Chapter II
Organ Donation and Utilization in the United States, 1998-2007

Overview

- Despite the work of the Organ Donation and Transplant Collaboratives, and the marked increases in deceased donors early in the effort, deceased donors only rose by 67 from 2006 and the number of living donors declined during the same time period.
- There continues to be increases in the use of organs from donors after cardiac death (DCD) and expanded criteria donors (ECD).
- This year has seen a major change in the way organs are offered with increased patient safety measures in those organ offers made by OPOs using DonorNet©.
- Unfortunately, the goals of 75% conversion rates, 3.75 organs transplanted per donor, 10% of all donors from DCD sources, and 20% growth of transplant center volume have yet to be reached across all donation service areas (DSAs) and transplant centers; however, there are DSAs that have not only met, but exceeded, these goals.
- Finally, the national transplant environment has changed in response to increased regulatory oversight and new requirements for donation and transplant provider organizations.

Introduction

The organ donation and transplantation community in the United States continues to undergo dramatic and sustainable change for better performance and quality. Organ transplantation remains the only lifesaving therapy for many patients with organ failure. Despite the work of the Organ Donation and Transplant Collaboratives, and the marked increases in deceased donors early in the effort, deceased donors only rose by a total of 67 from 2006 and the number of living donors declined during the same time period. There continues to be increases in the use of organs from donors after cardiac death (DCD) and expanded criteria donors (ECD). There is a continuation of the Health and Human Services/Health Resources and Services Administration (HHS/HRSA) sponsored collaborative efforts currently focusing on transplant centers, and their relationships with Organ Procurement Organizations (OPOs), in order to facilitate growth and efficiency via the Transplant Growth and Management Collaborative (TGMC). This year has seen a major change in the way organs are offered and increased patient safety measures in those organ offers made by OPOs by the use of DonorNet©. Unfortunately, the goals of 75% conversion rates, 3.75 organs transplanted per donor, 10% of all donors from DCD sources, and 20% growth of transplant center volume have yet to be reached across all donation service areas (DSAs) and transplant centers; however, there are DSAs that have not only met, but exceeded, these goals. Likewise, there are transplant centers that have embraced the changes necessary to increase their volume of cases, but not at the expense of quality in outcomes. Additionally, changes in organ preservation techniques took place this year, partly in response to expanding organ acceptance criteria and increasing numbers of ECDs and DCDs.

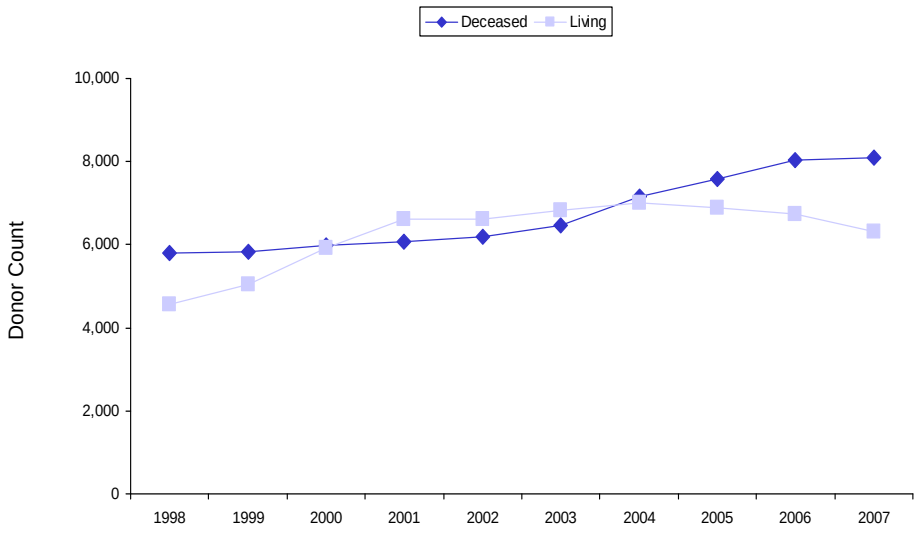
Finally, the national transplant environment has changed in response to the increased regulatory oversight and new requirements for donation and transplant provider organizations. Centers for Medicare & Medicaid Services (CMS) regulations for OPOs were published in 2006 and for transplant programs in 2007. These, in addition to voluntary Joint Commission (TJC) standards and requests by payers for data, have left some programs beset by the costs of building and maintaining a necessary infrastructure of personnel for the perceived divergent and redundant requirements for documentation and data submission by separate governing and regulatory bodies.

In the following discussion, we detail the ten year trends with data from the SRTR by organ, the current collaborative effort sponsored by the HRSA, and the success of those efforts and what still needs to be accomplished to reach the set goals for donor conversion, transplant center growth, the use of DCD and ECD organs, the transplant community's adaptation to DonorNet©, current trends in techniques for organ preservation, and increased regulatory oversight and transplant providers' response to these new changes.

Trends in Deceased Organ Donation

The rate of growth in the yearly number of deceased donors has shown a marked increase since 2002 (Figure II-1) *[Table 1.1]*, which corresponds to the initiation of the Organ

Figure II-1. Total Number of Living and Deceased Donors of All Organs Recovered for Transplant, 1998-2007



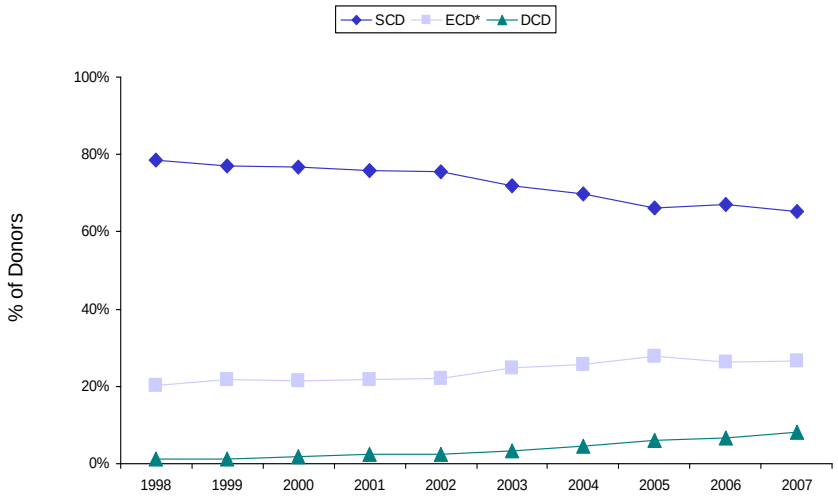
Source: *2008 OPTN/SRTR Annual Report*, Table 1.1.

Donation Breakthrough Collaborative (ODBC). Between 1998 and 2002 deceased donors (defined as at least one organ recovered) had increased at an average rate of 99 donors per year. Since 2002, the number of deceased donors increased by an average of 380 donors per year *[Table 1.1]*. This trend appears to have reached a plateau and the number of donors in 2007 increased by only 67 from 2006. The average increase in deceased donors contrasts with a faster increase, followed by a slower increase and then a decline in the number of living donors in the 1998-2007 time period. The number of deceased donors has continued to exceed the number of living donors over the past several years.

Between 2003 and 2004, there was a marked increase in the number of all three deceased donor types (standard criteria donors (SCD), ECD, and DCD) *[Table 2.12]*. This increase occurred despite a significant change in the makeup of the donor population. The percentage of SCD has been steadily declining, from 78% in 1998 to about 65% in 2007. This decline can be attributed to increases in the number and percentage of ECDs and DCDs (Figure II-2). Between 2002 and 2004, there was a rapid average increase of 240 ECDs per year compared with an average of 160 SCDs and 81 DCD donors; however, between 2006 and 2007 there was a 2% decrease in the number of SCDs, a modest 2% increase in the number of ECDs, and an increase of almost 24% in the DCD category. Whether this represents a possible saturation of utilization of the SCD and ECD pools, or a potential effect of DCD on brain-dead donors (DBD), remains to be seen. By far, the largest percentage increase in donors in recent years has been in DCDs, which has significant implications for overall organ utilization. This increase in DCD explains, in part, the fewer organs per donor that are recovered and transplanted overall and the

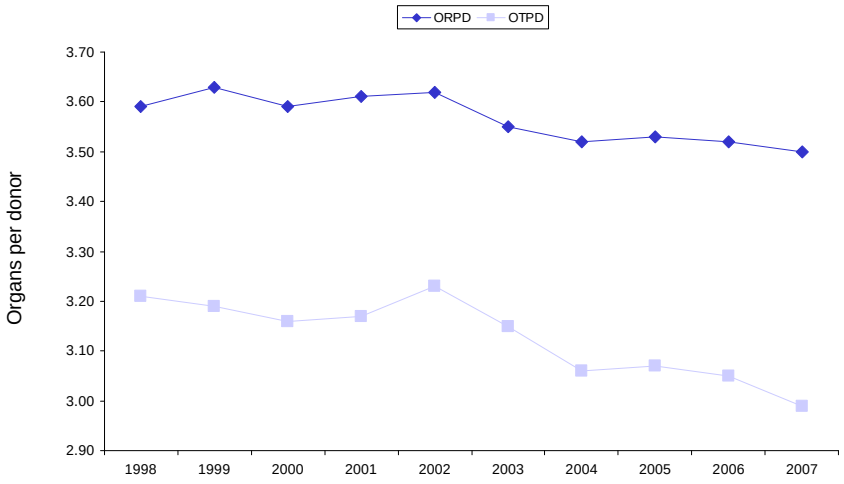
current state of less than 3.75 organs transplanted per donor (OTPD), since the OTPD was 2.08 for DCD, 1.72 for ECD and 3.63 for SCD in 2007*[Table 2.12]*.

Figure II-2. Deceased Donor Population, by Donor Type and Year (Percentage)



Source: *2008 OPTN/SRTR Annual Report*, Table 2.12; * includes DCD that meet ECD kidney criteria.

Figure II-3. ORPD, OTPD All Organs, 1998-2007



Source: *2008 OPTN/SRTR Annual Report*, Table 2.12.

Even though the numbers of consented and transplanted organs have increased since 2002, other important markers of organ donation have not dramatically changed much over the last 10 years (Figure II-3). The number of organs recovered per donor (ORPD) and OTPD have declined slightly since 2002. The ORPD dropped from 3.62 in 2002 to 3.5 in 2007, and the OTPD dropped from 3.23 in 2002 to 2.99 in 2007 *[Table 2.12]*. Among organ donor types, the ORPD and OTPD decreased most for DCD.

In 2007, the largest proportion of deceased donors was ages 50-64 and comprised almost 26% of the total donor pool *[Table 2.1]*. Donors between ages 18-34 made up an equivalent proportion of the donor pool. The number of donors increased the most (36%) in the less than 1 year old age group for the five-year period from 2003-2007, while the number of deceased donors ages 12-17 decreased by 6% in the same five-year period. The percentage of donors age 65 or older has increased slightly, from 8.9% in 2003 to 9.6% in 2007.

The percentage of donors dying from anoxia has increased over the last six years, growing from 11% in 1998 to 18% in 2007 *[Table 2.1]*. This has been accompanied by a similar decline in the percentage of deaths due to head trauma, dropping from 43% in 1998 to 37% in 2007. The distribution of causes of death in the other categories has remained relatively stable since 1998.

The growth in multicultural organ donation reflects a combined effect of increases in U.S. multicultural populations and efforts to increase donation rates among a variety of ethnic groups. Specifically, while African Americans made up only 11.5% of donors in 1998, by 2007 15.6% of the total U.S. organ donors were African American. Similarly, Hispanics were 9.9% of organ donors in 1998, but in 2007 Hispanics made up 14.1% of the donor population. Thus, these two groups have increased in both raw numbers and proportion of donors. The contribution of Asians to the proportion of organ donors has hovered in the 2.0-2.6% range over the last decade and has not significantly changed.

Recent increases in multicultural donation are substantial and meaningful, but they continue to lag behind the actual rates of transplantation and waiting list registrations for the same ethnic groups. In 2007, while African Americans represented 15.6% of donors, the group made up 19.4% of transplant recipients and a dramatic 28.5% of waiting list patients. Hispanics were 14.1% of donors, 13.0% of recipients, and 16.5% of the waiting list population; Asians were 2.4% of donors, 4.6% of recipients, and 6.4% of waiting list patients. The gap between donation rates and transplant rates remains, in part, because the percentage of recipients is also increasing for all three groups, with African Americans increasing from 17.3% of recipients in 1998 to 19.4% in 2007, Hispanics from 10.1% to 13.0%, and Asians from 3.7% to 4.6% *[Tables 1.4, 1.10, 2.1]*.

Deceased Kidney Donation and Utilization

In 2007 there were 15,793 potentially recoverable kidneys for which consent for donation was obtained. Of these, 1,409 (9%) were not recovered, 2,389 (15%) were recovered but discarded, 11,752 (74%) were transplanted, and 243 (1.5%) were recovered for research or the disposition was unknown *[Tables 3.1, 3.3]*. The distribution of organs in these

categories has been consistent over the 10 year period from 1998-2007. There was a modest average increase of 178 consented kidneys each year from 1998 to 2002 that accelerated to 1,047 between 2003 and 2006; however, between 2006 and 2007, this number only increased by 161 kidneys. The percentage of kidneys that were not recovered has gradually increased from 6.6% in 1998 to 8.9% in 2007. The kidney non-recovery figure is much lower than the overall average non-recovery rate of 50%. Despite the increase in non-recovery rates, the increase in the number of kidney donors has translated into an increase of 2,949 recovered kidneys in 2007 (26%) compared with 2003. The percentage of recovered kidneys that are discarded has increased gradually from 10% in 1998 to 17% in 2007. The increase was most rapid in 1998 to 2000, declining slightly until 2002, and steadily increasing each year since then. Despite the increase in discard rate, the large increase in recovered kidneys since 2002 has resulted in a large increase in the number of kidneys transplanted during this time, from 9,694 in 2002 to 11,752 in 2007, an increase of 21.2% compared with an increase of only 4.4% between 1998 and 2002. The percentage of consented kidneys that were transplanted in 2007 (74%) was high relative to the overall average of 43% for all organs. Of kidneys consented, the percentage transplanted has declined since 1998 (from 82%), but the percentage of all organs consented that were transplanted has declined, as well (down from 49% in 1998). Again, the increasing discard rate most likely reflects the increased aggressiveness of most OPOs in approaching donor types that would not have been considered in the past. This trend is confirmed in the increasing rates of organs transplanted from DCDs and ECDs.

Of the 2,949 additional kidneys recovered in the five-year period since 2003, 1,128 were SCD kidneys, 951 ECD, and 870 DCD. The combined ECD and DCD contributions represent almost 62% of the increase during that time. In 2007, there was only a minimal increase (less than 1%) in the number of kidneys recovered. There was a small increase in the number of ECD and DCD kidneys recovered, but 238 fewer SCD kidneys were recovered in 2007 than in 2006. Together, ECD and DCD kidneys now represent 33% of all kidneys recovered. There has been a shift in the distribution of recovered kidneys from SCD to ECD and DCD, which has an impact on utilization, since DCD and ECD kidneys have higher rates of discard. In 2007, 299 fewer SCD kidneys were transplanted (compared to 2006); there was an increase of 163 DCD non-ECD transplants. There was a small decrease in the number of transplanted ECD kidneys in 2007 compared to 2006 *[Table 2.13]*.

Deceased Liver Donation and Utilization

Of the 7,941 potentially recoverable (consented) livers in 2007, 6,229 (78%) were transplanted, 510 (6%) were discarded, 912 (11.5%) were not recovered at the time of donor surgery, and 290 (4%) were recovered for research, used for hepatocytes, or the disposition was not reported *[Tables 3.7, 3.9]*. The number of consents increased by less than 1% and the number of transplants decreased by about 2% in 2007 compared to 2006. The trend in liver consent was also similar to the overall average, showing an increase of 1,618 (26%) between 2003 and 2007 after an increase of only 401 livers (7%) between 1998 and 2002. Contrary to the trend among all organs, the non-recovery rate among livers has declined slightly from 12.6% in 1998 to 11.5% in 2007, a figure much lower than the average non-recovery rate among all consented organs of 50%. The percentage

of consented livers that are discarded remained relatively low between 1998 and 2006, averaging 4.6%. However, 6.4% of organs were discarded in 2007. While the number of livers transplanted increased by an average of 337 per year between 2003 and 2006, a 19% increase, in 2007 132 fewer livers were transplanted than in 2006. The 78.4% transplant rate among consented livers in 2007 was much higher than the overall average of 43% for all organs. The number of DCD livers recovered increased by about 9%, from 407 in 2006 to 444 in 2007, and now represents 6.4% of all recovered livers and 25% of all DCD organs *[Table 2.15]*.

Deceased Pancreas Donation and Utilization

Although the number of potential donor pancreata has increased by an average of 482 per year between 2003 and 2007, most of these consented organs have not been recovered; the number of pancreata recovered increased by only 157 between 2003 and 2007 compared with an increase of 1,928 consented pancreata during that period *[Tables 3.4, 3.6]*. The non-recovery rate among pancreata is at an all time high of about 72%. The discard rate among recovered pancreata has also increased gradually from 10.8% in 1998 to 19.8% in 2007. These trends have resulted in the number of transplanted pancreata remaining relatively unchanged since 2003. In 2007 there were 6,786 pancreata consented, with 382 (5.6%) discarded, 4,859 (71.6%) not recovered, 1,342 (19.8%) transplanted, and 203 (3.0%) with another disposition (recovered for research, recovered for islets, or unknown). The 20% transplant rate is lower than the average of 43% for all organs. The number of recovered DCD pancreata decreased to 64 in 2007 from around 72-74 in 2005 and 2006. The 64 DCD pancreata recovered in 2007 represent 3.3% of the total recovered *[Table 2.14]*.

Deceased Heart Donation and Utilization

After a period of slow increases since 1998, the number of potentially recoverable (consented) hearts rapidly increased by 1,421 organs (30%) between 2003 and 2007 at an average rate of 355 organs per year *[Tables 3.13, 3.15]*. In 2007, 6,138 hearts were consented, 2,239 (36%) were transplanted, 13 (0.2%) were discarded, 3,849 (63%) were not recovered, and the remaining 37 (0.6%) were recovered for research, heart valves, or the disposition was unknown. After gradually declining from 2,392 hearts in 1998, the number of heart transplants has been slowly increasing since 2004 and stood at 2,239 in 2007. The increase in available hearts has not translated into an increase in transplants, due to a growing non-recovery rate that was 62.7% in 2007. The discard rate for recovered hearts has remained very low since 1998, at 0.6% or less.

Deceased Intestine Donation and Utilization

In 2007, 6,341 intestines were consented, 197 (3.1%) of these were transplanted, 7 (0.1%) were discarded, 1 (0%) was recovered for research, and 6,136 (97%) were not recovered *[Tables 3.10, 3.12]*. While the number of available intestines has increased dramatically since 2003 (by 1,981, a 45% increase), most of these were not recovered, as intestines have the lowest recovery rate of any organ (between 2.2% and 3.5% over the last 10 years). However, because of the historically low discard rate among recovered intestines (3.4% in 2007), the increase in recoveries has led to an increase in the number of organs transplanted from 112 in 2003 to 197 in 2007.

Deceased Lung Donation and Utilization

In 2007, 13,317 lungs were potentially recoverable, 2,471 (18.6%) were transplanted, 70 (0.5%) discarded, 34 (0.3%) were recovered for research or disposition was unknown, and 10,742 (80.7%) not recovered *[Tables 3.16, 3.18]*. With a marked increase in the number of lungs available since 2003 (3,027 lungs, a 29% increase) and a very low discard rate among recovered organs (about 2.5% since 2000), the percentage and number of lungs transplanted is continuing to increase. There were 46% more lung transplants in 2007 (2,471) compared to 2003 (1,692). The contribution of DCD lungs remains low; only 19 of the 2,575 lungs recovered in 2007 were DCD *[Table 2.18]*.

Trends In Living Donation

The number of living donors has declined for the third consecutive year, after increasing by 53% from 1998 to 2004 *[Table 1.1]*. There were 6,308 living donors in 2007, down 424 (6.3%) from 2006 *[Table 1.1]*. Since 1998 the vast majority of living organs donated have been kidneys (almost 96% in 2007), followed distantly by livers (4% in 2007), and last (at less than 1%) by other organs. The small decrease in living donors in the past two years may represent a saturation point in the supply of living donors, or may be related to the increase in transplants from deceased donors.

Living Kidney Donation

After growing from 4,422 donors in 1998 to 6,647 donors in 2004, living kidney donation leveled off and has since declined slightly to 6,036 donors in 2007 *[Table 2.9]*. The trend towards an older age distribution of living donors continued in 2007. The percentage of donors ages 50-64 years continued its gradual 10-year increase to 23.5% in 2007, up almost 2% from 2006. Between 2006 and 2007 the percentage of donors in the 18-34 age group declined by about 0.8%, while donors ages 35-49 years declined by 1.4% to 44.2% *[Table 2.9]*. The very young and very old categories continue to represent only a small fraction of donors. There were no donors in the 12-17 age group in 2007, and only 1.4% (an increase from 2006) of all donors were older than 65 years.

The number of full sibling and parent living donors is at a decade-long low. Although there are still more living kidney donors in the ‘full sibling’ category than any other, they declined from 37% of all donors in 1998 to 24% in 2007 *[Table 2.9]*. The percentage of parent living donors has dropped from 18% in 1998 to 10.8% in 2007. The percentage of ‘spouse unrelated’ and ‘other relative’ donors in 2006 and 2007 remained stable at 12% and 8%, respectively. The largest increase has come in the ‘other unrelated’ category, which has risen from 362 donors in 1998 to 1,416 donors in 2007, and now represents about 24% of all donors, the second largest category. This increase in unrelated donors probably reflects a broader acceptance of living donation and the increasing recognition of potential donors outside the recipient’s immediate family (friends, coworkers, etc.), although live altruistic donors may also represent a small portion of this increase. Offspring living donors represented the third largest category at 16.2% in 2007.

The composition of living kidney donation by race and sex has not changed significantly over the last 10 years. The majority of donors have been white, representing about 70%

of the total number of living donors. In previous years African American and Hispanic/Latino donors each made up similar proportions of the living donor pool, but in 2007 13.1% of the living donors were Hispanic compared to 12.1% African Americans. Asian donation has ranged between 3%-4%, while donors in the 'Other/Multi-racial' and 'Unknown' categories have never represented more than about 1% of all donors. Female donors have consistently maintained a 14%-18% higher representation than males among living donors over the past decade *[Table 2.9]*.

Living Pancreas Donation

There were no living pancreas donations in 2007, continuing the declining trend from 2000, when there were 7 living donor pancreas donations *[Table 1.1]*.

Living Liver Donation

The number of living liver donors decreased slightly to 266 donors in 2007, down from 323 in 2005, where it had remained steady for three years after declining from a high of 522 donors in 2001 *[Table 2.10]*. In 1998, 63% of living liver donors were parents. By 2007, due to the increase in performance of adult live donor liver transplantation, this had dropped to 23%, almost the same proportion as offspring donors. Offspring now represent the leading category of living liver donors, 23.7% in 2007. 'Other relative' donors made up 12% of all living liver donors in 2007, and spouse donors made up 4.5%. In 1998, 59% of living liver donors were ages 18-34 years, 34% were in the 35-49 age group, and less than 8% were ages 50-64 years. Ten years later, in 2007, the percentage of donors in the 18-34 year-old group dropped to 42.5%, the percentage who were 35-49 years increased to 41.7%, and the percentage in the 50-64 bracket gradually increased to 14.7% *[Table 2.10]*. These age trends indicate a steady increase in the average age of living liver donors over the last ten years. The demographics of race and sex have remained relatively stable in the living liver donor population in the same period. The percentage of Asian donors in 2007 increased 1% since 1999 and the percentage of Hispanic liver donors increased in 2007 after having decreased since 2002 *[Table 2.10]*. A predominance of female donors exists in living related liver donation, as just a little over half (50.8%) of living liver donors were female in 2007.

Living Lung Donation

For the third year in a row, the number of living lung donors has been extremely small. There were only six living lung donors in 2007, after dropping from 25-29 living lung donors per year between 2002 and 2004 *[Table 2.11]*.

Transplant Growth And Management Collaborative

As a continuation of the Organ Donation and Transplant Collaboratives initiated in 2003, the Transplant Growth and Management Collaborative (TGMC) was launched in October 2007 to focus on the transplant programs. The goal of this new collaborative effort is to provide transplant programs the tools to share practices from high-performing transplant programs and to develop the necessary capacity in all programs to increase transplant volume by 20% by 2012. Through a systematic review of programs that already experienced this level of growth, and maintained or exceeded graft- and patient-survival

expectations, HRSA identified six strategies that appear fundamental to successful growth and were common amongst these centers (Table II-1). Together with OPO partners, more than 60 transplant hospitals have established growth goals for at least one major organ (heart, liver, pancreas, and/or kidney) and have been learning, testing, and

Table II-1. Best Practices

1	Institutional Vision and Commitment
2	Dedicated Team
3	Aggressive Clinical Style
4	Patient and Family Centered Care
5	Financial Intelligence
6	Aggressive Management of Performance Outcomes

reporting these changes at national meetings. Participating transplant programs have adopted internal structure and process changes to their hospital or health system in cooperation with their OPO to grow their programs. Some of the changes most frequently tested by TGMC teams involve recommitting/restructuring hospital administrative and clinical leadership and governance structures of the transplant program; using proven quality improvement methods to identify and test solutions to problems; creating/revising quality improvement dashboards; strengthening patient referral outreach programs; streamlining candidate pre-transplant evaluation processes; revising job descriptions to better match qualifications to responsibilities; and utilizing the Report of Organ Offer Turndown (ROOT) to systematically review the reasons for organ offer turndown decisions (and the ultimate disposition of declined organs) in collaboration with the OPO to educate clinicians and improve local organ acceptance. The ROOT was developed by UNOS using OPTN data and is available to every OPO and transplant program online.

An early performance metric of the TGMC participating teams is the time from patient referral to a center to the listing of the patient (1). Substantial decreases in the median number of days from the referral of a transplant candidate to activation on the waiting list has been demonstrated by monthly report cards by participating centers on the national results sharing site. This process improvement has been accomplished by a number of strategies, such as engaging patients in commitments to complete evaluations in specified time frames; restructuring job descriptions for nursing and non-nursing staff; and including referral to waiting list time targets in the transplant program's quality improvement dashboard.

Despite all of these process improvements, increasing transplant volume remains solely dependent on increasing organ availability. Since 2003, organ availability has increased in 47 of 58 DSAs in the U.S. and the magnitude of growth ranges from 1% to 100%. The national U.S. conversion rate continues climbing toward the 75% goal. It was at 69% for 2007, up from 50% at the inception of the ODBC in 2003. The number of OTPD has not increased. Monthly 2007 OTPD rates range from 2.96 – 3.15 (includes all donors) and remains relatively unchanged from 2006 (Figure II-4). There has been a steady increase

in the number of monthly transplants made possible by donors after cardiac death (Figure II-5).

Increasing the nation's conversion rate to 75% remains an important priority. At the conclusion of 2007, 19 of 58 DSAs achieved this performance benchmark, and an additional 13 DSAs exceeded the 70% level. Opportunities for improvement still exist in

Figure II-4. TGMC Actual OTPD by OPTN Region

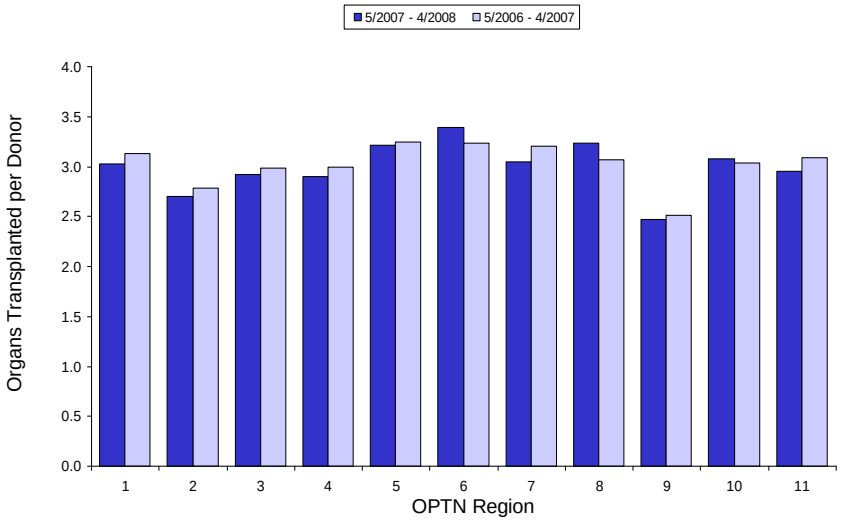
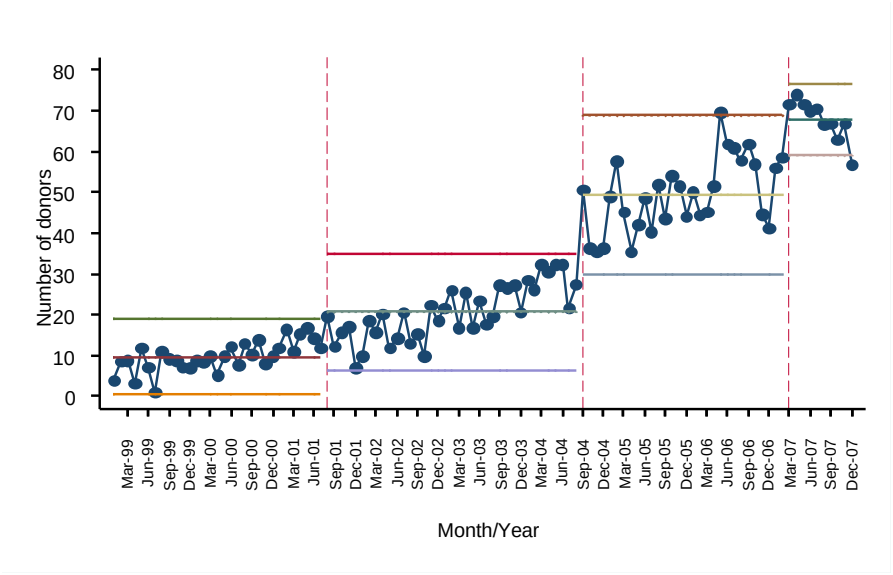


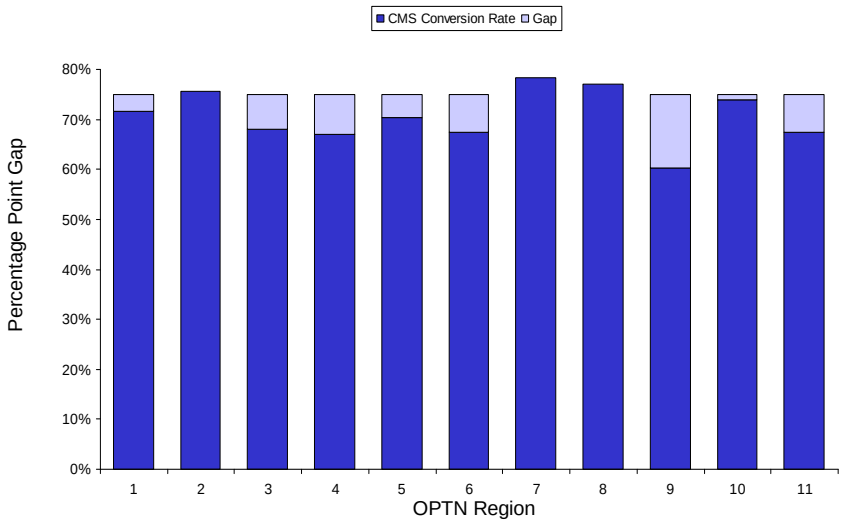
Figure II-5. HRSA Cumulative Collaborative Data Trends in Donation After Cardiac Death



Cardiac death donors standardized to 30-day month
Source: OPTN database as of 3/2008

all DSAs and likely hinge on the ability to convert more eligible donors among ethnic minorities. By reviewing the conversion rates by OPTN region the impact of donor demographics can be demonstrated, as only 3 of the 11 regions meet or exceed the 75% conversion rate (Figure II-6). Throughout 2007, the OPTN OPO Committee laid the foundation for demographic data to be collected on all eligible deaths (meeting the OPTN definition) and imminent deaths (those likely to meet the definition within the next 24-48 hours) that identify DSAs from which best practices in working with minority donor families and pediatric eligible donors can be learned. Using the Collaborative infrastructure, these practices can be shared, learned, and adapted by other DSAs with the goal of bringing each DSA to the 75% conversion rate benchmark.

Figure II-6. TGMC Conversion Gaps by OPTN Region, May 2007 – April 2008



Note: Range of conversion gap is 3.3 percentage points above the goal to 14.7 percentage points below the goal.

While progress toward bringing hospitals and entire DSAs to the 75% conversion rate level has been encouraging, similar success in increasing the number of organs transplanted per donor to a national average of 3.75 has not been evident. Since the start of the Transplant Collaboratives, the national rate of organs transplanted per donor has remained relatively unchanged. Unlike the conversion rate goal which has been measured and tracked at the hospital, DSA, and national levels, the OTPD goal has been perceived as a benchmark that could only be improved by implementing changes at the DSA level. One important DSA change that has been successfully achieved in a few DSAs is the integration of critical care specialists into the donor management process, such as the Baltimore (MDPC) DSA's real-time involvement of critical care specialists in donor management and the St. Louis (MOMA) DSA's goal-directed donor management process that is overseen by an advisory committee of critical care practitioners. Both DSAs are achieving increases in OTPD and organ availability that are directly related to

partnerships with hospital-based critical care experts. While DSA-level changes are necessary to generate nationwide improvements, developing hospital-level changes may prove instrumental in producing DSA-wide change.

Achieving the three collaborative goals (75% conversion rate, 3.75 OTPD, and 10% DCD) nationwide is most likely to occur if the nation's largest hospitals adopt and effectively implement leading donation practices. An essential aspect of any collaborative is disseminating the best practices developed by a few high performers to all participating hospitals, a process known as a "spread strategy." The Organ Donation Collaborative initiated its spread strategy in 2005, and since 2007 has focused on raising the performance of the 400 U.S. hospitals with 8 or more eligible deaths in a 12-month period to goal levels. In 2007, nearly 30% of the spread target hospitals met the 75% conversion rate goal, 50% met the DCD goal, but only 14% of target hospitals met the 3.75 OTPD goal. As with all aspects of organ donation performance, the effectiveness among the 11 OPTN regions in achieving the goals of the spread strategy varies (Figure II-4).

In mid-2006, the Collaborative and the OPTN embarked on a joint effort utilizing OPTN regional education forums as mini-collaboratives to educate and cultivate OPO, transplant program, and local donor hospital action to achieve the national goals. Since that time, individual regional teams have reviewed regional performance data and implemented half to whole day education sessions in conjunction with the regularly scheduled OPTN Regional Meetings. The agenda is designed to address topics that will help the regional DSAs recognize and close performance gaps. Meeting organizers and leaders consist of regional OPO representatives, key transplant surgeons/physicians, and critical care physicians. Based on performance needs, regional participants have already embarked on initiatives to better understand the reasons for organ discard; developing and evaluating the impact of meeting donor management goals on OTPD; improving pediatric OTPD; and incorporating DCD into end-of-life care programs. Travel to national collaborative meetings for all donor hospital, OPO, and transplant program staff is not practical and can be cost prohibitive. Providing the option of regional mini-collaborative meetings permits many more professionals to learn about, and commit to achieving, the goals of the Breakthrough Collaborative.

DonorNet

One of the most significant changes that has occurred during this time period has been the introduction, and widespread adoption, of a nationwide, electronic organ offer system. In April of 2007, the organ allocation system in the United States underwent a dramatic change with the OPTN-mandated conversion to what is known as the DonorNet© system. Creating an electronic system to offer organs by the OPO and field those same offers by the transplant center was mandated by the contract awarded to UNOS to administer the OPTN by the Division of Transplantation within the Department of Health and Human Services. The goals of the Federal regulators in requiring this change were multiple: 1) reduce and ultimately eliminate any skipping of the patient list in the organ offer process, such that members of the public and patients on the waiting list alike can be assured that offers were made in the order that patients are ranked on the

waiting list, 2) authenticate decisions made by the transplant center personnel in a way that these decisions and the appropriate refusal codes could be made in real time and could subsequently be audited, to adjudicate any conflicting account between OPO and transplant centers, and 3) speed the process of organ offers to maximize the number of patients who could potentially benefit from an available organ (2)..

The OPTN Operations Committee, charged with the responsibility of developing DonorNet© in conjunction with UNOS staff, seized the opportunity to try to design a system which maximized patient safety and efficacy of communication that a web-based electronic system could bring. The creation of DonorNet© forced OPOs to move away from a paper-based system and to one in which donor information was entered into an electronic database which would then be uploaded directly into DonorNet©. The reality of DonorNet© as an operational entity has facilitated the development of a sister entity, the TTSN (Transplant and Tissue Sentinel Network) spearheaded by the Centers for Disease Control. The goal of the TTSN is to trace forward any tissue donor, and to trace backward any organ donor, for communicable diseases (infectious or malignant) (3).

Once one or more preliminary acceptances for organs offered have been entered, the OPO may then contact the transplant center representative by phone to further explore the organ offer, answer any specific donor management questions, accept requests from the center(s) for additional information, and ultimately to confirm the acceptance of each organ by a center. When organs have been accepted, the offering OPO, the receiving OPO (if different), and the transplant center(s) then work to coordinate the recovery, transportation, necessary cross-matching, and eventual transplantation of the organs.

The DonorNet© system has numerous goals and potential benefits, including accurate documentation of all offers made and received, documentation of review of critical donor information with each offer by the accepting center (standard screen for ABO typing, results of serological testing, pressor or inotropic medication use), if it was accepted or declined, more accurate refusal codes, and other valuable information on allocation which can be studied to hopefully improve organ utilization. A primary goal of the system was to increase the number of offers made and the efficiency of making such offers with the desired ultimate outcome of increasing the number of organs successfully transplanted. It was also developed to improve patient safety on both the donor and recipient side (4). At least to this point in time, data would not tend to support the primary goal of increasing transplants per donor, as the number of organs placed per donor has essentially not changed in the early DonorNet© period from the period immediately pre-DonorNet© (4,5).

Despite the relative lack of impact on organs transplanted per donor, the success or failure of the DonorNet© system is, as of yet, to be determined. It has clearly made the allocation process uniform for data presentation to the accepting center, and ensured that issues of patient safety are addressed (i.e., ABO incompatibility). First, the point must be made that the data are very preliminary and drawing any significant conclusion currently assumes no change in the demographic of the donor population, despite the relative lack of impact on organs transplanted per donor (the reason for this may be multi-factorial and not *per se* the result of DonorNet use). A more thorough analysis of data, comparing

placement rates in subsets of donor demographics and drawn from data collected over a longer period of time, will be necessary before DonorNet can be evaluated thoroughly.

A second key point is that the DonorNet© system is clearly a work in progress (5), with key utilities, data points, and guidelines for use still in a relatively fluid development stage. Included examples of this fluidity are: changes in the patient and/or center-specific screening criteria that a center may enter, changes in how OPOs are allowed to handle zero mismatch kidney offers (through the UNOS Organ Center versus directly between OPO and transplant center), and the number of offers that an OPO can instruct the DonorNet© system to make simultaneously. These are but a few of the examples of adjustments to the system that theoretically have an impact on the overall effectiveness of DonorNet© and, therefore, a direct impact on any data that may be used for evaluation.

Finally, it must be noted that both OPOs and transplant centers are still learning how to efficiently use the system and are adapting themselves to the new world of electronic notifications. This evolution will likely take considerably more time until a standard of practice, or best practices, for utilization of DonorNet© is well-established.

For OPOs, some of the issues currently being evaluated are:

- Beyond the information required to make an offer, how much additional information is it optimal to enter before initiating placement and how often should that data be updated during the allocation process? In some DSAs, the OPO is entering limited information, sending out many offers, and then going into more details in the phone conversations that result from preliminary acceptance. In other DSAs, the OPO is entering significant amounts of lab, hemodynamic, and other data including reports or actual radiographs of cardiac angiograms, echocardiograms, and bronchoscopes before any attempt of organ placement is made.

- The number of offers to make initially and how far to go down the list before stopping are both unclear. Some single center OPOs have used the DonorNet© system to assure not only patient back-up, but center back-up for each organ, making large numbers of offers until they have several centers lined up for back-up (6).

- When and if to cease placement through the list and move to placement with aggressive centers (expedited placement) remains a topic of much discussion. In the pre-DonorNet© days, it was thought that DonorNet©, by virtue of expected speed and efficiency via electronic offers, would eliminate the need for expedited placement; however, with over a year of using DonorNet©, it is apparent that at times there is still a role for an expedited placement model in many OPOs' practice to prevent organ discard (7).

For transplant centers, some of the issues include:

- How to set the organ screens to minimize the amount of unwanted organ notifications and to maximize the amount of useable organ notifications (4)

- When and how to choose a DonorNet© intermediary that could potentially lower the organ donor screens without adding to fatigue of the physicians and surgeons with offers that may not be pristine. With the inception of DonorNet©, the number of calls has increased significantly to transplant programs (4,5). There is no funding from the payers or the OPTN to support such intermediaries, and in some DSAs, state laws and issues of malpractice coverage prevent some OPOs from acting as that intermediary (6).

- How to cope with the required adaptation to new technologies, including personal computers and PDAs. This is not an easy transition for many physicians and surgeons who have been in practice for decades.

- Regarding local donors, can the system be updated so that donors can be accepted if allocated as local, versus a separate notification for each organ to the same thoracic and abdominal program? One center could potentially receive seven notifications (heart, lung, heart-lung, liver, kidney, kidney-pancreas, and pancreas alone) as the system is currently configured, leading to fatigue, lack of efficiency in the placement of organs, and potential delay in recovery.

- For large centers, with large kidney and pancreas lists that are still based on waiting time to be transplanted, DonorNet© efficiency mandates that of the patients listed, all should be eligible for transplantation at the time of the organ offer (to streamline the offer process and avoid delays in offering the organ to a patient who is not ready to be transplanted). This requires closer monitoring of these patients by pre-transplant personnel, including physicians, social workers, financial coordinators, and histocompatibility personnel along with the availability of work-up data and routine health maintenance records by those making organ acceptance decisions. These requirements mandate more center clinical infrastructure in order to see patients more frequently and a tracking system or database that is available on- and off-site, to facilitate organ acceptance.

While this is only a superficial list of the issues and questions that have been identified in the early days of DonorNet©, it illustrates the amount that the transplant community does not yet know, understand, or agree upon regarding this exciting new tool. It is clear that DonorNet© and its system of electronic notification is much faster than making individual phone calls for offers and is potentially a beneficial tool in placing organs while maximizing recipient safety. However, careful study of the data that DonorNet© itself is allowing the OPTN to collect is necessary and, where needed, carefully planned adjustment of the system is also necessary to assure the success of DonorNet© in the long-term. DonorNet© as a communication tool has truly revolutionized information transfer from the OPO to the transplant center and is instrumental in ‘pushing’ available organs to the end-user.

Organ Preservation

In response to expanding organ acceptance criteria and increasing numbers of ECDs and DCDs, changes in organ preservation techniques took place this year. The percentage of

Table II-2. Unadjusted Percentages of Recovered Kidneys that were Discarded, Based on OPO Pumping Practices

Type	Pumping Practice						
	Pumped 0	*Pumped ≤50%*			*Pumped >50%*		
	Not pumped	Not Pumped	Pumped	Overall	Not Pumped	Pumped	Overall
SCD	7.4	7.5	13.9	7.8	20.7	4.9	9.3
ECD	41.2	43.7	30.8	40.2	69.9	23.0	33.6
DCD	22.9	16.6	17.7	17	41.5	17.4	20.5
All	15.3	13.4	21.1	14.2	30.9	8.5	14.8

Among kidneys recovered 1/1/2001 – 7/31/2004

deceased donor kidneys that are currently placed on pulsatile perfusion, or pumped, is increasing, with DCD kidneys pumped at the highest rates, followed by ECD kidneys and SCD kidneys (8). Local practices vary considerably; in some OPOs all kidneys are routinely pumped, in others only DCD or ECD kidneys are routinely pumped, and in others, kidneys are pumped selectively based on individual OPO criteria (9). Analyses of deceased donor kidney discard suggest that a kidney that is pumped is less likely to be discarded (10). While this suggests that OPOs can decrease discard rates by more frequent pumping, analyses performed by the OPTN Organ Availability Committee indicate that OPOs that pump a higher percentage of kidneys do not have lower discard rates (9). This apparent paradox appears to be best explained by the finding that discard rates of kidneys that are not pumped are significantly higher in OPOs that pump more frequently (Table II-2). In addition, kidneys that are pumped in OPOs that pump less frequently are much more likely to be discarded; however, OPO practices appear to matter less with respect to the discard of ECD kidneys, as pumped ECD kidneys are discarded less frequently regardless of OPO practice. This suggests that routine pumping of ECD kidneys may impact utilization (10).

Aside from the potential impact of pumping on utilization, multiple analyses have demonstrated significant reductions in the odds of delayed graft function for kidneys that are pumped (10, 11). This reduction in delayed graft function has implications for recipient length of stay and overall costs of transplantation. Cost analyses have demonstrated a beneficial effect of pumping on transplant finances (12). For these reasons, the OPTN Board of Directors approved the premise that access to machine preservation should be available in all DSAs.

Registry analyses do not demonstrate beneficial effects of machine perfusion on graft survival for any class of deceased donor kidneys (9). However, in the recent European prospective, randomized, controlled trial of machine perfusion, machine perfusion significantly reduced the risk of both delayed graft function (DGF) and graft failure (11). In addition, among those kidneys with DGF, graft survival at 6 months was 87% in the

pumped kidneys versus 76% in those not pumped. These data indicate a potential graft survival benefit to allografts that are implanted after pulsatile perfusion.

Another trend in organ preservation this year was an increasing use of an alternative preservation solution, histidine-tryptophan-ketoglutarate (HTK). The purported advantages of HTK in abdominal perfusion, over the more commonly used University of Wisconsin (UW) solution, are reduced costs and a potential for reduction in biliary complications in liver transplantation due to lower viscosity. While relatively limited, published literature exists regarding the efficacy of HTK compared to UW, and several single center analyses indicate equivalent rates of kidney graft survival and a reduction in delayed graft function associated with HTK, along with a significant cost savings (12-14). Multiple single center studies have also demonstrated equivalent outcomes in pancreas transplantation comparing HTK with UW (15-18) Similar results have been seen in liver transplantation, although the theoretical benefit on biliary complications has not been confirmed (19,20). While SRTR analyses performed for the OPTN have also not demonstrated an increased risk of graft failure associated with HTK in kidney or pancreas transplantation (21, 22), recent reports using OPTN data suggest significantly worse liver and pancreas graft survival rates associated with HTK preservation. These reports warrant continued evaluation of outcomes in light of the increasing use of HTK in organ preservation (23, 24).

Donation After Cardiac Death

Due in part to the goals set by HRSA for DCD development, the percentage of donors that come from DCD continues to increase. There has been a total increase in the percentage of donors that are categorized as DCD, from 8% in 2006 to 9.8% in 2007, and the number and percentages of DCD liver and kidney transplants continue to increase substantially *[Tables 2.1, 2.2, 2.4]*. Available data continue to support the notion that kidney transplant graft survival from DCD donors is equivalent to those of brain dead donors under most circumstances (25,26). A notable exception is older or “ECD –type” kidney donors where increased graft failure attributable to the DCD status has been noted (26, 27). The increased risk of graft failure associated with DCD liver transplants continues to limit the use of these organs (28). In addition, the significant risk of biliary complications that dramatically impairs recipient quality of life, if not graft survival, has become increasingly recognized (29,30). These concerns are reflected in the decreasing percentage of DCD donors in which a liver is used for transplant.

With the rapid increase in DCD relative to donation after brain death (DBD) in the past several years lies the possibility that some DCDs are occurring from donors that may have previously progressed to brain death. Since ORPD and OTPD are lower for DCD, this has potential implications for overall organ utilization. A 2005 SRTR analysis demonstrated a positive relationship between the number of DCDs and DBDs in a DSA. Although analyses of donor types by DSA in 2006 and 2007 do not show a significant correlation between changes in DCD and DBD within DSAs ($r=-.15$, $p=0.25$), there was a negative correlation between changes in DCD and SCD from 2006 to 2007 ($r= -.0.29$, $p<0.05$). Among the 17 DSAs which saw a decline in DCD from 2006 to 2007, the average increase in DBD and SCD was 2% and 5%, respectively. However, in those 37

DSAs where DCD increased in 2007, on average the numbers of both DBD and SCD declined (Table II-3).

There are many influences on the changes in donors over time. In addition, it is well established (although anecdotal) that a certain percentage of donations would not proceed were it not for the DCD option, either because of timing conditions placed on the

Table II-3. Changes in DCD and DBD Utilization within DSAs, 2006 to 2007

		Average Percent Change from 2006-2007			
Change in DCD	**Number of OPOS**	**Change in SCD**	**Change in ECD**	**Change in DCD & ECD***	**Change in Non-DCD**
Decrease	17	5.17	-0.30	-46.01	2.77
0 DCD both years	1	26.42	112.00	.	53.85
0%-50% increase	18	-1.69	7.42	59.42	-1.54
50%-100% increase	11	-5.28	3.73	-10.00	-3.50
> 100% increase	8	-1.94	23.46	275.00	-1.14
0 DCD in 2006, > 0 DCD in 2007	3	2.23	90.50	.	8.36
Total	58	0.29	12.77	28.45	0.87

* A total of 233 donors were donors after cardiac death and also meet expanded criteria. These donors are not included in the DCD only or ECD only categories.

consent, or due to lack of progression to brain death. Nevertheless, because of the potentially significant impact on utilization, the apparent inverse relationship between changes in DCD and DBD warrants further monitoring.

The potential progression of patients who would potentially qualify for DCD to brain death may also be impacted by the success of donor registries. As the number of potential donors who have participated in a registry increases, this may permit a greater propensity to wait for progression to brain death among donors initially considered for DCD.

CMS and Joint Commission Oversight/Regulations

Finally, one of the most recent significant changes in the transplant environment in the United States has been the increased regulatory requirements for donation and transplant provider organizations. In May 2006, CMS published its Final Rule outlining the conditions of participation (COPs) for OPOs in the United States. This document "establishes new conditions for coverage for OPOs that include multiple new outcome and process performance measures based on organ donor potential and other related factors in each service area of qualified OPOs." Its stated goal is "to improve OPO performance and increase organ donation" (31).

The Final Rule established the following outcome or performance measures. All three must be met (32):

1. Donation or Conversion Rate – The number of actual donors as a percentage of the potential donor pool. Specifically, the OPO is required to have a donation or conversion rate no more than 1.5 standard deviations below the national mean.

2. Expected Donation Rate –The OPO should have an observed donation rate that is not statistically lower than the expected donation rate for the OPO, as calculated by the SRTR, for 18 or more months of the 36 months of data used for re-certification.

3. At least two of the following three yield measures are achieved at no less than one standard deviation below the national mean:

    - Number of organs transplanted per SCD
    - Number of organs transplanted per ECD
    - Number of organs used for research per donor

The above are slightly modified for those OPOs functioning exclusively in non-contiguous states or territories in that number of organs transplanted is replaced by number of kidneys transplanted under performance measure three. The data to be used for evaluating OPO performance relative to expected donation rates is a 36 month period beginning January 1, 2007.

These performance measures represent a significant departure from the previous population-based measures (i.e., donors per million population) of the preceding COPs. In large part, this evolution began with a growing acceptance within the donation community that not all populations are demographically equal and therefore comparing/evaluating performance of 58 diverse OPOs based upon measures of anything per million population would be inherently flawed. The OPO community has changed to potential performance metrics (such as conversion rates which measure actual donors as a percentage of the eligible donor pool) or donor demographics (SCD vs. ECD). While it is still a bit early in the process of applying these new standards to evaluate their validity, the intent was to move toward performance measures driven more by donor potential and demographics than sheer numbers of people within the DSA.

Preliminary evaluation of data applicable to the OPO outcome measures is based upon SRTR data for OPOs from August 1, 2006 through December 31, 2007. The data includes the individual standard; the high value, low value, and the mean for the standard as determined by analyzing the 58 OPOs' data; and the number of OPOs that would currently fall below the outcome measure as defined by CMS.

Outcome measure one (donation or conversion rate): four of 58 OPOs fell more than 1.5 standard deviations below the national mean for the initial 17 months of the four year re-certification cycle. At this early date (roughly one-third of the way through the re-certification cycle) it is not possible to draw any significant conclusions regarding the performance of either individual OPOs, or the industry as a whole, but as the cycle progresses, and with more in-depth evaluation of those falling below the measure, it should be possible to evaluate the scientific merit and impact of this measure as it relates to the CMS re-certification process. What is possible at this time is to compare, in the

broader sense, the mean conversion rate for this limited timeframe (67.1%) to where the industry was at only five short years ago (roughly 50%). National focus on this performance measure has helped OPOs and the industry as a whole to progress significantly in a relatively short amount of time, with all but one OPO above what was the average until recently.

Outcome measure two (observed donation rate versus expected as calculated by the SRTR) was not evaluated for this paper, as expected data modeling has been revisited recently and 2007 expected data have not yet been published. When available, these data will be published for each OPO online at *www.ustransplant.org* and available to the public.

Of the three possibilities listed for the final outcome measure (see point three, above), research organs per donor: three of 58 OPOs fell more than 1 standard deviation from the mean for the initial 17 months of the 48 month cycle. It is very difficult to interpret these data, however, as it is unclear if CMS will include in their final analysis all organs sent to research of any kind, only those organs intended for research prior to recovery, or if there will be criteria set for research that will preclude certain types of uses from inclusion. What is clear is that a wide variety of practices exist with regard to use of organs for research and it is difficult to place any merit on the existing data because of the lack of common definitions either in the field or as published by CMS with regard to this measure.

It is important to qualify two other matters regarding this discussion. First, for the purposes of this chapter, there was no attempt to apply the separate "kidneys per SCD or ECD" standard for OPOs operating exclusively in non-contiguous U.S. states or territories, as this chapter is a preliminary overview of how application of these measures looks based upon limited data. Illustrating this does not necessitate the extra level of data analysis at this point; clearly, this differentiation will be crucial when CMS actually applies these standards at the end of the designation cycle. Second, the research information presented here is not screened or filtered in any way; in other words, all organs deemed as sent to research by the OPO have been included here regardless of intent at time of recovery and regardless of any definition of research that might include or exclude certain organs.

For transplant centers, the TJC standards were published in January of 2007, as well (Table II-4). Participation for certification was and is voluntary, with centers paying a fee for a TJC site visit and certification.

Table II-4. TJC Standards

Medicare provider agreement and participation in the OPTN
Organ procurement, recovery, and receipt
Organizational leadership structure
Selection of patients and living donors, as well as managing care and respecting patient and donor rights
Coordination of care, including pre- and post-surgical processes
Qualifications of caregivers
Staff competency and training

Information management
Standardized performance measurement and data submission
Performance assessment and improvement

While TJC certification program was developed in concert with the CMS standards published in March 2007, TJC standards assess a program's compliance with quality standards (31). The CMS COPs (Table II-5) are a direct response to public concern and comments regarding explicit standards of outcomes of transplant services. Prior to the new COPs, CMS relied on transplant centers to self report significant changes and major issues that might mandate a CMS site visit. The current COPs are expected to clarify and reinforce normal business practices of most transplant centers, as well as accountability for the services that they provide as an outcomes based system.

Table II-5. CMS COP Components

Data submission
Outcome measures
Process requirements

The data submission requirements are similar to those already in place for compliance with the OPTN requirements of 95% data submission within 90 days for deceased organ transplants. Outcome measures are based on the time period for patient and graft survival calculated by the SRTR. Graft and patient survival rates that fall below expectations will trigger a CMS review and corrective action. Process requirements address a number of issues in patient and donor selection and care during the transplant process. Perhaps, most importantly, the requirements focus on standardization of the living donor process, informed consent, separate living donor advocates, and transparent disclosure of what is known about short- and long-term risks of donation and the possibility of lack of health care coverage due to these complications. While the intent of these regulations is to help assure a standard quality of care for Medicare recipients, they also increase the resources necessary to operate a transplant program.

Transplant centers answer to many governing and regulatory bodies, including the OPTN, state and institutional regulators, CMS, payers, and potentially TJC. Responding to various audits, reviews, and requests for information takes time and personnel. For centers that do not meet the COP requirements, personnel will need to be hired, and potentially infrastructure created. For CMS, there will be expenses for audits and site visits that are likely to be passed along to the transplant centers. Often, transplant centers feel the burden of sometimes divergent and redundant requirements from these various entities. A similar environment existed in the patient safety arena until 2005, when regulatory harmonization between multiple regulatory bodies occurred (CMS, TJC, Leapfrog Group, Institute of Health Care Improvement, Agency for Healthcare Research and Quality) and was submitted to the National Quality Forum in order to update and streamline health care providers' and institutions' response to maintaining Safe Practices. This harmonization effort's intent was to limit confusion and redundancy amongst care providers while maintaining compliance with patient safety practices. This effort has been championed by the Safety leaders and participating organizations, and continues to

date (33). Such an effort may help rationalize the various requirements for transplantation.

Summary

In summary, the organ donation and utilization landscape in the United States has undergone dramatic changes in the past years. Attention to transplant center performance through the TGMC, organ allocation via a web-based system, and improved preservation techniques have led us as a community to perform more transplants over the time period of this report. However, we have reached a plateau in conversion rates, organs transplanted per donor, and organs from DCD. Due, in part, to the Collaborative and mutual accountability between OPOs, transplant centers, and donor hospitals, we have moved from a national professionally-regulated infrastructure to a national system managed for increasing performance and continuous quality improvement. New challenges that we need to examine are uniform donor management goals across critical care units, utilization of all splitable livers for our pediatric patients, new allocation policies for kidney transplantation, and wider sharing of living donor kidneys. Despite our recent successes, we still have more to accomplish if we are to serve every donor family and end deaths on the waiting list for our patients.

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