I will shatter the wall
Of darkness that rises
From gleaming day
And seeks to hide the sun.
I will turn this wall of
Darkness (that is night)
Into a thing of beauty.

Mae V Cowdery
“Goal”
With the great complexity of their disease burden, the care of ESRD patients poses many challenges for providers, public health officials, and policy makers. Over the past decade, improvements in ESRD care have been identified by a number of organizations. Most notable among these efforts is the assessment of provider performance under CMS’s ESRD Clinical Performance Measures (CPM) project, which looks at the implementation of NKF’s Kidney Dialysis Outcomes Quality Initiative (K/DOQI) guidelines. K/DOQI targets for dialysis therapy, vascular access, and clinical indicators are shown on the next page, along with other targets based on practice guidelines and on safety issues such as the maintenance of hemoglobin levels within various target ranges.

It appears, for instance, that the target for hemodialysis therapy—a Kt/V greater than or equal to 1.2 (single-pool kinetics), or a urea reduction ratio of 65 percent or greater—is reached in 93 percent of patients. Among CAPD patients, 90 percent reach a delivered weekly Kt/V of 1.7 or above, the target from the revised 2006 guidelines.

Guidelines related to vascular access, recommending increased use of arteriovenous fistulas, have been based on the considerable morbidity and mortality associated with dialysis catheters, and on marked differences in the use of simple fistulas in the U.S. compared to Europe, Japan, and other parts of the world.

Vascular access use in the hemodialysis population continues to be a major area of concern. The number of new patients using a fistula within the first year on dialysis has reached 28 percent—moving, albeit slowly, toward the new K/DOQI target of at least 50 percent. Prevalent use of fistulas also continues to rise, and at almost 39 percent is nearing the initial 40 percent target. As we show later in this chapter, catheter use in the prevalent population continues to be more frequent in women than in men. Catheter complications are very common, with high rates of removals, replacements, and sepsis events. And as we illustrate in Chapter Three, catheter use is also high at the initiation of dialysis, contributing to early mortality and increased complication rates.

An extended section of this chapter focuses on anemia treatment and the overshooting of target hemoglobin levels. Currently, target hemoglobin levels of 11 g/dl and above are achieved by 89 percent of prevalent dialysis patients. There is, however, a growing number of patients with hemoglobins exceeding 13 g/dl—57 percent in 2005—which is an issue of increasing concern. The FDA-required package insert for erythropoiesis stimulating agents (ESAs) lists a target monthly hemoglobin of 10–12 g/dl, while the K/DOQI recommended range is 11–12 g/dl. Just 45.5 percent of prevalent patients meet the first target each month, and 40.7 percent meet the second.

In the incident population, hemoglobin levels after the initiation of therapy are rising more quickly than in the past, and achieved levels within the first six months are higher as well. These changes have been concurrent with a dramatic rise in epoetin dosing between 1993 and 2005.

This year we introduce expanded data on the use of darbepoetin, a longer-acting ESA with a greater half life. Achieved hemoglobin levels in EPO and DPO patients have differed slightly, but
appear to be approaching each other as experience with the new drug increases. As first reported in the 2006 ADR, overshooting of target hemoglobin levels is very common, with 42 percent of patients reaching a level of 14 or more g/dl within six months of achieving 11 g/dl. Patients treated with DPO appear to overshoot slightly less often than those on EPO, a finding which may be related to provider practice, as most DPO use occurs in hospital-based units.

Peritoneal dialysis patient overshoot less frequently than hemodialysis patients, which may reflect less frequent dosing and fewer catheter complications. Additional information on hemoglobin levels and the overshooting of target ranges can be found in the Emerging Issues chapter and in Chapters Eight and Ten.

Rates of vaccination for influenza, pneumococcal pneumonia, and hepatitis B have improved modestly, but still do not meet recommended levels for population coverage to prevent the complications related to these diseases.

Overall, then, we show in this chapter that progress is being made in many areas of clinical care, such as monitoring related to cardiovascular risk factors and diabetes. Data on hemoglobin variability and the overshooting of target levels, however, are of particular concern in terms of patient safety. In Chapter Ten we look further at this issue, showing differences by provider which clearly need to be addressed.

**Figure 5.1** Kt/V & vascular access data: incident & prevalent dialysis patients; from 2005 ESRD CPM report—patient data from 2005; URR: prevalent hemodialysis patients, 2005; from Medicare claims. Hemoglobin: prevalent dialysis patients, 2005; from Medicare claims. Anemia management: Diabetic care: point prevalent patients initiating ESRD 90 days prior to January 1, 2004, age 18–75; on December 31, 2005, & alive through December 31, 2005, with diabetes as the primary cause of ESRD or a comorbidity on the Medical Evidence form, or with diabetes diagnosed during the first year; HbA1c & lipid tests are at least 30 days apart. Comprehensive monitoring includes at least four HbA1c tests per year, at least two lipid tests per year, & at least one diabetic eye examination per year. Influenza vaccinations: ESRD patients initiating therapy at least 90 days before September 1, 2005, & alive on December 31, 2005; vaccinations tracked between the two dates. Pneumococcal pneumonia vaccinations: ESRD patients initiating therapy at least 90 days before January 1, 2004, & alive on December 31, 2005; vaccinations tracked during entire period. Hepatitis B vaccinations: ESRD patients initiating therapy at least 90 days before January 1, 2005, & alive on December 31, 2005. Vaccinations tracked during entire period.
anemia & anemia treatment

CLINICAL INDICATORS & PREVENTIVE HEALTH

5.2 Patient distribution, by mean monthly hemoglobin (g/dl) period prevalent dialysis patients

5.3 Mean monthly hemoglobin & mean EPO dose per week period prevalent dialysis patients

Anemia treatment in incident dialysis patients, by modality & initial hemoglobin level

5.4 Mean monthly hemoglobin incident dialysis patients

5.5 Mean EPO dose per week incident dialysis patients

5.6 Mean monthly IV iron dose during the first six months of dialysis therapy incident dialysis patients
Early K/DOQI guidelines set a target hemoglobin of 11–12 g/dl. In 2006, the target was changed to 11+ g/dl, but then was changed back to 11–12 g/dl in 2007 because of clinical studies which raised safety concerns about higher levels (see additional data in the Precis and Chapters Eight and Ten). Between 1991 and 2005, the mean monthly hemoglobin in prevalent dialysis patients rose 2.4 g/dl, reaching 12 g/dl at the end of 2005 (Figures 5.2–3). Weekly EPO doses rose three-fold, to over 19,000 units.

At month six after initiation, the mean hemoglobin level was 12.2 g/dl in 2005, up from 10.2 in 1993 (Figure 5.4). The mean weekly EPO dose peaks at month two, reaching nearly 29,000 units in 2005 (Figure 5.5). And the percentage of all dialysis patients receiving an average monthly dose of more than 200 mg of IV iron during the first six months rose from 20.2 in 1993 to 78.8 in 2005 (Figure 5.6). By initial hemoglobin, this varies little in the hemodialysis population, but more so in peritoneal patients—91.9 percent receive an average monthly dose of less than 200 mg.

Claims for darbepoetin alfa (DPO) use in hemodialysis patients have grown 250 percent since mid-2004, while EPO claims have remained relatively stable (Figure 5.7). Mean hemoglobins in DPO-treated patients are slightly lower, and DPO use is more common in hospital-based units (Figures 5.8 and 5.10).


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**Figure 5.2–3** Period prevalent dialysis patients with EPO claims; monthly hemoglobin includes all claims with a hematocrit value between 10 & 10; weekly EPO dose includes all claims for patients with an average number of administrations per month of ≥2.0. EPO doses adjusted for inpatient days. Figures 5.4–6 incident dialysis patients with a first EPO claim within the first 30 days of ESRD start date & at least one EPO claim in each of the first six months. Graphs by modality, 2004–2005 combined. Hemoglobin group determined by patient’s hematocrit on the Medical Evidence form. EPO doses in Figure 5.5 adjusted for inpatient days. In Figure 5.6, mean dose for each patient obtained by averaging the total monthly dose on IV iron Medicare claims during the first six months of dialysis. Months with no IV claims assumed to have a dose of zero. Figures 5.7–10 Medicare ESrd patients; includes outpatient EPO & DPO claims from July 1, 2004, to September 30, 2006; multiple claims per month counted as one. Figure 5.11 Medicare ESrd patients with at least four outpatient EPO or DPO claims during the six-month period, restricted to patients treated exclusively with one ESA drug during the period.

**Figure 5.7** Patient claims for EPO & DPO Medicare ESrd patients

**Figure 5.8** Mean hemoglobin, by EPO & DPO use Medicare ESrd patients

**Figure 5.9** Mean monthly dose of EPO & DPO Medicare ESrd patients

**Figure 5.10** EPO & DPO use, by provider Medicare ESrd patients

**Figure 5.11** Standard deviation of hemoglobin, by EPO & DPO use Medicare ESrd patients

**Figure 5.12** Average of inpatient SD of hgb in patients on EPO or DPO Medicare ESrd pts
Higher hemoglobin levels have been a concern since the reporting of adverse outcomes in clinical trials of anemia correction when targeting treatment to levels of 13 g/dl and higher. In this spread we explore the likelihood of dialysis patients overshooting various hemoglobin levels.

In Figure 5.13 we show the probability of EPO-treated dialysis patients reaching higher hemoglobin levels once they have achieved the minimum level of 11 g/dl recommended by the NKF K/DOQI guidelines and by CMS’s ESRD Clinical Performance Measures (CPM) project. Six months after reaching 11 g/dl, for instance, 97 and 42 percent of patients, respectively, achieve a level of at least 12 or 14 g/dl.

After reaching a hemoglobin level of 12 g/dl or higher, 54 percent of prevalent dialysis patients treated with EPO spend at least three months at this level (Figure 5.14). Nearly 61 percent of those who reach a level of 13 g/dl or above remain at 12 g/dl or above for at least three months.

Interestingly, 95–98 percent of incident patients reach a hemoglobin level of 11 g/dl in the first six months of therapy, regardless of the level at which they initiate treatment (Figure 5.15). It also appears that half of incident patients reach a hemoglobin of 12 g/dl by the end of the second month on hemodialysis treatment, and approximately 60 percent reach 13 g/dl by the end of month four; by the end of the first six months on dialysis, nearly 40 percent will reach 14+ g/dl. The likelihood of reaching these levels varies little with the initial hemoglobin level reported on the Medical Evidence form, even when this level is less than 9 g/dl. The probability of overshooting is slightly lower for those being treated with DPO versus EPO, less likely in those treated with subcutaneous EPO, and significantly lower in those treated with peritoneal dialysis (Figures 5.16–18).
### 5.15 Probability of reaching hemoglobin levels of 11 g/dl or greater, by initial hemoglobin level (from the Medical Evidence form) incident dialysis patients, July, 2004, to June, 2005

### 5.16 Probability of reaching hemoglobin levels of 11 g/dl or greater, by EPO & DPO use incident dialysis patients, July, 2004, to June, 2005

### 5.17 Probability of reaching hemoglobin levels of 12 g/dl or greater, by method of ESA administration prevalent hemodialysis patients age 20 & older, 2004; ESRD CPM data

### 5.18 Probability of achieving hemoglobin levels of 12 g/dl or greater, by modality point prevalent dialysis patients

More on anemia & anemia treatment: p.16–17, el.3–8, 3.7–16, 5.2–12 (previous page), 8.22–28 (pediatric patients), 10.27–31 (by provider).
 Comprehensive diabetic monitoring
point prevalent ESRD patients

Geo. var. in the % of pts receiving comp.
diabetic monitoring, by HSA, 2005

Overall trends in comprehensive
diabetic monitoring

Comprehensive diabetic monitoring,
by modality

Comprehensive diabetic monitoring,
by age, race/eth., & modality, 2005

The American Diabetes Association recommends that patients with diabetes receive 2–4 glycosylated hemoglobin (HbA1c) tests each year. Progress toward this goal in ESRD patients has been encouraging, with rates for patients receiving four or more tests nearly doubling in this decade to 47 percent, and reaching 61.8 percent for patients residing in areas represented by the upper map quintile (Figures 5.19–20). It is noteworthy, however, that during 2004–2005 more than one-fifth of patients still received no testing at all.

Hemodialysis patients are the most likely to receive an HbA1c test four or more times per year, at 56.5 percent, followed by peritoneal dialysis patients, at 48 percent (Figure 5.21). Fewer than 20 percent of transplant patients, in contrast, receive frequent testing.

In the dialysis population, HbA1c testing is more evident in older patients, at 50.8, 55.4, 59.2, and 60.0 percent, respectively, for ages 41–50, 51–60, 61–70, and 71–75 (Figure 5.22). By race and ethnicity there is less variation—from a low of 54.2 percent in African Americans to a high of 59.6 percent in the Hispanic population. Native American transplant patients are the least likely to receive four or more tests, at 13 percent.

Lipid testing guidelines stipulate that at-risk patients receive two or more tests per year. Nearly half of the diabetic ESRD population met this criterion during 2004–2005—nearly a third, however, received no testing at all (Figures 5.23–24). Rates vary across the country, and average 66.9 and 29.1 percent, respectively, for patients residing in areas represented by the upper and lower quintiles.

In contrast to HbA1c testing, the proportion of diabetic transplant patients receiving two or more lipid tests is much higher than that of dialysis patients—at 66.3 percent versus 43.2 and 31.3 percent, respectively, in hemodialysis and peritoneal dialysis patients (Figure 5.25).

The proportion of diabetic dialysis patients who receive two or more lipid tests a year varies little among age groups (Figure 5.26). More variability exists among racial and ethnic categories, with 34.5 percent of Native Americans being tested compared to 49.1, 47.6, 46.3, and 41.0 percent, respectively, of Asians, Hispanics, whites, and African Americans.

Diabetes increases the likelihood of vision problems such as cataracts and glaucoma, but most threatening is diabetic retinopathy. In the 2004–2005 period, less than half of the diabetic ESRD population received at least one eye exam in a year; patients residing in the north-central tier of states and Northern New England were more likely to be tested, averaging 54.7 percent in the upper quintile (Figures 5.27–28). The proportion of patients tested is similar across modalities, at 43–48 percent, and rises with age. By race and ethnicity, Hispanics and whites are the most likely to be examined, at 46.7 and 45.7 percent, respectively (Figures 5.29–30).

The proportion of patients receiving "comprehensive" diabetic testing (see caption), while increasing, remains disturbingly low, in 2004–2005 reaching only 12.4 percent. Rates of monitoring average 19.1 and 52.2 percent, respectively, for patients residing in areas represented by the upper and lower map quintiles (Figures 5.31–32).

Comprehensive testing is more common among dialysis patients than among those with a functioning graft, at 13–14 percent compared to 9.5 (Figure 5.33). Rates of testing increase by age and, in the dialysis population, are highest in Hispanics and whites, at 16.2 and 15 percent, respectively (Figure 5.34).
Lipid testing rates show that 44 percent of prevalent ESRD patients received two or more tests in 2005, but more than a third were not tested at all. Geographically, rates average 66.6 and 23.0 percent, respectively, for patients residing in areas represented by the upper and lower map quintiles (Figures 5.35–36).

Transplant patients are more likely than dialysis patients to receive at least one lipid test, at 82.7 versus 60–64 percent (Figure 5.37). By age, the proportion of patients tested increases through age 70, with rates in older transplant patients nearly double those found in their dialysis counterparts (Figure 5.38). By race and ethnicity, Native American and African American dialysis patients are least likely to receive recommended testing, at 33.3 and 35.2 percent, respectively, compared to 43.4 percent of Hispanics, 41.2 percent of Asians, and 40.9 percent of whites. Testing in the transplant population averages nearly 65 percent across all racial and ethnic categories with the exception of Native Americans, of whom only 40 percent receive two or more tests.

Rates of vaccination for influenza rose from 41.9 to 57.8 percent between 1996 and 2005, and rates have remained highest for patients age 75 and older—at 68.1 percent in 2005 (Figure 5.39). By race and ethnicity, 60.3 percent of whites were vaccinated in 2005, compared to 54.4, 51.7, 56.3, and 53.4 percent, respectively, of African Americans, Native Americans, Asians, and Hispanics. Vaccination rates continue to be greatest in hemodialysis patients, at 62.7 percent compared to 55.4 and 40.4 percent in peritoneal dialysis and transplant patients, respectively.

Rates average 69.4 percent for patients residing in the central and northwestern portions of the country, as represented by the upper map quintile (Figure 5.40). The proportion of patients receiving a pneumococcal pneumonia vaccination during a two-year period increased from 10.0 to 19.2 percent between 1996 and 2005, and, with as influenza vaccinations, is highest in older patients (Figure 5.41). Rates vary least by race and ethnicity, and more widely by modality, with vaccinations most common in hemodialysis patients—at 21.9 percent compared to 18.5 and 17.7 percent in the peritoneal dialysis and transplant populations, respectively. Across the country, rates vary widely, averaging 36.4 percent for patients residing in areas represented by the upper map quintile (Figure 5.42).

Between 2004 and 2005, hepatitis B vaccination rates fell slightly from 21.7 to 20.7 percent, with similar decreases of 0.76–1.7 percentage points occurring across all age, race, and ethnicity categories, and across dialysis modalities. Rates average 27.8 for some Gulf Coast residents and for those residing in scattered areas along the East and West Coasts (Figures 5.43–44). Vaccination rates tend to be highest in older patients, at 22.9 and 28.5 percent, respectively, in those age 65–74 and 75 and older. By race and ethnicity, whites and Hispanics are the most likely to receive the vaccine, at 21.4 and 22.7 percent, and Asians the least likely, at 13.7 percent. Fewer than 2 percent of transplant patients received the vaccine in 2005.
5.39 Influenza vaccination rates, by age, race/ethnicity, & modality point prevalent ESRD patients

5.40 Influenza vaccination rates (%), by HSA, 2005 point prevalent ESRD patients

5.41 Pneumococcal pneumonia vaccination rates, by age, race/ethnicity, & modality point prevalent ESRD patients

5.42 Pneumonia vaccination rates (%), by HSA, 2004–2005 point prev. ESRD patients

5.43 Hepatitis B vaccination rates, by age, race/ethnicity, & modality point prevalent ESRD patients

5.44 Hepatitis B vaccination rates (%), by HSA, 2005 point prevalent ESRD patients

More on preventive care: 8.29–31 (pediatric patients), 10.44–49 (by provider).
Percentage of patients with a catheter, by age, gender, race/ethnicity, & geographic location prevalent hemodialysis patients age 20 & older; ESRD CPM data

Percentage of patients with an arteriovenous fistula, by age, gender, race/ethnicity, & geographic location prevalent hemodialysis patients age 20 & older; ESRD CPM data

Percentage of patients with an arteriovenous graft, by age, gender, race/ethnicity, & geographic location prevalent hemodialysis patients age 20 & older; ESRD CPM data
Catheter use in patients younger than 65 has grown dramatically, rising 50 percent between 1998 and 2004 (Figure 5.45). Women tend to be placed on catheters more often than men, and their use of the access has increased more as well—46 compared to 27 percent. Asians were the least likely to have a catheter in 2004, at 13.3 percent, compared to 18.7, 18.5, 16.7, and 15.3, respectively, in whites, African Americans, Native Americans, and Hispanics. It is noteworthy, however, that catheter use has grown 75.8 and 53.9 percent in Native Americans and Asians since 1998. Use does not seem influenced by location, with catheters used in 17.9 percent of patients residing in an urban location and 19.4 percent of those living in rural areas.

Fifty-one percent of younger prevalent hemodialysis patients had an arteriovenous fistula as their primary access in 2004—approximately 10 percent more than among those age 45–64, 65–74, and 75 and older (Figure 5.46). The rate of increase in fistula use in patients 65 and older is double that found in younger patients. In 2004, 52 percent of males had fistulas compared to 31.7 percent of females, although the rate of increase in use since 1998 is much higher in women, at 90.5 versus 37.6 percent. By race/ethnicity, African Americans were the least likely to have a fistula in 2004, while Native Americans and whites were the most likely, at 47.5 and 45.3 percent, respectively. African Americans, however, demonstrate the highest percent increase since 1998, at 62.9 percent.

Not surprisingly, with catheter and fistula use on the rise, use of grafts is declining, since 1998 falling 31–38 percent across all age groups, 34 and 33 percent in men and women, 29–35 percent across racial and ethnic groups, and 33–34 percent in urban and rural locations (Figure 5.47).

Among prevalent hemodialysis patients, the most common access-related event is replacement of the access with a catheter, at 0.62 events per patient year in 2004 for those already using a catheter, 0.12 for those with a fistula, and 0.25 for those with a graft (Figures 5.48–50). While access complication rates for hemodialysis patients have varied over time, rates of sepsis events are generally rising, reaching 2.0, 0.6, and 0.7 in patients with catheters, fistulas, and grafts, respectively.

Patients with arteriovenous accesses have experienced higher rates of angioplasties in recent years. Among those with fistulas, rates have more than doubled since 1998, to 0.35 per patient year; rates in patients with grafts have increased 71 percent, to 0.8 per patient year. Rates for infection, on the other hand, have decreased, falling 15.3 and 21.6 percent, respectively.

Rates of most peritoneal dialysis catheter events have fallen slightly since 1998, but rates of peritonitis have not changed, remaining at 2.2 per patient year in 2004 (Figure 5.51). Sepsis rates are 0.51, compared to rates of 1.96, 0.60, and 0.66, respectively in patients using catheters, AV fistulas, and AV grafts, respectively.
Between 1991 and 2005 the mean monthly hemoglobin in prevalent dialysis patients grew 2.4 g/dl, reaching 12 g/dl at the end of 2005. In the same period, weekly EPO doses rose three-fold, to over 19,000 units. Claims for darbepoetin alfa use in hemodialysis patients have grown 250 percent since mid-2004, while EPO claims have remained relatively stable (DPO was introduced in 2001).

Mean hemoglobin levels in patients treated with DPO are slightly lower, and use of the drug is more common in hospital-based units.

After reaching a hemoglobin level of 12 g/dl or higher, 54 percent of prevalent dialysis patients treated with EPO spend at least three months at this level. Half of incident patients reach a hemoglobin of 12 g/dl by the end of the second month on hemodialysis treatment, and approximately 60 percent reach 13 g/dl by the end of month four; by the end of the first six months on dialysis, nearly 40 percent will reach 14+ g/dl.

Hemodialysis patients with diabetes are the most likely to receive an HbA1c test four or more times per year, at 56.5 percent, followed by peritoneal dialysis patients, at 48 percent. Fewer than 20 percent of transplant patients, in contrast, receive frequent testing.

Nearly half of diabetic ESRD patients receive two or more lipid tests in a year; nearly a third, however, receive no testing at all. The proportion of patients receiving comprehensive diabetic testing, while increasing, remains disturbingly low, in 2004–2005 reaching only 12.4 percent.

Rates of vaccination for influenza rose from 41.9 to 57.8 percent between 1996 and 2005, and have remained highest for patients age 75 and older—at 68.1 percent in 2005. Rates continue to be greatest in hemodialysis patients, at 62.7 percent compared to 55.8 and 40.4 percent in peritoneal dialysis and transplant patients, respectively. By race and ethnicity, whites and Hispanics are the most likely to receive a hepatitis B vaccination, at 21.4 and 22.7 percent, and Asians the least likely, at 13.7 percent. Fewer than 2 percent of transplant patients received the vaccine in 2005.

Catheter use in patients younger than 65 has grown dramatically, rising 50 percent between 1998 and 2004. Women tend to be placed on catheters more often than men, and their use of the access has increased more as well—46 compared to 27 percent.

The rate of increase in fistula use in patients 65 and older is double that found in younger patients. Among prevalent hemodialysis patients, the most common access-related event is replacement of the access with a catheter.

National means & patient populations for maps can be found in the Excel file for this chapter—on our website at www.usrds.org, & also on the CD-ROM included at the back of this book.