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Heart Transplantation in the United States, 1998–2007

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The articles in this report are based on the reference tables in the 2008 OPTN/SRTR Annual Report. Table numbers are noted in brackets and may be found online at: http://www.ustransplant.org.

This article highlights trends in heart transplantation from 1998 to 2007, using data from the Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR). The number of candidates actively awaiting heart transplantation has declined steadily, from 2525 in 1998 to 1408 in 2007, a 44% decrease. Despite this decline, a larger proportion of patients are listed as either Status 1A or 1B, likely secondary to increased use of mechanical circulatory support. During this time, the overall death rate among patients awaiting heart transplantation fell from 220 to 142 patients per 1000 patient-years at risk; this likely reflects better medical and surgical options for those with end-stage heart failure. This trend was noted across all racial groups, both sexes, all disease etiologies (retransplantation excepted) and all status groups. Recipient numbers were relatively stable over the past decade. In 2007, 2207 transplants were performed, although the proportion of patients transplanted as Status 1A shifted from 34% to 50%. A trend toward transplanting more patients above 65 years of age was seen. Adjusted patient (and graft) survival at 3 months, 1, 5 and 10 years after transplantation has gradually, but significantly, improved during the same period; current patient survival estimates are 93%, 88%, 74% and 55%, respectively.

Key words: Graft survival, heart transplantation, OPTN, patient survival, SRTR

Introduction

This article reviews recent trends in heart transplantation in the United States. The data reported here are drawn from the 2008 *OPTN/SRTR Annual Report* and cover all aspects of heart transplantation over the last 10 years (1). The most recent change in the heart allocation system—the increased geographic sharing of hearts introduced on July 12, 2006—is having noticeable effects on transplantation trends. The broader sharing of hearts to patients with more urgent status designations increases access to organs for sicker candidates at greater distances in exchange for decreasing access to organs for more stable local patients. The data available for evaluating the beneficial effects of this allocation change remain limited, particularly in regard to posttransplant outcomes, but interesting results are becoming apparent, including improved waiting list survival. Improvement of the heart allocation policy is an ongoing process, particularly as new data elements are identified that may enhance the ability of the system to make the best use of this scarce resource.

Heart Waiting List and Recipient Characteristics

Candidate characteristics

The characteristics of heart transplant candidates are derived from patients actively awaiting heart transplantation at the end of each calendar year from 1998 to 2007. Overall, the number of active candidates declined 44% over the decade, from 2525 patients in 1998 to 1408 in 2007 *[Table 11.1a]*.

When examined by age, there was a modest but consistent increase on the active list in the proportion of pediatric patients, that is, those younger than 18 years (from 4% to 8% of the total number of candidates), as well as those over 65 years (from 7% to 12%) *[Table 11.1a]*. The demographics of the waiting list have changed slightly over the last 10 years. There has been a decrease in the proportion of white candidates (from 80% to 74%) and an increase in the proportion of both African American candidates (from 14% to 17%) and Hispanic/Latino candidates (from 5% to 7%). Candidate sex has also shifted from 20% to 25% female. Country of residence has remained stable, with 99.6% of patients residing within the United States. There persists a small, gradual, but sustained increase in candidates who themselves are recipients of other solid organ transplants (from 3% to 6%)

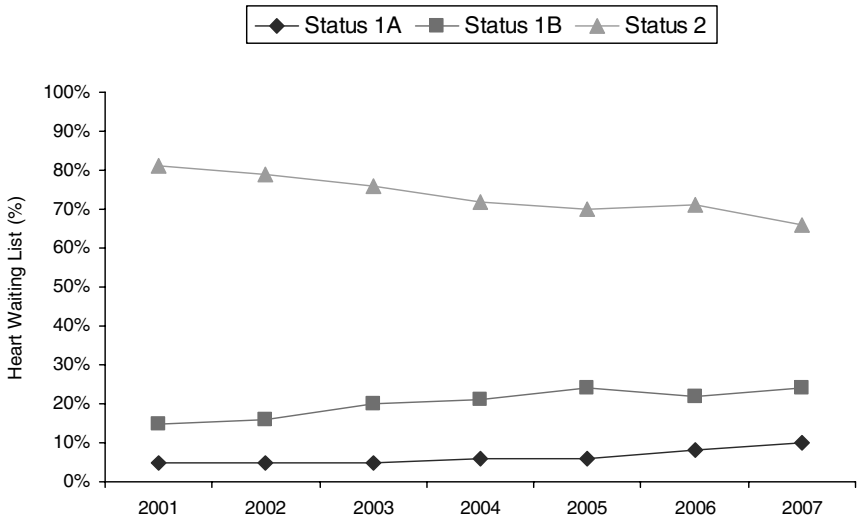


Figure 1: Status of heart transplant waiting list candidates, 2001–2007.

Source: *2008 OPTN/SRTR Annual Report*, Table 11.1a.

most in the form of candidates waiting for heart retransplant (from 3% to 5%). The proportion of candidates with coronary artery disease has decreased from 47% to 42%; the proportion with congenital heart disease has increased from 4% to 8%. The proportion of other diagnosis groups has remained similar across the decade (currently, primary cardiomyopathy in 41% and valvular disease in 2%) *[Table 11.1a]*.

The criteria by which adult patients are assigned a waiting list status (1A, 1B and 2) have not changed substantially since 1999 (the policy change in that year replacing Status 1 with 1A and 1B). Currently, Status 1A patients meet one or more of the following criteria: (1) mechanical circulatory support (defined as either a right and/or left ventricular assist device [RVAD and/or LVAD], with 30 days of Status 1A time allocated at the discretion of the transplant center), intra-aortic balloon pump, total artificial heart or extracorporeal life support/membrane oxygenation (ECLS/ECMO); (2) mechanical circulatory support with objective evidence of device-related complication; (3) mechanical ventilation; (4) high dose or multiple inotropes with continuous monitoring of left ventricular filling pressures or (5) other exceptional cases. Status 1B patients have either: (a) a ventricular assist device (VAD) beyond the 30 days of discretionary time and without evidence of device-related complication or (b) continuous infusion of inotropes without hemodynamic monitoring. Status 2 patients are all others not meeting criteria for Status 1A or 1B. Status 7 patients are inactive. There has been a slow but persistent increase in the proportion of Status 1A and 1B patients and a gradual decline in Status 2 patients over the last several years (Figure 1). This may be due to increased utilization of VADs as a bridge to transplant. Also, many centers choose not to pursue active listing for patients who are unlikely to receive an organ offer unless their clinical status deteriorates to the point of qualifying for Status 1A or 1B; this is the case for heavier patients of blood types O or A. In addition, there is some degree of doubt that all patients who are classified as 'stable' Status 2 receive mortality benefit from transplantation, particularly in the era of improved medical and anti-arrhythmia therapy. In concert with this, there has been a steady increase in the proportion of patients transplanted within the first 30 days of listing *[Table 11.1a]*. In 2006 and 2007, of those patients newly listed as Status 1A, 22.6% of patients

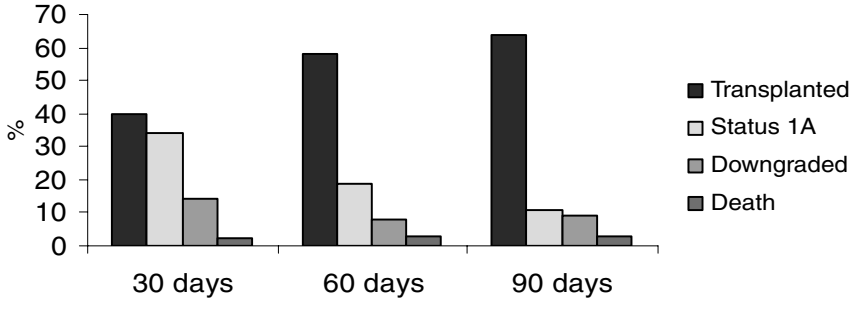
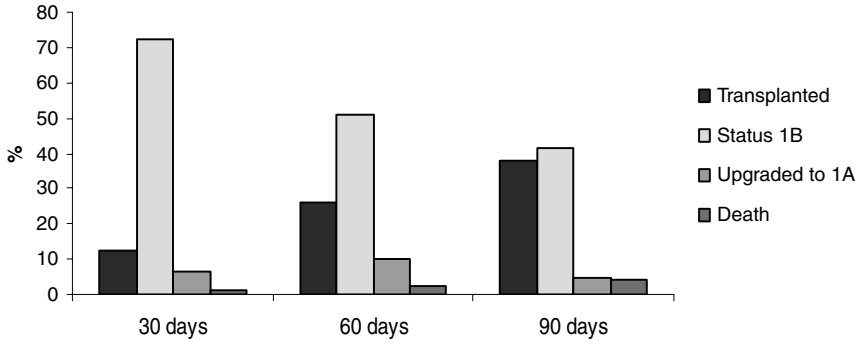


Figure 2: Condition of Status 1A patients on heart waiting list as of January 1, 2007 at 30, 60 and 90 days snapshots.

Source: *2008 OPTN/SRTR Annual Report*, Table 11.2b.



Source: *2008 OPTN/SRTR Annual Report*, Table 11.2b.

Figure 3: Condition of Status 1B patients on heart waiting list as of January 1, 2007 at 30, 60 and 90 days snapshots.

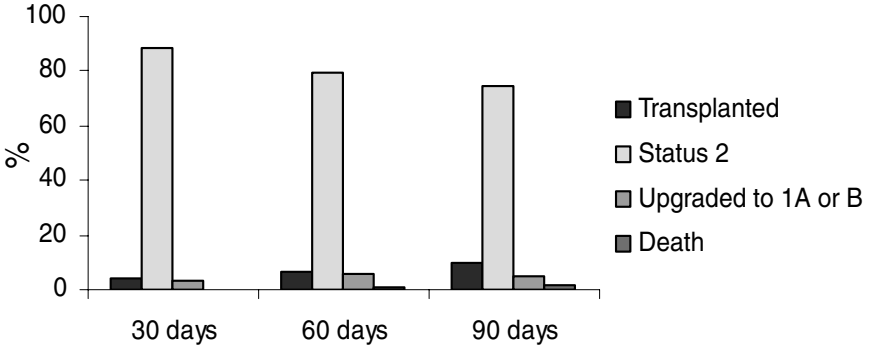
were transplanted after 7 days and 47.2% by 30 days (1.9% died by 7 days and 6.8% died by 30 days) *[Table 11.2a]*. Of those patients on the waiting list on January 1, 2007 (regardless of waiting time accrued), the following observations can be made: (1) Among Status 1A patients, 13% were 'downgraded' to Status 1B and waiting list mortality was stable over the subsequent 90-day period. (2) Among 1B patients, 10% were 'upgraded' to 1A over the first 60 days and 38% were transplanted by 90 days; there was a gradual increase in mortality over the period from 1.1% to 4.2%. (3) Only 10% of Status 2 patients were transplanted, with a waiting list mortality of 1.8% within the subsequent 90 days (Figures 2–4) *[Table 11.2b]*. There is also a sustained proportion (approximately 30–37%) of patients who wait more than 1 year. Interestingly, the number of inactive patients has remained surprisingly high—1251 patients at year-end in 2007 (47% of the entire list vs. 38% of the entire list in 1998 at year-end) *[Table 11.1b]*.

Deaths on the waiting list

The overall death rate of patients awaiting heart transplantation has decreased over the past 10 years, from 220 per 1000 patient-years at risk in 1998 to 142 per 1000 patient-years at risk in 2007 (Figure 5) *[Table 11.3]*. This trend was true across all adult age groups. Because of the relatively few numbers of pediatric patients, it is difficult to assign any level of certainty to trends associated with these younger age groups. Reduced death rates over the decade also were seen across major categories of race/ethnicity, sex, blood type (with too few in blood type AB for meaningful analysis) and diagnosis, with the exception of retransplant candidates *[Table 11.3]*. When examined by urgency status, the decline in waiting list mortality was evident across Status 1A, 1B and 2, although it was most pronounced for patients listed as Status 1A (Figure 6). This potentially reflects the impact of increased used of LVADs, and, perhaps for 2007 data, the regional sharing policy for Status 1A and 1B recipients that began in July 2006 (see later the Heart Allocation Policy Changes section). It should be noted that, although the decreased overall death rate is encouraging, the degree of illness for those listed as well as background medical and device therapy have also likely changed. Because of this, caution should be used when comparing these data from era to era.

Recipient characteristics

The overall number of heart transplants performed in the United States has varied by 14% over the past decade, from a high of 2348 in 1998 to a low of 2015 in 2004. After reaching that 10-year low in 2004, the number of heart transplants increased slightly in each of the past 3 years to a total of 2207 in 2007 (Figure 7) *[Table 11.4]*. There was also a 16% decrease in the rate of heart transplants per million U.S. residents over the last 10 years, although this trend appears to have leveled off over the



Source: *2008 OPTN/SRTR Annual Report*, Table 11.2b.

Figure 4: Condition of Status 2 patients on heart waiting list as of January 1, 2007 at 30, 60 and 90 days snapshots.

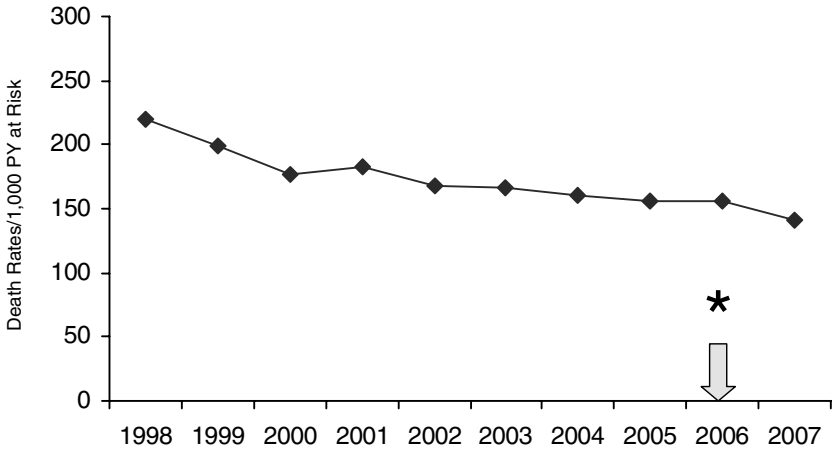


Figure 5: Annual death rate of patients awaiting heart transplantation per 1000 patient-years at risk 1998–2007.

* Denotes time point of policy change promoting broader geographic sharing of organs for higher status patients

Source: *2008 OPTN/SRTR Annual Report*, Table 11.3.

last few years (Figure 7) *[Table 11.5]*. Among patients transplanted, there has been a 21% decrease in transplants in the 50–64 year age group, with a concomitant rise in transplants performed in the very young and older patients. The distribution of organs between male and female recipients has been stable, with 26% of grafts going to women. There has been a 20% reduction in the number of white recipients, with a concomitant rise in transplants performed in the other major ethnicity/racial groups. A drop of 29% was seen in the number of patients transplanted with a diagnosis of coronary artery disease while there has been an increase in the proportion of patients transplanted for primary cardiomyopathy during the same period *[Table 11.4]*. These changes, in part, shadow reductions in white patients and those with coronary artery disease listing for transplantation. Retransplantation occurred in 4.4% of the 2007 cohort. From a population standpoint, the number of heart transplants performed (incidence) has fallen from 8.7 to 7.3 recipients per million; there also is wide state-to-state variability, from 0 to approximately 15 recipients per million *[Table 11.5]*. On the other hand, the overall numbers (prevalence) of heart transplant recipients within our society has risen from 14 810 in 1998 to 18 742 in 2006 *[Table 11.16]*.

Between the inception of the new classification system in 1999 and 2007, the distribution of patients among the different status groups at the time of heart transplantation

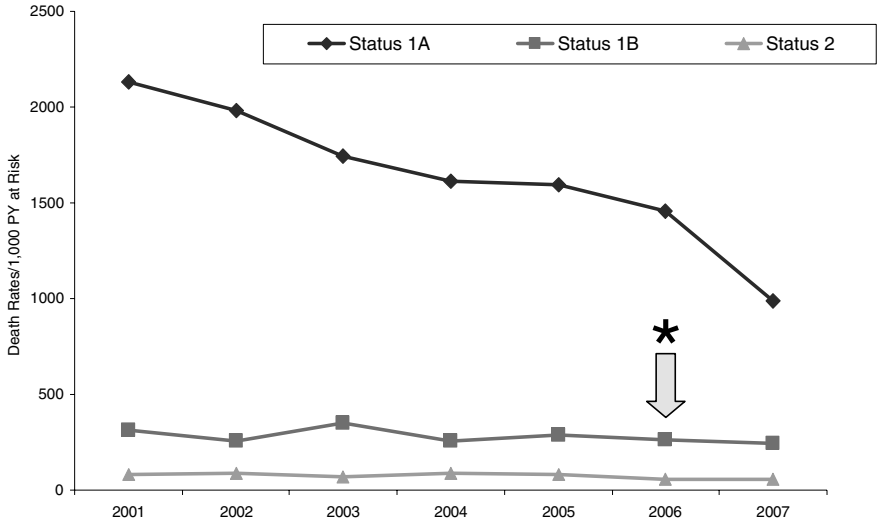
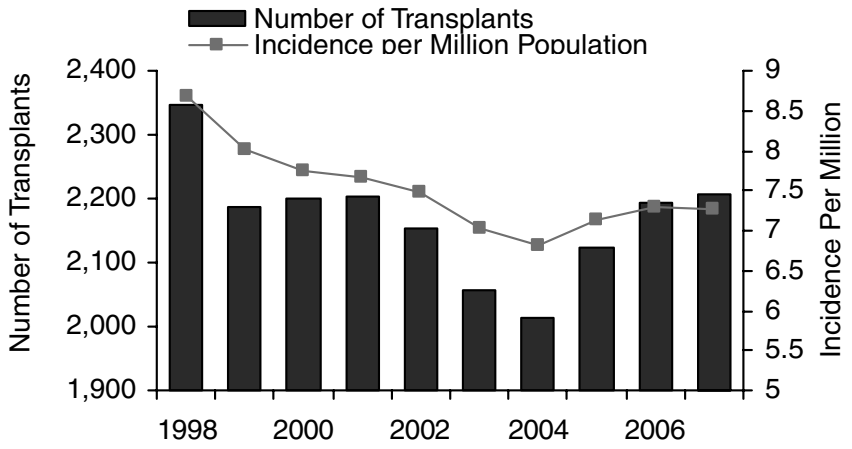


Figure 6: Annual death rates per 1000 patient-years on the heart waiting list by status, 2001–2007.

* Denotes time point of policy change promoting broader geographic sharing of organs for higher status patients

Source: *2008 OPTN/SRTR Annual Report*, Table 11.3 .



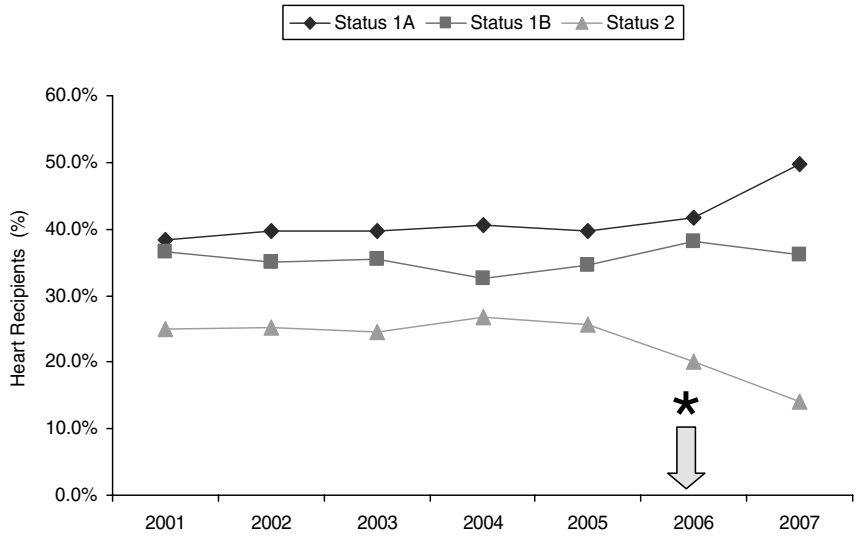
Source: *2008 OPTN/SRTR Annual Report*, Tables 11.4 and 11.5 .

Figure 7: Number of heart transplants and incidence of transplant per million population, 1998–2007.

has shifted toward the more urgent statuses. In 1999, patients transplanted as Status 1A, 1B and 2 comprised 34%, 36% and 26% of the entire cohort, respectively. In 2007, these proportions were 50%, 36% and 14%, respectively (Figure 8) *[Table 11.4]*. This change is likely attributable to the wider geographic sharing of donor hearts for candidates listed as Status 1A or 1B, a result of the change in the donor heart allocation process approved by the OPTN Board of Directors in November 2005 and implemented in July 2006. The policy was expected to lead to a decrease in Status 2 transplants in favor of candidates listed at a more urgent status. In the years before and after this policy change, the percentage of transplanted patients with organs having a cold ischemia time less than 180 min has remained similar (38% in 2005 vs. 37% in 2007). From 2005 to 2007, the increase in the proportion of donor organs with cold ischemia time between 271 and 360 min was <1%, and the increase in the proportion between 180 and 270 min only 4%. Other cold ischemia time categories showed even less of an increase or no increase at all *[Table 11.4]*.

Heart Transplant Outcomes

Patient survival, adjusted for age, sex, ethnicity/race and diagnosis across the entire cohort of patients have now reached 93%, 88%, 81%, 74% and 55% at 3 months, 1,



* Denotes time point of policy change promoting broader geographic sharing of organs for higher status patients

Source: *2008 OPTN/SRTR Annual Report*, Table 11.4 .

Figure 8: Status of heart transplant recipients, 2001–2007.

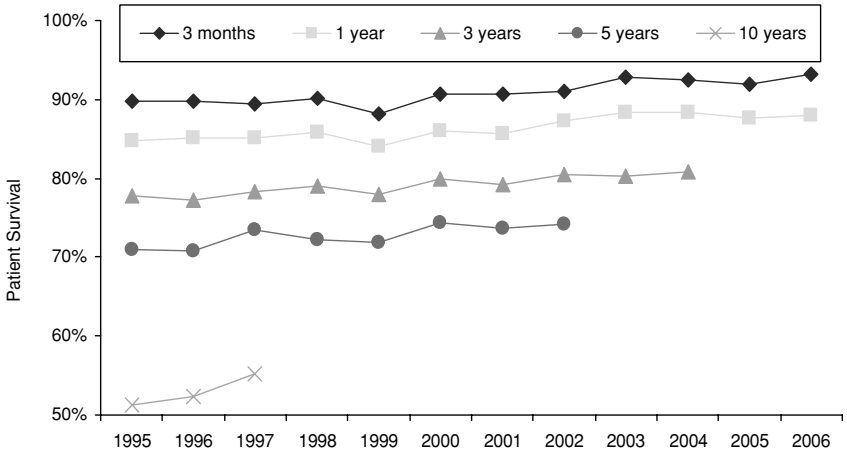


Figure 9: Adjusted short- and long-term survival of heart recipients, by year of transplant, 1995–2006.

Source: *2008 OPTN/SRTR Annual Report,* Table 11.13 .

3, 5 and 10 years, respectively (Figure 9) *[Table 11.13]*. In addition, there have been substantial improvements in survival as experience has accrued. For example, 3-month survival was noted to improve from 86% to 93% in patients transplanted in 1987 and 2006, respectively. Likewise, 10-year survival has improved from 46% to 55% for patients transplanted in 1987 and 1997, respectively. More recent patients have not yet accrued enough time following transplantation to determine actual survival.

Recent-era adjusted patient survival after heart transplantation at 3 months, 1 and 5 years posttransplant is similar across the range of adult patient ages, but there is a marked decrease in survival at 10 years for patients 65 years and older (54%, 57%, 55% and 44%, for age groups 18–34, 35–49, 50–64 and 65 years and older, respectively) *[Table 11.12]*.

At all time points, survival is slightly lower for women than for men. As an example, 5-year survival for men transplanted in 2001 or after is 75%, whereas survival for women in the same era is 72%. In addition, medium to long-term survival for African Americans is lower than in other ethnic/racial groups. For example, although 3-month survival is 92.5% and 92.6% for white and African American recipients, respectively, there is a divergence in survival that is seen 1-year posttransplant; 10-year survival is 57.2% and 43.9%, respectively, for whites and African Americans *[Table 11.12]*.

Adjusted survival rates for the pediatric population show somewhat different trends from adults. The lowest 3-month survival rate in all groups (including adults) is for recipients less than 1 year of age (85%), likely related to the technical challenges posed in surgical procedures for these very tiny patients *[Table 11.12]*. However, the highest 10-year survival is in that same group of recipients (66%), possibly related to the immaturity of the immune system in infancy. This would lead to a higher degree of tolerance and to presumably less transplant coronary artery

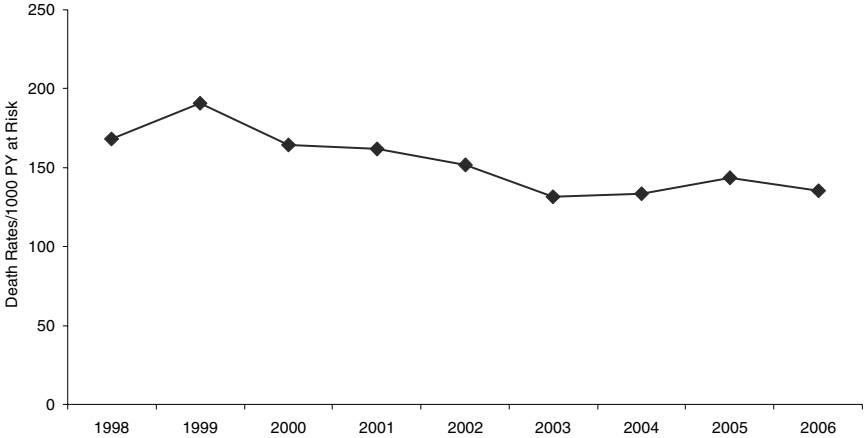
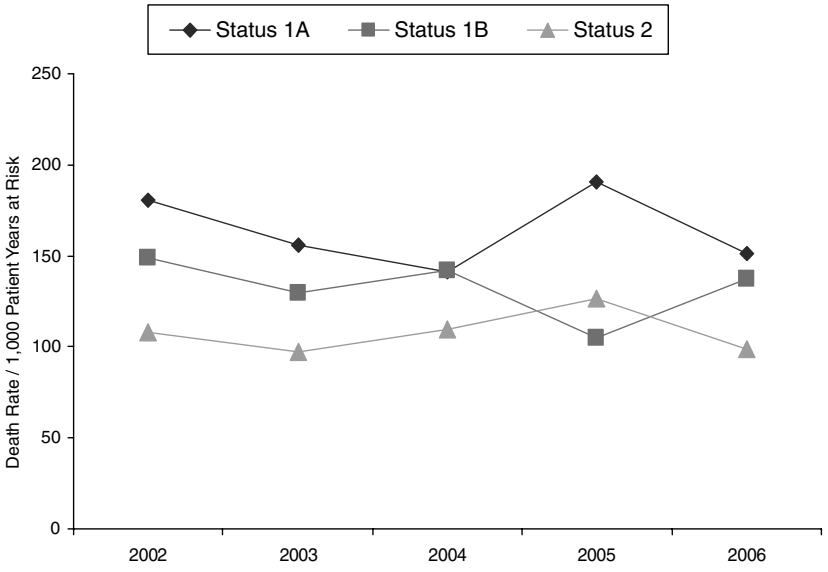


Figure 10: Annual death rate per 1000 patient-years at risk for recipients during first year after heart transplantation, 1998–2006.

Source: *2008 OPTN/SRTR Annual Report*, Table 11.7.



Source: *2008 OPTN/SRTR Annual Report*, Table 11.7 .

Figure 11: Annual death rate per 1000 patient-years at risk during first year after heart transplantation by status, 2002–2006.

disease and other forms of graft failure. Survival figures for children and adolescents lie between those of infancy and adulthood at 10 years following heart transplantation.

Death rates in the first year after heart transplantation have steadily decreased, from 168 deaths per 1000 patient-years at risk in 1998 to 136 deaths per 1000 patient-years at risk in 2006 (Figure 10) *[Table 11.7]*. All four adult patient age groups, 18–34, 35–49, 50–64 and 65 years and older have demonstrated a decrease in death rates in the first year over the same period. The largest decrease in the death rate has, in fact, occurred in the 65 years and older age group, from 242 to 145 deaths per 1000 patient-years at risk. There has been wide variability in death rates in the pediatric populations, likely because the small numbers preclude meaningful analysis; however, it is apparent that the highest actual death rates occur in recipients in infancy. There also has been a decrease in death rates in the first year after heart transplantation for all status groups since 1999 (the year the current status system for allocation was implemented; Figure 11) *[Table 11.7]*, as well as across both sexes and for whites and Hispanic/Latinos. This trend, however, is not apparent in the other ethnicity/race groups, including African Americans or Asians (Figure 12) *[Table 11.7]*.

Although there has been a decrease in the death rate in the first year after heart transplantation for each individual adult donor age group since 1998, there remains a marked increase in the death rate for each progressively older donor age group (109, 170 and 237 deaths per 1000 patient-years at risk in the 18–34, 35–49 and 50–64-year old donor groups, respectively) *[Table 11.7]*. There are too few donors above the age of 65 years for a meaningful analysis.

The death rates in the first year after transplantation have decreased for each cold ischemia time group. However, each progressively longer cold ischemia time grouping has a corresponding increased death rate (93, 105, 149 and 181 deaths per 1000 patient-years at risk in the 0–90, 91–180, 181–270 and 271–360 min of ischemia time groupings, respectively).

Patient Care Issues

Ventricular assist devices as a bridge to transplant

Despite aggressive organ donor initiatives, only a tiny fraction of patients with end-stage heart failure are treated by heart transplantation. In addition, about one patient dies on the waiting list for every five who receive a heart transplant (374 deaths on the waiting list vs. 2207 patients transplanted in 2007) *[Tables 11.3 and 11.4]*. Currently, over 64% of heart transplant recipients require life support as a bridge to transplant *[Table 11.4]*. This includes intravenous medications in the intensive care unit, mechanical ventilation, use of intra-aortic balloon pumps, ECLS, total artificial hearts and VADs. Because of the shortage of available organs for heart transplantation, mechanical circulatory support has been developed, primarily in the form of LVADs. Better survival rates have consistently been observed with devices designed to assist, instead of replace, the left (and occasionally right) ventricle(s). These VADs are now routinely used as bridges to transplant, and increasingly as either 'destination therapy' or as 'bridges to decision' for those patients who may need extra time and circulatory support while determination of transplant suitability is established, or occasionally for patients with extreme allosensitization.

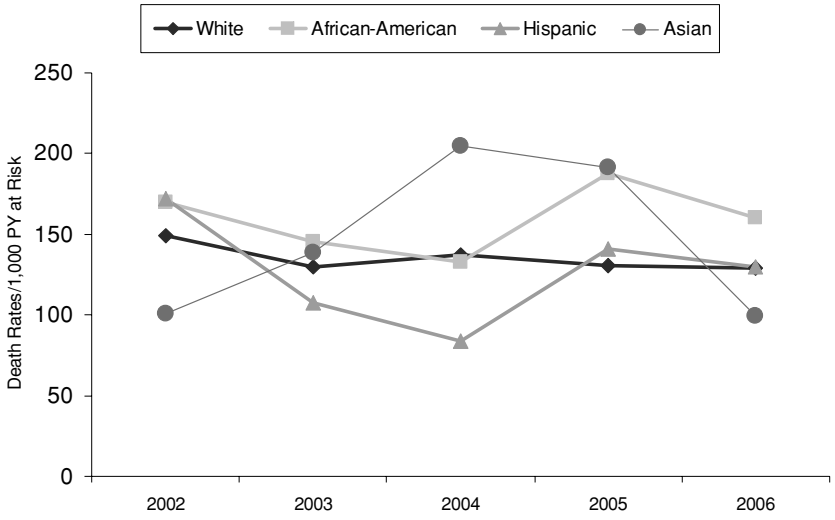


Figure 12: Annual death rates per 1000 patient-years during first year following heart transplantation by race/ethnicity, 2002–2006.

Source: *2008 OPTN/SRTR Annual Report*, Table 11.7.

Because of the shortcomings of the first generation devices (volume displacement, pulsatile pumps), new designs are in development, with the goal of improved durability (longer possible support times) with fewer complications. Axial flow devices have fewer moving parts and are smaller, thus better suited for smaller patients, particularly women and children. These new VADs have thinner, less obtrusive drivelines, with reduced likelihood of infection. A clinical trial of the HeartMate II LVAD recently demonstrated improved quality of life and functional status in a group of patients supported using the device as a bridge to transplant (2). This technology has recently gained Food and Drug Administration (FDA) approval for the indication of bridge to transplantation.

Increased use of VADs has led to a few notable trends in heart recipient characteristics, including a 45% reduction in the number of patients hospitalized in an intensive care unit before heart transplantation *[Table 11.4]*. There has also been a 15% reduction in the number of patients on a non-VAD form of life support (ECMO, intra-aortic balloon pump, prostaglandins, intravenous inotropes, inhaled nitric oxide and mechanical ventilation) at the time of heart transplantation over the past decade. To place this in perspective, between July 2006 and July 2008, the proportion of patients with a VAD at the time of listing was 13.4%. The proportion, of patients with a VAD ever while listed for transplant during that same time period was 19.8% (3), highlighting the fact that VAD technology has a major impact on patient management as it pertains to cardiac transplantation.

Ventricular assist technology is in rapid evolution and will provide a realistic alternative to transplantation in the near future. However, it has been difficult to integrate VAD use as a bridge to transplant in allocation policy because of the paucity of detailed information prospectively collected for the OPTN database; rapidly changing technology and outcomes compound this difficulty. The OPTN is aware of this data gap and is taking steps to collect these data on VAD placement and timing of placement, particularly when a status justification form is completed after listing. Cautious interpretation of these data will be needed.

The recent development of a national registry, the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS), a joint effort of the National Heart, Lung, and Blood Institute, FDA, and Centers for Medicare and Medicaid Services aims to help solve this problem. Only data from patients with FDA approved VADs who have the potential for discharge are being obtained within this registry (not intra-aortic balloon pump, ECLS or temporary VADs). Data from INTERMACS should be available in the next 3–5 years. This is likely to contribute to meaningful change in heart allocation policy for those patients who require mechanical circulatory support as a bridge to transplant.

Immunosuppression therapy for heart transplant recipients

The immunosuppression regimen for heart transplant recipients has continued to evolve over the past decade. Induction therapy in the form of equine antithymocyte globulin (Atgam®) or muromonab-CD3 (OKT3®) was used for 27% of patients in 1998. While use of induction therapy has gradually increased, reaching 54% in 2007, both these drugs have been largely replaced by the use of rabbit antilymphocyte globulin (Thymoglobulin®) in 19% of heart recipients or monoclonal antibody therapy directed against the IL-2 receptor, namely, daclizumab (Zenapax®) or basiliximab (Simulect®), in 27% of heart recipients *[Table 11.6a]*.

Over the past decade, the overwhelming majority (approximately 77%) of transplant recipients were discharged on triple drug therapy consisting of a calcineurin antagonist, mycophenolate mofetil/mycophenolic acid or other antimetabolite and steroid therapy. The two most common regimens in 1998 (72% of transplant recipients) were cyclosporine with either: (a) mycophenolate mofetil/myocophenolic acid or (b) another antimetabolite and steroids. In 2007, the most common discharge regimen, by far, was tacrolimus, mycophenolate mofetil/mycophenolic acid and steroids (52% of transplant recipients), and, to a lesser extent (24% of transplant recipients), cyclosporine, mycophenolate mofetil/mycophenolic acid and steroids. The use of the mTOR inhibitors sirolimus (Rapamune®) or everolimus (Certican®) at discharge, in various combinations with other agents, is only 3.4%, likely out of concern for impaired wound healing in the immediate postoperative period *[Table 11.6d-e]*.

At 1 year following transplantation, triple drug therapy with a calcineurin antagonist (principally tacrolimus), mycophenolate mofetil/mycophenolic acid and steroid therapy remains the predominant treatment regimen (approximately 54% of heart recipients). However, since 1997 there has been a small (approximately 33% of patients) but important trend toward steroid-free drug regimens by 1 year following transplantation. The use of either sirolimus or everolimus in various combinations with other agents between discharge and 1-year posttransplant is approximately 11%, reflecting the fact that mTOR inhibitors may have utility in preventing and/or retarding transplant coronary artery disease *[Table 11.f–g]*.

A notable trend is the declining number of recipients who needed treatment for rejection episodes during the first year following transplantation (22% in 2006 compared with 38% in 1997). The overwhelming majority of patients were treated with steroids (90% of rejection episodes), while approximately 19% were treated with any form of antibody therapy, most frequently with rabbit antilymphocyte globulin *[Table 11.6i]*. The decline in rejection episodes probably reflects the improved efficacy of the newer immunosuppression medications, but also may result from incremental improvements in the overall care of donors and recipients.

Heart Allocation Policy Changes

On July 12, 2006, the OPTN Thoracic Organ Transplantation Committee implemented an allocation policy change prioritizing Zone A 1A and 1B patients ahead of local (within the donor service area) Status 2 patients (4). It was predicted that the policy change would result in fewer deaths on the waiting list and overall. While not enough data have accrued to make evaluations with regard to posttransplant outcomes, initial data do exist to examine the overall rate of transplantation and experience on the heart waiting list. In 2005, the last complete year prior to the 2006 policy change allowing for broader sharing of hearts for the most urgent patients, there were 469 deaths on the heart waiting list. The number dropped to 374 in 2007, the first complete calendar year for which all transplants occurred under the new sharing rules *[Table 11.3]*. The decline in deaths was noticed in every active status category (148–107 for Status 1A, 94–73 for Status 1B and 81–51 for Status 2, respectively). There has also been a shift in the proportion of patients transplanted from the more urgent status groups. In 2005, 40% and 35% of recipients were transplanted from status groups 1A and 1B, respectively. In 2007, the proportion of recipients transplanted from status groups 1A and 1B increased to 50% and 36%, respectively. The corresponding change in transplants performed was 2125 in 2005 compared with 2207 in 2007 *[Table 11.4]*.

There has been some concern that implementation of broader sharing could affect posttransplant survival. Specifically, with a shift toward longer ischemia time and a greater proportion of patients transplanted from the more urgent status groups (and thus potentially a sicker patient population), posttransplant survival, in theory, could be diminished. In fact, survival has not changed appreciably, at least out to one year following transplantation. In addition, although there is a nonstatistically significant trend toward improved survival for Status 1A patients, 1-year posttransplant survival across the status groups remains unchanged (3).

In July 2006, the OPTN Pediatric Transplantation Committee was charged with developing a plan to reduce the number of deaths on the pediatric organ transplant waiting lists. In prior years, although the distribution of adolescent donor hearts (11–17 year old) were preferentially offered to pediatric candidates prior to adult candidates within each of the status categories and zones, this was not true for 'young' donors (age 0–10 years). Thus, the Pediatric and Thoracic Organ Transplantation committees suggested that these young donors follow an algorithm similar to that used with adolescent donor organs so as to share all pediatric organs more broadly to the sickest candidates.

In reviewing past performance, it was recognized that a sizeable proportion of 'young' donor heart offers made to adult recipients are refused owing to size mismatch, while a reasonable number of such 'young' donor organs are transplanted into adolescents. Moreover, the waiting list mortality for recipients in this younger age range (especially ages 1–5 years) remains substantial.

Accordingly, by the proposed plan, pediatric (age 0–17 years) donor offers would be allocated first to combined local and Zone A (within 500 nautical miles of the donor center) pediatric Status 1A candidates, then to local adult Status 1A candidates, then to combined local and Zone A pediatric Status 1B candidates, before then being offered to adults and pediatric candidates according to the

prior algorithm. Historically, only 0.5% of adults received hearts from pediatric donors less than 12 years old. Thus, the likelihood of this affecting adult waiting list survival is small; the possibility of it improving outcomes for those pediatric patients locally and in Zone A, however, is real. These proposed allocation changes have been approved by the OPTN Board of Directors as of June 2008 and will be evaluated in future reports as data are accrued (5).

Summary

The past decade has seen many changes in the field of heart transplantation. Despite the fact that heart failure is increasingly prevalent in our society, the number of patients who are listed for heart transplantation has declined. In addition, the number of actual heart transplants performed in the United States has fluctuated, with no real evidence that the number of donors has increased. Fortunately, the death rate of those listed for organ transplantation has declined significantly. For those who do undergo transplantation, survival has improved significantly, as posttransplant management strategies have become more sophisticated, balancing side effects with the beneficial effects of chronic immunosuppression. The addition of ventricular assist technology, a rapidly changing field, has added to our ability to manage the most critically ill of all listed patients, and may, in the very near future, offer a viable alternative to transplantation for a proportion of patients with end-stage heart failure.

Certainly, some of the improvements in outcomes seen in waiting list and posttransplant heart failure patients are related to policy change. The process of allocating donor hearts to patients on the waiting list has undergone substantial change over time, thus allowing broader sharing of organs to those most in need. However, there are still several groups of patients, such as those with restrictive cardiomyopathy, hypertrophic cardiomyopathy, congenital diseases and those with life-threatening arrhythmic substrate and/or extreme coronary artery disease, who may not be optimally served by our current methods of allocation. In addition, unlike the lung allocation system (6), which allocates organs based on medical urgency and expected posttransplant survival, allocation policy for the available pool of donor hearts is largely determined by medical urgency alone. In fact, the majority of organs are allocated to patients within status groups 1A and 1B, and discrimination between individual patients within these status groups is crude at best. Investigation as to the possibility of further allocation policy modification is ongoing in the hope of improving outcomes and promoting more equitable distribution of hearts.

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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.

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