

Chapter XIII

Analytical Methods

Key Words:

ESRD Medical Evidence
 ESRD Death Notification
 Renal transplantation
 Intent-to-treat
 Expected remaining lifetime

ESRD cost effectiveness
 Renal graft survival
 Measurement concepts
 Race classification
 Rate methodology

This chapter discusses the USRDS database, the analytical methods used in this *1997 Annual Data Report (ADR)*, and the differences between this ADR and the *1996 ADR*. The *Researcher's Guide to the USRDS Database* provides additional detail about the database and the Standard Analysis Files (See Chapter I).

What's New?

During 1996, there was more than the usual amount of change in the USRDS database. This section discusses the changes in the USRDS database, differences between this *1997 ADR* and the *1996 ADR*, as well as areas where methodologies finally have stopped changing and some continuing problem areas which need to be kept in mind.

These changes in data and methods mean that care must be used when comparing data between ADRs for different years. The USRDS policy has been that each ADR should 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. This policy has been difficult to follow this year because of substantial changes in the data. Many sections of this report will include *caveats* about making comparisons over time.

1. More recent data reported. This ADR is based on an update of the USRDS database with data reported through September 1996. It also includes Medicare paid claims data through calendar year 1995. In addition the HCFA ESRD data system has

substantially speeded up the flow of data. These changes allow us to report data through 1995 rather than through 1994 as would have been the case in previous years. The data for 1995 should be regarded as preliminary, as reported values for 1995 are likely to change somewhat when reported in the *1998 ADR*. Because of the many changes in the data system, we have little basis for estimating the amount of change which should be expected in the *1998 ADR*.

2. New Medical Evidence (2728) Form. A new HCFA Form 2728 (Medical Evidence Form), went into use in April 1995. Completion of this form now is required for all new dialysis patients, not just Medicare patients. As a result, the USRDS database now includes a substantial number of non-Medicare patients incident in 1994 and 1995. The new form also introduced a new coding scheme for the primary disease causing renal failure.

3. UNOS Transplant Data In July 1994, HCFA and the Health Resources Services Administration (HRSA) consolidated transplant data into a single collection the United Network for Organ Sharing (UNOS) under its contract with HRSA. The expanded transplant data are shared among HRSA, HCFA, and NIH and thus are available to the USRDS. This has resulted in the addition of data on a substantial number of non-Medicare transplants starting in 1994. Children are disproportionately represented in these non-Medicare transplants. UNOS transplant data for 1988 through 1993 became available to the USRDS too late to be included in the data for this ADR. As these data are incorporated

into the database and reconciled with the HCFA transplant data for those years, additional non-Medicare transplant patients will be added to the database for 1988 through 1993.

4. **Exclusion of patients with minimal data.**

In past ADRs, patients with minimal data indicating that they were ESRD were counted as ESRD patients. They were included in the incidence counts, were included in prevalence counts for two years, and became lost to followup at the end of two years. These patients have become a more than negligible portion of the total incident patients for 1994 and 1995. A decision was made not to count these patients for this ADR. This practice may change over the next year or two as the data restabilize after the current barrage of changes.

5. **Death and hospitalization rate methodology.**

Substantial changes were made to these methodologies. A statistical model is used to smooth the rates to decrease the variability of the rates for small cells in the tables. In addition, dialysis-unrelated deaths (defined as deaths due to accidents, street drugs, and AIDS) are dropped from the analysis.

6. **First transplantation rate table.** A table of national first transplant rate for patients under 65 by age group and modality has been added to the Reference Tables (F.36). The method for calculating these rates is discussed below. As in the death and hospitalization rate methodology, a statistical model is used to smooth the rates to decrease the variability of the rates for small cells in the tables. In addition, patients who die of AIDS are dropped from the analysis.

7. **Standard population for adjustment.**

The adjusted incidence, prevalence, survival, and death rates in this ADR now all use 1994, the year before the most recently reported year, as the standard population for adjustment. The practice of using the year before the last reported year began with the 1996 ADR, for which 1993 was the last year reported and 1992 was used as the standard population for adjustment.

8. **Lost to Followup Methodology.**

No changes were made to the lost to followup methodology this year.

9. **Race code.**

The race code used in the USRDS database is derived from a number of sources, and the coding of race in these sources has changed over time. One example is that the race

codes used by the Medicare system include a Hispanic category. Another example is that the race codes on the ESRD Medical Evidence Form include Pacific Islander, Arabian, and Indian Subcontinent. The result of these changes is a slight increase in the number of patients classified as "Other" race.

10. **Death Notification Form.** No change this year. 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 than on the pre-1990 form. On the pre-1990 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. This change makes it difficult to compare causes of death from before and after 1990. As in the 1996 ADR, the cause of death tables in Section D of the Reference Tables use only the new codes.

11. **Minimum Aggregation Size.** No change this year. Starting with 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. The exception is that for national tabulations by a single characteristic, aggregations of less than 10 are permitted. An example is tabulations of the occurrence of rare diseases.

This practice 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 table cell to aggregations of 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 table cells which are based on less than 10 patients.

Sources of Data for the USRDS Database

This section discusses the various sources of data for the USRDS database as background for discussions which follow. The sources are discussed from the point of view of their contribution toward compiling a complete picture of the ESRD population.

HCFA PMMIS Database

The major source of patient information is Program Management and Medical Information System (PMMIS), maintained by the Health Care Financing Administration (HCFA), the federal agency charged with administering the Medicare program. The PMMIS incorporates data from most of the other sources described below.

HCFA handles payment and administrative functions for all Medicare recipients on a regional (e.g., state) level through contracted intermediaries (Part A services) and carriers (Part B services). Furthermore, HCFA contracts with 18 regional ESRD Network offices that adjudicate patient grievances, quality of medical care assurance, research and data collection activities. HCFA maintains an ESRD-specific database (known as the ESRD Program Management and Medical Information System, PMMIS).

The HCFA is completing a transition from the way data are stored in the Program Management and Medical Information System (PMMIS), replacing its Medicare ESRD Support Subsystem (MESS) with an enhanced on-line data system known as the Renal Beneficiary and Utilization System (REBUS).

HCFA Form 2728, ESRD Medical Evidence

This form plays a central role in the USRDS database, and changes in this form in 1995 have had important effects which will be discussed in succeeding sections. A major route of entry into the HCFA database is through Medicare ESRD Medical Evidence Form (2728) which is completed at the dialysis unit for each new ESRD patient and sent to HCFA by way of the regional ESRD Networks.

This form, which is familiar to all dialysis providers, serves to: 1) establish Medicare eligibility for individuals who previously were not Medicare beneficiaries, 2) reclassify Medicare beneficiaries as ESRD patients, and 3) to provide demographic and diagnostic information on all new ESRD patients.

Before 1995, the Medical Evidence Form was only required for Medicare eligible patients. With adoption of a new Medical Evidence Form in 1995 (also called the 2728 form), dialysis providers are required to complete the form for all new ESRD patients, regardless of Medicare status. However, the form is not completed for every patient. There are cases for which the Medical Evidence Form is

lacking for both Medicare and non-Medicare entitled patients.

This form is the only source of information about the cause of ESRD. The new (1995) form uses a more modern and circumspect list of choices for the cause of ESRD. It also includes baseline laboratory values, comorbid conditions at the time of ESRD initiation, and employment status. The race code on the new form includes three new categories, as discussed later.

Medicare Enrollment Database

The Medicare Enrollment Database (EDB) is the master database of Medicare beneficiaries. It provides the PMMIS with data such as race, date of birth, date of death, and Medicare entitlement. It also tracks changes in patient ID numbers, allowing records for a given patient to be linked over time even when the patient's ID number changes. The USRDS goes directly to the EDB for data about Medicare entitlement, residence, and Medicare secondary payer status.

HCFA Paid claims Records

Even though a Medical Evidence form is requested for all new ESRD patients, the form is not always submitted. It appears that this is most likely for non-Medicare patients and for individuals who are already Medicare beneficiaries (on the basis of age or disability) at the time of ESRD. The latter group of patients will eventually be entered into the HCFA (and hence USRDS) database through the claims records. USRDS has access to the paid claims records and has been using the appearance of medical claims for dialysis services for a patient as a cause to include the patient in the USRDS database (if they are not already registered). Paid claims records supplement but do not replace other sources of incidence and prevalence information.

It is important to realize that HCFA may not pay the bills for Medicare-eligible patients who are covered through private insurance, HMOs, VA, and other sources as well as for non-Medicare eligible patients.

The PMMIS contains hospital records and quarterly summaries of dialysis treatments derived from the HCFA paid claims records. Starting with 1989, detailed files of Medicare paid claims are available in the HCFA Standard Analytical Files. These annual files are frozen in June of the year following the end of the calendar year in question.

The USRDS extracts from these files detailed medical procedure and cost data for all patients in the PMMIS plus any additional patients having outpatient dialysis records.

The USRDS supplements these files with data from the PMMIS hospital and quarterly dialysis records to capture claims which were processed after the June following the year of service and to provide data for years before 1989.

UNOS Transplant Database

In 1994 the collection of data about kidney transplantation was consolidated between HCFA and the United Network for Organ Sharing (UNOS). UNOS data for 1988 through 1993 also are available, although they have not yet been added to the USRDS database. Some ESRD transplant patients, primarily non-Medicare patients, are known only through these data files.

ESRD Network Census.

Periodically since December 1993, the 18 ESRD Networks provided HCFA with a census of ESRD patients alive on a particular date from their databases. Individuals who are listed on this report but not otherwise entered in the HCFA system are presumed to be receiving ESRD treatment independently of the Medicare program. Such patients are entered into the database for statistical enumeration purposes. These censuses also provide verification of the status of patients already in the database.

Age and sex are recorded in the database for these patients. However, in the absence of the Medical Evidence Form, there is currently no accurate listing of the cause of ESRD or the date of first ESRD service.

ESRD Annual Facility Survey.

In addition to the HCFA ESRD database described above, corroborating ESRD patient counts are available from the Annual Facility Survey that all dialysis units (and transplant centers) are required to complete at the end of each calendar year. The facility reports contain aggregated patient counts but no patient specific entries as provided with the other data sources. Hence, the report lacks demographic and diagnostic information. However, the AFS provides an independent, direct count of ESRD patients that complements the HCFA records.

The report includes prevalent patients at the end of the year as well as new (i.e. incident) ESRD patients during the year. Incident patients who die during the year are counted. The facility survey includes both Medicare and non-Medicare patients but gives this division for prevalent patients only. The accuracy of the Facility Survey depends on complete reporting by each facility and full reporting by all facilities. Unfortunately, neither of these processes have been validated. Since the number and names of some dialysis units change each year, it is difficult to confirm the completeness of facility reporting.

The First Service Date

The date of first ESRD service (first service date or FSD) is the single most important data item in the USRDS database. It is discussed here as background for discussions which follow.

A patient must have an FSD in order to be included in USRDS analyses, and the FSD is used as the start of ESRD. The FSD determines the year in which the patient is counted as incident and determines the first year in which the patient is counted as prevalent and is included in prevalent mortality rates. The FSD, or 90 days after the FSD, is the starting point for patient survival analyses.

The FSD is derived from a number of data sources:

- The date of start of dialysis for chronic renal failure from the Medicare 2728 form.
- The date of a kidney transplant as reported on a HCFA or UNOS transplant form or as reported on a Medicare 2728 form.
- The date of the first outpatient dialysis bill.
- The date of first Medicare entitlement, or 90 days after that date, if the original reason for Medicare entitlement is listed as renal only.
- The date of first service from an ESRD Network database.

Another indication that a patient has ESRD is the Medicare ESRD Death Notification Form. However, this form does not give any indication of the date of the start of ESRD and is not useful in establishing the FSD.

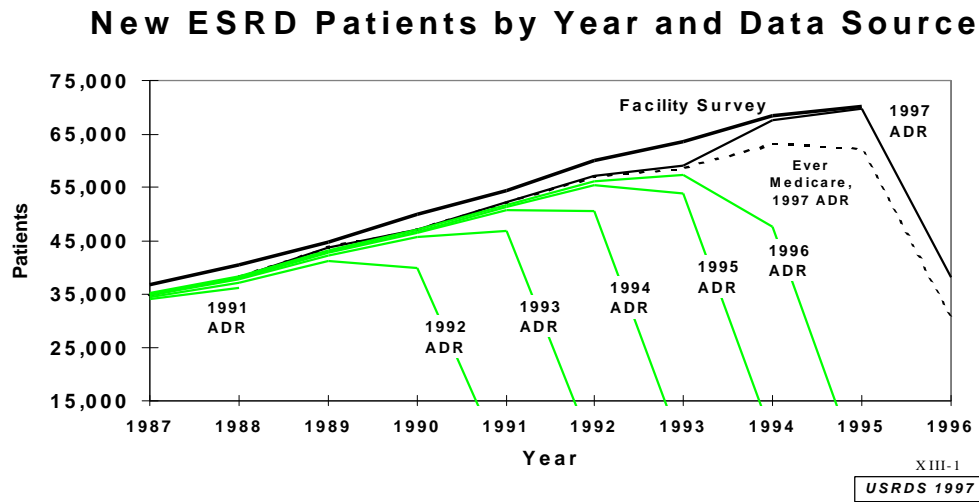


Figure XIII-1

Counts of new ESRD patients by year as reported in successive ADRs and as reported by the HCFA Annual Facility Survey.

Why do the numbers keep changing?

With each ADR, the counts of new patients by year increase somewhat for years which were reported in previous ADRs. Figure XIII-1 shows counts of new ESRD patients by year as reported in successive ADRs and as reported by the HCFA Annual Facility Survey. The line for each successive ADR is higher than the line for the previous ADRs; that is, the incident count for prior years goes up with each ADR, although after three years the change is minimal. In past ADRs, the incidence count could be expected to grow as much as 5 percent in the ADRs after that year was first reported.

The increases in incidence counts for past years from update to update may be due to at least the following 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 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. The HCFA and USRDS ESRD data systems are currently in a transition period and will incorporate data from the ESRD Network data systems and from the Medicare claims data. These new sources will contribute to more complete counts in the 1997 ADR.

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, their 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

New ESRD Patients by Source of Data

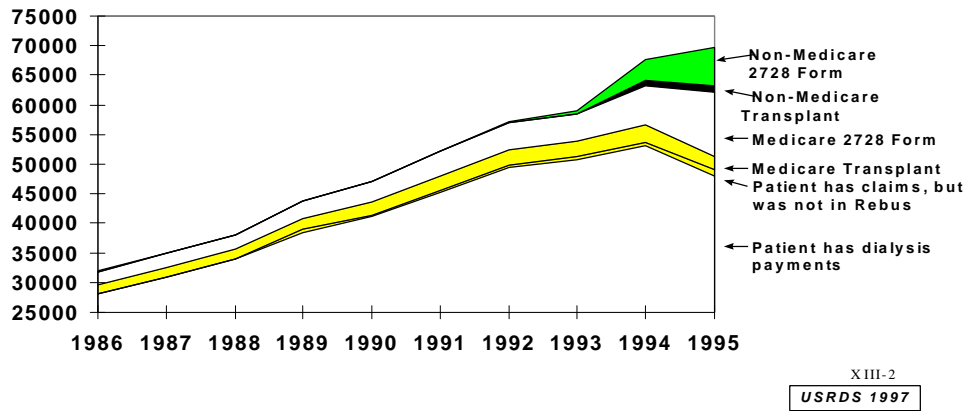


Figure XIII-2

New ESRD patients by the sources of data which establish first service date.

service date is corrected, then a patient may appear as incident in a different year than in a previous database update.

More Recent Data Now Reported

The last year for which incidence counts were reported in each ADR is the year at the highest point on the curve for that ADR in Figure XIII-1. For the 1993 through 1996 ADRs, the last year reported was the ADR year minus 3. For instance, the 1996 ADR was based on a database update through mid 1995, and 1993 was the last year reported. The incidence count for year ADR-2 (1994 for the 1996 ADR) is clearly incomplete as is not reported. Since the database is updated during year ADR-1, much less than a full year of data is available for that year.

In the past, the USRDS has followed a “15 month rule” and generally did 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 at the time of the 1996 ADR we had data through June 1995, the data were only considered complete through March 1994, and the 1996 ADR reported results only through December 31, 1993.

The line for the 1997 ADR in Figure XIII-1 shows a dramatic change from the lines for earlier ADRs and continues to rise until year ADR-2 (1995) rather than year ADR-3 (1994). In this 1997 ADR,

we generally report data through 1995, although the 1995 data must be treated with some caution as they are still likely to change when reported in the next ADR.

There appear to be two major reasons for the greater currency of the data. First of all, the improvements which HCFA has made to the PMMIS system have reduced the time lags in the processing of the data. Second, dialysis facilities are required to complete the new HCFA Form 2728 on all new dialysis patients, not just on Medicare patients. This change went into effect in April 1995. It means that non-Medicare patients are identified and that patients who will eventually be Medicare patients are identified more early.

Figure XIII-2 shows new ESRD patients by the sources of data which are available to establish the first service date. The lower four categories represent patients who have ever been Medicare entitled, although not all of these patients were Medicare entitled at the start of ESRD. The first group are those who have dialysis bills and may have a 2728 form or a transplant record. The earliest of these three sources yields the first service date.

The second category is very small and consists of patients for whom there are at least one quarter of Medicare dialysis claims but who were not in the PMMIS. The third category consists of patients who have a Medicare transplant record but do not have dialysis bills. These patients may also have a 2728 form. The last Medicare category consists of patients

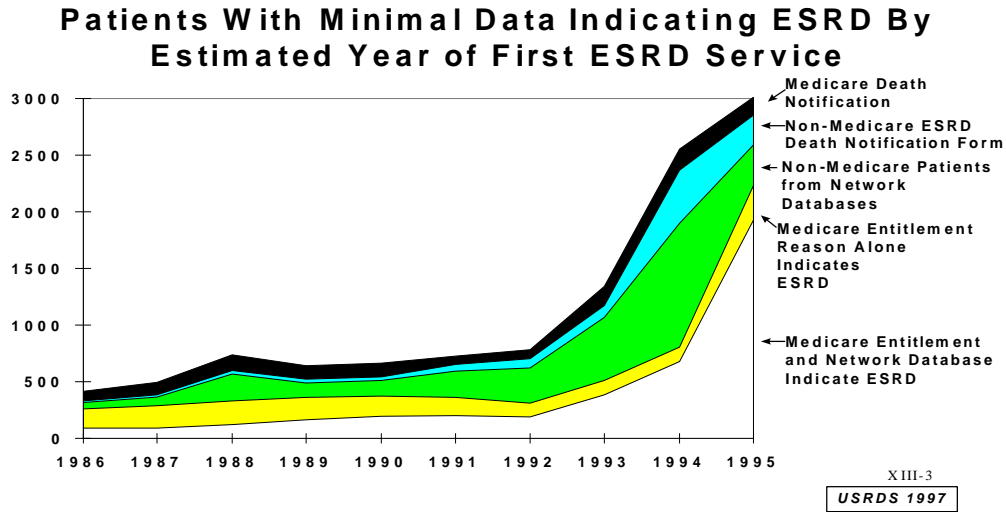


Figure XIII-3

Patients for whom minimal data exists to indicate ESRD. These patients have a single indication of ESRD and a minimal basis for determining a first service date. They account for 1-5 percent of total and are not included in the tabulations in this ADR but were included in previous ADRs.

for whom there is only a 2728 form and no dialysis claims or transplant records.

The decline in the patients with Medicare claims in 1995 is deceptive. This group is defined as patients who ever have had dialysis claims. This means that patients in other categories will move into this category in future ADRs as they begin to have Medicare dialysis claims.

The last two groups in Figure XIII-2 are patients who have a non-Medicare transplant record and those who have a non-Medicare 2728 Form.

In addition to the patients who are reported as ESRD in this ADR, there are patients for whom there are some minimal data indicating that the patient may be ESRD. In past ADRs, these patients were counted as incident, continued to be counted as prevalent for two years, and then became lost to followup.

For this ADR, a decision was made to exclude these patients. This decision may be reversed in future ADRs as the database stabilizes after the present round of changes have taken effect fully. Figure XIII-3 shows the various types of patients in this group and shows how their numbers have grown in the past two years.

The 1993 Discontinuity

Figure XIII-1 clearly shows the decline in the growth of the incident patient count in 1993 and the

recovery of that growth in 1994. The dip in 1993 appears to have been caused by a dip in the number of HCFA 2728 Forms filed in the summer of 1993. The reasons for this are not clear, but this appears to be a data problem and not an indication of an actual change in the incidence of ESRD in 1993.

Lost to Followup Methodology

There frequently are gaps in the dialysis billing data upon which the dialysis modality periods are based. Our convention is to assume that a treatment modality continues until the next modality-determining event. For a patient with a functioning transplant, the functioning transplant modality continues until a transplant failure is encountered. However, a dialysis modality is assumed to continue only for 365 days in the absence of dialysis payments or other confirmation that dialysis is continuing. After this 365 day period, the patient is counted as lost to followup until dialysis payments resume. The exception to this 365 day rule is that lost to followup does not begin until the end of the second year of ESRD.

With the 1996 ADR, a change was made in the lost to followup classification methodology. Previously, the lost to followup period began at the beginning, rather than at the end, of a 365 day period with no claim payment data. This change produces aggregate results which are more stable from one ADR to the next. The second change is that the lost to followup classification cannot begin until the end of the second

year of ESRD, where previously it could begin during the second year. The rationale for this first 2-years rule is that Medicare may be the secondary payer for up to the first 21 months of ESRD, delaying the appearance of Medicare claims.

The effect of these changes is to delay the start of lost to followup status. This, in turn, causes the counts of prevalent patients to increase by about two percent and calculated death rates to decrease slightly.

Death Notification Form

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

The new Death Notification Form uses a new set of codes and categories for cause of death, and withdrawal from dialysis is no longer a considered a cause of death. A separate question asks whether the ESRD treatment was stopped before the patient died and the reason for such stoppage.

In the 1993 and 1994 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 percent of the total in 1989 (old form) to about 16 percent in 1991 (new form). It seems likely that most of this change is due to the change in coding. Comparisons of cause of death before and after 1990 must be treated with caution.

For this reason the 1995 ADR reported cause-specific death rates only for the 1991-1992 period, during which only the new form was in use. The 1996 ADR reported cause specific death rates for 1991-1993. This 1997 ADR reports cause specific death rates for 1993-1995

Geography

Starting with the 1993 ADR, data for Puerto Rico and U.S. Territories have been reported separately from the data for 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 the United States resident population, which includes only the 50 states and

D.C. For Puerto Rico and the U.S. 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.

Location of residence is known down to the zip code level for most patients. The date of changes in residence frequently are not known with precision. We may know only that the residence changed between December 31 of one year and December 31 of the next. When data on location of residence are not available, we impute a county of residence based on the county in which the patient is receiving treatment.

The address and zip code recorded in the Medicare database is the mailing address to which claims-related communications are sent. For some elderly or incapacitated patients, this address may be that of a relative or someone else who handles these matters for the patient. This also may explain why residence may change after the patient dies. If there are delays in settling the final claims for the patient, then the mailing address may be changed after the patient dies to the address of the executor or attorney handling these matters.

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 specific population in a given time period, typically a year. Prevalence is the number of persons in a specific population 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, patients are classified as lost to followup 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 a more useful measure 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 reported 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/gender/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, gender, 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 5-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 1984 through 1993. Section J of the Reference Tables shows the July 1 population counts by year. The December 31 counts were computed as the midpoint between the July 1 counts for adjacent years.

The Census database used for the ADR is built from a series of Census Bureau files of estimates of July 1 population by county by age, race, and sex (U.S. Bureau of the Census). For 1995, estimates were available only for total population by county. The 1994 distribution of population by age, race, and sex for a given county was used to allocate the 1995 population estimate for that county to the age, race, sex categories. Estimates by county are needed because in California, county level data are necessary to compute rates for the two ESRD Networks in California.

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.

The race codes used for this ADR are derived from four race codes which are found in the various data sources from which the USRDS database is derived. These sources are shown in Table I. This table shows the distribution of values in each of the sources and the distribution of values of the race variable used for this ADR. This construction of this variable attempts to capture the most specific code provided by the various sources for a given patient.

The race codes used by the Social Security Administration have included 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.

The new HCFA Form 2728 which went into use in April 1995 has separate categories for Asian and Pacific Islander and added race categories for Indian Subcontinent and Arabian. We have recoded Pacific Islander into the Asian/Pacific Islander category and have recoded Indian Subcontinent and Arabian into Other. These changes also will tend to increase the number of patients in the Other and Unknown categories.

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, the population of Blacks with ESRD has a younger age distribution than does the population of 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 across rates unadjusted for age.

Sources of Race Codes in the USRDS Database: Incident Patients by Year by Race, 1986-1995

	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995
<u>TOTAL</u>	32238	35392	38871	44411	47764	52999	58024	60394	70256	72686
<u>MEDICAL EVIDENCE FORMS</u>										
. Missing	698	1,006	1,380	1,616	1,593	1,757	1,732	2,121	1,340	81
. Native Amer.	334	352	467	538	569	643	790	643	855	1,033
. Asian	509	565	667	809	1,026	1,110	1,274	1,364	1,815	1,593
. Black	8,138	9,025	9,827	11,678	12,349	14,122	15,739	15,235	17,975	18,525
. White	19,725	21,420	23,006	26,647	29,057	32,612	35,653	33,970	39,623	39,237
. Unknown	202	240	286	64	70	94	96	132	1,036	819
. Pac. Islndr	444	519	370	3	1	1		4	3	448
. Arabian		1						2	2	150
. Indian	1							2	3	132
. Other	1			3	3	3	2	2	25	1,489
. Not in this Source	2,186	2,264	2,868	3,053	3,096	2,657	2,738	6,919	7,579	9,179
<u>MEDICARE ENROLLMENT DATABASE</u>										
Native Amer	35	47	78	98	127	145	200	203	121	111
Asian	110	125	174	222	284	402	499	535	308	302
Black	8,563	9,559	10,551	12,080	12,978	14,459	16,058	16,391	17,016	17,104
White	20,626	22,430	24,058	27,139	29,191	32,219	35,051	35,564	37,815	37,634
Unknown	1,012	1,003	915	811	879	878	785	618	680	671
Other	1,494	1,736	2,297	2,533	2,810	2,940	2,817	3,791	7,035	7,141
< Hispanic >	303	378	525	703	971	1,228	1,542	1,601	952	776
Not in this Source	95	114	273	825	524	728	1,072	1,691	6,329	8,947
<u>HCFA AND UNOS TRANSPLANT REPORTS</u>										
Native Amer	54	60	92	89	88	87	83	57	78	37
Asian	196	187	217	229	205	184	166	151	155	108
Black	1,399	1,530	1,673	1,734	1,715	1,714	1,714	1,379	1,122	661
White	5,197	5,188	5,168	5,664	5,792	5,996	6,157	5,474	5,267	3,613
Unknown	295	382	423	402	436	421	351	349	218	146
Not in this Source	25,097	28,045	31,297	36,292	39,528	44,595	49,549	52,977	63,391	68,121
<u>RACE USED FOR THE ADR</u>										
Native Amer	372	399	519	592	651	704	857	780	930	1,131
Asian	1,029	1,160	1,146	932	1,162	1,294	1,462	1,662	2,022	2,299
Black	8,900	9,946	11,029	12,689	13,660	15,226	16,824	17,507	20,355	21,293
White	21,758	23,666	25,793	29,368	31,805	35,167	38,182	39,314	44,467	44,573
Unknown	84	85	213	736	402	508	611	928	1,946	1,802
Other	95	136	171	94	84	100	88	203	536	1,588

Source: HCFA 2728 Forms, Medicare Enrollment Database, HCFA and UNOS Transplant Reports

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Four race codes which are found in various data sources from which the USRDS database is derived.

It is now USRDS practice to use the relevant population from the year before the most recent reported year as the standard population for adjustment of rates. For adjustment of incidence and prevalence rates in Sections A and B of the Reference

Tables (1986-1995), the standard population is the July 1, 1994, United States resident population by 5-year age groups, four race categories, and gender. For adjustment of patient survival rates in Section E, the standard population is the 1993 incident ESRD population. For adjustment of graft survival rates in Section G, the standard population is all patients transplanted in 1992 through 1993.

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 gender or appropriate combinations of the three factors. For instance, in one of the standard table formats, rates by age are adjusted by race and gender, rates by race are adjusted by age and gender, rates by gender are adjusted by age and race, and rates by primary diagnosis and overall rates by year are adjusted by age, race, and gender. 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 gender 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 the other years (1982-90), regardless of changing age, race, and gender 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, Hospitalization and Transplantation Rate Methodologies

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. Similarly, Section H presents hospitalization rates based on the number of first admissions, total admissions and days in the hospital per year at risk. Both sets of rates are computed based on calendar year periods. In order to increase the stability of the estimated rates, three years (1993-1995) are pooled for some of these tables. The death rate and first hospital admission rate tables report only 1995 information. This change is discussed further below. Rates are presented by age, race, gender, and diabetic status for several groups of patients.

Several major changes were made to the methods for calculating national death rates and hospitalization rates this year. In all the rate tables (Reference Tables D.2, D.2, H.1, H.2, H.3, and H.4) dialysis-unrelated (DU) deaths were excluded from the calculations. DU deaths are defined as deaths reported to be due to AIDS, accidents unrelated to treatment such as violence, and street drug overdoses (regardless of the order of the 5 causes on the HCFA death notification form). For calculating death rates, both the deaths and person years of survival for patients who died of AIDS were excluded, but only the deaths were excluded for patients who died of other DU causes (i.e. followup was censored at death but the person years of survival were counted for DU causes other than AIDS). For calculating hospitalization rates, the rule above boils down to excluding patient years at risk from the calculations, retroactively, once we find that a patient died of AIDS. This exclusion is intended to make the rate tables more useful for comparing local death or hospitalization rates to national rates. The reasoning behind the exclusion of DU deaths is discussed in more detail in the National Death Rates section of Chapter V.

The second major change affects only the national death rate tables and the first hospital admission tables (Reference Tables D.1, D.2, H.1, H.2). The 1995 death rates and first hospital admission rates for

patient subgroups published in this report are estimated using a Poisson regression model. Three years (1993-95) were used to improve the stability of the rates, but only 1995 rates are reported. This new method yields more stable and interpretable estimates than does the previously used method of estimating the rates separately for each subgroup. The National Death Rates section of Chapter V gives a more detailed description of this model for the death rates. The first admission rate model is similar, but first admissions rather than deaths are used in the model.

These rates are designed to be used by ESRD Networks and dialysis and transplant facilities based on data about a group of patients. These rate tables can be used to compare local ESRD mortality and hospitalization 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.

Beginning with the 1994 ADR, we have included patients starting ESRD therapy during the year, as well as previously transplanted dialysis patients. However, there are still some other potential problems with hospitalization data, mostly involving patients for whom Medicare is likely to be the secondary payer. Patients in the first 18 months of Medicare eligibility may have their hospital stays covered by other insurance. 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. The procedures used in these analyses attempt to screen out these patients by requiring that Medicare dialysis payments be received before a patient is eligible for entry into the study.

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 meant that one third of the patients in a given dialysis unit were likely to be excluded from the analysis. Since the 1994 ADR, 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 new methodology has patients reenter the analysis on the first of the year after a transplant failure. If transplant failure occurs after November 1 or the previous year, the patient is also excluded from the hospitalization analysis in the upcoming year. In the future, this may be revised to have the patient reenter 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 for death is censored at transplant date if a transplant occurs during the year. The period at risk for hospitalization is censored three days prior to transplantation so that the hospital stay during which the transplant occurs is not counted.
- 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. Censoring procedures are the same as those describe above.
- 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. Censoring procedures are the same as those describe above.
- All ESRD patients.

Keep in mind that in tables that exclude DU deaths, patients who die of AIDS-related causes are excluded entirely from the calculations and that the deaths of patients who die of accidents unrelated to treatment or illegal drugs are not included in death rate calculations.

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 followup 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 followup patients is a change introduced with the 1992 Annual Data Report.

Death and Hospitalization Rates for Dialysis, Functioning Transplant, 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 Functioning Transplant" and "All ESRD" categories. Patients who are on dialysis on the starting date are also included in the "All Dialysis" category as well as the "All ESRD" category. A patient in the "All Dialysis" category may also be reported in one of two subgroups (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 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 reenter 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."

In all but the national death rate and first admission rate tables by age, race, sex, diabetes, and modality (Tables D.2, D.3, H.1, and H.2), the denominator for each rate is patient years at risk. For the remaining tables, the period at risk is calculated as described below and used in the Poisson regression model discussed above. 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 or December 31 (whichever is earliest). If a patient is transplanted, the time at risk for death ends on the date of the transplant; the time at risk for hospitalization ends three days prior to transplantation. 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. In tables which exclude DU deaths, patients who die of DU causes are censored at death (the death is not counted in the death rates) and patients who die of AIDS-related causes are removed entirely (the death is not counted in the death rates and the period at risk is not counted in the death or hospitalization rates).

Note that the period at risk is not censored at the start of a lost to followup 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 their years at risk to the denominator. The numerator is the number of events (either deaths or hospitalizations) which occurred during the at risk periods. Days at risk are divided by 365.25 to yield years at risk. Due to the low numbers in the numerator for death rates, this ratio is multiplied by 1,000 to yield deaths per 1,000 years at risk. Hospitalization rates are in terms of one year at risk.

Years may be pooled in this method to increase the cell sizes, as is done in Sections D and H of the Reference Tables. The analysis is still done in 1-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.

First-Transplantation Rates for Never Transplanted Dialysis Patients

The rules for classifying patients are the same for this table as those described in the section above except that only patients who have never been transplanted are included. The never transplanted patients in the "All Dialysis" category may also be in a subgroup (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 Dialysis" categories. Again, note that a given patient may be included in one ("All Dialysis") or two ("All Dialysis", and hemo or CAPD) categories.

The period at risk is calculated as discussed above with time at risk ending at first transplant, death, or the end of the year, whichever comes first. Patients who die of AIDS-related causes are removed entirely so the period at risk is not counted in the calculations of first transplantation rates

As in the death and hospitalization rate tables, the analysis is done in 1-year increments even though several years of data are used. A patient who is eligible at the beginning of more than one of the 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.

The 1995 first transplantation rates for patient subgroups published in this report are estimated using a Poisson regression model. Three years (1993-95) were used to improve the stability of the rates, but only 1995 rates are reported. This method yields more stable and interpretable estimates than estimating the rates separately for each subgroup. The first transplantation rates are reported by age group and modality only rather than age, race, sex, diabetes, and modality as for death and

hospitalization rates. The Poisson model used to estimate them is similar to the model for the death rates (discussed in detail in the National Death Rates section of Chapter V) but adjusts only for age and year (not race, sex, and diabetes).

Annual Death Rates for Transplant Patients

Beginning with the 1994 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 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, 1994, were included in the survival analysis. They were followed until December 31, 1995, giving a maximum followup of 15 years and a minimum followup of one year.

In each table in Section E, the survival rates for the most recent year extend into 1995. They are considered preliminary and must be used with caution.

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 1-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 2-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, gender, and primary disease.

One-, 2-, 5-, and 10-year Kaplan-Meier product limit estimates of survival probabilities were calculated for each age, race, gender, and primary disease group by the year of incidence.

Some survival results in Section E of the Reference Tables are adjusted for age, race, gender, 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, 1994 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 gender, 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 followup (December 31, 1995).

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 followup (December 31, 1995).

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 followup (December 31, 1995). 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 followup (December 31, 1995). 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

The expected remaining lifetime for a patient group is the *average* life expectancy for that group. Some individual patients within the cohort will live longer than, and some less than, the average. Although the average will not be known until all the patients in the cohort have died, the expected remaining lifetime can be *projected* by assuming that the cohort will experience the same death rates that have been observed among groups of recently prevalent ESRD patients.

For a subgroup of ESRD patients of a particular age, the expected remaining lifetime is the result of a calculation based on a survival function, which is in turn the result of a calculation based on observed death rates. The calculations start with USRDS ADR tables, which include observed death rates among ESRD patients for successive age ranges. Let $r(A)$ denote the death rate for a 5-year age group from those tables, where A identifies one of the listed age ranges. These death rates for successive age intervals, $r(A)$, are plotted versus age, A , and the area under the curve up through age A is denoted by $R(A)$. The survival function, $S(A)$, at age A is the fraction of patients that would survive to age A , for a hypothetical patient cohort that is subjected to those death rates throughout their lifetimes. The survival function at age A is related to the death rates by the equation $S(A) = \exp(-R(A))$, where “exp” denotes the exponential function. Among patients alive at age denoted by A , the fraction who survive for X more years is then $S_A(X) = S(A+X)/S(A)$. For a given starting age, A , the expected remaining lifetime is then equal to the area under the curve of $S_A(X)$ plotted versus X . This area is truncated at the upper age limit $A+X=100$, since few patients live beyond 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 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 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 1993-1994.

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 followup 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 followup is included as a category in these tables.

Cost Effectiveness Methodology

Section K of the Reference Tables and the Cost Effectiveness Chapter are based on the analysis of Medicare Claims data. The claims data were merged first with patient demographics and second with treatment modality information obtained from the USRDS data base.

Medicare Claims Data

There are two types of Medicare claims: institutional and physician/supplier. All the physician/supplier claims are Medicare Part B. The institutional claims consist of all Part A claims

(Inpatient, Outpatient, Skilled Nursing Facility, Home Health Agency, and Hospice) and some Part B claims, notably outpatient dialysis. Physician/supplier claims account for about 88 percent of the claims but only 20 percent of the dollars.

The structure and content of the two types of claims are different, and so are the files derived from them. For institutional claims, there are two types of file: the Institutional Claims (Claims) file and the Institutional Claims Detail file. The Claims file indicates the type of claim, the dollar amounts, and the type of dialysis involved (if any), and the dates of service. The Claims Detail file contains details like DRG, diagnoses, and procedures. For many analyses, the Claims Details file would not be needed.

For the physician/supplier claims, there is one type of file with one record for each claim line item. The file includes dollar amounts, dates of service, diagnosis and procedure codes, and type and place of service.

The Medicare Claims data are obtained from HCFA's Standard Analysis Files (HCFA SAFs). The HCFA SAFs are created on a calendar year basis six months following the end of the calendar year. HCFA estimates that the HCFA SAFs are 98 percent complete. The USRDS database contains data for about 50 million institutional claims (hospital inpatient and outpatient facilities, outpatient dialysis facilities, skilled nursing facilities, hospice facilities, and home health agencies) for 1989 through 1996. The database also contains data for 193 million physician/supplier claim line items for 1991 through 1995. The full claims data require a minimum of 20 gigabytes of disk storage.

Data were obtained for all patient ID numbers currently in the USRDS database plus all ID numbers which had outpatient dialysis claims or a kidney transplant during 1989-1996 (only 1991-1995 were used for the cost effectiveness methodology as physician/supplier claims are only available for these years). The HCFA enrollment database was used to gather all the cross-reference ID numbers for these IDs, that is all the ID numbers under which these patients may have had claims. Patients who are not currently in the PMMIS were not included in the analyses in this ADR.

Intent-to-Treat Model

Table K.1 in the Reference Tables shows aggregate Medicare payments by year and type of payment. The remaining tables are based on an

"intent-to-treat" model. This model computes payments per patient year at risk over the **5-year** period 1991 through 1995. It is referred to as an "intent-to-treat" model because patients are classified based on their treatment modality at the start of the analysis period and retain that classification even if their dialysis modality changes. Aggregation of Medicare payments was done on an "intent-to-treat" basis, attributing all subsequent payments to the patient's starting modality. The only exception to this rule was dialysis patients who later received a transplant. These patients were censored at date of transplant and a new record was created with transplant as the intent-to-treat modality. Only patients switching from dialysis to transplant could enter the model twice. All others remained assigned to their initial modality.

Patients are classified into four intent-to-treat modality categories: hemodialysis, CAPD/CCPD, uncertain dialysis, and transplant. The uncertain dialysis category includes cases where the dialysis modality is unknown or is not hemodialysis or CAPD/CCPD or where the patient has not been on the modality for 60 days at the start of the period.

The transplant category includes patients who have a functioning transplant at the start of the study period (January 1, 1991) and patients who receive a transplant during the study period (1991-1995). For dialysis patients who receive a transplant during the period, two periods are generated. The patient is classified into one of the dialysis periods until the date of the transplant at which point the dialysis period is censored and then a new period begins for that patient in the transplant category.

Table K.3 shows the distribution of patients into these groups and the aggregate payments of each type for these groups. The remaining tables in Section K drop "uncertain dialysis" as a separate category and add two aggregate categories: All ESRD and All Dialysis. The "uncertain dialysis" patients are included in the All ESRD and All Dialysis categories.

The intent-to-treat model spans the 5-years 1991 through 1995. ESRD patients prevalent on January 1, 1991 or incident at any time during 1991, 1992, 1993, 1994, or 1995 were potentially eligible for inclusion in the study sample. The study start date for a given patient was defined as thirty days after the latest of the following:

- January 1, 1991.
- The first ESRD service date in the USRDS database for the patient.

- The first month in which dialysis payments exceed \$675 (the tenth percentile of monthly dialysis reimbursement for all patients with dialysis in 1991).

Patients for whom Medicare is the secondary payer (MSP status) for all or part of the study period are excluded from the analysis. For patients who have employer paid group health insurance coverage, Medicare is the secondary payer for the first 18 months of ESRD. Data on the MSP status of patients is obtained from the Medicare enrollment database. MSP patients are excluded from the analysis because it is impossible to characterize the total costs of their care. Table K.2 shows that about 8 percent of the patients with Medicare payments during 1991 through 1995 were excluded because they were MSP for all or part of the period.

Medicare payments were aggregated from the study start date until the patient's date of death, date of transplantation, date lost to followup, or December 31, 1995, whichever came first. Patients were defined as lost to followup if there were a period of three consecutive months in which dialysis payments (institutional plus physician/supplier) did not sum to \$675 per month.

Total costs during the followup period were divided by the length of the followup period in order to express all costs as dollars per year at risk (YAR). Costs per year at risk were calculated for all ESRD patients, for all patients by modality, and stratified by modality, age, gender, race, and diabetic vs. non-diabetic cause of ESRD.

Diabetic ESRD status is based on the primary disease causing ESRD. A patient with a non-diabetes cause in some cases may also have diabetes, but the diabetes is not judged to be the cause of ESRD. Persons with cause of ESRD missing are included only in the All category for diabetic ESRD status.

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