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Current status of kidney and pancreas transplantation in the United States, 1994–2003

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This article reviews the OPTN/SRTR data collected on kidney and pancreas transplantation during 2003 in the context of trends over the past decade. Overall, the transplant community continued to struggle to meet the increasing demand for kidney and pancreas transplantation. The number of new wait-listed kidney registrants under the age of 50 has remained relatively stable since 1994, but the number of new registrants aged 50 to 64 has doubled. However, there was only a 2.3% increase in the total number of kidney transplants performed in 2003. Expanded criteria donor kidneys made up 20% of all recovered kidneys and 16% of all transplants performed, compared with 15% in the prior year. In May 2003, new rules were implemented to promote equity in kidney organ allocation. These changes seem to have improved access for historically disadvantaged groups, though they have reduced the quality of HLA matching. The effects on long-term outcomes have yet to be measured. Although the majority of SPK recipients are white (82%), the percentage of simultaneous kidney-pancreas recipients who are African-American has increased from 9% in 2000 to 16% in 2003. The percentage of Hispanic/Latino recipients increased from 5% to 9% over the same period.

Key words: Deceased donors, graft survival, kidney transplantation, kidney-pancreas transplantation, living donors, organ donation, pancreas transplantation, patient survival, SRTR, waiting list.

Introduction

A review of the extensive data collected on kidney and pancreas transplantation during 2003 is provided here in the context of trends over the past decade. The characteristics of the waiting list are discussed, followed by assessments of transplant recipient characteristics and of recipient and allograft survival. The characteristics of the recipients of expanded criteria donor (ECD) kidneys and the outcomes of these transplants are described, followed by sections addressing simultaneous kidney-pancreas, pancreas after kidney and isolated pancreas transplantation. Important changes have been made in the kidney transplant allocation algorithm in the last 2 years, and these are reviewed in a separate section. Though recent, the impact of these changes is reflected in some of the trends described in the text.

Unless otherwise noted, the statistics in this article are drawn from the reference tables in the *2004 OPTN/SRTR Annual Report*. Two companion articles in this report, 'Transplant data: sources, collection, and research considerations' and 'Analytical approaches for transplant research, 2004' explain the methods of data collection, organization and analysis that serve as the basis for this article (1,2). Additional detail on the methods of analysis employed herein may be found in the reference tables themselves or in the Technical Notes of the *OPTN/SRTR Annual Report*, both available online at http://www.ustransplant.org.

Note on sources: The articles in this report are based on the reference tables in the *2004 OPTN/SRTR Annual Report*, which are not included in this publication. Many relevant data appear in the figures and tables included here; other tables from the *Annual Report* that serve as the basis for this article include the following: Tables 2.2, 5.1, 5.2, 5.3, 5.4, 5.4a, 5.4b, 5.4c, 5.7a, 5.7c, 5.8b, 5.8c, 5.9a, 5.9b, 5.9c, 5.10b, 5.14, 6.1, 6.2, 6.3, 6.4, 6.9, 6.10, 6.12, 7.1, 7.2, 7.3, 7.4, 7.7, 7.9, 7.10, 7.12, 8.1, 8.2, 8.3, 8.4, 8.7, 8.9, 8.12, 8.13, and 8.14. All of these tables may be found online at http://www.ustransplant.org.

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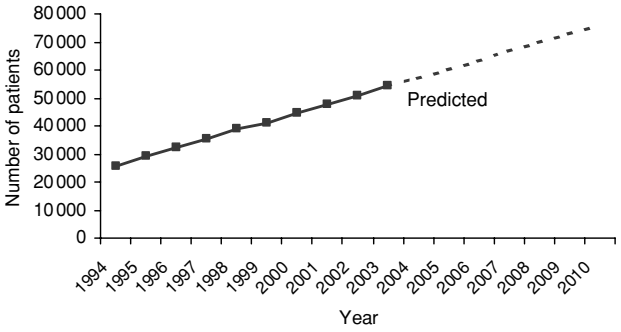

Figure 1: Growth in the waiting list for deceased donor kidneys, 1994–2003. Source: *2004 OPTN/SRTR Annual Report*, Table 5.1. Predicted values for 2004–2010 based on slope of the line from 1994–2003.

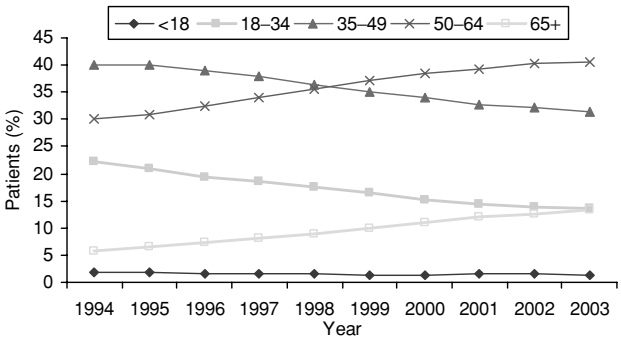

Figure 2: Percentage on the kidney waiting list by age group, 1994–2003. Source: 2004 *OPTN/SRTR Annual Report*, Table 5.1.

Kidney transplantation

The kidney transplant waiting list

The kidney transplant waiting list continues its inexorable expansion at a rate of 3000-4000 patients each year; by the end of 2003 the list comprised close to 55 000 candidates. If it continues to grow at the same rate, the waiting list will comprise approximately 76 000 registrants by the year 2010 (Figure 1). This estimate is somewhat lower than the estimate of 95 000 made by Xue et al. (3). The expansion of the waiting list is accompanied by a steady increase in the annual numbers of new registrants at a rate that is increasing by approximately 1000 per year, reaching close to 25 000 new registrants in 2003. The apparent slowdown in the growth of the list and of new registrants noted in the *2002 OPTN/SRTR Annual Report* has not been maintained (4).

The waiting list has continued to age in terms of both new registrants and those already registered (Figure 2). Representation on the list of children under the age of 18 years has remained at approximately 1.5% and is stable. The absolute number of listed patients aged between 18 and 34 years has increased, but they now represent 14% of the list compared with 22% in 1994. Patients between 35 and 49 years accounted for 31% of the list in 2003 compared with 40% in 1994. A reverse trend is seen in older patients. Those aged 50 years and over accounted for 54% of the waiting list in 2003 compared with 36% in 1994. The most notable change has been a 5-fold increase in the number of patients over the age of 65 years; they account for 13% of the list in 2003 compared with 6% in 1994. The number of new registrants under the age of 50 years has remained stable since 1994, but the number of new registrants aged 50–64 years has doubled, and the number of new registrants over the age of 64 years has more than tripled. In 1994, 35% of new registrants were over the age of 50 years, while in 2003, 51% were over the age of 50 years. The steady rise in both the absolute numbers and percentage of older patients newly registered and on the list means that younger adults are competing for kidneys with a steadily aging list.

The ratio of white to African American wait-listed patients has remained unchanged over the last decade. African Americans account for 36% of listed patients, which is similar to their representation in the chronic dialysis population (5) and is approximately three times their percentage in the general population. African Americans consistently account for 29% of new registrants. As will be discussed below, the higher percentage of African Americans on the list compared with those newly listed is accounted for by their slower rate of transplantation. For whites, the situation is reversed; whites account for 54% of the list compared with 63% of newly listed registrants, reflecting their higher rate of transplantation. As of 2003, approximately 16% of both listed patients and new registrants were Hispanic/Latino compared with approximately 12% in 1994. Representation of men remains approximately 15% greater than women and representation of the ABO blood groups is unchanged, with blood group O patients consistently making up more than 50% of the list. Over the last 6 years, 18–20% of patients have had a prior kidney or kidney-pancreas transplant and 19–21% have had a prior transplant of any organ. The percentage of patients with elevated levels (>10%) of panel reactive antibodies (PRA) has gradually fallen from 50% in 1994 to 33% in 2003, presumably as a result of the more selective administration of blood products to dialysis patients. Only 1% of registrants are designated as being non-resident aliens.

The primary diagnosis of wait-listed patients does not parallel the primary diagnosis of patients receiving chronic dialysis. Whereas patients designated as diabetic or hypertensive account for 40% and 28%, respectively, of the dialysis population (5) they account only for 26% and 19%, respectively, of wait-listed patients. On the contrary, whereas patients designated as suffering from glomerular diseases and polycystic kidney disease (PKD) account for 12% and 3% of the chronic dialysis population, respectively, they account for 22% and 6% of wait-listed patients. These

discrepancies are a reflection of the fact that hypertension and diabetes are more likely to be diagnosed in older patients with comorbid features that may exclude them from being wait-listed for transplantation. Patients with glomerular diseases and PKD are likely to be younger and have fewer comorbid features that contraindicate transplantation.

Patients are remaining on the list for increasingly prolonged periods. In 1994, 29% of the list had been waiting for more than 2 years compared with 43% in 2003. As of 2003, approximately 11% of patients had been waiting for more than 5 years. At the end of 2003, 15% of patients were defined as being inactive compared with 10–12% in previous years. Patients who are reported to United Network for Organ Sharing (UNOS) as being temporarily unsuitable for transplant are placed on inactive status and are not offered kidneys until they return to active status. In the past, inactive patients were only permitted to continue accruing waiting time during the first month of inactive status. As will be discussed below, as of June 2003 this policy was changed to permit accrual of waiting time while on inactive status. The increased percentage of patients with inactive status at the end of 2003 may represent an early reflection of this change, and the percentage is likely to increase.

In parallel with longer waiting times, the median time to transplant (indicating the number of days by which 50% of the registrants have been transplanted) for new registrants has been rising for all age groups other than for children under the age of 5 years. For older children (6 years or older) the median time to transplant has doubled to approximately 400 days, despite adjustments in the allocation algorithm designed to favor them (6). Adults wait much longer than children. Because median time to transplant cannot be calculated until half of the group has been transplanted, the most recent year with median time to transplant varies for different subgroups. For young adults (18–34 years) listed in 2001, the median waiting time was 987 days; for the oldest group of adults (65 years or greater) listed in 1999, the median waiting time was 1599 days. The increase in the median time to transplant with aging should not be understood as indicating that individual older registrants will wait longer for a transplant. Rather, it reflects that older registrants have a greater chance of dying before they receive a transplant, thereby increasing the time by which the median is reached for the older age cohort (Figure 3). It should also be noted that these data precede the introduction of new allocation policies by which ECD kidneys tend to be directed to older registrants (see below).

The time to transplant varies among blood types. Blood group O and B registrants wait the longest (median time to transplant was 1469 and 1815 days, respectively, for those listed in 1999); approximately twice as long as blood group A and four times as long as blood group AB (median time to transplant 740 and 396 days, respectively).

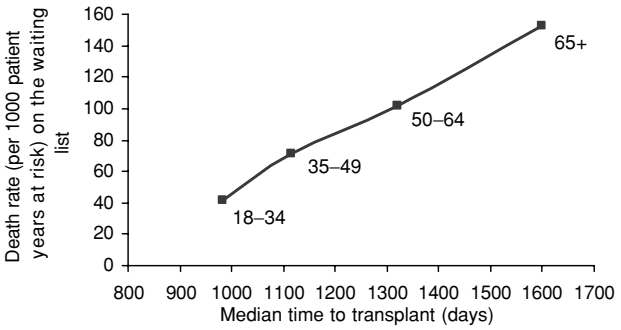

Figure 3: Death rate on the kidney waiting list versus median time to transplant by age group, 1999. Source: *2004 OPTN/SRTR Annual Report*, Tables 5.2, 5.3.

The time to transplant has been increasing steadily in all ethnic groups, but the increase has been greatest among African Americans who, for those listed in 1999, waited more than twice as long as whites. Waiting time for Asian registrants is approximately 85% longer than that for white registrants. Some of these differences may be reduced by changes made in the allocation algorithm to de-emphasize the importance of human leukocyte antigen (HLA) typing, but much of this difference is immutable, related to geographical differences in allocation. The waiting time for nonresident aliens does not differ from that of U.S. citizens.

The absolute number of new registrants with high PRA has been steady since 1994, but this subgroup represents a falling percentage of the total number of new registrants. In 1994, 33% of new registrants were reported to have a peak PRA of greater than 10% compared with 23% of new registrants in 2003. This trend explains the falling percentage of wait-listed patients with high PRA noted above. High PRA registrants wait approximately twice as long as those with a low PRA. As a group, previously transplanted new registrants wait approximately twice as long as those awaiting a first transplant. Not surprisingly, the PRA of previously transplanted new registrants is high, though there has been a trend toward a reduction in the degree of presensitization. In 1994, 64% of previously transplanted new registrants had a PRA of 10% or greater; this percentage has fallen steadily to reach 57% in 2003. For previously transplanted registrants with a low PRA there is little difference in the time to transplant compared with those with a low PRA who were not previously transplanted. Representation of new female registrants among low PRA registrants remains consistent at approximately 36%.

As expected, the death rate on the list increases with age; for the years 2000–2003 there have been approximately 35 deaths per 1000 patient years at risk for patients aged 18–34 years, increasing to over 100 deaths per 1000 patient years at risk for patient ages greater than 64 years (Figure 4). Expressed simply, a patient over the age of 64 years who is likely to wait 5 years for a kidney has an

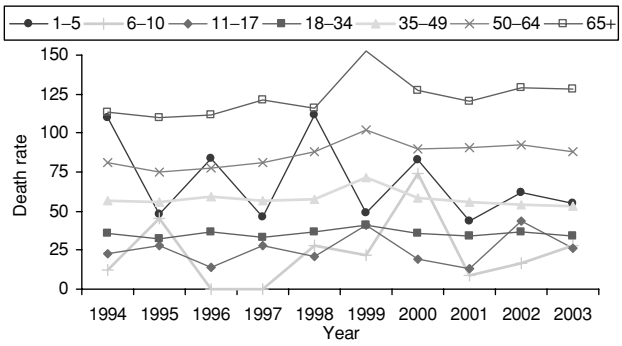

Figure 4: Death rate on the kidney waiting list by age group, 1994–2003. Source: *2004 OPTN/SRTR Annual Report*, Table 5.3.

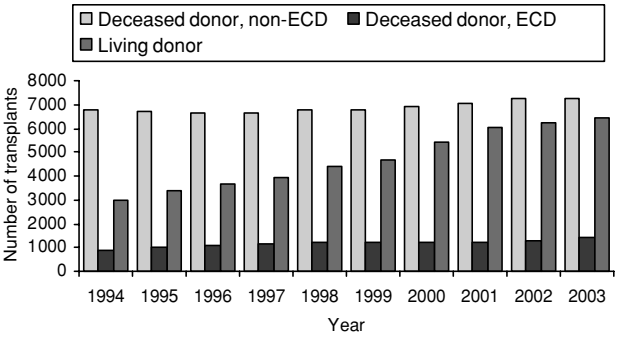

Figure 5: Deceased donor, deceased donor-ECD and living donor kidney transplants, 1994–2003. Source: *2004 OPTN/SRTR Annual Report*, Table 5.4a, 5.4b, 5.4c.

approximately 50% chance of dying before a kidney becomes available. Findings such as these are valuable for counseling older patients as to the available treatment options. The death rate varies among ethnic groups and is greatest among whites (83 deaths per 1000 patient years at risk for the year 2003). For African Americans, the rate is 68; for Hispanics/Latinos, the rate is 67 and for Asians, the rate is 54. The lower death rate on the list for African Americans compared with whites reflects their reported lower mortality on dialysis (5). The death rate on the list also increases with increasing time from the start of dialysis until time of listing. Compared to patients with 6–12 months of dialysis, patients with less than 6 months of dialysis have significantly lower rates of death on the list (RR = 0.78, $p < 0.0001$ for <1 month of dialysis; RR = 0.81, $p < 0.0001$ for 1–6 months of dialysis), and patients with more than 12 months of dialysis have a significantly higher rate of death on the list (RR = 1.28, $p < 0.0001$) (SRTR analysis, January 2003).

Kidney transplant recipients

There was a 2% increase in the total number of kidney transplants (deceased and living donor) performed in 2003, continuing an upward trend (Figure 5). The percentage of living donor kidney transplants remained constant at approximately 42%. Despite convincing evidence of the benefit of transplantation prior to the commencement of dialysis (7), only 13% of recipients were transplanted preemptively. Preemptive transplantation is relatively common for recipients of living donor kidneys (22%) but uncommon (6%) for recipients of deceased donor kidneys (SRTR analysis, June 2004).

Recipients of non-expanded criteria donor kidneys

The number of deceased donor non-ECD transplants remained stable between 2002 and 2003. In the preceding five years, the average increase was close to 2% per year. The age distribution of recipients mirrors that of the waiting list. In 1994, 35% were over 50 years old and 6% were over the age of 65 years, whereas in 2003, 49% were over 50 years and 11% were over 65 years. The percentage of recipients aged 18–34 years has fallen from 22% to 14% over the same time period. There has been no change in the primary renal disease of transplant recipients; 66% carry a diagnosis of glomerulonephritis, diabetes mellitus or hypertension. This percentage mirrors that of the waiting list.

The percentage of African American non-ECD recipients rose by 1.5% between 2002 and 2003, when it reached 30%. African Americans comprise 36% of the kidney transplant waiting list. Preliminary data suggest that the percentage of African American recipients is likely to rise in future years in response to changes in the allocation algorithm designed for this purpose. The percentage of non-ECD recipients who were prior organ transplant recipients did not change in 2003, remaining at 15%, which approximates their representation on the waiting list.

The percentage of recipients transplanted with zero-antigen-mismatched kidneys has remained stable at approximately 15%. However, the percentage transplanted with poorly matched kidneys has increased, with a decline in 1-, 2- and 3-antigen-mismatched kidneys corresponding to the increase in 4-, 5- and 6-antigen-mismatched kidneys (from 56% in 2002 to 62% in 2003). This decline in the degree of matching is likely to increase with the introduction of new allocation rules (see below). The percentage of highly sensitized (PRA 80%+) recipients receiving transplants has increased somewhat, from 2% in 1994 to 4% in 2003. There has been a continuing trend to reduction in cold ischemia times (CIT). In 1994, 11% of recipients received a kidney with a CIT of less than 11 h compared with 19% in 2003. Similarly, there has been a decline in the percentage of kidneys transplanted with CITs of more than 22 h, from 42% in 1994 to 26% in 2003 (Figure 6).

Recipients of expanded criteria donor kidneys

In an effort to facilitate deceased donor kidney transplantation, an adjustment of the kidney allocation algorithm was

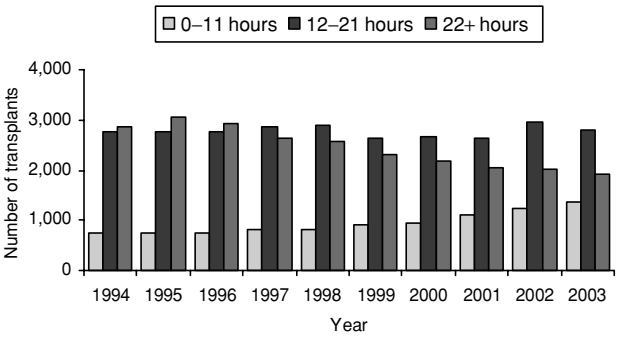

Figure 6: Deceased donor non-ECD kidney transplants, by cold ischemia time, 1994–2003. Source: *2004 OPTN/SRTR Annual Report*, Table 5.4a.

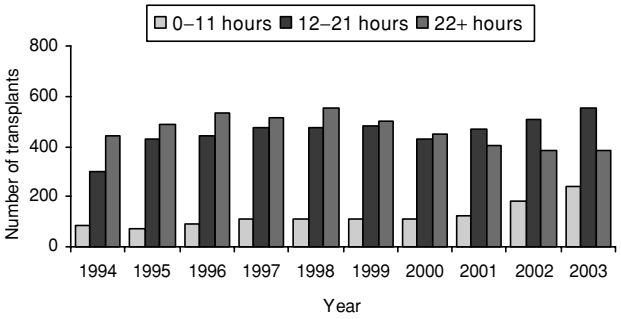

Figure 7: Deceased donor ECD kidney transplants, by cold ischemia time, 1994–2003. Source: *2004 OPTN/SRTR Annual Report*, Table 5.4b.

implemented in October 2002 to expedite the distribution of kidneys with less favorable donor characteristics to patients who had previously agreed to accept them. The definition of these ECD kidneys and the algorithm for allocating them was discussed in the *2002 SRTR Report on the State of Transplantation* (8). Briefly, donors over age 60 years and those aged 50–60 years who had two of three conditions (pre-donation serum creatinine >1.5 mg/dL, stroke as cause of death, or hypertension) were labeled ECD, according to the finding of an elevated risk of graft failure (9) of 1.7 times greater than that of a reference population of non-hypertensive, deceased donors between the ages of 10 and 39 years, whose cause of death was not from cerebral vascular accident and whose terminal creatinine was ≤1.5 mg/dL. The algorithm was predicted to improve preparation of potential recipients and to avoid delay in the placement of ECD kidneys. It was anticipated that overall outcomes would improve as discard rates decreased and the occurrence of delayed graft function lessened (10).

The transplantation of ECD kidneys has increased steadily over the past decade, from approximately 11% of kidney-alone transplants in 1994 to approximately 16% in 2003 (Figure 5). The overall increase from 2002 to 2003 is from 1261 to 1398 kidneys, an increase of 11% compared with an increase of 6% in the previous year. This increase in ECD transplantation most likely reflects an increase in the number of organs recovered, as well as an increase in the number of patients listed for ECD transplantation. Between November 2002, when the new policy for allocation of ECD kidneys was introduced (see below), and July 2003, a 14% increase in recoveries and a 7% increase in transplants from the prior year were noted (11). ECD kidneys made up 21% of all recovered kidneys and accounted for 16% of all transplants performed, compared with 15% in the prior time period.

As of July 2003, 43% of listed registrants were also listed for an ECD kidney (12). Registrants listed for ECD kidneys are more likely to be older, African American, diabetic and sensitized than those listed only for a non-ECD kidney.

In 2003, 60% of ECD recipients were white and 33% were African American. ECD recipients are more likely to be male. The new allocation policy for ECD kidneys does not include points for HLA matching, and the opportunity for zero-mismatch allocation is limited compared with the standard algorithm. As a result, ECD recipients are more highly mismatched; 52% have a 5 or 6 HLA mismatch, which is an increase from 40% in 2002. Only 7% of ECD kidneys were transplanted to zero-antigen-mismatched recipients. PRA at time of transplant in the majority of recipients is low, with only 10% of recipients having a PRA greater than 10%. CIT was under 22 h in approximately 57% of recipients, which represents an improvement of approximately 10% over the previous five years. Between 2001 and 2003, there was an improvement in the percentage of ECD kidneys transplanted within a CIT of less than 12 h, from 10% to 17%. These changes may be ascribed, to some extent, to the design of the ECD algorithm, which was anticipated to reduce CIT for these kidneys (Figure 7).

Registrants on the waiting list for ECD kidneys have the advantage of being eligible to receive offers for both ECD and non-ECD kidneys. Preliminary data suggest that registrants on the waiting list for ECD kidneys are more likely to get transplanted than those not on the ECD list (12).

Recipients of living donor kidneys

The number of living donor transplants has more than doubled since 1994; it has increased close to 4% in each of the last two years (Figure 5). There was no change in age distribution compared with 2002: 39% of recipients were over 50 years old and 8% over 65 years old. This compares with 20% aged over 50 years and 2% aged over 65 years in 1994. African American recipients continue to be under-represented among living donor recipients, comprising only 15% of the recipients of living donor kidney transplants in 2003; this compares with 30% of recipients

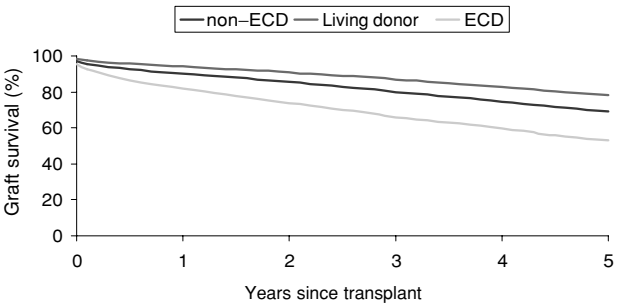

Figure 8: Graft survival (death as event) for recipients of renal transplants, 1997–1998. Source: SRTR Analysis. Data as of May 2004.

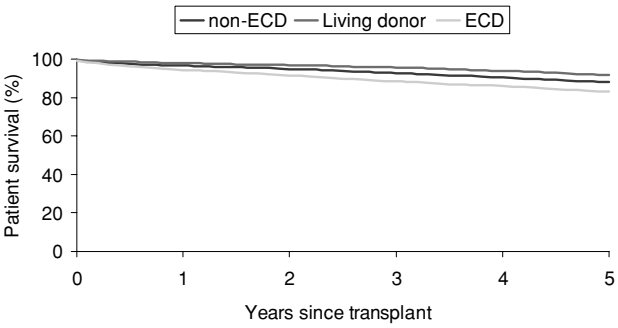

Figure 9: Patient survival for recipients of renal transplants, 1997–1998. Source: SRTR Analysis. Data as of May 2004.

of non-ECD kidneys, 33% of ECD kidneys and 36% of the waiting list.

The trend toward a greater number of living unrelated donors continues. In 1994, 77% of all living donors were first-degree relatives (i.e., either a parent, a child or a sibling), 4% were other relatives, 4% were spousal and 3% were 'other unrelated'. In 2003, 59% of all living donors were first-degree relatives, 7% were other relatives, 11% were spousal and 21% were 'other unrelated'. This trend is reflected in the worsening overall level of HLA mismatch in recipients of living donor kidneys. In 2003, 36% of living donor transplant recipients were mismatched for four or more antigens. This percentage has more than doubled since 1994.

Post-transplant outcomes: kidney

Deceased kidney donor recipients: graft survival

For recipients of non-ECD transplants performed between 2001 and 2002, unadjusted 1-year graft survival was 91% and for the period 1997–1998, 5-year graft survival rate was 69%. For the same time periods, unadjusted graft survival for ECD transplantation was 80% at 1 year and 51% at 5 years; for living donor transplant recipients, unadjusted graft survival was 95% at 1-year and 79% at 5 years. Graft survival over a 5-year period for non-ECD, ECD and living donor recipients transplanted between 1997 and 1998 is shown in Figure 8. Factors that have no impact on unadjusted graft survival from deceased donors included PRA at transplant and the number of transplants performed at the transplant center. For non-ECD transplants, there was a reduction in 5-year survival with increasing donor age, from 72% for donors aged 18–34 years to 61% for donors between ages 50 and 64 years. If dialysis was required in the first week post-transplant, 5-year graft survival was 56% compared with 73% if dialysis was not required. The impact of CIT on graft survival was initially small. At 1-year post-transplant, graft survival was 92% with 0–11 h of cold ischemia compared with 89% for 32–41 h of cold ischemia. At 5 years post-transplant, this difference had widened to 6%. Degree of HLA mismatch had some effect on 5-year graft survival outcomes and was 74% for zero-mismatch kidneys at 5 years compared with 64% for 6-antigen-mismatched kidneys. Five-year graft survival decreased as the number of mismatched HLA antigens increased. The reported larger difference in graft survival between zero-mismatched kidneys and 1-HLA-mismatched kidneys compared with the difference in graft survival between other HLA mismatch groups that differ by 1 mismatch was not observed (10).

When deceased donor graft survival data are adjusted for various demographic and comorbid factors, the overall 5-year survival rate is 50% for ECD kidneys. Graft survival data for ECD transplants show that recipients with PKD have the best outcomes, with 60% 5-year graft survival compared with 44% for diabetics and 47% for patients with nephrosclerosis. Recipients of either non-ECD or ECD deceased donor transplants did not do as well as recipients of living donor transplants, who had adjusted 5-year survival rates of 87% for PKD and 76% for diabetics.

For ECD kidney recipients, similar trends are seen as for non-ECD kidney recipients, although the survival percentages are lower. The worst results are seen for recipients over 65 years; their graft survival is 39% at 5 years. African American patients continue, again, to fare worse than other ethnic and racial groups, with 46% graft survival at 5 years compared with 56% for Hispanics/Latinos, 53% for whites and 60% for Asians. Both sex and recipient blood type continue to make little difference. Recipients of a previous transplant had 76% 1-year graft survival compared with 81% for recipients receiving their first kidney. This difference was also observed at 5 years post-transplant. Over time the 1-year graft survival of ECD kidneys has remained at approximately 80%.

Survival of deceased donor transplant recipients

Patient survival over a 5-year period for recipients of non-ECD, ECD and living donor kidneys transplanted in 1997–1998 is shown in Figure 9. The annual death rate following non-ECD kidney transplantation has dropped from

Table 1: Impact of various factors on patient survival after deceased donor kidney transplantation*

	Non-ECD	ECD
Overall	48	100
PKD	40	88
Diabetes	73	140
Recipient age (years)		
11–17	0	–
18–34	26	34
35–49	33	57
50–64	62	106
≥65	103	153
Zero mismatch†	43	101
6-antigen-mismatched†	57	73

Source: *2004 OPTN/SRTR Annual Report*, Tables 5.7a, 5.7b.
*Death rate per thousand patient years at risk in 2002.
†While there appear to be large differences in patient survival for different degrees of mismatch there were wide and inconsistent differences for intermediate degrees of mismatch.
ECD = expanded criteria donors.

56 deaths per 1000 patient years at risk in 1994 to 48 deaths per 1000 patient years at risk in 2002. For ECD transplantation, the death rate has remained relatively stable over time at approximately 100 deaths per 1000 patient years at risk. Various factors affecting the death rate for both non-ECD and ECD donor kidneys are shown in Table 1. The anticipated waiting time for a non-ECD transplant has been identified as a factor in determining the relative benefit of an ECD transplant. Among African Americans, Asians and patients over the age of 39 who are listed at donation service areas (DSAs) with a long median time to transplant (>1350 days), mortality risk is significantly lower for those transplanted with ECDs compared with those remaining on the waiting list (including those who later receive a non-ECD transplant) (13). However, among those listed at DSAs with short or medium waiting time, recipients of ECD transplants did not have a statistically significant lower mortality risk than did those remaining on the waiting list for any of the groups listed above. These data would suggest that ECD kidneys should be offered to selected candidates registered at DSAs with long waiting times in order to optimize mortality risk reduction.

Living donor recipients – graft survival

Age has a negative effect on 5-year graft survival for kidneys from living donors. Patients 65 years or older had 69% 5-year graft survival compared with 78% in the 18–34 year age group and 82% in the 35–49 year group. African American recipients had the lowest 5-year graft survival, 71%, compared with approximately 81% for Asians and whites. Recipients with PKD and congenital and metabolic disorders had the highest 5-year graft survival at approximately 85%, compared with survival rates of 74–80% for all other groups. It is of interest that 1-year graft survival in these groups, while showing similar trends, cannot be clearly distinguished among the age groups or the racial groups or even the primary disease groups. This suggests that events happening at times remote from transplant, such as changes in immunosuppression, compliance or comorbidities, may play an important role in long-term graft survival.

Living donor recipients – patient survival

The overall death rate following living donor transplant in the first year after transplant remained relatively constant over the period 1994–2002: 23 deaths per 1000 patient years at risk in both 1994 and 2002. As expected, the death rate was highest in recipients over the age of 65 years; 48 deaths per 1000 patient years at risk compared with 9 deaths per 1000 patient years at risk for recipients aged 18–34 years. Death rates were lowest for Asian recipients, although the number of recipients was small compared with African American and white recipients, who had approximately the same death rate in the first year following transplant. Patients with a prior transplant of any kind had a death rate of 22 deaths per 1000 patient years at risk in 2003 compared with 23 deaths in patients who had no previous organ transplants. Compared with all other groups of primary etiologies in 2002, the diabetic death rate was the highest—twice as high when compared with some etiologies of end-stage kidney disease. Diabetics had a death rate of 37 deaths per 1000 patient years at risk compared with 20 in PKD and 24 for recipients with hypertensive nephrosclerosis. There was no consistent trend in death rates among recipients with various degrees of HLA matching, except that zero-mismatched patients had an extremely low death rate of six deaths per 1000 patient years at risk period compared.

Kidney transplant prevalence and national distribution

From 2002 to 2003, there was a substantial increase in the prevalence of recipients living with a functioning kidney transplant from 80 824 to 95 347. The overall demographics did not change between 2002 and 2003. The majority of the recipients were aged 18–64 years (87%), white (74%), male (59%) and blood type O (45%); most received a deceased donor kidney (60%) and were transplanted with a PRA below 10% (84%). The geographical distribution of transplanted patients remains unchanged, with the large transplant centers performing the vast majority of both deceased donor and living donor kidney transplants.

Simultaneous kidney-pancreas transplantation

The kidney-pancreas waiting list

The number of patients on the waiting list for a simultaneous kidney pancreas transplant (SPK) increased from 989 in 1994 to 2366 in 2000 and has since remained essentially stable. The number of new registrants on the waiting list reached a peak of 2007 in 2000 and has declined for the third consecutive year to 1653 in 2003. The majority of patients are white (79%), though the percentages of

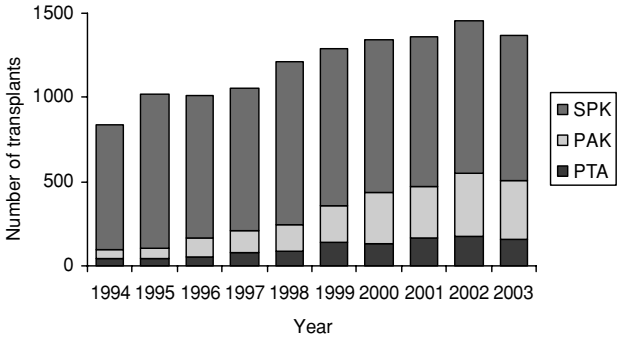

Figure 10: Pancreas transplants, 1994–2003. Source: 2004 *OPTN/SRTR Annual Report*, Tables 6.4, 7.4, 8.4.

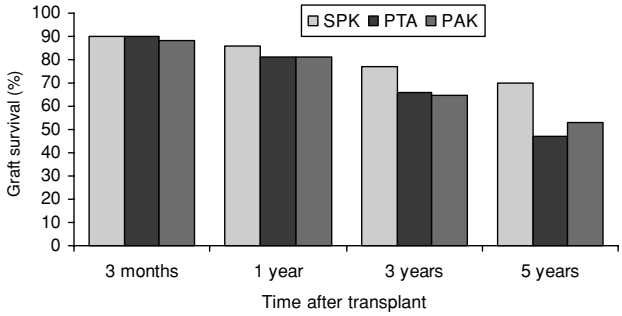

Figure 11: Pancreas graft survival among pancreas transplant recipients. Source: *2004 OPTN/SRTR Annual Report*, Tables 6.9, 7.9, 8.9. Cohorts are transplants performed during 2001–2002 for 3 months and 1 year; 1999–2000 for 3 years; and 1997–1998 for 5-year survival.

African American (19%) and Hispanic/Latino patients (9%) continue to increase. The number of patients on the waiting list has increased over the past decade for all adult age groups, though the age distribution has shifted upward. The percentage of patients who are aged 35–49 years has remained stable (60% in 2003) and the percentage of patients who are aged 50–64 years has increased from 7% in 1994 to 19% in 2003, whereas the percentage of patients who are aged 18–34 years has decreased from 34% in 1994 to 21% in 2003. The age trend for SPK transplant mirrors that for kidney transplant alone, discussed above. Of SPK patients, 14% had received a previous transplant; 4% had received a previous SPK. The annual death rate on the SPK waiting list fell from 96 per 1000 patient years at risk in 2001 to 88 in 2003.

There has been a steady decrease in the number of SPK transplants performed, from a peak of 970 in 1998 to 867 in 2003 (Figure 10). Since 1998, the decline in the number of SPK transplants has been accompanied by an increase in pancreas after kidney (PAK) transplants. In 2003, however, there was a decrease both in the number of PAK transplants and pancreas transplants alone (PTA). If this trend continues, it would indicate a reduction in whole organ pancreas utilization. Median times to SPK have decreased to 472 days for registrants listed in 2002, from a peak of 543 days for registrants listed in 2000. Time to transplant is longer for African American registrants (640 days in 2001 vs. 468 days for whites) and Hispanic/Latino registrants (586 days in 2001 vs. 484 days for non-Hispanic/non-Latino registrants). Blood group A and AB registrants had a shorter time to transplant than those with blood groups O and B, a trend that parallels that described for kidney transplant registrants.

Kidney-pancreas transplant recipients

The majority of SPK recipients are white (82%) and male (62%). The percentage of SPK recipients who are African American, however, has increased from 9% in 2000 to 16% in 2003; the percentage of those who are Hispanic/Latino has increased from 5% to 9% over the same period. The age distribution of recipients parallels that of the waiting list. Among SPK recipients, 15% were 50 years of age or older, compared with 10% in 1999. Most (90%) were unsensitized (PRA less than 10%). SPK recipients continue to receive substantially mismatched organs, with 80% of transplants having more than three HLA mismatches and only 1.4% receiving a zero-mismatch transplant. The greater degree of mismatching in SPK transplants compared with kidney transplants reflects the absence of national sharing of zero-mismatch pancreata and the policy of most DSAs to allocate pancreata based on waiting time alone, rather than a combination of waiting time and HLA matching.

Kidney-pancreas graft survival: kidney

Unadjusted kidney graft survival at 1 and 5 years following SPK transplantation was 91% and 77%, respectively. African Americans had somewhat poorer 5-year graft survival (72%) than whites (77%). Kidneys from older donors had the poorest graft survival. Five-year graft survival from donors older than 50 years was 68% compared with approximately 79% from donors aged 11–34 years. Recipients with a previous kidney transplant had 5-year graft survival that was 6% worse than for those without such a transplant. Five-year kidney graft survival tended to decrease with increasing levels of HLA mismatch.

Kidney-pancreas graft survival: pancreas

Unadjusted pancreas graft survival at 1 year and 5 years following SPK transplantation was 86% and 70%, respectively (Figure 11). It should be emphasized that pancreas graft failure is defined by report of graft loss by transplant centers to the OPTN and not by loss of organ function; as a result, graft survival may not be equivalent to insulin independence. Poorer 5-year graft survival was seen in African American (63%) and Asian recipients (64%) compared with whites (71%). Five-year graft survival from donors over age 50 years was 60% compared with approximately 70% from donors less than 35 years, including those ages less than 10 years. Recipients with a previous transplant (kidney, pancreas or both) had worse 1-year pancreas graft

survival. There was a trend toward decreased 5-year pancreas graft survival with increasing levels of HLA mismatch.

Simultaneous kidney-pancreas recipient survival

Death rates for recipients in the first year following transplant have steadily decreased, from 93 per 1000 patient years at risk in 1994 to 52 per 1000 patient years at risk in 2002. These rates continue to be lower than the corresponding death rates for candidates on the SPK waiting list. Older recipients (ages 50–64 years) and African American recipients tend to have higher death rates in the first year following transplantation.

Unadjusted patient survival at 1 year and 5 years following SPK transplantation was 95% and 85%, respectively. Race, ethnicity, sex and transplant center volume were not associated with decreased patient survival at 5 years. One-, 3- and 5-year patient survival rates have not changed significantly since 1995. There were 6861 recipients of SPK transplants alive with functioning grafts at the end of 2003. Registry analyses continue to demonstrate a mortality benefit of SPK transplantation compared with dialysis (14) or kidney transplantation alone (15).

Pancreas transplantation alone (PTA) and pancreas after kidney (PAK) transplantation

Waiting list

The number of patients awaiting isolated pancreas transplants in 2003 continues to increase, with 452 patients awaiting PTA (for diabetics without renal failure) versus 403 in 2002 and 925 awaiting PAK versus 784 in 2002. The increase in the number of patients listed for isolated pancreas transplant in the last five years is largely responsible for the trend toward an increase in the number of pancreas transplants being performed nationally. This may reflect the improved results of isolated pancreas transplants, the increase in the number of people receiving living donor kidneys and Medicare coverage for PAK since 1999. As noted above, this trend was not maintained in 2003.

The great majority of patients awaiting isolated pancreas transplants are white (94% for PTA, 90% for PAK); there have been no significant changes in the racial distribution over the last several years, unlike SPK. The underrepresentation of non-whites awaiting PTA and PAK may reflect the incidence of Type 1 diabetes in the respective populations, though it also may be related to access issues secondary to the relative difficulty in obtaining insurance coverage for PTA versus SPK. Although women constituted 56% of the PTA waiting list in 2003, they made up only 43% of the PAK waiting list. The majority of patients awaiting both PTA and PAK are between 35 and 49 years old. The number of older patients listed for PAK has increased somewhat, with 20% of the waiting list in 2003 being between the ages of 50 and 64 years. There has been a consistent increase in this age group since 1998, at which time they constituted only 9% of the PAK list. A similar trend has not been observed in the PTA waiting list.

The median time to transplant for PTA has varied between 210 and 838 days in the last five years, with median waiting times for 2002 at 365 days. The median time to transplant for PAK has gradually increased over the last five years, with the median waiting time for 2002 being 590 days. This is greater than the median time to transplant for SPK registrants. That waiting times for PTAs remain around 1 year suggests that solitary pancreata are more available than SPKs. In some DSAs this is a reflection of policies that prioritize solitary pancreas allocation over SPK allocation or that prioritize kidney-alone allocation for certain candidates over SPK. PAK and PTA patients with blood types O and B have historically had longer waiting times than those with type A and AB, a pattern observed in both kidney and SPK registrants.

The death rates among patients on the PAK and PTA waiting lists are highly variable. For PTA, the death rate ranged from 22 to 55 per 1000 patient years between 1999 and 2003. For PAK, it ranged from 21 to 40 per 1000 patient years between 1999 and 2003. The variability and accuracy of the death rates during the waiting period are important, since these figures may be compared with death rates following pancreas transplantation and may be used to counsel patients and caregivers. The year-to-year variability in death rates, both on the waiting list and following solitary pancreas transplantation, is due to the small number of actual deaths. Because of the small numbers of patients listed for and receiving PTA, cohorts covering longer time periods are required for mortality comparisons. Venstrom et al. (14) reported that registrants on the waiting lists for PAK and PTA had better survival rates than recipients who underwent these procedures. These findings have been challenged by Gruessner et al. (16), who reported better survival rates for recipients of solitary pancreas transplantation than registrants on the waiting list. These discrepancies may be related to methodological differences between the two analyses and thus may reflect the inherent difficulties in using data obtained from large registries.

Recipient characteristics and outcomes of pancreas after kidney transplantation

The age and race of recipients of PAK transplants in 2003 mirror the characteristics of candidates on the waiting list. In 2003, 91% of recipients were white, reflecting an ongoing disparity in racial distribution of solitary pancreas transplants that is even more marked than that of SPK transplants. More PAK recipients were male (59%). The age at transplant has remained relatively consistent over the last five years, with a slight shift to older patients receiving PAK. In 2003, 15% of the patients were between the ages of 18 and 34 years, 70% were between the ages of 35 and

49 years and 15% were between the ages of 50 and 64 years.

One-year unadjusted pancreas graft survival for recipients of a PAK transplant has improved in the last five years, although the 1-year unadjusted graft success decreased from 84% for PAK transplants performed in 2001 to 78% for PAK transplants performed in 2002. The 1-year graft survival for PAK has ranged between 72% and 84% since 1998, and this success may have prompted the overall increase in the number of PAK transplants being performed nationally. The unadjusted graft survival rates for PAK at 1 year (cohort of transplants performed during 2001–2002), 3 years (cohort of transplants performed during 1999–2000) and 5 years (cohort of transplants performed during 1997–1998) were 81%, 65% and 53%, respectively (Figure 11).

The unadjusted patient survival rates for PAK recipients at 1 year (cohort of transplants performed during 2001–2002), 3 years (cohort of transplant performed during 1999–2000) and 5 years (cohort of transplants performed during 1997–1998) were 96%, 90% and 82%, respectively. The annual death rates per 1000 patient years at risk for recipients in the first year following PAK transplantation have been constant over the last four years at approximately 45.

Recipient characteristics and outcomes of pancreas transplant alone

The age, race and sex of recipients of PTA in 2003 also mirror the characteristics of candidates on the waiting list. Of note, 59% of recipients were women and 41% were men, the reciprocal of the gender ratio for PAK. Of all forms of pancreas transplantation, the ethnic disparity was most pronounced in PTA recipients. White recipients received 98% of PTA. The reasons for this remarkable disparity, which is more pronounced for PTA than PAK recipients, is not evident from these data. One-year unadjusted pancreas graft survival for PTA has improved in the last five years to 83% for transplants performed in 2002. The unadjusted graft survival rates for PTA at 1 year (cohort of transplants performed during 2001–2002), 3 years (cohort of transplants performed during 1999–2000) and 5 years (cohort of transplants performed during 1997–1998) were 81%, 66% and 47%, respectively. HLA matching had no clear impact on graft survival, although the number of recipients in the different match grades may be too small to demonstrate an existing trend. There was a trend toward poor graft outcome when older donors (age: 50–64 years) were used for PTA (Figure 11). Overall, however, the results of PTA are now approximating those observed for PAK. The unadjusted patient survival rates for PTA recipients at 1 year (cohort of transplants performed during 2001–2002), 3 years (cohort of transplant performed during 1999–2000) and 5 years (cohort of transplants performed during 1997–1998) were 98%, 93% and 80%, respectively.

Allocation policy update

Since October 2002 several important changes have been made to the kidney and pancreas allocation algorithm. The impact of some of these changes is reflected in the data reviewed in this article but is likely to become more pronounced in the years to come. The allocation system for ECD kidneys was implemented in November 2002 (OPTN/UNOS Policy 3.5.12) and was discussed in previous reports (4,17); the current report presents an update on its impact.

In May 2003, a major change was implemented in the allocation algorithm for standard deceased donor kidneys, whereby the assignment of points for HLA-B similarity was eliminated (OPTN/UNOS Policy 3.5.11.2). Two points were provided for a zero HLA-DR mismatch and one point for a one HLA-DR mismatch. The allocation of one point for each year of waiting time was left unchanged. It was anticipated that this change would reduce the disadvantage suffered by African American registrants, while having a minimal detrimental effect on long-term graft survival (18). Preliminary evaluation of allocation trends suggests that since the introduction of this change more kidneys have been allocated to African Americans and fewer to whites (19). No change can yet be detected in graft survival.

The changed assignment of points for HLA matching has made allocation of standard deceased donor kidneys less unpredictable. The prior algorithm, whereby seven points were allocated for HLA matching, rendered the top seven years of the list eligible for allocation. The new algorithm renders only the top two years of the list open to the likelihood of allocation. The policy of assigning priority of allocation to zero-HLA-mismatched kidneys remains unchanged; however, the great majority of zero-mismatched kidneys are allocated to registrants within the first two years of listing (20). Approximately, 17% of kidneys are allocated in this manner. For registrants listed at DSAs with long waiting times, those not fortunate to receive a zero-HLA-matched kidney soon after listing may be destined to wait years with a low likelihood of allocation until they reach the top two years of the list when the points for HLA-DR matching come into play. This phenomenon will be exaggerated as the list becomes longer in the years to come. The policies of transplant programs with respect to management of the list may be altered as a result (10). For example, efforts can be concentrated on ensuring that candidates who are most likely to be offered an organ soon are indeed ready for transplant.

In November 2003, an important change was implemented relating to the accrual of points for time waiting for registrants who develop medical complications that temporarily preclude them from kidney allocation. Previous policy required that waiting time point accrual stopped 1 month after the registrant was placed on hold and the changed

medical status was reported to the OPTN (Status 7); accrual of waiting time was only restarted when resolution of the medical complication was reported to the OPTN. This policy served as a disincentive for transplant programs to accurately report the status of their registrants to the OPTN and caused delays in organ placement. The modified policy (OPTN/UNOS Policy 3.5.11.1 for standard donor kidneys and 3.5.12.1 for expanded criteria donor kidneys) enables registrants to continue waiting time accrual while on hold, thereby reducing the disincentive for accurate reporting. This policy modification may lead to an unanticipated new source of inequity, given that at some programs registrants may be listed and placed on hold before their medical evaluation is completed, whereas at other programs completion of the evaluation will be required before listing.

In June 2003, the policy whereby time on the kidney transplant waiting list is reinstated following early post-transplant allograft failure was expanded and simplified (OPTN/UNOS Policy 3.2.3.2). Prior to this change, reinstatement of waiting time was only permitted if it could be shown that early graft loss was technical rather than immunologic in nature. Convincing documentation of technical loss was often difficult and inconsistent. In the new policy, reinstatement of waiting time is permitted for all graft losses within 3 months of transplantation, irrespective of cause.

In May 2003, the policy guiding allocation of zero-mismatched blood type O deceased donor kidneys was modified to help address the disproportionately small fraction of minority registrants who were allocated these organs. Prior to this modification, zero-mismatched blood type O registrants were assigned priority for blood type O kidneys; if a zero-mismatched blood group O registrant was not available, the organ would be offered to the next zero-mismatched blood group A, B or AB registrant. Because blood group A occurs more frequently among whites, they were more likely to be offered the kidney when a blood group O registrant was not available. The new policy (OPTN/UNOS Policy 3.5.3.3.2) restricts allocation of these kidneys first to blood type O and then to blood type B zero-mismatched wait-listed registrants (whose waiting time is twice as long as blood group A) and only then to blood groups A and AB. Since African American registrants have a higher frequency of blood group B this policy change should serve to improve their chances of receiving a zero-mismatched kidney.

In November 2003, the OPTN Board of Directors approved a voluntary alternative allocation system to encourage living kidney donation in cases where, because of blood group incompatibility or a positive crossmatch, donation to the intended candidate is deemed to be contraindicated. In the modified allocation algorithm, a living donor kidney is offered to a suitable ABO compatible crossmatch negative candidate with the most waiting time points; the originally intended candidate for that kidney is assigned priority on the local waiting list after prior living organ donors, the highest-ranking local sensitized candidates, children with surpassed time goals and paybacks. To date, there is limited experience with this modification. Since most recipients of these living donor kidneys are likely to be blood group O, concern has been expressed that if this modification becomes widespread, blood group O wait-listed registrants who do not receive the living donor kidney will be disadvantaged as a result of their repeated displacement by originally intended living donor candidates.

A voluntary national study has also been approved to assess the impact of accruing waiting time from the initiation of dialysis rather than from completion of the transplant evaluation process. It has been suggested (21) and shown theoretically (22) that this change would serve to reduce the reported inequities in allocation that disadvantage African American registrants and those registrants without private medical insurance. This proposed change has generated considerable controversy, largely because of concern that its introduction would reduce the incentive of physicians and potential registrants to complete the evaluation process expeditiously.

Conclusion

The transplant community continued in 2003 to struggle to meet the increasing demand for kidney and pancreas transplantation and to allocate the available organs in an equitable manner. The size of the waiting lists for all types of kidney and pancreas transplants continued to grow, and the waiting list population continued to age. There were more ECD kidneys transplanted and more living donor kidney transplants, especially from unrelated donors. Though transplants increased in 2003, there were still many more patients waiting for transplants than there were organs available. New rules were implemented to promote equity in organ allocation. These changes seem to have improved access to transplant for historically disadvantaged groups, such as African Americans. However, they have reduced the quality of HLA matching. The changes in match quality are expected to have some effect on long-term outcomes for the recipients, and these effects will be studied as they become measurable.

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