



Redwood National Park, California

CLINICAL INDICATORS & PREVENTIVE CARE

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Over the past decade, improvements in ESRD care have been addressed by several organizations. Most notable is CMS's assessment of provider performance under the ESRD Clinical Performance Measures (CPM) project, which looks at the implementation of guidelines from the National Kidney Foundation's Dialysis Outcomes Quality Initiative (KDOQI). KDOQI targets for dialysis therapy, vascular access, and clinical indicators are shown on the next page, along with targets based on practice guidelines and safety issues. The CPM project is currently undergoing transition to a full web-based data entry system, including monthly laboratory data from providers. There have been challenges in implementing the system, but by the summer of 2012 most providers should be entering data. Until that time, some elements traditionally reported under the CPM program will not be up to date.

Views of anemia treatment continue to evolve, as safety concerns about targeting hemoglobin levels above 12 g/dl emerge from clinical trials. Reflecting these changes, there has been a dramatic shift since 2006 in patient distribution by mean monthly hemoglobin. By the end of 2010, 10.2 percent of patients in a single month had a hemoglobin less than 10 g/dl, up from levels of just above 6 percent in the middle of the decade. The percentage of patients with a hemoglobin greater than 12 g/dl has fallen from a peak of 50.7 in February, 2007, to 21.1 at the end of 2010. And a range of 10–12 g/dl is now reached by 69 percent of patients, a number last seen in 1998. Based on results from randomized clinical trials, these changes should reduce the risk of adverse cardiovascular events and strokes.

Anemia correction in patients treated with erythropoiesis stimulating agents (ESAs) has also changed. At six months after initiation, mean hemoglobin levels in these patients are now 11.35 g/dl, lower than the 11.99 noted in 2002, but the ESA doses used to achieve these levels are higher than in 2002, particularly in the first three months after initiation. It is not clear why such high doses are being used to achieve a lower hemoglobin level, but these differences imply that the current use of ESAs is now considerably less effective than in the past. Alternatively, providers have been pushing too hard to correct hemoglobin levels, and in 2010 still had incentives to use higher doses. They appear to cut back the dose when hemoglobin levels exceed 11.5 g/dl, using doses similar to those of 2002 by the fourth month of dialysis treatment.

The new bundled prospective payment system for dialysis patients, implemented in January, 2011, will substantially change incentives for ESA use. Recent changes in the FDA label for ESAs may also impact achieved hemoglobin levels. In the most recent change, implemented in June, 2011, the actual target range for hemoglobin level was eliminated, with dosing changes based on hemoglobin levels below 10 g/dl and on the reduction or interruption of ESA therapy when levels exceed 11 g/dl. Unfortunately, little guidance is provided on how long a dose should be held, when to restart dosing, and whether an absolute stoppage reduces not only the risk of higher hemoglobin levels but also that of levels below 10 g/dl.

We are still in transition from the notion of man as master of the earth to the notion of man as a part of it.

WALLACE STEGNER,
"A Capsule History
of Conservation"

Data on iron dosing practices show an increased use of iv iron products, and large doses given in the first six months of dialysis treatment, practices which may also change under the new dialysis payment system.

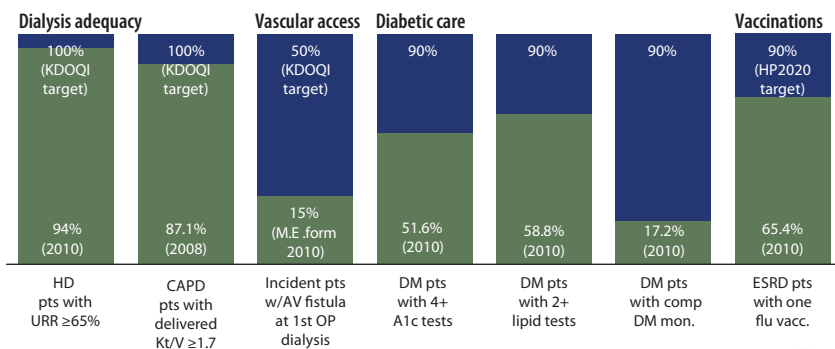
Comprehensive patient care has long been a focus of the ADR. Among diabetic patients, there continues to be slow but steady progress in the use of glyce- mic control monitoring, lipid monitoring, and eye examinations, although only 17.2 percent of prevalent patients received all three types of care in 2009–2010. Influenza vaccination rates have again begun to improve, reaching 65 percent among prevalent patients in 2010 — still, however, below the HP2020 target of 90 percent. And there has been progress in the pneumococcal pneumonia vac- cination rate, which reached 25.8 percent in 2008–2009.

Vascular access has received increased attention since the release of data on high catheter use at initiation and on increasing rates of hospitalization due to infection in the first months of therapy. The CMS Fistula First program has worked to increase the use of arteriovenous (AV) fistulas, with their lower complication rates and associated costs. Just 36 percent of 2010 incident hemodialysis patients, however, had an AV access either in use or maturing at the first outpatient dialysis treatment. In July, 2010, CMS began requiring the reporting of monthly data on vascular access use; as these data become available, the USRDS will examine preva- lent access use and transitions in vascular access during the first months of dialysis.

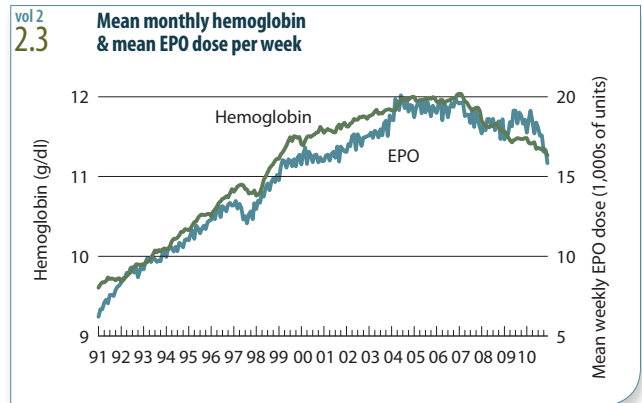
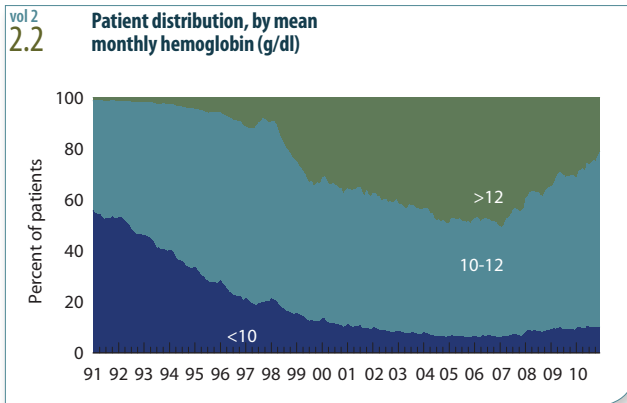
As long recognized, catheters are associated with the highest rates of infectious complications among patients on dialysis, and fistulas the lowest — particularly important when considering, as shown in Chapter Three, that such complications are a major source of morbidity. This year we show that hospitalizations due to vascular access infections are again declining. There has, however, been a steady rise in those for bacteremia/sepsis; because this growth has occurred across modalities, it is possible that shifts in coding practice may be at play. From this perspective it seems that data on overall infections are more useful, as they are less vulnerable to changing classifications and payment incentives for hospitals.

» **Figure 2.1;** see page 431 for analytical methods.

vol 2
2.1 Quality indicators: percentage of patients meeting clinical & preventive care guidelines

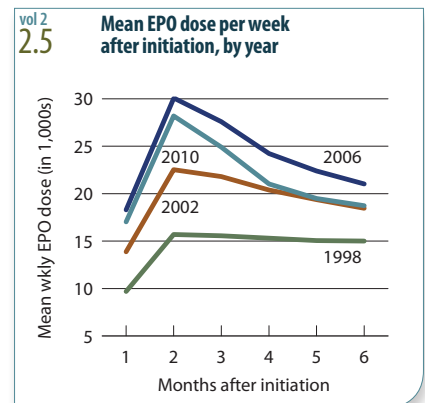
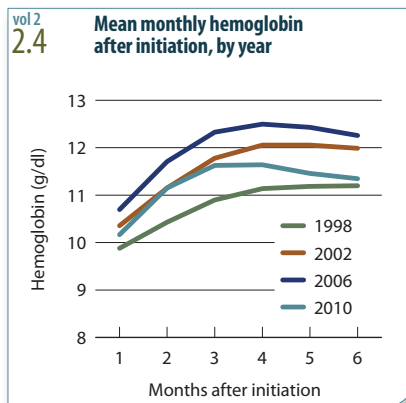


At the end of 2010, slightly more than two-thirds of prevalent dialysis patients had a mean monthly hemoglobin of 10–12 mg/dl. The mean EPO dose per week fell each month within the year, ending at 15,829 in the month of December, while the mean hemoglobin at that time was 11.3 g/dl. » **Figures 2.2–3**;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

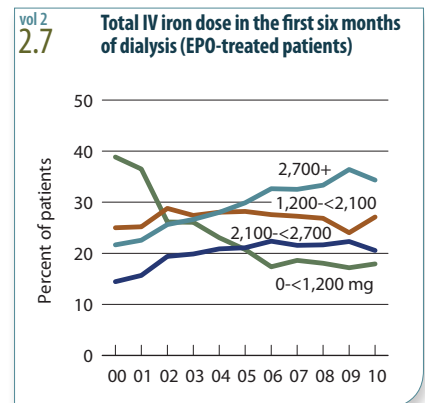
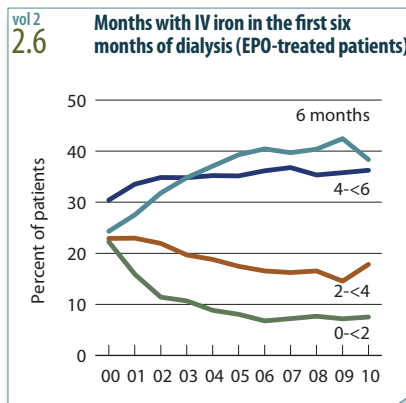


When compared to 2006 incident patients, those starting dialysis in 2010 did so with lower hemoglobins one month post-initiation, at 10.7 and 10.2 g/dl, respectively. At six months, mean hemoglobin levels were within recommended levels, at 11.4 mg/dl.

The mean EPO dose per week at six months after initiation was 18,734 units in 2010, compared to 21,046 in 2006. » **Figures 2.4–5**; see page 431 for analytical methods. *Incident dialysis patients; EPO doses in Figure 2.5 adjusted for inpatient days.*



In 2010, the proportion of incident dialysis patients receiving IV iron in each of the first six months of dialysis fell 4 percentage points, to 38.4 percent. Thirty-four percent of EPO-treated patients received total IV iron doses of 2,700 mg or more, while 18, 27, and 21 percent received total doses of 0–<1,200, 1,200–<2,100, and 2,100–<2,700 mg, respectively. » **Figures 2.6–7**; see page 431 for analytical methods. *Incident dialysis patients.*

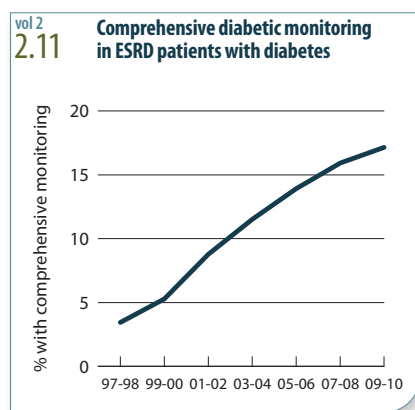
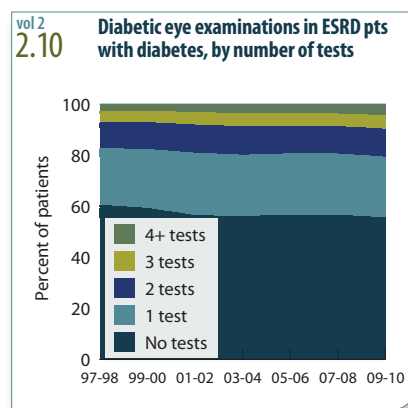
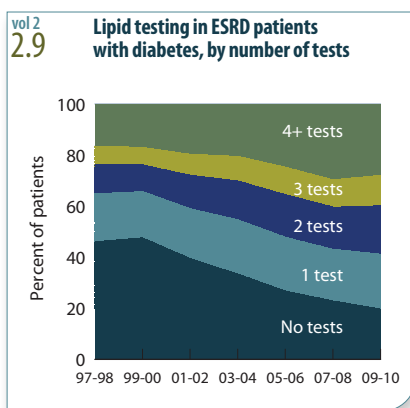
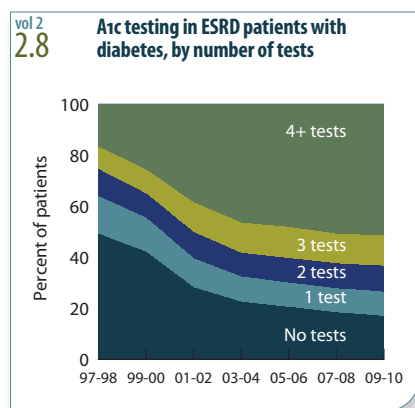


The American Diabetes Association recommends that patients with diabetes receive 2–4 glycosylated hemoglobin (A1c) tests per year, depending on changes in therapy and the attainment of treatment goals. In 2009–2010, 74 percent of diabetic ESRD patients received two or more A1c tests in a year, up from just 36 percent in 1997–1998.

Patients with diabetes are generally predisposed to lipid abnormalities, putting them at risk for cardiovascular disease. Ideally, fasting lipid profiles should be measured at least once per year in normal adults, and more often in those with

high-risk lipid values. In 1997–1998, just 35 percent of ESRD patients with diabetes had at least two annual lipid tests; this improved to 59 percent in 2009–2010.

While many patients with diabetes suffer from problems with vision due to cataracts, glaucoma, or retinopathy, frequent eye examinations continue to be uncommon among ESRD patients with diabetes. In 2009–2010, only one in five received two or more tests in a year. » **Figures 2.8–10**; see page 431 for analytical methods. *Point prevalent Medicare ESRD patients with diabetes, age 18–75.*



Comprehensive diabetic monitoring includes at least four A1c tests, two lipid profile tests, and one eye examination yearly. While the rate of comprehensive monitoring has been increasing over time, in 2009–2010 only 17 percent of prevalent ESRD patients with diabetes received this testing. » **Figure 2.11**; see page 431 for analytical methods. *Point prevalent Medicare ESRD patients with diabetes, age 18–75.*

vol 2 2.a Vaccination rates (percent), by age, race/ethnicity, & modality

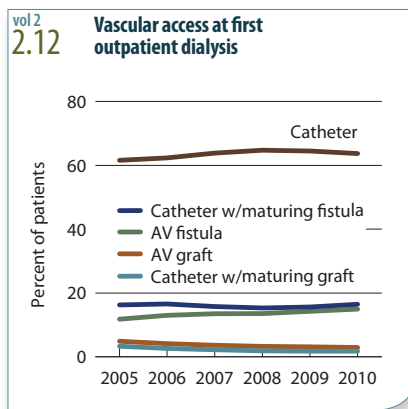
	Influenza			Pneumococcal pneumonia			Hepatitis B (3 per year)		
	2000	2005	2010	1999-00	2004-05	2009-10	2000	2005	2010
0–19	15.3	30.6	38.1	4.6	6.0	12.4	0.9	0.8	1.5
20–44	31.8	46.3	55.9	9.1	15.2	23.3	2.8	3.9	5.1
45–64	41.6	55.3	64.0	11.0	18.7	25.4	3.7	5.1	6.5
65–74	51.3	63.3	68.3	12.7	21.4	26.3	5.0	6.3	8.2
75+	54.3	67.6	73.1	13.5	22.5	27.7	6.0	8.3	10.8
White	48.6	62.0	67.6	11.9	19.7	23.7	4.2	6.0	8.2
Blk/Af Am	40.5	54.7	62.7	10.9	18.8	26.9	3.7	5.3	6.6
N Am	36.3	51.7	69.5	13.3	19.9	28.6	3.7	5.3	8.0
Asian	38.8	57.0	66.7	10.2	16.7	25.0	2.9	3.6	4.1
Hispanic	38.6	53.7	64.6	10.2	19.6	27.8	5.8	6.5	8.2
HD	48.4	62.7	70.1	12.3	21.7	30.1	5.3	7.4	9.7
PD	39.3	55.9	67.2	11.0	18.3	26.1	4.0	4.7	7.1
Transplant	28.9	40.6	48.6	8.2	11.7	12.2	0.3	0.3	0.5
All	44.0	58.0	65.4	11.3	19.2	25.6	4.1	5.7	7.4

Rates of reported influenza vaccinations continue to improve overall, reaching 65.4 percent in 2010, but remain noticeably lower in children than in adults. By modality, rates are highest in dialysis patients.

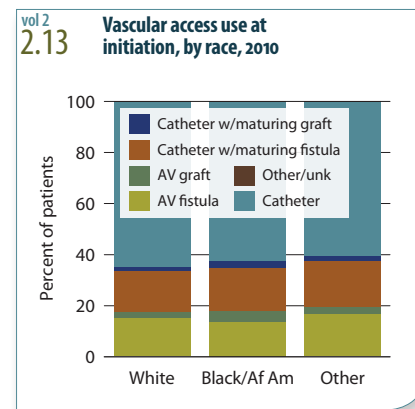
Overall, just over one in four ESRD patients received a vaccination for pneumococcal pneumonia in 2009–2010.

Dialysis patients should begin a series of three hepatitis B vaccinations soon after initiating therapy. The percentage receiving three vaccinations in a year remains low, with an overall rate of just 7.4 in 2010. » **Table 2.a**; see page 431 for analytical methods. *ESRD patients initiating treatment at least 90 days before tracking period: September 1–December 31 for influenza, a two-year period for pneumococcal pneumonia, yearly for hepatitis B; patients alive on the period's last day, & vaccinations tracked during the period.*

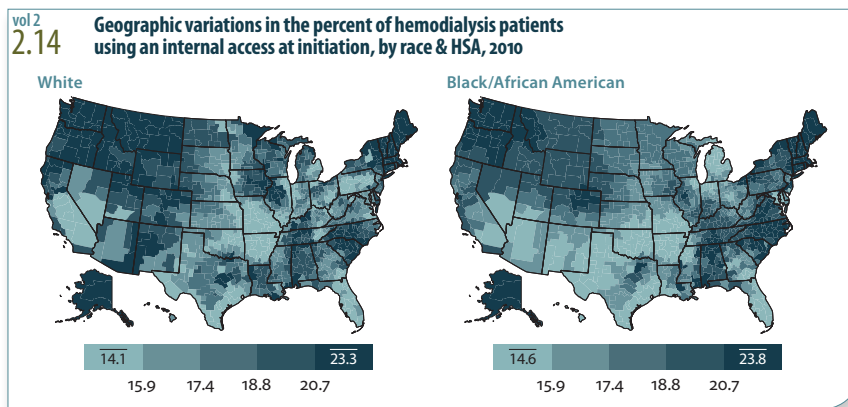
At their first outpatient hemodialysis session, nearly 64 percent of 2010 incident patients used a catheter alone as their vascular access—similar to rates in the previous two years. Eighty-two percent were using either a catheter alone or a catheter with a maturing arteriovenous fistula or graft. Fifteen percent of new patients now begin therapy with a fistula, compared to 12 percent in 2005. » **Figure 2.12**; see page 431 for analytical methods. *Incident hemodialysis patients.*



At the start of ESRD therapy in 2010, 65 percent of white hemodialysis patients were using a catheter alone, compared to 62 percent of blacks/African Americans and 60 percent of patients of other races. Arteriovenous fistula use at initiation varies from 13.7 percent among blacks/African Americans to 16.9 percent among patients of other races. » **Figure 2.13**; see page 431 for analytical methods. *Incident hemodialysis patients, 2010.*



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.*

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2.b

Access use in prevalent hemodialysis patients, by age, gender, & race/ethnicity (ESRD CPM data; percent)

	Catheter			AV fistula			AV graft		
	1999	2004	2007	1999	2004	2007	1999	2004	2007
20-44	10.9	15.0	15.0	35.8	47.2	60.9	52.7	37.8	24.1
45-64	11.7	18.0	17.4	28.8	37.5	53.4	59.1	44.5	29.1
65-74	15.4	19.3	18.8	21.3	33.9	53.5	63.2	46.8	27.7
75+	19.4	24.4	20.9	21.4	34.9	53.3	58.9	40.7	25.8
Male	11.0	14.5	13.3	37.8	49.0	64.2	50.9	36.5	22.5
Female	15.8	22.7	22.9	16.6	27.5	44.3	67.3	49.8	32.8
White	13.8	19.0	17.9	31.2	42.1	60.1	54.6	38.9	21.9
Blk/Af Am	12.9	19.2	18.6	23.2	31.1	46.5	63.6	49.7	34.9
N Am	9.5	10.3	15.1	40.5	55.2	64.3	50.0	34.5	20.6
Asian	8.6	10.7	11.3	31.1	50.4	59.7	59.8	38.9	28.6
Hispanic	12.8	16.4	14.2	29.1	41.1	58.9	57.4	42.5	26.8
All	13.2	18.5	17.7	27.9	38.6	55.0	58.5	42.9	27.2

As reported in the 2011 USRDS Annual Data Report, catheter use among prevalent adult hemodialysis patients remained at 18–19 percent between 2003 and 2007 (the most recent year of available CPM data). Overall, arteriovenous fistula use during this period increased from 38.6 to 55.0 percent, while use of arteriovenous grafts fell from 42.9 to 27.2 percent. » [Table 2.b](#); see page 431 for analytical methods. *Prevalent hemodialysis patients age 20 & older; ESRD CPM data.*

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2.C

Access events & complications in prevalent dialysis patients (ESRD CPM data; rate per patient year)

	Catheter			AV fistula			AV graft			Peritoneal dial. device		
	1998	2003	2007	1998	2003	2007	1998	2003	2007	1998	2003	2007
Events												
Replace with same type of access	0.50	0.85	0.86	0.04	0.03	0.01	0.08	0.05	0.04	0.07	0.04	0.03
Replace with HD catheter				0.17	0.15	0.12	0.29	0.30	0.24	0.50	0.41	0.36
Replace with internal HD device	0.09	0.14	0.16							0.60	0.51	0.44
Revision				0.09	0.05	0.05	0.24	0.17	0.11			
Removal	0.24	0.36	0.22	0.02	0.02	0.01	0.08	0.05	0.04	0.13	0.12	0.11
Complications												
Infection of access	1.24	1.67	1.45	0.24	0.22	0.18	0.44	0.42	0.39	0.46	0.51	0.56
Sepsis	1.65	2.89	2.32	0.43	0.54	0.52	0.67	0.74	0.61	0.49	0.52	0.44
Angioplasty				0.16	0.28	0.47	0.49	0.77	1.10			
Decлот				0.06	0.08	0.12	0.15	0.38	0.48			
Peritonitis (PD patients only)										0.65	0.63	0.61

Among prevalent adult hemodialysis patients in 2007 (the most recent year of available CPM data), the most common access-related event was replacement with a catheter, at 0.86 events per year for patients already using a catheter, and 0.12 and 0.24, respectively, for those with an arteriovenous (AV) fistula or graft. Sepsis is more common than infection, regardless of access type. In 2007, for example, the rate of sepsis among catheter patients was 1.6 times higher than the rate of infection; among AV fistula patients, the rate was three times higher.

In peritoneal dialysis patients, the rate of access replacement with another peritoneal access has decreased by a factor of two since 1998, while rates of replacement with an internal hemodialysis access or hemodialysis catheter have each fallen, but to a lesser degree. Rates of peritonitis have declined slightly since 1998, while rates of access infection have increased from 0.46 to 0.56; since 2003, the rate of sepsis has fallen from 0.52 to 0.44. » [Table 2.c](#); see page 431 for analytical methods. *Catheter, fistula, & graft: prevalent hemodialysis patients age 20 & older; ESRD CPM & claims data. Peritoneal dialysis device: prevalent peritoneal dialysis patients age 20 & older.*

ANEMIA TREATMENT

mean monthly hemoglobin after initiation, 2010 (mg/dl; Figure 2.4)

» month 1 · 10.2 » month 2 · 11.2 » month 3 · 11.6 » month 4 · 11.6 » month 5 · 11.5 » month 6 · 11.4

mean EPO dose per week after initiation, 2010 (units; Figure 2.5)

» month 1 · 17,043 » month 2 · 28,209 » month 3 · 24,905 » month 4 · 21,035 » month 5 · 19,510 » month 6 · 18,734

PREVENTIVE CARE

diabetic patients receiving recommended testing, 2009–2010 (percent with two or more tests in a year; Figures 2.8–10)

» A1c · 74% » lipid testing · 59% » eye examinations · 21%

vaccination rates, by age (Table 2.a)

influenza, 2010	» age 0–19 · 39%	» 20–44 · 56%	» 45–64 · 63%	» 65–74 · 68%	» 75+ · 71%
pneumococcal pneumonia, 2009–2010	· 11%	· 24%	· 26%	· 26%	· 28%
hepatitis B, 2010	· 8%	· 17%	· 20%	· 24%	· 30%

VASCULAR ACCESS

vascular access at first outpatient dialysis, 2010 (Figure 2.12)

» catheter · 64% » catheter with maturing AV fistula · 16.4% » catheter with maturing AV graft · 1.8%

» AV fistula · 15% » AV graft · 2.9%

arteriovenous fistula use at initiation, 2010 (Figure 2.13)

» white · 15.4% » black/African American · 13.7% » other race · 16.9%