

Chapter IV

Patient Characteristics at the Start of ESRD: Data from the HCFA Medical Evidence Form

Key Words:

Medical Evidence Report Form
End-Stage Renal Disease
Comorbidity
Validity

Cardiovascular Disease
Creatinine Clearance
Pre-ESRD Erythropoietin Use
Employment

One of the many goals of the United States Renal Data System (USRDS) is to characterize the end-stage renal disease (ESRD) population. The demographic characteristics and treatment modalities for the ESRD population have been described for all Medicare patients in each Annual Data Report (ADR) since the inception of the USRDS. Several USRDS Special Studies have collected data for representative samples of ESRD patients. In addition to meeting specific research goals, these studies also provided detailed descriptions of the comorbid conditions and other characteristics of the ESRD population based on medical record abstraction (USRDS 1992; USRDS 1996; USRDS 1997). These samples provided unique comprehensive snapshots of the ESRD population but, due to their limited longitudinal design, did not provide an ongoing surveillance of the ESRD population. Due to the implementation effort and cost required to carry out these Special Studies, this type of comprehensive data collection has only been performed for a sample of patients on an intermittent, rather than on an annual basis.

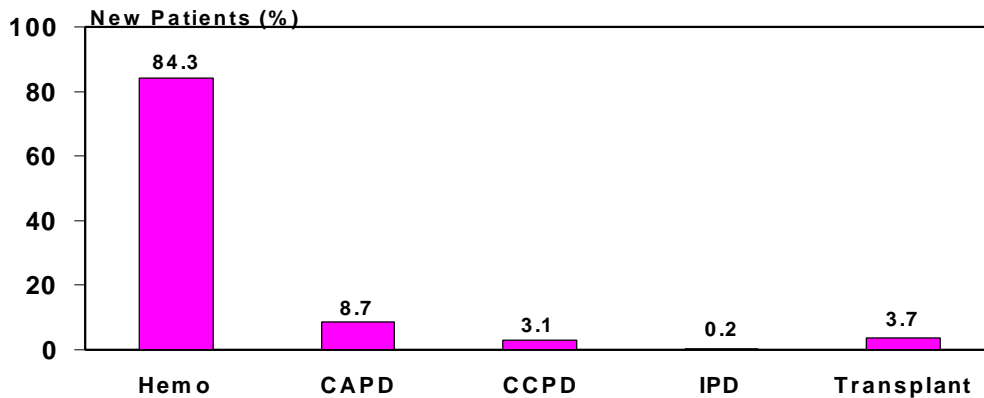
Before 1995, the USRDS data included few patient characteristics beyond age, race, sex, and diabetes measured for the census of ESRD patients. Additionally, prior to 1995, the USRDS data were

limited primarily to Medicare patients. Members of the renal community have recognized the importance of many other patient characteristics. For example, more detailed information on comorbid conditions, laboratory values, and nutritional status is important for characterizing the ESRD patient population and for understanding patient outcomes.

This need was one of the motivations for the Health Care Financing Administration (HCFA), in conjunction with input from the USRDS and others, to revise the Medical Evidence Report Form. The revision, made in April 1995, included the collection of data on specific comorbid conditions, employment status, and laboratory values at the start of ESRD. The comorbid conditions and laboratory values were chosen in part because they had been shown to be important predictors of outcomes in the ESRD population (USRDS 1992). In addition to expanding the data items recorded, the revised form was extended to be filled out for all patients, including non-Medicare patients.

This chapter describes the data collected from the revised Medical Evidence Report Form, first introduced as a necessary requirement to be completed by all new ESRD patients in the United States, in 1995. This chapter will focus on the

Primary ESRD Modality in New ESRD Patients, 1995-97*



*Reported on HCFA Medical Evidence Form

IV -1
USRDS 1999

Figure IV-1

Primary ESRD treatment modality in new ESRD patients as reported on the HCFA Medical Evidence Form, 1995-97. Source: Special Analysis.

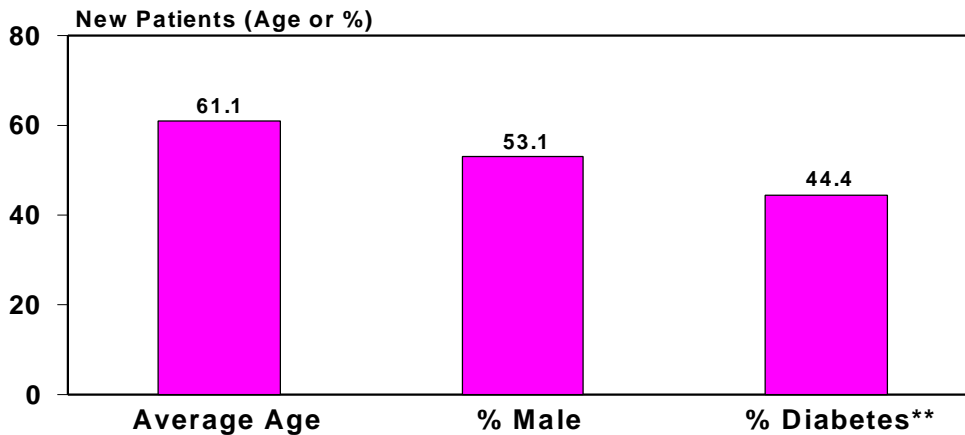
distribution of characteristics of new ESRD patients during the time period 1995-1997. Moreover, the chapter will provide ‘snapshots’ of the health status of these incident patients by year of incidence, permit observation of trends in patients characteristics over these years, and help identify conditions that require increased attention and more effective treatment.

HCFA’s New Medical Evidence Report Form

What is the Medical Evidence Report Form?

The Medical Evidence Report Form of the Health

Demographic Characteristics of New ESRD Patients, 1997*



*Reported on HCFA Medical Evidence Form
**Primary/contributing cause of ESRD

IV -2
USRDS 1999

Figure IV-2

Demographic characteristics of new ESRD patients as reported on the HCFA Medical Evidence Form, 1997. Percent diabetes refers to diabetes as a primary cause of ESRD. Source: Special Analysis and Reference Tables L.5 and L.11.

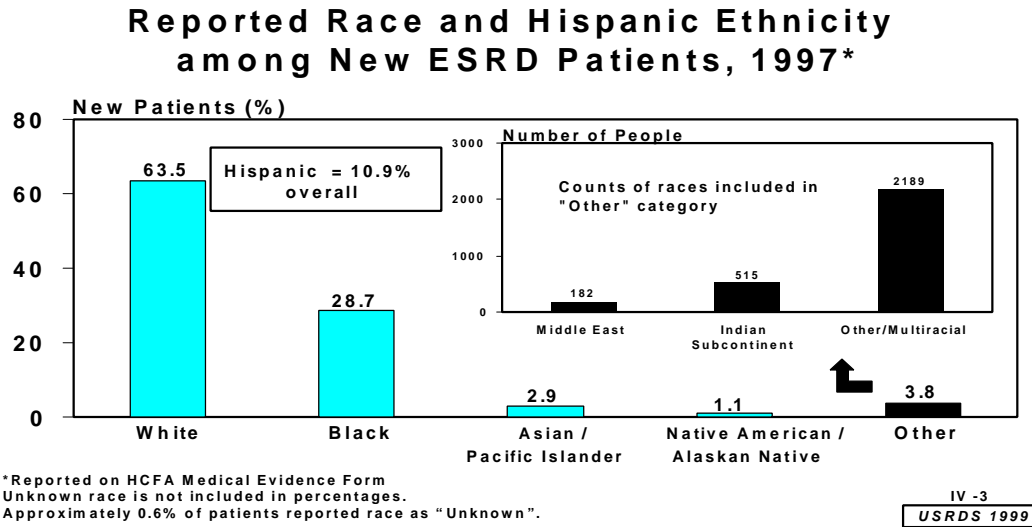


Figure IV-3

Distribution of race among new ESRD patients as reported on the HCFA Medical Evidence Form, 1997. Unknown race is not included in percentages (approximately 0.6 percent of patients). Counts of races included in "Other" are also shown. Source: Reference Tables L.5 and L.8.

Care Financing Administration is a document that is completed for ESRD patients, in the United States, beginning renal replacement therapy. The form fills the dual purpose of documenting Medicare entitlement and serving as patient registration. This form is used to collect data are collected on demographics, causes of ESRD, the utilization of treatment modalities, comorbid medical conditions, employment status, laboratory values, and indices of nutrition. The form was devised to serve both practical and epidemiological purposes. The primary objectives are:

- 1) To ensure all patients initiating dialysis are accounted for in the United States.
- 2) To capture data on the characteristics of new ESRD patients in the United States.
- 3) To utilize this collected data for epidemiological purposes.
- 4) To improve the outcomes for all ESRD patients.

Utilization of the Medical Evidence Report Form

There are over 221,000 patients (of the over 300,000 ESRD patients) in dialysis programs throughout the United States (See Chapters II and III). This large prevalent population, in part, is

maintained by a growing incidence rate, which is in excess of 79,000 patients per year. The Medical Evidence Report Form is completed for patients starting or returning to dialysis or for those who, instead of dialysis, receive a kidney transplant as their initial treatment of ESRD. A necessary component of the care provided by health workers is the ongoing monitoring of the health status of this high-risk population, which has a high morbidity and mortality rate. The Medical Evidence Report Form offers a unique opportunity to capture medical information on the health status of this entire ESRD population. The entire Medical Evidence Report Form is reproduced in the introduction to Section L of the Reference Tables.

The Medical Evidence Report Form is typically completed within 45 days of when a patient is diagnosed as having ESRD. It is the primary responsibility of the physician caring for each patient to ensure that the data recorded are complete and accurate. The attending physician and/or another designated individual may complete the form. To date, there is little standardization in the method by which the form is completed. Therefore, data quality is likely to be highly variable, particularly for data items that are not readily available in the dialysis facility. For the purpose of this chapter, analyses are limited to new ESRD patients only. Figures IV-1 to IV-5 and IV-11 to IV-18 relate to all new ESRD

Primary Detailed Disease Groups Reported among New ESRD Patients, 1997*

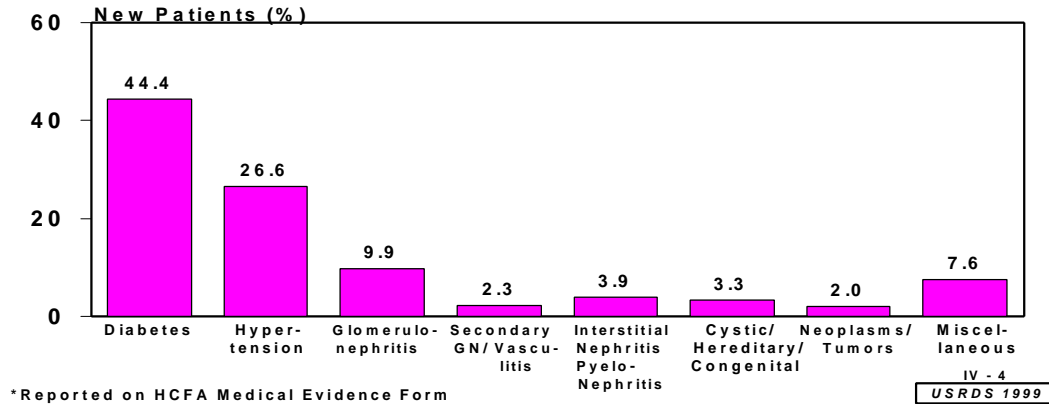


Figure IV-4

Distribution of primary detailed disease groups as reported on the HCFA Medical Evidence Form for new ESRD patients, 1997. Percentages sum to 100. Miscellaneous includes patients whose disease etiology is uncertain. Source: Reference Table L.11.

patients, whereas Figures IV-6 to IV-10 exclude transplant patients and relate to new dialysis patients only.

Modality Distribution of New ESRD Patients 1995-1997

Only a small fraction of the incident ESRD population in the United States is afforded renal transplantation as initial therapy. For the majority of

new ESRD patients, dialysis remains the standard modality of treatment. Figure IV-1 describes the distribution of initial ESRD modality use among incident ESRD patients in the United States as reported on the Medical Evidence Report Form, for the period 1995-1997. Pre-emptive transplantation was available for 3.7 percent of incident patients. Hemodialysis was the recorded mode of renal replacement therapy for 84.3 percent of patients, while peritoneal dialysis was the recorded mode for 12 percent. These patterns of utilization of renal

Primary Disease Reported among New ESRD Patients by Year, 1995-97*

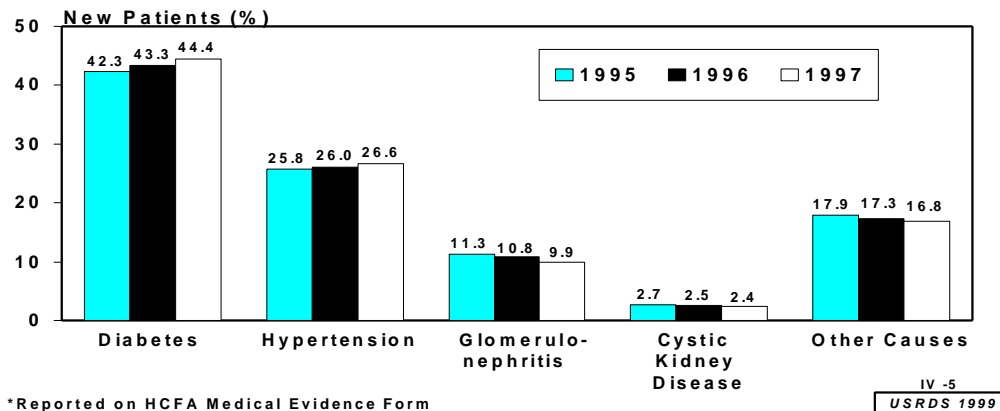


Figure IV-5

Distribution of primary disease among new patients by year as reported on the HCFA Medical Evidence Form, 1995-97. Percentages within each year sum to 100. Unknown causes of ESRD included in other causes; patients whose cause of ESRD is missing are excluded. Source: Reference Table L.20.

Cardiovascular Patient Characteristics among New Dialysis Patients, 1997*

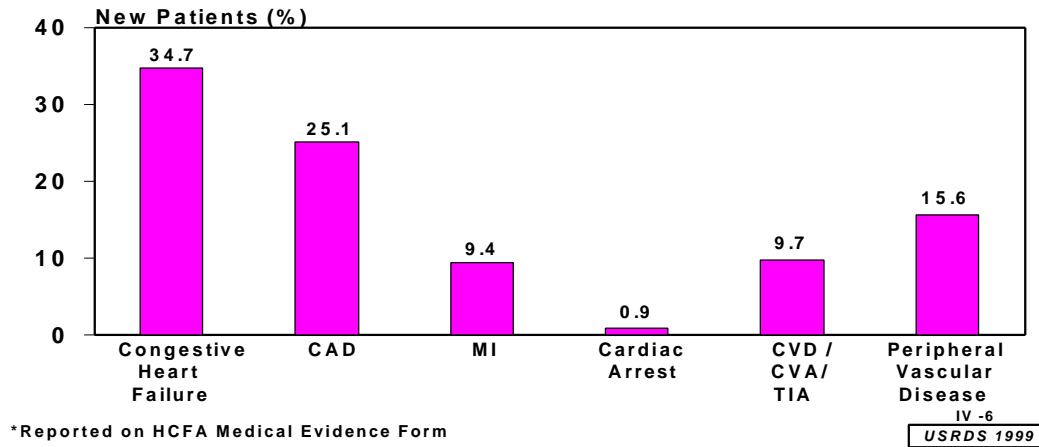


Figure IV-6

Cardiovascular patient characteristics among new dialysis patients as reported on the HCFA Medical Evidence Form, 1997. Source: Reference Table L.15.

replacement therapies are similar to those described in prior USRDS ADRs (USRDS 1998).

Demographic Characteristics of New ESRD Patients, 1995-1997

During the period 1995-1997, over 167,000 new patients started on renal replacement therapy in the United States. The demographic characteristics of these patients for 1997 are shown in Figures IV-2 and IV-3. Among this incident population, 53.1 percent were male, 44.4 percent were diabetic and the mean age was 61 years (Figure IV-2). These data are in agreement with other published USRDS ADRs. Figure IV-3 illustrates differences among incident patients with respect to race. By far the largest group is White, accounting for 63.5 percent of all incident patients. Black race also constitutes a large proportion (28.7 percent) of all incident patients, with Asian/Pacific Islander and Alaskan Native/Native American races comprising a smaller fraction (2.9 percent and 1.1 percent respectively) of the total. The racial group 'other' has been used to describe those patients who are not of the aforementioned groups and are of different racial origin or are multiracial. The collection of more detailed information on this category by the Medical Evidence Report Form allows further characterization of this heterogeneous group. The inset box in Figure IV-3 describes these groups as counts. It can be seen that the 'other/multiracial' group constitutes the largest

fraction within this group. Patients with origins from the Middle East and the Indian subcontinent are reported to contribute much smaller numbers.

Cause of ESRD Among New Dialysis Patients, 1997

The Medical Evidence Report Form lists 8 primary disease categories (diabetes, glomerulonephritis (GN), secondary glomerulonephritis/vasculitis, interstitial nephritis/pyelonephritis, hypertension/large vessel disease, cystic/hereditary/congenital diseases, neoplasms/tumor, miscellaneous conditions) and offers codes for 72 specific causes of ESRD. Figure IV-4 describes the prevalence of ESRD by primary disease as reported from the Medical Evidence Report Form. It should be noted that hypertension, as a cause of ESRD, is not a distinct entity but rather a composite category that includes several conditions including renal disease due to hypertension, renal artery stenosis/occlusion and atheroembolic disease. Figure IV-5 shows primary disease by year of incidence. Causes of ESRD other than diabetes, hypertension (defined above), primary glomerulonephritis and cystic kidney diseases are categorized as "other causes". Diabetes is the leading cause of ESRD among incident patients in the United States accounting for 44.4 percent of all ESRD in 1997. Hypertension, primary glomerulonephritis, cystic kidney disease, and "other causes" account for 26.6 percent, 9.9 percent, 2.4 percent, and

Ischemic Heart Disease (CAD) and Myocardial Infarction (MI) by Gender and Diabetes in New Dialysis Patients, 1997*

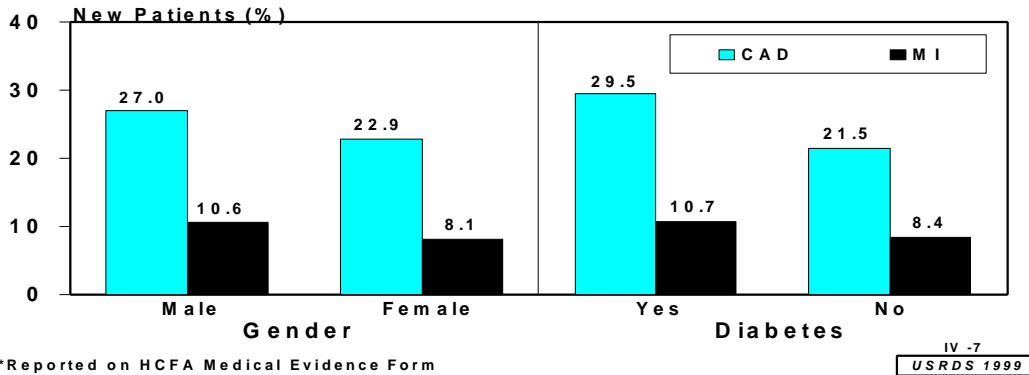


Figure IV-7

Ischemic heart disease (CAD) and Myocardial Infarction (MI) by gender and diabetes for new dialysis patients as reported on the HCFA Medical Evidence Form, 1997. Source: Reference Tables L.17 and L.19.

16.8 percent, respectively, in 1997. From 1995-1997, there has been an increase in the proportion of patients reported to have ESRD due to diabetes and hypertension, with a corresponding decrease in the proportion due to GN, cystic kidney diseases, and other causes.

New ESRD Patients

Patients with ESRD have a high prevalence of comorbid medical conditions, which contribute to their shortened survival span (USRDS 1992). The Medical Evidence Report Form requests information on the presence of 20 comorbid medical conditions in new dialysis patients. Figures IV-6 through IV-13 illustrate the distribution of cardiovascular and non-cardiovascular comorbid medical conditions reported among incident dialysis patients in 1997. The high percentage of cardiovascular diseases is striking, as

Comorbid Conditions Among New Dialysis Patients, 1997

Distribution of Comorbidities among

Ischemic Heart Disease (CAD) and Myocardial Infarction (MI) by Age for New Dialysis Patients, 1997*

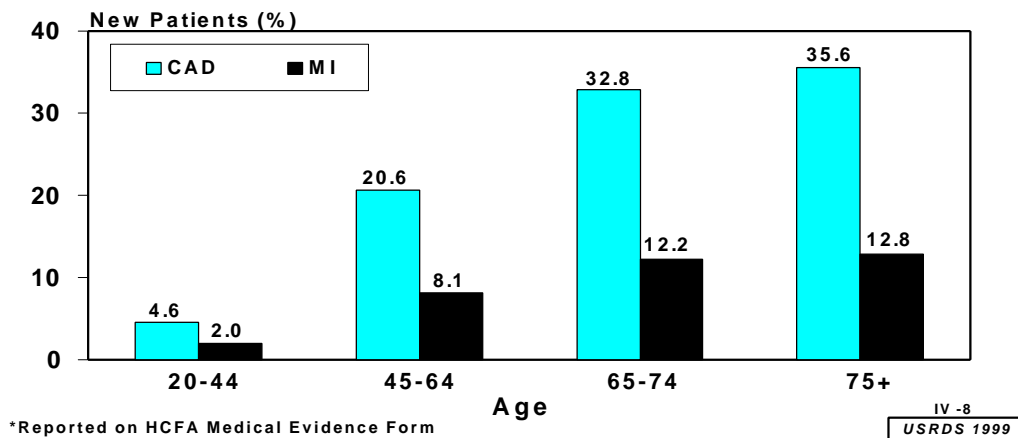


Figure IV-8

Ischemic heart disease (CAD) and Myocardial Infarction (MI) by age for new dialysis patients as reported on the HCFA Medical Evidence Form, 1997. Source: Reference Table L.16.

are the percentages of the underlying medical conditions that constitute this disease group. Less common but no less important are non-cardiovascular comorbid conditions, which are also reported. These conditions include chronic obstructive pulmonary disease (COPD) and cancer.

Cardiovascular Conditions Among New Dialysis Patients

Several studies have described the excess burden of cardiovascular disease that is present among new ESRD patients (USRDS 1992; Bloembergen; Stack 1998a). The high prevalence of coronary artery disease and its attendant sequelae in this patient population has prompted the establishment of a National Task Force on Cardiac Disease (NKF Task Force 1998). Their primary aim was to address the high prevalence of cardiac disease among patients with renal insufficiency, and offer guidelines for proposed methods of screening and intervention. The Medical Evidence Report Form has a useful role to play in surveillance of cardiovascular disease among incident dialysis patients as data collected may be used to follow trends in the prevalence of these conditions. Figure IV-6 describes the distribution of cardiovascular conditions reported for new ESRD

patients in 1997. Congestive heart failure was reported to be present in almost 34.7 percent of patients (a total count of 75,200 patients). Coronary artery disease (CAD) was reported in 25.1 percent of new ESRD patients, and 9.4 percent had prior myocardial infarction (MI). Furthermore, cerebrovascular disease (CVD) and peripheral vascular disease, associated atherosclerotic conditions were reported to be present in 9.7 percent and 15.6 percent of new ESRD patients respectively. Cardiac arrest was present in less than 1 percent.

The prevalence of cardiovascular disease among this incident dialysis population is far greater than in the general population (NKF Task Force 1998). The cause of this excess burden is unclear, but uremic toxins and novel atherogenic mediators may play a major role (Lindner; Witzum; Chauveau).

Although highly prevalent, as shown in Table IV-1, the presence of cardiac comorbid conditions is reportedly less frequent on the HCFA Medical Evidence Report Form than in the USRDS Special Study, the Dialysis Morbidity and Mortality Wave 2 (DMMS Wave 2). The DMMS is a study of over 4,000 patients starting hemodialysis (HD) or peritoneal dialysis (PD) in 1996 and 1997, in which

Reported Comorbid Conditions Among New Dialysis Patients by Source, 1996-97*

Cardiovascular Comorbid Conditions			
Pre-existing Risk Factor	HCFA 2728	DMMS Wave 2	Kappa
Congestive Heart Failure (%)	29.4	36.1	0.49
Coronary Artery Disease (%)	21.5	40.0	0.43
Myocardial Infarction (%)	7.9	16.3	0.40
Cardiac Arrest (%)	1.0	2.2	0.14
CVD / CVA / TIA (%)	8.2	12.0	0.50
Peripheral Vascular Disease (%)	13.6	19.6	0.40
Diabetes on Insulin (%)	26.8	33.1	0.71
COPD (%)	5.8	11.7	0.41
Cancer (%)	4.0	9.7	0.42
Pericarditis (%)	1.3	2.5	0.25

Non-Cardiovascular Comorbid Conditions			
Pre-existing Risk Factor	HCFA 2728	DMMS Wave 2	Kappa or Mean % Diff.
Inability to Ambulate (%)	2.6	10.1	0.19
Inability to Transfer (%)	0.9	8.5	0.13
Current Smoker (%)	6.9	41.8	0.16
Body Mass Index (kg/m ²)	25.9	25.5	6.7%
Serum Albumin (g/dl)	3.3	3.5	12.4%

* Matched patients from DMMS Wave 2 data and HCFA Medical Evidence Form (n=2443, 50% HD, 50% PD).
Source: Special Analysis.

Table IV-1

USRDS 1999

data on comorbidity was collected retrospectively by medical chart abstraction. CAD was reported among 40.0 percent of patients in the DMMS compared to 21.5 percent reported among patients using HCFA Medical Evidence Form data. Similarly, CVD was reported among 12.0 percent compared to 8.2 percent; peripheral vascular disease was reported among 19.6 percent compared to 13.6 percent, and congestive heart failure was reported among 36.1 percent compared to 29.4 percent. Furthermore the level of agreement between the two data sources is relatively poor for several comorbid measures, with Kappa values ranging from 0.13 to 0.71. The Kappa values provide a statistical assessment of agreement between two data sources, with 1.0 indicating perfect agreement. Levels below 0.50 indicate poor agreement. Agreement between the data sources is also discussed in the section entitled "Reporting of Comorbid Conditions among New Dialysis Patients".

Ischemic heart disease or CAD is a common form of heart disease among ESRD patients. A detailed description of the prevalence of ischemic heart disease among new ESRD patients, as reported by the Medical Evidence Report Form, serves two purposes. First, it serves to emphasize the great burden of coronary disease that is present among new patients starting dialysis, which predicts a shortened life span. Second, it implies that factors responsible for this excess burden of disease are present long before the

initiation of dialysis. The reported prevalence of coronary artery disease among incident dialysis patients in 1997 was 25.1 percent. Prior documented myocardial infarction was recorded on this form in 9.4 percent of new patients (Figure IV-6).

The distribution of coronary artery disease among dialysis patients, both incident and prevalent, has been addressed using data from prior USRDS Special Studies (Bloembergen; Stack 1998a). These data suggest that demographic differences exist in the prevalence of coronary disease. National data collected on incident dialysis patients as reported on the Medical Evidence Report Form also emphasize that similar differences exist. Males were reported to have a greater prevalence of ischemic heart disease and myocardial infarction than females (27.0 percent vs 22.9 percent and 10.6 percent vs. 8.1 percent) (Figure IV-7). Similarly, diabetics were reported to have a greater burden of clinical coronary disease than nondiabetics. The prevalence of ischemic heart disease and acute coronary events was observed to increase with age as it does in the general population as show in Figure IV-8. The distribution of coronary artery disease by race and ethnicity is shown in Figure IV-9. These data confirm observations of other USRDS Special Studies (Stack 1998a; Stack 1998b). White, Native American, and "Other" race had the highest prevalence of ischemic heart disease (CAD) (30.6 percent, 22.0 percent and 19.5 percent

Ischemic Heart Disease (CAD) and Myocardial Infarction (MI) by Race and Hispanic Ethnicity in New Dialysis Patients, 1997*

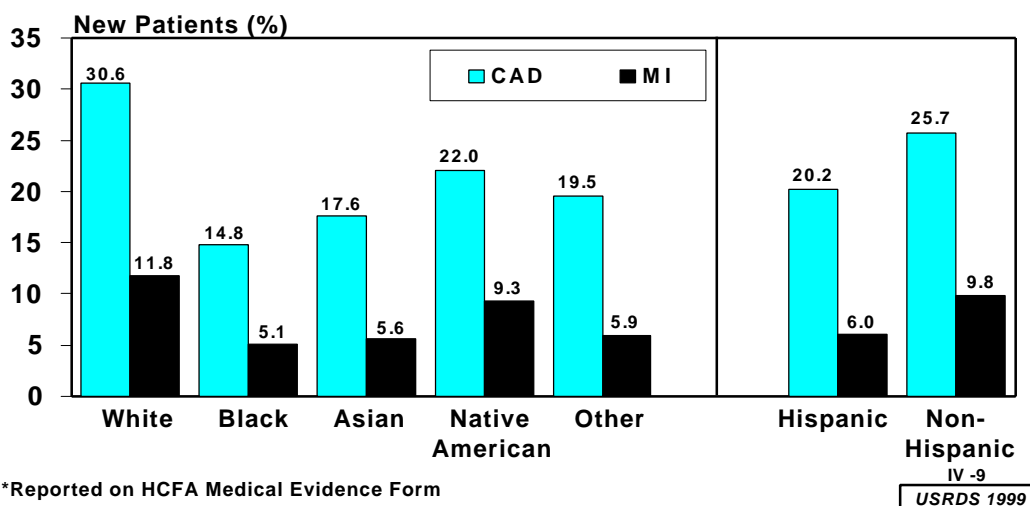


Figure IV-9

Ischemic heart disease (CAD) and Myocardial Infarction (MI) by race and Hispanic ethnicity for new dialysis patients, 1997. Source: Reference Table L.18.

Non-Cardiovascular Patient Characteristics among New Dialysis Patients, 1997*

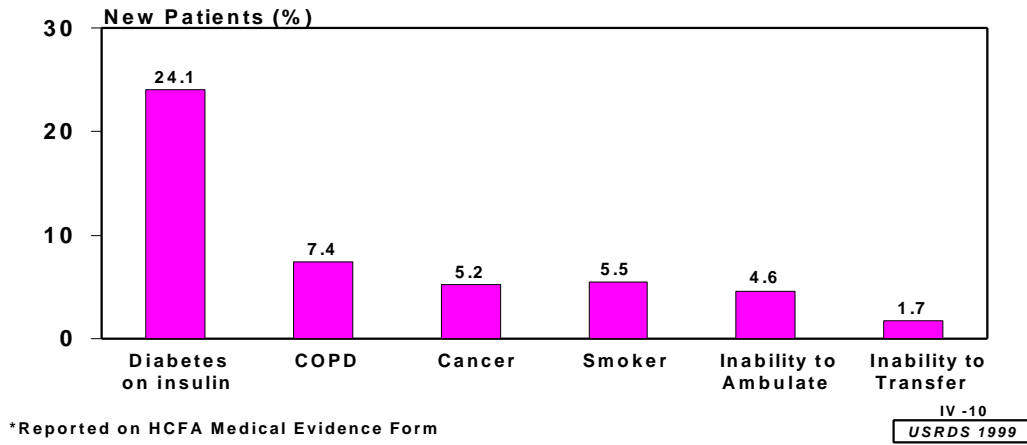


Figure IV-10

Non-cardiovascular patient characteristics among new dialysis patients, 1997. Source: Reference Table L.15.

respectively), while Black and Asian race were reported to have a lower prevalence (14.8 percent and 17.6 percent respectively). Similarly, higher prevalence rates of disease were observed in non-Hispanics than Hispanics. Although these prevalence percentages are unadjusted for several important factors, such as cause of ESRD and age, these differences may be due to differences in the prevalence of cardiac risk factors among racial groups. Alternatively, differences in health seeking behaviors among groups may lead to differences in the rates of detection of coronary disease.

Non-Cardiovascular Comorbidity Indicators Among New Dialysis Patients

Although the presence of cardiovascular disease is a useful indicator of comorbidity experienced by a population, there are several other surrogate ‘health’ markers that can be utilized to describe the well being of dialysis patients. The Medical Evidence Report Form provides data on other comorbid conditions and the functional status of all new ESRD patients. Furthermore, data are also collected on a number of important nutritional markers, including serum albumin and body mass index (calculated from dry weight and height of incident patients). Figure IV-10 describes the prevalence of these “non-cardiovascular” patient characteristics among new ESRD patients in 1997. Among incident patients, 7.4

percent reportedly had a history of COPD, 5.2 percent had a history of cancer, 4.6 percent were reported as unable to ambulate, and 1.7 percent were unable to transfer independently. These data illustrate the impact of disease on functional status among this incident population. Again the reported prevalence of these comorbid conditions were substantially lower than that observed in the DMMS Wave 2 study as shown in Table IV-1.

Figure IV-11 shows the mean serum albumin concentration before first dialysis by year of incidence, and the corresponding mean body mass index (BMI). BMI (a marker of energy nutritional status) is based on the reported dry weight and height for each patient. It is an attempt to determine whether or not an improvement in nutritional status, among new ESRD patients, has occurred over the 4-year period due to improved pre-ESRD care. At first glance, the relatively stable serum albumin throughout this period suggests that this is not the case. However, an improvement may be offset by an acceptance of sicker and older patients for dialysis. It is known that serum albumin may not be a ‘true’ nutritional indicator as it is influenced by a number of inflammatory cytokines (Bergstrom). A better baseline nutritional indicator might be BMI, which has increased slightly from 25.39 kg/m² to 26.05 kg/m² over the same period. These data however are unadjusted for several important demographic factors and comorbidities, which may influence the observed trends.

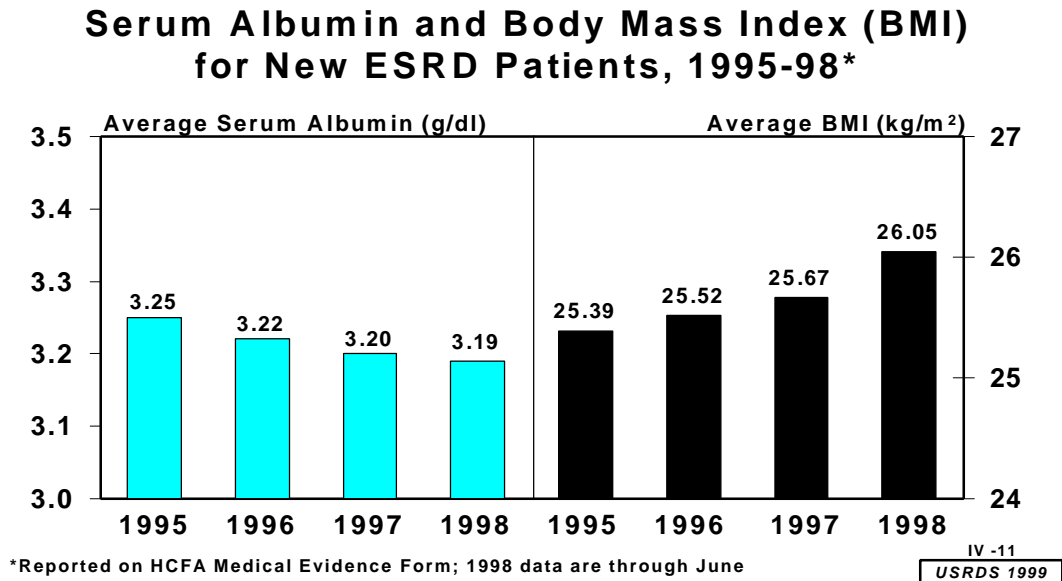


Figure IV-11

Average serum albumin (g/dl) and body mass index (BMI, kg/m²) by year for new ESRD patients as reported on the HCFA Medical Evidence Form, 1995 through June of 1998. BMI is computed as weight/(height)². Source: Reference Table L.21.

In 1998, the mean serum albumin before first chronic dialysis was reported to be 3.2 g/dl (Figure IV-11). This is far below the normal range of 4.0-5.0 g/dl. It highlights the fact that, on average, new patients to dialysis are considered “malnourished”, which maybe related to many pre-ESRD factors and the timing of dialysis initiation. As serum albumin is an important predictor of mortality, both in the short term and for up to 5 years following dialysis initiation (Leavey), our attention should be focused on improving pre-ESRD care and on interventions that might improve nutritional status. Similarly, in 1998 the average BMI was reported to be 26 kg/m² (Figure IV-11). This measure has also been shown to be an independent predictor of mortality among dialysis patients (Leavey).

Reporting of Comorbid Conditions Among New Dialysis Patients

It is recognized that inadequate data recording and the omission of pertinent patient characteristics may affect the validity of the data collected. The potential for poor recording of patient characteristics is increased as the workload of many dialysis units increases and resources are stretched. Longenecker et al. have addressed the issue of validity with respect to

data collected from the medical evidence form as compared to data collected from the Choices for Healthy Outcomes in Caring for ESRD study (CHOICE) (Longenecker). They found that the sensitivity of reporting for comorbid medical conditions was poor using data from the Medical Evidence Report Form, ranging between 17 percent to 78 percent. As such, the prevalence of comorbid medical conditions among new ESRD patients may be underestimated and reduce the validity of analyses utilizing these data.

The comparison of the percentage of comorbid conditions reported in the Medical Evidence Report Form data with the USRDS (DMMS) data can also be used to address the question of the validity of the data collected. The percent agreement (Kappa statistic) was generally low. It was highest for cardiovascular conditions and lowest for non-cardiovascular comorbid conditions. However, as there is no ‘gold standard’ that gives the “true” prevalence of comorbidity, one can only surmise that some conditions may be under-reported and others over-reported. The lack of agreement is of concern in that estimates of the true burden of disease is necessary for determining public health policies and allocating health resources.

In general, the prevalence of reported comorbid conditions was substantially lower for the HCFA Medical Evidence Form data compared to the DMMS Wave 2 data. As mentioned previously, there is likely to be substantial variation in the methods and personnel used to complete the Medical Evidence Report Form whereas the DMMS data collection instrument is completed in a standardized manner by detailed medical chart abstraction. It is conceivable that in many instances the Medical Evidence Report Form is completed using recall rather than using medical records. There has been some discussion as to which measurement technique is likely to be more clinically relevant. On one hand, the detailed chart abstraction is likely to be more complete. However, one may speculate that the use of recall may be more useful as only the clinically more significant conditions are recorded. Of interest is the fact that the presence of various comorbid conditions in both data sources have been predictive of outcome in the past. This suggests that either data source can be used for epidemiological studies. However, there is also the possibility that the section on comorbid conditions is simply “passed over” for some patients. One may speculate that this may not be a random event and that these practices may vary by facility. To further explore this possibility, Figure IV-12 shows the distribution of facilities by average number of comorbid conditions reported per incident patient during 1995-1997, as recorded on the HCFA Medical Evidence Report Form. In 92 percent of facilities,

the average number of comorbid conditions was one or more, with 35.4 percent of facilities having an average of 2 or more. On average, one would expect similar reporting of comorbidities by most facilities. However, as shown in Figure IV-13, this is not the case. In 33 percent of facilities, 20-30 percent of patients had zero comorbid conditions recorded; in 18.7 percent of facilities, 30 to 40 percent of patients have zero comorbid conditions reported; in 7.3 percent of facilities, 40 to 50 percent of patients had zero comorbid conditions recorded, and in a little over 6 percent of facilities over 50 percent of patients had no comorbid conditions reported. This suggests the possibility that there are facilities in which the section on comorbid conditions may simply not be completed for a large proportion of patients. As such, the value of this data source may be compromised. The overall objective to ultimately improve the outcome of patients with ESRD by epidemiological study of these data would be greatly enhanced by improved reporting of these comorbid conditions for all patients. There is a need for an increased awareness of the importance of this type of data collection in the renal community to achieve more accurate and complete reporting of comorbid conditions.

Are Incident Patients in the United States Being Started on Dialysis Earlier?

Distribution of Facilities by Average Number of Comorbidities Reported per Patient, 1995-97*

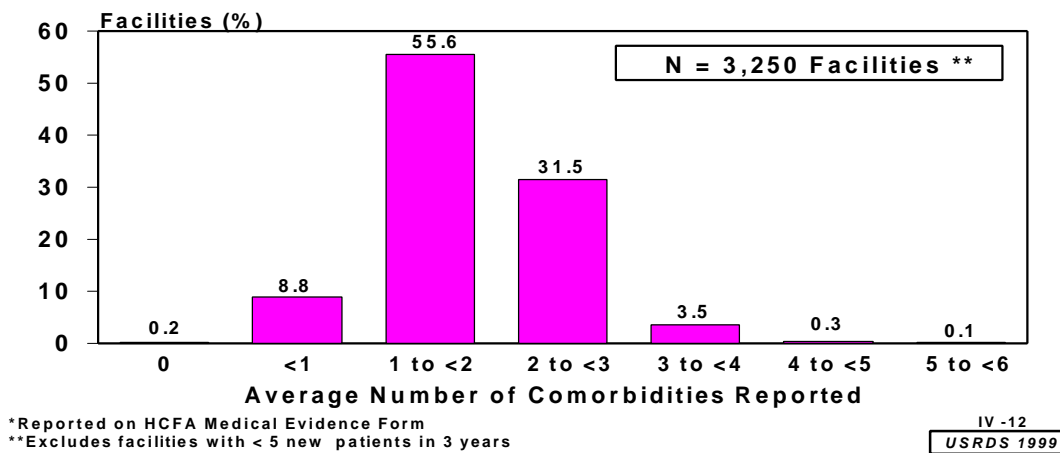


Figure IV-12

Distribution of facilities by average number of comorbidities per patient as reported on the HCFA Medical Evidence Form, 1995-97. Facilities with less than 5 new patients in 1995-97 are excluded. Source: Special Analysis.

Distribution of Facilities by Percent of Patients with Zero Comorbidities Reported, 1995-97*

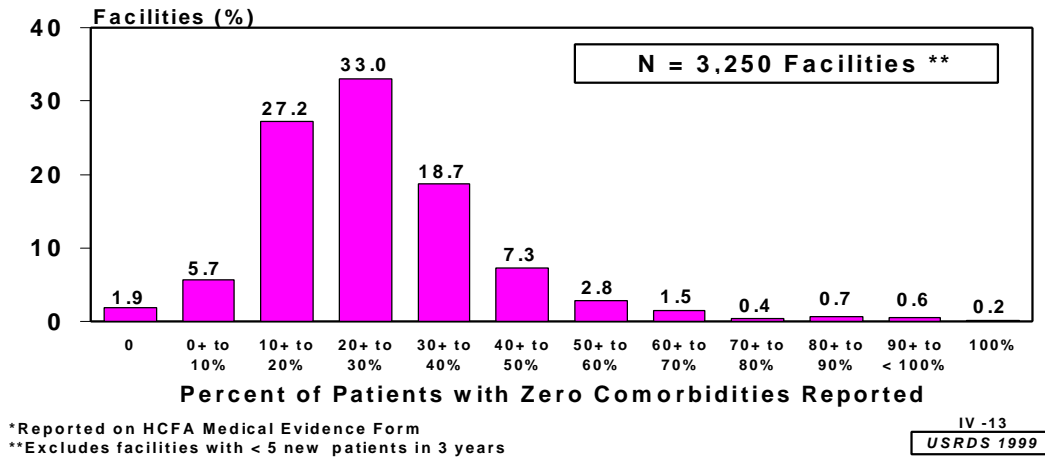


Figure IV-13

Distribution of facilities by percent of patients with zero comorbidities as reported on the HCFA Medical Evidence Form, 1995-97. Facilities with less than 5 new patients in 1995-97 are excluded. Source: Special Analysis.

The timing of dialysis initiation among patients with advanced renal disease is the subject of much controversy. While there are the protagonists of the “early start” hypothesis (Mehrotra), available data are suggestive but not conclusive that earlier initiation of dialysis confers a survival advantage. On the Medical Evidence Form, all new ESRD patients

initiating dialysis have a serum creatinine prior to first dialysis recorded in addition to dry weight and height. From these data, an individual’s residual renal function may be estimated.

Figure IV-14 allows the comparison of the mean serum creatinine to the estimated glomerular filtration rate (GFR) by the Modification of Diet in

Serum Creatinine and GFR for New ESRD Patients by Age Group, 1995-97*

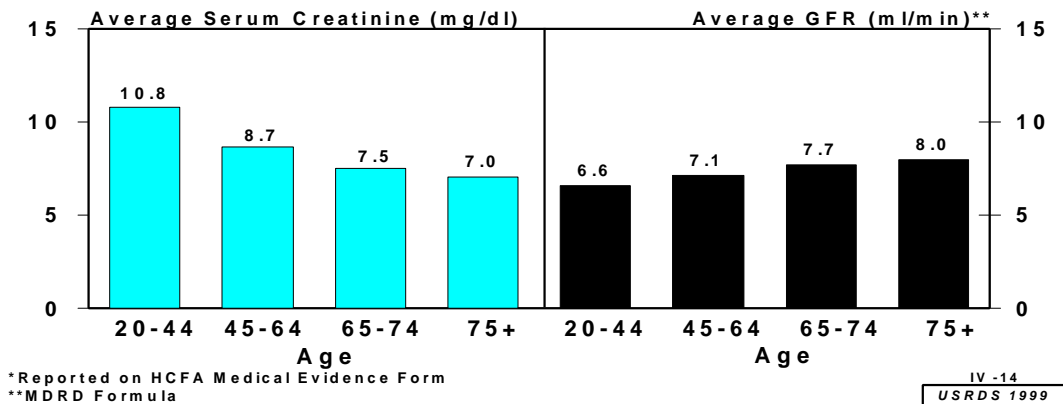


Figure IV-14

Average serum creatinine and GFR for new ESRD patients as reported on the HCFA Medical Evidence Form by age on first service date, 1995-97. Glomerular filtration rate (GFR) is computed using MDRD formula. Source: Reference Table L.23.

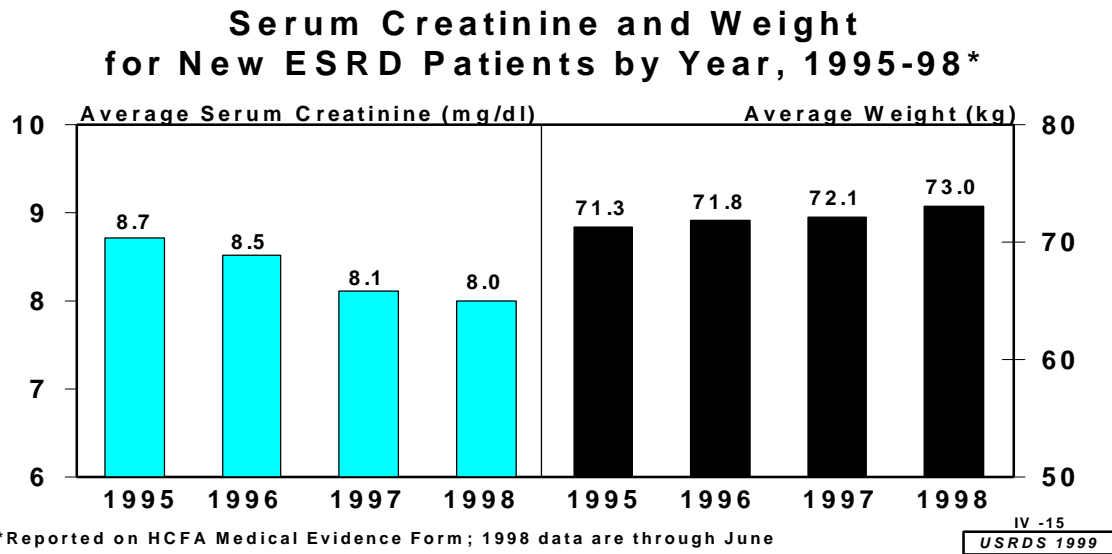


Figure IV-15

Average serum creatinine (mg/dl) and weight (kg) for new ESRD patients by year as reported on the HCFA Medical Evidence Form, incident in 1995-97. Source: Reference Table L.21.

Renal Disease Study Group (MDRD) formula (Levey) in all incident patients at dialysis initiation by age group. Increasing age is associated with a lower mean serum creatinine and a higher level of residual renal function. Thus older patients are initiated on dialysis at higher levels of residual function and lower serum creatinine. A plausible explanation is that older patients are initiated on dialysis earlier because of medical comorbidities or the effects of uremia (as they may be less tolerant of uremic complications than younger patients).

A comparison of mean serum creatinine and weight for all incident patients by year of incidence (Figure IV-15) addresses the question “Are incident patients in the United States starting dialysis Early?” From 1995 to 1998, the mean serum creatinine prior to dialysis initiation has decreased from 8.7 to 8.0. Although this may imply earlier initiation of dialysis among new patients in recent years, the acceptance of older and more malnourished patients (with less muscle mass) may also explain the observed trend. However, the average weight of patients has increased from 1995-1998, suggesting that there may be a trend toward earlier initiation of dialysis.

Pre-Dialysis Erythropoietin Utilization Among New ESRD Patients

The introduction of recombinant erythropoietin (EPO) has resulted in substantial changes in the treatment of anemia among dialysis patients. Nevertheless, anemia remains a common problem among patients with advanced renal insufficiency not yet on dialysis and new ESRD patients (USRDS 1995). Figure IV-16 describes the utilization of EPO before ESRD among new ESRD patients by age and gender from the Medical Evidence Report Form. EPO utilization is seen to increase with increasing age. Gender differences also exist: with females more likely to receive EPO than their male counterparts. Figure IV-17 serves to illustrate differences in EPO utilization among racial and ethnic groups. A greater fraction of Asian and White ESRD patients were receiving EPO prior to dialysis initiation compared to other racial groups. Differences in health seeking behaviors or in referral patterns may be responsible for the observed differences in EPO use. Similarly, EPO use is seen to be less common among Hispanics than non-Hispanics.

EPO Use before ESRD by Age and Gender for New ESRD Patients, 1995-97*

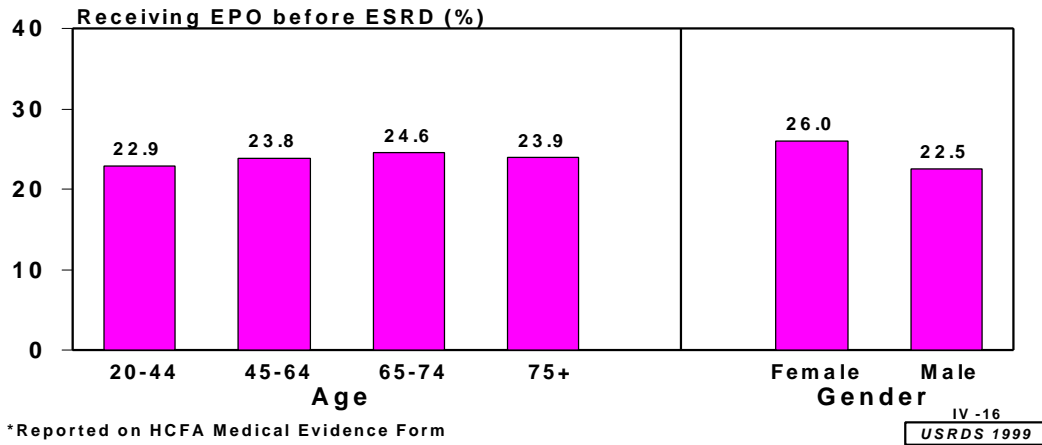


Figure IV-16

Erythropoietin (EPO) use before ESRD by age and gender for new ESRD patients as reported on the HCFA Medical Evidence Form, 1995-97. Source: Special Analysis.

Employment Status Among New Dialysis Patients: Before and at Initiation of Dialysis

Employment rates are low among new ESRD patients for many reasons. The acceptance of older patients with a greater prevalence of comorbid medical conditions contributes greatly to these low employment rates. Figure IV-18 compares em-

ployment status among patients ages 20-64 years, 6 months prior to and at the initiation of dialysis, from the Medical Evidence Report Form. Among the 90 percent of patients with information about their employment status at 6 months prior to dialysis initiation, approximately 32 percent were reportedly employed, 6 percent were homemakers, 1 percent were students, and 27 percent were unemployed. Another 33 percent were retired because of age or their medical condition, and 1 percent were on

EPO Use before ESRD for New ESRD Patients by Race and Hispanic Ethnicity, 1995-97*

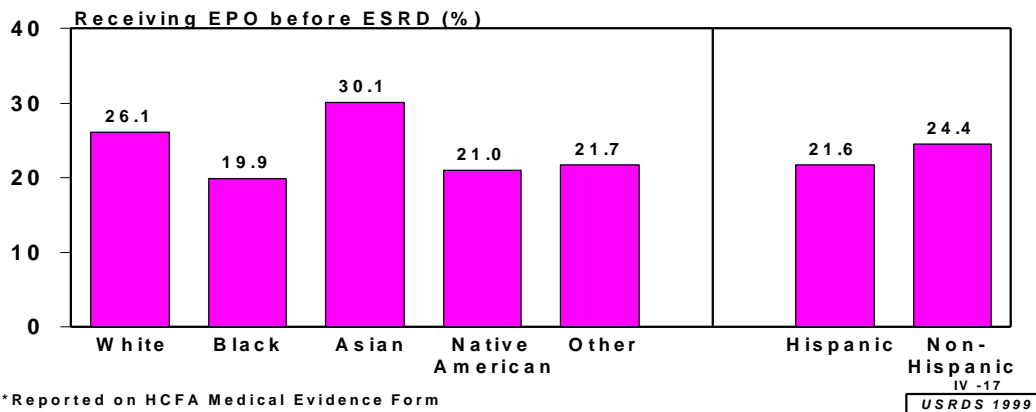


Figure IV-17

Erythropoietin (EPO) use before ESRD by race and Hispanic ethnicity for new ESRD patients as reported on the HCFA Medical Evidence Form, 1995-97. Source: Special Analysis.

Prior vs. Current Employment among New ESRD Patients, Ages 20-64, 1997*

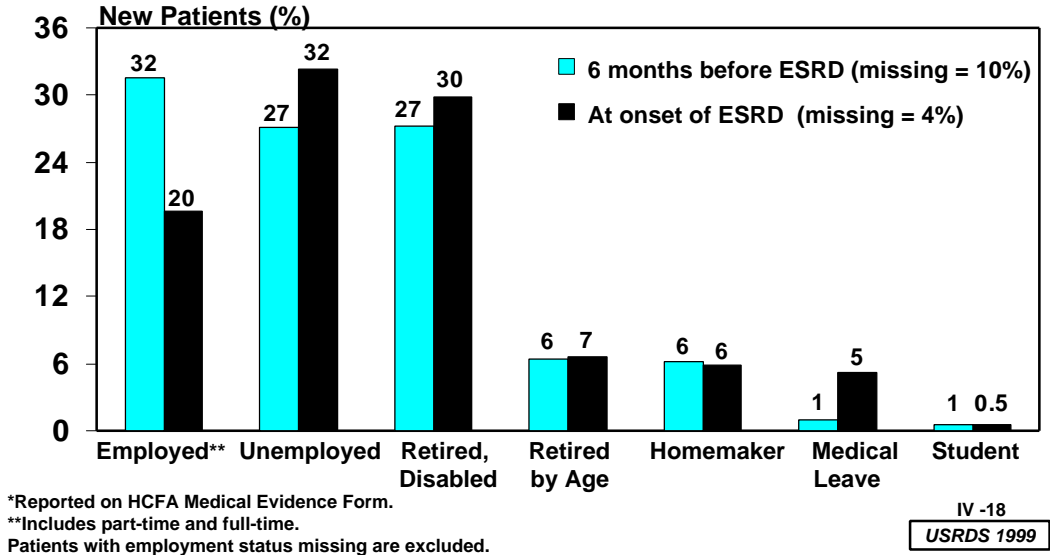


Figure IV-18

Prior and current employment among new ESRD patients (ages 20-64) as reported on the HCFA Medical Evidence Form, 1997. Prior is defined as employment status 6 months prior to ESRD diagnosis. Current is defined as employment status at onset of ESRD. Employed consists of both part-time and full-time employed patients. Patients with employment status missing are excluded. Source: Reference Tables L.13 and L.14.

medical leave of absence.

At dialysis initiation, the percent employed decreased by 12 percentage points or by one third. This change is explained by an increase in the groups labeled as unemployed, retired for disability, and medical leave of absence. Improved pre-ESRD care, particularly during the last 6 months, and achievement of a better health status may help improve employment rates in this patient population.

Summary

Data collected by the new Medical Evidence Report Form are useful in describing the characteristics of new ESRD patients. Such information may also be used to improve comparisons of outcomes between treatments and among facilities as part of quality assurance programs. This ESRD Registration Form offers a unique opportunity to describe the health status of the entire incident ESRD population. Despite the advantages available from this large database, the

limitations must also be recognized. Underreporting of medical conditions by facilities will underestimate the true prevalence of disease among patients. Imprecise estimates will reduce the validity of the data and the derived conclusions. Given the enormous potential afforded to the renal community from data collected on patients from the Medical Evidence Reporting Form, all members of the renal community should be aware of its importance and ensure that there is full and accurate completion of this form.

References

Bergstrom J, Lindholm B. Malnutrition, Cardiac Disease, and Mortality: An Integrated Point of View. *Am J Kidney Dis* 1998; 32: 834-84.

Bloembergen WE: Cardiac Disease in Chronic Uremia: Epidemiology. *AdvRRT* 1997; 4: 185-193.

- Chaveau P, Chadeaux B, Coude M. et al. Hyperhomocysteinemia, a risk factor for atherosclerosis in chronic uremic patients. *Kidney Int* 1993; 43 (suppl 44): S72-S77.
- Gutman RA, Stead WW, Robinson RR. Physical activity and employment status of patients on maintenance dialysis. *N Engl J Med* 1981; 304: 309-313.
- Leavey SF, Strawderman RL, Jones CA, Port FK, Held PJ. Simple nutritional indicators as independent predictors of mortality in hemodialysis patients *Am J Kidney Dis* 31 1998; 31 997-1006.
- Levey AS, Bosch JP, Breyer Lewis J, Greene T, Rogers N, Roth D. MDRD Study Group: A more accurate method to estimate glomerular filtration rate from serum creatinine: A new prediction equation. *Ann Intern Med* 1999; 130: 461-470.
- Lindner A, Charra B, Sherrard DJ, et al: Accelerated atherosclerosis in prolonged maintenance hemodialysis. *N Engl J Med* 1974; 290: 697-701.
- Longenecker JC, Klag MJ, Coresh J, Levey AS, Martin AA, Fink NE, Powe NR Validation of comorbid conditions on the ESRD Medical Evidence Report by medical record review: The choices for healthy outcomes in caring for ESRD (CHOICE) study. *J Am Soc Nephrol* 1998; 9:218A.
- Mehrotra R, Nolph KD. Argument for timely initiation of dialysis. *J Am Soc Nephrol* 1998; 9: 596-599.
- Stack A, Bloembergen WE. Predictors and clinical correlates of coronary artery disease among incident U.S. dialysis patients. *Am Soc Nephrol* 1998a; 9: 227A.
- Stack A, Bloembergen WE. Congestive Heart Failure among incident U.S. dialysis patients: predictors and clinical correlates. *Am Soc of Nephrol* 1998b; 9: 226A.
- Special Report from the National Kidney Foundation Task Force on the Cardiovascular Disease: Controlling the Epidemic of Cardiovascular Disease in Chronic Renal Disease: What do we know? What do we need to know? Where do we go from here? *Am J Kidney Dis* 1998 32: Suppl 3.
- U.S. Renal Data System Comorbid conditions and correlations with mortality risk among 3,399 incident hemodialysis patients. *Am J Kidney Dis* 20 (Suppl 2): 32-38 1992.
- U.S. Renal Data System, USRDS 1995 Annual Data Report. The National Institutes of Health, National Institutes of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, April 1995.
- U.S. Renal Data System, USRDS 1996 Annual Data Report. The National Institutes of Health, National Institutes of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, April 1996.
- U.S. Renal Data System, USRDS 1997 Annual Data Report. The National Institutes of Health, National Institutes of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, April 1997.
- U.S. Renal Data System, USRDS 1998 Annual Data Report. The National Institutes of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, April 1998.
- Witzum JL, Steinberg D: Role of oxidized low density lipoprotein in atherogenesis. *J Clin Invest* 1991; 88:1785-1792.