Trends and results for organ donation and transplantation in the United States, 2004

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Introduction

This summary offers a national overview of numerous aspects of solid organ transplantation in the United States, produced as part of the 2004 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). One of the purposes of providing such a detailed Annual Report is to gather the extensive and varied knowledge on the current state of transplantation in a single publication. This publication is intended to be useful for patients, the transplant community, the public and the Federal Government; its goal is to improve patient care and enhance equitable access to transplantation.

Note on sources: The articles in this report are based on the reference tables in the 2004 OPTN/SRTR Annual Report, which are not included in this publication. Many relevant data appear in the tables included here; other tables from the Annual Report that serve as the basis for this article include the following: Tables 1.1, 1.3, 1.5–1.7, 1.10, 1.11a, 1.13, 2.1, 2.2, 5.2, 5.4, 5.6a–13.6a, 5.6b–13.6b, 5.6d–13.6d, 5.9a–c, 8.9, 9.1, 9.3, 9.7a, 9.12a, 10.7, 11.1, 11.3, 11.7, 12.1, 12.11a, 12.13a, 13.1 and 13.11. All of these tables may be found online at http://www.ustransplant.org.

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Ten groups of authors drawn from across the U.S. transplant community, all experts in their fields, have produced a wealth of information in 10 peer-reviewed articles based on new analyses, figures and tables. The text of the following articles is based to a large extent on the detailed 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 are available as a compact disc. They may also be found online at www.ustransplant.org and www.optn.org.

Summary statistics for 2002–2003 on transplantation in the United States

During 2003, more than 25 000 organs were transplanted in the United States—over 18 000 from deceased donors and almost 7000 from living donors. Compared to data from the prior year (2002), these numbers reflect an increase in the number of deceased donor transplants by 2.2% overall and by 1.9% for deceased donors; a greater increase was noted for living donors (2.9%), as shown in Table 1. During the same period, more than 7000 patients were reported to have died while waiting for a transplant. The number of deaths on the waiting list did not change substantially from 2002 to 2003; however, there was a decrease in the overall death rate because of the increase in waiting list size.

The waiting list for deceased donor transplants has increased at more than twice the rate of increase in the number of transplants during the past year, by 5.1% versus 1.9% (Table 2). This large increase is a continuation from earlier years and provides a strong indication of the ever-increasing demand for organs. The total number of patients on the waiting list reached almost 86 500 in 2003. Table 2 demonstrates the increases in numbers of candidates by organ, comparing the numbers of patients on the waiting list in 2002 and 2003. When the number of patients waiting for a transplant increases, it demonstrates that the demand exceeds the supply-more patients are added to the list than are removed from it. Hopefully, these removals occur because of transplantation, but they also represent death and (occasionally) recovery from organ failure. The table shows clearly that the demand for kidney and pancreas transplants increased steeply; lung and liver transplant demand also increased, though to a lesser degree.

| Table 1: Growth in number of | f transplanted organs, | 2002-2003 |
|------------------------------|------------------------|-----------|
|------------------------------|------------------------|-----------|

| | Year | | | |
|-----------------|--------|--------|----------------|--|
| Organs | 2002 | 2003 | Percent change | |
| Total | 24 548 | 25 076 | 2.2% | |
| Deceased donor | 17 936 | 18 270 | 1.9% | |
| Living donor | 6612 | 6806 | 2.9% | |
| Kidney | 14 524 | 14 853 | 2.3% | |
| Deceased donor | 8288 | 8389 | 1.2% | |
| Living donor | 6236 | 6464 | 3.7% | |
| PTA | 140 | 117 | -16.4% | |
| PAK | 376 | 343 | -8.8% | |
| Kidney–pancreas | 902 | 868 | -3.8% | |
| Liver | 5060 | 5364 | 6.0% | |
| Deceased donor | 4699 | 5044 | 7.3% | |
| Living donor | 361 | 320 | 11.4% | |
| Intestine | 42 | 52 | 23.8% | |
| Heart | 2112 | 2024 | 4.2% | |
| Lung | 1041 | 1080 | 3.7% | |
| Deceased donor | 1028 | 1065 | 3.6% | |
| Living donor | 13 | 15 | 15.4% | |
| Heart–lung | 31 | 28 | -9.7% | |

Source: 2004 OPTN/SRTR Annual Report, Table 1.7. PTA: pancreas transplant alone; PAK: pancreas after kidney.

Table 2: Growth in number of patients on the waiting list, 2002–2003

| | End of year | | | |
|-----------------|-------------|--------|----------------|--|
| Organs | 2002 | 2003 | Percent change | |
| Total | 82 152 | 86355 | 5.1% | |
| Kidney | 53 392 | 57211 | 7.2% | |
| PTA | 406 | 455 | 12.1% | |
| PAK | 796 | 935 | 17.5% | |
| Kidney-pancreas | 2514 | 2472 | -1.6% | |
| Liver | 17 122 | 17 515 | 2.3% | |
| Intestine | 185 | 175 | -5.4% | |
| Heart | 3775 | 3529 | -6.5% | |
| Lung | 3765 | 3874 | 2.9% | |
| Heart-lung | 197 | 189 | -4.1% | |

Source: 2004 OPTN/SRTR Annual Report, Table 1.3. PTA: pancreas transplant alone; PAK: pancreas after kidney.

By contrast, the number of patients awaiting heart, heart– lung and intestine transplants decreased in 2003 compared to the prior year. Longer time trends for the past decade are demonstrated for each organ in the organ-specific articles that follow.

As a consequence of the steeply increasing demand for transplants and slowly increasing supply of organs, the waiting list is getting longer and the waiting times for transplant candidates, which are already long, are getting longer. The urgent need for more donor organs is suggested by many of the articles in this report; it is particularly pronounced for kidneys, pancreata and livers. Evaluation of the number of transplants performed by organ in 2003 compared with the prior year reveals large differences, as shown in Table 1. Kidney transplantation leads organ transplantation, and living donor kidney transplants accounted for 44% of all kidney transplants in 2003. Liver transplantation too continues to show a substantial growth (6%). By contrast, the number of living donor liver transplants decreased by 11% to 320 during the recent year. Living donor liver transplantation accounts for only 6% of all liver transplants. Heart transplantation decreased by 4.2% to 2024 transplants in 2003. Lung transplants number just over 1000 per year, and showed a 3.7% increase since 2002. Living lung transplants account for less than 2% of all lung transplants. Pancreas transplantation for Type 1 diabetics is most commonly performed simultaneously with kidney transplantation. It showed a reduction in 2003 compared to the prior year, which is consistent for all types of pancreas transplants. In 2003, there were 52 small intestine transplants, which suggests a substantial recent increase.

Two critical measures describe the key outcomes after transplantation: the function of the transplanted graft and survival of the transplant recipient. Patient survival after transplantation has been generally improving over time. Table 3 shows by organ the results for patient survival for the most recent years for which 1- or 5-year follow-ups are available (the former for recipients during 2001–2002 and the latter for recipients during 1997–1998). Corresponding numbers from cohorts transplanted 1 year earlier are also shown, for comparison. One-year patient survival for kidney and pancreas transplants were around 95–97%; corresponding survival rates were about 86% for liver and heart, about 80% for lung and intestine and lowest for combined heart–lung recipients.

Functional survival of the transplanted organ, i.e. graft survival, has improved substantially over the past decade and has been relatively stable in recent years. Table 4 shows the 1- and 5-year graft survival results for each organ for the same most recent years as for patient survival. Compared to the data for patient survival, figures for graft failure are usually lower. This is due to the fact that patients may survive a graft failure by receiving a timely second transplant, by returning to dialysis (for kidney transplant recipients), or by returning to insulin therapy (for pancreas transplant recipients). The survival trends observed in Tables 3 and 4 show generally small improvements from the prior year. More detailed trends over longer time spans are provided in the organ-specific articles of this report.

The articles in the 2004 SRTR Report on the State of Transplantation

The articles in this report encompass a broad range of topics related to solid organ transplantation in the United States. This year, in addition to updated information on

| Table 3: Unadjusted | 1- and 5-year | patient su | rvival by organ |
|---------------------|---------------|------------|-----------------|
|---------------------|---------------|------------|-----------------|

| | 1-year survival | | 5-year survival | |
|-----------------------|-----------------|-----------|-----------------|-----------|
| Organ transplanted | 2001–2002 | 2002–2003 | 1997–2002 | 1998–2003 |
| Kidney | | | | |
| Deceased donor | 94.2% | 94.5% | 80.7% | 81.0% |
| Living donor | 97.5% | 97.6% | 90.1% | 89.8% |
| Pancreas alone | 98.6% | 97.6% | 79.2% | 80.3% |
| Pancreas after kidney | 95.3% | 95.5% | 76.6% | 82.3% |
| Kidney–pancreas | 94.7% | 94.7% | 84.0% | 85.3% |
| Liver | | | | |
| Deceased donor | 86.3% | 86.5% | 72.1% | 72.6% |
| Living donor | 86.9% | 86.6% | 84.2% | 78.0% |
| Intestine | 79.1% | 81.3% | 47.4% | 56.8% |
| Heart | 85.6% | 86.3% | 72.0% | 72.5% |
| Lung | 78.1% | 80.0% | 45.1% | 46.0% |
| Heart-lung | 67.1% | 67.2% | 36.7% | 38.7% |

Source: 2004 OPTN/SRTR Annual Report, Table 1.13; 2003 OPTN/SRTR Annual Report, Table 1.14.

| Table 4: | Unadjusted | 1- and 5-year | graft surviva | l by organ |
|----------|------------|---------------|---------------|------------|
|----------|------------|---------------|---------------|------------|

| | 1-year survival | | 5-year survival | |
|----------------------------|-----------------|-----------|-----------------|-----------|
| Organ transplanted | 2001–2002 | 2002–2003 | 1997–2002 | 1998–2003 |
| Kidney | | | | |
| Deceased donor | 88.7% | 89.0% | 65.7% | 66.2% |
| Living donor | 94.3% | 94.6% | 78.6% | 79.2% |
| Pancreas alone | 77.3% | 80.5% | 41.8% | 46.6% |
| Pancreas after kidney | 79.4% | 80.9% | 46.0% | 52.6% |
| Kidney-pancreas (kidney) | 92.0% | 91.3% | 74.2% | 76.8% |
| Kidney–pancreas (pancreas) | 85.1% | 86.0% | 69.8% | 69.9% |
| Liver | | | | |
| Deceased donor | 80.6% | 81.4% | 64.1% | 65.4% |
| Living donor | 79.3% | 80.1% | 78.1% | 71.2% |
| Intestine | 71.8% | 69.5% | 33.3% | 29.8% |
| Heart | 85.3% | 85.8% | 70.6% | 71.4% |
| Lung | 77.0% | 78.7% | 43.6% | 44.7% |
| Heart-lung | 67.0% | 67.2% | 37.8% | 37.5% |

Source: 2004 OPTN/SRTR Annual Report, Table 1.13; 2003 OPTN/SRTR Annual Report, Table 1.14.

transplantation trends and practices, recent and significant allocation policy issues are discussed within the three major organ areas—kidney and pancreas, liver and intestine, and heart and lung. Throughout this report, the SRTR and its expert collaborators continue to provide timely, relevant interpretation and analysis of the transplant data provided through the OPTN and supplemental sources.

Articles on data sources and analytical approaches provide useful background information regarding analysis design and the statistical methods used to produce 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 issue, as well as more generally to a wider body of research.

The report concludes with a special focus article on new and useful methods for evaluating organ procurement organization (OPO) performance. Important issues regarding

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accuracy of death reporting, variations in OPO practices and methods to account for geographic differences in the potential donor supply are discussed.

Summaries and data highlights of each article follow.

Transplant data: sources, collection, and research considerations, 2004

A brief review of the scope of data available from the SRTR is included in this article, which seeks to outline up-to-date information about caveats based on extra ascertainment and patterns in data submission. The discussion of extra ascertainment of outcomes is expanded this year to examine graft failure events for kidneys on the basis of Medicare data to ascertain return to dialysis, as well as extra ascertainment of deaths. Finally, the effects of changes in data submission patterns resulting from OPTN data collection improvements and feedback reporting by both the SRTR

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and OPTN are emphasized as issues that should be carefully considered when choosing cohorts and data sources for analysis.

Organ donation and utilization in the United States, 2004

The vital importance of organ donation has been underscored most recently by the Organ Donation Breakthrough Collaborative, initiated by US Secretary of Health and Human Services Tommy G. Thompson. The goal of the collaborative is to evaluate and share best practices of organ donation, implemented by OPOs and major donor hospitals in the same donation service areas (DSAs).

This article discusses issues directly related to the donation process, including donor consent, donor medical suitability, non-recovery of organs, organs recovered but not transplanted, expanded criteria donors (ECD) and donation after cardiac death (DCD).

Some interesting findings are highlighted here:

- In 2002 and 2003, U.S. hospitals referred more than 1 million deaths or imminent deaths to the OPOs of their DSA. Referrals increased by nearly 10% from 2002 to 2003 (1 022 280–1 121 392).
- Donor consents have increased by about 5% and the number of total deceased donors has risen from 6187 to 6455. Since multiple organs are recovered from most donors, this increase allowed more than 500 additional wait-listed candidates to receive an organ transplant than in the prior year.
- Non-traditional donor sources have experienced a large rate of increase; in 2003 the number of ECD kidney donors increased by 8% and the number of DCD donors increased by 43%, from 189 donors in 2002 to 271 donors in 2003.

Immunosuppression: evolution in practice and trends, 1993–2003

This article discusses immunosuppression practices and trends for solid organ transplantation for the past decade. An organ-by-organ review of data identifies the trends that have evolved as well as the noticeable changes in immunosuppressive strategies as new immunosuppressive agents have become available for clinical use. A thorough review is presented, including organ-specific summaries of trends in the use of induction therapy and choice of agent at transplantation, maintenance immunosuppression therapies prior to discharge from the hospital and the frequency of rejection and antirejection treatment during the first year following transplant. Highlights from the article include the following:

Antibody induction continues to be used in the majority of kidney (70%), simultaneous pancreas-kidney (SPK, 79%), pancreas after kidney (PAK, 74%) and intestine recipients (74%), and in just under half of

thoracic organ recipients; it remains uncommon in liver transplant recipients (20%). Additionally, there has been an ongoing dramatic shift in the type of antibody preparation being utilized, from muromonab-CD3 (OKT3[®], Orthobiotech, Bridgewater, NJ, USA) and horse ATG (ATGAM[®], Pharmacia & Upjohn, Kalamazoo, MI, USA) to rabbit ATG (Thymoglobulin[®], SangStat Medical Corp., Fremont, CA, USA) and the monoclonal anti-IL2 receptor antagonists daclizumab (Zenapax[®], Roche, Nutley, NJ, USA) and basiliximab (Simulect[®], Novartis, East Hanover, NJ, USA). More recently, there has been growing interest in the use of alemtuzumab (Campath-1H[®], ILEX Pharmacenticals, San Antonio, TX, USA) at increasing numbers of centers, although its level of use is still low on a percentage basis.

- Maintenance immunosuppression has also seen an ongoing evolution. Calcineurin inhibitors continue to be used for most recipients, with a continuing shift in the calcineurin inhibitor used from cyclosporine to tacrolimus (this shift was less pronounced for heart transplantation). In 2003, 67% of kidney, 84% of SPK, 81% of PAK, 81% of pancreas transplant alone (PTA), 66% of lung and 41% of heart transplant patients received tacrolimus. An even more noticeable shift was seen in the type of antimetabolite used, from azathioprine to mycophenolate mofetil; the latter remains the most widely used immunosuppressive agent in solid organ transplantation: In 2003, 81% of kidney, 82% of SPK, 85% of PAK, 71% of PTA and 82% of heart recipients received mycophenolate mofetil as maintenance immunosuppression prior to hospital discharge.
- Corticosteroids continue to be used as maintenance immunosuppression for most recipients prior to discharge from their initial transplant hospitalization (in 2003, for 95% of lung, 93% of heart, 85% of kidney, 84% of SPK, 82% of liver, 81% of PAK and 62% of PTA recipients). However, the fact that these percentages are less than 100% indicate that efforts of steroid avoidance and near-avoidance protocols are starting to have an impact across all organs.
- The incidence of acute rejection in the first year after transplantation continues to decline. This decline partly explains the observed improvement in graft survival. Steroids and antibody therapy continue to be used as the mainstay in the treatment of acute rejection.

Pediatric transplantation, 1994–2003

Pediatric organ transplant recipients differ from their adult counterparts in several important aspects, including the underlying etiology of organ failure, the complexity of the surgical procedures, the pharmacokinetic properties of common immunosuppressants, the immune response following organ transplantation, the measures of success of the transplant procedure, the number and degree of comorbid conditions and the susceptibility to post-transplant complications, especially infectious diseases. Thus, specialized pediatric organ transplant programs have been

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developed to better address these problems. The transplant community has responded to the unique needs of children and has provided them special consideration in the allocation of deceased donor organs. This article summarizes these provisions. An important outcome of these programs, provisions and protocols has been that children frequently achieve the highest success with organ transplantation, with the outcomes for kidney, liver and heart transplantation ranking among the best. This report also demonstrates that improvement is still needed in adolescent outcomes, in pediatric outcomes of intestinal transplants and in waiting list mortality for pediatric heart and lung candidates.

The number of transplants in children has increased only by 16% from 1994 to 2003 while the number of total transplants has grown by 39%. The increase in pediatric transplants reflects the relatively high percentage of living donor organs directed toward children and the preference provided for them in deceased donor organ allocation, which is described further in this article.

Current status of kidney and pancreas transplantation in the United States, 1994–2003

This article reviews the extensive data collected on kidney and pancreas transplantation during 2003 in the context of trends over the past decade. Characteristics of wait-listed candidates are discussed, followed by assessments of transplant recipient characteristics and of recipient and allograft survival. Characteristics of ECD and ECD kidney recipient outcomes are also described. Sections on pancreas transplantation discuss trends for SPK, PAK and PTA. Important changes have been made in the kidney allocation algorithm in the past 2 years that are also addressed.

Notable highlights on trends include the following:

- The annual number of new wait-listed registrants under the age of 50 has remained fairly stable since 1994, but the number of new registrants aged 50–64 has doubled, and the number of new registrants over the age of 64 has more than tripled during the past decade.
- In contrast to the steep increase in the number of candidates, there was only a 2.3% increase in the total number of kidney transplants (deceased and living donor) performed in 2003, as a continuation of an upward trend. The fraction of kidney transplants from living donors remained nearly constant at approximately 44%.
- The transplantation of ECD kidneys has increased steadily over the past decade, from approximately 11% of kidney alone transplants in 1994 to approximately 16% in 2003. ECD kidneys made up 20% of all recovered kidneys and 16% of all transplants performed, compared with 15% in the prior year.
- Unadjusted graft survival for recipients of ECD transplants was 80% at 1 year and 51% at 5 years, com-

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pared to 91% and 69% for recipients of non-ECD transplants. For living donor recipients, results have been consistently better than for non-ECD deceased donor transplants, with 1- and 5-year unadjusted graft survival rates of 95% and 79%.

- Unadjusted kidney graft survival at 1 and 5 years following SPK transplantation was 91% and 77%, respectively. African Americans had somewhat poorer 5-year graft survival (72%) than whites (77%).
- As of May 2003, allocation points for HLA-B similarity were no longer assigned. Preliminary evaluation of allocation trends suggests that since the introduction of this change, more kidneys have been allocated to African Americans and other minorities and fewer to whites. Therefore, as predicted by SRTR analyses, this new allocation rule reduces a disadvantage due to HLA-B tissue types for minority kidney transplant candidates. No change can yet be detected in graft survival.

Liver and intestine transplantation: summary analysis, 1994–2003

With nearly 2 years of data available since the inception of the model for end-stage liver disease (MELD) and pediatric end-stage liver disease (PELD) allocation system in early 2002, a more thorough assessment of the effects of this alternative allocation system has become possible. This article provides a detailed monitoring of the progression of disease and corresponding changes in MELD/PELD scores during time on the liver waiting list, and their effect on waiting list outcomes. Comprehensive descriptions of observed trends in waiting list composition, waiting list mortality, transplant rates and patient and graft outcomes for liver and intestine transplantation are provided. Living donor liver transplantation is also a focus of this article. In addition, important aspects of recent liver allocation policy developments are described.

Some highlights include:

- Following a 6% reduction in the size of the waiting list immediately after MELD was implemented in 2002, the number of patients on the waiting list grew by 381 (2%) from 2002 to 2003, while the number of liver transplants increased by 304 (6%), from 5060 in 2002 to 5364 in 2003. Due to the increase in the number of inactive patients on the list, the number of active patients on the waiting list has actually dropped the past 2 years, from 14917 in 2001 to 13063 in 2002 and 12715 in 2003—a 12% drop from 2001 to 2002 and a further 3% decrease from 2002 to 2003.
- The overall death rate while on the liver waiting list has decreased considerably over the past 10 years, from 225 deaths per 1000 patient years in 1994 to 124 deaths in 2003. The annual death rates of patients on the intestine waiting list have varied over the past decade, although there has been a general downward

trend—from a high of 561 per 1000 patient years in 1998 to 295 in 2003.

- As with the waiting list death rates, post-transplant death rates have also displayed a decreasing trend over the past decade. The death rate in the first year following deceased donor liver transplant decreased from 197 per 1000 patient years in 1994 to 156 deaths in 2002. The annual death rate after intestine transplantation declined over the last year for which data are available, dropping from 404 in 2001 to 310 in 2002.
- Unadjusted 1-year patient survival for liver transplant recipients was 90% when the deceased donor age was between 11 and 17. Survival was progressively lower for older donor age groups (88% for donors aged 18–34, 87% for donors aged 35–49 and 85% for donors aged 50–64). A more substantial decrease in 1-year survival (79%) was seen for recipients of livers from donors who were 65 years or older. These trends continued at 3 and 5 years.
- Important allocation policy changes have resulted from recommendations from the OPTN liver and pediatric committees and the 2003 MELD/PELD conference, largely based on SRTR analyses, including the regional sharing for MELD scores ≥15 prior to local allocation to patients with MELD <15, and a lower number of exception points for hepatocellular carcinoma.
- The number of living donor liver transplants continued to fall for the second year in a row. It remains to be seen whether this trend will reverse in the future, as the effects of a highly publicized donor death lead to improved safeguards for potential donors.

Thoracic organ transplantation in the United States, 1994–2003

This article presents a detailed description of waiting list and post-transplant outcomes for thoracic organs over the past decade, providing insights into recognized trends and practices related to heart, lung and heart–lung transplantation. This year's report also includes a detailed explanation of the newly developed allocation system for lungs, which, instead of being based solely on waiting time, derives from the survival benefit of transplantation with consideration of urgency based on waiting list survival.

Highlights from this article include the following:

- Time spent on the heart waiting list has increased significantly over the past decade. The percentage of patients awaiting transplantation for more than 2 years increased from 23% in 1994 to 49% by 2003.
- Despite the trend toward increased waiting time for heart registrants, the larger proportions of older registrants, and the decrease in Status 2 registrants, there was a general decline in the waiting list death rate over the past decade: 274 deaths per 1000 patient years at risk in 1994 versus 162 deaths per 1000 patient years at risk in 2003.

- After remaining fairly constant from 1994 to 2001, the overall death rate within the first year post-transplant fell in 2002, from around 170 to 151 deaths per 1000 patient years at risk. This decline was seen across all recipient age groups, with the possible exception of those over the age of 65 years.
- Over the past year, the lung transplant waiting list reached a record high of 3836 registrants as of December 31, 2003. This growth reflects a small increase over 2002 and a more than threefold increase since 1994.
- Despite the relatively constant number of lung registrants over the past 7 years, the number of inactive patients has nearly doubled since 1998, likely a reflection of the common practice of early placement on the waiting list. With the inception of the new lung allocation policy, which de-emphasizes waiting time, the number of inactive patients may decline substantially.
- In contrast to earlier years, survival statistics for the most recent cohort of deceased donor lung recipients (2002) demonstrate that the 1-year patient survival was statistically significantly better for patients transplanted in 2002 than in 2001 (82% vs. 78%).
- The total number of patients awaiting a heart–lung transplant continues to decline from a high of 250 in 1998 to only 189 in 2003, with only 106 (56%) being active on the waiting list.
- The adjusted patient survival percentages for heartlung recipients are consistently worse than the corresponding rates for isolated lung transplants, primarily due to worse outcomes for heart-lung recipients with congenital heart disease.
- A new lung allocation system, approved by the OPTN Board of Directors in June 2004, is intended to maximize the survival benefit of lung transplantation by incorporating into organ allocation the predicted difference between measures of waiting list survival and post-transplant survival for each candidate. An additional goal is to minimize deaths on the waiting list; the new allocation rule is expected to balance the benefit calculation and the degree of medical urgency, as embodied in the waiting list survival measure.

Analytical approaches for transplant research, 2004

This article provides detailed explanations of the methods frequently employed in the outcomes' analyses performed by the SRTR. All aspects of the analytical process are discussed, including cohort selection, outcome definition, ascertainment of events and censoring. The methods employed for descriptive analyses are described, such as unadjusted mortality rates and survival probabilities, and the estimation of covariate effects through regression modeling. Additionally, this article describes recently developed specialized modeling strategies designed by the SRTR and aimed at specific organ allocation issues. The article concludes with a description of simulated allocation modeling (SAM), which has been developed by the SRTR for three organ systems: liver, thoracic organs and kidney–pancreas. SAMs are particularly useful for comparing outcomes for proposed national allocation policies. The use of SAMs has already helped to develop and implement a new policy for liver candidates with high MELD scores to be offered organs regionally before the organs are offered to candidates with low MELD scores locally.

Quantifying organ donation rates by donation service area

Previous measures of OPO performance based on population counts have been deemed inadequate, and the need for new methods has been widely accepted. The SRTR has been making significant progress in this area and has devoted this special focus article to explaining recent developments in the OPO performance evaluation methodology.

As a replacement for the previously established measure of OPO performance—donors per million population—the utilization of eligible deaths as a national metric has yielded promising results for understanding variations in donation rates among the DSA assigned to each OPO. A major improvement uses 'notifiable deaths' as a denominator describing a standardized maximal pool of potential donors. Notifiable deaths are defined as in-hospital deaths among ages 70 years and under, excluding certain diagnosis codes related to infections, cancers, etc. A most proximal denominator for determining donation rates is 'eligible deaths', which include only those deaths that meet the criteria for organ donation upon initial assessment. Neither of these measures is based on the population of a geographic unit, but on more or less restricted upper limits of deaths that could be potential donors in any one locale (e.g. hospital or OPO). The inherent strengths and weaknesses of metrics such as donors per eligible deaths, donors per notifiable deaths and the number of organs per donor are discussed in detail in this article.

Notification rates and donation rates vary widely in the DSAs of the OPOs. Similarly, SRTR data show that OPO experience with ECD and DCD organ distribution varies to a large degree. The Organ Donation Breakthrough Collaborative mentioned in the organ donation article has contributed to this area of research by affirming a set of standard metrics of organ donor analysis to evaluate donation and considering best practices at the OPO and donor hospitals.

Conclusion

This report provides a great deal of information on the current state of transplantation in the United States. The observed time trends over the past decade and the most recent 2 years give important perspectives on many areas of organ donation, immunosuppression, organ-specific issues and overall outcomes. Numerous impressive improvements are documented in this report, as are areas that need to be addressed with great urgency—such as enhancing organ donation to reduce the annually increasing gap between available organs and the growing need for life-saving transplantation.