

AN INTRODUCTION TO END-STAGE RENAL DISEASE IN THE U.S.

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JOHN MUIR, Travels in Alaska his year the USRDS not only reports on the traditional ESRD population, but presents data on the impact of the new bundled prospective payment system for dialysis. This section, included in Chapter Ten, focuses on how large and small dialysis organizations, hospital-based units, and independent unit have shifted costs under the new payment structure, and looks at the collateral impact on patient care.

The size of the ESRD population reached a new high in 2010, with 594,374 patients under treatment — just short of the 600,000 mark. The number of patients returning from a failed transplant fell 0.4 percent, to 5,586, while the number restarting dialysis increased to 3,744.

The number of patients starting ESRD therapy grew by only 500 in 2010, to a total of 116,946, while the prevalent dialysis population (including other peritoneal dialysis and unknown dialysis) reached 415,013 on December 31. The number of kidney transplants reached 17,778, just 42 more than in 2009, while the prevalent transplant population increased 4.0 percent, to 179,361, despite continued growth in the number of patients on the transplant waiting list. The median time on the kidney-only and kidney-pancreas waiting lists was 1.7 years, unchanged from prior years.

In the rest of this Précis we show that the rate of new ESRD cases remains quite stable, at 348 per million population in 2010 — similar to rates seen earlier in the decade. ESRD due to diabetes has been relatively stable over the last decade, with a rate of 152 in 2010, while the rate of ESRD caused by hypertension decreased 2.0 percent, falling to 99 per million in 2010. Age differences are most dramatic in data on ESRD due to diabetes, with rates 4–5 times higher in younger blacks/African Americans than in their white counterpars. We have examined this in prior ADRs, but the lack of change in these rates suggests that more needs to be done to address this major racial disparity. The prevalent rate of ESRD increased 1.7 percent in 2010, reaching 1,763.

Patients who see a nephrologist for more than 12 months before starting dialysis are the most likely to use a fistula or internal graft at the first outpatient dialysis treatment. Nephrologists are central to discussions with patients and families about ESRD treatment options, and greater pre-ESRD referral would help ensure increased use of fistulas, which are associated with the lowest rates of adverse events.

The treatment of anemia has changed during the last five years, after changes in product labeling from the FDA and in payment structures from CMS (implemented in January, 2011). Among patients receiving erythropoiesis stimulating agents (ESAS) prior to dialysis, hemoglobin levels at initiation have fallen below 10 g/dl, a level not seen since the mid-1990s, while pre-ESRD use of ESAS has also fallen — below 20 percent, a level not seen since April, 1996. Hemoglobin levels at six months following the start of ESRD therapy are now close to those seen in 1998, and levels in the prevalent dialysis population have decreased as well.

Hospitalizations continue to be an area of concern, with admissions for infection in hemodialysis patients 43 percent higher than in 1993, and showing no sign of improvement. The rate of hospitalization for bacteremia/sepsis is up, while admissions due to infection have fallen; as there has been little change in the overall rate of hospitalization due to infection, this suggests a shift in hospital coding.

New data on hospitalizations by day of the week show marked variations, with rates highest on the day of the long interval off treatment; these trends are similar to those we reported for mortality in the New England Journal of Medicine (September, 2011).

This year we present additional data on the Medicare Part D prescription drug benefit, which started in 2006. Many elderly, disabled individuals and those with

ESRD have Medicare coverage; these patients can enroll in Medicare Part D for prescription drug coverage. Seventy-seven and 64 percent of hemodialysis and peritoneal dialysis patients were enrolled in Part D in 2010, compared to 56-60 percent of general Medicare patients (with or without CKD) and transplant patients.

As we show here and in Chapter Five, mortality among peritoneal dialysis patients continues to fall, despite an expanding population. Outcomes for these patients will need close attention, as incentives to use peritoneal dialysis have changed under the new bundled payment system. Mortality in the first months of dialysis has also declined, a new finding when compared to 2004 and 1999. In an analysis parallel to that of hospitalization in Chapter Three, we present data on mortality by day of the week, assessing the entire hemodialysis population rather than the random sample examined in previous years. Interestingly, mortality due to infection is highest on the day after the first run of the week, while mortality due to cardiovascular causes is highest on the day of the first run.

The kidney transplant wait list for active and inactive patients continues to grow, reaching 87,000 in 2010; 17,778 transplants were performed during that year. Living donor donation rates appear to be rebounding, while donations from deceased donors have been stable. Hospitalizations due to cardiovascular disease and infection continue to be major issues for the transplant population, with heart failure and urinary tract infections leading these two major areas of morbidity.

Highlighted data on children with ESRD show that their rates of rehospitalization are as high as those seen in adults, and have remained unchanged over the past decade. Children younger than five, whether on peritoneal dialysis or hemodialysis, have the highest rates of hospitalization for infection, and peritoneal dialysis is associated with higher rates than hemodialysis. Rates of influenza vaccinations continue to be low across modalities — a continuing concern, given that pneumonia occurs frequently in this population. The lack of improvement in mortality rates among children is also a concern, one yet to be addressed.

This year we introduce data from the Canadian Organ Replacement Registry (CORR), comparing trends in pediatric ESRD in the United States and Canada. Over the last twenty years, incident and prevalent rates of ESRD have been 1-2 times higher for children in the U.S. than for those in Canada. The prevalence of ESRD due to cystic and congenital diseases has been growing in the U.S., but not in Canada.

Dialysis providers continue to consolidate, with Fresenius Medical Care announcing the purchase of additional units in July, 2011; the company thus maintains its position as the largest provider of dialysis care in the U.S. Overall, 95 percent of dialysis providers opted into the the new bundled prospective payment system for dialysis (introduced in January, 2011), including nearly 70 percent of hospital-based units and nearly 100 percent participation from Fresenius, DaVita, and DCI.

Data on monthly EPO dosing show a 27 percent decrease between September, 2010 and September, 2011; in DaVita and DCI units, dosing fell 37 percent. IV iron and vitamin D dosing fell 23 and 12 percent, respectively. Average hemoglobin levels fell 3.6 percent over the time period, while rates of transfusion events rose 24 percent.

DCI continues to have the lowest standardized hospitalization and mortality ratios among the large providers, while, among the smaller providers, hospital-based units have the highest standardized mortality ratios. DaVita this year had mortality ratios similar to those of DCI, a new finding.

We conclude the Précis with data on the costs of ESRD patient care, which rose to \$29 billion in 2010 (including Medicare Part D). Costs per person per year remain highest for hemodialysis patients, at \$87,561, compared to \$66,761 and \$32,914 for peritoneal dialysis and transplant patients. » Figure p.1; see page 428 for analytical methods. Period prevalent general (fee-for-service) Medicare patients. Diabetes, СКD, & congestive heart failure determined from claims, 1999-2000 & 2009-2010; costs are for calendar years 2000 & 2010.

vol 2



#### vol 2 Summary statistics on reported ESRD therapy in the United States, p.a by age, race, ethnicity, gender, & primary diagnosis, 2010

	Incidence <sup>A</sup>			December	31 point p	revalence					Kidney tra	nsplants	
			Adj.			Adj.					Deceased	Living	ESRD
	Count	%	rate <sup>B</sup>	Count <sup>c</sup>	%	rate <sup>B</sup>	Dialysis <sup>c</sup>	%	Tx <sup>c</sup>	%	donor	donor	deaths <sup>D</sup>
0-19 <sup>E</sup>	1,395	1.2	15.5	7,811	1.3	86	2,377	0.6	5,434	3.0	555	375	159
20-44	13,863	11.9	127.6	101,245	17.0	940	57,153	13.8	44,092	24.6	2,926	2,138	4,297
45-64	44,950	38.4	580.9	268,124	45.1	3,402	174,727	42.1	93,397	52.1	5,934	2,976	27,418
65-74	27,630	23.6	1,367.7	122,550	20.6	6,068	93,583	22.5	28,967	16.2	1,795	716	24,301
75+	29,055	24.8	1,772.6	94,644	15.9	5,865	87,173	21.0	7,471	4.2	236	68	34,826
Unknown	53	0.0						0.0		0.0			
White	77,030	65.9	275.3	360,289	60.6	1,311	232,499	56.0	127,790	71.2	6,555	4,633	61,693
Black/African American	32,018	27.4	924.0	187,864	31.6	5,242	152,540	36.8	35,324	19.7	3,709	882	24,704
Native American	1,422	1.2	465.2	8,085	1.4	2,566	6,032	1.5	2,053	1.1	177	80	1,008
Asian/Pacific Islander	5,853	5.0	388.6	32,862	5.5	2,101	21,155	5.1	11,707	6.5	884	620	3,198
Other/unknown	623	0.5		5,274	0.9		2,787	0.7	2,487	1.4	121	58	398
Hispanic	16,823	14.4	500.9	93,510	15.7	2,606	69,290	16.7	24,220	13.5	1,627	881	10,582
Non-Hispanic	100,123	85.6	338.0	500,864	84.3	1,717	345,723	83.3	155,141	86.5	9,819	5,392	80,419
Male	66,650	57.0	441.3	337,441	56.8	2,169	230,578	55.6	106,863	59.6	6,886	3,871	50,780
Female	50,288	43.0	275.2	256,920	43.2	1,425	184,425	44.4	72,495	40.4	4,560	2,400	40,219
Unknown	*	0.0		13	0.0		*	0.0	*	0.0		2	*
Diabetes	51,636	44.2	151.7	224,722	37.8	656	183,065	44.1	41,657	23.2	3,541	1,282	41,764
Hypertension	32,861	28.1	99.0	147,174	24.8	437	118,357	28.5	28,817	16.1	2,402	979	25,876
Glomerulonephritis	7,428	6.4	22.7	86,499	14.6	263	40,494	9.8	46,005	25.6	2,231	1,615	5,710
Cystic kidney disease	2,630	2.2	8.1	28,345	4.8	85	10,968	2.6	17,377	9.7	856	714	1,542
Urologic disease	1,585	1.4	4.7	13,220	2.2	40	7,329	1.8	5,891	3.3	223	149	1,456
Other known cause	14,940	12.8	45.8	65,402	11.0	202	38,654	9.3	26,748	14.9	1,541	1,067	10,491
Unknown cause	3,963	3.4	12.1	21,958	3.7	66	13,897	3.3	8,061	4.5	415	234	3,154
Missing cause	1,903	1.6	3.7	7,054	1.2	14	2,249	0.5	4,805	2.7	237	233	1008
All	116,946	100.0	347.8	594,374	100.0	1,763	415,013 <sup>F</sup>	100.0	179,361		11,446	6,273	91,001
Unadjusted rate <sup>G</sup>			369.4			1,870				Total t	ransplants <sup>H</sup>	17,778	

- А Incident counts: include all known ESRD patients, regardless of any incomplete data on patient characteristics and of U.S. residency status.
- Includes only residents of the 50 states and В Washington D.C. Rates are adjusted for age, race, and/or gender using the estimated July 1, 2005 U.S. resident population as the standard population. All rates are per million population. Rates by age are adjusted for race and gender. Rates by gender are adjusted for race and age. Rates by race are adjusted for age and gender. Rates by disease group and total adjusted rates are adjusted for age, gender, and race. Adjusted rates do not include patients with other or unknown race.
- С Patients are classified as receiving dialysis or having a functioning transplant. Those whose treatment modality on December 31 is unknown are assumed to be receiving dialysis. Includes all Medicare and non-Medicare ESRD patients, and patients in the U.S. Territories and foreign countries.
- D Deaths are not counted for patients whose age is unknown.
- Е Age is computed at the start of therapy for incidence, on December 31 for point prevalence, at the time of transplant for transplants, and on the date of death for death. F
- Includes patients whose modality is unknown. G Unadjusted total rates include all ESRD patients in the 50 states and Washington D.C.
- Total transplants as known to the USRDS: 59 Н transplants with unknown donor type excluded from counts.
- Adjustments using the Bureau of Labor Statistics L inflationary adjustment and the CMS inflation adjustment for the medical component.
- Values for cells with ten or fewer patients are suppressed. "." Zero patients in this cell.

Wait-list for kidney & kidney/pancreas transplants								
	New		Median					
	listings	N, as of	time on					
	in 2010	12.31.10	list (yrs)					
0-17	763	770	0.79					
18-34	4,141	9,038	1.52					
35-49	9,513	24,137	1.73					
50-64	14,567	37,490	1.73					
65+	5,919	15,957	1.79					
Male	21,229	51,346	1.66					
Female	13,675	36,047	1.80					
White	20,938	47,469	1.58					
African American	10,193	30,285	1.91					
Native American	436	1035	1.68					
Asian/Pacific Islander	2,506	6,651	1.90					
Other/unknown	831	1,953	1.48					
Hispanic	5,731	16,188	1.84					
Non-Hispanic	29,173	71,205	1.68					
Diabetes	11,953	29,593	1.60					
Hypertension	7,208	19,941	1.80					
Glomerulonephritis	6,030	15,637	1.90					
Cystic kidney disease	2,459	5,532	1.57					
Urologic disease	514	1,494	2.11					
Other known cause	5,042	11,496	1.69					
Unknown cause	1,000	2,665	1.96					
Missing cause	698	1035	1.06					
Blood type A	11,553	25,297	1.51					
В	5,056	14,008	1.86					
AB	1,384	2,598	1.28					
0	16,911	45,490	1.81					
PRA o%	23,789	53,493	2.80					
1-9	1,490	3,829	2.72					
10-79	5,538	15,126	3.01					
80+	4,061	14,907	3.84					
Unknown	26	38	0.62					
Total	34,904	87,393	1.71					

Medicare &	
non-Medicare spending	
Medicare spending for ESRD, 2010	
(billions of dollars)	
SAF paid claims (Part A & B)	28.70
2% incurred but not reported	0.57
HMO-Medicare risk	3.38
Organ acquisition	0.29
Total Medicare costs	32.94
Non-Medicare spending for ESRD, 2010	
(billions of dollars)	
EGHP (MSP)	3.22
Patient obligations	5.42
Non-Medicare patients	5.91
Total non-Medicare costs	14.55
Total ESRD costs (billions), 2010	47.49
Change in Medicare spending, 2009 to 20	010
Total	6.1
Per patient year	1.2
Adjusted for inflation <sup>1</sup> -0.3% to -2	.1%
Medicare spending per patient year, 2010	)
ESRD	\$75,043
Hemodialysis	\$87,561
Peritoneal dialysis	\$66,751

Transplant

\$32,914

# PRÉCIS: AN INTRODUCTION TO END-STAGE RENAL DISEASE IN THE UNITED STATES incident rates & racial differences

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In 2010, 116,946 new dialysis and transplant patients initiated ESRD therapy, for an adjusted rate per million population of 349. On December 31, 2010, there were 594,374 patients receiving treatment, for an adjusted rate of 1,763 per million population. More than 415,000 of these patients were being treated with dialysis, while 179,361 had a functioning graft; 91,001 ESRD patients died during the year. A total of 1,778 transplants were performed during 2010, including 6,273 from living donors. Almost 35,000 patients were added to the transplant wait list, 87,393 were on the kidney-alone and kidney/pancreas wait lists at the end of 2010, and the median time on the list (for pediatric and adult patients combined) was 1.7 years.

With Medicare spending for ESRD at \$32.9 billion, and non-Medicare spending at \$14.6 billion, total ESRD costs in 2010 reached \$47.5 billion. Medicare costs per person per year were more than \$75,000 overall, ranging from \$32,914 for transplant patients to \$87,561 for those receiving hemodialysis therapy. **» Table p.a;** see page 428 for analytical methods. *Dialysis & transplant patients, 2010*.

The number of new dialysis patients remained stable in 2010 — after a 3.5 percent increase in 2009 — at close to 113,000 patients. Close to 5,600 patients with graft failure returned to dialysis from transplant, a number also similar to that of the previous year. The number of patients restarting dialysis increased 7.2 percent, to 3,744. Overall, the CMS Annual Facility Survey showed 122,067 patients starting or restarting dialysis in 2010, up just 0.2 percent from 2009. **» Figure p.2;** see page 428 for analytical methods. *CMS Annual Facility Survey*.





The size of the prevalent dialysis population increased 3.8 percent in 2010, reaching 415,013, and is now 46 percent larger than in 2000. The size of the transplant population rose 4.0 percent, to reach 179,361 patients, while the number of incident patients rose just 0.4 percent, to 116,946. **» Figure p.3.** Incident & December 31 point prevalent ESRD patients.



After a 1.1 percent increase in 2009, the adjusted incident rate of end-stage renal disease fell 2.0 percent in 2010, to 348 per million population. Since 2000, changes in adjusted incident rates have shown little variation, ranging from -2.1 percent to 2.1 percent. **» Figure 1.2**; see page 429 for analytical methods. *Incident ESRD patients. Adj: age/gender/race; ref: 2005 ESRD patients.* 

The adjusted rate of prevalent cases of end-stage renal disease rose 1.7 percent in 2010 — slightly lower than the 1.9 percent growth in 2009 — to 1,763 per million population. This rate is 21 percent higher than that seen in 2000. The annual rate of increase has remained between 1.7 and 2.3 percent since 2004. **» Figure 1.10;** see page 429 for analytical methods. December 31 point prevalent ESRD patients. Adj: age/gender/race; ref: 2005 ESRD patients.

By race, adjusted incident rates of ESRD for blacks/African Americans and Native Americans in 2010 were 924 and 465 per million population, respectively — 3.4 and 0.5 times greater than the rate of 276 found among whites. Since 2000, the rate of new ESRD cases has grown 6.1 percent among whites and 2.5 percent among Asians, while falling 7.0 percent in the black/African American population.

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PRÉCIS: AN INTRODUCTION TO END-STAGE RENAL DISEASE IN THE UNITED STATES incidence & prevalence





In 2010, the adjusted incident rate of ESRD was 348 per million population, averaging 471 in the upper quintile. The highest adjusted rates occur in the Ohio Valley, portions of Texas and California, and the southwestern states. (Rates are not adjusted for ethnicity.) **» Figure 1.3;** see page 429 for analytical methods. *Incident ESRD patients. Adj: age/gender/race; ref: 2005 ESRD patients.* 

In 2010, the rate of prevalent ESRD was 1,752 per million population. Patterns generally follow those found in the incident population, with an additional pocket of higher rates in the Dakotas and Minnesota. Rates in the upper quintile average 2,457. (Rates are not adjusted for ethnicity.) **» Figure 1.11;** see page 429 for analytical methods. *Dec. 31 point prev. pts. Adj: age/gender/race; ref: 2005 ESRD pts.* 

Both the rates of incident ESRD caused by diabetes and their growth over time continue to vary widely by age and race/ethnicity. Among whites age 30-39, for example, the incident rate (adjusted for gender) has fallen just 1.0 percent since 2000, and in 2010 was 35.4 per million population. For blacks/African Americans of the same age, in contrast, the rate has increased 69 percent since 2000, to reach 133.8. The Native American population has seen a rise of 30.1 percent for this age group over the same time period, reaching 116 per million in 2010. And while rates of new ESRD cases among Asians remain comparatively low, among those age 30-39 they have nearly doubled since 2000, reaching 32.6 per million population in 2010.

Different patterns are seen among older populations. Among whites age 60-69, the rate of incident ESRD due to diabetes has fallen 3.6 percent since 2000, in contrast to a 29 percent increase in those age 70 and older. In blacks/African Americans, the rate for those age 60-69 has fallen 17.2 percent since 2000, while rates have decreased 40.4 and 18.4 percent, respectively, in Native Americans age 60-69 and those 70 and older. The rate for Hispanics age 60-69 has fallen 15.7 percent since 2000, to 1,166 in 2010, but has now surpassed the 2010 rate of 1,138 found in Native Americans of the same age. » Figure 1.8; see page 429 for analytical methods. Incident ESRD patients; rates are three-year rolling averages. Adj: gender; ref: 2005 ESRD patients.



Among hemodialysis patients who have seen a nephrologist for more than a year prior to starting ESRD therapy, 41.8 percent initiate treatment using a catheter; these patients have the greatest likelihood at initiation of having an arteriovenous fistula (AV) or maturing fistula, at 31.3 and 20.1 percent, respectively. Patients with no pre-ESRD nephrology care most frequently start treatment with a catheter, at 81 percent, while only 18.4 percent initiate with either a mature or maturing AV fistula or graph. **» Figure 1.19;** see page 429 for analytical methods. *Incident hemodialysis patients, 2010.* 



In the incident ESRD population, the mean hemoglobin at initiation has continued to fall from its peak in 2006, reaching 9.73 g/dl overall, 9.76 for patients receiving pre-ESRD treatment with an erythropoiesis stimulating agent (ESA), and 9.71 for patients without ESA treatment; 20 percent of new patients at the end of 2010 had received a pre-ESRD ESA. **» Figure 1.20;** see page 429 for analytical methods. *Incident ESRD patients*.



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ESRD

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PRÉCIS: AN INTRODUCTION TO END-STAGE RENAL DISEASE IN THE UNITED STATES patient characteristics | clinical indicators

At the end of 2010, slightly more than two-thirds of prevalent dialysis patients had a mean monthly hemoglobin of 10–12 mg/dl. The mean EPO dose per week fell each month within the year, ending at 15,829 in the month of December, while the mean hemoglobin at that time was 11.3 g/dl. **» Figures 2.2–3;** see page 431 for analytical methods. *Period prevalent dialysis patients*.

When compared to 2006 incident patients, those starting dialysis in 2010 did so with lower hemoglobins one month post-initiation, at 10.7 and 10.2 g/dl, respectively. At six months, mean hemoglobin levels were within recomended levels, at 11.4 mg/dl. » Figure 2.4; see page 431 for analytical methods. Incident dialysis patients; EPO doses in 2.5 adjusted for inpatient days.



In 2010, among both whites and blacks/African Americans, the percentage of hemodialysis patients starting ESRD with an arteriovenous fistula or graft varied across the county. In the lower quintile, an average of 14.1–14.6 percent initiated treatment with an internal access; means in the upper quintile were 23.3–23.8 percent.

By location, patients residing in the Pacific Northwest, Alaska, and New England were the most likely to initiate dialysis with an internal access. » **Figure 2.14**; see page 431 for analytical methods. *Incident hemodialysis patients*, 2010.





Rates of hospitalization for infection in the hemodialysis population have increased 43 percent since 1994 (in contrast to a 50 percent decrease in vascular access hospitalizations). Hospitals have made significant progress in using less costly settings to address vascular access interventions, but equivalent progress in lowering the rate of infectious complications is lacking. The use of dialysis catheters continues to have the largest associated risk, a finding well known in the dialysis community. **» Figure 3.1;** see page 432 for analytical methods. *Period prevalent ESRD patients; adjusted for age, gender, race, & primary diagnosis; ref: ESRD patients, 2005.* 





Adjusted cardiovascular admission rates for hemodialysis patients peaked in 2004, at 601 per 1,000 patient years, and have since fallen 13.5 percent. In the same period, rates for peritoneal dialysis and transplant patients fell 19 and 21 percent, respectively. Rates remain lowest for patients with a transplant, at 120 in 2010.

Peritoneal dialysis patients have the highest rate of admission for any infection, at 558 per 1,000 patient years in 2010, yet this rate is 16 percent lower than the 663 seen in 1996. The admission rate for peritonitis among these patients has been falling since the mid-1990s, from a peak of 169 in 1995 to 85 in 2010, and rates of admission for a peritoneal catheter infection have declined 23 percent since 2000, falling to 152 per 1,000 in 2010. Among hemodialysis patients, admissions for vascular access infection rose steadily until 2005, but since have fallen 24 percent, to 103 in 2010. Admissions for bacteremia/sepsis remain highest for hemodialysis patients, at 116 per 1,000 patient years in 2010. **» Figure 3.3;** see page 432 for analytical methods. *Period prevalent ESRD patients. Adj: age/gender/race/primary diagnosis; ref: ESRD patients, 2005.* 

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## Day of the dialysis week

- HD, Monday for patients on a Monday– Wednesday– Friday schedule; Tuesday for patients on a Tuesday– Thursday–Saturday schdule.
- HD<sub>1</sub>+1 Tuesday or Wednesday for the respective shedules.
- HD2 Wednesday or Thursday, respectively.
- HD<sub>2</sub>+1 Thursday or Friday, respectively.
- HD<sub>3</sub> Friday or Saturday, respectively.
- HD\_+1 Saturday or Sunday, respectively.
- HD\_+2 Sunday or Monday, respectively.

### Interdialytic intervals

- Day after long interdialytic interval: Monday for patients with a Monday– Wednesday–Friday dialysis schedule; Tuesday for patients with a Tuesday– Thursday–Saturday dialysis schedule.
- 2 Day after short interdialytic interval: Wednesday and Friday for patients with a Monday–Wednesday–Friday dialysis schedule; Thursday and Saturday for patients with a Tuesday– Thursday–Saturday dialysis schedule.
- 3 Days without dialysis: Other respective weekdays.

Maintenance hemodialysis is typically delivered three times a week, and concern has emerged that the two-day, or "long," interval may be associated with higher than expected rates of adverse outcomes. To explore this issue, we here present data on hospitalization rates by different days of the hemodialysis week among prevalent adult hemodialysis patients in 2010.

In the framework of the "hemodialysis week,"  $HD_1$ , for example, is defined as Monday for patients dialyzed on Monday, Wednesday, and Friday (MWF) and as Tuesday for those treated on Tuesday, Thursday, and Saturday (TTS).  $HD_3 + 2$ , the second day of the long interval, is Sunday for MWS and Monday for TTS.

As shown in Figure 3.11, hospitalization rates in the overall population are highest, at 2,101 per 1,000 patient years, on the day following the long interval ( $HD_1$ ), and a downward sawtooth pattern is apparent thereafter, with an opposing direction of changes on any pair of successive days and a decline when any pair separated by two days is studied.

This pattern is replicated across age groups. Figures 3.12 and 3.13 show corresponding analyses for hospitalization rates attributed to cardiovascular disease and infection, respectively, and show patterns similar to those seen with all-cause hospitalization. **» Figures 3.11–13**; see page 432 for analytical methods. January 1, 2010 point prevalent Medicare HD patients alive on January 31. Includes patients age 20 & older receiving hemodialysis three times weekly on a Monday–Wednesday–Friday or Tuesday–Thursday–Saturday schedule; HD<sub>1</sub>, HD<sub>2</sub>, & HD<sub>3</sub> are the first, second, & third hemodialysis sessions. Rates for all patients are adjusted for age, gender, race, Hispanic ethnicity, & primary diagnosis; rates by age are adjusted for the other four factors. Ref: all included HD patients in 2010.



In the 30 days following a live hospital discharge from a cardiovascular index hospitalization in 2010, 48 percent of rehospitalizations were for cardiovascular issues. Rehospitalization for overall infection and vascular access infection, respectively, followed 13 percent and 6 percent of discharges from index hospitalizations of the same category, compared to 8 percent and less than 2 percent of discharges from all-cause index hospitalization. **» Figure 3.7**; see page 432 for analytical methods. *Period prevalent hemodialysis patients, all ages (0-75+), 2010; unadjusted. Includes live hospital discharges from January 1 to December 1, 2010.* 

This figure uses the old/simple method and the new/complex method to estimate sCD rates in prevalent dialysis patients. The complex method yields a consistently lower rate for the past decade, an important consideration in clinical trial design. One important factor in this difference is the number of patients withdrawn from dialysis, a major cause of death which does not figure in clinical trials in the general population. **» Figure 4.2**; see page 435 for analytical methods. *Period prev. dialysis pts, age 20 & older.* 





In comparison to the marked reduction in sCD in prevalent dialysis patients (Figures 4.3–6), the reduction in the rates of sCD in the first 90 days of therapy is relatively modest. Between 2005 and 2009 this rate fell only 10 percent, from 105 to 96. The first 90 days after dialysis initiation constitute a period of heightened sCD risk. **» Figure 4.7**; see page 435 for analytical methods. *Incident dialysis patients age 20 & older; unadjusted, simple method.* 



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4.C intervent	ions, by di	agnosis & n	nodality (ro	w percent	)									
	2007		Beta	Clopid-			Amio-	2010		Beta	Clopid-			Amio-
	N	ACEI/ARB	blocker	ogrel	Warfarin	Statin	darone	N	ACEI/ARB	blocker	ogrel	Warfarin	Statin	darone
CHF														
Hemodialysis	56,199	43.5	56.7	17.4	12.2	33.1	5.3	59,664	46.6	66.0	21.7	14.0	42.7	6.3
Peritoneal dialysis	1,924	41.2	57.9	16.6	12.3	37.0	5.0	1,934	45.2	67.2	21.2	13.1	48.6	6.7
Transplant	3,811	41.4	70.0	14.5	17.3	50.4	4.1	4,792	42.2	76.3	16.7	19.4	58.5	4.5
AMI														
Hemodialysis	4,271	56.3	75.0	47.2	11.5	54.8	7.3	4,986	55.5	76.9	51.2	13.2	61.9	7.7
Peritoneal dialysis	200	47.5	78.5	53.5	9.5	56.5	8.5	216	52.8	78.2	61.1	12.5	69.9	6.0
Transplant	264	54.2	84.8	49.2	18.6	69.7	3.8	348	48.6	87.1	54.0	14.9	77.6	5.5
PAD														
Hemodialysis	47,291	39.5	51.6	19.3	12.2	34.8	4.3	50,148	41.9	59.3	23.9	13.6	43.6	5.0
Peritoneal dialysis	1,578	36.9	49.3	22.6	9.5	41.0	3.9	1,584	40.6	56.4	26.8	11.1	53.2	3.3
Transplant	4,387	39.9	59.9	15.3	13.2	51.0	2.1	5,237	41.5	67.6	19.7	13.9	58.0	2.2
CVA/TIA														
Hemodialysis	20,229	43.5	55.8	23.2	12.7	37.8	4.7	20,293	46.4	63.4	27.2	13.5	47.8	5.2
Peritoneal dialysis	719	41.6	55.5	23.9	11.0	47.0	4.5	787	46.0	59.2	27.2	14.4	51.5	4.1
Transplant	1,738	40.5	61.4	20.9	15.8	54.1	2.2	2,076	41.2	66.6	22.6	16.9	63.3	2.9
AFIB														
Hemodialysis	18,938	35.6	55.3	15.8	34.5	33.2	15.8	21,975	37.2	62.9	18.9	38.8	43.2	17.8
Peritoneal dialysis	625	31.0	55.0	16.3	39.8	38.7	17.8	791	33.9	63.8	15.4	43.4	50.7	19.2
Transplant	1,870	37.7	65.1	9.0	47.8	47.0	10.2	2,840	42.6	74.4	10.3	54.0	58.2	11.9
ICD/CRT-D														
Hemodialysis	734	55.3	72.8	29.3	19.6	45.6	13.1	610	58.0	76.6	30.3	22.1	47.5	17.4
Peritoneal dialysis	31	54.8	77.4	19.4	19.4	41.9	19.4	26	53.8	88.5	19.2	11.5	53.8	26.9
Transplant	48	56.3	89.6	27.1	33.3	60.4	8.3	46	52.2	87.0	26.1	34.8	76.1	15.2
Revascularization: PO	21													
Hemodialysis	3,507	55.0	76.0	83.1	9.5	60.5	5.2	4,214	54.8	77.4	83.5	9.6	67.8	5.6
Peritoneal dialysis	197	49.7	72.6	85.8	4.1	59.9	6.1	217	47.5	74.2	82.0	6.5	71.4	2.8
Transplant	296	49.7	76.4	86.5	12.2	70.6	3.4	407	49.9	82.1	83.3	8.1	76.9	1.2
Revascularization: C	ABG													
Hemodialysis	615	58.0	77.2	32.2	10.1	64.7	17.6	687	55.7	83.3	38.3	12.4	70.6	17.2
Peritoneal dialysis	38	57.9	84.2	34.2	21.1	65.8	21.1	54	46.3	81.5	44.4	9.3	70.4	20.4
Transplant	51	58.8	82.4	31.4	15.7	68.6	17.6	73	50.7	90.4	28.8	27.4	83.6	31.5
No cardiac event														
Hemodialysis	55,043	44.2	51.8	8.2	6.8	28.3	1.0	63,847	46.9	58.1	9.4	6.6	33.9	1.1
Peritoneal dialysis	6,320	43.5	47.5	5.4	3.6	33.7	0.6	6,840	49.0	55.9	5.9	4.3	39.7	0.6
Transplant	27,035	41.9	53.9	3.7	4.7	47.6	0.4	31,699	41.8	58.6	4.7	4.8	51.1	0.3

Two-thirds of dialysis patients diagnosed with CHF in 2010 received a beta blocker, while 47 percent of hemodialysis patients with this diagnosis received an ACEI/ARB. Beta blockers were used by more than three-quarters of ESRD patients with an AMI during 2010 and, remarkably, by 58 percent of hemodialysis patients with no cardiovascular diagnosis or intervention. At least with respect to medical therapy with beta blockers, if therapeutic nihilism in dialysis patients is not dead, it would certainly appear to be moribund. This is not to say that ESRD patients uniformly receive therapies to the same degree as patients in the general population, but, at least with respect to certain evidence-based therapies, such as beta blockers, the gap in utilization is markedly smaller than it was a decade ago.

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Cardiovaccular disease & nharmacelegical

The use of warfarin in hemodialysis patients with atrial fibrillation remains relatively low, perhaps reflecting concerns related to hemorrhagic risk in these patients. And given the relative paucity of data on amiodarone therapy in this population, the rates of amiodarone use are perhaps higher than would be expected.

Finally, despite the publication of the 4D and AURORA trials, there has been no discernible reduction in the use of statin therapy in U.S. dialysis patients. To the contrary, even in those without identified prevalent cardiovascular illness, 28 percent of hemodialysis patients and 34 percent of peritoneal dialysis patients in 2007 received statins, compared to 34 and 40 percent in 2010. In the population qualifying for secondary prevention (e.g., those with an AMI), the use of statin therapy in hemodialysis patients increased from 55 percent in 2007 to 62 percent in 2010. **» Table 4.c;** see page 435 for analytical methods. *January 1 point prevalent patients with Medicare Parts A, B, & D enrollment, with a first cardiovascular diagnosis or procedure in the year.* 



Between 1993 and 2003 there was little improvement in first-year death rates in the ESRD population. Between 2003 and 2009, however, these rates fell more than 14 percent, while secondyear death rates have fallen 16 percent. » Figure 5.1; see page 438 for analytical methods. Incident ESRD patients. Adj: age/gender/ race/primary diagnosis; ref: incident ESRD patients, 2005.

In the first year of hemodialysis, all-cause mortality and mortality due to cardiovascular disease or to other causes peak in month two following initiation, then fall. For incident hemodialysis patients in 2009, for example, all-cause mortality reached 435 deaths per 1,000 patient years at risk in month two, then fell to 206 in month 12. Cardiovascular mortality peaked at 169, and decreased to 78. Mortality due to infection peaks in months 2 and 3, at 40–43 per 1,000 patient deaths. **» Figure 5.3**; see page 438 for analytical methods. *Incident hemodialysis patients defined on the day of dialysis onset, without the 60-day rule. Adj: age/gender/race/Hispanic ethnicity/primary diagnosis; ref: incident hemodialysis patients, 2005.* 



ESRI



PRÉCIS: AN INTRODUCTION TO END-STAGE RENAL DISEASE IN THE UNITED STATES mortality







Maintenance hemodialysis is typically delivered three times a week, and concern has emerged that the two-day, or "long," interval may be associated with higher than expected rates of adverse outcomes. To explore this issue, we look here at mortality rates by different days of the hemodialysis week among prevalent adult hemodialysis patients in 2010.

In the framework of the "hemodialysis week,"  $HD_1$ , for example, is defined as Monday for patients dialyzed on Monday, Wednesday, and Friday (MWF) and as Tuesday for those treated on Tuesday, Thursday, and Saturday (TTS).  $HD_3 + 2$ , the second day of the long interval, is Sunday for MWS and Monday for TTS.

Mortality rates in the overall population are highest, at 174 per 1,000 patient years, on the day following the long interval (HD1), and a sawtooth pattern is apparent, with rates declining and increasing every two days thereafter. This pattern is replicated in patients age 65 and older, with rates varying between 185 and 226, but some differences are seen in younger age groups.

In patients age 20–39, mortality rates are highest on  $HD_2+1$  (57), lowest on  $HD_3$  (35), and the sawtooth pattern is absent. For ages 40–64, rates are substantially higher on  $HD_1$  (119), stable between  $HD_1 + 1$  (86) and  $HD_3 + 1$  (84), and intermediate on  $HD_3 + 2$  (96).

Figures 5.8 and 5.9 show corresponding analyses for mortality rates attributed to cardiovascular disease and infection. Rates are highest on HD<sub>1</sub> (87) for cardiovascular disease, and on HD<sub>1</sub> + 1 (17.7) for infection. **» Figures 5.7–9**; see page 438 for analytical methods. January 1, 2010 point prevalent Medicare hemodialysis patients alive on January 31. Includes patients age 20 & older receiving hemodialysis three times weekly on a Monday–Wednesday–Friday or Tuesday–Thursday–Saturday schedule; HD<sub>2</sub>, HD<sub>2</sub>, & HD<sub>3</sub>, are the first, second, & third hemodialysis sessions. Rates for all patients are adjusted for age, gender, race, Hispanic ethnicity, & primary diagnosis; rates by age are adjusted for the other four factors. Ref: all included hemodialysis patients in 2010.



Many elderly, disabled individuals and those with ESRD have Medicare coverage; these patients can enroll in Medicare Part D for prescription drug coverage. Seventy-seven and 64 percent of hemodialysis and peritoneal dialysis patients were enrolled in Part D in 2010, compared to 56–60 percent of general Medicare patients (with or without CKD) and transplant patients.

Compared to general Medicare and CKD patients enrolled in Part D, a higher proportion of Part D-enrolled hemodialysis, peritoneal dialysis, and transplant patients (73, 63, and 61 percent compared to 37–50 percent) receive the low-income subsidy (LIS). A higher percentage of patients on peritoneal dialysis or with a transplant have no known prescription drug coverage, but many of these patients are employed and may have coverage that is not tracked by Medicare. **» Figure 6.2;** see page 439 for analytical methods. *Point prevalent Medicare enrollees alive on January* 1, 2010.

Patients dually-enrolled in Medicaid and Medicare qualify for the LIS, and, if they do not choose a plan, are automatically enrolled in a Medicare Part D plan. Sixty-four percent of hemodialysis patients with Part D coverage are dually-eligible LIS beneficiaries, compared to 32 percent of the general Medicare population. An additional but smaller proportion of patients (6–12 percent) receive the LIS after an application documenting low income and resources. **» Figure 6.5;** see page 439 for analytical methods. *Point prevalent Medicare enrollees alive on January 1.* 



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Positioning of the top Part D medications used by dialysis patients changed between 2008 and 2010. Amlodipine has become the most frequently used drug, after being at fourth place in 2008. Sevelamer hydrochloride has dropped off the list as use has transitioned to sevelamer carbonate, now in fourth place. Use of calcium acetate and cinacalcet increased somewhat from 2008 to 2010, while use of lanthanum carbonate has declined. Together, sevelamer carbonate and hydrochloride maintain their status as the top medications, by cost, used by dialysis patients in 2010, with cinacalcet keeping second place. Use of carvediol has grown since 2008. As illustrated by days supply, medication use is a combination of use in the individual patient multiplied by the number of patients in the prevalent dialysis population, which continues to increase. » Table 6.f; see page 439 for analytical methods. Part D claims for all hemodialysis patients, 2010.



Patients enrolled in Part D, by dual eligibility

& low income subsidy (LIS) status, 2010

#### Top 15 drugs used by Part D-enrolled dialysis patients, by frequency & net cost, 2010

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By frequency Generic name	Total days supply	By net cost Generic name	Total days supply	Total cost (dollars)
Amlodipine	19,476,423	Cinacalcet	12,948,729	260,023,205
Insulin	19,185,188	Sevelamer carbonate	15,723,597	235,623,936
Metoprolol	18,897,578	Sevelamer HCL	5,580,405	96,695,276
Sevelamer carbonate	15,723,597	Insulin	19,185,188	76,032,463
Simvastatin	15,547,902	Lanthanum carbonate	2,790,692	63,996,592
Calcium acetate	14,777,969	Calcium acetate	14,777,969	51,855,070
Lisinopril	14,425,980	Clopidogrel bisulfate	10,529,417	48,746,816
Cinacalcet	12,948,729	Esomeprazole	4,916,511	27,757,642
Omeprazole	12,265,329	Atorvastatin	6,102,510	20,658,562
Carvedilol	11,904,875	Pantoprazole	3,992,742	14,284,534
Clonidine	11,349,738	Doxercalciferol	855,446	14,108,077
Levothyroxine	10,570,307	Valsartan	4,562,564	12,885,699
Clopidogrel bisulfate	10,529,417	Pioglitazone	2,130,208	12,426,793
Furosemide	9,888,422	Nifedipine	6,588,609	11,260,004
Warfarin	8,170,035	Clonidine	11,349,738	10,202,044

PRÉCIS: AN INTRODUCTION TO END-STAGE RENAL DISEASE IN THE UNITED STATES Part D prescription drug coverage

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## Vol 2Top 15 drugs used by Part D-enrolled transplant6.0patients, by frequency & net cost, 2010

By frequency Generic name	Total days supply	By net cost Generic name	Total days supply	Total cost (dollars)
Prednisone	7,547,599	Valganciclovir	982,135	45,474,908
Metoprolol	6,690,222	Insulin	6,497,226	28,914,728
Insulin	6,497,226	Tacrolimus	1,192,352	15,799,835
Amlodipine	5,202,017	Cinacalcet	862,809	15,790,929
Furosemide	4,184,856	Esomeprazole	1,666,478	9,430,347
Omeprazole	4,079,765	Mycophenolate mofetil	1,184,242	8,940,645
Trimethoprim/ sulfamethoxazole	4,040,453	Atorvastatin	2,830,453	8,685,651
Simvastatin	4,006,447	Epoetin alfa	197,966	6,086,743
Lisinopril	2,944,375	Clopidogrel bisulfate	1,376,772	5,917,211
Atorvastatin	2,830,453	Pantoprazole	1,190,918	4,307,687
Clonidine hydrochloride	2,405,996	Sirolimus	191,171	3,933,897
Levothyroxine	2,309,616	Mycophenolate sodium	229,983	3,432,389
Nifedipine	2,050,584	Darbepoetin alfa	71,610	3,226,774
Allopurinol	1,721,115	Pioglitazone	576,497	3,227,370
Calcitriol	1,694,629	Cyclosporine	686,376	3,092,528

Among transplant patients, prednisone (a generic immunosuppressant) was the most frequently used medication in 2010, followed by metoprolol and insulin; these ranks are unchanged since 2008. Trimethoprim-sulfamethoxazole, used for prophylaxis against pneumocystis carinii pneumonia, dropped from sixth to seventh place. No trade name immunosuppressant made the top 15 list in terms of frequency, not surprising given that most are covered under Medicare Part B. In terms of costs, insulin therapies moved from fourth place to second; insulin use increased at a faster pace than did the prevalence of patients with a functioning transplant. The use of valganciclovir, employed for prophylaxis against cytomegalovirus, rose slightly, and maintained its first position by

cost - not surprising, as it has noavailable generic. The immunosuppressants mycophenolate mofetil, sirolimus, cyclosporine, and mycophenolate sodium appear on the list by cost, implying that their costs are relatively higher than the frequency of their use. Although generic products became available starting in 2009, tacrolimus remained on the top cost list in 2010. Epoetin alfa and darbepoetin alfa, trade name products not among the most frequently used medications, were among those with the greatest cost, though their use has declined substantially since 2008. » Table 6.g; see page 439 for analytical methods. Part D claims for all kidney transplant patients, 2010. Therapeutic classification based on the Medi-Span's generic product identifier (GPI) therapeutic classification system.



In 2010, 16,843 kidney transplants were performed in patients age 20 and older in the United States — 135 more than in the previous year. There were 85 fewer living donor transplants performed in 2010 compared to 2009, a decrease of 1.4 percent, compared with a 2.0 percent increase in deceased donor transplants.

The number of adult candidates on the waiting list continues to increase, growing 6 percent in 2010 to reach 86,620 patients on December 31. The rate of new ESRD cases declined 1.1 percent from 2009 to 2010. » Figure 7.1; see page 440 for analytical methods. Unadjusted incident & transplant rates: limited to ESRD patients age 20 & older, thus yielding a computed incident rate higher than the overall rate presented elsewhere in the Annual Data Report. Wait list counts: patients age 20 & older listed for a kidney or kidney-pancreas transplant on December 31 of each year. Wait time: patients age 20 & older entering wait list in the given year. Transplant counts: patients age 20 & older as known to the USRDS.

The percentage of adult patients receiving a deceased donor transplant within three years of listing has fallen considerably since 1991, and varies by blood type. It continues to be highest for those of blood type AB — at 47 percent for patients listed in 2007 - and lowest for those of type 0 or B, at 20 percent. The percentage receiving a living donor transplant has been rising, and varies little by blood type. » Figure 7.4; see page 440 for analytical methods. Patients age 18 & older listed for a first-time kidney or kidneypancreas transplant.





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Since 2000, the number of deceased donor transplants among patients age 65 and older has more than doubled, to 2,031, and there has been an increase of 50 percent among patients age 50–64. Among those age 18–34, in contrast, transplants have fallen 23 percent, to 1,187. Among blacks/African Americans and Asians, the number of transplants has grown 53 and 111 percent, respectively. » **Figure 7.12**; see page 440 for analytical methods. Pts age 18 & older. Includes kidney-alone & kidney-pancreas transplants.

Among patients younger than 50, the number of living donor transplants has fallen 7–10 percent since 2000. For those age 50–64, in contrast, the number is now 42 percent higher, and for patients age 65 and older it has more than doubled. Living donor transplants among whites and blacks/African Americans have increased 8 and 16 percent in this period, and have more than doubled among Asians. **» Figure 7.14**; see page 440 for analytical methods. Pts age 18 & older. Includes kidneyalone & kidney-pancreas transplants.

In 2010, the rate of deceased donor transplants reached 6.8 per 100 dialysis patient years in Vermont, and 3.6–4.1 in Colorado, Iowa, and Wyoming. Rates of living donor transplants reached 3.4 in Minnesota, and 3.1 in North Dakota. **» Figure 7.16**; see page 440 for analytical methods. *Patients age 18 & older. Adj: age/gender/ race/primary diagnosis; ref: prevalent dialysis patients, 2010.* 



In the second year post-transplant, hospitalization rates for adult recipients are 54 percent lower than in the first year, at 67 admissions per 100 patient years. Admissions due to transplant complications fall 69 percent, to 12.1, while admissions due to cardiovascular causes and to infection fall 45 and 46 percent, to 8.2 and 18.1. **» Figure 7.21**; see page 440 for analytical methods. *First-time, kidney-only transplant recipients, age 18 & older, transplanted in* 2008; ref: transplant patients, 2005. In the first year after transplant, 21 percent of cardiovascular hospitalizations are due to congestive heart failure; this number rises in the second year, to 24 percent. Hospitalizations for coronary atherosclerosis and CVA/TIA also increase, from 5.8 and 5.0 percent, respectively, in year one to 10.5 and 9.7 percent in year two. Urinary tract infection, septicemia, and pneumonia are the most common diagnoses among transplant patients admitted for infection, at 15–16 percent in the second year after transplant. **» Figure 7.22;** see page 440 for analytical methods. *First-time, kidney-only transplant recipients, age 18 & older, with Medicare primary payor coverage, transplanted in 2006–2010.* 



At 36 months after transplant, the cumulative incidence of post-transplant lymphoproliferative disorder (PTLD) is more than three times greater among pediatric patients than among adults, at 1.63 percent compared to 0.48. Adults, in contrast, have a higher incidence of post-transplant diabetes, reaching 41 percent at 36 months, compared to 13 percent among pediatric patients. **» Figures 7.23–24**; see page 440 for analytical methods. *Patients receiving a first-time, kidney-only transplant, 2003–2007 combined.* 









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Almost 35 percent of children with ESRD are rehospitalized within 30 days of discharge. As with the adult population (discussed in Chapter Three), this rate has not changed in a decade. » **Figure 8.1**; see page 442 for analytical methods. *ESRD patients age 0–19. Adj: gender/race/primary diagnosis; ref: discharges in 2005.* 

For pediatric hemodialysis and peritoneal dialysis (PD) patients prevalent in 2007–2010, unadjusted rates of hospitalization for infection are highest in those age 0–4, at 1,130 per 1,000 patient years; in all age groups the lowest rates occur in pediatric patients with a transplant. By race, overall rates are highest in blacks/African Americans and lowest in whites, at 560 and 429, respectively. » **Figure 8.2**; see page 442 for analytical methods. *Period prevalent ESRD patients age 0–19*, 2007–2010; unadjusted.

Rates of vaccination against influenza in the pediatric ESRD population have improved, but remain below recommended levels. In 2007-2010, approximately one-third of children age 14 or younger received a vaccination. Rates are highest in those age 15-19, at nearly 40 percent, and vary little by race. In older patients, rates are generally higher in those on hemodialysis compared to those on peritonal dialysis or with a transplant. » Figure 8.7; see page 442 for analytical methods. Point prevalent ESRD patients age 0-19 prior to January 1 of each year, initiating therapy 90 days prior to September 1, & living through December 31 of each year. Vaccinations tracked between September 1 & December 31.

Between 2000-2004 and 2005-2009, one-year adjusted all-cause hospitalization rates per 1,000 patient years increased 29 and 17 percent, respectively, in patients age 0-9 and 15-19; in patients age 10-14, in contrast, rates fell one percent. By modality, rates rose 18-19 percent for dialysis patients and remained stable in those with a transplant; overall, all-cause hospitalization rates increased 16 percent between the two time periods.

The one-year adjusted all-cause mortality rate in children age 0-9 was 89.8 per 1,000 patient years in 2005-2009, nearly six times higher than the rate in patients age 10–14, and slightly more than three times higher than for patients age 15–19. The rate for children on hemodialysis was 58.2, compared to 48.0 and 11.9, respectively, for those on peritoneal dialysis or with a transplant. » Figures 8.10 & 13; see page 442 for analytical methods. *Incident ESRD* patients age 0–19. Adjusted for gender, race, primary diagnosis & Hispanic ethnicity (8.13). Ref: incident ESRD patients age 0–19, 2004-2005.











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In 2010, the incident rate of ESRD per million population was 16.0 for U.S. children compared to 9.2 for children in Canada. In both countries the rate is higher for adolescents age 15-19 compared to younger children; in the U.S., however, the rate for adolescents is 51 percent greater than for their Canadian counterparts, at 27. Rates of prevalent ESRD in 2010 reached 86.0 for U.S. children and 68.3 for those in Canada.

The rate of ESRD due to cystic kidney disease among pediatric patients is ten times greater in the U.S. than in Canada. Rates of ESRD due to glomerulonephritis and secondary glomerulonephritis are 16.9 versus 12.4 and 7.1 versus 3.9 per million population. » Figures 8.17, 22, & 25; see page 442 for analytical methods. Incident & December 31 point prevalent ESRD pts age 0–19; unadjusted.

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The Comprehensive Dialysis Study (CDS), a joint effort between the Nutrition Special Studies Center (ssc) and the Rehabilitation/Quality of Life ssc, enrolled incident dialysis patients from a stratified random sample of U.S. dialysis facilities.

A total of 1,678 participants were enrolled from 296 facilities, of whom 399 participated in the nutrition substudy.

Figure 9.1 shows the distribution of study participants, and Table 9.b shows their sociodemographic characteristics. CDS participants were slightly younger than the overall population of patients who started dialysis in 2005 and had a slightly greater percentage of patients initiating on peritoneal dialysis (10 percent). **» Figure 9.1 & Table 9.b;** see page 443 for analytical methods. CDS participants who started treatment between June 1, 2005, & June 1, 2007.

#### Sociodemographic characteristics of Comprehensive Dialysis Study participants

	All particip mean age at in	oants (n= 1,678) itiation 59.7 ±14.2	Nutrition study mean age at initia	<b>/ subset (n=399)</b> ation 60.9 ±13.8
	N	Percent	N	Percent
<40	143	8.5	27	6.8
40-49	234	13.9	49	12.3
50-59	442	26.3	102	25.6
60-69	415	24.7	105	26.3
70+	444	26.5	116	29.1
Male	923	55.0	206	51.6
White	1,148	68.4	270	67.7
Black/Af Am	480	28.6	109	27.3
Asian	34	2.0	17	4.3
Other	16	1.0	3	0.8
Hispanic	240	14.3	53	13.3
Hemodialysis	1,561	93.0	359	90.0



Both black/African American and white patients with early exposure to information about kidney transplantation are more likely to be wait-listed compared to those not reporting this early exposure. At the same time, white patients are significantly more likely to be wait-listed than blacks/African Americans. The differential early discussion/race effects on wait listing are not explained by other patient characteristics, nor by geographic region of the country. **» Figure 9.8;** see page 443 for analytical methods. *Incident dialysis patients who started treatment June 1, 2005 to June 1, 2007.* 



Seventy-three percent of CDS participants were frail, and even among participants younger than 40 years, the prevalence of frailty was 63 percent. As expected, women were more likely to be frail. There was not a substantial difference in the proportion of frail individuals based on age, a finding that differed from previous cohorts using slightly different definitions of frailty. White patients were slightly but not statistically more likely to be frail than non-white patients. **» Figure 9.10**; see page 443 for analytical methods. *Incident dialysis patients who started treatment June 1*, 2007.

Eighty percent of patients with depression also reported insomnia, restless leg syndrome (RLS) or both; 70 percent of RLS sufferers also reported depression and/or insomnia; and 57 percent of patients with insomnia also reported depression and/or RLS. These results highlight the heavy burden of symptoms among patients with ESRD and the potential for interdependence among symptom complexes. **» Figure 9.15;** see page 443 for analytical methods. *Incident dialysis patients who started treatment June 1, 2005 to June 1, 2007.* 

Frequency of symptom complexes

Restless legs 29.0%

CDS participants

Depressio

27.59

in CDS participants

Insomnia

52.5%



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2012 USRDS ANNUAl DATA REPORT At the end of 2010, 122,216 prevalent patients were being treated by Fresenius in 1,742 units, 110,299 were receiving care in one of DaVita's 1,556 units, and 13,023 patients were being treated by Dialysis Clinic Inc. (DCI), with 213 units. These three major providers manage the majority of the 5,760 dialysis units across the United States. Small dialysis organizations (SDOS), comprising 20–199 units, treated 44,793 patients in 605 units, while independent and hospital-based providers treated 58,090 and 38,596 patients in 848 and 796 units, respectively. **»** Figure 10.1; see page 444 for analytical methods. *CMS Annual Facility Survey*, 2010.

## vol 2<br/>10.1Distribution of patients,<br/>by unit affiliation, 2010

Large dialysis organizations (258,525 patients / 3,	640 uni	its)	SDOs (48,548 / 626)	
			American Renal Assoc. Innovative Dialysis Systems	Hospital-based (37,740 / 780)
			Liberty Dialysis	
			National Renal Institutes	Independent (57,241 / 823)
	/ 215)		Renal Research Institute	
	3,176,		Satellite Healthcare	
	Inc. (1			
	is Clinic,		Renal Advantage	
DaVita . (118,142 / 1,646) .	Dialys	iresenius 127,207 / 1,779)	U.S. Renal Care	



Here we examine care under the new Prospective Payment System for dialysis, or "bundle," which took effect in January, 2011, and show changes between the last two quarters of September, 2010 and the first two quarters of September, 2011. The three largest dialysis providers — Fresenius, DaVita, and DCI — adopted the bundled payment system in virtually all of their units, while 59 percent of the 571 hospital-based units opted into the system.

Figure 10.10 illustrates changes in the use of anemia therapeutics, in hemoglobin levels, and in transfusion events. Between September, 2010 and September, 2011, ESA doses fell 27.1 percent overall, and 37 percent in DaVita and DCI units, compared to 18 percent in units owned by Fresenius. IV iron doses dropped 23 percent overall, and 42 percent in DaVita units; doses declined only 1 percent in hospital-based units. Vitamin D dose declined 12 percent across all providers and 22–24 percent in DaVita and DCI units. **»Table 10.a & Figure 10.10;** see page 444 for analytical methods. Point prevalent dialysis patients 2010 & 2011. 10.a: only facilities opting into the new bundle. 10.10: all facilities; only patients with a dialysis claim during the month are included in graphs showing patients receiving EPO & those with a transfusion event.

# vol 2<br/>10.aDistribution of providers opting into<br/>the new dialysis composite rate

	Number of facilities	Number opting for bundle	Percent of facilities	Percent of patients
All providers	6,167	5,285	85.7	95.3
DaVita	1,609	1,605	99.8	100.0
DCI	209	209	100.0	100.0
Fresenius	1,765	1,757	99.5	99.9
Hospital-based	571	337	59.0	70.1
Independent	767	601	78.4	82.2
SDO	619	574	92.7	92.3



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In 2010, 38 percent of Medicare's ESRD dollars were spent on inpatient services, 34 percent on outpatient care, 21 percent on physician/supplier costs, and 7.2 percent on Part D prescription drugs. Part D costs for ESRD patients reached \$1.92 billion in 2010, 11 percent higher than in the previous year.

Per person per year Medicare ESRD costs rose just 1.4 and 1.7 percent for hemodialysis and peritoneal dialysis in 2010, to \$87,561 and \$66,751, while transplant costs fell 1.1 percent, to \$32,914. **» Figures 11.5 & 11.7**; see page 445 for analytical methods. Total Medicare ESRD costs from claims data; includes all Medicare as primary payor claims as well as amounts paid by Medicare as secondary payor (11.5). Period prevalent ESRD patients; patients with Medicare as secondary payor are excluded (11.7).



Of the \$2.8 billion spent in 2010 on injectables for dialysis patients, ESAS accounted for 67 percent, or \$1.87 billion. The proportions of total costs for IV vitamin D, IV iron, and other injectables were 18.5, 10.9 and 3.8 percent, or \$519 million, \$304 million, and \$106 million, respectively. **» Figure 11.9**; see page 445 for analytical methods. *Period prevalent dialysis patients*.

In 2010, per person per year (PPPY) outpatient dialysis expenditures were 5.1 percent higher in blacks/African Americans than in whites, at \$31,651 and \$30,106, respectively. By modality, costs for hemodialysis were generally 24 to 25 percent higher than those sustained by peritoneal patients in both matched and unmatched poplations. **» Figure 11.19**; see page 445 for analytical methods. *Period prevalent dialysis patients*, 2010.





Per person per year (PPPY) net Part D costs are much higher for LIS and non-LIS ESRD patients than costs incurred by patients in the general Medicare population. Among dialysis and transplant patients with the LIS, for example, net Part D costs in 2010 were \$7,424 and \$6,407, respectively, compared to costs of \$3,985 in the general Medicare population. In patients with no LIS, Part D costs were noticeably lower, at \$2,133 for dialysis, \$1,978 for transplant, and \$1,010 in the general population.

Out-of-pocket Part D costs for patients with LIS status are a fraction of those realized by patients without the LIS, at 1.7–2.8 percent of net costs compared to 65–68 percent. » Figure 11.29; see page 445 for analytical methods. Part D-enrolled general Medicare patients from the 5 percent sample & period prevalent dialysis & transplant patients, 2010. Net pay is estimated as the sum of Medicare covered amount & LIS amount.

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