Research is formalized curiosity. It is poking and prying with a purpose. It is a seeking that he who wishes may know the cosmic secrets of the world and that they dwell therein.

Zora Neale Hurston, Dust Tracks on a Road
Since beginning in 1972, the ESRD program has served more than 1.3 million patients through dialysis or renal transplantation. More than three decades after congressional authorization of the program, it is a good moment to take stock of how far we have come and the directions in which we may be heading. Using the most complete data available, we are able to report trends in ESRD since 1978. In that year the prevalent population was 42,324; 14,474 patients began ESRD therapy, and 5,705 had a functioning graft. ESRD was at this point truly a rare disease—a designation that ended in 1991, as the program reached the milestone of 201,458 patients under treatment. In the next decade the population doubled, reaching 406,081 by 2001. This rapid exponential growth has now begun to slow, but projections for the next quarter-century, as we show in Chapter One, are sobering. Taking into account the growth in diabetic and minority populations, and the aging of the baby boomer generation, we project that by 2030 there will be 1.3 million diabetics and 945,000 non-diabetics under ESRD treatment—a total of more than 2.2 million patients. While the program has been very successful, it consumes an ever-increasing portion of the Medicare budget—currently 6.4 percent, a 33 percent increase over the last decade. Expenditures for the program reached $22.8 billion in 2001, with Medicare spending at a level 11.5 percent higher than in 2000. This marked growth is related primarily to increases in the use of dialysis injectables, including IV vitamin D, IV iron, Epoetin, and others (see Chapter Eleven for more details). In 2001, 96,295 new patients entered the ESRD program, and 406,081 were under treatment on December 31, including 292,215 on dialysis and 113,866 with a functioning graft. Growth in the incident population has slowed to 2–3 percent, while the prevalent population has increased 4 percent. After peaking in 1998, the decline in the peritoneal dialysis population has slowed, as the number of kidney transplants reported on the CMS Annual Facility Survey increased slightly from 2000 levels, to 14,628. Hospital admission rates have fallen for hemodialysis patients who have been on dialysis less than three years, and grown for those of longer vintage, suggesting that comorbidities are now occurring later in the course of treatment. And regardless of patient vintage, admission rates for both cardiovascular disease and infection in hemodialysis patients have increased since 1993. Peritoneal dialysis patients continue to have the highest hospitalization...
rates for infection, and to spend the greatest number of days in the hospital each year. ■ Mortality rates for some patient populations have changed considerably over the past two decades. Rates for hemodialysis patients under treatment for less than three years, for example, have fallen steadily since the mid-1980s, though for patients of greater vintage the overall decline has been only slight, and rates for these patients have increased since 1998. In patients on peritoneal dialysis the rates have been falling slowly, but for vintages of three or more years they remain higher than those of hemodialysis patients. ■ Five-year survival rates for patients beginning ESRD therapy in 1992–1996 improved compared to those of patients starting in the previous five years—8 percent for hemodialysis patients, 17 percent for those on peritoneal dialysis, and 9 percent for those with a transplant. More than two-thirds of transplant patients are now alive five years after beginning therapy, compared to one-third of those on either type of dialysis. On a gross scale, clinical differences in the dialysis therapies are slight, particularly in comparison to the obvious advantage associated with receiving a renal transplant. ■ The care delivery system has altered rapidly since the late 1980s, with the majority of patients now receiving treatment in for-profit units operated by large chains. Costs of the program have also changed considerably. Outpatient expenditures, which include dialysis, have exceeded those of inpatient care for the last four years, and the difference between them is increasing. Expenditures for home health services fell dramatically after the 1998 changes in coverage for these services. ■ Most striking in the economic data is the emergence of dialysis outpatient costs as the leading expenditure for the dialysis population. While trends for inflation-adjusted total costs per patient year have been virtually zero for 2–3 years, these costs have seen an average inflation-adjusted increase of 6 percent. ■ During the past two decades we have certainly improved our ability to care for ESRD patients. With estimates, however, that the size of this vulnerable population will quadruple in the next 27 years, much remains to be done if we are to continue providing effective care.

p.2 · Costs of the ESRD & Medicare programs

Medicare dollars are obtained from the CMS Office of Financial Management, Division of Budget; ESRD dollars are calculated directly from claims (Table K.1 methods) & from estimated costs for HMOs & organ acquisition. Dollars in 2001 are inflated by 2 percent to account for costs incurred but not reported.
In 2001, 96,295 dialysis and transplant patients initiated ESRD treatment (Table p.a). Forty-four percent of these had diabetes listed as their primary cause of renal failure—a reflection of the growing incidence of diabetes in the general population. The overall incidence rate in 2001, adjusted for age, gender, and race, was 334 patients per million population.

The number of patients undergoing treatment on December 31, 2001, was 406,081, a 4.2 percent increase since 2000. Patients undergoing dialysis accounted for 72 percent (292,215) of this prevalent population, while 113,866 patients had a functioning transplant. The adjusted prevalent rate was 1,392 patients per million population. CM S's Annual Facility Survey reported that there were 14,628 transplants performed in 2001, only a slight increase from the 14,311 performed the previous year. And in 2000, 20 percent (76,584) of the prevalent population died.

Total Medicare costs for the ESRD program in 2001 were 15.4 billion—almost 12 percent higher than costs in 2000. Non-Medicare spending increased 11.5 percent to $7.7 billion (Table p.a and Figure p.6). USRDS data indicate that Medicare spending increased 11.5 percent (22.8 billion, an increase of 11.4 percent from 2000. Non-Medicare spending for ESRD was 2.49 billion (375 million) in 2001, 2.5 percent higher than costs in 2000. Non-Medicare costs for ESRD in 2001 were 15.42 billion.

The cost per patient per year increased 10.1 percent between 2000 and 2001. After adjusting for inflation, however, this increase was 5.8–6.6 percent.

The annual percent change in the ESRD population continues to decrease slowly (Figure p.3). USRDS data indicate that incident patient counts grew 1.8 percent between 2000 and 2001, while data from the CMS Facility Survey indicates a growth of 3.3 percent. Increases in prevalent counts were 4.2 and 4.6 percent, respectively.

Counts of incident and prevalent patients do not account for all patients who receive dialysis therapy. In 2001, 4,498 patients...
Figure p.3 incident patients: USRDS data contain all ESRD patients, while CMS Facility Survey data (FSD) contain dialysis patients only. Prevalent patients: USRDS data contain patients with the indicated modality on December 31, FSD data for “all” include dialysis patients only, & FSD data for dialysis include patients with the indicated modality at the time of the survey.

Figures p.4–5 aggregate dialysis patient counts from the CMS Facility Survey. Figure p.6 Medicare spending includes paid claims, estimated Medicare+ Choice costs, & estimated organ acquisition costs. Non-Medicare spending includes estimates of costs for EGHF patients & for non-Medicare ESRD patients, & estimates of patient obligations. See Appendix A for further details.

returned to dialysis after a failed transplant (Figure p.4). In other instances, dialysis therapy is stopped; in 2001, the CMS facility survey indicated that 4,120 patients recovered kidney function and 2,420 opted to discontinue treatment (Figure p.5).
Hospitalization & mortality

Hospital admission rates and the number of hospital days have changed by varying amounts since 1993. Overall admission rates by patient vintage—the amount of time a patient has had ESRD—have decreased slightly for both hemodialysis and peritoneal dialysis patients of younger vintage, and increased 2.1–5.2 percent for those who have had ESRD for three or more years (Figure p.7). Rates have been relatively steady for hemodialysis patients, but rose slightly for peritoneal dialysis patients during the mid-1990s.

Cardiovascular admissions have increased 7 percent for the newest hemodialysis patients, but more than 19 percent for patients with three or more years of ESRD. Admissions for infection, in contrast, have risen slightly more for patients of younger vintage—27.5 versus 23 percent. In peritoneal dialysis patients the changes have been less dramatic; admissions for cardiovascular disease and infection have decreased only slightly in patients of younger vintage, and grown 7.8 and 3.3 percent, respectively, in patients of older vintage. Overall, transplant patients are admitted less than half as often as those on dialysis.

Compared to newer patients, peritoneal dialysis patients of longer vintages had 7.5 percent more all-cause admissions in 2001. The number of hospital days for these patients, however, was 18 percent higher (Figure p.8). For hemodialysis patients, in contrast, vintage showed no association with the number of hospital days for all-cause admissions.

Adjusted mortality rates, using 2001 ESRD patients as the reference cohort, have been similar for hemodialysis and peritoneal dialysis patients of younger vintage since the late 1990s (Figure p.9). The amount of change by vintage, however, varies dramati-
ally between the two modalities. Compared to those of newer patients, the most recent all-cause mortality rates for older vintage patients on hemodialysis are 19 percent higher. In patients on peritoneal dialysis, this difference is 89 percent for all-cause mortality, and 147 percent for mortality due to infection. All-cause rates in peritoneal dialysis patients of older vintage are 58 percent higher than in their counterparts on hemodialysis.

Five-year survival probabilities for patients starting therapy in 1992–1996 improved over those of the previous period—8 percent for hemodialysis patients, 17 percent for those on peritoneal dialysis, and 9 percent for those with a transplant (Figure p.10). Seventy percent of transplant patients survive at least five years after beginning therapy, compared to 33 and 32 percent on the dialysis therapies.

In the first year of therapy, adjusted mortality rates for peritoneal dialysis patients are lower than those for patients on hemodialysis (Figure p.11). This alters, however, in subsequent years, as rates for peritoneal dialysis patients increase from first-year levels, and remain higher than those of other modalities.

Because changes in hospitalization and mortality rates differ with the amount of time on ESRD therapy, analyses of these data require careful attention to patient vintage. While incident-based studies are less biased, since the survival clock is tracking from a common starting point, assessing the outcomes of prevalent patients is clearly more complex than previously thought.

Figures p.7–8 period prevalent ESRD patients; adjusted for age, gender, race, & primary diagnosis. Patients from 2001 used as reference cohort. Figures p.9 period prevalent ESRD patients; adjusted for age, gender, race, & primary diagnosis. Patients from 2001 used as reference cohort. The Death Notification form was revised in September 1990 to include more detailed categories for cause of death; prior to this time cardiovascular deaths were often classified as being of “other” causes. Because of this, data for cardiovascular deaths prior to 1991 have been omitted here. Figures p.10–11 incident hemodialysis & peritoneal dialysis patients, & patients receiving a first transplant in the incident year; adjusted for age, gender, race, & primary diagnosis. Incident ESRD patients, 1996, used as reference cohort.
Care delivery systems

The source of ESRD patient care continues to change significantly, as do treatment choices and expenditures. Non-profit units, for instance, are treating a smaller proportion of the patient population, as evidenced by a three- to four-fold increase since 1988 in the number of patients treated in for-profit units (Figure p.12). The number of patients on hemodialysis in chain-affiliated units has increased proportionally; as of 2001, these units provided treatment to 86 percent more patients than their non-chain counterparts. These trends follow similar patterns in the peritoneal dialysis population, though the overall numbers of patients are noticeably lower, and the number of patients on this therapy has fallen since peaking in the mid-1990s.

Overall Medicare expenditures (derived from paid claims) for outpatient dialysis services in 2001 were approximately ten percent higher than those for inpatient services (Figures p.13–14). This difference is relatively new, as costs were similar prior to 1998, and appear related to the use by dialysis providers of more costly injectables. The greatest changes have occurred in skilled nursing facilities and hospice care, where costs in 2001 were 11–12 times higher than a decade earlier.

Costs for transplant services show similar patterns of growth, and, as expected, inpatient costs for these patients are far higher than outpatient costs. Inpatient expenditures per patient year for patients with a transplant within the year, while three times higher than those for dialysis patients, remained relatively constant between 1991 and 2001, and increased only 13 percent compared to 53 percent for dialysis patients over the same period.

Due to the growing number of patients, inpatient and Part B expenditures continue to rise for patients with a functioning graft, and Part B expenses for these patients have almost quadrupled since 1991.

Total outpatient costs for patients with graft failures have risen more than 200 percent since 1991, and the cost per patient year has increased by 76 percent. Inpatient expenses have increased more modestly, with the increase in cost per patient year being two and a half times lower than the increase in outpatient services over the same time period.

Figure p.12 December 31 point prevalent dialysis patients; data obtained from CMS’s annual End-Stage Renal Disease Facility Survey. Figures p.13–14 period prevalent ESRD patients, 2001; modalities determined using methods from the HCFA Research Report on End-Stage Renal Disease (publication number 03393); see Appendix A for further details. Totals are paid claims for all ESRD patients starting at first ESRD service date & continuing until death or the end of the study period. Patients with Medicare as secondary payor are excluded in Figure p.14.
p.13 - Growth in annual Medicare expenditures, by modality & type of service: prevalent patients

Total expenditures (in millions of dollars)
Expenditures per patient year (in thousands of dollars)

p.14 - Growth in Medicare expenditures per patient year, by modality & type of service: prevalent patients
2.79+ (2.81)
2.59 to <2.79
2.10 to <2.59
1.83 to <2.10
below 1.83 (1.53)

2.79+ (3.38)
2.59 to <2.79
2.10 to <2.59
1.83 to <2.10
below 1.83 (None)
NHANES

The National Health and Nutrition Examination Survey, conducted by the CDC, collects information on health, illness, and diet in the United States. We look here at data from NHANES III, collected from 1988 to 1994. By comparing them to NHANES III patients, it is evident that Medicare patients with CKD have an eGFR between 30–45 ml/min/1.73 m², indicating CKD of late Stage III (Figure p.15). Patients with a history of CHF, stroke, or AMI are more likely than those with other comorbidities to have CKD of Stage III or higher (Figure p.17). And as the number of comorbid conditions increases, eGFR levels consistently fall (Figure p.19).

Data show a direct relationship between higher levels of C-reactive proteins and lower eGFRs (Figure p.21). CRP levels are disproportionately high in patients with a history of stroke or diabetes.

Some investigators report no difference in survival for higher serum creatinine levels when comorbid conditions are considered. We looked at whether these findings relate to small sample size in NHANES I. Data from NHANES I show that elevated serum creatinine was a minor risk factor for survival. Data from the larger NHANES II cohort consistently show that survival is significantly lower in patients with elevated levels, particularly when accompanied by anemia (Figures p.22–23). It appears, therefore, that chronic kidney disease itself—beyond the associated comorbidity—is a major risk factor for survival.

Figure p.15 general Medicare patients: percent of patients with CKD identified by claims; data for each year include all non-ESRD patients alive, non-HMO, Medicare-eligible for the entire calendar year, & age 65 or older as of December 31 of the previous year. NHANES III population: for age distribution, patients age 18 & older; for gender & race distribution, patients age 65 & older. Figure p.16 NHANES III patients age 18 & older. Figures p.17–19 & 21 NHANES III patients age 20 & older; all comorbidities are self-reported. Figure p.20 data for each year include all non-ESRD patients alive, non-HMO, Medicare-eligible for the entire calendar year, & age 65 or older as of December 31 of the previous year; unadjusted. Figures p.22–23 NHANES I & II patients age 30–75; rates adjusted for age, gender, race, & comorbidity. Anemia defined by criteria from the World Health Organization.

Figures p.15–19 & 21 eGFR estimated by MDRD method using adjusted serum creatinine.
INTRODUCTION Figure p.1 In 2001 the ESRD program included 406,081 prevalent patients—292,215 on dialysis and 113,866 with a transplant; 96,295 patients began therapy. Figure p.2 Medicare ESRD costs in 2001 approached $15.4 billion—6.4 percent of the Medicare budget, and a 33 percent increase over the past ten years. TRENDS IN THE U.S. ESRD PROGRAM Table p.a The overall rate of growth in the incident hemodialysis population slowed to 3.3 percent during 1997–2001, and that of the prevalent population to 4.8 percent. Figure p.4 Approximately 4,500 patients returned to dialysis after transplantation in 2001, adding to the total number of patients initiating dialysis therapy during the year. Figure p.5 Based on CMS's Annual Facility Survey data, 4,120 patients recovered renal function in 2001, while 2,420 discontinued dialysis treatment. Figure p.6 Medicare ESRD expenditures have increased 166 percent over the past ten years, while non-Medicare expenditures for ESRD grew 236 percent, to $7.4 billion in 2001. HOSPITALIZATION & MORTALITY Figure p.7 Nine-year trends in hospital admission rates by patient vintage show a closing of the gap between hemodialysis patients who have been on ESRD therapy less than three years and those of older vintage. For peritoneal dialysis patients, in contrast, the gap has increased, while for those with a transplant it remains relatively unchanged. Figure p.8 The number of hospital days per patient year has declined since 1993 across all modalities, with patient vintage now having little association to the number of hospital days for hemodialysis patients, and more of an association for those on peritoneal dialysis. Figure p.9 Over the past two decades mortality rates have declined for hemodialysis patients of younger vintage, and increased slightly for those with longer times on the therapy. Mortality rates for patients on peritoneal dialysis have fallen overall, and remain consistently higher for those of older vintage. And in the transplant population, rates have remained stable for older vintage patients, and declined for newer patients. Figure p.10 Between the 1987–1991 and 1992–1996 periods, survival of the transplant population improved 6 percent, that of hemodialysis patients improved 2 percent, and that of patients on peritoneal dialysis grew 5 percent. Figure p.11 First-, second-, third-, and fourth-year mortality rates for incident patients have all declined across all modalities, with first-year rates for peritoneal dialysis patients showing the most striking fall—from over 400 to fewer than 200 deaths per 1,000 treatment years. Second-year mortality rates on peritoneal dialysis have now begun to approach those of the hemodialysis population. CARE DELIVERY SYSTEMS Figure p.12 Providers delivering care to prevalent hemodialysis patients are now dominated by for-profit units and those affiliated with large chains. Figures p.13–14 Outpatient Medicare expenditures for the dialysis population began to exceed inpatient expenditures in 1998, and the difference between them has continued to grow. Declines in home health and skilled nursing expenditures are a direct result of Medicare payment policies. NHANES Figure p.15 The percent of general Medicare patients carrying a diagnosis of chronic kidney disease is slightly higher than the percent of NHANES patients with estimated GFRs less than 30 ml/min. Previous estimates by the USRDS indicate an eGFR in the Medicare CKD population of 34 ml/min. Figure p.18 NHANES III patients with a diagnosis of CHF, stroke, or AMI have lower eGFRs than patients with other comorbidities. Figure p.19 In the NHANES III population, as the number of comorbid conditions increases, the eGFR declines. Figure p.21 Across all major cardiovascular comorbidities, inflammatory markers such as C-reactive proteins are higher in individuals with lower estimated GFRs, suggesting that CKD patients with advancing renal failure have increasing levels of inflammatory markers. Figure p.22 Patients in NHANES I and II who have serum creatinine levels above the normal ranges for men and women show lower survival than their counterparts with normal levels. Figure p.23 In NHANES III patients, interactions between an elevated serum creatinine and anemia (as defined by the World Health Organization) show that those with anemia and CKD have the lowest ten-year survival.

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