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Organ Donation and Utilization, 1995–2004: Entering the Collaborative Era

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Continued progress in organ donation will help enable transplantation to alleviate the increasing incidence of end-stage organ disease. This article discusses the implementation and effect of the federally initiated Organ Donation Breakthrough Collaborative; it then reviews organ donation data, living and deceased, from 1995 to 2004. It is the first annual report of the Scientific Registry of Transplant Recipients to include national data following initiation of the collaborative in 2003. Prior to that, annual growth in deceased donation was 2%–4%; in 2004, after initiation of the collaborative, deceased donation increased 11%. Identification and dissemination of best practices for organ donation have emphasized new strategies for improved consent, including revised approaches to minority participation, timing of requests and team design. The number of organs recovered from donation after cardiac death (DCD) grew from 64 in 1995 to 391 in 2004. While efforts are ongoing to develop methodologies for identifying expanded criteria donors (ECD) for organs other than kidney, it is clear DCD and ECD raise questions regarding cost and recovery. The number of living donor organs increased from 3493 in 1995 to 7002 in 2004; data show trends toward more living unrelated donors and those providing non-directed donations.

Note on sources: The articles in this report are based on the reference tables in the 2005 *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, 1.7, 2.1–2.14 and 3.3. All of these tables may be found online at http://www.ustransplant.org.

Key words: Deceased donors, donation after cardiac death (DCD), donation service area (DSA), expanded criteria donors, living donors, organ donation, Organ Donation Breakthrough Collaborative, organ procurement, organ procurement organization (OPO) SRTR

Introduction

Despite remarkable clinical and scientific advances in organ transplantation, organ donation continues to limit transplantation from reaching its full therapeutic potential. To address this problem, numerous initiatives aimed at improving organ donation have been introduced over the past decade. Among these are programs to educate the general public, improve minority participation, secure the involvement of key medical professionals and assure that all potential donors are identified and referred in a timely manner for management by organ donation specialists. Between 1995 and 2003, these efforts resulted in 2–4% annual growth in the number of deceased donors. In 2004, however, a dramatic increase of 11% in deceased donation was seen over the previous year. This 2004 total of 7152 deceased donors represents the first time that more than 7000 such donors were realized in a calendar year and the first time since 2000 that the number of deceased donors outnumbered living donors. These changes followed closely upon the April 2003 introduction of the Organ Donation Breakthrough Collaborative by the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA). This initiative represents the most significant commitment by the Federal Government to improve organ donation since passage of the Organ Procurement and Transplant Network (OPTN) Act of 1984. The charge of the collaborative is to identify the best practices of organ donation in the country and disseminate them rapidly throughout the organ procurement community.

The effect of these various efforts on organ donation and future goals can only be determined through rigorous ongoing analysis of national organ donor data. This report reviews the current organ donation process in the United States and introduces the Organ Donation Breakthrough Collaborative. Subsequent sections of this article examine trends for the past 10 years of consent for donation and the recovery and disposition of living and deceased donor

organs. This is the first annual donor report that includes a full year's data following the onset of the collaborative.

Unless otherwise indicated, the statistics in this article are drawn from the reference tables in the *2005 OPTN/SRTR Annual Report*. Please see the article 'Analytical Methods and Database Design: Implications for Transplant Researchers, 2005' in this report for an explanation of the methods of data collection, organization and analysis that serve as the basis for this article (1). Additional detail on the methods of analysis employed herein may be found in the reference tables themselves or in the technical notes of the *OPTN/SRTR Annual Report*, both available online at http://www.ustransplant.org.

Organ Donation: OPO to DSA

The United States is served by 58 organ procurement organizations (OPOs), entities that are designated by the Centers for Medicare and Medicaid Services (CMS) to provide donor services within defined geographic areas. Prior to the collaborative, the success of a region's organ donation services was considered the responsibility of its OPOs. With the collaborative came the recognition that successful organ donation is the joint responsibility of the OPO, its geographically proximate transplant center(s), and the donor hospitals that it services in the region. These three entities constitute a donation service area (DSA); each component plays a key role in the donation process. OPOs are responsible for providing state-of-the-art community and hospital donor education, donor management services, stewardship of the donated organ and fair and equitable distribution practices, set in accordance with OPTN policies. Transplant centers are responsible for providing state-of-the-art management, consultant and procurement services, as necessary; centers also must assure optimal utilization of the donated organs. Finally, donor hospitals are responsible for identifying all potential donors and for facilitating donor assessment, management, testing and organ procurement, as needed. Together, the 58 national DSAs define the U.S. working transplant community (Figure 1).

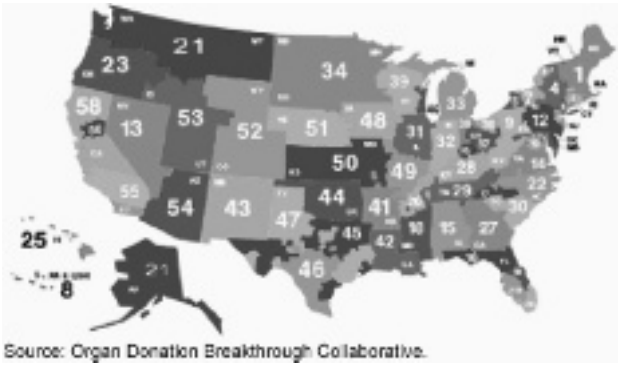


Figure 1: Donation service areas in the United States, 2005.

The Organ Donation Breakthrough Collaborative

Overview of the collaborative

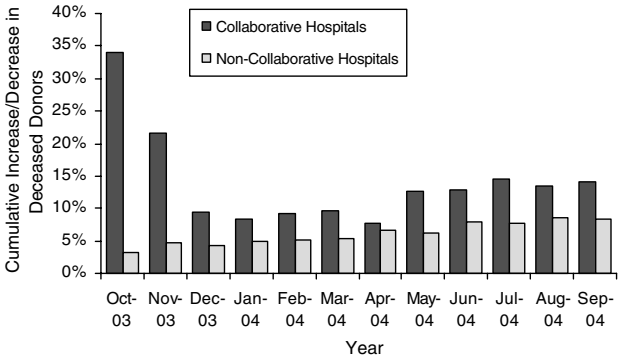
To fully appreciate the forces currently driving organ donation, it is necessary to have a working understanding of the collaborative process. The collaborative methodology was developed by the Institute for Healthcare Improvement in the early 1990s (2). The purpose of a collaborative is to facilitate breakthrough changes in the performance of organizations, based on their adoption of proven practices from top performers in the field. Specifically, the aim of the Organ Donation Breakthrough Collaborative is to save or enhance thousands of lives a year by spreading known best practices of organ donation to a group of the nation's hospitals with the greatest potential for organ donation. The goal established for the initiative was to achieve organ donation rates of 75% or higher in these hospitals. This goal was not arbitrary. It was chosen as ambitious, yet within the reach of the highest performers in the field. Furthermore, this target was not achievable through simple incremental annual change; it required creative, breakthrough thinking to accomplish. HHS and key leaders from national health care organizations, including the Association of Organ Procurement Organizations, the Joint Commission on the Accreditation of Healthcare Organizations and the Institute for Healthcare Improvement, publicly committed to the goal.

Breakthrough methodology

According to the methodology of the collaborative (2), expert faculty members are chosen, teams from the institutions of interest are established, and strategies to achieve the targeted goal are developed by the participants. These strategies are then put into practice, tested and modified, if necessary. Finally, successful practices are spread to other institutions. This last step is key to the collaborative process, as it makes possible immediate improvement for every participant involved.

Team formation

Two Organ Donation Breakthrough collaboratives have been conducted to date, and a third began in October 2005. Collaborative 1 ran from September 2003 through September 2004. This event targeted the 300 hospitals in the nation with the greatest potential for donation. Team members came from 95 of the 300 donor hospitals and the 43 OPOs affiliated with them. Collaborative 2 ran from September 2004 through May 2005. The cross-organizational teams for this collaborative included participants from 131 of the nation's 500 largest hospitals and the 50 OPOs affiliated with them. Collaborative 3 ascribes the new goal of improving 'yield' (the number of organs procured and transplanted) from each donor and brings transplant centers more fully into the process.



Source: Organ Donation Breakthrough Collaborative.

Figure 2: Cumulative increase/decrease in deceased donors in collaborative versus non-collaborative hospitals, by month.

Results of the first collaboratives

Ultimately, of the 552 largest U.S. hospitals collectively targeted by the first two collaboratives, 184 met and sustained the goal of a 75% conversion rate for a period of 12 months. (The conversion rate, also called donation rate, is calculated as the number of actual donors age 70 years or younger from whom at least one organ is recovered for the purpose of transplant divided by the total number of eligible deaths.) During the timeframe of the first collaborative, participating hospitals achieved a 14% increase in the number of deceased donors, compared with their own performances for the same period the prior year. The increase for hospitals not in the collaborative was 8% (Figure 2).

It is noteworthy that non-participating hospitals saw an 8% increase in donors over the prior year. This increase, which was far in excess of increases in previous years, was consistent with the anticipated result of the spread of successful practices to donor hospitals by the OPOs that worked within the collaborative.

Trends in Organ Donation

OPO/DSA donor activity

Overall, the trend in OPO recovery data was upward over the past 10 years. When comparing the most recent 3 years of data, 24 OPOs (41%) had 2 consecutive years of growth. Only five (8%) had 2 consecutive years of decline (Table 1). The high percentage of OPOs experiencing consecutive years of growth suggests that the increase nationally in both the number of deceased organ donors and organs transplanted from deceased donors is a broad-based trend; this is indicative of a healthy organ procurement system with good prospects for further growth.

Consent

Important strides in improving the consent rate were made during the past 10 years. The conversion rate for donors was 40% in 2001, the first year this statistic was recorded.

Table 1: Growth and decline in OPO recovery, 2003–2004

Pattern of recovery	Number of OPOs	Percentage of total
Two consecutive years of growth	24	41%
Two consecutive years of decline	5	8%
Growth in 2003 and decline in 2004	12	20%
Decline in 2003 and growth in 2004	14	24%
Growth in 2003 and no change in 2004	1	2%
No change in 2003 and decline in 2004	1	2%
No change in 2003 and growth in 2004	2	3%
Total	59	100%

Source: SRTR analysis, August 2005.

From 2002 to 2003, the conversion rate increased by 1.6%, and in 2004, it increased by 4.6%. For the first 4 months of 2005, the conversion rate is up 5.2% over 2003 (Table 2). Of particular interest were best practices identified by the collaborative that targeted specific impediments to consent, including minority participation and approach to the family.

Minority participation: Historically, minority consent rates have lagged behind those of the general population. Though there have been varying approaches and viewpoints over the years, best practices aimed at providing consent requestors of racial/ethnic backgrounds matched to those of the potential donor family have evolved in the last decade and are generally well accepted as addressing the issue of minority consent. Likewise, trained requestors speaking various languages other than English, most notably Spanish, have been employed to reach out to non-English speaking families (3–6).

Decoupling: Those analyzing best practice strategies have focused attention on the timing of requests to the families of potential donors. The technique of 'decoupling' for many years was considered optimal. This strategy entails separate conversations with the family, first informing family members of the patient's death and only later making the request for donation, a request often presented by a different person. In other words, the family would be notified of the death by a physician, who would explain and answer questions about the diagnosis of brain death. Following a time lapse, another individual or group of individuals would request permission for organ donation. This timing was considered successful by most, though not all, throughout much of the last decade or more (7–9). More recently, timing started to be addressed under the umbrella of so-called 'appropriately timed' requests. Instead of considering that the best time for approach would always be after a discussion of death and always after a time lapse, it was recognized that a better time to discuss donation is when a family is ready to make end-of-life decisions, a time that varies widely from one family to the next. In some cases, the discussion of donation options, including donation after cardiac death (DCD), occurs well before potential donors have reached brain death (if, indeed, they ever do). What is key are the actions and statements by family

Table 2: Reported eligible deaths, actual donors, and conversion rate August 2001–April 2005

	August–December 2001	2002	2003	2004	January–April 2005
Actual donors ≤ 70 years	2397	5746	5911	6448	2204
Reported eligible deaths	6021	11419	11394	11420	3856
Conversion rate	39.8%	50.3%	51.9%	56.5%	57.2%

Source: Organ Donation Breakthrough Collaborative.
Conversion rate = Actual donors ≤70 years/reported eligible deaths.

members, which indicate their readiness to have a conversation about end-of-life issues, including donation.

Team design: During the past decade, the approach to the family has evolved into a shared responsibility between OPO staff, hospital staff (nurses, physicians and others) and members of the clergy. This cooperative group provides a flexible team that is better able than a single person to address the varying needs of individual families. As with the approach to timing a donation request, each family is unique in terms of those with whom members feel comfortable and those to whom they reach out for assistance.

A key concept that has evolved, which is additive to such strategies as appropriately timed requests and increased sensitivity regarding minority participation, is that of the 'team huddle'. In this approach, team members determine a strategy they feel best meets the needs of the potential donor family. This huddle allows for presentation of multiple points of view and sharing of expertise; it serves as a way to enlighten all participants regarding the nuances of the particular family situation. While it would be difficult to impossible to say what impact each of these strategies has had on the national consent rate, it is reasonable to say that together they have contributed significantly to its improvement.

The importance of consent: When individuals referred by hospitals as potential donors fail to become actual donors, the reasons fall into four categories: lack of medical suitability, non-referral, logistical/legal issues and no consent. Lack of medical suitability is straightforward; it removes a death from the potential donor pool. As for non-referral, laws that require the timely reporting of all potential donors are now in place. In fact, 'conditions of participation', issued by CMS, went into effect in 1998 and ensure that only those hospitals that refer potential donors in a timely fashion to their contracted OPO remain eligible to receive Medicare benefits (10). However, simple referral in the absence of effective consent will not increase donation. And, while important, logistical and legal issues seem far less likely to preclude donation than nonconsent. Therefore, it is reasonable to assign much of the success in increased conversion rates following the collaborative to strategies that addressed and raised consent rates.

Through the collaborative process, the strategies discussed above took many practical forms, some of which will undoubtedly be reported in the literature for months and years to come. However, data that accurately reflect the reasons for declining consent are necessary in order to design programs that effectively address issues that discourage some population groups from consenting to donate (11,12). Unfortunately, data regarding reasons for declining consent are sketchy. Currently available 'turn down codes' used to classify the reason that consent for donation was denied are presented in Table 3. Unfortunately, this group of codes is so general in nature as to provide little insight. Of the 36 000 turn down codes recorded over the years, 57% were due to 'emotional' reasons and 39% were due to 'other'. Given that tens of thousands of potential organs were lost because of lack of consent, the revision of these codes should have a high priority.

Table 3: Refusal codes for withholding consent to donate, 2004

Code	Reason	Number of cases
100	Emotional	20,562 (56.5%)
101	Cultural beliefs	431 (1.19%)
102	Religious beliefs	198 (0.54%)
103	Family conflict	1249 (3.43%)
199	Other specify	13,930 (38.3%)

Source: Organ Donation Breakthrough Collaborative.

Deceased Organ Donation

Prior reviews documented a 2%–4% increase per year in deceased organ donation between 1995 and 2003 (13). In 2004, deceased donation increased 11% over 2003, (7152 donors up from 6457). Compared with 1995, organ donation in 2004 increased by 33%. Increased organ donation was noted for all organs, with the exception of the heart. Heart donation decreased in 9 of the previous 10 years. The exact cause for this is unclear. Although the deceased donor population continues to age, this may not be a significant factor. While the average age of deceased donors increased steadily from 34.2 years in 1995 to 39.8 years in 2004, with the percentage of donors aged 50–64 years increasing from 19% of donors in 1995 to 25% in 2004 (SRTR analysis, May 1, 2005), the age distribution of heart donors remained flat for all age levels throughout the entire 10-year period.

The number of deaths due to trauma decreased slightly in 2004 compared with 2003 (39.1% from 40.5%).

Table 4: Deceased donor classifications

Term	Definition
Expanded criteria donors (ECD)	For kidney, any deceased donor over the age of 60 years; or from a donor over the age of 50 years with two of the following: a history of hypertension, a terminal serum creatinine >1.5 mg/dL, or death resulting from a cerebral vascular accident (stroke)
Donation after cardiac death (DCD)	Donation of any organ from a patient whose heart has irreversibly stopped beating. Includes donors who also qualify as ECD under the kidney definition above
Standard criteria donors (SCD)	For kidney, a deceased donor who is neither ECD nor DCD. These donors often have fewer risks associated with graft failure

Source: 2004 OPTN/SRTR Annual Report.

Because organs from trauma victims tend to function well, even a modest decrease in deaths due to head trauma is a concern. It appears this decrease is partly due to a slight increase in the number of deaths due to anoxia, which is more damaging to organs, and which has been trending upward (14% from 11% five years previously). However, there are no trends apparent in the circumstances and mechanisms of death data that bear out a major change.

Demographics generally have been stable otherwise, including the interesting differences in distribution of the sexes, which is reproducible year after year (female to male about 42%–58% for kidney, lung and liver, but 34–66% for heart and pancreas). The reason for this difference in donor ratios between the sexes for the different organs is not intuitively obvious.

The absolute number of standard criteria donors (SCD) for kidney increased almost proportionally with the overall trend in donation, although the fraction of SCD donors compared with the total was slightly lower in 2004 compared with 2003 (74% of 4678 donors compared with 75% of 4329 donors). Note that SCD kidneys exclude expanded criteria donors (ECD), DCD and DCD/ECD donors (Table 4). The decreased percentage of SCD compared with the total donor population appears to be due mainly to the increase in DCD (5% up from 4%).

Nationally, minorities participated fully in the remarkable increase in deceased donation noted in 2004 compared with the prior 9 years. In 2004, there were 1008 African American donors up from 893 in the prior year, and 950 Hispanic/Latino donors up from 822 donors the year before. These increases calculate to 13% and 16%, respectively, as compared with the 11% national increase.

The data indicate there may have been opportunities to increase the number of organs donated from existing deceased donors. In 2004, there were only 17 donors providing pancreas and kidney only, since such donors would be likely to have other organs donated as well. However, there were 747 combined pancreas-liver-only or pancreas-intestine-only donors. It is worth examining how so many donors were qualified to provide liver and pancreas but not kidneys. Although in some cases an older donor would be considered for liver but not kidney donation, these donors that include pancreas should not be in that group, since older age is a relative contraindication for using the pancreas. Some of these cases may have been due to intrinsic chronic renal disease in the donor, but the incidence of this would not explain the large number that were not kidney donors (14–16). Equally striking is the observation that only 89% of all donors were kidney donors.

Another possible opportunity regards pancreas donors. There were 3556 donors consented for pancreas in which the organ was not recovered. Of these, in 685 instances the reason was 'Donor Medical/Social History'. This contrasts with kidney, for which there were only 1240 donors consented with no kidney recovered; of these, 247 were due to 'Donor Medical/Social History'. 'Hepatitis/HIV/HTLV-1' and 'Poor Organ Function/Infection', both alternate categories, were not the dominant reasons for nonrecovery. Thus, it appears that for a substantial number of donors under consideration for kidney and pancreas recovery, 'Donor Medical/Social History' was reported as an exclusion reason for recovery of the pancreas but not the kidneys.

These observations reflect the overall national statistics, making it difficult if not impossible to determine if they are universally valid. Additional opportunities for donation may be present in specific DSAs based on differences in DSA practices. Exploring differences between DSA practices in an attempt to identify additional opportunities for organ procurement and transplantation is a major task of the next collaborative.

ECD donation

Candidates on the general list for kidney transplantation may choose to be added to the ECD list for kidneys. In 2004, ECD kidney donors numbered 1341 (1278 ECD-only and 63 ECD/DCD combined); this is 21% of all kidney donors. However, as mentioned above, the current definition of ECD is specific to kidney; expanded criteria or any other guidelines for evaluating the other solid organs have yet to be generally accepted. Given this lack of definition for 'marginal' or 'expanded criteria' livers, pancreata, hearts and lungs, the impact of using 'less standard' organs on other donor pools is unclear.

Recently, a number of groups, including a New York State Task Force, attempted to define the ECD liver donor by identifying those donor characteristics that lead to a relative risk of graft failure of 1.7 times higher than expected. These criteria were similar to those used to define ECD kidney donor (17). In their analysis, they found that increasing

donor age, DCD, split donor liver and some donor causes of death (e.g., cerebral-vascular accident, central nervous system tumor or drug overdose) were associated with poorer outcomes for liver. New work by the SRTR is refining these findings to develop a continuous scale of donor quality (18). Thus, the characteristics that define an ECD kidney donor and an ECD liver donor are different. It is, therefore, possible that a given donor may donate SCD kidneys but also an ECD liver.

Since characteristics associated with higher relative risk of allograft failure differ for one organ compared with another, even from the same donor, the concept of the ECD donation may be labeled more specifically as expanded criteria 'organ' donation: for example, expanded criteria kidney (ECK), expanded criteria liver (ECL), and so on.

Donation after cardiac death

As the number of deceased organ donors grew over the last decade, there was a concurrent increase in DCD. Between 1995 and 2004, the number of donors providing organs after cardiac death increased more than sixfold, from 64 to 391, a much steeper rate of increase than for donors providing organs after brain death. Some of the overall increase in deceased donor numbers was due to these rapidly increasing instances of DCD. If one removes the DCD from the deceased donor data, the increase from 1995 to 2004 is reduced from 33% to 28%. Although DCD makes up a relatively small fraction of the national percentage of deceased donors (5% in 2004), the full potential for DCD to expand the national deceased organ donor pool is best appreciated by the fact that only seven DSAs accounted for 58% of all instances of DCD, and, in these DSAs, DCD accounted for 17%–20% of their donors (Figure 3). In summary, DCD represents a small (5%) subset of all deceased donors, but it has the potential to substantially add to the total deceased donor pool.

Table 5: Organs recovered from DCD donors, 2004

Organ	Number of donors	Percentage of total DCDs (391)
Kidney	371	95%
Pancreas	49	13%
Liver	242	62%
Lung	5	1%

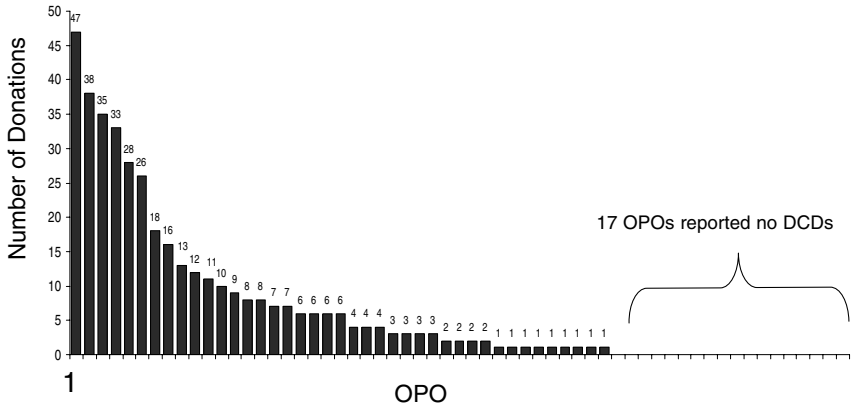
Source: *2005 OPTN/SRTR Annual Report*, Tables 2.2–2.4, 2.7.

National data on DCD reveal that organs recovered from DCD in 2004 were predominantly kidneys and livers. DCD pancreas recovery was 13% (Table 5).

DCD kidney donors: Of the 7152 deceased organ donors in 2004, 6327 (88%) were kidney donors. This number is up from 5003 in 1995, an increase of 26%. Among these 6327 donors, 308 (5%) were instances of DCD. Using the classification of deceased kidney donors as 'standard, ECD or DCD' (Table 4), 1278 out of the 6327 donors (20%) met the definition for ECD; 63 donors (1%) met both ECD and DCD criteria. Nearly 80% of those who donated after cardiac death (308 DCD/non-ECD of 391) were kidney donors, somewhat less than the percentage in deceased donors overall.

DCD pancreas donors: Over the last 10 years, pancreata for transplantation have been almost exclusively recovered from SCD donors. Of the 2021 pancreata procured in 2004, only 49 (2%) were from DCD. This number, though small, doubled from 22 in 2003. Pancreata were recovered in 13% (49 of 391) instances of DCD.

DCD liver donors: There were 6321 deceased liver donors in 2004, representing an increase by 46% since 1995. Of the 6321 donors, 242 (4%) were DCD. Next to kidney, liver is the most commonly used organ from DCD, with 62% being liver donors. It is possible that this



Source: SRTR Analysis, May 2005.

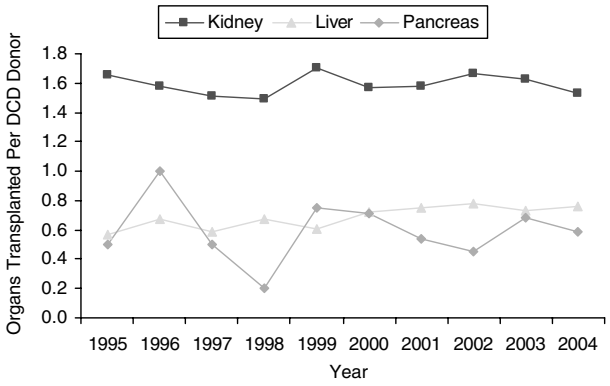
Figure 3: Number of donations after cardiac death (DCD), by OPO, 2004.

percentage may increase substantially once there is a better understanding of the relative risk factors for DCD versus SCD livers.

DCD lung donors: In 2004, lungs were procured from 1065 deceased donors. Among these were five instances of DCD, which represents an increase from 0% in 1996 to 0.5% in 2004. The first lung DCD took place in 1997; a second did not occur until 2001. In the following years, one, three and five lung donations occurred following cardiac death. For the five instances of DCD for lung in 2004, both lungs were retrieved. The potential for DCD to add significantly to the lung donor pool will depend on the outcomes observed from this initial experience.

DCD intestine donors: Only 166 (2%) of all deceased donors in the United States in 2004 were intestine donors and none were DCD. This likely reflects the relatively small demand for intestinal allografts compared with other organs and/or a poor understanding of the characteristics that predict short- and long-term outcomes for DCD intestinal allografts.

Utilization of DCD organs: As seen above, recovery of DCD organs increased rapidly over the past 10 years. Kidney was the first organ to be routinely recovered following cardiac death, and kidney utilization from DCD has remained relatively stable at about 1.6 kidneys transplanted per DCD donor. Utilization of livers has been increasing, with livers transplanted per instance of DCD increasing from 0.33 in 2000 to 0.47 in 2004 (Figure 4). More recently, lungs have been successfully procured for transplantation from DCD, a trend that is likely to continue. Functional outcomes of organs from these donors in terms of short- and long-term survival will necessarily be the subject of close evaluation and will determine the potential for DCD to add significantly to the deceased organ donor pool. Use of organs varies according to donor characteristics. The number of organs procured and transplanted per donor after DCD are summarized in Table 6.



Source: *2005 OPTN/SRTR Annual Report*, Tables 2.12, 2.13, 2.14.

Figure 4: Organs transplanted per DCD donor by organ type, 1995–2004.

Table 6: Utilization of DCD organs, 2004

Number of DCD individuals	ORPD*	OTPD**
Kidney (n = 371)	1.88	1.45
Pancreas (n = 49)	0.13	0.07
Liver (n = 242)	0.62	0.47
Lung (n = 5)	0.03	0.03

Source: *2005 OPTN/SRTR Annual Report*, Tables 2.12–2.14, 2.17.
*Organs recovered per donor.
**Organs transplanted per donor.

Implications of current ECD and DCD practices

Economic considerations: ECD and DCD organs have potential cost implications for both organ procurement and transplantation. As experience with ECD and DCD has grown over the past 10 years, two trends have become apparent. First, the number of liver-only donors has risen from 320 in 2000 nationally to 655 in 2004, a growth from 5% to 9% (Table 7). These instances of donation incur nearly all the cost of a multi-organ donor if other organs are thoroughly evaluated but ultimately not recovered, yet provide only one organ from which to recover the cost through a standard acquisition charge (SAC). Depending upon whether kidneys are recovered but not transplanted, whether the intent is to recover other organs or not, and how the CMS intermediary interprets each donor case and directs the OPO to assign cost, overhead costs not recovered from organ SACs may make their way into the various cost centers and may, eventually, lead to increased organ SAC rates. At the very least, the increase in liver-only donors will drive up liver SACs; the effect on other organs is less clear but bears further study.

Second, the number of kidneys undergoing pulsatile perfusion (PP) has nearly doubled, from 1464 in 2000 to 2780 in 2004, or from 13% of all deceased donor kidneys in 2000 to 22% in 2004 (Table 8). While this technique, which circulates a preservation solution through the organ rather than packing it in an iced solution, is more effective than static storage—especially for organs that may be compromised—it represents a significant additional cost when compared with non-PP cold storage (19). Capital equipment (pumps), disposable supplies (cassettes) and the effort required to perform PP are all additional costs not incurred with cold storage and are costs that find their way into the renal SAC.

These trends and similar developments, which will become apparent as instances of ECD and DCD continue to rise, are worth further study. A thorough cost and outcome analysis of ECD, DCD and SCD as they compare with each other is necessary if we are to fully understand the implications of increased use of these donors.

Table 7: Trends in liver-only donors, 1995–2004

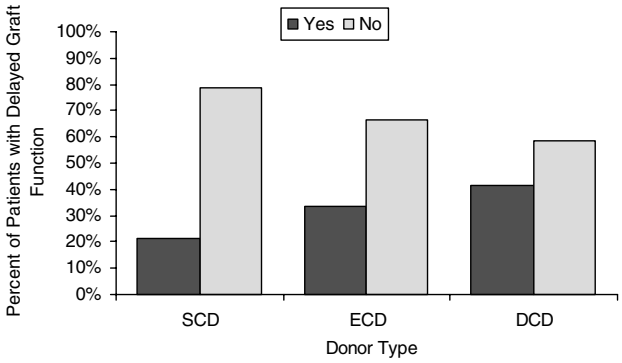
	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
Total deceased donors	5363	5418	5479	5793	5824	5985	6080	6190	6457	7152
Total non-kidney donors	360	380	395	454	438	496	552	552	703	825
Liver-only donors	164	205	216	273	275	320	378	382	532	655
% Liver-only to total donors	3.1	3.8	3.9	4.7	4.7	5.3	6.2	6.2	8.2	9.2

Source: SRTR Analysis, June 2005.

Table 8: Frequency (%) of pumped kidneys, 1995–2004

	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
Total kidneys recovered	9937	10020	10091	10594	10703	10909	10986	11196	11437	12575
Pumped kidneys	1526	1618	1530	1556	1267	1464	1666	1816	2133	2780
% Kidneys pumped	15.4	16.1	15.2	14.7	11.8	13.4	15.2	16.2	18.6	22.1

Source: SRTR Analysis, June 2005.



Source: SRTR Analysis, April 2005.

Figure 5: Kidney delayed graft function by deceased donor type, 2000–2004.

Potential impact of DCD and ECD donation: While ECD and DCD appear to have significantly increased the number of donated organs, it is apparent that these practices increase the cost of organ donation. It also appears that caring for the recipients of these organs increases the cost of caring for organ transplant recipients. For example, the national reported rate for delayed graft function, which creates the need for at least one dialysis session after transplantation, was 23% for SCD kidney allografts but 38% for ECD kidneys and 43% for DCD kidneys in 2000–2004 (Figure 5).

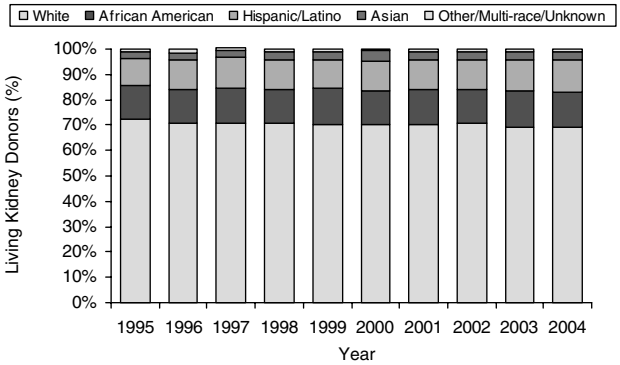
There can be little doubt of the added clinical benefits that can be achieved by ECD and DCD donation. However, it is important to recognize the potential for procurement and transplantation of organs from these types of donors to increase SACs and recipient costs. As increased costs for procurement and transplantation have the potential to negatively affect organ donation services and organ transplantation, accurate tracking of cost data specifically related to ECD and DCD should have a high priority. The information to be gained will help the DSA community work with the CMS and third party carriers to assure that reimbursement for ECD and DCD donation and transplantation is adequate.

Living Donation

Increased public awareness of the organ donor shortage is demonstrated by the year-to-year increase in the number of organs donated by living donors between 1995 and 2004. Over the past 10 years, the number of donated organs increased from 3493 to 7002. In fact, from 2001 to 2003, the number of living organ donors surpassed the number of deceased donors.

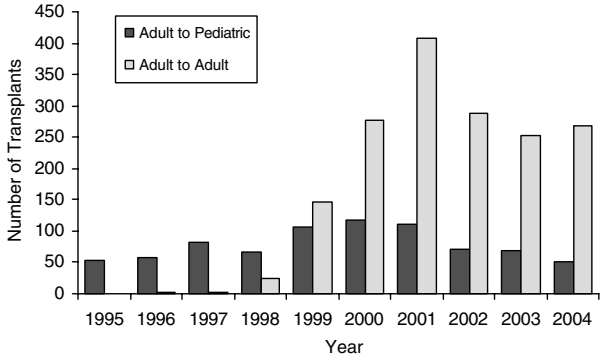
Living kidney donation

Kidney donation by living donors has increased steadily by approximately 200 donors per year for the last 3 years. As in prior years, the majority of living kidney donors were female (58% in 2004). Several characteristics of the donor population have changed significantly over the last 10 years. In 1995, parents and full siblings made up two-thirds of the living donor population; in 2004, this figure had dropped to only one-third. The largest increase was in the 'other unrelated' category of donor, which increased from 5% to 21%. This category does not include spousal donors, who increased from 8% to 12%. In addition, 212 or 3% of the living kidney donor population in 2004 are listed in the *2005 OPTN/SRTR Annual Report* as having an 'unknown' relationship. The reason for this is unclear. The number of donors of 'unknown age' also increased in this year's report to 73 (1%), from one or two in most of the previous years. Regardless, over the past 10 years the majority of living donors have shifted from related to unrelated. It seems likely that at least part of this trend has occurred as the result of the increased use of laparoscopic donor nephrectomy, which is less invasive than major surgery. Furthermore, increased public awareness encourages transplant centers to freely discuss donation with all potential donors.



Source: *2005 OPTN/SRTR Annual Report*, Table 2.9.

Figure 6: Living kidney donor ethnicity, 1995–2004.



Source: SRTR Analysis, May 2005.

Figure 7: Comparison of adult-to-adult and adult-to-pediatric living liver transplants, 1995–2004.

The present living kidney donor population is older than in 1995; in that year, 559 of 3392 (16%) were of age 50 years or more. In 2004, the same group comprised 1368 of 6,645 (21%) of the donors. This is probably due to the general aging of the population and the more proactive position of transplant centers and recipients on using kidneys from older donors. The racial composition of the living kidney donor population has not changed significantly since 1995. About 70% of these donors are white, almost exactly the same percentage as in deceased donors (Figure 6). There were no living pancreas transplants reported in the United States in 2004; the numbers in this category have exceeded 10 for the entire country only once in the last 10 years.

Living liver donation

The number of living liver donor transplants increased from 54 in 1995 to 92 in 1998. In 1999, however, there was a quantum step up in the number of living liver donors, growing to 253 donors, a 175% increase over the prior year. This increase was primarily due to adult-to-adult liver transplantation. The absolute number of living liver donors peaked at 518 in 2001 and has remained stable at approximately 320 for the past few years. The future potential for growth in adult-to-adult living donor liver transplantation will depend on short and longer term outcomes data.

In 2004, 87% of living liver donors were under age 50 years. In 1995, 93% of these donors were parents of recipients, presumably mostly children. By 2004, however, the percentage of parental donors had fallen to 14%, with offspring making up 26% and other unrelated persons 22% of total living liver donors (Figure 7).

Living lung donation

Only 28 living lung cases were performed in the United States in 2004. This number has been flat since 2002, having declined from its peak of 58 in 1999. Even among this small number of transplants, the number of donors categorized as 'other unrelated' has increased, from 5 of 45 in 1995 to 11 of 28 in 2004.

Living non-directed donation

Living non-directed donation is a phenomenon of the last 5 years. Of the 297 living non-directed donations reported for the last 10 years, only seven occurred between 1995 and 1999. Of the 290 donors reported from 2000 to 2004, 175 (60%) occurred in 2003 and 2004 (Table 9). Participants from centers actively involved in living non-directed donation recently met at a symposium focused on this topic. There was general consensus that the growing number of living non-directed donors results from two factors: (1) increasing public awareness of the organ donor shortage, and (2) a new willingness on the part of transplant centers and OPOs to participate in these cases. No best methods for donor evaluation, organ distribution or donor follow-up were identified as forthcoming. But it was the unanimous consensus of the conference that the members of the transplant community who participate in this type of donation have a heightened level of responsibility to assure the well being of these individuals (Personal communication: Toward Understanding Living non-Directed Donation. Seattle, October 2004).

In summary, living organ donation continues to increase, driven almost entirely by increases in kidney donors. These donors are somewhat older and definitely less closely related than they were 10 years ago.

Summary

Improved rates of organ donation are essential to respond to increasingly large waiting lists and to take advantage of continuing advancements in organ transplantation. The Organ Donation Breakthrough Collaborative, which began its work in September 2003, is demonstrably successful in its efforts to identify and disseminate organ donation best practices. By building on the partnership inherent in

Table 9: Living unrelated and non-directed donation, 1995–2004

	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
Total living donors	3493	3790	4059	4568	5037	5928	6606	6629	6826	7002
Living unrelated donors*	421	580	664	929	1112	1542	1835	1993	2231	2352
Non-directed donation	0	0	0	2	5	21	35	59	87	88

Source: SRTR Analysis, June 2005.
*Does not include living/deceased exchange.

the concept of the DSA, the collaborative has challenged OPOs, transplant centers and donor hospitals to identify, improve and share their most effective strategies for converting eligible deaths to transplanted organs. Deceased donation increased 11% in 2004 over 2003 to 7152 donors; much of this improvement may well be traced to the efforts of the collaborative.

The concepts of ECD and DCD are further expanding deceased donor organ availability, though many questions remain to be answered about the impact of these less standard organs on transplantation and outcomes. While both ECD and DCD clearly are producing increased numbers of organs, they raise problematic issues of increased cost and complexity. Efforts must be ongoing in the transplant community to track costs associated with delayed graft function and nonprocurement of consented organs. Work must also continue on the development of organ-specific definitions of expanded criteria organs besides kidney. This is best accomplished by studying factors associated with higher relative risk of allograft failure by type of organ, recognizing that factors may differ, so that one donor could yield both ECD and non-ECD organs. Finally, living donation continues to make strides, as the number of such organs increased from 3493 in 1995 to 7002 in 2004. Changes in the makeup of the living donor population, including more unrelated donors and those who provide non-directed donations, demand continued study.

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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.

References

1. Levine GN, McCullough KP, Rodgers AM, Dickinson DM, Ashby VB, Schaubel DE. Analytical methods and database design: Implications for Transplant Researchers, 2005. Am J Transplant 2006; 6(Part 2): 1228–1242.
2. Langley G, Nolan K, Nolan T, Norman C, Provost L. The Improvement Guide: A Practical Approach to Enhancing Organizational Performance, Hoboken, NJ. Jossey-Bass, 1996.
3. Pietz CA, Mayes T, Naclerio A, Taylor R. Pediatric organ transplantation and the Hispanic population: Approaching families and obtaining their consent. Transplant Proc 2004; 36: 1237–1240.
4. Siminoff LA, Lawrence RH, Arnold RM. Comparison of black and white families' experiences and perceptions regarding organ donation requests. Crit Care Med 2003; 31: 146–151.
5. Shafer TJ, Van Buren CT, Andrews CA et al. Program development and routine notification in a large, independent OPO: A 12-year review. J Transpl Coord 1999; 9: 40–49.
6. Trevino R. Minority donation: Does the race of the requestor make a difference. Minority donation: Part 3. J Transpl Coord 1993; 3: 126–127.
7. Linyear AS, Tartaglia A. Family communication coordination: A program to increase organ donation. J Transpl Coord 1999; 9: 165–74.
8. Gortmaker SL, Beasley CL, Sheehy E et al. Improving the request process to increase family consent for organ donation. J Transpl Coord 1998; 8: 210–217.
9. Siminoff LA, Lawrence RH, Zhang A. Decoupling: What is it and does it really help increase consent to organ donation? Prog Transplant 2002; 12: 52–60.
10. Federal Register, 1998: 63: 33856–33875.
11. Siminoff LA, Burant C, Youngner SJ. Death and procurement: Public beliefs and attitudes. Soc Sci Med 2004; 59: 2325–2334.
12. Siminoff LA, Gordon N, Hewlett J, Arnold RM. Factors influencing families' consent for donation of solid organs for transplantation. JAMA 2001; 286: 71–77.
13. Delmonico FL, Sheehy E, Marks WH, Baliga P, McGowan JJ, Magee JC. Organ donation and utilization in the United States 2004. Am J Transplant 2005; 5(Part 2): 862–873.
14. Krieger NR, Odorico JS, Heisey DM et al. Underutilization of pancreas donors. Transplantation 2003; 75: 1271–1276.
15. Douzdjian V, Gugliuzza KG, Fish JC. Multivariate analysis of donor risk factors for pancreas allograft failure after simultaneous pancreas-kidney transplantation. Surgery 1995; 118: 73–81.
16. Gruessner AC, Barrou B, Jones J et al. Donor impact on outcome of bladder-drained pancreas transplants. Transplant Proc 1993; 25: 3114–3115.
17. New York State Department of Health Workgroup. Workgroup on expanded criteria organs for liver transplantation. Liver Transplant 2005; 11: 1184–1192.
18. Feng S, Goodrich NP, Bragg-Gresham JL et al. Characteristics associated with liver graft failure: The concept of a donor risk index. Am J Transplant, 2006; 6(4): 783–790.
19. Burdick JF, Rosendale JD, McBride MA, Kauffman HM, Bennett LE. National impact of pulsatile perfusion on cadaveric kidney transplantation. Transplantation 1997; 64: 1730–1733.