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Organ donation and transplantation trends in the United States, 2001

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Introduction

This summary provides an overview of solid organ transplantation in the United States produced as part of the *2002 Annual Report*. This report is produced 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). This publication addresses a range of activities related to solid organ transplantation in the United States and is intended to be useful to patients, the transplant community, the public, and the Federal Government.

In a departure from previous years, the *2002 OPTN/SRTR Annual Report* was written by numerous national experts in the field, rather than by local experts at the OPTN, SRTR, and HRSA. The most important findings of these authors constitute the articles in this Supplement to the *American Journal of Transplantation*; the articles also appear at the beginning of the *2002 OPTN/SRTR Annual Report*. Our aim has been to produce a knowledgeable report on the state of transplantation that will receive broader circulation than previous reports. This new publication will make transplantation topics more accessible in libraries and online; its peer-reviewed status and distinguished list of authors will also ensure wider acceptance of this information.

University Renal Research and Education Association (URREA) has been the contractor for the SRTR since October 2000 and prepared the tables in the *2002 Annual Report*, which is published by the HRSA of the Department of Health and Human Services. Most of the articles in this supplement are based on tables from the *2002 OPTN/SRTR Annual Report*. These detailed tables can be found online at http://www.ustransplant.org and http://www.optn.org.

Summary Statistics on the Current State of Transplantation in the United States

During 2001, more than 23 000 patients received an organ transplant–over 17 000 from deceased donors and 6500 from living donors. During the same period, more than 6000 patients were reported to have died while waiting for a transplant.

The need for organs can be well described by the number of patients on the waiting list for transplants from deceased donors. During each year of the last decade, this list has been growing for most organs. Table 1 shows the numbers of patients on the waiting list in 2000 and 2001, demonstrating the increases by organ in just 1 year. An increase in the number of patients waiting for a transplant indicates that more patients are added to

Table 1: Growth in number of wait-listed patients, 2000–2001

Organs	Year 2000	Year 2001	Percent increase
Total	72393	78265	8.1%
Kidney	44966	48405	7.6%
PTA	318	395	24.2%
PAK	457	675	47.7%
Kidney–pancreas	2380	2399	0.8%
Liver	16253	18173	11.8%
Intestine	150	177	18.0%
Heart	4088	4076	−0.3%
Lung	3580	3756	4.9%
Heart–lung	201	209	4.0%

Source: *2002 OPTN/SRTR Annual Report* (Table 1.3). PTA = pancreas transplant alone, PAK = pancreas after kidney.

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This is a US Government-sponsored work. There are no restrictions on its use.
Note on Sources: The articles in this supplement are based on the reference tables in the *2002 OPTN/SRTR Annual Report*, which are not included in this publication. Many relevant data appear in figures and tables directly referred to in the article; other tables from the *Annual Report* that serve as the basis for this article include the following: Tables 1.3, 1.7, 1.8, and 1.14. All of these tables are available online at http://www.ustransplant.org.

the list than removed (mostly for transplantation and death). This suggests that the supply of organs does not meet the need. The need for more donor organs appears as a common theme in many of the articles in this report, though it is particularly pronounced for pancreata, livers, and kidneys.

The number of transplants performed in the most recent year with complete data (2001) and the prior year are shown by organ in Table 2. The annual increase in the number of organs transplanted from deceased donors is relatively small compared to the substantial increase in waitlisted candidates for such organs. The percentage change in the number of transplants from 2000 to 2001 varied greatly by organ and was several times greater for living donor transplants. The articles that follow provide more detailed insight into these changes as the patterns have varied for some organs by time period and by patient group.

Outcomes for transplant recipients generally show improvements over time, even in the last 5 years, and are shown for each organ in the following articles. Patient survival data for the most recent years are shown in Table 3 for all recipients by organ. The unadjusted first-year survival percentage refers to patients transplanted during 1999–2000, while the corresponding 5-year data are for those transplanted during 1995–96. Since 1995, the survival rates for transplanted organs and for patients have improved but at the same time recipient characteristics have changed, e.g. increasing numbers of older recipients. Therefore, future 5-year survival results may be different from those shown for those transplanted during 1995–96. Results for recipients of kidneys from living donors are superior to those from deceased donors, but this appears less consistent for livers. When interpreting the results for 5-year survival, one needs to consider that recipients in the early time period were more predominantly pediatric. More detail on this point, with stratification by age, is shown in the article on liver transplantation (1).

Functional survival of the transplanted organ (graft survival) has improved substantially over the past decade. Table 4 shows graft survival data for 1 and 5 years for each organ for the most recent available years (following through the end of 2001). As these analyses evaluate the same group of patients, Tables 3 and 4 can be compared, although patients may have more than one graft failure in these analyses. As patients may survive a graft failure through a second transplant (or, for kidneys, a return to dialysis), the graft survival figures are usually lower than those for patient survival. Results for living donor organs are superior to those from deceased donors, except for

Table 2: Growth in number of transplanted organs, 2000–2001

Organs	Year 2000	Year 2001	Percent increase
Total	22784	23848	4.7
Deceased donor	17065	17343	1.6
Living donor	5719	6505	13.7
Kidney	13261	14024	5.7
Deceased donor	7946	8055	1.4
Living donor	5315	5969	12.3
PTA	122	131	7.3
PAK	299	304	1.6
Kidney–pancreas	912	884	−3.1
Liver	4798	4989	4.0
Deceased donor	4418	4474	1.3
Living donor	380	515	35.5
Intestine	28	40	42.9
Heart	2165	2171	0.3
Lung	955	1053	10.3
Deceased donor	940	1034	10.0
Living donor	15	19	26.7
Heart–lung	46	27	−41.3

Source: *2002 OPTN/SRTR Annual Report* (Table 1.8). PTA = pancreas transplant alone, PAK = pancreas after kidney.

Table 3: 1- and 5-year patient survival by organ

Organ transplanted	1-year survival	5-year survival
Kidney		
Deceased donor	94.0%	79.9%
Living donor	97.7%	89.7%
Pancreas alone	97.8%	76.7%
Pancreas after kidney	95.4%	77.3%
Kidney–pancreas	95.1%	82.6%
Liver		
Deceased donor	86.3%	72.4%
Living donor	85.2%	85.6%
Intestine	80.7%	48.6%
Heart	85.1%	69.8%
Lung	77.3%	42.4%
Heart–lung	59.6%	48.5%

Source: *2002 OPTN/SRTR Annual Report* (Table 1.14).

Table 4: 1- and 5-year graft survival by organ

Organ transplanted	1-year survival	5-year survival
Kidney		
Deceased donor	88.3%	63.3%
Living donor	94.4%	76.5%
Pancreas alone	80.7%	32.0%
Pancreas after kidney	78.3%	45.5%
Kidney–pancreas (kidney)	92.0%	72.8%
Kidney–pancreas (pancreas)	83.8%	69.2%
Liver		
Deceased donor	80.2%	63.5%
Living donor	76.5%	73.0%
Intestine	63.2%	19.7%
Heart	84.4%	68.0%
Lung	76.2%	40.5%
Heart–lung	60.1%	46.9%

Source: *2002 OPTN/SRTR Annual Report* (Table 1.14).

livers, where the more recent short-term results include more adult recipients. This topic is explored in more detail in the article on liver transplantation (1).

Articles in the SRTR Report on the State of Transplantation

The articles in this report address the trends, practices, and characteristics of organ transplantation through data collected by the OPTN and analyzed by the SRTR. Three articles focus on practice areas (organ donation, immunosuppression, and pediatric transplantation) and three focus on specific organ areas (kidney and pancreas, liver and intestine, and heart and lung). Pediatric transplantation receives special emphasis, as many issues in transplantation are unique in children—partly explained by physiological and size considerations, but also by original cause of organ failure and immunological issues.

These six articles are bookended by two related articles that present the technical aspects of the data preparation and analysis work that go into the results reported in other articles. An article on data sources and structure describes the data resources used by the SRTR and the OPTN. A second article on analytical approaches describes many of the decisions required for designing analyses and the statistical methods and related issues involved in the *Annual Report*, the Center-Specific Reports, and other SRTR analyses. These detailed discussions of methods are essential, as they apply to all the articles in this report, as well as more generally to a wider body of research.

The final article is a special report on expanded criteria donors for kidney transplantation. This is an especially timely topic given that new allocation rules that became effective in October 2002 will likely change kidney transplantation practice in the United States.

Summaries and data highlights of each article follow.

Data Sources and Structure (2)

This article describes the data resources used by the SRTR and the OPTN for the two primary functions carried out by these organizations: transplantation research and organ allocation. It describes the OPTN data collection system, its evolution, and issues of data quality; the organization of these data for research purposes; and the integration of data from other sources. By examining these aspects, we hope to stimulate new research initiatives and help with study design—and to improve the understanding of existing results.

Auxiliary sources may be used for a wide variety of measures, such as incidence of post-transplant tumors, enumeration of organs available from deceased donors, and, most importantly, additional ascertainment of graft and patient survival. Additional ascertainment of patient survival can be gleaned from sources including the Social Security Death Master File (SSDMF), the Centers for Medicare and Medicaid Services (CMS) files for kidney patients, and the National Death Index (NDI). In this article, the relative contributions of the sources were evaluated by measuring the additional deaths contributed by each source as they are added to the OPTN data in the order listed above. Most deaths are identified by more than one source, though both the OPTN and SSDMF files identify a substantial number of deaths uniquely.

As a percentage of the total number of deaths identified by any of these sources, the non-OPTN sources make a much larger difference for kidney and pancreas transplants—for which alternative treatments such as dialysis are more available—than for other organs. For the years 1991–99, OPTN data provided ascertainment for only 75% of the deaths recorded after a kidney or pancreas transplant, compared to 96% of deaths for all other organs. However, for deaths in the first year after transplantation, ascertainment for all organs is substantially higher, including 95% for kidneys and pancreata. In later years, the SSDMF identifies almost all of the remaining deaths among the non-OPTN sources (30% for kidney and pancreas deaths and 10% for all other organs, at least 5 years following transplantation). The CMS and NDI data together identify only another 0.8% of deaths.

Among the three available sources beyond the OPTN, we find that those sources agree on most of the deaths, and that after SSDMF, the CMS and NDI add few additional deaths. While the additional sources do not give a definitively complete set of death dates, the fact that the two sources added last contribute so few additional deaths suggests that a satisfactory fraction of deaths is now found. Furthermore, evidence provided in 'Analytical Approaches', a companion article in this report, suggests that the survival rates for patients lost during follow-up are similar to those followed, and that (at a national level) a reliable estimate of survival can be obtained using available data.

Organ Donation in the United States (3)

The first section of this article provides an overview of the organ procurement system in the United States. The sections that follow provide a review of efforts to improve organ donation, and an examination of trends in the recovery and disposition of organs. The following are a few salient points from the article, based on OPTN/SRTR data.

- The total number of organ donors increased by 78% between 1992 and 2001. The number of living donors increased by a factor of 2.5; the number of deceased donors increased 34%. Since the average deceased donor provided 3.6 organs, the total increase in recovered cadaveric organs from 1992 to 2001 produced by this 34% swell was substantially higher than the increase in the number of organs from living donors during the same years.

- The deceased donor profile has continued to shift away from the young adult who dies from a traumatic head injury to the older adult who dies from a cerebrovascular event.
- While failure to obtain consent to donation from the next of kin of deceased donors remains a major challenge, a large fraction of medically suitable organs remained unrecovered even after consent for donation was obtained. In 2001 there were 40 465 cadaveric organs donated, 54% of which (22 007) were recovered. Nonrecovery was highest for intestines (97%) and lowest for kidneys (7%).
- The advent of living liver and lung donations has offered new options for candidates needing these organs. The aging of the deceased donor population continues and has exceeded that of the general population since 1996. The most notable development among living donors is the 10-fold increase in biologically unrelated donors over the decade, to a total of 1596 in 2001.

Immunosuppression: Practice and Trends (4)

This article presents analyses of immunosuppression strategies for organ transplantation over the past 10 years. An organ-by-organ review of data identifies trends that have evolved as new immunosuppressive agents have become available for clinical use. The article includes summaries, by organ, on a number of relevant topics, including induction therapy at transplantation, immunosuppression therapies employed at discharge from the hospital and several points thereafter, and antirejection treatments. Highlights include the following:

- Drug regimens used for maintenance immunosuppression at discharge varied widely by transplanted organ. Most notable was the wide variation in the choice of calcineurin inhibitor. Tacrolimus has always been the predominant agent for intestinal transplants, and its use surpassed that of cyclosporine formulations for pancreas transplants in 1995, liver in 1996, kidney–pancreas in 1997, and kidney and lung transplants in 2001.
- Corticosteroids were widely used in over 95% of cases for pancreas, heart, lung and heart–lung recipients in 2001. Between 75% and 90% of liver and intestine transplant recipients received corticosteroids.
- There has been a downward trend in the percentage of recipients with antirejection treatment noted in the first post-transplant year for most types of transplant. In 2000 (the latest year for which 1-year follow-up is available) the percentage of kidney, pancreas, and kidney–pancreas transplants with reported rejection treatment during Year 1 decreased to approximately 20%, and rejection treatments for liver transplants dropped to 30%. Interestingly, the percentage of heart, lung and heart–lung transplants treated for rejection remained at about 40%.

Pediatric Transplantation (5)

This article presents data from across all transplant procedures for an overview of the state of transplantation among children. The number of pediatric registrants on the waiting list continued to increase, with the greatest stability seen in the number of such patients awaiting heart and kidney transplants. The greatest percentage increase was observed in the number of pediatric registrants on the intestine and lung waiting lists; the liver waiting list contained the largest absolute number of pediatric registrants. and while the raw number of pediatric donors remained steady over the last 10 years, the proportion of total donations represented by these children declined to 16% in 2001, underscoring the importance of increased awareness about the need for pediatric organ donation.

- Infants and young children undergoing living and deceased donor kidney transplantation now have the best long-term survival of all age groups, in contrast to poor outcomes for these youngest patients in the past. Fortunately, mortality rates for children aged 6–17 on the kidney waiting list remain relatively low.
- Over the decade, waiting time for children in need of a liver transplant steadily increased, but mortality on the waiting list decreased for all age groups except for those under 1 year. Patient survival among pediatric liver transplant recipients compared favorably with that of adults.
- Increasing numbers of children aged 11–17 years received living donor liver grafts. Until 1998, the majority of such transplants were performed in children under the age of 1 year. Patient and graft survival rates for children receiving living donor grafts were excellent.
- For the very youngest patients awaiting a heart transplant, waiting list mortality was nine times the overall rate for cardiac transplant candidates. Early post-transplant graft and patient survival rates in these children showed increased early mortality, perhaps because of the complexities of congenital heart disease. By 5 years, however, graft and patient survival rates in these youngest cardiac patients showed marked improvement.
- In 2001, 61 intestinal transplants were performed in children, a dramatic increase over the 10 such procedures performed in 1992.

Kidney and Pancreas Transplantation (6)

Kidney transplantation has been established longer than other organ transplants and accounted for 59% of organ transplants in 2001. It differs from other solid organ

transplants because an alternative treatment exists for chronic organ failure—namely, dialysis.

The most significant findings noted in this section include the following:

- The kidney waiting list continues to grow in the face of a fairly static supply of deceased kidney donors. This discrepancy between supply and demand has led to longer waiting times. Since 1998, the number of transplants in each year has been only one-fifth the size of the waiting list. Despite mounting evidence of the benefits of early transplantation for end-stage renal disease (ESRD) patients, these benefits are unrealized for most cadaveric kidney recipients.
- This year's data highlight the growing importance of living kidney donors, who now account for almost 52% of all kidney donors in the United States. Not only are recipients of living donor kidneys spared the rigors of years on dialysis while on the waiting list, but they enjoy substantially better long-term results than recipients of kidneys from deceased donors.
- The disadvantage in time to kidney transplantation for minority candidates has continued to grow, despite awareness of this problem for more than a decade. Without the limited changes in the organ allocation algorithms designed to foster greater equity, one can assume that the differences would be even greater.
- The number of simultaneous kidney–pancreas (SPK) transplants has remained static since 1995, but the waiting list has doubled in size. The benefits of early SPK transplantation for Type 1 diabetic patients have been noted previously, but as waiting times lengthen, increasing numbers of diabetic registrants cannot receive them at all.
- Rapid growth was observed in the numbers and success rates of isolated pancreas transplantation, a trend that makes living donor kidney and separate cadaveric pancreas transplantation even more attractive than before for a Type 1 diabetic with ESRD.

Liver and Intestine Transplantation (1)

Liver transplantation is the second most common transplant (21% of all organ transplants), while intestine transplants occur only rarely. The biggest development in liver transplantation in the United States over the last several years has been the rapid increase in the number of living donor transplants. Although this procedure accounts for only 10% of the liver transplants performed in 2001, the number has doubled since 1999.

Early graft survival after living donor transplantation appears to be lower than that following deceased donor transplantation. However, it is hoped that the additional benefit of reduced waiting list mortality from earlier transplantation along with continued maturation of this new surgical procedure will offer benefit to patients awaiting liver transplantation.

The Model for End-Stage Liver Disease (MELD) and the Pediatric End-Stage Liver Disease (PELD) models were instituted for a refined prioritization of patients with chronic liver disease awaiting transplantation. Despite the very recent institution of the new allocation policy (February 2002), some analyses of waiting list characteristics and outcomes for a substantial number of patients on the waiting list are available and are reported in this article.

Thoracic Transplantation (7)

This article presents an overview of factors associated with thoracic transplantation outcomes over the past decade. These analyses are a valuable source of information on the heart, lung, and heart–lung waiting lists, as well as information about thoracic organ transplant recipients. Waiting list and post-transplant information is used to assess the importance of patient demographics, risk factors, and primary cardiopulmonary disease on outcomes. The following are a few of the most significant findings in this section.

- The number of registrants on the heart transplant waiting list steadily increased, from 2655 in 1992 to 4149 in 1998. This number has remained fairly stable since 1998, with 4096 registrants at the end of 2001. The total number of heart transplants remained relatively stable over the decade, with 2170 transplants performed in 1992 and 2202 performed in 2001. Patients in their fourth, fifth, and sixth decades of life accounted for the majority of heart recipients every year since 1992; the percentage of recipients older than 65 rose from 4% in 1992 to 10% in 2001.
- The lung waiting list continued to expand during the past year, reaching a record high of 3802 registrants in 2001—up 5% from 2000 and up fourfold from 1992. Shorter times to transplant were observed for older registrants on the lung waiting list. For those listed in 2000, 25% of patients aged 50–64 years received lungs within 290 days and 25% of recipients over age 65 received lungs within 67 days. In contrast, 25% of patients aged 11–17 years, 18–34 years, and 35–49 years received lungs, respectively, within 575 days, 601 days, and 509 days of listing.
- After rising steadily between 1992 and 1998, the total number of registrants awaiting heart–lung transplant decreased by 18% in the next 3 years, to 209 as of 2001 year-end. The heart–lung waiting list death rate is among the highest for any group of transplant patients.

The article ends by analyzing the measurable effects of changes in thoracic organ allocation policies over the decade. The general aim of all the analyses in this article is to draw attention to the evolution of thoracic transplantation, to provide insights that may lead to more efficient allocation policies of organs and that may improve patient and graft outcomes.

Analytical Approaches for Transplant Research (8)
This comprehensive article describes many of the statistical methods and issues involved in the various articles in this report. The same methods are used in the *Annual Report*, Center-Specific Reports, and other SRTR analyses.

In addition to a general description of the statistical methods used by the SRTR for analysis of time to event data–time to transplant or patient survival–the Analytical Approaches article demonstrates the value of additional mortality ascertainment data from the SSDMF to the OPTN data on survival results. Inclusion of SSDMF death data requires that patient survival time also be extended. That is, patients are not censored from the analysis when they become lost to follow-up by the transplant center. At the national level, survival results were virtually unchanged by the additional data, indicating that the loss of patients to follow-up over time is random and does not bias the results based upon OPTN data alone. With only a few exceptions, the difference in center-specific mortality rates resulting from the inclusion of extra ascertainment is small, with survival rates increasing and decreasing depending on the individual center. The extra death ascertainment is a useful tool both for obtaining accurate data at the center level and for improving public confidence in the results.

Expanded Criteria Donors for Kidney Transplantation (9)
The widening disparity between the size of the kidney transplantation waiting list and the number of kidneys recovered from deceased donors has resulted in efforts to expand this donor source to include kidneys previously considered less suitable for transplantation. These expanded criteria donor (ECD) kidneys have been shown to add extra life years to recipients when compared to prospects of remaining on the waiting list for transplantation. However, it is often difficult to identify suitable recipients for such organs, and many are discarded due to disparate practice patterns and prolonged cold ischemia time. The recent development of a uniform ECD definition prompted a successful effort to modify the kidney allocation system with the expectation that placement of such donor kidneys will be expedited and utilization increase. This article details what is known about the characteristics of ECD kidneys procured and transplanted under the existing allocation system as a preview of what may be expected in the future.

This special focus article reviews the past year's efforts that resulted in the ECD definition, which includes all donors over age 60 years and those donors over age 50 years meeting at least two of the following criteria: death from a cerebrovascular accident, history of hypertension, or preprocurement creatinine >1.5 mg/dL. The article presents data on ECD kidney recipients, along with associated patient and graft survival rates.

Conclusion

This report is a comprehensive review of data from the most intensively studied and tracked field of medicine. A world-class group of authors has come together to scrutinize these data, offering insights and identifying the most important trends in organ transplantation in the United States today. Ultimately, we rely on the staff of transplant centers and organ procurement organizations across the country to provide the most accurate and up-to-date data to the OPTN so that this and future reports can be made possible.

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