

Chapter VII

Renal Transplantation: Access and Outcomes

A total of 10,954 kidneys were transplanted into Medicare and non-Medicare recipients in the U.S. in 1993. Although 74 percent of these allografts were from cadaver donors, there has been a steady increase in the number of transplants from living donors. It is now well established that recipients of living-related donor (LRD) and cadaveric donor (CAD) transplants have better survival than comparable dialysis patients (Weller 1982, Garcia-Garcia 1985, Port 1993, Ojo 1994). Renal allograft survival, which improved dramatically after the introduction of cyclosporine in 1983-84 has continued to improve in recent years with one-year cadaveric renal graft survival now over 85 percent in many centers. The annual increase in the rate of kidney transplantation continues to be much slower than the growth in the number of patients on the waiting list. The widening gap between organ donation and need is in part due to the overall increase in ESRD incidence, improved patient survival on dialysis and relaxed transplant eligibility criteria (USRDS 1995 ADR). In addition, previously transplanted patients now account for 25-30 percent of candidates on the waiting list (OPTN 1994, Whelchel 1993). The foregoing combination of factors has produced a burgeoning waiting list, exceeding 30,700 ESRD patients in 1995 (UNOS, 1995). The critical shortage of organs continues to be a dominant issue in solid organ transplantation today. In order to expand the benefits of kidney transplantation, such as better allograft and patient longevity, improved physical and psychosocial functioning and enhanced economic rehabilitation potential (Chapman 1989, Evans 1985) to eligible ESRD patients, it is necessary to intensify current efforts to increase organ supply and better elucidate the mechanism and treatment of chronic rejection in order to minimize early and late allograft loss. Without substantial improvement in long-term

allograft survival, current rates of increases in organ supply may be negated by recirculation of repeat transplant candidates to the waiting list.

This chapter provides an overview of the trends in access and outcomes of kidney transplantation in the U.S. The summary of analyses presented here is based on an updated census of all Medicare-funded U.S. renal transplants for patients alive at any time since 1977. In departure from previous Annual Data Reports, data on the pediatric transplant population have been incorporated into this chapter. Patients less than 20 years of age are considered here as pediatric ESRD patients. Treatment modalities and patient outcomes for these patients differ significantly from those of the adult ESRD population (Held 1992, Alexander 1990, USRDS 1995). For pediatric patients, different treatment modalities fulfill distinct physical, social, and emotional needs. Factors that influence the choice of treatment modality in young patients include: 1) the relatively greater availability of LRD transplants, particularly from parents; 2) limitations on educational and social opportunities with center hemodialysis; 3) difficulties associated with small vessels for vascular access; and 4) the reduced growth rate of children receiving dialysis compared with those receiving transplants. With respect to the resultant choice of treatment modalities, the largest difference between the adult and pediatric ESRD populations is in transplantation rate (see also Chapter III).

Methods

The materials used in preparing this chapter of the 1996 Annual Data Report (ADR) are derived from the USRDS patient database. This database contains information from the HCFA Medicare data files covering all pediatric and adult Medicare-eligible

ESRD patients (approximately 93 percent of patients in the United States). The database further includes data from the HCFA Annual Facility Survey (AFS) which covers all adult and pediatric kidney transplants performed each year, including those not eligible for Medicare benefits. In addition, some of the non-Medicare patients treated by U.S. Department of Veterans Affairs facilities have been included in the database since July, 1990. In order to ensure complete patient and facility information, the data are considered for analysis after a 6-month consolidation period (see Chapter XIV). Because the information from the AFS is not patient-specific, the data presented for non-Medicare patients may be incomplete. Information concerning transplant facilities, however, are complete for all U.S. renal transplant centers through December 31, 1994. Unless noted otherwise, this report is based on an updated census of all renal transplants in the USRDS, which includes 123,000 transplants since 1977. For most statistical analyses, the year 1983 was chosen as the starting point since several facets of transplantation changed with the introduction of cyclosporine in late 1983. Because of the 6-month interval allowed before data analysis, information about patient and graft survival for transplants performed in 1993 are only preliminary. In previous editions of the Annual Data Report, such preliminary data reported by the USRDS were 97-98 percent complete. Although there has been an increase in the number of kidney transplantation from living biologically unrelated donors (Terasaki 1995), the

results presented here include only cadaveric and living-related donor transplants.

Statistical analysis

Both patient and renal allograft survival are calculated using the Kaplan-Meier (KM) product-limit method (Kaplan and Meier, 1958). As throughout this report, the age, sex, race, and primary kidney disease distributions of 1992 incident ESRD patients are used as reference for the standardization of *patient* survival (Chapter V). To improve the stability of adjusted graft survival rates, the reference population consists of all Medicare ESRD patients transplanted between 1990 and 1992 (see Chapter XII). Unless noted otherwise, if a figure is group specific, e.g., race-specific, the data in it are adjusted for the 3 remaining covariates, e.g., age, sex, and primary kidney disease. Patient age-group refers to the age at transplantation. Since patients older than 65 years represent less than 3 percent of transplant recipients, they generally are not included in the statistical analyses.

Patient Survival

Figure VII-1 illustrates adjusted one-year patient survival rates for recipients whose first transplant was performed between 1984 and 1993. The survival rates are separated by kidney donor source (LRD or CAD) and adjusted for age, sex, race, and primary kidney disease. Throughout the period, recipients of CAD transplants had uniformly lower one-year

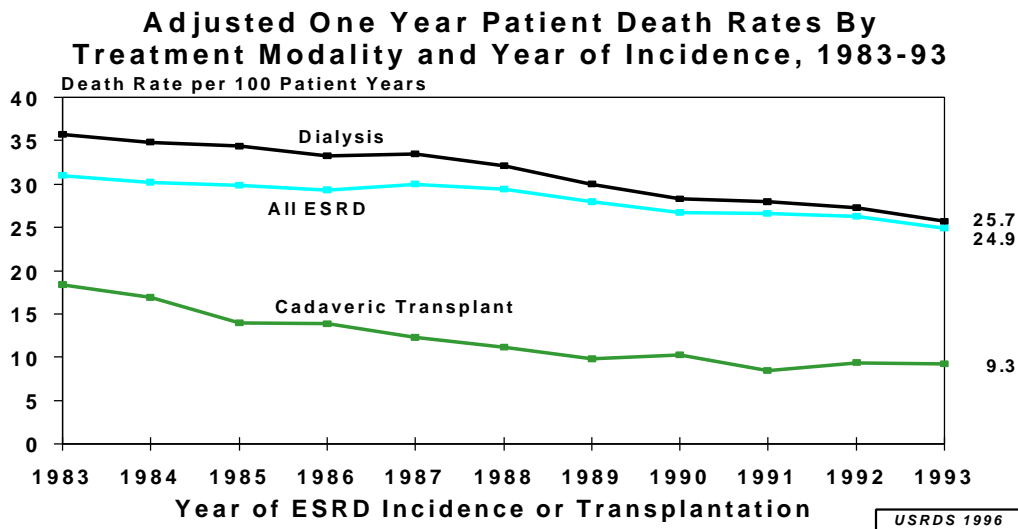


Figure VII - 1

Average One-year patient survival, first transplants adjusted for age, sex, race and cause of ESRD by donor type and year, 1984-93. Source: Reference Table E.42

One-Year Adjusted Medicare *Graft Survival*, First Transplant, by Donor Type and Year, 1984-1993

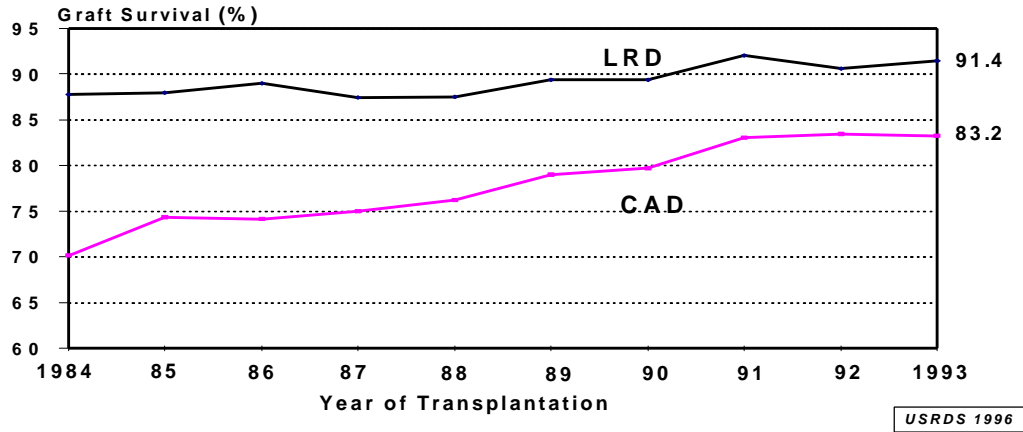


Figure VII - 2

One-year graft survival, first transplants adjusted for age, sex, race by donor type and year, 1984-93. Source: Reference Table G.17,G.31.

survival rates than did recipients of LRD transplants. For LRD recipients, survival increased from 89 percent in 1984-85 to 96 percent in 1992-93, a 9 percent gain. Survival for CAD transplant recipients also improved, from 86 percent to 91 percent from 1984-85 through 1992-93, respectively. These patients survival can not be directly compared to dialysis patient survival (Chapter V) because of patient selection. In fact wait-listed dialysis patients have only half the mortality risk of non-wait-listed

dialysis patients (Port 1994, Ojo 1993).

Kidney Graft Survival

Figure VII-2 presents adjusted one-year allograft survival rates for kidneys transplanted between 1984 and 1993. Only first-time transplants are included in this figure. There has been a 16 percent increase in CAD allograft survival over this period (from 70 percent in 1984 to 83 percent in 1993). There was

Pediatric One Year Death Rates by Age Group and Treatment Modality, 1991-1993

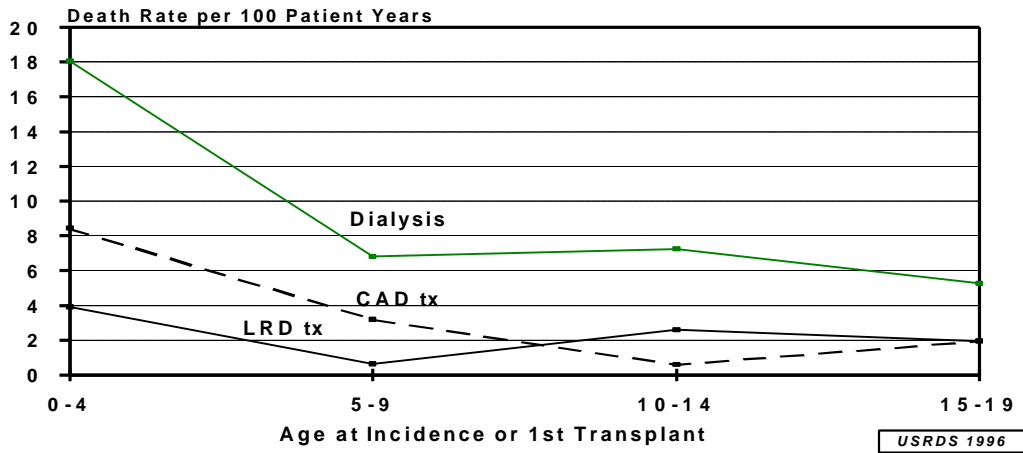


Figure VII - 3

Living related kidney graft survival, first transplants, adjusted for age, sex, race and cause of ESRD, 1986-93. Source: Reference Table G.23, G.27.

also a marked but relatively smaller improvement in LRD graft survival which rose from 88 percent in 1984 to 92 percent in 1993, a 7 percent increase.

Figures VII-3 and VII-4 depict graft survival rates for two-year cohorts which were adjusted for patient age, sex, race, and primary disease. Combining the results over 2 years (1986-1987, 1988-1989, etc.) improves the stability of the KM product-limit estimator for graft survival. In most cases, the graft failure date was the earliest date of: graft removal, death, or return to dialysis as obtained from the Transplant Followup form. For a small fraction of cases, the graft failure date was obtained from other sources, including the Chronic Renal Disease Medical Evidence Form and the quarterly dialysis billing records (see Chapter XII). Post-transplantation followup varied according to the year of transplantation; thus, grafts transplanted prior to 1990 had 5 years of followup whereas those transplanted during 1992-1993 had 1 year of followup.

Living Related Graft Survival

Figure VII-3 demonstrates first LRD allograft survival rates from 1986 to 1993, combined in two-year cohorts and adjusted as described above. One-year graft survival improved steadily from 88 percent in 1986-1987 to 92 percent in 1992-1993. Two- and three-year LRD allograft survival showed similar trends. Long-term LRD allograft survival (five-year-survival) improved from 69 percent for LRD transplants performed in 1985-1986 to 72 percent for

those performed in 1988-1989.

Cadaveric Graft Survival

Figure VII-4 shows graft survival rates for first CAD transplantations performed between 1986 and 1993. Graft survival rates were also combined over 2-years to improve the stability of estimates in addition to being adjusted for patient age, sex, race, and primary disease. CAD allograft survival improved steadily between the years 1986 to 1993. During this period, the adjusted one-year allograft survival improved from 75 percent to 84 percent while adjusted two-year survival increased from 68 percent to 76 percent, and three-year graft survival rose from 61 percent to 71 percent. These notable improvements in CAD graft survival have occurred simultaneously with a considerable increase in the proportion of diabetic CAD transplant recipients over the period was observed. The proportion of CAD transplant recipients with diabetic-ESRD rose from 14 percent in 1982 to 26 percent in 1993, making this group of patients the fastest growing group of CAD transplant recipients as demonstrated in the 1995 Annual Data Report.

Although the onset of the improvement in allograft survival were related to the introduction of cyclosporine in 1983, as depicted in figures VII-3 and VII-4, better short-term allograft survival and relatively smaller improvement in long-term allograft survival have been sustained beyond the period of the penetration of cyclosporine-based immuno-

First Cadaveric Graft Survival, Adjusted, by Year, 1986-93

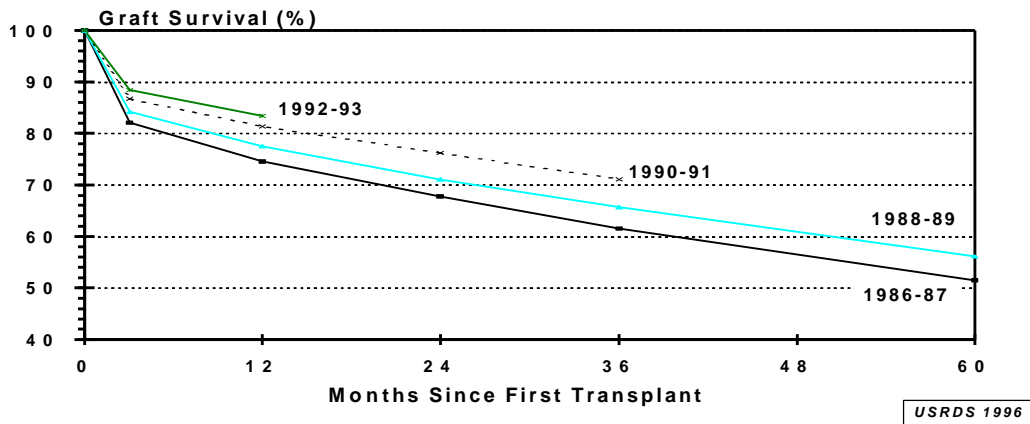


Figure VII - 4

Cadaveric donor kidney graft survival, first transplant, adjusted for age, sex, race, and cause of ESRD, 1986-93. . Source: Reference Table G.11 - G.15.

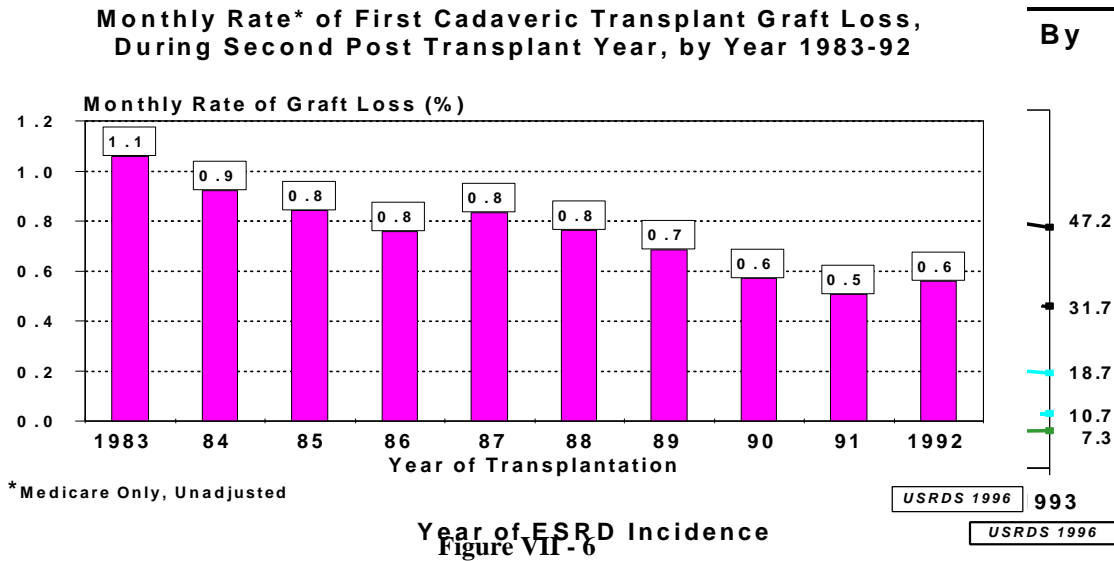


Figure VII - 5
~~Monthly rate of graft loss during the second year after transplantation for first cadaveric donor transplants by year, 1983-92. Source: Special Analysis.~~
 Monthly rate of graft loss for first cadaveric donor transplants during the first 3 months after transplantation by year, 1983-93. Source: Reference Table G.11.

suppression (1984-1987). The more recent improvement in allograft outcomes are probably due to improvements in transplant management (i.e. the diagnosis of acute transplant rejection and drug toxicity); the treatment and prevention of cardiovascular and infectious complications; patient survival; and in immunosuppressive and anti-rejection treatments; e.g., the introduction of monoclonal antibodies (Gaston 1992, Van Buren 1991).

Trend in Cadaveric Graft Loss

The risk of graft loss varies during the post-transplant period, being highest during the first 3 months and decreasing at a gradual rate thereafter (Figures VII-4). Similar results are observed in LRD with significantly better graft survivals than with CAD (Figure VII-3). Figure VII-5 illustrates the monthly rate of first CAD graft loss for the years 1983-1993. This more detailed examination of allograft survival aids in understanding the factors associated with the trend in improved outcomes. The average rate of allograft loss for the three months immediately following a first CAD transplantation was 8.8 per month in 1983 and 6.0 per month in 1985, a 32 percent reduction over a short time span. This precipitous decline coincided with, and may be attributed to the widespread utilization of cyclosporine-based maintenance immunosuppression. From 1985 to 1993, the monthly rate of CAD allograft loss also declined substantially, from 6.0 to

3.9 per month. The latter decline may also be related to the expansion of cyclosporine use in addition to a better understanding of its pharmacokinetics (Ojo 1995, Schroeder 1994). Between 1991 and 1993, the average monthly rate of CAD allograft loss in the initial three months post-transplant remained relatively constant (3.9 per month). Over the entire decade, however, the average monthly risk of CAD allograft loss in the 3-month post-transplant period decreased a remarkable 56 percent; a trend that has substantially increased the number of functioning CAD allografts in the early post-transplant period.

A steady, albeit smaller decline in monthly rate of allograft loss is noticeable beyond the first posttransplant year. Figure VII-6 shows the monthly rates of graft loss between the first and second transplant anniversary. In the decade between 1983 and 1992, monthly graft loss rate after year one was reduced by 45 percent with over half of the reduction occurring during the last four years of the decade. For the most part, the decline in late graft loss rate account for the improvement in long-term graft survival depicted in Figure VII-4.

Kidney Transplantation and HLA Antigen Matching

More recently, knowledge of the benefits of HLA matching in kidney transplantation has improved considerably (Kallich 1993, OIG 1991). Contributing to the evolution of public policies aimed at promoting

the equitable allocation of kidneys for transplantation. However, there remains a lack of consensus on the optimal level of HLA matching that simultaneously satisfy the need for equity and maximum achievable outcomes. (Held 1994, Sanfilippo 1994, Gaston 1993). The preponderance of evidence suggests that optimal HLA matching in LRD kidney transplants and zero-mismatching in CAD kidney transplants is beneficial for long-term allograft survival. For the majority of CAD transplants which have one or more HLA mismatches, the effect on allograft survival is relatively small (Koyama 1994, Takemoto 1994, Gaston 1993, Held 1994).

With few exceptions, efforts to improve HLA matching beyond the current national mandate, which gives priority to zero-mismatched organ-sharing, would cause a shift in allocation away from minority populations; populations disproportionately affected by end-stage renal disease (Gaston 1993). Furthermore, it is more important to avoid delayed graft function by limiting preservation time since establishment of allograft function on the first day after transplantation predict better allograft survival than that in transplants with zero-HLA mismatch who suffered delayed graft function (Terasaki 1995, Ojo 1996).

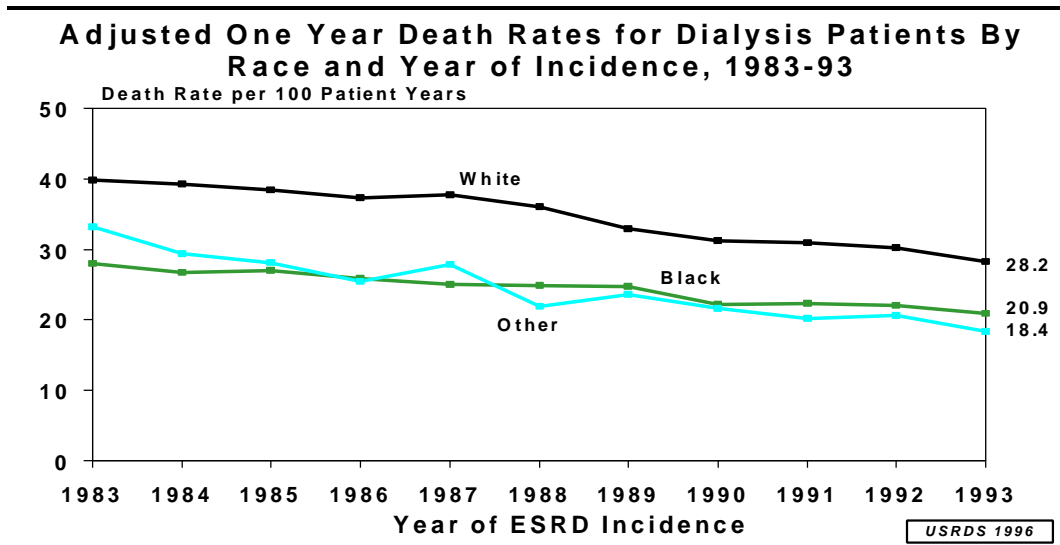


Figure VII - 7

Mean number of HLA A, B, DR mismatches for first cadaveric transplants, by recipient race, 1993. Source: Special Analysis.

First Cadaveric and Living Related Transplantation Rate* by Age, Medicare Only, 1993

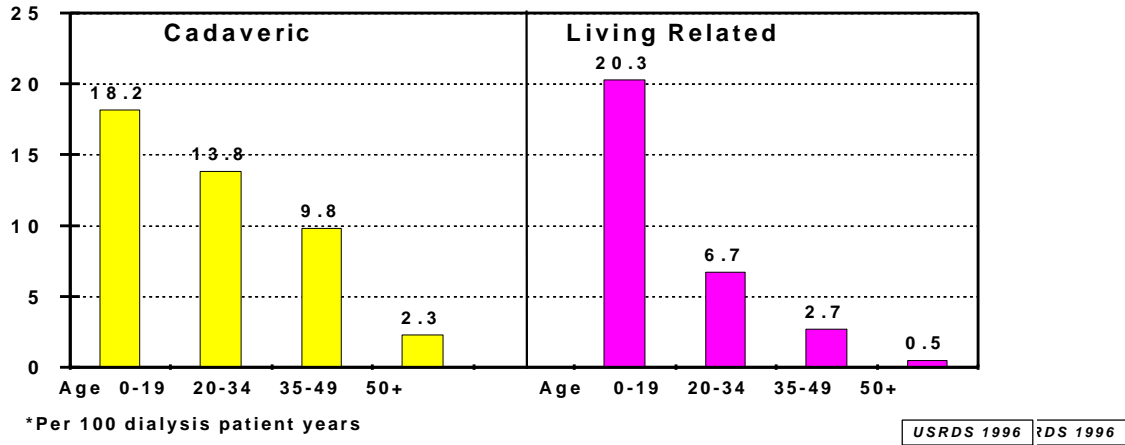


Figure VII-8

Cadaveric renal transplantation with zero HLA(A, B, DR) mismatches by age, transplantation, Source: Special Analysis: Reference Table F.17.

Figure VII-7 shows the average number of HLA mismatches at the A, B, and DR loci for first-time CAD recipients in four race groups in 1993. White recipients have a consistently lower mean mismatch (3.5) than other race groups.

There has been a gradual increase in the fraction of zero-mismatched CAD transplants as shown in Figure VII-8. The proportion of zero-mismatched CAD transplants increased more than three fold

between 1987 and 1993 (from 2.1 percent to 6.1 percent). This trend probably indicates broader implementation of the UNOS policy rather than an increase in the availability of zero-mismatched kidneys.

Supply of Kidneys for Transplantation

Since 1988, the rate of cadaveric kidney donation

Adjusted One Year Death Rates for Dialysis Patients By Diagnosis and Year of Incidence, 1983-93

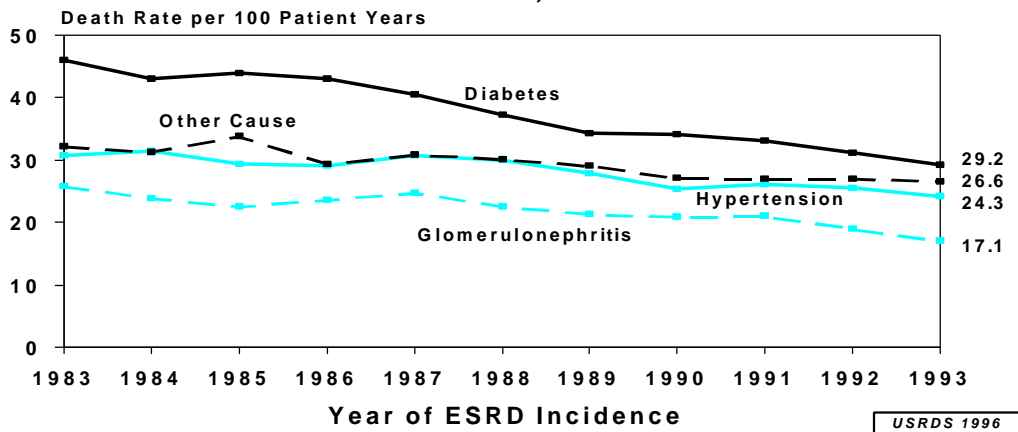


Figure VII-9

Each cadaveric transplant is made to a patient on dialysis for 105 years by age by recipient race, at 1993, Source: Special Analysis.

has remained remarkably constant despite a slow increase in cadaveric organ donation, reflecting the fact that donation rates lag behind a faster growth in the ESRD population (UNOS Update 1994, Ellison 1993). The donation rate varies among race groups. The donation rate was calculated for each race as the number of organs harvested divided by the total population of U.S. citizens ≤65 years old in the same race group (scaled to million population). Figure VII-9 shows the race-specific CAD donation rates (excluding harvested but discarded organs) relative to the racial distribution in the 1993 U.S. population of eligible donors (rate per million population ≤65 years old). Averaged over 1992 and 1993, Whites and Blacks have the highest proportion of donated organs transplanted, 32.2 pmp and 26.0 pmp, respectively. Asians and Native Americans had significantly lower donation rates, 13.2 pmp and 11.4 pmp, respectively. The reason for the low rates of CAD kidney donation in these groups is unknown. The data presented here may not reflect the total rate of CAD kidney donation in each racial group because the fraction of harvested but not transplanted organs (discard rate) may differ by donor race. In 1992 and 1993, discard rate among donors > 60 years varied from 55 percent for Whites to 52 percent for Blacks and 60 percent for Asians (UNOS Update 1994). Although, it has been suggested that Blacks have a relatively lower rate of kidney donation, the rate in Blacks for 1993 was 81 percent that of Whites and more recent data from the Organ Procurement and Transplant Network indicate that the actual donation rates for Blacks and Whites

may be similar to their representation in the U.S. population (OPTN Report 1994).

Access to Kidney Transplantation

Striking differences still exist in access to kidney transplantation along socioeconomic and demographic lines (Held 1988, OIG 1991, Gaylin 1993). The fact that access to kidney transplantation is not completely independent of income, race, and other sociodemographic characteristics of potential recipients has important implications for organ allocation and patient recruitment and selection at all levels of the health care system (OIG 1987). An index of access to transplantation is the transplantation rate which is calculated per 100 dialysis patient years and can be interpreted as the percent of dialysis patients of a particular age-group who received a kidney transplant during that calendar year. The rates of first LRD and CAD transplantation in 1993 according to age, race and gender groups are depicted in Figures VII-10 and VII-11. The rate of kidney transplantation varies inversely with the recipient age cohort. Disparity in transplantation rate by age group is most striking for LRD for which the rate in the 50+ age group is 2.5 percent of the rate in the 0-19 year age group (0.5 vs. 20.3 per 100 dialysis patient year). This difference reveals an emphasis on living related donors for pediatric transplantation, perhaps in response to a limited supply of cadaver donors. The substantially higher rates of CAD transplantation in pediatric patients may also reflect

First Cadaveric and Living Related Transplantation Count by Recipient Age, Medicare Only, 1993

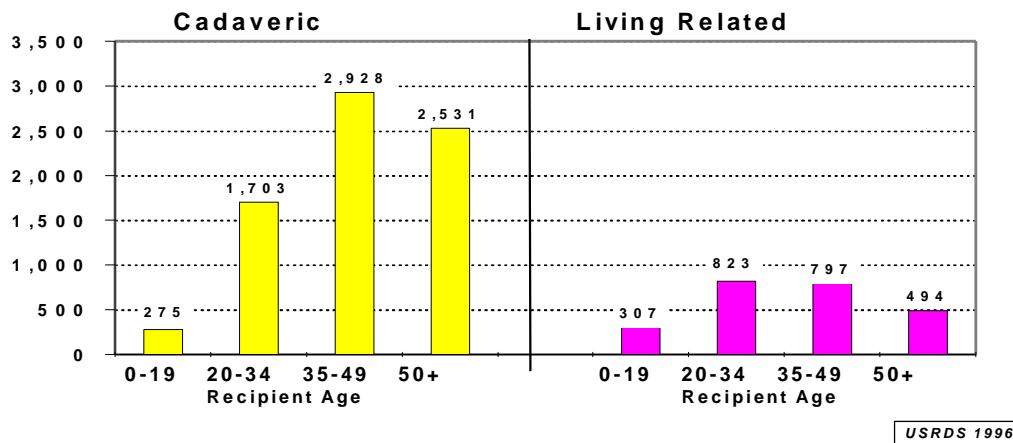


Figure VII -12

Total number of first kidney transplants by donor type and recipient age group, 1993. Source: Special Analysis.

Adjusted One Year Death Rates for Dialysis Patients by Sex and Year of Incidence, 1983-93

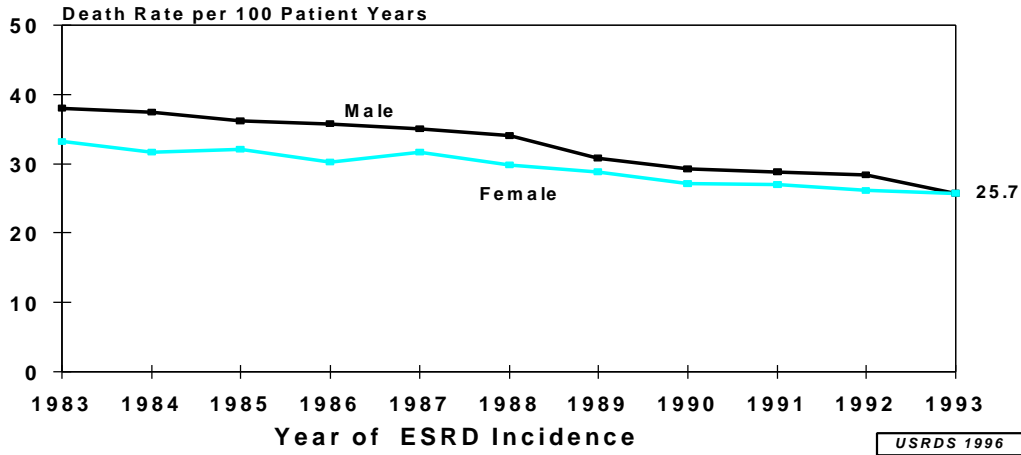


Figure VII-13

Number of renal transplants by donor source and year, 1991-1993. Source: Reference Table F.1.

both the emphasis placed on transplantation as the preferred modality in pediatric ESRD and the slight priority (additional points) given to a subset of wait-listed pediatric patients in the kidney allocation system (OPTN 1994). Blacks have lower transplantation rates than Whites in each age group and White males have higher transplantation rates than females but the gender differences in the rates for Blacks is much smaller and age dependent. This is illustrated in Figure VII-11 which show that, among pediatric patients, the rates in White and Black females are 81 percent and 96 percent that of White and Black males, respectively. However, in the 20-44 year age group, Black males and females have the same rate (6.4 per 100 dialysis patient years) whereas the rate in White females is 87 percent that of their male counterparts. The reasons for larger gender disparities in Whites are unknown. The transplantation rates for Blacks are 29 percent to 74 percent lower than that of Whites in the same age group. Both medical and non medical reasons have been advanced to explain the lower transplantation rates in Blacks (Kallich 1993, Gaylin 1993, Kjellstrand 1990).

Although transplantation rates are substantially higher in the pediatric age group, most kidney transplants occur in older age groups (Figure VII-12). In 1993, 96 percent and 87 percent of primary CAD and LRD transplants, respectively, went to adult recipients.

The variable rates of transplantation among race, age and gender groups described in the preceding

figures reflect the combined impact of the distribution of disease burden, organ allocation policy, and perhaps differences in graft survival and the willingness to donate both cadaveric and living-related organs. A comprehensive analysis of these issues can be found in recent publications (Held 1994, Koyama 1994, Gaston 1993, Sanfilippo 1994). As these differential access and outcomes issues are considered in debates and scientific writings, it is important to recognize two key facts. Firstly, Blacks constitute 12 percent of U.S. population and 32 percent of the ESRD population, thus CAD donation in Blacks cannot meet organ requirements in this race group. Current levels of CAD organ donation in Blacks and Whites approximate their respective representation in the general population (OPTN 1994 Annual Report) and the expectation of an increased minority organ donation beyond the current level is unrealistic (Gaston 1993). Secondly, an allocation policy that emphasizes maximal matching is likely to have a limited impact on graft survival but will divert a substantial number of organs from Blacks and other minority groups who are disproportionately affected by ESRD. A fruitful additional strategy to address critical organ supply is an aggressive promotion of living organ donation from suitable relatives of potential recipients (Ojo 1993).

In 1993, there was an 8 percent increase over 1992 figures in the total number of kidney transplants performed. As shown in Figure VII-13, the largest increase occurred in transplantation from living biologically unrelated donors which increased by 36 percent. CAD and LRD transplants increased by 7

percent and 10.6 percent, respectively. Despite poorer HLA antigen mismatches, transplants from spousal donors have a similar or even slightly higher survival rates than offspring-to-parent grafts with one HLA-haplotype mismatch (Terasaki 1995). Thus, living biologically unrelated kidney transplantation has a large potential to bring the benefits of this therapeutic modality to several thousands ESRD patients.

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