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Organ donation and transplantation trends in the USA, 2003

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Introduction

This summary provides an overview of solid organ transplantation in the USA, produced as part of the *2003 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). A wide range of activities related to solid organ transplantation in the USA are thoughtfully addressed in this publication with the intention of providing useful information to patients, the transplant community, the public, and the Federal Government.

The peer-reviewed articles in this report include a wealth of new analysis from 10 new groups of authors drawn from across the US transplant community. These 10 articles are based on the detailed reference tables in the *Annual Report*, which have been prepared by the University Renal Research and Education Association (URREA), the contractor for the SRTR since October 2000. Both tables and articles are included in the *Annual Report*, available this year as a compact disc; they may also be found online at http://www.ustransplant.org and http://www.optn.org.

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Funding: The articles in this report are based on the reference tables in the *2003 OPTN/SRTR Annual Report*, which are not included in this publication. Many relevant data appear in the figures and tables included here, other tables from the *Annual Report* that serve as the basis for this article include the following: Tables 1.1–1.4, 1.7, 1.8, 1.10, 1.14, 2.1, 3.1–3.3, 3.6, 3.9, 3.12, 3.15, 3.18, 5.1, 5.2, 5.4a, 5.4b, 5.9a, 7.6b, 8.4, 8.6b, 9.1, 9.2, 9.4b, 9.6b, 10.6b, 11.1, 11.6b, 12.1, 12.2, 12.6b, 13.6b and 13.7. All of these Tables are also available online at http://www.ustransplant.org.

Summary Statistics on the Current State of Transplantation in the USA

During 2002, more than 24 000 organs were transplanted in the USA—nearly 18 000 from deceased donors and 6600 from living donors. During the same period, more than 6000 patients were reported to have died while waiting for a transplant.

The number of patients on the waiting list for transplants from deceased donors is a good indicator of the increasing demand for organs. For most organs, this list grew during each year of the last decade. Table 1 compares the numbers of patients on the waiting list in 2001 and 2002, demonstrating the increases by organ in a single year. An increase in the number of patients waiting for a transplant indicates that more patients are added to the list than removed (usually for transplantation, sometimes for death, and occasionally for recovery from organ failure). While the demand for kidney and pancreas transplants continues to increase, the number of patients awaiting liver transplantation decreased in 2002 for the first time in over a decade. This decrease may be attributable to the February 2002 introduction of the Model for End-stage Liver Disease and Pediatric End-stage Liver Disease allocation system (MELD/PELD), which greatly de-emphasizes waiting time in the prioritization of liver candidates for transplantation. The number of transplants and waiting list deaths did not increase substantially during the same period.

The problem of long waiting times for transplant candidates and the continued growth in waiting list size underscores a simple reality: 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; it is particularly pronounced for pancreata, livers, and kidneys.

Table 1: Growth in number of patients on the waiting list, 2001–2002

Organs	End of year 2001	End of year 2002	Percentage increase
Total	77 334	79 387	2.7
Kidney	47 830	50 855	6.3
PTA	387	408	5.4
PAK	671	781	16.4
Kidney-pancreas	2378	2425	2.0
Liver	18 047	16 974	–5.9
Intestine	170	187	10.0
Heart	3934	3803	–3.3
Lung	3708	3756	1.3
Heart-lung	209	198	–5.3

Source: *2003 OPTN/SRTR Annual Report*, Table 1.3. PTA: Pancreas transplant alone. PAK: Pancreas after kidney.

Table 2: Growth in number of transplanted organs, 2001–2002

Organs	Year 2001	Year 2002	Percentage increase
Total	23 902	24 544	2.7
Deceased donor	17 359	17 934	3.3
Living donor	6543	6610	1.0
Kidney	14 066	14 523	3.2
Deceased donor	8065	8287	2.8
Living donor	6001	6236	3.9
PTA	128	141	10.2
PAK	306	376	22.9
Kidney-pancreas	889	902	1.5
Liver	4986	5060	1.5
Deceased donor	4468	4701	5.2
Living donor	518	359	−30.7
Intestine	42	44	4.8
Heart	2171	2111	−2.8
Lung	1054	1041	−1.2
Deceased donor	1034	1028	−0.6
Living donor	20	13	−35.0
Heart-lung	27	31	14.8

Source: *2002 OPTN/SRTR Annual Report*, Table 1.8. PTA: Pancreas transplant alone. PAK: Pancreas after kidney.

The number of transplants performed in 2002 compared with the prior year are shown by organ in Table 2. While the overall percentage increase in the number of transplanted organs equaled the percentage increase in the size of the waiting list in 2002 (2.7% for both), the problem of inadequate organ supply remains a serious one, given the long waiting times and the critical condition of many candidates. The substantial drop in living donor liver and lung transplants observed for 2002, if sustained in the future, suggests that living donation may not provide a viable solution to the problem of scarcity of these organs. Concerns about donor safety, early graft survival, and limited applicability to critically ill patients may have limited the use of living liver donors.

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

Organ transplanted	Survival (%) 1-year	Survival (%) 5-year
Kidney		
Deceased donor	94.2	80.7
Living donor	97.5	90.1
Pancreas alone	98.6	79.2
Pancreas after kidney	95.3	76.6
Kidney-pancreas	94.7	84.0
Liver		
Deceased donor	86.3	72.1
Living donor	86.9	84.2
Intestine	79.1	47.4
Heart	85.6	72.0
Lung	78.1	45.1
Heart-lung	67.1	36.7

Source: *2003 OPTN/SRTR Annual Report,* Table 1.14.

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 2000–2001, while the corresponding 5-year data are for those transplanted during 1996–1997. Since 1996, the survival for transplanted organs and for patients has improved, but during the same period recipient characteristics have changed – for example, the number of older recipients has risen. Thus, future 5-year survival results may be different than those shown for those transplanted during 1996–1997.

Functional survival of the transplanted organ (graft survival) has improved substantially over the past decade. Table 4

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

Organ transplanted	Survival (%) 1-year	Survival (%) 5-year
Kidney		
Deceased donor	88.7	65.7
Living donor	94.3	78.6
Pancreas alone	77.3	41.8
Pancreas after kidney	79.4	46.0
Kidney-pancreas (kidney)	92.0	74.2
Kidney-pancreas (pancreas)	85.1	69.8
Liver		
Deceased donor	80.6	64.1
Living donor	79.3	78.1
Intestine	71.8	33.3
Heart	85.3	70.6
Lung	77.0	43.6
Heart-lung	67.0	37.8

Source: *2003 OPTN/SRTR Annual Report,* Table 1.14.

shows 1- and 5-year graft survival data for each organ for the most recent available years (follow-up through to the end of 2002). Patients may survive a graft failure through a timely second transplant (or, for kidneys, a return to dialysis), therefore the graft survival figures are usually lower than those for patient survival.

Articles in the SRTR Report on the State of Transplantation

The articles in this report address the trends, practices, and characteristics of organ transplantation revealed through analyses conducted by the SRTR and its collaborators, using data collected by the OPTN and other auxiliary sources. Individual articles are devoted to each of the three major organ areas (kidney and pancreas, liver and intestine, and heart and lung). Areas of practice are the focus of three additional articles (organ donation, immunosuppression, and pediatric transplantation), with special emphasis given to pediatric transplantation because of the many issues unique to children. These differences are in part explained by physiological and size considerations but also by original cause of organ failure and immunological issues.

These six articles fall between two related articles that present the technical aspects of the data preparation and analytical work that goes 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 because they apply to all the articles in this issue, as well as more generally to a wider body of research.

Unique to the 2003 Report on the State of Transplantation is a special focus article devoted to the discussion of MELD/PELD. Since the introduction of the MELD/PELD system for liver allocation in February 2002, monitoring patient outcomes on the liver waiting list has become a primary objective. The impact of MELD/PELD-based allocation is discussed from several angles in this report, and results from the initial months of MELD/PELD implementation are presented.

Summaries and data highlights of each article follow.

Transplant data: sources, collection, and caveats

It is the goal of the article by Dickinson et al. to further the understanding of the available data on transplantation among researchers in the transplant community, both those who use existing research and those who create new analyses with these data. We hope to enable better interpretation of research results, sharper awareness of data limitations, and clearer concepts of how new analyses might proceed. By examining the sources, quality, and organization of the different types of transplant data available, we hope to improve the understanding of existing results, help researchers with study design, and stimulate new exploratory initiatives. Some of the ideas covered in this article include the following:

- Extensive technological improvements in the data collection process for the primary transplant data source, the OPTN, have enabled transplant centers and organ procurement organizations to more easily, quickly, and accurately report data about their patients and donors. These improvements have led to increased compliance with reporting requirements, as well as more accurate data.
- Auxiliary data sources are combined with these data, both to expand the scope of analyses that a researcher may complete with transplant data, as well as to validate the data reported by centers. Additional ascertainment of post-transplant outcomes, gleaned from sources such as the Social Security Death Master File and the National Death Index, has not only facilitated statements about the overall completeness of patient follow-up, but also allowed researchers to perform more accurate mortality analyses.
- These mortality data may be used to measure outcomes not expected to be reported by transplant centers, such as mortality outcomes for patients removed from the waiting list, thus enabling researchers to make more appropriate comparisons between waiting list and post-transplant mortality.

Any researcher using transplant data should be aware of the complex collection and reporting process, which leads to potential pitfalls or the need for specific analytical methods. Patterns in the timing of reporting adverse events differ from those for 'positive' events, yielding the need to be extremely careful in the choice of cohorts and censor dates to avoid bias. Choices of censor dates are further complicated by the use of multiple sources of data, with different time lags and reporting patterns. This article serves as a good introduction for researchers beginning work with transplant data from these sources, and, at the same time, serves seasoned researchers with some more up-to-date observations about data quality and reporting patterns.

Organ donation and utilization in the USA

The processes leading to donor identification, consent, organ procurement, and allocation continue to dominate debates and efforts in the field of transplantation. A huge shortage of donors remains while the number of patients needing organ transplantation increases. Ojo et al. review the main trends in organ donation practices and procurement patterns from both deceased and living sources in the USA. Some noteworthy points follow:

- Organizations such as the Association of Organ Procurement Organizations (AOPO), the United Network for Organ Sharing (UNOS), the Coalition on Donation, and the Southeastern Organ Procurement Foundation (SEOPF), among others, have made significant efforts to understand and overcome the limiting factors in organ donation and have increased their public outreach and donation-related education efforts.
- In 2002, the number of deceased donors increased by only 1.6% (101 donors). As pointed out in this report last year, an increase in donation from deceased donors provides more organs for transplantation than a comparable increase in the number of living donors, because an average of 3.6 organs are recovered from each deceased donor.
- The total number of organs recovered from deceased donors increased by 2.1% (462 organs).
- Poor organ quality continued to be the major reason given for nonrecovery of consented organs from deceased donors. This reason was noted for 61% of kidneys, 48% of pancreata, 60% of livers, 29% of intestines, 64% of hearts, and 76% of lungs that were not recovered.
- Despite evidence of comparable kidney transplant outcomes with organs from donors after cardiac death (DCD), the use of DCD donor kidneys remains low. In 2002, organs were recovered from 191 DCD donors. These represent only 3% of total deceased donors, but do reflect a 13% increase from 2001 and a fivefold increase over the decade.
- The kidney is the organ most likely to be discarded after recovery has occurred. Over the past decade the discard rate of recovered kidneys has increased from 6% to 11%. Many of these are expanded criteria donor kidneys.
- Although there have been increases in living donation in recent years, 2002 witnessed a much more modest growth of 1%. Absolute declines in living liver and lung donation were also noted in 2002.

Immunosuppression: practice and trends

Kaufman et al. examine immunosuppression for solid organ transplantation from 1993 to 2002. Over the past decade, there have been marked changes in the clinical practice of transplantation in general and in immunosuppressive strategies in particular. Notably strong components observed include the scale and pace by which the new immunosuppressive molecules and antibodies have become incorporated into the daily activities of transplant medicine. A careful organ-by-organ review of the data indicates how much has changed over the 10-year span beginning in 1993. Some highlights of this article include the following:

- The proportion of patients receiving induction therapy varied widely among organs. The highest use (over 70%) was reported for simultaneous pancreas-kidney (SPK) and pancreas after kidney (PAK) transplant recipients in 2002, followed by pancreas transplant alone (PTA) (67%), kidney (65%), intestine (57%), and thoracic (over 40%). The use of induction therapy was much less common in liver transplants (only 18%).
- Corticosteroids continue to be used as discharge maintenance immunosuppression in over 87% of the recipients of kidney, SPK, PAK, and thoracic transplants, and in over 70% of the recipients of PTA. Prior to 2002, corticosteroid use in intestine transplants was reported in over 80% of recipients, but this number dropped to 64% in 2002.
- A shift in the calcineurin inhibitor used for the majority of patients from cyclosporine to tacrolimus for maintenance immunosuppression occurred for PTA transplants in 1994, for liver transplants in 1995, for PAK in 1996, for SPK in 1997, for lung in 2000, and for kidney and heart-lung in 2001. For heart transplants, cyclosporine remained the calcineurin inhibitor of choice, whereas tacrolimus has been the predominant calcineurin inhibitor agent for intestine since 1994.
- Although the proportion of recipients reported with antibody treatment for rejection has fluctuated over the years, overall, there is a decreasing trend in its use during the first post-transplant year for most organs.

The result of immunosuppression changes in clinical practice seems to indicate that the short-term outcomes have improved, based on the observation that rates of rejection within the first year post-transplant have diminished. Future surveys of trends in immunosuppression use are unlikely to show a great deal of change over the next few years, but subtle signs of immunosuppression minimization (diminished use of steroids) and new induction therapies, such as alemtuzumab (Campath®, ILEX Pharmaceuticals, San Antonio, TX), are likely to surface.

Pediatric transplantation

Analysis of the OPTN/SRTR database demonstrates that, in 2002, pediatric recipients accounted for 7% of all recipients, while pediatric individuals accounted for 14% of deceased organ donors. For children fortunate enough to receive a transplant, there has been continued improvement in outcomes following all forms of transplantation. Some notable findings in Magee et al.'s article include the following:

- Current 1-year graft survival is generally excellent, with survival rates following transplantation in many cases equaling or exceeding those of all older recipients.
- In renal transplantation, despite excellent early graft survival, there is evidence that long-term graft survival for adolescent recipients is well below that of other recipients. A causative role for noncompliance is possible.

- While the significant improvements in graft and patient survival are laudable, waiting list mortality remains high. Pediatric candidates awaiting liver, intestine, and thoracic transplantation face mortality rates generally greater than those of their adult counterparts. This finding is particularly pronounced in patients aged 5 years and younger.

While mortality awaiting transplantation is an important consideration in refining organ allocation strategies, it is important to realize that other issues, in addition to mortality, are critical for children. Consideration of the impact of end-stage organ disease on growth and development is often equally important, both while awaiting transplant and after transplantation.

Kidney and pancreas transplantation

Kidney transplantation continues to be recognized as the treatment of choice for medically suitable patients with end-stage renal disease. As the number of transplant candidates added per year exceeded the number of donated kidneys, the size of the kidney transplant waiting list continued to increase, from 47 830 in 2001 to 50 855 in 2002. The particular advantage of kidney transplantation prior to the initiation of dialysis is now well recognized and is being progressively exploited, especially by patients receiving living donor kidney transplants. The following are important highlights in Wynn et al.'s article:

- Over the decade from 1993 to 2002, living donation has become much more common, with living donor kidney transplants increasing from 28% of total kidney transplants in 1993 to 43% in 2002.
- Concern regarding potential inequities in the current kidney allocation system have led the OPTN to modify the weight assigned to human leukocyte antigen (HLA) matching in the kidney allocation system. Minority candidates, who experience longer waiting times for transplantation, have been found to receive a much lower percentage of zero HLA mismatched kidneys compared with whites. The deficit in access of African-American candidates to deceased donor kidneys may be further ameliorated by the elimination of allocation points for HLA-B identity.
- Policies and procedures to expedite the allocation of kidneys with less favorable donor characteristics, or expanded criteria donor (ECD) kidneys, were developed and implemented by the OPTN during 2002. ECD kidneys constituted only 8% of deceased donor transplants in 1993; this percentage increased to over 16% by 1996. In 2002, 15% of deceased donor transplants were performed with ECD kidneys. As expected, ECD kidneys had lower deceased donor allograft survival rates. Unadjusted 3-month, and 1-, 3-, and 5-year deceased donor kidney allograft survivals were 90%, 81%, 67%, and 51% for recipients of ECD kidneys, and 95%, 90%, 81%, and 68% for recipients of non-ECD kidneys, respectively.
- Although more patients have been placed on the kidney-pancreas waiting list, the number of these simultaneous transplants has declined from a peak of 970 in 1998 to 905 in 2002. This decline may be due to the increasing numbers of PAK transplants during this period, because many potential recipients may have been listed for both procedures.

Liver and intestine transplantation

The most significant development in liver transplantation in the USA over the past year was the full implementation of the MELD- and PELD-based allocation policy, which has shifted emphasis from waiting time within broad medical urgency status to one based on prioritization by risk of waiting list death. A separate article has been included to discuss the impact of MELD/PELD on liver transplantation in 2002. Some highlights from Brown et al.'s article follow:

- The trend over the last several years of increasing numbers of adult living donor liver transplants has been interrupted by a more than 30% decline in the number of these procedures in 2002. A greater percentage of women received living donor liver transplants in 2002 (43%) compared with deceased donor organs (34%), possibly because of size considerations.
- From 1993 to 2001, the waiting list increased more than sixfold, from 2902 patients to 18 047 patients. For the first time, a waiting list decrease of 6% was observed in 2002, to a total of 16 974 patients at year-end. The percentage of temporarily inactive liver candidates at year-end increased from 17% in 2001 to 23% in 2002, therefore the net decrease in the active waiting list for 2002 was 12%.
- Intestine transplantation remains a low-volume procedure limited to a few transplant centers, and one still fraught with significant pre- and post-transplantation risks. As this procedure matures, its application may increase to include recipients at an earlier stage of their disease with better likelihood of success.

Thoracic organ transplantation

Pierson III et al. present an overview of factors associated with thoracic transplantation outcomes over the past decade and provide valuable information regarding the heart, lung, and heart-lung waiting lists and 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. Important points from this article include the following:

- The time that the typical listed patient has been waiting for a heart, lung, or heart-lung transplant has markedly increased over the past decade, while the number of

transplants performed has declined slightly and survival after transplant has plateaued. Waiting list mortality, however, appears to be declining for each organ and for most diseases and high-severity subgroups, perhaps in response to recent changes in organ allocation algorithms.
- Based on perceived inequity in organ access and in response to a mandate from the HRSA, the lung transplant community is developing a lung allocation system designed to minimize deaths on the waiting list while maximizing the benefit of transplant by incorporating post-transplant survival and quality of life into the algorithm. Areas where improved data collection could inform evolving organ allocation and candidate selection policies are emphasized.

Analytical approaches for transplant research

This comprehensive article by Wolfe et al. describes many of the statistical methods and issues involved in the various articles in this report. A variety of methods are used in the *Annual Report*, Center-Specific Reports, and other SRTR analyses. Here follow some of the points discussed:

- It is highly desirable to base decisions designed to improve medical practice or organ allocation policies on the analyses of the most recent data available. Yet there is often a need to balance this desire with the added value of evaluating long-term outcomes (e.g. 5-year mortality rates), which require the use of data from earlier years. This article explains the methods used by the SRTR in order to achieve these goals simultaneously.
- The analysis of waiting list and transplant outcomes depends strongly on statistical methods that can combine data from different cohorts of patients that have been followed for different lengths of time. A variety of statistical methods have been designed to address these goals, including the Kaplan-Meier estimator, Cox regression models, and Poisson regression.
- An in-depth description of the statistical methods used for calculating the waiting times associated with the various types of organ transplants is provided. Risk of mortality and graft failure, adjusted analyses, cohort selection, and the many complicating factors surrounding the calculation of follow-up time for various outcomes analyses are also discussed in this article.

Improving liver allocation: MELD and PELD

On February 27, 2002, the liver allocation system changed from a status-based algorithm to one that uses a continuous MELD/PELD severity score in order to prioritize patients on the waiting list. Several aspects of the new allocation system are discussed, including the original development and evolution of MELD for adults and PELD for pediatric patients, the relationship between the two scoring systems, and the resulting effect on access to transplantation and waiting list mortality. Additional considerations, such as regional differences in MELD/PELD at transplant, the predictive effects of rapidly increasing/decreasing MELD/PELD, and the use of simulation software to model potential policy changes are also addressed in this special focus article by Freeman Jr et al. Among its findings are the following:

- Death or removal from the waiting list for being too sick for a transplant has decreased in the MELD/PELD era for both children and adults. Children younger than 2 years of age, however, still have a considerably higher rate of death on the waiting list than adults.
- Children awaiting combined liver-intestine transplant have a high mortality on the waiting list, justifying the assignment of a higher PELD score than the calculated score in order to compensate for the increased relative risk of death on the waiting list.
- A limited definition of ECD livers suggests that such livers are used more frequently for patients with lower MELD scores.

Conclusion

This report provides a comprehensive review of national data on organ transplantation, 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 USA today. Ultimately, we rely on the staff of transplant centers and organ procurement organizations across the country to provide the most accurate and current data to the OPTN to make this and future reports possible.