Technical Methods for the Program-Specific Reports

Reports Released January 2017,
For the Fall 2016 Cohorts

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Introduction

The program-specific reports (PSRs) contain tables and figures that report statistics for individual transplant center programs. When the report refers to statistics for a center, it indicates the statistics for a specific organ transplant program at that center. The statistics are based on data available from the Organ Procurement and Transplantation Network (OPTN) as of October 31, 2016. Tables contained in the report are described individually below. A table is suppressed from the report if there are no patients for that specific table for that program.

PDF Program-Specific Reports Methods

Section A: Program Summary

The program summary table presents selected statistics that are shown in greater detail in other tables and figures. Statistics included in the program summary are generally those of most interest, including waitlist activity, transplant and mortality rates for candidates on the waiting list, and posttransplant outcomes.

Figure A1: Waiting list and transplant activity

Waitlist and transplant activity statistics include total numbers of candidates on the waiting list at the end of the 12-month period, active on waiting list at the end of the 12-month period, and newly added to the waiting list during the period (details under Table B1); total numbers of transplants, deceased donor transplants, and living donor transplants (details under Table B4, Figures B1-B3).

Table A1: Census of transplant recipients

Table A1 summarizes the census of transplant recipients, showing numbers of patients who underwent transplant and were followed at the program. Recipients are considered to be followed at the program if the program submitted a posttransplant follow-up form for a transplant that took place before the 12-month measurement period.

Figure A2: Transplant rates

Methods for transplant rates are specified under Table B4, Figures B1-B3.

Figure A3: Waiting list mortality rates

Methods for waiting list mortality rates are specified under Table B5, Figures B4-B6.

Figure A4: First-year adult graft and patient survival

Methods for first-year adult graft and patient survival are specified under Tables C5-C10, Figures C1-C12.

Figure A5: First-year pediatric graft and patient survival

Methods for first-year pediatric graft and patient survival are specified under Tables C11-C16, Figures C13-C23.

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Section B: Waiting List Information

Table B1: Waiting list activity summary

Table B1 shows movement of candidates on and off the waiting list between July 1, 2014, and June 30, 2016, reported in two separate yearly intervals for the program, the program's OPTN region, and the US as a whole. The data are presented as counts and percentages of candidates on the waiting list at the start of the period to allow comparison of waitlist activity at the program with the OPTN region and the US.

Inclusion criteria
Transplant candidates on the organ-specific waiting list or added to the waiting list any time between July 1, 2014, and June 30, 2016 are included.

Exclusion criteria
Candidates who underwent living donor transplant but were never added to the waiting list are excluded. Candidates listed only for pancreatic islets are excluded from pancreas reports.

Table details
On waiting list at start: The number of candidates on the program's waiting list at the start of a period. This is defined as the number of candidates who were on the waiting list at midnight the morning of the beginning of the measurement period (e.g., June 30, 2014) and who had not been removed as of that time.

Additions: The number of candidates added to the waiting list during the given period. Candidates added multiple times during the interval after previously being removed from the list would be counted multiple times.

Removals: Removals of candidates from the waiting list are reported by reason for removal. These include: transferred to another program, received living donor transplant, received deceased donor transplant, died, medically unsuitable, deteriorated (medical condition had deteriorated), recovered, and other reasons. Removals are counted only if they occur during the period. Candidates removed multiple times during the interval after one or more re-listings would be counted multiple times.

Table B1 shows percentages in the OPTN region and the US as a whole for comparison with program statistics. These percentages are calculated by dividing the number of candidates added, removed, or remaining on the waiting list during the period by the number of candidates on the waiting list at the beginning of the period. The result is multiplied by 100 to produce the percentage.

Percentage of additions: The number of new waiting list additions during the period is divided by the number of candidates on the waiting list at the start of the period, and the result is multiplied by 100 to produce the percentage.

Percentage of removals: The number of removals from the waiting list for a given reason during the period is divided by the number of candidates on the waiting list at the start of the period, and the result is multiplied by 100 to produce the percentage. If more candidates are added to the waiting list than are removed during a period, the "percentage" of patients on the waiting list at the end of the period will be greater than 100%. For example, if the US percentage of kidney transplant candidates on the waiting list at the end of the period was 108.8%, this indicates an 8.8% growth of the kidney transplant waiting list during the period.

On waiting list at end of period: The number of candidates on the waiting list at the end of a period is the number at the start of the period, plus additions during the period, minus removals during the period. The number of

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candidates on a program's waiting list at the end of a given period is the same as the number of candidates at the beginning of the following period.

Additional observations and caveats
Information regarding the number of candidates removed from the waiting list for various reasons at a given program depends on data submitted to OPTN and provided to SRTR. For example, it is possible for a candidate to be reported as removed from the kidney transplant waiting list due to undergoing living donor transplant, even though no such transplant was reported by the program, according to information contained in the OPTN database. Only a small number of such data anomalies have occurred, likely due to discrepancies in the data reported by programs on different data collection forms. Data used for transplant tables later in the report are derived from different elements in the database and therefore counts of waitlist removals due to transplant and counts of reported transplants may not always correspond.

Tables B2-B3: Demographic and medical characteristics of waiting list candidates

Tables B2 and B3 show the distribution of various characteristics among waitlist candidates at the program, in the program's OPTN region, and in the US as a whole. These data are presented for new candidates whose listing date was between July 1, 2015, and June 30, 2016, and for all candidates who were on the waiting list on June 30, 2014.

Inclusion criteria
Candidates added to the waiting list between July 1, 2015, and June 30, 2016, are included in the new waiting list registrations counts and descriptions. All candidates on the waiting list on June 30, 2016, are included in the all waiting list registrations counts and descriptions.

Exclusion criteria
None.

Table details
Candidate counts are displayed at the top of each column for the program, the program's OPTN region, and the US as a whole (e.g., *n* = 544 indicates that the population is 544 candidates). These counts are used to calculate the percentages in that column. The percentages are reported for each characteristic; these add to 100%, except for rounding errors. Candidates with missing information for a characteristic are designated other or unknown.

Reported characteristics of waitlist candidates vary by organ type. Reported characteristics include: ethnicity/race, age, gender, blood type, previous transplants, initial calculated panel-reactive antibodies (CPRA; for kidney, pancreas, and kidney/pancreas only), years since diabetes onset (for pancreas only), primary disease (not shown for pancreas and kidney/pancreas), and medical urgency status at the time of listing (for liver and heart only). A more detailed description of each characteristic appears in *Appendix A: Definitions of Candidate, Recipient, and Donor Characteristics*.

Additional observations and caveats
In Table B2, race and ethnicity are reported together as a single data element, reflecting how the data are collected (either race or ethnicity is required to be reported, but not both). Patients formerly coded as white and Hispanic are coded as Hispanic.

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For the primary disease data in Table B3, when retransplant is reported as the primary diagnosis in data collection, the primary diagnosis reported for the initial transplant is used to indicate the initial primary disease causing organ failure. The missing category may include some patients for whom retransplant is reported but no prior diagnosis can be found.

Table B4, Figures B1-B3: Transplant rates

Table B4 and Figures B1-B3 report transplant rates for candidates on the waiting list at any time between July 1, 2015, and June 30, 2016, along with the expected rates and observed-to-expected ratios. For liver and kidney programs, data on transplant rates are presented in two ways: 1) including both living donor and deceased donor transplants in Table B4 and Figures B1-B3, and 2) including only deceased donor transplants in Table B4D, and Figures B1D-B3D. For all other organs, only deceased donor transplants are shown in Table B4 and Figures B1-B3.

Inclusion criteria
All candidates on the program's waiting list at any time during the observation period are included. Active/inactive status is not considered, so time at risk and transplant events are counted regardless of whether the candidate is active or inactive during the observation period.

Exclusion criteria
None.

Details
Count on waiting list at start: The total number of candidates on the waiting list at midnight the morning of the beginning of the period is reported. Counts in this table may be lower than similar counts in other waitlist tables, such as Table B1. A small percentage (~1%) of patients are found to have died or undergone transplant before being removed from the waiting list, so these patients are excluded if the event occurred before the start of the study period. Candidates who are inactive on the waiting list are included in the calculations for this table.

Person-years*:* Since candidates may be on the waiting list for all or for only part of a full year, person-years are reported. Person-years are calculated as the number of days the candidate was on the waiting list and converted to a fraction of a year for each candidate. For example, if a candidate is on the list for 365 days, this would count as one person-year; if a candidate is on the list for 183 days, this would count as 0.5 person-years. The number of days on the waiting list is calculated from the latter of the start date of the period or the date of first listing during the period, until the earliest of the date of death, transplant, removal from the waiting list, or the end of the period. Time the candidate was listed as inactive is included in the calculation of person-years. Person-years for each candidate are summed to yield the total person-years.

Removals for transplant: This is the number of waitlist candidates who were removed from the waiting list due to undergoing transplant during the period.

Transplant rate (per 100 person-years on the waiting list): This is calculated by dividing the number of removals due to transplant at this program by the total number of person-years on the waiting list at this program, multiplied by 100.

Expected transplant rate: The expected transplant rate is the rate that would be expected at this program based on national experience. The expected rate takes into account various patient characteristics in an attempt to

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adjust for differences among programs. For more detail about how the expected transplant rate is estimated, please refer to *Appendix B: Detailed Statistical Methods*.

Ratio of observed to expected transplant rates: This is calculated by dividing the transplant rate by the expected transplant rate. A ratio less than 1 indicates a lower than expected transplant rate, while a ratio greater than 1 indicates a higher than expected transplant rate.

95% confidence interval (95% CI): The 95% confidence interval provides a measure of the statistical uncertainty associated with the estimated ratio of observed to expected transplant rates. Smaller transplant programs generate less information to use in estimating transplant rates, so their confidence intervals are wider. The lower and upper bounds define a range likely to include the true ratio. If the confidence interval includes 1, we cannot conclude that this program's transplant rate is statistically different from what would be expected, and any differences observed could be due to random chance. For more information, please refer to *Appendix B: Detailed Statistical Methods*.

P value: The *P* value (e.g., $P < 0.01$) indicates whether the transplant rate is statistically significantly different from the expected transplant rate. A value less than 0.05 indicates that the rate is significantly different (higher or lower) from the expected rate. For more detail, please refer to *Appendix B: Detailed Statistical Methods*.

Additional observations and caveats
Candidates listed for a combined liver and intestine transplant are often also listed for a pancreas transplant for the purpose of maintaining vascular continuity. Candidates listed for a pancreas transplant who are simultaneously on the intestine transplant waiting list are excluded from this measure.

These data are also presented by age (adult versus pediatric candidates). Expected results are not included in the age breakdowns.

Table B5, Figures B4-B6: Waiting list mortality rates

Table B5 and **Figures B4-B6** report waitlist mortality rates for candidates on the waiting list at any time between July 1, 2015, and June 30, 2016, along with expected waitlist mortality rates and the ratio of observed to expected waitlist mortality rates.

The mortality rate statistics were designed to provide information about mortality *once* listed rather than *while* listed. Therefore, time at risk and deaths following removal from the waiting list for reasons other than transplant, transfer, or recovery, and before any subsequent transplant, are included. In addition to deaths reported as the reason for waitlist removal, we also include deaths obtained from the National Technical Information Service Death Master File (NTIS DMF) and Centers for Medicare & Medicaid Services (CMS) to allow death ascertainment for candidates through the end of the follow-up period. For the purpose of comparison, corresponding rates for the second interval in this program's donation service area (DSA) and OPTN region and in the US as a whole are also reported.

Inclusion criteria
All candidates on the program's waiting list at any time during the interval are included. Active/inactive status is not considered; i.e., time at risk and transplant/death events are counted regardless of whether the candidate is active or inactive during the observation period.

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Exclusion criteria
None.

Count on waiting list at start: This is the count of candidates on the program's waiting list at the beginning of the measurement period. Counts in this table may be lower than similar counts in other waitlist tables, such as Table B1. A small percentage (~1%) of candidates are found to have died or undergone transplant before being removed from the waiting list, and are excluded if the event occurred before the start of the study period. Inactive time on the waiting list is included in the calculations for this table.

Person-years: Candidates are followed from (a) the date of registration on the waiting list or (b) the beginning of the measurement period until the earliest of (a) the date of death, (b) the date of transplant, (c) 60 days after removal from the list due to recovery or transfer, or (d) the end of the measurement period. We follow patients beyond removal from the waiting list (if removed for reasons other than transplant, transfer, or recovery). Therefore, we refer to observation time rather than waitlist time when discussing person-years for waitlist mortality. Since patients may be observed for all or part of a full year, person-years are reported. Person-years are calculated as the number of days the patient was observed, converted to fractional years for each patient. For example, if a patient is observed for 365 days, this would count as one person-year; if a patient is observed for 183 days, this would count as 0.5 person years. Any time the patient was listed as inactive is included in the calculation of person-years. Person-years for each patient in the program are summed to yield the total person-years.

Number of deaths: The number of deaths that occurred after addition to the waiting list during the period is reported. This includes deaths reported to OPTN as the reason for waitlist removal and deaths identified using the NTIS DMF and CMS data.

Death rate: The death rate is calculated by dividing the number of deaths by the number of person-years and is interpreted as number of deaths per person-year of observation.

Expected death rate: The expected death rate is the rate that would be expected at this program based on national experience. The expected rate takes into account various patient characteristics in an attempt to adjust for differences among programs. For more detail about how the expected death rate is estimated, please refer to *Appendix B: Detailed Statistical Methods*.

Ratio of observed to expected deaths: The ratio of observed to expected deaths is calculated by dividing the death rate by the expected death rate. A ratio of less than 1 indicates a lower than expected death rate, while a ratio greater than 1 indicates a higher than expected death rate.

95% confidence interval: The 95% confidence interval provides a measure of the statistical uncertainty associated with the estimated ratio of observed to expected death rates. Smaller transplant programs generate less information to use in estimating death rates, so their confidence intervals are wider. The lower and upper bounds define a range likely to include the true ratio. If the confidence interval includes 1, we cannot conclude that this program's death rate is statistically different from what would be expected, and any differences observed could be due to random chance. For more information, please refer to *Appendix B: Detailed Statistical Methods*.

P value: The *P* value indicates whether the death rate is statistically significantly different from the expected death rate. A value less than 0.05 indicates that the program's death rate is significantly different (higher or lower) from the expected death rate. For more detail, please refer to *Appendix B: Detailed Statistical Methods*.

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Additional observations and caveats
Candidates listed for a combined liver and intestine transplant are often also listed for a pancreas transplant for the purpose of maintaining vascular continuity. Candidates listed for a pancreas transplant who are simultaneously on the intestine transplant waiting list are excluded from all statistics.

These data are also presented by age (adult versus pediatric candidates). Expected results are not included in the age breakdowns.

Table B6: Waiting list candidate status after listing

Table B6 shows the status of candidates at this program at 6, 12, and 18 months after being added to the waiting list:. For purposes of comparison, corresponding data for the US as a whole are reported at the same time points.

Inclusion criteria
Candidates who were added to the waiting list at this program between January 1, 2014, and December 31, 2014 are included.

Exclusion criteria
None.

Table details
Candidate waitlist status is determined using waitlist removal codes.

Alive on waiting list: Candidates who had not been removed from the waiting list at a given time point were considered to be alive on the waiting list at that time point.

Died on the waiting list without transplant: Candidates who had not been removed from the waiting list before death were considered to have died on the waiting list without transplant.

Removed without transplant: Candidates who had been removed from the waiting list due to worsened condition, improved condition, refusing transplant, or other reason are considered to have been removed without transplant.

Transplant: Candidates who had been removed from the waiting list due to transplant were considered to have undergone transplant. Status of the patient posttransplant was determined from follow-up records collected after the transplant. Posttransplant waitlist and survival status categories include: functioning (alive), graft is functioning, patient is alive; failed-retransplanted (alive), graft failed, patient underwent another transplant, patient is alive; failed-alive no retransplant, graft failed, patient did not undergo another transplant, patient is alive; and died, patient died. Candidates with removal codes indicating transplant but with no transplant record or follow-up record on or after the given time point associated with that candidacy are categorized under the appropriate transplant heading (living or deceased donor) and designated “status yet unknown.” For a small number of recipients, a recipient follow-up form had not become due by the given time point; these recipients may be designated “status yet unknown.”

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***Lost or transferred (status unknown*):** Patients who were lost to follow up and whose status is unknown.

Percentages on the lines in Table B6 above the "total" line add to 100%. The last four lines of the table contain summary death and transplant percentages, including:

- *Total % known died on waiting list or after transplant:* Includes all patients reported to have died by that follow-up point, including those who died before or after a possible transplant.
- *Total % known died or removed as unstable:* All patients in % above, plus those who were removed from the waiting list due to deteriorating medical condition but were not reported to have died.
- *Total % removed for transplant:* Patients removed from the waiting list due to transplant on or before the reporting time point, regardless of the current status of the transplant.

Total % with known functioning transplant (alive): All living patients whose grafts were still functioning at the reporting time point.

Additional observations and caveats
The death counts reported here include only deaths reported as waitlist removals due to death and deaths reported on transplant recipient follow-up forms. These data sources are not designed to identify all deaths, so the deaths reported may be an under-count. Similarly, the graft failures reported here are based on transplant follow-up forms and do not include failures that occur after patients are reported as lost to follow-up.

For liver programs, additional tables provide the same data stratified by medical urgency status at the time of listing.

Tables B7-B8: Percent of candidates with deceased donor transplants by demographic and medical characteristics

Tables B7-B8 report the percentages of candidates added to the waiting list from July 1, 2010, through June 30, 2013, who underwent transplant at the specified times (1 month, 1 year, 2 years, and 3 years after listing), for the program and, for purposes of comparison, for the US as a whole.

Inclusion criteria
Candidates added to the waiting list between July 1, 2010, and June 30, 2013, are included. The analysis includes candidates whose waitlist status was temporarily inactive.

Exclusion criteria
Candidates who were removed from the waiting list with a removal code indicating transplant from a living donor are excluded. Candidates listed only for pancreatic islets are excluded from pancreas reports.

Table details
The percentages are calculated as simple fractions by dividing the number of candidates in a given category by the total number of candidates. The analysis continues to follow candidates over time who were removed from the waiting list for reasons other than undergoing transplant. Therefore, candidates who die before undergoing transplant are counted at all reported time points as not having undergone transplant. Each percentage is calculated for all patients and within subpopulations defined by the following: ethnicity/race, age, gender, blood type, previous transplant, primary cause of disease, peak PRA (kidney, pancreas, and kidney/pancreas programs

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only), years since diabetes onset (pancreas and kidney/pancreas programs only), and medical urgency status (heart and liver programs only). For primary disease reporting, when retransplant is noted in data collection as the primary diagnosis, the primary diagnosis reported for the initial transplant is used to indicate the initial primary disease causing organ failure. The missing category may include some patients for whom retransplant is indicated but no prior diagnosis can be found. A more detailed description of each characteristic appears in *Appendix A: Definitions of Candidate, Recipient, and Donor Characteristics*.

The percentages are calculated as: 100 × (number of candidates added to the waiting list between July 1, 2010, and June 30, 2013, who underwent transplant before a specified number of months after listing)/(total number of candidates added to the waiting list between July 1, 2010, and June 30, 2013).

The national statistics count patients with multiple listings multiple times to be comparable to the program-level statistic, which counts each candidate at the program and only transplants at that program.

Table B9: Time to transplant for waiting list candidates

Table B9 provides estimates of time to transplant at the program. The 5th, 10th, 25th, 50th (median), and 75th percentile waiting times until transplant (deceased or living donor) for candidates added to the waiting list between July 1, 2010, and December 31, 2015, are shown when applicable. For example, if the 25th percentile time to transplant is 10.5 months, 25% of the candidates listed at this program during the period underwent transplant 10.5 months after being listed. For purposes of comparison, corresponding times to transplant at each percentile in this program's OPTN region and the US as a whole are also reported. Patients with multiple listings are counted multiple times in this analysis.

Inclusion criteria
All patients added to the waiting list at this program between July 1, 2010, and December 31, 2015, are included.

Exclusion criteria
None.

Table details
Waiting time until transplant is calculated as the time (in months) after a candidate is added to the waiting list by which the corresponding percentage of all candidates initially listed had been removed from the list due to undergoing transplant. A Kaplan-Meier model was used with censoring on a) December 31, 2016, for candidates still waiting on that date, b) the date of removal from the list due to recovery, or c) the date of removal from the list due to transfer. Patient follow-up is not censored in the event of death or removal due to deteriorated medical status. These patients are considered not to have undergone transplant for all remaining percentile estimates. The model also includes time during which a candidate may be in temporary inactive status. The longest possible observation time in this analysis is 72 months (from July 1, 2010, to last follow-up on December 31, 2016).

A designation of "Not Observed" indicates that fewer than that percentile of patients had undergone transplant. For example, the 50th percentile of time to transplant is the time when 50% of candidates have undergone transplant. If waiting times are long, then the 50th percentile may not be observed during the follow-up period. Also, if more than 50% of candidates are removed from the list due to death or other reasons before undergoing transplant, then the 50th percentile of time to transplant will not be observed.

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At the time a candidate is listed for transplant and while the candidate is waiting, accurate predictions of waiting time are difficult to make. Many factors influence waiting time, including the candidate's health status, blood and tissue types, the allocation system, and the program's organ acceptance behavior, so the time to transplant for the program's entire list may not accurately depict waiting times for an individual candidate.

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Section C: Transplant Information

Tables C1-C2: Transplant recipient demographic and medical characteristics

Tables C1-C2 summarize the characteristics of transplant recipients who underwent transplant between July 1, 2015, and June 30, 2016, at this program, with corresponding values for recipients in this program's OPTN region and the US as a whole. Tables C1 and C2 report deceased and living donor transplants for kidney, liver, and lung programs. For all other programs, only data for deceased donor transplants are shown. Percentages are reported for each characteristic. These add to 100%, except for rounding anomalies. Recipients with missing information are categorized as unknown or missing.

Inclusion criteria
For kidney, liver, and lung programs, all patients undergoing transplant during the 1-year period (July 1, 2015, through June 30, 2016) are included; recipients of deceased donor and living donor transplants are reported separately. For all other program types, only recipients of deceased donor transplants are included.

Exclusion criteria
For programs other than kidney, liver, and lung, recipients of living donor transplants are excluded.

Table details
Patient count (n): The numbers of patients who underwent transplant during the period at this program, in this program's OPTN region, and in the US as a whole are reported. The percentages shown in Tables C1-C2 are based on these patient population counts.

Body mass index: Body mass index (BMI) is calculated at transplant as the recipient's weight (kg) divided by the height (m) squared: BMI = weight (kg)/ height^2 (m^2). Percentages of recipients in each of several BMI ranges (0-20, 21-25, 26-30, ≥ 31) are reported.

Recipient medical condition at transplant: Percentages of recipients in intensive care, hospitalized, and not hospitalized are reported. The percentage with no condition reported is shown as unknown.

Recipient mechanical, ventilated, or organ-perfusion support status at transplant (heart only): Life support status is divided into 3 groups: no support mechanism, devices (including ventricular assist devices [VAD], extracorporeal membrane oxygenation [ECMO], intraaortic balloon pump [IABP], total artificial heart [TAH]), other support mechanism, and unknown [no status reported]).

Additional recipient characteristics (organ dependent) include: ethnicity/race, age, gender, blood type, previous transplants, peak PRA (kidney, pancreas, and kidney/pancreas programs only), primary diagnosis group (not shown for pancreas and kidney/pancreas programs), recipient medical urgency status at the time of listing (liver and heart programs for patients with deceased donors only), recipient medical urgency status at transplant (liver and heart programs for patients with deceased donors only). A more detailed description of each characteristic appears in *Appendix A: Definitions of Candidate, Recipient, and Donor Characteristics*.

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Table C3: Donor characteristics

Table C3 summarizes the characteristics of donors between July 1, 2015, and June 30, 2016, whose organs were used for transplant at this program, with corresponding values for donors in this program's OPTN region and in the US as a whole. Only donors whose organs were transplanted into recipients at this program, in the OPTN region, and in the US as a whole are included. Table C3 reports deceased and living donor transplants separately for kidney, liver, and lung programs. For all other programs, only data for deceased donor transplants are shown.

Inclusion criteria
All donors whose organs were transplanted into recipients during the period are included.

Exclusion criteria
Donors whose organs were recovered for transplant but not transplanted are excluded.

Table details
Donor count (n): The total number of donors whose organs were transplanted at this program during the time period and were of the program's organ type is reported. The percentages in Table C3 are based on this donor population count.

Cause of death: For deceased donors, the percentage of organs recovered and transplanted from donors in each of the major cause-of-death categories is reported. The categories for cause of death are stroke, motor vehicle accident (MVA), and other.

Expanded criteria donors (deceased kidney donors only): The percentages of donors who did and did not meet the expanded criteria donor definition are reported. Donors who meet the expanded criteria are:

- aged older than 60 years, or
- aged between 50 and 59 years and meeting 2 of the following 3 conditions: died of a stroke, history of hypertension, serum creatinine level greater than 1.5 mg/dL.

Additional donor characteristics (organ dependent) include: age, ethnicity/race, gender, and blood type. A more detailed description of each characteristic appears in *Appendix A: Definitions of Candidate, Recipient, and Donor Characteristics*.

Table C4: Deceased donor transplant characteristics

Table C4 summarizes the characteristics of deceased donor transplants performed between July 1, 2015, and June 30, 2016, at this program, with corresponding values for transplants performed in this program's OPTN region and in the US as a whole. For kidney, liver, and lung programs, a comparable table summarizing characteristics of living donor transplant operations is also provided.

Inclusion criteria
For kidney, liver, and lung programs, all transplants during the 1-year period (July 1, 2015, through June 30, 2016) are included, with deceased donor and living donor transplants reported separately. For all other program types, only deceased donor transplant are included for the 1-year period.

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Exclusion criteria
For programs other than kidney, liver, and lung, living donor operations are excluded.

Table details
Patient count (n): The total numbers of deceased donor transplants during this period at this program, in this program's OPTN region, and in the US as a whole are reported. For kidney and liver programs, the total numbers of living donor transplants during this period at this program, in this program's OPTN region, and in the US as a whole are also reported. The percentages in Table C4 are based on these patient population counts.

Cold ischemic time (deceased donor transplants only): The percentages of transplants in each category of cold ischemic time are reported by whether the donated organ was procured locally or from outside the DSA (see Sharing below). This time is divided into 90-minute increments for thoracic organs and by ranges of hours for other organs.

Relation with donor (living donor transplants only): The percentages of organs whose living donor was biologically related, such as sibling, parent, or other family member, and biologically unrelated, such as spouse, anonymous donor, or paired exchange, are reported. The percentages of organs with unknown relation (not reported) is also given.

Level of mismatch: Level of HLA mismatch (0-6) is calculated by comparing antigen values for the A, B, and DR loci between donors and their respective recipients, accounting for known antigen splits as detailed in Appendix A to OPTN Policy 3 (available online at optn.transplant.hrsa.gov).

Procedure type: The procedure type, i.e., whether the organ was transplanted alone or with other organs, is shown.

Dialysis in first week after transplant (kidney and kidney-pancreas only): The percentage of patients who received dialysis treatment within 1 week after transplant is shown.

Sharing (deceased donor transplants only): The percentage of transplants for which the organ was procured from outside the program's DSA (shared) and the percentage for which the organ was procured from within the DSA (local) are shown.

Median time in hospital after transplant: The median number of days the patient remained in the hospital after undergoing transplant is shown. If a patient undergoes multiple transplants of the same organ during the same hospital stay, the number of days is from the first transplant until the final discharge date. Multiple organ transplants are excluded from this statistic in most cases. The kidney-pancreas and heart-lung tables include kidney-pancreas or heart-lung transplants, but not other multi-organ transplants.

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Tables C5-C10, Figures C1-C12: Graft survival

Tables C5-C10 and Figures C1-C12 report graft survival (the fraction of patients alive with functioning grafts) at 1 month, 1 year, and 3 years after transplant for the program, with corresponding values for the US.

Inclusion criteria (graft survival)
For the 1-month and 1-year statistics, transplants occurring between July 1, 2013, and December 31, 2015, are included. For the 3-year statistics, transplants occurring between January 1, 2011, and June 30, 2013, are included.

Exclusion criteria (graft survival)
Living donor transplants are included only for kidneys and livers. The heart, lung, liver, kidney, and pancreas tables include only single-organ transplants. The kidney-pancreas and heart-lung tables include only kidney-pancreas or heart-lung transplants, but not other multi-organ transplants. The intestine tables include single-organ intestine, liver-intestine, pancreas-intestine, and pancreas-liver-intestine transplants. Heterotopic heart and liver transplants are excluded. Pancreas graft survival reporting has been suspended due to concerns about inconsistent reporting of pancreas graft failures. SRTR intends to resume reporting pancreas graft survival after the OPTN Pancreas Transplantation Committee standardizes criteria for reporting pancreas graft failures.

For the purpose of excluding multi-organ transplants from the heart, lung, liver, kidney, and pancreas reports, a multi-organ transplant is defined as receiving more than one organ from the same deceased donor. In addition, a living donor kidney transplanted with a deceased donor pancreas is considered a multi-organ transplant if the two transplants took place within 3 days of each other.

Details (graft survival)
Statistics are reported separately for adult (age 18 years or older) and pediatric (age younger than 18 years) recipients. In addition, statistics are reported separately by donor type (deceased or living) for kidney and liver programs. For some organs or patient subgroups, too few transplants or events occurred to allow for calculation of meaningful statistics. Table 2 indicates which statistics are calculated for each organ.

Table 2. Statistics Reported in Graft Survival Figures by Organ

	Counts of Transplants and Estimated[1] Graft Survival		Expected[2] Graft Survival	
Organ	**Age ≥ 18 Years**	**Age < 18 Years**	**Age ≥ 18 Years**	**Age < 18 Years**
Heart	Yes	Yes	Yes	Yes
Heart-lung	Yes	No	No	No
Lung	Yes	Yes	Yes	No
Liver	Yes	Yes	Yes	Yes
Kidney	Yes	Yes	Yes	No
Intestine	Yes	Yes	No	No
Pancreas	No	No	No	No

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	Counts of Transplants and Estimated[1] Graft Survival		Expected[2] Graft Survival	
Organ	**Age ≥ 18 Years**	**Age < 18 Years**	**Age ≥ 18 Years**	**Age < 18 Years**
Kidney from a kidney-pancreas	Yes	No	Yes	No
Pancreas from a kidney-pancreas	No	No	No	No

[1]Graft survival was estimated using Kaplan-Meier methodology to allow inclusion of patients with incomplete follow-up.
[2]Expected graft survival is based on data from the US as a whole to evaluate the survival expected for patients at each program, based on their characteristics.

Methods for calculation and follow-up: Follow-up was not complete for all transplant recipients through the end of the time interval. However, all available follow-up data for each graft were used in the calculation of the statistics reported here using standard censored data methods of survival analysis (Cox 1972, Kaplan-Meier 1958). Additional data from the Social Security Death Master File (SSDMF) and from CMS have been incorporated into the graft survival rates.

Recipients of transplants performed in the last 6 months of the accrual period for the 1-year reporting time point are followed for only 6 months after transplant because the 1-year follow-up information is not yet available in the current OPTN data. Standard survival analysis methods are used to incorporate the first 6 months of experience for this subset of patients.

The observed percentages of grafts surviving at 1 month, 1 year, and 3 years are calculated from the follow-up data using the Kaplan-Meier method, and are estimates of the fraction of all grafts that would continue to function at the reporting time point had they been followed to that time. The Kaplan-Meier method uses all data, including the incomplete data for patients who were lost to follow-up before the end of the period. The Kaplan-Meier method assumes that the failure rate would be the same for patients lost to follow-up as was observed for patients with complete data.

Transplants for which graft failure was recorded as having occurred before the transplant date and transplants with no follow-up forms, missing last follow-up date, or last follow-up date before the transplant date are analyzed as censored (lost to follow-up) on the day of transplant.

Number of transplants: The total numbers of transplants meeting the inclusion/exclusion criteria during the accrual periods for the 1-month, 1-year, and 3-year graft survival analyses are shown for each patient/age cohort. The 1-month and 1-year counts are the same because the accrual periods are the same.

Estimated graft survival: For all organs, deaths are considered to be graft failures. Once a patient dies, the length of time the graft would have functioned had the patient lived cannot be determined. The SSDMF and CMS data are used in conjunction with OPTN data to identify deaths. In the case of conflicting death dates from various sources, the OPTN death date takes precedence. If there is no OPTN death date and dates from SSDMF and CMS conflict, the SSDMF date takes precedence.

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Graft failure is defined differently for different organs. A graft is counted as failed when follow-up information indicates that one of the following has occurred before the reporting time point: 1) graft failure (except for heart and liver, when retransplant dates are used instead), 2) retransplant (for all transplants except heart-lung and lung), or 3) death. OPTN follow-up forms are used to identify graft failure and retransplant dates.

- *Lung and heart-lung:* Patients are followed until graft failure or death, with follow-up censored at the last OPTN follow-up date. If the patient dies before the last OPTN follow-up, the death date is the graft failure date. Deaths after this date are not included in the analyses. If a patient is recorded as lost to follow-up on one follow-up record, any subsequent follow-up records are disregarded. These calculations do not include deaths that occur after loss to follow-up in the OPTN database, because the date of graft failure is unknown and may have occurred before the death.

- *Kidney, pancreas, kidney-pancreas, and intestine:* Patients are followed until graft failure, retransplant, or death, with follow-up censored at the last OPTN follow-up date. If the patient dies or undergoes retransplant before the last OPTN follow-up, the death or retransplant date is used as the graft failure date. Deaths or retransplants after this date are not included in the analyses. For these organs, after a patient is recorded as lost to follow-up on one follow-up record, any subsequent follow-up records are disregarded. These calculations do not include deaths that occur after loss to follow-up in the OPTN database, because the date of graft failure is unknown and may have occurred before the death.

- *Heart and liver:* Patients are followed until retransplant or death. For the heart and liver analyses, extra ascertainment of graft failure after the last OPTN follow-up date is not needed because there is no alternative therapy. A patient whose graft fails will undergo retransplant or die. The calculations of graft failure therefore can continue until the reporting time-point even if the recipient is lost to follow-up in the OPTN data. Accordingly, for heart and liver transplants, follow-up for graft survival is not censored at the last OPTN follow-up date and the OPTN graft failure date is not used. Instead, only deaths and retransplants are used as graft failure dates.

Expected graft survival: Expected graft survival is the fraction of grafts that would be expected to be functioning at each reported time point, based on the national experience for recipients similar to those at this program. If the observed graft survival is greater than the expected graft survival, then graft survival is better at this program than would be expected based on the national transplant experience for similar grafts and recipients. The national experience was analyzed using data for all grafts at all programs in the US. A Cox proportional hazards regression model for time to graft failure (Cox 1972) was fit to the national data, and yielded the probability of graft failure for each patient based on each patient's characteristics at the reporting time point. The expected survival is the average of these computed probabilities. Models are fit separately by age group (adult and pediatric) and cohort (1-month/1-year and 3-year). For kidney and liver transplants, models are also fit separately for living and deceased donor transplants. The expected graft survival for each organ is adjusted for the patient, donor, and transplant characteristics as listed in the risk-adjustment models, available on the SRTR website at http://www.srtr.org/csr/current/modtabs.aspx. A more detailed description of the methodology used to compute expected graft survival appears in *Appendix B: Detailed Statistical Methods*.

Hazard ratio: For statistical comparisons, it is appropriate to estimate a program's graft failure rate compared with the expected graft failure rate, based on donor and recipient characteristics. A ratio greater than 1 indicates that more graft failures occurred than would have been expected based on the national experience, while a ratio less than 1 indicates that fewer graft failures occurred than would have been expected based on the national experience. For example, a ratio of 1.20 indicates that the graft failure rate at the program was, on average, 20%

higher than the national rate. A ratio equal to 1.00 indicates that the graft failure rate was the same as the national rate. The hazard ratio shown in the reports is the posterior mean hazard ratio. The posterior distribution of the hazard ratio is a function of the prior distribution of the hazard ratio and the likelihood of the program's data. The prior distribution used is a gamma distribution with mean 1 and variance 0.5. The observed number of graft failures follows a Poisson distribution with mean equal to the number of expected graft failures. The resulting posterior distribution is also a gamma distribution whose mean is (2 + number of observed graft failures)/(2 + number of expected graft failures).

95% credible interval: The 95% credible interval shows a range of likely values for the hazard ratio. There is a 95% posterior probability that the hazard ratio is within the interval. The 95% credible interval is calculated as a central interval, which means that there is a 2.5% posterior probability that the hazard ratio is higher than the upper limit of the interval and a 2.5% posterior probability that the hazard ratio is lower than the lower limit of the interval.

MPSC review criteria (SRTR secure site release only): This section contains information used by the OPTN Membership and Professional Standards Committee (MPSC) to identify programs for review: 1) (probability hazard ratio > 1.20) > 75% (i.e., there is more than a 75% probability that the program's graft failure rate is at least 20% higher than expected), OR 2) (probability hazard ratio > 2.50) > 10% (i.e., there is more than a 10% probability that the program's graft failure rate is at least 150% higher than expected). This section is for each program's information and review and will not appear on the public version of the reports.

Tables C11-16, Figures C13-C23: Patient survival

Tables C11-16 and Figures C13-C24 report patient survival (the fraction of patients who are still alive) at several time points after first transplant of this organ type. Patient survival is reported at the 1-month, 1-year, and 3-year reporting time points for each program, with corresponding rates for the US.

Inclusion criteria (patient survival)
For the 1-month and 1-year statistics, transplants that occurred between July 1, 2013, and December 31, 2015, are included. For the 3-year statistics, transplants that occurred between January 1, 2011, and June 30, 2013, are included. These tables and figures include all patients who underwent first transplant of this organ type during the accrual period. Patients who had previously undergone transplant of this type, whether the previous transplant occurred during the accrual period or not, are not included. For this reason, the patient count in Tables C11-C16 and Figures C13-C24 may be smaller than the transplant count in Tables C5-C10 and Figures C1-C12.

Exclusion criteria (patient survival)
Patients undergoing subsequent transplant of this type are excluded from patient survival analyses. Patients undergoing living donor transplants are included only for kidneys and livers. The heart, lung, liver, kidney, and pancreas tables include only patients undergoing single-organ transplants. The kidney-pancreas and heart-lung tables include only patients undergoing kidney-pancreas or heart-lung transplants, but not other multi-organ transplants. The intestine tables include patients undergoing single-organ intestine, liver-intestine, pancreas-intestine, or pancreas-liver-intestine transplants, but not other multi-organ transplants. Patients undergoing heterotopic heart and liver transplants are excluded.

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For the purpose of excluding multi-organ transplants from the heart, lung, liver, kidney, and pancreas reports, a multi-organ transplant is defined as receiving more than one organ from the same deceased donor. In addition, a living donor kidney transplanted with a deceased donor pancreas is considered a multi-organ transplant if the two transplants took place within 3 days of each other.

Table details (patient survival)
Statistics are reported separately for adult (age 18 years or older) and pediatric (age younger than 18 years) patients. In addition, statistics are reported separately by donor type (deceased or living) for kidney and liver programs. For some organs or subgroups of patients, there are too few transplants or too few events to calculate meaningful statistics. Table 3 indicates which statistics are calculated for each organ.

Table 3. Statistics Reported in Patient Survival Figures, by Organ

	Counts of Transplants and Estimated[1] Patient Survival		Expected[2] Patient Survival	
Organ	**Age ≥ 18 Years**	**Age < 18 Years**	**Age ≥ 18 Years**	**Age < 18 Years**
Heart	Yes	Yes	Yes	Yes
Heart-lung	Yes	No	No	No
Lung	Yes	Yes	Yes	No
Liver	Yes	Yes	Yes	Yes
Kidney	Yes	Yes	Yes	No
Intestine	Yes	Yes	No	No
Pancreas	Yes	No	Yes	No
Kidney-pancreas	Yes	No	Yes	No

[1]Graft survival was estimated using Kaplan-Meier methodology to allow inclusion of patients with incomplete follow-up.
[2]Expected graft survival is based on data from the US as a whole to evaluate the survival expected for patients at each program, based on their characteristics.

Additional data from the SSDMF and from CMS have been incorporated into the patient survival rates. The SSDMF and CMS data are used in conjunction with OPTN data to determine whether each patient is alive at the end of the follow-up period.

Number of patients: The total number of patients reported to have undergone first transplant of the organ type during the accrual periods for the 1-month, 1-year, and 3-year patient survival analyses are shown for each patient/age cohort. The 1-month and 1-year counts are the same since the accrual periods are the same. This reports patient counts, not transplants counts, and therefore differs from the transplant counts in Tables C5-C10 and Figures C1-C12.

Estimated patient survival: A patient is counted as having died when OPTN follow-up information, SSDMF data, or CMS data indicate that a death has occurred before the reporting time point. In the case of conflicting death dates from various sources, the OPTN death date takes precedence. If there is no OPTN death date and dates from SSDMF and CMS conflict, the SSDMF date takes precedence. Patients not reported to have died in any source are assumed to be alive.

Patients who undergo transplant in the last 6 months of the accrual period for the 1-year reporting time point are followed for only 6 months after transplant because the 1-year follow-up information is not yet available in the current OPTN data. Standard survival analysis methods are used to incorporate the first 6 months of experience for this subset of patients.

The follow-up time for each patient (days at risk) is the number of days from transplant until death or the reporting time point (e.g., 1 month, 1 year, or 3 years) occurs, whichever is earliest. The observed patient survival at 1 month, 1 year, and 3 years was calculated using the Kaplan-Meier method. It is an estimate of the fraction of all accrued patients who would still be alive at the reporting time point had they been followed to that time.

Expected patient survival: Expected patient survival reflects the fraction of patients who would be expected to be alive at each reported time point, based on the national experience for patients similar to those at this program. If the observed patient survival is greater than the expected patient survival, then patient survival is better than would be expected based on the national transplant experience for similar patients. The national experience was analyzed using data for all accrued transplants at all programs in the US. A Cox proportional hazards regression model for time to death (Cox 1972) was fit to the national data, which yielded the probability of survival to the reporting time point for each patient, based on the characteristics of each recipient, donor, and transplant, and on the reporting time point. The expected survival is the average of these computed probabilities. Models are fit separately by age group (adult and pediatric) and cohort (1-month/1-year and 3-year). For kidney and liver transplants, models are also fit separately for living and deceased donor transplants. The expected patient survival for each organ is adjusted for patient, donor, and transplant characteristics as listed in the risk-adjustment models available on the SRTR website at: http://www.srtr.org/csr/current/modtabs.aspx. See *Appendix B: Detailed Statistical Methods* for details on the calculation of the expected patient survival.

The patient survival model-fitting procedure for pancreas transplant recipients is somewhat different. First, separate models are used for three different categories of pancreas transplant: pancreas after kidney transplant (PAK), pancreas transplant alone (PTA), and simultaneous pancreas-kidney (SPK). Second, the fitted models used an expanded cohort that included the standard 2.5-year cohort of recipients used for reporting and the preceding 2.5-year cohort. The goal of the expanded cohort is to generate more reliable models given the limited number of pancreas transplants performed. The models feature two strata, one for each 2.5-year cohort.

Hazard ratio: For statistical comparisons, it is appropriate to estimate a program's death rate compared with the expected death rate, based on donor and recipient characteristics. A ratio greater than 1 indicates that more deaths occurred than would have been expected based on the national experience, while a ratio less than 1 indicates that fewer deaths occurred than would have been expected based on the national experience. For example, a ratio of 1.20 indicates that the death rate was, on average, 20% higher than the national rate. A ratio equal to 1.00 indicates that the death rate was the same as the national rate. The hazard ratio shown in the reports is the posterior mean hazard ratio. The posterior distribution of the hazard ratio is a function of the prior distribution of the hazard ratio and the likelihood of the transplant program's data. The prior distribution used is a gamma distribution with mean 1 and variance 0.5. The observed number of deaths follows a Poisson distribution

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with mean equal to the number of expected deaths. The resulting posterior distribution is also a gamma distribution whose mean is (2 + number of observed deaths)/(2 + number of expected deaths).

95% credible interval: The 95% credible interval shows a range of likely values for the hazard ratio. There is a 95% posterior probability that the hazard ratio is within the interval. The 95% credible interval is calculated as a central interval, which means that there is a 2.5% posterior probability that the hazard ratio is higher than the upper limit of the interval and a 2.5% posterior probability that the hazard ratio is lower than the lower limit of the interval.

MPSC review criteria (SRTR secure site release only): This section contains information used by the MPSC to identify programs for review: 1) (probability hazard ratio > 1.20) > 75% (i.e., there is more than a 75% probability that the program's patient failure rate is at least 20% higher than expected), OR 2) (probability hazard ratio > 2.50) > 10% (i.e., there is more than a 10% probability that the program's patient failure rate is at least 150% higher than expected). This section is for each program's information and review and will not appear on the public version of the reports.

Section D: Living Donor Information

Table D1: Living Donor summary

Table D1 shows the number and percentage of living donors at this program for whom timely clinical and lab data were reported at 6, 12, and 24 months following donation. This includes living donors at this program from July 1, 2013 to December 31, 2015. Follow-up completion standards through 2 years post-donation were implemented in OPTN policy on February 1, 2013 so follow-up information is not summarized prior to this date. National statistics are also provided for comparison.

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Appendix A: Definitions of Candidate, Recipient, and Donor Characteristics

Ethnicity/Race

The percentage of candidates, recipients, or donors in each of five race categories is reported. The current OPTN data collection forms do not distinguish between the concepts of *race* (e.g., Asian) and *ethnicity* (e.g., Hispanic), but the forms allow users to indicate any and all races and ethnicities as appropriate. While many subcategories of race are available to choose from, we collapse race into five major categories: Asian/Pacific Islander, African-American, white, Hispanic/Latino, a combined group for other races (including multi-racial), and unknown. Patients coded as both white and Hispanic are coded as Hispanic. Missing values are reported as unknown.

Age

Age is determined as of the date of addition to the waiting list, transplant, or organ procurement for each candidate, recipient, and donor, respectively, unless otherwise indicated in a specific table. The percentage in each of several age ranges is reported.

Blood Type

The percentage of candidates, recipients, or donors by ABO type (A, B, AB, O) is reported. Those with ABO type A1 or A2 are classified as A. Those with ABO type A1B or A2B are classified as AB.

Previous Transplants

The percentage of candidates or recipients for whom data forms indicate any previous transplant is reported.

Initial Calculated Panel-Reactive Antibody (CPRA)

The candidate's initial CPRA when added to the waiting list is shown for kidney, pancreas, or kidney/pancreas transplants.

Peak Panel-Reactive Antibody (PRA)

The candidate's or recipient's highest CPRA or traditional PRA when added to the waiting list and at the time of transplant is shown for candidates for and recipients of kidney, pancreas, or kidney/pancreas transplants. Both CPRA and PRA are considered because the reporting timeframe overlaps the period of time when CPRA was being implemented. The percentage of candidates in each of several PRA ranges (0-9, 10-79, ≥ 80) is reported.

Body Mass Index (BMI)

BMI is calculated at transplant as the recipient's weight divided by the height squared (BMI = weight (kg)/height^2 (m^2)). The percentage of recipients in each of several BMI ranges (0-20, 21-25, 26-30, ≥ 31) is reported. Shown in transplant recipient characteristics only.

Primary Diagnosis Group

The percentage of patients in each of the major categories of primary causes of organ failure is reported. The major categories for each organ are shown below. Primary diagnosis group is not shown for pancreas and kidney/pancreas programs because virtually all such patients undergo transplant due to diabetes mellitus.

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Kidney

- Glomerular diseases
- Tubular and interstitial disease
- Polycystic kidney disease
- Congenital, familial, and metabolic kidney diseases
- Diabetes mellitus
- Renovascular and vascular diseases
- Neoplasms
- Hypertensive nephrosclerosis
- Retransplant/graft failure
- Other kidney diseases
- Missing

Liver

- Acute hepatic necrosis
- Non-cholestatic cirrhosis
- Cholestatic liver disease/cirrhosis
- Biliary atresia
- Metabolic diseases
- Malignant neoplasms
- Other
- Missing

Intestine

- Short-gut syndrome
- Functional bowel problem
- Retransplant/graft failure
- Other
- Missing

Heart

- Cardiomyopathy
- Coronary artery disease
- Retransplant/graft failure
- Valvular heart disease
- Congenital heart disease
- Other
- Missing

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Lung

- Congenital disease
- Retransplant/graft failure
- Primary pulmonary hypertension
- Cystic fibrosis
- Idiopathic pulmonary fibrosis
- Alpha-1-antitrypsin deficiency
- Emphysema/chronic obstructive pulmonary disease (COPD)
- Other
- Missing

Heart-Lung

- Congenital disease
- Retransplant/graft failure
- Primary pulmonary hypertension
- Cystic fibrosis
- Idiopathic pulmonary fibrosis
- Alpha-1-antitrypsin deficiency
- Emphysema/chronic obstructive pulmonary disease (COPD)
- Other
- Missing

Recipient Medical Urgency Status When Added to the Waiting List

The medical urgency status of the candidate when registered on the waiting list and of the recipient at the time of transplant are shown for liver and heart programs. The percentage of recipients in each status type (livers: status 1A, 1B, model for end-stage liver disease (MELD)/ pediatric end-stage liver disease (PELD), temporarily inactive; hearts: status 1A, 1B, 2, temporarily inactive) is reported. MELD and PELD scores, implemented February 27, 2002, are computed based on the candidate's laboratory measures at the time of listing or transplant. If not all of the necessary laboratory values were measured, the candidate was assigned a MELD or PELD of 6, depending on age. This information is included for liver and heart programs for transplants with deceased donors only.

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Appendix B: Detailed Statistical Methods

In this appendix, we provide additional detail regarding how SRTR determines expected outcomes from transplant programs.

Determination of Expected Outcomes

SRTR estimates expected outcomes for two waitlist outcomes (reported in Table B1): the transplant rate and the death rate. The expected rates are defined as follows:

- Expected transplant rate: the number of waitlist candidates expected to have been removed from the waiting list due to undergoing transplant divided by the number of person-years on the waiting list.
- Expected waitlist death rate: The number of deaths expected to have occurred after registration on the waiting list divided by the number of person-years of observation after registration on the waiting list.

In addition, SRTR estimates expected counts of graft failures and deaths posttransplant (reported in Tables C5-C16 and Figures C1-C24). The methodologies used to estimate these expected event rates and counts are similar across the different outcomes.

The national experience is analyzed using data for waitlist outcomes, graft survival, and patient survival at all programs in the US. A Cox proportional hazards regression model (Cox 1972) for time to event (removal from waiting list, post-listing death, graft failure, and posttransplant death) was fit to the national data to obtain the expected probability of event for each patient based on the characteristics of each patient, donor, and transplant (as appropriate for the outcome being studied) and the reporting time point. Models for posttransplant outcomes are fit separately by age group (adult and pediatric), donor type (for kidney and liver) and reporting cohort (1-month/1-year and 3-year). The models use various patient, donor, and transplant characteristics to risk-adjust the expected event probability. The characteristics accounted for in the risk-adjustment models are reported on the SRTR website at http://www.srtr.org/csr/current/modtabs.aspx.

The factors included in the risk-adjustment models differ for each organ and patient cohort, so we refer to the list of characteristics generically with the notation *x*. Individual patients are numbered sequentially from 1 to the total number of patients (N), and we refer generically to the *i*th patient. The specific values of the characteristics for patient *i* are denoted by x_i. Based on a model, we calculate $S_i(t)$, the probability of survival to time *t* for patients with characteristics x_i. The probability of survival at time point t_0 for patient *i* is $S_i(t_0)$. The average survival for the *n* accrued patients at the program is calculated as: $\left(\frac{1}{n}\right)\sum S_i(t_0)$ (Zucker). The expected number of events during follow-up for each patient was calculated as $-ln\left(S_i(t_i)\right)$, where $S_i(t_i)$ is the risk-adjusted survival curve for patient *i* and t_i is the follow-up time for patient *i* up to time t_0 (SAS/STATA User's Guide, Andersen, Collett). The expected number of events is $\sum -ln\left(S_i(t_i)\right)$ for the *n* transplants during the follow-up times for the patients at this program.

Details of the risk-adjustment models available on the SRTR website at www.srtr.org indicate the value of the coefficients for each characteristic in each of the models (betas, β) and the corresponding standard error and a *P* value indicating if the coefficient is significantly different from 0. The relative risk (RR) for mortality or graft loss associated with a particular patient characteristic, compared with the reference group for that characteristic, can be calculated as: e^{β}. For continuous variables, this is interpreted as the RR associated with 1 unit higher value (e.g., for ischemia time, the RR associated with time 1 hour longer). However, these models are estimated for the purposes of adjustment, not for interpretation of coefficients. Some standard errors are large, which reflects

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uncertainty in the interpretation of the corresponding covariate but does not adversely affect the accuracy of the adjusted estimate. For example, coefficients more negative than -7 can occur when there are no events in the corresponding group of patients.

Missing Data

In general, patients with missing values for variables entered into the model as categorical variables are included in their own category or in the reference group. Missing values for variables entered into the model as continuous values are either replaced with the mean value (these mean values are included as footnotes in the risk-adjustment tables) or with a value of 0. In some cases, there is also a categorical variable indicating whether the value was missing. Characteristics such as age are included in some models as categorical variables and in others as continuous variables.

The risk-adjustment tables list all the covariates included in each model and indicate (indirectly) how missing values were handled in each case. The variables corresponding to a particular characteristic or value in a model will indicate whether missing values are included in a category. If there is not a separate category for the missing values, patients with missing values are included in the reference group. For continuous values, there may be a category for patients with missing values, but these patients are also assigned a value for the continuous variable itself. If the reference indicated for the variable is the average value, then missing values are replaced with this average value (listed in the footnotes for each model description table). When the reference is the average value, the average value is subtracted from the patient's actual value as described below in the calculation section. Replacing missing values with this average therefore ultimately results in a 0 value for patients with missing data. If the reference is not indicated or is 0, then missing values are replaced with 0. In these cases, the actual value is used, again resulting in a 0 value for patients with missing data. Using the average value or a value of 0 for missing data does not affect the resulting estimates of coefficients, but it is necessary to know what was done when carrying out calculations based on these tables.

P values and Confidence Intervals

The *P* value measures the statistical significance (or evidence) for testing the (2-sided) hypothesis that the difference between the actual and expected rate is 0 or that the true ratio of rates for the program versus the nation equals 1.00. A smaller *P* value tends to occur when the ratio differs more greatly from 1.00 and when more patient data are used to calculate the ratio. A *P* value less than 0.05 is often taken as evidence that the ratio of observed and expected rates is different from 1.00 or that the difference between the actual and expected rate is probably real and is not due to random variation (or chance). A *P* value greater than 0.05 indicates that the difference between observed and expected could plausibly be due to random chance. However, a small *P* value does not indicate whether or not the magnitude of the difference between the rates at the program and the nation is clinically important. The actual quantitative value of the ratio reflects the clinical importance of the difference between the program and national rates. A ratio that differs greatly from 1.00 is more important while a ratio in the range 0.95 to 1.05 may not be interpreted as clinically important.

The *P* value is calculated by testing whether a program's observed numbers of transplants, graft failures, or deaths were greater or less than the expected numbers, based on the Poisson distribution using an exact Poisson test for the observed numbers of transplants, graft failures, or deaths. These values are not shown if no expected rate was calculated.

Note about 1-sided vs. 2-sided P values: The 2-sided *P* values presented in the PSRs are used to identify cases in which observed rates are statistically different from (above or below) expected rates. In other words, a 2-sided *P*

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value is used when the direction of the difference is not hypothesized. Since PSRs are intended to measure a difference in either direction, a 2-sided *P* value is shown. A 1-sided *P* value is used to test a hypothesis of a difference in a specific direction (e.g., lower than expected). To compute a 1-sided *P* value, divide the 2-sided *P* value in half, for the cases in which the observed difference is in the hypothesized direction. For example, the MPSC uses a 1-sided *P* value to test the hypothesis that more deaths or graft failures are observed than would be expected at a program. In this case, for a program with a 2-sided *P* value of 0.046 and an observed death count exceeding the expected death count, the 1-sided *P* value would be 0.023.

Confidence intervals are given to indicate the precision with which we can estimate the ratio of observed and expected rates, and are designed to give a plausible range within which the true ratio of observed and expected rates is likely to lie given the observed data. Confidence intervals for the ratio of observed and expected rates are calculated as:

$$L = \frac{O}{E}\left(1 - \frac{1}{9O} - \frac{Z\alpha_{/2}}{3\sqrt{O}}\right)^3$$

$$U = \frac{(O+1)}{E}\left(1 - \frac{1}{9(O+1)} + \frac{Z\alpha_{/2}}{3\sqrt{O+1}}\right)^3$$

where L is the lower bound of the confidence interval and U is the upper bound of the confidence interval, E is the expected count, and O is the observed count. For a 95% confidence interval, $Z\alpha_{/2}$= 1.96. When the observed event count is 0, L is set to 0 (Wolfe 1994).

Hazard Ratio and 95% Credible Interval for the Hazard Ratio

The hazard ratio provides an estimate of how the program's results compare with expected results based on modeling the transplant outcomes from all US programs. A ratio above 1 indicates higher than expected rates, and a ratio below one indicates lower than expected rates. If a program's rate was precisely the same as the expected rate, the estimated hazard ratio would be 1.0.

The 95% credible interval indicates the location of the program's true hazard ratio with 95% probability. If the credible interval includes 1.0 (e.g., credible interval of 0.8 to 1.2), the hazard ratio cannot be considered to be significantly different from 1.0.

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