OPTN/SRTR 2011
Annual Data Report:

ABSTRACT

Since 2005, the number of new active adult candidates on the heart transplant waiting list increased by 19.2%. The transplant rate peaked at 78.6 per 100 wait-list years in 2007, and declined to 67.8 in 2011. Wait-list mortality declined over the past decade, including among patients with a ventricular assist device at listing; in 2010 and 2011, the mortality rate for these patients was comparable to the rate for patients without a device. Median time to transplant was lowest for candidates listed in 2006-2007, and increased by 3.8 months for patients listed in 2010-2011. Graft survival has gradually improved over the past two decades, though acute rejection is common. Hospitalizations are frequent and increase in frequency over the life of the graft. In 2011, the rate of pediatric heart transplants was 124.6 per 100 patient-years on the waiting list; the highest rate was for patients aged less than 1 year. The pre-transplant mortality rate was also highest for patients aged less than 1 year. Short- and long-term graft survival has continued to improve. The effect on wait-list outcomes of a new pediatric heart allocation policy implemented in 2009 to reduce pediatric deaths on the waiting list cannot yet be determined.

KEY WORDS
End-stage heart failure, heart transplant, transplant outcomes, ventricular assist device.

I want to do everything possible, because I don’t want to waste any of the time I’ve been given. I am lucky, and I will do everything I can to make sure others get the same chance at life as I have been given. I tell everyone how important it is to be a donor. It really is about giving life.

Lacey, heart recipient
Introduction

Heart transplant has long been the best option for selected patients with end-stage heart failure. However, improvements in ventricular assist device (VAD) technology and increased experience with mechanical circulatory support have led to 1-year survival rates approaching those of heart transplant (1). The projected duration of current VADs is at least 5 years, and complications such as stroke and infection have declined substantially compared with complications related to older-generation devices. VADs bridge patients with end-stage heart failure safely to transplant and effectively treat heart failure. Thus, for many patients whose conditions are stable with a VAD, there is no urgency to proceed with listing for heart transplant. Durable devices have dramatically changed the way end-stage heart failure is managed and have resulted in shifts in post-transplant and wait-list trends.

Over the past decade, there have been minor fluctuations in the number of transplants performed per year, with a relatively consistent increase since 2004 (Figure 3.1). This increase in transplants has been mirrored by increases in donation rates, new listings, and transplant rates during the same period (Figures 1.1, 1.4, 2.1). This trend may be explained by policy changes that promote broader sharing. Substantial geographic variation in transplant rates still exists (Figure 3.4). Although geographic variations in donation rates may explain this trend, other factors may include regional donor use, access to the waiting list, geographic variations in listing practices, and death on the waiting list. Over the past decade, two major revisions to heart allocation policy have affected current trends: 1) in 2002, the policy regarding candidates with a VAD was changed to allow listing as status 1A for 30 days at any time after implant; 2) in 2006, the Organ Procurement and Transplantation Network (OPTN) implemented a broader sharing policy to preferentially allocate hearts to combined local and zone A status 1A and 1B candidates (2). In this report, when possible, we highlight trends that may have been influenced by these revisions.

Under the current allocation system, which was revised in 2002, all VAD patients, including those with complications as well as those who are stable, may accrue 30 days of status 1A time without a requirement for hospital admission. If patients with a VAD are not listed as status 1A, they can be listed indefinitely as status 1B. This revision, combined with the growing number of candidates with a VAD, has contributed to the increased proportion of status 1A and 1B registrations over the past decade and the decline in the proportion of status 2 registrations (Figures 1.2, 1.3, 1.12). Although candidates using intravenous inotropes can be listed as status 1A, the proportion of recipients receiving inotropes has declined over the past decade from 51% to 35%, presumably due to increased use of VADs in candidates who previously may have been prescribed inotropic therapy and the recognized survival benefit of VADs compared with inotropic therapy (3,4) (Figure 3.7). While these policies were developed during the early era of mechanical circulatory support, there have been substantial gains in VAD survival; thus the policies may need to be revised to reflect current clinical practice. Disease severity may vary widely among VAD patients. Variability in stability among VAD patients may contribute to differences in wait-list survival and possibly post-transplant survival. Currently, the OPTN Thoracic Organ Transplantation Committee is reassessing allocation policies in favor of a system that can better distinguish severity of illness among VAD patients. Furthermore, status 2 candidates are waiting longer due to changing trends in listing practices and the downstream effects of the broader sharing initiative. It remains to be seen whether longer waiting times will be detrimental to wait-list survival of status 2 candidates.

Adult Heart Transplant Waiting List Trends

New Listings, Wait-List Mortality, and Time to Transplant

Since 2004, the number of new active adult (aged 18 years or older at listing) candidates on the waiting list has increased by 19.2% (Figure 1.1). As expected, implementation of the broader geographic sharing policy and revision of the VAD policy have affected listing practices. Since 2006, the proportions of candidates who were first listed as status 1A and status 1B have increased by 5.4% and 7.3%, respectively, and the proportion initially listed as status 2 has declined by 11.7% (Figure 1.3).
The transplant rate peaked at 78.6 per 100 wait-list years in 2007 and has been declining since; in 2011, the rate was 67.8 per 100 wait-list years (Figure 1.4). Among candidates who were listed for transplant in 2008, 66.0% underwent transplant within 12 months of listing, 25.0% were still waiting at 12 months, and 9.5% had died. By 36 months, 69.7% had undergone transplant, 8.2% were still waiting, and 9.5% had died (Figure 1.6).

Wait-list mortality declined over the past decade, from 16.9 deaths per 100 wait-list years in 2001 to 11.6 per 100 wait-list years in 2011 (Figure 1.10). Trends were similar for men and women (data not shown), all age groups, all race categories, and all medical urgency status categories. In 2011, mortality by age was lowest for candidates aged 35 to 49 years; mortality was comparable for women and men (data not shown), and lowest for Asians. Wait-list mortality improved dramatically among candidates with a VAD at listing (Figure 1.10). Trends among candidates with a VAD at listing are notable. VAD survival has improved greatly. Historically, wait-list mortality has been substantially lower for candidates without a VAD than for candidates with a VAD; however, over the past decade, wait-list mortality improved among candidates with a VAD at listing, declining from 102.2 per 100 wait-list years in 2001 to 12.9 per 100 wait-list years in 2011. In 2010 and 2011, the mortality rate was comparable to the rates for candidates without a VAD at listing, a testament to improvements in VAD technology, experience, and application over the past 10 years (Figure 1.10). These data should be interpreted cautiously, however, as a marked proportion of candidates without a VAD at listing; these candidates were included in the analysis as patients without a VAD at listing.

As expected with the broader sharing policy implemented in 2006, wait-list mortality declined substantially. Between 2006 and 2011, wait-list mortality for candidates listed as status 1A and 1B declined from 92.1 and 32.4 deaths per 100 wait-list years, respectively, to 36.9 and 11.0 deaths per 100 wait-list years. Wait-list mortality remains low for status 2 candidates, declining from 9.7 to 8.1 deaths per 100 wait-list years during this same time period (Figure 1.10). Mortality among candidates listed as active remained stable at 12.3 deaths per 100 wait-list years in 2011. Wait-list mortality remains highest for status 1A candidates compared with other medical urgency status categories.

Over the past decade, median time to transplant was lowest for candidates listed in 2006-2007, and has been increasing since. Overall, the duration of waiting time to transplant for candidates listed in 2010-2011 was 3.8 months longer than for the 2006-2007 cohort. In candidates listed as status 1A, median time to transplant increased from less than 1 month to 1.7 months. The trend was notable in candidates listed initially as status 1B and 2, for whom median waiting time increased by 3.5 months and 9.3 months, respectively (Figure 1.7). This trend does not, however, account for status upgrades or downgrades after listing. Median waiting time for candidates with a VAD at listing was 2.2 months less than for candidates without a VAD. Although waiting time also increased in recent years for candidates with a VAD, the magnitude was slightly less than for candidates without a VAD at listing, at 3.4 months compared with 4.4 months (Figure 1.7). As stated before, this analysis included candidates initially listed without a VAD who received a VAD after listing as candidates without a VAD at listing. The proportion of candidates listed in 2010 who underwent transplant within 1 year of listing varied widely by donation service area (DSA), from 27.1% to 81.0% (Figure 1.8). This variability may be due at least in part to differences among DSAs in listing practices and status changes after listing.

Nationwide, the proportion of candidates undergoing transplant within 1 year of listing declined to 54.6% in recent years (Figure 1.9). Transplant within 1 year of listing was most likely for candidates with blood group AB and least likely for candidates with blood group O (Figure 1.9).

Candidate Characteristics
Since 2001, the proportion of candidates aged 18 to 34 years increased from 8.8% to 10.7%, and the proportion of those aged 65 years or older increased from 12.5% to 19.2%. While candidates aged 50 to 64 years compose the largest proportion
of heart transplant candidates, 49.5% in 2011, the size of this age group has declined in recent years (Figure 1.2). Over the past decade, the proportion of women increased by 4.2%. The proportions of ethnic minorities also increased; most notably, the proportion of black candidates increased substantially, from 13.8% to 21.2% between 2001 and 2011 (Figure 1.2). This increase may in part reflect the disproportionate and earlier occurrence of heart failure in black patients (5). The proportion of candidates with cardiomyopathy surpassed the proportion with coronary artery disease in 2003, and the proportion with congenital heart disease increased to 3.9% in 2011. In 2011, a smaller proportion of candidates (14.4%) waiting for heart transplant spent 3 or more years on the waiting list, compared with 2001 (23.2%). Listing practices, that is, centers electing to list candidates only when they qualify at a higher urgency status, may be partially responsible for shorter waits. Finally, the proportions of status 1A and 1B candidates on the waiting list have grown remarkably from 2001 to 2011, increasing from 9.6% to 14.1% for status 1A and from 17.2% to 35.0% for status 1B (Figure 1.2). These trends may be a consequence of increased use of VADs and of centers listing only candidates who qualify for higher urgency statuses. The increasing proportions of candidates awaiting heart transplant at a higher urgency status suggest increased morbidity among candidates, although the impact of VAD availability cannot be discounted. A comparison of candidates on the waiting list on December 31, 2001, and December 31, 2011, reveals similar trends (Figure 1.12).

**Donation**

The rate of heart donation among people aged less than 65 years has not changed substantially over the past decade; in 2010 this rate was 3.6 per 1,000 patient deaths. Donation rates since 2000 increased by approximately 20% in groups aged 0 to 14, 15 to 34, and 35 to 44 years, and declined by 23.5% and 40.6% in groups aged 45 to 54 and 55 to 64 years, respectively (Figure 2.1). Donation rates among blacks and Hispanics increased (Figure 2.1). Donors aged 18 to 34 years have consistently composed the greatest proportion of heart donors, and in 2011 represented 48.6% (Figure 2.7). The proportion of hearts recovered per organ donor declined from 0.37 in 2001 to 0.28 in 2004 and has since plateaued (Figure 2.3). The proportion of recovered hearts that are discarded has been declining over the past decade, and in 2011 ranged from 0.2% (1 heart) among heart donors aged 0 to 17 years to 1.8% (3 hearts) among heart donors aged 50 to 64 years (Figure 2.5). For the 17 recovered hearts discarded in 2011, the most common reason for discard was other (47.1%), followed by anatomical abnormalities (17.6%) (Figure 2.6). The most common cause of death among donors is head trauma (52.8%). For heart transplant donors, the prevalence of head trauma as a cause of death is slowly declining over time while the prevalence of anoxia is increasing (Figure 2.8).

**Adult Heart Transplant**

**Trends in Transplant Rates**

Overall, the number of adult heart transplants performed was stable between 2000 and 2011 (1,926 and 1,949, respectively). However, in 2004, this number reached a nadir of 1,724 (Figure 3.1). The transplant rate peaked in 2007 and has since declined for all status codes except status 1A (Figure 3.3). The anticipated effect of the broader sharing policy was more rapid transplants in status 1A and 1B candidates. Although the transplant rate for candidates listed at status 1A increased to 315 per 100 patient-years in 2011, the rate declined for status 1B candidates, from 267 to 103 transplants per 100 patient-years between 2007 and 2011. As expected, the transplant rate for status 2 candidates also declined, from 59 to 35 transplants per 100 patient-years. Among candidates with a VAD at the time of listing, the transplant rate decreased from 203 to 99 transplants per 100 patient-years between 2007 and 2011 (Figure 3.3). Despite this dramatic decline, candidates with a VAD continue to undergo transplant at higher rates than candidates without a VAD at listing, in part due to shorter waiting times. Candidates who received a VAD after listing are not accounted for in this analysis; these candidates were included in the analysis as patients without a VAD at listing; therefore, caution is warranted in interpretation.

Geographic trends in transplant rates are highly variable due to variations in center listing practices, donor availability...
and perhaps DSA practices (Figure 3.4). Transplant rates varied from 0 to more than 200 transplants per 100 patient-years.

Trends in life support, including respiratory support and circulatory support, are also changing. Since 2001, the proportions of recipients who received intravenous inotropes immediately before transplant decreased from 51.1% to 35.1%. Since 2004, the proportion of recipients who received a left-VAD before transplant more than doubled, from 16.0% to 35.4% in 2011. Intra-aortic balloon pump use and ventilator use have been stable, as has right-VAD use (Figure 3.7).

Recipient Characteristics
The mean age of adult heart transplant recipients is 50.9 years and has not changed appreciably over the past decade (Figure 3.5); however, an increasing number of recipients are aged 65 years or older. Increasing proportions of recipients are female, are members of ethnic minorities, have cardiomyopathy, and have a VAD at the time of transplant (Figures 3.2, 3.9). Sensitization of heart transplant candidates remains a challenge and has increased since 2007. Increased use of VADS, evolving diagnostic methods to detect and quantify anti-HLA antibody, and increasing use of virtual cross-match, which may help increase access of sensitized candidates to heart transplant, have contributed to the growing number of sensitized candidates (Figure 4.1).

Transplant Outcomes
Aside from minor fluctuations, the overall adjusted probability of short-term graft failure (6 months and 1 year, adjusted for age, sex, and race) has been declining over the past decade, and in general is low, 0.07 at 6 months and 0.09 at 1 year for patients who underwent transplant in 2010. In addition, graft failure at 3, 5, and 10 years post-transplant has steadily declined (Figure 5.1). Early graft failure, within the first 6 weeks post-transplant, has declined, and occurred in only 4.9% of heart transplant recipients in 2011 (Figure 5.2). Overall, 5-year graft survival was 74.9%, and was similar among all status codes and disease groups (Figure 5.3). The greatest decline in graft survival occurred within the first 12 months post-transplant, when survival decreased by 12.7% (Figure 5.3). Graft survival has gradually improved over the past two decades. In recipients who underwent transplant in 2009 and had a functioning graft at 1 year, the predicted half-life, conditional on 1 year of survival, was 14.0 years (Figure 5.4). The number of heart transplant survivors is increasing; in 2011, 21,457 adult recipients were alive with a functioning graft, compared with 16,259 in 2001 (Figure 5.5). Among patients who underwent transplant between 2005 and 2006, 5-year survival was reduced in blacks compared with whites (68.2% vs. 77.9%); in recipients aged 18 to 34 years compared with those aged 35 to 49, 50 to 64, and 65 years or older (69.9%, 77.4%, 76.3%, and 73.9%, respectively); and in recipients with a non-durable VAD compared with those without a VAD and those with a durable VAD (54.9%, 76.6%, and 73.5%, respectively) (Figure 5.9). Only 51 recipients were included in the non-durable VAD category. Recipients with biventricular assist devices involving both durable and non-durable VADS were included in the durable category: 6 patients had a Heartmate XVE combined with a non-durable device. Among recipients in whom the cause of death post-transplant is known, cardiovascular disease remains the most common primary cause (Figure 5.10).

Post-Transplant Morbidity
Acute rejection during the first year post-transplant is common, occurring in 24.5% of recipients who underwent transplant 2005-2009. By 5 years post-transplant, 50.9% of recipients had at least one episode of rejection (Figure 5.6). Hospitalizations are frequent during the first year, occurring in 39.3% of recipients who underwent transplant 2006-2011, and continue to increase over the life of the graft; within 4 years post-transplant, 65.3% of recipients have been hospitalized (Figure 5.7). Post-transplant lymphoproliferative disorder (PTLD) is relatively infrequent in adults and is closely linked to Epstein-Barr virus (EBV) status (Figure 5.8).

Summary
This year’s report highlights several successes, including notable improvements in wait-list survival and in patient and
graft survival. The broader sharing policy and increased VAD use have contributed to these successes but have introduced new challenges regarding allocation of donor hearts. Median time to transplant is increasing, particularly among status 2 candidates. Numbers of candidates listed as status 2 are declining; the appropriateness of performing transplants in status 2 candidates is even being questioned (6). Transplant rates are declining for status 1B and status 2 candidates. To continue allocating hearts to the highest urgency candidates, the allocation policy will need to further distinguish severity of illness between status 1A and status 1B candidates. Revisions to the heart allocation policy are currently being considered; these revisions are anticipated to further define VAD complications to ensure that criteria used for justification of medical urgency are more uniform. Finally, wide geographic variations persist in donation rates, transplant rates, and wait-list mortality. While these analyses are currently not adjusted for medical urgency, which may contribute to the perceived variations, the causes of these disparate trends warrant further investigation to assess equitable access to donor hearts around the country.

Pediatric Heart Transplant

Pediatric Waiting List Trends

Since 1998, the number of new pediatric candidates added to the heart transplant waiting list has increased slightly, and few candidates have been added as inactive. The number of prevalent wait-list candidates remained stable between 250 and just over 300 in the past decade. Historically, more candidates were listed as inactive than as active, but in a shift since 2008, 57.1% of candidates are now listed as active (Figure 7.1). The age distribution changed over the past 3 years; the percentage of wait-listed candidates aged 11 to 17 years increased, with a corresponding decrease in the percentage aged less than 1 year (Figure 7.2). Eight percent of candidates on the waiting list in 2010-2011 were waiting for a re-transplant. Among all candidates on the list, 2.3% of those aged 0 to 5 years were waiting for a re-transplant, as were 15.8% of those aged 6 to 10 years and 14.7% of those aged 11 to 17 years (Figure 7.3). Of candidates newly listed in 2008, 70.2% underwent transplant within 3 years; 14.7% died, 11.8% were removed from the list, and 3.3% were still waiting (Figure 7.5). Pre-transplant mortality decreased for all age groups. The pre-transplant mortality rate was highest for candidates aged less than 1 year, at 49 deaths per 100 wait-list years in 2010-2011 (Figure 7.7).

Pediatric Transplant

The number of pediatric heart transplants performed each year increased from 274 in 1998 to 375 in 2011 (Figure 7.8). In 2011, the rate of pediatric heart transplant was 124.6 per 100 patient-years on the waiting list; the highest rate was for recipients aged less than 1 year, at 271.3 transplants per 100 patient-years on the waiting list (Figure 7.9). Over the past decade, congenital defects remain the most common primary cause of disease, affecting 43.4% of recipients in 2009-2011 (Figure 7.10). The percentage of patients who underwent transplant as status 1A increased from 62.2% in 1999-2001 to 87.1% in 2009-2011. This increase may reflect the policy implemented in 2009 that prioritized pediatric candidates awaiting heart transplant as status 1A in the combined local DSA and zone A as the first unit of allocation. This policy also preferentially allocates all pediatric hearts to pediatric recipients, a change from the previous policy, which prioritized adolescent donor hearts for pediatric candidates. VAD use increased from only 7.6% of pediatric transplant recipients in 1999-2001 to 18.3% in 2009-2011. Development of the Berlin Heart, a VAD for pediatric patients; the HeartMate II, a left VAD smaller than its predecessor; and other newer-generation devices allowed expansion of durable and non-durable support to pediatric candidates.

Pediatric Immunosuppression and Outcomes

Substantial changes in maintenance immunosuppression have occurred. Tacrolimus use increased from 23.8% in 1998 to 83.2% in 2011. Mycophenolate mofetil use increased from 33.2% in 1998 to 90.0% in 2011. In 2010, mammalian target of rapamycin inhibitors were used in 1.4% of patients at the time of transplant and in 7.2% at 1 year post-transplant. Steroids were used in 75.2% of patients at the time of transplant in 2010,
and use decreased to 36.1% at 1 year (Figure 7.13). In 2011, no induction immunosuppression was used in 32.6% of recipients, T cell depleting agents were used in 48.0%, and interleukin-2 receptor antagonists were used in 25.7% (Figure 7.13).

Graft survival, both long-term and short-term, has continued to improve. Graft survival for heart transplants performed in 2005 was 87.5% at 6 months, 84.6% at 1 year, and 72.1% at 5 years (Figure 7.14). Graft survival for heart transplants performed in 2010 was 92.7% at 6 months and 91.2% at 1 year. The rate of late graft failure is traditionally measured by the graft half-life conditional on 1-year survival, defined as the time to when half of grafts surviving at least 1 year are still functioning. For heart transplants performed in 2009-2010, the 1-year conditional graft half-life was 17.4 years (Figure 7.15). Incidence of first acute rejection increased over time post-transplant; 24.4% of patients experienced rejection in the first 12 months and 38.2% by 24 months post-transplant (Figure 7.16). The highest risk for EBV infection and PTLD occurred in EBV-negative recipients. Incidence of PTLD was 8.4% at 5 years post-transplant among EBV-negative recipients and 2.7% among EBV-positive recipients (Figure 7.12).

Policy Updates
In 2009, a new pediatric heart allocation sequence was implemented that preferentially allocates pediatric hearts to status 1A pediatric candidates in a combined allocation unit composed of the local DSA and zone A before local adult status 1A candidates and status 1B pediatric candidates; compared with the previous policy, which prioritized local status 1A pediatric candidates, the new policy prioritizes both local and zone A status 1A pediatric candidates. The ultimate goal of this policy is to reduce pediatric deaths on the waiting list and to expedite allocation of pediatric hearts to pediatric candidates at highest risk of wait-list mortality. Although it is too early to determine the effect of this policy on wait-list outcomes, during 2010-2011, wait-list mortality appeared to decline among pediatric candidates in all age categories compared with 2008-2009 (Figure 7.7). Future OPTN/SRTR data reports will focus on the impact of these allocation policy changes.

References
**Wait List**

**HR 1.1 Adult patients waiting for a heart transplant**

Patients waiting for a transplant. A “new patient” is one who first joins the list during the given year, without having listed in a previous year. However, if a patient has previously been on the list, has been removed for a transplant, and has relisted since that transplant, the patient is considered a “new patient.” Patients concurrently listed at multiple centers are counted only once. Those with concurrent listings and active at any program are considered active; those inactive at all programs at which they are listed are considered inactive.

**HR 1.2 Distribution of adult patients waiting for a heart transplant**

Patients waiting for a transplant any time in the given year. Age determined on the earliest of listing date or December 31 of the given year. Concurrently listed patients are counted once. Ventricular assist device information comes from the OPTN Transplant Candidate Registration form at the time of listing, and includes LVAD, RVAD, TAH, and LVAD + RVAD. Medical urgency status is the earliest available per year for each patient.
HR 1.3 Distribution of adult patients newly listed for a heart transplant
A newly listed patient is one who first joins the list during the given year, without having listed in a previous year. However, if a patient has previously been on the list, has been removed for a transplant, and has relisted since that transplant, the patient is considered a newly listed patient. Patients concurrently listed at multiple centers are counted only once. Ventricular assist device information comes from the OPTN Transplant Candidate Registration form at the time of listing, and includes LVAD, RVAD, TAH, and LVAD + RVAD.

HR 1.4 Heart transplant rates among adult waiting list candidates, by age
Patients waiting for a transplant; age as of January 1 of the given year. Yearly period-prevalent rates computed as the number of deceased donor transplants per 100 patient years of waiting time in the given year. All waiting time per patient per listing is counted, and all listings that end in a transplant for the patient are considered transplant events.

HR 1.5 Heart transplant waiting list activity among adult patients
Patients with concurrent listings at more than one center are counted once, from the time of earliest listing to the time of latest removal. Patients listed, transplanted, and re-listed are counted more than once. Patients are not considered "on the list" on the day they are removed. Thus, patient counts on January 1 may be different from patient counts on December 31 of the prior year.

HR 1.6 Outcomes for adult patients waiting for a heart transplant among new listings in 2008
Patients waiting for a transplant and first listed in 2008. Patients with concurrent listings at more than one center are counted once, from the time of the earliest listing to the time of latest removal.

Data behind the figures can be downloaded from our website, at www.srtr.org
Adult wait-listed patients who received a deceased donor heart transplant within one year.

Patients waiting for a transplant, with observations censored in December 2011. Kaplan-Meier method used to estimate time to transplant. If an estimate is not plotted for a certain year, 50% of the cohort listed in that year had not been transplanted at the censoring date. Only the first transplant is counted.

Percent of adult wait-listed patients, 2010, who received a deceased donor heart transplant within one year, by DSA.

Patients with concurrent listings at more than one center are counted once, from the time of earliest listing to the time of latest removal. Patients listed, transplanted, and re-listed are counted more than once.

Adult wait-listed patients who received a deceased donor heart transplant within one year, by year of listing.

Patients with concurrent listings in a single DSA are counted once in that DSA, and those listed in multiple DSAs are counted separately per DSA.

Median months to transplant for wait-listed adult patients.

Patients waiting for a transplant, with observations censored in December 2011. Kaplan-Meier method used to estimate time to transplant. If an estimate is not plotted for a certain year, 50% of the cohort listed in that year had not been transplanted at the censoring date. Only the first transplant is counted.

Median months to transplant for wait-listed adult patients, by year.

Patients waiting for a transplant, with observations censored in December 2011. Kaplan-Meier method used to estimate time to transplant. If an estimate is not plotted for a certain year, 50% of the cohort listed in that year had not been transplanted at the censoring date. Only the first transplant is counted.

Percent of adult wait-listed patients who received a deceased donor heart transplant within one year, by race.

Patients waiting for a transplant, with observations censored in December 2011. Kaplan-Meier method used to estimate time to transplant. If an estimate is not plotted for a certain year, 50% of the cohort listed in that year had not been transplanted at the censoring date. Only the first transplant is counted.

Percent of adult wait-listed patients who received a deceased donor heart transplant within one year, by blood type.

Patients waiting for a transplant, with observations censored in December 2011. Kaplan-Meier method used to estimate time to transplant. If an estimate is not plotted for a certain year, 50% of the cohort listed in that year had not been transplanted at the censoring date. Only the first transplant is counted.
Pre-transplant mortality rates among adult patients wait-listed for a heart transplant

Patients waiting for a transplant. Mortality rates are computed as the number of deaths per 100 patient-years of waiting time in the given year. For rates shown by different characteristics, waiting time is calculated as the total waiting time in the year for patients in that group. Only deaths that occur prior to removal from the waiting list are counted. Age is calculated on the latest of listing date or January 1 of the given year. Other patient characteristics come from the OPTN Transplant Candidate Registration form. Medical urgency status is the earliest known status in the given year.
HR 1.1 Mortality within 90 days of listing for heart transplant, by DSA, 2009–2010
Patients with concurrent listings in a single DSA are counted once in that DSA, and those listed in multiple DSAs are counted separately per DSA. Deaths occurring within 90 days, but after transplant or removal from the waiting list, are included.

HR 1.11 Characteristics of adult patients on the heart transplant waiting list on December 31, 2001 & December 31, 2011
Patients waiting for a transplant on December 31, 2001 and December 31, 2011, regardless of first listing date; active/inactive status is on this date, and multiple listings are not counted.
**HR 2.1 Deceased donor heart donation rates**
Numerator: Deceased donors age less than 65 whose organ(s) were recovered for transplant. Denominator: US deaths per year, age less than 65. (Death data available at http://www.cdc.gov/nchs/products/nvsr.htm.)

**HR 2.2 Deceased donor heart donation rates (per 1,000 deaths), by state**
Numerator: Deceased donors residing in the 50 states whose heart was recovered for transplant in the given year range. Denominator: US deaths by state during the given year range (death data available at http://www.cdc.gov/nchs/products/nvsr.htm). Rates are calculated within ranges of years for more stable estimates.

**HR 2.3 Hearts recovered per donor & hearts transplanted per donor**
Denominator: all deceased donors with at least one organ of any type recovered for transplant. Numerator for recovery rate: number of hearts recovered for transplant in the given year; hearts recovered for other purposes are not included. Numerator for transplant rate: all deceased donor hearts transplanted in given year.
HR 2.4 Deceased donor hearts transplanted with another organ
All patients receiving a deceased donor heart transplant. A transplant is considered multi-organ if any organ of a different type is transplanted at the same time. A multi-organ transplant may include more than two different organs in total; if so, each non-heart organ will be considered separately.

HR 2.5 Discard rates for hearts recovered for transplant, by age
Percent of hearts discarded out of all hearts recovered for transplant.

Reasons for discard | Percent | N
--- | --- | ---
Other, specify | 47.06 | 8
Anatomical abnormalities | 17.65 | 3
Diseased organ | 5.88 | 1
Donor medical history | 5.88 | 1
Missing | 5.88 | 1
Organ trauma | 5.88 | 1
Poor organ function | 5.88 | 1
Too old on ice | 5.88 | 1

HR 2.6 Reasons for discards, 2011
Reasons for discard among hearts recovered for transplant but not transplanted in 2011.

HR 2.7 Heart donor age
Transplanted hearts from US donors; age calculated at date of donation.

HR 2.8 Cause of death among deceased heart donors
Deceased donors whose heart was transplanted. CNS = central nervous system.
HR 3.1  Total adult heart transplants
Patients receiving a transplant. Retransplants are counted.

HR 3.2  Adult heart transplants
Patients receiving a transplant. Retransplants are counted.
**HR 3.3  Heart transplant rates in adult waiting list candidates**

Patients waiting for a transplant. Transplant rates are computed as the number of transplants per 100 patient-years of waiting time in the given year. For rates by VAD and status, waiting time is calculated as the total waiting time in the given year for patients in each VAD/status group. All waiting time per patient per listing is counted, and all listings that end in a transplant for the patient are considered transplant events. Medical urgency status is updated each year, using the earliest known status in the given year.

- VAD at listing
- Medical urgency status

**HR 3.4  Deceased donor heart transplant rates per 100 patient years on the waiting list among adult candidates, by DSA, 2010–2011**

Transplant rates by DSA of the listing center, limited to those on the waiting list in 2010 and 2011; deceased donor transplants only. Maximum time per listing is two years.

**HR 3.5  Age at transplant for adult heart recipients**

Patients receiving a transplant in the given year. Retransplants are included.

**HR 3.6  Total ischemia time for adult heart transplants**

Patients receiving a transplant in the given year. Retransplants are included. Total ischemia time includes cold, warm, and anastomotic time.
Adult heart recipients on circulatory support prior to transplant

Patients may have more than one type of circulatory support. The ‘other’ category includes types of circulatory support found in less than 1% of patients each year: total artificial heart, ECMO, inhaled NO, prostaglandins, and others.

Insurance coverage among adult heart transplant recipients at time of transplant

Patients receiving a transplant. Retransplants are counted.

Characteristics of adult heart transplant recipients, 2001 & 2011

Patients receiving a transplant. Retransplants are counted. Ventricular assist device information comes from the OPTN Transplant Recipient Registration form and includes LVAD, RVAD, TAH, and LVAD + RVAD. Smoking history and VAD status were not collected on the TRR form in 2001.
HR 4.1  PRA at time of heart transplant in adult recipients
PRA is the maximum of the most recent values recorded at the time of transplant. If “most recent PRA” is not provided, peak PRA is used.

HR 4.2  Total HLA mismatches among adult heart transplant recipients
Donor and recipient antigen matching is based on the OPTN’s antigen values and split equivalences policy as of 2011.

HR 4.3  HLA-A mismatches among adult heart transplant recipients
Donor and recipient antigen matching is based on the OPTN’s antigen values and split equivalences policy as of 2011.

HR 4.4  HLA-B mismatches among adult heart transplant recipients
Donor and recipient antigen matching is based on the OPTN’s antigen values and split equivalences policy as of 2011.

HR 4.5  HLA-DR mismatches among adult heart transplant recipients
Donor and recipient antigen matching is based on the OPTN’s antigen values and split equivalences policy as of 2011.
### Heart donor-recipient matching

**HR 4.6** Adult heart donor-recipient cytomegalovirus (CMV) serology matching, 2007–2011

Adult transplant cohort from 2007–2011. Donor serology is reported on the OPTN Donor Registration forms; recipient serology is reported on the OPTN Recipient Registration forms. Any evidence for a positive serology is taken to indicate that the person is positive for the given serology; if all fields are unknown, not done, or pending the person is considered to be “unknown” for that serology; otherwise, serology is assumed negative.

<table>
<thead>
<tr>
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<th>Total</th>
</tr>
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<tbody>
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**HR 4.7** Adult heart donor-recipient Epstein-Barr virus (EBV) serology matching, 2007–2011

Adult transplant cohort from 2007–2011. Donor serology is reported on the OPTN Donor Registration forms; recipient serology is reported on the OPTN Recipient Registration forms. Any evidence for a positive serology is taken to indicate that the person is positive for the given serology; if all fields are unknown, not done, or pending the person is considered to be “unknown” for that serology; otherwise, serology is assumed negative.

<table>
<thead>
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<th>Total</th>
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<td>0.0</td>
<td>1.7</td>
<td></td>
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<tr>
<td>Total</td>
<td>99.9</td>
<td>0.0</td>
<td>0.1</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

**HR 4.8** Adult heart donor-recipient hepatitis B core antibody (HBcAb) serology matching, 2007–2011

Adult transplant cohort from 2007–2011. Donor serology is reported on the OPTN Donor Registration forms; recipient serology is reported on the OPTN Recipient Registration forms. Any evidence for a positive serology is taken to indicate that the person is positive for the given serology; if all fields are unknown, not done, or pending the person is considered to be “unknown” for that serology; otherwise, serology is assumed negative.

<table>
<thead>
<tr>
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<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Total</td>
<td>97.9</td>
<td>2.0</td>
<td>0.1</td>
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</tr>
</tbody>
</table>

**HR 4.9** Adult heart donor-recipient hepatitis B surface antigen (HBsAg) serology matching, 2007–2011

Adult transplant cohort from 2007–2011. Donor serology is reported on the OPTN Donor Registration forms; recipient serology is reported on the OPTN Recipient Registration forms. Any evidence for a positive serology is taken to indicate that the person is positive for the given serology; if all fields are unknown, not done, or pending the person is considered to be “unknown” for that serology; otherwise, serology is assumed negative.

<table>
<thead>
<tr>
<th>DONOR</th>
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<th>Positive</th>
<th>Unknown</th>
<th>Total</th>
</tr>
</thead>
<tbody>
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<td>0.1</td>
<td>92.1</td>
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<tr>
<td>Total</td>
<td>99.9</td>
<td>0.0</td>
<td>0.1</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

**HR 4.10** Adult heart donor-recipient hepatitis C serology matching, 2007–2011

Adult transplant cohort from 2007–2011. Donor serology is reported on the OPTN Donor Registration forms; recipient serology is reported on the OPTN Recipient Registration forms. Any evidence for a positive serology is taken to indicate that the person is positive for the given serology; if all fields are unknown, not done, or pending the person is considered to be “unknown” for that serology; otherwise, serology is assumed negative.

<table>
<thead>
<tr>
<th>DONOR</th>
<th>RECIPIENT</th>
<th>Negative</th>
<th>Positive</th>
<th>Unknown</th>
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<td>91.2</td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>1.9</td>
<td>0.0</td>
<td>0.0</td>
<td>2.0</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>6.8</td>
<td>0.0</td>
<td>0.0</td>
<td>6.8</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>99.9</td>
<td>0.1</td>
<td>0.0</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

**HR 4.11** Adult heart donor-recipient human immunodeficiency virus (HIV) serology matching, 2007–2011

Adult transplant cohort from 2007–2011. Donor serology is reported on the OPTN Donor Registration forms; recipient serology is reported on the OPTN Recipient Registration forms. Any evidence for a positive serology is taken to indicate that the person is positive for the given serology; if all fields are unknown, not done, or pending the person is considered to be “unknown” for that serology; otherwise, serology is assumed negative.
outcomes

HR 5.1  Graft failure among adult heart transplant recipients
Cox proportional hazards models reporting probability, adjusting for age, sex, and race.

HR 5.2  Graft failure within the first 6 weeks after transplant among adult heart transplant recipients
All-cause graft failure is identified from multiple data sources, including the OPTN Transplant Recipient Registration, OPTN Transplant Recipient Follow-up, as well as death dates from the Social Security Administration.

HR 5.3  Graft survival among adult heart transplant recipients transplanted in 2006
Graft survival estimated using unadjusted Kaplan-Meier methods.
HR 5.4 Half-lives for adult heart transplant recipients
Estimated graft half-lives and conditional half-lives. Half-lives are interpreted as the estimated median survival of grafts from the time of transplant. Conditional half-lives are interpreted as the estimated median survival of grafts which survive the first year.

HR 5.5 Recipients alive & with a functioning heart transplant on June 30 of the year
Transplants before June 30 of the year that are still functioning. Patients are assumed alive with function unless a death or graft failure is recorded. A recipient can experience a graft failure and drop from the cohort, then be retransplanted and re-enter the cohort.

HR 5.6 Incidence of first acute rejection among adult patients receiving a heart transplant in 2005–2009
Acute rejection defined as a record of acute or hyperacute rejection, or a record of an anti-rejection drug being administered on either the Transplant Recipient Registration form or the Transplant Recipient Follow-up Form. Only the first rejection event is counted, and patients are followed for acute rejection only until graft failure, death, or loss to follow-up. Cumulative incidence, defined as the probability of acute rejection at any time prior to the given time, is estimated using Kaplan-Meier methods.

HR 5.7 Reported cumulative incidence of rehospitalizations among adult patients receiving a heart transplant in 2006–2011
Cumulative incidence of rehospitalization post-transplant; hospitalization identified from the OPTN Transplant Recipient Follow-up form. Patients required to be alive with graft function at each time period, so denominators reduce over time.

HR 5.8 Incidence of PTLD among adult patients receiving a heart transplant in 2005–2009, by recipient Epstein-Barr virus (EBV) status at transplant
The cumulative incidence, defined as the probability of post-transplant lymphoproliferative disorder (PTLD) being diagnosed between the time of transplant and the given time, is estimated using Kaplan-Meier methods. PTLD is identified as either a reported complication or cause of death on the Transplant Recipient Follow-up forms or on the Post-transplant Malignancy form as polymorphic PTLD, monomorphic PTLD, or Hodgkin’s Disease. Only the earliest date of PTLD diagnosis is considered, and patients are followed for PTLD until graft failure, death, or loss to follow-up. Patients are censored at graft failure because malignancies are not reliably reported after graft failure.
HR 5.9  Patient survival among adult heart transplant recipients, 2005–2006
Percent patient survival using unadjusted Kaplan-Meier methods. For patients with more than one transplant during the period, only their first transplant is considered. VAD status for each patient comes from time of transplant. Patients with both durable and non-durable VADs are included in the durable group.

HR 5.10  Cause of death among adult heart transplant recipients
Patients who died in a given year are included regardless of when transplant was received. Primary cause of death is as reported by the OPTN from the Transplant Follow-up forms. Other causes of death include hemorrhage, trauma, non-compliance, unspecified other, unknown, etc.
**HR 6.1** Initial immunosuppression regimen in adult heart transplant recipients, 2011

Patients transplanted in 2011 and discharged with a functioning graft. Top three baseline immunosuppression regimens are given, plus the “all others” group. Regimens are defined by use of calcineurin inhibitors (TAC=Tacrolimus, Cyclo=Cyclosporine), anti-metabolites (AZA=Azathioprine, MMF/MPA=Mycophenolate), and mTOR inhibitors (mTOR). Data within each regimen are reported separately by steroid use.

**HR 6.2** Induction agents used at time of heart transplant, adult recipients, 2011

Patients transplanted in 2011 and discharged with a functioning graft.

**HR 6.3** Immunosuppression at one year in adult heart transplant recipients, 2010

Patients transplanted in 2010 and remaining alive with graft function one year post-transplant. Top three one-year immunosuppression regimens are given, plus the “all others” group. Regimens are defined by use of calcineurin inhibitors (TAC=Tacrolimus, Cyclo=Cyclosporine), anti-metabolites (AZA=Azathioprine, MMF/MPA=Mycophenolate), and mTOR inhibitors (mTOR). Data within each regimen are reported separately by steroid use.

**HR 6.4** Immunosuppression use in adult heart transplant recipients

One-year post-transplant data for mTOR inhibitors and steroids limited to patients alive with graft function one year post-transplant. One-year post-transplant data are not reported for 1998 transplant recipients, as follow-up data were very sparse.
**HR 7.1 Pediatric patients waiting for a heart transplant**

Patients waiting for a transplant. A “new patient” is one who first joins the list during the given year, without having listed in a previous year. However, if a patient has previously been on the list, has been removed for a transplant, and has relisted since that transplant, the patient is considered a “new patient”. Patients concurrently listed at multiple centers are counted only once. Those with concurrent listings and active at any program are considered active; those inactive at all programs at which they are listed are considered inactive.

**HR 7.2 Distribution of pediatric patients waiting for a heart transplant**

Patients waiting for a transplant any time in the given year. Age determined on the lastest of listing date or January 1 of the given year. Concurrently listed patients are counted once.

**HR 7.3 Prior heart transplant in pediatric patients waiting for a heart transplant, by age**

Prior transplant is obtained from the OPTN Transplant Candidate Registration form.
## Heart transplant waiting list activity among pediatric patients

Patients with concurrent listings at more than one center are counted once, from the time of earliest listing to the time of latest removal. Patients listed, transplanted, and re-listed are counted more than once. Patients are not considered “on the list” on the day they are removed. Thus, patient counts on January 1 may be different from patient counts on December 31 of the prior year.

### Patients at start of year
- 2009: 287
- 2010: 304
- 2011: 293

### Patients added during year
- 2009: 537
- 2010: 487
- 2011: 536

### Patients removed during year
- 2009: 518
- 2010: 497
- 2011: 536

### Patients at end of year
- 2009: 306
- 2010: 294
- 2011: 301

### Removal reason
- Received a transplant: 365, 364, 384
- Patient died: 82, 65, 69
- Patient refused transplant: 1, 1, 0
- Improved, tx not needed: 47, 43, 47
- Too sick to transplant: 19, 19, 23
- Other: 4, 5, 13

## Outcomes for pediatric patients waiting for a heart transplant among new listings in 2008

Patients waiting for a transplant and first listed in 2008. Patients with concurrent listings at more than one center are counted once, from the time of the earliest listing to the time of latest removal.

### Transplant rates in pediatric waiting list candidates, by age

Patients waiting for transplant. Transplant rates are computed as the number of transplants per 100 patient-years of waiting time in the given year. Patients with concurrent listings at multiple centers are counted once.
### HR 7.10 Characteristics of pediatric heart transplant patients, 1999–2001 & 2009–2011

Patients receiving a transplant. Retransplants are counted.

<table>
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<tr>
<th>Level</th>
<th>1999-2001</th>
<th>2009-2011</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Age</td>
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<tr>
<td>&lt;1</td>
<td>197</td>
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<tr>
<td>1-5</td>
<td>206</td>
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</tr>
<tr>
<td>6-10</td>
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<td>13.9</td>
</tr>
<tr>
<td>11-17</td>
<td>284</td>
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<tr>
<td>Sex</td>
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<tr>
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<td>5.3</td>
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<tr>
<td>All patients</td>
<td>798</td>
<td>100.0</td>
</tr>
</tbody>
</table>

### HR 7.11 Insurance coverage among pediatric heart transplant recipients at time of transplant

Patients receiving a transplant in given year; reported primary insurance payer at time of transplant. Retransplants are counted.

### HR 7.12 Incidence of PTLD among pediatric patients receiving a heart transplant, 1999–2009, by recipient Epstein-Barr virus (EBV) status at transplant

The cumulative incidence, defined as the probability of post-transplant lymphoproliferative disorder (PTLD) being diagnosed between the time of transplant and the given time, is estimated using Kaplan-Meier methods. PTLD is identified as either a reported complication or cause of death on the Transplant Recipient Follow-up forms or on the Post-transplant Malignancy form as polymorphic PTLD, monomorphc PTLD, or Hodgkin’s Disease. Only the earliest date of PTLD diagnosis is considered, and patients are followed for PTLD until graft failure, death, or loss to follow-up. Patients are censored at graft failure because malignancies are not reliably reported after graft failure.
HR 7.13 Imunosuppression use among pediatric heart transplant recipients
One-year post-transplant data for mTOR inhibitors and steroids limited to patients alive with graft function one year post-transplant. One-year post-transplant data are not reported for 1998 transplant recipients, as follow-up data were very sparse.

HR 7.14 Graft failure among pediatric heart transplant recipients
Cox proportional hazards model reporting probability, adjusting for age, sex, and race.

HR 7.15 Half-lives for pediatric heart transplant recipients
Estimated half-lives and conditional half-lives. Half-lives are interpreted as the estimated median survival of grafts from the time of transplant. Conditional half-lives are interpreted as the estimated median survival of grafts which survive the first year.

HR 7.16 Incidence of first acute rejection among pediatric patients receiving a heart transplant in 2005–2010
Acute rejection defined as a record of acute or hyperacute rejection, or a record of an anti-rejection drug being administered on either the Transplant Recipient Registration form or the Transplant Recipient Follow-up Form. Only the first rejection event is counted, and patients are followed for acute rejection only until graft failure, death, or loss to follow-up. Cumulative incidence, defined as the probability of acute rejection at any time prior to the given time, is estimated using Kaplan-Meier methods.
HR 8.1 Centers performing adult heart transplants in 2011, within Donation Service Areas (DSAs)
HR 8.2 Centers performing pediatric heart transplants in 2011, within Donation Service Areas (DSAs)
HR 8.3 Centers performing adult heart transplants in 2011, within OPTN regions