We used to think that if we knew one, we knew two, because one and one are two. We are finding that we must learn a great deal about ‘and.’

ARTHUR EDINGTON, in Mackay, *The Harvest of a Quiet Eye*
This 2002 Annual Data Report documents the activities of the ESRD program in the United States since its legislative authorization in 1972, when the ESRD Act gave Medicare entitlement to patients younger than 65 who develop ESRD and require dialysis or transplantation. More than 1,250,000 individuals have been treated since the mid-1970s, including more than 375,000 patients currently in the program—almost 100,000 of them new to treatment in 2000. Medicare spending for the ESRD program is approaching $14 billion, while non-Medicare costs are close to $5.5 billion.

In this Précis we provide information on the size and breadth of the ESRD program, using the different data sources available from the Centers for Medicare and Medicaid Services (CMS, formerly HCFA), the ESRD networks, and the USRDS. ESRD patient data are documented in several ways: on the CMS Medical Evidence form (2728) at the initiation of treatment, on the census of prevalent patients reported to the ESRD networks, in the CMS Annual Facility Survey (AFS) of dialysis and transplant centers, in transplantation information from the United Network for Organ Sharing (UNOS), and in Medicare ESRD patient claims. We have spent considerable time this year reconciling these different data sources so as to provide the most consistent findings possible.

In the first section we present summary statistics on patients in 2000, including incident and prevalent counts and rates. We compare patient populations for the 1992–1996 and 1996–2000 periods, and provide total ESRD costs for both the Medicare and non-Medicare populations.

The next spread addresses both the care of patients and their advancing comorbidity as they approach ESRD therapy. There has been little information published on the fate of patients with chronic kidney disease, particularly their likelihood of survival in the follow-up years and of advancement to ESRD. The National Kidney Foundation recently estimated that 25 million Americans have some degree of chronic kidney disease, yet the number of patients beginning ESRD treatment each year is approximately 100,000, or 0.4 percent of the population at risk. As a starting point for investigations of what happens to individuals with chronic kidney disease, we show that these patients are far more likely to die than to be diagnosed with end-stage renal disease, an important reality highlighting the complexity of these patients.

Following this discussion of chronic kidney disease and the incidence of ESRD we examine trends in rates of hospitalization and mortality after the initiation of ESRD treatment. We show, in part, that mortality rates for patients of greater dialysis vintage (time on the therapy) are rising, while survival for patients who have been on dialysis less than three years is beginning to improve. These findings are discussed further in Chapter Nine.

In the final spread we provide information on recent changes in the renal provider system, focusing on profit status and chain affiliation. Growth in the number of chain-affiliated units over the past ten years has been dramatic; in later chapters we investigate the changes in costs and clinical parameters of care associated with this growth.

In the past, methods used to report incident and prevalent populations, both overall and by modality, have varied by data source and by the government organizations providing data. This year, however, we have collaborated with
CMS and the ESRD networks to reconcile the differences in these methods and to therefore provide a more consistent view of the ESRD program.

In Figure p.1 we present information on the incident population as tracked by the CMS Annual Facility Survey (AFS) and by the USRDS, using the Medical Evidence form. Because the USRDS also reviews dialysis claims within the Medicare system, we count more incident dialysis patients than the Facility Survey. For 2000, Facility Survey data indicates a total of 91,679 incident dialysis patients, compared to 94,022 incident dialysis patients in the USRDS database. By treatment modality, the USRDS database reported 83,635 hemodialysis patients, 7,101 peritoneal dialysis patients, and 2,170 pre-emptive transplant patients in 2000.

Figure p.2 shows a similar comparison for the prevalent population. Because we obtain information from Medicare claims, the USRDS has consistently counted more dialysis patients than the AFS, particularly between 1994 and 1998. And because claims are not available on Medicare HMO and non-Medicare patients, it is more difficult to determine modality for prevalent patients than for those just beginning treatment. The AFS data, which include direct census reports from the dialysis units, therefore report a higher number of peritoneal dialysis patients than does the USRDS.

To report the transplant population, the USRDS adopts methods similar to those used in the AFS, and uses information from the UNOS registry. Results from the two sources are, then, quite close (Figure p.3). The USRDS reports that 14,427 renal transplants were performed in 2000, while the AFS indicates 14,311.

We have adopted new methods to account for the increasing number of patients with Employer Health Group Plan (EGHP) coverage. These patients must wait thirty months for Medicare to become their primary payor, and thus have no Medicare claims during this period. The USRDS previously defined lost-to-followup patients as those with no claims in a 24-month period. But because of the increasing number of EGHP patients falling into this category, we have this year extended the lost-to-followup period to 36 months. As a result, the number of existing patients now more closely matches that of the ESRD network census and the AFS data.
During the year 2000, 96,192 new dialysis and transplant patients started ESRD treatment (Table p.a). Diabetes was the primary cause of ESRD in 43.4 percent of these patients, while hypertension and glomerulonephritis were primary diagnoses in 25.5 and 8.4 percent, respectively. These three diagnoses thus accounted for 77.4 percent of all new ESRD patients. The overall incidence rate in 2000, adjusted for age, gender, and race, was 334 new patients per million population.

The number of patients under ESRD treatment on December 31, 2000 was 378,862, including 275,053 dialysis patients and 103,809 patients with a functioning transplant; this created a prevalent rate of 1,311 patients per million population. As reported in the CMS Annual Facility Survey (AFS), 14,311 transplants were performed during 2000. Nineteen percent of the prevalent ESRD population died during 2000. Nineteen percent of the prevalent ESRD population died during the period.

The average annual percent change in the prevalent patient census during 1992–1996 and 1996–2000 shows that the annual growth in the hemodialysis population decreased from 7.3 to 5.1 percent. The peritoneal dialysis population, which grew an average of 3.7 percent per year during the earlier period, declined 6.6 percent per year between 1996 and 2000. And the number of patients receiving a transplant at the beginning of ESRD treatment increased 6.2 percent per year from 1992 to 1996, but only 4.8 percent per year for the 1996–2000 period.

Medicare costs for the ESRD program in 2000 were $13.82 billion, while non-Medicare spending accounted for $5.53 billion. Expenditures for the total ESRD program thus totaled $19.35 billion, an increase of 6.2 percent between 1999 and 2000. The HMO Medicare risk population accounts for approximately one billion dollars of the Medicare spending for ESRD.

On a per patient per year basis, the costs for each ESRD patient increased 2.6 percent between 1999 and 2000. After adjustments for inflation (using the Bureau of Labor Statistics inflationary adjustment or the CMS inflation adjustment for the medical component), however, actual costs of the ESRD program per patient per year declined between 0.8 and 1.5 percent.

As documented by both the USRDS and the CMS Annual Facility Survey, the annual percent change in ESRD patient populations has been decreasing slowly (Figure p4). Between 1999 and 2000, for example, the USRDS estimates that incident patient counts grew 5.2 percent, and the AFS data documents a 3.2 percent increase. In the prevalent hemodialysis population, the USRDS shows an increase of 5.3 percent.
and the AFS data 6.1 percent. The prevalent peritoneal dialysis population, in contrast, decreased 3.8 percent by USRDS methods and 1.4 percent in the AFS report. Both data sources report a comparable increase of 6.0–6.1 percent in the number of prevalent transplant patients.

The number of incident and prevalent patients does not account for all patients who receive dialysis therapy. In 2000, for example, 4,166 patients returned to dialysis after a failed renal transplant (Figure p.5). Other patients stop dialysis therapy; the AFS reports that 3,754 patients recovered renal function in 2000, while 2,157 chose to discontinue dialysis (Figure p.6).

New methods used by the USRDS now allow us to track 15,221 patients who were previously classified as lost-to-followup (Figure p.7).

Medicare expenditures for the ESRD program rose 26.6 percent between 1996 and 2000, while non-Medicare costs for the program grew 27.9 percent—an overall growth 27.6 percent (Figure p.8).
Information on the care of patients in the pre-ESRD period is difficult to obtain, since more than half of the patients who initiate dialysis therapy do not have Medicare as their primary payor prior to their diagnosis of ESRD. Patients already in the Medicare system, however, do have pre-ESRD claims, as well as Medical Evidence form information. To more carefully document pre-ESRD services, we studied Medicare patients age 67 and older with two years of claims before the initiation of dialysis.

The number of older patients initiating dialysis increased 34.2 percent between 1995 and 1999 (Figure p.9). The percentage of enrollees covered by Medicare risk HMO programs nearly doubled, an increase offset by a 9.8 percent increase in fee-for-service coverage (Figure p.10).

Mean hemoglobin levels in the two years prior to starting dialysis are relatively constant at 10.1 g/dl (Figure p.11). After initiation, hemoglobins increase from a low of 9.9 g/dl to almost 11 g/dl over the first six months. Average EPO doses range from 7,000 to 7,600 units per week. Figure p.12 shows an increasing trend in erythropoietin (EPO) treatment until 1999, when, according to information on the Medical Evidence form, 27.9 percent of patients received treatment. Only 20.7 percent, however, had treatment claims.

Figure p.13 shows the growth in the percent of patients receiving EPO through services billed to Medicare. A higher percent of peritoneal dialysis patients receive EPO before starting dialysis.

Congestive heart failure and complications of infection are the leading causes of hospitalization in the pre-ESRD period—not surprising, since these are major indications for starting ESRD therapy (Figure p.14). Ischemic heart disease and general renal failure are comparable in the time before ESRD. As expected, vascular access hospitalizations accelerate during the month of dialysis initiation.

Dialysis catheters were used most widely in 1995; by 2000, however, there was a transition to the use of permanent catheters (Figures p.15–16). For approximately 40 percent of patients there was no evidence of an access being placed prior to the initiation of dialysis. Geographically, as few as 34.7 percent of patients in some regions receive a catheter, compared to other areas with a rate near 50 percent.

Seventy percent of diabetic pre-ESRD patients receive only one HbA1c test, 53 percent receive two tests, and only 28 percent receive four tests in the two years before initiation (Figure p.17). The American Diabetes Association recommends at least two tests per year. Similar low levels of monitor-
ing occur for diabetic eye exams and lipid testing. These data indicate that general medical care for CKD patients approaching ESRD needs considerable improvement.

All figures data from the pre-ESRD CMS files, which contain information on patients 67 & older.

Figures p.9-10 incident ESRD patients. Figure p.11 fee-for-service (FFS) patients with EPO claims; EPO dosing is dose per week. Figures p.11 & p.14 incident patients, 1995–1999 combined; claims from January 1, 1993 to June 30, 2000. Figure p.12 FFS patients with Medical Evidence forms (2728). Figure p.13 FFS patients; hemodialysis & peritoneal dialysis identified from the Medical Evidence form. Figure p.14 FFS patients. Figure p.15 HMO patients & patients with Medicare as secondary payor are excluded. Figure p.16 incident patients age 67 or older at incidence, 1995–1999 combined, by HSA; non-Medicare, Medicare as secondary payor, & HMO patients are excluded. Figure p.17 diabetic incident patients, 1999; HMO patients & patients with Medicare as secondary payor during 1999 are excluded.
To further study individuals with chronic kidney disease, the USRDS obtained data on a five percent sample of the general Medicare population, excluding individuals with ESRD. From these patient claims we can study the distribution of diabetes, chronic kidney disease, congestive heart failure, and anemia. These conditions are defined using methods similar to those used by the National Committee for Quality Assurance (NCQA) to define diabetes.

Figure p.18 shows that a minority of patients—those who carry a diagnosis of chronic kidney disease, diabetes, or congestive heart failure, in any combination—generate the vast majority of ESRD cases, and that this patient distribution is influenced by the presence of chronic anemia. This high-risk population merits thorough attention to diagnosis and treatment.

Figure p.19 shows that the prevalence of chronic kidney disease (CKD) diagnoses increases with age, and that it grew between 1996 and 1999. The abrupt change at age 65 reflects the fact that younger enrollees are eligible only due to disability, while older participants have no such restrictions. Figure p.20 demonstrates the increasing prevalence of diabetes between 1996 and 1999, and the faster growth of CKD prevalence among diabetics compared to non-diabetics.

Figures p.22–23 show that death is a far more likely outcome than ESRD for all patients, especially those who are older and less healthy. In patients with no diagnosis of CKD the likelihood of death is, in fact, over 100 times greater than that of ESRD. And even in patients age 65 and older with both CKD and diabetes, the likelihood of death is still almost five times greater than that of ESRD.

Finally, Figures p.24–25 compare prevalence information from two sources: the five percent general Medicare sample and the NHANES III study of patients age 65 and older. The presence of CKD claims corresponds to reasonably severe renal insufficiency, as defined in the guidelines of National Kidney Foundation’s Dialysis Outcomes Quality Initiative (DOQI). The USRDS estimates that patients with claims documentation of CKD have GFR levels at 32.1 ml/min, or late stage three or early stage 4 chronic kidney disease in the NKF classification.

Figure p.18 1997–1998 general Medicare patients continuously enrolled in Medicare Part A & Part B during 1997–1998 & alive on December 31, 1998. Patients enrolled in an HMO or diagnosed with ESRD any time during the two-year period are excluded. Each condition (chronic kidney disease, congestive heart failure, diabetes, & anemia) identified from diagnosis codes: one from Part A inpatient.
Development of ESRD & mortality in the general Medicare population

p.22 - ESRD & death in the followup period

p.23 - Life table estimates for the probability of developing ESRD & of death

p.24 - Identified diseases, by data source

p.25 - Glomerular filtration rate & hemoglobin levels (NHANES III data)
Compared to patients who have been on dialysis for three or more years, those with shorter vintages have slightly higher hospitalization rates, even without considering hospitalization at the initiation of therapy (Figure p.26). Hemodialysis patients have the highest rates of hospitalization, while rates for transplant patients are a great deal lower.

Rates for hemodialysis patients have fluctuated over the past five years, but do not show a trend (Figure p.27). Rates for peritoneal dialysis patients do show a marked decline, but this trend should be interpreted with caution, since the peritoneal dialysis population has been shrinking, and the lower rates may only reflect patient selection.

There is wide geographic variation in the hospitalization rates for transplant patients, and rates in the upper quintile are twice as high as those in the lower (Figures p.28–29). The reasons for this large variation are unclear.

Figures p.30–31 present death rates for the period prevalent population during 1998–2000, again divided into younger and older vintages. Figure p.30 shows that, in patients of younger vintage, death rates due to infection or ischemic heart disease are comparable between hemodialysis and peritoneal dialysis patients. Deaths due to congestive heart failure are more common in peritoneal dialysis patients, while those due to other cardiac diseases are occur more frequently in the hemodialysis population. In patients of older vintage, those on peritoneal dialysis have higher rates of death due to infection, and lower rates due to other causes. The death rates for all transplant patients, regardless of vintage, are dramatically lower than those for dialysis patients.

There are striking differences in death rate trends by patient vintage (Figure p.31). Except for a recent slight increase, possibly due to the inclusion of patients with greater comorbidity, the rate for patients of younger vintage has been declining steadily. That for patients who have been treated for longer periods of time, in contrast, has been increasing. This distinction may be attributed to longer survival of new patients, who subsequently die of cardiovascular disease. It may also indicate an improvement in the care of newer patients that is not shared by those who have received therapy for longer periods. Further investigation of death rates by patient vintage is needed in order to ensure that patient selection bias does not complicate the results.

Figure p.32 shows a reasonably flat death rate for hemodialysis patients in the first year after ESRD, possibly due to a combi-
The highest death rates for dialysis patients occur primarily in the northern half of the country (Figure p.33). Rates for transplant patients, while not showing as clear a pattern, are highest in many of the regions in which rates for dialysis patients are low. Between the lowest and the highest quintiles rates differ 36 percent for patients on dialysis, and 25 percent for transplant patients.

Any analyses which include patients of different vintages require careful attention, since the most dramatic improvements in survival have occurred in patients relatively new to dialysis therapy. These improvements fade from view as patients of older vintages are included. A similar situation is noted in Chapter Nine in the comparison of death rates in incident and prevalent patients.

The data here suggest that significant progress has been made in reducing death rates, but that older vintage patients appear not to have benefited from these improvements. This suggests that more careful attention is needed in the care of patients who have been on dialysis for longer periods of time.

The nation of improving care and increasing complexity of the patients who enter treatment. Those who survive to the second year show a distinct decline in the death rate, possibly reflecting improved dialysis and anemia therapy. Most striking, however, is the death rate for peritoneal dialysis patients, which during the first year is significantly lower than the rate for hemodialysis patients, yet increases to a comparable level in the second year.

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Figure p.26 period prevalent ESRD patients, 2000. Figure p.27 period prevalent ESRD patients. Figure p.28 hospital admissions per 1,000 patient years at risk, period prevalent ESRD patients, 2000, by HSA, unadjusted. Figure p.29 hospital days per patient year at risk, period prevalent ESRD patients, 2000, by HSA, unadjusted. Figure p.30 period prevalent ESRD patients, 1998–2000 combined, unadjusted. Figure p.31 period prevalent ESRD patients, unadjusted. Figure p.32 incident ESRD patients, adjusted for age, gender, race, & primary diagnosis. Figure p.33 deaths per 1,000 patient years at risk, period prevalent ESRD patients, 2000, by HSA, unadjusted.
Both the provider delivery system and the cost of caring for ESRD patients continue to change significantly. More patients, for instance, are being treated in for-profit units, while the number of patients in non-profit units has fallen (Figure p.34). These growth patterns are comparable to those seen in freestanding versus hospital-based units, reflecting the fact that freestanding units are predominantly for-profit. Also, the number of patients in chain-affiliated units, as determined from CMS’s annual End-Stage Renal Disease Facility Survey and Independent Renal Dialysis Facilities Cost Reports, is increasing, while the number of patients in non-affiliated units has declined. This is expected, as dialysis units are steadily being acquired into large chains.

The results of the change in reimbursement policy can be seen in growing outpatient expenditures for dialysis patients, and decreasing expenditures for inpatient services (Figures p.36–37). For transplant recipients, inpatient expenditures have also declined slightly overall.

For patients with a functioning graft, inpatient expenditures per patient year have remained unchanged. Overall inpatient expenditures, however, have increased, due to the growing number of patients. Physician/supplier payments per patient year have also grown.

In terms of total expenditures, the largest increases in costs over the last six years have been related to inpatient, outpatient, and physician services. Further information on providers and the economics of the ESRD treatment program is provided in Chapters Eleven and Twelve.

Figures p.34–35 dialysis patients; data obtained from CMS’s annual End-Stage Renal Disease Facility Survey, CMS’s Independent Renal Dialysis Facilities Cost Reports, & the CDC’s National Surveillance of Dialysis-Associated Diseases in the United States. Figures p.36–37 period prevalent ESRD patients. HCFA model; transplant data include an estimate of organ acquisition costs ($25,000 per transplant). Decreased home health expenditures in 1999 were caused by changes in Medicare reimbursement policies for home health agencies. Figure p.37 patients with Medicare as secondary payor are excluded.
Maps: National means & patient populations

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Patient populations & analytical methods

- Figures p.9–16 include ESRD patients from 1995–1999 who were age 67 or older at the time of incidence. Claims-based analyses (Figures p.11–16) include only those patients who were fee-for-service during the 30-month study period (non-Medicare, Medicare as secondary payor, and HMO risk patients are excluded). EPO and hemoglobin data are obtained from Part A and B claims. Cause of hospitalization (Figure p.14) is determined from ICD-9-CM diagnosis codes for inpatient claims.
- Figures p.26–27 show hospitalization rates per 1,000 patient years at risk for period prevalent ESRD patients of different vintages. Vintage is defined as the time from the first ESRD service date until January 1 of the year for prevalent patients, or, for incident patients, as less than one year. Calculations of unadjusted rates in Figures p.26–29 follow methods used in the morbidity and hospitalization section, discussed under Chapter Six and Section E of Appendix A.

Conclusions

- The percent of patients using temporary or permanent catheters is significant, and there is geographic variation in the use of these accesses.
- Preventive health care measures in the diabetic population are significantly underutilized during the period preceding ESRD. Rates of glycemic control monitoring, diabetic eye exams, and lipid testing for these patients are far below those recommended by the American Diabetes Association or the American Heart Association.
- Three percent of the general Medicare population accounts for almost two-thirds of the Medicare population with ESRD.
- Eighteen percent of Medicare patients have diabetes. Rates of chronic kidney disease in diabetics are almost four times greater than among non-diabetics.
- In the Medicare population the likelihood of death is five to 100 times greater than the likelihood of developing ESRD.
- The estimated glomerular filtration rate in the elderly Medicare population is 58 ml/min, and 32.1 ml/min in individuals with chronic kidney disease. This suggests that Medicare claims data document only those individuals who have Stage 4 or higher chronic kidney disease.
- Hospitalization rates have declined among peritoneal dialysis patients over the last five years, and have remained relatively stable in the hemodialysis population. Hospitalization rates for transplant patients are far lower than in the dialysis population.
- While overall death rates among prevalent dialysis patients have decreased over the past decade, rates for those who have been on dialysis three or more years have grown. First-year death rates in the incident population have remained fairly stable, and second-year rates have declined for both hemodialysis and peritoneal dialysis patients.
- Patterns in the death rates suggest that survival has improved for patients new to dialysis therapy, but that patients who have been on ESRD for longer periods have not experienced the survival benefits associated with improved dialysis therapy and anemia treatment.
- The ESRD provider system has changed dramatically over the last ten years, and the majority of units are now for-profit.
- The number of patients cared for by non-profit units has declined since the mid-1990s, and the number of patients treated in chain-affiliated units is now almost 60 percent greater than the number receiving care in non-chain units.
- Dialysis costs per patient year have been fairly stable for the physician/supplier and inpatient components, while costs for outpatient services have increased.

- The number of patients treated with hemodialysis increased 5.6 percent per year over the last five years, while the number of peritoneal dialysis patients declined 4.7 percent each year.
- Total Medicare expenditures for the ESRD program in 2000 were $13.82 billion, while non-Medicare costs totaled $5.53 billion. After adjustments for inflation, the actual cost of the Medicare ESRD program declined between 0.8 and 1.5 percent.
- Approximately 20 percent of patients age 67 and older receive EPO, and these patients have an average hemoglobin of 10 g/dl. The percentage of patients receiving EPO has increased over the last six years.
- Congestive heart failure and infectious complications occur frequently as patients with chronic kidney disease advance towards ESRD.