

Recent Trends and Results for Organ Donation and Transplantation in the United States, 2005

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Introduction

This overview provides a summary of many aspects of solid organ transplantation in the United States, and is produced as part of the *2005 OPTN/SRTR Annual Report*. The *Annual Report* is prepared by the Scientific Registry of Transplant Recipients (SRTR) in collaboration with the Organ Procurement and Transplantation Network (OPTN) under contract with the Health Resources and Services Administration (HRSA). The *Annual Report* is intended to provide valuable information to patients, the transplant community, the public, and the Federal Government by publishing a vast array of knowledge on activities related to solid organ transplantation.

Ten groups of authors, all experts in various areas of transplantation, have produced the 10 detailed articles in this report. Each article provides an in-depth look at the current state of specific aspects of transplantation, as well as trends over the last decade. The text and figures in these articles contain some new analyses but are based mainly

Note on sources: The articles in this report are based on the reference tables in the *2005 OPTN/SRTR Annual Report*, which are not included in this publication. Many relevant data appear in the tables included here; other tables from the *Annual Report* that serve as the basis for this article include the following: Tables 1.1, 1.2, 1.3, 1.7, 1.13, 2.1, 2.8, 5.1a, 5.2, 5.4, 5.11a–c, 5.14, 6.4, 7.4, 8.7, 8.11, 8.12, 8.13, 11.1a, 11.3, 11.5, 12.2, 13.1a, 13.4 and 13.12. All of these tables may be found online at <http://www.ustransplant.org>.

on the wealth of information in the reference tables of the *Annual Report*, which have been prepared by the University Renal Research and Education Association (URREA), the contractor for the SRTR since October 2000. These 10 articles and reference tables are included in the *Annual Report* and may be found online at www.ustransplant.org and www.optn.org.

Summary Statistics on Organ Transplantation in the United States for 2003–2004

There were over 14 000 organ donors in the United States in 2004, an increase of 695 donors (7%) over 2003. During this time the number of living donors increased by 3% to 7002, while the number of deceased donors grew by 11% to 7152, the largest annual increase in deceased donors in the last 10 years. This increase in donors led to an additional 2240 deceased donor organs recovered for transplantation from the previous year, an increase of 10% (Table 1). Some of this increase can likely be attributed to efforts that focus on increasing the supply of organs for transplantation, such as the Organ Donation Breakthrough Collaborative, which started in the fall of 2003. The trends in organ donation are discussed in detail in an accompanying article, 'Organ Donation and Utilization 1995–2004: Entering the Collaborative Era'.

The impact of the increase in the number of organs recovered is evident in the number of transplants performed in 2004. Just over 26 500 organs were transplanted in the United States during 2004, over 19 500 of them from deceased donors and almost 7000 from living donors. These numbers represent an increase of 6% in the total number of organs transplanted, a 3% increase in living donor transplants and a 7% increase in deceased donor transplants compared to 2003, as shown in Table 2. There were just over 7300 deaths reported for patients waiting for a transplant in 2004. This is an increase over the number reported in 2003 (7091). However, since the size of the waiting list also increased during this time, the overall death rate showed a slight decrease.

Even with the increasing number of transplants being performed, the demand for transplantation far exceeds the supply of available organs. The increasing demand for transplantation is made apparent by the increasing

Table 1: Growth in number of deceased donor organs recovered, 2003–2004

Organs	End of year		Percent change
	2003	2004	
Total	22 997	25 237	9.7%
Kidney	11 437	12 575	10.0%
Pancreas	1773	2021	14.0%
Liver	5773	6405	10.9%
Intestine	122	167	36.9%
Heart	2120	2096	−1.1%
Lung	1772	1973	11.3%

Source: 2005 OPTN/SRTR Annual Report, Table 1.2.

Table 2: Growth in number of transplanted organs, 2003–2004

Organs	Year		Percent change
	2003	2004	
Total	25 083	26 539	5.8%
Deceased donor	18 272	19 549	7.0%
Living donor	6811	6990	2.6%
Kidney	14 856	15 671	5.5%
Deceased donor	8388	9025	7.6%
Living donor	6468	6646	2.8%
PTA	117	132	12.8%
PAK	343	418	21.9%
Kidney-pancreas	868	879	1.3%
Liver	5364	5780	7.8%
Deceased donor	5043	5457	8.2%
Living donor	321	323	0.6%
Intestine	52	52	0.0%
Heart	2026	1961	−3.2%
Lung	1080	1168	8.1%
Deceased donor	1065	1153	8.3%
Living donor	15	15	0.0%
Heart-lung	28	37	32.1%

Source: 2005 OPTN/SRTR Annual Report, Table 1.7. PTA: Pancreas transplant alone. PAK: Pancreas after kidney.

number of candidates on the waiting list for a deceased donor organ. As seen in previous years, more patients are added to the waiting list than are removed due to transplantation, death, or on rare occasion, for recovery from organ failure. There were over 86 000 patients waiting for an organ at the end of 2004, over 4000 more than at the end of 2003 (Table 3). As seen in Table 3, the number of patients waiting for a kidney, pancreas, or intestine transplant displayed the largest percent increases for 2004 compared to 2003; during the same time period, the number of patients waiting for a liver or a lung increased only slightly (~1%), and the number of candidates waiting for a heart or heart-lung actually decreased by about 7% and 10%, respectively. For the kidney, liver, and lung waiting lists (and in the total number of candidates awaiting any organ), the greatest growth has been among those aged 50–64 and 65 and older. Longer time trends and more detailed discussions of waiting list characteristics can be found in the three accompanying organ-specific articles of the report.

Table 3: Growth in number of patients on the waiting list, 2003–2004

Organs	End of year		Percent change
	2003	2004	
Total	82 259	86 378	5.0%
Kidney	53 840	57 910	7.6%
PTA	454	504	11.0%
PAK	919	973	5.9%
Kidney-pancreas	2370	2403	1.4%
Liver	17 032	17 133	0.6%
Intestine	168	196	16.7%
Heart	3475	3237	−6.8%
Lung	3812	3851	1.0%
Heart-lung	189	171	−9.5%

Source: 2005 OPTN/SRTR Annual Report, Table 1.3. PTA: Pancreas transplant alone. PAK: Pancreas after kidney.

Table 4: Unadjusted one- and five-year patient survival by organ

Organ transplanted	1-year survival	5-year survival
Kidney		
Deceased donor	94.6%	81.1%
Living donor	97.9%	90.2%
Pancreas alone	96.2%	90.6%
Pancreas after kidney	95.5%	84.4%
Kidney-pancreas	95.3%	85.9%
Liver		
Deceased donor	86.8%	73.1%
Living donor	87.7%	77.4%
Intestine	85.7%	53.5%
Heart	87.5%	72.8%
Lung	83.0%	49.3%
Heart-lung	57.9%	40.2%

Source: 2005 OPTN/SRTR Annual Report, Table 1.13.

Key outcomes after transplantation include (1) survival of the transplant recipients and (2) the function of transplanted grafts. Table 4 displays 1- and 5-year unadjusted patient survival for all transplant recipients by organ, using the most recent cohort for which adequate follow-up exists. The cohort used to compute 1-year survival consists of recipients transplanted in 2002–2003, while the cohort for 5-year survival is based on the recipients transplanted in 1998–2003. One-year patient survival rates were highest for kidney and pancreas recipients, ranging from about 95–98%; corresponding survival for liver, intestine and heart recipients was approximately 86–88%, about 83% for lung, and lowest for the small number of heart-lung recipients with around 58% surviving at 1-year.

Table 5 shows graft survival, the percentage of transplanted organs that are still functional 1 and 5 years after transplantation by type of organ. As with patient survival, graft survival was calculated based on the most recent cohort for which sufficient follow-up was available. Graft survival rates are lower than the corresponding patient survival

Table 5: Unadjusted one- and five-year graft survival by organ

Organ transplanted	1-year survival	5-year survival
Kidney		
Deceased donor	89.0%	66.7%
Living donor	95.1%	80.2%
Pancreas alone	76.9%	55.8%
Pancreas after kidney	77.6%	56.7%
Kidney-pancreas (kidney)	91.7%	76.5%
Kidney-pancreas (pancreas)	85.8%	71.0%
Liver		
Deceased donor	82.2%	66.9%
Living donor	81.7%	69.7%
Intestine	73.8%	37.6%
Heart	86.8%	71.8%
Lung	81.4%	47.5%
Heart-lung	55.8%	37.6%

Source: 2005 OPTN/SRTR Annual Report, Table 1.13.

rates due to the fact that patients may survive a graft failure by receiving a second transplant or with an alternative therapy, such as dialysis for kidney transplant recipients or insulin therapy for pancreas transplant recipients.

The Articles in the 2005 SRTR Report on the State of Transplantation

The articles in this report cover a broad range of topics related to solid organ transplantation in the United States. Individual articles are devoted to each of the three main organ areas: kidney and pancreas, liver and intestine, and heart and lung. There are also articles devoted to organ donation, immunosuppression and pediatric transplantation.

The structure and use of the OPTN/SRTR data are discussed in an article on analytical approaches and database design. This article also outlines some of the analytical methods used by the SRTR and provides some insight into many of the challenges faced in analyzing the transplant data. In addition, one article is devoted to the analytical methods behind the SRTR's regular public reports on transplant center and OPO performance.

The special article in this year's report describes the development and implementation of a new lung allocation policy that went into effect on May 4, 2005. A tremendous amount of effort has been invested into developing the new allocation policy that distributes organs to candidates waiting for a lung transplant based on transplant benefit rather than solely on waiting time.

Summaries and data highlights of each article follow.

Organ donation and utilization

This year's article is the first to report a full year's worth of data on organ donation and usage following initiation of the

Organ Donation Breakthrough Collaborative. The Collaborative effort, which began in September 2003 and continues today, seeks to save lives and improve outcomes by challenging organ procurement organizations, transplant centers and donor hospitals to develop and disseminate their best practices. As background, the article reviews the philosophical transition involved in the development of the donation service area before turning to the Collaborative effort and its major findings. The article also includes a review of 10-year trends for deceased donor organs, expanded criteria organs, donation after cardiac death and living donation. Among the highlights are the following findings:

- (i) Of the 552 largest U.S. hospitals targeted by the first Collaboratives, 184 met and sustained the goal of a 75% conversion rate for a period of 12 months. Participating hospitals achieved a 14% increase in the number of deceased donors, compared with their own performances for the same period the prior year. The increase for hospitals not in the collaborative was 8%, a substantial jump over previous years that indicated dissemination of best practices was successful.
- (ii) Overall, the trend in organ procurement organization (OPO) recovery data was upward over the past 10 years. When comparing the most recent 3 years of data, 24 OPOs (41%) had two consecutive years of growth. Deceased donation in 2004 increased 11% over 2003, (7152 donors up from 6457). Compared with 1995, organ donation in 2004 increased by 33%. Increased organ donation was noted for all organs, with the exception of the heart.
- (iii) Between 1995 and 2004, the number of donors providing organs after cardiac death increased more than 6-fold, from 64 to 391, a much steeper rate of increase than for donors providing organs after brain death. Although donation after cardiac death (DCD) makes up a relatively small fraction of the national percentage of deceased donors (5% in 2004), the full potential for DCD to expand the national deceased organ donor pool is reflected by the fact that only seven DSAs accounted for 58% of all instances of DCD, and, in these DSAs, DCD accounted for 17–20% of their donors.
- (iv) Increased public awareness of the organ donor shortage is demonstrated by the year-to-year increase in the number of organs donated by living donors between 1995 and 2004. Over the past 10 years, the number of donated organs increased from 3493 to 7002. In fact, from 2001 to 2003, the number of living organ donors surpassed the number of deceased donors.

Immunosuppression

This article presents an organ-by-organ review of immunosuppression use over the last 10 years. New to this year's report is a wealth of data on immunosuppressive regimens that include more than one drug; in previous years, use of drugs was reported only individually.

In response to the concerns about the adverse effects associated with steroid-based regimens, many transplant recipients are being taken off corticosteroids as a maintenance therapy (steroid withdrawal) or not being given it in the first place (steroid avoidance). Tables and figures new to this year's report provide useful windows on this important changing trend. Highlights of the article follow:

- (i) Antibody-based induction therapy continues to be used for the majority of kidney and pancreas recipients, including pancreas after kidney and simultaneous pancreas-kidney transplant recipients (72–81% in 2004); it was used for approximately half of all intestine, heart and lung recipients and remains uncommon for liver recipients (21% in 2004).
- (ii) For recipients of most organs, the use of calcineurin inhibitors as maintenance therapy at the time of discharge was characterized by a clear transition from cyclosporine to tacrolimus.
- (iii) Corticosteroids were still administered to the majority of patients, though regimens of steroid avoidance and steroid withdrawal have been increasing in use.
- (iv) The percentage of patients treated for acute rejection during the first year following transplantation has continued to fall.

Pediatric transplantation

This article provides a comprehensive review of trends in pediatric donation over the past 10 years. Pediatric patients, those 17 years and younger, have characteristics specific to their age, among them distinct etiologies of organ failure, complexity of surgical procedures and differing pharmacokinetic disposition of immunosuppressants. The article investigates waiting list characteristics and transplantation and survival outcomes by organ for this age group. In total, there were 2269 pediatric organ transplant candidates at the end of 2004, reversing a 3-year trend of decreases. The article concludes with a review of recent updates in organ allocation policy and raises further research challenges. Some specific highlights from the article include the following:

- (i) In 2004, there were more candidates in all age groups except 1- to 5-year-old children. Candidates younger than 11 years of age continue to account for just over half of pediatric candidates. However, the increase in candidates in 2004 did not reverse the ongoing decline of pediatric candidates as a percentage of all candidates; children currently account for 3% of all transplant candidates.
- (ii) Current 3-year graft and patient survival for pediatric recipients is comparable to adult survival for all but intestine (where interpretation is limited by small numbers of recipients).
- (iii) During the past decade, the graft survival rate of kidneys transplanted into pediatric recipients has improved, especially for young recipients aged less than

11 years. Adolescent recipients have not manifested similar superior graft survival rates.

- (iv) The policy of allocating kidneys to pediatric candidates was revised so that kidneys from donors less than 35 years old are now offered preferentially to pediatric candidates. The new pediatric preference algorithm for liver shares pediatric donor livers regionally to pediatric candidates based on a model for end-stage liver disease/pediatric end-stage liver disease (MELD/PELD) score rather than on a waiting list mortality risk. Pediatric donor lungs are now offered preferentially to pediatric candidates before being offered to adult candidates.

Kidney and pancreas transplantation

This article reviews kidney and pancreas transplantation data for 2004 and the past decade, following trends in kidney alone, simultaneous kidney-pancreas, pancreas after kidney and isolated pancreas transplantation. Data on kidney recipient characteristics and transplant outcomes are extensively reviewed, including differences in patient and graft survival rates between recipients of expanded criteria donor (ECD) non-ECD and living donor kidneys. Characteristics of wait-listed registrants' time spent on the waiting list are discussed. A special section on DCD presents data on the risk of delayed graft function and survival rates following transplantation of DCD kidneys. The section on pancreas transplantation includes a discussion of pancreas utilization. The article also covers recent changes in policies covering kidney-pancreas allocation. Highlights of the article include the following:

- (i) The number of patients waiting for deceased donor kidney transplants continues its relentless increase. At the end of 2004, there were 57 910 patients on the waiting list. There were 27 131 new kidney waiting list registrations in 2004, an increase of 11% since 2003 and 52% since 1995.
- (ii) The overall number of donors continues to increase. The total number of kidneys transplanted increased by 6% between 2003 and 2004, from 14 856 to 15 671, after an average annual increase of approximately 4% since 1995.
- (iii) Deceased donor kidney transplants increased by 8% between 2003 and 2004, by far the largest increase in the decade, while living donor transplants increased only 3%. This represents a reversal of previous trends, but the number of living kidney donors continues to exceed the number of deceased donors.
- (iv) African Americans made up 35% of the active kidney waiting list at the end of 2004, while whites made up 39%. While the percentage of African Americans active on the waiting list has remained stable over the past decade, the percentage of whites has decreased by about 10% as a representation of Hispanics and Asians has increased. The age group with the greatest percentage increase in registrations since 2003 was

the group aged 65 years and older (20%), followed by the 50- to 64-year-old age group (15%).

- (v) Donation after cardiac death has increased steadily since 2000. Although the absolute numbers remain small, kidneys transplanted from DCD donors increased by 39% between 2003 and 2004.
- (vi) One-year patient survival ranged from 91% for deceased donor ECD kidney recipients to 98% for patients receiving kidneys from living donors. By 5 years after transplantation, recipient survival is 20% lower among recipients of deceased donor ECD kidneys (70%) than among living donor kidneys (90%) and 15% less than among deceased donor non-ECD kidney recipients (85%).
- (vii) The number of people living with a functioning kidney transplant doubled from 1995 to 2004. Health care providers in all settings are increasingly likely to be exposed to these organ transplant recipients.
- (viii) Patient survival following simultaneous pancreas-kidney (SPK) transplantation is excellent and has increased incrementally since 1995. Death rates for recipients in the first year following transplant have decreased, from 60 per 1000 patient-years at risk in 2001 to 45 in 2003.
- (ix) The number of solitary pancreas transplants increased dramatically in 2004, with 419 pancreas after kidney (PAK) and 185 pancreas transplant alone (PTA) transplants performed. This is an 18% increase in pancreas utilization for PAK and a 14% increase in PTA since 2003.

Liver and intestine transplantation

This article reviews liver and intestine transplantation, using the last decade's worth of data. The article covers liver waiting list characteristics, transplant recipient characteristics, patient and graft survival and posttransplant death rates. The increasing prominence of hepatitis C as an indication for transplantation is also highlighted. Special attention is given to the impact of MELD and PELD throughout the liver section, as there are now 3 years of survival data since the implementation of the system. In the intestine section, similar areas are discussed. Highlights of the article include:

- (i) The increased utilization of deceased donor livers and a resurgence in living-donor transplants has enabled the number of liver transplants performed yearly to surpass 5500.
- (ii) Although waiting time for all patients on the liver waiting list has not declined, pretransplant death rates have.
- (iii) In general, the 1-year posttransplant death rate increased with an increasing MELD score. In the pediatric population, a similar trend was observed for higher PELD scores, but since the number of transplants performed in the pediatric population with PELD values above 30 is limited, death rates for this group could not be calculated.

- (iv) Utilizing livers from donors over 50 years of age is associated with a significant decline in long-term survival.
- (v) Long-term survival following liver transplantation appears to be reduced in patients with chronic hepatitis C virus.
- (vi) The number of patients who received a small intestine transplant has gradually increased over the past 10 years from 46 in 1995 to 152 in 2004.
- (vii) Posttransplant intestine graft survival has increased stepwise since 2000 and patient survival at 1 year now exceeds 80% for the first time.

Thoracic transplantation

This article describes the current state of heart, lung and heart-lung transplantation and examines trends over the past decade. Although the number of thoracic organ transplants performed has declined in recent years, transplantation remains an important treatment option for selected patients with a failing heart, failing lungs or both. The article covers waiting list characteristics, death rates of patients on the waiting list, characteristics of transplant recipients and posttransplant outcomes for heart, lung and combined transplants. A few highlights of the article include:

- (i) The number of heart transplants per million population continued to decrease over the past decade (from 8.99 procedures per million population in 1995 to 6.87 procedures per million population in 2004). The most notable decline was among those ages from 50 to 64—from 35.86 transplants per million population in 1995 to 19.12 transplants per million population in 2004.
- (ii) The total number of patients active on the heart waiting list continued to decline during the period. This is primarily a reflection of the decline in the percentage of transplant candidates with a coronary artery disease classification.
- (iii) The status of patients on the heart waiting list at the end of each calendar year has changed significantly since the creation of waiting list Status 1A and Status 1B. The percentage of Status 2 patients declined from 84% in 1997 to 72% in 2004. At the same time, the percentage of Status 1B patients steadily increased, from 14% in 1999 to 21% in 2004.
- (iv) Both the number and the rate of deaths of patients on the heart waiting list have declined significantly since 1995. Annual death rates per 1000 patient-years at risk declined from 259 in 1995 to 156 in 2004.
- (v) The waiting time for new lung waiting list registrants decreased significantly among registrants aged 11 years and older between 1999 and 2004.
- (vi) For the sixth consecutive year, the number of patients on the active waiting list for a heart-lung transplant continued to decrease. From a high of 179 patients in 1998, the total number of active patients decreased to 83 in 2004. There were only 39 combined heart-lung transplants performed in 2004, a decline from a high of 69 in 1995 and an increase from a low of 27 in 2001.

(vii) Reported unadjusted patient survival rates at 3 months, 1 year, 3 years and 5 years for heart-lung recipients were 70%, 58%, 52% and 40%, respectively—lower than those for heart or lung recipients alone.

Center-specific reporting

This article describes the purpose and methods of center-specific reporting by focusing on how to interpret analyses of a particular set of posttransplant outcomes for transplant center-specific reports, though the methods and concerns discussed are applicable to other analyses presented in the reports for both transplant centers and OPOs. Reporting the results obtained from transplant centers and OPOs is one of the many contract responsibilities of the SRTR. These analyses are used for different purposes by patients and families, by transplant professionals, by insurance companies and other payers and by regulatory bodies both within and outside of the OPTN.

The technical issues discussed the focus on the concept of 'expected survival', which addresses the critical question, 'What rate is expected for the patients at this center, if they had outcomes comparable to the national experience for similar patients?' In addition to an overall discussion of the analytical methods used to address this question, we also examine the technical details of how to ensure that graft and patient survival are risk-adjusted for the donor and recipient characteristics of the particular center by including the right variables for modeling, how to aggregate observed and expected events at that center, and different methods for calculating loss to follow-up.

The article concludes with a detailed description of the screening process for transplant centers—the statistical and clinical criteria used, and the procedures followed by the OPTN Membership and Professional Standards Committee when a center is flagged for review.

Special focus article: lung allocation

In May 2005, the OPTN changed the lung allocation policy from a system based exclusively on waiting time to one that includes estimates of survival probability. The new Lung Allocation Score incorporates and compares candidates' estimated survival rate for remaining on the waiting list and for receiving a transplant. A key component of the new system is a candidate's expected 1-year transplant benefit, calculated by subtracting a waiting list urgency measure from a posttransplant survival measure.

A great deal of clinical, statistical and ethical consideration went into the development of this new system, as detailed in this article. Highlights include the following:

- (i) A historical overview of lung allocation and lung allocation policy, particularly the actions of the OPTN Tho-

racic Organ Transplantation Committee and Lung Allocation Subcommittee.

- (ii) Discussion of the ethical issues involved in developing the new system, including the effort to balance justice with utility.
- (iii) Detailed explanations of how the new allocation algorithm was developed, including the decisions made in diagnosis grouping, determining how to incorporate measures of waiting list urgency and transplant benefit, the use of the Thoracic Simulated Allocation Model and special rules governing the allocation of organs from pediatric donors and to pediatric candidates.
- (iv) It is expected and hoped that this important change in policy will both reduce the number of deaths on the lung waiting list and minimize the number of futile transplants.

Analytical methods and database design

This article is a combination of two articles that were published separately in previous reports, covering the database and analytical issues faced by the SRTR. The first section of the article focuses mainly on issues in transplant data sources and data collection. A brief summary of the scope of data available is given, along with discussion on the improvements of data submission patterns both on the waiting list and after transplant, as well as their implications for analysis. As in previous years, we discuss the value that the various extra ascertainment sources which the SRTR uses gives the data.

The second half of this article centers on methods of analysis using these data for transplant research. Essential analytical approaches used by the SRTR are reviewed, with special attention placed on unadjusted and covariate-adjusted analyses.

The article concludes with a description of Simulated Allocation Modeling and its importance for comparing outcomes based on current versus proposed national allocation policies.

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This study was approved by HRSA's SRTR project officer. HRSA has determined that this study satisfies the criteria for the IRB exemption described in the "Public Benefit and Service Program" provisions of 45 CFR 46.101(b)(5) and HRSA Circular 03.