chapter FIVE

clinical indicators & preventive health

Noting the sea’s health,
it’s insistence on turbulence,
I kept skimming the beaches;
now seated on waves
I keep the bitter green smell
of a lifetime’s apprenticeship
to live on in the whole of my motion.

Pablo Naruda, “The Same”
translated from the Spanish by Ben Belitt
Over the past decade, improvements in ESRD care have been addressed by several organizations. Most notable is the assessment of provider performance under the ESRD Clinical Performance Measures (CPM) project of the Centers for Medicare and Medicaid Services, 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.

Ninety-three percent of patients receive the recommended amount of hemodialysis, and 87 percent the correct amount of peritoneal dialysis — levels relatively stable over the last several years, and limited by vascular access blood flow issues, dialysis catheter use, the limitations of peritoneal dialysis catheters, and the small number of patients new to dialysis who run only twice a week because they have residual kidney function. Such function, not reported in the dialysis populations, may be an important aspect of care, as it makes volume control and interdialytic weight gain easier to manage.

Vascular access has received increased attention since the release of data on high catheter use at initiation and on increasing rates of infectious hospitalization 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. But the original KDOQI target — that 50 percent of new patients start therapy with a fistula — has not been realized. Just 30.8 percent of 2008 incident hemodialysis patients used an AV fistula on their first outpatient dialysis run, while another 16 percent had a catheter with a maturing fistula. ESRD CPM data do show that 41 percent of new patients have a functioning fistula in the first year of dialysis (see Figure hp.11), and that 55 percent of prevalent patients use the access — a new high. Further increase may be limited by the high failure rate of fistula placement, recently reported by the NIH vascular access network study of preventive care for vascular access thrombosis. Pre-ESRD fistula placement is infrequent, at less than 15 percent, consistent with late referral to a nephrologist and thus with insufficient time for evaluation and for access placement and maturation. The new Medicare CKD education benefit, addressing modality selection and early evaluation and placement of either an internal hemodialysis access or a peritoneal dialysis catheter, is intended to increase fistula use and lower the use of dialysis catheters.
Views of anemia treatment have evolved over the last several years, as safety concerns about targeting higher hemoglobin levels have emerged from clinical trials. The FDA’s recommended target — a range of 10–12 g/dl — is achieved by 68 percent of prevalent patients. In the 2011 ADR the USRDS Coordinating Center will continue to monitor the extent to which patient hemoglobin levels exceed 12 and 13 g/dl, and the duration of time spent at these levels.

Comprehensive patient care has long been a focus of the ADR. Among diabetic patients, there continues to be slow but steady progress in glycemic control monitoring, lipid monitoring, and the use of eye examinations, although only 16 percent of prevalent patients received all three types of care in 2006–2008. Influenza vaccination rates have again begun to improve, reaching 62.4 percent among prevalent patients — still, however, below the target of 90 percent. And there has been progress in the pneumococcal pneumonia vaccination rate, which reached 23 percent in 2007–2008. These vaccinations are limited by the package insert recommendations to once every five years — longer than the average survival of a dialysis patient, limiting the number who can achieve high use of this preventive care. Importantly, the CDC has not reported adverse reactions in those vaccinated more frequently. Several studies have shown that dialysis and transplant patients may not retain their antibodies longer than two years, which may limit vaccination effectiveness. These areas will need more investigation to help guide reasonable targets.

We next examine vascular access placement and complications. As long recognized, catheters have the highest rates of infectious complications, and fistulas the lowest — particularly important when considering, as shown in Chapter One, that infectious complications on dialysis are a major source of morbidity. This year we show in Chapter Six that infectious hospitalizations due to vascular access complications are again declining; there has, however, been a steady rise in those for bacteremia/sepsis. These changes need to be monitored, as the use of cuffed catheters may still expose patients to infectious risks.

We conclude the chapter with two new spreads on the Medicare Part D benefit, looking at enrollment among ESRD, CKD, and general Medicare patients, and reporting on the most frequently used medications. These analyses will be expanded in the 2011 ADR, as the 2008–2009 Part D files become available to the USRDS.

+ Figure 5.1; see page 473 for analytical methods.
In 2007, the KDOQI target hemoglobin was reestablished at 11–12 g/dl; 37–38 percent of prevalent dialysis patients met this goal in 2008. Mean monthly hemoglobin levels seem to reflect attempts to reach the target, as they have fallen from their peak of 12.0 g/dl in early 2007 to 11.6 g/dl at the end of 2008; mean weekly EPO doses have declined in parallel, from close to 20,000 units in late 2006 and early 2007 to 17,000–18,000 in 2008.

Overall, patients who start therapy on hemodialysis do so with slightly lower hemoglobin levels than those who initiate on peritoneal dialysis. In 2007–2008, first-month hemoglobin levels in hemodialysis and peritoneal dialysis patients were 10.57 and 10.7 g/dl, respectively; by month six, however, hemoglobin levels in hemodialysis patients exceeded those found in peritoneal dialysis patients, at 11.88 compared to 11.7 g/dl.

The mean weekly EPO dose is lowest in the first month of therapy, and peaks in month two. For 2008 incident dialysis patients, the mean dose was 17,563 units at initiation, and rose to 28,705 at month two. By month six, it fell to 19,722 units — slightly lower than the 20,665 seen for incident patients in 2004. **Figures 5.2–5.3**; see page 473 for analytical methods. Period prevalent dialysis patients (5.2–3); incident dialysis patients (5.4–5). EPO doses in 5.5 adjusted for inpatient days.
In the first six months of dialysis, 40.4 percent of 2008 EPO-treated incident patients received IV iron each month, while 24.3 percent received iron for three or fewer months. Time on iron therapy during this period does not vary greatly by access type; 41 percent of patients with a catheter or arteriovenous (AV) graft receive six months of therapy, compared to 46 percent of those with an AV fistula.

One in three EPO-treated dialysis patients incident in 2008 received at least 2,700 units of IV iron in the first six months of therapy, while 18 percent were given less than 1,200 units. There are only slight variations in dosing by access type. A total of 2,700 or more units, for example, was received by 33 percent of patients with an AV graft, and 36 percent of those with an AV fistula.

Recent studies (CHOIR and CREATE) in the CKD population have shown that adverse outcomes can occur in EPO-treated patients when hemoglobin levels exceed and remain at 13 g/dl or greater. These results are similar to those of the normal hematocrit trial in dialysis patients. The percentage of incident dialysis patients with a hemoglobin above 13 g/dl in the first six months of therapy has declined over the last three years — for whites, from 68 percent in 2006 to 51 percent in 2008, and for African Americans, from 68 to 54 percent.

Among incident dialysis patients receiving EPO in the first year of therapy, and with an initial hemoglobin of 10 g/dl or greater, the probability of reaching a hemoglobin of 12 g/dl or higher in the first 12 months has remained stable, at 0.98–0.99. The probability of a hemoglobin of 13 g/dl or higher, in contrast, has fallen, from 0.86 for 2005 incident patients to 0.79 for those beginning treatment in 2007.

*Figures 5, 6–9; see page 473 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 1995–1996, only 30.7 and 22.9 percent of white and African American patients were tested for A1c two or more times in a year. By 2007–2008, however, these numbers reached 72.8 and 71.7 percent.

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 annually in normal adults, and more often in those with high-risk lipid values. In 1995–1996, just 16.6 and 17.0 percent, respectively, of white and African American ESRD patients with diabetes had at least two annual lipid tests. By 2007–2008 frequency had improved dramatically, to 59.9 and 54.0 percent.

Many patients with diabetes suffer from problems with vision due to cataracts, glaucoma, or retinopathy. Results in the ESRD population show that frequent eye examinations continue to be uncommon in these at-risk patients. In 2007–2008, for example, only 20.7 percent of white patients, and 17.8 percent of African Americans, received two or more tests in a year.

Comprehensive diabetic monitoring includes at least four A1c tests, two lipid profile tests, and one eye examination yearly. In 2007–2008, comprehensive monitoring was carried out in only 15.9 percent of diabetic ESRD patients overall, and in 17.0 and 14.4 percent, respectively, of whites and African Americans.

* Figures 5.10–13: see page 473 for analytical methods. Point prevalent Medicare ESRD patients with diabetes, age 18–75.
Rates of reported influenza vaccinations continue to improve overall, reaching 62.4 percent in 2008, though they remain noticeably lower in children than in adults. Rates in adults increased to 51.9, 60.4, 66.6, and 70.9 percent, respectively, for those age 20–44, 45–64, 65–74, and 75 and older. In 2008, rates in white, Native American, Asian, and Hispanic patients ranged between 61.0–64.5 percent, while the rate for African Americans was slightly lower, at 58.9 percent. By modality, influenza vaccination rates are highest in hemodialysis patients, at 67 percent, compared to 61.8 and 46.1 percent in peritoneal dialysis and transplant patients. Rates should be interpreted with caution, as patients may be vaccinated through non-Medicare programs.

Overall, just over one in five ESRD patients received a vaccination for pneumococcal pneumonia in 2007–2008. Rates increase with age, ranging from 10 percent in children to 24.6 percent in those age 75 and older. Native Americans are the most likely by race to receive a pneumococcal pneumonia vaccination, at 24.7 percent, compared to 21.1–23.8 percent in Asians, whites, African Americans, and Hispanics.

Dialysis patients should begin a series of three hepatitis B vaccinations soon after initiating therapy. The likelihood of receiving just one vaccination remains low, however, evidenced by an overall rate of just 22 percent in 2008. *Figures 5.14-16; see page 473 for analytical methods.*
Despite ongoing initiatives to reduce catheter use, such as KDOQI and the CMS Fistula First program, the use of catheters has remained at 17–18 percent since 2003. ESRD Continuous Performance Measures (CPM) data for 2007 show that 17.7 percent of prevalent hemodialysis patients used a catheter as their dialysis access. Catheter use continues to be more common in women than in men, at 22.9 versus 13.3 percent. Use by white and African American patients is similar, and fell slightly in 2007 for both populations, to 17.9 and 18.6 percent, respectively.

Overall, arteriovenous fistula use increased from 50.3 to 55.0 percent between 2006 and 2007, a positive sign, and use has increased across all patient groups. Fistula use rates are highest in patients age 20–44, males, and Native Americans, at 60.9, 64.2, and 64.3 percent, respectively.

With the use of catheters remaining constant, and fistula use on the rise, the percentage of patients using arteriovenous grafts continues to fall. In 2007, 27.2 percent of patients dialyzed while using an arteriovenous graft, a 53.5 percent relative decrease from the 1998 level of 58.5 percent. *Figures 5.17–19; see page 473 for analytical methods. Prevalent hemodialysis patients age 20 & older; ESRD CPM data.*
Among 2008 prevalent hemodialysis patients, the most common access-related event was replacement with a catheter, at 0.86 events per year for patients already using a catheter, and 0.13 and 0.24, respectively, for those with an arteriovenous (AV) fistula or AV graft.

Access complication rates tend to vary over time. Among hemodialysis patients, sepsis is more common than infection, regardless of access type. In 2008, for example, sepsis rates among catheter and AV graft patients were 58–60 percent higher than rates of infection; among AV fistula patients, they were three times higher.

In peritoneal dialysis patients, the rate of access replacement with another peritoneal access has fallen 55 percent since 1998, while rates of replacement with an internal hemodialysis access or hemodialysis catheter have each fallen 27 percent. Peritoneal access infections have increased 22 percent since 1998, while sepsis rates have decreased 9.6 percent, to 0.44 per patient year in 2007. And in 2007, sepsis rates for peritoneal dialysis catheters were 14.8 and 27.8 percent lower, respectively, than rates for AV fistulas or grafts. *Figures 5.20–23; see page 473 for analytical methods. Prevalent hemodialysis patients age 20 & older, ESRD CPM & claims data (5.20–22); prevalent peritoneal dialysis patients age 20 & older (5.23).
Compared to 44.4 percent of the general Medicare population, 50.2 percent of CKD patients, 59.6 percent of those with a kidney transplant, and nearly 70 percent of dialysis patients were enrolled in the Medicare Part D prescription drug plan in 2007. *Figure 5.24; see page 474 for analytical methods. January 1, 2007 point prevalent patients age 20 & older (ESRD) & age 66 & older (non-ESRD).

Compared to ESRD patients older than 65, a higher percentage of younger patients enrolled in Part D in 2007, suggesting that a large proportion of them may not have creditable prescription drug coverage from other sources. African Americans and patients of other races had higher rates of enrollment than whites. *Figure 5.25; see page 474 for analytical methods. January 1, 2007 point prevalent patients age 20 & older (ESRD) & age 66 & older (non-ESRD).

The percentage of Part D enrollees using their benefits is higher for ESRD patients than for CKD and general Medicare patients, at 95 compared to 74–75 percent. Benefit use differs little by low income subsidy (LIS) status for ESRD patients, while in the CKD and general populations LIS enrollees were less likely to have a Part D claim in 2007. *Figures 5.26–27; see page 474 for analytical methods. January 1, 2007 point prevalent patients age 20 & older (ESRD) & age 66 & older (non-ESRD).

In 2007, a higher annual cumulative number of Part D drugs was used by dialysis patients compared to those with a transplant, by whites compared to African Americans and patients of other races, and by low income subsidy (LIS) enrollees compared to their non-LIS counterparts. Of note, drugs administered in dialysis units (ESAs, IV vitamin D, or iron) are not included here. *Figure 5.28; see page 474 for analytical methods. January 1, 2007 point prevalent ESRD patients age 20 & older.

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Across age and race groups, approximately 60 percent of dialysis patients enrolled in Part D in 2007 used beta blockers, while angiotensin-converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), or renin inhibitors were used in approximately 50 percent. Fewer than 8 percent used non-dihydropyridine (NDP) calcium channel blockers (CCBs), compared to 40–50 percent using dihydropyridine (DP) CCBs. For both dialysis and transplant patients, beta blocker use predominated over that of ACEIs/ARBs/renin inhibitors.

Except in the oldest patients, use of all agents in the transplant population tends to increase with age. African American transplant patients use more cardiovascular medications than do whites or patients of other races.

Among both dialysis and transplant patients enrolled in Part D in 2007, statins were the predominant lipid-lowering agent. Use was far greater, however, in the transplant population, at 41–62 percent compared to 21–49 percent. This may reflect the fact that transplant patients tend to have higher LDL cholesterol levels, while patients on dialysis tend to have higher triglyceride levels. In addition, recent clinical trials have shown no mortality benefit or reduction in cardiovascular endpoints with statin use in hemodialysis patients. The use of fibrates, a triglyceride-lowering therapy, is, however, also lower in dialysis patients.

Regardless of modality, white patients utilize more lipid-lowering agents than do African Americans.
Among dialysis and transplant patients enrolled in Part D in 2007, there was very little detectable use of oral precursor vitamin D products (e.g. cholecalciferol or ergocalciferol) — not surprising, as vitamins are excluded from the standard Part D benefit, though some enhanced plans may provide coverage. Oral vitamin D hormones (doxercalciferol, paricalcitol, and calcitriol) are, however, covered by Part D, and were received by a small percentage of both dialysis and transplant patients in 2007. The majority of use in the dialysis population is likely attributable to peritoneal and home dialysis patients. Calcitriol use predominates in both dialysis and transplant patients, although overall use of oral vitamin D hormones is low in both populations.

Use of oral vitamin D hormones is higher among African Americans in the transplant population than among patients of other races. *Figures 5.33–5.34; see page 474 for analytical methods.*

In 2007, nearly 80 percent of Part D-enrolled dialysis patients received at least one phosphate binder through their Part D benefit. Sevelamer hydrochloride was predominant, at 42–55 percent, followed by calcium acetate (36–40 percent) and lanthanum (8–17 percent). Fourteen to 24 percent received a combination of these agents. Use of phosphate binders tends to fall with age, and does not vary widely by race, though sevelamer use is higher among African Americans and patients of other races than among whites.

Phosphate repletion agents were used in 2–5 percent of kidney transplant patients enrolled in Part D during 2007. The low apparent use may reflect the exclusion of minerals from the standard Part D benefit. *Figures 5.35–5.36; see page 474 for analytical methods.*
Among 2007 Part D enrollees with diabetes, the percentage using insulin, sulfonylureas, or thiazolidinediones (TZDs) was generally higher for transplant patients than for those on dialysis. Insulin, for example, was used by 58–59 percent of transplant patients age 45–74, compared to 46–49 percent of their counterparts on dialysis. Metformin was used by less than 1 percent of dialysis patients, and by 2–7 percent of those with a transplant.

Compared to that of white patients, use of diabetes agents is generally lower among African American patients on dialysis, and higher among those with a transplant. *Figures 3.37–3.38* see page 474 for analytical methods. *January 1, 2007 point prevalent ESRD patients age 20 & older.*

Twenty-seven to 53 percent of transplant patients enrolled in Part D in 2007 used a diuretic, compared to 12–20 percent of those on dialysis. In both populations, diuretic use increases with age, and loop diuretics are the predominant diuretic class. A small percentage of transplant patients uses potassium-sparing diuretics; diuretic use is virtually undetectable among dialysis patients.

By race, use of diuretics is greatest among whites in the dialysis population, and among African Americans in the transplant population. *Figures 3.39–4.0; see page 474 for analytical methods. January 1, 2007 point prevalent ESRD patients age 20 & older.*
In 2008, 37–38 percent of prevalent dialysis patients had a hemoglobin of 11–12 g/dl, the target set by KDOQI; the mean monthly hemoglobin was 11.6 g/dl. FIGURES 5.2–3

Among incident dialysis patients receiving EPO in the first year of therapy, and with an initial hemoglobin of 10 g/dl or greater, the probability of reaching a hemoglobin of 13 g/dl or higher has fallen from 0.86 for 2005 incident patients to 0.79 for those beginning treatment in 2007. FIGURE 5.9

In 1995–1996, only 30.7 and 22.9 percent of white and African American patients received two more A1c tests in a year; by 2007–2008, these rates had increased to 72.8 and 71.7 percent. FIGURE 5.10

In 2007–2008, comprehensive diabetic monitoring — at least four A1c tests, two lipid profile tests, and one eye examination yearly — was carried out in only 15.9 percent of diabetic ESRD patients. FIGURE 5.13

AV fistula use increased from 50.3 to 55.0 percent between 2006 and 2007. FIGURE 5.18

In 2008, sepsis rates among catheter and AV graft patients were 58–60 percent higher than rates of infection, and in AV fistula patients were three times higher. FIGURES 5.20–22

Fifty percent of CKD patients, 59.6 percent of those with a kidney transplant, and nearly 70 percent of dialysis patients were enrolled in the Medicare Part D prescription drug plan in 2007. FIGURE 5.24