Special Feature

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# Kidney and Pancreas Transplantation in the United States, 1999–2008: The Changing Face of Living Donation

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Note on sources: The articles in this report are based on the reference tables in the 2009 OPTN/SRTR Annual Report. Table numbers are noted in brackets and may be found online at: http://ustransplant.org.

The waiting list for kidney transplantation continued to grow between 1999 and 2008, from 41 177 to 76 089 candidates. However, active candidates represented the minority of this increase (36951-50624, a 37% change), while inactive candidates increased over 500% (4226–25 465). There were 5966 living donor (LD) and 10551 deceased donor (DD) kidney transplants performed in 2008. The total number of pancreas transplants peaked at 1484 in 2004 and has declined to 1273. Although the number of LD transplants increased by 26% from 1999 to 2008, the total number peaked in 2004 at 6647 before declining 10% by 2008. The rate of LD transplantation continues to vary significantly as a function of demographic and geographic factors, including waiting time for DD transplant. Posttransplant survival remains excellent, and there appears to be greater use of induction agents and reduced use of corticosteroids in LD recipients. Significant changes occurred in the pediatric population, with a dramatic reduction in the use of LD organs after passage of the Share 35 rule. Many strategies have been adopted to reverse the decline in LD transplant rates for all age groups, including expansion of kidney paired donation,

adoption of laparoscopic donor nephrectomy and use of incompatible LD.

Key words: Deceased donors, expanded criteria donors, kidney transplantation, living donors, OPTN, paired donation, pancreas transplantation, pediatric kidney transplantation, retransplantation, simultaneous pancreas-kidney transplantation, SRTR, survival, waiting list

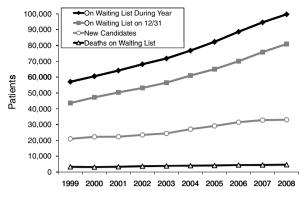
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### Introduction

Despite a decade of efforts to increase access to kidney transplantation, thousands of patients remain on waiting lists around the United States. Among the most successful strategies to reduce waiting time and improve posttransplant outcome is the expansion of living donor (LD) transplantation. The use of kidneys from LDs offers numerous advantages, including reduced waiting times, improved opportunity for preemptive transplantation, shorter and less expensive hospital stays and improved posttransplant outcome (1–3). Unfortunately, there appears to be steady erosion in the use of LD renal transplantation over the past 4 years, a development that threatens to increase morbidity and mortality among patients with end-stage renal disease (ESRD).

The first two sections of this article will review overall trends in waiting list activity for kidney and pancreas transplantation, as well as transplant rates and outcomes. These data provide an important overview of the trends in waiting times, donor demographics and expected survival following both deceased donor (DD) and LD kidney and DD pancreas transplantation.

The remainder of the article focuses on the changing landscape of LD kidney transplantation. First, current trends in donor and recipient characteristics are reviewed. Next, the ongoing variation in the rates of LD transplant is considered. Particular attention is paid to disparities associated with race, socioeconomic status and geography. Posttransplant outcome and management is then assessed to determine if changes in donor demographics or



Source: 2009 OPTN/SRTR Annual Report, Tables 1.3, 5.2, 5.3

Figure 1: Number of new and prevalent kidney waiting list patients and deaths on the waiting list, 1999–2008.

immunosuppression strategies have influenced outcome. The special case of LD pediatric kidney transplantation is then considered in light of improved access to DD transplantation resulting from the Share 35 policy, which preferentially allocates DD kidneys from donors younger than 35 years to pediatric recipients. Finally, current strategies to expand access to living donation are presented, including paired donation (donor exchange) programs, increased use of laparoscopic donor nephrectomy and increasing use of ABO incompatible donors.

Unless otherwise noted, the statistics in the sections on kidney and pancreas transplantation are drawn from the reference tables of the 2009 OPTN/SRTR Annual Report. Statistics for the third section about LD kidney transplantation are drawn from both the reference tables and from special analyses prepared by the SRTR. Additional information about the methods of data collection and analysis may be found in the data tables themselves and in the Technical Notes of the Annual Report, both online at http://www.ustransplant.org.

# **Kidney Transplantation**

# Kidney transplant waiting list trends

Over the past 10 years, the annual number of kidney-alone transplants performed nationally grew by 27%, from 12 633 transplants in 1999 to 16 067 transplants in 2008 [Table 1.7]. During this period, the total number of candidates listed for a kidney-alone transplant at any time during the calendar year increased by 75%, from 57 058 to 99 750 [Table 5.3], while the total number of candidates wait-listed at year-end for a kidney-alone transplant rose by 86%, from 43 632 to 80 972 [Table 1.3] (Figure 1). Growth in the number of wait-listed patients has been accompanied by a similar increase of 40% in deaths on the waiting list, from 3318 in 1999 to 4638 in 2008 [Table 5.3]. However, while the absolute number of deaths has increased,

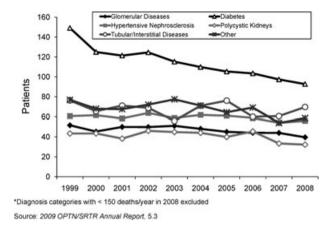
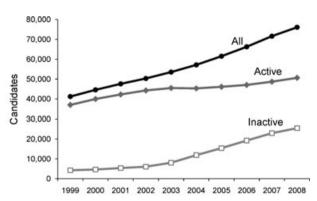


Figure 2: Waiting list death rates by diagnosis,\* 1999-2008.

it is notable that the annual death rate for waiting list candidates has decreased, from 84 deaths per 1000 patientyears at risk in 1999 to 63 deaths per 1000 patient-years at risk in 2008 [Table 5.3]. During this period, the annual death rate for waiting list candidates decreased by more than 30% for adult and pediatric age groups. Among diagnoses, there was more variation in the trend of death rates over time. For candidates with diabetes and glomerular diseases, the unadjusted waiting list mortality rate decreased by 38% and 23%, respectively. For candidates with hypertensive nephrosclerosis or tubular and interstitial diseases, however, waiting list mortality rates decreased by 8% and 9%, respectively (Figure 2). While it is probable that these trends reflect improvements in dialysis outcomes (4), they may also reflect changes in transplant candidate selection and preparation (see appendix H, table H.12 in Ref. 4).

Between December 31, 2002 and December 31, 2008, the total number of candidates on the national kidney transplant waiting list increased by 51% (Figure 3). However, not all of the components of the waiting list grew



Source: 2009 OPTN/SRTR Annual Report, Tables 5.1a, 5.1b.

Figure 3: Active/inactive status of kidney waiting list candidates at year-end, 1999–2008.

proportionally. While the number of active patients on the waiting list rose by 14% [Table 5.1a], most of the recent growth in the overall size of the waiting list reflects an increase in the use of Status 7 (inactive status), as the number of inactive patients on the waiting list grew by 322% [Table 5.1b]. Specifically, the number of active patients, which was 36951 on December 31, 1999, was 442623 years later (a positive trend of 2437 per year), but 6 years later in 2008 was 50624 (a trend of 1060 per year). In contrast, the number of inactive patients on the kidney transplant waiting list increased slowly, from 4226 candidates at year-end in 1999 to 6034 candidates in 2002 (a trend of 603 per year). The number then more than quadrupled to 25465 patients by December 31, 2008 (a trend of 3239 per year). This increase in the use of Status 7 has been attributed to changes in OPTN policy in 2003 that allowed wait-listed candidates to accrue waiting time during the entire period that they are listed, whether active or inactive (http://optn.transplant.hrsa.gov/PoliciesandBylaws2/ policies/pdfs/policy\_7.pdf, see policy 3.5.11.1) (5). The rate of increase in the number of active patients has declined in recent years. From 1999 to 2003, there was a 23% increase in active patients (corresponding to an average increase of 5.3% per year). In 2004, there was a slight decrease, and the yearly percentage increase afterwards was 2%, 2%, 3% and 4% in 2008 (compared with 2007).

The proportion of candidates on the active kidney transplant waiting list over the age of 50 years has increased during the past decade, from 47% to 59% [Table 5.1a] (Table 1). This shift in the age distribution of the waiting list reflects changes in the rates of wait listing among the different age groups. New listings for candidates under age 50 increased 23%, from 11482 to 14173 during 1999-2008, whereas the number of candidates aged 50 years or older nearly doubled, from 9520 in 1999 to 18878 in 2008 [Table 5.2]. The number of active candidates younger than 50 years grew from 19681 in 1999 to 21248 in 2003 but remained between 20340 and 20772 over the next 5 years. The number of active candidates over age 50 rose from 17 270 in 1999 to 24 227 in 2003, and then to 29 852 in 2008 [Table 5.1a]. In contrast, the number of inactive candidates younger than 50 years increased from 2118 in 1999 to 3550 in 2003, and then to 9621 by 2008. The number of inactive candidates over 50 years grew dramatically, from 2108 in 1999 to 4488 in 2003 and then to 15844 in 2008 [Table 5.1b]. As shown in Table 1, the percentage of candidates by age group on the waiting list in either active or inactive status is roughly proportional to their representation on the total waiting list.

The distribution of race among candidates active on the kidney waiting list has also changed over the past 10 years (Table 1). The number of white and African American active candidates grew from 15 784 and 13 486, respectively, in 1999 to 19 243 and 17 091 in 2008 [Table 5.1a]. At the same time, however, the percentage of white candidates on the active waiting list declined, from 43% to 38%, and

**Table 1:** Annual number and distribution of kidney waiting list patients by patient characteristic and status at year-end, 1999–2008

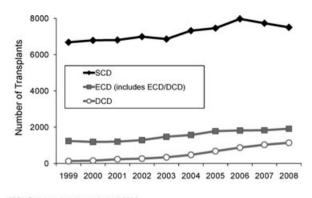
		Active			Inactive		
Characteristic	1999	2004	2008	1999	2004	2008	
N	36 951	45 290	50 624	4226	11851	25 465	
<35 years	18%	15%	12%	16%	13%	11%	
35-49 years	35%	31%	29%	34%	30%	27%	
50-64 years	37%	41%	42%	37%	42%	44%	
65+ years	10%	14%	17%	12%	16%	18%	
White	43%	39%	38%	46%	40%	39%	
African American	36%	35%	34%	38%	39%	38%	
Hispanic/Latino	13%	17%	18%	10%	15%	17%	
Asian	6%	8%	8%	4%	5%	5%	
Other/multirace	1%	1%	1%	2%	1%	1%	
Glomerular diseases	24%	22%	21%	23%	20%	18%	
Diabetes	23%	27%	28%	25%	27%	31%	
Hypertensive nephrosclero- sis	18%	20%	23%	14%	19%	22%	
Other	35%	31%	29%	38%	34%	29%	

Source: Tables 5.1a, b and SRTR analysis, November 2009.

the percentage of African American candidates decreased slightly, from 36% to 34%. The total number of active Hispanic/Latino candidates nearly doubled, from 4870 in 1999 to 9314 in 2008; Asian candidates also increased over the same time, from 2385 to 4265 [Table 5.1a]. These changes are reflected by a proportionate increase in the percentage representation of Hispanic/Latino and Asian candidates in both active and inactive status on the waiting list.

The pattern of diagnoses (glomerular diseases, hypertensive nephrosclerosis, diabetes and other diseases) of candidates on the active kidney waiting list has also evolved over the past 10 years (Table 1). Overall, the percentage of active candidates with diabetes and hypertension has increased, from 23% to 28% and from 18% to 23%, respectively, whereas the percentage with glomerular disease has declined, from 24% to 21%. In 2008, the distribution of diagnoses was roughly proportional between active and inactive candidates on the waiting list and may reflect changes in the overall demographic characteristics of the list (age, race, sex) [Tables 5.1a and 5.1b]. Thus, it does not appear that the use of Status 7 is disproportionately associated with any specific demographic or diagnostic characteristics.

Among new candidates listed between 1999 and 2005, there has been relatively little change in the median time to receive any kidney transplant, that is, from either a DD or LD. In 1999, the median time to any kidney transplant was 1127 days; in 2005 (the most recent year for which this calculation is possible), the median time to any kidney transplant was 1269 days [Table 5.2].



HRSA Collaboratives began in April 2003
Source: 2009 OPTWSRTR Annual Report, Table 5.4

Figure 4: SCD, ECD and DCD kidney transplants, 1999-2008.

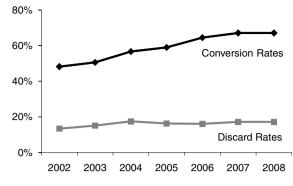
# Kidney transplant trends

The annual number of DD kidney transplants, including multiorgan transplants but excluding simultaneous pancreas kidney (SPK) transplants, rose from 8043 in 1999 to a peak of 10 659 in 2006, and then fell to 10 551 transplants in 2008 [Table 5.4]. Non-SPK multiorgan transplants increased by 80%, from 255 in 2002 to 460 in 2008 [Table 1.8]. In 2008, kidney-liver (379) and kidney-heart (66) made up 97% (99%, if kidney-liver-other and kidney-heart-other are included) of these transplants.

The number of standard criteria donor (SCD) transplants, expanded criteria donor (ECD) transplants and non-ECD transplanted kidneys recovered through donation after cardiac death (DCD) grew by 12%, 55% and 794%, respectively, between 1999 and 2008 [Table 5.4] (Figure 4).

In these analyses, the ECD definition includes DCD kidneys that meet the OPTN ECD criteria. In 2008, there were 7503 SCD, 1912 ECD (120 of which were ECD/DCD) and 1136 DCD kidney transplants performed. The greatest numerical increment compared with 2002 has been in DCD transplants, with a gain of 872. SCD increased by 513, and ECD (includes ECD/DCD) by 627 [Table 5.4]. There were 37 fewer total transplants in 2008 (10551) than in 2007 (10588); this change represented 227 fewer SCD, 83 more ECD (includes ECD/DCD) and 107 more DCD transplants [Table 5.4]. Although the percentage of SCD kidneys allocated to candidates younger than 50 years has declined, from 58% in 1999 to 46% in 2008 [Table 5.4a], these younger candidates continued to receive SCD kidneys at a higher rate than their proportion on the waiting list, which was 53% in 1999 and 40% in 2008 [Table 5.1a, 5.1b].

The 24% growth in DD kidney transplantation since 2002 appears to be largely driven by the increase in conversion rates [Table 5.4] (Figure 5). This rate is defined as the number of DD that met eligibility criteria for donation divided



HRSA Collaboratives began in April 2003 Source: SRTR analysis, July 2009

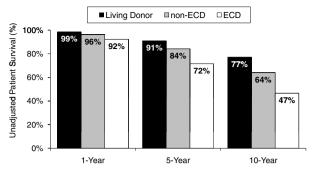
Figure 5: Average conversion and discard rates for all OPOs, 2002–2008.

by the number of eligible deaths defined as any ventilated death reported by a hospital that is evaluated and that meets organ donor eligibility requirements. Nationally, the average conversion rate grew from 48% in 2002 to 67% in 2008 (Figure 5). However, there was also an increase in the discard rate, from 13% in 2002 to 17% in 2008. Conversion rates may have been affected by the efforts of the Health Resources and Services Administration (HRSA) Transplant Growth and Management collaboratives, which began in 2003. The HRSA transplant collaborative has focused attention on successful strategies to improve conversion rates to reach a goal of 75%.

#### Kidney transplant patient and graft survival trends

At the end of 2007, 144 805 patients had a functioning kidney transplant compared with 83 545 in 1999, an increase of 73% [Table 5.16]. These numbers represent a substantial increase over those reported in prior Annual Reports, given that they are based on calculations that more completely incorporate data from the Centers for Medicare and Medicaid Services (CMS) on ESRD patients. For single kidney transplants (multiorgan and SPK transplants excluded) performed prior to 2008, 1-, 5- and 10-year patient survival was best for recipients of LD kidneys, intermediate for non-ECD DD recipients, and lowest for those receiving ECD kidneys (Figure 6). Unadjusted patient survival rates at 5 years were 91% for recipients of LD kidneys, 84% for non-ECD DD kidneys and 72% for ECD kidney transplants.

Kidney graft survival followed the same pattern as that seen for recipient survival (Figure 7). Graft survival was best for recipients of LD kidneys, intermediate for non-ECD transplants and lowest for ECD transplants. At 5 years, the unadjusted graft survival rate was 81% for LD, 72% for non-ECD and 57% for ECD transplants. Each year since 2002, the adjusted and unadjusted first-year graft survival has either improved or remained the same for ECD and non-ECD kidney transplants. For LD transplants, this



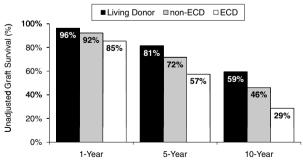
Source: 2009 OPTN/SRTR Annual Report, Tables 5.14a, b, d.

Figure 6: Unadjusted 1-year (2006–2007), 5-year (2002–2007) and 10-year (1997–2007) kidney recipient survival, by donor type.

has been true as well, except for the 2003–2004 drop of 0.2–0.3% [Tables 5.9 a, b, d and 5.11 a, b, d]. The 1-year unadjusted graft survival in 2007 compared with 2002 was 97% versus 95% for LD, 93% versus 91% for non-ECD, and 86% versus 80% for ECD transplants [Tables 5.9 a, b, d and 5.11 a, b, d]. These differences were all statistically significant, with p < 0.0001.

## Regional differences in waiting times

Once an ESRD patient is listed, access to a kidney transplant is dependent upon several factors, including blood type, HLA, age (pediatric vs. adult) and willingness to accept an ECD kidney. One important factor in determining waiting times is the donation service area (DSA), as illustrated in Figure 8. This figure displays the DSAs according to the median waiting time, that is, the number of months it took for half of the candidates listed from July 1, 2002 to December 31, 2007 to receive transplants. In five DSAs, fewer than half of the candidates during this period had received transplants as of June 30, 2008; these DSAs received the darkest shading on the map. Different DSAs can have very different waiting times: a guarter of the DSAs had



\*Death is included as an event.

Source: 2009 OPTN/SRTR Annual Report, Tables 5.10a, b, d.

Figure 7: Unadjusted 1-year (2006–2007), 5-year (2002–2007) and 10-year (1997–2007) kidney graft survival,\* by donor type.

median waiting times shorter than 19 months and a quarter had median waiting times longer than 37 months.

# **Pancreas Transplantion**

# Pancreas transplant waiting list trends

The number of pancreata recovered peaked at 2045 in 2005, fell slightly in 2006 to 2032 and fell further in 2008 to 1831 [Table 1.1]. At the end of 2008, there were 3765 people waiting for a solid organ pancreas transplant: 2310 for an SPK, 870 for a pancreas after kidney (PAK) and 585 for a pancreas transplant alone (PTA). This was a 41% increase over the total number in 1999, indicating a growing discrepancy between the number of candidates wait-listed for pancreas transplantation and organs available [Table 1.3]. More recently, the PTA and SPK waiting list populations have remained almost constant, with the 2008 counts differing from the 2007 counts by one and three patients, respectively. PAK counts decreased from 933 to 870 in 2007 and 2008 [Table 1.3].

The downward trend in new registrations for SPK or PAK continued in 2008 (Figure 9). The total number of new pancreas waiting list registrations grew from 2329 in 1999 to a high of 2796 in 2000, but fell to 2349 by 2008. New PAK waiting list registrations rose from 307 in 1999 to a high of 624 in 2004, falling to 334 in 2008. New SPK registrations rose from 1804 in 1999 to a high of 2007 in 2000, and then declined to 1603 in 2008. PTA registrations showed continued growth between 1999 and 2008, from 218 to 412 [Table 1.5].

Median waiting times decreased in 2007 for SPK and PTA transplants, from 444 to 406 days and from 436 to 260 days, respectively. The median waiting time for PAK has increased, from 219 days in 1999 to 887 days in 2006, with data not available yet for 2007 [Table 1.5].

# Pancreas transplant trends

The overall number of pancreas transplants rose from 1300 in 1999, peaked at 1484 in 2004 and has since declined to 1273 (Figure 10). The number of SPK transplants remained between 871 and 941 from 1999 to 2006, dropping to 836 in 2008; the number of PAK transplants peaked at 420 in 2004, dropping to 214 in 2008. The cause of this decrease in pancreas transplant numbers is uncertain but has been attributed to several factors, including OPTN rules that prohibit the use of kidneys for SPK transplants in DSAs that owe a high number of kidneys to other regions under the payback system. Other factors include an uneven distribution of pancreas transplant programs across the United States, caution by many transplant programs in the acceptance of pancreata recovered outside their own DSA, and age and obesity trends in the donor population (6,7). The preponderance of pancreas transplants are SPK, accounting for 66% of all pancreas transplants in 2008.

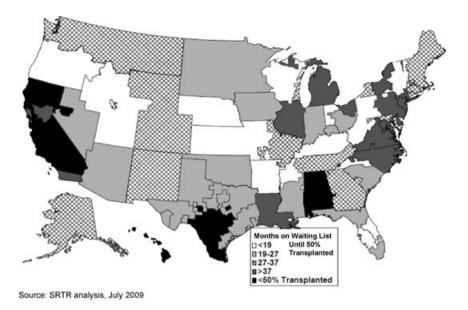


Figure 8: Unadjusted median time to transplant by OPO (listed from July 1, 2002-December 31, 2007) for kidney.

# Pancreas transplant patient and graft survival trends

Despite trends toward fewer pancreas transplants and waiting list registrations, the total number of patients alive with a functioning pancreas graft increased 60%, from 6031 in 1999 to 9678 in 2007 (Figure 11). The largest relative increases over the past 9 years occurred in the PAK and PTA populations, both of which grew roughly 3-fold. Nonetheless, SPK recipients represent by far the largest cohort of patients alive with a functioning pancreas graft.

Patient survival rates were similar for SPK, PAK and PTA recipients at 1 year (ranging from 96% to 98%) and 3 years (roughly 92%) (Figure 12). The 5- and 10-year unadjusted patient survival rates were statistically (p < 0.07) lowest for PAK recipients at 85% and 68%, respectively, and higher for SPK (87% and 71%, respectively) and PTA recipients (89% and 76%, respectively) [Table 1.13]. Among pancreas recipients, those with SPK transplants experienced the best unadjusted pancreas graft survival rates: 85% at 1 year (p = 0.01) and 55% at 10 years (p < 0.001) (Figure 13). Graft survival rates for PAK and PTA recipients were lower than for SPK recipients, with 1-year rates of 80% and 76%, respectively, and 10-year rates of 37% and 35%, respectively [Table 1.13].

# **LD Kidney Transplantation: Challenges** and Opportunities

# LD trends

There were 5966 LD kidney transplants in 2008 [Table 5.4dl. This represents a 26% increase in the number of LD transplants compared with 1999. Trends in livingrelated and living-unrelated kidney donors are shown in Figure 14. The number of living-related kidney donors grew from 3629 in 1999 to 4352 in 2001, where it remained roughly constant until 2004 at 4341. Since then, the number of living-related donors has decreased, falling

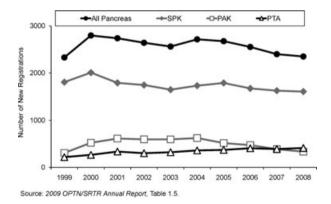
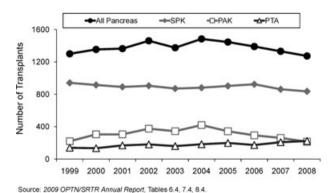
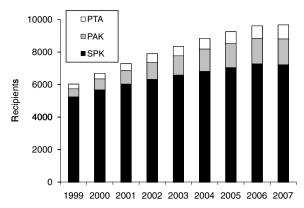


Figure 9: New registrations on pancreas waiting list, by transplant type, 1999-2008.





Source: 2009 OPTN/SRTR Annual Report, Tables 6.16, 7.16, 8.16.

Figure 11: Number of recipients living with a functioning pancreas transplant at end of year, 1999–2007.

to 3498 in 2008. From 1999 to 2006, the number of living-unrelated kidney donors grew steadily, from 1053 to 2350. Between 2004 and 2008, the number of living-unrelated kidney donors remained between 2195 and 2350 (Figure 14). The cause of decline in LDs is unclear but may reflect several factors: an aging recipient population with a more limited number of potential donors; a declining emphasis on recruitment of LDs; changes in economic factors leading to increased reluctance to donate and the impact of improved access to DD kidneys for pediatric patients.

The mean age of the LD among adult recipients has shown a steady increase, from 39.6 years in 1999 to 41.4 years in 2008 (Figure 15). Since 2005, living donation decreased for adult donors below 50 years but increased for adult donors over age 50 [Table 2.9]. There were 89 donors (1.5% of all LDs) age 65 and over in 2008. In spite of the relative increase in the mean age of the LD, the trend of the mean preoperative renal function in this group has remained relatively stable from 1997 to 2008 (mean creatinine between

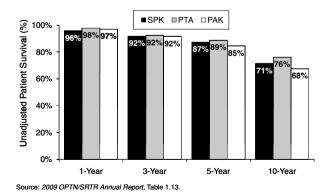
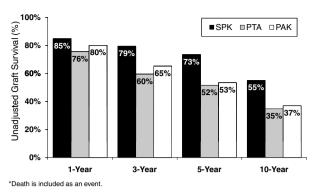


Figure 12: Unadjusted 1-year, 3-year, 5-year and 10-year pancreas patient survival, by transplant type.



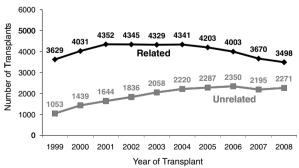
Source: 2009 OPTN/SRTR Annual Report, Table 1.13.

Figure 13: Unadjusted 1-year, 3-year, 5-year and 10-year pancreas graft survival,\* by transplant type.

0.88 and 0.92 mg/dL from 1999 to 2008 among LDs who donated to adult recipients) (Figure 16).

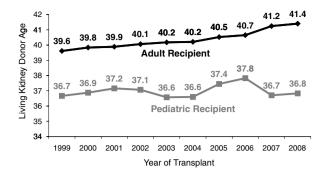
From 1999 to 2007, the pattern of living donation for men and women was similar. But in 2008, female LDs increased by 112, from 3506 the previous year to 3618, while male LDs decreased by 188, down to 2350 [Table 2.9]. The numbers of Hispanic/Latino and Asian LDs in 2008, 820 and 237, respectively, were very similar to those in 2004 [Table 2.9]. LD transplants decreased from 2004 to 2008 in both whites (4593 to 4126) and African Americans (937 to 717) [Table 2.9].

Use of LD kidneys for retransplantation after failed renal transplant: The total number of repeat kidney transplants increased steadily, from 1559 in 1999 to 2103 in 2006, and then declined to 1851 in 2008. Overall, the number of patients retransplanted using an LD (regardless of the source of the original organ) increased from 429 in 1999 to 714 in 2005, then declined to 612 in 2008 (Figure 17, Table 2). In 2008, regardless of the source of the first donor, patients were more likely to be



Source: 2009 OPTN/SRTR Annual Report, Table 5.4d

Figure 14: Trends in living related and living unrelated donors, 1999–2008.



Source: SRTR Analysis, July 2009

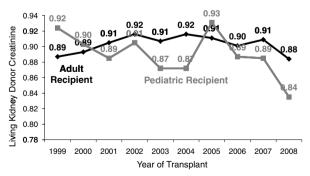
Figure 15: Trends in LD age, 1999-2008.

retransplanted using a DD rather than an LD. Patients with a prior DD transplant were less likely to be retransplanted with an LD organ (22%) compared with patients with a prior LD who received a second LD (46%).

**LD after extra-renal transplantation:** From 1999 to 2008, there were 3318 kidney transplants following extrarenal transplantation (lung, liver or heart); 1555 were from LDs and 1763 from DDs (Table 3). Annual use of LD transplants following extra-renal transplants increased from 86 to 194 between 1999 and 2003 and thereafter declined to 146 in 2008. DD kidney transplants in recipients of prior lung, liver or heart transplants followed a similar pattern, increasing from 115 in 1999 to a peak of 240 in 2006 and then declining to 227 in 2008.

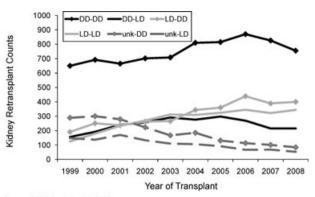
## Variation and disparity in access to LD transplantation

Despite the clear survival benefits of LD transplantation, there are significant, ongoing disparities in access to LD organs that may exacerbate the declining rates of transplantation noted above. Analyses of trends in the rate of transplant during the past decades reveal substantial variation among potential recipients based on age, sex and race. Furthermore, the use of LD transplant differs markedly



Source: SRTR Analysis, July 2009

Figure 16: Trends in living donor creatinine, 1999-2008.



Source: SRTR Analysis, July 2009

Figure 17: Trends in LD retransplantation, 1999-2008.

across geographic regions, potentially as a function of waiting time and demographic differences.

**Demographic and clinical factors associated with LD access:** Among candidates waiting for transplant, the youngest children are the most likely to receive an LD transplant; however, the percentage declines among older children (Figure 18). This trend abruptly reverses at age 18, when pediatric priority is no longer in effect. Younger adults without access to the pediatric list are much more likely than older recipients to receive an LD transplant. The propensity to undergo LD transplant then steadily decreases beyond age 35.

Members of racial and ethnic minorities who receive transplants continue to be significantly less likely to have received an LD transplant even after adjustment for demographic factors, insurance and socioeconomic status. Among patients who received a transplant, African-American recipients are less than half as likely to have received an LD transplant as white patients (odds ratio [OR] 0.42 95%; confidence interval [CI] [0.40, 0.44]). Hispanic/Latino candidates (OR 0.82 [0.75, 0.89]) and

Table 2: Total number of repeat kidney transplants, 1999–2008

Year of Re-Tx	DD- DD	DD- LD	LD- DD	LD- LD	unk- DD	unk- LD	Total Re-tx with LD	Total Re-tx
1999	650	156	191	125	289	148	429	1559
2000	692	192	251	179	300	137	508	1751
2001	665	240	237	233	279	170	643	1824
2002	702	257	263	270	223	133	660	1848
2003	708	291	266	312	167	110	713	1854
2004	810	276	343	309	185	106	691	2029
2005	815	298	360	324	131	92	714	2020
2006	870	269	439	345	113	67	681	2103
2007	826	215	389	322	101	68	605	1921
2008	755	215	400	344	84	53	612	1851

Source: SRTR Analysis, August 2009.

Re-Tx = repeat transplant; DD = deceased donor kidney; LD = living donor kidney; and unk = unknown.

**Table 3:** Number of kidney transplants, including living donor, following extra-renal transplantation (lung, liver and heart)

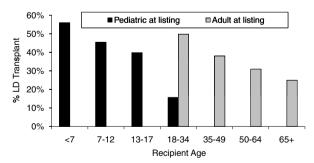
Year of	Any previous extra renal ever, unless involved kidney		prev extra mult invo	est one vious renal, iorgan olving lney	Total	Total	
transplant	LD	DD	LD DD		LD	DD	Total
1999	49	82	37	33	86	115	201
2000	75	101	34	37	109	138	247
2001	90	111	50	44	140	155	295
2002	108	94	60	44	168	138	306
2003	133	96	61	45	194	141	335
2004	135	120	58	58	193	178	371
2005	125	170	61	54	186	224	410
2006	114	177	54	63	168	240	408
2007	112	144	53	63	165	207	372
2008	114	167	32	60	146	227	373
Total	1055	1262	500	501	1555	1763	3318

Source: SRTR Analysis, August 2009.

LD = living donor.

candidates of 'other' racial classifications are similarly disadvantaged (OR 0.53 [0.50, 0.56]). Despite near universal coverage for patients with ESRD, type of insurance also has a significant effect on access to LD transplantation. Patients with private health insurance were nearly three times more likely to receive an LD kidney compared with those with Medicare only (OR 2.74 [2.61, 2.88]). However, the difference was smaller for candidates with Medicaid compared with Medicare (OR 1.09 [1.01, 1.16]). Higher educational achievement was also associated with an increased rate of LD transplant (OR 1.28 [1.24, 1.33]) for patients with at least some college education.

A variety of clinical factors that affect the use of LD transplantation were analyzed in a multivariate model. After adjusting for demographic and socioeconomic status, patients with a body mass index greater than 35 (OR



Percentages adjusted through random effects model using DSA/blood type Source: SRTR Analysis, July 2009

Figure 18: Percentage of living donor kidney-alone transplant by recipient age, 1999–2008 data.

0.92 [0.88, 0.97] vs. 25–30), panel reactive antibody (PRA) greater than or equal to 80% (OR 0.45 [0.42, 0.50]) and male sex (OR 0.83 [0.81, 0.86]) were all less likely to receive an LD kidney. Interestingly, compared with patients with glomerulonephritis, candidates with diabetes were significantly more likely to undergo LD transplant (OR 1.35 [(1.28, 1.44]), as were candidates with hypertension (OR 1.16 [1.10, 1.22]), polycystic kidney disease (OR 1.24 [1.17, 1.32]) or other and/or missing causes of renal failure (OR 1.79 [1.63, 1.96]). A prior history of malignancy also increased the chance of receiving an LD transplant (OR 1.14 [1.06, 1.21] (SRTR analysis, August 2008).

Geographic variation in LD use and access: LD use varies markedly by geography. Using DSA coverage areas, LD transplant rates were compared with the underlying population of patients with ESRD (Figure 19). The mean ratio of LD recipients per 100 incident ESRD patients under the age of 75 during 1999–2007 was 8.2, with an interquartile range of 4.9–10.5. The DSA with coverage in Minnesota, South Dakota, North Dakota and parts of Wisconsin had the highest rate of LD transplant at 32.98 of ESRD patients, while the DSA with coverage in Mississippi had the lowest at 0.15 (Figure 19). After adjusting for differences in the underlying population demographics to the national mean for age, race, sex and diabetes, the ratio of LD recipients per 100 incident ESRD patients still varied from 0.17 to 26.57.

# Effect of DD waiting time on the use of LD transplant:

Among the factors that influence the use of LD kidneys is the waiting time within the region. As the waiting time within a given OPO increases, it appears that use of LD organs increases proportionately (Figure 20).

To determine the effect of waiting time on LD rates, use of LD transplantation was examined in each OPO for each blood group over the period 1999–2008. This analysis included 123 127 transplants, of which 49% were LD. Recipients of multiorgan transplants and those transplanted with nonlocal organs were excluded. Assessments of the effect of waiting time were adjusted for recipient demographic and clinical factors.

Overall, the odds of receiving an LD transplant compared with a DD transplant increased by 48% for each additional year of waiting (OR 1.48 [1.36, 1.60]) after adjustment for other donor and recipient covariates. This effect appears to have diminished over the past several years from a peak in 2001, although the relationship in 2008 is still highly significant (OR 1.31 [1.20, 1.44]). While the relationship between waiting time and the percentage of LD transplants varied by patient demographic, it was still positive for all adult groups. Pediatric recipients tended to have higher percentages of transplants than other age groups; these percentages tended not to be affected by the length of waiting times in their DSAs.

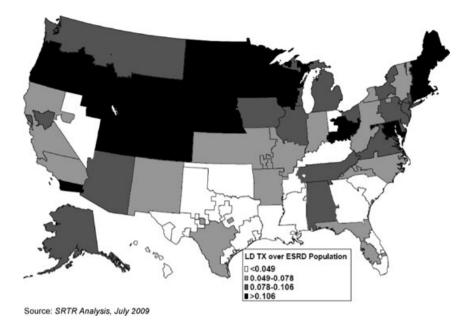
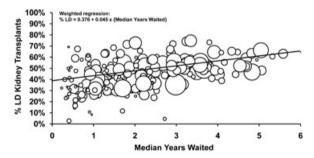


Figure 19: Living donor transplants/ ESRD population, 1999–2008.

# Trends in posttransplant outcomes among LD kidney recipients

**Recipient characteristics and outcomes:** Graft survival for LD kidney transplant recipients was at or above 95% through 1 year for all age groups over 1 year of age. Interestingly, by 5 years, LD kidney transplant graft survival, adjusted for the average 1-year cohort demographics, dips below 80% for individuals who were adolescents or young adults at time of transplant (age 12–17 years, 76%; age 18–34 years, 79%), as well as for individuals over age 65 at transplant (74%). At 10 years posttransplant, fewer than two-thirds of grafts were functioning within all age groups, save for individuals who were transplanted at age 5 or younger [Table 5.8d].

African-American LD transplant recipients had lower rates of unadjusted and adjusted graft survival at 5- and 10-years (adjusted graft survival at 5 years, 73%; 10 years, 45%)



Each data point is a single blood group within a single DSA. The size of the circle corresponds to the sample size during 1999-2008, from 12 to 3169 transplants Source: SRTR Analysis, July 2009

Figure 20: DSA/ABO median wait time versus percentage living donor transplantation, 1999–2008.

compared with other races and ethnicities. There were no major differences in unadjusted or adjusted graft survival between male and female recipients, or in unadjusted graft survival rates across blood types. First-time transplant recipients had statistically significantly better unadjusted graft survival at 5 years (82% vs. 78%, p < 0.001) and at 10 years (60% vs. 55%, p < 0.001) [Tables 5.8d, 5.10d].

While nearly all LD kidney transplant diagnosis groups had relatively similar rates of graft survival through 3 months, 1 year and 5 years, individuals who had diabetes or renovascular or other vascular diseases as the primary diagnoses for kidney failure were more likely to have failed grafts at 10 years (adjusted graft survival diabetes, 48%; renovascular and other, 49%) [Table 5.8d].

**Transplant-related variables and trends over time:** The need for dialysis within the first week after an LD transplant (4% of kidney-alone transplants in 2006–2007) was associated with a marked reduction in graft survival at every time point compared with individuals who did not need dialysis early after LD transplant [Table 5.10d].

Outcomes were generally similar above an annual center volume of 47 transplants per year. However, facilities with 29–47 transplants per year had statistically significant reductions in graft survival compared with facilities with more than 47 transplants per year (p-values ranging from 0.003 to 0.07 by 3-month–10-year time period, and by size: 48–81 or 82+ transplants). The range of 10-year adjusted graft survival across all states with at least 100 LD recipients from 1997 to 2007 was 39%–77%, with the majority of states reporting survival of 55%–65% at 10 years [Table 5.8d]. Donor age over 65 years was associated with a marked reduction in 5- and 10-year unadjusted graft survival (5 years, 61%; 10 years, 29%) [Table 5.10d].

Between 1999 and 2007, unadjusted graft survival increased from 95% to 97% at 1 year. Three- and 5-year survival rates also improved since 1999, but the improvement in 5-year graft survival between 1999 and 2003 was not statistically significant. By 2005, the latest year for which 3-year posttransplant survival is available, 3-year graft survival had improved to 89%, compared with 88% in 1999. By 2003, 5-year graft survival had improved to 81%, compared with 80% in 1999 [Table 5.11d].

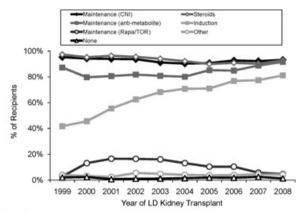
Adjusted patient survival following LD kidney transplant for all age groups was at or above survival for those 65 years and older: 99% at 3 months and 97% at 1 year [Table 5.12d]. At 5 years after transplant, recipients between the ages of 1–49 years at transplant had at least 93% survival; recipients ages 50–64 years decreased to 89% survival and those 65 years and older had even lower survival at 79%. Similar trends were found at 10 years [Table 5.12d].

African-American recipients had slightly lower adjusted 10-year patient survival rates than whites (73% vs. 77%), while Hispanic/Latinos experienced better survival (83%) than both groups (p < 0.001 for all groups) [Table 5.12d]. There were no statistically significant differences in adjusted LD patient survival when comparing males and females. There were also no differences comparing individuals with different blood types at 3 months and 1 year; however, type A recipients had significantly lower unadjusted survival than type O recipients at 5 years (90% vs. 92%) and 10 years (76% vs.78%) [Table 5.14d].

Having renal disease related to diabetes or neoplasm was associated with reduced adjusted patient survival at 5 years in contrast with the other disease categories; this was statistically significant for diabetes. By 10 years, individuals with diabetes as a primary cause of kidney failure had only 58% unadjusted patient survival after an LD transplant. This was even lower than that for individuals who had renovascular and other vascular diseases (70% 10-year unadjusted survival) or neoplasms (71% 10-year unadjusted survival) as primary causes of kidney failure [Table 5.14d].

The need for dialysis within the first week following an LD transplant was associated with reduced patient survival. At 5 years after an LD transplant, unadjusted patient survival was 79% versus 92% for those not in need of dialysis; this difference persisted at 10 years (62% vs. 78%) [Table 5.14d]. We report these figures with the caveat that dialysis within the first week captures both delayed graft function and primary nonfunction.

There were no marked differences in outcomes in unadjusted patient survival when categorized by center volumes, with the exception of the smallest centers (0–12 per year) with statistically significant better survival at 5-and 10-years [Table 5.14d]. In evaluating unadjusted patient survival in states that had more than 100 recipients reported, the range of 5-year patient survival was 88–97%. The range for 10-year unadjusted patient survival was 66–



Source: SRTR Analysis, July 2009

Figure 21: Trends in recipient steroids, maintenance and induction therapy, 1999–2008.

87%. There appeared to be a modest effect, albeit not statistically significant, in reduced unadjusted patient survival for individuals with PRA levels at 80% or greater at 5 years after an LD transplant. However, survival for this group was higher (although, again, not reaching statistical significance) at 10 years than for recipients with 0–9% or 10–79% PRA levels [Table 5.14d].

As with graft survival, donor age ≥65 years was associated with a marked difference in patient survival at 10 years following LD transplant in contrast to all younger categories of donor age (unadjusted 10-year survival, 46%; all of the other age categories, ≥74%) [Table 5.14d].

Immunosuppression in the LD recipient: Immunosuppression management of the LD kidney recipient has changed dramatically over the past decade (Figure 21). The use of any induction regimen has increased between 1999 and 2008, from 42% of transplants to 81%. The most frequently used agents in 1999 were IL-2 receptor antagonists, which were used in 31% of patients overall. In 2008, 41% of patients received rabbit antithymocyte globulin (Thymoglobulin), 30% received an IL-2 receptor antagonist and 12% were treated with alemtuzumab (Campath).

Maintenance immunosuppression regimens have also evolved in the LD transplant recipient. In 1999, 96% of recipients were discharged with steroids; 31% were on tacrolimus and 63% were on a cyclosporine preparation. By 2008, only 59% of patients were discharged on steroids, while 86% were on tacrolimus and 8% on cyclosporine. The use of maintenance steroids following transplant has also decreased over time. In 1999, 83% of LD recipients remained on triple therapy at 1 year after transplant (calcineurnin inhibitors [CNI], antimetabolyte, corticosteroids) compared with only 55% in 2008. The most common regimen for patients on dual therapy in 2008 was tacrolimus/mycophenolate mofetil (32% of

Table 4: Comparison of pediatric kidney transplants pre- and post-Share 35 by donor type and recipient age

Policy period		Recipient age (years)							
	Donor type	0–5		6–10		11–18		Pediatric total	
		N	%	N	%	N	%	N	%
Pre-Share 35 9/28/02 through 9/27/2005	Deceased	154	33.3	195	46.2	744	58.1	1093	46.5
	Living	309	66.7	227	53.8	720	41.9	1256	53.5
	All	463	100.0	422	100.0	1464	100.0	2349	100.0
Post-Share 35 9/28/05 through 9/27/08	Deceased	214	46.9	261	62.3	1077	67.5	1552	62.8
	Living	242	53.1	158	37.7	519	32.5	919	37.2
	All	456	100.0	419	100.0	1596	100.0	2471	100.0

Source: Organ Procurement and Transplantation Network. OPTN/UNOS Pediatric Transplantation Committee Descriptive Data Request. Final: Evaluation of modification to OPTN/UNOS policy on pediatric priority for kidneys from deceased donors under age 35. March 26, 2009.

recipients). Only 2% of patients were on tacrolimus monotherapy (SRTR analyses, data as of July 2009).

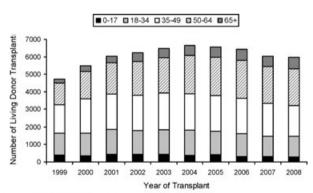
# Decrease in living donation among pediatric transplants after share 35

Since September 28, 2005, under the Share 35 allocation policy (http://optn.transplant.hrsa.gov/ PoliciesandBylaws2/policies/pdfs/policy\_7.pdf), children listed for kidney transplant before the age of 18 years have received first priority for kidneys from DDs younger than 35 years, when the kidneys are not shared mandatorily for the following reasons: 0 HLA mismatching, renal/nonrenal organ allocation, locally for prior living organ donors or for candidates 18 years or older with PRA levels 80% or greater. In the first 3 years after Share 35 (post-Share 35), the total number of kidney transplants for children increased, primarily in the 11-18 year age group, and the total number of DD transplants increased in every pediatric age group, compared with the 3-year period just prior (pre-Share 35) (Table 4). There was a corresponding substantial decrease in the number of LD transplants for children in all age groups. The decrease in LD transplants reflects a general downward trend for all LD transplants since 2004, but for children post-Share 35, the 24% decrease was out of proportion to the smaller 18% and 16% decreases for adults aged 18-34 and 35-49 years, respectively, during the same time period (Figure 22). Parent-to-child donation, the most common type of LD transplant for children, decreased from 899 (72% of LD transplants) to 623 (68%) after Share 35 (8).

The reasons for the decline in pediatric LD kidney transplants after Share 35 are unclear. The demographic characteristics for pediatric LD accepted and completing donation post-Share 35 have not been different from pre-Share 35, so selection criteria do not seem to be more stringent (8). However, no data exist to evaluate the general health of the LD pool and whether factors such as obesity, diabetes and hypertension—which have increased in prevalence in the adult population in the last decade—have adversely affected the LD rate, causing more potential donors to be screened out. It is likely that a shorter waiting time and greater availability of DD kidneys for pediatric patients af-

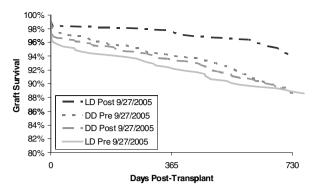
ter Share 35 may be influencing parents and candidates to wait for a DD kidney rather than putting family members or friends through the LD process; parents and candidates may be saving an LD kidney for a future repeat kidney transplant when needed.

With more pediatric patients, especially adolescents, receiving DD kidney transplants that are poorly matched immunologically—more than 5-6 antigen mismatches and 2 DR mismatches (8)—compared with living related donor kidneys, concern arises about long-term consequences, such as decreased graft survival and patient sensitization for future transplant. The short follow-up time since implementation of Share 35 in 2005 does not allow for this concern to be fully addressed. At 2 years of followup, no significant difference has been observed in incidence of delayed graft function, 6- or 12-month acute rejection rates, or median serum creatinine at 12 months (8). Short-term graft survival for all pediatric kidney transplants, regardless of donor type, is no different for pre- and post-Share 35. Early analysis suggests post-Share 35 LD kidney transplants may demonstrate improved graft survival compared with post-Share 35 DD, pre-Share 35 LD and pre-Share 35 DD transplants (Figure 23). Long-term follow-up



Source: 2009 OPTN/SRTR Annual Report, Table 5.4d.

Figure 22: Living donor recipient age by year of transplant, 1999–2008.



Source: SRTR Analysis, July 2008

Figure 23: Graft survival for pediatric kidney transplants by donor type performed in the 2 years pre- or post-Share 35.

is needed before a difference in graft survival can really be demonstrated.

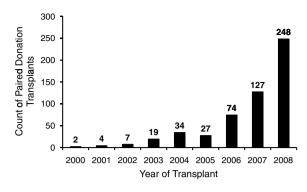
### Strategies to increase living kidney donation

Despite the outstanding outcomes associated with LD kidney transplantation, medical and logistical barriers to living donation still exist. Over the last decade, efforts have been made to increase the feasibility of live donation for healthy, willing donors through a number of different modalities. These include the growth of programs for transplantation across immunological or blood group incompatibilities, the development of kidney paired donation (KPD) programs, wider dissemination of laparoscopic donor nephrectomy to reduce donor recovery time, and a national program to defray the costs associated with live donation.

Incompatible kidney transplantation: Estimates suggest that hundreds of candidates each year are relegated to the DD waiting list because of blood type or HLA incompatibilities with their healthy, willing, intended live donors (9). Options for these patients include KPD (10,11), ABO incompatible (ABOi) transplantation (12–15) and LD positive-crossmatch (posXM) desensitization (16,17).

The original paradigm of KPD, where two or more incompatible pairs exchange donors such that compatible transplants result (18), has been expanded to include the use of compatible pairs (19) and nondirected donors (20,21). Geographic barriers have also been overcome by mathematical optimization (11) and by replacing donor travel with organ transport (22,23). As a result, according to LD relationships reported to the OPTN, the use of KPD has doubled each year since 2005 (Figure 24).

Growth has also been seen in ABOi and posXM programs. The increasing numbers of ABOi transplants, as well as the blood type distributions of the donor/recipient pairs,



Source: SRTR Analysis, July 2009

Figure 24: Trends in paired donation, 2000-2008.

are shown in Table 5. Although the use of desensitization is not reported to the OPTN, some inferences regarding growth of posXM transplantation can be made by studying the number of highly sensitized recipients (PRA  $\geq$  80%) transplanted each year, particularly those with non-HLA-identical donors (Table 5).

The increase in ABOi and posXM transplants can also be seen in terms of center-level clustering. In other words, an increase in the number of incompatible transplants performed can be indicative of increased numbers of incompatible transplants at a small number of specialty referral centers, or wider dissemination of these protocols (13). To examine this, the cumulative distributions in LD transplants of ABOi and PRA  $\geq$  80%, over time, are shown in Figure 25.

In 1999–2000, 244 centers performed at least one LD transplant, 83 performed at least one transplant of a recipient with PRA  $\geq 80\%$  with a non-HLA-identical donor and 31 centers transplanted at least one ABOi pair. Over the ensuing decade, the number of centers performing LD transplants did not increase (244–242) but the number performing non-HLA-identical PRA  $\geq 80\%$  (83–126) and ABOi (31–50) increased significantly. Furthermore, there has been increased dissemination of these techniques, with fewer high-volume centers and broad adoption (as indicated by a flatter slope of the ABOi and PRA  $\geq 80\%$  curves in 2007–2008 when compared with 1999–2000) (Figure 25).

Laparoscopic donor nephrectomy: Since the first laparoscopic donor nephrectomy reported at Johns Hopkins in 1995, use of this operation has become increasingly widespread, with more than 90% of LD nephrectomies performed laparoscopically in recent years (Figure 26). Variations in laparoscopic nephrectomy now include transperitoneal and retroperitoneal approaches, pure laparoscopic and hand-assisted techniques and, most recently, the single-port procedure (24).

Table 5: Sensitized and ABO-incompatible transplants, by year of transplant

Year of transplant	PRA 80+			ABO incompatible						
	Total <sup>1</sup>	MM > 0	MM = 0	Total	A2-B	A->B	AB->O	B->A		
1999	116	82	31	26	4	7	13	6		
2000	138	86	50	31	0	2	25	4		
2001	172	125	45	26	4	4	19	3		
2002	168	135	32	39	2	6	28	5		
2003	250	201	48	52	6	9	36	7		
2004	261	220	37	64	1	7	51	6		
2005	347	283	60	79	4	15	55	9		
2006	340	271	68	95	2	19	68	8		
2007	316	272	43	91	0	9	66	16		
2008	320	260	53	90	4	23	54	13		

Source: SRTR Analysis, August 2009. PRA = panel reactive antibody.

<sup>&</sup>lt;sup>1</sup>Includes living donor transplants where HLA MM information is missing.

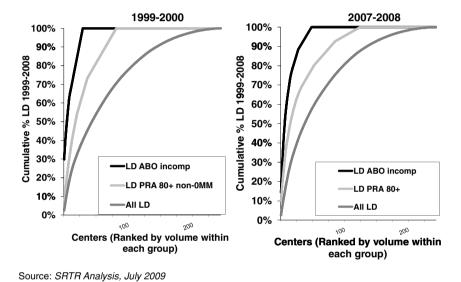


Figure 25: Facility clustering by ABO incompatible and PRA 80+ (non-0 mismatch), 1999–2000 versus 2007–2008.

As with incompatible transplantation above, the broad use of this operation can be seen not only in numbers but in distribution by transplant center (Figure 27). For example, in 1999–2000, 242 centers performed LD nephrectomies (with nonmissing data on the procedure type), but only 149 had performed at least one laparoscopic nephrec-

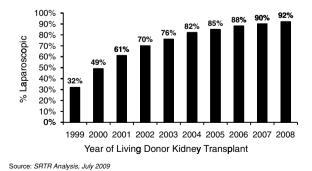
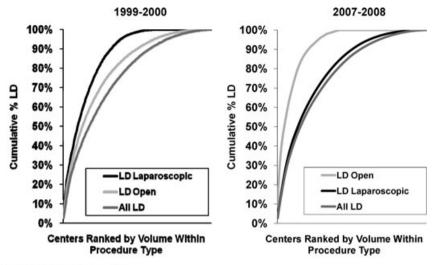


Figure 26: Trends in procedure type, 1999-2008.

tomy. Furthermore, there was more clustering of the laparoscopic approach when compared with the distribution of LD transplants in general (Figure 27, left panel). However, in 2007–2008, while the number of centers that performed LD transplants was still 242, 231 performed at least one laparoscopic nephrectomy and only 101 performed at least one open nephrectomy. This is also reflected by clustering, where the open procedure is now more clustered among a small proportion of transplant centers, while the distribution of laparoscopic nephrectomy mirrors that of LD transplantation in general (Figure 27, right panel).

**National LD assistance center:** In October 2007, HRSA established the National Living Donor Assistance Center (NLDAC) to 'provide reimbursement for travel and subsistence expenses incurred toward living organ donation'. Donors and recipients with incomes within 300% of the HHS poverty guidelines, or those with an official statement of financial hardship from a transplant center representative, are eligible for up to \$6,000 of financial assistance for travel, lodging and meals for the donor and up to two



Source: SRTR Analysis, July 2009

Figure 27: Facility clustering by procedure type, 1999–2000 versus 2007–2008

accompanying persons. As of June 2009, NLDAC had received 663 applications, of which 571 were approved. Approved applications have facilitated 295 completed donor surgeries; 200 surgeries remain pending and 76 have been cancelled.

# Conclusion

Living donation remains the best strategy to improve access to kidney transplantation. LD transplants have the best outcomes of any kidney transplant, resulting in the greatest number of life years from transplant. The decreasing availability of this resource is particularly alarming, given the decline in the number of SCD DD kidneys available. The transplant community should focus on strategies to improve access to living donation for recipients of all races, ethnicities and socioeconomic status. Through the adoption of laparoscopic donor nephrectomy, KPD and, perhaps, ABOi transplant, we hope to reverse the downward trend in LD transplants. It may also be necessary to consider greater economic support of donors through the donor assistance program to remove nonclinical barriers to organ transplantation.

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### Conflict of Interest Statement

The authors declare no conflicts of interest.

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