# Chapter XIV

# Analytical Methods

This chapter discusses the analytical methods used in this *1995 Annual Data Report* (ADR), and the differences between this ADR and the *1994 ADR*. The *Researcher's Guide to the USRDS Database* provides additional detail about the database and the Standard Analysis Files (See Chapter I).

## Differences Between 1994 and 1995 Reports

**1) New Data.** The largest change is the addition of a new year of data. Data are now reported through 1992 for detailed patient data and through 1993 for provider-based data. Some basic counts are projected and/or estimated from 1993 patient data as well. There are also changes in data which apply to years reported in past ADRs. This includes data which are delayed in reaching the USRDS database, and new sources of data, such as increased reporting by Department of Veterans Affairs facilities. See "New Data in the Database" below.

For Chapter X, Cost Effectiveness, claims data were obtained from the Health Care Financing Author (HCFA) for 1,700 Medicare eligible incident patients from the Case Mix Adequacy Special Study. See "New Data in the Database" below.

**2) Death Notification Form** A new ESRD Death Notification Form (HCFA-2746) came into use during 1990. More detailed cause of death categories are used on the new form. On the old form, withdrawal from dialysis was one of the possible causes of death. On the new form, whether ESRD treatment was stopped prior to death is asked separately from the cause of death question, and withdrawal from dialysis is no longer in the list of causes of death.

Because of these changes, the cause of death tables in Section D of the Reference Tables use only the new codes. Cause-specific rates are computed only for a two year period because 1991 and 1992 are the only years with complete data in which only the new form was used. Other death rate tables use a 3 year period. In addition, a table of death rates by the new codes for withdrawal from treatment are also provided. Chapter VII discusses the impact of this change.

**3) Death rate methodology.**

The basic death rate methodology is unchanged from the 1994 ADR, as discussed under "Annual Death Rate Methodology" below. The death rate tables continue to include incident patients and dialysis patients who have had a prior transplant as well as prevalent dialysis patients.

One change in the tables is that cause-specific death rates are computed for patients with a functioning transplant at the beginning of the year. This was necessary because there are only two years of data available with the new death cause codes. In the 1994 ADR, death rates for transplanted patients were computed for three years and started with the date of transplant.

Although the death rate tables in Section D of the Reference Tables are unadjusted for computation of Standard Mortality Rates, the tables appearing in Chapter VII are adjusted for relevant socio-demographic factors, treatment differences and underlying disease differences.

**4) Standard population for adjustment.** The adjusted incidence, prevalence, survival, and death rates in this ADR now all use 1991, the year before the most recently reported year, as the standard population for adjustment. In the 1994 ADR, the 1990 Census population was used for adjusting incidence and prevalence rates, but 1991 ESRD population was used for adjusting survival rates.

## Incidence Counts by Year by Database Update Year and Change in Counts Between Updates For Updates from 1989 through 1994

| | Year of Update | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Incident** | **1989** | | **1990** | | **1991** | | **1992** | | **1993** | | **1994** |
| **Year** | (1989 ADR) | | (1990 ADR) | | (1991 ADR) | | (1993 ADR) | | (1994 ADR) | | (1995 ADR) |
| 1983 | 24929 | 0.25% | 24991 | 0.12% | 25020 | 0.57% | 25,163 | 0.02% | 25169 | -0.02% | 25163 |
| 1984 | 26336 | 0.24% | 26399 | 0.29% | 26475 | 0.59% | 26,631 | 0.19% | 26681 | -0.01% | 26677 |
| 1985 | 29156 | 0.25% | 29228 | 0.46% | 29361 | 0.79% | 29593 | 0.18% | 29647 | 0.04% | 29658 |
| 1986 | 31195 | 0.64% | 31394 | 0.64% | 31594 | 0.68% | 31,810 | 0.21% | 31876 | 0.11% | 31911 |
| 1987 | 33578 | 1.43% | 34058 | 1.10% | 34433 | 0.88% | 34,737 | 0.49% | 34908 | 0.18% | 34971 |
| 1988 | | | 36160 | 2.69% | 37133 | 1.59% | 37,723 | 0.72% | 37994 | 0.33% | 38120 |
| 1989 | | | | | 41269 | 2.44% | 42,278 | 1.00% | 42702 | 0.58% | 42949 |
| 1990 | | | | | 39863 | 14.76% | 45,745 | 1.56% | 46458 | 0.68% | 46775 |
| 1991 | | | | | 1938 | | 46803 | 8.30% | 50689 | 1.21% | 51301 |
| 1992 | | | | | | | 5480 | | 50523 | 9.84% | 55495 |
| 1993 | | | | | | | | | 5746 | | 53879 |
| 1994 | | | | | | | | | | | 8233 |

Notes: The horizontal line indicates the last year reported from this update. The percentages are the percent changes from the year on the left to the year on the right.

**Table XIV-1**

**5) State and Network Rates** The new availability of a consistently defined series of Census Bureau data by state and county from 1981 on allows incidence and prevalence rates by state and by ESRD Network to be computed for the past 10 years rather than just for the most recent year as in past reports.

**6) Race code** The race codes now in use by the Medicare system include a Hispanic category. This creates an inconsistency with the race categories reported on the ESRD Medical Evidence Form. This will result in a slight increase in the number of patients classified as "Other" race.

**7) Minimum Aggregation Size.** As in the 1994 ADR, in the Reference Tables and in the graphics and tables in the text, aggregations of less than 10 persons generally are not reported. This is consistent with the restriction imposed by Section F of the USRDS Agreement for Release of Data.

This restriction is imposed to insure the confidentiality of patient-specific data. In a cross-tabulation of patients by patient characteristics, if an individual cell in the table represents only one person, then it is conceivable that one could identify that person and learn something about that person. By restricting cell sizes to 10 or more persons, such identification becomes virtually impossible. The general convention in the Reference Tables is to replace the number with an asterisk (*) in cells which are based on less than 10 patients.

The above changes in data, methodologies, and methods mean that care must be used when comparing data between ADRs for different years. However, this ADR follows the USRDS policy that each ADR present data for a series of years using a consistent set of definitions so that the reader can make valid comparisons among years within that report.

## Completeness of the data

Recent analysis of the patients in the Case Mix Adequacy special study suggests that the HCFA PMMIS file may understate the number of ESRD patients by as much as 5 percent. This is suggested by the proportion of patients in this sample whom the dialysis facility recorded as Medicare but who are not in the PMMIS file. The USRDS is continuing to evaluate this question using a variety of data such as the HCFA billing files, the Facility Survey, the master Medicare Enrollment Database, and the census of dialysis patients which was generated by the ESRD Networks as a base for selecting the sample for the new DMMS special study.

## New Data in the Database

Table XIV-1 shows the incidence counts by year as reported in the 1990 through 1995 ADRs. Each ADR shows higher incident counts for all years than

## Change in Yearly Incident Counts From Prior Update, by Number of Years Before Update Year

| Prior Year | Year of USRDS Database Update: 1992 (1993 ADR) | 1993 (1994 ADR) | 1994 (1995 ADR) | Average | Expected Cmulative After first report | |
|---|---|---|---|---|---|---|
| -9 | 0.00% | 0.02% | -0.01% | 0.00% | | |
| -8 | 0.57% | 0.19% | 0.04% | 0.27% | 5.01% | 8th yr |
| -7 | 0.59% | 0.18% | 0.11% | 0.29% | 4.74% | 7th yr |
| -6 | 0.79% | 0.21% | 0.18% | 0.39% | 4.45% | 6th yr |
| -5 | 0.68% | 0.49% | 0.33% | 0.50% | 4.06% | 5th yr |
| -4 | 0.88% | 0.72% | 0.58% | 0.73% | 3.55% | 4th yr |
| -3 | 1.59% | 1.00% | 0.68% | 1.09% | 2.83% | 3rd yr |
| -2 | 2.44% | 1.56% | 1.21% | 1.74% | 1.74% | 2nd yr |
| -1 | 14.76% | 8.30% | 9.84% | 10.97% | | |

Example: The outlined cell refers to the second year before 1994 (1992). The incidence count reported for 1992 increased by 1.21% from the 1993 update (reported in1994 ADR) to the 1994 update (reported 1995 ADR). Data below the line are not reported.

The Average column is an average of the changes over the past 3 updates.

The Expected Cumulative column is based on the average change column. It shows how much we expect the second year before the update year (1992 for the 1994 update, first reported in the 1995 ADR) to grow in years after that year is first reported.

**Table XIV-2**

did the previous ADR. The greatest increases occur in the most recent two years.

Table XIV-2 presents these changes from a different perspective. The years are shown relative to the year of the update rather than as calendar years. Table XIV-2 illustrates the reason for this: the data for the year prior to an update show changes on the order of 8 percent to 14 percent on the next update. The incidence counts can be expected to increase by 5% over the 8 years starting with the ADR in which the year is first reported.

The increases in incidence counts for past years from update to update may be due to at least three factors:

**Delays in receiving data**. This is probably the main factor in the most recent years. The USRDS generally waits 15 months before reporting data for a given time period because of this problem.

An example of a delay in receiving data is a patient who is covered under private health insurance and for whom Medicare would be the secondary payer for the first 21 months. If the private health insurance covers all of the dialysis costs, then the Medical Evidence Form might not be filed until a year or more after the start of ESRD. Since there may be no Medicare claims, the patient will not appear in the USRDS database until the Medical Evidence Form is filed. When the form is filed, the date of start of chronic renal dialysis entered on the form should be the date dialysis started, even though it was not covered by Medicare at that point. Thus this patient appears as an incident case in the earlier year rather than the year in which the form was filed.

**New data sources.** The data starting with the 1993 ADR include Department of Veterans Affairs (DVA) patients being reported to HCFA for the first time. This is one reason the percentage increases shown in Table XIV-1 are higher for the 1993 ADR than for prior ADRs.

For the 1995 report, Medicare claims data for 1990 through 1993 were obtained from HCFA for 1,700 ESRD Medicare eligible patients who were incident patients in the Case Mix Adequacy Study. Hospital inpatient, skilled nursing facility, hospice, home health agency, and outpatient, both freestanding and hospital, data were obtained for the study and were aggregated for the patients. These data have served as a pilot for developing the methods for adding Medicare claims data for all patients in the database.

**Delays in Medicare eligibility**. If a patient is covered by some other insurance (such as DVA) for four years and then becomes eligible for Medicare and has a Medical Evidence Form filed, his/her first service date would be four years prior to appearing in the file.

**Errors in first service date.** The physician completing the Medical Evidence Form may report the first dialysis ever rather than the start of maintenance dialysis. There may be clerical or keypunch errors in the year of the first dialysis date. The software for determining first service date may be wrong. Thus, patients added in a given update can appear as incident in a much earlier year. If a first service date is corrected, then a patient may appear as incident in a different year than in a previous database update.

### The "Fifteen Month Rule"

The USRDS generally does not report data for periods later than 15 months prior to the update date. Because of delays in the submission and processing of Medicare bills, these data generally are not considered to be complete until 15 months have passed. Thus, although we have data through June 1994, the data are only considered complete through March 1993, and this *ADR* reports results only through December 31, 1992.

The USRDS CC is currently evaluating this rule. Some analyses in this ADR use data from 1993. These analyses are labeled as preliminary and should be treated with caution.

## Death Notification Form

In March of 1990, a new ESRD Death Notification Form (HCFA-2746) came into use. A few deaths from 1989 were reported in 1990 using the new form. Both forms were in use in 1990. After 1990 only a few old forms were filed.

The new form uses a new set of codes and categories for cause of death. Another substantial change is that withdrawal from dialysis is no longer a cause of death, but a separate question asks whether the ESRD treatment was stopped before the patient died and the reason for such stoppage.

In the past two ADRs, the cause of death categories from the new form were recoded into the categories used on the old form. Patients who stopped treatment before death were recoded into the withdrawal from dialysis category. This resulted in an increase in the withdrawal category from about 10% of the total in 1989 (old form) to about 16% in 1991 (new form). It seems likely that most of this change is due to the change in coding. For this reason, cause-specific death rates are reported only for the 1991-1992 period, during which only the new form was in use.

## Geography

Starting with the 1993 ADR, Puerto Rico and United States Territories have been reported separately from the 50 states and the District of Columbia in the incidence and prevalence Reference Tables (Tables A.1, A.3, B.1, B.4).

The population base used in computing incidence and prevalence rates is United States resident population, which includes only the 50 states and D.C. For Puerto Rico and United States Territories, only counts are reported, and rates are not computed. Puerto Rico, the Virgin Islands, and the Pacific Territories are not included in computing the incidence and prevalence rates in Sections A and B for the New Jersey and Northern California ESRD Networks, respectively. In Reference Tables sections other than A and B, all patients are counted, and tables by Network include Puerto Rico, the Virgin Islands, and the Pacific Islands.

## Measurement Concepts: Incidence, Acceptance, and Prevalence

Incidence and prevalence are two concepts used in measuring the extent of a disease. The incidence of a disease is the number of persons diagnosed with that disease in a given time period, typically a year. Prevalence is the number of persons who have that disease at a given point in time (point prevalence) or who have the disease during a given time period (period prevalence). Thus, annual period prevalence consists of persons who have the disease at the end of the year plus those who had the disease at some time during the year and died before the end of the year. The prevalence measures combine the effects of those who get the disease (incidence) and those who die (mortality).

Note that the USRDS considers successful transplantation as a therapy rather than a "recovery" from ESRD.

The terms "incidence" and "prevalence" of ESRD imply that information is available about all patients with ESRD, but, as discussed earlier, this is not the

case. Actually, the data are for persons receiving ESRD therapy as reported through HCFA and do not include patients who die of ESRD before receiving treatment and those who are not reported through HCFA. For these reasons, the terms incidence and prevalence are qualified as incidence and prevalence of reported ESRD therapy.

As discussed earlier and in Chapter XIV, patients are classified as lost to follow-up if one year has passed with no dialysis, death, or transplant data. Starting with the 1992 ADR, these patients are not included in the point prevalence counts. The Reference Tables show the number of patients not counted for this reason.

The term "acceptance into ESRD therapy" is used by some other ESRD registries, such as the European Dialysis and Transplantation Association. The USRDS chose not to use this term because "incidence of reported ESRD therapy" is more precise, and because "acceptance" implies that the remaining patients are rejected, when in fact they may be unidentified as ESRD cases or unreported through HCFA.

Incidence tends to be a more useful measure for medical and epidemiological research which examines the causes of disease and the differences in how sub-populations are affected by these causes. Point prevalence may be more useful for public health research, since it measures the overall burden of the disease on the health care delivery system. Period prevalence may be more useful for cost analysis, since it indicates the total burden of the disease over the course of the year.

Sections A and B of the Reference Tables present parallel sets of counts and rates for incidence and December 31 point prevalence. Section B also presents annual period prevalence counts (but not rates). This de-emphasis of period prevalence reflects our experience over the past year with the general lack of demand for more than overall counts of period prevalence.

### Census Population Base

Incidence and prevalence counts indicate the absolute level of occurrence of ESRD as defined by its treatment. Incidence and prevalence rates per million population indicate the level of the disease relative to the population and provide a convenient method of comparing the occurrence of the disease over time, among population subgroups, and with other diseases. This report generally uses rates per million population, although for some tables rates per ten million population are used. The size of the population base is chosen largely to produce rates with three significant digits to the left of the decimal point. Rates for diseases which occur more frequently than ESRD might use a smaller population base size.

Note that rates for a specific age/sex/race population group use that group for both the numerator and denominator of the rate. Thus the incidence rate for 40-45 year old white males uses the Census population counts for 40-45 year old white males as the base. Rates by primary disease causing ESRD for 40-45 year old white males also use the Census population counts for 40-45 year old white males as the base.

The population base for computing incidence rates is the total United States resident population on July 1 of each year by race, sex, and age. For point prevalence rates, the population on December 31 is used. Race is divided among four race groups: black, white, Asian, and Native American. Age is divided among eighteen five-year age groups: the first group includes persons who are 0-4 years of age, while the 18th group includes persons who are 85 years of age and older. For this ADR, rates are reported for 1983 through 1992. Section J of the Reference Tables shows the July 1 population counts. The December 31 counts were computed as the midpoint between the July 1 counts for adjacent years.

### Race Classifications

The race codes in the USRDS database classify patients into the categories of Native American/Alaskan Native, Asian/Pacific Islander, Black, White, Other, and Unknown. As mentioned earlier, the Native American and Asian categories became available only with patients starting ESRD therapy in 1982. Since 1982, the proportion of new patients in the Other and Unknown categories has remained under two percent.

Incidence and prevalence rates are computed and adjusted by race using only the following categories: black, white, Asian, and Native American. Only counts are reported for the "other" and "unknown" categories, and these categories are dropped from all tables which report rates by race. In addition, rates by race are only reported for years starting with 1982 because of the change in the reporting of race that year.

Only four categories are used in computing incidence and prevalence rates because the Census population estimates used in computing the rates place the entire population into four categories and do

not include a residual "other" or an "unknown" category. Since almost two percent of the patients in the USRDS database fall into the "other" and "unknown" categories, the rates reported in this report will be biased slightly low. If bias is uniform across races, then comparisons of rates by race are not significantly biased.

The USRDS is not able to produce tabulations for the Hispanic population because it does not have this data item for all patients. An item on Hispanic ethnicity will appear on the new HCFA Medical Evidence Form, which will go into use in 1995, so that this item will be available for most patients starting ESRD in 1995 or later.

As mentioned earlier, the race codes now in use by the Social Security Administration include codes for Asian American, Native American, and Hispanic. The treatment of Hispanic as a race category is inconsistent with the classifications used by the Census Bureau. In Census tabulations, Hispanic is a category separate from race.

The race recorded in the Social Security records is one of the sources of race in the USRDS database, along with the Medical Evidence Form. The effect of this change in the coding of race will be a small increase in the number of patients identified as Asian, Native American, and other. Patients with Hispanic as the Social Security race code are recoded as "other" if race from the Medical Evidence Form is not available.

## Adjustment and Standardization of Rates

Adjustment or standardization of rates is a method for comparing rates between different sub populations or time periods to remove the effect of differences in the composition of the populations being compared. For instance, blacks with ESRD have a younger age distribution than do whites. One way to remove the effect of this age difference on observed rates is to compare the rates for specific age groups between blacks and whites. Age adjustment provides a method of obtaining summary rates (across age groups) for blacks and whites with the effect of age differences removed.

Age adjusted rates indicate what the rates for the two groups, for example blacks and whites, would have been if the age specific rates for each age group had occurred in the same standard population. Age adjustment operates by taking the age specific rates for blacks, applying them to a standard population distribution stratified by age, summing the resulting ESRD population, and computing a new overall rate per million population using the total of the standard population. The same procedure is followed for whites. After age adjustment, the overall 1986 incidence rate for blacks changes from 300 to 373, and that for whites changes from 105 to 99. Blacks have higher rates of ESRD than whites at almost every age group, but the fact that the black population has a younger age distribution masks some of this difference in the across age unadjusted rates, since there are relatively fewer patients in the younger age groups.

It is now USRDS practice to use the relevant population from the most recent reported year as the standard population for adjustment of rates. However, in this ADR, the year before the most recently reported year was used. For adjustment of incidence and prevalence rates in Sections A and B of the Reference Tables, the standard population is the July 1, 1991, United States resident population by five-year age groups, four race categories, and sex. For adjustment of patient survival rates in Section E, the standard population is the 1991 incident ESRD population. For adjustment of graft survival rates in Section G, the standard population is all patients transplanted in 1989 through 1991.

The adjustment method described here is the "direct standardization" method and is the method used through most of this report. For the rates by state and ESRD Network in Sections A and B of the Reference Tables, the "indirect standardization" method is used because of problems with small population counts (Fleiss).

In addition to adjustment by age, the tables in this report frequently adjust by race and sex or appropriate combinations of the three factors. For instance, in one of the standard table formats, rates by age are adjusted by race and sex, rates by race are adjusted by age and sex, rates by sex are adjusted by age and race, and rates by primary diagnosis and overall rates by year are adjusted by age, race, and sex. Adjustment for multiple factors requires stratifying the populations by the multiple factors rather than just by age. Such adjustments are particularly useful when comparing rates over time to control for the changing characteristics of the ESRD population. Most tables showing adjusted rates are followed by a parallel table showing standard errors of the adjusted rates.

It should be noted that the process of standardization across age, race, and sex produces rates that are different than those encountered if considering one rate separately. For example, someone familiar with the total ESRD incidence rate for 1987 would find the adjusted rate (135/million population, see Reference Table A.6) to be lower than the real or "crude" rate (139/million). This difference does not indicate that the standardized rate is incorrect; rather, the standardized rate is "adjusted" so that rates for 1987 can be compared to rates for all of the other years (1982-90), regardless of changing age, race, and sex compositions of the ESRD population during these years.

Thus, while standardized rates are not "real" in one sense, they are the most useful measures for comparing rates across strata or years. If one is interested in the actual rate for any one year, then the unadjusted rates should be used.

## Annual Death Rate Methodology

Section D of the Reference Tables presents death counts and death rates expressed as the number of ESRD patient deaths per 1,000 patient years at risk. The death rates are computed based on calendar year periods. In order to increase the stability of the estimated death rates, three years (1988-1990) are pooled for the tables. Death rates are presented by age, race, sex, and primary disease.

This death rate methodology has been used by the USRDS since 1991. It was designed to be used by ESRD Networks and dialysis and transplant facilities based on data about a group of patients. These death rate tables can be used to compare local ESRD mortality rates to national rates. (Wolfe) The time period for the local data does not need to be a calendar year and can be more or less than one year in length as long as the period at risk is measured in units of years and all other aspects of the methodology are followed.

Tables of death rates by cause of death age, race, sex, and primary disease are also included.

In response to suggestions from users of this methodology, some major changes were made starting with the 1994 ADR: patients starting ESRD therapy during the year are included, previously transplanted dialysis patients are included, different categories of patients are used, and a different methodology is used for patients with functioning transplants.

**Incident Patients**. The original methodology was based only on patients alive on January 1 who had reached day 91 of ESRD and followed those patients for the rest of the calendar year. Patients who entered ESRD therapy during the year did not enter the analysis until January 1 of the following year. This means that one third of the patients in a given dialysis unit are likely to be excluded from the analysis. In the new methodology, patients who reach day 91 of ESRD during the year are included in the analysis and are followed from that day until the end of the calendar year (or until the censoring date for other time periods).

**Previously Transplanted Patients.** In the original methodology, previously transplanted dialysis patients were excluded. The 1992 ADR reported that previously transplanted dialysis patients had a nine percent lower mortality rate than did never-transplanted dialysis patients and accounted for 13 percent of all dialysis patients. In order not to lose those 13 percent from the analysis, the new methodology has patients re-enter the analysis on the first of the year after a transplant failure. In the future, this may be revised to have the patient re-enter the analysis 60 days after the transplant failure.

**New categories.** Below is a list of the categories for which mortality rates are reported in this ADR, along with an explanation of the changes in the categories:

- All dialysis patients. *No longer restricted to those who have not received a transplant.* The period at risk is censored at transplant date if a transplant occurs during the year.
- Dialysis patients who are on hemodialysis (including home hemodialysis) at the start of the period and who have been on this modality for at least 60 days. *No longer restricted to those who have not received a transplant.* The period at risk is censored at the time of a new transplant.
- Dialysis patients not yet transplanted who are on CAPD or CCPD at the start of the period and who have been on this modality for at least 60 days. *No longer restricted to those who have not received a transplant.* The period at risk is censored at the time of a new transplant.
- All ESRD patients.

The "All ESRD" category will be less useful than the others but is included for completeness and as an

overall reference. The following categories have been replaced by the separate methodology for patients with a functioning graft, which is described later.

- All patients with a functioning transplant.
- Patients with a functioning cadaveric first transplant.

The cohort of patients used in this method is defined as those who are alive and not lost to follow-up at the beginning of a year, and who have had ESRD for at least 90 days, plus those patients who reach day 91 during the year. A patient who dies on December 31 of the prior year is excluded, but a patient who dies on January 1 is included with one day at risk. In effect, we are assuming that all deaths occur at 11:59 PM on the death date. Eliminating lost to follow-up patients is a change introduced with the 1992 Annual Data Report.

### Annual Death Rates for Dialysis and All ESRD

All patients who have reached day 91 of ESRD on January 1 or who reach day 91 later in the year are included and are followed until the end of the calendar year. The starting date is either January 1 or the day the patient reaches day 91 of ESRD.

Patients who have a functioning transplant on the starting day are included only in the "All ESRD" category. Patients who are on dialysis on the starting date are also included in the "All Dialysis" category. A patient in the "All Dialysis" category may also be reported in one of two sub-groups (Hemodialysis or CAPD/CCPD) based on the dialysis modality on the starting date and whether the patient has been on that modality for at least 60 days. Dialysis patients who are not on hemodialysis or CAPD/CCPD or who have been on that modality for less than 60 days are included only in the "All ESRD" and "All Dialysis" categories. Note that a given patient may be included in one ("All ESRD" only), two ("All ESRD" and "All Dialysis") or three ("All ESRD", "All Dialysis", and hemo or CAPD) categories.

For patients alive on January 1 to be classified as a hemodialysis or CAPD/CCPD patient, the patient must have been on the indicated treatment modality for 60 days before the start of the year. For incident patients, the 60 day test is applied on day 91. For patients returning from a transplant, the 60 day test is applied when they re-enter the analysis on the next January 1.

In determining whether the patient has been on the same modality for at least 60 days, a short (less than 60 days) spell on a different modality is not considered a change in modality if it is preceded and followed by periods of at least 60 days on the primary modality. See Chapter XIII of the 1992 ADR or the *Researcher's Guide to the USRDS Database* for a description of the application of this "60 day rule."

The denominator for the mortality rate is patient years at risk. For the "All Dialysis" category, the period at risk is from the starting date through the death date or December 31, whichever is earliest. For patients on dialysis at the beginning of the year, the period at risk is from the starting date through the death date, the date of the next transplant (if any during the year), or December 31(again, whichever is earliest). Note that a dialysis patient who is transplanted during the year will have different periods of risks when he is used in the "All ESRD" and "All Dialysis" categories.

Note that the period at risk is not censored at the start of a lost to follow-up period during the year. Note also that if a patient is on dialysis and receives a transplant on January 1, then the days at risk are censored at the transplant date, and the patient has 0 days at risk.

Each patient contributes his/her years at risk to the denominator. The numerator is the number of deaths which occurred during the at risk periods. If death occurs during the at risk period for that patient, then the patient contributes a death to the numerator. Days at risk are divided by 365.25 to yield years at risk. The ratio is multiplied by 1,000 to yield deaths per 1,000 years at risk.

Years may be pooled in this method to increase the cell sizes, as is done in Section D of the Reference Tables. The analysis is still done in one year increments. A patient who is alive at the beginning of more than one of the pooled years will be used more than once in this method. A patient who dies during the second of the three years would contribute a full year at risk for the first year and a partial year at risk and one death for the second year. For each year, the patient's age and treatment modality will be determined as of the beginning of that year. Thus, a patient could be classified as a 45 year old dialysis patient one year and as a 46 year old functioning transplant patient the next.

It should be noted that this method excludes about 14 percent of the deaths which occur in a given year. About 10 percent are excluded because the patient

died before day 91 of ESRD, and about 4 percent are excluded because the patient is classified as lost to follow-up on January 1.

### Annual Death Rates for Transplant Patients

Beginning with the 1994 this ADR, annual death rates for the first year post transplant and for the next two years post transplant are reported for patients transplanted in the previous three years, i.e. 1988-1990. The last transplant year is 1990 so that it is possible for all of the patients to experience three years post transplant, if they survive. The denominator for both rates is still the patient years at risk. For the first year rate, patient years are measured in days from the date of transplant to the death date or the end of the year for the first year at risk, i.e., 365 days exactly. For the rate for the second two years, the time at risk is measured from the anniversary date, i.e., exactly one year (365 days) following the transplant date, to the death date or the end of the period, i.e., exactly two years at risk.

Mortality rates for transplant patients with functioning grafts older than three years are not reported. In earlier ADRs, such patients rates were mixed with survival rates for more recent transplants; this practice somewhat distorted the mortality rates.

## Patient Survival Analysis Methodology

All new Medicare eligible ESRD patients who passed the USRDS quality control filters and who had a first service (dialysis or transplant) between January 1, 1977 and December 31, 1991, were included in the survival analysis. They were followed until December 31, 1992, giving a maximum follow-up of 15 years and a minimum follow-up of one year.

In each table in Section E, the survival rates for the most recent year are preliminary and must be used with caution. The analysis periods for the most recent year in each table extends into 1992. The period for which data are considered complete for the current database update ends in February 1992. Thus, the death data for the most recent year in each table may be incomplete.

Patient survival probabilities and standard errors are estimated using the Kaplan-Meier method (KAPLAN) as implemented in the SAS LIFETEST (SAS) procedure and Greenwood's formula. The probabilities are expressed as percentages varying from 0 to 100 (rather than probabilities varying from 0 to 1).

Survival probabilities are computed for annual cohorts for the groups shown below. For the four groups which represent subsequent rather than initial modalities, the median times from ESRD to these modalities are also presented.

In the tables for all patients and for dialysis patients, the cohorts are defined as patients starting ESRD therapy in a calendar year and surviving at least 90 days after starting ESRD therapy. Thus, the one year survival probability is the probability of surviving from day 91 to one year plus 90 days (days 91 to 455, or 3 to 15 months). The two year survival probability is the probability of surviving from day 91 to two years plus 90 days. This delay is necessary because many patients under age 65 do not become eligible for Medicare for up to 90 days, and the database does not have data until the patient becomes eligible. Additional tables for patients 65 and over are presented, showing survival from date of ESRD to day 90 and from date of ESRD to day 365. The latter results can be compared with the earlier tables for survival from day 91 to day 455.

Given the likely selection bias involved in categorizing patients into modalities, patient characteristics may vary substantially between modality groups. Therefore, differences in survival across modality groups may not necessarily be ascribed to differences in the efficacy of the treatment modalities, even after adjustments for age, race, sex, and primary disease.

One, two, five, and ten-year Kaplan-Meier product limit estimates of survival probabilities were calculated for each age, race, sex, and primary disease group by the year of incidence.

Some survival results in Section E of the Reference Tables are adjusted for age, race, sex, and primary disease. Starting with this ADR, the standard population for these adjustments is the incident ESRD population for the year before the most recently reported year, 1991 for this ADR.

The procedure used is the direct method of adjustment described earlier in this chapter and used for incidence and prevalence. The number of cells was limited to four age, two sex, three race, and four diagnosis groups. These limitations were imposed because more cells would have led to undesirable smaller sample sizes and the Kaplan-Meier survival estimates are biased high with small cell sizes.

### All Patients

The cohort consists of all ESRD patients starting renal replacement therapy in a calendar year and surviving beyond day 90. Patients are censored only at the end of follow-up (December 31, 1992).

### Dialysis Patients (Censored at First Transplant)

The cohort consists of all ESRD patients starting renal replacement therapy in a calendar year, surviving beyond day 90, and not receiving a transplant by day 91. Patients are censored at transplantation or at end of follow-up (December 31, 1992).

### First Renal Transplant (Cadaveric)

Patients in this cohort satisfy two conditions: 1) they received their first transplant in the designated year, and 2) the transplant donor is cadaveric. Transplants where the donor type is recorded as "other" or "unknown" are excluded from both the cadaveric and living related groups. The cohort is defined based on the year of first transplant regardless of the year of first ESRD service. Patients are followed from date of transplantation, and age is computed at the time of transplantation. Patients are censored only at end of follow-up (December 31, 1992). These patients appear in the "All ESRD" group above, and most also appear in the dialysis modality group. The median time in days from first ESRD service to first transplantation is also presented for these patients.

### First Renal Transplant (Living Related)

Patients in this cohort satisfy two conditions: 1) they received their first transplant in the designated year, and 2) the transplant donor is living related. Transplants where the donor type is recorded as "other" or "unknown" are excluded from both the cadaveric and living related groups. The cohort is defined based on the year of first transplant regardless of the year of first ESRD service. Patients are followed from date of transplantation, and age is computed at the time of transplantation. Patients are censored only at end of follow-up (December 31, 1992). These patients appear in the "All ESRD" group above, and most also appear in the dialysis modality group. The median time in days from first ESRD service to first transplantation is presented for these patients.

## Expected Remaining Lifetime Methodology

Reported values for the expected remaining lifetime of a patient cohort are estimates of the life expectancy for the typical patient in a particular cohort. Without making assumptions about the parametric form of the distribution of lifetimes within a patient cohort, the expected remaining lifetime for a patient cohort cannot be estimated until all of the patients have died(Gross). In order to give timely (and thus practically useful) estimates of expected remaining lifetime, we truncated lifetimes at age 100.

## Graft Survival Analysis Methodology

The methodology for graft survival analysis is the same Kaplan-Meier methodology used for patient survival. For persons who have received multiple transplants, only the first transplant is analyzed. For the patient survival analysis, once a patient receives a transplant, that patient is thereafter classified as a transplant patient even if the graft fails. Graft survival analyses are presented separately for cadaveric and living related first transplants. Transplants where the donor type is recorded as "other" or "unknown" are excluded.

The starting date for the graft survival analysis is the date of the first transplant. The ending date is the earlier of death or graft failure. The derivation of the graft failure date is discussed in Chapter XIV and in the *Researcher's Guide to the USRDS Database*.

Standard errors (after 90 days, 1, 2, 3, 5, and 10 years) are presented for both patient survival and graft survival analyses. The calculation of the standard error of the difference between two graft survival curves (Chapter VII) is the square root of the sum of the squared individual standard errors, since the covariance is zero. The p values reported in Chapter VII for the differences between survival curves are based on a t test of the difference in survival.

Some adjusted survival probabilities are computed using the same methods as for patient survival. For this ADR, the standard population for these adjustments is patients who received a transplant in 1989-1991.

## Treatment Modality

The treatment modality categories and the procedures for determining treatment modality are described in the *Researcher's Guide to the USRDS Database*. In Section C of the Reference Tables, the "60 day rule" is applied. This rule requires that the patient be on a new modality for at least 60 days before it is considered a change in modality. Patients who are lost to follow-up are not included in the year end modality counts.

Section C of the Reference Tables also includes tabulations of patients by modality at two years. Lost to follow-up is included as a category in these tables.

## EPO Data

Four of the figures included in Chapter V (Treatment Modalities) show data about the use of erythropoietin (EPO) in conjunction with dialysis treatment in 1990 through 1993. This section describes the data and methodology used for these figures.

These data come from the data in the Quarterly Dialysis Records (QDR) in the USRDS database. The QDRs report on outpatient claims filed by institutions and do not report on claims filed by physicians and other Medicare Part B providers. Each QDR summarizes treatments received by one patient in one calendar quarter from one provider. A patient who uses more than one provider in a quarter will have more than one record for that quarter.

The treatment modality shown on the QDR is the last treatment modality in the quarter, and this is used to classify a patient by treatment modality for that quarter. Patients are classified as hemodialysis, CAPD/CCPD, or other. Patients with more than one QDR in a quarter are classified as "other" if the records do not all show the same modality.

**Percent of Medicare Dialysis Patients Receiving EPO.** Estimates are computed as *epo_patients / total_patients* for each modality, PD and HD. *Epo_patients* is the sum of Medicare patients where the EPO administration field or the EPO dollars field in the QDR is greater than zero in that quarter. *Total_ patients* is the sum of any patients with a record in the QDR. Each patient is counted only once per quarter.

**Hemodialysis patients receiving outpatient blood transfusions by Quarter.** Estimates are computed as *blood_patients / total_patients.* *Blood_patients* is the sum of patients where blood units received, reported in the QDR, is greater than 0 in that quarter. Total patients is the sum of any patients with a record in the QDR.

**Average patient hematocrit and EPO Dose, Center hemodialysis patients only.** Estimates are computed as mean hematocrit among patients for whom a hematocrit is reported and mean and median EPO dose among patients for who EPO dose is reported. Patients were classified as center hemodialysis excluding any HD patient where the dialysis setting field in the QDR was 'home'.

The EPO dose field on the QDRs is somewhat problematic. Before January 1991, the EPO dose field in the QDR was defined as the last EPO dose in the period. Since January 1991, the repeated dose has been defined as the average over the billing period. This average dose is calculated by HCFA using an input of the total EPO units from the claim.

Because patients in the QDR have one record per patient provider in that quarter, in the case of more than one record per patient, the latest of the EPO dose field and the hematocrit field were taken.

## Hospitalization

The USRDS database contains data on more than 3.1 million inpatient hospital stays. Section H of the Reference Tables reports on hospital days and hospital admissions per year at risk for hospitalization using a method which closely parallels the mortality rate method described above. A three year period is used in order to dampen the effect of short term variations.

In ADRs before 1994, the algorithm used for calculating hospital length of stay counted the day of admission as well as the day of discharge. In the 1994 ADR, this algorithm was changed to count the day of admission but not the day of discharge. Patients discharged on the day of admission and patients discharged on the next day are counted as staying one day. This change was made to bring the *ADR* calculation into agreement with the Commission on Professional and Hospital Activities (CPHA) algorithm, which has been used extensively in hospitals and in hospital utilization research since 1955.

The cohort for this analysis is the same as for the mortality rate methodology, with the additional restriction that the date recorded in the HIM ID POST DATE variable must have been reached by the

starting date (January 1 or day 91 of ESRD for this patient). This date defines the beginning of the period for which the hospitalization data are "complete." This period is constrained by Medicare eligibility and by the transmission of hospitalization data from the Medicare billing system to the HCFA ESRD PMMIS data system and then to the USRDS. From 10 percent to 15 percent of patients alive on January 1 are removed from the cohort by this requirement.

The term "complete" is placed in quotes because there is uncertainty about the quality and completeness of the hospitalization data. Known constraints on the completeness of the data are described below. For patients under 65 who are not already eligible for Medicare due to disability, Medicare eligibility may not start until up to 90 days after the start of therapy. During this period, hospitalization data are not expected to be complete. Similarly, some transplant patients lose Medicare eligibility after three years of a successful transplant.

Hospital records are passed from the Medicare billing system to the ESRD PMMIS system if the record shows dialysis or a kidney transplant, or if both systems recognize the patient as an ESRD patient. The point at which this recognition occurs is most reliably indicated by the HIM posting date in the PMMIS and USRDS databases. Before this date, at least some of the hospitalizations will be missing. In most cases this date is shortly after the start of Medicare eligibility, or at the change from non-ESRD to ESRD eligibility. Both of these problems constrain the starting date for the period of complete data, and affect most dramatically patients who are in the program for shorter periods. There is likely to be some downward bias in the data because hospitalization immediately following renal failure may not be counted.

In addition to the above limitations, the data from the HCFA PMMIS excluded one night stays before 1992. Also, Medicare rules now require that for the first 21 months (18 months after the Medicare entitlement date) Medicare is the secondary payer after any other employer paid group health insurance which the patient may have. This may result in less complete hospitalization data in the first 21 months if the other insurer covers the complete cost of the hospitalization. The limited comparisons that have been made to date between USRDS data and actual hospital records have produced mixed and inconclusive results

The USRDS is now incorporating hospitalization data from the HCFA Standard Analysis Files. These data will avoid most of the data completeness limitations described above and will allow the USRDS more precisely to identify the Medicare secondary payer period.

## Cost Effectiveness Methodology

Incident patients from the Case Mix Adequacy Study were identified for the cost effectiveness study. Approximately 1,700 patients were incident in 1990. For these patients Medicare Health Insurance code numbers and cross reference numbers were obtained and were utilized to subset HCFA claims data to obtain charge and reimbursement data. The HCFA data bases containing hospital inpatient records, skilled nursing facility records, home health agency records, hospice records and outpatient records were obtained for 1990 through 1993.

In addition physician/supplier data for 1992 were obtained. Constraints on the use of the HCFA data bases and the HCFA computer system prevented obtaining additional years of physician/supplier data for this annual report. Unexpectedly low correlations between physician/supplier payments and all other payments precluded using the 1992 physician/supplier data together with other payment data to predict additional years of physician/supplier payments. As a result, the physician/supplier payments were not included in the cost effectiveness study in Chapter X although they will be included in future reports.

For each patient, an analysis start date was calculated that was the latest of 1) the first dialysis date as reported in the Case Mix Adequacy (CMA) Study plus 30 days, 2) the first service date from the USRDS Patients data base plus 30 days, 3) the Part B eligibility date from the USRDS patients data base plus 30 days, and 4) the date of the first dialysis bill encountered in the claims data plus 30 days. In general, the addition of 30 days was to account for the batch posting of dialysis bills. If the analysis date occurred after 120 days past the first dialysis date as reported in the CMA Study, the patients was removed from the analysis. Similarly if the patient did not have a significant per diem for dialysis treatments in the first month following the analysis start date, the patient was dropped from the study.

For each patient, the date of the first vascular access revision was found and payments were aggregated from the analysis start date to the first revision, transplant, death, or the end of the study, December 31, 1992. In addition total payments were

aggregated to a censoring event, death, transplant, or the end of the study.

For analyses of the cost effectiveness of alternative types of vascular access, both patient follow-up and corresponding Medicare reimbursements were censored (stopped) at the earliest of transplant, end of the study (December 31, 1992) or the event of interest (death or access revision). Medicare reimbursements were therefore estimated as right-censored parameters using Kaplan-Meier techniques (KM 1958) as implemented in the SAS procedure LIFETEST (SAS). The same procedure was used to estimate the probability of patient survival and vascular access survival. As applied to cost, the Kaplan-Meier techniques estimate the probability that the patient will have at least some dollar amount of reimbursements over the survival period.

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