

Organ Donation and Utilization in the United States, 1997–2006

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Deceased organ donation has increased rapidly since 2002, coinciding with implementation of the Organ Donation Breakthrough Collaborative. The increase in donors has resulted in a corresponding increase in the numbers of kidney, liver, lung and intestinal transplants. While transplants for most organs have increased, discard and nonrecovery rates have not improved or have increased, resulting in a decrease in organs recovered per donor (ORPD) and organs transplanted per donor (OTPD). Thus, the expansion of the consent and recovery of incremental donors has frequently outpaced utilization. Meaningful increases in multicultural donation have been achieved, but donations continue to be lower than actual rates of transplantation and waiting list registrations for these groups. To counteract the decline in living donation, mechanisms such as paired donation and enhanced incentives to organ donation are being developed. Current efforts of the collaborative have focused on differentiating ORPD and OTPD targets by donor type (standard and expanded criteria donors and donors after cardiac death), utilization of the OPTN regional structure and enlisting centers to increase transplants to match increasing organ availability.

Key words: Deceased donors, donation after cardiac death (DCD), donation service area (DSA), expanded criteria donor (ECD), living donor, multicultural donation, Organ Donation Breakthrough Collaborative, Organ Procurement and Transplantation Network (OPTN), organ procurement organization (OPO), organs recovered per donor (ORPD), Organ Transplantation Breakthrough Collaborative, organs transplanted per donor (OTPD), Scientific Registry of Transplant Recipients (SRTR)

Introduction

The major challenge in transplantation continues to be a need for transplantable organs that far exceeds the available supply. This disparity and the ensuing waiting time to receive a transplant result in considerable morbidity and mortality among transplant candidates. A variety of initiatives in the past several years have been successful in significantly accelerating what previously had been a relatively slow increase in organ donation. Nevertheless, the continued development of methods to increase organ donation and utilization is necessary to accommodate the increase in the number of individuals who may benefit from transplantation.

The increase in the supply of organs for transplantation is multifactorial in origin. Much of the growth in organ donation has coincided with the establishment of the National Organ Donation Breakthrough Collaborative through the guidance of the Health Resources and Services Administration (HRSA) in September 2003. Focused efforts to encourage multicultural donation have increased consent and donation rates for most ethnic groups. The growth of donor registries and recognition of the primacy of first-person consent documentation have been instrumental in increasing donation, as has the expansion of the donor pool by increasing use of expanded criteria donors (ECD), donors after cardiac death (DCD) and those standard criteria donors (SCD) not previously considered for organ donation. These influences are interrelated and have led to unprecedented numbers of donor consents and organ recoveries.

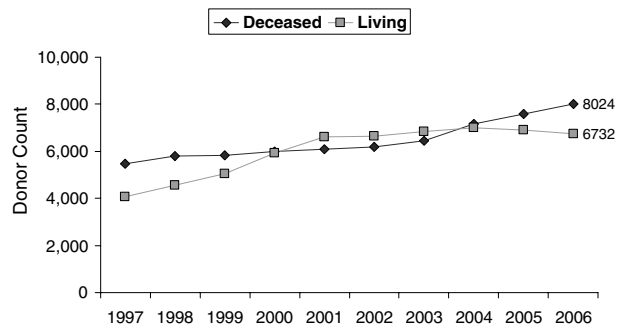
As this article will describe, the effect of these increases in donation on organ recovery rates and, in turn, on transplantation rates is often incomplete. The degree of inefficiency varies by organ and may be reflected in increases in nonrecovery of organs, discard rates or both. The coordination of criteria for organ recovery by organ procurement organizations (OPOs) with criteria for transplantability by centers is a particular focus of current organ donation initiatives. Efforts are aimed at increasing organ utilization by centers, more precisely defining transplantability by OPOs, and more efficiently placing and transporting marginal organs to centers willing to use them. To this end, recent emphasis has focused on creating and evaluating opportunities for increased organ utilization by transplant centers.

Efforts and Accomplishments of the Collaborative in the Past Year

In 2003, HRSA, part of the Department of Health and Human Services, joined with key national leaders and practitioners from the nation’s transplantation and hospital communities to launch the Organ Donation Breakthrough Collaborative. The goal of this initiative and its successors, the Organ Transplantation Breakthrough Collaborative (initiated in 2005) and the Organ Donation and Transplantation Breakthrough Collaborative (initiated in 2006), is to increase the number of organs available for transplantation and the number of organ transplants in the United States. This collaborative process has been described elsewhere but is based upon techniques of improvement science described by Berwick (1). These practices include establishment of goals, agreement on best practices, rapid adoption of those practices and a review of the results among the constituencies of the improvement effort. In the transplant community, that constituency has involved OPOs, donor hospitals and transplant centers.

Organs available for transplant increased 24% after the initiation of the Organ Donation Breakthrough Collaborative, with a concomitant decline in deaths on the waiting lists nationally. In 2006, the total number of donors increased to over 700 donors per month for several months in a row. There was a significant increase in all types of donors, with the largest numerical increase seen in SCD.

During the past year, the Organ Donation and Transplantation Breakthrough Collaborative has been charged with meeting the established goals of 3.75 organs transplanted per donor (OTPD) and a 75% conversion rate for all potential organ donors. The conversion 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). The Collaborative has also been tasked with increasing DCD to 10% of all deceased donors without decreasing the number of donors after brain death (DBD). In order to acknowledge different achievable results from each donor type, in 2007 OTPD targets were reset based on organ donor type. New sub-goals of 4.3 OTPD for SCD, 2.5 OTPD for ECD and 2.75 OTPD for DCD were established. Information shared at collaborative learning sessions involved donor management goals to (i) increase the number of organs recovered and improve their outcomes, (ii) define thresholds to increase DCD and (iii) develop recommendations for systems designed to maximize organ acceptance. Unlike previous initiatives, the Organ Donation and Transplantation Breakthrough Collaborative has been actively integrated into the efforts of donation service area (DSA) national improvement leaders, the Organ Donation and Transplantation Alliance, and numerous professional

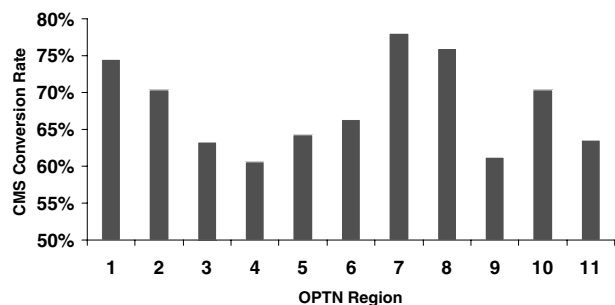


Source: 2007 OPTN/SRTR Annual Report, Table 1.1.

Figure 1: Total number of deceased donors of all organs recovered for transplant, 1997–2006.

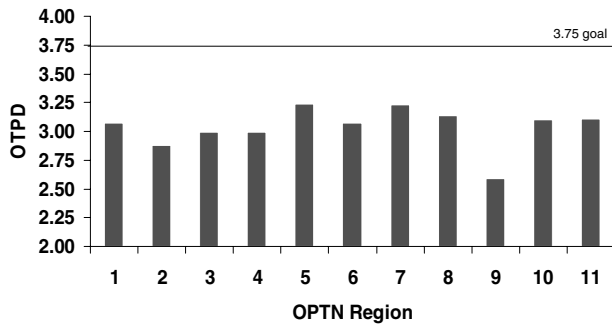
societies such as the American College of Healthcare Executives.

In 2007, the collaborative reached out to the OPTN regional structure to assist in evaluation of performance gaps for donor conversion rates and OTPD and to provide an administrative structure to regionalize collaborative efforts. A meeting was held in April 2007 in Atlanta to perform gap analysis (comparison of the current state versus the desired state of conversion rates) with representatives from OPOs, donor hospitals, transplant centers and the OPTN. By enlisting the established OPTN administrative structure, the collaborative is enabling the transplant centers and OPOs to work together on a regional basis to improve conversion rates in their regions. Using the 8024 deceased donors realized in 2006 (Figure 1), if every OPTN region and DSA met target rates, there would be 5535 more transplants per year, a 23% increase. In Figures 2 and 3, the conversion and OTPD gaps are delineated by OPTN regions, with a wide range of rates for both metrics. Similar variability exists at the DSA level.



Source: 2007 Organ Transplantation Breakthrough Collaborative.

Figure 2: Collaborative conversion rate by region, 2006.



Source: 2007 Organ Transplantation Breakthrough Collaborative.

Figure 3: Actual OTPD by region, 2006.

The current Transplant Growth and Management Collaborative was created in 2007 to focus attention on nationwide transplant center capacity. While there has been an identifiable increase in the number of organs available, it is unclear if transplant center capacity across the country is adequate to use all transplantable organs. The aim of this initiative is to increase the number of organs transplanted at each program by giving centers the tools to examine their own practices. Goals have been set for increasing the number of transplants performed by each center by 50% over the next 5 years. Similar to other collaborative initiatives, transplant centers were identified that were already meeting established goals. These centers were identified by high volumes of transplants, high transplant center growth rates, and low graft failure and patient mortality rates. These centers represented myriad administrative structures, including traditional academic medical centers, for-profit organizations and private-practice centers. Once identified, they were visited by members of the HRSA team, collaborative faculty and an independent consulting group to discern what practices allowed these centers to perform at a high level. The policies, management styles, organizational structure and financial aspects of each center were evaluated. The inclusion of financial practices and efficiency among 'best practices' is noteworthy, amid concerns about the costs associated with increasing use of ECD and DCD organs (2,3). These practices were then vetted through an expert panel in the spring of 2007 to establish a set of 'common drivers of change'.

The most important common feature among high performing centers was a clear and established institutional commitment and vision, such that transplant services were part of the strategic plan of their health systems. Transplant services were recognized by these institutions for both financial contributions to the organization and non-monetary benefits such as trainee education and research opportunities. In most centers, there was a clear, collaborative administrative structure between the chief executive officers (CEOs), chief financial officers and the transplant

center director. High performing centers also focused on recruitment and retention of a dedicated team of proactive personnel, including clinical and administrative leaders, financial and nurse coordinators, pharmacists and physician extenders. There was a clear 'chain of command' in these centers for both clinical and fiscal decisions; there was also a collegial, nonhierarchical team approach to care such that team members were valued for what they could contribute to the overall mission and program. All centers shared a proactive clinical management approach that was learning based, through both experience and knowledge of pertinent medical literature. In most cases, each program had a biweekly or weekly conference to review organs accepted and rejected, with OPO follow-up for those organs transplanted elsewhere. By reviewing these types of program-specific thresholds, organ-acceptance thresholds could be raised or lowered based on the programmatic and literature experience (Table 1).

As with many patient safety initiatives, hospital leadership is being engaged from the outset to ensure that within each institution, programs and teams have sufficient support. Invitations to transplant center CEOs and department chairs to participate in this new effort have been extended across the country by HRSA. Institutional teams have been charged with analyzing the potential for growth and outcomes in their individual transplant programs. Team composition must include a transplant surgeon and/or physician, a transplant coordinator, a transplant administrator, a quality improvement expert and a senior procurement representative from the OPO. Teams from each center and representatives from their OPOs convened a national learning congress in October 2007 to begin the dissemination of best practices and the transfer of knowledge that can lead to an increase in transplant capacity nationally.

Trends in Deceased Organ Donation

Deceased donors

The rate of growth in the yearly number of deceased donors has markedly increased since 2002 (Figure 1), which corresponds to the initiation of the Organ Donation Breakthrough Collaborative. Prior to 2002, deceased donors had increased since 1997 at an average rate of 142 donors per year. Since 2002 that increase has jumped to a yearly average of 459 donors per year. This continued between 2005 and 2006 with an increase of 431 donors to 8024.

While increases are observed in all three donor categories (SCD, ECD and DCD), their distribution among the donor population has changed since 2002. The decline in the percentage of SCD seen since 1997 accelerated in 2002, due to larger increases in the numbers and percentage of ECD and DCD (Figure 4). (In the Annual Report tables, DCD that

Table 1: Best practices from high performing transplant programs from the Transplant Growth and Management Collaborative

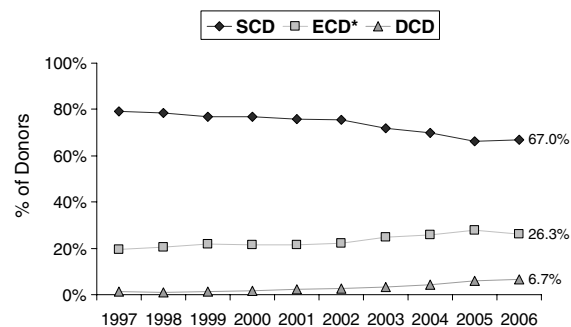
Driver/strategy for change	Key change concepts	Examples of action items
1. Institutional vision and commitment	Establish transplant as a high priority for health systems	Establish transplantation as a priority service for the hospital and set goals for transplant program growth
	Develop a business plan that will secure institutional investment and support	Demonstrate the clinical, economic and nonmonetary benefits of transplant
	Organize transplant services into a service line	Integrate all transplant services into a single service line with designated budget and decision-making authority
2. Dedicated team of personnel	Organize around proactive surgeons and medical doctors	Recruit and retain aggressive, experienced and high-performing surgeons and medical doctors with a passion for, commitment to and focus on growing transplantation
	Recruit, train and retain program staff who are specialized, dedicated and committed	Have transplant program staff that work exclusively on either transplant or one organ-specific transplant program
	Establish and live by a collegial, nonhierarchical team approach to care	
3. Build a financial case	Track and understand your program costs and revenues	Establish the transplant program as a separate cost center
	Negotiate payer contracts with awareness of program finances and strengths	Model contracts and rates after program costs and actual patient resource use
4. Patient and family centered care	Offer a broad array of services	Offer end-stage organ care with transplant services as part of the continuum
	Educate patients and families early and often	Conduct regular, accessible education sessions for potential transplant candidates and their families about the benefits and risks of transplant and the personal and financial commitment required of patients and families
5. Practice case-based learned aggressive clinical style	Create a high threshold for refusing organs	Surgeons take all calls and there is a senior advisor always available
	Be on the cutting edge of research	Participate in innovative clinical trials, new immunotherapy regimes

meet the ECD kidney definition are classified as ECD.) The most rapid numerical increase since 2002 has been in ECD, with an average yearly increase of 186 donors per year compared with an average of 177 SCD and 96 DCD. However, between 2005 and 2006 there was an increase of only one ECD donor, from 2108 to 2109, while SCD increased from 5033 to 5377, a 7% increase. The largest percentage increase in donors in recent years has been in DCD. DCD continues to increase in number, from 452 in 2005 to 538 in 2006 (19% increase).

The number of organs consented (potentially recoverable organs from all donors who have donated at least one solid organ) per year has increased significantly since 2002, with a 34% overall increase (14152 organs) between 2002 and 2006 (Figure 5). A similar trend was seen in the number of organs transplanted per year, which increased by 4051 (20%) between 2003 and 2006. However, the increase was even more pronounced for the number of organs that were not recovered, which increased by 8321 (44%) between 2002 and 2006. Discarded organs increased by 54% (1050 organs) between 2003 and 2006. These trends continued between 2005 and 2006 with an increase of 307 discarded

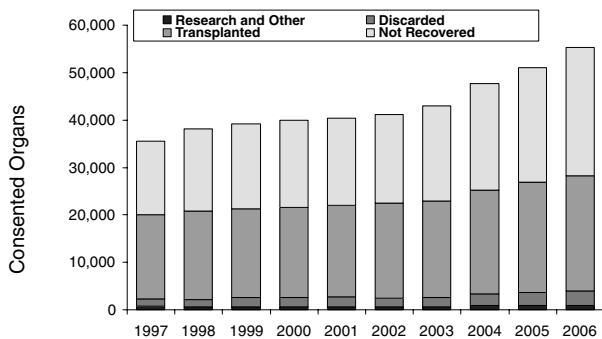
organs, 1123 organs transplanted (21% incremental discard rate) and 2896 organs not recovered.

In 2006, 55360 organs were consented (potentially recoverable), 44% of which were transplanted, 49% not



Source: 2007 OPTN/SRTR Annual Report, Table 2.12; * includes DCD that meet ECD kidney criteria.

Figure 4: Deceased donor population, by donor type and year (percentage).



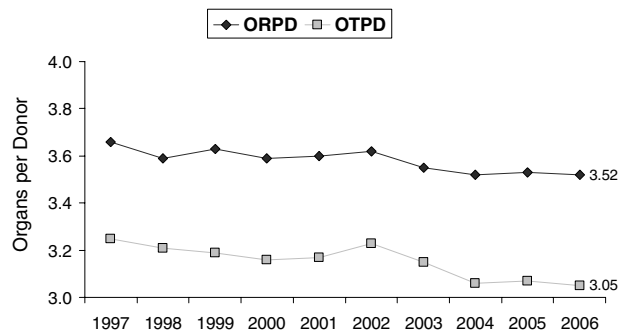
Source: 2007 OPTN/SRTR Annual Report, 3.1, 3.3, 3.4, 3.6, 3.7, 3.9, 3.10, 3.12, 3.13, 3.15, 3.16, 3.18.

Figure 5: Number and disposition of all consented organs* from deceased donors, 1997–2006. (*Potentially recoverable organs from all donors who have donated at least one solid organ.)

recovered, 5% discarded and 1.6% used for research or other purposes. The percentage of consented organs that were transplanted has declined slightly from 49% in 2002, while the percentage not recovered increased slightly to 49% over the same time interval. The percentage of recovered organs discarded has increased from 8% in 2003 to 11% in 2006. These data indicate that while consents, recoveries and transplants are all increasing, rates of nonrecovery and discard are also increasing. This is perhaps not surprising, as the incremental increase in consents and recoveries are likely to be primarily from individuals (and of organs) not previously considered to be suitable for donation (or transplant). It is also important to note that while it is routine to obtain consent for all organs from every potential donor, not every organ from a suitable donor is suitable for transplant.

Even though the numbers of consents, recoveries and transplanted organs have increased, especially since 2002, other important markers of organ donation have not dramatically changed much over the last 10 years (Figure 6). The number of organs recovered per donor (ORPD) and OTPD have declined slightly since 2002. The ORPD dropped from 3.62 in 2002 to 3.52 in 2006, and the OTPD dropped from 3.23 to 3.05. These trends also probably reflect increases in donors that are not multiorgan donors, including significant increases in DCD. Thus, the increase seen in the number of organs transplanted has resulted from increases in consents and recoveries rather than in improvements in their rate of recovery or discard. These trends coincide with the implementation of the Organ Donation Breakthrough Collaborative, and trends in donation and utilization of individual organs tend to follow these overall patterns.

This trend in decrease of ORPD and OTPD is not necessarily surprising, as some of the increase in organ donors is likely to be from older or less healthy donors. In addition to the aging of the US population, incidence and preva-



Source: 2007 OPTN/SRTR Annual Report, Table 2.12.

Figure 6: ORPD, OTPD All Organs, 1997–2006.

lence rates for several chronic diseases are rising. The demographic shifts, individual behaviors and environmental effects combine to create significant negative effects on health outcomes. This burden of chronic disease has a notable impact on the supply as well as the demand for organs. One of the factors limiting the supply of available organs is the number of organs rejected by transplant centers because of poor organ function or an unsatisfactory medical history of the donor related to a chronic disease or other medical condition. While to date, no published descriptive report has looked at the possible impact of chronic disease on organ transplantation and donation in the United States, the disparity between the increase in consented organ donors and the more modest increase in transplants can be at least partially attributed to an overall decrease in organ quality based on chronic disease and the increasing numbers and types of organ donors being considered.

The age distribution of deceased donors is increasing, albeit somewhat slowly. The percentage of donors age 17 years or less was 12% in 2006 compared with 15% in 2002, while the percentage of age group 18–34 years decreased from 28% to 26% over the same time interval. In contrast, the percentage of donors age group 50–64 years increased from 23% in 2002 to 26% in 2006 and those of age 65 years or older increased from 9% to 10%. In the past year, this trend stabilized. There was an increase of 0.7% in donors ages 35 to 49 years, which was matched by a similar decrease in donors ages 65 years or older.

With the changing donor demographic, the cause of death among donors has also shifted. The percentage of donors dying from anoxia has increased over the last 6 years, growing from 10% in 2000 to 17% in 2006. This has been accompanied by a similar decline in the percentage of deaths due to head trauma, dropping from 42% in 2002 to 38% in 2006. The distribution of causes of death in the other categories (cerebrovascular/stroke, central nervous system tumor and other) has remained relatively stable since 1997.

Race, ethnicity and multicultural donation

The number of African American and Hispanic/Latino organ donors each year in the United States has doubled over the past 10 years, while Asian donors have increased by 62%. This growth reflects a combined effect of increases in US multicultural populations and increases in donation rates among two of these three ethnic groups. Specifically, while African Americans constituted 12.2% of the US population in 2000, they made up only 11.9% of donors in that year. By 2006, the African American population had changed only slightly to 12.3%, but African American donors made up 15.6% of total US organ donors. Similarly, Hispanic/Latinos were 12.6% of the population in 2000 and 10.4% of organ donors; by 2006, Hispanic/Latinos were 14.8% of the US population and 13.7% of the donor population. Thus, these two groups have increased in both raw numbers and proportion of donors. The US Asian population has also grown as a percentage of population, increasing from 3.8% in 2000 to 4.4% in 2006, but Asian donors as a percentage of total US donors remained flat at 2.4%, despite a 39% increase in the actual number of Asian donors over the same time period (4).

The sources of this growth, identified by OPO staff and the Organ Donation Breakthrough Collaborative, have come primarily in areas with large concentrations of specific ethnic groups, such as the West and Southwest for Hispanic/Latino donors and the Midwest and eastern urban areas for African American donors. Those OPOs demonstrating the highest rates of increase have routinely focused specific staff and training investments to ensure that approach and consent staff members have language skills and cultural awareness experience and training to address the specific needs of these distinct audiences. Areas with statistically smaller populations of multicultural staff have a harder time allocating resources to serve these groups, as well as difficulty recruiting staff with specific capabilities to fulfill these needs. Thus, need for and experience with serving the specific needs of multicultural communities is strongly associated with improved consent rates among those communities. Another area of OPO and community investment often associated with higher multicultural donation rates is public education, such as paid media advertising and school programs focused on these groups. The data to support these claims remains sparse, but Spanish language donation advertising may show an association with increased consent rates and with significant increases in donor registration during and following focused media buys.

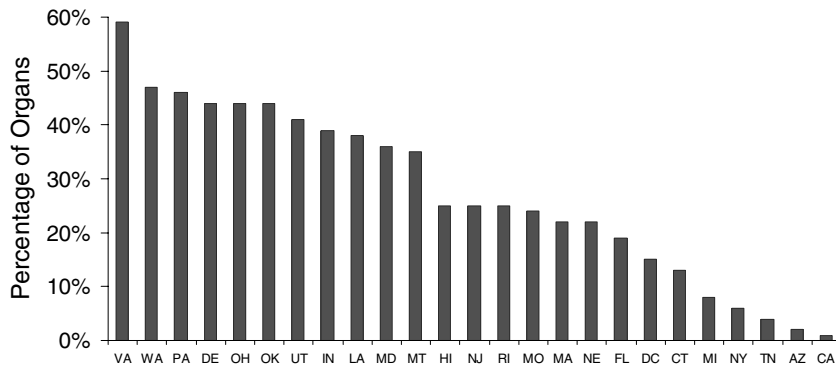
These increases in multicultural donation are substantial and meaningful, though they remain lower than the actual rates of transplantation and waiting list registrations for these groups. In 2006, while African Americans represented 15.6% of donors, the group made up 19.4% of transplant recipients and 27.9% of waiting list pa-

tients. Hispanic/Latinos were 13.7% of donors, 12.5% of recipients and 16.0% of the waiting list population. Asians were 2.4% of donors, 4.4% of recipients and 6.3% of the waiting list patients. The gap between donation rates and transplant rates remains, in part, due to an even greater representation of some groups among waiting list registrants relative to their population proportion. This discrepancy likely reflects a greater burden of chronic disease, which also may limit organ donation potential.

The measure of donation rate relative to potential—first reported in the 2004 edition of this analysis (5)—highlights the opportunity that remains. That measurement, from the Association of Organ Procurement Organizations (AOPO) Death Record Review study, identified that African Americans constituted 20.6% of the potential donors and 12% of donors that year, while whites were 82.8% of donors but only 70.9% of potential donors (6). Similarly, Hispanic/Latino, Asian and 'Other' potential donors for that period made up 8.5% of the US total donor potential, but only 5.2% of actual donors for the period. Thus, while increases in multicultural donation have led to donation rates that often exceed population proportions, disproportionate representation of these groups among potential donors suggests opportunity for further improvement in donation rates among all three ethnic groups.

This gap is currently measured only by individual OPOs tracking consent and conversion rates by race, and it has not been consistently captured in the OPTN reporting procedure. Recently adopted changes in OPTN policy should result in this information being collected for the 2008 calendar year. Having this data may be useful for OPOs, helping them focus donor development efforts, public education campaigns and approach and consent methods of OPO staff. The results of these improvements are underscored by data showing the 16 OPOs with conversion rates of 75% and higher in 2006–2007 (based on data from the Organ Donation and Transplantation Breakthrough Collaborative, using data from hospitals with eight or more eligible deaths). Of this group, the proportion of donors classified as white was as high as 96%, with a mean of 78.5% and a median of 84.8% (7).

These data lead to the conclusion that while substantial progress has been made in the effort to increase multicultural donation, consent and conversion rates among African American, Hispanic/Latino and Asian populations, donation rates for each of these groups still lag behind those of the white population. These data identify opportunity for focused efforts to increase donor designation for these groups on donor registries and for OPOs to tailor and equip approach and consent processes and staff to address the unique information needs and sensitivities of multicultural potential donors and their families.



Source: Donate Life America Donor Designation Collaborative Dashboard Data Snapshot, 2007.

Figure 7: Percentage of deceased organ donors identified by a registry, 10Q 2007.

State donor registries: a critical role

The growth in state-authorized organ and tissue donor registries since 1993 has given donors, families and transplant-related organizations an invaluable tool to help increase consent rates and recovery of organs, eyes and tissues for transplant. Unlike donor cards, computerized state registries do not rely on a paper document that is rarely available when a family is approached for consent. In most states, a donor designation through a state registry constitutes first-person consent that is legally binding and thus cannot be rescinded by family members. In addition, because consent is preauthorized in such cases, the organ placement and recovery process begins sooner, saving precious time that can result in more organs remaining viable for transplant.

As of August 2007, 44 states have registries to sign up designated donors (8). The share of designated donors varied greatly by state, but 16 states have signed up more than half of their licensed drivers as such. The range of licensed drivers registered as donors among established registries runs from California's 2-year old program at 5% to Utah's long-established registry at 71%. Among the 25 states reporting data for the first quarter of 2007, 25% of recovered organ donors were authorized (in first-person consent states) or identified (in intent-only states, i.e., participation-designated intent that carries no legal status) through donor registries (8). This ranges from a high of 59% in Virginia to a low of 1% in California (Figure 7). In addition, of 24 states reporting during the same period, 25% of recovered tissue donors were authorized or identified through registries (8).

The most effective registries are those affiliated with their respective state departments of motor vehicles and offering a check-box sign-up process. A national initiative, Donate Life America's Donor Designation Collaborative, is focused on designing registries to be as effective as possible and sharing best practices to meet the national goal of 100 million actionable donor designations.

These data indicate that donor registries are beginning to play a critical role in donation and transplantation and should be expected to be of growing significance as the Donor Designation Collaborative continues to share registry best practices in the coming years.

DonorNet 2007

One of the most notable recent developments in organ donation has been the introduction of DonorNet 2007, which was developed by the United Network for Organ Sharing. By permitting the simultaneous electronic notification of organ offers, this system represents a fundamental change in the organ placement process, one designed to improve efficiency and therefore utilization.

Because DonorNet 2007 makes it possible to make multiple offers simultaneously, the extraordinary increase in the volume of offers has resulted in unwanted offers for many centers. In response to feedback from the transplant community, the OPTN has implemented mechanisms that increase the flexibility of the system by allowing transplant centers to be more specific and selective in the offers they will receive for their candidates. These modifications should enable users to tailor the system to their needs; the current emphasis is on the addition of capabilities to allow centers to restrict the offers made for their patients to those they are most likely to accept. A specific example is the change that allows centers to specify distance for kidney/pancreas and pancreas offers for their respective centers; this modification resulted in a 24% decrease in pancreas offers. Another recent modification permits transplant center organ-specific acceptance criteria to be separated between local and import offers, which is likely to significantly decrease the number of unwanted organ offers. Future implementations may allow centers to stratify organ acceptance criteria by candidate.

The OPTN has been working in conjunction with the leadership of AOPO through its Procurement Council to disseminate best practices and lessons learned in

using DonorNet 2007 so that organs are placed efficiently. Additional upgrades are a result of specific feedback that the transplant community has provided to OPTN staff and the Electronic Organ Placement Working Group. These measures should help reduce the required resources devoted to organ offer evaluation and acceptance that may have transiently increased under the new system. Equally important, the elimination of unwanted offers should enhance the efficiency of organ placement by restricting offers to those centers most likely to accept them. Such efficiency should reduce times to offer, increase acceptance rates, reduce discard rates, decrease cold ischemia times and improve outcomes.

Organ-specific deceased donation and utilization

While the overall patterns of increase in consent and utilization for specific organs parallel those for organ donors in general, organ-specific considerations may affect how these patterns are reflected in specific utilization metrics. Lack of use can be reflected in either nonrecovery or discard (research use also represents a small percentage of those organs not transplanted). Whether an organ is not recovered or is discarded depends on donor-specific factors, but may also be determined by how organs are evaluated. For organs that are evaluated exclusively either preoperatively or intraoperatively by the transplanting center, such as heart, liver, lung and intestine, lack of use is much more likely to take the form of nonrecovery, and corresponding discard rates are low (<5%). In addition, the discard rate of <1% for hearts is likely to reflect the limited cold ischemia time and corresponding logistic constraints. For some organs, such as kidney and, to a lesser extent, pancreas, an important part of the evaluation process occurs postrecovery, and the organs are often recovered by teams not affiliated with the transplant center. These organs are much more likely to be recovered and subsequently discarded; thus their discard rates are higher (>10%).

To place donation and utilization trends in context with the overall imbalance of organ supply and demand, waiting list data are provided below for each organ type.

Deceased kidney donation and utilization. The number of candidates on the kidney transplant waiting list stood at 66961 at the end of the year 2006, an increase of 88% since 1997. In 2006, there were 15630 potentially recoverable (consented) kidneys. Of these, 1348 (9%) were not recovered, 2127 (14%) were recovered but discarded and 11906 (76%) were transplanted, all increases over 2005. The percentage of kidneys that were not recovered has gradually increased from 6% in 1997 to 9% in 2006. This is much lower than the overall average nonrecovery rate of 49%. The percentage of recovered kidneys that were discarded has gradually increased from 10% in 1997 to 16% in 2006. Despite the increase in discard rate, the large increase in recovered kidneys since 2002 has resulted in a corresponding increase in the number of kidneys trans-

planted, from 9694 in 2002 to 11906 in 2006, a 23% increase. The percentage of consented kidneys that were transplanted in 2006 (76%) was high relative to the overall average of 44% for all organs.

Since 2002, of 3086 additional kidneys recovered, 1218 of these have been SCD kidneys, 1137 ECD and 731 DCD. The combined ECD and DCD contributions represent almost 61% of the increase during that time. However, of the 969 additional kidneys recovered between 2005 and 2006, 651 (67%) were SCD, 133 (14%) were ECD and 185 (19%) were DCD. Together ECD and DCD kidneys now represent almost 31% of all kidneys recovered. While the percentage of recovered SCD and ECD kidneys that were transplanted decreased in 2006 from the previous year (91.7% from 91.9% and 57.9% from 59.4%, respectively), the percentage of recovered DCD kidneys transplanted increased from 82% to 86%. These trends indicate that the continued expansion of the DCD kidney donor pool includes a greater percentage of kidneys likely to be transplanted than for SCD and ECD, where increases in recoveries have outpaced increases in transplants.

Organ preservation solutions and pumping of kidneys.

Viaspan, also known as University of Wisconsin solution or Belzer's solution, has been the primary flush solution for abdominal organs over the past decade in the United States. Custodiol, also known as HTK (histidine-tryptophan-ketoglutarate) solution, had been used extensively in Europe, and was recently approved by the FDA for use as an organ preservation solution in this country. Trends in kidney flush solution use, recorded by OPO as the final flush solution, indicate an increase in the use of Custodiol and a decrease in the use of Viaspan during the last 3 years (Figure 8) (SRTR analysis, May 2007), with Viaspan accounting for 63% of flushed kidneys, Custodiol 28% and 'others' or 'no flush' 9% (SRTR analysis, July 2007). An SRTR analysis of final flush solution of kidneys and delayed graft function (DGF) found no difference in DGF rates between Viaspan and Custodiol (OPTN Organ Availability Committee [OAC] Report of 10/31/2006).

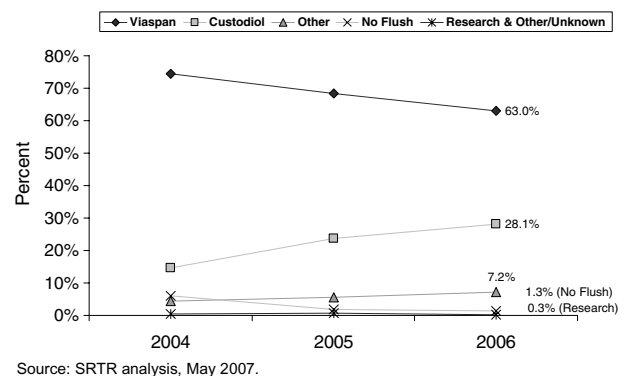


Figure 8: Flush solutions for recovered kidneys, 2004–2006.

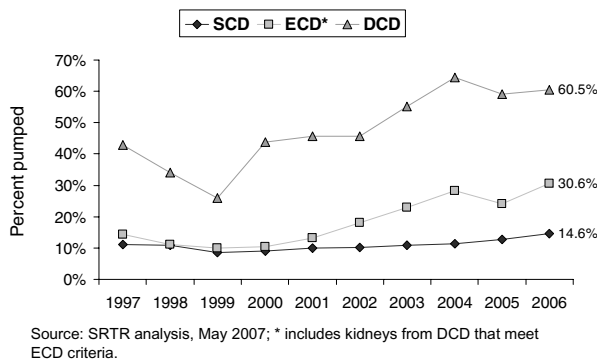
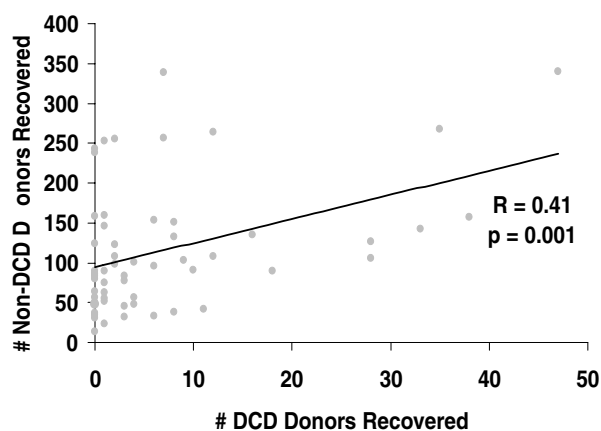


Figure 9: Kidney pumping trends.

As experience grows with the use of Custodiol, more information on graft survival should be available.

While a few centers have consistently used pumping for nearly all recovered kidneys, the majority of kidneys recovered over the last decade were not pumped. With the recovery of a greater number of ECD and DCD kidneys, there has been renewed interest in the use of pumping, not only to improve vasospasm and reduce DGF, but also to assess vascular resistance as a method to identify kidneys that may not be suitable for transplant. The greatest increase in pumping over the last decade has been for ECD and DCD kidneys, with upward of 60% of recovered DCD kidneys now pumped (Figure 9) (SRTR analysis, May 2007). An SRTR analysis of pumping data from 2004 to 2006 found that the overall impact of pumping on DGF appears to be significant. If the pumping is initiated at the time of recovery by the OPO, the rate of DGF for SCD kidneys is 15% compared with 24% for those not pumped (OAC Committee Report of October 31, 2006). Interestingly, there was not a significant decrease in DGF rates for DCD kidneys



Source: SRTR analysis, 2005.

Figure 10: Relationship between DCD and non-DCD recovered in 2004 (N = 59 DSAs).

that were pumped, with a DGF rate in these kidneys of around 40%. There were also no trends in the risk of graft failure for either increasing cold ischemia time or pumping category for any type of kidney. Therefore, the ability of pumping to decrease DGF for DCD or to improve graft failure outcomes for DCD or ECD kidneys was not demonstrated. Further discussions regarding the role of pumping, and the possibility of a pumping mandate, continue.

Deceased liver donation and utilization. At the end of 2006, 16 861 candidates were on the liver transplant waiting list, an 82% increase from 1997. In 2006, of 7888 consented livers from organ donors, 6360 (81%) were transplanted, 431 (5%) were discarded and 804 (10%) were not recovered. These are all increases from 2005. The non-recovery rate has declined slightly from 12% in 1997 to 10% in 2006.

The percentage of recovered livers that are discarded has remained relatively low over the 10-year interval, and was 6% in 2006. The increase in recovery since 2002, coupled with the low discard rate, has resulted in a 28% increase in transplanted livers between 2002 and 2006. The 81% transplant rate among consented livers in 2006 was much higher than the overall average of 44% for all organs. The number of recovered DCD livers increased by about 5%, from 389 in 2005 to 407 in 2006, and now represents 6% of all recovered livers and 63% of all DCD donors. Overall, 89.9% of recovered livers were transplanted in 2006, a decrease of 0.4% from 2005. While this percentage decreased from 91.6% to 91.1% for DBD, it increased from 69.7% to 71.0% for DCD donors.

Deceased pancreas donation and utilization. At year-end 2006, there were 600 candidates on the waiting list for a pancreas transplant alone, 994 candidates on the waiting list for a pancreas after kidney transplant and 2360 candidates on the waiting list for a simultaneous kidney-pancreas transplant. These figures represent increases of 167%, 572% and 58%, respectively, from 1997. Although the number of potentially recoverable pancreata increased by 1839 (39%) between 2002 and 2006, most of these organs have not been recovered: the number of pancreata recovered increased by only 154 between 2002 and 2006. The nonrecovery rate among pancreata is high and has been increasing since 2002, from 60% to 69% in 2006. The discard rate among recovered pancreata has also increased gradually from 11% in 1997 to 18% in 2006. These trends have resulted in the number of transplanted pancreata remaining relatively unchanged since 2002, after a 38% increase between 1997 and 2002. In 2006, there were 6524 pancreata consented, with 366 (6%) discarded, 4498 (69%) not recovered and 1404 (22%) transplanted. In 2006, 59 pancreata were used for islet transplantation, a decrease from a high of 90 in 2002. The 22% transplant rate is lower than the average of 44% for all organs. Recovered DCD pancreata increased dramatically over the past 10 years from 4 to 73. The 73 DCD pancreata recovered in 2006 represent 4% of the total. Of these recovered DCD

pancreata, 35 were transplanted (48%), compared with 32 in 2005.

The low recovery and transplant rates of deceased donor pancreata are a focus of OPTN allocation policy efforts (9). Pancreas recovery and transplantation are also characterized by extensive regional variation in these markers of utilization, and efforts to facilitate the rapid placement of pancreata to high volume regions and centers are being investigated. The effectiveness of the electronic notification system implemented in DonorNet 2007 regarding the placement of pancreata will undoubtedly be assessed in the next few years. The low utilization of pancreata from donors older than 50 years and with a body mass index greater than 30 provided the basis for a modification of the OPTN pancreas allocation algorithm in 2006 to prioritize these donors for allocation for islet transplantation after local whole pancreas transplant.

Deceased heart donation and utilization. At the close of 2006, 2814 candidates were on the heart transplant waiting list, down 26% since 1997. The number of potentially recoverable (consented) hearts increased by 1583 (36%) between 2002 and 2006. In 2006, of 6019 hearts from organ donors, 2220 (37%) were transplanted, 12 (0.2%) were discarded and 3744 (62%) were not recovered. Since 2004, the number of transplanted hearts has increased only slightly from 2055 to 2220 in 2006. The increase in consents has not translated into an increase in transplants due to a nonrecovery rate that has been growing since 2001. The discard rate for recovered hearts has remained very low since 1997, less than 0.7%.

Deceased intestine donation and utilization. At the end of 2006, 238 candidates were on the intestine transplant waiting list, an increase of 171% since 1997. In 2006, of 6145 intestines from organ donors, 172 of these (3%) were transplanted, eight (0.1%) were discarded and 5961 (97%) were not recovered. While the number of available intestines has increased dramatically since 2002 (by 2074 organs, a 51% increase), most of these organs were not recovered; intestines have the lowest recovery rate of any organ (between 2% and 3.5% over the last 10 years). This is a result of the small numbers of candidates on the waiting list and the limited number of programs performing intestinal transplants. However, because of the historically low discard rate among recovered intestines (4% in 2006), the increase in recoveries has resulted in an additional 66 organs transplanted in 2006 (62% increase) compared with 2002.

Deceased lung donation and utilization. At the close of 2006, there were 2857 candidates on the lung transplant waiting list, an increase of 11% from 1997, but a decrease from 3124 candidates in 2005, when the Lung Allocation Score was introduced. In 2006, of 13154 lungs from organ donors, 2360 of these (18%) were transplanted, 46 (0.35%) discarded and 10694 (81%) not recovered. With a marked increase in the number of lungs consented since

2002 (3212 lungs, a 32% increase) and a very low discard rate among recovered organs (under 5% since 1997), the percentage of lungs transplanted has increased since 2002, despite a historically low recovery rate between 15% and 20%. The 2360 lungs transplanted in 2006 reflect an increase of 739 organs (46%) over 2002. The contribution of DCD lungs remains low but continues to grow slowly, up from 16 lungs recovered in 2005 to 22 lungs recovered in 2006. This represents less than 1% of the total recovered. All 22 lungs recovered from DCD in 2006 were transplanted.

DCD trends and impact on donation after brain death

DCD have increased 15% (from 561 to 645) from 2005 to 2006. Concerns have been raised that this increase has occurred at the expense of non-DCD, since theoretically some DCD could progress to DBD if DCD did not occur. Since ORPD and OTPD are lower for DCD, this has potential implications for organ utilization. With implementation of the first accreditation standard for DCD by the Joint Commission, clarification of this issue is important. The relationship between DSA donation rate (defined as the number of donors meeting eligibility criteria [non-DCD, age ≤ 70 years divided by the number of eligible deaths]) and DCD as a percentage of total donors is neutral, indicating that non-DCD donation is not necessarily a driving force for increased DCD (SRTR analysis, April 2005). Indeed, the 16 DSAs accounting for 80% of DCD show an increase in all donor types, namely SCD, ECD and DCD. In 2004, donation counts for non-DCD versus DCD in the 59 DSAs were positively correlated ($R = 0.41$, $p = 0.001$) (Figure 10) (SRTR analysis, April 2005). This indicates that DSAs that increased DCDs had a corresponding increase in non-DCDs. The same relationship was demonstrated when the analysis was repeated with SCD only (excluding ECD) versus DCD ($R = 0.39$, $p = 0.004$, not shown). Finally, there was no relationship demonstrated between the DSA change in DCD between 2003 and 2004 and the change in DBD over the same interval, indicating that DSAs that increased DCD appeared not to do so by preempting DBD (SRTR analysis, April 2005).

Trends in Living Donation

The number of living donors declined for the second consecutive year, after increasing by 73% since 1997. There were 6732 living donors in 2006, down 166 (2%) from 2005. This trend, combined with the recent increase in deceased donors, has resulted in the number of deceased donors exceeding the number of living donors for the third straight year. Since 1997 the vast majority of organs from living donors have been kidneys (96% in 2006), followed distantly by livers (4% in 2006), and last (less than 0.1%) by other organs. The small decrease in living donors in the past 2 years may represent a saturation point in the supply of living donors, or it may be related to the increase in transplants from deceased donors. An important

potential influence is the increased emphasis at multiple levels (transplant community, regulatory agencies, media) on preserving the health of the living donor.

Living kidney donation

After growing from 3933 donors in 1997 to 6647 donors in 2004, living kidney donation leveled off and has since declined slightly to 6436 donors in 2006. The percentage of donors in the age group 50–64 years has increased gradually over the past decade to 22% in 2006, up 1% from 2005. Between 2005 and 2006 the percentage of donors in the 18- to 34-year age group remained unchanged at 32%, while donors in the age group 35–49 years declined to 46%. The youngest and oldest age categories continue to be represented by only a small fraction of donors; there were no donors in the 11- to 17-year age group in 2006, and only 1% of all donors were older than 65 years.

The number of full sibling and parent living donors has not changed much over the last 10 years, but the percentage of all donors in those categories has declined as other donor relationships have become more common. Although there are still more living kidney donors in the 'full sibling' category than any other, they declined from 40% of all donors in 1997 to 25% in 2006. The percentage of parent living donors has dropped from 19% in 1997 to 10% in 2006. The percentage of 'spouse unrelated' and 'other relative' donors has remained relatively constant over the past 10 years. The most dramatic increase has come from 'other unrelated' donors, which has increased from 274 in 1997 to 1538 in 2006, and now represents 24% of all donors, the second largest category. These types of donors may include friends, co-workers, and also nondirected or 'Samaritan' donors. Offspring living donors represent the third largest category, unchanged at 18% for the last 2 years.

The race and sex distribution of living kidney donors has not changed significantly over the last 10 years. The majority of donors have been white, representing about 69% to 71% of the total. African American and Hispanic/Latino donors have each made up similar proportions, around 13–15% and 11–13%, respectively. Asian donation has ranged between 3% and 4%, while donors in the 'other/multi-racial' and 'unknown' categories have never represented more than 1% of all donors. Female donors have been more common over the decade, ranging from 57% to 59%.

Living liver donation

The number of living liver donors decreased slightly to 287 in 2006, from 323 in 2004 and from a high of 520 donors in 2001. The composition of the living liver donor population has changed over the past decade. In 1997, 84% of living liver donors were parents. By 2006, due to the increase in the performance of adult living donor liver transplantation, this dropped to 17%, the same percentage as full sibling donors and 'other unrelated' donors. Offspring now rep-

resent the leading category of living liver donors, 27% in 2006. 'Other relative' donors make up an additional 12% of all living liver donors in 2006, and spousal donors make up 5%. In 1997, 71% of living liver donors were in the age group of 18–34 years, almost 26% were in the 35- to 49-year age group, and less than 4% were in the age group of 50–64 years. By 2006 the percentage of donors in the 18- to 34-year group dropped to 49%, the percentage who were 35–49 years increased to 36% and the percentage in the 50- to –64-year group gradually increased to 15%. These age trends indicate a steady increase in the average age of living liver donors over the last 10 years. The demographics of race and sex have remained relatively stable in the living liver donor population in the same period. The percentage of white donors in 2006 was 81%, increased only slightly from 77% in 1997. Just more than half (51%) of living liver donors were females in 2006. In 2006, the most common diagnoses for living donor liver recipients were noncholestatic cirrhosis (40%), cholestatic liver disease/cirrhosis (23%) and biliary atresia (13%). This represents a marked difference from 1997 when biliary atresia accounted for 57% of living donor liver recipient diagnoses, compared with noncholestatic cirrhosis at 9% and cholestatic liver disease/cirrhosis at 5%. The diagnosis of 'malignant neoplasms' among living donor liver recipients started at a low of 2% in 1998, spiked to its highest point of 9.1% in 1999 and then fluctuated over the years and was at 8.7% in 2006.

Living pancreas donation

There was only one living donation of a pancreas in 2006.

Living lung donation

For the second year in a row, the number of living lung donors has been very small. There were only five living lung donors in 2006 and two in 2005, after dropping from 25 to 29 living lung donors per year between 2002 and 2004.

Paired kidney exchange

Willing living kidney donors found to be incompatible by blood type or cross-match with their planned recipient could potentially donate to another unrelated compatible recipient who also has an incompatible donor, thereby setting up a paired kidney exchange. Over the last few years, there has appeared to be a growing interest in establishing paired exchanges within transplant programs, within regions and possibly on a national level. With increasing numbers of donors and recipients entered into such a program, the chances of finding compatible pairs or even multiple exchange possibilities (three-way or four-way exchanges) increases (10). Unfortunately, the concept of this exchange of kidneys was felt to possibly assign a value to an organ, which is not allowed under the National Organ Transplant Act (NOTA) passed in 1984. The Department of Justice ruling in March 2007 that kidney exchange programs do not violate NOTA has paved the way for the further

development of paired exchange programs. In addition, the passage of the Charlie W. Norwood Living Organ Donation Act by unanimous vote both in the House of Representatives and in the Senate further removes legal obstacles to paired donation, if enacted.

Paired exchange has not yet enjoyed widespread application, with only 165 recipients undergoing paired exchange transplant in the United States through 2006 (11). Several consortia have been established, and other single center programs have been established as well, using variations of computer matching programs to identify pairs within the center's list. The drive to establish a national program remains in the discussion and planning phase.

Before a nationwide program could be established, several issues with exchanges between patients at different centers need to be settled. These include the level of work-up needed before a 'pair' is entered into the database for matching; the logistics (and willingness) of donors and recipients to travel, and of centers to ship kidneys (12); the issue of dealing with levels of comfort on the part of various programs with proceeding with a given transplant; and lastly how to handle the added expense and manpower needed to allow such a complex program to run efficiently. The role of paired donation over list-paired donation schemes is also a controversial point that has an effect not only on the success of paired exchanges, but also on waiting times for deceased donor recipients, especially in blood group O. The exact impact of these exchange programs on overall transplant rates remains to be seen.

Reimbursement of living organ donors

The receipt of valuable consideration in exchange for organs is specifically prohibited by NOTA. However, ethically and legally acceptable compensation mechanisms for expenses or other financial losses incurred by donors and their families as part of the donation process are being considered.

In 2006, HRSA awarded a grant to provide reimbursement of travel expenses and subsistence costs for living organ donors, removing an important financial disincentive to living organ donation. Awarded to the American Society of Transplant Surgeons (ASTS) and the University of Michigan, the grant will provide resources for the project team and HRSA to develop an efficient national system to identify potential living organ donors facing financial hardship in meeting travel and subsistence expenses associated with the process of evaluation and undergoing live organ donation procedures.

Under provisions of the grant, a National Living Donor Assistance Center will be established, and the vast majority of the \$8 million grant will be used for direct reimbursements to potential and actual living donors. The impact of the reimbursement program on facilitating live organ do-

nations that would not otherwise have been possible will be a specific research question. It is estimated that the grant will make live organ donation possible for an additional 800–1000 individuals annually.

Summary

Rapid increases in deceased organ donation have been achieved since the implementation of the Organ Donation Breakthrough Collaborative in 2003, and have largely been attributed to this effort. While on a percentage basis the greatest recent increase has been in DCD, the greatest numerical increase has actually been from SCD. Meaningful increases in multicultural donation have been achieved. The continued development and effectiveness of donor registries have also contributed to the increase in organ donation, with about 25% of donors having participated in a registry (8).

This increase in organ donation has resulted in a corresponding increase in the numbers of kidney, liver, lung and intestine but not heart or pancreas transplants. However, even for organs where transplants have increased, discard and nonrecovery rates generally have not improved, which has resulted in a decrease in the ORPD and OTPD. Thus, the incremental increases in consent and recovery have exceeded those in utilization, and waiting lists for most organs continue to increase. Efforts at increasing utilization, such as perfusion of kidneys and the electronic notification system implemented in DonorNet 2007, continue to be developed. Other mechanisms designed specifically to reverse the decline in living donation, including living paired donation of kidneys and enhanced incentives to organ donation, are also being pursued.

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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, 1.3, 1.4, 1.10, 2.1, 2.9, 2.10, 2.11, 2.12, 2.13, 2.14, 2.15, 2.18, 3.1, 3.3, 3.4, 3.6, 3.7, 3.9, 3.10, 3.12, 3.13, 3.15, 3.16, 3.18 and 9.4b*. All of these tables may be found online at: www.ustransplant.org.

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