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

Incidence

- In 2016, there were 124,675 newly reported cases of ESRD; the unadjusted (crude) incidence rate was 373.4 per million/year (Table 1.1). Since 2011, the crude rate had risen; however, the standardized rate appears to have plateaued (Figure 1.1).
- The age-sex-race standardized incidence rate of ESRD in the United States rose sharply in the 1980s and 1990s, leveled off in early 2006, and has declined slightly since its peak in 2006 (Figure 1.1).
- In 2016, the age-sex-standardized ESRD incidence rate ratio, compared with Whites, was 2.9 for Blacks/African Americans, 1.2 for American Indians/Alaska Natives, and 1.1 for Asians (Figure 1.5). All these represent reductions in the relative rate of ESRD for these minorities compared to Whites over the past 16 years. The incidence rate ratio for Hispanics versus non-Hispanics was 1.3 (Figure 1.6).
- Based on 2013 data, the lifetime risk of being diagnosed with ESRD from birth was 4.0% in males and 2.9% in females. Among males, the lifetime risk ranged from a low of 3.4% in Whites to a high of 8.1% in Blacks/African Americans; in females, it ranged from 2.3% in Whites to 6.8% in Blacks/African Americans. (Figure 1.7 and Table 1.3).

Prevalence

- On December 31, 2016, there were 726,331 prevalent cases of ESRD; the crude prevalence was 2,160.7 per million in the U.S. population (Table 1.4).
- The number of prevalent ESRD cases has continued to rise by about 20,000 cases per year (Table 1.4). In contrast to the standardized incidence rate, the age-sex-race-standardized prevalence of ESRD has continued to increase since 2006 (Tables 1.1 and 1.4).
- Compared to Whites, ESRD prevalence in 2016 was about 9.5 times greater in Native Hawaiians/Pacific Islanders, 3.7 times greater in Blacks, 1.5 times greater in American Indians/Alaska Natives, and 1.3 times greater in Asians (Figure 1.12).

Characteristics of Incident ESRD Cases

- In 2016, 35.4% of incident ESRD patients received little or no pre-ESRD nephrology care (Table 1.8.a).
- Mean eGFR at initiation of dialysis in 2016 was 9.7 ml/min/1.73 m^2 (Table 1.10), down from a peak of 10.4 in 2010. The percentage of incident ESRD cases starting with eGFR ≥10 ml/min/1.73 m^2 rose from 12.9% in 1996 to 42.6% in 2010 but decreased to 38.6% in 2016 (Figure 1.19).

Treatment Modalities

- In 2016, 87.3% of incident individuals began renal replacement therapy with hemodialysis (HD), 9.7% started with peritoneal dialysis (PD), and 2.8% received a preemptive kidney transplant (Figure 1.2).
- On December 31, 2016, 63.1% of all prevalent ESRD patients were receiving HD therapy, 7.0% were treated with PD, and 29.6% had a functioning kidney transplant (Figure 1.9). Among HD cases, 98.0% used in-center HD, and 2.0% used home HD (*Reference Table D.1)*.

Introduction

In this chapter, we describe the population of those individuals living with end-stage renal disease (ESRD) in the United States, the numbers and relative rates of new and existing 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 2018 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, population frequencies, and temporal trends. We examine the distribution of ESRD frequency by age, sex, race, and ethnicity. The population is also described in terms of geographic residence, the primary cause of ESRD as listed in the Centers for Medicare & Medicaid Services (CMS) form 2728, the type of renal replacement therapy (RRT) chosen for treatment, and individual medical characteristics such as receipt of pre-ESRD care, 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 here 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. Also, 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 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 in each calendar year are approximated by the mid-year census for the population in that year. Incidence rates are expressed per million (population)/year.

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 prevalence at the end of each year is expressed per million. 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.

Risk of ESRD

Disease incidence in a population may be quantified in two ways: as a rate, described above; and as a risk. Disease risk is the probability of persons initially without the disease getting (diagnosed with) the disease during a given period, e.g., between ages 60 and 65, from January 1, 2010, through December 31, 2014, or during the first five years of follow-up in a cohort study or randomized clinical trial. As a probability, risk is a dimensionless quantity; therefore, it can be expressed as a percent (unlike a rate). Note that a risk has a specific period referent. For example, suppose 100 persons without ESRD (e.g., CKD stages 3-4) are followed for five years without loss to follow-up (i.e., no censoring). If 10 of those persons at risk are diagnosed with ESRD during that period, the 5-year risk is 10/100 = 10%. Also note that risk applies to individuals, whereas the rate is strictly a population measure that has no meaning for individuals. Thus, physicians often talk to their patients about risks when discussing the likelihood of developing a disease or other health event during a given period, e.g., the next ten years or their lifetime. Previous editions of the ADR have not included estimates of ESRD risk.

Estimating the risk of disease is straightforward when all individuals in the study population are followed for detection of disease occurrence, as in a cohort study; but that is not the case in a disease surveillance system such as the USRDS because

individuals in the U.S. general population are not followed. Rather, incident cases (numerators) are identified from medical providers and institutions; then they are linked with appropriate census counts (denominators) within categories (strata) of demographic factors such as age, sex, and race or ethnicity. Risk estimation with USRDS data is further complicated by the need to take into account competing events, e.g., deaths from diseases other than kidney disease that occur among persons still at risk for ESRD. Thus, the probability of being diagnosed with ESRD is expected to decline sharply late in life, in part due to increasing frequency of deaths from other causes.

A special life-table method developed by Fay (2004) has been employed to overcome the challenges described above for estimating ESRD risks using USRDS data. In addition to age-specific incidence rates of ESRD for a given period (January 1 through December 31, 2013), the method also requires age-specific mortality rates for ESRD and all other diseases combined, which are estimated with data obtained from the National Center for Health Statistics. Risks—called "cumulative incidences" when using this method—are estimated for a large hypothetical cohort of births followed to age 100+, assuming those age-specific rates in 2013 are constant across calendar time. Thus, for example, we might want to estimate the lifetime cumulative incidence of ESRD or the 10-year cumulative incidence for a 40-year old. Calculations are done with version 6.7 of DevCan software (2005). This method has been applied to males and females separately with further stratification by race or ethnicity.

It is important to recognize that the risks estimated from data in a given year reflect a hypothetical population assumed to be in a steady state, such that all age-specific rates are constant over calendar time. In fact, the U.S. population is not in a steady state with respect to kidney disease; the overall incidence rate of ESRD in the United States rose sharply in the 1980s and 1990s, leveled off in the 2000s, and declined slightly since its peak in 2006. Furthermore, those changes did not occur to the same extent in different age or racial/ethnic groups. Thus, risk estimates presented in this chapter are useful statistics for understanding the frequency of ESRD in demographic groups and potentially guiding doctor-patient communication, but they are not likely to correspond closely to the actual lifetime experience of persons born in 2013. Indeed, that is beyond the reach of any empirical method.

Methods

This chapter uses data from the Centers for Medicare & Medicaid Services (CMS). Findings were primarily drawn from special analyses based on the USRDS ESRD Database. Details of the USRDS database 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 standardized 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." Age was stratified into 5 categories, and race was stratified into 5 groups (White, Black/African American, Asian, American Indian/Alaska Native, and Native Hawaiian/Pacific Islander). 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 incidence rate or prevalence for a given group or year is interpreted as the expected (crude) rate or prevalence if that group or year had exhibited the age-sex-race distribution of the 2011 U.S. population. (Note: the standard population is different from the reference population to which a given index group is compared.) Because we are standardizing only for age, race, and sex, the trends we see may be due to other variables such as differences in treatment and/or patient case-mix.

For an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter, see the section on *Chapter 1* in the *ESRD Analytical Methods* chapter. Downloadable Microsoft

Excel and PowerPoint files containing the data and graphics for these figures and tables are available on the *USRDS website*. A "special analysis" means that the source of data for a given table or figure was not a Reference Table available in this ADR.

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 the 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; Longenecker et al., 2000).

For diabetes mellitus (DM) and hypertension (HTN), the main problem may be over-reporting of those conditions as the primary cause of ESRD. 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 the primary cause of ESRD reflect ESRD patients who have DM but not necessarily as the primary cause of their ESRD. This parallels reports of biopsy-confirmed diabetic nephropathy, although there is likely selection bias in patients who undergo biopsy. Also, there may be a need to reclassify etiologies of ESRD that are listed on the form CMS 2728 to improve accuracy and to keep pace with scientific developments (Tucker and Freedman, 2018).

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 purported 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 standardized 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 estimates should be viewed in that context.

Incidence of ESRD: Counts, Rates, and Trends

Overall Incidence Counts and Rate

In 2016, there were 124,675 incident cases of ESRD in the United States; the crude incidence rate was 373.4 per million/year. After a year-by-year rise in the number of incident ESRD cases from 1980 through 2000, the count plateaued between 2007 and 2011 but rose again from 2012 to 2016. Table 1.1 and Figure 1.1 provide the annual counts and crude and age-sex-race standardized incidence rates of ESRD from 1980 through 2016.

It should be noted that the crude and standardized incidence rates of ESRD were the same in 2011; that is not a coincidence but rather reflects the fact that the standard population (the source of stratum-specific weights) was the 2011 U.S. population. The trends in crude and standardized rates are different, however. The crude ESRD incidence rate (and count) increased steadily from 1980 through 2006, remained relatively

stable until 2011, and increased again in recent years. This recent trend implies that the burden of kidney failure in the United States— concerning the expected impact on health-care utilization and costs— continues to increase, due to the aging U.S. population and the rise of obesity and DM.

In contrast, the standardized ESRD incidence rate increased from 1980 through 2001, leveled off through 2006, and has since declined slightly in most years (Table 1.1). The standardized rate of 348.2 per million in 2016 was the lowest rate since 1998. The specific implication of this recent downward trend is more difficult to interpret, but it likely reflects improvements in the prevention or postponement of kidney failure in the United States, possibly due to increases in blood-pressure control and the use of statins in the general population.

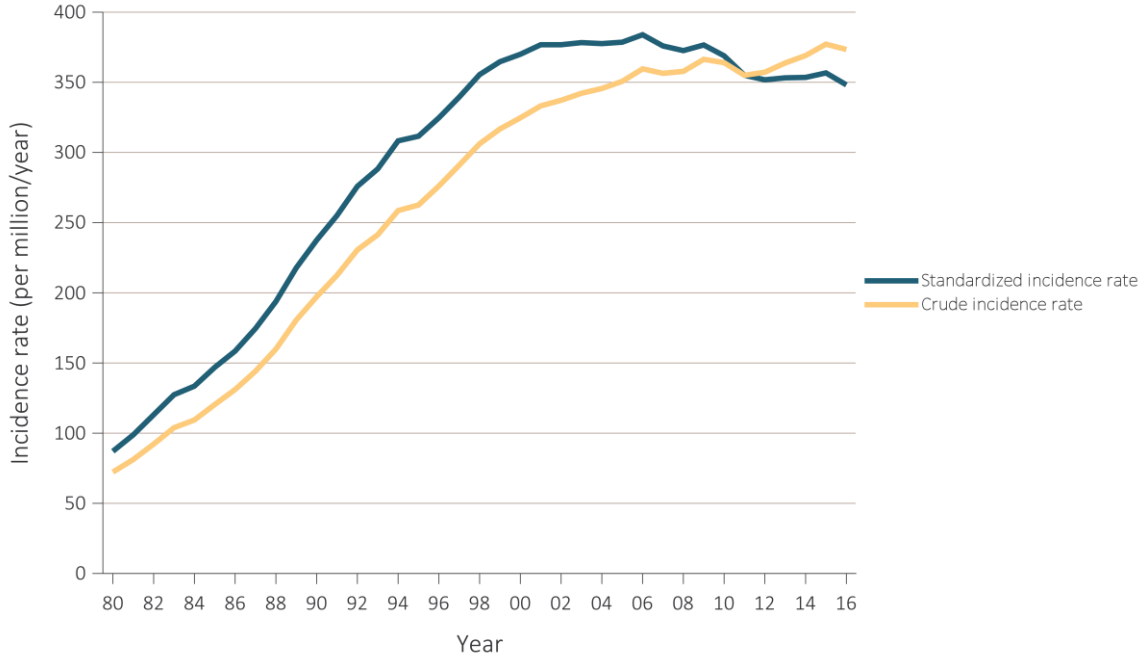
vol 2 Table 1.1 Trends in annual number of ESRD incident cases, crude and standardized incidence rates of ESRD, and annual percentage change in the U.S. population, 1980-2016

Year	Incident count		Crude rate		Standardized rate	
	No. cases	% Change from previous year	Crude rate (per million/yr)	% Change from previous year	Standardized rate (per million/yr)	% Change from previous year
1980	17,903	n/a	72.3	n/a	87.1	n/a
1981	20,039	11.9	81.2	12.3	98.8	13.4
1982	22,568	12.6	92.2	13.5	113.1	14.5
1983	25,775	14.2	103.9	12.7	127.4	12.6
1984	27,324	6.0	109.4	5.3	133.5	4.8
1985	30,214	10.6	120.4	10.1	146.9	10.0
1986	33,112	9.6	131.1	8.9	158.5	7.9
1987	36,605	10.5	144.2	10.0	174.6	10.2
1988	40,991	12.0	159.9	10.9	193.8	11.0
1989	46,303	13.0	180.6	12.9	217.8	12.4
1990	50,830	9.8	197.2	9.2	237.5	9.0
1991	55,387	9.0	212.5	7.8	255.1	7.4
1992	60,886	9.9	230.6	8.5	275.9	8.2
1993	64,485	5.9	241.4	4.7	288.3	4.5
1994	69,958	8.5	258.6	7.1	308.3	6.9
1995	72,202	3.2	262.6	1.5	311.6	1.1
1996	77,003	6.6	276.1	5.1	324.7	4.2
1997	82,119	6.6	291.0	5.4	339.5	4.6
1998	87,327	6.3	306.2	5.2	355.5	4.7
1999	91,405	4.7	316.8	3.5	364.7	2.6
2000	94,704	3.6	324.7	2.5	370.0	1.5
2001	97,964	3.4	333.2	2.6	376.8	1.8
2002	100,180	2.3	337.2	1.2	376.8	0.0
2003	102,607	2.4	342.2	1.5	378.3	0.4
2004	104,480	1.8	345.6	1.0	377.6	-0.2
2005	106,636	2.1	350.7	1.5	378.6	0.3
2006	110,354	3.5	359.6	2.5	383.9	1.4
2007	110,342	0.0	356.4	-0.9	375.9	-2.1
2008	111,908	1.4	357.8	0.4	372.6	-0.9
2009	115,564	3.3	366.4	2.4	376.6	1.1
2010	115,921	0.3	364.0	-0.7	368.9	-2.0
2011	113,809	-1.8	355.0	-2.5	355.0	-3.8
2012	115,549	1.5	357.2	0.6	351.8	-0.9
2013	118,367	2.4	363.8	1.8	353.2	0.4
2014	121,338	2.5	369.1	1.5	353.5	0.1
2015	124,868	2.9	377.2	2.2	356.7	0.9
2016	124,675	-0.2	373.4	-1.0	348.2	-2.4

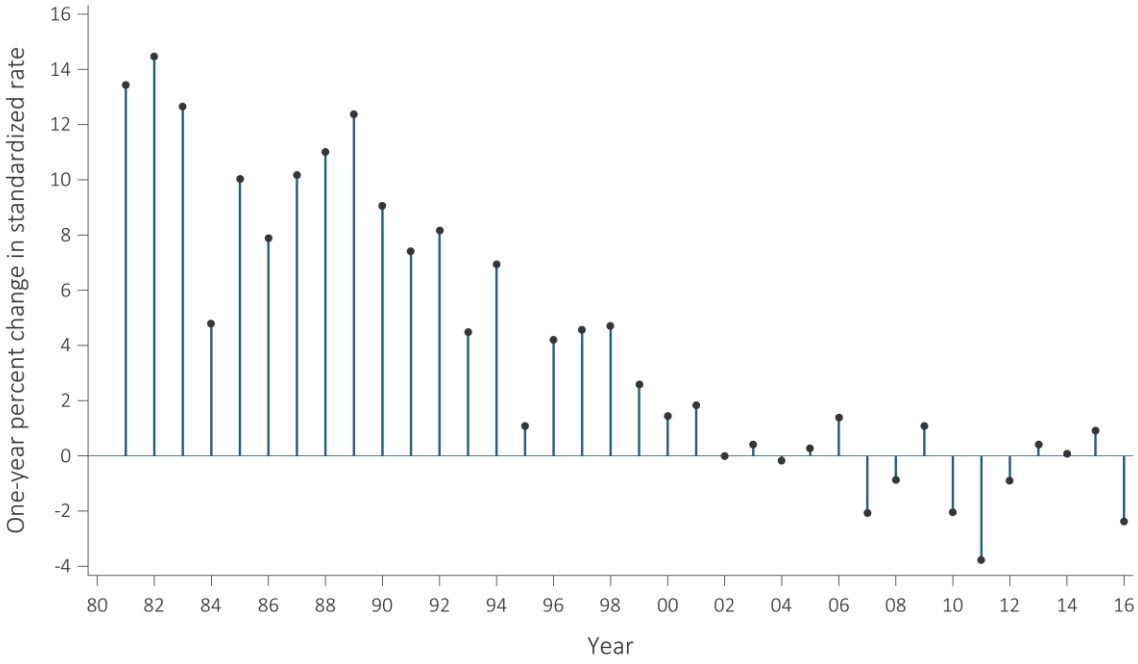
Data Source: Special analyses, USRDS ESRD Database. The special analyses exclude U.S. territories, unknown age, and unknown/other races. Standardized to the age-sex-race distribution of the 2011 U.S. population. Abbreviations: ESRD, end-stage renal disease; n/a, not applicable; yr, year.

vol 2 Figure 1.1 Trends in the (a) crude and standardized incidence rates of ESRD, and (b) the annual percentage change in the standardized incidence rate of ESRD in the U.S. population, 1980-2016

(a) Incidence rate per million/year



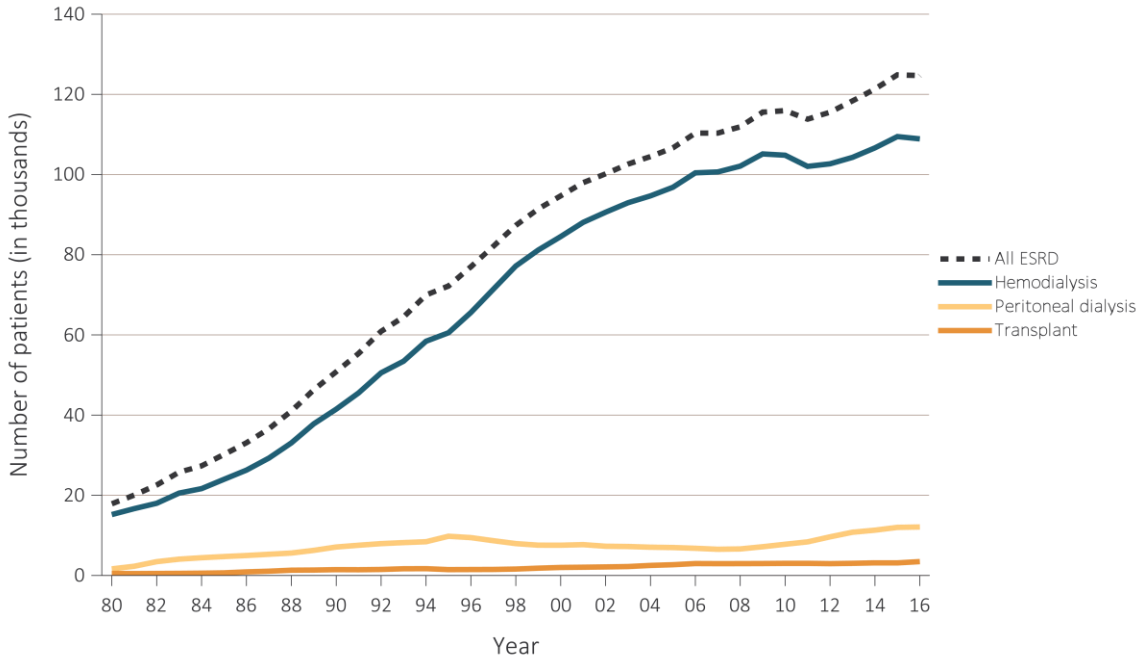
(b) One-year percentage change in standardized incidence rate



Data Source: Special analyses, USRDS ESRD Database. The special analyses exclude U.S. territories, unknown age, and unknown/other races. Standardized to the age-sex-race distribution of the 2011 U.S. population. Abbreviation: ESRD, end-stage renal disease.

In all years since 1980, hemodialysis was the predominant form of initial therapy among incident cases (Figure 1.2). The number of incident peritoneal dialysis patients peaked in the mid-1990s, then declined for more than a decade, and has been increasing again since 2008; the number in 2016 was 12,095.

vol 2 Figure 1.2 Trends in the annual number of ESRD incident cases, by modality, in the U.S. population, 1980-2016



Data Source: Reference Table D.1 and special analysis of USRDS ESRD Database. Persons with "Uncertain Dialysis" were included in the "All ESRD" total, but are not represented separately. Abbreviation: ESRD, end-stage renal disease.

Incidence Rate: By Region

Variation in ESRD incidence rates among the 18 ESRD Networks remained substantial in 2016 (Table 1.2). Standardizing for age, sex and race, the rate (per million/year) was lowest in Network 1 (CT, MA, ME, NH, RI) at 254, and in Network 16 (AK, ID, MT, OR, WA) at 259; the rate was highest in Network 14 (TX) at 442 and Network 18 (S. CA) at 409. The high rates in the latter two networks are partly due to the relatively large proportions of Hispanics (38%) compared with 18% nationwide and to the higher incidence rate in Hispanics than in non-Hispanics. There are some notable differences between the ranking of networks by standardized rate (as ordered in Table 1.2) and crude rates. For example, the shift of Network 8 (AL, MS, TN) from the highest crude incidence rate of ESRD (478 per million/year) to a relatively lower standardized rate (381 per million/year) is due to the much larger proportion of African Americans in AL, MS, and TN (44.9%) than in the total U.S. population (26.0%), and to the higher ESRD incidence rate in African Americans than in other racial groups. That is, race is a strong confounder of the ESRD incidence rate by network. Network incidence rates for renal replacement therapy (RRT) modality are also presented in Table 1.2; these findings are discussed in the section, Modality of Renal Replacement Therapy: Incident ESRD Cases, later in this chapter.

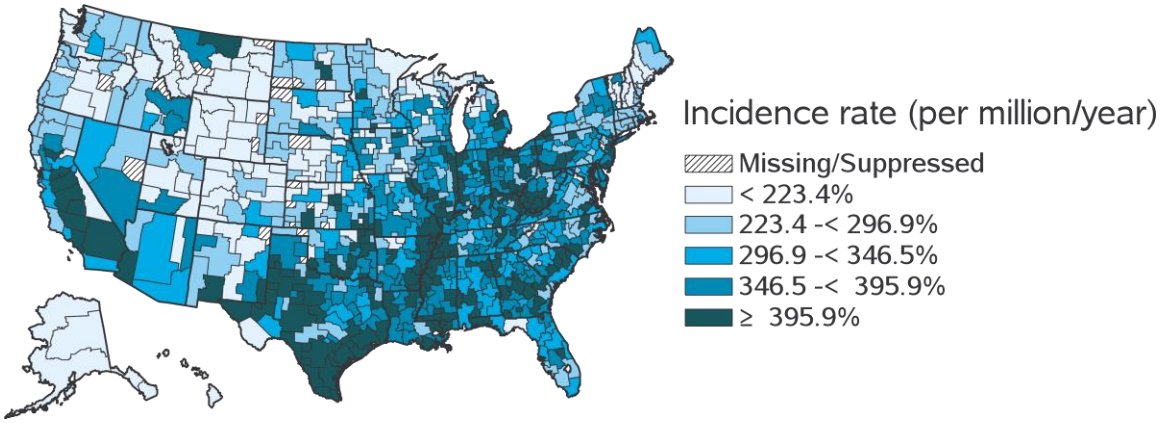
vol 2 Table 1.2 Crude and standardized incidence rates of ESRD and annual number of ESRD incident cases, overall and by modality and ESRD Network (ordered from highest to lowest standardized rate), in the U.S. population, 2016

Network	States* in Network	Total ESRD			Hemodialysis		Peritoneal dialysis		Transplant	
		No. of ** cases	Crude incidence rate (per million/yr)	Standardized incidence rate (per million/yr)	No. of cases	% of network	No. of cases	% of network	No. of cases	% of network
14	TX	11,433	409	442	10,234	89.5	910	8.0	262	2.3
18	S. CA	9,465	384	409	8,330	88.0	948	10.0	179	1.9
13	AR, LA, OK	5,113	439	387	4,481	87.6	540	10.6	89	1.7
9	IN, KY, OH	9,245	407	382	8,145	88.1	865	9.4	196	2.1
10	IL	5,297	412	382	4,496	84.9	616	11.6	154	2.9
8	AL, MS, TN	6,940	478	381	5,944	85.6	884	12.7	108	1.6
3	NJ, PR, VI	5,310	420	378	3,393	90.1	253	6.7	119	3.2
12	IA, KS, MO, NE	4,693	333	346	3,953	84.2	601	12.8	139	3.0
17	N. CA, HI, GU, AS, MP	6,318	369	345	5,083	83.9	830	13.7	138	2.3
6	NC, SC, GA	11,093	435	339	9,659	87.1	1,214	10.9	213	1.9
2	NY	7,600	382	335	6,945	91.4	388	5.1	261	3.4
4	DE, PA	5,285	384	335	4,663	88.2	451	8.5	153	2.9
11	MI, MN, ND, SD, WI	7,625	333	334	6,610	86.7	650	8.5	330	4.3
5	MD, DC, VA, WV	6,986	410	333	6,135	87.8	626	9.0	218	3.1
7	FL	8,342	403	318	7,458	89.4	732	8.8	141	1.7
15	AZ, CO, NV, NM, UT	6,015	282	297	5,145	85.5	649	10.8	215	3.6
16	AK, ID, MT, OR, WA	3,664	245	259	3,088	84.3	465	12.7	111	3.0
1	CT, MA, ME, NH, RI, VT	3,980	269	254	3,463	87.0	343	8.6	167	4.2
	All networks	124,675	388	361	107,225	87.5	11,965	9.8	3,193	2.6

*Data Source: Reference Table A.10 and special analyses, USRDS ESRD Database. *Standardized to the age-sex-race distribution of the 2011 U.S. population. Listed from highest to lowest standardized rate per million/year. The special analyses exclude U.S. territories, unknown age, sex, network, and unknown/other races. ** Includes 50 states, Washington, D.C. (DC), Puerto Rico (PR), Guam (GU), American Samoa (AS), U.S. Virgin Islands (VI), and the Northern Mariana Islands (MP). Northern and Southern California (CA) are split into Networks 17 and 18. Abbreviations: ESRD, end-stage renal disease; yr, year.*

Age-sex-race-standardized incidence rates of ESRD are shown geographically in Figure 1.3 by Health Service Area (HSA) in 2012-2016. Across 784 HSAs in the United States, the average rate during that 5-year period ranged from 59 to 1,152 per million/year (interquartile range: 254 to 392; Figure 1.3). Without further geospatial analyses, specific geographic patterns based on these HSA-level data are difficult to identify. In general, the standardized rates were highest in the South, central Midwest, Atlantic states, and California, and lowest in the mountain areas of Montana, Wyoming, Colorado, Utah, New Mexico, and Alaska.

vol 2 Figure 1.3 Map of the standardized incidence rate of ESRD, by Health Service Area, in the U.S. population, 2012-2016

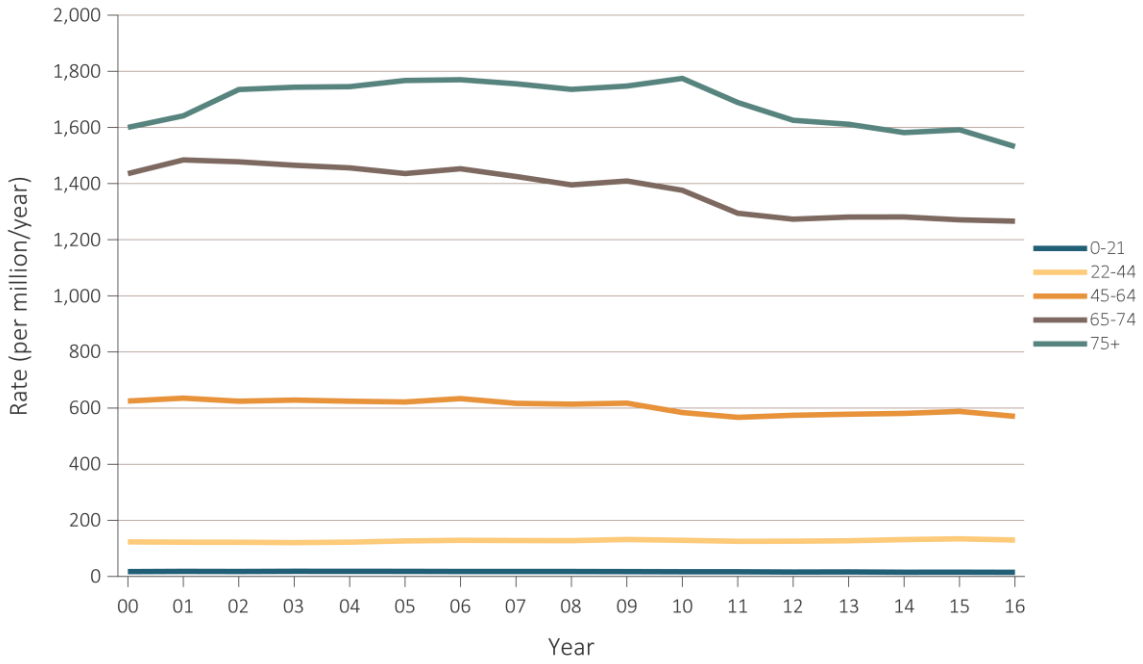


Data Source: Special analyses, USRDS ESRD Database. Standardized to the age-sex-race distribution of the 2011 U.S. population. Special analyses exclude unknown age, sex, HSA, and unknown/other race. Values for cells with 10 or fewer patients are suppressed. Abbreviation: ESRD, end-stage renal disease.

Incidence Rate: By Age

Sex-race-standardized incidence rates of ESRD have been generally stable since 2000 for younger age groups, and they have declined somewhat since 2010 for older persons (Figure 1.4).

vol 2 Figure 1.4 Trends in standardized ESRD incidence rate, by age group, in the U.S. population, 2000-2016



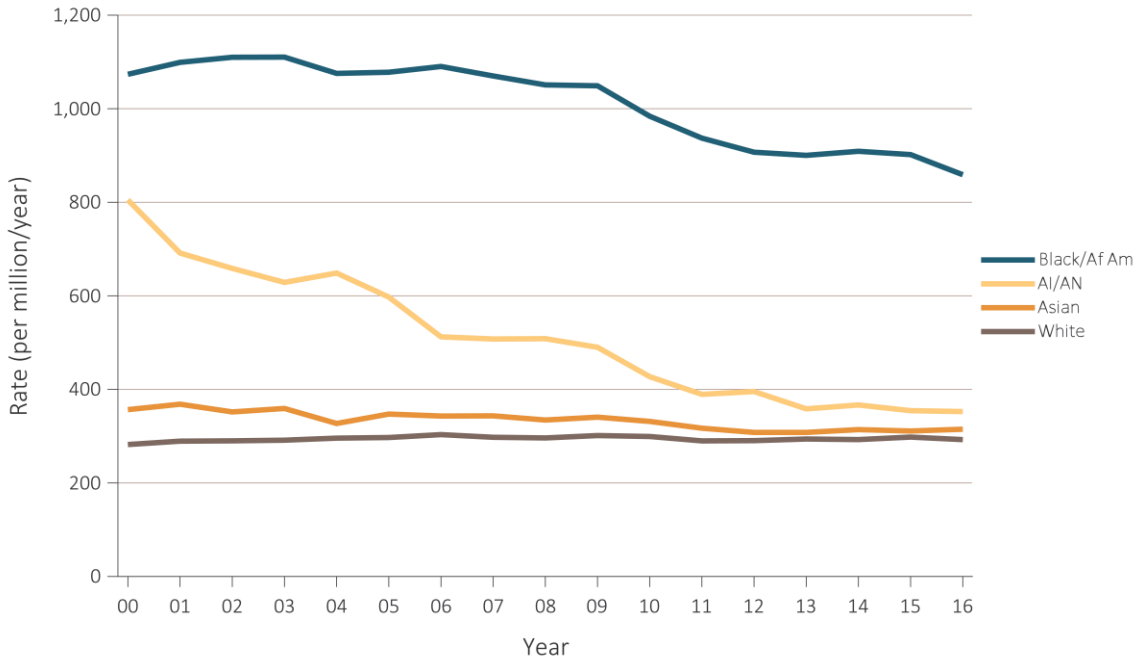
Data Source: Special analyses, USRDS ESRD Database. Standardized to the sex-race distribution of the 2011 U.S. population. Special analyses exclude unknown age, sex, and unknown/other race. Abbreviation: ESRD, end-stage renal disease.

Incidence Rate: By Race and Ethnicity

As shown in Figure 1.5, there were appreciable differences in the age-sex-standardized ESRD incidence rates among racial groups. The standardized incidence rate among Blacks was much higher than the rate among Whites; in 2016, the age-sex-standardized incidence rate ratio (Blacks/Whites) was 2.9. The standardized ESRD incidence rate among Whites has been generally stable since around 2000, but has declined in other race groups, especially among American Indians/Alaska Natives. The net result is that the excess rate of ESRD among minorities compared to Whites has decreased markedly. Between 2000 and 2016, the standardized rate ratio (vs. Whites) declined from 3.8 to 2.9 in African Americans, from 2.9 to 1.2 in American Indians/Alaska Natives, and from 1.3 to 1.1 in Asians, in whom there is no longer a higher rate. These changes may represent a reduction in health inequalities in the population with chronic kidney disease.

Standardized incidence rates for Native Hawaiians and Pacific Islanders (NH/PIs) are not included in Figure 1.5, because our estimates were unexpectedly too high to seem accurate (though similar estimates were included in the 2017 ADR, Figure 1.5). The underlying problem appears to be a difference in how race is classified in the USRDS ESRD database (from which numerators of the incidence rates are obtained) and in the U.S. Census (from which denominators are obtained). In particular, the reporting of multiple races as a category is often used in the Census, but rarely used now in the USRDS database (including the form CMS 2728, required of all newly treated patients with ESRD). This difference in reporting is most relevant for NH/PIs because nearly half of all persons in the 2010 U.S. Census who self-reported their race as NH/PI also reported one or more other races. If the denominators of the incidence rates for NH/PIs include only persons who report that one race—to be comparable with the numerators for which only one race is reported—ESRD incidence rates will be over-estimated by nearly 50%. However, sorting this out to obtain accurate estimates of standardized incidence rates of ESRD in NH/PIs has additional complications; thus, more work is needed before re-introducing these rates into the ADR.

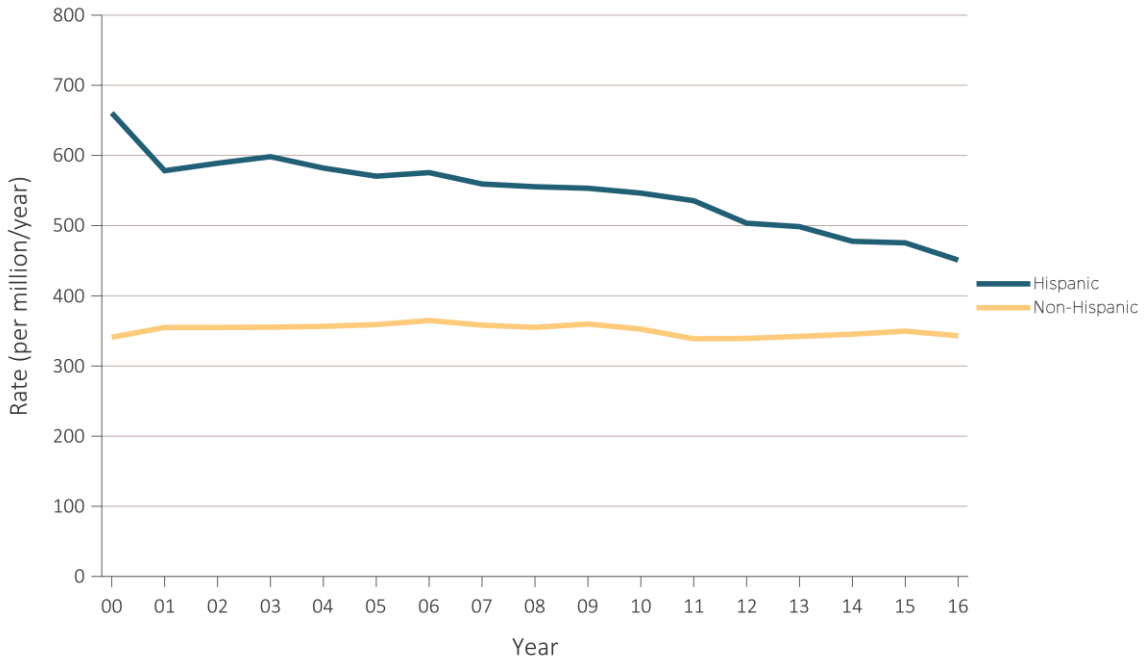
vol 2 Figure 1.5 Trends in standardized ESRD incidence rate, by race, in the U.S. population, 2000-2016



Data Source: Special analyses, USRDS ESRD Database. Standardized to the age-sex distribution of the 2011 U.S. population. Special analyses exclude unknown age, sex, and unknown/other race. Abbreviations: Af Am, African American; AI/AN: American Indian/Alaska Native; ESRD, end-stage renal disease.

While the age-sex-race-standardized incidence rate of ESRD has remained fairly stable in the non-Hispanic population since 2000, it has declined appreciably in Hispanics (Figure 1.6). Thus, the inequality between ethnic groups has also declined, though the rate remained 31.4% higher in Hispanics than non-Hispanics in 2016.

vol 2 Figure 1.6 Trends in standardized ESRD incidence rate, by Hispanic ethnicity, in the U.S. population, 2000-2016



Data Source: Special analysis. Standardized to the age-sex-race distribution of the 2011 U.S. population. Special analyses exclude unknown age, sex, and unknown/other race. Abbreviation: ESRD, end-stage renal disease.

Risk: Cumulative Incidence by Age, Sex, Race, and Duration of Follow-up

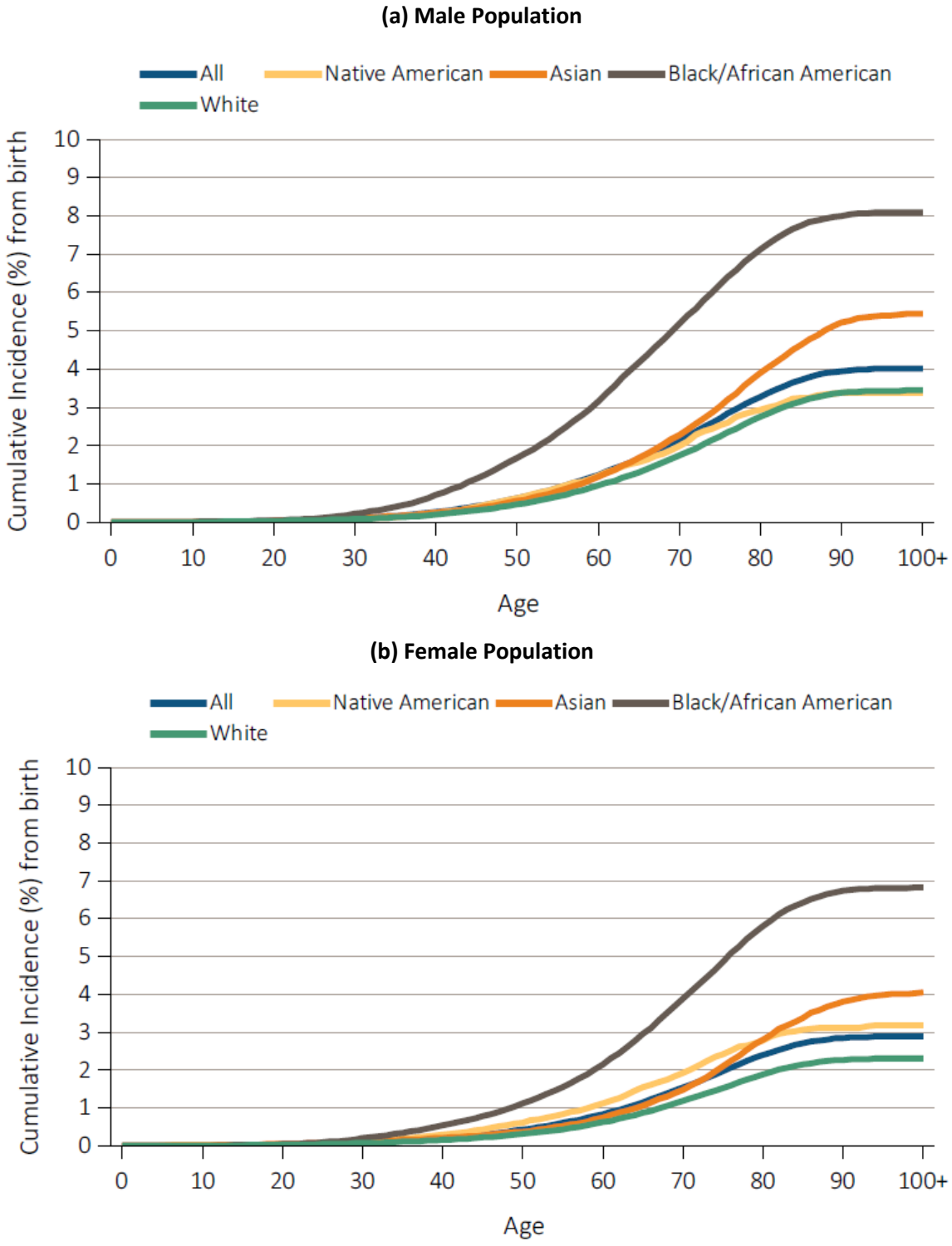
Unlike incidence rates that are strictly population measures, risks are probabilities of disease occurrence (in practice, diagnosis) during a given follow-up period among persons without the disease at the start of that period (baseline). In this section, we introduce the estimation of risks in the ADR, using USRDS data from 2013 to construct a large hypothetical cohort of at-risk persons followed from birth to death (age 100+) (Albertus et al., *AJKD*, 2016). With this method, a risk is referred to as a "cumulative incidence."

The cumulative incidence of ESRD from birth is shown separately for non-Hispanic males and females, by age and race, in Figure 1.7. At each age, starting in the 20s, the cumulative incidence is greater for males than females. Among all races combined, the lifetime cumulative incidence from birth is 4.02% in males and 2.89% in females. Substantial differences in the cumulative incidences of ESRD are observed among racial groups. Among males, the lifetime cumulative incidence from birth ranged from a low of 3.43% in Whites to a high of 8.09% in Blacks/African Americans. Similarly, among females, the lifetime cumulative incidence ranged from a low of 2.32% in Whites to a high of 6.83% in Blacks/African Americans. In both sexes, the elevated risk of ESRD in Blacks/African Americans, relative to all other racial groups, started at a young age—around 30.

Table 1.3 shows the cumulative incidence and 95% confidence interval (CI) of ESRD from a given baseline age (birth to 100), by sex and the duration of follow-up (10 years to lifetime). For example, consider a male who is free of ESRD at age 40 (Table 1.3.a). His 10-year cumulative incidence of ESRD (by age 50) is 0.35% (95% CI: 0.35%, 0.36%); his 30-year cumulative incidence (by age 80) is 3.07% (95% CI: 3.04%, 3.10%); and his lifetime cumulative incidence at age 40 is 3.94% (95% CI: 3.91%, 3.98%). Short-term cumulative incidences are low for both sexes. The 10-year cumulative incidence, which is highest at age 70, is 1.54% (95% CI: 1.52%, 1.57%) for males and 1.05% (95% CI: 1.03%, 1.07%) for females. As expected, the longer someone remains free of ESRD, the less likely that person will be treated for the disease in his or her

lifetime. Note, however, how that lifetime cumulative incidence declines more sharply late in life. That accelerated decline is due to the increasing risk of dying from other diseases (competing causes of death) late in life before being treated for ESRD.

vol 2 Figure 1.7 Cumulative incidence (%) of ESRD from birth to age 100+, by race/ethnicity, in the U.S. (a) male and (b) female populations, 2013



Source: Albertus et al. (Am J Kidney Dis, 2016). Abbreviation: ESRD, end-stage renal disease.

vol 2 Table 1.3 Cumulative incidence (%) of ESRD from baseline age to follow-up age in the U.S. (a) male and (b) female populations, 2013

(a) Male population

Baseline age	Duration of Follow-up										
	10 Years	20 Years	30 Years	40 Years	50 Years	60 Years	70 Years	80 Years	90 Years	100 Years	Lifetime**
Birth	0.01 (0.01-0.01)	0.03 (0.03-0.03)	0.09 (0.09-0.10)	0.25 (0.24-0.25)	0.58 (0.57-0.59)	1.16 (1.15-1.17)	2.05 (2.03-2.06)	3.14 (3.12-3.17)	3.86 (3.83-3.89)	3.96 (3.93-3.99)	3.96 (3.93-3.99)
10 Years	0.02 (0.02-0.02)	0.08 (0.08-0.09)	0.24 (0.23-0.24)	0.58 (0.57-0.59)	1.16 (1.15-1.17)	2.05 (2.03-2.07)	3.16 (3.13-3.18)	3.88 (3.85-3.91)	3.98 (3.95-4.01)		3.98 (3.95-4.02)
20 Years	0.06 (0.06-0.07)	0.22 (0.21-0.23)	0.56 (0.55-0.57)	1.15 (1.13-1.16)	2.04 (2.02-2.06)	3.15 (3.13-3.18)	3.88 (3.85-3.91)	3.98 (3.95-4.01)			3.98 (3.95-4.01)
30 Years	0.16 (0.15-0.16)	0.50 (0.50-0.51)	1.10 (1.08-1.11)	2.01 (1.99-2.02)	3.13 (3.11-3.16)	3.87 (3.84-3.90)	3.97 (3.94-4.00)				3.97 (3.94-4.00)
40 Years	0.35 (0.34-0.36)	0.96 (0.94-0.97)	1.88 (1.86-1.90)	3.03 (3.00-3.05)	3.78 (3.75-3.81)	3.88 (3.85-3.91)					3.88 (3.85-3.91)
50 Years	0.63 (0.62-0.63)	1.58 (1.57-1.60)	2.77 (2.74-2.80)	3.55 (3.51-3.58)	3.65 (3.62-3.69)						3.65 (3.62-3.69)
60 Years	1.04 (1.02-1.05)	2.32 (2.30-2.35)	3.16 (3.13-3.20)	3.28 (3.24-3.31)							3.28 (3.25-3.31)
70 Years	1.51 (1.49-1.53)	2.49 (2.46-2.53)	2.63 (2.60-2.66)								2.63 (2.60-2.67)
80 Years	1.42 (1.39-1.45)	1.61 (1.58-1.64)									1.61 (1.58-1.65)
90 Years	0.51 (0.48-0.54)										0.52 (0.49-0.55)
100 Years											0.07 (0.02-0.17)

Table 1.3 continued on next page.

vol 2 Table 1.3 Cumulative incidence (%) of ESRD from baseline age to follow-up age in the U.S. (a) male and (b) female populations, 2013 (continued)

(b) Female population

Baseline age	Duration of Follow-up										
	10 Years	20 Years	30 Years	40 Years	50 Years	60 Years	70 Years	80 Years	90 Years	100 Years	Lifetime**
Birth	0.01 (0.01-0.01)	0.02 (0.02-0.02)	0.08 (0.08-0.08)	0.19 (0.19-0.20)	0.40 (0.39-0.41)	0.78 (0.77-0.79)	1.45 (1.43-1.46)	2.29 (2.26-2.31)	2.78 (2.76-2.81)	2.84 (2.81-2.87)	2.84 (2.81-2.87)
10 Years	0.02 (0.02-0.02)	0.07 (0.07-0.08)	0.19 (0.18-0.19)	0.39 (0.39-0.40)	0.78 (0.77-0.79)	1.45 (1.43-1.47)	2.29 (2.27-2.32)	2.79 (2.77-2.82)	2.85 (2.83-2.88)		2.85 (2.83-2.88)
20 Years	0.06 (0.05-0.06)	0.17 (0.16-0.17)	0.38 (0.37-0.39)	0.77 (0.75-0.78)	1.44 (1.42-1.45)	2.28 (2.26-2.30)	2.78 (2.76-2.81)	2.84 (2.81-2.87)			2.84 (2.82-2.87)
30 Years	0.11 (0.11-0.12)	0.32 (0.32-0.33)	0.71 (0.70-0.72)	1.39 (1.37-1.40)	2.24 (2.22-2.26)	2.74 (2.72-2.77)	2.80 (2.77-2.83)				2.80 (2.77-2.83)
40 Years	0.21 (0.21-0.22)	0.61 (0.60-0.62)	1.29 (1.27-1.30)	2.15 (2.13-2.17)	2.65 (2.63-2.68)	2.71 (2.69-2.74)					2.71 (2.69-2.74)
50 Years	0.40 (0.40-0.41)	1.10 (1.09-1.11)	1.98 (1.96-2.00)	2.50 (2.47-2.52)	2.56 (2.53-2.58)						2.56 (2.53-2.58)
60 Years	0.73 (0.72-0.74)	1.65 (1.63-1.67)	2.20 (2.17-2.22)	2.26 (2.23-2.29)							2.26 (2.24-2.29)
70 Years	1.02 (1.00-1.04)	1.62 (1.60-1.65)	1.69 (1.67-1.72)								1.69 (1.67-1.72)
80 Years	0.78 (0.76-0.79)	0.87 (0.85-0.89)									0.87 (0.85-0.89)
90 Years	0.19 (0.18-0.21)										0.20 (0.18-0.21)
100 Years											0.02 (0.01-0.05)

*Source: Albertus et al. (Am J Kidney Dis, 2016). Abbreviation: ESRD, end-stage renal disease. **Lifetime corresponds to follow-up of more than 100 years*

Prevalence of ESRD: Counts, Prevalence, and Trends

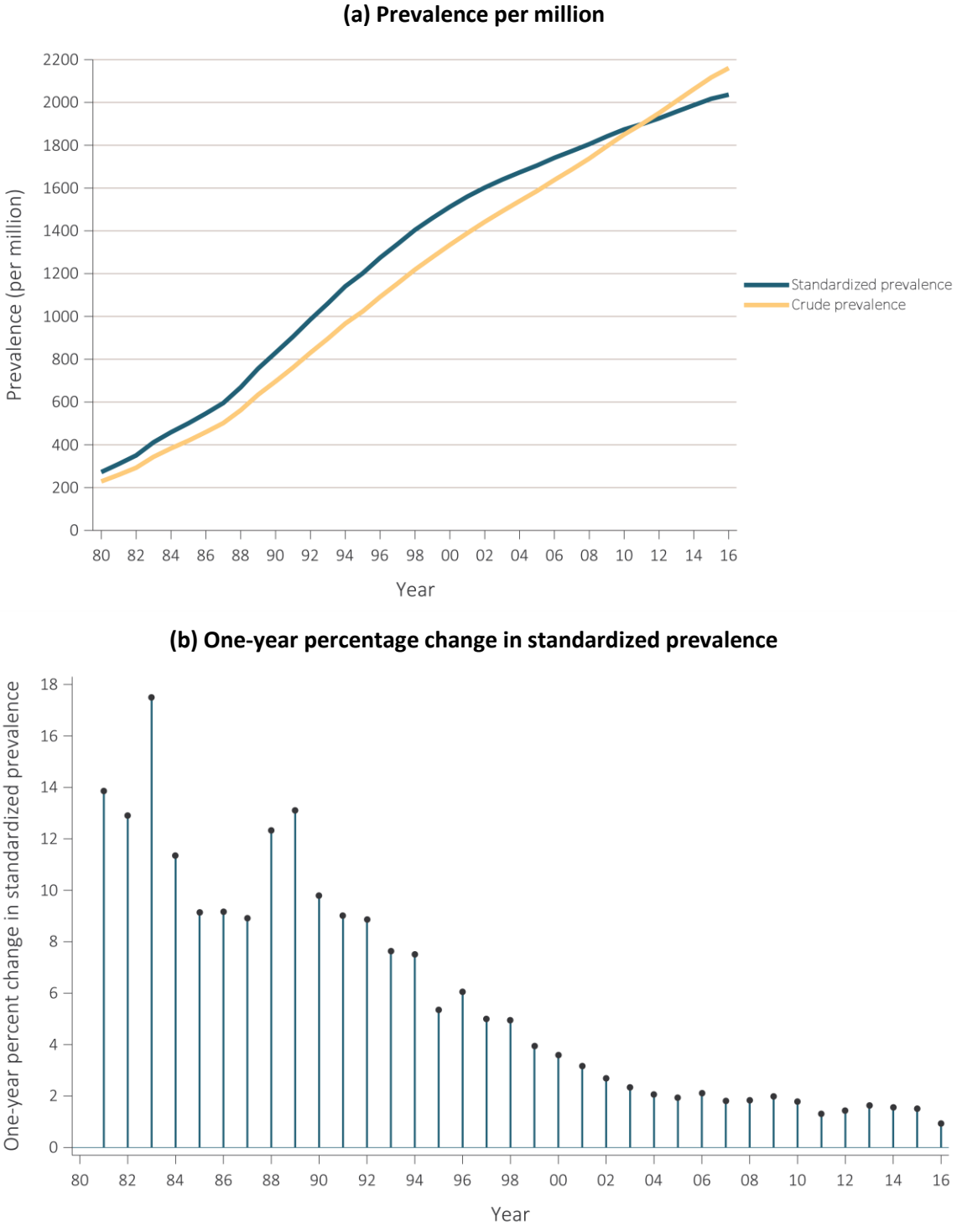
Overall Prevalence

On December 31, 2016, there were 726,331 prevalent cases of ESRD in the United States; this represents an increase of 3.0% since 2015, and of 86.0% since 2000 (Table 1.4 and Figure 1.9). The crude ESRD prevalence reached 2,161 per million, an increase of 2.1% since 2015 and 61.9% since 2000 (Table 1.4).

As shown in Table 1.4 and Figure 1.8, both crude and age-sex-race-standardized prevalence of ESRD increased steadily between 1980 and 2016. In general, however, the absolute and proportional yearly changes were a little greater for the crude prevalence than for the standardized prevalence, particularly after 2000 (Table 1.4). The increasing prevalent count and crude prevalence indicate the need for additional resources to manage ESRD in the U.S. population, as demonstrated in Volume 2, Chapter 9: *Healthcare Expenditures for Persons with ESRD*.

Because prevalence reflects both the incidence and course of the disease, these ESRD prevalence trends result from not only an increasing number of incident cases (Table 1.1) but also longer survival among ESRD patients. This is supported by the mortality data shown in *Volume 2, Chapter 5* and *Reference Table H*. Table H.2 shows that the crude mortality rate among all ESRD patients declined from 185.6 per 1,000/year in 1996 to 136.3 per 1,000/year in 2016, an absolute decrease of 49.3 per 1,000/year. Had the 1996 mortality rate been seen in the 2016 prevalent cohort, there would have been over 30,000 additional deaths. Improving survival in the ESRD population was clearly the primary cause of increasing prevalence in the past two decades.

vol 2 Figure 1.8 Trends in the (a) crude and standardized prevalence of ESRD, and (b) annual percentage change in the standardized prevalence of ESRD, in the U.S. population, 1980-2016



Data Source: Special analyses, USRDS ESRD Database. The special analyses exclude U.S. territories, unknown age, and unknown/other races. Standardized for age, sex, and race. Abbreviation: ESRD, end-stage renal disease.

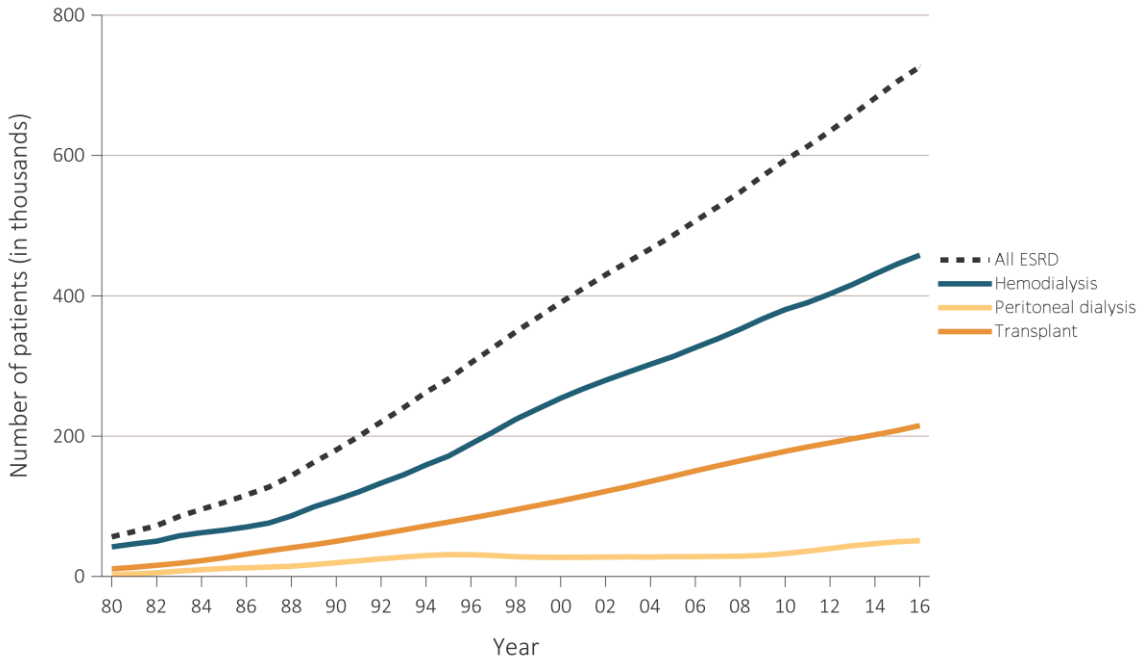
Among prevalent ESRD cases on December 31, 2016, 63.1% used hemodialysis as their renal replacement therapy, 7.0% used peritoneal dialysis, and 29.6% had a functioning kidney transplant (Figure 1.9). The size of the prevalent HD population increased from 2000 to 2016 by 80.2% (Figure 1.9); the prevalent PD population increased by 87.2%, and the transplant population increased by 99.4% during the same period.

vol 2 Table 1.4 Trends in annual number of ESRD prevalent cases, crude and standardized ESRD prevalence, and annual percentage changes, in the U.S. population, 1980-2016

Year	Prevalent count		Crude prevalence		Standardized prevalence	
	No. of cases	% Change from previous year	Prevalence (per million year)	% Change from previous year	Prevalence (per million year)	% Change from previous year
1980	56,435	n/a	59.2	n/a	65.3	n/a
1981	64,258	13.9	74.6	26.0	83.1	27.3
1982	72,499	12.8	90.6	21.4	101.3	21.9
1983	85,581	18.0	109.4	20.8	123.1	21.5
1984	95,897	12.1	131.8	20.5	148.9	21.0
1985	105,432	9.9	157.4	19.4	178.6	19.9
1986	116,119	10.1	190.5	21.0	217.0	21.5
1987	127,476	9.8	226.6	19.0	259.7	19.7
1988	143,526	12.6	284.1	25.4	329.6	26.9
1989	162,708	13.4	349.4	23.0	407.0	23.5
1990	180,526	11.0	395.9	13.3	461.7	13.4
1991	199,554	10.5	442.8	11.8	515.8	11.7
1992	220,345	10.4	500.0	12.9	581.2	12.7
1993	240,552	9.2	549.3	9.9	637.7	9.7
1994	262,627	9.2	607.2	10.5	704.2	10.4
1995	281,564	7.2	729.3	20.1	847.6	20.4
1996	304,420	8.1	865.1	18.6	1,004.3	18.5
1997	326,218	7.2	979.1	13.2	1,132.0	12.7
1998	348,761	6.9	1,080.6	10.4	1,244.1	9.9
1999	369,625	6.0	1,166.3	7.9	1,333.8	7.2
2000	390,566	5.7	1,243.6	6.6	1,410.6	5.8
2001	410,507	5.1	1,311.1	5.4	1,474.2	4.5
2002	429,887	4.7	1,372.7	4.7	1,526.8	3.6
2003	448,543	4.3	1,427.9	4.0	1,571.3	2.9
2004	467,088	4.1	1,480.0	3.6	1,610.2	2.5
2005	485,984	4.0	1,531.1	3.5	1,647.3	2.3
2006	506,764	4.3	1,585.6	3.6	1,686.8	2.4
2007	526,899	4.0	1,637.3	3.3	1,721.5	2.1
2008	548,019	4.0	1,690.7	3.3	1,756.4	2.0
2009	570,790	4.2	1,749.0	3.4	1,794.1	2.1
2010	593,172	3.9	1,805.7	3.2	1,829.0	1.9
2011	613,050	3.4	1,855.1	2.7	1,855.1	1.4
2012	634,728	3.5	1,908.5	2.9	1,884.1	1.6
2013	657,947	3.7	1,965.2	3.0	1,916.7	1.7
2014	681,783	3.6	2,021.7	2.9	1,948.2	1.6
2015	705,492	3.5	2,077.1	2.7	1,979.1	1.6
2016	726,331	3.0	2,120.5	2.1	1,998.3	1.0

Data Source: Special analyses of the USRDS ESRD Database. The special analyses exclude U.S. territories, unknown age, and unknown/other races. Standardized to the age-sex-race distribution of the 2011 U.S. population. Abbreviations: ESRD, end-stage renal disease; n/a, not applicable.

vol 2 Figure 1.9 Trends in the number of ESRD prevalent cases, by modality, in the U.S. population, 1980-2016



Data Source: Reference Table D.1 and special analysis of USRDS ESRD Database. Abbreviation: ESRD, end-stage renal disease. Persons with "Uncertain Dialysis" were included in the "All ESRD" total, but are not represented separately.

Prevalence: By Region

Among the 18 ESRD Networks, the age-sex-race-standardized prevalence of ESRD ranged from 2,870 per million in Network 3 (NJ, PR, VI) to 1,640 per million in Network 1 (CT, MA, ME, NH, RI, VT) (Table 1.5). Renal replacement modality use by region, also presented in Table 1.5, is discussed in the section Modality of Renal Replacement Therapy: Incident ESRD Cases later in this chapter.

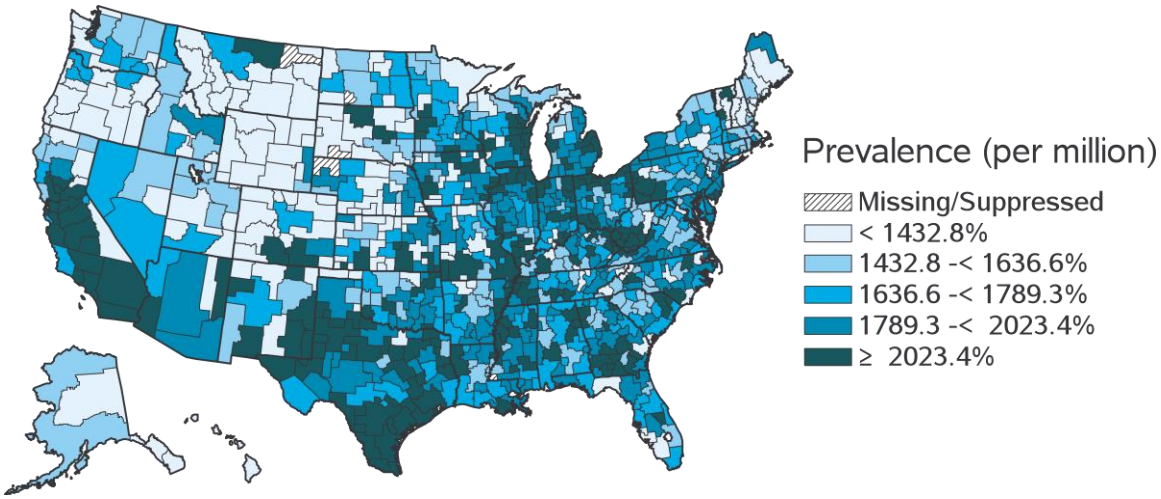
vol 2 Table 1.5 Crude and standardized* prevalence of ESRD (per million) and annual number of ESRD prevalent cases, overall and by modality (hemodialysis, peritoneal dialysis, and transplantation) and ESRD Network (ordered from highest to lowest standardized rate), in the U.S. population, 2016

		Total ESRD			Hemodialysis		Peritoneal dialysis		Transplant	
Network	States in network*	No. of cases**	Crude prevalence (per million)	Standardized prevalence (per million)	No. of cases	% of network	No. of cases	% of network	No. of cases	% of network
3	NJ, PR, VI	28,864	3,141	2,870	13,398	63.7	1,005	4.8	6,572	31.2
18	S. CA	60,362	2,446	2,618	40,597	67.3	4,737	7.8	14,895	24.7
14	TX	65,415	2,321	2,490	45,145	69.0	4,237	6.5	15,837	24.2
10	IL	31,906	2,473	2,293	19,367	60.7	2,274	7.1	10,176	31.9
17	N. CA, HI, GU, AS	39,881	2,417	2,270	23,726	61.2	3,349	8.6	11,541	29.8
11	MI, MN, ND, SD, WI	46,573	2,025	2,094	25,869	55.6	2,682	5.8	17,860	38.4
9	IN, KY, OH	48,366	2,120	2,060	30,458	63.0	3,747	7.7	13,965	28.9
12	IA, KS, MO, NE	26,282	1,860	2,025	14,553	55.4	2,241	8.5	9,403	35.8
4	DE, PA	30,504	2,212	2,010	18,529	60.7	1,929	6.3	9,946	32.6
13	AR, LA, OK	26,851	2,300	1,981	18,078	67.3	2,289	8.5	6,359	23.7
2	NY	45,334	2,258	1,966	29,576	65.2	1,655	3.7	14,008	30.9
8	AL, MS, TN	37,446	2,568	1,948	25,368	67.7	3,063	8.2	8,908	23.8
15	AZ, CO, NV, NM, UT	37,416	1,746	1,877	21,892	58.5	2,800	7.5	12,623	33.7
5	MD, DC, VA, WV	41,439	2,430	1,867	26,224	63.3	2,591	6.3	12,485	30.1
6	NC, SC, GA	64,220	2,501	1,814	43,859	68.3	5,334	8.3	14,849	23.1
7	FL	43,988	2,102	1,738	28,314	64.4	3,170	7.2	12,337	28.1
16	AK, ID, MT, OR, WA	23,081	1,532	1,694	12,555	54.4	1,998	8.7	8,442	36.6
1	CT, MA, ME, NH, RI, VT	24,583	1,653	1,640	13,379	54.4	1,451	5.9	9,648	39.2
	All networks	726,331	2,274	2,138	450,887	63.2	50,552	7.1	209,854	29.4

*Data Source: Reference Table B.10 and special analyses, USRDS ESRD Database. *Standardized to the age-sex-race distribution of the 2011 U.S. population. Listed from highest to lowest standardized rate per million/year. The special analyses exclude U.S. territories, unknown age, sex, network, and unknown/other races. **No. of cases does include 50 states, Washington, D.C. (DC), Puerto Rico (PR), Guam (GU), and American Samoa (AS). Northern and Southern California (CA) split into Networks 17 and 18. Abbreviations: Af Am, African American; ESRD, end-stage renal disease; Hisp, Hispanic; N Am, Native American.*

Across 801 Health Service Areas, the standardized prevalence of ESRD in 2012-2016 ranged from 299 per million to 6,219 per million (interquartile range: 1,481 to 2,023 per million; Figure 1.10). Although specific geographic patterns are difficult to identify without further geospatial analyses, ESRD prevalence in 2016 tended to be relatively high or low in roughly the same areas as observed for ESRD incidence (Figure 1.3).

vol 2 Figure 1.10 Map of the standardized prevalence of ESRD, by Health Service Area, in the U.S. population, 2012-2016*

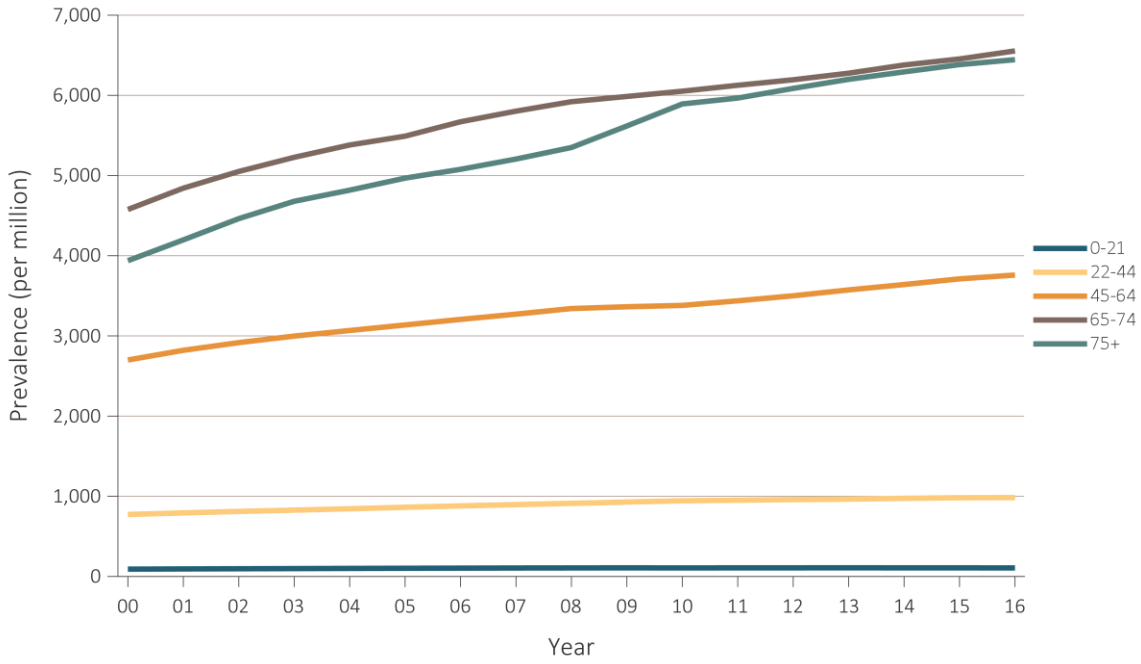


*Data Source: Special analyses, USRDS ESRD Database. Standardized to the age-sex-race distribution of the 2011 U.S. population. Special analyses exclude unknown age, sex, HSA, and unknown/other race. *Four Health Service Areas were suppressed because the ratio of crude rate to standardized rate or standardized rate to crude rate was greater than 3. Values for cells with 10 or fewer patients are suppressed. Abbreviation: ESRD, end-stage renal disease.*

Prevalence: By Age

The sex-race-standardized ESRD prevalence has risen over time, with steeper increases among the older age groups (Figure 1.11). These increases contrast with the ongoing declines in standardized ESRD incidence rates across age groups (Figure 1.4). The pattern of this discrepancy likely results from improvement in survival over calendar time among ESRD patients and the transition of surviving incident ESRD patients in each age group to older groups. ESRD prevalence was highest for persons 65-74 years of age until 2010 when the gap with persons 75 years of age and older started to narrow. Although the incidence rate was highest in the oldest group (≥75), ESRD prevalence was a little lower, due to greater mortality among the oldest ESRD patients.

vol 2 Figure 1.11 Trends in the standardized prevalence of ESRD, by age group, in the U.S. population, 2000-2016



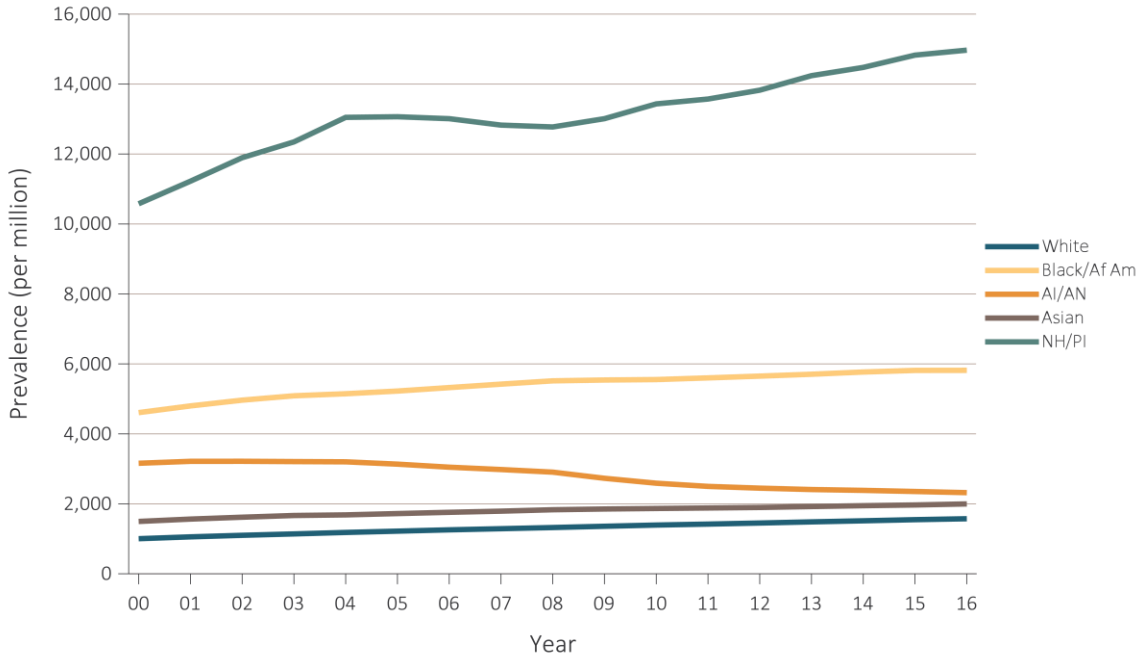
Data Source: Special analyses, USRDS ESRD Database. Point prevalence on December 31 of each year. Standardized to the sex-race distribution of the 2011 U.S. population. Special analyses exclude unknown age, sex, and unknown/other race. Abbreviation: ESRD, end-stage renal disease.

Prevalence: By Race and Ethnicity

In 2016, the age-sex-standardized prevalence of ESRD (per million) was 14,969 among Native Hawaiians/Pacific Islanders, 5,816 among Blacks/African Americans, 2,319 among American Indians/Alaska Natives, 1,997 among Asians, and 1,573 among Whites (Figure 1.12). 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 7.5-fold higher than Asians, 6.5-fold higher than American Indians/Alaska Natives, and nearly 2.6-fold higher than Blacks/African Americans.

The standardized prevalence of ESRD has continued to rise, especially since 2008, in all racial groups except American Indians/Alaska Natives (Figure 1.5). The remarkable decline in the incidence rate among this latter group has resulted in a 36% reduction in the prevalence of ESRD, from 3,159 per million in 2000 to 2,319 per million in 2016 (Figure 1.12).

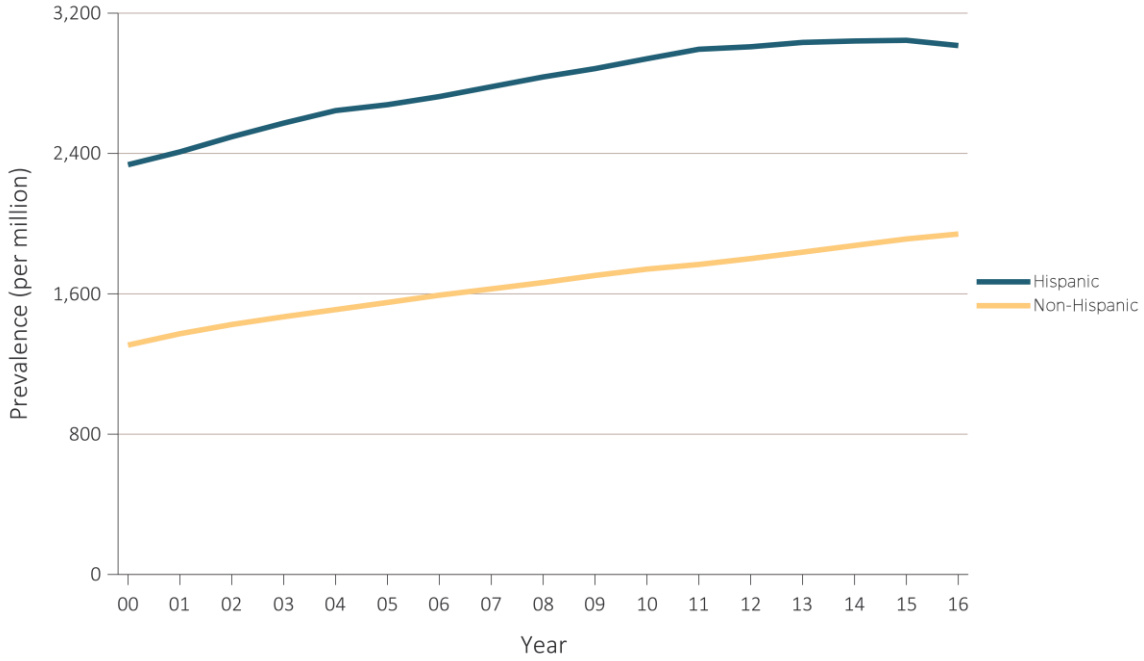
vol 2 Figure 1.12 Trends in the standardized prevalence of ESRD, by race, in the U.S. population, 2000-2016



Data Source: Special analyses, USRDS ESRD Database. Point prevalence on December 31 of each year. Standardized to the age-sex distribution of the 2011 U.S. population. Special analyses exclude unknown age, sex, and unknown/other race. Abbreviations: Af Am, African American; AI/AN: American Indian/Alaska Native; ESRD, end-stage renal disease; NH/PI: Native Hawaiian/Pacific Islander.

In 2016, the age-sex-race-standardized ESRD prevalence was 1,941 per million among non-Hispanics, and 55.3% higher, at 3,015 per million, among Hispanics (Figure 1.13). The standardized ESRD prevalence has risen for both non-Hispanics and Hispanics, though since 2011, it has shown signs of plateauing among Hispanics. The absolute difference in standardized prevalence between Hispanics and non-Hispanics was about the same in 2000 and 2016.

vol 2 Figure 1.13 Trends in the standardized prevalence of ESRD, by Hispanic ethnicity, in the U.S. population, 2000-2016



Data Source: Special analysis, USRDS ESRD Database. Point prevalence on December 31 of each year. Standardized to the age-sex-race distribution of the 2011 U.S. population. Special analyses exclude unknown age, sex, and unknown/other race. Abbreviation: ESRD, end-stage renal disease.

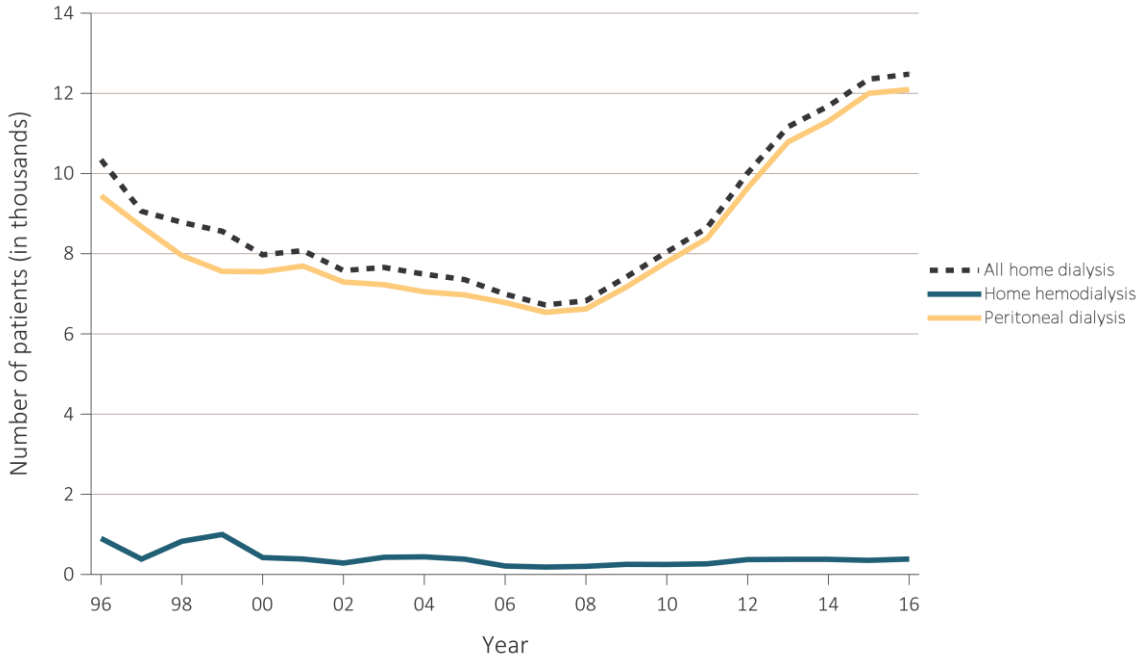
Modality of Renal Replacement Therapy: Incident ESRD Cases

As shown previously in Figure 1.2, among incident ESRD patients in 2016, 87.3% used hemodialysis as their renal replacement therapy, 9.7% used peritoneal dialysis, and 2.8% received a preemptive kidney transplant. Since 2000, the number of incident HD patients has increased by 28.8%; the number of incident PD patients has increased by 60.2%, and the number of preemptive transplants has increased by 73.1%. By comparison, the U.S. population was 14.6% larger in 2016 than in 2000.

Trends in Incident Counts: By Renal Replacement Therapy Modality

Use of home dialysis among incident ESRD patients decreased from 1996 to 2007, but has increased appreciably since 2008 through 2016 (Figure 1.14). Overall, home dialysis use in 2016 was 85.6% higher than at its least utilized point in 2007. In 2016, use of PD and home HD were 85.0% and 108.1% higher, respectively, than in 2007. PD has continued to be the dominant form of home dialysis. Despite the large proportional rise in home HD, its overall use was only 3.1% of all incident ESRD patients receiving dialysis in 2016 (*Reference Table D.1*).

vol 2 Figure 1.14 Trends in the number of incident ESRD cases using home dialysis, by type of therapy, in the U.S. population, 1996-2016



Data Source: Reference Table D.1 and special analysis, USRDS ESRD Database. Abbreviations: ESRD, end-stage renal disease.

Renal Replacement Therapy Modality Use: By Patient Characteristics

Use of peritoneal dialysis and preemptive kidney transplants were markedly more common in 2016 among younger ESRD patients than among older patients, and they were a little less common among Black/African American and Hispanic ESRD patients than in White patients (Table 1.6). Use of PD and preemptive kidney transplants were more common among ESRD patients with glomerular or cystic kidney disease as the primary cause of ESRD than in ESRD patients with other primary causes of ESRD. This difference is partially due to age, as both glomerular and cystic kidney disease are more common in younger patients.

vol 2 Table 1.6 Number and percentage of incident ESRD patients receiving hemodialysis (HD), peritoneal dialysis (PD), and a transplant, by age, sex, race, ethnicity, and primary cause of ESRD, in the U.S. population, 2016

	Total	Hemodialysis		Peritoneal dialysis		Transplant	
		n	%	n	%	n	%
Age							
0-21	1,386	714	51.5	396	28.6	276	19.9
22-44	13,648	10,742	78.7	2,055	15.1	851	6.2
45-64	47,374	40,745	86.0	4,996	10.5	1,633	3.4
65-74	33,641	30,076	89.4	2,912	8.7	653	1.9
75+	28,407	26,618	93.7	1,736	6.1	53	0.2
Sex							
Male	72,049	62,923	87.3	7,092	9.8	2,034	2.8
Female	52,407	45,972	87.7	5,003	9.5	1,432	2.7
Race							
White	83,662	72,645	86.8	8,475	10.1	2,542	3.0
Black/African American	31,921	29,047	91.0	2,547	8.0	327	1.0
American Indian or Alaska Native	1,203	1,048	87.1	95	7.9	60	5.0
Asian	5,396	4,273	79.2	772	14.3	351	6.5
Native Hawaiian or Pacific Islander	1,578	1,421	90.1	147	9.3	10	0.6
Other or Multiracial	407	317	77.9	53	13.0	37	9.1
Unknown	289	144	49.8	*	2.1	139	48.1
Ethnicity							
Hispanic	18,273	16,309	89.3	1,662	9.1	302	1.7
Non-Hispanic	104,869	91,999	87.7	10,361	9.9	2,509	2.4
Unknown	1,314	587	44.7	72	5.5	655	49.8
Primary cause of ESRD							
Diabetes	58,136	52,489	90.3	5,245	9.0	402	0.7
Hypertension	34,784	31,201	89.7	3,290	9.5	293	0.8
Glomerulonephritis	9,108	7,047	77.4	1,596	17.5	465	5.1
Cystic Kidney	3,513	2,143	61.0	803	22.9	567	16.1
Other/Unknown	18,915	16,015	84.7	1,161	6.1	1,739	9.2
Total	124,456	108,895	87.5	12,095	9.7	3,466	2.8

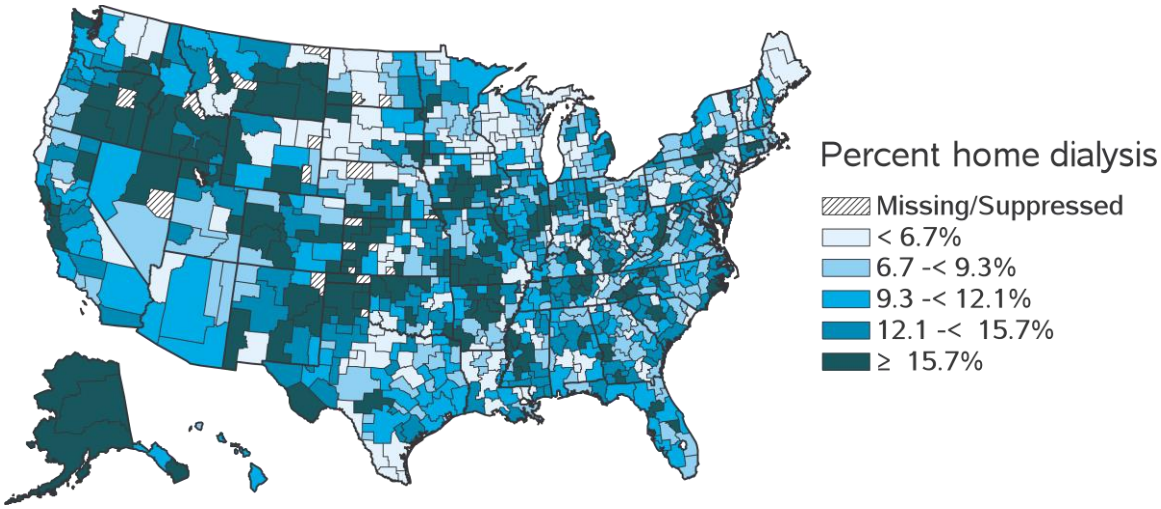
*Data Source: Reference Table D.10 and special analyses, USRDS ESRD Database. The numbers in this table exclude "Uncertain Dialysis." Hemodialysis includes home hemodialysis and in-center hemodialysis. *Values for cells with 10 or fewer patients are suppressed. Abbreviation: ESRD, end-stage renal disease.*

Renal Replacement Therapy Modality Use: By Region

Among incident ESRD cases in 2016, hemodialysis was the predominant modality in all networks, ranging from 84.2% in Network 12 (IA, KS, MO, NE) to 91.4% in Network 2 (NY; Table 1.2). Use of PD varied more than 2-fold, from 5.1% in Network 2 (Table 1.2) to 13.7% in Network 17 (N.CA, HI, GU, AS) (Table 1.2). Overall, preemptive kidney transplantation remained an uncommon initial RRT modality, at 2.6%, although its use ranged more than 3-fold from 1.6% in Network 8 (AL, MS, TN) to 4.3% in Network 11 (MI, MN, ND, SD, WI).

The proportion of incident dialysis patients using home dialysis in 2012-2016 varied substantially across 785 HSAs, ranging from 0% to 67% (interquartile range: 7.3% to 14.1%; Figure 1.15). 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. However, relative to the geographic distribution of the standardized ESRD incidence rate during the same 5-year period (Figure 1.3), home dialysis was proportionally more common in the Western United States.

vol 2 Figure 1.15 Map of the percentage of incident dialysis cases using home dialysis (peritoneal dialysis or home hemodialysis), by Health Service Area, 2012-2016



Data Source: Special analyses, USRDS ESRD Database. Values for cells with 10 or fewer patients are suppressed. Abbreviation: ESRD, end-stage renal disease.

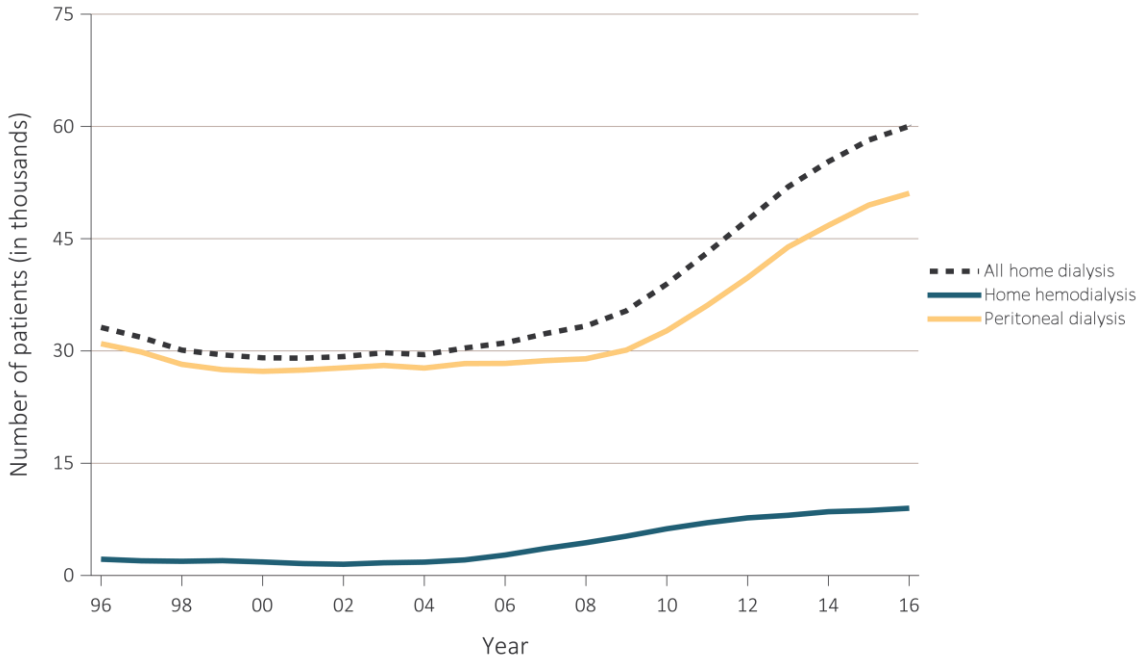
Modality of Renal Replacement Therapy: Prevalent ESRD Cases

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 1.16), mirroring the trend shown for incident dialysis (Figure 1.14).

Home dialysis accounted for 8.3% of all prevalent dialysis patients in 2016, up from a low of 6.1% in 2008 (*Reference Table D.1*). In this home dialysis group, the proportion using HD vs. PD was much higher in 2016 (17.6%) than in 2000 (6.7%) (Fig 1.16).

vol 2 Figure 1.16 Trends in number of prevalent ESRD cases using home dialysis, by type of therapy, in the United States, 1996-2016



Data Source: Reference Table D.1. December 31 prevalent ESRD patients. Peritoneal dialysis consists of continuous ambulatory peritoneal dialysis (CAPD), continuous cycling peritoneal dialysis (CCPD), and intermittent peritoneal dialysis (other PD) only. Abbreviation: ESRD, end-stage renal disease.

Renal Replacement Therapy Modality Use: By Patient Characteristics

Distributions of the modality used by prevalent ESRD patients (Table 1.7), by patient characteristics, generally reflect those distributions for incident ESRD patients (Table 1.6). 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 1.7).

vol 2 Table 1.7 Number and percentage of prevalent ESRD patients receiving hemodialysis, peritoneal dialysis, and a transplant, by age, sex, race, ethnicity, and the primary cause of ESRD, in the United States, 2016

	Total	HD		PD		Transplant	
		n	%	n	%	n	%
Age							
0-21	9,705	1,697	17.5	1,027	10.6	6,981	71.9
22-44	103,213	51,001	49.4	9,110	8.8	43,102	41.8
45-64	316,051	188,339	59.6	22,369	7.1	105,343	33.3
65-74	176,579	119,105	67.5	11,698	6.6	45,776	25.9
75+	118,527	97,815	82.5	6,853	5.8	13,859	11.7
Sex							
Male	419,275	262,716	62.7	28,469	6.8	128,090	30.6
Female	304,745	195,214	64.1	22,587	7.4	86,944	28.5
Race							
White	444,789	259,731	58.4	33,928	7.6	151,130	34
Black/African American	220,616	164,223	74.4	12,391	5.6	44,002	19.9
American Indian or Alaska Native	7,693	5,375	69.9	464	6.0	1,854	24.1
Asian	35,082	20,037	57.1	3,386	9.7	11,659	33.2
Native Hawaiian or Pacific Islander	9,067	6,706	74.0	670	7.4	1,691	18.7
Other or Multiracial	3,508	1,332	38.0	173	4.9	2,003	57.1
Unknown	3,320	553	16.7	45	1.4	2,722	82
Ethnicity							
Hispanic	127,337	85,415	67.1	8,058	6.3	33,864	26.6
Non-Hispanic	579,637	370,249	63.9	42,751	7.4	166,637	28.7
Unknown	17,101	2,293	13.4	248	1.5	14,560	85.1
Primary Cause of ESRD							
Diabetes	278,409	211,695	76.0	19,205	6.9	47,509	17.1
Hypertension	186,213	135,279	72.6	14,174	7.6	36,760	19.7
Glomerulonephritis	114,155	45,363	39.7	8,911	7.8	59,881	52.5
Cystic Kidney	34,987	10,907	31.2	2,600	7.4	21,480	61.4
Other/Unknown	110,311	54,713	49.6	6,167	5.6	49,431	44.8
Total	724,075	457,957	63.2	51,057	7.1	215,061	29.7

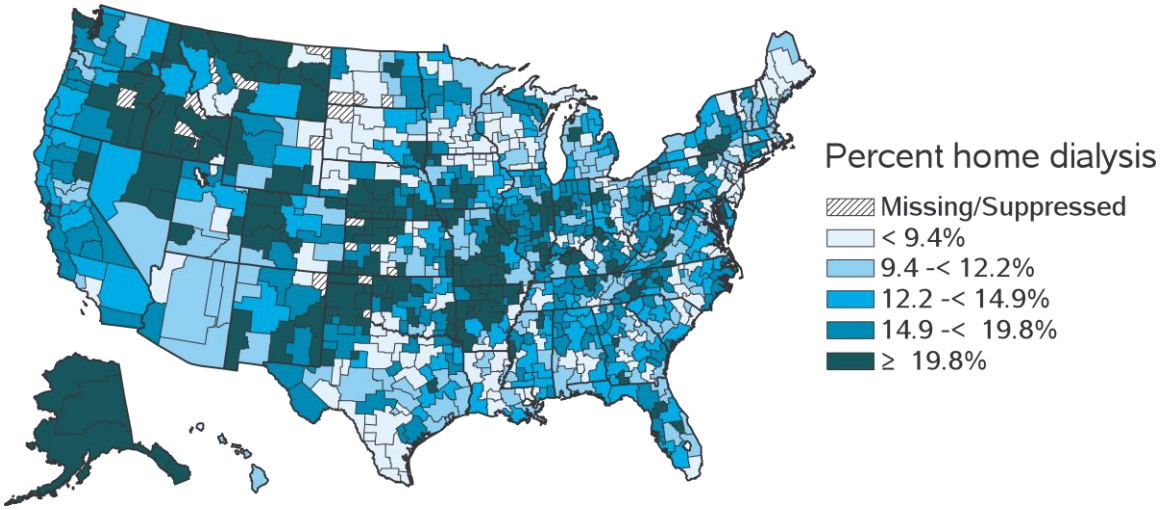
Data Source: Reference Table D.11 and special analyses, USRDS ESRD Database. The numbers in this table exclude "Uncertain Dialysis" and include "Unknown sex." Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis.

Renal Replacement Therapy Modality Use: By Region

As observed for incident dialysis, RRT modality use among the prevalent ESRD population varied by region. Use ranged across networks, from 54.4% to 69.0% for HD, 3.7% to 8.7% for PD, and from 23.1% to 39.2% for transplantation (Table 1.5). The percentage of patients on HD was generally higher, and the percentage with a transplant was generally lower in the networks with a higher prevalence of ESRD.

The geographic distribution of home dialysis in 2012-2016 among all prevalent dialysis patients (Figure 1.17) is similar to the distribution observed for incident dialysis patients during the same period (Figure 1.15). In contrast to the distribution of standardized ESRD prevalence (Figure 1.10), home dialysis was proportionally more common in the Western and central mid-Western regions of the United States, and it varied considerably across 787 HSAs in 2012-2016. The percentage of all prevalent dialysis patients using home dialysis ranged from 1.7% to 76.9% (interquartile range: 9.9% to 18.1%; Figure 1.17).

vol 2 Figure 1.17 Map of the percentage of prevalent dialysis cases using home dialysis, by Health Service Area, 2012-2016



Data Source: Special analyses, USRDS ESRD Database. Values for cells with 10 or fewer patients are suppressed. Abbreviation: ESRD, end-stage renal disease.

Patient and Treatment Characteristics at ESRD Onset

Pre-ESRD care

In 2016, 20.8% of patients starting ESRD therapy were reported on the CMS 2728 form as not having received nephrology care before ESRD onset (Table 1.8), a decrease of 1.2% from 2015. An additional 14.6% 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 35.4% of new ESRD cases received little or no pre-ESRD nephrology care (Table 1.8.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 (43.8%), and adults 22-44 years old were least likely (28.4%) to have had 12 months or more of pre-ESRD nephrology care. Blacks were slightly less likely to have had pre-ESRD care than were other racial groups, and Hispanics were less likely to have had pre-ESRD care than were non-Hispanics.

ESRD patients with a primary cause of their disease reported as 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 hypertension 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.

Both dietary care and ESA use were more prevalent among incident ESRD cases in 2016 who had the longest duration of pre-ESRD nephrology care (Table 1.8.b). The prevalence of dietary care was 12.9% in patients with >12 months of pre-ESRD nephrology care and only 0.3% in patients with no such care. Similarly, the prevalence of ESA use was 22.7% in patients with >12 months of pre-ESRD nephrology care and only 1.9% in patients with no such care. The association between eGFR at the start of renal replacement therapy and duration of pre-ESRD nephrology care was slightly non-monotonic. The prevalence of starting RRT early (≥15 ml/min/1.73 m^2) and late (<5 ml/min/1.73 m^2) was greatest for patients with no pre-ESRD nephrology care (12.4% and 19.8%, respectively). Use of a catheter only for vascular access was strongly and inversely associated with duration of pre-ESRD nephrology care, being 35.6% for patients with >12 months of pre-nephrology care and 80.1% for patients with no such care. In contrast, AV fistula use was much more common for patients with >12 months of pre-ESRD nephrology care (25.4%) than for patients with no such care (2.3%).

vol 2 Table 1.8.a Distribution (in %) of the reported duration of pre-ESRD nephrology care, by category of each demographic variable, among incident ESRD cases in the U.S. population, 2016

(a) Demographic characteristics (% within row)

		Duration of pre-ESRD nephrology care					
	No. of cases	>12 months	6-12 months	0-6 months	None	Unknown /Missing	Unknown /Missing
Variable Category	**121,198**	**31.8**	**19.3**	**13.6**	**20.8**	**14.6**	**100**
Age							
0-21	1,412	43.8	14.5	15.9	18.8	6.9	100
22-44	13,487	28.4	18	14	26.7	13	100
45-64	45,766	29.6	19.8	14.1	22.3	14.2	100
65-74	32,687	33.6	19.7	13.4	18.4	14.9	100
75+	27,846	34.2	18.8	12.7	18.5	15.9	100
Sex							
Female	51,326	31.8	19.7	13.7	20	14.8	100
Male	69,872	31.8	19	13.4	21.4	14.4	100
Race							
White	81,985	33.6	19.4	13.4	20.1	13.5	100
Black	31,298	26.9	19.1	13.6	22.9	17.5	100
American Indian/Alaska Native	1,188	29.5	18.4	16.8	21	14.2	100
Asian	5,167	34	19.2	15.2	17.7	14	100
Native Hawaiian/ Pacific Islander	1,558	27.9	21.5	14.5	24	12.1	100
Other/Unknown	*	50	*	*	50	*	100
Ethnicity							
Hispanic	17,294	25.8	18.9	14.3	26.1	14.9	100
Non-Hispanic	103,904	32.7	19.4	13.4	19.9	14.5	100
Primary diagnosis							
Diabetes	58,308	32.2	21.4	13.9	18.3	14.2	100
Hypertension	34,906	29.1	18.7	13.2	21.7	17.3	100
Glomerulonephritis	9,189	40.3	17.7	13.6	19.7	8.7	100
Cystic kidney	3,546	55.8	16.9	10	9.7	7.6	100
Other/Unknown	15,249	25.4	14.5	14	31.4	14.8	100

Table 1.8 continued on next page.

vol 2 Table 1.8.b Distribution (in %) of clinical characteristics, by reported duration of pre-ESRD nephrology care, among incident ESRD cases in the U.S. population, 2016 (continued)

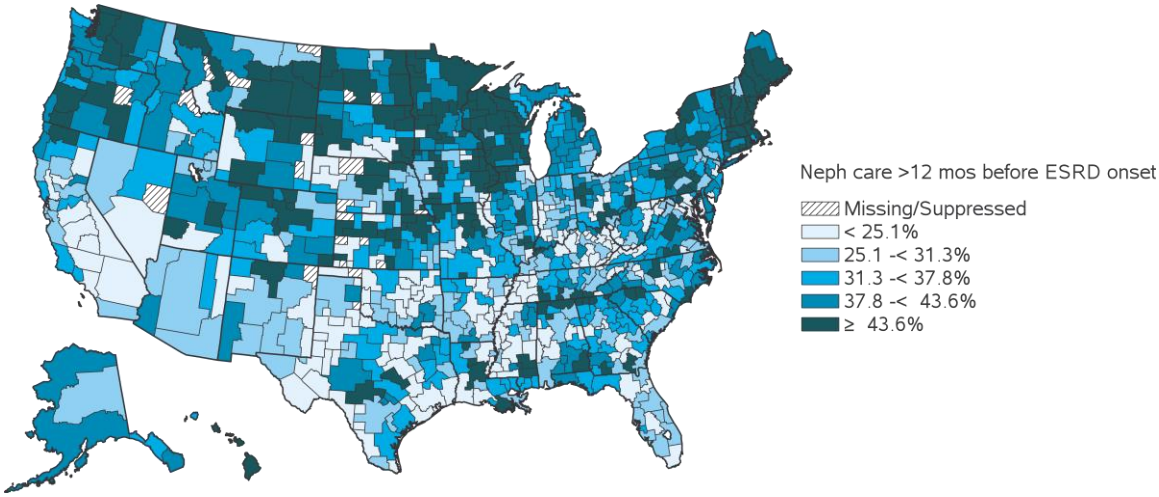
(b) Clinical characteristics (% within row)

		Duration of pre-ESRD nephrology care				
	No. of cases	>12 months	6-12 months	0-6 months	None	Unknown /Missing
Dietary care						
No	111,834	87.1	90.4	87.8	99.7	99.7
Yes	9,364	12.9	9.6	12.2	0.3	0.3
ESA use						
No	105,009	77.3	83.2	82.4	98.1	99.1
Yes	16,189	22.7	16.8	17.6	1.9	0.9
eGFR at RRT start						
<5	17,075	12.1	12.2	12.6	19.8	14.0
5-<10	57,247	50.0	49.2	47.2	43.5	44.0
10-<15	33,138	28.4	28.3	27.9	24.2	27.9
≥15	13,676	9.5	10.2	12.2	12.4	14.0
Vascular access						
AV fistula	17,855	25.4	18.7	10.0	2.3	8.3
AV graft	3,237	3.7	3.5	2.4	1.1	1.9
CV Catheter with maturing fistula/graft	18,879	16.2	17.8	16.3	13.0	14.5
CV Catheter only	66,770	35.6	45.4	59.9	80.1	70.6
Other/Unknown	14,457	19.2	14.6	11.4	3.5	4.8
Total	121,198	100	100	100	100	100

*Data Source: Special analyses, USRDS ESRD Database. Population only includes incident cases with the form CMS 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 2016 with greater than 12 months of pre-ESRD nephrology care varied substantially across 785 HSAs, ranging from a low of 5.5% to a high of 66.2% (interquartile range: 26.0% to 42.0%; Figure 1.18). 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 before ESRD.

vol 2 Figure 1.18 Map of the percentage of incident cases who had received >12 months of pre-ESRD nephrology care, by Health Service Area, 2012-2016

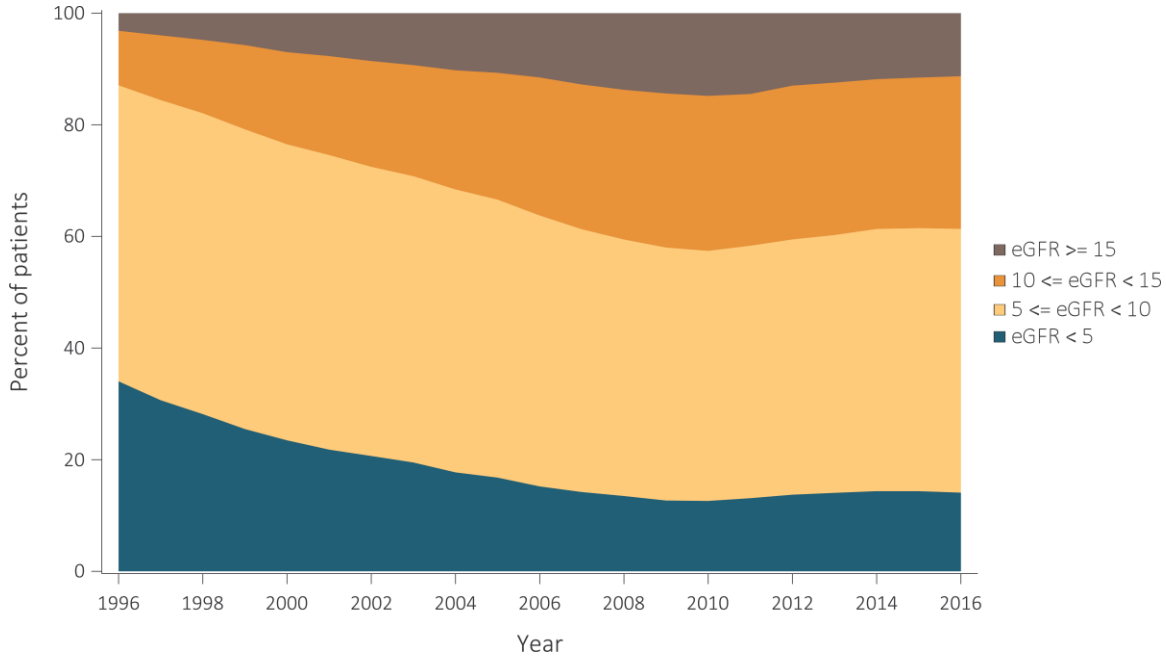


Data Source: Special analyses, USRDS ESRD Database. Population only includes incident cases with the form CMS 2728. Values for cells with 10 or fewer patients are suppressed. Abbreviations: ESRD, end-stage renal disease; mos, months; Neph, nephrology.

eGFR at ESRD Onset

Figure 1.19 shows that the percentage of incident ESRD patients who initiated renal replacement therapy at higher eGFR levels increased steadily from 1996 to 2016. Since 2010, eGFR at the start of dialysis has remained stable or has slightly declined. More specifically, the percentage of incident ESRD cases starting with eGFR at ≥10 ml/min/1.73 m² (the two top bands in the figure) rose from 12.9% in 1996 to 42.6% in 2010, then decreased to 38.6% in 2016. The percentage that started therapy at eGFR <5 ml/min/1.73 m² (the bottom band in the figure) decreased from 34.0% in 1996 to 12.6% in 2010, then increased slightly to 14.1% in 2016. The trend after 2010 could reflect the influence of several publications questioning the advisability of starting dialysis early.

vol 2 Figure 1.19 Trends in the distribution of eGFR (ml/min/1.73 m^2) among incident ESRD patients, 1996-2016



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

Mean eGFR at ESRD start among incident ESRD patients in 2016 was higher in young patients (≤21 years), males, Whites, non-Hispanics, and those with diabetes as their primary cause of ESRD (Table 1.9). Incident ESRD patients with cystic kidney disease listed as the primary cause had higher mean Hgb levels at ESRD onset than did other groups. ESA usage among incident ESRD patients was greater in young patients (≤21 years), females, and Whites.

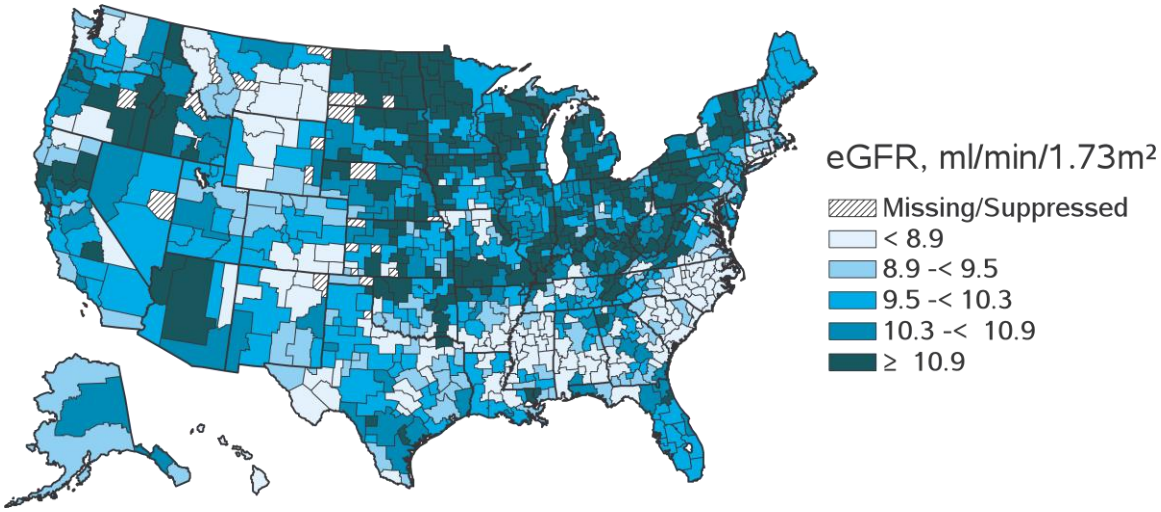
Mean eGFR at ESRD start during 2012-2016 varied substantially by HSA. HSAs with higher mean eGFRs at the initiation of ESRD clustered in the North and Midwest regions, while those with lower mean eGFRs clustered in the South (Figure 1.20).

vol 2 Table 1.9 Distributions of laboratory values (mean) and treatment characteristics (%), by age, sex, race, ethnicity, and the primary cause of ESRD, among incident ESRD cases, 2016

		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)	HbA1c (%)
Age								
0-21	13.4	3.4	40.3	9.7	28.5	176.3	104.3	5.4
22-44	9.4	3.2	7.2	9.2	9.7	170.5	101.3	6.8
45-64	10.0	3.2	7.6	9.3	11.2	160.4	94.7	6.9
65-74	10.2	3.2	7.5	9.3	13.5	148.7	85	6.6
75+	10.3	3.2	6.6	9.4	15.1	141	79.7	6.4
Sex								
Male	10.4	3.2	7.8	9.4	11.7	148.5	87.1	6.7
Female	9.7	3.1	7.4	9.2	14.2	164.9	94.9	6.8
Race								
White	10.3	3.2	7.8	9.5	12.9	152.2	87.9	6.7
Black/African American	9.8	3.2	6.6	9.1	11.5	160.8	96.6	6.7
American Indian/Alaska Native	9.1	2.9	7.8	9.3	9.5	146.6	82.2	6.9
Asian	8.9	3.3	10.1	9.3	18.3	162.5	90.9	6.6
Native Hawaiian/Pacific Islander	8.4	3.1	9.7	9.2	14.5	149.9	88.5	7.0
Ethnicity								
Yes	9.5	3.1	7.6	9.2	12.0	154.1	89	6.8
No	10.2	3.2	7.6	9.4	13.0	155	90.4	6.7
Primary Cause of ESRD								
Diabetes	10.3	3.1	7.2	9.3	13.9	153.9	89.4	7.1
Hypertension	9.5	3.3	6.0	9.3	11.1	152.5	89.1	6.1
Glomerulonephritis	9.2	3.2	11.0	9.4	16.9	173.1	102.4	5.7
Cystic kidney	9.8	3.8	18.0	10.2	16.7	163.5	95.5	5.6
Total	10.1	3.2	7.6	9.3	12.7	154.9	90.2	6.7

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

vol 2 Figure 1.20 Map of mean eGFR at initiation of renal replacement therapy, by Health Service Area, 2012-2016

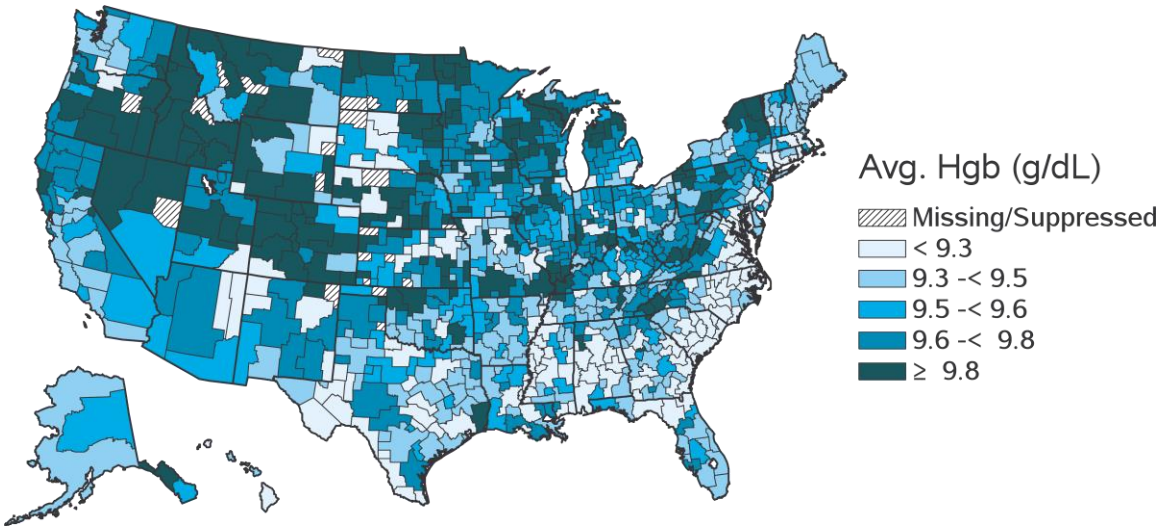


Data Source: Special analyses, USRDS ESRD Database. Population only includes incident cases with the form CMS 2728. eGFR calculated using the CKD-EPI equation (CKD-EPI eGFR (ml/min/1.73 m²)) for those aged ≥18 and the Schwartz equation for those aged <18. Values for cells with 10 or fewer patients are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

Anemia at ESRD Onset

In 2016, the overall mean hemoglobin (Hgb) level at ESRD onset was 9.3g/dL (Table 1.10). Figure 1.21 shows the distribution of mean Hgb levels by HSA across the United States. HSAs with higher average Hgb levels are observed in the Rocky Mountains region and scattered throughout the North.

vol 2 Figure 1.21 Map of mean hemoglobin level at initiation of renal replacement therapy, by Health Service Area, 2012-2016



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

Variation in Treatment Characteristics by ESRD Network

Geographic variation in pre-ESRD care was also evident by ESRD Network (Table 1.10). Most pronounced was more than 2-fold variation in the percentage of incident ESRD patients with pre-ESRD nephrology care of greater than 12 months. Over a period of 12 months in 2016, pre-ESRD nephrology care ranged from a high of 47.8% in Network 1 (CT, MA, ME, NH, RI, and VT) to a low of 22.0% in Network 18 (S. CA). Mean eGFR at ESRD start ranged from a low of 8.9 ml/min/1.73 m^2 in Network 6 (NC, SC, and GA) to a high of 10.5 ml/min/1.73 m^2 in Network 9 (IN, KY, OH) and Network 11 (MI, MN, ND, SD, WI). Mean Hgb at ESRD start ranged from 9.2 in Network 2 (NY), Network 8 (AL, MS, TN), Network 14 (TX), Network 5 (MD, DC, VA, WV), Network 1 (CT, MA, ME, NH, RI, VT) and Network 6 (NC, SC, GA) to 9.6 g/dL in Network 15 (AZ, CO, NV, NM, UT, WY) and Network 16 (AK, ID, MT, OR, WA). At the ESRD Network level, there was little ecologic association between mean eGFR at ESRD initiation and duration of pre-ESRD nephrology care.

vol 2 Table 1.10 Distribution of duration of pre-ESRD nephrology care (in %), mean hemoglobin level, and mean eGFR, by ESRD Network, among incident ESRD cases in the U.S. population, 2016

Network	States in network*	Duration of pre-ESRD nephrology care (row percentages sum to 100)					Mean eGFR (ml/min/1.73 m^2)	Mean hemoglobin
		>12 months	6-12 months	0-6 months	None	Unknown		
18	S. CA	22.0	17.8	17.7	22.2	20.2	10.1	9.4
14	TX	25.6	18.6	13.5	26.6	15.6	9.4	9.2
7	FL	26.2	19.1	13.1	22.5	19.0	10.0	9.3
10	IL	27.1	17.2	13.2	18.4	24.1	10.3	9.3
5	MD, DC, VA, WV	28.8	21.1	14.1	17.9	18.1	9.4	9.2
8	AL, MS, TN	29.2	21.3	12.8	23.7	12.9	9.1	9.2
3	NJ, PR, VI	30.1	19.7	11.1	29.9	9.3	9.5	9.4
13	AR, LA, OK	30.2	18.7	12.8	23.7	14.5	9.6	9.3
17	N. CA, HI, GU, AS, MP	31.6	22.1	15.9	18.7	11.6	9.4	9.4
9	IN, KY, OH	32.2	21.6	11.9	17.3	17.0	10.5	9.4
2	NY	32.5	17.4	11.3	22.0	16.8	9.2	9.2
15	AZ, CO, NV, NM, UT, WY	32.6	19.6	16.1	19.2	12.6	10.2	9.6
6	NC, SC, GA	34.2	19.3	13.4	19.4	13.7	8.9	9.2
12	IA, KS, MO, NE	37.0	19.0	12.4	21.7	9.9	10.4	9.5
4	DE, PA	38.0	19.9	13.8	17.2	11.1	9.9	9.4
11	MI, MN, ND, SD, WI	42.3	17.4	14.1	17.6	8.6	10.5	9.5
16	AK, ID, MT, OR, WA	43.6	18.1	14.9	17.6	5.8	9.7	9.6
1	CT, MA, ME, NH, RI, VT	47.8	20.2	10.6	13.3	8.2	9.1	9.2
	All networks	31.8	19.3	13.6	20.8	14.5	9.7	9.3

*Data Source: Special analyses, USRDS ESRD Database. Population only includes incident cases with the form CMS 2728. 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. 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 (VI), and the Northern Mariana Islands (MP). Northern and Southern California (CA) split into Networks 17 and 18. Abbreviations: CKD-EPI, chronic kidney disease epidemiology calculation; eGFR, estimated glomerular filtration rate; ESRD, end-stage renal disease.*

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Notes

Chapter 2: Clinical Indicators and Preventive Care

Anemia

- In May 2017, the majority (64.5%) of hemodialysis (HD) patients had hemoglobin (Hgb) levels from 10 to <12 g/dL, while 14.5% had Hgb ≥12 g/dL, 14.4% had Hgb from 9 to <10 g/dL, and 6.6% had Hgb <9 g/dL. The mean Hgb was 10.8 g/dL (Figure 2.1.b).
- In May 2017, the majority (56.1%) of peritoneal dialysis (PD) patients had Hgb levels from 10 to <12 g/dL, while 21.4% had Hgb ≥12 g/dL, 15.2% had Hgb from 9 to <10 g/dL, and 7.3% had Hgb <9 g/dL. The mean Hgb was 10.9 g/dL (Figure 2.1.b).
- As of 2016, three different erythropoiesis-stimulating agents (ESAs) were prescribed to dialysis patients in the United States (U.S.). December 2016 claims data indicated monthly use rates among HD patients on dialysis ≥90 days of 34.4% for epoetin (EPO) alfa, 17.9% for darbepoetin, and 24.4% for pegylated EPO (PEG-EPO) beta. 22.0% of HD patients were not using an ESA. Among PD patients, 31.2% were using EPO alfa, 13.0% darbepoetin, and 13.1% PEG-EPO, while 41.7% of PD patients were not using an ESA (Figures 2.2.d and 2.8.d.).
- For U.S. HD patients between 2015 and 2016, a small increase was seen in monthly percent intravenous (IV) iron use (60.0% to 61.8%), whereas mean monthly IV iron dose declined slightly (from 294.1 mg to 291.8 mg; Figure 2.4). Similarly, for PD patients a small increase was also seen in monthly percent IV iron use (25.3% to 26.5%) and decline in mean monthly IV iron dose (from 196.2 mg to 190.9 mg; Figure 2.10).
- Serum ferritin levels increased slightly in all dialysis patients from 2015 to 2017. As of May 2017, 30.4% and 25.5% of HD patients had serum ferritin levels of 801-1200 and >1200 ng/mL. Among PD patients, 22.4% and 17.2% had serum ferritin levels of 801-1200 and >1200 ng/mL (Figures 2.6 and 2.12).

Serum Albumin, Calcium, and Phosphorus

- In May 2017, 18.9% of HD and 44.3% of PD patients were hypoalbuminemic (<3.5 g/dL, Figure 2.1.d).
- In May 2017, 60.5% of HD and 57.5% of PD patients had serum calcium levels within the range of 8.4-9.5 mg/dL. About 1.3% of HD patients and 1.9% of PD patients had serum calcium levels greater than 10.2 mg/dL and 16.9% of HD patients and 23.1% of PD patients had serum calcium levels less than 8.4 mg/dL (Figures 2.14 and 2.15).
- In May 2017, 66.1% of HD patients and 71.6% of PD patients had serum phosphorus levels greater than 4.5 mg/dL (Figures 2.16 and 2.17).

Preventive Care

- In 2016, 83.4% of diabetic end-stage renal disease (ESRD) patients received at least one hemoglobin A1c (HbA1c) test, while 68.9% of patients received at least two HbA1c tests, 69.8% a lipid test, and 46.9% a dilated eye exam. However, only 28.8% of diabetic ESRD patients received comprehensive diabetes monitoring that includes at least two HbA1c tests and one of each of a lipid exam and a diabetic eye exam. This was a decline from 36.4% comprehensive monitoring in 2010, although in 2010, one HbA1c exam was accepted as the clinical standard (Figure 2.18).
- In the 2015-2016 flu season, 71.3% of patients received an influenza vaccination. Although this rate has been stable over the last two years, the percent vaccinated has increased from 59.3% a decade earlier (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.

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. Downloadable Microsoft Excel and PowerPoint files containing the data and graphics for this chapter's figures and tables are available on the *USRDS website*.

See the section addressing *Chapter 2* in the *ESRD Analytical Methods* chapter for an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter. Limits were applied regarding the maximum allowable IV iron and ESA doses shown in this chapter as follows: (1) for erythropoetin alfa (EPO) dose calculations - patients were excluded for a given month if their monthly average EPO dose was either <250 units or >400,000 units per week; there were no darbepoetin or PEG-EPO doses that exceeded the EPO dose maximum after applying conversion factors often used for darbepoetin and PEG-EPO in comparison to EPO; (2) for IV iron dose calculations, analysis was restricted to patients receiving 7 to 18 IV administrations in a month, and in the case of iron sucrose and ferrous gluconate received 50-1800 mg or 12.5-1800 mg, respectively.

Clinical Indicators

In Figure 2.1, we present CROWNWeb data from May 2017 for a selection of clinical indicators relating to dialysis adequacy, achieved Hgb level, serum calcium, and serum albumin. Figure 2.1.a shows that achievement of dialysis adequacy targets for HD was nearly universal, with 97.1% 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 89.1% (Figure 2.1.a). These targets are part of the QIP, and were set based on clinical trial and observational evidence demonstrating associations with mortality.

Views on anemia treatment with ESAs have evolved in recent years towards maintaining hemoglobin levels at lower target ranges than previously, due, in part, to safety concerns that emerged from controlled CKD clinical trials related to anemia correction. In these trials, greater risks of death, serious adverse cardiovascular reactions, and stroke were observed for study participants 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 (*https://www.fda.gov/Drugs/DrugSafety/ucm259639.htm*). In addition, current guidelines do not specify an appropriate lower limit, which likely has also contributed to generally lower Hgb levels among dialysis patients during the past decade. Moreover, a financial disincentive for prescribing higher ESA doses came about in 2011, when CMS implemented the End-Stage Renal Disease Prospective Payment System (PPS), which bundled injectable medications such as ESAs into the payment received by HD facilities for providing dialysis for ESRD patients.

CROWNWeb includes data from both Medicare and non-Medicare insured patients, and thus presents a more representative view of Hgb levels for the

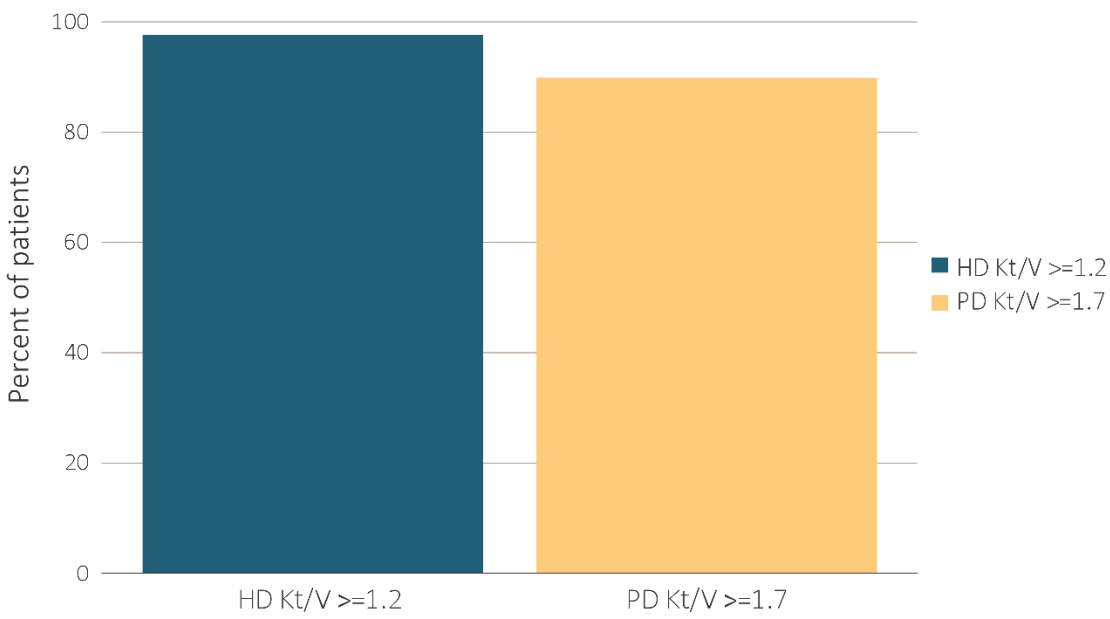
dialysis population than was previously possible through analyses based only upon claims data (Figure 2.1.b). In May 2017, the majority (64.5%) of both ESA-treated and non-ESA treated HD patients had Hgb levels in the range of 10 to 12 g/dL, with 14.5% having Hgb ≥12 g/dL. The pattern was similar with PD patients, though a somewhat higher percentage (21.4%) had Hgb ≥12 g/dL. Later in this chapter, we utilize Medicare claims through 2016 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 2017 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 ESRD QIP. The rationale for this quality measure is to avoid elevated levels of calcium given the associations with vascular calcifications and cardiovascular events. For both modalities, the percent of patients with hypercalcemia has declined compared to May 2016, with 0.7% and 1.0% of HD and PD patients having a 3-month mean serum calcium >10.2 mg/dL as of May 2017. Later in the chapter, we present additional CROWNWeb data on trends in both serum calcium and phosphorus levels, which have also been associated with cardiovascular mortality.

Figure 2.1.d presents CROWNWeb data as of May 2017 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 its strong association with mortality, we include national information on albumin levels. As of May 2017, 18.9% of HD and 44.3% 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 due in part to peritoneal losses of protein during peritoneal dialysis.

vol 2 Figure 2.1 ESRD clinical indicator levels among prevalent hemodialysis and peritoneal dialysis patients in CROWNWeb data, May 2017: (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

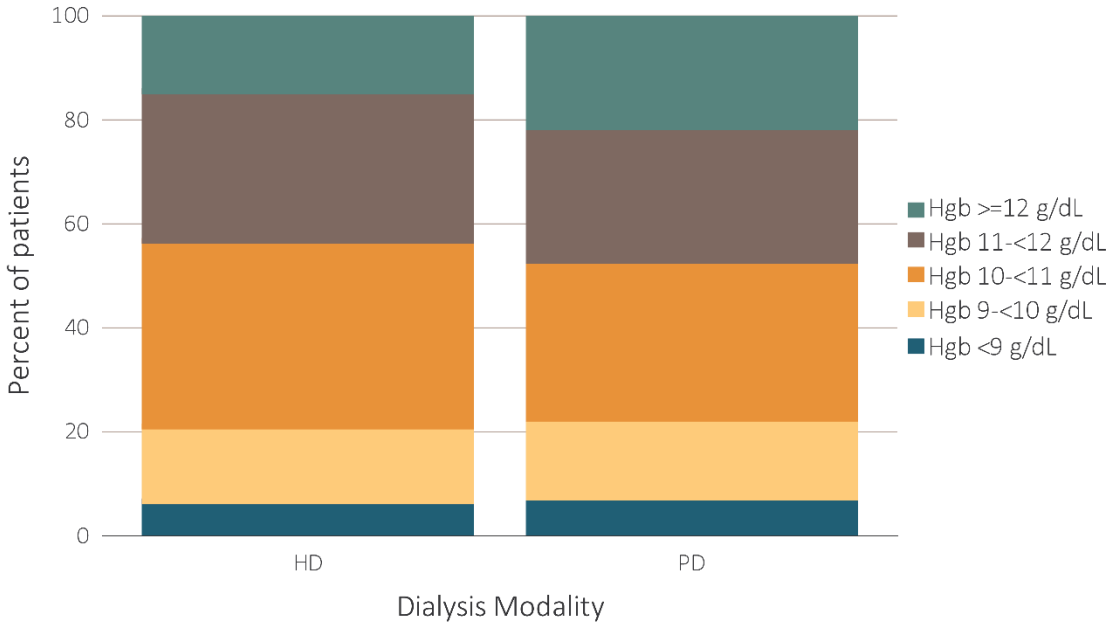
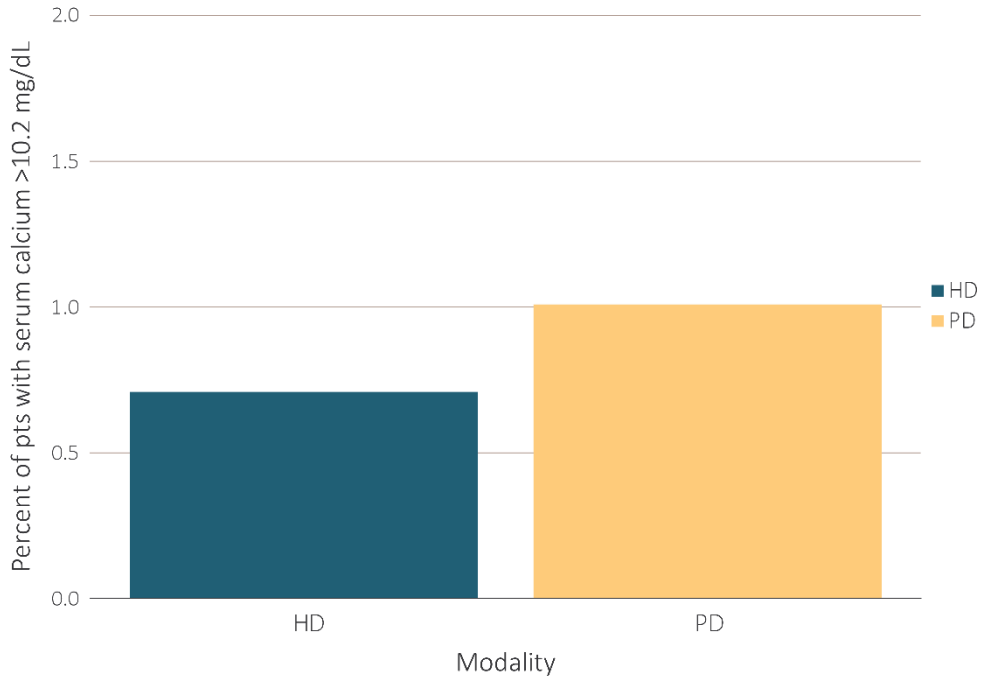


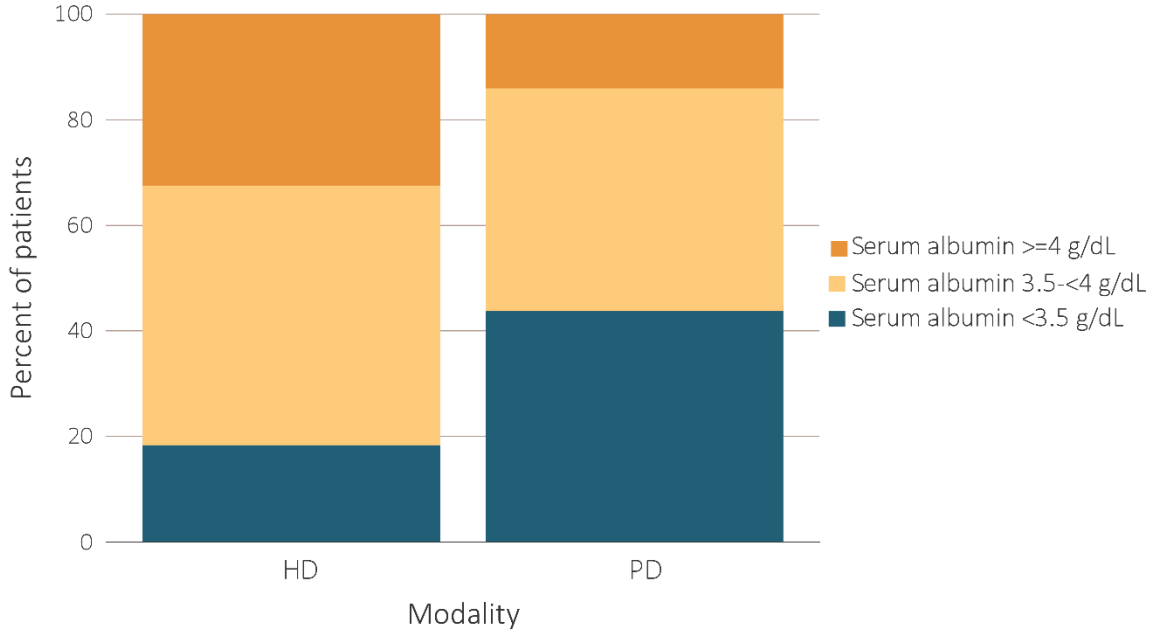
Figure 2.1 continued on next page.

vol 2 Figure 2.1 ESRD clinical indicator levels among prevalent hemodialysis and peritoneal dialysis patients in CROWNWeb data, May 2017: (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 2017, restricted to patients as follows: (a) dialysis patients initiating treatment for ESRD at least 1 year prior to May 1, 2017, and who were alive through May 31, 2017; (b) dialysis patients initiating treatment for ESRD at least 90 days prior to May 1, 2017, who were ≥18 years old as of May 1, 2017, and who were alive through May 31, 2017; (c) hemodialysis and peritoneal dialysis patients initiating treatment for ESRD at least 90 days prior to May 1, 2017, who were ≥18 years old as of May 1, 2017, and who were alive through May 31, 2017; and (d) dialysis patients initiating treatment for ESRD at least 90 days prior to May 1, 2017, who were ≥18 years old as of May 1, 2017, and who were alive through May 31, 2017. 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, type, and dose, IV iron use and dose, levels of iron store markers, and red blood cell transfusion rates. We report analyses of CMS claims data by dialysis modality through 2016. Starting in 2011, a striking practice change is seen in anemia management of U.S. dialysis patients manifested by a large decline in hemoglobin levels, tightly coupled with a substantial decline in ESA use, and administered ESA and IV iron doses. This practice change was largely in response to the January 2011 implementation of the CMS ESRD Prospective Payment System (PPS) - which provided a financial disincentive for administration of injectable drugs - and the FDA's communication in June 2011 recommending more conservative ESA use and dosing (*https://www.fda.gov/Drugs/DrugSafety/ucm259639.htm*). In addition, the types of ESAs available for treating anemia have increased over time, now including agents with substantially longer half-lives compared to the shorter acting epoetin alfa introduced in 1989. In this regard, darbepoetin and pegylated erythropoietin beta (PEG-EPO) use began in 2005 and 2015 in the United States, respectively, with a little more than half of all ESA use now occurring via these two longer acting ESAs in 2016. There are a number of different considerations made by physicians and dialysis units in deciding which ESA type to prescribe for their patients, and doses of ESAs and IV iron to prescribe (e.g., most appropriate drug for a particular patient based upon a variety of patient-level considerations, financial costs, how drug administration relates to staffing time/expertise and how it is distributed and applied during dialysis shifts, etc.).

Changes in availability of certain types of anemia management-related data have occurred over time. Monthly mean IV iron doses are provided starting in 2005. 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 has allowed for comparisons of Hgb values for ESA-treated patients, non-ESA treated patients, and all patients combined starting in April 2012.

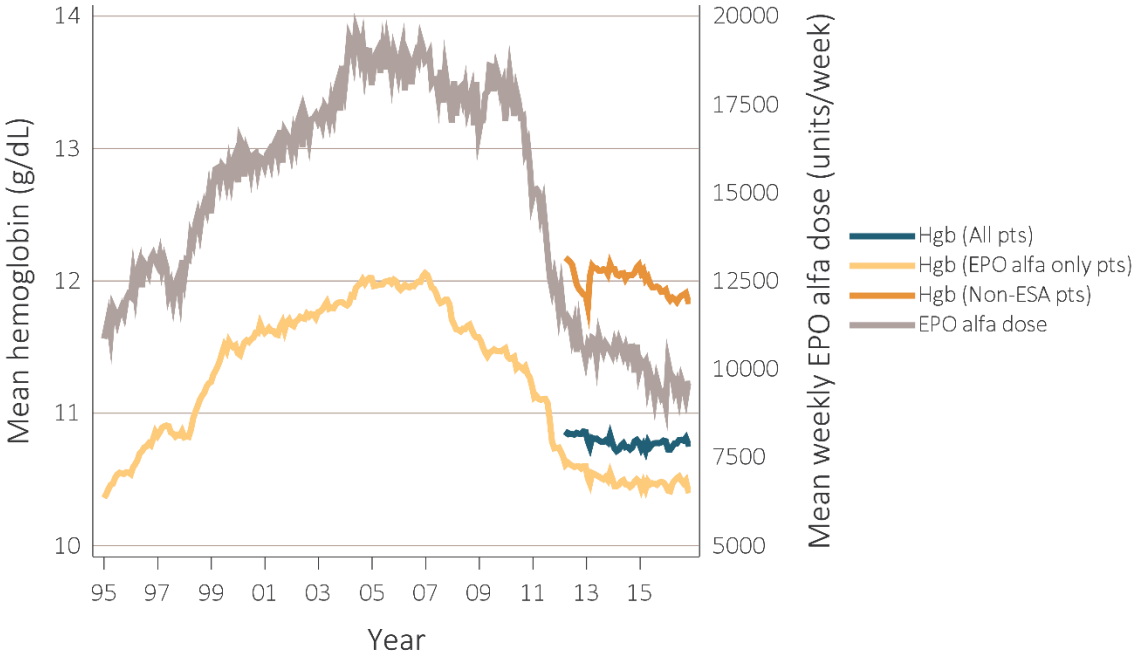
Hgb Levels, ESA Use and Dose by ESA type, in Hemodialysis Patients

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 levels 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 10.4 g/dL in 2016. Mean monthly Hgb values in 2016 were 10.8 g/dL for all HD patients on dialysis ≥90 days and 11.9 g/dL for non-ESA treated patients. In 2016, mean monthly Hgb levels were quite similar across the types of ESA used, with mean Hgb levels of 10.4, 10.4 and 10.5 g/dL seen for patients prescribed EPO alfa, darbepoetin, and PEG-EPO, respectively, in December 2016.

In 2016, 78%-80% 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 5.0% 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. In 2016, the shift away from EPO alfa slowed a bit. The percentages became 34.4%, 17.9%, and 24.4% for EPO alfa, darbepoetin, and PEG-EPO, respectively, in 2016. Between December 2007 and December 2016, mean weekly EPO alfa doses (averaged over a month) declined by more than 50% in HD patients to 9616.1 units/week by December 2016. The mean monthly darbepoetin and PEG-EPO doses that were prescribed in December 2016 were 149.4 mcg/month and 158.3 mcg/month, respectively. The mean weekly EPO alfa dose (averaged monthly) declined slightly from 2015 to 2016.

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 monthly ESA use, Medicare claims, 1995-2016

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



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

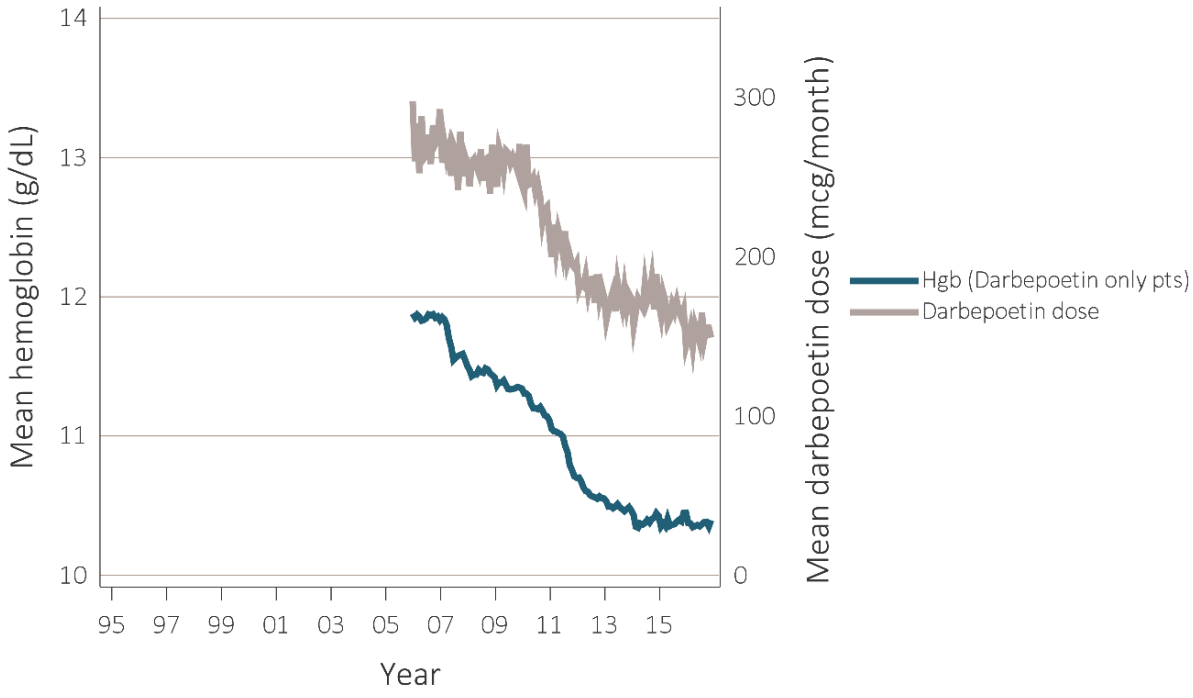
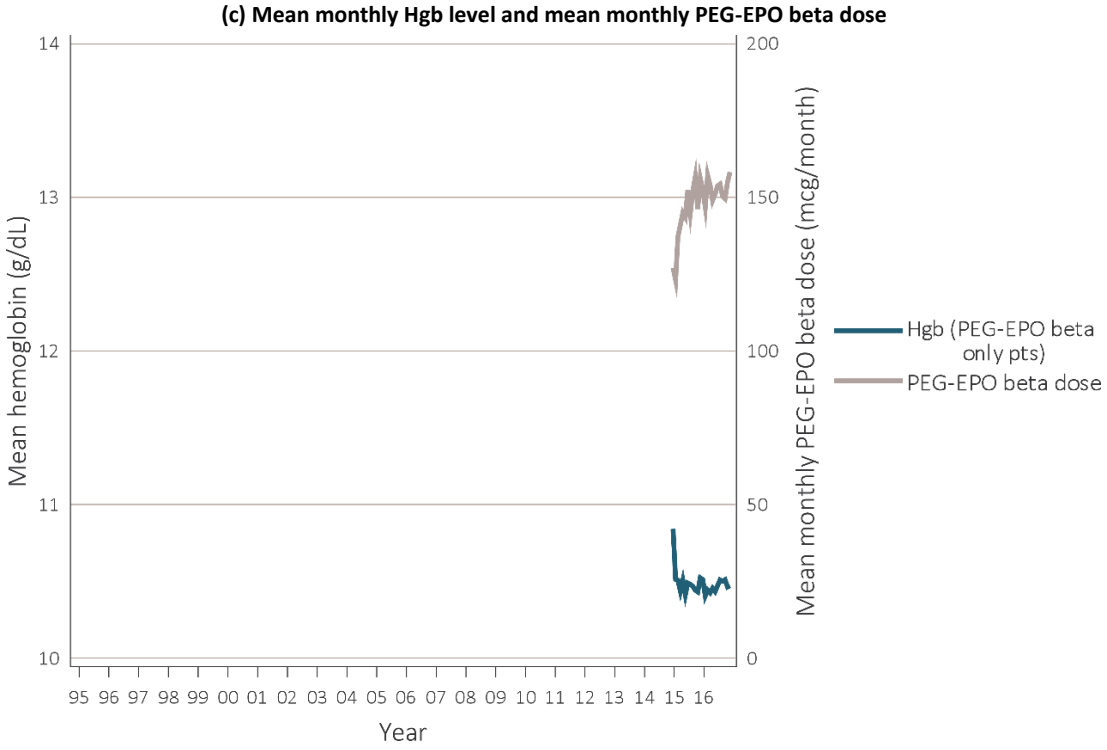
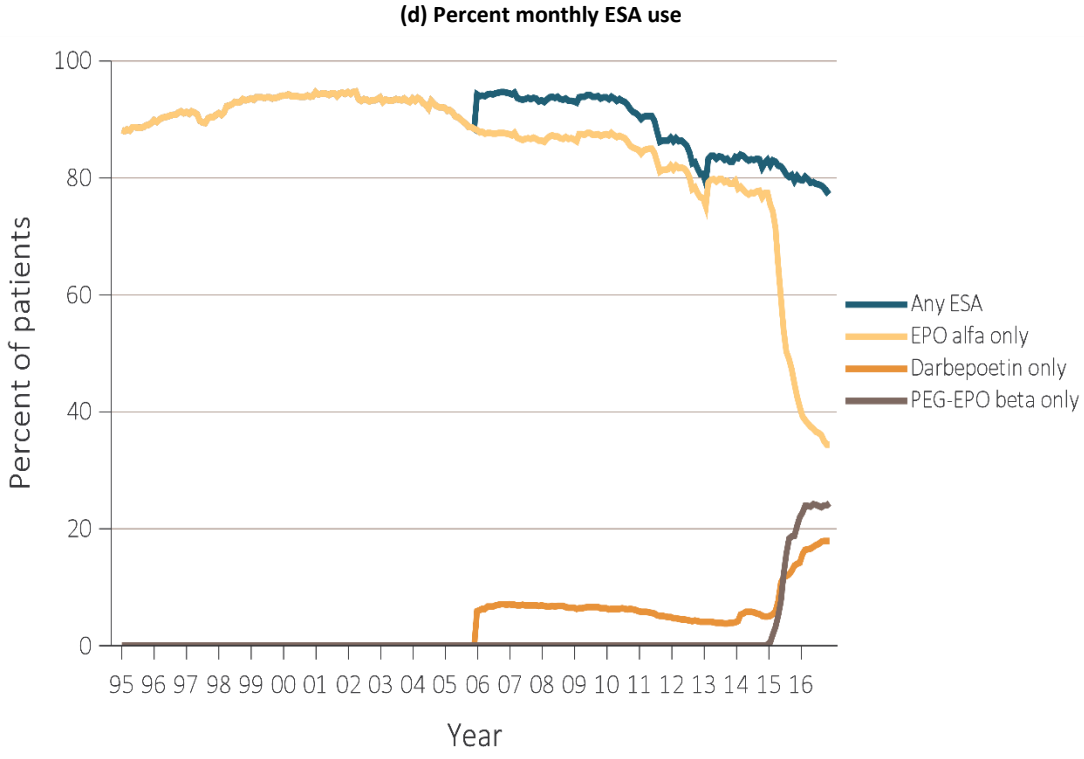


Figure 2.2 continued on next page.

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 monthly ESA use, Medicare claims, 1995-2016 (continued)

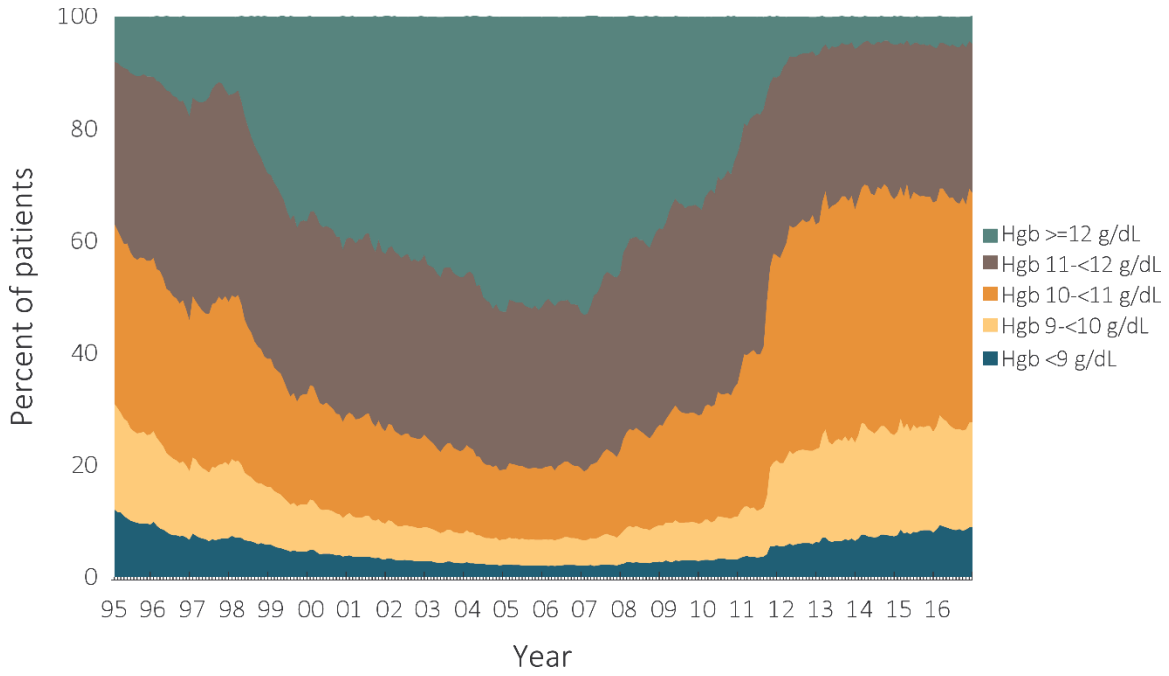




Data Source: Special analyses, USRDS ESRD Database. Mean monthly Hgb level among (a)EPO alfa (b) darbepoetin (c) PEG-EPO beta patients on dialysis ≥ 90 days (1995-2016) or (a) mean monthly Hgb level among all adult hemodialysis patients (April 2012 to December 2016 only) who, within the given month had a Hgb claim (only 1st reported Hgb values 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 within 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; ESRD, end-stage renal disease; PEG-EPO beta, pegylated erythropoetin beta; ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

Between 2007 and 2016, a large shift occurred in the percentage of ESA-treated adult HD patients who had the highest versus lowest levels of Hgb (Figure 2.3). Among ESA-treated patients on dialysis ≥90 days, the percentage with Hgb between 9 to 10 g/dL increased from 5.0% in 2007 to 18.5% in 2016, while the percentage with Hgb ≥12 g/dL declined nearly 10-fold from 48.5% in 2007 to 5.1% in 2016. For the group of all HD patients on dialysis ≥90 days in December 2016, 8.9% had Hgb <9 g/dL, 18.7% had Hgb of 9 to <10 g/dL, 40.9% had Hgb between 10-<11 g/dL, 26.6% had Hgb between 11-<12 g/dL, and 5.0% 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, 1995-2016

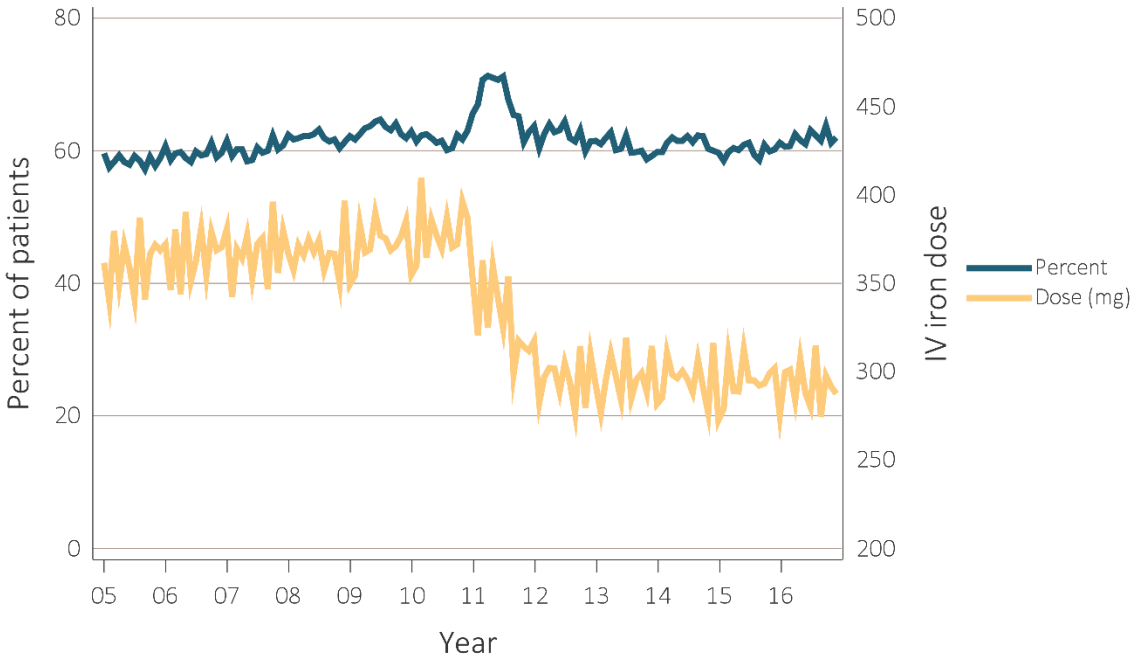


Data Source: Special analyses, USRDS ESRD Database. Distribution of monthly Hgb levels among hemodialysis patients within a given month who had claims for Hgb level and ESA use, were on dialysis ≥90 days and ≥18 years old at the start of the month. Abbreviations: ESRD, end-stage renal disease; ESA, erythropoiesis-stimulating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

Intravenous (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 2016 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 62% by December 2016, similar to rates prior to the start of the bundled PPS in 2011. 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, and since have gradually declined further to 292 mg in 2016. Thus, since 2011, both IV iron use and the average monthly IV iron dose have declined among HD patients in the United States.

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, 2005-2016

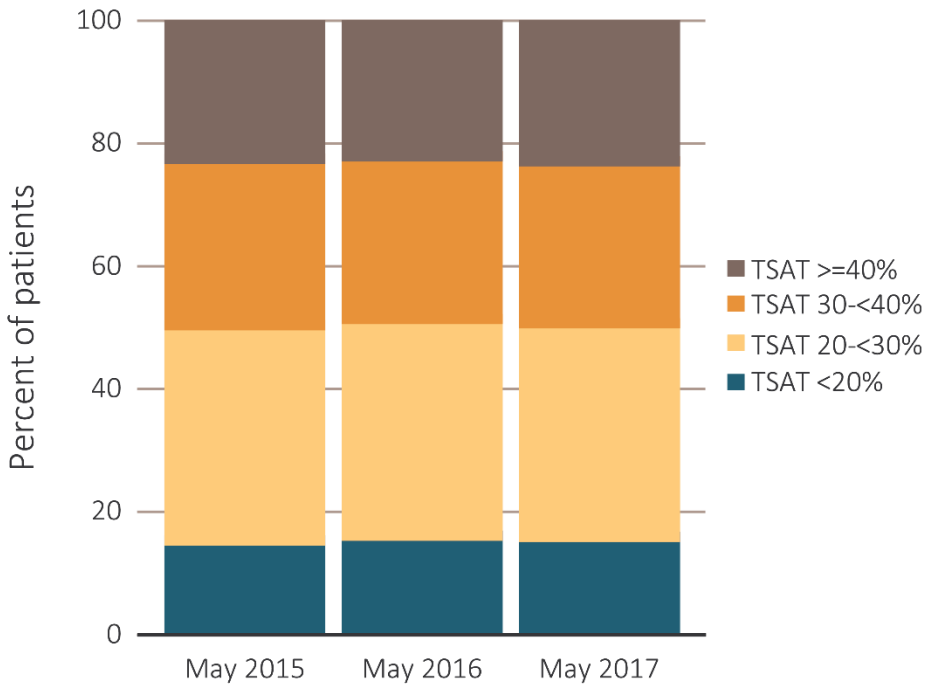


Data Source: Special analyses, USRDS ESRD Database. Monthly IV iron use is among hemodialysis patients on dialysis ≥90 days and ≥18 years old at the start of the given month. Mean IV iron dose was calculated as the average number of mg of IV iron given to all such patients during a month, among patients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

U.S. dialysis units now report iron store measures, transferrin saturation (TSAT), and serum ferritin as part of CROWNWeb data collection. Reporting of these measures to CROWNWeb has increased over time.

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 2015-2017. Averaged across this period, 15.8% of patients had a TSAT <20%, with 35.1%, 26.7%, and 22.5% 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 15.3% to 15.9% from May 2015-2017, and is seen to be modestly lower with increasing age and higher among Whites compared to other HD patients in 2017 (Table 2.1). During 2015-2017, on average 4.9% of patients had serum ferritin ≤200 ng/mL, with 16.0%, 24.8%, 31.0%, and 23.3% of patients having serum ferritin levels of 201-500, 501-800, 801-1200, and >1200 ng/mL. In 2017, serum ferritin levels were markedly higher among patients of older age with a nearly 2-fold higher prevalence of ferritin >1200 ng/mL among patients ≥75 years old (29.2%) versus patients 0-21 years old (14.7%). Furthermore, 2017 serum ferritin levels were modestly higher among females compared to males, whereas patients with cystic kidney disease as the primary cause of ESRD had somewhat lower serum ferritin level (Table 2.2).

vol 2 Figure 2.5 Distribution of TSAT levels in adult hemodialysis patients on dialysis for at least 90 days, CROWNWeb data, May 2015, 2016, and 2017



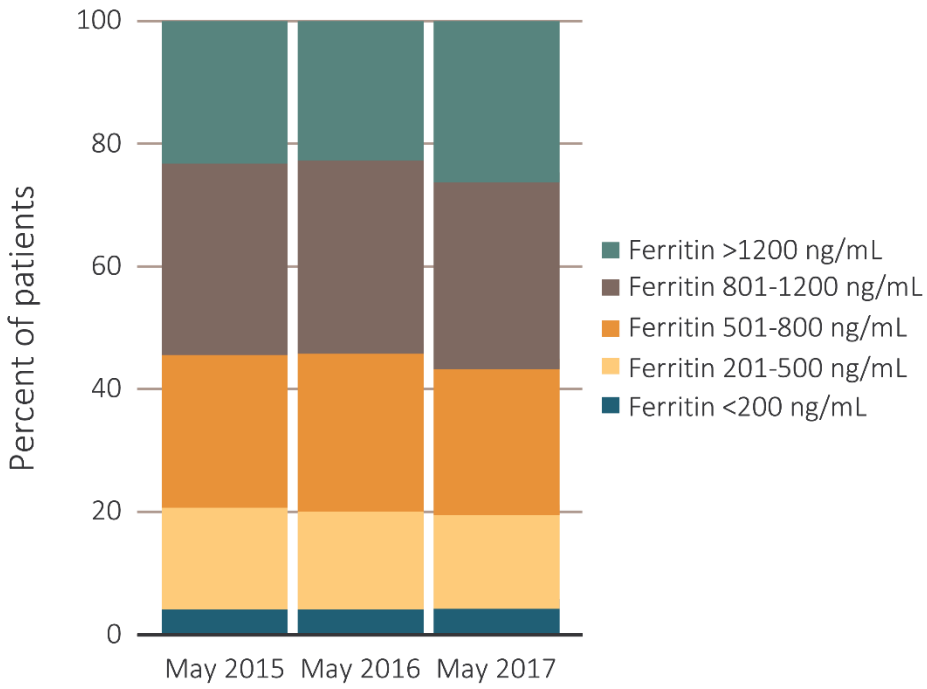
Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2015, 2016, and 2017. Dialysis patients on treatment for ESRD at least 90 days before the time of measurement of TSAT level for that year, ≥18 years old as of May 1 of that year and who were alive through May 31 of that year. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease; TSAT, transferrin saturation.

vol 2 Table 2.1 TSAT by age, sex, race, and primary ESRD cause in hemodialysis patients, May 2017

	N	TSAT <20%	TSAT 20-<30%	TSAT 30-<40%	TSAT≥40%
Overall	**441,443**	**15.9%**	**34.8%**	**26.4%**	**22.8%**
Age					
0-21	1,043	21.5	25.2	23.3	30.0
22-44	50,498	16.8	34.5	25.4	23.4
45-64	183,368	16.1	35.2	26.2	22.4
65-74	114,918	15.5	34.6	27.1	22.8
75+	91,616	15.3	34.7	26.7	23.4
Sex					
Male	252,263	15.8	34.6	27.1	22.5
Female	189,163	16.0	35.1	25.6	23.3
Race					
White	250,955	16.3	34.4	26.4	22.8
Black/African American	159,310	15.3	35.7	26.6	22.4
American Indian or Alaska Native	5,379	15.7	33.5	26.0	24.9
Asian	17,991	14.6	33.5	26.2	25.8
Primary cause of ESRD					
Diabetes	206,682	15.9	35.5	26.5	22.0
Hypertension	130,743	15.5	34.5	26.6	23.4
Glomerulonephritis	45,037	16.0	33.9	26.3	23.8
Cystic Kidney	11,161	17.3	35.7	26.9	20.1
Other/Unknown	45,199	16.1	33.3	25.7	24.9

Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March through May of 2017. 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, 2017 and who were alive through May 31, 2017. Table includes row percentages within demographic categories from May 2017. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease; TSAT, transferrin saturation.

vol 2 Figure 2.6 Distribution of the most recent serum ferritin level taken between March and May in adult hemodialysis patients on dialysis for at least 90 days, CROWNWeb data, May 2015, 2016, and 2017



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2015, 2016, and 2017. 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. Figure includes row percentages within demographic categories from May 2017. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease.

vol 2 Table 2.2 Serum ferritin by age, sex, race, and primary ESRD cause in hemodialysis patients, May 2017

	N	Ferritin <200 ng/mL	Ferritin 201-500 ng/mL	Ferritin 501-800 ng/mL	Ferritin 801-1200 ng/mL	Ferritin >1200 ng/mL
Overall	**436,264**	**5.0%**	**15.3%**	**23.8%**	**30.4%**	**25.5%**
Age						
0-21	1,033	9.2	29.3	24.3	22.5	14.7
22-44	49,927	6.8	18.9	24.7	28.0	21.5
45-64	181,274	5.7	16.3	24.2	29.8	24.2
65-74	113,489	4.3	14.3	23.4	31.2	26.7
75+	90,541	3.3	12.7	22.9	31.9	29.2
Sex						
Male	249,218	5.9	16.9	24.6	29.6	23.0
Female	187,029	3.8	13.3	22.7	31.4	28.9
Race						
White	247,758	5.3	16.3	24.6	30.3	23.5
Black/African American	157,733	4.6	14.0	22.3	30.2	28.9
American Indian or Alaska Native	5,363	5.9	17.5	25.8	29.6	21.2
Asian	17,813	3.6	13.4	25.3	31.8	25.9
Primary cause of ESRD						
Diabetes	203,988	4.4	15.6	24.5	30.8	24.7
Hypertension	129,318	4.7	14.7	23.1	30.5	27.0
Glomerulonephritis	44,653	5.9	14.9	23.1	29.6	26.5
Cystic Kidney	11,092	12.5	18.4	22.0	27.5	19.6
Other/Unknown	44,641	5.3	15.6	23.7	29.6	25.9

Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May 2017. 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, 2017, and who were alive through May 31, 2017. Table includes row percentages within demographic categories from May 2017. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease.

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 2012 through 2016, is shown in Figure 2.7.a. The results represent the 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. The frequency of red blood cell transfusions decreased during 2012 to 2016.

In 2012, 23.9% of HD patients received ≥1 red blood cell transfusions. This decreased to 21.3% of patients in 2014 and further to 16.6% in 2016. Across this five-year period, typically 10.3%-13.8% of patients received one red blood cell transfusion per year, 3.4%-5.4% received two, 1.3%-2.1% received three, and 1.6%-2.6% received four or more red blood cell transfusions per year.

Trends from 2011-2016 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 3.3% in the first quarter of 2014 to 2.4% by the third quarter of 2016. 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 2016, an average of 2.3% of White patients had one or more red blood cell transfusions in a month compared to 1.6% of African American/Black patients and 2.5% of those of Other or Unknown race. Note that since these differences were small, only the overall trend 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 claim 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 HD session, 2012-2016

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

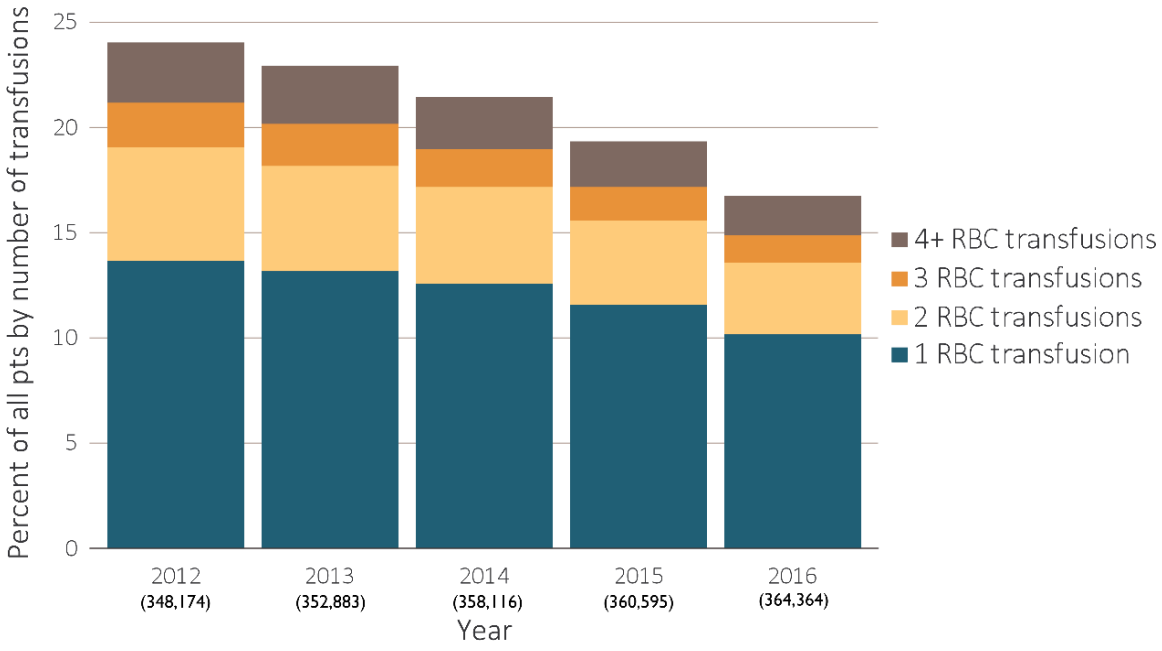
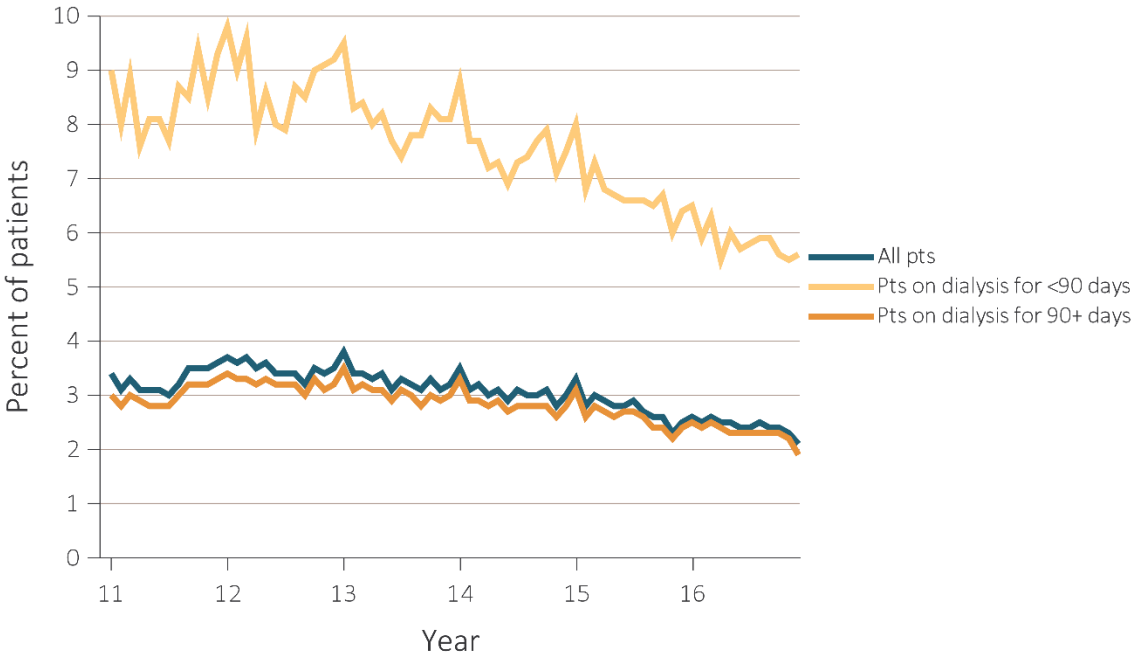


Figure 2.7 continued on next page.

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 claim 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 HD session, 2012-2016 (continued)

(b) Percent of all 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. (a) The percent of hemodialysis patients ≥18 years with total number of red blood cell transfusion claims in a given year among dialysis patients having a claim for at least one hemodialysis session during the year. (b) 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. Abbreviations: ESRD, end-stage renal disease; RBC, red blood cell; Pts, patients.

Hemoglobin (Hgb) Levels, and ESA Use and Dose, by ESA type, in Peritoneal Dialysis Patients

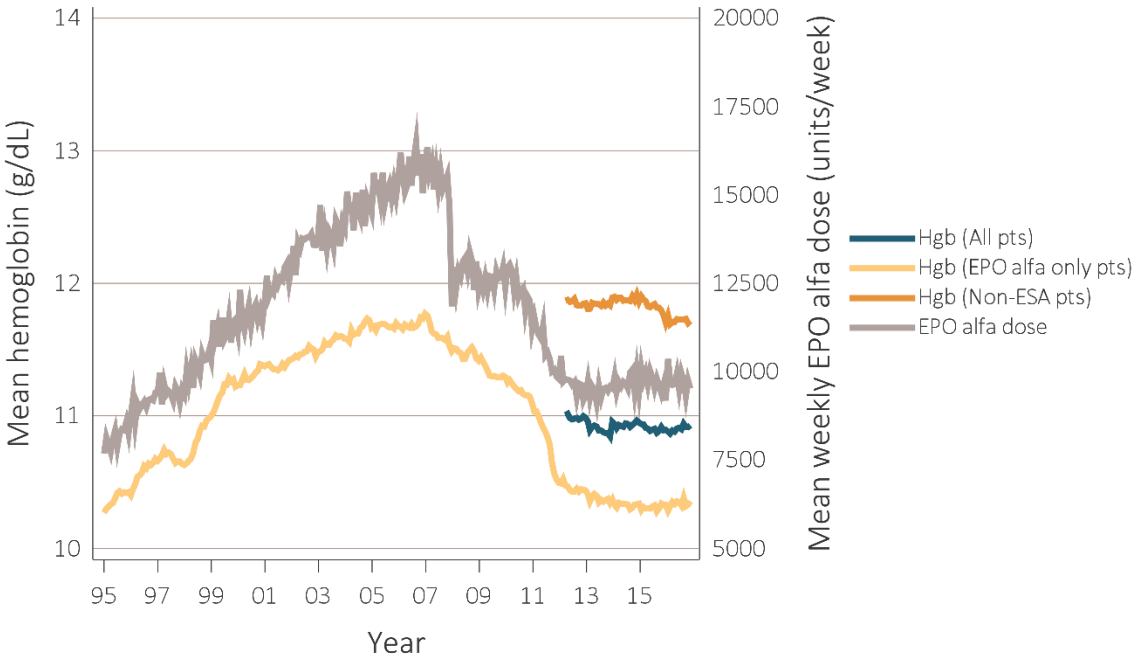
Claims data indicate that mean Hgb levels have declined substantially in ESA-treated PD patients since peaking near 11.8 g/dL in January 2007 (Figure 2.8.a). During 2011, patients' mean Hgb levels declined by 0.6 g/dL, from 11.1 g/dL to 10.5 g/dL. This was a larger decline, with a lower achieved mean Hgb level than that seen among ESA-treated hemodialysis patients overall during 2011. Since then, levels have continued to decline to a mean monthly Hgb of 10.3 g/dL in 2016 among ESA-treated PD patients on dialysis ≥90 days. In contrast, in 2016, mean monthly Hgb values of 10.9 g/dL were seen for all PD patients on dialysis ≥90 days, and 11.7 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 2016, at 58%-60% of patients (Figure 2.8.d). From December 2014 to December 2016, there was a large shift in the type of ESA prescribed to PD patients, with 57.1% and 4.5% prescribed EPO-alfa and darbepoetin in December 2014, compared to 31.2%, 13.02%, and 13.1% prescribed EPO alfa, darbeopoetin, and PEG-EPO beta in December 2016.

Among PD patients on dialysis ≥90 days in December 2016, the mean weekly EPO alfa dose was 9525.9 units/week, which was similar to that prescribed in 2014 and 2015. For the other two ESA types, the mean monthly darbepoetin and PEG-EPO doses that were prescribed in December 2016 were 152.6 mcg/month and 152.2 mcg/month, respectively. 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, (c) mean monthly Hgb level and mean monthly PED-EPO beta dose, and (d) percent monthly ESA use, Medicare claims, 1995-2016

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



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

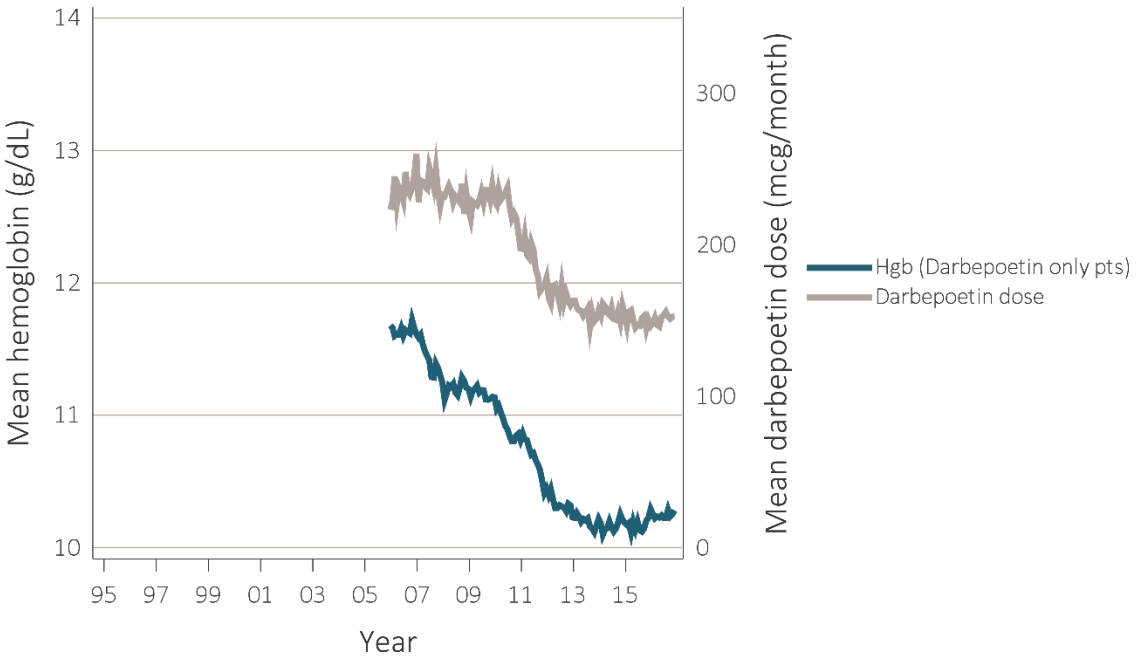


Figure 2.8 continued on next page.

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, (c) mean monthly Hgb level and mean monthly PED-EPO beta dose, and (d) percent monthly ESA use, Medicare claims, 1995-2016 (continued)

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

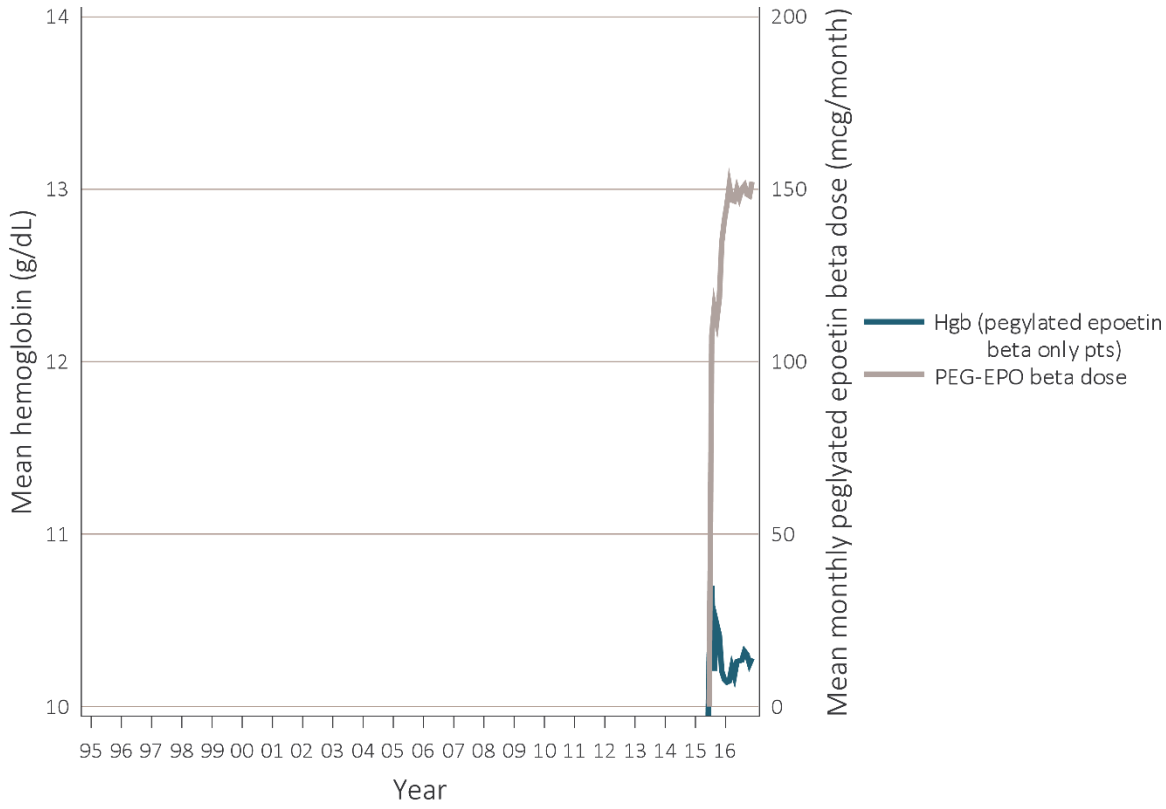
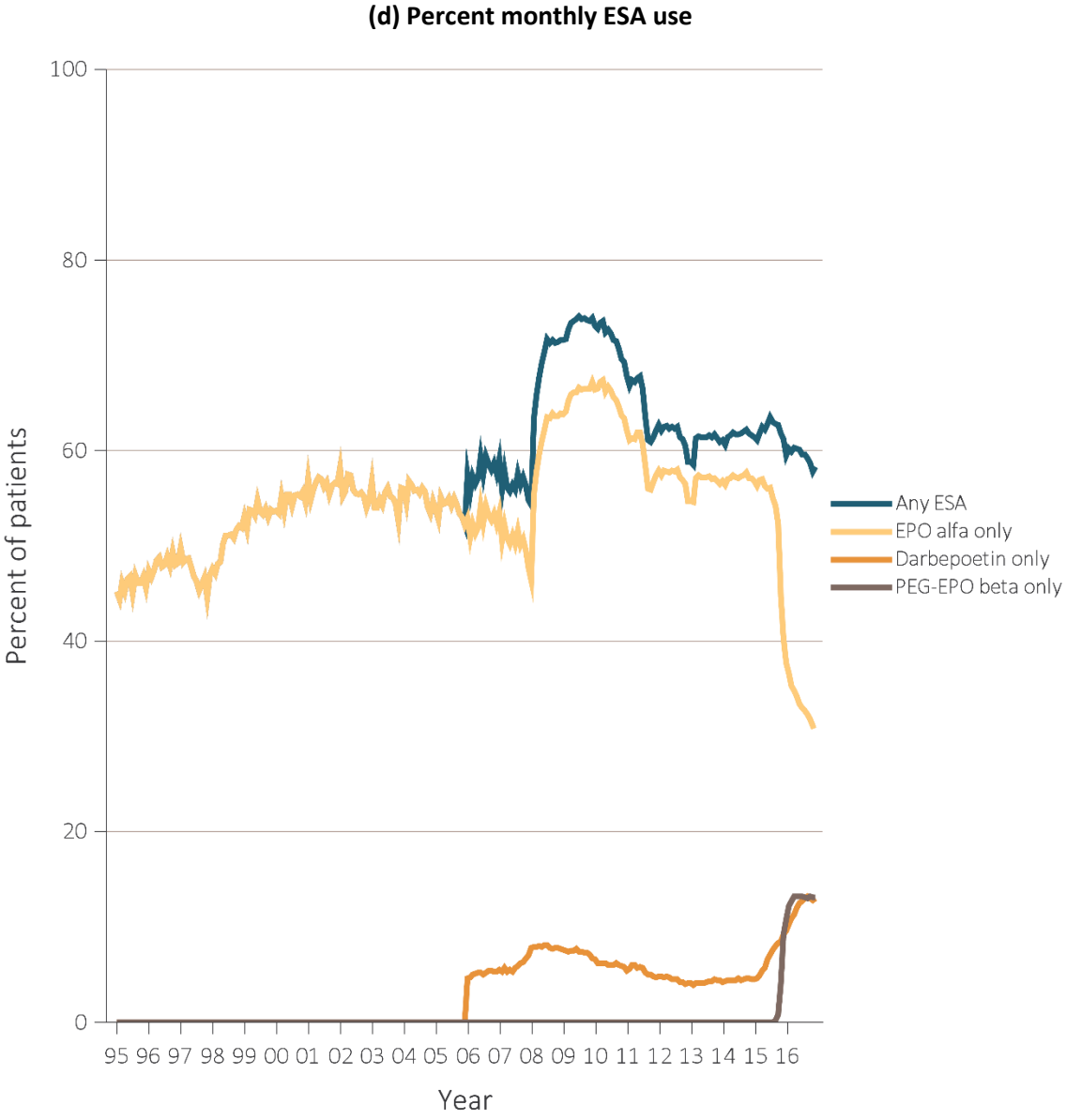


Figure 2.8 continued on next page.

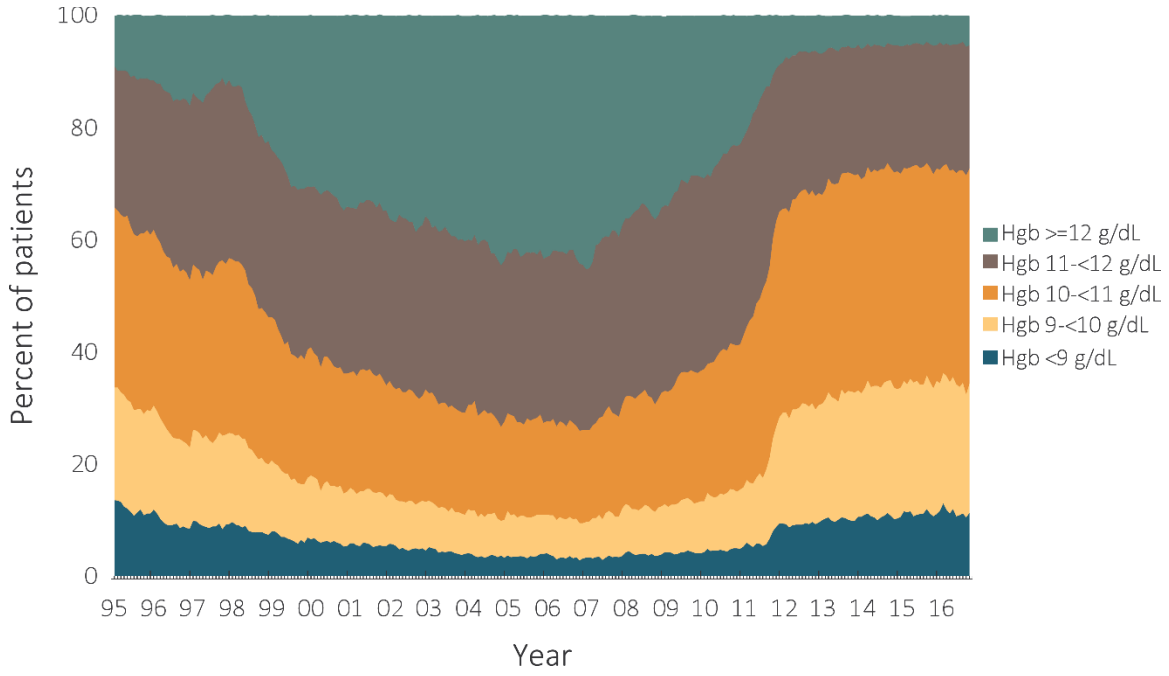
vol 2 Figure 2.8 Anemia measures among adult peritoneal dialysis patients on dialysis ≥90 days: (a) mean monthly Hgb level and mean weekly EPO alfa dose (averaged over a month), (b) mean monthly Hgb and mean monthly darbepoetin dose, (c) mean monthly Hgb level and mean monthly PED-EPO beta dose, and (d) percent monthly ESA use, Medicare claims, 1995-2016 (continued)



Data Source: Special analyses, USRDS ESRD Database. Mean monthly Hgb level among (a) EPO alfa-, (b) darbepoetin, (c)PEG-EPO beta on dialysis ≥ 90 days (1995-2016) or (a) mean monthly Hgb level among all adult peritoneal dialysis patients (April 2012 to December 2016 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 2.8.a) or monthly (darbepoetin, Figure 2.8.b & PEG-EPO beta, Figure 2.8.C) 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 and PEG-EPO beta doses 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 (EPO alfa, Darbepoetin, or PEG-EPO beta) in all peritoneal dialysis patients who were ≥ 18 years and on dialysis ≥ 90 days. Abbreviations: EPO alfa, erythropoietin alfa; ESRD, end-stage renal disease; PEG-EPO beta, pegylated erythropoetin beta; ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

Between 2007 and 2014, a large shift occurred in the percentage of PD patients in the highest versus lowest Hgb concentration categories, but has remained relatively stable from 2014-2016 (Figure 2.9). Among ESA-treated adult patients on PD ≥90 days, the percentage with Hgb between 9 and 10 g/dL increased from 7.4% in 2007 to 23.1% in 2016, while the percentage with Hgb ≥12 g/dL declined from 37.5% in December 2007 to 5.5% in December 2016. Among all PD patients on dialysis ≥90 days in December 2016, 10.8% had Hgb <9 g/dL, 22.3% had Hgb of 9 to <10 g/dL, 38.6% had Hgb between 10-<11 g/dL, 22.9% had Hgb between 11-<12 g/dL, and 5.5% 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, 1995-2016

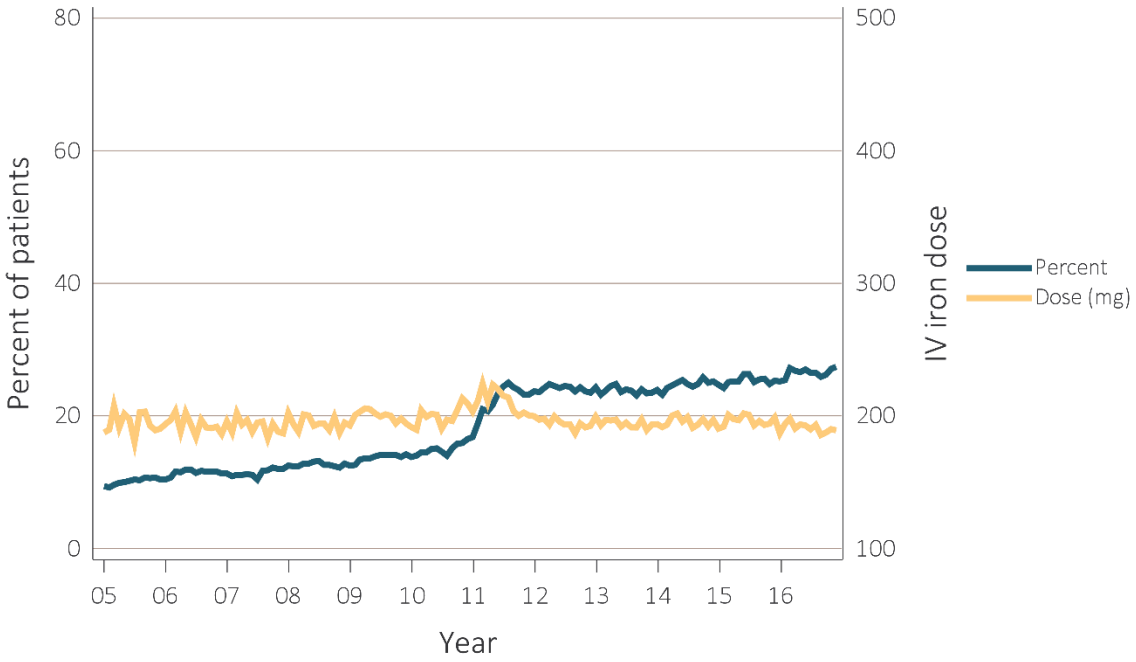


Data Source: Special analyses, USRDS ESRD Database. Distribution of Hgb levels among peritoneal dialysis patients within a given month who had claims for Hgb level and ESA use, were on dialysis ≥90 days and ≥18 years old at the start of the month. Abbreviations: ESA, erythropoiesis-stimulating agents;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

Intravenous (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 2016 (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 2016, IV iron use among PD patients on dialysis ≥90 days remained higher, at 26.9%. 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 from 195 mg in 2012 to 191 mg in 2016. Thus, since 2011, IV iron use in the United States has increased slightly among PD patients, while the average monthly IV iron dose has declined among PD patients prescribed IV iron.

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, 2005-2016

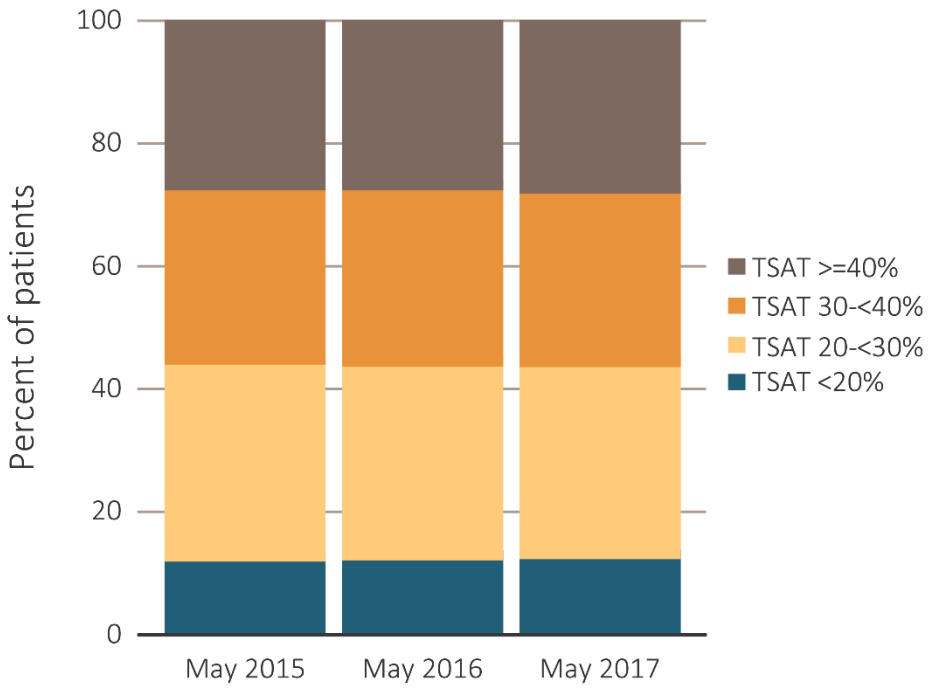


Data Source: Special analyses, USRDS ESRD Database. Monthly IV iron use is among peritoneal dialysis patients on dialysis ≥90 days and ≥18 years old at the start of the given month. Mean IV iron dose was calculated as the average number of mg of IV iron given to all such patients during a month, among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

As mentioned previously, reporting of iron store measures, transferrin saturation (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 38,940 PD patients in 2015 versus 46,583 PD patients in 2017. TSAT was reported for 39,957 PD patients in 2015 compared to 47,539 PD patients in 2017.

Across the three mid-year cross-sections shown in Figures 2.11 and 2.12, the distribution of TSAT levels among PD patients on dialysis ≥90 days did not differ appreciably, whereas a gradual shift to somewhat higher serum ferritin levels has been seen from May 2015 to May 2017. Averaged across the three years, 12.9% of patients had a TSAT<20%, with 31.7%, 28.5%, and 27.0% of patients having levels of 20% to <30%, 30% to <40%, and ≥40%. No distinctive differences were seen in 2017 TSAT levels across most of the patient characteristics displayed in Table 2.3, except with a slightly greater prevalence of high TSAT levels (≥40%) seen for patients of ages <45 years compared to older aged patients. Across the 2015-2017 period, on average, 13.1% of patients had a serum ferritin ≤200 ng/mL, with 25.5%, 23.3%, 22.5%, and 15.7% of patients having levels of 201-500, 501-800, 801-1200, and >1200 ng/mL. Similar to HD patients, 2017 serum ferritin levels were higher among PD patients of older age and among females compared to males, whereas patients with cystic kidney disease as the primary cause of ESRD had somewhat lower serum ferritin levels (Table 2.4).

vol 2 Figure 2.11 Distribution of TSAT levels in adult peritoneal dialysis patients on dialysis for at least 90 days, CROWNWeb data, May 2015, 2016, and 2017



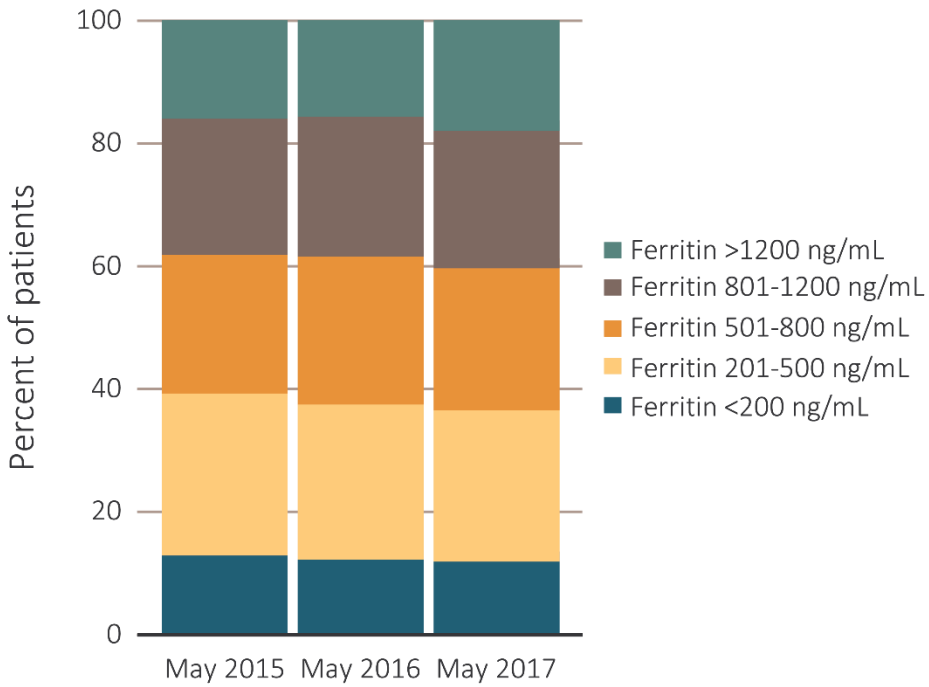
Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2015, 2016, and 2017. Dialysis patients on treatment for ESRD at least 90 days before the time of measurement of TSAT level for that year, ≥18 years old as of May 1 of that year and who were alive through May 31 of that year. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease; TSAT, transferrin saturation.

vol 2 Table 2.3 TSAT by age, sex, race, and primary ESRD cause in peritoneal dialysis patients, May 2017

	N	TSAT <20%	TSAT 20-<30%	TSAT 30-<40%	TSAT≥40%
Overall	**47,539**	**13.1%**	**31.3%**	**28.3%**	**27.3%**
Age					
0-21	300	12.3	24.3	25.0	38.3
22-44	8,659	12.7	29.5	26.2	31.6
45-64	21,217	13.4	32.1	28.1	26.5
65-74	11,020	13.2	31.6	29.6	25.6
75+	6,343	12.7	30.5	29.9	26.9
Sex					
Male	26,512	13.0	31.8	28.6	26.6
Female	21,027	13.3	30.6	28.0	28.2
Race					
White	31,623	13.5	31.6	28.4	26.5
Black/African American	11,611	12.4	31.3	28.5	27.9
American Indian or Alaska Native	438	15.5	30.6	28.1	25.8
Asian	3,044	11.3	28.5	26.9	33.3
Primary cause of ESRD					
Diabetes	18,107	13.4	32.6	29.0	25.0
Hypertension	13,487	12.6	30.2	29.1	28.0
Glomerulonephritis	8,338	13.2	30.3	26.4	30.1
Cystic Kidney	2,366	13.7	34.1	28.8	23.4
Other/Unknown	4,959	13.1	29.4	26.7	30.8

Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March through May of 2017. 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, 2017 and who were alive through May 31, 2017. Table includes row percentages within demographic categories from May 2017. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease; 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 2015, 2016, and 2017



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2015, 2016, and 2017. 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. Figure includes row percentages within demographic categories from May 2017. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease.

vol 2 Table 2.4 Serum ferritin by age, sex, race, and primary ESRD cause in peritoneal dialysis patients, May 2017

	N	Ferritin <200 ng/mL	Ferritin 201-500 ng/mL	Ferritin 501-800 ng/mL	Ferritin 801-1200 ng/mL	Ferritin >1200 ng/mL
Overall	**46,583**	**12.7**	**24.7**	**23.1**	**22.4**	**17.2**
Age						
0-21	289	30.5	24.9	19.0	14.9	10.7
22-44	8,488	14.3	27.6	22.6	21.0	14.4
45-64	20,796	12.1	24.5	23.5	22.7	17.3
65-74	10,787	12.0	23.3	22.9	23.4	18.5
75+	6,223	12.6	23.7	23.3	21.7	18.8
Sex						
Male	25,983	13.3	26.4	23.7	21.6	15.1
Female	20,600	11.9	22.5	22.4	23.3	19.9
Race						
White	30,960	14.1	25.9	23.3	21.5	15.1
Black/African American	11,366	9.5	21.7	22.6	24.3	21.9
American Indian or Alaska Native	441	12.5	32.0	22.5	18.1	15.0
Asian	2,997	10.0	22.4	23.0	23.6	21.1
Primary cause of ESRD						
Diabetes	17,709	11.6	25.6	24.5	22.3	16.0
Hypertension	13,233	12.5	23.6	22.4	22.7	18.9
Glomerulonephritis	8,164	12.7	23.4	22.1	23.7	18.1
Cystic Kidney	2,311	20.9	29.0	20.2	19.0	10.9
Other/Unknown	4,892	12.9	24.0	23.2	21.3	18.6

Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May 2017. 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, 2017, and who were alive through May 31, 2017. Table includes row percentages within demographic categories from May 2017. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease.

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 2016. 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, interpretation of results should be made with this in mind.

In 2012, 23.2 of PD patients received one or more red blood cell transfusions. This has continually declined to 21.7 of PD patients in 2013, 20.2 in 2014, 18.3 in 2015, and 15.1 of PD patients in 2016 having received ≥1 red blood cell transfusions within the indicated year. Across this five-year period, typically 9.3-13.2 of PD patients received one red blood cell transfusion per year, 3.2-5.3 received two per year, 1.2-2.1 received three, and 1.4-2.6 received four or more red blood cell transfusions.

Trends in the percentage of PD patients receiving one or more red blood cell transfusions within a month during 2012-2016 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 3.5 in the first quarter of 2012 to 2.0 by the third quarter of 2016. When comparing monthly red blood cell transfusion rates among incident versus prevalent PD patients, transfusion rates were in fact slightly lower for patients on PD <90 days compared with those on PD ≥90 days. From January to November 2016, on average 1.5 of White patients had one or more red blood cell transfusions in a month compared to 1.9 of Black patients and 2.1 of those of Other or Unknown race. Note that since 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 claim 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, 2012-2016

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

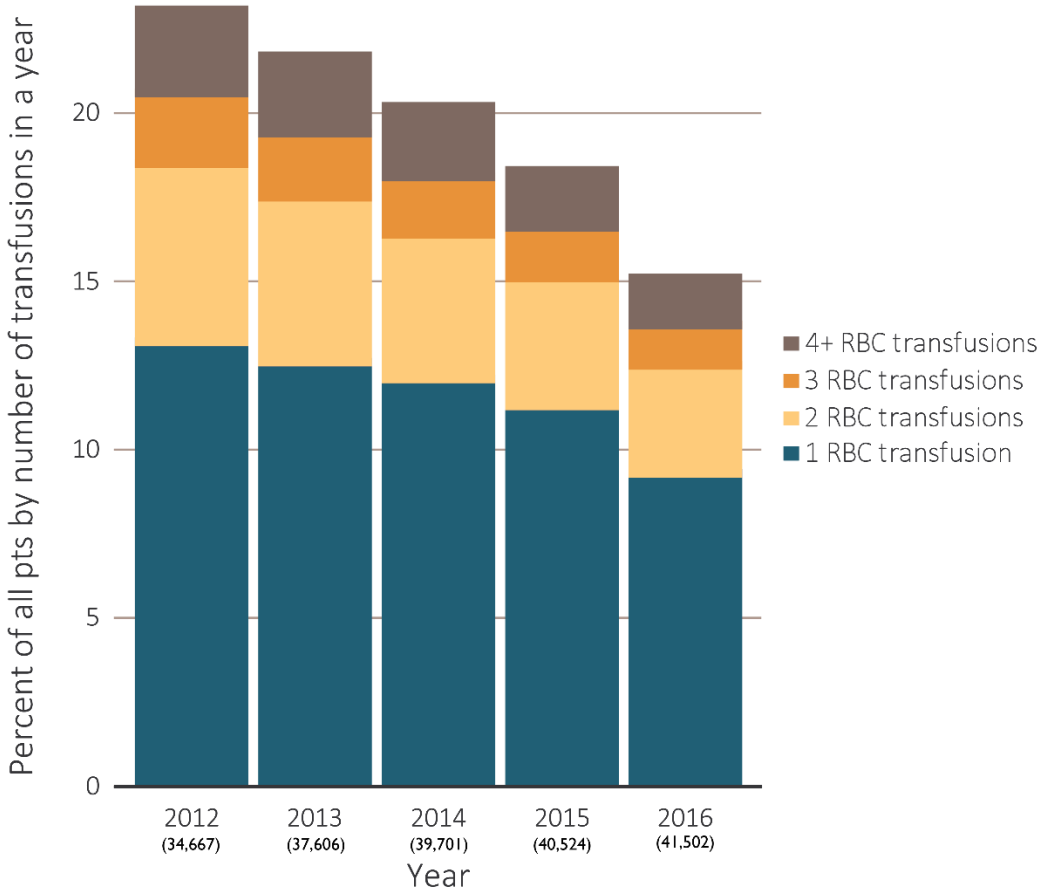
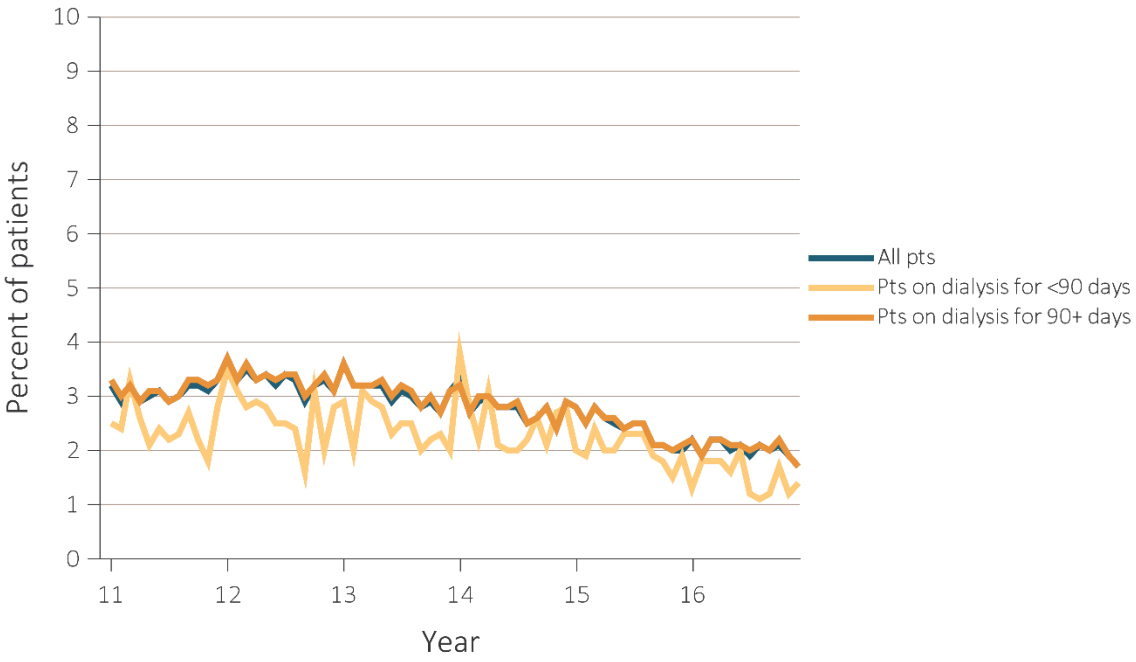


Figure 2.13 continued on next page.

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 claim 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, 2012-2016 (continued)

(b) Percent of all 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. (a) The percent of peritoneal dialysis patients ≥18 years with total number of red blood cell transfusion claims in a given year among dialysis patients having a claim for at least one peritoneal dialysis session during the year. (b) 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. Abbreviations: ESRD, end-stage renal disease; RBC, red blood cell.

Mineral and Bone Disorder Marker Management

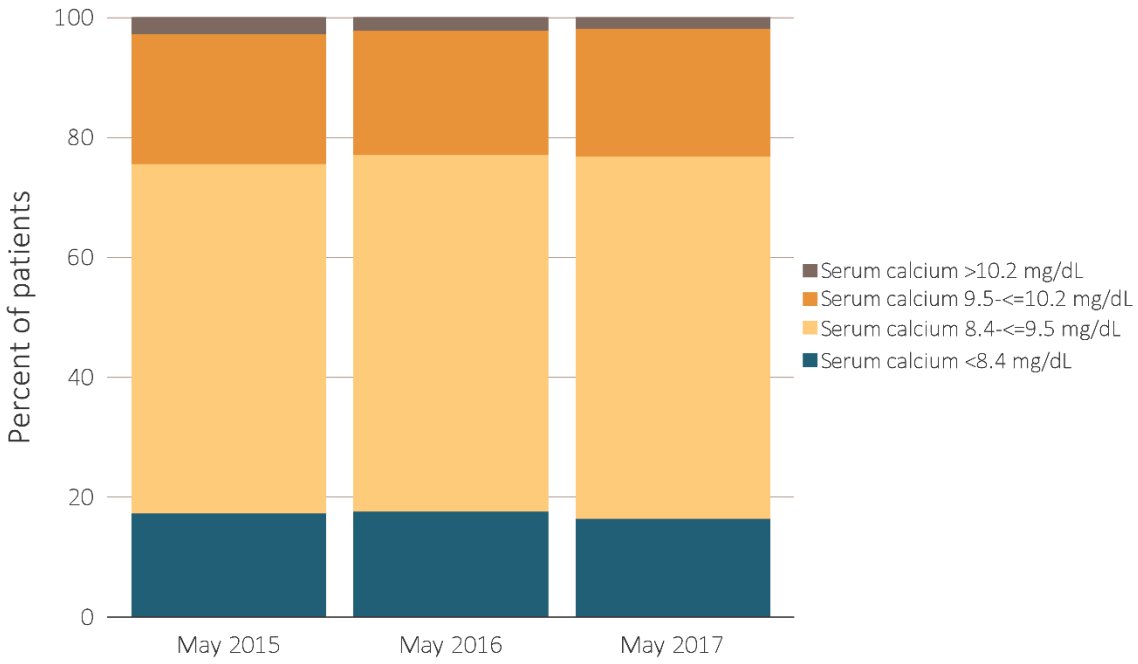
Evidence from basic scientific and epidemiological studies supports the role of abnormalities in markers of mineral and bone metabolism in the pathogenesis of vascular calcifications and cardiovascular disease—major causes of increased hospital admissions and mortality in the chronic dialysis population. Specifically, elevated levels of calcium, phosphorus, and parathyroid hormone (PTH) have been associated with increased cardiovascular events and mortality. Very low serum calcium, phosphorus, and PTH 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 2015 and 2017, no substantial change was observed in serum calcium distributions. The majority of 2017 patients (HD: 60.5, PD: 57.5) had calcium levels within the normal reference range (8.4-9.5 mg/dL), while a very small percentage (HD: 1.3, PD: 1.9) had particularly elevated serum calcium levels of >10.2 mg/dL, a cut point that reflects the quality measure that is currently included in the QIP and DFC

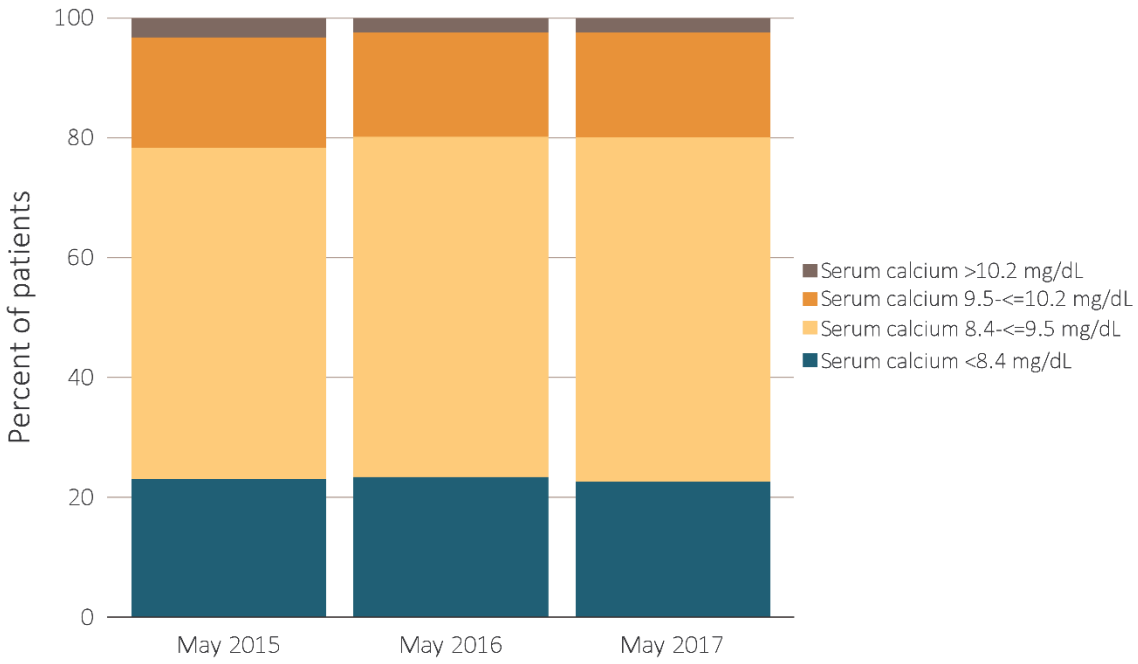
programs based on associations with cardiovascular mortality above that level. The May 2017 prevalence of very low calcium levels (<8.4 mg/dL) was higher in patients on PD, at 23.1, than for HD patients at 16.9, which may be due in part to lower levels of serum albumin levels among patients on PD.

vol 2 Figure 2.14 Distribution of serum calcium levels in adult hemodialysis patients on dialysis for at least 1 year, CROWNWeb data, May 2015, 2016, and 2017



Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for May for years 2015, 2016, and 2017. 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. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network ESRD, end-stage renal disease.

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 2015, 2016, and 2017

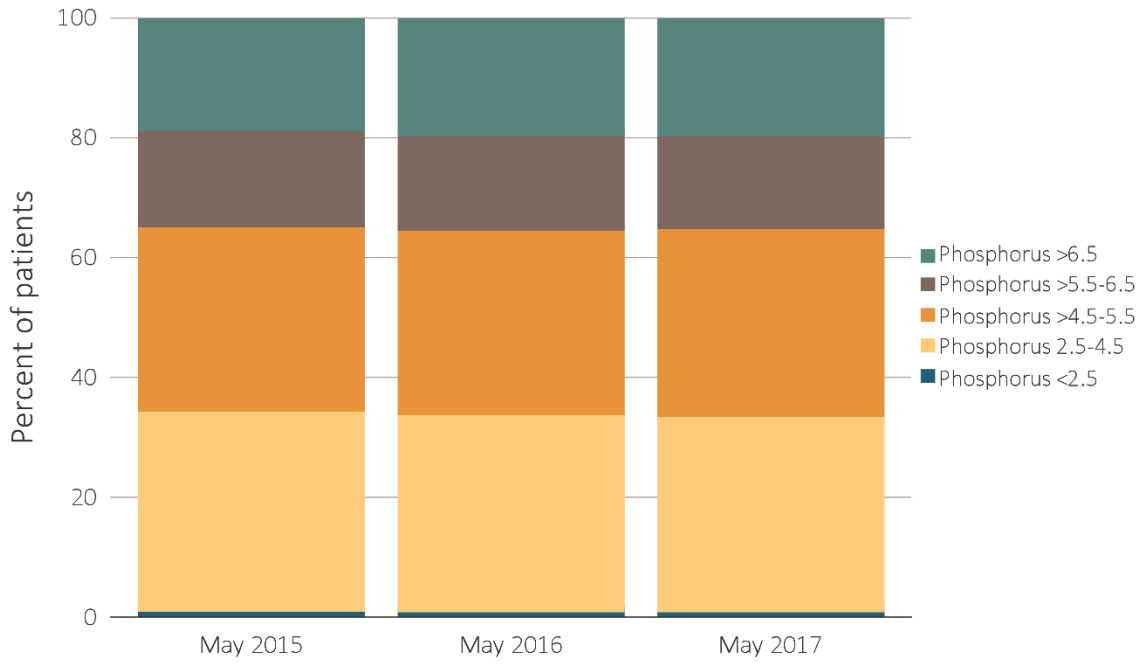


Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for May for years 2015, 2016, and 2017. Dialysis patients on treatment for ESRD at least 1 year at the time of measurement of serum calcium for that year, ≥18 years old as of May 1 of that year and who were alive through May 31 of that year. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network ESRD, end-stage renal disease.

Serum Phosphorus

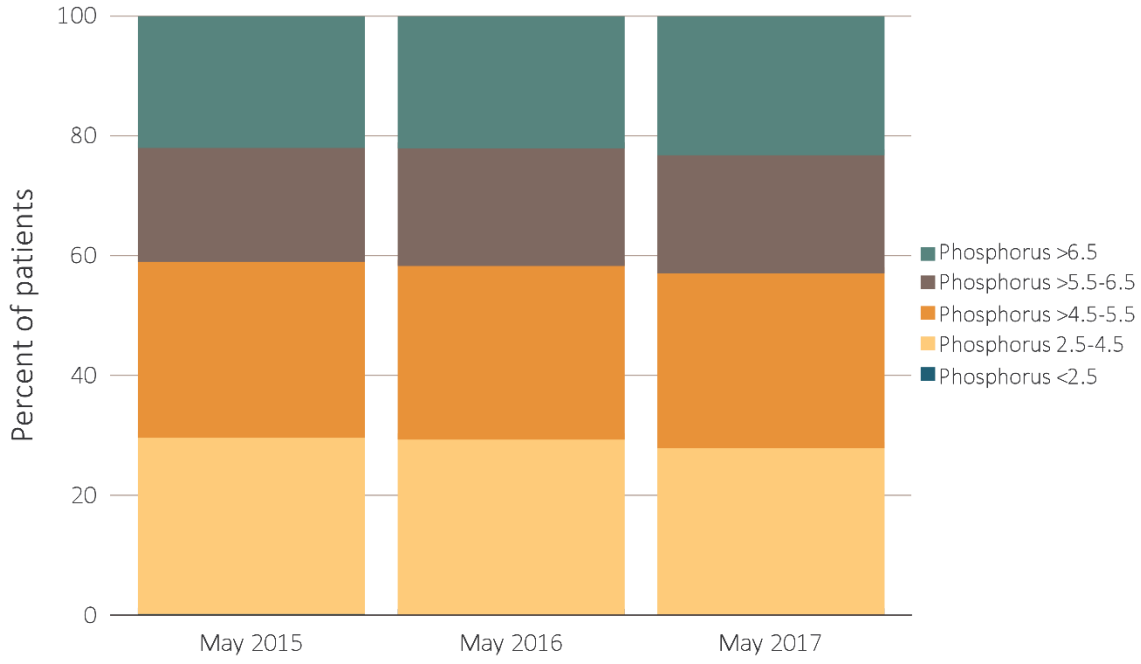
Figures 2.16 and 2.17 illustrate the distributions of serum phosphorus levels among adult HD and PD patients. Between 2015 and 2017, there has been little change in mean serum phosphorus among HD and PD patients (HD: from 5.30 to 5.31 mg/dL; PD: from 5.49 to 5.54 mg/dL). Both the 2009 and 2017 KDIGO CKD-Mineral and Bone Disorder (MBD) guidelines recommend maintaining serum phosphorus levels within the normal laboratory reference range, which is typically between 2.5 and 4.5 mg/dL. Among HD patients in May 2017, approximately two-thirds (66.1) had serum phosphorus >4.5 mg/dL. This percentage was even higher among patients on PD (71.6), 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 2015 to 2017 CROWNWeb data, 1.3-1.4 of HD patients and 0.5-0.7 of PD patients had serum phosphorus levels <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 2015, 2016, and 2017



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for May 2015, May 2016, and May 2017. 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. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease.

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 2015, 2016, and 2017



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for May 2015, May 2016, and May 2017. 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. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease.

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.

As shown in Figure 2.18, from 2004 to 2016, Medicare claims showed a slight increase in the percentage of ESRD patients with diabetes who received at least one glycosylated hemoglobin test (HbA1c; 81.8 in 2004 to 83.4 in 2016). In 2016, 93.6 of Medicare PPO, 93.5 of Medicare HMO, 89.3 of commercial PPO, 90.6 of commercial HMO, and 86.7 of Medicaid HMO patients 18-75 years of age with a diagnosis of type 1 or type 2 diabetes had at least one HbA1c test ("Comprehensive Diabetes Care," National Committee for Quality Assurance, 2018). However, the percentage of ESRD patients with diabetes who received two or more HbA1c tests decreased from 71.7 in 2004 to 68.9 in 2016. The American Diabetes Association has recommended that HbA1c tests be performed at least 2 times a year in patients who are meeting treatment goals and who have stable glycemic control and more frequently in patients whose therapy has changed or who are not meeting glycemic goals. The percentage of ESRD patients with diabetes who received at least one lipid test increased steadily from 2004 to 2010 (68.8 to 81.4), followed by a steady decrease between 2010 and 2016 (81.4 in 2010 to 68.9 in 2016; Figure 2.18). In 2013, 87.7 of Medicare PPO, 88.9 of Medicare HMO, 81.3 of Commercial PPO, 84.9 of Commercial HMO, and 76.0 of Medicaid HMO patients 18-75 years of age with a diagnosis of diabetes had at least one lipid test ("HEDIS Measures of Care," National Committee for Quality Assurance, 2014). The National Committee for Quality Assurance retired its LDL-C screening measure in 2013.

The lower rates of HbA1c testing in diabetic patients with ESRD 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 2016, 46.9 of diabetic ESRD patients had at least one diabetic eye exam (Figure 2.18). This did not meet the Healthy People 2020 target of 58.7 (2018). In 2016, 69.6 of Medicare PPO, 70.4 of Medicare HMO, 47.5 of commercial PPO, 53.6 of commercial HMO, and 54.9 of Medicaid HMO patients 18-75 years of age with a diagnosis of type 1 or type 2 diabetes had at least one diabetic eye exam ("Comprehensive Diabetes Care," National Committee for Quality Assurance, 2018). A similar pattern exists for the patients receiving ≥2 HbA1c tests, at least one lipid test, and at least one diabetic eye exam—approximately 29 in the most recent data year, down from a high of 33 in 2010. 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, 2004-2016

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.

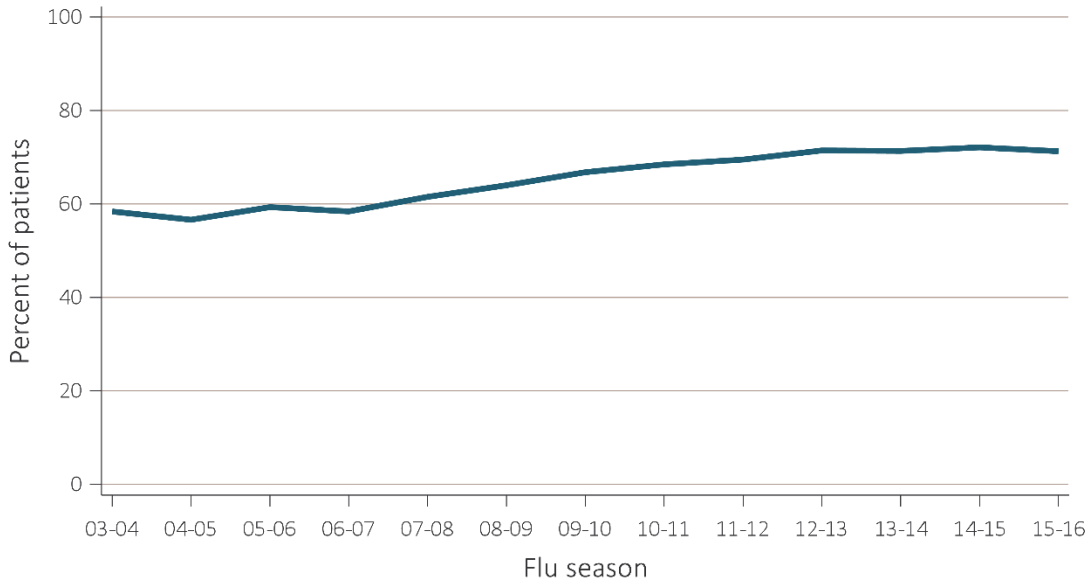
Vaccination

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 59.3 in the 2005-2006 season to 71.3 in the 2015-2016 season, though rates appear to have plateaued in the last few reporting years (Figure 2.19.a). These reported percentages may be underestimates, however, as they were derived from claims data that may not completely capture all vaccination events.

The percentage of patients vaccinated is presented by modality stratified further by age due to substantially different distributions of age between the transplant and dialysis populations (Figures 2.19.b-d). Overall, HD patients were vaccinated at the highest frequency—78.0 in the most current data—compared with 76.1 of PD patients and 48.9 of kidney transplant patients in the 2015-2016 season. Among the transplant patients, the vaccination frequency has been dropping since the 2013-2014 season for the younger age categories (0-64) (Figure 2.19.d). This trend may in part relate to higher transplant rates in these groups in recent years, as vaccination is often delayed after a new transplant due to concerns about an ineffective immune response or the possibility of triggering an acute rejection episode. 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 70.4 in the 2015-2016 season (Figures 2.19.e and 2.19.f).

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 and hemodialysis treatment, (c) by age and peritoneal dialysis, (d) by age and transplantation, (e) by race, and (f) by ethnicity, Medicare data, 2003-2016

(a) Overall



(b) Age and hemodialysis treatment

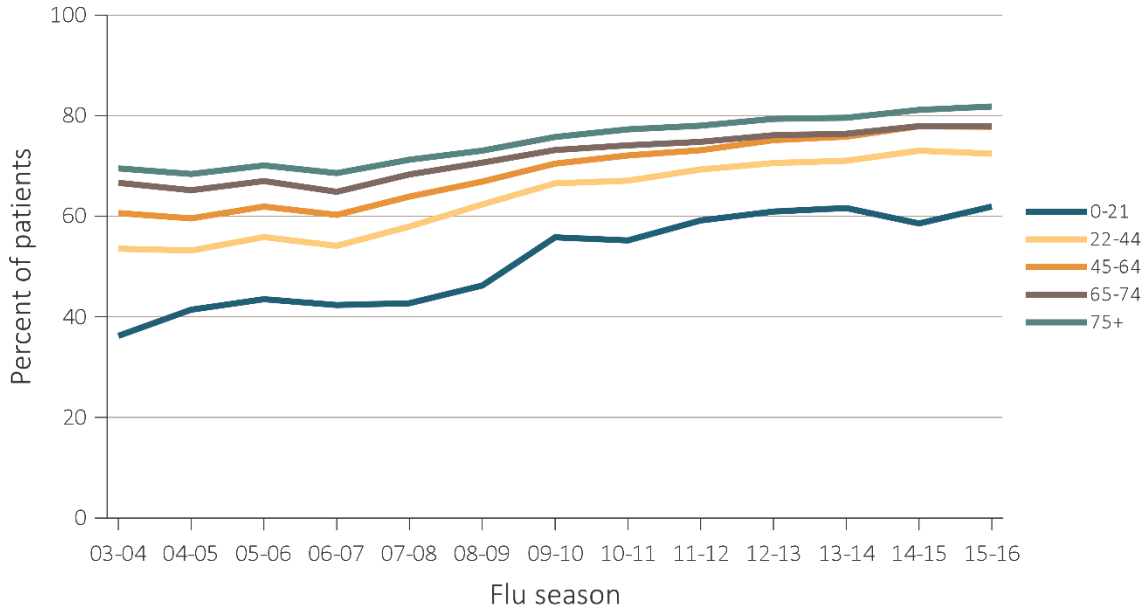
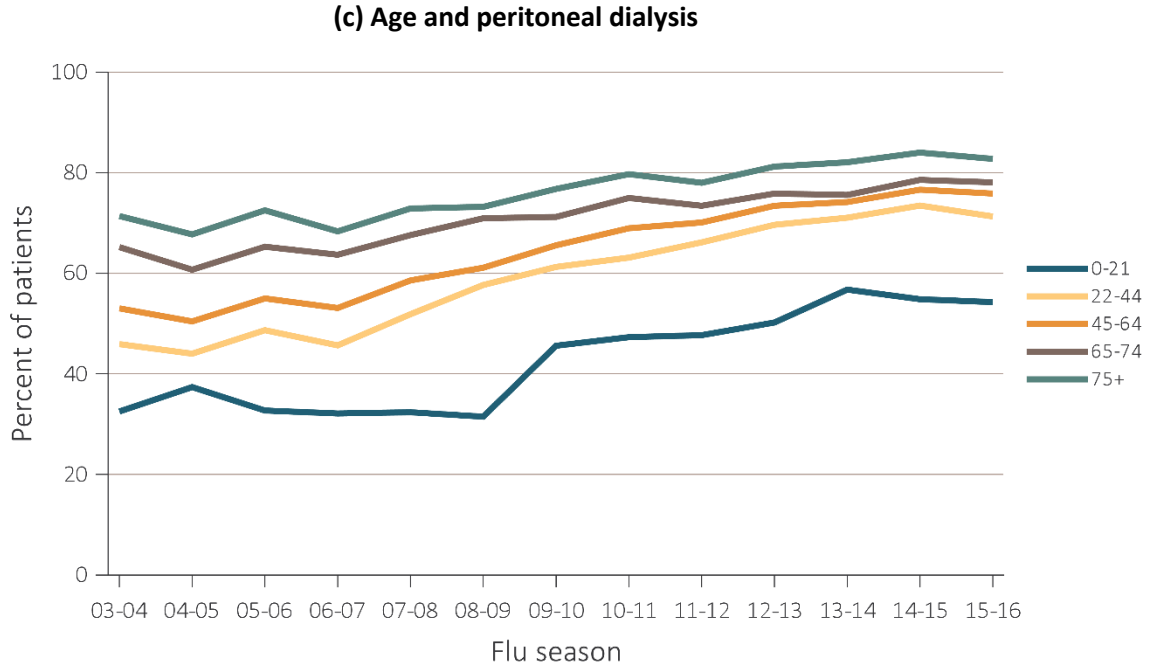


Figure 2.19 continued on next page.

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 and hemodialysis treatment, (c) by age and peritoneal dialysis, (d) by age and transplantation, (e) by race, and (f) by ethnicity, Medicare data, 2003-2016 (continued)



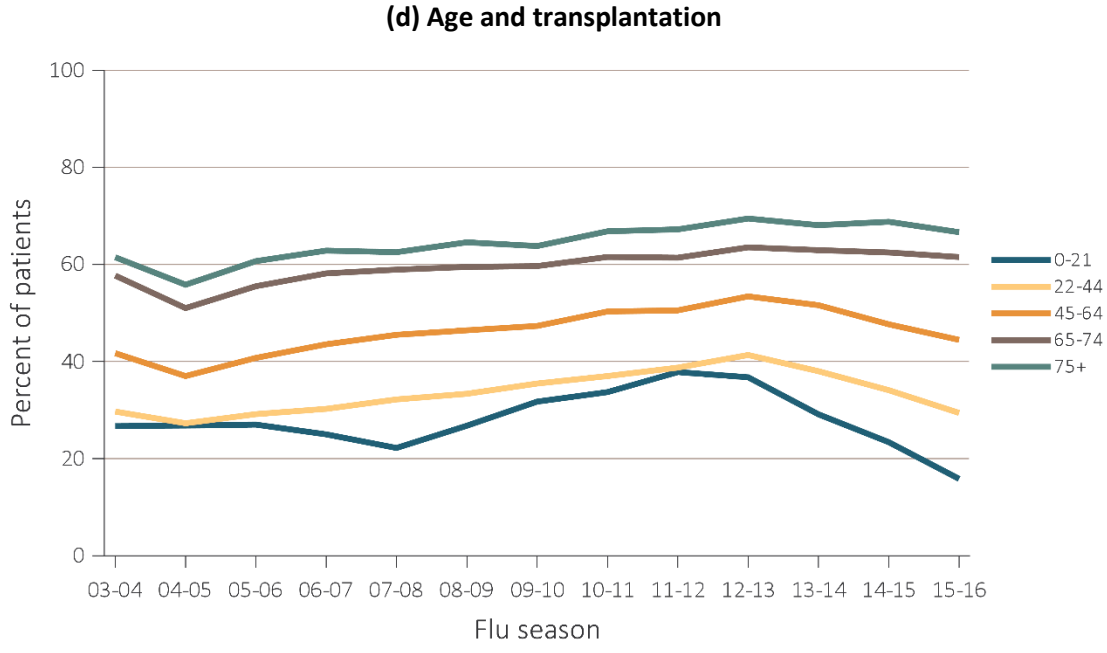
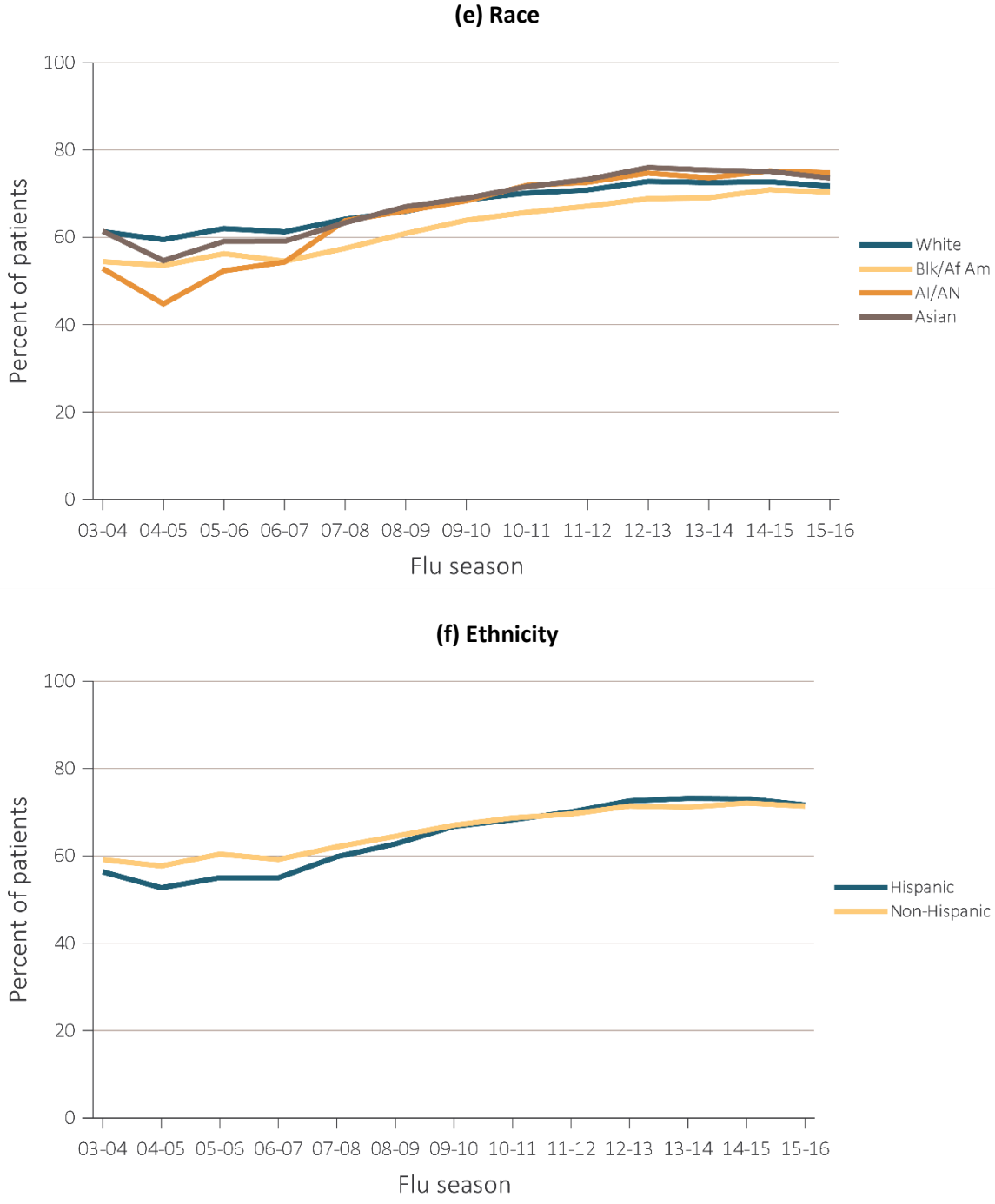


Figure 2.19 continued on next page.

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 and hemodialysis treatment, (c) by age and peritoneal dialysis, (d) by age and transplantation, (e) by race, and (f) by ethnicity, Medicare data, 2003-2016 (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: AI, American Indian; AN, Alaska Native; Blk/Af Am, Black/African American; ESRD, end-stage renal disease.

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Chapter 3: Vascular Access

- In 2016, 80% of patients were using a catheter at hemodialysis (HD) initiation (Figure 3.1).
- At 90 days after the initiation of HD, 69% 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 2005-2016 (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% over the same period (Figure 3.1).
- Seventeen percent of patients used an AV fistula exclusively at dialysis initiation. This increased to 64% by the end of one year on HD, and to 71% 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 17% at two years (Figure 3.7.a).
- At one year after HD initiation, 79% 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 2017, 62.8 % of prevalent dialysis patients were using an AV fistula (Figure 3.6).
- Of AV fistulas placed between June 2014 and May 2016, 39% failed to mature sufficiently for use in dialysis. Of those that did mature, the median time to first use was 108 days (Table 3.7).
- Patient demographic characteristics appear to contribute to success with AV fistula; at younger ages, the percent of AV fistulas that successfully mature is higher and the median time to first use is somewhat shorter (Table 3.7). Males had a higher AV fistula maturation rate compared to females, as well as shorter time to first use. Blacks experienced the highest AV fistula maturation failure rates, compared to other races.

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, referred to as catheters) are associated with higher risks of death, infection, and cardiovascular events than 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 patient comorbidity distribution by catheter type, 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 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 United States, 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 medical care, 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 AV fistula maturation was a secondary outcome, revealed a high failure rate of newly placed fistulas that never came into use (Dember et al., 2008). Between primary surgical failures and maturation failures, 36.2% of AV fistula placements in the United States are unsuccessful (Woodside et al., 2018). 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, although dialysis vintage, age, geographic factors, and other demographic and medical comorbidities are associated with risk of maturation failure. Also, patients may benefit should surgical training programs further emphasize skill in AV fistula placement (Saran et al., 2008; Goodkin et al., 2010).

A systematic, multilevel approach is required for ensuring optimal vascular access for every HD patient (Huber, 2015), since many additional factors likely influence successful AV fistula placement. These are often beyond the capacity of individual practitioners, and include patient motivation for access placement, timeliness of referrals for nephrology and vascular access intervention, and institutional and payer support for pre-ESRD care. The role of coordination of dialysis access placement and maintenance is therefore critical.

The above considerations and other salient issues make it imperative to track carefully and comprehensively trends in vascular access placements, interventions, related practices, and outcomes. Despite the emphasis on improving AV fistula success rates, at the time of dialysis initiation, 80.3% of patients used a catheter (USRDS, 2016). Well-coordinated pre-dialysis care during the critical transition period to ESRD is likely to 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, since the mid-2000s. In addition, we explore national variation in time-to-first-use of AV fistulas after placement, as a surrogate for AV fistula maturation time.

Methods

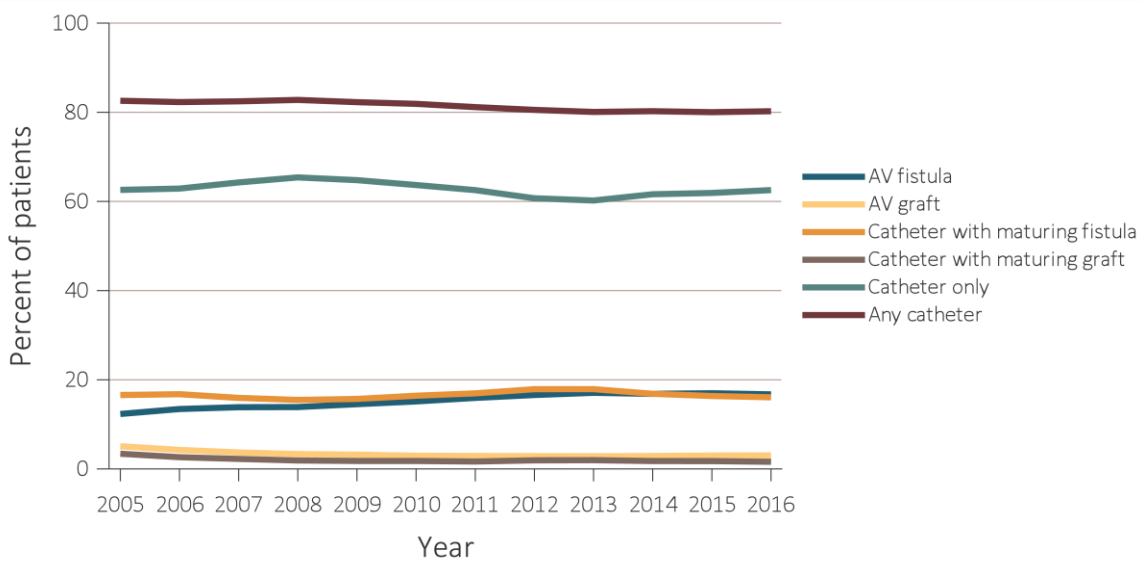
This chapter examines and reports data from the Centers for Medicare & Medicaid Services (CMS). Details of this data source are described in the *Data Sources* section of the *ESRD Analytical Methods* chapter.

For an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter, see the section on *Chapter 3* within the *ESRD Analytical Methods* 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 2016, 80.2% of patients were using a catheter at HD initiation, a rate that has changed only marginally since 2005. Figure 3.1 shows that in 2016, 62.5% 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 65.4% in 2008, and has remained relatively stable since 2012, at just above 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 16.7% in 2016, which may be reaching a plateau. Over the same period, the percentage of patients with either an AV fistula or a maturing AV fistula increased from 28.9% to 32.8%.

vol 2 Figure 3.1 Vascular access use at hemodialysis initiation, from the ESRD Medical Evidence form (CMS 2728), 2005-2016



Data Source: Special analyses, USRDS ESRD Database. ESRD patients initiating hemodialysis in 2005-2016. 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 (82.2%) and lowest percentage of AV fistula use (7.1%). 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 quite 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 (18.0%), with slightly lower levels seen for individuals 75 years or older (16.6%) and those between 45-64 years (16.9%).

Patients of Hispanic ethnicity or Black/African American race displayed the lowest proportion of AV fistula use (14.7%) at HD initiation, with those of Hispanic ethnicity having the highest use of a catheter alone (66.1%). Non-Hispanic Blacks/African Americans displayed the highest proportion of AV graft use at HD initiation (4.6%), with lower AV graft use among Other races and Hispanic ethnicity combined (3.4%), while the lowest observed rate was for Hispanic ethnicity alone (1.9%).

Consistent with previous years, those with cystic kidney disease had higher rates of AV fistula use at HD initiation (38.0%), perhaps related to younger age at disease detection, slower progression of underlying CKD, earlier nephrology referral, more consistent pre-dialysis nephrology care, or relatively well preserved vasculature.

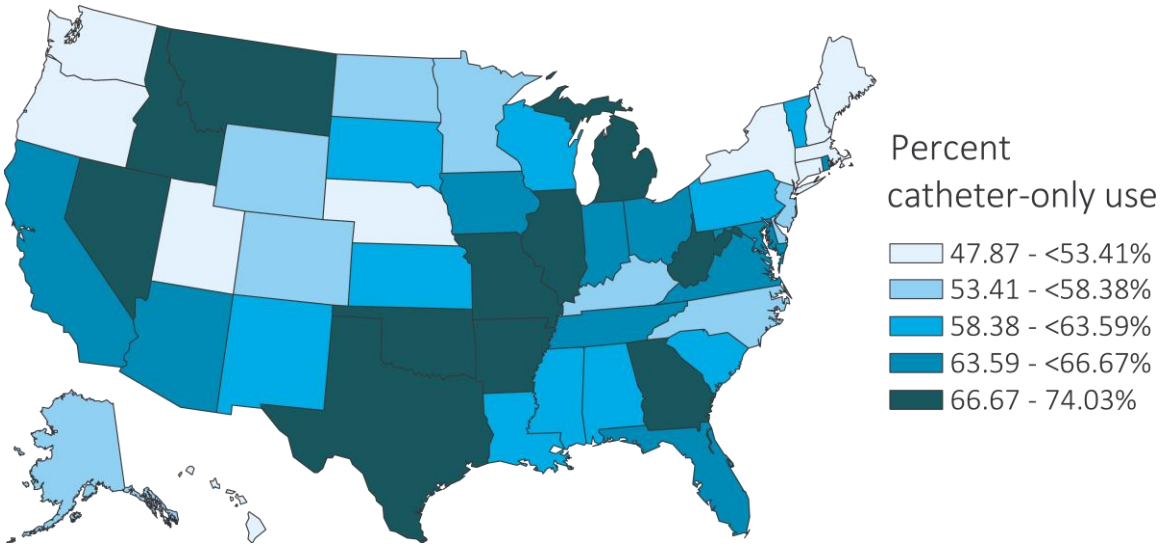
vol 2 Table 3.1 Vascular access used at hemodialysis initiation by patient characteristics from the ESRD Medical Evidence form (CMS 2728), 2016

	AV fistula	AV graft	Catheter with maturing fistula	Catheter with maturing graft	Catheter only
All	16.7	3.0	16.1	1.6	62.5
Age					
0-21	7.1	0.9	9.7	0.1	82.2
22-44	13.4	1.8	16.3	1.2	67.4
45-64	16.9	2.8	17.2	1.6	61.4
65-74	18.0	3.2	16.4	1.5	60.9
75+	16.6	3.7	14.0	1.9	63.7
Sex					
Male	18.3	2.3	16.6	1.3	61.5
Female	14.7	4.0	15.4	2.0	63.9
Race					
White	17.3	2.4	15.7	1.4	63.2
Black/African American	14.7	4.5	16.7	2.3	61.8
American Indian or Alaska Native	18.5	2.6	19.9	0.8	58.2
Asian	19.8	3.4	16.8	1.6	58.3
Other or Multiracial	18.2	3.1	16.1	1.1	61.4
Ethnicity					
Hispanic	14.7	1.9	16.2	1.2	66.1
Non-Hispanic	17.1	3.2	16.1	1.7	62
Race/Ethnicity					
Non-Hispanic White	18.0	2.6	15.6	1.4	62.4
Non-Hispanic Black/African	14.7	4.6	16.7	2.3	61.8
Primary Cause of ESRD					
Diabetes	17.4	3.2	18.3	1.7	59.4
Hypertension	17.0	3.3	15.5	1.6	62.7
Glomerulonephritis	17.5	2.4	14.1	1.7	64.3
Cystic kidney	38.0	4.6	13.2	1.1	43
Other urologic	14.4	2.0	13.5	1.3	68.9
Other cause	9.0	1.8	10.1	1.4	77.7
Unknown/Missing	9.6	2.3	8.6	0.8	78.7
Comorbidities					
Diabetes	16.5	3.1	17.4	1.7	61.3
Congestive heart failure	12.3	2.6	16.9	1.7	66.4
Atherosclerotic heart disease	16.1	3.1	17.5	1.7	61.6
Cerebrovascular disease	14.9	3.4	16.5	2.0	63.2
Peripheral vascular disease	13.9	2.8	18.1	1.8	63.4
Hypertension	17.3	3.1	16.5	1.6	61.5
Other cardiac disease	13.7	2.5	15.9	1.7	66.3

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

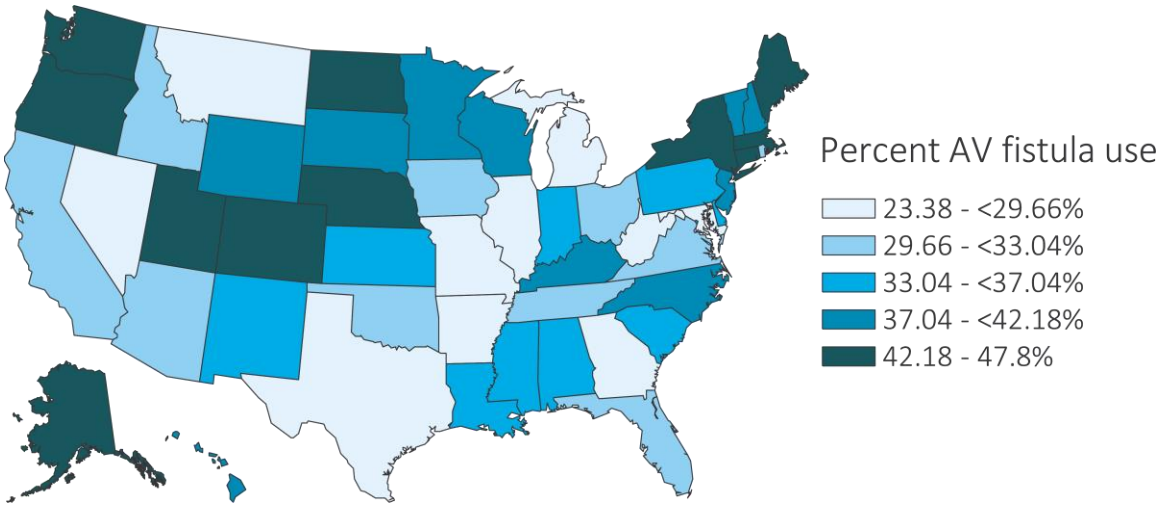
Figures 3.2 and 3.3 illustrate geographic variation by state in the use of catheters alone and AV fistulas (including catheters with a maturing AV fistula) at HD initiation. Considerable variation occurred in both of these categorizations across states. New England, the Northwest, Utah, and Nebraska tended to have a lower percentage of catheter use and a higher percentage of AV fistula use at initiation. Some Upper Midwest 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), 2016



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), 2016



Data Source: 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 2017, 64.5% of these patients were using an AV fistula. In general, demographic variation among prevalent patients 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 AV graft use. Multiracial patients and those in the Other race category reported the highest catheter use. When examined by primary cause of ESRD, individuals with cystic kidney disease maintained the highest fistula usage. However, the differences in vascular access use among prevalent HD patients with different etiologies were smaller than those observed in incident dialysis patients. (Table 3.1).

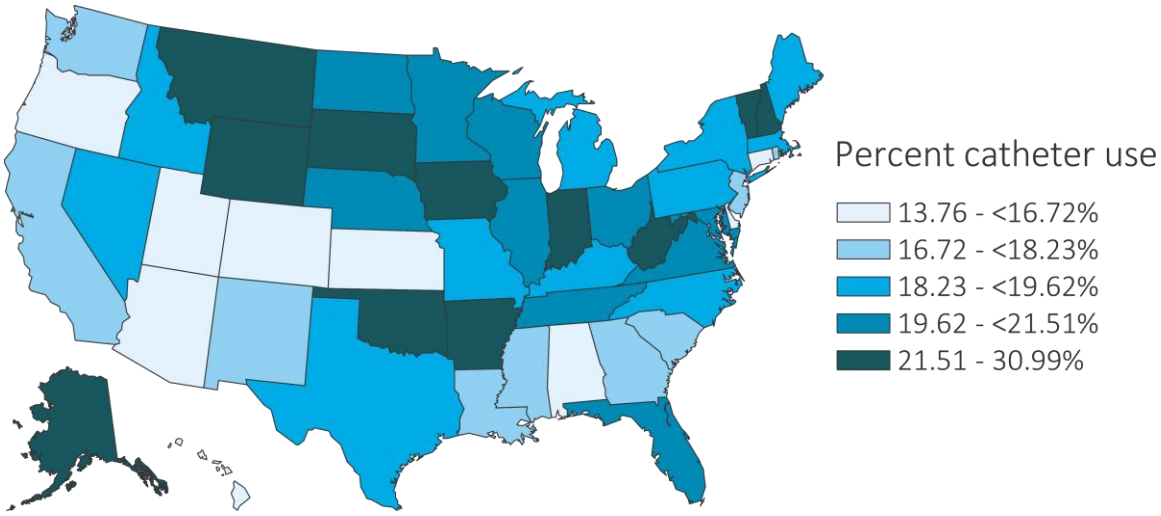
vol 2 Table 3.2 Distribution of type of vascular access in use among prevalent hemodialysis patients in 2017, from CROWNWeb data, May 2017

	AV fistula	AV graft	Catheter
All	64.5	16.6	18.9
Age			
0-21	44.0	6.8	49.3
22-44	66.2	13.6	20.2
45-64	66.6	15.5	18.0
65-74	63.9	17.4	18.7
75+	60.9	19.4	19.7
Sex			
Male	70.4	12.6	17.0
Female	56.7	21.9	21.4
Race			
White	67.3	12.8	19.9
Black/African American	59.1	23.1	17.8
American Indian or Alaska Native	75.8	10.1	14.1
Asian	68.4	15.6	16.0
Other or Multiracial	62.3	12.9	24.8
Ethnicity			
Hispanic	70.3	13.4	16.3
Non-Hispanic	63.3	17.3	19.4
Race/Ethnicity			
Non-Hispanic White	65.8	12.6	21.6
Non-Hispanic Black/African-American	59.1	23.2	17.7
Primary Cause of ESRD			
Diabetes	65.1	16.2	18.7
Hypertension	64.5	17.4	18.1
Glomerulonephritis	66.4	16.8	16.8
Cystic kidney	70.6	14.3	15.1
Other urologic	62.9	15.5	21.6
Other cause	58.5	16.2	25.3
Unknown/Missing	59.6	15.8	24.6

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; ESRD, end-stage renal disease.

Figure 3.4 presents geographic variation of the proportion of prevalent HD patients using a catheter in 2017. Rates varied widely across the country. High catheter utilization was evident in Montana, Wyoming, South Dakota, Iowa, Indiana, West Virginia, Oklahoma, Arkansas, Vermont, New Hampshire, and Alaska. In contrast, Oregon, Utah, Arizona, Colorado, Kansas, Alabama, Hawaii, Delaware, and Connecticut exhibited lower catheter use.

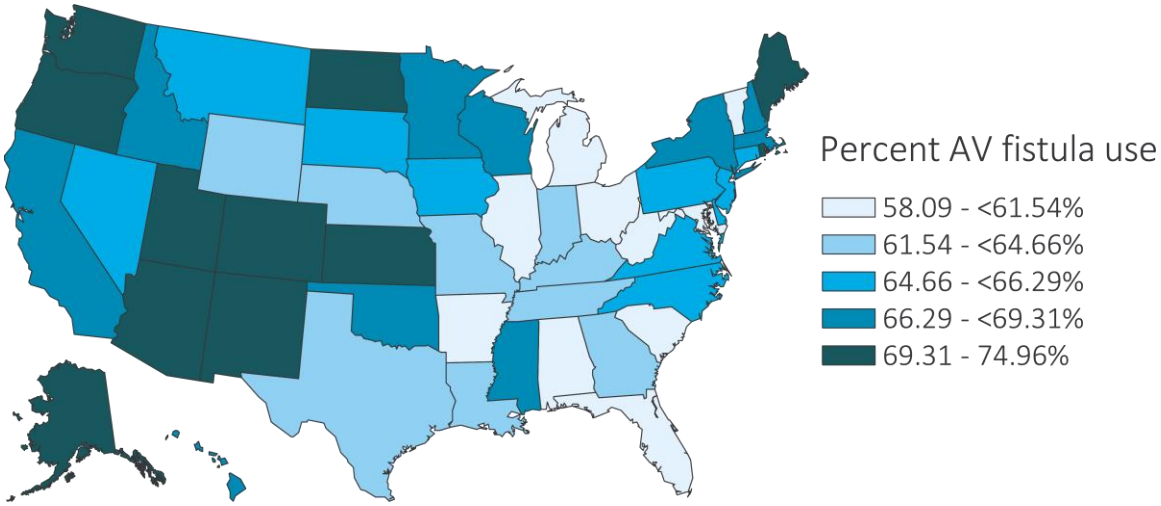
vol 2 Figure 3.4 Geographic variation in percentage catheter use among prevalent hemodialysis patients by state, from CROWNWeb data, May 2017



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

Figure 3.5 shows variation in AV fistula use among 2017 prevalent HD patients. Higher fistula use was most apparent in the Northwest, North Dakota, Maine, Rhode Island, Kansas, and the Southern Mountain States. Florida, Alabama, South Carolina, Arkansas, Michigan, Illinois, Ohio, West Virginia, Maryland, and Vermont have lower rates of fistula use.

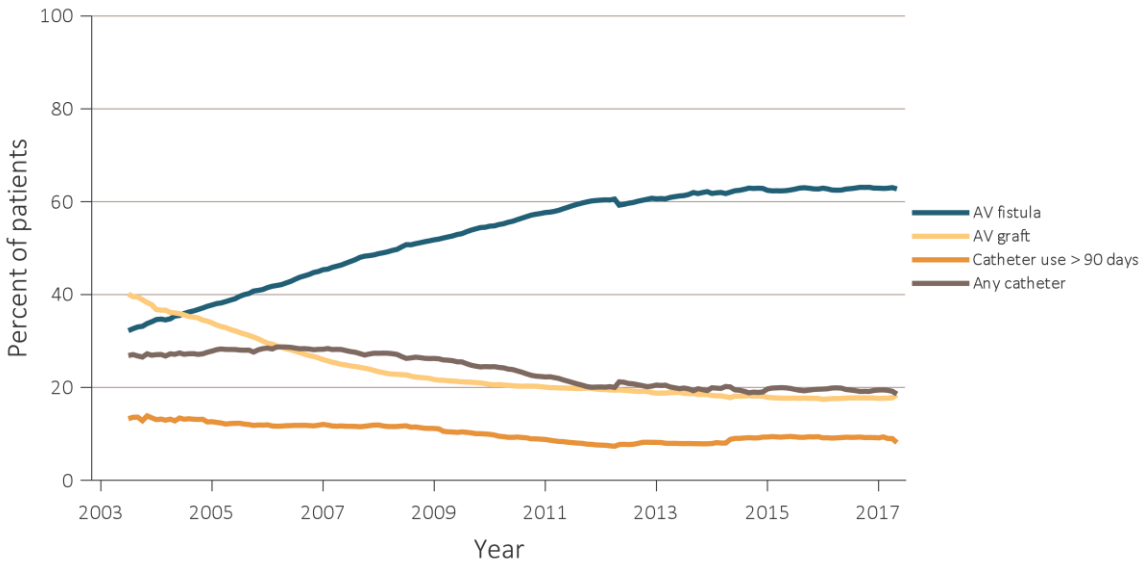
vol 2 Figure 3.5 Geographic variation in percentage AV fistula use among prevalent hemodialysis patients by state, from CROWNWeb data, May 2017



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

Figure 3.6 displays trends in vascular access use among prevalent HD patients from 2003 to mid-2017. Between July 2003 and April 2012, these data reflect the monthly point prevalence of vascular access at dialysis facilities from the Fistula First Breakthrough Initiative and from May 2012 through May 2017 from monthly CROWNWeb clinical data. A large increase in AV fistula use has occurred since 2003, rising from 32% to 62.8% of patients, although this change has recently plateaued. In contrast, AV graft use has decreased from 40% to 18.4% over the same period. Catheter use has had a complementary decline, decreasing from 27% to 18.6%. In May 2017, only 8.1% 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, 2003-2017



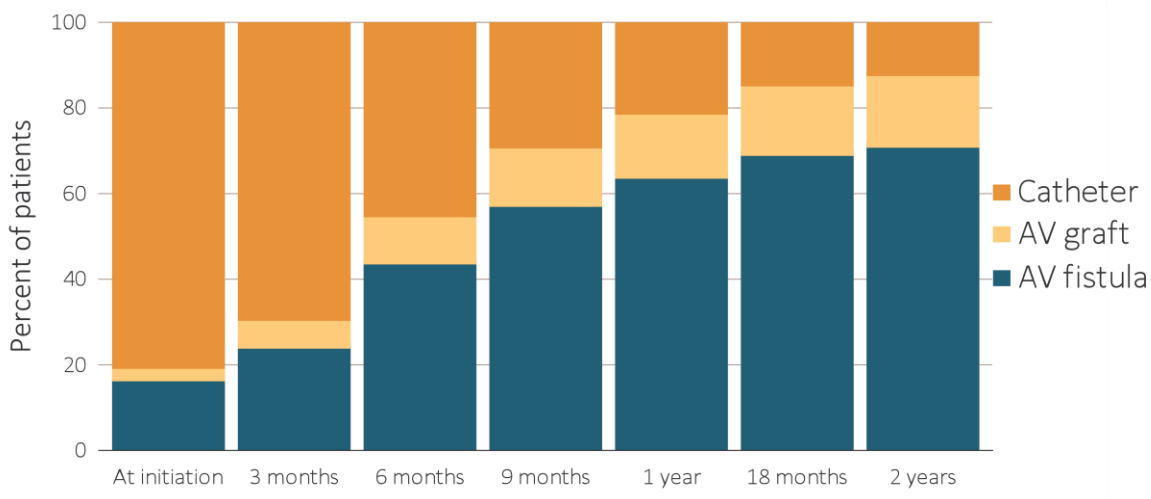
Data Source: Special analyses, USRDS ESRD Database and Fistula First data. Fistula First data reported from July 2003 through April 2012, CROWNWeb data are reported from June 2012 through May 2017. Abbreviations: AV, arteriovenous; CROWNWeb, Consolidated Renal Operations in a Web-enabled Network; ESRD, end-stage renal disease.

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

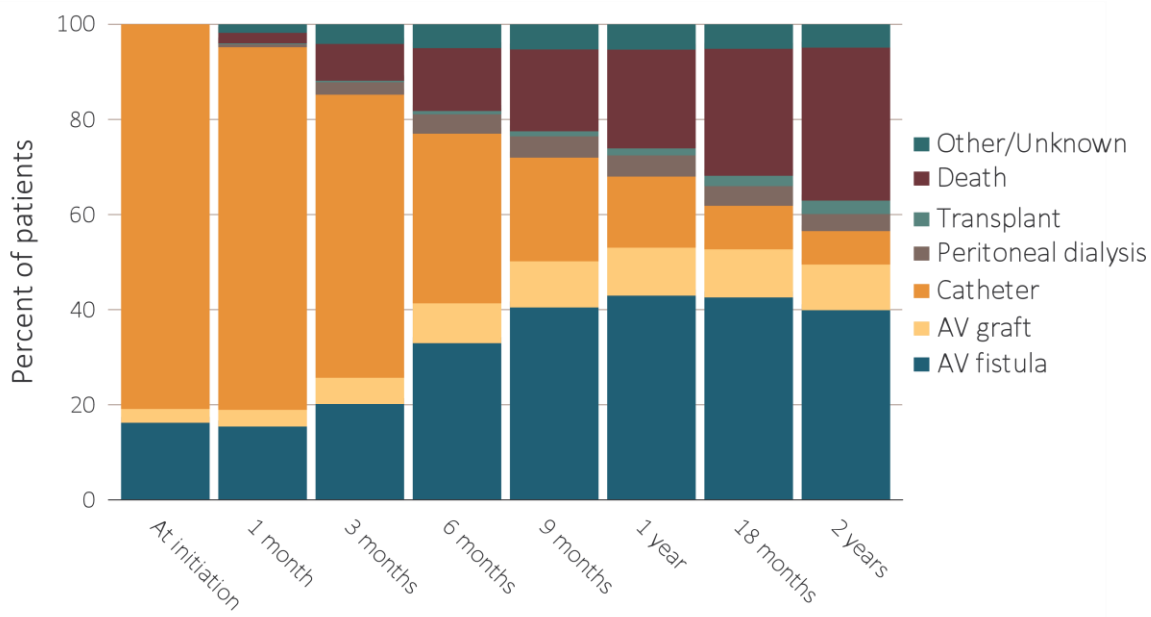
Figure 3.7.a shows cross-sectional data from both the CMS Medical Evidence form (CMS 2728) for vascular access information at initiation, and CROWNWeb for follow-up data with respect to vascular access in use at three, six, nine, and eighteen months, and one and two years. At 90 days, the majority of 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 64%, and to 71% 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 17% 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 two-year longitudinal changes in vascular access use and other outcomes in the cohort of patients who initiated ESRD via HD in 2014. In the incident ESRD HD cohort, 80.3% of patients initiated HD using a central venous catheter. After 12 months, 43.6% were using an AV fistula, 10.1% were using an AV graft, and 14.9% were dialyzing with a catheter only. Of this cohort, 1.5% were living with a kidney transplant, 4.5% were receiving peritoneal dialysis, 20.8% had died, and 4.7% were classified as having an Other/Unknown outcome. After two years, 40.5% were using an AV fistula, 9.6% were using an AV graft, and 7.0% were dialyzing with a catheter only. Of this cohort, 2.8% were living with a kidney transplant, 3.6% were receiving peritoneal dialysis, 32.2% had died, and 4.3% were classified as having an Other/Unknown outcome.

vol 2 Figure 3.7 Change in type of vascular access during the first two years of dialysis among patients starting ESRD via hemodialysis in 2014: (a) type of vascular access in use (cross-sectional), and (b) longitudinal changes in vascular access use and other outcomes, ESRD Medical Evidence form (CMS 2728) and CROWNWeb, 2014-2017

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



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



Data Source: Special analyses, USRDS ESRD Database. Data from January 1, 2014 to May 30, 2017: (a) Medical Evidence form (CMS 2728) at initiation and CROWNWeb for subsequent time periods. (b) ESRD patients initiating hemodialysis (N =104,102). 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.

Tables 3.3 through 3.5 show cross-sectional distributions of vascular access use at several time points during the first two years of HD therapy, stratified by age, race, and sex. Catheter use was most common at initiation, at the end of one year, and at the end of two years 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 and two years. At one year, approximately 20% of persons in all age groups, except the 0-21 year old cohort, used catheters. This number decreased to approximately 12% at two years. This indicates that barriers remain in establishing surgical access, even after one year of dialysis therapy.

Black patients had the highest proportion of AV graft use at initiation, one year, and two years. At one year, 20.2% of Black patients were using an AV graft compared to 13.1% of Asians and 12.7% 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 and two years, catheter use was highest among Other or Multiracial, and female patients. For most adult patients, an AV fistula prevalence greater than 60% was achieved by one year on HD. At one year, males and those of American Indian/Alaska Native race had the highest proportions of AV fistula use, while females and Blacks had the lowest AV fistula proportions.

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 2014, by age group, from the ESRD Medical Evidence form (CMS 2728) and CROWNWeb, 2014-2017

Age	Access type	Time						
		At initiation	3 months	6 months	9 months	1 year	18 months	2 years
0-21	AV fistula	6.2	12.0	32.4	40.9	47.5	53.0	55.0
	AV graft	0.7	0.8	1.6	3.7	3.8	4.8	5.0
	Catheter	93.0	87.2	66.0	55.3	48.7	42.2	40.1
22-44	AV fistula	13.9	21.4	44.1	58.4	66.0	72.1	74.1
	AV graft	1.9	4.4	7.6	10.0	10.8	12.1	12.7
	Catheter	84.3	74.1	48.3	31.7	23.2	15.9	13.2
45-64	AV fistula	16.6	24.5	45.1	59.4	66.2	71.9	73.9
	AV graft	2.8	5.6	9.5	11.8	13.1	14.4	14.8
	Catheter	80.6	69.9	45.4	28.8	20.7	13.7	11.2
65-74	AV fistula	18.4	26.2	45.4	58.6	64.9	69.6	71.5
	AV graft	3.1	6.6	11.4	14.1	15.5	17.0	17.6
	Catheter	78.5	67.2	43.3	27.3	19.5	13.4	10.9
75+	AV fistula	17.0	24.1	41.5	53.5	59.3	64.3	66.0
	AV graft	3.4	8.9	14.9	18.0	19.7	20.7	21.0
	Catheter	79.6	66.9	43.6	28.5	21.0	15.0	13.0

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 3.4 Cross-sectional distributions of vascular access use, quarterly during the first two years of hemodialysis among patients new to hemodialysis in 2014, by race, from the ESRD Medical Evidence form (CMS-2728) and CROWNWeb, 2014-2017

Race/Ethnicity	Access type	Time						
		At initiation	3 months	6 months	9 months	1 year	18 months	2 years
White	AV fistula	17.4	25.6	45.9	59.7	66.4	72.0	74.0
	AV graft	2.4	5.4	9.4	11.7	12.7	13.6	14.0
	Catheter	80.3	69.0	44.8	28.6	20.9	14.4	12.0
Black/African American	AV fistula	15.3	21.4	39.3	51.9	58.2	63.2	65.1
	AV graft	4.2	9.2	15.0	18.3	20.2	22.0	22.6
	Catheter	80.5	69.4	45.8	29.7	21.6	14.9	12.3
American Indian or Alaska Native	AV fistula	16.0	25.9	53.8	67.8	75.1	79.4	79.8
	AV graft	2.0	4.0	6.8	8.3	9.4	9.9	10.6
	Catheter	81.9	70.1	39.4	23.9	15.5	10.7	9.6
Asian	AV fistula	19.5	28.2	50.2	63.2	70.4	75.7	77.1
	AV graft	3.0	7.0	10.6	12.4	13.1	14.5	15.1
	Catheter	77.5	64.8	39.2	24.4	16.5	9.8	7.8
Native Hawaiian or Pacific Islander	AV fistula	17.4	21.9	43.3	59.2	67.2	73.2	77.4
	AV graft	2.4	4.9	8.6	10.5	12.5	14.1	13.9
	Catheter	80.2	73.3	48.1	30.3	20.4	12.7	8.8
Other or Multiracial	AV fistula	14.5	20.0	40.7	60.3	65.1	71.4	71.1
	AV graft	3.9	5.6	11.3	11.4	11.8	14.3	14.2
	Catheter	81.6	74.4	48.0	28.3	23.1	14.3	14.7
Hispanic	AV fistula	14.0	22.1	43.7	59.1	66.3	72.8	75.4
	AV graft	2.1	5.0	8.9	11.3	12.6	13.7	14.3
	Catheter	84.0	72.8	47.4	29.6	21.1	13.4	10.4
Non-Hispanic	AV fistula	17.4	24.9	44.2	57.3	63.7	68.8	70.5
	AV graft	3.1	6.8	11.4	14.1	15.5	16.8	17.3
	Catheter	79.6	68.3	44.3	28.6	20.8	14.4	12.2
Non-Hispanic White	AV fistula	18.3	26.6	46.5	59.8	66.3	71.5	73.3
	AV graft	2.5	5.5	9.5	11.8	12.8	13.7	13.9
	Catheter	79.2	67.9	44.0	28.4	20.9	14.8	12.7
Non-Hispanic Black/African American	AV fistula	15.3	21.5	39.3	52.0	58.3	63.2	65.1
	AV graft	4.2	9.2	15.0	18.4	20.2	22.0	22.6
	Catheter	80.5	69.3	45.6	29.6	21.5	14.8	12.2

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.

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 2014, by sex, from the ESRD Medical Evidence form (CMS 2728) and CROWNWeb, 2014-2017

Sex	Access type	Time						
		At initiation	3 months	6 months	9 months	1 year	18 months	2 years
Male	AV fistula	18.3	27.7	50.0	64.0	70.6	75.5	77.2
	AV graft	2.2	5.1	8.6	10.6	11.5	12.4	12.8
	Catheter	79.4	67.2	41.4	25.5	17.9	12.1	10.0
Female	AV fistula	14.8	20.0	36.2	49.0	55.5	61.3	63.4
	AV graft	3.8	8.5	14.4	17.8	19.7	21.5	22.2
	Catheter	81.4	71.5	49.5	33.2	24.8	17.2	14.4

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

The Fistula First Breakthrough Initiative, later renamed Fistula First Catheter Last, was 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 extent of 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 or 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 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 or AV graft at initiation.

ESRD Network 17 (American Samoa, Guam, Mariana Islands, Hawaii, and Northern California) displayed the highest odds of patients using an AV fistula, and of AV fistula or AV graft use, at HD initiation. ESRD Networks 15 (Arizona, Colorado, Nevada, New Mexico, Utah, and Wyoming) and 16 (Alaska, Idaho, Montana, Oregon, and Washington) had outcomes approaching those of ESRD Network 17. ESRD Network 7 (Florida) had the lowest odds of patients using an AV fistula, as well as AV fistula or AV graft, at initiation.

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 (Table 3.6). 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 ESRD Medical Evidence form (CMS 2728), 2016

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	0.05	0.05	0.06	0.07	0.06	0.07
>0 - <6 months	0.27	0.26	0.29	0.29	0.27	0.30
6 - 12 months	0.61	0.59	0.64	0.63	0.60	0.65
>12 months	Ref.			Ref		
Unknown	0.21	0.20	0.22	0.21	0.20	0.23
Age 0-21	0.31	0.23	0.41	0.29	0.22	0.38
22-44	0.85	0.80	0.91	0.80	0.75	0.85
45-64	Ref.			Ref.		
65-74	0.98	0.94	1.02	1.00	0.97	1.05
75+	0.85	0.81	0.89	0.93	0.89	0.97
Sex Female	0.74	0.72	0.77	0.86	0.83	0.89
Male	Ref.			Ref.		
Race						
White	Ref.			Ref.		
Black/African American	0.94	0.91	0.99	1.14	1.09	1.18
American Indian or Alaska Native	1.01	0.86	1.20	1.04	0.88	1.22
Asian	1.07	0.98	1.16	1.08	0.99	1.17
Other or Multiracial	0.97	0.84	1.13	0.98	0.85	1.13
Ethnicity Hispanic	0.97	0.92	1.03	0.94	0.89	1.00
Non-Hispanic	Ref.			Ref		
Diabetes as cause of ESRD	0.96	0.92	0.99	0.98	0.95	1.01
Facility census < 20	Ref.			Ref.		
20-50	0.89	0.85	0.92	0.88	0.85	0.91
51-100	0.79	0.72	0.85	0.74	0.69	0.80
101-200	0.59	0.38	0.91	0.58	0.39	0.86
>200	0.43	0.25	0.74	0.36	0.22	0.60
ESRD network (vs. average network)						
1 CT, ME, MA, NH, RI, VT	1.28	1.18	1.38	1.29	1.20	1.39
2 NY	1.17	1.10	1.25	1.15	1.08	1.22
3 NJ, PR, VI	0.77	0.71	0.84	0.82	0.76	0.89
4 DE, PA	1.04	0.96	1.12	1.03	0.96	1.10
5 VA, WV, MD, DC	0.98	0.91	1.05	0.99	0.92	1.05
6 GA, NC, SC	0.89	0.84	0.94	0.86	0.82	0.91
7 FL	0.71	0.66	0.76	0.71	0.67	0.76
8 AL, MS, TN	0.96	0.89	1.03	0.97	0.91	1.04
9 IN, KY, OH	0.89	0.84	0.95	0.89	0.84	0.94
10 IL	0.91	0.83	0.99	0.94	0.87	1.02
11 MN, MI, ND, SD, WI	0.90	0.84	0.96	0.89	0.84	0.95
12 IA, KS, MO, NE	0.86	0.78	0.93	0.83	0.77	0.90
13 AR, LA, OK	1.02	0.94	1.10	0.94	0.87	1.01
14 TX	0.73	0.69	0.78	0.73	0.69	0.78
15 AZ, CO, NV, NM, UT, WY	1.32	1.22	1.41	1.26	1.17	1.34
16 AK, ID, MT, OR, WA	1.39	1.27	1.51	1.42	1.31	1.54
17 AS, GU, MP, HI, Northern CA	1.42	1.32	1.52	1.57	1.47	1.68
18 Southern CA	1.18	1.11	1.26	1.15	1.08	1.22

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

Of all AV fistulas placed between June 2014 and May 2016, 38.9% failed to mature sufficiently for use in dialysis. Of those that matured and were eventually used, the median time to first use was 108 days (Table 3.7). Younger patients tended toward higher maturation rates, with patients over age 75 displaying higher failure rates than overall. Patients aged 65-74 had the longest median time to first AV fistula use (112 days), while patients aged 22-44 had the shortest (104 days). Males had a higher maturation rate compared to females, as well as shorter time to first use. AV fistula use at initiation of dialysis was lowest among Blacks compared to Whites and other races. Blacks also experienced the highest AV fistula maturation failure rates, compared to other races.

Summary and Conclusion

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 2014-2016 (excludes patients not yet ESRD when fistula was placed), from Medicare claims and CROWNWeb, 2014-2017

	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	86,848	38.9	120	108	73	156
Age						
0-21	345	32.2	123	106	76	148
22-44	9,698	35.4	116	104	69	150
45-64	32,284	37.2	119	106	71	156
65-74	24,697	39.4	123	112	76	159
75+	19,824	42.7	121	109	76	156
Race						
White	54,415	37.9	121	109	75	155
Black/African American	27,154	42.0	120	108	70	160
American Indian or Alaska Native	1,109	31.6	123	113	78	153
Asian	2,980	32.8	113	104	67	146
Native Hawaiian or Pacific Islander	905	33.4	126	110	73	172
Other or Multiracial	241	38.2	114	103	44	153
Unknown	44	34.1	139	121	76	196
Ethnicity						
Hispanic	12,340	33.8	117	105	73	150
Non-Hispanic	73,952	39.7	121	109	73	157
Race/Ethnicity						
Non-Hispanic White	42,406	39.1	122	110	76	157
Non-Hispanic Black/African American	26,657	41.9	120	108	70	159
Sex						
Male	49,393	34.2	116	105	71	148
Female	37,455	45.1	128	115	76	169
Primary Cause of ESRD						
Diabetes	40,722	38.8	123	111	75	160
Hypertension	25,986	38.7	119	108	73	155
Glomerulonephritis	7,621	36.8	113	103	66	148
Cystic kidney	1,489	36.5	113	104	68	148
Other urologic	1,259	35.7	119	107	73	156
Other cause	7,554	42.5	118	107	73	153
Unknown cause	2,217	40.6	119	106	69	155

*Data Source: Special analyses, USRDS ESRD Database. *Fistulas placed between June 1, 2014 and May 31, 2016, with follow-up through May 2017; follow-up is censored at one year after fistula placement date; date of first use was the date the given access was first reported in CROWNWeb to be in used in a particular patient. Abbreviations: AV, arteriovenous; CROWNWeb, Consolidated Renal Operations in a Web-enabled Network; ESRD, end-stage renal disease.*

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Notes

Chapter 4: Hospitalizations, Readmissions, Emergency Department Visits, and Observation Stays

- ESRD patients continue to experience a relatively high frequency of hospitalization, although over the last decade the frequency of admissions has declined. Between 2007 and 2016, adjusted hospital admission rate for dialysis patients declined from 2.0 to 1.7 per patient-year (PPY), a reduction of 15%. During that same period, admission rate for transplant patients declined from 1.0 to 0.8 PPY, a 20% reduction (Figure 4.1).
- Hospitalization rates for HD patients were highest in their first year but fell considerably through the first three years of HD, whereas PD patients generally experienced increasing hospitalization rates over years after dialysis initiation (Figure 4.3).
- All-cause hospitalization rates among adult HD patients decreased by 14.2% from 2007 to 2014 and have remained stable in 2015-2016 (see Table 4.1). Hospitalizations due to cardiovascular events and those for vascular access infection fell by 18.9% and 54.6% from 2007 to 2016, respectively.
- Select patient groups continue to exhibit more frequent hospitalization. For 2015-2016, adjusted hemodialysis (HD) patient hospitalization rates were higher for those aged 22–44 years or 75 years and older, females, and those of Non-Hispanic White or Black/African American race and for those who had diabetes as their primary cause of kidney failure (Table 4.1).
- Among ESRD patients in 2016, more than one in three live hospital discharges were followed by a readmission within 30 days (35.4%), compared to 21.6% for patients with chronic kidney disease (CKD) and only 15.3% for older Medicare beneficiaries without a diagnosis of kidney disease (Figure 4.7).
- The frequency of 30-day readmissions among dialysis patients was stable from 2007-2011 at approximately 39%, fell somewhat in 2012-2013, and has remained at approximately 37% during 2014-2016. Readmissions for transplant patients were approximately 8 percentage points lower but followed a similar time trend (Figure 4.8).
- Dialysis patients frequently visit the emergency department (ED) at rates that have increased over time. Between 2007 and 2016, unadjusted ED visit rates for HD patients increased from 2.6 to 3.0 PPY, while rates for peritoneal dialysis (PD) patients increased from 2.2 to 2.4 PPY, and rates for transplant patients increased from 1.3 to 1.4 PPY (Figure 4.14).
- Observation stays were relatively rare for ESRD patients, but approximately doubled in frequency from 2007-2016. Unadjusted rates of observation stays for HD patients increased from 0.16 to 0.38 PPY, while rates for PD patients increased from 0.12 to 0.25 PPY, and rates for transplant patients increased from 0.08 to 0.15 PPY (Figure 4.17).

Introduction

Hospital admissions, subsequent readmissions, and emergency department visits are a major burden for patients with ESRD. On average, patients with ESRD are admitted to the hospital more than once a year, and more than one in three hospital discharges are followed by a readmission within 30 days. 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: *Healthcare 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 health care use including

hospitalization, readmission, and emergency department visits. Several studies have suggested that a sizable portion of readmissions may be preventable (Coleman et al., 2006; MedPAC, 2007; Rich et al., 1995; Stewart et al., 1999) and emergency department visits could be avoided (Oster and Bindman, 2003; Ballard et al., 2010, University of Michigan Kidney Epidemiology and Cost Center, 2016). Trends in hospitalization, readmission, and emergency department visits broadly reflect health care utilization, may reveal important aspects of quality of care, and help with identification of potential gaps therein, and evaluation of cost-effectiveness of health care.

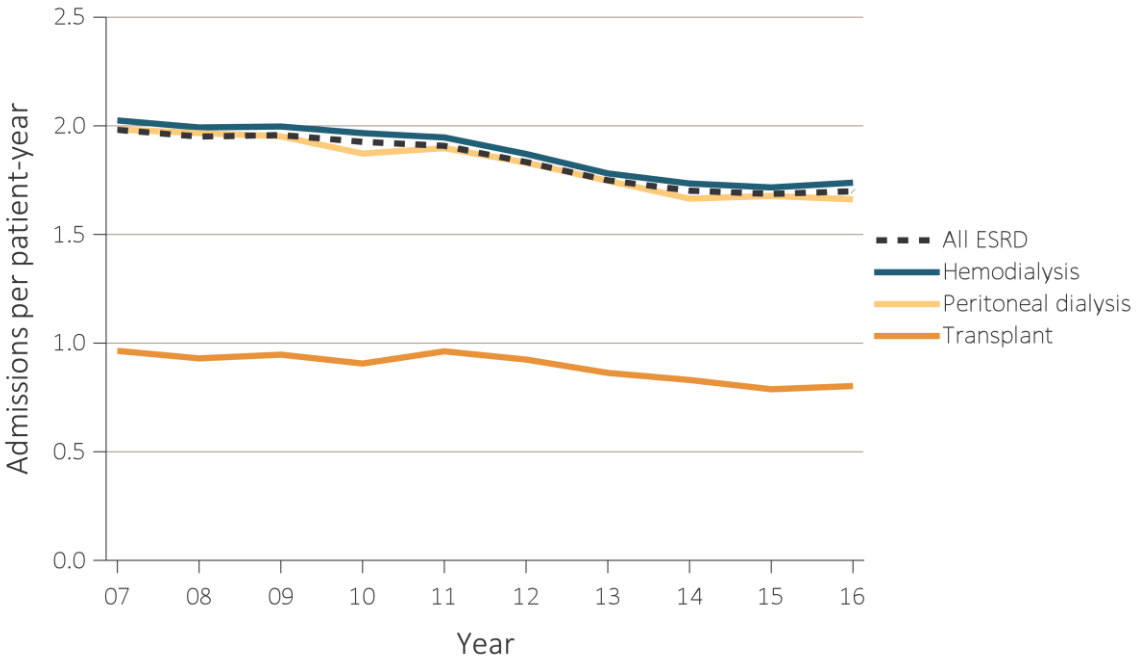
Methods

The findings presented in this chapter were drawn from data sources from the Centers for Medicare & Medicaid Services (CMS). The analyses in this chapter rely on claims data from traditional Medicare (Parts A and B); patients who primarily rely on other sources of health insurance are excluded (e.g. employer/group coverage and Medicare Advantage). Methodological details are described fully in the *Data Sources* 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, see the section on *Chapter 4* in the *ESRD Analytical Methods* 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 gradually declined; in recent years (2014-2016), however, they appear to have stabilized. As shown in Figure 4.1, in 2016 the adjusted rates of admission for HD and PD patients decreased to 1.7 PPY as compared to 2.0 in 2007, a reduction of 15.0%. Over that same period, admission rates for transplant patients fell by 20.0%, from 1.0 in 2007, to 0.8 PPY in 2016.

vol 2 Figure 4.1 Adjusted hospitalization rates for ESRD patients, by treatment modality, 2007-2016



Data Source: Special analyses, USRDS ESRD Database. Period prevalent ESRD patients; adjusted for age, sex, race, ethnicity, primary cause of kidney failure, and vintage; 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 topic, with a focus on hospitalizations resulting from infections and cardiovascular conditions. Hospitalizations for these causes have also declined over the 2007-2016 period, albeit the declines in these categories are less than the decline in all-cause hospitalization (see Figure 4.2). The decline in hospitalizations due to infection was most pronounced among patients receiving PD from 2007 to 2014. These improvements likely reflect, at least in part, greater attention to infection control practices among dialysis patient, particularly in those on peritoneal dialysis.

vol 2 Figure 4.2 Adjusted all-cause & cause-specific hospitalization rates for ESRD patients, by treatment modality, 2007-2016

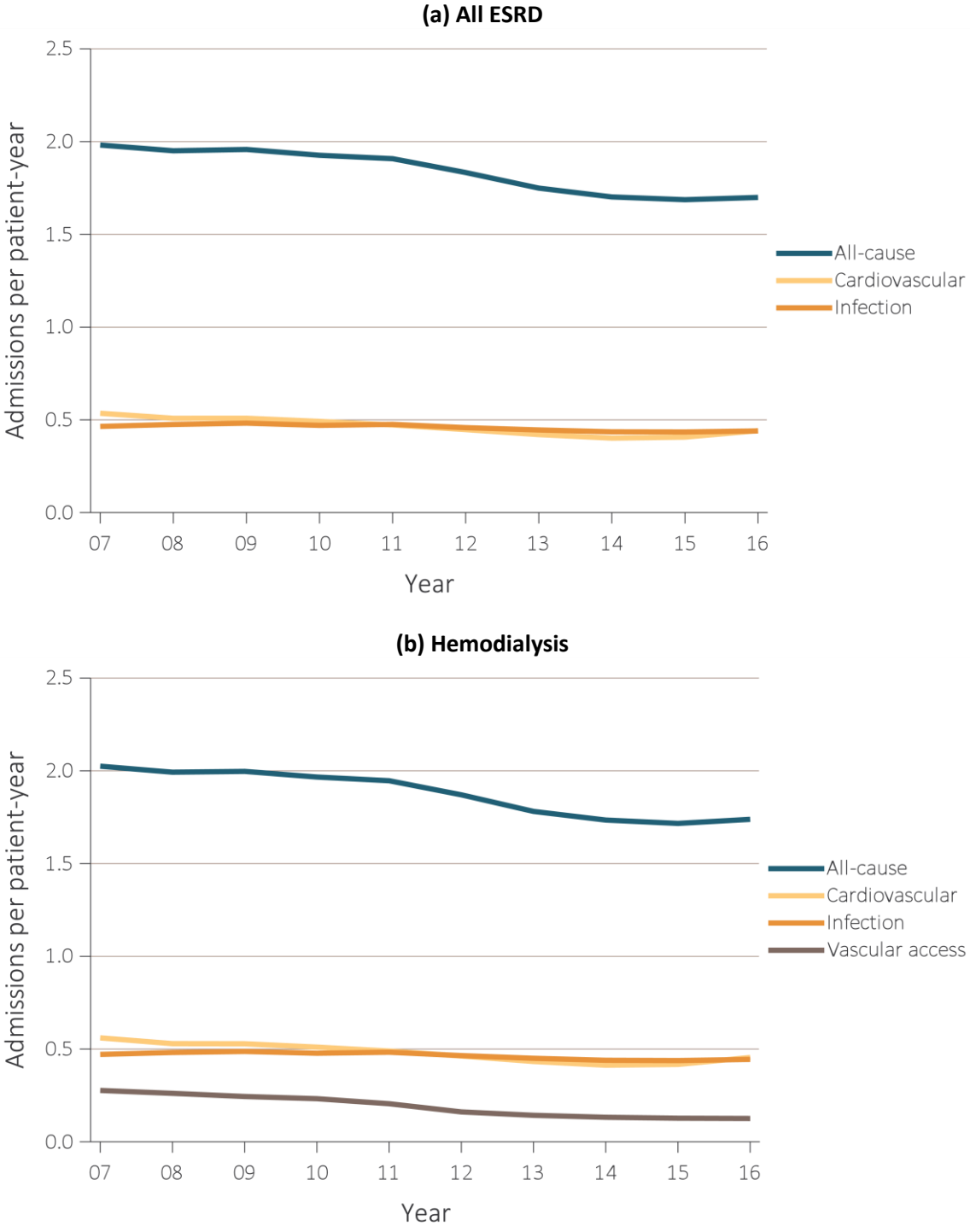
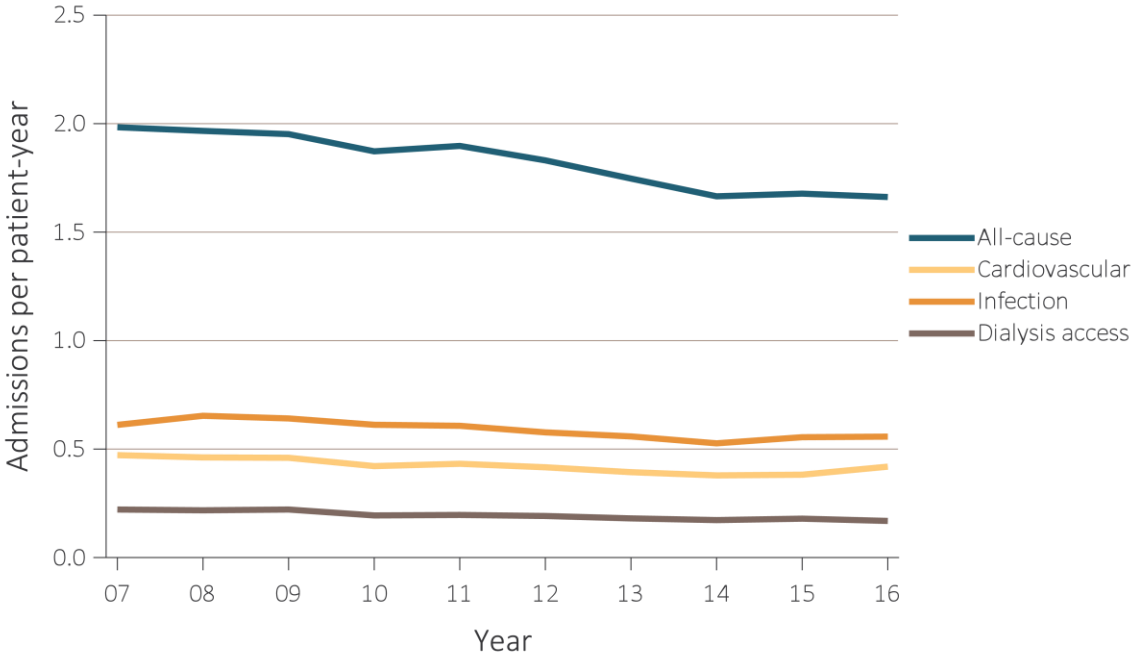


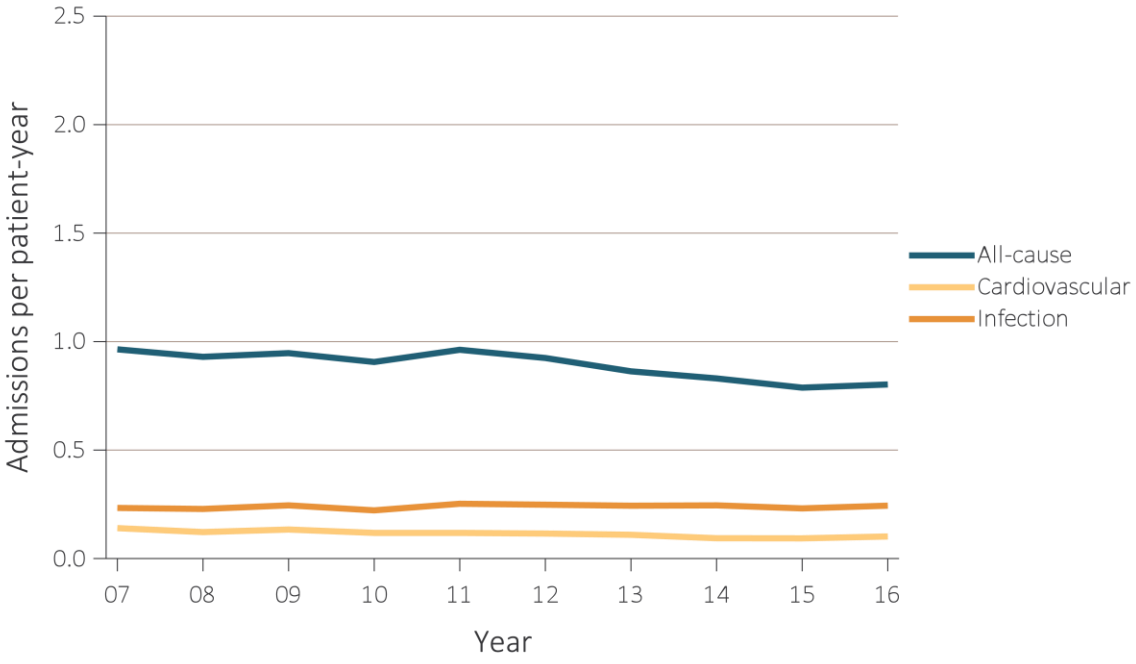
Figure 4.2 continued on next page.

vol 2 Figure 4.2 Adjusted all-cause & cause-specific hospitalization rates for ESRD patients, by treatment modality, 2007-2016 (continued)

(c) Peritoneal dialysis



(d) Transplant



Data Source: Special analyses, USRDS ESRD Database. Period prevalent ESRD patients; adjusted for age, sex, race, ethnicity, primary cause of kidney failure, and vintage; standard population: ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease.

All-cause hospitalization rates among adult HD patients decreased by 14.2% from 2007 to 2014 and have remained stable in 2015-2016 (see Table 4.1). Hospitalizations due to cardiovascular events and those for vascular access infection fell by 18.9% and 54.6% from 2007 to 2016. Patient groups with a higher risk of overall hospitalization included those aged 22–44 years or 75 years and older, females, and those of Non-Hispanic 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. In the most recent data, it appears hospitalization rates have stabilized and are no longer declining.

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). Incident HD patients in more recent cohorts consistently experienced lower hospitalization rates throughout their time on HD than did previous cohorts. Incident HD patients in 2014 had a relatively low hospitalization rate of 1.9 PPY during their first year of treatment, compared to the previous cohorts, who experienced hospitalization rates of 2.2-2.4 PPY in the first year of HD (Figure 4.3.a).

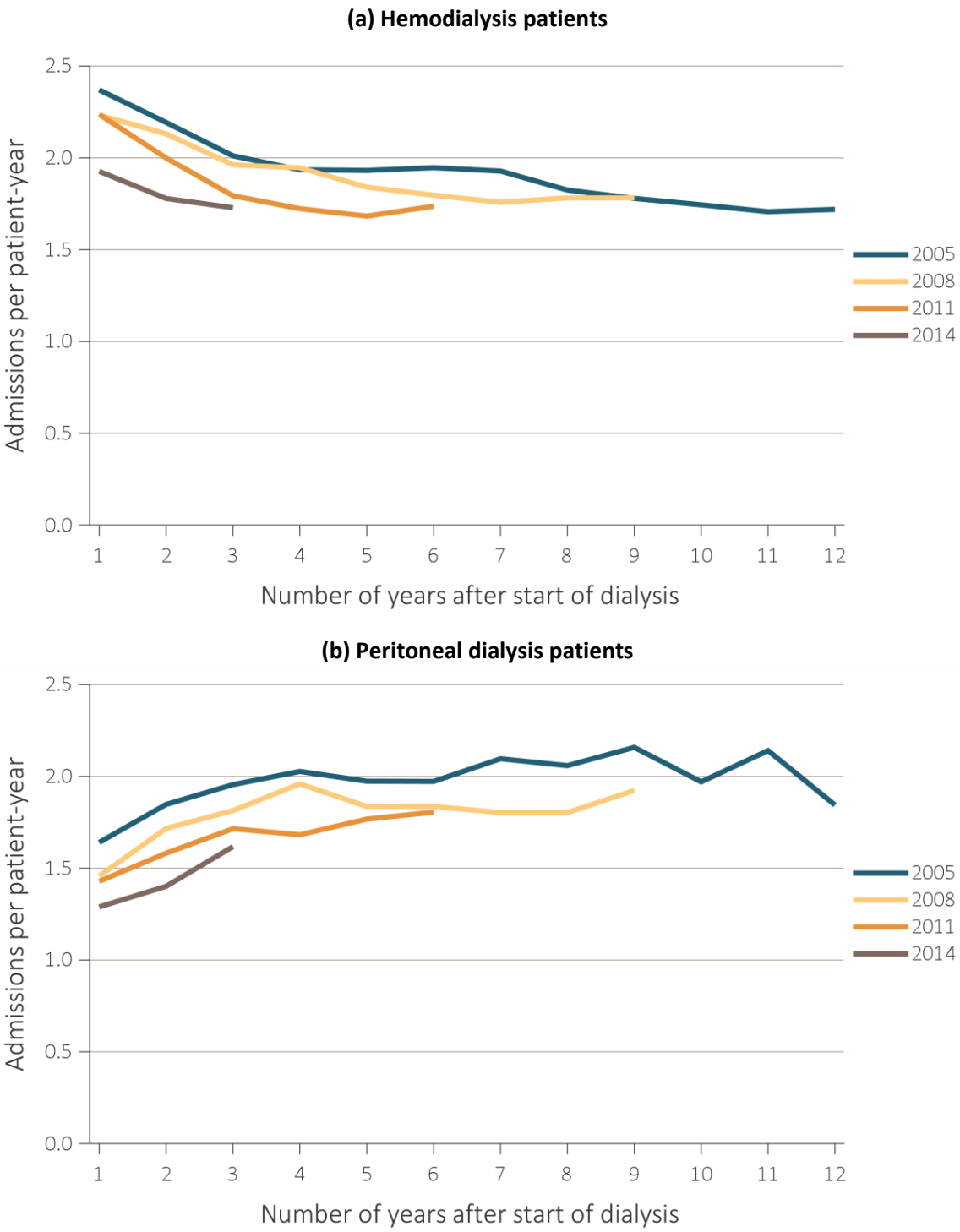
While patients on HD experienced falling hospitalization rates as they accumulated time on dialysis, PD patients saw rising hospitalization rates. However, recent cohorts of incident PD patients still had fewer hospitalizations overall than did the older cohorts. Incident PD patients in 2014 had 1.3 hospitalizations PPY, rising to 1.6 PPY by the third year of PD (Figure 4.3.b).

vol 2 Table 4.1 Adjusted rates of all-cause & cause-specific hospitalization per patient-year for adult hemodialysis patients, 2007-2016

	All	Cardiovascular	Any infection	Vascular access infection
2007-2008	1.99	0.53	0.48	0.26
2009-2010	1.97	0.51	0.48	0.23
2011-2012	1.87	0.46	0.46	0.16
2013-2014	1.74	0.41	0.44	0.13
2015-2016	1.74	0.46	0.44	0.13
2015-2016, by patient characteristics				
Age				
22-44	1.98	0.43	0.46	0.16
45-64	1.71	0.44	0.43	0.12
65-74	1.71	0.47	0.44	0.11
75+	1.75	0.48	0.47	0.12
Sex				
Male	1.60	0.43	0.42	0.11
Female	1.92	0.48	0.48	0.15
Race				
White	1.76	0.45	0.47	0.12
Black/African American	1.75	0.47	0.42	0.14
American Indian or Alaska Native	1.50	0.32	0.46	0.07
Asian	1.21	0.33	0.32	0.09
Native Hawaiian or Pacific Islander	1.29	0.33	0.38	0.10
Other or Multiracial	1.52	0.40	0.44	0.13
Ethnicity				
Hispanic	1.56	0.41	0.42	0.12
Non-Hispanic	1.78	0.47	0.45	0.13
Non-Hispanic White	1.88	0.48	0.50	0.12
Non-Hispanic Black/African American	1.76	0.47	0.42	0.14
Cause of renal failure				
Diabetes	1.95	0.51	0.50	0.13
Hypertension	1.61	0.46	0.38	0.12
Glomerulonephritis	1.51	0.38	0.38	0.12
Other cause	1.70	0.38	0.47	0.13
Vintage				
<1 year	1.81	0.46	0.50	0.14
1-<2 years	1.73	0.45	0.43	0.11
2-<5 years	1.72	0.46	0.42	0.10
5+ years	1.73	0.45	0.45	0.14

Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients aged 22 & older; adjusted for age, sex, race, ethnicity, primary cause of kidney failure, and vintage; standard population: ESRD patients, 2011. See Vol. 2, ESRD Analytical Methods for principal ICD-9-CM and ICD-10-CM diagnosis codes included in each cause of hospitalization category. Abbreviation: ESRD, end-stage renal disease.

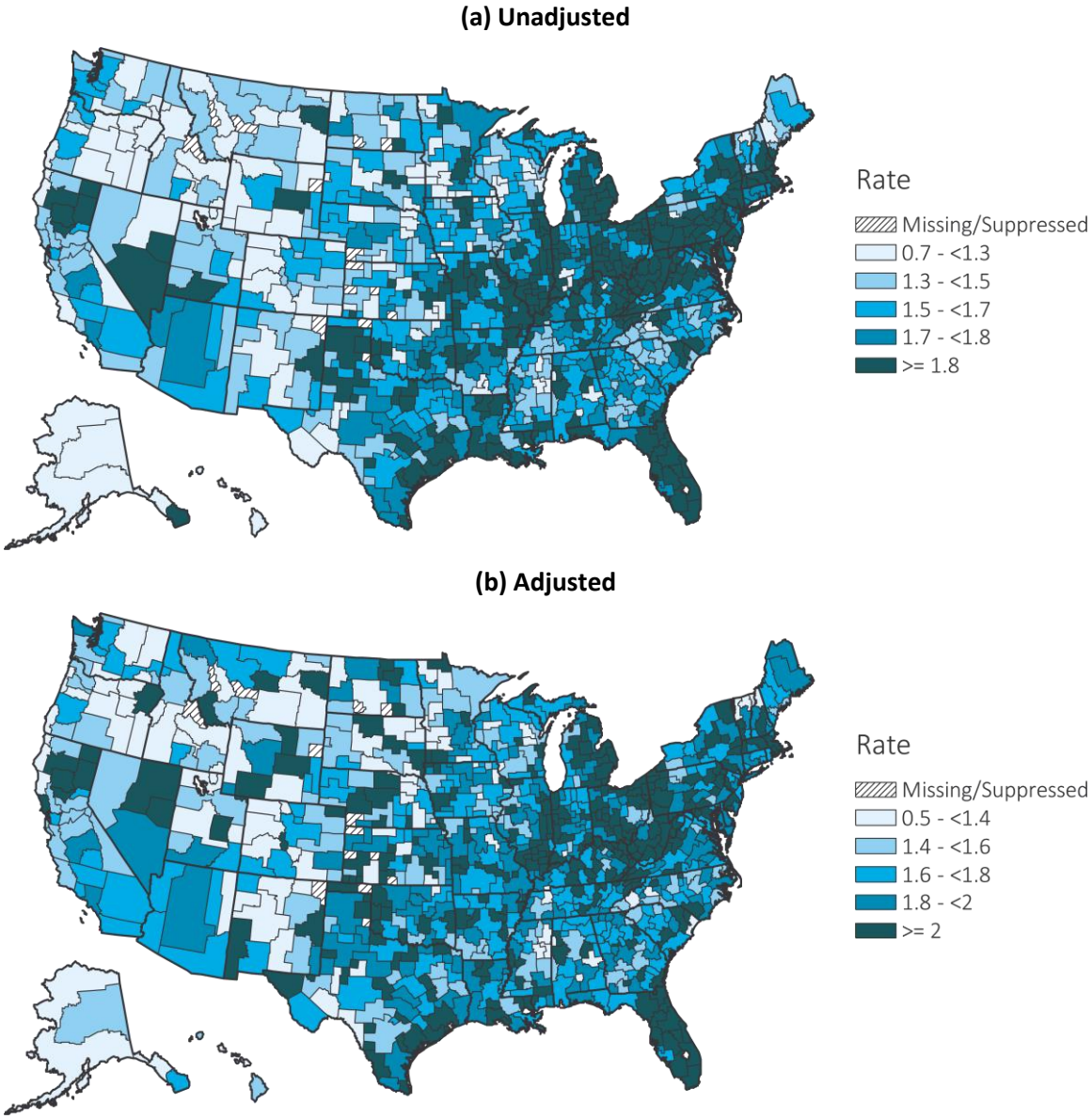
vol 2 Figure 4.3 Adjusted all-cause hospitalization rates by treatment modality and number of years after start of dialysis, for cohorts of incident patients in 2005, 2008, 2011, and 2014



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. Abbreviation: ESRD, end-stage renal disease.

The 2013-2016 unadjusted hospitalization rates among patients with ESRD varied considerably across 805 U.S. Health Service Areas (HSAs), from a low of 0.7 PPY in Mitchell County in Iowa to a high of 2.7 PPY in Letcher County in Kentucky (interquartile range: 0.4 PPY; Figure 4.4.a). The rates were generally highest in a wide band stretching from the Midwest through the Northeast. After adjusting for demographic differences among the HSAs, we find adjusted hospitalization rates were somewhat attenuated in several HSAs in the Midwest and Northeast; states in the western United States continued to have generally lower hospitalization rates, but several HSAs in this region appear to compare less favorably after demographic adjustment (Figure 4.4.b).

vol 2 Figure 4.4 Map of the hospitalization rates of ESRD, by Health Service Area, in the U.S. population, 2013-2016

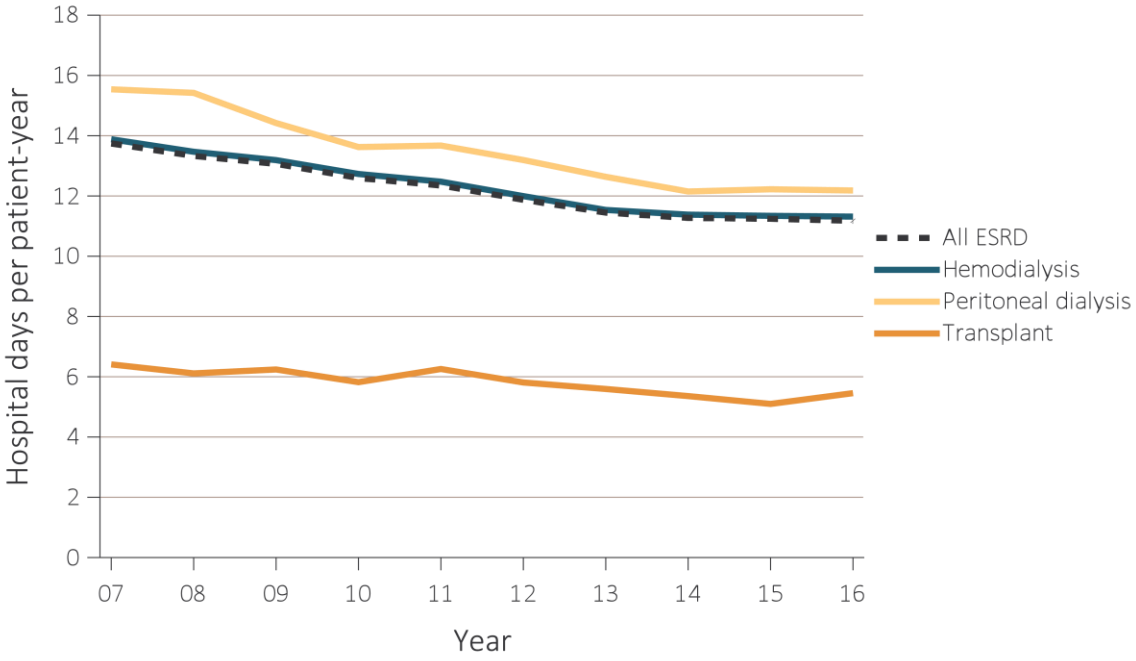


Data Source: Special analyses, USRDS ESRD Database. Period prevalent ESRD patients; adjusted for age, sex, race, ethnicity, primary cause of kidney failure, and vintage; standard population: ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease.

Hospital Days

Continuing a downward trend observed since 2007, the number of total hospital days among all patients with ESRD has decreased from 13.7 PPY to 11.2 PPY (Figure 4.5). From 2007 to 2016, hospital days PPY decreased from 13.9 to 11.3 for HD patients, from 15.5 to 12.2 for PD patients, and from 6.4 to 5.5 days for those with a functioning kidney transplant. Most of the decline in hospital days during 2007-2016 occurred during 2007-2014, similar to the trends observed above for hospital admissions.

vol 2 Figure 4.5 Adjusted hospital days for ESRD patients, by treatment modality, 2007-2016



Data Source: Special analyses, USRDS ESRD Database. Period prevalent ESRD patients; adjusted for age, sex, race, ethnicity, primary cause of kidney failure, and vintage; standard population: ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease.

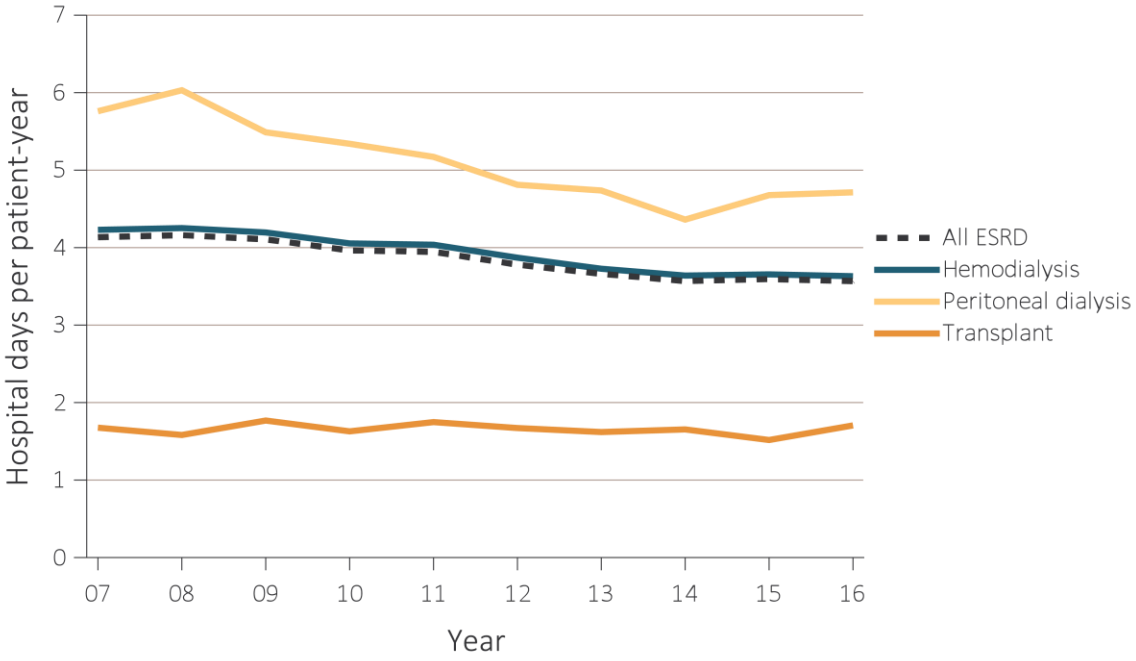
With adjustment for differences in patient characteristics, from 2007-2016 the number of infection-related hospital days decreased by 14.1% for HD patients, 18.2% for those on PD, and increased by 1.8% for patients with a kidney transplant (Figure 4.6.a). From 2007-2016, the number of inpatient days for cardiovascular hospitalization for all patients with ESRD fell from 3.1 days to 2.2 days, a decline of 28.1%; however, since 2014 the number of inpatient days due to cardiovascular hospitalization has increased from 2.2 days in 2014 to 2.6 days in 2016 (Figure 4.6.b). However, this increase in cardiovascular inpatient days is not accompanied by a corresponding increase in all-cause inpatient days, which have been relatively stables since 2013. The increase in cardiovascular inpatient days may be reflective of changes in hospital diagnosis coding practices with the national transition from ICD-9-CM to ICD-10-CM in October 2015; however, this requires further investigation and monitoring.

The number of inpatient days for cardiovascular hospitalization fell by 29.8% for those with a transplant during 2007-2016 (Figure 4.6.b).

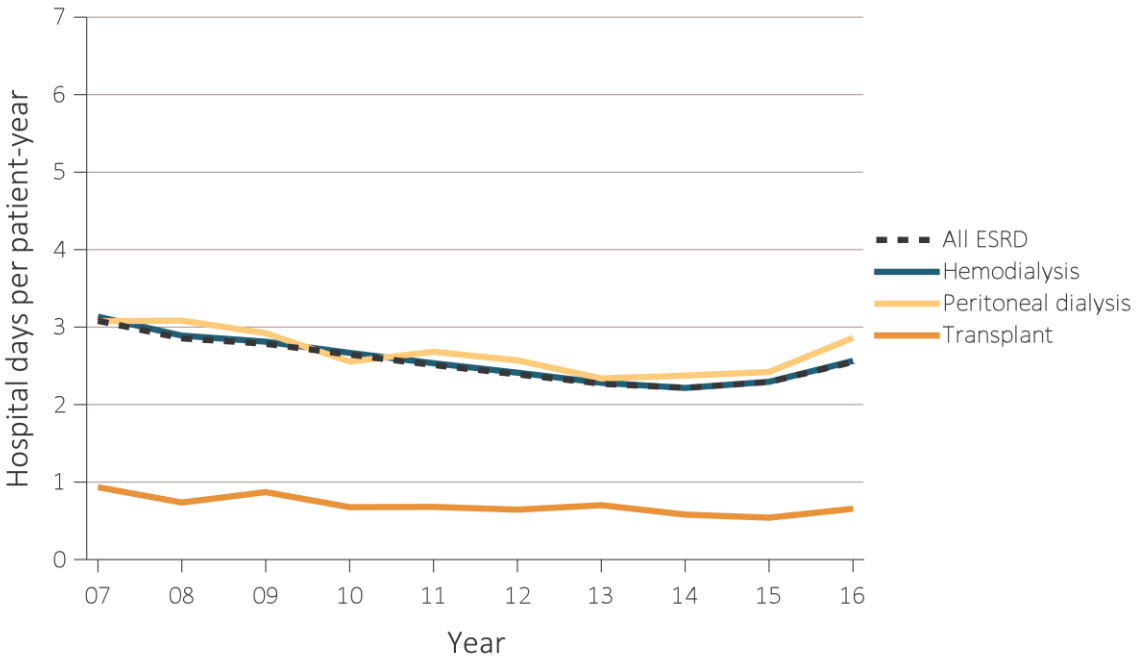
Even after adjustment, the number of hospital days due to infections and cardiovascular events for patients on dialysis were more than twice that of those with a transplant. For HD and PD patients in 2016, infection-related hospital days were 3.6 and 4.7 PPY, compared to 1.7 PPY for transplant recipients. Hospital days for cardiovascular admissions were approximately four times more frequent for patients on dialysis than for those with a transplant—2.6 and 2.9 PPY for HD and PD patients, as compared to 0.7 PPY for transplant recipients.

vol 2 Figure 4.6 Adjusted hospital days for infection & cardiovascular causes, for ESRD patients by their treatment modality, 2007-2016

(a) Infection



(b) Cardiovascular



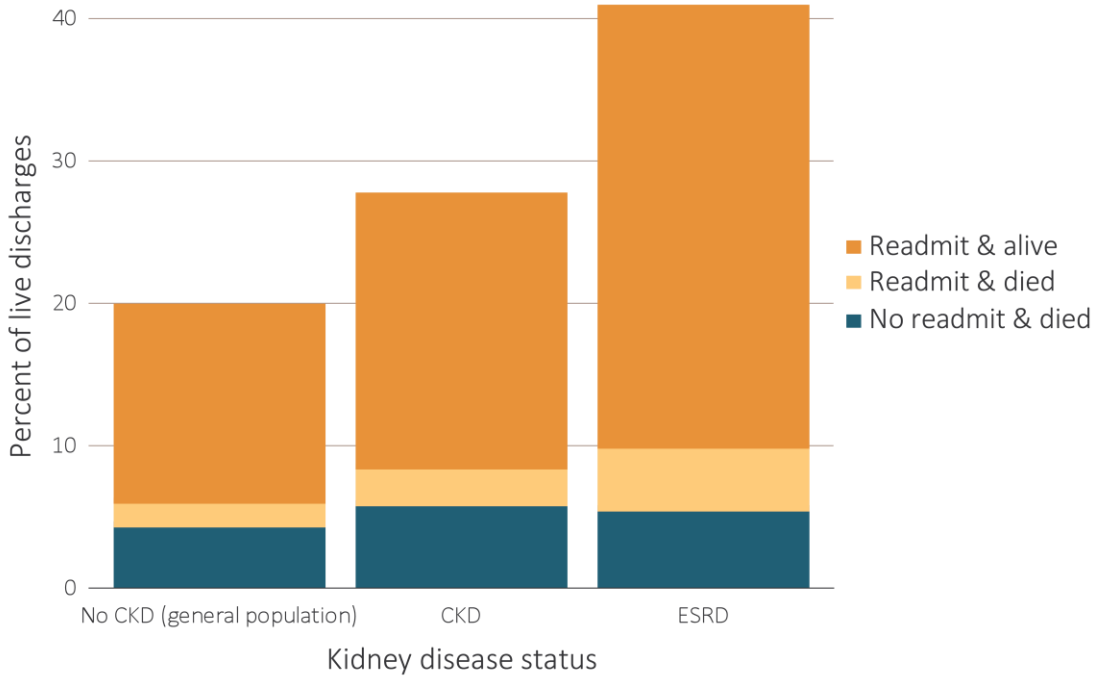
Data Source: Special analyses, USRDS ESRD Database. Period prevalent ESRD patients, adjusted for age, sex, race, ethnicity, primary cause of kidney failure, and vintage; standard population: ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease.

Readmission

Readmissions following a hospital discharge are an important predictor of subsequent adverse clinical events, both in the general and ESRD populations, and may also be related to quality and coordination of care at the time of discharge. Among dialysis patients, readmissions 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, 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 30-day readmissions following 21.6% and 35.4% of hospital discharges, respectively, as compared to only 15.3% of older Medicare beneficiaries without a diagnosis of kidney disease (Figure 4.7). This held true for the combined outcome of post-discharge death and/or readmission—experienced by 27.6% of CKD patients and 41.0% of those with ESRD, versus only 19.8% 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 readmitted or died within 30 days of discharge, by kidney disease status, 2016



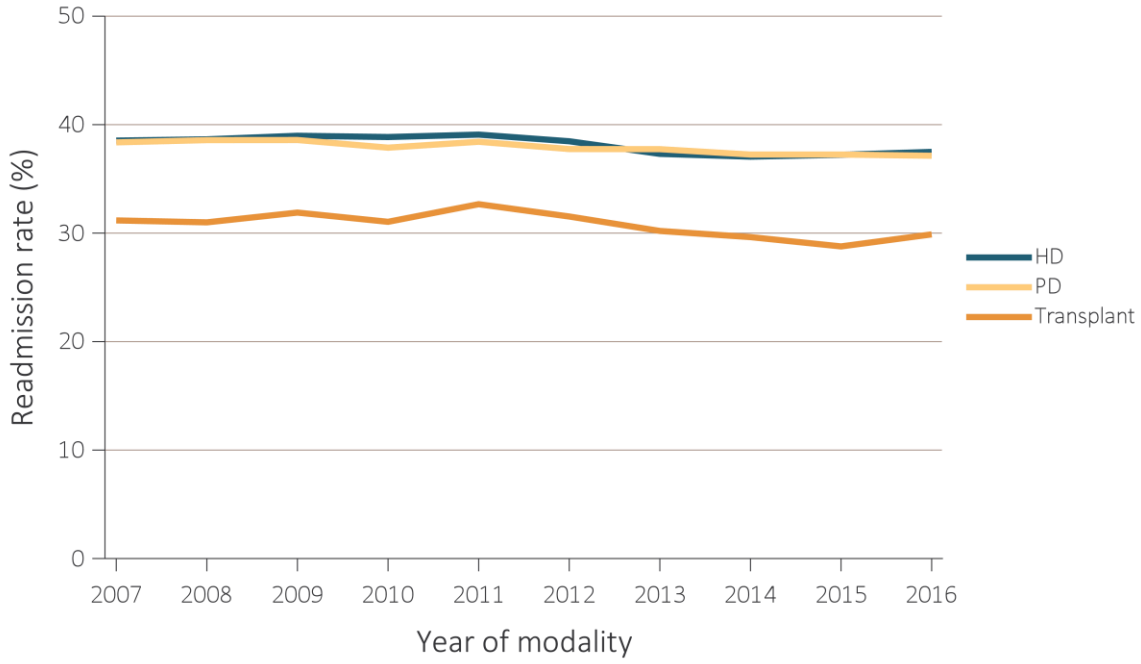
Data Source: Special analyses, USRDS ESRD Database and Medicare 5% sample. January 1, 2016 point prevalent Medicare patients aged 66 & older on December 31, 2016. For general Medicare: January 1, 2016 point prevalent, Medicare patients aged 66 & older, discharged alive from an all-cause index hospitalization between January 1, 2016, and December 1, 2016, unadjusted. CKD determined using claims for 2016. Abbreviations: CKD, chronic kidney disease; ESRD, end-stage renal disease; readmit, readmission.

The frequency of 30-day readmissions for dialysis patients that was stable from 2007-2011 at approximately 39%, fell somewhat in 2012-2013, and has remained at approximately 37% during 2014-2016 (Figure 4.8). Readmissions for transplant patients were approximately 8 percentage points lower but followed a similar time trend. The timing of the decline in readmissions corresponds to declines observed in the broader Medicare fee-for-service population in response to the Medicare Hospital Readmissions Reduction Program (Zuckerman et al., 2016).

Beginning in 2015, the Centers for Medicare & Medicaid Services began using risk-adjusted measures of readmissions for public reporting on the Dialysis Facility Compare website and for value-based purchasing as part of the ESRD Quality Incentive

Program (QIP). So far, we observe no clear immediate changes in national readmissions occurring with the initial implementation of these programs in 2015-2016 relative to 2013-2014. The response to these programs may change over time as patients and health care providers gain experience with the programs and the use of readmission as a quality measure.

vol 2 Figure 4.8 Proportion of ESRD patients readmitted within 30 days, by treatment modality, 2007-2016



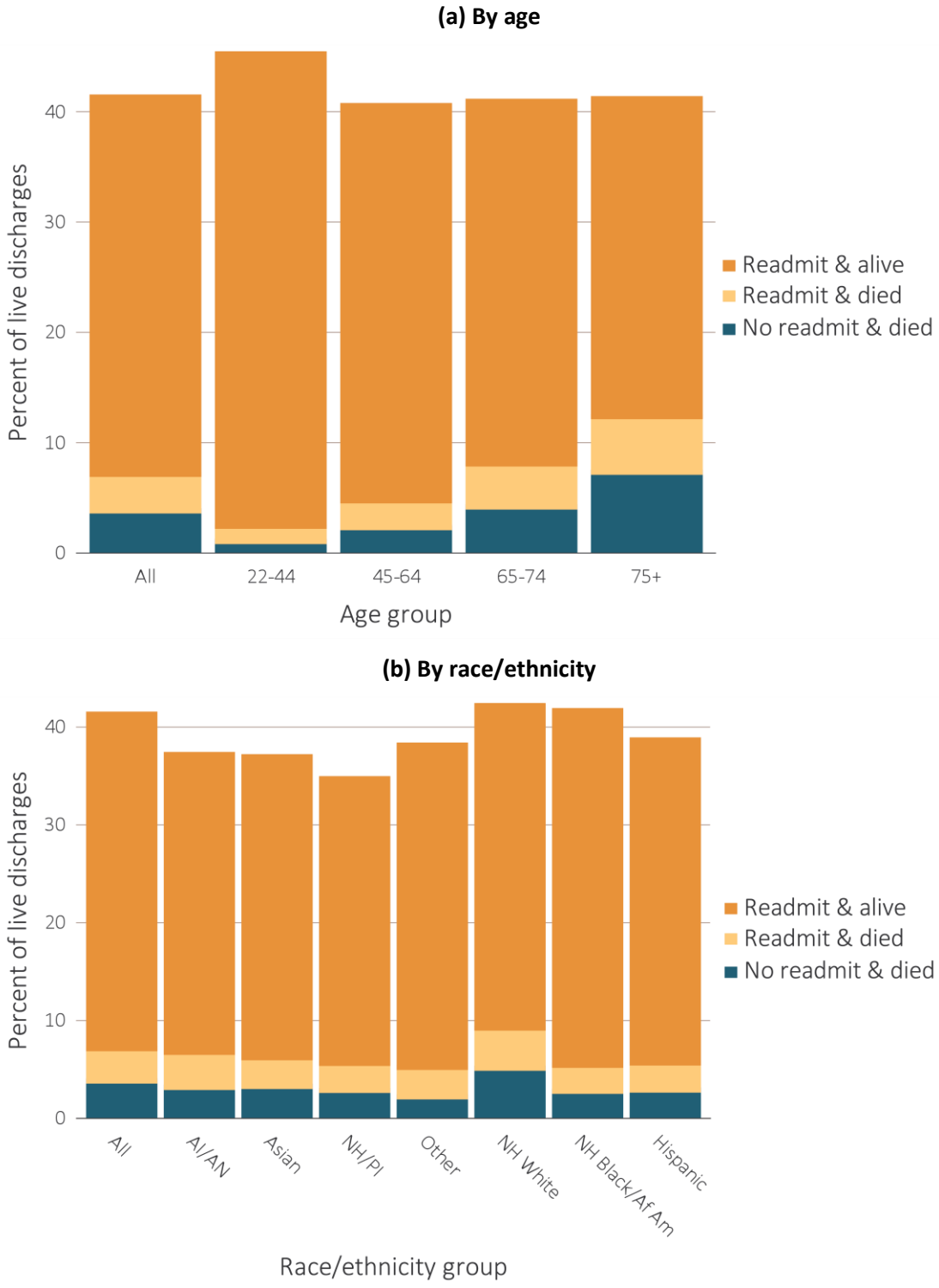
Data Source: Special analyses, USRDS ESRD Database. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis.

Among HD patients prevalent in 2016, 37.5% of discharges from a hospitalization for any cause were followed by a readmission within 30 days (see Figure 4.9.a). For older patients, readmissions were observed to be less frequent; however, mortality was observed to be more frequent, illustrating these competing risks, as death precludes readmission. Not surprisingly, rate of post-discharge death without readmission, for example, was the highest in patients aged 75 years and older, at 7.3%, while these patients had the lowest occurrence of readmission, at 33.8%.

The highest proportion of readmission 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 readmission followed by either survival or death, the highest proportion was again seen among patients aged 22–44 years, at 44.4%. The proportion surviving following readmission exceeded the two combined death outcomes for all age groups (34.1% vs. 7.1%), even in patients aged 75 and older, at 28.8% and 12.4%. These data illustrate that the observed, elevated proportion being readmitted among younger versus older cohorts was not entirely due to the competing risk of mortality in the aged.

We examined the proportion of HD patients discharged alive who were either readmitted or died within 30 days of discharge, by race and ethnicity (Figure 4.9.b). The highest proportions being readmitted were observed among Non-Hispanic Blacks—36.2% were readmitted and lived while 38.9% were readmitted with the combined outcome of either survival or death. They were followed by the Other or Multiracial group (32.9% vs. 35.9%). The lowest such rates occurred among Native Hawaiians and Pacific Islanders, of whom 29.1% were readmitted and lived, and 31.9% were readmitted with the combined outcome of either survival or death. The highest proportion of post-discharge deaths occurred among Non-Hispanic White HD patients at 9.2%, possibly influenced by the older average age among this group.

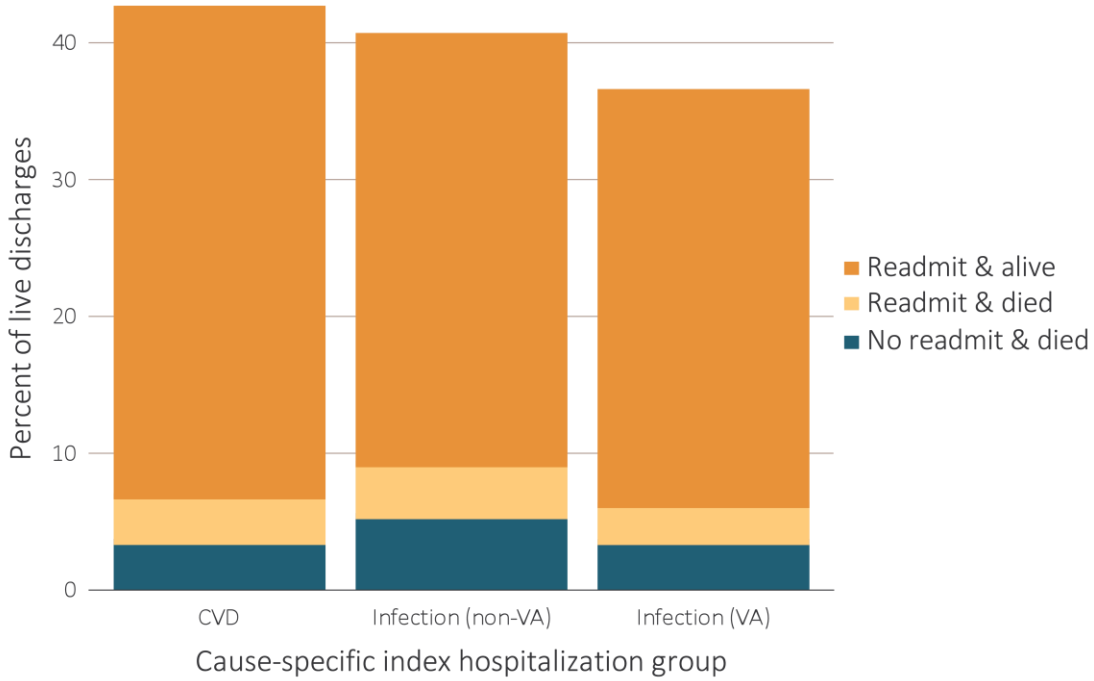
vol 2 Figure 4.9 Proportion of hemodialysis patients discharged alive from the hospital who either were readmitted or died within 30 days of discharge, by demographic characteristics, 2016



Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients, all ages, 2016, 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, 2016. Cause-specific hospitalizations are defined by principal ICD-10-CM codes. See Vol. 2, ESRD Analytical Methods for principal ICD-10-CM diagnosis codes included in each cause of hospitalization category. Abbreviations: Af Am, African American; AI, American Indian; AN, Alaska Native; ESRD, end-stage renal disease; 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; readmit, readmission.

For HD patients in 2016, the proportion of all-cause readmission was 37.5% (Figure 4.9.a). For index hospitalizations due to cardiovascular conditions, infections, and vascular access infections, 39.2%, 35.1%, and 32.9% of these patients were readmitted within 30 days (Figure 4.10), respectively.

vol 2 Figure 4.10 Proportion of hemodialysis patients discharged alive that either were readmitted or died within 30 days of discharge, by cause of index hospitalization, 2016



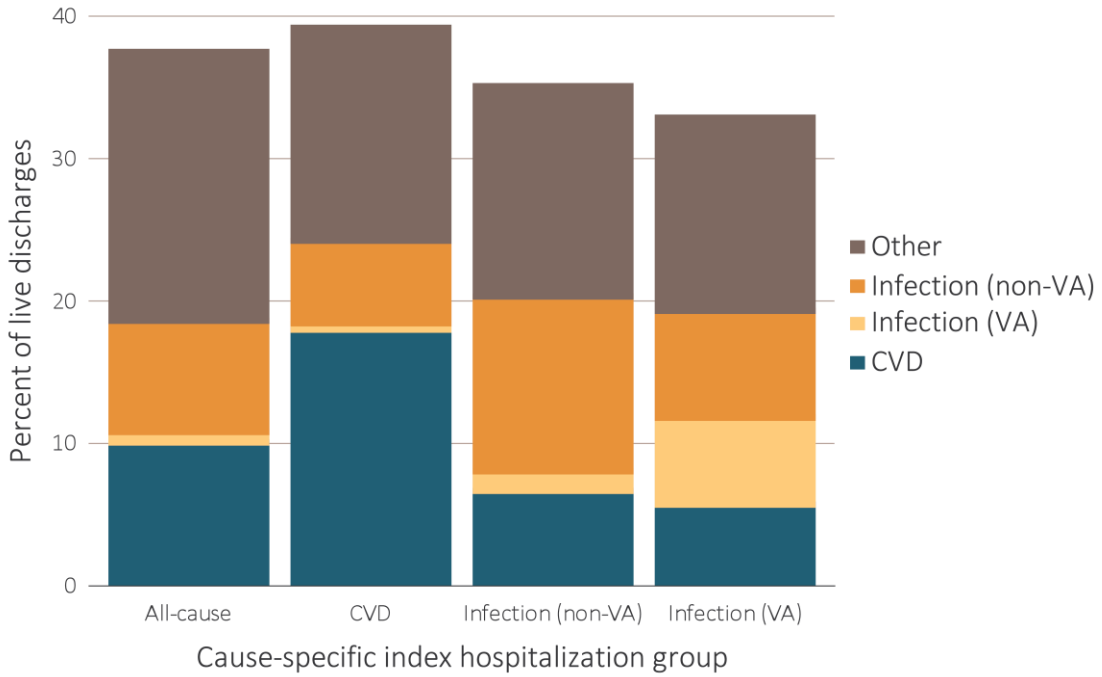
Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients, all ages, 2016, unadjusted. Includes live hospital discharges from January 1 to December 1, 2016. Cause-specific hospitalizations are defined by principal ICD-10-CM codes. See Vol. 2, ESRD Analytical Methods for principal ICD-10-CM diagnosis codes included in each cause of hospitalization category. Abbreviations: CVD, cardiovascular disease; ESRD, end-stage renal disease; readmit, readmission; VA, vascular access.

Figure 4.11 illustrates that readmission in the 30 days following a hospital discharge does not always result from a similar diagnostic cause as the index hospitalization.

During 2016, of those admitted for treatment of cardiovascular issues and then soon readmitted, nearly half (45.8%) were admitted to treat the same or another cardiovascular condition. However, this pattern differed for those initially hospitalized to address vascular access infection (18.5%), and other types of infections (34.9%). The proportion of cause-specific readmission among those with all-cause index hospitalization were also fairly low—only 26.8% returned for additional cardiovascular treatment, 2.0% for vascular access infection, and 20.8% to address other types of infection.

The patterns of readmission 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 4.11 Proportion of hemodialysis patients with cause-specific readmissions within 30 days of discharge, by cause of index hospitalization, 2016

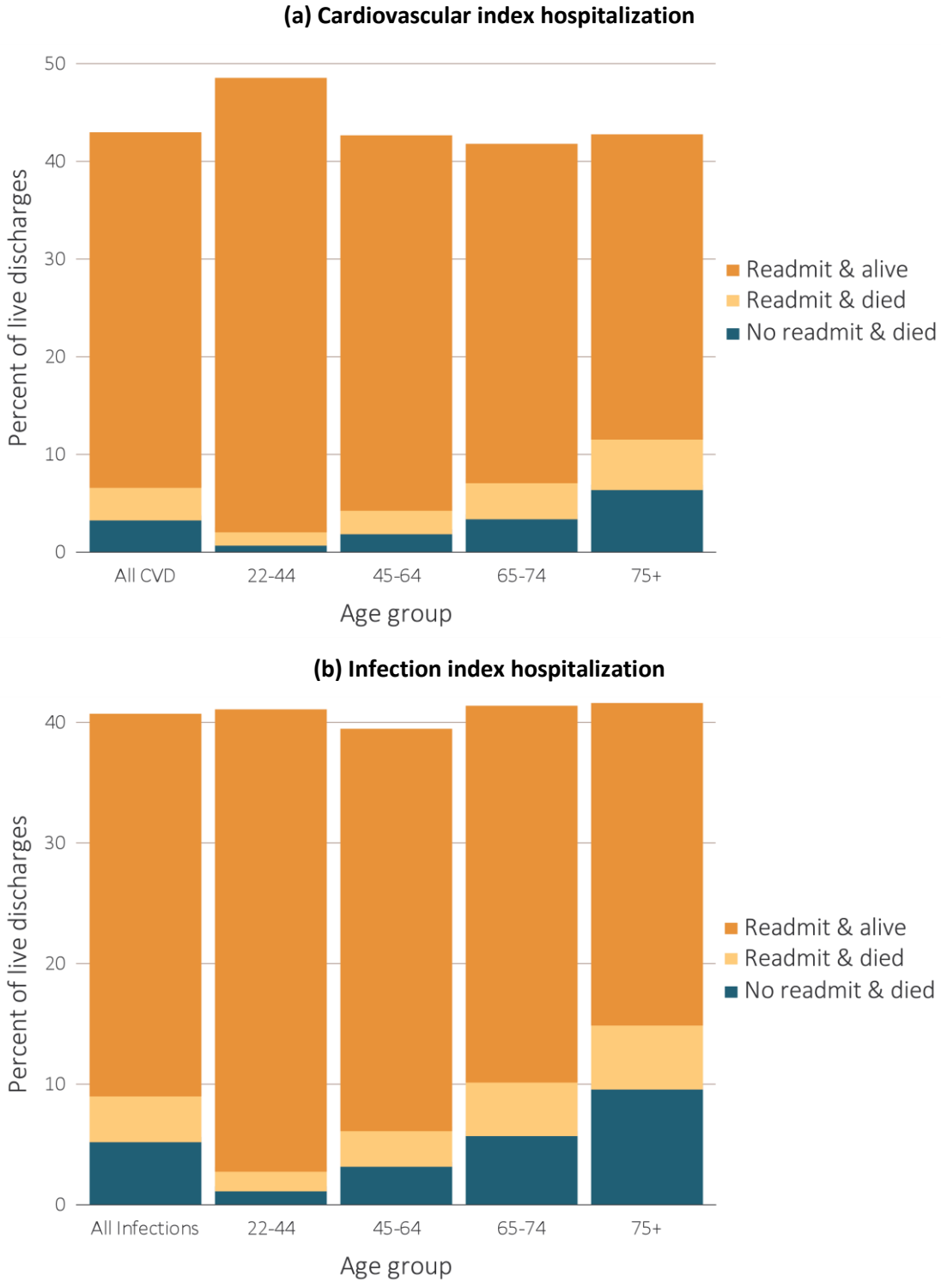


Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients, all ages, 2016, unadjusted. Includes live hospital discharges from January 1 to December 1, 2016. Cause-specific hospitalizations are defined by principal ICD-10-CM codes. See Vol. 2, ESRD Analytical Methods for principal ICD-10-CM diagnosis codes included in each cause of hospitalization category. Abbreviations: CVD, cardiovascular disease; ESRD, end-stage renal disease; VA, vascular access.

Readmissions following discharge from a cardiovascular index hospitalization were slightly higher among younger adults compared with all other age groups, for whom the readmission appeared similar. For those aged 22–44, for example, 47.3% of such discharges were followed by a readmission within 30 days (Figure 4.12.a). In general, these rates mirrored those for all-cause index hospitalizations as seen in Figure 4.9.a, although the rates in Figure 4.12.a for those aged 22-44 were slightly higher.

Similarly, readmission following discharge from an infection index hospitalization followed the same trend among the age groups. In those aged 22-44, 39.5% of these discharges were followed by a readmission within 30 days (Figure 4.12.b). Generally, as age increased, the frequency of readmission slightly decreased while the frequency of patients dying within the 30 days after discharge without a readmission increased.

vol 2 Figure 4.12 Proportion of hemodialysis patients discharged alive who were either readmitted or died within 30 days of discharge for (a) cardiovascular index hospitalization and (b) infection index hospitalization, by age, 2016

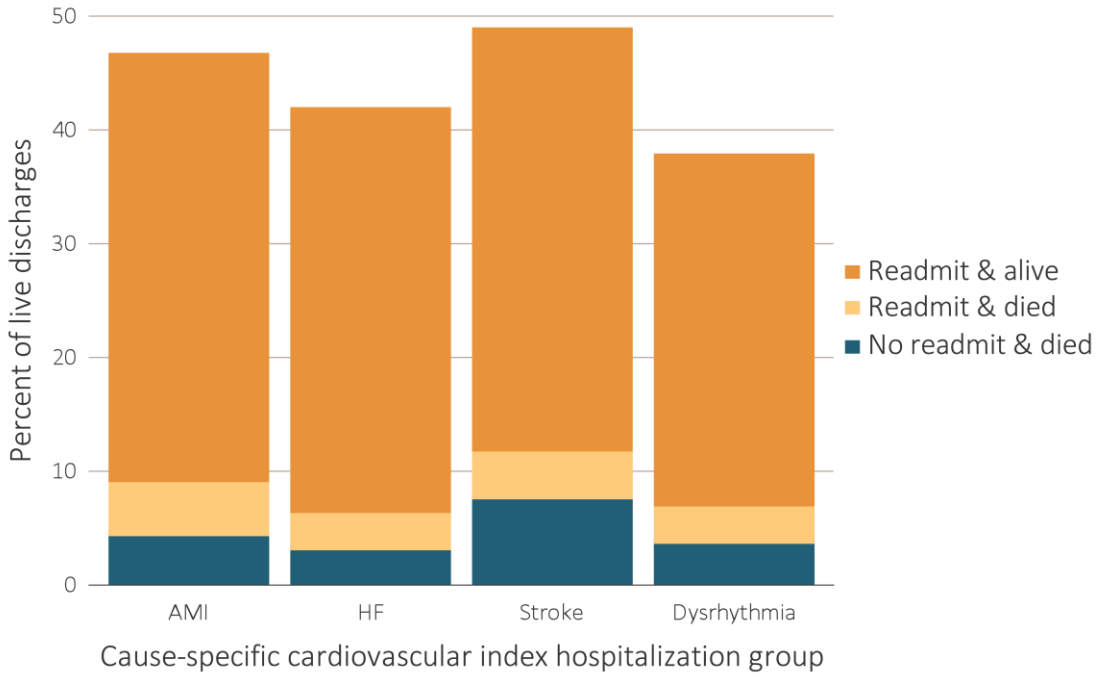


Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients, all ages, 2016, unadjusted. Patients less than age 22 are not represented as a group due to insufficient sample size. Includes live hospital discharges from January 1 to December 1, 2016. Cause-specific hospitalizations are defined by principal ICD-10-CM codes. See Vol. 2, ESRD Analytical Methods for principal ICD-10-CM diagnosis codes included in each cause of hospitalization category. Abbreviation: ESRD, end-stage renal disease; readmit, readmission.

In subgroups of cardiovascular index hospitalizations (Figure 4.13), readmission occurred most frequently following discharge from treatment of acute myocardial infarction (AMI), at 41.9%, and stroke, at 40.9%. The lowest frequency of readmission occurred following discharge after dysrhythmia, at 33.8%. When not readmitted, stroke patients had the highest post-discharge mortality, with 7.8% dying within 30 days of discharge.

As comorbid cardiovascular disease and its complications have a critical interaction with kidney disease of all types, this 2018 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 4.13 Proportion of hemodialysis patients discharged alive who were either readmitted or died within 30 days of discharge for cardiovascular index hospitalization, by cause-specific cardiovascular index hospitalization, 2016



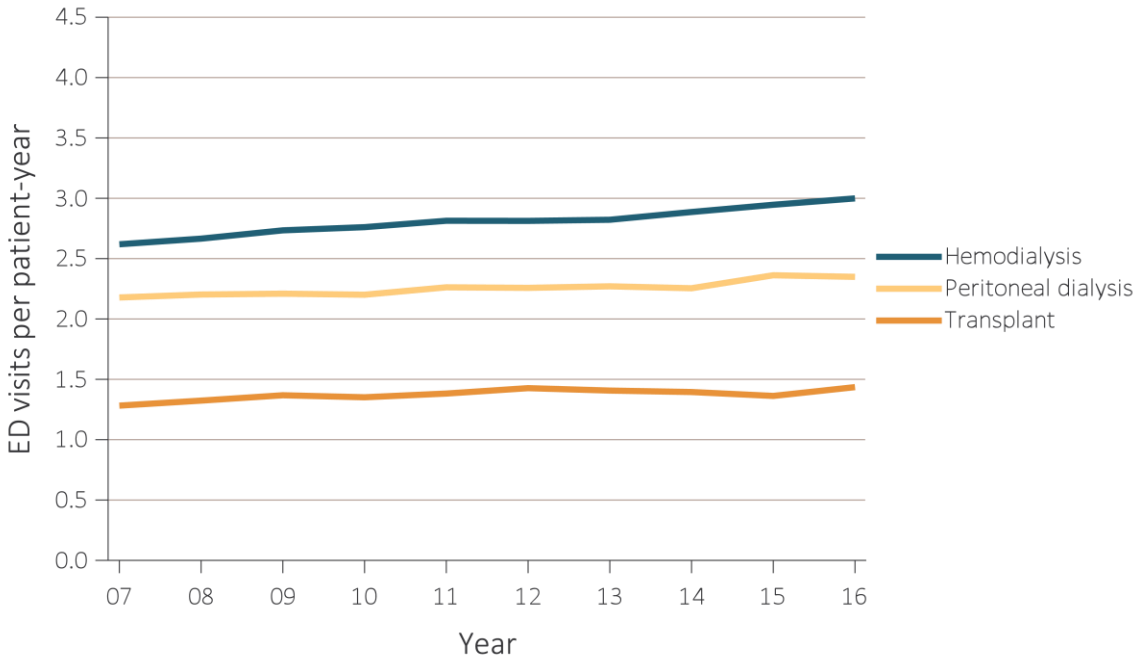
Data Source: Special analyses, USRDS ESRD Database. Period prevalent hemodialysis patients, all ages, 2016, unadjusted. Includes live hospital discharges from January 1 to December 1, 2016. Cause-specific hospitalizations are defined by principal ICD-10-CM codes. See Vol. 2, ESRD Analytical Methods for principal ICD-10-CM diagnosis codes included in each cause of hospitalization category. Abbreviations: AMI, acute myocardial infarction; ESRD, end-stage renal disease; HF, heart failure; readmit, readmission.

Emergency Department Visits and Observation Stays

New for the 2018 Annual Data Report, we present data on emergency department (ED) visits and observation stays. Our comprehensive assessment of ED visits includes those resulting in discharge from the emergency department as well as those resulting in hospital admission. In contrast to declining trends over time in hospital admission rates (see Figure 4.1 above), it is notable that rates of ED visit have increased over time. Between 2007 and 2016, unadjusted ED visit rates for HD patients increased from 2.6 to 3.0 PPY, while rates for peritoneal dialysis (PD) patients increased from 2.2 to 2.4 PPY, and rates for transplant patients increased from 1.3 to 1.4 PPY (Figure 4.14).

The frequency of ED visits is relatively high in ESRD populations; the Agency for Healthcare Research and Quality (AHRQ) reports rates of ED use among the general population of 0.38 per person aged <18 years, 0.40 per person aged 18-44 years, 0.47 per person aged 15-64 years, and 0.58 per person aged 65 years and older (AHRQ, 2018a). They also report the frequency of ED use increasing over time in the general population.

vol 2 Figure 4.14 Unadjusted ED visit rates for ESRD patients, by treatment modality, 2007-2016



Data Source: Special analyses, USRDS ESRD Database. Abbreviations: ED, emergency department; ESRD, end-stage renal disease.

The increase in ED visits over time has been primarily among those ED visits that end in discharge from the ED rather than a hospital admission. The percentage of ED visits that end with discharge has grown from 51% of ED visits in 2007 to 56% of ED visits in 2016.

ESRD patients 22 to 44 years of age consistently had the highest rate of ED visits during 2007-2016, with the rate of ED visits also increasing faster over time (Figure 4.15). Previously in this chapter, we have reported this age group has a higher hospital admission rate (Table 4.1) and a high frequency of readmission (Figure 4.9.a). This difference in disease burden may be due to different causes and etiology of ESRD among young adults as well as indicative of a potential subpopulation that may benefit from quality improvement activities or care coordination.

vol 2 Figure 4.15 Unadjusted ED visit rates for ESRD patients, by age group and treatment modality, 2007-2016

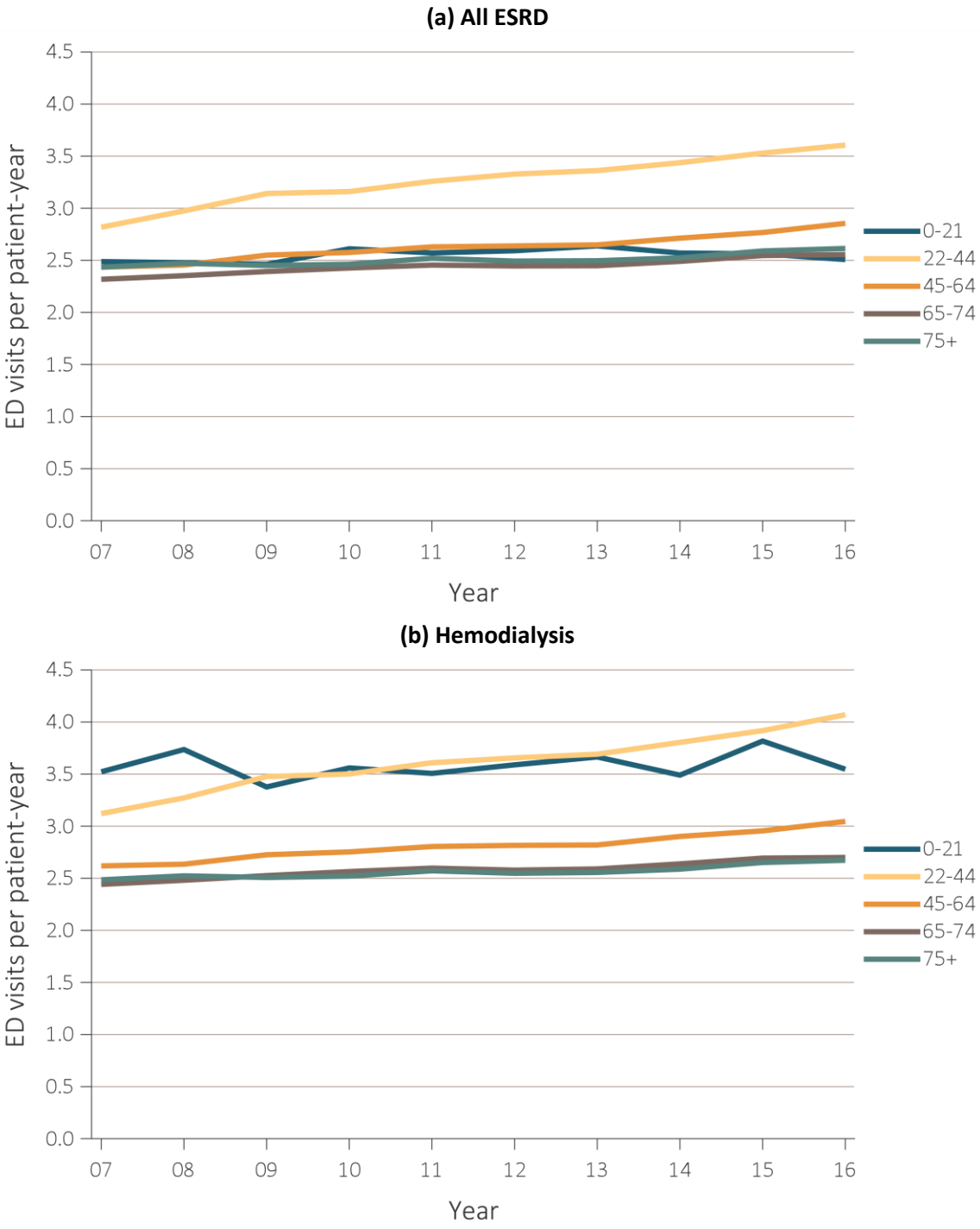
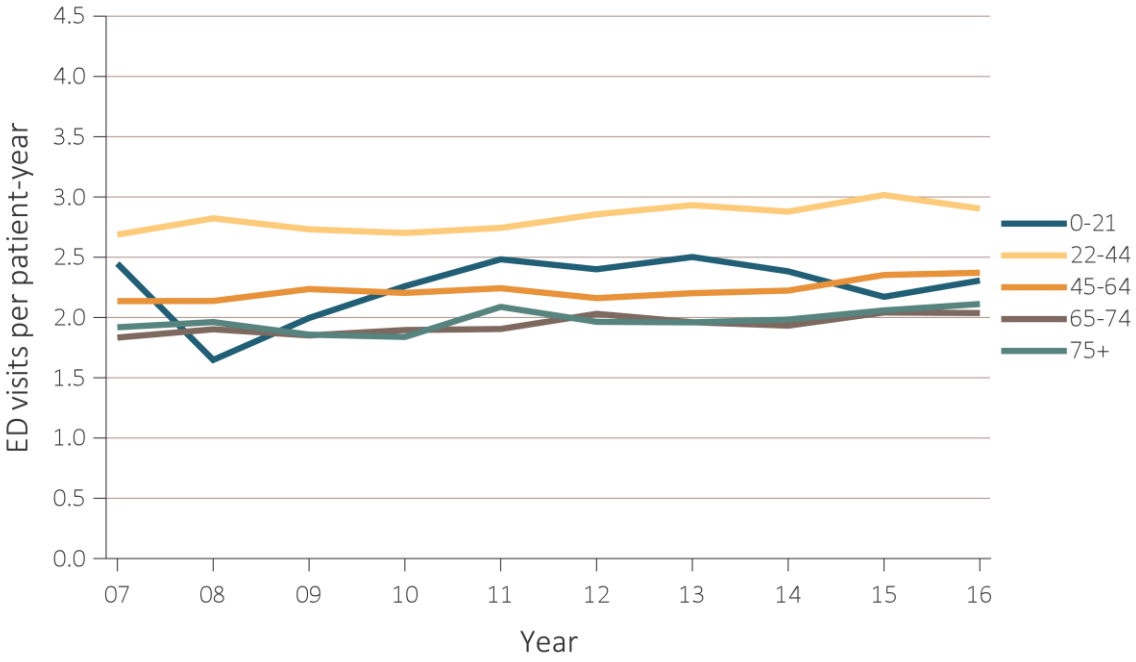


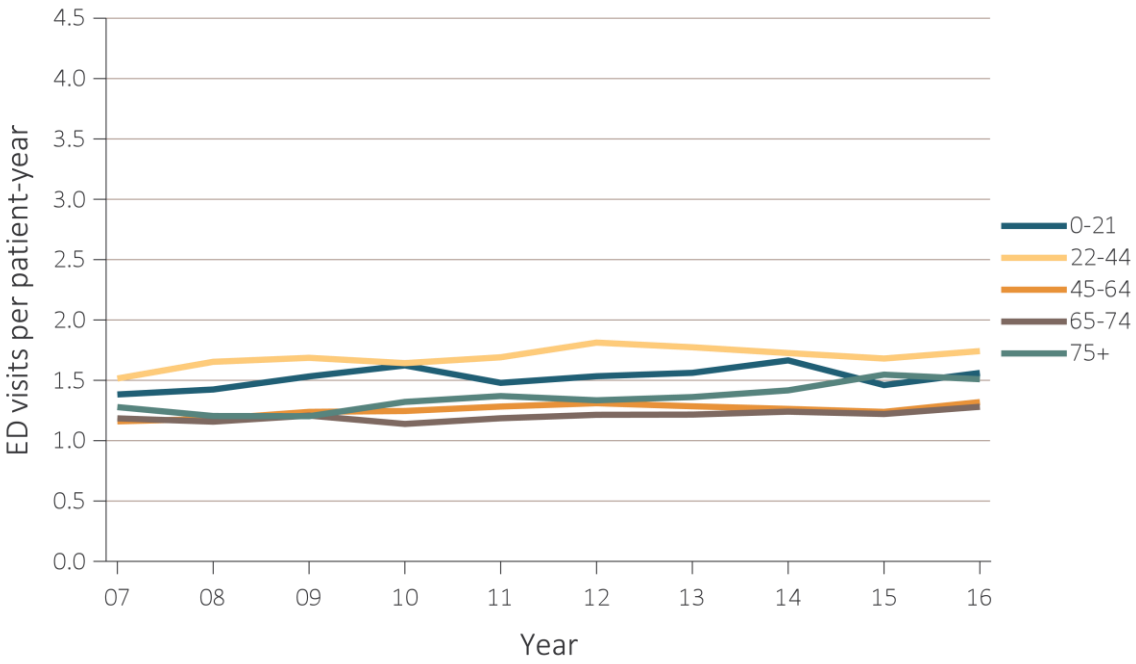
Figure 4.15 continued on next page.

vol 2 Figure 4.15 Unadjusted ED visit rates for ESRD patients, by age group and treatment modality, 2007-2016 (continued)

(c) Peritoneal dialysis



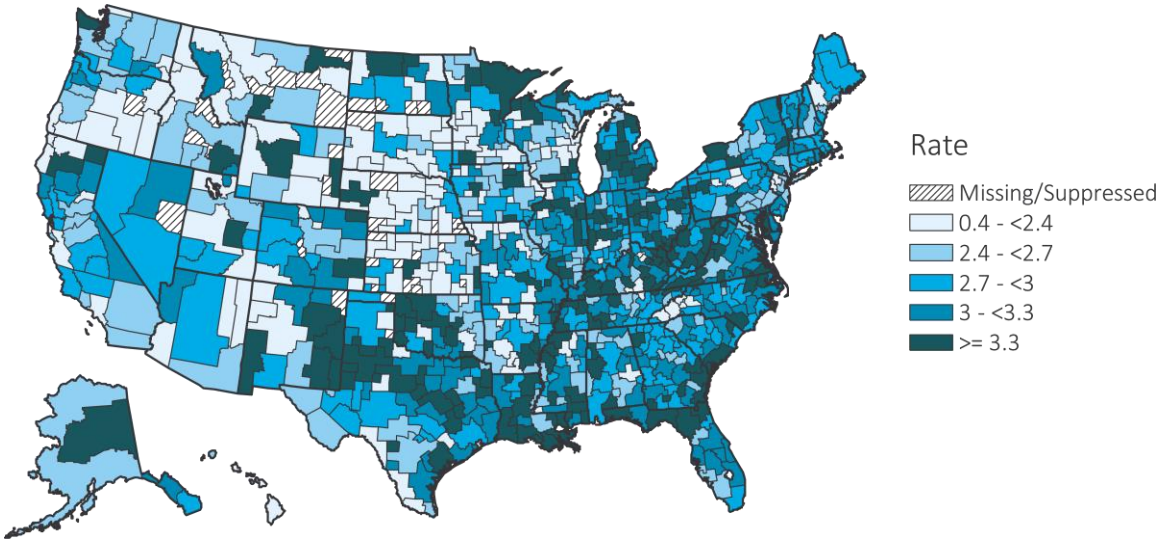
(d) Transplant



Data Source: Special analyses, USRDS ESRD Database. Abbreviations: ED, emergency department; ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis.

There is substantial geographic variation in ED visit rates across HSAs, with relatively high rates of ED visits found in parts of the Midwest and South, moderate rates in the Northeast, and relatively low rates in the Plains States and the Western United States (Figure 4.16). In general, geographic trends tend to be similar to those observed for hospitalization rates (Figure 4.4).

vol 2 Figure 4.16 Map of the unadjusted ED visit rates of ESRD, by Health Service Area, in the U.S. population, 2016

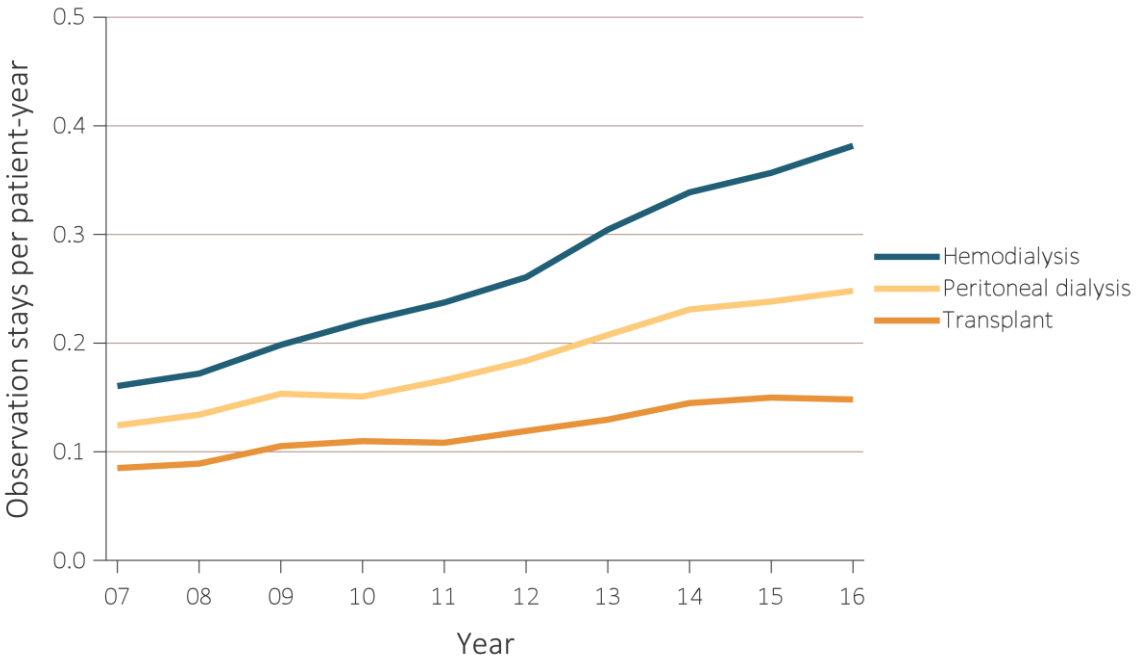


Data Source: Special analyses, USRDS ESRD Database. Abbreviations: ED, emergency department; ESRD, end-stage renal disease.

Observation stays are used by some hospitals as an alternative when an inpatient admission may not strictly be warranted, but a patient could benefit from a period of medical supervision, for example, to rule out serious illness or while waiting for important/critical laboratory results and in some instances for ensuring relief from significant symptoms e.g., bronchospasm or pain. Observation stays are relatively rare compared to other health care services examined in this chapter; however, observation stay rates for ESRD patients approximately doubled in frequency from 2007-2016. Unadjusted rates of observation stays for HD patients increased from 0.16 to 0.38 PPY, while rates for PD patients increased from 0.12 to 0.25 PPY, and rates for transplant patients increased from 0.08 to 0.15 PPY (Figure 4.17).

Increases in the use of observation stays have been noted in other populations. The Medicare Payment Advisory Commission found the number of outpatient observation stays increased by 88 percent in the general Medicare population between 2006 and 2012, from 0.028 to 0.053 visits per beneficiary (MedPAC, 2015). Notably, this shows observation stays are used considerably more often for ESRD patients when compared to the general Medicare population.

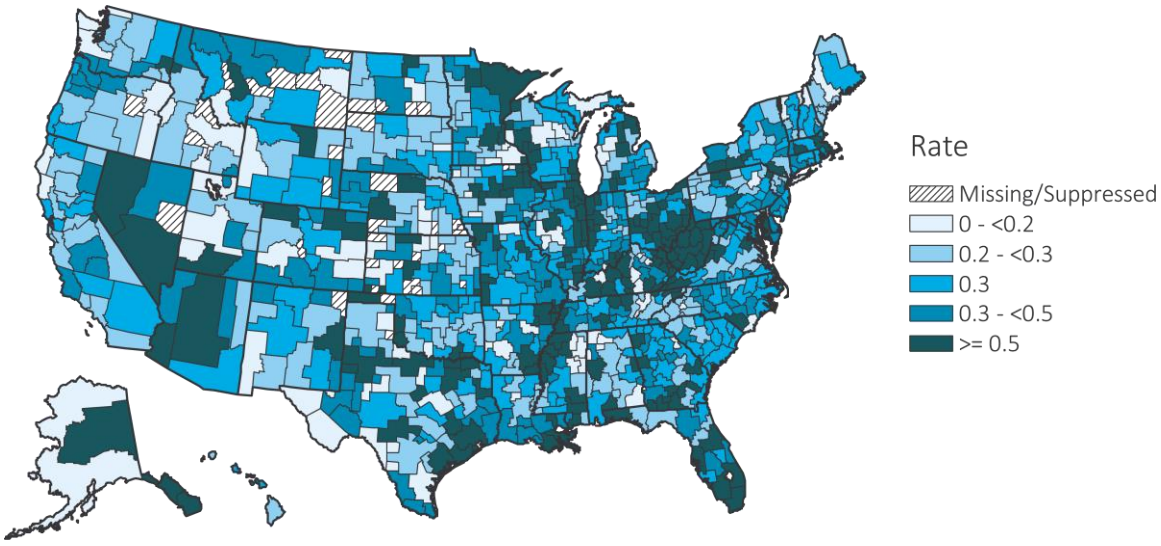
vol 2 Figure 4.17 Unadjusted observation stay rates for ESRD patients, by treatment modality, 2007-2016



Data Source: Special analyses, USRDS ESRD Database. Abbreviation: ESRD, end-stage renal disease.

The rate of observation stays varies geographically, with relatively high rates in several HSAs in the Midwest and South (Figure 4.18). Regional variation in the frequency of observation stays may reflect a variety of factors, including patient appropriateness for observation, local practice patterns, and availability and capacity of observation units.

vol 2 Figure 4.18 Map of unadjusted observation stay rates of ESRD, by Health Service Area, in the U.S. population, 2016



Data Source: Special analyses, USRDS ESRD Database. Abbreviation: ESRD, end-stage renal disease.

This chapter examines several forms of health care utilization; there are differences in the conditions treated across health care settings. We applied the Agency for Healthcare Research and Quality Clinical Classification Software (AHRQ, 2018b) to group the principal diagnosis codes observed on Medicare claims into 283 clinically meaningful categories. Table 4.2 shows the ten most common clinical classifications in each form of health care utilization discussed in this chapter. The most common clinical conditions were relatively similar for hospitalizations, readmissions, and emergency department visits that resulted in a hospital admission. In these settings, septicemia was the most common followed by complication of device. Nonspecific chest pain was the leading clinical condition in emergency department visits without a hospital admission and observation stay.

vol 2 Table 4.2 Top ten most common principal diagnosis clinical classifications for patients with ESRD, by service type, 2016

Hospitalization (N = 870,783)		Readmission (N = 168,002)		ED with admission (N = 487,492)		ED w/o admission (N = 562,078)		Observation stay (N = 124,223)	
Septicemia (except in labor)	9.3%	Septicemia (except in labor)	8.6%	Septicemia (except in labor)	9.2%	Nonspecific chest pain	6.0%	Nonspecific chest pain	13.0%
Complication of device; implant or graft	9.2%	Complication of device; implant or graft	8.5%	Complication of device; implant or graft	7.6%	Chronic kidney disease	5.5%	Hypertension with complications and secondary hypertension	9.4%
Hypertension with complications and secondary hypertension	8.2%	Hypertension with complications and secondary hypertension	7.4%	Hypertension with complications and secondary hypertension	6.8%	Complication of device; implant or graft	5.4%	Complication of device; implant or graft	9.0%
Diabetes mellitus with complications	5.1%	Fluid and electrolyte disorders	5.6%	Fluid and electrolyte disorders	5.8%	Hypertension with complications and secondary hypertension	5.2%	Fluid and electrolyte disorders	6.5%
Fluid and electrolyte disorders	4.5%	Diabetes mellitus with complications	5.0%	Congestive heart failure; nonhypertensive	4.5%	Abdominal pain	4.5%	Chronic kidney disease	4.6%
Congestive heart failure; nonhypertensive	4.4%	Congestive heart failure; nonhypertensive	4.5%	Diabetes mellitus with complications	4.4%	Other lower respiratory disease	3.5%	Other lower respiratory disease	3.4%
Pneumonia (except that caused by tuberculosis or sexually transmitted disease)	3.5%	Complications of surgical procedures or medical care	4.0%	Pneumonia (except that caused by tuberculosis or sexually transmitted disease)	4.1%	Diabetes mellitus with complications	3.0%	Diabetes mellitus with complications	3.3%
Complications of surgical procedures or medical care	3.1%	Other nervous system disorders	3.0%	Acute myocardial infarction	2.5%	Superficial injury; contusion	2.9%	Syncope	2.4%
Respiratory failure; insufficiency; arrest (adult)	2.6%	Pneumonia (except that caused by tuberculosis or sexually transmitted disease)	2.9%	Complications of surgical procedures or medical care	2.5%	Fluid and electrolyte disorders	2.8%	Deficiency and other anemia	2.2%
Acute myocardial infarction	2.6%	Respiratory failure; insufficiency; arrest (adult)	2.8%	Respiratory failure; insufficiency; arrest (adult)	2.4%	Other connective tissue disease	2.7%	Abdominal pain	2.2%

Data Source: Special analyses, USRDS ESRD Database. Abbreviations: ED, emergency department; ESRD, end-stage renal disease.

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Chapter 5: Mortality

- In 2016, adjusted mortality rates for ESRD, dialysis, and transplant patients were 134, 164, and 29 per 1,000 patient-years. By dialysis modality, mortality rates were 166 for hemodialysis (HD) patients and 154 for peritoneal dialysis (PD) patients, per 1,000 patient-years (Figure 5.1).
- Between 2001 and 2016, adjusted mortality rates decreased for dialysis patients by 29%. The net reductions in mortality from 2001 to 2016 were 28% for HD patients and 43% for PD patients (Figure 5.1).
- Between 2001 and 2016, unadjusted (crude) mortality rates decreased by 2% 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).
- Dialysis patients over the age of 65 continued to have substantially higher mortality compared to the general population and Medicare populations with cancer, diabetes, or cardiovascular disease. The relative decline in mortality for dialysis patients in the past 20 years has been similar to that of Medicare patients with cancer and diabetes, and greater than for Medicare patients with cerebrovascular disease or an acute myocardial infarction (Table 5.5, Figure 5.5).
- The decline in mortality shown in this chapter has important implications for both patients and resource allocation. Increasing lifespan among ESRD patients is a 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 end-stage renal disease (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 the 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 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 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).

For an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter, see the section on *Chapter 5* within the *ESRD Analytical Methods* 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 2016, the unadjusted death rate (not shown) for the ESRD population decreased by 27%, from 187 to 136 per 1,000 patient-years, while the adjusted death rate (Figure 5.1.a) decreased by 29%. The unadjusted death rate for the dialysis population decreased by 27%, while the adjusted death rate decreased by 29%. The unadjusted death rate for the transplant population decreased by 2%, while the adjusted death rate decreased by 40%.

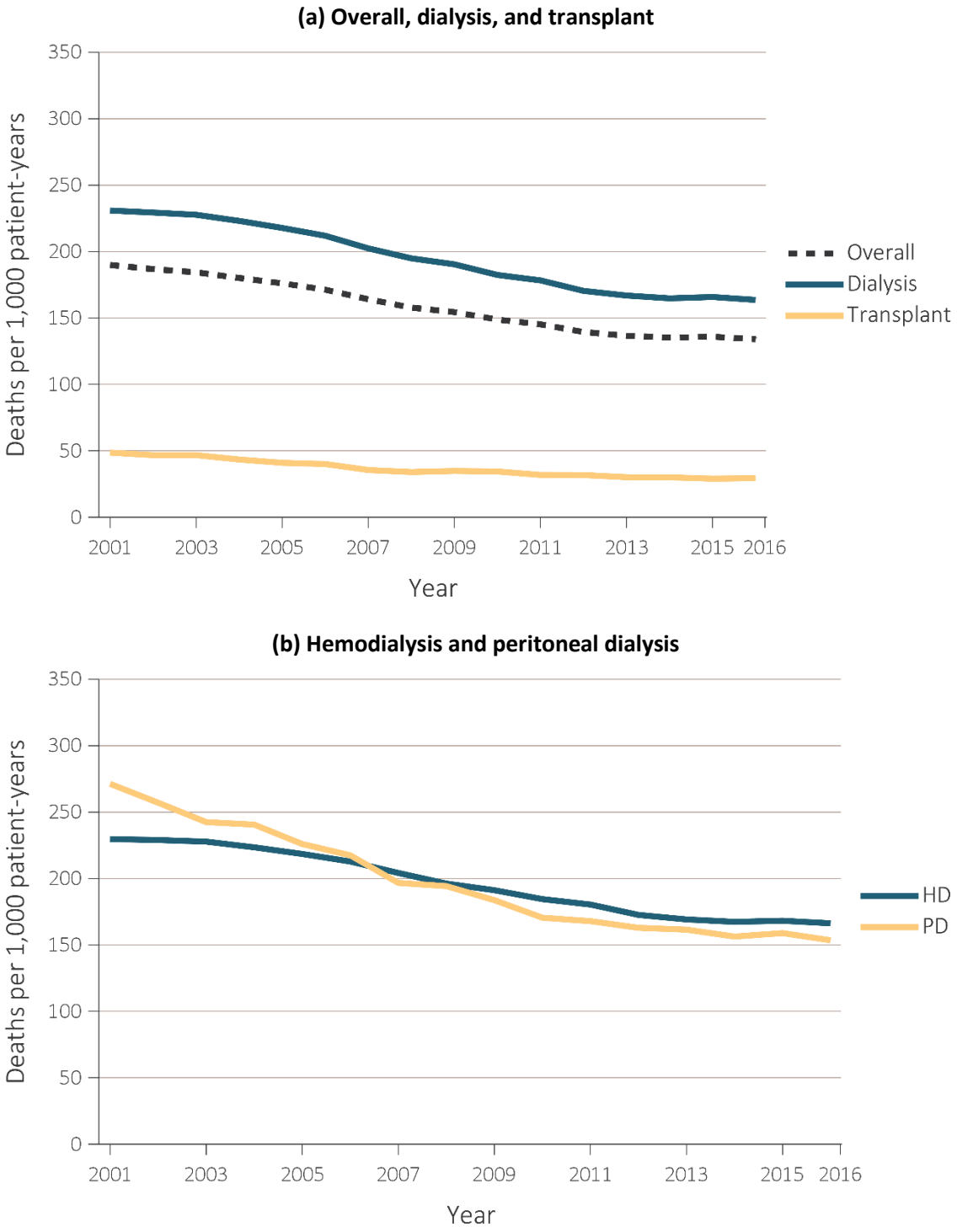
Differences between the unadjusted and adjusted rates largely reflect changes in the age distribution of the ESRD population. Death rates for dialysis and transplant patients decreased by over 30% between 2001 and 2016 within most age groups, and the adjusted rate reflects this decrease. The unadjusted rate was affected by both this decrease and by the fact that the ESRD population was older in 2016 than in 2001, which offsets the effect. For example, patients over the age of 65 comprised 43% of the dialysis population in 2001 and 44% in 2016; in the same years, transplant recipients over the age of 65 comprised 8% and 24% of the transplant recipient population. Thus, the increase in age among transplant patients masked overall improvements in mortality.

From 2001 to 2006, the adjusted mortality rate decreased by 10%, and by 18% from 2007 to 2016 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 19% from 2007 to 2016 (Figure 5.1.a). Among transplant patients, adjusted mortality decreased by 18% from 2001 to 2006 and by 17% from 2007 to 2016.

Among HD patients, the adjusted mortality rate decreased by 7% from 2001 to 2006 and by 19% from 2007 to 2016. Among PD patients, the mortality rate decreased by 20% from 2001 to 2006 and by 22% from 2007 to 2016 (Figure 5.1.b). The net reductions in mortality from 2001 to 2016 were 28% for HD patients and 43% for PD patients.

Adjusted mortality rates in 2016 were 134, 164, and 29 per 1,000 patient-years for ESRD, dialysis, and transplant patients. By dialysis modality, mortality rates were 166 per 1,000 patient-years for HD patients and 154 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, 2001-2016



Data Source: Reference Tables H.2_adj, H.4_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: ESRD, end-stage renal disease; 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, diagnosis, and vintage, the rate was lowest at 121.3 per 1,000 patient-years at risk in Network 15 (AZ, CO, NV, NM, UT, and WY), and highest at 152.2 in Network 13 (AR, LA, and OK), 25% higher than Network 15.

vol 2 Table 5.1 Unadjusted and adjusted all-cause mortality by ESRD network and modality, 2014-2016, ranked by network ESRD adjusted mortality

		Deaths per 1000 patient-years							
		Total ESRD		Hemodialysis		Peritoneal dialysis		Transplant	
Network	States* in Network	Adjusted	Unadjusted	Adjusted	Unadjusted	Adjusted	Unadjusted	Adjusted	Unadjusted
13	AR, LA, OK	**152.2**	149.6	190.2	190.8	163.4	137.9	31.8	33.9
8	AL, MS, TN	**148.8**	147.8	183.1	186.2	174	139.8	35.5	37.5
9	IN, KY, OH	**146.2**	164	179.4	220.3	164.9	159.8	33.3	38.9
14	TX	**143.1**	134.1	174.1	169.5	162.4	122.6	30.1	29.3
3	NJ, PR, VI	**141.2**	142.4	178.1	192	158.8	122.5	29.7	32.3
6	NC, SC, GA	**139.3**	136.4	171.7	172.5	158.6	121.3	30.3	33.1
7	FL	**139**	149.6	176.2	198.2	153.5	132.8	28.4	33.6
5	MD, DC, VA, WV	**133.7**	134.9	170.7	182.4	156.3	135.2	30.8	32.3
4	DE, PA	**132.8**	144.9	167.7	201.7	154.5	143.6	29.8	36.8
10	IL	**131.8**	135.5	168.8	188.7	160.7	136.4	28.4	32
12	IA, KS, MO, NE	**131.5**	139.5	170.4	203.8	160.4	162	27.8	32.4
11	MI, MN, ND, SD, WI	**130.4**	136.9	167.4	203.5	154.7	144.4	31.3	37.5
2	NY	**128**	132.6	157.7	178.2	145.8	145.2	28.2	32.3
18	S. CA	**125.9**	120.7	152.4	156	132.2	101	26	27.2
16	AK, ID, MT, OR, WA	**124.8**	126.8	156.8	187.4	140.4	131.9	28.9	33.2
17	N. CA, HI, GU, AS, MP	**124.5**	119.6	157.2	162.2	130.3	104.3	25.8	28.5
1	CT, MA, ME, NH, RI, VT	**123.5**	129.9	156	197.6	154.7	138.2	29	32.5
15	AZ, CO, NV, NM, UT, WY	**121.3**	123.4	156.2	173.2	140.4	121.6	28	32.7
	Overall	**134.3**	136.9	167.6	184.1	153.7	130.7	29.5	33.1

*Data Source: Special analyses, USRDS ESRD Database. Adjusted (age, sex, race, ethnicity, vintage, and primary diagnosis) all-cause mortality among 2014-2016 period prevalent patients. Reference population: period prevalent ESRD patients, 2011. * Includes 50 states, Washington, D.C. (DC), Puerto Rico (PR), Guam (GU), American Samoa (AS), U.S. Virgin Islands (VI), and Northern Mariana Islands (MP). Northern and Southern California (CA) split into Networks 17 and 18. Abbreviations: ESRD, end-stage renal disease; N, Northern; S, Southern.*

Mortality by Duration of Dialysis, Including Trends over Time

Among HD patients, from 1997-2012 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, 1997, 2002, 2007, and 2012

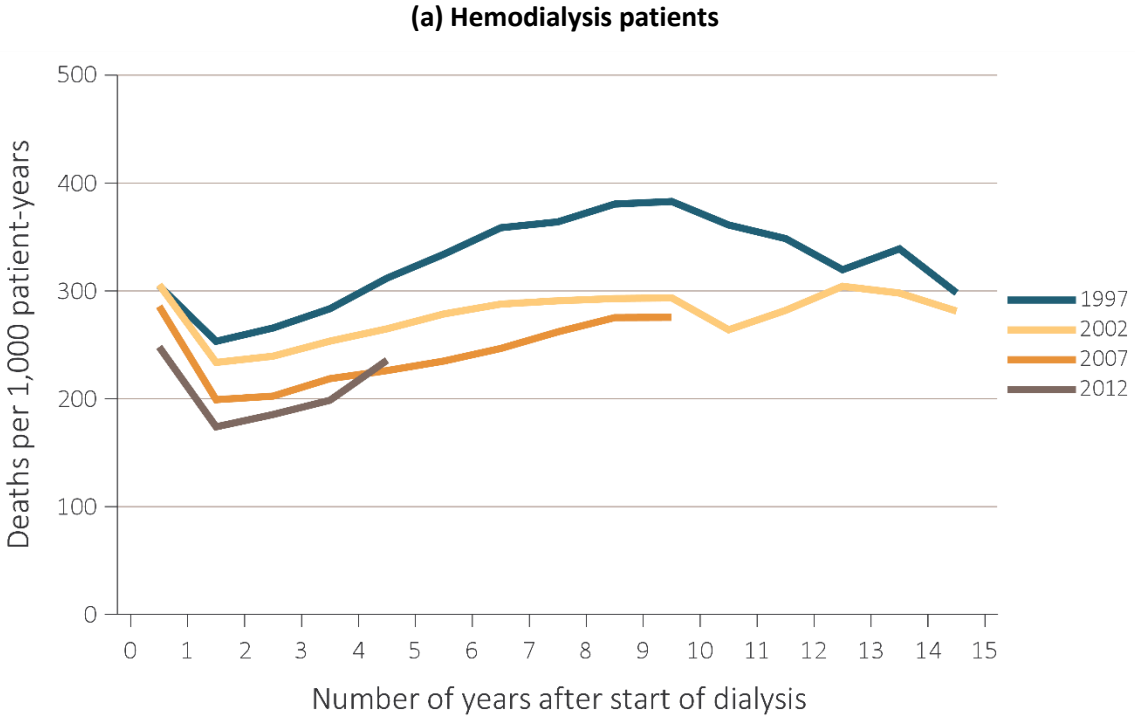
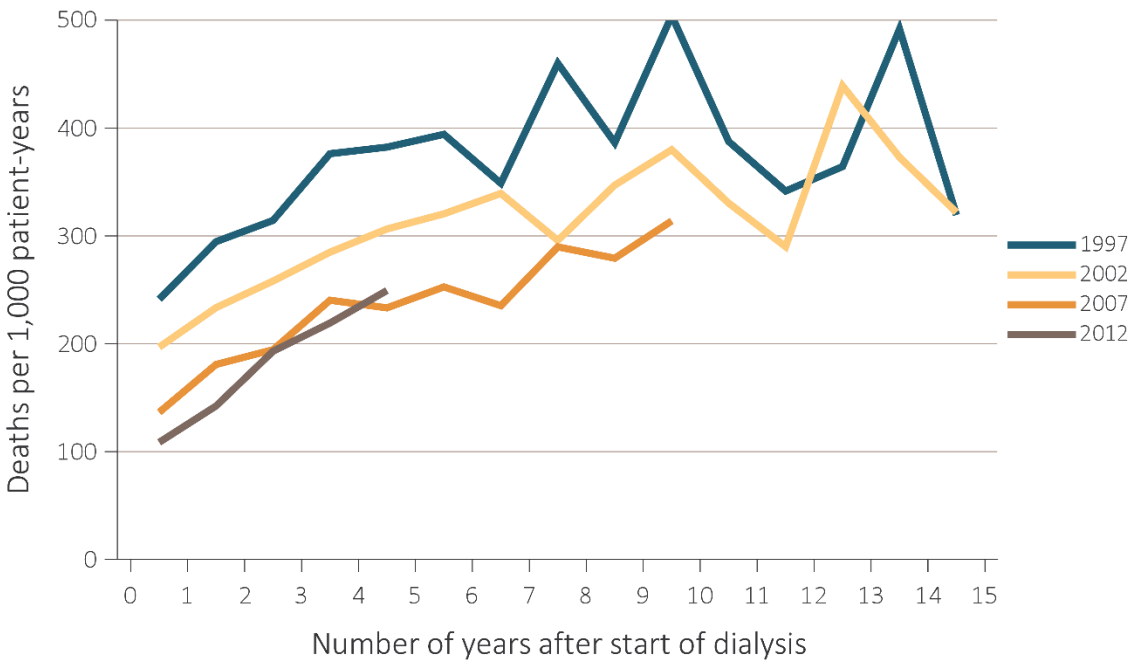


Figure 5.2 continued on next page.

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, 1997, 2002, 2007, and 2012 (continued)

(b) Peritoneal dialysis patients



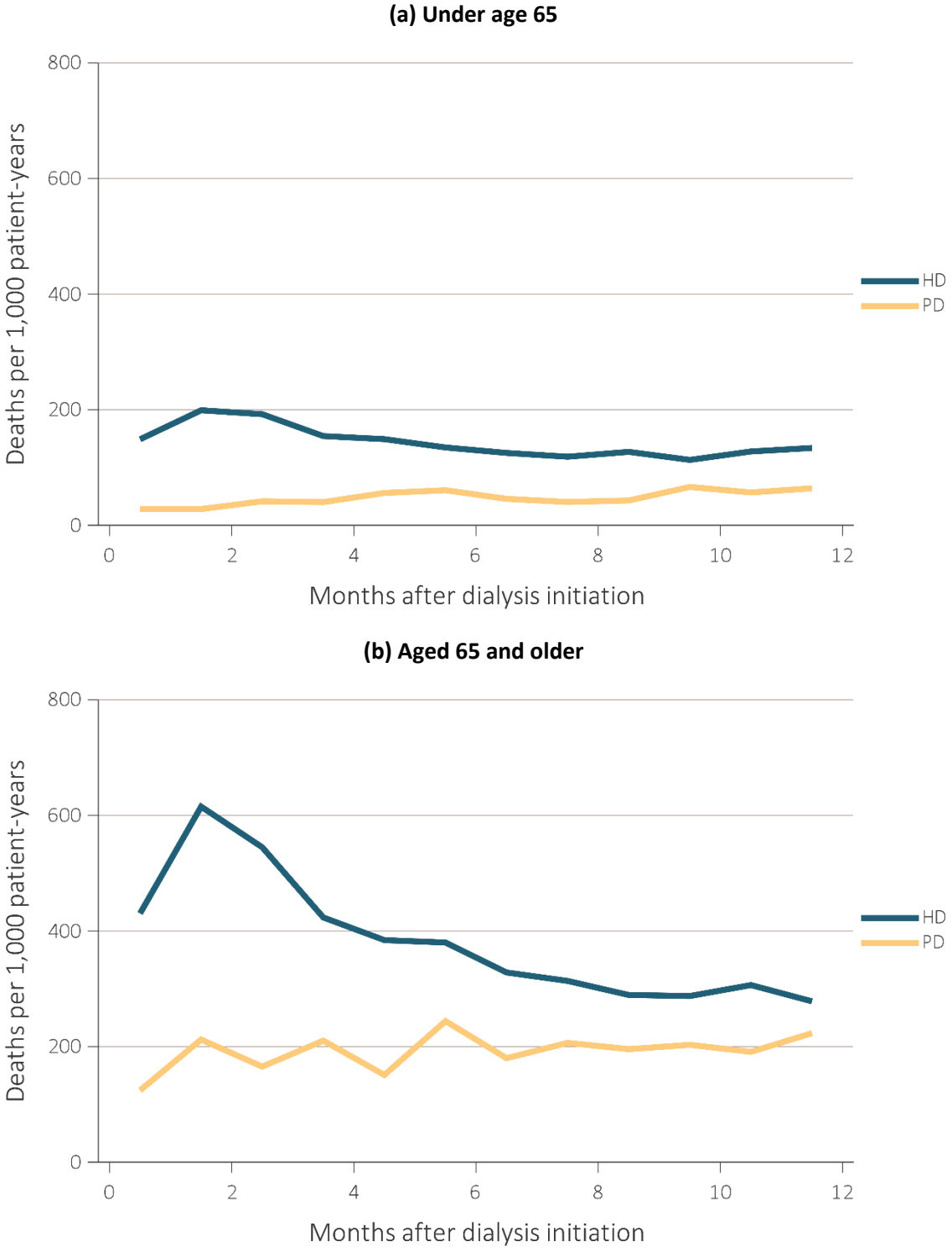
Data Source: Special analyses, USRDS ESRD Database. Adjusted for age, sex, race, and primary diagnosis. Reference population: period prevalent ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease.

Mortality during the First Year of ESRD

Among patients starting HD in 2015, 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 200 deaths per 1,000 patient-years in month 2 to 134 in month 12. Among patients aged 65 and over, mortality dropped from 615 deaths per 1,000 patient-years in month 2 to 278 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 28 deaths per 1,000 patient-years in month 1 to 64 deaths per 1,000 patient-years in month 12. Among patients aged 65 and over, mortality increased from 124 deaths per 1,000 patient-years in month 1 to 223 deaths per 1,000 patient-years 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 followed a generally decreasing trend over 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, 2015



Data Source: Special analyses, USRDS ESRD Database. Adjusted (age, race, sex, ethnicity, and primary diagnosis) mortality among 2015 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 increased with age, as expected. Among dialysis 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 0-21 years, White patients on dialysis had lower mortality rates than Black patients. However, Black patients 45 years and older had a consistent survival advantage on dialysis compared to Whites. 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 is likely to have resulted in lowering the otherwise higher mortality rate observed among the overall 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	8	26	3
	Black/African American	19	36	4
	Other	9	14	9
22-44	White	34	66	8
	Black/African American	45	56	10
	Other	16	31	3
45-64	White	113	162	31
	Black/African American	102	116	33
	Other	80	108	22
65-74	White	217	257	71
	Black/African American	182	197	70
	Other	146	170	54
75+	White	387	407	123
	Black/African American	295	303	99
	Other	262	273	81

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

Age	Sex	ESRD	Dialysis	Transplant
0-21	Male	10	26	3
	Female	15	33	5
22-44	Male	38	58	9
	Female	45	70	9
45-64	Male	100	137	32
	Female	100	135	30
65-74	Male	195	239	71
	Female	188	223	66
75+	Male	364	388	121
	Female	339	356	118

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.

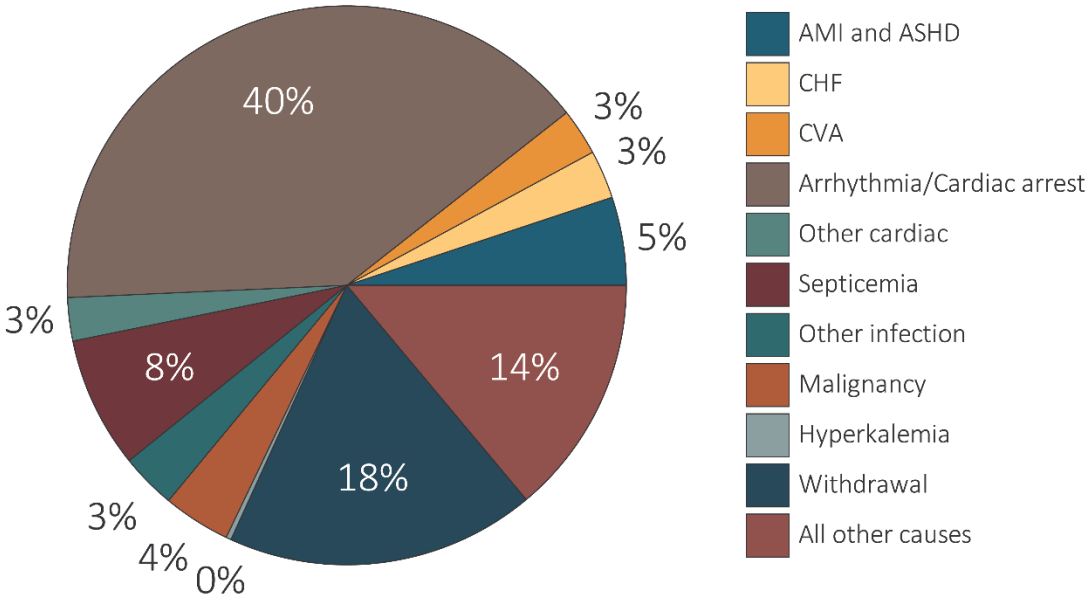
Cause-Specific Mortality Rates

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 27% of dialysis patients and 74% of transplant patients. Note that lacking cause of death information does not imply that the date of death is missing. The date of death comes from several potential sources, including OPTN transplant data (see "Death date determination" in the ESRD Analytical Methods chapter). For example, in 2015 the form 2746 was the source of date of death for 86% of dialysis patients, but only 34% of transplant patients. Most of the other death dates came from the CMS enrollment database, which does not include cause of death information. Figures 5.4.a and 5.4.b show the distributions of deaths in 2015, excluding missing and unknown causes as categories, while Figures 5.4.c and 5.4.d show the distributions including 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.

We recognize that while medical terminology calls for use of the term heart failure, since not all heart failure is congestive, this chapter uses the term congestive heart failure based on the data source — CMS 2746, ESRD Death Notification form.

vol 2 Figure 5.4 Unadjusted percentages of deaths in 2015 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

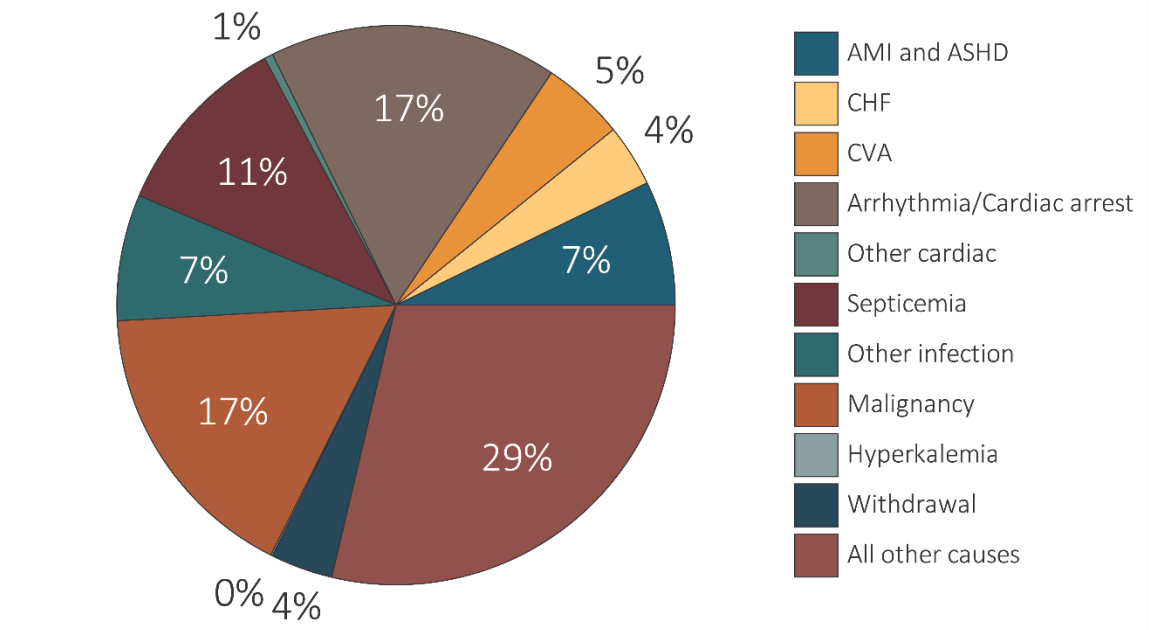
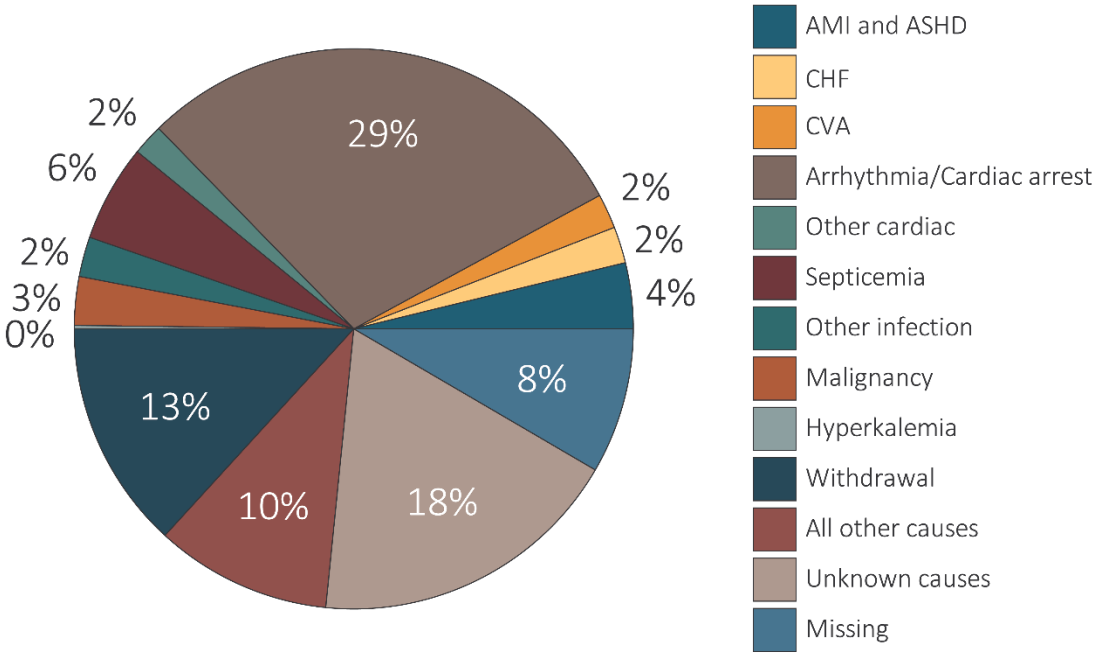


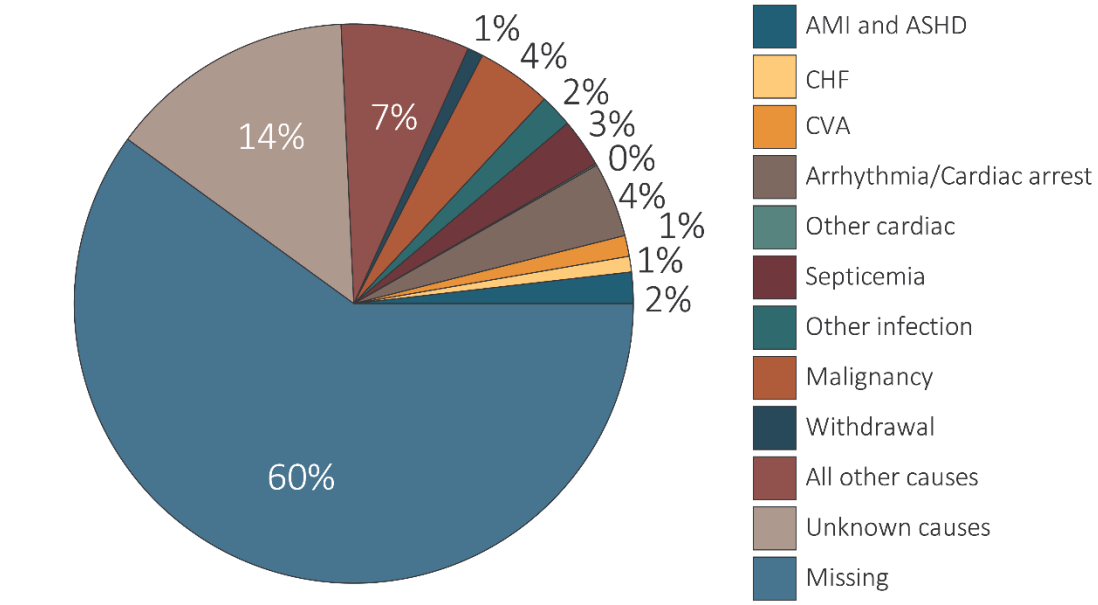
Figure 5.4 continued on next page

vol 2 Figure 5.4 Unadjusted percentages of deaths in 2015 by cause, with and without missing data, by modality among dialysis patients and transplant recipients (continued)

(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 2015 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: AMI, acute myocardial infarction; ASHD, atherosclerotic heart disease; CHF, congestive heart failure; CVA, cerebrovascular accident.

Survival Probabilities for ESRD Patients

Survival has improved between the 2003 and 2011 incident ESRD cohorts for all modalities. For example, five-year survival rose from 37% to 42% among HD patients, from 43% to 52% among PD patients, from 69% to 77% among deceased-donor transplant patients, and from 78% to 84% 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 2011 is only 57% at three years after ESRD onset (Table 5.3). For PD patients, adjusted survival is 70% at three years. For deceased-donor and living-donor recipients, three-year survival is 86% and 91% respectively. The 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 95% 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 2015").

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					
2003	91.0	74.8	61.8	51.4	36.6
2005	91.2	75.4	62.7	53.0	38.6
2007	91.6	76.3	64.2	54.6	40.0
2009	91.8	77.5	65.7	56.2	41.6
2011	92.1	78.3	66.8	57.4	42.0
Peritoneal dialysis					
2003	96.3	83.9	69.0	57.7	42.9
2005	96.5	85.6	72.2	61.6	45.7
2007	96.9	87.5	74.8	64.5	48.8
2009	97.4	87.8	76.6	66.7	51.5
2011	97.7	89.7	79.0	69.5	52.1
Deceased-donor transplant					
2003	95.7	89.9	84.5	79.5	69.2
2005	95.6	89.7	84.9	80.3	71.0
2007	96.7	92.2	88.1	83.7	73.3
2009	96.7	92.0	88.2	84.0	75.1
2011	97.1	93.9	90.4	86.4	76.8
Living-donor transplant					
2003	98.1	95.3	91.3	86.9	77.9
2005	98.2	95.2	91.7	88.2	80.3
2007	99.0	97.0	94.3	91.0	83.5
2009	98.9	97.1	94.4	91.1	84.1
2011	98.9	96.3	94.3	91.2	84.1

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 69% to 85% 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, prevalent transplant patients (2016), and the general U.S. population (2015), based on USRDS data and the National Vital Statistics Report (2015)

	ESRD patients 2016				General U.S. population 2015	
	Dialysis		Transplant			
Age	Male	Female	Male	Female	Male	Female
0-14	23.3	20.9	60.3	59.3	70.6	75.4
15-19	21.4	18.7	47.6	49.1	59.6	64.3
20-24	18.5	15.8	43.7	45.2	54.9	59.4
25-29	16.0	14.0	39.6	41.1	50.2	54.6
30-34	14.1	12.7	35.3	37.1	45.6	49.8
35-39	12.4	11.4	31.2	33.1	41.0	45.0
40-44	11.0	10.2	27.4	29.1	36.5	40.3
45-49	9.3	8.7	23.6	25.2	32.0	35.7
50-54	7.9	7.6	20.0	21.7	27.7	31.2
55-59	6.7	6.6	16.8	18.2	23.7	26.8
60-64	5.6	5.7	14.0	15.2	19.9	22.7
65-69	4.6	4.8	11.4	12.5	16.3	18.6
70-74	3.8	4.1	9.3	10.1	12.9	14.8
75-79	3.3	3.6	7.6[a]	8.3[a]	9.8	11.4
80-84	2.7	3.0			7.2	8.4
85+	2.2	2.4			3.8	4.4

Data Source: Reference Table H.13; special analyses, USRDS ESRD Database; and National Vital Statistics Report. "Table 3. Life expectancy at selected ages, by race and Hispanic origin, and sex: United States, 2015 (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 and female dialysis patients over the age of 75 years experienced mortality rates 3.9 times higher than their peers in the general Medicare population (Table 5.5). Among kidney transplant patients aged 65-74, mortality rates were 2.3-3.0 times higher than for the general Medicare population, and 1.4-1.5 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, 2015

Age	Sex	Dialysis	Transplant	All Medicare	Cancer	Diabetes	CHF	CVA/TIA	AMI
65-74	Male	225	65	28	72	41	111	74	90
	Female	211	54	18	65	30	97	58	100
75+	Male	345	129	88	131	106	223	156	182
	Female	316	111	81	131	99	221	148	187

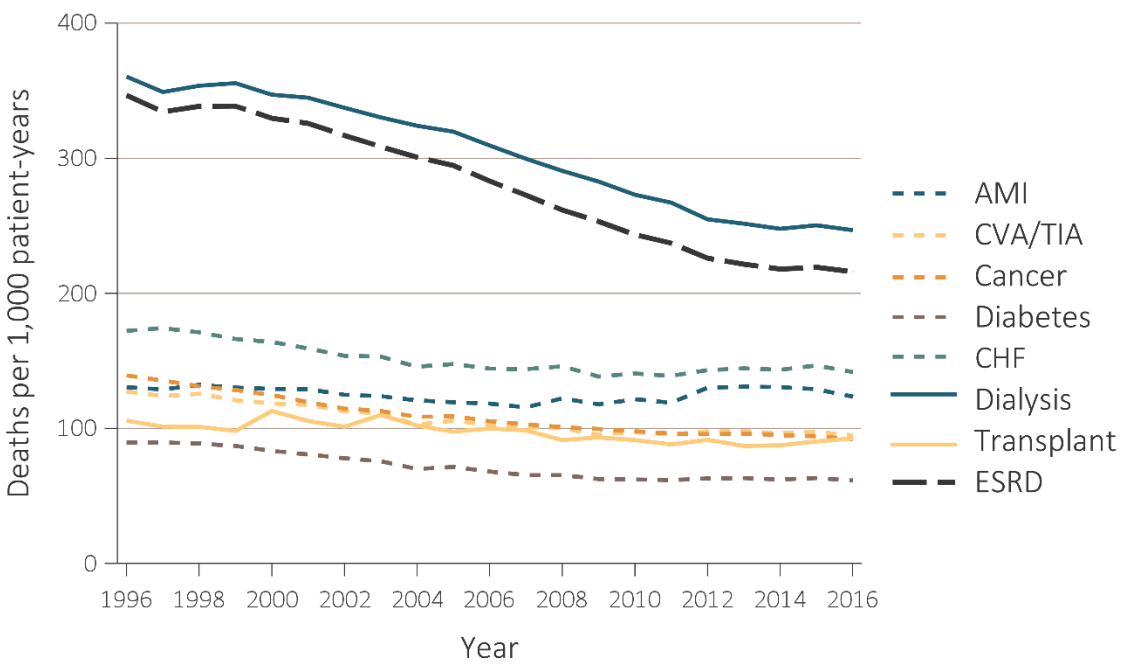
Data Source: Special analyses, USRDS ESRD Database and Medicare 5% sample. Adjusted for race. Medicare data limited to patients with at least one month of Medicare eligibility in 2015. Reference population: Medicare patients, 2015. Abbreviations: AMI, acute myocardial infarction; CHF, heart failure; CMS, Centers for Medicare & Medicaid Services; CVA/TIA, cerebrovascular accident/transient ischemic attack; ESRD, end-stage renal disease.

Comparison to Comorbidity-Specific Medicare Patients

From 1996 to 2016, adjusted mortality among ESRD patients aged 65 years and older declined by 38%, from 347 to 216 per 1,000 patient-years (Figure 5.5). Among dialysis patients, adjusted mortality fell 32%, from 361 to 247. Among transplant patients, adjusted mortality fell 12%, from 106 to 93. The decline in mortality for dialysis patients was greater than for heart failure (CHF), cerebrovascular accident/transient ischemic attack (CVA/TIA), and acute myocardial infarction (AMI). Adjusted mortality fell 34% for patients with cancer and 31% for patients with diabetes mellitus (DM), but had a lower reduction for cardiovascular conditions, at 18% for CHF, 25% for CVA/TIA, and 5% for AMI.

In 2016, mortality rates among dialysis patients aged 65 years and older ranged from 1.7 times higher than for CHF 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, 1996-2016



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

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Chapter 6: Transplantation

- In 2016, 20,161 kidney transplants were performed in the United States (19,301 were kidney-alone; Figure 6.6).
- Fewer than a third (28%) of kidneys transplanted in 2016 were from living donors (Figure 6.6).
- From 2015 to 2016, the cumulative number of recipients with a functioning kidney transplant increased by 3.4%, from 208,032 to a total of 215,061 (Figure 6.7).
- On December 31, 2016, the kidney transplant waiting list had 81,418 candidates on dialysis, 51,238 (62.9%) of whom were active. Eighty-five percent of all candidates were awaiting their first transplant (Figure 6.1).
- Among candidates newly wait-listed for either a first or repeat kidney-alone transplant (living or deceased-donor) during 2011, the median waiting time to transplant was 4.0 years (Figure 6.4). This waiting time varied greatly by region of the country, from a low of 1.4 years in Nebraska to a high of 5.1 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 2.5 per 100 dialysis patient-years for recipients from deceased donors and about 1.0 per 100 dialysis patient-years for recipients from living donors (Figure 6.8).
- The number of deceased kidney donors, aged 1-74 years, with at least one kidney retrieved increased by 62.7%, from 5,981 in 2001 to 9,732 in 2016 (Figure 6.19.a).
- The rate of kidney donation from deceased Blacks/African Americans nearly doubled from 2002 to 2016, from 4.5 to 7.9 donations per 1,000 deaths (Figure 6.21.b). This rate overtook that of Whites in 2009. Asians consistently had the highest rate of deceased kidney donation during this time, at about 9 per 1,000 deaths.
- Since 1999, Whites have had the highest rate of living kidney donation, although this has been in decline along with all other races except Asians, who as of 2016 showed rates of living donation essentially equivalent to Whites (Figure 6.16.b).
- Eighteen percent of kidneys recovered from deceased donors were discarded in 2016; this rate has increased slightly since 2010.
- The number of kidney paired donation transplants has risen sharply since 2005, with 642 performed in 2016, which represented 11% of living-donor transplants that year. The rate plateaued during 2012-2014 but increased again in 2016 (Figure 6.18).
- Since 1999, the probabilities of graft survival have improved among recipients of both living and deceased-donor kidney transplants, over both the short-term (one-year survival) and long-term (five and ten-year survival) (Figure 6.25).
- In 2015, the probabilities of one-year graft survival were 93% for deceased and 98% for living-donor kidney transplant recipients (Figure 6.25).
- In 2015, the probabilities of patient survival within one-year post-transplant were 96% and 99% of deceased- and living-donor kidney transplant recipients (Figure 2.6).
- The one-year graft-survival and patient-survival advantages experienced by living-donor transplant recipients persisted at five and ten years post-transplant (Figures 6.25 and 6.26).

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 trends in the proportion of patients transplanted within one year of being wait-listed (Figure 6.5).

The Organ Procurement and Transplantation (OPTN) network conducted major revisions of the kidney allocation system (KAS) which 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 the following:

(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 donor (SCD) or extended criteria donor (ECD) types 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) Priority changes for sensitized candidates, with priority given via a logarithmic point system based on their calculated panel reactive antibodies (PRA). The new approach is thought to more accurately reflect difficulty in donor-recipient matching.

(4) The inclusion of pre-waiting list dialysis time in a candidate's waiting time (OPTN, 2015). This particular change was instituted to partially dissipate the effects of late referral for transplantation. Under the new KAS, waiting time includes time from the point of listing, with a requirement for a GFR ≤20 mL/min, or the time from initiation of dialysis (or return to dialysis if the patient had a failed kidney transplant).

In this year's chapter, where relevant, we highlight any trend changes that may have resulted from the new policy. As this chapter includes data through the end of 2016, we are able to assess the impact of the allocation policy change through the first two full years of its implementation.

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 *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

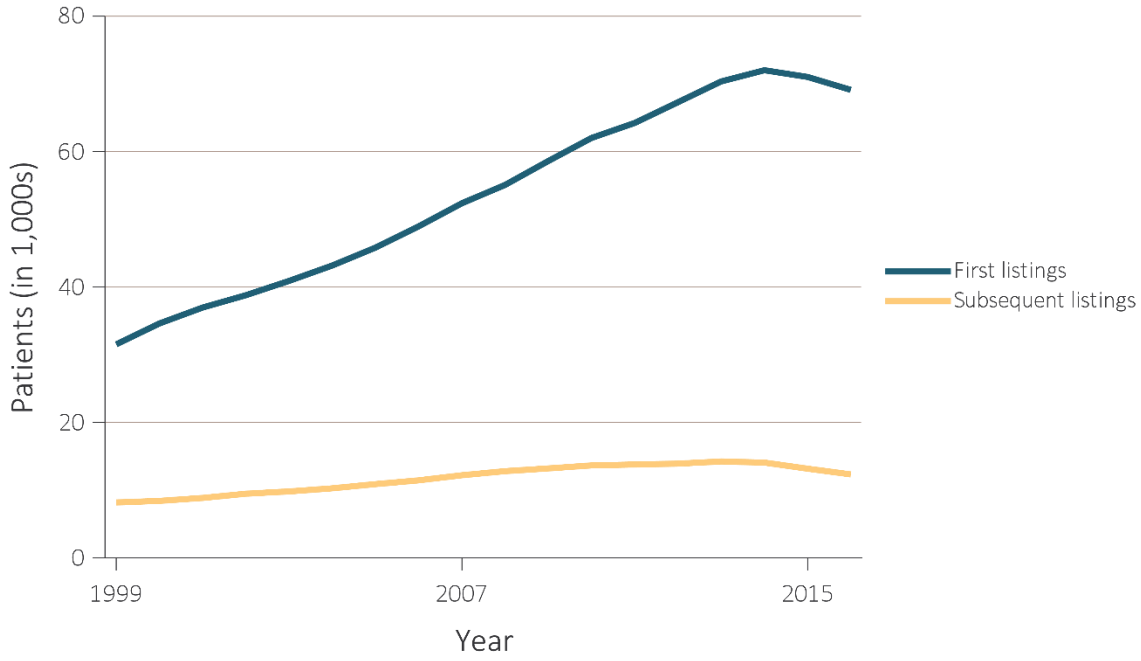
As of December 31, 2016, the number of people on the kidney transplant waiting list continued to decline, for the second year in a row, by 3.3% over the previous year, to 81,418 candidates (dialysis patients only), 85% of whom were awaiting their first kidney transplant (Figure 6.1). This decline was primarily driven by a reduction in the number of inactive wait-listed candidates to 30,180, a 3.6% 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 change reduces the incentive to list dialysis patients until they are actively ready for transplantation, and may also diminish resistance to delisting of patients.

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 about 20,000 kidney transplants performed in the United States in 2016, the active waiting list remains substantially larger than the supply of donor kidneys, which presents a continuing challenge.

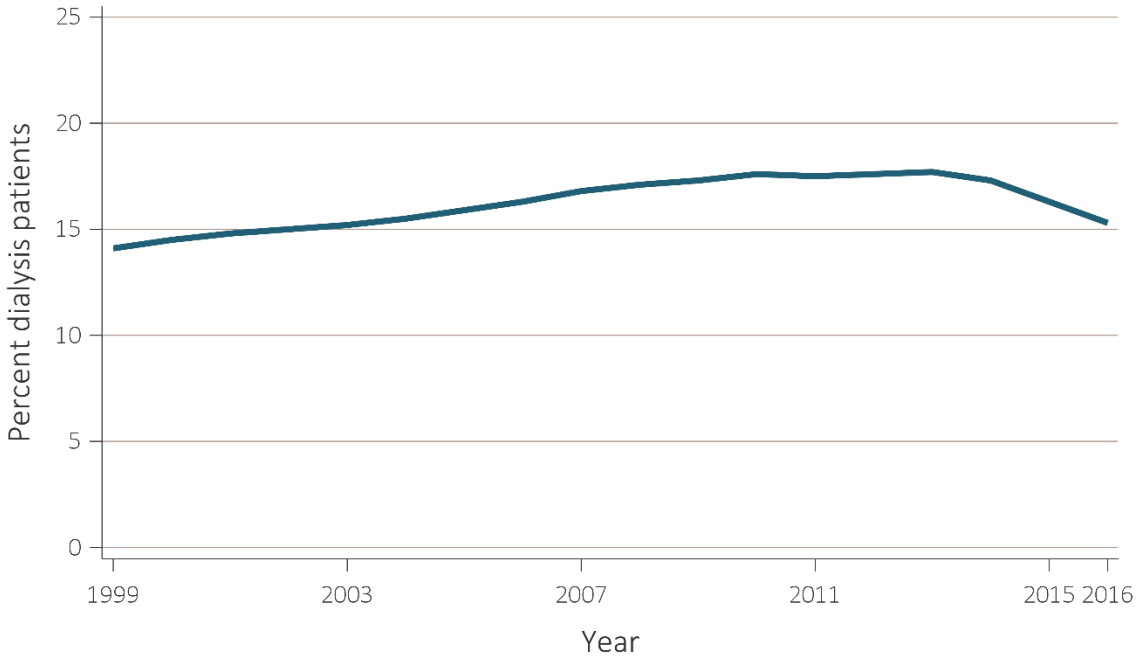
Like the trends shown in Figure 6.1, the percentage of prevalent dialysis patients wait-listed for a kidney has also recently declined (Figure 6.2).

vol 2 Figure 6.1 Number of patients wait-listed for kidney transplant, 1999-2016



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, as more fully described in the text.

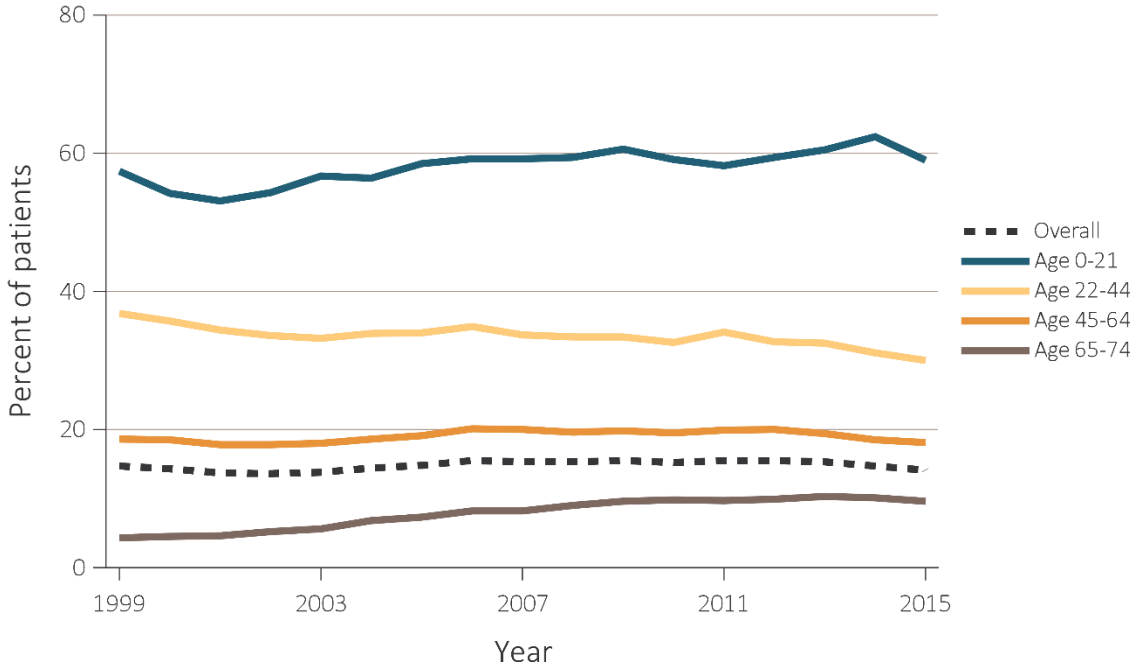
vol 2 Figure 6.2 Percentage of dialysis patients who were wait-listed, 1999-2016



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 as described more fully in the text above.

In 2015, 14.1% 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 overall percentage of patients wait-listed or receiving a transplant in their first ESRD-year has remained relatively flat. However, there has been a slight decline in 2015, which may relate to the allocation policy change. As previously mentioned, the KAS policy reduced the imperative to wait-list patients until they are actively ready for transplantation and would provide priority for transplantation for patients waiting for a long duration on dialysis.

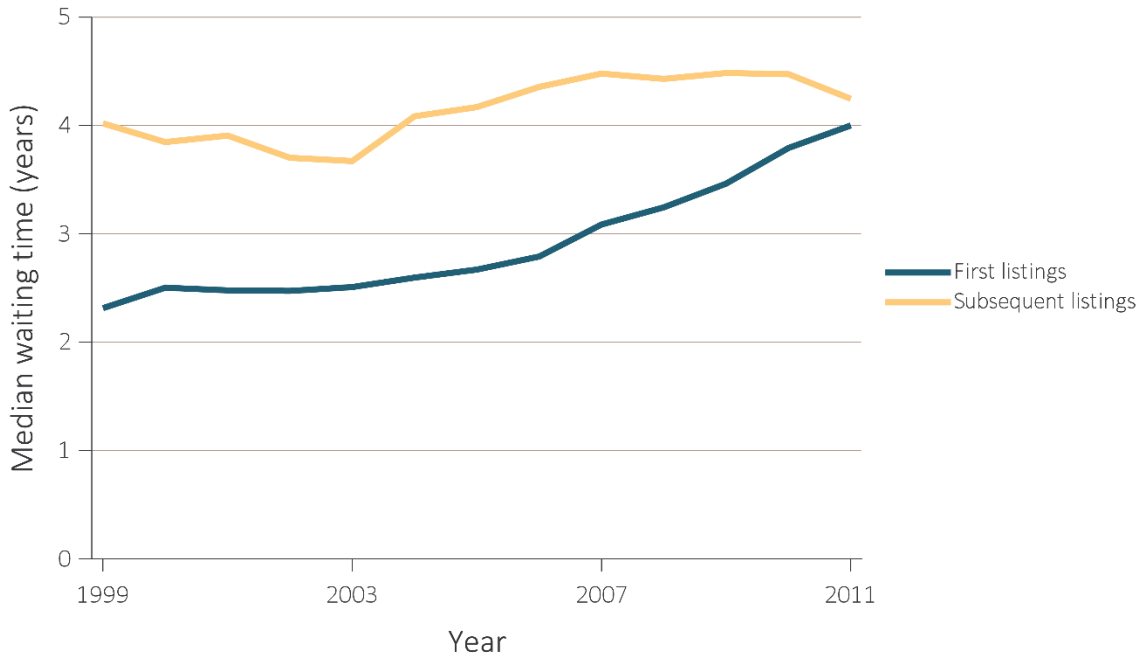
vol 2 Figure 6.3 Percentage of incident patients who were wait-listed or received a kidney transplant within one year of ESRD initiation, by age, 1999-2015



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, as more fully described in the text above. Abbreviation: ESRD, end-stage renal disease.

Median waiting time to transplantation continues to increase for those listing for the first time, whereas recently it has declined slightly for subsequent listings (Figure 6.4). Among 2011 candidates newly wait-listed for either an initial or subsequent kidney-alone transplant, the median waiting time (deceased or living-donor) was 4.0 years—i.e. 50% of these patients received a transplant within 4.0 years after being wait-listed. For first-time listings, the median 2011 waiting time to transplantation (deceased or living-donor) was 4.0 years, only about 2 months shorter than that for candidates listed for subsequent transplants at 4.2 years. The narrowing gap may represent an impact of the KAS policy, which provided additional priority for highly sensitized candidates. There are also large regional differences in waiting time (Reference Table E.2.2). Two states, Texas and Georgia, have waiting times greater than five years. Four states have waiting times of less than two years, with the lowest seen in Nebraska (1.4 years), Arkansas (1.6 years), and New Hampshire (1.7 years).

vol 2 Figure 6.4 Median waiting time for kidney transplant, 1999-2011

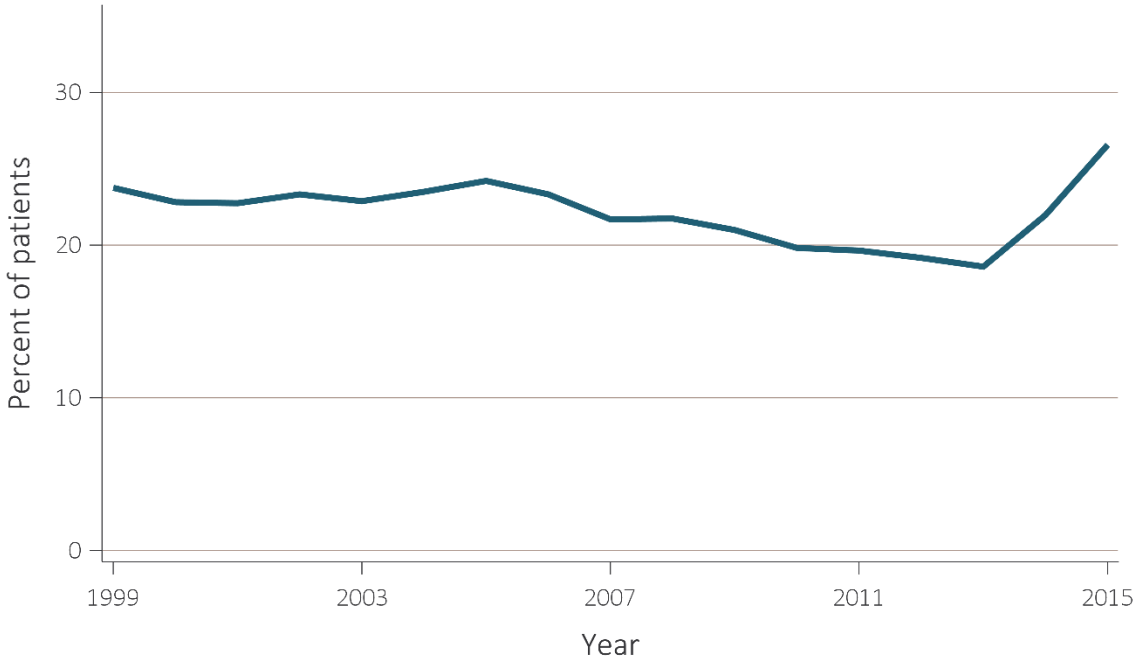


Data Source: Reference Tables E.2. Median waiting time to kidney transplant. Median waiting time is calculated for all candidates enrolled on the waiting list in a given year.

Figure 6.5 displays trends over time in the percent of patients transplanted (deceased or living donor) within one year of their wait-listing date. There is a recent sharp increase corresponding to implementation of the KAS policy, reversing the prior downward trend. This reversal likely relates to the change in policy, which set qualifying time to the start date of dialysis (for patients already on dialysis), rather than the actual date of wait-listing. As such, patients who have been on dialysis for a long duration at the time of new wait-listing would receive priority, potentially allowing for relatively rapid receipt of a deceased-donor transplant.

Table 6.1 displays outcomes within three years of follow-up for candidates who were first listed in 2013, as a function of their blood type, PRA, and age. Results are shown separately among patients who did not receive a living-donor transplant in order to provide information on the outcome of electing to wait for a deceased donor. Among those not receiving a living-donor transplant, at three years 24% had received a deceased-donor transplant, a quarter had died or been removed from the waiting list, and half 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 of the strata of patients aged 65 years or older. As expected, blood type also affected the outcomes. Table 6.2 displays the corresponding outcomes within five years of follow-up for candidates who were first listed in 2011, as a function of their blood type, PRA, and age. Overall, among those not receiving a living-donor transplant, at five years 39% had received a deceased-donor transplant, 37% had died or been removed from the waiting list, and a quarter remained on the waiting list.

vol 2 Figure 6.5 Percent of patients transplanted (living or deceased donor) within one year of wait-listing, 1999-2015



Data Source: Special analyses, USRDS ESRD Database and the Organ Procurement and Transplantation Network (OPTN). Abbreviation: ESRD, end-stage renal disease.

vol 2 Table 6.1 Reported outcomes within three years since first listing in 2013, 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			
Blood Type	PRA	Age		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 A	PRA<20	0≤Age≤21	122	233	73	18	9
		22≤Age≤44	540	1,268	34	47	19
		45≤Age≤64	764	3,694	28	49	24
		Age≥65	234	1,349	30	37	34
	PRA≥20	0≤Age≤21	*	*	50	*	*
		22≤Age≤44	27	107	36	46	18
		45≤Age≤64	36	242	40	37	23
		Age≥65	*	76	30	28	42
Blood Type B	PRA<20	0≤Age≤21	34	117	65	28	7
		22≤Age≤44	176	706	19		18
		45≤Age≤64	255	1,734	16	61	23
		Age≥65	71	586	15	48	37
	PRA≥20	0≤Age≤21	*	*	75	.	*
		22≤Age≤44	*	55	20	71	9
		45≤Age≤64	17	111	29	49	23
		Age≥65	*	34	*	35	41
Blood Type AB	PRA≥0	0≤Age≤21	15	36	89	*	*
		22≤Age≤44	60	157	57	31	11
		45≤Age≤64	94	461	51	30	19
		Age≥65	22	171	54	20	26
Blood Type O	PRA<20	0≤Age≤21	128	388	65	27	7
		22≤Age≤44	639	2,196	19	62	19
		45≤Age≤64	839	5,686	17	59	24
		Age≥65	232	1,876	17	46	37
	PRA≥20	0≤Age≤21	*	20	60	*	*
		22≤Age≤44	35	156	27	53	20
		45≤Age≤64	38	335	26	48	26
		Age≥65	*	88	30	40	31
All			4,378	21,882	24%	51%	24

*Data Source: Special analyses, USRDS ESRD Database and the Organ Procurement and Transplantation Network (OPTN). Reported outcomes within three years since first listing in 2013, 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. Abbreviations: ESRD, end-stage renal disease; PRA, panel reactive antibodies.*

vol 2 Table 6.2 Reported outcomes within five years since first listing in 2011, 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			
Blood Type	PRA	Age		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 A	PRA<20	0≤Age≤21	105	241	81	8	10
		22≤Age≤44	543	1,233	54	22	24
		45≤Age≤64	873	3,469	46	20	34
		Age≥65	224	1,215	41	10	49
	PRA≥20	0≤Age≤21	*	*	100	.	.
		22≤Age≤44	23	79	63	19	18
		45≤Age≤64	39	236	52	17	31
		Age≥65	*	69	49	*	45
Blood Type B	PRA<20	0≤Age≤21	46	93	76	11	13
		22≤Age≤44	177	585	35	36	29
		45≤Age≤64	316	1,557	28	35	37
		Age≥65	63	516	26	19	55
	PRA≥20	0≤Age≤21	*	*	40	20	40
		22≤Age≤44	15	40	28	30	43
		45≤Age≤64	17	121	35	31	34
		Age≥65	*	36	39	11	50
Blood Type AB	PRA≥0	0≤Age≤21	13	37	84	*	*
		22≤Age≤44	58	151	70	10	21
		45≤Age≤64	91	433	64	10	27
		Age≥65	25	170	55	5	40
Blood Type O	PRA<20	0≤Age≤21	160	419	77	12	11
		22≤Age≤44	666	2,036	33	37	29
		45≤Age≤64	940	5,083	29	32	39
		Age≥65	220	1,707	27	19	54
	PRA≥20	0≤Age≤21	*	22	64	23	14
		22≤Age≤44	34	150	37	29	34
		45≤Age≤64	43	351	39	20	40
		Age≥65	*	115	30	12	58
All			4,691	20,164	39	25	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 2011, 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. Abbreviations: ESRD, end-stage renal disease; PRA, panel reactive antibodies.*

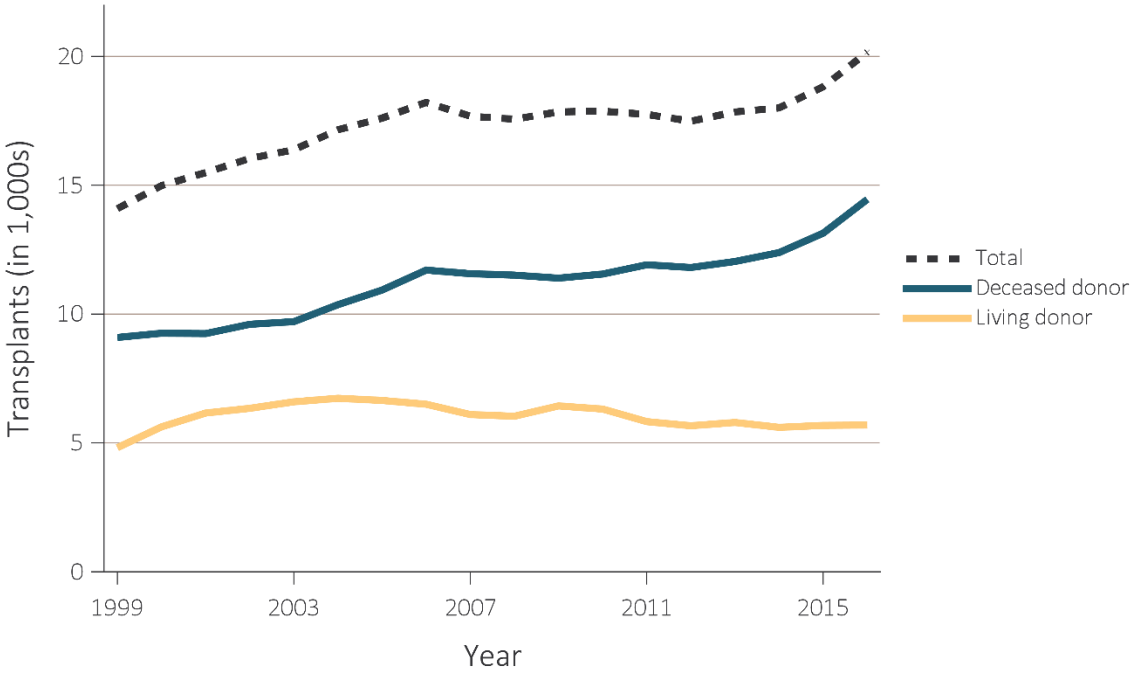
Transplant Counts and Rates

During 2016, 20,161 kidney transplants were performed in the United States (19,301 were kidney-alone; Figure 6.6), a record number. The increase was exclusively from deceased donors. Of the transplants, 5,692 were identified as originating from living donors (28.2%) and 14,451 (71.7%) from deceased donors.

The cumulative number of recipients living with a functioning kidney transplant continued to grow, reaching 215,061 in 2016, a 3% increase over 2015 (Figure 6.7).

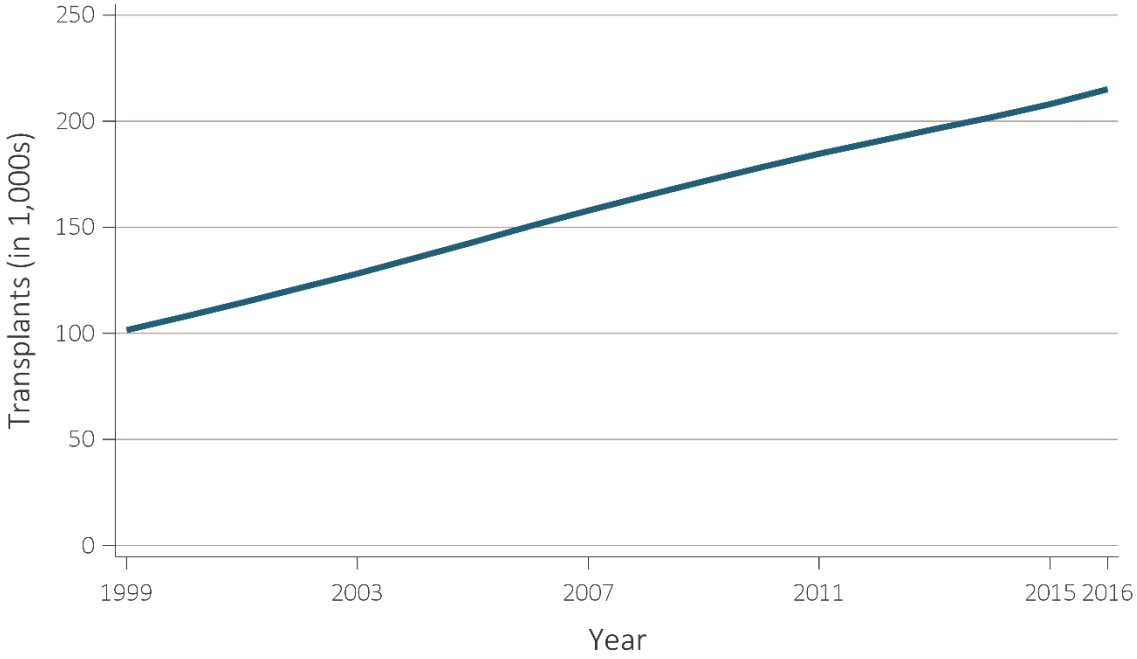
As the overall dialysis population expanded, the annual unadjusted transplant rate per 100 dialysis patient-years saw a continuous decline, although it plateaued since 2013 (Figure 6.8), and has recently started to increase slightly. The rise is likely driven by the relatively large increase in deceased-donor counts since 2015.

vol 2 Figure 6.6 Number of kidney transplants by donor type, 1999-2016



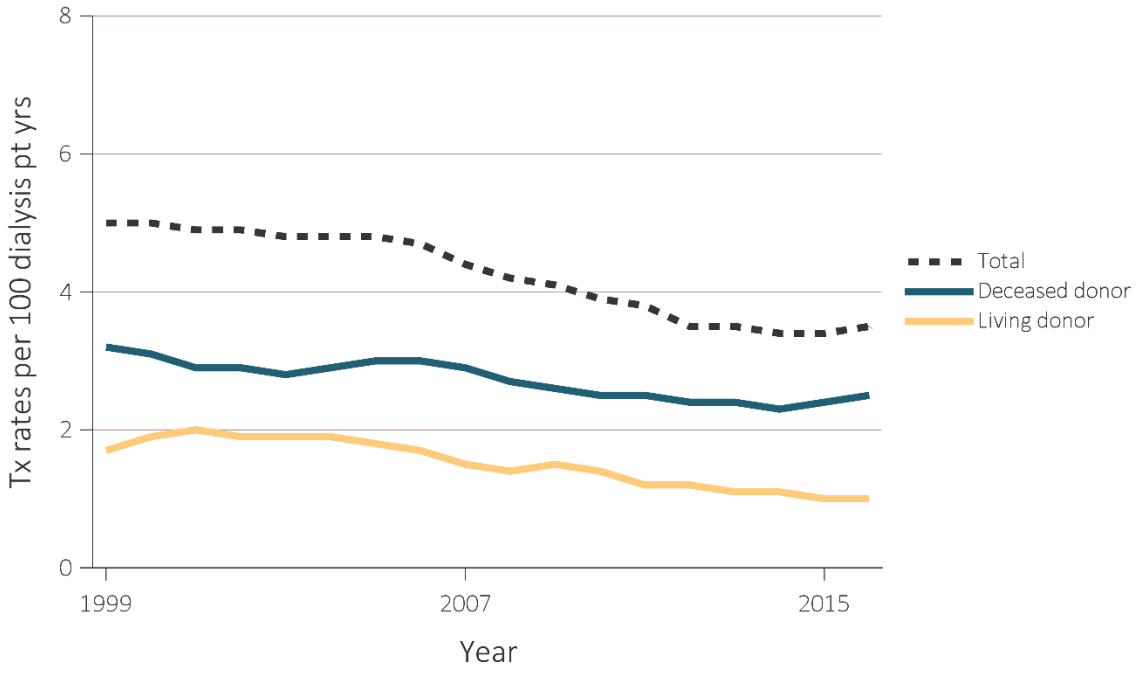
Data Source: Reference Tables E.8, E.8(2), and E.8(3). Number of kidney transplants by donor type. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014.

vol 2 Figure 6.7 Number of patients with a functioning kidney transplant, 1999-2016



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.

vol 2 Figure 6.8 Unadjusted kidney transplant rates, by donor type, 1999-2016



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 2016, transplant rates remained stable relative to 2015 for most patient categories (Table 6.3). In upcoming sections, we present counts and rates of transplants separately for deceased- versus living-donor sources, as trends differed substantially for certain subgroups. These changes resulted from KAS policy changes, which primarily influence deceased-donor transplants.

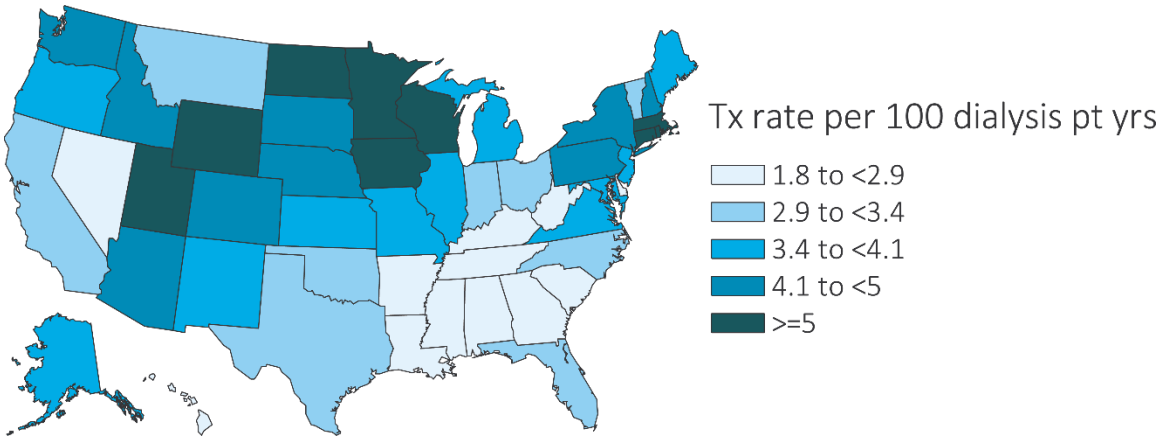
vol 2 Table 6.3 Unadjusted kidney transplant rates, all donor types, by age, sex, race, and primary cause of ESRD, per 100 dialysis patient-years, 2007-2016

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Age										
0-21	31.6	32.5	34.7	32.8	32.0	32.5	31.6	31.9	33.4	34.4
22-44	9.5	8.8	8.7	8.1	7.7	7.6	7.3	7.2	8.6	8.5
45-64	5.4	5.1	4.9	4.8	4.5	4.2	4.3	4.1	4.0	4.3
65-74	2.5	2.6	2.6	2.6	2.6	2.5	2.4	2.4	2.2	2.4
75 and older	0.4	0.3	0.4	0.4	0.4	0.4	0.3	0.4	0.3	0.3
Sex										
Male	4.9	4.6	4.4	4.3	4.1	3.9	3.8	3.7	3.7	3.7
Female	3.8	3.7	3.7	3.5	3.3	3.1	3.1	3.0	3.1	3.3
Race										
White	5.2	4.9	4.8	4.5	4.3	4.1	4.0	3.9	3.7	3.9
Black/African American	3.0	2.9	2.9	2.9	2.8	2.5	2.5	2.4	2.7	2.7
American Indian/Alaska Native	2.9	3.5	3.6	2.8	3.0	2.4	2.1	2.6	3.0	2.8
Asian	5.2	5.4	5.0	4.9	4.7	4.6	4.6	4.6	4.9	5.1
Native Hawaiian or Pacific Islander	3.3	3.2	3.1	2.9	2.4	2.4	2.2	2.6	2.6	2.4
Other or Multiracial	4.9	5.2	6.1	6.9	6.7	6.6	3.0	4.1	3.6	4.7
Unknown	12.5	13.3	11.1	8.6	9.4	8.3	8.4	12.3	12.2	10.2
Primary Cause of ESRD										
Diabetes	3.0	2.8	2.7	2.6	2.5	2.3	2.3	2.2	2.0	2.1
Hypertension	3.0	2.9	2.8	2.7	2.5	2.5	2.5	2.4	2.5	2.6
Glomerulonephritis	8.5	8.2	8.1	8.2	7.8	7.4	7.2	7.0	7.6	7.4
All	4.4	4.2	4.1	3.9	3.8	3.5	3.5	3.4	3.4	3.5

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.

Rates of transplantation per 100 dialysis patient-years are presented by geographic region in Figure 6.9, without statistical adjustment. The upper Midwest Plains states, Rocky Mountain states, and New England demonstrated the highest transplant rates, with lowest rates found in Nevada, 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 Figure 6.9 Geographic distribution of unadjusted transplant rates by state, 2016



Data Source: Special analyses, USRDS ESRD Database. Geographic distribution of unadjusted transplant rates by state, 2016. 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.

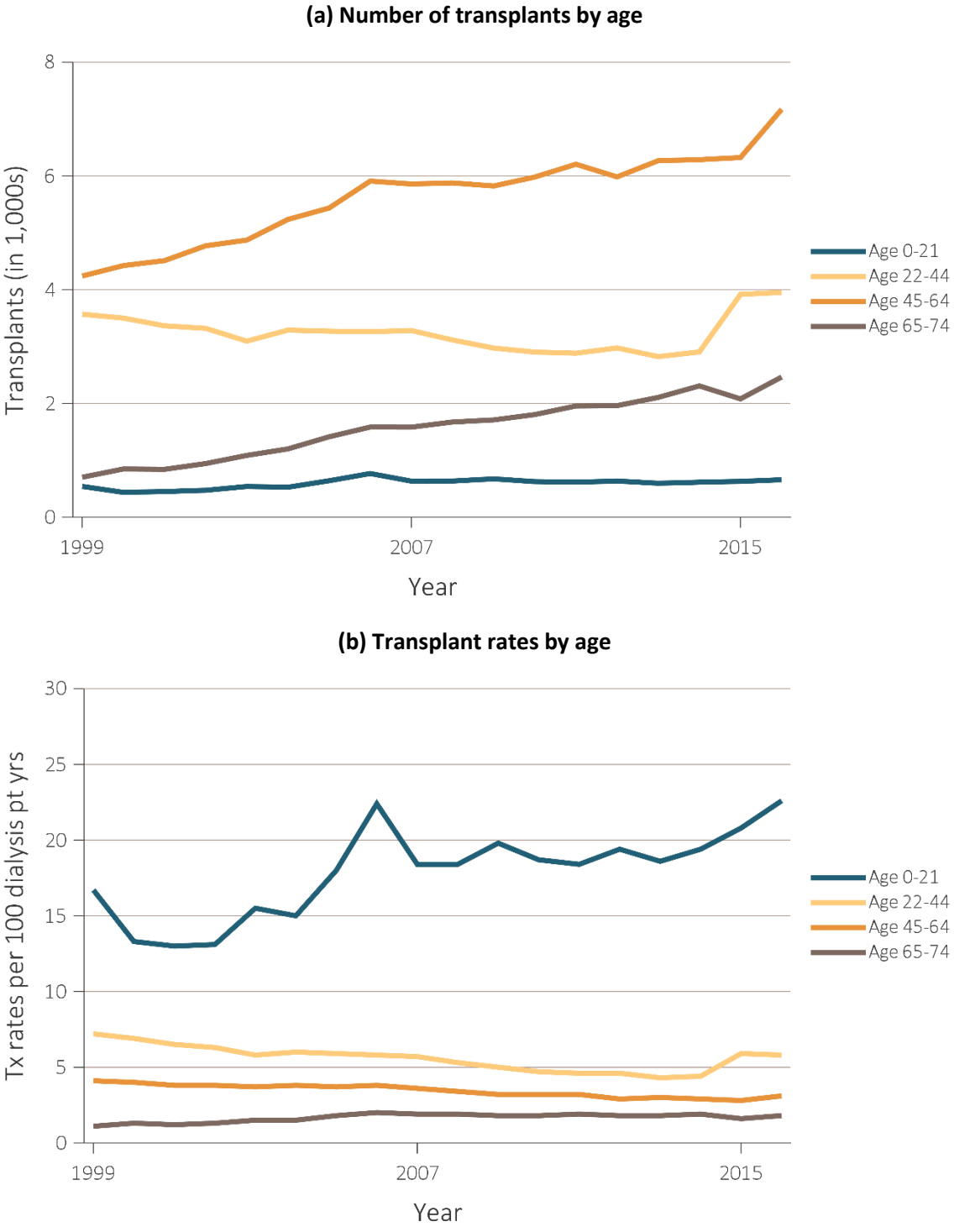
Counts and Rates of Deceased-Donor Transplants

As presented above in Figure 6.6, 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 6.10-6.13).

Counts and rates of deceased-donor transplantation per 100 dialysis patient-years are presented by age category in Figure 6.10, without statistical adjustment. Counts in 2016 rose relative to 2015 for all age categories, though patterns varied. For recipients aged 45-64 years, there was a sharp increase in 2016, to 7,172 deceased-donor transplants, a 13.4% rise compared to 2015 (Figure 6.10.a). In contrast, for those aged 22-44 years the number of deceased-donor transplants increased sharply from 2,906 in 2014 to 3,915 in 2015 but only increased slightly in 2016 to 3,952.

The patterns for deceased-donor transplant counts shown in Figure 6.10.a contrast with the rates shown in Figure 6.10.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 (since the numbers have been stable and the rate increased, this corresponds to a decrease in incident ESRD in this population as shown in Figure 1.4 of Volume 2, *Chapter 1*: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities). There has been a slow reduction in deceased-donor kidney transplantation rates for those aged 45-64 and 65-74 years over time, which appears to have plateaued in 2016. The rate for those aged 22-44 years rose sharply in 2015, but plateaued in 2016.

vol 2 Figure 6.10 Number of deceased-donor transplants and unadjusted transplant rates among deceased-donor kidney recipients, by recipient age, 1999-2016



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. Abbreviations: pt yrs, patient-years; tx, transplant.

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 6.11.a). Males received substantially more deceased-donor transplants than did females, on average 52.6% more annually since 1999. 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 had been declining since 2006 for both male and female dialysis patients (Figure 6.11.b), but have risen in recent years, particularly among females. The difference in transplantation rates between males and females has therefore narrowed. The latter finding may have resulted from the additional prioritization of sensitized candidates in the new allocation policy.

vol 2 Figure 6.11 Number of deceased-donor transplants and unadjusted transplant rates among deceased-donor kidney recipients, by recipient sex, 1999-2016

(a) Number of transplants by sex

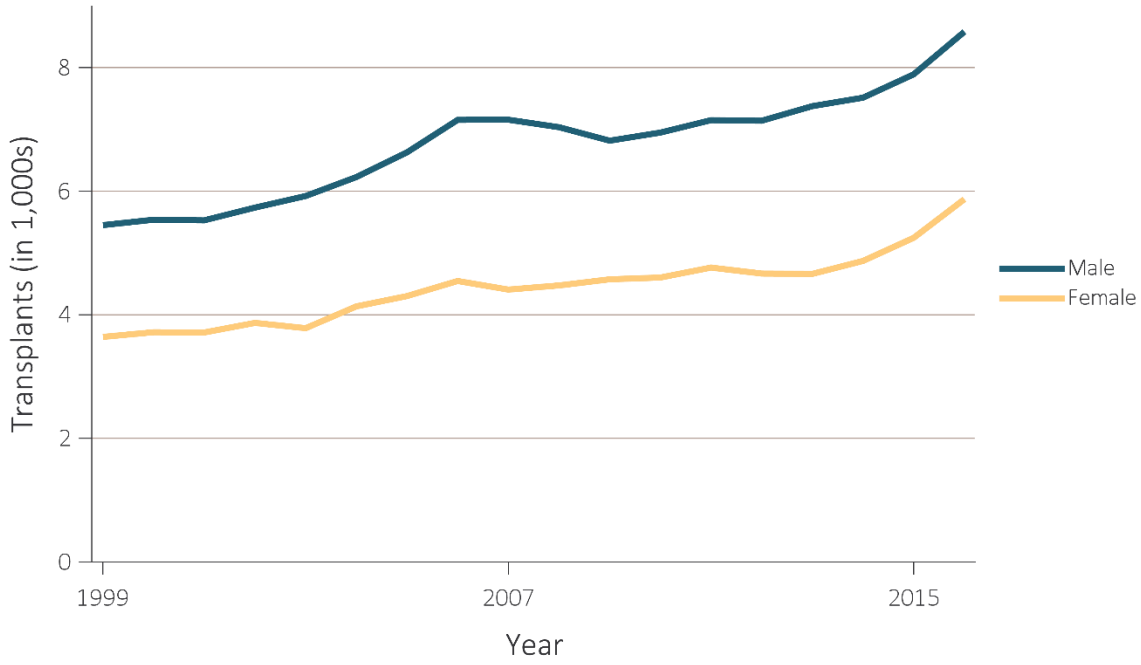
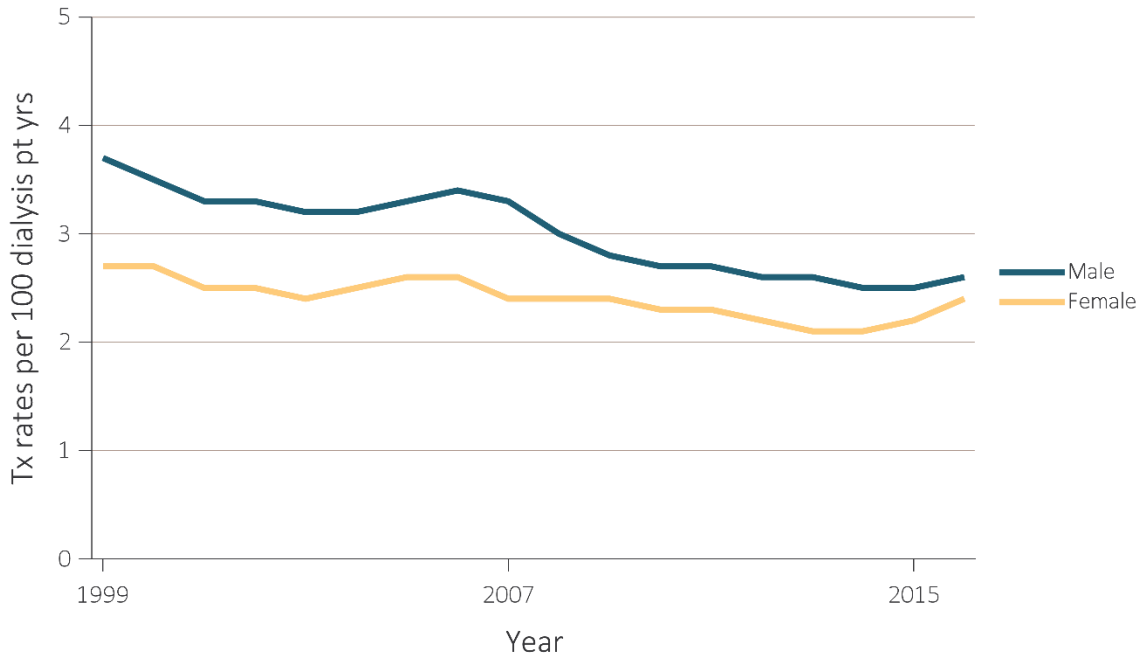


Figure 6.11 continued on next page.

vol 2 Figure 6.11 Number of deceased-donor transplants and unadjusted transplant rates among deceased-donor kidney recipients, by recipient sex, 1999-2016 (continued)

(b) Transplant rates by sex

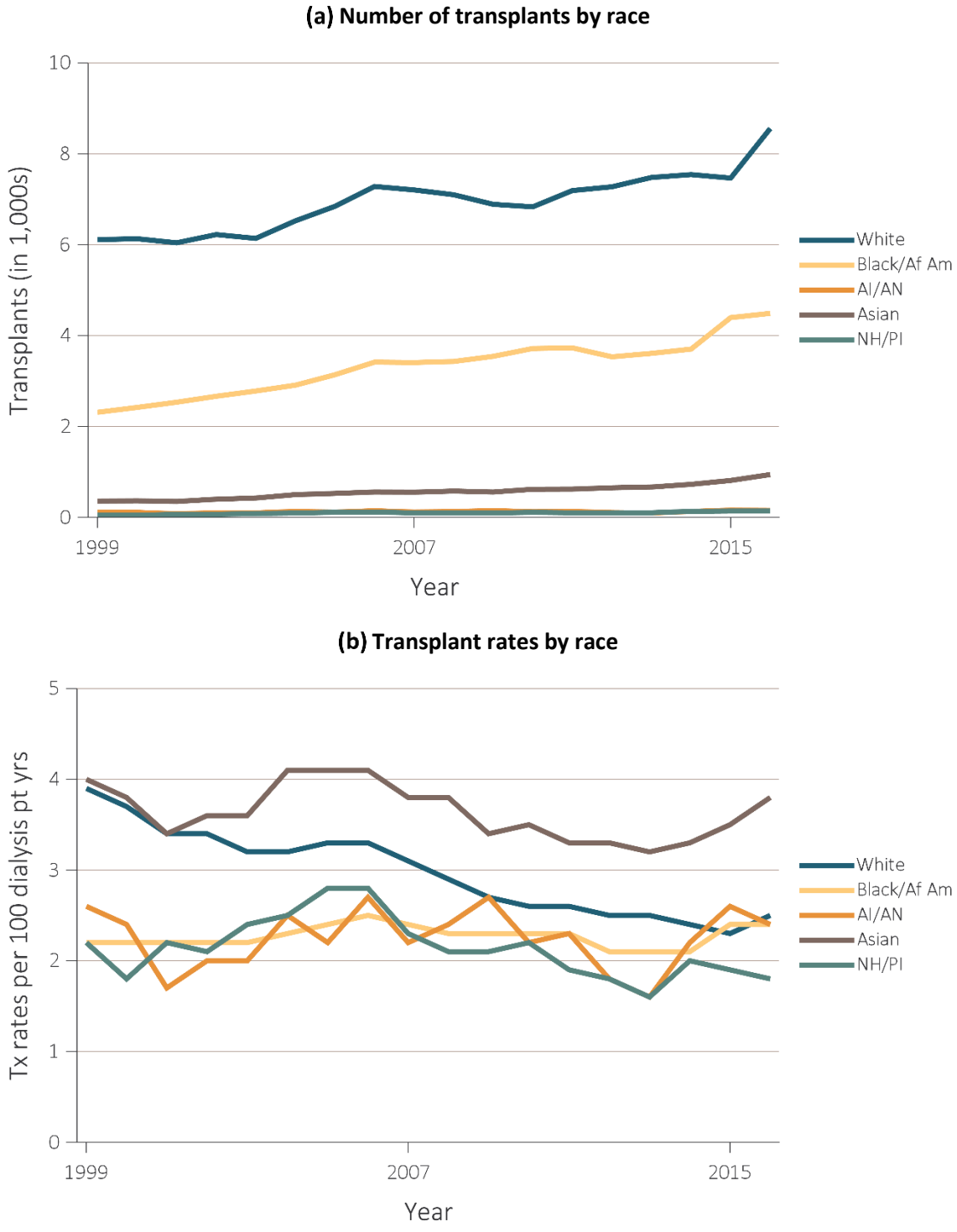


Data Source: Reference Tables E.8(2) and E.9(2). (a) Deceased-donor kidney transplant counts by recipient sex. (b) Unadjusted deceased-donor kidney transplant rates by recipient sex. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December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

For dialysis patients of White race there was a sharp increase in the number of transplants in 2016, whereas there was a modest rise among Black patients, following a sharper increase in those patients in 2015 soon after the new allocation system was instituted (Figure 6.12.a).

Deceased-donor transplant rates for White patients had been declining since 1999 but rose slightly in 2016 (Figure 6.12.b). Since 2002, deceased-donor transplant rates have been highest for Asians. In 2016, the rates of deceased-donor transplants for Blacks and American Indians/Alaska Natives were 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 wait-listed.

vol 2 Figure 6.12 Number of deceased-donor transplants and unadjusted transplant rates among deceased-donor kidney recipients, by recipient race, 1999-2016



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 yrs, patient-years; tx, transplant.

When considering transplant counts by primary cause of ESRD, the largest growth in deceased-donor transplantation numbers has been among recipients with DM or hypertension (HTN; Figure 6.13.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 had been in relative decline since 2006 (Figure 6.13.b). This trend has either reversed or stabilized in 2016 across all diagnosis groups.

vol 2 Figure 6.13 Number of deceased-donor transplants and unadjusted transplant rates among deceased-donor kidney recipients, by recipient primary cause of ESRD, 1999-2016

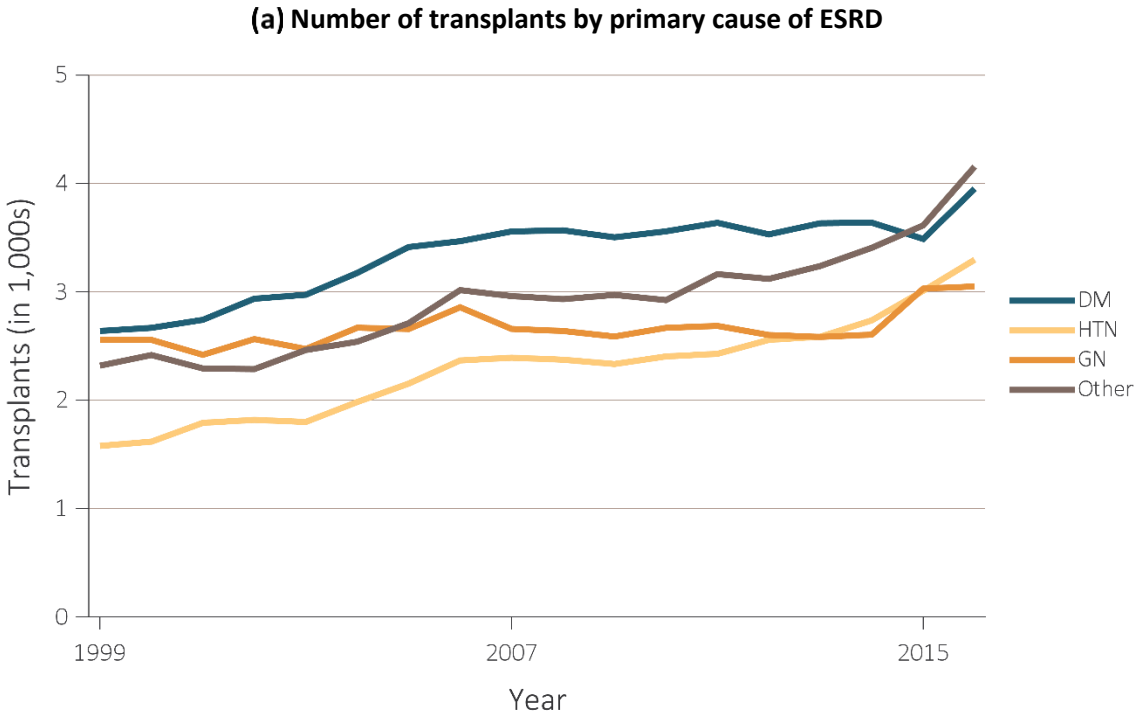
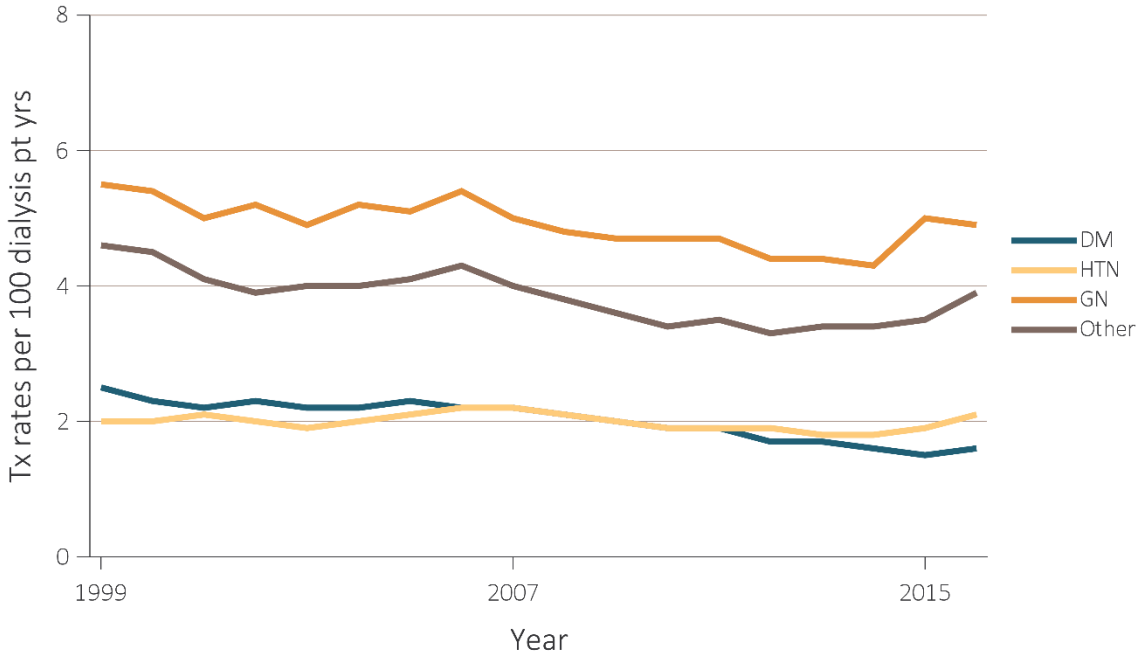


Figure 6.13 continued on next page.

vol 2 Figure 6.13 Number of deceased-donor transplants and unadjusted transplant rates among deceased-donor kidney recipients, by recipient primary cause of ESRD, 1999-2016 (continued)

(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, diabetes mellitus; ESRD, end-stage renal disease; GN, glomerulonephritis; HTN, hypertension; pt yrs, patient-years; tx, transplant.

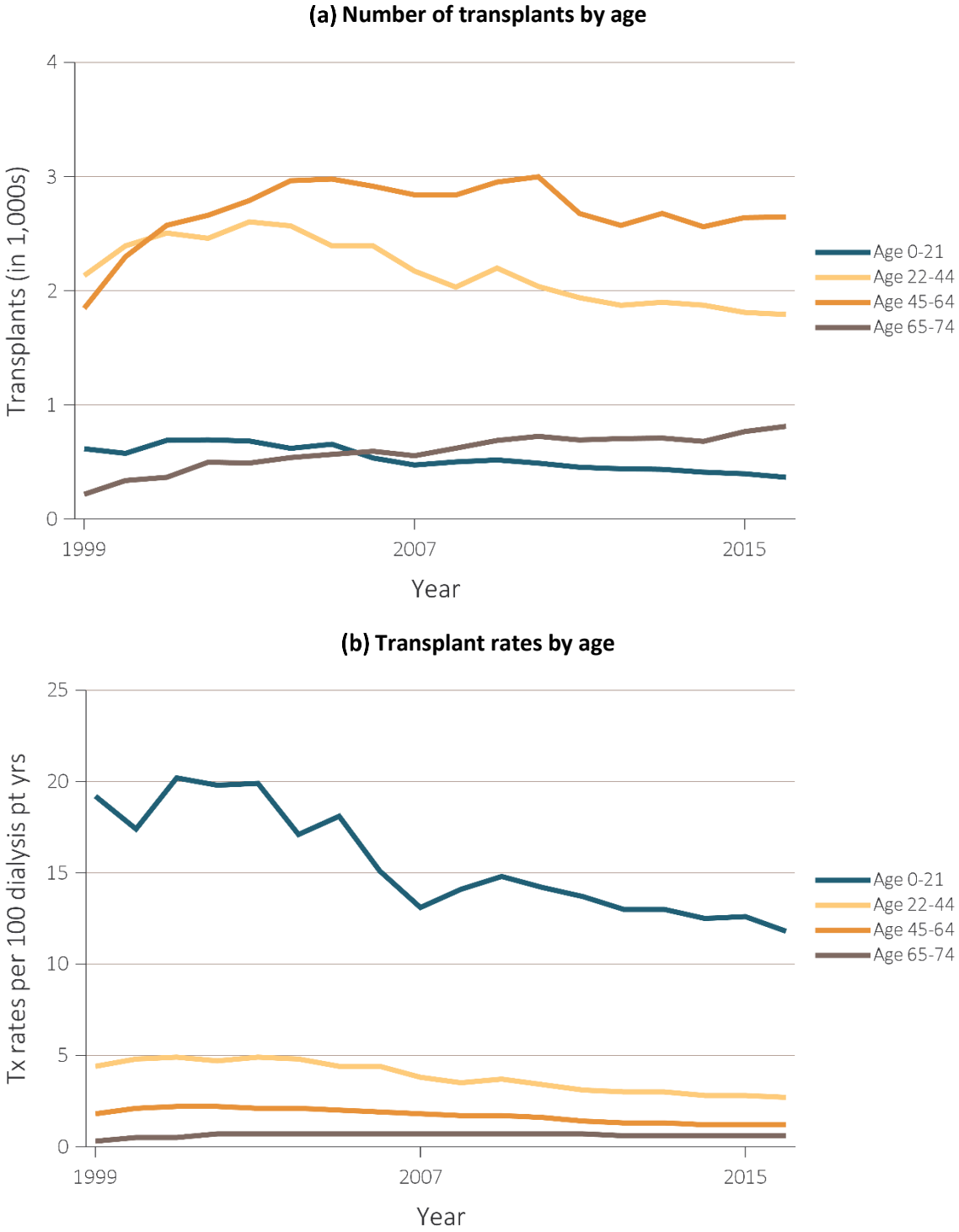
Counts and Rates of Living-Donor Transplants

Since 2004 there has been an annual decline in living-donor kidney transplant counts, although this appears to have plateaued in recent years (Figure 6.6). 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 6.14-6.17).

Counts of living-donor transplants for those aged 22-44 years decreased from 2,505 in 2003 to 1,791 in 2016 (Figure 6.14.a). The number of living-donor transplants for the group aged 45-64 years has been stable in more recent years, at 2,645 in 2016, after a fall starting in 2011. 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 6.14.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 shown a more modest decline. 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 increased slightly over the past decade.

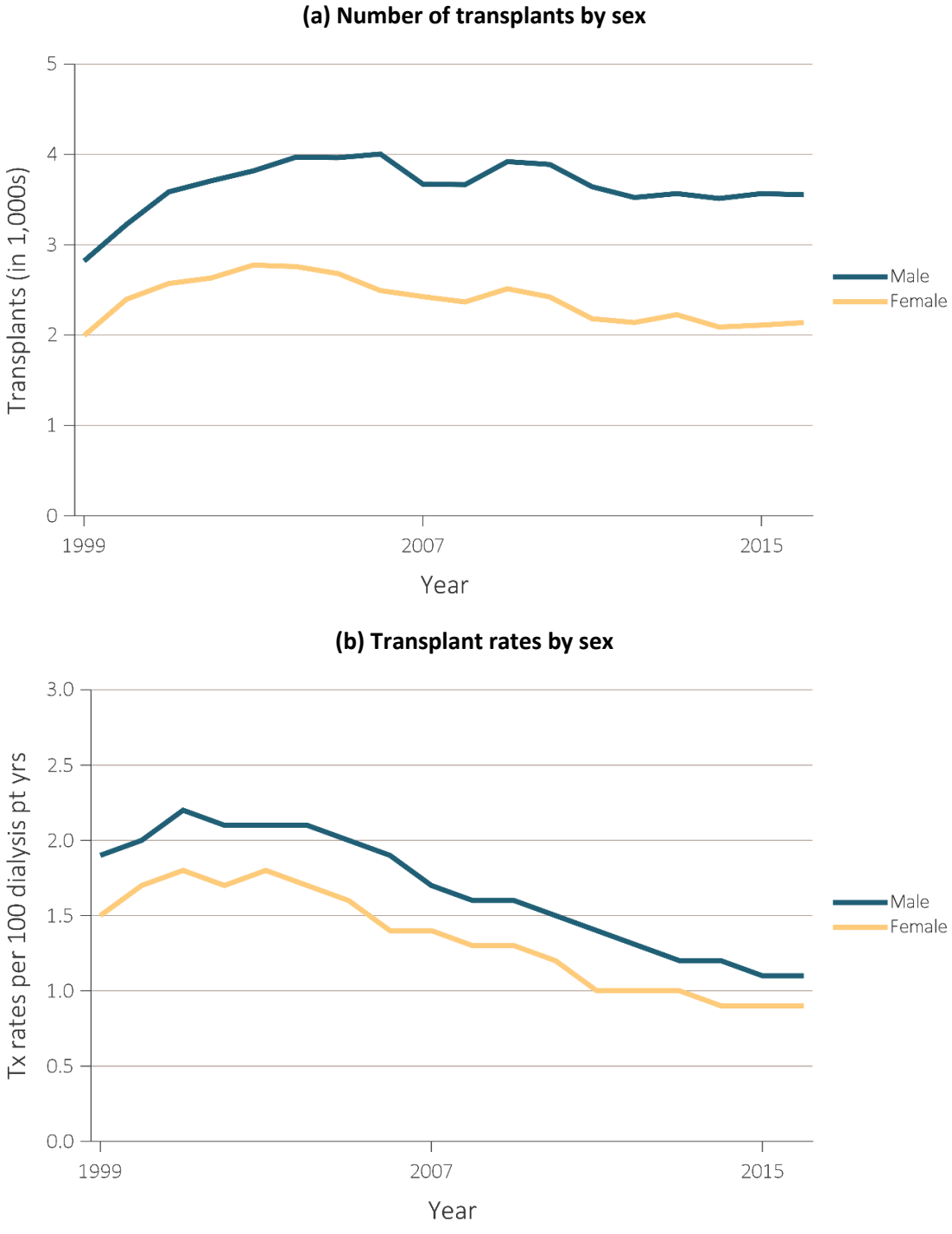
vol 2 Figure 6.14 Number of living-donor transplants and unadjusted transplant rates among living-donor kidney recipients, by recipient age, 1999-2016



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 yrs, patient-years; tx, transplant.

The annual counts of living-donor kidney transplantation by sex showed consistently higher numbers of male recipients (Figure 6.15.a). However, while the living-donor transplant rates continued to remain higher for males than for females, the difference was relatively small (Figure 6.15.b).

vol 2 Figure 6.15 Number of living-donor transplants and unadjusted transplant rates among living-donor kidney recipients, by recipient sex, 1999-2016



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 6.16.a). Since then, the annual number of living-donor kidney transplants has decreased for Whites and Blacks, though most recent counts have been relatively stable. The counts for Asians have shown a small increase over time. 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 6.16.b).

vol 2 Figure 6.16 Number of living-donor transplants and unadjusted transplant rates among living-donor kidney recipients, by recipient race, 1999-2016

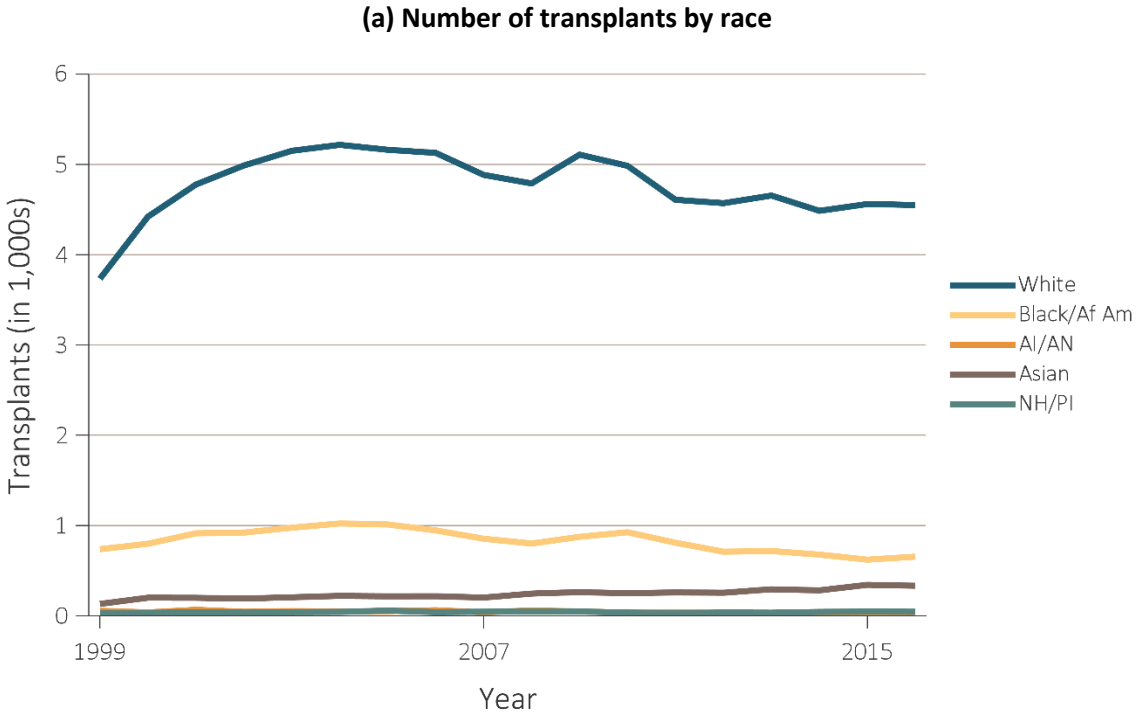
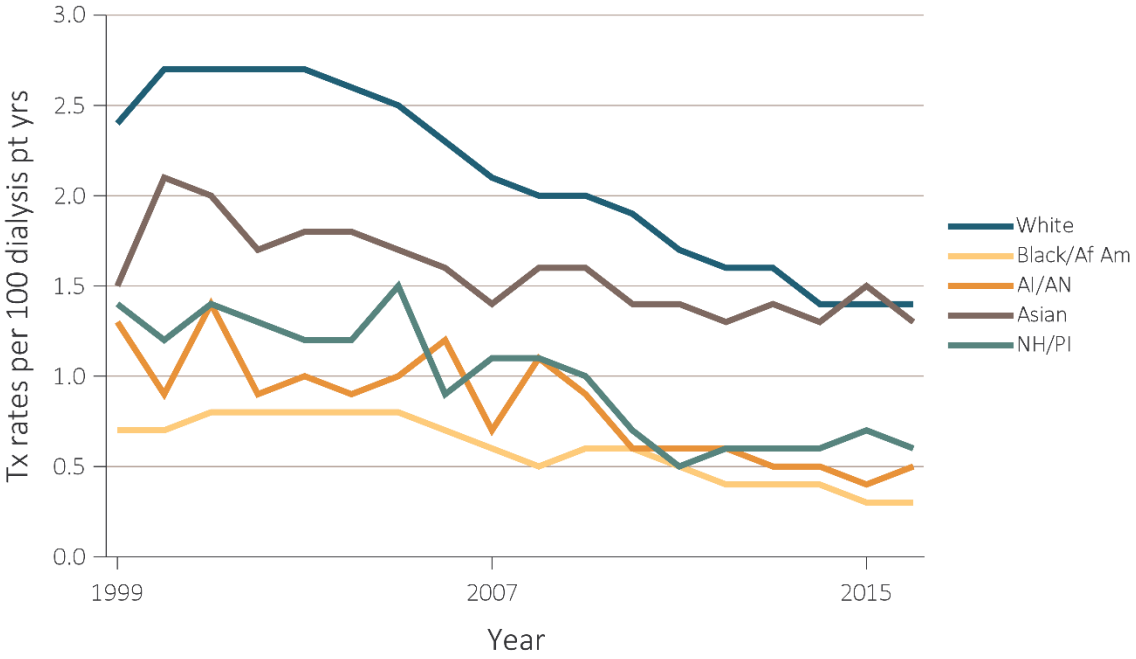


Figure 6.16 continued on next page.

vol 2 Figure 6.16 Number of living-donor transplants and unadjusted transplant rates among living-donor kidney recipients, by recipient race, 1999-2016 (continued)

(b) Transplant rates by race

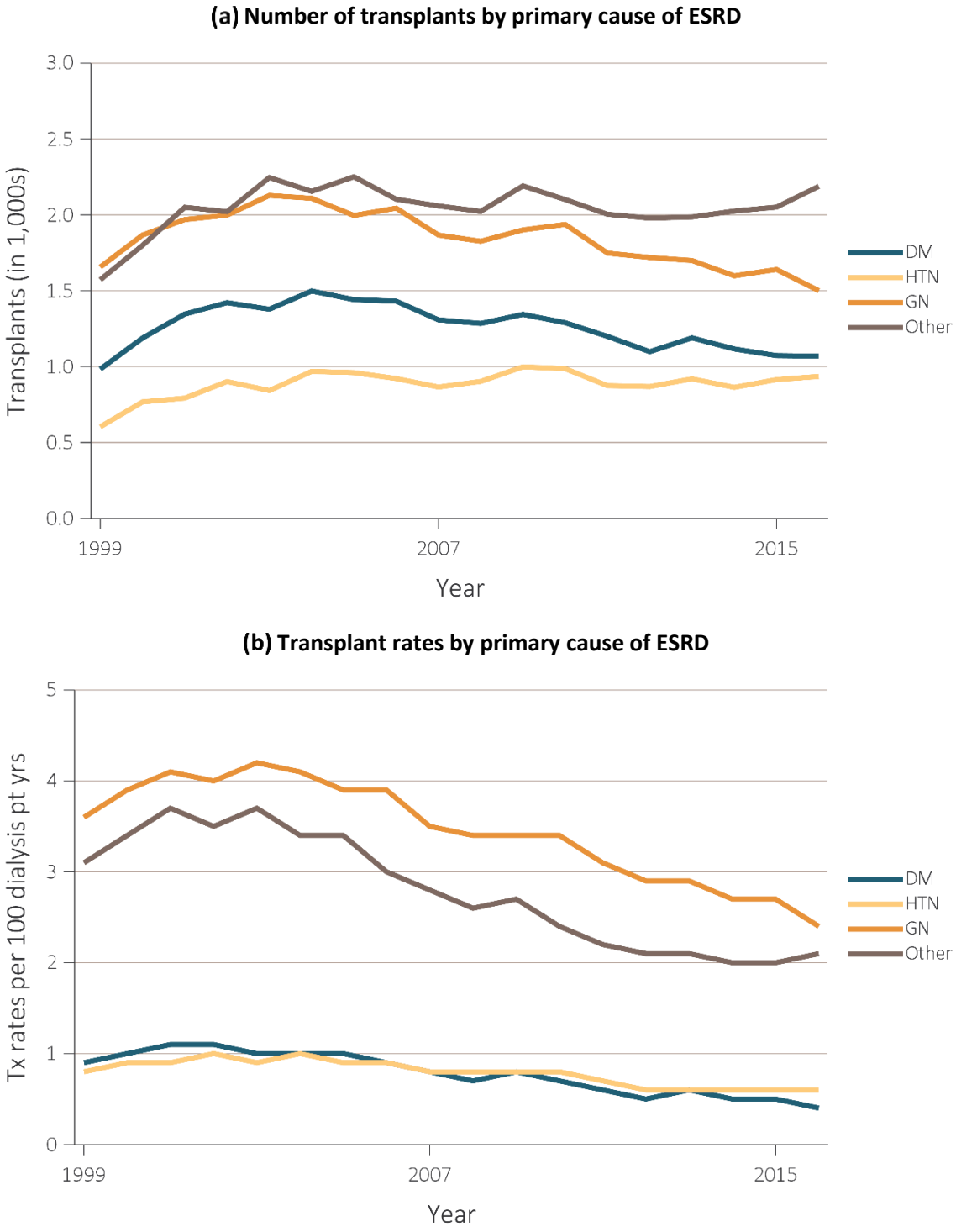


Data Source: Reference Tables E.8(3) and E.9(3). (a) Living-donor kidney transplant counts by recipient race. (b) Unadjusted living-donor kidney transplant rates by recipient race. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December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

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 6.17.a). This trend contrasts with the pattern among deceased-donor recipients (Figure 6.13.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 6.17.b). Like the rates of deceased-donor transplants, those from living donors occur most often among patients with glomerular disease. In frequency, glomerular disease is followed by Other causes (including cystic disease), with rates lowest for those with HTN and DM.

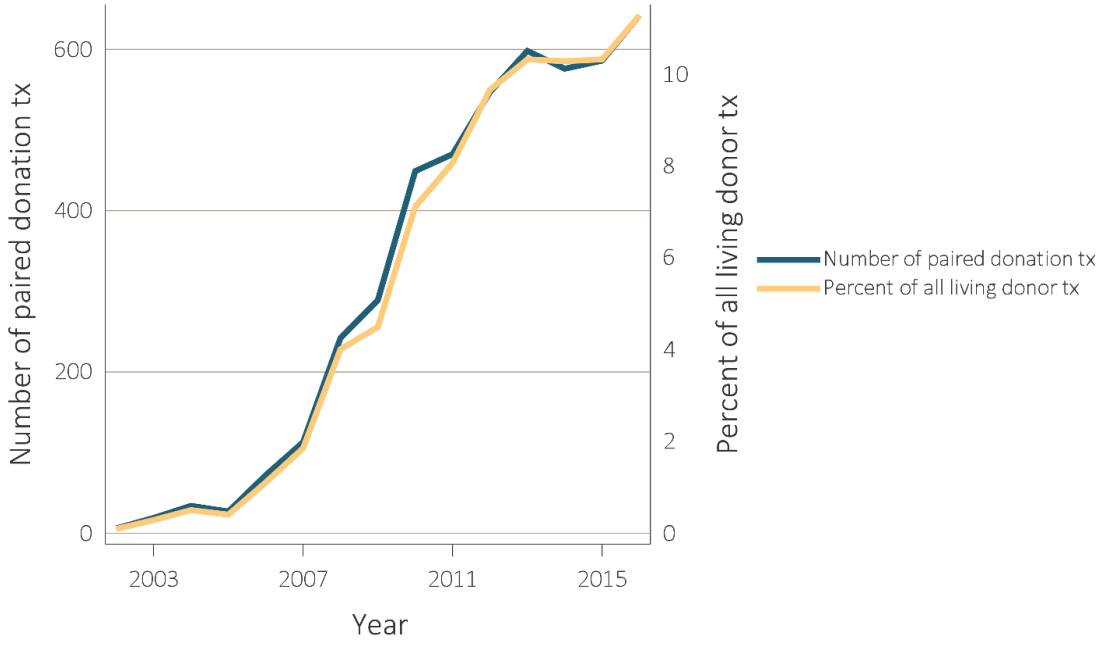
vol 2 Figure 6.17 Number of living-donor transplants and unadjusted transplant rates among living-donor kidney recipients, by recipient primary cause of ESRD, 1999-2016



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, diabetes mellitus; ESRD, end-stage renal disease; GN, glomerulonephritis; HTN, hypertension; pt yrs, patient-years; tx, transplant.

A relatively recent initiative aimed at increasing the availability of living-donor transplants is the process of kidney paired donation (KPD). This approach 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 rose sharply initially, appeared to plateau in 2012, but increased again in 2016, representing 11.3% of living-donor transplants that year (Figure 6.18).

vol 2 Figure 6.18 Number of paired donation transplants and percent of all living-donor transplants, 2002-2016



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.

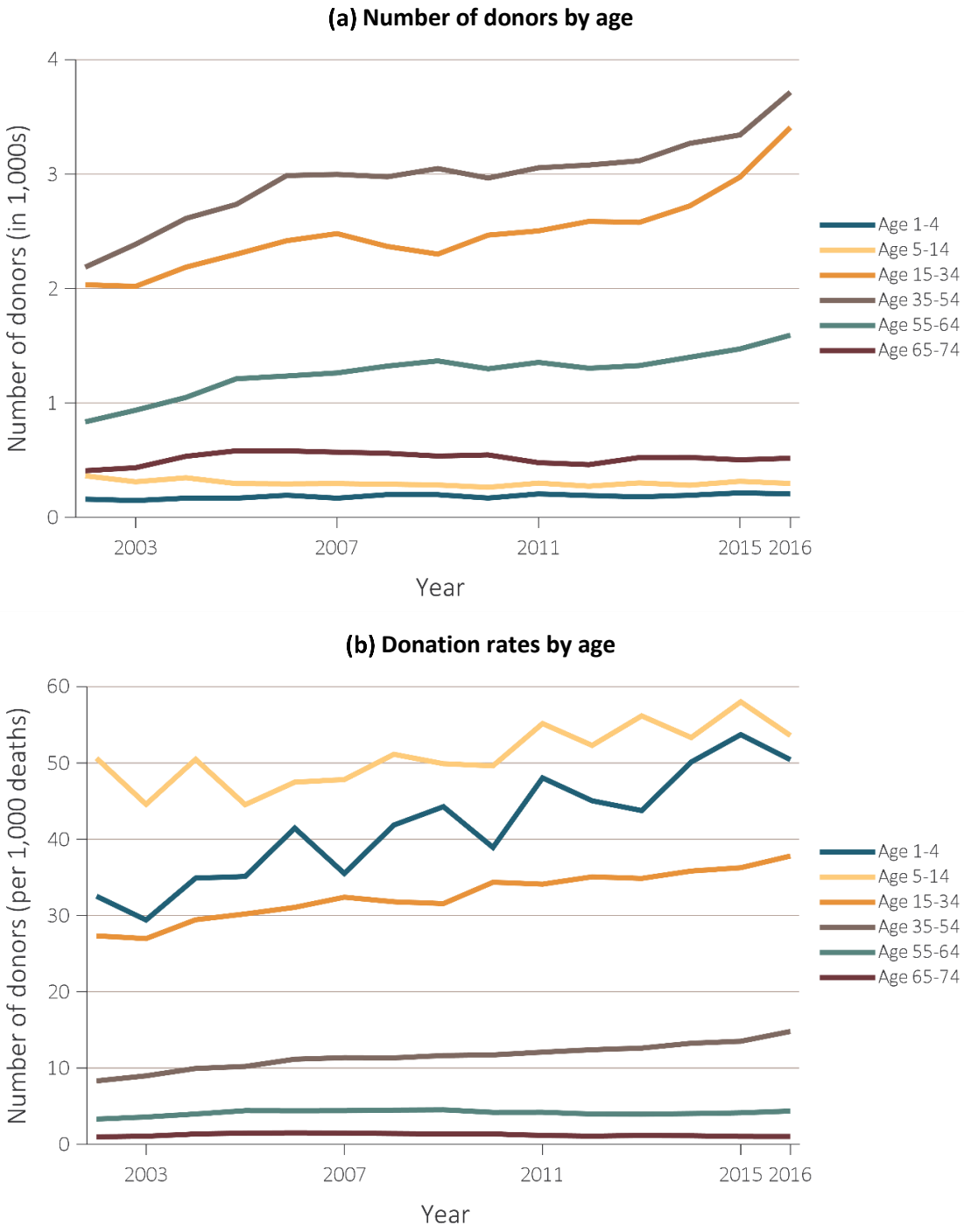
Deceased Donation Counts and Rates among All-cause Deaths

The number of deceased donors, aged 1-74 years, with at least one kidney retrieved increased from 5,981 in 2002 to 9,732 in 2016 (Figure 6.19.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 2016, among the 19,135 kidneys that were recovered from deceased donors, 3,423 (18%) were discarded for various reasons. During 2012-2016, the percentage of kidneys discarded ranged from 17%-18% (OPTN, 2017).

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 15-34 years has been increasing, 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, 2018). The overall donation rates ranged from 5.8 per 1,000 deaths in 2002 to 7.9 per 1,000 deaths in 2016 (Figure 6.19.b). The highest donation rates were among those aged 5-14 years, reaching 53.6 per 1,000 deaths in 2016, followed by those 15-34 years, from whom donations rose from 27 per 1,000 deaths in 2002 to 38 per 1,000 deaths in 2016.

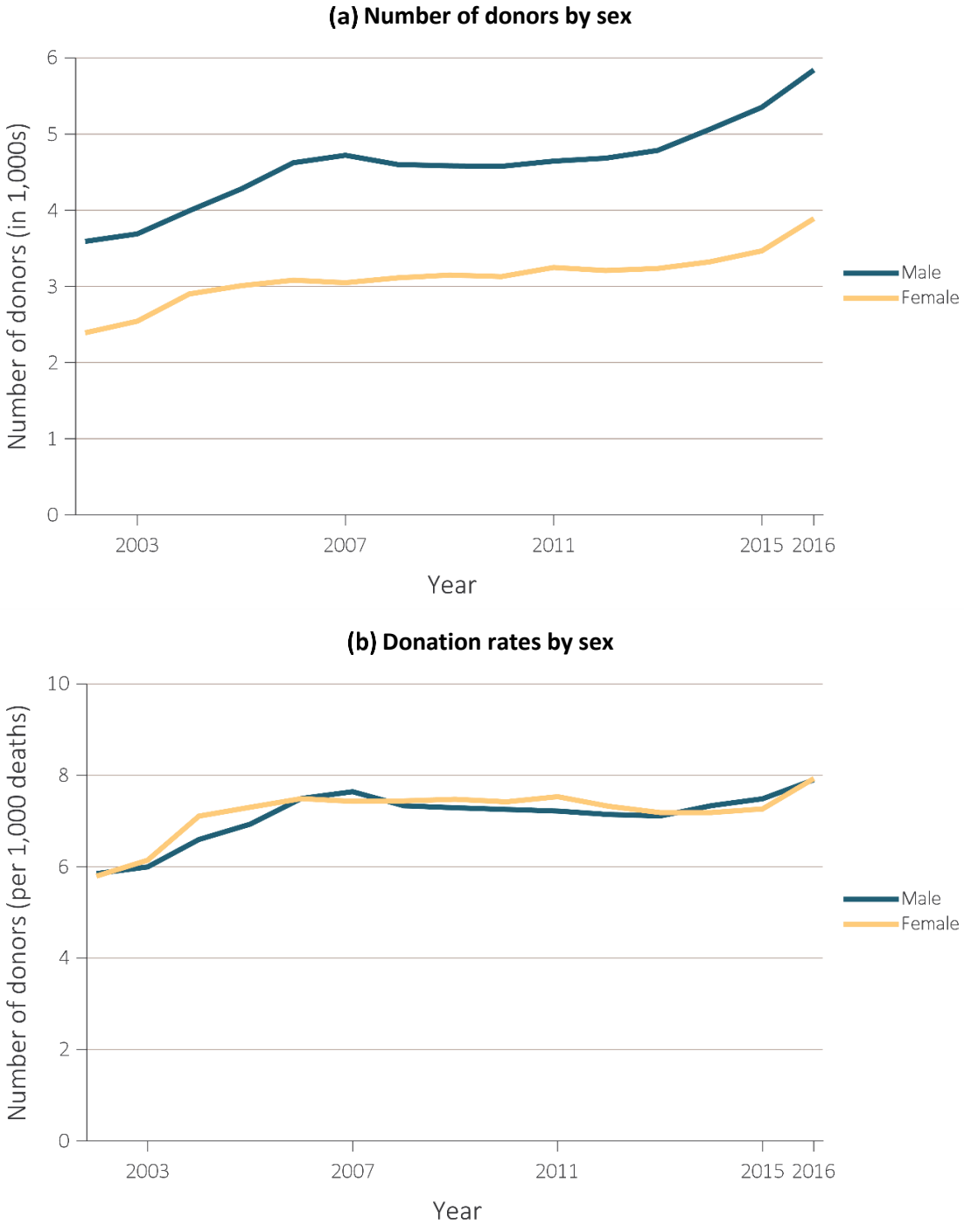
vol 2 Figure 6.19 Number of deceased kidney donors and unadjusted kidney donation rates, by donor age, 2002-2016



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 6.20.a). However, the donation rates were similar between males and females (Figure 6.20.b). Both groups have demonstrated an increase in rates of donation, particularly over the last two years.

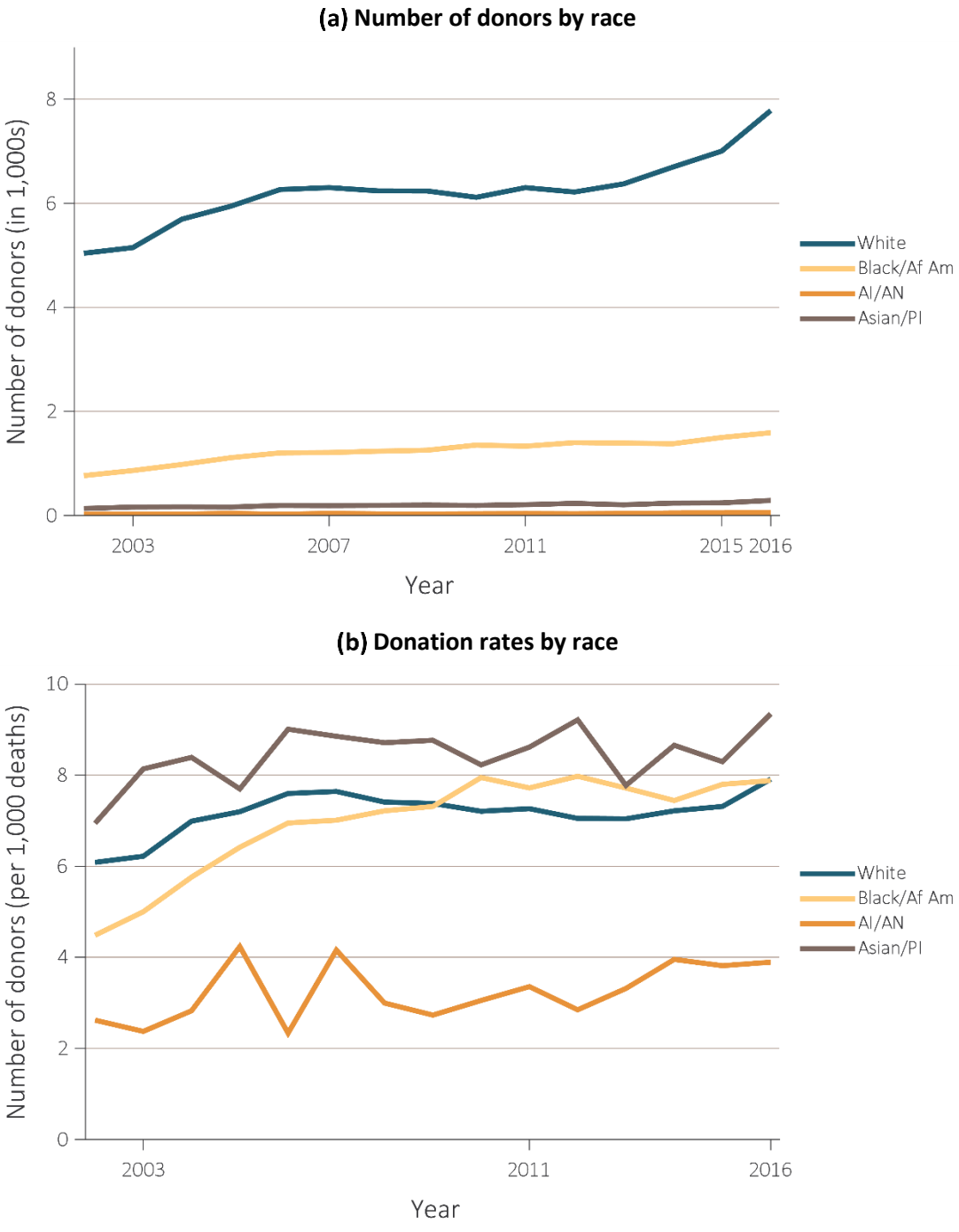
vol 2 Figure 6.20 Number of deceased kidney donors and unadjusted kidney donation rates, by donor sex, 2002-2016



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 2002 to 2016 (Figure 6.21.a). The rate of deceased donors per 1,000 deaths among Blacks has almost doubled during this period (Figure 6.21.b), however, with current donation rates being similar among Blacks, Whites, and Asians or Pacific Islanders.

vol 2 Figure 6.21 Number of deceased kidney donors and unadjusted kidney donation rates, by donor race, 2002-2016



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 6.22.a). There were 2,770 such donations in 2016, representing 28% 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, 2018).

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 6.22.a). Donation rates from traumatic deaths were highest among those aged 5-34 years (46 per 1,000 deaths, Figure 6.22.b). In 2016, 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 6.22 Number of deceased kidney donors and unadjusted kidney donation rates, for traumatic deaths, by donor age, 2002-2016

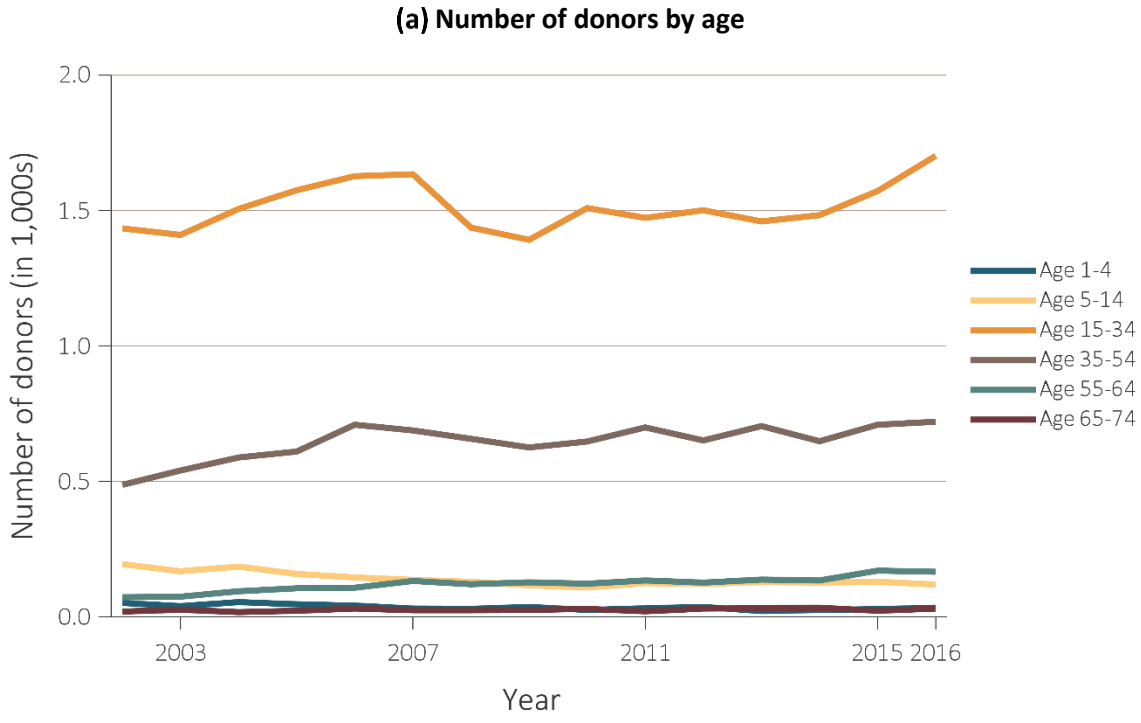
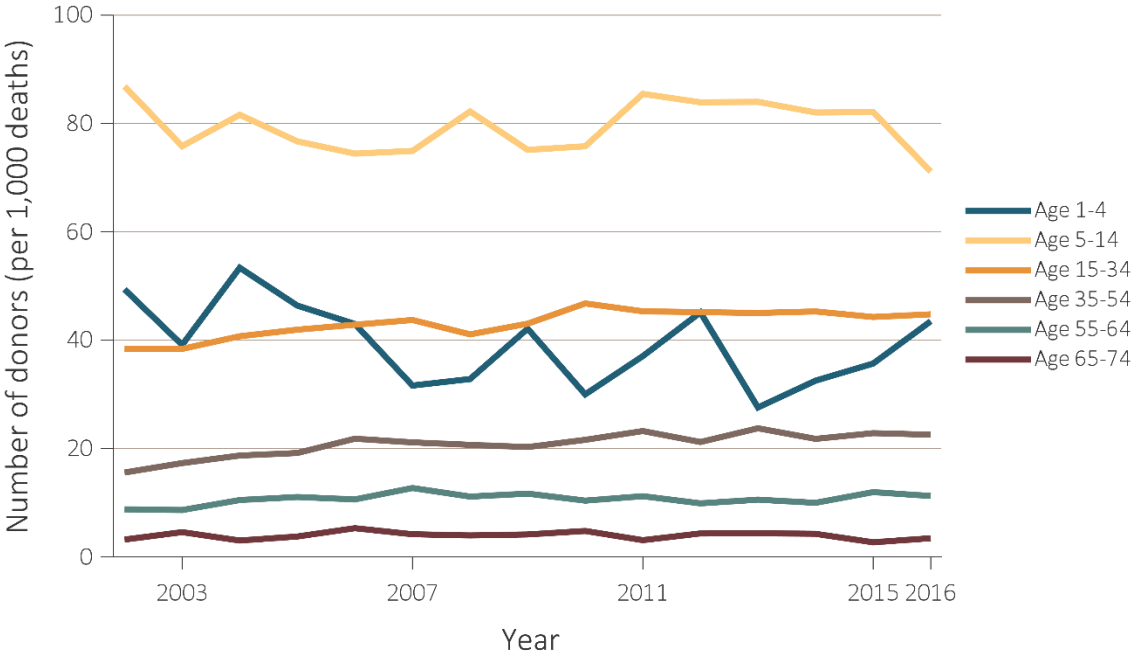


Figure 6.22 continued on next page.

vol 2 Figure 6.22 Number of deceased kidney donors and unadjusted kidney donation rates, for traumatic deaths, by donor age, 2002-2016 (continued)

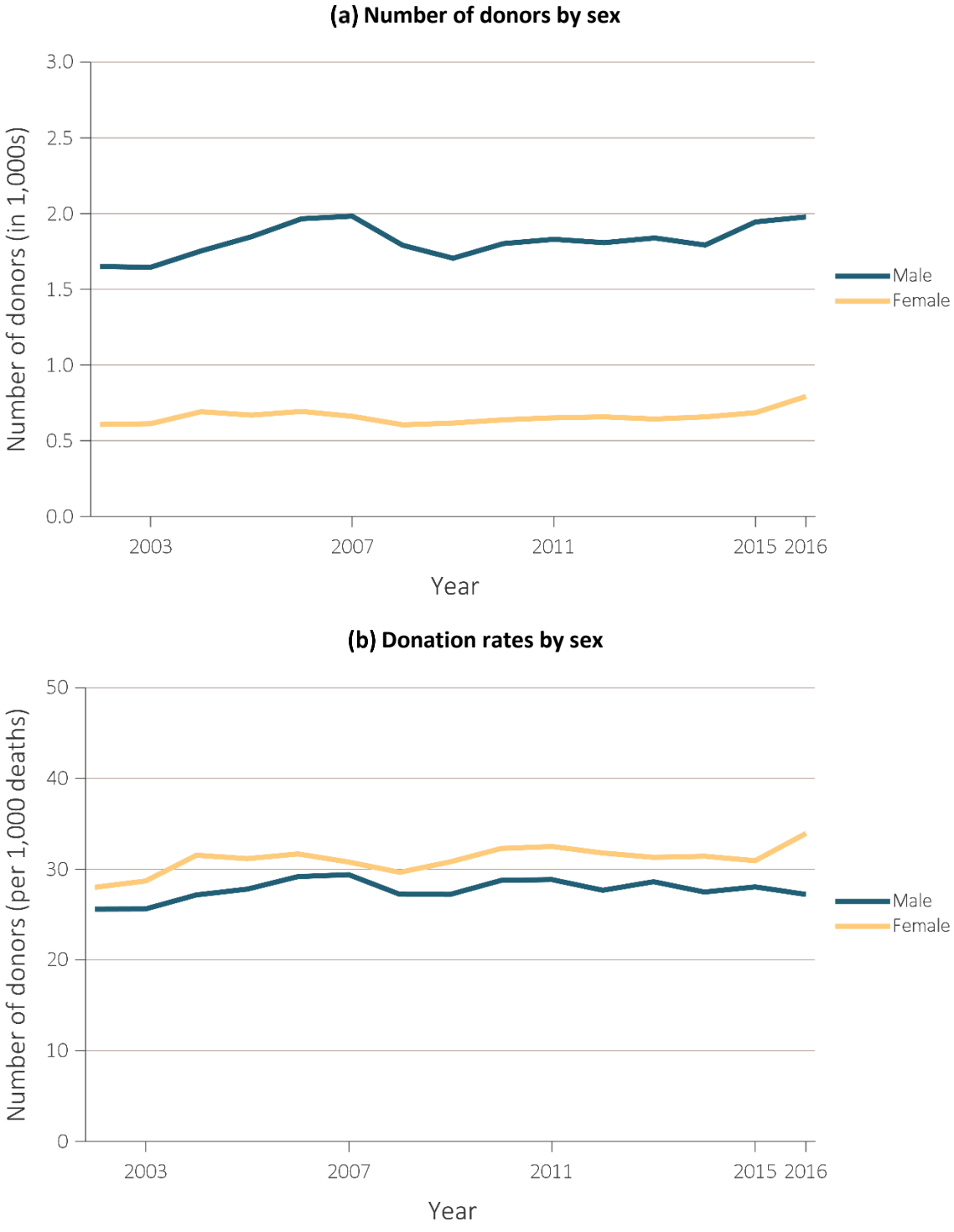
(b) Donation rates by age



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 6.23.a), donation rates by sex were similar (Figure 6.23.b).

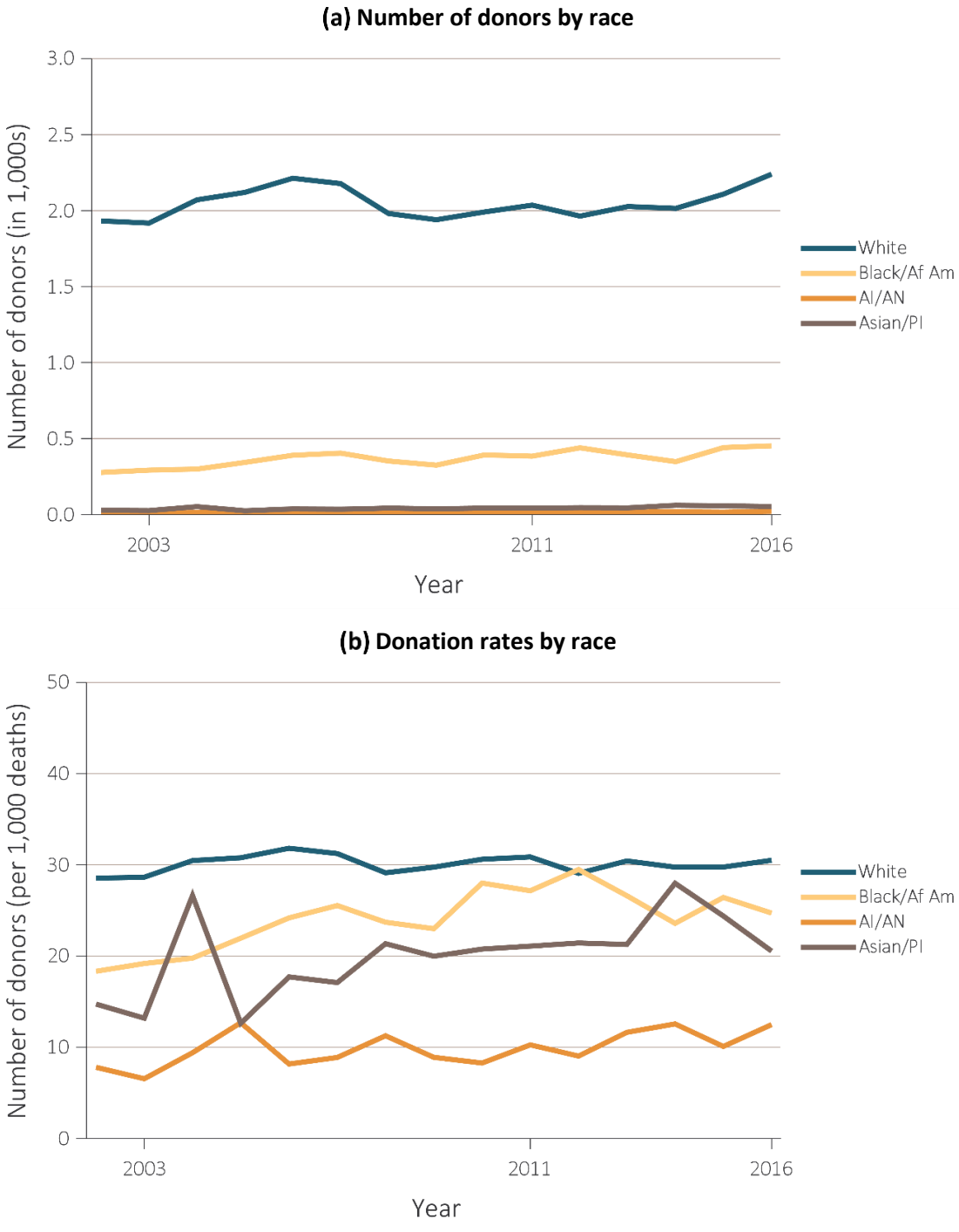
vol 2 Figure 6.23 Number of deceased kidney donors and unadjusted kidney donation rates, for traumatic deaths, by donor sex, 2002-2016



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 2002-2016 (Figure 6.24.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 6.24.b).

vol 2 Figure 6.24 Number of deceased kidney donors and unadjusted kidney donation rates, for traumatic deaths, by donor race, 2002-2016



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 survival (not censored for death) and patient survival, at one, five, and ten years post-transplant.

During 1999-2015, kidney transplant patients generally experienced improved graft outcomes (Figure 6.25). It has frequently been stated that improvements in short-term (one-year) graft survival have not been accompanied by improvements in longer term outcomes. However, for the most recent years available, improvements in long-term (five- and ten-year) survival, although not contemporaneous, have been similar to improvements in short-term graft survival. Among the recipients of deceased-donor kidney transplants, the 2015 probability of one-year graft survival was 93%, improved from 87% in 1999. The 2011 probability of five-year graft survival for deceased-donor kidney transplants was 75%, improved from 66% in 1999. The 2006 probability of ten-year graft survival for deceased-donor kidney transplants was 48%, improved from 44% in 1999. Similar patterns of improvement over time are evident for living-donor kidney transplants, though across the board outcomes are better than for deceased-donor transplants. For the most recent years of data available, the probability of graft survival for living-donor transplants was 98%, 85%, and 65%, for one-, five-, and ten-year periods post-transplant, respectively.

vol 2 Figure 6.25 Trends in 1-, 5-, & 10-year kidney transplant graft survival, 1999-2015

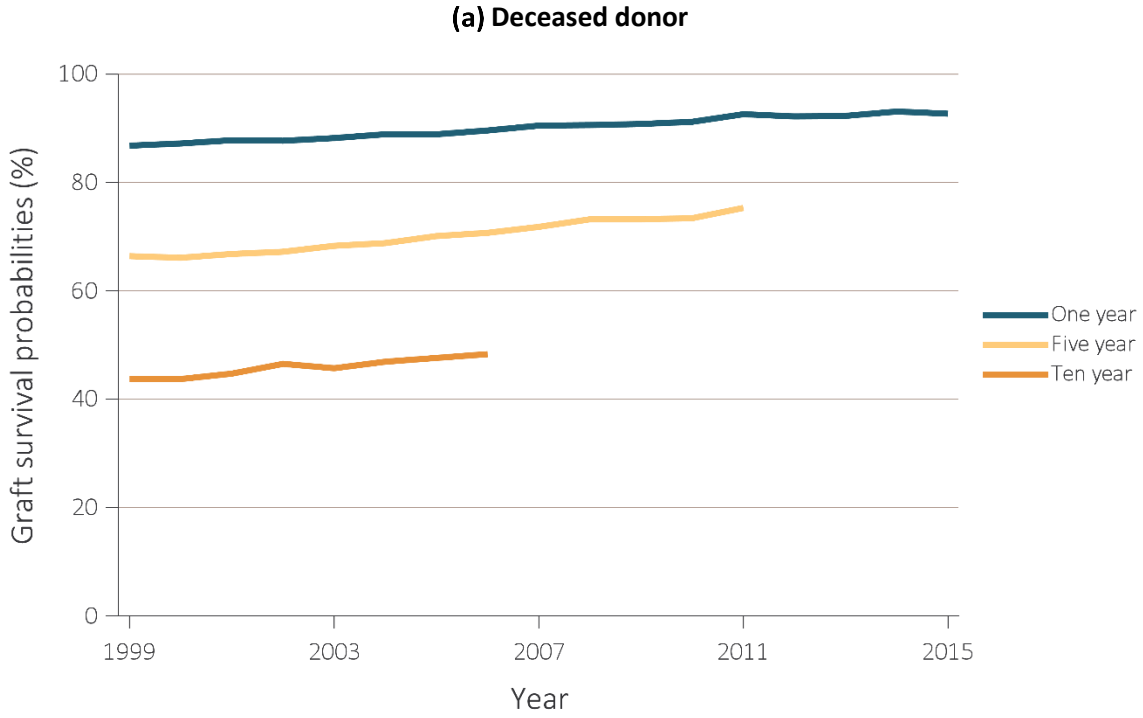
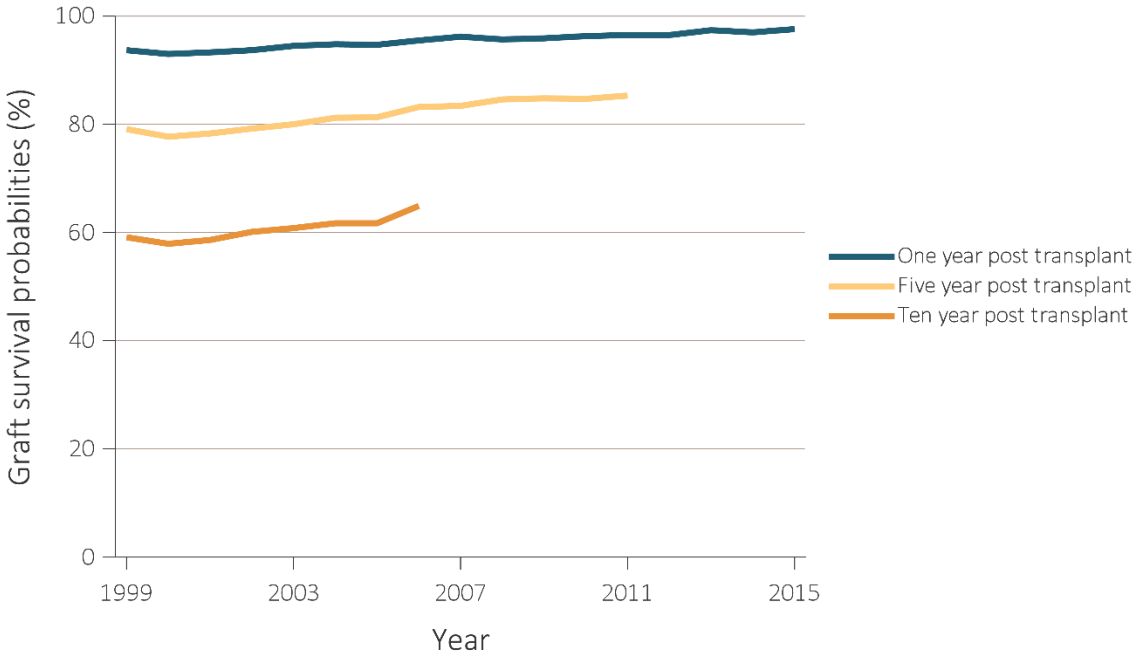


Figure 6.25 continued on next page.

vol 2 Figure 6.25 Trends in 1-, 5-, & 10-year kidney transplant graft survival, 1999-2015 (continued)

(b) Living donor

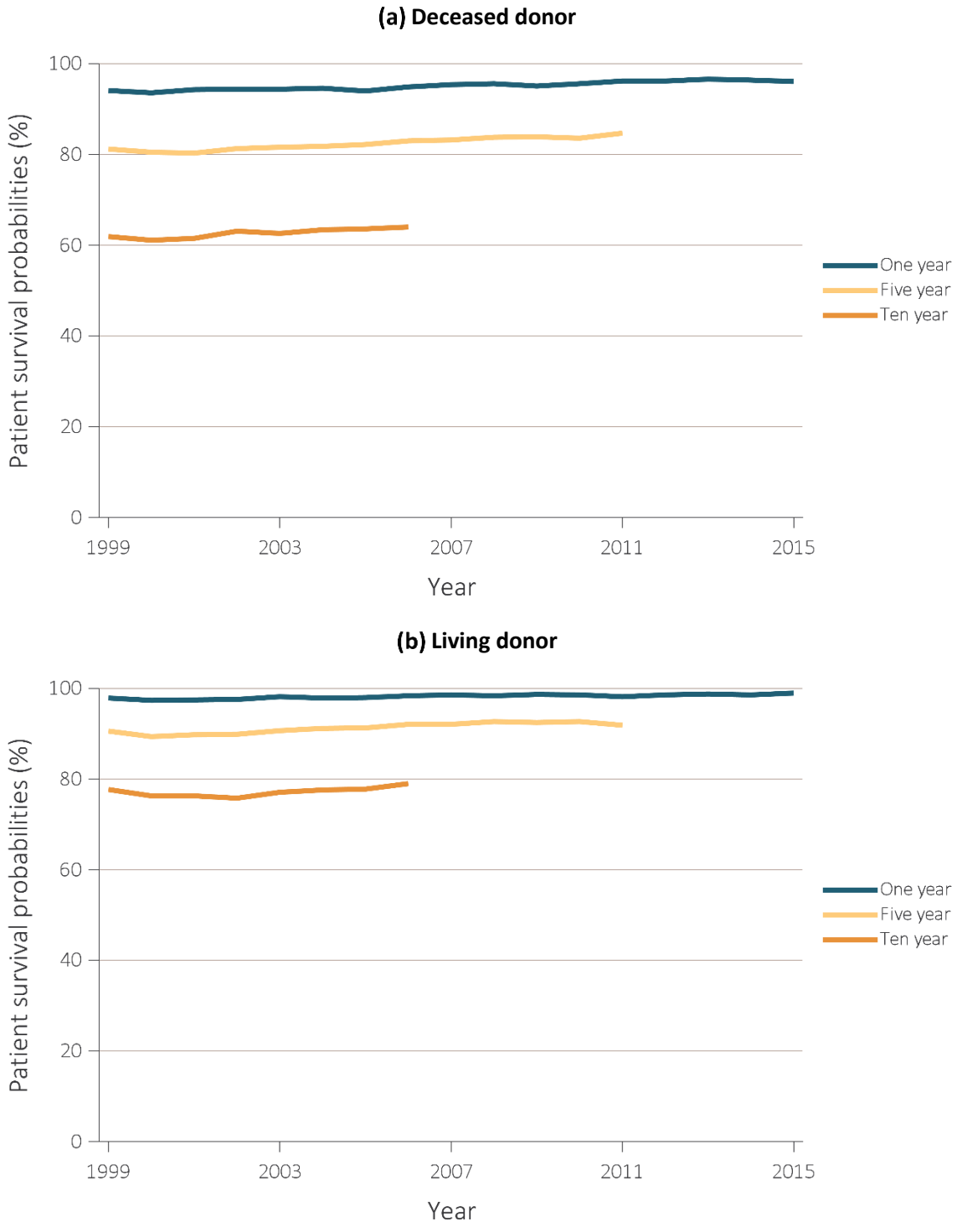


Data Source: Reference Tables F.2, F.14, F.5, F.17, F.6, F.18. Outcomes among recipients of a first-time deceased-donor kidney transplant, unadjusted. Note that trends may be influenced by changes to the kidney allocation system (KAS) policy that were implemented in December 2014.

With respect to patient survival, there has also been an overall improvement in outcomes over time although more modest, and not as consistent, when compared to changes in graft survival (Figure 6.26). Among the recipients of deceased-donor kidney transplants, the 2015 probability of one-year patient survival was 96%, improved from 94% in 1999. The 2011 probability of five-year patient survival for deceased-donor kidney transplants was 85%, improved from 81% in 1999. The 2006 probability of ten-year graft survival for deceased-donor kidney transplants was 64%, improved from 62% in 1999. Similar patterns of improvement over time are evident for living-donor kidney transplants, though across the board outcomes are better than for deceased-donor transplants. For the most recent years of data available, the probability of graft survival for living-donor transplants was 99%, 92%, and 79%, for one-, five- and ten-year periods post-transplant, respectively.

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.

vol 2 Figure 6.26 Trends in 1-, 5-, & 10-year kidney transplant patient survival, 1999-2015



Data Source: Reference Tables I.26, I.29, I.30, I.32, I.35, I.36. Survival probabilities 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.

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

- The number of children and adolescents beginning end-stage renal disease (ESRD) care is steadily decreasing from a high of 17.5 per million in 2004 to 13.8 per million population in 2016, representing a decrease of 21.1% (Figure 7.1.a).
- As of December 31, 2016, the point prevalence of children and adolescents, 0 to 21 years of age, with ESRD was 9,721, or 99.1 per million population (Figure 7.1.b).
- The one-year ESRD patient mortality decreased by 20.4% over the last decade, with the greatest improvement observed in the 0-4 year age group with a 35.0% decrease. (Figure 7.8.a & b).
- 20% of incident and 72% of prevalent children and adolescents with ESRD have kidney transplants, in 2016 (Figure 7.1.a & b).
- 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 (51.9%; Figure 7.4.a).
    - Since 1978, a total of 19,441 survivors of childhood onset ESRD transitioned into adulthood. 81% of these individuals were still alive as of December 31, 2016 (Figure 7.17).

Introduction

This chapter presents an overview of end-stage renal disease (ESRD) in children and adolescents. In this age group, ESRD is caused by congenital and acquired disorders which are largely distinct from the predominant etiologies of diabetes and hypertension reported in adults with ESRD. The majority of children with ESRD will depend on a spectrum of the available renal replacement therapies (RRT) throughout their lifetime including hemodialysis (HD), peritoneal dialysis (PD), and transplantation. Throughout the ESRD experience, children are at risk for growth failure, frequent hospitalizations, and significantly higher mortality than the general pediatric population. Hospitalizations are a particular burden to the ESRD population. These hospitalizations may be due to medical or surgical indications. In this 2018 chapter of the Annual Data Report (ADR), hospitalizations have been newly classified as surgical and medical to provide additional insight. A section on young adult survivors of childhood onset ESRD is provided in order to improve our understanding of this resilient population.

Pediatric chronic kidney disease (CKD) is addressed in a separate chapter of the 2018 ADR – Volume 1, Chapter 6: *CKD Among Children, Adolescents, and Young 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.

The analytical methods used to generate the study cohorts, figures, and tables in this chapter can be found in the section on *Chapter 7* within the *Analytical Methods Used in the ESRD Volume* chapter. Downloadable Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available on the *USRDS website*.

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 13.8 PMP in 2016—a decline of 21.1% (Figure 7.1.a). The ESRD incidence varies by age group; in 2016 there were 204 cases in those aged 0-4 years, 139 aged 5-9, 202 aged 10-13, 295 aged 14-17, and 532 aged 18-21 years, for a total of 1,372 children with incident ESRD in 2016. Within these age-based cohorts, incidence rates in 2016 were 9.2 PMP per year for 0-4 year olds, 6.4 for 5-9 year olds, 11.0 for 10-13 year olds, 15.5 for those aged 14-17 years, and 29.0 PMP for those aged 18–21 years.

As of December 31, 2016, the point prevalence of children, 0 to 21 years of age, with ESRD was 9,721, or 99.1 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

Although PD is not frequently used in adults, its use is much greater in young children. However, children initiate ESRD therapy with HD more frequently than PD or transplantation. In 2016, 702 (51.2%) initiated therapy with HD, 353 (25.7%) with PD, and 275 (20.0%) with transplant.

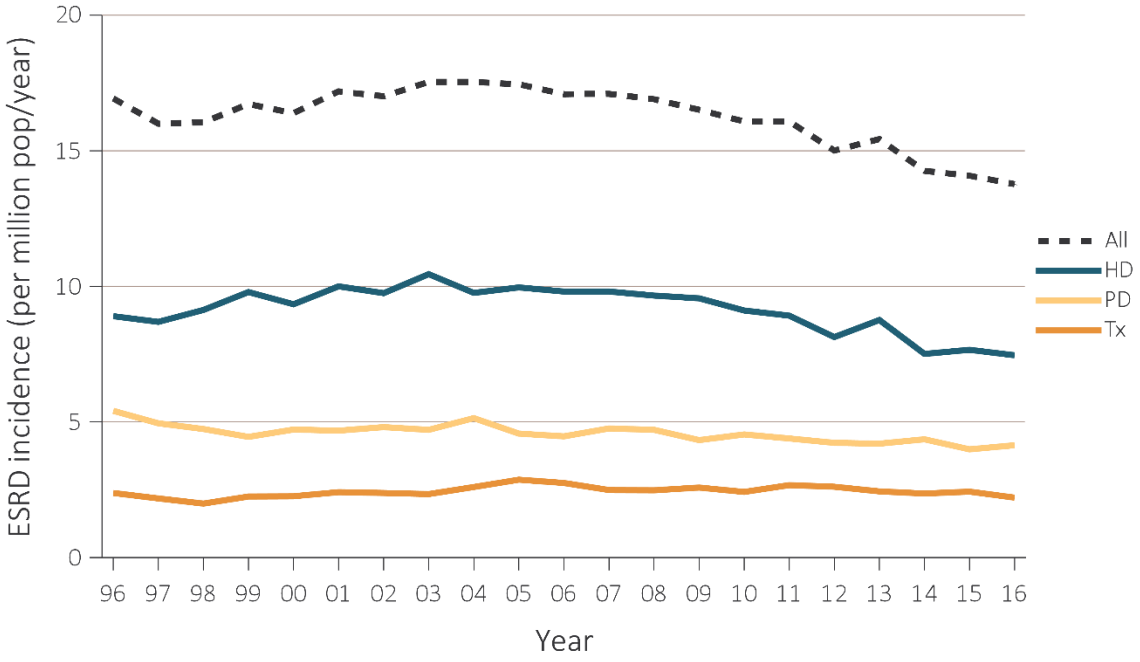
When examined by age, PD was the most common initial ESRD treatment modality for children aged 9 years and younger (Figure 7.2.a), and HD was the most common initial modality for patients aged 10 years and older. Similar relationships are shown by patient weight (which of course is highly correlated with age), with PD most commonly prescribed as the initial modality in children weighing less than 20 kilograms (kg) (Figure 7.2.b). For children less than 10kg: 9.0% for HD, 86.1% for PD and 4.9% for TX. For 10-<20 kg: 26.9% for HD, 47.3 for PD and 25.8% for TX (data not shown).

The modality at initiation varied greatly by race, with HD most commonly reported for those of Black/African American race (71.0%) compared to White (49.9%) and Other (43.0%) races (Figure 7.2.c). Examination of longitudinal changes in initial ESRD modality by race, the recent five-year window showed consistent HD use in Blacks/African Americans of 69.7%, Whites 48.4%, and Others 38.4%. The 21% overall decline in ESRD incidence was shown most remarkably in Black/African American children where the decline was twice as great, at 40%, decreasing from 33 per million to 20 per million.

Of the 9,619 children and adolescents under 22 years of age with prevalent ESRD as of December 31, 2016, kidney transplant was the most common ESRD modality (6,927, 72.0%), followed by HD (1,651, 17.2%) and PD (1,019, 10.6%) (Figure 7.1.b). This equates to a point prevalence PMP children of 17.5 for HD, 10.8 for PD, and 70.7 for transplant.

vol 2 Figure 7.1 (a, c) Incidence, and (b, d) December 31 point prevalence of ESRD among pediatric patients (aged 0–21 years) per million population per year, by modality and race, 1996-2016

(a) Incidence by modality



(b) Point prevalence by modality

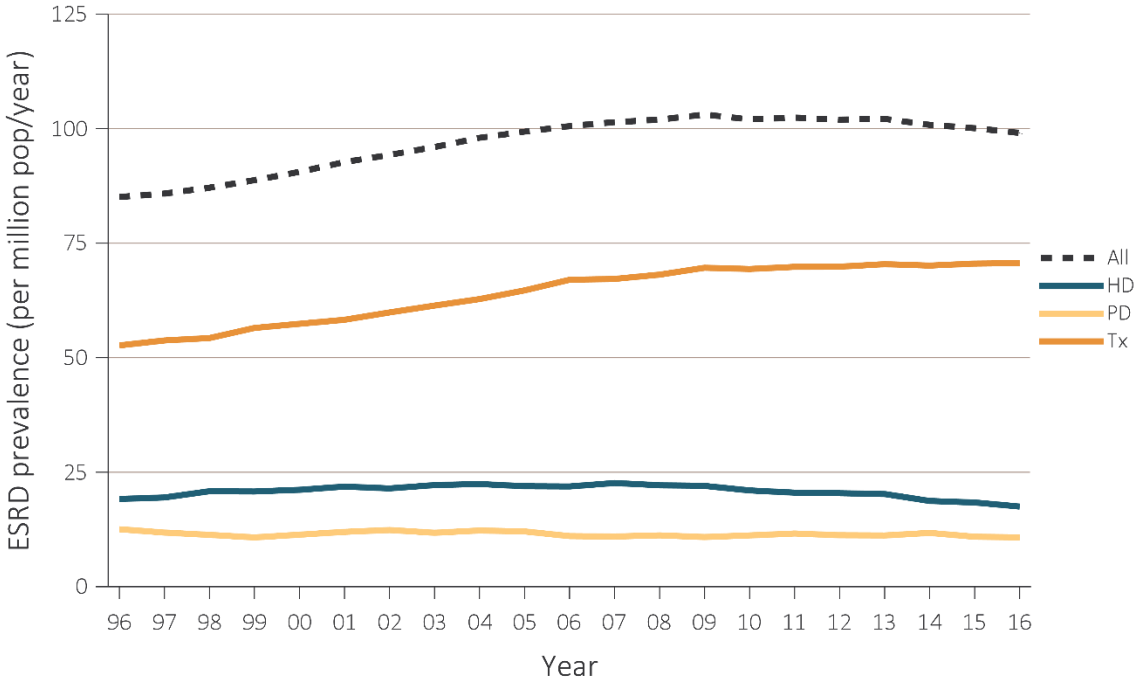
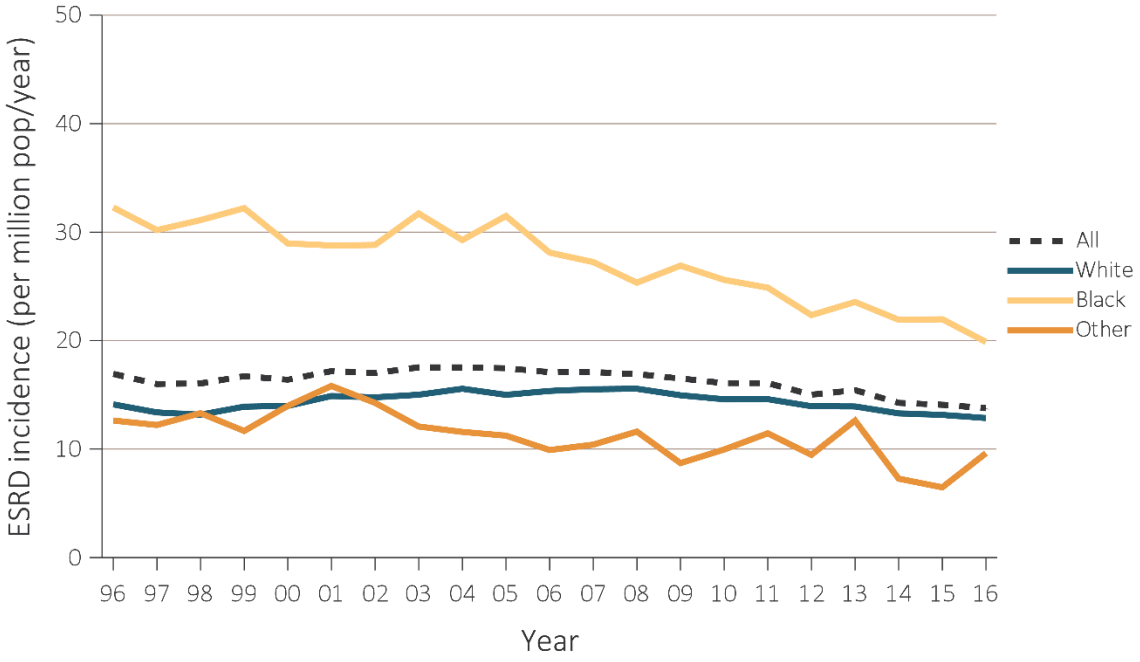


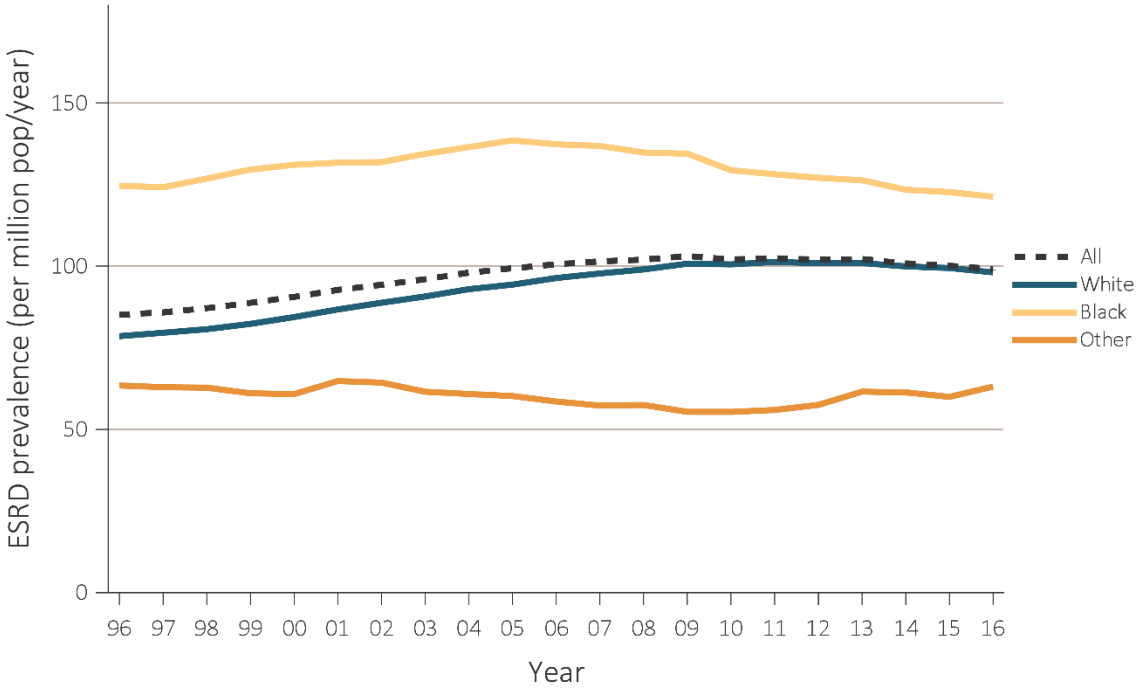
Figure 7.1 continued on next page.

vol 2 Figure 7.1 (a, c) Incidence, and (b, d) December 31 point prevalence of ESRD among pediatric patients (aged 0–21 years) per million population per year, by modality and race, 1996-2016 (continued)

(c) Incidence by race



(d) Point prevalence by race



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 distribution in pediatric ESRD modality at initiation, by patient (a) age, (b) weight, and (c) race, 1996-2016

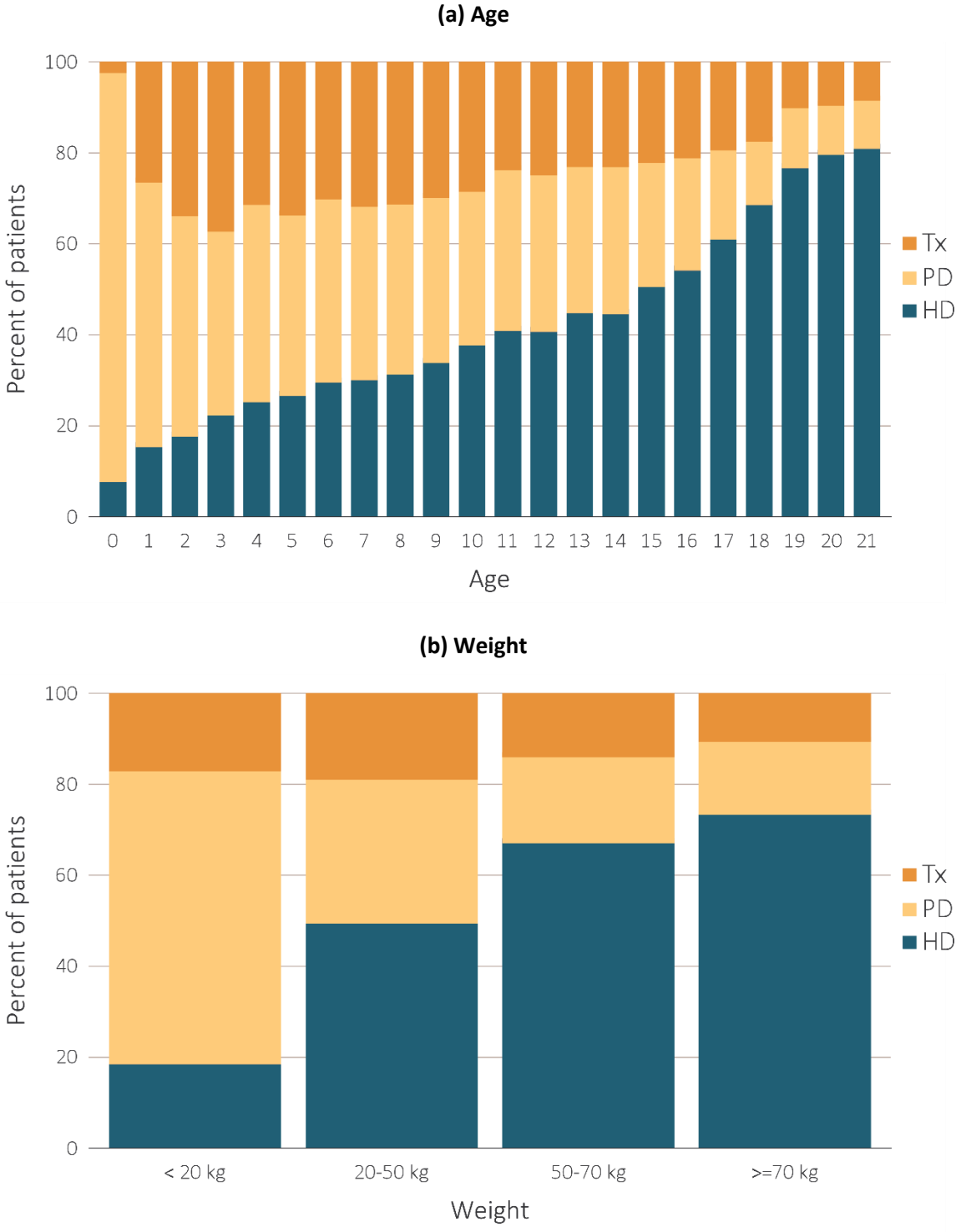
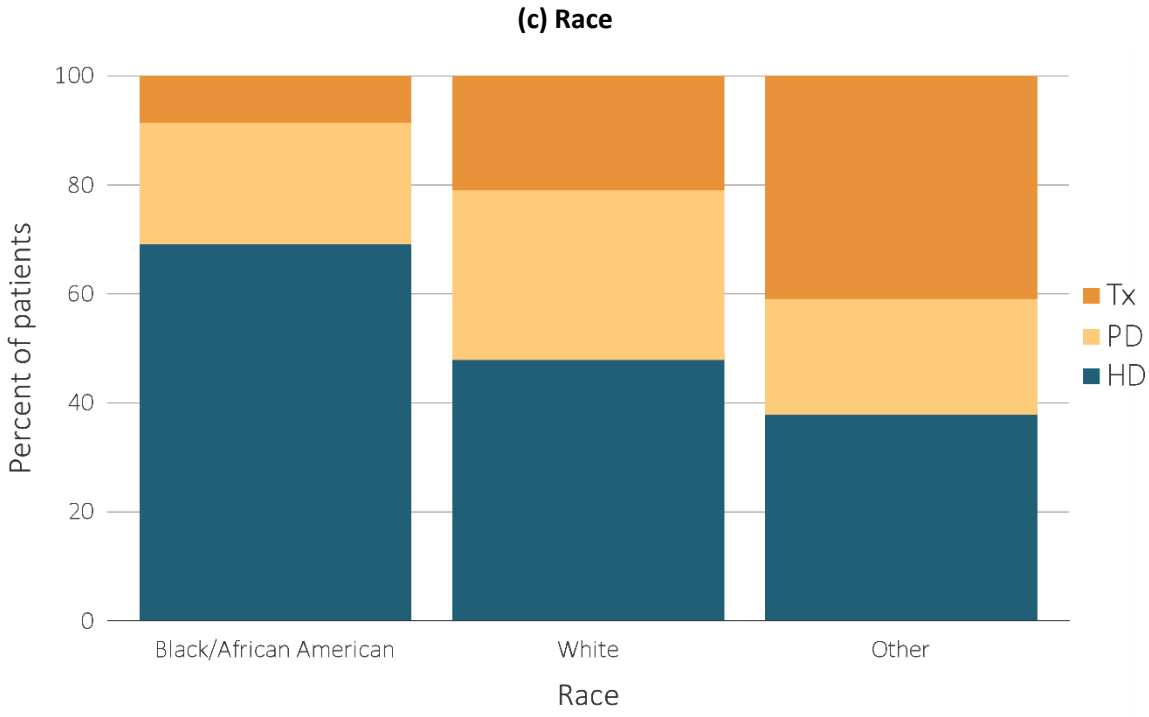


Figure 7.2 continued on next page.

vol 2 Figure 7.2 Cross-sectional distribution in pediatric ESRD modality at initiation, by patient (a) age, (b) weight, and (c) race, 1996-2016 (continued)



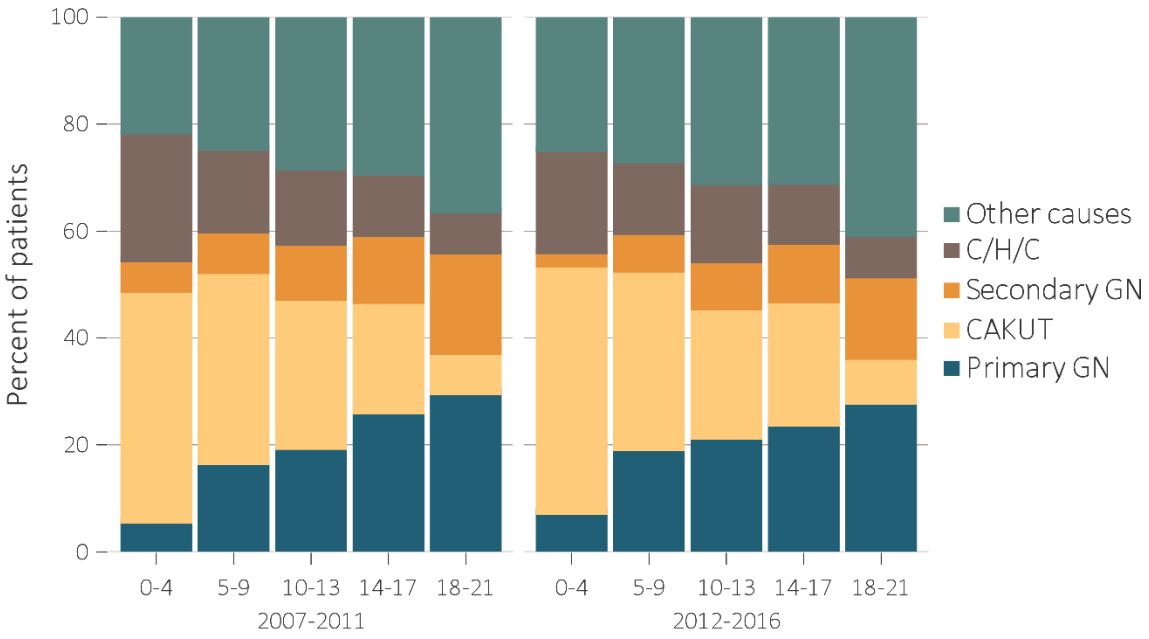
Data Source: Special analyses, USRDS ESRD Database. Includes incident ESRD patients in 1996-2016. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

Etiology

Table 7.1 shows that the leading causes of incident ESRD in children during 2012-2016 were primary glomerular disease (22.3%), CAKUT (congenital anomalies of the kidney and urinary tract; 21.9%), cystic/hereditary/congenital disorders (11.7%), and secondary glomerular disease/vasculitis (10.7%). The most common individual diagnoses associated with pediatric ESRD included focal glomerulosclerosis (828, 11.5%), renal hypoplasia/dysplasia (744, 10.4%), congenital obstructive uropathies (665, 9.3%), systemic lupus erythematosus (405, 5.6%), and unspecified with renal failure (503, 7.0%).

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 2007-2011 and 2012-2016. The combined unspecified, uncertain, and missing reported ESRD etiologies accounted for over 1,000 incident cases between 2012 and 2016 (19.3%) (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 2007-2011 and 2012-2016



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, 2007-2011 (Period A) and 2012-2016 (Period B)

	Total patients		Percent incidence		Median age		Percent males		Percent White		Percent Black/ African American		Percent Other race	
Primary Disease Groups	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**
All ESRD, (reference)	8,154	7,176	100.0	100.0	16	16	56.3	56.9	66.1	66.2	24.6	23.5	9.3	10.3
CAKUT	1,682	1,574	20.6	21.9	11	11	70.1	68.7	75.6	74.8	17.8	18.9	6.5	6.2
Congenital obstructive uropathies	739	665	9.1	9.3	11	10	83.6	83.2	72.4	71.1	22.2	23.9	5.4	5.0
Renal hypoplasia, dysplasia, oligonephronia	749	744	9.2	10.4	9	9	63.0	59.0	76.4	75.7	16.6	17.3	7.1	7.0
Chronic pyelonephritis, reflux nephropathy	194	165	2.4	2.3	16	16	45.9	54.5	85.1	86.1	6.2	6.1	8.8	7.9
Cystic/Hereditary/Congenital Diseases	1,002	839	12.3	11.7	13	13	59.5	59.1	78.2	77.8	15.7	15.7	6.1	6.4
Polycystic kidneys, adult type (dominant)	49	45	.6	.6	18	18	53.1	35.6	77.6	84.4	20.4	11.1	2.0	4.4
Polycystic, infantile (recessive)	159	134	1.9	1.9	4	2	47.8	47.8	76.7	80.6	17.6	14.2	5.7	5.2
Medullary cystic disease, including nephronophthisis	118	107	1.4	1.5	13	12	43.2	43.9	86.4	77.6	6.8	13.1	6.8	9.3
Tuberous sclerosis	*	13	.1	.2	19	15	60.0	46.2	60.0	53.8	40.0	46.2	0	0
Hereditary nephritis, Alports syndrome	180	142	2.2	2.0	17	17	85.0	88.7	73.3	74.6	19.4	19.0	7.2	6.3
Cystinosis	60	38	.7	.5	13	11	51.7	57.9	93.3	86.8	6.7	7.9	0	5.3
Primary oxalosis	18	15	.2	.2	12	11	66.7	73.3	88.9	66.7	0	13.3	11.1	20.0
Congenital nephrotic syndrome	135	127	1.7	1.8	3	6	57.8	48.8	78.5	83.5	13.3	13.4	8.1	3.1
Drash syndrome, mesangial sclerosis	29	15	.4	.2	1	1	55.2	46.7	82.8	73.3	17.2	20.0	0	6.7
Other (congenital malformation syndromes)	226	188	2.8	2.6	13	16	60.2	66.0	81.0	79.8	11.5	12.2	7.5	8.0
Sickle cell disease/anemia	22	13	.3	.2	20	20	63.6	69.2	9.1	7.7	90.9	92.3	0	0
Primary Glomerular Disease	1,902	1,603	23.3	22.3	18	17	55.0	55.4	61.6	64.6	30.8	27.7	7.6	7.7
Glomerulonephritis (GN) (histologically not examined)	372	312	4.6	4.3	19	18	60.2	57.1	68.8	67.6	21.8	23.4	9.4	9.0
Focal glomerulosclerosis, focal sclerosing GN	989	828	12.1	11.5	17	17	56.0	55.9	53.6	60.5	40.7	34.3	5.7	5.2
Membranous nephropathy	39	44	.5	.6	17	19	51.3	72.7	43.6	59.1	46.2	36.4	10.3	4.5
Membranoproliferative GN type 1, diffuse MPGN	108	61	1.3	.9	17	17	45.4	45.9	66.7	72.1	22.2	16.4	11.1	11.5
Dense deposit disease, MPGN type 2	29	24	.4	.3	16	16	58.6	50.0	86.2	87.5	3.4	8.3	10.3	4.2
IgA nephropathy	194	169	2.4	2.4	19	19	62.4	60.9	74.7	75.1	14.9	8.3	10.3	16.6
IgM nephropathy	18	12	.2	.2	19	19	55.6	66.7	61.1	66.7	38.9	25.0	0	8.3
With lesion of rapidly progressive GN	64	45	.8	.6	16	16	25.0	35.6	76.6	68.9	12.5	20.0	10.9	11.1
Other proliferative GN	89	108	1.1	1.5	17	16	39.3	44.4	75.3	62.0	15.7	30.6	9.0	7.4
Secondary Glomerular Disease/Vasculitis	1,092	769	13.4	10.7	18	18	28.7	29.5	55.3	56.2	37.9	36.5	6.8	7.3
Lupus erythematosus, (SLE nephritis)	611	405	7.5	5.6	19	19	17.3	20.0	39.4	39.5	52.2	53.1	8.3	7.4

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, 2007-2011 (Period A) and 2012-2016 (Period B) (continued)

	Total patients		Percent incidence		Median age		Percent males		Percent White		Percent Black/ African American		Percent Other race	
Primary Disease Groups	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**
Henoch-Schonlein (IgA Vasculitis)	34	26	.4	.4	17	15	58.8	42.3	88.2	80.8	5.9	7.7	5.9	11.5
Hemolytic uremic syndrome	136	98	1.7	1.4	9	9	40.4	37.8	81.6	77.6	14.0	16.3	4.4	6.1
Polyarteritis and other vasculitis	118	86	1.4	1.2	14	15	37.3	25.6	75.4	76.7	17.8	11.6	6.8	11.6
ANCA-associated vasculitis	65	83	.8	1.2	16	17	43.1	49.4	86.2	72.3	10.8	20.5	3.1	7.2
Goodpasture syndrome	55	35	.7	.5	19	19	36.4	54.3	89.1	97.1	5.5	0	5.5	2.9
Secondary GN, other	27	13	.3	.2	18	18	55.6	46.2	77.8	76.9	14.8	23.1	7.4	0
AIDS nephropathy	40	16	.5	.2	20	21	57.5	50.0	5.0	0	95.0	100.0	0	0
Tubulointerstitial Diseases	286	234	3.5	3.3	17	16	59.4	58.5	75.2	76.1	17.5	17.1	7.3	6.8
Chronic interstitial nephritis	81	86	1.0	1.2	17	17	58.0	53.5	75.3	77.9	17.3	15.1	7.4	7.0
Acute interstitial nephritis	*	21	.1	.3	20	17	55.6	52.4	55.6	66.7	44.4	28.6	0	4.8
Tubular necrosis	185	113	2.3	1.6	15	12	59.5	61.9	77.3	76.1	15.7	16.8	7.0	7.1
Transplant Complications	145	92	1.8	1.3	16	17	57.2	57.6	71.7	68.5	20.0	25.0	8.3	6.5
Kidney transplant complication	60	*	.7	.1	16	18	63.3	66.7	73.3	83.3	21.7	0	5.0	16.7
Other transplant complication	79	83	1.0	1.2	16	16	53.2	56.6	70.9	67.5	20.3	26.5	8.9	6.0
Diabetes	101	80	1.2	1.1	20	20	41.6	36.3	53.5	42.5	42.6	52.5	4.0	5.0
Diabetes with renal manifestations Type 2	47	39	.6	.5	20	20	38.3	38.5	59.6	43.6	38.3	51.3	2.1	5.1
Diabetes with renal manifestations Type 1	54	41	.7	.6	20	20	44.4	34.1	48.1	41.5	46.3	53.7	5.6	4.9
Neoplasms/Tumors	48	39	.6	.5	8	10	41.7	53.8	70.8	76.9	20.8	10.3	8.3	12.8
Renal tumor	39	28	.5	.4	7	5	41.0	53.6	71.8	71.4	25.6	10.7	2.6	17.9
Hypertensive/Large Vessel Disease	19	41	.2	.6	14	18	57.9	61.0	78.9	82.9	10.5	9.8	10.5	7.3
Renal artery stenosis	*	19	.1	.3	14	20	62.5	57.9	75.0	63.2	12.5	21.1	12.5	15.8
Renal artery occlusion	*	21	.1	.3	11	11	44.4	61.9	77.8	100.0	11.1	0	11.1	0
Miscellaneous Conditions	888	1,025	10.9	14.3	19	18	60.1	60.4	63.9	63.7	29.7	28.8	6.4	7.5
Acquired obstructive uropathy	50	104	.6	1.4	17	14	72.0	66.3	80.0	74.0	16.0	21.2	4.0	4.8
Nephrolithiasis	16	16	.2	.2	18	15	31.3	43.8	93.8	87.5	0	12.5	6.3	0
Traumatic or surgical loss of kidney(s)	15	34	.2	.5	9	15	66.7	55.9	73.3	70.6	13.3	17.6	13.3	11.8
Other renal disorders	246	311	3.0	4.3	15	14	54.5	55.9	77.6	74.3	13.8	14.8	8.5	10.9
Nephropathy caused by other agents	46	51	.6	.7	17	16	58.7	49.0	89.1	74.5	8.7	19.6	2.2	5.9
Unspecified with renal failure	507	503	6.2	7.0	20	20	62.9	63.8	52.1	53.1	42.6	41.0	5.3	6.0
Etiology Uncertain	689	342	8.4	4.8	16	16	59.1	54.7	73.7	70.2	18.9	19.9	7.4	9.9
Missing	300	538	3.7	7.5	15	15	63.7	59.9	20.7	40.9	7.0	9.9	72.3	49.3

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; SLE, secondary lupus erythematosus. Diagnoses with 10 or fewer total patients for year categories are suppressed.*

vol 2 Table 7.2 Proportion of missing, unknown, and unspecified etiology of ESRD in children and adolescents, by age group, 2012-2016

	0-4	5-9	10-13	14-17	18-21	All
ESRD etiology missing, unknown, or unspecified	10.4%	13.8%	15.3%	17.9%	26.1%	19.3%

Data Source: Special analyses, USRDS ESRD Database. Abbreviation: ESRD, end-stage renal disease.

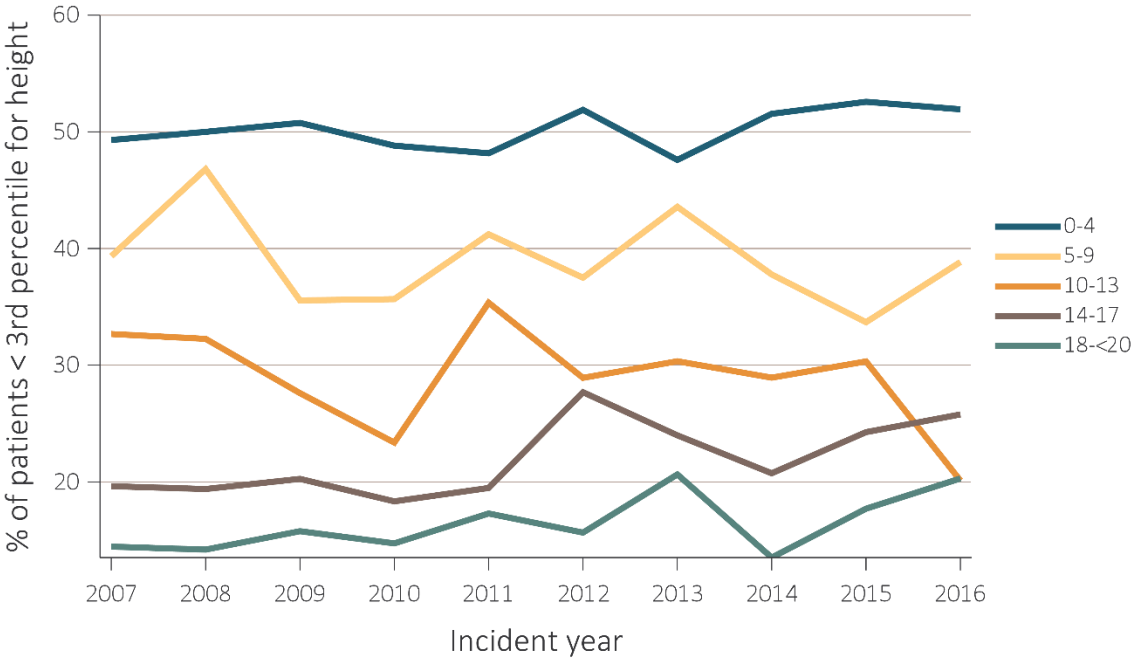
Growth

Children with ESRD are at risk for growth impairment, requiring intensive intervention to optimize growth. Using data reported in the CMS 2728 form from 2007-2016, pre-ESRD dietitian support was provided to 48.4% of children under 18 years of age and was highest among patients aged 5-9 years (55.9%), and lowest among patients aged 14-17 (42.8%). Over the past 10 years, the 0-4 age group consistently had the highest proportion of children with short stature, defined as height less than third percentile for age, at ESRD incidence (Figure 7.4.a). In 2016, the percentage of incident ESRD patients with short stature continued to be the highest in the youngest patients, 51.9% in the 0-4 age group, compared with 38.8% in the 5-9 age group, 20.1% in the 10-13 age group, 25.8% in the 14-17 age group, and 20.3% in the 18-<20 age group. Comparison of the 2007 and 2016 data demonstrates that the prevalence of short stature in the incident pediatric ESRD population has not improved over the past 10 years.

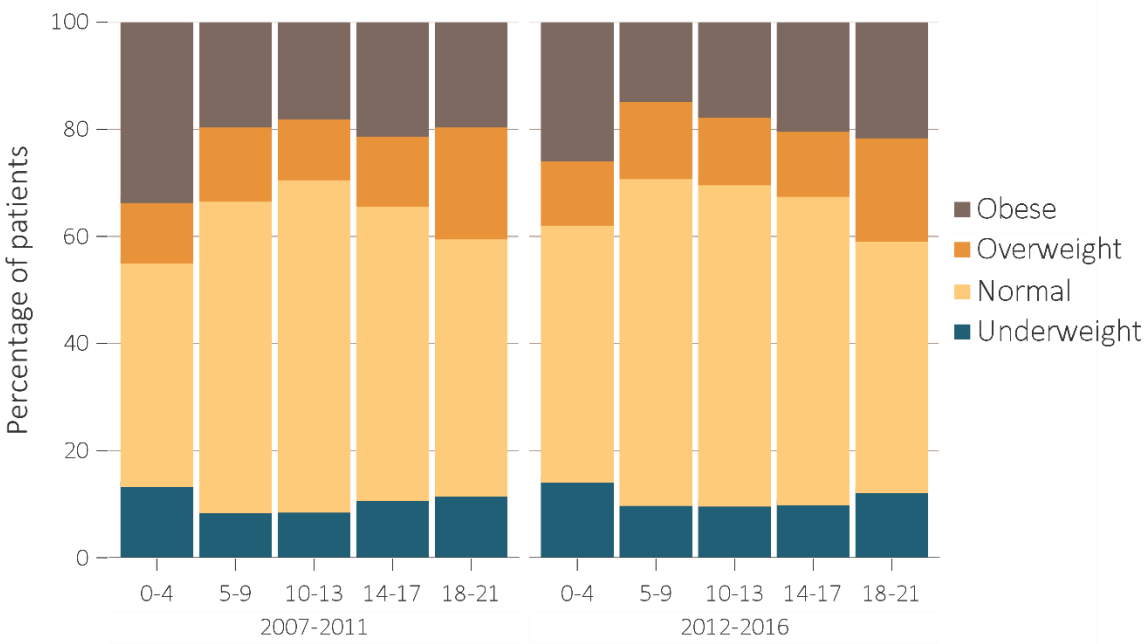
Weight status is based on age-based body mass index norms. Comparison between the periods 2007-2011 and 2012 – 2016 shows that the percent overweight and obese has been decreasing in the most recent period. The percent with unhealthy weight (underweight or obese) has been generally stable (Figure 7.4.b). In the most recent 5-year reporting period, 2012-2016, children with incident ESRD between 0-4 years of age had the largest proportion of unhealthy weight status, including underweight (14.5%) and obese (25.4%; Figure 7.4.b). This contrasts with the adult population where obese patients accounted for 41.6% of the incident population in 2016. In total, 55.1% of children aged 0-4 who were obese at ESRD initiation also had short stature, suggesting that nutritional support alone is insufficient to restore the majority of patients to an age-appropriate 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 <20 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

This year we categorize hospitalization by surgical and non-surgical types. Surgery accounted for less than 20.0% of one-year hospitalizations in incident children (Figure 7.5.a). The adjusted all-cause hospitalization rates were highest in the youngest children, 0-4 years of age (Figure 7.5.a). During the 2011-2015 reporting years, the overall rate of hospitalization dropped by 1.8%, from 1,874 to 1,841 admissions per 1,000 patient-years. While they account for a minority of hospitalizations in children with incident ESRD, we report the one-year hospitalizations associated with cardiovascular disease (CVD) (2.2%) and infection (29.2%). 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 (12.5%), complications of dialysis, including access complications (6.2%), complications of kidney transplant (5.2%), dehydration (2.0%), fever (unspecified) (1.8%), and hyperkalemia (1.6%).

vol 2 Figure 7.5 One-year adjusted all-cause hospitalizations in incident pediatric patients (aged 0-21 years), by (a) age and (b) modality, 2006-2010 and 2011-2015

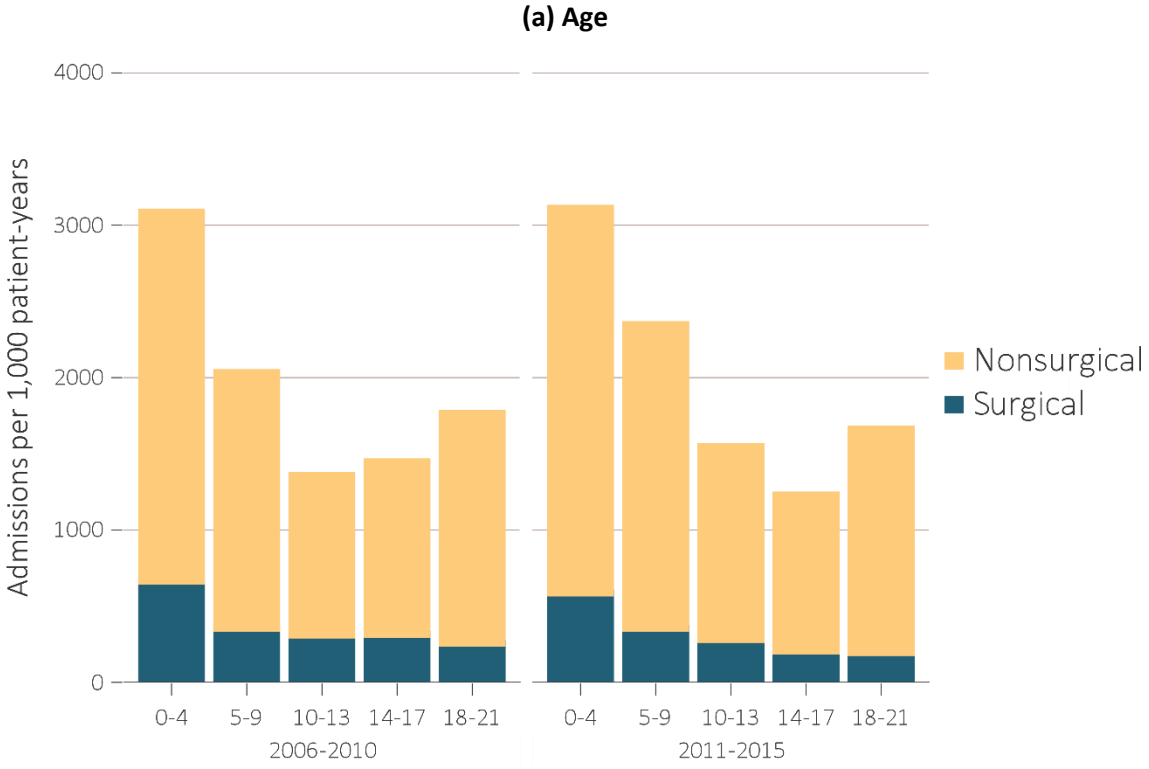
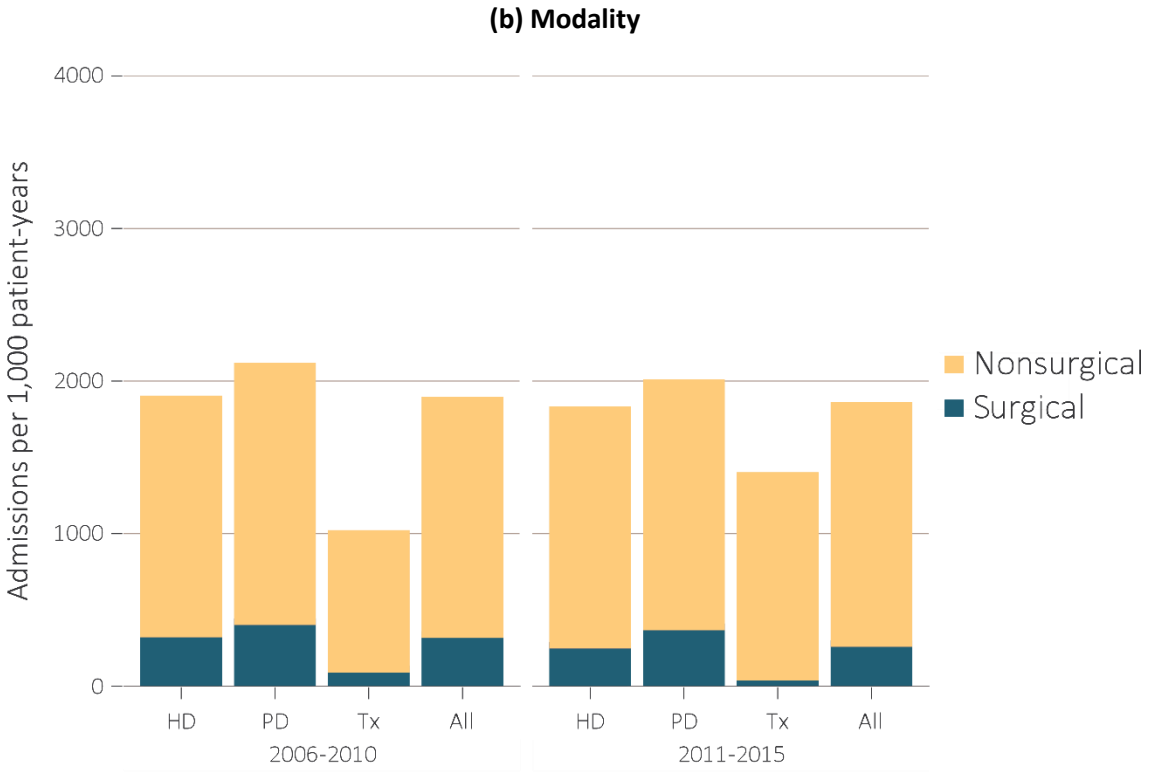


Figure 7.5 continued on next page.

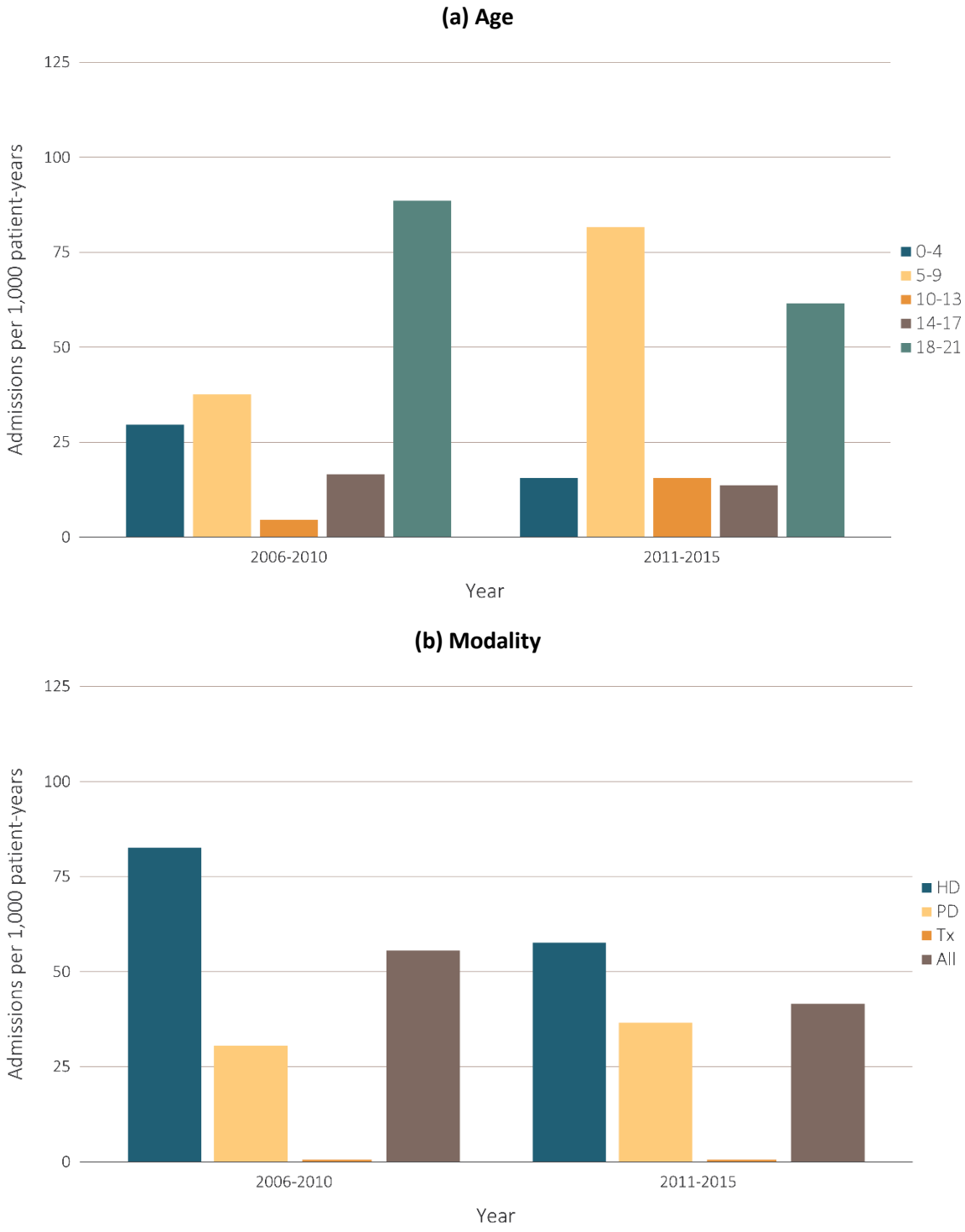
vol 2 Figure 7.5 One-year adjusted all-cause hospitalizations in incident pediatric patients (aged 0-21 years), by (a) age and (b) modality, 2006-2010 and 2011-2015 (continued)



Data Source: Special analyses, USRDS ESRD Database. Includes incident pediatric ESRD patients in the years 2006-2015, surviving the first 90 days after ESRD initiation and followed from day 90. (a) Adjusted for sex, race, primary cause of ESRD, and Hispanic ethnicity. (b) Adjusted for age, 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 55 per 1,000 patient-years from 2006-2010, and 41 from 2011-2015 (Figure 7.6.b), a decrease of 25.5%. 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). CVD hospitalizations decreased for ages 0-4, 14-17, and 18-21, while increasing for ages 5-9 and 10-13.

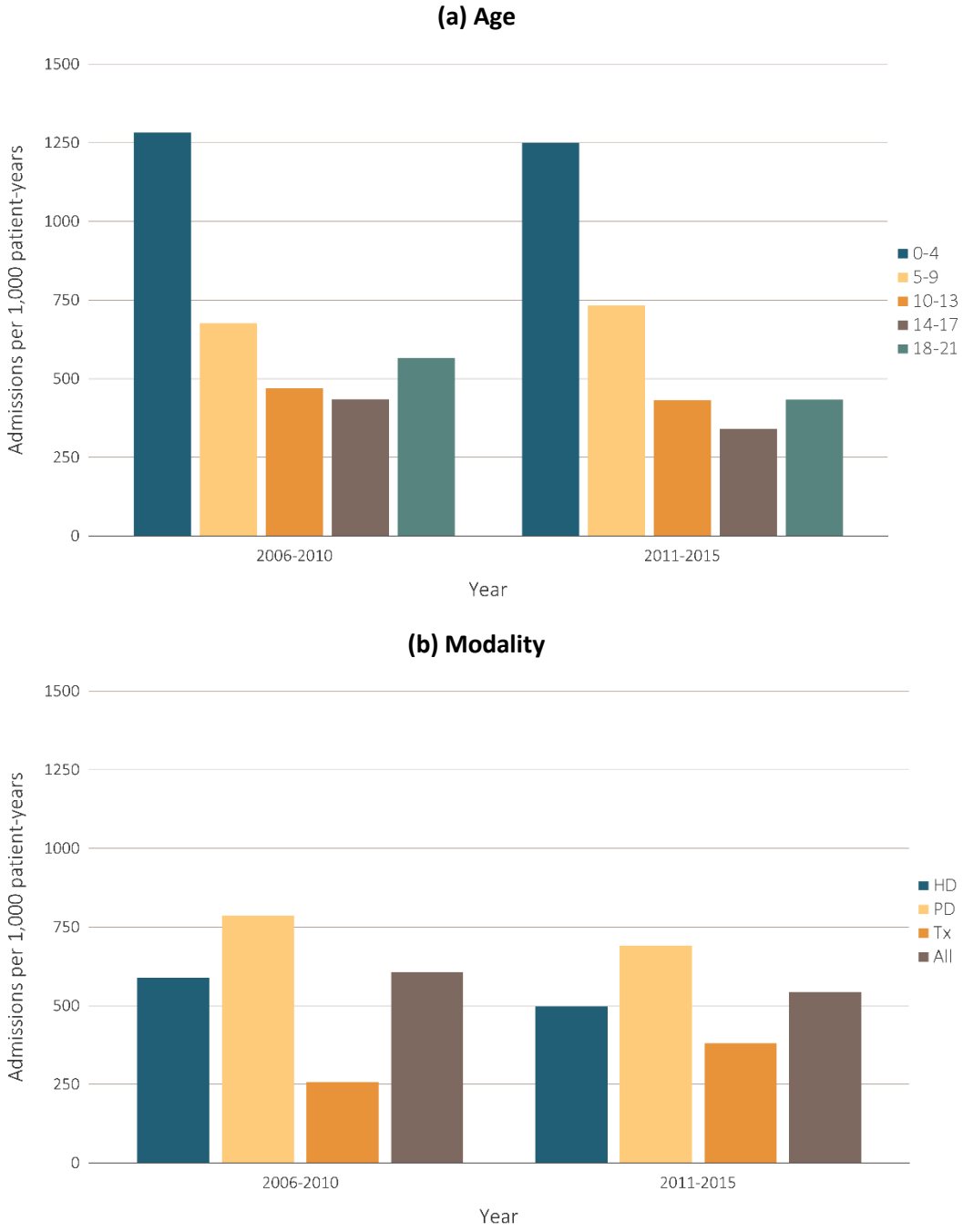
vol 2 Figure 7.6 One-year cardiovascular hospitalizations in incident pediatric patients (aged 0-21 years), by (a) age and (b) modality, 2006-2010 and 2011-2015



Data Source: Special analyses, USRDS ESRD Database. Includes incident pediatric ESRD patients in the years 2006-2015, 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) Adjusted for age, sex, race, primary cause of ESRD and Hispanic ethnicity. When examining cardiovascular associated hospitalizations, hypertension is not considered a cardiovascular diagnosis. 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 537 admissions per 1,000 patient-years during 2011-2015, which was 10.4% lower than during 2006-2010 (Figure 7.7.b). These first-year infection-related hospitalizations in children increased by 49.2% in transplant patients, but decreased 15.5% and 12.2% in HD and PD patients in the most recent 5-year reporting window, respectively. In examining between-modality statistics, children on PD had the highest rates of infection-related hospitalizations, followed by HD and transplanted children (Figure 7.7.b).

vol 2 Figure 7.7 One-year adjusted hospitalizations for infection in incident pediatric patients (aged 0-21 years), by (a) age and (b) modality, 2006-2010 and 2011-2015



Data Source: Special analyses, USRDS ESRD Database. Includes incident pediatric ESRD patients in the years 2006-2015, surviving the first 90 days after ESRD initiation and followed from day 90. (a) Adjusted for sex, race, primary cause of ESRD, and Hispanic ethnicity. (b) Adjusted for age, 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

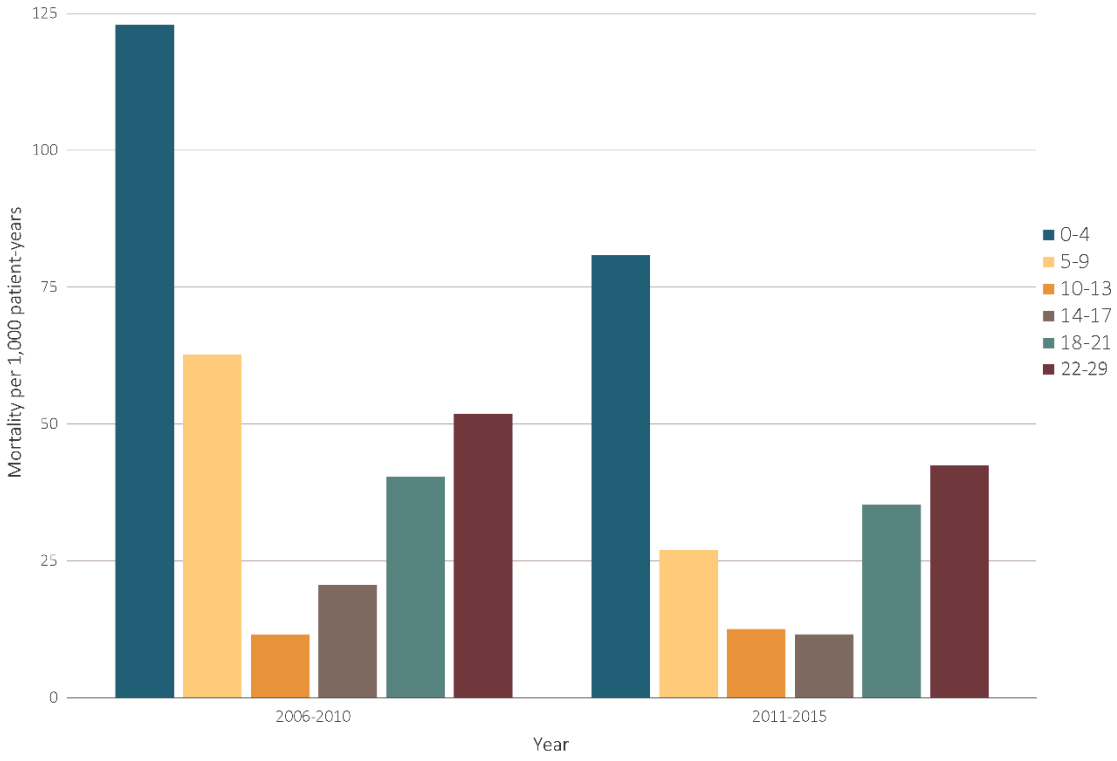
During 2011-2015, the one-year adjusted all-cause mortality rate was 39 per 1,000 patient-years, a decrease of 20.4% from the 49 per 1,000 patient-years seen in 2006-2010 (Figure 7.8.b). Reduced mortality was reported in almost all age categories, with the greatest reduced mortality by 35.0% in children ages 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: 39.9% vs age 2 to <5: 13.3% reduction in mortality).

When comparing the 2006-2010 and 2011-2015 periods, adjusted one-year all-cause mortality rates by modality showed decreases of 16.9% among HD patients, 35.5% 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 2011-2015, a difference in mortality by modality remained, with HD- and PD-associated one-year all-cause mortality rates 5.4 and 2.2 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, sepsis, cerebrovascular accident including intracranial hemorrhage and pulmonary infection for children aged 0 to 21 years. The youngest children had similar reported causes when compared with older children and adolescents.

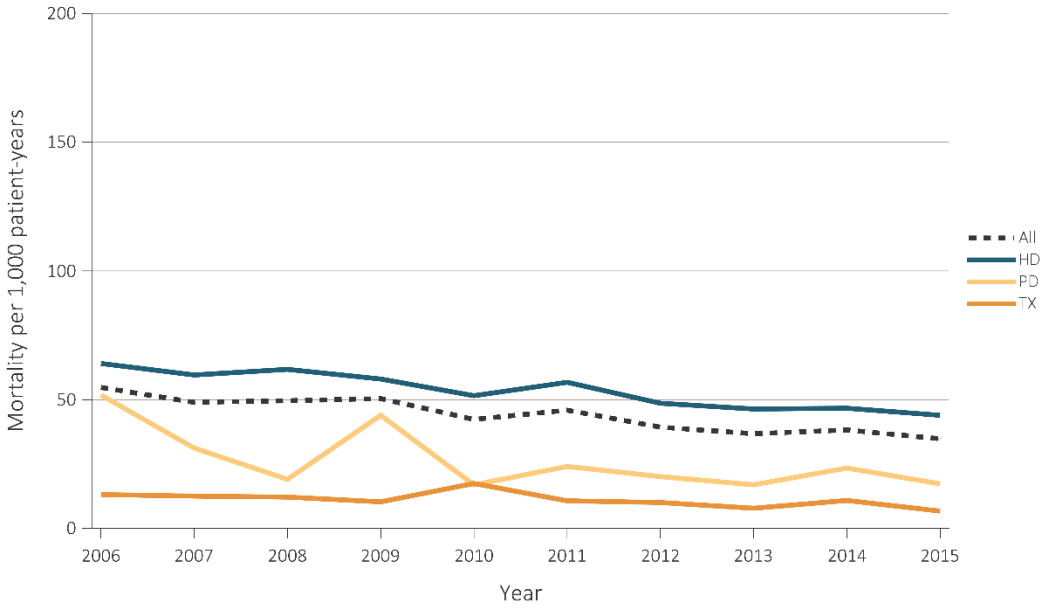
Assessment of expected remaining lifetime based on age and modality at ESRD incidence is presented in Table 7.3, and compared with published general population estimates from the U.S. Social Security Administration. Children treated with dialysis have a 40 to 55 year deficit in life expectancy compared to the general population while transplanted patients have an estimated 12 to 20 year deficit.

vol 2 Figure 7.8 One-year adjusted all-cause mortality in incident pediatric patients with ESRD by (a) age with comparison to young adults (aged 0-29 years), 2006-2010 and 2011-2015 and (b) modality, 2006-2015 (aged 0-21 years only)

(a) Age



(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, 2016. (a) Adjusted for sex, race, primary cause of ESRD, and Hispanic ethnicity. (b) Adjusted for age, 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.

vol 2 Table 7.3 Expected remaining lifetime in years of prevalent patients by initial ESRD modality, 2015

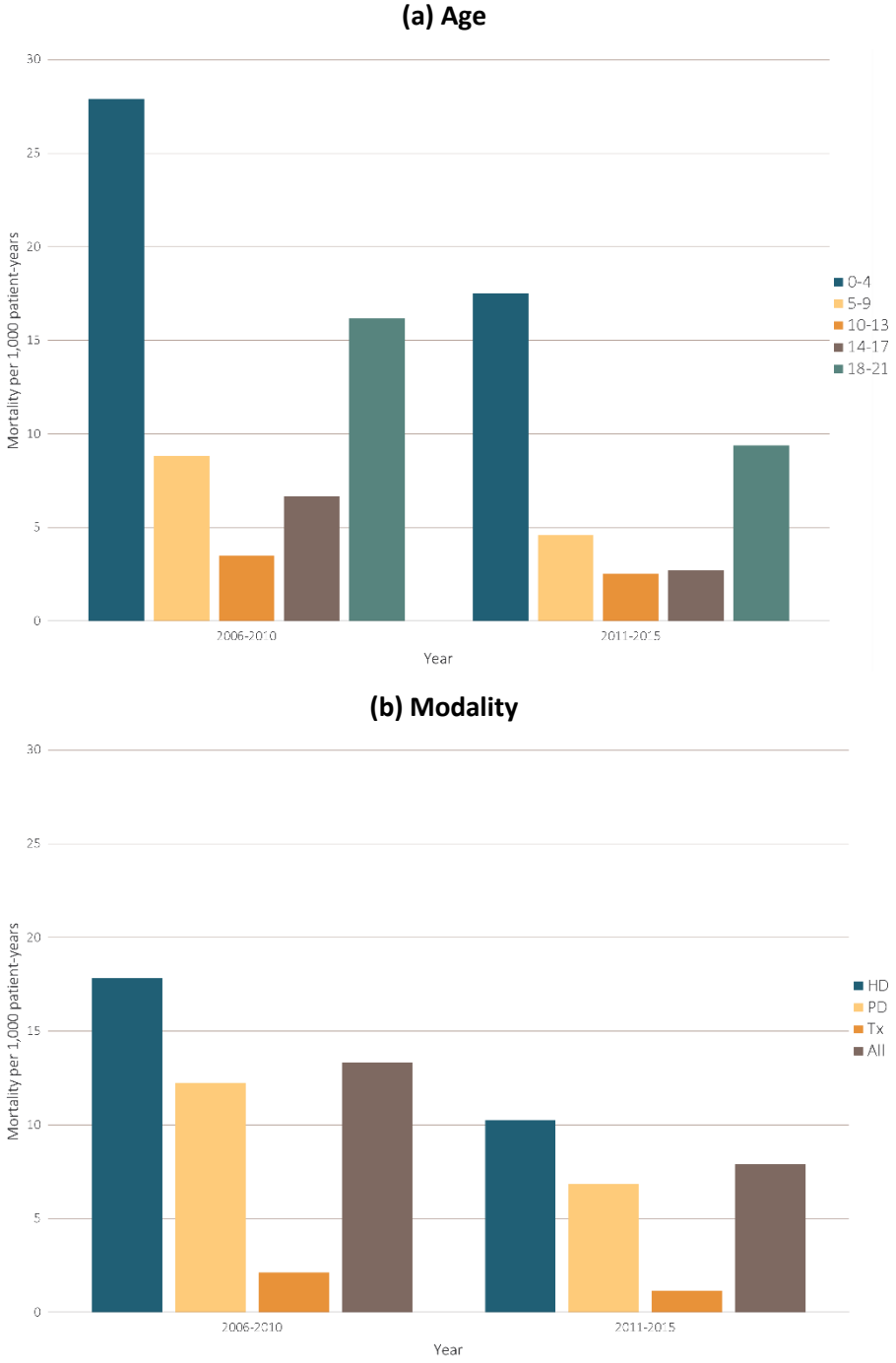
Age group	Dialysis patients	Transplant patients	General population
0-4	22.0	57.7	77.0
5-9	22.8	56.2	72.1
10-13	23.3	52.1	67.6
14-17	20.6	48.9	63.7
18-21	17.6	45.6	59.8
22-29	15.7	42.3	54.1

Data Source: Special analyses, USRDS ESRD Database, USA SSA (Social Security Administration) Period Life Table 2015. Includes period prevalent ESRD dialysis and transplant patients in 2015. Abbreviation: ESRD, end-stage renal disease.

During 2011-2015, the one-year adjusted CVD mortality rate was eight per 1,000 patient-years, a decrease of 38.5% from the 2006-2010 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 2006-2010 and 2011-2015, 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).

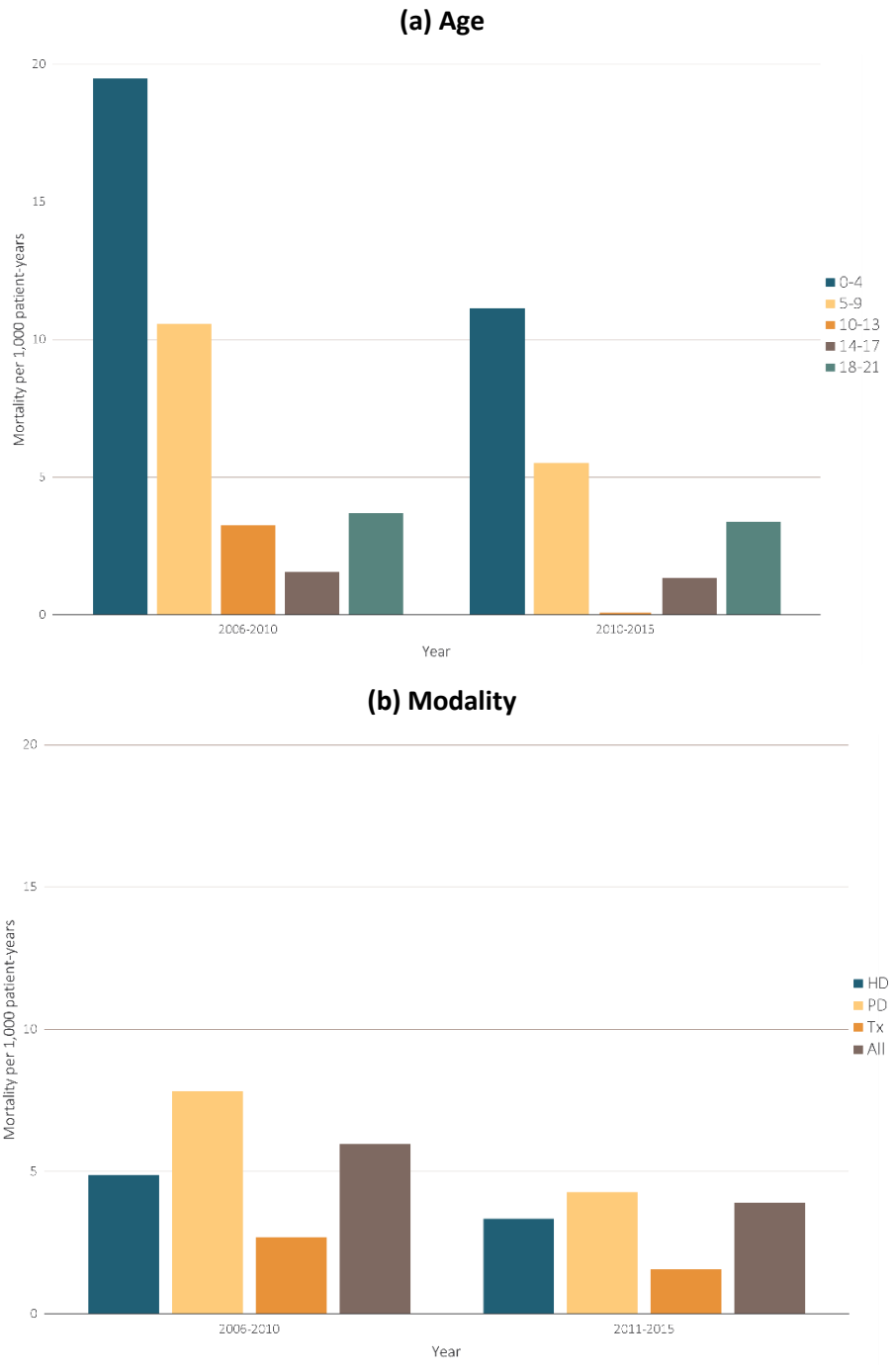
vol 2 Figure 7.9 One-year adjusted cardiovascular mortality in incident pediatric patients with ESRD (aged 0-21 years), by (a) age and (b) modality, 2006-2010 and 2011-2015



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, 2016. (a) Adjusted for sex, race, primary cause of ESRD, and Hispanic ethnicity. (b) Adjusted for age, sex, race, primary cause of ESRD and Hispanic ethnicity. Reference population: incident ESRD patients aged 0-21, 2010-2011. When examining cardiovascular associated mortality, hypertension is not considered a cardiovascular diagnosis. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

During 2011-2015, the one-year adjusted infection-related mortality rate decreased from six to four per 1,000 patient-years when compared to the 2006-2010 period (Figure 7.10.b). This mortality rate decreased in those aged 0-4 years by 42.1% (Figure 7.10.a), followed with the same trend in other age groups. During 2011-2015, the modality associated mortality rate was quite low, ranging from two to four per 1,000 patient years in children with incident ESRD (Figure 7.10.b).

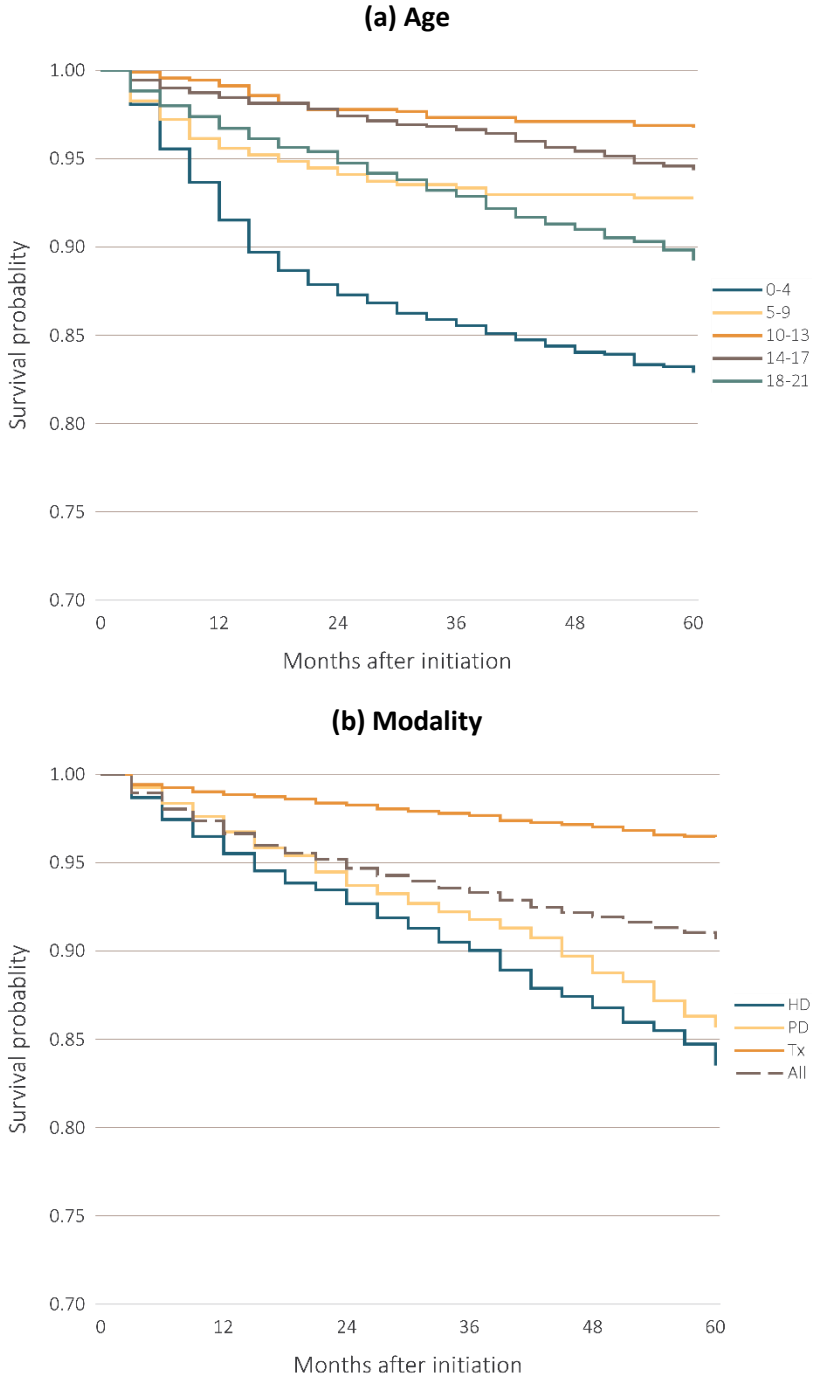
vol 2 Figure 7.10 One-year adjusted mortality due to infection in incident pediatric patients with ESRD (aged 0-21 years), by (a) age and (b) modality, 2006-2010 and 2011-2015



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, 2016. (a) Adjusted for sex, race, primary cause of ESRD, and Hispanic ethnicity. (b) Adjusted for age, 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.

For patients beginning ESRD therapy during 2007-2011, the probability of five-year survival was 0.91 (Figure 7.11.b). The probability of surviving five years by age was the worst for the youngest and oldest subsets, including 0.83 for ages 0-4 and 0.89 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 0.84 with HD, and 0.86 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, 2007-2011



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, 2016. (a) Adjusted for sex, race, primary cause of ESRD, and Hispanic ethnicity. (b) Adjusted for age, 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.

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 may 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, short transplant waiting times, and high transplant rates in the initial year of ESRD. The technical challenge of AV fistula placement in small children and an expected short waiting time until a kidney transplant becomes available may influence the recommendations of initial vascular access for children who initiate therapy with HD. Since 2006, approximately 81.5% of incident pediatric ESRD patients have started HD with a catheter (ranging from 77.7% to 82.9%; Figure 7.12.a). The predominant catheter use was observed across all age groups of children and adolescents (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.

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, 2006-2016

(a) Year

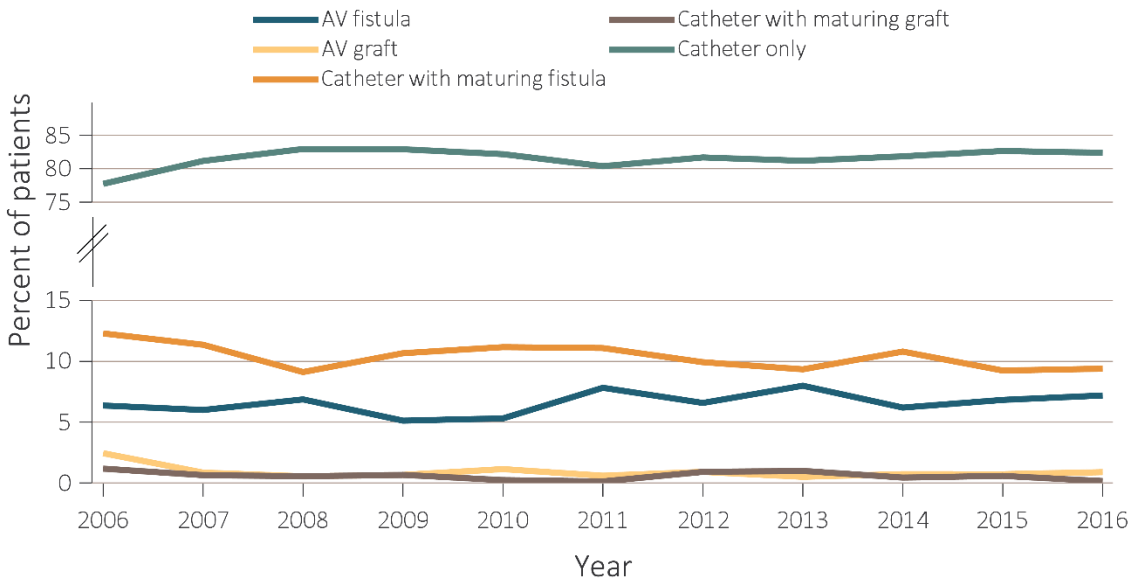
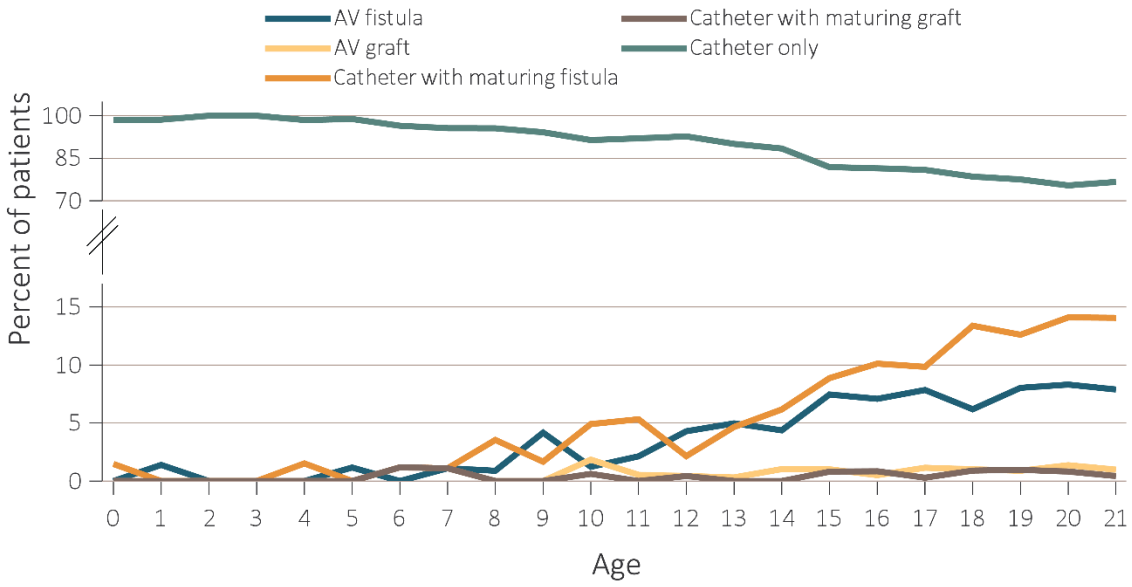


Figure 7.12 continued on next page.

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, 2006-2016 (continued)

(b) Age (all years combined)



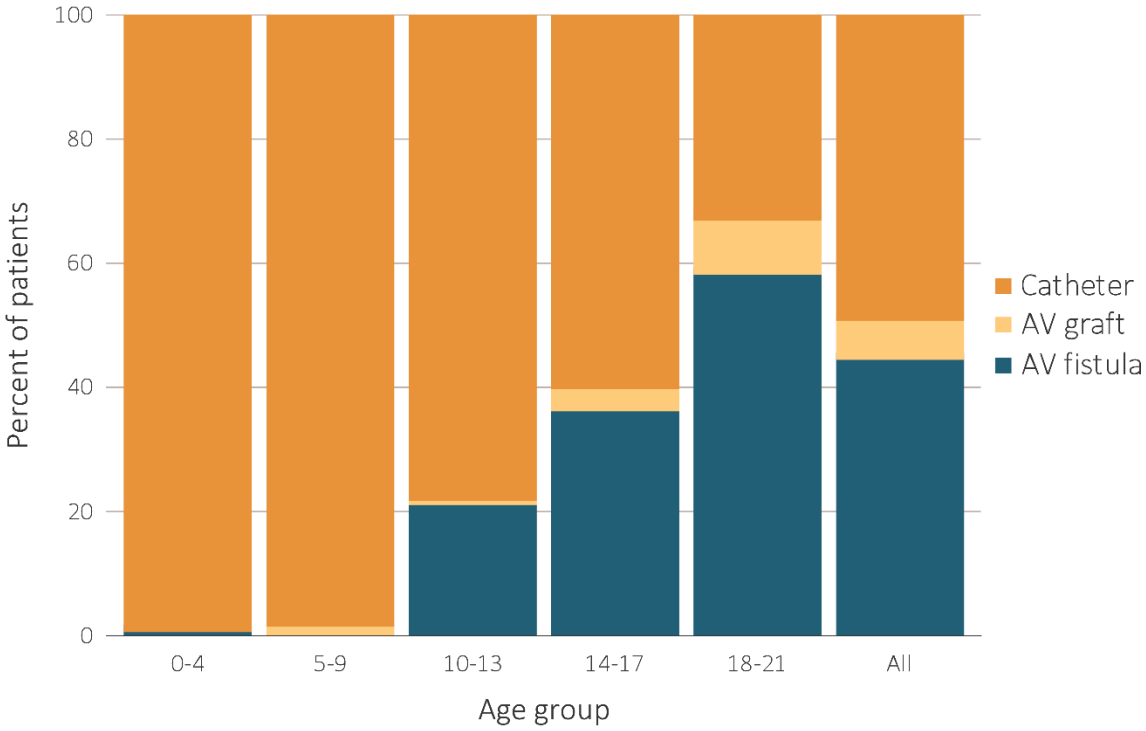
Data Source: Special analyses, USRDS ESRD Database. ESRD patients initiating hemodialysis in 2006-2015. Abbreviations: AV, arteriovenous; ESRD, end-stage renal disease.

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 (22.3%), 14-17 (40.3%), and 18-21 (67.4%) than in children under age 10 (Figure 7.13).

A cross-sectional analysis of point prevalent ESRD patients aged 0-21 years in May 2017 showed that 51.3% 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 40.3% for those aged 14-17 and 67.4% for those aged 18-21 years.

When examining race and etiology of ESRD in age-adjusted analysis (see downloadable Volume 2, Chapter 7: Excel Web Data File), there were subtle differences in vascular access in the prevalent hemodialysis patients. Whites had higher use of catheters (52.0%) when compared to Blacks/African American (44.0%) and Other races (44.2%). Blacks/African Americans and Other races had a higher proportion of AV graft use (8.7% and 8.0%) when compared to Whites (4.5%). Overall, patients with primary glomerular disease as the etiology of ESRD had the highest proportion of surgical access in place (AV fistula 48.1% or AV graft 7.1%). In age-adjusted analysis, the highest rate of catheter use was in those with Other etiologies of ESRD (53.7%).

vol 2 Figure 7.13 Distribution of vascular access type in prevalent pediatric hemodialysis patients (aged 0-21 years* as of May 31, 2017)



*Data Source: Special analyses, CROWNWeb clinical extracts for May 2017. Hemodialysis patients initiating treatment for ESRD at least 90 days prior to May 1, 2017, *who were <22 years old as of May 1, 2017, and who were alive through May 31, 2017; Catheter=any catheter use; fistula and graft use shown are without the use of a catheter. Abbreviations: AV, arteriovenous; ESRD, end-stage renal disease.*

Trends in Pediatric Kidney Transplantation

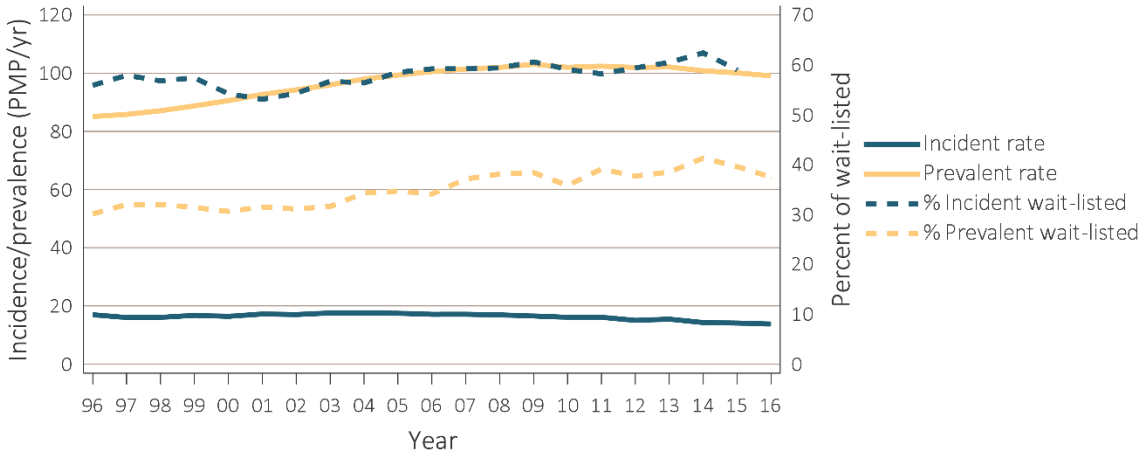
When examining race and etiology of ESRD in age-adjusted analysis, 36.3% of children received a kidney transplant within their first year of ESRD care, including 30.3% of children with weight greater than or equal to 10 kg (data not shown). In 2016 the rate of transplants was 34.9 per 100 dialysis patient-years—a stable trend since 2007 (Figure 7.14.a).

In 2016, 1,119 children were wait-listed for a kidney transplant, including 785 patients listed for the first time and 334 patients listed for repeat transplant. The number of patients awaiting a kidney transplant has ranged from 1,119 to 1,324 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. In 2016, the median waiting time for first transplant was 12.94 months (Figure 7.16.a). Over the past 10 years, 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 1999-2015 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 2016, 1,020 children received a kidney transplant (Figure 7.14.c). Prior to 2005, pediatric transplants were most commonly from living donors. In 2016, living donors accounted for 35.7% of kidney transplants, a 17.7% decrease since 2009. Stratifying kidney transplants by age group, adolescents between age 18 and 21 have had a consistently low number of transplants annually compared with children less than 18, totaling less than 300 per year for adolescents and 750 per year in children (Figures 7.14.d and 7.14.e).

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

(a) ESRD incident rate, prevalent rate, and percent of patients wait-listed



(b) Kidney transplant counts and waiting list times

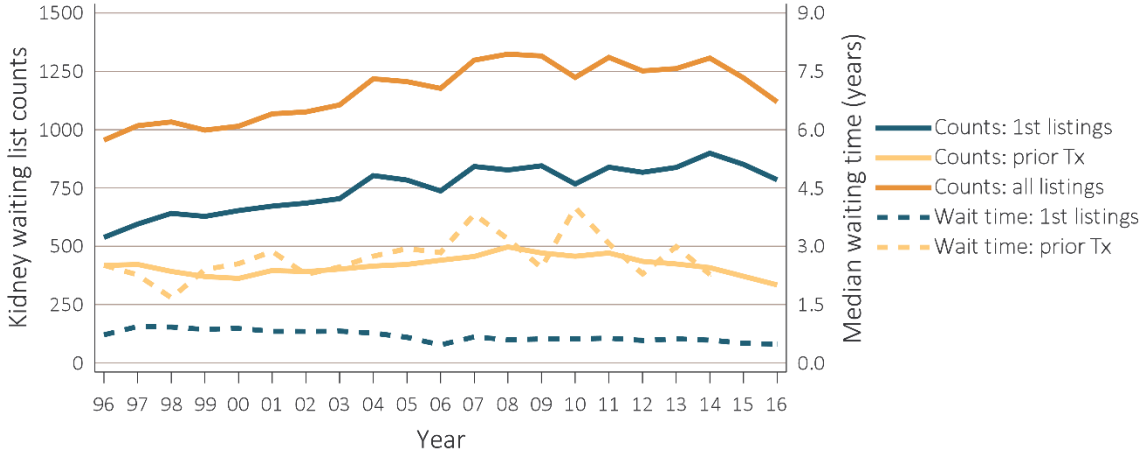
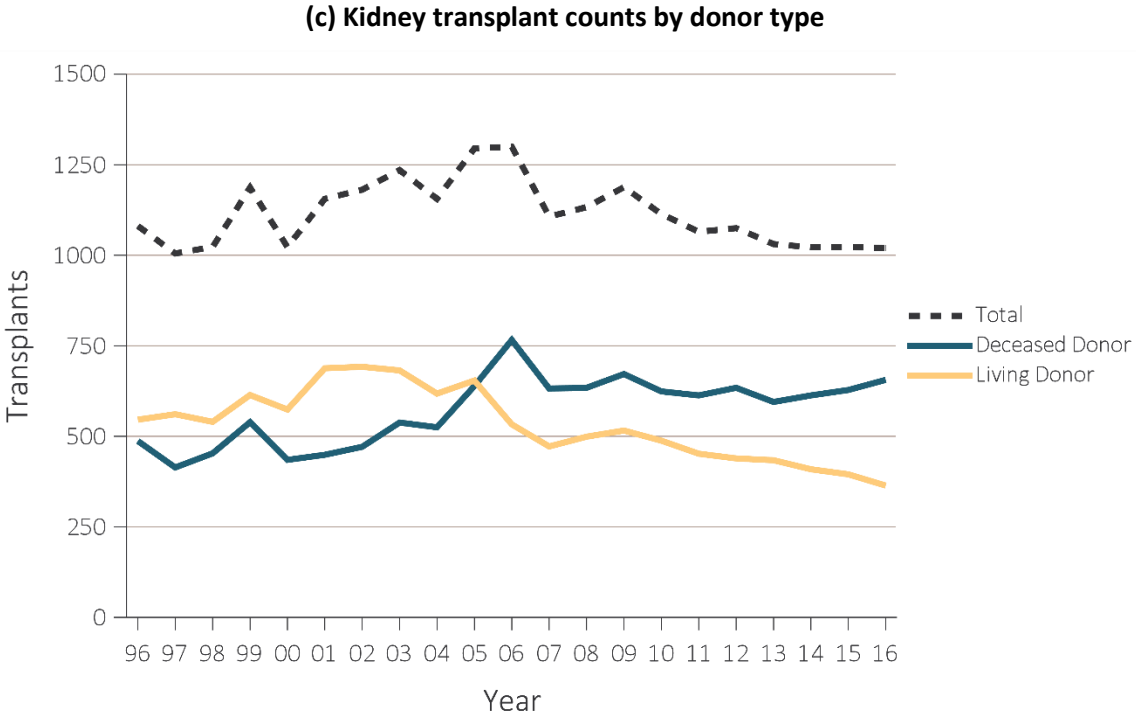


Figure 7.14 continued on next page.

vol 2 Figure 7.14 Trends in pediatric transplantation (aged 0-21 years), by (a) ESRD incident and prevalent rates, and percent of patients wait-listed, (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)



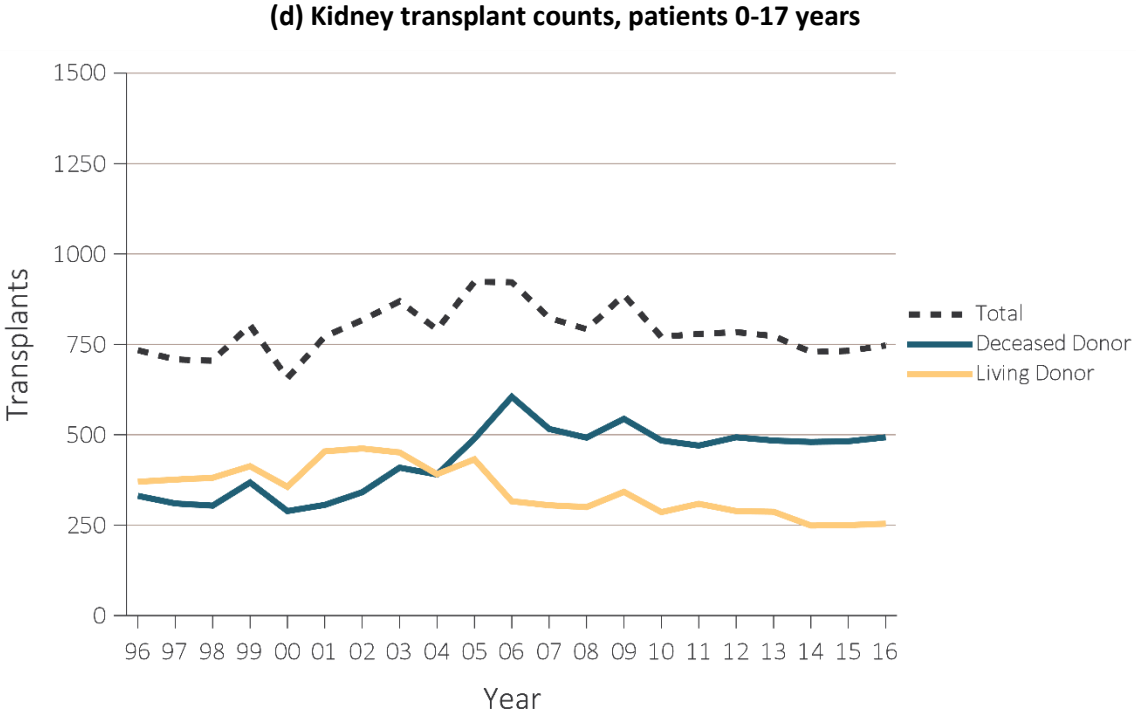
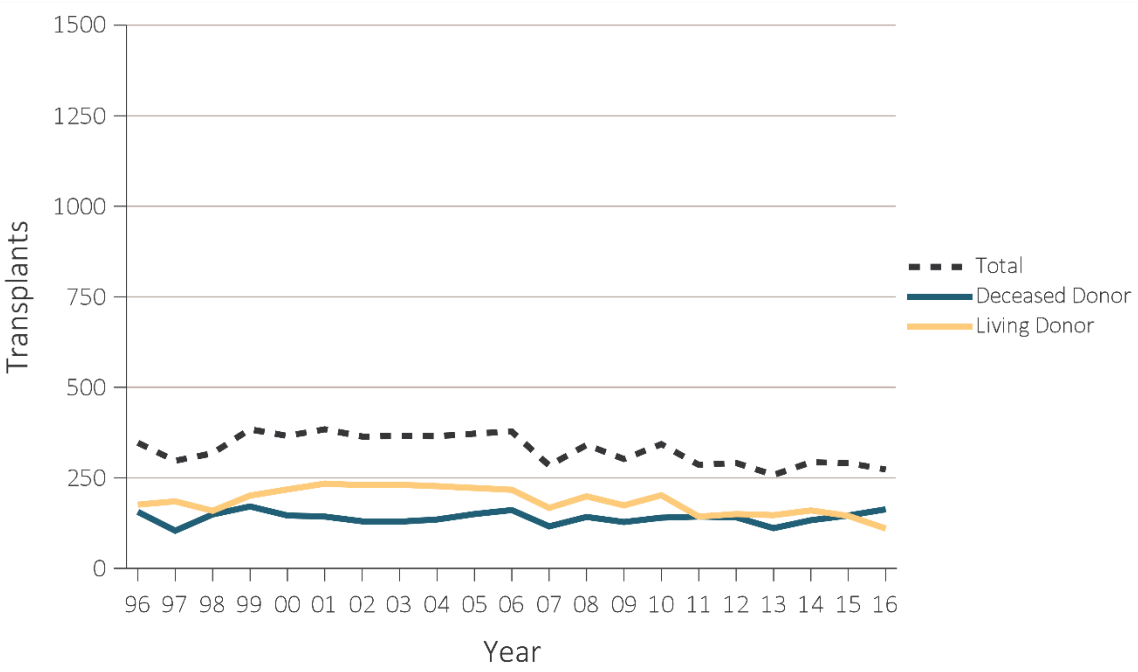


Figure 7.14 continued on next page.

vol 2 Figure 7.14 Trends in pediatric transplantation (aged 0-21 years), by (a) ESRD incident and prevalent rates, and percent of patients wait-listed, (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 E.4 and E.5(2). Incidence and December 31 point prevalence of ESRD among pediatric patients (aged 0-21 years) per million population per year, 1996-2016, percent of pediatric patients either wait-listed or receiving a kidney within one year of ESRD initiation date, 1996-2015 and percent of prevalent dialysis pediatric patients wait-listed for a kidney, 1996-2016. (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 E.8, E.8(2), E.8(3). This figure represents kidney alone and kidney plus pancreas transplant counts for all pediatric candidates. Abbreviations: ESRD, end-stage renal disease; PMP, per million population; Tx, transplant; yr, year.

Within this section we present details about annual transplant rates using three-year rolling averages to smooth the undue influence of fluctuations in the data in a single year. The rate of transplants relative to dialysis has remained between 30 and 38 per 100 dialysis years since 2016 (Figure 7.15.a). In 2016, patients aged 5-9 and 10-13 years had the highest average rates of transplants, 51.4 and 53.1 per 100 dialysis patient years respectively, and those aged 18-21 years had the lowest average rate at 20.6 (Figures 7.15.a and 7.15.b).

In 2016, males with ESRD were transplanted at average rates compared with females, at 36.0 versus 30.8 per 100 dialysis patient years. The average transplant rate remained lower in Black/African American dialysis patients compared with Whites, at 20.7 versus 37.0 per 100 dialysis patient years (Figures 7.15.c and 7.15.b). Analyses for Native and Asian Americans were not conducted due to the low number of transplants in these pediatric populations.

vol 2 Figure 7.15 Annual average rates of transplants in pediatric dialysis patients (aged 0-21 years), by (a) living donor by age, (b) deceased donor by age, (c) living donor by race, (d) deceased donor by race, 1998-2016

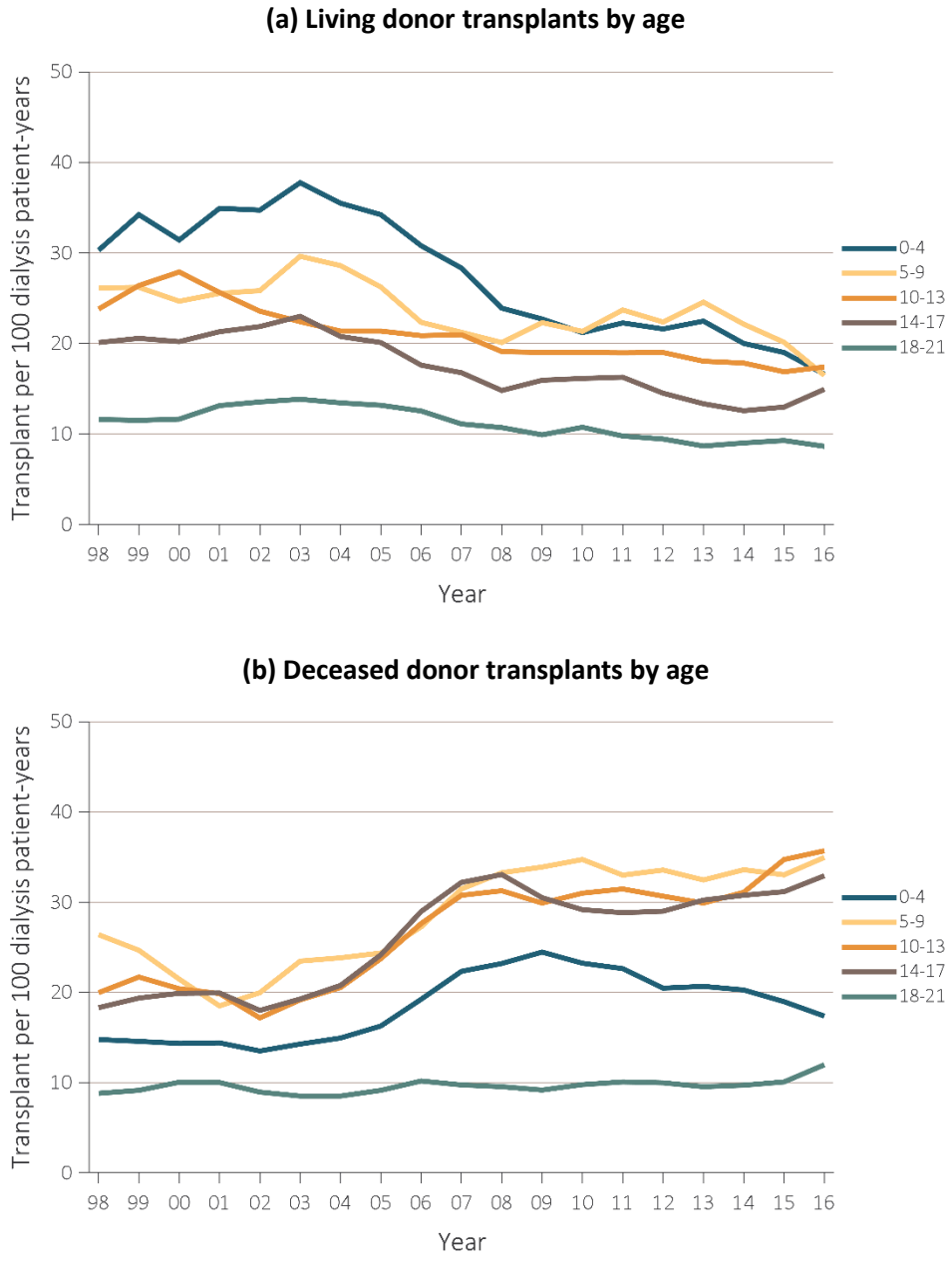
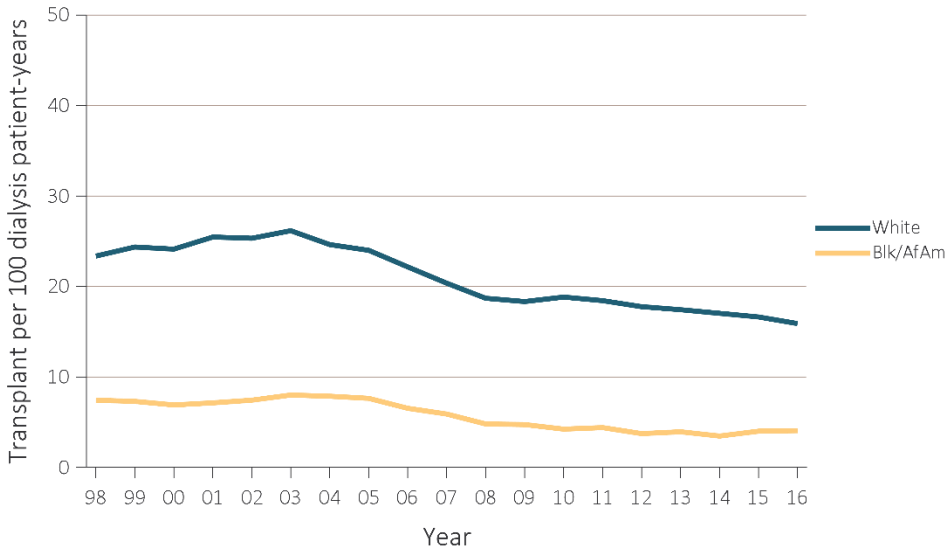


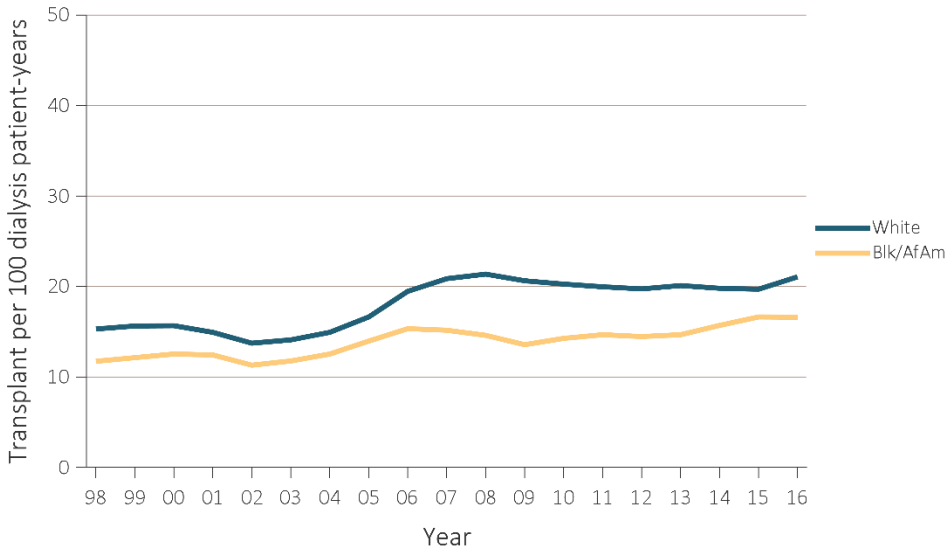
Figure 7.15 continued on next page.

vol 2 Figure 7.15 Annual average rates of transplants in pediatric dialysis patients (aged 0-21 years), by (a) living donor by age, (b) deceased donor by age, (c) living donor by race, (d) deceased donor by race, 1998-2016 (continued)

(c) Living donor transplants by race



(d) Deceased donor transplants by race



Data Source: Special analyses, USRDS ESRD Database. Includes transplant year between 1998–2016. Three-year rolling average rate is the mean among the rates of the current year and of the two years prior. Abbreviations: Blk/Af Am; Black/African American; ESRD, end-stage renal disease.

The trend in median time to first transplant for incident patients on dialysis has been improving. In 2002, the median time to first transplant peaked at 22.3 months then began to decline, with the most dramatic improvement occurring after 2005 (Figure 7.16.a). This coincided with the October 2005 change in the OPTN organ allocation policy, which gave priority to pediatric candidates for allografts from deceased donors aged less than 35 years. The goal of this policy change was to provide pediatric patients with high quality organs, reduce the delay in assignment of donor organs to all ages and reduce pediatric wait times. Since 2005, the median time from dialysis initiation to initial transplantation has continued to decrease, and was at its lowest in 2015, at 12.9 months. In 2015, the median time to transplant was shorter for HD patients (12.1 months) compared with PD patients (13.6 months).

The time to first transplant varied by age and ESRD etiology. In patients younger than 18 years of age, the median time from incident dialysis to transplant has been improving from 1996 to 2015 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 time from dialysis initiation to initial transplant. In 2014, the median time for children 0-4 years old surpassed that of patients 18-21 years old. Patients with glomerulonephritis (GN) as the primary cause of their ESRD had the longest median time between dialysis and initial transplant, with a median of 14.1 months in 2015 (Figure 7.16.c). The longer dialysis to initial transplant time for GN patients may be related to manifestations of GN such as nephrotic syndrome or uncontrolled systemic vasculitis which require a time on dialysis to restore necessary health parameters to support a successful transplant.

In 1996, the median time between dialysis initiation and first transplant among Whites was a 34% shorter period than Blacks/African Americans (Figure 7.16.d). Since then, the median time for dialysis patients to first transplant has improved significantly for all patients, and the gap between races has narrowed substantially. Consequently, the most recent median times between dialysis initiation and first transplant are now similar between groups (Whites 12.5 and Blacks 13.8 months). With the resolution of the dialysis to first transplant-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 time between dialysis initiation and first transplant from a deceased donor has decreased steadily since 2010, such that the difference in median time between living- and deceased-donor organs was less than three months in 2015 (Figure 7.16.e).

Finally, Tables 7.4 and 7.5 display the one-, five- and ten-year kidney transplant outcomes between 1996 and 2015 for deceased- and living-donor transplants. During this time the deceased-donor one-year graft failure rate has decreased from 15.9% to 3.0%, five-year graft failure has improved from 43.6% to 23.8% and the ten-year graft failure has improved from 65.5% to 53.2% (Table 7.4). Living-donor transplants have achieved similar improvements with the one-, five- and ten-year graft failure rates in the most recent reporting year of 3.1%, 17.2%, and 39.4%, respectively. Comparison of these donor types continues to suggest a graft survival advantage for living-donor organs but the patient survival at one and five years exceeds 97% for both donor types.

vol 2 Figure 7.16 Median time from incident dialysis to first transplant, by (a) modality, (b) age, (c) primary cause of ESRD, (d) race, and (e) donor type, 1996-2015

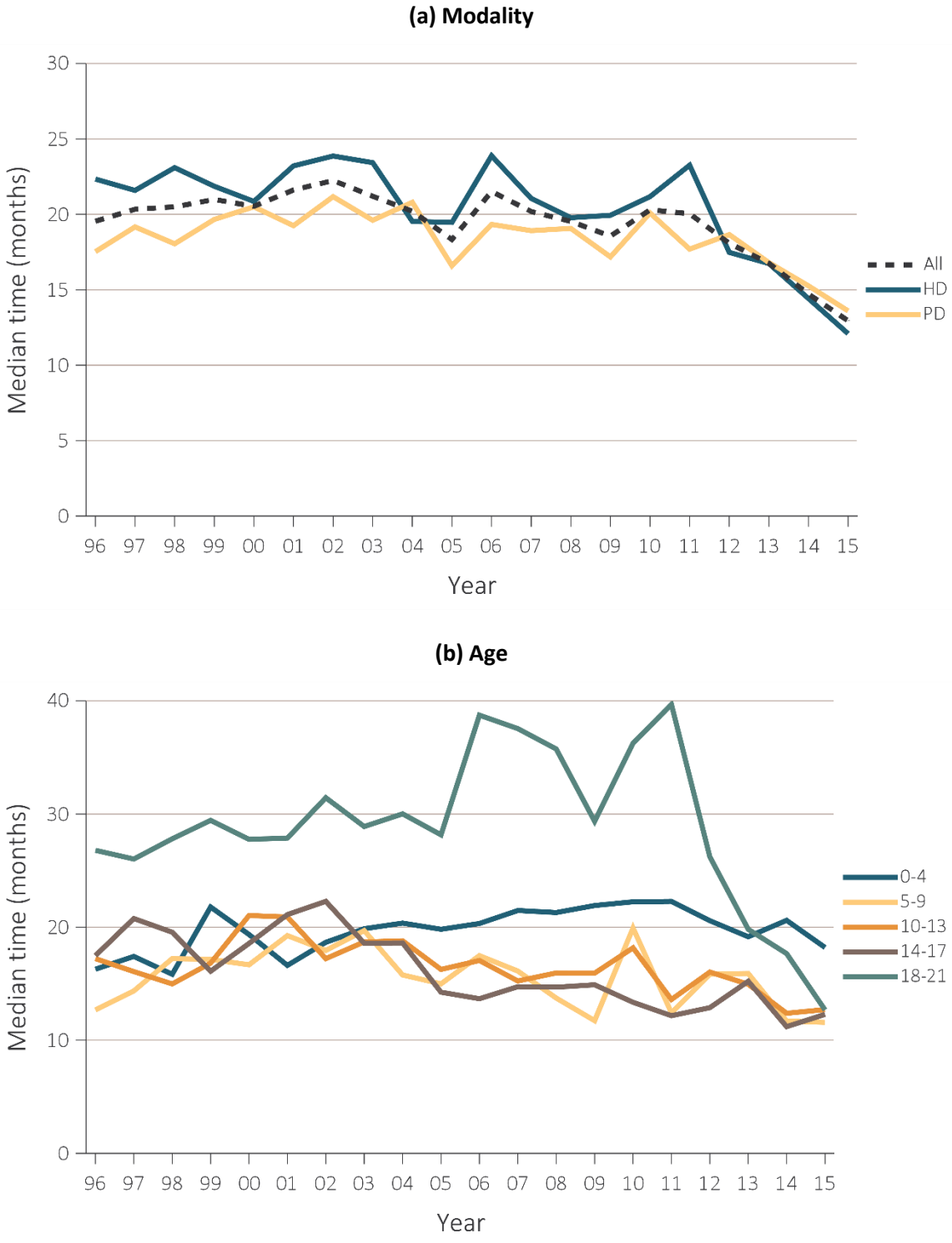


Figure 7.16 continued on next page.

vol 2 Figure 7.16 Median time from incident dialysis to first transplant, by (a) modality, (b) age, (c) primary cause of ESRD, (d) race, and (e) donor type, 1996-2015 (continued)

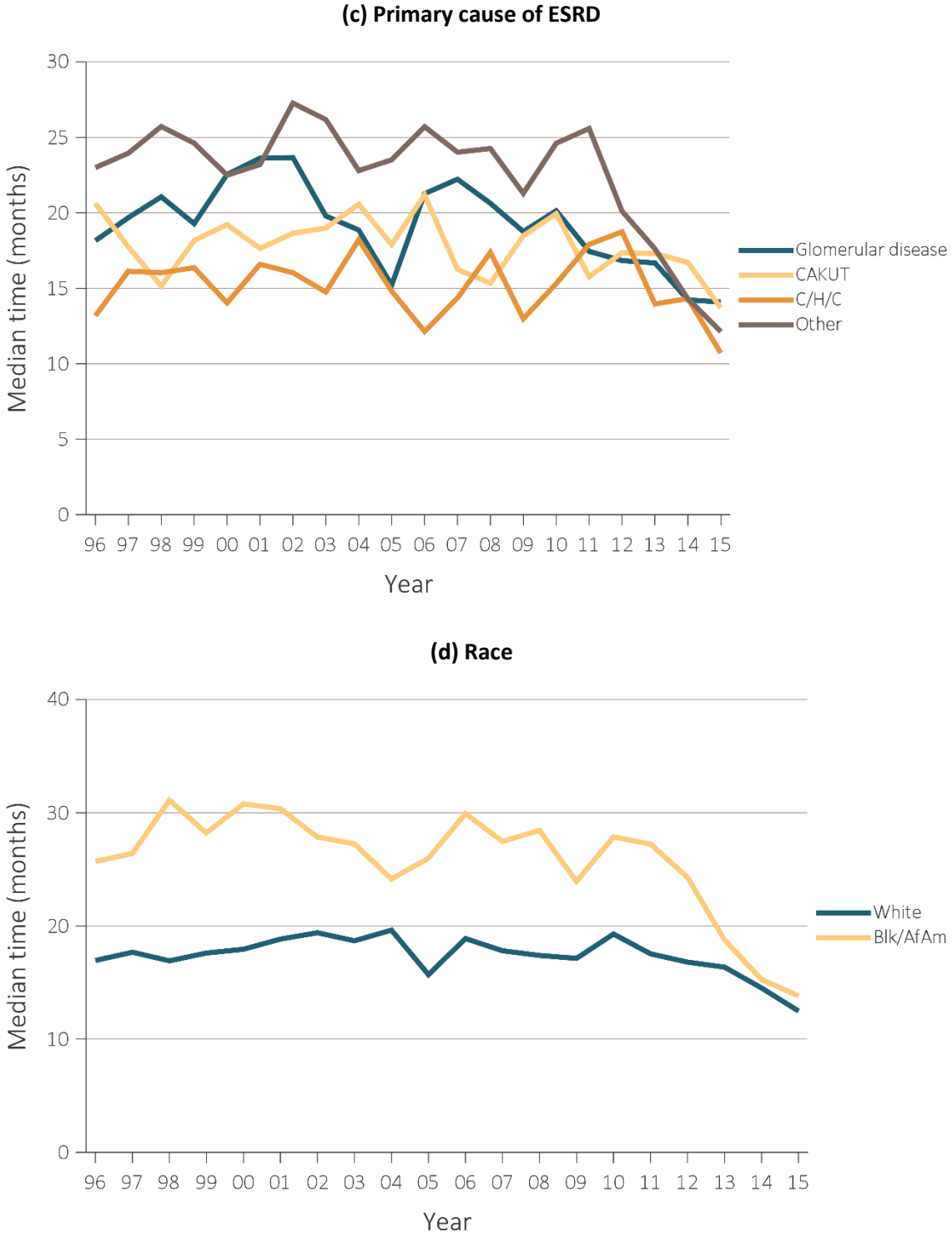
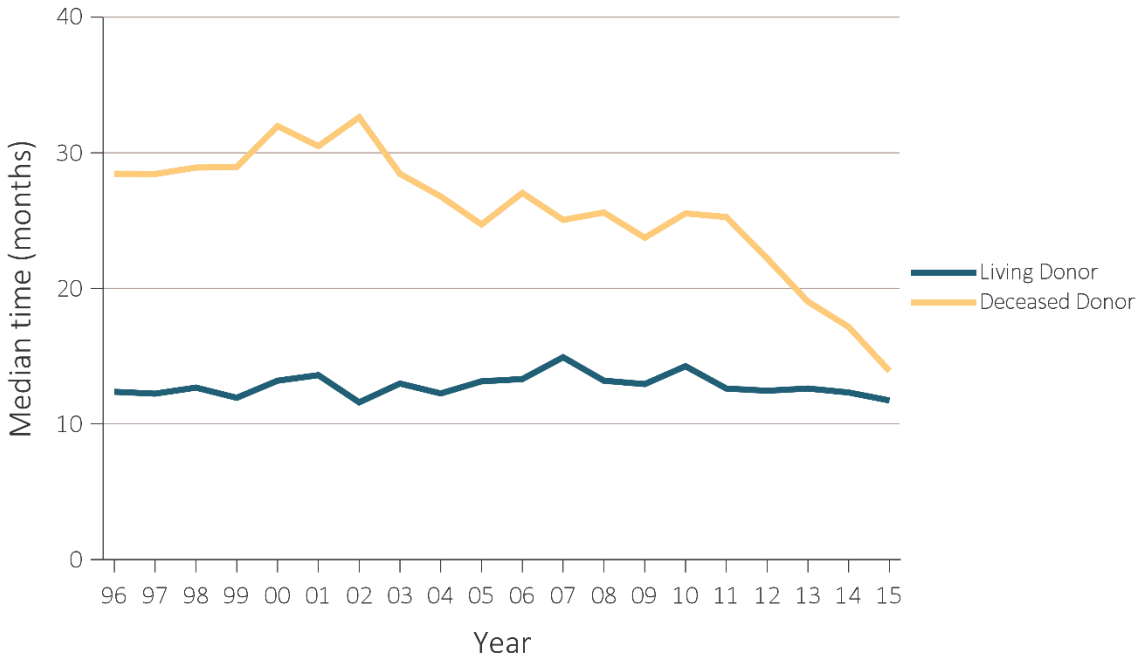


Figure 7.16 continued on next page.

vol 2 Figure 7.16 Median time from incident dialysis to first transplant, by (a) modality, (b) age, (c) primary cause of ESRD, (d) race, and (e) donor type, 1996-2015 (continued)

(e) Donor type



Data Source: Special analyses, USRDS ESRD Database. Sample restricted to children initiating ESRD care with dialysis. Time 0 is defined at the date of initiation of dialysis with the 60 day rule. Includes pediatric patients (aged 0-21 years) starting initiation of HD or PD in 1996-2015 and having the first transplant before 12/31/2017. Note that the percentage of unknown donor type is 1.32% in 1996, 1.00% 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, 0.22% in 2006, 0.13% in 2011, and 0% in 2005, 2007-2010, 2012-2015. Abbreviations: Blk/Af Am, Black/African American; 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.

vol 2 Table 7.4 Adjusted outcomes for deceased-donor kidney transplants in pediatric patients (aged 0-21 years) by year, 1996-2015

	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 (%)
1996	15.9	13.7	2.0	43.6	40.5	8.6	65.5	62.4	15.9
1997	12.9	11.2	2.6	39.2	36.6	6.3	63.2	59.7	15.1
1998	14.8	13.4	2.0	38.4	36.3	6.1	57.8	55.7	11.2
1999	14.2	11.8	2.2	37.6	34.8	4.7	59.2	56.3	14.2
2000	11.7	9.9	1.4	41.0	38.6	5.3	59.9	56.6	11.3
2001	11.5	10.7	1.7	36.6	34.8	6.0	57.0	54.1	12.3
2002	10.2	9.0	0.9	35.7	33.1	3.7	52.0	48.6	7.1
2003	10.5	8.7	2.5	36.7	34.1	7.0	54.4	51.2	14.6
2004	8.7	6.7	1.7	37.7	35.0	4.9	59.4	56.6	8.8
2005	9.4	8.0	2.2	35.2	32.5	5.6	55.6	52.6	10.3
2006	9.0	7.9	1.4	32.9	31.1	3.8	53.2	50.9	8.2
2007	7.8	6.4	2.2	31.4	29.0	6.0			
2008	9.1	7.4	1.8	28.2	25.2	4.4			
2009	7.6	6.5	1.1	29.3	27.1	4.3			
2010	6.7	5.6	1.1	23.9	22.6	2.7			
2011	4.3	4.1	0.3	23.8	22.7	2.6			
2012	5.4	4.2	0.9						
2013	5.8	5.4	0.4						
2014	5.5	5.1	0.3						
2015	3.0	2.6	0.2						

Data Source: Reference Tables F.2, F.5, F.6, F.14, F.17, F.18, I.26, I.29, I.30. 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.

vol 2 Table 7.5 Adjusted outcomes for living-donor kidney transplants in pediatric patients (aged 0-21 years) by year, 1996-2015

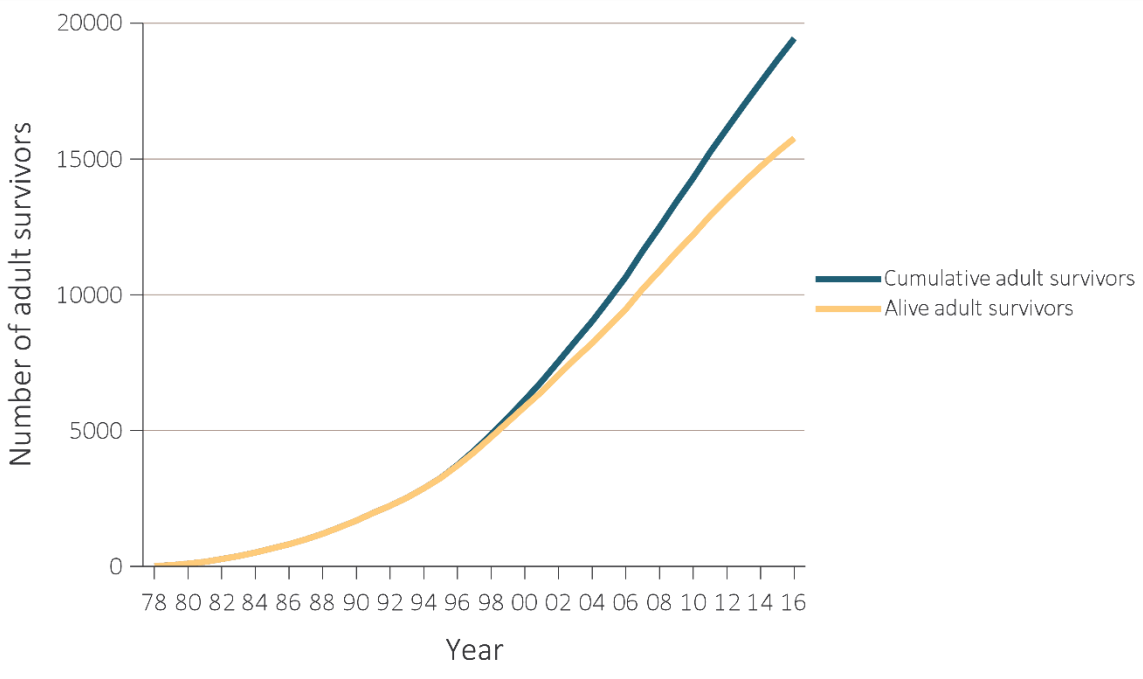
	One year post-transplant			Five years post-transplant			Ten years post-transplant		
Year	Probability of all-cause graft failure (%)	Probability of return to dialysis or repeat transplant (%)	Probability of death (%)	Probability of all-cause graft failure (%)	Probability of return to dialysis or repeat transplant (%)	Probability of death (%)	Probability of all-cause graft failure (%)	Probability of return to dialysis or repeat transplant (%)	Probability of death (%)
1996	9.2	8.0	1.8	30.1	28.0	5.9	51.1	49.1	12.0
1997	8.0	7.1	1.1	29.6	26.2	9.5	48.8	45.9	15.1
1998	7.1	6.5	0.8	25.3	24.1	2.5	48.5	46.3	9.8
1999	7.3	6.5	1.0	27.4	25.6	5.9	49.6	47.2	13.0
2000	8.3	7.7	1.6	28.4	26.6	7.3	51.2	48.2	14.7
2001	7.5	6.7	1.1	26.6	24.2	5.4	48.8	45.9	13.1
2002	6.4	5.5	1.6	25.6	23.6	7.1	42.0	39.8	13.1
2003	6.8	5.6	1.5	25.1	22.9	5.3	42.7	39.9	11.1
2004	5.9	4.9	1.0	25.8	23.3	3.9	43.7	41.0	6.2
2005	7.0	6.4	1.1	27.4	25.6	5.7	47.7	45.5	11.3
2006	3.9	3.7	0.3	20.8	19.4	2.4	39.4	37.3	6.0
2007	4.7	3.9	0.8	23.2	21.3	4.1			
2008	5.3	4.5	1.5	21.5	19.4	4.7			
2009	5.0	3.9	0.9	18.9	17.3	1.7			
2010	3.9	3.2	0.6	20.3	18.6	1.3			
2011	4.0	3.2	1.2	17.2	16.1	2.8			
2012	5.5	4.4	1.7						
2013	3.3	1.6	1.2						
2014	4.7	3.8	1.0						
2015	3.1	3.0	0.0						

Data Source: Reference Tables F.8, F.11, F.12, F.20, F.23, F.24, I.32, I.35, I.36. 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 with Childhood Onset ESRD

In this section, adult survivors of childhood onset ESRD (survivors) are defined as individuals who initiated ESRD care before the age of 19 years and survived beyond their nineteenth birthday. As of December 31, 2016, the cumulative number of survivors between 1978 and 2016 is 19,441 in the United States with 15,765 (81.1%) still surviving on December 31, 2016. Prevalence trends in this cohort are shown in Figure 7.17.

vol 2 Figure 7.17 Prevalent adult survivors of childhood onset ESRD, 1978-2016



Data Source: Special analyses, USRDS ESRD Database. Survivorship cohort is defined as the patients with ESRD incidence in childhood who survive to adulthood by the end of each year and with ESRD onset year on and after 1978. Cumulative adult survivors include patients who reached adulthood but died by the end of each year. Alive adult survivors excludes patients who died during the year. Abbreviation: ESRD, end-stage renal disease.

Focusing on survivors with an ESRD initiation date between 1995 and 2016, a summary of the contemporary survivorship cohort is presented in Table 7.6. Survivors initiated ESRD care at any age between 0 and 18 years, with the majority entering as adolescents. The leading primary causes of ESRD were categorized as glomerular disease (39.7%), cystic/hereditary/congenital (11.4%), and other etiologies combined (48.9%). Hypertension was common at ESRD initiation. Cardiovascular disease and diabetes were present in less than 3% of the survivorship cohort at ESRD initiation.

The majority of survivors received at least one kidney transplant throughout their ESRD experience. The mean transplant number was 1.08 per patient and the maximum number of transplants was 5. The average length of time on ESRD modality for these survivors was 112.6 months for patients with a functioning graft, 52.5 months for patients on HD, and 28.0 months for patients on PD (Table 7.6).

vol 2 Table 7.6 Initiation characteristics and treatment modality of adult survivors of childhood onset ESRD, inclusive of patients initiating ESRD care between 1995 and 2016

Survivorship Cohort	All (N=13,981)	
	Frequency	Percent
Age of ESRD onset		
Less than 5	537	3.8%
5-9	1,287	9.2%
10-13	2,906	20.8%
14-18	9,251	66.2%
Sex		
Male	7,823	56.0%
Female	6,158	44.0%
Race		
White	9,526	68.1%
Black	3,533	25.3%
Other/Unknown	922	6.6%
Ethnicity		
Hispanic	3,580	25.6%
Non-Hispanic	10,354	74.1%
Unknown	47	0.3%
BMI Category		
Underweight	1,434	10.3%
Healthy Weight	7,994	57.2%
Overweight	2,109	15.1%
Obesity	2,444	17.5%
Cause of ESRD		
Glomerulonephritis / Secondary GN / Vasculitis	5,557	39.7%
Cystic / Hereditary / Congenital	1,589	11.4%
Other	6,835	48.9%
ESRD onset year		
1995-2004	8,244	59.0%
2005-2015	5,737	41.0%
Modality at initiation		
HD	7,251	51.9%
PD	4,160	29.8%
TX	2,514	18.0%
Cumulative time on HD (months)	52.5 (SD=52.3)	
Cumulative time on PD (months)	28.0 (SD=29.0)	
Cumulative time with functioning transplant (months)	112.6 (SD=66.6)	
Number of transplants	1.1 (SD=0.6)	
Co-existing conditions at ESRD incidence		
Heart Failure	276	2.0%
Coronary Artery and Cardiac Disease	302	2.2%
Other Vascular Disease	110	0.8%
Hypertension	6,048	43.3%
Diabetes	254	1.8%
Other	2,727	19.5%

Data Source: USRDS ESRD Database. Survivorship cohort is defined as the patients with ESRD incidence in childhood that survive to adulthood by the end of 2016 and with ESRD onset year after 1994 and with completed 2728 form information, including patients who reached adulthood but died by the end of 2016. Abbreviations: ESRD, end-stage renal disease; GN, glomerulonephritis; HD, hemodialysis; PD, peritoneal dialysis.

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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—are likely to suffer from cardiovascular disease (Figures 8.2.a and 8.2.b).
- The presence of cardiovascular diseases is associated with both worse 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 8.4).

Introduction

Patients with end-stage renal disease (ESRD) are among the highest risk populations for cardiovascular diseases (CVDs)—a major cause of death in ESRD patients. The relationship between kidney disease and CVD 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 acute myocardial infarction (AMI), coronary artery disease (CAD), heart failure (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 the role of Medicare as the primary health care payer for ESRD patients, our analyses are based primarily on data from the national Medicare population.

Methods

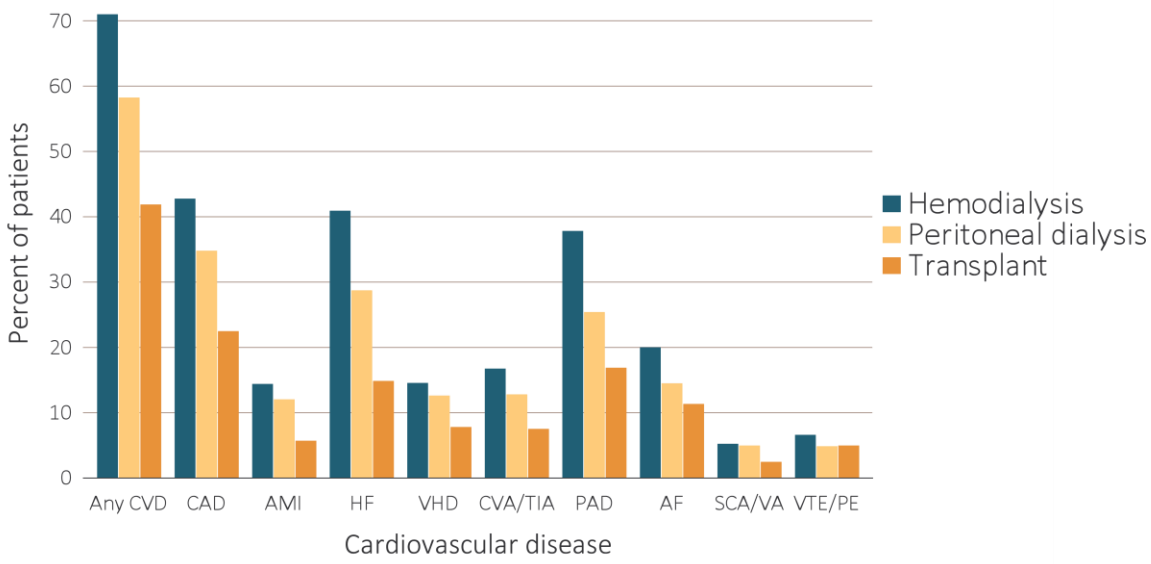
The findings presented in this chapter were drawn from data sources from the Centers for Medicare & Medicaid Services (CMS). Details of these are described in the *Data Sources section* of the *ESRD Analytical Methods* chapter.

See the section addressing *Chapter 8* in the 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, in 2016 ESRD patients had a high burden of CVD across a wide range of conditions (Figure 8.1). Mechanisms by which ESRD increases CVD risk include metastatic calcification, alterations in sodium and fluid balance, and exacerbation of inflammatory processes including atherosclerosis. Stable CAD and HF were the two most common 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. Aortic stenosis, in particular, may progress more aggressively in ESRD patients than in those without kidney disease (Kim et al., 2016). In general, the prevalence of these cardiovascular diseases was highest among ESRD patients who received HD (70.6%), followed by PD (57.8%), and those with kidney transplants (41.4%).

vol 2 Figure 8.1 Prevalence of cardiovascular diseases in adult ESRD patients, by treatment modality, 2016

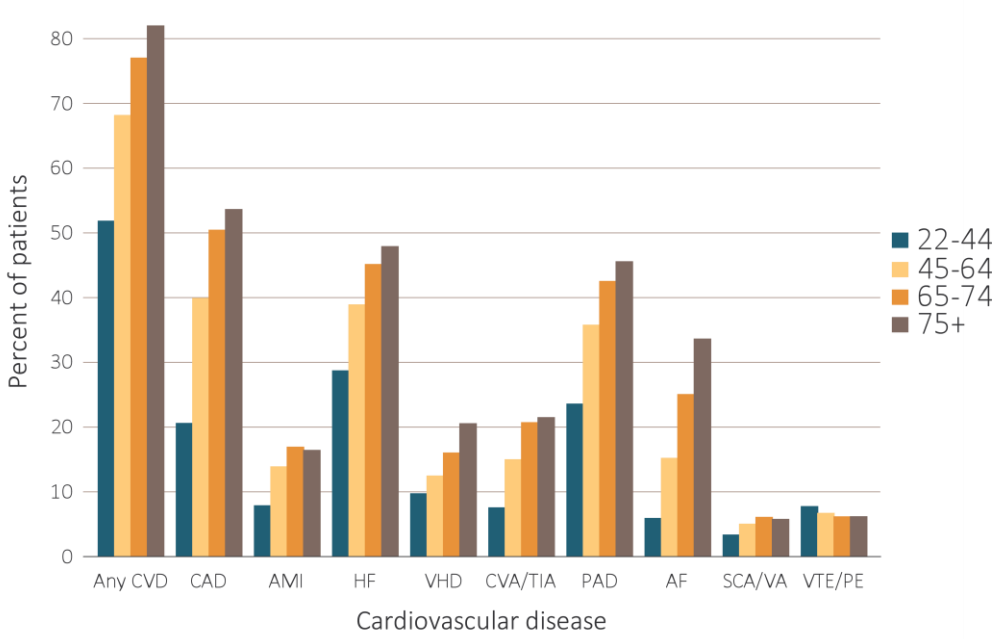


Data Source: Special analyses, USRDS ESRD Database. Point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older, who are continuously enrolled in Medicare Parts A and B, and with Medicare as primary payer from January 1, 2016 to December 31, 2016, and ESRD service date is at least 90 days prior to January 1, 2016. Abbreviations: AF, atrial fibrillation; AMI, acute myocardial infarction; CAD, coronary artery disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; CVD, cardiovascular disease; ESRD, end-stage renal 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.

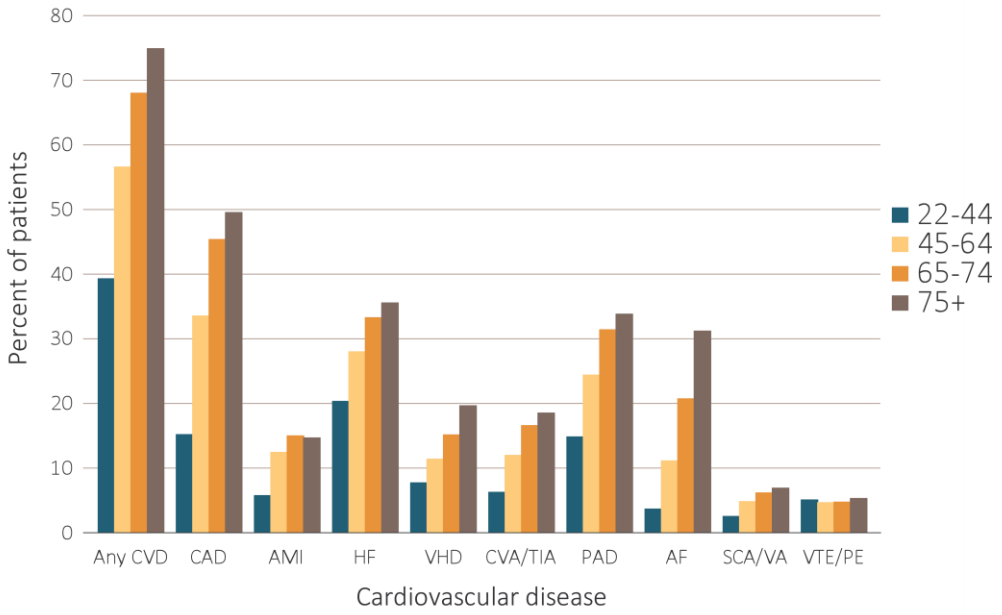
Peritoneal dialysis patients had a lower burden of certain cardiovascular conditions, including CAD, HF, and PAD, as compared to their HD counterparts. Older ESRD patients tended to have a higher prevalence of cardiovascular conditions than did younger patients, whether they were receiving HD or PD (Figures 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 (51.4%), although a much higher prevalence was observed among those 45 years or older (67.8% to 81.6%). The same pattern was true for PD patients. CAD 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, 2016

(a) Hemodialysis patients



(b) Peritoneal dialysis patients



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, 2016 to December 31, 2016, and ESRD service date is at least 90 days prior to January 1, 2016. Abbreviations: AF, atrial fibrillation; AMI, acute myocardial infarction; CAD, coronary artery disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; CVD, cardiovascular disease; ESRD, end-stage renal 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, older 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, 2016

	(a) Cardiovascular comorbidities												
	# Patients	Percentage of patients (%)											
		Overall	22-44	45-64	65-74	75+	White	Black	AI/AN	Asian	NH/PI	Other	Male	Female
Any CVD													
Hemodialysis	218,720	70.6	51.4	67.8	76.6	81.6	66.9	61.3	72.7	68.3	67.1	52.0	68.9	72.7
Peritoneal dialysis	22,023	57.7	38.7	56.2	67.6	74.5	49.8	51.3	60.0	54.5	51.1	35.0	60.7	54.3
Transplant	75,313	41.4	17.9	37.2	55.2	65.7	33.8	40.1	42.6	39.7	37.0	28.0	43.6	38.2
Coronary artery disease (CAD)													
Hemodialysis	218,720	42.3	20.2	39.5	50.0	53.2	41.8	34.3	46.2	37.5	39.0	29.5	42.6	42.0
Peritoneal dialysis	22,023	34.4	14.8	33.1	45.0	49.1	29.5	25.8	37.4	28.6	31.9	15.0	39.2	28.7
Transplant	75,313	22.1	5.6	19.2	31.7	38.0	19.5	21.8	23.3	19.0	19.4	12.0	24.9	17.9
Acute myocardial infarction (AMI)													
Hemodialysis	218,720	14.0	7.5	13.5	16.5	16.0	13.3	11.5	15.3	12.3	12.0	7.0	14.0	14.0
Peritoneal dialysis	22,023	11.6	5.4	12.0	14.6	14.3	8.4	8.8	12.8	9.5	12.8	10.0	13.3	9.7
Transplant	75,313	5.3	1.6	4.8	7.3	8.4	3.3	4.9	5.8	4.3	3.0	4.0	5.9	4.3
Heart failure (HF)													
Hemodialysis	218,720	40.4	28.3	38.5	44.7	47.5	35.8	32.8	40.8	40.8	38.6	27.3	38.5	43.1
Peritoneal dialysis	22,023	28.3	19.9	27.6	32.7	35.2	23.4	22.5	28.3	29.5	23.4	20.0	29.3	26.9
Transplant	75,313	14.4	6.0	12.4	19.5	24.9	11.4	12.7	14.1	16.2	10.9	12.7	14.8	13.9
Valvular heart disease (VHD)													
Hemodialysis	218,720	14.1	9.3	12.1	15.6	20.1	13.6	9.6	15.4	12.7	12.0	10.1	13.0	15.6
Peritoneal dialysis	22,023	12.2	7.3	11.0	14.7	19.3	10.0	9.2	13.0	10.9	8.5	10.0	12.0	12.4
Transplant	75,313	7.4	2.2	5.4	10.9	16.0	6.2	4.6	7.9	6.3	7.8	6.7	7.1	7.8
Cerebrovascular accident/transient ischemic attack (CVA/TIA)													
Hemodialysis	218,720	16.3	7.1	14.6	20.3	21.1	15.1	11.4	16.5	16.4	12.6	8.8	14.9	18.2
Peritoneal dialysis	22,023	12.4	5.9	11.6	16.2	18.1	9.4	6.3	13.3	11.1	10.6	15.0	12.2	12.5
Transplant	75,313	7.1	1.9	5.6	10.6	13.4	6.0	6.5	7.3	6.8	6.3	7.3	7.0	7.2
Peripheral artery disease (PAD)													
Hemodialysis	218,720	37.4	23.2	35.3	42.1	45.2	30.5	31.9	39.0	36.0	34.9	25.6	37.0	37.9
Peritoneal dialysis	22,023	25.0	14.4	24.0	31.0	33.4	17.2	23.8	27.0	21.9	14.9	25.0	26.9	22.8
Transplant	75,313	16.5	6.2	14.9	22.1	26.5	11.6	17.6	16.9	16.0	16.0	10.0	18.1	14.1
Atrial fibrillation (AF)													
Hemodialysis	218,720	19.6	5.5	14.8	24.6	33.2	19.3	11.3	23.2	15.1	16.3	7.9	20.2	18.9
Peritoneal dialysis	22,023	14.1	3.3	10.7	20.3	30.8	12.5	7.1	16.4	9.2	8.5	15.0	16.8	10.9
Transplant	75,313	10.9	1.6	7.3	17.2	27.1	8.0	7.4	12.3	7.8	7.2	4.7	12.2	9.0
Cardiac arrest and ventricular arrhythmias (SCA/VA)													
Hemodialysis	218,720	4.8	2.9	4.6	5.7	5.4	3.6	2.6	4.8	5.0	3.5	2.2	5.2	4.3
Peritoneal dialysis	22,023	4.6	2.1	4.4	5.8	6.5	3.4	2.9	4.6	4.7	2.1	5.0	5.4	3.6
Transplant	75,313	2.0	0.6	1.6	3.1	3.8	1.5	1.5	2.1	2.0	2.7	2.0	2.3	1.6
Venous thromboembolism and pulmonary embolism (VTE/PE)													
Hemodialysis	218,720	6.2	7.3	6.3	5.8	5.8	4.0	3.3	5.4	7.5	6.3	4.4	5.5	7.1
Peritoneal dialysis	22,023	4.4	4.7	4.3	4.3	4.9	1.7	3.8	4.2	5.7	4.3	5.0	4.0	5.0
Transplant	75,313	4.6	3.3	4.1	5.6	6.0	1.7	3.2	4.4	5.7	2.9	4.0	4.6	4.4

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, 2016 (continued)

	(b) Cardiovascular procedures												
	# Patients	Percentage of 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	92,625	4.9	4.4	5.6	5.0	3.6	4.8	5.6	5.1	4.5	6.1	7.5	5.0	4.8
Peritoneal dialysis	7,570	6.1	6.1	6.9	5.7	5.2	4.5	0.0	6.6	5.1	13.3	0.0	6.5	5.6
Transplant	16,615	3.3	4.2	3.5	3.1	2.9	3.2	2.3	3.5	2.4	2.0	11.1	3.4	3.1
Revascularization – coronary artery bypass graft (CABG)													
Hemodialysis	92,625	1.7	1.7	2.4	1.7	0.7	1.6	1.7	1.9	1.4	1.7	0.0	2.1	1.3
Peritoneal dialysis	7,570	3.4	2.8	3.9	4.1	1.4	2.8	8.1	3.6	2.7	6.7	0.0	3.9	2.5
Transplant	16,615	1.0	0.4	1.1	1.1	0.6	1.3	1.2	1.1	0.5	1.0	0.0	1.1	0.8
Implantable cardioverter defibrillators & cardiac resynchronization therapy with defibrillator devices (ICD/CRT-D)													
Hemodialysis	88,377	0.9	0.9	1.0	1.0	0.7	0.6	1.0	1.0	0.9	1.1	1.6	1.2	0.6
Peritoneal dialysis	6,181	1.1	0.6	1.2	1.3	0.8	1.4	1.9	1.2	0.8	9.1	0.0	1.4	0.7
Transplant	10,851	0.8	0.1	0.7	0.9	1.0	1.0	0.0	0.8	0.6	0.0	5.3	1.0	0.4
Carotid artery stenting and carotid artery endarterectomy (CAS/CEA)													
Hemodialysis	130,581	0.4	0.1	0.3	0.5	0.4	0.2	0.4	0.5	0.2	0.0	0.0	0.4	0.4
Peritoneal dialysis	10,445	0.6	0.1	0.4	0.9	0.6	0.0	2.0	0.6	0.4	0.0	0.0	0.6	0.5
Transplant	24,331	0.4	0.1	0.2	0.5	0.6	0.3	0.8	0.5	0.2	0.0	3.3	0.5	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, 2016 to December 31, 2016, and ESRD service date is at least 90 days prior to January 1, 2016. (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; ESRD, end-stage renal 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 increase short- and long-term mortality 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). 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 these procedures (Figure 8.4.d). Patients who underwent PCI, ICD-CRT-D placement, and CAS/CEA had higher mortality rates than patients who did not undergo these procedures, while those who underwent CABG had a lower mortality rate than non-CABG patients. However, these descriptive results in the adult ESRD population are observational and require careful interpretation. Comparative effectiveness research with appropriate statistical methods would be 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, 2015-2016

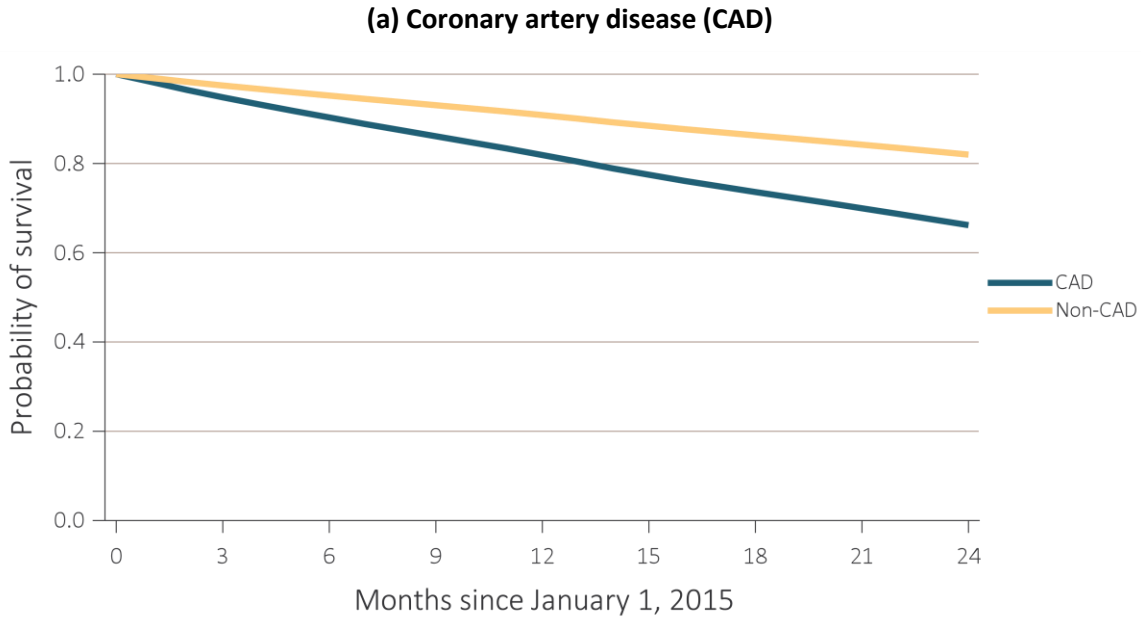
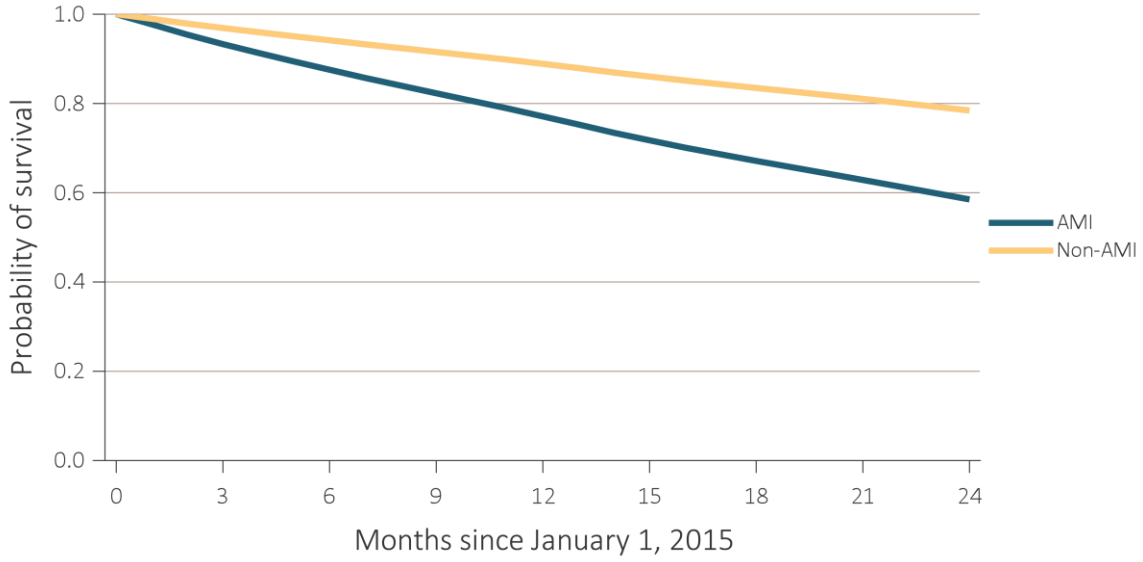


Figure 8.3 continued on next page.

vol 2 Figure 8.3 Probability of survival of adult ESRD patients with or without a cardiovascular disease, adjusted for age and sex, 2015-2016 (continued)

(b) Acute myocardial infarction (AMI)



(c) Heart failure (HF)

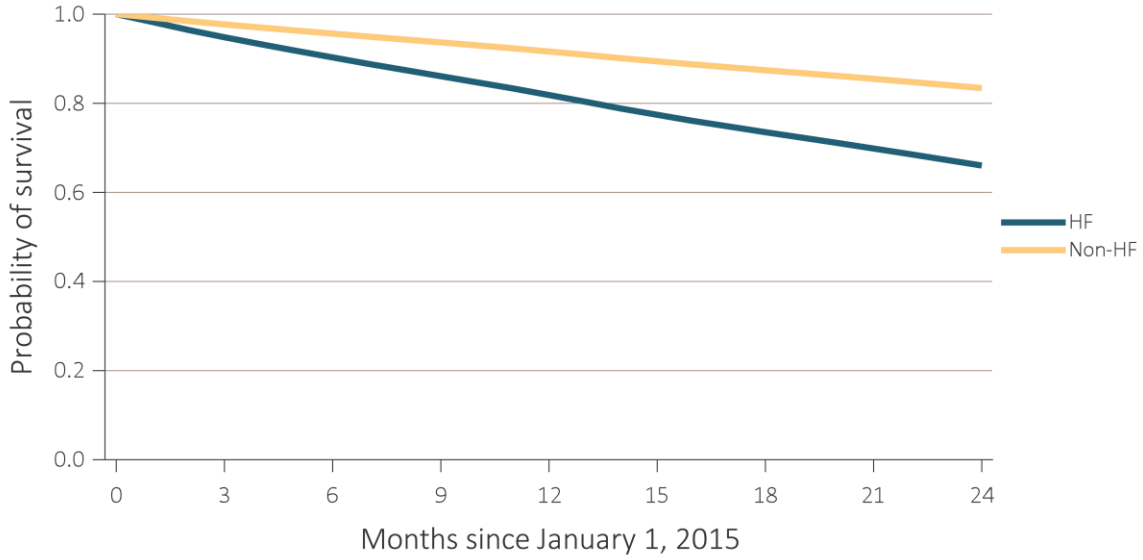
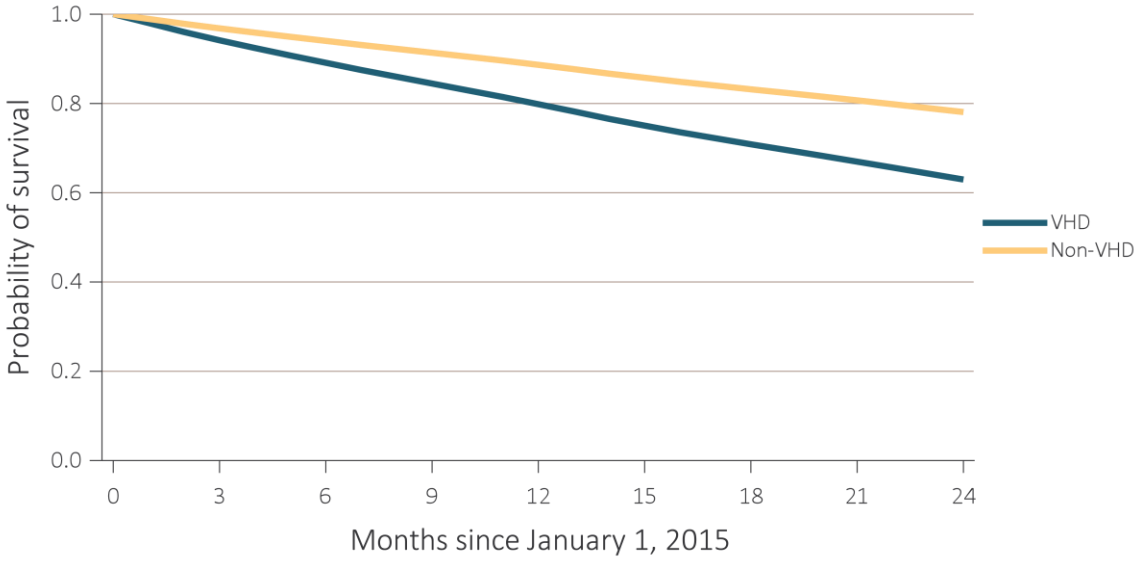


Figure 8.3 continued on next page.

vol 2 Figure 8.3 Probability of survival of adult ESRD patients with or without a cardiovascular disease, adjusted for age and sex, 2015-2016 (continued)

(d) Valvular heart disease (VHD)



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

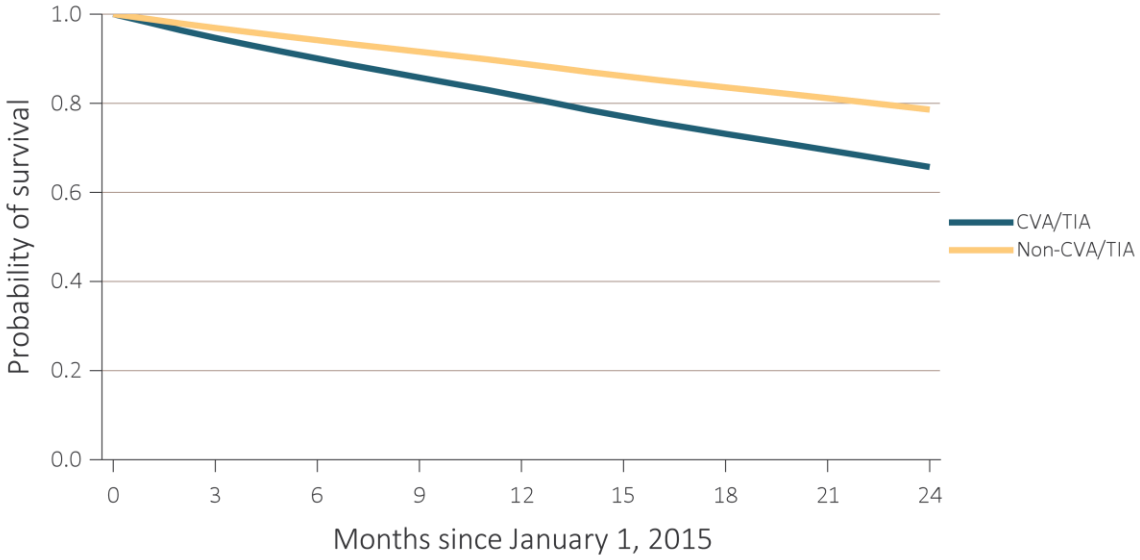
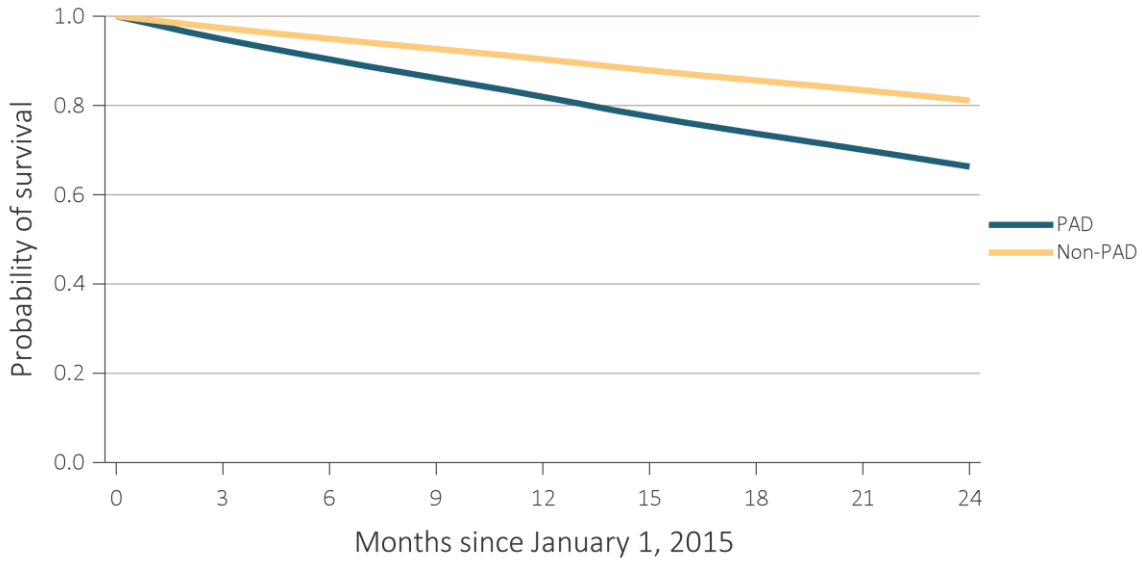


Figure 8.3 continued on next page.

vol 2 Figure 8.3 Probability of survival of adult ESRD patients with or without a cardiovascular disease, adjusted for age and sex, 2015-2016 (continued)

(f) Peripheral arterial disease (PAD)



(g) Atrial fibrillation (AF)

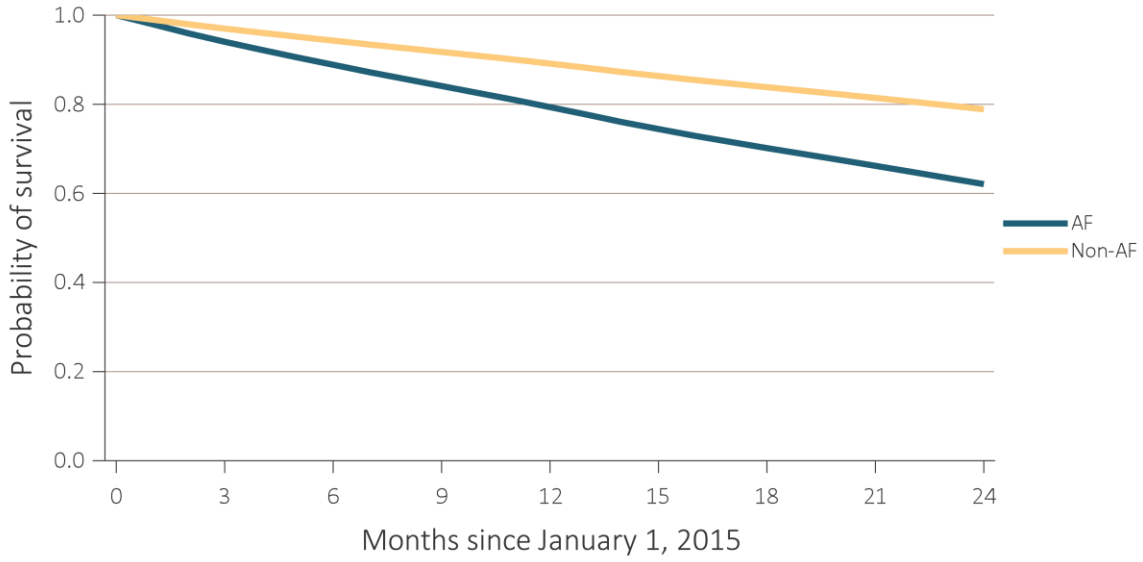
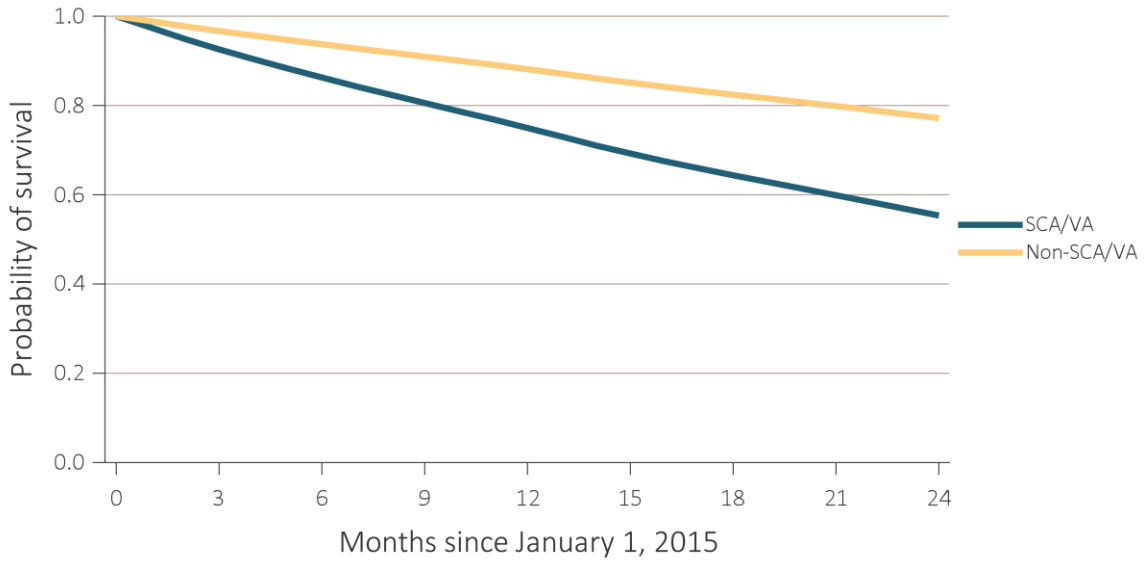


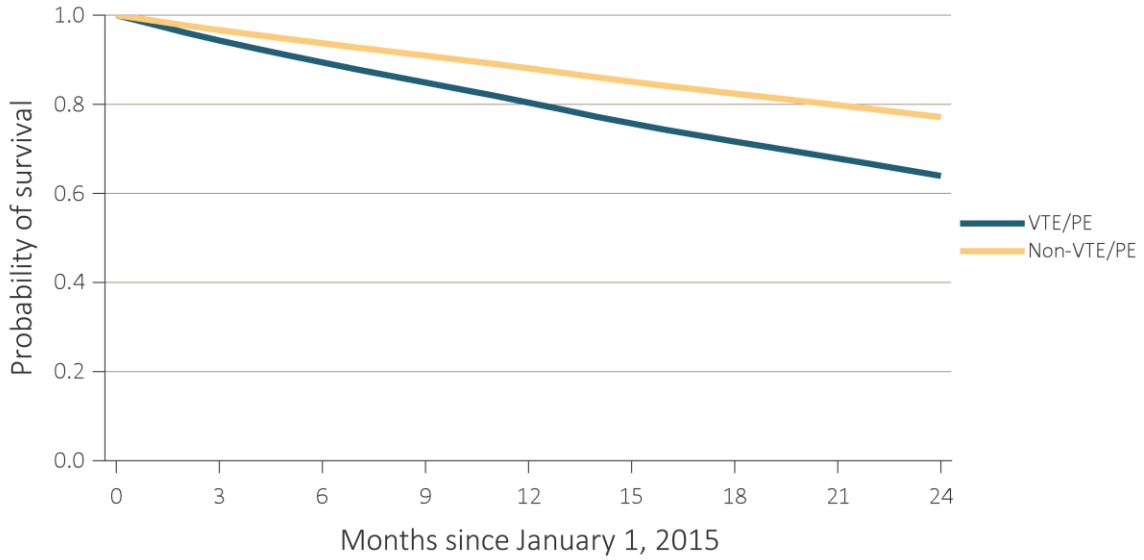
Figure 8.3 continued on next page.

vol 2 Figure 8.3 Probability of survival of adult ESRD patients with or without a cardiovascular disease, adjusted for age and sex, 2015-2016 (continued)

(h) Sudden cardiac arrest and ventricular arrhythmias (SCA/VA)



(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, 2014 to December 31, 2014, and whose first ESRD service date is at least 90 days prior to January 1, 2014, and survived past 2014. Abbreviations: AF, atrial fibrillation; AMI, acute myocardial infarction; CAD, coronary artery disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; ESRD, end-stage renal 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.

vol 2 Table 8.2 Two-year survival of adult ESRD patients with or without a cardiovascular disease, adjusted for age and sex, 2015-2016

	Presence of cardiovascular disease	
Cardiovascular disease	**Survival when present (%)**	**Survival when not present (%)**
CAD	66.2	82.0
AMI	58.5	78.4
HF	66.0	83.4
VHD	63.0	78.1
CVA/TIA	65.7	78.6
PAD	66.3	81.1
AF	62.1	78.9
SCA/VA	55.3	77.2
VTE/PE	63.9	77.1

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, 2014 to December 31, 2014, and whose first ESRD service date is at least 90 days prior to January 1, 2014, and survived past 2014. Abbreviations: AF, atrial fibrillation; AMI, acute myocardial infarction; CAD, coronary artery disease; CVA/TIA, cerebrovascular accident/transient ischemic attack; ESRD, end-stage renal 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.

vol 2 Figure 8.4 Probability of survival of adult ESRD patients with or without a completed cardiovascular procedure, adjusted for age and sex, 2015-2016

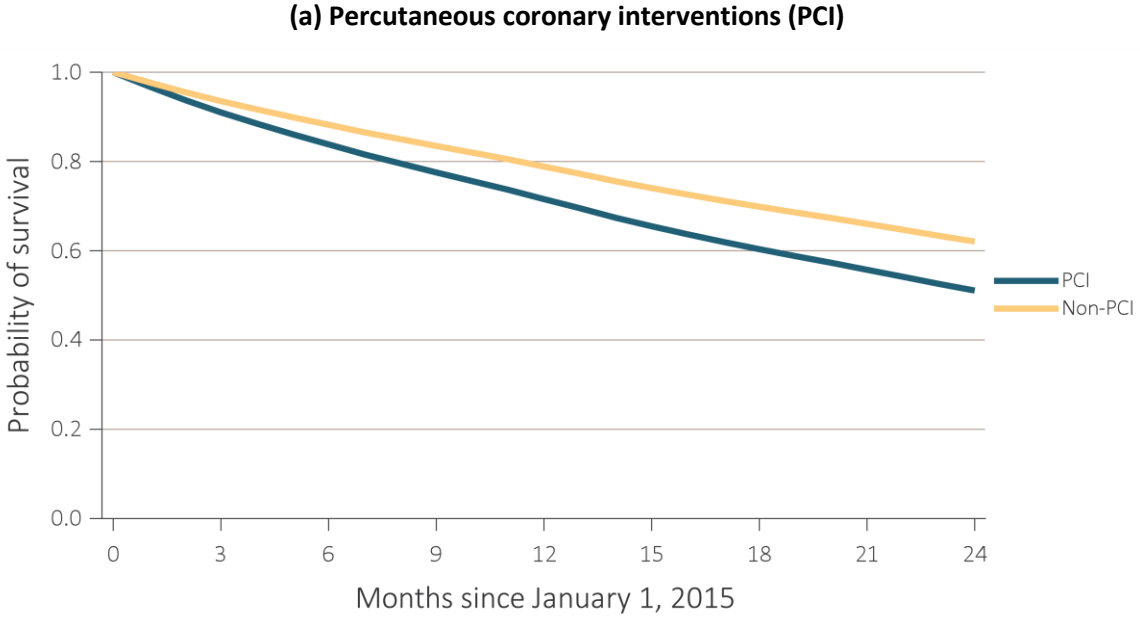
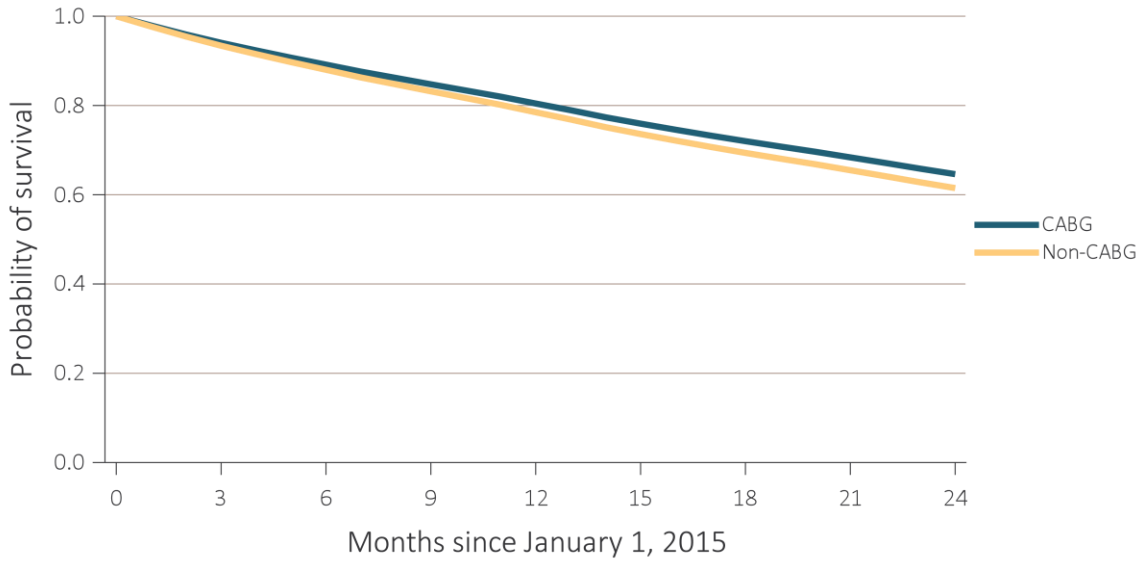


Figure 8.4 continued on next page.

vol 2 Figure 8.4 Probability of survival of adult ESRD patients with or without a completed cardiovascular procedure, adjusted for age and sex, 2015-2016 (continued)

(b) Coronary artery bypass grafting (CABG)



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

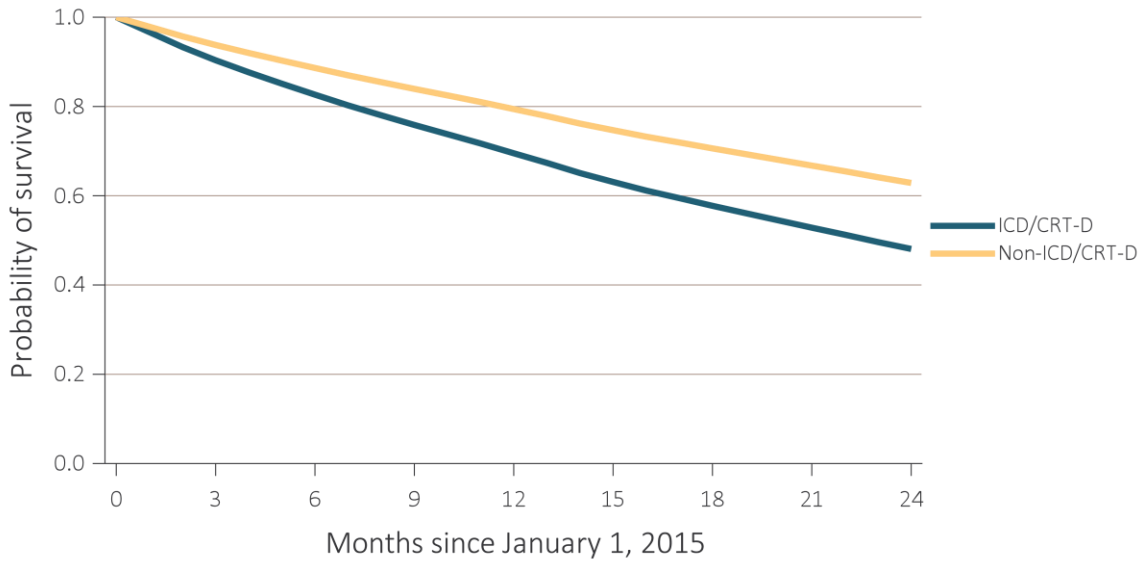
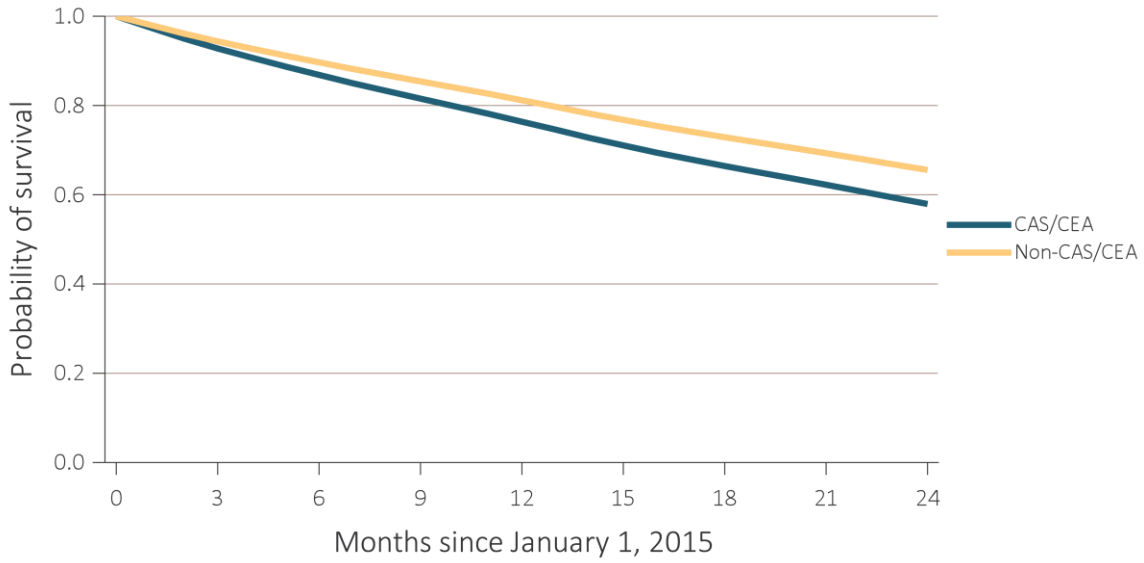


Figure 8.4 continued on next page.

vol 2 Figure 8.4 Probability of survival of adult ESRD patients with or without a completed cardiovascular procedure, adjusted for age and sex, 2015-2016 (continued)

(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, 2014 to December 31, 2014, and whose first ESRD service date is at least 90 days prior to January 1, 2014, and survived past 2014. 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.

vol 2 Table 8.3 Two-year survival of adult ESRD patients with or without a completed cardiovascular procedure, adjusted for age and sex, 2015-2016

	Presence of cardiovascular procedure	
Cardiovascular procedure	**Survival when present (%)**	**Survival when not present (%)**
PCI	51.1	62.1
CABG	64.6	61.5
ICD/CRT-D	48.1	62.9
CAS/CEA	57.9	65.6

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, 2014 to December 31, 2014, and whose first ESRD service date is at least 90 days prior to January 1, 2014, and survived past 2014. Abbreviations: CABG, coronary artery bypass grafting; CAS/CEA, carotid artery stunting and carotid artery endarterectomy; ESRD, end-stage renal disease; 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 Angiotensin converting enzyme inhibitor and angiotensin receptor blocker (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 32.5% of HD and 31.5% of PD patients with AF were treated with warfarin (Table 8.4). 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 9.4% of HD and 9.4% of PD patients. Note that Medicare claims data do not capture all prescription drugs taken by beneficiaries, as drugs purchased without insurance coverage are not included (Colantonio et al., 2016). Patients purchase aspirin most commonly over the counter rather than by prescription, thus we could not 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, 2016

	(a) Cardiovascular comorbidities						
	# Patients	Percentage of patients (%)					
		Beta-blockers	Statins	P2Y12 inhibitors	Warfarin	Direct oral anticoagulants	ACEIs/ ARBs
Any CVD							
Hemodialysis	154,310	60.8	48.6	20.0	13.0	3.6	35.9
Peritoneal dialysis	12,713	61.0	49.1	18.5	11.4	3.1	41.6
Transplant	31,208	59.1	53.9	13.5	13.7	6.7	33.0
Coronary artery disease (CAD)							
Hemodialysis	92,625	64.7	56.6	27.6	13.4	4.0	37.5
Peritoneal dialysis	7,570	63.3	56.7	26.1	11.8	3.3	42.0
Transplant	16,615	63.6	60.4	20.6	12.2	6.5	34.2
Acute myocardial infarction (AMI)							
Hemodialysis	30,572	69.3	61.9	36.5	15.0	4.5	41.1
Peritoneal dialysis	2,559	68.0	61.5	36.3	13.6	3.9	44.9
Transplant	3,976	68.3	63.8	30.1	15.2	8.5	35.2
Heart failure (HF)							
Hemodialysis	88,377	66.2	50.6	21.8	14.2	4.2	39.6
Peritoneal dialysis	6,181	66.2	50.4	20.6	13.5	3.7	44.4
Transplant	10,851	65.9	55.9	14.9	16.5	8.6	34.6
Valvular heart disease (VHD)							
Hemodialysis	30,906	63.9	49.7	22.1	18.0	4.8	37.9
Peritoneal dialysis	2,687	62.4	49.0	19.2	16.8	4.8	41.5
Transplant	5,561	61.0	53.5	14.1	17.7	7.9	33.3
Cerebrovascular accident/transient ischemic attack (CVA/TIA)							
Hemodialysis	35,710	64.2	58.3	28.1	13.8	4.4	38.8
Peritoneal dialysis	2,726	63.2	57.3	26.4	12.9	3.3	44.3
Transplant	5,347	59.2	59.8	20.9	14.3	7.2	34.4
Peripheral artery disease (PAD)							
Hemodialysis	81,792	60.4	51.3	24.5	13.4	3.9	35.3
Peritoneal dialysis	5,501	60.6	52.4	24.3	12.0	3.3	41.4
Transplant	12,394	59.2	55.4	18.2	12.5	5.9	33.9
Atrial fibrillation (AF)							
Hemodialysis	42,853	61.0	49.5	18.3	32.5	9.4	30.5
Peritoneal dialysis	3,098	60.7	50.4	16.7	31.5	9.4	35.2
Transplant	8,222	63.1	51.8	9.5	32.6	17.8	32.0
Cardiac arrest and ventricular arrhythmias (SCA/VA)							
Hemodialysis	10,531	67.7	52.7	25.2	19.5	5.7	38.1
Peritoneal dialysis	1,003	62.5	50.9	22.5	18.4	5.2	40.1
Transplant	1,540	65.3	54.4	16.8	19.9	9.6	33.7
Venous thromboembolism and pulmonary embolism (VTE/PE)							
Hemodialysis	13,522	58.8	45.0	18.2	38.7	9.7	32.8
Peritoneal dialysis	978	59.5	45.3	14.3	40.2	10.1	38.4
Transplant	3,428	56.1	47.2	9.0	42.4	17.0	30.8

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, 2016 (continued)

	(b) Cardiovascular procedures						
	# Patients	Percentage of patients (%)					
		Beta-blockers	Statins	P2Y12 inhibitors	Warfarin	Direct Oral Anticoagulants	ACEIs/ ARBs
Revascularization – percutaneous coronary interventions (PCI)							
Hemodialysis	4,553	75.1	73.1	77.1	12.5	3.8	49.5
Peritoneal dialysis	466	70.4	70.0	71.5	11.4	3.9	45.7
Transplant	542	74.7	72.3	72.1	11.3	6.1	43.5
Revascularization – coronary artery bypass graft (CABG)							
Hemodialysis	1,612	76.4	75.9	39.9	17.6	4.1	47.3
Peritoneal dialysis	257	74.3	73.2	38.1	12.1	3.5	47.9
Transplant	162	69.1	67.3	30.2	15.4	5.6	34.0
Implantable cardioverter defibrillators & cardiac resynchronization therapy with defibrillator (ICD/CRT-D)							
Hemodialysis	848	72.2	55.1	28.9	27.0	8.0	46.8
Peritoneal dialysis	74	66.2	56.8	32.4	14.9	6.8	41.9
Transplant	92	70.7	62.0	27.2	22.8	12.0	41.3
Carotid artery stenting and carotid artery endarterectomy (CAS/CEA)							
Hemodialysis	465	66.0	68.8	51.0	13.8	2.6	42.6
Peritoneal dialysis	58	65.5	60.3	37.9	12.1	0.0	41.4
Transplant	94	69.1	64.9	34.0	18.1	12.8	34.0

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, 2016 to December 31, 2016, and ESRD service date is at least 90 days prior to January 1, 2016. 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; ESRD, end-stage renal 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.

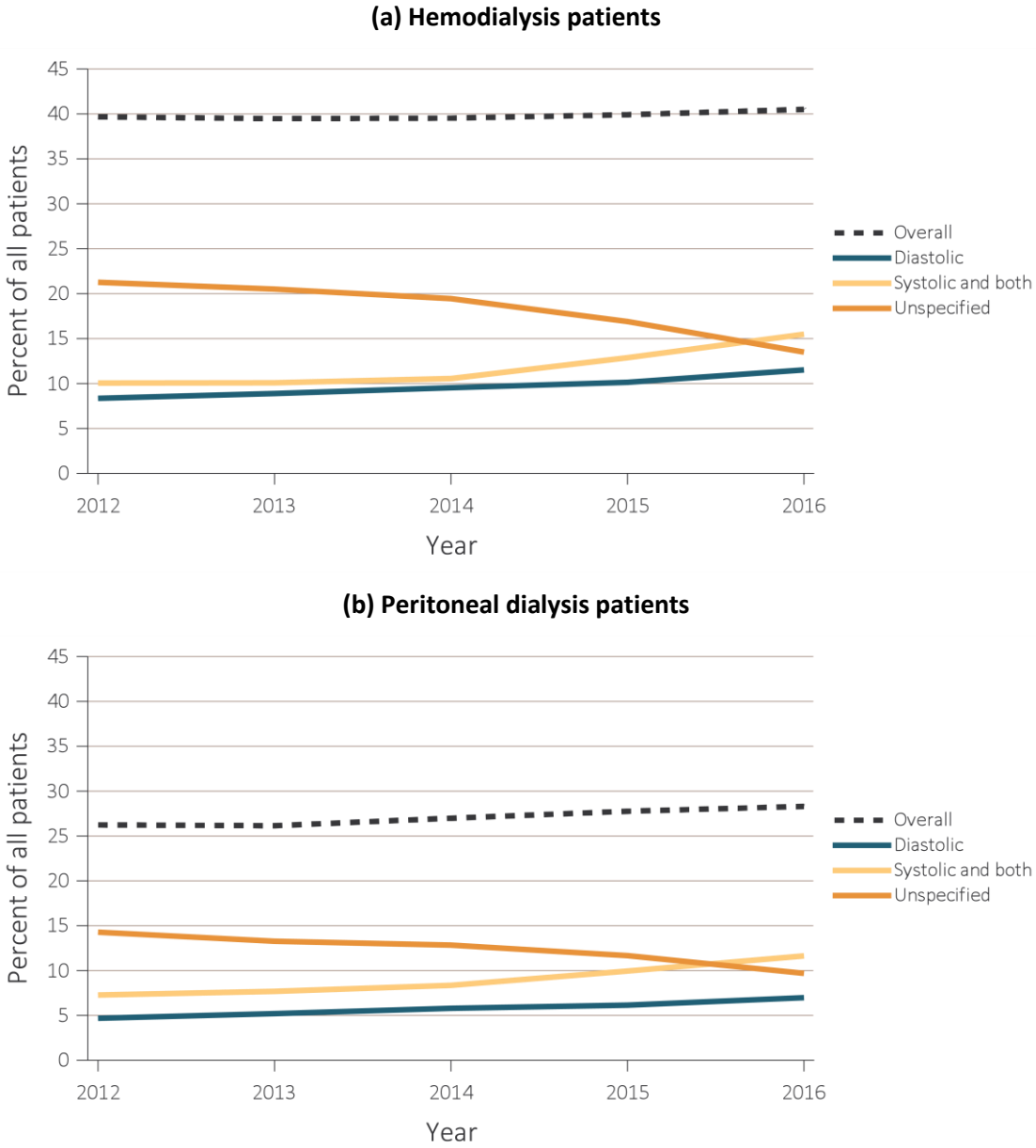
Heart Failure among ESRD Patients

Heart failure (HF) is a highly prevalent CVD among ESRD patients. Common cardiac structural and functional changes that predispose ESRD patients to clinical heart failure include left ventricular hypertrophy associated with left ventricular diastolic dysfunction, left and right ventricular dilation and systolic dysfunction, and aortic and mitral valve disease. In the absence of meaningful renal function, volume status assessment and management are very challenging, given the limitations of the physical exam, lack of objective criteria by which to quantify intra- and extravascular volume, and patients' variable adherence to sodium and fluid restriction recommendations. Moreover, intradialytic hypotension, a complex and multifactorial problem that is more common among hemodialysis patients with HF, may limit ultrafiltration volumes (Reeves and McCausland, 2018). Most patients will experience at least some improvement in HF symptoms with ultrafiltration, but many remain dyspneic even when euvolemic (Chawla et al., 2014).

HF in ESRD patients is stratified in Figure 8.5 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 in 2012, with a trend toward more specific classification into systolic and diastolic heart failure over the ensuing years, such that systolic heart failure was more prevalent than unspecified heart failure in 2016. The relative proportion of patients with systolic HF was slightly higher than diastolic HF throughout 2012-2016 (Figure 8.5). These patterns were 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, 2012-2016



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, 2012 to December 31, 2016, and ESRD service date is at least 90 days prior to January 1, 2012. Abbreviation: ESRD, end-stage renal disease.

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Chapter 9: Healthcare Expenditures for Persons with ESRD

- Between 2015 and 2016, Medicare fee-for-service spending for beneficiaries with end-stage renal disease (ESRD) rose by 4.6%, from $33.8 billion to $35.4 billion, accounting for 7.2% of overall Medicare paid claims, a figure that has remained stable since 2004 (Figure 9.2). This marks the fifth year of modest growth relative to historical trends, and follows the 2011 implementation of the bundled payment system.
- When $79 billion in expenditures for chronic kidney disease (CKD) are added (Volume 1, Chapter 7, https://www.usrds.org/2018/view/v1_07.aspx, Tables 7.1 and 7.3), total Medicare expenditures for both CKD and ESRD are over $114 billion, an increase of 16%.
- In 2016, ESRD spending per person per year (PPPY) increased by 2.5% (Figure 9.4). For the second year in a row, most of the increase in Medicare expenditures for beneficiaries with ESRD was attributable to higher PPPY spending, rather than growth in the number of covered lives.
- For hemodialysis (HD) care, both total and PPPY spending increased between 2015 ($26.8 billion and $88,782) and 2016 ($28.0 billion and $90,971) (Figures 9.7 and 9.8).
- During this period, total peritoneal dialysis (PD) spending grew by 5.7%, as the share of patients receiving PD continued to rise. However, while PPPY spending on PD rose 1.4% from 2015 to 2016, PD remained less costly on a per-patient basis than HD (Figures 9.7 and 9.8).
- Total and PPPY kidney transplant spending have increased by 4.6% and 2.1%. Total spending for transplant patients increased from $3.3 billion to $3.4 billion, and per capita spending increased from $34,080 to $34,780 (Figures 9.7 and 9.8).
- Total inpatient spending for patients with ESRD grew rapidly from 2004 until 2009, followed by slower growth from 2009 until 2011, remained quite stable from 2011 to 2015, but then increased by 5.3% in 2016 (Figure 9.5).

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 2016, this patient group grew to 511,270. 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. Research linked the implementation of 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 appear to 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, while changes in practices implied cost reductions in excess of 2%. 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, including data up to 2016, in both total Medicare spending and spending by type of service.[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 costs for ESRD beneficiaries covered by original Medicare (fee-for-service) for their Medicare Parts A, B, and D benefits. ESRD beneficiaries who are covered by the Medicare Advantage program managed care plans are included separately 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 made 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, their private insurance will be considered the primary payer of ESRD services. Medicare acts as the secondary payer and may reimburse some services not covered by the private insurance carrier. At month 31 the roles are reversed, and Medicare becomes the primary payer with the private insurance designated the secondary payer. Medicare becomes primary at any time if the person loses private coverage.

Additionally, Medicare eligibility based solely on ESRD ends for those ESRD patients who receive a kidney transplant or discontinue dialysis. Medicare coverage ends 12 months after the last dialysis treatment and 36 months after a successful transplant. However, if a transplant recipient also qualifies for disability or is over the age of 65, then Medicare entitlement will continue. If a transplant fails and the recipient returns to dialysis, Medicare eligibility is reinstated.

[1] The reader may find information on Medicare Health Maintenance Organizations (HMO; managed care), and private insurer spending through 2011 in the 2013 Annual Data Report (USRDS, 2013).

In 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.

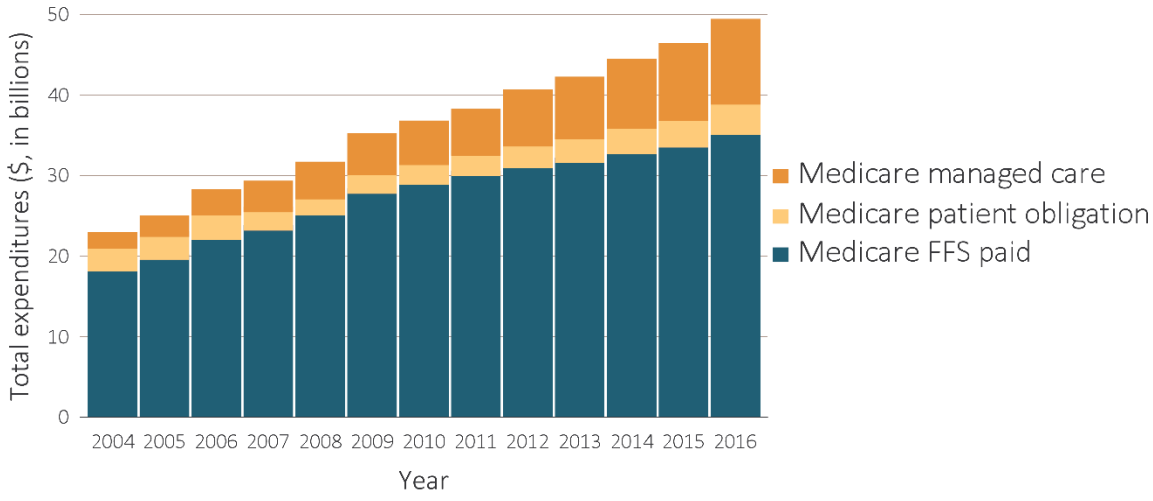
A more complete picture of total ESRD-related spending would take into account more than just expenditures by the Medicare program. It would include expenses such as those incurred by private insurance carriers when Medicare is the secondary payer, costs during the waiting period for initial Medicare 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 beneficiaries' deductible, and their co-insurance amounts for ESRD services. In 2016, the Part A and Part B deductibles were $1,288 and $166.00, respectively, and 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.

For an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter, see the section on *Chapter 9* within the *ESRD Analytical Methods* 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 2004-2016. This represents about three quarters of all spending for the care of U.S. ESRD patients (USRDS, 2014). Medicare fee-for-service (FFS) ESRD spending rose by 4.6% from 2015 to 2016. 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 9.6% of the total fee-for-service Medicare Allowable Payments in 2016. Medicare payments to managed care plans under the Medicare Advantage coverage option also increased from 2004 to 2016.

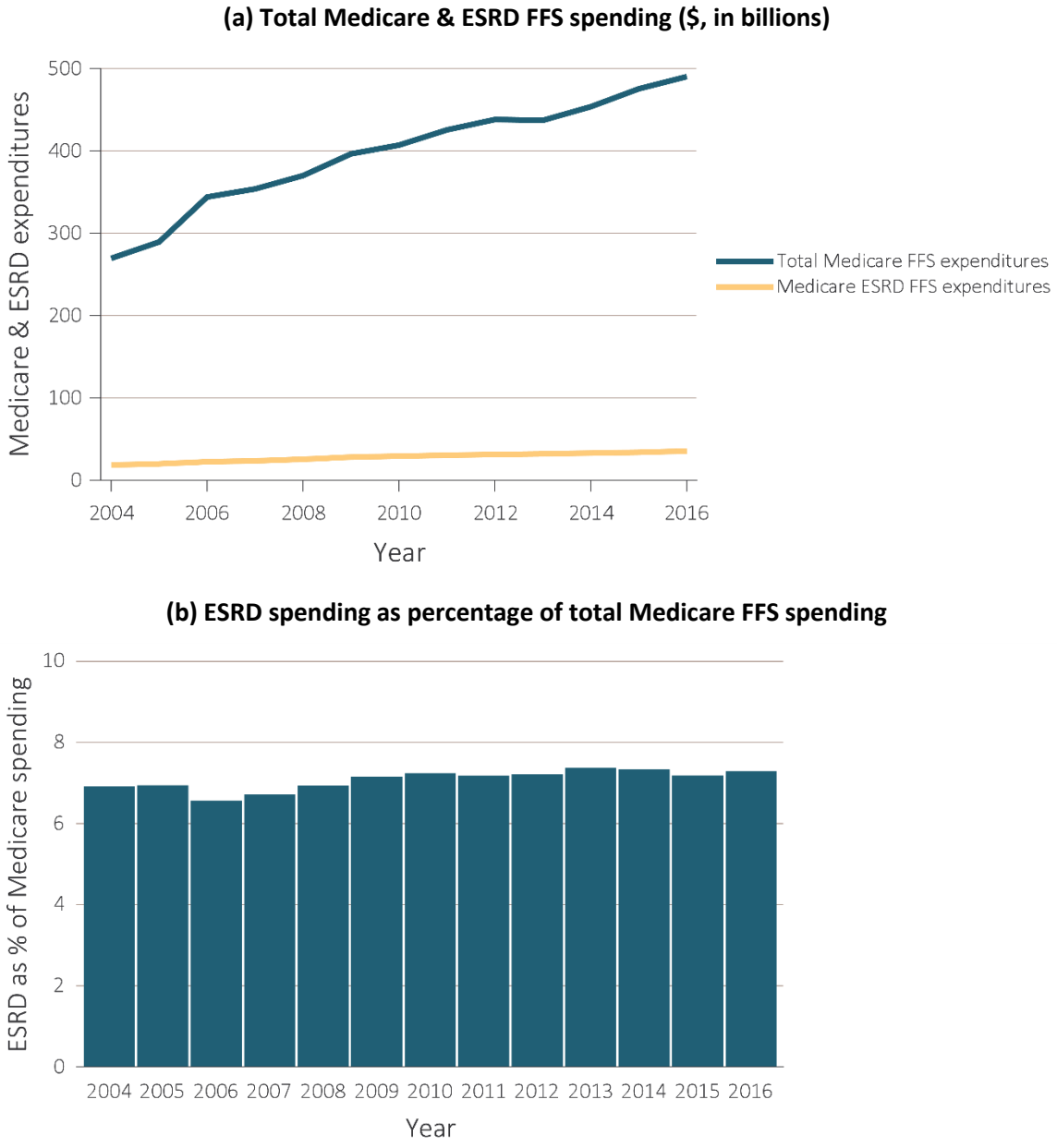
vol 2 Figure 9.1 Trends in fee-for-service ESRD expenditures, 2004-2016



Data Source: USRDS ESRD Database; Reference Table K.1. Abbreviations: ESRD, end-stage renal disease; FFS, fee-for-service.

As illustrated in Figure 9.2, total Medicare fee-for-service spending in the general Medicare population increased by 3.1% in 2016 to $490.1 billion. The spending for ESRD patients of $35.4 billion accounted for 7.2% of the overall Medicare paid claims in the fee-for-service system, a share that has remained approximately constant during the current decade.

vol 2 Figure 9.2 Trends in (a) total Medicare & ESRD fee-for-service spending ($, in billions), and (b) ESRD spending as percentage of Medicare fee-for-service spending, 2004-2016

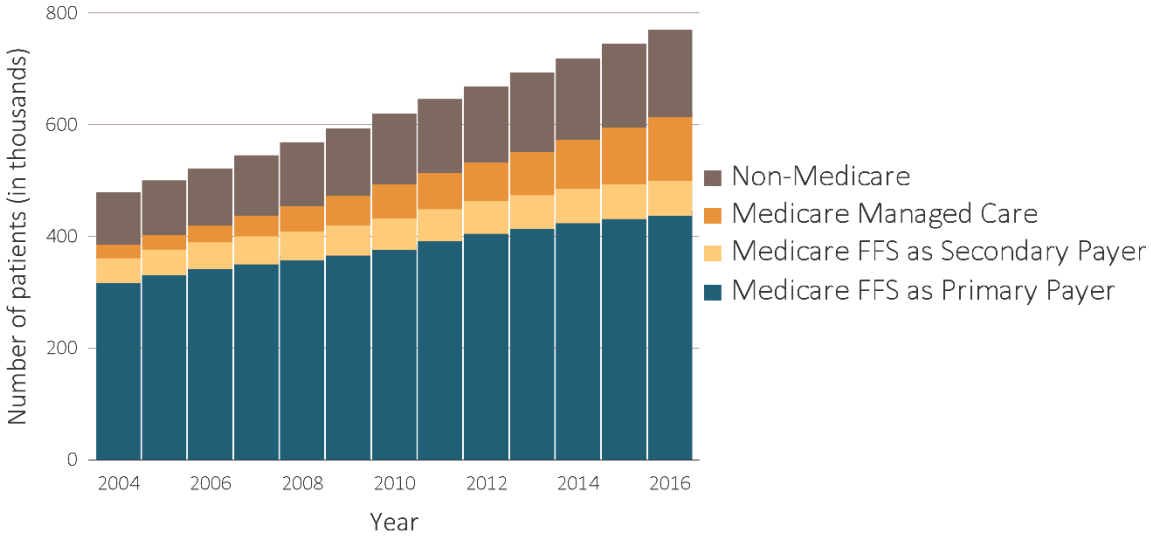


Data Source: Total ESRD spending obtained from USRDS ESRD Database; Reference Table K.1. Total Medicare expenditures obtained from Trustees Report, Table II.B1 https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/TrusteesReports.html*. Abbreviations: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

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 fee-for-service as primary payer (MPP), Medicare fee-for-service as secondary payer (MSP), 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 1.2% from 2015 (435,873) to 2016 (441,162). The MSP ESRD population increased by 2.8% from 2015 (61,610) to 2016 (63,340), while the Medicare managed care and non-Medicare ESRD population increased by 12.4% and 3.8%, to 114,316 and 146,354, respectively.

vol 2 Figure 9.3 Trends in numbers of point prevalent ESRD patients, 2004-2016



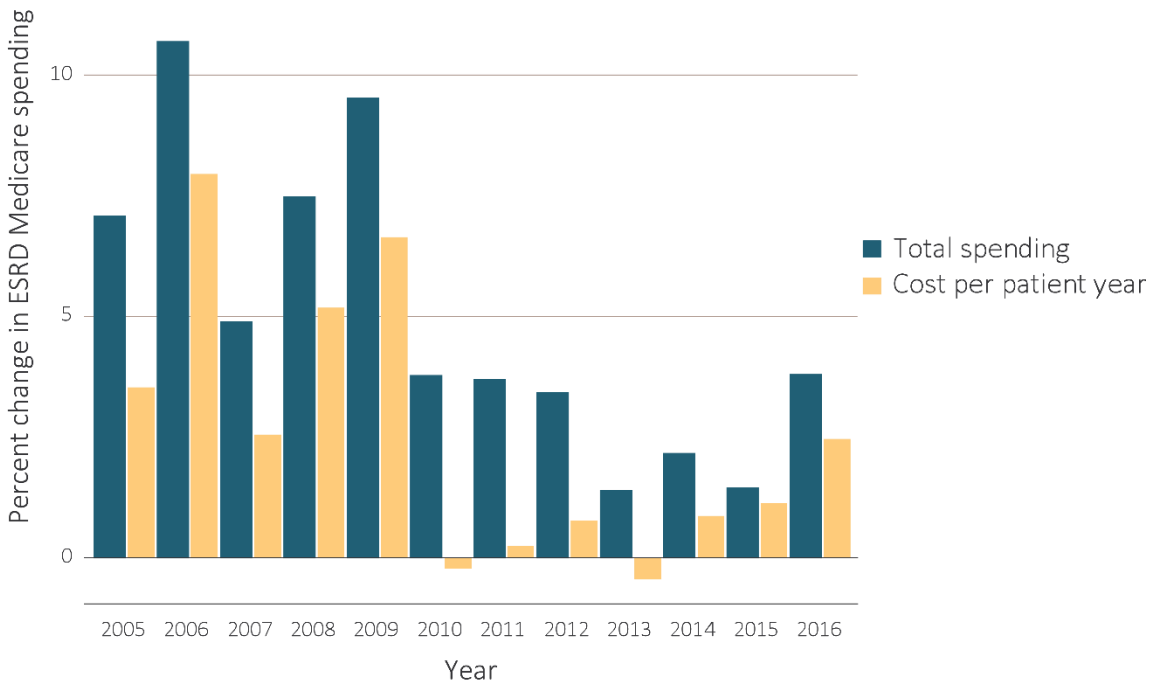
Data Source: USRDS ESRD Database. December 31 point prevalent ESRD patients. Abbreviations: ESRD, end-stage renal disease; FFS, fee-for-service.

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 seventh consecutive year, the annual increase in total Medicare ESRD spending for beneficiaries with primary payer status was less than 5%. In 2016, total Medicare paid claims for ESRD services and supplies increased by 3.7% to $32.2 billion (see Figure 9.4; for total and specific values see *Reference Table K.4*).

In 2016, ESRD PPPY spending increased by 2.5%. For the second year in a row, most of the increase in Medicare expenditures for beneficiaries with ESRD was attributable to higher PPPY spending rather than growth in the number of covered lives. This reverses the trend from 2010-2103 when increases in covered lives were the primary cause of spending growth. In 2014, changes in PPPY spending and covered lives contributed about equally to total spending growth.

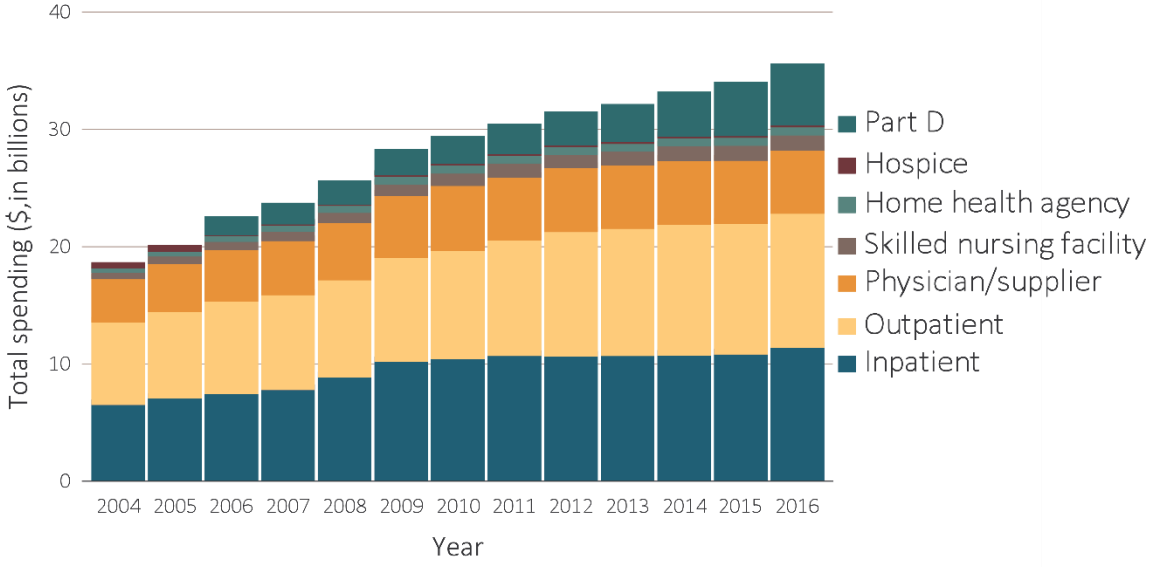
vol 2 Figure 9.4 Annual percent change in Medicare ESRD spending, 2004-2016



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. Between 2015 and 2016, spending for Part D claims grew faster (15.7%) than spending for any other claim type. 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 6%. The smallest share of Medicare spending for ESRD patients was for hospice care, which increased by 5.8% in 2016.

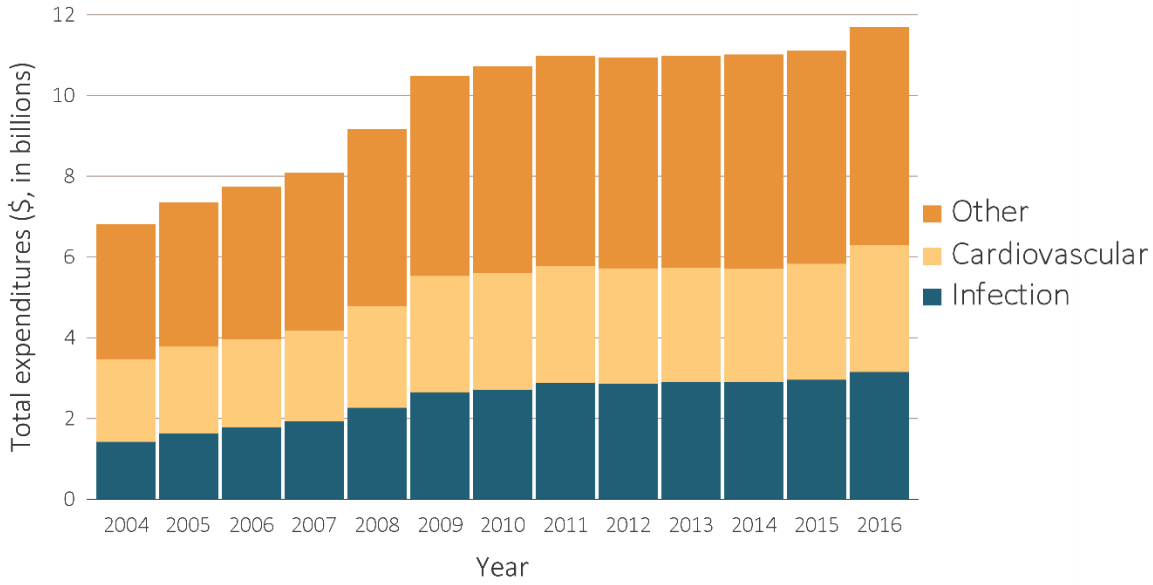
vol 2 Figure 9.5 Trends in total Medicare fee-for-service spending for ESRD, by type of service, 2004-2016



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

Of 2016 spending on inpatient hospitalization for those with ESRD, 27.7% resulted from admissions to treat infections and 27.1% to treat cardiovascular conditions (Figure 9.6). Total spending on hospitalizations has remained quite stable between 2009 and 2015 as decreasing hospitalization rates offset increasing costs of each hospitalization (see *Volume 2, Chapter 4, Hospitalization*). However, hospitalization spending rose 5.3% in 2016, reflecting 2.8% increase in hospitalizations for 2016 as compared to 2015 and 2.4% increase in spending per hospitalization.

vol 2 Figure 9.6 Total Medicare fee-for-service inpatient spending by cause of hospitalization, 2004-2016



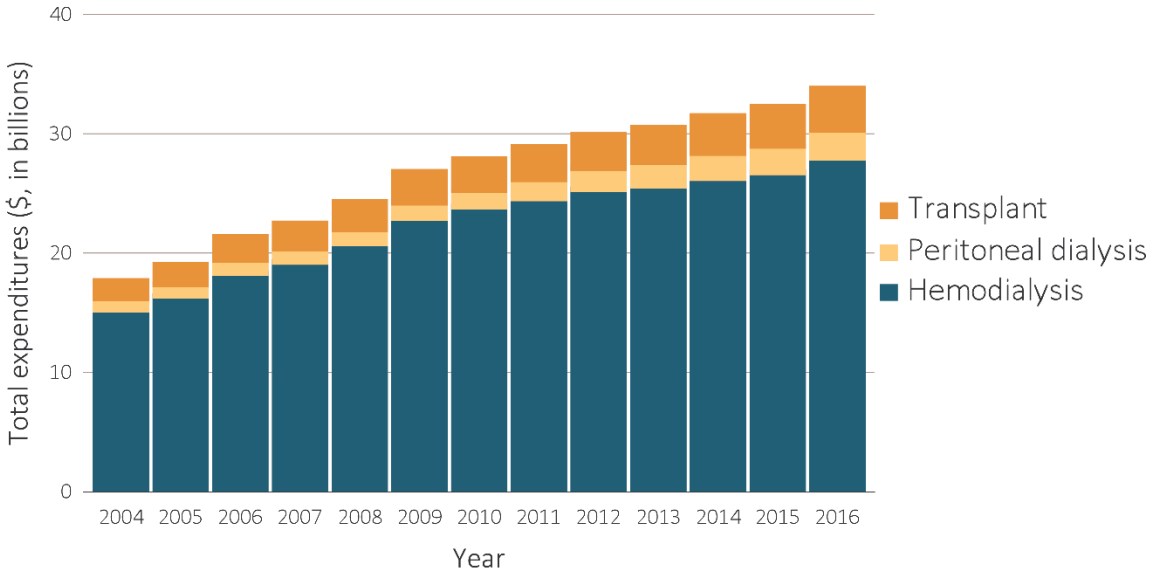
Data Source: USRDS ESRD Database. Total Medicare costs from claims data. Unknown hospitalization cost (<0.01%) was combined with 'Other'. Abbreviation: ESRD, end-stage renal disease.

ESRD Spending by Modality

For patients receiving HD, both total and PPPY fee-for-service spending increased by 4.6% and 2.5%, respectively, between 2015 and 2016 (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.

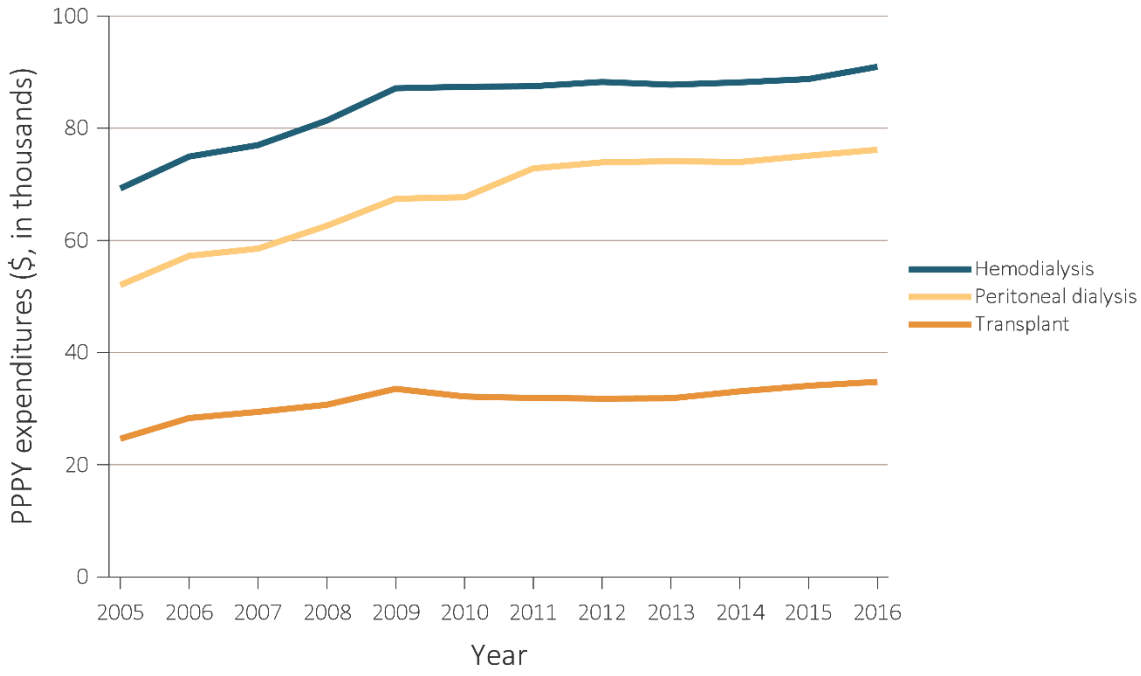
Between 2015 and 2016, total spending on PD increased by 5.7%, as the share of patients receiving PD continued to rise. However, while growth on PD spending on a PPPY basis also increased slightly between 2015 and 2016 (1.4%), it remained less costly on a per-patient basis in 2016 ($76,177) than HD ($90,971). Finally, transplant spending in 2016 increased from 2015 levels by 4.6% in total and 2.1% in PPPY expenditures. In 2016, the PPPY cost for transplant patients, $34,780, remained far lower than spending for either dialysis modality.

vol 2 Figure 9.7 Total Medicare ESRD expenditures, by modality, 2004-2016



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, 2004-2016



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. Abbreviations: ESRD, end-stage renal disease; PPPY, per person per year.

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Notes

Chapter 10: Prescription Drug Coverage in Patients with ESRD

- In this 2018 Annual Data Report (ADR), we introduce new chapter features:
    - Because of the continuing prescription opioid epidemic, this year we retain the section of analgesic use and update the map of non-steroidal anti-inflammatory agents (NSAIDs) and opioid use in the United States using 2016 data.
    - Because of increasing use of high-cost antivirals nationally, this year we specifically investigate the spending and utilization rates of antivirals, including prescription antiretrovirals, nucleosides and nucleotides, and protease inhibitors.
- Among beneficiaries with Medicare Part D enrollment, a higher proportion of those treated with hemodialysis (HD; 65.5%), peritoneal dialysis (PD; 52.3%), and kidney transplant (50.3%) received the Low-income Subsidy (LIS) than did the general Medicare population (30.2%; Figure 10.1).
- In 2016, per patient per year (PPPY) Medicare Part D spending on prescriptions for end-stage renal disease (ESRD) patients with stand-alone Part D plans was 4.1 times higher than among the general Medicare population ($13,310 vs. $3,559; Figure 10.5.a).
- Of patients enrolled in stand-alone Part D plans, dialysis patients had a higher PPPY spending on prescriptions than did transplant patients (HD, $14,922; PD, $13,882; transplant, $8,693; Figure 10.5.a).
- In both the general Medicare and ESRD populations, PPPY Part D spending was 2.8-3.6 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. LIS beneficiaries' out-of-pocket costs represented only 0.6-1.2% of total Part D expenditures, compared to 21.6-26.9% in the non-LIS populations (Figure 10.5.b).
- In 2016, ESRD patients were most frequently prescribed ion-removing agents, β-adrenergic blocking agents (beta blockers), antibacterials, analgesics, antipyretics, and lipid-lowering agents (Table 10.6).
- The highest costing medications for ESRD patients were ion-removing agents, cinacalcet, antidiabetic agents, antivirals, and immunosuppressive agents (Table 10.7).
- In the United States, the overall proportions of ESRD patients using prescription NSAIDs and opioids were 8.3% and 49.0%, respectively (Figures 10.6 and 10.7).
- In 2016, approximately 5.8%, 5.6%, and 24.1% of HD, PD, and transplant patients had at least one filled prescription antiviral; PPPY Medicare Part D spending among these users was $918, $844, and $2,104, respectively (Figures 10.9 and 10.10).

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.

Starting in 2017, we annually select a different drug class for a more detailed investigation of medication use patterns. In the 2017 ADR, we reported analgesics used by ESRD patients. Because of the continuing opioid epidemic, we continue that analysis this year, but we have also added a section on prescription antivirals, a category with high, and growing costs.

A parallel examination of prescription drug use and associated costs in patients with CKD can be found in Volume 1, Chapter 8: *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 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 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% ESRD population, using the period prevalent, as-treated actuarial model (Model 1, described in ESRD Reference Table K).

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. Patient obligations (out-of-pocket costs) were defined as the sum of the deductible and co-payment.

Medicare Part D Coverage Plans

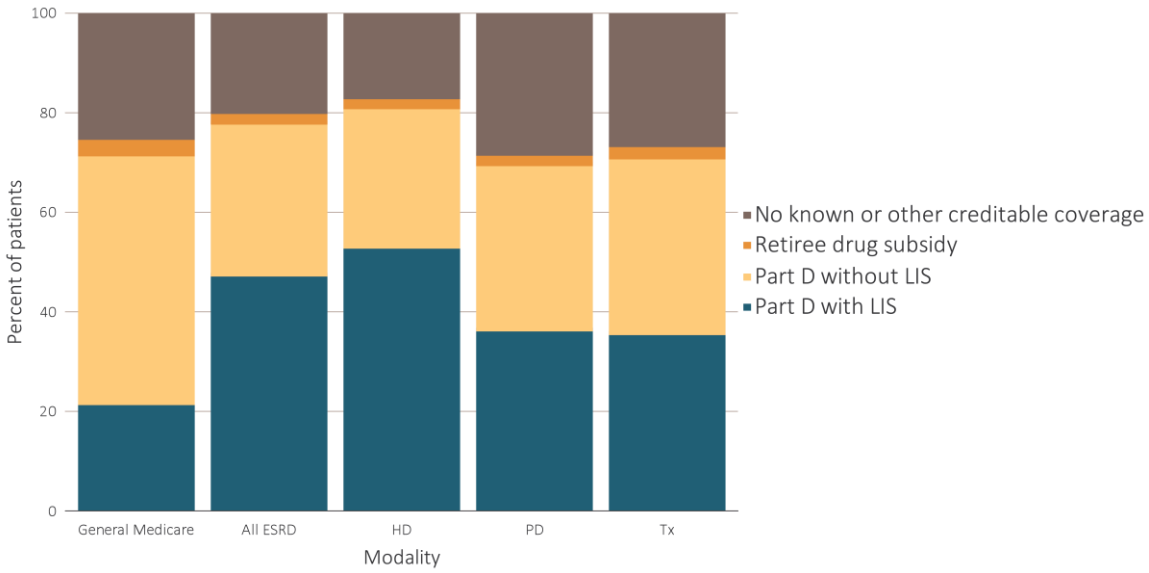
After more than a decade of availability, the Medicare Part D prescription drug benefit has become an integral component of Medicare coverage. Before this program began on January 1, 2006, some Medicare beneficiaries were able to obtain drug coverage through various private insurance plans, state Medicaid 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 2016, 71.6% 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 78.0% participation. The differences in benefit use between the ESRD and general Medicare cohorts extended to other areas. About 60.9% of Medicare beneficiaries with ESRD who enrolled in Part D received the LIS benefit, compared to only 30.2% of the general Medicare Part D population (Figure 10.1).

Other factors varied by renal replacement modality—81.1% of HD, 69.7% of PD, and 71.0% of kidney transplant patients enrolled in Part D (Figure 10.1). By modality, 65.5%, 52.3%, and 50.3% of enrolled HD, PD, and transplant patients qualified for the LIS.

vol 2 Figure 10.1 Sources of prescription drug coverage in Medicare ESRD enrollees, by population, 2016



Data source: 2016 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2016. 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 2016 (Table 10.1). Total enrollment was higher in the dialysis population than in the general Medicare population, but the growth between 2011 and 2016 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

Year	General Medicare (%)	All ESRD (%)	Hemodialysis (%)	Peritoneal dialysis (%)	Transplant (%)
2011	60.1	69.3	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	68.6	68.2
2015	70.4	77.3	80.6	69.2	69.7
2016	71.6	78.0	81.1	69.7	71.0

Data source: 2016 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2016. 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 Centers for Medicare & Medicaid Services (CMS) provides participating 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 2011 and 2016. In 2016, for example, beneficiaries shared costs with the PDP through co-insurance or co-payments until the combined total during the initial coverage period reached $3,310. 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 2016, beneficiaries received a 50% discount on brand name drugs from manufacturers plus 5% coverage from their Part D plans; plans also paid 42% of generic drug costs in the gap (Q1 Medicare, 2016). Beneficiaries who reached annual out-of-pocket drug costs of $4,850 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, 2016).

vol 2 Table 10.2 Medicare Part D parameters for defined standard benefit, 2011 & 2016

	2011	2016
Deductible After the deductible is met, the beneficiary pays 25% of total prescription costs up to the initial coverage limit.	$310	$360
Initial coverage limit The coverage gap ("donut hole") begins at this point. The beneficiary pays 100% of their prescription costs up to the out-of-pocket threshold	$2,840	$3,310
Out-of-pocket threshold The total out-of-pocket costs including the "donut hole"	$4,550	$4,850
Total covered Part D prescription out-of-pocket spending Catastrophic coverage begins after this point (including the coverage gap) *	$6,448	$7,063
Generic/preferred multi-source drug	$2.50	$2.95
Other drugs	$6.30	$7.40
2016 Example:		
$360 (deductible)$320 (deductible)	$310	$360
+(($3,310-$360)*25%)(initial coverage) +(($2,960-$320)*25%)(initial coverage)	$633	$738
+(($7,063-$3,310)*100%)(coverage gap)+(($6,680-$2,960)*100%)(coverage gap)	$3,608	$3,753
Total (maximum out-of-pocket costs prior to catastrophic coverage, excluding plan premium)	$4,550	$4,850

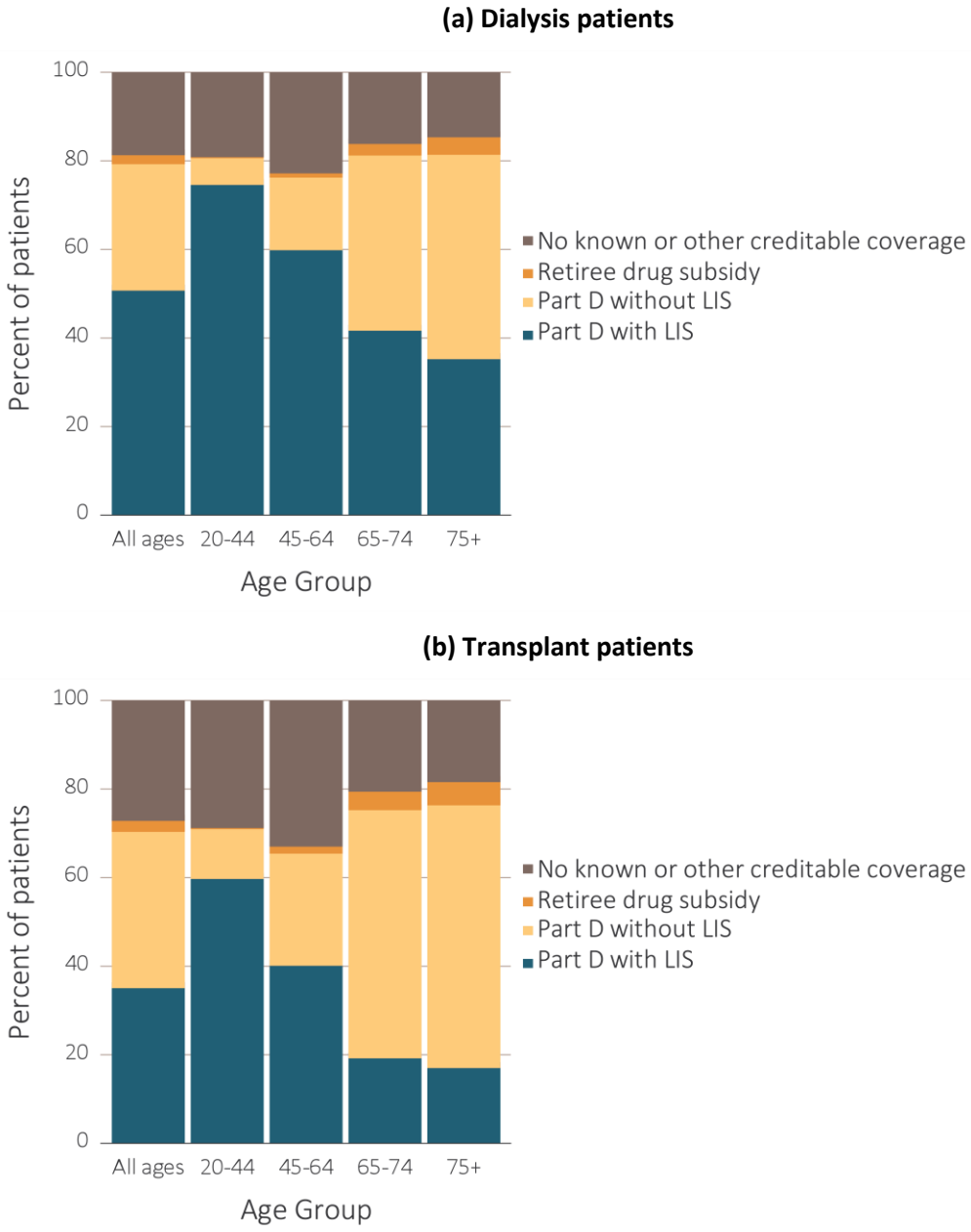
Data Source: Table adapted from http://www.q1medicare.com/PartD-The-2016-Medicare-Part-D-Outlook.php. **The catastrophic coverage amount is the greater of 5% of medication cost or the values shown in the chart above. In 2016, beneficiaries were charged $2.95 for those generic or preferred multisource drugs with a retail price less than $59 and 5% for those with a retail price over $59. For brand name drugs, beneficiaries paid $7.40 for those drugs with a retail price less than $148 and 5% for those with a retail price over $148. In 2016, beneficiaries received a 50% discount on brand name drugs from manufacturers plus 5% coverage from their Part D plans; plans also paid 42% of generic drug costs in the gap. Abbreviation: Part D, Medicare prescription drug coverage benefit.*

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 (ESAs), 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). Receipt of the LIS decreased substantially with age in both populations. In each age category, transplant patients were markedly less likely than those on dialysis to receive the LIS benefit.

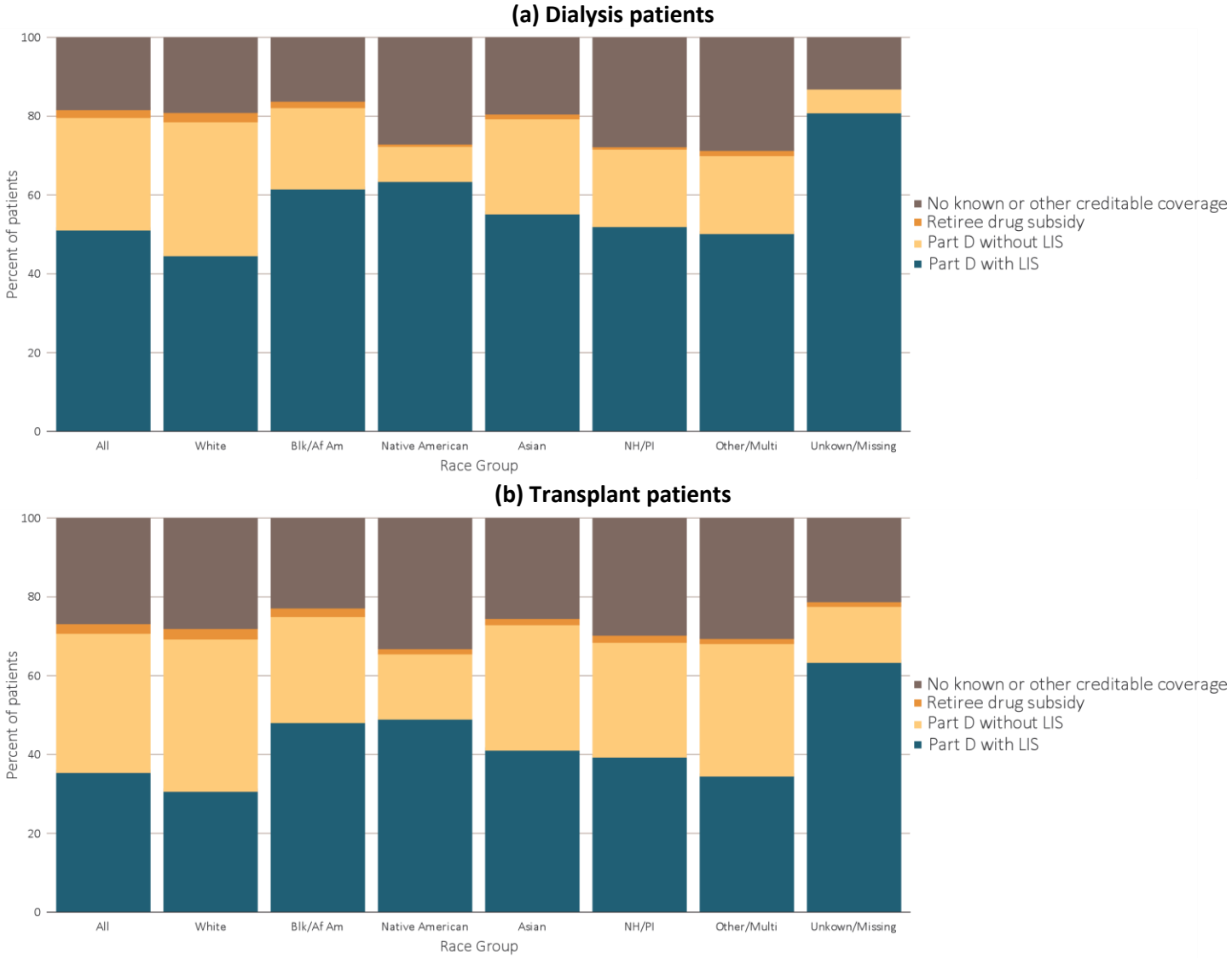
vol 2 Figure 10.2 Sources of prescription drug coverage in Medicare ESRD enrollees, by age & modality, 2016



Data source: 2016 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2016. 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. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage; LIS, Low-income Subsidy.

Overall, 79.9% 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 (78.9%), Native American/Alaska Native (72.6%), or Asian (79.6%). About 71.0% of transplant patients enrolled in Part D. By race, 69.6% of White, 75.3% of Black, 65.8% of Native American/Alaska Native, and 73.2% of Asian transplant patients enrolled. A larger share of dialysis patients with Part D coverage had the LIS (64.3%), compared to 50.3% of transplant patients (Figure 10.3).

vol 2 Figure 10.3 Sources of prescription drug coverage in Medicare ESRD enrollees, by race/ethnicity & modality, 2016



Data source: 2016 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2016. 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, 2016

	General Medicare (%)	All ESRD (%)	Hemodialysis (%)	Peritoneal dialysis (%)	Transplant (%)
All	30.2	60.9	65.5	52.3	50.3
White					
All ages	23.6	53.4	58.2	45.6	44.5
20-44	88.5	88.3	91.7	88.3	82.5
45-64	51.7	70.8	76.6	64.1	57.5
65-74	14.4	39.0	48.1	23.4	20.9
75+	17.8	33.3	37.0	16.6	17.8
Black/African American					
All ages	56.3	73.3	75.4	68.9	64.3
20-44	93.0	92.7	94.2	91.2	88.1
45-64	74.9	80.9	83.4	74.1	70.5
65-74	41.2	58.2	62.5	40.4	39.2
75+	47.2	57.6	59.7	36.0	37.5
Native American/Alaska Native					
All ages	67.1	85.3	88.1	82.4	74.8
20-44	93.8	95.2	97.1	95.8	86.1
45-64	81.3	90.0	91.4	89.3	84.8
65-74	54.3	75.0	81.0	46.5	56.2
75+	55.6	74.7	78.8	64.3	56.5
Asian					
All ages	61.8	66.6	71.9	54.1	56.5
20-44	90.7	87.5	91.0	85.7	83.2
45-64	65.1	72.4	77.6	59.2	65.0
65-74	52.5	56.9	65.4	39.4	42.8
75+	69.9	64.7	69.1	47.5	41.8
Hawaiian Native/Pacific Islander					
All ages	NA	70.6	73.9	60.5	57.6
20-44	NA	90.2	91.5	89.7	85.6
45-64	NA	78.5	82.0	63.6	63.3
65-74	NA	57.4	62.0	39.7	44.7
75+	NA	60.5	63.6	53.2	36.6
Other/multiple race					
All ages	29.9	61.5	72.5	65.4	50.9
20-44	86.9	85.2	93.4	94.1	76.8
45-64	47.2	68.4	82.9	78.6	53.3
65-74	20.9	47.5	60.8	31.6	38.4
75+	32.2	45.9	53.5	22.2	36.4
Unknown/missing					
All ages	28.9	86.9	94.0	81.5	81.7
20-44	91.6	94.8	97.7	100.0	96.7
45-64	28.9	87.7	92.8	72.7	80.3
65-74	18.9	71.5	89.5	50.0	66.1
75+	83.1	93.8	100.0	NA	100.0

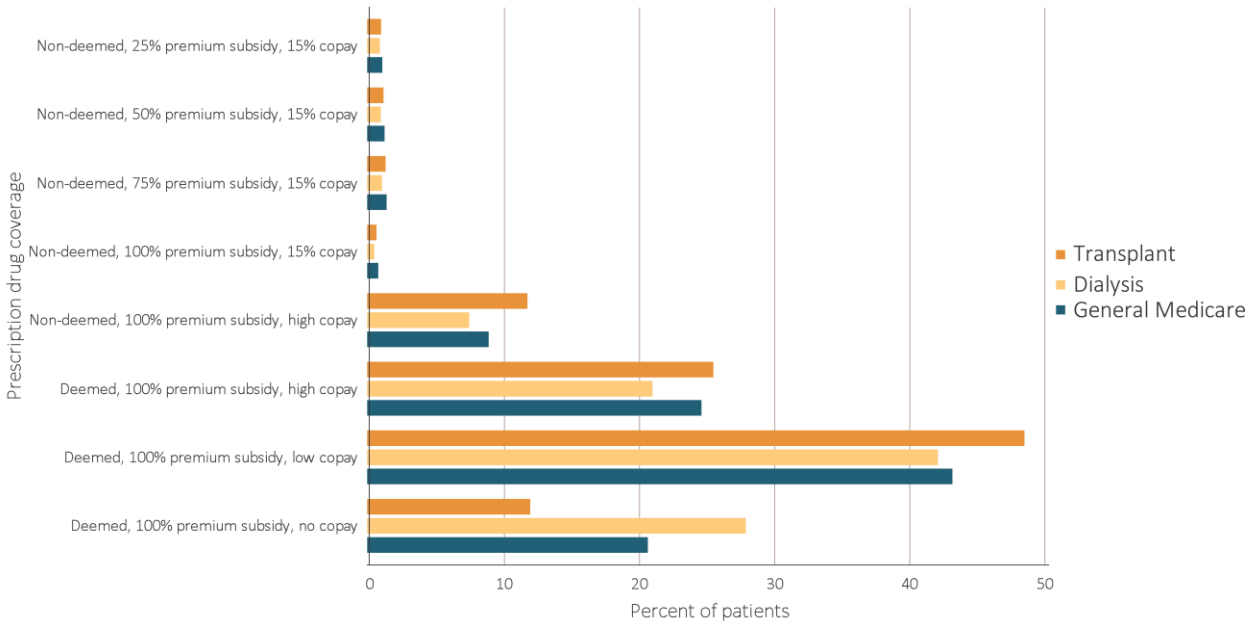
Data source: 2016 Medicare data, point prevalent Medicare enrollees alive on January 1, 2016. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage. ESRD patients aged under 20 were not presented.

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 Social 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 2016, 90.4% of dialysis patients with Part D LIS coverage were deemed LIS beneficiaries, compared to 85.4% of transplant, and 87.9% 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, 2016



Data source: 2016 Medicare data, point prevalent Medicare enrollees alive on January 1, 2016. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage.

Insurance Spending for Prescriptions

In recent years, Medicare Part D spending for beneficiaries with ESRD increased by 1.1 times from $1.8 billion in 2011 to $3.7 billion in 2016 (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 USRDS ESRD *Reference Table K.1*. Medicare Part D spending in 2016 was 2.1, 2.5, and 1.9 times as great as in 2011 for HD, PD, and kidney transplant patients. These rates of increase far outpaced the 50% spending growth that occurred in

the general Medicare population. The increase of overall Medicare Part D spending for ESRD patients arose from the increase in the prevalence of ESRD and from the increase in Medicare part D spending per capita. However, the per capita increases were much greater for ESRD than for Medicare in general. The $3,122 per capita for general Medicare was 16% greater than the $2,691 per capita in 2011. However, for ESRD patients, the per capita increases ranged from 51% for transplant patients ($5,348 and $8,089) to 78% for hemodialysis patients ($8,080and $14,383). The reasons for this disparity in drug cost growth are unexplained.

vol 2 Table 10.4 Estimated Medicare Part D spending for enrollees, 2011-2016

	General Medicare		All ESRD		Hemodialysis		Peritoneal Dialysis		Transplant	
Year	Medicare spending (in billions)	Medicare spending (PPPY)	Medicare spending (in billions)	Medicare spending (PPPY)	Medicare spending (in billions)	Medicare spending (PPPY)	Medicare spending (in billions)	Medicare spending (PPPY)	Medicare spending (in billions)	Medicare spending (PPPY)
2011	$46.0	$2,691	$1.8	$7,417	$1.4	$8,080	$0.1	$8,006	$0.3	$5,348
2012	$40.1	$2,594	$2.0	$7,873	$1.6	$8,647	$0.1	$8,433	$0.3	$5,522
2013	$52.1	$2,586	$2.3	$8,316	$1.8	$9,155	$0.1	$8,665	$0.3	$5,881
2014	$58.1	$2,831	$2.7	$9,601	$2.1	$10,464	$0.2	$9,669	$0.4	$7,274
2015	$63.4	$3,027	$3.2	$11,387	$2.5	$12,583	$0.2	$11,826	$0.5	$8,057
2016	$68.8	$3,122	$3.7	$12,740	$2.9	$14,383	$0.2	$13,082	$0.5	$8,089

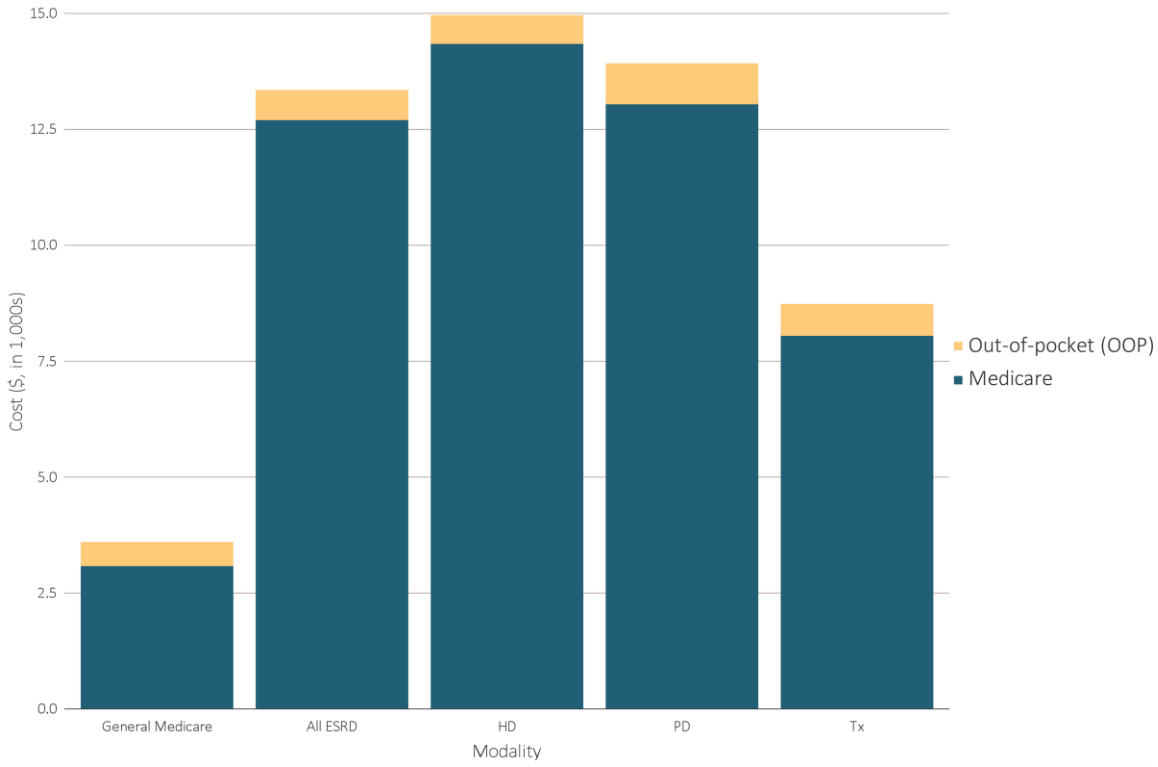
Data source: 2011-2016 Medicare data, period prevalent Medicare enrollees alive on January 1, excluding those in Medicare Advantage Part D plans and Medicare secondary payer, using as-treated actuarial model (see ESRD Methods chapter for analytical methods). Part D spending represents the sum of the Medicare covered amount and the Low-income Subsidy amount. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage; PPPY, per person per year.

Per patient per year Medicare Part D spending was 4.1 times greater for beneficiaries with ESRD than for general beneficiaries in the Medicare population. As a proportion of total prescription spending, however, out-of-pocket costs were lower for beneficiaries with ESRD than all general beneficiaries (4.3% vs. 12.3%). However, since total prescription spending was so much higher for beneficiaries with ESRD, out-of-pocket spending was still higher for beneficiaries with ESRD than the general population. By modality, total prescription spending was higher for dialysis patients than transplant patients in those covered by stand-alone Part D plans (HD,$14,922; PD, $13,882; transplant, $8,693; Figure 10.5.a).

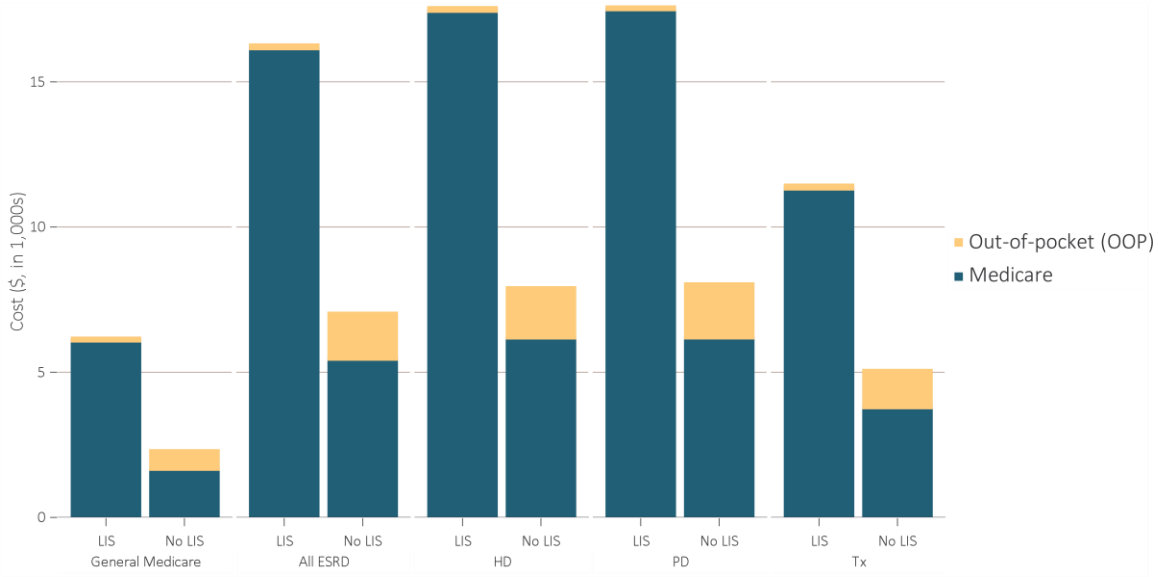
Across general Medicare and ESRD populations, PPPY Medicare Part D spending was 2.8-3.6 times greater for beneficiaries with LIS benefits than for those without. In the LIS population, however, out-of-pocket costs represented only 0.6-1.2% of total prescription spending, compared to 21.6-26.9% among general Medicare and ESRD beneficiaries who did not receive the subsidy. PPPY Medicare Part D spending was 2.7 and 3.3 times greater for those with ESRD than for general Medicare beneficiaries in the LIS and non-LIS populations (Figure 10.5.b).

vol 2 Figure 10.5 Per person per year Medicare Part D spending & out-of-pocket costs for enrollees, 2016

(a) Medicare



(b) Medicare by Low-income Subsidy status



Data source: Medicare Part D claims for Part D enrollees with traditional Medicare (Parts A & B). Costs are per person per year for calendar year 2016, using as-treated actuarial model (see ESRD Methods chapter for analytical methods). Medicare Part D spending represents the sum of the Medicare covered amount and the Low-income Subsidy amount. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage.

Total PPPY insurance spending for prescriptions (excluding patient obligations) varied by coverage, age, sex, and race (Table 10.5). Overall, Medicare Part D spending for beneficiaries with ESRD was higher than in the general population. For both the general and ESRD cohorts, PPPY Medicare Part D spending was highest in Medicare Part D with LIS ($6,087 and $16,153). Generally, younger beneficiaries aged 20-44 or 45-64 years, had higher costs than older patients. Medicare Part D spending varied only modestly by sex.

vol 2 Table 10.5 Per person per year Medicare Part D spending for enrollees, 2016

	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	6,087	1,670	16,153	5,460	17,440	6,191	17,495	6,192	11,321	3,788
20-44	6,134	2,745	16,410	4,899	18,782	6,341	18,069	5,650	10,413	3,191
45-64	8,028	2,895	17,484	6,364	18,943	7,406	18,080	6,452	11,856	4,239
65-74	5,212	1,585	14,807	5,674	15,700	6,606	15,241	6,622	11,163	3,893
75+	4,497	1,558	12,095	4,413	12,759	4,808	12,079	5,236	8,146	2,784
Sex										
Male	6,161	1,819	16,452	5,519	17,751	6,156	18,541	6,419	11,833	4,027
Female	6,035	1,560	15,811	5,370	17,091	6,246	16,562	5,849	10,639	3,429
Race										
White	6,214	1,650	15,624	5,320	17,167	6,140	17,672	6,312	10,861	3,667
Black/African American	6,415	2,062	17,068	5,949	17,985	6,338	17,098	5,504	12,492	4,459
Native American/Alaska Native	5,082	3,071	10,539	5,050	10,771	5,677	13,301	4,464	8,969	2,999
Asian	5,137	1,283	15,767	5,457	17,277	6,294	19,176	6,809	10,491	3,709
Native Hawaiian/Pacific-Islander	NA	NA	16,751	4,524	17,739	4,949	17,168	5,372	10,981	3,219
Other race	5,345	1,601	14,552	4,552	16,145	7,059	16,651	5,468	11,564	3,011
Unknown/missing	4,730	1,579	16,472	6,723	19,646	9,259	23,122	13,923	9,618	5,954

Data source: Medicare Part D claims. Costs are per person per year for calendar year 2016, 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. Abbreviations: ESRD, end-stage renal disease; LIS, Low-income Subsidy; Part D, Medicare Part D prescription drug coverage.

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 2016. ESRD patients were most frequently prescribed ion-removing agents, β-adrenergic blocking agents (beta blockers), antibacterials, analgesics, and lipid-lowering agents (Table 10.6).

vol 2 Table 10.6 Top 15 drug classes received by ESRD cohorts, by modality, 2016

	Hemodialysis		Peritoneal dialysis		Transplant	
Rank	**Drug class**	**%**	**Drug class**	**%**	**Drug class**	**%**
1	Ion-removing agents	71.5	Ion-removing agents	61.9	Antibacterials	73.9
2	B-Adrenergic blocking agents	64.1	B-Adrenergic blocking agents	61.5	β-Adrenergic blocking agents	63.0
3	Antibacterials	57.9	Antibacterials	58.7	Antiulcer agents and acid suppressants	58.8
4	Analgesics and antipyretics	57.3	Lipid-lowering agents	48.5	Lipid-lowering agents	56.8
5	Lipid-lowering agents	51.0	Calcium-channel blocking agents	48.1	Calcium-channel blocking agents	50.7
6	Calcium-channel blocking agents	48.2	Analgesics and antipyretics	46.4	Analgesics and antipyretics	48.2
7	Renin-angiotensin-aldosterone system inhibitors	46.3	Renin-angiotensin-aldosterone system inhibitors	44.1	Adrenals	47.1
8	Antiulcer agents and acid suppressants	37.9	Antiulcer agents and acid suppressants	39.8	Antidiabetic agents	39.0
9	Antidiabetic agents	36.9	Diuretics	35.5	Renin-angiotensin-aldosterone system inhibitors	35.7
10	Anticonvulsants	32.7	Antidiabetic agents	33.6	Diuretics	33.3
11	Hypotensive agents	32.4	Anti-infectives	32.9	Psychotherapeutic agents	25.2
12	Psychotherapeutic agents	32.2	Psychotherapeutic agents	28.2	Diabetic consumables	24.6
13	Cinacalcet	31.9	Hypotensive agents	27.4	Antivirals	24.4
14	Antithrombotic agents	31.0	Cinacalcet	26.7	Anticonvulsants	22.7
15	Anxiolytics, sedatives, and hypnotics	25.1	Anticonvulsants	25.0	Antithrombotic agents	20.2

Data source: Medicare Part D 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. Abbreviations: ESRD, end-stage renal disease; LIS, Low-income Subsidy; Part D, Medicare Part D prescription drug coverage.

The highest costing medications for ESRD patients were ion-removing agents, cinacalcet, antidiabetic agents, antivirals, and immunosuppressive agents (Table 10.7). Ion-removing agents incurred the greatest costs for dialysis patients, at about 40% of overall Medicare Part D spending. Antivirals ranked highest in cost for transplant patients with Medicare Part D.

vol 2 Table 10.7 Top 15 drug classes received by different ESRD cohorts, by modality and Medicare Part D spending, 2016

	Hemodialysis			Peritoneal Dialysis			Transplant		
Rank	Drug class	Spending (in millions)	%	Drug class	Spending (in millions)	%	Drug class	Spending (in millions)	%
1	Ion-removing agents	$1,145.3	39.8	Ion-removing agents	$94.3	41.3	Antivirals	$124.7	26.5
2	Cinacalcet	$701.3	24.4	Cinacalcet	$51.7	22.6	Antidiabetic Agents	$86.1	18.3
3	Antidiabetic agents	$214.1	7.4	Antidiabetic agents	$23.0	10.1	Cinacalcet	$56.0	11.9
4	Antivirals	$183.5	6.4	Antivirals	$14.6	6.4	Immunosuppressive Agents	$22.3	4.7
5	Antineoplastic agents	$71.9	2.5	Antineoplastic agents	$5.6	2.5	Adrenocortical Insufficiency	$12.2	2.6
6	Vasodilating agents	$34.0	1.2	Antilipemic agents	$3.1	1.4	Antilipemic Agents	$11.8	2.5
7	Caloric agents	$32.1	1.1	Antiulcer agents and acid suppressants	$2.1	0.9	Antiulcer Agents and Acid Suppressants	$10.1	2.1
8	Antilipemic agents	$31.5	1.1	Antibacterials	$1.8	0.8	Serums	$9.5	2.0
9	Analgesics and antipyretics	$30.8	1.1	Vasodilating agents	$1.7	0.8	Antineoplastic Agents	$8.5	1.8
10	Antiulcer agents and acid Suppressants	$29.4	1.0	Analgesics and antipyretics	$1.6	0.7	Hematopoietic Agents	$8.0	1.7
11	Anticonvulsants	$29.2	1.0	Anticonvulsants	$1.6	0.7	Antibacterials	$7.8	1.7
12	Antibacterials	$26.1	0.9	Antithrombotic agents	$1.4	0.6	Anticonvulsants	$7.0	1.5
13	Anti-inflammatory agents	$23.5	0.8	Pituitary	$1.3	0.6	Antithrombotic Agents	$6.5	1.4
14	Antithrombotic agents	$22.5	0.8	Disease-modifying antirheumatic agents	$1.2	0.5	Analgesics and Antipyretics	$6.0	1.3
15	Psychotherapeutic agents	$21.8	0.8	Anti-inflammatory agents	$1.2	0.5	Psychotherapeutic Agents	$5.8	1.2

Data source: Medicare Part D claims. Medicare 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. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage.

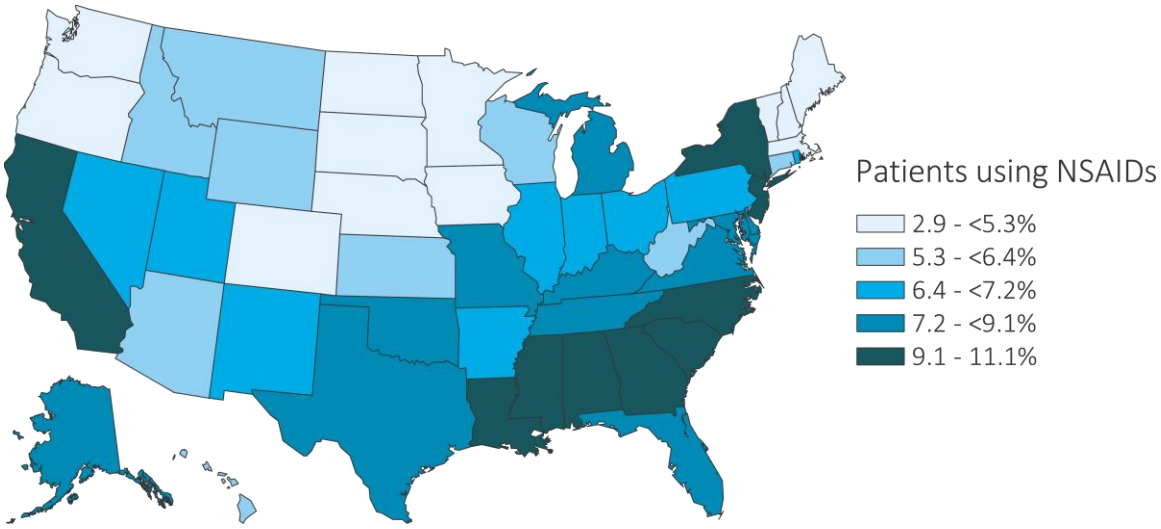
Medications for Pain Management

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 a higher frequency among ESRD patients than the general population (e.g., gastrointestinal bleeding, respiratory depression; Pham et al., 2009). Figures 10.6 and 10.7 display the state-specific proportions of ESRD Medicare Part D patients prescribed NSAIDs and opioid analgesics in 2016.

The overall national proportion of prescription NSAID use in ESRD patients was 8.3%. California, southern states, and the District of Columbia 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.

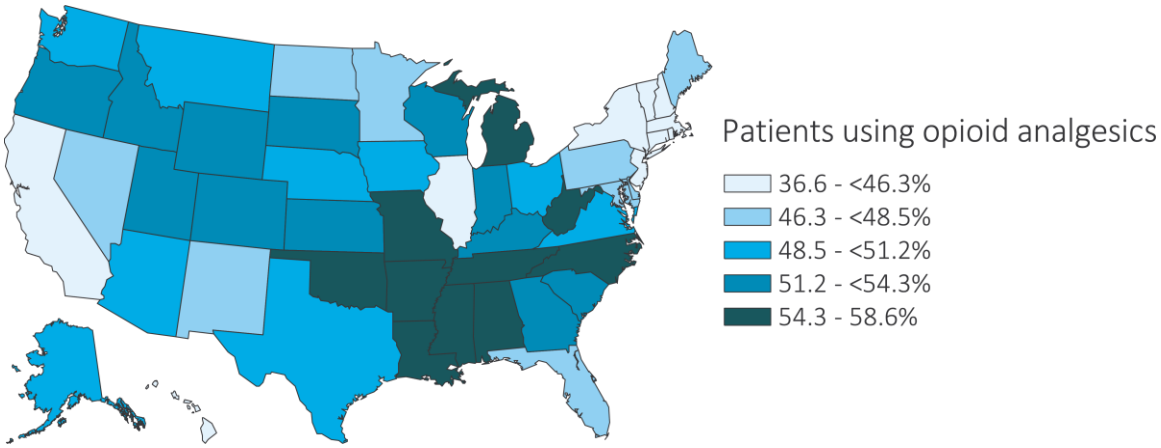
The proportion of patients using opioid analgesics was very high, at 49.0%. Use was greatest in the south central region (Alabama, Louisiana, Oklahoma, and Mississippi). These state differences could reflect varying prevalence of coexisting conditions, pain management practices, and preferences by state.

vol 2 Figure 10.6 Estimated utilization rate of prescription NSAIDs by state, Medicare ESRD patients, 2016



Data source: Medicare Part D claims. ESRD patients with Medicare Part D stand-alone prescription drug plans. Abbreviations: ESRD, end-stage renal disease; Part D, Medicare Part D prescription drug coverage; 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, 2016



Data source: Medicare Part D claims. ESRD patients with Medicare Part D stand-alone prescription drug plans. Abbreviation: ESRD, end-stage renal disease.

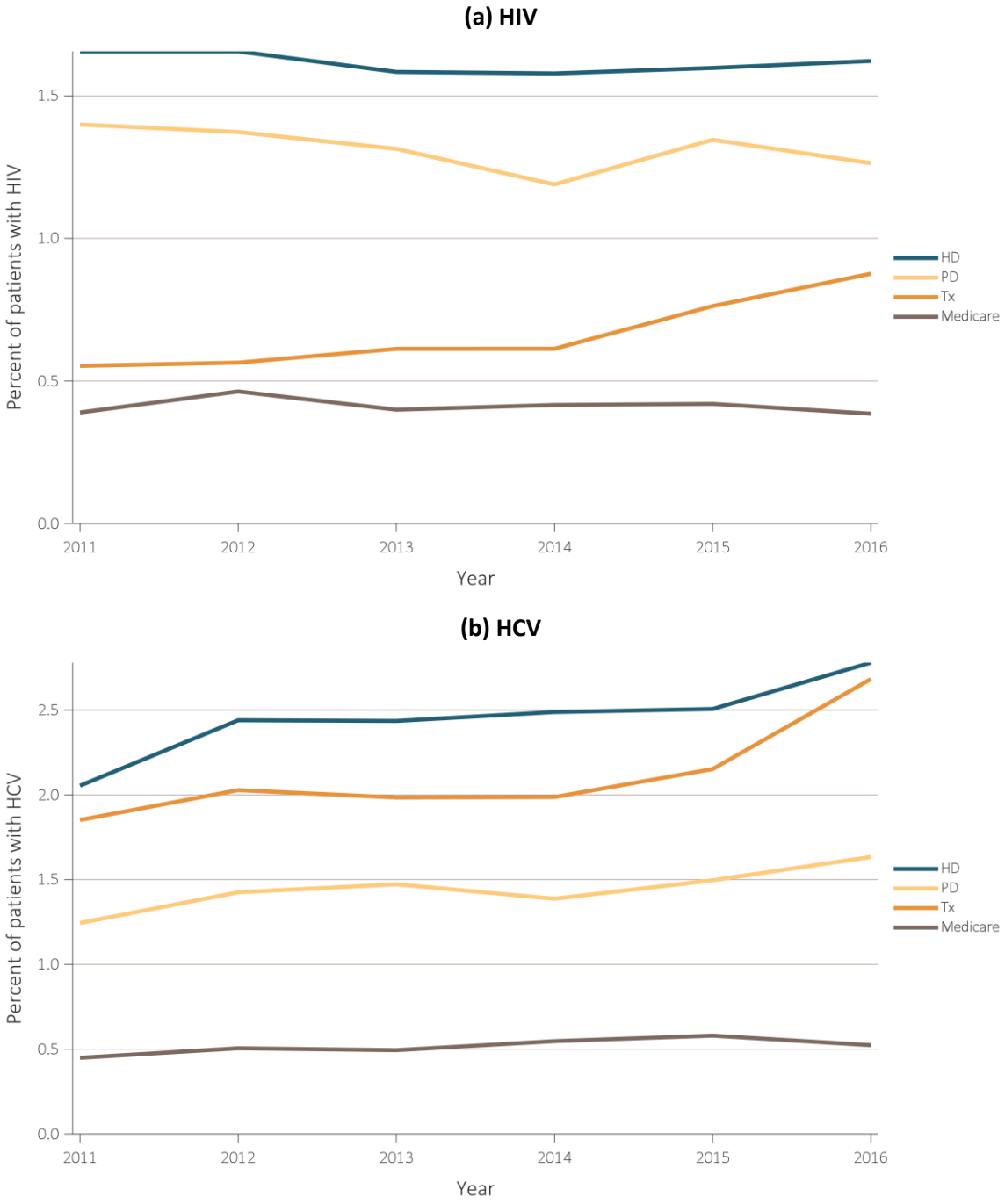
Antiviral Medications

ESRD patients are more vulnerable to viral infections than the general population (Figure 10.8). For example, the prevalence of the human immunodeficiency virus (HIV) is stable in dialysis patients, but increased considerably in transplant patients from 2011-2016 (Figure 10.8.a). The prevalence of hepatitis C (HCV) gradually increased in all ESRD modalities since 2011, and was highest in hemodialysis patients, followed by transplant patients and peritoneal dialysis patients (Figure 10.8.b). In this section, we examine use of prescribed antiviral medications in Medicare Part D enrollees and particularly assess three main drug classes used for antiviral management — prescription antiretrovirals, nucleosides and nucleotides, and protease inhibitors. These classes of agents are prescribed solely or in combination with others to treat HIV, herpes virus infections, HCV, and hepatitis B.

Figure 10.9 displays the proportions of Medicare Part D enrollees prescribed antivirals in 2011-2016. The proportion using antivirals was relatively stable in ESRD patients over the past six years, regardless of renal replacement therapy modality. In 2016, use was significantly higher in transplant patients compared to HD, PD, and the general population (24.1% versus 5.8%, 5.6%, and 4.9%).

Figure 10.10 displays the PPPY Medicare Part D spending on antivirals by ESRD modality from 2011 to 2016. There was a notable increase in PPPY Medicare Part D spending on antivirals in transplant patients, from $1,063 to a peak of $2,945 in 2014, with a sharp decline to $2,104 in 2016. Unlike transplant patients, Medicare Part D spending gradually increased in HD and PD patients, from $315 and $298 in 2011 to $918 and $844 in 2016, respectively. Medicare Part D spending on antivirals was higher in transplant patients than dialysis patients and general Medicare beneficiaries. Spending on protease inhibitors has also increased dramatically since 2013 in general Medicare beneficiaries as well as ESRD patients.

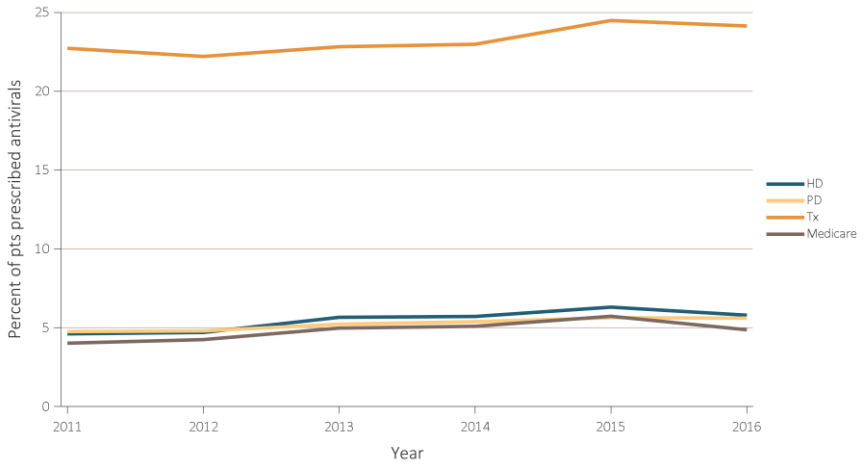
vol 2 Figure 10.8 Estimated prevalence of HIV and HCV in Medicare Part D enrollees, by ESRD modality, 2011-2016



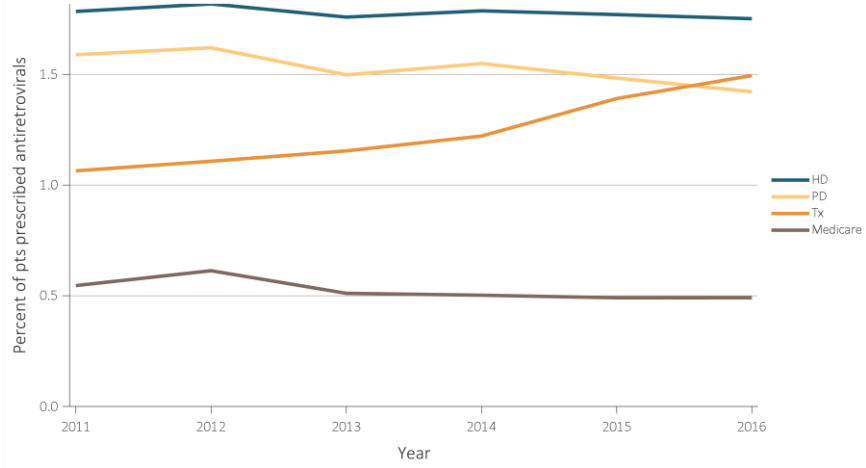
Data source: 2016 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2016. Abbreviations: ESRD, end-stage renal disease; HCV, hepatitis C; HD, hemodialysis; HIV, human immunodeficiency virus; Part D, Medicare Part D prescription drug coverage; PD, peritoneal dialysis; Tx, transplant.

vol 2 Figure 10.9 Estimated utilization rate of prescription antivirals in Medicare Part D enrollees, by ESRD modality, 2011-2016

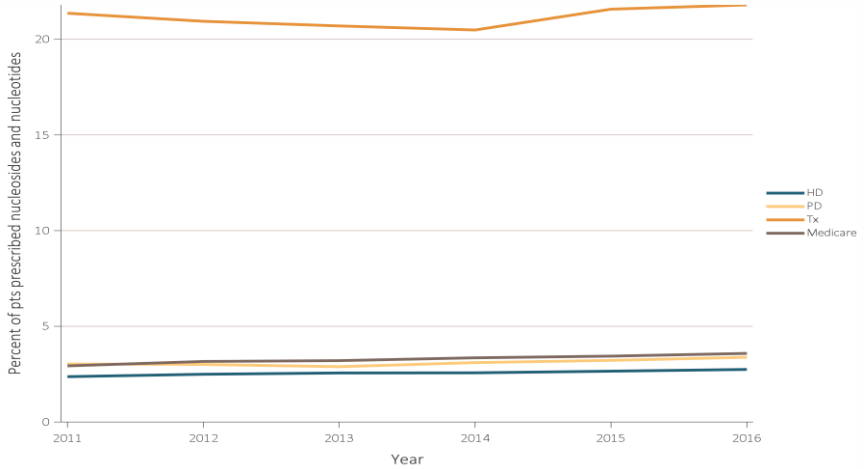
(a) All antivirals



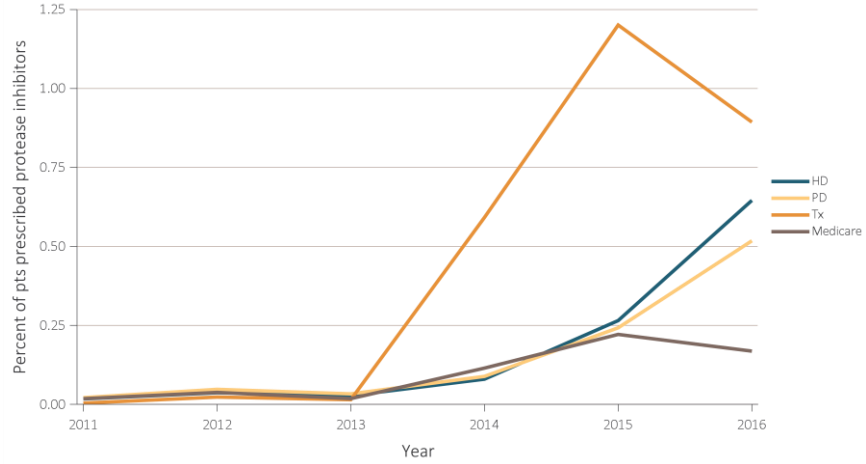
(b) Antiretrovirals



(c) Nucleosides and nucleotides

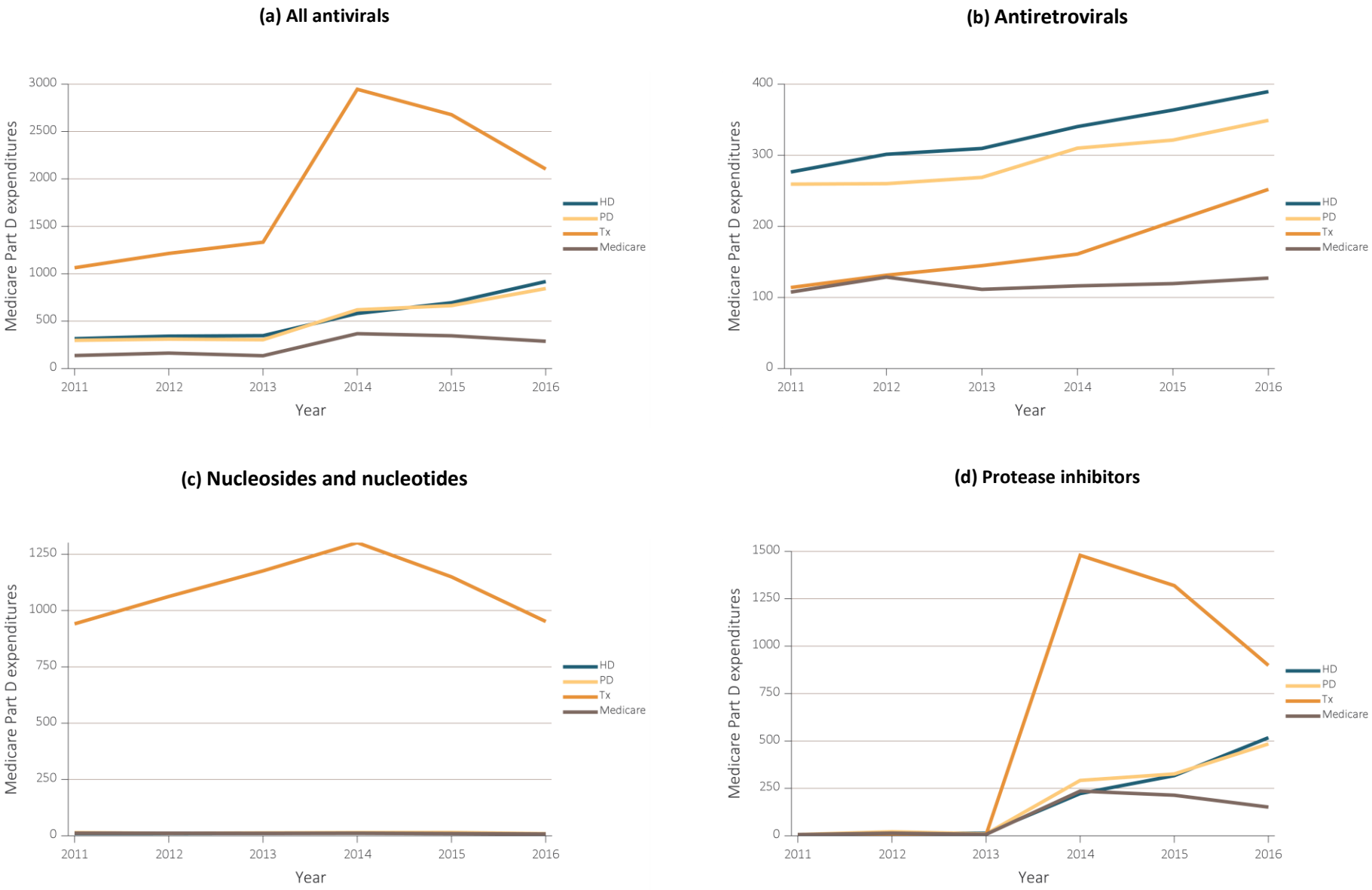


(d) Protease inhibitors



Data source: 2016 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2016. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; Part D, Medicare Part D prescription drug coverage; PD, peritoneal dialysis; Tx, kidney transplant.

vol 2 Figure 10.10 Estimated PPPY Medicare Part D spending of antivirals in Medicare Part D enrollees, by ESRD modality, 2011-2016



Data source: 2016 Medicare Data, point prevalent Medicare enrollees alive on January 1, 2016. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; Part D, Medicare Part D prescription drug coverage; PD, peritoneal dialysis; PPPY, per person per year; Tx, kidney transplant.

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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):111-118.

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Chapter 11: International Comparisons

- In 2016, as seen over the past decade, Taiwan, the United States, and the Jalisco region of Mexico reported the highest incidence of treated ESRD, with rates of 493, 378, and 355 patients per million general population (PMP; Figure 11.2), respectively. Nearly 40% of countries had incidence rates of treated ESRD <120 patients PMP, with South Africa reporting the lowest incidence rate of 22 treated ESRD patients PMP in 2016.
- Incidence rates of treated ESRD have remained relatively stable in approximately half of countries since 2003, either declining modestly or rising by only 1% or less per year from 2003 to 2016 in countries which reported data over this time period. In contrast, treated ESRD incidence rates rose an average of 2% to 4% per year in nearly 30% of countries (including the United States at 2% per year), and rose an average of 6% to 19% per year from 2003-2016 in Thailand, Malaysia, the Republic of Korea, the Jalisco region of Mexico, Singapore, the Philippines, and Taiwan (Figure 11.3.b).
- In 2016, large variation was seen across countries in whether diabetes mellitus (DM) was the primary cause of ESRD among incident treated ESRD patients, ranging from: approximately 66% of incident treated ESRD patients in Malaysia, Singapore, and the Jalisco region of Mexico, to less than 16% in Norway, Latvia, and Romania (Figure 11.4.b). From 2003 to 2016, the Jalisco region of Mexico and Malaysia had the highest average yearly increases overall in the rates of ESRD incidence due to diabetes (Figure 11.5).
- In 2016, among young adults (aged 20-44 years), the United States reported the highest ESRD incidence rate at 134 PMP, followed by Malaysia at 111 PMP, with most countries having treated ESRD incidence rates <50 PMP in this young age group (Figure 11.7.a).
- Taiwan, Japan, the United States, and Singapore had the highest reported prevalence of treated ESRD in 2016, at 3,392, 2,599, 2,196, and 2,076 PMP (Figure 11.9). In contrast, 13%, 50%, and 31% of countries had a prevalence of treated ESRD PMP of <500, 500-999, and 1,000-1,999, respectively.
- From 2003 to 2016, Taiwan and Thailand reported the highest average yearly increase in the prevalence of treated ESRD PMP (Figure 11.11.b) with prevalence rising by 122 and 106 persons PMP per year, respectively. In comparison, 44%, 33%, and 17% of countries had an average yearly increase in the prevalence of treated ESRD of <25, 25-48, and 53-84 persons PMP per year over the time period from 2003 to 2016.
- Large international variation exists in the use of the different renal replacement therapies (RRT; Figure 11.12). In approximately one-fourth of countries, 50-70% of treated ESRD patients are living with a kidney transplant—particularly in northern European countries. In contrast, in approximately one-third of countries, less than 20% of treated ESRD patients are living with a kidney transplant. In most nations, in-center hemodialysis (HD) was the predominant RRT modality.
- Among dialysis patients, in-center HD was the chosen modality for greater than 80% of dialysis in 79% of countries (Figure 11.15). In 2016, the highest utilization of peritoneal dialysis (PD) occurred in Hong Kong (71%), the Jalisco region of Mexico (61%), Guatemala (57%), New Zealand (30%), Thailand (28%), and Qatar (27%); for the remaining countries, PD utilization was less than 22% of dialysis patients.
- In 2016, the Jalisco region of Mexico, Spain, the United States, and the Netherlands reported the highest rates of kidney transplantation, with 59-79 transplants PMP (Figure 11.16.a). When expressed relative to the size of the prevalent dialysis population, the highest rates of kidney transplantation per 1,000 dialysis patients occurred in Kazakhstan (171 per 1,000), Belarus (167 per 1,000), Norway (162 per 1,000), the Netherlands, Finland, and Scotland (from 119 to 152 per 1,000). Thirty-one percent of countries indicated less than 30 kidney transplants per 1,000 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 79, with the addition of Iraq. We welcome our newest contributor.

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 sincerely thank all the country registries for their dedicated efforts in providing their data for this effort. Specific contributors to this effort are listed at the end of the chapter. The information in this chapter is designed to serve as a resource for the worldwide ESRD community—to inform health care policies, while stimulating meaningful research designed to improve care of ESRD patients.

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; therefore any direct comparisons require caution.

In some countries (e.g., United States), 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 countries/registries, however, 100% ascertainment of persons treated for ESRD may not be feasible.

The international comparisons presented in this chapter do not adjust for demographic differences. Most European countries, Japan, and other nations have rapidly aging populations. As ESRD rates tend to rise with age, such nations may report higher rates of ESRD as compared to those with younger populations, although many other factors play a role (mortality rates, acceptance rates to an ESRD program, etc.). This chapter is intended to broadly characterize (i.e., provide descriptive data on) the populations receiving renal replacement therapy around the world. Thus whether a registry achieves 90%, 95%, or >99% ascertainment of ESRD within their country, the key messages in this chapter remain very relevant.

The degree of unrecognized ESRD and access to renal replacement therapy (RRT) varies widely across countries. Where access to RRT is limited, reported ESRD incidence and prevalence may substantially underestimate the true rates of irreversible kidney failure. On the other hand, in some countries where RRT is widely available, when patients decline dialysis or transplantation true ESRD incidence may also 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). The information presented in this chapter reflects only patients who are currently on dialysis or have received a kidney transplant. Thus, the data and trends reported represent "treated ESRD."

The United States Renal Data System (USRDS) welcomes any suggestions to further improve the content of this chapter for the benefit of the international community, and invites all renal registries to participate in this data collection and collaboration. Feel free to contact us via email at USRDS@usrds.org – as there are many countries not yet represented. Efforts to increase international engagement and enhance the content will continue to be a focus of this chapter. We also wish to make readers aware of the Share-RR initiative (SHARing Expertise to support the set-up of Renal Registries), which is an advocacy effort supported by the International Society of Nephrology (ISN), with collaboration by many different national renal registries. The goal of Share-RR is to develop informational resources that can be used by leaders to help develop a renal registry in their country (https://www.theisn.org/advocacy/share-rr). Through this effort, a survey recently has been distributed to registries in >90 countries to understand the types of processes used for registry

data collection within each country; its goal is to inform current and future registries regarding different approaches used for registry data collection. We are also excited by the development of a newly established international pediatric registry, the *International Pediatric Nephrology Association Global RRT Registry,* which is very useful for understanding numerous aspects of ESRD among pediatric patients across many countries (*http://ipna-online.org/content/registry-0*).

Methods

The findings presented in this chapter result from analyses of each country's aggregate data provided in 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*.

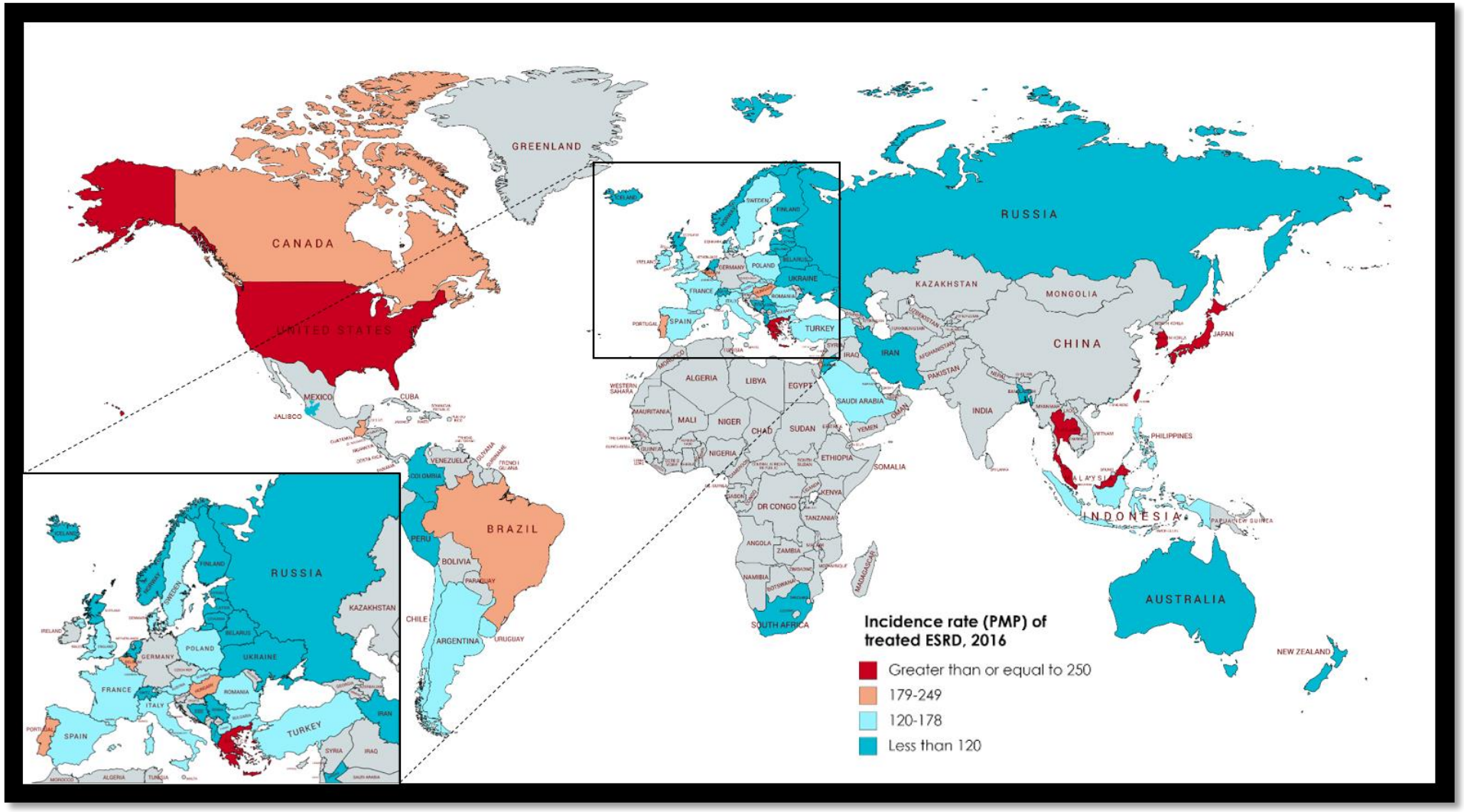
Data tables formerly presented within the content of this chapter are now located in *Reference Table N.* For an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter, see the section on *Chapter 11* in the *ESRD Analytical Methods* chapter. Downloadable Microsoft Excel and PowerPoint files containing the data and graphics for these figures are available on the *USRDS website*.

Incidence of Treated ESRD

In 2016, reported incidence rates of treated ESRD varied greatly across countries (Figures 11.1 and 11.2). Taiwan, the United States, the Jalisco region of Mexico, and Thailand reported the highest incidence of treated ESRD, at 493, 378, 355, and 346 individuals per million general population (PMP). The next highest rates, ranging from 200–333 PMP, were reported by Singapore, the Republic of Korea, Japan, Malaysia, Greece, Portugal, Hungary and Canada. The lowest treated ESRD incidence rates, ranging from 22 to 85 PMP, were reported by South Africa, Ukraine, Belarus, Bangladesh, Russia, Jordan, Peru, Colombia, Iran, Albania, and Estonia.

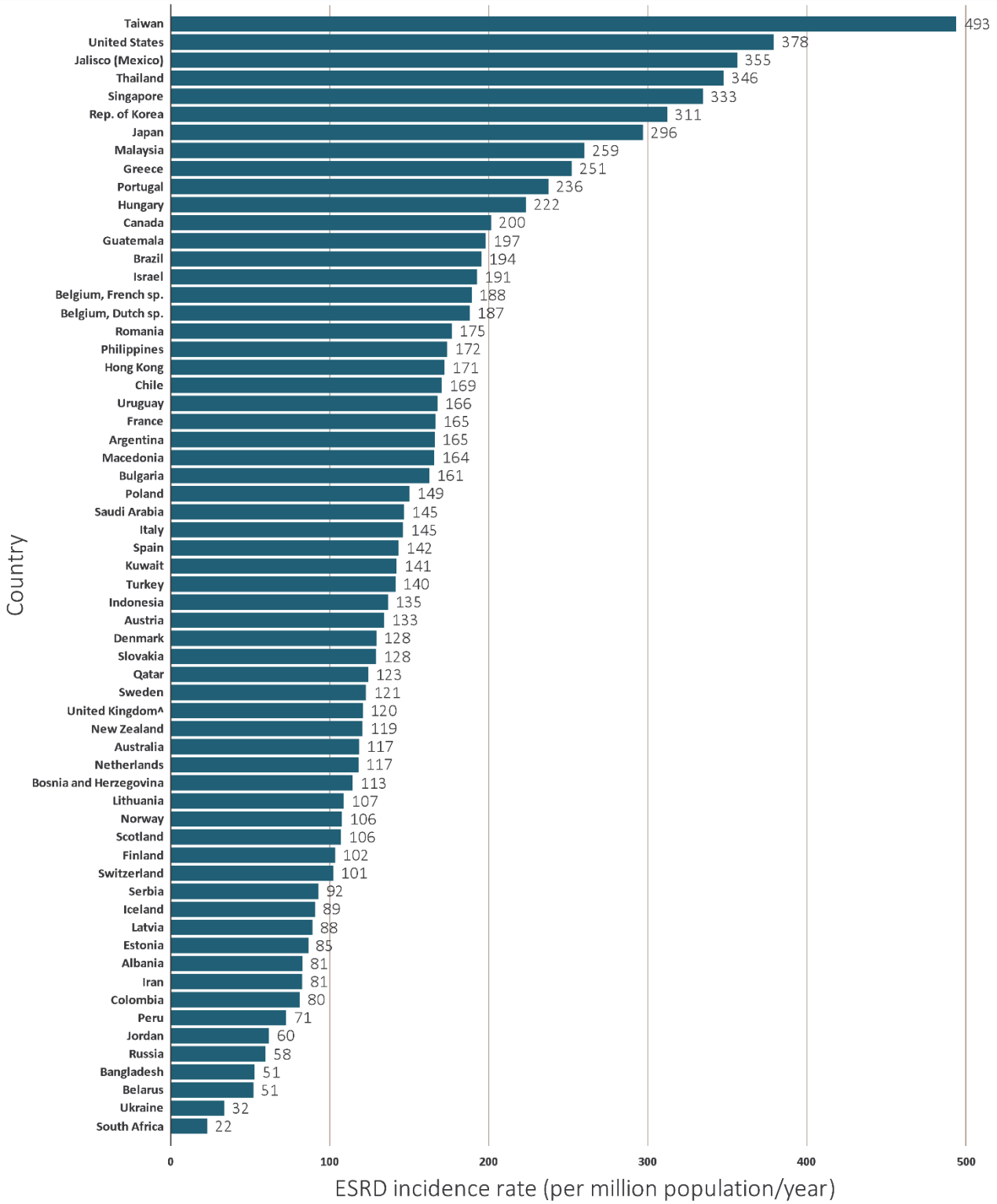
Trends in the incidence of treated ESRD from 2003 to 2016 also varied greatly across countries, as shown in Figure 11.3. Incidence rates of treated ESRD have remained relatively stable in approximately half of countries since 2003, either declining modestly or rising ≤1.0% per year from 2003 to 2016 in countries which reported data over this time period. In contrast, treated ESRD incidence rates rose an average of 2% to 4.1% per year in nearly 30% of countries (including the U.S. at 2.2% per year), and rose an average of 6% to 19% per year from 2003-2016 in Thailand, Malaysia, the Republic of Korea, the Jalisco region of Mexico, Singapore, the Philippines, and Taiwan.

vol 2 Figure 11.1 Geographic variation in the incidence rate of treated ESRD (per million population), by country, 2016



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. Data unavailable for countries pictured above in gray. All rates are unadjusted. Data for Belarus from 43 of 51 RRT centers. Data for Canada exclude Quebec. Data for France exclude Martinique. Data for Guatemala exclude pediatric ESRD patients and patients receiving non-institutional RRT. Data for Indonesia represent the West Java region. Data for Italy representative of 35% (7 out of 19 regions) of ESRD patient population. Japan includes dialysis patients only. Data from Latvia representative of 80% of ESRD patient population. Data for Serbia approx. 30% less than reported in 2015 due to incomplete reporting. United Kingdom: England, Wales, Northern Ireland (Scotland data reported separately). Abbreviation: ESRD, end-stage renal disease; PMP, per million population; RRT, renal replacement therapy. 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), by country, 2016



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. All rates are unadjusted. Data for Belarus from 43 of 51 RRT centers. Data for Canada exclude Quebec. Data for France exclude Martinique. Data for Guatemala exclude pediatric ESRD patients and patients receiving non-institutional RRT. Data for Indonesia represent the West Java region. Data for Italy representative of 35% (7 out of 19 regions) of ESRD patient population. Japan includes dialysis patients only. Data from Latvia representative of 80% of ESRD patient population. Data for Serbia approx. 30% less than reported in 2015 due to incomplete reporting. United Kingdom^: England, Wales, Northern Ireland (Scotland data reported separately). Abbreviations: ESRD, end-stage renal disease; RRT, renal replacement therapy; 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, 2003-2016

(a) Ten countries having the highest percent increase in ESRD incidence rate in 2003/04 versus that in 2015/16, plus the United States

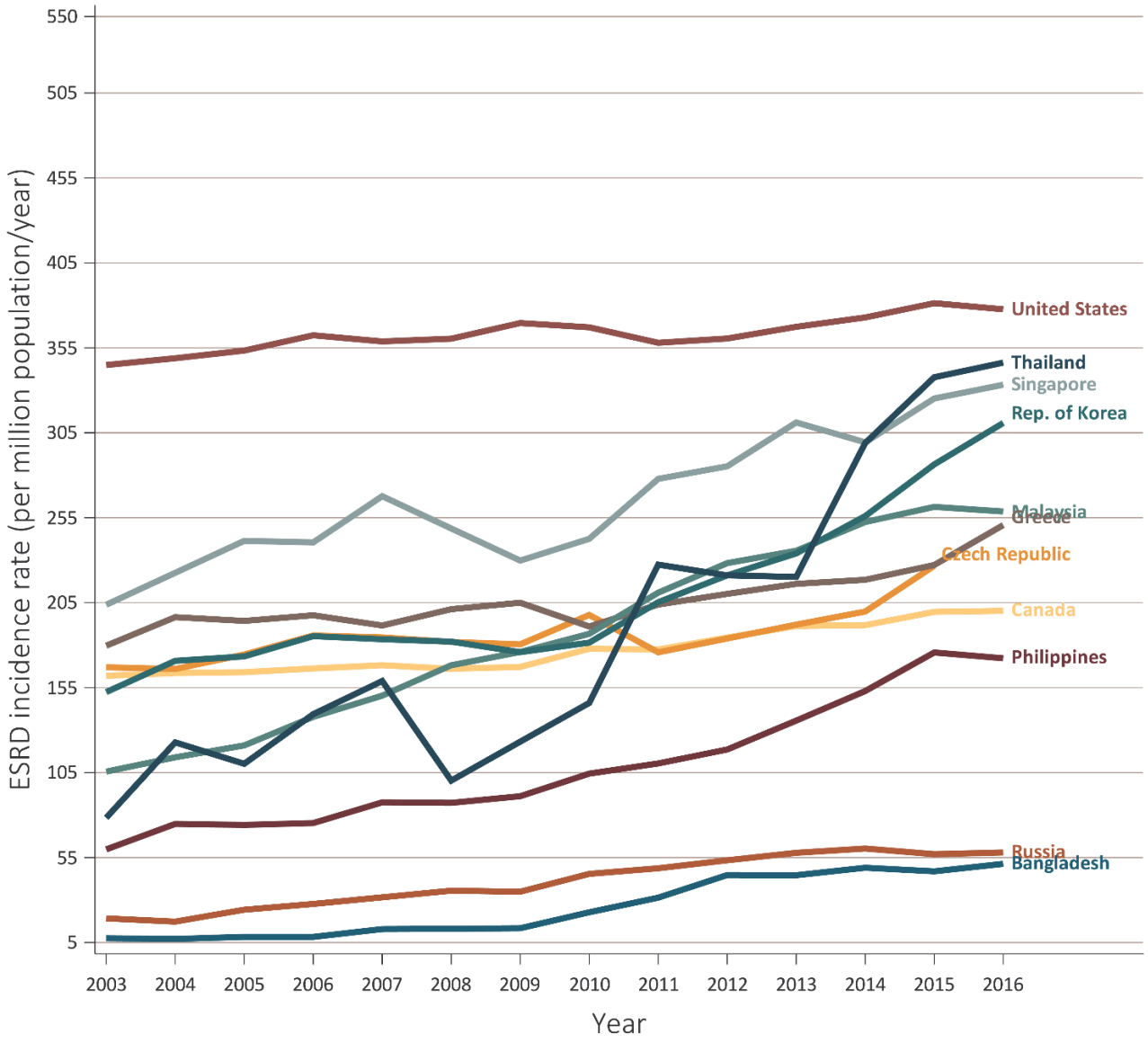
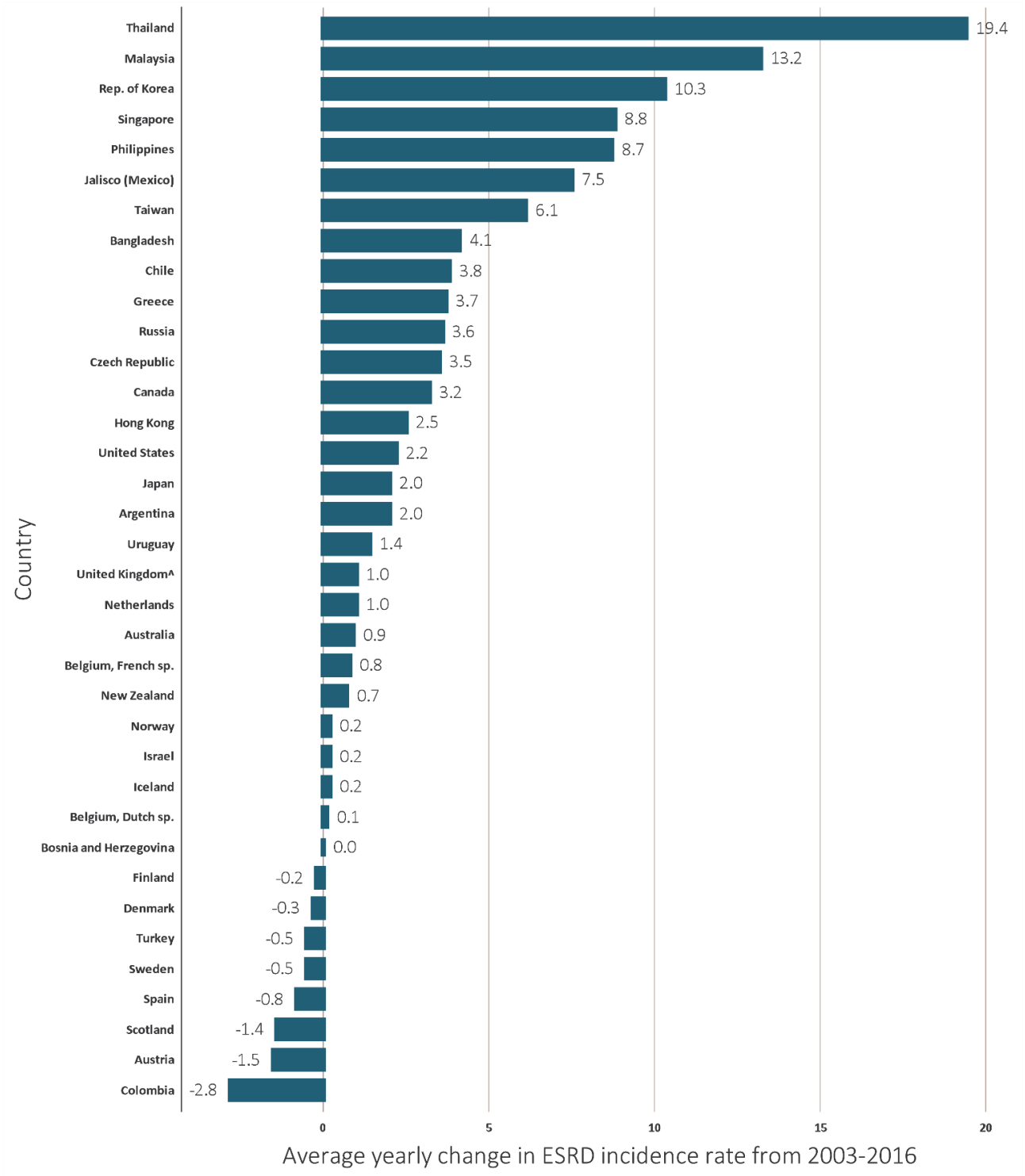


Figure 11.3 continued on next page.

vol 2 Figure 11.3 Trends in the incidence rate of treated ESRD (per million population/year), by country, 2003-2016 (continued)

(b) Average yearly change in the treated ESRD incidence rate from 2003-2016



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information were available. All rates are unadjusted. (a) Ten countries having the highest percentage rise in 2015-2016 versus that in 2003-2004, plus the United States. (b) Estimates derived from linear regression. 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 highlight diabetes mellitus (DM) as the predominant likely underlying cause of treated ESRD worldwide. It should be noted that many other etiologies of kidney disease and ESRD exist, including hypertension, a variety of glomerulonephritides, tubulointerstitial disorders, inherited or congenital disorders, cancer, environmental toxins or drug toxicity, and other dietary or environmental factors that may be particularly relevant in some regions.

Nearly 71% of the countries participating in this report provided data on the incidence of treated ESRD with assigned primary cause being DM—a key contributor to the global burden of kidney disease and ESRD. In 2016, Malaysia, Singapore, and the Jalisco region of Mexico reported the highest proportions of patients with new ESRD due to DM, at 67%, 66%, and 65% (Figure 11.4.a). Furthermore, DM was listed as the primary cause of new ESRD for 40-50% of patients in Brazil, Slovakia, Uruguay, Hungary, Thailand, Jordan, Japan, Qatar, Kuwait, Taiwan, the U.S., Indonesia, Chile, New Zealand, Hong Kong, Israel, and the Republic of Korea. In contrast, in 2016, DM was the primary cause of ESRD for 20% or less of new ESRD patients in Albania, South Africa, the Netherlands, Russia, Italy, Estonia, Lithuania, Iceland, Norway, Latvia, and Romania.

In 2016, the Jalisco region of Mexico had the highest ESRD incidence rate due to DM, at nearly 231 new ESRD patients PMP (Figure 11.4.b). Thirty countries provided incidence rates of ESRD due to DM for the entire period from 2003 to 2016 (Figure 11.5) These data indicate an overall rise in the incidence of treated ESRD due to DM in most, but not all, of these nations. The greatest average yearly increase in diabetes-related ESRD incidence rates from 2003 to 2016 has occurred in the Jalisco region of Mexico and Malaysia where incidence rates of treated ESRD due to diabetes have increased an average of 7.8 and 9.5 patients PMP per year, respectively, over this 14 year time period. In some countries, the overall percent increase from 2003 to 2016 has been especially large—from 50% to 360% (Figure 11.6). These included Hong Kong, Australia, the United Kingdom, Bosnia and Herzegovina, Singapore, the Republic of Korea, Malaysia, the Philippines, Iceland, and Russia. Furthermore, in Thailand the incidence of ESRD due to DM has more than doubled since 2010.

It is conceivable that the practice of assigning primary cause of ESRD may have changed 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.

vol 2 Figure 11.4 Incidence of treated ESRD due to diabetes as the assigned primary cause of ESRD cause, by country, 2016

(a) Percentage of incident ESRD patients

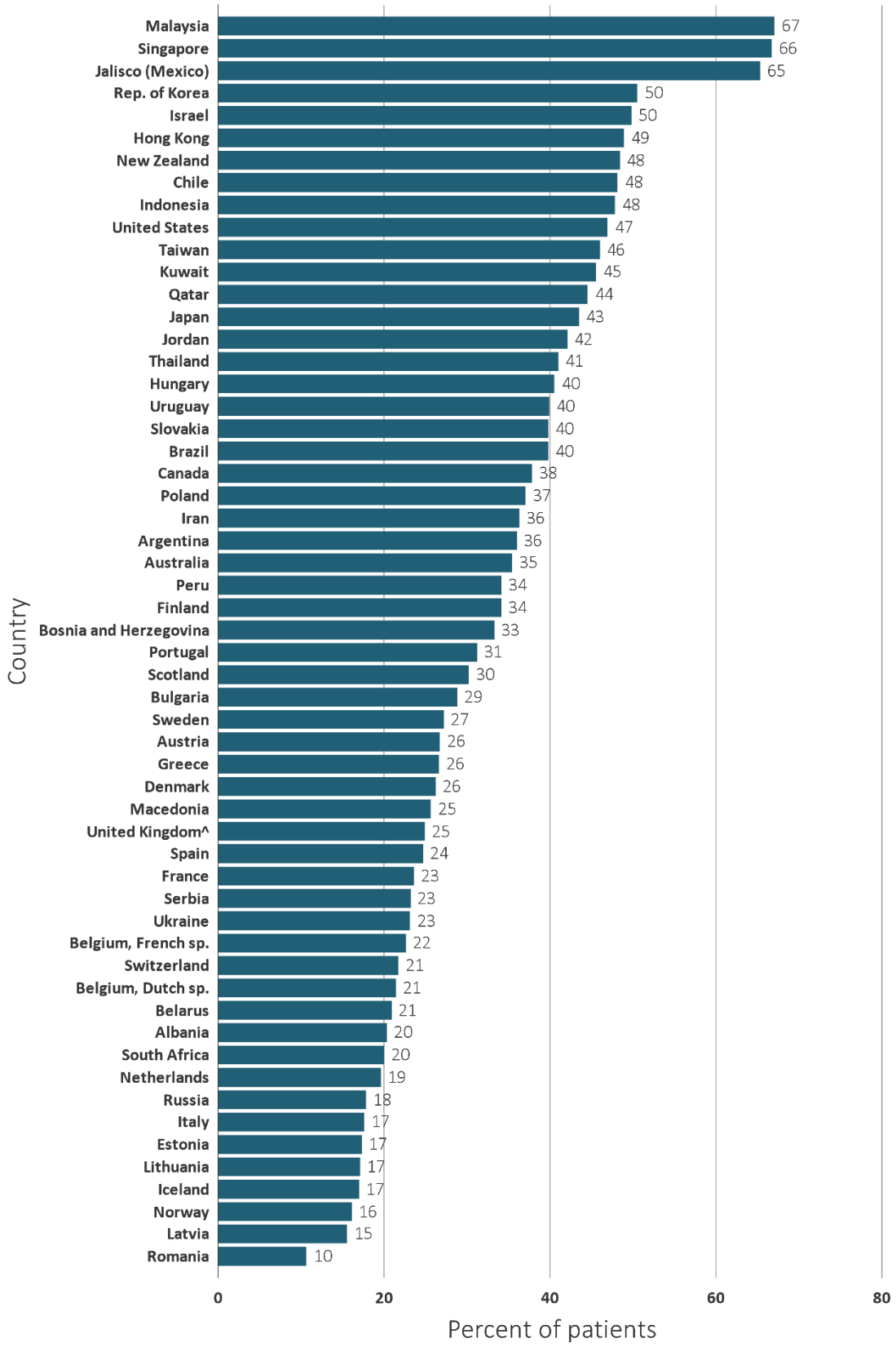
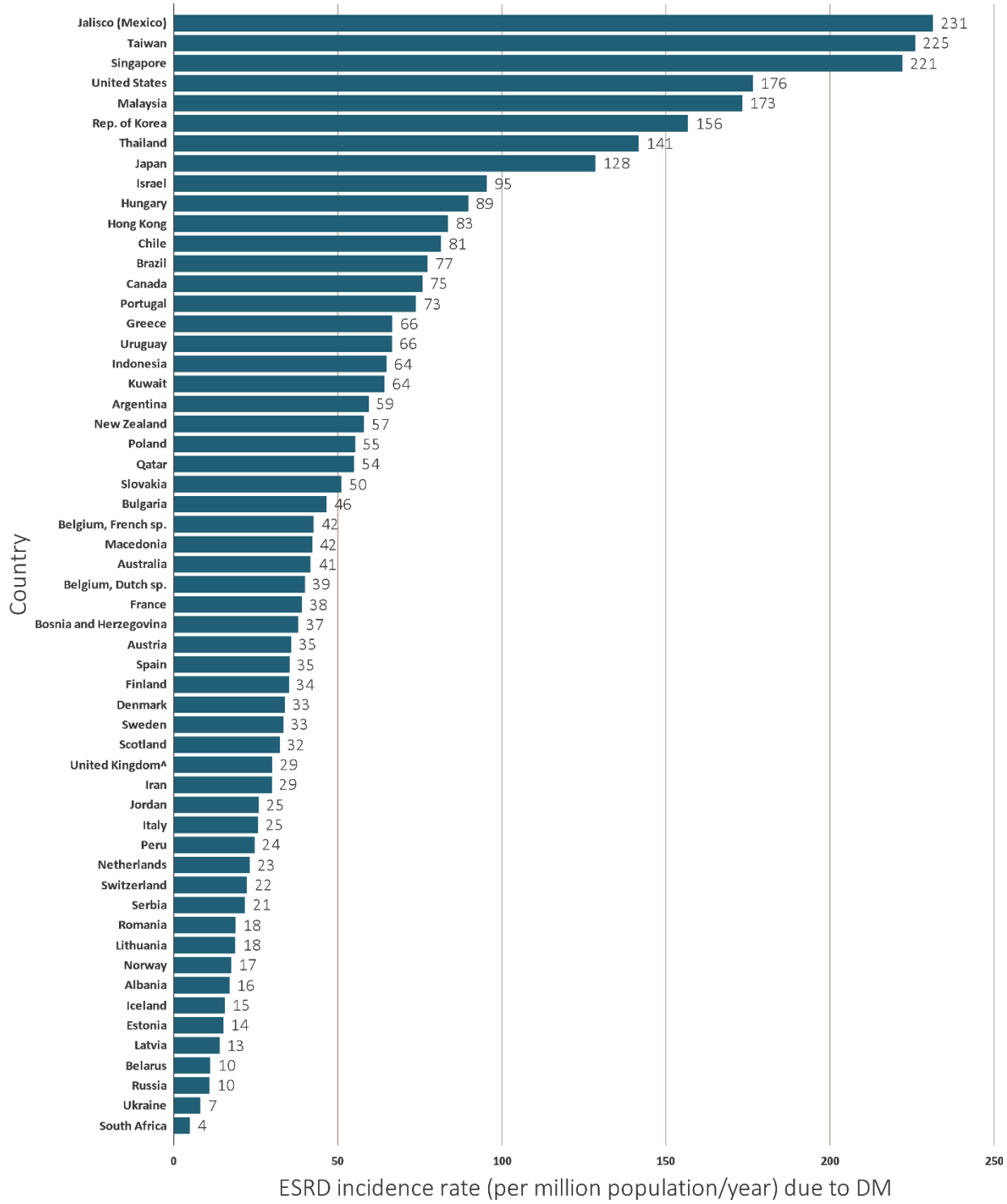


Figure 11.4 continued on next page.

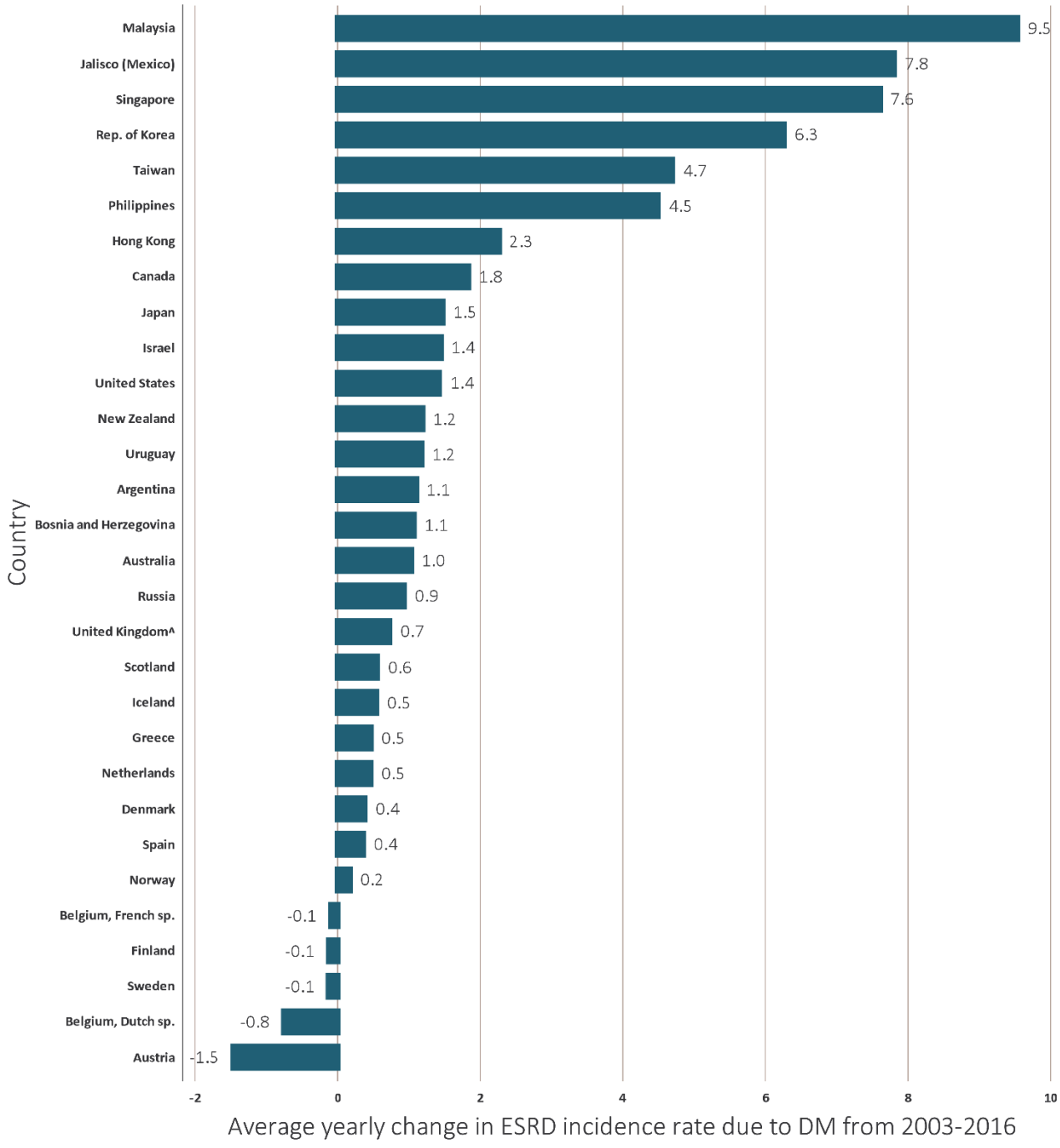
vol 2 Figure 11.4 Incidence of treated ESRD due to diabetes as the assigned primary cause of ESRD cause, by country, 2016 (continued)

(b) Incidence rate of treated ESRD (per million population)



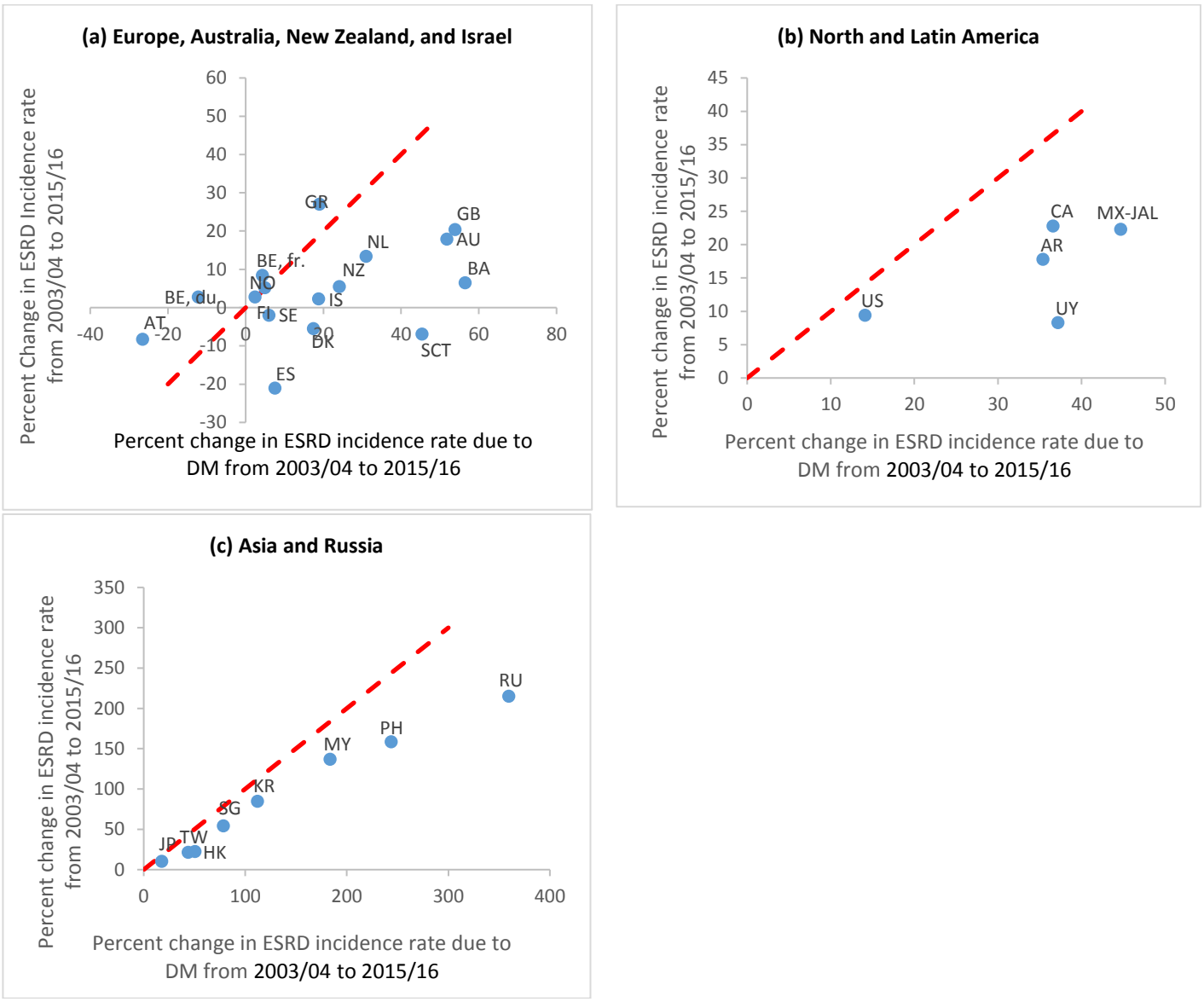
Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information were available. Data for Belarus from 43 of 51 RRT centers. Data for Canada exclude Quebec. Data for France exclude Martinique. Data for Indonesia represent the West Java region. Data for Italy representative of 35% (7 out of 19 regions) of ESRD patient population. Japan includes dialysis patients only. Data from Latvia representative of 80% of ESRD patient population. Data for Serbia approx. 30% less than reported in 2015 due to incomplete reporting. United Kingdom^: England, Wales, Northern Ireland (Scotland data reported separately). Abbreviations: ESRD, end-stage renal disease; RRT, renal replacement therapy; sp., speaking. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

vol 2 Figure 11.5 Average yearly change in the incidence rate of treated ESRD due to diabetes as the assigned primary ESRD cause (per million population/year), by country, 2003-2016



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information were available. Estimates derived from linear regression. Abbreviation: ESRD, end-stage renal disease; Rep., Republic; sp., speaking. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

vol 2 Figure 11.6 Country-level correlation of the percentage change in ESRD incidence with the percentage change in ESRD incidence due to diabetes, from 2003-2016, 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 2003/04-2015/16. Countries listed in order of lowest to highest percentage change in ESRD incidence due to diabetes in each panel. (a) Europe, Australia, New Zealand, and Israel: (-27-57%) Austria (AT), Belgium, Du. speaking (BE, du.), Finland (FI), Belgium, fr. speaking (BE, fr.), Norway (NO), Sweden (SE), Spain (ES), Denmark (DK), Israel (IS), Greece (GR), New Zealand (NZ), Netherlands (NL), Scotland (SCT), Australia (AU), United Kingdom (GB), and Bosnia and Herzegovina (BA); (b) North and Latin America: (2-45%) Uruguay (UY), United States (US), Argentina (AG) Canada (CA), Jalisco (Mexico, MX-JAL); (c) Asia and Russia: (18-360%) Japan (JP), Taiwan (TW), Hong Kong (HK), Singapore (SG), Rep. of Korea (KR), Malaysia (MY), Philippines (PH), Russia (RU). Abbreviation: du., Dutch; ESRD, end-stage renal disease; fr., French; Rep., Republic. 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 2016 incidence of treated ESRD by age group. In all Western and the majority of Northern European countries, Canada, the United States, Japan, Taiwan, Austria, Macedonia, and Greece, treated ESRD incidence rates were highest among patients aged 75 years or older, with the highest rates in this age group occurring in Taiwan, with 2,869 PMP/year followed by the United States at 1360 PMP/year. In contrast, the incidence of treated ESRD was 8-60% lower in the population aged 75 years or older, as compared to those aged 65-74 years in Australia, New Zealand, the South American countries (Argentina, Peru, and Uruguay), in a majority of the Eastern European countries (Albania, Belarus, Latvia, Romania, Serbia, and Slovakia), and in Jordan, Estonia, Iceland, Hong Kong, Russia and Malaysia. In 2016, among the population of younger adults aged 20-44 years, relative to other countries, the United States reported the highest ESRD incidence rate at 134 PMP, followed by Malaysia at 111 PMP, but with many countries having treated ESRD incidence rates <50 PMP in this young age group of adults 20-44 years old.

In Figure 11.8, we compare the incidence of treated ESRD by sex. In almost every country except Jordan, the rate was substantially higher for males than for females. ESRD incidence was at least two times higher for males in Estonia, Austria, Japan, Denmark, Spain, Serbia, Finland, Lithuania, and Greece, and was 1.0-1.9 times higher for males in most other countries. The ratio of male to female ESRD incidence in Jordan was 0.74. In the United States, males had a higher ESRD incidence rate, despite CKD being less prevalent among males than females, as reported in Volume 1, Chapter 1: *CKD in the General Population*.

The considerably lower ESRD incidence for females in nearly all countries shown in Figure 11.8 is consistent with published data from 12 countries participating in the Dialysis Outcomes and Practice Patterns Study (DOPPS) (Hecking et al., 2014) as well as the higher lifetime risk of ESRD among males in all race groups, based on a detailed analysis of U.S. ESRD and Census data (Albertus et al., 2016). The observed sex differences in incidence rates from the vast majority of countries, including the United States, raises the question of whether the explanation is mostly biological or environmental, or whether it might also represent a sociocultural or healthcare disparity.

vol 2 Figure 11.7 Incidence rate of treated ESRD (per million population/year), by age group and country, 2016

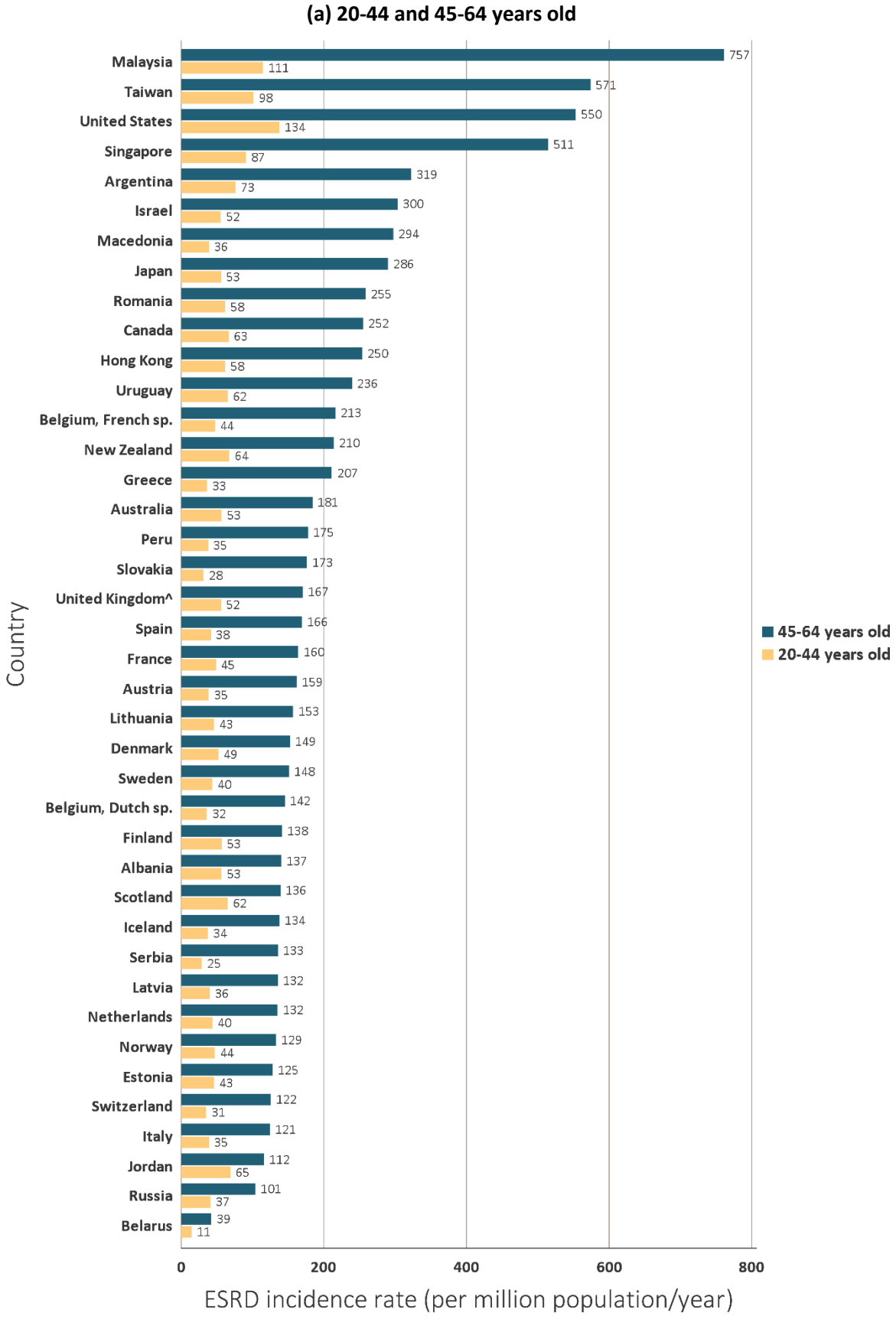
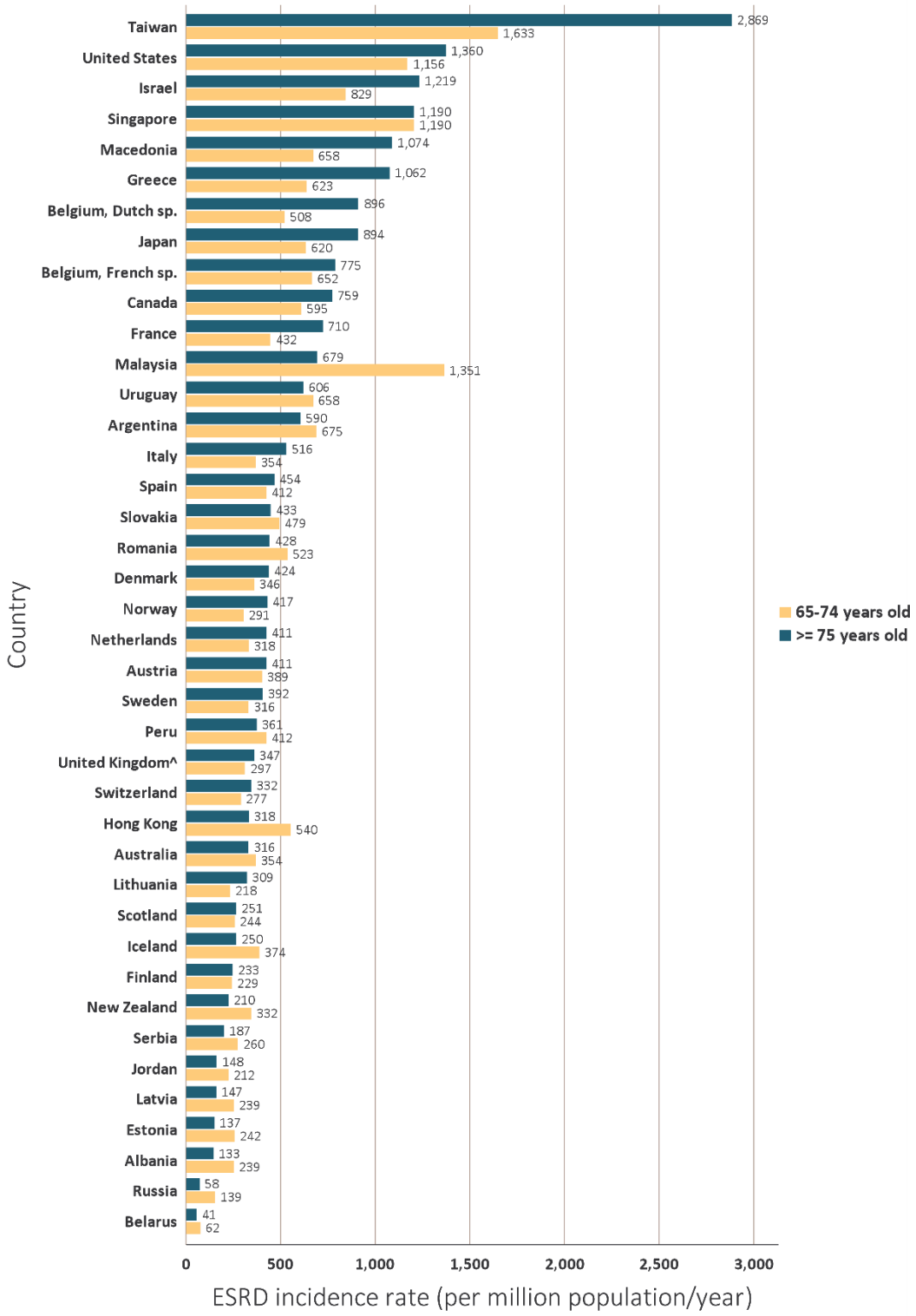


Figure 11.7 continued on next page.

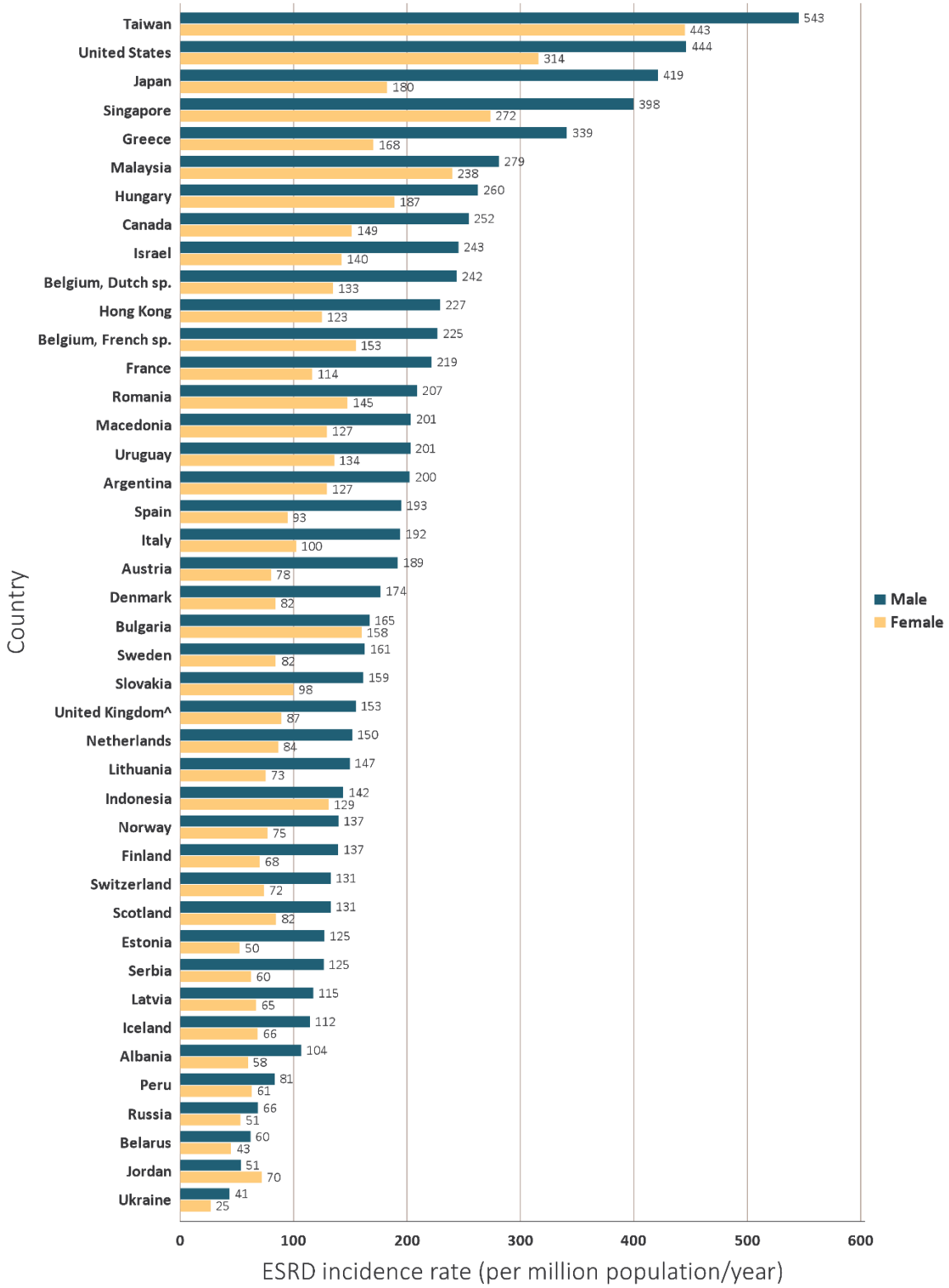
vol 2 Figure 11.7 Incidence rate of treated ESRD (per million population/year), by age group and country, 2016 (continued)

(b) 65-74 and ≥75 years old



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. Data for Belarus from 43 of 51 RRT centers. Data for Canada exclude Quebec. Data for France exclude Martinique. Data for Indonesia represent the West Java region. Data for Italy representative of 35% (7 out of 19 regions) of ESRD patient population. Japan includes dialysis patients only. Data from Latvia representative of 80% of ESRD patient population. Data for Serbia approx. 30% less than reported in 2015 due to incomplete reporting. United Kingdom^: England, Wales, Northern Ireland (Scotland data reported separately). For graph (a), data for Spain include patients 15-64 years old, and data for the United States include patients 22-64 years old. Abbreviations: ESRD, end-stage renal disease; fr., French; 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, 2016



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. Data for Belarus from 43 of 51 RRT centers. Data for Canada exclude Quebec. Data for France exclude Martinique. Data for Indonesia represent the West Java region. Data for Italy representative of 35% (7 out of 19 regions) of ESRD patient population. Japan includes dialysis patients only. Data from Latvia representative of 80% of ESRD patient population. Data for Serbia approx. 30% less than reported in 2015 due to incomplete reporting. United Kingdom^: England, Wales, Northern Ireland (Scotland data reported separately). Abbreviations: ESRD, end-stage renal disease; Rep., Republic; RRT, renal replacement therapy; sp., speaking. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

Prevalence of ESRD

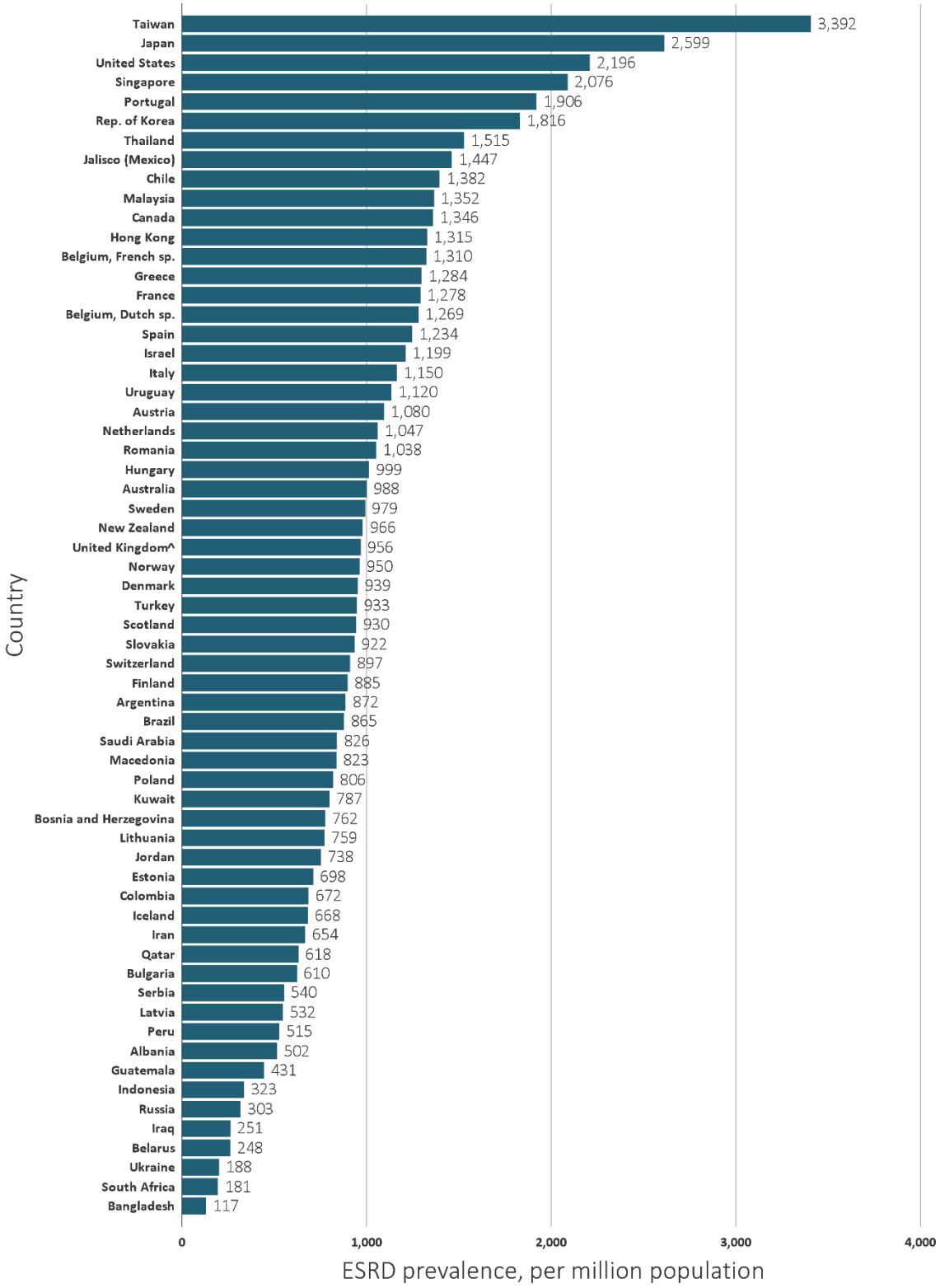
In 2016, 2,455,004 patients were treated for ESRD across all reporting countries. The number was by far the highest in the United States, with 709,501 treated patients accounting for 29% of the total, and followed by Japan and Brazil with approximate cohorts of 328,000 and 180,000 prevalent patients (*Reference Table N.4.a*). Iran, Spain, the United Kingdom., Turkey, Taiwan, France, the Republic of Korea, and Thailand reported between 52,000 and 100,000 treated ESRD patients in 2016, while all other countries indicated smaller populations (range 224 in Iceland to 44,544 in Russia, with approximately 9,800 treated patients in the median country of Hungary).

In 2016, ESRD prevalence varied nearly 30-fold across represented countries (Figure 11.9). Taiwan reported the highest treated ESRD prevalence of 3,392 PMP, followed by Japan (2599 PMP) and the United States (2196 PMP). Singapore, Portugal, the Republic of Korea, Thailand, and the Jalisco region of Mexico also reported a very high prevalence, ranging from 1447-2076 PMP. In just over one-quarter 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, Colombia, and Brazil, and the Middle Eastern nations of Qatar, Iran, Kuwait, Jordan, and Saudi Arabia. Lowest prevalence rates ranging from 117 to 540 PMP were reported by Bangladesh, South Africa, Ukraine, Belarus, Iraq, Russia, Indonesia, Guatemala, Albania, Peru, Latvia, Serbia, and Bulgaria.

Although ESRD incidence rates have been stable or decreasing in many countries during recent years, ESRD prevalence PMP has steadily increased in all 36 countries that provided data from 2003 to 2015 and/or 2016 (Figures 11.11.a and 11.11.b). Over this period, the median percent increase in ESRD prevalence was 43%, varying from an 11% to a 548% rise. These trends support 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 2003/04 and 2015/16 were observed in the Jalisco region of Mexico, Thailand, and the Philippines, ranging from 213% to 548%, followed by rises of 113% to 212% in the Republic of Korea, Turkey, Brazil, Malaysia, and Russia. In the United States, ESRD prevalence increased 42% overall from 2003/04 to 2015/16, with a nearly average annual increase of 53.3 patients PMP per year. When overall absolute yearly change in ESRD prevalence PMP was calculated for each country over the time period from 2003 to 2016 (Figure 11.11b), average annual increases in prevalence PMP ranged from 4 in Bangladesh to 122 in Taiwan (median average rise = 26 PMP/year). The 8 countries with the highest average annual increases in ESRD prevalence were Taiwan (122), Thailand (106), the Jalisco region of Mexico (84), the Republic of Korea, Malaysia, Japan, and Singapore (61-76), and the United States (53).

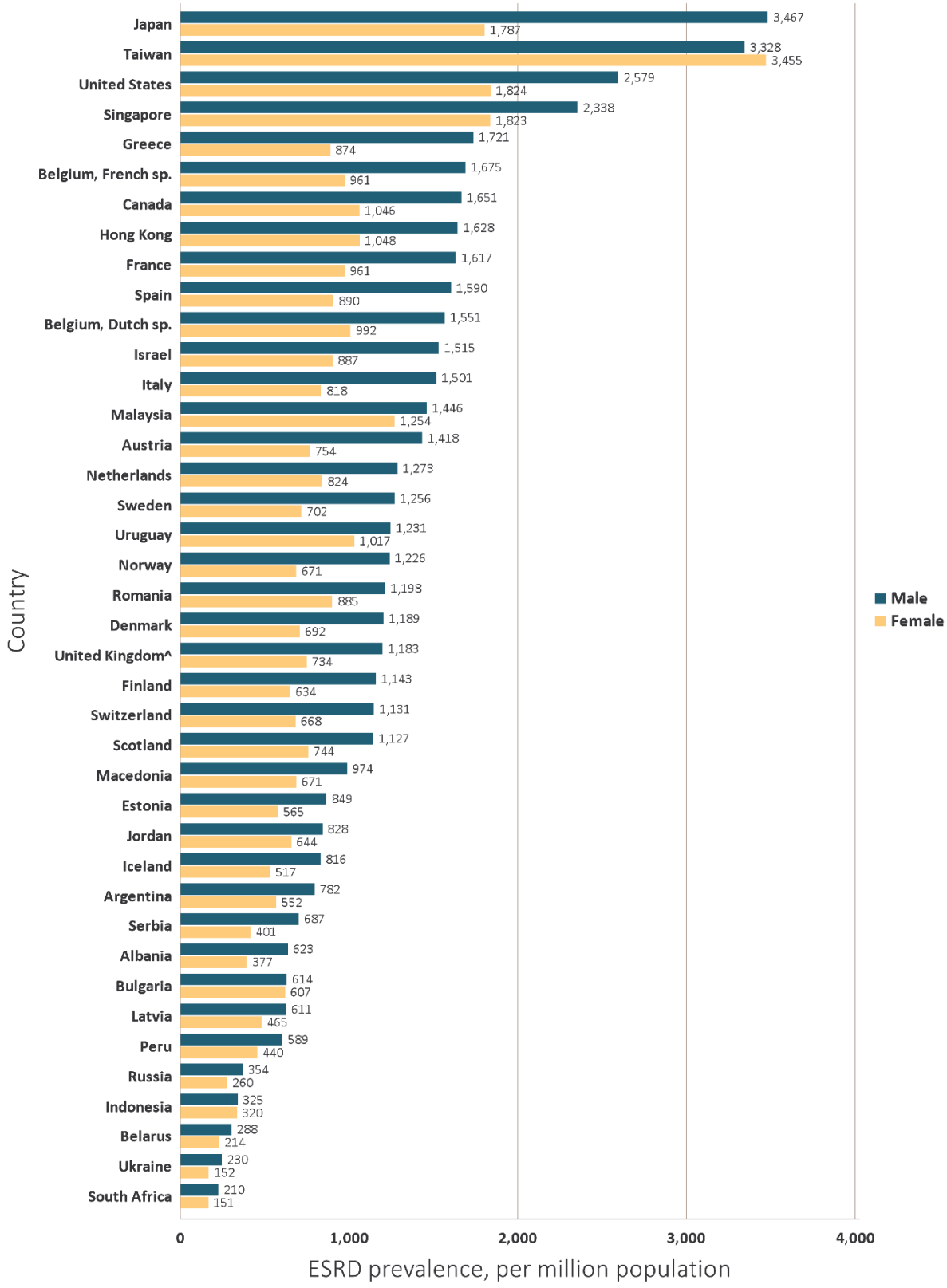
Similar to incidence of ESRD typically being higher among males than females in nearly every country, prevalence of ESRD PMP was higher for males than females in every country except in Taiwan (Figure 11.10).

vol 2 Figure 11.9 Prevalence of treated ESRD (per million population), by country, 2016



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. Data for Belarus from 43 of 51 RRT centers. Data for Canada exclude Quebec. Data for France exclude Martinique. Data for Guatemala exclude pediatric ESRD patients and patients receiving non-institutional RRT. Data for Indonesia represent the West Java region. Data for Italy representative of 35% (7 out of 19 regions) of ESRD patient population. Data from Latvia representative of 80% of ESRD patient population. Prevalent functioning graft data for Slovakia only available for prevalent transplant patients. United Kingdom^: England, Wales, Northern Ireland (Scotland data reported separately). Abbreviations: ESRD, end-stage renal disease; Rep., Republic; RRT, renal replacement therapy; 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, 2016



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. Data for Belarus from 43 of 51 RRT centers. Data for Canada exclude Quebec. Data for France exclude Martinique. Data for Indonesia represent the West Java region. Data for Italy representative of 35% (7 out of 19 regions) of ESRD patient population. Data from Latvia representative of 80% of ESRD patient population. Prevalent functioning graft data for Slovakia only available for prevalent transplant patients. United Kingdom^: England, Wales, Northern Ireland (Scotland data reported separately). Abbreviations: ESRD, end-stage renal disease; Rep., Republic; RRT, renal replacement therapy; 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, 2003-2016

(a) Ten countries having the highest percentage rise in ESRD prevalence rate in 2003/04 versus that in 2015/16, plus the United States

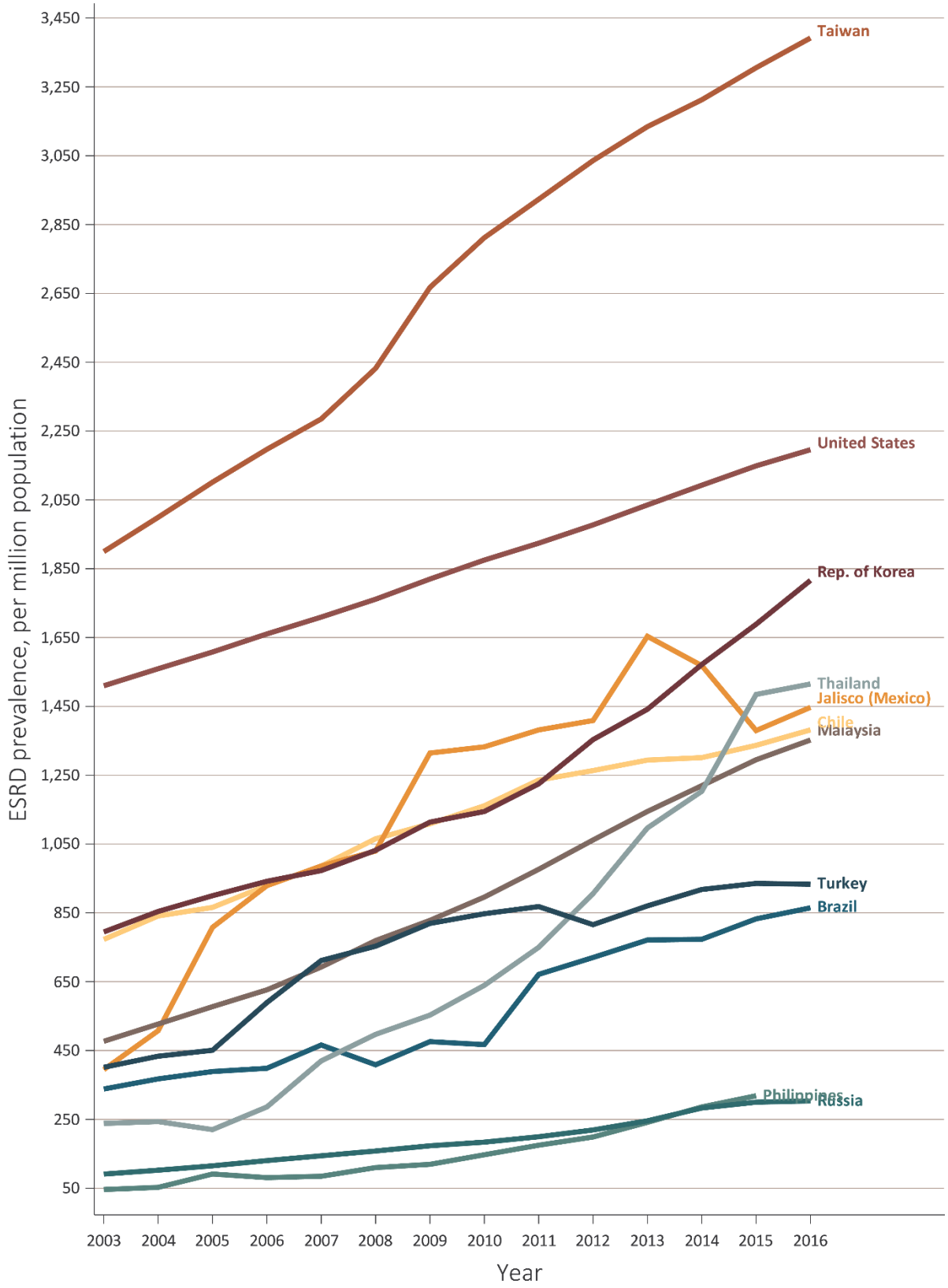
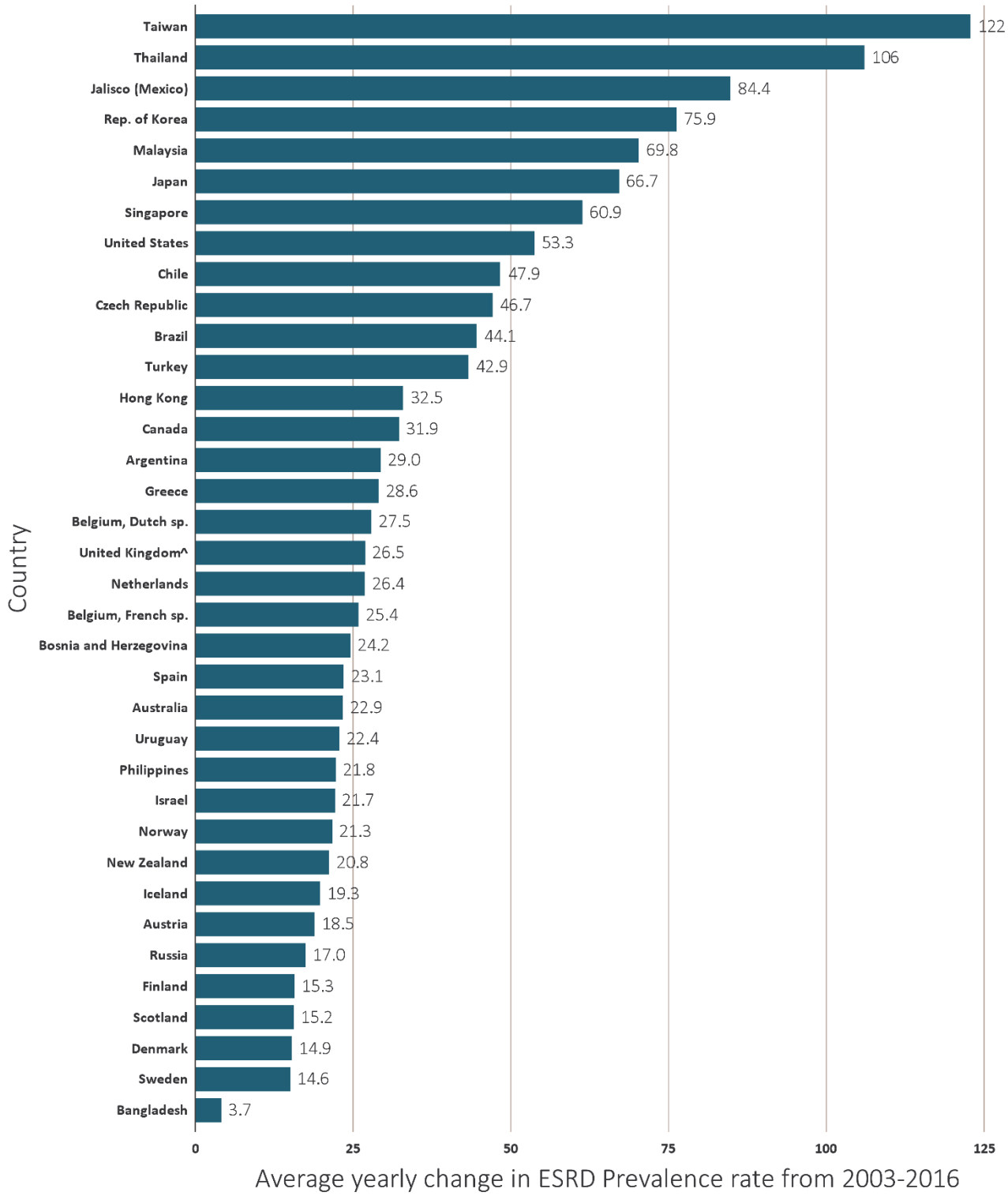


Figure 11.11 continued on next page

vol 2 Figure 11.11 Trends in the prevalence of treated ESRD per million population, by country, 2003-2016 (continued)

(b) Average yearly change in ESRD prevalence rate from 2003-2016



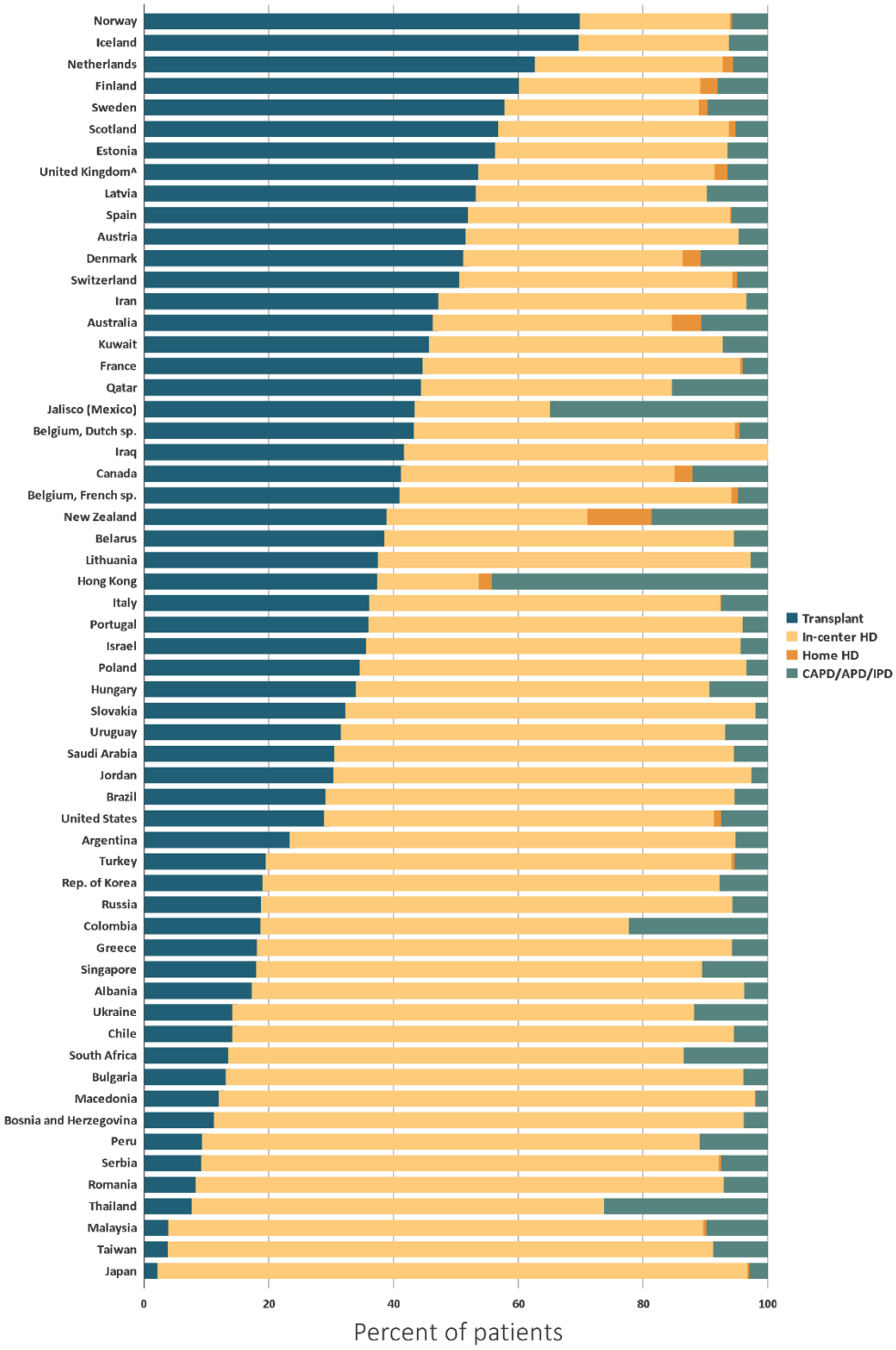
Data source: Special analyses, USRDS ESRD Database. (a)*Ten countries having the highest percentage rise in ESRD prevalence: 2015/16 versus that in 2003/04, plus the United States ESRD prevalence is unadjusted. United States is shown for comparison purposes. (b) Estimates derived from linear regression. Abbreviation: ESRD, end-stage renal disease Rep., Republic; sp., speaking;. 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 varies considerably across countries. Dialysis is more commonly utilized than kidney transplantation as a therapeutic approach for treatment of ESRD in the majority of countries. 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 2016, transplantation for patients with ESRD ranged from less than 10% in Peru, Serbia, Romania, Thailand, Malaysia, Taiwan, and Japan to greater than 50% in the Nordic countries of Denmark, Finland, Iceland, Norway, and Sweden, and in Estonia, Latvia, the Netherlands, Switzerland, the United Kingdom (including Scotland), Spain, and Austria (Figure 11.12). Not surprisingly, countries with the highest proportion of kidney transplants among ESRD patients also tended to have lower treated ESRD incidence rates of approximately 85 (Estonia) to 142 (Spain) PMP/year (Figure 11.2). Hong Kong, the Jalisco region of Mexico, Iceland, and Norway had the lowest use of in-center HD (16% to 24%) to treat ESRD patients (Figure 11.12); this was achieved through a combination of greater use of kidney transplantation and/or home dialysis.

vol 2 Figure 11.12 Percentage distribution of type of renal replacement therapy modality used by ESRD patients, by country, in 2016



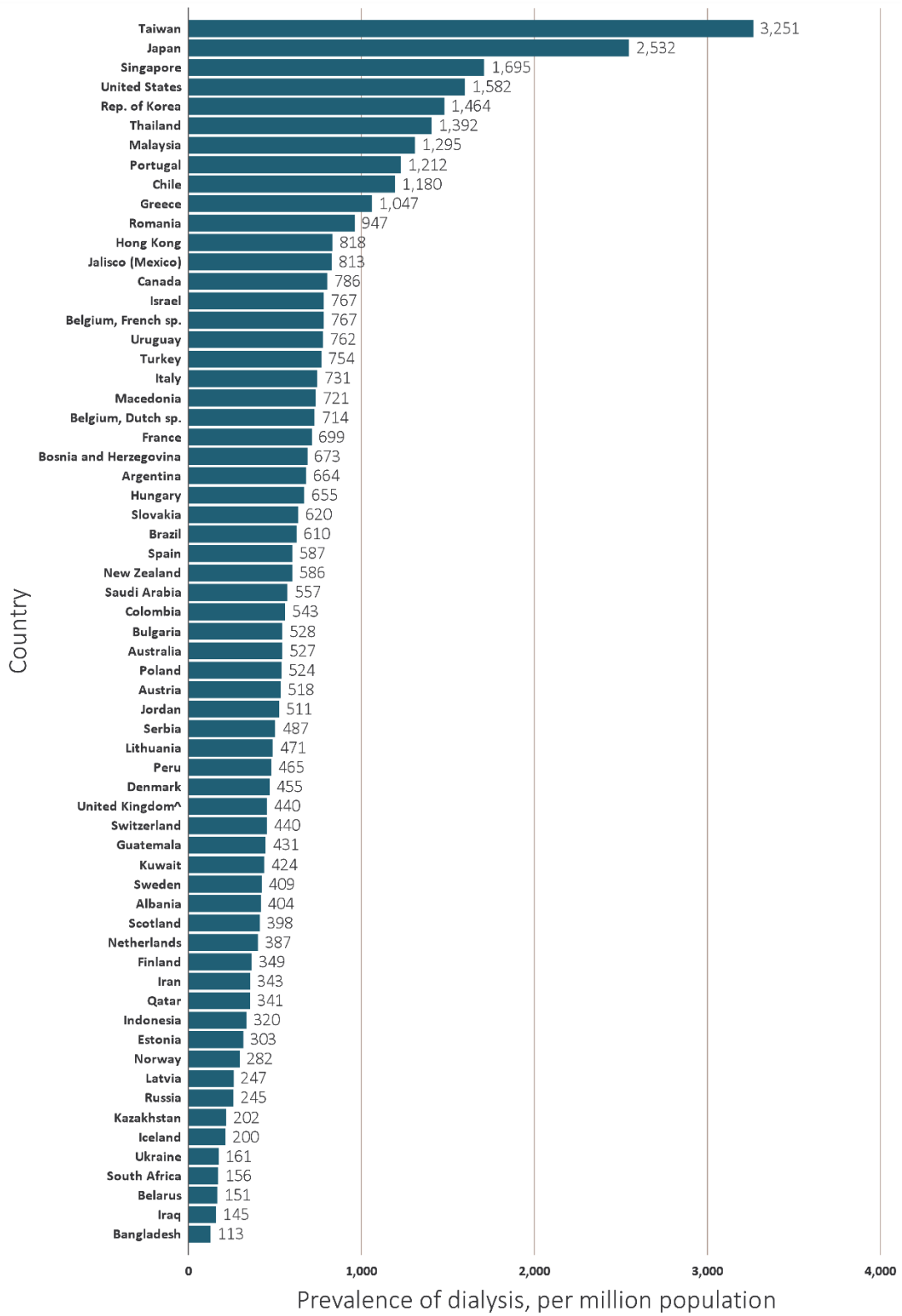
Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. Denominator is calculated as the sum of patients receiving HD, PD, Home HD, or treated with a functioning transplant; does not include patients with other/unknown modality. Data for Belarus from 43 of 51 RRT centers. Data for Canada exclude Quebec. Data for France exclude Martinique. Data for Indonesia represent the West Java region. Data for Italy representative of 35% (7 out of 19 regions) of ESRD patient population. Data from Latvia representative of 80% of ESRD patient population. Prevalent functioning graft data for Slovakia only available for prevalent transplant patients. United Kingdom^: England, Wales, Northern Ireland (Scotland data reported separately). Abbreviations: CAPD, continuous ambulatory peritoneal dialysis; APD, automated peritoneal dialysis; IPD, intermittent peritoneal dialysis; ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Rep., Republic; RRT, renal replacement therapy; sp., speaking. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

Dialysis Therapy for ESRD

In 2016, the number of ESRD patients receiving dialysis PMP varied nearly 30-fold across countries, from 113 to 200 in Bangladesh, Iraq, Belarus, South Africa, Ukraine, and Iceland to 2,532 in Japan and 3,251 in Taiwan (Figure 11.13). Some countries have experienced very large rises in the prevalence of dialysis since 2003/04, with an approximate increase of 486% in the Philippines and 551% in Thailand, and a rise ranging from 119% to 231% reported by the Republic of Korea, Malaysia, and Russia (Figure 11.14.a, *Reference Table N.6.b*).

When overall absolute yearly change in the prevalence of number of dialysis patients PMP was calculated for each country over the time period from 2003 to 2016, average annual increases in dialysis patients PMP ranged from -0.6 in Denmark to 109 in Taiwan (median average rise = 16 PMP/year) (Figure 11.14.b). The 6 countries with the highest yearly change in the prevalence of number of dialysis patients PMP from 2003-2016 were Taiwan (109) and Thailand (98), followed by Malaysia, the Republic of Korea, Japan, and Singapore (54-70 PMP/year). 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 2016. However, in 2016, PD was used by 71% of dialysis patients in Hong Kong, by 61% in the Jalisco region of Mexico, and by 57% of patients in Guatemala (Figure 11.15). Furthermore, 27-30% PD use was reported in Qatar, Colombia, Thailand, and New Zealand with 18% to 22% PD use seen in Norway, Finland, Australia, Iceland, Canada, Latvia, 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, Canada, Chile, Oman, Spain, Thailand, and the United States. (*Reference Table N.7.e*). In contrast, PD use has declined over this same time period in countries such as Australia, Belgium, Bosnia and Herzegovina, Brazil, Colombia, Finland, France, Greece, Hong Kong, Israel, Japan, the Netherlands, New Zealand, the Philippines, the Republic of Korea, Romania, Scotland, Singapore, Sweden, Turkey, and the United Kingdom. In 2016, home HD therapy was provided to 9% and 17% of dialysis patients in Australia and New Zealand (Figure 11.15). Home HD was also used by 2% to 7% of dialysis patients in the United States, the French-speaking region of Belgium, Scotland, Hong Kong, Sweden, the United Kingdom, the Netherlands, Canada, Denmark, and Finland. However, in all other countries, home HD was either not provided, or was used by fewer than 2% of dialysis patients.

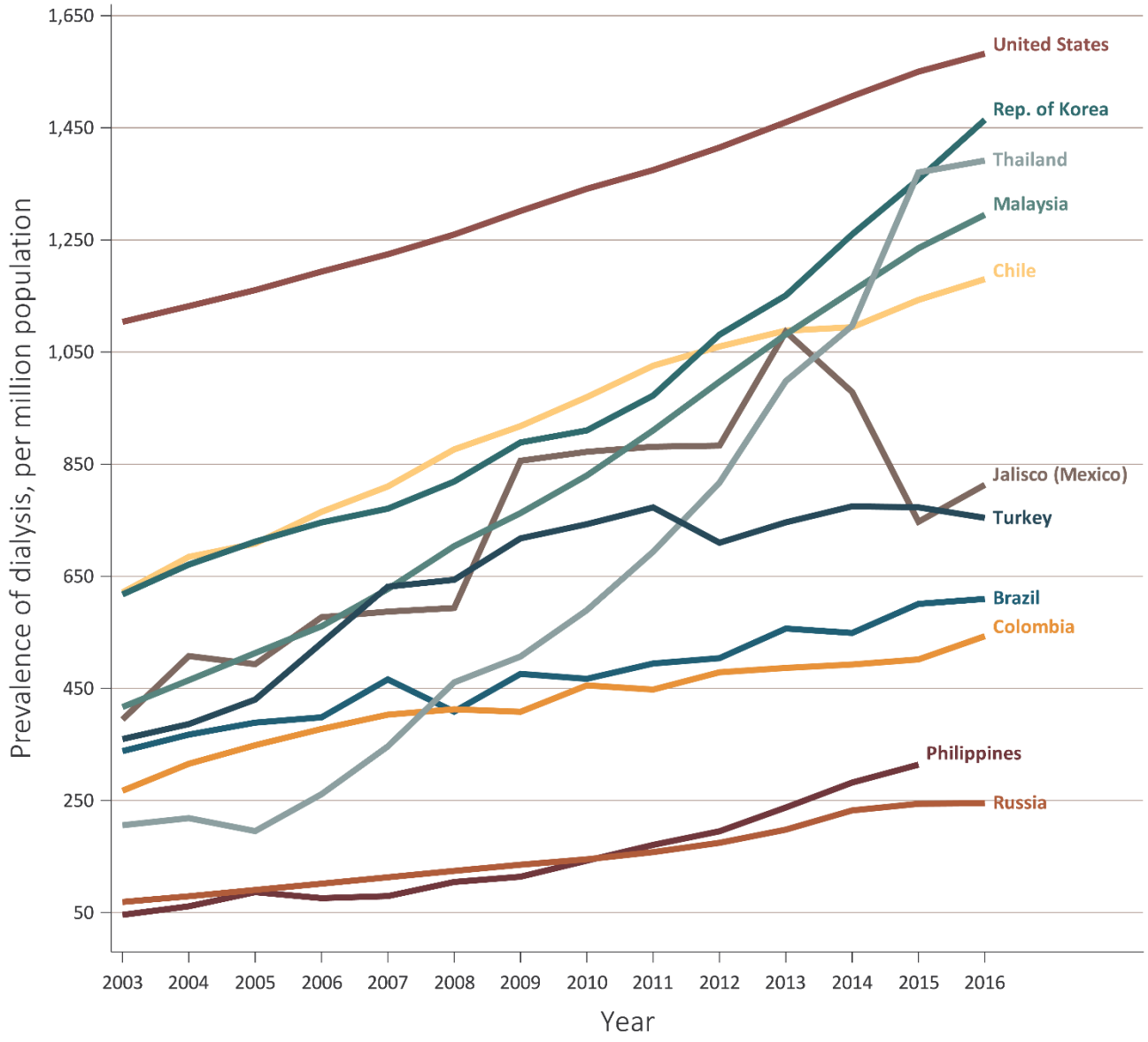
vol 2 Figure 11.13 Prevalence of dialysis (per million population), by country, 2016



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. ESRD prevalence is unadjusted and reflects prevalence at the end of 2016. Data for Belarus from 43 of 51 RRT centers. Data for Canada exclude Quebec. Data for France exclude Martinique. Data for Guatemala exclude pediatric ESRD patients and patients receiving non-institutional RRT. Data for Indonesia represent the West Java region. Data for Italy representative of 35% (7 out of 19 regions) of ESRD patient population. Data from Latvia representative of 80% of ESRD patient population. United Kingdom^: England, Wales, Northern Ireland (Scotland data reported separately). Abbreviation: ESRD, end-stage renal disease; Rep., Republic; RRT, renal replacement therapy; 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, 2003-2016

(a) Ten countries having the highest percentage rise in dialysis prevalence rate in 2003/04 versus that in 2015/16, plus the United States



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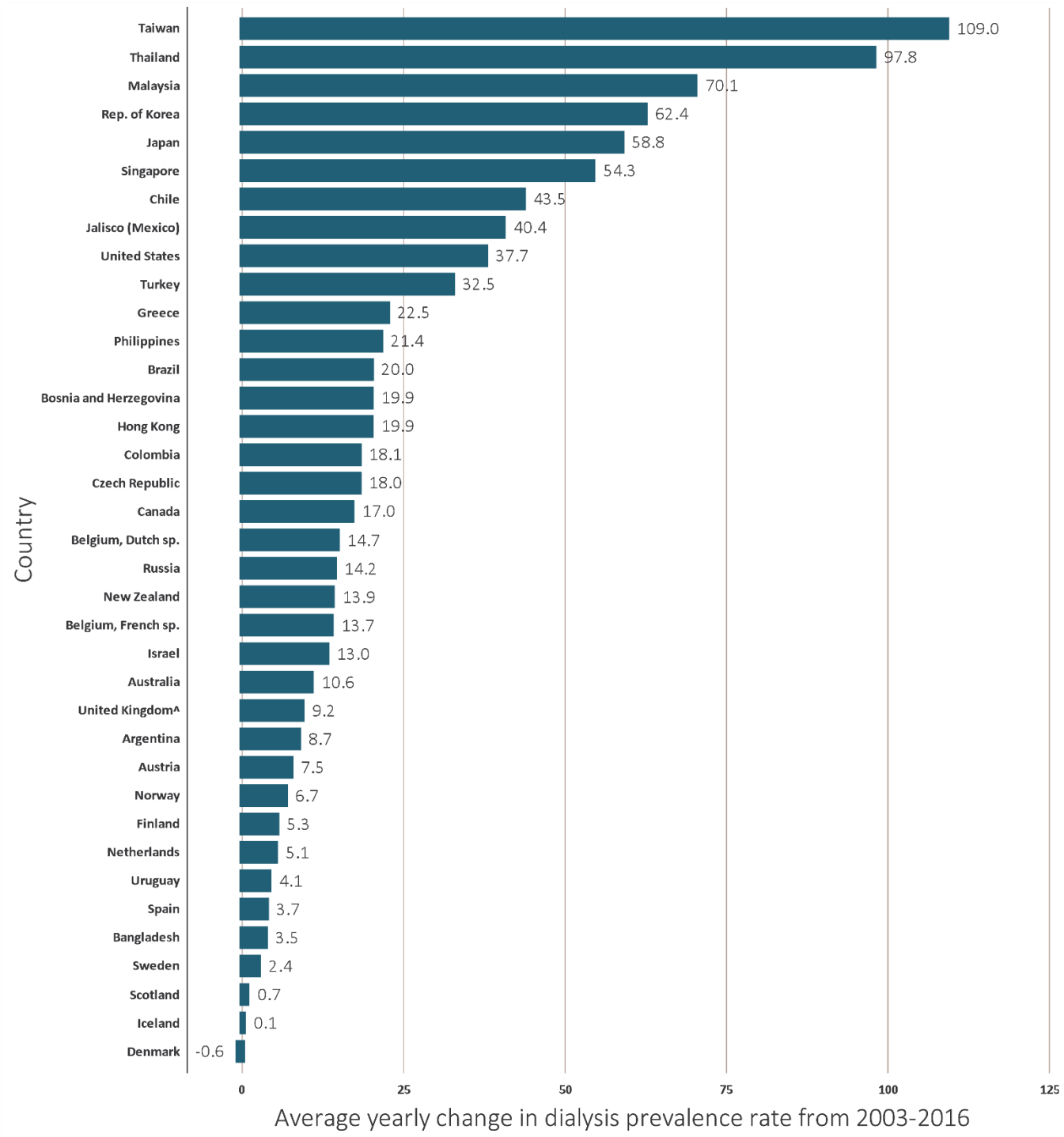
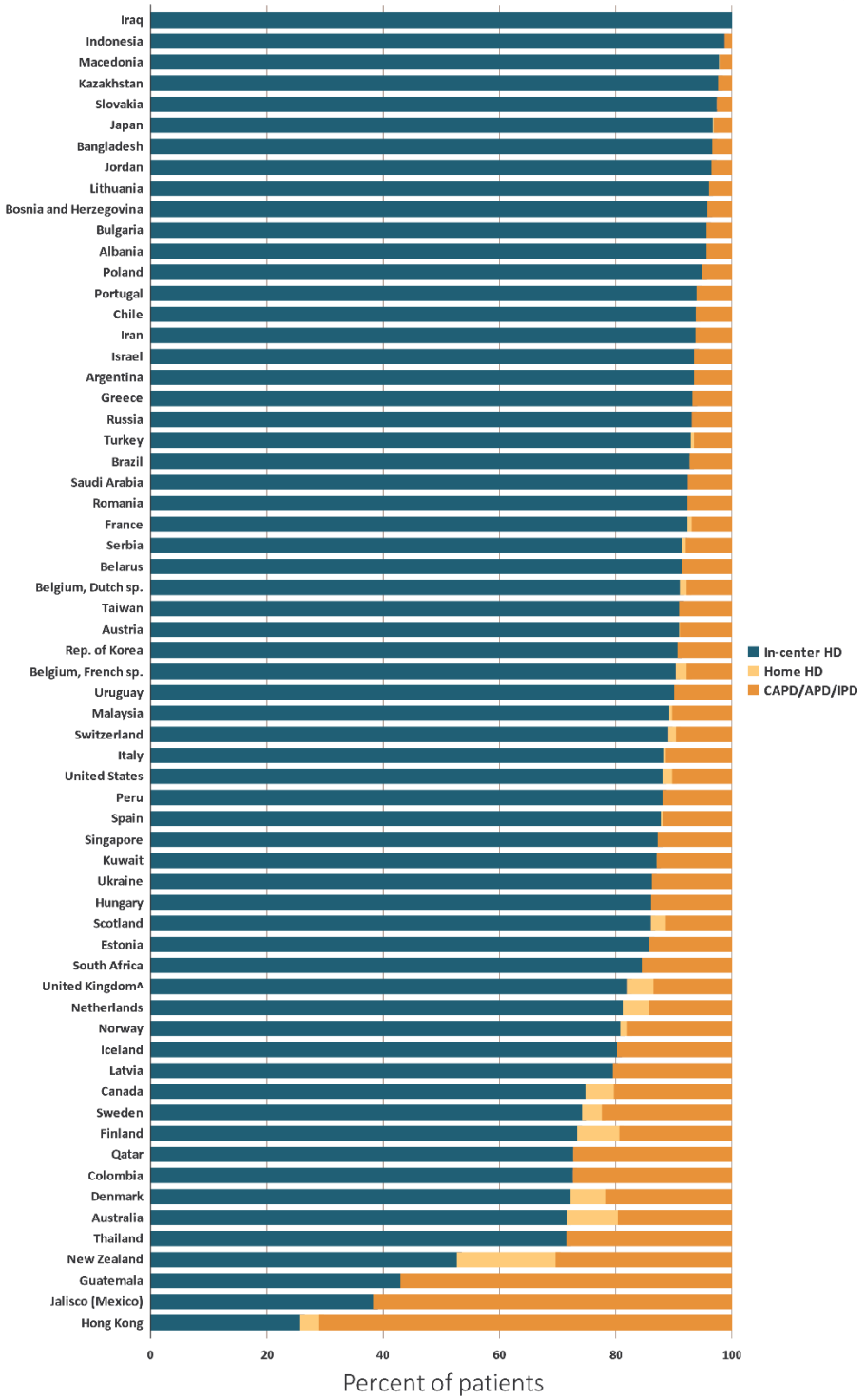
vol 2 Figure 11.14 Trends in the prevalence of dialysis per million population, by country, 2003-2016 (continued)

(b) Average yearly change in dialysis prevalence rate from 2003-2016



Data source: Special analyses, USRDS ESRD Database. (a) Ten countries having the highest percentage rise in dialysis prevalence: 2015/16 versus that in 2003/04, plus the United States. The prevalence is unadjusted and reflects prevalence of dialysis at the end of each year. (b) Estimates derived from linear regression. Abbreviation: ESRD, end-stage renal disease; Rep., Republic; RRT, renal replacement therapy; sp., speaking. 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), 2016



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. Denominator was calculated as the sum of patients receiving HD, PD, Home HD; does not include patients with other/unknown modality. Data for Belarus from 43 of 51 RRT centers. Data for Canada exclude Quebec. Data for France exclude Martinique. Data for Guatemala exclude pediatric ESRD patients and patients receiving non-institutional RRT. Data for Indonesia represent the West Java region. Data for Italy representative of 35% (7 out of 19 regions) of ESRD patient population. Data from Latvia representative of 80% of ESRD patient population. United Kingdom^: England, Wales, Northern Ireland (Scotland data reported separately). Abbreviations: APD, automated peritoneal dialysis; CAPD, continuous ambulatory peritoneal dialysis; ESRD, end-stage renal disease; HD, hemodialysis; IPD, intermittent peritoneal dialysis; PD, peritoneal dialysis; Rep., Republic; RRT, renal replacement therapy; sp., speaking. 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 1,000 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 United States ranks third in the world in terms of transplants PMP, yet ranks 39th of 61 reporting countries in transplants per 1,000 dialysis patients. This may be due, in part, to the high numbers of dialysis patients in the United States.

Kidney transplant rates varied more than 80-fold across countries, from less than 1 to 79 PMP, in 2016 (Figure 11.16.a). The highest kidney transplant rate was reported for the Jalisco region of Mexico (79 PMP), followed by Spain (64 PMP) and the United States (62 PMP). Kidney transplant rates have now been provided for the first time for all of Mexico in this international chapter. Transplants in the Jalisco region (79 PMP) make up approximately one-fifth of all transplants in Mexico, which has an overall transplant rate of 25 PMP. Kidney transplant rates ranged from 30-60 kidney transplants PMP for 44% of countries, 11-29 transplants PMP for 27% of countries, and 1–10 PMP for the remaining 25%. Countries reporting the lowest rates of kidney transplantation, at 1-5 PMP, included Bangladesh, Malaysia, Ukraine, Macedonia, South Africa, the Philippines, Peru, and Bulgaria.

Kidney transplant rates when expressed per 1,000 dialysis patients also varied greatly across countries, from 2 to 171 in 2016 (Figure 11.16.b). The highest rates per 1,000 dialysis patients occurred in Kazakhstan (171), Belarus (167), Norway (162), the Netherlands (152), Finland (136), Scotland (119), Spain (110), and Latvia (110). Transplant rates of 90 to 108 per 1,000 dialysis patients were reported in Iran, Austria, Kuwait, the Jalisco region of Mexico, Denmark, Sweden, Estonia, and the United Kingdom Twenty-one percent of reporting countries reported rates of 53 to 86 per 1,000 dialysis patients, 21% had rates of 30-48, and the remaining 30% of countries reported rates of less than 30 transplants per 1,000 dialysis patients in 2016. During 2016 in the United States, 39 kidney transplants were performed per 1,000 dialysis patients.

Since 2003, some countries have shown a substantial increase in kidney transplant rates PMP (Figure 11.17.a). When comparing transplant rates in 2015/16 to 2003/04, Turkey, Russia, Iceland, Colombia, the Republic of Korea, Bangladesh, Thailand, Scotland, Brazil, and the Jalisco region of Mexico demonstrated the largest increases, from 46% to 394% (*Reference Table N.8*). Additionally, during the same period, kidney transplantation rates PMP were 22-45% higher in the Netherlands, Hong Kong, Australia, Canada, Denmark, the United Kingdom, Finland, Singapore, New Zealand, and the Dutch-speaking region of Belgium.

Overall absolute yearly change in kidney transplant rates PMP was calculated over the time period from 2003 to 2016 (Figure 11.17.b), and ranged from an average yearly decrease of 0.9 kidney transplants PMP per year in Greece to an average yearly increase of 3.2 kidney transplants PMP per year in Turkey (median country had an average yearly increase of 0.4 kidney transplants PMP per year). Other countries with high average yearly increases (range: 1.0 to 2.1) in the number of kidney transplants PMP per year from 2003-2016 were: the Republic of Korea, Scotland, the Netherlands, the United Kingdom, the Jalisco region of Mexico, Colombia, Denmark, Australia, Iceland, Canada, and Brazil.

vol 2 Figure 11.16 Kidney transplantation rate, by country, 2016

(a) Per million population

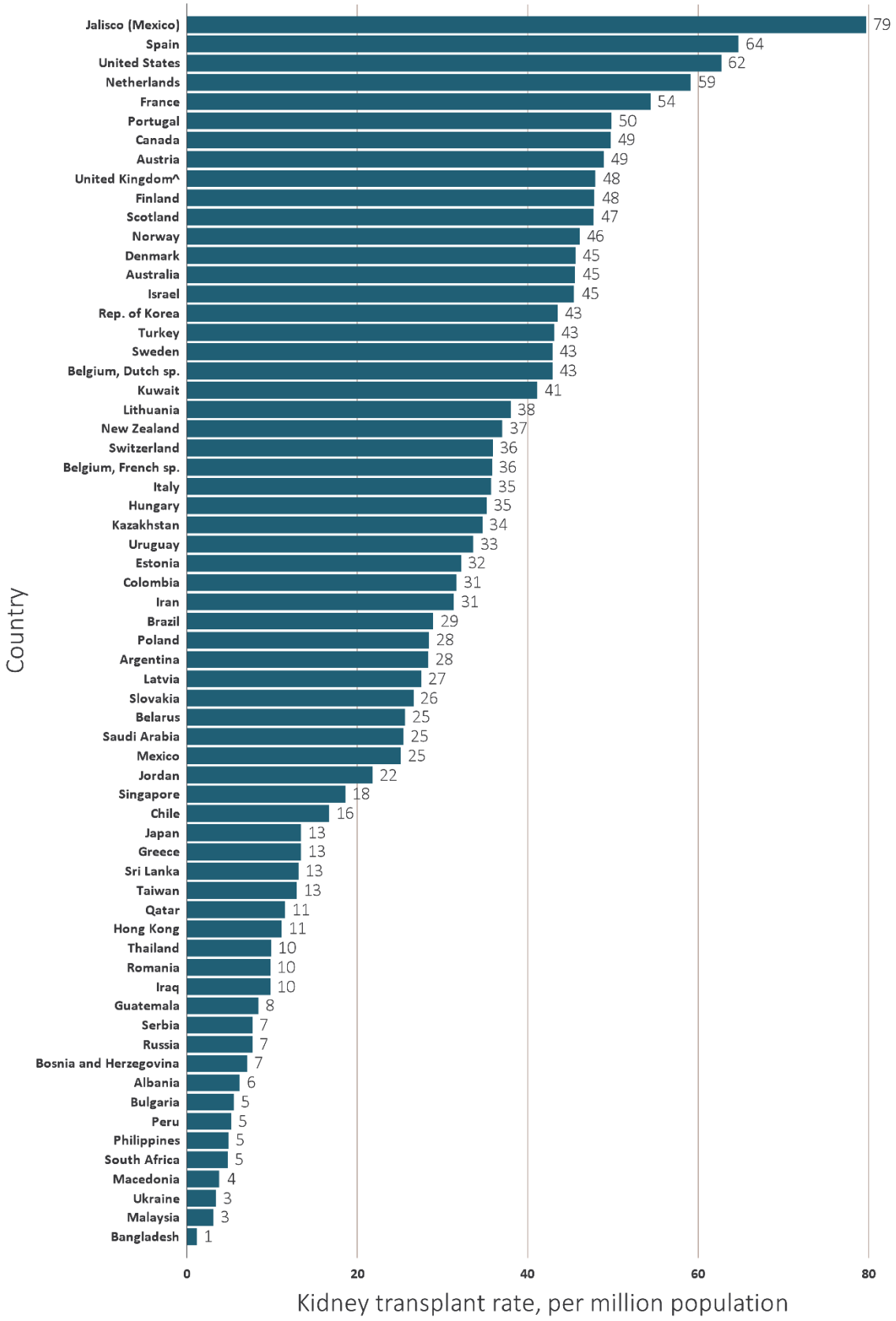
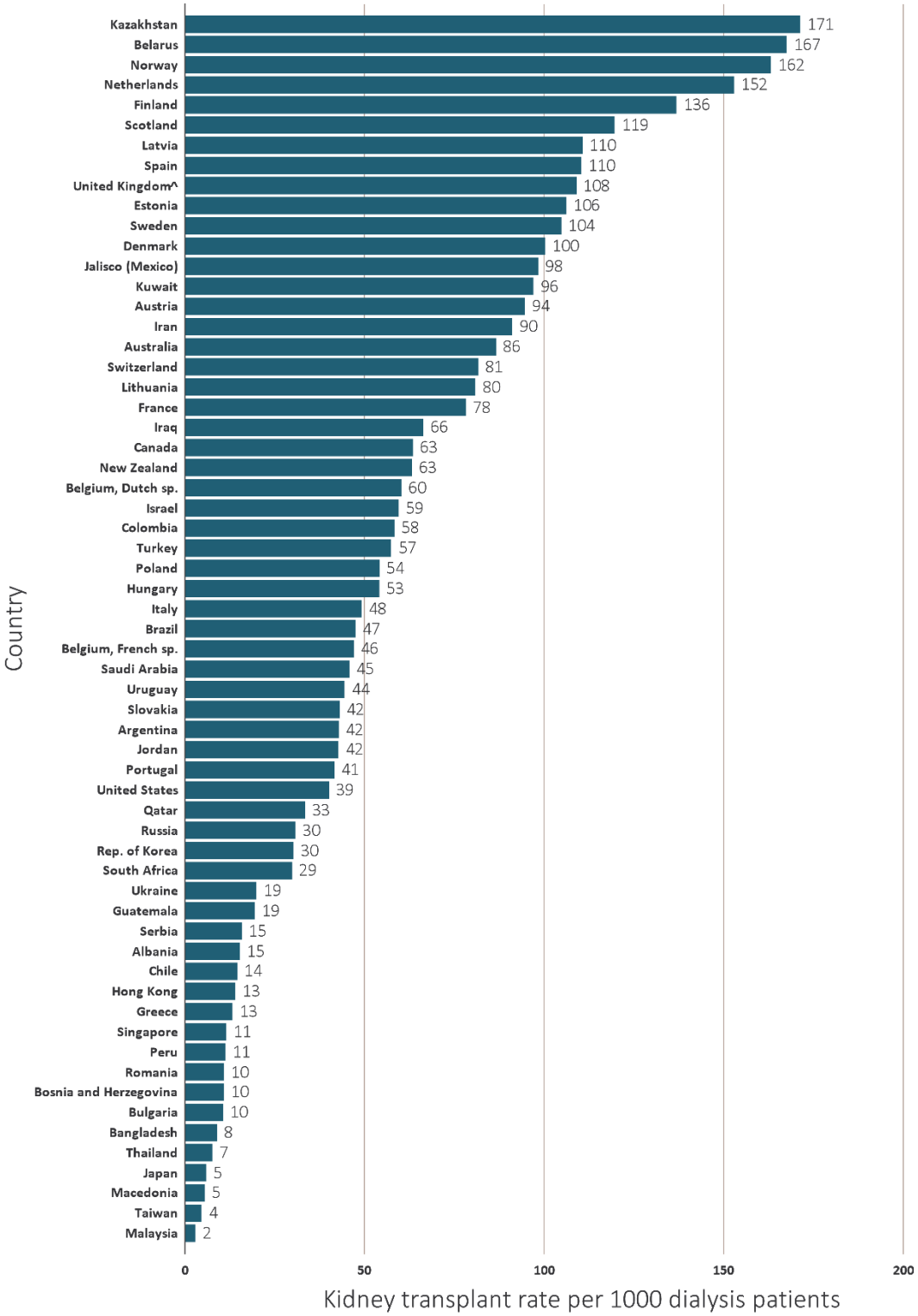


Figure 11.16 continued on next page

vol 2 Figure 11.16 Kidney transplantation rate, by country, 2016 (continued)

(b) Per 1,000 dialysis patients



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. All rates are unadjusted. Data for Belarus from 43 of 51 RRT centers. Data for Canada exclude Quebec. Data for France exclude Martinique. Data for Guatemala exclude pediatric ESRD patients and patients receiving non-institutional RRT. Data for Indonesia represent the West Java region. Data for Italy representative of 35% (7 out of 19 regions) of ESRD patient population. Overall transplantation rate for Mexico presented in addition to the rate for the Jalisco region of Mexico only. Data for Sri Lanka is from seven government hospitals. United Kingdom^: England, Wales, Northern Ireland (Scotland data reported separately). Abbreviation: ESRD, end-stage renal disease; Rep., Republic; RRT, renal replacement therapy; 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, 2016

(a) Ten countries having the highest percentage rise in kidney transplantation rate in 2003/04 versus that in 2015/16, plus the United States

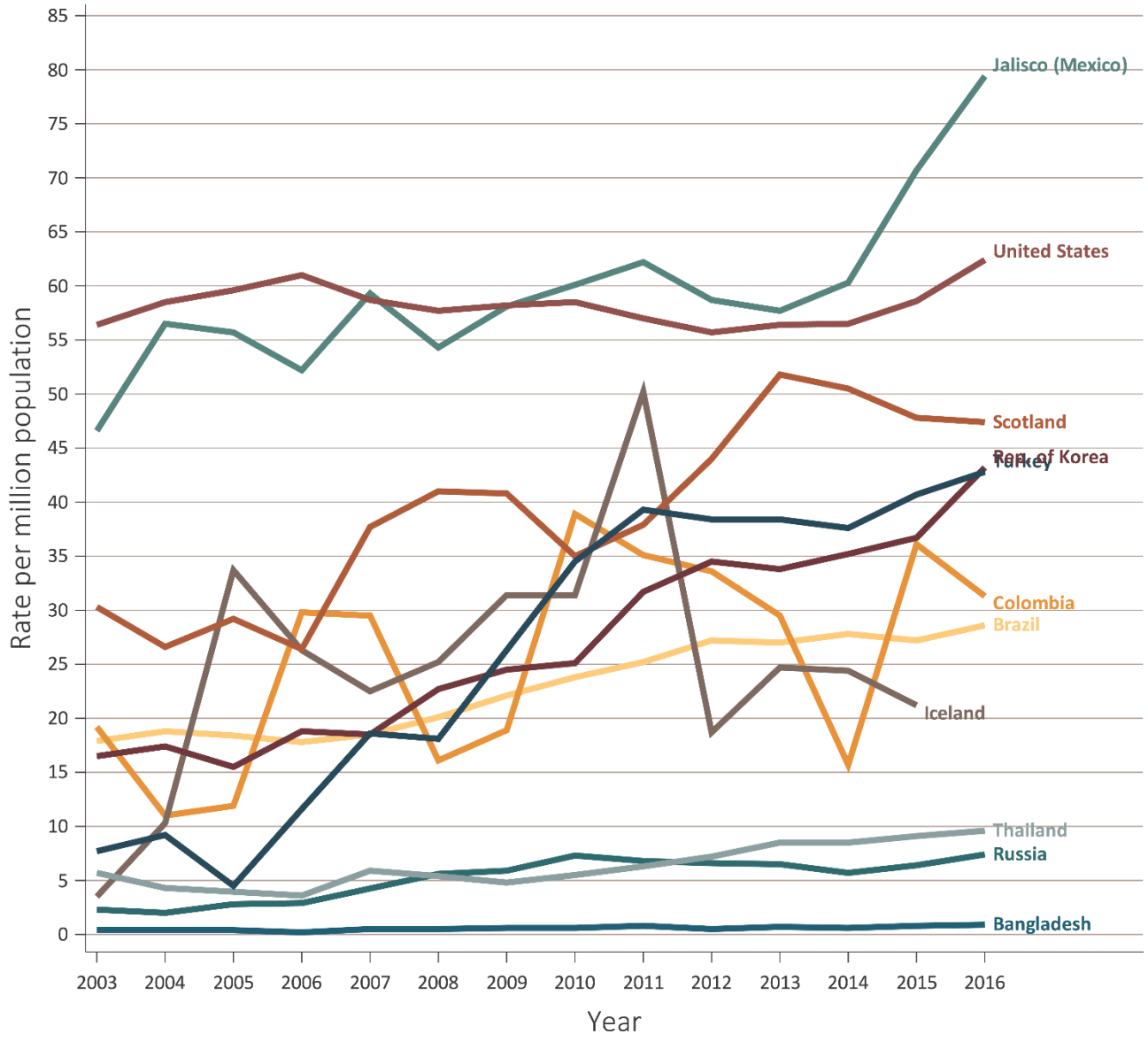
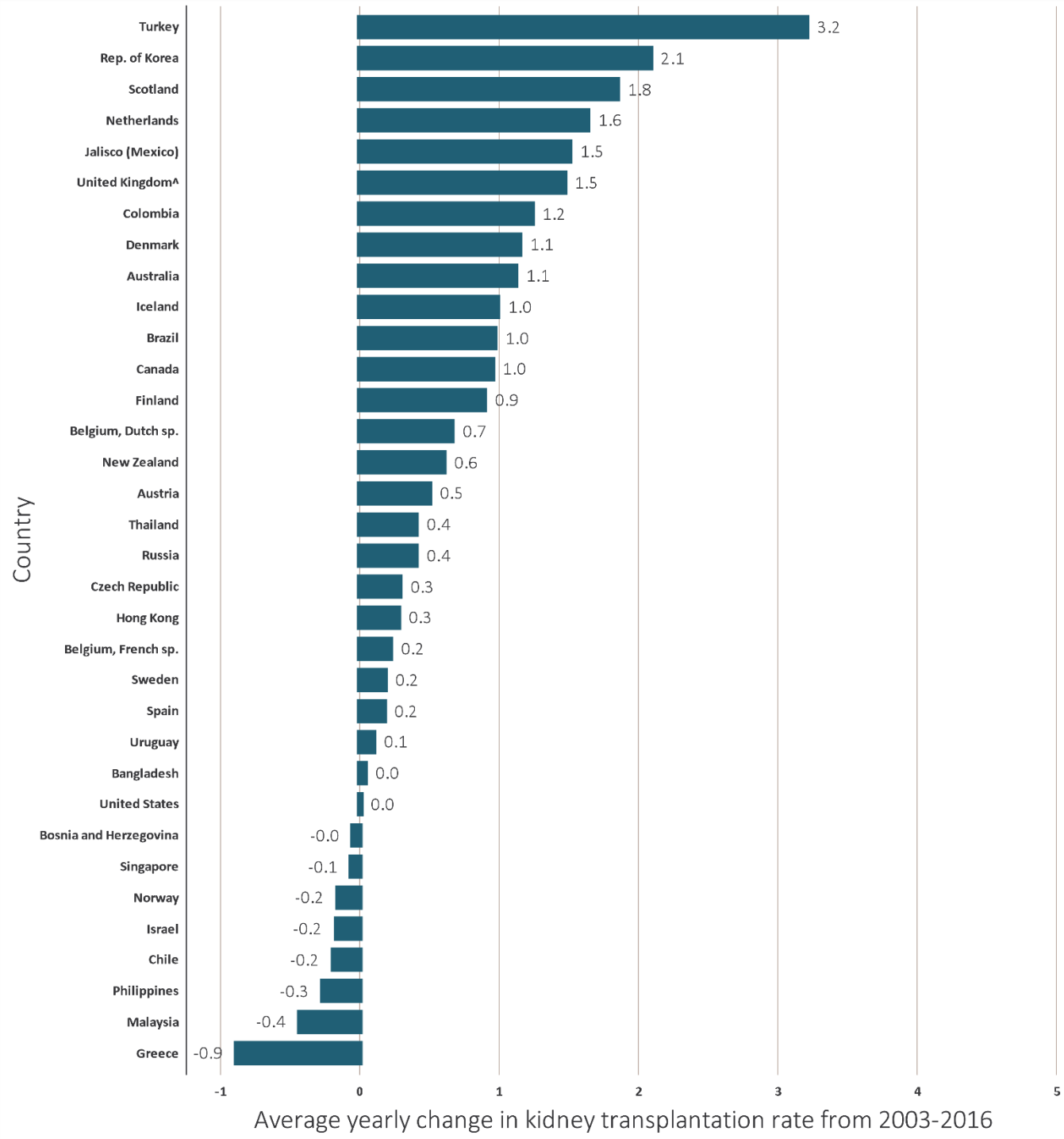


Figure 11.17 continued on next page.

vol 2 Figure 11.17 Trends in kidney transplantation rates per million population, by country, 2016 (continued)

(b) Average yearly change in kidney transplantation rate from 2003-2016



Data source: Special analyses, USRDS ESRD Database. (a) Ten countries having the highest percentage rise in kidney transplantation rate: 2015-2016 versus that in 2003-2004, plus the United States. All rates are unadjusted. (b) Estimates derived from linear regression. Abbreviations: ESRD, end-stage renal disease; Rep., Republic; sp., speaking. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

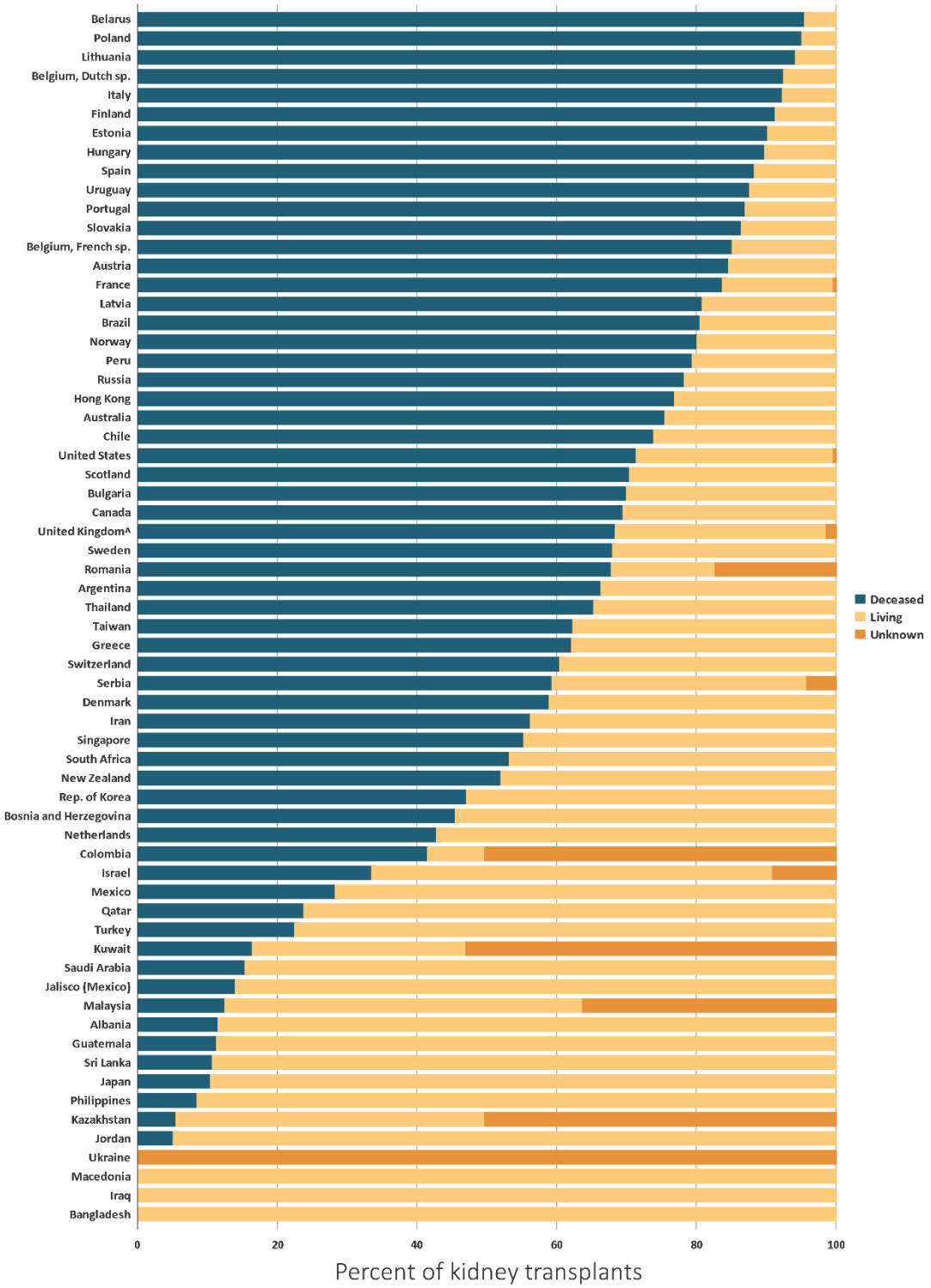
Large international differences were also seen in the types of kidney donors. Rates of living-donor transplantation ranged from 80%-100% in Saudi Arabia, the Jalisco region of Mexico, Albania, Guatemala, Sri Lanka, Japan, the Philippines, Jordan, Bangladesh, Iraq, and Macedonia to 10% or lower in Hungary, Estonia, Finland, Colombia, Italy, the Dutch-speaking region of Belgium, Lithuania, Poland, and Belarus (Figure 11.18). In nearly 67% of countries, donation from deceased individuals was the predominant form of kidney donation during 2016.

In 2016, Spain, the Netherlands, the United States, Norway, and Portugal reported the highest prevalence of ESRD patients living with a kidney transplant PMP, at 646 to 693 PMP (Figure 11.19). Twenty-five percent of countries indicated 457 to 634 prevalent ESRD patients PMP living with a kidney transplant, while the remaining 66% of countries were nearly evenly divided between having less than 202, or 208-432 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.

The average yearly change in the prevalence of ESRD patients living with a kidney transplant PMP from 2003 to 2016 was calculated for countries with available data (Figure 11.20). Results ranged from an average yearly decrease of 0.3 ESRD patients living with a kidney transplant PMP per year in Malaysia to an average yearly increase of 21 ESRD patients living with a kidney transplant PMP per year in the United Kingdom and the Netherlands (Sweden, the median country, had an average yearly increase of 12.2 ESRD patients living with a kidney transplant PMP per year). Other countries with higher average yearly increases (range: 16.4 to 19.4) in the number of ESRD patients living with a kidney transplant PMP per year from 2003-2016 were: Denmark, the United States, Spain, Iceland, and Uruguay.

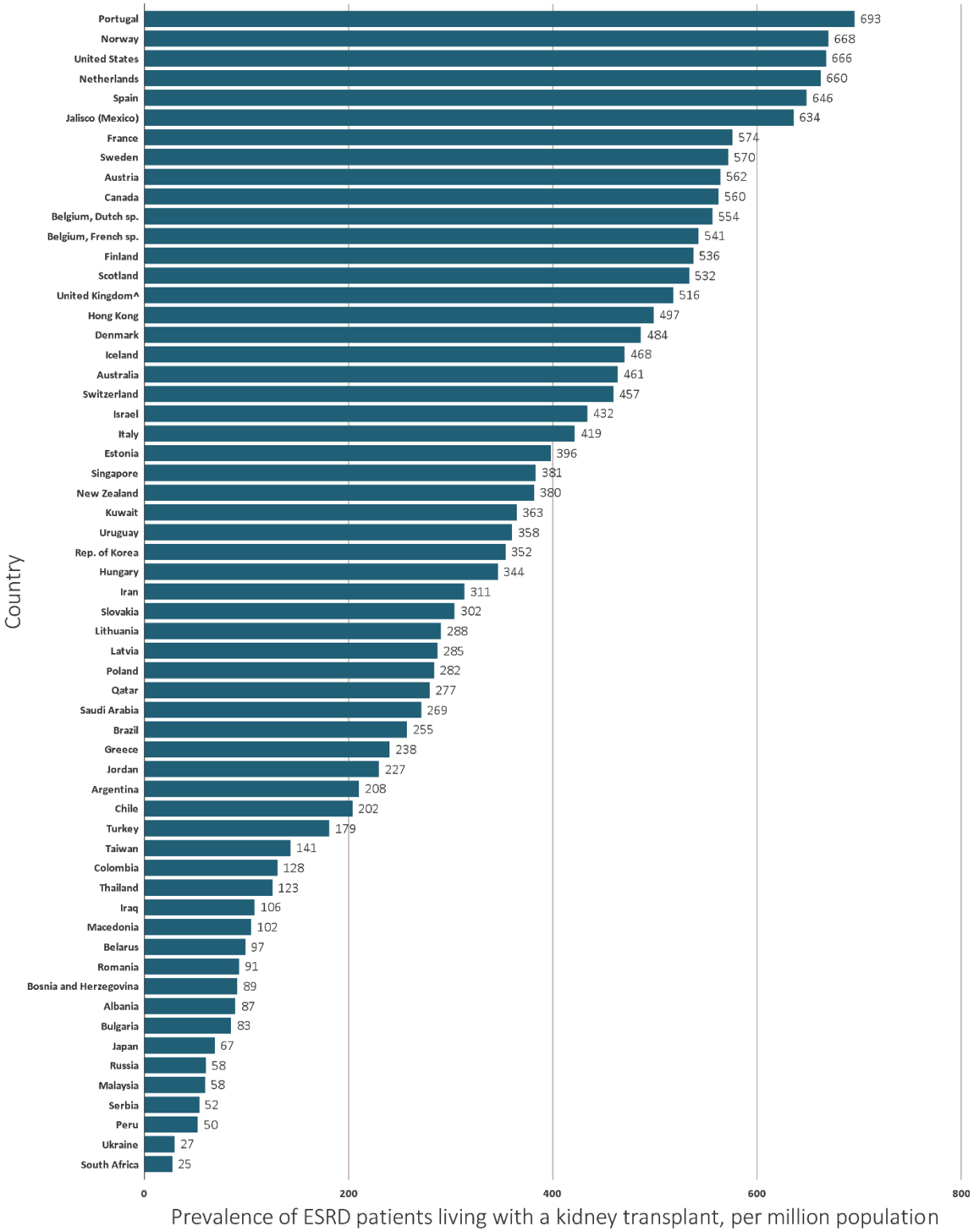
Earlier, in Figure 11.12, large variability was noted across countries in the percentage of ESRD patients living with a kidney transplant. From 2003-2016 the percentage of all ESRD patients living with a kidney transplant remained relatively constant within most countries (*Reference Table N.9.c*). However, some nations have demonstrated a continuing increase in the percentage of all ESRD patients living with a kidney transplant, particularly in: Australia, Bosnia and Herzegovina, Canada, Denmark, Iceland, the Netherlands, Scotland, Spain, Sweden, Turkey, the United Kingdom, and Uruguay. In contrast, the percentage of ESRD patients living with a kidney transplant declined substantially in Chile, France, Malaysia, the Philippines, Russia, Singapore, and Thailand from 2003-2016.

vol 2 Figure 11.18 Distribution of the percentage of kidney transplantations by kidney donor type and country, 2016



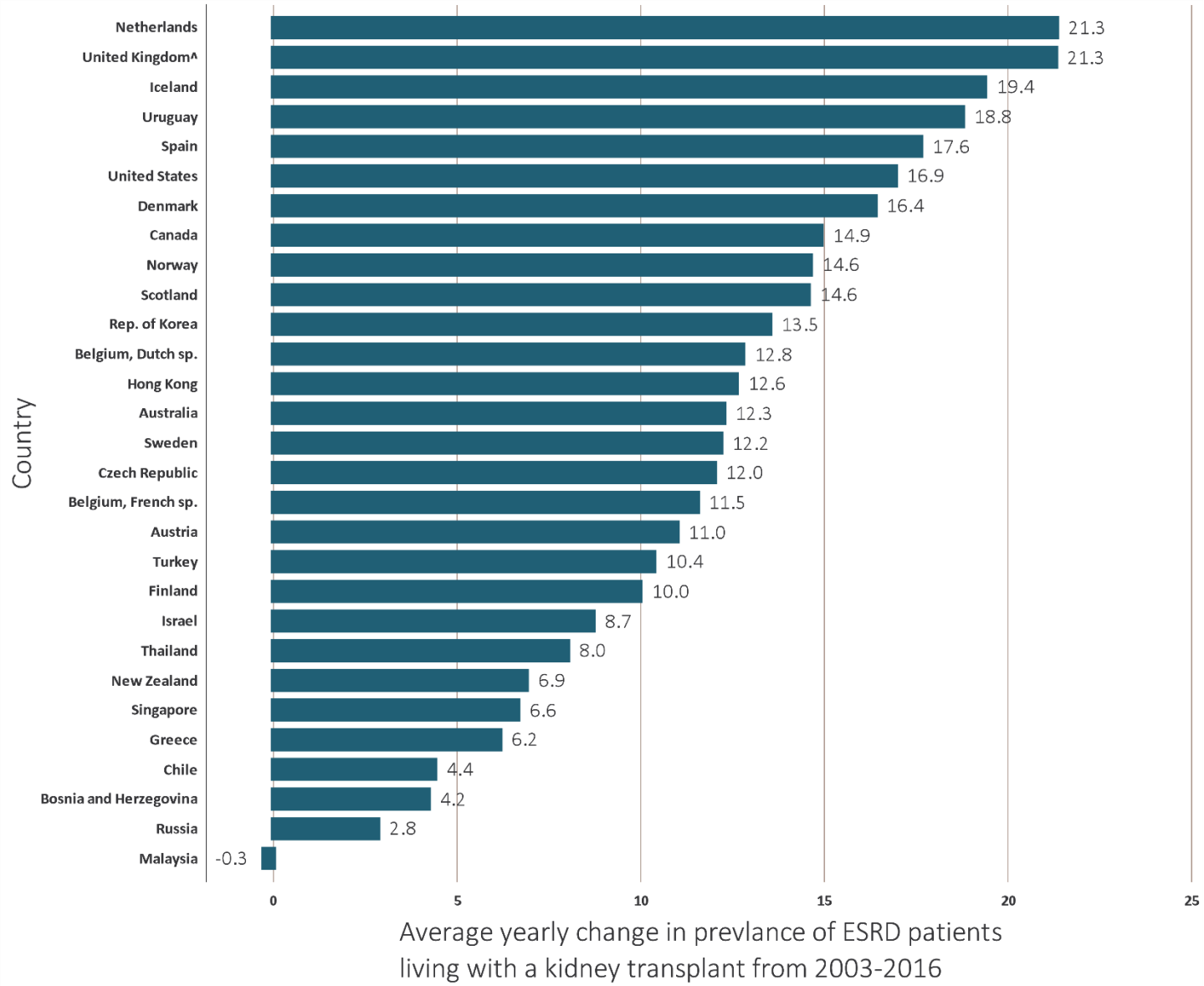
Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. Denominator is calculated as the sum of deceased, living-donor, and unknown transplants. Data for Belarus from 43 of 51 RRT centers. Data for Canada exclude Quebec. Data for France exclude Martinique. Data for Guatemala exclude pediatric ESRD patients and patients receiving non-institutional RRT. *Data for Indonesia represent the West Java region. Data for Italy representative of 35% (7 out of 19 regions) of ESRD patient population. Overall transplantation rate for Mexico presented in addition to the rate for the Jalisco region of Mexico only. Data for Sri Lanka is from seven government hospitals. United Kingdom^: England, Wales, Northern Ireland (Scotland data reported separately). Abbreviation: ESRD, end-stage renal disease; Rep., Republic; RRT, renal replacement therapy; sp., speaking. 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, 2016



Data source: Special analyses, USRDS ESRD Database. Data presented only for countries from which relevant information was available. The prevalence is unadjusted. Data for Belarus from 43 of 51 RRT centers. Data for Canada exclude Quebec. Data for France exclude Martinique. Data for Indonesia represent the West Java region. Data for Italy representative of 35% (7 out of 19 regions) of ESRD patient population. Prevalent functioning graft data for Slovakia only available for prevalent transplant patients. United Kingdom^: England, Wales, Northern Ireland (Scotland data reported separately). Abbreviations: ESRD, end-stage renal disease; Rep., Republic; RRT, renal replacement therapy; sp., speaking. NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

vol 2 Figure 11.20 Trends in the prevalence of treated ESRD patients with a functioning kidney transplant, by country, 2003-2016



Data source: Special analyses, USRDS ESRD Database. Estimates derived from linear regression. Abbreviations: ESRD, end-stage renal disease; Rep., Republic; sp., speaking . NOTE: Data collection methods vary across countries, suggesting caution in making direct comparisons.

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Notes

Chapter 12: End-of-life Care for Patients with End-Stage Renal Disease, 2000-2015

- Between 2000 and 2015:
  - 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 63% (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 died in the hospital decreased from 49% to 39% (Figure 12.5).
  - 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 23% to 32% (Figure 12.6).
  - Between 2012 and 2015:
  - The percentage of Medicare beneficiaries with ESRD seen by 10 or more physicians during the last 90 days ranged from 53% to 55% (Figure 12.7).
  - The percentage of Medicare beneficiaries with ESRD seen by 5 or more medical specialties during the last 90 days of life ranged from 65% to 62% (Figure 12.8).
  - Between 2000 and 2015:
  - The percentage of patients with ESRD who discontinued maintenance dialysis treatments before death increased from 19% to 23.3% (Figure 12.9).
  - The percentage of Medicare beneficiaries with ESRD who were enrolled in hospice at the time of death increased from 11% to 26% (Figure 12.10), with the most marked increases occurring among those who discontinued dialysis.
- For patients with ESRD who died in 2015, median per person costs under Medicare Parts A and B were $103,932 (IQR $65,345, $159,451) over the last year of life, $19,734 (IQR, $9,217, $34,979) over the last 30 days of life, and $7,687 (IQR, $1,866, $14,822) over the last seven days of life. Costs were progressively lower for patients who spent a longer period of time enrolled in hospice (Figure 12.11).

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) through 2015 using the most recently available data from the United States Renal Data System (USRDS) Coordinating Center. New to this chapter this year is information on the percentage of decedents seen by 10 or more physicians and the percentage seen by 5 or more specialists during the last 90 days of life from 2012-2015.

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) provider encounters during the last 90 days of life (5) patterns of dialysis discontinuation before death, (6) patterns of hospice utilization before death, 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 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.

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=N), dates of hospice utilization (HCFASAF=S), and receipt of hospice care at the time of death (HCFASAF=S on or after the date of death or Discharge Status from hospice=40, 41, or 42). Episodes of Intensive Care Unit (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).

We adapted two measures of physician care intensity at the end of life from the *Dartmouth Atlas of Healthcare*: the percentage of patients seeing 10 or more physicians in the last 90 days of life, and the percentage of patients seeing 5 or more medical specialties in the last 90 days of life. We used the Physician/Supplier Claims file to identify all physician claims during the last 90 days of life, and recorded the number of visits from unique physicians based on National Provider Identifier (NPI) and the provider's medical specialty, excluding non-physician specialties such as optometry and occupational therapy, and specialty codes associated with a supplier or facility rather than an individual provider (excluded codes: 00,41,42,43,45,47,48,49,50-65,67-69,71-75,80,87-89,95-97,99,AX,BX,C1). These analyses were limited to the years 2012 to 2015, because the NPI was not available prior to 2012.

Information on dialysis discontinuation before death comes from the Centers for Medicare & Medicaid Services (CMS) Death Notification form (CMS 2746). The denominator population includes all patients for whom dialysis was listed as the most recent modality before death on the 2746 form who had complete information on whether dialysis was discontinued before death. Information on hospice use as a function of whether dialysis was discontinued before death was obtained from the subset of Medicare beneficiaries in the denominator population, with complete information on whether dialysis was discontinued before death from the CMS 2746 form.

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.

Results for all years are based on the most current SAFs and linked Medicare claims from USRDS. Percentages in the text are rounded to the nearest whole number.

Characteristics of Decedents with ESRD

We identified 1,397,039 patients listed in the USRDS Patients file who died between calendar years 2000 and 2015. The mean age (± standard deviation) of decedents was 68.6 (±13.6) years (Table 12.1). Overall, 67% of decedents were White, 27% were Black/African American, 1% were American Indian or Alaska Native, 3% were Asian, 1% were Pacific Islander or Native Hawaiian, and 1% were of Other race or Multiracial; 12% of decedents were Hispanic, 55% Non-Hispanic White, and 26% Non-Hispanic Black/African American; and 55% of decedents were male.

The most recent modality prior to death was hemodialysis (HD) in 88% of patients, peritoneal dialysis (PD) in 5%, and transplant in 5%. During 2000-2015, the mean age of decedents rose from 67.5 (±13.7) years to 69.3 (±13.1) years. The percentage of decedents of White race increased from 66% to 69% and the percentage of decedents of Black or African American race decreased from 28% to 26%. The percentage of decedents of Hispanic ethnicity increased from 10% to 13% over the same time period. The percentage of decedents who were male increased from 52% to 57%. The percentage of decedents with PD as their most recent modality ranged from 7% in 2000 to 4% in 2000-2010 to 6% in 2015. The percentage of decedents who had received a kidney transplant increased over time from 5% to 6%. The percentage of Medicare beneficiaries with ESRD with fee-for-service Medicare Parts A and B as primary payer during the last 90 days of life decreased from 73% to 62%.

vol 2 Table 12.1 Characteristics of decedents with ESRD by death year, 2000-2015

	2000	2003	2006	2009	2012	2015	Total
n	72,794	82,414	87,521	89,866	91,773	99,868	1,397,039
%	5.2	5.9	6.3	6.4	6.6	7.2	
Age (mean)	67.49 (13.73)	67.94 (13.79)	68.46 (13.78)	68.73 (13.65)	69.21 (13.37)	69.27 (13.06)	68.60 (13.58)
Age category							
0-19	0.18	0.19	0.16	0.12	0.10	0.08	0.13
20-44	6.78	6.11	5.46	5.06	4.38	4.13	5.22
45-64	28.75	29.38	29.90	29.92	29.54	28.75	29.38
65-74	29.19	27.32	26.02	26.70	27.71	29.50	27.54
75-84	27.65	28.26	28.31	27.05	26.32	26.08	27.37
≥85	7.46	8.74	10.14	11.16	11.95	11.47	10.36
Missing		0.00	0.00	0.00			0
Race*							
White	65.95	65.78	67.07	67.52	68.68	68.78	67.37
Black	28.15	28.14	27.67	27.12	26.14	26.04	27.17
American Indian or Alaska Native	1.23	1.12	1.08	1.14	1.02	0.94	1.07
Asian	2.24	2.34	2.46	2.63	2.90	3.10	2.61
Native Hawaiian or Pacific Islander	0.55	0.66	0.78	0.82	0.78	0.84	0.75
Other or Multiracial	1.68	1.82	0.86	0.67	0.37	0.22	0.92
Hispanic							
Hispanic	10.11	11.04	11.21	11.76	12.86	13.13	11.69
Non-Hispanic White	52.87	54.72	55.40	55.18	55.50	55.72	55.18
Non-Hispanic Black/African American	23.90	26.80	26.67	26.24	25.23	25.49	25.96
Non-Hispanic Others	5.19	5.16	5.53	5.89	5.85	5.28	5.49
Unknown	7.93	2.28	1.19	0.92	0.56	0.39	1.67
Sex							
Female	47.83	46.86	45.77	44.27	43.60	43.07	45.12
Male	52.17	53.13	54.20	55.71	56.39	56.93	54.86
Missing	0.00	0.01	0.03	0.02	0.00	0.01	0.02
Last treatment modality							
Hemodialysis	86.72	88.47	88.92	89.03	87.82	87.45	88.28
Peritoneal dialysis	7.38	5.86	4.89	4.31	5.1	5.87	5.39
Transplant	4.66	4.71	5.05	5.54	6.12	6.37	5.39
Missing	1.25	0.96	1.14	1.13	0.95	0.31	0.94
Medicare Parts A & B as ESRD payer for last 3-months of life (Yes)	73.46	75.09	73.59	69.33	67.25	62.16	70.19

*Data Source: Special analyses, USRDS ESRD Database. Denominator is all decedents. Abbreviation: ESRD, end-stage renal disease. * Race does not add up to 100%, because "unknown" category is not presented in this table.*

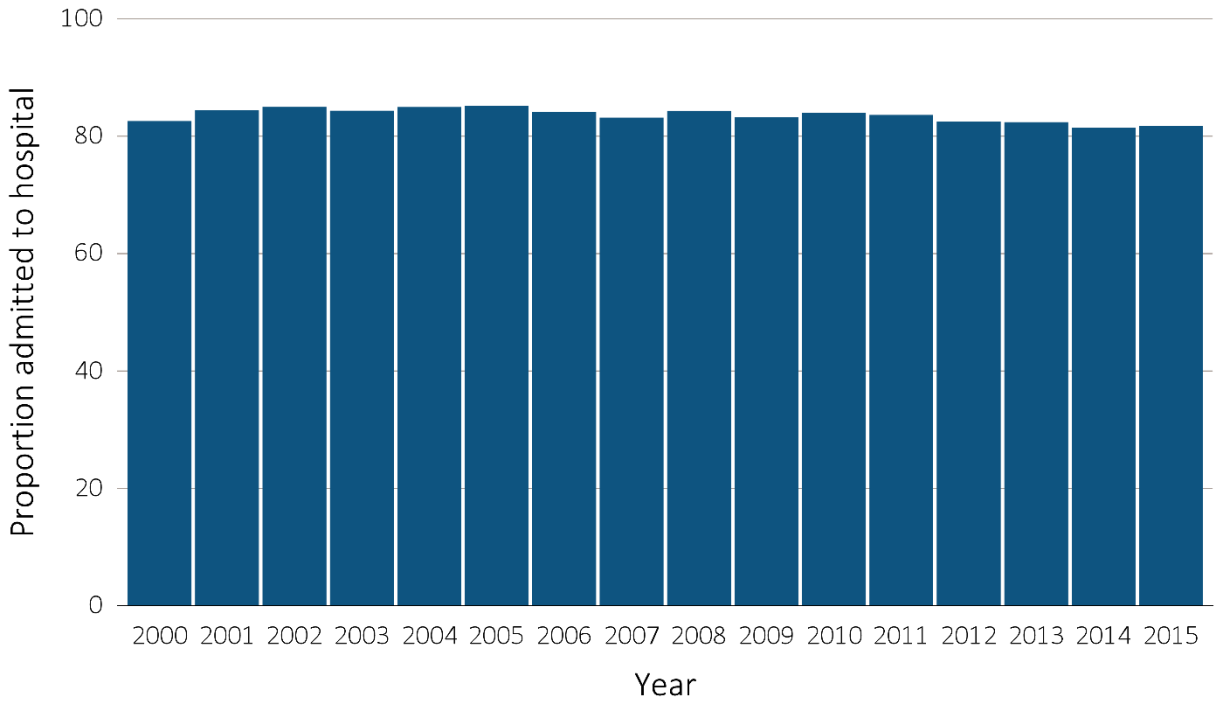
Inpatient Utilization during the Last 90 Days of Life among Medicare Beneficiaries with ESRD

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 2000-2015: (1) hospital admission, (2) days spent in the hospital, (3) ICU admission, (4) receipt of intensive procedures, and (5) inpatient deaths.

Hospital admission

More than 4 in every 5 patients were admitted to the hospital at least once during the last 90 days of life throughout the 16-year follow-up period, ranging from 81%-84% (Figure 12.1). This is higher than the rate of 65.2% reported for fee-for service Medicare beneficiaries for 2015 (Teno et al., 2018).

vol 2 Figure 12.1 Hospital admission during the last 90 days of life among Medicare beneficiaries with ESRD, 2000-2015

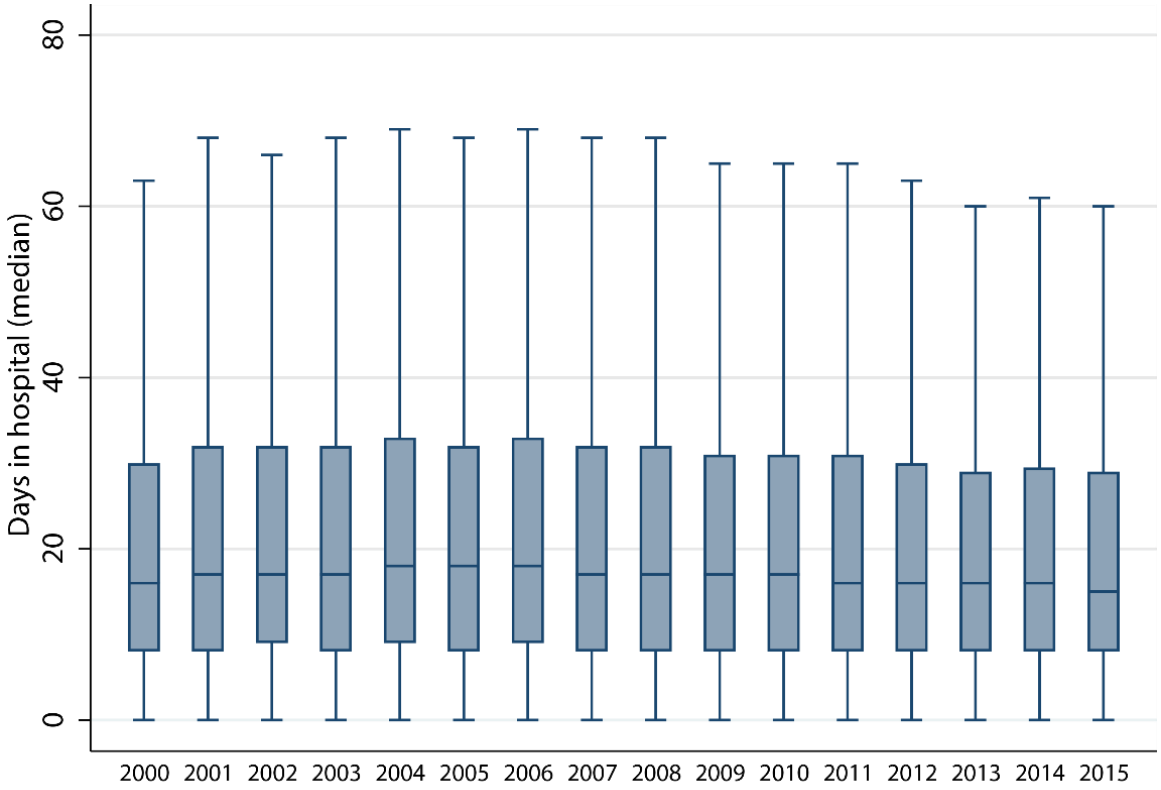


Data Source: Special analyses, USRDS ESRD Database. Denominator is all decedents with Medicare Parts A and B throughout the last 90 days of life. Includes hospital stays in both short- and long-stay hospitals. Abbreviation: ESRD, end-stage renal disease.

Days spent in the hospital

Those admitted to the hospital at least once during the last 90 days of life spent a median stay of between 15 and 18 days in the hospital during each year of follow-up ranging from a high of 18 days in 2004-2006 to a low of 15 days in 2015 (Figure 12.2).

vol 2 Figure 12.2 Days spent in the hospital during the last 90 days of life among Medicare beneficiaries with ESRD, 2000-2015



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

The percentage of decedents admitted to an ICU in the last 90 days of life ranged from 50% in 2000 to 63% in 2015 (Figure 12.3) and varied by demographic characteristics, modality, and by U.S. state of residence (Figure 12.3.g). In 2015, 68% of young adults (20-44 years) had an ICU admission, decreasing to 56% among those 85 years and over. By region, the highest ICU use rates were in the Southwest and Midwest states.

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, 2000-2015

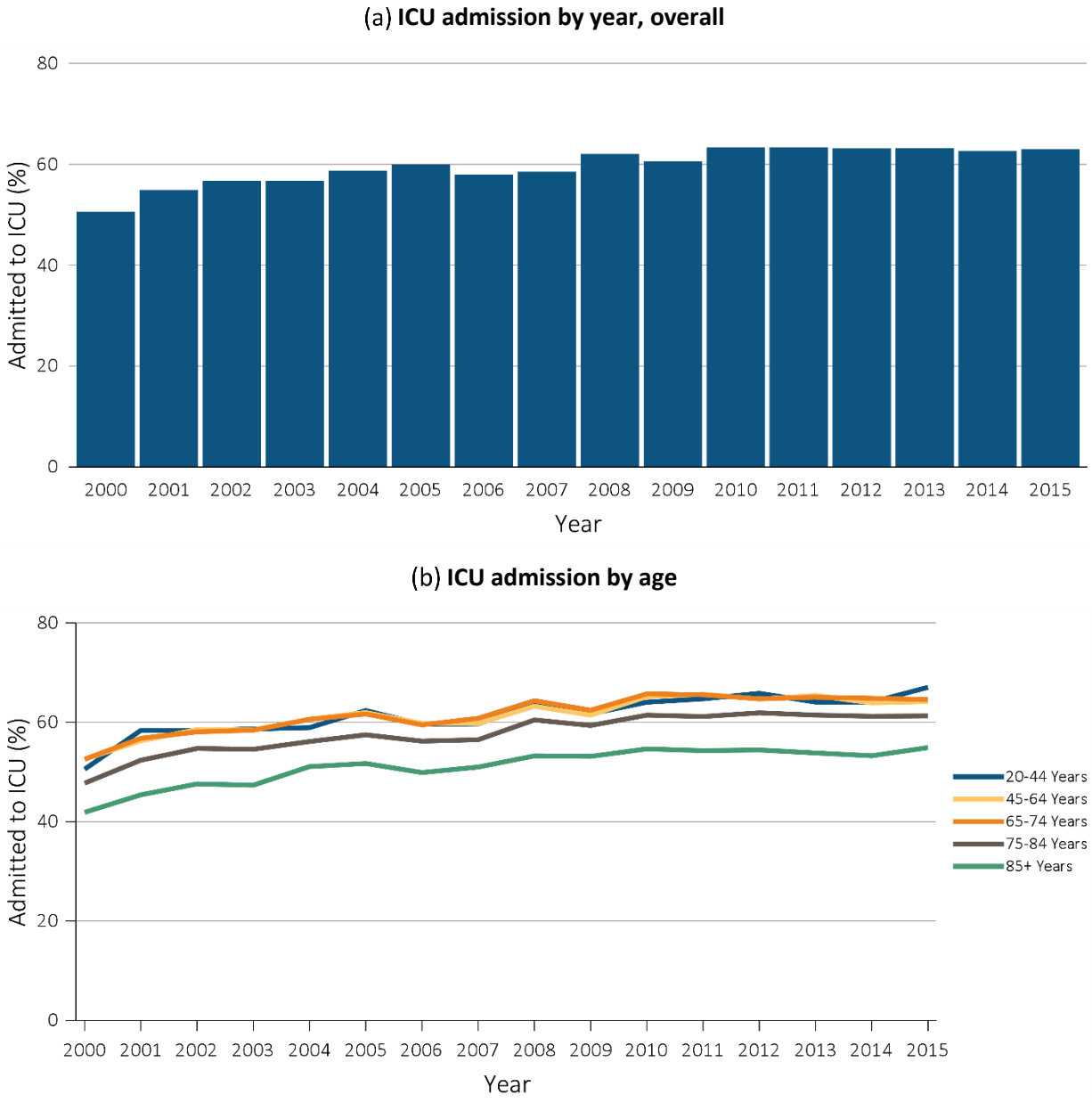


Figure 12.3 continued on next page.

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, 2000-2015 (continued)

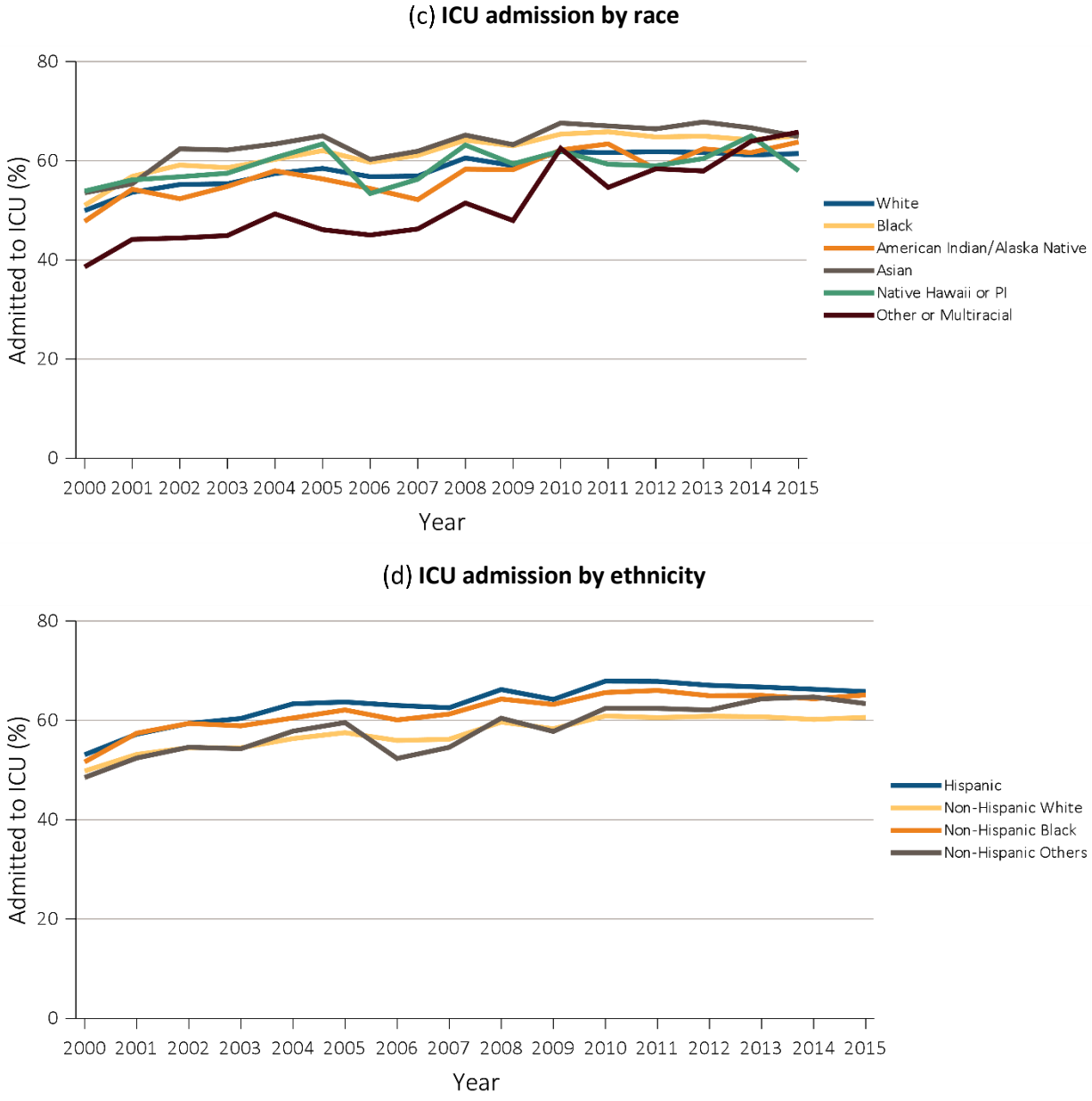


Figure 12.3 continued on next page.

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, 2000-2015 (continued)

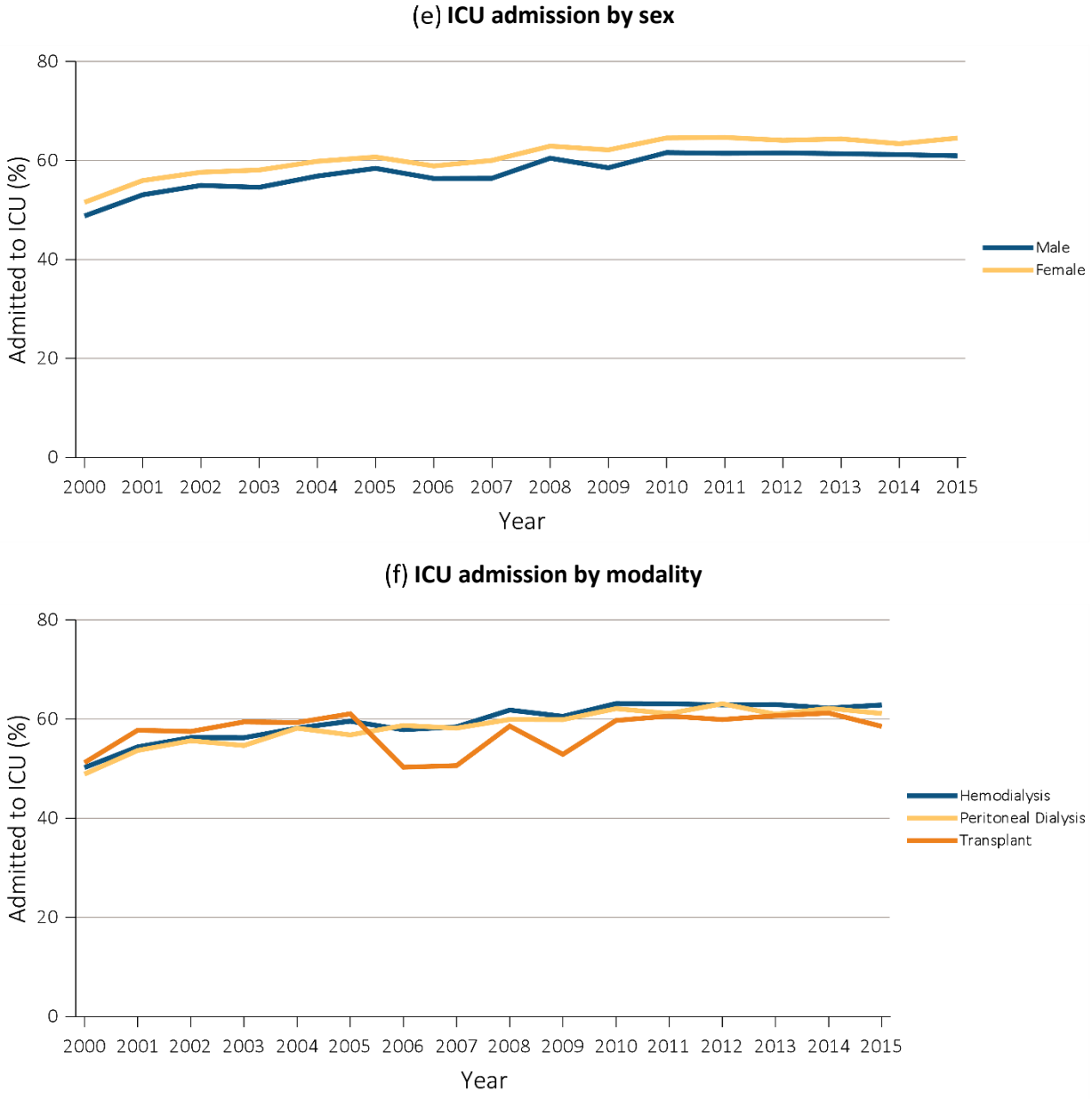
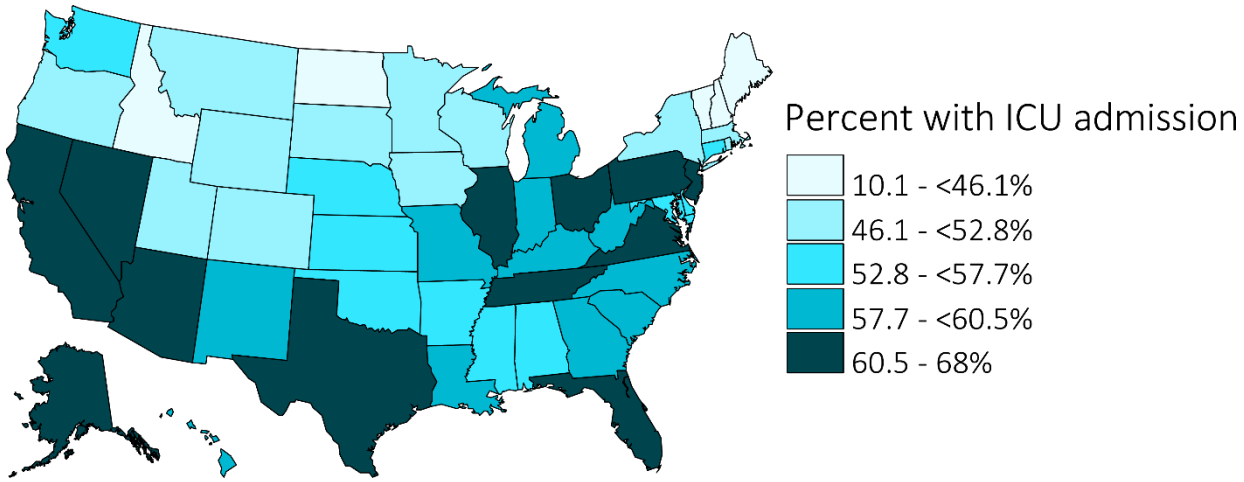


Figure 12.3 continued on next page.

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, 2000-2015 (continued)

(g) **ICU admission by state of residence**



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

The percentage of decedents who had an inpatient intensive procedure during the last 90 days of life ranged from 28% in 2000 to 34% in 2015. Intubation/mechanical ventilation was the most common intensive procedure, with the percentage of decedents receiving this procedure in the last 90 days of life ranging from 21% in 2000 to 30% in 2015. The percentage of decedents who received one or more intensive procedures during the last 90 days of life varied by demographic characteristics, modality, and by state of residence. Intensive procedures were used for 50% of the youngest age group (20-44 years) and only 20% of the oldest (85+ years). By region, use of intensive procedures was about twice as great in the Southeast and California as in the rest of the country.

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, 2000-2015

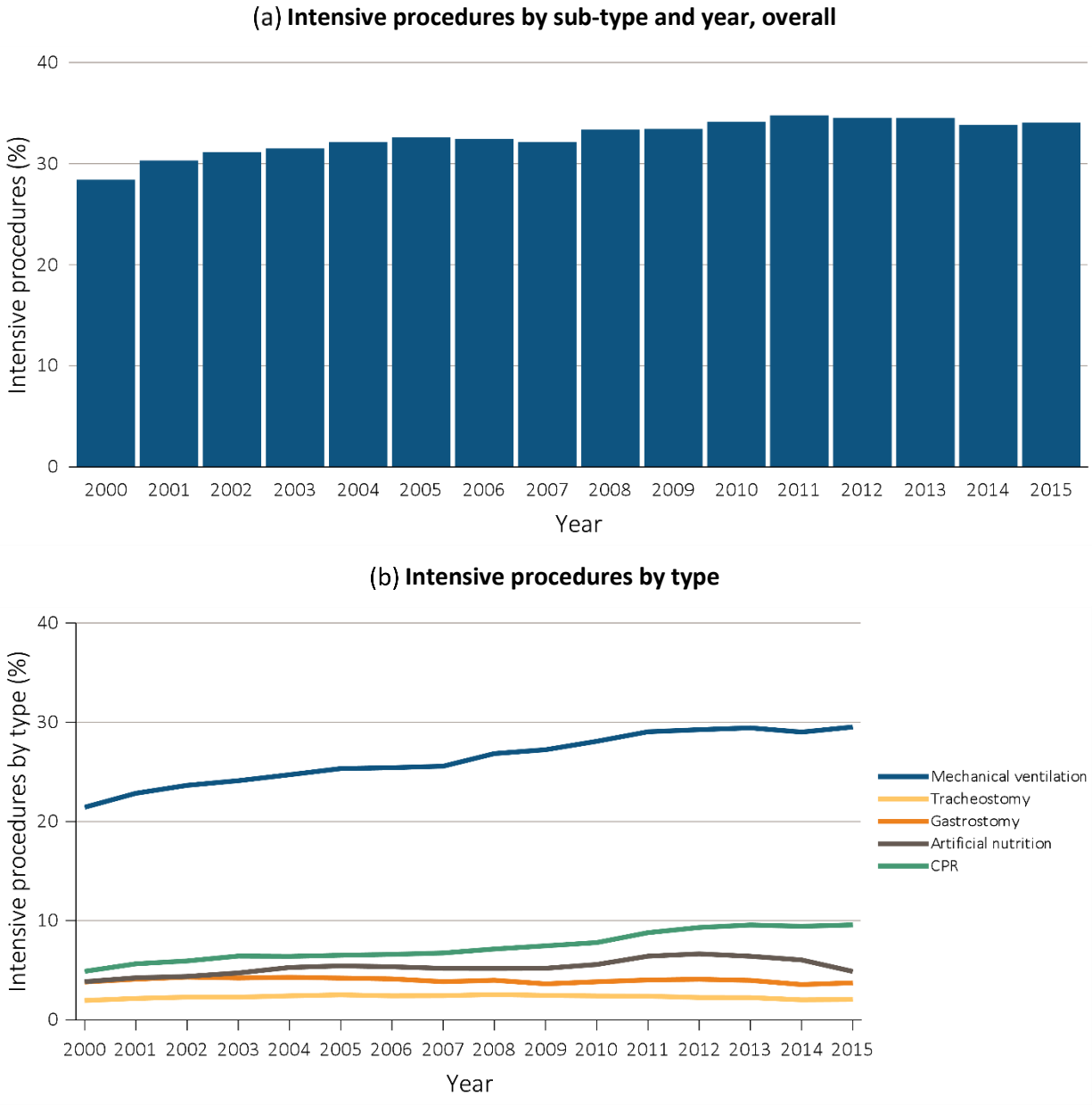


Figure 12.4 continued on next page.

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, 2000-2015 (continued)

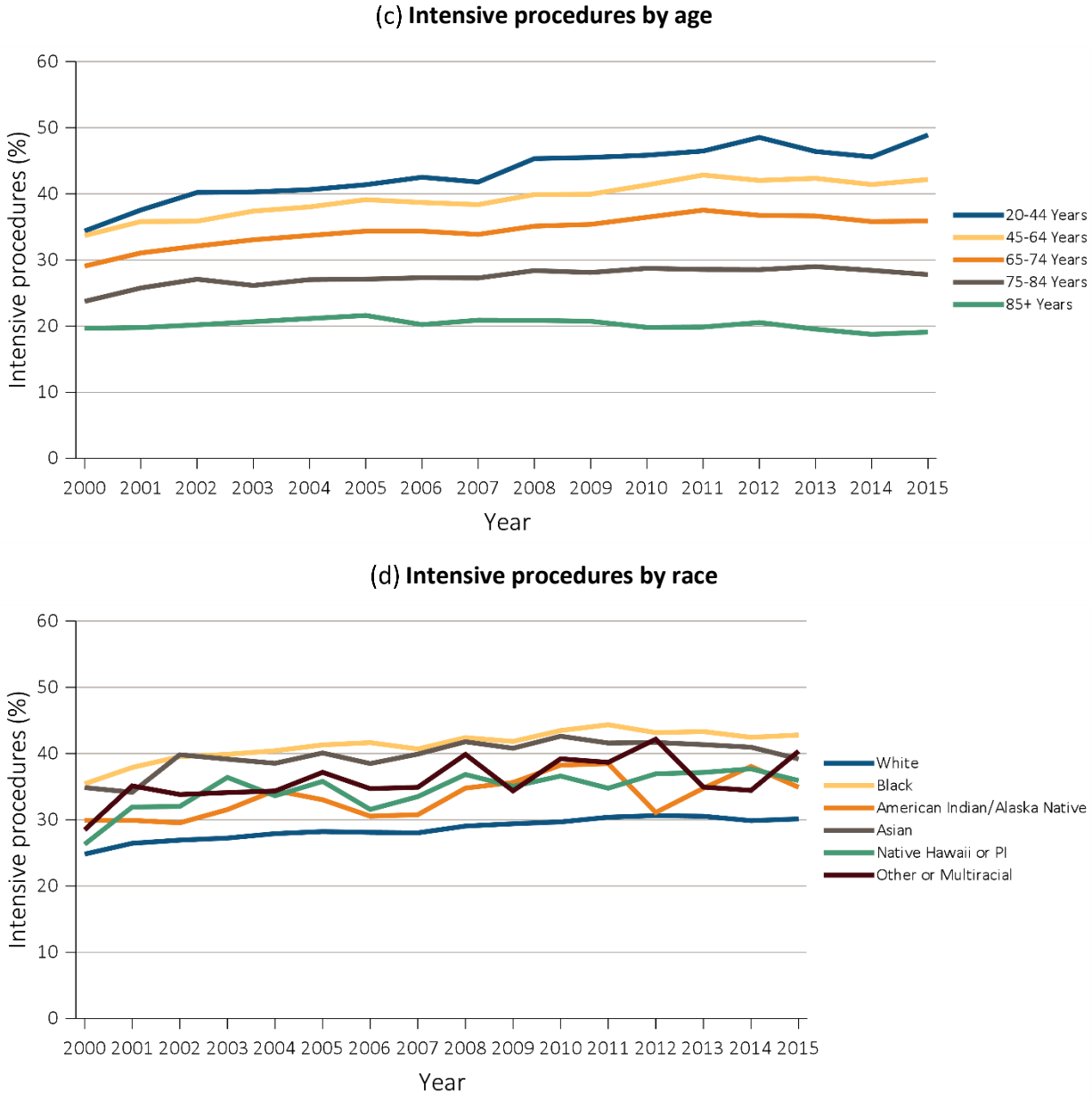
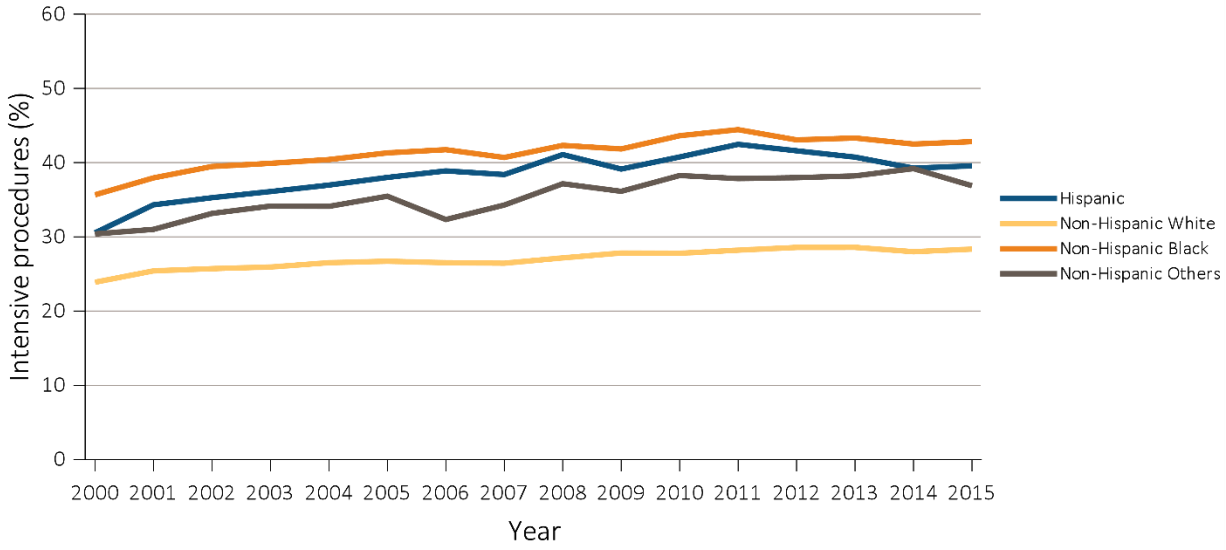


Figure 12.4 continued on next page.

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, 2000-2015 (continued)

(e) **Intensive procedures by ethnicity**



(f) **Intensive procedures by sex**

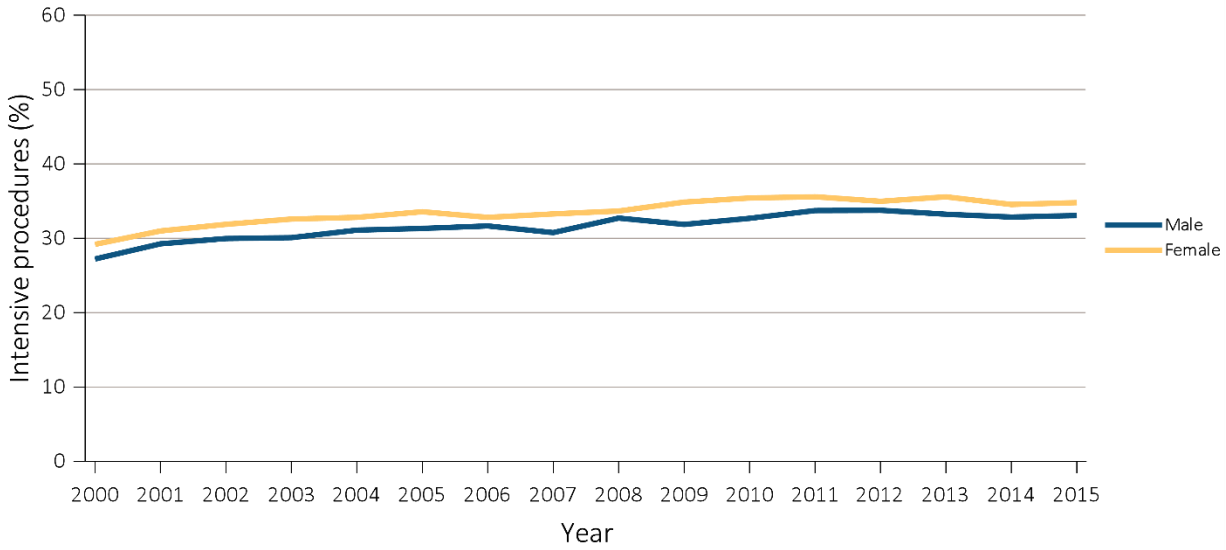
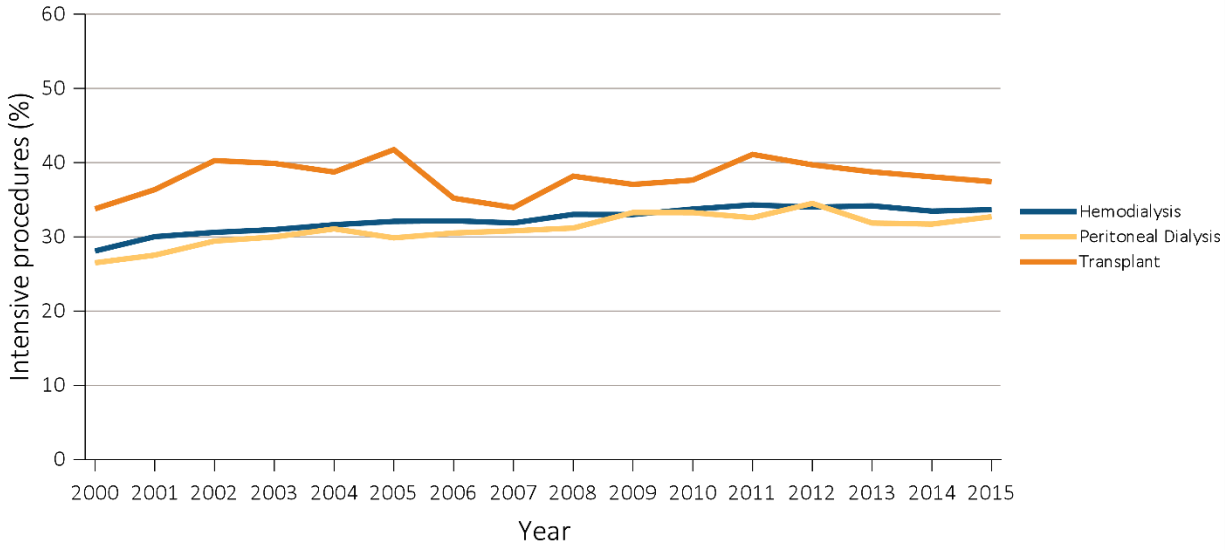


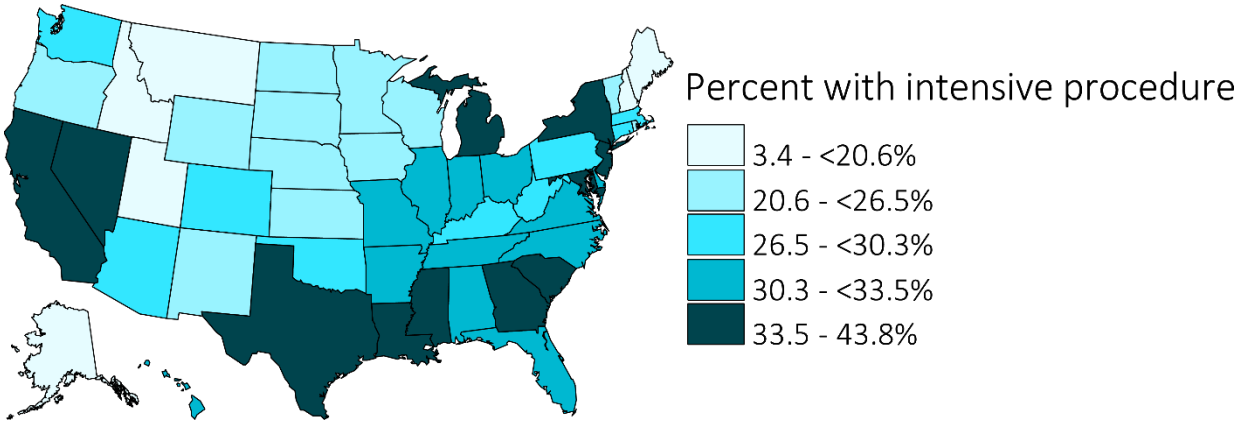
Figure 12.4 continued on next page.

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, 2000-2015 (continued)

(g) **Intensive procedures by modality**



(h) **Intensive procedures by state of residence**



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

INPATIENT DEATHS

The percentage of decedents with ESRD who died in the hospital based on Medicare claims decreased from 49% in 2000 to 39% in 2015 (Figure 12.6). By comparison, the percentage of fee-for-service Medicare beneficiaries dying during an acute hospital admission decreased from 32.6 in 2000 to 24.6% in 2009 (Teno et al., 2013).

The proportion of deaths occurring in the hospital varied by demographic characteristics and modality. The oldest decedents were the least likely to die in the hospital.

vol 2 Figure 12.5 Inpatient deaths among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2015

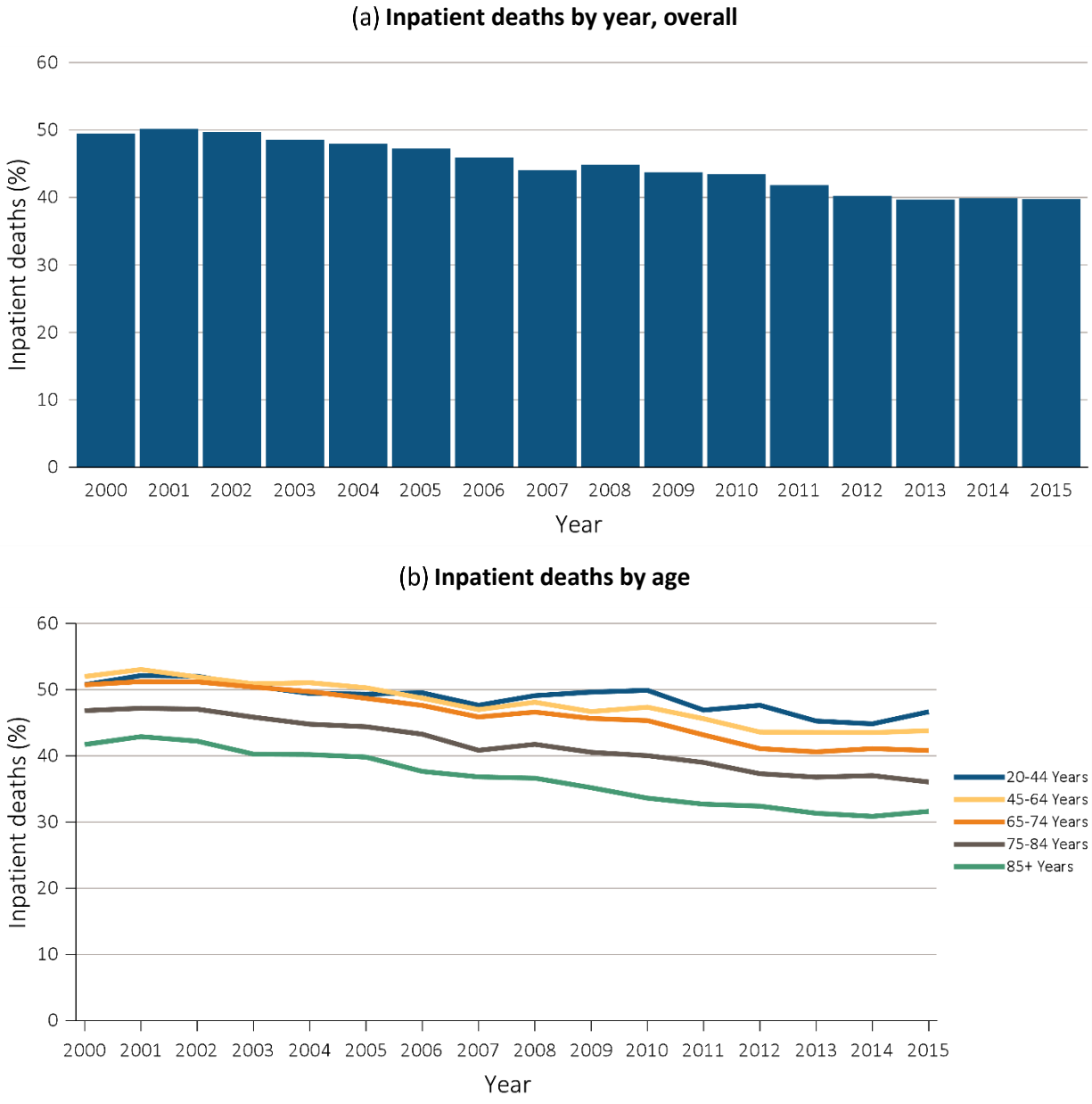


Figure 12.5 continued on next page.

vol 2 Figure 12.5 Inpatient deaths among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2015 (continued)

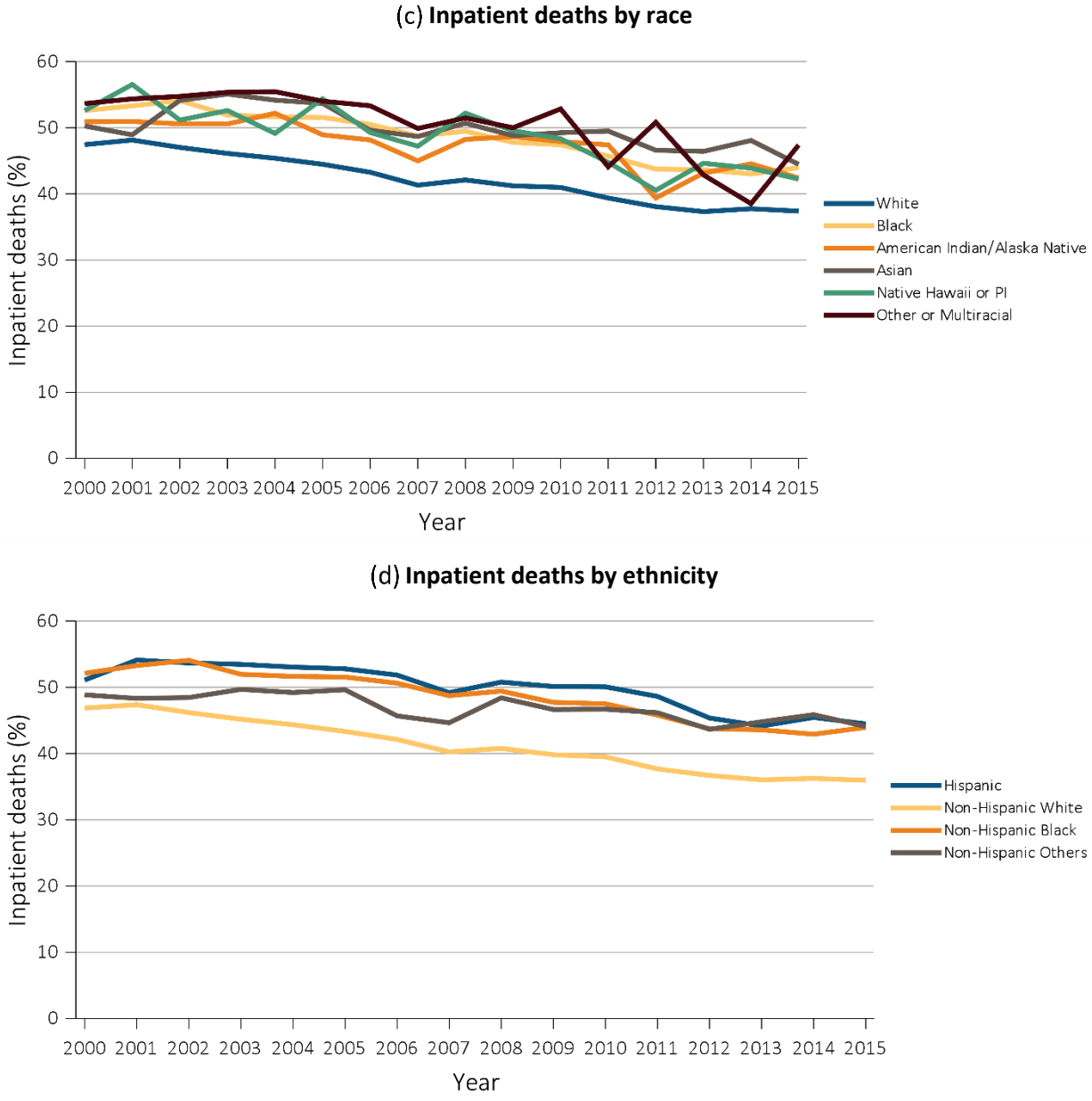
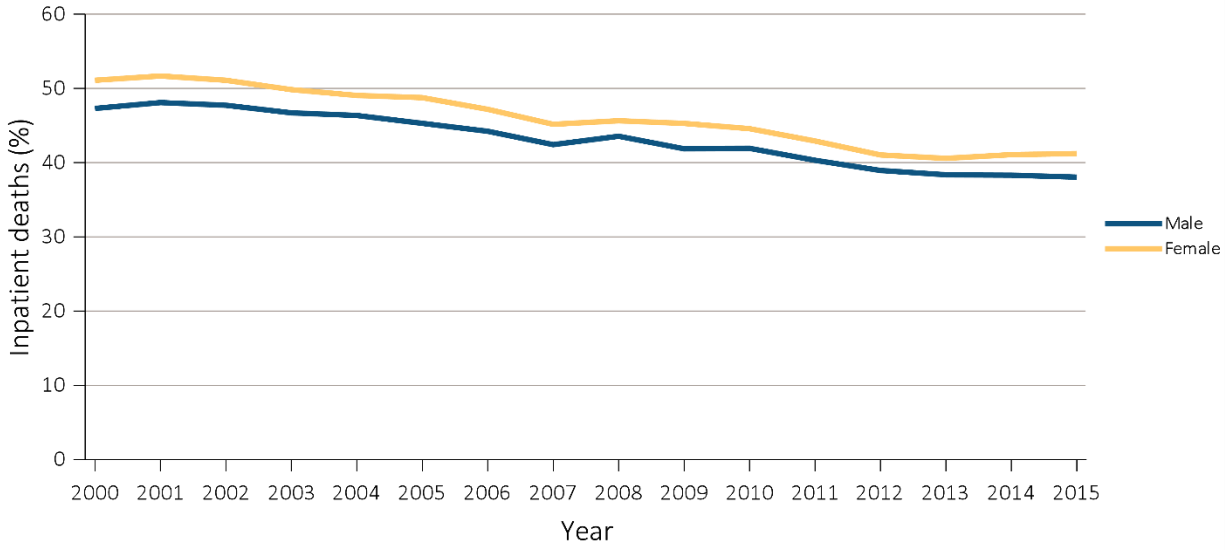


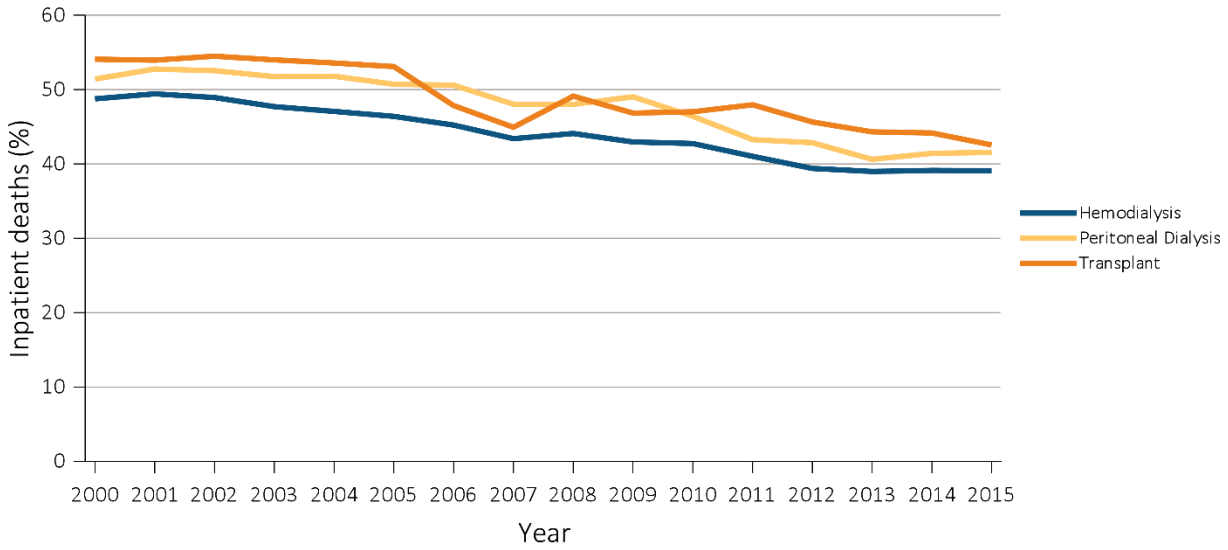
Figure 12.5 continued on next page.

vol 2 Figure 12.5 Inpatient deaths among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2015 (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. Does not include observation stays. Abbreviation: ESRD, end-stage renal disease.

Skilled Nursing Facility Utilization

The percentage of decedents admitted to a SNF during the last 90 days of life ranged from 24% in 2000 to 32% in 2015 (Figure 12.7). The percentage of decedents admitted to a skilled nursing facility during this time frame varied by demographic characteristics and modality. Age was strongly related to SNF use, with those decedents 85 years and over 4 times as likely to have SNF use as the youngest age group (20-44 years). SNF use was also more prevalent among White beneficiaries.

vol 2 Figure 12.6 Skilled nursing facility utilization among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2015

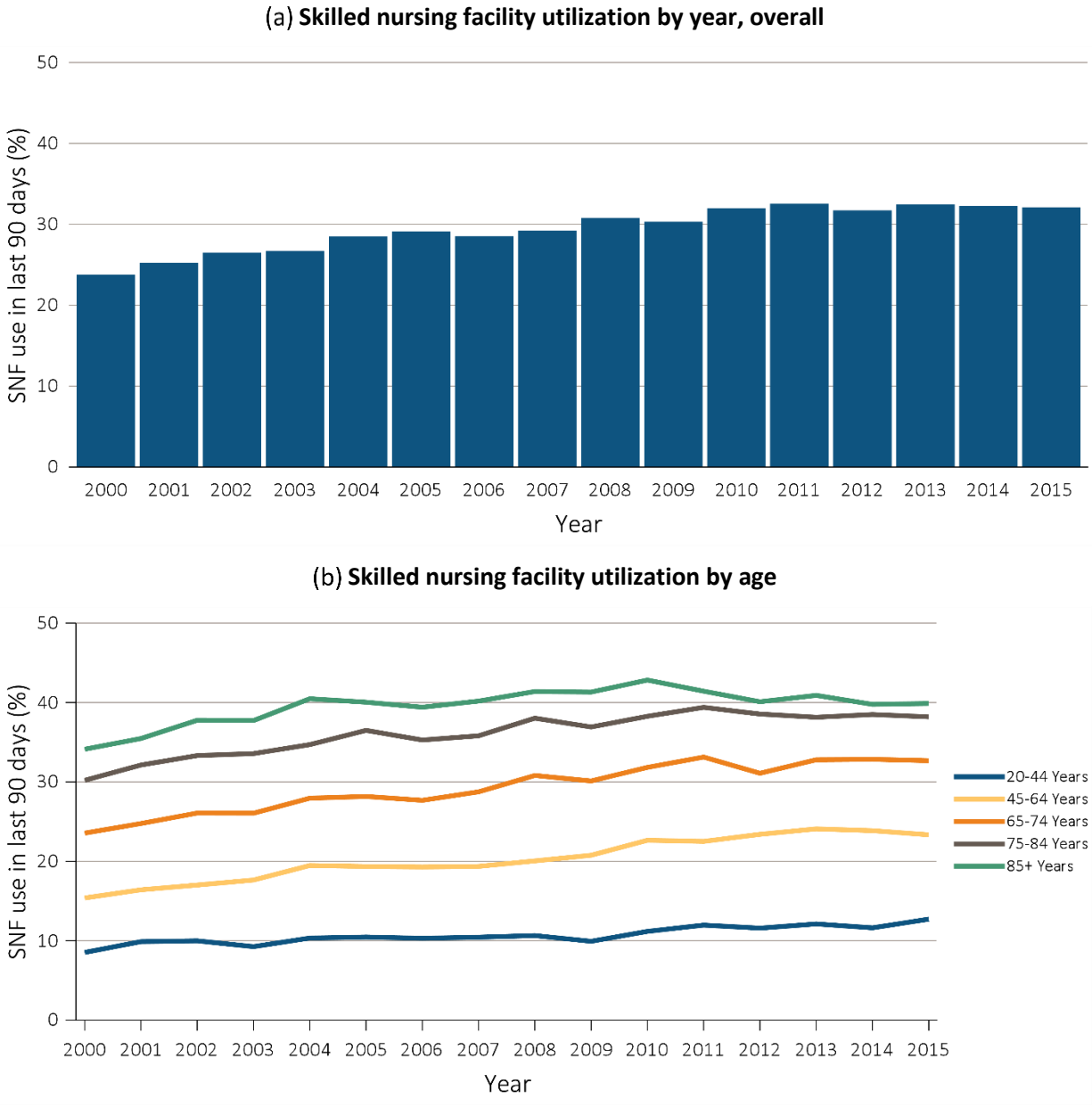


Figure 12.6 continued on next page.

vol 2 Figure 12.6 Skilled nursing facility utilization among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2015 (continued)

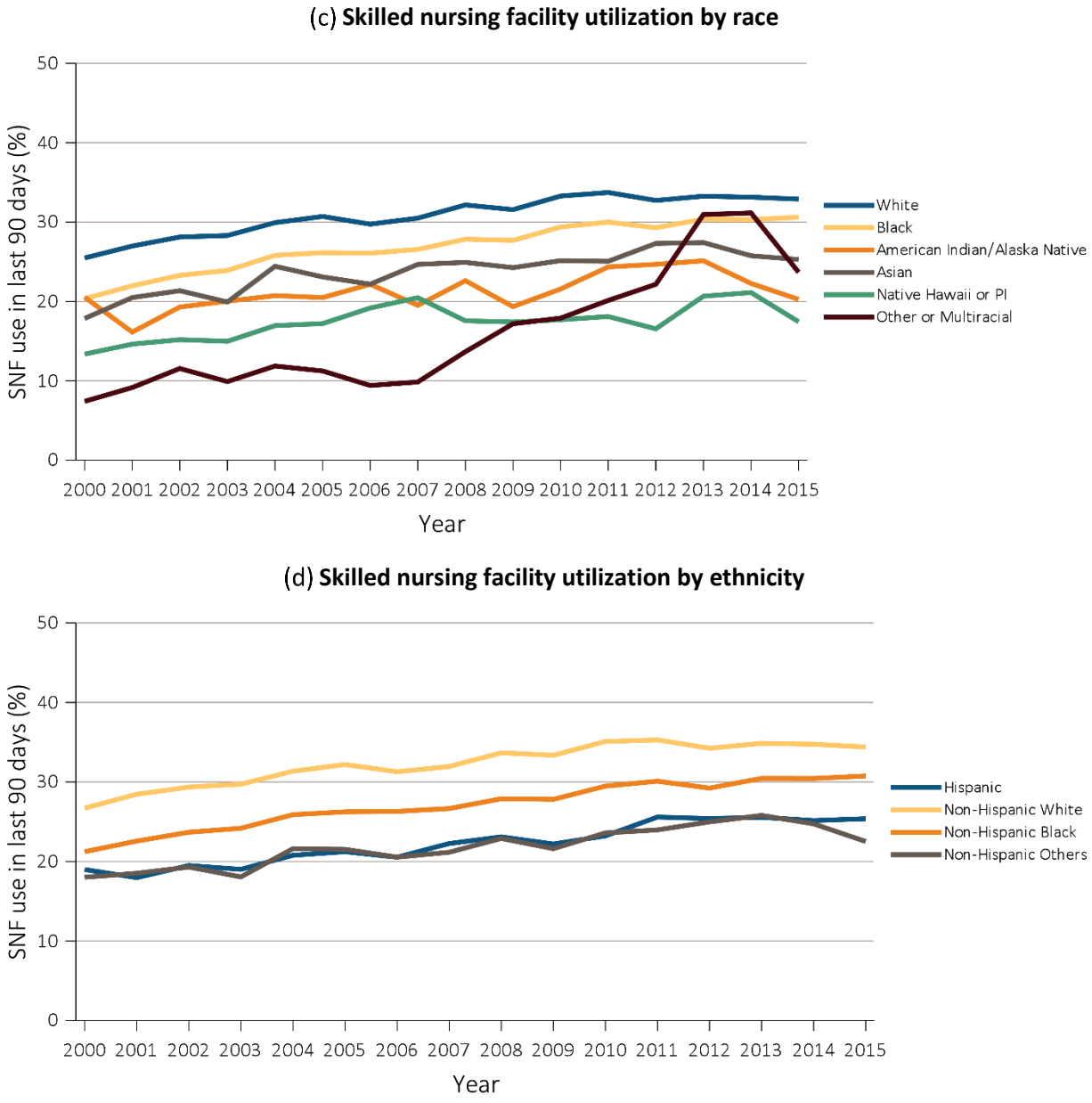
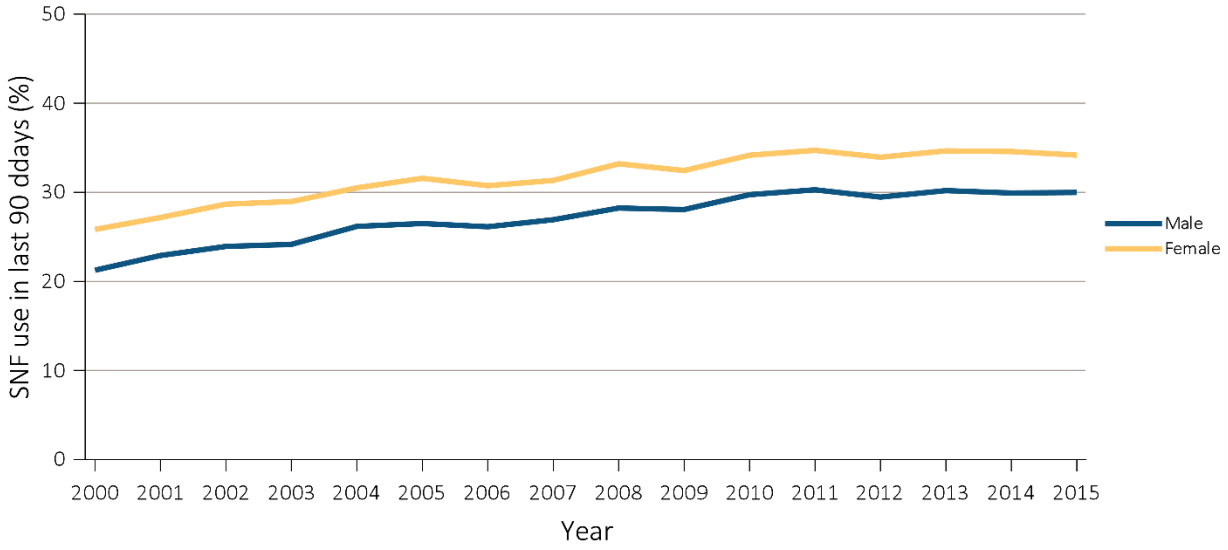


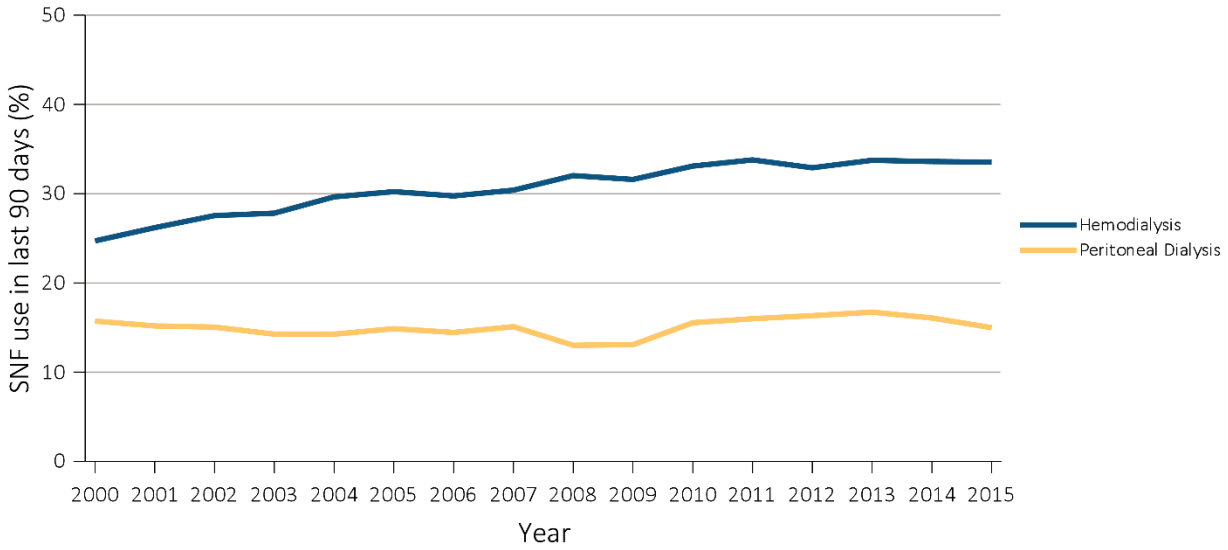
Figure 12.6 continued on next page.

vol 2 Figure 12.6 Skilled nursing facility utilization among Medicare beneficiaries with ESRD overall, and by age, race, ethnicity, sex, and modality, 2000-2015 (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. Abbreviations: ESRD, end-stage renal disease; SNF, skilled nursing facility.

Provider Encounters during the Last 90 Days of Life among Medicare Beneficiaries with ESRD

Percentage of patients seen by ≥10 physicians in last 90 days of life

The percentage of patients who were seen by 10 or more physicians in the last 90 days of life changed little between 2012 and 2015 (from 53% to 55%). By comparison, 49.5% of fee-for-service Medicare beneficiaries were seen by 10 or more physicians in the last six months of life (*Dartmouth Atlas of Health Care*).

There was little variation by demographic characteristics, modality, and by state of residence. Higher rates were seen in the Eastern part of the United States than in the West.

vol 2 Figure 12.7 Percentage of Medicare beneficiaries with ESRD seen by 10 or more physicians in the last 90 days of life, overall, and by age, race, ethnicity, sex, and modality, 2012-2015

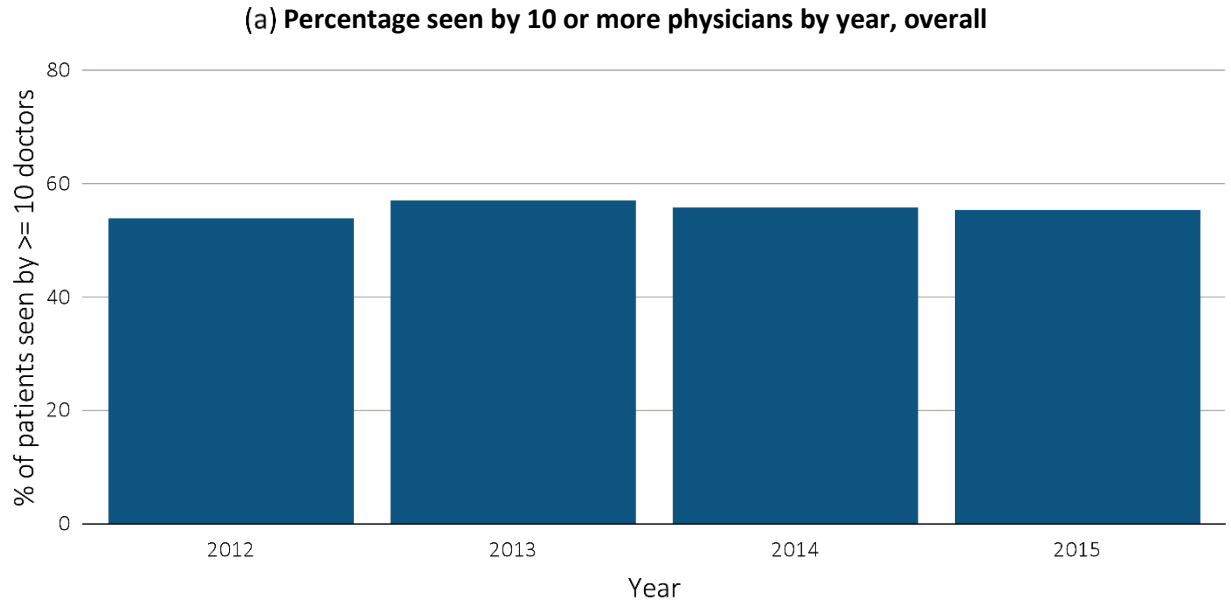
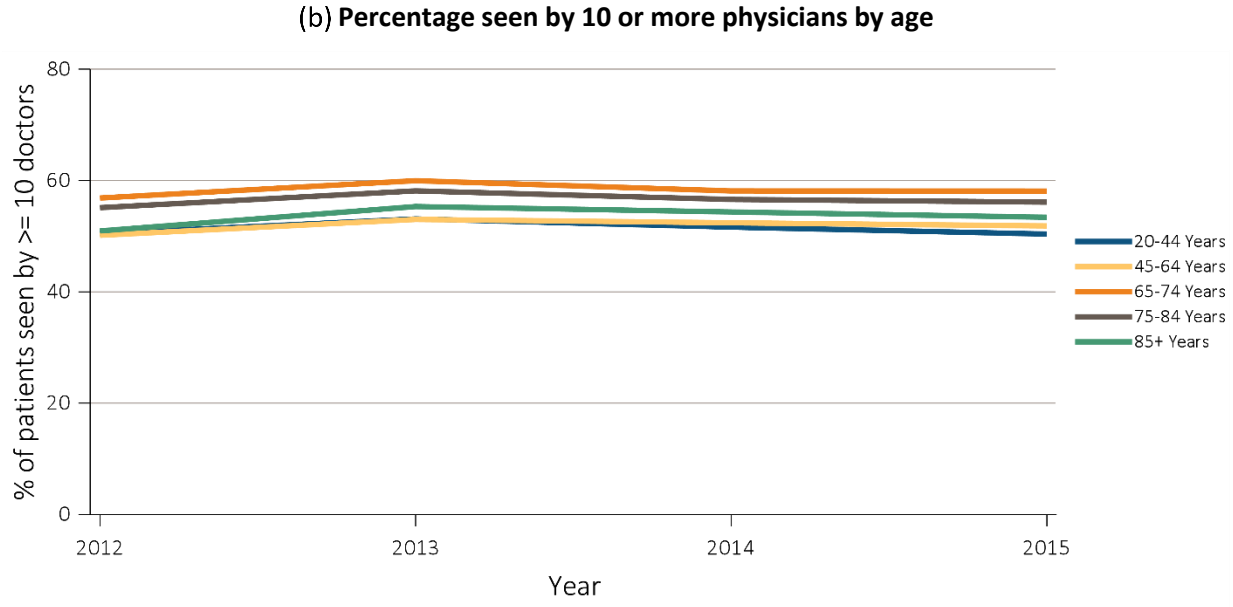
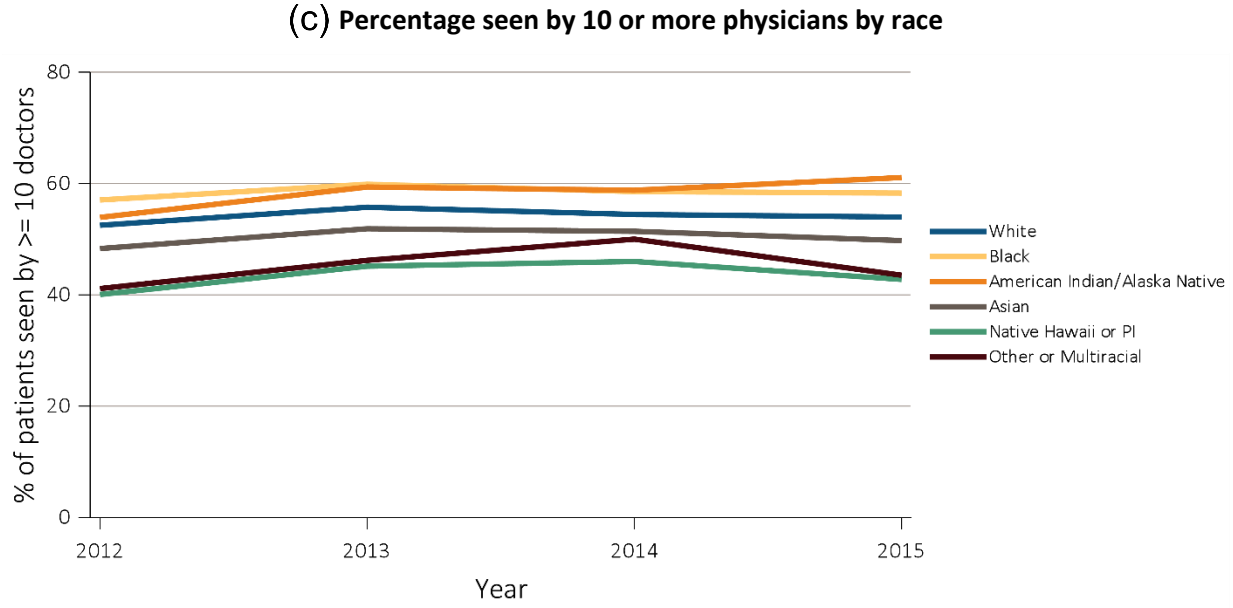


Figure 12.7 continued on next page.

vol 2 Figure 12.7 Percentage of Medicare beneficiaries with ESRD seen by 10 or more physicians in the last 90 days of life, overall, and by age, race, ethnicity, sex, and modality, 2012-2015 (continued)





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vol 2 Figure 12.7 Percentage of Medicare beneficiaries with ESRD seen by 10 or more physicians in the last 90 days of life, overall, and by age, race, ethnicity, sex, and modality, 2012-2015 (continued)

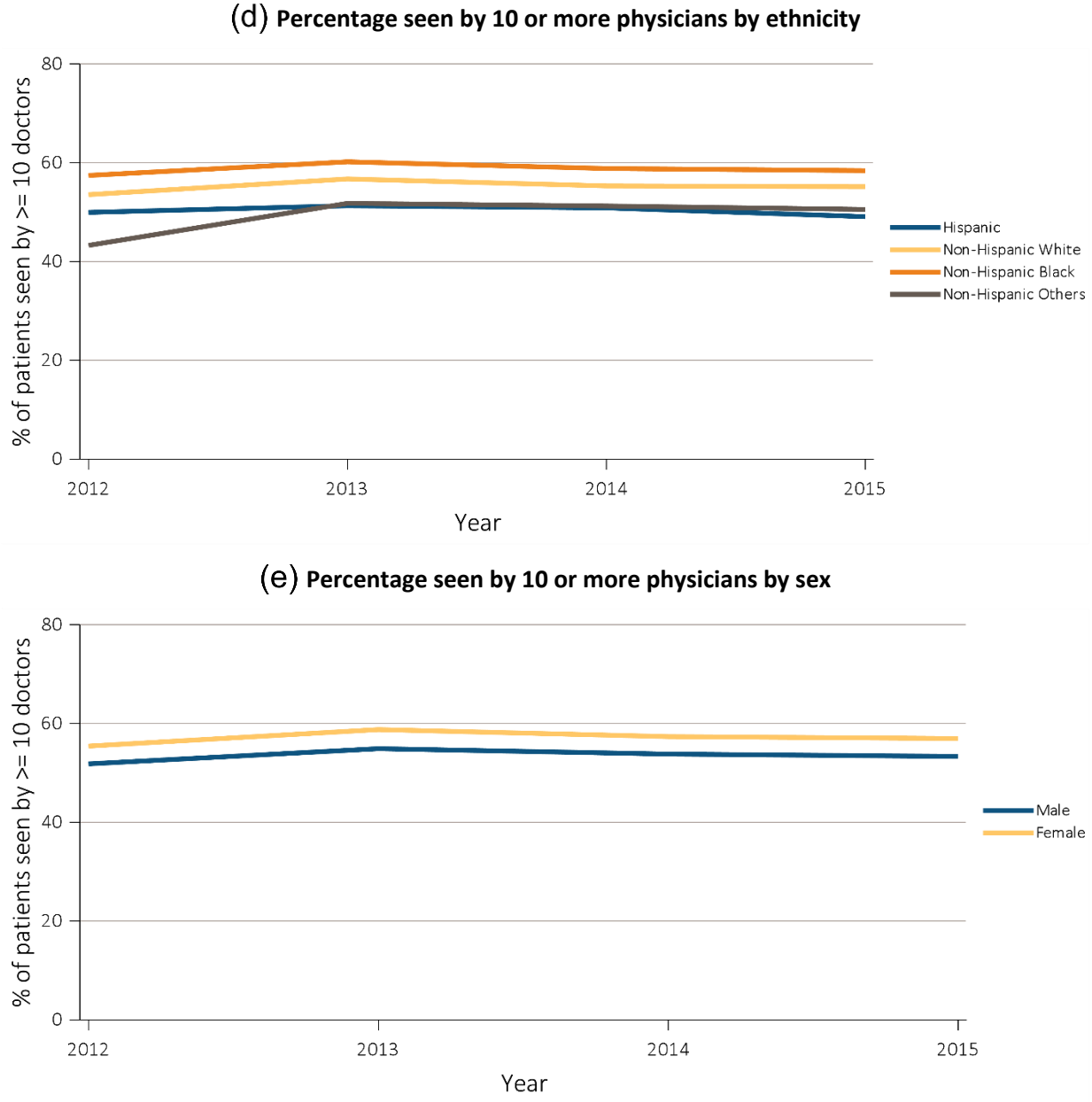
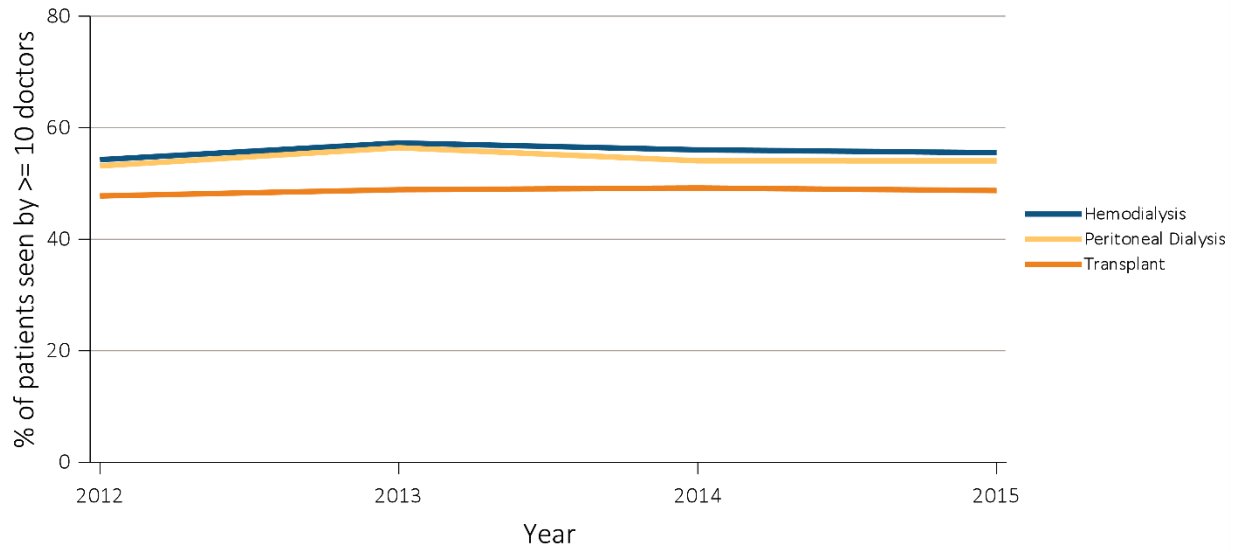


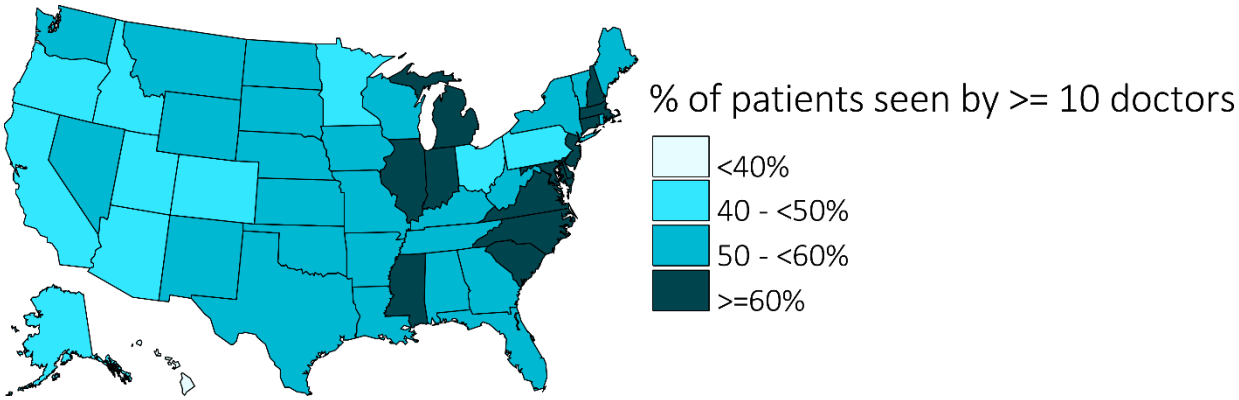
Figure 12.7 continued on next page.

vol 2 Figure 12.7 Percentage of Medicare beneficiaries with ESRD seen by 10 or more physicians in the last 90 days of life, overall, and by age, race, ethnicity, sex, and modality, 2012-2015 (continued)

(f) **Percentage seen by 10 or more physicians by modality**



(g) **Percentage seen by 10 or more physicians by state of residence**

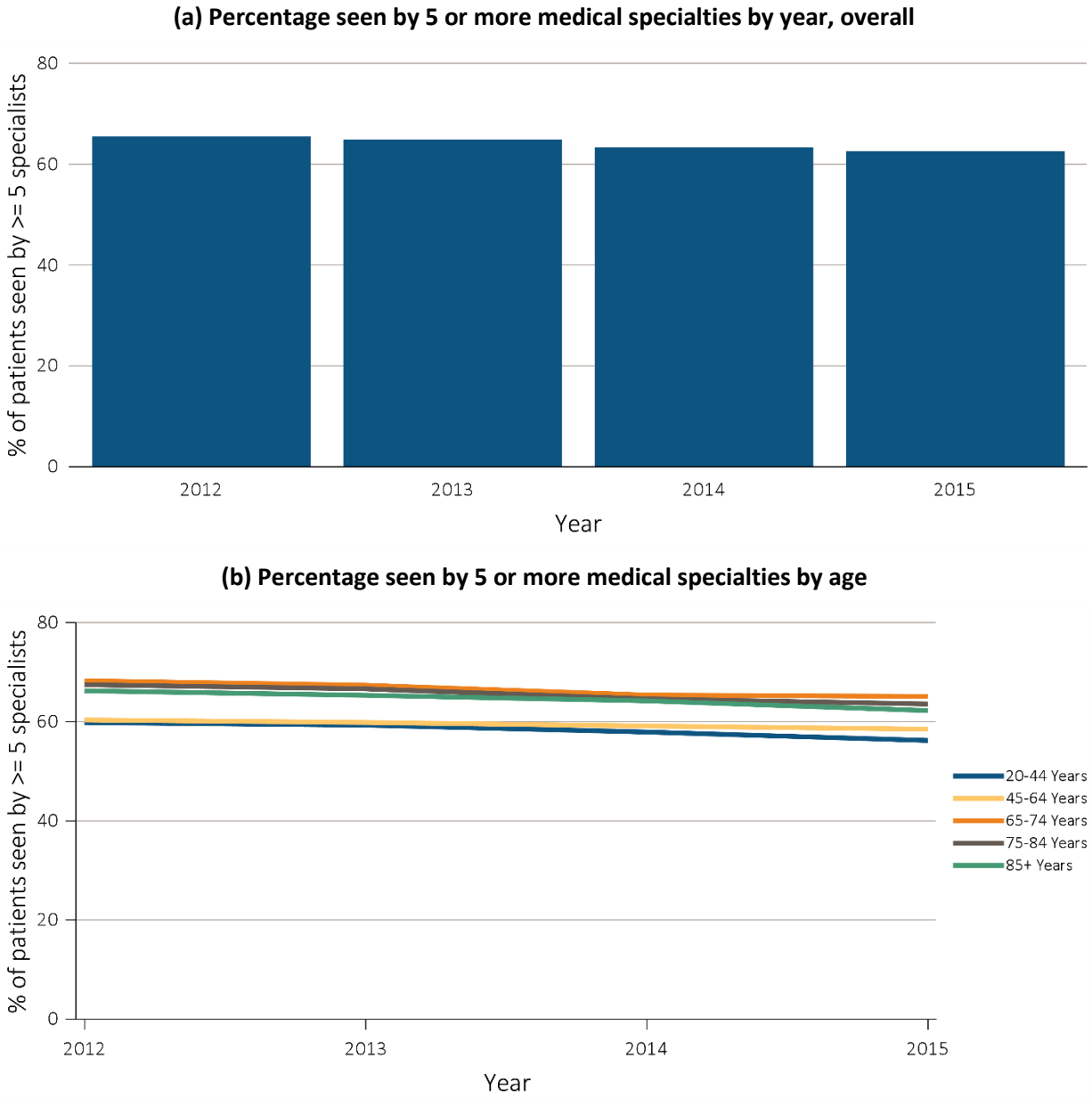


Data Source: Special Analyses, USRDS ESRD Database. Denominator population is all decedents with Medicare Parts A and B throughout the last 90 days of life who died between 2012 and 2015. Abbreviation: ESRD, end-stage renal disease.

Percentage of patients seen by ≥5 medical specialties in last 90 days of life

The percentage of patients who were seen by 5 or more medical specialties in the last 90 days of life declined from 65% in 2012 to 62% in 2015. Percentages varied by demographic characteristics, modality, and state of residence. The top 3 medical specialties delivering care at the end of life for fee-for-service Medicare beneficiaries with ESRD were Internal Medicine, Nephrology, and Radiology (Table 12.2).

vol 2 Figure 12.8 Percentage of Medicare beneficiaries with ESRD seen by 5 or more medical specialties in the last 90 days of life, overall, and by age, race, ethnicity, sex, and modality, 2012-2015



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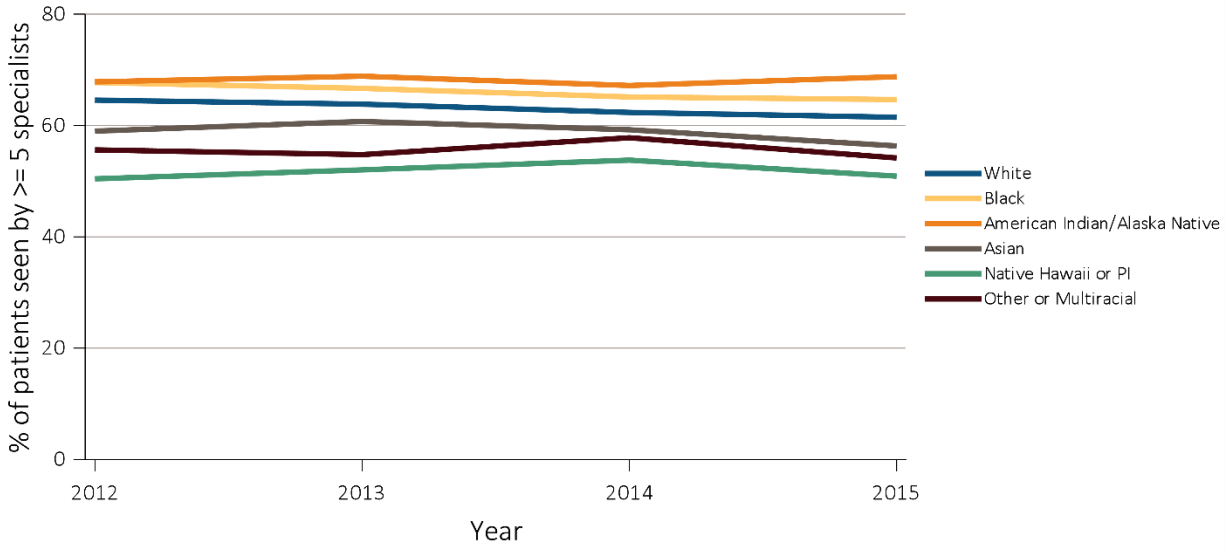
vol 2 Figure 12.8 Percentage of Medicare beneficiaries with ESRD seen by 5 or more medical specialties in the last 90 days of life, overall, and by age, race, ethnicity, sex, and modality, 2012-2015 (continued)

(c) Percentage seen by 5 or more medical specialties by race



(d) Percentage seen by 5 or more medical specialties by ethnicity

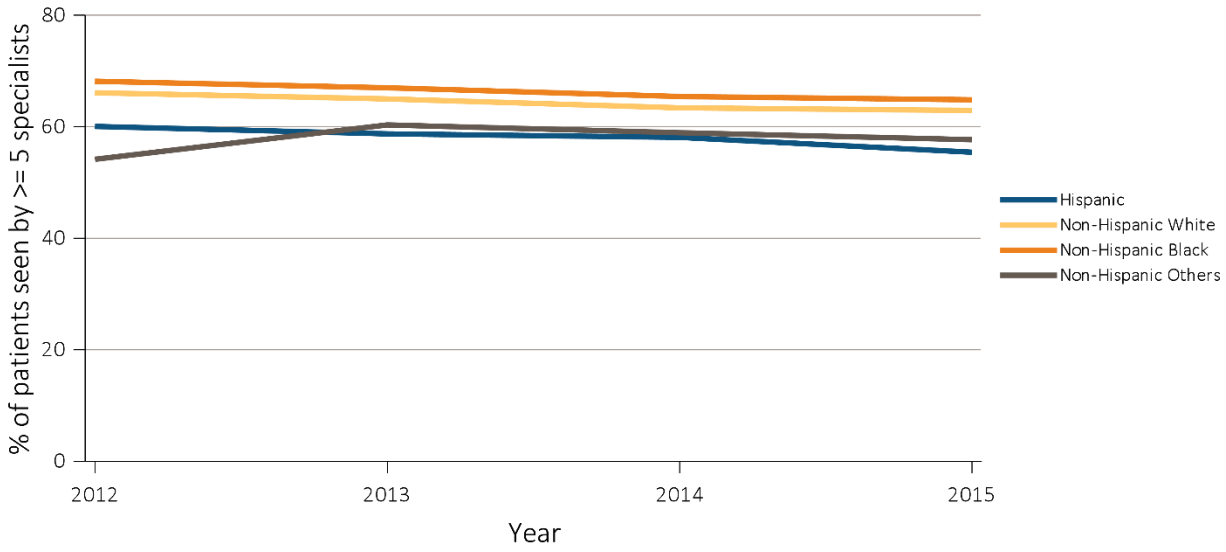
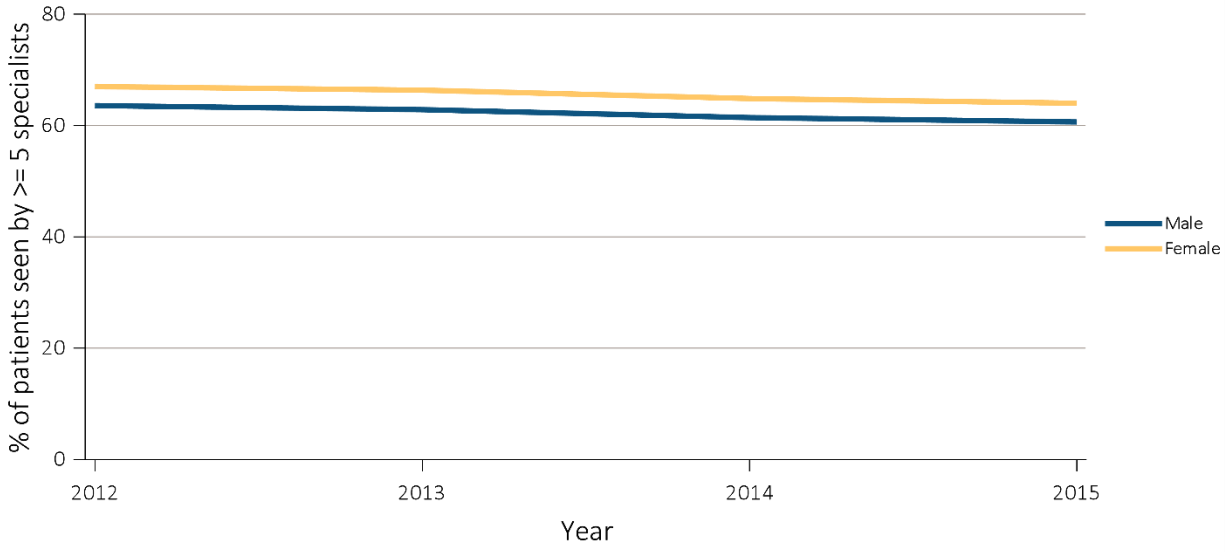


Figure 12.8 continued on next page.

vol 2 Figure 12.8 Percentage of Medicare beneficiaries with ESRD seen by 5 or more medical specialties in the last 90 days of life, overall, and by age, race, ethnicity, sex, and modality, 2012-2015 (continued)

(e) Percentage seen by 5 or more medical specialties by sex



(f) Percentage seen by 5 or more medical specialties by modality

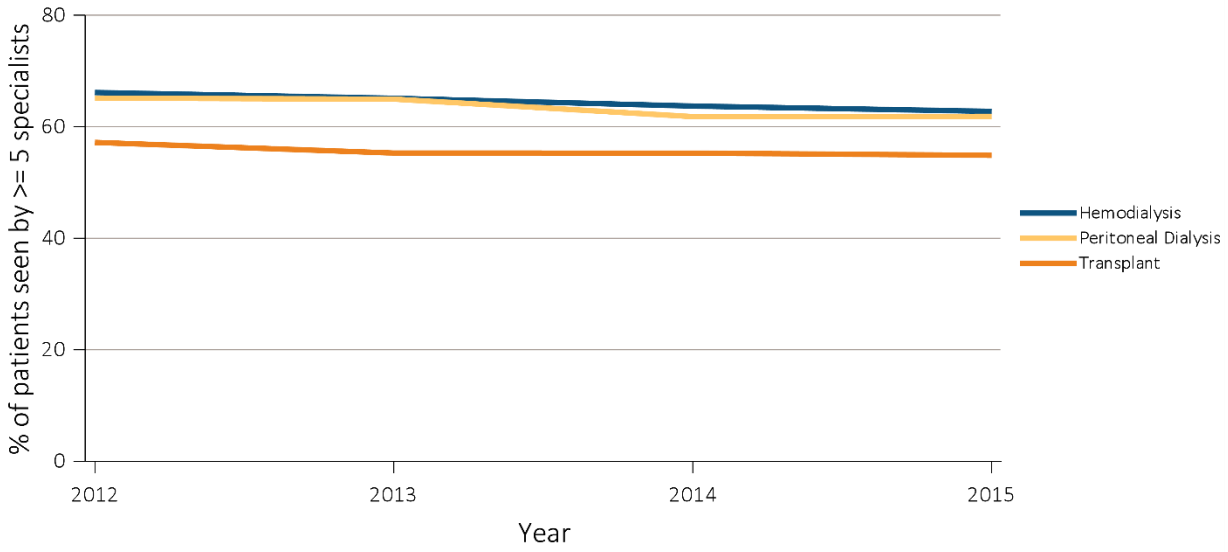
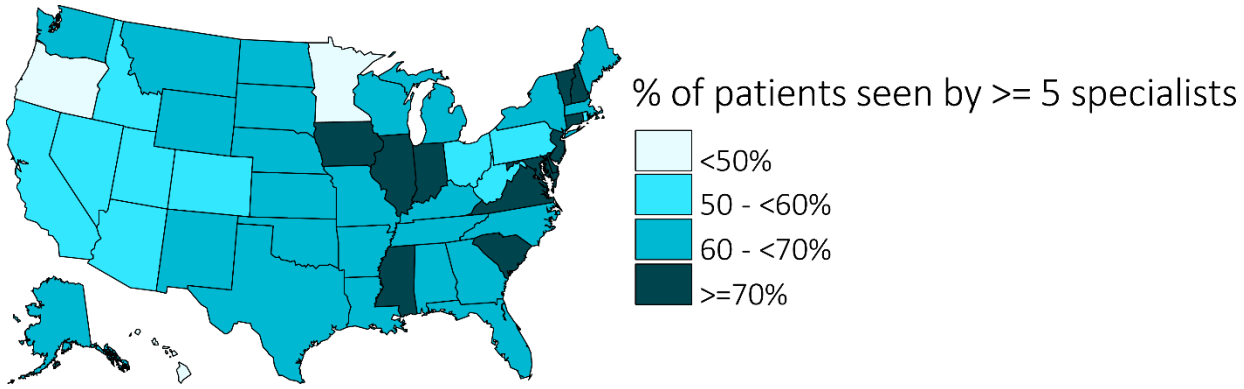


Figure 12.8 continued on next page.

vol 2 Figure 12.8 Percentage of Medicare beneficiaries with ESRD seen by 5 or more medical specialties in the last 90 days of life, overall, and by age, race, ethnicity, sex, and modality, 2012-2015 (continued)

(g) Percentage seen by 5 or more medical specialties by state of residence



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 who died between 2012 and 2015. Abbreviation: ESRD, end-stage renal disease.

vol 2 Table 12.2 Percent of patients seen by a specialist and median number of visits in the last 90 days of life, from 2012 to 2015

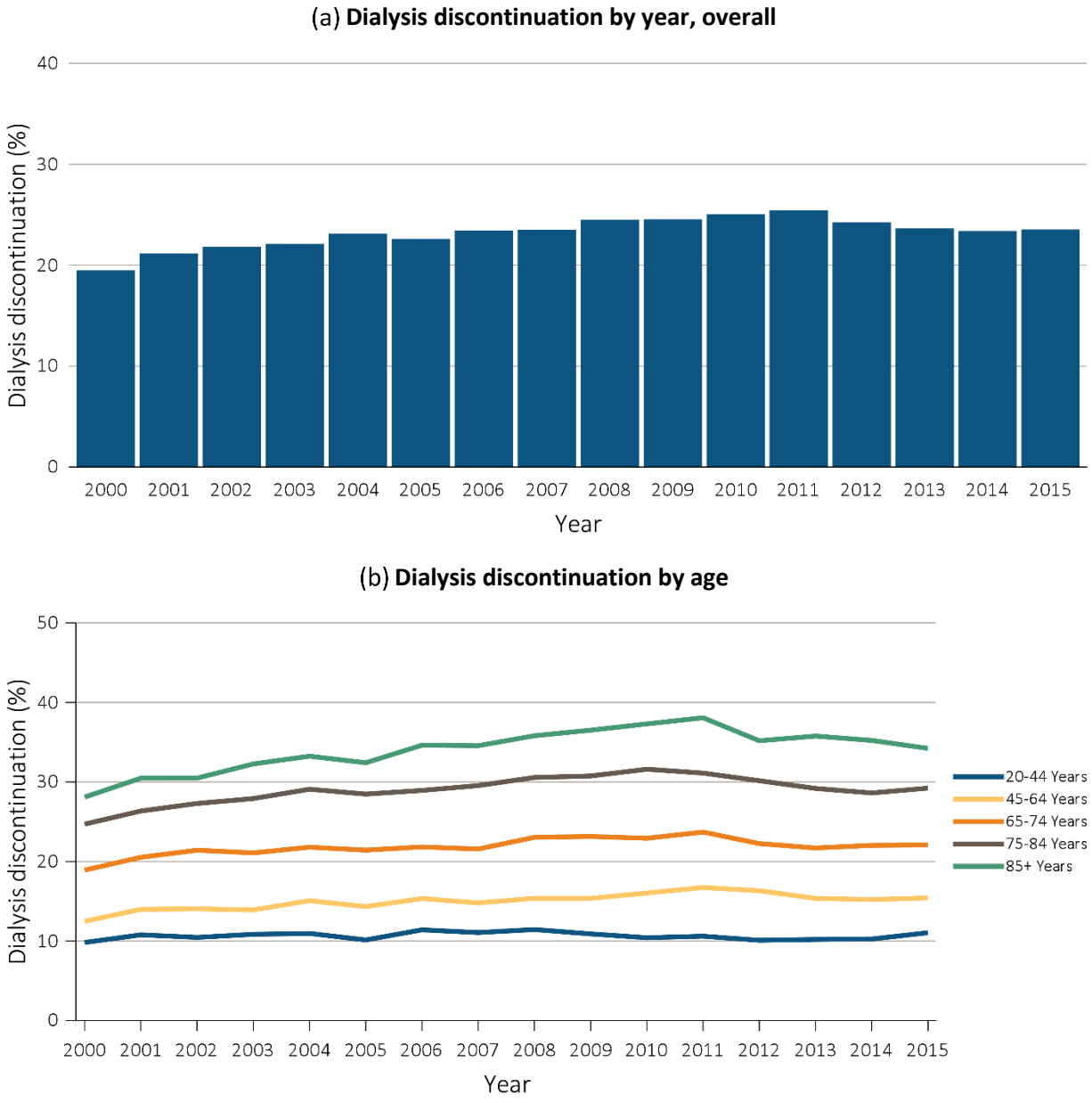
Specialty	% of patients seen by specialist	Mean number of visits in last 90 days
Nephrology	67%	14.8
Diagnostic radiology	66%	13.3
Internal medicine	63%	17.0
Emergency medicine	59%	4.5
Cardiology	55%	8.6
Family practice	33%	6.6
Pulmonary disease	31%	8.9
Anesthesiology	27%	4.5
General surgery	25%	5.0
Pathology	25%	3.6

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 who died between 2012 and 2015. Abbreviation: ESRD, end-stage renal disease.

Dialysis Discontinuation before Death

The percentage of patients with either HD or PD listed on the CMS 2746 as their most recent modality, and who were reported as having discontinued dialysis treatments before death, ranged from 19% in 2000 to 23% in 2015, peaking at 25% in 2011 (Figure 12.8). The frequency of dialysis discontinuation before death varied by demographic characteristics, modality, and by state of residence. Discontinuation was nearly 4 times as common among decedents 85+ years as among decedents 20-44 years. Whites were more likely than other races to discontinue dialysis, as were women. By region, discontinuation rates were twice as high in the Northwest as in the Southeast.

vol 2 Figure 12.9 Dialysis discontinuation before death among decedents overall, and by age, race, ethnicity, sex, and modality, 2000-2015



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vol 2 Figure 12.9 Dialysis discontinuation before death among decedents overall, and by age, race, ethnicity, sex, and modality, 2000-2015 (continued)

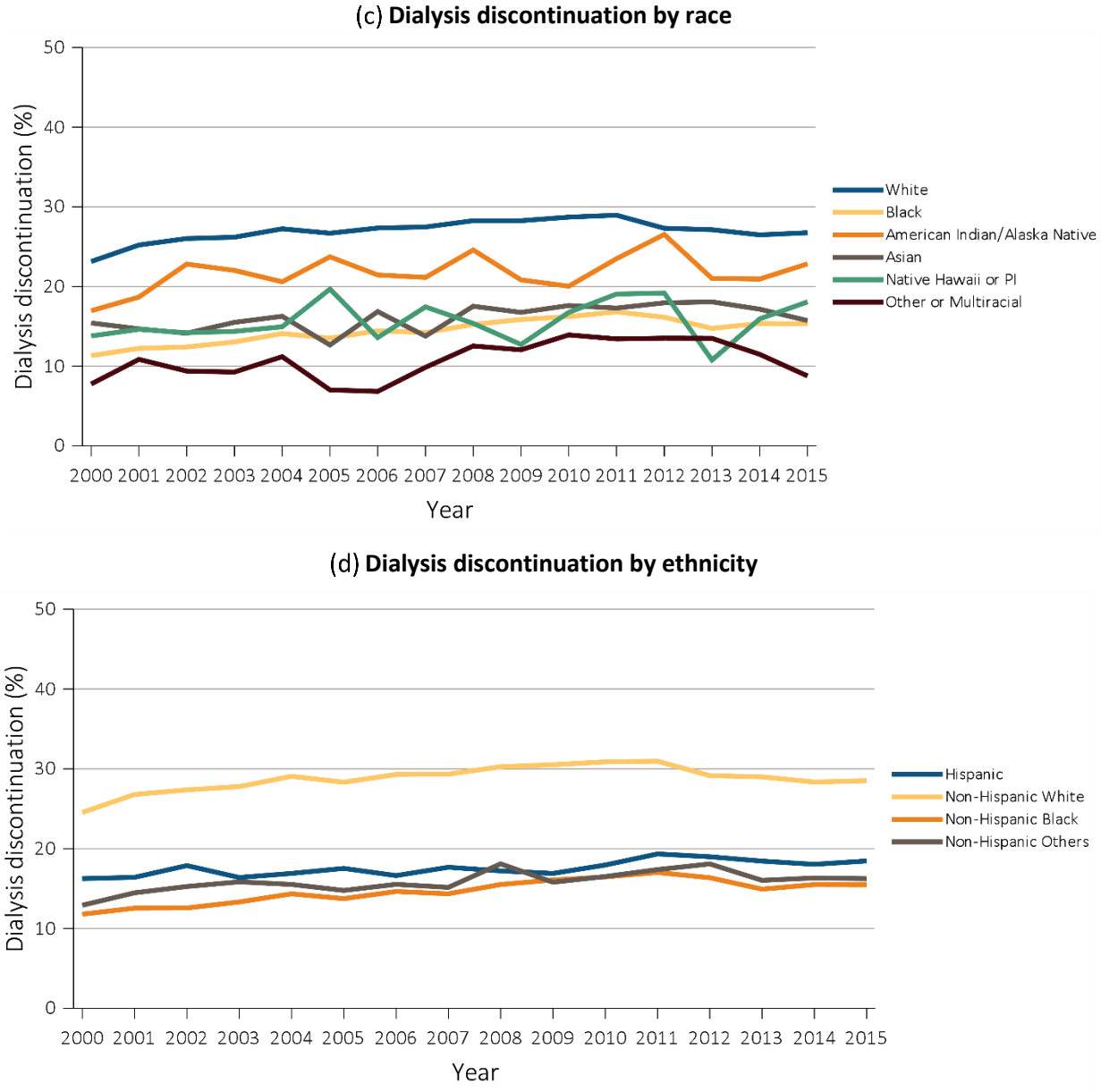


Figure 12.9 continued on next page.

vol 2 Figure 12.9 Dialysis discontinuation before death among decedents overall, and by age, race, ethnicity, sex, and modality, 2000-2015 (continued)

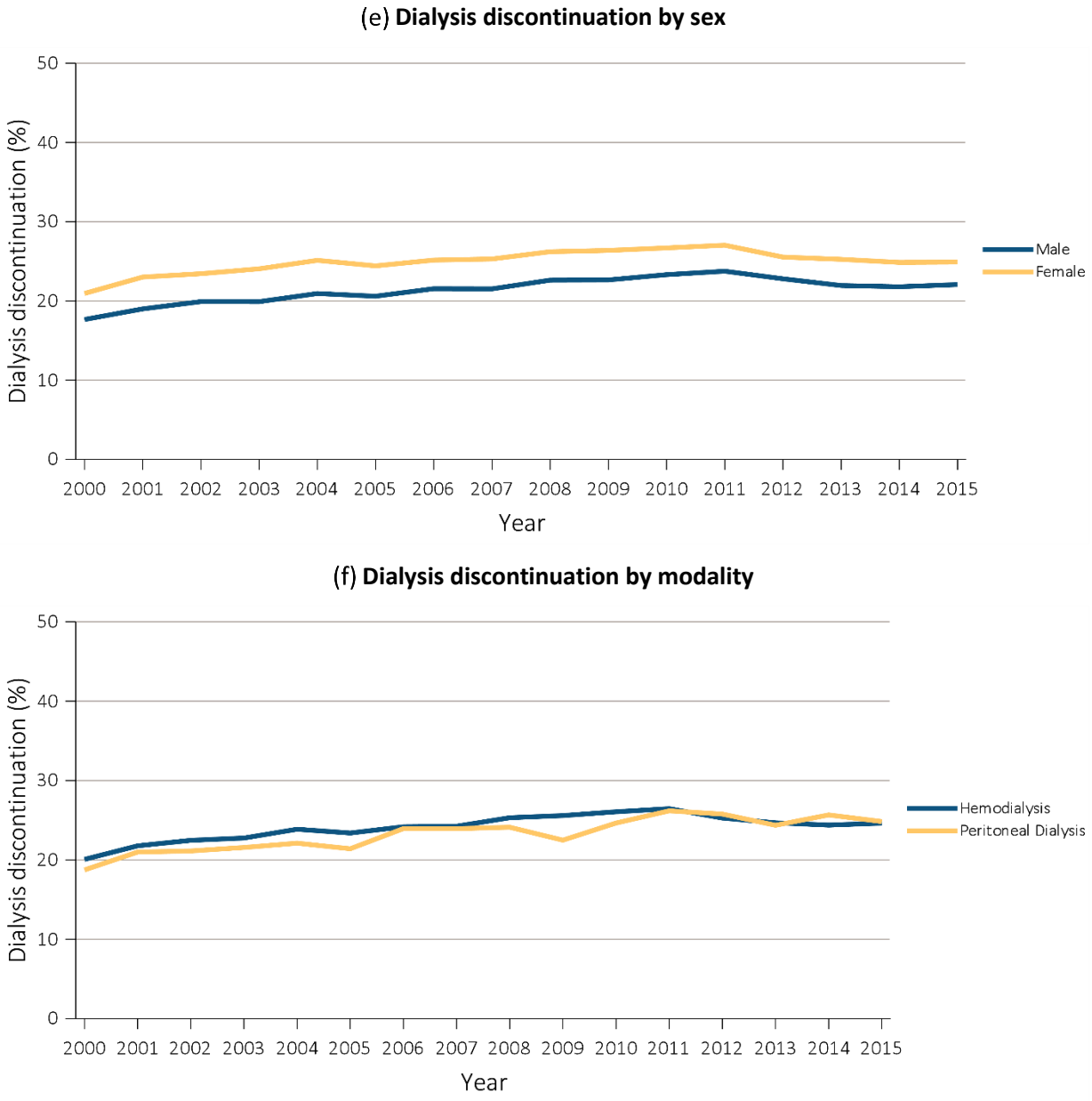
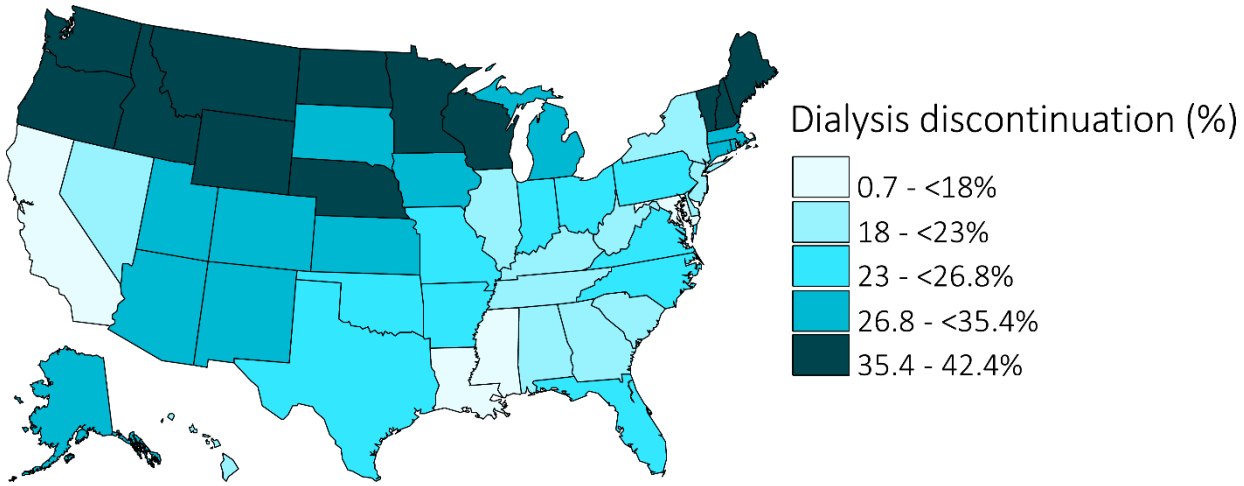


Figure 12.9 continued on next page.

vol 2 Figure 12.9 Dialysis discontinuation before death among decedents overall, and by age, race, ethnicity, sex, and modality, 2000-2015 (continued)

(g) **Dialysis discontinuation by state of residence**

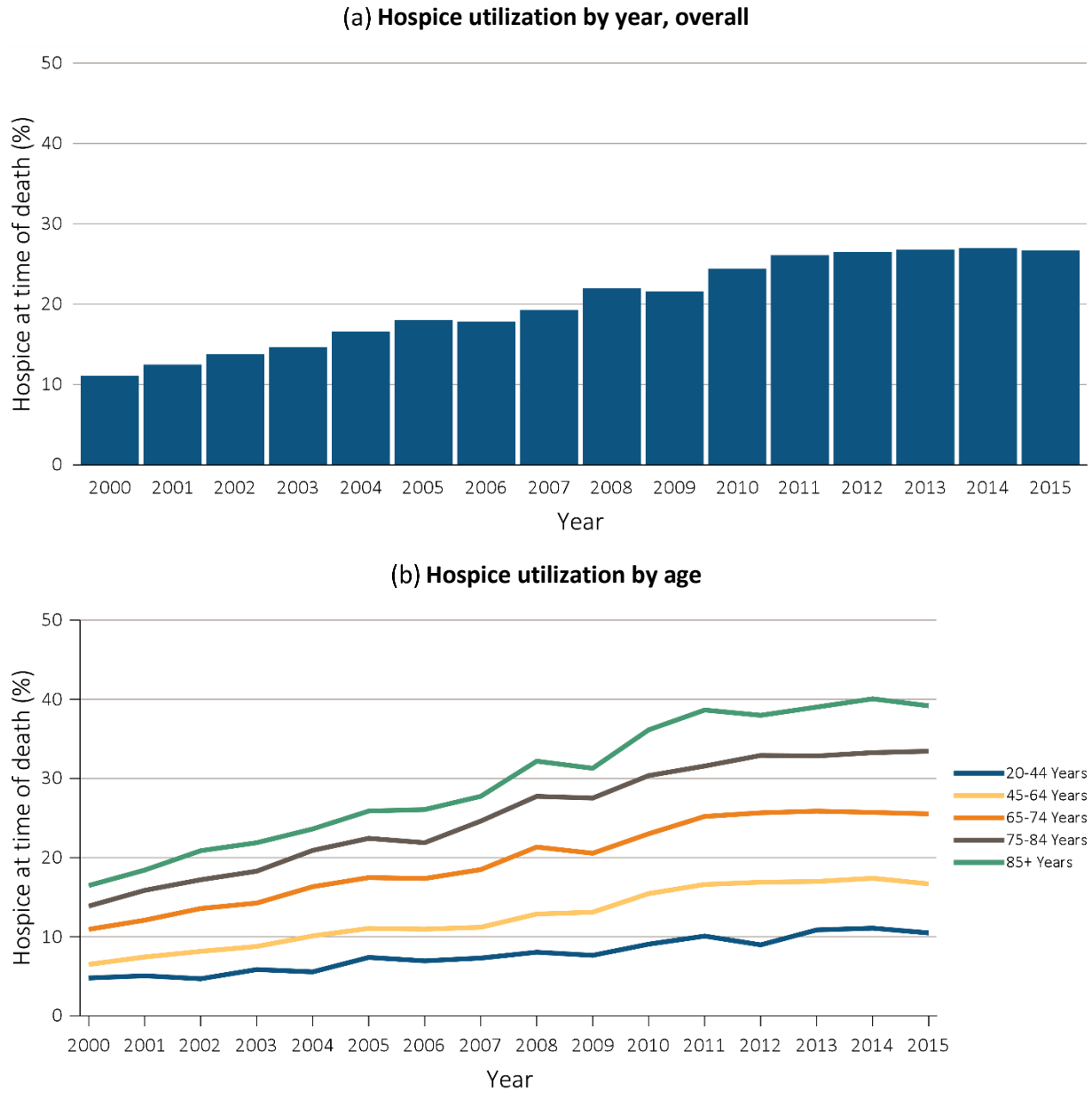


Data Source: Special analyses, USRDS ESRD Database. Denominator population is all patients with complete data on dialysis discontinuation from the CMS ESRD Death Notification form (CMS 2746) whose last modality was listed as dialysis. Abbreviation: ESRD, end-stage renal disease.

Patterns of Hospice Utilization before Death

The percentage of decedents with ESRD receiving hospice services at the time of death based on Medicare claims ranged from 11% in 2000 to 26% in 2015 (Figure 12.9). By comparison, rates of hospice use at death among the wider population of fee-for-service Medicare beneficiaries ranged from 21.6% in 2000 to 50.4% in 2015 (Teno et al., 2018). Among the overall population of fee-for-service Medicare beneficiaries, use of hospice services at the time of death varied by demographic characteristics, modality, and by state of residence. In addition, 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. For those who discontinued dialysis, the percentage receiving hospice at the time of death based on Medicare claims increased from 36% in 2000 to 62% in 2015. For those who did not discontinue dialysis treatments before death, the percentage receiving hospice services at the time of death increased from 5% in 2000 to 16% in 2015. Age at death was again a major predictor of hospice use with those 85 years and over using hospice (40%) at 4 times the rate of the youngest decedents (10%). Hospice was also much more common among White decedents than other races. There was also a two-fold difference in hospice use across the states, with generally higher rates in the central portions of the country.

vol 2 Figure 12.10 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, 2000-2015



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vol 2 Figure 12.10 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, 2000-2015 (continued)

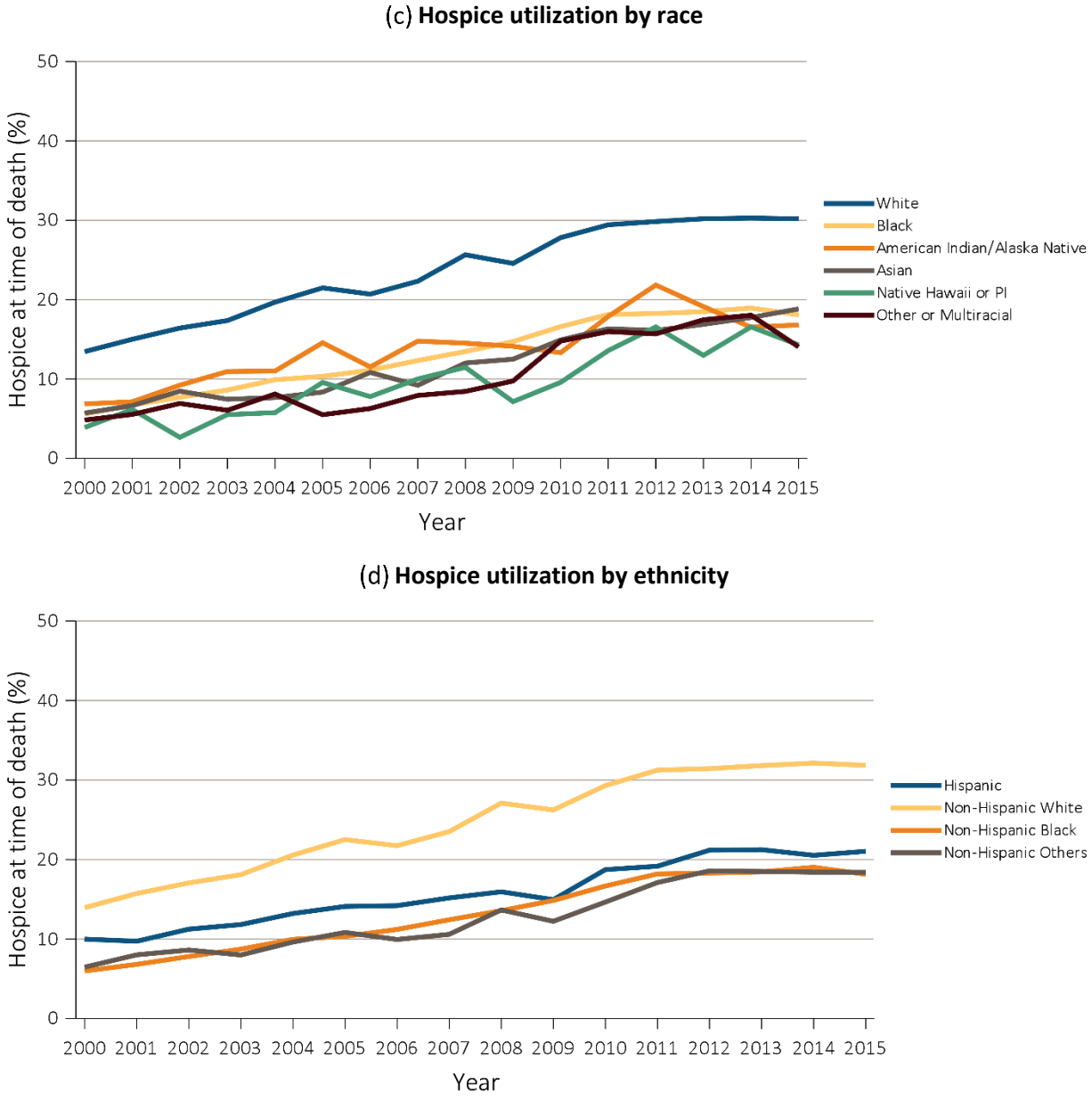
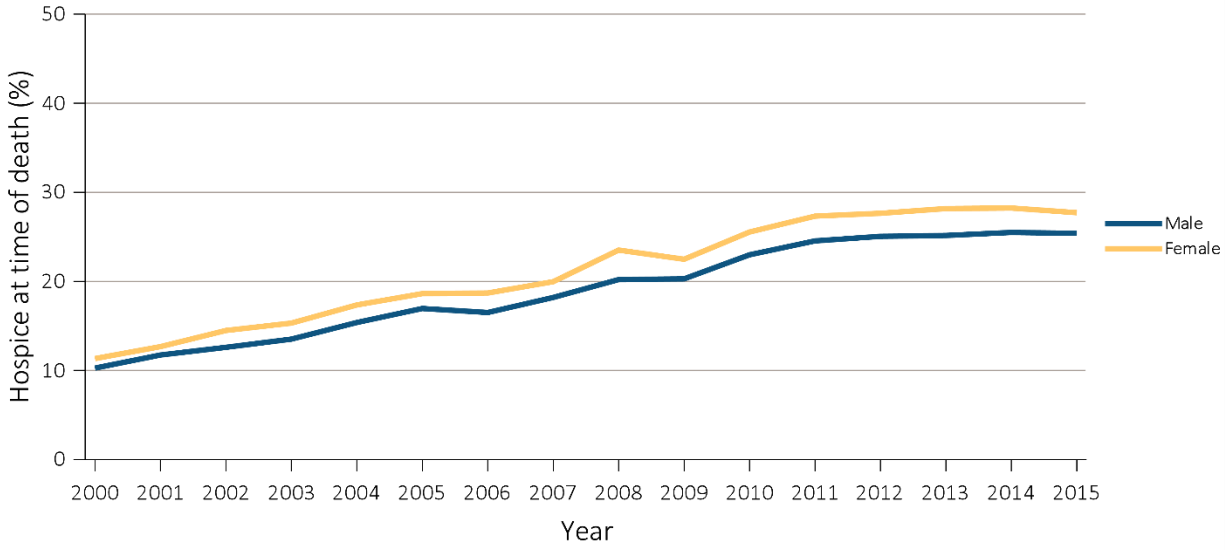


Figure 12.10 continued on next page.

vol 2 Figure 12.10 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, 2000-2015 (continued)

(e) **Hospice utilization by sex**



(f) **Hospice utilization by modality**

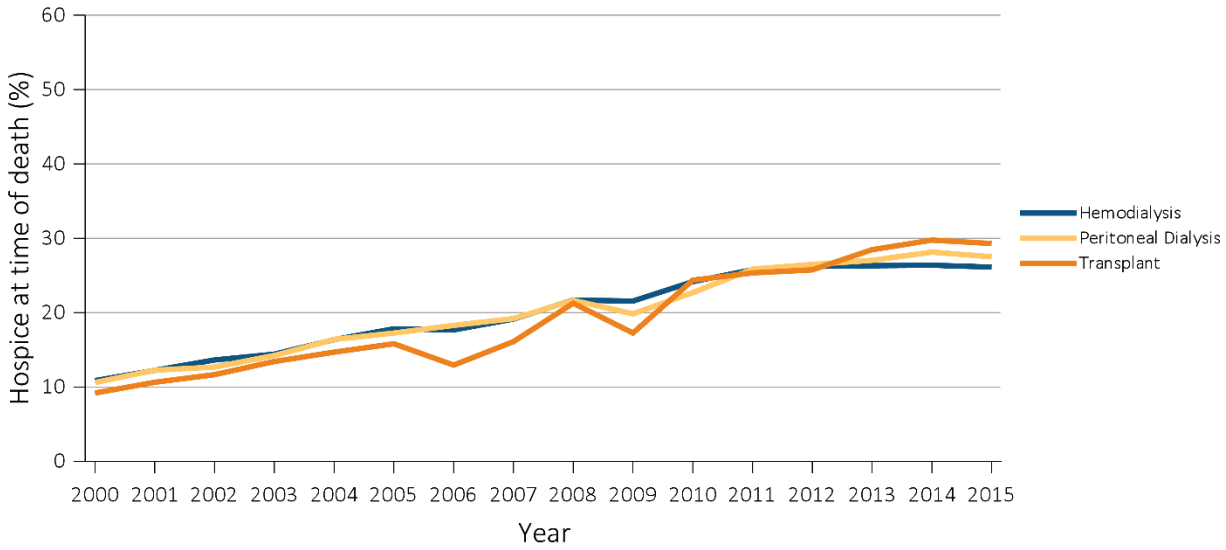
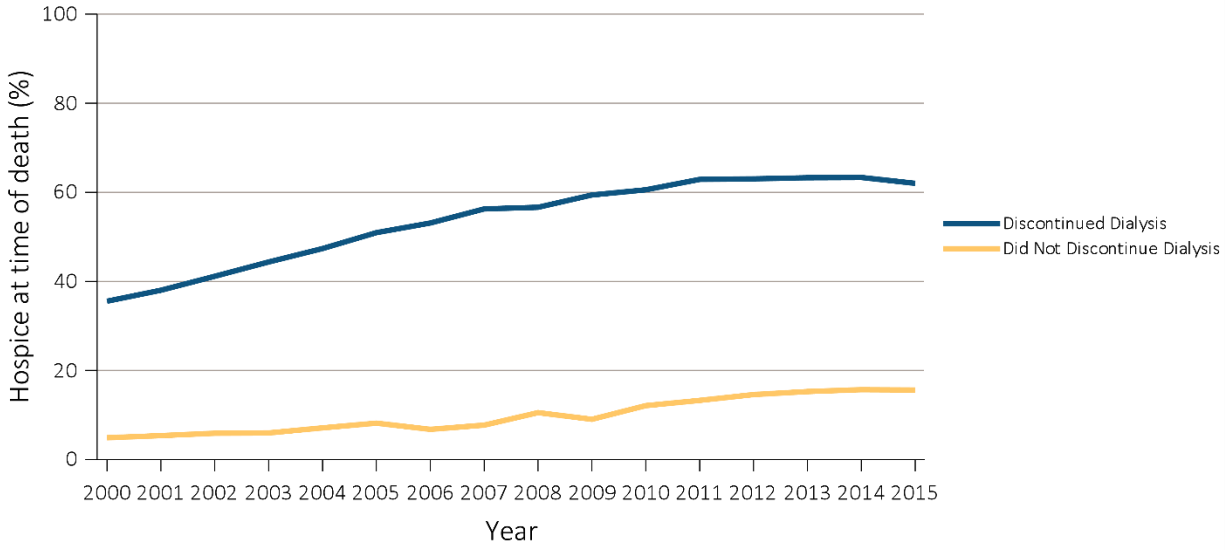


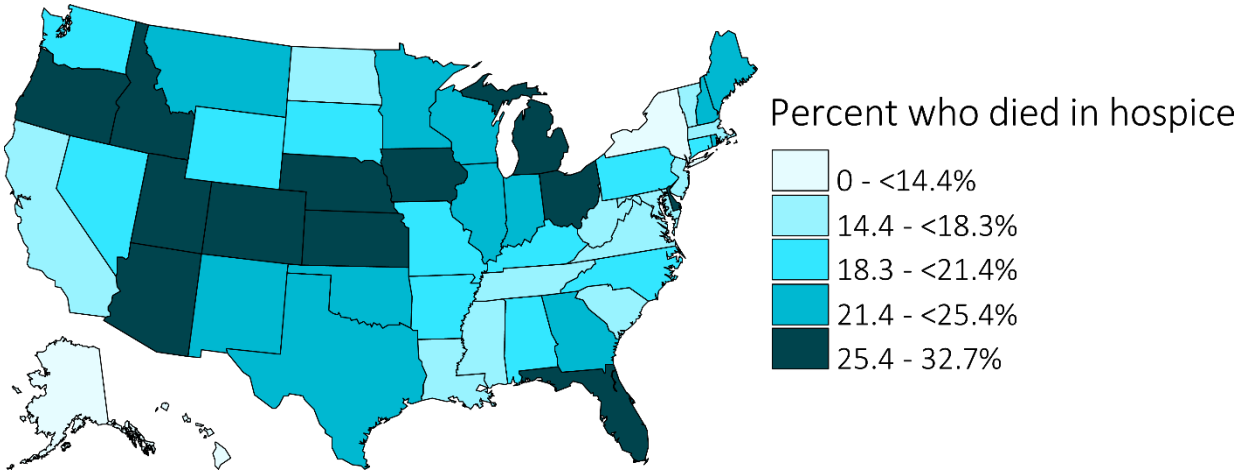
Figure 12.10 continued on next page.

vol 2 Figure 12.10 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, 2000-2015 (continued)

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



(h) **Hospice Utilization by state of residence**



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 (HCFASAF=S) on or after the date of death or Discharge Status from hospice=40, 41, or 42. Abbreviation: ESRD, end-stage renal disease.

Costs in the Last Year, Month, and Week of Life

For patients with ESRD who died in 2015, median per person costs under Medicare Parts A and B were $103,932 (IQR $65,345, $159,451) over the last year of life, $19,734 (IQR, $9,217, $34,979) over the last 30 days of life, and $7,687 (IQR, $1,866, $14,822) over the last seven days of life. Median costs during each of these time frames were progressively lower for patients with a longer time interval between the first claim for hospice and death, and were higher for those who received two or fewer days of hospice than for those who were not referred to hospice (Figure 12.15).

vol 2 Figure 12.11 Costs in the (a) last 30 days of life, and (b) last 7 days of life in relation to timing of hospice care, 2000-2015

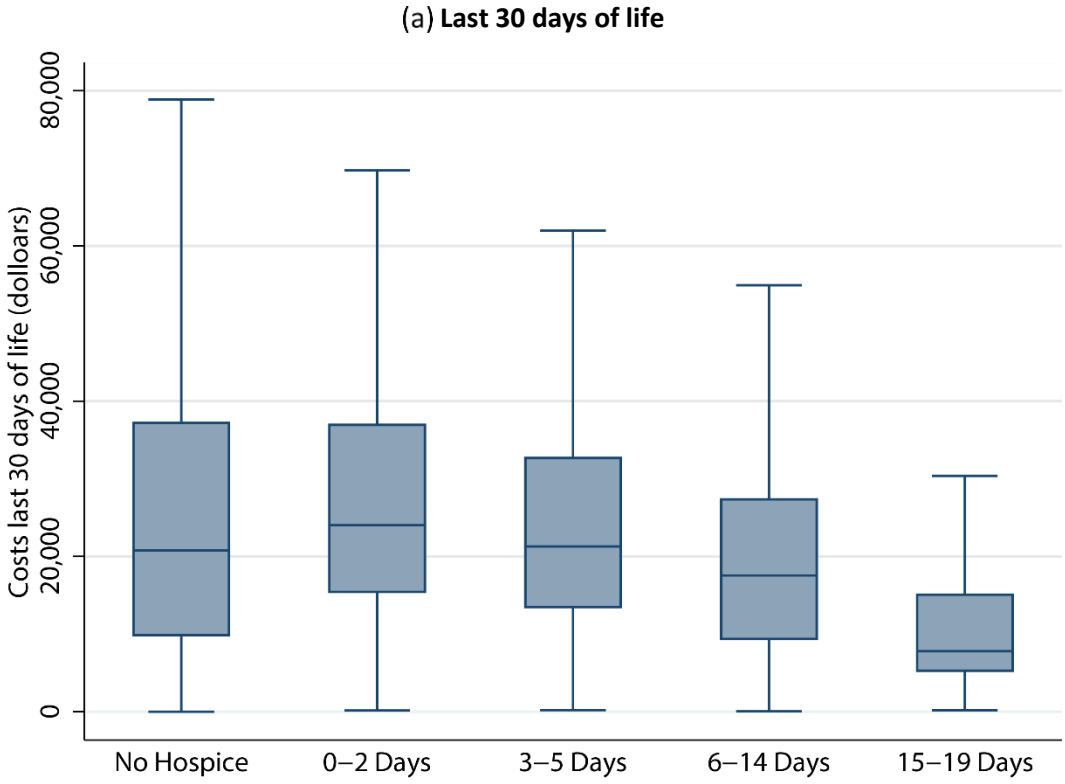
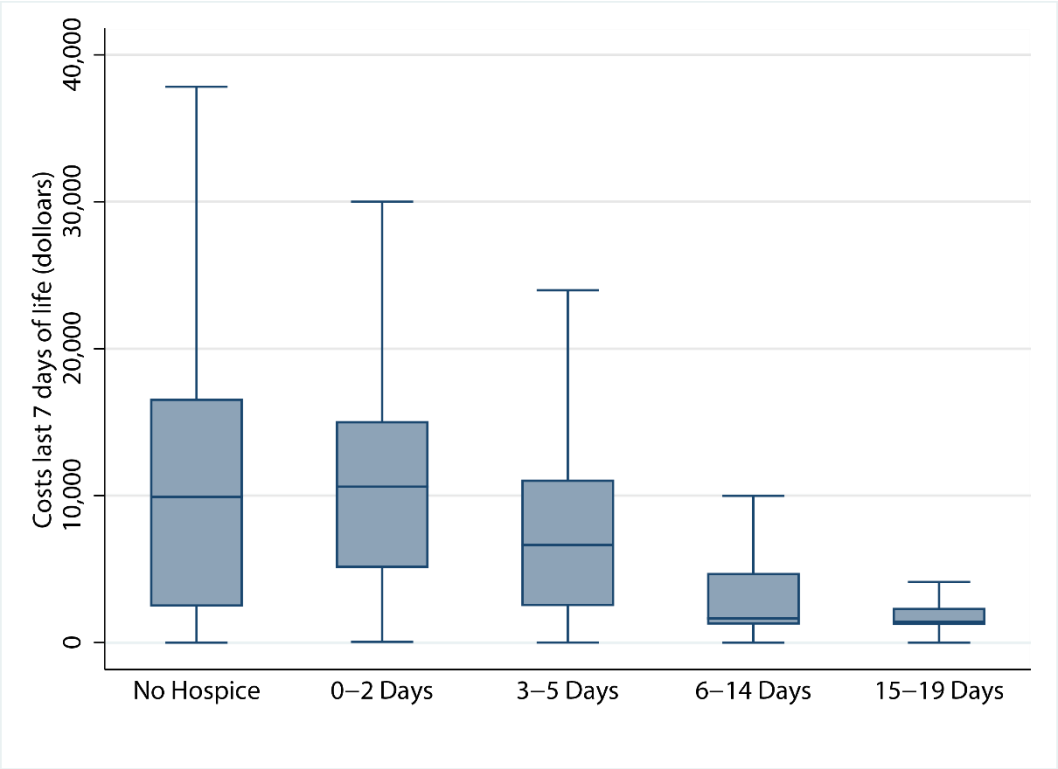


Figure 12.11 continued on next page.

vol 2 Figure 12.11 Costs in the (a) last 30 days of life, and (b) last 7 days of life in relation to timing of hospice care, 2000-2015 (continued)

(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=S) 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. Abbreviation: ESRD, end-stage renal disease.

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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, 2016. 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. 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), 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 Proposals was issued for the development of the United States Renal Data System (USRDS). NIDDK awarded the contract in May 1988 to the Urban Institute, with a subcontract to the University of Michigan, and the first USRDS Annual Data Report on the ESRD population was released in 1989.

In 1995, HCFA transitioned PMMIS to 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 & 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. Integrating SIMS events data into the USRDS Database improved the tracking of patients beyond treatment initiation. 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 United States. This system was implemented nationally in May 2012. In addition to replacing the existing patient tracking functionality of SIMS, CROWNWeb 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. Laboratory values for hematocrit, creatinine clearance, blood urea nitrogen (BUN), and urea clearance were no longer collected. Added laboratory values were hemoglobin A1c (HbA1c) 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 diagnosis and procedure detail as compared to ICD-9-CM codes, resulting in a better understanding of the patient's health. In addition, CMS implemented options of "<6 months" for Fields 18a-c, "Prior to ESRD therapy".

The Medical Evidence form is the only reliable 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, 1995, 1987) are provided in the USRDS Core SAF dataset and are available on the USRDS website in the USRDS Researcher's Guide, Appendix D: Data Collection Forms: *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 it 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. From 2007 to 2011, 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 (OPTN) Database

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 Transplantation 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, 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 ESRD 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 2018 SAFs include all claims up to December 31, 2016.

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 2018 ADR includes 2006-2016 PDE data.

Medicare 5% Standard Analysis Files (SAFs)

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 the 2015 ADR, the USRDS has received the 5% sample from the CMS Chronic Conditions Warehouse.

The Medicare 5% 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 sets of files, distinguished by the type of medical service received — inpatient, outpatient, home health agency, hospice, or skilled nursing facility. Physician/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 seven sets of

files collectively are referred to as the Medicare 5% files in the ADR.

The Medicare 5% files are used for Healthy People 2020 objectives and comparing preventive care and other non-ESRD disease treatments in general Medicare and ESRD patients. The Medicare 5% files are also used to construct CKD, diabetes, and congestive heart disease cohorts based on billing data. Table 13.1 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 13.1 ICD-9-CM and ICD-10-CM diagnosis codes used to define chronic kidney disease in the Medicare claims files

	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; 581-583; 585; 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; 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; N18.1-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 CKD		
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 or N18.6 with no CMS 2728 form
Stage unknown or unspecified	Patient has no claims with codes 585.1-585.6 but has: 016.0; 095.4; 189.0; 189.9; 223.0; 236.91; 250.4; 271.4; 274.1; 283.11; 403; 404; 440.1; 442.1; 477.3; 572.4; 581-584; 585.9; 586-588; 591; 642.1; 646.2; 753.12-753.19; 753.2; 794.4	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; 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 digits, 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).

United States Census

For the 2016 and prior ADRs, the U.S. population data were 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.

Starting with the 2017 ADR, the U.S. population data are obtained from the Census unbridged postcensal file. The USRDS summarizes this data by race, age, and sex at state and national levels.

Database Definitions

ESRD is defined as chronic renal failure requiring renal replacement treatment — dialysis or transplant — to sustain life. It is not the same as acute renal failure, from which patients are expected to recover within weeks or months. Renal providers must complete a Medical Evidence form for all ESRD patients, this registers them in the CMS ESRD database via CROWNWeb and allows them to apply for Medicare 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 through 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 worksheet/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 (1995-2005), the OPTN transplant follow-up worksheet/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 (1995-2005)
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 procedures:

- 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 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 a fraction of the patients in the USRDS database does not have Medicare as their primary payer 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 13.2 CROWNWeb events

Events	
New ESRD Patient	Recover Function
Transfer In	Lost to Follow-Up
Restart	Modality Change
Dialysis after Transplant Failed (at Dialysis Facility)	Transplant
Transfer Out for a Transplant	Continuing
Transfer Out	Transplant Failure (at Transplant Facility)
Discontinue	Interruption in Service
Death	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. See Table 13.2 for a list of CROWNWeb events. 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 claims 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 ADR 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, 2016.

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. See Table 13.3.

vol 2 Table 13.3 Diagnosis codes for primary cause of ESRD

Primary Cause of ESRD	ICD-9-CM	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; 593.83	I10; I12; I12.0; I12.9; I13.10; I13.2; I15.0; I15.8; I75.81
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; 710.0; 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; 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; 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; 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 Revision, Clinical Modification.

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.

The standard race categories used by the USRDS since the 2016 ADR are White, Black/African American, American Indian or Alaska Native, Asian, Native Hawaiian or Pacific Islander, Other or Multiracial, and Unknown.

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 13.4 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 13.4 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[a]	White; Mid-East Arabian	White
Black/African American	Black	Black or African American	Black	Black
American Indian or Alaska Native	American Indian or Alaska Native	American Indian or Alaska Native	American Indian or Alaska Native	Native American
Asian	Asian; Indian Sub-Continent	Asian; Indian Sub-Continent[a]	Asian; Indian Sub-Continent	Asian
Native Hawaiian or Pacific Islander	Pacific Islander	Native Hawaiian or Other Pacific Islander[a]	Pacific Islander	--
Unknown	Unknown; Missing	Unknown[a]; Missing	Unknown; Missing	Unknown; Missing
Other or Multiracial	Other or Multiracial	Other[a] or Multiracial	Other or Multiracial	Other or Multiracial

[a] On 2728 form in use from 1995-2005, Pacific Islander used instead of Native Hawaiian or Pacific Islander.

The data sources for ethnicity are (from highest to lowest priority):

- Medical Evidence form
- CROWNWeb patient list
- Medicare Enrollment Database

Similar to the race categorization, if information is missing from the CROWNWeb patient list, then the other two 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. The methods used to create the figures and tables for Volume 2 chapters are described below in a section corresponding to each chapter. When figure or table data are drawn directly from a particular reference table, please refer to the *ESRD Reference Table Methods* section for additional details.

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

Incidence of ESRD: Counts, Rates, and Trends

Disease incidence in a population may be quantified in two ways: as a rate and as a risk. Risk of ESRD is newly added in the 2018 ADR.

Race has been standardized across the ADR. In the 2017 ADR, for the first time, the Native Hawaiian/ Pacific Islander racial group was presented as separate from Asian, except for Table 1.3 and Figure 1.7. Direct adjustment was used as described in the *Methods* section of Chapter 1. Rates per million population used Census data that are 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 standardized rates geographically by Health Service Areas (HSA).

For Figures 1.4-1.6, incidence rates were from special analyses using the same standardized method. 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.

Risk: Cumulative Incidence by Age, Sex, Race, and Duration of Follow-up

A full description of the methods for this section can be seen in the paper by Albertus et al. (2016). They are summarized here.

Risks (probabilities) of being diagnosed with ESRD during a given age interval were estimated using DevCan software (version 6.7.2) developed at the National Cancer Institute. A competing-risks framework is used to estimate risks (cumulative incidences) from incidence data. The challenge is to obtain risk estimates for any age interval during the life span based on age-specific incidence rates obtained for a given calendar period, taking into account competing causes of death. DevCan applies the incidence and mortality rates of ESRD and mortality rates of all other causes of death (competing events) to a large hypothetical cohort that is "aged" from birth until death.

The age-sex-race/ethnicity distribution at birth for this hypothetical cohort is the same as the age-sex-race/ethnicity distribution of the United States in that year. Five-year age intervals were used to estimate rates and generate a hypothetical cohort, stratifying on sex and race/ethnicity (non-Hispanic White, non-Hispanic Black, non-Hispanic Native American, non-Hispanic Asian/Pacific Islander, and Hispanic). DevCan incorporates a "piecewise mid-age group joinpoint model" to smooth out risk estimates within 5-year age intervals, effectively assuming incidence rates are constant within half-year age intervals. Figure 1.7 shows the cumulative incidence of ESRD by race and sex — male in 1.7.a and female in 1.7.b. Table 1.3 shows this by age and sex — male in 1.3.a and female in 1.3.b.

Prevalence of ESRD: Counts, Prevalence, and Trends

In the chapter, point prevalence is as of December 31, while period prevalence is 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 are counted as prevalent patients.

Beginning with the 1992 ADR, lost to follow-up patients are not included in the point prevalent counts, they are reported in *Volume 2 Reference Table B.1.*

Prevalence adjustments in this chapter are the same as the corresponding incidence rates detailed above. Prevalence estimates also use direct standardization and intercensal population estimates.

Results for Table 1.4, Figures 1.8, 1.10, 1.11, 1.12, and 1.13 were from 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.

Statistics for Table 1.5 were taken from *Reference Table B* and special analyses. Table 1.5 shows prevalence counts, crude and standardized prevalence, and count by modality (hemodialysis, peritoneal dialysis, and transplant). Specifically, prevalent cases correspond to those found in B.10 and prevalence was from special analyses. Figure 1.9 shows prevalence counts over time by modality and used Reference Table D1 and special analyses.

Modality of Renal Replacement Therapy

Modality figures and the associated reference tables describe the treatment modalities of all known ESRD patients, both Medicare and non-Medicare, who are not classified as lost to follow-up or as having 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 13.5.

vol 2 Table 13.5 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 or 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 through 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.

Figures 1.14 shows incident counts by home dialysis modality across time using data from *Reference Table D.1* and special analyses. Table 1.6 counts were taken from *Reference Table D.10* with additional special analyses. The maps in Figures 1.15 and 1.17 were created by tabulating modality data by HSA. Figure 1.16 shows the prevalent counts across time and was taken from *Reference Table D.1*. Table 1.7 used data from *Table D.11*.

Patient and Treatment Characteristics at ESRD onset

For Tables 1.8, 1.9, and 1.10, and Figures 1.18-1.21, 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. See the chapter, *CKD Analytical Methods*, for the full CKD-EPI equation.

Chapter 2: Clinical Indicators and Preventive Care

Clinical Indicators

Figure 2.1 data were obtained from CROWNWeb clinical extracts for May 2017. The adequacy (Kt/V) analyses (Figure 2.1.a) were restricted to patients at least 18 years old as of May 1, 2017. Patients must have been alive as of May 31, 2017, and must have had ESRD for at least one year at the time of measurement. If multiple measurements were 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, 2017, and alive as of May 31, 2017, 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, 2017, and had ESRD for at least 90 days as of the time of measurement of an uncorrected serum calcium value. In Figure 2.1.d, all adult (aged 18 and older) patients who were on dialysis for at least 90 days as of May 1, 2017, and alive as of May 31, 2017 were included. If multiple serum albumin measurements were available for a patient, the last one in the month was used. The categorical distribution of serum albumin (g/dL) is shown for both HD and PD patients.

Anemia Treatment by Modality

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 erythropoietin stimulating agent (ESA) 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. Epoetin alfa (EPO) was identified using HCPCS codes J0885, J0886, and Q4081, and value code 68, darbepoetin by codes J0881 and J0882, and 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 (Q0139).

Hemoglobin levels are shown in Figures 2.2, 2.3, 2.8, and 2.9. Hemoglobin values are based upon the first reported claim in each month for HD patients (Figures 2.2, 2.3) or for PD patients (Figures 2.8, 2.9). When hemoglobin levels were not available in claims data, hematocrit values, if available, were divided by 3 to serve as a proxy estimate. Patients were excluded in a given month if the hemoglobin level (or hemoglobin values estimated from hematocrit values) was <5 g/dL or >20 g/dL. Results are shown for 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 hemoglobin or hematocrit level, and (2) at the start of the month, were on dialysis for 90 days or more and were aged 18 or older. In Figures 2.2 and 2.8, hemoglobin levels are also provided for all patients, and the same restrictions were used as described in statement 2 above, but not limited to patients with an ESA claim within the given month. In addition, hemoglobin levels for patients not on any ESA drugs in a month are also shown for HD patients (Figure 2.2) and PD patients (Figure 2.8).

Figures 2.2.a (HD) and 2.8.a (PD) show trends in mean hemoglobin (for EPO alfa-only patients, for non-ESA patients and for all patients) and mean EPO alfa-only weekly dose. Mean monthly EPO alfa dose is shown for patients who, within a given month, had an EPO alfa claim only (no darbepoetin or epoetin beta), were on dialysis for 90 days or longer, and were 18 years or older at the start of the month. EPO alfa dose is expressed as mean EPO alfa 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 alfa dose was either less than 250 units per week or greater than 400,000 units per week. These criteria resulted in <0.001% of patients being excluded.

In exactly the same way, Figures 2.2.b (HD) and 2.8.b (PD) respectively show mean monthly Hgb for darbepoetin-only patients and mean monthly darbepoetin-only dose for HD and PD patients. Mean monthly Hgb for epoetin beta dose-only patients and mean monthly epoetin beta dose (only) are shown for HD patients in Figure 2.2.c and PD patients in Figure 2.8.c. Darbepoetin and epoetin beta doses were calculated in the same way as EPO alfa dose, but no upper or lower limits were imposed. Sensitivity analyses precluded the need for dosage limits on darbepoetin and epoetin beta, as a very small number of patients on these drugs received doses outside the acceptable clinical range.

Monthly ESA use is shown for HD patients in Figure 2.2.d and for PD patients in Figure 2.8.d. Monthly "EPO alfa only" use (EPO alfa and not darbepoetin or epoetin beta), "darbepoetin only" use (darbepoetin and not EPO alfa or epoetin beta), "epoetin beta only" use (epoetin beta and not EPO alfa or darbepoetin), and "Any ESA" use (any or a combination of EPO alfa, darbepoetin, or epoetin beta) were calculated among patients who were on dialysis for at least 90 days and 18 years or older at the start of the given month. Figure 2.3 shows categorical levels of Hgb for ESA-using HD patients, and Figure 2.9 shows the same for ESA-using PD patients.

Intravenous (IV) iron use and IV iron dose are shown in Figures 2.4 (HD) and 2.10 (PD). Monthly intravenous iron use was assessed among patients on dialysis for 90 days or longer and 18 years or older at the start of the given month. Mean IV iron dose was calculated as the average dose (mg) of IV iron (iron sucrose and ferrous gluconate) a patient received, among patients receiving iron during the month. This analysis was restricted to patients who had more than six IV iron sessions but less than or equal to 18 sessions in a month. The permissible range of values considered for sucrose and ferrous gluconate were respectively 50-1800 mg and 12.5-1800 mg.

CROWNWeb data is used for the iron storage measures—transferrin saturation (TSAT) and serum ferritin. Categorical distributions of the iron store measures for May 2015, May 2016, and May 2017, are shown for HD patients in Figures 2.5 and 2.6. Figures 2.11 and 2.12 show the same categorical distributions of TSAT and serum ferritin for PD patients. Tables 2.1 and 2.2 stratify the categorical distributions of TSAT and serum ferritin, among HD patients for May 2017, by age, sex, race, and primary cause of ESRD. Tables 2.3 and 2.4 provide the same stratifications of categorical TSAT and serum ferritin distributions among PD patients.

Figures 2.5 and 2.11 include dialysis patients treated for ESRD for at least 90 days at the time of TSAT measurement for 2015, 2016, and 2017. Patients were required to have been ≥18 years old as of May 1 of the given year and alive through May 31 of the given year. For each year, the latest non-missing TSAT value during March-May was used.

Figures 2.6 and 2.12 include dialysis patients treated for ESRD for at least 90 days at the time of serum ferritin measurement for 2015, 2016, and 2017, who were ≥18 years old as of May 1 of the given year, and who were alive through May 31 of the given year. For

each year, the latest non-missing serum ferritin value during March-May was used.

Figures 2.7.a (HD) and 2.13.a (PD) show the percentage of Medicare patients with one, two, three, or four or more red blood cell transfusions per year from 2012-2016 using Medicare claims. Here, the denominator includes all patients having a claim for at least one dialysis session during the month who were 18 years or older at the start of the month. The numerator consists of the total number of transfusion claims a patient had in a given year. Patients' modality was determined by the first treatment of the year.

The percentages of dialysis patients with one or more claims for red blood cell transfusions in a given month (2012-2016) 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 dialysis session during the month who were 18 years or older at the start of the month. Codes used to identify transfusions are shown in Table 13.6.

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 2015, May 2016, and May 2017. Analyses for Figure 2.14 and 2.15 included HD (Figure 1.14) or PD (Figure 1.15) patients with ESRD for at least one year at the time of serum calcium measurement who were 18 years or older as of May 1 of each year and alive through May 31 of each year. Serum phosphorous analyses shown in Figure 2.16 (HD patients) used the same sample restrictions as defined above. Similar analyses were completed for PD patients, as shown in Figure 2.17.

vol 2 Table 13.6 Codes identifying a red blood cell transfusion

Code	Code Type	Code Description
36430	HCPCS	Transfusion, blood or blood components
36430	HCPCS	Blood (whole), for transfusion, per unit
36430	HCPCS	Blood, split unit
36430	HCPCS	Red blood cells, leukocytes reduced, each unit
36430	HCPCS	Red blood cells, each unit
36430	HCPCS	Red blood cells, washed, each unit
36430	HCPCS	Red blood cells, irradiated, each unit
36430	HCPCS	Red blood cells, deglycerolized, each unit
36430	HCPCS	Red blood cells, leukocytes reduced, irradiated, each unit
36430	HCPCS	Whole blood or red blood cells, leukocytes reduced, CMV-negative, each unit
36430	HCPCS	Whole blood or red blood cells, leukocytes reduced, frozen, deglycerol, washed, each unit
36430	HCPCS	Whole blood, leukocytes reduced, irradiated, each unit
36430	HCPCS	Red blood cells, frozen/deglycerolized/washed, leukocytes reduced, irradiated, each unit
36430	HCPCS	Red blood cells, leukocytes reduced, CMV-negative, irradiated, each unit
36430	ICD-9	Other operations on heart and pericardium
36430	ICD-9	Other transfusion of whole blood; transfusion: blood NOS, hemodilution, NOS
36430	ICD-9	Transfusion of packed cells
36430	ICD-10	Transfuse Nonaut Whole Blood in Peripheral Vein, Open Approach
36430	ICD-10	Transfuse Nonaut Whole Blood in Peripheral Vein, Percutaneous Approach
36430	ICD-10	Transfuse Nonaut Whole Blood in Central Vein, Open Approach
30243H1	ICD-10	Transfuse Nonaut Whole Blood in Central Vein, Percutaneous Approach
30250H1	ICD-10	Transfuse Nonaut Whole Blood in Peripheral Artery, Open Approach
30253H1	ICD-10	Transfuse Nonaut Whole Blood in Peripheral Artery, Percutaneous Approach
30260H1	ICD-10	Transfuse Nonaut Whole Blood in Central Artery, Open Approach
30263H1	ICD-10	Transfuse Nonaut Whole Blood in Central Artery, Percutaneous Approach
30230N1	ICD-10	Transfuse Nonaut Red Blood Cells in Peripheral Vein, Open Approach
30230P1	ICD-10	Transfuse Nonaut Frozen Red Cells in Peripheral Vein, Open 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
30240N1	ICD-10	Transfuse Nonaut Red Blood Cells in Central Vein, Open Approach
30240P1	ICD-10	Transfuse Nonaut Frozen Red Cells in Central Vein, Open 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
30250N1	ICD-10	Transfuse Nonaut Red Blood Cells in Peripheral Artery, Open Approach
30250P1	ICD-10	Transfuse Nonaut Frozen Red Cells in Peripheral Artery, Open 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
30260N1	ICD-10	Transfuse Nonaut Red Blood Cells in Central Artery, Open Approach
30260P1	ICD-10	Transfuse Nonaut Frozen Red Cells in Central Artery, Open 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

Figure 2.18 presents statistics on diabetic preventive care across time. 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 patients being alive, with a valid birth date, and residing in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. Patients were also required to have Medicare Parts A and B coverage with no Medicare Advantage participation. Patients were required not to have been lost to follow-up in both years one and two. Claims from year one were searched for diagnoses indicating diabetes mellitus (DM; see Table 13.3 for diagnosis codes). 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 13.7 shows the various diagnosis and procedure codes used to define each diabetes care measure. Comprehensive diabetic care includes at least one hemoglobin A1c (HbA1c) test, at least one lipids test, and at least one eye exam. HbA1c and lipid tests should occur at least 30 days apart.

vol 2 Table 13.7 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					
Lipids	*<none>*	*<none>*	80061; 82465; 82470; 83695; 83700-83705; 83715-83721; 84478	*<none>*	*<none>*
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; 95.02-95.04; 95.11; 95.12; 95.16; V72.0	
	ICD-10 Procedure Codes:	085G3ZZ; 085H3ZZ; 08943ZX; 08953ZX; 089A00Z; 089A0ZZ; 089A0ZX; 089A30Z; 089A3ZX; 089A3ZZ; 089B00Z; 089B0ZZ; 089B0ZX; 089B30Z; 089B3ZX; 089B3ZZ; 089E30Z; 089E3ZX; 089E3ZZ; 089F30Z; 089F3ZX; 089F3ZZ; 089G30Z; 089G3ZX; 089G3ZZ; 089H30Z; 089H3ZX; 089H3ZZ; 08B43ZX; 08B53ZX; 08B6XZZ ; 08B7XZZ; 08BA0ZX; 08BA3ZX; 08BB0ZX; 08BB3ZX; 08BE3ZX; 08BE3ZZ; 08BF3ZZ; 08CG3ZZ; 08CH3ZZ; 08H031Z; 08H0X1Z; 08H131Z; 08H1X1Z; 08J0XZZ; 08J1XZZ; 08NA0ZZ; 08NA3ZZ; 08NB0ZZ; 08NB3ZZ; 08NE3ZZ; 08NF3ZZ; 08NG3ZZ; 08NH3ZZ; 08QA0ZZ-08QB3ZZ; 08QE3ZZ; 08QF3ZZ; 08QG3ZZ; 08QH3ZZ; 08RG37Z; 08RG3JZ; 08RGKZ; 08RH37Z; 08RH3JZ; 08RH3KZ; 08SG3ZZ; 08SH3ZZ; 08U00JZ; 08U03JZ; 08U10JZ; 08U13JZ; 08UE07Z; 08UE0JZ; 08UE0KZ; 08UE37Z; 08UE3JZ; 08UE3KZ; 08UF07Z; 08UF0JZ; 08UF0KZ; 08UF37Z; 08UF3JZ; 08UF3KZ; 08UG07Z; 08UG07Z; 08UG37Z; 08UG3JZ; 08UG3KZ; 08UH07Z; 08UH0JZ; 08UH0KZ; 08UH37Z; 08UH3JZ; 08UH3KZ; 3E0C3GC; 3E0CXSF; B30N0ZZ-B30NYZZ; C8191ZZ; C819YZZ; C81YYZZ		

Abbreviations: HCPCS, Healthcare Common Procedure Coding System, ICD 9/10, International Classification of Diseases, Ninth/Tenth Revision.

Figure 2.19 presents data on influenza vaccinations for prevalent ESRD patients overall (2.19.a), by age and HD treatment (2.19.b), by age and PD treatment (2.19.c), by age and transplantation (2.19.d), by race (2.19.e), and by ethnicity (2.19.f). 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 on April 30 of year two, with a valid birth date, residence in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, and Medicare Parts A and B coverage with no Medicare Advantage participation, Patients were also required not to have been lost to follow-up. Age was calculated at the end of the study period. Influenza vaccination was assessed between August 1 of year one and April 30 of year two. 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 are obtained from the Medical Evidence form (CMS 2728). Data are restricted to the 2005 and 2015 versions of the CMS 2728 form and incorporate 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 2005-2016. Table 3.1 and Figures 3.2-3.3 present data for patients who began dialysis in 2016. Age was calculated as of the date on which regular, chronic dialysis began.

In Figures 3.2 and 3.3 we illustrate geographic variation by state in the 2016 percentages of catheter-only use and arteriovenous (AV) fistula use at hemodialysis initiation. These figures exclude patients not living in the 50 states or the District of Columbia.

Table 13.8 shows the various codes used for vascular access in *Volume 2, Chapter 3: Vascular Access*.

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 were used to determine vascular access use for May 2017. Catheter use included any catheter, whereas AV fistula and AV graft use excluded the use of a central venous catheter.

Figures 3.4 and 3.5 show geographic variation by state in the percentages of catheter-only and AV fistula use among prevalent hemodialysis patients, these analyses used CROWNWeb data from May 2017, 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 2017. 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, 2017, 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 taken 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 Two Years 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 2014-2015. Data from January 1, 2014 to May 30, 2017 were used. Data at initiation were from the Medical Evidence form (CMS 2728) and from 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 from dialysis initiation to two 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.

vol 2 Table 13.8 Diagnosis and procedure codes used for vascular access

(a) HCPCS codes for vascular access

All vascular access HCPCS codes
00532; 01784; 01844; 34101; 35190; 35321; 35458; 35460; 35475; 35476; 35484; 35875; 35876; 35900; 35903; 35910; 36005; 36011; 36145; 36488; 36489; 36490; 36491; 36533; 36534; 36535; 36550; 36555; 36556; 36557; 36558; 36565; 36575; 36580; 36581; 36584; 36589; 36593; 36596; 36597; 36800; 36810; 36815; 36818; 36819; 36820; 36821; 36825; 36830; 36831; 36832; 36833; 36834; 36835; 36838; 36860; 36861; 36870; 37190; 37201; 37205; 37206; 37207; 37208; 37607; 49419; 49420; 49421; 49422; 75790; 75820; 75860; 75896; 75960; 75962; 75978; 75998; 76937; 90939; 90940; G0159; M0900; 77001; G0392; G0393; 36147; 36148; 75791; 37238; 37239
Insertion codes
36011; 36488; 36489; 36490; 36491; 36533; 36800; 36810; 36818; 36819; 36820; 36821; 36825; 36830; 36835; 36555; 36556; 36557; 36558; 36565; 36580; 36581; 36584; 49419; 49420; 49421; 76937
Fistula insertion
36819; 36820; 36821; 36825; 36818
Graft insertion
36830
Catheter insertion
36488; 36489; 36490; 36491; 36533; 36800; 36555; 36556; 36557; 36558; 36565; 36580; 36581; 76937
PD catheter insertion
49419; 49420; 49421
Complications
34101; 35190; 35321; 35458; 35460; 35475; 35476; 35484; 35875; 35876; 35900; 35903; 35910; 36005; 36534; 36535; 36550; 36575; 36580; 36581; 36584; 36589; 36593; 36596; 36597; 36815; 36831; 36832; 36833; 36834; 36838; 36860; 36861; 36870; 37190; 37201; 37205; 37206; 37207; 37208; 37607; 49422; 75790; 75820; 75860; 75896; 75960; 75962; 75978; 75998; 76937; 90939; 90940; G0159; M0900; 77001; G0392; G0393; 36147; 36148; 75791; 37238; 37239
Codes needing a confirmatory diagnosis
00532; 01784; 34101; 35190; 35321; 35458; 35460; 35475; 35476; 35484; 35875; 35876; 35900; 35903; 35910; 36005; 36011; 36488; 36489; 36490; 36491; 36533; 36534; 36535; 36550; 36555; 36556; 36557; 36558; 36565; 36575; 36580; 36581; 36584; 36589; 36596; 36597; 36834; 37190; 37201; 37205; 37206; 37207; 37208; 75820; 75860; 75896; 75960; 75962; 75978; 75998; 76937; 77001
Revisions
01844; 35190; 36534; 36815; 36832; 36833; 36834; 37190
Non-specific codes indicating an access but not what type
01844; 34101; 35190; 35321; 35458; 35460; 35475; 35476; 35484; 36005; 36145; 36593; 36834; 37190; 37201; 37205; 37206; 37207; 37208; 75790; 75820; 75860; 75896; 75960; 75962; 75978; 75998; M0900; 36593
Catheter
00532; 36011; 36488; 36489; 36490; 36491; 36533; 36534; 36535; 36550; 36800; 36555; 36556; 36557; 36558; 36565; 36575; 36580; 36581; 36584; 36589; 36596; 36597; 76937; 75998; 49419; 49420; 49421; 49422
Fistula
01784; 35190; 36818; 36819; 36820; 36821; 36825; 36831; 36832; 36833; 37607
Fistula or graft
36870; 90939; 90940; G0159; 36838
Graft
35875; 35876; 35900; 35903; 35910; 36830
Shunt
36810; 36815; 36835; 36860; 36861
To define PD
49419; 49420; 49421; 49422

Table 13.8 continued on next page.

vol 2 Table 13.8 Diagnosis and procedure codes used for vascular access (continued)

(b) ICD inpatient procedure codes

All vascular access codes – ICD-10
05HY33Z; 06HY33Z; 03130ZD; 03140ZD; 03150ZD; 03160ZD; 03170ZD; 03180ZD; 03190ZF; 031A0ZF; 031B0ZF; 031C0ZF; 031209D; 031209F; 03120AD; 03120AF; 03120JD; 03120JF; 03120KD; 03120KF; 03120ZD; 03120ZF; 031309D; 031309F; 03130AD; 03130AF; 03130JD; 03130JF; 03130KD; 03130KF; 03130ZD; 03130ZF; 031409D; 031409F; 03140AD; 03140AF; 03140JD; 03140JF; 03140KD; 03140KF; 03140ZD; 03140ZF; 031509D; 031509F; 03150AD; 03150AF; 03150JD; 03150JF; 03150KD; 03150KF; 03150ZD; 03150ZF; 031609D; 031609F; 03160AD; 03160AF; 03160JD; 03160JF; 03160KD; 03160KF; 03160ZD; 03160ZF; 031709D; 031709F; 03170AD; 03170AF; 03170JD; 03170JF; 03170KD; 03170KF; 03170ZD; 03170ZF; 031809D; 031809F; 03180AD; 03180AF; 03180JD; 03180JF; 03180KD; 03180KF; 03180ZD; 03180ZF; 031909F; 03190AF; 03190JF; 03190KF; 03190ZF; 031A09F; 031A0AF; 031A0JF; 031A0KF; 031A0ZF; 031B09F; 031B0AF; 031B0JF; 031B0KF; 031B0ZF; 031C09F; 031C0AF; 031C0JF; 031C0KF; 031C0ZF; 03PY07Z; 03PY0JZ; 03PY0KZ; 03PY37Z; 03PY3JZ; 03PY3KZ; 03PY47Z; 03PY4JZ; 03PY4KZ; 03130JD; 03140JD; 03150JD; 03160JD; 03170JD; 03180JD; 03190JF; 031A0JF; 031B0JF; 031C0JF; 031B0JF; 031C0JF; 03PY0JZ; 03PY3JZ; 03PY4JZ; 03WY0JZ; 03WY3JZ; 03WY4JZ; 03WYXJZ; 0JH60WZ; 0JH60XZ; 0JH63WZ; 0JH63XZ; 0JH80WZ; 0JH80XZ; 0JH83WZ; 0JH83XZ; 0JHD0WZ; 0JHD0XZ; 0JHD3WZ; 0JHD3XZ; 0JHF0WZ; 0JHF0XZ; 0JHF3WZ; 0JHF3XZ; 0JHL0WZ; 0JHL0XZ; 0JHL3WZ; 0JHL3XZ; 0JHM0WZ; 0JHM0XZ; 0JHM3WZ; 0JHM3XZ
All vascular access codes – ICD-9
38.95; 39.27; 39.42; 39.43; 39.93; 39.94; 86.07
Insertion codes – ICD-10
05HY33Z; 06HY33Z; 03130ZD; 03140ZD; 03150ZD; 03160ZD; 03170ZD; 03180ZD; 03190ZF; 031A0ZF; 031B0ZF; 031C0ZF; 03130JD; 03140JD; 03150JD; 03160JD; 03170JD; 03180JD; 03190JF; 031A0JF; 031B0JF 031C0JF; 0JH60WZ; 0JH60XZ; 0JH63WZ; 0JH63XZ; 0JH80WZ; 0JH80XZ; 0JH83WZ; 0JH83XZ; 0JHD0WZ; 0JHD0XZ; 0JHD3WZ; 0JHD3XZ; 0JHF0WZ; 0JHF0XZ; 0JHF3WZ; 0JHF3XZ; 0JHL0WZ; 0JHL0XZ; 0JHL3WZ; 0JHL3XZ; 0JHM0WZ; 0JHM0XZ; 0JHM3WZ; 0JHM3XZ
Insertion codes – ICD-9
38.95; 3927; 3993; 8607
Complications – ICD-10
031209D; 031209F; 03120AD; 03120AF; 03120JD; 03120JF; 03120KD; 03120KF; 03120ZD; 03120ZF; 031309D; 031309F; 03130AD; 03130AF; 03130JD; 03130JF; 03130KD; 03130KF; 03130ZD; 03130ZF; 031409D; 031409F; 03140AD; 03140AF; 03140JD; 03140JF; 03140KD; 03140KF; 03140ZD; 03140ZF; 031509D; 031509F; 03150AD; 03150AF; 03150JD; 03150JF; 03150KD; 03150KF; 03150ZD; 03150ZF; 031609D; 031609F; 03160AD; 03160AF; 03160JD; 03160JF; 03160KD; 03160KF; 03160ZD; 03160ZF; 031709D; 031709F; 03170AD; 03170AF; 03170JD; 03170JF; 03170KD; 03170KF; 03170ZD; 03170ZF; 031809D; 031809F; 03180AD; 03180AF; 03180JD; 03180JF; 03180KD; 03180KF; 03180ZD; 03180ZF; 031909F; 03190AF; 03190JF; 03190KF; 03190ZF; 031A09F; 031A0AF; 031A0JF; 031A0KF; 031A0ZF; 031B09F; 031B0AF; 031B0JF; 031B0KF; 031B0ZF; 031C09F; 031C0AF; 031C0JF; 031C0KF; 031C0ZF; 03PY07Z; 03PY0JZ; 03PY0KZ; 03PY37Z; 03PY3JZ; 03PY3KZ; 03PY47Z; 03PY4JZ; 03PY4KZ; 031B0JF; 031C0JF; 031B0JF; 031C0JF; 03PY0JZ; 03PY3JZ; 03PY4JZ; 03WY0JZ; 03WY3JZ; 03WY4JZ; 03WYXJZ
Complications – ICD-9
39.42; 39.43; 39.94

Table 13.8 continued on next page.

vol 2 Table 13.8 Diagnosis and procedure codes used for vascular access (continued)

(c) Diagnosis codes

ICD-10 diagnosis codes whose presence confirms that certain HCPCS codes are dialysis-related E10.10; E10.11; E10.21; E10.29; E10.311; E10.319; E10.36; E10.39; E10.40; E10.51; E10.618; E106.20; E10621; E10.622; E10.628; E10.630; E10.638; E10.641; E10.649; E10.65; E10.69; E10.8; E10.9; E11.00; E11.01; E11.21; E11.29; E11.311; E11.319; E11.36; E11.39; E11.40; E11.51; E11.618; E11.620; E11.621; E11.622; E11.628; E11.630; E11.638; E11.641; E11.649; E11.65; E11.69; E11.8; E11.9; I12.0; I12.9; N0.03; N0.08; N0.09; N01.3; N02.2; N03.2; N03.3; N03.5; N03.8; N03.9; N04.0; N04.3; N04.4; N04.8; N04.9; N05.2; N05.5; N05.8; N0.59; N08; N17.0; N17.1; N17.2; N17.8; N17.9; N18.1; N18.2; N18.3; N18.4; N18.5; N18.6; N18.9; N19; N25.0; N25.1; N25.81; N25.89; N25.9; N26.9; N27.0; N27.1; N27.9; T82.390A; T82.391A; T82.392A; T82.49XA; T82.590A; T82.591A; T82.593A; T82.595A; T82.598A; T82.7XXA; T82.818A; T82.828A; T82.838A; T82.848A; T82.858A; T82.868A; T82.898A; Z49.01; Z49.02; Z49.31; Z49.32; Z91.15; Z9.92
ICD-9 diagnosis codes whose presence confirms that certain HCPCS codes are dialysis-related 250.xx; 403.xx; 580.xx-589.xx; 593.xx; 996.1x; 996.62; 996.73; V45.1; V45.11; V45.12; V56.xx
ICD-10 diagnosis codes T80.219A; T82.390A; T82.391A; T82.392A; T82.49XA; T82.590A; T82.591A; T82.593A; T82.595A; T82.598A; T82.7XXA; T82.818A; T82.828A; T82.838A; T82.848A; T82.858A; T82.868AT82898A; T85.691A; T85.71XA; Z49.01; Z49.02
ICD-9 diagnosis codes 996.1x; 996.62; 999.31; 996.73; 996.56; 996.68; V56.1; V56.2
ICD-10 codes for hemodialysis T80.219A; T82.390A; T82.391A; T82.392A; T82.49XA; T82.590A; T82.591A; T82.593A; T82.595A; T82.598A; T82.7XXA; T82.818A; T82.828A; T82.838A; T82.848A; T82.858A; T82.868A; T82.898A; Z49.01
ICD-9 codes for hemodialysis 996.1x; 996.62; 9967.3; 999.31; V56.1
ICD-10 codes for peritoneal dialysis T85.691A; T85.71XA; Z49.02
ICD-9 codes for peritoneal dialysis 996.56; 996.68; V56.2
PD device infection ICD-9 = 996.68; ICD-10 = T8571XA
Peritonitis – ICD-9 540.0x; 540.1x; 567.xx614.5; 614.6
Peritonitis – ICD-10 K35.2; K35.3; K65.0; K65.1; K65.2; K65.3; K65.4; K65.8; K65.9; K67; K68.12; K68.19; K68.9; N73.3; N73.6
Sepsis ICD-9 = 03.8; ICD-10=A40.3; A40.9; A41.01; A41.02; A41.1; A41.2; A41.3; A41.4; A41.50; A41.51; A41.52; A41.53; A41.59; A41.89; A41.9
Abbreviations: HCPCS, Healthcare Common Procedure Coding System, ICD-9/10, International Classification of Diseases, Ninth/Tenth Revision, PD, peritoneal dialysis.

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, sex, age, race, ethnicity, pre-ESRD nephrology care, and diabetes as cause of ESRD from the Medical Evidence form (CMS 2728). The facility census was from the Annual Facility Survey and ESRD network.

Fistula Maturation

Table 3.7 includes patients with a fistula placed at any point between June 1, 2014 and May 31, 2016 who were already determined to be ESRD at time of placement, with follow-up through May 2017. 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 2017. 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 and Emergency Department Visits

Inclusion and exclusion of subjects

Methods used to examine hospitalization in prevalent patients generally echo those used for the tables in *Reference Table G: Morbidity and Hospitalization* (described below). Inclusion and exclusion criteria are generally the same, as are the methods for counting hospital admissions and days, and defining the follow-up time at risk. 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*, 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.

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Methods for Figures 4.1-4.2 and 4.4 follow those for *Reference Table G: Morbidity and Hospitalization*. Figure 4.1 presents adjusted rates of total hospital admissions per patient-year for prevalent ESRD patients.

Figure 4.2 shows the adjusted hospitalization rates since 2007 for period prevalent ESRD patients. Included patients had Medicare as primary payer and were 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.

For PD patients, dialysis access hospitalizations were those defined as "pure" inpatient dialysis access events, as described for Reference Tables G.11-G.15. For HD patients, vascular access (VA) hospitalizations included "pure" inpatient VA events, and VA 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 are used to identify cardiovascular and infection admissions. Table 13.9 shows the ICD-9-CM and ICD-10-CM codes used to classify a hospitalization as cardiovascular or infectious. Codes for VA-related hospitalizations are listed in Table 13.14 in the section describing the methods for *Reference Table G: Morbidity and Hospitalization*.

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 2005, 2008, 2011, and 2014. This figure did not include adjustment for vintage. For prevalent ESRD patients, Figure 4.4 presents unadjusted (4.4.a) and adjusted (4.4.b) rates of total hospital admissions per patient-year by Health Service Area in 2013 through 2016.

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 infectious hospitalizations are shown in Table 13.9.

vol 2 Table 13.9 Diagnosis codes used to characterize cause of hospitalization for the chapter

	Principal diagnosis for hospital stay	
Hospitalization cause	**ICD-9-CM codes**	**ICD-10-CM codes**
Cardiovascular	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	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-T85.79XA; T86.842; T87.40-T87.44; T88.0XXA
Vascular access-related	See Table 13.14	See Table 13.15
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 Revision; Clinical Modification.

Readmission rates

Figure 4.7 shows the 30-day disposition of live hospital discharges: died without readmission, 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 January 1, 2016, who were aged 66 and older on December 31, 2016. For general Medicare patients with and without CKD, CKD was defined during 2016, 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 all-cause hospitalizations) from January 1 to December 1, 2016 were included, the latter date providing a 30-day period following the latest discharge. 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.

Figure 4.8 shows the fraction of patients with discharges that were followed by readmission (with or without death) by ESRD modality. If a patient has a transplant, was lost to follow-up, or changed payer status during the 30 days after discharge, that discharge was excluded. Patients with a modality of transplant are those alive with a functioning graft from a transplant that occurred before the index admission. These patients are censored at two years and 11 months following the transplant to ensure that complete claims are available during the 30-day post-discharge period. Medicare coverage ends for those who were entitled to Medicare because of ESRD at three years post-transplant. For hemodialysis patients discharged alive from the index hospitalization, Figure 4.9 shows readmission and/or death by age group (4.9.a) and race/ethnicity (4.9.b).

Figures 4.10-4.13, categories of cause-specific index admissions are based on principal ICD-9-CM and ICD-10-CM diagnosis codes of the index hospitalization. The primary (or first) procedure code of the index hospitalization is used to identify VA, heart catheterization, and other cardiovascular procedures. Codes to define the specific causes of hospitalization are shown in Table 13.9. Cause-specific readmissions are defined the same way as cause-specific index hospitalizations, using the readmission claim principal diagnosis and procedure. Figure 4.10 shows the three rehospitalization categories (death with no readmission, readmission and alive, readmission and death) for three categories of cause of hospitalization — cardiovascular, VA infection, and non-VA infection. Figure 4.11 shows a cross-tabulation of cause of index hospitalization by cause of readmission, among those readmitted within 30 days of the index hospitalization discharge. Figure 4.12 shows the readmission categories by age group for cardiovascular (4.12.a) and infectious (4.12.b) index hospitalizations. Figure 4.13 shows further detailed diagnoses within the cardiovascular category, among those with a cardiovascular index hospitalization.

Emergency Department Visits and Observation Stays

Figures 4.14 through 4.16 show unadjusted rates of emergency department (ED) visits. This data came from inpatient and outpatient claims from 2007 to 2016 using the following Revenue Center codes: 0450-0459 and 0981. Figures 4.17 and 4.18 show unadjusted rates of observation stays. This data came from outpatient claims from 2007 to 2016 using Revenue Center code 0762. ED visits were then combined with inpatient claims (IP) where the discharge date of the ED visit is the admission date of a hospitalization. Table 4.2 shows the top ten most common principal diagnoses for all hospitalizations, readmissions, ED with inpatient claim, ED without inpatient claim, and observation stays.

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 2001-2016. Modalities for Figure 5.1.a are ESRD (overall category), dialysis, and first transplant, while modalities for Figure 5.1.b are HD and peritoneal

dialysis. 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, 2016. Transplant patients begin follow-up at the date of transplant and are censored on December 31, 2016.

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 2014-2016, combined to increase sample size. 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 followed for each year after the first service date for cohorts of patients incident in 1997, 2002, 2007, and 2012 by modality — hemodialysis (5.2.a) and peritoneal dialysis (5.2.b). 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 each of the years used, stratified by year, and 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 (hemodialysis or peritoneal dialysis). 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 native 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 per 1,000 patient-years by race and age categories (5.2.a) and by sex and age categories (5.2.b) among period prevalent transplant, dialysis, and all ESRD patients in 2016. 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 and missingness — dialysis patients (5.4.a) or transplant patients (5.3.b) without missing/unknown causes of death and with missing and unknown causes of death included in the denominator for dialysis (5.4.c) and transplant patients (5.8.d). The distributions of causes of death are derived from the rates presented in *Reference Table H: Mortality and Causes of Death*, Tables H.12_Dialysis and H.12_Tx.

Survival Probabilities for ESRD Patients

Table 5.3 presents adjusted three-month, one-year, two-year, three-year, and five-year survival by modality (hemodialysis, peritoneal dialysis, deceased

donor transplant, and living donor transplant) and incident year. Data are obtained from *Reference Table I: Patient Survival*, *Table*s I.1_adj through I.36_adj.

For the comparison with the general population in the discussion in the chapter 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 2015 Period 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 2015. The mean three-year survival was calculated for these age- and sex-matched estimates within each modality.

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

Table 5.4 presents expected remaining lifetimes in years for the 2015 general U.S. population and for 2016 prevalent dialysis and transplant patients. For period prevalent dialysis and transplant patients in 2016, 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 3, "Life expectancy at selected ages, by race and Hispanic origin, and sex: United States, 2015" (CDC, 2017).

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

Table 5.5 shows adjusted all-cause mortality in the dialysis and transplant and general Medicare populations (those with the comorbidities of cancer, diabetes mellitus, heart failure, cerebrovascular accident or transient ischemic attack, and acute myocardial infarction) over the age of 65 using the Medicare 5% sample, for male and female sex. Patients can be in more than one comorbidity category. Each prevalent sample is defined by the Medicare Parts A and B beneficiaries not in a Medicare Advantage plan available on December 31 of the preceding year. Follow-up for ESRD patients 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 switch to managed care (Medicare Advantage). Adjusted mortality is adjusted for age and race, with 2015 Medicare patients serving as the reference population. Figure 5.5 shows the same without the breakdown by sex.

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, 1999-2016. Waiting list counts include all candidates listed for a first or subsequent kidney transplant on December 31 of each year. The data source is *Reference Table E: Transplantation: Process*, Table E.3.

Figure 6.2 shows the percentage of dialysis patients that were on the kidney waiting list, 1999-2016. The data source is *Reference Table E, Transplantation: Process*, Table E.4.

Figure 6.3 shows the percentage of incident ESRD patients who were waiting for or received a kidney transplant within one year of ESRD initiation, stratified by age, from 1999 to 2015. The data source is *Reference Table E, Transplantation: Process*, 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 from listing when 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 from 1999 to 2011. The data source is *Reference Table E, Transplantation: Process*, Table E.2.

Figure 6.5 displays trends over time in the percent of patients transplanted (deceased or living donor) within one year of their wait-listing date. The

percentage is calculated as the number of patients who received a transplant within one year following their most current listing divided by the total number of people on the wait list for each calendar year.

Table 6.1 displays the reported outcomes within three years since first listing for kidney-alone transplant in 2013, by blood type, panel reactive antibody score (PRA), and age, and Table 6.2 shows these results for five years. Patients from 2013 are followed for three years (Table 6.1), and patients form 2011 are followed for five years after listing (Table 6.2). The reported outcomes included 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 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.

Transplant Counts and Rates

Figure 6.6 shows the number of transplants by donor type during 1999-2016. The data source is *Reference Table E, Transplantation: Process*, Tables E.8, E.8(2), and E.8(3).

Figure 6.7 shows the prevalent counts of patients with a functioning kidney-alone or kidney-pancreas transplants as of December 31 of each year during 1999-2016. The data source is *Reference Table D: Treatment Modalities*, Table D.9.

Figure 6.8 shows the unadjusted transplant rates by donor type for all dialysis patients, 1999-2016. The data source is *Reference Table E, Transplantation: Process*, 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 2007-2016. The data source is *Reference Table E, Transplantation: Process*, Table E.9.

Figure 6.9 illustrates the geographic distribution of the unadjusted transplant rate per 100 dialysis patient-years by state in 2016. Both deceased and living donor transplants are included.

Figures 6.10-6.13 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 1999-2016. The data source is *Reference Table E, Transplantation: Process*, Tables E.8(2) and E.9(2).

Figures 6.14-6.17 present the counts and unadjusted rates of living donor kidney transplants by age, sex, race, and recipient primary cause of ESRD, during 1999-2016. The data source is *Reference Table E, Transplantation: Process*, Tables E.8(3) and E.9(3).

Figure 6.18 shows the number of kidney paired donation transplants and the percent of all living-donor transplants that were kidney paired donation during 2002-2016. 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/worksheet) 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 the OPTN database.

Deceased Donation Counts and Rates Among All-cause Deaths

Figures 6.19-6.21 present the counts and unadjusted rates of deceased donation among all deaths within the U.S. population younger than 75 years old, by age, sex, and race, during 2002-2016. Donors had at least one kidney recovered. Data on the deceased donors are obtained from OPTN data, 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 6.22-6.24 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 2002-2016. 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 data, 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

Figure 6.25 displays one-, five-, and ten-year graft outcomes for recipients who received a first kidney transplant during 1999-2015 for deceased donor (5.25.a) and living donor (5.25.b) transplant. One-year graft survival needs a year of follow-up so only the years through 2015 are included. By the same logic, five-year graft survival includes 1999-2011, and ten-year graft survival includes 1999-2006. Data sources for one-, five-, and ten-year trends are from *Reference Table F: Transplantation: Outcomes*, Tables F.2, F.14, F.5, F.17, F.6, and F.18, respectively.

Figure 6.26 displays one-, five-, and ten-year patient survival for recipients who received a first kidney transplant from a deceased (5.26.a) or living (5.26.b) donor during 1999-2015. Data sources for one-, five-, and ten-year trends are *Reference Table I: Patient Survival*, Tables I.26, I.29, I.30, I.32, I.35, and I.36, respectively.

In both Figures 6.25 and 6.26, 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 1996-2016, from the Medical Evidence form and CROWNWeb data, a data cleaning process was deemed necessary for this chapter. There were 273 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, Prevalence, and Modality

For a discussion of methods for this section, 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. Age and weight are at the time of ESRD initiation and taken from the ESRD Medical Evidence Form (CMS 2728 form).

Etiology

The underlying etiologies of ESRD are generated from the CMS 2728 form. 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, complications of transplanted intestine, complications of other specified transplanted organ, urolithiasis, other disorders of calcium metabolism, Fabry's disease, sickle cell trait and other sickle cell (HbS/Hb other), urinary tract tumor (malignant), renal tumor (benign), lymphoma of kidneys, multiple myeloma, other immunoproliferative neoplasms, amyloidosis, cholesterol emboli and renal emboli, and hepatorenal syndrome are suppressed from Table 7.1 due to the diagnosis having 10 or fewer total pediatric patients. See the section on methods for *Reference Tables A: Incidence and B: Prevalence* 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 is presented. Stature is 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 (CDC, 2000). 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

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 2006-2010 and 2011-2015. 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). For Figure 7.5, we divided hospitalizations into two groups, surgical and nonsurgical, using the diagnosis related group (DRG). Since patients who are younger than 65 and not disabled cannot enroll in Medicare 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, 2016, 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 13.9 in the section on *Chapter 4: Hospitalization and Emergency Department Visits*. Changes are made for the cardiovascular hospitalization codes 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; 424.1; 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; 447.0-449; 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

Figures 7.8 presents adjusted all-cause mortality in the first year of ESRD, by age (7.8.a) and modality (7.8.b), for 2006–2010 and 2011-2015 incident patients younger than 30 years old (7.8.a) or age 0-21 (7.8.b). For Figure 7.8.a the patients are divided into five age groups (ages 0-4, 5-9, 10-13, 14-17 and 18-21) with an additional comparison group of those aged 22-29.

Table 7.3 presents the expected remaining lifetime in years of prevalent patients by initial ESRD modality. The method for calculating expected remaining lifetimes is described in the *Statistical Methods* section. Life expectancy of the general population was obtained from the U.S. Social Security Administration Period Life Table 2015.

Figures 7.9 and 7.10 show adjusted one-year mortality from cardiovascular causes and infectious causes of death in patients aged 0-21 by age (7.9.a, 7.10.a) and modality (7.9.b, 7.10.b). Categories of age and modality are the same as in Figure 7.8 without the comparison to those aged 22-29. Figure 7.11 shows five-year adjusted survival rates for 2007-2011 incident ESRD patients aged 0-21 years, by age (7.11.a) and modality (7.11.b). Methods follow those of Figures 7.8.

Modality at incidence is determined without using the 60-day stable modality rule (see *60-day Stable Modality Rule: Treatment History File* in the *Database Definitions, Modalities* section at the beginning of this

chapter). Dialysis patients are followed from the day of ESRD onset until December 31, 2016, and censored at loss to follow-up, transplantation, or recovered renal function. Transplant patients who receive a first transplant in a given calendar year are followed from the transplant date to December 31, 2016. Rates by age are adjusted for sex, race, Hispanic ethnicity, and primary cause of ESRD (i.e., not adjusted for age) while rates by modality are adjusted for age, sex, race, Hispanic ethnicity, and primary cause of ESRD. Incident ESRD patients who were younger than 22 years in 2010-2011 are used as the reference cohort.

Cardiovascular mortality is defined using codes from past and current Death Notification forms:

- 01, 02, 03, 04, 1, 2, 3, 4, 23, 25, 26, 27, 28, 29, 30, 32, 36, and 61

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, and 74

Vascular Access

Figure 7.12 shows vascular access type at initiation of hemodialysis in pediatric hemodialysis patients who began dialysis during 2006-2016, by year and age. Data are obtained from the CMS 2728 Medical Evidence form, restricted to the 2005 and 2015 versions. Age is calculated as of the date regular chronic dialysis began. Figure 7.13 shows data from CROWNWeb. All HD pediatric patients who had ESRD for at least 90 days prior to May 1, 2017, were included. Patients must have been less than 22 years old as of May 1, 2017 and alive as of May 31, 2017. Patients with missing vascular access data are excluded from each figure. Catheter includes those with a maturing fistula or graft that are still using a catheter. Arteriovenous fistula and graft only include patients not using a catheter.

Transplantation

Figure 7.14 presents an overview of the transplant population among children and adolescents. Figure 7.14.a shows the incidence rate and prevalence of ESRD among those aged 0-21 years and the percent of incident dialysis patients and point prevalence on 12/31 of each year of prevalent dialysis patients for 1996-2016. Pre-emptive transplant patients were included in both the numerator and the denominator. Figure 7.14.b shows the number of transplants during the calendar year for all listing and by first listing or listing for those with a prior transplant. It also shows the count 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 listing to kidney transplantation for new candidates (i.e., the time by which 50% of newly wait-listed candidates had received a kidney transplant) by whether the it's the first listing or a return to listing after a transplant failure. 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 groups 0-17 years and 18-21 years.

Figure 7.15 presents three-year rolling average transplant rates per 100 dialysis patient-years among dialysis patients (0-21 years old). Three-year rolling average rate is the mean among the rates of the current year and of the two years prior. Figure 7.15.a presents rates by recipient age group for patients with a living donor transplant, while Figure 7.15.b shows the same for those with a deceased donor transplant. Figure 7.15.c presents rates by Black/African American and White recipient race for living donor transplants, and Figure 7.15.d shows the same for deceased donor transplants.

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. Figure 7.16.a shows this by initial modality, and Figure 7.16.b shows this by age. Patient age in Figure 7.16.b was defined as the age at initiation of HD or PD. Figure 7.16.c shows median waiting time by primary cause of ESRD, which is taken from the Medical Evidence form. Figure 7.16.d shows this by Black/African American or White race, and Figure 7.16.e by donor type. 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 1996-2015, and having the first transplant before 12/31/2017.

Table 7.4 presents adjusted one-year, five-year and ten-year patient outcomes of all-cause graft failure, probability of returning to dialysis or having a repeat

transplant, and probability of death for pediatric recipients (ages 0-21) who received a kidney transplant from a deceased donor by year from 1996 to 2015. Table 7.5 shows the same statistics as Table 7.4 for living donor 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. For the all-cause graft failure analyses, probabilities are adjusted for age, sex, race, primary cause of ESRD, and first versus subsequent transplant. The probabilities are then standardized to the characteristics of pediatric patients receiving a kidney-only transplant in 2011. 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. 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.

Young Adults with Childhood Onset ESRD

Young adults with childhood onset ESRD are defined as individuals who initiated ESRD care before the age of 19 years and survived beyond their nineteenth birthday. Methods for Figure 7.17 are the same as those for Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. The prevalence of adult survivors of childhood onset ESRD is shown for the years 1978 to 2016. The sample used for Table 7.6 is adult survivors of childhood onset ESRD who initiated care between 1995 and 2016. They were required to have survived to adulthood by the end of 2016 and to have complete Medical Evidence form (CMS 2728) information. This includes patients who reached adulthood but died before the end of 2016.

Chapter 8: Cardiovascular Disease in Patients with ESRD

This chapter describes the prevalence of cardiovascular comorbidities and selected cardiovascular procedures in patients with ESRD. 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-9/10-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 was used to define these cardiovascular conditions using the ICD-9-CM or ICD-10-CM code values in Table 13.10.

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 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 13.11 shows the codes and type of claims used to identify each procedure.

vol 2 Table 13.10 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 (AF)	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 (HF)	398.91; 402.01; 402.11; 402.91; 404.01; 404.03; 404.11; 404.13; 404.91; 404.93; 422[a]; 425[a]; 428; V42.1[a]	A18.84; I09.81; I11.0; I13.0; I13.2; I40.0-I43; I50.1-I50.9; Z48.21; Z48.280; Z94.1; Z94.3
Systolic or both systolic & diastolic	428.2; 428.4	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 digits, 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. [a]These codes are used when heart failure is an outcome variable.

vol 2 Table 13.11 Procedure codes (ICD-9-CM, ICD-10-CM, and HCPCS) & claims files used to define cardiovascular procedures in the USRDS ADR

	(a)
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	
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 13.11 continued on next page.

vol 2 Table 13.11 Procedure codes (ICD-9-CM, ICD-10-CM, and HCPCS) & claims files used to define cardiovascular procedures in the USRDS ADR (continued)

	(b)
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 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

Table 8.1 displays the prevalence of cardiovascular comorbidities and procedures, by modality, age, race and sex, among ESRD patients in 2016. The cohort includes point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older on January 1, 2016, who are continuously enrolled in Medicare Parts A and B and with Medicare as primary payer from January, 1, 2016 to December 31, 2016, and whose ESRD first service date is at least 90 days prior to January 1, 2016. We exclude patients with unknown sex 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 is out of cohort members with CAD, the percent with ICD/CRT-D is 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 all patients who had cardiovascular comorbidities by modality (Figure 8.1) and age and modality (Figure 8.2), respectively, among adult ESRD patients in 2016. The cohort is the same one used for Table 8.1.

Figures 8.3 and 8.4 illustrate the adjusted survival of patients by cardiovascular diagnosis (Figure 8.3) or procedure (Figure 8.4). The cohort includes point prevalent hemodialysis, peritoneal dialysis, and transplant patients aged 22 and older on January 1, 2014, who were continuously enrolled in Medicare Parts A and B and with Medicare as primary payer from January, 1, 2014 to December 31, 2014, whose ESRD first service date was at least 90 days prior to January 1, 2014, and who survived past 2014. Patients with HF, PAD, and CVA/TIA are those whose Medicare claims indicated the diagnosis or procedure in 2014 or whose 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 2014. Patients are followed from January 1, 2015, until the earliest date of death, modality change, transplant, lost to follow-up, recovery of renal function, or December 31, 2016. The adjusted probability of survival was calculated using the results of a Cox model, in which significant factors included age group and sex.

Tables 8.2 and 8.3 use the same methods as Figures 8.3 and 8.4, and show the adjusted two-year survival by cardiovascular comorbidity (Table 8.2) and procedure (Table 8.3).

Cardiovascular Disease and Pharmacological treatments

This section of the chapter uses data from the Medicare Part D program, which include enrollment information and claims for prescription fills and refills for medication prescribed by a healthcare professional and filled through Part D insurance (the prescription drug event, PDE, file). Enrollees are not required to fill all of their medications through Part D and may pay out of pocket for some. Use of over the counter medications is not included in the Part D data, therefore, we have no information on such medication use.

Table 8.4 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 were also required to be enrolled in Medicare Part D for the entire calendar year. The percentages shown in the table are the row percentages, and the denominator is the number of patients with the cardiovascular diagnosis or procedure, by modality.

All drugs in the PDE file were matched to a therapeutic category according to the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification©. Claims for 2016 were searched for each drug class, and a patient was defined as having a medication in a given drug class if they had a claim for at least one filled or refilled medication in the drug class during 2016. The prescription must be part of the AHFS Classification group and have a generic name as specified in Table 13.12.

vol 2 Table 13.12 Drug classes used in Volume 2, Chapter 8 of the USRDS ADR

Drug class	AHFS classification	Generic drug name
Beta blockers	242400	*<no restriction>*
Statins	240608	*<no restriction>*
$P2Y_{12}$ inhibitors	201218	prasugrel, ticagrelor, or clopidogrel
Warfarin	201204	warfarin
Direct oral anticoagulants	201204	apixaban, rivaroxaban, dabigatran
Angiotensin converting enzyme inhibitors (ACEs) or angiotensin II receptor blockers (ARBs)	243204; 243208	*<no restriction>*

Abbreviations: AHFS, American Hospital Formulary Service, $P2Y_{12}$, a group of antiplatelet medications.

Heart Failure Among ESRD Patients

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 13.10) 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 8.5 shows the distribution of heart failure type by modality in 2012-2016 for the same study cohort as in Table 8.1, except 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: Healthcare Expenditures for Persons with ESRD

Overall & per Person per Year Costs of ESRD

For the 2018 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. Amounts shown are nominal costs that are not adjusted for inflation.

Figure 9.1 displays Medicare paid amounts for period prevalent ESRD patients from 2004-2016, 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 history files (PAYHIST) 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 II.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 (December 31) of Medicare as primary payer, Medicare as secondary payer, Medicare Advantage, and non-Medicare ESRD patients by year using the payer history file.

Figure 9.4 describes the percent change in ESRD Medicare spending in total and per patient per year, for patients with Medicare as primary payer only. Medicare spending was abstracted from *Reference Table K: Healthcare Expenditures for ESRD*, 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, Healthcare Expenditures for ESRD*, 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. Cardiovascular and infectious hospitalizations are defined in the same way as *Chapter 4: Hospitalization and Emergency Department Visits*, with codes shown in Table 13.9.

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 Table K, Healthcare Expenditures for ESRD,* Table K.7, K.8, and K.9.

Chapter 10: Prescription Drug Coverage in Patients with ESRD

This chapter describes prescription drug coverage and usage. New for the 2018 ADR, we investigate the spending and utilization rates of antivirals in Medicare Part D enrollees.

For inclusion in the analyses, general Medicare enrollees had to be enrolled in Medicare Parts A and B in the calendar year of interest. General Medicare estimates use the Medicare 5% sample. 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 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).

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 those with no months of low-income subsidy are classified as "Part D without LIS". 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 the beneficiary is enrolled in an employer-sponsored prescription drug plan that qualifies for Part D's retiree drug subsidy. In previous years, if the patient was not in a Part D plan or employer-sponsored plan, they were classified as "Other Creditable Coverage" if the Creditable Coverage Switch had 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 met none of the situations described above, the beneficiary was classified as "No Known Coverage." However, in the data received from the Chronic Conditions Warehouse for claim year 2016, the Creditable Coverage Switch was not available. For the 2018 ADR, the categories of "No Known Coverage" and "Other Creditable Coverage" are combined into one category. 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 2011-2016 in the General Medicare and ESRD cohorts. Table 10.2 is an adaptation of data presented in the 2016 Medicare Outlook section of the *www.q1medicare.com* website 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, and 75 and older) for dialysis patients (Figure 10.2.a) and transplant patients (Figure 10.2.b). Figure 10.3 shows the prescription drug coverage categories by race groups (White, Black/African American, Native American or Alaska Native, Asian, Native Hawaiian or Pacific Islander, Other or multiracial, and Unknown or missing) for dialysis patients (10.3.a) and transplant patients (10.3.b).

Table 10.3 is limited to beneficiaries who were enrolled in Part D prescription plans for at least one month of the analysis year. Part D plan enrollment and receipt of LIS 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, the ESRD cohort, and by ESRD modality. 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 and by dialysis or transplant.

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 Volume 2 *Reference Table K: Healthcare Expenditures for ESRD*). Per person per year (PPPY) costs are calculated by dividing the total cost amount by the person years at risk. Person years at risk are separately calculated for the ESRD and general populations. 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) and by ESRD modality 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, Healthcare Expenditures for Persons with*

ESRD, which show Medicare spending on Parts A and B benefits for those not in Medicare Advantage plans.

For those in fee-for-service Part D plans, Figure 10.5.a shows Part D spending by Medicare and patient out-of-pocket amounts PPPY for the General Medicare and ESRD cohorts and by ESRD modality. Figure 10.5.b shows these expenditures by LIS status. 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.

Table 10.5 shows PPPY spending by age, sex, and race for the General and ESRD cohorts broken out by use of the low-income subsidy (LIS) and by ESRD modality.

Prescription Drug Classes

Tables 10.6.and 10.7 list the top 15 drug classes used among ESRD patients by 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 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 on each drug class and its percentage of total prescription drug plan expenditures.

Figures 10.6 and 10.7 show utilization of 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.

New for the 2018 ADR, this chapter has a special focus on antiviral drugs. Figure 10.8.a shows the prevalence of Human Immunodeficiency Virus (HIV) in Medicare Part D enrollees by ESRD modality, and Figure 10.8.b shows the same for Hepatitis C virus (HCV). Diagnosis codes for HIV are 042 (ICD-9) and all of B20 (ICD-10). For HCV, the codes are 070.54 (ICD-9) and B18.2x (ICD-10) — all of the codes beginning with B18.2.

The antiviral class of drugs was defined as AHFS class 0818. We focused on antiretrovirals (081808), nucleosides and nucleotides (0818320), and protease inhibitors (081840). Figure 10.9 shows the utilization of these three drug classes over time, and Figure 10.10 shows per-patient per-year spending on these drugs by the Medicare program.

Chapter 11: International Comparisons

Data Collection

Each country was provided a data-collection form spreadsheet (Microsoft Excel) to complete for years 2012 through 2016. 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 given year. Prevalence was reported for all patients at the end of the calendar year (December 31, 2016), except where otherwise noted. Data for the United States is taken directly from *Volume 2 Reference Tables M: Census Populations*, *A: Incidence, B: Prevalence*, *D: Treatment Modalities*, and *E: Transplantation: Process*.

Data Loading and Cleaning

The data were imported into SAS from Microsoft Excel and data quality checks were performed, with follow-up with the registries, as needed.

Analysis of Country-level Trends over Time

Simple linear regression was used throughout the chapter for ease of interpretation in describing country-level trends in incidence, prevalence, and transplantation rates among the international ESRD population. Though linear regression assumes a linear trend in the outcome of interest over time (year-by-year), results should be interpreted with caution, as the true country-level data do not always adhere to this assumption. To be included in linear regression models, countries needed to have reported relevant data for either 2003 or 2004, at least five of the years from 2005-2013, and for either 2015 or 2016. Additionally, percent change from 2003/04 to 2015/16 is also used to reflect trends in incidence, prevalence, and transplantation rates over time. To be included in this calculation, countries needed to have reported relevant data for 14 years overall, and at least one of the first two years (2003 and 2004) and one of the last two years (2015 and 2016).

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 from 2003/04-2015/16. The percent change in incidence rate was calculated as the percent difference between the average incidence rate in 2015 and 2016 and the average in 2003 and 2004. Figure 11.3.b presents the average yearly change in the incidence rate (per million population) for each country from 2003-2016, based on a univariate linear regression model.

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.a 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 11.4.b presents the incidence rate of treated ESRD due to diabetes as the assigned primary ESRD cause, by country, for 2016. The incidence rate was calculated as the number of patients new to ESRD during the year, where diabetes was the designated primary cause of ESRD, divided by the total population for that year, multiplied by one million. Figure 11.5 presents the average yearly change in incidence rate (per million population) of treated ESRD due to diabetes for each country from 2003-2016, based on a univariate linear regression model. Figure 11.6 presents three regional scatter plots showing the country-level correlation of the percent change in ESRD incidence with the percent change in ESRD incidence due to diabetes from 2003/04-2015/16. Percent change was calculated as the percent difference between the average incidence of treated ESRD or treated ESRD due to diabetes in 2015 and 2016 and the average in 2003 and 2004.

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 the sex-specific category, 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.a presents the ten countries with the highest percent increase in prevalence of ESRD from

2003/04-2015/16. The percent change in prevalence of ESRD was calculated as the percent difference between the average prevalence of ESRD in 2015 and 2016 and the average in 2003 and 2004. Figure 11.11.b presents the average yearly change in the prevalence of ESRD (per million population) for each country from 2003-2016, based on a univariate linear regression model. Figure 11.12 presents each country's distribution of the type of renal replacement therapy modality for prevalent patients. 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 is the total number of ESRD patients on dialysis divided by the total population for that year, multiplied by one million. Figure 11.14.a presents the ten countries with the highest percent increase in prevalence of dialysis from 2003/04-2015/16. The percent change in prevalence of dialysis was calculated as the percent difference between the average prevalence of dialysis in 2015 and 2016 and the average in 2003 and 2004. Figure 11.14.b presents the average yearly change in the prevalence of dialysis (per million population) for each country from 2003-2016, based on a univariate linear regression model. 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, 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 1,000. Figure 11.17.a presents the ten countries with the highest percent increase in the kidney transplantation rate from 2003/04-2015/16. The percent change in kidney transplantation rate was calculated as the percent difference between the average transplantation rate in 2015 and 2016 and the average in 2003 and 2004. Figure 11.17.b presents the average yearly change in the kidney transplantation rate (per million population) for each country from 2003-2016, based on a univariate linear regression model. Figure 11.18 presents the percentage of kidney transplantations by kidney donor type (deceased, living, unknown). The denominator is calculated as the sum of deceased, living, and unknown donors. 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. Figure 11.20 presents the average yearly change in the prevalence of ESRD patients with a functioning kidney transplant (per million population) for each country from 2003-2016, based on a univariate linear regression model.

To contribute data from your country's registry, please contact international@usrds.org.

Chapter 12: USRDS Special Study on End-of-Life Care for Patients With ESRD, 2000-2015

Methods for the creation of the figures and tables in Chapter 12 are described within the chapter itself.

ESRD Reference Table Methods

Downloadable ESRD Reference Tables are found on this page: *https://www.usrds.org/reference.aspx*.

Reference Tables A: Incidence and B: Prevalence

The data sources for information on both incident and prevalent patients are CROWNWeb, OPTN, the 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 transplantation on a certain date (point prevalence) or within a specified time period (period prevalence). Both incidence rates

and prevalence are adjusted to a reference population using the direct method.

The 2018 ESRD Reference Tables present parallel sets of counts and rates for incidence (Table A) and December 31 point prevalence (Table B) from 1996 to 2016 for counts and 2000 to 2016 for rates. The rates for years earlier than 2000 are not presented because census data for the seven categories of race are limited. Reference Table B also presents annual period prevalent counts (B.12) and counts of lost to follow-up patients (those who lack any evidence of payment activity in the Medicare database for one year).

The data in Reference Tables A and B should be considered complete for 2016, although the prevalence or incidence counts for a given year may have small changes at a later date due to lag time, patients with recovered renal function, and patients who die before chronic dialysis treatment is fully established. Note that the incident patients who stop chronic dialysis and then restart are counted as prevalent, and incident patients who have a modality change, i.e., return to dialysis after a failed transplant, are not counted as incident ESRD patients.

Patients with unknown age are dropped in all tables. For incident patients, age is computed as of the beginning of ESRD therapy while for prevalent patients, age is computed as of December 31 of the year. Patients with unknown/other or multiracial race, sex or ethnicity are dropped based on different requirements as presented below.

- No exclusions (except unknown age) are made for these tables:
  - A.1; A.6; A.6(1); A.7; A.7(2); A.8; A.8(2); A.8(3) and A.10
  - B.1; B.6; B.6(1); B.7; B.7(2); B.8; B.8(2); B.8(3); B.10 and B.12
- Unknown and other/multiracial races are dropped in these tables:
  - A.1(2); A.1.1-A.1.4; A.2; A.2(2); A.2.1-A.2.4; A.3; A.3.1; A.4; A.4.1; A.5; all A.5.1; A.8.1; A.8.1(2); A.9; A.9(2); A.9(3) and A.11
  - B.1(2); B.1.1-B.1.4; B.2; B.2(2); B.2.1-B.2.4; B.3; B.3.1; B.4; B.4.1; B.5; all B.5.1; B.8.1; B.8.1(2); B.9; B.9(2); B.9(3) and B.11
- Unknown sex and unknown ethnicity are dropped in these tables:
  - A.2; A.2(2); A.2.1-A.2.4; A.3; A.3.1; A.5; all A.5.1; A.9; A.9(2); A.9(3) and A.11
  - B.2; B.2(2); B.2.1-B.2.4; B.3; B.3.1; B.5; all B.5.1; B.9; B.9(2); B.9(3) and B.11
- Unknown ESRD network is dropped in Tables A.11 and B.11.
- The "Other cause" category in primary diagnosis (cause of ESRD) in Tables A.4, A.5, B.4, and B.5, includes patients with cystic kidney disease, other urologic diseases, other causes, unknown cause, and missing cause categories that are listed in the eight category primary diagnosis groups used in Table A.1 and B.1.
- "Other race" includes American Indian or Alaska Native, Asian, and Native Hawaiian or Pacific Islander in these tables:
  - A.2.1; A.2.2.; A.2.3; A.2.4 and A.3
  - B.2.1; B.2.2.; B.2.3; B.2.4 and B.3
- Because the U.S. population (shown in Reference Table M) used in the ADR includes only residents of the 50 states and the District of Columbia, most tables are limited to patients from these areas. However, the following tables present data specific to patients in Puerto Rico and the U.S. territories, or include these patients in the total patient population.
  - A.1; A.6; A.8; and A.10
  - B.1; B.6; B.8; and B.10
- Rates in these tables are adjusted for age, sex, race, and ethnicity with the 2011 national population as reference:
  - A.2(2); A.2.1-A.2.4; A.3.1; A.5; all A.5.1; A.9; A.9(2); A.9(3) and A.11
  - B.2(2); B.2.1-B.2.4; B.3.1; B.5; all B.5.1; B.9; B.9(2); B.9(3) and B.11
- Rates in Tables A.3 and B.3 unadjusted and adjusted for age, sex, and race with the CDC diabetes population estimates used as the denominator.

A new Medical Evidence form (CMS 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 13.13 shows this mapping.

vol 2 Table 13.13 Mapping to pre-2015 detailed diagnosis groups from the Medical Evidence Form (2728)

(a)

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; E13.9**
Diabetes with renal manifestations Type 1	**E10.2**; E10.22; E10.29; **E10.9**
Glomerulonephritis	
Glomerulonephritis (GN) (histologically not examined)	N00.8; **N00.9;** 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	**N02.2**; N03.2; N04.2; **N05.2**
Membranoproliferative GN type 1, diffuse MPGN	N03.5; N04.5; **N05.5**
Dense deposit disease, MPGN type 2	N03.6; N04.6
IgA nephropathy, Berger's 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**; M32.0; M32.10; M32.14; M32.15
Henoch-Schonlein syndrome	D69.0
Scleroderma	**L94.0;** M34.89
Hemolytic uremic syndrome	D59.3
Polyarteritis	M31.7
Wegener's granulomatosis	**M31.30**; 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
Goodpasture's 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	**N11.0**; 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**; **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 13.13 continued on next page.

vol 2 Table 13.13 Mapping to pre-2015 detailed diagnosis groups from the Medical Evidence Form (2728) *(continued)*

(b)

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, Alport syndrome	N07.0; N07.8; **N07.9**; Q87.81
Cystinosis	E72.04
Primary oxalosis	E72.53
Fabry 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, **Q61.3**
Renal hypoplasia, dysplasia, oligonephronia	Q61.4
Prune belly syndrome	Q79.4
Other (congenital malformation syndromes)	**Q60.0**; Q60.2; Q61.8; **Q62.6;** 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	**T86.89**-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	*Not on 2015 version of Form 2728 and not in data*
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	**K70.30**; 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; **Z87.44**
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

Codes in boldface type are those that have appeared in the data but are not listed on the 2015 Medical Evidence form (CMS 2728). Abbreviations: AIDS, acquired immunodeficiency syndrome, GN, glomerulonephritis, HbS/Hb other, sickle hemoglobin/hemoglobin other, MPGN, membranoproliferative glomerulonephritis, SBE, subacute bacterial endocarditis, SLE, systemic lupus erythematosus.

Reference Table C: Patient Characteristics

Data in Reference Table C are based on information collected with the 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 laboratory results values are excluded from the analysis, see Table 13.14 for acceptable ranges.

vol 2 Table 13.14 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 Reference Table C 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 not shown in the tables. Data shown are based on the incident population with a completed Medical Evidence form within the given year. Tables C1-C3 use data for three years combined for three time periods (2008-2010, 2011-2013, and 2014-2016). Tables C.4-C.6 and C.11 show two time periods (2011-2013 and 2014-2016) while Tables C.7-C.8 show all years from 2012-2016.

Table C.1 contains data on biochemical markers (item 19 on CMS 2728) for 2008-2010 (C.1), 2011-2013 (C.1(2)), and 2014-2016 (C.1(3)). Glycosylated hemoglobin, total cholesterol, low-density lipoprotein, high-density lipoprotein, and triglycerides were added to the 2005 Medical Evidence form. Blood urea nitrogen (BUN) was dropped from the 2005 form, therefore, BUN data are not shown in Table C.1.

Table C.2 shows patients' prior and current employment status (item 16 on CMS 2728) for 2008-2010 (C.2), 2011-2013 (C.2(2)), and 2014-2016 (C.2(3)). 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 category should be selected for each. If the patient is under 6 years old, the employment status questions should be left blank according to form instructions. 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 categories are shown for patients under 14.

Table C.3 shows patient medical insurance coverage (items 11 and 12 on CMS 2728) for 2008-2010 (C.3), 2011-2013 (C.3(2)) and 2014-2016 (C.3(3)). There

are seven 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 (item 17 on CMS 2728) for 2011-2013 (C.4) and 2014-2016 (C.4(2)). 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) for 2011-2013 (C.5) and 2014-2016 (C.5(2)).

Table C.6 presents whether patients on dialysis were informed about kidney transplant options (items 26 and 27 on CMS 2728) for 2011-2013 (C.6) and 2014-2016 (C.6(2)). Patients 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 describe care received prior to ESRD therapy (item 18 on CMS 2728) for 2012-2016. Table C.7 shows data for pre-ESRD nephrology care (item 18.b). Table C.8 shows data for pre-ESRD kidney dietician care (item 18.c). Table C.9 shows data for vascular access at initiation of renal replacement therapy (item 18.d). 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 (item 18.a).

Table C.11 presents primary dialysis settings at initiation of renal replacement therapy (item 22 on CMS 2728) for 2011-2013 (C.11) and 2014-2016 (C.11(2)). 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 at 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 for 2012-2014 combined. 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 (vintage) 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 (2008, 2012, and 2016), by demographic characteristics, payer category, and treatment modality. Age is computed at 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)
- Medicare as secondary payer: with employer group health plan (EGHP) or not with EGHP
- Medicare Advantage or Medicare+Choice plans also called HMO (health maintenance organization)
- 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 (first vs. subsequent transplant), 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. Median waiting time 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 loss to follow-up, death, or the end of the analysis period (which is 12/31/2016 for the 2018 Reference Tables).

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 2018 Table E.2 only shows data up to year 2011.

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, time on the list, and active status.

Table E.4 is the percent of dialysis patients that are on the kidney wait list by year. The denominator is the count of point prevalent dialysis patients on 12/31 of each year, and the numerator is the count of the point prevalent dialysis patients on the waiting list for a kidney on 12/31 of each year. Table E.4 reports this by demographics and primary cause of ESRD. E.4.2 reports it by state/territory and Table E.4.3 by renal network.

Table E.5 presents the percent 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 and 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 (American Samoa, Guam, Northern Marianas, and Foreign) 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 one or more other organs, are included, 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 worksheet/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 worksheet/form. Table E.8.3 reports data for living donors, and donor relationship 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 at risk 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 one or more other organs, 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 (on the day of transplant), sex, race, ethnicity, primary cause of ESRD, and first vs. 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, 2016). 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. "Other cause" in the primary cause of ESRD stratification includes patients with missing data, unknown cause, and causes other than diabetes, hypertension, and glomerulonephritis.

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, ethnicity, primary cause of ESRD, and first vs. subsequent transplant, and standardized to 2011 recipient characteristics. Adjusted survival probabilities presented by each of the covariates (age, sex, race, ethnicity, primary cause of ESRD or first vs. subsequent transplant) are standardized to the distribution of the remaining five covariates using the 2011 ESRD cohort as the standard population. For example, survival by age is adjusted for sex, race, ethnicity, primary cause of ESRD, and first vs. subsequent transplant.

Reference Table G: Morbidity and Hospitalization

Reference Table G presents adjusted total admission and hospital day rates, by year, 2004-2016. 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 Primary Payer patients may be absent or 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.

Reference Table G includes 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. Tables G.1–G.10 exclude records where the age or sex is unknown. 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 diabetes, 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 dialysis 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 at the start of the period at risk
- Transplant: patients with a functioning transplant received less than three years prior to the start of the period at risk
- All-ESRD: all patients

Patients who do not have Medicare coverage, have Medicare as a secondary payer or have Medicare Advantage coverage will have incomplete or no hospitalization data in the claims files. For that reason, cohorts for these tables include only patients with fee-for service Medicare Parts 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 Parts A and B coverage or Medicare as a primary payer.

For patients in the all dialysis, HD, and CAPD/CCPD 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 Parts A and B coverage, or December 31. Modality change is considered a censoring event only in the case of a change from dialysis to transplant.

For dialysis patients in the all ESRD category, in contrast, the analysis period is censored only at death, end of Medicare Parts A and B coverage, or December 31 of the given year, a modality change is not used as a censoring event.

For transplant patients in the all-ESRD and transplant categories, the period is censored at the earliest of death, three years after the transplant date, end of Medicare Parts A and B coverage, or December 31 of the given year. Censoring of transplant patients at three years following the transplant is necessary because Medicare eligibility may be lost, and hospitalization data may be incomplete for these patients.

Time at risk is calculated differently for hospital days and total admissions. Since a hospitalized patient remains at risk for additional hospital days, rates for hospital days include hospital days in the time at risk value. Since a currently hospitalized patient is not, however, at risk for a new admission, hospital days for each year 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 and 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 methods for computing adjusted total admission and hospital day rates use 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, one-fourth, and one-eighth. Adjusted rates are then calculated using the direct adjustment method with all 2011 ESRD patients as the reference cohort.

Tables G.11-G.15 show inpatient utilization in 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. Rates are unadjusted and reflect total admissions per 100 patient-years for 2008-2010, 2011-2013, and 2014-2016 (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. "Dialysis access" contains both vascular access and PD access hospitalizations that are 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 13.15. 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 13.16. ICD-10-CM codes may be requested by contacting the USRDS Coordinating Center through usrds@usrds.org.

vol 2 Table 13.15 DRG and ICD-9-CM procedure and diagnosis 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 OR 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 OR procedures for injuries with MCC
908 Other OR procedures for injuries with CC
909 Other OR procedures for injuries without CC/MCC

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. Abbreviations: CC, complicating conditions, DRG, diagnosis-related group, ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, clinical modification, MCC, major complicating conditions, OR, operating room.

vol 2 Table 13.16 Diagnosis codes used to define cause of hospitalization in Reference Table G

Cause of hospitalization		ICD-9-CM diagnosis codes
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	140-234	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-CM, International Classification of Diseases, Ninth/Tenth Revision, clinical modification.

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 seven race groups

(White, Black/African American, American Indian and Alaska Native, Asian, Native Hawaiian and Pacific Islander, Other or multiracial, and Unknown), as well as adjusted for ethnicity (Hispanic, non-Hispanic, and Unknown). A small number of patients missing sex were excluded (0.01%).

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 (H.2_unadj) and adjusted (H.2_adj) annual mortality rates by age, sex, race, ethnicity, primary cause of ESRD, and years of ESRD treatment (vintage) 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, ethnicity, primary cause of ESRD, and years of ESRD treatment, while rates for each individual category are adjusted for the other five factors. The reference population includes 2011 prevalent ESRD patients. Table H.2_1 presents unadjusted mortality rates by age, sex, race, and ethnicity, within primary cause of ESRD categories for 2016 prevalent ESRD patients, rates are again smoothed using a generalized linear model.

The same methods are used for Tables H.3, H.4_unadj, H.4_adj, and H.4_1 (dialysis), H.5_unadj and H5_adj (dialysis patients never on the transplant waiting list), H.6_unadj and H.6_adj (dialysis patients on the transplant waiting list), H.7_unadj and H7_adj (dialysis patients returned to dialysis from transplant), H.8_unadj, H.8_adj, and H.8_1 (HD), H.9_unadj, H.9_adj and H.9_1 (CAPD/CCPD), and H.10_unadj, H.10_adj and H.10_1 (transplant).

For Table H.13_gen_pop, general U.S. population life expectancy, the data source is supplemental Table 3 of the *National Vital Statistics Report (NVSR), Deaths: Final Data for 2015* (see *References* at the end of this chapter). 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. We used a different methodology for the remaining lifetime tables of prevalent patients (H.13_Dial, H.13_Tx, H.13_Dial_DM, H.13_Tx_DM, H.13_Dial_NDM, H.13_Tx_NDM). Mortality rates were estimated using patient level data and then aggregated by age group, sex, race, and ethnicity. We then calculated average remaining lifetime.

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 or age is unknown. All new ESRD patients with an ESRD first service date between January 1, 1996 and December 31, 2016, are included in the analysis. These patients are followed from day one (ESRD onset) until death, loss to follow-up, or December 31, 2016. For dialysis patients, both HD and CAPD/CCPD, 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: Provider Characteristics

For Reference Table J, data are obtained from the CMS ESRD Facility Survey (CMS 2744, 1996 to the present), the Renal Dialysis Facilities Cost Report (CMS 265-94, 1996-2000), the Dialysis Facility Compare (DFC) database (2001-2013), the CROWNWeb database (2012-present) and 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. Facilities switched from submitting form CMS 2744 via the ESRD Networks to submitting via CROWNWeb in 2012. This new method of input and submission may lead to unanticipated changes in trends beginning in 2012.

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 2014-2016) or the profit status field of the DFC database (2001-2013).

Residents of the 50 states, the District of Columbia, Puerto Rico and the U.S. territories are all included in these tables.

Table J.1 shows counts of the facilities by year for 1996 through 2016 by type of facility. The number of patients in these facilities is also shown. These facilities are the source for all tables reported in this section. Tables J.2-J.11 present data from fields in form CMS 2744.

Reference Table K: Healthcare Expenditures for ESRD

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. Our claims databases are created annually six months after the end of each calendar year and are downloaded directly from CMS. 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. For example, a claim that starts in December of Year 1 and ends in January of Year 2 will be counted in Year 2. Cross-payer claims are considered to be associated with the payer status that exists at the start of the claim. For example, a patient that is Medicare Primary when the claim starts and not Primary when the claim ends is categorized as Medicare Primary for that 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 vs. 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.

For K.1 and K.2, 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 collected for 30 days prior to the transplant date 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 detailed service type categories that are shown in K.1, K.4, K.a, K.b, and K.b.1-54.

In tables that report on a specific modality, note that only claim records whose start and end dates fall within the patient's modality and payer start and end dates are included in the cost analysis.

Payer File

The payer history file is similar in concept to the USRDS treatment history file (RXHIST). Payer status is tracked for each ESRD patient from the ESRD first service date until death or the end of the study period. Data from the Medicare Enrollment Database and dialysis claims information are used to categorize payer status as Medicare Primary payer (MP), Medicare Secondary payer (MS), or non-Medicare. The claims database contains data only for MP and MS patients, so expenditure calculations 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 when they have this MS coverage.

Payment Information

The expenditure calculations for this section focus on the claim payment amount, which is the amount of the payment made from the Medicare trust fund for

the services covered by the claim record. These analyses also include the pass-through per diem amount, which applies to inpatient claims and reimburses the provider for capital-related costs, direct medical education costs, and an estimate of organ acquisition costs ($25,000 in 2018).

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.1-54 are all Medicare 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 payment system for dialysis, adding a set of dialysis-related drugs, laboratory tests and supplies to the dialysis payment bundle. Prior to 2011, outpatient spending for these services was reported on claim detail lines. Beginning in 2011, total spending appears on one detail line while other related details are zero (with the exception of dialysis facilities who elected to transition to the new payment system over a four year period, for which partial spending amounts for the newly bundled services still appear on individual claim lines). This is why there are significant increases and decreases between 2010 and 2011 in some Outpatient subgroups in sheets K.1 and K.4.

Time at risk

Time at risk is the time in which the patients are contributing claims to the cost aggregation. For this to happen, they must be alive, an ESRD patient, and have Medicare Primary payer status. For tables by modality, the aggregation begins at the start day of the modality. More specifically, time at risk is calculated by taking the latest date from (1) the first of the year, (2) the first service date, (3) the start of modality, or (4) the start of Medicare Primary payer, as the start date of the time at risk. The end date of the time at risk is considered the earliest of (1) the end of the year, (2) the date of death, (3) the end of modality, or (4) the end of primary payer status. Claims are only counted in the total expenditure calculations if they occur within the patient's time at risk.

Reference Table L: Vascular Access

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 shows the percentages of PD patients who had at least one event in the given complication category (sepsis, peritonitis, PD catheter infection) in the prevalent year. Follow-up on these patients is censored at death, change in modality, change in payer status, a claim for HD vascular access placement, or the end of the prevalent year.

See Table 13.8 for HCPCS, and ICD-9 /10 diagnosis, and procedure codes used for identifying access placements and complications.

Reference Table M: Census Populations

Reference Table M.1 includes the U.S. resident population on July 1 by year, age, sex and race for years 2000-2016. For the 2016 and earlier ADRs, the data source was the U.S. Census, intercensal and postcensal population estimates from the CDC Bridged-Race Population Database. Starting with the 2017 ADR, data are now taken from the U.S Census unbridged postcensal file. 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 that 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 direct comparisons should be made with caution.

See *Data Collection* in the section on *Chapter 11: International Comparisons* for how the data were obtained.

Prevalence was reported for all patients at the end of the calendar year (December 31), except where otherwise noted. The percent changes in Tables N.1.b, N.2, N.4.b, N.6.b, N.8.b, and N.9.b are defined as the percent difference between the average in 2015 and 2016 and the average in 2003 and 2004, which are used to reflect trends in incidence, prevalence, and transplantation rates over time. To be included in this calculation, countries needed to have reported relevant data for 14 years overall, for at least one of the first two years (2003 and 2004), and for one of the last two years (2015 and 2016). The estimates of the average yearly change from 2003-2016 in these tables were determined from a univariate linear regression model, using year as the only independent variable. Though linear regression assumes a linear trend in the outcome of interest over time (year-by-year), results should be interpreted with caution, as the true country-level data do not always adhere to this assumption. To be included in linear regression models, countries needed to have reported relevant data for either 2003 or 2004, at least five of the years from 2005-2013, and for either 2015 or 2016.

Tables N.1-N.3 present the incident counts and incidence of ESRD patients in different countries. Incidence was calculated as the count of patients who started 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.a and N.1.b show the trends in the incident counts and incidence rates of treated ESRD patients, 2003-2016. Table N.2 shows the trends in the incidence of treated ESRD patients due to diabetes, 2003-2016. N.1.a and N.1.b use total incident patient count, while the count for N.2 is a subset of total incident patients whose kidney failure was due to diabetic nephropathy. Tables N.3.a and N.3.b show the 2016 incident counts and incidence rates 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 prevalent counts and prevalence of ESRD in different countries, 2003-2016. 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 prevalent ESRD patient counts. Table N.4.b shows the trends in unadjusted prevalence of ESRD patients. Tables N.5.a and N.5.b present the 2016 ESRD prevalent counts and prevalence in different countries, by five age groups, 0-19, 20-44, 45-64, 65-74, and 75+.

Tables N.6-N.7 present the prevalence counts and prevalence of patients treated with dialysis therapy for ESRD, 2003-2016. Tables N.6.a and N.6.b show the trends in the prevalent counts and unadjusted prevalence of patients receiving dialysis. Tables N.7.a-N.7.f show the distribution of different modality use in prevalent dialysis patients, including counts and percentage of in-center hemodialysis (N.7.a, N.7.d), counts and percentage of CAPD/APD/IPD (N.7.b, N.7.e), and counts and percentage of home hemodialysis (N.7.c, N.7.f). The denominator was calculated as the sum of patients receiving HD, PD, or home HD, excluding patients with other/unknown modality.

Tables N.8-N.9 present data regarding kidney transplantation in different countries, 2003-2016. Tables N.8.a and N.8.b present the counts and 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. Tables N.9.a and N.9.b show the trends in the prevalent counts and unadjusted prevalence of treated ESRD patients with a functioning kidney transplant. Table N.9.c 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 in one year divided by the 2015 population size in one year and, if the unit is per million population, multiplied by one million for rates measured as per million per year. The 2015 death rate for prevalent ESRD patients, meanwhile, 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. A count-based rate describes the proportion having the "event," and a 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. A model-based method can improve the stability of these estimates by smoothing the estimates across calendar years. 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: Mortality and Causes of Death*.

Measurement Unit for Rates

Both observed and model-based rates are calculated per unit of population (e.g., per 1,000 patients) and per unit of follow-up time (e.g., 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 13.17 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	1,143	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 13.17. Group B also has three patients.

Patients 1 to 6 respectively contribute 0.25, 0.5, 1.0, 1.0, 0.75, and 1.0 patient-years at risk. The first hospitalization rate per thousand patients is 889 for all patients (in either group) in 2015. However, 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. The rate for Group B is calculated as (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.

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

Direct adjustment is a rate-adjustment method that allows rates to be compared adjusting for differences in the patient population. 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 want 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 prevalent population at the end of 2015 — with five race groups (White, Black/African American, Native American, Asian, and Other).

Using the State A's incidence rates which come from State A's race-specific incidence rates and its

own population's racial distribution, it has an overall unadjusted incidence rate in 2015 is 196.2 per million population per year. The race-specific rates of State A, State A's race distribution and the racial distribution of the national population are as shown in Table 13.18. The adjusted incidence rate of state A (with the national population as reference) is calculated by using State A's unadjusted race-specific incidence rates multiplied by the U.S. national racial distribution, as in this equation: (153 x 75.1%) + (250 x 12.3%) + (303 x 0.9%) + (174 x 3.6%) + (220 x 8.0%) = 172.2 per million population. This means that if state A had the same racial distribution as the entire country, its incidence rate would be 172.2 instead of 196.2. If state B had an adjusted incidence rate of 205 (calculated the same way), we could say that state B had a higher incidence rate than state A if both states had the same racial distribution as the whole country.

vol 2 Table 13.18 Example of adjusted incident rate calculation

	Incidence rate of state A	State A racial distribution (%)	National population racial distribution (%)
White	153	50	75.1
Black/African American	250	20	12.3
Native American or Alaska native	303	10	0.9
Asian	174	10	3.6
Other	220	10	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 2: Clinical Indicators and Preventive Care*, *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 (i.e., varying greatly from year to year), 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). 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. 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, …, 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 incorporate age (categorical), ethnicity, race, sex, diabetes status (unless stratified by diabetes) and year, and all the two-way interaction terms except between race and ethnicity. Models in the "_adj" worksheets are also adjusted for vintage and all the two-way interaction terms except 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.

The adjusted mortality rates for prevalent cohorts in *Reference Table H: Mortality and Causes of Death* are calculated using direct standardization and based on the category-specific mortality rates from the generalized linear models.

Generalized Linear Model for Hospitalization Rates

In this ADR, *Reference Table G: Morbidity and Hospitalization* presents rates of total admissions and hospital days. We use a generalized linear model with log link and Poisson distribution, the model includes age, sex, race, primary cause of ESRD, and their 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.

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, the expected remaining lifetime is calculated using a survival function based on conditional piecewise exponential survival, where the death rate is assumed to be constant within each age group (mostly 5-year age groups). For a given starting age A, the expected remaining lifetime is then equal to the area under this piecewise exponential survival curve. Because few patients live beyond 100, this area is truncated at the upper age limit of 100 years.

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_0.

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 $S(t_0)$ and $S(t_1)$ using the Kaplan-Meier method from the data available, where $t_0<t_1$ and t_1 is within the follow-up

$$\mu = \frac{t_1 - t_0}{(ln[S(t_0)] - ln[S(t_1)])},$$

the estimate of the conditional half-life = $\mu \cdot ln(2)$.

This method can be used only when the hazard is a constant after t_0 and t_1 is chosen to be big enough to obtain a stable estimate of $\ln(S(t_0))-\ln(S(t_1))$.

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. Some maps are by health service areas (HSAs). HSAs are defined as one or more counties that are relatively self-contained with respect to the provision of hospital care (Makuc et al., 1991).

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