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# Kidney and Pancreas Transplantation in the United States, 1997–2006: The HRSA Breakthrough Collaboratives and the 58 DSA Challenge

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**Growth in the number of active patients on the kidney transplant waiting list has slowed. Projections based on the most recent 5-year data suggest the total waiting list will grow at a rate of 4138 registrations per year, whereas the active waiting list will increase at less than one-sixth that rate, or 663 registrations per year. The last 5 years have seen a small trend toward improved unadjusted allograft survival for living and deceased donor kidneys. Since 2004 the overall number of pancreas transplants has declined. Among pancreas recipients, those with simultaneous kidney-pancreas transplants experienced the highest pancreas graft survival rates.**

**In response to the ongoing shortage of deceased donor organs, the US Health Resources and Services Administration launched the Organ Donation Breakthrough Collaborative in September 2003 and the Organ Transplantation Breakthrough Collaborative (OTBC) in October 2005. The 58 DSA Challenge is prominent among the goals adopted by the OTBC. Its premise: were each of the 58 existing donation service areas to increase the number of kidney transplants performed within their boundaries by 10 per month, an additional 7000 transplants over current annual levels would result. Such an increase could potentially eliminate the national kidney transplantation waiting list by 2030.**

**Key words: Deceased donor kidneys, 58 DSA Challenge, donation service areas, expanded criteria donors, 7000 Kidney Challenge, kidney transplantation, living donor transplantation, OPTN, Organ Donation Breakthrough Collaborative, organ procurement organization, Organ Transplantation Breakthrough Collaborative, pancreas transplantation, SRTR, survival**

## Introduction

The first two sections of this article will review recent trends in kidney and pancreas transplant waiting list activity, transplant rates and outcomes. New to this year's report are figures covering trends in active and inactive kidney waiting list status. Previous policies of the Organ Procurement and Transplantation Network (OPTN) allowed accrual of waiting time during the first 30 days of Status 7 (inactive status) designation, only. However, in November 2003, the OPTN implemented a new policy that permits accrual of waiting time during the entire period that a patient remains in Status 7. This modification in OPTN policy appears to have precipitated a marked change in transplant center practice, resulting in much smaller growth in the active kidney transplant waiting list than had previously been expected.

Concurrent with this reduction in the rate of growth of the active kidney transplant waiting list, the Health Resources and Services Administration (HRSA) launched the Breakthrough Collaborative initiatives in September 2003, which seek among other objectives to reduce the gap between the size of the transplant waiting list and the deceased donor pool by improving consent rates and the utilization of deceased donor organs. The third section of this article will present the rationale behind the 58 DSA Challenge, a bold initiative, first proposed as the 7000 Kidney Challenge and adopted by the Organ Transplant Breakthrough Collaborative (OTBC), to increase the transplantation of kidneys from all donor sources. The goal of the 58 DSA Challenge is to reduce the kidney transplant waiting list to zero by 2030.

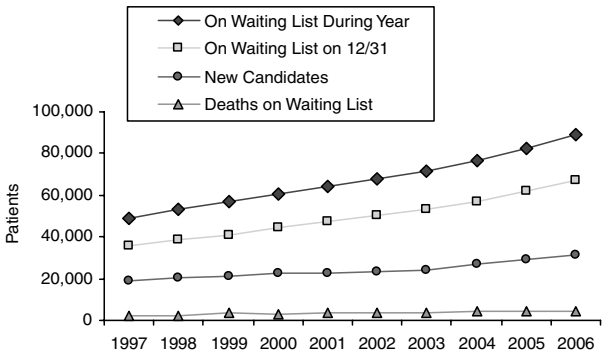
## Kidney Transplantation

### *Kidney transplant waiting list trends*

Over the past 10 years, the annual number of kidney transplants performed nationally grew by 44%, from

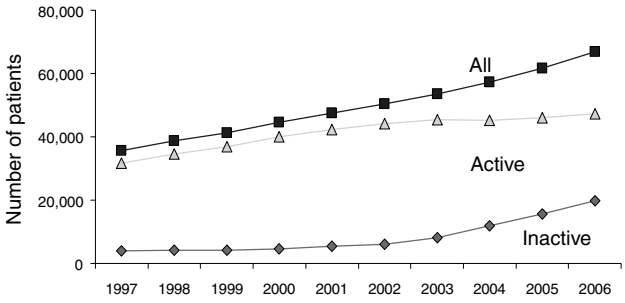
11 561 transplants in 1997 to 16 646 transplants in 2006. During this same timeframe, the national OPTN kidney transplant waiting list has grown linearly. Figure 1 demonstrates this trend, showing the period prevalence counts (candidates alive at any time during the year), point prevalence counts (candidates alive on the waiting list on December 31 of each year) and new candidate counts by year from 1997 to 2006. During this decade, perhaps reflecting the increased prevalence of end-stage renal disease (ESRD) (1), the total number of candidates on the kidney transplant waiting list at any time during the calendar year increased by 81%, from 49 208 to 88 877, while the total number of patients on the kidney waiting list at year-end rose by more than 88% from 35 526 to 66 961. Growth in the number of wait-listed patients has been accompanied by a more than doubling of deaths on the waiting list from 2184 in 1997 to 4456 in 2006. The increase in the number of waiting list deaths perhaps reflects the effects of a combination of influences, including an increase in waiting list size, longer waiting times for deceased donor transplantation, more liberal wait-listing standards and an increasing average age of wait-listed kidney transplant candidates. Support for the theory that an increase in waiting list size contributed to the increase in the number of waiting list deaths is found in the concurrent decrease in the annual death rate for waiting list candidates from a high of 84 deaths per 1000 patient-years at risk in 1999 to 70 deaths per 1000 patient-years at risk in 2006. During the same period, the annual death rate for waiting list candidates age 50–64 years dropped from 99.6 deaths to 80.4 deaths, while the death rate for candidates age 65+ years dropped from 150 to 113. Most notably, the death rate for waiting list candidates with diabetes dropped from 148.9 in 1999 to 102.4 in 2006.

Although the overall numbers of candidates on the waiting list have increased steadily, the number of active patients on the waiting list has changed little since 2001. In fact, the most recent increases in the size of the overall waiting list largely reflect an increase in Status 7 listings (Figure 2). The number of active patients, 31 662 on 31 December 1997, rose to 44 265 at the end of 2002. However, by the end of 2006, only an additional 2989 patients had been added to the active candidate list, bringing the total number of active candidates on 31 December 2006 to 47 254. In contrast, the number of inactive patients on the kidney transplant waiting list increased slowly from 3864 candidates at year-end in 1997 to 6064 candidates in 2002 and then more than tripled to 19 707 patients by 31 December 2006.




Source: *2007 OPTN/SRTR Annual Report,* Tables 1.3, 5.2, 5.3

**Figure 1: Number of new and prevalent kidney waiting list candidates and deaths on the waiting list, 1997 to 2006.**




Source: *2007 OPTN/SRTR Annual Report,* Table 5.1a.

**Figure 2: Active status kidney waiting list patients at year-end, 1997–2006.**

Among the possible explanations for the increased use of Status 7 by transplant centers is a change in OPTN policy implemented in November 2003 that provides for the accrual of waiting time during the entire interval that wait-listed candidates are designated as inactive. Prior to this policy change, candidates ceased accruing waiting time after remaining in Status 7 for 30 days, and further waiting time accrual resumed only after the Status 7 designation was removed. It is possible that removal of this restriction has led to more candidates being designated as Status 7 when they suffer adverse changes in their health status. It is additionally possible that some of this increase in the use of Status 7 may reflect a change in the demographics of the waiting list, specifically the increasing age and morbidity of wait-listed candidates. However, it may be that this change in policy has encouraged the practice of listing patients in Status 7 prior to completing their evaluation and activating them when their pre-transplant evaluation is complete. This latter explanation is supported by the data shown in Table 1 documenting an increase in the percentage of candidates who are placed into Status 7 at the time they are registered on the kidney transplant waiting list. In 2003, 11% of inactive candidates were designated as being in Status 7 at the time of wait-listing. By 2006, that percentage had increased to 44%. The cumulative

**Table 1:** Distribution of time to first inactive status among inactive registrants, 2002–2006

| Year of inactive status | Number of inactive registrants | Time to inactive status (N%) | | | | | |
|---|---|---|---|---|---|---|---|
| | | At listing | | 1–90 days after listing | | 91+ days after listing | |
| 2002 | 5059 | 603 | 12% | 668 | 13% | 3788 | 75% |
| 2003 | 6445 | 680 | 11% | 848 | 13% | 4917 | 76% |
| 2004 | 10192 | 2525 | 25% | 1186 | 12% | 6481 | 63% |
| 2005 | 10485 | 3720 | 35% | 1298 | 12% | 5467 | 52% |
| 2006 | 10571 | 4666 | 44% | 1427 | 14% | 4478 | 42% |

Source: SRTR Analysis, August 2007.

probability of becoming active was calculated for these inactive patients. Among candidates who were inactive at waitlisting before the policy change, 83% became active or received a living donor transplant after 1 year, while among candidates who were listed in Status 7 after the policy change, 78% became active or received a living donor transplant after 1 year (SRTR analysis, December 2007).

The proportion of the active kidney transplant waiting list over the age of 50 years has increased during the past decade from 42% to 57% (Table 2). This shift in the age distribution of the waiting list reflects changes in the rates of wait-listing of the different age groups. Wait-listing for candidates under 50 years of age declined in recent years, while growth in the new listings has been almost exclusively among candidates aged 50 years or older. The number of active candidates younger than 50 years of age grew from 18 550 in 1997 to 21 114 in 2002 but then decreased to 20391 by 2006. The number of active candidates over age 50 rose from 13 112 in 1997 to 23 151 in 2002 to 26 863 in 2006. In contrast, the number of inactive candidates younger than 50 years increased from 2042 in 1997 to 2749 in 2002, and then to 7815 by 2006; the number of inactive candidates over 50 years grew from 1822 in 1997 to 3315 in 2002 and then to 11 892 in 2006 (SRTR analysis, May 2007).

The distribution of race among candidates active on the kidney waiting list has also evolved over the past 10 years (Table 2). The number of white and African American active candidates grew, respectively, from 14 048 in 1997 to 18 148 in 2006 and from 11 339 to 16 056. The distribution of white candidates on the active waiting list has declined from 44% to 38% and the distribution of African American candidates has decreased slightly from 36% to 34%. In contrast, the total number of active Hispanic/Latino candidates more than doubled from 3910 in 1997 to 8560 in 2006, and Asian candidates increased from 1954 to 3828. This has been reflected by an increase in the percentage representation of those latter groups on the active waiting list, as well.

The distribution of the diagnoses (glomerular diseases, hypertensive glomerulosclerosis, diabetes and other diseases) of candidates on the active kidney waiting list has evolved over the past 10 years (Table 2). Overall, the percentage of candidates with diabetes and hypertension has increased from 24% to 28% and from 15% to 21%, respectively, whereas the percentage with glomerular disease has declined from 24% to 21%. In 2006, the distribution of diagnoses was similar between those candidates who were active on the waiting list and those who were in Status 7. Thus, it does not appear that the increased fractions of listed diabetic and hypertensive

**Table 2:** Annual number and distribution of kidney waiting list patients by patient characteristic and status at year-end, 1997–2006

| Characteristic | Active | | | Inactive | | |
|---|---|---|---|---|---|---|
| | 1997 | 2002 | 2006 | 1997 | 2002 | 2006 |
| N | 31 662 | 44 265 | 47 254 | 3864 | 6064 | 19 707 |
| <35 years | 21% | 16% | 13% | 17% | 13% | 12% |
| 35–49 years | 38% | 32% | 30% | 36% | 33% | 28% |
| 50–64 years | 34% | 40% | 42% | 37% | 40% | 43% |
| 65+ years | 8% | 12% | 15% | 11% | 14% | 17% |
| White | 44% | 40% | 38% | 48% | 44% | 39% |
| African American | 36% | 36% | 34% | 38% | 40% | 39% |
| Hispanic/Latino | 12% | 15% | 18% | 10% | 11% | 16% |
| Asian | 6% | 7% | 8% | 3% | 3% | 5% |
| Other/multi-race | 1% | 1% | 1% | 1% | 2% | 2% |
| Glomerular diseases | 24% | 23% | 21% | 22% | 21% | 19% |
| Diabetes | 24% | 25% | 28% | 25% | 26% | 29% |
| Hypertensive nephrosclerosis | 15% | 20% | 21% | 11% | 18% | 21% |
| Other | 37% | 33% | 29% | 42% | 36% | 31% |

Source: Table 5.1a and SRTR Analysis, May 2007.

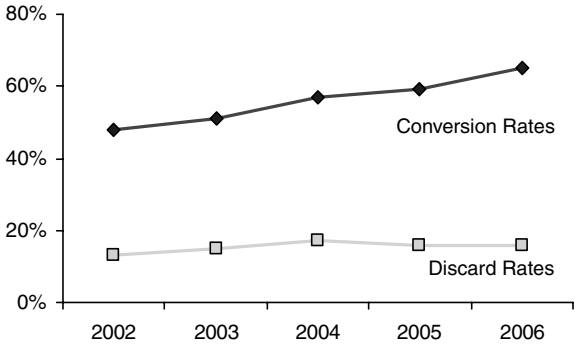
candidates are driving the increase in the use of the Status 7 designation.

The median time to transplant for new candidates has ranged around 1100 to 1200 days between 1998 and 2003 (the most recent year for which median times to transplant may be calculated). During the same time period, the median time to transplant for candidates age 50–64 years ranged from 1277 to 1416 days. In 2002, the median time to transplant for white candidates was 769 days, while the median waiting time for all other races was over 1300 days.

### *Kidney donation and transplant trends*

At the end of 2005, 97 556 patients had a functioning kidney transplant compared with 60 427 in 1997, an increase of 61%. The annual number of deceased donor transplants rose 37%, from 7774 transplants in 1997 to 10 659 transplants in 2006. The number of standard criteria donor (SCD) transplants, expanded criteria donor (ECD) transplants and transplanted kidneys recovered through donation after cardiac death (DCD) grew by 22%, 59% and 684%, respectively, during this same time interval (Figure 3). Despite the higher percentile rates of growth among ECD and DCD transplants, the greatest numerical increment compared with 2002 has been in SCD transplants, with a gain of 984 SCD, 530 ECD (includes ECD/DCD), and 606 DCD. Although the percentage of SCD kidneys allocated to candidates age <50 years has declined from 69% in 1997 to 49% in 2006, these candidates continue to receive SCD kidneys at higher rates than their proportion on the waiting list, which was 53% in 1997 and 40% in 2006.

Most of the growth (25%) in deceased donor kidney transplantation since 2002 is driven by an increase in conversion rates. This rate is defined as the number of deceased donors meeting eligibility criteria (aged 0–70 years with neurological death) divided by the number of eligible deaths (any ventilated death reported by a hospital that is evaluated and meets organ donor eligibility requirements). Among all donation service areas (DSAs), the average conversion rate grew from 48% in 2002 to 65% in 2006 (Figure 4). In contrast, the counterbalancing average discard rate was 13% in 2002 and 16% in 2006.




HRSA Collaboratives began in April 2003

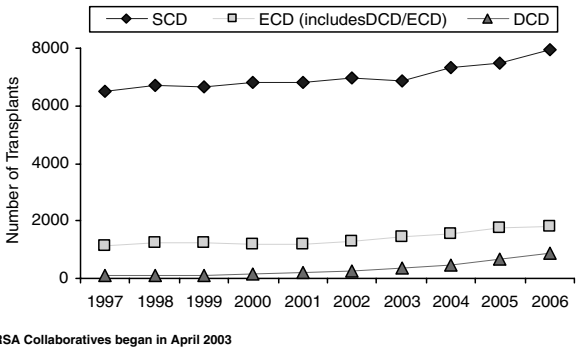
Source: SRTR analysis, August 2007

**Figure 4: Average conversion and discard rates for all OPOs, 2002–2006.**

There were 6434 living donor kidney transplants in 2006. This represents a 64% increase in the number of living donor transplants compared with 1997. Trends in living related and living unrelated kidney donors are shown in Figure 5. The number of living-related kidney donors grew from 3224 in 1997 to a peak of 4349 in 2001. Since then, the number of living related donors has decreased to 3952 in 2006. From 1997 to 2006, the number of living unrelated kidney donors grew steadily from 655 to 2312. However, it appears that the rate of growth in the living unrelated donor population has also slowed over the past 2 years.

### *Kidney transplant patient and allograft survival trends*

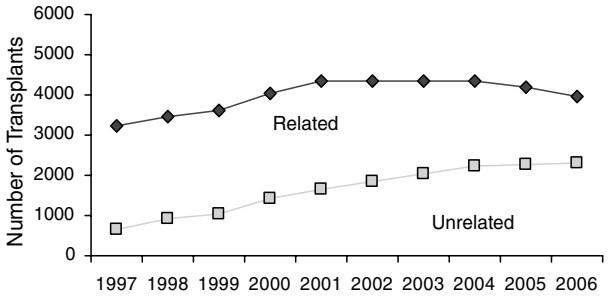
For single kidney transplants (multi-organ transplants excluded) performed from 2000 to 2005, 1-, 3- and 5-year




HRSA Collaboratives began in April 2003

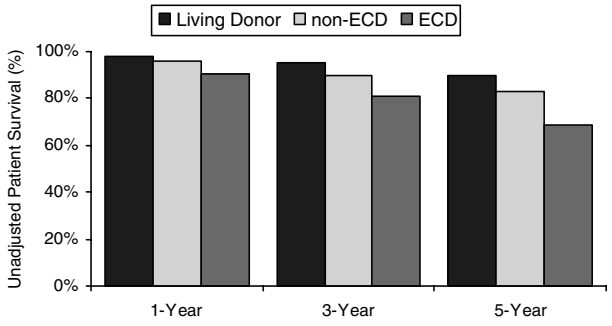
Source: *2007 OPTN/SRTR Annual Report,* Table 5.4

**Figure 3: SCD, ECD and DCD kidney transplants,1997–2006.**



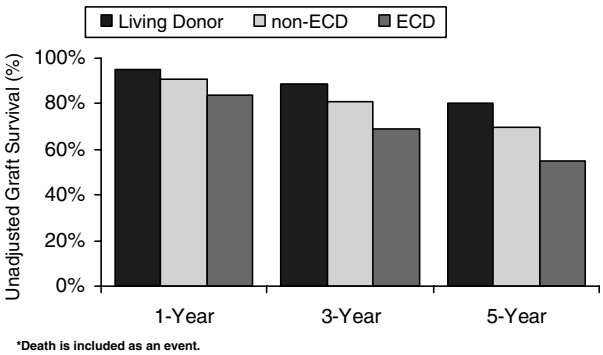

Source: *2007 OPTN/SRTR Annual Report,* Table 5.4c

**Figure 5: Trends in living-related and living-unrelated donors, 1997–2006.**




Source: *2007 OPTN/SRTR Annual Report,* Tables 5.14a, b, c .

**Figure 6: Unadjusted 1-year, 3-year, and 5-year kidney recipient survival, by donor type: 2000–2005.**




*Death is included as an event.

Source: *2007 OPTN/SRTR Annual Report,* Tables 5.10a, b, c .

**Figure 7: Unadjusted 1-year, 3-year, and 5-year kidney graft survival,* by donor type: 2000–2005.**

patient survival was best for recipients of living donor kidneys, intermediate for non-ECD deceased donor recipients and lowest for those receiving ECD kidneys (Figure 6). Unadjusted patient survival rates at 5 years were 90% for recipients of living donor kidneys, 83% for non-ECD kidneys and 69% for ECD transplants (Table 3).

Kidney allograft survival follows the same pattern as that seen for recipient survival (Figure 7). Graft survivals were best for recipients of living donor kidneys, intermediate for non-ECD transplants and lowest for ECD transplants. At 5 years, the unadjusted graft survival rate was 80% for living donor, 70% for non-ECD and 55% for ECD transplants (Table 3). Although kidney transplant patient survival percentages were not different when the first 5 years of the decade under consideration were compared with the second half (all $p > 0.05$), there is a significant trend toward improvement in allograft survival (all $p < 0.05$).

## Pancreas Transplantation

### *Pancreas transplant waiting list trends*

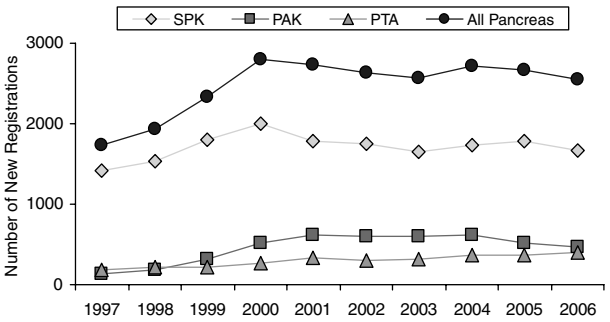
The number of pancreata recovered in 2006 increased by 53% compared with 1997. However, there were approximately 4000 people waiting for pancreas transplants at the end of 2006, which is more than double the number in 1997, indicating a growing discrepancy between the number of candidates wait-listed for pancreas transplantation and organs available. Corresponding to this is an increase in waiting times for all types of pancreas candidates. The median waiting time for a pancreas after kidney (PAK) transplant has increased from about 220 days for candidates on the list in the late 1990s to 562 days for candidates placed on the list in 2004. The median waiting time for a simultaneous kidney-pancreas (SPK) transplant has risen from 380 days in 1997 to 451 days in 2005. The greatest growth over the past decade in wait-listed patients has been among those waiting for a PAK transplant (563%) or a pancreas transplant alone (PTA) (166%); in contrast, the number of SPK transplant candidates increased by 'only' 58%.

It is notable, however, that there have been recent downward trends in SPK, PAK and total pancreas transplant registrations (Figure 8). The total number of new pancreas waiting list registrations grew from 1740 in 1997 to a high of 2796 in 2000, and then fell to 2548 by 2006. Only PTA registrations showed a consistent increase from 1997 to 2006, growing from 187 to 404. New PAK waiting list

**Table 3:** Unadjusted graft and patient survival at 5 years among deceased donor (non-ECD and ECD) and living donor kidney transplant recipients, 1994–1999 and 2000–2005

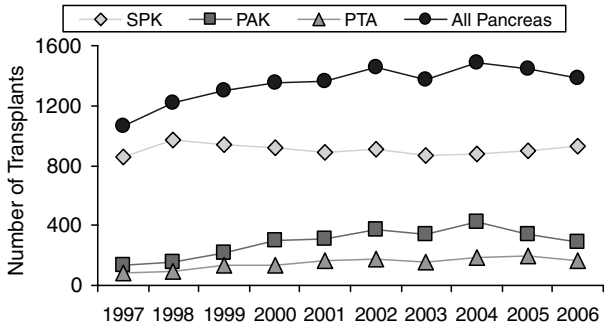
| | Graft survival | | Patient survival | |
|---|---|---|---|---|
| Donor type | 1994–1999 | 2000–2005 | 1994–1999 | 2000–2005 |
| Living donor | 79.0% | 80.2% | 90.2% | 90.3% |
| Non-ECD | 67.6% | 69.8% | 82.7% | 82.8% |
| ECD | 51.0% | 55.1% | 70.9% | 69.4% |

Source: Tables 5.10abc and SRTR Analysis, May 2007.




Source: *2007 OPTN/SRTR Annual Report,* Tables 6.2, 7.2, 8.2.

**Figure 8: New registrations on pancreas waiting list, by transplant type, 1995–2004.**




Source: *2007 OPTN/SRTR Annual Report,* Tables 6.4, 7.4, 8.4.

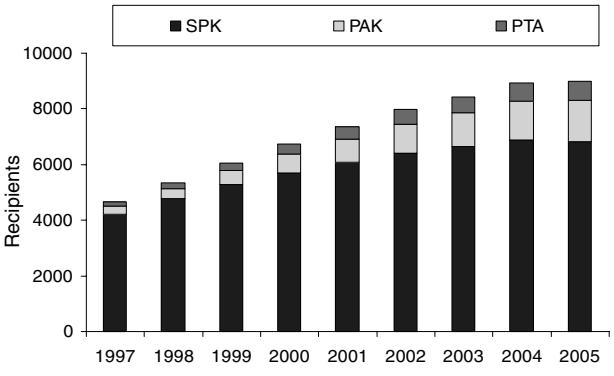
**Figure 9: Pancreas transplants, by transplant type, 1997–2006.**

registrations rose from 141 new registrations in 1997 to a high of 623 in 2004, falling to 473 in 2006. New SPK registrations rose from 1412 in 1997 to a high of 2007 in 2000 and then declined to 1671 in 2006.

### *Pancreas transplant trends*

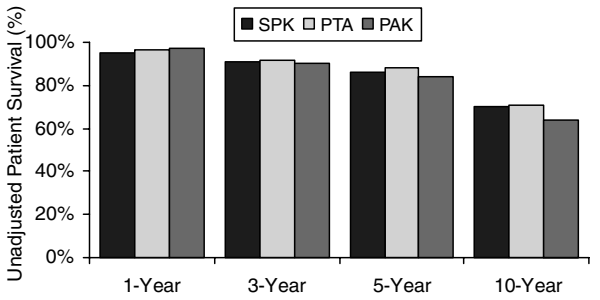
The overall number of pancreas transplants rose from 1062 in 1997 to 1483 in 2004 and has since declined to 1386 (Figure 9). The number of SPK transplants peaked in 1998 and the number of PAK transplants in 2004. The preponderance of pancreas transplants are SPK, accounting for 67% of all pancreas transplants in 2006.

Despite these trends toward fewer pancreas transplants and waiting list registrations, the total number of people alive with a functioning pancreas allograft increased 92%, from 4670 in 1997 to 8984 in 2005 (Figure 10). The largest relative increases occurred in the PAK and PTA populations, which experienced 5-fold and 4-fold increases, respectively. Nonetheless, SPK recipients represent by far the largest cohort of patients alive with a functioning pancreas allograft.




Source: *2007 OPTN/SRTR Annual Report,* Tables 6.16, 7.16, 8.16.

**Figure 10: Number of recipients living with a functioning pancreas transplant at end of year, 1997–2005.**



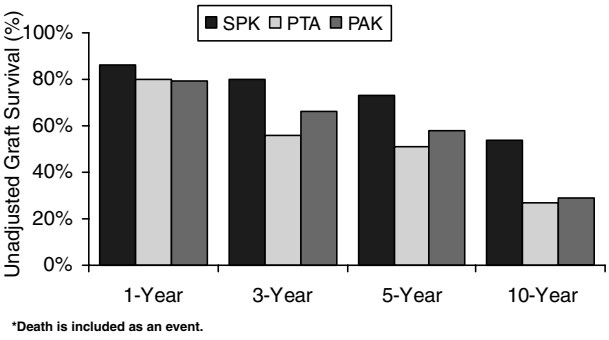

Source: *2007 OPTN/SRTR Annual Report,* Table 1.13.

**Figure 11: Unadjusted 1-year, 3-year, 5-year and 10-year pancreas patient survival, by transplant type.**

### *Pancreas transplant patient and allograft survival trends*

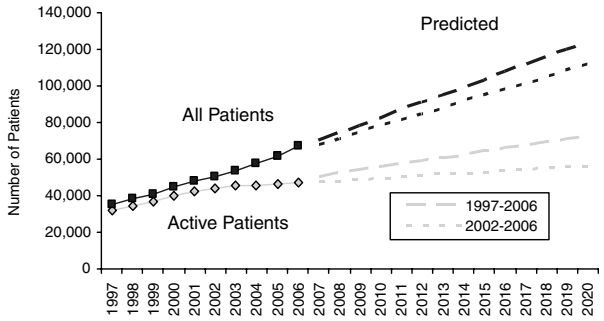
Patient survival rates were similar for PAK, SPK and PTA recipients at 1 year (ranging from 95% to 97%), 3 years (ranging from 91% to 92%) and 5 years (ranging from 84% to 88%) (Figure 11). But, the 10-year patient survival rate was lowest for PAK recipients at 64% and similar for SPK and PTA recipients, with rates of 70% and 71%, respectively.

Among pancreas recipients, those with SPK transplants experienced the best pancreas graft survival rates: 86% at 1 year and 54% at 10 years (Figure 12). Graft survival rates for PAK and PTA recipients were similar to one another, with 1-year rates of 79% and 80%, respectively, and 10-year rates of 29% and 27%, respectively.



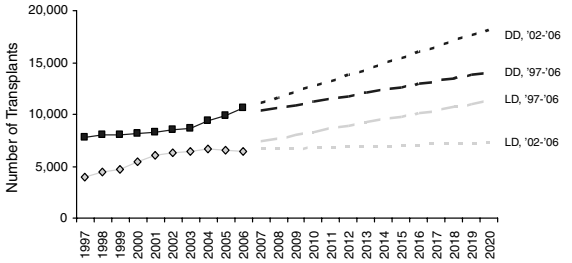

Source: *2007 OPTN/SRTR Annual Report,* Table 1.13.

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




Source: *2007 OPTN/SRTR Annual Report*, Tables 1.3 and 5.1a. Predicted values for 2007-2020 based on slope of the line from 1997-2006 and 2002-2006 and assumes current rates of waitlisting and transplantation.

**Figure 13: Projected growth in the total and active waiting list for deceased donor kidneys.**




Source: *2007 OPTN/SRTR Annual Report*, Table 1.1. Predicted values for 2007-2020 based on slopes of the lines from 1997-2006 (long-dashed line) and 2002-2006 (short-dashed). DD (dark line) = deceased donor; LD (light line) = living donor.

**Figure 14: Projected growth in living and deceased kidney transplants, 1997–2020.**

## The National Organ Donation Breakthrough Collaborative, the National Organ Transplantation Breakthrough Collaborative and the 58 DSA Challenge

Over the past decade, the number of kidney donations from living and deceased donor sources has not kept pace with growth in the total national kidney transplant waiting list. However, since 2003, the growth in the waiting list has been primarily among inactive (Status 7) candidates (Figure 2). Figure 13 projects growth of the kidney transplant waiting list, based upon 10-year and 5-year trends. The projected yearly growth for active and total wait-listed patients and for deceased and living donor transplants is summarized in Table 4. From projections based upon the most recent 5-year data, the total waiting list is estimated to grow at a rate of 4138 registrations per year, whereas the active waiting list is projected to increase at less than one-sixth that rate, or 663 registrations per year (Figure 13). The projected growth in the number of living and deceased donor kidney transplants is shown in Figure 14 and Table 4. Projections based on 10-year data suggest an increase in the rate of living donor transplantations of 305 per year, while the 5-year trend is considerably smaller, with growth projected at only 49 incremental living donors per year. Figure 14 and Table 4 also demonstrate the impact of recent changes in DSA practices on deceased donor transplant rates. The number of deceased donor transplants is projected to increase by 289 per year based on the 10-year trend, but by 549 per year based on the most recent 5-year experience. Taken together, these data suggest that, should current trends continue, the gap between the combined living and deceased kidney transplantation rates and the growth in the active waiting list is narrowing (Table 4).

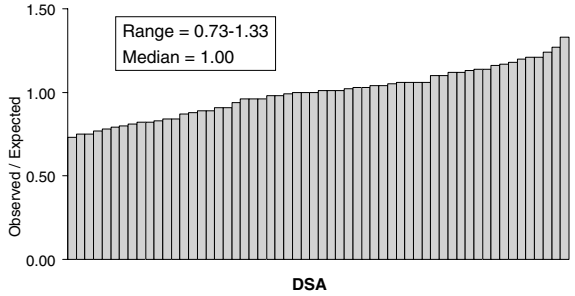
**Table 4:** Projected yearly growth of the kidney transplant total and active waiting lists and of deceased and living donor transplants, based on 10-year (1997–2006) and 5-year (2002–2006) trends

| | Projected yearly growth based on | |
|---|---|---|
| Measure | 10-year trend | 5-year trend |
| Total on waiting list | 3355 | 4138 |
| Active waiting list | 1710 | 663 |
| Living donor transplants | 305 | 49 |
| Deceased donor transplants | 289 | 549 |

Source: SRTR Analysis, May 2007.

In response to the ongoing shortage of deceased donor organs, HRSA launched the National Organ Donation Breakthrough Collaborative in September 2003 with the goal of increasing national donation conversion rates to 75% (Figure 4). Recognizing that opportunities to increase the pool of available organs extend beyond increasing conversion rates, a second round of the Collaborative, the National Organ Transplantation Breakthrough Collaborative, was convened in October 2005 with the objective of increasing the average number of organs transplanted per donor to 3.75. Underpinning the Collaborative strategy is the belief that generating the will to change a specific health care system requires the adoption of ambitious objectives that can only be achieved by implementing dramatic or 'breakthrough' improvements (2). Therefore, the Breakthrough Collaboratives have focused on developing consensus around 'stretch goals' that render existing work processes inadequate and require that new systems be implemented for targets to be achieved (2). Additionally, the Collaborative built a framework through which best practices can be shared among DSAs, both during and between the formal Breakthrough Collaborative Learning Sessions.

Among the innovations promoted by Collaborative participants are the practices of placing in-house coordinators (trained requestors) in large donor hospitals and the involvement of critical care specialists (intensivists) to establish well-defined goals and processes for the management of potential deceased donors (3,4). In addition, establishment of donor and recipient DCD and ECD selection criteria have been shown to be effective in increasing utilization of such donor organs. DCD outcomes from donors




The Expected Donation Rate is the rate expected based on national experience for OPOs serving similar donation service areas and hospitals. The Expected Donation Rate is adjusted for the following characteristics: Level 1 or 2 trauma center, Metropolitan Statistical Area size, CMS Case Mix Index, total bed size, number of ICU beds, childrenshospital, resident training program, presence of a neurosurgery unit, and hospital control/ownership.; OPO Specific Reports, Published July 2007

**Figure 15: Adjusted kidney deceased donor donation rates by DSA, 2006.**

under age 50 years have been shown to be comparable to those of SCDs (5), and ECD kidneys provide survival advantages for select recipients in DSAs with long waiting times (6). At some programs, kidneys with previous excellent function from selected donors with otherwise acceptable donor profiles but with acute renal failure or kidneys with glomerulosclerosis have been transplanted with reasonable recipient outcomes (7,8). Another under-utilized but important source of organs for transplantation is the otherwise desirable donor with a history of high-risk behavior (e.g. intravenous drug abuse or unprotected sexual behaviors) for the transmission of hepatitis C or HIV. Nucleic acid testing (NAT) has been adopted in many OPOs as an adjunct to traditional serologic testing. NAT is extremely sensitive for active viremia and will allow safe transplantation of organs from donors with higher social and infectious risks (9). Such donors may represent up to 5% of the donor pool and may provide significant societal and recipient benefits (10). These strategies and others appear to be catalyzing improvements in DSA performance. Since the first Organ Breakthrough Collaborative in 2003 and through 2006, national organ donation rates have increased 23% and the number of transplantable organs from deceased donors has increased by 25%.

The increases in organ availability that have resulted from improvements in conversion rates and in organ transplant rates per donor are highly encouraging. Meeting the needs of wait-listed candidates and achieving and exceeding the goals of the Collaborative will also be advanced by the adoption of organ-specific strategies. In this regard, it is important to realize that there exists considerable additional untapped kidney donor potential. This perspective was first presented at the 17 February 2006 meeting in Los Angeles (Learning Session 2) of the National Organ Transplantation Breakthrough Collaborative by one of the authors of this article (ABL) and formally adopted by the Collaborative as the '7000 Kidney Challenge'. Since then, the initiative has been renamed the '58 DSA Challenge' to reflect the perspective that while the objective of reaching 7000 additional kidney transplants per year compared with the 2006 baseline is a national goal, this target can only be achieved if the challenge is met at the level of the individual DSA.

The 58 DSA Challenge is based upon the observation that DSA practices vary widely in the recovery and utilization of kidneys from existing and primarily conventional donor sources. Across the United States, adjusted deceased donor kidney transplant rates vary almost 2-fold from 0.73 to 1.33 (Figure 15). Furthermore, the ratio of living donor to deceased donor kidney transplants ranges from 4% to 81% across US kidney transplant programs (Figure 16), and the ratio of living unrelated donor to living related donor

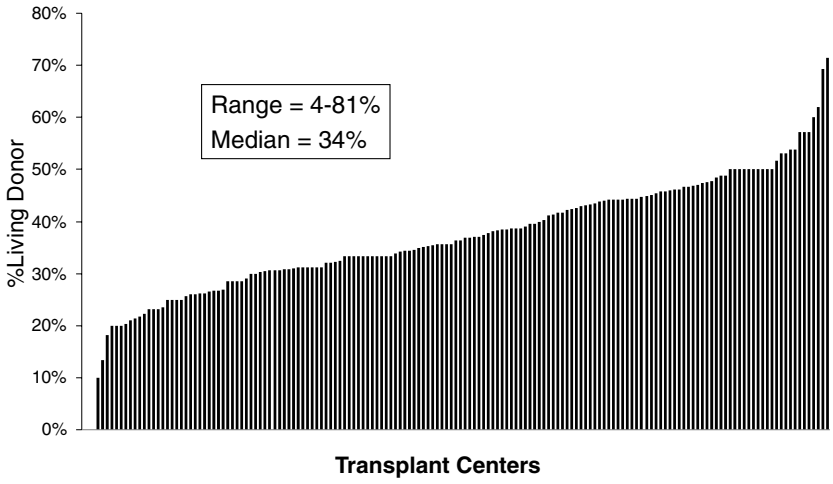
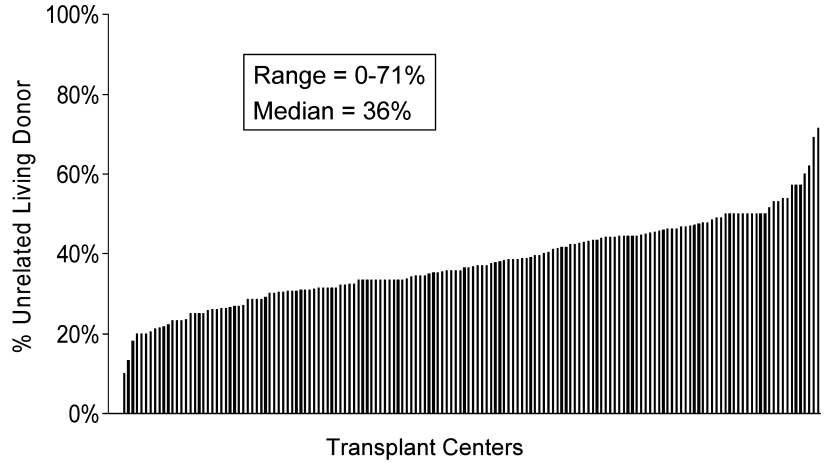



**Figure 16: Percent living donor kidney transplants by transplant center,* 2006.**

***Among centers with >20 transplants**
Source: SRTR analysis, July 2007



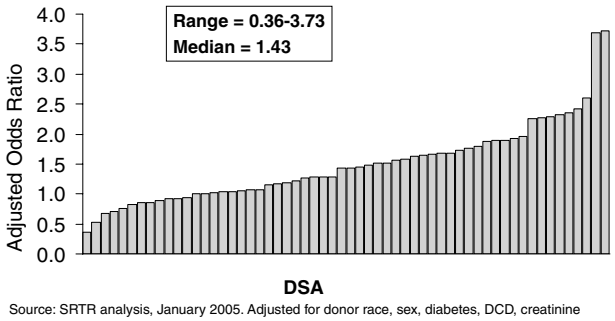

*Among centers with >10 kidney living donor transplants

Source: SRTR analysis, July 2007

**Figure 17: Percent living unrelated donors among all living kidney donor transplants by transplant center,* 2006.**

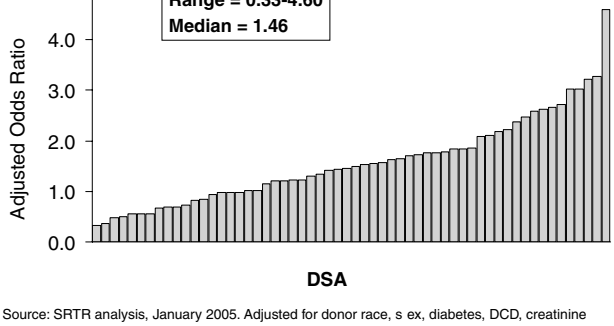
kidney transplants ranges from 0% to 71% (Figure 17). There is disparate participation in the ECD expedited kidney allocation system. In 2005, Sung et al. (11) showed that the percentage of patients wait-listed in a DSA for an ECD kidney ranged from 2% to 95%; the percentage of those receiving an ECD kidney transplant among all deceased donor kidney transplants in a DSA ranged from 0% to 31%. Furthermore, an SRTR analysis showed that discard rates by DSA varied more than 10-fold for non-ECD and 14-fold for ECD deceased donor kidneys (Figure 18 and Figure 19, respectively). In addition, few transplant centers have established paired donation, intended-candidate donation and candidate desensitization protocols. And, while it is controversial whether pre-implantation kidney biopsies and pulsatile perfusion practices reduce discard, use of these practices also varies considerably across the United States.

Taken together, these observations suggest that there now exist multiple proven strategies by which individual kidney transplant programs, donor hospitals and OPOs can work together to increase DSA-wide kidney transplantation rates. To be optimally effective, DSAs need to maximize their utilization of all sources of potential donor kidneys. Small increments in several or all of the potential donor sources enumerated above have the capacity when considered collectively to markedly increase kidney availability for transplantation. For example, a DSA recovering only one additional donor from each of these potential sources per month could conceivably increase its total number of monthly transplants by 15, i.e. one SCD (two kidneys), one ECD (two kidneys), one DCD (two kidneys), one living-related donor (one kidney), one living unrelated donor (one kidney), one paired donation (two kidneys), one intended-candidate donation (one kidney), one desensitization protocol for a potential living donor recipient (one kidney), one *en bloc* or dual kidney transplant (one kidney transplant) and one hepatitis C antibody or hepatitis B core antibody positive donor (two kidneys). Such a hypothetical DSA would transplant as many as 15 extra candidates in the month



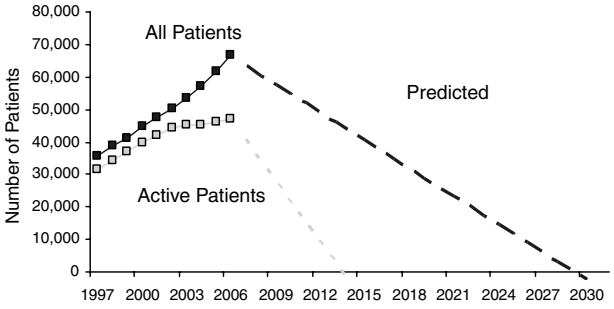

Source: SRTR analysis, January 2005. Adjusted for donor race, sex, diabetes, DCD, creatinine clearance, pumping, and biopsy.

**Figure 18: Adjusted odds ratio of discard for non-ECD kidneys by DSA, 1999–2002.**




Source: SRTR analysis, January 2005. Adjusted for donor race, s ex, diabetes, DCD, creatinine clearance, pumping, and biopsy.

**Figure 19: Adjusted odds ratio of discard for ECD kidneys by DSA, 1999–2002.**




Source: *2007 OPTN/SRTR Annual Report*, Tables 1.3 and 5.1a. Predicted values are based on slope of the line from 2002-2006.

**Figure 20: Projected growth in the waiting list for deceased donor kidneys, 1997–2030: with prediction of 7000 incremental transplants per year.**

under consideration. The pragmatism of this suggestion lies in the recognition of untapped potential in the overall donor pool and in the strategy of DSAs focusing on several sources to increase the number of kidneys available for transplant and not limiting themselves to only one or two mechanisms to generate all incremental transplants.

Can a DSA perform 10 more kidney transplants per month? The answer, for many, is yes. And, while the goal of 10 extra kidney transplants per month may be beyond the capacity of some smaller DSAs, it is certainly within the reach of many, if not all, of the larger ones to exceed these targets. The impact of increasing the average number of transplants from all sources by a total of 10 per DSA is potentially profound:

58 DSAs × 10 incremental kidney transplants =
580 incremental kidney transplants nationally/month
580 incremental kidney transplants nationally/month x 12 months =
6960 incremental kidney transplants nationally/year

Figure 20 projects the time it would take to eliminate the kidney transplant waiting list based upon current projections for waiting list growth. Recognition that the growth in the rate of ESRD has slowed (1) and assuming that current rates of both growth and listing as Status 7 persist, fulfillment of the 58 DSA Challenge would eliminate the active kidney transplant waiting list by 2015. If it were to be assumed that all the listed patients were transplantable, the waiting list would disappear by 2030. Since it is likely that a shortened waiting list would motivate more aggressive listing practices and unlikely that all Status 7 candidates would become active, these dates probably describe the logical upper and lower boundaries at which resolution of the waiting list could be achieved.

The implications of achieving the goals of the 58 DSA Challenge are immense. The duration of pre-transplant dialysis exposure is recognized as having a significant adverse effect on posttransplant kidney allograft and patient survival. Minimizing waiting time by increasing the donor pool may therefore lead to better posttransplant survival by reducing the interval of pretransplant ESRD time. Furthermore, in the 2006 SRTR Report on the State of Transplantation, Ashby et al. reported that nationally access to the OPTN kidney transplant waiting list varied more than 2.5-fold by state (12). It is at least theoretically possible that a shortened national waiting list might lead to liberalized wait-listing practices and new opportunity for deserving and potentially listable candidates in areas of the country that currently have relatively lower rates of wait-listing. Furthermore, should waiting time largely disappear, dependence on some currently controversial donation practices (use of ECD kidneys and of hypertensive or diabetic living donors) and the rationale for adoption of compensated living donation may resolve.

Additionally, since 2003, the OPTN Kidney Transplantation Committee has been working to develop a deceased donor kidney allocation system that is proposed to include, among other elements, an estimate of the extra years of life that a transplant candidate might achieve by receiving a kidney transplant from a specific deceased donor compared with that candidate's expected life span on dialysis. This estimate has been termed Life Years From Transplant, or 'LYFT'. Wolfe et al. provide a comprehensive summary of the methodology used to calculate LYFT (13). It is anticipated that any proposal for a new kidney allocation system incorporating LYFT will also provide allocation priority for children and adolescents, sensitized candidates, years on dialysis and prior living donation. Additional allocation concerns including, but not limited to, predictability of time to transplantation and incorporation of an index of donor quality are also under consideration.

Some of the criticisms of LYFT-based allocation are predicated on the concern that such a system might, by preferentially allocating deceased donor kidneys to those candidates with the best potential for additional posttransplant survival, leave some older or more frail but still deserving candidates with a reduced opportunity to receive a kidney transplant. Elimination of the kidney transplant waiting list would change this dialogue by providing certainty of transplantation for all viable candidates. It would also foster the opportunity for the allocation system to match those deceased donor kidneys and candidates with the longest potential survival, thereby reducing the rate of death with a functioning transplant and increasing the total number of years of life that can be achieved from the existing deceased donor pool.

## Summary

During the last 10 years, the total number of candidates on the kidney transplant waiting list at any time during the calendar year increased by 81%. However, growth in the number of active patients on the waiting list has slowed. Comparing 2002 with 2006, only an additional 2989 patients were added to the active candidate list, whereas an additional 13 000 wait-listed patients were listed in Status 7 (inactive status). From projections based upon the most recent 5-year data, the total waiting list is estimated to grow at a rate of 4138 registrations per year, while the active waiting list is projected to increase at less than one-sixth that rate, or 663 registrations per year.

Patient survival rates at 5 years were 90% for recipients of living donor kidneys, 83% for non-ECD kidneys and 69% for ECD transplants. At 5 years, the graft survival rate was 80% for living donor, 70% for non-ECD and 55% for ECD transplants. The last 5 years have seen a small trend toward improved unadjusted allograft survival for living and deceased donor kidneys.

In contrast with the growth seen in kidney transplantation, the number of new registrations for a pancreas transplant and the number of such transplants have declined in recent years. Among pancreas recipients, those with SPK transplants experienced the best pancreas graft survival rates: 86% at 1 year and 54% at 10 years. Graft survival rates for PAK and PTA recipients were similar to each other, with 1-year rates of 79% and 80%, respectively, and 10-year rates of 29% and 27%, respectively.

In response to the ongoing shortage of deceased donor organs, HRSA launched the National Organ Donation Breakthrough Collaborative with the goal of increasing national donation conversion rates to 75%. This was followed by the National Organ Transplantation Breakthrough Collaborative in October 2005, with the objective of increasing the average number of organs transplanted per donor to 3.75. The Collaborative strategy is based on the belief that generating the will to change a specific health care system requires the adoption of 'stretch goals' that render existing work processes inadequate and require new systems be implemented for targets to be achieved. The Breakthrough Collaboratives have also provided a framework through which best practices can be shared among DSAs.

A principal example of a stretch goal promoted by the Organ Transplantation Breakthrough Collaborative is the 58 DSA Challenge. The premise of the challenge is simple. If each of the 58 existing DSAs were to increase the number of kidney transplants performed within their boundaries by only 10 per month, an extra 7000 transplants per year (over current levels) would be accomplished nationally; this would represent an increment in kidney transplantation of greater than 40%. Such an increase could potentially reduce the active national kidney transplantation waiting list to zero within the next 10 to 20 years. The Breakthrough Collaboratives are providing the transplant community with a forum and a framework to foster improvement in organ donation rates and to meet the transplantation needs of patients with ESRD.

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This study was approved by HRSA's SRTR project officer. HRSA has determined that this study satisfies the criteria for the IRB exemption described in the 'Public Benefit and Service Program' provisions of 45 CFR 46.101(b)(5) and HRSA Circular 03.

*Note on sources:* The articles in this report are based on the reference tables in the *2007 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 1.1, 1.2, 1.3, 1.5, 1.7, 1.13, 5.1a, 5.2, 5.3, 5.4ac, 5.10abc, 5.14abc, 5.16, 6.2, 6.4, 6.16, 7.2, 7.4, 7.16, 8.2, 8.4, 8.16. All of these tables may be found online at: www.ustransplant.org.

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