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REVIEW

Increasing organ donation and transplantation: the U.S. experience over the past decade

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Summary

The growing gap between the need for and supply of transplantable organs in the U.S. led to several initiatives over the past decade. UNOS implemented policies intended to facilitate the use of expanded criteria donor kidneys with mixed success. The U.S. government sponsored several organ donation and transplantation collaboratives, leading to significant increases in organ donation over several years. The use of organs from donors dying from cardiac death has increased steadily over the past decade, with such donors now exceeding 10% of the total. Revisions of state anatomic death acts allowed persons to declare their intention to donate by enrolling in state donor registries, facilitating the identification of willing donors by organ procurement organization. Despite these initiatives, the disparity between organ demand and supply has continued to grow, primarily as a result of marked increase in the number of candidates awaiting kidney transplantation.

Introduction

The United States organ transplantation community entered the current millennium facing daunting challenges in its effort to provide transplantation to patients with end-stage organ disease. In 1987, the year that the United Network for Organ Sharing (UNOS) began administering the national Organ Procurement And

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Transplantation Network (OPTN), 6976 patients received deceased donor kidney transplants, while 11 922 patients were awaiting kidney transplants nationally. By the end of 2000, the kidney waiting list had grown to 44 719 patients – a 25% annual increase since 1987 – and the gap between the number of patients awaiting kidney transplants and those actually receiving transplants had increased to 36 599. For patients awaiting liver transplantation, the increase in demand was even more striking. In 1993, 498 more patients received liver transplants than were on the liver waiting list at the end of the year. By 2000, in contrast, over 12 000 more patients were awaiting liver transplants than were transplanted.[1]

In recognition of the growing need for organ transplantation, the federal Medicare Conditions of Participation were revised in 1998 to require hospitals to contact their affiliated organ procurement organization (OPO) in a timely manner about individuals who died or whose death was imminent and to insure that only OPO or trained hospital staff (designated requestors) approached families about organ donation. All hospitals receiving federal funds for the care of patients entitled to receive Medicare or Medicaid benefits must meet the Conditions of Participation, and these requirements therefore applied to the vast majority of U.S. hospitals. Despite this, the total number of organ donors increased <2% annually over the subsequent 4 years.

In an attempt to address the ever-increasing disparity between the need for and the supply of transplantable organs from deceased donors, several innovative approaches were undertaken during the past decade. We would like to focus on four important initiatives: OPTN policies to encourage the use of kidneys from expanded-criteria donors (ECD), the several breakthrough collaboratives sponsored by the Division of Transplantation of the Health Resources and Services Administration of the federal Department of Health and Human Services, the renewed utilization of organs from donors who had suffered cardiac death, and early attempts to prospectively identify willing organ donors through the use of state registries.

[1]Data regarding organ transplantation in the United States are readily available online through the OPTN/SRTR Annual Reports (http://optn.transplant.hrsa.gov and http://www.ustransplant.org) as well as through the US Renal Data Systems (http://www.usrds.org). The waiting list and transplant event numeric counts and OPO performance measure results included in this manuscript were obtained from those sites or, for Collaborative performance measures, were based on OPTN data as of June 4, 2010.

The United States transplant system

The U.S. transplant system is composed of a network of transplant centers (most of which are part of an academic medical center), OPOs, and donor hospitals, the large majority of which are nonacademic general hospitals and are not formally associated with a transplant center. Each donor hospital has a single designated OPO with which it works to promote organ donation and recovery. Organ donation and transplantation policies are determined by the national OPTN, which is administered under federal contract by the UNOS, a large organization to which every transplant center and OPO belongs as a member. Federal oversight of OPTN activities is provided by the Division of Transplantation of the Health Services and Resources Administration, part of the federal Department of Health and Human Services. As mentioned above, essentially all hospitals must meet the federal Medicare Conditions of Participation and most also meet the accreditation requirements of the Joint Commission, both of which contain provisions related to organ donation.

Definition of and UNOS policies regarding ECD

As the number of patients awaiting transplantation increased, more attention was focused on the outcome of transplantation from deceased donors who were less than ideal from a medical standpoint. Early results suggested that transplantation using organs from so-called 'marginal' donors would be appropriate for some patients [1,2]. Fostering the appropriate use of kidneys from such donors was an important focus of a consensus conference held in 2001, and UNOS eventually adopted and implemented policies in October, 2002 that were intended to maximize the recovery and use of ECD kidneys while facilitating efficient kidney placement and minimizing kidney cold ischemia time [3,4]. The UNOS policy, consistent with analysis by the U.S. Scientific Registry of Transplant Recipients (SRTR), identified ECD kidneys as those whose relative risk of graft loss was >1.7 when compared with normotensive donors aged 10–39 years with normal renal function who did not die from a cerebrovascular accident, and included all kidneys from donors 60 years of age or older as well as donors aged 50–59 years who had any two of the following characteristics: history of hypertension, death caused by a cerebrovascular accident or terminal serum creatinine immediately prior to organ recovery >1.5 mg/dl [5]. The UNOS policy also required that patients consent to receive an ECD kidney, allocated ECD kidneys solely on the basis of waiting time, and required OPOs to identify potential ECD recipients within a shorter period of time than allowed for standard donors.

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Since the implementation of the ECD policies, donors who meet the ECD definition have constituted 21–23% of the deceased donor population. While the number of ECD kidneys recovered increased 64% from 2232 in 2002 to 3478 in 2007, the number of ECD kidneys that were actually transplanted increased by only 51%, while the discard rate increased from 39% to 44% over that time. There has been marked variability among UNOS regions in the percentage of kidney candidates wait-listed for an ECD kidney and in the fraction of donors qualifying as ECD, which ranged from 6% to 43% in 2009. In addition, the ECD kidney discard rate has varied widely among donor service areas (DSAs),[2] ranging from 14% to 60%. The presence of glomerulosclerosis on biopsy has a profound impact on discard rates, which increased to over 80% of ECD kidneys with >20% glomerulosclerosis [6]. Of interest, the degree of glomerulosclerosis has not been correlated with kidney failure when subjected to critical multivariate analysis, bringing its use as a primary determinant of kidney discard into question [6,7].

While the development and implementation of the UNOS ECD policy focused attention on the proper use of ECD kidneys, the continued high discard rates are of great concern. Failure to clarify initially which candidates were best suited to receive ECD kidneys is likely to have contributed to the problem. The ECD kidney cohort was shown to have widely variable outcomes in the original study, where the relative risk of graft failure ranged from 1.74 to 2.69, depending on the characteristics of the donor [5]. Ongoing interest in a more discriminating measure of donor kidney risk has led to the development of the kidney donor risk index, which incorporates many more donor factors than does the ECD classification [8]. A similar index is currently being considered to replace the ECD classification in the UNOS kidney allocation system.

The collaboratives

Introduced in 2003 as part of the U.S. Department of Health and Human Services' Gift of Life Donation Initiative, the Organ Donation Breakthrough Collaborative was a national effort to increase organ donation by identifying best practices at high-performing OPOs and transplant centers and encouraging their adoption, study, and improvement by other DSAs [9].

The collaborative approach, developed by the Institute for Healthcare Improvement, is a strategy designed to achieve dramatic (breakthrough) improvements in system performance over a relatively short time period, typically 6–15 months [10]. Following the IHI model, the Organ Donation Breakthrough Collaborative convened a group of experts in 2001 to identify characteristics and practices of OPOs and transplant centers that were associated with higher rates of organ donation. A series of workshops was then held, through which multidisciplinary teams from OPOs, transplant centers, and donor hospitals were introduced to the best practices and explored methods through which the practices could be applied locally. Follow-up workshops were held to convey and discuss results and process refinements that had been successful and to encourage their spread throughout the donation and transplantation community. The initial goals of the Organ Donation Breakthrough Collaborative included increase in the donor conversion rate (see below) to 75%, increase in organ donors by up to 1900 per year, and increase in transplants by up to 6000 per year. By 2005, the goals were expanded to include increase in the donation consent rates in participating hospitals by 30% and increase the number of donations after cardiac death (DCD) to 10% of all donors.

In recognition of the pivotal role of the transplant center in insuring effective use of donated organs, the Organ Transplantation Collaborative was launched in 2005 with the goal of increasing the organs transplanted per donor rate to >3.75. In 2006, the Collaborative efforts were merged as the Organ Donation and Transplantation Collaborative. The final Collaborative effort – the Transplant Growth and Management Collaborative – began in 2007 to increase transplant center capacity in order to facilitate further the organ transplantation in addition to organ recovery [11].

A key focus of the Collaboratives has been standardized information reporting to allow comparisons among OPOs, transplant centers, and DSAs. Currently, there are four primary outcome metrics that are monitored for each DSA, each UNOS region, and for the nation on a monthly basis: organs transplanted, consent rate, conversion rate, and organs transplanted per donor.[3]

Dynamic changes in the composition of the pool of potential donors and in neurologic, neurosurgical, and

[2]Defined in the U.S. system as an OPO along with its affiliated transplant centers and donor hospitals.

[3]Several key definitions were adopted that have come into general use in the U.S. transplant community:
eligible death – a patient 70 years old or younger legally declared brain dead who is free of a number of potentially transmissible infectious or neoplastic diseases and who is not suffering from multi-system organ failure;
eligible donor – an eligible death that becomes a donor;
conversion rate – the ratio of eligible donors to eligible deaths;
consent rate – the fraction of eligible deaths in whom consent for donation is obtained; and
organs transplanted per donor (*OTDP*) – the average number of solid organs transplanted per donor.

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Table 1. Organ donation performance measures.

Metric	Performance target	National results	DSAs meeting target
Organs transplanted	35 000 yearly	24 205	n/a
Consent rate	80%	72.4%	17%
Conversion rate of eligible deaths	75%	69.3%	24%
Collaborative conversion rate	75%	73.4%	43%
DCD (% of total)	10%	11.5%	52%
OTPD			
Overall	3.75	3.02	0
Standard	4.3	3.67	0
ECD	2.75	1.81	3.5%
DCD	2.75	2.08	0

DCD, donations after cardiac death; ECD, expanded criteria donors. Results for calendar year 2009, based on OPTN data as of June 4, 2010.

Consent rate is based on the consent rate for eligible deaths as reported by the OPOs to the OPTN on a monthly basis, including only non-DCD potential donors <70 years of age without specific disqualifying conditions (positive serology, etc.).

Conversion of eligible deaths is the number of actual donors recovered that meet the eligible death criteria divided by the number of reported eligible deaths. DCD and donors over the age of 70 years are excluded.

Collaborative conversion rate is the number of actual donors divided by the total number of reported deaths, including DCD and donors over 70 years of age in both the numerator and denominator.

OTPD: organs transplanted per donor; overall means all donors; standard means non-ECD and non-DCD.

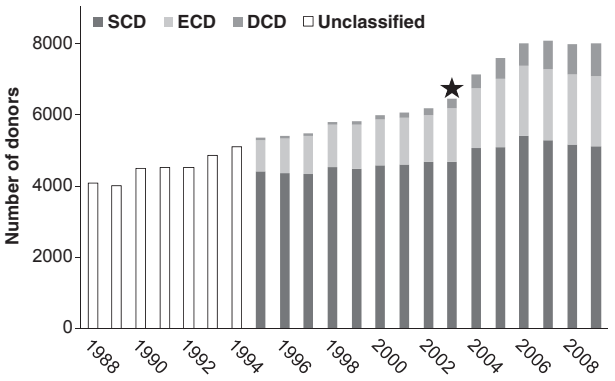

Figure 1 Organ donation in the U.S. Data to fully characterize donor type not collected until mid-1990s. SCD, standard criteria donor; ECD, expanded criteria donor; DCD, donation after cardiac death. Star indicates year of initial Organ Donation Breakthrough Collaborative.

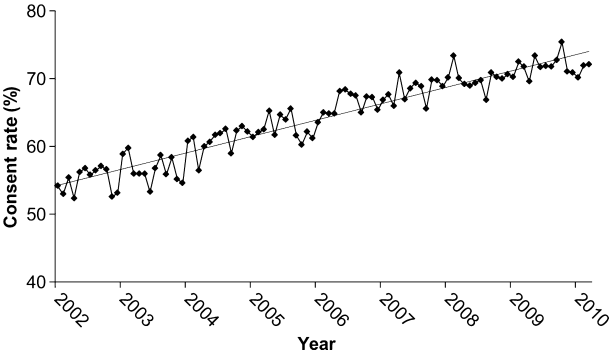

Figure 2 National consent rate. The Collaborative goal is 80%.

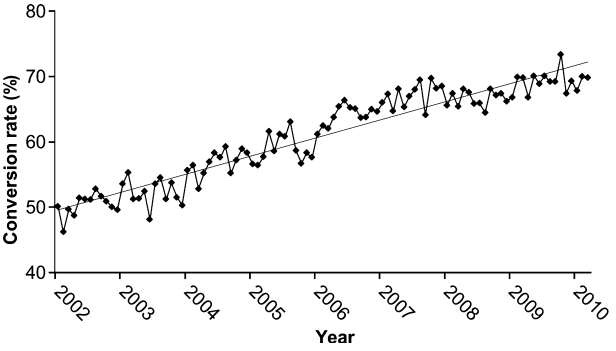

Figure 3 Conversion of eligible deaths. The Collaborative goal is 75%.

critical care over the last decade make evaluating the success of the Collaboratives difficult (Table 1). Nonetheless, the early results in increasing organ donation were impressive, with total deceased donors increasing by 30% from 2002 to 2006 (Fig. 1). Since 2006, however, the number of deceased donors has not increased. Closer examination shows that while the reported consent rate and conversion rates continued to increase steadily, the number of reported eligible deaths dropped almost 15% from 2006 through 2009. The Collaborative OTPD goals have been particularly difficult to meet, with none of the DSAs reaching the overall, SCD or DCD targets. The national overall OTPD rate has actually dropped slightly over the past decade, because of decreases in organ utilization from ECD and DCD donors (Figs 2–5).

The failure to increase the number of organs transplanted per donor has emphasized the impact of organ acceptance criteria and transplant center behavior on organ utilization and transplant rates. The final Collaborative effort – the Transplant Growth and Management Collaborative – was begun in 2007 to increase transplant center capacity and identify best practices in the acceptance and utilization of less-than-ideal recovered organs without adversely affecting expected transplant success rates. Focused study of several high-performing transplant centers led to the identification of factors associated with high transplantation rates, including institutional

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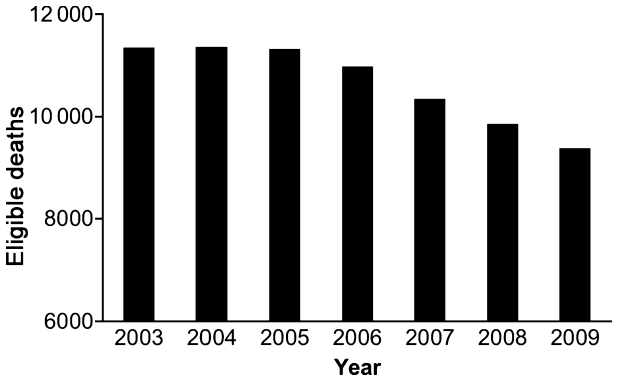

Figure 4 Eligible deaths in the United States, as reported by OPOs.

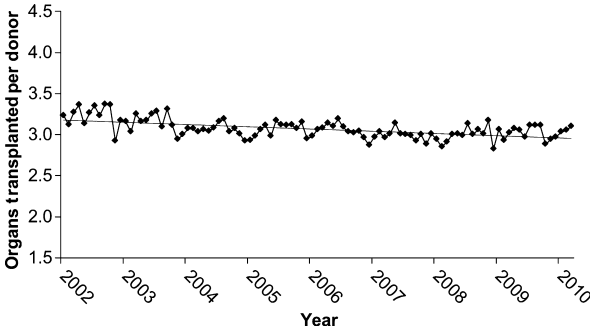

Figure 5 Organs transplanted per donor, including standard, DCD, and ECD donors. The Collaborative goal is 3.75.

commitment to transplantation, presence of a dedicated transplant team, and a clinical philosophy that embraces the use of high-risk organs for appropriate patients [11]. Despite these efforts, widespread failure to meet the organs transplanted per donor targets persists (Table 1). Some of the reasons for the failure to increase organ utilization are discussed below.

Responsibility for continuing the collaborative effort to increase organ donation was assumed in 2006 by the not-for-profit Organ Donation and Transplantation Alliance (http://www.organdonationalliance.org), led by representatives from many organizations in the donation and transplantation community, including individual OPOs and transplant centers, UNOS, American Society of Transplantation, American Society of Transplant Surgeons, Association of Organ Procurement Organizations, the Joint Commission and others.

Donation after cardiac death

Although donation after cardiac death was the norm in the United States before the enactment of brain-death legislation in the early 1970s, such donors constituted only

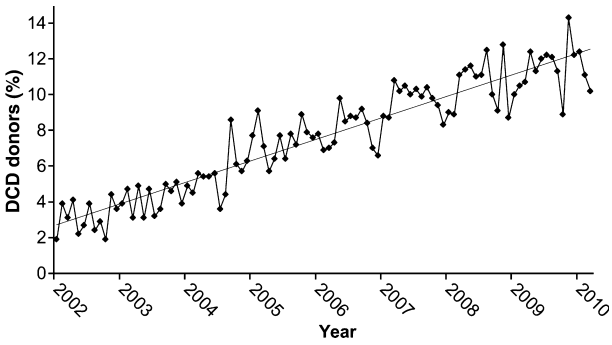

Figure 6 Percent DCD donors. The Collaborative goal is 10%.

2% of the total in 2000. Acknowledging the growing gap between organ supply and demand and the excellent results that could be obtained with transplantation of DCD organs [12,13], the Collaboratives adopted increasing donation after cardiac death to at least 10% without negatively impacting donation after brain death as a primary performance goal. The ethical basis for donation after cardiac death had been affirmed earlier by the Institute of Medicine, which concluded that 'recovery of organs from NHBDs is an important, medically effective, and ethically acceptable approach' in meeting the need for donated organs [14]. A 2005 national conference on donation after cardiac death supported the clinical utility and ethical propriety of donation after cardiac death, and suggested actions to be taken by several different organizations to promote donation after cardiac death [15]. The Joint Commission (the primary U.S. healthcare accrediting organization) subsequently adopted a requirement that hospitals develop DCD policies in order to be accredited, UNOS modified its by-laws so that transplant hospitals were required to develop protocols to facilitate DCD organ recovery, and the American Society of Transplant Surgeons published comprehensive evidence-based clinical guidelines regarding controlled donation after cardiac death in 2009 [16].

Nationally, the proportion of DCD donors exceeded 10% for the first time in March, 2007, and has continued to increase slowly since (Fig. 6). There continues to be wide variation in DCD among OPOs, however, ranging in 2009 from a maximum of 32% to <5% in 13 OPOs. Recent single-center results of DCD kidney transplantation have confirmed earlier findings that DCD kidneys provide excellent long-term graft function, albeit with a much higher initial delayed graft function rate [17,18]. The results of DCD liver transplantation have not been as favorable, with considerably higher rates of biliary complications and graft loss in some centers, but not in others [19–21]. Enthusiasm for DCD transplantation has also been tempered by its economic impact, with estimates of

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30% increase in postliver transplant costs in one center and 53% higher hospital charges for patients receiving DCD kidneys in another [22,23].

State donor registries and the Uniform Anatomical Gift Act

Laws governing organ and tissue donation in the United States are written primarily at the state level. The publication of the 2006 revision of the Uniform Anatomical Gift Act (UAGA), which has been adopted by 44 of the 53 states, districts and territories subsequently, was pivotal in allowing the development of effective state organ donor registries [24]. This model legislation, for the first time, allowed persons to indicate their intention to donate by enrolling in a donor registry, and actually foresaw a time when enrollment in a registry would become the primary means by which intention to donate would be recorded. It also included important provisions that more strongly prevented others from overriding a person's decision to be a donor. Concurrent with the publication of the revised act, Donate Life America, a not-for-profit membership organization dedicated to increasing organ donation in the U.S., redirected its activities toward developing effective organ donor registries in every state in the United States. Donor registries, which allow individuals to record their intent to become an organ and tissue donor, had existed for years in some states, but were not generally well-subscribed and, in many instances, were not available for real-time access by OPO staff during initial evaluation of potential donors. In addition, prior to 2006, many OPOs were reluctant to proceed with organ recovery without consent of the legal next-of-kin, even when the potential donor had previously documented his intention to donate by signing a donor card or other legal instrument. Once adopted, the UAGA revision provided assurance to OPO staff that they were within legal bounds when they proceeded with organ recovery in accordance with the donor's expressed wishes, irrespective of the desires of others.

Donate Life America convened the Donor Designation Collaborative in 2006 with the goal of enlisting state donor advocates in an effort to develop donor registries where they did not exist, improve the registries that currently existed, and increase enrollment in registries throughout the country (David W. Fleming, President and CEO, Donate Life America, personal communication). At that time, there were an estimated 57 million persons enrolled in state registries, most registries did not allow real-time access to determine enrollment, many suffered from a protracted time lag between enrollment and actual registry listing, and many states did not have a registry at all. The cooperative efforts of Donate Life America, its local affiliates, many OPOs, and state driver registration units have since led to the establishment of donor registries in all but one state. Effective donor registries (see Table 2) have been established in 36 states. The Donor Designation Collaborative adopted national goals of (i) over 100 million registrants and (ii) a >50% rate of registry enrollment of persons being issued driver's licenses or identification cards. As of April, 2010, over 86 million donors were registered, representing a 24% increase since 2007. During the fourth quarter of 2009, over 35% of driver's license and identification card applicants enrolled as donors, and nine states had met the goal of enrolling over 50% of such applicants as donors [25].

The ultimate goal, of course, is to increase organ donation. While effective donor registries provide obvious operational benefit to OPO personnel, and while there has been a substantial increase in the proportion of actual donors who had previously enrolled in a donor registry (Fig. 7), it is not yet clear whether donor registries will result in more persons actually becoming donors. It is encouraging that, in the first quarter of 2010, 32% of

Table 2. Elements of effective donor registries.

Effective donor registry design
Donor designation is considered legally binding consent
Includes consent for tissue donation
Individuals can enroll through a dedicated website
State Department of Motor Vehicles enrolls donors via driver's license and ID card applications and renewals
No follow-up step required for State Department of Motor Vehicles or online enrollment
State Department of Motor Vehicles exports donor records to registry database
Organ, eye, and tissue recovery agencies can effectively access donor designations

Adopted from Ref. [25].

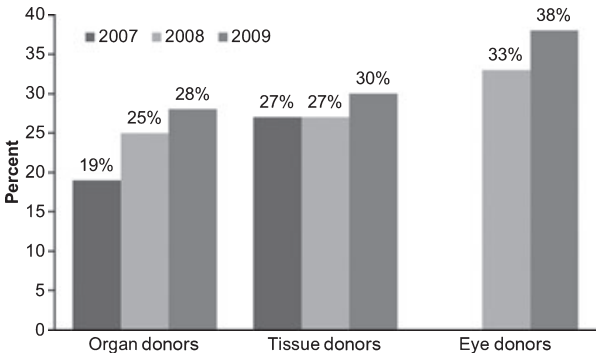

Figure 7 Designated donors among recovered donors. From Ref. 25. Eye donor information is not available for 2007.

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recovered organ donors were authorized via state registries (Fleming, personal communication).

Ongoing issues and new approaches

Appropriate use of donated organs

As noted above, organ discard rates remain high in the U.S., particularly of what are perceived as high-risk organs. Concerns about the impact of expanded criteria organ transplantation on transplant program-specific outcomes may underlie reluctance to use these organs. Program-specific outcomes are readily available for public scrutiny through the SRTR at its website (http://www.ustransplant.org). Although the analytic models used by the SRTR incorporate multiple risk adjustments, there have been concerns that the adjustments do not reflect adequately the increased risk accompanying the use of expanded criteria organs. In recent years, the use of these outcome data by the U.S. Centers for Medicare and Medicaid Services to qualify programs for transplant reimbursement by federal insurance providers and by private insurers to qualify programs for inclusion in their transplant provider networks has led transplant programs to focus on their outcomes even more intensely, and may have led centers to avoid using what are thought to be high-risk organs for transplantation [26,27]. In addition, the impact of transplanting ECD and DCD organs on transplant program fiscal performance may inform the decisions regarding the use of such organs. Recipients of high-risk organs have longer lengths of stay and higher costs, as noted above. While pulsatile kidney preservation has been shown to be effective in reducing the delayed graft function rate of ECD kidneys and in reducing hospitalization costs, its direct costs are several thousand dollars per kidney, perhaps discouraging OPOs and transplant centers from implementing pump preservation programs [28–30]. Efforts to encourage CMS to modify program reimbursement practices in order to cover the additional costs of ECD kidney transplantation have not been successful as yet.

Although systems to characterize extrarenal organ risk have been developed [31], they have not been incorporated in UNOS allocation systems, and processes to facilitate the rapid placement of high-risk organs remain rudimentary. As pointed out by Klein *et al.*, initial transplant center refusal of livers based on donor quality considerations does not correlate with transplant outcomes, as there is no large difference in average MELD score and liver transplant graft survival between recipients of livers accepted on first offer and those initially declined by multiple centers because of concerns regarding donor quality [32]. Development of a system to expedite the early placement of high-risk donor livers was overwhelmingly supported by the participants in a recent UNOS-sponsored forum on liver allocation and has been adopted as a policy development goal of the UNOS Liver and Intestinal Transplantation Committee (W. Kenneth Washburn, committee chair, personal communication).

The impact of the U.S. kidney allocation system, which is basically a queue based on time on the waiting list and which allows candidates access to the entire donor pool irrespective of candidate or donor age, on program and patient organ acceptance practices has not been critically examined. It may be that once a candidate reaches the top of the list and begins receiving kidney offers, the candidate – or program – may elect to bypass offers of ECD kidneys in the hopes of receiving an offer of a standard criteria kidney in the near future. A new kidney allocation system is under consideration, which may include a provision that would initially offer donor kidneys only to candidates within a few years of the donor's age, hopefully encouraging older candidates to accept otherwise acceptable kidney from donors close to their own age and reducing discards of kidneys from older donors.

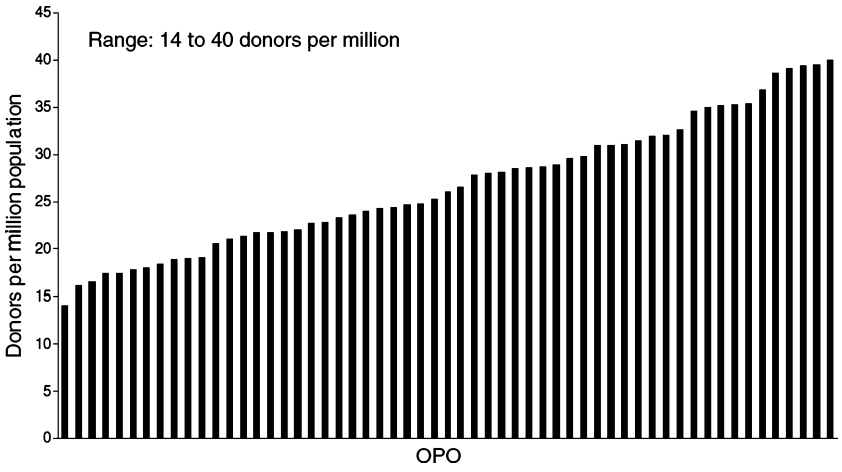

Figure 8 Organ procurement organization (OPO) variation in donors recovered per million population. From Ref. 32. Source: SRTR analysis. Data as of May, 2009.

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Table 3. The U.S. organ transplant waiting list.

	Number of candidates	
	1/1/2000	7/31/2010
Kidney	46 489	91 072
Liver	14 709	16 647
Heart	4121	3141
Kidney–pancreas	2225	2259
Lung	3636	1791
Pancreas	725	1463
Intestine	116	256
Heart–lung	234	76
Total	72 255	116 705

Improving DSA/OPO performance

Wide variation in DSA performance, irrespective of the assessment measure examined, continues to be of great concern. When examined on a population-adjusted basis, the number of deceased donors recovered by each OPO varies widely from 14 to 40 donors per million (Fig. 8). There is little doubt that differences in death rates and in OPO performance in potential donor conversion both contribute to this variation. OPO and/or regional assessment of donor potential will allow groups like Donate Life America to focus their efforts to achieve maximal increase in donation, while risk-adjusted assessment of OPO performance (recently developed by the SRTR and implemented by UNOS) will help clarify the relative impact of OPO performance and population characteristics and should encourage poorly performing OPOs in their improvement efforts.

Current status and conclusions

Despite the initiatives outlined above, the U.S. organ transplant waiting list continues to grow, due almost totally to increases in the number of kidney candidates (Table 3). Early Collaborative success in increasing organ donation has not been sustained, and the promise of increased donation as a result of enrollment in state registries has yet to be realized. Increased DCD donation has simply mitigated the decrease in donation by non-DCD donors. The ever-increasing gap between organ supply and demand has not been met by deceased organ donation, requiring the U.S. transplant community to continue to struggle with how to use this very scarce medical resource most appropriately.

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