since 2012, the USRDS has received the facility survey data directly from CROWNWeb.

Organ Procurement and Transplantation Network Database (OPTN)

In the early 1980s, CMS began collecting data on all Medicare-paid 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 all organ transplants, not just those paid for by Medicare.

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.

Medicare ESRD Claims Files

The CMS ESRD Claims Standard Analysis Files (SAFs) contain data from final action claims for medical services provided to Medicare beneficiaries, in which all adjustments have been resolved. To compile institutional claims, the USRDS uses the following 100% SAFs:

- Inpatient (IP)
- Outpatient (OP)
- Skilled Nursing Facility (SN)
- Home Health Agency (HH)
- Hospice (HS)

For non-institutional claims, the USRDS uses the following 100% SAFs:

- Physician/Supplier (PS)
- Durable Medical Equipment (DME)

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 they are finalized at 18 months, after which files are frozen and will not include late arriving claims. The data lag for the ascertainment of death and graft loss is about nine months. The annual files used in the ADR are approximately 98% complete. The USRDS 2017 SAF includes all claims up to December 31, 2015.

Medicare Prescription Drug Event File (PDE)

In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), amending the Social Security Act by adding the Part D prescription benefit under Title XVIII. With this new Part D coverage, health plans must submit a summary record called the prescription drug event (PDE) to CMS whenever a Medicare beneficiary fills a prescription. Each drug is identified by a National Drug Code (NDC). The prescription record also contains dosage information, drug costs above and below the out-of-pocket threshold, other true out-of-pocket (TrOOP) amounts, plan paid amounts, and low-income cost sharing subsidy amounts. The USRDS 2017 ADR includes 2006-2015 PDE data.

Medicare 5% Standard Analytical Files (SAF)

The CMS 5% general Medicare SAFs are a random sample of 5% of the entire Medicare population. These 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). Once in the sample, a beneficiary will remain a part of all future data files until death or a change in the HIC number. The sample design has the effect of creating a built-in longitudinal panel dataset. Since 2012, the USRDS has received the 5% sample from the CMS Chronic Conditions Warehouse.

The SAFs include the Master Beneficiary Summary File (formerly the Denominator file), that contains 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, distinguished by the type of medical service received—inpatient, outpatient, home health agency, hospice, or skilled nursing facility. Physician and Supplier claims (also referred to as Carrier Claims) contain two separate files for durable medical equipment and 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. Table 14.1 shows the codes used to identify CKD and its stages. The total Medicare 5% sample is used to develop total Medicare cost and utilization data for comparison to the diagnosis-specific cohorts.

vol 2 Table 14.1 ICD-9-CM and ICD-10-CM diagnosis codes used to define chronic kidney disease in the health insurance claim data files

Condition name	ICD-9-CM codes	ICD-10-CM codes
Chronic kidney disease (CKD)	016.0; 095.4; 189.0,189.9; 223.0; 236.91; 250.4; 271.4; 274.1; 283.11; 403; 404; 440.1; 442.1; 477.3; 572.4; 581-588; 591; 642.1; 646.2; 753.12-753.19; 753.2; 794.4	A18.11, A52.75, B52.0, C64.x, C68.9, D30.0x, D41.0x-D41.2x, D59.3, E08.2x, E09.2x, E10.2x, E10.65, E11.2x, E11.65, E13.2x, E74.8, I12.xx, I13.0, I13.1x, I13.2, K76.7, M10.3x, M32.14, M32.15, N01.x-N08.x, N13.1, N13.1x-N13.39, N14.x,N15.0, N15.8, N15.9, N16, N17.x, N18.1-N18.5, N18.8, N18.9, N19, N25.xx, N26.1, N26.9, O10.4xx, O12.xx, O26.83x, O90.89, Q61.02, Q61.1x-Q61.8, Q26.0-Q26.39, R94.4
Staging of chronic kidney disease		
Stage 1	585.1	N18.1
Stage 2	585.2	N18.2
Stage 3	585.3	N18.3
Stage 4	585.4	N18.4
Stage 5	585.5 or 585.6 with no CMS 2728 form	N18.5
Stage unknown or unspecified	Patient only has no claims with codes 585.1-585.6 but has: 016.0; 095.4; 189.0,189.9; 223.0; 236.91; 250.4; 271.4; 274.1; 283.11; 403; 404; 440.1; 442.1; 477.3; 572.4; 581-584; 585.9; 586-588; 591; 642.1; 646.2; 753.12-753.19; 753.2; 794.4	Patient has no claims with codes N18.1-N18.6 but has: A18.11, A52.75, B52.0, C64.x, C68.9, D30.0x, D41.0x-D41.2x, D59.3, E08.2x, E09.2x, E10.2x, E10.65, E11.2x, E11.65, E13.2x, E74.8, I12.xx, I13.0, I13.1x, I13.2, K76.7, M10.3x, M32.14, M32.15, N01.x-N08.x, N13.1, N13.1x-N13.39, N14.x,N15.0, N15.8, N15.9, N16, N18.8, N18.9, N19, N25.xx, N26.1, N26.9, O10.4xx, O12.xx, O26.83x, O90.89, Q61.02, Q61.1x-Q61.8, Q26.0-Q26.39, R94.4

Source: ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification. ICD-9-CM diagnosis codes can have up to five digits with a decimal point between the 3rd and 4th digit, while ICD-10-CM codes have seven digits. Codes listed with three digits include all existing 4th and 5th digits, and those listed with four digits include all existing 5th digits.

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. This included 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. The information was aggregate and not patient-specific. Because the CDC terminated this program in 2003, the last surveillance report was for 2002 data. The CDC did not conduct a survey in 1998.

United States Census

The U.S. population data are obtained from the 2000 and 2010 U.S. Census and 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_documentation.htm. The USRDS summarizes this data by racial grouping, at state and national levels.

Optum Clinformatics™ Data Mart Database (OptumInsight, Eden Prairie, MN)

The Optum Clinformatics™ Data Mart provides paid medical and prescription claims and enrollment information for participants in commercial insurance plans and Medicare Advantage plans of a large U.S. managed care health insurance company. The data are purchased from OptumInsight and include plan members enrolled in both a medical and a prescription plan. All areas of the country are represented in the data. With our data delivery in 2017, OptumInsight expanded the number of diagnosis and procedure codes in the MEDICAL claims table to 25 from the previous five diagnosis codes and three procedure codes. Because of this, our analyses detect more disease conditions and procedures than in the 2016 ADR.

The Optum Clinformatics™ data license requires that their data not be merged with any other files, so we are unable to match these individuals with the USRDS ESRD databases to comprehensively identify ESRD patients. Therefore, we assign these individuals a first service date for ESRD as the earliest date of either the first claim with a diagnosis of ESRD, a procedure code for outpatient dialysis, or a diagnosis related group (DRG) code for a kidney transplant surgery. See Table 14.2 for specific code values. We present Optum Clinformatics™ data from 2005 through 2015 in the 2017 ADR.

To comply with the Health Insurance Portability and Accountability Act of 1996 (HIPPA) and prevent the re-identification of individuals in the database, certain combinations of sensitive data elements are not permitted. OptumInsight provides the data as different "views", each containing a limited amount of sensitive data. For this report, we used the Date of Death (DOD) view of the data; detailed geographic and socio-economic data are not available in the files, but date of death is included. The other available data views do not contain death date. Enrollment and member information, such as year of birth, sex, race/ethnicity, state of residence, and plan participation are contained in the MEMBER and MEMBER_DETAIL data tables. All services for both inpatient and outpatient care are located in the MEDICAL claims data table, with the confinement ID variable indicating inpatient institutional claims. With the admission and discharge dates from the inpatient institutional claims, we then identify all medical services performed for the patient during that period as inpatient services.

vol 2 Table 14.2 ICD diagnosis, HCPCS procedure, and DRG codes used to define ESRD in the Optum Clinformatics™ dataset

Type of code		Code values
ICD-9-CM diagnosis codes		585.6, 996.81, V42.0, V45.1, V56.0, V56.1, V56.2, V56.3, V56.31, V56.32, V56.8, E879.1
ICD-10-CM diagnosis codes		N18.9, T86.10-T86.13, T86.19
HCPCS codes		90935, 90937,90940, 90945, 90947, 90951-90970, 90989, 90993, 90997, 90999; *codes from earlier years: 90918-90925*
DRG codes	Prior to FY2007:	302,512
	FY2007-present:	652,008

Abbreviations DRG, diagnosis related group, FY, fiscal year (10/1/06 to 9/30/07), HCPCS, Healthcare Common Procedure Coding System, ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification.

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

Date of death information is provided as month and year only, and not a specific date. We set all deaths to the first day of the reported month to create a specific death date from the month and year combination. Insurance claims do not have information on death unless the death occurred during a covered inpatient stay as identified through the discharge status (*dstatus*). The insurance company may only be informed that the member's coverage has ended. However, the Optum Clinformatics™ Data Mart is augmented with data from the Social Security Death Master File (SSDMF). In November of 2011, some states stopped reporting death information to the SSDMF, causing a 30% drop in the number of death records contained in the database (OptumInsight 2015). This may overstate the survival statistics as more deaths will go undetected. For this reason, we do not present analysis of mortality rates for the Optum Clinformatics™ dataset, although other chapters do use date of death to censor time to event analyses.

Optum Clinformatics™ information on expenditures for medical services is included for the first time in the 2017 ADR, as are analyses of prescription drug usage. To account for differences in pricing across health plans and provider contracts, OptumInsight applies standard pricing algorithms to the claims data in the Optum Clinformatics™ Data Mart. These algorithms are designed to create standard prices that reflect allowed payments across all provider services. Standard pricing amounts are included in the MEDICAL and the RX claims tables.

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. Renal providers must immediately complete a Medical Evidence form for all ESRD patients; this registers them in the CMS ESRD database, and allows them 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, when there is other evidence of chronic dialysis that meets the criteria of ESRD, or upon registering as a candidate for kidney transplant though the OPTN. The identification of ESRD patients does not rely on the International Classification of Diseases (ICD) codes for ESRD.

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 often are not included in the CMS ESRD database.

ESRD first service date

The ESRD first service date is the single most important data element in the USRDS database; 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, or
- the first Medicare dialysis claim.

There are two exceptions to the ESRD first service date determination:

- If (1) the CROWNWeb event and Medical Evidence form agree (within 30 days of each other) and (2) 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 (1) the Medical Evidence form date is one year earlier than the first CROWNWeb event date, and (2) 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 next most critical piece of information in the USRDS 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, and inpatient claims. Because multiple sources report death information for the same patient, an individual may have several reported dates. For these patients, the accepted death date is based on the priority order below:

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

Transplant events can be identified from the OPTN data, Medical Evidence forms indicating transplant as the initial modality, CROWNWeb transplant events, and inpatient claims. Each transplant event found in the Transplant file of the USRDS Core SAF dataset is a unique event. To resolve any conflicts among the data sources and to 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.
- 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.
- After 1994, all transplant events found in OPTN files are used.
- Additionally, transplant events for patients who are reported incident on the Medical Evidence form are used if the date is at least 30 days before or after a previously accepted transplant event. Transplant events found in CMS inpatient claims records are also included, as are transplants found in the CROWNWeb patient events data.

Graft Failure

We assume a graft failure date is correct as reported in the OPTN transplant follow-up or REMIS identification file 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, or
- 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% of individuals are eligible for Medicare. Those who are younger than 65 tend to

have more serious health conditions than do others their age in the general population as they become 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. 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 30-month 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. All ESRD patients, regardless of their Medicare Eligibility status, are included in the CROWNWeb system.

The USRDS recognizes that non-Medicare patients are true ESRD patients and should be included in patient counts for incidence, prevalence, and treatment modality, as well as in mortality and transplant rate calculations. Calculations of hospitalization statistics or any outcomes derived from Medicare claims (e.g., 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 in the USRDS database fulfills Medicare primary payer criteria at any given time. For this reason, the ADR analyses construct a denominator cohort using the PAYHIST file. See the *Payers* section below for more details.

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. We use this history to identify incident and prevalent cohorts and to determine censoring points and outcomes for observational studies.

Vol 2 Table 14.3 CROWNWeb events

Event
New ESRD Patient
Transfer In
Restart
Dialysis after Transplant Failed (at Dialysis Facility)
Transfer Out for a Transplant
Transfer Out
Discontinue
Death
Recover Function
Lost to Follow-Up
Modality Change
Transplant
Continuing
Transplant Failure (at Transplant Facility)
Interruption in Service
Resume Service

The CROWNWeb event database is the primary source of the modality sequence file, and 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 do not appear in the CROWNWeb events file, whose only event is "New ESRD Patient", or who have gaps in facility assignment, the Medicare dialysis claim file is used.

For "Transfer Out" and "Transfer Out for a Transplant" events followed by gaps of seven days or more, claims falling in those gaps are included, unless the "Transfer Out for a Transplant" event has a corresponding transplant or transplant failure event within 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, 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", "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 are also treated as lost to follow-up, beginning one year after the first service date. A number of different events can result in the lack of dialysis data, and eventual reclassification of a patient as lost to follow-up, including:

- recovery of renal function,
- no longer a resident of the United States, or
- the patient has died, but this was not reported to the Social Security Administration or to CMS.

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 who had 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 data sources are evaluated in the following order: CROWNWeb data, Medical Evidence form, claims data, and transplant data. The modality indicated in CROWNWeb and the Medical Evidence form may be temporary, as patients often change to a new modality during the first 90 days of treatment; it can be difficult to track modality during this time. Patients aged 65 and older or those with disabilities have Medicare claims in the first 90 days that contain revenue codes designating modality. Most patients younger than 65 and in employer group health plans (EGHP), 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 modality-specific outcomes from their data should be viewed with caution. These patients are not considered 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.

60-day Stable Modality Rule: Treatment History File

The 60-day stable modality rule requires that a modality continue for at least 60 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 60-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.

Recovered Renal Function (RRF)

A new modality event—recovered renal function (RRF)—was introduced in the 2007 ADR. Prior to the 2016 ADR, this event required the recovery of function to occur within 180 days of the first service date and to persist for at least 90 days. Starting with the 2016 ADR, every indication of 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; they are defined in the chapter-specific analytical methods sections that follow this section.

Payers

For analyses using claims data, it is important to know whether Medicare is the primary payer (MPP) for the beneficiary, since claims are only filed with Medicare for those beneficiaries. Information on payers is obtained primarily from the Medicare Enrollment Database (EDB). We also examine Medicare outpatient claims to find beneficiaries with at least three consecutive months of dialysis treatment covered by Medicare. Regardless of their status in the EDB, these patients are designated as having MPP coverage.

From these two data sources we construct a Payer Sequence file to provide payer history, identifying 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, 2015.

Payer status information prior to the start of ESRD (ESRD first service date) is available from the back-casted Payer Sequence file. The Pre-ESRD Payer Sequence file is similar to the standard ESRD Payer Service file, except it begins at the first evidence of Medicare enrollment from the EDB, rather than ESRD first service date. The Pre-ESRD payer sequence ends the day before the ESRD first service date.

Constructing denominators based on payer history is essential for analyses using Medicare claims-defined outcomes—any outcome using a specific diagnostic or procedure code. International Classification of Diseases (ICD) diagnosis codes are used for all claims, while ICD procedure codes are used for inpatient claims. Healthcare Common Procedure Coding System (HCPCS) codes are used in the Physician Supplier claims and the revenue portion of the institutional claims.

Only a minority of dialysis patients have Medicare primary payer status when they start dialysis, which increases to about 60% of patients 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. 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 during a given period of time as MPP (established in the SAF PAYHIST), Medicare as secondary payer (MSP) with an employer group health plan (EGHP), MSP non-EGHP, Medicare Advantage (Medicare + Choice), Medicare or Medicaid only, or a combination of payers (see the *Researcher's Guide to the USRDS Database* for more information).

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 ICD-9-CM and ICD-10-CM codes.

vol 2 Table 14.4 Diagnosis codes for primary cause of ESRD

Primary Cause of ESRD	ICD-9-CM or CMS 2728 codes	ICD-10-CM codes
Diabetes	250.00, 250.01, 250.40, 250.41	E10.22, E10.29, E10.9, E11.21, E11.22, E11.65, E11.9
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	I10, I12, I12.0, I12.9, I13.10, I13.2, I15.0, I15.8, 175.81
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	N00.8, N01.9, N02.8, N03.0, N03.1, N03.2, N03.3, N03.4, N03.5, N03.6, N03.7, N03.9, N03.9, N04.0, N04.1, N04.2, N04.3, N04.4, N04.5, N04.6, N04.7, N04.8, N04.9, N05.1, N05.9, N07.0
Cystic kidney	583.9, 753.1, 753.13, 753.14, and 753.16	Q56.0, Q61.91, Q61.2, Q61.3
Other urologic	223.0, 223.9, 274.1, 590.0, 591.0, 592.0, 592.9, 599.0, and 599.6	D30.00, D30.01, D30.02, D30.9, M10.30-M10.39, N13.1, N13.2, N13.30, N13.39, N13.9, N20.0, N20.2, N20.9, N22, N39.0
Other known 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, 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	C64.1, C64.2, C64.9, C65.1, C65.2, C65.9, C68.9, C82.53, C82.55, C82.56, C84.93, C84.95, C84.96, C84A3, C84A5, C84A6, C84Z3, C84Z5, C84Z6, C85.13, C85.15, C85.16, C85.23, C85.25, C85.26, C85.83, C85.85, C85.86, C85.93, C85.95, C85.96, C86.2, C86.3, C88.0, D57.00-D57.20, D57.811-D57.819, E20.1, E72.00, E72.02, E72.04, E72.09, E72.52, E72.53, E74.4, E74.8, E75.21, E75.22, E75.240-E75.3, E77.0-E77.9, E78.71, E78.72, E83.59, I76, K76.7, M05.412, M05.531-M05.59, M05.70, M05.711-M06.09, M06.20-M06.639, M06.80-M06.9, M1A.10X0, M1A.10X1, M1A.1110-M1A.1791, M1A.18X0, M1A.18X1. M1A.19X0, M1A.19X1, M31.1, M35.4, M62.20-M62.28, M62.89, M72.8, N00.8, N03.0, N03.8, N05.0, N05.1, N05.6-N06.1, N06.6-N06.8, N07.0, N07.1, N07.6-N07.8, N14.0-N15.0, N15.8, N15.9, N17.0-N17.2, N20.0, N28.82, N28.89, N28.9, N29, N39.0, O08.4, Q60.0-Q606, Q62.0-Q62.2, Q63.0-Q63.9, Q79.4, Q79.51, Q85.1, Q87.2, Q87.3, Q87.5, Q87.81, Q87.89, Q89.8, T39.1X1A-T39.1X4A, T39.91XA-T3994XA, T50.8X1A-T50.8X4A, T52.4X1A-T528X4A, T5291XA-T5294XA, T56.0X1-T56.0X4, T86.00-T86.49, T86.810-T86.819, T86.830-T86.839, T86.850-T86.899
Unknown cause	239.5, 428.0, 500, 582.0, 586.0, 589.0, 589.1, 589.9, 592.1, 593.1, 799.9, 999.9, and ICD-9-CM codes not covered by the causes listed above	D49.5, I50.20-I50.9, J60, N03.2, N13.2, N19, N20.1, N20.2, N27.0-N27.9, N28.81, R69, R99, T81.81XA, T88.4XXA, T88.7XXA, T88.8XXA, T88.9XXA
Missing cause	no code listed	no code listed

Abbreviations: CMS 2728, Medical Evidence form, ESRD, end-stage renal disease, ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Edition.

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. The Medical Evidence form asks patient race and Hispanic ethnicity in two separate questions, so they can be treated independently or combined. Patient ethnicity became a required field on the 1995 revision of the Medical Evidence form, but because the form did not go into effect until midway through 1995, data for that year are incomplete. Therefore, information on Hispanic patients is presented starting in 1996. The non-Hispanic category includes all non-Hispanics, but does not include those of unknown ethnicity, which is a separate category.

Because of the small number of ESRD patients of some races, and the specifics of race categorization in the U.S. Census data, we present our results with the racial populations of White, Black/African American, American Indian or Alaska Native, Asian, Native Hawaiian or Pacific Islander, and Other or Multiracial. We will present data on patients of other races 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 highest to lowest priority):

- 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 14.5 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.

vol 2 Table 14.5 Race categories used in the USRDS ESRD database data sources

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
American Indian or Alaska Native	American Indian or Alaska Native	American Indian or Alaska Native	American Indian orAlaska Native	Native American
Asian	Asian; Indian Sub-Continent	Asian; Indian Sub-Continent	Asian; Indian Sub-Continent	Asian
Native Hawaiian or Pacific Islander	Pacific Islander	Pacific Islander	Pacific Islander	
Unknown	Unknown; Missing	Unknown; Missing	Unknown; Missing	Unknown; Missing
Other or Multiracial	Other or Multiracial	Other or Multiracial	Other or Multiracial	Other or Multiracial

The data sources for ethnicity are (from highest to lowest priority):

- Medical Evidence form
- CROWNWeb Patient list
- Clinical Performance Measures (CPM)
- 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 get 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. The methodologies used to create the figures and tables in Volume 2 are described below in the corresponding chapter of the *Analytical Methods Used in the ESRD Volume* section. When figure or table data are drawn directly from a particular reference table, please refer to the *ESRD Reference Table Methods s*ection for additional detail.

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

Incidence of ESRD: Counts, Rates, and Trends

Adjustments for the rates in this chapter were as follows:

- Overall rates (including those in the maps) were adjusted for age, sex, and race.
- Rates by age were adjusted for sex and race.
- Rates by race or ethnicity were adjusted for age and sex.
- Rates by primary cause of ESRD were adjusted for age, sex, and race.

Race has been standardized across the ADR, and this year the Native Hawaiian/Pacific Islander racial group is presented as separate from Asian. Direct adjustment was used as described in the *Methods* section of the chapter. Rates per million population used Census data that are now based on intercensal estimates; for details, see the section on the *United States Census* in the *Data Sources* section of this chapter.

Incidence rates are presented in Tables 1.1 and 1.2 and Figure 1.1, while Figure 1.2 shows the number of incident patients by modality. Figure 1.3 presents adjusted rates geographically by Health Service Areas (HSA).

For Figures 1.4-1.6, incidence rates were taken directly from Reference Table A.2(2). For details on the methods used and rate calculations, refer to the sections *Reference Tables A: Incidence and B: Prevalence* and *Statistical Methods,* both later in this chapter.

All maps were created using five years of data; results were suppressed for the HSAs with 10 or fewer total cases.

Prevalence of ESRD: Counts, Prevalence, and Trends

In the chapter, point prevalence was as of December 31, while period prevalence was reported for a calendar year. Annual period prevalent data thus consists both of patients who had the disease at the end of the year, and those who had the disease during the year and died before the year's end. Patients with a functioning transplant were counted as prevalent patients.

Beginning with the 1992 ADR, lost to follow-up patients were not included in the point prevalent counts; they are reported in Reference Table B.1.

Prevalence adjustments in this chapter were the same as the corresponding incidence rates detailed above. Prevalence also used direct standardization and intercensal population estimates.

Statistics for Table 1.3, Figures 1.7, 1.10, and 1.12 were taken directly from Reference Table B. Specifically, prevalent cases correspond to those found in B.1 and prevalence rates correspond to those found B.2(2). Table 1.4 results were taken from Reference Table B.10 and special analyses. For details on the methods used and rate calculations, refer to the sections *Reference Tables A: Incidence and B: Prevalence* and *Statistical Methods,* both later in this chapter. Figure 1.8 data is found in *Reference Table D: Treatment Modalities*.

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 were not classified as lost to follow-up or as having recovered renal function (RRF). Unless noted otherwise, incident and point prevalent cohorts without the 60-day stable modality rule were used in these analyses. Treatment modalities are defined in Table 14.6.

vol 2 Table 14.6 ESRD treatment modality definitions

Modality	Description
Center Hemodialysis	Hemodialysis treatment received at a dialysis center
Center Self Hemodialysis	Hemodialysis administered by the patient at a dialysis center, usually combined with Center Hemodialysis
Home Hemodialysis	Hemodialysis administered by the patient at home; cannot always be reliably identified in the database
CAPD	Continuous Ambulatory Peritoneal Dialysis
CCPD	Continuous Cycling Peritoneal Dialysis
Peritoneal Dialysis	Includes intermittent peritoneal dialysis
Other Peritoneal Dialysis	Primarily intermittent peritoneal dialysis. This is a small group of patients, common among very young children
Uncertain Dialysis	A period in which the dialysis type is unknown of multiple modalities occur but do not last 60 days
Unknown Dialysis	A period in which the dialysis modality is not known such as in-hospital dialysis
Renal Transplantation	A functioning graft from either a living or deceased donor
Death	A category not appearing in the year-end modality tables, which report only on living patients. Often used as an outcome.
Larger Groupings	
Center Hemodialysis	Center hemodialysis and Center Self hemodialysis
Peritoneal Dialysis	CAPD, CCPD, Peritoneal Dialysis, Other peritoneal dialysis
Other/Unknown Dialysis	Uncertain dialysis, Unknown dialysis

Facilities began submitting patient data via CROWNWeb 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 1.7, 1.8, and 1.9, and Figures 1.17-1.20, laboratory values and treatment characteristics were derived from questions on the ESRD Medical Evidence form. All estimated glomerular filtration rate (eGFR) values were calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation from data acquired from the ESRD Medical Evidence form.

Chapter 2: Clinical Indicators and Preventive Care

Clinical Indicators

Figure 2.1 data were obtained from CROWNWeb clinical extracts for May 2016. The adequacy (Kt/V) analyses were restricted to patients at least 18 years old as of May 1, 2016. Patients must have been alive as of May 31, 2016, and must have had ESRD for at least one year as of the time of the measurement. If multiple measurements are available for a patient, the last one in the month was used. In Figure 2.1.b, all adult (aged 18 and older) patients who were on dialysis for at least 90 days as of May 1, 2016, and alive as of May 31, 2016, were included. If multiple hemoglobin (Hgb) measurements were available for a patient, the last one in the month was used. The categorical distributions of Hgb are shown for both HD and PD patients. In Figure 2.1.c, the hypercalcemia

measure was calculated as a 3-month rolling average for both HD and PD patients, who were alive as of May 31, 2016, and had ESRD for at least 90 days as of the time of measurement of an uncorrected serum calcium value.

Anemia Treatment by Modality[claims]

All of the findings in this section are based on Medicare claims data. The modality of the patient in each month was determined from the primary modality that was indicated on the claim for the Hgb, iron dose, and epoetin alfa (EPO) dose variables in the given month. For transfusion analyses, patients with at least one claim for HD or PD therapy were assigned to HD or PD in that month. Very few patients were treated with both modalities within the same month.

Dialysis claims were identified by revenue center codes 0800-0809, 0820-0889, and 0989. Hematocrit level was determined by value code 49 and hemoglobin by value code 48. EPO was identified using HCPCS codes J0885, J0886, and Q4081, and value code 68, darbepoetin by codes J0881 and J0882, epoetin beta by codes J0887, Q9972, and Q9973. Several types of iron were identified by HCPCS codes: sodium ferric gluconate (codes J2915 and J2916), iron dextran (J1750, J1751, J1752, and J1760), iron sucrose (J1755 and J1756), iron carboxymaltose (J1439 and Q9970), and ferumoxytol by (Q0139).

Hemoglobin levels are shown in Figures 2.2, 2.3, 2.8, and 2.9. Hemoglobin values were based upon the first reported claim in each month for HD patients (Figures 2.2-2.3) and PD patients (Figure 2.8-2.9). When Hgb levels were not available in claims data, any available hematocrit values were divided by three to serve as a proxy estimate. Patients were excluded in a given month if the Hgb level (or Hgb 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 2.2, 2.3, 2.8, and 2.9, 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 Hgb 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 2.2.d and 2.8.c, hemoglobin levels are also provided for all patients, with the same restrictions as in statement (2) above; these analyses were not limited to patients with an ESA claim within the given month.

Mean monthly EPO dose is shown for HD patients in Figure 2.2 and PD patients in Figure 2.8. To be included in the analysis sample, patients must have had an EPO claim in the given month, been 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 <250 units or >400,000 units per week; these criteria resulted in <0.001% of patients being excluded. Figure 1.1.a shows mean monthly EPO dose for those on erythropoetin alpha, Figure 2.2.b those on darbopoetin, and Figure 2.2.c those on pegylated (PEG)-EPO beta. Figure 2.2.d shows the percent of all patients with erythropeotin stimulating agent (ESA) use. Figure 2.3 shows categorical levels of Hgb for ESA using patients.

Intravenous (IV) iron use and IV iron dose are shown in Figures 2.4 (HD) and 2.10 (PD). The sample for monthly intravenous iron use contained patients on dialysis for 90 days or longer and who were 18 years or older at the start of the given month. For patients receiving IV iron during a month, the mean dose was calculated for the iron sucrose and ferrous gluconate they received. This analysis was restricted to those patients who had more than six but 18 or less IV iron sessions in a month. The permissible range of values considered for sucrose and ferrous gluconate were 50-1800 mg and 12.5-1800 mg.

The categorical distribution of iron store measures, transferrin saturation (TSAT) and serum ferritin for May 2014, May 2015, and May 2016, from CROWNWeb, are shown in Figures 2.5 (TSAT) and 2.6 (serum ferritin) for HD patients. Similar statistics for PD patients are shown in Figures 2.11 and 2.12. For Figure 2.5, the study cohort included dialysis patients receiving treatment for at least 90 days at the time of TSAT value measurement, who were 18 years or older as of May 1 of that year, and were alive through May 31. For each year, the latest non-missing TSAT value during March-May was used. For Figure 2.6, the same criteria apply to serum ferritin. Similar analyses were performed for PD patients. Figure 2.7.a shows the percentage of Medicare patients with one, two, three,

or four or more red blood cell transfusions per year from 2011-2015. 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. The numerator consisted of the total number of claims for transfusions a patient had in a given year. Patients' modality is the modality was determined by the first treatment of the year. Similarly, Figure 2.13.a shows the distribution of the number of red blood cell transfusions received by PD patients, by year.

The percentages of dialysis patients with one or more claims for red blood cell transfusions in a given month (2011-2015) are shown in Figures 2.7.b (HD) and 2.13.b (PD). For this calculation, the numerator consisted of dialysis patients with one or more red blood cell transfusion claims in a given month; the denominator included all patients having a claim for at least one session during the month and who were 18 years or older at the start of the month. Codes used to identify transfusions are shown in Table 14.7.

Mineral and Bone Disorder

Distributions of serum calcium levels from CROWNWeb data for HD and PD patients are shown in Figures 2.14 and 2.15 for May 2014, May 2015, and May 2016. Analyses for Figure 2.14 included HD patients with ESRD for at least one year at the serum calcium laboratory result, 18 years or older as of May 1 of that year, and were alive through May 31 of that year. Serum phosphorous analyses shown in Figure 2.16 used the same sample restrictions as defined above. Similar analyses were completed for PD patients, and are shown in Figures 2.15 and 2.17.

vol 2 Table 14.7 Transfusion codes identifying a red blood cell transfusion

Code	Code Type	Code Description
36430	HCPCS	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
30233H1	ICD-10	Transfuse Nonaut Whole Blood in Peripheral Vein, Percutaneous Approach
30233N1	ICD-10	Transfuse Nonaut Red Blood Cells in Peripheral Vein, Percutaneous Approach
30233P1	ICD-10	Transfuse Nonaut Frozen Red Cells in Peripheral Vein, Percutaneous Approach
30243H1	ICD-10	Transfuse Nonaut Whole Blood in Central Vein, Percutaneous Approach
30243N1	ICD-10	Transfuse Nonaut Red Blood Cells in Central Vein, Percutaneous Approach
30243P1	ICD-10	Transfuse Nonaut Frozen Red Cells in Central Vein, Percutaneous Approach
30253H1	ICD-10	Transfuse Nonaut Whole Blood in Peripheral Artery, Percutaneous Approach
30253N1	ICD-10	Transfuse Nonaut Red Blood Cells in Peripheral Artery, Percutaneous Approach
30253P1	ICD-10	Transfuse Nonaut Frozen Red Cells in Peripheral Artery, Percutaneous Approach
30263H1	ICD-10	Transfuse Nonaut Whole Blood in Central Artery, Percutaneous Approach
30263N1	ICD-10	Transfuse Nonaut Red Blood Cells in Central Artery, Percutaneous Approach
30263P1	ICD-10	Transfuse Nonaut Frozen Red Cells in Central Artery, Percutaneous Approach

Data Source: USRDS ESRD Database. Abbreviations: CMV, cytomegalovirus, HCPCS, Healthcare Common Procedure Coding System, ICD-9/10, International Classification of Diseases, Ninth/Tenth Revision; Nonaut, Nonautologous, NOS, not otherwise specified.

Preventive Care[claims]

Figure 2.18 presents statistics on diabetic preventive care. The claims data analysis for this figure used a one-year entry period to determine the presence of diabetes, referred to as 'year one.' Patients were required to have started ESRD treatment at least 90 days prior to January 1 of year one. Patient cohort criteria included alive, with a valid birth date, residing in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, Medicare Parts A and B coverage with no Medicare Advantage participation, and not lost to follow up in both years one and two. Claims from year one were then searched for diagnoses indicating diabetes mellitus (DM). The presence of testing was ascertained in the following year (year two); tests were at least 30 days apart. Age was calculated at the end of year two.

Patients were 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. Table 14.8 shows the various diagnosis and procedure codes used to define each diabetes-care measure. Comprehensive diabetic care includes at least one hemoglobin A1c (HgbA1c) test, at least one lipids test, and at least one eye exam. HgbA1c and lipid tests should occur at least 30 days apart

Table 14.8 Diagnosis and procedure codes used for diabetes-related care

	ICD-9 Diagnoses	ICD-10 Diagnoses	HCPCS	ICD-9 Procedures	ICD-10 Procedures
Diabetes Mellitus	250; 357.2; 362.0; 366.41 or Medical Evidence form	E08.311-E08.36; E08.40; E08.42; E09.311-E09.36; E09.40; E09.42; E10.10-E13.9 or Medical Evidence form	*<none>*	*<none>*	*<none>*
Testing					
Hemoglobin A1c	*<none>*	*<none>*	83036; 83037	*<none>*	*<none>*
Diabetic eye exam	V72.0	Z01.00; Z01.01	67028-67113; 67121-67228; 92002-92014; 92018; 92019; 92225; 92226; 92225-92260; S0620; S0621, S0625; S3000	14.1-14.5; 14.9; 95.02; 95.11; 95.12; 95.16	085E3ZZ; 085F3ZZ; 08943ZX; 08953ZX; 089A0ZX; 089A3ZX; 089B0ZX; 089B3ZX; 089E3ZX; 089F3ZX; 089G3ZX; 089H3ZX; 08B43ZX-08B53ZZ; 08B6XZZ ; 08B7XZZ; 08BA0ZX; 08BA3ZX; 08BB0ZX; 08BB3ZX; 08BE3ZX-08BF3ZZ; 08H031Z; 08H031Z; 08H0X1Z; 08H131Z; 08H1X1Z; 08J0XZZ; 08J1XZZ; 08QA0ZZ-08QB3ZZ; 08QE3ZZ; 08QF3ZZ; 08U00JZ; 08U03JZ; 08U10JZ; 08U13JZ; 08UE0JZ; 08UE3JZ; 08UF0JZ; 08UF3JZ; 3E0C3GC; 3E0CXSF; B30N0ZZ-B30NYZZ; C8191ZZ-C81YYZZ
Lipids	*<none>*	*<none>*	80061; 82465; 82470; 83695; 83700-83705; 83715-83721; 84478	*<none>*	*<none>*

Abbreviations: HCPCS, Healthcare Common Procedure Coding System; ICD 9/10, International Classification of Diseases, Ninth/Tenth version.

Figure 2.19 (a-d) presents data on influenza vaccinations for prevalent ESRD patients overall and by age, race/ethnicity, and modality. Claims were searched between August of one year and April of the following year. The cohort for influenza vaccinations included all ESRD patients initiating therapy at least 90 days prior to August 1 of the first year. Patients must have been alive, with a valid birth date, residing in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, have Medicare Parts A and B coverage with no Medicare Advantage participation, and not be lost to follow up. Age was calculated at the end of the study period. HCPCS codes used to identify influenza vaccinations were 90724, 90657, 90658, 90659, 90660, and G0008.

Chapter 3: Vascular Access

Vascular Access Use at Initiation of Hemodialysis

Data for Figures 3.1-3.3 and Table 3.1 were obtained from the Medical Evidence form (CMS 2728). Data were restricted to the 2005 and 2015 versions of the CMS 2728 form and incorporated the recent change in diagnosis codes from ICD-9-CM to ICD-10-CM. Patients with missing vascular access data were excluded. Figure 3.1 presents data for patients who began hemodialysis during 2005-2015. Table 3.1 and Figures 3.2-3.3 present data for patients beginning dialysis in 2015. Age was calculated as of the date that regular, chronic dialysis began. Race and ethnicity categories changed this year from previous ADRs (see *Race and Ethnicity* in the *Database Definitions* section above for details); tables 3.1, 3.2, 3.4, 3.6, and 3.7 reflect those adjustments.

In Figures 3.2 and 3.3 we illustrate geographic variation in the 2014 percentages of catheter-only use and arteriovenous (AV) fistula use at hemodialysis initiation. There figures 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 3.2 and Figures 3.4-3.6.

For Table 3.2, CROWNWeb data was used to determine vascular access use for December 2015. Catheter use included any catheter, whereas AV fistula and AV graft use were without the use of a central venous catheter.

Figures 3.4 and 3.5 show geographic variation in the percentages of catheter-only and AV fistula use among prevalent hemodialysis patients by HAs; these analyses used CROWNWeb data from December 2015, and excluded patients not living in the 50 states or the District of Columbia.

Figure 3.6 presents data as reported from the Fistula First Initiative from July 2003 to April 2012 and CROWNWeb from June 2012 to May 2016. May 2012 data was not included in the analysis to denote the breakpoint between the two sources. The denominator was obtained from the treatment history file, and limited to hemodialysis patients beginning dialysis between January 1, 2013 and May 30, 2016, who were not transplanted, and were alive at the end of each month. The numerator was obtained from vascular access extract files in CROWNWeb for the same time period. Access type at initiation was from the Medical Evidence form; vascular access data for all other time points were obtained from CROWNWeb. There was a 15-day look-back and 15-day look-forward period to determine vascular access.

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

Figure 3.7.a and Tables 3.3-3.5 include a cross-section of patients who were incident and alive at each time point in 2013. They used data from January 1, 2013 to May 30, 2016, from the Medical Evidence form (CMS 2728) data at initiation and CROWNWeb for subsequent time periods. Data were restricted to the 2005 and 2015 versions of the Medical Evidence form (CMS 2728). Patients with missing vascular access data were excluded.

Figure 3.7.b follows a cohort of patients (N=101,453) from dialysis initiation to one year after initiation. As with Figure 3.7.a, Figure 3.7.b used 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.

Predictors of AV Fistula Use at Hemodialysis Initiation

Table 3.6 presents two models of the odds of AV fistula use at initiation and AV fistula or AV graft use at initiation. These two multiple logistic regression models used vascular access type at initiation, demographic, and facility information from the 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.

Fistula Maturation

Table 3.7 includes patients with a fistula placed at any point between June 1, 2014 and May 31, 2015 who were already on ESRD at time of placement, with follow-up through June 2016. Fistula placement was identified through inpatient, outpatient, and physician/supplier Medicare claims using the HCPCS codes 36818, 36819, 36820, 36821 and 36825.

Subsequent first use of the placed fistula was determined by finding evidence in CROWNWeb through June of 2016. In order to be included in the analyses, patients were required to have vascular access use data in CROWNWeb following the fistula placement. If fistula use following the placement (and prior to any later fistula placements) was indicated in CROWNWeb, the fistula was considered to have successfully matured for use. If the fistula use following placement was not present in CROWNWeb, it was assumed to have failed to mature. 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" cannot currently be determined from CROWNWeb. Patients that died following the fistula placement were also included in the analysis.

Chapter 4: 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*[claims] (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. Included patients have Medicare as primary payer, with Part A coverage at the start of follow-up, and without Medicare Advantage 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. Hospitalization data do not exclude inpatient stays for the purpose of rehabilitation therapy.

Statistical models

Inpatient institutional claims were used for the analyses, and methods for cleaning claims follow those described for *Reference Table G*. Adjusted rates were calculated using the model-based adjustment method on the observed category-specific rates. Predicted rates were calculated with a Poisson model, and adjusted rates were 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*[CLAIMS], and in the *Statistical Methods* section later in this chapter.

Unless otherwise indicated, in all analyses where adjustments were made, rates were adjusted for age, sex, race, ethnicity, primary cause of ESRD, vintage, and their two-way interactions (except for race and ethnicity) with the 2011 ESRD cohort used as the reference.

Trends in Hospitalization rates

Methods in Figures 4.1-4.2 and 4.4 follow those for *Reference Table G: Morbidity and Hospitalization*[CLAIMS]. Figure 4.1 presents adjusted rates of total hospital admissions per patient year for prevalent ESRD patients.

Figure 4.2 shows the hospitalization rates since 2006 for period prevalent ESRD patients. Included patients had Medicare as primary payer and are

residents of the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. Patients with AIDS as a primary or secondary cause of death were excluded, as were patients with missing age or sex information.

New dialysis access codes for PD patients appeared in late 1998. For PD patients, dialysis access hospitalizations were those defined as "pure" inpatient vascular/dialysis access events, as described for Reference Tables G.11-G.15. For HD patients, vascular access hospitalizations included "pure" inpatient vascular access events, and vascular access for HD patients excluded codes specific to PD catheters (996.56, 996.68, and V56.2).

Principal ICD-9-CM and ICD-10-CM diagnosis codes were used to identify cardiovascular and infection admissions. Table 14.9 shows the ICD-9-CM and ICD-10-CM codes used to classify a hospitalization as cardiovascular or infectious. Codes for vascular access related hospitalizations are listed in Table 14.14 in the section describing the methods for *Reference Table G: Morbidity and Hospitalization*[CLAIMS] .

Figure 4.3 shows the all-cause hospitalization rates by treatment modality and number of years after the start of dialysis for the cohorts of incident patients in 2004, 2007, 2010, and 2013. This figure did not include adjustment for vintage. For prevalent ESRD patients, Figure 4.4 presents unadjusted and adjusted rates of total hospital admissions per patient year by Health Service Area in 2014 and 2015.

Hospitalization Days

Figure 4.5 shows adjusted hospital days per patient year by treatment modality among prevalent ESRD patients. Figure 4.6 shows adjusted infectious and cardiovascular hospital days per patient year among prevalent ESRD patients. Principal ICD-9-CM and ICD-10-CM codes for cardiovascular and infection hospitalizations are shown in Table 14.9.

vol 2 Table 14.9 Diagnosis codes used to characterize cause of hospitalization for the chapter

	Principle diagnosis for hospital stay	
Hospitalization cause	**ICD-9-CM codes**	**ICD-10-CM codes**
Cardiovascular hospitalizations	276.6; 394-398; 401-405; 410-420; 421.9; 422.90, 422.99, 423-438; 440-459	E08.51; E08.52; E09.51; E09.52; E10.51; E10.52; E11.51; E11.52; E13.51; E13.52; G45.0-G46.8; I05.0-I09.1; I09.81-I32; I33.9-I38; I40.1; I40.9; I42-I67.82; I67.841-I87.9; I89.0-I97.2; I99.8; I99.9; K64.0-K64.9; M30.0-M31.9; M32.11; M32.12; N26.2; R00.0; R58; T80.0XXA; T81.72XA;T82.817A; T82.818A
Infectious hospitalizations	001-139; 254.1; 320-326; 331.81; 372.0-372.3; 373.0-373.2;382.0-382.4; 383; 386.33, 386.35; 388.6; 390-391; 392.0, 392.9; 393; 421.0, 421.1; 422.0, 422.91-422.93; 460-466; 472-473; 474.0; 475; 476.0, 476.1;478.21, 478.22, 478.24, 478.29; 480-490; 491.1; 494; 510; 511; 513.0; 518.6; 519.01; 522.5, 522.7; 527.3; 528.3; 540-542; 566-567; 569.5; 572.0-572.1; 573.1-573.3; 575.0-575.12; 590; 595.1-595.4;597; 598.0; 599.0; 601; 604; 607.1-607.2; 608.0, 608.4; 611.0; 614-616.1, 616.3, 616.4, 616.8; 670; 680-686; 706.0; 711; 730.0-730.3, 730.8-730.9; 790.7, 790.8; 996.6; 998.5; 999.3	A00.0-A32.9; A35-B99.9; D86.0-D86.9; E32.1; E83.2; G00.0-G04.02;G04.2-G09; G14; G37.4; G92; G93.7; H00.011-H10.9; H16.251-H16.269; H32; H66.001-H66.43; H67.1-H67.9; H70.001-H70.93; H75.00-H75.83; H83.01-H83.09; H92.10-H92.13; H95.00-H95.199; I00-I02.9; I09.2; I32; I33.0; I39-I40.8; I41;I67.3; J00-J18.1; J18.8-J21.9; J31.0-J32.9; J35.01-J35.03; J36;J37.0; J37.1; J39.0-J39.2; J40; J41.1; J47.0-J47.9; J85.0-J85.2;J86.0-J92.9; J94.0-J94.9; J95.02; K04.6; K04.7; K11.3; K12.2;K35.2-K37; K50.014; K50.114; K50.814; K50.914; K51.014;K51.214; K51.314; K51.414; K51.514; K51.814; K51.914; K57.00; K57.01; K57.20; K57.21; K57.40; K57.41; K57.80;K57.81; K61.0-K61.4; K63.0; K65.0-K65.9; K67-K68.9; K71.0-K71.9; K75.0-K75.3; K75.81-K75.9; K76.4; K77; K81.0-K81.9;K90.81; L01.0-L08.9; L44.4; L70.2; L88; L92.8; L94.6; L98.0;L98.3; M00.00-M01.X9; M02.10-M02.19; M02.30-M02.89;M35.2; M46.20-M46.39; M86.00-M86.9; M90.80-M90.89;N10-N12; N13.6; N15.1; N15.9; N16; N28.84-N28.86; N30.0-N30.31; N30.80; N30.81; N34.0-N34.3; N35.111-N35.12; N37-N39.0; N41.0-N41.9; N45.1-N45.4; N47.6; N48.1-N48.29; N49.0-N49.9; N51; N61; N70.01-N74; N75.1; N76.0-N76.4; N77.1; N98.0; O85; O86.12; O86.81; O86.89; R09.1; R11.11; R78.81;T80.211A-T80.29A; T81.4XXA; T82.6XXA; T82.7XXA; T83.51xXA-T83.6XXA; T84.50XA-T84.7XXA; T85.71XA-T85.79XAT86.842; T87.40-T87.44; T88.0XXA
Vascular access-related hospitalizations	See Table 14.14	See Table 14.14
Vascular access infections	996.62; 999.31	T80218A; T80219A; T827XXA
Acute myocardial infarction	410.00; 410.01; 410.10; 410.11; 410.20; 410.21; 410.30; 410.31; 410.40; 410.41; 410.50; 410.51; 410.60; 410.61 410.70; 410.71; 410.80; 410.81; 410.90; 410.91	I21.02-I22.9
Heart failure	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 425; 428;	A18.84; I09.81; I11.0; I13.0; I13.2; I42.0-I43; I50.1-I50.9;
Stroke	430-434	I60.00-I66.9
Dysrhythmia	426; 427	I44.0-I49.9; R00.1

Abbreviations: ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth version.

Rehospitalization rates

Figures 4.7-4.12 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 were identified as index hospitalizations; the latter date provided a 30-day period following the latest discharge to evaluate rehospitalization. The unit of analysis was hospital discharge rather than patients. Transfers and discharges with a same-day admission to long-term care or a critical access hospital were excluded.

For HD patients in Figures 4.7-4.12, discharges with a transplant, loss to follow-up, or end of payer status before 30 days after discharge were excluded. For ESRD patients in Figure 4.7, the same exclusions applied except as related to transplant. As transplant patients lose their Medicare entitlement three years after transplant, discharges for transplant patients are excluded if they occur after two years and 11 months following the most recent transplant, to ensure that complete claims are available during the 30-day post-discharge period.

Figure 4.7 shows the 30-day disposition of hospital discharges in 2015: died without rehospitalization, rehospitalized and died by day 30, and rehospitalized and alive on day 30. This is shown for three patient groups: general Medicare, CKD, and ESRD. The sample includes point prevalent Medicare patients on December 31, 2014, who were aged 66 and older. For general Medicare patients with and without CKD, CKD was defined during 2014, and patients in the sample were without ESRD, had continuous enrollment in Medicare Parts A and B, and were without Medicare Advantage coverage. Live hospital discharges from January 1 to December 1, 2015 were included.

Figures 4.7 and 4.8 included all-cause index hospitalizations, while in Figures 4.9-4.12 categories of cause-specific admissions were based on principal ICD-9-CM and ICD-10-CM diagnosis codes of the index hospitalization. Codes to define the specific causes of hospitalization are shown in Table 14.9.

Chapter 5: Mortality

Unless otherwise specified, patient cohorts underlying the analyses presented in Chapter 5 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 5.1 shows trends in mortality rates by modality among incident ESRD patients during 2001-2015. Modalities include ESRD, dialysis, HD, CAPD/CCPD (peritoneal dialysis), 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, 2015. Transplant patients begin follow-up at the date of transplant and are censored on December 31, 2015.

Adjusted mortality rates for each period after first treatment are computed separately by taking an appropriately 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 generalized linear model serves as the basis for the predicted rates, adjusted for age, sex, race, ethnicity, vintage, and primary cause of ESRD. The reference population consists of 2011 period prevalent ESRD patients.

All-cause mortality by ESRD Network and Modality

Table 5.1 shows both adjusted and unadjusted all-cause mortality by ESRD network and modality during 2013-2015. The adjusted rates are based on the predicted rates from separate generalized linear models within each modality and overall ESRD population. The reference population consists of 2011 period prevalent ESRD patients.

Mortality by Duration of Dialysis, Including Trends Over Time

Figure 5.2 shows adjusted all-cause mortality among incident patients during each year after

incidence. The rates are based on the predicted cumulative hazard for patients in the reference dataset from an adjusted Cox model of survival based on incident patients in 2013, adjusted to period prevalent patients in 2011.

Mortality During the First Year of ESRD

Figure 5.3 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 (5.3.a) and aged 65 and over (5.3.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 5.2.

Mortality by Age and Race

Table 5.2 shows the death rates by race and age categories (5.2.a) and by sex and age categories (5.2.b) among period prevalent transplant and dialysis patients in 2015. Adjusted rates are calculated as described in the *Statistical Methods* section, under *Methods for Adjusting Rates*. The table showing death rates by race and age is adjusted for sex and primary cause of ESRD, and the table showing death rates by sex and age is adjusted for race and primary cause of ESRD.

Cause-Specific Mortality Rates

Figure 5.4 shows unadjusted cause-specific mortality percentages by modality (dialysis patients and transplant recipients). 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), coronary artery disease, cardiomyopathy, cardiac arrhythmia, cardiac arrest (cause unknown), valvular heart disease, pulmonary edema due to exogenous fluid, 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, AIDS, 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 5.3 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 5.3, 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 2014 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 5.

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

Table 5.4 presents expected remaining lifetimes in years for the 2013 general U.S. population, and for 2014 prevalent dialysis and transplant patients. For period prevalent ESRD patients in 2014, 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 and calculating the area under this piecewise-exponential survival curve. The method for calculating expected remaining lifetimes is described in the *Statistical Methods* section, under *Expected Remaining Lifetimes*. 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 5.5 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 not in a Medicare Advantage plan 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 5.5 presents adjusted all-cause mortality in the ESRD, dialysis, transplant populations, and among general Medicare patients from the 5% sample with cancer, diabetes mellitus, heart failure, cerebrovascular accident/transient ischemic attack, and acute myocardial infarction. 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. The current analysis does not use race in the standardization. The form change in 2005 resulted in altered definitions of some of the racial groups, particularly "other" race. Adjusting for these categories resulted in mortality trends that reflected the changing racial definition more than underlying case-mix-adjusted mortality rates. We have limited the adjustments used in this analysis to factors which were not affected by the form change.

Chapter 6: Transplantation

Kidney Transplant Waiting List

Figure 6.1 shows the number of patients on the waiting list for kidney transplant by first and subsequent listings, 1998-2015. Waiting list counts include all candidates listed for a kidney transplant on December 31 of each year. The data source is Reference Table E.3.

Figure 6.2 shows the percentage of dialysis patients on the kidney waiting list, 1998-2015. The data source is Reference Table E.4.

Figure 6.3 shows the percentage of incident patients waiting for or receiving a deceased or living donor kidney-alone or kidney plus additional organ transplant within one year of ESRD initiation, 0-74 years old, stratified by age, during 1998-2014. The data source is Reference Table E.5(2).

Figure 6.4 shows the median waiting time (in years) from wait-listing to kidney transplant 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 on the waiting list in each given year during 1998-2010. The data source is Reference Table E.2.

Table 6.1 displays the median waiting time (in years) from wait-listing to kidney transplant for candidates for kidney transplant, by blood types and panel reactive antibodies (PRA), during 1998-2010. The same methods used to calculate the median waiting time in Figure 6.4 are used for Table 6.1. Median waiting time cannot be calculated if the estimated time to transplant probability had not reached 50% (median) at the end of the follow up. Data are obtained from the USRDS ESRD database and OPTN.

Table 6.2 displays the reported outcomes within five years since first listing for kidney-alone transplant in 2010, by blood type, PRA, and age. Patients were followed until five years after being listed. The reported outcomes include receiving a living donor transplant, receiving a deceased donor transplant, still waiting for a transplant by end of follow-up, or being removed from waiting list due to death or other reasons other than transplant. Among patients with

blood type AB, PRA is not dichotomized as among the other blood types, due to small sample size. Data are obtained from the USRDS ESRD database and OPTN.

Transplant Counts and Rates

Figure 6.5 shows the number of transplants by donor type during 1998-2015. The data source is Reference Tables E.8, E.8(2), and E.8(3).

Figure 6.6 shows the prevalent counts of patients with a functioning kidney-alone or kidney-pancreas transplants as of December 31 of each year during 1998-2015. The data source is Reference Table D.9.

Figure 6.7 shows the unadjusted transplant rates by donor type for all dialysis patients, 1998-2015. The data source is Reference Table E.9.

Table 6.3 displays the unadjusted kidney transplant rates of all donor types, by age, sex, race, and primary cause of ESRD, per 100 dialysis patient years, during 2006-2015. The data source is Reference Table E.9.

Figure 6.8 illustrates the geographic distribution of the unadjusted transplant rate per 100 dialysis patient years by state in 2015. Both deceased and living donor transplants are included.

Figures 6.9-6.12 present the counts and unadjusted rates of deceased donor kidney-alone and simultaneous kidney-pancreas transplants by age, sex, race, and recipient primary cause of ESRD, during 1998-2015. The data source is Reference Tables E.8(2) and E.9(2).

Figures 6.13-6.16 present the counts and unadjusted rates of living donor kidney-alone and simultaneous kidney-pancreas transplants by age, sex, race, and recipient primary cause of ESRD, during 1998-2015. The data source is Reference Tables E.8(3) and E.9(3).

Figure 6.17 shows the number of kidney paired donation transplants and the percent of all living donor transplants that were kidney paired donation during 2001-2015. 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." For the percent of living donor transplants, the denominator is any kidney-alone or kidney plus at least one other organ transplant from a living donor. Data are obtained from OPTN.

Deceased Donation Counts and Rates Among All-cause Deaths

Figures 6.18-6.20 present 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 2001-2015. 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 6.21-6.23 present the counts and unadjusted rates of deceased donor donation among traumatic deaths within the U.S. population younger than 75 years old, by age, sex, and race, during 2001-2015. 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 6.4 displays one-, five-, and ten-year graft and patient outcomes for recipients who received a first kidney transplant from a deceased donor during 1998-2014. Data sources for one-, five-, and ten-year trends are from Reference Tables F.2, F.14, I.26; F.5, F.17, I.29; and F.6, F.18, I.30, respectively.

Table 6.5 displays one-, five-, and ten-year graft and patient outcomes for recipients who received a first kidney transplant from a living donor during 1998-2014. 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 6.4 and 6.5, 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 transplant, return to dialysis, and death. Death outcome is not censored at graft failure, repeat transplant, or return to dialysis.

Chapter 7: ESRD Among Children, Adolescents, and Young Adults

Information on children, adolescents, and young adult 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 0-4 years old from 1996-2015, from the Medical Evidence form and CROWNWeb data, a data cleaning process was deemed necessary for this chapter. There were 244 patients with unreasonable height and weight values for children under four, 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 relevance. 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 7.1 due to 10 or fewer total pediatric patients for year categories. See the section on Reference Table A for conversion of the 2015 Medical Evidence form to the categories on the 2005 Medical Evidence form.

Growth

Growth status at the time of ESRD initiation was presented. Stature reported for age < 21 per growth percentile guidelines. Percentiles for children greater or equal to 24 months of age and up to less than 20 years of age are calculated following Centers for Disease Control and Prevention (CDC) growth charts. Percentiles for children less than 24 months of age are calculated following World Health Organization (WHO) growth charts. Short stature is defined as height less than 3rd percentile for sex and age. BMI categories are defined differently for patients by age:

- For those younger than 18:
    - Underweight: BMI < 5th percentile
    - Normal: 5th percentile ≤ BMI < 85th percentile
    - Overweight: 85th percentile ≤ BMI < 95th percentile
    - Obese: BMI ≥ 95th percentile
- For patients 18 and older:
    - Underweight: BMI < 18.5
    - Normal: 18.5 ≤ BMI < 25 percentile
    - Overweight: 25 ≤ BMI < 30
    - Obese: BMI ≥ 30

Hospitalization[claims]

Figures 7.5-7.7 present adjusted admission rates in the first year of ESRD, by age, and modality, for incident patients younger than age 22 in 2005-2009 and 2010-2014. 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 patients who are younger than 65 and not disabled cannot bill Medicare 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, 2015, 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 population is incident ESRD patients aged 0-21 years in 2010-2011. Principal ICD-9-CM and ICD-10-CM diagnosis codes used for infectious hospitalizations are shown in Table 14.9 in the Hospitalization section. Changes are made for the cardiovascular hospitalization codes in order to reflect the events considered appropriate for children. The cardiovascular category consists of:

- Principal ICD-9-CM diagnosis codes 391.0-391.9, 398.0-398.99, 402.00-402.91, 404.02, 404.03, 404.12, 404.13, 404.92, 404.93, 411.0, 411.1, 412, 413.0-414.02, 414.05-414.9, 420.91, 421.0, 422.91, 424.0, 424.0, 424.1, 424.3, 425.0, 425.2-425.9, 426.0-426.13, 426.3, 426.4, 426.6, 426.7, 426.9-427.41, 427.5, 427.81-428.9, 429.0-429.9, 430-432.9, 434.00-434.11, 435.0-437.1, 437.3-438.22, 438.81-438.85, 438.9, 440.1, 440.21-440.29, 440.4-440.9, 441.3, 441.4, 441.9, 443.21-443.29, 443.9, 442.0, 442.2, 442.3, 442.82, 443.0, 443.1, 443.82, 444.21, 446.1, 446.5, 447.0-447.5-449, 459.10-459.9, 471.0, 745.0-745.9, 746.1-746.89, 747.0, 747.11-747.60, 747.62-747.9, V43.3
- Principal ICD-10-CM diagnosis codes – Contact usrds@usrds.org to request a detailed listing of all ICD-10-CM code values.

Mortality and Survival

Table 7.3 shows expected remaining lifetimes by modality while Figures 7.8-7.9 present adjusted all-cause and cause-specific mortality in the first year of ESRD, by age and modality, for 2005-2009 and 2010-2014 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) and 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, 61

Mortality due to infection is also 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 7.11 shows five-year survival rates for 2006-2010 incident ESRD patients aged 0-21 years, by age and modality. Methods follow those of Figures 7.8 and 7.9 above.

Vascular Access

Data for Figure 7.12 and Figure 7.13 are obtained from the Medical Evidence form; data are restricted to the 2005 and 2015 versions. Figure 7.13 also includes data from CROWNWeb. Patients with missing vascular access data are excluded. Figure 7.12 presents statistics for pediatric patients who began dialysis during 2006-2015; age is calculated as of the date regular chronic dialysis began. In Figure 7.13, 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 7.14 presents an overview of the transplant population among children and adolescents.

Figure 7.14.a shows the incidence rate of ESRD among those aged 0-21 years in the U.S. population and the rate of transplantation in patients 0-21 at transplant during 1996- 2015. Pre-emptive transplant patients were included in both the numerator and the denominator.

Figure 7.14.b shows the number of ESRD-certified candidates 0-21 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 7.14.c-7.14.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 7.15 presents transplant rates per 100 dialysis patient years among dialysis patients (0-21 years old). Figure 7.15.a presents rates by age group and donor type (living v. deceased). Figure 7.15.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 7.16 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 7.16.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 7.16 includes pediatric patients (0-21 years old) starting initiation of HD or PD in 1996-2014, and having the first transplant before 12/31/2015. Primary cause of ESRD in Figure 7.16.c is from the Medical Evidence form.

Table 7.4 presents adjusted ten-year patient 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. Statistics shown are reported as adjusted probabilities of each outcome happening 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, probabilities are adjusted for age, sex, race, primary cause of ESRD, and first versus subsequent transplant. They are then standardized to 2011 patient characteristics. All-cause graft failure includes re-transplant, return to dialysis, and death.

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 retransplant 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 8: Cardiovascular Disease[claims]

This chapter describes the prevalence of cardiovascular comorbidities and selected cardiovascular procedures in eligible fee-for-service, Medicare enrollees. According to a previously validated method for using Medicare claims to identify diabetic patients, a patient is considered to have diabetes 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 and ICD-10-CM diagnosis codes over a one-year 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 coronary artery disease (CAD), acute myocardial infarction (AMI), heart failure (HF), valvular heart disease (VHD), cerebrovascular accident/transient ischemic attack (CVA/TIA), peripheral arterial disease (PAD), atrial fibrillation (AF), sudden cardiac arrest and ventricular arrhythmias (SCA/VA), and venous thromboembolism and pulmonary embolism (VTE/PE). The algorithm above is used to define these

cardiovascular conditions using the ICD-9-CM or ICD-10-CM code values in Table 14.10.

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 diagnosis or a claim for a procedure. Table 14.11 shows the codes and type of claims used to identify each procedure.

vol 2 Table 14.10 ICD-9-CM and ICD-10-CM diagnosis codes used to define cardiovascular disorders

Condition name	ICD-9-CM diagnosis codes	ICD-10-CM diagnosis codes
Any cardiovascular disease (CVD)	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 410-414; 422; 425-428; 430-438; 440-444; 447; 451-453; 557; V42.1, V45.0, V45.81, V45.82, V53.3	A18.84; E08.51 E08.52; E09.51; E09.52; E10.51; E10.52; E11.51; E11.52; E13.51; E13.52; G45.0-G45.2; G45.4-G46.8; I09.81; I11.0; I12.00-I22.9; I13.0; I13.2; I21.01-I22.9; I24.0-I25.9; I25.2; I34.0-I39; I40.0-I43; I46.2-I47.0; I47.2; I48.0-I48.92; I49.01; I49.02; I49.3; I49.49; I50.1-I50.9; I60.00-I66.9; I67.0; I67.1; I67.2; I67.4-I67.82; I67.841-I69.998; I70.0-I74.9; I77.0-I77.9; I79.0-I79.8; I81-I82.91; K55.0; K55.1; K55.8; K55.9; M31.8; M31.9; M32.11; Z48.21; Z48.280; Z94.1; Z94.3; Z95.1; Z95.5; Z98.61
Acute myocardial infarction (AMI)	410; 412	I21.01-I22.9; I25.2
Atrial fibrillation (AFIB)	427.3	I48.0-I48.92
Cerebrovascular accident/ transitory ischemic attack (CVA/TIA)	430–438	G45.0-G45.2; G45.4-G46.8; I60.00-I66.9; I67.1; I67.2; I67.4-I67.82; I67.841-I69.998
Coronary artery disease (CAD)	410-414; V45.81, V45.82	I12.00-I22.9; I24.0-I25.9; Z95.1; Z95.5; Z98.61
Heart failure (CHF)	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 422[a]; 425[a]; 428; V42.1[a]	A18.84; I09.81; I11.0; I13.0; I13.2; I40.0-I43; I50.1-I50.9; Z48.21; Z48.280; Z94.1; Z94.3
Systolic or both systolic & diastolic	428.2, 428.4	I50.20-I50.23; i50.40-I50.43
Diastolic only	428.3	I50.30-I50.33
Heart failure, unspecified	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 422[a]; 425[a]; 428 (not 428.2-428.4); V42.1[a]	A18.84; I09.81; I11.0; I13.0; I13.2; I40.0-I43; I50.1; I50.9; Z48.21; Z48.280; Z94.1; Z94.3
Peripheral arterial disease (PAD)	440–444; 447; 557	E08.51; E08.52; E09.51; E09.52; E10.51; E10.52; E11.51; E11.52; E13.51; E13.52; I67.0; I70.0-I74.9; I77.0-I77.9; I79.0-I79.8; K55.0; K55.1; K55.8; K55.9; M31.8; M31.9
Sudden cardiac arrest/ventricular arrhythmias (SCA/VA)	427.1, 427.4, 427.41, 427.42, 427.5, 427.69	I46.2-I47.0; I47.2; I49.01; I49.02; I49.3; I49.49
Valvular heart disease (VHD)	424	A18.84; I34.0-I39; M32.11
Venous thromboembolism and pulmonary embolism (VTE/PE)	452-453.9	I81-I82.91

Data Source: ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification. ICD-9-CM diagnosis codes have up to five digits with a decimal point between the 3rd and 4th digit, while ICD-10-CM codes are seven digits. Codes listed with three digits include all existing 4th and 5th digits, and those listed with four digits include all existing 5th digits. Peripheral arterial disease is defined as having a diagnosis and/or a procedure.

vol 2 Table 14.11 Procedure codes (ICD-9-CM and HCPCS) & claims files used to define cardiovascular procedures in the USRDS ADR

Peripheral arterial disease (PAD)	
ICD-9-CM Procedure codes:	
Claims files searched: IP, OP, SN	
Values:	*39.25, 39.26, 39.29; 84.0, 84.1, 84.91*
ICD-10-CM Procedure codes:	
Claims files searched: IP, OP, SN	
Values:	*All of: 0312090-031309K; 0315091-031G0ZG; 031K09J-031N0ZK; 0414093-041N4ZS; 051707Y-051V4ZY; 061307Y-061V4ZY; 061307Y-0X6W0Z3; 0Y620ZZ-0Y6Y0Z3. All except xxxxxx3, xxxxxx4, xxxxxx5: 0410090-04104ZR; All except xxxxxxM, xxxxxxN: 03130J0-03140ZK; All except xxxxxxG: 031H09J-031J0ZK*
HCPCS codes:	
Claims files searched: PB, OP-revenue	
Values:	*24900, 24920, 25900, 25905, 25920, 25927, 27295, 27590, 27591, 27592, 27598, 27880, 27881, 27882, 27888, 27889, 28800, 28805, 34900, 35131, 35132, 35141, 35142, 35151, 35152, 34051, 34151, 34201, 34203, 34800–34834, 35081–35103, 35331, 35341, 35351, 35355, 35361, 35363, 35371, 35372, 35381, 35450, 35452, 35454, 35456, 35459, 35470, 35471, 35472, 35473, 35474, 35480, 35481, 35482, 35483, 35485, 35490, 35491, 35492, 35493, 35495, 35521, 35531, 35533, 35541, 35546, 35548, 35549, 35551, 35556, 35558, 35563, 35565, 35566, 35571, 35583, 35585, 35587, 35621, 35623, 35646, 35647, 35651, 35654, 35656, 35661, 35663, 35665, 35666, 35671*
Percutaneous coronary interventions (PCI)	
ICD-9-CM Procedure codes:	
Claims files searched: IP, OP, SN	
Values:	*00.66; 36.01, 36.02, 36.05, 36.06, 36.07*
ICD-10-CM Procedure codes:	
Claims files searched: IP, OP, SN	
Values:	*02703ZZ; 02704ZZ; 02713ZZ; 02714ZZ; 02723ZZ; 02724ZZ; 02733ZZ; 02734ZZ*
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*
ICD-10-CM Procedure codes:	
Claims files searched: IP, OP, SN	
Values:	All of: 0210083-02100ZF; 0210483-02104ZF; 211088-021108C; 021208C; 021208W; 021209C; 021209W; 02120AC; 02120AW; 02120JC; 02120JW; 02120KC; 02120KW; 02120ZC; 021248C; 021248W; 021249C; 021249W; 02124AC; 02124AW; 02124JC; 02124JW; 02124KC; 02124KW; 02124ZC; 021308C; 021308W; 021309C; 021309W; 02130AC; 02130AW; 02130JC; 02130JW; 02130KC; 02130KW; 02130ZC; 021348C; 021348W; 021349C; 021349W; 02134AC; 02134AW; 02134JC-02134JW; 02134KC; 02134KW; 02134ZC; All except xxxxxxF, xxxxxx3, xxxxxx4: 211088-02110ZC; 211488-02114ZC

Table 14.11 continued on next page.

vol 2 Table 14.11 Procedure codes (ICD-9-CM and HCPCS) & claims files used to define cardiovascular procedures in the USRDS ADR *(continued)*

Implantable cardioverter defibrillators & cardiac resynchronization therapy with defibrillator (ICD/CRT-D)	
ICD-9-CM Procedure codes:	
Claims files searched: IP, OP, SN	
Values:	*00.51; 37.94*
ICD-10-CM Procedure codes:	
Claims files searched: IP, OP, SN	
Values:	*02H60KZ; 02H63KZ; 02H64KZ; 02H70KZ; 02H73KZ; 02H74KZ; 02HK0KZ; 02HL3KZ; 02HL4KZ; 02PA0MZ; 02PA3MZ; 02PA4MZ; 02PAXMZ; 0JH608Z; 0JH609Z; 0JH638Z; 0JH639Z; 0JH808Z; 0JH809Z; 0JH838Z; 0JH839Z; 0JPT0PZ; 0JPT3PZ*
Carotid artery stunting and carotid artery 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*
ICD-10-CM Procedure codes:	
Claims files searched: IP, OP, SN	
Values:	*037x34Z, 037x3DZ, 037x3ZZ, 037x44Z, 037x4DZ, 037x4ZZ, for x=G to Q, except I & O; 03Bx0ZZ, 03Bx4ZZ, for x=G to V, except I & O; 03CG0ZZ, 03CG3Z6, 03CG3ZZ, 03CG4Z6, 03CG4ZZ, 03Cx0ZZ, 03Cx3ZZ, 03Cx4Z6, 03Cx4ZZ for x=H to V, except I & 0; 03Cx3Z6 for x=R to V; 03RG07Z-03RV4KZ; 057L3DZ, 057L4DZ, 057M3DZ, 057M4DZ, 057N3DZ, 057N4DZ, 057P3DZ, 057P4DZ,057Q3DZ, 057Q4DZ, 057R3DZ, 057R4DZ, 057S3DZ, 057S4DZ, 057T3DZ, 057T4DZ, 05Bx0ZZ, 05BLx4ZZ for x=L to V, except O. 05RL07Z-05RV4KZ; 06R307Z-06R34KZ*
HCPCS codes:	
Claims files searched: PB, OP-revenue	
Values:	*37215, 37216*

Data Source: ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification. ICD-9-CM procedure codes have up to four digits with a decimal point between the 2nd and 3rd digits, while ICD-10-CM codes have seven digits. Codes listed with three digits include all possible 4th digits. HCPCS codes have 5 digits without a decimal point. Peripheral arterial disease is defined as having a diagnosis and/or a procedure. 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[claims]

Table 8.1 displays the prevalence of cardiovascular comorbidities and procedures, by modality, age, race and gender, among ESRD patients in 2015. The cohort includes point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older on January 1, 2015, who are continuously enrolled in Medicare Parts A and B and with Medicare as primary payer from January, 1, 2015 to December 31, 2015, and whose ESRD first service date is at least 90 days prior to January 1, 2015. We exclude patients with unknown 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 CAD, the percent with ICD/CRT-D was out of cohort members with HF, and the percent with CAS/CEA was out of cohort members with CAD, CVA/TIA, or PAD.

Figures 8.1 and 8.2 show the percentage of patients who had cardiovascular comorbidities, by modality and age, respectively, among adult ESRD patients in 2015. The cohort is the same one used for Table 8.1.

Figure 8.3 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 on January 1, 2013, who are continuously enrolled in Medicare Parts A and B and with Medicare as primary payer from January, 1, 2013 to December 31, 2013, whose ESRD first service date is at least 90 days prior to January 1, 2013, and who survived past 2013. Patients with HF, PAD, and CVA/TIA are those whose Medicare claims indicated the diagnosis or procedure in 2013 or Medical Evidence forms reported the comorbidities. Patients with CAD, AMI, VHD, AF, SCA/VA, VTE/PE, PCI, CABG, ICD/CRT-D, or CAS/CEA are those whose Medicare claims indicate the diagnosis or procedure in 2013. Patients are followed from January 1, 2014, until the earliest date of death, modality change, transplant, lost to follow-up, recovery of renal function, or December 31, 2015. The adjusted probability of survival was calculated using the results of a Cox model, in which significant factors included age group and sex.

Table 8.2 uses the same methods as Figure 8.3, and shows the adjusted two-year survival by cardiovascular comorbidity/procedure.

Cardiovascular Disease and Pharmacological treatments

Table 8.3 shows the percentage of patients prescribed pharmacological treatments by cardiovascular diagnosis or procedure. The cohort is the same one used for Table 8.1, except patients must also be enrolled in Medicare Part D for the entire calendar year. The percentages shown in the table are the row percentages, because the denominator is the number of patients with the cardiovascular diagnosis or procedure, by modality.

Heart Failure Among ESRD Patients[claims]

Type of heart failure (HF) for the calendar year was determined by frequency of diagnoses and a hierarchy. The presence of systolic (428.2x or 428.4/I50.2x or I50.4x), diastolic (428.3x/I50.3x), and unspecified (all other HF diagnosis codes in Table 14.10) 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 8.4 shows the distribution of heart failure type by modality in 2015 for the same study cohort as

in Table 8.1, 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 9: Medicare Expenditures for Persons with ESRD [claims]

Overall & per Person per Year Costs of ESRD

For the 2017 ADR, reported costs of ESRD include only those ESRD beneficiaries covered by Original Medicare (fee-for-service) for their Medicare Part A, B, and D 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 risk-adjusted, per-capita basis and not by specific claims for services.

Figure 9.1 displays Medicare paid amounts for period prevalent ESRD patients from 2004-2015, 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. Medicare expenditures for managed care (Medicare Advantage) plans are estimated using the total equivalent eligible managed care months (determined from the USRDS payer sequence) multiplied by the monthly payment rates published by CMS (https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html).

In Figure 9.2, 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 9.3 presents point prevalence of Medicare as primary payer, Medicare as secondary payer, Medicare Advantage, and non-Medicare ESRD patients by year using the USRDS ESRD database.

Figure 9.4 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 9.5 shows the total ESRD Medicare fee-for-service 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 9.6 presents total Medicare fee-for-service inpatient spending by cause of hospitalization during 2004-2015.

ESRD Spending by Modality

Figure 9.7 describes total Medicare ESRD expenditures by modality. Medicare costs are from claims data.

Figure 9.8 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 10: Prescription Drug Coverage in Patients With ESRD [claims]

This chapter describes prescription drug coverage and usage. New for the 2017 ADR, it shows prescription drug utilization from the Optum Clinformatics™ dataset for both those in Medicare Advantage plans and those in commercial plans.

For inclusion in the analyses, general Medicare enrollees had to be enrolled in Medicare Parts A and B in the calendar year of interest. To create HD, PD, and kidney transplant cohorts, we identified all point prevalent patients (the total ESRD population). Point prevalent cohorts include all patients alive and enrolled in Medicare on January 1 of the calendar year, with ESRD onset at least 90 days earlier; treatment modality is identified on January 1. Incident cohorts include all patients alive and enrolled in Medicare exactly 90 days after ESRD onset before January 1

through December 31 of the index year; modality is identified on this date (first service date + 90 days).

For beneficiaries selected from the Clinformatics™ data, we applied the same eligibility algorithm as for the Medicare population. Beneficiaries were required to be covered by either a Medicare Advantage plan or commercial insurance on January 1 of the calendar year of interest. Those with Medicare Advantage have prescription drug coverage at least as generous as the stand-alone Part D plans. Dialysis and transplant cohorts were identified by claims- based diagnosis codes (see table m.2) and many of these codes did not distinguish HD from PD patients, so dialysis as a whole is shown. All of the beneficiaries in the Clinformatics™ dataset had prescription drug coverage.

Medicare Part D Coverage Plans and Medicare Part D Enrollment Patterns

Figures 10.1-10.3 summarize the prescription drug insurance coverage for Medicare beneficiaries by source, comparing the General Medicare and ESRD populations, showing results overall and by age and race categories. The sources of coverage across the calendar year are combined into mutually exclusive and exhaustive categories in a hierarchical manner. Enrollment in a Part D plan is determined by the first digit of the Part D Plan Contract Number variable (one for each month) being "E" (an employer direct plan, a valid value starting in 2007), "H" (a managed care organization other than a regional preferred provider organization (PPO)), "R" (a regional PPO), or "S" (a stand-alone prescription drug plan). A beneficiary is considered to be enrolled in a Part D plan for the year if he or she was enrolled for one month or more of the analysis year. If a beneficiary is enrolled in a Part D plan and received a low-income subsidy (LIS) in at least one month, he or she is classified as "Part D with LIS", and as "Part D without LIS" otherwise. The receipt of a low income subsidy is determined by the monthly Cost Sharing Group Code values "01" through "08." For beneficiaries not enrolled in a Part D plan, there are several options for non-Medicare prescription drug coverage as reported to the Medicare program. Beneficiaries are classified as "Retiree Drug Subsidy" if they are not enrolled in a Part D plan but have at least one month with a Part D Retiree Drug Subsidy Indicator value of "Y" (yes), indicating he or she is enrolled in an employer-sponsored prescription drug plan that qualifies for Part D's retiree drug subsidy. If the patient is not in a Part D plan or employer-sponsored plan, they are classified as "Other Creditable Coverage" if the Creditable Coverage Switch has a value of "1", indicating another form of drug coverage that is at least as generous as the Part D benefit. This alternate coverage is known as creditable coverage because beneficiaries who maintain it do not have to pay a late enrollment penalty if they subsequently enroll in Part D. If a beneficiary meets none of the situations described above, he or she is classified as "No Known Coverage." Figure 10.1 presents the distribution of this categorical variable for the General Medicare and ESRD cohorts described above.

Table 10.1 shows the percent of beneficiaries with Part D coverage for the past five years in the General Medicare and ESRD cohorts. Table 10.2 is an adaptation of data presented in the 2015 Medicare Outlook section of the www.q1medicare.com web site and has no analyses. Figure 10.2 shows the categories of prescription drug coverage (described above for Figure 10.1) by age groups (20 to 44/45 to 64/65 to 74/75 and older) for dialysis patients (Panel A) and transplant patients (Panel B), while Figure 10.3 shows it by race groups (White/Black or African American/Asian/Other).

Table 10.3 is limited to beneficiaries who are enrolled in Part D prescription plans for at least one month of the analysis year. Part D plan enrollment and receipt of LIS are determined as described for Figures 10.1. Table 10.3 shows the percent of Part D enrollees with LIS within each race group ("all ages" row) and by age groups within the race group (also defined as above) for the General Medicare cohort and the ESRD cohort. Figure 10.4 is limited to those enrolled in a Part D plan with LIS and shows the different types of LIS, as determined by the values of the Cost Sharing Group Code, for the General Medicare and ESRD cohorts.

Insurance Spending for Prescriptions

Costs for ESRD patients are based on the 100 percent ESRD population, using the period prevalent, as-treated actuarial model (model 1 described in ESRD reference table K). Per person per year (PPPY) costs

are calculated as dividing the total cost amount by the person years at risk. Person years at risk are calculated for the ESRD and general populations separately. For ESRD patients, person years at risk are calculated by subtracting the start date (the latest of prescription coverage start date, date of developing ESRD, and January 1 of the year) from the end date (the earliest of prescription coverage end date, death, and December 31 of the year). For the general population, person years at risk is calculated by subtracting the start date (the latest of prescription coverage start date and January 1 of the year) from the end date (the earliest of prescription coverage end date, date of developing ESRD, death, and December 31 of the year).

Table 10.4 and Figure 10.5 present data on Medicare spending for Part D benefits. The Part D benefit expenditure for a prescription drug event (PDE) is the sum of the amount of cost sharing for the drug that is paid by the Part D low-income subsidy (LIS Amount) and the net amount that the Part D plan pays for the PDE (Covered Part D Plan Paid Amount). Table 10.4 shows the total Medicare Part D benefit expenditures for the General Medicare and ESRD cohorts (defined above) for beneficiaries enrolled in stand-alone Part D plans (i.e., spending for Medicare Advantage prescription drug plans is not submitted to Medicare). These cost numbers are, therefore, comparable to the statistics presented in Chapter 9, which show Medicare spending on Parts A and B benefits for those not in Medicare Advantage plans.

Figure 10.5, Panel A shows spending and patient out-of-pocket amounts per-person, per-year for the General Medicare plan member and ESRD cohorts for those in fee-for-service Part D plans, Panel B shows Optum Clinformatics™ Medicare Advantage plans, and Panel C shows Optum Clinformatics™ commercial insurance plans. Out-of-pocket cost is the sum of the amounts the patient pays without being reimbursed by a third party (for fee-for-service Medicare, the Patient Payment Amount) which includes all copayments, coinsurance, deductible, or other patient payment amounts, and for fee-for-service Medicare, the amount of any payment made by other third-party payers that reduced the beneficiary's liability for the PDE or prescription claim (Other True Out-of-Pocket Amount).Two examples of this are payments by qualified state pharmacy assistance programs or charities. Panel D breaks out these costs by whether the patient receives any low income subsidies.

Table 10.5 shows PPPY spending by age, sex, and race for the General and ESRD cohorts by fee-for-service Medicare with LIS, fee-for-service Medicare without LIS, Optum Clinformatics™ Medicare Advantage plans and Optum Clinformatics™ commercial insurance plans.

Prescription Drug Classes

Tables 10.6.and 10.7 list the top 15 drug classes used among ESRD patients by insurance coverage, modality, the percent of patients with at least one prescription filled in the class (Table 10.6) and insurance spending on the drug class (Table 10.7). All drugs in the PDE file and Optum Clinformatics™ RX table are matched to a therapeutic category according to the American Hospital Formulary Service classification system. Note that the Medicare cohort for Tables 10.6 and 10.7 is limited to those in the ESRD cohort who have stand-alone prescription drug coverage. Each therapeutic category is summarized and the percent of patients with ESRD who filled at least one prescription for a drug in the given class is calculated, as well as the total amount spent by Medicare or the plans in the Optum Clinformatics™ dataset on each drug class and its percentage of total prescription drug plan expenditures.

Table 10.6 shows the top 15 drug classes ranked by the highest percent of ESRD patients with at least 1 prescription filled in that class for fee-for-service Medicare, Optum Clinformatics™ Medicare Advantage and Optum Clinformatics™ commercial insurance. Table 10.7 shows the top 15 drug classes ranked by spending. The column following the drug class name shows the total amount spent by Medicare (panel A), Optum Clinformatics™ Medicare Advantage (panel B) and Optum Clinformatics™ commercial insurance (panel C) on each drug class for ESRD patients and the next column shows that drug class' cost as a percentage of all plan expenditures for these patients.

New for the 2017 ADR, this chapter has a special focus on the analgesics drugs. Analgesics are identified as members of the AHFS classes 280804 – nonsteroidal anti-inflammatory agents (NSAIDs), 280808 – opiate agonists, and 280812 – opiate partial agonists. The cohort is the same as the Medicare

cohort used in Tables 10.6 and 10.7; it excludes those with Medicare Advantage Part D plans. Analgesic use in patients with ESRD is defined as having filled or refilled at least one prescription for a drug in the drug classes listed above. The state of residence is from the Medicare Enrollment Database. Figure 10.6 tabulates the use of NSAIDs (yes/no) by state, divides the states by quintiles, and shows the results in a map. Figure 10.7 does the same with the use of opiates.

Chapter 11: International Comparisons

Data Collection

Each country was provided a data-collection form spreadsheet (Microsoft Excel) to complete for years 2011 through 2015. Countries were asked to report patient count data for each year, if available, for the entire population, by sex (male, female), and 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 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 31st of the given year; (6) total number of kidney transplants performed during the year, by type of donor (deceased, living, other); and (7) the number of dialysis patients, HD patients, CAPD/APD/IPD patients, and home HD patients on December 31st of the indicated year. Prevalence was reported for all patients at the end of the calendar year (December 31, 2015), except where otherwise noted. Data for the United States is taken directly from Reference Tables *M: Census Populations*, *A: Incidence and 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. Follow-up with the registries occurred as needed.

Incidence rate of treated ESRD

The incidence rate for Figures 11.1, 11.2, 11.7, and 11.8 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 age-specific 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 11.3.a presents the countries with the highest percent increase in incidence rate and 11.3.b presents the countries with the largest percent decline in incidence rate from 2002/03-2014/15. The percent change in incidence rate was calculated as the percent difference between the average incidence rate in 2015 and 2014 and the average in 2002 and 2003.

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 contributes to observed changes in the percentage of patients with diabetes as cause of ESRD in incident patients. Figure 11.4 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 11.5 presents the ten countries with the highest percent increase from 2002/03-2014/15. 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 2015 and 2014 and the average in 2002 and 2003. Figures 11.6 through 11.8 show the correlation between change in ESRD incident rate and incident rate for ESRD patients with diabetes as primary cause of ESRD, incidence of treated ESRD by age and country, and incidence of treated ESRD by sex and country.

Prevalence of ESRD

The prevalence for figures 11.9 and 11.10 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 11.11 presents the ten countries with the highest percent increase in prevalence of ESRD from 2002/03-2014/15. The percent change in prevalence of ESRD was calculated as the percent difference between the average prevalence of ESRD in 2015 and 2014 and the average in 2002 and 2003. Figure 11.12 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 11.13 was the total number of ESRD patients on dialysis divided by the total population for that year, multiplied by one million. Figure 11.14 presents the ten countries with the highest percent increase in prevalence of dialysis from 2002/03-2014/15. The percent change in prevalence of dialysis was calculated as the percent difference between the average prevalence of dialysis in 2015 and 2014 and the average in 2002 and 2003. Figure 11.15 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 11.16.a is calculated as the total number of kidney transplants divided by the population total, multiplied by one million and the rate in Figure 11.16.b is calculated as the total number of kidney transplants divided by the prevalent number of dialysis patients, multiplied by 1000. Figure 11.17 presents the ten countries with the highest percent increase in the kidney transplantation rate from 2002/03-2014/15. The percent change in kidney transplantation rate was calculated as the percent difference between the average transplantation rate in 2015 and 2014 and the average in 2002 and 2003. Figure 11.18 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 11.19 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 12: USRDS Special Study Center on End-of-Life Care for Patients With ESRD

Methods for the creation of the figures and tables in Chapter 12 are described within the chapter itself.

ESRD Reference Table Methods

Reference Tables A: Incidence and B: Prevalence

The data sources for information on both incident and prevalent patients are CROWNWeb, OPTN, ESRD Medical Evidence form (CMS 2728), and Medicare claims. 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 rates and prevalence are adjusted to a reference population using the direct method.

The 2017 ESRD Reference Tables present parallel sets of counts and rates for incidence (Table A) and December 31 point prevalence (Table B) from 1996 to 2015 for counts and 2000 to 2015 for rates because census data for the seven categories of race are limited. 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.

Patients with unknown age are dropped in all tables. Patients with unknown/other or multiracial race, sex or ethnicity are dropped in some tables. Unknown and other/multiracial races are removed in tables A1(2), A1.1-A1.4, A4, A4.1, A5 and all A5.1, A8.1, A8.1(2). Unknown sex, ethnicity, unknown and

multiracial races are dropped in rate tables A2, A2(2), A2.1-A2.4, A3, A3.1, and A9.

Table A11 excludes unknown network as well as unknown sex, ethnicity, unknown and multiracial races. No exclusion is applied to tables A1, A6, A6.1, A7, A7(2), A8, A8(2), A8(3), and A10.

“Other cause” for the primary cause of ESRD includes patients with cystic kidney disease, other urologic, other cause, unknown cause, and missing.

"Other race” includes American Indian or Alaska Native, Asian, Native Hawaiian and Pacific Islander.

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 2015. 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.

A new Medical Evidence form (2728) version was released in 2015 to switch to ICD-10-CM diagnosis codes. To continue the detailed diagnosis categories in tables A.7 and B.7, clinicians reviewed the diagnoses listed on the 2015 Medical Evidence form and classified them into the pre-2015 detailed cause of ESRD groupings. Table 14.12 shows this mapping.

vol 2 Table 14.12 Mapping to pre-2015 detailed diagnosis groups from the Medical Evidence Form (2728)

Pre-2015 Diagnosis Grouping	2015 ICD-10-CM codes for Primary Cause of ESRD
Diabetes	
Diabetes with renal manifestations Type 2	E11.21, E11.22, E11.29, E11.65, E11.9, E13.9
Diabetes with renal manifestations Type 1	E10.22, E10.29, E10.9
Glomerulonephritis	
Glomerulonephritis (GN) (histologically not examined)	N00.8, N03.0, N03.8, N03.9, N04.0, N04.8, N04.9, N05.8, N05.9
Focal glomerulosclerosis, focal sclerosing GN	N03.1, N04.1, N05.1
Membranous nephropathy	N03.2, N04.2
Membranoproliferative GN type 1, diffuse MPGN	N03.5, N04.5
Dense deposit disease, MPGN type 2	N03.6, N04.6
IgA nephropathy, Bergers disease (proven by immunofluorescence)	N02.8
IgM nephropathy (proven by immunofluorescence)	*Not on 2015 version of Form 2728 and not in data*
With lesion of rapidly progressive GN	N01.9
Post infectious GN, SBE	*Not on 2015 version of Form 2728 and not in data*
Other proliferative GN	N03.3, N03.4, N03.7, N04.3, N04.4, N04.7
Secondary GN/Vasculitis	
Lupus erythematosus, (SLE nephritis)	M32.0, M32.10, M32.14, M32.15
Henoch-Schonlein syndrome	D69.0
Scleroderma	M34.89
Hemolytic uremic syndrome	D59.3
Polyarteritis	M31.7
Wegeners granulomatosis	M31.31
Nephropathy due to heroin abuse and related drugs	*Not on 2015 version of Form 2728 and not in data*
Other Vasculitis and its derivatives	I77.89
Goodpastures syndrome	M31.0
Secondary GN, other	M31.1
Interstitial Nephritis/Pyelonephritis	
Analgesic abuse	N14.0
Radiation nephritis	*Not on 2015 version of Form 2728 and not in data*
Lead nephropathy	N14.3
Nephropathy caused by other agents	N14.1, N14.2
Gouty nephropathy	M10.30
Nephrolithiasis	N20.0
Acquired obstructive uropathy	N13.8
Chronic pyelonephritis, reflux nephropathy	N13.70
Chronic interstitial nephritis	N11.9
Acute interstitial nephritis	N10
Urolithiasis	*Not on 2015 version of Form 2728 and not in data*
Other disorders of calcium metabolism	E83.52
Hypertensive/Large Vessel Disease	
Unspecified with renal failure	I10, I12.0, I12.9, I13.10, I13.2, I15, I15.0, R03.0
Renal artery stenosis	I15.8
Renal artery occlusion	*Not on 2015 version of Form 2728 and not in data*
Cholesterol emboli, renal emboli	I75.81

Table 14.12 continued on next page.

vol 2 Table 14.12 Mapping to pre-2015 detailed diagnosis groups from the Medical Evidence Form (2728)

Pre-2015 Diagnosis Grouping	2015 ICD-10-CM codes for Primary Cause of ESRD
Cystic/Hereditary/Congenital Diseases	
Polycystic kidneys, adult type (dominant)	Q61.2
Polycystic, infantile (recessive)	Q61.19
Medullary cystic disease, including nephronophthisis	Q61.5
Tuberous sclerosis	Q85.1
Hereditary nephritis, Alports syndrome	N07.0, N07.8, Q87.81
Cystinosis	E72.04
Primary oxalosis	E72.53
Fabrys disease	E75.21
Congenital nephrotic syndrome	*Not on 2015 version of Form 2728 and not in data*
Drash syndrome, mesangial sclerosis	Q56.0
Congenital obstruction of ureterpelvic junction	Q62.11
Congenital obstruction of uretrovesical junction	Q62.12
Other Congenital obstructive uropathy	N31.9
Renal hypoplasia, dysplasia, oligonephronia	Q61.4
Prune belly syndrome	Q79.4
Other (congenital malformation syndromes)	Q60.0, Q60.2, Q61.3, Q61.8, Q63.8, Q64.2, Q86.8, Q87.1
Neoplasms/Tumors	
Renal tumor (malignant)	C64.9, C80.1
Urinary tract tumor (malignant)	*Not on 2015 version of Form 2728 and not in data*
Renal tumor (benign)	*Not on 2015 version of Form 2728 and not in data*
Urinary tract tumor (benign)	D30.9
Renal tumor (unspecified)	D41.00
Urinary tract tumor (unspecified)	D41.9
Lymphoma of kidneys	C85.93
Multiple myeloma	C90.00
Other immunoproliferative neoplasms (including light chain nephropathy)	C88.2
Amyloidosis	E85.9
Complications of transplanted organ	
Complications of transplanted organ unspecified	T86.90-T86.99
Complications of transplanted kidney	T86.10
Complications of transplanted liver	T86.40
Complications of transplanted heart	T86.20
Complications of transplanted lung	T86.81, T86.819
Complications of transplanted bone marrow	T86.00
Complications of transplanted pancreas	*Not on 2015 version of Form 2728 and not in data*
Complications of transplanted intestine	T86.85, T86.859
Complications of other specified transplanted organ	T86.89, T86.899
Miscellaneous Conditions	
Sickle cell disease/anemia	D57.1
Sickle cell trait and other sickle cell (HbS/Hb other)	D57.3
Post partum renal failure	O90.4
AIDS nephropathy	B20
Traumatic or surgical loss of kidney(s)	S37.00, S37.009, S37.009A, Z90.5
Hepatorenal syndrome	K76.7
Tubular necrosis (no recovery)	N17.0, N17.1, N17.9, N28.0
Other renal disorders	A18.10, N15.9, N28.9, I50.9, N25.89, N26.9, N28.89
Etiology Uncertain	Not on 2015 version of Form 2728 and not in data
Missing	E87.5, I29 <not valid code>, I43, I43.17 <not valid code>, N18.5, N18.6, N18.9, R69

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.

Patients with unknown age are dropped in all tables. Unknown and other/multiracial races are removed in tables B1(2), B1.1-A1.4, B4, B4.1, B5 and all B5.1, B8.1, B8.1(2); unknown sex, ethnicity, unknown and multiracial races are dropped in rate table B2, B2(2), B2.1-B2.4, B3, B3.1, B9; B11 excludes unknown network as well as unknown sex, ethnicity, unknown and multiracial races; No exclusion is applied to tables B1, B6, B6.1, B7, B7(2), B8, B8(2), B8(3), B10, and B12.

"Other cause" in primary diagnosis includes patients with cystic kidney disease, other urologic, other cause, unknown cause, and missing.

"Other race" includes American Indian or Alaska Native, Asian, Native Hawaiian or Pacific Islander.

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 B.1, B.6, B.8, and B.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.

Rates in Reference Tables 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 and 2015 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". Extreme and implausible values are excluded from the analysis, see table m.13 for acceptable ranges.

vol 2 Table 14.13 Acceptable values for laboratory results

Measurement Name	Range	Units
Serum Albumin	0.5-6.5	g/dl
Serum Creatinine	0.1-33.0	mg/dl
Hematocrit	9-60	%
Hemoglobin	3-20	g/dl
Hemoglobin A1c	3-30	%
Height	15-250	cm
Weight	0.45-250	kg
Total Cholesterol	30-1200	mg/dl
Low-Density Lipoprotein	30-350	mg/dl
High-Density Lipoprotein	1-110	mg/dl
Triglycerides	10-10,000	mg/dl
Body Mass Index	10-80	kg/m^2
Age	0-120	years

Abbreviations: cm, centimeters, dl, deciliter, g, grams, kg, kilograms, m, meter, mg, milligrams

Each table in this section shows population characteristics by age, sex, race, ethnicity, and primary cause of ESRD. Mid-East/Arabian race and Indian Subcontinent race were dropped from the 2005 form; therefore, Mid-East/Arabian and Indian Subcontinent are no longer values in the race group. Hispanic, non-specific ethnicity was 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.

Table C.1 contains data on biochemical markers (item 19 on CMS 2728) from 2007-2015. Glycosylated hemoglobin (HbA1c), total cholesterol (TC), low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglycerides (TG) were added to the Medical Evidence form in 2005. Blood urea nitrogen (BUN) was dropped from the 2005 form; therefore, BUN data are not shown in Table C.1.

Table C.2 shows the patient's prior and current employment status (item 16 on CMS 2728) from 2007-2015. Employment status is collected at the time the form is filled out and for six months prior. 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 blank (employed full time, employed part time, homemaker, retired due to age/preference, retired (disability), and medical leave of absence). Only student and unemployed data are shown for patients under 14.

Table C.3 shows patient medical insurance coverage (items 11 and 12 on CMS 2728) from 2007-2015. There are eight categories of insurance coverage for item 12 — Medicare, Medicaid, Employer Group Health Insurance, Department of Veterans Affairs (DVA), Medicare Advantage, Other, and None. Item 11, "Is the patient applying for ESRD Medicare coverage?", allows an additional category to be added to insurance status.

Table C.4 presents patient comorbidity from 2010-2015 (item 17 on 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 on CMS 2728) from 2010-2015.

Table C.6 presents the whether patients on dialysis were informed about kidney transplant options (items 26 and 27 on CMS 2728) from 2010-2015. Patients who are not informed of transplant options have additional information on the reason for not being informed (item 27). A single patient could have multiple reasons for not being informed.

Tables C.7-C.10 describes care received prior to ESRD therapy (item 18 on CMS 2728) from 2011-2015. 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 on CMS 2728) from 2011-2015. The 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 of incident and prevalent patients alive at the end of each year by demographics, geographic location, and treatment modality. 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 the date of first service for all incident patients from 2011 to 2013. 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 ESRD first 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., 2007, 2011, 2015), 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 (Medicare as primary payer)
- Medicare/Medicaid (dually eligible)
- MSP (Medicare as secondary payer): employer group health plan (EGHP) and non-EGHP
- HMO (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 cause of ESRD, 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-to-follow-up, death, or the end of the analysis period (which is 2015 for the 2017 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 2017 Table E.2 only shows data up to year 2010.

Table E.2 reports data by demographics, primary cause of ESRD, 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 cause of ESRD, transplant number, blood type, PRA level, and time on the list.

Table E.4 includes point prevalent dialysis patients on the waiting list for a kidney on December 31 of the given year. Table E.4 reports data by demographics and primary cause of ESRD. 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 on the waiting list 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. Patients receiving a deceased or living 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 cause of ESRD; 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 cause of ESRD, blood type, transplant number, and PRA level determined from the OPTN Recipient Histocompatibility form, and shows a cross-tabulation 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 deceased 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 Outcomes 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 post-transplant. 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 post-transplant. Recipients are followed from the transplant date to graft failure, death, or the end of the follow-up period (December 31, 2015). 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 ESRD first 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 Hospitalization[claims]

Reference Table G presents adjusted total admission and hospital day rates, by year, 2004-2015. The model-based adjustment method used in these tables is discussed later in this section and in the *Statistical Methods* section.

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 4, 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 at 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 Medicare Advantage coverage, and who therefore have incomplete hospitalization data, cohorts include only patients with fee-for service 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 fee-for-service 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, switch to Medicare Advantage plan, 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, switch to a Medicare Advantage plan, 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, switch to a Medicare Advantage plan 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 a new admission, 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 model-based 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 distribution. For prevalent patient cohorts, this model uses data from the current and previous two years, with respective weights of 1, ¼, and ⅛Adjusted 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 2007-2009, 2010-2012, and 2013-2015 (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 or ICD-10-CM principal diagnosis code, or an ICD-9-CM or ICD-10-CM principal procedure code in conjunction with a certain diagnosis-related group (DRG) code. Codes for vascular access hospitalizations are listed in Table 14.14. 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 shown in Table 14.15.

vol 2 Table 14.14 DRG, ICD-9-CM, and ICD-10-CM codes for vascular access and peritoneal dialysis access hospitalizations

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]	ICD-10-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	031n0xD, 031n0xF for n=2-8 and x=9, A, J, K, Z; 031n0xF for n=9, A-C and x=9, A, J, K; 03PYx7Z, 03PYxJZ, 03PYxKZ for x=0, 3, 4; 03WY0JZ; 03WY3JZ; 03WY4JZ; 03WYXJZ; 05HY33Z; 06HY33Z; 0JH83XZ; 0JHD0WZ; 0JHD0XZ; 0JHD3WZ; 0JHD3XZ; 0JHF0WZ; 0JHF0XZ; 0JHF3WZ; 0JHF3XZ; 0JHL0WZ; 0JHL0XZ; 0JHL3WZ; 0JHL3XZ; 0JHM0WZ; 0JHM0XZ; 0JHM3WZ; 0JHM3XZ

ICD-9-CM diagnosis codes[b]	ICD-10-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	T80.218A; T80.219A; T82.310A-T82.531A; T82.511A; T82.513A-T82.518A; T82.520A; T82.521A; T82.523A-T82.531A; T82.533A-T82.538A; T82.590A; T82.591A; T82.593A-T82.598A; T82.7XXA; T82.818A; T82.828A; T82.838A; T82.848A; T82.858A; T82.868A; T82.898A; T85.611A; T85.621A; T85.631A; T85.691A; T85.71XA; Z49.01; Z49.02

[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.

vol 2 Table 14.15 Diagnosis codes used to define cause of hospitalization in Reference Table G

Cause of Hospitalization	ICD-9-CM	ICD-10-CM
Circulatory	390-459	A18.83; E08.51; E08.52; E09.51; E09.52; E10.51; E10.52; E11.51; E11.52; E13.51; E13.52; G45.0-G45.2; G45.4-G46.8; I00-I67.2; I67.4-I6.782; I67.841-I87.9; I89.0-I95.9; I97.0-I97.2; I99.8; I99.9; K64.0-K64.9; M30.0-M31.9; M32.11; M32.12; N26.2; R00.1; R58; T80.0XXA; T81.1718A; T81.73XA; T82.817A; T82.818A
Digestive	520-579	A69.0; B25.1; B25.2; E08.43; E08.630; E08.638; E09.43; E09.630; E09.638; E10.43; E10.630; E11.43; E11.630; E13.43; E13.630; J86.0; K00.0-K31.6; K31.811-K63.4; K63.81-K63.9; K65.0-K67; K68.12-K904; K90.89-K91.2; K91.5; K91.850; K91.858; K91.89-K95.89; M26.00-M27.9; N99.4; R11.10; R11.13; R18.8; R68.2
Genitourinary	580-629	A18.14; A56.01; A56.02; A56.11; B52.0; E08.21-E08.29; E09.21-E09.29; E23.0; M32.14; M32.15; M35.04; N00.0-N22; N25.0-N39.3; N39.8-N97.9; N99.110-N99.3; N99.510-N99.518; N99.518; R10.2; R31.0-R31.9; R36.1; R80.2; R83.711A; R83.721A
Endocrine and Metabolic	240-279	C88.0; C96.5; C96.6; D47.2; D80.0-D849; D89.0-D89.9; E00.0-E03.4; E03.8-E07.1; E07.89-E35; E40-E74.9; E75.21; E75.22; E75.240-E75.249; E75.3; E75.5-E78.70; E78.79-E78.9; E79.1-E83.19; E83.30-E89.6; H49.811-H49.819; M10.00-M10.9; M1A.00X0-M1A.09X0; M1A.20X0-M1A.9XX1; M35.9; M83.0-M83.9; N20.0; N98.1
Respiratory	460-519	A22.1; A37.01; A37.11; A37.81; A37.91; B25.0; B44.0; B44.81; B77.81; D57.01; D57.211; D57.411; D57.811; J00-J01.91; J02.8; J02.8; J02.9; J03.80-J95.3; J95.811-J95.822; J95.84; J96.00-J99; M32.13; M33.01; M33.11; M33.21; M33.91; M34.81; M35.02; R09.1; R09.81
Infectious	001-139	A00.0-A329; A35-A48.0; A48.2-B44.7; B44.89-B78.0; B78.7-B99.9; D86.0-D86.9; G02; G14; H32; I32; I39; I67.3; J02.0; J03.00; J03.01; J17; J20.0-J20.7; K90.81; L08.1; L44.4; L94.6; M00.00-M00.89; M02.30-M02.39; M60.009; N34.1; R11.11
Cancer	140-172, 174-208, 230-231, 233-234	C00.0-C43.9; C45.0-C75.9; C76.0-D03.9; D05.00-D09.9
Other	*codes not listed above*	*codes not listed above*

Abbreviations: ICD-9/10, International Classification of Diseases, Ninth/Tenth version.

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. Reference Table H does not apply the 60-day stable modality rule and 90-day rule.

The cohorts in Tables H.1-H.12 are comprised of period prevalent patients, including those alive on January 1 and those incident during the calendar year. All patients are followed from either January 1 (for prevalent patients) or from the date of onset of ESRD (for incident patients). 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 the transplant waiting list); H.6 (dialysis patients on the 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 supplemental Table 7 of the *National Vital Statistics Report (NVSR), Deaths: Final Data for 2014*. 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 an ESRD first service date between January 1, 1996 and December 31, 2015, are included in the analysis. These patients are followed from day one (ESRD onset) until death, loss to follow-up, or December 31, 2015. 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 subgroup-specific 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, a chain-affiliated unit is defined 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 2014-2015) 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 2015 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[claims]

Cost information in this section is derived from the 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. There are no subcategories excluded. Cross-year claims are claims that start in one calendar year and end in the following year and are included only in the following year's costs. Cross-payer claims are when a patient is Medicare Primary when claim starts and not primary when the claim ends and are considered to be associated with the payer status that exists at the start of the claim.

Note that originally, the distinction between ESRD and pre-ESRD claims was made by the claim start date and only claims that started on or after the ESRD first service date were considered ESRD claims. Starting with the 2016 ADR, the pre-ESRD v. ESRD distinction is made using the claim end date instead thereby including claims that overlapped with the first service date as ESRD claims. This change was implemented for 2010 claims onward, so users may see a slight jump between 2009 and 2010 that is the result of an increased number of claims being designated ESRD.

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 claims associated with the transplant. Claims data are obtained for all patient identification numbers in the USRDS 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 is added.

In tables that report on a specific modality, only claim records whose start and end dates overlap with a patient's modality start and end dates are included in the cost analysis.

Payer File

The payer sequence file is similar in concept to the USRDS treatment history. Payer status is tracked for each ESRD patient from the ESRD first service date until death, loss to follow-up 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 (MP), Medicare secondary payer (MS), or non-Medicare. The claims database contains data only for MP and MS 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 and direct medical education costs, and an estimate of organ acquisition costs ($25,000 in 2017).

Model 1: As-treated actuarial model

Model 1 and Model 2 differ by how modality is treated. In Model 1, 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.

Tables K.5-9, K.a, K.b, and K.b.1-53 are all primary payer only and Model 1 modality. Model 1 modality is derived from the patient treatment history and is one of:

- Hemodialysis (HD)
- CAPD/CCPD (peritoneal dialysis)
- Other
- Transplant
- 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.

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

Outpatient bundling

In 2011 CMS implemented a new prospective payment system for dialysis. Facilities now receive a standard payment for a bundle of dialysis services instead of billing each individual service such as drugs, laboratory tests and supplies. This is why there are significant increases and decreases between 2010 and 2011 in some Outpatient subgroups in sheets K1 and K4.

Time at risk

Time at risk is the time in which the patients qualify to be included on a particular reference table sheet. The claims for a patient will only be included in a particular table if their time at risk overlaps. For example, if a Medicare primary payer, dialysis patient's time at risk was March 3 – October 5, only claim that overlap that same time period are included. If the patient had ten different claims for that year, and one of them was January 1 – March 2, that cost would not be included.

Time at risk is 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

Reference Table L: Vascular Access[claims]

Within Reference Table L, Tables L.1-L.6 include period prevalent HD patients with Medicare as primary payer. Vascular access placements are identified from inpatient, outpatient, and physician-supplier Medicare claims. Rates represent the total number of events divided by the total time at risk and are converted from days to patient years. Time at risk is defined as the time between the first day of a given year and the 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

Note that data collection methods vary considerably across countries, and therefore direct comparisons should be made with caution.

See Data Collection in the section on Chapter 11: International Comparisons for how the data was obtained.

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 2014 and 2015 and the averages in 2002 and 2003, except in N.3. In N.3, the percent change is defined as the percent difference between the average incidence rates in 2014 and 2015 and the averages in 2006 and 2007 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, then multiplied by one million. Table N.1 shows the trends in the incidence of treated ESRD patients, 2001-2015. Table N.2 shows the trends in the incidence of treated ESRD patients due to diabetes, 2001-2015. N.1 uses total incident patient count, and the count for N.2 is a subset of total incident patients whose kidney 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, 2001-2015. 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 2015 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, 2001-2015. 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 in-center 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, 2001-2015. 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 2015, for example, is the observed incident count divided by the 2015 population size and, if the unit is per million population, multiplied by one million. The 2015 death rate for prevalent ESRD patients is the number of deaths in 2015 divided by the total follow-up time (patient years) in 2015 of the 2015 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 that 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 follow-up time for a group of patients.

vol 2 Table 14.16 Example data for time at risk calculation

			Time at risk			
Patient	**Group**	**Event date**	**Begin date**	**End date**	**Days**	**Patient-years**
1	A	3/31/15	1/1/15	3/31/15	90	0.25
2	A	6/30/15	1/1/15	6/30/15	180	0.50
3	A		1/1/15	12/31/15	365	1.00
4	B	12/31/15	1/1/15	12/31/15	365	1.00
5	B	9/30/15	1/1/15	9/30/15	270	0.75
6	B		1/1/15	12/31/15	365	1.00

	Overall	**Group A**	**Group B**
Number of events	4	2	2
Patient-years at risk	4.5	1.75	2.75
Hospitalization rate	889	1143	727

Take, for example, a calculation of 2015 first hospitalization rates for two groups of patients, all receiving dialysis therapy on January 1, 2015. Group A consists of three patients as shown in Table 14.16. Group B also has three patients.

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 889 for all patients (in either group) in 2015. But the first hospitalization rate per thousand patient years at risk is 1,143 for Group A and 727 for Group B. The rate for Group A is calculated as (2 total events / 1.75 total patient years at risk) x 1,000 and for Group B is (2 total events / 2.75 patient years at risk) x 1,000. 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 follow-up 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 2015 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 2015 — with five race groups (White, Black/African American, Native American, Asian, and Other).

Assuming the incidence rate of state A in 2015 is 173 per million population, and the race-specific rates and race distribution of the national populations are as shown in Table 14.17, the adjusted incidence rate of state A with the national population as reference is (153 x 75.1%) + (250 x 12.3%) + (303 x 0.9%) + (174 x 3.6%) + (220 x 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 14.17 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 model-based 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 0 to 100. The mortality/event rate in the period of (0,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 (such as different causes of death) exist, the estimate of the cumulative incidence function of a specific cause of death 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 dying from cause k before time t (including time t), Prob(T≤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 $t_1, t_2, \ldots, t_m$, the cumulative incidence function of cause k at time t is estimated by

$$I_k(t) = \sum \hat{\lambda}_\kappa(t_j)\hat{S}(t_j\text{-}1)$$

where $\hat{\lambda}_\kappa(t_j)=D_{kj}/n_j$, $\hat{S}(t_j\text{-}1)$ is the Kaplan-Meier estimate of survival at time t_j-1, D_{kj} is the number of patients dying 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 two-way 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, cross-classified 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[CLAIMS]

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 two-way 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 chain-level SMR is used to compare mortality in prevalent dialysis patients — after adjusting for age, race, ethnicity, sex, diabetes (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[claims]

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, diabetes mellitus (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 and some will live less than 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.

Median Time (Half-Life)

Conditional Half-life

The conditional half-life is conditional on having survived a given period of length T_0 without the event, where 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_o and t_1 is chosen to be big enough to obtain a stable estimate of $\ln(S(t_o))-\ln(S(t_1))$.

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.

References

Blagg CR, Bovbjerg RR, Fitzsimmons SC. Here are (almost all) the data: The evolution of the U.S. Renal Data System. *Am J Kidney Dis* 1989 14(5):347-353.

Breslow NE, Day NE. *Statistical methods in cancer research. Volume II — The design and analysis of cohort studies*. Lyon: International Agency for Research on Cancer, Scientific Publications Series. 1987;82:1-406.

Centers for Disease Control and Prevention. Table 7. Life expectancy at selected ages, by race, Hispanic origin, race for non-Hispanic population, and sex: United States, 2012. *Natl Vital Stat Rep* 2015;63(9):29. http://www.cdc.gov/nchs/data/nvsr/nvsr63/nvsr63_09.pdf. Accessed September 2, 2016

Centers for Medicare & Medicaid Services. Fact sheet: Medicare End-stage Renal Disease (ESRD) Network Organization Program, 2012. https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations/Downloads/ESRDNWBackgrounder-Jun12.pdf. Accessed September 2, 2016

Centers for Medicare & Medicaid Services. Privacy Act of 1974; Report of a modified system of record. *Fed Regist* 2007;72(88):26126-26131. https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/Downloads/0520-PMMIS.pdf. Accessed September 2, 2016

Centers for Medicare & Medicaid Services. Renal Management Information System (REMIS), 2012. http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/IdentifiableDataFiles/RenalManagementInformationSystem.html. Accessed September 2, 2016

Centers for Medicare & Medicaid Services. Systems of records. http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/CMS-Systems-of-Records.html. Accessed September 2, 2016

Collett D. Modeling *Survival data in medical research*. London, England: Chapman and Hall; 1994.

Cook RJ, Lawless JF. *The statistical analysis of recurrent events*. New York: Springer; 2007.

Cox DR. Regression models and life-tables. *J R Stat Soc Series B Stat Methodol* 1972;34:187-220.

Davids MR, Marais N, Jacobs JC. South African Renal Registry Annual Report, 2012. Cape Town, South Africa: South African Renal Society; 2014.

Elzein H. National kidney registry in Lebanon annual report, 2012. Beirut, Lebanon: Lebanese Society of Nephrology and Hypertension; 2012. http://kidneyregistrylb.com/wp-content/uploads/2013/09/UploadAR-Covers-R21.pdf. Accessed September 2, 2016

Health Care Financing Administration. End Stage Renal Disease Research Report, 1993-1995. Baltimore, MD: U.S. Dept. of Health and Human Services; 1997.

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.

Italian Registry of Dialysis and Transplant. Annual report of the Italian registry, 2010. Rome, Italy: Italian Society of Nephrology.

Kalbfleisch JD, Prentice RL. *The statistical analysis of failure time data*. 2nd ed. New York: John Wiley & Sons; 2002.

Kolesnyk I, Noordzij M, Kolesnyk M, Kulyzky M, Jager KJ. Renal replacement therapy in Ukraine: epidemiology and international comparisons. *Clin Kidney J* 2014;7(3):330-335.

Lawless JF, Nadeau C. Some simple robust methods for the analysis of recurrent events. *Technometrics* 1995;37(2):158-168.

Lin DY, Wei LJ, Yang I, Ying Z. Semiparametric regression for the mean and rate functions of recurrent events. *J R Stat Soc Series B Stat Methodol* 2000;62(4):711-730.

Liu D, Schaubel DE, Kalbfleisch JD. Computationally efficient marginal models for clustered recurrent event data. *Biometrics* 2012;68(2):637-647.

Liu J, Louis TA, Pan W, Ma JZ, Collins AJ. State-level adjusted ESRD incident rates: use of observed vs model-predicted category-specific rates. *Kidney Int* 2006;69(8):1459-1463.

Marinovich S, Lavorato C, Celia E, et al. Registro Argentino de Diálisis Crónica 2014-2015. Buenos Aires, Argentina: Sociedad Argentina de Nefrología (SAN) and Instituto Nacional Central Unico Coordinador de Ablación e Implante (INCUCAI); 2016.

McDonald S, Clayton P, Hurst K, eds. 36th Annual ANZDATA Registry Report. Adelaide, South Australia: Australia and New Zealand Dialysis and Transplant Registry; 2013. http://www.anzdata.org.au/v1/report_2013.html. Accessed September 2, 2016

Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Public Law 108-173. *USC* 117;2003:2066-2480. https://www.gpo.gov/fdsys/pkg/PLAW-108publ173/pdf/PLAW-108publ173.pdf. Accessed September 2, 2016

Merriman K, Asper FM. Differences in how the Medicare 5% files are generated. Minneapolis, MN: Research Data Assistance Center, University of Minnesota; March 2007 [ResDAC Publication Number TN-011].

Murphy SL, Xu J, Kochanek KD. Deaths: Final data for 2010. Natl Vital Stat Rep. Hyattsville, MD: National Center for Health Statistics 2013; Vol 61:4. http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_04.pdf. Accessed September 2, 2016

National Organ Transplant Act of 1984. Public Law 98-507. *USC* 42;1984:2339-2348. https://www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg2339.pdf. Accessed September 2, 2016

Omnibus Budget Reconciliation Act of 1986. Public Law 99-509. *USC* 42;1986:1874-2078 https://www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg1874.pdf. Accessed September 2, 2016

National Committee for Quality Assurance. HEDIS 2008. Washington, DC: National Committee for Quality Assurance; 2007 (Vol 2).

Pickle LW, White AA. Effects of the choice of age-adjustment method on maps of death rates. *Stat Med* 1995;14(5-7):615-627.

Putter H, Fiocco M, Geskus RB. Tutorial in biostatistics: Competing risks and multi-state models. *Stat Med* 2007;26:2389-2430.

Richard A. Rettig and Norman G. Levinsky, Eds., Kidney failure and the federal government. Committee for the Study of the Medicare End-Stage Renal Disease Program. Institute of Medicine. Division of Health Care Services. Washington, D.C., National Academy Press: 1991

SAS Institute Inc. 2004. SAS/STAT 9.1 User's guide. Cary, NC: SAS Institute Inc.: 3213-3329.

Social Security Amendments of 1972. Public Law 92-603. *USC* 86;1972:1329-1493 www.gpo.gov/fdsys/pkg/STATUTE-86/pdf/STATUTE-86-Pg1329.pdf. Accessed September 2, 2016

Wilson EB, Hilferty MM. The distribution of chi-square. *Proc Natl Acad Sci U S A* 1931;17(12):684-688.

Notes