United States Organ Transplantation

OPTN & SRTR ANNUAL DATA REPORT 2010

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SUGGESTED CITATION

Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). OPTN/SRTR 2010 Annual Data Report. Rockville, MD: Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation; 2011.

contents

Figure titles specify adult and pediatric populations; if not listed, figure includes patients of all ages. (For lung data, patients aged 12 and older are grouped with adults.) And unless otherwise indicated, data in all figures are for solitary organ transplants.

Each chapter contains (when relevant to the specific organ) the following sections:

- wait list
- deceased donation
- live donation
- transplant
- donor-recipient matching
- outcomes
- immunosuppression
- pediatric transplant
- center characteristics
- maps of transplant centers

preface

This Annual Report of the Organ Procurement and Transplantation Network (OPTN) and the US Scientific Registry of Transplant Recipients (SRTR) is the 20th such annual report and is based largely on data pertaining to the 12-year period from 1998 to 2009.

This publication was developed for the US Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation, by the SRTR contractor, the Minneapolis Medical Research Foundation (MMRF), and the OPTN contractor, the United Network for Organ Sharing (UNOS), under contracts HHSH250201000018C and 234-2005-37011C, respectively.

As the SRTR contractor, the MMRF, through its Chronic Disease Research Group (CDRG), determined which data to present, conducted the required analyses, created the figures and tables, drafted the text, and designed the document. As the OPTN contractor, UNOS critiqued the draft report and provided the glossary. This Annual Data Report will be made available at http://www.srtr.org. This preface describes the changes from previous reports and also serves as an introduction to the sections that follow.

OVERVIEW AND HIGHLIGHTS

This is the first Annual Data Report to which the current SRTR contractor has contributed. It features a new design and format, consistent with the broader goals of providing information about transplantation in the US that is accessible to patients, caregivers, researchers, and the general public.

This Annual Data Report includes chapters on kidney, pancreas, liver, intestine, heart, and lung transplantation, chapters on deceased donor organ donation and allocation policy, and an appendix. The organ-specific chapters include sections describing the waiting list, deceased donor organ donation, living donor organ donation, transplant, donor-recipient matching, outcomes, immunosuppression, pediatric transplant, and center characteristics. When possible, similar data and formats are used for each chapter and section. However, this is not always possible because some data are not pertinent to all organs. Graphical presentation of the data is emphasized, but the data behind each figure are available on the above-mentioned website in a spreadsheet format. Data tables are also provided on the site.

Milestone dates in the production of this Report: Data were cut: October 2010. Data were analyzed: November 2010 through April 2011. Draft submitted to HRSA: May 2011. Approved by HRSA: September 2011. Posted to website: October 2011. Submitted to the American Journal of Transplantation: October 2011.

DATA REQUESTS TO THE SRTR

Simple data requests can be fulfilled with existing data, do not require additional programming or analyses, can generally be fulfilled quickly (i.e., in less than 4 hours), and do not require a data use agreement (DUA) or payment.

Data requests for a standard analytical file (SAF) or a simulated allocation model (SAM) require a DUA and payment. SRTR offers a student discount for researchers who qualify.

Data requests requiring linkages with other public or private data sources can often be accommodated. To protect the privacy of individuals in the transplant registry, SRTR will perform linkages and analyses that require use of personal identifiers;

SRTR will release the resulting data as summary data or as individual data with encrypted identifiers. In exceptional circumstances, identifiers may be released to other government agencies or to investigators for linkage, but only after authorization by the SRTR Technical Advisory Committee and the SRTR Project Officer at HRSA.

Data requests for additional SRTR programming will be considered depending on available resources and reviewed on a case-by-case basis by SRTR and the SRTR Project Officer at HRSA. Requesters must sign a DUA. An hourly rate will be assessed for time spent on the request; cost to fulfill the request is based solely on the programming time required. Data sets require payment in addition to that for programming time.

WEBSITES

WWW.SRTR.ORG is a public website containing transplant program-specific reports, organ procurement organization (OPO)-specific reports, summary tables, archives of past reports, timelines for future reports, risk-adjustment models, methods, basic references for researchers who use SRTR data files, a link to the Annual Data Report and its supporting documentation and data tables, answers to frequently asked questions, and other information.

HTTPS://SECURESRTR.TRANSPLANT.HRSA.GOV is a secure website that provides access to the pre-release program- and OPO-specific reports, survival spreadsheets, and other useful information. Each transplant program and OPO has its own username and password for access to the site.

HTTP://UNOS.ORG is a public website containing information on donation and transplantation, data collection instruments, data reports, education materials for patients and transplant professionals, policy development, and other information. This website also links to the OPTN website.

HTTP://OPTN.TRANSPLANT.HRSA.GOV is a public website containing news, information, and resources about transplantation and donation, including transplant data reports; policy development; and related boards and committees. It also contains allocation calculators, a calendar of events, answers to frequently asked questions, and other information.

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804-782-4730 (OPTN)
612-337-8960 (SRTR)

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SUGGESTED CITATIONS

Full citation: Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). OPTN/SRTR 2010 Annual Data Report. Rockville, MD: Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation; 2011. To specify a page number, add it at the end of the citation as follows (for example): …2011:96.

Or, provide the URL for the webpage cited and the access date: Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). OPTN/SRTR 2010 Annual Data Report. Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation; 2011. Available at [insert URL here]. Accessed [insert date here].

Abbreviated citation: OPTN/SRTR 2010 Annual Data Report. HHS/HRSA/HSB/DOT.

PUBLICATIONS BASED ON DATA IN THIS REPORT OR SUPPLIED ON REQUEST MUST INCLUDE A CITATION AND THE FOLLOWING STATEMENT:
The data and analyses reported in the 2010 Annual Data Report of the Organ Procurement and Transplantation Network and the US Scientific Registry of Transplant Recipients have been supplied by the Minneapolis Medical Research Foundation and UNOS under contract with HHS/HRSA. The authors alone are responsible for reporting and interpreting these data; the views expressed herein are those of the authors and not necessarily those of the US Government.

introduction

This Introduction provides a brief overview of transplantation in the United States, emphasizing a few pertinent comparisons between organs.

DECEASED DONOR TRANSPLANT WAITING LISTS

Separate waiting lists are maintained for each deceased donor organ that is allocated for transplant by the Organ Procurement and Transplantation Network (OPTN). Some patients undergo living donor transplant and never appear on a deceased donor waiting list. However, many patients who undergo living donor transplant have also been listed on the deceased donor waiting list. The kidney transplant waiting list has the largest number of patients by far (Figure 1a). On December 31, 2009, 52,503 active patients were waitlisted for kidney transplant, 1,218 for simultaneous pancreas-kidney (SPK) transplant, 432 for pancreas transplant alone (PTA) or pancreas after kidney (PAK) transplant, 12,454 for liver transplant, 148 for intestine transplant, 1,992 for heart transplant, and 1,207 for lung transplant. Some patients are listed for multiple organs and appear on more than one waiting list. Starting in 2011, the pancreas transplant waiting lists are combined into a single list, but this is not reflected in the current Annual Data Report.

The number of patients on the kidney transplant waiting list has steadily increased. In the past decade, the number of active patients on the waiting list has increased almost 2-fold, from 34,120 in 1998 to 52,503 in 2009 (Figure 1a). This number does not include patients listed as inactive, who comprised 34.8% of the total in 2009. Much of the growth in the waiting list can be attributed to new patients being added at a rate greater than the rate of transplants. In the past decade, the number of new patients (active and inactive) added every year to the kidney transplant waiting list increased 65.1%, from 17,588 in 1998 to 29,031 in 2009 (Figure 1b). In 2009, 30.0% of newly listed patients were inactive.

The numbers of patients on waiting lists for SPK and PTA/PAK have declined steadily in the past few years (Figure 1a), and the numbers of new listings have paralleled these declines (Figure 1b). Reasons for this are not entirely clear.

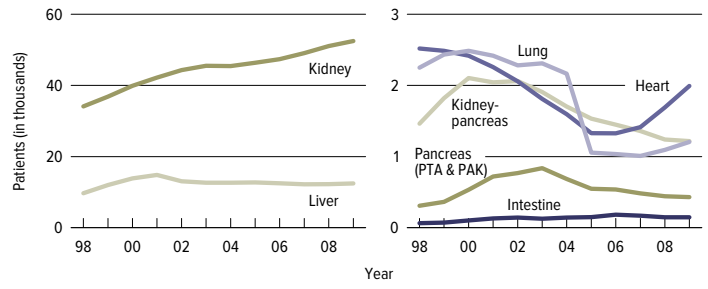
The number of patients on the waiting list for intestinal transplant, albeit small, has steadily grown over the past decade (Figure 1a). This is due at least in part to growth in the number of new listings (Figure 1b).

The liver transplant waiting list has grown less than the kidney list. However, the number of active patients on the liver transplant waiting list increased 28.4%, from 9,700 in 1998 to 12,454 in 2009 (Figure 1a). The number of new patients (active and inactive) added to the list every year increased 17.5%, from 8,608 in 1998 to 10,115 in 2009 (Figure 1b). The number of patients on the waiting list does not tell the full story if patients who may have benefited from a liver transplant were never listed.

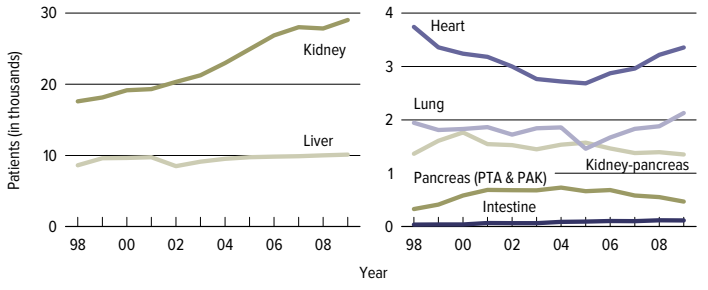
From 1998 to 2006, the number of active patients on the heart transplant waiting list declined 47.3%, but this number increased 50% from 2006 to 2009 (Figure 1a). The decline and increase have been accompanied by parallel changes in new heart transplant listings (Figure 1b).

In 2005, a new allocation system based on the Lung Allocation Score (LAS) was implemented

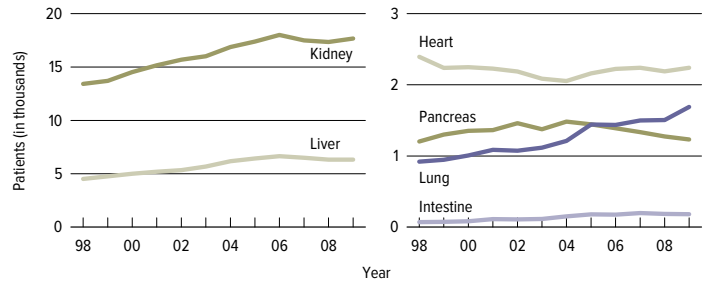
INT 1a **Patients on the waiting list on December 31 of the year (active listings only)**



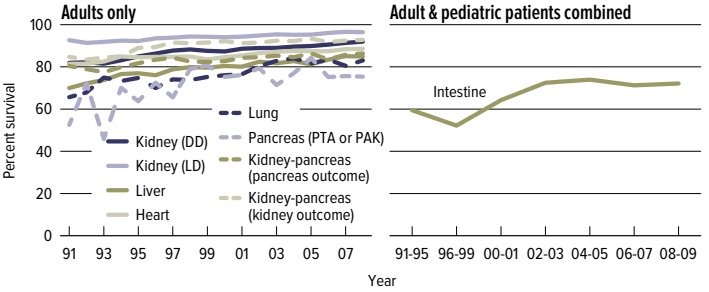
INT 1b **Patients added to the waiting list during the year (active & inactive at listing)**



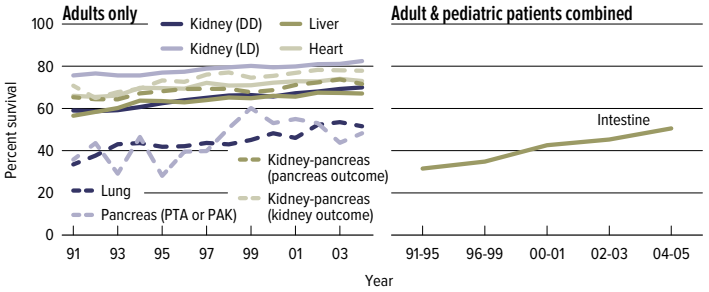
INT 2 **Transplants performed during the year (adult & pediatric combined)**



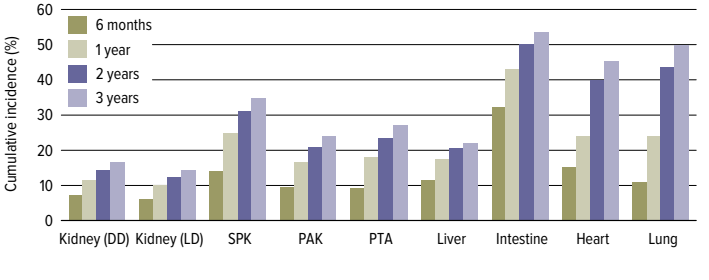
INT 3a **First-year all-cause graft survival**



INT 3b **Five-year all-cause graft survival**



INT 4 **Cumulative incidence of first reported acute rejection, 2005–2009**



in an attempt to allow sicker patients to undergo lung transplants more quickly. With implementation of this new system, many patients who would not undergo transplant were removed from the lung transplant waiting list, resulting in a precipitous decline in the number of patients listed (Figure 1a). However, the number of new listings has been relatively stable (Figure 1b).

TRANSPLANTS

The number of kidney transplants (deceased and living donor) peaked at 18,013 in 2006, declined to 17,357 in 2008, and increased again in 2009 to 17,682 (Figure 2). Pancreas transplants increased from 1,204 in 1998 to 1,483 in 2004, but declined to 1,233 in 2009. Liver transplants rose from 4,518 in 1998 to 6,651 in 2006, declined to 6,319 in 2008, and remained at 6,320 in 2009. Intestinal transplants increased more than 2-fold, from 70 in 1998 to 180 in 2009. Heart transplants fell from 2,395 in 1998 to 2,055 in 2004, but gradually increased to 2,241 in 2009. Lung transplants increased 83.7%, from 920 in 1998 to 1,690 in 2009.

OUTCOMES

One-year graft survival (survival with a functioning organ) improved over the past decade for all organ transplants (Figure 3a). One-year kidney graft survival was 92.0% for deceased donor transplants performed in 2008, and 96.5% for living donor transplants; 1-year graft survival rates were similar for pancreas after SPK (86.4%), liver (84.9%), heart (88.6%), and lung (83.1%). However, 1-year graft survival for pancreas after PTA or PAK was only 75.4%, and 1-year graft survival after intestinal transplant in 2008–2009 was 72.2%.

Five-year graft survival was 70.0% for deceased donor kidney transplants in 2004, and 82.5% for living donor transplants (Figure 3b). Five-year pancreas graft survival after SPK was 71.6%. Five-year liver graft survival was 67.1% and heart graft survival, 73.1%. However, 5-year pancreas graft survival after PTA or PAK was only 48.3%. Similarly disappointing was 5-year intestine graft survival of 50.6% (in 2004–2005) and 5-year lung graft survival of 51.6%.

The incidence of acute allograft rejection varies substantially by organ (Figure 4), and is lowest for kidneys. One-year incidence of acute rejection was 11.6% for deceased donor kidneys and 10.0% for living donor kidneys; 24.8% for pancreata after SPK, and 16.6% and 17.9% for pancreata after PAK and PTA, respectively; and 17.5% for livers, 43.1% for intestines, 24.0% for hearts, and 23.8% for lungs.

kidney

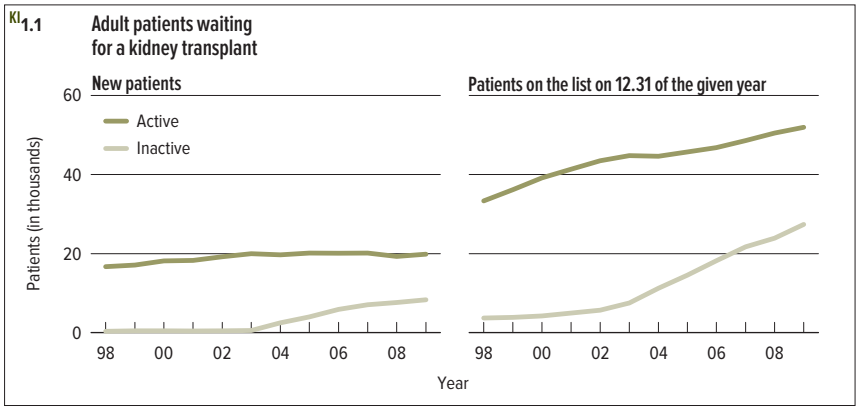
Kidney transplant highlights include the fact that the shortage of donor kidneys continues. Although 16,830 patients on the waiting list underwent kidney transplant in 2009, 5,412 listings were removed due to death (Figure 1.6). The shortage of kidneys has been accompanied by the use of deceased donor kidneys that are at increased risk to fail. Indeed, the Kidney Donor Risk Index (KDRI), which reflects the overall quality of deceased donor kidneys, has increased (Figure 2.6), and expanded criteria donor (ECD) kidneys comprised 16% of deceased donor kidneys in 2009 (Figure 2.7). At the same time, the discard rate for deceased donor kidneys has increased slightly (Figure 2.5).

Importantly, the number of kidney transplants was higher in 2009 than in 2008, reversing a trend. From 1998 to 2006, the total number of adult kidney transplants in the United States (US) increased annually (Figure 4.1), with a 34% increase during this period. Also during those years, the number of deceased donor transplants increased 26%, while the number of living donor transplants increased 51%. However, from 2006 to 2009, the total number of transplants fell 1.8%, with a 2.1% decline in deceased donor transplants and a 1.2% decline in living donor transplants. The decline in living donor transplants was first apparent in 2005; from 2004 to 2008 living donor transplants declined 9.4%. Thus, it is encouraging that in 2009 there was a 1.4% increase in total kidney transplants compared with 2008. This increase was entirely due to a 6.6% increase in living donor transplants; deceased donor transplants declined 1.4% between 2008 and 2009.

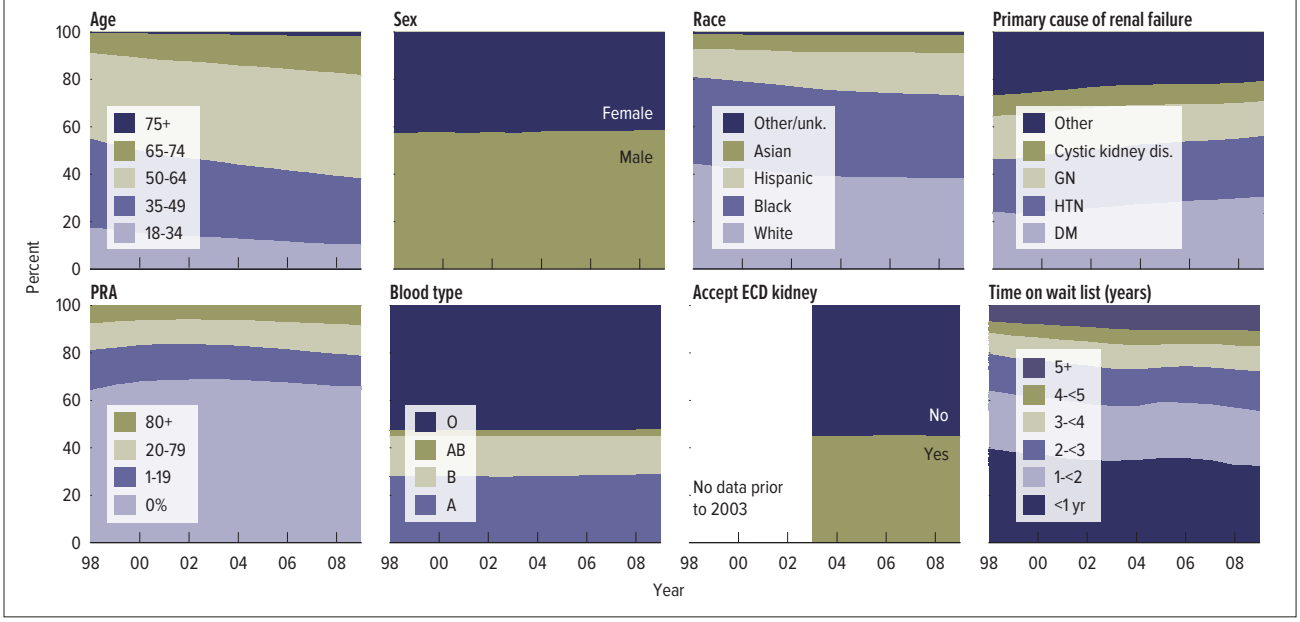
It's overwhelming what human beings can do, and to have the chance to save someone else's life is incredible.

Andrea, kidney recipient

KI 1.1 Adult patients waiting for a kidney transplant



KI 1.2 Distribution of adult patients waiting for a kidney transplant

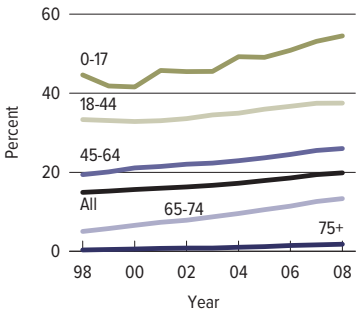


wait list

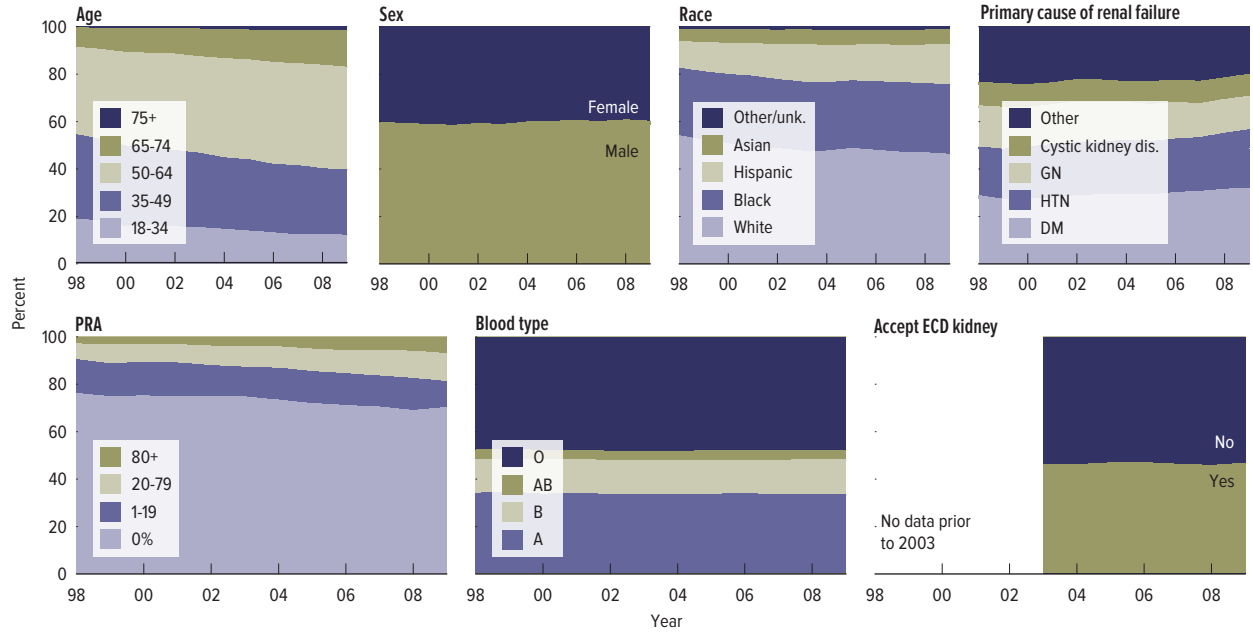
Over the past 12 years, there has been a small but steady increase in the number of new patients added to the waiting list for a deceased donor kidney, contributing to an increase in the total number of patients on the waiting list (Figure 1.1). In 2003, a major Organ Procurement and Transplantation Network (OPTN) policy change (Policy 3.5.11.1; http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_7.pdf) allowed patients on the list to accrue waiting time while inactive. Before 2003, an unknown number of patients on the list had been listed as active so they could accrue waiting time, even though they would not have accepted a kidney offer. After 2003, without this incentive to list inactive patients as active, the number of patients listed as inactive grew incrementally (Figure 1.1). Nevertheless, the growth in the total number of patients on the waiting list has been almost linear, suggesting that the growth in inactive listings since 2003 is indeed an artifact of the OPTN policy change.

The demographic profile of the deceased donor kidney transplant waiting list has changed (Figure 1.2), as have the profiles of patients added to the waiting list (Figure 1.3). The proportions of men and women have remained relatively constant. However, the proportions of whites and blacks have declined slightly, while

KI 1.4 Prevalent dialysis patients wait-listed for a kidney transplant, by age



KI 1.3 Distribution of adult patients newly listed for a kidney transplant

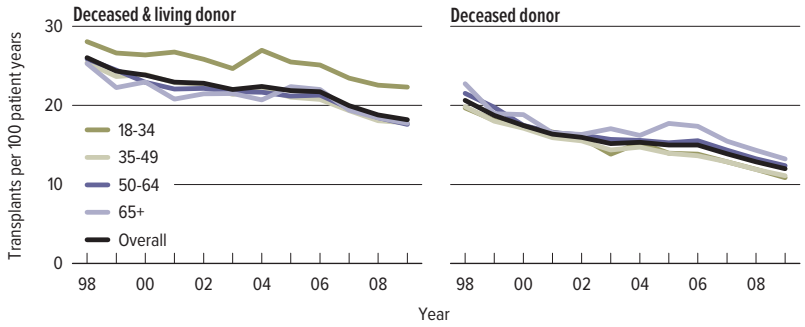


the proportion of Hispanics has grown. The proportions of patients on the waiting list due to end-stage renal disease (ESRD) from diabetes and hypertension have grown. The most striking demographic changes have been the increase in the proportion of older patients on the waiting list (Figure 1.2) and the proportion of newly listed patients who are older (Figure 1.3).

The proportions of waiting-list patients (Figure 1.2) and newly listed patients (Figure 1.3) with panel reactive antibody (PRA) higher than 0% have declined, but only slightly. The policy allowing individuals to accept an ECD kidney went into effect in 2004 (Policy 3.5.1; http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_7.pdf). Since then, 45% of listed patients have agreed to accept an ECD kidney, if offered; that proportion has varied very little since 2004.

The waiting time for prevalent patients on the deceased donor waiting list has also increased. Between 1998 and 2009, the percentage of patients waiting 2 or more years increased from 36.0% to 44.7% (Figure 1.2). Obviously, the increase in new listings has not been matched by an increase in transplants. Hence, the percentage of prevalent dialysis patients on the deceased donor kidney transplant waiting list has also increased slightly over the past 12 years (Figure 1.4). This increase has occurred in all age groups.

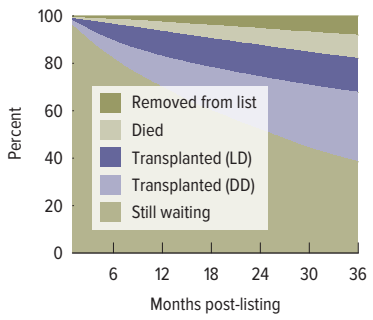
KI 1.5 Transplant rates among adult patients wait-listed for a kidney transplant, by age



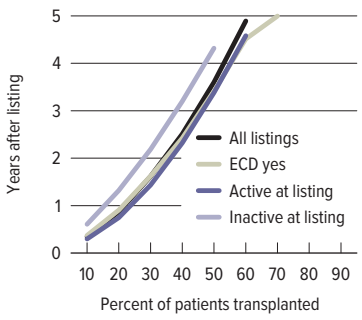
KI 1.6 Kidney transplant waiting list activity among adult patients

	2007	2008	2009
Listings at start of year	68,754	74,501	79,161
Listings added during year	31,988	32,097	33,215
Listings removed during year	26,241	27,437	27,762
Listings at end of year	74,501	79,161	84,614
Removal reason			
Deceased donor transplant	11,796	11,828	11,765
Living donor transplant	4,369	4,572	5,065
Patient died	5,041	5,306	5,412
Patient refused transplant	266	259	307
Transferred to another ctr	1,581	1,510	1,401
Improved, tx not needed	121	133	132
Too sick to transplant	992	1,243	1,475
Changed to kid.-pan. list	266	243	221
Other	1,809	2,343	1,984

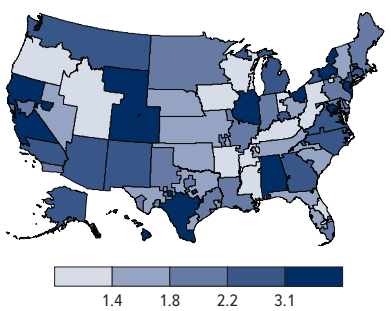
KI 1.7 Kidney tx waiting list status by month post-listing among new adult listings in 2006



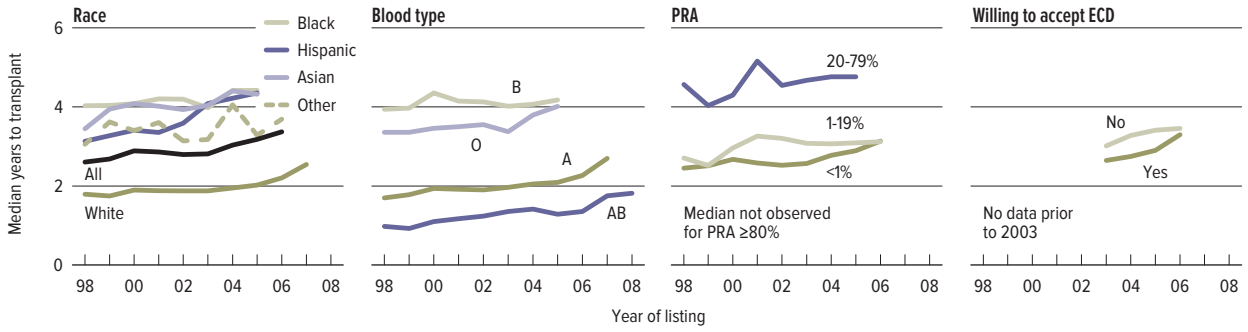
KI 1.8 Percentiles of time to kidney transplant for new adult listings, 2005–2009



KI 1.9 Median years to kidney tx (deceased donor) for adult pts transplanted in 2009, by DSA



KI 1.10 Median years to kidney transplant for wait-listed adult patients



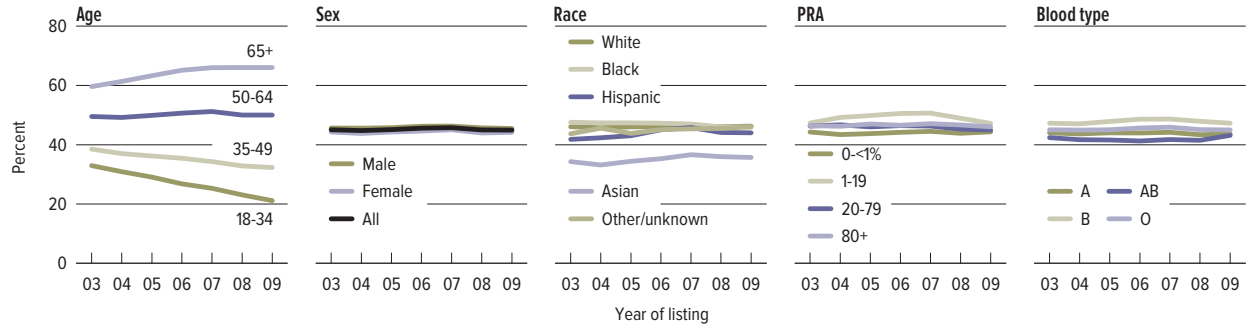
wait list

Because the number of patients needing a kidney transplant has increased at a greater rate than the number of available organs, the rate of transplants per 100 patient-years on the waiting list has continued to decline (Figure 1.5). Rates are similar among age groups, but the overall rate is higher for patients aged 18 to 34 years, reflecting a higher living donor transplant rate in this group (Figure 1.5).

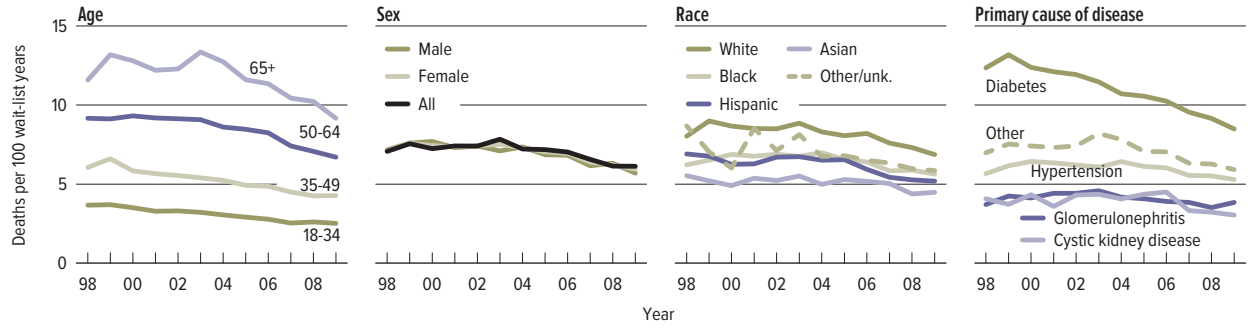
On January 1, 2009, there were 79,161 deceased donor listings. Patients listed at more than one center are counted once per listing. After additions and removals there were 84,614 listings at the end of 2009 (Figure 1.6). A kidney was received by 16,830 patients, but 5,412 listings were removed due to death, making death the second most common reason for removal from the waiting list. The number of listings removed because the patient was too sick for transplant increased from 992 in 2007 to 1,243 in 2008 and 1,475 in 2009.

By 3 years after placement on the deceased donor waiting list, only 29.7% of listings had received a deceased donor kidney (Figure 1.7). The time from listing to transplant is longer for patients listed as inactive (Figure 1.8). The waiting time for a deceased donor kidney varies by region (Figure 1.9). Median waiting times are longer for minorities than for whites (Figure 1.10). Blood type and PRA strongly influence waiting time. Waiting times were slightly shorter for patients who agreed to accept an ECD kidney,

KI 1.11 Adult listings willing to accept an ECD kidney



KI 1.12 Pre-transplant mortality rates among adult patients wait-listed for a kidney transplant



KI 1.13 Characteristics of adult patients on the kidney transplant wait list on December 31, 2009

	Level	N	%
Age	18-44	20,893	26.3
	45-64	43,999	55.4
	65-74	12,838	16.2
	75+	1,631	2.1
Gender	Male	46,446	58.5
	Female	32,915	41.5
Race	White	30,273	38.1
	Black	27,713	34.9
	Hispanic	14,322	18.0
	Asian	6,019	7.6
	Other/unk.	1,034	1.3

	Level	N	%
Primary cause of disease	Diabetes	24,104	30.4
	Hypertension	20,326	25.6
	Glomerulonephritis	11,663	14.7
	Cystic kidney dis.	6,708	8.5
	Other/unknown	16,560	20.9
Tx history	Listed for first tx	66,802	84.2
	Listed for sub. tx	12,559	15.8
Blood type	A	22,715	28.6
	B	12,868	16.2
	AB	2,348	3.0
	O	41,430	52.2

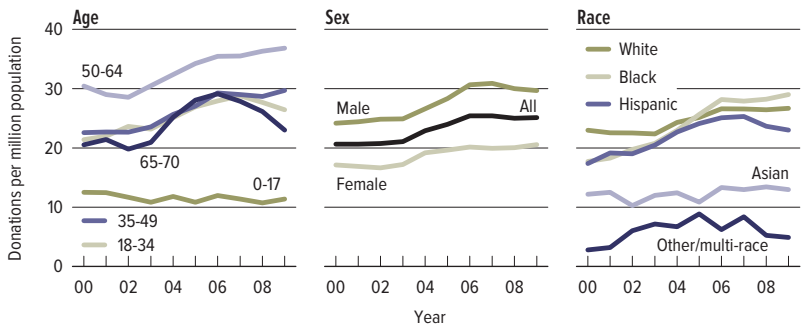
	Level	N	%
PRA	<10%	59,361	74.8
	10%+	19,999	25.2
	Unknown	1	0.0
Time on list	<1 year	25,630	32.3
	1-<2	18,287	23.0
	2-<3	13,259	16.7
	3-<4	8,362	10.5
	4-<5	5,088	6.4
	5+	8,735	11.0
ECD kidney	Will not accept	43,821	55.2
	Will accept	35,540	44.8

but it is important to remember that these differences are not adjusted for other factors that may affect waiting time (Figure 1.10).

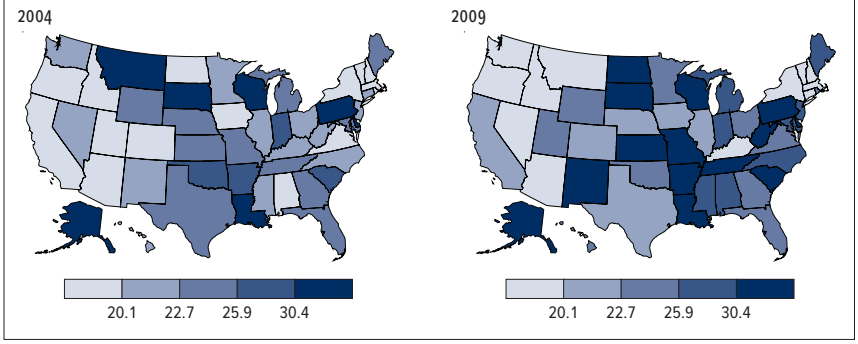
Since 2003, equal proportions of men and women have agreed to accept an ECD kidney (Figure 1.11). Older patients are more likely to be listed for an ECD kidney. Willingness to accept an ECD kidney is increasing slightly among patients aged 65 years or older and decreasing in those aged younger than 50 years (Figure 1.11). Interestingly, blood type and PRA influence waiting time dramatically (Figure 1.10) but do not seem to affect the proportions of patients listing for ECD kidneys (Figure 1.11). Mortality rates on the waiting list vary by age, as expected (Figure 1.12). Mortality rates are highest for whites compared with other groups. Mortality rates are highest for patients with ESRD caused by diabetes as opposed to other causes.

On December 31, 2009, 73.7% of wait-listed patients were aged 45 years or older and 18.3% were aged 65 years or older (Figure 1.13); 38.1% were white, 34.9% black, 18.0% Hispanic, and 7.6% Asian. Most (56.0%) had kidney disease caused primarily by diabetes or hypertension. There were 15.8% on the list for a repeat kidney transplant, and 44.8% were listed for an ECD kidney. Forty-five percent had been waiting at least 2 years, and 11.0% had been waiting at least 5 years.

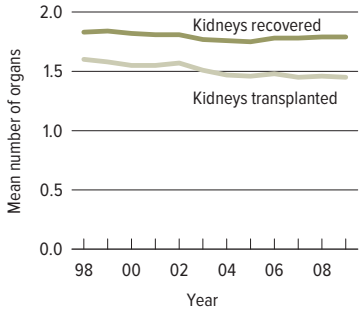
KI 2.1 Kidney donations from deceased donors per million population



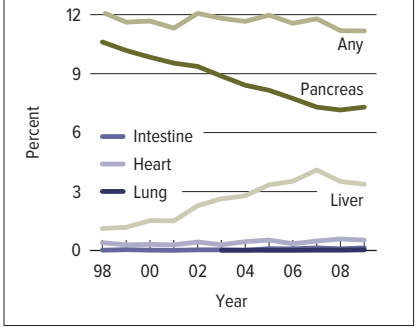
KI 2.2 Deceased donor kidney donation rates (per million population)



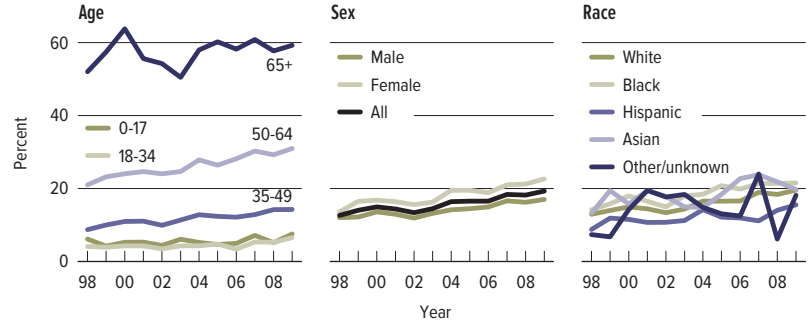
KI 2.3 Kidneys recovered per donor & kidneys transplanted per donor



KI 2.4 Deceased donor kidneys transplanted with another organ



KI 2.5 Discard rates for kidneys recovered for transplant



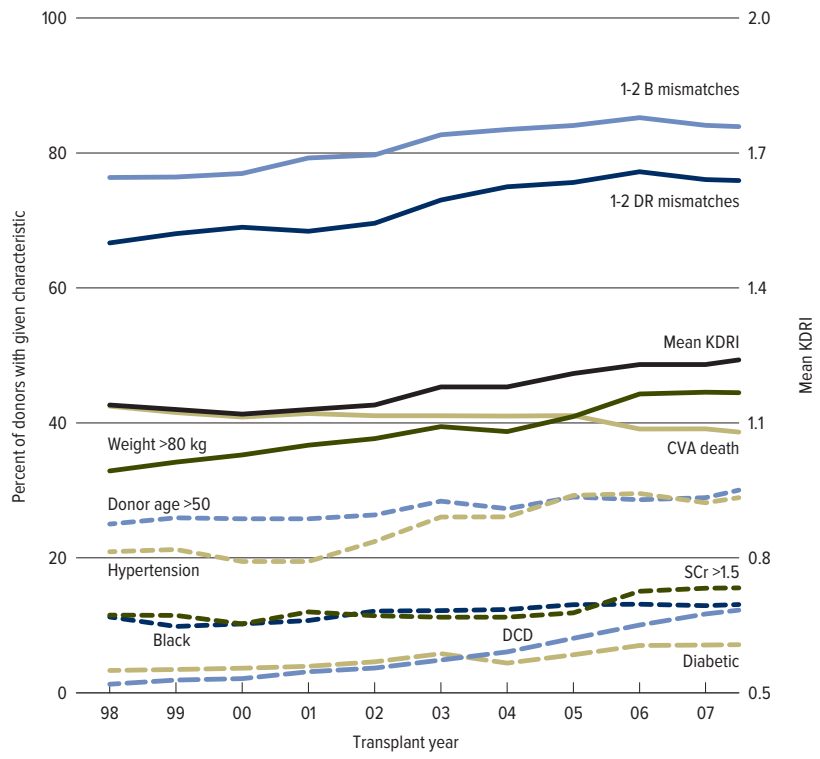
deceased donation

Ideally, the deceased donation rate should reflect donations among eligible donors. However, it is difficult to collect reliable data using uniform definitions of eligible deaths. Data on donations per million population (pmp), although crude, have been collected worldwide. Deceased donations pmp have increased over the past decade (Figure 2.1). Deceased donations pmp are similar for ages 18 to 49 and 65 to 70 years, higher for ages 50 to 64 years, and lowest for children and adolescents. Deceased donation rates tend to be higher for men than women. Donation rates are similar for whites, blacks, and Hispanics, but lower for Asians. There is substantial geographic heterogeneity in rates of deceased kidney donation (Figure 2.2). The number of kidneys recovered and transplanted per donor has declined only slightly (Figure 2.3).

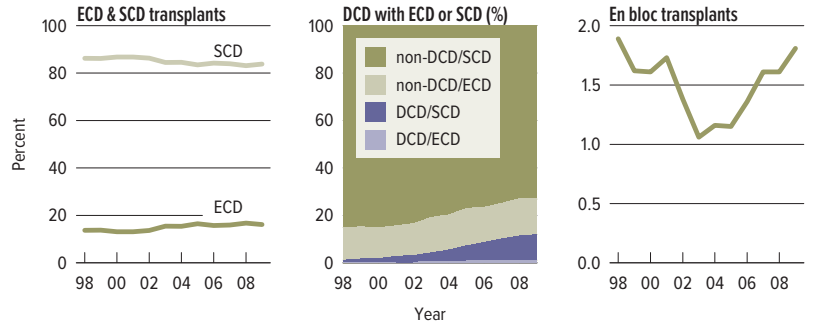
In 2009, 11.2% of deceased donor kidneys were transplanted with another organ; this has changed little over the past 12 years (Figure 2.4). However, the number of deceased donor kidneys transplanted with a pancreas declined, while the number transplanted with a liver increased, each plateauing in the past 2 to 3 years.

The discard rate for deceased donor kidneys has increased slightly over the past several years (Figure 2.5). Discard rates are proportionally higher for older donor age, and are as high as 60% for donors aged 60 years or older. The KDRI predicts kidney allograft survival based on characteristics of the deceased donor kid-

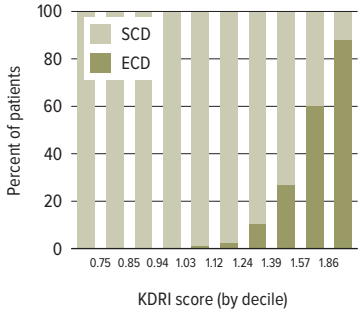
KI 2.6 Major components of kidney donor risk index (KDRI) over time, against mean KDRI



KI 2.7 ECD, SCD, DCD, & en bloc kidney transplants



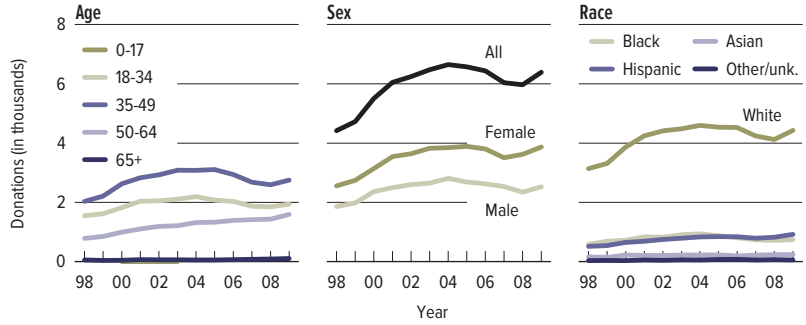
KI 2.8 Kidney donor risk index (KDRI) scores for ECD & SCD kidneys, 2009



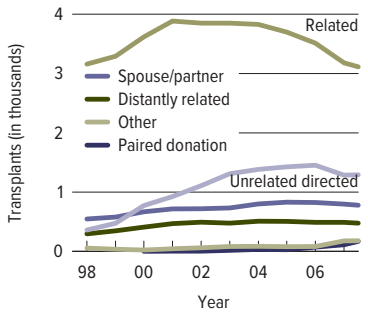
ney, adjusted for characteristics of the recipient and the transplant. A higher KDRI indicates a higher risk of graft failure than a lower KDRI. The mean KDRI for patients receiving a deceased donor kidney has increased (Figure 2.6). The components of the KDRI have changed at different rates over time.

An ECD kidney is a kidney from any brain-dead donor aged 60 years or older, or from a donor aged 50 to 59 years with 2 of the following: hypertension, terminal serum creatinine greater than 1.5 mg/dL, or death from a cerebrovascular accident (http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_7.pdf). Donation after circulatory death (DCD) can yield ECD or standard criteria donor (SCD) kidneys. From 1998 to 2009, the overall percentage of non-DCD/ECD deceased donors has remained relatively constant (13.6% in 1998 to 15.0% in 2009), whereas the percentage of DCD/SCD donors has risen over that time (from 1.1% in 1998 to 10.8% in 2009). Conversely, the overall percentage of non-DCD/SCD donors has fallen (85.2% in 1998 to 73.1% in 2009). DCD/ECD donors have become slightly more prevalent (0.1% in 1998 to 1.1% in 2009). Two kidneys can be transplanted *en bloc*; this strategy has been used to transplant kidneys that otherwise have a high risk of failure. Currently, only 1.8% of adult deceased donor kidneys are transplanted *en bloc* (Figure 2.7). Kidneys with higher KDRI scores are increasingly likely to be ECD kidneys and vice versa (Figure 2.8).

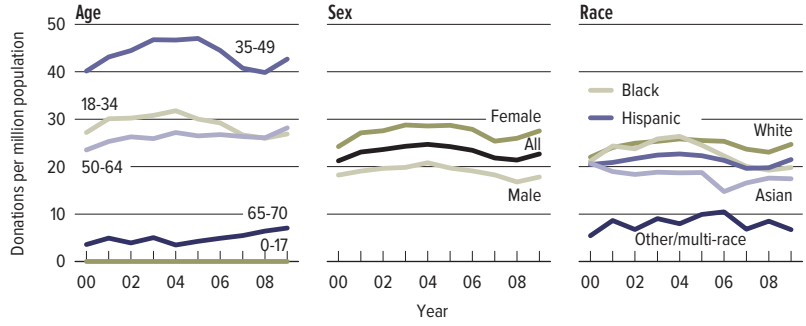
KI 3.1 Kidney donations from living donors



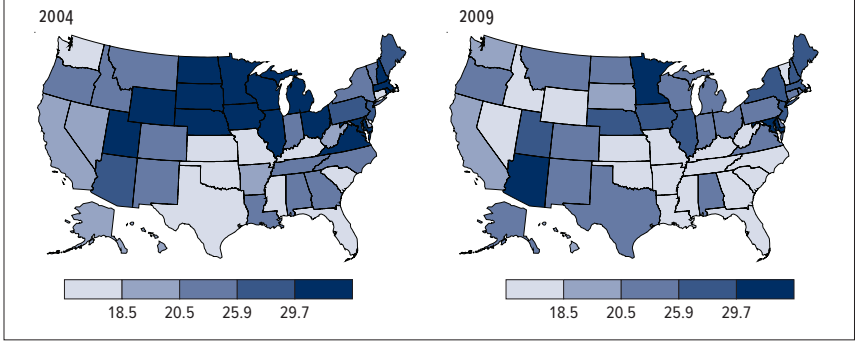
KI 3.2 Kidney transplants from living donors, by donor relation



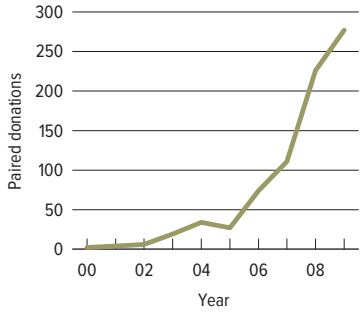
KI 3.3 Living donor kidney donation rates per million population



KI 3.4 Living donor kidney donation rates per million population (age <70), by state



KI 3.5 Paired kidney donations



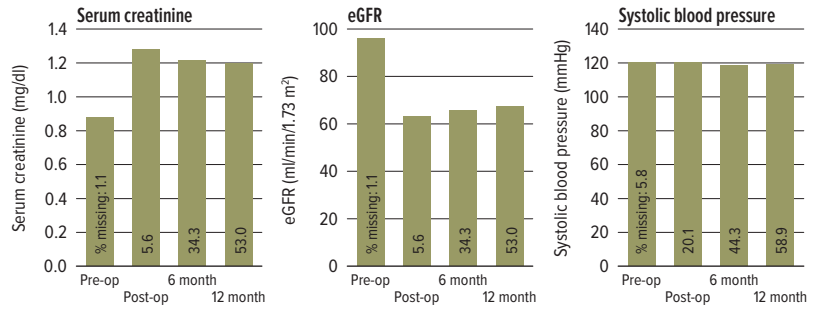
live donation

Living kidney donations increased every year from 1998 to 2004, declined from 2005 to 2008, and increased by 7.0% in 2009 compared with 2008 (Figure 3.1). The 2009 increase in living donations was seen in all age groups and was greatest in Hispanics (12.0%). The increase in living donors in 2009 compared with 2008 was 3.3% for related donors, 8.4% for distantly related donors, 10.4% for spouses/partners, and 6.3% for unrelated donors (Figure 3.2).

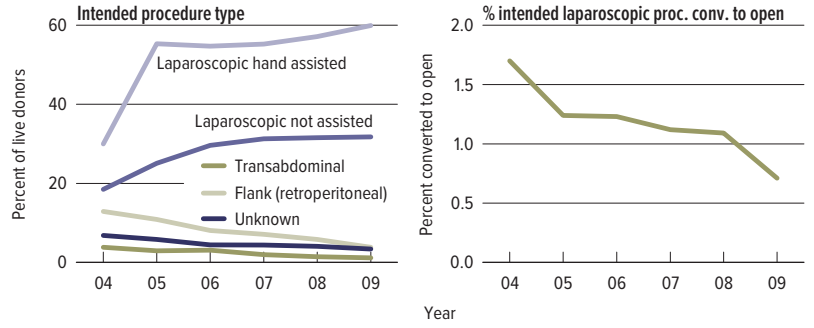
Parallel increases occurred in the rates of living kidney donation pmp in 2009 compared with 2008 (Figure 3.3). The rate of living kidney donation was highest for patients aged 35 to 49 years and lowest for those aged 0 to 17 years. Rates were higher for women than men, and were similar for whites, blacks, and Hispanics, and slightly lower for Asians. Substantial geographic variation remains in the rates of living kidney donation (Figure 3.4). Rates are high in New England and the north central US, and lowest in the southeast.

The use of kidney donations for paired exchange is relatively new in the US. The numbers, albeit small, are notable given that recipients are often patients for whom it is difficult to find an appropriate match (Figure 3.5). Despite an effort to improve reporting for living kidney donor follow-up, the number of donors without follow-up data remains high (Figure 3.6). For patients who donated a kidney in 2008, the proportions of serum creati-

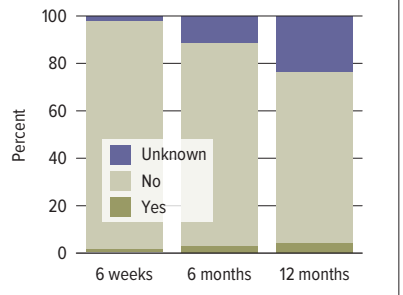
KI 3.6 Mean pre- & post-operative serum creatinine, eGFR, & systolic blood pressure among kidney donors, 2008



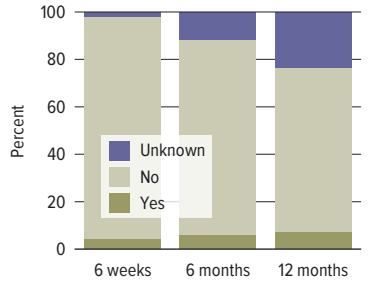
KI 3.7 Intended kidney transplant procedure type, & percent of intended laparoscopic procedures converted to open



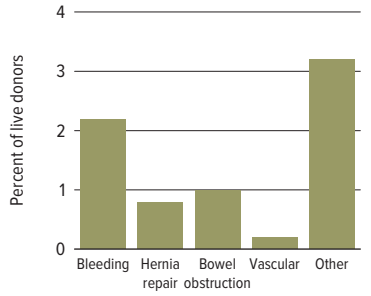
KI 3.8 Readmission to the hospital among live kidney donors, 2008



KI 3.9 Kidney complications among live kidney donors, 2008



KI 3.10 Type of complications among live kidney donors in the first six weeks, 2008

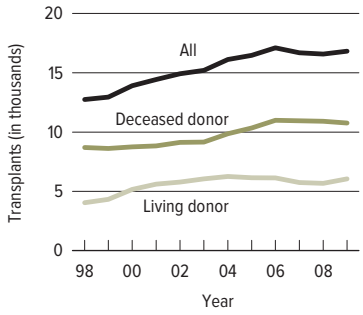


nine values that were missing at post-op, 6 months, and 12 months were 5.6%, 34.3%, and 53.0%, respectively (Figure 3.6). The proportions with missing blood pressure values were even higher, missing at post-op, 6 months, and 12 months in 20.1%, 44.3%, and 58.9%, respectively.

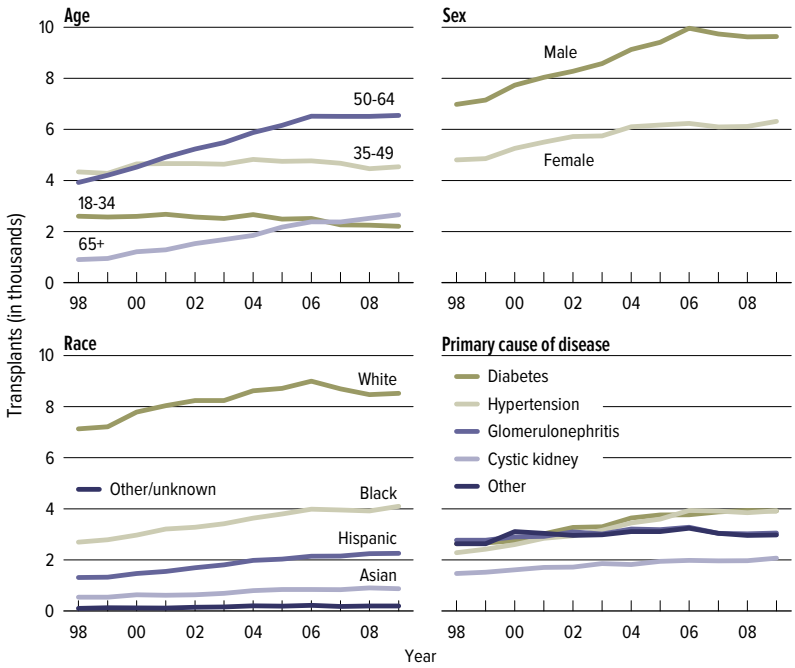
Most donor nephrectomies are now performed laparoscopically, with almost twice as many hand-assisted as not (Figure 3.7). In 2009, only 4.9% of donor nephrectomies used a retroperitoneal flank (3.8%) or intra-abdominal (1.1%) approach. The proportion of intended laparoscopic donor nephrectomies that were converted to open procedures declined to less than 1% in 2009 (Figure 3.7).

Readmission rates (Figure 3.8) and complications (Figure 3.9) appear to be low for living kidney donors in the first year; some information is not known, however. In 2008, major complications included bleeding in 2.2%, need for wound hernia repair in 0.8%, and bowel obstruction in 1.0% (Figure 3.10). The numbers of living donor deaths occurring within 30 days of donation and thought to be donation-related were 0 in 2005, 1 in 2006, 0 in 2007, 1 in 2008, and 1 in 2009. The numbers (and percentages) of living donor deaths from any cause that occurred within 1 year of donation were 2 (0.03%) in 2005, 5 (0.08%) in 2006, 3 (0.05%) in 2007, 3 (0.05%) in 2008, and 2 (0.05%) in 2009.

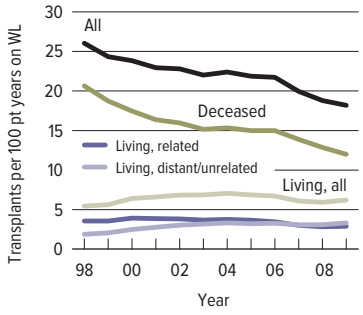
KI 4.1 Total adult kidney transplants (includes kidney-pancreas)



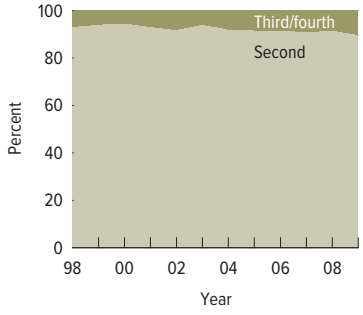
KI 4.2 Adult kidney transplants



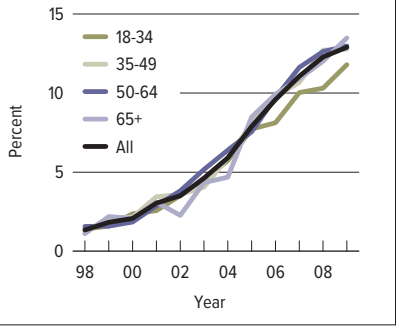
KI 4.3 Kidney transplant rates in adult recipients



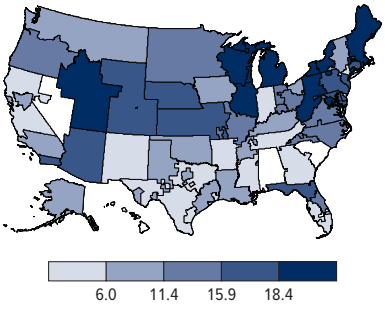
KI 4.4 Distribution of re-transplants among adult patients with two or more transplants



KI 4.5 Use of DCD kidneys among adult, kidney-alone transplant recipients, by recipient age



KI 4.6 Percent of adult, deceased donor, kidney transplants that are DCD, by DSA, 2009



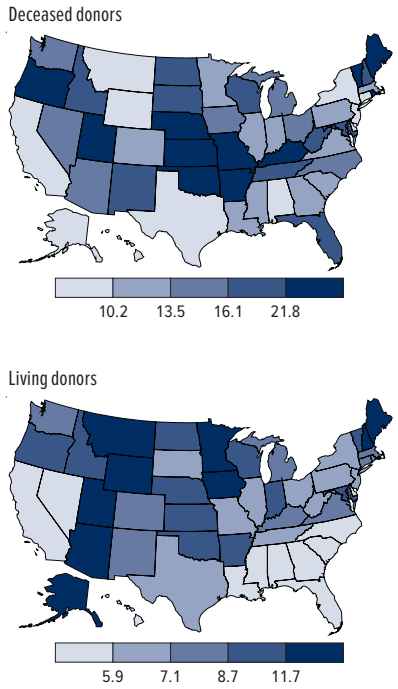
transplant

From 1998 to 2006, the number of adult kidney transplants increased 34%; deceased donor transplants increased 26%, and living donor transplants increased 51% (Figure 4.1). However, from 2006 to 2009, the number of transplants fell 1.8%, with a 2.1% decline in deceased donor transplants and a 1.2% decline in living donor transplants. It is therefore encouraging that, between 2008 and 2009, there was a 1.4% increase in kidney transplants, which was entirely due to a 6.6% increase in living donor transplants, while deceased donor transplants declined 1.4%.

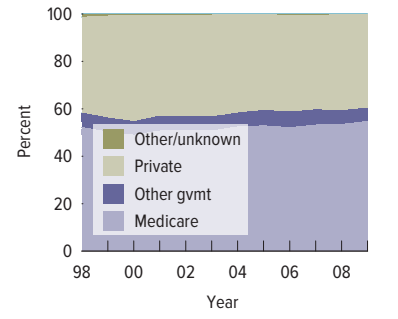
The largest increase in transplants between 2008 and 2009 was in patients aged 65 years or older (5.6%); transplants in patients aged 18 to 34 years declined 2.1% (Figure 4.2). Most of the increase was in women (3.3%) versus men (0.1%). The 2009 increase was greatest in blacks (4.8%).

Unfortunately, the increase in 2009 was not enough to keep pace with the increase in the number of patients on the deceased donor waiting list. Hence, the rate of transplants per 100 patient-years on the waiting list declined 3.2% in 2009 (Figure 4.3). Since 1998, the rate of adult kidney transplants has declined by more than 30%. In 2009 12.1% of transplants were repeat transplants, and 89.5% of the repeat transplants were second, 9.5% third, and 1.0% fourth transplants (Figure 4.4). The proportion of deceased donor transplants using DCD kidneys has grown more than 8-fold, and

KI 4.7 Kidney transplant rates per 100 pt years on the waiting list, adult patients, 2009



KI 4.9 Insurance coverage among adult kidney transplant recipients at time of transplant



KI 4.8 Characteristics of adult kidney transplant recipients, 2009

	Level	All N	All %	Deceased N	Deceased %	Living N	Living %
Age	18-34	2,208	13.8	1,000	10.1	1,208	20.0
	35-49	4,541	28.4	2,643	26.7	1,898	31.4
	50-64	6,556	41.1	4,363	44.0	2,193	36.2
	65+	2,659	16.7	1,906	19.2	753	12.4
Gender	Female	6,322	39.6	3,969	40.0	2,353	38.9
	Male	9,642	60.4	5,943	60.0	3,699	61.1
Race	White	8,525	53.4	4,530	45.7	3,995	66.0
	Black	4,105	25.7	3,259	32.9	846	14.0
	Hispanic	2,259	14.2	1,376	13.9	883	14.6
	Asian	874	5.5	602	6.1	272	4.5
	Other/unknown	201	1.3	145	1.5	56	0.9
Primary cause of disease	Diabetes	3,921	24.6	2,581	26.0	1,340	22.1
	Hypertension	3,931	24.6	2,759	27.8	1,172	19.4
	Glomerulonephritis	3,060	19.2	1,676	16.9	1,384	22.9
	Cystic kidney disease	2,070	13.0	1,126	11.4	944	15.6
	Other cause	2,982	18.7	1,770	17.9	1,212	20.0
Blood type	A	5,954	37.3	3,646	36.8	2,308	38.1
	B	2,096	13.1	1,294	13.1	802	13.3
	AB	768	4.8	534	5.4	234	3.9
	O	7,146	44.8	4,438	44.8	2,708	44.7
PRA	<10%	11,257	70.5	6,666	67.3	4,591	75.9
	10%+	3,667	23.0	2,631	26.5	1,036	17.1
	Unk.	1,040	6.5	615	6.2	425	7.0
History of renal	Preemptive transplant	2,639	16.5	905	9.1	1,734	28.7
replacement therapy	<1 year	2,169	13.6	687	6.9	1,482	24.5
	<3 years	4,056	25.4	2,536	25.6	1,520	25.1
	<5 years	2,856	17.9	2,371	23.9	485	8.0
	5+ years/unknown	4,244	26.6	3,413	34.4	831	13.7
Insurance	Private	6,270	39.3	2,677	27.0	3,593	59.4
	Medicare	8,729	54.7	6,581	66.4	2,148	35.5
	Other	965	6.0	654	6.6	311	5.1
HLA mismatches with donor	0	1,264	7.9	787	7.9	477	7.9
	1	371	2.3	87	0.9	284	4.7
	2	1,391	8.7	405	4.1	986	16.3
	3	2,904	18.2	1,301	13.1	1,603	26.5
	4	3,594	22.5	2,630	26.5	964	15.9
	5	4,221	26.4	3,117	31.4	1,104	18.2
	6	2,089	13.1	1,516	15.3	573	9.5
	Unk.	130	0.8	69	0.7	61	1.0
Kidney transplant history	First transplant	14,037	87.9	8,653	87.3	5,384	89.0
	Subsequent transplant	1,927	12.1	1,259	12.7	668	11.0
DCD status *	Non-DCD			8,633	87.1		
	DCD			1,279	12.9		
SCD/ECD status *	SCD			7,892	79.6		
	ECD			2,020	20.4		
Total		15,964	100.0	9,912	100.0	6,052	100.0

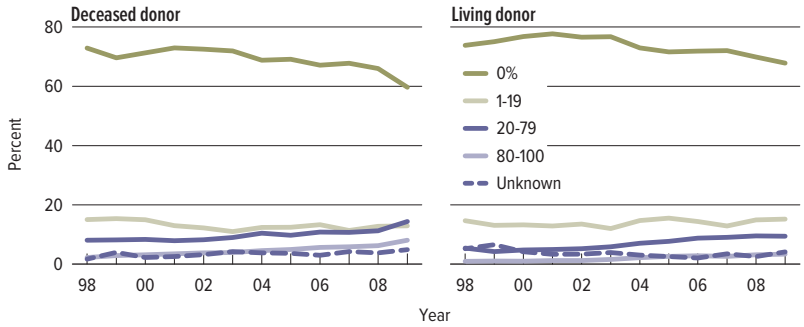
* for deceased donor transplant only

in 2009 DCD kidneys comprised 13% of deceased donor kidneys (Figure 4.5). There is remarkable heterogeneity among donor service areas (DSAs) in the proportion of deceased donor transplants using DCD kidneys, from 0% to 38% in 2009 (Figure 4.6).

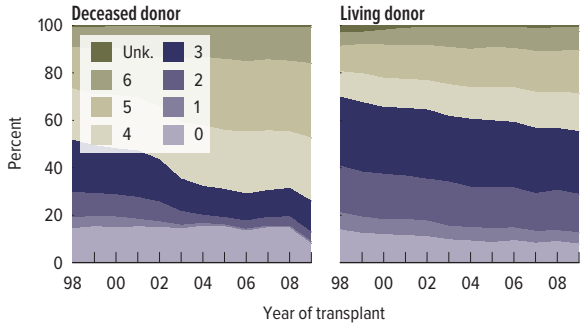
The rates of deceased and living donor kidney transplants per 100 patient-years on the waiting list also show remarkable geographic variation (Figure 4.7). Rates of deceased donor kidney transplants were 6.5 and 9.7 per 100 patient-years on the waiting list in California and Texas, respectively, but in neighboring states Oregon and Oklahoma, the rates were more than 2-fold higher, 32.8 and 21.8 per 100 patient-years on the waiting list, respectively. Rates for living donor transplants were lowest in California, Nevada, and the southeastern states and were 2- to 3-fold higher in Minnesota, Iowa, New England, and some western states (Figure 4.7).

In 2009, 54.7% of kidney transplant recipients had Medicare as their primary insurance provider (Figures 4.8 and 4.9). In 2009, 16.5% of kidney transplants were preemptive (transplant before beginning maintenance dialysis), but 12.1% were repeat transplants, and 26.6% were for patients who had been on renal replacement therapy for 5 or more years before transplant (Figure 4.8). Also in 2009, 12.9% of deceased donor kidney transplants used DCD kidneys, and 20.4% used ECD kidneys (Figure 4.8).

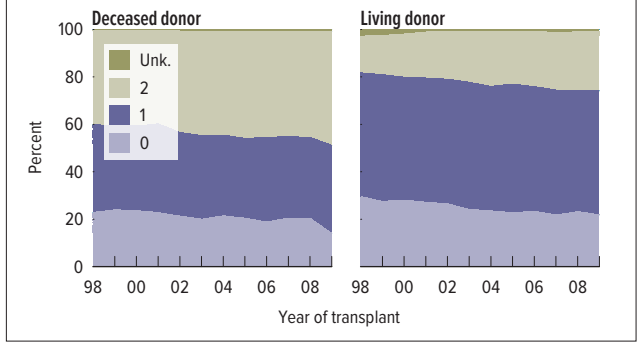
KI 5.1 PRA at time of kidney transplant in adult recipients



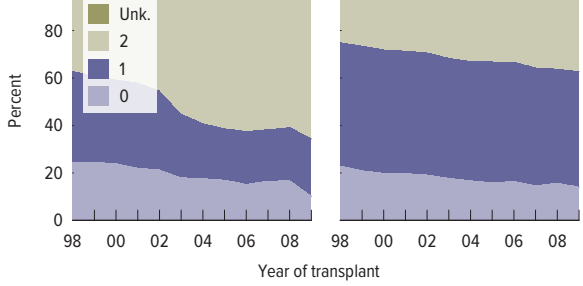
KI 5.2 Total HLA mismatches among adult kidney transplant recipients



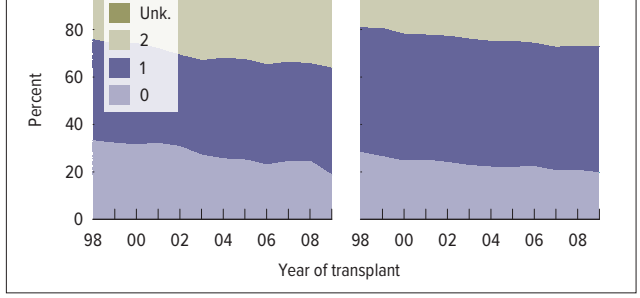
KI 5.3 HLA-A mismatches among adult kidney transplant recipients



KI 5.4 HLA-B mismatches among adult kidney transplant recipients



KI 5.5 HLA-DR mismatches among adult kidney transplant recipients



donor-recipient matching

In general, the immunological risk of kidney transplant has increased over the past 12 years. For recipients of deceased donor kidneys, the proportion with a PRA level of 0% at the time of transplant has declined from 72.9% in 1998 to 59.7% in 2009 (Figure 5.1). Over the same period, the proportion with a PRA level of 80% to 100% has increased from 2.2% to 8.1%. For recipients of living donor kidneys, the proportion with a PRA level of 0% at the time of transplant declined only slightly, from 73.8% in 1998 to 67.9% in 2009, while the proportion with a PRA level of 80% to 100% increased from 0.9% to 3.4%.

Over the past several years, the proportion of patients with 3 or fewer donor/recipient human leukocyte antigen (HLA) mismatches has been decreasing (Figure 5.2). For example, the percentage of 0 HLA mismatches declined from 14.3% in 1998 to 7.9% in 2009 for deceased donor transplants, and from 13.9% to 7.9% for living donor transplants. Similar declines in the degree of HLA matching are seen for HLA-A (Figure 5.3), HLA-B (Figure 5.4), and HLA-DR mismatches (Figure 5.5).

The risk for cytomegalovirus (CMV) infection after transplant is largely determined by the donor and recipient antibody status (indicating prior CMV infection). The highest risk for transmission of CMV occurs when the donor has had CMV infection and the recipient has not. Between 2005 and 2009, 17.4% of deceased

KI 5.6 Adult kidney donor-recipient cytomegalovirus (CMV) serology matching, 2005–2009

	DECEASED DONOR				LIVING DONOR			
RECIPIENT	Neg.	Pos.	Unk.	Total	Neg.	Pos.	Unk.	Total
Negative	11.4	17.4	0.1	29.0	20.9	14.4	3.3	38.6
Positive	23.1	42.8	0.3	66.1	18.9	32.6	4.9	56.4
Unknown	1.8	3.0	0.0	4.9	1.3	1.4	2.3	5.0
Total	36.3	63.2	0.5	100	41.1	48.4	10.6	100

KI 5.7 Adult kidney donor-recipient Epstein-Barr virus (EBV) serology matching, 2005–2009

	DECEASED DONOR				LIVING DONOR			
RECIPIENT	Neg.	Pos.	Unk.	Total	Neg.	Pos.	Unk.	Total
Negative	0.6	7.7	2.7	11.0	2.1	5.8	3.1	10.9
Positive	3.0	40.1	17.1	60.3	3.9	46.1	11.6	61.5
Unknown	1.2	16.5	11.1	28.8	0.9	5.9	20.8	27.5
Total	4.8	64.3	30.9	100	6.8	57.7	35.5	100

KI 5.8 Adult kidney donor-recipient hepatitis B core antibody (HBcAb) serology matching, 2005–2009

	DECEASED DONOR				LIVING DONOR			
RECIPIENT	Neg.	Pos.	Unk.	Total	Neg.	Pos.	Unk.	Total
Negative	68.1	2.9	0.2	71.2	61.1	1.4	12.1	74.6
Positive	7.2	1.0	0.0	8.3	3.1	0.5	1.0	4.6
Unknown	19.6	0.9	0.0	20.6	6.1	0.1	14.6	20.8
Total	95.0	4.8	0.2	100	70.3	2.1	27.6	100

KI 5.9 Adult kidney donor-recipient hepatitis B surface antigen (HBsAg) serology matching, 2005–2009

	DECEASED DONOR				LIVING DONOR			
RECIPIENT	Neg.	Pos.	Unk.	Total	Neg.	Pos.	Unk.	Total
Negative	87.8	0.0	0.2	88.0	77.7	0.0	12.1	89.7
Positive	2.3	0.0	0.0	2.3	1.3	0.0	0.2	1.5
Unknown	9.7	0.0	0.0	9.8	3.9	0.0	4.9	8.8
Total	99.7	0.0	0.3	100	82.8	0.0	17.2	100

KI 5.10 Adult kidney donor-recipient hepatitis C serology matching, 2005–2009

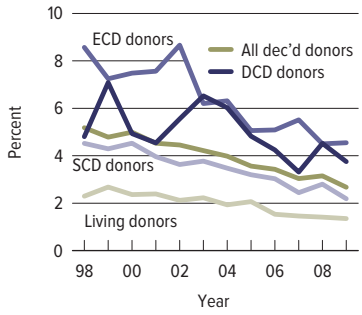
	DECEASED DONOR				LIVING DONOR			
RECIPIENT	Neg.	Pos.	Unk.	Total	Neg.	Pos.	Unk.	Total
Negative	82.8	0.3	0.2	83.2	78.4	0.5	9.5	88.4
Positive	4.7	1.9	0.0	6.6	2.7	0.0	0.3	3.0
Unknown	9.8	0.3	0.0	10.1	4.2	0.0	4.4	8.6
Total	97.3	2.5	0.2	100	85.3	0.6	14.2	100

KI 5.11 Adult kidney donor-recipient human immunodeficiency virus (HIV) serology matching, 2005–2009

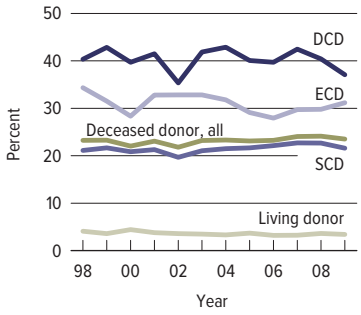
	DECEASED DONOR				LIVING DONOR			
RECIPIENT	Neg.	Pos.	Unk.	Total	Neg.	Pos.	Unk.	Total
Negative	80.3	0.0	0.1	80.4	72.9	0.0	9.1	82.0
Positive	0.5	0.0	0.0	0.5	0.2	0.0	0.1	0.3
Unknown	19.2	0.0	0.0	19.2	3.9	0.0	13.8	17.7
Total	99.9	0.0	0.1	100	77.0	0.0	23.0	100

donor recipients were in this high-risk category, as indicated by a serology match between a donor positive and a recipient negative (D+/R-) for CMV. Among living donor transplant recipients, 14.4% were D+/R- (Figure 5.6). Of even more concern is transmission of Epstein-Barr virus (EBV) infection, which can cause PTLD. At increased risk (D+/R-) for EBV and PTLD were 7.7% of adult deceased donor kidney recipients and 5.8% of living donor kidney recipients (Figure 5.7). Few patients appeared to be at risk for hepatitis B virus (HBV) infection from the transplanted kidney; 2.9% of deceased donor recipients were cases of D+/R- for hepatitis B core antibody (HBcAb; indicating prior HBV infection); for living donor recipients, the percentage was 1.4% (Figure 5.8). Interestingly, only 2.3% of deceased and 1.5% of living donor recipients were HBV surface antigen (HBsAg) positive, indicating either prior infection or immunization (recommended in guidelines) (Figure 5.9). Only 0.3% of deceased donor recipients were cases of D+/R- for hepatitis C virus (HCV) antibody, and 1.9% were D+/R+ for HCV. There were 0.5% living donor kidney recipients D+/R- for HCV and 0.0% D+/R+ for HCV (Figure 5.10). Fortunately, there were no recorded instances of recipients receiving kidneys from donors positive for human immunodeficiency virus (HIV) antibody (Figure 5.11).

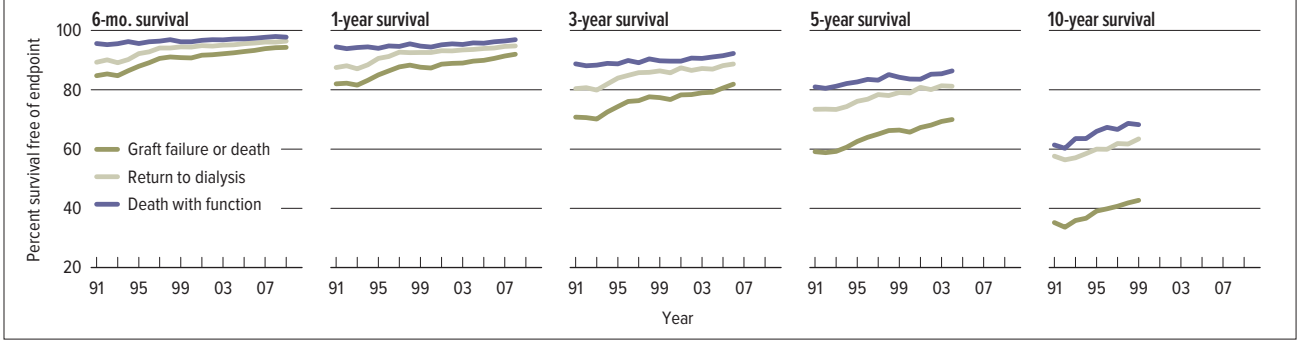
KI 6.1 Graft failure within 90 days among adult kidney transplant recipients



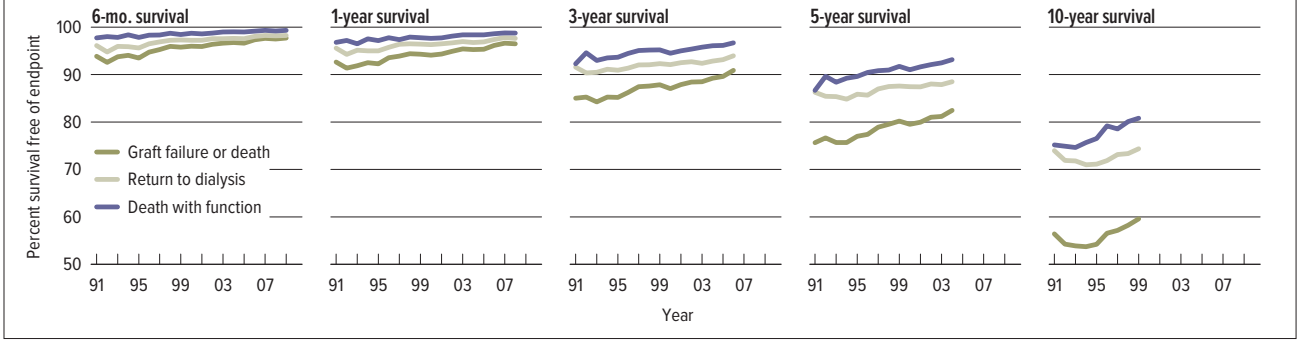
KI 6.2 Delayed graft function among adult kidney transplant recipients



KI 6.3 Outcomes among adult kidney transplant recipients: deceased donor



KI 6.4 Outcomes among adult kidney transplant recipients: living donor



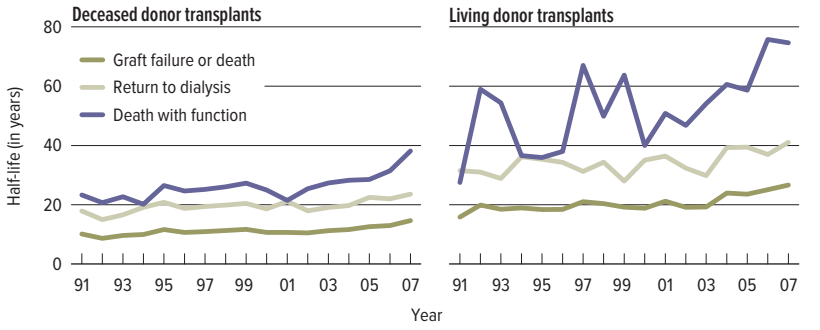
outcomes

Outcomes have continued to improve after kidney transplant. The loss of a kidney graft within 90 days of transplant declined from 5.2% in 1998 to 2.7% in 2009 (Figure 6.1). In 2009, the proportion of patients with primary non-function was 1.4% for living donor kidneys and 2.7% for deceased donor kidneys (4.6% for ECD, 3.8% for DCD, and 2.2% for SCD).

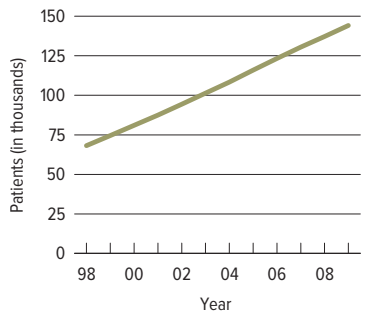
In 2009, delayed graft function (DGF), defined as the need for dialysis during the first week after transplant, occurred in 23.5% of recipients of deceased donor kidneys and 3.4% of recipients of living donor kidneys (Figure 6.2). In 2009, DGF occurred in 21.6% of SCD kidney recipients, 31.2% of ECD kidney recipients, and 37.1% of DCD kidney recipients. The incidence of DGF has changed little over the past 12 years.

Graft survival (i.e., survival with a functioning graft) has continued to improve. Graft survival for deceased donor kidneys in 2009 was 94.4% at 6 months; for transplants in 2008, 92.0% at 1 year; for transplants in 2006, 81.9% at 3 years; for transplants in 2004, 70.0% at 5 years; and for transplants in 1999, 42.7% at 10 years (Figure 6.3). Graft survival for living donor transplants in 2009 was 97.7% at 6 months; for transplants in 2008, 96.5% at 1 year; for transplants in 2006, 90.9% at 3 years; for transplants in 2004, 82.5% at 5 years; and for transplants in 1999, 59.6% at 10 years (Figure 6.4). One-year graft survival will be difficult to

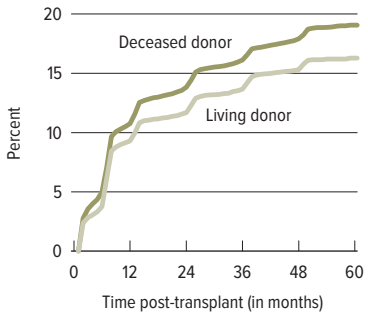
KI 6.5 Half-lives for adult kidney transplant recipients surviving with a functioning graft for at least one year



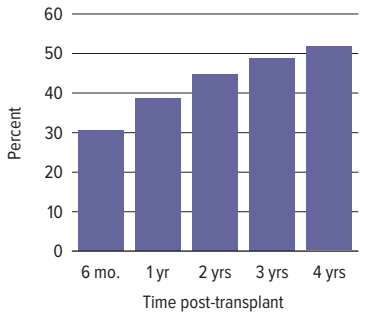
KI 6.6 Adult recipients alive & with a functioning kidney transplant on June 30 of the year



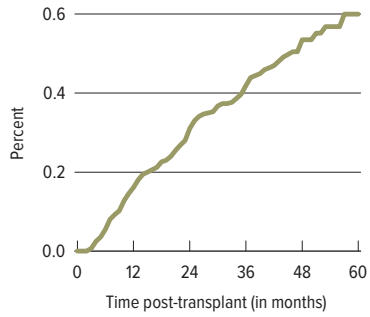
KI 6.7 Incidence of first acute rejection among adult pts receiving a kidney tx in 2005–09



KI 6.8 Reported hospitalizations among adult pts receiving a kidney transplant in 2005–2009



KI 6.9 Incidence of PTLD among adult pts receiving a kidney transplant in 2005–2009

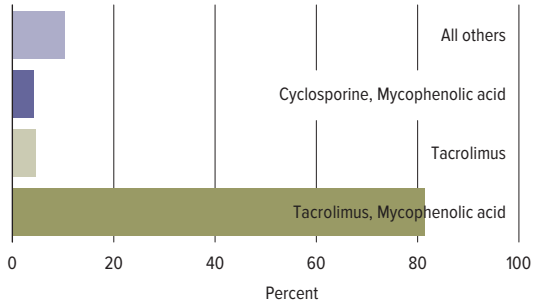


improve on, but there is much room for improvement in 10-year graft survival.

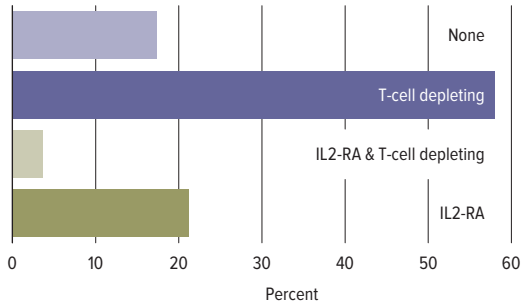
The rate of late graft failure is traditionally measured by the graft half-life conditional on 1-year survival, defined as the time to when half of grafts surviving at least 1 year are still functioning. Graft half-lives for deceased and living donor kidneys have increased (Figure 6.5). For deceased donor kidneys, the half-life increased 45%, from 10.1 years for transplants in 1991 to 14.7 years for transplants in 2007. For living donor kidneys, the half-life increased 68.2%, from 15.8 years for transplants in 1991 to 26.6 years for transplants in 2007. Remarkably, the half-life of a deceased donor kidney in 2007 (14.7 years) is substantially less than the half-life of a living donor kidney in 1991 (26.6 years). This suggests there is substantial room to improve the rate of late graft failure, at least for recipients of deceased donor kidneys.

The number of patients with a functioning kidney graft has doubled, from 68,200 in 1998 to 144,180 in 2009 (Figure 6.6). The proportion of patients with acute rejection has declined. For transplants in 2005–2009, only 11.6% of patients with deceased donor kidneys and 10.0% of patients with living donor kidneys experienced acute rejection by 1 year post-transplant (Figure 6.7). Hospitalization is common (Figure 6.8). PTLD is an uncommon but potentially lethal complication (Figure 6.9).

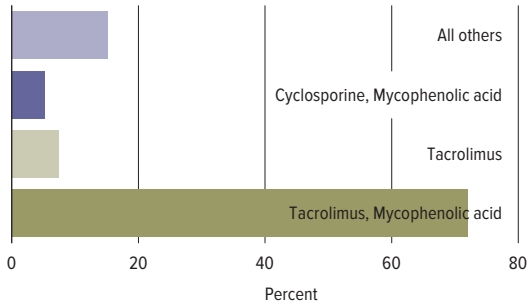
KI 7.1 Initial immunosuppression regimen in adult kidney transplant recipients, 2009 (steroids not considered)



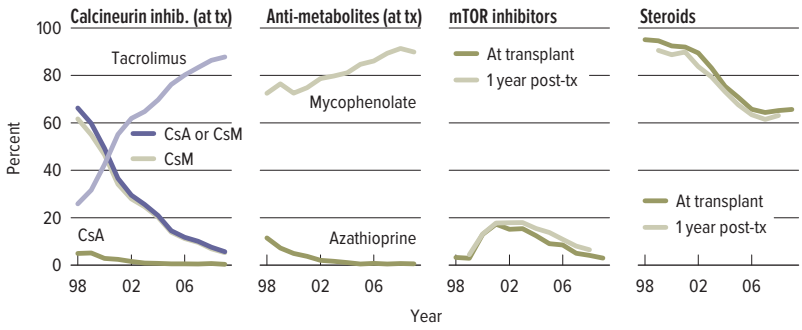
KI 7.2 Induction agents used at time of kidney transplant, adult recipients, 2009



KI 7.3 Immunosuppression regimen at one year in adult kidney transplant recipients, 2008 (steroids not considered)



KI 7.4 Immunosuppression use in adult kidney transplant recipients



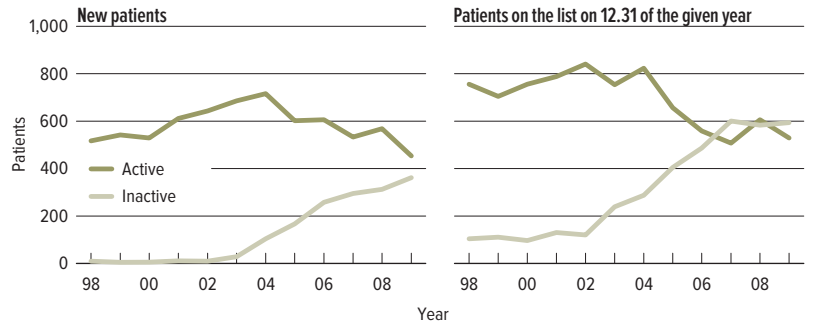
immunosuppression

In 2009, 81% of kidney transplant recipients' initial maintenance immunosuppression included tacrolimus and mycophenolate (Figure 7.1). Use of an induction antibody has grown; in 2009, 58% of patients received a T-cell depleting antibody, 21.2% an interleukin-2 receptor antagonist (IL2-RA), and 3.6% both a T-cell depleting antibody and an IL2-RA; only 17.2% did not receive induction (Figure 7.2). At 1 year after transplant, 72.1% of patients were receiving tacrolimus and mycophenolate, and only 5.3% were receiving cyclosporine A and mycophenolate (Figure 7.3).

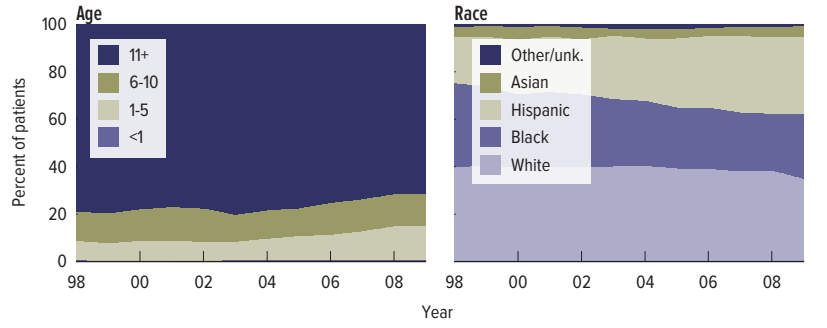
Use of cyclosporine for initial immunosuppression has declined from 66.3% in 1998 to 5.7% in 2009 (Figure 7.4). During this time, use of tacrolimus increased from 25.9% to 87.8 %. From 1998 to 2009, use of azathioprine declined from 11.5% to 0.6%, while use of mycophenolate as initial immunosuppression increased from 72.5% to 89.9%. Use of mammalian target of rapamycin (mTOR) inhibitors peaked in 2001, being used in 17.2% of patients as initial immunosuppression and 17.8% at 1 year after transplant. However, use of mTOR inhibitors declined to 3.0% at the time of transplant in 2009, and 6.5% at 1 year post-transplant in 2008.

Use of corticosteroids for initial maintenance immunosuppression was as high as 95.1% in 1998, declined to 65.8% in 2006, and was almost unchanged at 65.7% in 2009. Use of corticosteroids at 1 year post-transplant declined from 90.6% in 1999 to 63.5% in 2006, and remained unchanged at 63.1% in 2008.

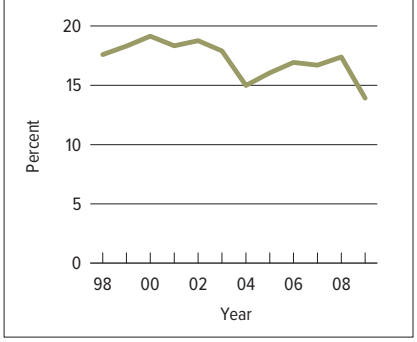
KI 8.1 Pediatric patients waiting for a kidney transplant



KI 8.2 Distribution of pediatric patients waiting for a kidney transplant



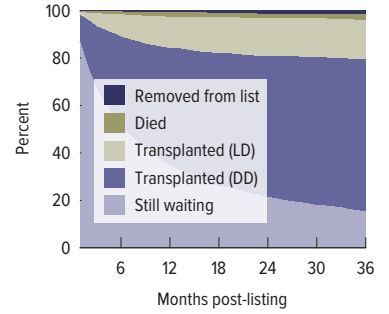
KI 8.3 Prior kidney transplant in pediatric patients waiting for a kidney transplant



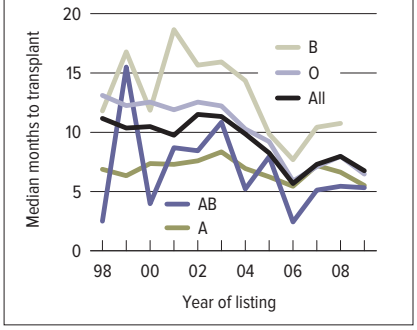
KI 8.4 Kidney transplant waiting list activity among pediatric patients

	2007	2008	2009
Listings at start of year	1,068	1,126	1,225
Listings added during year	874	955	876
Listings removed during year	816	856	957
Listings at end of year	1,126	1,225	1,144
Removal reason			
Deceased donor transplant	575	571	641
Living donor transplant	148	170	203
Patient died	22	26	24
Patient refused transplant	1	0	3
Transferred to another ctr	43	50	58
Improved, tx not needed	5	13	5
Too sick to transplant	1	5	2
Changed to kid.-pan. list	1	2	0
Other	20	19	21

KI 8.5 Kidney tx waiting list status by month post-listing among new pediatric listings in 2006



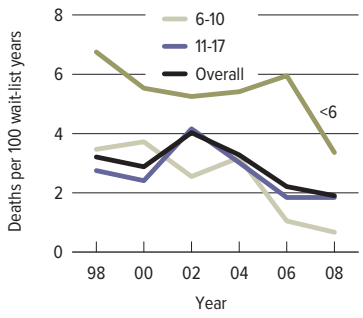
KI 8.6 Median months to kidney transplant for wait-listed pediatric patients, by blood type



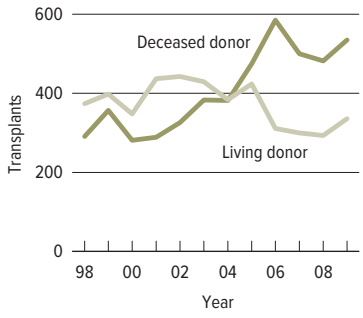
pediatric transplant

Beginning in 2003, the number of children listed as inactive on the kidney transplant waiting list increased dramatically; as for adults (Figure 1.1), this was likely a result of the change in policy allowing waiting time accrual while inactive on the list. The number of active patients on the waiting list declined between 1998 and 2009 (Figure 8.1). The age and race distribution of the waiting list has changed little (Figure 8.2). In 2009, 13.9% of patients on the waiting list were waiting for re-transplants (Fig 8.3). Fortunately, few children and adolescents die on the waiting list (Figure 8.4). For children and adolescents who were listed for a deceased donor kidney in 2006, by 3 years after listing, 64.6% had undergone deceased donor transplant, 16.7% had undergone living donor transplant, 2.3% had died, 1.7% had been removed from the list, and only 14.7% were still waiting for a transplant (Figure 8.5). The median waiting time for children and adolescents declined from 11.2 months in 1998 to 6.8 months in 2009 (Figure 8.6). The decline in waiting time was mostly for individuals with blood type O.

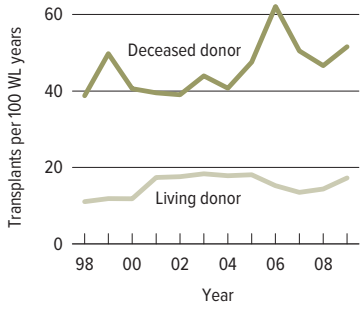
KI 8.7 Pre-tx mortality rates among pediatric pts wait-listed for a kidney transplant, by age



KI 8.8 Pediatric kidney transplants (includes kidney-pancreas)



KI 8.9 Pediatric kidney transplant rates



KI 8.10 Characteristics of pediatric kidney transplant recipients, 2007–2009

		All		Deceased		Living	
	Level	N	%	N	%	N	%
Age	<1	7	0.3	3	0.2	4	0.4
	1-5	478	19.6	245	16.3	233	25.1
	6-10	446	18.3	274	18.2	172	18.5
	11-17	1,504	61.8	984	65.3	520	56.0
Sex	Female	1,019	41.8	640	42.5	379	40.8
	Male	1,416	58.2	866	57.5	550	59.2
Race	White	1,262	51.8	630	41.8	632	68.0
	Black	439	18.0	352	23.4	87	9.4
	Hispanic	629	25.8	455	30.2	174	18.7
	Asian	72	3.0	46	3.1	26	2.8
	Other/unknown	33	1.4	23	1.5	10	1.1
Primary cause of disease	Diabetes	2	0.1	1	0.1	1	0.1
	Hypertension	56	2.3	45	3.0	11	1.2
	Glomerulonephritis	495	20.3	330	21.9	165	17.8
	Cystic kidney dis.	852	35.0	505	33.5	347	37.4
	Other cause	1,030	42.3	625	41.5	405	43.6
Blood type	A	791	32.5	465	30.9	326	35.1
	B	285	11.7	171	11.4	114	12.3
	AB	90	3.7	56	3.7	34	3.7
	O	1,269	52.1	814	54.1	455	49.0
PRA	<10%	1,990	81.7	1,233	81.9	757	81.5
	10%+	272	11.2	177	11.8	95	10.2
	Unk.	173	7.1	96	6.4	77	8.3
History of renal replacement therapy	Preemptive tx	715	29.4	346	23.0	369	39.7
	<1 year	673	27.6	397	26.4	276	29.7
	<3 years	669	27.5	480	31.9	189	20.3
	<5 years	170	7.0	130	8.6	40	4.3
	5+ years	208	8.5	153	10.2	55	5.9
Insurance	Private	1,006	41.3	498	33.1	508	54.7
	Medicaid	592	24.3	419	27.8	173	18.6
	Medicare	648	26.6	480	31.9	168	18.1
	Other public	160	6.6	92	6.1	68	7.3
	Other	29	1.2	17	1.1	12	1.3
HLA mismatches with donor	0	83	3.4	40	2.7	43	4.6
	1	82	3.4	6	0.4	76	8.2
	2	284	11.7	34	2.3	250	26.9
	3	523	21.5	151	10.0	372	40.0
	4	523	21.5	453	30.1	70	7.5
	5	587	24.1	514	34.1	73	7.9
	6	331	13.6	302	20.1	29	3.1
	Unknown	22	0.9	6	0.4	16	1.7
Transplant history	First transplant	2,221	91.2	1,353	89.8	868	93.4
	Subsequent	214	8.8	153	10.2	61	6.6
DCD status *	Non-DCD			1,441	95.7		
	DCD			65	4.3		
SCD/ECD status *	SCD			1,506	100.0		
All patients		2,435	100	1,506	100	929	100

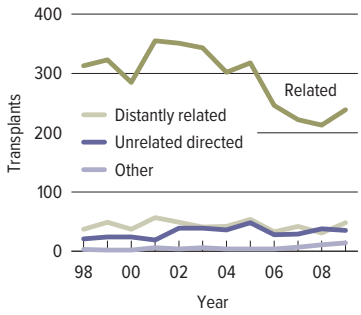
* for deceased donor tx only

pediatric transplant

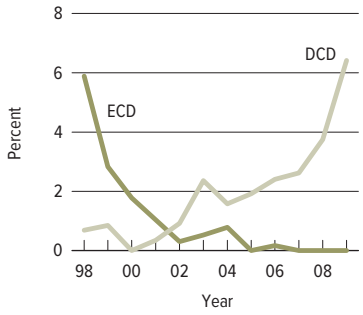
Death rates on the waiting list vary by age, but have declined since 1998 (Figure 8.7). Overall, from 1998 to 2009, the number of transplants increased 31.0%. However, the increase was due to an 83.8% increase in deceased donor transplants; living donor transplants declined 10.2% (Figure 8.8). In 2005, pediatric patients began to receive additional priority in the deceased donor kidney allocation system. It is interesting, therefore, that between 1998 and 2004, the rate of deceased donor kidney transplants (per 100 ESRD patient-years) increased 5.0%, from 38.8 to 40.7, but from 2004 to 2009 the rate increased an additional 26.6%, to 51.6 (Figure 8.9). In contrast, between 1998 and 2004, the rate of living donor transplants (per 100 wait list patient-years) increased 61.4%, from 11.1 to 17.8, while from 2004 to 2009 the rate declined 3.5%, to 17.2 (Figure 8.9). The apparent shift from living donor to deceased donor transplants may have been partly due to the allocation policy change. Between 2007 and 2009, 29.4% of transplants were preemptive, and 27.6% of patients were on renal replacement therapy for less than 1 year before transplant (Figure 8.10). Only a small number of deceased donor kidneys were from DCD donors.

Among living donor transplants, 85.4% of patients received kidneys from related or distantly related donors in 2009 (Figure 8.11). However, the number of living related or distantly related donors

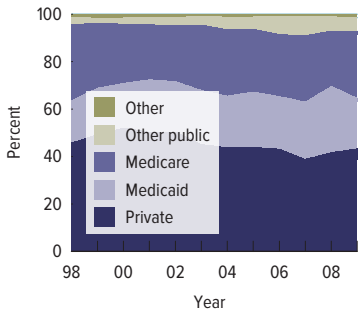
KI 8.11 Pediatric kidney transplants from living donors, by donor relation



KI 8.12 Use of ECD or DCD donors in pediatric kidney transplant recipients



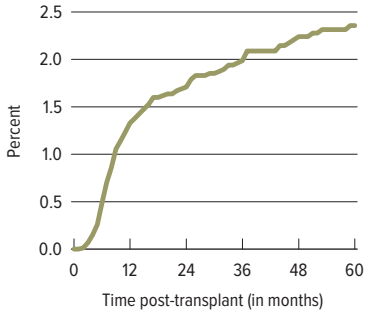
KI 8.13 Insurance coverage among pediatric kidney transplant recipients at time of tx



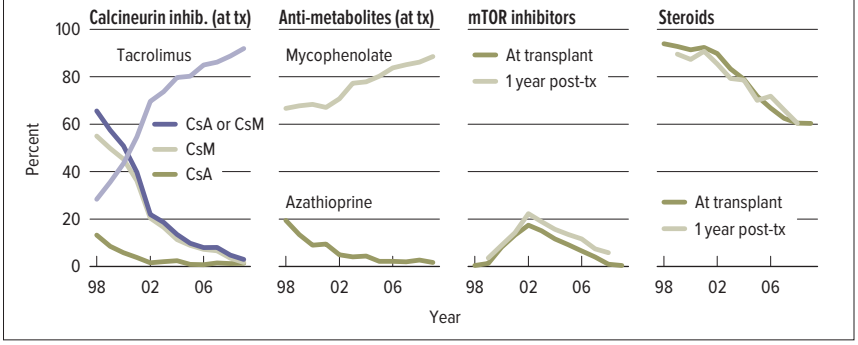
KI 8.14 Kidney donor-recipient Epstein-Barr virus (EBV) serology matching for pediatric transplant recipients, 2005–2009

	DECEASED DONOR				LIVING DONOR			
RECIPIENT	Neg.	Pos.	Unk.	Total	Neg.	Pos.	Unk.	Total
Negative	2.6	22.6	8.2	33.4	5.2	29.7	9.2	44.1
Positive	4.0	32.4	15.8	52.2	3.8	31.7	7.6	43.1
Unknown	0.9	8.1	5.5	14.5	0.8	6.4	5.7	12.9
Total	7.4	63.1	29.4	100	9.7	67.8	22.5	100

KI 8.15 Pediatric kidney transplant recipients with reported PTLD, 2000–2009

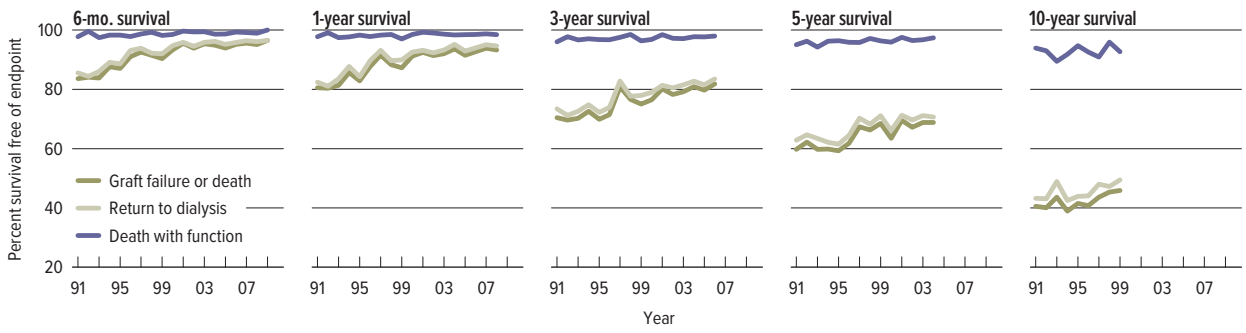


KI 8.16 Immunosuppression use in pediatric kidney transplant recipients

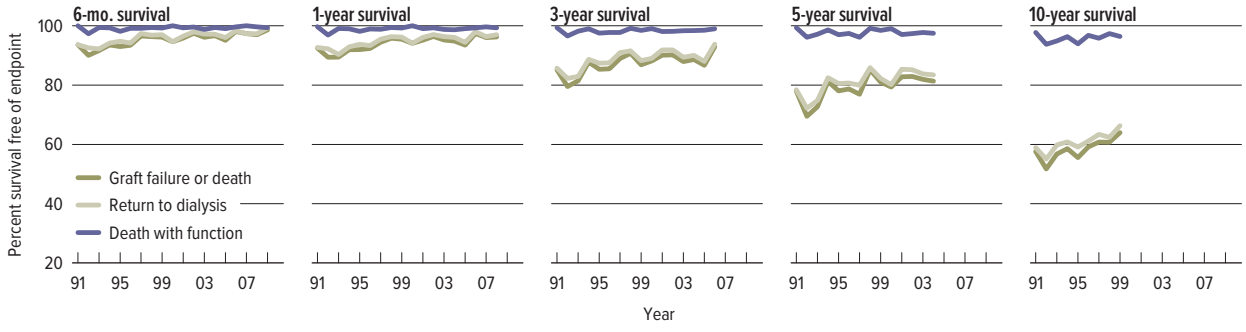


declined 18.0% between 1998 and 2009. In 2009, no ECD donor kidneys were transplanted into pediatric patients; however, 6.4% of deceased donor kidneys were DCD kidneys (Figure 8.12). Among pediatric patients who underwent transplants in 2009, the primary insurance was private for 43.3%, Medicare for 28.3%, Medicaid for 21.2%, other public source for 5.8%, or other for 1.4% (Figure 8.13). Pediatric patients are at higher risk for PTLD than adults because they are less likely to have antibodies to EBV. The highest risk for EBV infection and PTLD occurs for EBV(-) recipients of EBV(+) donor kidneys. For transplants in 2005–2009, this was the case in 22.6% of recipients of deceased donor kidneys and 29.7% of recipients of living donor kidneys (Figure 8.14), that is, much more often than in adults (Figure 5.7). For pediatric patients who underwent transplants in 2000–2009, the incidence of PTLD was 0.49% at 6 months, 1.3% at 1 year, 1.7% at 2 years, 2.0% at 3 years, 2.2% at 4 years, and 2.4% at 5 years post-transplant (Figure 8.15). Trends in maintenance immunosuppressive medications for pediatric patients (Figure 8.16) are similar to trends for adults (Figure 7.4). In 2009, 91.9% of pediatric patients received tacrolimus as part of the initial maintenance immunosuppressive medication regimen, and 88.6% received mycophenolate. Steroids were used in 60.4% of transplant recipients at 1 year post-transplant; 79% of patients receiving kidneys received induction therapy: IL2-RA, 33%; T-cell depleting antibody, 42%; no induction therapy, 21%.

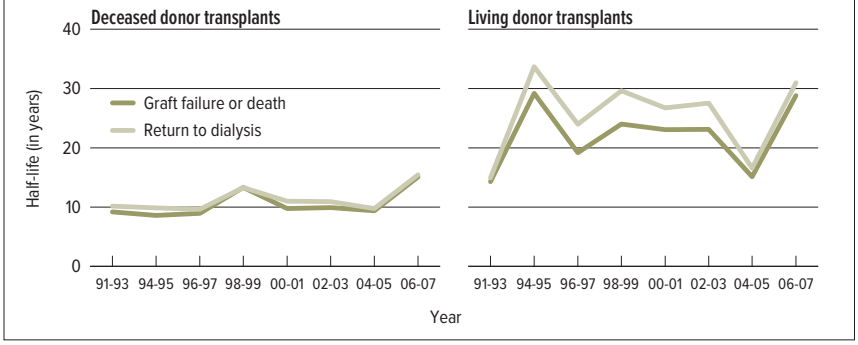
KI 8.17 Outcomes among pediatric kidney transplant recipients: deceased donor



KI 8.18 Outcomes among pediatric kidney transplant recipients: living donor



KI 8.19 Half-lives for pediatric kidney transplant recipients surviving with a functioning graft for at least one year

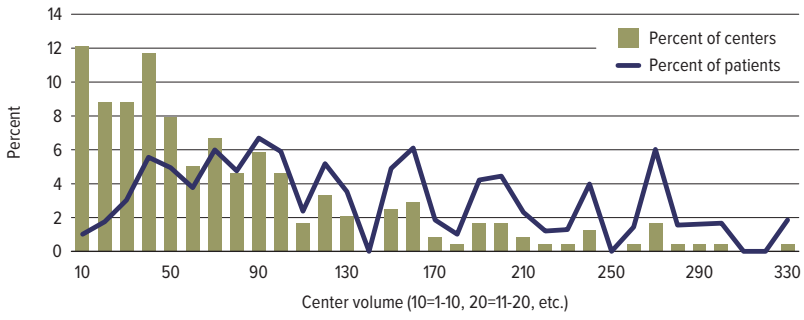


pediatric transplant

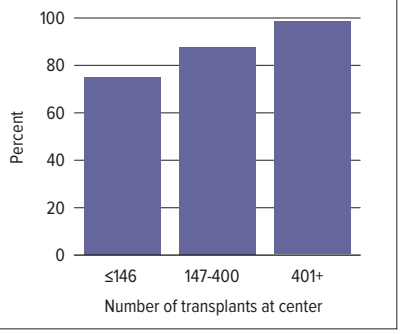
Graft survival (i.e., survival with a functioning graft) has continued to improve over the past decade. Graft survival for deceased donor kidneys in 2009 was 96.5% at 6 months; for transplants in 2008, 93.3% at 1 year; for transplants in 2006, 81.8% at 3 years; and for transplants in 2004, 68.8% at 5 years (numbers were too small to calculate 10-year graft survival) (Figure 8.17). Graft survival for living donor kidneys in 2009 was 98.6% at 6 months; for transplants in 2008, 96.3% at 1 year; for transplants in 2006, 92.9% at 3 years; for transplants in 2004, 81.4% at 5 years; and for transplants in 1999, 64.0% at 10 years (Figure 8.18). These graft survival numbers are almost identical to those for adults (Figure 6.3 and 6.4).

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. Graft half-lives for deceased and living donor kidneys have changed little over the past 17 years, although from year to year there is substantial variability due to the small numbers used in these calculations (Figure 8.19). For transplants in 2006–2007, the half-life was 15.1 years for deceased donor kidneys and 28.8 years for living donor kidneys.

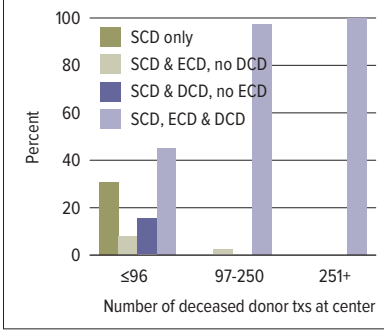
KI 9.1 Distribution by center volume of the number of kidney transplants performed (includes kidney-pancreas), 2009



KI 9.2 Kidney programs performing multi-organ transplants, by volume, 2005–2009



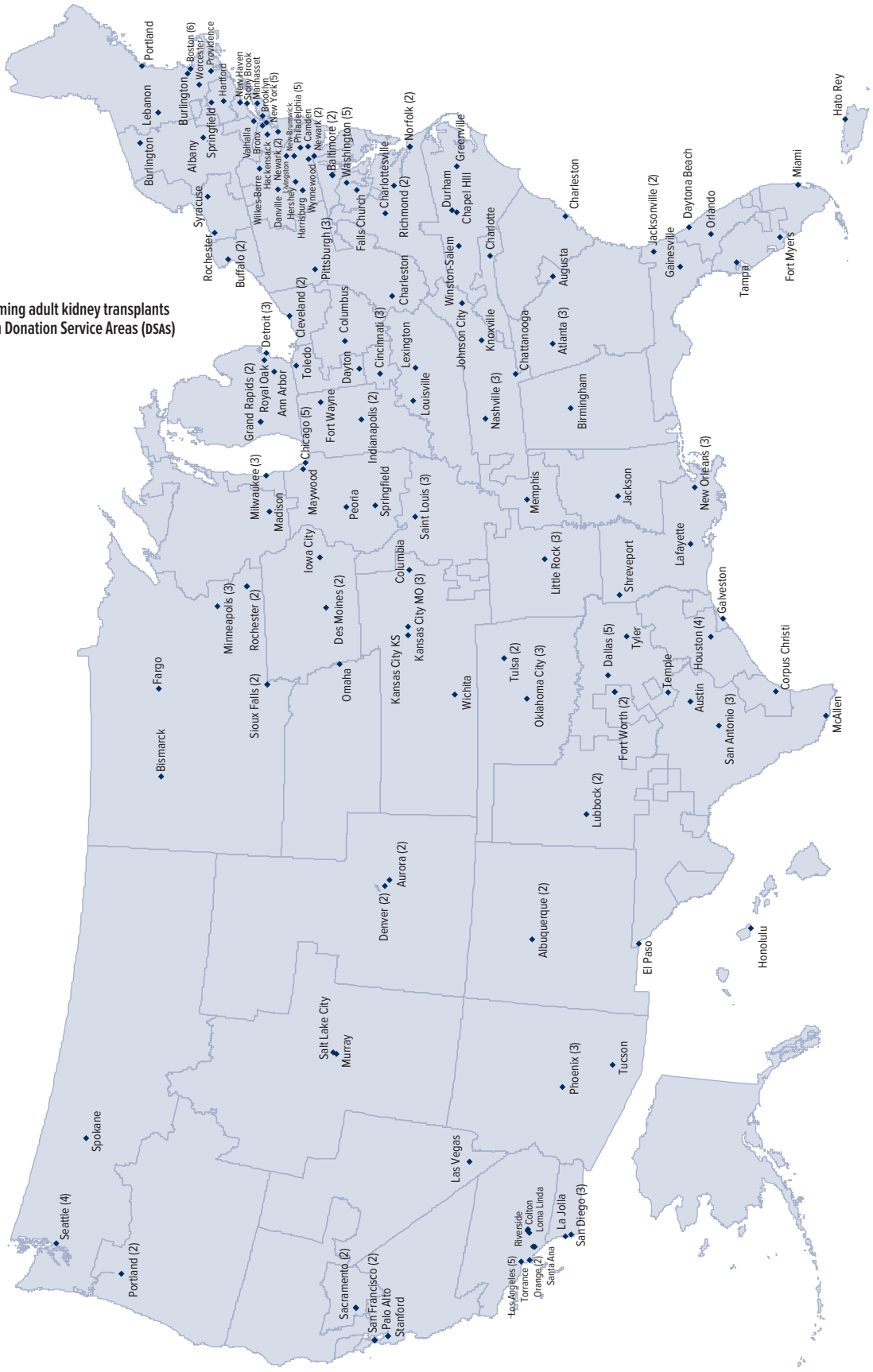
KI 9.3 Ctrs transplanting ECD & DCD dec'd donor kidneys (incl. KP), by volume, 2005–2009



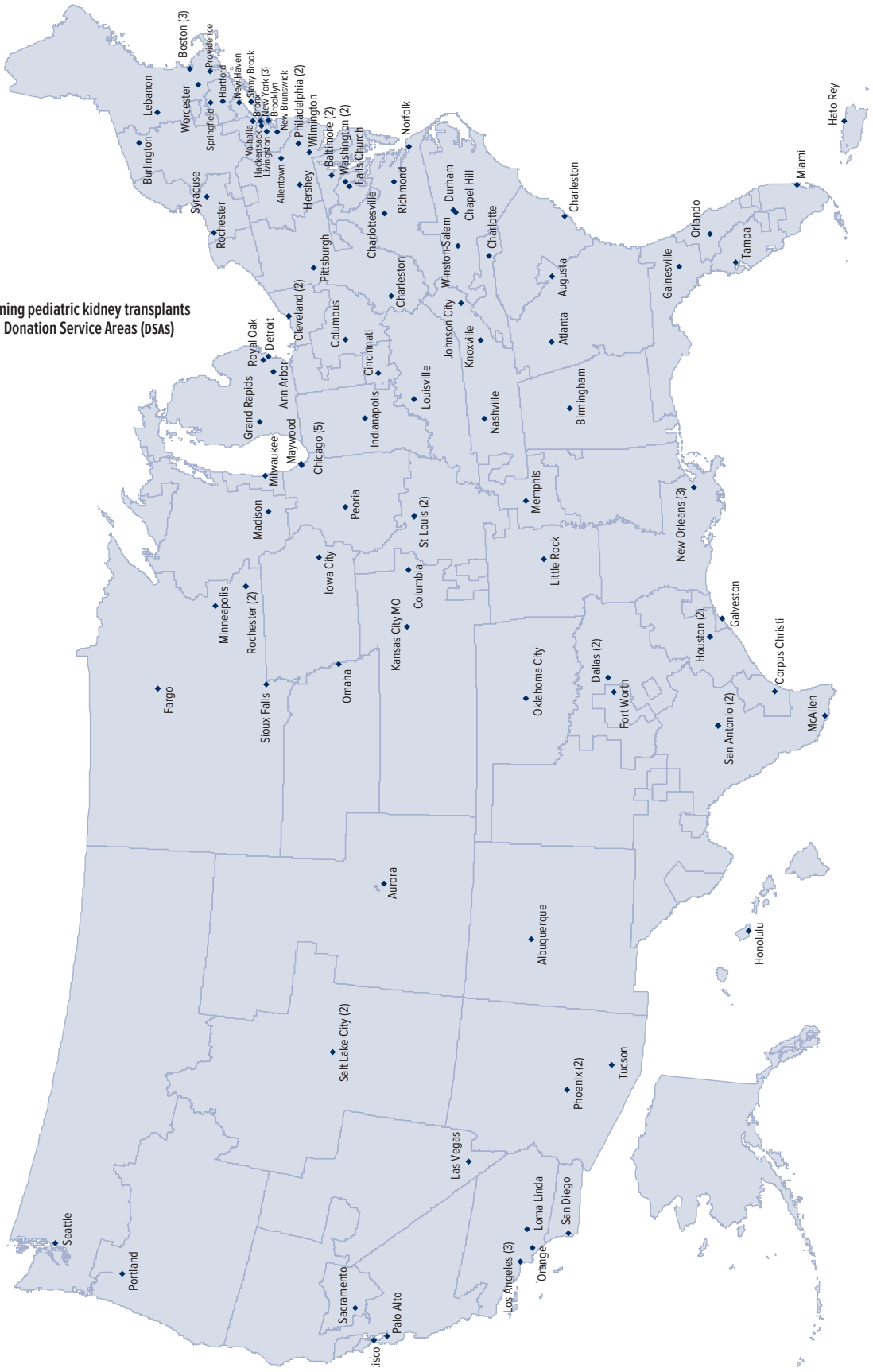
center characteristics

In 2009, 12.1% of transplant centers performed 10 or fewer adult and pediatric kidney transplants (Figure 9.1). In contrast, 9 centers transplanted more than 250 kidneys in 2009, including 1 center that transplanted 330 kidneys. Half of all centers performed fewer than 50 kidney transplants in 2009. In 2005–2009, one-third of centers performed 146 transplants or fewer (i.e., less than approximately 30 transplants per year), one-third performed more than 400 (i.e., more than approximately 80 per year), and one-third performed 147 to 400. Among low-volume centers, 25.0% transplanted kidneys alone, that is, did not perform kidney transplants along with other organs (Figure 9.2). In contrast, among high-volume centers, only 1.4% transplanted kidneys only. Thus, multi-organ transplants that include kidneys are more likely at high-volume centers than at low-volume centers. Similarly, among low-volume centers, 31.0% performed deceased donor kidney transplants using only SCD kidneys in 2005–2009, while none of the high-volume centers performed only SCD deceased donor kidney transplants (Figure 9.3). Of low-volume centers, 60.7% used DCD kidneys, but all high-volume centers used at least some DCD kidneys in 2005–2009.

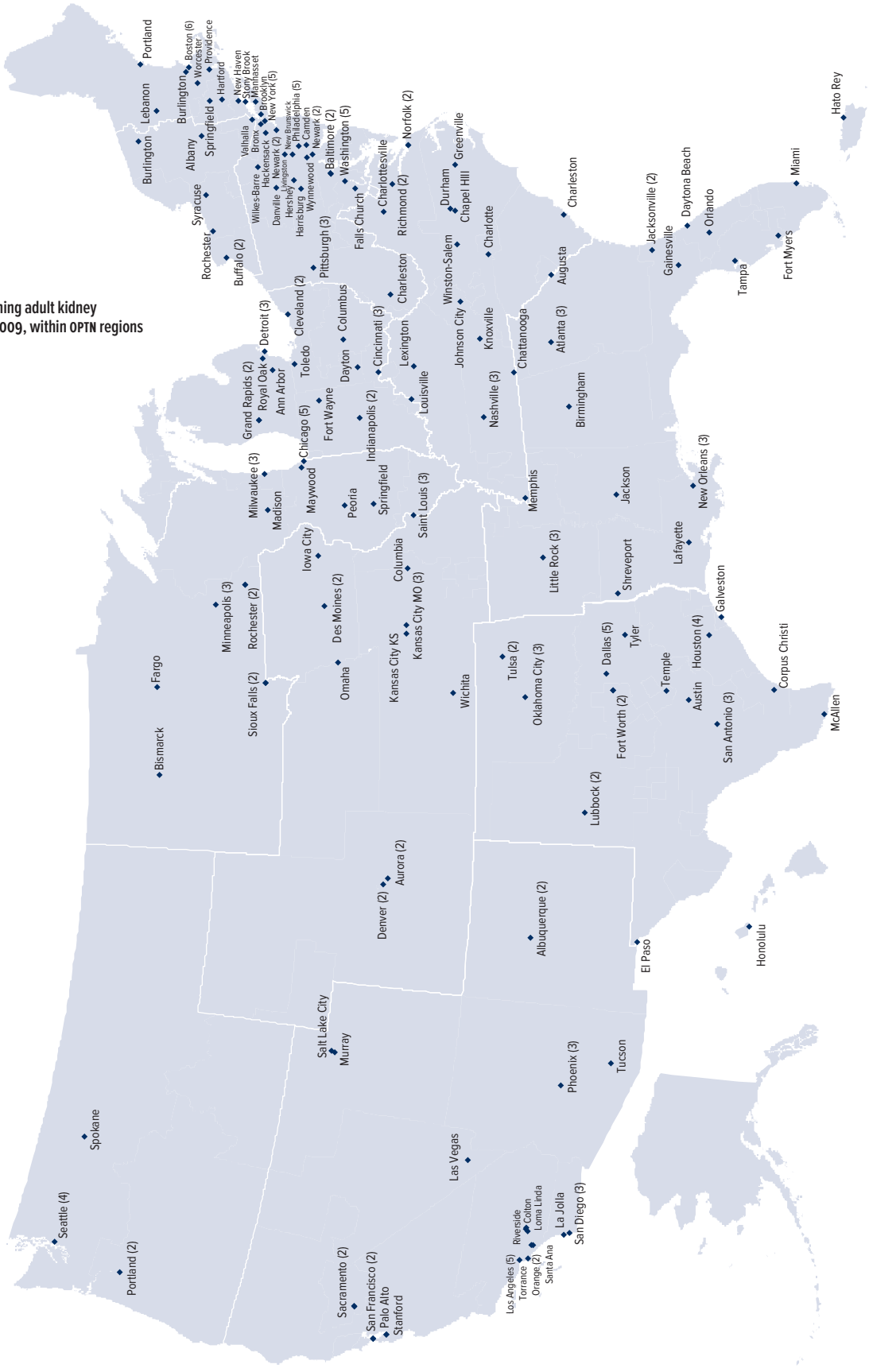
KI 10.1 **Centers performing adult kidney transplants in 2009, within Donation Service Areas (DSAs)**



KI 10.2 **Centers performing pediatric kidney transplants in 2009, within Donation Service Areas (DSAs)**



KI 10.3 **Centers performing adult kidney transplants in 2009, within OPTN regions**



pancreas

The number of new patients waiting for pancreas transplant rose and fell over the past decade (Figure 1.1). Transplant rates for adult patients wait-listed for pancreas transplant have dropped, with the most pronounced drop among pancreas after kidney transplant (PAK) recipients (Figure 1.4). Three years after listing, 59.3% of patients had undergone pancreas transplant alone (PTA), 57.1% simultaneous pancreas-kidney transplant (SPK), and 50.8% PAK (Figure 1.6). The median time to transplant for all candidates who were active at listing was 7.0 months for PTA, 11.5 months for SPK, and 12.8 months for PAK (Figure 1.7). A cross-section of the waiting list on December 31, 2009, shows that most PTA and SPK patients were aged 18 to 44 years. Four percent of PTA, 10% of SPK, and 6% of PAK candidates self-reported type 2 diabetes (Figure 1.11).

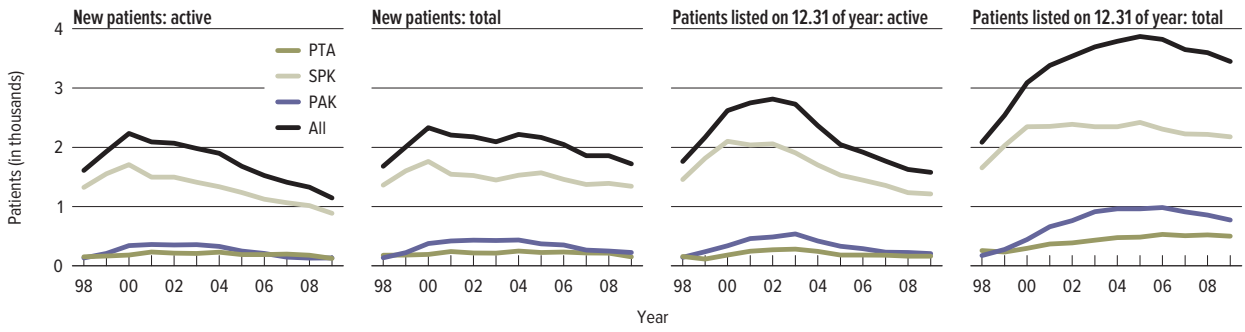
The number of adult pancreas transplants steadily decreased since peaking at 1,454 in 2004, and is currently at 1,170. The decline is most marked for PAK (Figure 3.1). Recipient age has gradually shifted toward ages 50 years or older and away from ages 18 to 34 years. The proportion of recipients with body mass index (BMI) 25.0 to 29.9 kg/m^2 has increased, and the proportion with BMI 18.5 to 24.9 kg/m^2 has decreased (Figure 3.2).

The 1-year PTA graft survival was 75.4% for transplants in 2008 (Figure 5.2). The 1-year graft survival of the pancreas in SPK recipients was at a high of 86.4% (Figure 5.3). The 1-year pancreas graft survival in PAK recipients decreased slightly from 2008, falling to 79.3% from 81.1% (Figure 5.5). Estimated half-lives for pancreas allografts transplanted in 2007 are 20.6, 12.0, and 5.1 years for SPK, PAK, and PTA, respectively (Figure 5.7).

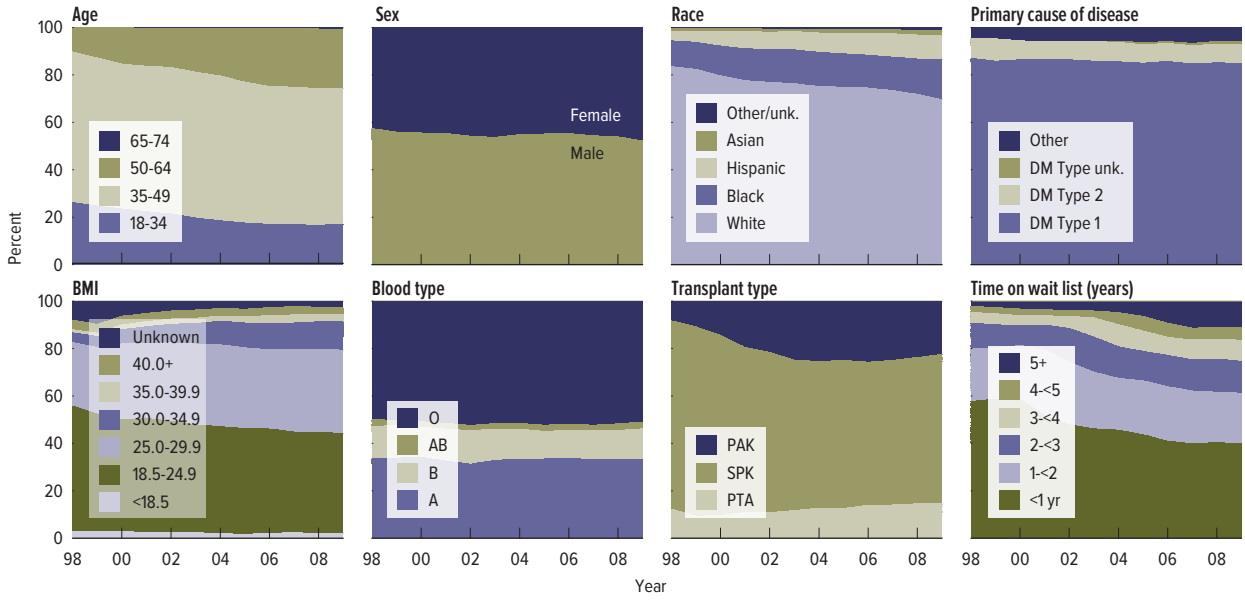
Jesse was able to enhance the lives of eight people at the time of his death. At our time of great sorrow it was nice to know that others could rejoice as he was able to share the gift of life with them. Jesse's generous and giving nature made any answer other than "yes" seem impossible to the entire family.

Audre, donor mom

PA1.1 Adult patients waiting for a pancreas transplant



PA1.2 Distribution of adult patients waiting for a pancreas transplant

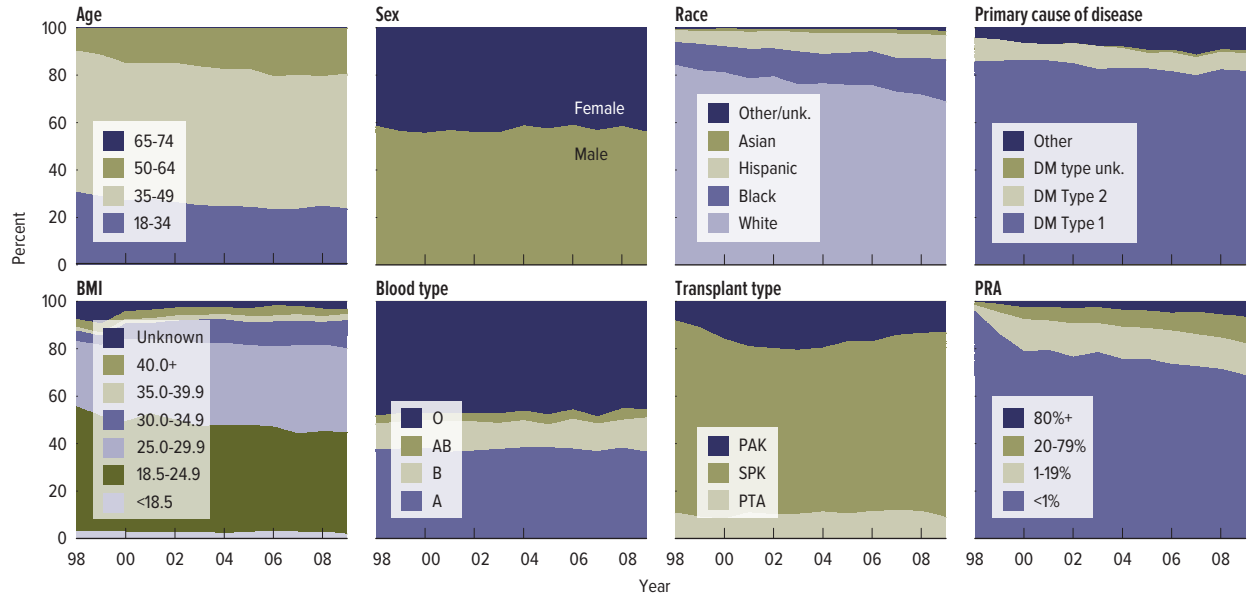


wait list

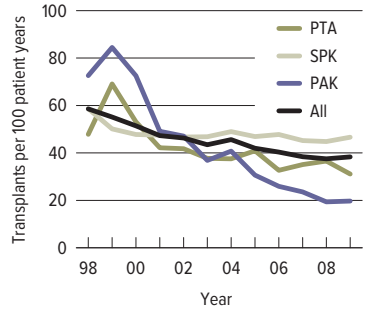
The number of new patients waiting for pancreas transplant has changed over the past decade, with a net increase in counts on all three lists until 2004–2005, after which counts declined to levels similar to 1998. Over the past 6 years, the number of active patients has decreased sharply, especially those awaiting SPK transplant (Figure 1.1). In 2003, a policy change by the Organ Procurement and Transplantation Network (OPTN) allowed individuals on the waiting list to accrue time while inactive.

Since 1998, the number of older patients (aged 50 to 64 years) has gradually increased and the number of younger patients (aged 18 to 34 years) has decreased correspondingly. Numbers of Hispanic and black patients have increased, with a corresponding decrease in numbers of white patients. In 2009, 8.1% of patients self-reported type 2 diabetes. The percentage of obese patients (BMI greater than 30 kg/m^2) is steadily increasing, with most obese patients having a BMI of 30 to 35 kg/m^2. The blood group distribution on the waiting list has remained stable. The number of PAK listings increased between 1999 (when PAK transplants received Medicare approval) and 2005; since then, the number of PAK listings has gradually declined and the number of SPK listings has gradually increased. PTA transplants constitute a minority

PA 1.3 **Distribution of adult patients newly listed for a pancreas transplant**



PA 1.4 **Transplant rates among adult patients wait-listed for a pancreas transplant**



PA 1.5 **Pancreas transplant waiting list activity among adult patients**

	PTA			SPK			PAK		
	2007	2008	2009	2007	2008	2009	2007	2008	2009
Listings at start of year	539	517	526	2,368	2,297	2,292	1,001	929	867
Listings added during year	293	321	257	1,612	1,600	1,559	386	335	309
Listings removed during year	315	312	282	1,683	1,605	1,610	458	397	385
Listings at end of year	517	526	501	2,297	2,292	2,241	929	867	791
Removal reason									
Living donor kidney transplant	.	.	.	132	137	144	.	.	.
Deceased donor transplant	195	193	165	1,018	982	1,012	229	184	166
Patient died	23	21	18	233	215	185	24	27	34
Too sick for transplant	9	6	7	57	53	72	37	31	27
Condition improved	14	5	7	25	15	14	8	4	5
Other	74	87	85	218	203	183	160	151	153

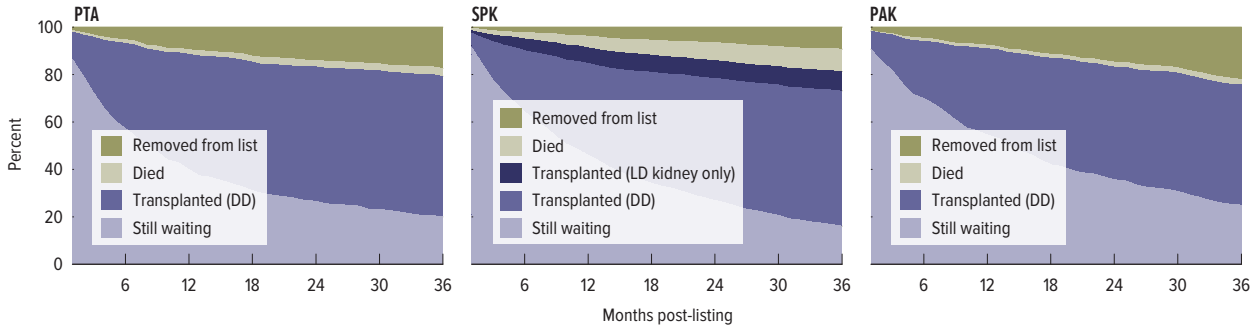
and have remained stable. Time on the waiting list has gradually increased since 2002 (Figure 1.2).

Changes in the demographics of newly listed adult patients over the past decade are similar to those seen with currently wait-listed patients. The number of sensitized patients (panel reactive antibody [PRA] greater than 0%) is steadily increasing (Figure 1.3).

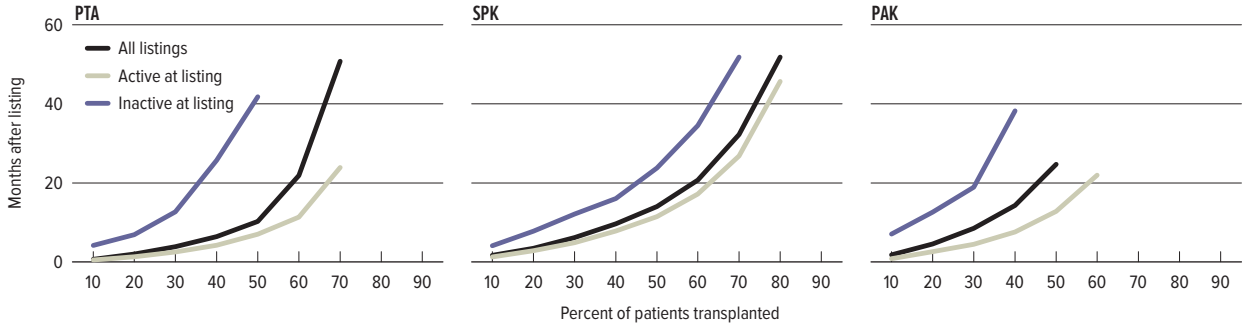
Transplant rates for adult patients wait-listed for a pancreas transplant have dropped over the past decade, with the most pronounced drop among PAK recipients. In 2009 (compared with 2008), the overall transplant rates marginally increased from 33.8 to 34.3 per 100 patient-years; however, the rate for the PTA group fell from 36.7 to 31.2 per 100 patient-years.. This is the lowest transplant rate for PTA in the past decade (Figure 1.4).

In 2009, 144 living donor kidney transplants were performed in SPK wait-listed patients, compared with 132 in 2007 and 137 in 2008. This is consistent with the 6.6% increase in living donor kidney transplants from 2008 to 2009 (see Kidney chapter). The number of patients on each pancreas waiting list at the end of 2009 was the lowest in the 3-year period starting in 2007 (Figure 1.5).

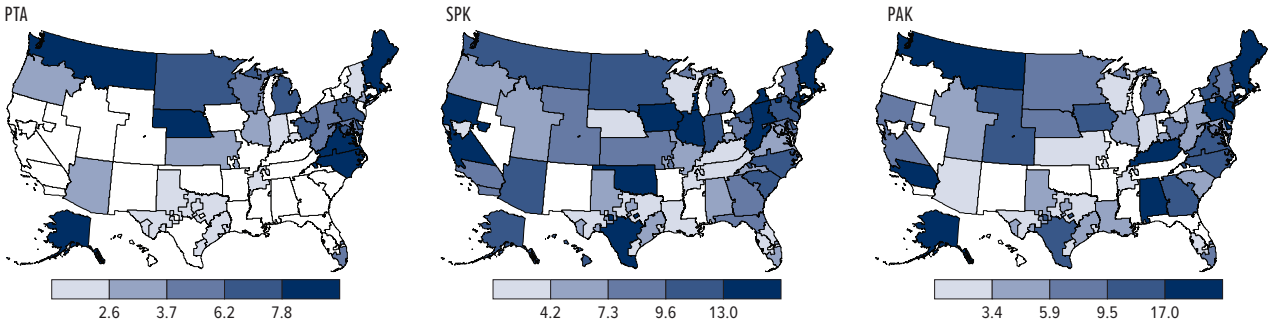
PA1.6 **Pancreas transplant waiting list status by month post-listing among new adult listings in 2006**



PA1.7 **Percentiles of time to pancreas transplant for new adult listings, 2005–2009**



PA1.8 **Median months to pancreas transplant for adult patients transplanted in 2009, by DSA**



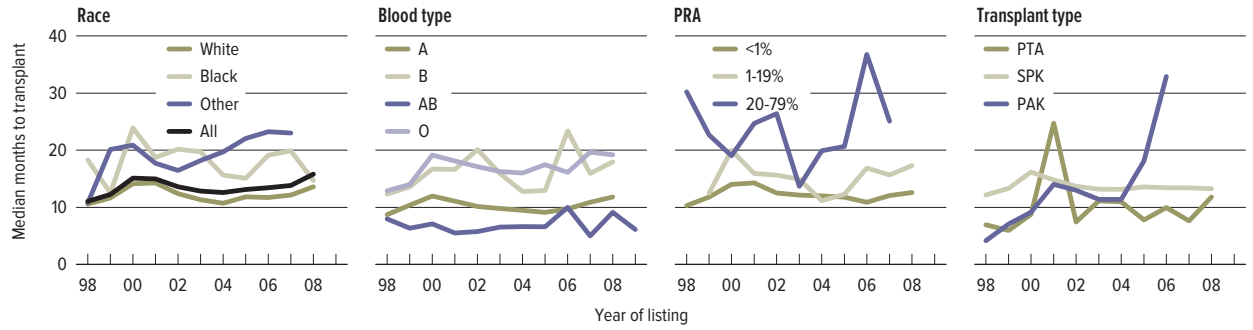
wait list

Three years after joining a given waiting list, 59.3% of patients had undergone PTA, 65.2% SPK or a living donor kidney transplant, and 50.8% PAK (Figure 1.6). At 3 years, 3.3% of patients wait-listed for PTA had died, as had 9.4% of those listed for SPK and 2.5% of those listed for PAK. In addition, 17.4% of those awaiting PTA, 9.3% of those awaiting SPK, and 21.7% of those awaiting PAK had been removed from the list. At the end of 3 years, 20.0%, 16.1%, and 24.9% were still awaiting PTA, SPK, and PAK, respectively.

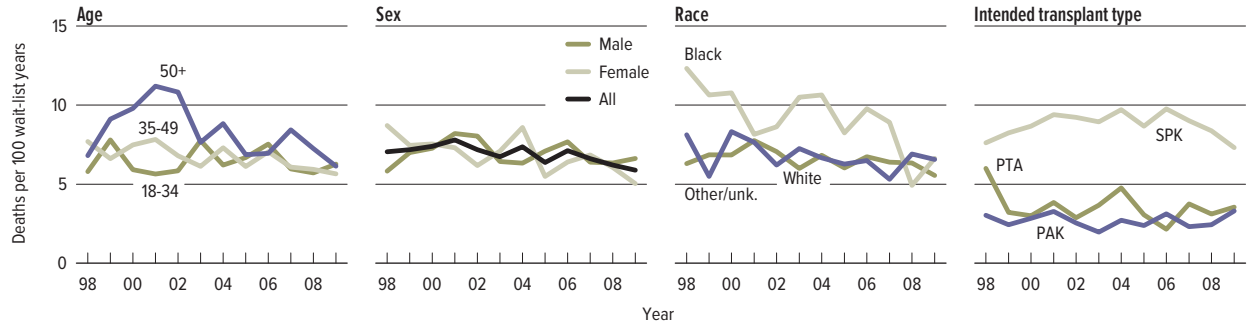
The median time to transplant for all candidates who were active at listing was 7.0 months for PTA, 11.5 months for SPK, and 12.8 months for PAK (Figure 1.7). It is not uncommon for PAK-listed patients to be activated at the time of living donor kidney transplant in case a deceased donor pancreas becomes available then. After undergoing living donor kidney transplant, a patient may not be listed as active again for 6 weeks to 3 months, depending on center practice and patient condition. This could account for the prolonged waiting times for PAK.

The median months to deceased donor pancreas transplant for patients undergoing transplant in 2009 was 3.5 for PTA, 8.3 for SPK, and 6.9 for PAK. The geographical variations by donor service area (DSA) in waiting times for SPK closely mirror those for kidneys

PA 1.9 Median months to pancreas transplant for wait-listed adult patients



PA 1.10 Pre-transplant mortality rates among adult patients wait-listed for a pancreas transplant



(see Figure 1.9, Kidney chapter). For PTA and PAK, the waiting times are low except in some scattered areas (Figure 1.8).

The median time to pancreas transplant has increased in the past decade (1998–2008), with the sharpest increase noted in PAK (4.1 months in 1998 to 32.9 months in 2006). For PTA, median time was 6.9 months in 1998 and 11.8 months in 2008; for SPK, 12.2 months in 1998 and 13.3 months in 2008. The difference in waiting times between whites and blacks seems to be decreasing, with the most recent year showing a 1-month difference. However, the waiting time for other racial groups has been steadily increasing. Blood group and PRA disparities resemble those for kidney transplants (see Figure 1.10, Kidney chapter), with the O and B groups waiting longer than the AB group, and the high PRA (20% to 79%) group waiting the longest (Figure 1.9). Median wait times for the highest PRA group (80%+) were not consistently observed.

Pre-transplant mortality trends have held steady over the past decade, with the highest mortality, as expected, in the SPK group. The trend toward higher mortality in recipients aged 50 years or older seen in 2001–2002 has improved. Blacks had higher pre-transplant mortality a decade ago, but this has progressively decreased (Figure 1.10).

PA 1.11 Characteristics of adult patients on the pancreas transplant waiting list on December 31, 2009

	Level	PTA N	%	SPK N	%	PAK N	%
Age	18-44	260	52.0	1,243	57.1	379	49.2
	45-64	233	46.6	927	42.6	388	50.3
	65+	7	1.4	8	0.4	4	0.5
Gender	Male	211	42.2	1,166	53.5	421	54.6
	Female	289	57.8	1,012	46.5	350	45.4
Race	White	442	88.4	1,352	62.1	605	78.5
	Black	26	5.2	471	21.6	85	11.0
	Hispanic	23	4.6	257	11.8	70	9.1
	Asian	6	1.2	55	2.5	8	1.0
	Other/unknown	3	0.6	43	2.0	3	0.4
Primary cause of disease	Diabetes Type 1	433	86.6	1,793	82.3	700	90.8
	Diabetes Type 2	19	3.8	217	10.0	43	5.6
	Diabetes type unk.	3	0.6	25	1.1	14	1.8
	Other cause/unk.	45	9.0	143	6.6	14	1.8
Transplant history	Listed for first tx	430	86.0	2,012	92.4	572	74.2
	Listed for sub. tx	70	14.0	166	7.6	199	25.8

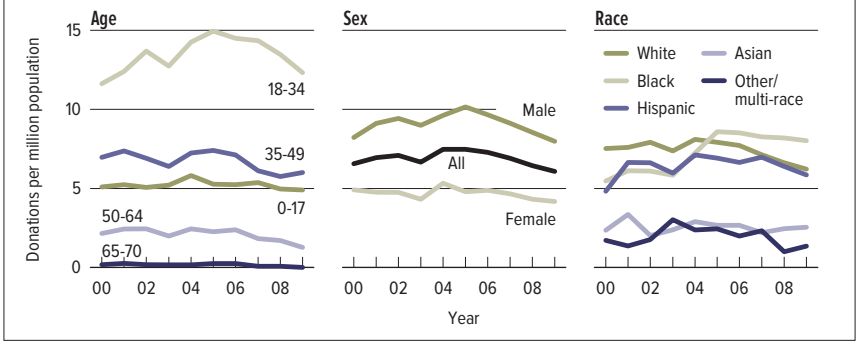
	Level	PTA N	%	SPK N	%	PAK N	%
Blood type	A	185	37.0	686	31.5	275	35.7
	B	50	10.0	310	14.2	86	11.2
	AB	10	2.0	65	3.0	24	3.1
	O	255	51.0	1,117	51.3	386	50.1
PRA	<10%	369	73.8	1,614	74.1	571	74.1
	10%+	131	26.2	564	25.9	200	25.9
Time on list	<1 year	158	31.6	1,000	45.9	224	29.1
	1-<2	106	21.2	495	22.7	139	18.0
	2-<3	50	10.0	287	13.2	125	16.2
	3-<4	37	7.4	173	7.9	88	11.4
	4-<5	30	6.0	91	4.2	63	8.2
	5+	119	23.8	132	6.1	132	17.1
BMI (kg/m^2)	<18.5	18	3.6	34	1.6	15	1.9
	18.5-24.9	211	42.2	923	42.4	323	41.9
	25.0-29.9	173	34.6	760	34.9	281	36.4
	30.0-34.9	63	12.6	312	14.3	100	13.0
	35.0-39.9	15	3.0	69	3.2	29	3.8
	40.0+	1	0.2	20	0.9	4	0.5
	Unknown	19	3.8	60	2.8	19	2.5
Total		500		2,178		771	

wait list

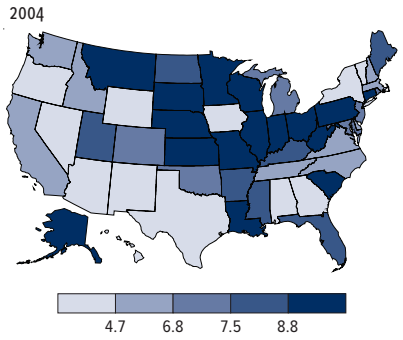
A cross-section of the waiting list on December 31, 2009, shows that most PTA and SPK patients were aged 18 to 44 years; PAK patients aged 45 to 64 years were a slim majority. Most PTA candidates were female (58%), and most SPK and PAK candidates were male (54% and 55%, respectively). Whites comprised 88% of the PTA, 62% of the SPK, and 79% of the PAK lists. Analysis for type of diabetes, a self-reported variable, showed that 4% of PTA, 10% of SPK, and 6% of PAK candidates self-reported type 2 diabetes (Figure 1.11).

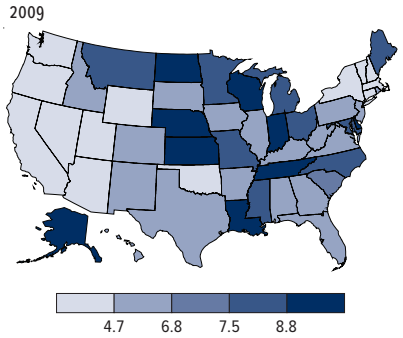
The percentage of patients listed for re-transplant varied widely by list: 14% of PTA, 8% of SPK, and 26% of PAK listed patients were waiting for a re-transplant. Patients with blood type O accounted for 51% of listings, and type A 33%. PRA greater than 10% was recorded in 26% of patients. Seventy-seven percent of listed patients had a BMI between 18.5 and 29.9 kg/m^2, 14% had a BMI between 30 and 34.9 kg/m^2, and 4% had a BMI greater than 35 kg/m^2. With regard to time on the waiting list, 32% of PTA, 46% of SPK, and 29% of PAK listed patients had been on the list less than 1 year, while 24% of PTA, 6% of SPK, and 17% of PAK listed patients had been on the list for 5 or more years. (Figure 1.11).

PA 2.1 Pancreas donations from deceased donors per million population

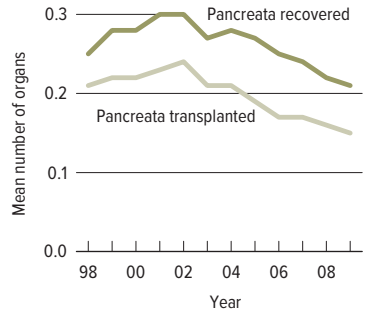


PA 2.2 Deceased donor pancreas donation rates (per million population)

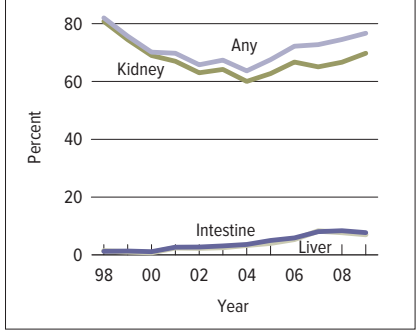




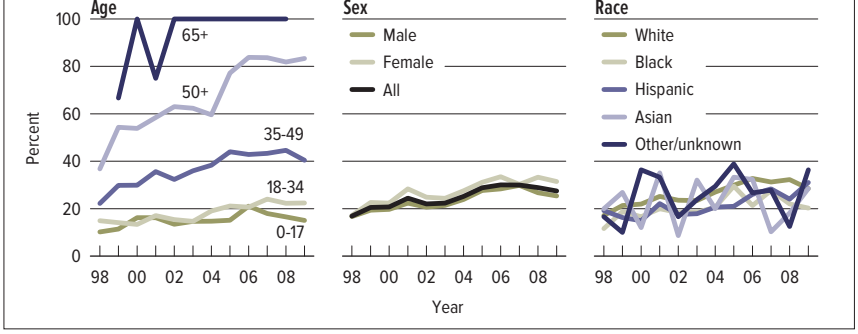
PA 2.3 Pancreata recovered per donor & pancreata transplanted per donor



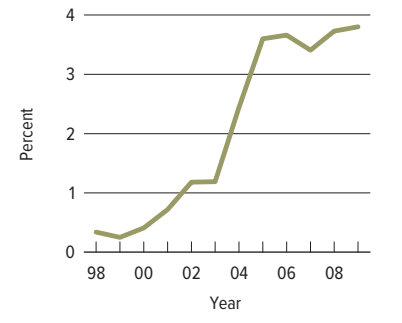
PA 2.4 Deceased donor pancreata transplanted with another organ



PA 2.5 Discard rates for pancreata recovered for transplant



PA 2.6 Pancreas donors who are DCD



donation

Deceased pancreas donation rates, per million population (pmp), have decreased since 2005. This may reflect the overall increase in the age of the deceased donor pool and the use of only ideal donors for pancreas transplant. Rates were highest for patients aged 18 to 34 years (12 pmp in 2009), followed by those aged 35 to 49 years (6 pmp) and those younger than 18 years (5 pmp). Male donation rates have been twice rates for females. Blacks have become the racial group with the highest donation rates (8 pmp in 2009) (Figure 2.1). Geographic heterogeneity in donation rates is substantial (Figure 2.2).

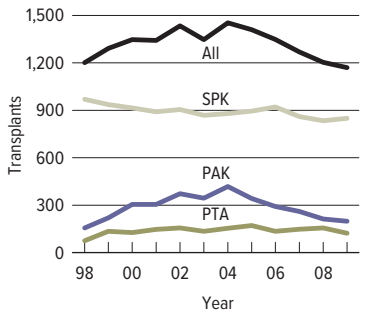
In 1998, 0.25 pancreata were recovered for per donor; this number peaked at 0.30 in 2002, and declined to 0.21 in 2009. In 2009, 0.15 pancreata were transplanted per donor (Figure 2.3).

Approximately 76% of pancreata were co-transplanted with another organ in 2009, mostly with kidneys (70%). However, the numbers of livers and intestines co-transplanted with a pancreas have increased (Figure 2.4). Many of these are pancreas transplants for technical reasons, not diabetes.

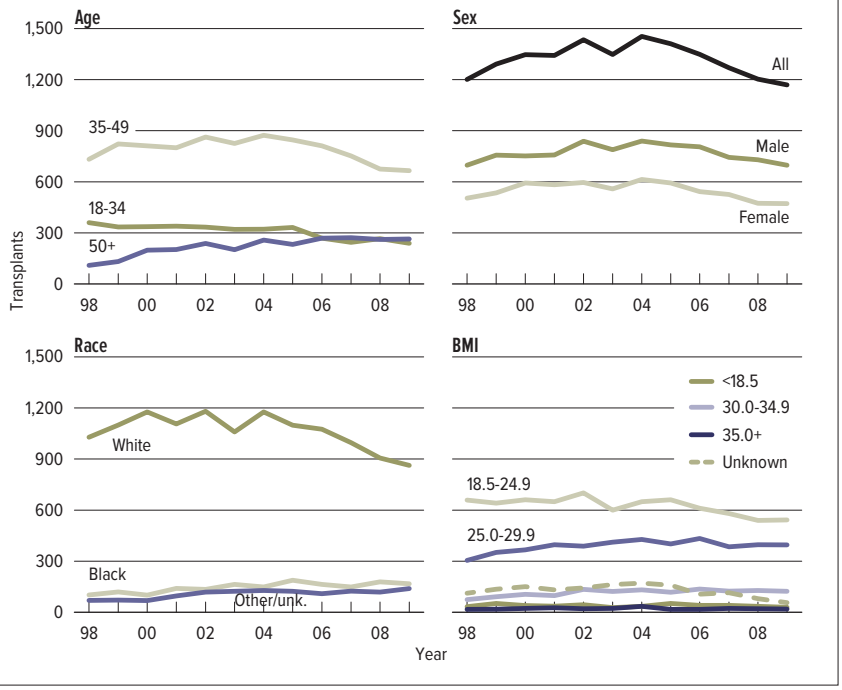
Discard rates have increased across all age groups since 1998, though most dramatically for donors aged 50 to 64 years (36.8% to 83.3% in 2009). The overall discard rate, which was 17% in 1998, peaked at 30% in 2006, and was at 27% in 2009 (Figure 2.5).

The number of donations after circulatory death (DCD) has been increasing steadily. DCD donations were 0.34% in 1998 and 3.8% in 2009 (Figure 2.6).

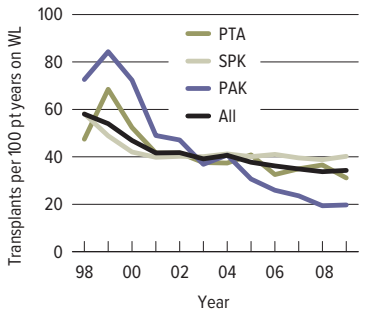
PA 3.1 Total number of adult pancreas transplants



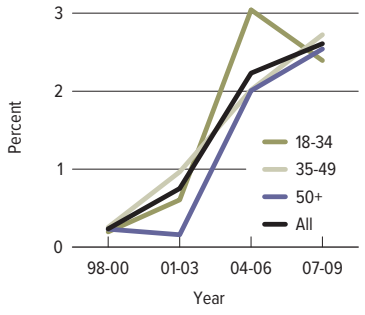
PA 3.2 Adult pancreas transplants



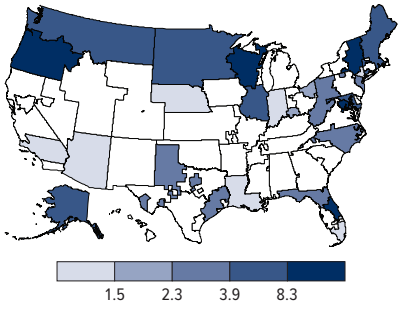
PA 3.3 Pancreas transplant rates in adult recipients



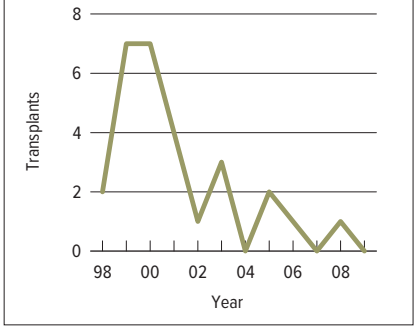
PA 3.4 Use of DCD pancreata among adult recipients, by recipient age



PA 3.5 Percent of adult, deceased donor pancreas transplants that are DCD, by DSA, 2007–09



PA 3.6 Adult pancreas transplants from living donors



transplant

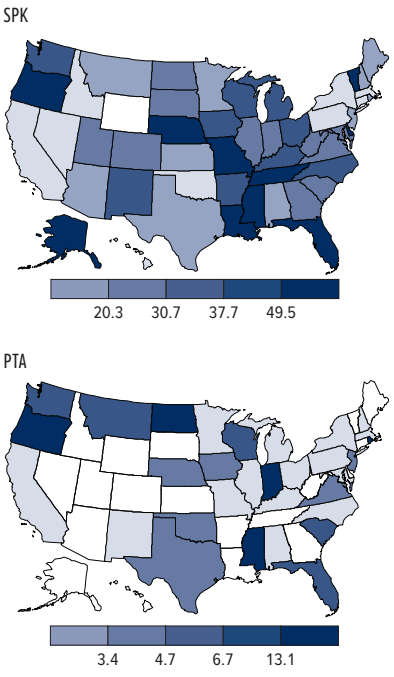
The number of adult pancreas transplants has steadily decreased since peaking at 1,454 in 2004, and is currently at 1,170. The decline is most marked for PAK transplants. After CMS approved coverage for PAK transplants in 1999 (http://www.cms.gov/transmittals/downloads/R124CIM.pdf), the number almost doubled over the next 2 years, peaked in 2004, and has declined gradually since. SPK transplants, on the other hand, have seen a gradual decrease over the past decade (Figure 3.1).

Recipient ages have gradually shifted toward 50 years or older and away from 18 to 34 years. The percentage of minority recipients (black or other/unknown) has increased steadily. The proportion of recipients with BMI 25.0 to 29.9 kg/m^2 has increased, and the proportion with BMI 18.5 to 24.9 kg/m^2 has decreased (Figure 3.2).

Transplants per 100 patient-years on the waiting list had been decreasing over 9 years, but this decline leveled off in 2009. This may be the result of a combination of improved list management and regional allocation variances allowing for preferences to SPK transplants (Figure 3.3).

Willingness to use DCD pancreata is recent (Figure 3.4). By DSA, use of DCD pancreata showed wide variation (Figure 3.5).

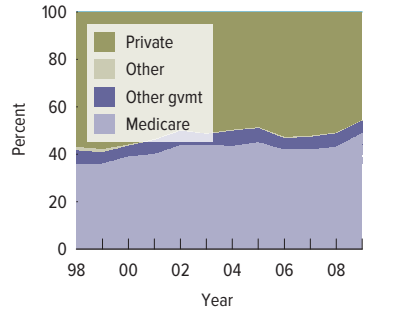
PA 3.7 Pancreas transplant rates per 100 patient years on the waiting list, adult pts, 2009



PA 3.8 Characteristics of adult pancreas transplant recipients, 2009

		All		PTA		SPK		PAK	
	Level	N	%	N	%	N	%	N	%
Age	18-34	240	20.5	35	28.5	170	20.0	35	17.7
	35-49	666	56.9	53	43.1	497	58.5	116	58.6
	50-64	261	22.3	34	27.6	180	21.2	47	23.7
	65+	3	0.3	1	0.8	2	0.2	0	0.0
Gender	Female	472	40.3	76	61.8	321	37.8	75	37.9
	Male	698	59.7	47	38.2	528	62.2	123	62.1
Race	White	863	73.8	117	95.1	583	68.7	163	82.3
	Black	168	14.4	3	2.4	156	18.4	9	4.5
	Hispanic	111	9.5	2	1.6	87	10.2	22	11.1
	Asian	20	1.7	1	0.8	16	1.9	3	1.5
	Other/uknown	8	0.7	0	0.0	7	0.8	1	0.5
Primary cause of disease	Diabetes Type 1	1,018	87.0	94	76.4	736	86.7	188	94.9
	Diabetes Type 2	67	5.7	0	0.0	61	7.2	6	3.0
	Diabetes type unk.	9	0.8	1	0.8	4	0.5	4	2.0
	Other cause/unk.	76	6.5	28	22.8	48	5.7	0	0.0
Blood type	A	433	37.0	55	44.7	293	34.5	85	42.9
	B	143	12.2	10	8.1	110	13.0	23	11.6
	AB	49	4.2	4	3.3	37	4.4	8	4.0
	O	545	46.6	54	43.9	409	48.2	82	41.4
BMI (kg/m²)	<18.5	30	2.6	7	5.7	17	2.0	6	3.0
	18.5-24.9	543	46.4	49	39.8	410	48.3	84	42.4
	25.0-29.9	396	33.8	38	30.9	291	34.3	67	33.8
	30.0-34.9	124	10.6	16	13.0	86	10.1	22	11.1
	35.0-39.9	14	1.2	1	0.8	13	1.5	0	0.0
	40.0+	6	0.5	1	0.8	4	0.5	1	0.5
	Unknown	57	4.9	11	8.9	28	3.3	18	9.1
Time on waiting list	<30 days	133	11.4	23	18.7	88	10.4	22	11.1
	31-60 days	92	7.9	21	17.1	55	6.5	16	8.1
	61-90 days	83	7.1	11	8.9	59	6.9	13	6.6
	3-<6 months	194	16.6	22	17.9	138	16.3	34	17.2
	6-<12 months	310	26.5	26	21.1	239	28.2	45	22.7
	1-<2 years	209	17.9	9	7.3	160	18.8	40	20.2
	2-<3 years	77	6.6	5	4.1	58	6.8	14	7.1
	3+ years	72	6.2	6	4.9	52	6.1	14	7.1
Insurance	Private	535	45.7	81	65.9	362	42.6	92	46.5
	Medicare	570	48.7	29	23.6	442	52.1	99	50.0
	Other government	62	5.3	12	9.8	43	5.1	7	3.5
	Other	3	0.3	1	0.8	2	0.2	0	0.0
Pancreas tx history	First transplant	1,075	91.9	114	92.7	833	98.1	128	64.6
	Subsequent transplant	95	8.1	9	7.3	16	1.9	70	35.4
Total		1,170	100.0	123	100.0	849	100.0	198	100.0

PA 3.9 Insurance coverage among adult pancreas transplant recipients at time of transplant

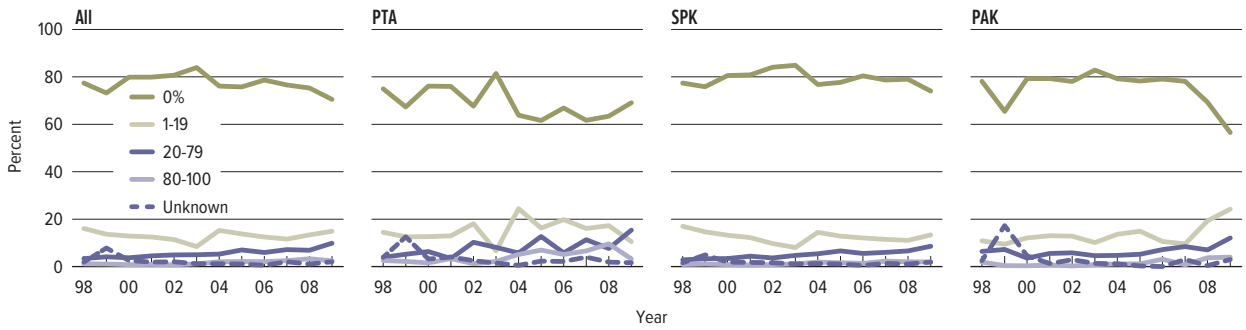


The number of living donor pancreas transplants has decreased in the last decade, with 2 transplants nationwide in the past 4 years, and none in 2009 (Figure 3.6). Transplant rates for all types of pancreas transplants show wide geographic variation (Figure 3.7).

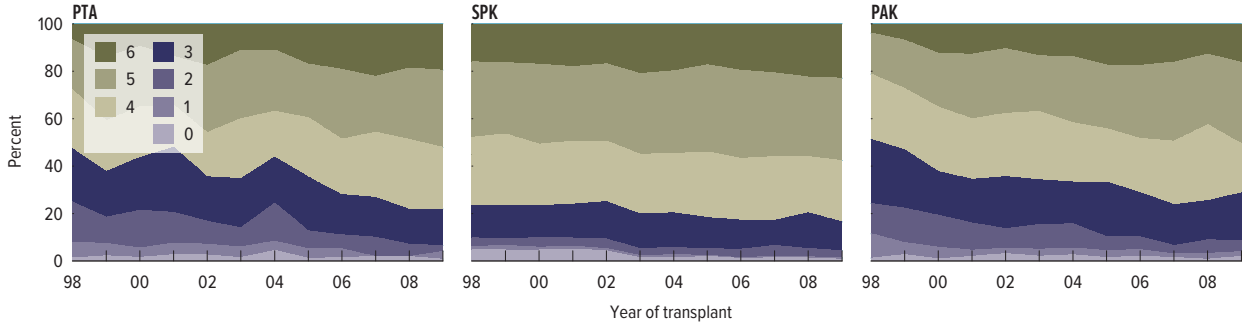
The characteristics of patients undergoing transplant in 2009 are summarized in Figure 3.8. The greatest proportion of transplants was performed in patients aged 35 to 49 years for SPK, PAK, and PTA. Women predominated in the PTA group compared with other groups. With regard to primary cause of disease, it is interesting that 23% of PTA recipients were classified as other cause/unknown; some of these cases can be accounted for by surgical diabetes after pancreatectomy for chronic pancreatitis or premalignant tumors, although the question arises as to whether PTA is being performed for other causes, such as disabling exocrine failure with or without diabetes. In 2009, private insurance paid for 65.9% of PTA transplants, 42.6% of SPK, and 46.5% of PAK. Medicare was the primary payer for 23.6%, 52.1%, and 50.0% of PTA, SPK, and PAK transplants, respectively.

The percentage of recipients covered by Medicare increased steadily over the past decade, from 35.8% in 1998 to 48.7% in 2009. Private insurance coverage declined from 57.1% to 45.7% during this period (Figure 3.9).

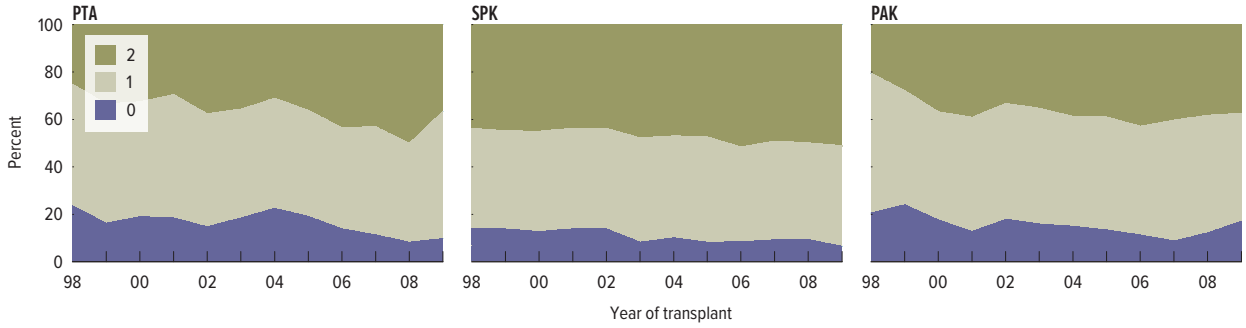
PA 4.1 PRA at time of pancreas transplant in adult recipients



PA 4.2 Total HLA mismatches among adult pancreas transplant recipients



PA 4.3 HLA-A mismatches among adult pancreas transplant recipients

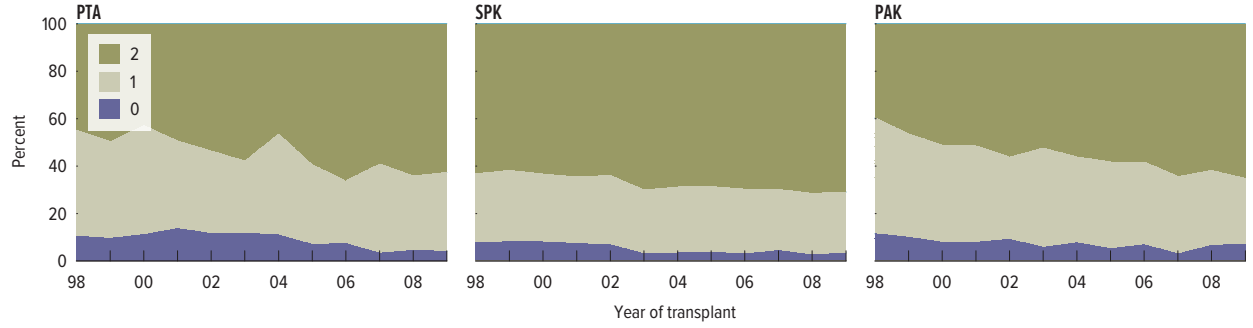


donor-recipient matching

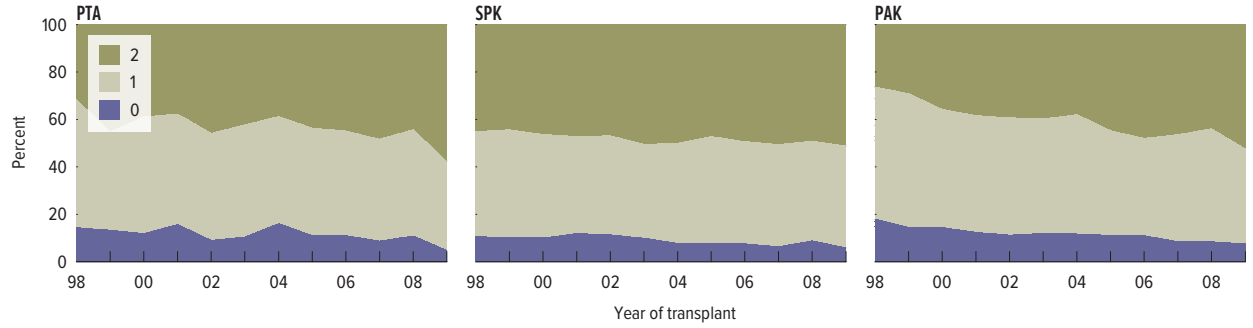
The percentage of unsensitized (PRA 0%) pancreas recipients has decreased over the past few years as the number of re-transplants has likely increased the rate of sensitization. Between 1998 and 2009, the percentage of unsensitized pancreas recipients declined from 77.4% to 70.6%. The decline was from 75.0% to 69.1% in PTA, from 77.5% to 74.1% in SPK, and from 78.2% to 56.6% in PAK. As expected, the proportion of sensitized (PRA > 0%) recipients is highest in the PAK group, likely due to the previous kidney transplant, although 60.0% of these sensitized patients had only a low level of sensitization, i.e., PRA 1% to 19% (Figure 4.1).

Human leukocyte antigen (HLA) matching trends for pancreas transplants show that the percentage of highly mismatched transplants (5 and 6 HLA mismatches) has increased over the past decade. Between 1998 and 2009, the percentage with 5 or 6 HLA mismatches increased from 27.7% to 51.2% for PTA, from 47.6% to 57.6% for SPK, and from 21.2% to 50.5% for PAK (Figure 4.2). In 2009, 55.7% of all pancreas transplants had 5 or 6 antigen mismatches (up from 42.9% in 1998); the increase in the total number of HLA mismatches for all pancreas transplants correlates with the drop in solitary pancreas transplants (PTA and PAK) as a percentage of overall pancreas transplants (Figure 3.1), where HLA matching is considered more important.

PA 4.4 HLA-B mismatches among adult pancreas transplant recipients



PA 4.5 HLA-DR mismatches among adult pancreas transplant recipients



Similarly, the number of 0 HLA mismatched pancreas transplants has been steadily decreasing, down from 4.1% in 1998 to 1.1% in 2009, indicative of gradual changes in policy and practices regarding mandatory sharing for 0 HLA mismatches. This decline can be almost entirely accounted for by the decline in 0 HLA mismatched SPK, from 4.8% in 1998 to 0.9% in 2009, while over this same time period there was a small increase from 1.3% to 2.0% for PAK and only a small decline from 1.3% to 0.8% for PTA. The HLA-B loci are the most mismatched, with 69.0% of pancreas transplants showing 2 (complete) HLA-B mismatches, 61.8% of PTAs , 71.0% of SPKs, and 65.2% of PAKs (Figures 4.3, 4.4, and 4.5).

PA4.6 Adult pancreas donor-recipient cytomegalovirus (CMV) serology matching, 2005–2009

	DONOR			
RECIPIENT	Negative	Positive	Unknown	Total
Negative	18.7	28.0	0.3	46.9
Positive	17.9	29.1	0.2	47.2
Unknown	2.2	3.7	0.0	5.8
Total	38.8	60.8	0.5	100

PA4.7 Adult pancreas donor-recipient Epstein-Barr virus (EBV) serology matching, 2005–2009

	DONOR			
RECIPIENT	Negative	Positive	Unknown	Total
Negative	0.7	9.9	2.6	13.3
Positive	4.1	39.8	20.0	63.9
Unknown	1.0	11.5	10.3	22.8
Total	5.8	61.2	33.0	100

PA4.8 Adult pancreas donor-recipient hepatitis B core antibody (HBcAb) serology matching, 2005–2009

	DONOR			
RECIPIENT	Negative	Positive	Unknown	Total
Negative	71.6	0.8	0.3	72.7
Positive	3.1	0.1	0.0	3.2
Unknown	23.8	0.2	0.0	24.0
Total	98.6	1.1	0.3	100

PA4.9 Adult pancreas donor-recipient hepatitis B surface antigen (HBsAg) serology matching, 2005–2009

	DONOR			
RECIPIENT	Negative	Positive	Unknown	Total
Negative	85.0	0.0	0.2	85.1
Positive	1.2	0.0	0.0	1.2
Unknown	13.7	0.0	0.0	13.7
Total	99.8	0.0	0.2	100

PA4.10 Adult pancreas donor-recipient hepatitis C serology matching, 2005–2009

	DONOR			
RECIPIENT	Negative	Positive	Unknown	Total
Negative	85.0	0.0	0.2	85.2
Positive	3.2	0.0	0.0	3.2
Unknown	11.5	0.0	0.0	11.6
Total	99.7	0.1	0.2	100

PA4.11 Adult pancreas donor-recipient human immunodeficiency virus (HIV) serology matching, 2005–2009

	DONOR			
RECIPIENT	Negative	Positive	Unknown	Total
Negative	77.0	0.0	0.1	77.1
Positive	0.0	0.0	0.0	0.0
Unknown	22.9	0.0	0.0	22.9
Total	99.9	0.0	0.1	100

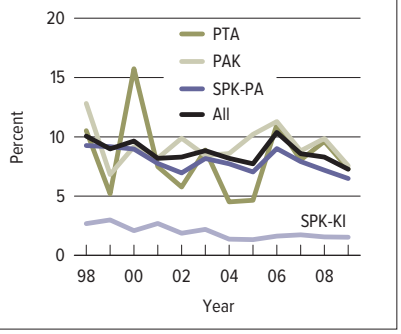
donor-recipient matching

Donor-recipient virology data were analyzed for 2005–2009. Cytomegalovirus (CMV) analysis shows that the high-risk group (donor positive and recipient negative, or D+/R-) was 28% of the total, higher than in the kidney transplant cohorts (see Figure 5.6, Kidney chapter). The difference is attributable mostly to the R+ percentage in pancreas transplant, which is much lower than in deceased donor kidney transplants (66% vs. 47%). The D+/R+ group was the largest by a slim margin in pancreas transplants (29%) (Figure 4.6).

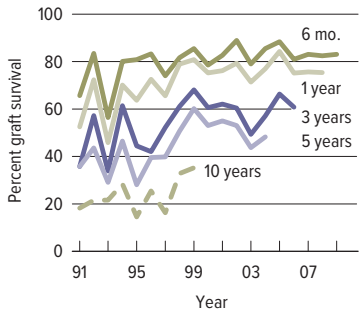
Overall, donor-recipient serologic status for Epstein-Barr virus (EBV) in pancreas transplants was similar to that seen in deceased donor kidney transplants (see Figure 5.7, Kidney chapter), with the high-risk group (D+/R-) accounting for 9.9%, slightly higher than in deceased donor kidney transplants (7.7%) (Figure 4.7).

Hepatitis B virus, hepatitis C virus, and human immunodeficiency virus (HIV) rates of positive serology were extremely low in donors and recipients. Only 1.1% of pancreas recipients received a hepatitis B core antibody positive donor pancreas (Figure 4.8), and no donors were positive for hepatitis B surface antigen (Figure 4.9). However, 3.2% of recipients were positive for hepatitis core antibody (Figure 4.8), and 1.2% were hepatitis B surface antigen positive (Figure 4.9). For antibody to hepatitis C, only 3.2% of recipients were positive (Figure 4.10). There were no reported HIV-positive donors or recipients during this period (Figure 4.11).

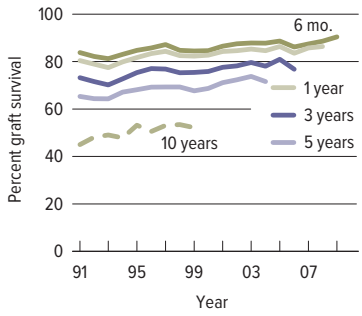
PA 5.1 Early (reported w/i 6 wks of tx) graft failure among adult pancreas transplant recipients



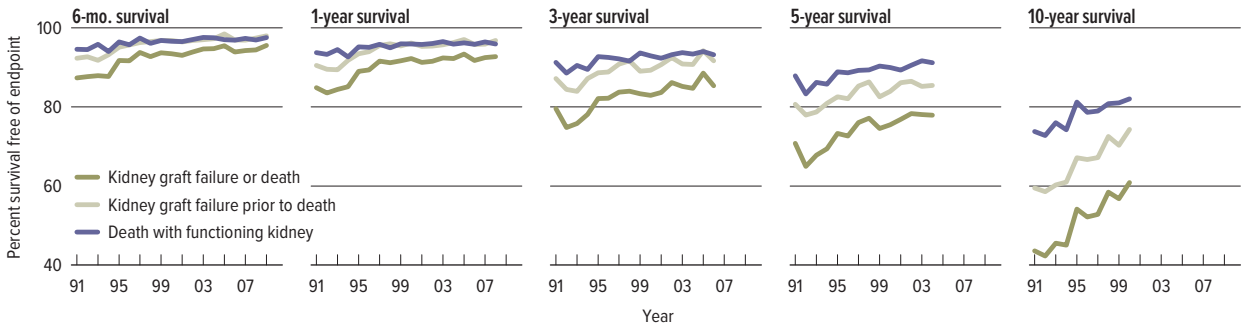
PA 5.2 Graft failure among adult PTA transplant recipients



PA 5.3 Graft failure among adult SPK transplant recipients: pancreas outcomes



PA 5.4 Outcomes among adult SPK transplant recipients: kidney outcomes



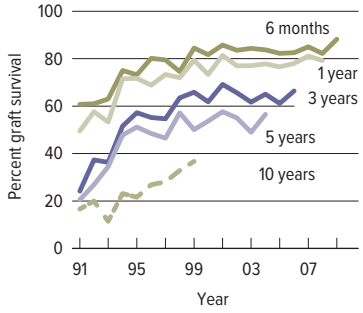
outcomes

The number of early (within the first 6 weeks after transplant) pancreas graft failures has gradually decreased since 2006 for SPK, PAK, and PTA (Figure 5.1). In 2009, early pancreas graft failures were reported in 6.5%, 7.6%, and 7.3%, respectively. Most noticeable are the large improvements in preventing early graft loss and thrombosis in the pre-uremic pancreas transplant recipients, compared with results in 2006–2008 (Figure 5.1). Hopefully, improvements in early outcomes for pre-uremic pancreas recipients with higher rates of graft thrombosis will translate to improved long-term results.

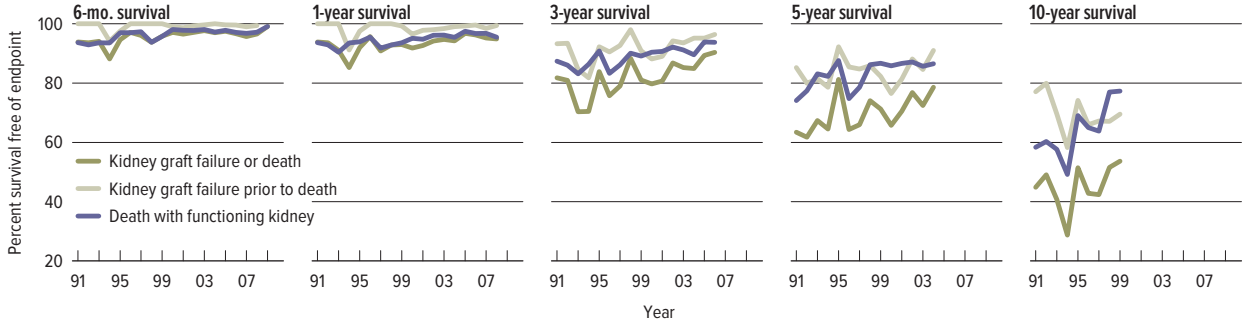
One-year PTA graft survival was 75.4% for transplants in 2008 (Figure 5.2). For PTA recipients in 2004, 5-year graft survival was 48.3%. Although graft loss was not specifically defined, centers presumably reported loss of function as return to insulin therapy. With early graft success for PTA now approximating that of the pancreas in SPK, hopefully further refinement in immunosuppressive strategies will make the long-term results for PTA comparable to the more successful long-term results for SPK transplant.

In 2009, 1-year graft survival of the pancreas in SPK recipients reached a high of 86.4% (Figure 5.3). Five-year graft survival of the pancreas in SPK transplants performed in 2004 was 72%; again, longer-term improvements may be expected in this group of patients, who have enjoyed a marked benefit from simultaneous transplant of the pancreas and kidney. One-year graft survival of the kidney (not censored for death) in SPK recipients remains excellent, at 93% (Figure 5.4).

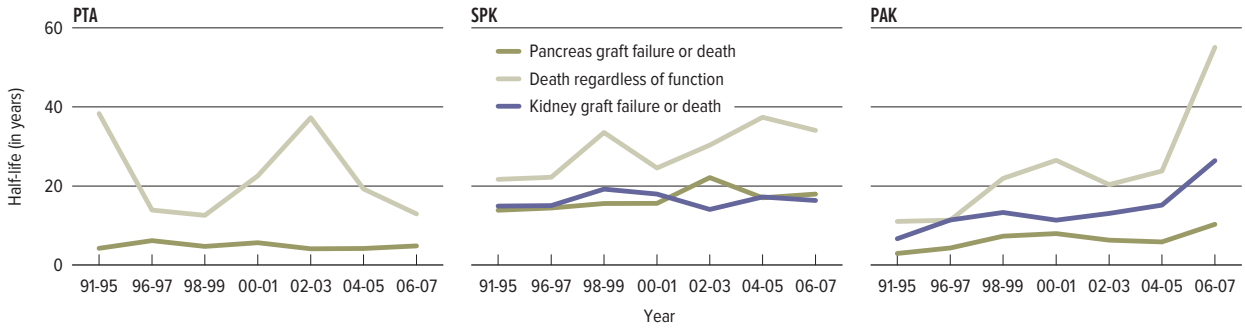
PA 5.5 Pancreas graft failure among adult PAK transplant recipients



PA 5.6 Outcomes among adult PAK transplant recipients: kidney outcomes (from time of pancreas transplant)



PA 5.7 Half-lives for adult pancreas transplant recipients surviving with a functioning pancreas for at least one year



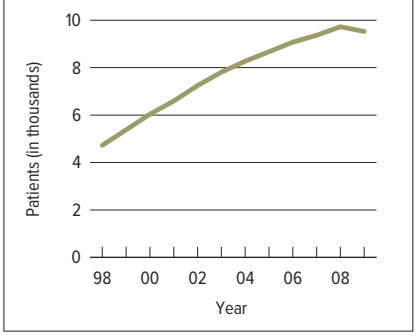
outcomes

Six-month pancreas survival in PAK transplants also was at a high, improved from 82.2% for transplants performed in 2008 to 88.2% for those performed in 2009 (Figure 5.5). Of equal significance, almost no loss of kidney grafts from the time of the PAK occurred, with 6-month graft survival of the kidney for PAK performed in 2008 at 99.1% (Figure 5.6). Graft half-lives (estimated median survival time of the graft for patients alive with function at 1 year post-transplant) were generally stable for PTA and SPK (Figure 5.7). Kidney graft half-life and patient survival half-life appear to have improved for PAK recipients. Estimated half-lives for the pancreas allograft (not censored for death) for 2006–2007 transplants (conditional on 1-year post-transplant survival) are 17.9, 10.3, and 4.8 years for SPK, PAK, and PTA transplants, respectively (Figure 5.7).

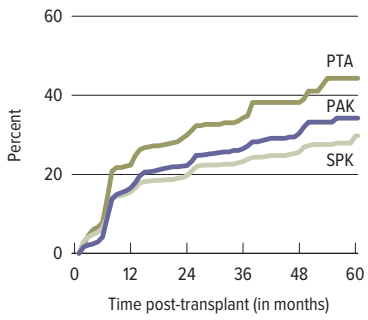
The 2-fold growth in the number of patients alive with a functioning transplanted pancreas, from 4,726 in 1998 to 9,725 in 2008, is remarkable (Figure 5.8). However, recent declines in new pancreas transplants have led to a slight decline in the number of pancreas transplant recipients who are alive with a functioning pancreas, to 9,535 in 2009.

Figure 5.9 shows the cumulative incidence of acute pancreas rejection after PTA and PAK, and acute pancreas and/or kidney rejection after SPK. The rejection rates for pancreata have decreased over the past decade, but remain higher than rates for kidneys. Pancreas

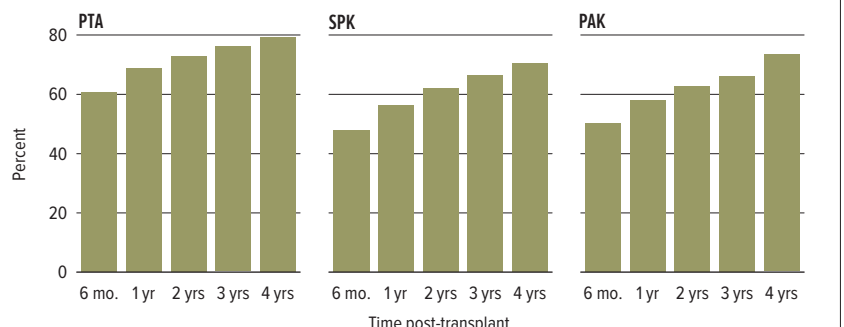
PA 5.8 Adult recipients alive & with a functioning pancreas transplant on June 30 of the year



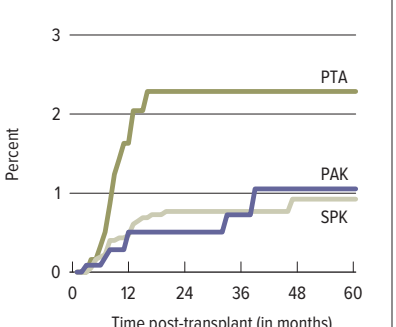
PA 5.9 Incidence of first acute rejection among adult pts receiving a pancreas tx in 05–09



PA 5.10 Reported hospitalizations among adult patients receiving a pancreas transplant in 2005–2009



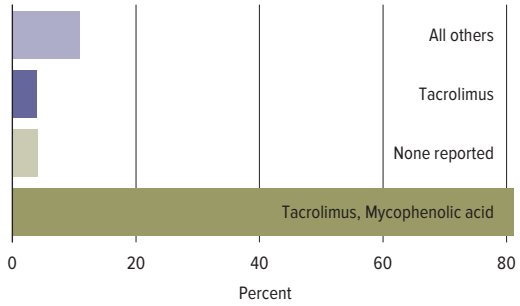
PA 5.11 Incidence of PTLD among adult pts receiving a pancreas transplant in 2005–2009



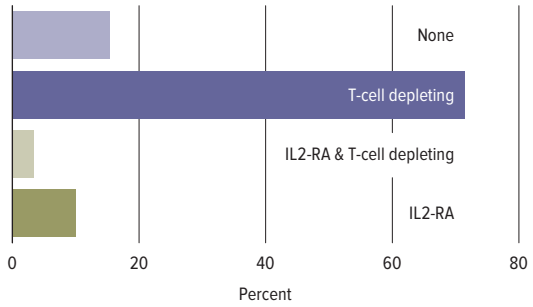
transplants performed in pre-uremic diabetic patients have higher rejection rates in PTA (44.3% at 5 years) than in PAK or SPK (34.3% and 29.7%, respectively) (Figure 5.9). This may be secondary to a more robust immune system in the non-uremic recipient.

The complexity of and high degree of morbidity after pancreas transplant are reflected in the high frequency of hospitalizations. More than 70% of patients are hospitalized within 4 years (Figure 5.10). The cumulative incidence of post-transplant lymphoproliferative disorder (PTLD) at 4 years was 2.3% after PTA, 0.9% after SPK, and 1.1% after PAK (Figure 5.11). The higher frequency of PTLD in PTA patients is likely related to their increased immunosuppressive requirements and higher rates of acute rejection.

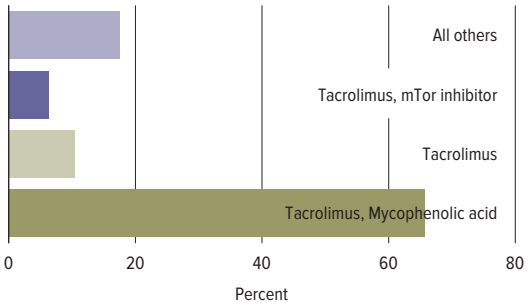
PA6.1 Initial immunosuppression regimen in adult pancreas transplant recipients, 2009 (steroids not considered)



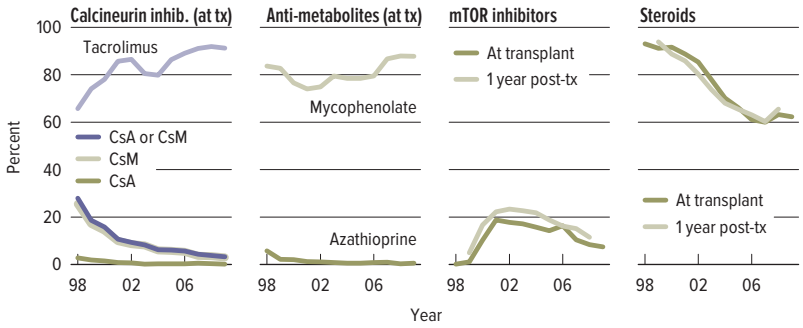
PA6.2 Induction agents used at time of pancreas transplant, adult recipients 2009



PA6.3 Immunosuppression regimen at one year in adult pancreas transplant recipients, 2008 (steroids not considered)



PA6.4 Immunosuppression use in adult pancreas transplant recipients

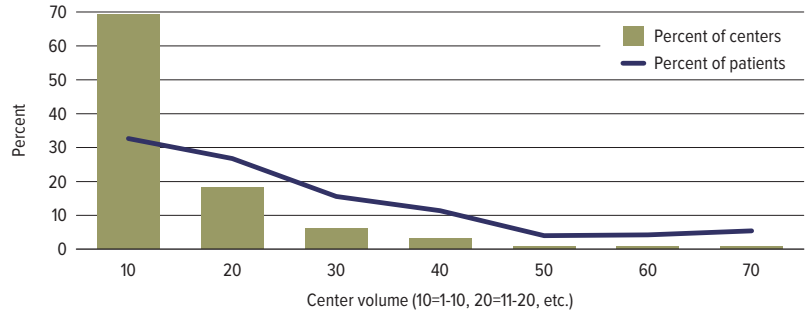


immunosuppression

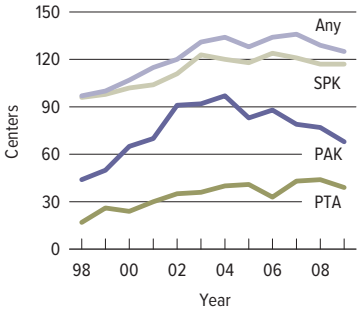
The effect of the higher rejection rates observed with pancreas transplant is reflected in the more aggressive immunosuppressive regimens used with most pancreas transplant recipients. Induction therapy using the potent lymphocyte depleting regimens was used in 71.4% of the recipients, and anti-interleukin-2 (IL2-RA) receptor antibodies were used as the sole induction agent in only 10% (Figure 6.2). Maintenance immunosuppression included both tacrolimus and mycophenolate in more than 80% of cases (Figure 6.1). Furthermore, most of these recipients were on the calcineurin inhibitor and anti-metabolite at 1 year (65.7%) (Figure 6.3).

Despite the increased use of potent induction and maintenance therapy with tacrolimus and mycophenolate over the past decade, it is interesting that there has been a trend toward steroid avoidance (Figure 6.4). Currently, approximately 40% of the recipients have been maintained on a steroid-free regimen. It is important to note that in this group of steroid-free recipients, the avoidance of steroids appeared to be from the time of transplant, as the percentage of steroid-free recipients was the same at the time of transplant and 1 year after transplant. The use of mammalian target of rapamycin (mTOR) inhibitors continues to decrease, and was reported in 7.5% of the pancreas transplant recipients in 2009.

PA 7.1 Distribution by center volume of the number of pancreas transplants performed (includes kidney-pancreas), 2009



PA 7.2 Centers performing pancreas transplants

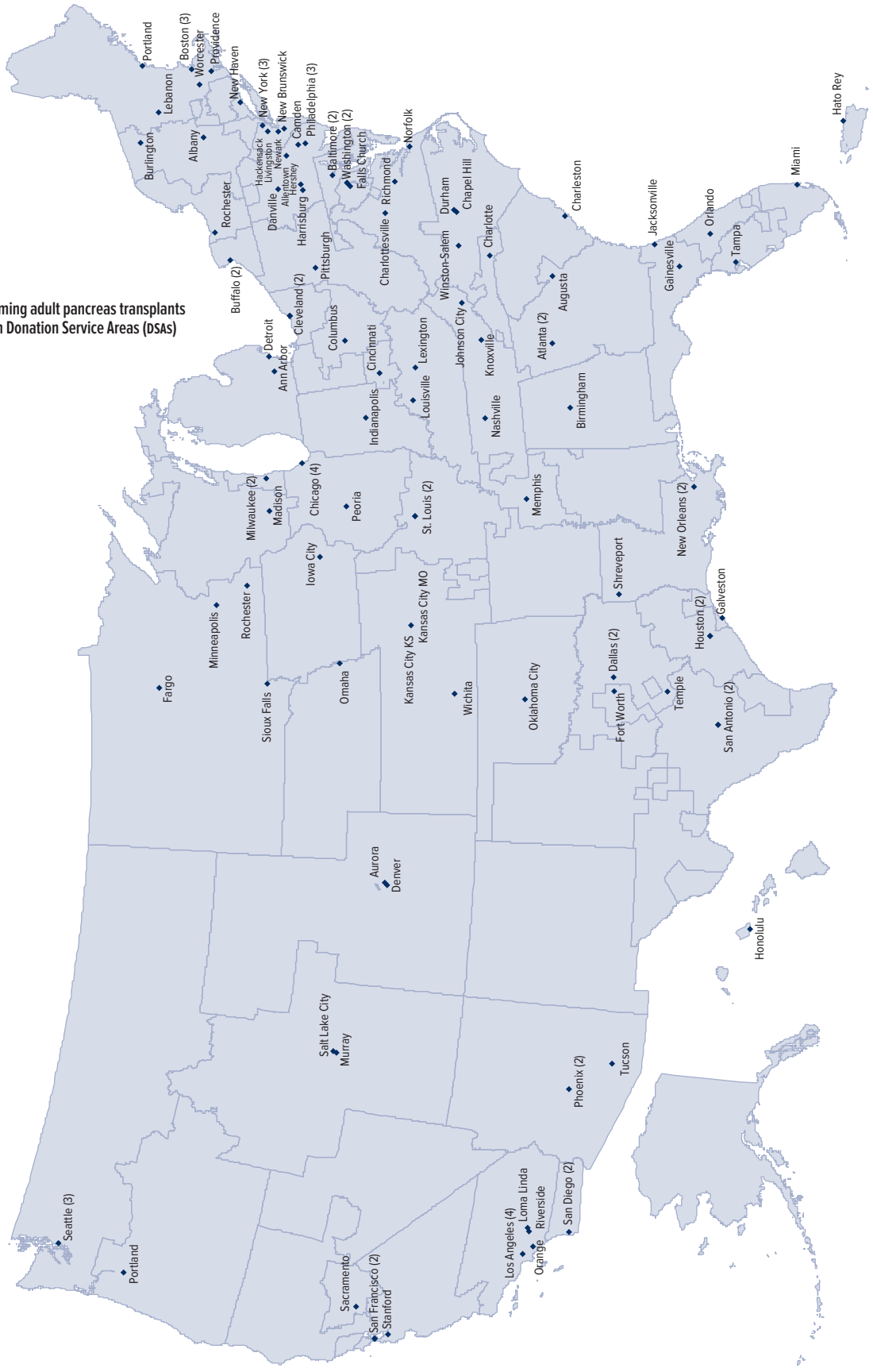


center characteristics

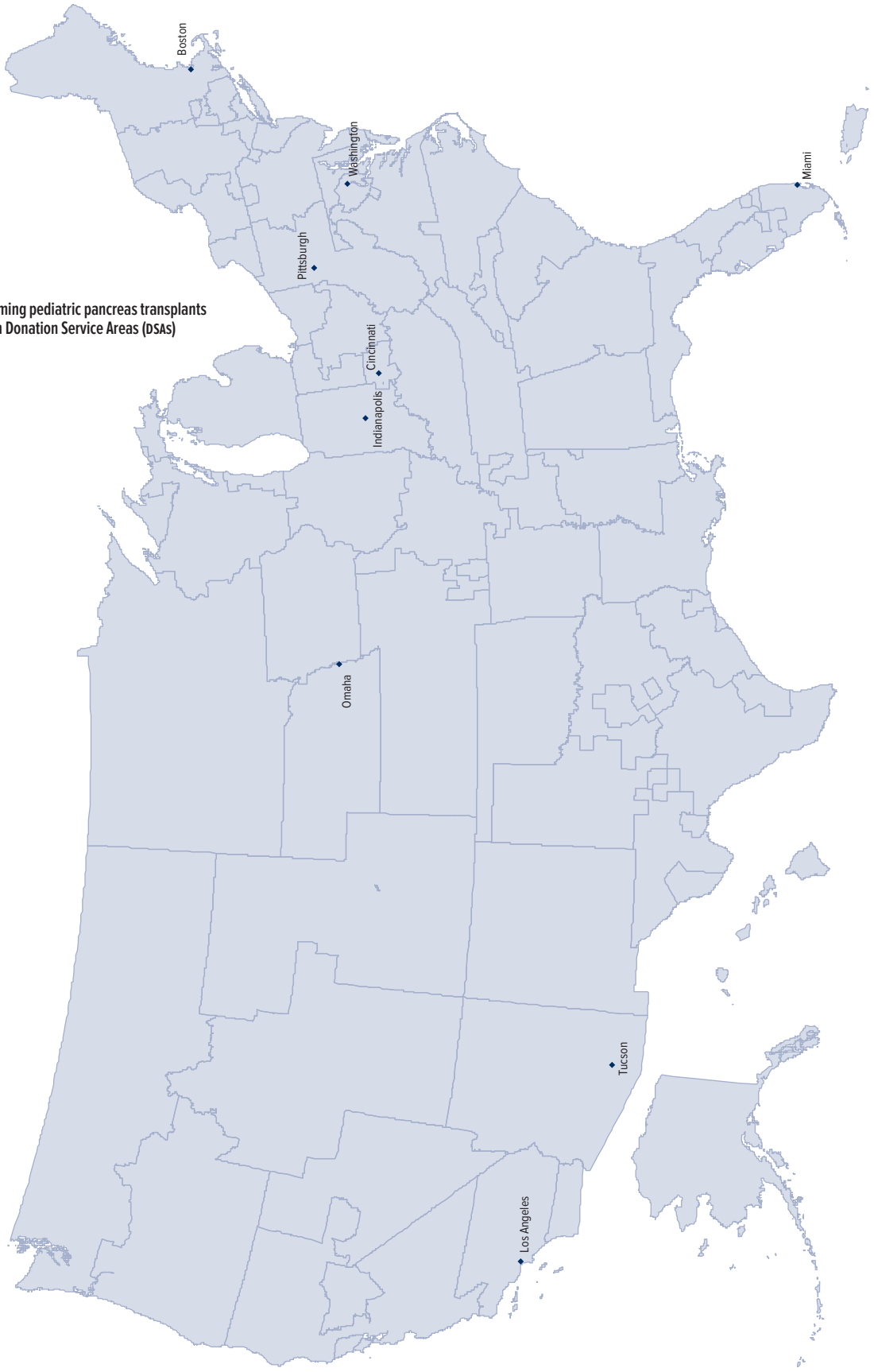
Very few pancreas transplants are performed in recipients aged younger than 18 years. In 2009, only 63 pancreas transplants (58 PTA, 5 SPK) were performed in children and adolescents, and most of these were performed as part of a multi-organ transplant procedure. Few pancreas transplants in children and adolescents are performed for diabetes. Given the very small numbers of these transplants, these data are not shown.

Seventy percent of pancreas transplant centers performed 10 or fewer pancreas transplants in 2009 (Figure 7.1). Only 5.6% of centers performed more than 30 during that time. Of 125 centers that performed pancreas transplants in 2009, 117 performed SPK, 68 PAK, and only 39 performed PTA (Figure 7.2).

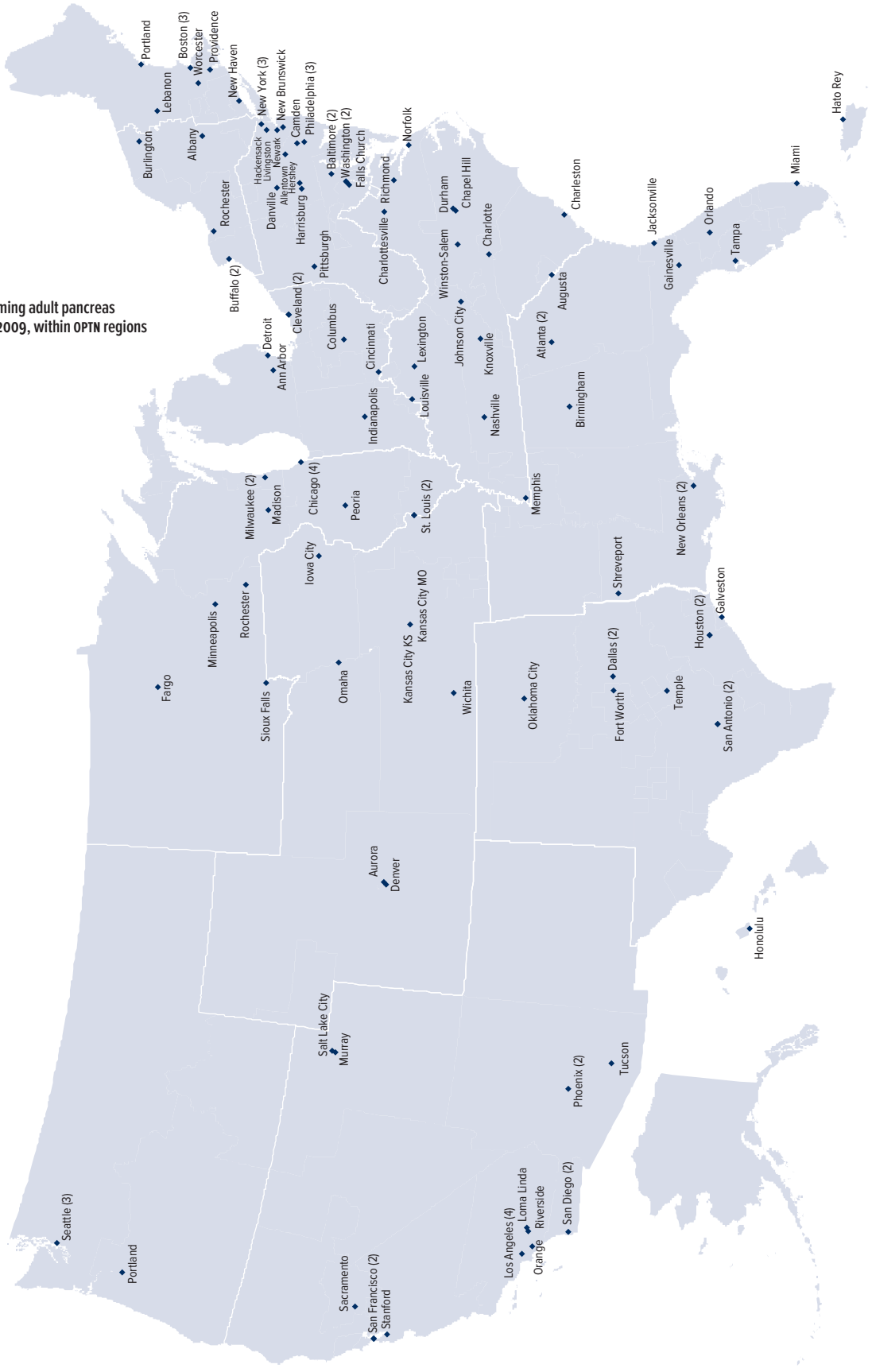
PA 8.1 **Centers performing adult pancreas transplants in 2009, within Donation Service Areas (DSAs)**



PA 8.2 **Centers performing pediatric pancreas transplants in 2009, within Donation Service Areas (DSAs)**



PA 8.3 **Centers performing adult pancreas transplants in 2009, within OPTN regions**



liver

The number of adult recipients of deceased donor liver transplants peaked in 2006, and has remained relatively stable over the past 2 years (Figure LI 4.1). In 2009, only 168 of 5,748 transplanted livers (2.9%) were from living donors. Concerns about donor safety, and generally good outcomes after deceased donor liver transplant, have limited use of living donors. The proportion of livers transplanted from living donors is greater for pediatric than for adult recipients (Figure 8.8). In 2009, only 51 of 572 pediatric liver transplants (8.9%) used organs from living donors. Most recovered livers were transplanted. For example, in 2009, livers were recovered from 85% of all deceased donors, and 76% of deceased donors were transplanted.

Implementation of the model for end-stage liver disease (MELD) system in 2002 led to a sharp reduction in liver transplant waiting list registrations (Figure 1.1). After transplant, the most common reason for removal from the waiting list is death (Figure 1.5). In 2009, reasons for removal were transplant (56.9%), death (22.8%), becoming too ill for transplant (3.1%), improving enough not to need transplant (5.6%), transferring to another center (1.8%), and other (9.8%). High mortality on the liver transplant waiting list is thus a major challenge.

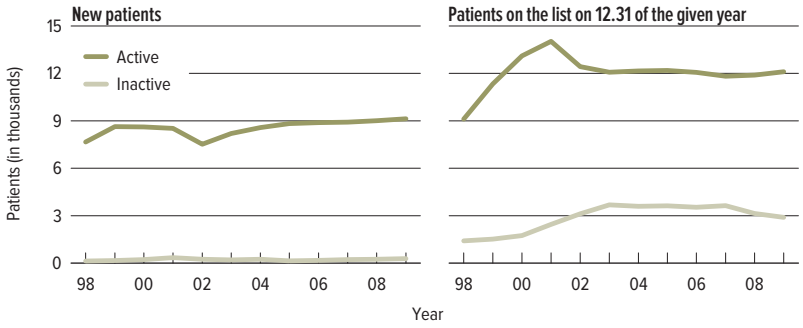
In adjusted analysis of deceased donor liver graft survival (Figure 6.2), 6-month graft survival increased from 74.3% in 1991 to 89.8% in 2009; 1-year graft survival increased from 70.0% in 1991 to 84.9% in 2008; 3-year graft survival increased from 62.4% in 1991 to 75.0% in 2006; 5-year graft survival increased from 56.6% in 1991 to 67.1% in 2004; and 10-year graft survival increased from 43.4% in 1991 to 51.3% in 1999. Living donor liver graft survival has improved similarly (Figure 6.3).

Without treatment, patients with Anna's condition often only live about two years. We are just so appreciative that another family made the generous decision to share life with our daughter.

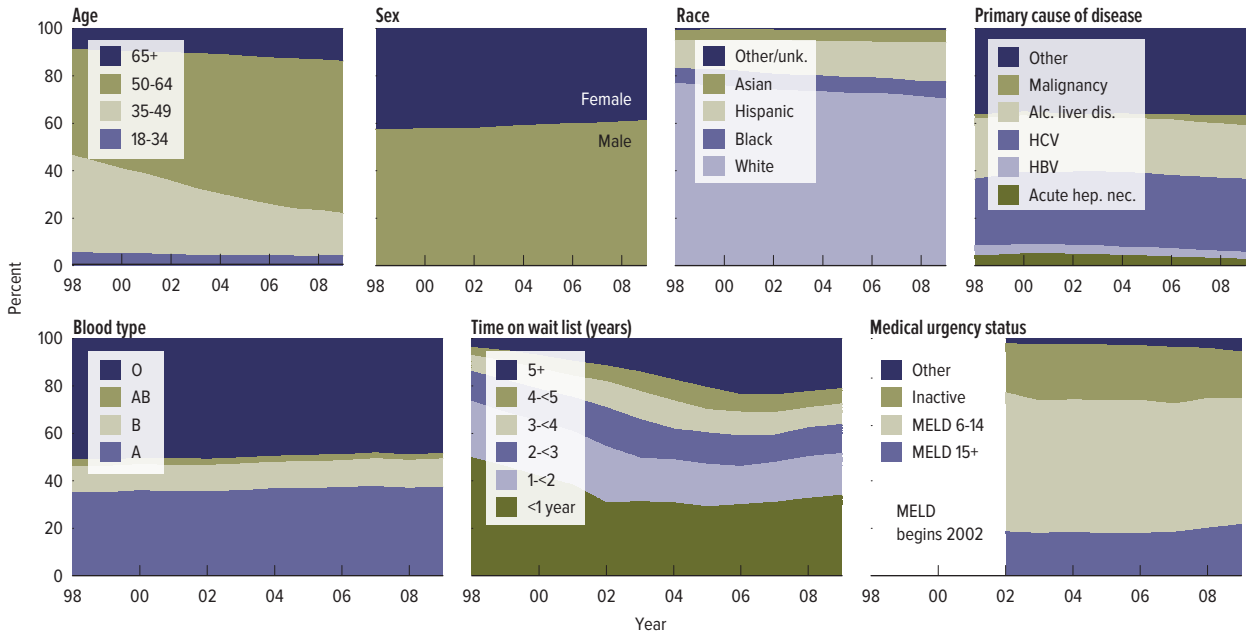
Kim, mother of liver recipient

OPTN SRTR SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

LI 1.1 Adult patients waiting for a liver transplant



LI 1.2 Distribution of adult patients waiting for a liver transplant



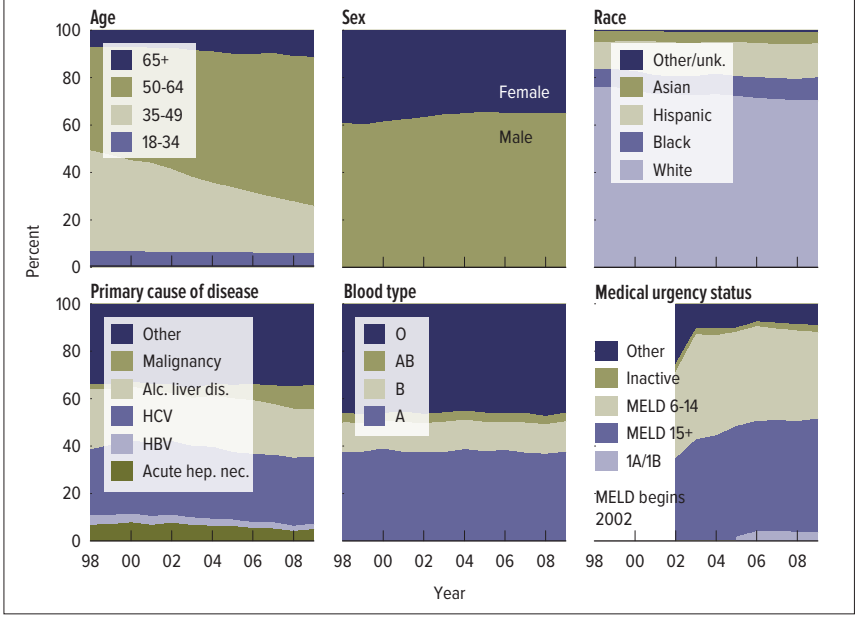
wait list

On February 27, 2002, use of the MELD score as the main criterion for liver allocation began. MELD is a numerical score based on 3 objective variables: the serum concentrations of total bilirubin and creatinine, and the international normalized ratio (INR) for prothrombin time. By adopting MELD, the allocation policy operationalized the "sickest-first" policy.

Implementation of the MELD system led to a sharp reduction in liver transplant waiting list registrations (Figure 1.1) because, unlike under the previous allocation scheme, accrual of waiting time was no longer necessary. The impact of the MELD system is more pronounced when the number of prevalent patients is considered (Figure 1.1). The number of patients waiting for a liver transplant had been increasing continuously, but has essentially remained flat since 2002.

The age distribution of wait-listed registrants has changed noticeably in that the age group 50 to 64 years has increased substantially in the past decade (Figures 1.2 and 1.3). This likely reflects changes in the epidemiology of liver disease in the United States. The most common cause of disease among liver transplant candidates is the end-stage consequences of chronic hepatitis C virus (HCV) infection (Figures 1.2 and 1.3), which mostly affects Americans in their 50s and 60s. Thus, the age shift seen in these figures partly reflects the aging of the cohort of HCV-infected patients over time. Another contributing factor may be the increasing number of wait-listed registrants with obesity-related

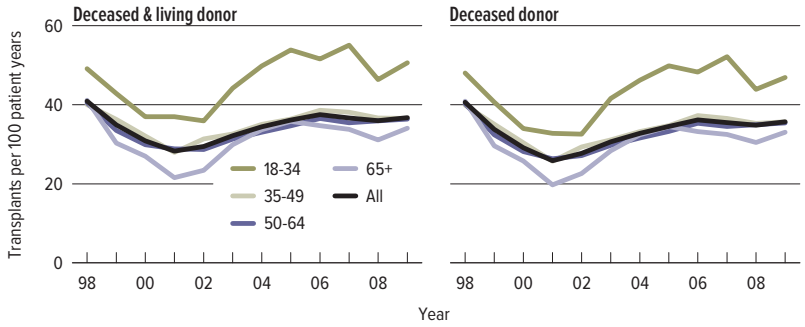
LI 1.3 Distribution of adult patients newly listed for a liver transplant



fatty liver disease. The rapid increase in the prevalence of obesity in the US is well recognized. One of the complications of obesity is so-called nonalcoholic liver disease, which is grouped under Other diagnosis. Some of these patients develop end-stage liver disease, most commonly after they pass middle age. Related to these epidemiologic trends is a clear rising trend in the incidence of hepatocellular carcinoma (HCC). Some patients with HCC who meet the eligibility criteria (the "Milan criteria") can be cured of the malignancy by liver transplant. The proportion of wait-listed registrants for this indication has increased noticeably.

Although the MELD system provides no advantage to patients who are registered early in the course of disease progression, a substantial number of wait-listed registrants are not at an immediate risk of death, as reflected by their low (< 15) MELD scores. By design, these patients are not selected for liver transplant and will accumulate significant time, not infrequently longer than 5 years, on the waiting list before their disease progresses to a MELD score high enough for liver transplant.

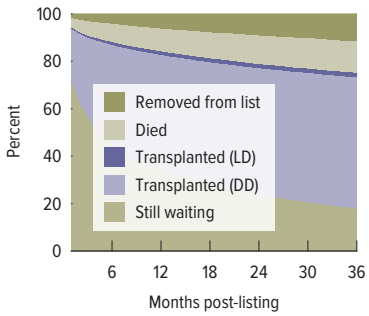
LI 1.4 Transplant rates among adult patients wait-listed for a liver transplant, by age



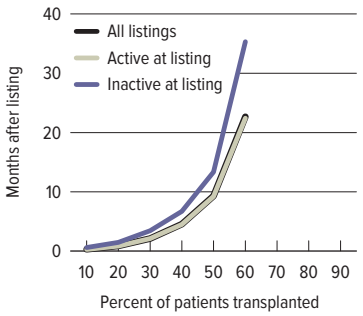
LI 1.5 Liver transplant waiting list activity among adult patients

	2007	2008	2009
Listings at start of year	16,085	15,990	15,641
Listings added during year	10,261	10,344	10,478
Listings removed during year	10,356	10,693	10,494
Listings at end of year	15,990	15,641	15,625
Removal reason			
Deceased donor transplant	5,951	5,791	5,807
Living donor transplant	191	173	168
Patient died	2,336	2,451	2,396
Trans. to another center	263	190	184
Too sick to transplant	269	280	327
Improved, tx not needed	476	585	586
Other	870	1,223	1,026

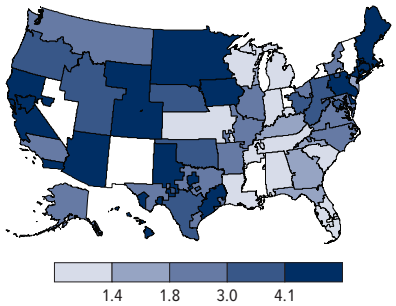
LI 1.6 Liver tx waiting list status by month post-listing among new adult listings in 2006



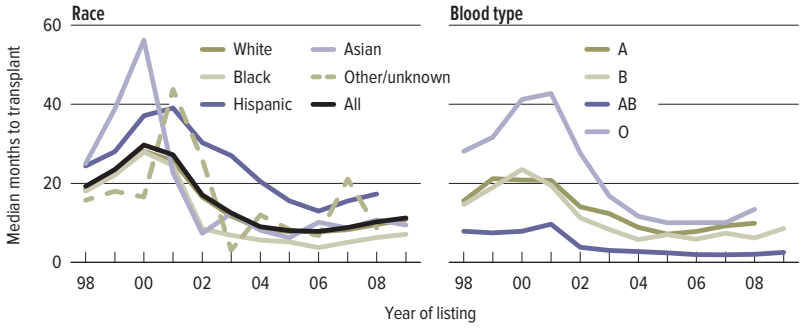
LI 1.7 Percentiles of time to liver transplant for new adult listings, 2005–2009



LI 1.8 Median months to liver transplant for adult patients transplanted in 2009, by DSA



LI 1.9 Median months to liver transplant for wait-listed adult patients

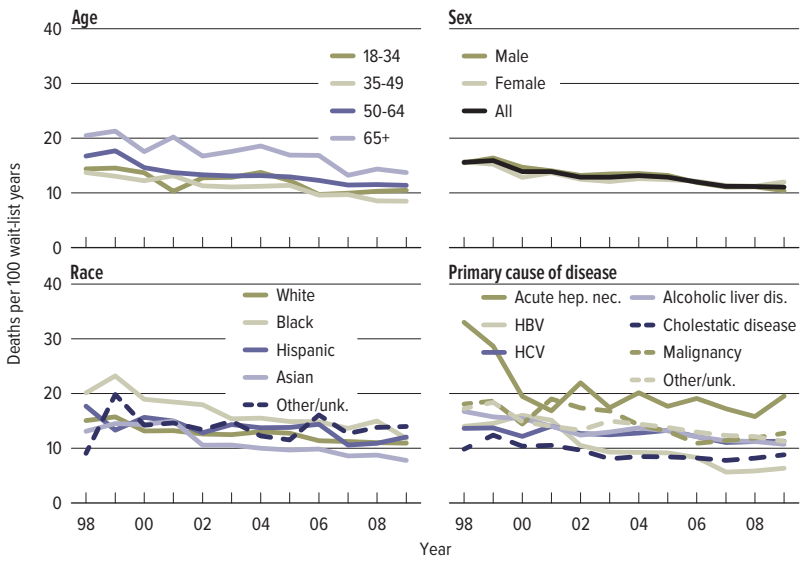


wait list

The rate of liver transplant, which had been decreasing before implementation of MELD in 2002, has been stable since then (Figure 1.4). Other factors contributed to this trend reversal, such as an increased number of donor organs, including expanded criteria donors (ECD).

A similar trend is shown in the median time to transplant. Implementation of the sickest-first policy using the MELD score reversed the previous trend of increasing time to transplant (Figure 1.9). This affected all race and blood type categories. The slight upturn in the curve is a potential cause of concern and may suggest that the degree to which optimization of organ allocation can affect transplant rates is limited. The most common reason for being removed from the waiting list but not undergoing liver transplant is death. In 2009, reasons for removal from the waiting list were transplant (56.9%), death (22.8%), becoming too ill for transplant (3.1%), improving enough not to need transplant (5.6%), transferring to another center (1.8%), and other (9.8%). The high mortality rate on the liver transplant waiting list is thus a major challenge. A substantial degree of variability remains in transplant rates (Figure 1.4), and an improved organ distribution policy may be necessary for waiting times to continue to decrease (Figure 1.9).

LI 1.10 Pre-transplant mortality rates among adult patients wait-listed for a liver transplant



LI 1.11 Characteristics of adult patients on the liver tx waiting list on December 31, 2009

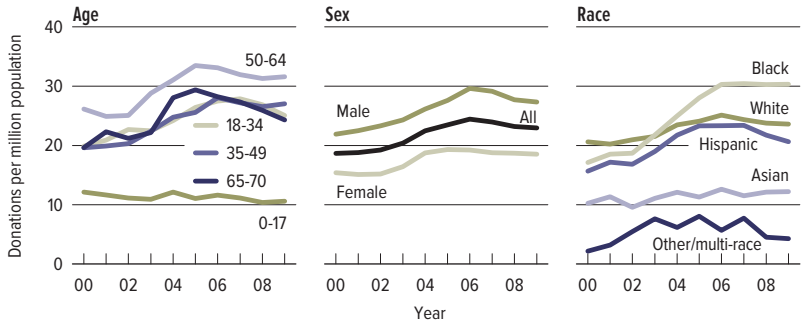
	Level	N	%
Age	18-44	1,726	11.5
	45-64	11,230	74.9
	65-74	1,967	13.1
	75+	78	0.5
Gender	Male	9,178	61.2
	Female	5,823	38.8
Race	White	10,555	70.4
	Black	1,065	7.1
	Hispanic	2,485	16.6
	Asian	752	5.0
	Other/unk.	144	1.0
Primary cause of disease	Acute hepatic necrosis	413	2.8
	HBV	448	3.0
	HCV	4,606	30.7
	Alcoholic liver disease	3,390	22.6
	Cholestatic disease	1,427	9.5
	Malignancy	632	4.2
	Other/unk.	4,085	27.2
Transplant history	Listed for first tx	14,542	96.9
	Listed for sub. tx	459	3.1
Blood type	A	5,622	37.5
	B	1,780	11.9
	AB	356	2.4
	O	7,243	48.3
Time on wait list	<1 year	5,095	34.0
	1-<2	2,649	17.7
	2-<3	1,835	12.2
	3-<4	1,298	8.7
	4-<5	961	6.4
	5+	3,163	21.1
Status	Active	12,069	80.5
	Inactive	2,932	19.6
Medical urgency status	1A/1B	5	0.0
	MELD> 30	83	0.6
	MELD 21-30	631	4.2
	MELD 15-20	2,538	16.9
	MELD 11-14	3,610	24.1
	MELD 6-10	4,363	29.1
	HCC T1	3	0.0
	HCC T2	571	3.8
	Other exceptions	265	1.8
	Inactive	2,932	19.6

Figures 1.5 to 1.9 summarize outcomes of waiting. In 2007–2009, the liver transplant waiting list was essentially in a steady state, with roughly the same number of candidates listed and removed each year.

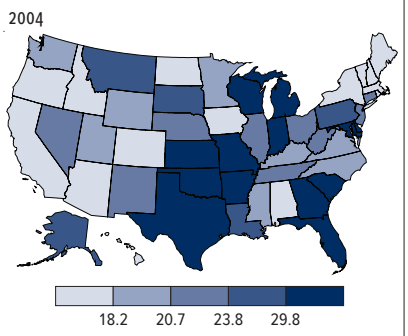
Encouragingly, wait-list mortality has continued to decline in the past decade (Figure 1.10). Further, this decrease occurred for both sexes and all race and age groups, and it affected both acute and chronic liver disease patients. Patients with acute hepatic necrosis by nature are faced with a high risk of mortality, which remains higher than in patients with end-stage complications of chronic liver disease. Status 1 patients are ranked ahead of patients listed with a MELD score at the local and regional level. As of 2009, patients with cholestatic liver disease and hepatitis B virus (HBV) experienced a lower risk of death than others with chronic liver disease.

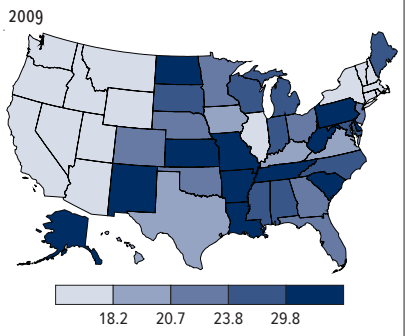
Figure 1.11 is a snapshot of wait-listed patients at the end of 2009. The most typical profile of a wait-listed registrant was age between 45 and 64 years, male, and white, with HCV and blood type O. More than half (53%) of the wait-listed patients had a low (< 15) MELD score, and a substantial number were inactive status.

LI 2.1 Liver donations from deceased donors per million population

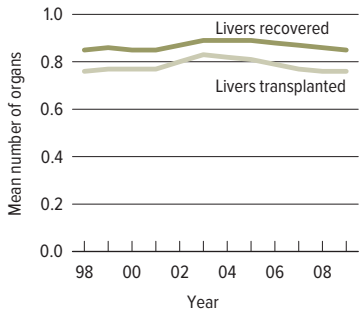


LI 2.2 Deceased donor liver donation rates (per million population, age <70), by state

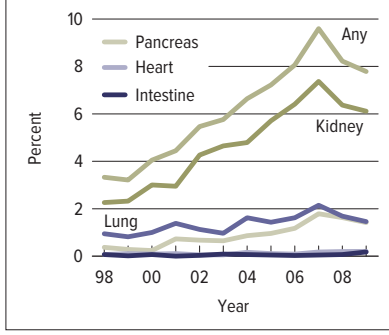




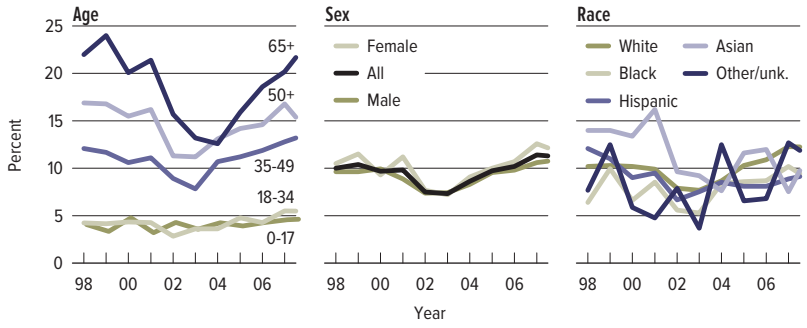
LI 2.3 Livers recovered per donor & livers transplanted per donor



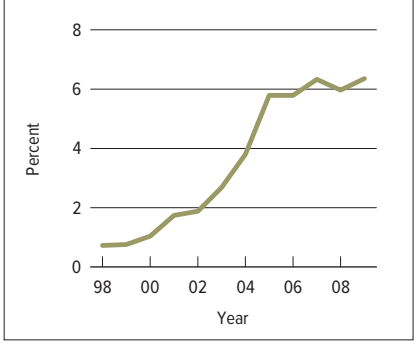
LI 2.4 Deceased donor livers transplanted with another organ



LI 2.5 Discard rates for livers recovered for transplant



LI 2.6 Liver donors who are DCD

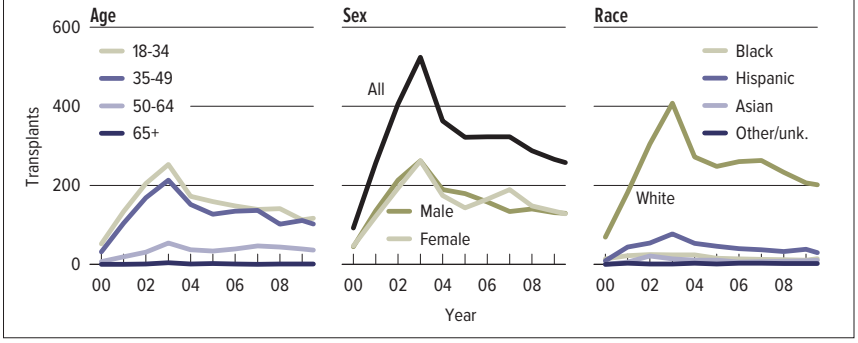


deceased donation

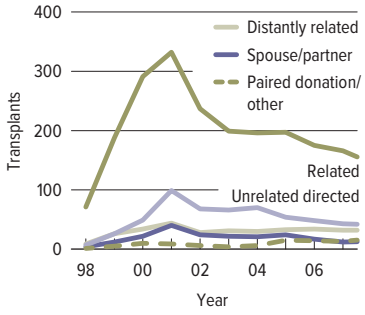
The overall donation rate rose until 2006, when it reached a plateau (Figure 2.1). Rates in older patients (aged 50 years or older) are declining, especially, since 2004, in those aged 65 to 70 years. Rates are highest for blacks, followed by whites, Hispanics, and Asians; the reasons for variability likely include incidence of brain death and age distribution of decedents, and the influence of cultural and belief systems. Some of these factors may underlie the geographic variability in donation rates (Figure 2.2). Rates are lower in the western regions and in the northeast, regions known for the longest waiting times for liver transplant. However, many reasons may account for longer waiting times, including access to transplantation.

Livers are recovered from nearly 90% of donors (Figure 2.3). Both the recovery and transplant rates seem to be falling. The discard rate is highest for older donors: 20% of recovered livers from donors aged 65 years or older were discarded in 2009 (Figure 2.5). This may reflect recognition of the deleterious outcome of older donor organs in recipients with HCV infection, and the trend toward increasing numbers of ECDs being sought, some of whose organs may be found unacceptable. The proportion of donation after circulatory death (DCD) donors increased rapidly in the early 2000s, then remained stationary (Figure 2.6). The increasing trend toward multi-organ transplant in liver recipients is well recognized (Figure 2.4). This may be attributable in part to the MELD system, although the rising trend began before MELD was implemented in 2002.

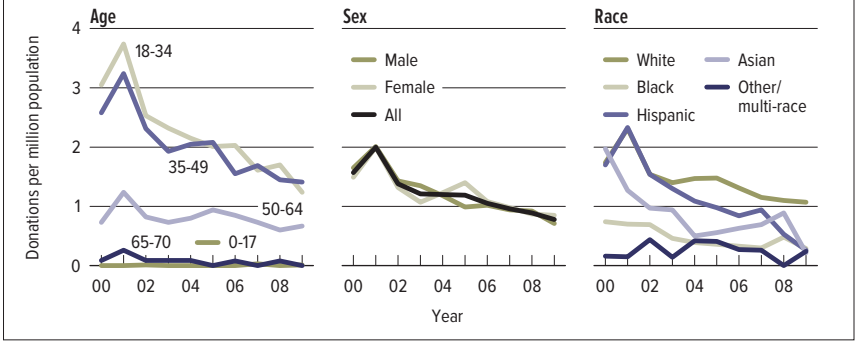
LI 3.1 **Liver donations from living donors**



LI 3.2 **Liver transplants from living donors, by donor relation**



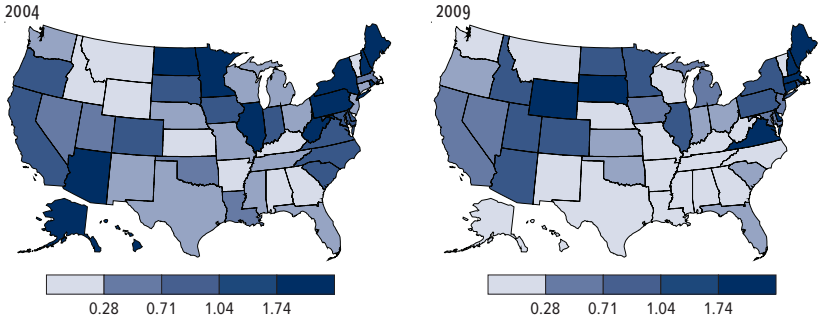
LI 3.3 **Living donor liver donation rates per million population**



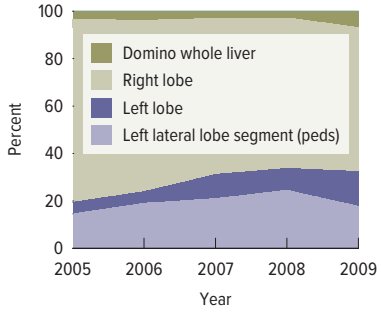
live donation

The number of living donor liver transplants performed in 2009 (n = 219) reflects a continued decrease since the peak in 2001 and a further decrease since 2008 (n = 249). This trend likely reflects ongoing concern related to the relatively higher risks of donor morbidity and mortality compared with risks for living kidney donors. Demographic characteristics of living liver donors have not changed regarding age, sex, race (Figure 3.1), or donor relation (Figure 3.2). In 2009 most living donors (83%) were younger than 50 years old, reflecting the concern regarding higher rates of morbidity in older living donors. Although related donors remain the majority of living donors, the numbers decreased more in proportion to unrelated, distantly related, unrelated directed, and paired exchange donors (Figure 3.2). Rates of living donations (per million population) have also declined (Figure 3.3).

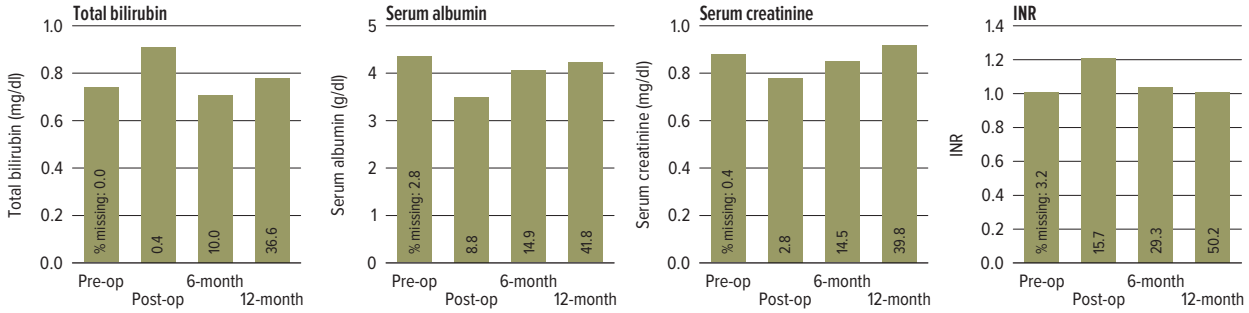
LI 3.4 **Living donor liver donation rates (per million population, age <70), by state**



LI 3.5 **Living donor liver transplant graft type**



LI 3.6 **Mean pre- & post-operative total bilirubin, serum albumin, serum creatinine, & INR among liver donors, 2008**

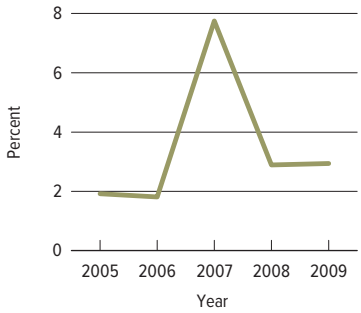


live donation

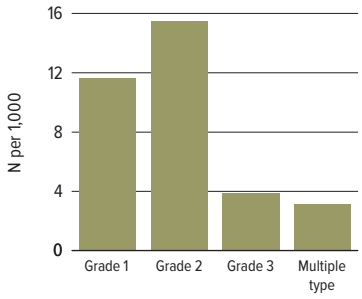
Significant geographic disparities remain regarding rates of living donor liver donation. Certain regions in the southeast and Pacific Northwest have extremely low or absent rates of living donor liver transplants (Figure 3.4), possibly reflecting shorter waiting times for deceased donor organs at the local center. Many centers performing living donor liver transplants proceed with a living donor only if the donor risks are justified by long waiting times and higher MELD requirements or if a deceased donor organ cannot be allocated within a safe time period.

Although fewer living donor transplants were performed in 2009, the number of left-lobe transplants increased relative to right-lobe transplants (Figure 3.5). Right lobes continue to represent most living donor transplants, at 63% and 60.7% of all living donor transplants in 2008 and 2009, respectively. Left lobes made up only 9.2% of living donor transplants in 2008, increasing to 14.6% in 2009. The relative increase in left-lobe transplants is consistent with the overall concern in the transplant community to minimize donor morbidity, as donation of the left lobe is considered a relatively safer procedure. Also of interest was a significant decrease in the number of left lateral segment living donor transplants performed in 2009 (n = 39), down from 2008 (n = 61). It is unclear whether the decrease in living donation to children relates to increased access to split deceased donor livers; this will be important to monitor in

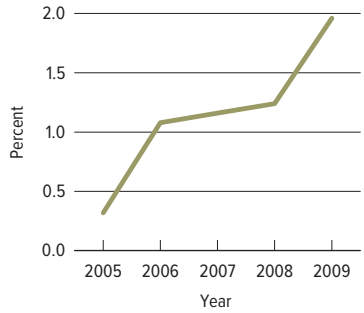
LI 3.7 Biliary complications among live liver donors



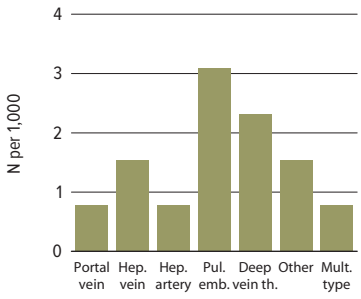
LI 3.8 Type of biliary complications among live liver donors



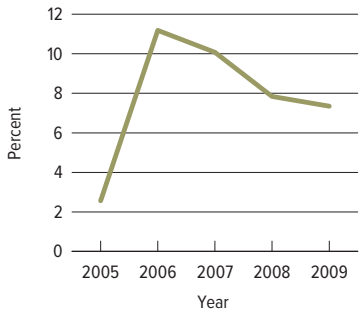
LI 3.9 Vascular complications (requiring intervention) among live liver donors



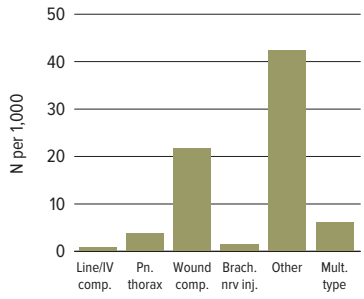
LI 3.10 Type of intervention for vascular complications among live liver donors



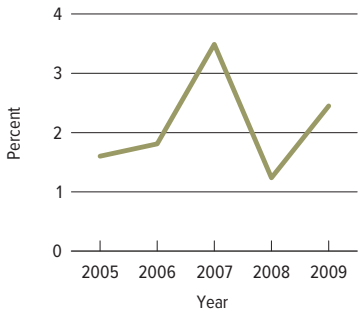
LI 3.11 Other complications (requiring intervention) among live liver donors



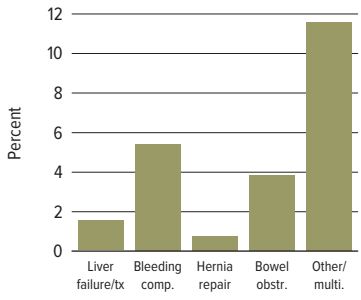
LI 3.12 Type of intervention for other complications among live liver donors



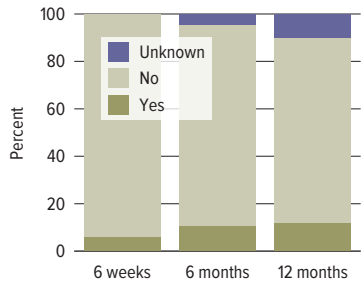
LI 3.13 Re-operation within the first six weeks among live liver donors



LI 3.14 Reason for reoperation among live liver donors



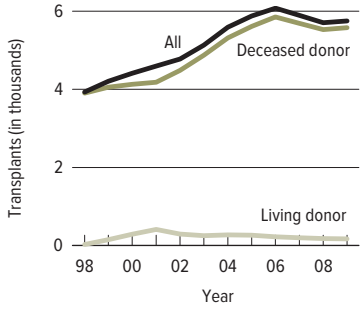
LI 3.15 Readmission to the hospital in the first year among live liver donors, 2008



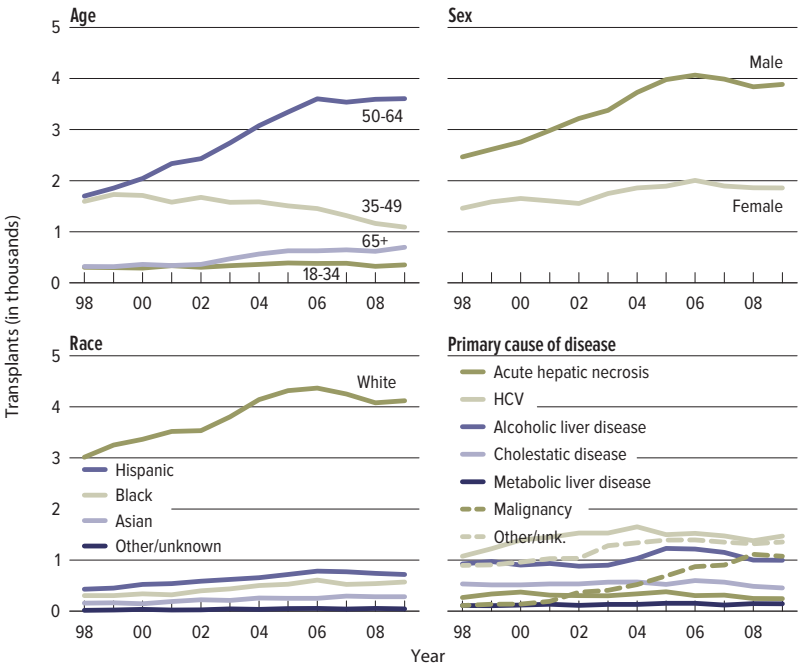
the coming years. When children were given increased access to deceased donor kidneys, the number of living donor transplants decreased substantially. The relation between access to deceased donor livers and rates of living donation should be monitored over the next several years, and will undoubtedly affect rates of living donation and the development of new allocation algorithms.

Twelve-month follow-up for living donors from 2008 shows no significant impact on donor serum bilirubin, serum albumin, serum creatinine, or INR (Figure 3.6). The number of biliary complications following donation has remained fairly constant (1.8% to 2.9%), although the frequency in 2007 was aberrantly higher at 7.8% (Figure 3.7). Most biliary complications were reported as grade 2 (Figure 3.8). Vascular complications following living liver donation were infrequent (< 2.0%) and largely related to deep venous thrombosis and pulmonary embolus (Figures 3.9 and 3.10). In 2009, no living donor deaths occurred within 30 days of transplant; 1 reported death occurred within 1 year of transplant. Rates of other complications and hospitalization have been relatively low (Figures 3.11 to 3.15).

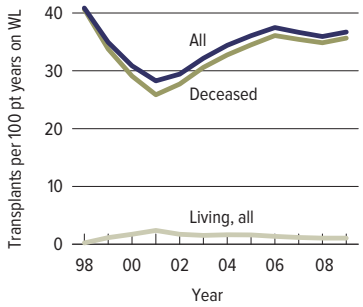
LI 4.1 Total adult liver transplants



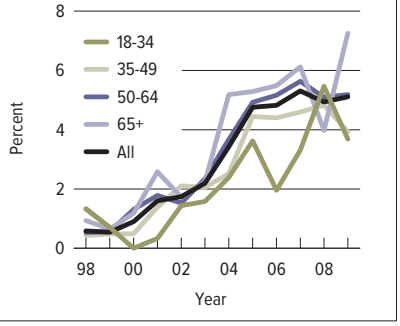
LI 4.2 Adult liver transplants



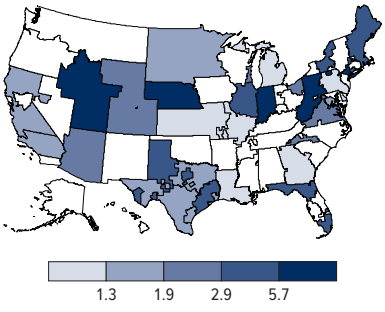
LI 4.3 Liver transplant rates in adult candidates



LI 4.4 Use of DCD livers among adult recipients, by recipient age



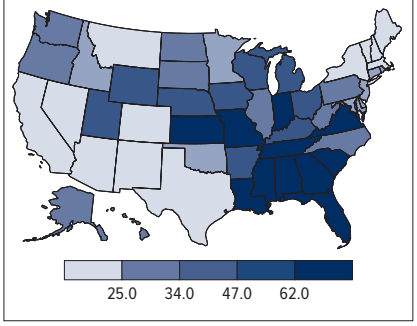
LI 4.5 Percent of adult, deceased donor liver transplants that are DCD, by DSA, 2009



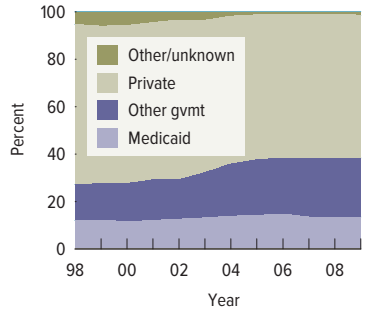
transplant The number of adult recipients of deceased donor livers peaked in 2006 and has remained relatively stable over the past 2 years (Figures 4.1 and 4.3). The average age of adult recipients increased steadily over the past 10 years; in 2009, approximately 75% were aged older than 50 years (Figure 4.2). Male recipients predominated, at a 2:1 male-to-female ratio (Figure 4.2). Most liver transplant recipients are white, 71.8% in 2009. The most frequent cause of liver disease leading to transplant remains HCV infection (25.6%); however, the number of patients listed in the unknown/other category continues to increase, representing 23.6% of patients in 2009 (Figure 4.2). This likely represents the increasing role of nonalcoholic steatohepatitis as the cause of liver disease leading to transplant.

Although the frequency of DCD livers increased substantially among adult recipients in 2000–2006, use of DCD livers has stabilized at approximately 5% of all recipients (Figure 4.4). Lack of further increase in overall use of DCD organs may in part reflect increasing concern about the higher rate of biliary complications observed with these donors. Regions of the country where there is high use of DCD are likely also regions with longer waiting times to receive a deceased donor liver (Figures 4.5 and 4.6). Marked

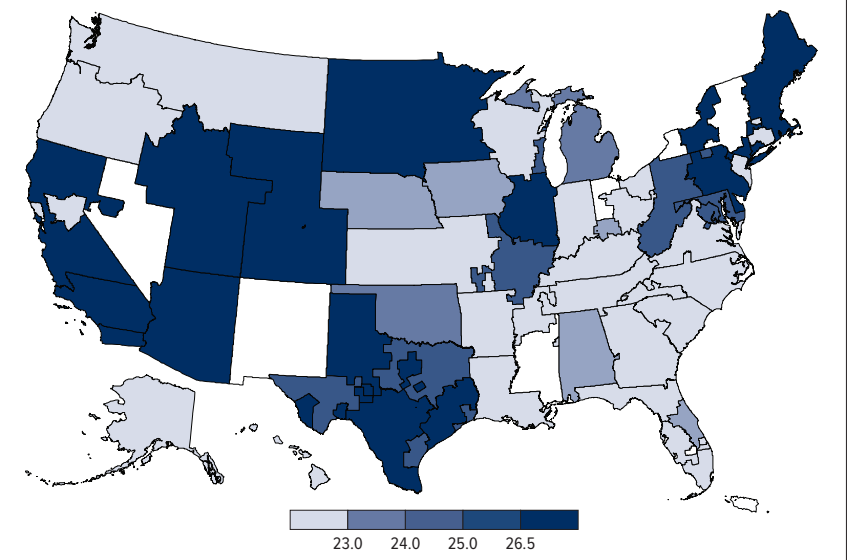
LI 4.6 Deceased donor liver tx rates per 100 pt years on the waiting list, adult pts, 2009



LI 4.7 Insurance coverage among adult liver transplant recipients at time of transplant



LI 4.9 Median MELD score for adult deceased donor liver transplants, by DSA, 2009

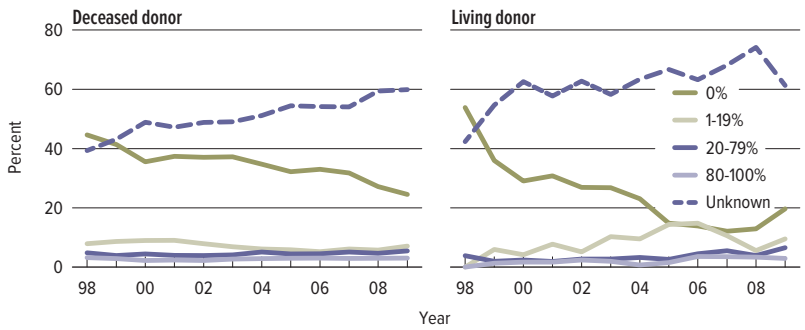


geographic disparity remains in deceased donor transplant rates across the country, with higher rates in the northwest and southeast (Figure 4.6). These maps of DCD organ use, transplant rates, and median MELD scores at the time of transplant can be superimposed. Regions of the country with high transplant rates, low DCD use rates, and high median MELD scores at the time of transplant are roughly similar. Private payers constitute the largest insurance coverage group for liver transplant, and in 2009 represented 60.1% of the providers.

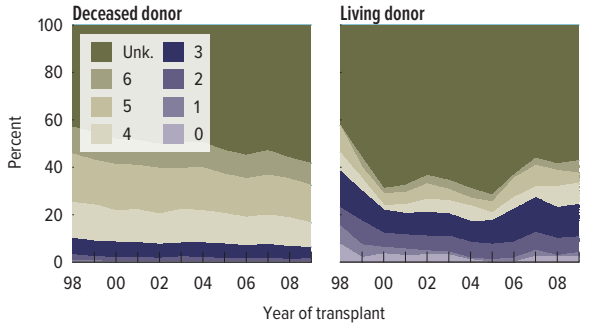
LI 4.8 Characteristics of adult liver transplant recipients, 2009

	Level	N	%
Age	18-34	352	6.1
	35-49	1,092	19.0
	50-64	3,608	62.8
	65+	696	12.1
Sex	Female	1,861	32.4
	Male	3,887	67.6
Race	White	4,126	71.8
	Black	572	10.0
	Hispanic	720	12.5
	Asian	282	4.9
	Other/unknown	48	0.8
Primary cause of disease	Acute hep. necrosis	246	4.3
	HCV	1,470	25.6
	Alcoholic liver dis.	999	17.4
	Cholestatic dis.	455	7.9
	Metab. liver dis.	143	2.5
	Malignancy	1,077	18.7
	All others	1,358	23.6
Blood type	A	2,112	36.7
	B	769	13.4
	AB	264	4.6
	O	2,603	45.3
Time on waiting list	<30 days	2,015	35.1
	31-60 days	683	11.9
	61-90 days	424	7.4
	3-<6 months	877	15.3
	6-<12 months	753	13.1
	1-<2 years	511	8.9
	2-<3 years	197	3.4
	3+ years	288	5.0
BMI	<18.5	142	2.5
	18.5-24.9	1,601	27.9
	25.0-29.9	1,957	34.0
	30.0-34.9	1,150	20.0
	35.0-39.9	508	8.8
	40.0+	209	3.6
	Unknown	181	3.1
Medical condition	Hosp.: ICU	676	11.8
	Hosp.: not ICU	1,052	18.3
	Not hospitalized	4,020	69.9
Patient wait listing status before tx	Status 1A/1B	260	4.5
	MELD 30-40	1,443	25.1
	MELD 15-29	3,8 64	67.2
	MELD 6-14	180	3.1
	Other status	1	0.0
Primary payer	Private	3,457	60.1
	Medicaid	779	13.6
	Other	1,512	26.3
Procedure type	Whole liver	5,519	96.0
	Partial, rest not tx	156	2.7
	Split liver	73	1.3
Donor type	Deceased	5,580	97.1
	Living	168	2.9
Pt on life support	Yes	377	6.6
Prev. abdom. surg.	Yes	2,524	43.9
Diabetes	Yes	28	0.5
Portal vein throm.	Yes	360	6.3
Incident tumor at tx	Yes	176	3.1
Spon. bac. perit. (SBP)	Yes	357	6.2
Total		5,748	100

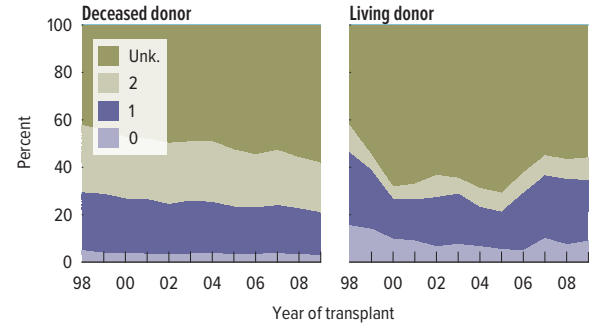
LI 5.1 PRA at time of liver transplant in adult recipients



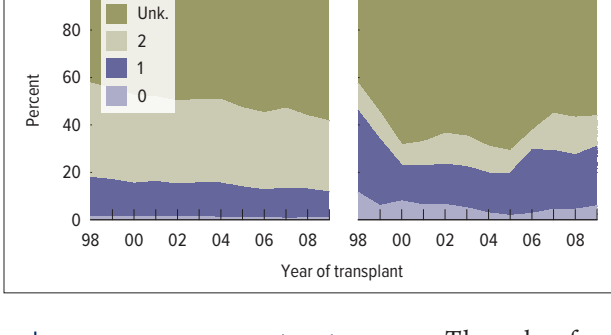
LI 5.2 Total HLA mismatches among adult liver transplant recipients



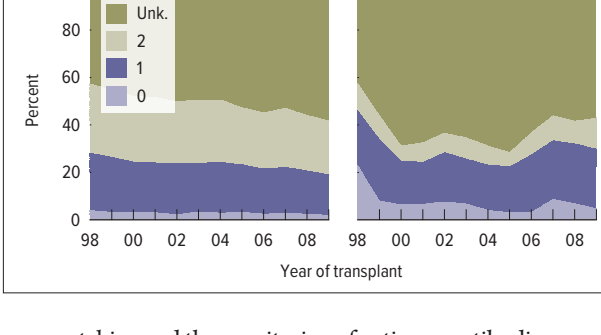
LI 5.3 HLA-A mismatches among adult liver transplant recipients



LI 5.4 HLA-B mismatches among adult liver transplant recipients



LI 5.5 HLA-DR mismatches among adult liver transplant recipients



donor-recipient matching

The role of anti-human leukocyte antigen (HLA) antibodies and HLA matching has historically not held high interest in the field of liver transplantation (Figures 5.1 to 5.5). This is reflected in the lack of recipient panel reactive antibody and HLA information for more than half of recipients, and in the high frequency of HLA-A, HLA-B, and HLA donor-recipient mismatching in deceased donor liver transplants (Figures 5.2 to 5.5). HLA typing has not been a requirement for listing for liver transplant unless the candidate is also listed for kidney transplant. Recent data suggesting a role for antibody-mediated rejection in liver transplant may increase the importance of HLA matching and the monitoring of anti-HLA antibodies.

The cytomegalovirus (CMV) status of donor and recipient was identified for almost all donors and for over 90% of recipients, reflecting the importance of this information for guiding post-transplant prophylaxis. CMV matching between donor and recipient is not used in the allocation process, as shown by the relatively high frequency (18.6%) of CMV-positive deceased donors used with CMV-negative recipients (Figure 5.6). Similarly, Epstein-Barr virus (EBV) serologic status is not used in the allocation process, but post-transplant EBV monitoring may be particularly important in the pediatric population (Figure 5.7).

Ongoing concern about transmission of HBV from core antibody (HBcAb)-positive recipients is responsible for the low use

LI 5.6 Adult liver donor-recipient cytomegalovirus (CMV) serology matching, 2005–2009

	10.3	18.6	0.1	29.0	24.4	11.0	6.4	41.8
	20.6	40.9	0.3	61.8	23.0	21.0	9.1	53.1
	2.8	6.3	0.1	9.2	2.4	1.3	1.5	5.1
	33.7	65.8	0.5	100	49.9	33.2	17.0	100

LI 5.7 Adult liver donor-recipient Epstein-Barr virus (EBV) serology matching, 2005–2009

	DECEASED DONOR				LIVING DONOR			
RECIPIENT	Neg.	Pos.	Unk.	Total	Neg.	Pos.	Unk.	Total
Negative	0.5	7.6	2.4	10.5	0.8	4.6	2.9	8.2
Positive	2.4	35.8	17.2	55.4	2.4	40.0	17.7	60.0
Unknown	1.1	20.8	12.2	34.1	2.4	13.4	15.9	31.7
Total	4.0	64.2	31.8	100	5.6	57.9	36.5	100

LI 5.8 Adult liver donor-recipient hepatitis B core antibody (HBcAb) serology matching, 2005–2009

	DECEASED DONOR				LIVING DONOR			
RECIPIENT	Neg.	Pos.	Unk.	Total	Neg.	Pos.	Unk.	Total
Negative	61.3	2.6	0.2	64.1	60.5	1.6	7.8	69.8
Positive	18.7	2.2	0.1	21.0	12.0	0.9	1.6	14.5
Unknown	14.2	0.7	0.0	15.0	4.5	0.0	11.3	15.7
Total	94.3	5.5	0.3	100	77.0	2.4	20.6	100

LI 5.9 Adult liver donor-recipient hepatitis B surface antigen (HBsAg) serology matching, 2005–2009

	DECEASED DONOR				LIVING DONOR			
RECIPIENT	Neg.	Pos.	Unk.	Total	Neg.	Pos.	Unk.	Total
Negative	83.8	0.0	0.2	84.0	75.3	0.0	6.3	81.6
Positive	5.4	0.0	0.0	5.4	3.2	0.0	0.3	3.5
Unknown	10.5	0.0	0.1	10.6	4.1	0.0	10.9	14.9
Total	99.7	0.0	0.3	100	82.5	0.0	17.5	100

LI 5.10 Adult liver donor-recipient hepatitis C serology matching, 2005–2009

	DECEASED DONOR				LIVING DONOR			
RECIPIENT	Neg.	Pos.	Unk.	Total	Neg.	Pos.	Unk.	Total
Negative	47.4	0.1	0.1	47.5	48.6	0.1	5.1	53.8
Positive	37.6	2.5	0.1	40.1	24.7	0.1	3.1	27.9
Unknown	11.9	0.4	0.0	12.4	6.5	0.0	11.7	18.2
Total	96.8	3.0	0.2	100	79.8	0.2	20.0	100

LI 5.11 Adult liver donor-recipient human immunodeficiency virus (HIV) serology matching, 2005–2009

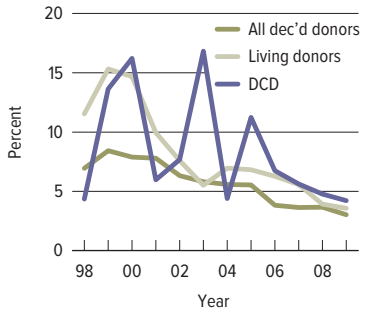
	DECEASED DONOR				LIVING DONOR			
RECIPIENT	Neg.	Pos.	Unk.	Total	Neg.	Pos.	Unk.	Total
Negative	80.5	0.0	0.1	80.5	69.0	0.0	6.6	75.6
Positive	0.5	0.0	0.0	0.5	0.2	0.0	0.1	0.3
Unknown	19.0	0.0	0.0	19.0	4.8	0.0	19.4	24.2
Total	99.9	0.0	0.1	100	73.9	0.0	26.1	100

rates of core positive donors, particularly in surface antibody negative recipients. Nonetheless, 2.6% of deceased donor transplants were performed between core antibody positive donors and core antibody negative recipients. The risk/benefit ratio of transmitting HBV through a core positive donor favors use of these organs to expedite transplant over the risk of HBV transmission, particularly with the efficacy and availability of prophylactic antiviral agents directed against hepatitis (Figure 5.8). No known cases of surface antigen positive donors being used for liver transplants occurred between 2005 and 2009 (Figure 5.9).

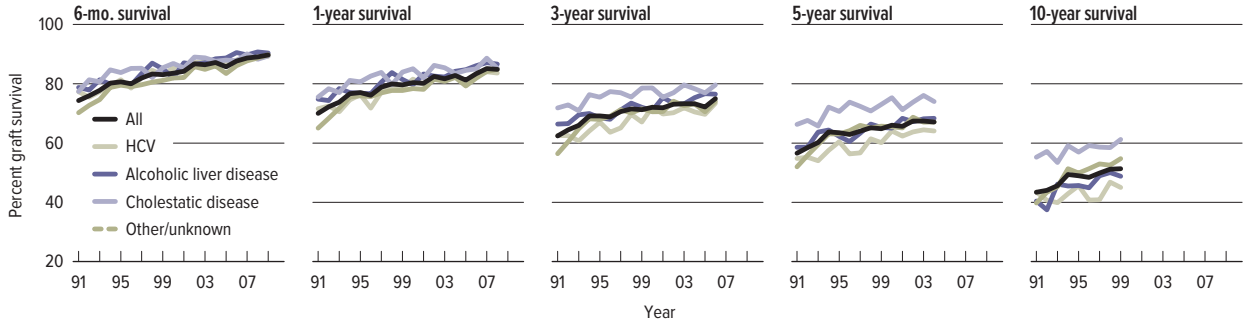
Only 3.0% of deceased liver donors were reported as HCV positive between 2005 and 2009 (Figure 5.10). Most of these organs were transplanted into HCV-positive recipients, as expected, but this reflected only 2.5% of all deceased liver donor transplants. Interestingly, 0.1% of all deceased donor transplants involved transplanting an HCV-positive donor liver into an HCV-negative recipient. The latter mismatches presumably occurred in the scenario of the urgent requirement for a donor liver in the setting of fulminant failure.

In 2005–2009, 0.5% of recipients of deceased donor livers and 0.3% of recipients of living donor livers were serologically positive for human immunodeficiency virus (HIV) (Figure 5.11). This number will likely increase in the next decade, given the success of antiretroviral therapy against HIV and the high rate of HBV and HCV co-infection (> 30%) in this population. Of note, no HIV-positive donors were reported during this time period.

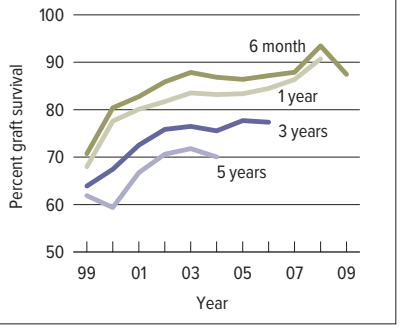
LI 6.1 Early (reported w/i 6 wks of tx) graft failure among adult liver transplant recipients



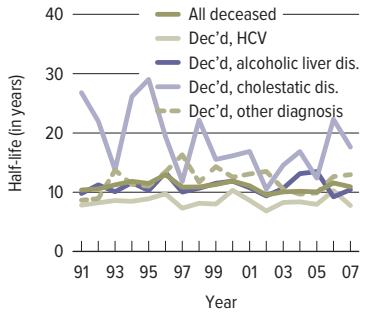
LI 6.2 Graft failure among adult liver transplant recipients: deceased donor



LI 6.3 Graft failure among adult liver transplant recipients: living donor



LI 6.4 Half-lives: adult dc'd donor liver tx recipients surviving with a funct. liver at least one year



outcomes

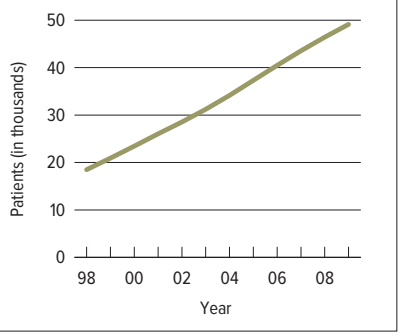
The ultimate goal of liver transplant is to prolong survival and improve quality of life. Over the past 2 to 3 decades, the outcome has improved substantially.

Regardless of donor type, incidence of graft failure reported within the first 6 weeks after transplant among adult recipients has declined in the past decade (Figure 6.1). Early graft failures in deceased donor recipients decreased from 6.9% in 1998 to 3.0% in 2009. This is remarkable because over this decade, more recipients had a high level of disease severity (in part as a result of the MELD-based organ allocation system) and more donors were less than ideal, including donors aged 50 years or older.

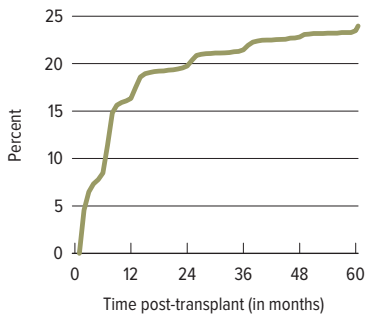
Figure 6.2 compares longer term liver transplant outcome by year of transplant and liver disease diagnosis. It is encouraging that transplant outcome is better in more recent years. This occurred across all diagnosis categories, suggesting that improvement in medical management may underlie this trend. Figure 6.3 demonstrates similar data for adult living donor recipients, in that survival numbers have in general improved over the past decade.

Overall, in deceased donor recipients who survived 1 year with a functioning graft, the expected half-life of the organ is 10 years (Figure 6.4). The half-life of living donor organs in adult recipients has been stable over the past 10 years, although numbers are relatively small.

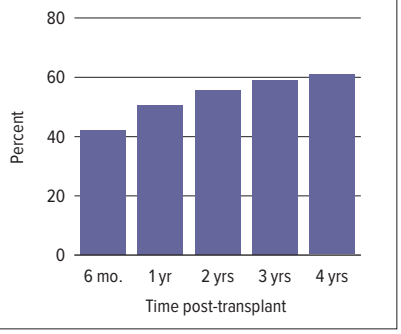
LI6.5 Adult recipients alive & with a functioning liver transplant on June 30 of the year



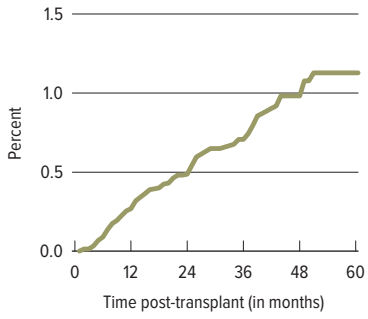
LI6.6 Incidence of first acute rejection among adult pts receiving a liver tx in 2005–2009



LI6.7 Reported hospitalizations among adult pts receiving a liver transplant in 2005–2009



LI6.8 Incidence of PTLD among adult patients receiving a liver transplant in 2005–2009



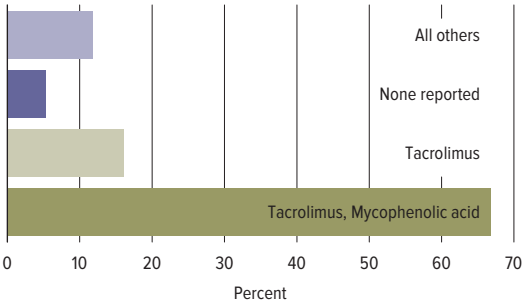
These improvements in outcomes have resulted in a rapid increase in the number of recipients with a functioning liver graft. The number of American transplant recipients living with a liver graft as of June 2009 was nearly 50,000, more than double a decade earlier (Figure 6.5).

Incidence of acute rejection is highest in the first year post-transplant (Figure 6.6). Except for recipients with HCV infection, early acute cellular rejection has no detrimental impact on long-term survival. On the other hand, rejections that occur 12 to 60 months after transplant may represent future opportunities to further improve the outcome of liver transplant.

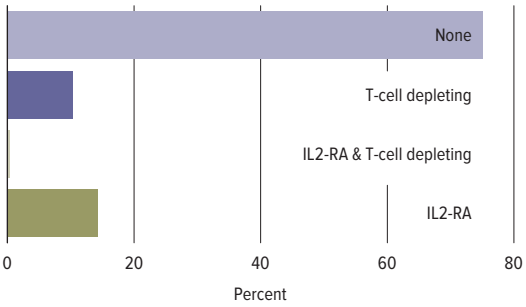
Given the severity of illness in patients undergoing liver transplant in recent years, re-hospitalization remains common, especially in the first few months (Figure 6.7).

Post-transplant lymphoproliferative disorder (PTLD) is a serious and potentially devastating complication that occurs in liver transplant recipients as a result of immunosuppression and/or EBV infection (Figure 6.8). Although cumulative incidence is not high (approximately 1% at 4 years), the incidence increased steadily through the first 5 years post-transplant.

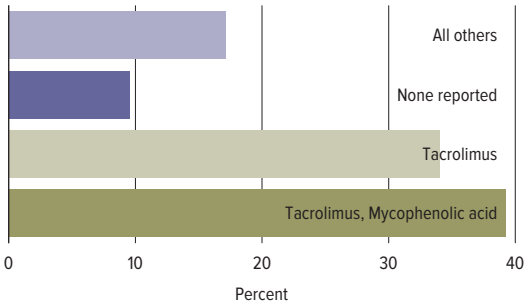
LI 7.1 Initial immunosuppression regimen in adult liver transplant recipients, 2009 (steroids not considered)



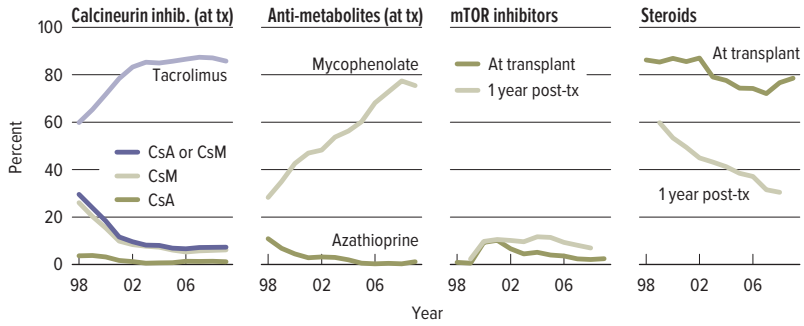
LI 7.2 Induction agents used at time of liver transplant, adult recipients, 2009



LI 7.3 Immunosuppression regimen at one year in adult liver transplant recipients, 2008 (steroids not considered)



LI 7.4 Immunosuppression use in adult liver transplant recipients

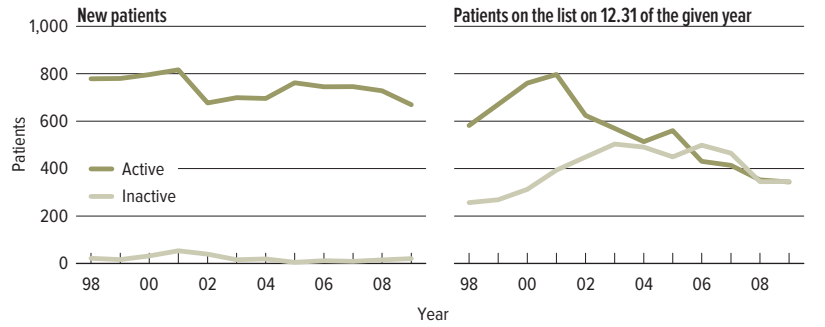


immunosuppression

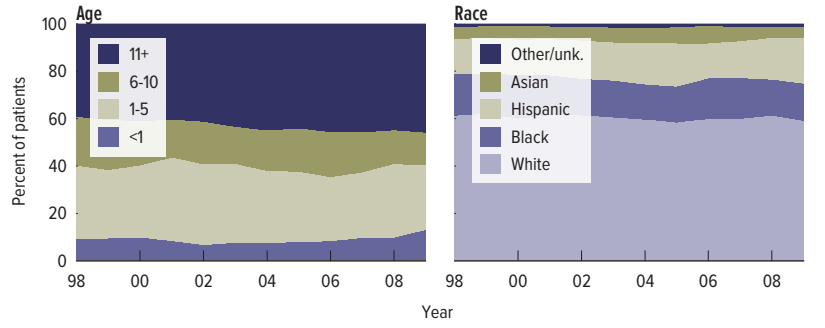
Immunosuppressive strategies based on tacrolimus and mycophenolate continue to be the dominant early regimen (Figures 7.1 and 7.3). In 2009, the alternative calcineurin inhibitor cyclosporine was used relatively infrequently (7.3%) compared with tacrolimus (85.8%) (Figure 7.4). Similarly, mycophenolate has almost completely replaced azathioprine as the antiproliferative agent of choice. Although 76.7% of patients were using a steroid at the time of transplant in 2008, only 30.5% remained on steroids 1 year after transplant (Figure 7.4). Mammalian target of rapamycin (mTOR) inhibitors were used infrequently, with only 2.5% of patients reported to be on this agent in 2009 (Figure 7.4).

The controlled rejection in liver transplant recipients is suggested by the relatively low use rates for interleukin-2 (IL2-RA) receptor inhibitors (14.3%) or T-cell depleting agents (10.3%) as induction agents (Figure 7.2). Over the past decade, the trend has been toward less use of corticosteroids. By 1 year post-transplant, many patients are weaned off corticosteroids (Figure 7.4).

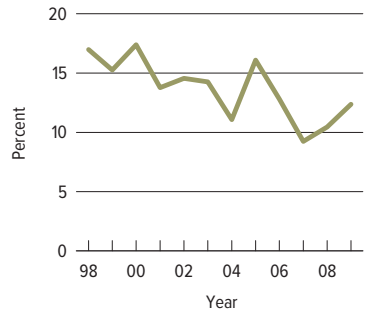
LI 8.1 Pediatric patients waiting for a liver transplant



LI 8.2 Distribution of pediatric patients waiting for a liver transplant



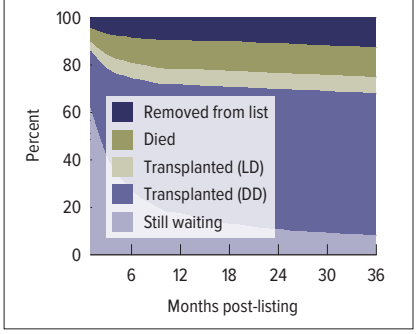
LI 8.3 Prior liver transplant in pediatric patients waiting for a liver transplant



LI 8.4 Liver transplant waiting list activity among pediatric patients

	2007	2008	2009
Listings at start of year	945	888	705
Listings added during year	822	832	784
Listings removed during year	879	1015	792
Listings at end of year	888	705	697
Removal reason			
Deceased donor transplant	558	566	538
Living donor transplant	68	69	50
Patient died	82	93	63
Patient refused transplant	1	1	2
Trans. to another center	19	23	22
Improved, tx not needed	95	179	88
Pt too sick to transplant	16	20	12
Other	40	64	17

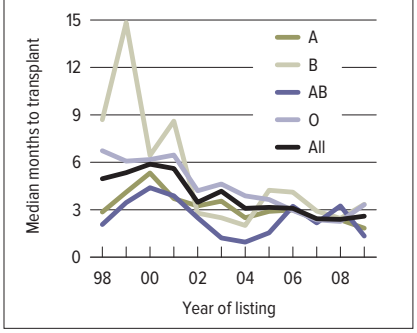
LI 8.5 Liver tx waiting list status by month post-listing among new pediatric listings in 2006



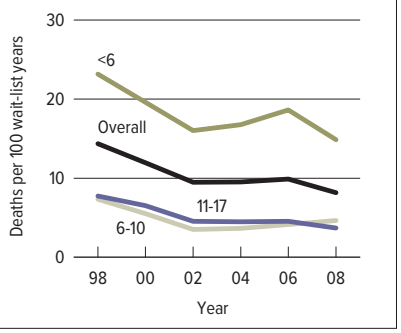
pediatric transplant

Since 1998, the number of children and adolescents new to the liver transplant waiting list has remained between 691 and 800 (Figure 8.1). Among prevalent patients on the waiting list for a liver transplant in 2009, almost equal numbers were active and inactive. The age distribution of patients on the waiting list has changed little; children aged 11 years or older account for 46% of patients (Figure 8.2). In 2009, 59% of patients on the waiting list were white, 16% were black, and 19% were Hispanic. In 2009, 12.4% of patients on the list were waiting for a re-transplant (Figure 8.3). Death as the reason for removal from the list remained stable in 2007–2009 at less than 10% (Figure 8.4). For the 2006 cohort of patients on the waiting list, after 3 years, 60.4% received a deceased donor transplant, 6.8% received a living donor transplant, 12.8% were removed from the list, 12.5% died, and 7.5% were still waiting (Figure 8.5).

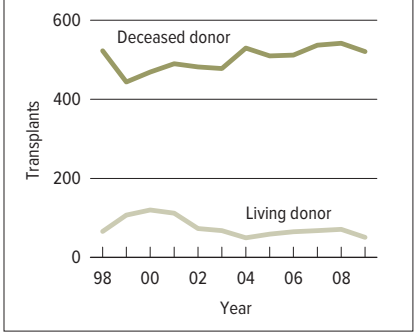
LI 8.6 Median months to liver transplant for wait-listed pedatric patients, by blood type



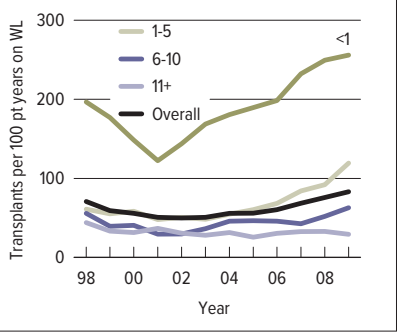
LI 8.7 Pre-tx mortality rates among pediatric pts wait-listed for a liver transplant, by age



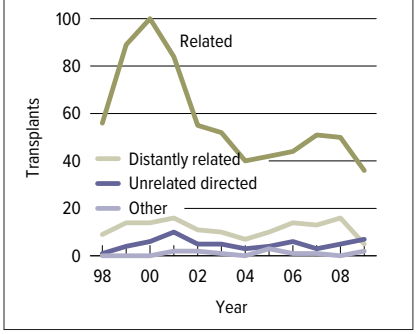
LI 8.8 Pediatric liver transplants



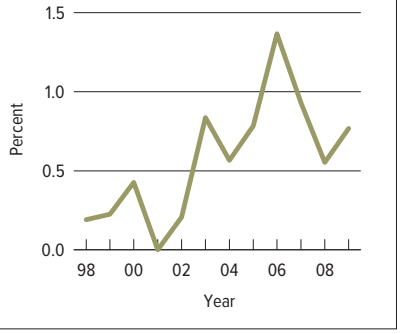
LI 8.9 Pediatric liver transplant rates, by age



LI 8.11 Pediatric liver transplants from living donors



LI 8.12 Use of DCD donors in pediatric liver transplant recipients



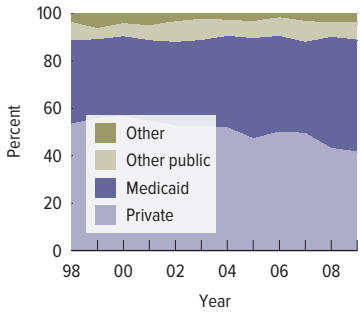
LI 8.10 Characteristics of pediatric liver transplant recipients, 2007–2009

	Level	N	%
Age	<1	542	30.3
	1-5	692	38.7
	6-10	232	13.0
	11-17	324	18.1
Sex	Female	891	49.8
	Male	899	50.2
Race	White	927	51.8
	Black	319	17.8
	Hispanic	387	21.6
	Asian	117	6.5
	Other/unk.	40	2.2
Primary cause of disease	Acute hep. necrosis	186	10.4
	HCV	7	0.4
	Cholestatic disease	809	45.2
	Metabolic liver dis.	184	10.3
	Malignancy	282	15.8
	All others	322	18.0
Transplant history	First transplant	1,617	90.3
	Subsequent	173	9.7
Blood type	A	629	35.1
	B	245	13.7
	AB	68	3.8
	O	848	47.4
Primary payer	Private	802	44.8
	Medicaid	789	44.1
	Other public	135	7.5
	Other	64	3.6
Time on wait list	<30 days	744	41.6
	31-60 days	294	16.4
	61-90 days	180	10.1
	3-<6 months	256	14.3
	6-<12 months	158	8.8
	1 - <2 years	110	6.1
	2- <3 years	17	0.9
	3+ years	25	1.4
	No listing date	6	0.3
Medical condition	Hospitalized: ICU	456	25.5
	Hosp.: not ICU	322	18.0
	Not hospitalized	1,012	56.5
Medical urgency status	1A	274	15.3
	1B	207	11.6
	MELD/PELD 30+	521	29.1
	MELD/PELD 15-29	532	29.7
	MELD/PELD <15	250	14.0
	Other/unknown	6	0.3
Procedure type	Whole liver	1,149	64.2
	Partial liver, remainder not tx	363	20.3
	Split liver	278	15.5
Donor type	Deceased	1,600	89.4
	Living	190	10.6
Previous ab. surg.	Yes	1,042	58.2
Portal vein throm.	Yes	65	3.6
Inc. tumor at tx	Yes	17	0.9
Sp. bact. perit. (SBP)	Yes	40	2.2
All patients		1,790	100

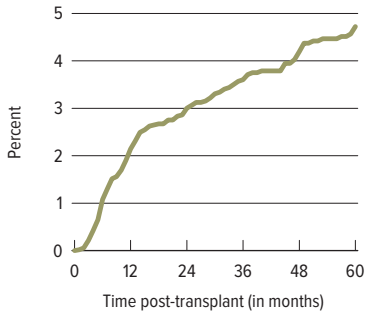
pediatric transplant

Among pediatric patients, the median number of months waiting for a liver-alone transplant for all blood types was 2.6 in 2009 (Figure 8.6). Pre-transplant mortality declined for patients wait-listed for a liver-alone transplant, from 14.4 deaths per 100 wait-list years in 1998 to 8.2 in 2008 (Figure 8.7). Patients on the waiting list aged younger than 6 years have the highest death rate, but this improved from 23.2 deaths per 100 wait-list years in 1998 to 14.9 in 2008. The number of deceased donor liver transplants has remained steady, while the number of living donor transplants decreased from a peak of 120 in 2000 to 51 in 2009 (Figure 8.8). The rate of pediatric liver transplant has increased since 2002 to the current rate of 83.1 transplants per 100 patient-years on the waiting list (Figure 8.9). Patients aged 1 to 5 years are the most common recipients. Whites accounted for more than half of recipients. The most common etiology of liver disease was cholestatic disease. Among children and adolescents who underwent transplant in 2007–2009, 58% were on the waiting list for 60 days or less. Fifteen percent of patients were status 1A at transplant, and 29% had a MELD/pediatric end-stage liver disease (PELD) score of 30 or higher. Sixty-four percent of patients received a whole liver.

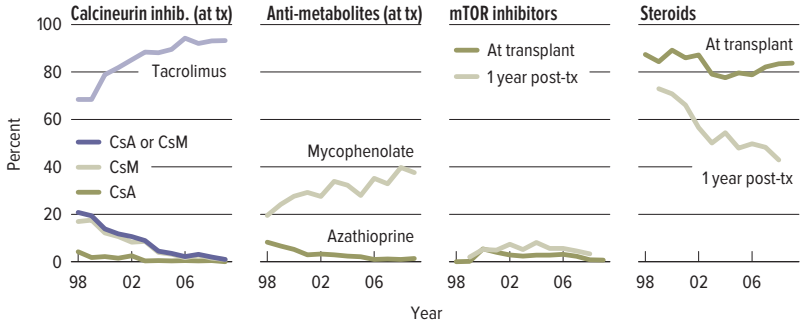
LI 8.13 Insurance coverage among pediatric liver transplant recipients at time of transplant



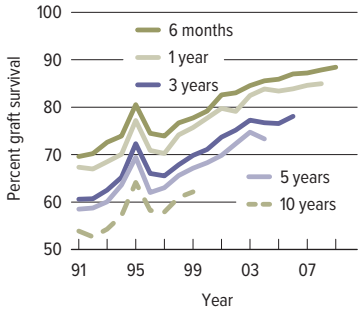
LI 8.14 Pediatric liver transplant recipients with reported PTLD, 2000–2009



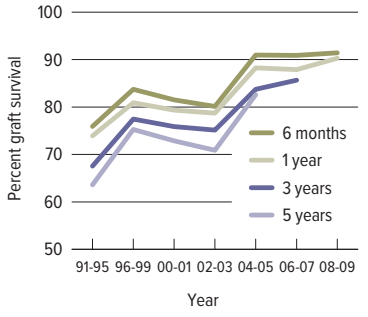
LI 8.15 Immunosuppression use among pediatric liver transplant recipients



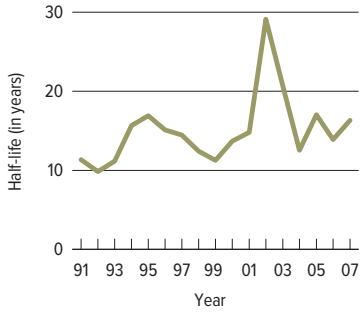
LI 8.16 Graft failure among pediatric liver transplant recipients: deceased donor



LI 8.17 Graft failure among pediatric liver transplant recipients: living donor



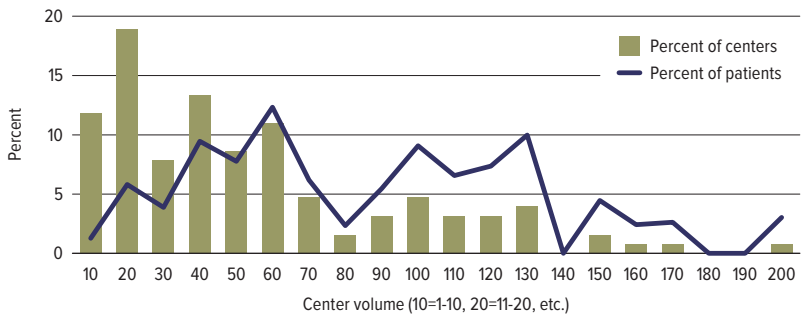
LI 8.18 Half-lives for pediatric liver tx pts surviving with a functioning liver at least one year



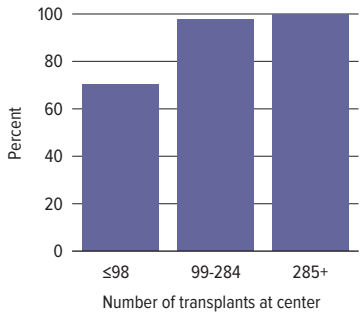
Among living donor liver transplants, 72% were from related donors in 2009 (Figure 8.11). Only a small number of transplants were from DCD donors (Figure 8.12).

Private insurance coverage for liver transplant recipients declined from 56.5% in 2000 to 41.6% in 2009; Medicaid coverage increased from 33.6% to 47.2% (Figure 8.13). For children and adolescents who underwent transplant in 2000–2009, cumulative incidence of PTLD was 1.1% at 6 months, 2.1% at 1 year, 3.0% at 2 years, and 4.7% at 5 years after transplant (Figure 8.14). In 2009, 93.4% of patients received tacrolimus as part of the initial maintenance immunosuppressive medication regimen, and 37.6% received MMF (Figure 8.15). Among patients transplanted in 2008, 83.5% received steroids at the time of transplant; only 43.0% continued to use steroids at 1 year post-transplant. Graft survival has continued to improve. Graft survival for deceased donor transplants in 2009 was 88.4% at 6 months; for transplants in 2008, 84.9% at 1 year; for transplants in 2006, 78.1% at 3 years; for transplants in 2004, 73.3% at 5 years; and for transplants in 1999, 62.2% at 10 years (Figure 8.16). Graft survival for living donor transplants in 2008–2009 was 91.4% at 6 months and 90.3% at 1 year; for transplants in 2006–2007, 85.7% at 3 years; and for transplants in 2004–2005, 82.6% at 5 years (Figure 8.17). 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 have failed among those surviving a year. The graft half-life for deceased donor liver transplants in 2007 was 16.3 years (Figure 8.18).

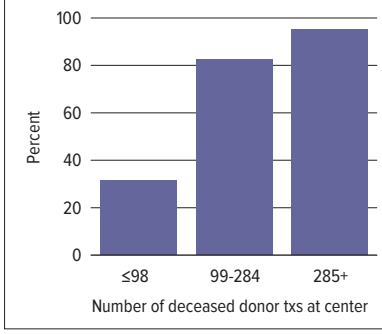
LI 9.1 **Distribution by center volume of the number of liver transplants performed, 2009**



LI 9.2 **Liver programs performing multi-organ transplants, by volume, 2005–2009**



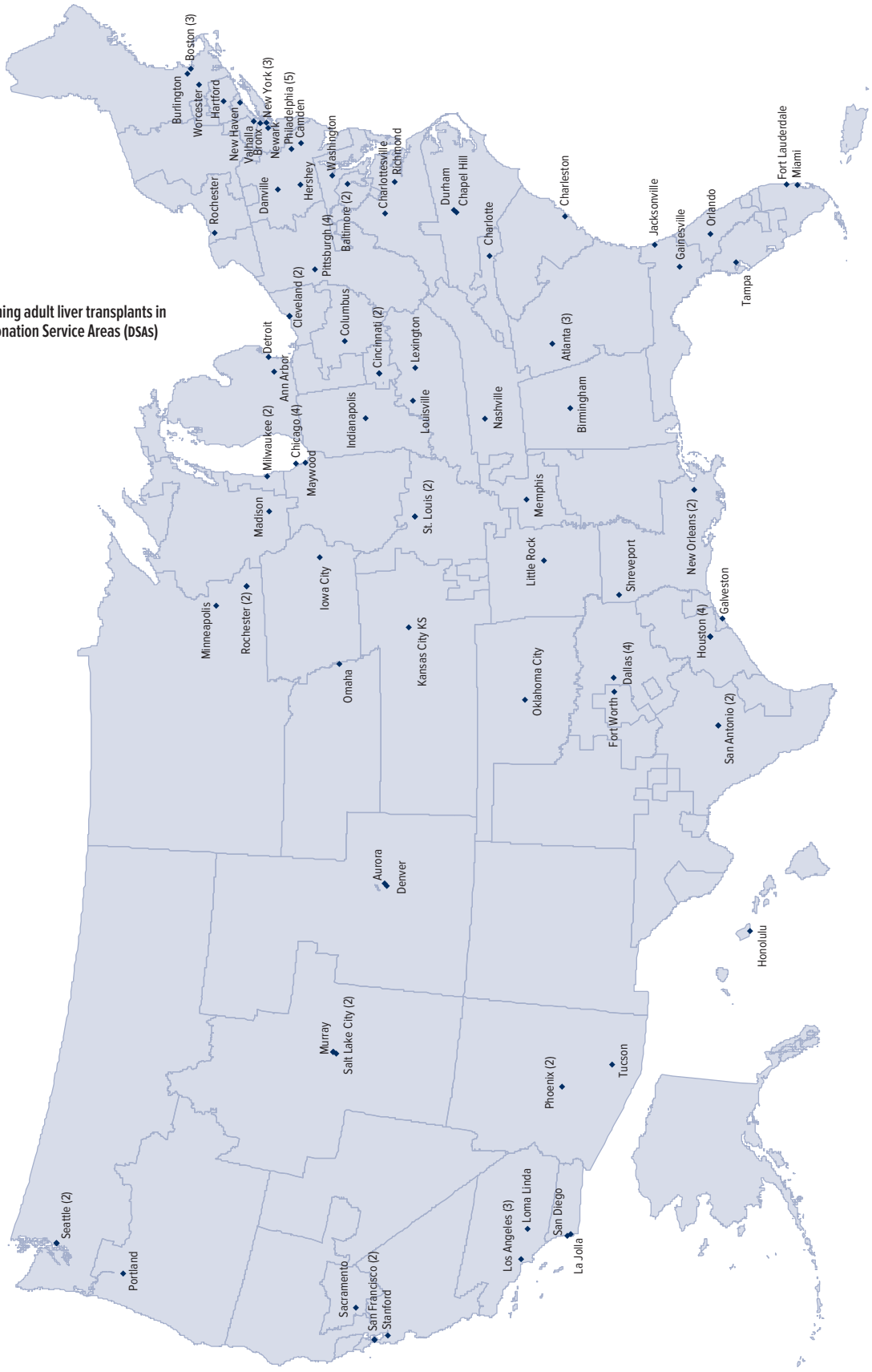
LI 9.3 **Centers transplanting DCD livers, by volume, 2005–2009**



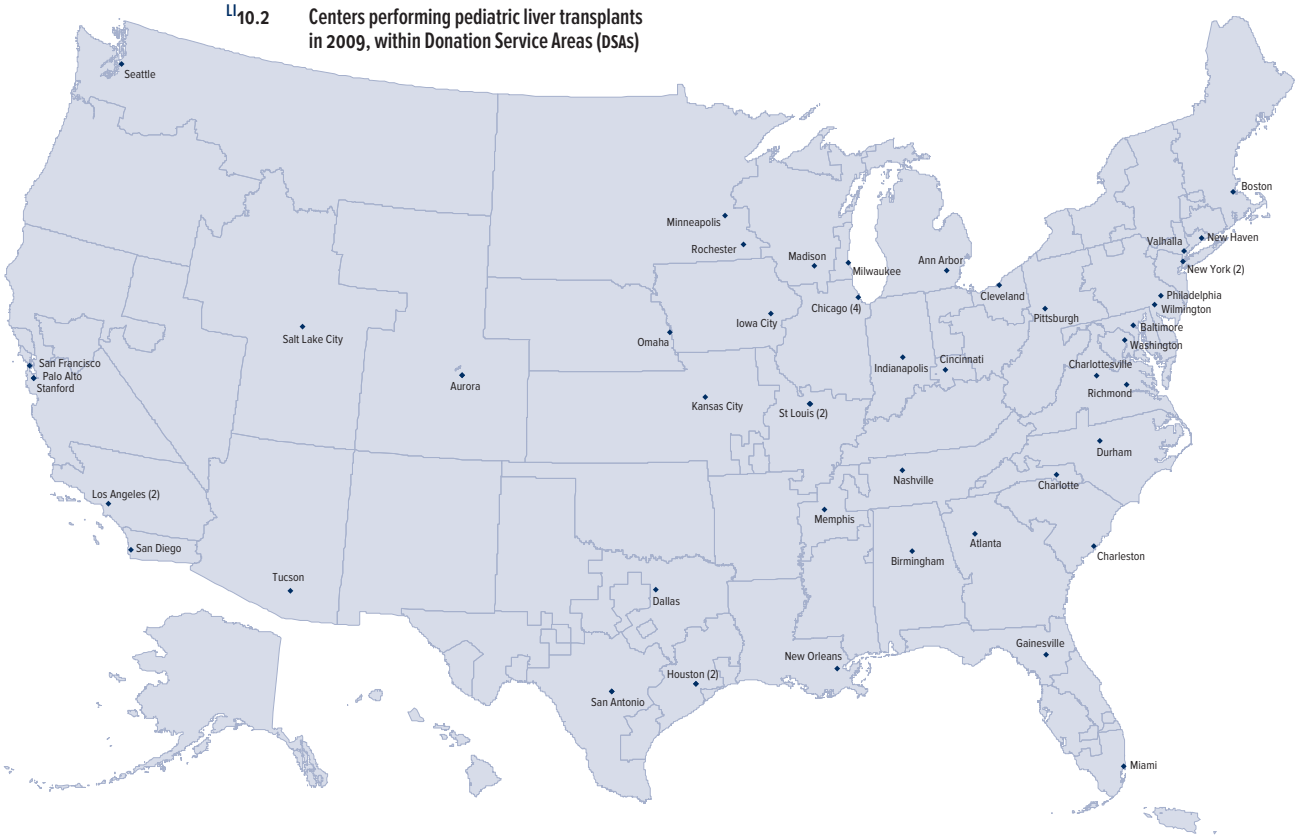
center characteristics

In 2009, 127 unique transplant centers performed liver transplants in the US. This included 58 centers that performed pediatric transplant. Figure 9.1 displays the distribution of the number of transplant procedures performed at each center. The minimum volume was 1 and the maximum was 192; the median was 40. Eighteen centers performed more than 100 transplants, and 13 centers performed fewer than 10 transplants for the year. Some of the low-volume centers were dedicated pediatric transplant centers. As expected, high-volume centers tend to be willing to accept more complicated cases, such as multi-organ or DCD organ transplants. Figure 9.2 displays tertiles of center volume. Essentially all centers with a volume of 99 or higher in 2005–2009 performed multi-organ transplants, most of which were simultaneous liver and kidney grafts. Similarly, Figure 9.3 shows that higher-volume centers performed more DCD transplants during the same period.

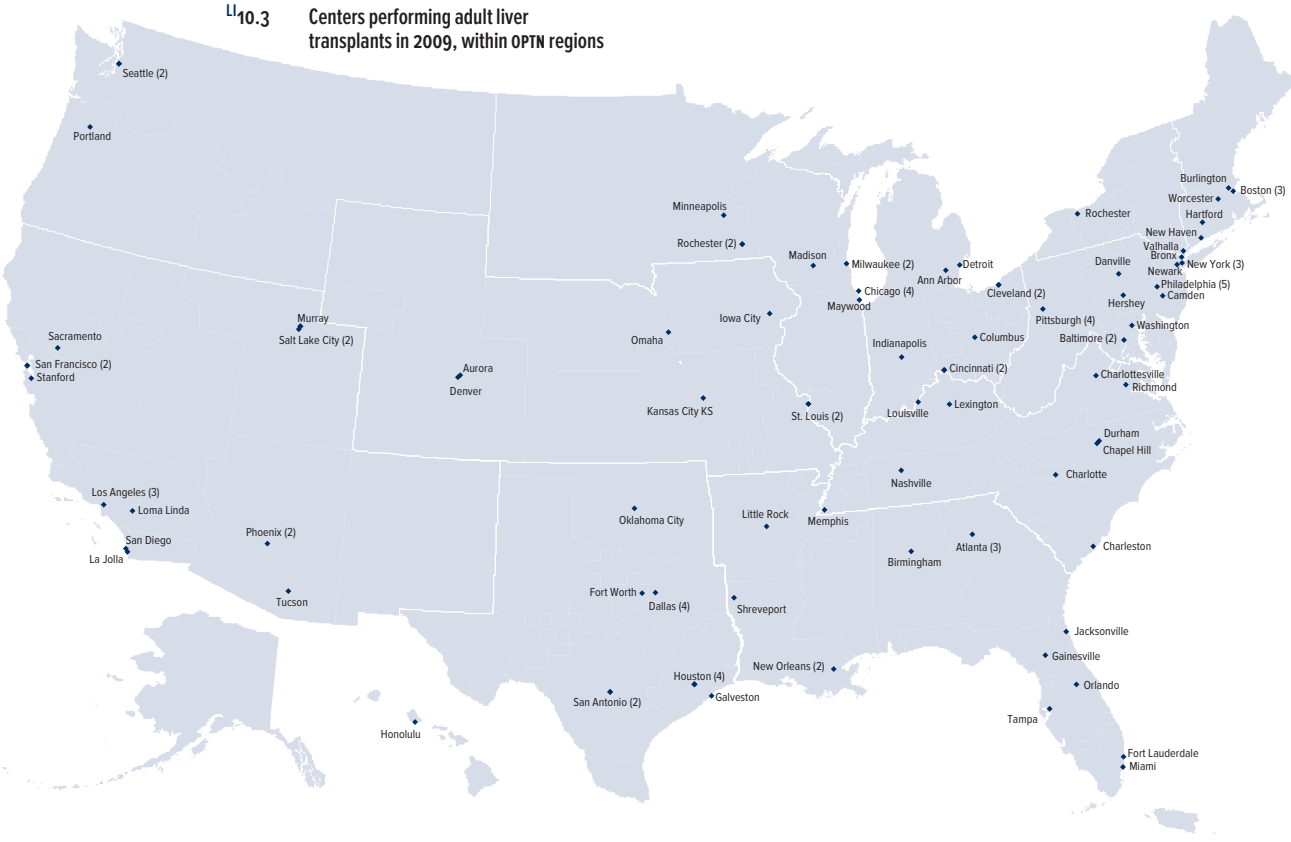
LI10.1 **Centers performing adult liver transplants in 2009, within Donation Service Areas (DSAs)**



LI 10.2 Centers performing pediatric liver transplants in 2009, within Donation Service Areas (DSAs)



LI 10.3 Centers performing adult liver transplants in 2009, within OPTN regions



intestine

Over the past 20 years, intestinal transplantation has progressed from experimental therapy to accepted treatment for children and adults with intractable, life-threatening intestinal failure. Intestinal transplants may be performed in isolation, with a liver transplant, or as part of a multivisceral transplant that may include liver, intestine, and pancreas. The number of new patients listed for intestinal transplant has been increasing (Figure 1.1). In 2009, 51.8% of those on the waiting list were aged 5 years or younger, 19.6% were aged 6 to 17 years, and 28.6% were aged 18 years or older (Figure 1.2). However, the relative proportion of new patients listed who are aged 18 years or older has been increasing (Figure 1.3). Among those listed in 2006, 60.3% had received an allograft by 3 years after listing, 20.2% had died, 10.7% had been removed from the list, and only 8.8% were still waiting (Figure 1.6). The mortality rate of patients placed on the waiting list has declined remarkably, from 61.1 to 13.1 per 100 wait-list years between 1998 and 2009 (Figure 1.9).

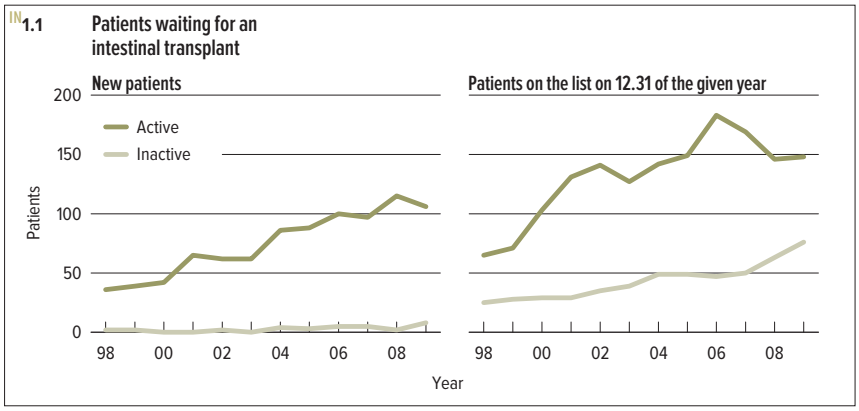
Roughly half of intestinal transplants have been combined with liver transplants, and all but a few have been deceased donor transplants (Figure 3.1). One-year graft survival has increased from 59.5% for transplants in 1991–1995 to 72.2% for transplants in 2008–2009 (Figure 4.2). However, long-term graft survival rates remain relatively low. Five-year graft survival improved from 31.6% for transplants in 1991–1995 to 50.6% for transplants in 2004–2005 (Figure 4.2). Acute rejection remains a challenge, with 43.1% of recipients in 2005–2009 having had an acute rejection by 1 year after transplant (Figure 4.5). Infectious complications are also a major cause of morbidity and mortality after intestinal transplant.

To know that Brian's life is still blessing lives through his gift of life, which was his spoken desire months before his unexpected death, is a good feeling. Loss is complex and deep, but the gift of life brought us one positive facet.

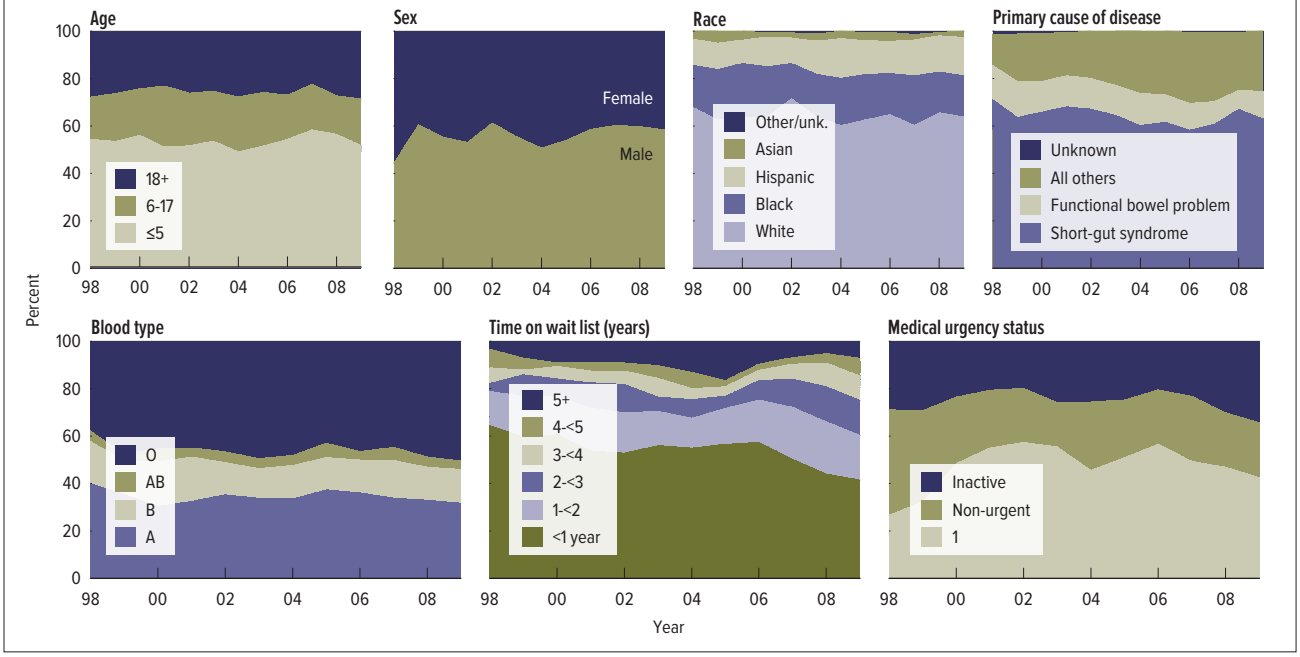
Deb, donor mom

OPTN SRTR SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

IN 1.1 Patients waiting for an intestinal transplant



IN 1.2 Distribution of patients waiting for an intestinal transplant

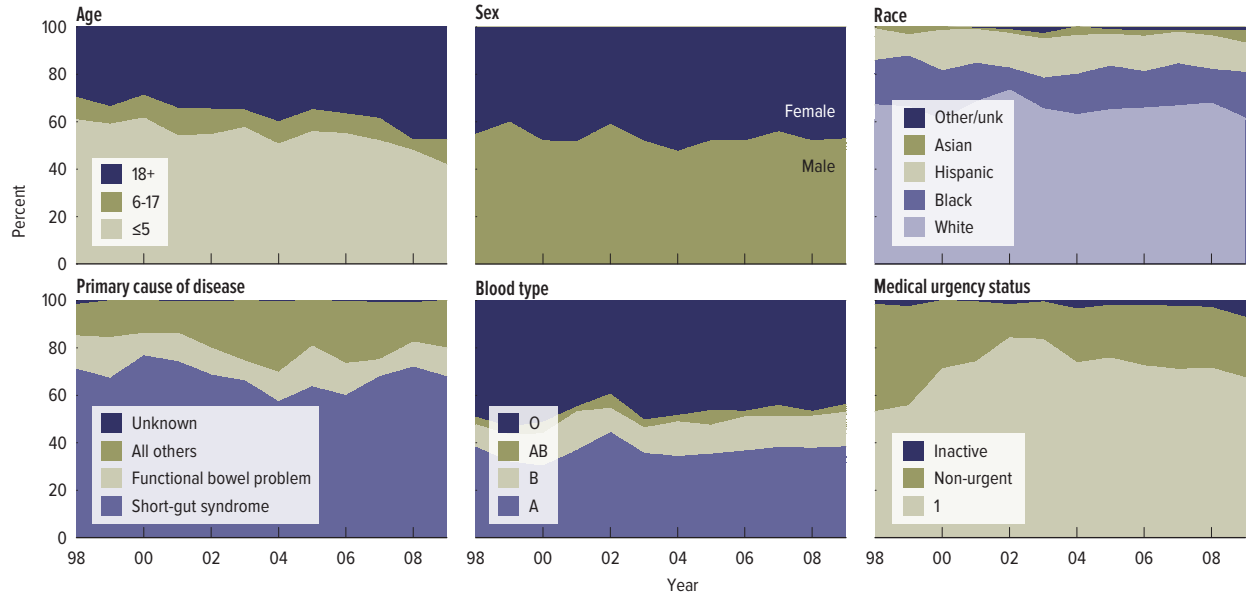


wait list

From 1998 to 2009, the number of new patients listed for an intestinal transplant (with or without another organ) increased 3-fold, from 38 to 114 (Figure 1.1). For the same years, the number of patients listed on December 31 of the year increased more than 2-fold, from 90 to 224, with one-third of patients listed as inactive in 2009 (Figure 1.1). In 2009, 51.8% of those on the waiting list for an intestinal transplant were aged 5 years or younger, 19.6% were aged 6 to 17 years, and 28.6% were aged 18 years or older (Figure 1.2). There have been more males than females on the waiting list; in 2009, 58.5% were male. The racial composition of the waiting list has changed little; in 2009, 63.8% were white, 17.4% were black, 16.1% were Hispanic, and 2.7% were Asian. The most common etiology of intestinal failure was short-gut syndrome. In 2009, 63.0% of patients on the waiting list had short-gut syndrome, while 11.6% had a functional bowel problem; in 25.5%, the etiology was other or unknown. Time on the waiting list has been increasing slightly, although in 2009, 41.5% had been on the list for less than 1 year, and only 7.1% had been on the list for 5 or more years. Since 1998, there has been an increase in the number of patients listed as medically urgent (status 1), from 26.7% in 1998 to 42.4% in 2009.

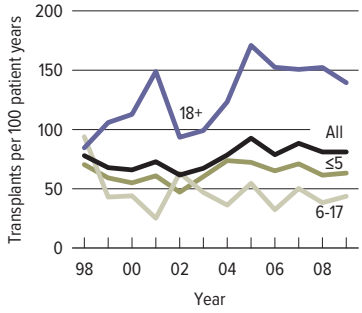
The relative proportion of newly listed patients aged 18 years or older has been increasing (Figure 1.3). Between 1998 and 2009,

IN 1.3 Distribution of patients newly listed for an intestinal transplant



the proportion of newly listed patients who were aged 18 years or older increased from 29.7% to 47.5%, while the proportion aged 6 to 17 years changed little, from 9.4% to 10.4%, and the proportion aged 5 years or younger declined from 60.9% to 42.1%. Over the past decade, there have been no changes in the sex or racial distribution of patients newly listed for intestinal transplant. Similarly, there have been no changes in the cause of disease in these patients, although the categories chosen may not precisely define the true causes of intestinal failure. Medical urgency (status 1) increased from 53.1% in 1998 to 83.6% in 2003, and then declined to 67.5% in 2009.

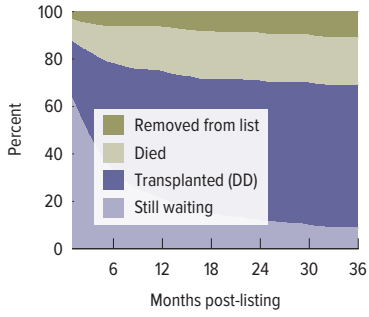
IN 1.4 Transplant rates among patients wait-listed for an intestinal transplant, by age



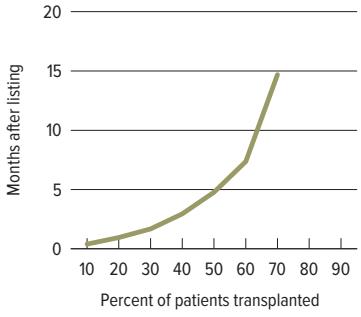
IN 1.5 Intestinal transplant waiting list activity

	2007	2008	2009
Listings at start of year	234	222	213
Listings added during year	281	267	260
Listings removed during year	293	276	246
Listings at end of year	222	213	227
Removal reason			
Deceased donor transplant	196	190	181
Living donor transplant	.	.	1
Patient died	55	49	30
Patient refused transplant	1	2	1
Trans. to another center	3	3	5
Improved, tx not needed	11	17	17
Too sick to transplant	9	4	7
Other	18	11	4

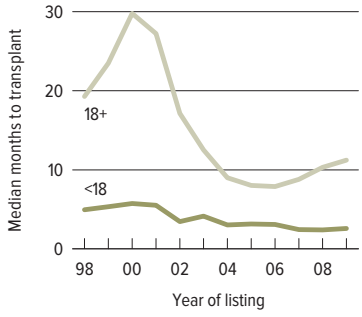
IN 1.6 Intestinal tx waiting list status by month post-listing among new listings in 2006



IN 1.7 Percentiles of time to intestinal transplant, new listings 2005–2009



IN 1.8 Median months to intestinal transplant for wait-listed patients



wait list

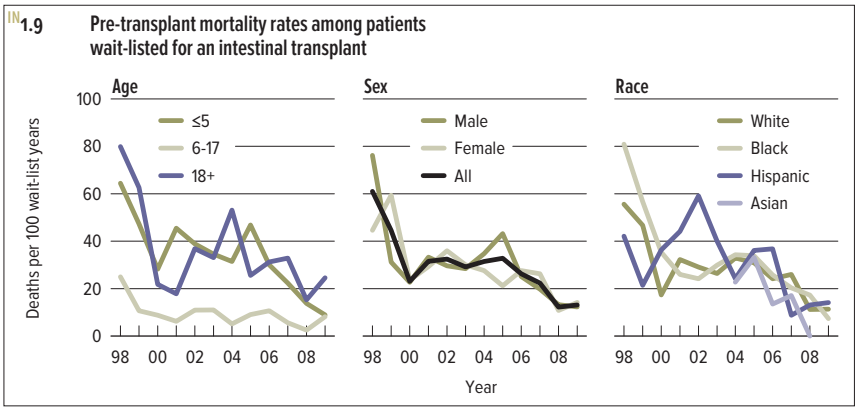
The overall intestinal transplant rate has remained relatively stable, from 78.0 per 100 patient-years on the waiting list in 1998 to 81.0 in 2009 (Figure 1.4). However, the rate within each age group has seen significant changes over this time period, with most of the growth occurring among adults. Indeed, among recipients aged 18 years or older, the transplant rate has increased from 84.7 per 100 patient-years to 139.5. In 2009, the transplant rate for patients aged 5 years or younger was 63.2 per 100 patient-years and among patients aged 6 to 17 years, 43.6 per 100 patient-years on the waiting list.

From 2007 to 2009, death as a reason for removal from the waiting list decreased from 19% to 12% of listings removed (Figure 1.5). In 2009, the number removed because a transplant was no longer needed was only 6.9% of those removed. Among listings for an intestinal transplant in 2006, 60.3% received a deceased donor organ, 20.2% died, 10.7% were removed from the list, and 8.8% were still waiting 3 years after listing (Figure 1.6).

Among patients listed in 2005–2009, 50% underwent transplant in 4.8 months (Figure 1.7). The median time to transplant has decreased for waiting list candidates younger than 18 years old, from 5.8 months in 2000 to 2.6 months in 2009 (Figure 1.8). Among candidates aged 18 years or older, there has been a decrease in median time to transplant, from a peak of 29.8 months in 2000 to 11.2 months in 2009.

Importantly, death on the waiting list has decreased from 61.1 per 100 wait-list years in 1998 to 13.1 per 100 wait-list years in 2009

IN 1.9 **Pre-transplant mortality rates among patients wait-listed for an intestinal transplant**

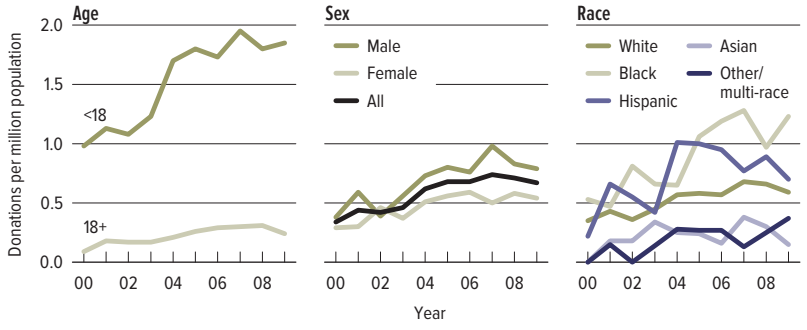


IN 1.10 **Characteristics of patients on the intestinal tx waiting list on December 31, 2009**

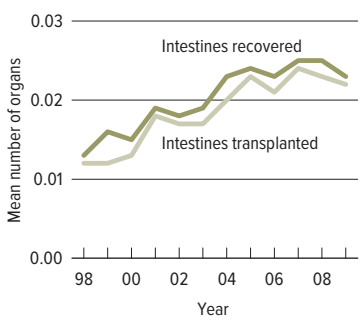
	Level	N	%
Age	0-5	116	51.8
	6-17	44	19.6
	18-34	22	9.8
	35-49	20	8.9
	50-64	19	8.5
	65+	3	1.4
Sex	Female	131	58.5
	Male	93	41.5
Race	White	143	63.8
	Black	39	17.4
	Hispanic	36	16.1
	Asian	6	2.7
	Other/unknown	0	0.0
Primary cause of disease	Short-gut syndrome	141	63.0
	Func. bowel problem	26	11.6
	All others	57	25.5
	Unknown	0	0.0
Transplant history	Listed for first tx	207	92.4
	Listed for subseq tx	17	7.6
Blood type	A	71	31.7
	B	32	14.3
	AB	8	3.6
	O	113	50.5
Time on wait list	<1 year	93	41.5
	1-<2	42	18.8
	2-<3	33	14.7
	3-<4	23	10.3
	4-<5	17	7.6
	5+	16	7.1
Medical urgency status	Status 1	95	42.4
	Non-urgent	52	23.2
	Inactive	77	34.4
	Unknown	0	0.0

(Figure 1.9). Among patients listed for intestinal transplant at the end of 2009, 51.8% were aged 5 years or younger, 19.6% were aged 6 to 17 years, and 28.6% were aged 18 years or older (Figure 1.10). White recipients accounted for 63.8% of patients listed, followed by blacks (17.4%) and Hispanics (16.1%). The leading cause of intestinal failure was short-gut syndrome, which accounted for 63.0% of patients. Most patients (92.4%) were listed for a first intestinal transplant. Most patients (60.3%) spent less than 2 years on the waiting list, and 39.7% waited 2 or more years. Status 1 listings accounted for 42.4% of patients, and 34.4% of patients were listed as inactive.

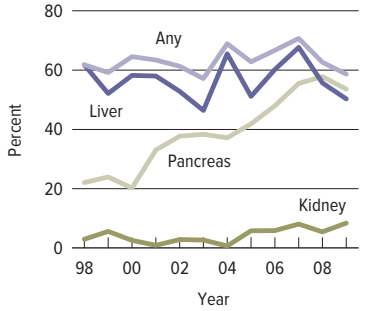
IN 2.1 Intestinal donations from deceased donors (per million population, age <70)



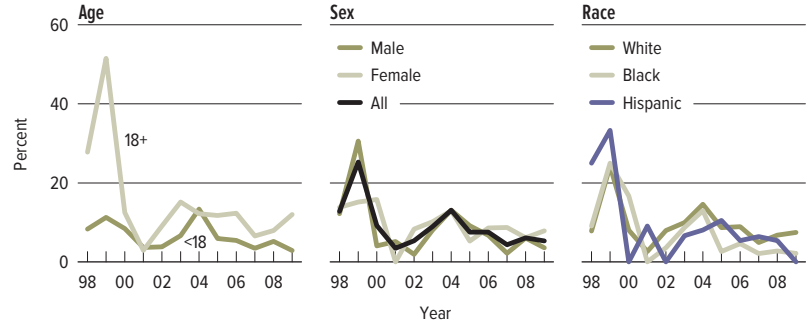
IN 2.2 Intestines recovered per donor & intestines transplanted per donor



IN 2.3 Deceased donor intestines transplanted with another organ



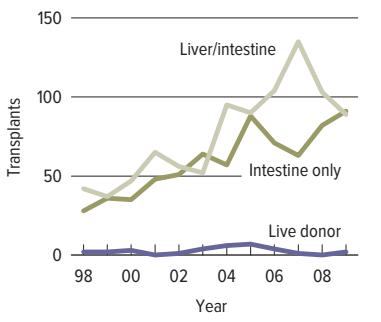
IN 2.4 Discard rates for intestines recovered for transplant



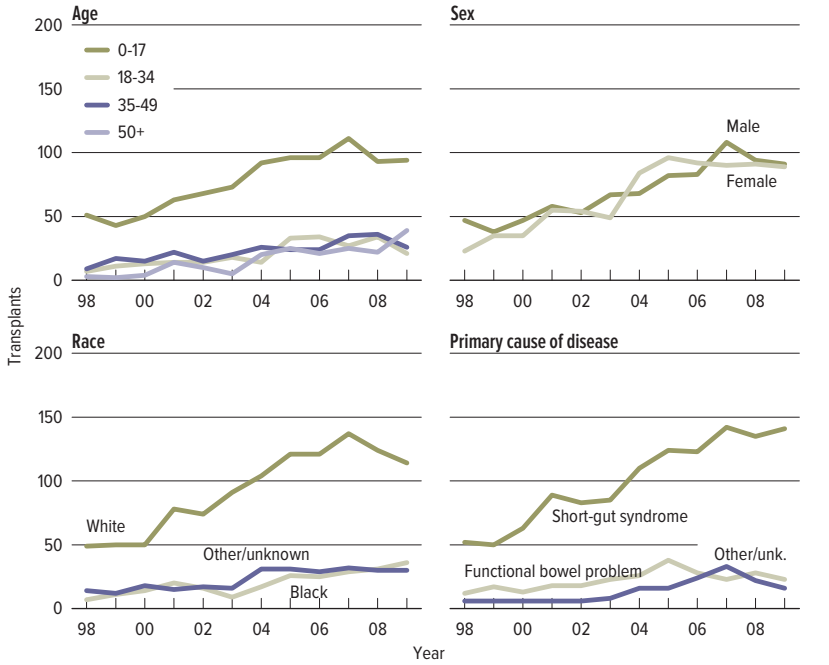
deceased donation

Most deceased donor intestinal allografts have been from donors younger than 18 years old (Figure 2.1). In addition, from 2000 to 2009 there was an increase in donations from deceased donors, consistent with the increase in the number of intestinal transplants during this period. Donations from deceased donors younger than 18 years old increased from 0.98 per million population in 2000 to 1.85 per million population in 2009. Deceased donation rates were higher for males than females. Donation rates were highest for blacks, followed by Hispanics and whites. The number of intestines recovered and transplanted per donor has increased over the past 12 years, and most intestines recovered from deceased donors were indeed transplanted (Figure 2.2). Fifty-nine percent of deceased donor intestines were transplanted with another organ in 2009; this has changed little over the past 12 years (Figure 2.3). Liver has been the organ most commonly transplanted with intestine, while the number of times a pancreas was transplanted with an intestine has increased dramatically. This increase is likely attributable to several factors, including changes in policy, reporting, and surgical technique. In 2009, 50.3% of intestinal transplants were performed with a liver transplant, while 53.6% were with a pancreas, and 8.4% were with a kidney. The overall discard rate for donor intestines has decreased over the past several years, from 12.8% in 1998 to only 5.3% in 2009 (Figure 2.4).

IN 3.1 Total intestinal transplants



IN 3.2 Intestinal transplants

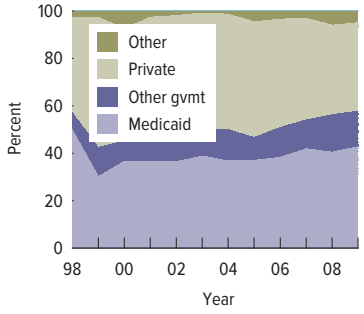


IN 3.3 Intestinal transplant rates

transplant

In the past decade, the number of intestinal transplants increased more than 2-fold, from 70 in 1998 to 180 in 2009 (Figure 3.1). This increase was due to roughly equivalent increases in intestine alone (from 28 to 91) and liver/intestine (from 42 to 89) transplants. The increase in intestinal transplants over the past decade has occurred in all age groups, in males and females, and in whites and blacks (Figure 3.2). In 2009, there were 94 intestinal transplants in those aged 17 years or younger, 21 in those aged 18 to 34 years, 26 in those aged 35 to 49 years, and 39 in those aged 50 years or older. From 2000 to 2009, the rate of deceased donor intestinal transplant increased from 65.2 transplants per 100 patient-years on the waiting list to 80.5 per 100 patient-years (Figure 3.3). The rate of living donor intestinal transplant remains very low; in 2009 it was 0.5 transplants per 100 patient-years on the waiting list. There was 1 living donor intestinal transplant in 2007; there were none in 2008 and 2 in 2009.

IN 3.4 **Insurance coverage among intestinal transplant recipients at time of transplant**



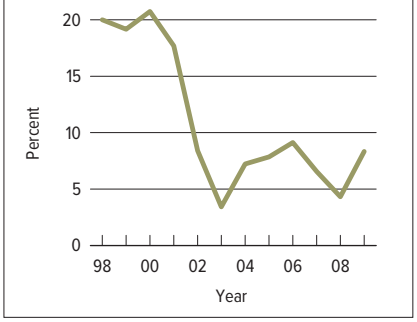
IN 3.5 **Characteristics of intestinal transplant recipients, 2009**

	Level	N	%
Age	0-17	94	52.2
	18-34	21	11.7
	35-49	26	14.4
	50-64	38	21.1
	65+	1	0.6
Sex	Female	89	49.4
	Male	91	50.6
Race	White	114	63.3
	Black	36	20.0
	Hispanic	20	11.1
	Asian	8	4.4
	Other/unknown	2	1.1
Primary cause of disease	Short-gut syndrome	141	78.3
	Functional bowel problem	23	12.8
	Other/unknown	16	8.9
Blood type	A	78	43.3
	B	26	14.4
	AB	7	3.9
	O	69	38.3
Time on waiting list	<30 days	69	38.3
	31-60 days	27	15.0
	61-90 days	19	10.6
	3-<6 months	28	15.6
	6-<12 months	22	12.2
	1-<2 years	7	3.9
	2-<3 years	4	2.2
	3+ years	4	2.2
BMI	<18.5	69	38.3
	18.5-24.9	71	39.4
	25.0-29.9	14	7.8
	30.0-34.9	8	4.4
	35.0-39.9	1	0.6
	40.0+	0	0.0
	Unknown	17	9.4
Medical condition	Hospitalized: ICU	21	11.7
	Hospitalized: not ICU	41	22.8
	Not hospitalized	118	65.6
Primary payer	Private	67	37.2
	Medicaid	77	42.8
	Other	36	20.0
Donor type	Deceased	178	98.9
	Living	2	1.1
Intestine transplant history	First transplant	155	86.1
	Subsequent transplant	25	13.9
Patient on life support	Yes	33	18.3
Total		180	100.0

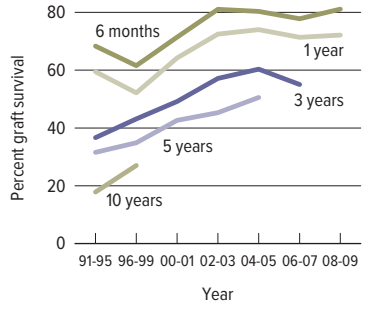
transplant

In 2009, 42.8% of intestinal transplant recipients had Medicaid as their primary insurance provider, and 37.2% had private insurance (Figure 3.4). This payer mix is consistent with the large proportion of intestinal transplants that are performed in children; few qualified for Medicare, for example. Among intestinal transplant recipients in 2009, 52.2% were aged 0 to 17 years, 11.7% were aged 18 to 34 years, 14.4% were aged 35 to 49 years, and 21.7% were aged 50 years or older (Figure 3.5). Roughly equal numbers were male and female. By race, 63.3% of recipients were white, 20.0% black, 11.1% Hispanic, and 4.4% Asian. Short-gut syndrome was the etiology of intestinal failure in 78.3% of recipients, followed by functional bowel problems in 12.8%. Fifty-three percent of patients spent 60 days or fewer on the waiting list. At the time of transplant, 38.3% of patients had a body mass index (BMI) of less than 18.5 kg/m^2, and 39.4% had a BMI between 18.5 and 24.9 kg/m^2. Most patients (65.6%) were not hospitalized at the time of transplant. For 86.1% of transplant recipients, this was their first intestinal transplant.

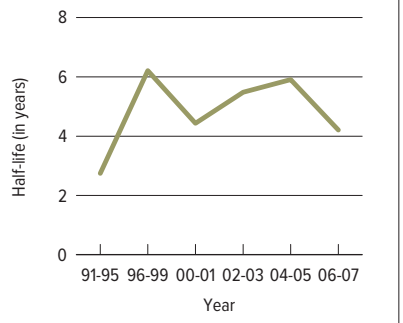
IN 4.1 Early (reported w/i 6 wks of tx) graft failure among intestinal transplant recipients



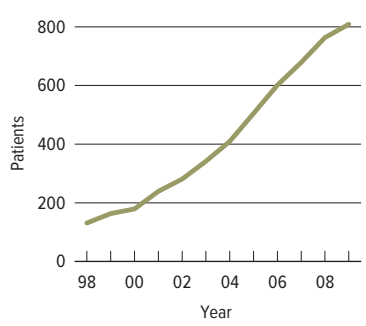
IN 4.2 Graft failure among intestinal transplant recipients: deceased donor



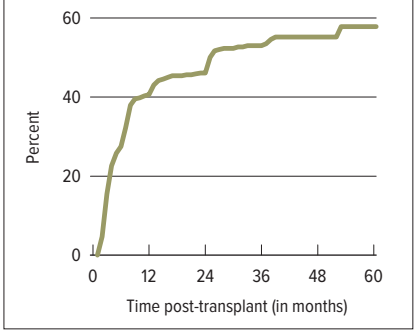
IN 4.3 Half-lives for int. tx recipients surviving with a funct. intestine for at least one year



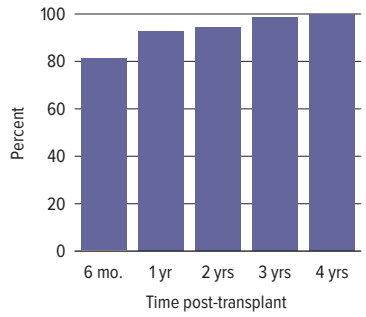
IN 4.4 Recipients alive & with a functioning intestinal transplant on June 30 of the year



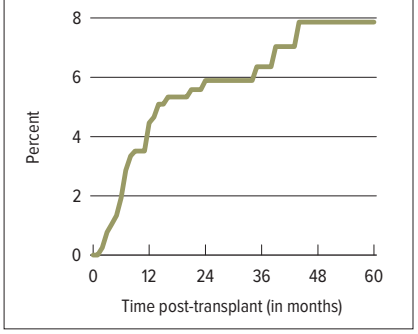
IN 4.5 Incidence of first acute rejection among pts receiving an intestinal tx in 2005–2009



IN 4.6 Reported hospitalizations among patients receiving an intestinal tx in 2005–2009



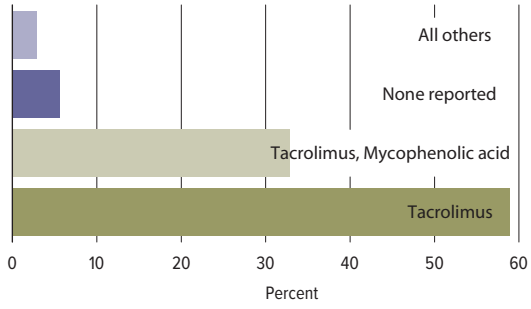
IN 4.7 Incidence of PTLD among patients receiving an intestinal transplant in 2005–2009



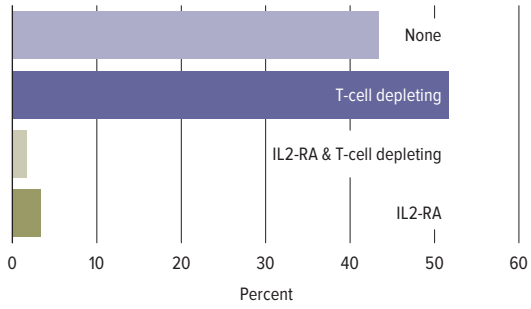
outcomes

There has been a decline in early graft failure, from 20.0% in 1998 to 8.3% in 2009 (Figure 4.1). Graft survival has continued to improve over the past decade. Among those transplanted in 2008–2009, 6-month graft survival was 81.1%. For patients transplanted in 2006–2007, 1-year graft survival was 71.3%; for patients transplanted in 2004–2005, 3-year graft survival was 60.3%; for patients transplanted 2002–2003, 5-year graft survival was 45.3%; and for patients transplanted 1996–1999, 10-year graft survival was 27.0% (Figure 4.2). However, graft half-life, conditional on 1-year survival, has remained relatively low and has not increased substantially over the past decade (Figure 4.3). Nevertheless, there has been a steady increase in the number of recipients alive with a functioning intestinal graft over the past 12 years (Figure 4.4). Acute rejection and hospitalization were very common among intestinal transplant recipients. For patients transplanted in 2005-2009, the cumulative incidence of first acute rejection was 43.1% by 12 months post-transplant (Figure 4.5). Hospitalization occurred in 81.3% of patients by 6 months post-transplant and in all patient by 4 years post-transplant (Figure 4.6). For patients who underwent transplant in 2005–2009, the cumulative incidence of post-transplant lymphoproliferative disorder was 1.9% at 6 months, 4.5% at 1 year, 5.9% at 2 years, 6.4% at 3 years, 7.9% at 4 years, and 7.9% at 5 years after transplant (Figure 4.7).

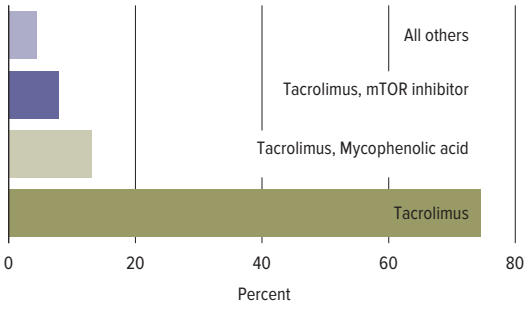
IN 5.1 Initial immunosuppression regimen in intestinal transplant recipients, 2009 (steroids not considered)



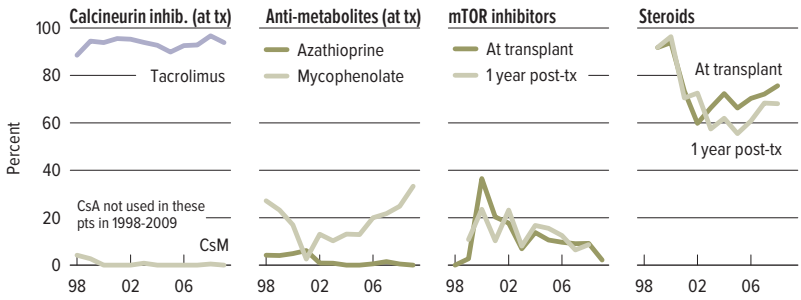
IN 5.2 Induction agents used at time of intestinal transplant, 2009



IN 5.3 Immunosuppression regimen at one year in intestinal transplant recipients, 2008 (steroids not considered)



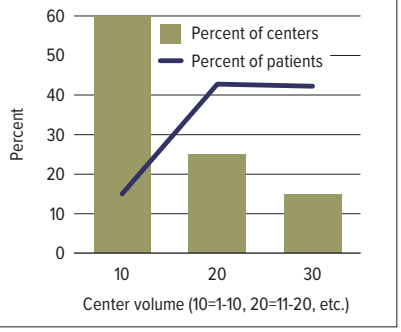
IN 5.4 Immunosuppression use in intestinal transplant recipients



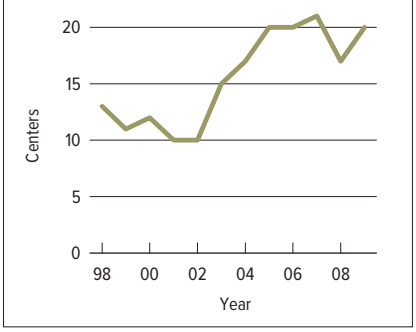
immunosuppression

The most common initial immunosuppression regimen was tacrolimus alone, with or without corticosteroids, which was reported in 58.9% of patients transplanted in 2009. The second most common regimen was tacrolimus and mycophenolate, reported in 32.8% of patients (Figure 5.1). For induction therapy, 51.7% of patients received T-cell depleting agents, 43.3% received no induction, 3.3% received interleukin-2 (IL2-RA) receptor antagonists, and 1.7% received both T-cell depleting agents and IL-2 receptor antagonists (Figure 5.2). At one year post-transplant, tacrolimus remained the most common immunosuppression regimen, reported in 74.6% of patients transplanted in 2008. The second most common regimen at one year post-transplant was tacrolimus and mycophenolate, reported in 13.0% of patients (Figure 5.3). Over the past decade, tacrolimus has been the main calcineurin inhibitor used; in 2009 it was used in 93.9% of patients (Figure 5.4). Mycophenolate use has increased to 33.3% in 2009, while mTOR inhibitor use has decreased from 36.6% in 2000 to 2.2% in 2009. Among patients transplanted in 2008, steroids were used in 75.7% at the time of transplant and 68.1% at 1-year post-transplant.

IN 6.1 **Distribution by ctr volume of the number of intestinal transplants performed, 2009**



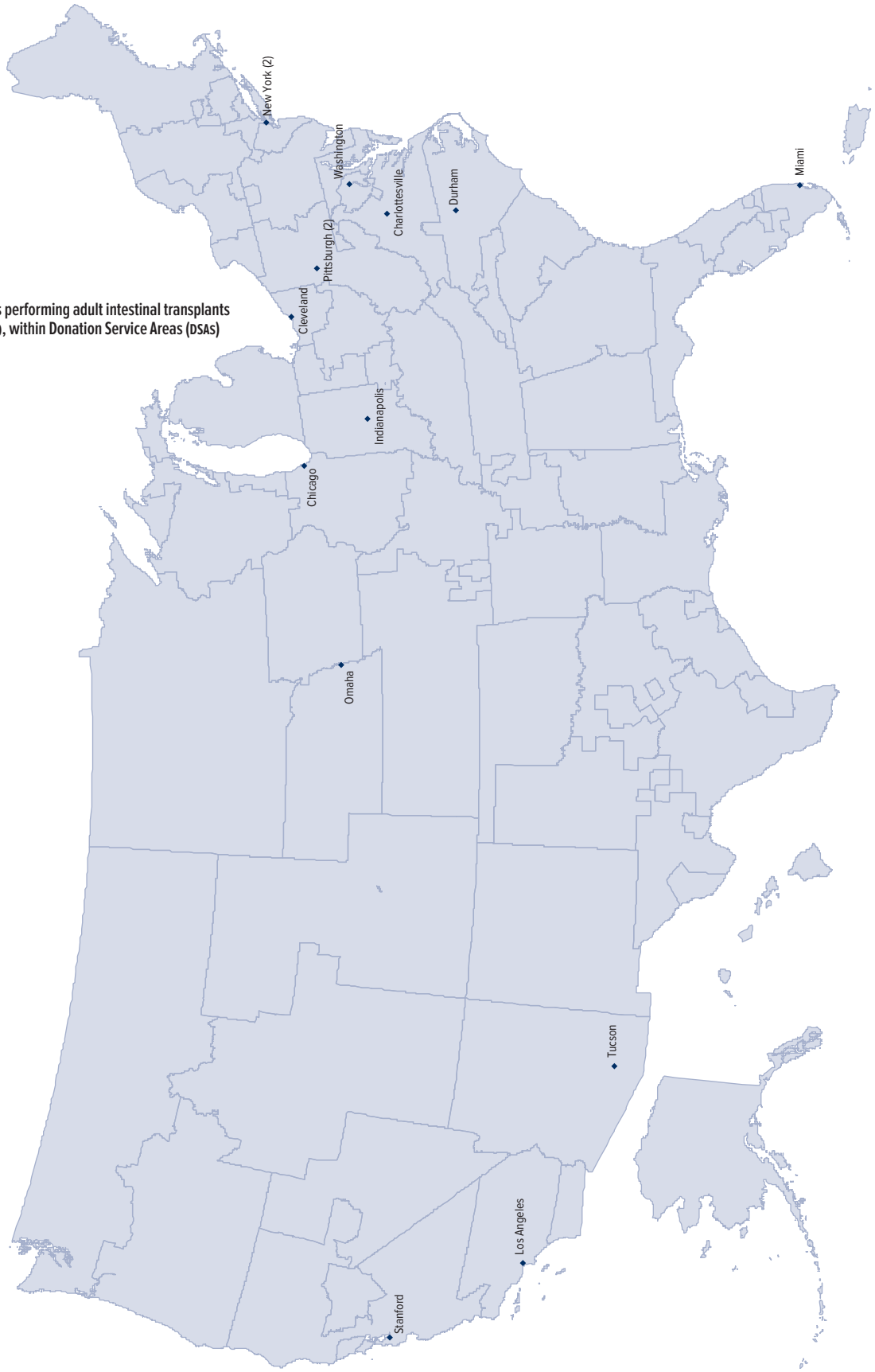
IN 6.2 **Centers performing intestinal transplants**



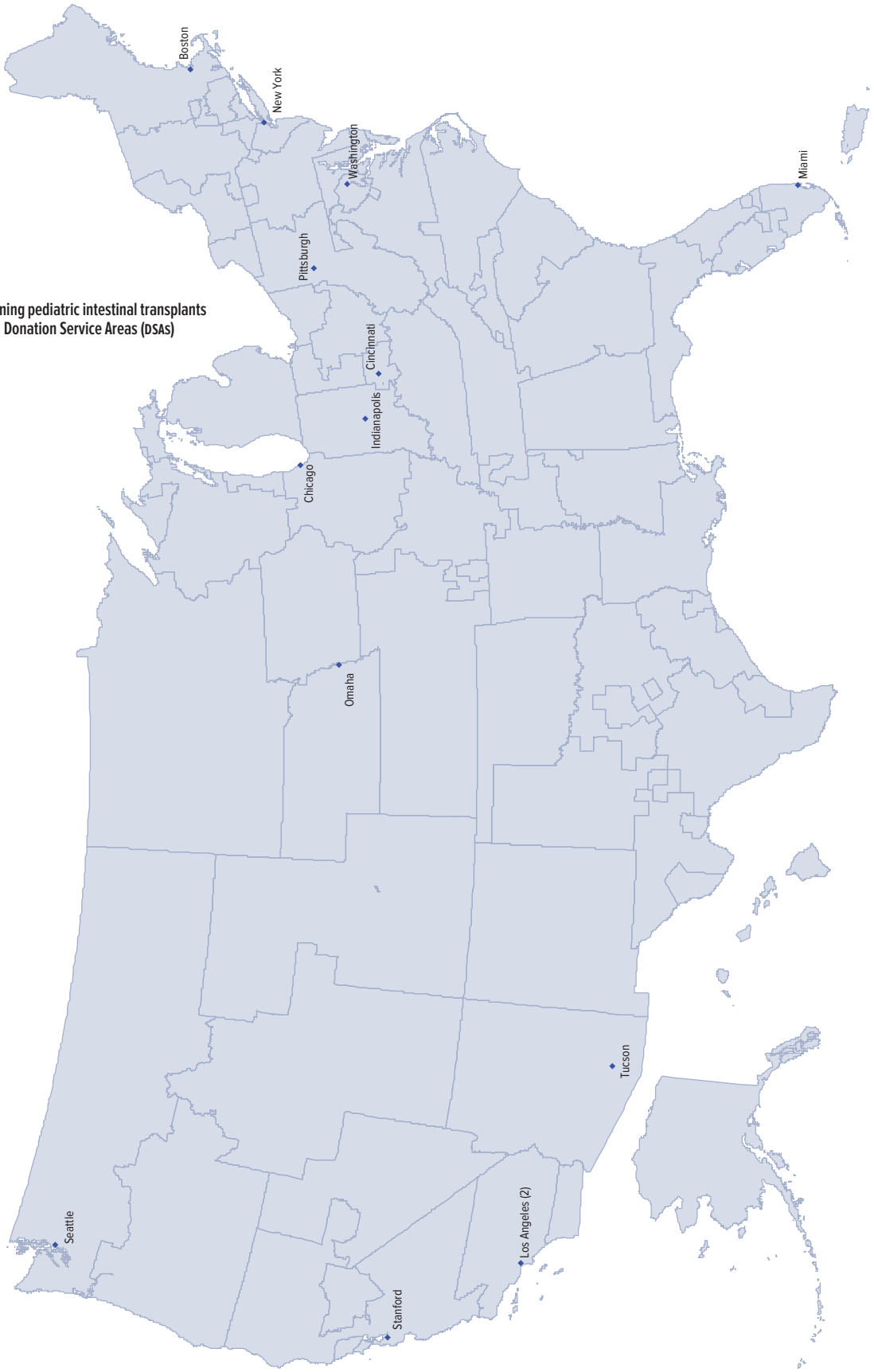
center characteristics

In 2009, 60.0% of centers performed between 1 and 10 intestinal transplants, 25.0% performed 11 to 20 transplants, and 15.0% performed 21 to 30 intestinal transplants (Figure 6.1). There has been an increase in the number of centers performing intestinal transplants, from 13 in 1998 to 20 in 2009 (Figure 6.2); 14 (70.0%) of these 20 centers performed intestinal transplants in children and adolescents.

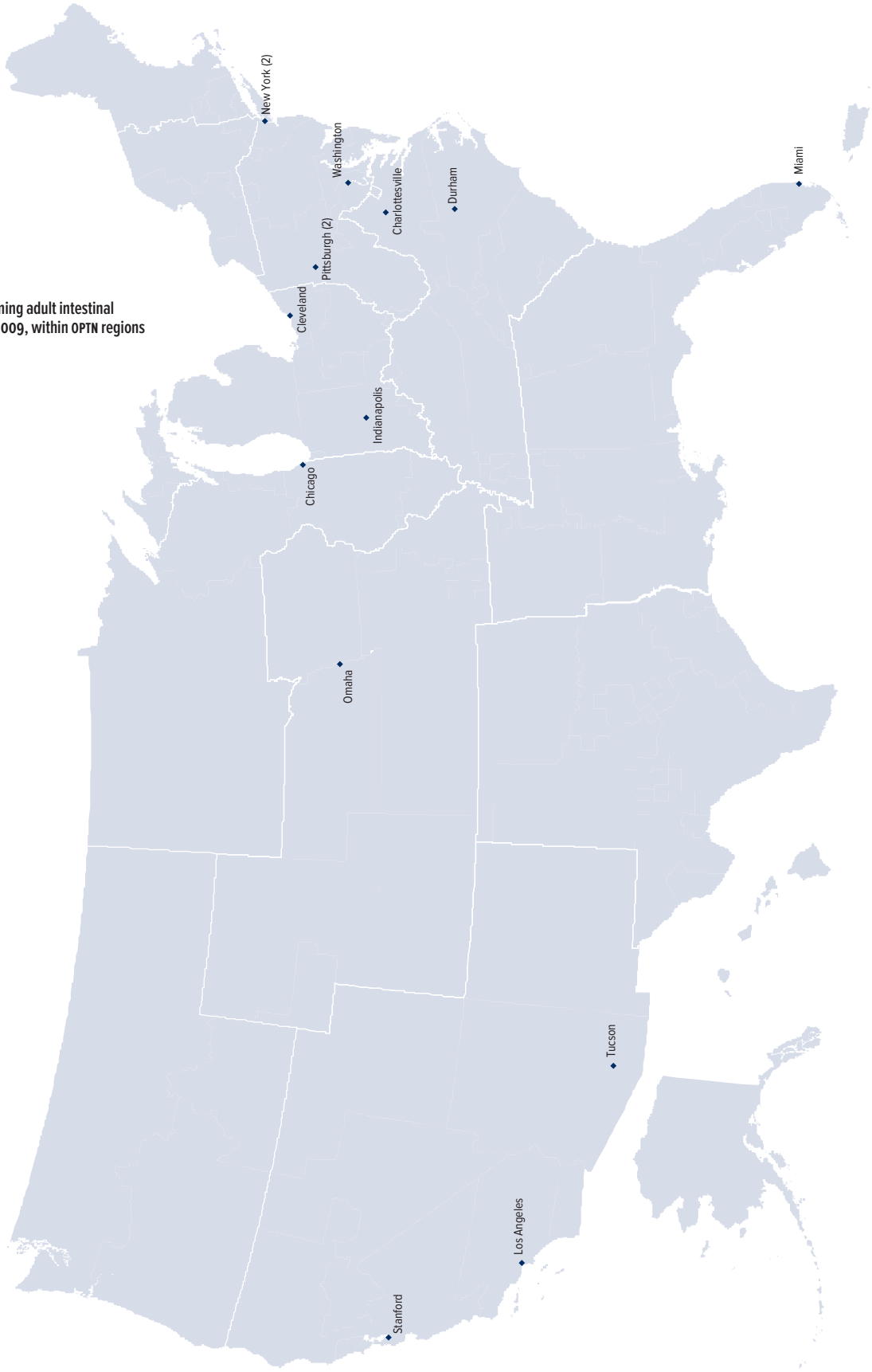
IN 7.1 **Centers performing adult intestinal transplants in 2009, within Donation Service Areas (DSAs)**



IN 7.2 **Centers performing pediatric intestinal transplants in 2009, within Donation Service Areas (DSAs)**



IN 7.3 **Centers performing adult intestinal transplants in 2009, within OPTN regions**



heart

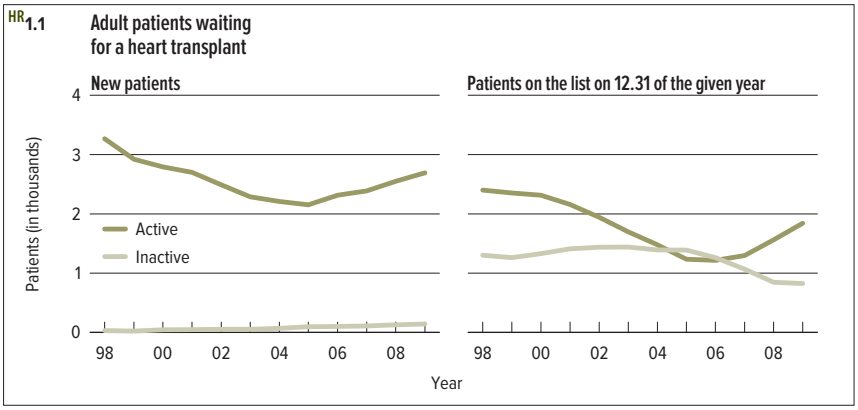
Despite the availability of successful medical therapies for end-stage heart failure, and now of mechanical circulatory support, heart transplant remains the best option for appropriate candidates with end-stage heart failure. The total number of heart-alone transplants performed has varied over the past 12 years. Between 1998 and 2004, the number of heart transplants declined from 2,083 to 1,724; however, in 2005 the downward trend reversed, and numbers achieved a plateau between 2005 and 2009 (Figure 3.1). In 2009, 1,853 heart transplants were performed. Both short-term and long-term graft survival rates have improved over the past decade. In 2009, the 6-month graft survival rate was 91.6%; the 1-year rate was 88.6%. This trend toward improvement, however, is tempered by the fact that long-term graft survival remains poor; 10-year graft survival in 1999 transplants was 53% (Figure 5.1). Overall, the number of new patients added to the heart transplant waiting list declined over the past 12 years. This trend reached a nadir in 2005, and has reversed in more recent years (Figure 1.1). A similar trend was seen in the number of patients actively awaiting transplant. Despite downward trends in recovery rates and donations, and increased waiting time, the mortality rate on the waiting list declined over the past 12 years from 20.7% to 13.7% (Figure 1.10). Multi-organ transplants are increasing; in 2009, 2.77% of hearts were transplanted with a kidney and 0.58% were transplanted with a liver. The proportion of hearts transplanted with a lung has declined, continuing a decade-long trend (Figure 2.4). Finally, the standard immunosuppression regimen has changed; in 2008, the combination of tacrolimus and mycophenolate was used in 55.6% of heart transplant recipients at one year post-transplant (Figure 6.3).

This heart saved my life. I am so grateful for my donor, my angel in heaven.

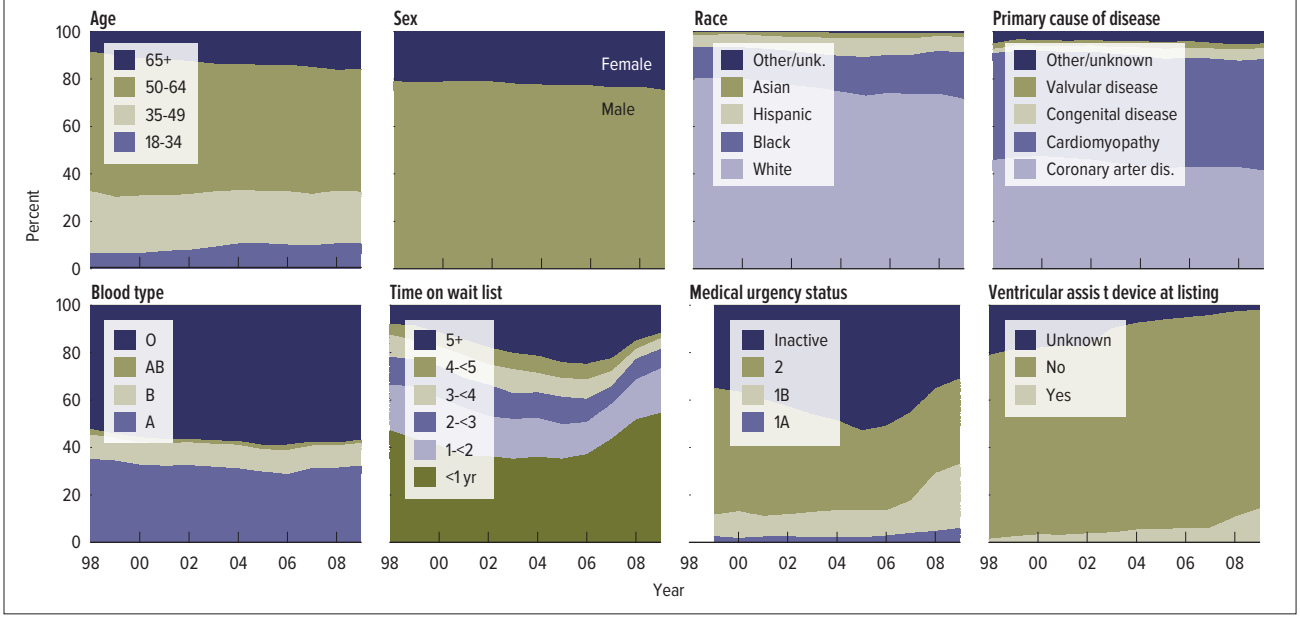
Sonja, heart recipient

OPTN SRTR SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

HR1.1 Adult patients waiting for a heart transplant



HR1.2 Distribution of adult patients waiting for a heart transplant



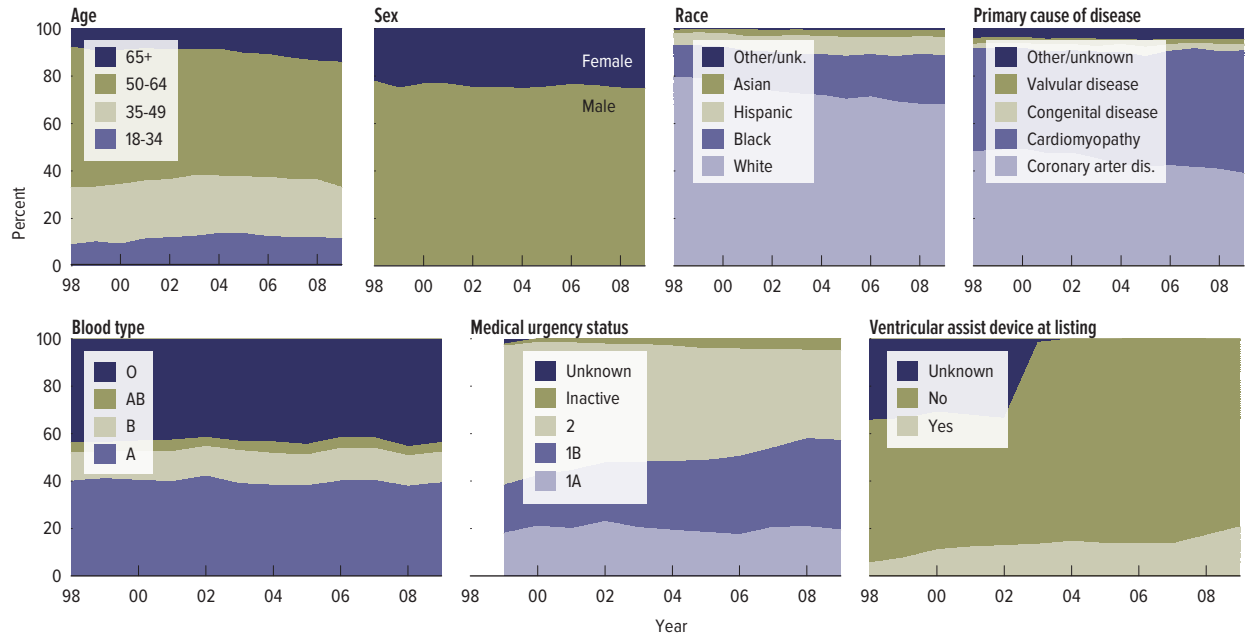
wait list

Heart transplant remains the best option for many patients with end-stage heart failure. Although the prevalence of heart failure continues to increase, the number of new patients added to the active heart transplant waiting list declined from 3,265 to 2,153 between 1998 and 2005, resulting in a decline in the total number of patients on the waiting list during this period. Since 2006, however, there has been a resurgence in the number of additions to the waiting list (Figure 1.1), and in 2009 the number of new active patients totaled 2,692. In October, 2002, discontinuation of CMS requirements for reimbursement after implantation of a left-ventricular assist device (LVAD) likely resulted in an increase in the proportion of patients initially listed as inactive (Figure 1.1). The changing trend in waiting list status may also reflect the practice of some centers to postpone actively listing potential recipients who have LVADs until their condition qualifies them for status 1A or 1B.

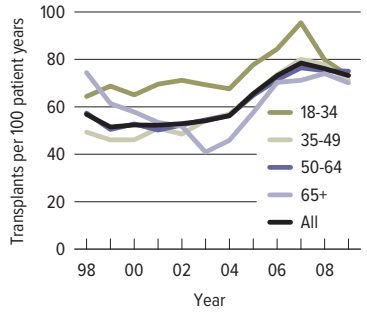
Nearly 52% of patients awaiting heart transplant are aged 50 to 64 years. This represents an overall decline in this age group since 1998 (Figure 1.2). The number of newly listed candidates aged 65 years or older almost doubled between 1998 and 2009 (Figure 1.3). Between 1998 and 2009, the proportion of whites on the waiting list gradually declined (Figure 1.2).

In 2009, 47.0% of patients awaiting transplant had cardiomyopathy, the most prevalent cause of end-stage heart failure among

HR1.3 Distribution of adult patients newly listed for a heart transplant



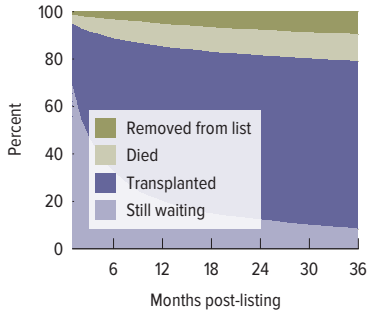
HR1.4 Transplant rates among adult patients wait-listed for a heart transplant, by age



HR1.5 Heart transplant waiting list activity among adult patients

	2007	2008	2009
Listings at start of year	2,478	2,361	2,413
Listings added during year	2,633	2,825	2,966
Listings removed during year	2,750	2,773	2,710
Listings at end of year	2,361	2,413	2,669
Removal reason			
Deceased donor transplant	1,879	1,804	1,855
Patient died	388	442	446
Too sick to transplant	39	38	68
Improved, tx not needed	300	246	193
Other	144	243	148

HR1.6 Heart tx waiting list status by month post-listing among new adult listings in 2006



listed patients. The proportion with coronary artery disease, the most common reason for listing between 1998 and 2002, declined to 41.2% in 2009 (Figure 1.2).

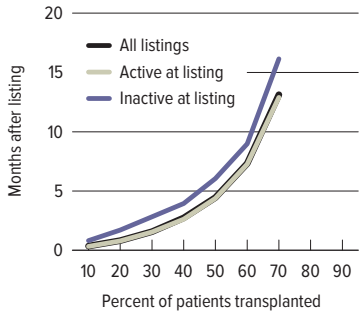
In 2006, Organ Procurement and Transplantation Network (OPTN) policy changed to allow prioritization of zone A status 1A and 1B patients ahead of local status 2 patients. As a result, prevalence of patients waiting for more than 2 years has declined (Figure 1.2).

Prevalence of patients awaiting heart transplant as status 1B has grown substantially. This is most likely a reflection of growing LVAD use and the ability to more readily list these patients as 1B (Figures 1.2 and 1.3).

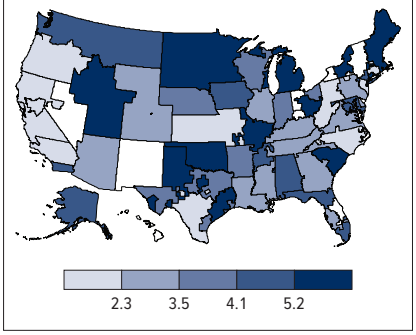
The rate of heart transplant (per 100 patient-years) has increased since 1998 from 56.9 to 73.3 in 2009. The transplant rate for patients aged 50 to 64 years, at 75.1, exceeded rates for other age groups (Figure 1.4). In 2009, 1,855 listings were removed from the list because the patient received a heart transplant; 446 died while awaiting transplant (Figure 1.5).

Among patients newly listed for heart transplant in 2006, 8% were still waiting, 71% had undergone transplant, and just over 11% had died by 3 years after listing. In 2006, the greatest proportion of heart transplants was performed during the first year of listing. The greatest proportion of deaths also occurred during the first year (Figure 1.6).

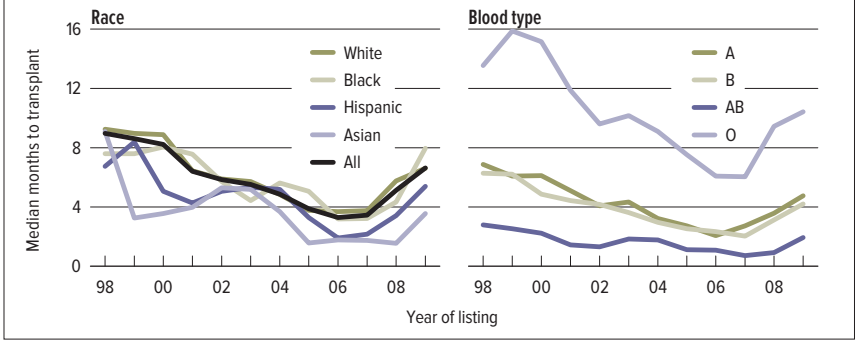
HR1.7 Percentiles of time to heart transplant for new adult listings, 2005–2009



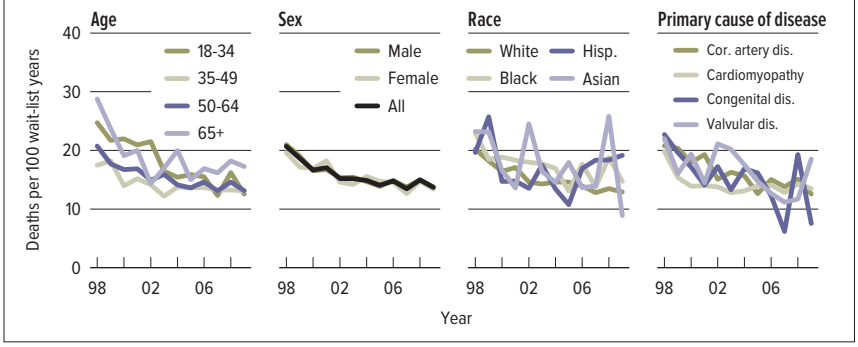
HR1.8 Median months to heart transplant for adult patients transplanted in 2009, by DSA



HR1.9 Median months to heart transplant for wait-listed adult patients



HR1.10 Pre-transplant mortality rates among adult patients wait-listed for a heart transplant



HR1.11 Characteristics of adult patients on the heart tx waiting list on December 31, 2009

	Level	N	%
Age	18-34	279	10.5
	35-49	583	21.9
	50-64	1,378	51.7
	65+	426	16.0
Sex	Female	662	24.8
	Male	2,004	75.2
Race	White	1,905	71.5
	Black	520	19.5
	Hispanic	175	6.6
	Asian	46	1.7
	Other/unknown	20	0.8
Primary cause of disease	Cor. artery disease	1,099	41.2
	Cardiomyopathy	1,253	47.0
	Congenital disease	122	4.6
	Valvular disease	56	2.1
	Other/unknown	136	5.1
Transplant history	Listed for first tx	2,554	95.8
	Listed for subseq tx	112	4.2
Blood type	A	858	32.2
	B	254	9.5
	AB	40	1.5
	O	1,514	56.8
Time on wait list	<1 year	1,451	54.4
	1-<2	502	18.8
	2-<3	218	8.2
	3-<4	121	4.5
	4-<5	62	2.3
	5+	312	11.7
Medical urgency status	1A	157	5.9
	1B	724	27.2
	2	960	36.0
	Inactive	825	31.0

wait list

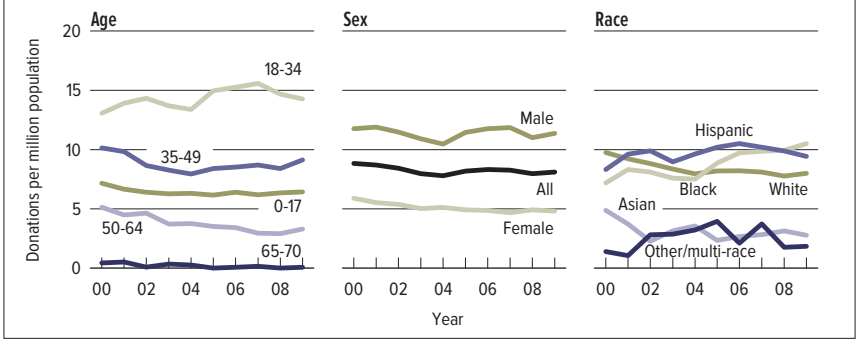
Among candidates wait-listed for heart transplant in 2005–2009, 50% underwent transplant in less than 5 months. The median time to transplant was 135 days (Figure 1.7). For patients who underwent transplant in 2009, the median waiting time by donor service area ranged from 1.1 months to 12.4 months (Figure 1.8).

In 2009, the median waiting time was shortest for Asians, at 3.6 months; median waiting time for blacks was 8 months. The overall median waiting time has increased to 6.6 months, despite a decline of almost two-thirds between 1998 and 2006. This increase was more pronounced in racial minority groups, which experienced a more than 2-fold increase between 2006 and 2009 (Figure 1.9).

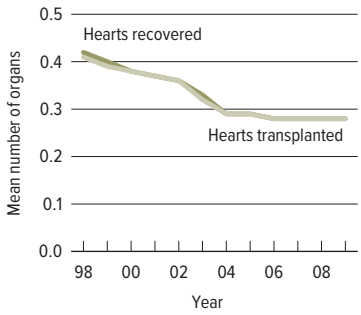
The pre-transplant mortality rate (per 100 wait-list years) has fluctuated since 1998 within age and race groups, and in 2009 was highest for patients aged 65 years or older and Hispanics (Figure 1.10).

On December 31, 2009, 52% of patients on the waiting list were aged 50 to 64 years, 22% were aged 35 to 49 years, and 16% were aged 65 years or older; 72% were white, 20% were black, approximately 7% were Hispanic, and nearly 2% were Asian. Ninety-six percent were listed for a first heart transplant and 4% for a subsequent transplant. Fifty-four percent had been waiting less than 1 year and 12% for 5 years or more. Only 6% were listed as status 1A; 36% were listed as status 2 (Figure 1.11).

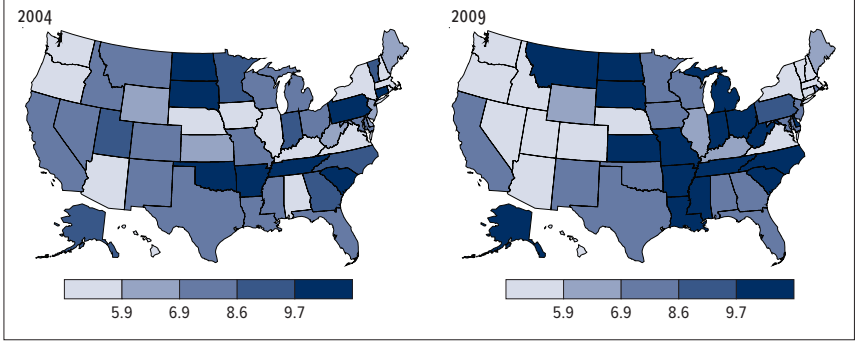
HR2.1 Heart donations from deceased donors per million population



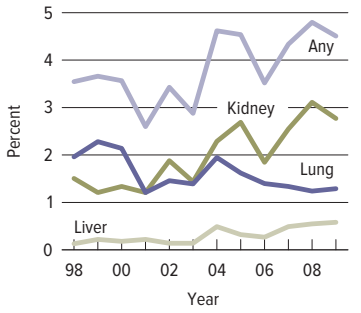
HR2.2 Hearts recovered per donor & hearts transplanted per donor



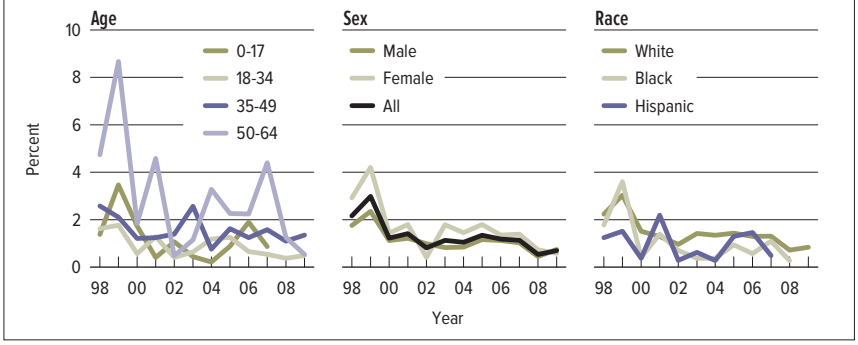
HR2.3 Deceased donor heart donation rates (per million population), by state



HR2.4 Deceased donor hearts transplanted with another organ



HR2.5 Discard rates for hearts recovered for transplant



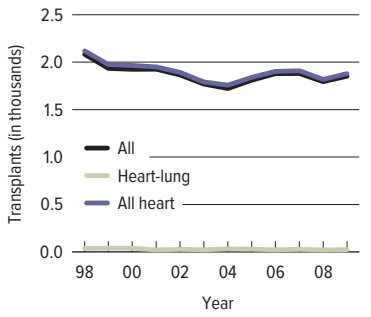
deceased donation

Overall, heart donations have dropped from 8.83 per million population (pmp) to 8.11 pmp since 2000 (Figure 2.1). Deceased donations pmp have been consistently highest in patients aged 18 to 34 years. Heart donation rates tend to be higher in men than in women. Donation rates for blacks increased substantially between 2000 and 2009, from 7.18 pmp to 10.5 pmp (Figure 2.1). Considerable geographic variation in deceased heart donation remains (Figure 2.3).

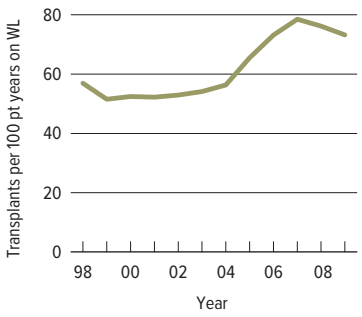
The transplant rate of hearts per donor has been nearly identical to the rate of recovery, reflecting optimal use of recovered hearts (Figure 2.2). Among 2009 heart recipients, 4.5% have at least one other transplanted organ, part of an increasing trend over the past 12 years primarily due to a rise in simultaneous kidney and simultaneous liver transplants (Figure 2.4). Kidneys were the most common organs transplanted with hearts, reaching a peak of 3.1% in 2008. Simultaneous lung transplants reached a plateau over the past 5 years (Figure 2.4).

The low discard rate for deceased donor hearts trended downward between 2005 and 2008. Discard rates were lowest for heart donors aged 34 years or younger. In general, male hearts were discarded less frequently than female hearts except in 2002, when the discard rate of female hearts appeared to decline substantially (Figure 2.5).

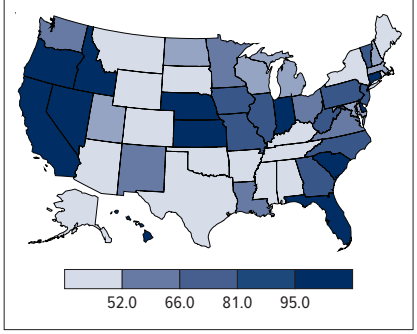
HR 3.1 Total adult heart & heart/lung transplants



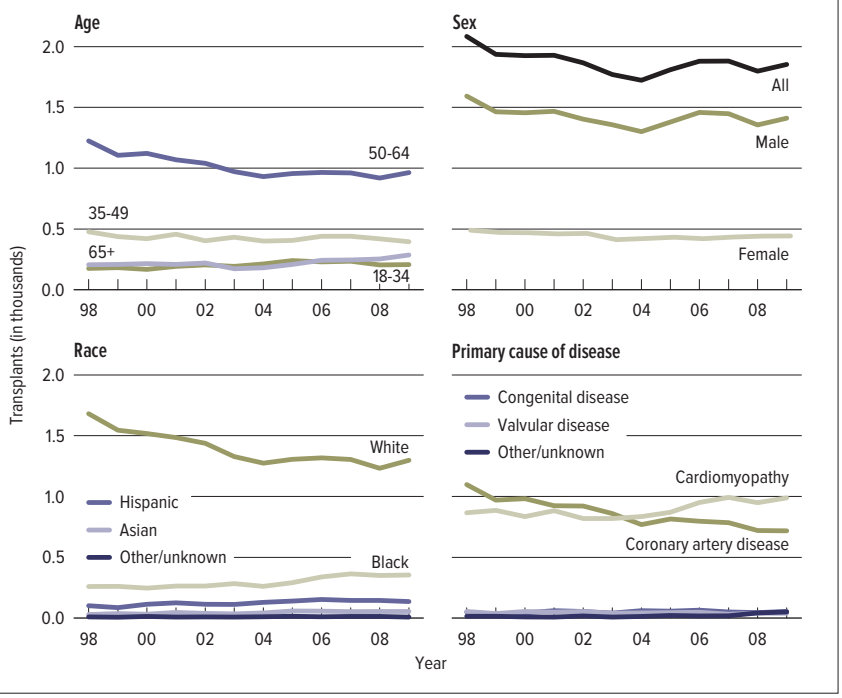
HR 3.2 Heart transplant rates in adult recipients



HR 3.3 Heart transplant rates per 100 pt years on the waiting list, adult patients, 2009



HR 3.4 Adult heart transplants



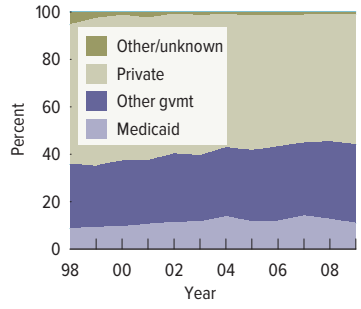
transplant The number of heart and heart/lung transplants has decreased by 11% since 1998 (Figure 3.1). In 2009, 1,853 heart transplants and 26 heart/lung transplants were performed. The rate of heart transplants (per 100 patient-years on the waiting list) has increased notably, from 56.9 in 1998 to 73.3 in 2009 (Figure 3.2). Geographic variation is wide (Figure 3.3). More than half of all transplant recipients were aged 50 to 64 years. Men underwent heart transplant more than 3 times more frequently than women. The proportion of white recipients decreased from 80.7% of all recipients in 1998 to 70.0% in 2009. In contrast, the proportions of racial minority groups have increased; between 1998 and 2009, proportions of blacks increased from 12.5% to 19.2%, Hispanics from 4.9% to 7.4%, and Asians from 1.4% to 2.9%. Cardiomyopathy was the single most important reason for heart transplant (53.4%), followed by coronary artery disease (38.7%). Valvular disease was an infrequent reason for transplant (2.2%) (Figure 3.4). The proportion of patients with valvular heart disease who experienced pre-transplant mortality has increased since 2008 (Figure 1.10).

The percentage of heart transplant recipients with Medicaid or other government health care coverage has increased, although most recipients are still insured by private insurance (Figure 3.5).

HR 3.6 Characteristics of adult heart transplant recipients, 2009

	Level	N	%
Age	18-34	207	11.2
	35-49	395	21.3
	50-64	964	52.0
	65+	287	15.5
Sex	Female	443	23.9
	Male	1,410	76.1
Race	White	1,298	70.0
	Black	355	19.2
	Hispanic	137	7.4
	Asian	55	2.9
	Other/unk.	8	0.5
Primary cause of disease	Cor. artery disease	718	38.7
	Cardiomyopathy	989	53.4
	Congenital dis.	54	2.9
	Valvular disease	40	2.2
	Other/unk.	52	2.8
Transplant number	First	1,789	96.5
	Subsequent	64	3.5
Blood type	A	772	41.7
	B	276	14.9
	AB	89	4.8
	O	716	38.6
Primary payer	Private	1,020	55.0
	Medicaid	203	11.0
	Other government	614	33.1
	Other/Unknown	16	0.9
Time on wait list	<30 days	450	24.3
	31-60 days	260	14.0
	61-90 days	187	10.1
	3-<6 months	369	19.9
	6-<12 months	321	17.3
	1-<2 years	175	9.4
	2-<3 years	42	2.3
	3+ years	49	2.6
Medical urgency status	1A	964	52.0
	1B	744	40.2
	2	145	7.8
Reported history of cigarette smoking at listing	No	964	52.0
	Yes	869	46.9
	Unknown	20	1.1
Patient on VAD at transplant	No	1,135	61.3
	Yes	718	38.7
Total		1,853	100.0

HR 3.5 Insurance coverage among adult heart transplant patients at time of transplant

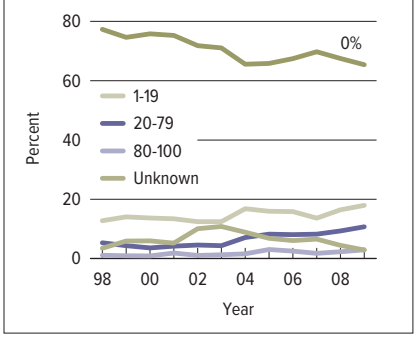


In 2009, 11.0% of patients had Medicaid as primary insurance at the time of transplant, 33.1% had another government source, and 55.0% had private insurance.

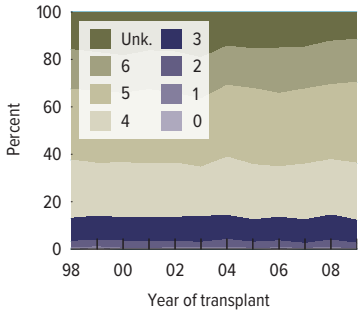
Of the 1,853 heart transplants performed in 2009, 52.0% of recipients were aged 50 to 64 years, and 15.5% were aged 65 years or older; 23.9% of recipients were women, and 70.0% were white (Figure 3.6). Cardiomyopathy was the primary cause of end-stage heart failure for most patients (53.4%). Most patients (96.5%) underwent transplant for the first time and 3.5% underwent subsequent transplant. Blood group A was the most common blood group. Waiting time was less than 1 month for 24.3% of patients, and only 2.6% experienced waiting times of 3 or more years. Most patients were status 1A at the time of transplant, 46.9% were reported to be smokers at the time of listing, and 38.7% were receiving VAD support.

Thus, the typical patient who underwent heart transplant in 2009 was a white, nonsmoking man, aged 50 to 64 years, with a history of nonischemic cardiomyopathy as the reason for transplant. His blood group was A, he had private insurance, and he was listed as status 1A at the time of transplant. He waited less than 30 days (Figure 3.6).

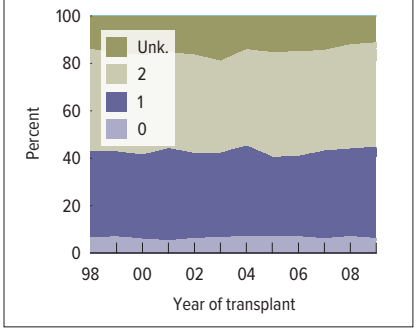
HR 4.1 PRA at time of heart transplant in adult recipients



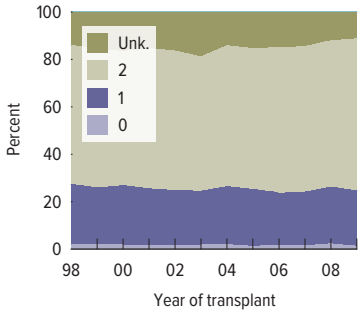
HR 4.2 Total HLA mismatches among adult heart transplant recipients



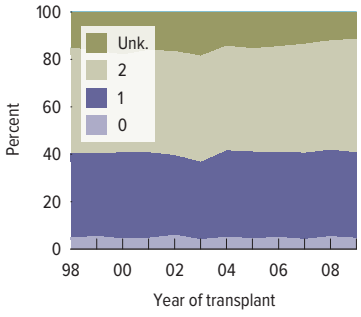
HR 4.3 HLA-A mismatches among adult heart transplant recipients



HR 4.4 HLA-B mismatches among adult heart transplant recipients



HR 4.5 HLA-DR mismatches among adult heart transplant recipients



donor-recipient matching

Prevalence of sensitized patients undergoing heart transplant with panel reactive antibody (PRA) between 20% and 79% increased substantially between 1998 and 2009, from 5.3% of patients to 10.7%. The percentage of highly sensitized patients (PRA 80% to 100%) remains low, at 3.0%; however, the overall prevalence of this high-risk group has almost tripled since 1998, from 1.1% to 3.0%. Virtual cross-matching is increasing in adult heart transplant programs and has allowed consideration of sensitized patients who might have previously been excluded (Figures 4.1 and 4.2).

Human leukocyte antigen (HLA) matching is not used in allocation for heart transplant. As a result, HLA mismatches are common (Figures 4.2–4.5); 76.3% of heart transplant recipients have 4 or more mismatches. Multiple HLA-B mismatches were most common; 64.1% of recipients have 2 HLA-B mismatches. This represented a 9.2% increase since 1998. Smaller increases in mismatches were seen for HLA-A and HLA-DR also.

Cytomegalovirus (CMV) infection is associated with significant morbidity after heart transplant and with development of cardiac allograft vasculopathy. The greatest risk of CMV infection occurs with CMV transmission to a recipient who is seronegative. Previous exposure to CMV, however, is common in the general popula-

HR4.6 Adult heart donor-recipient cytomegalovirus (CMV) serology matching, 2005–2009

	DONOR			
RECIPIENT	Negative	Positive	Unknown	Total
Negative	13.4	21.6	0.1	35.0
Positive	21.3	37.4	0.3	59.0
Unknown	2.4	3.5	0.0	5.9
Total	37.1	62.5	0.4	100

HR4.7 Adult heart donor-recipient Epstein-Barr virus (EBV) serology matching, 2005–2009

	DONOR			
RECIPIENT	Negative	Positive	Unknown	Total
Negative	0.7	8.8	3.0	12.5
Positive	3.3	42.3	19.3	65.0
Unknown	0.8	13.3	8.3	22.5
Total	4.8	64.5	30.7	100

HR4.8 Adult heart donor-recipient hepatitis B core antibody (HBcAb) serology matching, 2005–2009

	DONOR			
RECIPIENT	Negative	Positive	Unknown	Total
Negative	75.6	1.7	0.3	77.6
Positive	3.9	0.2	0.0	4.2
Unknown	17.9	0.3	0.1	18.2
Total	97.5	2.2	0.3	100

HR4.9 Adult heart donor-recipient hepatitis B surface antigen (HBsAg) serology matching, 2005–2009

	DONOR			
RECIPIENT	Negative	Positive	Unknown	Total
Negative	89.4	0.0	0.2	89.6
Positive	1.7	0.0	0.0	1.7
Unknown	8.7	0.0	0.0	8.7
Total	99.8	0.0	0.2	100

HR4.10 Adult heart donor-recipient hepatitis C serology matching, 2005–2009

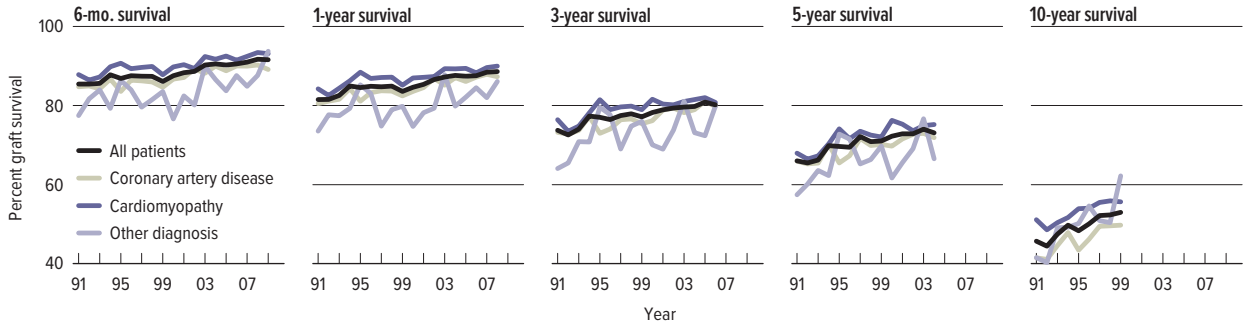
	DONOR			
RECIPIENT	Negative	Positive	Unknown	Total
Negative	86.7	0.2	0.2	87.1
Positive	1.9	0.0	0.0	1.9
Unknown	10.9	0.0	0.0	11.0
Total	99.6	0.2	0.2	100

HR4.11 Adult heart donor-recipient human immunodeficiency virus (HIV) serology matching, 2005–2009

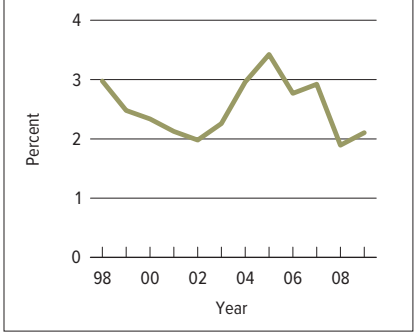
	DONOR			
RECIPIENT	Negative	Positive	Unknown	Total
Negative	86.3	0.0	0.1	86.4
Positive	0.1	0.0	0.0	0.1
Unknown	13.5	0.0	0.0	13.5
Total	99.9	0.0	0.1	100

tion, and between 2005 and 2009, 62.5% of donors and 59.0% of recipients were seropositive; 21.6% of recipients were in the high-risk category of donor antibody positive and recipient antibody negative (D+/R-) (Figure 4.6). Epstein-Barr virus (EBV) is also of great concern due to its association with post-transplant lymphoproliferative disorders (PTLD); 8.8% of recipients were high-risk EBV mismatches, that is, D+/R- (Figure 4.7). Prior hepatitis B infection was relatively uncommon; only 2.2% of donors whose serostatus was known had previous evidence of infection, that is, positive hepatitis B core antibody, and 1.7% of recipients were at high risk of transmission from a positive donor (Figure 4.8). None of the donors demonstrated immunity to hepatitis B (positive hepatitis B surface antibody) (Figure 4.9). Hepatitis C seropositivity among donors was extremely uncommon, at 0.2%, but all hearts from these donors were transplanted into seronegative recipients (Figure 4.10). Human immunodeficiency virus (HIV) serostatus was known for 99.9% of all donors; none were HIV positive (Figure 4.11)

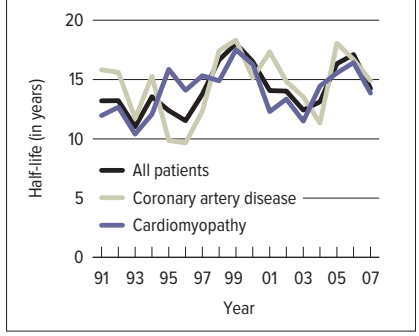
HR5.1 Graft failure among adult heart transplant recipients



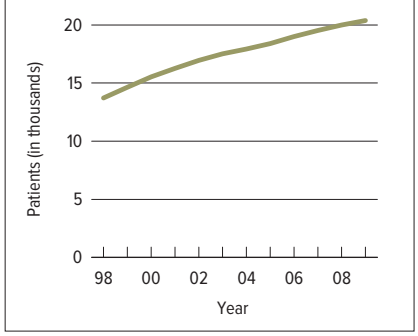
HR5.2 Early (reported w/i 6 wks of tx) graft failure among adult heart transplant recipients



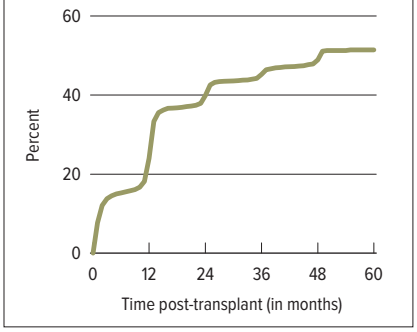
HR5.3 Half-lives for adult heart tx pts surviving with a functioning heart for at least one year



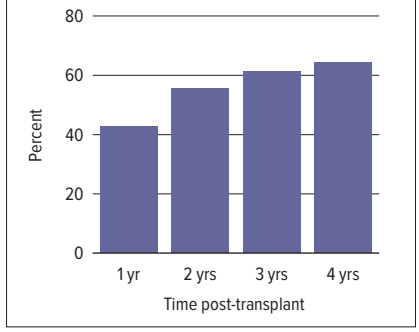
HR5.4 Adult recipients alive & with a functioning heart transplant on June 30 of the year



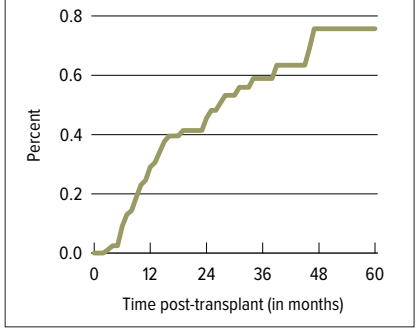
HR5.5 Incidence of first acute rejection among adult pts receiving a heart tx in 2005–2009



HR5.6 Reported hospitalizations among adult pts receiving a heart transplant in 2005–2009



HR5.7 Incidence of PTLD among adult patients receiving a heart transplant in 2005–2009

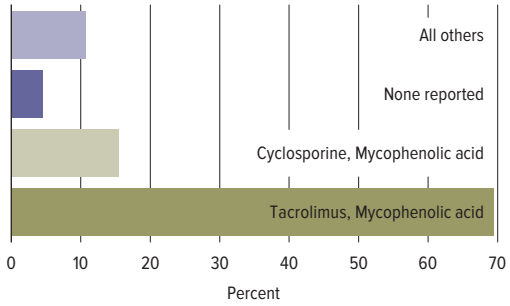


outcomes

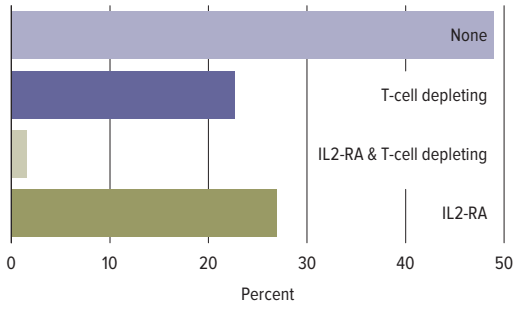
One-year graft survival increased from 81.5% to 88.6% between 1991 and 2008 (Figure 5.1). Six-month graft survival improved from 86.1% to 91.6% between 1999 and 2009. Cardiac allograft vasculopathy, PTLD, and malignancy continue to be major contributors to reduced long-term survival. Nevertheless, five-year graft survival increased from 66.2% to 73.1% between 1993 and 2004. Ten-year graft survival also increased, from 45.7% to 53% between 1991 and 1999. Aside from minor fluctuations, trends in improved survival have been similar for patients with different diagnoses.

Incidence of early graft failure, which peaked at 3.4% in 2005, declined 38.5% since 2005 (Figure 5.2). Overall, the median survival for recipients with a functioning graft 1 year post-transplant has trended upward (Figure 5.3). The number of heart transplant recipients who are alive with functioning grafts increased almost 50% from 13,715 in 1998 to 20,369 in 2009 (Figure 5.4). Acute rejection after heart transplant remains a challenge; 24.0% of patients who underwent transplant between 2005 and 2009 experienced a first rejection during the first year post-transplant, and by year 5, 51.4% experienced at least 1 episode (Figure 5.5). Hospitalizations are also common; by the fourth year post-transplant, nearly two-thirds of patients have been hospitalized (Figure 5.6). PTLD in adult heart transplant recipients is rare, occurring in less than 1%. More than one-third of cases occurred during the first post-transplant year (Figure 5.7).

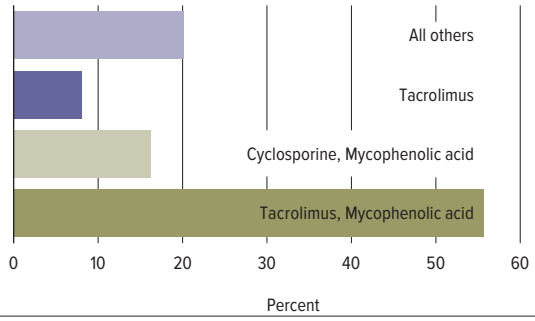
HR6.1 Initial immunosuppression regimen in adult heart transplant recipients, 2009 (steroids not considered)



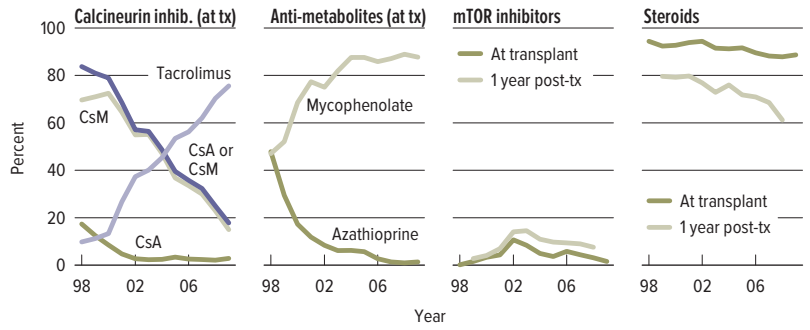
HR6.2 Induction agents used at time of heart transplant, adult recipients, 2009



HR6.3 Immunosuppression at one year in adult heart transplant recipients, 2008 (steroids not considered)



HR6.4 Immunosuppression use in adult heart transplant recipients

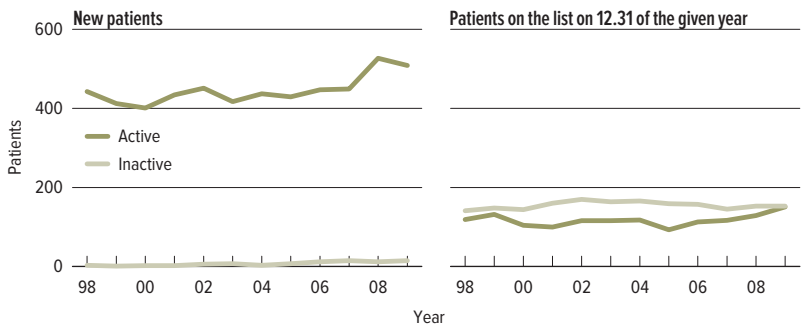


immunosuppression

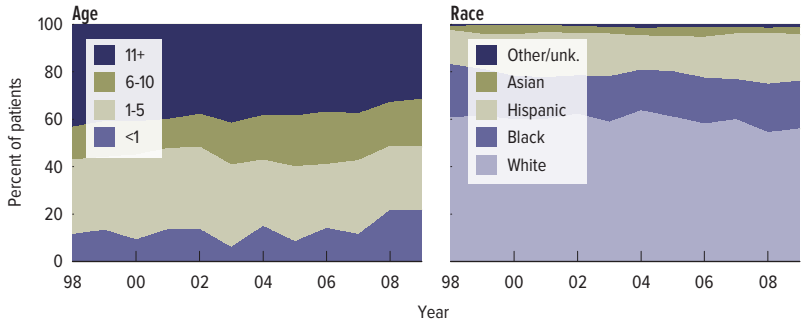
In 2009, 69.5% of heart transplant recipients received tacrolimus and mycophenolate as initial maintenance immunosuppression (Figure 6.1). Induction agents were used with approximately one-half of heart transplant recipients in 2009; 26.9% received an interleukin-2 (IL2-RA) receptor antagonist and 22.6% received a T-cell depleting agent (Figure 6.2). At 1 year post-transplant, 55.6% of patients were receiving tacrolimus and mycophenolate, and 16.2% were receiving cyclosporine A and mycophenolate. Interestingly, 8.0% were receiving tacrolimus as monotherapy within the first year post-transplant (Figure 6.3).

Over the past 12 years, tacrolimus has emerged as the calcineurin inhibitor of choice (Figure 6.4). Between 1998 and 2009, azathioprine use declined from 47.9% to 1.4%, and mycophenolate use increased from 47.0% to 87.7%. The use of mammalian target of rapamycin (mTOR) inhibitors as initial immunosuppression peaked at 10.8% in 2002, and declined to 1.6% in 2009. A similar peak was seen in the use of mTOR inhibitors at 1 year post-transplant, 14.5% in 2003 and declining to 7.5% in 2008. Corticosteroid use at the time of transplant declined slightly to 88.3% in 2007, but use has been stable since then. Maintenance corticosteroid use at 1 year remains common, but has declined in recent years from nearly 80% in 1999 to 61.2% in 2008 (Figure 6.4).

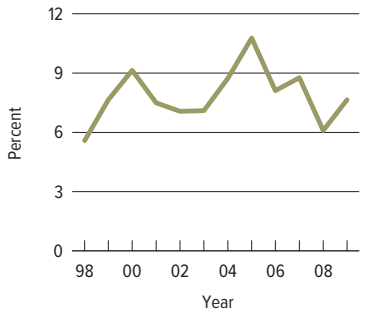
HR 7.1 Pediatric patients waiting for a heart transplant



HR 7.2 Distribution of pediatric patients waiting for a heart transplant



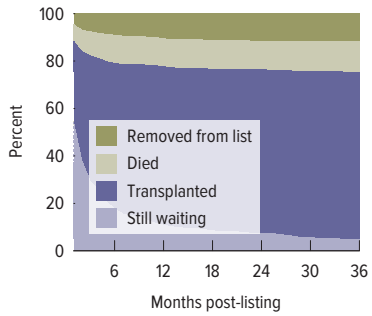
HR 7.3 Prior heart transplant in pediatric patients waiting for a heart transplant



HR 7.4 Heart transplant waiting list activity among pediatric patients

	2007	2008	2009
Listings at start of year	269	263	282
Listings added during year	479	558	549
Listings removed during year	485	539	529
Listings at end of year	263	282	302
Removal reason			
Received a transplant	332	368	364
Patient died	67	102	83
Patient refused transplant	2	0	1
Transferred to another ctr	2	3	9
Improved, tx not needed	64	34	47
Too sick to transplant	14	28	23
Other	4	4	2

HR 7.5 Heart tx waiting list status by month post-listing for pediatric pts first listed in 2006



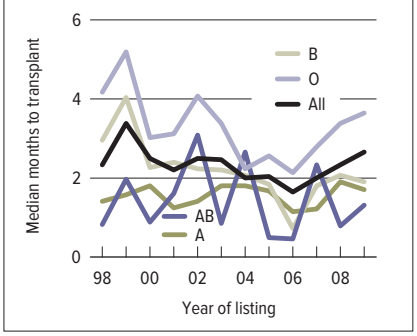
pediatric transplant

Since 1998, the number of new pediatric patients waiting for heart transplants has increased slightly (Figure 7.1). The number of prevalent patients has remained stable at approximately 250 to 300, with almost equal numbers of active and inactive patients. The percentage of patients on the waiting list aged younger than 1 year increased from 11.3% in 1998 to 21.7% in 2009 (Figure 7.2). The percentage of patients waiting for re-transplant has ranged between 5.6% and 10.8% over the past 12 years (Figure 7.3). Death was the second most common reason for removal from the waiting list, occurring in 13.8% to 18.9% of listings in 2007–2009 (Figure 7.4).

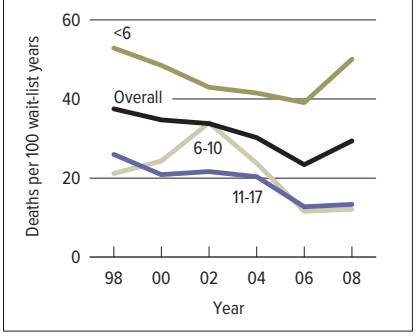
In the 2006 waiting list cohort, after 3 years, 70.9% underwent transplant, 12.7% died, 11.6% were removed from the list, and 4.8% were still waiting (Figure 7.5).

The median number of months waiting for a heart transplant was 2.7 in 2009 (Figure 7.6). Pre-transplant mortality for patients wait-listed for heart transplant declined from 37.5 deaths per 100 wait-list years in 1998 to 29.4 in 2008. Patients on the waiting list aged younger than 6 years consistently have the highest death rate, with 50.1 deaths per 100 wait-list years in 2008 (Figure 7.7). In 2009, numbers of heart transplants (including heart-lung) were 116 in patients aged younger than 1 year, 83 in patients aged 1 to 5 years, 60 in patients aged 6 to 11 years, and 103 in patients

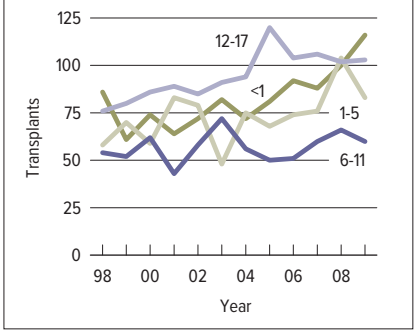
HR 7.6 Median months to heart transplant for wait-listed pediatric patients, by blood type



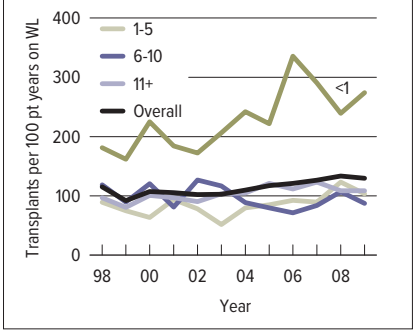
HR 7.7 Pre-tx mortality rates among pediatric patients wait-listed for a heart transplant



HR 7.8 Pediatric heart transplants (including heart-lung), by age



HR 7.9 Pediatric heart transplant rates, by age

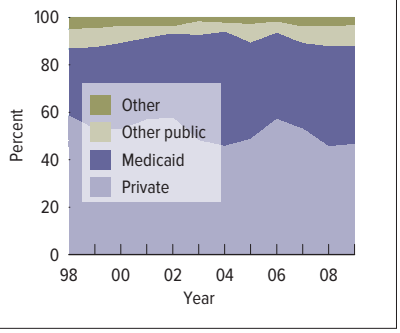


HR 7.10 Characteristics of pediatric heart transplant recipients, 2007–2009

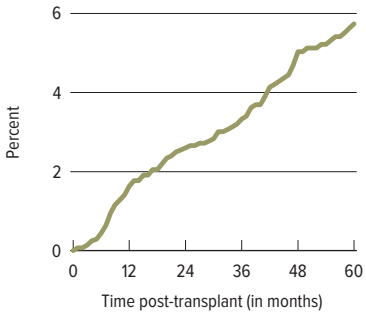
	Level	N	%
Age	<1	303	28.8
	1-5	259	24.6
	6-10	151	14.4
	11-17	339	32.2
Sex	Female	477	45.3
	Male	575	54.7
Race	White	560	53.2
	Black	211	20.1
	Hispanic	196	18.6
	Asian	62	5.9
	Other/unk.	23	2.2
Primary cause of disease	Congenital defect	444	42.2
	Dilated myopathy: idiopathic	317	30.1
	Restr. myopathy: idiopathic	69	6.6
	Dil. myopathy: myocarditis	49	4.7
	All others	173	16.4
Transplant history	First transplant	978	93.0
	Subsequent	74	7.0
Blood type	A	379	36.0
	B	146	13.9
	AB	41	3.9
	O	486	46.2
Primary payer	Private	507	48.2
	Medicaid	421	40.0
	Other public	85	8.1
	Other	39	3.7
Time on wait list	<30 days	436	41.4
	31-60 days	203	19.3
	61-90 days	124	11.8
	3-<6 months	151	14.4
	6-<12 months	96	9.1
	1-<2 years	24	2.3
	2-<3 years	12	1.1
	3+ years	6	0.6
Status	1A	867	82.4
	1B	111	10.6
	2	74	7.0
Patient on VAD	No	885	84.1
	Yes	167	15.9
All patients	--	1,052	1,052

aged 12 to 17 years (Figure 7.8). Rates of pediatric heart transplants per 100 patient-years on the waiting list have increased since 1998 to the current rate of 129.7; the highest rate is for patients aged younger than 1 year, at 274.1 (Figure 7.9). Among heart transplant recipients in 2007–2009, 28.8% were aged younger than 1 year, 24.6% 1 to 5 years, 14.4% 6 to 10 years, and 32.2% 11 to 17 years (Figure 7.10). Whites accounted for more than half of recipients (53.2%) followed by blacks (20.1%) and Hispanics (18.6%). The most common etiology of heart disease was congenital defects, in 42.2% of patients. Forty-one percent of patients underwent transplant in less than 30 days; 82.4% were status 1A, and 15.9% were on a VAD.

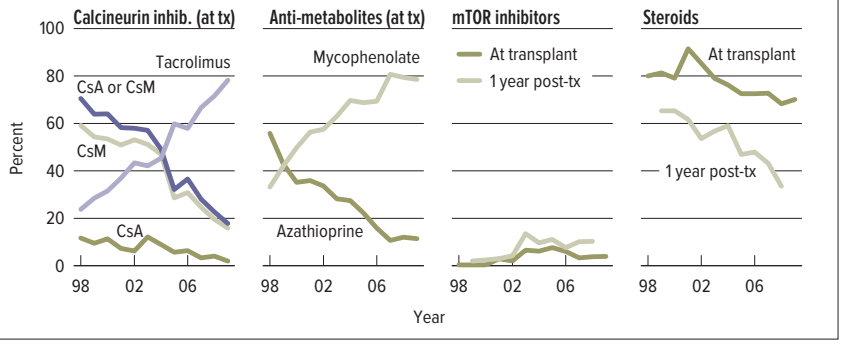
HR 7.11 Insurance coverage among pediatric heart transplant recipients at time of transplant



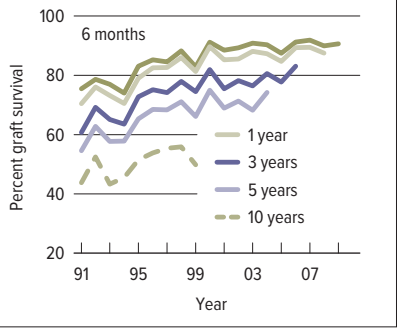
HR 7.12 Percent of pediatric heart transplant recipients with reported PTLD, 2000–2009



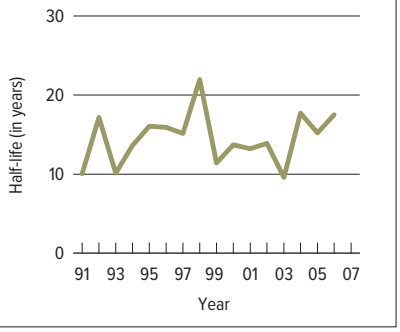
HR 7.13 Immunosuppression use among pediatric heart transplant recipients



HR 7.14 Graft failure among pediatric heart transplant recipients



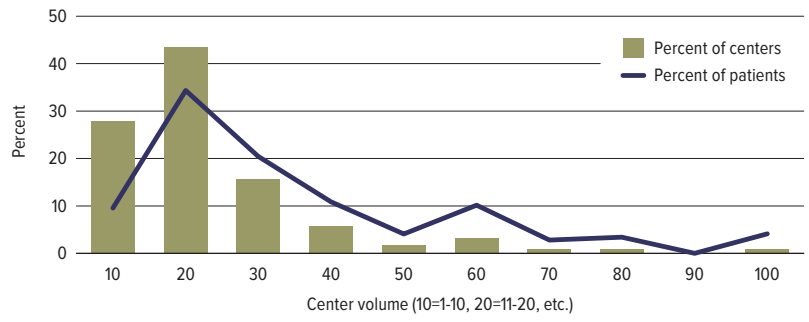
HR 7.15 Half-lives in pediatric heart tx recipients surviving with function for at least one year



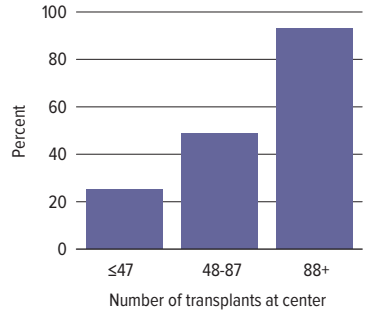
pediatric transplant

Private insurance coverage for pediatric heart transplant recipients declined from 58.5% of patients in 1998 to 46.5% in 2009, with a corresponding increase in Medicaid coverage from 28.3% to 41.5% (Figure 7.11). For children and adolescents who underwent transplant in 2000–2009, the incidence of PTLD was 0.44% at 6 months, 1.63% at 1 year, 2.60% at 2 years, 3.33% at 3 years, 5.03% at 4 years, and 5.74% at 5 years (Figure 7.12). Substantial changes in maintenance immunosuppression have occurred. Tacrolimus use increased from 23.8% in 1998 to 78.3% in 2009. Mycophenolate use increased from 33.2% in 1998 to 78.6% in 2009. In 2009, mTOR inhibitors were used in 3.9% of patients at the time of transplant and 10.3% at 1 year post-transplant. Steroids were used in 70.2% of patients at the time of transplant in 2009, and use decreased to 33.5% at 1 year (Figure 7.13). Graft survival has continued to improve. Graft survival for heart transplants in 2009 was 90.6% at 6 months; for transplants in 2008, 87.5% at 1 year; for transplants in 2006, 83.0% at 3 years; for transplants in 2004, 74.3% at 5 years; and for transplants in 1999, 49.8% at 10 years (Figure 7.14). 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 2007, the graft half-life was 33.9 years (Figure 7.15).

HR 8.1 **Distribution by center volume of the number of heart transplants performed (includes heart-lung), 2009**



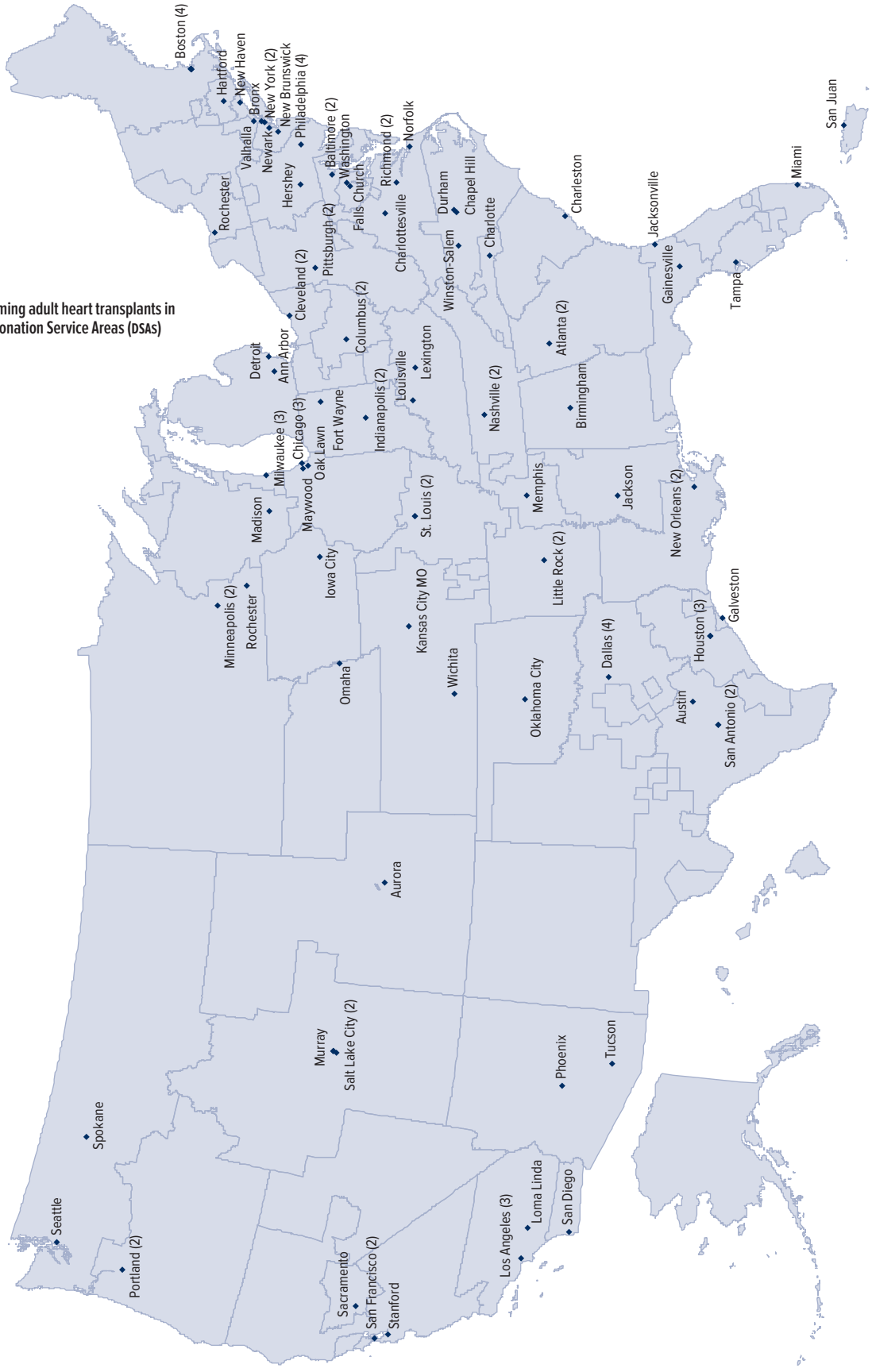
HR 8.2 **Heart programs performing multi-organ transplants, by volume, 2005–2009**



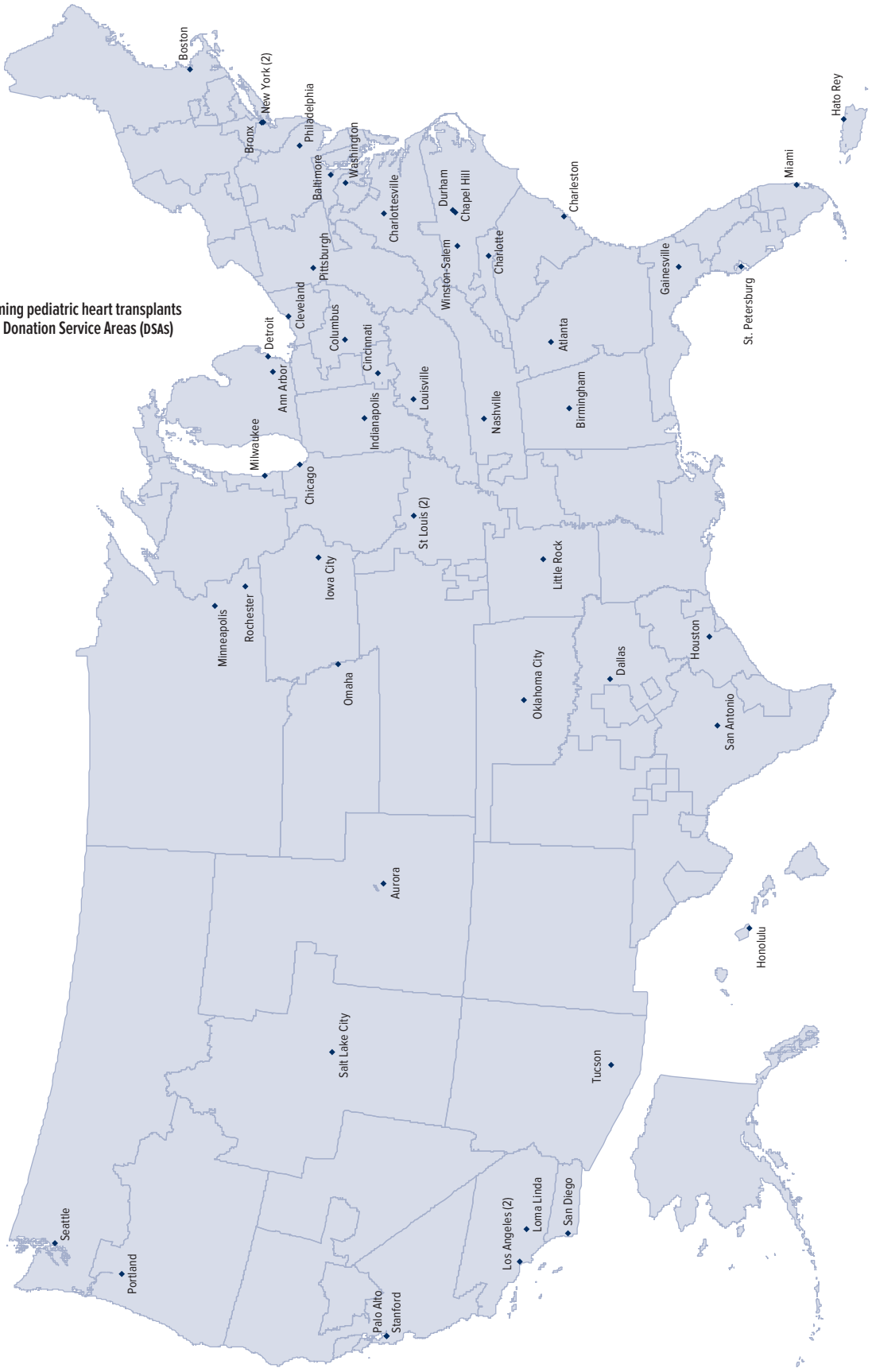
center characteristics

In 2009, nearly 28% of heart transplant centers performed 10 or fewer adult and pediatric heart transplants. Forty-three percent of centers performed 11 to 20 transplants per year, and 15.6% performed 21 to 30 transplants per year. In contrast, only 2.5% of centers performed more than 60 transplants per year (Figure 8.1). Between 2005 and 2009, among heart transplant programs, one-third of centers performed fewer than 47 heart transplants per year, one-third between 48 and 87, and one-third more than 87. Among centers in the lowest tertile of center volume, 25.5% performed multi-organ transplants; 93.3% of centers in the highest tertile performed multi-organ transplants (Figure 8.2). Thus, higher-volume centers are more likely than lower-volume centers to perform multi-organ transplants that include a heart transplant.

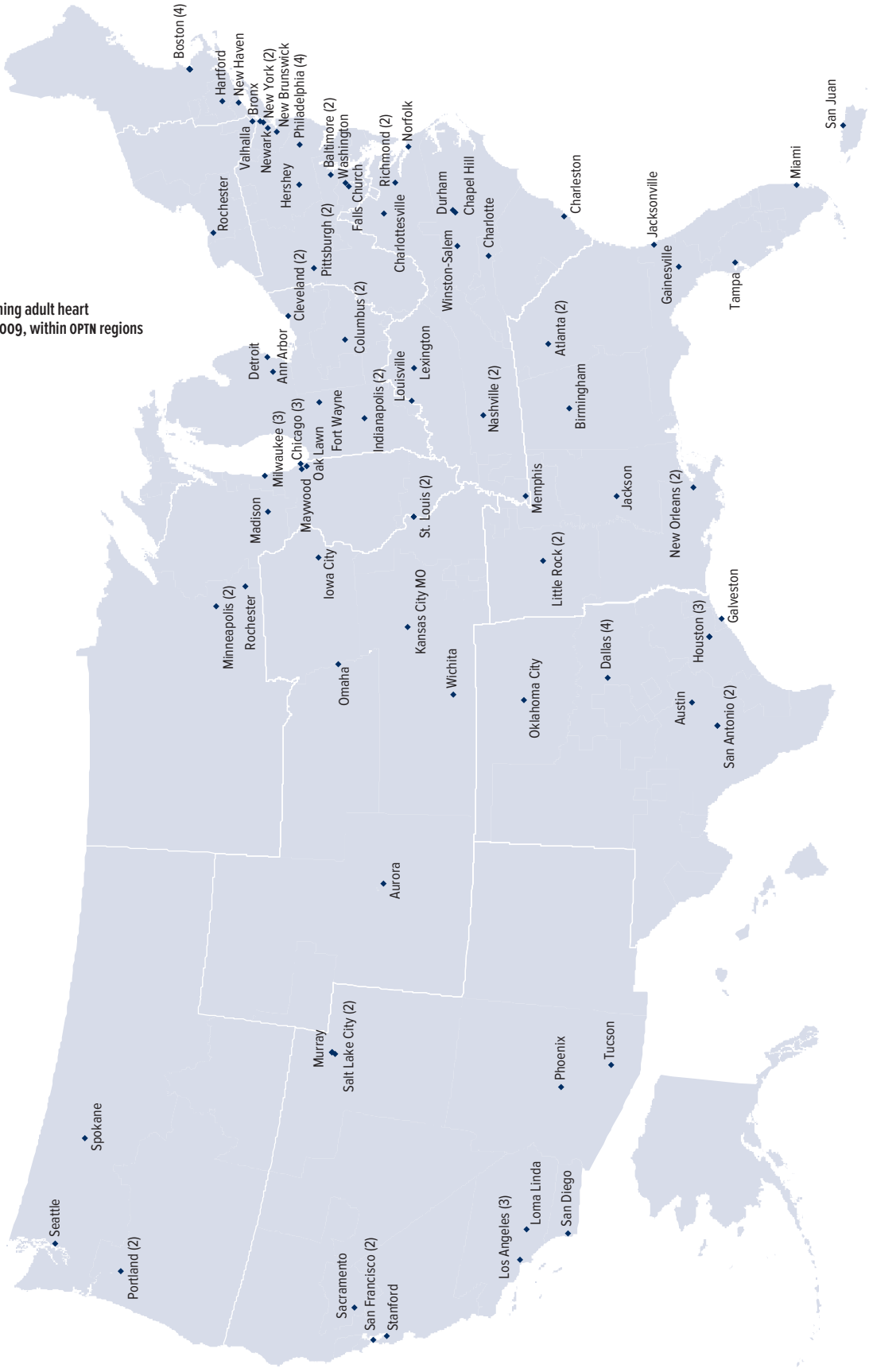
HR 9.1 **Centers performing adult heart transplants in 2009, within Donation Service Areas (DSAs)**



HR9.2 **Centers performing pediatric heart transplants in 2009, within Donation Service Areas (DSAs)**



HR9.3 **Centers performing adult heart transplants in 2009, within OPTN regions**



lung

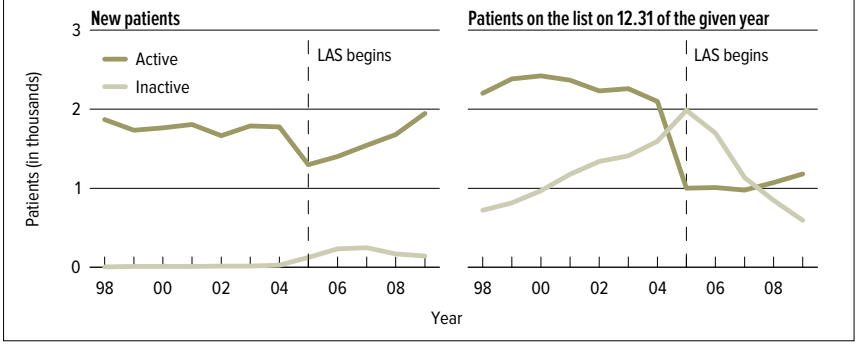
Implemented in 2005, the lung allocation score (LAS) system has had remarkable effects on the size of the lung transplant waiting list, the rate of lung transplants, and the distribution of lung allografts among diagnosis groups. As we move further from its implementation, we are now able to see clearly how the LAS system has changed lung allocation and what remains to be improved. A marked shortage in available lungs for those in need continues; 2008 was the first year since adoption of the LAS that the number of patients on the waiting list increased over previous years, a trend that continued in 2009. At the end of 2009, 1,181 people were waiting for lungs, compared with a low of 978 in 2007. Despite this increase in the waiting list, 1,670 lung transplants (1,644 lung, and 26 heart-lung) were performed in 2009 — more than ever before. Wait-list mortality has begun to rise again, after a decline following LAS implementation.

As part of the development of the LAS, disease diagnoses leading to lung transplant were grouped into 4 categories, to associate diseases with similar outcomes. The goal was to create groups that would act as predictors of disease progression. The 4 groups are: group A, obstructive lung disease (chronic obstructive pulmonary disease/emphysema, alpha-1 antitrypsin deficiency, bronchiectasis, lymphangioleiomyomatosis, etc.); group B, pulmonary vascular disease (idiopathic pulmonary arterial hypertension, Eisenmenger syndrome, etc.); group C, cystic fibrosis and immunodeficiency disorders (cystic fibrosis, hypogammaglobulinemia, etc.); and group D, restrictive lung disease (idiopathic pulmonary fibrosis, sarcoidosis, re-transplant, etc.). A fifth category, group E, comprises all pediatric patients aged younger than 12 years.

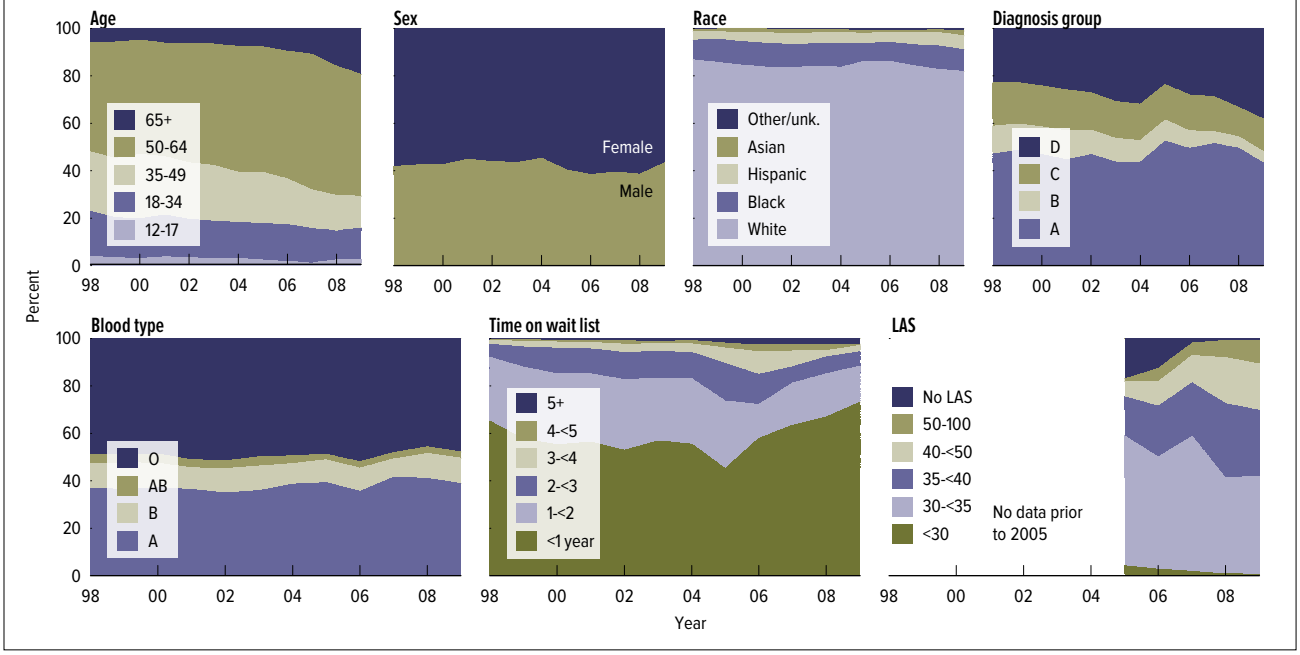
Each and every morning I give thanks for my donor. I know not the dignity of my donor's life, nor the tragedy of their death, but I do know I received the greatest gift of all, the gift of life.

Marie, lung recipient

LU 1.1 Adult patients waiting for a lung transplant



LU 1.2 Distribution of adult patients (active) waiting for a lung transplant



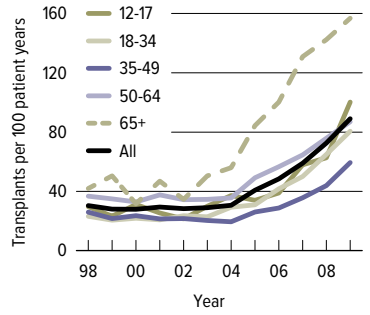
wait list

Upon the introduction of the LAS for deceased donor lung allocation in 2005, the number of active patients on the waiting list for a lung transplant in the United States sharply decreased (Figure 1.1). That trend stabilized through 2007, and since then the number of patients waiting for a lung transplant has begun to increase, by about 10% in 2008 and again in 2009.

The demographics of patients awaiting a lung transplant have remained fairly constant in terms of race, sex, and blood type (Figure 1.2). However, over the past 10 years, the age distribution of those on the waiting list has changed substantially. In 2009, 16.8% of the wait-listed patients were aged 65 years or older, up from 13.4% in 2008 and 4.6% in 2004 (before the LAS system). This reflects an increasing trend toward performing transplants for patients aged 65 years or older. Since 2005, the percentage of patients with an LAS of 35 or higher has increased from 24.1% to 57.1% of the waiting list. This shift indicates that, on the whole, patients on the waiting list are sicker and have a higher risk of mortality.

The transplant rate has been steadily increasing, with a sharp increase after 2004 (Figure 1.3). The sharpest increase is in patients aged 65 years or older, indicating that older patients are not only gaining access to the waiting list in increased numbers, but are receiving transplants more frequently as well. Transplant rates are increasing in all age groups, though the rate remains lowest in patients aged 35 to 49 years; this group appears to be decreasing in prevalence on the waiting list as well. By diagnosis, patients in

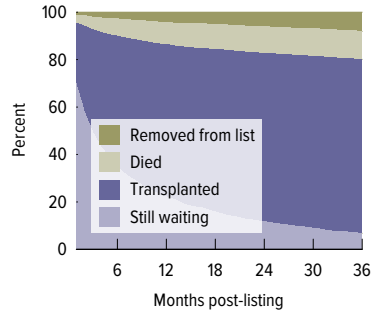
LU 1.3 **Transplant rates among adult patients wait-listed for a lung transplant, by age**



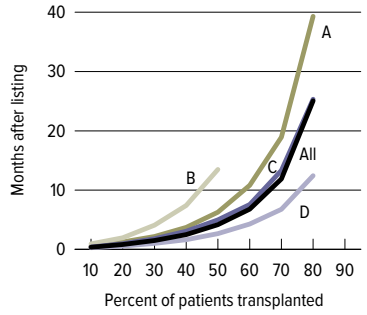
LU 1.4 **Lung transplant waiting list activity among adult patients**

	2007	2008	2009
Listings at start of year	2,736	2,128	1,926
Listings added during year	1,914	1,973	2,241
Listings removed during year	2,522	2,175	2,384
Listings at end of year	2,128	1,926	1,783
Removal reason			
Deceased donor transplant	1,470	1,490	1,666
Living donor transplant	3	0	1
Patient died	376	315	342
Patient refused transplant	18	11	7
Transferred to another ctr	35	26	26
Improved, tx not needed	376	202	140
Too sick to transplant	35	33	54
Other	209	98	148

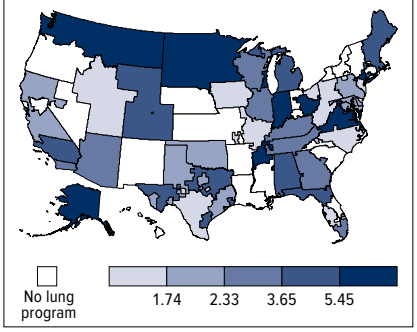
LU 1.5 **Lung tx waiting list status by month post-listing among new adult listings in 2006**



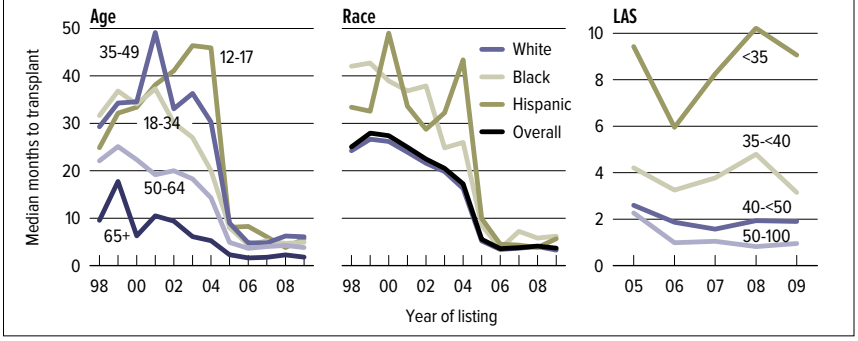
LU 1.6 **Percentiles of time to lung tx for new adult listings, by diagnosis group, 2005–2009**



LU 1.7 **Median months to lung transplant for adult patients transplanted in 2009, by DSA**



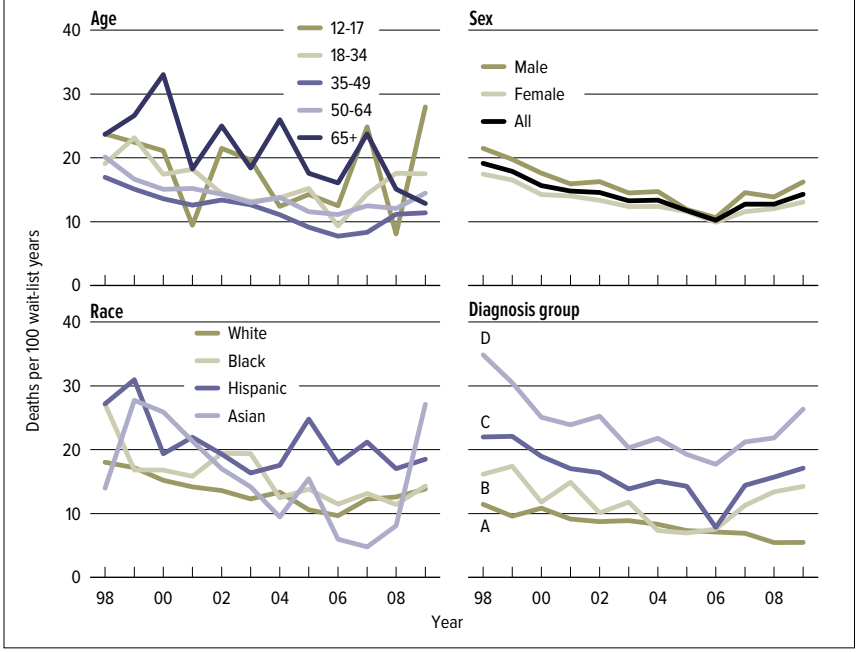
LU 1.8 **Median months to lung transplant for wait-listed adult patients**



diagnosis groups C and D are gaining access to lungs faster than those in groups A and B (Figure 1.6).

Median months to transplant from time of listing may be leveling off from the precipitous decline after the implementation of the LAS (Figure 1.8). Overall median wait time is less than 6 months, with a median wait of less than 2 months for candidates aged 65 years or older. A higher LAS corresponds to a shorter wait time, down to a median of 1 month for patients with an LAS of 50 or higher. Wait time for a lung transplant seems to have some notable geographic variation (Figure 1.7), with patients across the northern and northwestern US experiencing longer wait times than those in the central and eastern regions.

LU 1.9 **Pre-transplant mortality rates among adult patients wait-listed for a lung transplant**



LU 1.10 **Characteristics of adult patients on the lung tx waiting list on December 31, 2009**

	Level	N	%
Age	12-17	43	2.4
	18-34	220	12.4
	35-49	349	19.6
	50-64	900	50.6
	65+	266	15.0
Gender	Female	1,076	60.5
	Male	702	39.5
Race	White	1,455	81.8
	Black	178	10.0
	Hispanic	98	5.5
	Asian	33	1.9
	Other/unk.	14	0.8
Diagnosis group	A	811	45.6
	B	163	9.2
	C	229	12.9
	D	574	32.3
	Other/unknown	1	0.1
Most recent lung allocation score (LAS)	30-<35	875	49.2
	35-<40	346	19.5
	40-<50	217	12.2
	50-100	96	5.4
	No LAS*	179	10.1
Blood type	A	676	38.0
	B	187	10.5
	AB	50	2.8
	O	865	48.7
Time on waiting list	<1 month	155	8.7
	1 -<3 months	203	11.4
	3 -<6 months	241	13.6
	6 -<12 months	278	15.6
	1 - <2 years	293	16.5
	2 - <3 years	142	8.0
	3+ years	466	26.2
Status	Inactive	602	33.9
	Active	1,176	66.1
Transplant history	Listed for first tx	1,721	96.8
	Listed for sub. tx	57	3.2

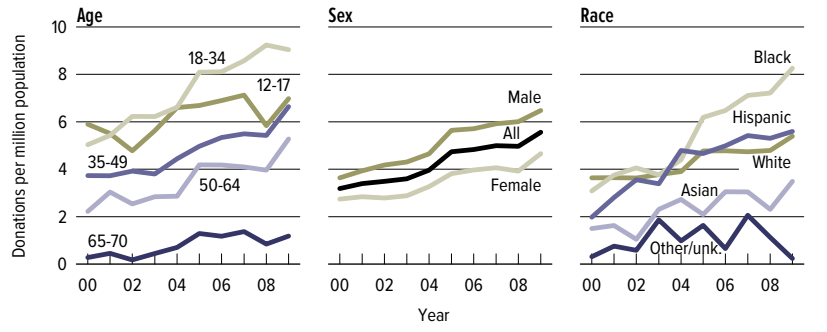
* all but 2 patients with unknown LAS were listed prior to May 4, 2005

wait list

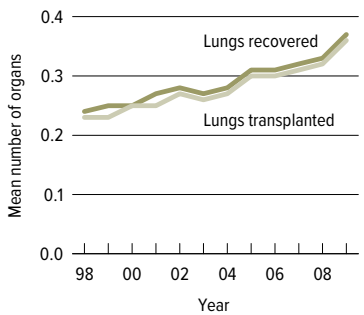
Wait-list mortality appears to have increased during the past 3 years, reversing a trend from the pre-LAS period (Figure 1.9). All diagnosis groups except group A experienced notable increases in pre-transplant mortality, with group D patients at the highest risk, at 26.4 deaths per 100 wait-list years. The most common reason for removal from the waiting list, after transplant, was death, with over 300 patients dying each year (Figure 1.4). Transplant candidates aged 65 years or older have experienced a substantial decline in wait-list mortality, from 26.0 deaths per 100 wait-list years in 2004 to 12.9 in 2009. Meanwhile, candidates aged 18 to 34 years have experienced increasing mortality rates since the LAS began, from 9.3 deaths per 100 wait-list years in 2006 to 17.5 in 2009. The variability in mortality for candidates aged 12 to 17 years is likely due to small cohort size. A recent dramatic increase also appears to have occurred in the pre-transplant mortality of Asian candidates, from 8.1 deaths per 100 wait-list years in 2008 to 27.1 in 2009. This may reflect the small number of Asian candidates.

Figure 1.10 shows basic characteristics for patients on the 2009 waiting list. The list continues to be dominated by white candidates and candidates from diagnosis group A. The age distribution reflects the increased listing of older patients, with two-thirds of listed patients aged 50 years or older.

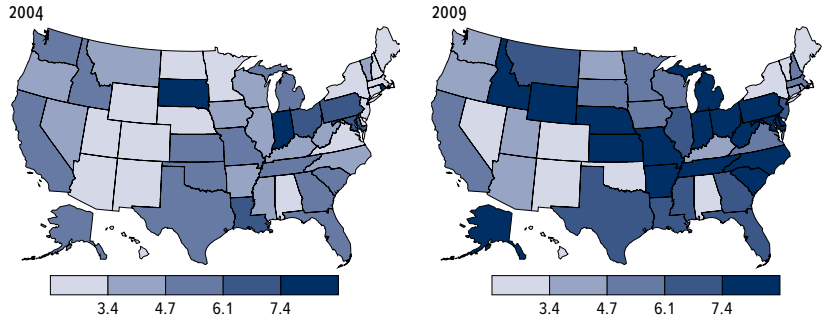
LU 2.1 Lung donations from deceased donors per million population



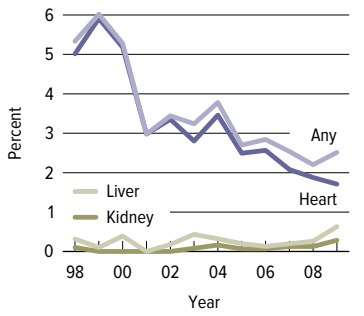
LU 2.2 Lungs recovered per donor & lungs transplanted per donor



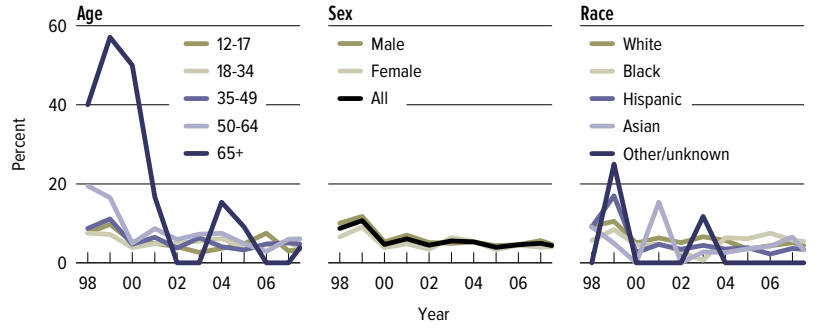
LU 2.3 Deceased donor lung donation rates (per million population)



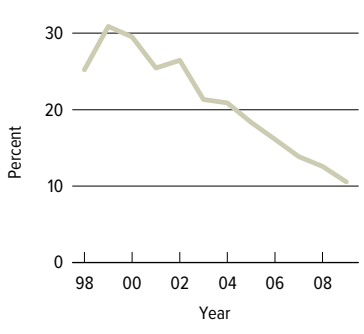
LU 2.4 Deceased donor lungs transplanted with another organ



LU 2.5 Discard rates for lungs recovered for transplant



LU 2.6 Lung donors with smoking history



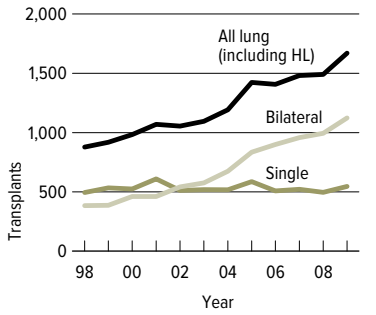
deceased donation

Lung donation rates are increasing, but continue to be low compared with other organs. The fragility of the lung makes it difficult for every willing donor to donate. The overall donation rate in 2009 was 5.6 lungs per million population. Other than a slight decline in donations from donors aged 18 to 34 years, donation rates have been slowly increasing for 10 years across age and racial groups (Figure 2.1). Given the increasing size of the waiting list, donations have not kept pace with demand.

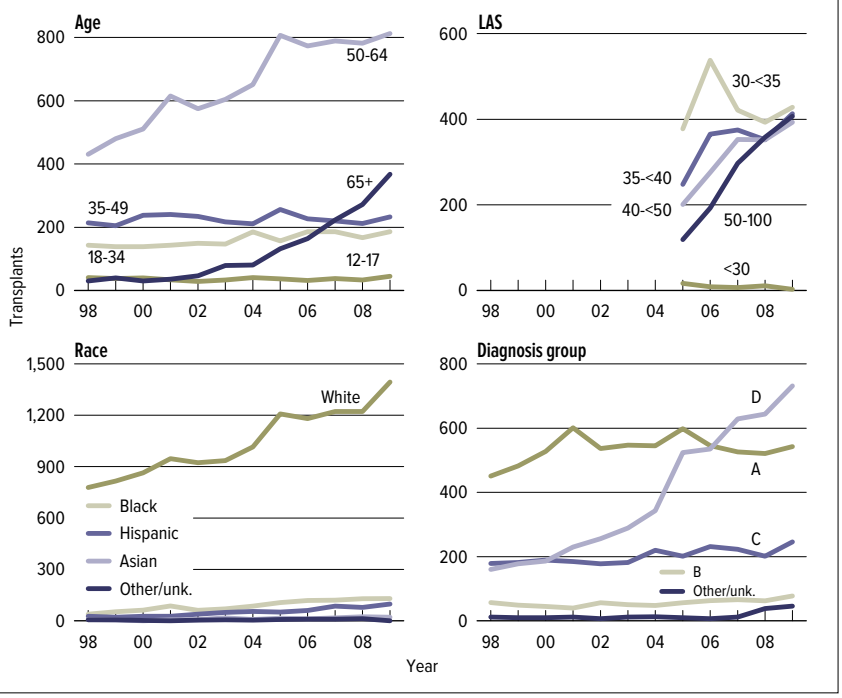
Donation rates vary substantially by geographic region, but are improving across the country (Figure 2.3). There is a band of reliable donation in the middle of the country. This is in contrast to lower donation rates in some western states, such as Nevada and Colorado. Continued efforts to increase awareness regarding deceased donation will be critical to ease growing demands.

Lungs have a low rate of discard; more than 90% of recovered lungs are used (Figure 2.5). The acceptability of lungs from donors aged 65 years or older varies, although data suggest that this variation may be easing. There is evidence that some donors may have a history of smoking, but it is unclear how recent or severe that smoking may have been (Figure 2.6). The trend appears to indicate a preference for donors with no history of smoking.

LU 3.1 Total adult lung transplants



LU 3.2 Adult lung transplants



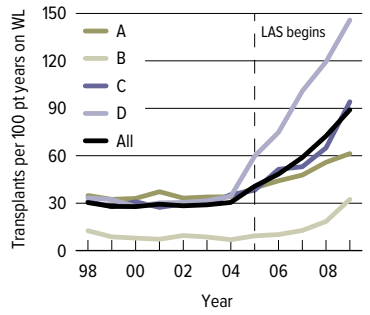
transplant In 2009, 1,670 adults underwent lung transplants (Figure 3.1). Twenty-six of these were heart-lung transplants. Adults aged 50 to 64 years continued to undergo the most transplants, but the number of adults aged 65 years or older undergoing transplants increased sharply (Figure 3.2). In 1998, 3.5% of transplants were performed in adults aged 65 years or older, but in 2009 that cohort represented 22.4% of transplants. The number of transplants among whites also increased in 2009, continuing a trend that started in the mid-1990s.

After the LAS was implemented, the diagnostic distribution of lung transplants changed dramatically. Before LAS, group A patients represented the majority of lung transplants. Today most lung transplants are in group D patients. The number of transplants in group D continues to rise, with 732 transplants in 2009, a more than 13% increase over the previous year. Transplants for all diagnosis groups continue to increase, with the largest increase occurring in group D (Figure 3.3).

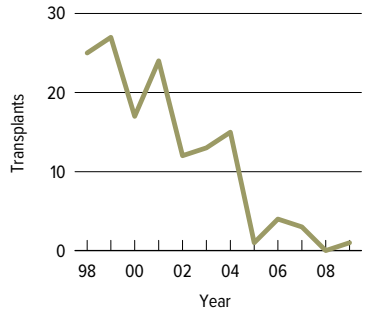
Bilateral lung transplant is increasingly chosen over single lung transplant (Figure 3.1). Bilateral transplants now account for more than two-thirds of all lung transplants.

Living lung donation has virtually ceased over the past 10 years (Figure 3.4). Never a frequently used option, living donation has dropped from a high of 27 procedures in 1999 to only 1 in 2009.

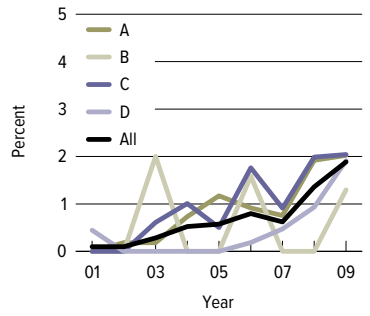
LU 3.3 Lung transplant rates in adult patients, by diagnosis group



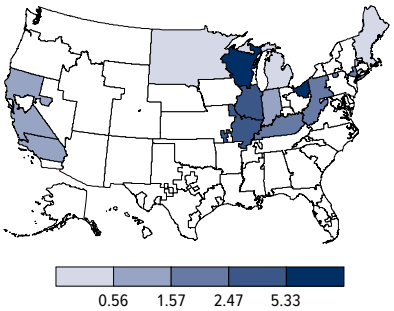
LU 3.4 Adult live donor lung transplants



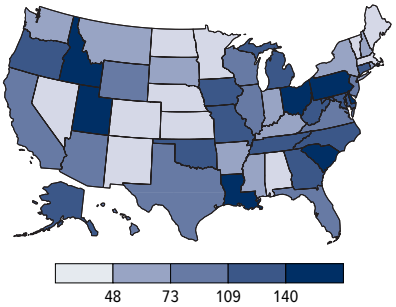
LU 3.5 Use of DCD lungs among adult lung tx recipients, by recipient diagnosis group



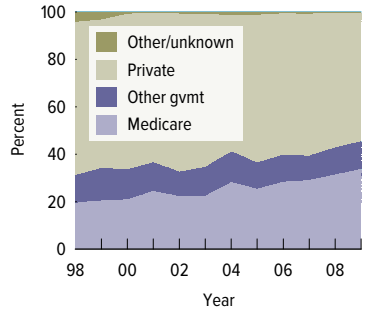
LU 3.6 Percent of adult, deceased donor lung transplants that are DCD, by DSA, 2005–09



LU 3.7 Deceased donor lung tx rates per 100 pt years on the waiting list, adult pts, 2009



LU 3.8 Insurance coverage among adult lung transplant recipients at time of transplant



LU 3.9 Characteristics of adult lung transplant recipients, 2009

	Level	N	%
Age	12-17	45	2.7
	18-34	186	11.3
	35-49	233	14.2
	50-64	812	49.4
	65+	368	22.4
Sex	Female	701	42.6
	Male	943	57.4
Race	White	1,394	84.8
	Black	130	7.9
	Hispanic	99	6.0
	Asian	21	1.3
Diagnosis group	A	543	33.0
	B	77	4.7
	C	246	15.0
	D	732	44.5
	Other/unknown	46	2.8
Lung allocation score (LAS)	<30	3	0.2
	30-<35	428	26.0
	35-<40	413	25.1
	40-<50	393	23.9
	50-100	407	24.8
Blood type	A	698	42.5
	B	183	11.1
	AB	64	3.9
	O	699	42.5
Time on waiting list	<1 month	554	33.7
	1 -<3 months	414	25.2
	3 -<6 months	243	14.8
	6 -<12 months	200	12.2
	1 - <2 years	132	8.0
	2 - <3 years	41	2.5
	3+ years	60	3.6
Pre-tx medical condition	Hospitalized: ICU	152	9.2
	Hospitalized: not ICU	159	9.7
	Not hospitalized	1,333	81.1
Pt on vent. imm.ly pre-tx	No	1,514	92.1
	Yes	130	7.9
Procedure type	Lobe	1	0.1
	Single	546	33.2
	Bilateral	1,097	66.7
Donor type	Deceased	1,643	99.9
	Living	1	0.1
Primary payer	Private	891	54.2
	Medicare	553	33.6
	Other government	192	11.7
	Other	8	0.5
Total	All patients	1,644	100.0

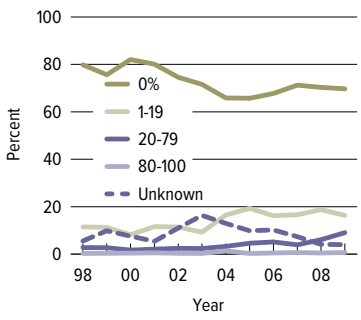
Donation after circulatory death (DCD) was thought to yield suboptimal outcomes in lung recipients, but recently outcomes for DCD lungs have been comparable to outcomes for lungs from non-DCD donors. Currently, DCD transplants are performed only at the largest transplant centers (Figures 3.6 and 8.3).

Transplant rates vary greatly by state, from a low of less than 25 transplants per 100 patient-years in Kansas and Colorado to more than 200 transplants per 100 patient-years in Utah and Louisiana (Figure 3.7). Transplant center access may affect these rates. North Dakota, a state without a lung transplant center, had zero transplants per 100 patient-years in 2009; by contrast, the District of Columbia, whose residents have access to several nearby transplant centers, had a transplant rate of 434.8 transplants per 100 patient-years.

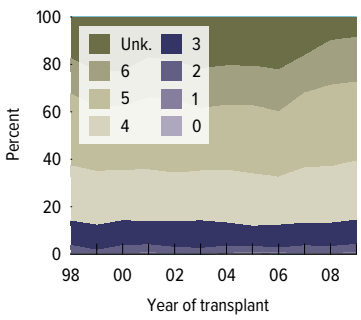
Reported insurance coverage among lung transplant recipients was 99.5% in 2009 (Figure 3.8). The trend toward increased coverage through Medicare continued. Government programs combined paid for 45.3% of lung transplants in 2009, a marked increase from 1998, when only 31.1% of transplants were covered by government-funded insurance plans.

Patients aged 65 years or older underwent 22.4% of the transplants in 2009; patients aged 35 to 49 years underwent 14.2% (Figure 3.9). Patients aged 65 or older constituted 15.0% of the list in 2009, and those aged 35 to 49 years, 19.6% (Figure 1.10).

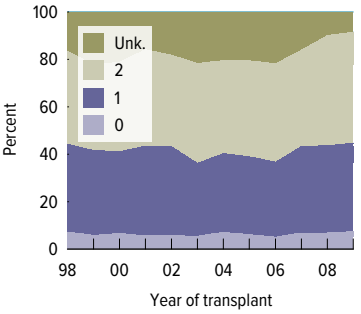
LU 4.1 PRA at time of lung transplant in adult recipients



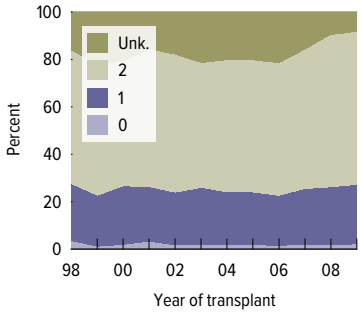
LU 4.2 Total HLA mismatches among adult lung transplant recipients



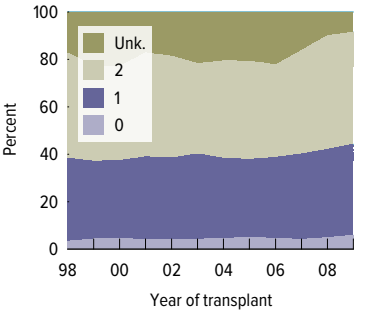
LU 4.3 HLA-A mismatches among adult lung transplant recipients



LU 4.4 HLA-B mismatches among adult lung transplant recipients



LU 4.5 HLA-DR mismatches among adult lung transplant recipients



donor-recipient matching

In general, the closer the immunological or human leukocyte antigen (HLA) match between a donor and a recipient, the less likely it is that rejection will occur. Most lung transplant recipients have 0% panel reactive antibodies (PRA) at the time of transplant; in 2009, 69.8% had 0% PRA. Since the implementation of the LAS, the percentage of transplant patients with high numbers of HLA mismatches has increased. Indeed, in the past decade there seems to be a trend toward more liberally performing transplants for patients with high PRA or HLA mismatches (Figures 4.1–4.5). It is unclear whether this is the result of changing practices at transplant centers or recent changes in methods that make the detection of anti-HLA antibodies more sensitive.

LU 4.6 Adult lung donor-recipient cytomegalovirus (CMV) serology matching, 2005–2009

	DONOR			
RECIPIENT	Negative	Positive	Unknown	Total
Negative	15.7	23.4	0.2	39.3
Positive	19.1	35.5	0.3	54.8
Unknown	2.4	3.5	0.0	5.9
Total	37.2	62.3	0.5	100

LU 4.7 Adult lung donor-recipient Epstein-Barr virus (EBV) serology matching, 2005–2009

	DONOR			
RECIPIENT	Negative	Positive	Unknown	Total
Negative	0.8	8.5	3.4	12.7
Positive	4.0	45.7	20.9	70.7
Unknown	0.8	10.9	4.9	16.6
Total	5.6	65.1	29.3	100

LU 4.8 Adult lung donor-recipient hepatitis B core antibody (HBcAb) serology matching, 2005–2009

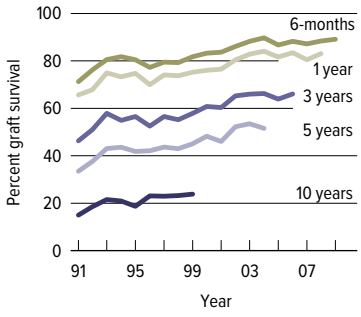
	DONOR			
RECIPIENT	Negative	Positive	Unknown	Total
Negative	74.3	1.8	0.2	76.4
Positive	3.2	0.2	0.0	3.4
Unknown	19.7	0.5	0.1	20.2
Total	97.2	2.5	0.3	100

LU 4.9 Adult lung donor-recipient hepatitis B surface antigen (HBsAg) serology matching, 2005–2009

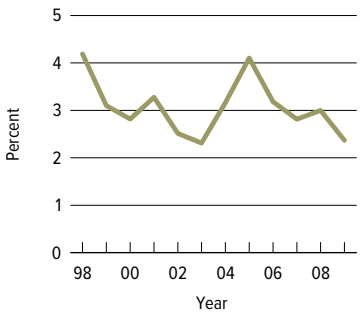
	DONOR			
RECIPIENT	Negative	Positive	Unknown	Total
Negative	90.5	0.0	0.2	90.7
Positive	1.9	0.0	0.0	1.9
Unknown	7.4	0.0	0.0	7.4
Total	99.8	0.0	0.2	100

In most transplants, donor cytomegalovirus (CMV) status and recipient CMV status are matched or CMV-positive patients receive CMV-negative lungs (Figure 4.6). This practice decreases the chances of a CMV-negative recipient being exposed to CMV and its potential consequences. However, 23.4% of lung transplants are from a CMV-positive donor to a CMV-negative recipient, which could increase the incidence of post-transplant CMV infection. Similarly, donors and recipients are often matched on the basis of Epstein-Barr virus (EBV) status; in 2005–2009, only 8.5% of lung transplants went from an EBV-positive donor to an EBV-negative recipient (Figure 4.7). No donor was hepatitis B virus (HBV) surface antigen (HBsAg) positive (Figure 4.9). HBsAg positive status indicates either prior infection or immunization. The vast majority of donors were hepatitis B core antibody negative (Figure 4.8). Positive status indicates prior HBV infection.

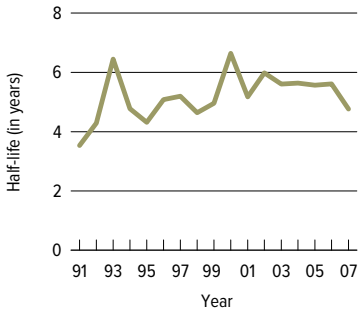
LU 5.1 Graft failure among adult lung transplant recipients



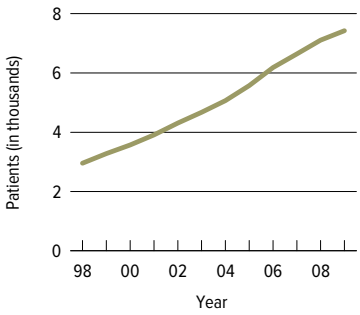
LU 5.2 Early (reported w/i 6 wks of tx) graft failure among adult lung transplant recipients



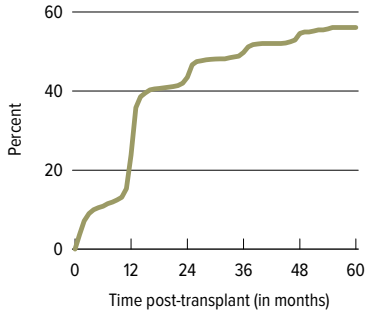
LU 5.3 Half-lives for adult lung transplant recipients surviving at least one year



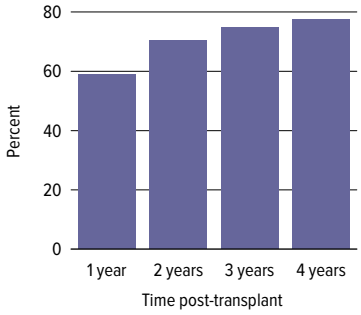
LU 5.4 Adult lung transplant recipients alive on June 30 of the year



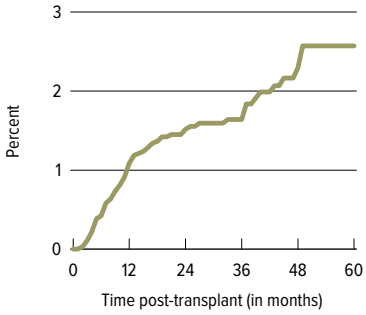
LU 5.5 Incidence of first acute rejection among adult pts receiving a lung tx in 2005–2009



LU 5.6 Reported hospitalizations among adult pts receiving a lung transplant in 2005–2009



LU 5.7 Incidence of PTLD among adult patients receiving a lung transplant in 2005–2009

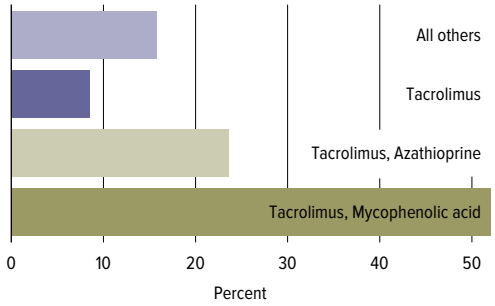


outcomes

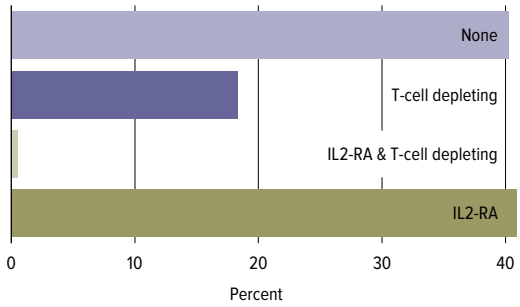
Immediately after the LAS was implemented, graft survival rates decreased, likely the result of performing transplants for the sickest patients on the waiting list. Implementation of the LAS placed patients with the highest pre-transplant urgency at the top of the waiting list, and was associated with a decrease in post-transplant graft survival from 89.8% to 86.8% at 6 months (Figure 5.1). By the end of 2007, 6-month graft survival was 87.2%, virtually unchanged from the immediate drop after LAS implementation. In 2009, graft survival rates appear to have returned to pre-LAS levels, with 6-month graft survival at 89.2% overall. Graft survival rates in the first 6 weeks post-transplant improved in 2009 compared with 2008 (Figure 5.2) Next year will mark 5 years since implementation of the LAS, and we will be able to determine the effect of the system on 5-year graft survival.

For adult lung transplant recipients who survive 1 year after transplant, the overall half-life for lung grafts is 4.8 years. This is lower than the previous high of 6.6 years in 2000 (Figure 5.3). At the end of June 2009, 7,425 people in the US were living with a lung allograft, more than twice the number of living recipients 10 years ago (Figure 5.4).

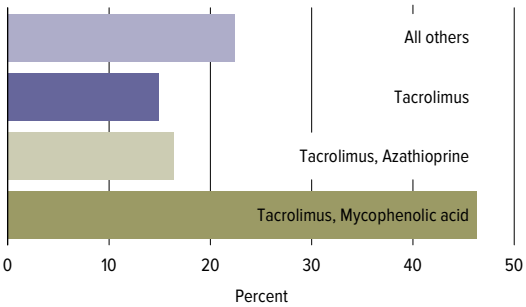
LU 6.1 Initial immunosuppression regimen in adult lung transplant recipients, 2009 (steroids not considered)



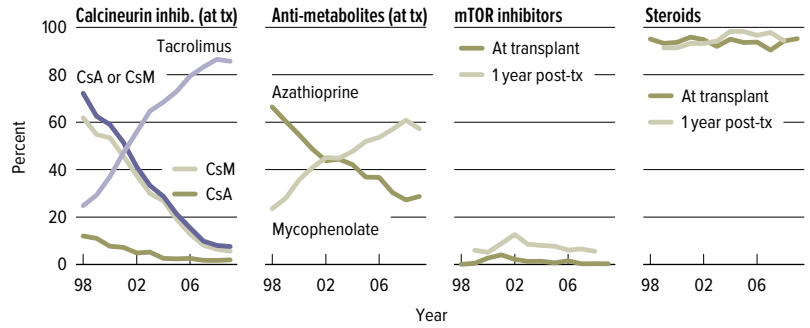
LU 6.2 Induction agents used at time of lung transplant, adult recipients, 2009



LU 6.3 Immunosuppression at one year in adult lung transplant recipients, 2008 (steroids not considered)



LU 6.4 Immunosuppression use in adult lung transplant recipients

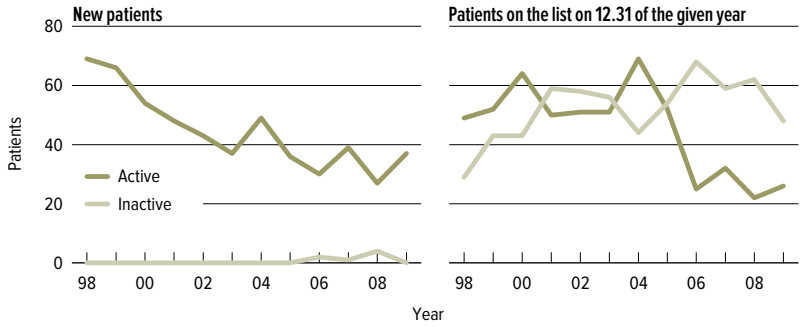


immunosuppression

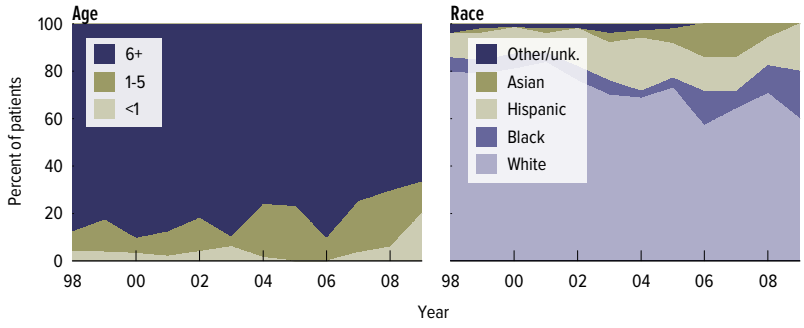
Trends in immunosuppression among lung transplant recipients have remained stable over the past several years. Since 1998, use of tacrolimus as the primary calcineurin inhibitor has steadily increased (Figures 6.1, 6.3, and 6.4). Today, it is used in virtually all lung transplant recipients. Mycophenolate is still the predominant anti-metabolite used in lung transplant recipients. Steroid use is also virtually universal and extends from the immediate post-transplant period through at least 1 year post-transplant. Mammalian target of rapamycin (mTOR) inhibitors are used rarely, if at all, immediately after transplant (Figure 6.4).

Use of induction agents after transplant is mixed, with 40.3% of patients not receiving them. For those patients who receive an induction agent, interleukin-2 receptor antagonists (IL2-RA) are the primary agents chosen, with a minority of patients receiving a T-cell depleting agent (Figure 6.2).

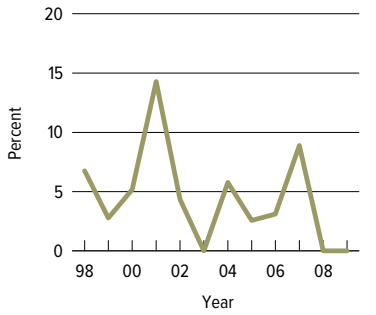
LU 7.1 Pediatric patients waiting for a lung transplant



LU 7.2 Distribution of pediatric patients waiting for a lung transplant



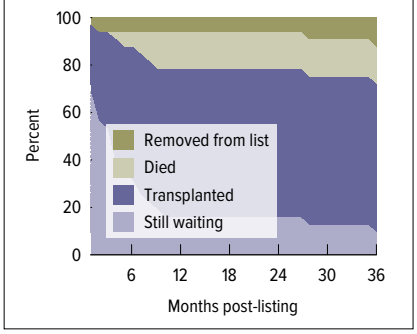
LU 7.3 Prior lung transplant in pediatric patients waiting for a lung transplant



LU 7.4 Lung transplant waiting list activity among pediatric patients

	2007	2008	2009
Listings at start of year	93	91	84
Listings added during year	45	32	39
Listings removed during year	47	39	49
Listings at end of year	91	84	74
Removal reason			
Received a transplant	18	15	22
Patient died	10	13	7
Transferred to another ctr	3	1	1
Improved, tx not needed	10	4	13
Too sick to transplant	0	3	2
Other	6	3	4

LU 7.5 Lung tx waiting list status by month post-listing among new pediatric listings in 2006

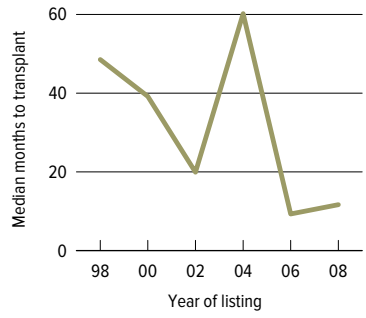


pediatric transplant

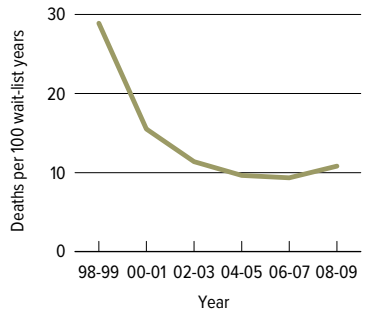
Prior to November 22, 2010, candidates aged less than 12 years received allocation priority based on waiting time. Since November, 2010, pediatric candidates receive allocation priority by medical urgency status. Since 1998, the number of active pediatric patients on the waiting list has decreased (Figure 7.1). Patients aged younger than 6 years account for one-third of the pediatric patients waiting for a lung transplant in 2009 (Figure 7.2). Since 2006, the number of patients on the waiting list aged younger than 1 year has increased. White patients made up 60.0% of the waiting list in 2009, and black and Hispanic patients 20.0% each (Figure 7.2). The number of patients with prior transplants has declined since 2007 (Figure 7.3). Reasons for removal from the waiting list in 2009 included transplant (44.9%), improvement in condition (26.5%), and death (14.3%) (Figure 7.4). For children and adolescents who were listed for a lung transplant in 2006, by 3 years after listing, 62.5% had undergone transplant, 15.6% had died, 12.5% had been removed from the list, and 9.4% were still awaiting a transplant (Figure 7.5).

The median waiting time for children and adolescents fell from 48.5 months in 1998–1999 to 11.7 months in 2008–2009 (Figure 7.6). Death rates on the waiting list have decreased since 1998 (Figure 7.7). Overall, the number of lung transplants (including heart-lung) has decreased from a total of 42 in 1998 to 20 in 2009 (Figure 7.8). While the number of wait-listed patients aged

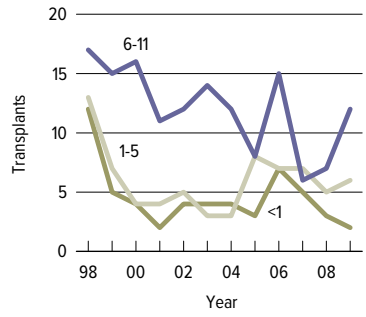
LU 7.6 Median months to lung transplant for wait-listed pediatric patients



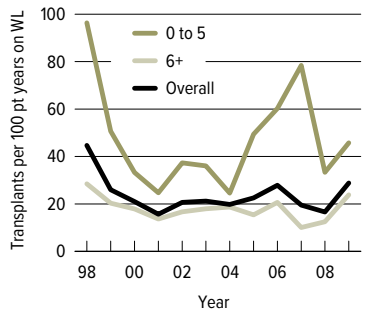
LU 7.7 Pre-transplant mortality rates among pediatric pts wait-listed for a lung transplant



LU 7.8 Pediatric lung transplants (including heart-lung), by age



LU 7.9 Pediatric lung transplant rates, by age

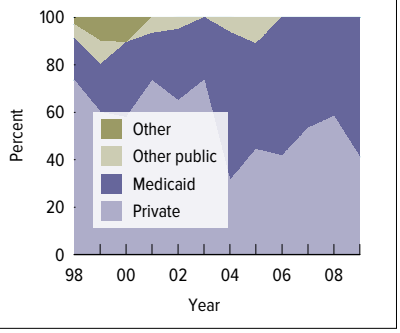


younger than 1 year is on the rise, the number of transplants for these patients is falling. In 2009, the overall pediatric lung transplant rate was 28.9 per 100 patient-years on the waiting list (Figure 7.9). Among pediatric lung transplant recipients in 2007–2009, 47.7% were aged 6 to 11 years, 31.8% were aged 1 to 5 years, and 20.5% were aged younger than 1 year (Figure 7.10); 63.6% were white, 15.9% Hispanic, 13.6% black, and 4.5% Asian. Cystic fibrosis was the primary diagnosis in 20.5% of recipients, followed by idiopathic pulmonary hypertension and obliterative bronchiolitis, each at 13.6%. Almost 60% of patients spent less than 3 months on the waiting list. Forty-one percent were hospitalized in the intensive care unit before transplant.

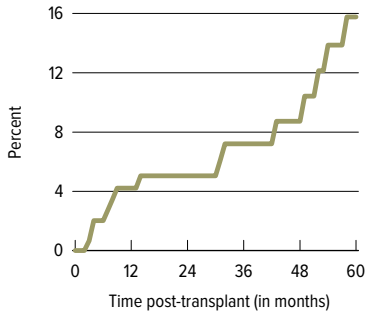
LU 7.10 Characteristics of pediatric lung transplant recipients, 2007–2009

	Level	N	%
Age	<1	9	20.5
	1-5	14	31.8
	6-11	21	47.7
Sex	Female	25	56.8
	Male	19	43.2
Race	White	28	63.6
	Black	6	13.6
	Hispanic	7	15.9
	Asian	2	4.5
	Other/unk.	1	2.3
Primary diagnosis	Cystic fibrosis	9	20.5
	Primary pulmonary HTN	6	13.6
	Obliterative bronchiolitis	6	13.6
	Surfactant B deficiency	4	9.1
	All others	19	43.2
Transplant number	First	42	95.5
	Subsequent	2	4.5
Blood type	A	15	34.1
	B	7	15.9
	AB	6	13.6
	O	16	36.4
Time on waiting list	<1 month	9	20.5
	1 -<3 months	17	38.6
	3 -<6 months	6	13.6
	6 -<12 months	10	22.7
	1 - <2 years	1	2.3
	2+ years	1	2.3
Pre-transplant medical condition	Hospitalized: ICU	18	40.9
	Hospitalized: not ICU	9	20.5
	Not hospitalized	17	38.6
Pt on vent. imm.ly pre-tx	No	25	56.8
	Yes	19	43.2
Procedure type	Bilateral sequential	40	90.9
	Bilateral en-block	4	9.1
Donor type	Deceased	44	100.0
Primary payer	Private	22	50.0
	Medicaid	22	50.0
All patients	--	44	100.0

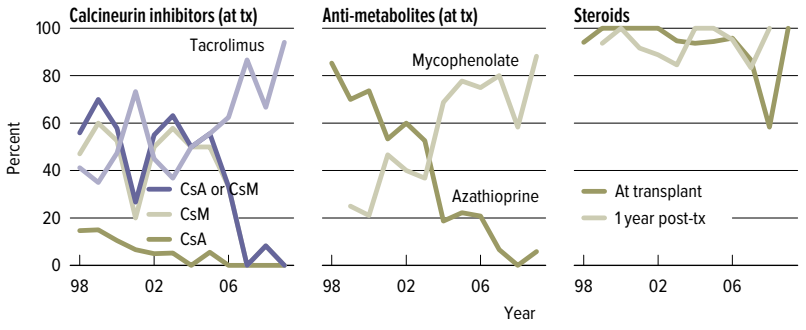
LU 7.11 Insurance coverage among pediatric lung transplant recipients at time of transplant



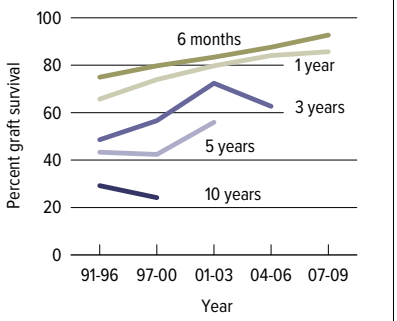
LU 7.12 Pediatric lung transplant recipients with reported PTLD, 2000–2009



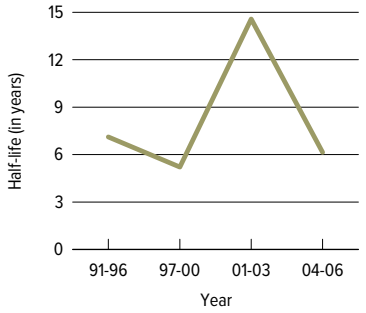
LU 7.13 Immunosuppression use among pediatric lung transplant recipients



LU 7.14 Graft failure among pediatric lung transplant recipients



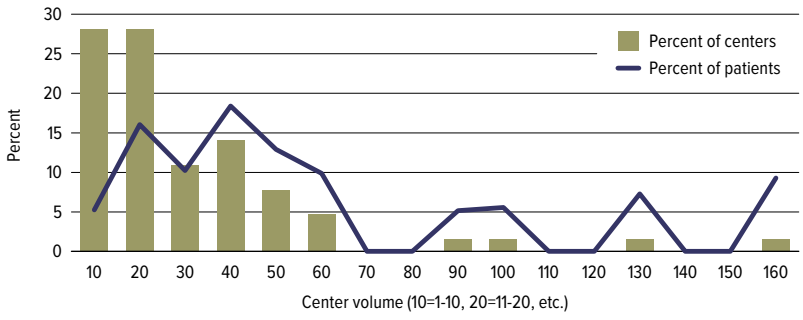
LU 7.15 Half-lives among pediatric lung transplant recipients surviving at least one year



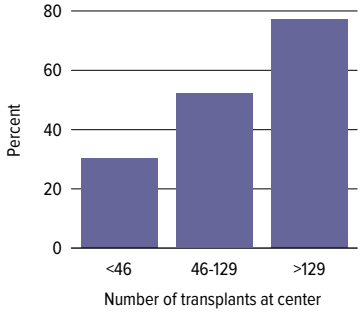
pediatric transplant

Among children and adolescents undergoing transplants in 2009, Medicaid covered payment for nearly 60% (Figure 7.11). For those undergoing transplants in 2000–2009, the incidence of post-transplant lymphoproliferative disorder (PTLD) was 2.0% at 6 months, 4.2% at 1 year, 5.0% at 2 years, 7.2% at 3 years, 8.7% at 4 years, and 15.8% at 5 years (Figure 7.12). There have been notable changes in the immunosuppression used in pediatric lung transplant recipients. The trends in pediatric lung transplant immunosuppression are similar to those seen in adult post-transplant immunosuppression. Tacrolimus is increasingly used and is now the dominant calcineurin inhibitor. Likewise, the use of mycophenolate has increased, and it is now the primary anti-metabolite. In 2009, 94.1% of patients received tacrolimus as part of the initial maintenance immunosuppressive medication regimen, 88.2% received mycophenolate, and 100% received steroids (Figure 7.13). Graft survival has continued to improve over the past decade. Graft survival for transplants performed in 2007–2009 was 92.8% at 6 months and 85.7% at 1 year; for transplants in 2004–2006, 62.7% at 3 years; for transplants in 2001–2003, 56.0% at 5 years; and for transplants in 1997–2000, 24.1% at 10 years (Figure 7.14).

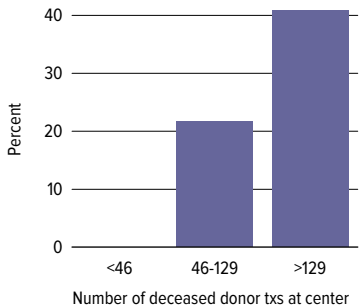
LU 8.1 **Distribution by center volume of the number of lung transplants performed (includes heart-lung), 2009**



LU 8.2 **Lung programs performing multi-organ transplants, by volume, 2005–2009**



LU 8.3 **Centers transplanting DCD lungs, by volume, 2005–2009**

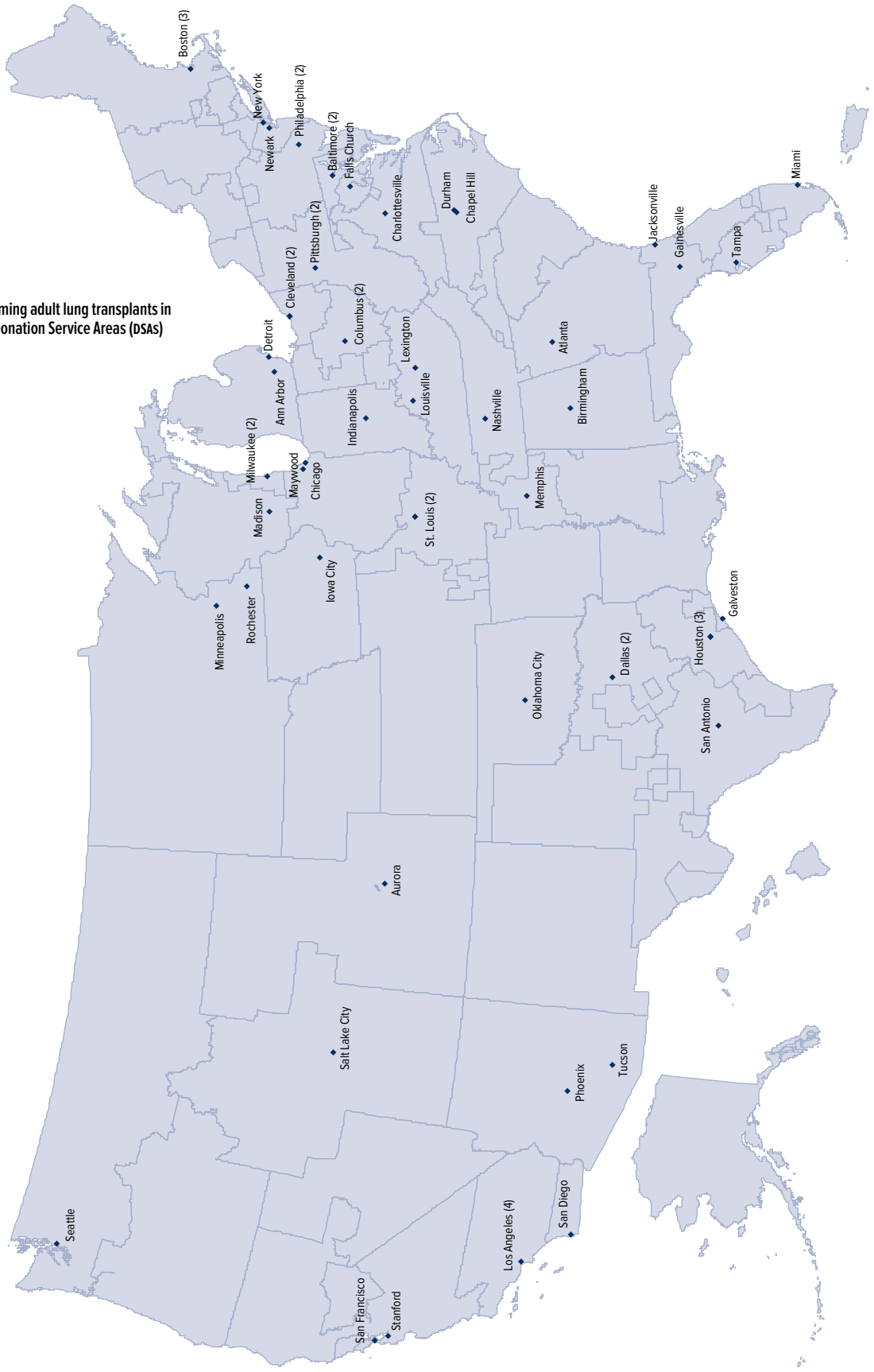


center characteristics

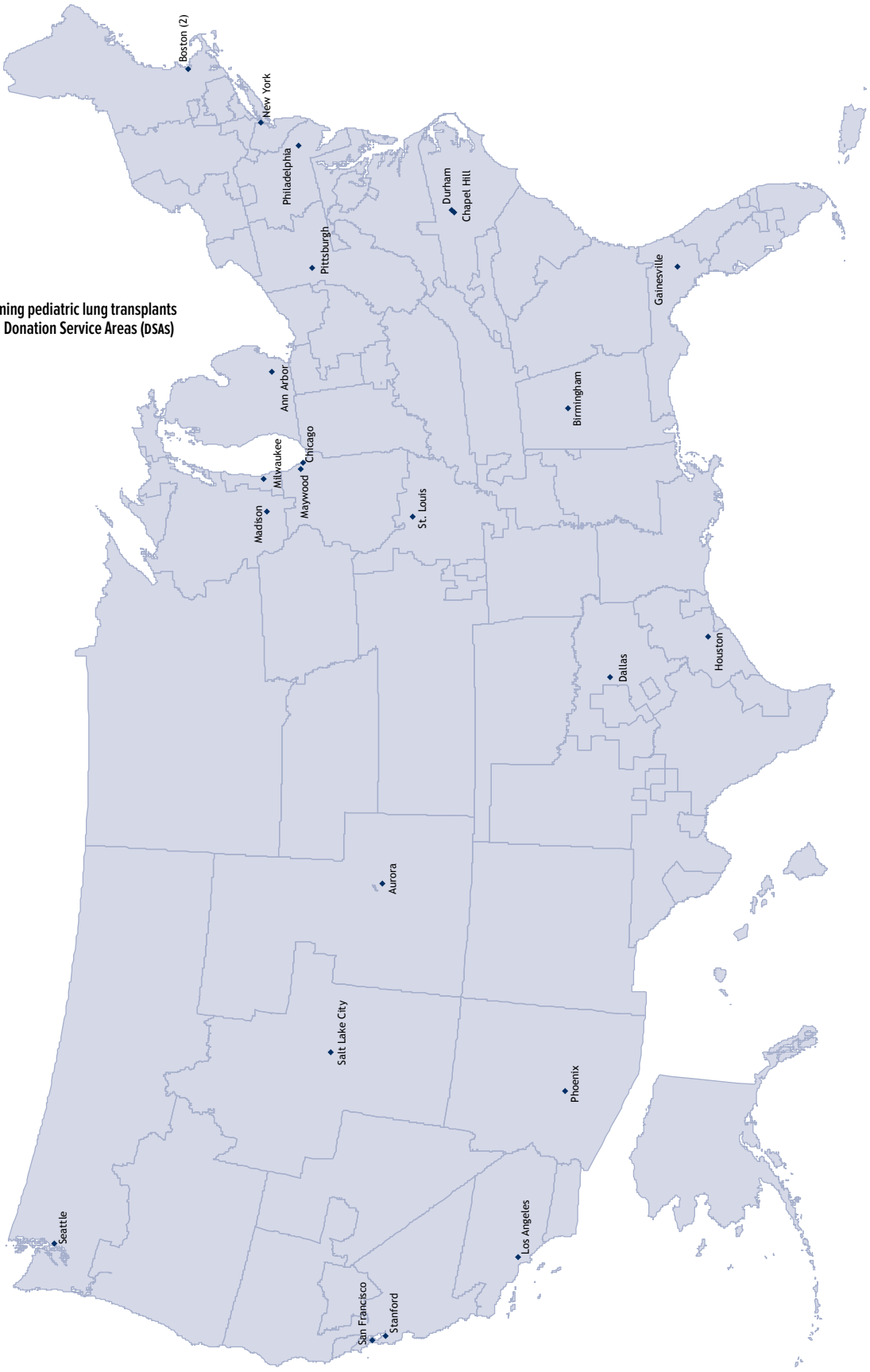
Most lung transplant centers in the US are relatively low-volume, performing 20 or fewer transplants per year, while a small number of high volume centers perform 100 or more transplants per year (Figure 8.1). Many small centers offer lung-only transplants, which results in sicker, multi-organ transplant patients being sent to higher-volume transplant programs for the more complex procedures. Multi-organ transplants were performed at 30.4% of lung transplant programs in the bottom tertile of volume, those that performed 45 or fewer transplants from 2005–2009. In contrast, 77.3% of lung transplant centers in the top tertile of volume, those performing more than 129 transplants from 2005–2009, did multi-organ transplants (Figure 8.2). It is unclear whether this practice has effects on post-transplant outcomes.

There is a trend among higher-volume centers (those with more than 46 transplants 2005–2009) to transplant DCD lungs (Figure 8.3). We will follow this trend to determine the effects on organ availability and patient survival.

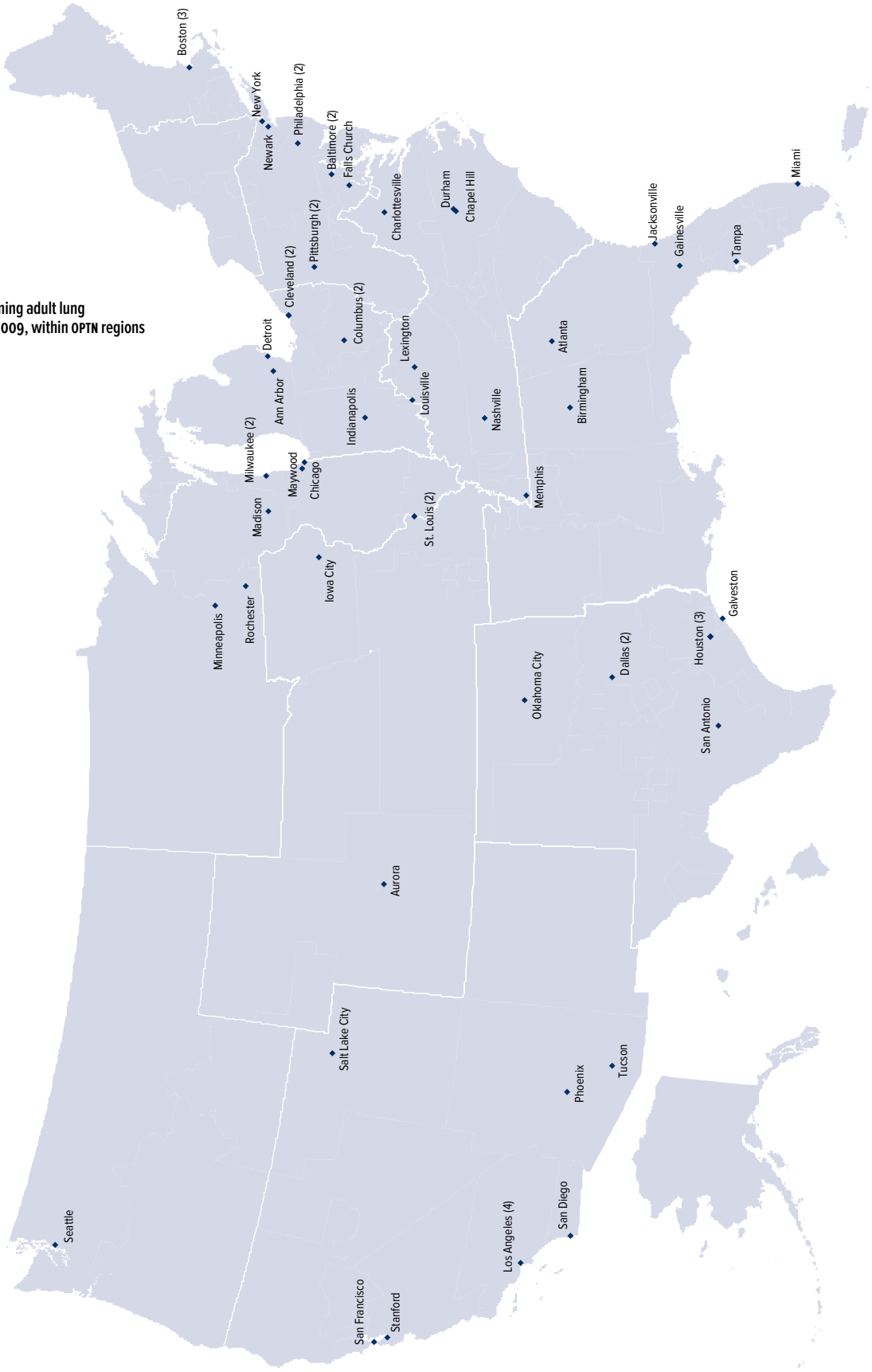
LU 9.1 **Centers performing adult lung transplants in 2009, within Donation Service Areas (DSAs)**



LU9.2 **Centers performing pediatric lung transplants in 2009, within Donation Service Areas (DSAs)**



LU 9.3 **Centers performing adult lung transplants in 2009, within OPTN regions**



deceased organ donation

Organ donation rates, number of organs recovered, number of organs transplanted, and number discarded per donor varied substantially across different regions of the country. Among donor service areas (DSAs), the lowest organ donation rate in 2009 was 51 per 100 eligible deaths, and the highest was 91 (Figure 1.2). Similarly, the number of organs recovered per donor varied widely across DSAs (Figures 2.2 and 2.3). In 2009, the mean number of organs transplanted per donor was 3.0; however, wide variation was seen (Figures 3.2 and 3.3). The discard rate for standard criteria donor (SCD) organs also varied (Figure 4.3), as did the use of expanded criteria donors (ECD) (Figure 5.1) and donation after circulatory death (DCD) (Figure 6.1). The waiting time for transplants also varied by DSA in 2009 (Figure 7.1).

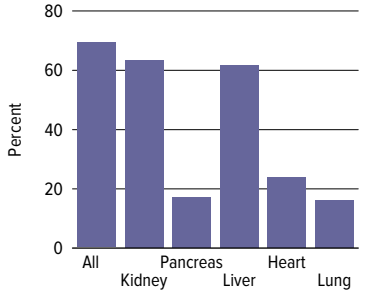
Over the past 12 years, more organs were recovered per donor from SCDs than from ECDs or DCDs (Figure 2.4). In 2009, 4.0 organs per donor were recovered from SCDs, compared with 2.7 from ECDs and 2.6 from DCDs. However, the number of kidneys recovered per donor from DCDs was higher than or similar to the number of organs recovered from SCDs. For example, in 2009, 1.9 kidneys were recovered per donor from DCDs (Figure 2.5), more than the 1.8 and 1.6 kidneys recovered per donor from SCDs and ECDs, respectively. This trend of more organs recovered per donor from DCDs than from SCDs or ECDs was seen only for kidneys, which are arguably more resistant than other organs to potential long-term effects of ischemia (Figure 2.6). In 2009, 0.84 livers were transplanted per donor from SCDs, slightly more than the 0.73 livers transplanted per donor from ECDs (Figure 3.6).

Through organ donation, Jeff's kindness and generosity toward others has been extended to his life after death. For us, his family, it continues to remind us of who he was and why we miss him.

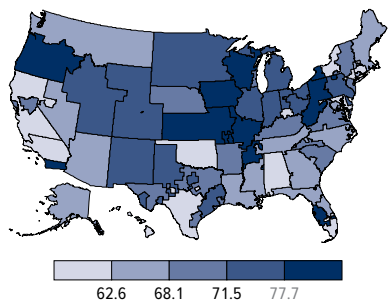
Kent, donor dad

OPTN SRTR SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

DOD 1.1 Overall & organ-specific donation rates per eligible deaths, 2009



DOD 1.2 Overall donation rates (per 100 eligible deaths), by DSA, 2009

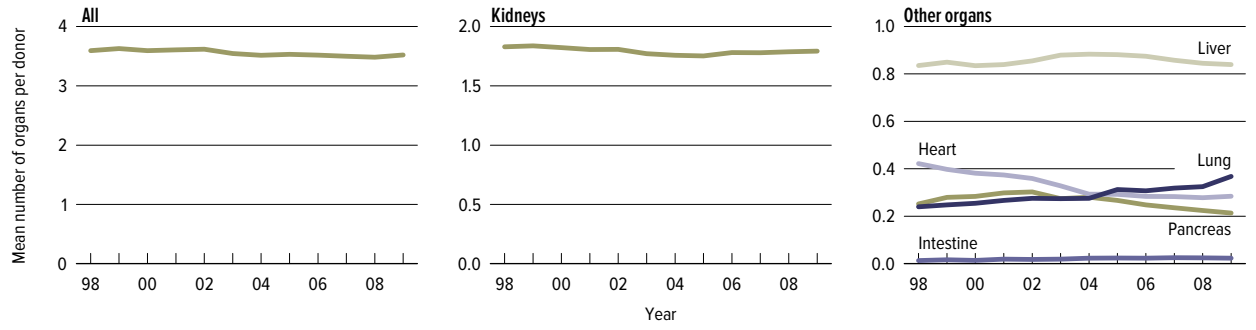


organ-specific donation rates

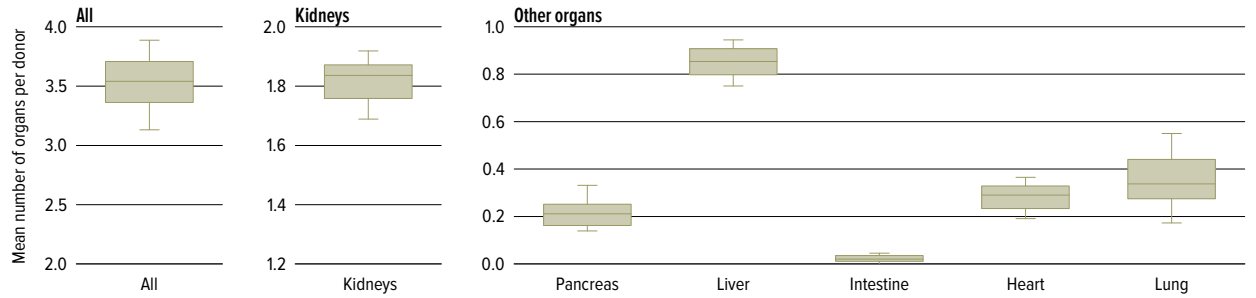
The donation rate is calculated as the number of deceased donors per 100 eligible deaths, where an eligible death for organ donation is defined as the death of a patient aged 70 years or younger who is legally declared brain dead according to hospital policy and meets other specific organ donor eligibility requirements. The donation rate varied by organ type and is presented as organ-specific rates (Figure 1.1). The organ-specific donation rates for kidney and liver donors were similar, and higher than rates for thoracic and pancreas donors. Among thoracic organs, organ-specific donation rates were higher for heart donors than for lung donors (note that throughout this chapter, lung donation refers to 1 or 2 lungs recovered). The overall donation rate was 69.4 per 100 eligible deaths in 2009.

The organ donation rate varies geographically. The lowest organ donation rate was 50.8 and the highest was 90.7 per 100 eligible deaths (Figure 1.2). Factors such as donor age and ethnicity may play a role in this variation. Geographic variation suggests opportunities to share best practices from regions with high organ donation rates to improve the overall rate. The organ donation rate and organ-specific donation rates, along with the adjusted rates, are provided biannually in the SRTR's program-specific reports to all organ procurement organizations (OPOs).

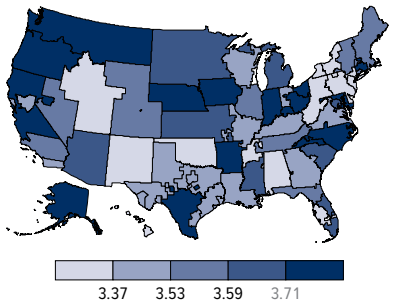
DOD 2.1 Organs recovered per donor (ORPD)



DOD 2.2 Organs recovered per donor (ORPD), by DSA, 2009



DOD 2.3 Organs recovered per donor (ORPD), by DSA, 2009

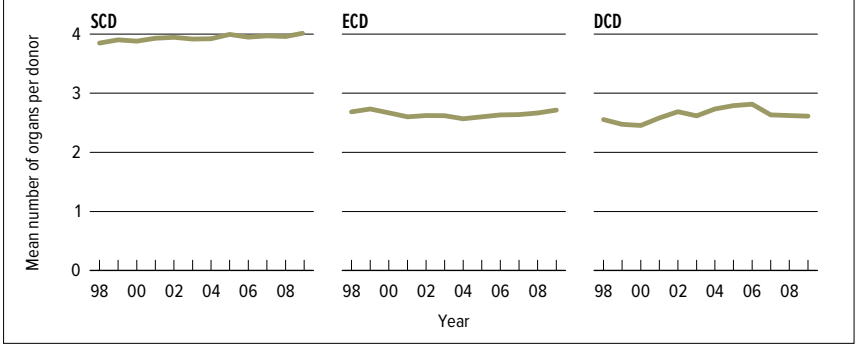


organs recovered per donor

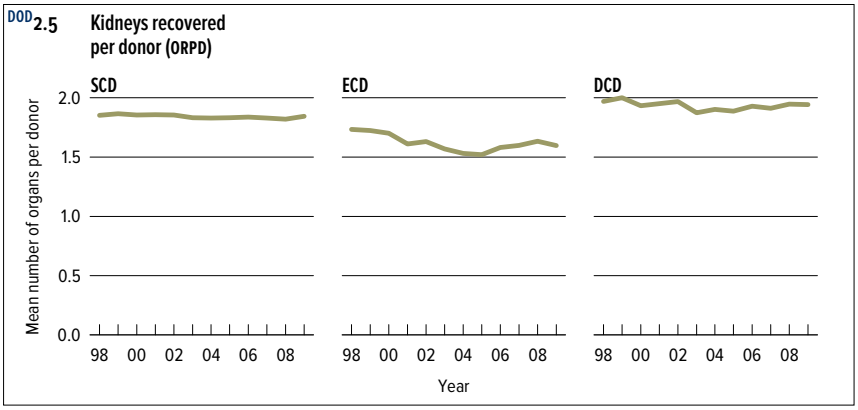
Over the past 12 years, the number of organs recovered per donor has been relatively stable, at about 3.5 (Figure 2.1). The number of lungs recovered per donor increased from 0.28 in 2004 to 0.37 in 2009. The number of hearts recovered per donor decreased from 0.38 in 2000 to 0.28 in 2009. The number of pancreata recovered per donor also decreased, from 0.28 in 2000 to 0.21 in 2009.

The number of organs recovered per donor varied widely across DSAs, with a low of 2.9 and a high of 4.1 per donor (Figures 2.2 and 2.3). The mean number of kidneys recovered per donor across DSAs was 1.8, the mean number of livers was 0.85, and the mean number of hearts was 0.28. Across DSAs, variation was wider in the number of lungs recovered per donor, compared with the number of hearts, with a mean of 0.35 lungs recovered per donor. The presence or absence of a lung transplant program within an appropriate distance from the recovering hospital may explain the wider variation across DSAs for lungs.

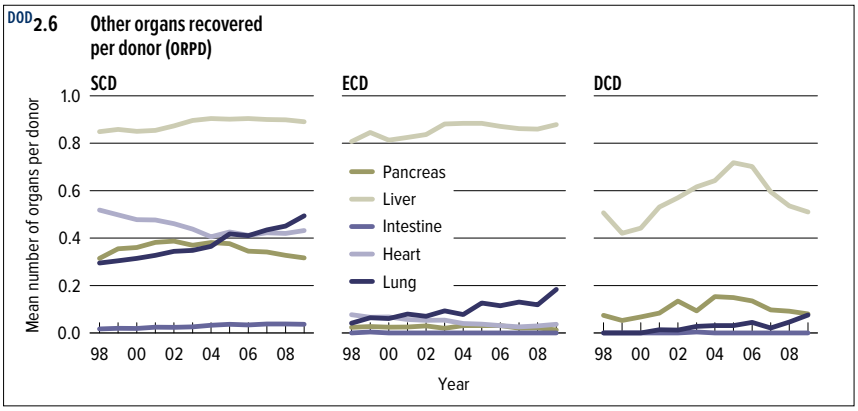
DOD 2.4 Total organs recovered per donor (ORPD)



DOD 2.5 Kidneys recovered per donor (ORPD)



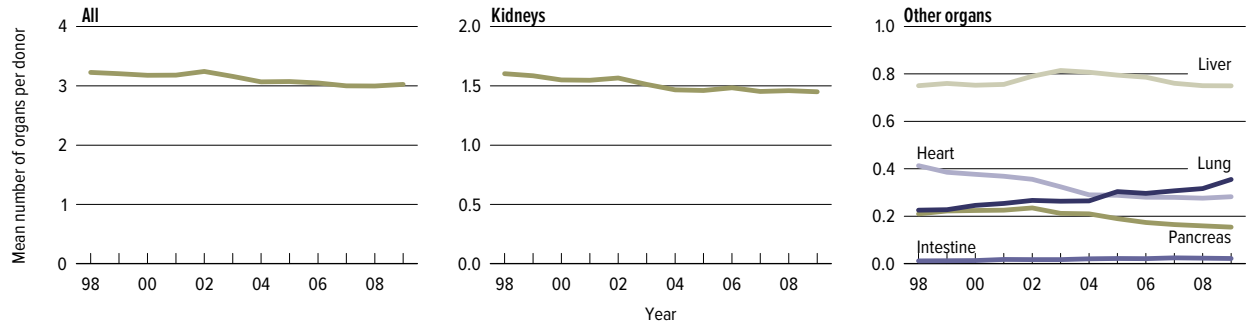
DOD 2.6 Other organs recovered per donor (ORPD)



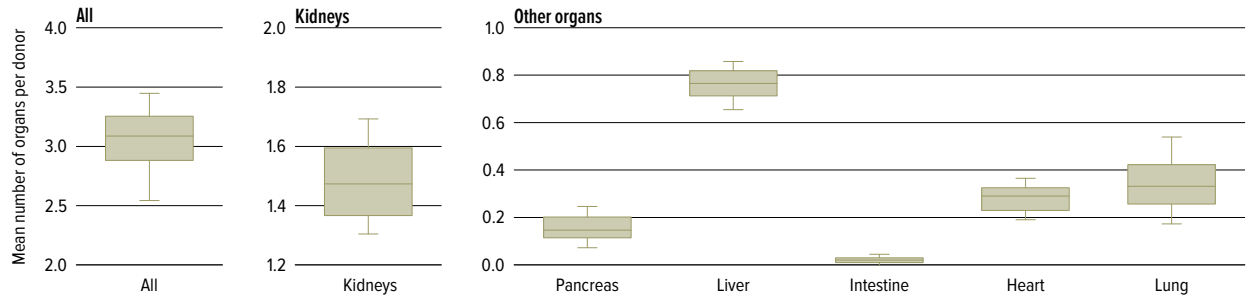
organs recovered per donor

The number of organs recovered per donor varied depending on donor type, SCD versus ECD or DCD. Over the past 12 years, more organs were recovered per donor from SCDs than from ECDs or DCDs (Figure 2.4). In 2009, 4.0 organs per donor were recovered from SCDs, compared with 2.7 from ECDs and 2.6 from DCDs. In 2009, 1.9 kidneys per donor were recovered from DCDs (Figure 2.5). In contrast, 1.8 and 1.6 kidneys per donor were recovered from SCDs and ECDs, respectively. This trend of more organs recovered per donor from DCDs than from SCDs and ECDs was not seen for organs other than the kidney (Figures 2.6). In 2009, the number of livers recovered per donor from SCDs was similar to the number recovered per donor from ECDs. The number of livers recovered per donor from DCDs has declined since 2006 and is much lower than the number of kidneys recovered from DCDs. For ECDs, the next most common organ recovered per donor after liver was lung. For DCDs, the next most common organ recovered per donor after liver was pancreas. The number of pancreata recovered per donor from DCDs has declined since 2005, and the number of lungs recovered per donor from DCDs has increased since 2007.

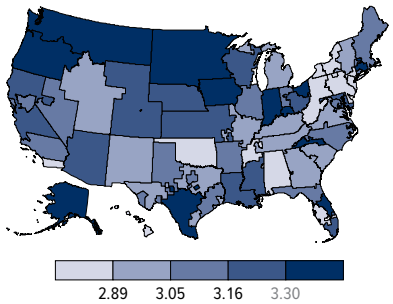
DOD 3.1 Organs transplanted per donor (OTPD)



DOD 3.2 Organs transplanted per donor (OTPD), by DSA, 2009



DOD 3.3 Organs transplanted per donor (OTPD), by DSA, 2009

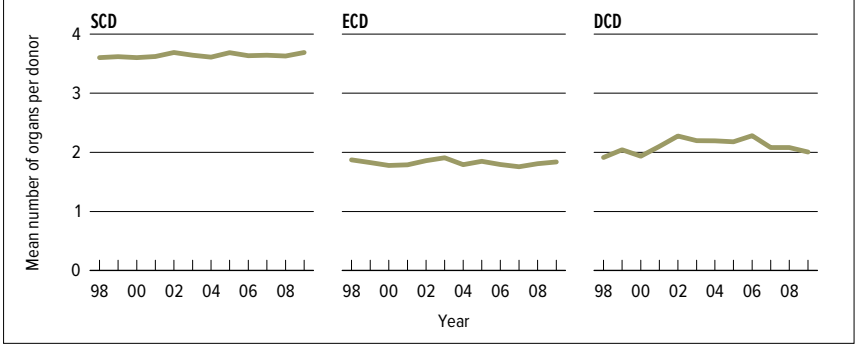


organs transplanted per donor

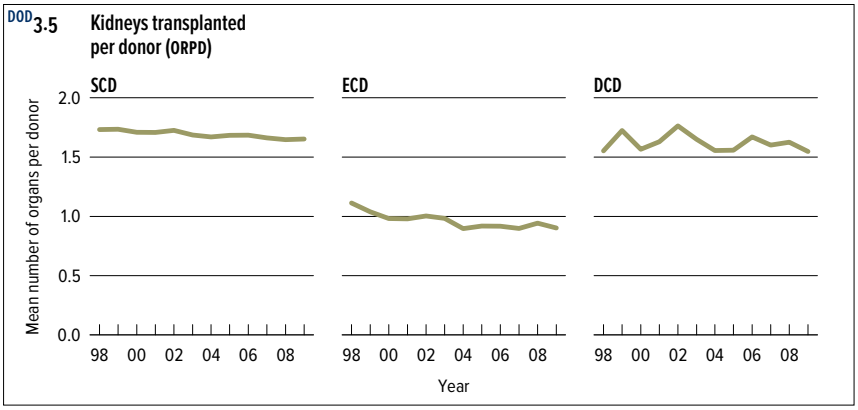
Over the past 12 years, the total number of organs transplanted per donor has declined slightly; approximately 3.0 organs per donor were transplanted in 2009 (Figure 3.1). Over the same period, the number of kidneys transplanted per donor declined only slightly. Numbers of livers, hearts, and pancreata transplanted per donor have also declined slightly. In contrast, the number of lungs transplanted per donor has increased, likely reflecting an increased demand for lung transplants. The number of intestinal transplants per donor, albeit low, has remained stable.

In 2009, by DSA, the mean number of organs transplanted per donor was 3.1. Variation across DSAs was wide, ranging from a low of 2.4 to a high of 3.6 (Figures 3.2 and 3.3). The mean number of kidneys transplanted per donor across DSAs was 1.5, the mean number of livers transplanted per donor was 0.76, and the mean number of hearts transplanted per donor was 0.28. Across DSAs, variation was wider in the number of lungs transplanted per donor compared with the number of hearts. The mean number of lungs transplanted per donor was 0.34.

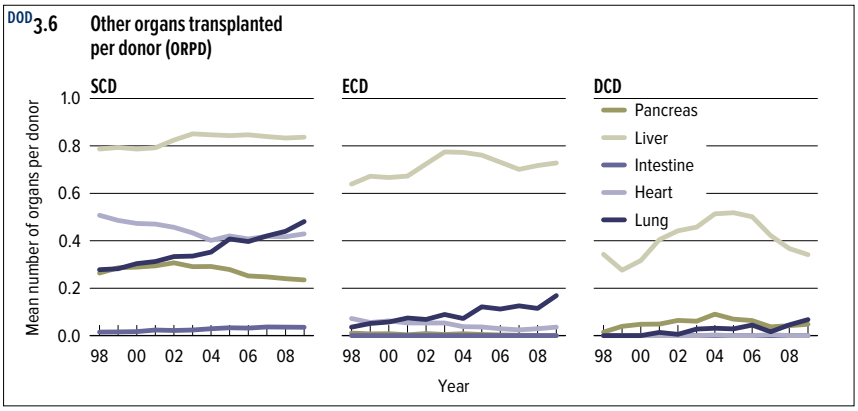
DOD 3.4 Total organs transplanted per donor (ORPD)



DOD 3.5 Kidneys transplanted per donor (ORPD)



DOD 3.6 Other organs transplanted per donor (ORPD)

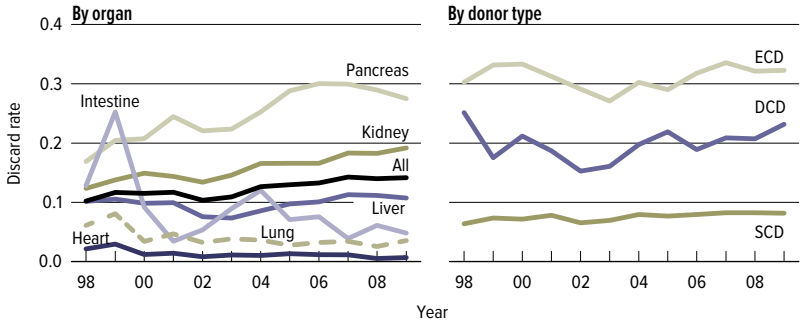


organs transplanted per donor

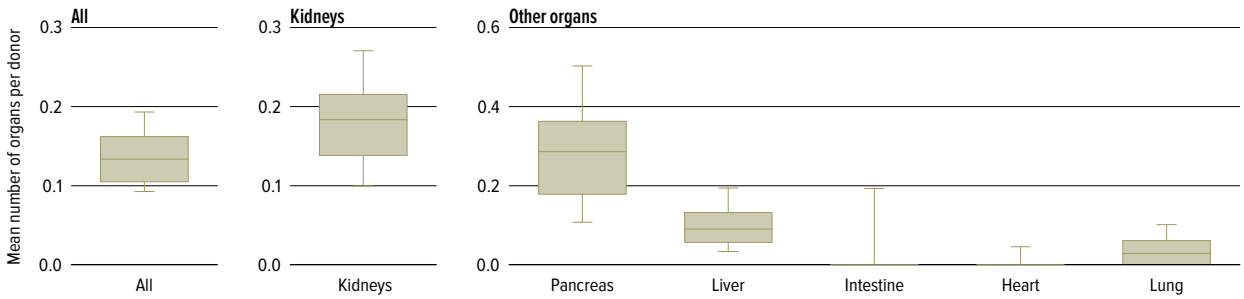
Not surprisingly, the number of organs transplanted per donor varied according to whether the donor was SCD, ECD, or DCD. Over the past 12 years, more organs were transplanted per donor from SCDs than from ECDs or DCDs (Figure 3.4). In 2009, 3.7 organs per SCD were transplanted, compared with 1.8 per ECD and 2.0 per DCD. Similarly, in 2009, 1.7 kidneys were transplanted per SCD, compared with 0.9 per ECD and 1.6 per DCD (Figure 3.5). Compared with kidneys, even fewer other organs were transplanted from ECDs and especially from DCDs, likely due to the relatively greater sensitivity of non-kidney organs to ischemia (Figure 3.6). For example, in 2009, 0.84 livers were transplanted per SCD, compared with 0.73 per ECD and only 0.34 per DCD. Compared with kidneys and livers, per ECD donor, even fewer pancreata (0.00 per donor), hearts (0.04 per donor), and lungs (0.17 per donor) were transplanted. Likewise, compared with kidneys and livers, per DCD donor, many fewer pancreata (0.05 per donor), hearts (0.00 per donor,), and lungs (0.07 per donor) were transplanted.

Over time, the number of organs transplanted per donor has changed little in SCD, ECD, and DCD donors. The exception is the increase in number of lungs transplanted per donor, probably reflecting the increase in lung transplantation in general (Figure 3.6).

DOD 4.1 Organ discard rates



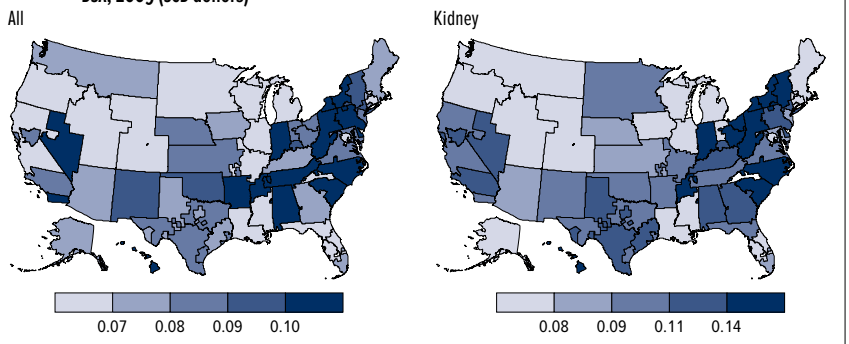
DOD 4.2 Variation in organ discard rates, by DSA, 2009



organ discards

The number of organs discarded is calculated by subtracting the number of organs transplanted from the number of organs recovered, and the discard rate divides this number by the number of organs recovered. From 2002 to 2007, the overall organ discard rate for all organs combined increased from 0.10 per donor to 0.14 per donor, but this rate has remained stable since 2007 (Figure 4.1). For kidneys, the organ discard rate has increased since 2002, reaching 0.19 per donor in 2009. In contrast, the organ discard rate for pancreata declined from 2007 to 2009. Over the same period, the organ discard rates for livers, lungs, and hearts have been stable. The discard rate for SCDs was lower than the rates for DCDs and ECDs (Figure 4.1). In 2009, the mean number of organs discarded per donor was 0.14, but variation across DSAs was wide, ranging from a low of 0.07 to a high of 0.28 organs discarded per donor (Figure 4.2). By organ, the highest discard rate was for pancreata (0.27 per donor), followed by kidneys (0.19) and livers (0.11). The discard rates for intestines (0.05 per donor), hearts (0.01), and lungs (0.04) were considerably lower across all DSAs.

DOD 4.3 Organ discard rates, by DSA, 2009 (SCD donors)

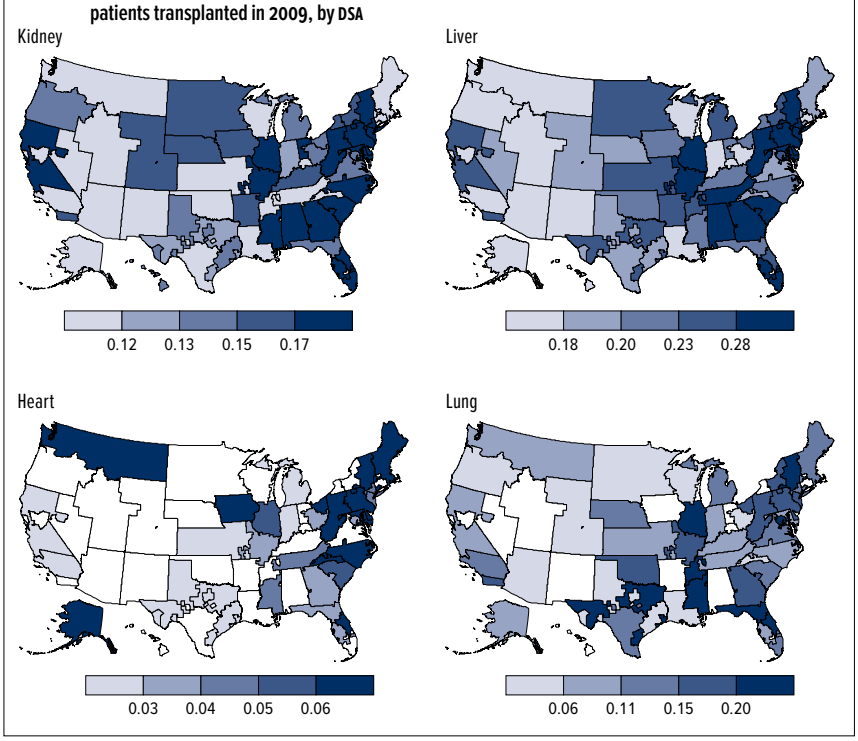


organ discards

The discard rate for SCDs varied by DSA in 2009 (Figure 4.3). Discard rates in a region may vary by organ. For example, for DSAs in the northwest, the lowest rates were for kidneys. In this same region, rates for pancreata and livers were higher compared with surrounding regions. Similarly, some DSAs in the mid-Atlantic region had the highest discard rates for kidneys but not the highest discard rates for pancreata. These differences may reflect the activity and demand for organs from transplant centers more than they reflect characteristics of OPOs.

The geographical distribution of discard rates varies by organ. Discard rates are highest for pancreata, followed by kidneys and livers. The discard rates for hearts, lungs, and intestines are very low (and are thus not shown); for hearts and lungs, this is probably due to the organs being procured by the surgical team that intends to transplant them.

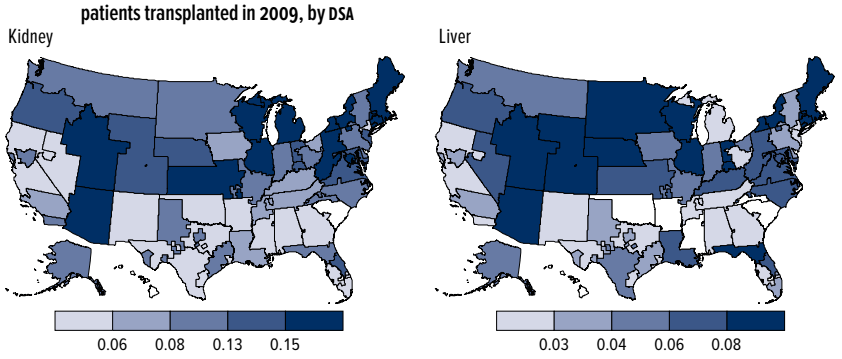
DOD 5.1 **Variation in the use of ECD donors for patients transplanted in 2009, by DSA**



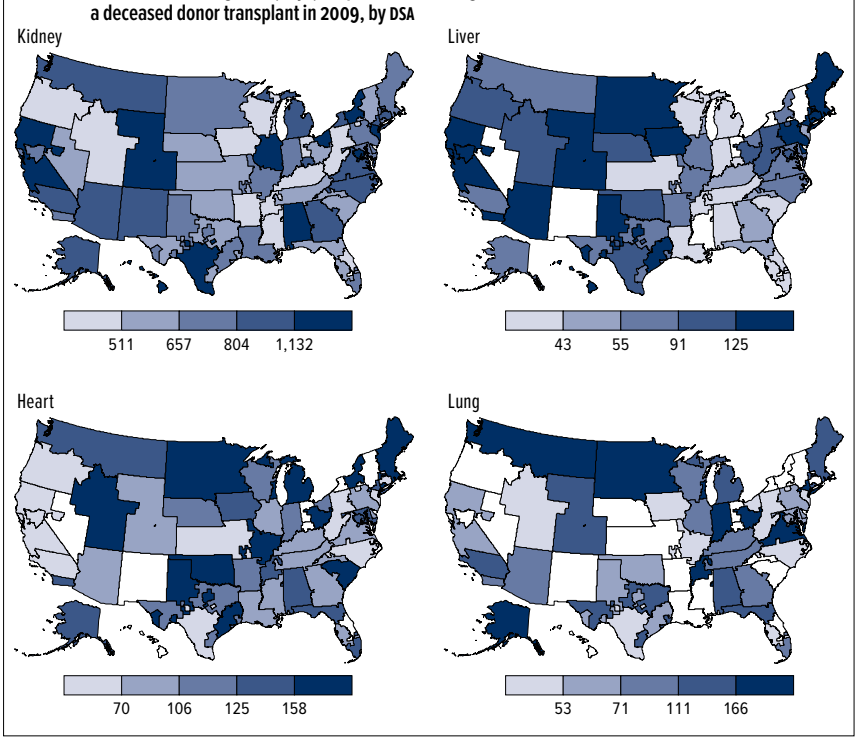
ECD donors

In 2009, the rate of ECD donor use varied by DSA for kidneys, livers, hearts, and lungs (Figure 5.1). The rates of ECD donor use in a region may vary by organ. For example, the DSAs in the northwest had the lowest rate of ECD kidney use, and this same region had a relatively higher rate of ECD heart use compared with surrounding regions. However, the distribution of ECD kidney and liver use rates was relatively similar across the country. For example, the northeast and southeast had high rates of ECD kidney and liver use compared with surrounding regions. Because rates of ECD organ use vary across organs, the geographical distribution of the rates varies by organ. The range of ECD organ use rates was highest for livers, followed by kidneys, lungs, and finally hearts. The variation in use of ECD hearts is remarkable because many DSAs do not use ECD hearts. Use of ECD intestines and pancreata is not shown because none of the DSAs used these ECD organs in 2009.

DOD 6.1 Variation in the use of DCD donors for patients transplanted in 2009, by DSA



DOD 7.1 Variation in waiting time (days) for patients receiving a deceased donor transplant in 2009, by DSA



DCD donors | waiting time

In 2009, rates of DCD organ use varied by DSA for kidneys and livers (Figure 6.1). However, distribution of DCD kidney and liver use rates was relatively similar across the country. The ranges of DCD use rates are higher for kidneys than for livers. Rates of DCD organs used varied geographically for kidneys and livers. Use of DCD intestines and pancreata is not shown because none of the DSAs used these DCD organs in 2009. A small number of DCD lungs were used.

Waiting times for patients who underwent transplant in 2009 varied by DSA (Figure 7.1). The range of waiting times varied by organ; the longest waiting times were for kidneys, followed by livers, hearts, and finally lungs. Longer waiting times in a region for one organ did not necessarily mean that the region also had longer waiting times for other organs.

allocation policies

kidney allocation

Organ Procurement and Transplantation Network (OPTN) kidney allocation policy attempts to balance justice and medical utility by focusing on antigen matching/mismatching, blood type, sensitization, and waiting time. With exceptions for the best-matched organs, kidneys are offered initially to patients on the local list, then regionally, and then nationally. The rank order of patients on the local, regional, or national lists is determined primarily by assigning points based on the candidate's waiting time, degree of sensitization, and degree of biological match with the donor. Waiting time for kidney allocation is defined as the duration of time that the candidate has been listed on the kidney transplant waiting list while meeting certain medical criteria.

Candidates who have received blood transfusions, been pregnant, or undergone a previous organ transplant may be sensitized to the antigens of others (i.e., these candidates are less likely to have an acceptable biological match with some or most of the donated kidneys). For this reason, sensitized candidates receive additional priority for the kidneys with which they match. Since the degree of biological match between the donor and the recipient is important to survival (i.e., better matching tends to equate to longer graft and patient survival), points are also awarded for matching at certain biological markers.

Donated kidneys are classified as being from a standard criteria donor (SCD) or an expanded criteria donor (ECD) based on the donor's age and previous medical history (Table 1). Kidneys from ECD donors are allocated only to candidates who have previously agreed to accept these organs, and the ECD allocation system is designed to expedite placement.

I am constantly reminded of how blessed I am, how fragile life is and how the generosity and compassion of others is so precious and necessary in this world.

Jasmine, mother of liver recipient

OPTN SRTR SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Additionally, kidneys from donors aged younger than 35 years are allocated preferentially to pediatric candidates (after perfectly matched candidates) in recognition of the unique problems associated with dialysis and of the disruption to expected growth and development processes in children who experience renal failure.

The description below provides a detailed, yet incomplete, description of how the deceased donor kidney allocation system works. The allocation system is more complex than depicted and is also subject to change. For more details and the most recent allocation policy, see the OPTN allocation policy, available on the internet: http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_7.pdf.

A SHORT SYNOPSIS OF OPTN KIDNEY ALLOCATION POLICY

Table 1. Expanded Criteria Donor (ECD) and Standard Criteria Donor (SCD)

A kidney is an ECD kidney if the deceased donor is

- Aged ≥ 60 years, or
- Aged 50–59 years with at least two of:
  1) Cerebrovascular accident (CVA) as cause of death,
  2) History of hypertension at any time,
  3) Serum creatinine > 1.5 mg/dL.

All other kidneys are SCD kidneys.

ABO blood type O kidneys must be transplanted into blood type O recipients, and ABO blood type B kidneys must be transplanted into type B recipients except for zero antigen mismatches.

For a pediatric candidate or a non-local adult candidate with calculated panel reactive antibodies (CPRA) > 20% and a zero antigen mismatch (except kidneys procured for simultaneous non-renal organ transplant or DCD kidneys), the kidney goes first to identical blood type zero antigen mismatched candidates in descending point sequence in the case of SCD kidneys, and by waiting time in the case of ECD kidneys, in Usual Allocation Sequence (Table 2):

Table 2. Usual Allocation Sequence

Zero-antigen mismatches

1) local candidates;
2) ≥ 80% CPRA candidates on the list of organ procurement organizations (OPOs) that are owed a payback kidney;
3) ≥ 80% CPRA candidates on the regional waiting list;
4) ≥ 80% CPRA candidates on the national waiting list;
5) < 80% CPRA candidates aged < 18 years on the list of OPOs that are owed a payback kidney;
6) < 80% CPRA candidates aged < 18 years on the regional waiting list;
7) < 80% CPRA candidates aged < 18 years on the national waiting list;
8) 21%–79% CPRA candidates on the list of OPOs that are owed a payback kidney;
9) 21%–79% CPRA candidates on the regional waiting list;
10) 21%–79% CPRA candidates on the national waiting list.

Then

(1) For blood type O donor kidneys, to blood type B zero antigen mismatched candidates, first, by Rank Order Point System (Table 3) in the case of SCD kidneys, and by waiting time in the case of ECD kidneys, as in the Usual Allocation Sequence

(Table 2), and, then, to blood type A and AB zero antigen mismatched candidates, also by Rank Order Point System (Table 3) in the case of SCD kidneys, and by waiting time in the case of ECD kidneys, as in the Usual Allocation Sequence (Table 2), and

(2) For blood type A, B, and AB donor kidneys, to all pediatric and sensitized adult candidates (CPRA > 20%) who are blood type compatible zero antigen mismatched candidates by Rank Order Point System (Table 3) in the case of SCD kidneys, and by waiting time in the case of ECD kidneys, as in the Usual Allocation Sequence (Table 2).

After being offered to candidates who have a zero antigen mismatch with the donor, the kidney is offered first to local prior living organ donors, then to local pediatric candidates. The kidney is then offered to candidates at OPOs that are owed a payback debt before being offered to local adult candidates. The kidney is then offered to regional pediatric candidates, regional adult candidates, national pediatric candidates, and national adult candidates.

Kidneys from ECD donors must be offered to candidates who have agreed to receive ECD organs in accordance with the Geographic Sequence (Table 4) of deceased kidney allocation and pursuant to the Rank Order Point System (Table 3).

Table 3. Rank Order Point System

Candidates with ABO blood type compatible with that of the donor are assigned points as follows:

- 1 point for waiting the longest period, with fractions of points assigned proportionately to all other candidates, according to their relative time of waiting.
- 2 points if there are no DR mismatches, or
- 1 point if there is 1 DR mismatch.
- 4 points for a CPRA ≥ 80%.
- 1 point if aged <11 and donor <35 and not a 0 mismatch kidney.
- 4 points if aged < 11 years for zero antigen mismatch kidneys.
- 3 points if aged ≥ 11 years but < 18 years for zero antigen mismatch kidneys.
- 4 points for prior donation for transplant within the US.

Kidneys from donors aged < 35 years that are not shared for 0 human leukocyte antigen (HLA) mismatches are offered first for transplant candidates aged < 18 years, except for candidates assigned 4 points for PRA ≥ 80%.

Table 4. Geographic Sequence of Deceased Kidney Allocation

In general, kidneys are to be allocated locally first, then regionally, and then nationally.

Locally: With the exception of kidneys that are 1) shared as a result of a zero antigen mismatch, 2) offered as payback, or 3) allocated according to a voluntary organ sharing arrangement, kidneys are allocated first to local candidates.

Regionally: If an SCD kidney is not accepted by any of the local transplant centers for local candidates, the kidney is to be allocated next via the regional list consisting of all candidates on the waiting lists of other members within the same region (Table 5) according to the Rank Order Point System (Table 3).

Nationally: If an SCD kidney is not accepted by any transplant center in the region in which the member that procured the kidney is located, the kidney is to be allocated to members for specific candidates in the other regions (Table 5) nationally according to the Rank Order Point System (Table 3).

Table 5. OPTN Regions

Region 1:	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Region 2:	Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Northern Virginia, West Virginia
Region 3:	Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
Region 4:	Oklahoma, Texas
Region 5:	Arizona, California, Nevada, New Mexico, Utah
Region 6:	Alaska, Hawaii, Idaho, Montana, Oregon, Washington
Region 7:	Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
Region 8:	Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming
Region 9:	New York
Region 10:	Indiana, Michigan, Ohio
Region 11:	Kentucky, North Carolina, South Carolina, Tennessee, Virginia

pancreas allocation

Pancreas candidates are categorized depending on their antibody sensitivity, HLA match with the donor, and geographic proximity to the donor.

Pancreata are first offered locally, then regionally (Table 5), and then nationally. Highly sensitized potential transplant recipients who have zero

HLA mismatches with the donor are offered the pancreas before any potential transplant recipient who is not highly sensitized. Within each respective geographic area, highly sensitized candidates are categorized ahead of other candidates. Multiple potential transplant recipients within each respective classification are stratified by the length of time they have been waiting.

The candidate's transplant center may ask not to be offered pancreata if the donor meets criteria that make the organ unsuitable for that candidate (HLA mismatches, age, body mass index, serologies, lab values, etc.).

Pancreata may also be allocated for islet transplant. The decision is based in part on donor age (50 years and younger, or not) and donor body mass index (BMI; 30 kg/m^2 and less, or not). Similar to the process of allocating the whole pancreas, islet offers follow the local, regional, national allocation order, and potential recipients are stratified by waiting time.

Table 6 provides a detailed, yet incomplete, description of how the deceased donor pancreas allocation system currently works. The allocation system is also subject to change. For more details and the most recent allocation policy, see the OPTN allocation policy, available on the internet: http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_10.pdf.

In November 2010, OPTN approved a restructuring of pancreas allocation policy that is designed to provide greater equity in access to transplants and waiting time across the country, standardize kidney-pancreas allocation practices nationally, maximize use of available pancreata, and improve the efficiency and cost-effectiveness of the organ allocation system. A description of how this new allocation system will work under the restructured pancreas allocation policy is provided in Table 7.

A SHORT SYNOPSIS OF OPTN PANCREAS ALLOCATION POLICY

Table 6. Current Pancreas and Islet Allocation

For local pancreas allocation, recipients may be selected from candidates awaiting an isolated pancreas, kidney-pancreas combination, or combined solid organ-islet transplant from the same donor.

ORDER OF ALLOCATION TO PANCREAS, KIDNEY-PANCREAS, AND KIDNEY CANDIDATES

Organs must be offered first to zero mismatch kidney-pancreas candidates with a CPRA ≥ 80% before kidneys can be offered to isolated kidney candidates. Kidneys must be offered to zero mismatch pediatric kidney candidates and zero mismatch adult kidney candidates with a CPRA ≥ 80% before they are offered to non-zero mismatch kidney-pancreas candidates. If an OPO has 6 or more payback debts for a particular blood group, kidneys must be offered through the payback debt classification before they are offered to non-zero mismatch kidney-pancreas candidates. Other than these requirements, the OPO may choose whether to offer the kidneys to kidney-pancreas or isolated kidney candidates.

BLOOD TYPE O KIDNEY-PANCREAS ALLOCATION

For combined kidney-pancreas candidates, blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.1, unless there is a zero HLA antigen mismatch and the candidate has a CPRA ≥ 80%.

ALLOCATION SEQUENCE FOR PANCREAS CANDIDATES

Pancreata and pancreas islets from donors aged ≤ 50 years and BMI ≤ 30 kg/m^2 are allocated in the following sequence:

1) Local zero mismatch pancreas candidates with a CPRA ≥ 80%;
2) Local pancreas candidates with a CPRA ≥ 80%;
3) Regional zero mismatch pancreas candidates with a CPRA ≥ 80%;
4) National zero mismatch pancreas candidates with a CPRA ≥ 80%;
5) Local pancreas candidates;
6) Regional pancreas candidates with a CPRA ≥ 80%;
7) Regional pancreas candidates;
8) National pancreas candidates with a CPRA ≥ 80%;
9) National pancreas candidates;
10) Local pancreas islet candidates;
11) Regional pancreas islet candidates;
12) National pancreas islet candidates.

Pancreata and pancreas islets from donors aged > 50 years or BMI > 30 kg/m^2 are allocated in the following sequence:

1) Local zero mismatch pancreas candidates with a CPRA ≥ 80%;
2) Local pancreas candidates with a CPRA ≥ 80%;
3) Regional zero mismatch pancreas candidates with a CPRA ≥ 80%;
4) National zero mismatch pancreas candidates with a CPRA ≥ 80%;
5) Local pancreas candidates;
6) Local pancreas islet candidates;

7) Regional pancreas islet candidates;
8) National pancreas islet candidates;
9) Regional pancreas candidates with a CPRA ≥ 80%;
10) Regional pancreas candidates;
11) National pancreas candidates with a CPRA ≥ 80%;
12) National pancreas candidates.

ALLOCATION SEQUENCE FOR KIDNEY-PANCREAS CANDIDATES

1) Local zero mismatch kidney-pancreas candidates with a CPRA ≥ 80%;
2) Regional zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
3) National zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
4) Local kidney-pancreas candidates with a CPRA ≥ 80%;
5) Local kidney-pancreas candidates;
6) Regional kidney-pancreas candidates with a CPRA ≥ 80%;
7) Regional kidney-pancreas candidates;
8) National kidney-pancreas candidates with a CPRA ≥ 80%;
9) National kidney-pancreas candidates.

Table 7. Proposed Pancreas and Islet Allocation

ORDER OF ALLOCATION TO PANCREAS, KIDNEY-PANCREAS, AND KIDNEY CANDIDATES

Organs from the combined pancreas/kidney-pancreas match run must be offered first to the local pancreas and kidney-pancreas candidates before being offered to isolated kidney candidates.

BLOOD TYPE O KIDNEY-PANCREAS ALLOCATION

For combined kidney-pancreas candidates, blood type O kidneys must be transplanted into blood type O recipients (ABO "O" Kidneys into ABO "O" Recipients), unless there is a zero HLA antigen mismatch and the candidate has a CPRA ≥ 80%.

ALLOCATION SEQUENCE

Pancreata, kidney-pancreas combinations, and pancreas islets from donors aged ≤ 50 years and BMI ≤ 30 kg/m^2 are allocated in the following sequence:

1) Local zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
2) Local pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
3) Regional zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
4) National zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
5) Local pancreas and kidney-pancreas candidates;
6) Regional pancreas candidates and kidney-pancreas candidates with a CPRA ≥ 80%*;
7) Regional pancreas candidates and kidney-pancreas candidates*;
8) National pancreas candidates and kidney-pancreas candidates with a CPRA ≥ 80%*;
9) National pancreas candidates and kidney-pancreas candidates*;
10) Local pancreas islet candidates;
11) Regional pancreas islet candidates;
12) National pancreas islet candidates.

Pancreata, kidney-pancreas combinations, and pancreas islets from donors aged > 50 years or BMI > 30 kg/m^2 are allocated in the following sequence:

1) Local zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
2) Local pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
3) Regional zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
4) National zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
5) Local pancreas and kidney-pancreas candidates;
6) Local pancreas islet candidates;
7) Regional pancreas islet candidates;
8) National pancreas islet candidates;
9) Regional pancreas candidates and kidney-pancreas candidates with a CPRA ≥ 80%*;
10) Regional pancreas candidates and kidney-pancreas candidates*;
11) National pancreas candidates and kidney-pancreas candidates with a CPRA ≥ 80%*;
12) National pancreas candidates and kidney-pancreas candidates.*

If a kidney is not available, the OPO may offer the pancreas to pancreas-alone candidates.

*If the Host OPO chooses.

liver allocation

Candidates are listed on the liver waiting list with their model for end-stage liver disease (MELD) score or pediatric end-stage liver disease (PELD)

score, or in status 1A or 1B. The MELD and PELD scores represent a candidate's risk of death while on the waiting list, with higher scores equating to higher risk.

- Candidates aged ≥ 12 years receive a MELD score based on laboratory tests of organ function (serum creatinine, bilirubin, and international normalized ratio [INR]), and based on whether the patient is currently on dialysis. The MELD score ranges from 6 to 40.
- Candidates aged < 12 years receive a PELD score based on laboratory tests of organ function (serum albumin, bilirubin, and INR), and on whether the patient was listed at age < 1 year, and/or has experienced growth failure. The PELD score can be a negative value, and can be as high as 99.
- Status 1A is reserved for very urgent adult and pediatric candidates who have a life expectancy of less than 7 days and have sudden liver failure or are in need of an immediate re-transplant.
- Status 1B is reserved for sick, chronically ill pediatric candidates with a MELD or PELD score ≥ 25 who require mechanical ventilation, or have significant gastrointestinal bleeding, renal failure/insufficiency, or impaired consciousness.
- Candidates whose MELD or PELD scores do not reflect their immediate need for a transplant, such as those with liver cancer, may be assigned a higher score if they meet specific criteria outlined in policy, or if their physician makes an application for a higher score that is approved by their Regional Review Board.

Priority is given to the most urgent patients (status 1A and 1B) and those with the highest MELD or PELD scores, as these patients tend to benefit more from a transplant than patients with lower scores. Within status 1A or 1B, candidates are ranked based on points assigned for blood type compatibility with the donor and waiting time in each status. Within each MELD or PELD score, candidates are ranked by their blood type compatibility with the donor. Within each category, candidates are then ranked based on the waiting time at that score. In general, pediatric donors are directed toward pediatric patients, who are in need of smaller-sized livers.

Table 8 provides a detailed, yet incomplete, description of how adult deceased donor liver allocation works. The allocation system is also subject to change. For more details and the most recent allocation policy, and for pediatric allocation policy, see the OPTN allocation policy on the internet: http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_8.pdf.

A SHORT SYNOPSIS OF OPTN LIVER ALLOCATION POLICY

Table 8. Adult Liver Allocation

At each level of distribution, adult livers (ages ≥18 years) are allocated in the following sequence:

LOCAL AND REGIONAL

1) Status 1A candidates in descending point order.
2) Status 1B candidates in descending point order.

LOCAL

3) Candidates with MELD/PELD scores ≥ 15 in descending order of mortality risk scores.

REGIONAL

4) Candidates with MELD/PELD scores ≥ 15 in descending order of mortality risk scores.

LOCAL

5) Candidates with MELD/PELD scores < 15 in descending order of mortality risk scores.

REGIONAL

6) Candidates with MELD/PELD scores < 15 in descending order of mortality risk scores.

NATIONAL

7) Status 1A candidates in descending point order.
8) Status 1B candidates in descending point order.
9) All other candidates in descending order of mortality risk.

MELD score = 0.957 x Ln(creatinine mg/dL) + 0. 378 x Ln(bilirubin mg/dL) + 1.120 x Ln (INR) + 0.643

Laboratory values less than 1.0 are set to 1.0.

The MELD score for each liver transplant candidate is rounded to the tenth decimal place and then multiplied by 10. The MELD score will be limited to a total of 40 points maximum.

heart allocation

The primary components of heart allocation include medical urgency status, geography, candidate age, donor age, and blood group compatibility. All heart candidates are given a medical urgency status. The active statuses, in descending order of urgency, are status 1A, status 1B, and status 2. An adult or pediatric candidate may qualify for listing as status 1A or 1B by meeting specific policy definitions; or, if the treating physician believes that the candidate should receive a more urgent classification, the

physician may apply to a regional review board for an adjustment in status.

The first unit of organ distribution is the local donation service area (DSA). The distribution units beyond local are based on concentric circles with 500 nautical mile increments centered at the donor hospital. Within each status and geographic zone, candidates are prioritized based on blood group compatibility and waiting time within the status or higher urgency status.

Pediatric candidates receive priority over adult candidates for offers of pediatric donor hearts. There is no distinction in candidate age for prioritization of offers of adult donor hearts. The prioritization of status and geographic zone combinations differs for adult (aged 18 years or older) and pediatric donors.

lung allocation

Since 2005, prioritization of candidates for deceased donor lung offers has used the Lung Allocation Score (LAS) for candidates aged ≥ 12 years, and waiting list urgency status for candidates aged < 12 years.

The LAS is a statistical computation that predicts a candidate's medical urgency for a transplant and survival after transplant. The LAS, in combination with other medical characteristics, prioritizes a candidate for a lung offer. Candidates aged younger than 12 years receive a medical urgency classification: priority 1 or priority 2. Priority 1 candidates have higher urgency for transplant.

For candidates aged > 12 years, transplant clinicians may request a higher LAS, a diagnosis group not provided in UNetSM, or an estimated value, by submitting an exception request to the national Lung Review Board (LRB). For candidates aged < 12 years, transplant clinicians may request priority 1 by submitting an exception request to the LRB.

Waiting time breaks a tie between 2 or more candidates with identical scores in the LAS system, and prioritizes candidates aged younger than 12 years for a lung offer in the priority system.

A lung from a deceased donor aged 11 years or younger is offered, by priority and blood group compatibility, first to candidates of the same age who reside in the combined local, zone A, and zone B geographic area. If no such candidates exist or if their physicians do not accept the organ, then it is offered to adolescents (aged 12 to 17 years, inclusive), by LAS and blood group compatibility, who reside in the combined local and zone A geographic area by LAS. If the lung remains available, then it is offered to adults by LAS, geography (DSA and then zone A, B, C, and D), blood group compatibility, and other medical characteristics.

A lung from an adult deceased donor is offered, by LAS and blood group compatibility, first to candidates aged 12 years or older and in the donor's local geographic area. If the lung remains available, then it is offered to candidates aged younger than 12 years by priority and blood group compatibility. This organ distribution system process repeats itself through each geographic zone (A, B, C, D, and E) until the lung is accepted or discarded due to its medical unsuitability for transplant.

The description below provides a detailed, yet incomplete, description of how the deceased donor thoracic allocation system works. The allocation system is also subject to change. For more details and the most recent allocation policy, see the OPTN allocation policy, available on the internet: http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_9.pdf.

Patients first listed prior to implementation of the LAS system may remain on the waiting list with no LAS or with an LAS of zero, depending on which data elements are missing.

heart and lung allocation

A SHORT SYNOPSIS OF OPTN HEART AND LUNG ALLOCATION POLICY

Geographic Sequence of Thoracic Organ Allocation

Thoracic organs (hearts, heart-lung combinations, single and double lungs) are generally allocated locally first, then within the following zones in the sequence. Five zones are delineated by concentric circles of 500, 1,000, and 1,500 and 2,500 nautical mile radii with the donor hospital at the center:

- Zone A extends to all transplant centers that are within 500 miles of the donor hospital, but not in the local area of the donor hospital.
- Zone B extends to all transplant centers that are at least 500 miles from the donor hospital, but not more than 1,000 miles from the donor hospital.
- Zone C extends to all transplant centers that are at least 1,000 miles from the donor hospital, but not more than 1,500 miles from the donor hospital.
- Zone D extends to all transplant centers that are beyond 1,500 miles from the donor hospital, but not more than 2,500 miles from the donor hospital.
- Zone E extends to all transplant centers that are beyond 2,500 miles from the donor hospital.

HEART CANDIDATE STATUS

Each candidate awaiting heart transplant is assigned a status code that corresponds to how medically urgent it is that the candidate undergo transplant. Medical urgency is assigned to a heart transplant candidate at the time of listing, and can be updated at any time. Urgency is classified (by detailed criteria) as: status 1A, status 1B, status 2, and status 7 (inactive on the waiting list for medical reasons).

LAS System

Candidates aged ≥ 12 years are assigned priority for lung offers based upon the Lung Allocation Score, which is calculated using the following measures:

1) Wait-list urgency measure (expected number of days lived without a transplant during an additional year on the waiting list),
2) post-transplant survival measure (expected number of days lived during the first year post-transplant), and
3) transplant benefit measure (post-transplant survival measure minus wait-list urgency measure).

Candidate groupings are shown in Table 9. The wait-list urgency measure and post-transplant survival measure (used in the calculation of the transplant benefit measure) are developed using Cox proportional hazards models. Factors determined to be important predictors of wait-list mortality and post-transplant survival are listed below in Tables 8.10 and 8.11. It is expected that these factors will change over time as new data are available and added to the models. The OPTN Thoracic Organ Transplantation Committee reviews these data periodically and proposes changes to Tables 10 and 11 as appropriate.

Table 9. Candidate Groupings

Group A Includes candidates with obstructive lung disease, including without limitation chronic obstructive pulmonary disease (COPD), alpha-1-antitrypsin deficiency, emphysema, lymphangioleiomyomatosis, bronchiectasis, and sarcoidosis with mean pulmonary artery (PA) pressure ≤ 30 mmHg.

Group B Includes candidates with pulmonary vascular disease, including primary pulmonary hypertension (PPH), Eisenmenger syndrome, and other uncommon pulmonary vascular diseases.

Group C Includes candidates with cystic fibrosis (CF) and immunodeficiency disorders such as hypogammaglobulinemia.

Group D Includes candidates with restrictive lung diseases, including without limitation, idiopathic pulmonary fibrosis (IPF), pulmonary fibrosis (other causes), sarcoidosis with mean PA pressure > 30 mmHg, and obliterative bronchiolitis (nonretransplant).

The OPTN Contractor provides a complete list of diagnoses in UNetSM.

Table 10. Factors Used to Predict Risk of Death on the Lung Transplant Waiting List

1) Forced vital capacity (FVC)
2) Pulmonary artery (PA) systolic pressure (Groups A, C, and D)
3) O_2 required at rest
4) Age
5) Body mass index (BMI)
6) Diabetes
7) Functional status
8) Six-minute walk distance
9) Continuous mechanical ventilation
10) Diagnosis
11) PCO_2
12) Bilirubin: current bilirubin, all groups; change in bilirubin, group B (bilirubin has been board-approved, but implementation is pending)

Table 11. Factors That Predict Survival After Lung Transplant

1) FVC (groups B and D)
2) Pulmonary capillary wedge (PCW) pressure ≥ 20 mmHg (Group D)
3) Continuous mechanical ventilation
4) Age
5) Serum creatinine
6) Functional status
7) Diagnosis

The calculations define the difference between transplant benefit and wait-list urgency: Raw Allocation Score = Transplant Benefit Measure – Waiting List Urgency Measure.

Raw allocation scores range from –730 days up to +365 days, and are normalized to a continuous scale from 0–100 to determine Lung Allocation Scores. The higher the score, the higher the priority for receiving lung offers. Lung Allocation Scores are calculated to sufficient decimal places to avoid assigning the same score to multiple candidates.

appendix

As time passes and healing occurs, I realize donation was a gift given to us as well as to the recipients. It is a real comfort to know that quality life was made possible by our decision to donate.

Judy, donor mother

OPTN SRTR SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

methods

POPULATIONS REPORTED

Figure titles indicate adult or pediatric populations; if not specified, data include all patients of all ages.

With the exception of the "total transplants" figure in each organ-specific chapter (i.e., KI 4.1), and of pancreas figures which specify SPK and PAK transplants, all figures in these chapters are limited to patients on the waiting list for a single-organ transplant (i.e, not heart-lung, not kidney-pancreas).

PEDIATRIC FIGURES

Pediatric figures use the same methods as those defined for the equivalent figures in other sections. To help in the location of these methods, the table below lists the pediatric figures for each organ-specific chapter; the left-hand column shows the first listed figure using the same methods.

AGE

Adult patients are defined as those 18 and older for all organs except lung; lung allocation policy treats patients 12 and older as adults. For wait-list figures, age is defined at time of listing unless otherwise specified.

RACE/ETHNICITY

Multi-racial patients are defined as other/unknown.

PRA

PRA is defined as the first non-missing value of the initial allocation PRA, current PRA, peak PRA, and calculated PRA.

ECD KIDNEYS

Data on willingness to accept an ECD kidney are available from 2003.

PANCREAS DATA

Pancreas data encompass the three types of pancreas wait lists or transplants: simultaneous kidney-pancreas, pancreas after kidney, and pancreas-alone.

LUNG ALLOCATION SCORE

The lung allocation score (LAS) became available in 2005. Data by LAS are presented using the most recent LAS before December 31 of each year.

wait list

KI 1.1, 8.1; PA 1.1, 7.1; LI 1.1, 8.1; IN 1.1; HR 1.1, 7.1; LU 1.1, 7.1

Patients waiting for a transplant. A "new patient" is defined as one who first joins the list (or, for pancreas, one of the three lists) during the given year, without having listed in a previous year. However,

Pediatric figures: for methods, see text for figure in left-hand column

Adult KI	Kidney	Pancreas	Liver	Heart	Lung
KI 1.1	KI 8.1	PA 7.1	LI 8.1	HR 7.1	LU 7.1
KI 1.2	KI 8.2	PA 7.2	LI 8.2	HR 7.2	LU 7.2
KI 1.6	KI 8.4	PA 7.4	LI 8.4	HR 7.4	LU 7.4
KI 1.7	KI 8.5	PA 7.5	LI 8.5	HR 7.5	LU 7.5
KI 1.10	KI 8.6	PA 7.6	LI 8.6	HR 7.6	LU 7.6
KI 1.12	KI 8.7	PA 7.7	LI 8.7	HR 7.7	LU 7.7
KI 4.1	KI 8.8	PA 7.8	LI 8.8	HR 7.8	LU 7.8
KI 4.3	KI 8.9	PA 7.9	LI 8.9	HR 7.9	LU 7.9
KI 4.8	KI 8.10	PA 7.10	LI 8.10	HR 7.10	LU 7.10
KI 3.2	KI 8.11		LI 8.11		
	KI 8.12		LI 8.12		
KI 4.9	KI 8.13	PA 7.11	LI 8.13	HR 7.11	LU 7.11
KI 5.7	KI 8.14				
KI 6.9	KI 8.15	PA 7.12	LI 8.14	HR 7.12	LU 7.12
KI 7.4	KI 8.16	PA 7.13	LI 8.15	HR 7.13	LU 7.13
KI 6.3	KI 8.17		LI 8.16		LU 7.14
KI 6.4	KI 8.18		LI 8.17		
KI 6.5	KI 8.19		LI 8.18	HR 7.15	LU 7.15
wait list	KI 8.3	PA 7.3	LI 8.3	HR 7.3	LU 7.3
outcomes					
PA 5.2		PA 7.14			
PA 5.3				HR 7.14	LU 7.14

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." Persons listed at multiple centers are counted only once. Those with multiple listings and active at any program are considered active; those inactive at all programs at which they are listed are considered inactive.

KI 1.2, 8.2; PA 1.2, 7.2; LI 1.2, 8.2; IN 1.2; HR 1.2, 7.2; LU 1.2, 7.2

Patients waiting for a transplant on December 31 of each year. Age determined on this date, and each patient counted only once. For HR 1.2, ventricular assist device information comes from the TCR form at the time of listing, and includes LVAD, RVAD, TAH, and LVAD + RVAD. For LU 1.2, patients first listed prior to LAS implementation may remain scoreless after 2005 due to missing data among elements required to compute LAS.

KI 1.3, PA 1.3, LI 1.3, IN 1.3, HR 1.3

New patients per year, defined as in Figure 1.1. For HR 1.3, ventricular assist device information comes from the TCR form at the time of listing, and includes LVAD, RVAD, TAH, and LVAD + RVAD.

KI 1.4

Prevalent dialysis patients, all ages, wait-listed for a kidney-alone transplant. Percentage calculated as the sum of wait-list patients divided by the sum of point prevalent dialysis patients on December 31 of each year (data from the United States Renal Data System). Counts of dialysis patients are taken from the USRDS 2008 Annual Data Report, reference table D.6.

KI 1.5, PA 1.4, LI 1.4, IN 1.4, HR 1.4, LU 1.3

Patients waiting for a transplant; age as of January 1 of the given year. Yearly period-prevalent rates for all transplants/deceased-donor transplants are computed as the number of all transplants/deceased-donor transplants per 100 patient years of waiting time in the given year (for pancreas, within each list). All waiting time per patient per listing is counted, and all listings that end in a transplant for the patient are considered transplant events.

KI 8.3, PA 7.3, LI 8.3, HR 7.3, LU 7.3

Prior transplant is obtained from the OPTN Transplant Candidate Registration form.

KI 1.6, 8.4; PA 1.5, 7.4; LI 1.5, 8.4; IN 1.5; HR 1.5, 7.4; LU 1.4, 7.4

Patients waiting for a transplant; multiple listings counted.

KI 1.7, 8.5; PA 1.6, 7.5; LI 1.6, 8.5; IN 1.6; HR 1.6, 7.5; LU 1.5, 7.5

Patients waiting for a transplant and first listed in 2006; multiple listings counted.

KI 1.8, PA 1.7, LI 1.7, IN 1.7, HR 1.7, LU 1.6

Patients waiting for a transplant and listed in 2005–2009; multiple listings counted, and percentiles of time to transplant obtained by Kaplan-Meier estimates. Observation ended at December 31, 2009. Lines in the figures stop at the last observed percentile per cohort group. For example, only 60% of all kidney listings between 2005–2009 were transplanted as of December 31, 2009.

KI 1.9, PA 1.8, LI 1.8, HR 1.8, LU 1.7

Patients receiving a deceased-donor transplant in 2009. Observed median time to transplant presented by DSA of the transplanting center. DSAs with no transplant program are shown in white.

KI 1.10, 8.6; PA 1.9, 7.6; LI 1.9, 8.6; IN 1.8; HR 1.9, 7.6; LU 1.8, 7.6

Patients waiting for transplant, with observations censored at December 31, 2009; 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 as of the censoring date. Only the first transplant is counted. Data by LAS use the LAS at listing, and are not provided until 2005, when LAS went into use.

KI 1.11

Patients waiting for a kidney-alone transplant, 2003 (beginning of ECD program) to 2009; multiple listings counted.

KI 1.12, 8.7; PA 1.10, 7.7; LI 1.10, 8.7; IN 1.9; HR 1.10, 7.7; LU 1.9, 7.7

Patients waiting for a transplant. Rates by age are shown by the patient's age in the given year. Yearly mortality rates computed as deaths per 100 patient years of waiting time in the given year. Total waiting time per patient per listing per year is counted. Counted deaths are those in which patients were removed from list because of death, and not transplanted before death.

KI 1.13, PA 1.11, LI 1.11, IN 1.10, HR 1.11, LU 1.10

Patients waiting for a transplant on December 31, 2009, regardless of first listing date; active/inactive status is on this date, and multiple listings are not counted.

deceased donation

KI 2.1, PA 2.1, LI 2.1, IN 2.1, HR 2.1

Deceased donors whose organ(s) were recovered for transplant. Denominator: US population age 70 and younger (population data downloaded from http://www.census.gov/popest/national/asrh/2009-nat-res.html). Donors are limited to those age 70 and younger.

LU 2.1

Lungs recovered from deceased donors and transplanted in the given year. Donors who donate two lungs are counted twice. Denominator: US population age 12–70 (population data downloaded from http://www.census.gov/popest/national/asrh/2009-nat-res.html).

KI 2.2, PA 2.2, LI 2.2, HR 2.3, LU 2.3

Deceased donors residing in the 50 states whose organ(s) were recovered for transplant in the given year. Denominator: US population age 70 and younger (population data downloaded from http://www.cdc.gov/nchs/nvss/bridged_race.htm).

KI 2.3, PA 2.3, LI 2.3, IN 2.2, HR 2.2, LU 2.2

Denominator: all deceased donors with at least one organ recovered for transplant. Numerator for recovery rate: number of organs recovered for transplant in the given year; organs recovered for other purposes are not included. Numerator for transplant rate: all deceased donor organs transplanted in given year.

KI 2.4, PA 2.4, LI 2.4, IN 2.3, HR 2.4, LU 2.4

All patients receiving a deceased donor transplant. A transplant is considered multi-organ if any other organ is transplanted at the same time. Two of the same organ (kidney, lung) is not considered multi-organ. A multi-organ transplant may include more than two different organs in total.

KI 2.5, PA 2.5, LI 2.5, IN 2.4, HR 2.5, LU 2.5

Denominator: organs recovered for transplant. Numerator: organs recovered for transplant but not transplanted.

KI 2.6

Patients receiving a kidney-only, deceased-donor transplant.

PA 2.6, LI 2.6

Deceased donors whose relevant organ was recovered for transplant. DCD status is reported on the OPTN registration forms.

KI 2.7

Deceased kidney donors. DCD status and ECD are reported on the OPTN registration forms.

KI 2.8

Patients receiving a kidney-only, deceased-donor transplant, 2009.

LU 2.6

Smoking history is reported on the OPTN registration forms.

KI 8.12, LI 8.12

Patients receiving a deceased donor transplant.

live donation

KI 3.1–2, 8.11; LI 3.1–2, 8.11

Number of living donor donations; characteristics recorded on donor registration form.

KI 3.3, LI 3.3

Number of living donors whose relevant organ was recovered for transplant each year. Denominator: US population age 70 and younger (population data downloaded from http://www.census.gov/popest/national/asrh/2009-nat-res.html).

KI 3.4, LI 3.4

Number of living donors residing in the 50 states whose relevant organ was recovered for transplant in the given year. Denominator: US population age 70 and younger (population data downloaded from http://www.cdc.gov/nchs/nvss/bridged_race.htm).

KI 3.5

Counts include "domino" donation chains.

LI 3.5

Living donors by graft type for each year. Denominator: total number of living liver donors for each year.

KI 3.6, LI 3.6

eGFR estimated by CKD-EPI formula. (Levey AS et al., Chronic Kidney Disease Epidemiology Col-

laboration (CKD-EPI). A new equation to estimate glomerular filtration rate. Ann Intern Med., 2009 May 5; 150(9):604–12).

KI 3.7
Data sparse prior to 2004.

KI 3.8, LI 3.15
Cumulative readmission to the hospital. "Unknown" means that patient has been lost to follow-up as of this follow-up visit. The six-week time point is recorded at the earliest of discharge or six weeks post-transplant.

KI 3.9
Complications defined as a readmission, a reoperation, a complication requiring intervention, or an "other" interventional procedure. The six-week time point is recorded at the earliest of discharge or six weeks post-transplant.

KI 3.10
Limited only to complications requiring reoperation. Donors could experience more than one complication.

LI 3.7–15
Living liver donors, excluding domino donors. For LI 3.13, the six-week time point is recorded at the earliest of discharge or six weeks post-transplant.

transplant

KI 4.1, 8.8
Patients receiving a kidney-alone or simultaneous kidney-pancreas transplant. Retransplants are counted.

KI 4.2, PA 3.1–2, 7.8; LI 4.1–2, 8.8; IN 3.1–2; HR 3.1, 3.4, 7.8; LU 3.1–2, 7.8
Patients receiving a transplant. Retransplants are counted.

KI 4.3, 8.9; PA 3.3 (limited to deceased-donor transplants only), 7.9; LI 4.3, 8.9; IN 3.3; HR 3.2, 7.9; LU 3.3, 7.9
Patients waiting for a transplant; age as of January 1 of the given year. Yearly period-prevalent rates for all transplants/deceased-donor transplants are computed as the number of all transplants/deceased-donor transplants per 100 patient years of waiting time in the given year (for pancreas, within each list). All waiting time per patient per listing is counted, and all listings that end in a transplant for the patient are considered transplant events.

KI 4.4
Patients receiving their second, third, or fourth kidney-alone transplant in the given year.

LU 3.4
Living donor lung transplants.

KI 4.5, PA 3.4, LI 4.4, LU 3.5
Percent of deceased-donor transplants using a DCD donor.

KI 4.6, PA 3.5, LI 4.5, LU 3.6
Percent of deceased-donor transplants using a DCD donor, by DSA of the transplanting center, 2007–2009.

PA 3.6
Living donor transplants.

KI 4.7, PA 3.7, LI 4.6, HR 3.3, LU 3.7
Deceased-donor transplant rates by state of residence, limited to those on the waiting list in 2009. Maximum time per person on the list is one year. If no residents of a given state received a transplant of that type in 2009, the transplant rate is 0.

KI 4.8–9, 8.10, 8.13; PA 3.8–9, 7.10–11; LI 4.7–8, 8.10, 8.13; IN 3.4–5; HR 3.5–6, 7.10–11; LU 3.8–9, 7.10–11
Patients receiving a transplant. Retransplants are counted. For HR 3.5, ventricular assist device information comes from the TRR form at the time of listing, and includes LVAD, RVAD, TAH, and LVAD + RVAD.

LI 4.9
Deceased donor liver transplants; DSA of transplant center location. Patients with status 1A, 1B and inactive status excluded, and allocation MELD score used.

donor–recipient matching

KI 5.1, PA 4.1, LI 5.1, HR 4.1, LU 4.1
PRA is most recent value recorded at the time of transplant. If "most recent PRA" is not provided, peak PRA is used.

KI 5.2–5, PA 4.2–5, LI 5.2–5, HR 4.2–5, LU 4.2–5
Donor antigens and recipient unacceptable antigens are reported on the OPTN Donor Histocompatibility form and the Recipient Histocompatibility form, respectively.

KI 5.6–11, 8.14; PA 4.6–11, LI 5.6–11, HR 4.6–11, LU 4.6–9

Patients transplanted 2005–2009. Donor serology is reported on the OPTN donor registration forms; recipient serology is reported on the OPTN recipient registration forms. Data are shown as the overall percentage in each donor/recipient group.

outcomes

KI 6.1, PA 5.1, LI 6.1, IN 4.1, HR 5.2, LU 5.2

Early graft failure identified from the Transplant Recipient Registration orm (TRR) and defined as a transplant failure that occurred prior to or at discharge, a graft functional status of 'N' on the TRR, or, for kidney, within 90 days of transplant.

KI 6.2

Delayed graft function defined as receiving dialysis within a week post-transplant.

PA 5.2, 7.14

Cox proportional hazards models, adjusting for age, gender, and white/non-white race.

PA 5.3, LI 6.2–3, IN 4.2; HR 5.1, 7.14; LU 5.1, 7.14

Cox proportional hazards models, adjusting for age, gender, and race.

KI 6.3–4, 8.17–18; PA 5.4; LI 8.16–17

Cox proportional hazard models, adjusting for age, gender, and race, and, for kidney, primary cause of disease. Death with function defined as no graft failure prior to death; return to dialysis defined as graft failure preceding death.

PA 5.5

PAK transplants, with pancreas transplant in 1991–2009. Cox proportional hazard models used, adjusting for age, gender, and race.

PA 5.6

PAK transplants, with pancreas transplant in 1991–2009; uses most recent kidney transplant prior to the pancreas transplant. Cox proportional hazards models used, adjusting for age, gender, and race. Follow-up begins at pancreas transplant; estimates conditional on surviving to pancreas transplant without recorded kidney graft failure or retransplant.

KI 6.5, 8.19; PA 5.7; LI 6.4, 8.18; IN 4.3; HR 5.3, 7.15; LU 5.3, 7.15

Estimates of conditional half-lives are conditional on first-year graft survival, and estimated from the cumulative hazard between years one and two. Conditional half-lives are interpreted as the estimated median survival of grafts which survive the first year. Cox proportional hazards models used, adjusting for age, gender, and race, and, for kidney, primary cause of disease.

KI 6.6, PA 5.8, LI 6.5, IN 4.4, HR 5.4, LU 5.4

Transplants before June 30 of the year that are still functioning and are actively being followed by their center after June 30 of that year. A recipient can experience a graft failure and drop from the cohort, then be retransplanted and re-enter the cohort.

KI 6.7, PA 5.9, LI 6.6, IN 4.5, HR 5.5, LU 5.5

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. For simultaneous kidney-pancreas recipients, an acute rejection may be of the kidney or pancreas, and graft failure is the first of kidney or pancreas graft failure. Cumulative incidence estimated using Kaplan-Meier method.

KI 6.8, PA 5.10, LI 6.7, IN 4.6, HR 5.6, LU 5.6

Cumulative rate of hospitalization; hospitalization identified from follow-up form. Patients required to be alive with graft function at each time period, so denominators reduce over time.

KI 6.9, 8.15; PA 5.11, 7.12; LI 6.8, 8.14; IN 4.7; HR 5.7, 7.12; LU 5.7, 7.12

Cumulative incidence of post-transplant lymphoproliferative disease (PTLD) after transplant. PTLD identified as either a reported complication or cause of death on the Transplant Recipient Follow-up forms. Only the first PTLD record is counted, and patients are followed for PTLD only until graft failure, death, or loss to follow-up. For simultaneous kidney-pancreas recipients, graft failure is defined as the first of kidney or pancreas graft failure. Cumulative incidence estimated using Kaplan-Meier method.

immunosuppression

KI 7.1, PA 6.1, LI 7.1, IN 5.1, HR 6.1, LU 6.1

Top three baseline immunosuppression regimens are given, plus the "all others" group. Regimens are defined by use of calcineurin inhibitors, antimetabolites, and mTor inhibitors. Steroids are not

included in regimen definition, and are reported in the last figure of the section.

KI 7.2, PA 6.2, LI 7.2, IN 5.2, HR 6.2, LU 6.2

Patients transplanted in 2009.

KI 7.3, PA 6.3, LI 7.3, IN 5.3, HR 6.3, LU 6.3

Patients transplanted in 2008 and remaining alive with graft function one year post-transplant, as reported on the one-year follow-up form. Top three one-year immunosuppression regimens shown, plus the "all others" group. Regimens defined by use of calcineurin inhibitors, anti-metabolites, and mTor inhibitors. Steroids are not included in regimen definition, and are reported in the last figure of the section.

KI 7.4, 8.16; PA 6.4, 7.13; LI 7.4, 8.15; IN 5.4; HR 6.4, 7.13; LU 6.4, 7.13

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 medication follow-up was very sparse that year. CsA is cyclosporine A, CsM is cyclosporine microemulsion.

center characteristics

KI 9.1, PA 8.1, LI 9.1, IN 6.1, HR 8.1, LU 8.1

Denominator is all active centers transplanting the specific organ, 2009. Centers are grouped by transplant volume in that year.

KI 9.2, LI 9.2, HR 8.2, LU 8.2

All active centers transplanting the specific organ, grouped by total number of transplants performed during 2005–2009. A center is defined as a multi-organ transplant center if it performed at least one multi-organ transplant during 2005–2009.

PA 8.2, IN 6.2

All active transplant centers within a given year.

KI 9.3, LI 8.3, LU 8.3

All active kidney transplant centers, grouped by total number of deceased donor transplants performed during 2005–2009. A center is defined as transplanting DCD or ECD organs if it used at least one DCD or ECD donor during 2005–2009.

glossary

Acute rejection The host recognizes the graft as foreign and mounts an immunological attack on the graft tissues. Most acute rejections occur in the first year.

Allocation The process of determining how organs are distributed. Allocation includes the system of policies and guidelines, which ensure that organs are distributed in an equitable, ethical and medically sound manner.

Allocation analysis Review of the allocation of an organ to determine whether the allocation policies were followed. The analysis is performed by the OPTN contractor through the peer review process of the OPTN Membership and Professional Standards Committee.

Allograft An organ or tissue that is transplanted from one person to another of the same species: i.e. human-to-human. Example: a transplanted kidney.

Anti-rejection drugs (immunosuppressive drugs) Drugs that are used to prevent and/or treat rejection of a transplanted organ.

Antibody A protein molecule produced by the immune system in response to a foreign body, such as virus or a transplanted organ. Since antibodies fight the transplanted organ and try to reject it, recipients are required to take anti-rejection (immunosuppressive) drugs.

Antigen An antigen is any substance that causes your immune system to produce antibodies against it. An antigen may be a foreign substance from the environment such as chemicals, bacteria, viruses, pollen, or foreign tissues. An antigen may also be formed within the body, as with bacterial toxins.

Biopsy A tissue sample from the body, removed and examined under a microscope to diagnose for disease, determine organ rejection, or assess donated organs or tissues.

Blood vessels The veins, arteries and capillaries through which blood flows in the body. Certain blood vessels can be donated and transplanted.

Brain death Irreversible cessation of cerebral and brain stem function; characterized by absence of electrical activity in the brain, blood flow to the brain, and brain function as determined by clinical assessment of responses. A brain dead person is dead, although his or her cardiopulmonary functioning may be artificially maintained for some time.

Candidate A person registered on the organ transplant waiting list. When an organ is offered on behalf of the candidate, he or she is then referred to as a Potential Transplant Recipient (PTR).

Cardiac Having to do with, or referring to, the heart.

Cardiac death Death defined as the irreversible cessation of circulatory and respiratory functions. Death is declared in accordance with hospital policy and applicable state and local statues or regulation.

Chronic Developing slowly and lasting for a long time, possibly the rest of a person's life. For example: chronic kidney failure.

Chronic Disease Research Group (CDRG) A division of Minnesota Medical Research Foundation (MMRF). MMRF is the nonprofit research subsidiary of Hennepin Faculty Associates, the academic medical group that staffs Hennepin County Medical Center, a teaching hospital in Minneapolis, Minnesota. The CDRG conducts research primarily focused in the areas of chronic kidney disease and organ transplantation. The MMRF-CDRG is responsible for the administration of the Scientific Registry of Transplant Recipients (SRTR).

Chronic rejection Slow, continuous immunological attack of the host immune system on the transplanted organ usually resulting in progressive loss of organ function.

Cirrhosis A disease of the liver in which normal, healthy tissue is replaced with nonfunctioning fibrous scar tissue and healthy, functioning liver cells are lost; usually occurs when there is a lack of adequate nutrition, an infection or damage caused by alcohol abuse.

Committees The OPTN currently maintains approximately 20 standing committees, a fluctuating number of ad hoc committees (established by the President to address a specific issue as it arises), subcommittees and joint subcommittees (created and maintained by standing committees). Committees are comprised of professionals, at least one Patient/Public representative, Minority Affairs Committee Representative, Pediatric Committee Representative, and one or more SRTR representatives. Permanent Standing Committees also include representatives form each of the 11 Regions. HRSA's OPTN Project Officer and Director of DoT, or their designees, serve as ex-officio non-voting members of all committees. Each committee is provided administrative, policy, analytic, clinical and technical support by one or more committee liaisons from the UNOS staff.

Corticosteroid A synthetic hormone used to reduce the body's normal immune reaction to infection and foreign tissue, such as a transplanted organ. Prednisone is a corticosteroid.

Criteria (medical criteria) A set of clinical or biologic standards or conditions that must be met.

Cyclosporine A drug used to prevent rejection of the transplanted organ by suppressing the body's defense system. Considered an immunosuppressant.

Deceased donor An individual from whom at least one solid organ is recovered or the purpose of transplantation after suffering brain death or cardiac death.

Deceased donor transplant The transplant of an organ from a deceased donor.

Department of Health and Human Services (DHHS or HHS) The department of the federal government responsible for health-related programs and issues.

Dialysis A mechanical process designed to partially perform kidney functions, including correcting the balance of fluids and chemicals in the body and removing wastes. See Hemodialysis and Peritoneal Dialysis.

Diastolic blood pressure The bottom number in the blood pressure measurement (80 in a blood presure of 120/80), indicating the pressure in the arteries when the heart is at rest.

Division of Transplantation (DoT) DoT is the office within HHS/HRSA whose principal responsibilities include the oversight of management of the Organ Procurement and Transplantation Network (OPTN), the Scientific Registry of Transplant Recipients (SRTR) and the National Marrow Donar Program (NMDP) contracts; public education to increase organ and tissue donation; and technical assistance to organ procurement organizations (OPOs).

Domino transplant A procedure in which an organ is removed from one transplant candidate and immediately transplanted into a second patient, with the first patient receiving a new organ from a deceased donor.

Donate Life America Formerly the Coalition on Donation, Donate Life America is a national not-for-profit alliance of local affiliates and corporate partners that have joined forces to inspire all people to Donate Life through organ, eye and tissue donation. At the core of the organization's education efforts are the ongoing qualitative and quantitative research of public attitudes about organ and tissue donation and the development and dissemination of effective, motivating public service campaigns. Distributed at the national and community level, these multi-media campaigns effectively communicate two core messages: Transplants give people their life back, and here is how you can help. Founded by the transplant community in 1992, the Coalition publishes brochures, program kits and other materials; provides technical assistance, training, information and referral services; and coordinates the National Campaign for Organ and Tissue Donation. It is comprised of national organizational members and local coalitions across the U.S. that coordinate donation related activities at the local level. Volunteer advertising agencies work with the Coalition and its committees to develop targeted mass media campaigns.

Donation Service Area (DSA) The geographic area designated by CMS that is served by one organ procurement organization (OPO), one or more transplant centers, and one or more donor hospitals. Formerly referred to as Local Service Area or OPO Service Area.

Donor Someone from whom at least one organ or tissue is recovered for the purpose of transplantation. A deceased donor is a patient who has been declared dead using either brain death or cardiac death criteria, from whom at least onevascularized solid organ is recovered for the purpose of organ transplantation. A living donor is one who donates an organ or segment of an organ for the intent of transplantation.

Donor registries Available 24 hours a day, seven days a week, online registries provide authorized professionals access to a confidential database of registered organ donors, allowing easy and quick confirmation of an individual's consent to organ donation. All registries are voluntary and some are affiliated with the local motor vehicle bureau, while others are independently operated or OPO-based.

End-stage organ disease A disease that leads to the permanent failure of an organ.

Ethnicity For OPTN data purposes, the use of categories such as white, black or African-American, Hispanic, Asian, American Indian/Alaskan Native, Pacific Islander, multiracial.

Expanded criteria donor (ECD) kidney A kidney donated for transplantation from any brain dead donor over the age of 60 years; or from a donor over the age of 50 years with two of the following: a history of hypertension, the most recent serum creatinine greater than or equal to 1.5 mg/dl, or death resulting from a cerebral vascular accident (stroke). This definition applies to the allocation of deceased donor kidneys.

Functional status A way to measure the effects that lung disease may have on a person's ability to perform routine daily tasks. Functional status is used in the Lung Allocation Score.

Glomerular filtration rate (GFR) A measure used to determine kidney function, the GFR indicates the kidney's ability to filter and remove waste products.

Graft A transplanted organ or tissue.

Graft survival The length of time an organ functions successfully after being transplanted.

Hemodialysis A treatment for kidney failure where the patient's blood is passed through a filtering membrane to remove excess fluid and wastes.

Hepatic Having to do with, or referring to, the liver.

Hepatitis A viral infection or non-specific inflammation of the liver that can lead to liver failure. Hepatitis C is the leading cause of liver failure that leads to transplantation.

High blood pressure See hypertension.

Histocompatibility The examination of human leukocyte antigens (HLA) in a patient, often referred to as "tissue typing" or "genetic matching." Tissue typing is routinely performed for all donors and recipients in kidney and pancreas transplantation to help match the donor with the most suitable recipients to help decrease the likelihood of rejecting the transplanted organ. See Human Leukocyte Antigen System (HLA System).

Human immunodeficiency virus (HIV) A virus which destroys cells in the immune system, which makes it difficult for the body to fight off infections; toxins, or poisons; and diseases. HIV causes AIDS, a late stage of the virus characterized by serious infections, malignancies, and neurologic dysfunctions.

Hypertension High blood pressure. Occurs when the force of the blood pushing against the walls of the blood vessels is higher than normal because the blood vessels have either become less elastic or have gotten smaller. Hypertension causes the heart to pump harder to move blood through the body. It can cause kidney failure and heart disease if not treated.

Immune response The body's natural defense against foreign objects or organisms, such as bacteria, viruses or transplanted organs or tissue.

Immune system The organs, tissues, cells and cell products in your body that work to find and neutralize foreign substances including bacteria, viruses and transplanted organs.

Immunosuppression Prevention or inhibition of the immune system to respond to foreign substances in the body. Medications often used to prevent a recipient's immune system from rejecting a transplanted organ or tissue include prednisone, methylprednisolone, azathioprine, mycophenolate mofetil, cyclosporine, tacrolimus, and sirolimus, among others.

Immunosuppressive Relating to the weakening or reducing of your immune system's responses to foreign material; immunosuppressive drugs reduce your immune system's ability to reject a transplanted organ.

Induction therapy Medications given for a short finite period in the perioperative period for the purpose of preventing acute rejection. Though the drugs may be continued after discharge for the first 30 days after transplant, it will not be used long-term for immunosuppressive maintenance.

Infection A condition that occurs when a foreign substance, such as bacteria, enters your body, causing your immune system to fight the intruder. All transplant recipients can get infections more easily because their immune systems are suppressed. It is more difficult for them to recover from infection (such as urinary tract infections, colds and the flu).

Inflammation The swelling, heat and redness produced when the body is injured or infected.

International normalized ratio (INR) A measure of a patient's coagulation (clotting) system. INR is used in the MELD and PELD calculations.

Kidneys A pair of organs that remove wastes from the body through the production of urine. All of the blood in the body passes through the kidneys about 20 times every hour. Kidneys can be donated from living and deceased donors and transplanted into patients with kidney failure.

Leukocyte A white blood cell.

Liver The largest organ in the body, made up of a spongy mass of wedge-shaped lobes. The liver secretes bile, which aids in digestion, helps process proteins, carbohydrates, and fats, and stores substances like vitamins. It also removes wastes from the blood. A living donor can give part of their liver, after which the liver will regenerate itself in both the donor and recipient.

Match The compatibility between the donor and the recipient. The more appropriate the match, the greater the chance of a successful transplant.

Medicaid A partnership between the Federal government and the individual states to share the cost of providing medical coverage for recipients of welfare programs and allowing states to provide the same coverage to low-income workers not eligible for welfare. Programs vary greatly from state to state.

Medicare The program of the Federal government that provides hospital and medical insurance, through social security taxes, to people age 65 and over, those who have permanent kidney failure and certain people with disabilities.

Multiple listing Being on the waiting list for the same organ at more than one transplant center.

National Organ Transplant Act (NOTA) The National Organ Transplant Act (1984 Public Law 98-507), approved October 19, 1984 and amended in 1988 and 1990, outlawed the sale of human organs and provided for the establishment of the Task Force on Organ Transplantation; authorized the Secretary of HHS to make grants for the planning, establishment, and initial operation of qualified OPOs; and established the formation of the Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR).

New York Heart Association Functional Classification (NYHA) An assessment of a patient's heart failure based on the severity of symptoms. Range is Class I-IV.

Noncompliance 1) Failure of patients to follow the instructions of the medical team, 2) Failure of OPTN members to adhere to the policies and bylaws of the OPTN.

Organ A part of the body made up of tissues and cells that enable it to perform a particular function. Transplantable organs are the heart, liver, lungs, kidneys, pancreas and intestines.

Organ donation To give an organ or a part of an organ to be transplanted into another person. Organ donation can occur with a deceased donor, who can give kidneys, pancreas, liver, lungs, heart, intestinal organs, and with a live donor, who can give a kidney, or a portion of the liver, lung, or intestine.

Organ preservation Methods used to preserve organs while they are out of the body, between procurement from a donor and transplantation into a recipient.

Organ procurement The removal or retrieval of organs from a donor for transplantation.

Organ Procurement and Transplantation Network (OPTN) In 1987, Congress passed the National Organ Transplant Act that mandated the establishment of the OPTN and Scientific Registry of Transplant Recipients. The purpose of the OPTN is to improve the effectiveness of the nation's organ procurement, donation and transplantation system by increasing the availability of and access to donor organs for patients with end-stage organ failure. The Act stipulated that the Network be a non-profit, private sector entity comprised of all U.S. transplant centers, organ procurement organizations and histocompatibility laboratories. These members along with professional and voluntary healthcare organizations and the representatives of the general public are governed by a Board of Directors which reports to the Division of Transplantation, HRSA and ultimately HHS. UNOS holds the OPTN contract.

Organ Procurement Organization (OPO) An organization designated by the Centers for Medicare and Medicaid Services (CMS) and responsible for the procurement of organs for transplantation and the promotion of organ donation. OPOs serve as the vital link between the donor and recipient and are responsible for the identification of donors, and the retrieval, preservation and transportation of organs for transplantation. They are also involved in data folow-up regarding deceased organ donors. As a resource to the community OPOs engage in public educationon the critical need for organ donation. See also Donation Service Area (DSA).

Pancreas Irregularly shaped gland that lies behind the stomach and secretes pancreatic enzymes into the small intestines to aid in

the digestion of proteins, carbohydrates and fats. Islet cells within the pancreas secrete glucagon, which regulates blood sugar levels and insulin, which lowers blood sugar levels. If the pancreas fails, the individual becomes diabetic, and may need to take insulin. The pancreas can be donated and transplanted.

Panel reactive antibody (PRA) The percent PRA value is a measure of a patient's level of sensitization to HLA antigens. It is the percentage of cells from a panel of blood donors against which a potential recipient's serum reacts. The PRA reflects the percentage of the general population that a potential recipient makes antibodies (is sensitized) against. For example, a patient with a PRA of 80 percent will be incompatible with 80 percent of potential donors. Kidney patients with a high PRA are given priority on the waiting list. The higher the PRA, the more sensitized a patient is to the general donor pool, and thus the more difficult it is to find a suitable donor. A patient may become sensitized as a result of pregnancy, a blood transfusion, or a previous transplant.

PCO_2 A blood gas test is performed to measure the amount of CO_2 in the blood. When the lung's ability to exchange oxygen and CO_2 becomes impaired, the PCO_2 level may become increased. The candidate's current PCO_2 and change in PCO_2 are both considered in the lung allocation score calculation to reflect worsening PCO2 values. PCO_2 is used in the Lung Allocation Score.

Peritoneal dialysis A treatment technique for kidney failure that uses the patient's own body tissues inside of the (abdominal cavity to act as a filter. The intestines lie in the abdominal cavity, the space between the abdominal wall and the spine. A plastic tube called a "dialysis catheter" is placed through the abdominal wall into the abdominal cavity. A special fluid is then flushed into the abdominal cavity and washes around the intestines. The lining (peritoneum) of the abdominal cavity and of intra-abdominal organs act as a filter between this fluid and the blood stream. By using different types of solutions, waste products and excess water can be removed from the body through this process.

Plasmapheresis A process in which plasma is removed from blood and the remaining components, mostly red blood cells, are returned to the donor. The process may be used in transplantation to remove pre-formed antibodies.

Procurement The surgical procedure of removing an organ from a donor. Also referred to as recovery.

Pulmonary Having to do with, or referring to, the lungs.

Race See ethnicity.

Recipient A person who receives a transplant.

Recovery (organ) The surgical procedure of removing an organ from a donor.

Rejection A phenomenon that occurs when a recipient's immune system attacks a transplanted organ, tissue, or cell. Immunosuppressive drugs help prevent or treat rejection.

Renal Having to do with, or referring to, the kidneys.

Required request Hospitals must tell the families of suitable donors that their loved one's organs and tissues can be used for transplant. This law is expected to increase the number of donated organs and tissues for transplantation by giving more people the opportunity to donate.

Retransplantation Due to rejection or failure of a transplanted organ, some patients receive another transplant.

Retrieval The surgical procedure of organ recovery. Also referred to as procurement.

Risk pools State-created, nonprofit associations that do not require tax dollars for operational purposes. The risk pools are a temporary stopping place for individuals who are denied health insurance for medical reasons. Risk pools often help individuals who, because of their physical condition, are unable to purchase health insurance at any price.

Scientific Registry of Transplant Recipients (SRTR) As called for by the National Organ Transplant Act (NOTA), the purpose of the SRTR is to provide ongoing evaluation of clinical data about donors, transplant candidates, and recipients, as well as patient and graft survival rates. With oversight and funding from the DoT, the SRTR is currently administered by the Chronic Disease Research Group (CDRG) of the Minneapolis Medical Research Foundation (MMRF).

Sensitization Transplant candidates are "sensitized" if their immune system makes antibodies against a general donor pool. Sensitization usually occurs as a consequence of pregnancy, blood transfusions, or previous transplantation. The degree of sensitization is measured by panel reactive antibody (PRA). Highly sensitized patients are less likely to match with available donors and more likely to reject an organ than unsensitized patients.

Status An indication of the degree of medical urgency for patients awaiting heart or liver transplants. Examples: status 1A, status 1B, or status 2.

Steroids Naturally occurring hormones in the body that help control important body functions. Synthetic or man-made steroids can be used to suppress the immune system.

Survival rates Survival rates indicate the percentage of patients that are alive and the grafts (organs) that are still functioning after a certain amount of time. Survival rates are used in developing OPTN policy.

Systolic blood pressure The top number in the blood pressure (the 120 in a blood pressure of 120/80) measures the maximum pressure exerted on the vessel wall when the heart contracts.

Tissue An organization of a great many similar cells that perform a special function. Examples of tissues that can be transplanted are blood, bones, bone marrow, corneas, heart valves, ligaments, saphenous veins, and tendons.

Tissue typing A blood test that helps evaluate how closely the tissues of the donor match those of the recipient.

Uniform Determination of Death Act (UDDA) The 1981 Uniform Determination of Death Act is a model statute defining "brain death." Versions of this Act have been adopted in 39 states and the District of Columbia. The act states that an individual who has sustained either (a) irreversible cessation of circulatory or respiratory functions or (b) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.

United Network for Organ Sharing (UNOS) The private, nonprofit membership organization that coordinates the nation's transplant system through HRSA's OPTN contract. As OPTN contractor, UNOS is responsible for meeting all contract requirements. As contractor since the first OPTN contract award in 1986, UNOS has established and continually strives to improve tools, systems and quality processes that support OPTN contract objectives and requirements. These include:

- Managing the national organ transplant waiting list

- Collecting, managing and reporting of sensitive clinical data in a secure, fail-safe environment
- Facilitating an open, inclusive forum for development and continuous refinement of evidence-based policies and standards
- Member and policy performance assessment to ensure equitable, safe treatment of candidates and recipients
- Increasing donation and making the most of every organ that is donated through professional education, outcomes research, patient services and resources and public and professional education
- Continuously improving the care, quality of life and outcomes of organ transplant candidates and recipients

Varices (esophageal) Enlarged and swollen veins at the bottom of the esophagus, near the stomach. A common condition caused by increased venous pressure in the liver. These veins can ulcerate and bleed.

Vascular Referring to blood vessels and circulation.

Ventilator A machine that "breathes" for a patient when the patient is not able to breathe properly.

Virus A group of tiny organisms capable of growing and copying themselves while living within cells of the body.

Warm ischemic time (WIT) If the donor is a DCD donor, the warm ischemic time is the time from:

1. the time of Agonal Phase onset (from the time of cardiac arrest when the systolic pressure meets the following conditions for greater than five (5) minutes) to the time when core cooling is initiated. Agonal Phase onset:
   a. Newborn up to 28 days, with a systolic blood pressure less than 60 mmHg, OR
   b. b. 29 days up to 12 months, with a systolic blood pressure less than 70 mmHg, OR
   c. 1 year up to 10 years, with a systolic blood pressure less than 70 mmHg, plus 2 times the age of the patient in years, not to exceed 79 mmHg, OR
   d. 11 years or older, with a systolic blood pressure less than 80 mmHg, OR when the oxygen saturation is less than 80% at any age,
- The calculated time using the serial data to be collected beginning with the agonal phase and ending with the initiation of core cooling.

Xenograft An organ or tissue procured from a different species for transplantation into a human.

Glossary adapted from transplantliving.org, a UNOS website.

abbreviations

BMI	body mass index
BRFSS	Behavioral Risk Factor Surveillance System
CDC	Centers for Disease Control and Prevention
CDRG	Chronic Disease Research Group
CMV	cytomegalovirus
COPD	chronic obstructive pulmonary disease
CPRA	calculated panel reactive antibody
CSA	cyclosporine A
CSM	cyclosporine microemulsion
DCD	donation after cardiac death/donation after circulatory death
DD	deceased donor
DHHS	Department of Health and Human Services
DM	diabetes
DOT	Division of Transplantation
DSA	Donation Service Area
EBV	Epstein-Barr virus
ECD	expanded criteria donor kidney
ESRD	end-stage renal disease
eGFR	estimated glomerular filtration rate
GN	glomerulonephritis
HIV	human immunodeficiency virus
HLA	human leukocyte antigen
HMO	health maintenance organization
HTN	hypertension
INR	international normalized ratio
KDRI	kidney donor risk index
LAS	lung allocation score
LD	living donor
LVAD	left ventricular assist device
MTOR	mammalian target of rapamycin
NOTA	National Organ Transplant Act
NYHA	New York Heart Association Functional Classification
OPO	Organ Procurement Organization
OPTN	Organ Procurement and Transplantation Network
PAK	pancreas after kidney transplant
PPO	preferred provider organization
PRA	panel reactive antibody
PTA	pancreas transplant alone
PTLD	post-transplant lymphoproliferative disorder
RRT	renal replacement therapy
RVAD	right ventricular assist device
SCD	standard criteria donor
SPK	simultaneous pancreas-kidney transplant
SRTR	Scientific Registry of Transplant Recipients
STAC	SRTR Scientific and Technical Advisory Committee
TAH	total artificial heart
TCR	transplant candidate registration
TRR	transplant recipient registation
UDDA	Uniform Determination of Death Act
UNOS	United Network for Organ Sharing
USRDS	United States Renal Data System
VAD	ventricular assist device
WIT	warm ischemia time