

Organ donation and utilization in the United States, 2004

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This article discusses issues directly related to the organ donation process, including donor consent, donor medical suitability, non-recovery of organs, organs recovered but not transplanted, expanded criteria donors (ECD), and donation after cardiac death (DCD). The findings and topics covered have important implications for how to evaluate and share best practices of organ donation as implemented by organ procurement organizations (OPOs) and major donor hospitals in the same donation service areas (DSAs). In 2002 and 2003, US hospitals referred more than one million deaths or imminent deaths to the OPOs of their DSA. Referrals increased by nearly 10% from 2002 to 2003 (1,022,280 to 1,121,392). Donor consents have increased by about 5% and the number of total deceased donors has risen from 6,187 to 6,455. Since multiple organs are recovered from most donors, this increase

Note on sources: The articles in this report are based on the reference tables in the 2004 OPTN/SRTR Annual Report, which are not included in this publication. Many relevant data appear in the figures and tables included here; other tables from the Annual Report that serve as the basis for this article include the following: Tables 1.1, 2.1–2.11, 3.1–3.10, 3.12, 3.13, 3.15, 3.16, 3.18, 5.1, 6.1, 8.1, 9.1 and 11.1. All of these tables may be found online at <http://www.ustransplant.org>.

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allowed more than 500 additional wait-listed candidates to receive an organ transplant than in the prior year. Non-traditional donor sources have experienced a large rate of increase; in 2003 the number of ECD kidney donors increased by 8% and the number of DCD donors increased by 43%, from 189 donors in year 2002 to 271 donors in 2003.

Key words: Deceased donors, donation rates, living donors, OPOs, organ donation, organ procurement, SRTR

Introduction

Organ donation is vital to the success of transplantation. Its importance has been underscored most recently by the Organ Donation Breakthrough Collaborative, which was initiated by U.S. Department of Health and Human Services Secretary Tommy G. Thompson. The goal of the collaborative is to test and share organ donation best practices, as observed nationally by organ procurement organizations (OPOs) and large donor hospitals in the OPO service area. The collaborative has emphasized that the assessment of performance is given not only by OPO activity but also by a shared responsibility of the hospitals within the service area of the OPO to develop and implement highly effective organ donation systems. To better reflect the joint responsibility shared among these organizations, their collective performance is measured over the donation service area (DSA). DSA is the term used to define the geographical service area designated by the Federal government and assigned to an OPO for recovery of organs from all hospitals in that region. In 2003, the most current year discussed in this report, there were 59 DSAs in the United States.

To adequately assess practices, it is necessary to develop and refine a set of standard metrics of organ donor analysis. These metrics reflect assessments of donor potential, rates of donation, timely notification of deaths to an OPO for evaluation of medical suitability, use of effective request practices and donation rates based upon rates of conversion of potential to actual donors. This report uses all these tools to describe the activity of DSAs and the current state of organ donation in the United States. In the coming months, the collaborative will continue to focus on increasing the number of deceased donors and the donation rate as well as the number of organs transplanted

Table 1: Eligible, actual and additional donors, 2002–2003

	2002	2003
Eligible deaths*	12 015	12 031
Consents for donation	6370	6630
Actual deceased donors**	5743	5908
Donation rate†	48.7%	49.8%
Additional deceased donors‡	444	547
Total deceased donors	6187	6455

*Eligible deaths include any heartbeating individuals meeting, or imminently meeting, death by neurological criteria, aged 70 or under, who have not been diagnosed with exclusionary medical conditions.

**At least one organ recovered for transplant from deceased donors that meet the definition of an eligible death.

†Excludes Additional Donors (SRTR Analysis, May 2004).

‡At least one organ recovered for transplant from deceased donors that do not meet the definition of an eligible death (e.g. are over 70 years of age or declared dead after cardiac arrest).

per donor (Table 1). The definitions used in this report to describe the various steps in the organ donation process are provided in Table 2. The sequence of events, from death to transplant, is illustrated in Figure 1.

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

The pattern and profile of deceased organ donation

The last decade has seen a steady increase in the number of deceased organ donors, from 5099 donors in 1994 to

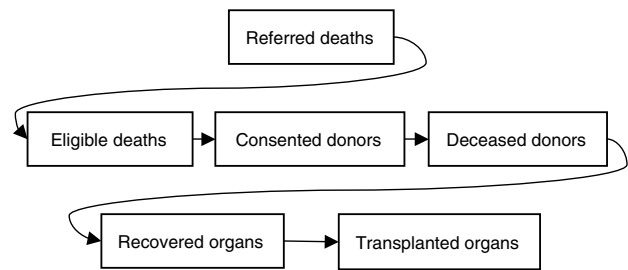


Figure 1: Donation process sequence. Source: *2004 OPTN/SRTR Annual Report*.

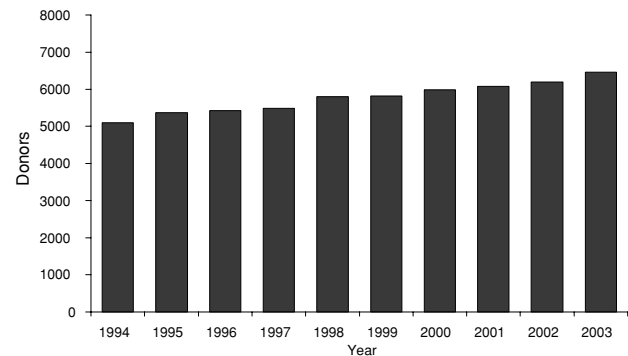


Figure 2: Deceased organ donors, 1994–2003. Source: *2004 OPTN/SRTR Annual Report*, Table 1.1.

5985 donors in 2000, and then to 6455 in 2003 (Figure 2). This increase of approximately 3% per year has occurred in the face of decreasing in-hospital deaths (3).

In ongoing efforts to increase the number of donors, measures continue to be developed to better utilize older donors and donors with pre-existing medical comorbidities. On an organ-specific level, the only formal criteria for such donors are in kidney transplantation, where a subset of donors with a higher risk of graft failure has been designated as expanded criteria donors (ECD). In addition, a

Table 2: Organ donation terms

Term	Definition
Referred deaths	All deaths or imminent deaths reported by a hospital to the OPO within the DSA (OPTN)
Eligible deaths	Heartbeating individuals meeting, or imminently meeting, death by neurological criteria, aged 70 or under, who have not been diagnosed with exclusionary medical conditions (OPTN)
Potential donors	Patients who meet the criteria for brain death with no absolute contraindications to organ donation as defined by a standardized list from the <i>International Classification of Diseases, Ninth Revision</i> (AOPO)
Deceased donors	Individuals whose tissues or organs are donated upon death (SRTR)
Actual donors	Deceased donors, with at least one organ recovered for transplant, who meet the definition of an eligible death (SRTR)
Additional donors	Deceased donors who do not meet the criteria of an eligible death, e.g. over age 70 years or having sustained cardiac death (SRTR)
Donation rate	The number of actual donors from whom at least one organ is recovered for the purpose of transplant divided by the total number of eligible deaths (SRTR)

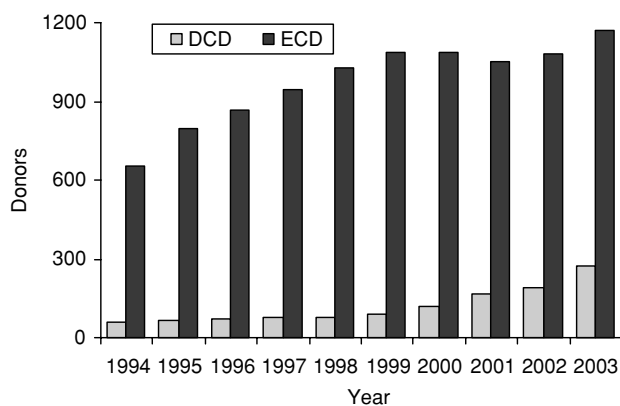


Figure 3: DCD (all organs) and ECD (kidney) donors, 1994–2003. Source: 2004 OPTN/SRTR Annual Report, Tables 2.1 and 2.2.

steady increase can be seen in the use of organs recovered from donors who sustained cardiac death. Donation after cardiac death (DCD) provided the initial source of organs in the early days of transplantation before brain death was clearly defined. The growth in the number of both ECD and DCD donors has been dramatic (Figure 3). The number of older donors also grew markedly over the past decade, with donors aged 50–64 years increasing from 19% to 25%. In 2003, there was a net increase of 268 donors across all age groups compared with 2002. Over the past year, there were an additional 238 deceased donors aged 50 years and older. Since 1996, more than 40% of donors each year have died of a cerebrovascular accident (CVA) or stroke. However, following a 77% increase in the number of deceased donors with CVA as cause of death, between 1994 and 1999, the rate has risen by only 6% since 2000.

Recovery of organs

The changing characteristics of the donor pool appear to have resulted in an increase in the non-recovery of consented organs (Figure 4). Non-recovery occurs because of unsuitable characteristics, such as medical history or poor organ function, or following surgical inspection of the organ in the operating room at the time of intended recovery. The number of non-recovered organs increased between 2002 and 2003, for all organs except the liver. It is likely that the high recovery rate of livers for transplantation reflects recognition of the resilience of this organ to the effects of age and other stressors associated with transplantation. In 2003, there were 574 donors older than 65 years. From these 574 donors, 5 hearts, 8 lungs, 519 livers, 2 pancreata and 397 kidneys were recovered for transplantation. While it is vital to make sure that every effort is directed to minimizing discarded organs and non-recovery, it is also important to understand that expanding the donor pool as

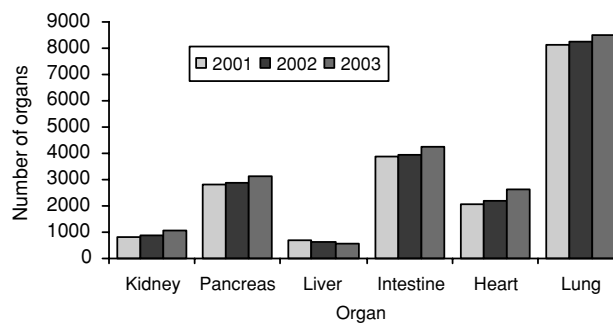


Figure 4: Non-recovery of consented organs, 2001–2003. Source: 2004 OPTN/SRTR Annual Report, Tables 3.1, 3.3, 3.4, 3.6, 3.7, 3.9, 3.10, 3.12, 3.13, 3.15, 3.16 and 3.18.

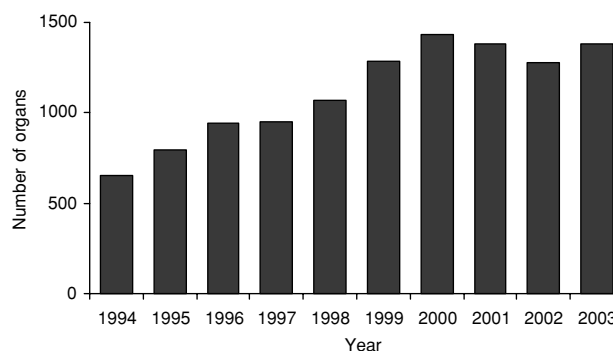


Figure 5: Non-use of recovered kidneys, 1994–2003. Source: 2004 OPTN/SRTR Annual Report, Table 3.2. Does not include kidneys used for research or exported outside the US.

it relates to a specific organ (e.g. liver), will make it appear that the discard rate of other organs is increasing, since the total number of donors will increase, while utilization of these donors may not be appropriate for other organs.

The accumulation of discarded kidneys over the past decade now exceeds 11 000 (Figure 5). This figure suggests the possibility that further analyses into reasons for non-use might lead to practice changes resulting in improved utilization.

Living versus deceased organ donors

The number of living donors continues to exceed the number of deceased donors, as it has since 2001 (Figure 6). However, it is also noteworthy that the rate of increase in living donors has not been sustained; instead, the number has almost plateaued. Among living kidney donors, women more commonly donate than do men. This imbalance of female to male living kidney donation has persisted throughout the past decade. In 2003, women constituted nearly 60% of living donors. In contrast, there have been more men who donate liver segments or lung lobes than

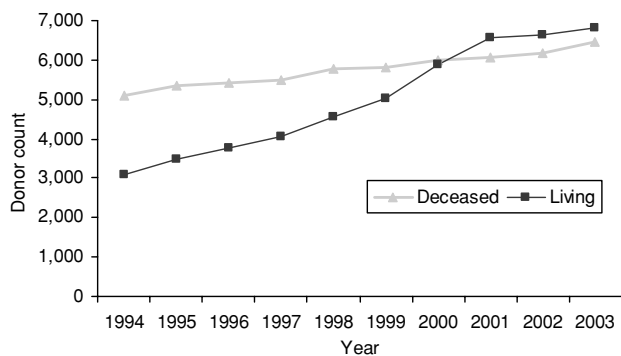


Figure 6: Deceased and living donors for all organs, 1994–2003. Source: 2004 OPTN/SRTR Annual Report, Table 1.1.

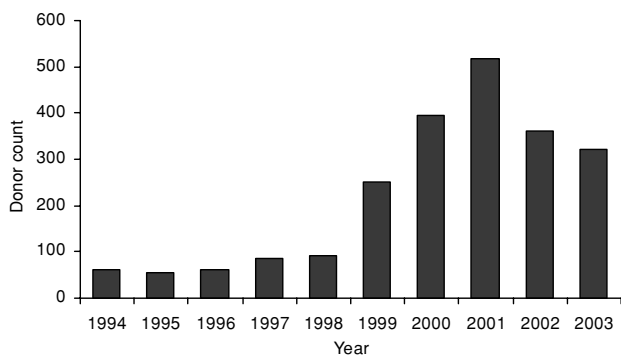


Figure 7: Living donors, liver, 1994–2003. Source: 2004 OPTN/SRTR Annual Report, Table 1.1.

women. However, the total number of living liver donors continued to fall in 2003 from a peak in 2001 (Figure 7). The number of living lung donors in 2003 was 29, also representing a continuing decline from a high of 56 in 1999.

Relationship of the living kidney donor to the recipient

In 2003, 32% of living kidney donors were either spousal or otherwise unrelated to the recipient (Figure 8). This increase represents a continuing trend, and has been associated with excellent survival (Table 3). The adjusted 5-year allograft survival for an unrelated kidney transplant is not different from the survival achieved by the transplant of a kidney from a parent or child of the recipient, regardless of HLA mismatch (SRTR analysis, May 2004). These observations have influenced practice; there is little concern today about the degree of HLA match if a blood-type and cross-match compatible living donor can be identified, either known or, in some instances, unknown by the recipient.

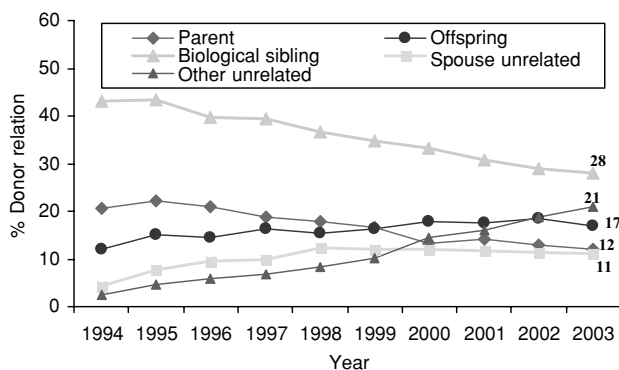


Figure 8: Living donor relation to recipient for kidney, 1994–2003. Source: 2004 OPTN/SRTR Annual Report, Table 2.9. 2003 values do not add up to 100% because 11% of living kidney donors fell into categories not shown in this figure.

Ethnicity and organ donation

There are many factors associated with individual decisions to pursue or not pursue donation; one of the most frequently cited is the effect of race and ethnicity on donation. Examination of the OPTN/SRTR data demonstrates that, over the last decade, the donor pool was derived from all races at rates roughly proportionate to their distribution in National Census data. In 2003, African Americans represented 13% of the U.S. population and 14% of all organ donors. The distribution of kidney, liver and heart donors by race was also proportionate. Organ donation by ethnicity also approximated the distribution in the general population, with the Hispanic/Latino population constituting 13% of all donors and 13% of the U.S. population. Over the past 10 years, there has been a gradual increase in the percentage of non-white and Hispanic/Latino donors (Table 4). While these data suggest that minority populations donate at a rate proportionate to their representation in the general population, this analysis does not reflect how many donor families were approached regarding donation, and how often consent was obtained. In this context, some studies have revealed a rate of donation significantly lower among minority populations (4,5).

A retrospective analysis performed by the Association of Organ Procurement Organizations (AOPO) from 1997 through 2000 provides useful insight regarding the impact of race on approach for donation, consent for donation and actual donation. As shown in Figure 9, the percentage of potential donor families approached regarding consent ranged from 76% to 86% across all races. Families of white donors were more likely to be approached compared with non-white donors (6).

For whites, consent for donation was granted only 61% of the time it was requested. For non-white donors, this consent rate was dramatically lower. Only 30% of the families

Table 3: Adjusted graft survival according to donor relationship to recipient

	5-year adjusted graft survival	p-value	n (recipients)
Living related donor, full sibling	0.90	Ref.	11 500
Living related donor, parent/child	0.87	<0.001	10 760
Living related donor, half sibling	0.85	0.008	460
Living related donor, other relative	0.87	0.005	2238
Living unrelated donor, spousal	0.88	0.020	3584
Living unrelated donor, non-spousal	0.88	0.005	3472

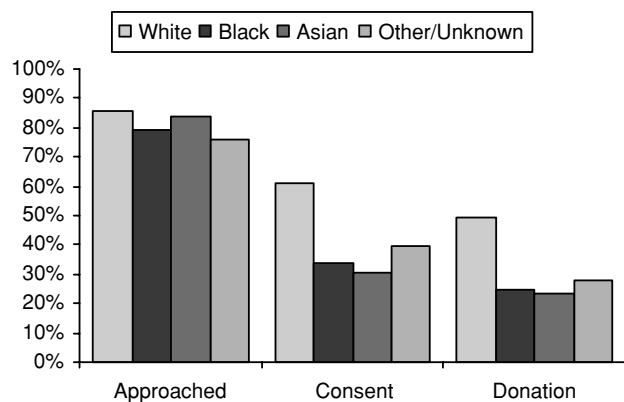
SRTR Data Analysis, May 2004.

Additional donor/recipient relationships (relationship type missing, identical twin, living/deceased donor exchange) not included (n = 367). Follow-up time at risk was censored at death for patients who died with a functioning renal graft or without a documented graft failure event.

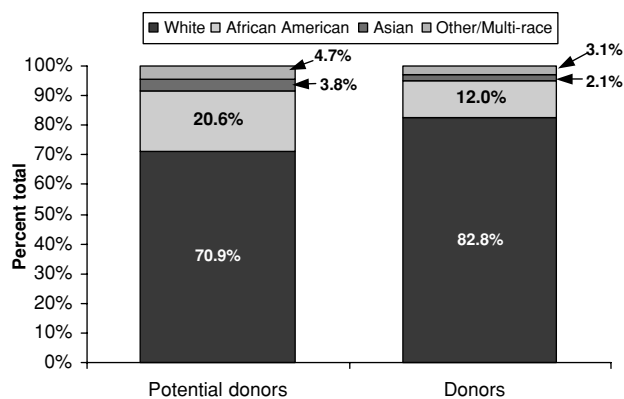
Table 4: Race and ethnicity of deceased donors, 1994–2003

	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
Donor race										
White	85.9%	86.0%	85.3%	84.8%	86.0%	85.6%	85.3%	84.4%	83.9%	82.4%
African American	11.7%	11.7%	12.3%	12.4%	11.7%	11.2%	11.9%	12.4%	12.9%	13.8%
Asian	1.8%	1.6%	1.7%	2.0%	1.8%	2.1%	2.1%	2.4%	2.0%	2.3%
Other/multi-race	0.5%	0.7%	0.6%	0.6%	0.5%	0.9%	0.6%	0.7%	1.0%	1.1%
Unknown	0.1%	0.0%	0.1%	0.1%	0.1%	0.2%	0.1%	0.1%	0.1%	0.4%
Donor ethnicity										
Hispanic/Latino	8.3%	9.1%	9.0%	10.2%	10.4%	11.0%	10.7%	12.1%	12.2%	13.4%
Non-Hispanic/Non-Latino	87.3%	90.7%	90.2%	89.5%	89.1%	88.8%	89.2%	87.9%	87.8%	86.6%
Unknown	4.4%	0.3%	0.8%	0.3%	0.6%	0.2%	0.0%	–	–	–

SRTR Analysis, May 2004.

**Figure 9: Donation approach rate, consent rate and donation rate by race, 1997–2000.** Source: AOPO DRR Report.

of Asian donors granted consent and 34% of the African American families granted consent. The combined effect of these factors is apparent when the organ donation rate is calculated by dividing the number of donors where at least one organ is recovered for the purpose of transplant by the total number of potential donors. Only 49% of white potential organ donors became actual donors. The donation rate is even lower in the minority population, with only 25% of all potential African American organ donors and 23% of all Asian potential donors actually providing organs for transplant (6).

**Figure 10: Distribution of potential organ donors and actual donors by race, 1997–2000.** Source: AOPO DRR Report.

The effect of the lower donation rate in minority populations on the overall donor supply is illustrated in Figure 10. African American and Asian individuals represented 21% and 4% of all potential organ donors, respectively, but only 12% and 2% of actual organ donors (6).

The reasons for lower donation rates in minority populations may include misinterpretation of religious tenets, distrust of the medical establishment, fear of premature declaration of death if a donor card had been signed and concern among minority donors regarding the relative allocation of organs to minority recipients (7–14). Some

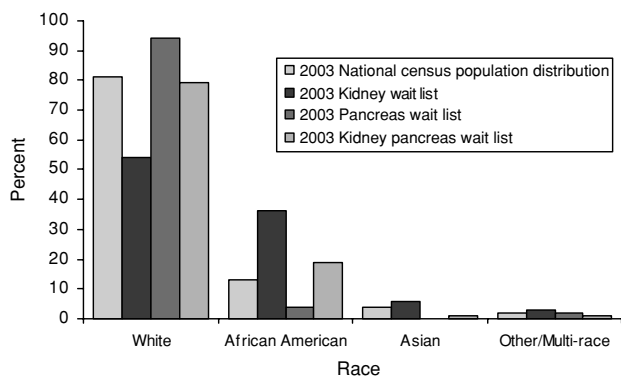


Figure 11: Kidney, pancreas and kidney/pancreas waiting list by organ and racial group compared to national census, 2003. Source: 2004 OPTN/SRTR Annual Report, Tables 5.1, 6.1 and 8.1.

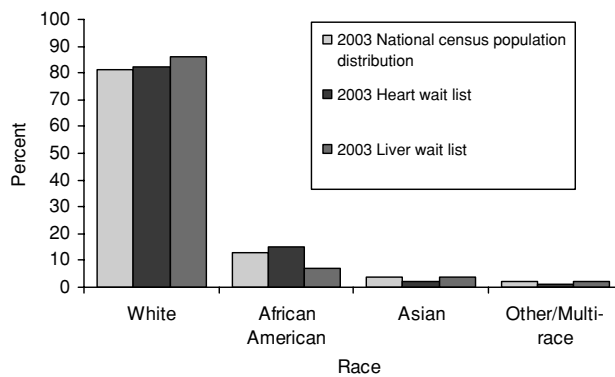


Figure 12: Heart and liver waiting list by organ and racial group compared to national census, 2003. Source: 2004 OPTN/SRTR Annual Report, Tables 9.1 and 11.1.

investigators have suggested that a lack of understanding about the process generates a reluctance to donate, and that this reluctance is hidden under the guise of religious beliefs or mistrust of the medical system (15,16). Additionally, specific misconceptions about the process are perhaps more influential in the decision not to donate rather than a generalized lack of knowledge about transplantation and donation (7,17,18).

The lower donation rate in minority populations does not reflect a lack of need within these groups for transplantation. Figure 11 illustrates the relative distribution of race within the U.S. population compared with the kidney, pancreas and kidney–pancreas waiting lists. The representation of African Americans on the kidney transplant waiting list is nearly threefold higher than that found in the general population, undoubtedly reflecting the higher incidence of hypertension and diabetes in this population. Figure 12 demonstrates a similar analysis for the heart and liver waiting lists. Again, all races are represented on both waiting lists, though the percentage of whites on the liver waiting list is slightly higher relative to the percentage of whites in the overall population. Conversely, there exists a higher percentage of African Americans on the heart waiting list. As with the kidney waiting list, this finding may reflect, at least in part, a difference in the incidence of end-stage liver and heart disease or a difference in access to care in these populations.

Assessing donor potential

Although the number of organ donors and resulting transplants in the United States is easily tallied, the number of individuals who could become organ donors across the country can only be estimated (Figure 13; SRTR analysis, June 2004). Several estimates of donor potential have relied on retrospective reviews of hospital medical records of deceased patients. The AOPO has spearheaded a multi-year chart review study with submission of data from more

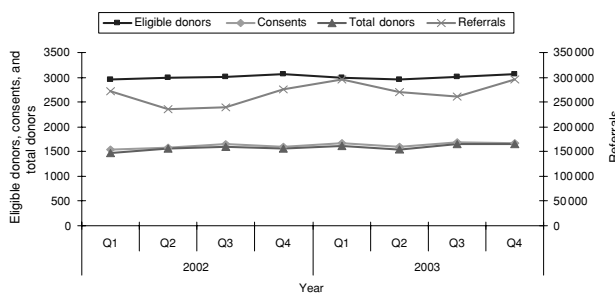


Figure 13: U.S. potential organ donor and actual donors by quarter, 2002–2003. Source: 2004 OPTN/SRTR Annual Report, SRTR Data Analysis, June 2004.

than 30 DSAs. The study, published in 2003, estimated that from 1997 to 1999 the annual number of brain-dead potential organ donors was between 10 500 and 13 800 (6).

Implicit in the AOPO chart review process or in any attempt to study organ donation is the need for the definition of a medically suitable organ donor. Consensus on the definition of what constitutes such a donor is not easily reached, because wide variation exists in the acceptance of organs among transplant centers and regions. Without a consistent definition by which to report data, comparisons across DSAs must be examined in the context of a broader array of measures and information.

In an attempt to quantify the number of medically suitable organ donors, the OPTN currently defines the term eligible death as a patient 70 years old or younger who, prior to death, is reported by a hospital to an OPO, and who is ultimately declared brain-dead according to hospital policy independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in case, and independent of local acceptance criteria or transplant center practice.

Furthermore, this patient exhibits no absolute contraindication to organ donation, such as metastatic cancer or seropositivity for human immunodeficiency virus. By restricting the pool to ages 70 years and younger who are reported by the hospital to the OPO, donors over the age of 70 years are excluded from this definition, as are patients who are declared brain-dead and meet the criteria but are never reported to the OPO. This definition also excludes patients who never meet brain death criteria, but who might be considered for DCD.

Since 2001, OPOs have been submitting monthly data to the OPTN on the number of referrals (deaths or imminent deaths) received from hospitals and the number of eligible deaths in their service area. These data are combined with OPTN data on total deceased donors recovered and reported by each DSA to the OPTN. Deceased donors comprise 'actual' donors, who meet the criteria of eligible death, and 'additional' donors, who are outside the definition of eligible death, e.g. patients who were over 70 years old or died after cardiac arrest. OPOs were able to see data for their own DSAs on a secure SRTR website for 6 months and encouraged to check and report discrepancies that appeared. In January 2004, DSA-specific data on referrals, eligible deaths, consents for donation, total deceased donor (including both actual and additional donors) and donation rates became publicly available online at www.ustransplant.org.

Referrals, eligible deaths and actual donors

In 2002 and 2003, U.S. hospitals referred more than 1 million deaths or imminent deaths to the OPOs in their DSA. Referrals increased by nearly 10% from 2002 to 2003 (1 022 280–1 121 392), likely because of ongoing efforts to ensure that hospitals comply with the conditions of participation developed by the Centers for Medicare & Medicaid Services (CMS). These conditions require hospitals to refer all deaths in a timely manner to their local OPO. The AOPO Death Record Review study corroborates this trend of increasing referrals, and the latest available data from the study suggest that, in 2001, 89% of all potential organ donors were referred, up from a 76% referral rate in 1997.

Despite the increase in the number of referrals, the number of eligible deaths reported remained virtually flat from 2002 to 2003: 12 015 in 2002 and 12 031 in 2003 (SRTR analysis, June 2004). The number of eligible deaths reported for 2002 and 2003 is consistent with the estimated number of potential organ donors from the published chart review studies (6). It is important to recall that approximately 10% of AOPO potential donors were never referred to the OPO and would be absent from these data, as would be patients over the age of 70 years, those who sustain cardiac death, and patients excluded because of their medical history or other clinical parameters.

Consents increased 4% and actual donors rose 3% from 2002 to 2003. The donation rate (defined as the number of actual donors divided by the number of eligible deaths) increased from 48% in 2002 to 49% in 2003. In sharp contrast to this overall modest growth, the number of 'additional' donors (those over the age of 70 years or donors after cardiac death) rose 23%, from 444 in 2002 to 547 in 2003 (SRTR data analysis, May 2004; Table 1).

Differences in potential and donation by donation service area

A comparison for 2003 across the 59 DSAs is complicated by the fact that DSA population, number of transplant centers and patients, and geographic coverage vary dramatically. In prior years, performance was measured and compared across DSAs using the standard metric 'organ donors per million population'. Although it was easily calculated, the per million living population was inherently flawed and potential organ donors per million varies dramatically across DSAs (19). The AOPO Death Record Review study reported a more than twofold difference in potential donors (using the AOPO criteria) per million at the DSA level. Based on the data from 16 DSAs over a 3-year period, the number of potential donors per year ranged from 28 to 63 per million population (mean, 41). The number of deceased donors per year ranged from 16 to 28 per million population (mean, 20) and the donation rate for the 1997–1999 period ranged from 32% to 58% (mean, 49%). The study found no significant relationship between the number of donors per million population and the donation rate ($R^2 = 0.124$) (6).

Despite the SRTR/OPTN data showing an essentially flat number of eligible deaths from 2002 to 2003 at the national level, comparing the reported number of eligible deaths across DSAs for 2002 and 2003 illustrates enormous variability year-to-year in the underlying donor potential at the DSA level. Seventeen DSAs experienced at least a 10% increase from 2002 to 2003 in eligible deaths while 15 DSAs experienced at least a 10% decrease in eligible deaths. The remaining 27 DSAs had eligible deaths in 2003 within 10% of their 2002 number. The 2002–2003 changes ranged from a 43% decrease in eligible deaths to a 47% increase in eligible deaths. Across all DSAs, the total increase in eligible deaths from 2002 to 2003 was 16, representing a 0.1% increase overall (SRTR analysis, August 2004).

Donation rates at the DSA level also vary dramatically. The 2003 national donation rate (calculated as actual donors divided by reported eligible deaths) was 49%, but donation rates within the 59 DSAs ranged from a low of 31% to a high of 85%. Twenty-six DSAs fell below the national average, 3 were at the national average and 30 were above the national average donation rate for 2003. It bears repeating that these comparisons must be undertaken within the context of acknowledging the lack of consistent baseline

definitions for data reporting; it must be considered, too, that these rates do not account for donors over the age of 70 years, donors after cardiac death or potential organ donors who are not referred to the OPO (SRTR analysis, August 2004).

Differences in procurement and utilization

Although there have been several proposals (Joint Commission on Accreditation of Healthcare Organizations white paper [3], Crystal City conference [20] and Health and Human Services Collaborative) to encourage best practices in organ donation, wide variations exist in the number of organs recovered and transplanted across regions (3).

Donation after cardiac death

These differences are particularly evident among donors after cardiac death (all organs). Twelve DSAs accounted for 77% of DCD, 23 DSAs accounted for the remaining 23% of DCD and 24 DSAs had no DCD in 2003 (SRTR analysis, May 2004). In the DSA with the largest fraction of DCD, such donors comprised over 23% of the DSAs deceased organ donors in 2003, an increase of 93% in deceased organ donors over the prior year. Nationally, the increase in DCD recoveries has been dramatic (all organs) (Figure 14). This subset of donors has increased by 43%, from 189 donors in year 2002 to 271 donors in 2003.

During the last decade, there were 1180 occurrences of DCD. The number of donors after cardiac death increased steadily through this period, with 57 in 1994 and 271 in 2003. This decade of experience progressed in two distinct eras (Figure 14). During Era 1 (1994–1998), there were 345 total DCD (average = 69/year) of which 340 (average = 68/year) donated kidneys. In Era 2 (1999–2003), the number of DCD increased to 835 (average = 167/year), of which 800 (average = 160/year) donated kidneys. The absolute number of DCD increased dramatically in the last 2 years, from 189 cases in 2002 to 271 cases in 2003 (Figure 14; SRTR analysis, May 2004).

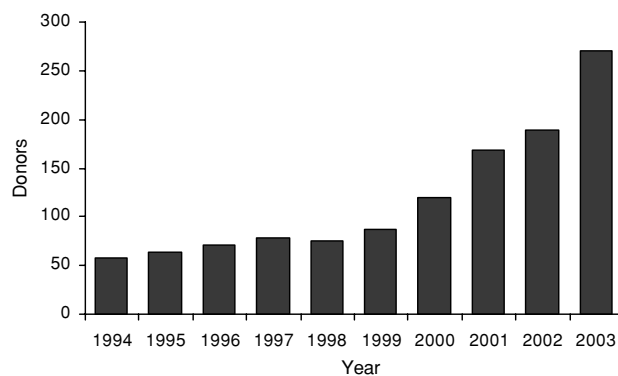


Figure 14: DCD donors, 1994–2003. Source: 2004 OPTN/SRTR Annual Report, Table 2.1.

While DCD organs make up a small fraction of organs recovered for transplant, they appear to be good quality organs. The number of organs transplanted per donor versus the number of organs recovered per donor for DCD is 2.04 versus 2.57. This translates to approximately 79% of organs recovered from DCD donors being transplanted, which compares favorably with non-DCD (89%). Among kidney donors, 82% of DCD organs recovered are transplanted, which is significantly greater than the 62% of recovered kidneys transplanted from ECD (Table 5). The difference in the number of recovered kidneys transplanted between DCD and ECD donors likely represents the better medical condition of DCD donors compared with ECD donors. Nonetheless, despite these observations, as well as increasing experience with DCD kidneys and several reports that support the use of intra-abdominal organs from DCD, relatively few OPOs currently perform DCD recoveries (SRTR analysis, May 2004).

Between 1999 and 2003, 44 of 59 OPOs reported at least one DCD recovery. Of these 44 OPOs, 26 accounted for 95% of DCD activity, and 18 of these OPOs handled five or fewer DCD cases in either era (SRTR analysis, May 2004). In 2003, only eight OPOs performed 10 or more DCD recoveries.

Some instances of DCD also have characteristics that fulfill expanded kidney donor criteria. Among the 256 DCD kidney donors in 2003, 46 (18%) also fulfilled ECD criteria.

Heart

The number of hearts recovered declined from a peak of 2525 in 1994 to 2121 in 2003 (Figure 15). The heart is one of the most highly utilized organs after recovery, with a discard rate of only 1% after procurement. The regional variation of use for this organ is minimal, with only seven DSAs having less than 95% of recovered hearts transplanted. The number of shared hearts across DSAs since 1997 has remained constant, between 30% and 35%. However, after consent, the number of hearts not procured doubled from 1292 in 1994 to 2601 in 2003. This increase in the turn-down rate probably reflects a change in number of donors with a CVA as cause of death. Recent reports of hormonal resuscitation to stabilize donors may allow for a further increase in utilization of cardiac donors in the future (21).

Lung

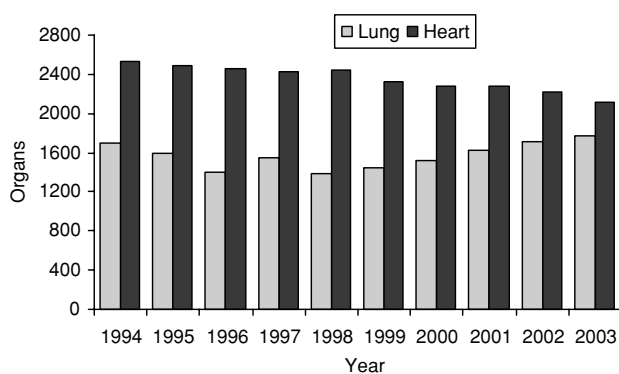
Lung procurement has remained unchanged in the last decade, with 1694 lungs procured in 1994 compared with 1772 in 2003 (Figure 15). The number of lungs shared across DSAs has remained constant at about 40% for the past 3 years. Similar to the cardiac experience, the decline in the number of lung offers is notable, as non-recovery of consented organs has increased from 6321 in 1994 to 8521 in 2003. Two-thirds of donors were turned down because of poor lung function. Although the mean number of

Table 5: U.S. kidneys recovered and transplanted from deceased donors by donor type, 1994–2003

	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
SCD										
Recovered	8123	8237	8163	8057	8412	8370	8518	8587	8685	8608
Transplanted	7560	7668	7542	7523	7871	7782	7847	7892	8074	7902
% transplanted	93.1	93.1	92.4	93.4	93.6	93.0	92.1	91.9	93.0	91.8
ECD*										
Recovered	1295	1574	1720	1880	2033	2159	2166	2079	2142	2321
Transplanted	864	1020	1136	1213	1306	1298	1252	1262	1314	1447
% transplanted	66.7	64.8	66.0	64.5	64.2	60.1	57.8	60.7	61.3	62.3
DCD[†]										
Recovered	111	126	137	151	148	174	225	321	365	508
Transplanted	83	106	109	116	110	148	177	253	306	416
% transplanted	74.8	84.1	79.6	76.8	74.3	85.1	78.7	78.8	83.8	81.9

SRTR Analysis, May 2004.

*Does not include DCD organs.

[†]Includes some organs with ECD characteristics.**Figure 15: Hearts and lungs recovered, 1994–2003.** Source: 2004 OPTN/SRTR Annual Report, Tables 3.13 and 3.16.

organs transplanted was 1.76 lungs per donor nationwide, four DSAs transplanted fewer than 1.5 lungs per donor and three DSAs had zero lung donors (SRTR Analysis, May 2004).

Liver

Liver procurement has continued to increase each year, from 4093 donors in 1994 to 5680 donors in 2003 (Figure 16). In 2003, there was an increase of 7% compared with 2002. A continual increase has been seen in donors 50–64 years of age. The number of livers recovered from donors aged 50–64 years doubled since 1994, from 680 to 1348 liver donors in 2003, with a 30% increase in just the last 5 years, from 1036 in 1999 to 1348 donors in 2003. Similar trends are seen in the procurement of livers from donors over 65 years of age, with the number of liver donors increasing from 164 in 1994 to 519 this past year. The most dramatic increase has been in the number of livers obtained from DCD donors in the last 5 years: 38 (0.8%) in 1999 were DCD donors compared with 158 (3%) in 2003.

Overall, compared with other abdominal transplants, there is high utility for liver, with only 4% of recovered organs discarded. The majority of organs discarded were because of biopsy results. In addition, 548 consented donors did not undergo procurement, predominantly because of issues pertaining to graft quality. Not surprisingly, the non-procurement rates were higher among older donors and DCD donors compared with donors <60 years old.

Intestine

Of the many types of transplant procedures, intestinal transplantation is performed least often and only by a small number of centers. Two-thirds of the recovered organs are transplanted outside the DSA in which they were recovered. In 2003, 122 intestines were recovered.

Kidney

The number of kidneys procured has continued to show a slight increase, approximately 2% each year, mirroring the increase in the number of donors each year. Although in recent years the increase in kidney donation appears, in large part, because of increased numbers of older or ECD, the percentage of procured kidneys that are discarded and the frequency of the reasons given for discard have remained essentially unchanged since 1995. Each year, 10–14% of recovered kidneys are discarded. Adverse biopsy result is the reason given for discard for approximately 40% of discarded recovered kidneys. However, the characteristics of a donor kidney biopsy that predict the quality of organ function are not universally accepted (22–26). An additional 25% of recovered kidneys are declined based on clinical judgment, with reasons for declining classified as 'organ unsatisfactory' or 'poor organ function/infection'.

Similar to the thoracic experience, the number of kidneys not recovered after consent was obtained has increased each year. Only 469 donor organs were not recovered after consent in 1994 compared with 1053 in 2003. In 1994, only 44% of the non-recovered kidneys were deemed unsatisfactory or had poor organ function; however, in

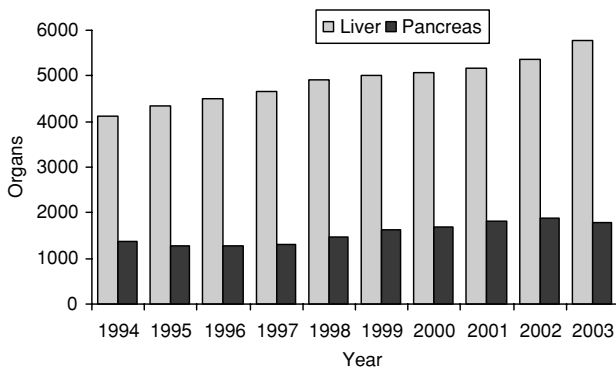


Figure 16: Livers and pancreata recovered, 1994–2003.
Source: 2004 OPTN/SRTR Annual Report, Tables 3.4 and 3.7.

the more recent era, 1999–2003, almost 60% met these criteria.

Pancreas

Pancreas procurement seems to have plateaued in the last few years at approximately 1800 per year from 2000 to 2003 (Figure 16). The discard rate is almost twice that of renal organs, approximately 17% of recovered pancreata. As with kidneys, the majority of the discards result from concerns about poor quality. Among recovered pancreata that were discarded in 2003, unavailability of the recipients was the reason for discard in 14% of cases. An additional 10% of pancreata were not recovered after consent, because recipients were unavailable (SRTR analysis, May 2004).

Expanded criteria kidney donors

OPTN Policy 3.5.1 defines ECD as a kidney donor older than age 60 years, or between ages 50 and 59 years and including one of the following medical criteria: died from a stroke, had a history of hypertension or had a serum creatinine >1.5 mg/dL at the time of death. Overall, in 2003, the number of ECDs increased by 8% to 1169 kidney donors compared with a 1% decrease among standard criteria donors (SCD) for kidney (SRTR analysis, May 2004).

The national mean of kidneys recovered per donor was constant at 1.99 for SCD, DCD and ECD; however, the transplant rates were only 1.83, 1.63 and 1.24 kidneys per donor, respectively. Utilization of recovered organs varied widely. In the past, the criteria for ECD had been left to the interpretation of individual centers. Several reports suggested that the outcomes of renal allografts from donors who are older or have hypertension, died from a CVA, or have elevated creatinine exhibited a lower graft survival rate. While the intent has been to increase the use of these organs and to ensure that candidates are informed about ECD transplant outcomes, the mean number of kidneys transplanted from ECD donors was only 1.24 compared with 1.78 organs from all donors <60 years of age. The number of kidneys transplanted from ECD donors may

represent an underestimate. Some centers transplant both kidneys from a single ECD donor into a single recipient and count this procedure as a single transplant. However, for accounting purposes, OPOs count both kidneys separately as recovered organs. The regional variation was greatest in ECD organs, with many programs having a more conservative clinical practice. Of the 59 OPOs, 23 (39%) reported transplant rates for ECD kidneys in their DSAs of less than 1.20 kidneys per donor, with 12 (20%) reporting a rate of 1.0 or less.

Potential for defining expanded criteria liver donors

There are several deterrents that prevent procurement and transplant of livers from expanded donors. The most limiting factor is the lack of objective criteria, e.g. cardiac anatomy and function for hearts or oxygen challenge in lungs, that can be uniformly applied. The decision to use a particular donor liver continues to be subjective and is best described by Heaton and colleagues, who note that the decision is not proven right until after transplant (27). These decisions are made given the reality that no reliable support exists for a failed liver and that even the best clinical judgment may result in the need for retransplant of the recipient.

Expanded criteria for kidney donors were developed based on lower graft survival in certain categories. Similarly, criteria could be developed for liver donors to allow for improved use of liver grafts and better information for recipients. In most instances, the decision to procure and transplant a graft is based on a constellation of clinical data. Each one of these factors by itself may not jeopardize outcome. None of the functional tests (such as the monoethylglycinexylidide [MEGx] test, which utilizes lidocaine metabolism) have withstood the test of time (28).

One potential criterion is donor age. Liver donor age has increased steadily over time. Although initial studies suggested that organs from donors older than 50 years have poor outcomes, more recent studies indicate that only donors older than 65 or 70 years have lower patient and graft survival at 2 years. Rull et al. reported a higher rate of graft loss in recipients who received grafts from donors older than 65 years, in particular, if there are other factors such as steatosis on the liver biopsy. If the recipient had a difficult surgery with a blood replacement requirement >10 units, one-half of the grafts failed early in the post-transplant course (29). In a more recent report (2001), Busquets et al. observed that liver allografts from donors older than 70 years had a 6-month survival of 56%; survival at 54 months was 25% (30). DebRoy et al. have demonstrated an important interaction between older donor age and prolonged cold ischemia time, such that the combination is associated with particularly poor outcomes (31).

Another likely criterion would be the degree of steatosis. The escalating incidence of obesity among the general population suggests that steatosis could be an increasing concern in evaluating donor livers. The reported incidence is estimated to be between 9% and 26%. Steatotic livers have been associated with an increased incidence of poor graft function and primary non-function. There is consensus that grafts with greater than 60% fat should not be used for transplant (32). In a time-matched control study, Marsman et al. have shown that grafts with moderate steatosis up to 30% have decreased graft survival at 4 months and also decreased patient survival at 2 years (33). Recent studies report no increased risk from using grafts with microvesicular steatosis (34). However, the interpretation of fat on biopsy is subject to the judgment of the local pathologist and transplant surgeon.

Other widely accepted clinical criteria that increase risk of non-function include ICU stay > 5 days, particularly without nutritional support; hypernatremia with serum sodium >160 mEq/dL; hypoxia; vasopressor use with an increase in liver chemistries, and prolonged cold ischemia time. Cause of death does not appear to be a predictor of non-function among liver donors.

In addition to these donor-specific criteria, the decision whether to use a liver from an extended donor must take into account the severity of illness of the intended recipient. Such grafts placed into severely ill recipients provide a recipe for a dismal outcome, suggesting that these grafts should be directed away from recipients with high model for end-stage liver disease (MELD) scores, perhaps greater than 30 (35). On the other end of the illness scale, recent data presented by Merion et al. suggest that those candidates with a MELD score <15 had a higher risk of mortality with transplant than did medically managed patients on the waiting list (36). Clearly, the use of an extended donor liver in these healthier candidates is not in the best interest of such candidates. It may be reasonable to offer such livers first to recipients with a MELD score between 15 and 30, after obtaining informed consent. As more data are collected, these criteria may need to be modified.

Summary

This article provides an overview of organ donation trends in the United States. Recently, the number of deceased donor organs recovered per year has been increasing gradually. Non-traditional donor sources have experienced a much larger rate of increase; the number of ECD kidney donors has increased 8% and the number of DCD donors has increased 43% during the past year (Figure 3). The relative percentages of Hispanic/Latino and African American donors have trended upward as well. Although the number of living donors continues to exceed the number of deceased donors, the rate of growth from this source

was smaller in 2003 (Figure 6). Unrelated living kidney donation has been shown to achieve excellent graft survival. Currently, unrelated donors make up over 30% of all living kidney donors.

The number of potential donors in the United States is estimated to be between 10 500 and 13 800 (6), which is consistent with the number of eligible deaths reported by DSAs nationwide. Despite the fact that the total number of eligible deaths remained flat in 2003, there exists a large amount of variability in donor potential at the DSA level. Donation rates among DSAs also vary considerably—although these rates currently do not account for DCD or donors above 70 years of age.

References

1. Dickinson DM, Dykstra DM, Levine GM, Li S, Welch JC, Webb RL. Transplant data: sources, collection, and research considerations, 2004. *Am J Transplant*. 2005; 5(Part 2): 850–861.
2. Schaubel DE, Dykstra DM, Murray S et al. SRTR Report on the state of transplantation: analytical approaches for Transplant Research, 2004. *Am J Transplant*. 2005; 5(Part 2): 950–957.
3. Health care at the crossroads: Strategies for narrowing the organ donation gap and protecting patients: JCAHO.
4. Siminoff LA, Gordon N, Hewlett J, Arnold RM. Factors influencing families' consent for donation of solid organs for transplantation. *JAMA* 2001; 286: 71–77.
5. 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.
6. Sheehy E, Conrad SL, Brigham LE et al. Estimating the number of potential organ donors in the United States. *N Engl J Med* 2003; 349: 667–674.
7. Morgan SE, Miller JK, Arasaratnam LA. Similarities and differences between African Americans and Europeans Americans' attitudes, knowledge, and willingness to communicate about organ donation. *J Appl Soc Psychol* 2003; 23: 693–714.
8. Davidson MN, Devney P. Attitudinal barriers to organ donation among black Americans. *Transplant Proc* 1991; 23: 2531–2532.
9. Yancey AK, Coppo P, Kawanishi Y. Progress in availability of donors of color: the National Marrow Donor Program. *Transplant Proc* 1997; 29: 3760–3765.
10. Hall LE, Callender CO, Yeager CL, Barber JB, Jr., Dunston GM, Pinn-Wiggins VW. Organ donation in blacks: the next frontier. *Transplant Proc* 1991; 23: 2500–2504.
11. Arnason WB. Directed donation. The relevance of race. *Hastings Cent Rep* 1991; 21: 13–19.
12. McNamara P, Guadagnoli E, Evanisko MJ et al. Correlates of support for organ donation among three ethnic groups. *Clin Transplant* 1999; 13(1 Pt 1): 45–50.
13. Siminoff LA, Arnold R. Increasing organ donation in the African-American community: altruism in the face of an untrustworthy system. *Ann Intern Med* 1999; 130: 607–609.
14. Spigner C, Weaver M, Pineda M et al. Race/ethnic-based opinions on organ donation and transplantation among teens: preliminary results. *Transplant Proc* 1999; 31: 1347–1348.
15. Parisi N, Katz I. Attitudes toward posthumous organ donation and commitment to donate. *Health Psychol* 1986; 5: 565–580.

16. Sanner M. Attitudes toward organ donation and transplantation. A model for understanding reactions to medical procedures after death. *Soc Sci Med* 1994; 38: 1141–1152.
17. Morgan SE, Cannon T. African Americans' knowledge about organ donation: closing the gap with more effective persuasive message strategies. *J Natl Med Assoc* 2003; 95: 1066–1071.
18. Morgan SE, Miller J. Communicating about gifts of life: the effect of knowledge, attitudes, and altruism on behavior and behavioral intentions regarding organ donation. *J Appl Commun Res* 2002; 30: 163–178.
19. Luskin RS, Delmonico FL. Assessing organ donation from the dead should not be done by reporting a census of the living. *Am J Transplant* 2003; 3: 1185–1187.
20. Rosengard BR, Feng S, Alfrey EJ et al. Report of the Crystal City meeting to maximize the use of organs recovered from the cadaver donor. *Am J Transplant* 2002; 2: 701–711.
21. Lloyd-Jones H, Wheeldon DR, Smith JA, Potter CD, Wallwork J, Large SR. An approach to the retrieval of thoracic organs for transplantation. *AORN J* 1996; 63: 416–423, 425–426.
22. Edwards EB, Posner MP, Maluf DG, Kauffman HM. Reasons for non-use of recovered kidneys: the effect of donor glomerulosclerosis and creatinine clearance on graft survival. *Transplantation* 2004; 77: 1411–1415.
23. Papadimitriou JC, Coale R, Farney A et al. Biopsy of the marginal kidney donor: correlation of histology with outcome. *Transplant Proc* 2004; 36: 742–744.
24. Vistoli F, Boggi U, Vanadia Bartolo T et al. Kidney transplantation from donors aged more than 65 years. *Transplant Proc* 2004; 36: 481–484.
25. Howie AJ, Ferreira MA, Lipkin GW, Adu D. Measurement of chronic damage in the donor kidney and graft survival. *Transplantation* 1995; 60: 334–339. *Transplantation* 2004; 77: 1058–1065.
26. Gaber LW, Moore LW, Alloway RR, Amiri MH, Vera SR, Gaber AO. Glomerulosclerosis as a determinant of posttransplant function of older donor renal allografts. *Transplant* 1995; 60: 334–339.
27. Vilca Melendez H, Rela M, Murphy G, Heaton N. Assessment of graft function before liver transplantation: quest for the lost ark? *Transplantation* 2000; 70: 560–565.
28. Oellerich M, Armstrong VW. The MEGX test: a tool for the real-time assessment of hepatic function. *Ther Drug Monit* 2001; 23: 81–92.
29. Rull R, Vidal O, Momblan D, Gonzalez FX, Lopez-Boado MA, Fuster J. Evaluation of potential liver donors: Limits imposed by donor variables in liver transplantation. *Liver Transpl* 2003; 9: 389–393.
30. Busquets J, Xiol X, Figueras J et al. The impact of donor age on liver transplantation: influence of donor age on early liver function and on subsequent patient and graft survival. *Transplantation* 2001; 71: 1765–1771.
31. DebRoy M, Dykstra DM, Robert JP et al. The impact of cold ischemic time and donor age on liver transplant outcome. *Am J Transplant* 2003; 3(Suppl. 5): 451.
32. Loinaz C, Gonzalez EM. Marginal donors in liver transplantation. *Hepato-Gastroenterology* 2000; 47: 256–263, 2000.
33. Marsman WA, Wiesner RH, Rodriguez L et al. Use of fatty donor liver is associated with diminished early patient and graft survival. *Transplantation* 1996; 62: 1246–1251.
34. Fishbein TM, Fiel MI, Emre S et al. Use of livers with microvesicular fat safely expands the donor pool. *Transplantation* 1997; 64: 248–251.
35. Farmer DG, Anselmo DM, Ghobrial RM et al. Liver transplantation for fulminant hepatic failure: experience with more than 200 patients over a 17-year period. *Ann Surg* 2003; 237: 666–676.
36. Merion RM, Schaubel DE, Dykstra DM, Freeman RB, Port FK, Wolfe RA. The survival benefit of liver transplantation. *Am J Transplant* 2005; 5: 307–313.