

# 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 *1999 Annual Data Report (ADR)*, and the differences between this ADR and the *1998 ADR*. It is intended primarily to be a reference for the more technical aspects of the database and the methodologies. 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 changes in the USRDS database, differences between this *1999 ADR* and the *1998 ADR*, 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 reported in 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.

**1. More recent data reported.** This ADR is based on an update of the USRDS database with data reported to the Health Care Finance Administration (HCFA) through September 1998. It also includes Medicare paid claims data through calendar year 1997. Table XIII-1 shows

various reference dates for the past five ADRs and provides a reference for comparisons of ADRs over time. Beginning at the time of the *1997 ADR*, the HCFA ESRD data system substantially speeded up the flow of data. A shorter period is now required before the data are considered nearly complete. This allows us to report data through 1997. The data for 1997 still should be regarded as preliminary, as reported values for 1997 are likely to change somewhat when reported in the *2000 ADR*. For instance, the counts of new ESRD patients reported for 1996 increased about 3 percent between the *1998 ADR* and this *1999 ADR*. A similar change can be anticipated for the 1997 data between the *1999 ADR* and next year's *ADR*.

- 2. New adjustment methodology for survival analysis.** The methodology for the analyses of patient survival (Section E) and kidney graft survival (Section G) has been modified to use Cox models to compute the adjusted survival probabilities. This change has become practical because the dramatic increase in computer speed and memory capacity.
- 3. Section K.** A number of problems were corrected in the tables in Section K of the Reference Tables. The largest effect will be seen in the physician/supplier claim payments for the transplant modality. Some of the physician claims for the transplant operation were missed in previous *ADRs*. A new table of Medicare

payments by treatment modality and state of residence appear in the Table of Contents for Section K but are available only on the USRDS Web site and on the USRDS ADR CD, not in the paper version of the ADR.

4. **New Reference Tables based on the Medical Evidence Form (HCFA-2728).** A revised Medical Evidence Form (HCFA-2728), went into use in April 1995. This year we have added a new Section (L) to the Reference Tables based on data from this form, and have devoted Chapter IV to an examination of characteristics of new patients based on these data. The effects of the new form also can be seen in the counts of non-Medicare patients starting in 1995. In addition, the new form also introduced a new coding scheme for the primary disease causing renal failure.
5. **Elimination of duplicates.** HCFA has made considerable progress over the past year in identifying and correcting cases in the database in which the same patient is represented 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 1998 ADR. The USRDS CC and HCFA are continuing to work together to develop ongoing procedures for identifying and correcting resolving new duplicate cases as they occur.

6. **Missing and unknown cause of death.** Because of changes in the HCFA Renal Beneficiary and Utilization System (REBUS), we are no longer able to distinguish between deaths where the physician indicated that the cause of death is unknown and cases where there is no Death Notification Form for the patient.
7. **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 transplant data 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. However, the UNOS data do

## 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 Adjustment of Incidence and Prevalence Rates	5) Year of Standard Population for Adjustment of Patient and Graft Survival
<i>1994 ADR</i>	May 1993		1991	1990, 1991	
<i>1995 ADR</i>	May 1994		1992	1991	
<i>1996 ADR</i>	Sept. 1995	December 1994	1993	1992	
<i>1997 ADR</i>	Sept. 1996	December 1995	1995	1994	1993
<i>1998 ADR</i>	Sept. 1997	December 1996	1996	1995	1994
<i>1999 ADR</i>	Sept. 1998	December 1997	1997	1996	1995

1) Patient data, including death date, are updated from the HCFA REBUS/PMMIS 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 incidence and prevalence rates. It is the year before the most recent year reported for incidence and prevalence. The standard population is U.S. resident population.

5) This is the year of the standard population for adjustment of patient and graft survival rates (Reference Tables Sections E and G). This is the year before the most recent year reported in these Sections. For survival rates, the most recent year reported is one year earlier than the first year reported for incidence and prevalence because one year must be allowed for followup in computing the survival. The standard population for patient survival is incident ESRD patients for the standard population year. For graft survival, the standard population is patients transplanted in the standard population year.

**USRDS 1999**

**Table XIII-1**

not include some transplants for which we have Medicare claims data. Records were added for about 700 transplants with dates in 1994 and later years, although only minimal data are available for these transplants. Prior to 1994, HCFA created transplant records for such cases.

- 8. Standard population for adjustment.** The adjusted incidence, prevalence, survival, and death rates in this ADR all use the year before the most recently reported year as the standard population for adjustment. The standard populations for adjustment are described in more detail in the section on "Adjustment and Standardization of Rates" later in this chapter.
- 9. Death, hospitalization, and transplant rate methodology.** Minimal new changes have been made to these methodologies this year. Starting with the 1998 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. Also, dialysis patients must have \$675 of Medicare paid dialysis bills in one month before being included in the hospitalization rate analysis. This is the same criterion used for including a patient in the intent-to-treat model in Section K of the Reference Tables and is intended to assure that information on hospitalizations is complete for all patients included in the years at risk. The amount approximates the tenth percentile for monthly dialysis payments.
- 10. 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 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 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 were classified as lost-to-followup at the end of 2 years. The number of such patients increased substantially in 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.

- 11. Minimum aggregation size reported in data tables.** 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.

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## Year 2000 Compliance

The two primary systems used to store and manipulate the USRDS database have always stored dates in a format that is unaffected by the change in century at the end of 1999. To use the current jargon, they are Y2K compliant. In 1998, the handling of dates in the Fortran and C programs used in the processes of updating the database and of producing the Annual Data Report was revised so that these programs now are Y2K compliant. The computer hardware and operating systems used by the USRDS CC are reported to be Y2K compliant by their manufacturers. The USRDS CC will continue to review its software library to identify any more obscure Y2K problems.

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## Changes in the HCFA Data System

HCFA is currently undertaking an ambitious overhaul of its ESRD data system that promises significant improvements in completeness, accuracy, timeliness, and detail in the data available to the USRDS database. The USRDS Coordinating Center staff have been actively involved in a number of areas of this effort.

The first part of this overhaul is the development of a Standardized Information Management System (SIMS) for the ESRD Networks. SIMS will be the

route for the data collected by the ESRD Networks on the Medical Evidence, Death Notification, and Facility Survey forms. It also will maintain current data about each patient's treatment modality and dialysis provider. SIMS will further standardize the Network data collection efforts, will provide better tracking of patients who move between Network areas, and will improve the timeliness and accuracy of the data. SIMS is scheduled to begin full operation by the end of 1999.

The second part of the overhaul is the replacement of the current Renal Beneficiary and Utilization System/Program Management and Medical Information System (REBUS/PMMIS) with a new Renal Management Information System (REMIS/PMMIS). This will be HCFA's central database of ESRD data and will be the source for much of the data in the USRDS database. Key aspects of this development will be use of a more technologically advanced database management system, a revised data structure, improved user interfaces, and more sophisticated database integrity checking. SIMS will forward much of its data on to REMIS. REMIS is scheduled to be operational in the Spring of 2000.

The third part of the overhaul is the development of a Facility Data System (FDS) to be used by dialysis facilities for collection of data that is required to be reported to HCFA. The FDS will feed data electronically to SIMS. Among the objectives of this system are improving the timeliness and accuracy of the data reported to the ESRD Networks. A pilot of the FDS is to be developed this year for initial testing beginning in January 2000.

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## Database

This section discusses the various sources of data for the USRDS database as background for discussions that follow.

### HCFA REBUS/PMMIS Database

The major source of patient information for the USRDS is the REBUS/PMMIS maintained by the Health Care Financing Administration (HCFA), the federal agency that administers the Medicare program.

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.

The REBUS/PMMIS incorporates data from most of the other sources described below.

### 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 (see also chapter IV). 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 eligible Medicare beneficiaries as ESRD patients, and 3) provide demographic and diagnostic information on all new ESRD patients regardless of Medicare entitlement.

Before 1995, the Medical Evidence Form was required to be filed for Medicare eligible patients only. 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 eligibility status.

This form is the only source of information about the cause of ESRD. The new form uses a somewhat different list of diseases than was used in the earlier version of the form. The USRDS database stores the codes actually reported on each version of the form so that detail is not lost through trying to convert one set of codes to the other. Reference Tables A.36-A.39 (available on the Web site and ADR CD only) provide tabulations by the detailed disease codes and by the disease groups used in the *ADR*.

### Death Notification Form

In March of 1990, a revised 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 of the old version forms were filed.

The new Death Notification Form uses a revised set of categories for cause of death, and withdrawal from dialysis is no longer 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 1999 ADR reports cause specific death rates for 1995-1997.

As indicated earlier, because of changes in the REBUS/PMMIS system at HCFA, we are no longer able to distinguish between deaths where the physician indicated that the cause of death is unknown and cases where there is no Death Notification Form for the patient.

## Medicare Enrollment Database

The Medicare Enrollment Database (EDB) is the master database of Medicare beneficiaries. It provides the REBUS/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 obtains data about Medicare entitlement, residence, and Medicare secondary payer status directly to the EDB.

## 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 REBUS/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 REBUS/PMMIS records were 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 that are not included in either the HCFA or the UNOS file. The USRDS CC has created six 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 UNOS transplant for that patient within 30 days of the 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 SAF contains the detailed data from the HCFA transplant file. A researcher who needs additional variables can merge the main transplant SAF 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. Two transplant followup files are also available, one containing followup details collected by HCFA, the other containing followup details collected by UNOS.

Finally, a kidney transplant waiting list SAF has been constructed from the UNOS waiting list files. This file provides the dates of first entry onto the waiting list for each patient ever listed on the waiting list. This file can be used to identify dialysis patients who have been candidates for transplantation for comparison with patients who actually were transplanted.

## 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/PMMIS database for statistical enumeration purposes. In the absence of a 2728 Form, Medicare outpatient 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 (AFS), which all dialysis units and transplant centers are required to complete at the end of each calendar year. The AFS contains aggregated patient counts but do not contain patient-specific data. Hence, the AFS lacks demographic and diagnostic information. However, the AFS provides an independent, direct count of ESRD patients that complements the HCFA records.

The AFS 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 AFS reports both Medicare and non-Medicare patients at the end of the year. The accuracy of the AFS 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 AFS.

## 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. Because there has been minimal use of these reports, data for years after 1995 are not currently available.

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## How Do We Know That These Patients Have ESRD?

We know that these patients have ESRD because a physician certified so on a Medical Evidence Form (HCFA-2728) and/or because we have other evidence that they have received chronic dialysis or a kidney transplant. Actually, what we know is that these patients have received chronic renal replacement therapy. We try to exclude patients who experience acute renal failure and are on dialysis for days or weeks but then recover kidney function. We miss some patients who die soon after kidney failure and may or may not have received dialysis before they died.

A more precise operational answer to this question is that we count patients for whom we can establish a date of first ESRD service (first service date or FSD) and who do not have serious data problems. For instance, we do not count patients who

have serious conflicts in important dates (like death date before birth date) and patients who appear to be duplicated in the database. Of the 984,376 patients currently in the USRDS database, 6.8 percent are not used for the ADR tables or for other analyses because there is too little data to establish an FSD, and 1.1 percent are not counted because of serious data problems.

Because of this operational definition of who is an ESRD patient, the date of first ESRD service is the single most important data item in the USRDS database. 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 by taking the earliest of the following dates:

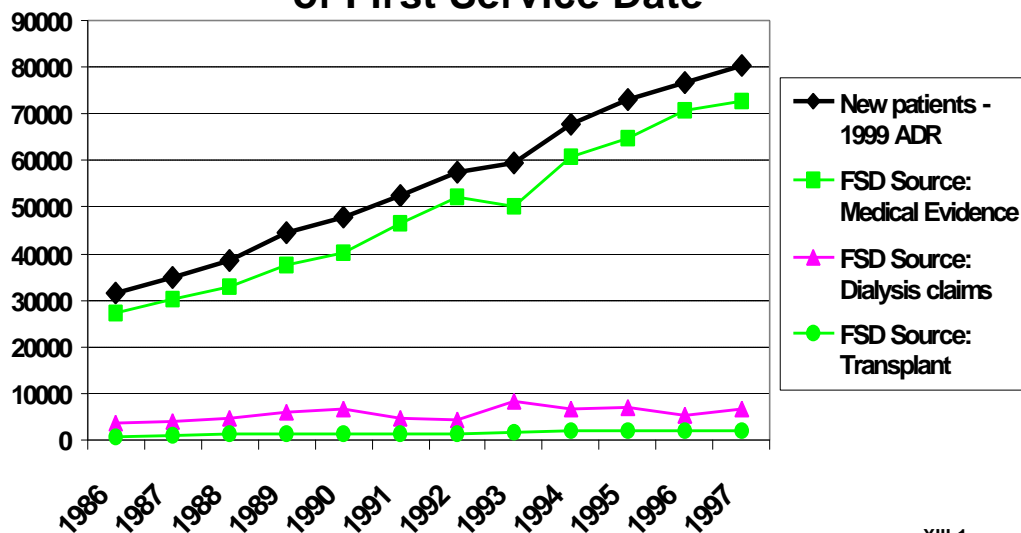
- The date of start of dialysis for chronic renal failure reported on the Medical Evidence Form.
- The date of a kidney transplant as reported on a HCFA or UNOS transplant form, a Medical Evidence Form, or a hospital inpatient claim.
- The date of the first Medicare outpatient dialysis

claim.

Figure XIII-1 shows new ESRD patients by year and by the source of the FSD. The date of first dialysis reported on the Medical Evidence Form is the predominant source for the FSD. When there is not a Medical Evidence Form, the date of the first Medicare dialysis claim usually supplies the FSD. In a few cases, the date of the earliest claim is earlier than the first dialysis date on the Medical Evidence Form, so that the earliest claim date is used as the FSD. In a small number of cases, a transplant date is the earliest date and provides the FSD. One example is the case where there was an early transplant (as early as the 1960s), but a Medical Evidence Form was not filed until the patient returned to dialysis when the transplant failed many years later.

As indicated earlier, about 6.7 percent of the patients in the USRDS database are not counted because there are not enough data to establish an FSD. Some of these patients have a Medicare ESRD Death Notification Form indicating 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. In addition, the HCFA REBUS/PMMIS system includes patients who have an FSD based on data from the databases of the 18 HCFA ESRD Network

### New ESRD Patients And Main Sources of First Service Date



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Figure XIII-1

How Do We Know That These Patients Have ESRD? See text for explanation. Source: Special Analysis.

## How Sure are We That These Patients Have ESRD?

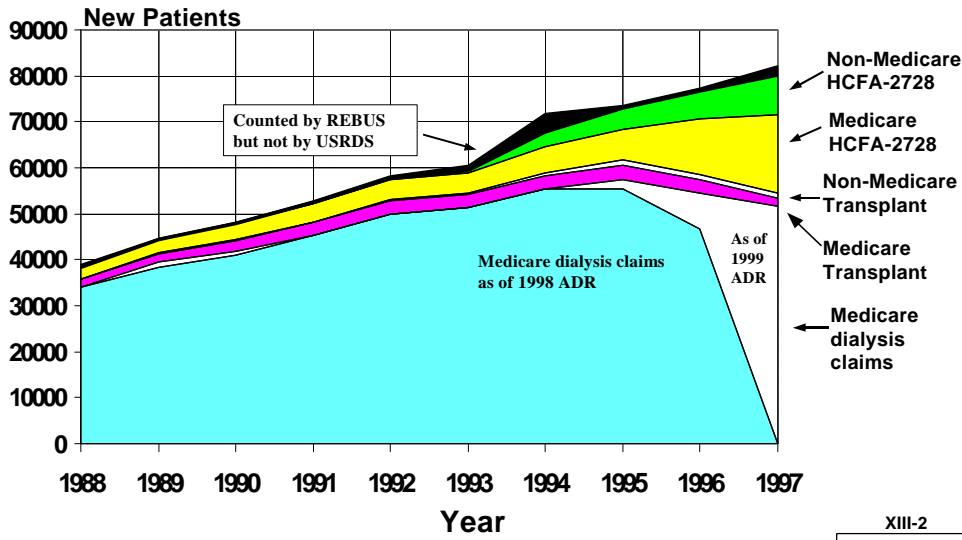


Figure XIII-2

XIII-2  
USRDS 1999

How Sure Are We That These Patients Have ESRD? See text for explanation. Source: Special Analysis.

organizations. The USRDS does not count these patients in the absence of a Medical Evidence Form, a transplant record, or Medicare outpatient dialysis claims.

### Are We Sure That These Patients Have ESRD?

The previous section looked at how we determine the date of first ESRD service and thereby count the patient as an ESRD patient. In some cases a single Medical Evidence Form is the only indicator the person has ESRD. In other cases there is a long history of dialysis claims.

Figure XIII-2 looks at the question of how sure we are that these patients have ESRD by classifying patients using the hierarchy described below, in which a lower level in the hierarchy indicates greater certainty that the patient is ESRD.

At the first level of the hierarchy are the patients about whom we are most sure—those for whom we have Medicare dialysis claims. These patients may or may not have a Medical Evidence Form and may or may not have a transplant. At the second level are patients for whom we have no dialysis claims but for

whom there is a transplant record. These patients may or may not have a Medical Evidence Form.

At the third level of the hierarchy are the patients for whom the only evidence of ESRD is a Medical Evidence Form. Some of these patients will remain non-Medicare patients, for whom little additional data will be received.

At the fourth level of the hierarchy are the patients for whom none of the other data sources are present, but for whom HCFA’s REBUS/PMMIS system has a first service date based on the ESRD Network databases or on the date of Medicare entitlement. This last group is not counted as ESRD in the ADR. Some of these patients have a Medicare ESRD Death Notification Form, but that form provides no data to establish a first service date.

For the transplant and Medical Evidence Form levels of the hierarchy, Figure XIII-2 divides the patients into patients who have ever been Medicare entitled and those who have never been Medicare entitled.

As years pass and more data arrives, patients may move from higher to lower levels of the hierarchy. For instance, many patients are classified in the third (Medical Evidence Form) level this year because a



Medical Evidence Form has been filed, but Medicare claims have not started yet. Next year, many of these patients will have Medicare dialysis claims and will move to the first level.

Keep in mind that the Medicare dialysis claims category means that the patient has such claims at some time, not necessarily in the year of incidence. Similarly, the transplant category means that the patient has a transplant at some time, not necessarily in the year of incidence. As an illustration of this, we have divided the group with dialysis claims into those who had claims at the time of the 1998 ADR and those who began to have claims in the succeeding year.

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

### 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. Figure XIII-3 shows the most recent year reported for each of the last 5 ADRs.

Figure XIII-3 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

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

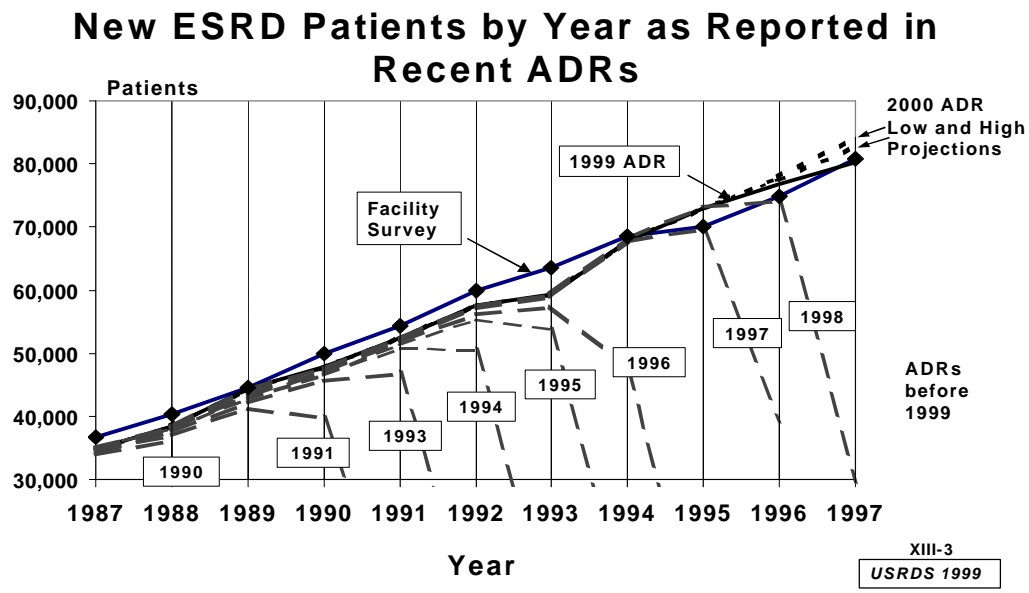


Figure XIII-3

New ESRD patients by year as reported in recent Annual Data Reports. Source: Special Analysis.

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-3 shows a dramatic change from the lines for earlier ADRs, resulting from a sharp improvement in the timeliness of the data. Because of this improvement, 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 the 1998 ADR, the 1995 incidence count did indeed increase by about 5 percent. Similarly, between the 1997 and 1998 ADRs the incidence counts for 1996 increased by about 3 percent. With this 1999 ADR, we continue the practice of generally reporting data through year ADR-2, or 1997. Again, the data for 1997 must be treated as preliminary and are likely to change with the 2000 ADR.

There appear to be two major reasons for the greater currency of the data since 1995. First of all, the improvements that HCFA has made to the REBUS/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.

### The 1993 Discontinuity

Figure XIII-3 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.

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### 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. From this treatment history, we create the Treatment History Standard Analysis File, 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 current method of starting at the end of the 365-day period produces aggregate results that 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.

A number of factors can result in a cessation of dialysis data and eventual reclassification of the patient to lost-to-followup status.

- The patient may have recovered renal function and no longer be ESRD.
- The patient may have left the country.
- The patient’s dialysis therapy may be covered by a payer other than Medicare or the patient may have received a transplant not paid for by Medicare and not reported to UNOS.
- The patient may be enrolled in a Medicare HMO, so that Medicare claims for dialysis are not generated even though the patient is covered by Medicare.
- The patient’s death may not have been reported to the Social Security System or to Medicare.

In the future, we expect to be able to identify more accurately Medicare ESRD patients who are enrolled in HMOs. Also, the changes to the HCFA data systems described earlier in this chapter should result in better tracking of non-Medicare dialysis patients and to a reduction in the number of patients who must be classified as lost-to-followup.

Figure XIII-4 shows period prevalent patients by year by status at the end of the year and by the lost-to-followup experience of the patient. Also shown is patients lost-to-followup at the end of the year as a percentage of all patients alive and not lost-to-followup at the end of the year. Since 1984, the number of lost-to-followup patients has been under 7.3 percent of the

number of living patients not lost-to-followup. From 1989 through 1995, the percentage was between 5 percent and 5.5 percent. In 1996 and 1997, the percentage rose reaching 7.19 percent in 1997. These percentages represent the percent increase in the ESRD population that would result if these patients were counted as ESRD patients rather than as lost-to-followup.

Figure XIII-5 shows the patterns of lost-to-followup experience in the USRDS database by the year of the patient’s first ESRD service. The chart shows patients who ever were lost-to-followup, broken down by the pattern of their lost-to-followup experience. The proportion of patients ever lost-to-followup decrease steadily from 18.4 percent among patients starting in 1978 to 7.2 percent for those starting in 1987. The percentage remains under 7 percent through 1993, then increases to 11.3 percent in 1995. The figure stops with 1995 since two years are required before a patient can become classified as lost-to-followup.

The upper two bands in Figure XIII-5 represent patients who do return from lost-to-followup. It is the shrinking of these bands that accounts for the steady decline in the overall percentage. These patients have a first service date that is well before the start of dialysis claims, but they do eventually start having

### Period Prevalent Patients by Year End Status and Lost-to-Followup History

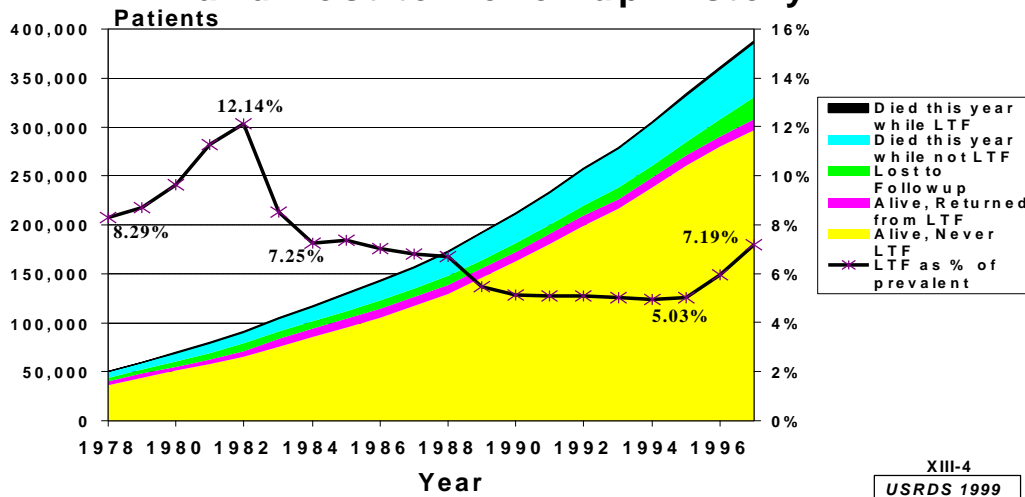


Figure XIII-4

Period Prevalent Patients by Year End Status and Lost-to-Followup History. Source: Special Analysis.

### Patterns of Lost-to-Followup (LTF) Experience by Year: Percent of New ESRD Patients Ever LTF by Year and Type of LTF

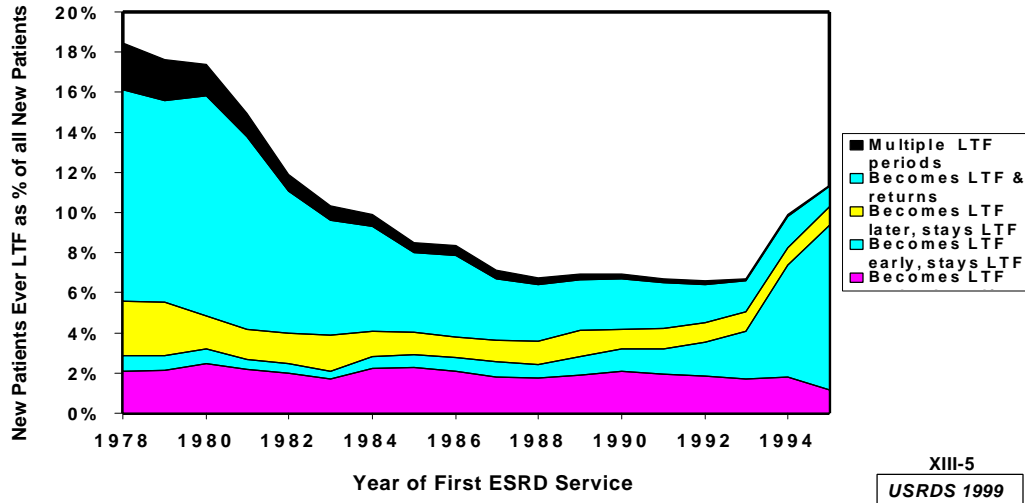


Figure XIII-5

XIII-5  
USRDS 1999

Pattern of Lost-to-Followup (LTF) Experience by Year: Percentage of New ESRD Patients to Ever LTF by Year and Type of LTF. Source: Special Analysis.

claims, at which point they return.

The bottom three bands in Figure XIII-5 represent patients who become lost-to-followup and never return to active status. This “never returned” group remains at a stable level until 1993. The sharp upturn in the overall percentage after 1993 is driven entirely by the subgroup of “never returned” patients labeled ‘Becomes LTF early...’ in Figure XIII-5. These are patients for whom we have a Medical Evidence Form, but no further information. This in turn is the effect of the requirement that Medical Evidence Forms be completed on all new dialysis patients starting in 1995. These patients are non-Medicare dialysis patients who become lost-to-followup at the end of the second year of ESRD because they have no Medicare dialysis claims.

Again, the changes to the HCFA data systems described earlier in this chapter should result in better tracking of non-Medicare dialysis patients and to a reduction in the number of patients who must be classified as lost-to-followup.

### 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 and/or state of residence based on the county and state in which the patient is receiving treatment, which may be a different county and/or state than those 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.

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## 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 newly 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). We generally report point prevalence as of December 31. Period prevalence generally is reported for a calendar year. 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 but 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 that 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 current 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 ESRD relative to the population and provide a convenient method of comparing the occurrence of ESRD 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 to provide 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/Pacific Islander, and Native American/Alaskan Native. Age is divided into 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, age, race, and sex (U.S. Bureau of the Census). 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 1988 through 1997. 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. Tables A.1 and B.1 report counts for the “other” and “unknown” categories, but these categories are dropped from all incidence and prevalence rate tables which report rates by race.

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 new Medicare Medical Evidence Form (HCFA-2728) includes a question on Hispanic ethnicity, and tabulations based on this question appear in Chapter IV and in Section L of the Reference Tables.

The race codes used for this ADR are derived from four race codes that are found in the various data sources from which the USRDS database is derived. Table XIII-2 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 (SSA) include codes for Asian American, Native American, and Hispanic. The treatment of Hispanic as a race category in this SSA coding scheme 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 SSA 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 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.

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## Adjustment and Standardization of Rates

Adjustment, or standardization, of rates is a method which allows comparing rates between different sub populations or time periods by removing

## Sources of Race Codes in the USRDS Database: New or Transplanted Patients by Year and Race

		YEAR										
For each data source, counts over time of each race code		1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	
Data Source	Race	ALL										
Medicare Enrollment Database (EDB)												
	ALL	597,831	38,433	44,449	47,873	52,415	57,610	59,378	67,748	72,960	76,716	80,249
	1 Native Amer.	2,422	91	130	163	191	277	309	400	343	313	205
	2 Asian	7,231	246	331	409	580	716	953	1,113	1,133	1,000	750
	3 Black	157,465	10,420	12,412	13,037	14,439	16,131	16,668	18,067	19,119	19,064	18,108
	4 White	346,097	23,835	27,281	29,390	31,925	34,923	35,512	38,617	40,271	41,283	43,060
	5 Unknown	6,269	903	789	853	823	711	502	379	428	420	461
	9 Other/ Milt	32,450	2,104	2,377	2,601	2,593	2,369	2,234	3,137	3,690	5,139	6,206
	< Hispanic >	18,609	660	941	1,231	1,602	2,029	2,469	2,593	2,728	2,491	1,865
	x	27,288	174	188	189	262	454	731	3,442	5,248	7,006	9,594
Medical Evidence Form (HCFA-2728)												
	ALL	615,888	36,898	42,909	49,096	54,364	60,848	60,668	76,590	71,301	78,890	84,324
	Missing	30,765	2,338	2,843	3,283	3,864	4,641	5,886	7,834	74	1	1
	1 Native Amer.	8,193	419	516	651	669	819	695	954	1,136	1,357	977
	2 Asian	14,023	665	812	1,073	1,121	1,318	1,439	2,063	1,779	1,894	1,859
	3 Black	171,022	9,636	11,748	13,152	14,669	16,619	16,197	20,276	20,859	23,507	24,359
	4 White	377,537	23,074	26,856	30,831	33,901	37,338	36,279	44,437	44,007	48,026	52,788
	5 Unknown	4,062	310	102	84	117	98	152	1,009	1,017	622	551
	6 Pac. Islndr	2,241	456	32	22	23	15	20	14	486	584	589
	7 Arabian	576	..	..	..	..	..	..	..	160	207	209
	8 Indian	1,183	..	..	..	..	..	..	..	119	488	576
	9 Other/ Milt	6,286	..	..	..	..	..	..	3	1,664	2,204	2,415
HCFA REBUS System												
	ALL	597,831	38,433	44,449	47,873	52,415	57,610	59,378	67,748	72,960	76,716	80,249
	Missing	12,091	627	942	474	499	659	1,065	1,280	2,171	1,766	2,608
	1 Native Amer.	7,875	463	555	603	650	788	692	871	1,119	1,251	883
	2 Asian	15,614	1,008	823	1,039	1,128	1,291	1,447	1,951	2,255	2,394	2,278
	3 Black	168,849	10,329	12,390	13,172	14,836	16,525	17,007	19,261	20,805	22,277	22,247
	4 White	379,856	25,386	29,373	32,286	35,011	38,072	38,730	42,916	43,624	45,687	48,771
	5 Unknown	13,543	620	366	298	291	275	437	1,469	2,985	3,340	3,462
HCFA Transplant Forms (HCFA-2745)												
	ALL	54,360	8,266	8,240	9,056	9,348	9,426	10,024	..	..	..	..
	1 Native Amer.	513	74	78	76	93	98	94	..	..	..	..
	2 Asian	1,419	182	217	248	238	265	269	..	..	..	..
	3 Black	10,610	1,557	1,608	1,739	1,830	1,881	1,995	..	..	..	..
	4 White	38,393	5,820	5,930	6,317	6,723	6,591	7,012	..	..	..	..
	5 Unknown	3,425	633	407	676	464	591	654	..	..	..	..
UMDS Transplant Database												
	ALL	106,945	9,043	8,989	9,877	10,125	10,230	11,020	11,391	11,899	12,139	12,232
	Missing	64	..	..	..	..	3	1	..	..	2	58
	1 Native Amer.	904	79	79	65	76	83	81	112	109	122	98
	2 Asian	1,597	37	53	66	65	83	68	220	235	352	418
	3 Black	22,343	1,840	1,802	1,949	2,010	2,074	2,249	2,495	2,563	2,631	2,730
	4 White	78,893	6,752	6,760	7,422	7,634	7,617	8,234	8,044	8,743	8,896	8,791
	5 Unknown	260	6	3	22	2	35	22	148	14	2	6
	9 Other/ Milt	2,884	329	292	353	338	338	363	371	235	134	131
USRDS (derived from above sources)												
	ALL	597,831	38,433	44,449	47,873	52,415	57,610	59,378	67,748	72,960	76,716	80,249
	1 Native Amer.	8,433	494	583	641	686	847	781	968	1,189	1,315	929
	2 Asian	17,811	1,157	977	1,189	1,339	1,495	1,747	2,227	2,541	2,662	2,477
	3 Black	174,803	10,891	13,015	13,721	15,166	16,833	17,444	20,204	21,841	22,673	23,015
	4 White	388,872	25,627	29,625	32,117	35,008	38,163	38,995	43,688	45,804	48,111	51,734
	5 Unknown	1,461	98	118	107	113	145	199	243	162	137	139
	9 Other/ Milt	6,451	166	131	98	103	127	212	418	1,423	1,818	1,955

Table XIII-2

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 observed for each race 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 number of ESRD cases, and computing a new overall rate per million population using the total of the standard population as the denominator. The same procedure is followed for Whites using the same standard population. After age adjustment, the overall 1997 incidence rate for Blacks changes from 675 to 873, and that for Whites changes from 231 to 218. 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 if observed rates are not adjusted for age.

The USRDS uses the relevant population from the year before the most recent year for which data are reported in the ADR as the standard population for adjustment of rates. For this 1999 ADR, the most recent year reported is 1997, so the standard populations will be from 1996 (See Table XIII-1). For adjustment of incidence and prevalence rates in Sections A and B of the Reference Tables (1988-1997), the standard population is the July 1, 1996, United States resident population. The adjustment method described here is the "direct standardization" method and is the method used through most of this report for standardized incidence and prevalence rates.

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 demographic 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 1997 would find the adjusted rate (287/million population, see Reference Table A.6) to be lower than the real or "crude" rate (289/million). This difference does not indicate that the standardized rate is incorrect; rather, the standardized rate is "adjusted" so that rates for 1997 can be compared to rates for all the other years (1988-96), 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.

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## 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 age 65. All of these rates are computed based on calendar year periods. In order to increase the stability of the estimated rates, data from three years (1995-1997) are pooled for some of these tables. The death rate, first hospital admission rate, and first transplant rate tables report only 1997 values. This 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 that are 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. These include deaths due to AIDS, accidents reported as unrelated to treatment, such as violence and automobile accidents, and street drug overdoses.



- The 1997 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.

### Dialysis-Unrelated Deaths

The 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 D.2 and D.3). 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 of mortality, hospitalization, and transplantation rates. 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 rates and first admission rates are reported for 248 patient subgroups defined by age (16 groups), race (4 groups), sex (2 groups), and diabetes as the cause of ESRD (2 groups), where all patients less than 15 years of age were classified as having a nondiabetic cause of ESRD. First transplantation rates are reported only for 11 patient age groups, for never transplanted dialysis patients under age 65. Before the 1997 ADR, these rates were calculated based on the observed mortality, admissions, or transplants 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 rates reported in Reference Tables D.2, D.3, H.1, H.2, and F.29 are based on this regression model.** The model uses data from 1995-1997. Although 3 years were used to improve the stability of the rates, only 1997 death, first admission, or first transplantation rates are reported.

The model used to stabilize the death rates and first admission rates was 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 (1995-1997). The rates that are reported for 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.

The model used to stabilize the first transplantation rates is similar to that described above but does not include terms for race, sex, or diabetes. Transplantation rate statistics are not adjusted for sex, race, or diabetes because it is generally felt that access to transplantation should not be based on sociodemographic factors such as sex or race, and

because diabetic and nondiabetic patients both benefit substantially from transplantation.

These rate tables can be used to compare local ESRD mortality, hospitalization, and transplantation rates to national rates (Wolfe). The time period for the local data does not need to be a calendar year; it can be more or less than 1 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 in the calculations of annual death, hospitalization, and transplantation rates. 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 3 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, described in more detail below, 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. 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 dialysis patient analysis dataset on the first day of the year after a transplant failure. However, if transplant failure occurs after November 1 of the previous year, the patient does not reenter the dialysis patient dataset for the hospitalization analysis until the following 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 in a period in which the patient has Medicare claim activity. The period of Medicare claims activity is defined by the dates specified below:

**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 in a period in which the patient has Medicare claim activity. The period of Medicare claims activity is defined by the dates specified below:

- 30 days after the first month in which there were at least \$675 of Medicare paid dialysis claims.
- The end of a 3-month period in which there were less than \$675 of paid claims in each month.

The amount \$675 represents approximately the tenth percentile of monthly dialysis claims per patient. These rules are similar to the rules used for the intent-to-treat cost analyses in Chapter X and in Section K of the Reference Tables, except that the paid claims dates only come into play for the start date. The end date of the hospitalization analysis is still the earliest of death, 3 days prior to transplant, and December 31 of the year. Medicare claims activity does not affect the end date of the hospitalization analysis.

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. 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 prior to the 1998 ADR did not adequately screen patients for whom Medicare was the secondary payer. Consequently, a number of such patients (particularly in the later years) were included who contributed relatively sparse information on hospitalization. The failure to capture these events and/or days in the hospital may have biased the various rates towards zero. This bias may have varied differentially by age. The new criteria should lead to summary rates that better reflect the true hospitalization experience of Medicare eligible 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 described above.
- Patients with a functioning transplant at the start of the period and who 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 of ESRD treatment 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.

### 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 Hemodialysis 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.”

The rates in all of the tables, except for 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), are simple observed rates of event counts divided by patient years at risk (described below). For Tables D.2, D.3, H.1, and H.2, the observed rates are used in a Poisson regression model discussed above to yield more stable values. 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).

When a dialysis patient is reclassified as lost-to-followup during a year, the period at risk continues until the end of the calendar year. The patient is not included in the analysis for the next calendar year because the patient is classified as lost-to-followup at the beginning of that year. If the patient later returns from lost-to-followup status, then the patient will be included in the analysis for the next calendar year following the return from lost-to-followup status.

Note that if a patient is on dialysis and receives a transplant on January 1, then the days at risk are censored at the transplant date, and the patient has 0 days at risk.

Each patient contributes his or her years at risk to the denominator. The numerator is the number of events (either deaths or hospitalizations) which occurred during the at risk periods. The total number of days at risk is 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 day 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 Hemodialysis 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.

## Annual Death Rates for Transplant Patients

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 1992-1994. The last transplant year is 1994 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.

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## Patient Survival Analysis Methodology

The USRDS is a consistent data series that can show how patient survival has changed for successive cohorts of patients starting ESRD therapy. For each cohort, the survival curve shows the fraction of patients still alive at various numbers of years after first treatment for ESRD. The entire survival curve is a function of time and would require a lot of space to display for each successive cohort. For parsimony, the USRDS tabulates the fraction of patients alive at 1, 2, 5, and 10 years after the start of treatment. These surviving fractions are calculated separately for groups of patients starting treatment during successive calendar years, which are called incident cohorts. The USRDS carries out incident cohort analyses for the most recent 11 years.

These results are reported in Section E of the Reference Tables. Similar analyses are carried out for the fraction of transplant patients for time to transplant failure and are reported in Section G of the Reference Tables (see the section below on graft survival).

All new ESRD patients who had a first ESRD service (dialysis or transplant) date between January 1, 1977, and December 31, 1996, were included in the survival analysis. They were followed until

December 31, 1997, 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 1997. These rates for the most recent year are considered preliminary and must be used with caution.

Survival probabilities are computed for annual cohorts for five groups: all ESRD, dialysis (censored at first transplant), first transplant-cadaveric, first transplant-living donor, and the over 65 age group. For the two transplant groups, the annual cohort is based on the date of transplant rather than upon the date of first treatment for ESRD. 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 months 3 to 15 ). The 2-year survival probability is the probability of surviving from day 91 to 2 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 the database may not be complete during this 90 days. 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 for patients over age 65.

The “All ESRD Patients” 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, 1997).

The cohort “Dialysis Patients (Censored at First Transplant)” 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, 1997).

The “First Renal Transplant” cohorts (Cadaveric and Living Related) consist of patients who satisfy two conditions: 1) they received their first transplant in the designated year, and 2) the transplant donor is cadaveric or 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, 1997). 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.

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 subgroup by the year of incidence. These unadjusted patient survival probabilities are estimated using the Kaplan-Meier method (Kaplan) as implemented in the SAS LIFETEST procedure (SAS 1985). 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).

## Methods for Calculating Adjusted Survival Curves

### Objectives

Changes in the fractions surviving for different cohorts of patients could be due to differences in the characteristics of the patients starting treatment in the different years, or to differences in treatment among the years. Statistical adjustment is a method to account for differences in patient characteristics, in order to attempt to isolate differences that could be due to changes in treatment. This year, the method used to compute adjusted survival curve was changed from a direct-adjustment method to a regression-based method. The standard populations are defined in Table XIII-3.

Survival curve probabilities are computed for successive annual cohorts of incident patients and are reported in the reference tables (E.14 through E.53 in the 1999 Annual Data Report). Both adjusted and unadjusted probabilities are reported. The intent of the adjustment is to make the results comparable across years by reporting adjusted probabilities that would have arisen if each incident cohort had had the same age-race-sex-primary diagnosis distribution as the reference population.

## Standard Population Definitions and Characteristics

Population	All ESRD	Age > 65 ESRD	Dialysis	Transplant
	Incident 1995	Incident 1995-96, age>65	Incident 1995	Transplanted during 1995
Size (N)	67,533	69,511	65,223	10,931
Age (Years)	58.8	73.7	59.5	42.0
Female %	47.2%	48.9%	47.4%	39.1%
Black %	30.7%	22.0%	31.0%	24.1%
Other Race %	7.5%	6.2%	7.5%	5.7%
Diabetic %	41.1%	39.0%	41.9%	25.2%

Table XIII-3

For all ADRs through 1998, weighted averages of Kaplan-Meier survival curves for each of several subgroups in an aggregate group of patients were used to calculate an “average” survival curve for that group. The Kaplan-Meier survival curve estimates the fraction of patients surviving for a group, without accounting for the characteristics of the patients in each group. The weighted average was computed based on the Kaplan-Meier survival curves for each age-race-sex-primary diagnosis subgroup. The weights were computed based on a reference population and the same weights were used for all incident cohorts reported in a particular ADR. This weighted calculation is a method to adjust for the changing characteristics of incident cohorts.

### New Method

Starting with this ADR (1999), a new method is used to calculate adjusted survival probabilities. The new method uses a proportional hazards regression model to carry out the statistical adjustment (Cox). A proportional hazards model estimates the differences in mortality for different types of patient within a group and can estimate the fraction surviving for a particular type of patient within that group, such as for an “average” patient. The survival curves for each year are adjusted to the same reference values of patient mix, as defined by age, race, sex, and primary cause of ESRD by adjusting to the average values for these characteristics, as shown in the Table XIII-3. The average values of age used for age subgroups are defined within each age subgroup and are not reported. Age is adjusted for as a continuous linear factor. Race, sex, and primary diagnosis (diabetes) are adjusted for as categorical measures with dummy variables for each category. The survival curve is estimated for the “average” patient, who is of average age and is a percent mixture of the various race-sex-primary diagnosis groups. Separate analyses are carried out by incident cohort year and for aggregate groups within each incident cohort year. Covariates that do not vary within a subgroup (the race covariates within a particular race subgroup, for example) are not adjusted for in a subgroup analysis.

### Implementation

The analyses are carried out using PROC PHREG in SAS 6.12 (SAS 1996). Analyses are carried out by year of incident cohort. Separate analyses are carried out overall, by age group, by race group, by sex, and by primary diagnosis in each year. 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; mortality after

transplant failure is attributed to the transplant group. Survival probabilities and their corresponding standard errors (after 90 days, and 90 days after 1, 2, 3, 5, and 10 years) are presented for both patient survival and graft survival analyses.

For most analyses, race is adjusted for 3 groups: White, Black, and other races. Due to small sample sizes, mortality results for the age 0 to 19 group are not adjusted for diabetes or race and mortality results for living related transplant mortality is race adjusted for groups Black versus non-Black.

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## 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.

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## Graft Survival Analysis Methodology

The methodology for graft survival analysis is the same methodology used for patient survival. For persons who have received multiple transplants, only the first transplant is analyzed. 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. Survival for living unrelated transplants is not reported because of the small number of such transplants.

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*.

Survival probabilities and their corresponding standard errors (after 90 days, 1, 2, 3, 5, and 10 years) are presented for both patient survival and graft survival analyses.

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 first received a transplant in 1995.

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## 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.

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## 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 1997. The database also contains data for 313 million physician/supplier claim line items for 1991 through 1997. The full claims data require a minimum of 30.3 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 1989-1997. 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 REBUS/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 1993 through 1997. 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, 1993) and patients who receive a transplant during the study period (1993-1997). 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 1993 through 1997. ESRD patients prevalent on January 1, 1993 or incident at any time during 1993 through

1997 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, 1993.
- 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 5 percent of the patients with Medicare payments during 1993 through 1997 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, 1997, 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 being diabetes. 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.

For the 1999 ADR, the categories Hemodialysis unit supplies and PD unit supplies were dropped from the list of physician/supplier categories in Tables K.1, K.2, K.3, K.4, and K.7 as the sum of payments in

these categories is zero or nearly zero in the years 1993-97.

This year we were finally able to test the output of FORTRAN/C++ programs that produce the intent to treat model sums using SAS. The current version of SAS can finally handle the volume of records in the physician/supplier data. The test pointed out a deficiency between the physician/supplier sums produced by the FORTRAN/C++ programs and sums produced by SAS. Inspection of the code led to finding two problems with the FORTRAN/C++ programs. First, for dialysis patients who receive a transplant during the intent to treat period, the physician/supplier payments were not being aggregated. Second, physician/supplier claims of one day duration with that day being the start of the intent to treat period were not being aggregated. The addition of the physician/supplier claims for dialysis patients who receive a transplant adds some payments to the total physician/supplier payment amount, but the overall payments per year at risk were not significantly affected. The second error, however, caused a very significant difference in the physician/supplier payments for one category of patients. Patients, who receive a transplant during the intent to treat period, have one day physician/supplier claims on the day of transplant from the surgeon for the transplant, from the anesthesiologist, from surgeon assistants if any, etc. The physician/supplier transplant row in Tables K.2, K.3, and K.7 is where the significant change occurs, the physician/supplier total row is also affected in these tables as is the Medicare total. The transplant row in the 1999 report for Table K.2 has a total of \$99.3 million whereas in the 1998 report the total was \$27.9 million and in the 1997 report \$28.8 million. In Table K.4 the payment rate for the transplant row and column is \$397 per year at risk as opposed to \$99 per year at risk in the 1998 report. The physician/supplier total column is \$3,785 per year at risk in the 1999 report for the transplant column and \$3,213 per year at risk for the 1998 report. The Medicare total for the same column is \$17,495 as opposed to \$17,307 in the 1998 report. The transplant column in Tables K.2, K.3, and K.7 is also affected by these changes. In Table K.5, the primary effects of the correction appear in the transplant modality group subtables.

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## References

- Cox DR. Regression Models and life tables (with discussion). *J R Stat Soc* 1972; 34: 197-220.
- Kaplan EL, Meier P. Nonparametric Estimation from Incomplete Observations. *J Am Statist Assoc* 1958; 53:457-481.
- Robinson, G. K. That BLUP is a good thing: the estimation of random effects. *Statistical Science* 6, 15-32, 1991.
- SAS Institute Inc. SAS User's Guide: Statistics, version 5 edition. Cary, NC: SAS Institute Inc. 1985.
- SAS Institute Inc. SAS User's Guide: SAS/STAT Software: Changes and Enhancements through Release 6.11. Cary, NC: SAS Institute Inc. 1996.
- U.S. Bureau of the Census, Estimates of the Population of Counties by Age, Sex, and Race/Hispanic Origin: 1990 to 1997 (machine readable data file). PE-64. U.S. Bureau of the Census, Washington, DC. 1998. [http://www.census.gov/population/estimates/count/casrh/casrh\\_rl.txt](http://www.census.gov/population/estimates/count/casrh/casrh_rl.txt)
- U.S. Bureau of the Census, Revised Estimates of the Population of Counties by Age, Sex, and Race, 1980 to 1989 (machine readable data file). U.S. Bureau of the Census, Washington, DC.
- Wolfe RA, Gaylin DS, Port FK, Held PJ, Wood CL. Using USRDS generated mortality tables to compare local ESRD mortality. *Kidney Int* 1992; 42:991-996.