Chapter VII

Renal Transplantation: Access and Outcomes

Key Words:
Cadaveric renal transplants
Living related renal transplants
Transplant patient survival
Renal graft survival
Race in transplantation
Cadaveric graft loss
Access to transplantation
Organ allocation
Gender in transplantation

Although cyclosporine remains the cornerstone of immunosuppressive strategy in renal transplantation, newer drugs have been introduced in the recent past. In the last few years, the Federal Drug Administration has given approval for the use of mycophenolate mofetil (Cellcept), Neoral (Cyclosporine microemulsion), Tacrolimus (Prograf), and Daclizumab (Zenapax – humanized monoclonal IgG1 interleukin-2 (IL-2) receptor antibody) as immunosuppressive agents in renal transplant recipients (Vincenti 1998, Mayer 1997, The Tricontinental Mycophenolate Mofetil Renal Transplant Study Group 1996). These newer agents have been effective in preventing acute rejection and are associated with some improvement in short-term allograft survival. One-year allograft survival for cadaveric (CAD) renal transplant is reported at 90 percent or higher in some patient series (Halloran 1997, Mayer 1997). The clinical trials of the recently approved drugs have not shown a demonstrable impact on long-term graft survival either because sufficient long-term endpoints have not accrued or due to sample size limitations. However, reports in this *1998 Annual Data Report (ADR)* show a sustained trend towards improved long-term renal allograft survival for transplants performed in last decade.

In the current report, transplant data collected by the United Network for Organ Sharing (UNOS) and the Health Care Financing Administration (HCFA) have been consolidated to allow extended and more complete reporting of ESRD treatment provided to patients in the United States. This chapter of the ADR provides a general overview of both Medicare and non-Medicare kidney transplants performed between 1977 and 1996. A more detailed focus was given to the 108,650 renal transplants performed between 1986 and 1996.

Methods

The data presented this chapter were derived from multiple sources including: the Health Care Financing Administration (HCFA) Medicare data files; the United Network for Organ Sharing (UNOS) transplant registration and followup files; the HCFA Annual Facility Survey (AFS); and the non-Medicare patient files treated by U.S. Department of Veterans Affairs facilities. Collectively, these data sources cover 98 percent of all adult and pediatric kidney transplants in the United States. In order to ensure complete patient and facility information, the data are considered for analysis after a 6-month consolidation period (see Chapter XIII). Information concerning transplant activities are updated for all U.S. renal transplant centers through December 31, 1996. Some of the statistical analyses presented here are limited to more recent years (e.g. 1993-1996) or two separate epochs (e.g. 1990-1991 vs. 1995-1996) when such to be more germane to the subject under consideration. The transplant counts and rates reported here for 1996 should be considered preliminary. In previous

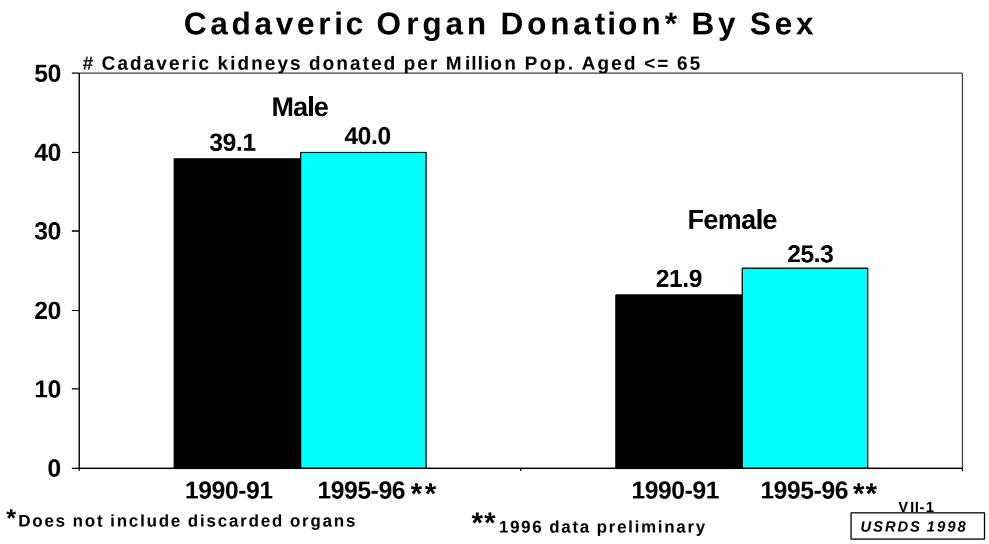

Figure VII-1

Cadaveric organ donation U.S. population by sex, 1990-91 and 1995-96. Source: Special Analysis

editions of the Annual Data Report, preliminary data reported for the most recent years were 97-98 percent complete. Lastly, changes in transplant counts or rates are reported as percentages, that is, the relative proportional change instead of the absolute difference (percentage points).

Statistical analysis

The product-limit estimation method of Kaplan-Meier (KM) (Kaplan and Meier, 1958) was used to calculate both patient and renal graft survival. Deaths were counted as graft failures. The patient survival estimates were directly standardized to the age, sex, race, and primary kidney disease distributions among 1995 incident ESRD patients while the allograft survival estimates were standardized to the distributions of the transplants performed in 1994-1995. Patient and allograft survivals were aggregated in two consecutive years to improve stability of the survival estimates (see Chapter XIII). The tables and figures for various patient populations have been adjusted for race, age, sex, and the original cause of ESRD (primary disease). For example, a race-specific figure has been adjusted for the 3 other variables, e.g., age, sex, and primary kidney disease. Figures with different adjustment covariates are indicated as such. Patient age group refers to the age at transplantation. Less than 3 percent of transplant recipients were older than 65 years of age and they were generally excluded in the statistical analyses.

Supply of Kidneys for Transplantation

The number of transplantable cadaver kidneys donated annually ranged from 8,327 in 1994 to 8,526 in 1996, representing an increase of less than 100 kidneys per year. The static state of cadaveric kidney donation has been recognized for over a decade, during which time, the number of patients on the cadaveric renal transplant waiting list increased 2.5 fold from 13,943 in 1988 to 35,000 in 1997 (UNOS 1996, UNOS 1997). The gap between waiting list registrations and organ donation is particularly alarming in view of the enormous resources committed to enhancing organ donation.

Cadaveric kidney donation rates vary between genders. Figure VII-1 shows the CAD kidney donation per million population (pmp) for males and females in the U.S. population aged ≤65 years during two recent time periods (1990-1991 and 1995-1996). The data shown include only the cadaver kidneys that were procured and transplanted, excluding discarded organs. In the 1990-1991 period, the donation rate was 44 percent lower in females. However, between 1990-1991 and 1995-1996, the donation rate increased by 16 percent in females (21.9 pmp vs. 25.3 pmp) while the increase in males was only 2 percent (39.1 pmp vs. 40.0 pmp). Therefore, the gender difference in CAD donation shrunk from 44 percent in 1990-1991 to 37 percent in 1995-1996. The higher

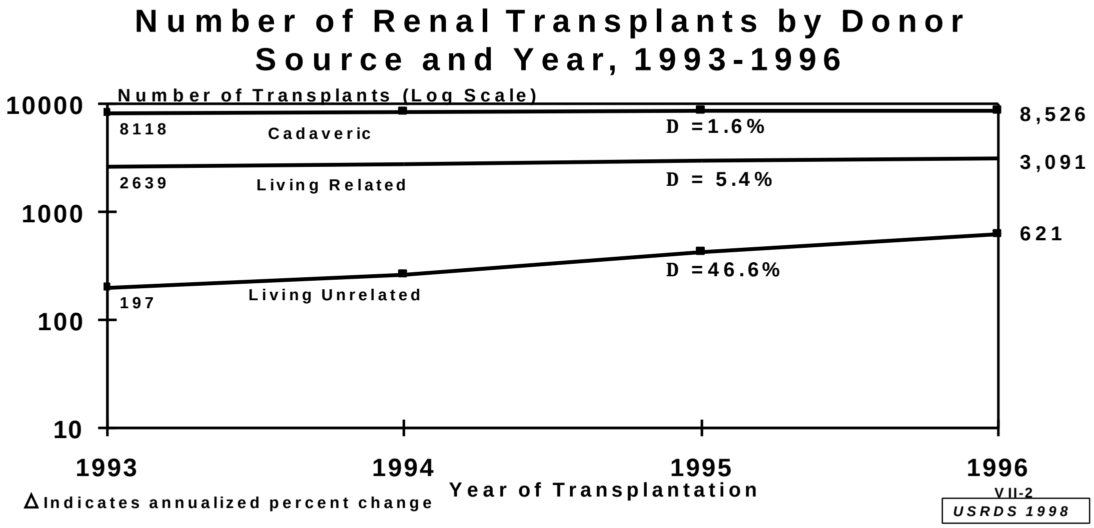

Figure VII-2

Total number of renal transplants by donor source and year, 1993-1996. Source: Table F.1 Facility Survey

CAD kidney donation rates in males may be due to higher death rates from causes which are more likely to produce suitable cadaver donors, that is, greater likelihood of primary brain death (e.g. industrial and motor vehicle accidents, cerebrovascular disease, and firearms). The substantial increase in the donation rate among females between the two time periods has not been previously noted and the factors responsible for this improvement are unknown. One speculation is that increased awareness among health care providers in approaching the families of suitable potential female donors.

Figure VII-2 shows the count and annualized percentage increase for each kidney donor source between 1993 and 1996. During this period, kidney donation from spousal and biologically unrelated donors increased annually by 46.6 percent whereas living-related kidney donation increased annually by 5.4 percent and cadaveric donation showed a minimal increase (1.6 percent per year). The substantial increase in kidney donation from living non-biologic relatives may be due to several unrelated factors. Amongst them is the worsening shortage of cadaver kidneys and consequent prolongation of the waiting time on the cadaveric renal transplant waiting list. Secondly, more recent evidence suggests that even with the use of poorly matched living donors (LD), avoidance of cold ischemia time and other hazards entailed in the procurement of cadaver kidneys may have an overriding impact on allograft survival. Indeed, registry data have shown superior renal allograft survival in spousal donor kidneys when compared 6-HLA antigen matched cadaver kidneys inspite of HLA mismatching (Terasaki 1995). ABO blood group incompatibility still remains a barrier to the expansion of the living donor pool (Fehrman-Ekholm 1996, Bia 1995). The impressive results with the use of living biologically unrelated renal donors have prompted calls for innovative programs such as the establishment of living renal exchange registry where potential recipients can swap their potential donors on the basis of ABO compatibility (Ross 1997). Although, a living donor exchange registry may not be cost-effective in increasing donor supply, new strategies are needed to enhance the supply of transplantable kidneys in the foreseeable future.

Access to Kidney Transplantation

The age of the ESRD patient has a strong influence on the prospect of kidney transplantation. In the pediatric age-group, kidney transplantation is much favored because of its beneficial effect on growth and psychosocial development. In adults with chronic renal failure, the prospect of kidney transplantation is governed by a number of factors including age, primary cause of ESRD, concurrent illness (comorbidity), race, gender, and the availability of suitable living donors. These factors may exert their influence singly, jointly and severally on the patient's access to kidney transplantation. Patients with diabetic ESRD are the fastest growing group of CAD transplant recipients (1996 ADR).

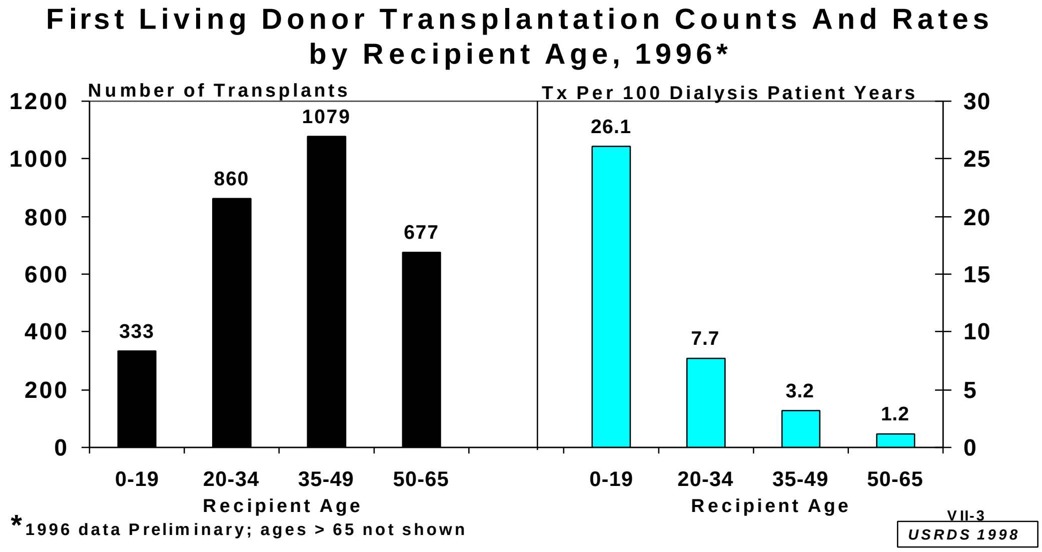

Figure VII-3

First living donor transplantation counts and rates by recipient age, 1996. Source: Special Analysis

Non-Whites, females and older ESRD patients are less likely to be treated with kidney transplantation even if the are medically suitable transplant candidates (Held 1988, OIG 1991, Gaylin 1993, Kallich 1993, Kjellstrand 1990, Bloembergen 1997, Wolfe 1997a).

Figures VII-3 and VII-4 show the total number of kidney transplants performed in 1996 and the adjusted transplantation rates from living and cadaver donors, respectively by recipient age group. The transplantation rate was calculated per 100 dialysis patient years at risk. Pediatric patients (age group 0-19 years) received a relatively small number (10.8 percent) of living donor transplants and of CAD renal transplants (3.4 percent) (Figure VII-5). However, the pediatric renal transplantation rates (divided by the relatively small number of pediatric dialysis patients) were much higher than rates for the adult age group with the highest transplantation rate (age

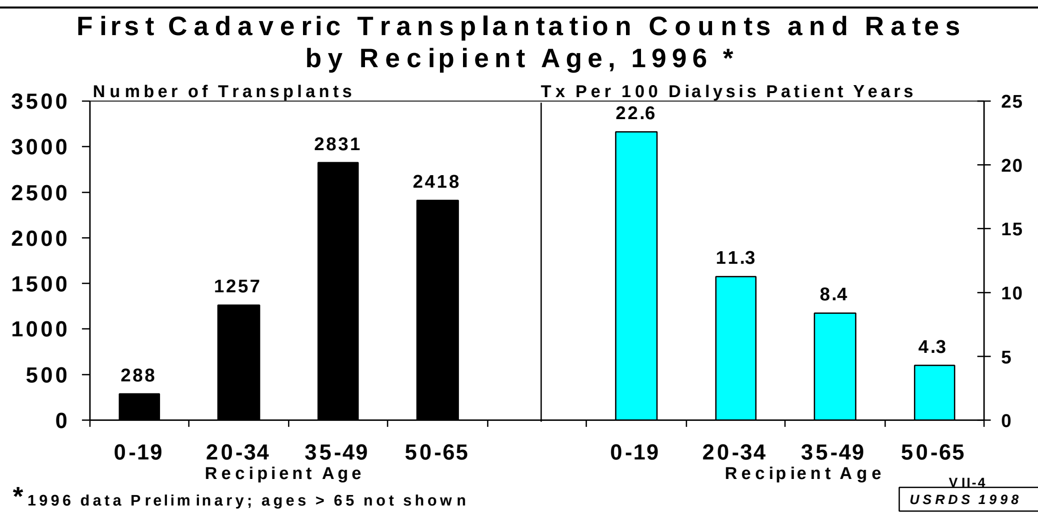

Figure VII-4

First cadaveric transplantation counts and rates by recipient age, 1996. Source: Special Analysis

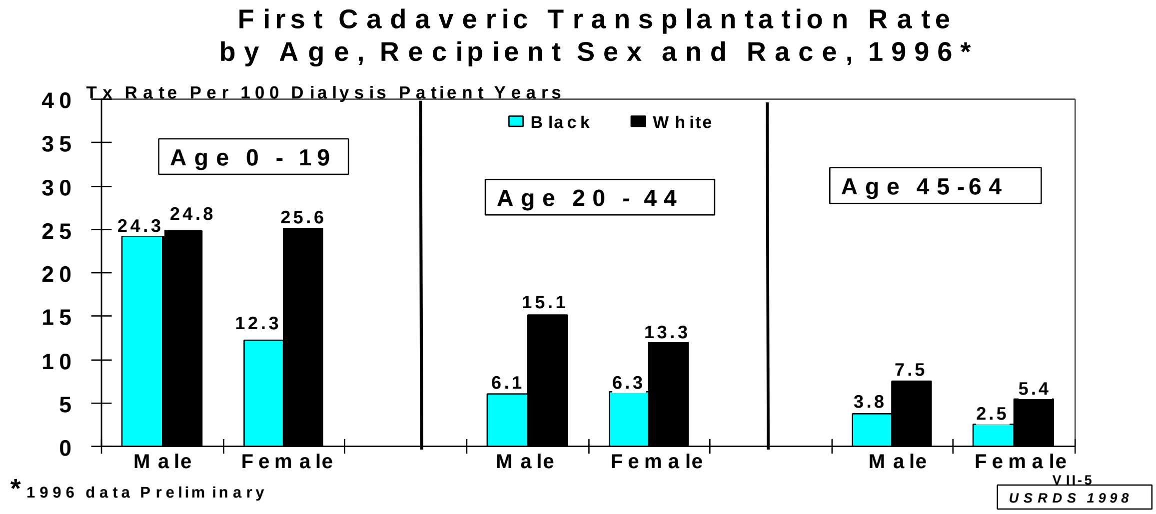

Figure VII-5

First cadaveric transplantation rate per 100 dialysis patient years by age, recipient sex, and race, 1996. Source: Special Analysis

group 20-34 years). The LD transplantation rate for pediatric patients was 3.4 times greater than for young adults (age group 20-34 years). The CAD transplantation rate was two fold greater in pediatric patients than in the young adults.

Older age groups, had lower transplantation rates (for both LD and CAD) with patients aged 50-65 years having rates of 1.2 and 4.3 per 100 dialysis patient-years for LD and CAD transplantation, respectively. The relatively low transplantation rates in the ESRD patient age group 50-65 years belie the staggering incidence of ESRD in this population compared to younger age groups. In fact, the median age of onset of ESRD is 62 years (Chapter II) and patients who are 50 years and older account for 40 percent of the current registrants on the cadaveric renal transplant waiting list (UNOS 1997). Patients in

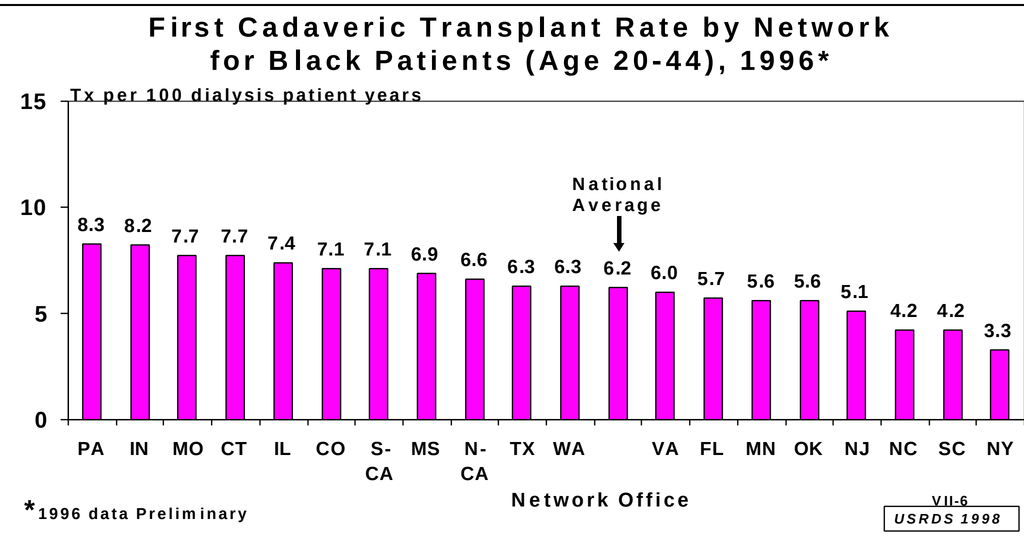

Figure VII-6

First cadaveric transplantation rate per 100 dialysis patient years by network for Black patients (age 20-44), 1996. Source: Table F.28 the 50-65-year age group received more than twice as many LD organs than the pediatric group and more CAD organs than the two younger age groups combined (age 0-34 years).

The results of an analysis of transplantation rates by race, gender, and age group are shown in Figure VII-5. In the age group 0-19, Black and White males have similar transplantation rates but Black females had 50 percent lower rate than White females. The middle age group (age 20-44) that receives the largest proportion of all renal transplants, had no gender difference in the transplantation rates among Blacks, but the rate in White females was 12 percent lower than that of White males for 1996 transplants. This pattern had previously been noted for 1993 (1996 ADR). In the older age group, females have lower transplantation rates. With the exception of the pediatric age group, Blacks of both genders have lower transplantation rates than their White counterparts. In adults, the racial difference in transplantation rate was least pronounced among females aged 45-64 years (54 percent lower rate in Blacks) and greatest among males aged 20-44 years (60 percent lower in Blacks). Comprehensive review of the possible explanation for the race and gender disparities in transplantation rates can been found in other sources (Held 1988, Kallich 1993, Gaston 1993, OIG 1987, OIG 1991, Koyoma 1994, Bloembergen 1997).

Just as the efficiency of cadaveric organ procurement varies between the Organ Procurement Organizations (Evans 1993), there were marked differences between the ESRD networks in the CAD transplantation rates. Figure VII-6 and VII-7 illustrates the CAD transplantation rates according to the patient's ESRD Network of residence. Among Black ESRD patients aged 20-44 (Figure VII-6), the CAD transplantation rate ranged from 3.3 per 100 dialysis patient years in New York to 8.3 per 100 dialysis patient years for residents of Pennsylvania and Maryland. The national average for Black CAD transplantation rate was 6.2 per 100 dialysis patient years for ages 20-44 years. The national average for Whites in the same 20-44-year age group (Figure VII-9) was more than two fold higher (14.4 per 100 dialysis patient years).

Although, the CAD transplantation rate was higher in Whites than in Blacks in each of the eighteen networks, the racial disparity was more marked in some networks than in others. For example, the rate in Whites was 4 times higher in the New York Network but only 2 times higher in the Indiana network. The ESRD networks with the

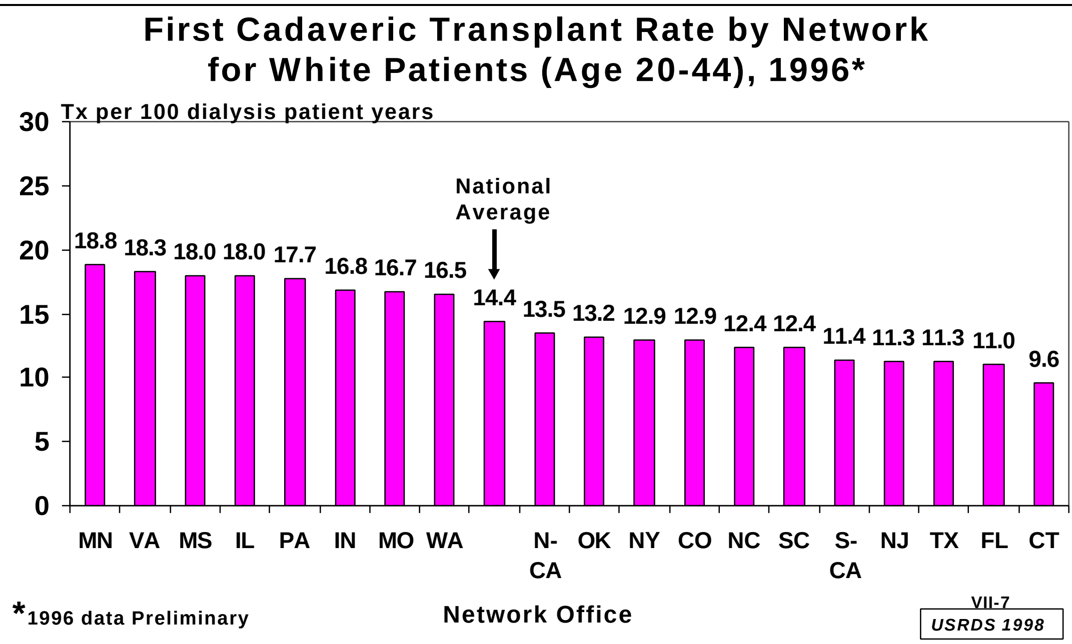

Figure VII-7

First cadaveric transplantation rate per 100 dialysis patient years by Network for White patients (age 20-44), 1996. Source: Table F.28

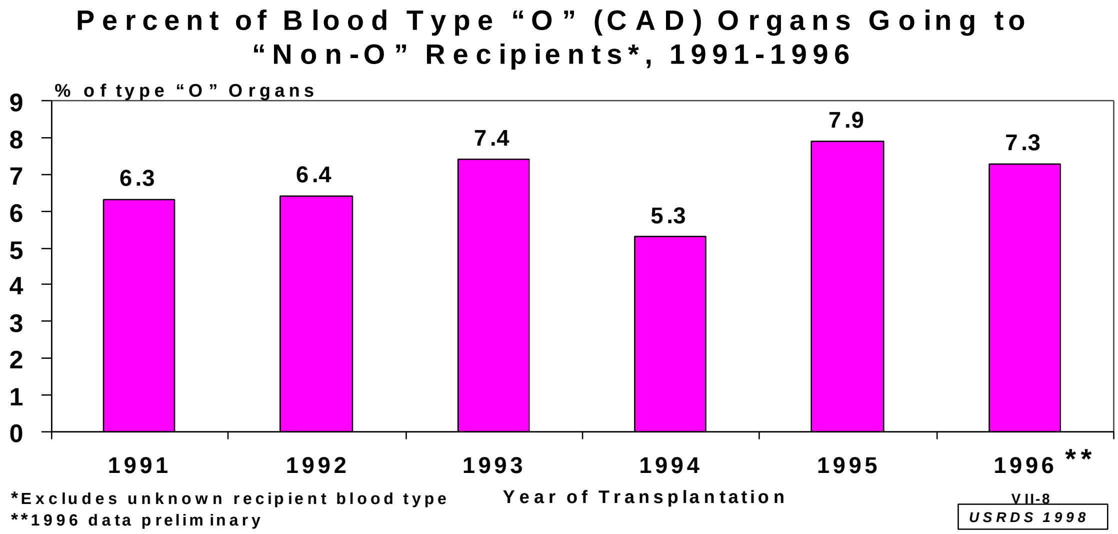

Figure VII-8

Percent of blood type "O" organs going to "non-O" recipients, 1991-1996. Source: Special Analysis

largest racial disparities did not necessarily have the highest transplantation rates for Whites. Some Networks have similar patterns by race while others have discrepant results.

The geographic differences and the within region racial disparities in CAD transplantation rates is complex and further compounded by the fact that patients may receive CAD kidney transplantation outside their network of residence. Moreover, the CAD transplantation rate may not reflect the organ procurement efficiency of the OPO serving that particular network. Thus, it would be an oversimplification and potentially misleading to use the CAD transplantation rate as a yardstick of access to transplantation or as an indicator of performance efficiency of the respective ESRD networks. However, the large differences described here for the 20-44-year age group raise difficult questions that should be addressed by future studies.

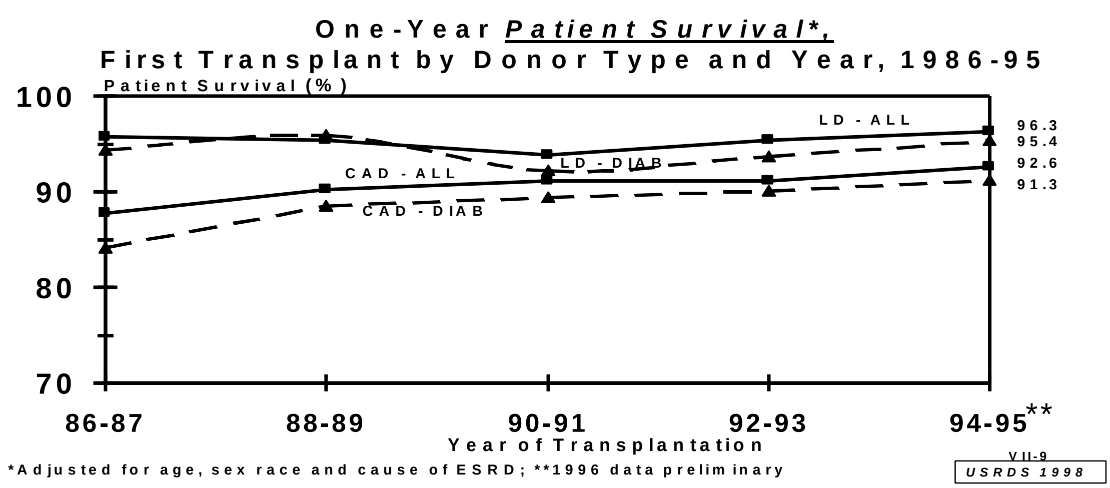

Figure VII-9

Average 1-year patient survival, first transplants adjusted for age, sex, race, and cause of ESRD by donor type and year, 1986-95. Source: Tables E.70 (CAD) and E.87 (LD)

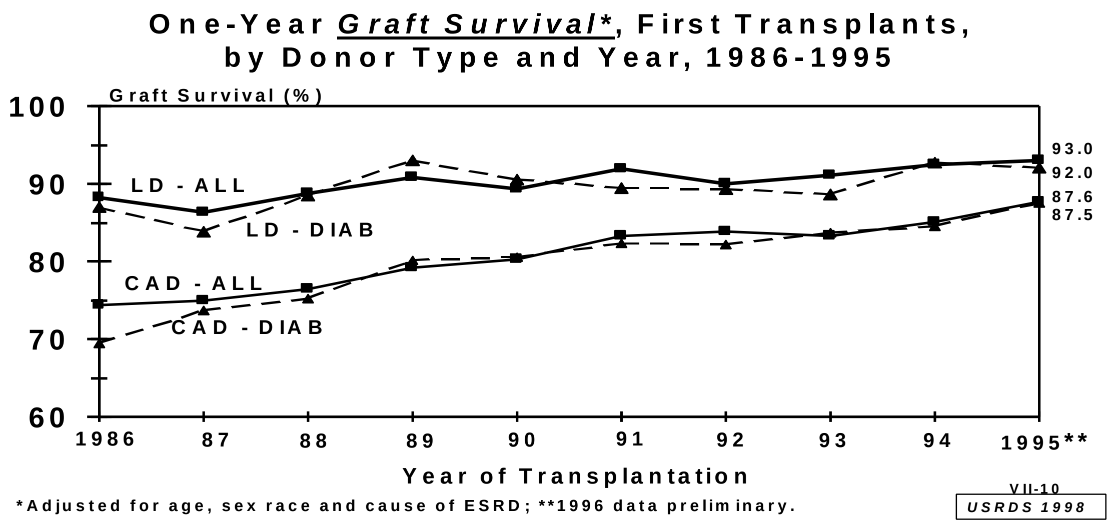

Figure VII-10

One-year graft survival, first transplants adjusted for age, sex, race, by donor type and year, 1986-95. Source: Tables G.19 (CAD) and G.43 (LD)

ABO Blood Group and Kidney Transplantation

The existing UNOS kidney allocation policy requires that blood group "O" kidneys should be transplanted to blood group "O" candidates with the exception of the mandatorily shared zero-HLA mismatched kidneys and simultaneous kidney-extrarenal organ transplants. Figure VII-8 shows the proportion of kidneys from blood group "O" cadaver donors going to non-"O" recipients between 1991 and 1996. This fraction of "O" kidneys going to non"O" recipients has declined sharply from 13.0 percent in 1985 (1995 ADR) following the implementation of the UNOS policy. Although, blood group "O" mismatched CAD kidney transplantation still range from 5.3 percent in 1994 and 7.3 percent in 1996, this

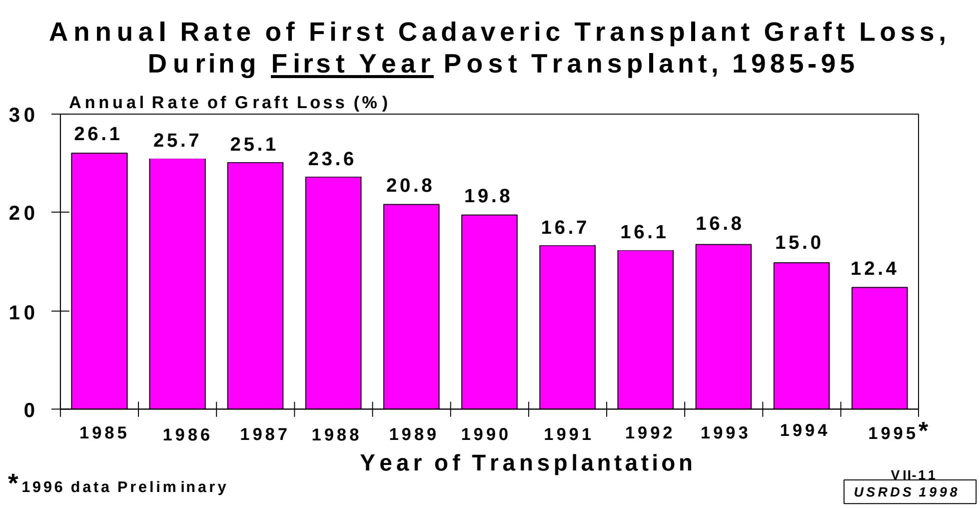

Figure VII-11

Annual rate of graft loss for first cadaveric donor transplants during the first year after transplantation by year, adjusted for age, sex, race, and cause of ESRD, 1985-95. Source: Table G.19 anomaly at least in part represents the effect of the exceptions operative under the current UNOS policy. The effect of a 5-7 percent diversion of "O" organs from "O" patients on the waiting list is large when considered cumulatively and contributes to the prolonged waiting times for type "O" transplant candidates (Port 1991).

Patient Survival

It is well established that renal transplantation confers a survival advantage over dialysis (Port 1993, Ojo 1995, Wolfe 1997b). Whereas patient survival with both peritoneal dialysis and hemodialysis varies according to the primary cause of ESRD (Bloembergen 1995), the primary disease has a relatively small influence on the survival of renal transplant recipients. Even, among diabetic ESRD patients who are known to have markedly lower survival on dialysis, their patient survival with renal transplantation is only slightly lower than that of recipients with nondiabetic ESRD. Figure VII-9 shows the 1-year renal transplant recipient survival stratified by diabetic-ESRD status and transplant donor type. The trends indicate diminished 1-year patient survival among diabetic CAD recipients in 1986-1987 (87.8 percent vs 84.1 percent in nondiabetic ESRD) followed by improved survival in all patient groups but with diabetics having greater proportional improvement in survival. In the most recent years (1994-1995), 1-year patient survival for cadaveric renal transplant recipients was 91.3 percent for diabetic and 92.6 percent for nondiabetic renal transplant recipients. The 1-year patient survival for LD transplant recipients was 95.4 percent and 96.3 percent for diabetic and nondiabetic ESRD patients, respectively.

The improvement in patient survival between 1986 and 1995, particularly among diabetic and cadaveric renal transplant recipients, have paralleled two potentially related developments. Firstly, there had been a steady improvement in the 1-year functional renal allograft survival and secondly, death from infectious complications have diminished while cardiovascular disease has become the predominant cause of death in renal transplant recipients (Chapter VI and Basadonna 1992). These events in addition to better management of concurrent illness may have contributed to the improvement in patient survival in renal transplant recipients.

Renal Allograft Survival

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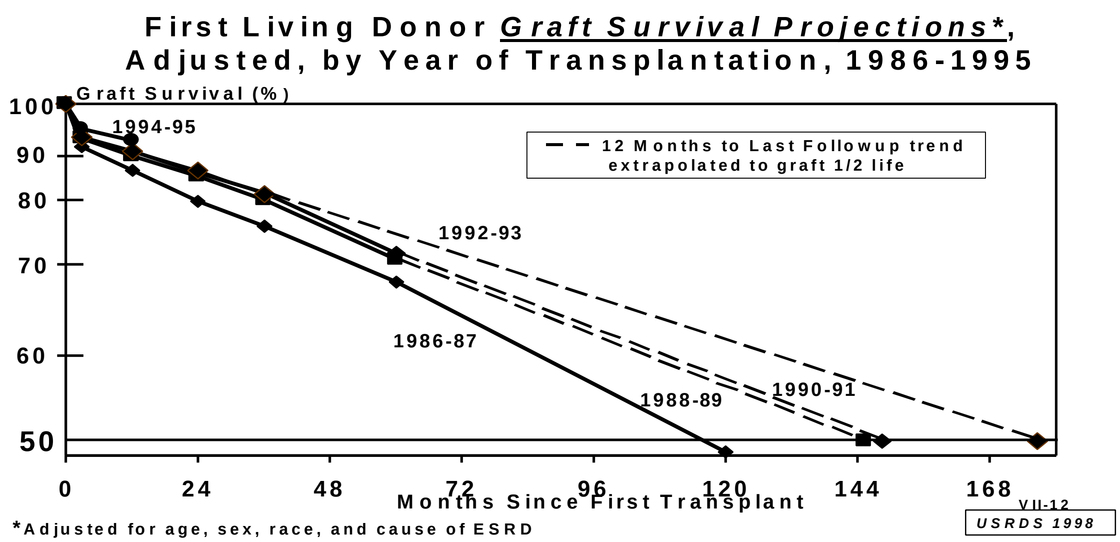

Figure VII-12

Living donor kidney graft survival and projections to the median graft survival (half life) for first transplants, adjusted for age, sex, race, and cause of ESRD, 1986-95. Source: Tables G.43-G.51

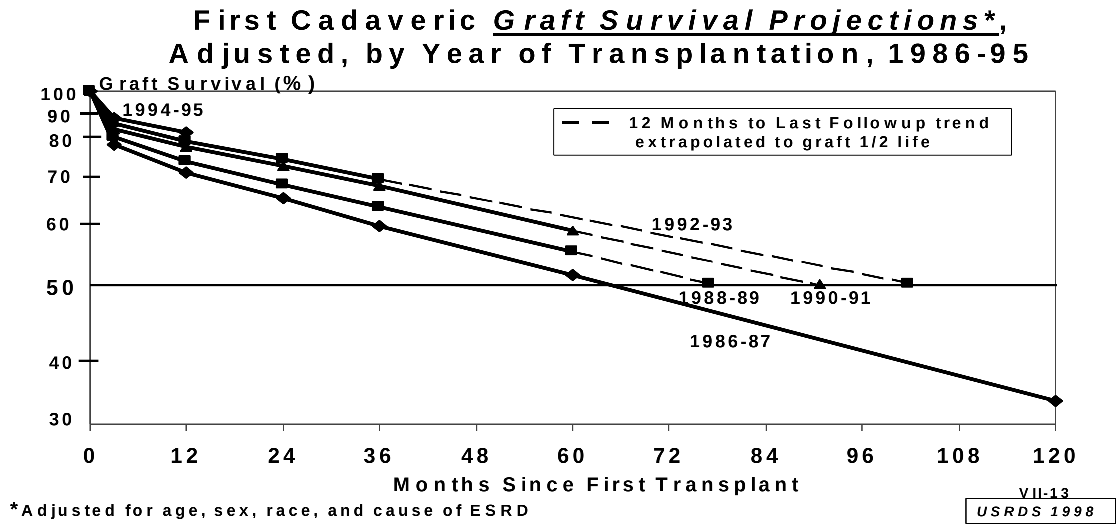

Figure VII-13

Cadaveric kidney graft survival and projections to the median graft survival (half life) for first transplants, adjusted for age, sex, race and cause of ESRD, 1986-95. Source: Tables G.19-G.27

presenting the results of kidney transplantation. The short graft survival is represented by Kaplan-Meier estimates of 1-year renal allograft survival and the long-term result are presented as the median graft survival (in months). The median graft survival is the time interval from transplantation until 50 percent of allografts have been lost, that is the probability of renal allograft surviving beyond the median is 0.50. In producing the median graft survival estimates, the rate of graft loss was assumed to be constant within each cohort after the first transplant anniversary. Death with a functioning allograft was counted as a failure (not censored) in both the short- and long-term estimation of graft survival. Only primary renal transplants were included in the graft survival analysis.

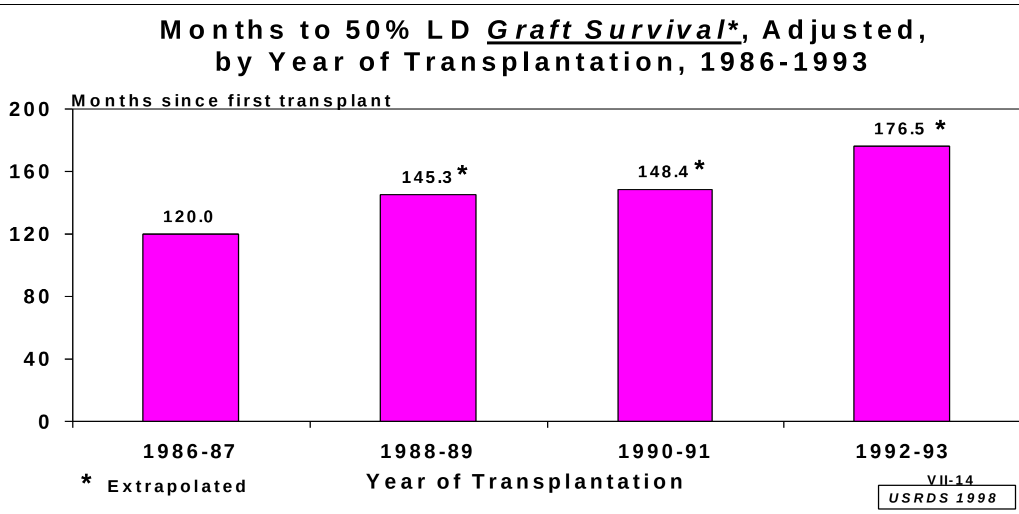

Figure VII-14

Months to 50 percent living donor graft survival, adjusted for age, sex, race, and cause of ESRD, 1986-93. Source: Figure VII-14

Short-term Allograft Survival

Figure VII-10 shows the stratified (by donor type and diabetic-ESRD status) 1-year graft survival for primary renal transplants performed between 1986 and 1995. During this decade, CAD one-year graft survival improved from 70 percent in diabetic ESRD recipients and 75 percent in nondiabetic recipients to 88 percent in both groups. One-year graft survival in LD transplants performed in 1986 was 87 percent and 88 percent in diabetics and nondiabetics, respectively. By 1995, 1-year graft survival in LD transplants had risen to 92 percent and 93 percent in diabetics and nondiabetics, respectively. The proportionally greater improvement in graft survival in diabetic CAD transplants (26 percent vs. 17 percent for nondiabetics) could in part be explained by the concurrent greater improvement in patient survival among diabetics (vide supra). Future ADR reports will include assesment of kidney and pancreas transplants in type-1 diabetics.

The improvement in short-term graft survival observed over the last decade occurred in a sustained fashion. This is best illustrated in Figure VII-11 which shows the rate of primary CAD allograft loss during the first posttransplant year from 1985-1995. After the initial dramatic reduction in the first year allograft loss rate associated with the introduction of cyclosporine in 1983 (1994 ADR), the rate was relatively stable between 1985 and 1987. Between 1988 and 1995, first year allograft loss rate dramatically decreased by almost 50 percent (from 23.6 percent in 1988 to 12.4 percent in 1995). During this period several immunosuppressive drugs designed to prevent acute allograft rejection entered clinical trial phases and some received final approval from the FDA (Vanrenterghem 1997).

Long-term Allograft Survival

Long-term renal allograft survival curves are shown in Figures VII-12 and VII-13. The survival curves are stratified in 2-year cohorts to illustrate trends. Median allograft survival (months) derived from the survival curves are displayed as bar charts in Figures VII-14 and VII-15. Several important findings can be noted. Median primary CAD graft survival improved from 64.5 months in 1986-1987 to 101.8 months in 1992-1993. This substantial increase by 58 percent occurred in a steady fashion between the time periods studied. Median primary LD graft survival also increased by 52 percent from 116 months in 1986-1987 to 176.5 months in 1992-1993. These findings are similar to the near 50 percent improvement in first year graft survival and argue against the prevailing notion that long-term graft survival has not improved as much as the increment seen in short-term graft survival. The rate of allograft loss is relatively low after first posttransplant year (Figure VII-16), therefore a large number of events and or extended followup is required to accrue

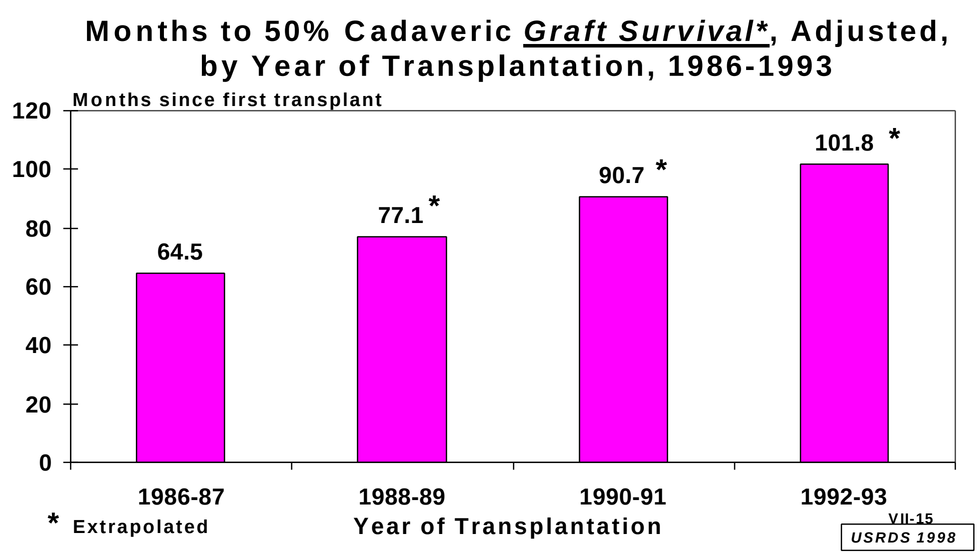

Figure VII-15

Months to 50 percent cadaveric donor graft survival, adjusted for age, sex, race, and cause of ESRD, 1986-93. Source: Figure VII-15

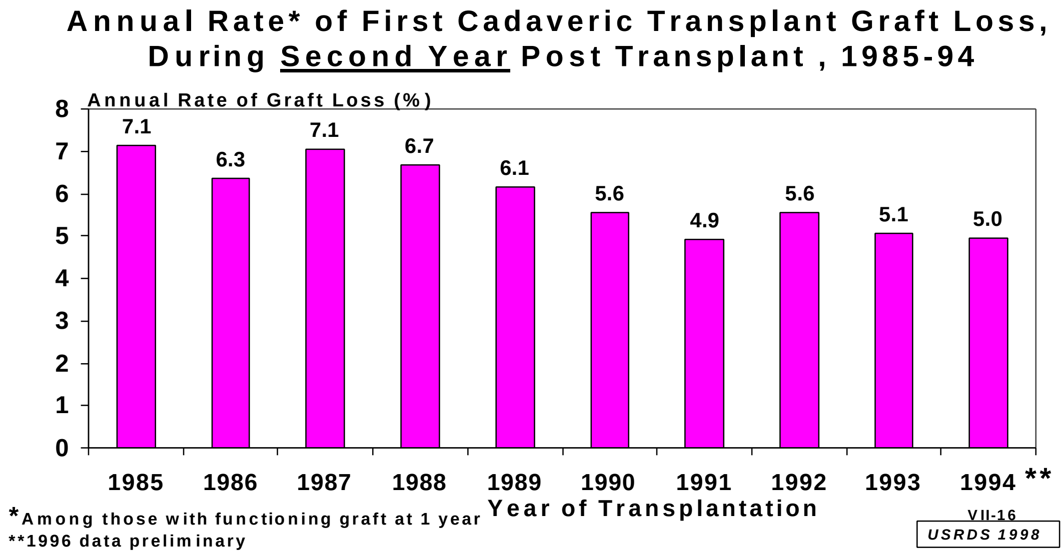

Figure VII-16

Annual rate of graft loss for first cadaveric donor transplants during the second year after transplantation by year, adjusted for age, sex, race, and cause of ESRD, 1985-94. Source: Tables G.19, G.20

sufficient events (failures) to permit detection of a meaningful change. For most, only registry data have requisite capacity to detect such changes (Hunsicker 1995).

In summary, recent advances in immunosuppressive therapy have contributed to improved short-term renal allograft survival. Comprehensive evaluation of registry data suggests an encouraging trend in long-term allograft survival. Sustained improvement in both short- and long-term graft survival will minimize need for retransplantation and have a positive effect on the transplant waiting times. Stagnant cadaveric kidney donation has been resistant to conventional strategies to promote organ donation. The number of biologically unrelated living donors is expanding rapidly. Marked demographic differences in access to kidney transplantation are compounded by unexplained regional variations in cadaveric renal transplantation rates. Special studies would be required to shed additional insight into these issues so that the benefits of renal transplantation may become a more realistic expectation for thousands of potential recipients who are waiting for a renal transplant.

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