Chapter Two

Patient characteristics

...things don't fall apart. Things hold. Lines connect in ways that last and last and lives become generations made out of pictures and words just kept.

Lucille Clifton, Generations: A Memoir
Within Chapter One we provide detailed information on the incidence and prevalence of ESRD patients, in some cases making comparisons to the general population. Such basic epidemiological parameters can be supplemented by detailed information on the disease burden of the incident population, and on biochemical measures that can illustrate adverse conditions at the beginning of ESRD therapy.

In this chapter we focus, then, on data provided on the Medical Evidence form. As mentioned in the previous chapter, prior to its revision in 1995 this form collected only limited demographic information, and its submission was required only for Medicare patients. The revised form, however, contains questions on comorbidity, height and weight, and biochemical parameters (including hematocrit, blood urea nitrogen, serum creatinine, and serum albumin). With this new information, and with the requirement that the form be submitted for all patients regardless of their Medicare status, it is now possible to create a comprehensive picture of the population entering ESRD treatment.

We provide information here, for instance, on the changing complexity of the patient population at the beginning of ESRD therapy. In addition to data from the Medical Evidence form, we use information from inpatient hospitalization records to show how the number of incident patients with cardiovascular comorbidity has increased dramatically since 1984. We also look at shifts in the diabetic status of incoming and established patients, and at changes in albumin levels at the initiation of therapy.

To illustrate anemia treatment in the period prior to ESRD treatment, we next look at trends in pre-ESRD EPO therapy and in mean hemoglobin levels at initiation. While both EPO doses and hemoglobin levels have been increasing for patients of all age, racial, and ethnic groups, there are still dramatic variations across those groups, and across the country as well.

As shown by Medical Evidence form data on biochemical and anthropometric measures, patients are now beginning ESRD therapy with lower BUN and serum creatinine levels, and with higher estimated glomerular filtration rates. Body mass indices have been rising as well, as they have in the general population. These changes may reflect earlier initiation on ESRD therapy due to increasing comorbidity.

We next look further at estimated GFR levels at initiation, exploring their relation to disease severity and to hospitalization and survival rates. Further information on these rates is presented in Chapters Six and Nine.

To show how insurance coverage can influence patient care, we have presented payor-specific data on pre-ESRD EPO use, and on hemoglobin levels and cardiovascular comorbidity at initiation. We have also supplied additional information on the distribution of new ESRD patients by initial insurance coverage, both overall and by HSA. The significant variations in coverage across the country may influence outcome studies conducted in different areas, and should be investigated further.

While diabetes is the leading cause of ESRD for patients of all ethnicities, some ethnic groups carry a disproportionate burden of the disease (Figure 2.1). ESRD is caused by diabetes in 43 percent of non-Hispanics, but in 65 percent of Hispanic-Mexican patients and 55 percent of Hispanic patients of other origins. With hypertension, in contrast, the pattern is reversed, as the disease causes ESRD in a larger proportion of non-Hispanic patients.

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The proportion of new ESRD patients with a primary diagnosis of diabetes is highest in the southwestern states, the northern plains, and the Ohio Valley (Figure 2.2). Data in this map are not adjusted for Hispanic ethnicity, clearly an important factor since the prevalence of diabetes in Hispanics of Mexican origin is almost 50 percent higher than in non-Hispanics. But despite this limitation, the map’s portrayal of disparate disease burdens (with rates of diabetes that vary 28 percent between the lowest and highest quintiles) illustrates how ESRD resources might be challenged within certain areas of the country.

The presence of cardiovascular comorbidity—a major complication of diabetes and hypertension—in incident ESRD patients can be assessed in part from comorbidity information on the Medical Evidence form. In Figure 2.3 we present the geographic distribution of incident ESRD patients who have cardiovascular comorbidity, including congestive heart failure, ischemic heart disease, myocardial infarction, cardiac arrest, cardiac dysrhythmia, and pericarditis. Striking in the maps of both diabetic and non-diabetic populations is the pattern of low rates in the West and Southwest, in contrast to high rates in the Northeast and the Great Lakes region. The reasons for such differences have not yet been explored.

There are limitations to the use of comorbidity information from the Medical Evidence form. The USRDS and others have shown, for instance, that data reported on the form may under-represent the true breadth of comorbidity in the incident population. We have thus also included data from other sources in order to provide insight into the advancing disease complexity of the incident population.
Because comorbid conditions were not included on the Medical Evidence form until the form’s revision in 1995, it is difficult to assess long-term trends in the comorbidity of incident ESRD patients. We are able, however, to use REBUS inpatient hospitalization records to track cardiovascular comorbidity since 1984.

Cardiovascular disease rates in ESRD patients have remained relatively steady since 1990 (Figure 2.4). In patients who survive at least one year after the start of ESRD, more than 38 percent of diabetics, and 30 percent of non-diabetics, now have some form of cardiovascular disease.

Since comorbidity is documented on inpatient hospitalization records, and more ESRD care is now being performed in the outpatient setting, Medical Evidence form data may not fully describe the extent of cardiovascular disease within the entire ESRD population. We therefore looked as well at cardiovascular disease in patients age 67 and older, since their Medicare eligibility means that treatment data is available for the two years prior to ESRD. In these patients, more than 93 percent of diabetics, and almost 90 percent of non-diabetics, carried a diagnosis of cardiovascular disease in 1999.

In terms of overall comorbidity, the proportion of patients beginning ESRD treatment with three or more comorbid conditions has increased since 1995, while the percent with no reported comorbidity has fallen over the same period (Figure 2.6).

While rates of diabetes as the cause of ESRD are frequently reported, the total burden of diabetes has rarely been assessed. The proportion of new patients with diabetes as their primary diagnosis grew to 44.8 percent by 1999 (Figure 2.7). The total burden of diabetes in patients surviving one year, however, rose from 54.7 percent in 1995 to 60.3 percent in 1999. In Native American and Hispanic patients surviving the study period the numbers are especially dramatic, with 82 percent and 74.4 percent, respectively, carrying a diagnosis of diabetes.

Though the numbers have not increased dramatically, more patients are beginning ESRD therapy with albumin levels below the test’s lower limit (Figure 2.8). Levels are lowest in Native American patients.

*Figures 2.4–8* incident ESRD patients. *Figure 2.9* incident ESRD patients, by HSA, unadjusted.

The lower limit of albumin measured by bromcresol purple is 3.2 gm/dl, & by bromcresol green is 3.5 gm/dl. The Medical Evidence form indicates the lower limit (± the test used) along with the patient’s albumin level; data here reflects all patients whose levels fall below the reported limit.
2.7 - Trends in the occurrence of diabetes, by race/ethnicity

Serum albumin at initiation

2.8 - Percent of patients at initiation with serum albumin less than test’s lower limit, by age, gender, race, & primary diagnosis

2.9 - Geographic variations in the percent of patients at initiation with albumin levels below the test’s lower limit

Percent change 1995–2000
The National Kidney Foundation has set a target hemoglobin for dialysis patients of 11 g/dl. Recent studies have suggested that comparable targets be set for individuals with chronic kidney disease. Because anemia management in the pre-ESRD period is a strong indicator of the clinical care received by patients with progressive renal insufficiency, we look here at hemoglobin levels and EPO use during this period.

While the percent of patients receiving EPO prior to ESRD treatment has increased since 1996 for patients of all age, gender, racial, and ethnic groups, rates of EPO use are still low (Figures 2.10–11). At the current rate of increase, it will be more than five years before half of the patients beginning ESRD therapy receive EPO prior to treatment.

Pediatric patients are more likely to receive pre-ESRD EPO than adults, while blacks and Hispanics appear to be undertreated compared to other patients.

Since early 1995 the overall mean hemoglobin level at initiation has increased from 9.3 to 10.0 g/dl (Figure 2.12). Patients treated with EPO prior to ESRD therapy have hemoglobin levels approximately 1/2 g/dl higher than those of untreated patients.

The percent of new ESRD patients who receive pre-ESRD EPO varies widely across the country (Figure 2.13).

The sand diagram in Figure 2.14 illustrates a gradual achievement of higher mean hemoglobin levels in the incident ESRD population. Between May 1995 and June 2001, the percent of patients with hemoglobin levels ≥11 g/dl grew from 15.9 to 25.6, a 61 percent increase.

Pediatric patients have the lowest initial hemoglobin levels of all patients (Figure 2.15), despite the fact that they are most likely to receive EPO prior to ESRD treatment. Girls, in particular, have low hemoglobin levels at initiation. Levels are

### EPO & hemoglobin at initiation

#### 2.10 - Trends in EPO use prior to initiation, by age & gender

#### 2.11 - Trends in EPO use prior to initiation, by race/ethnicity & gender

#### 2.12 - Trends in mean hemoglobin at initiation, by EPO treatment

#### 2.13 - Geographic variations in the percent of patients receiving EPO prior to initiation, by race
2.14 - Trends in patient distribution, by mean monthly hemoglobin at initiation

2.15 - Trends in mean hemoglobin at initiation, by age & gender

2.16 - Trends in mean hemoglobin at initiation, by race/ethnicity & gender

2.17 - Trends in mean hemoglobin at initiation, by modality

Mean hemoglobin at initiation

2.18 - Geographic variations in mean hemoglobin

Highest in older patients, particularly those age 65 or older.

Among the racial groups, blacks continue to have consistently lower hemoglobin levels at initiation, perhaps due in part to less use of pre-ESRD EPO (Figure 2.16).

Initial hemoglobin levels have increased since 1995 for patients of all modalities, and are highest in patients who begin ESRD therapy with a renal transplant (Figure 2.17). Patients who begin with hemodialysis, in contrast, consistently have the lowest initial levels.

Hemoglobin levels at the initiation of therapy show a more defined geographic pattern than that seen with pre-ESRD EPO (Figure 2.18). Higher levels occur primarily in the northern and western states.

The level of renal function at the initiation of dialysis has been suggested as a potential marker for early versus late referral to dialysis. Markers of renal function such as blood urea nitrogen or serum creatinine are, however, influenced by both nutritional and clinical factors. A high BUN at the start of dialysis may indicate a late referral. But it may also reflect a high protein intake or a high catabolic rate caused by gastrointestinal bleeding, or, in patients with congestive heart failure, pre-renal azotemia. Trends in lower serum creatinine at initiation may reflect advancing comorbidity related to poor nutritional status or to heart failure. It is important to note that serum creatinine is also less reliable as a renal function test because of non-renal excretion in the latter stages of chronic renal disease.

Overall, BUN and serum creatinine levels decreased quite dramatically from 1996 to 2000 across most patient groups (Figures 2.19–22). It is not clear whether these changes show that patients are beginning dialysis at earlier stages of chronic renal disease, or if they are a result of worsening nutritional status or increased comorbidity. A less dramatic rise in estimated glomerular filtration rate during the same period is also evident (Figure 2.24), and may indicate earlier initiation of dialysis. Further studies will be required to differentiate these factors.

Body mass index is highest in patients residing in the Upper Midwest, the Ohio Valley, and portions of the East Coast (Figure 2.25). Increased weight could reflect better nutrition or an emerging pattern of obesity predisposing patients to diabetes. Programs should be instituted to determine the reasons for these patterns of weight gain.

Data showing increases in body mass index from 1996 to 2000 (Figure 2.26) suggest that reductions in BUN and creatinine could be related to factors other than nutritional status, such as early referral, early initiation, or clinical conditions involving advanced comorbidity.

Figures 2.27–28 show the distribution of body mass indices in patients with cardiovascular disease and strokes and in diabetic patients. Children and Asians tend to have the lowest BMI levels in both groups, while levels are highest in Native American patients.

Figures 2.19, 2.21, 2.23, & 2.25 incident ESRD patients, by HSA, unadjusted. Figures 2.20, 2.22, 2.24, & 2.26 incident ESRD patients.

Figures 2.23–24 eGFR calculation for ages 0–18 from Schwartz et al., & for ages 19 & above from Levey et al.
2.23 · Geographic variations in mean eGFR at initiation

2.24 · Trends in mean eGFR at initiation, by age & race/ethnicity

2.25 · Geographic variations in mean BMI at initiation

2.26 · Trends in mean BMI at initiation, by age & race/ethnicity

2.27 · Patients with cardiovascular disease & stroke

2.28 · Patients with diabetes
Previous sections of this chapter have illustrated recent changes in biochemical markers at the initiation of dialysis. It is unclear, however, whether lower BUN and creatinine levels and higher eGFRs show that patients are beginning dialysis earlier because of increased comorbidity or because they have better pre-ESRD care. To investigate this question we look here at eGFR levels at the initiation of therapy and at subsequent patient outcomes.

Estimated GFR levels increase with age in both males and females, and in diabetics and non-diabetics (Figure 2.29). Diabetics appear to have higher eGFRs at initiation than non-diabetics. Since comorbidity also increases with age, these associations fit the hypothesis that eGFR is a surrogate for increased comorbidity. Lower eGFRs in non-diabetic Asian patients are consistent with the lower comorbidity and better survival in this population. In Native American patients, lower eGFRs may represent poor nutritional status, not easily separated from comorbidity issues.

Because disease severity can be assessed by evaluating a patient’s disease burden prior to ESRD, we analyzed a cohort of patients age 67 or older, assessing the number of hospital days in the two-year pre-ESRD period. Estimated GFR levels at the initiation of dialysis increase with more pre-ESRD hospital days (Figure 2.30), and the association between advancing age and pre-ESRD hospital days is clear as well.

Figure 2.31 presents even stronger evidence that comorbidity at initiation is related to eGFR. We calculated Charlson scores (a measure of comorbidity) for patients age 67 or older who had two years of medical services prior to the start of ESRD. In both males and females, and with increasing age, there is an almost linear relationship between higher Charlson scores and higher eGFR levels.

Together, these figures provide strong evidence that lower BUN and creatinine levels at the initiation of dialysis therapy, along with higher eGFR levels, are related not to improved care, but rather to increased comorbidity in the patient population.

To test the competing hypotheses that earlier initiation of dialysis leads to improved survival and that higher eGFRs are a surrogate for increased comorbidity and mortality, we developed probability models for the risk of hospitalization and death. We obtained Medical Evidence form data on age, gender, race, primary diagnosis, ethnicity, body mass index, and eGFR, and looked at outcomes in a one-year followup period.

Probabilities of hospitalization and death follow the same patterns, increasing with
Patients with the highest eGFRs at the start of dialysis therapy have the highest risk of hospitalization and of death. This again strongly supports the hypothesis that eGFR at initiation is a surrogate for disease severity, and a predictor of poor patient outcomes.

Placed within a clinical context, it seems reasonable to assume that patients and physicians are more likely to initiate dialysis at later stages if patients are in other ways stable, since few patients would rush to radically alter their lifestyles by beginning dialysis. It is equally likely that physicians initiate patients earlier due to indications of fluid overload, acidosis, hyperkalemia, declining nutritional status, or pericarditis, the usual indications for starting renal replacement therapy. These types of selection bias, intrinsic in observational data, complicate any interpretation of outcomes associated with eGFR.

Figure 2.29 incident ESRD patients, 2000. Figure 2.30 incident ESRD patients, 1999. Figure 2.31 incident ESRD patients, 1999. The Charlson Score is a measure of overall comorbidity. Categories of comorbidity are determined using inpatient hospital claims, and each category is weighted based on the severity of the condition and the associated risk of one-year mortality. The weights are added together and the cumulative score reflects the burden of comorbidity and likelihood of one-year mortality. Figures 2.32–33 incident dialysis patients, 1998–1999 combined. Adjusted data are adjusted for age, gender, race, primary diagnosis, and BMI. Figure 2.34 incident dialysis patients, 1998–1999 combined.
Because ESRD patients can receive insurance coverage from many different sources, and because a patient’s condition at the start of dialysis can have a significant impact on clinical outcomes, we look here at the relationship between insurance coverage and parameters of care such as erythropoietin treatment, hemoglobin levels, and the presence of cardiovascular disease at initiation. We also provide information on the geographic distribution of insurance coverage in the U.S.

Patients insured by Medicare and also carrying supplemental insurance or employer group health plan (EGHP) coverage are more likely to receive erythropoietin therapy prior to starting dialysis treatment (Figure 2.35). Not surprisingly, these patients also tend to have higher hemoglobin levels at initiation (Figures 2.36). Minorities, particularly blacks, have lower rates of EPO utilization and lower hemoglobin levels compared to whites.

The degree of comorbidity appears directly related to insurance coverage, which in turn reflects the age of the population. Patients with EGHP coverage, for example, tend to be younger than 65, and this group has the lowest proportion of patients with cardiovascular disease (Figure 2.37). With the exception of Native Americans, the percent of patients with cardiovascular disease is also low in those with no insurance, in contrast to the Medicare/Medicaid population, whose patients carry the greatest burden of cardiovascular disease at the initiation of dialysis.

Minority populations are disproportionately represented among patients with Medicaid or Medicare/Medicaid coverage, and among those with no insurance (Figure 2.38). Types of coverage for Hispanics parallel those in the minority populations.

Geographic variations in insurance coverage are quite striking (Figure 2.39). Patients with Medicare or Medicaid only are concentrated primarily on the West Coast and in the southern and southeastern parts of the U.S. (These rates are not adjusted for race, and Medicaid coverage is greatest among minority populations.) Patients covered by the Department of Veteran Affairs are concentrated in the western half of the country, while those with Medicare plus other coverage are more heavily represented in the northern and upper Midwest.

Since the point of service may influence subsequent patient management, outcome analyses should take into account the association between insurance coverage and pre-dialysis care.

Figures 2.35–38 incident ESRD patients, 2000. Figure 2.39 incident ESRD patients, 2000, by HSA, unadjusted.
2.38 · Racial & ethnic distribution, by insurance type at initiation

![Graph showing racial and ethnic distribution by insurance type.]

**Insurance groups**
- M/caid · Medicaid only
- M/care · Medicare only
- M w/oth · Medicare with other
- M & M · Medicare & Medicaid
- M + EGHP · Medicare with EGHP
- DVA/oth · DVA or other
- EGHP · EGHP only
- None · No insurance

2.39 · Geographic variations in the percent of patients with insurance at initiation

**Medicaid only**
- 11.04+ (12.79)
- 9.32 to <11.04
- 7.82 to <9.32
- 7.00 to <7.82
- below 7.00 (6.49)

**Medicare only**
- 16.9+ (19.3)
- 14.7 to <16.9
- 12.7 to <14.7
- 10.4 to <12.7
- below 10.4 (9.2)

**Medicare with other**
- 33.2+ (39.6)
- 26.2 to <33.2
- 20.7 to <26.2
- 15.6 to <20.7
- below 15.6 (13.0)

**Medicare with Medicaid**
- 15.6+ (19.5)
- 11.9 to <15.6
- 10.0 to <11.9
- 8.7 to <10.0
- below 8.7 (7.8)

**Medicare with EGHP**
- 8.64+ (13.60)
- 6.41 to <8.64
- 5.08 to <6.41
- 3.79 to <5.08
- below 3.79 (3.20)

**DVA or other**
- 12.76+ (15.80)
- 10.13 to <12.76
- 8.59 to <10.13
- 7.00 to <8.59
- below 7.00 (6.00)
Chapter Two

Maps: National means & patient populations

Patient populations

- Patient data at initiation is obtained from the CMS Medical Evidence form (2728), which serves to: 1) establish Medicare eligibility for individuals who previously were not Medicare beneficiaries, 2) reclassify previous Medicare beneficiaries as ESRD patients, and 3) provide demographic and diagnostic information on all new ESRD patients regardless of Medicare entitlement. The form also establishes the date of first ESRD service, and is the only source for the physician’s diagnosis of the primary disease causing renal failure. A more detailed version of the form was introduced in April 1995, and units are required to complete this form for all new patients regardless of Medicare entitlement.

Conclusions

- By ethnicity, the percent of patients with diabetes as the primary cause of ESRD is highest in the Hispanic population (65 percent), and lowest in patients who are not Hispanic (42 percent).
- The highest percentages of new patients whose ESRD is caused by diabetes are located in the southwest, the Northern Plains, and the Ohio Valley.
- There are clear geographic differences in the percent of new ESRD patients, both diabetics and non-diabetics, with cardiovascular comorbidity. The highest rates are clustered in the northeastern states and Great Lakes region, while the lowest rates occur in the West and Southwest.
- The comorbidity of the ESRD population has increased dramatically since 1984. The percent of patients with various comorbid conditions has, however, begun to plateau.

- The burden of diabetes in the ESRD population continues to increase, particularly when analyzed beyond its occurrence as a primary or secondary diagnosis.
- Serum albumin levels have decreased slightly since 1996, which may reflect increased comorbidity.
- While erythropoietin treatment in the pre-ESRD period has improved over the last five years, fewer than 30 percent of patients receive EPO before beginning ESRD therapy.
- Pediatric patients are most likely to receive pre-ESRD EPO, but still have the lowest hemoglobin levels, with girls having a hemoglobin of only 9.1 g/dl at initiation.
- Among the racial and ethnic groups, black patients continue to have the lowest hemoglobin levels at initiation.
- At the beginning of ESRD therapy, patients placed on peritoneal dialysis have hemoglobin levels that are half a gram higher than those of their counterparts on hemodialysis.
- BUN and serum creatinine levels in patients starting ESRD treatment have decreased over the past five years, while body mass indices have increased. This may reflect an increasing severity of disease in the ESRD population.
- Insurance coverage during the pre-ESRD period significantly influences EPO use and hemoglobin levels. Geographic variations in coverage across the country merit further exploration, as the types of primary and secondary insurance available to patients may influence outcome studies conducted in different areas.