

Chapter XIII

Analytical Methods

Key Words:

ESRD Medical Evidence
 ESRD Death Notification
 Renal transplantation
 Intent-to-treat model
 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 *1998 Annual Data Report (ADR)*, and the differences between this ADR and the *1997 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?

This section discusses the changes in the USRDS database, differences between this *1998 ADR* and the *1997 ADR*, as well as some continuing problem areas and areas where methodologies changed in recent years but now are no longer changing.

These changes in data and methods mean that care must be used when comparing data between ADRs published in 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 way that the data are obtained. 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 August 1997. It also includes Medicare paid claims data through calendar year

1996. Table XIII-2 shows various reference dates for the past five ADRs and provides a reference for comparisons of ADRs over time. As reported in the *1997 ADR*, the HCFA ESRD data system has substantially speeded up the flow of data, requiring a shorter period before the data were considered complete enough to report. This allows us to report data through 1996. The data for 1996 should be regarded as preliminary, as reported values for 1996 are likely to change somewhat when reported in the *1999 ADR*. For instance, the counts of new ESRD patients reported for 1995 increased about 5 percent between the *1997 ADR* and this *1998 ADR*. A similar change can be anticipated between this ADR and the next for the 1996 data.

- 2. Elimination of Duplicates.** We identified about 8000 cases in the database in which the same patient appeared twice under different ID numbers. The effect of resolving these duplicate counts of the same patient is that some counts reported for prior years are slightly lower in this ADR compared with the *1997 ADR*. The USRDS CC and HCFA are working together to resolve the remaining duplicates and to set up ongoing procedures for resolving new duplicates as they occur.
- 3. Exclusion of patients with minimal data.** In determining whether a patient in the database is an ESRD patient, we require that there be a Medicare Medical Evidence (2728) Form, an

Reference Dates for Recent ADRs

ADR Year	1) Database Update Through	2) Includes Medicare Claims Data Through	3) Most Recent Year Reported (preliminary data)	4) Year of Standard Population for Rate Adjustment
1994 ADR	May 1993		1991	1990,1991
1995 ADR	May 1994		1992	1991
1996 ADR	Sept. 1995	December 1994	1993	1992
1997 ADR	Sept. 1996	December 1995	1995	1994
1998 ADR	Sept. 1997	December 1996	1996	1995

1) Patient data, including death date, are updated from the HCFA REBUS system, the Medicare Enrollment Database, and the UNOS transplant files through this month. Mortality followup is considered complete through the end of the prior year.

2) Medicare paid claims data are complete through this month.

3) This is the last year for which data are reported in the Reference Tables. Data for this year should be considered preliminary. For instance, incidence counts may increase by as much as 5% when reported in the next ADR.

4) This is the year of the standard populations used for adjusting rates. For the 1994 ADR, different years were used for different rates.

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Table XIII-1

outpatient dialysis claim, or a report of a kidney transplant. For some patients in the database, the only indication of ESRD is a Medicare ESRD Death Notification form, the Medicare reason for entitlement listed as renal, or the listing of the patient in an ESRD Network patient census file. In *past ADRs* prior to 1997, such patients with minimal data indicating ESRD were counted as ESRD patients. They were included in the incidence counts, were included in prevalence counts for 2 years, and became lost-to-followup at the end of 2 years. The number of such patients has increased substantially since 1994, primarily because of patients added from the ESRD Network databases. Starting with the 1997 ADR, these patients have not been included in the data for the ADR. This practice may change over the next year or two as the data restabilize after the current barrage of changes.

4. **New Medical Evidence (2728) Form.** A new HCFA Form 2728 (Medical Evidence Form), went into use in April 1995. We now have two years of data from this form, and we are beginning to understand the numerous effects of this change in the form. 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 later years. The new form also introduced a new

coding scheme for the primary disease causing renal failure. The new 2728 Forms for non-Medicare patients are one of the sources of the duplicates mentioned above. For example, a 2728 Form for a non-Medicare (or not-yet-Medicare) patient is filed when the patient starts dialysis. Since the patient does not have a Medicare ID number at this point, a temporary ID is created. If the patient later becomes Medicare entitled, the new ID may not be matched with the earlier 2728 Form, resulting in a pair of duplicates.

5. **UNOS Transplant Data** In July 1994, HCFA and the Health Resources Services Administration (HRSA) consolidated their transplant data collection efforts. The United Network for Organ Sharing (UNOS), under its contract with HRSA, is now the single source for HRSA, HCFA, NIH, and 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. The handling of the multiple sources for transplant data is described below under "Sources of Data." Three new Standard Analysis Files are now available to make the UNOS transplant data more accessible. For the first time, data on the date of first wait listing for a kidney transplant are available.

6. **Death and hospitalization rate methodology.** Substantial changes were made to these methodologies with the 1997 ADR. A statistical model is used to smooth the rates in order 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. These methodologies are continued this year with the changes listed in the next two items.
7. **Exclusion of patients from hospitalization rate calculation who do not have enough Medicare paid dialysis.** Starting in the 1998 ADR, in addition to the rules used before for including patients in the hospitalization rates, dialysis patients must reach a certain level of Medicare paid dialysis bills. This new criterion is intended to assure that information on hospitalizations is complete for all patients included in the years at risk.
8. **First transplantation rate table.** A table of rates of first transplantation for patients under 65 by age group and modality was added to the Reference Tables (F.36) with the 1997 ADR. 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 in order 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.
9. **Standard population for adjustment.** The adjusted incidence, prevalence, survival, and death rates in this ADR now all use 1995, the year before the most recently reported year, as the standard population for adjustment. See Table XIII-2. The standard populations for adjustment are described in more detail in the section on "Adjustment and Standardization of Rates" later in this chapter.
10. **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 size 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 that follow. The sources are discussed from the point of view of their contribution toward compiling a complete picture of the ESRD population.

HCFA PMMIS/REBUS Database

The major source of patient information is ESRD Program Management and Medical Information System (PMMIS) maintained by the Health Care Financing Administration (HCFA), the federal agency that administers the Medicare program. The HCFA has completed the transition from the way data previously were 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). 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 (Medicare Part A services) and carriers (Medicare Part B services). Furthermore, HCFA contracts with 18 regional ESRD Network offices that perform resolution of patient grievances, continuous quality of medical care assurance, research, and data collection activities.

HCFA Form 2728, Chronic ESRD Medical Evidence Form

This form plays a central role in the USRDS database. Changes in this form in 1995 have had important effects, which will be discussed in succeeding sections of this chapter. A major route of

entry into the HCFA database is through the Medicare ESRD Medical Evidence Form (2728). This form is completed at the dialysis unit for each new ESRD patient treated at that unit and is sent to HCFA through the regional ESRD Networks.

The 2728 Form, which is familiar to all dialysis providers, serves to: 1) establish Medicare eligibility for individuals who previously were not Medicare beneficiaries, 2) reclassify previously Medicare beneficiaries as ESRD patients, and 3) to provide demographic and diagnostic information on all new ESRD patients regardless of Medicare entitlement.

Before 1995, the Medical Evidence Form was only required to be filed for Medicare eligible patients. With adoption of a new 2728 Form in 1995, dialysis providers are required to complete the form for all new ESRD patients, regardless of Medicare status.

This form is the only source of information about the cause of ESRD. The new form uses a somewhat different list of diseases.

Death Notification Form

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

The new Death Notification Form uses a revised set categories for cause of death, and withdrawal from dialysis is no longer a considered a cause of death. Instead, 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 apparent increase in the percentage of deaths due to withdrawal 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 1998 ADR reports cause specific death rates for 1994-1996.

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 to occur 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 some Medicare-eligible patients may not have bills paid by Medicare. These include patients who are covered through private insurance, HMOs, Medicaid, and the DVA.

The PMMIS contains hospital records and quarterly summaries of dialysis treatments. These are derived from the HCFA paid claims records, but contain no actual dollar payment amounts. For years before 1989, these PMMIS records are the only source for the USRDS for Medicare claims data. For 1989 and later years, detailed files of Medicare paid claims are available in the HCFA Standard Analytical Files. These annual files contain all claims processed through 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 Medicare ESRD patients.

UNOS Transplant Database

HCFA collected detailed data about all Medicare kidney transplants starting about 1980. In 1987, the United Network for Organ Sharing (UNOS) was created to provide a national system for allocating donor organs and to maintain a scientific registry on organ transplantation. As part of this effort, UNOS also collected detailed data about all transplants. In 1994, these two data collection efforts were consolidated, and UNOS became the single source for transplant data.

The HCFA and UNOS transplant data files overlap for the years 1987-1993. Additionally, some Medical Evidence Forms indicate transplants which are not included in either the HCFA or the UNOS file. The USRDS CC has created three transplant Standard Analysis Files from these three sources.

The main Transplant SAF provides a roster of all of the transplants indicated by the three sources. In order to resolve the conflicts among the three sources, the following procedure is used. First, all of the UNOS transplants are accepted into the file. Second all HCFA transplants from before 1987 are accepted. Third, HCFA transplants from 1987-1993 are accepted if there is not already a transplant for that patient within 30 days of that HCFA transplant. It is common for the transplant dates to differ by 1 day between these two sources. Finally, Transplants indicated on the Medical Evidence Forms are accepted if there is not already a transplant for that patient within 30 days of the Medical Evidence transplant.

The main transplant SAF has a small number of variables describing the recipient and the donor and indicating the graft failure date computed by the USRDS. The UNOS transplant SAF contains the detailed data from the UNOS transplant file, and the HCFA transplant details file contains the detailed data from the HCFA transplant file. A researcher who needs additional variables can merge the file with either the UNOS or the HCFA details file. The tables in Section F of the Reference Tables are produced primarily from the main and UNOS transplant files.

ESRD Network Census

Periodically since December 1993, the 18 ESRD Networks have provided HCFA with a census from their databases of ESRD patients alive on a particular date. Patients who are listed in this census but are not already in the HCFA system are presumed to be

receiving ESRD treatment independently of the Medicare program. Such patients are entered into the HCFA REBUS database for statistical enumeration purposes. In the absence of a 2728 Form, Medicare dialysis claims, or a transplant record, these patients known only from the Network census are not included in USRDS analyses.

ESRD Annual Facility Survey

In addition to the HCFA ESRD database described above, corroborating ESRD patient counts are available from the Annual Facility Survey, which all dialysis units and transplant centers are required to complete at the end of each calendar year. The Facility Survey contains aggregated patient counts but do not contain patient-specific data. Hence, the Facility Survey lacks demographic and diagnostic information. However, the AFS provides an independent, direct count of ESRD patients that complements the HCFA records.

The Facility Survey reports counts of patients being treated at the end of the year, new ESRD patients starting during the year, and patients who died during the year. The Facility Survey reports both Medicare and non-Medicare patients at the end of the year. The accuracy of the Facility Survey depends on complete reporting by each facility and full reporting by all facilities. Unfortunately, neither of these processes has been validated. Since the number and names of some dialysis units change each year, it is difficult to confirm the completeness of facility reporting on the Facility Survey.

HCFA ESRD Facility Cost Reports

All Medicare-certified dialysis facilities are required to submit a detailed cost report giving a breakdown of costs by detailed categories of labor and non-labor resources. Different reporting formats are used for hospital-based and freestanding units. These reports provide data on staffing patterns as well as on costs.

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 that follow.

The FSD is used as the start of ESRD in the USRDS database, and a patient must have an FSD in order to be included in USRDS analyses. 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. Ninety days after the FSD is used as the starting point for most of the patient survival analyses.

The FSD is derived from a number of data sources:

- The date of start of dialysis for chronic renal failure reported on 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 presence of a Medicare ESRD Death Notification Form indicates that a patient may have been an ESRD patient. However, this form does not give any indication of the date of the start of ESRD and is not useful in establishing the FSD.

Why do reported numbers change?

With each ADR, the counts of new patients by calendar year increase somewhat for years that were reported in previous ADRs. Table XIII-2 shows the most recent year reported for each of the last 5 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.

Delays in receiving data or in identifying a patient as ESRD are probably the main factors in the most recent years. An example of what might cause 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 (now 30 to 33 months) of ESRD. If the private health insurance covers all the dialysis costs, then the Medical Evidence Form, which should be filed immediately by the dialysis unit, 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 finally is filed, the date of start of chronic renal dialysis entered on the form should be the date dialysis started, even though Medicare did not pay for the dialysis at that point. Thus this patient would be newly counted as an incident case for the earlier year

New ESRD Patients by Year as Reported in Recent ADRs

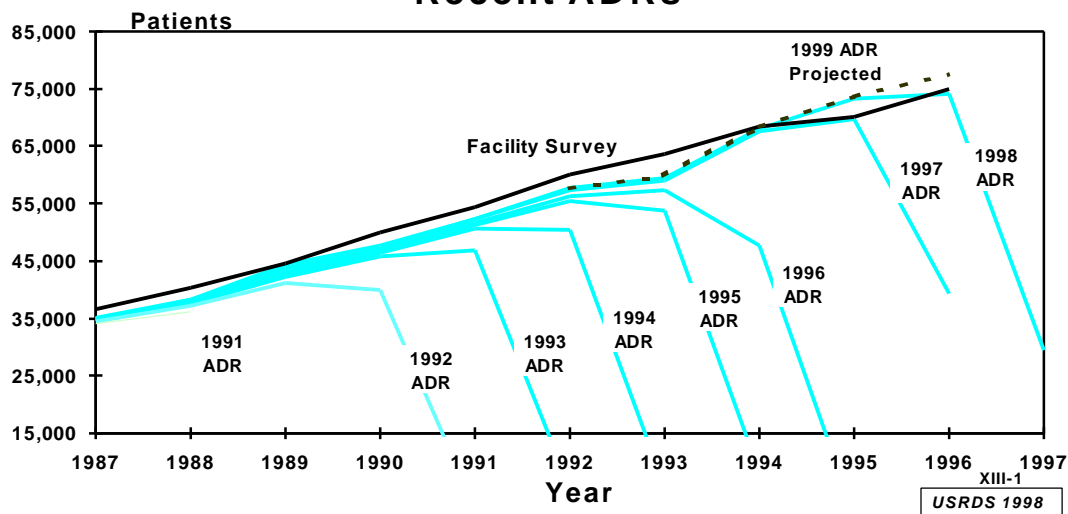


Figure XIII-1

New ESRD patients by year as reported in recent Annual Data Reports.

rather than for the year in which the form was filed and Medicare began paying for dialysis.

In some cases in the past, the addition of new data sources may affect data for prior years. For example, as of the 1993 ADR, data on Department of Veterans Affairs (DVA) patients were reported to HCFA for the first time. In other cases, correction of errors may cause changes. The physician completing the Medical Evidence Form may report the first dialysis ever performed rather than the start of irreversible maintenance dialysis. There may be clerical or keypunch errors in the first dialysis date. The software for determining first service date may be faulty. If a first service date is corrected, then a patient may appear as incident in a different year than was reported in a previous database update.

In the past, the USRDS has followed a "15-month rule" and generally did not report data for periods more recent 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. Because of this shift, in the 1997 ADR we generally reported data through 1995, with a warning that the 1995 data must be treated with some caution as they are still likely to change when reported in the next ADR. With this 1998 ADR, the 1995 incidence count did indeed increase by about 5 percent. With this 1998 ADR, we continue the practice of generally reporting data through year ADR-2, or 1996. Again, the data for 1996 must be treated as preliminary and are likely to change with the 1999 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 earlier.

Figure XIII-2 shows new ESRD patients by the sources of data that are available currently to establish the first service date. The lower three categories represent patients who have ever been Medicare entitled, although not all of these patients were Medicare entitled at the start of ESRD. The

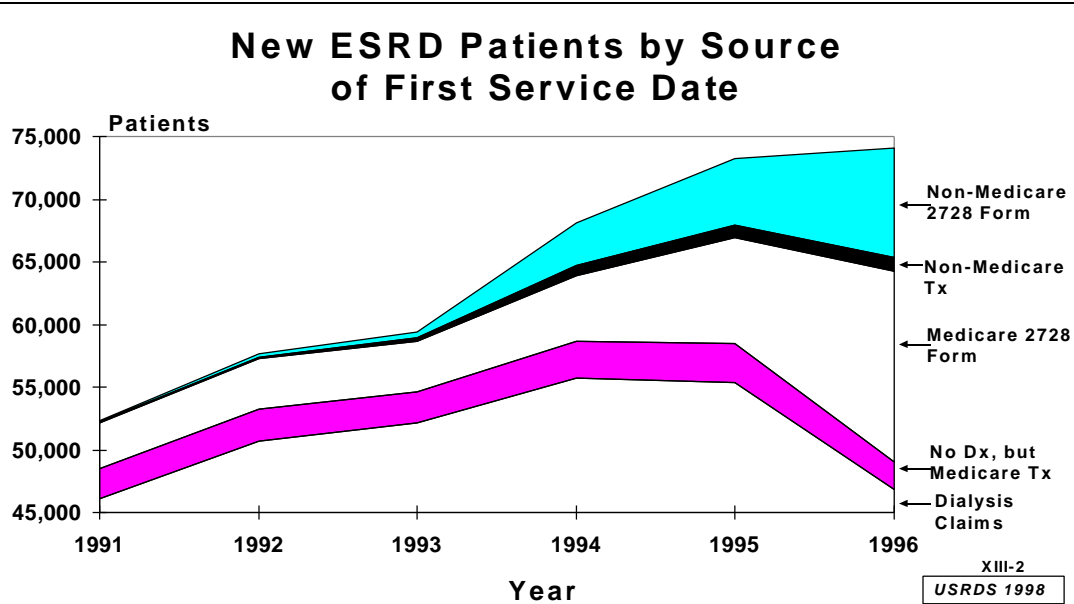


Figure XIII-2

New ESRD patients by source of first service date. See text for explanation

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 from the bottom consists of patients who have a Medicare transplant record but do not have dialysis bills. These patients may also have a 2728 form. The topmost Medicare category consists of patients for whom there is only a 2728 form and no dialysis claims or transplant records.

The decline in the patients with Medicare claims in 1996 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. Starting with the 1997 ADR, these patients have been excluded. We will continue to evaluate the best way to handle these cases.

The 1993 Discontinuity

Figure XIII-1 clearly shows the decreased 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 rate of increase in the incidence of ESRD in 1993.

Lost-to-Followup Methodology

The USRDS creates a “treatment history” for each patient in the database, drawing on all of the data for that patient. This treatment history becomes one of the USRDS Standard Analysis Files provided to researchers, as described in Chapter I.

In constructing the treatment history, we find frequent 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 or death. For a patient with a functioning transplant, the functioning transplant modality continues until a transplant failure or death is encountered. However, a dialysis modality is assumed to continue only for 365 days in the absence of death or 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, two changes were made in the lost-to-followup classification methodology. Previously, the lost-to-followup period was started at the beginning, rather than at the end, of a 365-day period with no claim payment data. The change to the end of the 365-day period in the start of the lost-to-followup period 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.

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 dates 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, which may be a different county than that in which the patient actually resides.

The address and zip code recorded in the Medicare database is the mailing address to which claims-related communications are sent, which may be in a different county or state from the patient's residence. For instance, 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 billing address problem also may explain why a patient's residence may appear to 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.

Note that the USRDS treats successful transplantation as a therapy rather than a "recovery" from ESRD. Patients with a functioning transplant are counted as prevalent patients.

The terms "incidence" and "prevalence" of ESRD imply that information is available about all patients with ESRD, but this is not the case. Actually, the data are for persons receiving ESRD therapy as reported to HCFA and do not include patients who die of ESRD before receiving treatment and those who are not reported to 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 they have had ESRD for at least 2 years and 1 year has passed with no dialysis, death, or transplant data. Starting with the 1992 ADR, patients classified as lost-to-followup are not included in the point prevalence counts, but are reported separately in Table B.1 of the Reference Tables. 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.

The Reference Tables present parallel sets of counts and rates for incidence (Section A) and December 31 point prevalence (Section B). Section B also presents annual period prevalence counts (but not rates) and counts of patients classified as lost-to-followup.

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.

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 classified into 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.

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 1996, 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 1996 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.

For this ADR, rates are reported for 1987 through 1996. 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.

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. The Native American and Asian categories came into use only with patients starting ESRD therapy in 1982 and later. 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 of ESRD reported in this report will be biased slightly low. If bias is uniform across races, then *comparisons* of rates by race are not substantially biased.

The USRDS has not produced tabulations for the Hispanic population because it does not have this data item for all patients. An item on Hispanic ethnicity appears on the new HCFA Medical Evidence Form, which went 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 (Table 2). This table shows the distribution of values in each of the data sources and the distribution of values of the race variable used for this ADR. The USRDS race 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 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. Patients with Hispanic as the Social Security race code are recoded as "other" if race from the Medical Evidence Form is not available.

**Sources of Race Codes in the USRDS Database:
Incident Patients by Year by Race, 1987-1996**

	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996
MEDICAL EVIDENCE FORMS										
Native Amer	344	419	516	652	671	821	697	1,066	1,170	1,356
Asian	535	665	815	1,072	1,124	1,321	1,457	2,347	1,875	1,893
Black	9,139	9,639	11,752	13,164	14,685	16,660	16,344	22,372	21,698	23,525
White	21,767	23,082	26,869	30,856	33,934	37,455	36,595	50,081	46,849	48,102
Unknown	254	310	104	85	121	104	154	1,118	1,018	623
Pacific Islander	508	456	31	22	23	15	20	14	489	587
Mid-East/Arabian									159	206
Indian Subcontinent									120	488
Other								2	1,696	2,209
Not in this Source	1,532	2,030	2,460	2,776	3,199	3,722	4,900	6,861	134	1
TOTAL	34,079	36,601	42,547	48,627	53,757	60,098	60,167	83,861	75,208	78,990
MEDICARE ENROLLMENT DATABASE										
Native Amer	53	81	116	149	165	247	280	323	279	238
Asian	142	192	269	340	476	607	789	791	788	668
Black	9,414	10,425	12,243	12,978	14,386	16,047	16,494	17,581	18,396	17,389
White	22,094	23,856	27,027	29,195	31,811	34,794	35,264	37,995	39,229	38,336
Unknown	986	920	798	869	844	751	550	478	522	447
Other	1,634	2,169	2,447	2,680	2,750	2,552	2,686	4,408	4,998	5,390
Hispanic*	414	590	817	1,103	1,423	1,813	2,127	2,038	2,018	1,844
Not in this Source	31	62	708	391	473	701	1,112	4,312	6,862	9,692
TOTAL	34,768	38,295	44,425	47,705	52,328	57,512	59,302	67,926	73,092	74,004
HCFA TRANSPLANT REPORTS										
Native Amer	55	74	78	76	93	98	94			
Asian	188	182	217	248	238	265	269			
Black	1,627	1,557	1,608	1,739	1,830	1,881	1,995			
White	6,170	5,820	5,930	6,317	6,723	6,591	7,012			
Unknown	355	634	408	676	464	594	654			
TOTAL	8,395	8,267	8,241	9,056	9,348	9,429	10,024			
UNOS TRANSPLANT REPORTS										
Native Amer	14	78	77	63	75	81	80	112	109	121
Asian	4	29	45	52	50	66	45	220	229	340
Black	397	1,839	1,800	1,945	2,010	2,064	2,246	2,496	2,557	2,616
White	1,566	6,748	6,761	7,419	7,629	7,597	8,229	8,040	8,698	8,790
Unknown	28	45	33	55	4	57	31	151	14	1
Other	84	341	301	368	357	367	389	372	237	134
TOTAL	2,093	9,080	9,017	9,902	10,125	10,232	11,020	11,391	11,844	12,002
RACE USED FOR THE ADR										
Native Amer	395	507	585	645	693	851	775	958	1,170	1,278
Asian	1,150	1,141	958	1,169	1,308	1,486	1,715	2,163	2,462	2,475
Black	9,774	10,888	12,843	13,661	15,112	16,751	17,338	20,010	21,609	21,885
White	23,310	25,561	29,283	31,826	34,769	37,928	38,717	43,505	45,437	46,472
Unknown	27	35	649	324	354	395	571	869	1,028	156
Other	112	163	107	80	92	101	186	421	1,386	1,738
TOTAL	34,768	38,295	44,425	47,705	52,328	57,512	59,302	67,926	73,092	74,004

Source: HCFA 2728 Forms, Medicare Enrollment Database, HCFA and UNOS Transplant Reports
*Hispanic is included as an ethnicity category in the Medical Evidence and transplant files.

Table XIII-2

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 Mid-East/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 subpopulations 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 differences in age distribution 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 rates that are not adjusted for age.

The USRDS to use as the standard population for adjustment of rates the relevant population from the year before the most recent year for which data are reported in the ADR. For this 1998 ADR, the most recent year reported is 1996, so the standard populations will be from 1995. For adjustment of incidence and prevalence rates in Sections A and B of the Reference Tables (1987-1996), the standard population is the July 1, 1995, United States resident population. For adjustment of patient survival rates

in Section E, the standard population is the 1995 incident ESRD population. For adjustment of graft survival rates in Section G, the standard population is all patients transplanted in 1994 through 1995. The standard populations are subclassified by 5-year age groups, four race categories, and gender

The adjustment method described here is the "direct standardization" method and is the method used through most of this report.

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 the 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 and total admissions per 1,000 patient year at risk, and days in the hospital per year at risk. Section F presents transplant rates per 1,000 patient years at risk for never transplanted dialysis patients under 65. All of these 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, first hospital admission, and first transplant rate tables report only 1996 values. This change is discussed further below. Rates are presented by age, race, gender, and diabetic status for several groups of patients.

Methods

Starting with the 1997 ADR, several major changes were made to the methods for calculating the national death, first admission, and first transplantation rates for prevalent patients reported in Tables D.2, D.3, H.1, H.2, and F.29.

1. Specific dialysis-unrelated deaths (DU deaths) were excluded from the calculations (deaths due to AIDS, accidents unrelated to treatment such as violence, and street drug overdoses).
2. The 1996 rates for patient subgroups published in this report are estimated using a Poisson regression model. This new method yields more stable and interpretable estimates than does the previously used method of estimating the rates separately for each subgroup.

These changes are discussed below. Further details were reported in abstracts presented at the 1996 American Society of Nephrology meeting (Turenne, Wolfe 1996).

Dialysis-unrelated deaths

Cause of death categories available on the ESRD death notification form include: AIDS, accidents unrelated to treatment, and street drug overdoses. These particular categories are classified as dialysis-unrelated deaths (DU deaths) and were not included in the death count when we computed the national ESRD and dialysis death rates (Reference Tables, Section D). The DU deaths continue to be counted as deaths in the survival curve calculations (Reference Tables, Section E). **Our intent in excluding the DU deaths is to make the death rate tables more useful as a norm for evaluating the care given to ESRD patients.** Since the deaths due to AIDS, accidents

unrelated to treatment (e.g. violence), and street (illegal) drug overdoses are largely beyond the control of the ESRD caregivers and may differ regionally, we have excluded them from the death rate calculations.

For DU deaths from accidents unrelated to treatment and street drug overdoses, the death was not counted, but the person years of survival were counted. In statistical terms, the patient was considered censored at the time of their DU death. For patients who died of AIDS, both the deaths and person years of survival were excluded from the calculations. Although most AIDS deaths were unrelated to dialysis, some may have been dialysis-related, and we were unable to make this distinction from the data. For the hospitalization and transplantation rates, this change means only that patients who died of AIDS are not included in the tables (their years at risk are not counted).

Table V-7 in the 1997 ADR reported that DU deaths during 1993 were only 1.9 percent of all deaths. Although the DU deaths account for only a small fraction of the total deaths among ESRD patients, they can account for a larger fraction of deaths at some facilities. Studies that make comparisons to these new USRDS published death rates should also exclude deaths due to AIDS, accidents unrelated to treatment, and street drug overdoses from their calculations.

Stabilized rates

Death and first admission rates are reported for 248 patient subgroups defined by age (16 groups), race (4 groups), sex (2 groups), and diabetes (2 groups), where all patients less than 15 years of age were classified as having a nondiabetic cause of ESRD. Before the 1997 ADR, these rates were calculated based on the observed mortality or admissions among patients in each subgroup during a 3-year period. Starting with the 1997 ADR, a regression model was used to stabilize the rate estimates for these patient subgroups. **The new rates were used for Reference Tables D.2, D.3, H.1, H.2, and F.29.** The model was based on data from 1994-1996. Although three years were used to improve the stability of the rates, only 1996 death or first admission rates are reported.

We used a log-linear Poisson regression model with 2-way interactions between diabetes, sex, race, and age (linear), as well as extra terms for the two youngest age groups (0-14, and 15-19) when warranted. In addition, the model included

adjustments to estimate the overall percentage differences in rates among the 3 years. The reported rates in a category are a weighted average of the observed rates and the rates predicted by the regression model for that category. More weight is given to the observed data for categories with many patients and more weight is given to the regression model for categories with few patients. The model is called a “random effects model” and the resulting estimates are called “best linear unbiased predictors” in the statistical literature (Robinson). Further details are available from the Coordinating Center upon request. The new method yields rate values that are much more stable over time and allow more consistent and interpretable results.

First transplantation rates are calculated in a similar fashion but are reported only for 11 patient age groups for never transplanted dialysis patients under age 65. Again, the rates are based on data from 1994-1996, with results for first transplantation rate reported only for 1996. The log-linear Poisson regression model is similar to that described above but does not include terms for race, sex, or diabetes.

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.

Changes in Who is Included

Beginning with the 1994 ADR, we have included patients starting ESRD therapy during the year (incident patients), as well as previously transplanted dialysis patients. These two changes are discussed further below. 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. Starting in the 1998 ADR, in addition to the rules used before for

including patients in the hospitalization rates, dialysis patients must reach a certain level of Medicare paid dialysis bills. This new criterion is intended to assure that information on hospitalizations is complete for all patients included in the years at risk.

Incident Patients. The original methodology for death and hospitalization rates 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 for death and hospitalization rates, previously transplanted dialysis patients were excluded. The new methodology has patients reenter the analysis dataset for dialysis patients 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.

Additional Criteria for Patients to Enter Hospitalization Analyses: Data used in the hospitalization rate calculations (Section H) are now limited to patients whose start date for each year (January 1 or day 91 of ESRD) falls in between the start and end dates, based upon Medicare payment activity, used for the cost studies in this ADR. In particular, dialysis patient start dates (January 1 of the year for prevalent patients and day 91 of ESRD for incident patients) must fall between the start and end dates based on Medicare paid dialysis claims described below.

- The **start date based on Medicare paid dialysis claims** is 30 days after the first month in which there are at least \$675 of Medicare paid dialysis claims.
- The **end date based on Medicare paid dialysis claims** is the end of a 3-month period in which they had less than \$675 of paid claims in each month.

These rules are similar to the rules used for the cost analyses (Chapter X) except that the paid claims dates only come into play for the start date. The end date is still the earliest of death, 3 days prior to transplant, and December 31 of the year.

Using an individual's Medicare cost profile to determine eligibility for inclusion in the analysis of hospitalization increases the likelihood of capturing all available information on hospitalization. Hospitalization is a major component of these costs, and patients for whom Medicare is the secondary payer for all or part of the study period are automatically excluded from the analysis because the Medicare bills are unlikely to include all hospitalizations for such patients. Eligibility criteria used in previous years did not adequately screen patients for whom Medicare was the secondary payer and consequently a number of such patients (particularly in the later years) contributed relatively sparse information on hospitalization. The failure to capture these events and/or days in the hospital may have biased (perhaps even differentially by age) the various rates towards zero. The new criteria should lead to summary rates that better reflect the true hospitalization experience of ESRD patients.

Patient Categories for Mortality and Hospitalization Rates

Below is a list of the categories for which mortality and hospitalization 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 at death or at 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 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.

- Patients with a functioning transplant at the start of the period and have had the transplant for at least 60 days. Only mortality rates are reported for this category of patients. There are no special censoring procedures for calculating the period at risk for mortality for these patients
- All ESRD patients. The period at risk for hospitalization is censored at death. This category will be less useful than the others but is included for completeness and as an overall reference.

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 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 1 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.

Mortality 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 (described below). For the remaining tables, the period at risk is calculated in the same way and used in the Poisson regression model discussed above. 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) with one exception: if the patient is transplanted, the time at risk for death ends on the date of the transplant; the time at risk for hospitalization ends 3 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. First admission and total admission rates are also reported per 1,000 patient years at risk. Hospital days rates are in terms of 1 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 contribute days at risk to all years during which he/she is alive. 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 Under 65 Years

The rules for classifying patients are the same for this table as those described in the section above except that only patients under 65 who have never been transplanted are eligible to be 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 for first transplantation rates 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 contribute days at risk to all years during which he/she is alive. 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.

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 three years 1991-1993. The last transplant year is 1993 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 separately.

Patient Survival Analysis Methodology

All new ESRD patients who had a first service (dialysis or transplant) between January 1, 1977, and December 31, 1995, were included in the survival analysis. They were followed until December 31, 1996, giving a maximum followup of 15 years and a minimum followup of 1 year.

In each table in Section E, the survival rates for the most recent year extend into 1996. They are considered preliminary and must be used with caution.

Patient survival probabilities are estimated using the Kaplan-Meier method (KAPLAN) as implemented in the SAS LIFETEST (SAS) procedure. Standard errors are estimated using 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 four groups: all, dialysis censored at first transplant), first transplant-cadaveric, and first transplant-living donor). For the two transplant groups, the classification is based on subsequent rather than initial modality. For these groups, the median times from onset of ESRD to first treatment with these modalities also are 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 1 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 90-day delay is necessary because many patients under age 65 do not become eligible for Medicare for up to 90 days, and for most patients the database does not have data until the patient becomes eligible. Additional tables for patients 65 and over are presented, showing survival from onset of ESRD to day 90 (early survival) and from onset 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 selecting patients to be treated using a given modality, patient characteristics and comorbid conditions 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 are made 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 cause of ESRD sub-group by the year of incidence.

Some survival results in Section E of the Reference Tables are adjusted for age, race, gender, and primary cause of ESRD. The standard population for these adjustments is the incident ESRD

population for the year before the most recently reported year, or 1995 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 subgroups was limited to four age, two gender, three race, and four primary cause of ESRD groups. These limitations were imposed because more cells would have led to undesirable smaller sample sizes and the Kaplan-Meier survival estimates become biased toward high estimates with small cell sizes.

All ESRD 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, 1996).

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, 1996).

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, 1996). 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, 1996). 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 1994-1995.

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 to be a change in modality. Patients who are classified as 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 database.

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, namely outpatient dialysis claims. Physician/supplier claims account for about 88 percent of the claims but only 20 percent of the dollars. Part B outpatient dialysis claims are submitted on Part A claims forms not on Part B forms.

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 6 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 65 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 240 million physician/supplier claim line items for 1991 through 1996. The full claims data require a minimum of 25 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. 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 except Table K-8 are based on an "intent-to-treat" model. This model computes payments per patient year at risk over the 5-year period 1992 through 1996. 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 in the analysis even if their dialysis modality changes over the 5-year period. 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, 1992) and patients who receive a transplant during the study period (1992-1996). 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 1992 through 1996. ESRD patients prevalent on January 1, 1992 or incident at any time during 1992 through 1996 were potentially eligible for inclusion in the study sample. The study start date for a given patient was defined as 30 days after the latest of the following:

- January 1, 1992.
- 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 1992 through 1996 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 or transplantation, date lost-to-followup, or December 31, 1996, whichever came first. Patients were defined as lost-to-followup if there were a period of three consecutive months in which dialysis payments per month (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. nondiabetic cause of ESRD.

Diabetic ESRD status is based on the primary disease causing ESRD. A patient with a nondiabetes 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.

An additional table, Table K.8 was added to Section K this year. In Table K.8 Medicare payments are aggregated by physician/supplier specialty type. More than 100 HCFA specialty types were collapsed to form 51 categories of physician/supplier specialty type. The table presents the payment per year at risk for calendar years 1992-1996.

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