Final Report

OPTN Heart Committee | Descriptive Data Request

Two-Year Monitoring of Heart Allocation
Proposal to Modify the Heart Allocation System

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Background/Purpose

On October 18, 2018 the Organ Procurement and Transplantation Network (OPTN) implemented modifications to the adult heart allocation system. Since this implementation, the OPTN Thoracic Organ Transplantation Committee split into the Lung Transplantation Committee and the Heart Transplantation Committee. The Heart Transplantation Committee (The Committee) will continue the monitoring of the implemented modifications to the adult heart allocation system. The modifications made to the adult heart allocation system were intended to better stratify the most medically urgent heart transplant candidates, reflect the increased use of mechanical circulatory support devices (MCSD) and prevalence of MCSD complications, and address geographic disparities in access to donors. The implementation involved creating new adult heart medical urgency statuses and altering how organs were shared based on medical urgency and distance from the donor hospital. On October 18, 2018, new guidelines also went into effect governing how Regional Review Boards (RRBs) evaluated exception requests. Historically, RRBs reviewed exceptions from their own OPTN region. When the new adult heart allocation policy went into effect this was changed such that OPTN regions were assigned to review exceptions from other OPTN regions.

This report does not address the removal of donation service area (DSA) from thoracic organ allocation, a change implemented on January 9, 2020. Although this report, unlike the previous reports (3, 6, and 12-month), does contain data from the DSA removal post-implementation period, a separate report addresses the monitoring of this change.

This report serves as a look at the impact of the modifications to adult heart allocation and will be followed by more and more extensive analyses as often as every six months for the first two years after implementation, then annually until five years post-implementation. This timeline is subject to change based on the results.

Strategic Plan Goal or Committee Project Addressed

Improve equity in access to heart transplants

Committee Request

This report assesses the impact of changes to the adult heart allocation system by comparing metrics pre- and post-implementation. For pre- and post-implementation comparisons involving medical urgency status an approximate correspondence will be used and referred to as the equivalent status: old Status 1A compared to Adult Statuses 1-3, old Status 1B compared to Adult Statuses 4 and 5, and old Status 2 compared to Adult Status 6. As outlined in the monitoring plan for this policy change, specific measures examined will include:

- Waiting list additions stratified by:
  - Medical urgency status, region, and medical urgency status within region
  - Criteria within medical urgency status and criteria within medical urgency status within region
  - Mechanical circulatory support devices (MCSD) and MCSD within region
- Waiting list composition at a specific date and time by criteria within medical urgency status
- Candidates ever waiting by medical urgency status
- Waiting list mortality rates by medical urgency status, medical urgency status within region and criteria within medical urgency status
- Transplants stratified by:
  - Medical urgency status, region, and medical urgency status within region
  - Criteria within medical urgency status and criteria within medical urgency status within region
  - Mechanical circulatory support devices (MCSD) and MCSD within region
  - Zone (DSA, Zone A, Zone B, etc.), share type (Local, Regional, National), and distance traveled
- Transplant rates by medical urgency status, medical urgency status within region and ciriteria within status
- Total ischemic time at transplants
- Time from first electronic offer to cross clamp and sequence number of acceptor on adult heart match runs
- Transplant center volume
- Median time to transplant by medical urgency status and medical urgency status within region
- Graft and patient survival stratified by medical urgency status and criteria within medical urgency status
- Utilization of deceased donor hearts stratified by donor age, region, and DCD versus non-DCD donors
- Status justification forms stratified by:
  - Medical urgency status, region, and medical urgency status within region
  - Initial versus extension requests
  - Standard review versus exception
  - Conclusions of justification forms and conclusions of justification forms by region
- Pediatric analyses:
  - Waiting list additions by age group and medical urgency status
  - Waiting list mortality by age group and medical urgency status
  - Transplants by age group and medical urgency status
  - Transplant rates by age group and medical urgency status

Data and Methods

Data Sources: These analyses use data from the OPTN waiting list, the Deceased Donor Registration (DDR) form, the Transplant Candidate Registration (TCR) form, the Transplant Recipient Registration (TRR) form, and the Transplant Recipient Followup (TRF) form. Analyses are based on OPTN data as of June 11, 2021 and are subject to change based on future data submission or correction.

Methods:

Adults (age >= 18) added only to the heart waiting list between October 18, 2016 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2020 (post) were stratified by medical urgency status, region, medical urgency status within region, criteria for medical urgency status at listing, and criteria for medical urgency status at listing within region.

Waiting list mortality rates and transplant rates were calculated based on a cohort of adult (age >= 18) candidates ever waiting only on the heart waiting list between October 18, 2016 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2020 (post). Rates were assessed based on the ratio of death or transplant to patient-years of exposure, and rates are displayed as deaths or transplants per 100 patient-years. The OPTN database was supplemented with deaths from verified external sources. Since candidates may be removed from the waiting list shortly prior to death as their health deteriorates, the waiting list mortality rate calculation included deaths within seven days of waiting list removal and those removed from the waiting list as a result of becoming too sick to transplant. Candidates who had received any previous transplant were excluded from the waiting list mortality and transplant rate analyses.

Candidates ever waiting were also stratified by medical urgency status. The distribution of medical urgency status for candidates ever waiting was further stratified by whether the listing center performed more or fewer transplants post-implementation than pre-implementation, and the distributions were compared using the Chi-squared test.

Adult (age >=18) deceased donor heart recipients transplanted between October 18, 2016 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2020 (post) were stratified by medical urgency status, region, medical urgency status within region, criteria for medical urgency status at transplant and criteria for medical urgency status at transplant within region, zone, share type, and distance traveled to transplant. Total ischemic time at transplant was compared across eras using Student's t-test, while distance traveled to transplant was compared across eras using the Wilcoxon rank-sum test.

Measures of median waiting time to transplant were based on a Fine-Gray competing risks analysis. For the purpose of these analyses, days waiting is total days on the waiting list, regardless of active status; a candidate is considered to have been transplanted if they were removed from the waiting list after receiving a deceased donor heart transplant; and a death on the waiting list is defined as either removal from the waiting list as a result of death or becoming too sick for transplant or death within seven days of removal from the waiting list for any reason but deceased donor transplant.

Electronic offer data for adult (age >= 18) deceased donors recovered between October 18, 2016 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2020 (post) were used to assess the time between first electronic offer and cross clamp and the sequence number of the acceptor on adult heart match runs. The distribution of the offer number of the acceptor on heart match runs was summarized using the median, 10th percentile, and 90th percentile.

MCSD data were derived from three sources: MCSDs reported on the TCR at listing, MCSDs reported on the TRR after transplant, and MCSDs reported on Waitlist status justification forms. Justification form data are restricted to the post-implementation period, as data collection was different pre-implementation. Waiting list additions and transplants were stratified by MCSDs reported on the TCR or TRR, respectively, by era and region, and also stratified by MCSDs reported on status justification forms post-implementation.

Utilization and discard rates were calculated based on a cohort of adult (age >= 18) deceased donors recovered between October 18, 2016 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2020 (post). For the purposes of this report, the utilization rate is defined as the number of adult deceased donor hearts recovered during a period divided by the total number of deceased donors recovered in that period and the discard

rate is defined as one minus the number of adult deceased donor hearts transplanted in a period divided by the total number of adult deceased donor hearts recovered in that period.

Outcomes analyses were performed on a subset of adult heart transplant recipients with the potential for at least one year of follow-up plus a two-month data lag, which included recipients transplanted between October 18, 2016 and October 17, 2017 in the pre-implementation cohort and between October 18, 2018 and October 17, 2019 in the post-implementation cohort. It is important to note that the post-implementation follow-up period contains COVID-Era data. The COVID-19 crisis has created challenges to conducting routine outpatient activities, including clinical testing, which are needed to obtain information required for transplant candidates, recipients, and living donors. Current OPTN policy requires that transplant programs submit data for transplant recipients and living donors. The emergency policy from the OPTN Executive Committee temporarily relaxed requirements for follow-up form submission (https://optn.transplant.hrsa.gov/media/3716/covid-19_emergency_policypackage_and_minibrief.pdf). The intent of the policy is to prevent unnecessary exposure risk to transplant recipients and living donors and to alleviate potential data burden for centers in the midst of COVID-19 crisis. The TRF and LDF Data Submission During COVID-19 Amnesty Period emergency policy temporarily suspends the requirements for data collection and submission for the living donor follow-up (LDF), organ specific transplant recipient follow-up (TRF), and recipient malignancy (PTM) forms. The suspension of these requirements is backdated to forms expected between March 13, 2020, and at least December, 31, 2020 if the Executive Committee or Board of Directors has not acted before that date. It does not suspend the requirement to report recipient death or graft failure, but extends the time frame for reporting that information for transplant recipients from 14 days to 30 days of knowledge of the event. We expect higher rates of patient status censoring as a result of the amnesty policy. To account for this increase, survival analyses were run assuming recipients were alive unless their death was reported to the OPTN or identified in external sources and a three-month data lag was included. Assume-alive and standard patient survival curves are presented but graft survival was omitted due to the lack of access to external sources to verify information. Survival curves were constructed using unadjusted Kaplan-Meier methodology and compared using the log-rank test.

Adult (age $>=$ 18) heart and heart-lung exception requests (initial or extension) submitted between September 18, 2018 and October 17, 2019 were stratified by medical urgency status requested, region, medical urgency status requested within region, initial versus extension, month submitted, form conclusion, and standard review versus exception. This report includes forms submitted to the RRB as well as standard extension forms that are required by policy to go to the RRB.

Pediatric (age $<$ 18) candidates added only to the heart waiting list between April 18, 2017 and October 17, 2018 (pre) or between October 18, 2018 and April 17, 2020 (post) were stratified by medical urgency status and age group and medical urgency and age group within region.

Pediatric (age $<$ 18) deceased donor heart recipients transplanted between October 18, 2016 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2020 (post) were stratified by medical urgency status and age group and medical urgency and age group within region.

Pediatric waiting list mortality rates and transplant rates were derived from a cohort of candidates (age $<$ 18) ever waiting only on the heart waiting list between October 18, 2016 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2020 (post). Rates were assessed based on the ratio of death or transplant to patient-years of exposure, and rates are displayed as deaths or transplants per 100 patient-years. The OPTN database was supplemented with deaths reported in the Social Security Administration Death Master File (SSDMF). Since candidates may be removed from the waiting list shortly prior to death as their health deteriorates, the waiting list mortality rate calculation included deaths within seven days after waiting list removal and those removed from the waiting list as a result of becoming too sick to transplant. Candidates who received any previous transplant were excluded from the waiting list mortality and transplant rate analyses.

Statistical analyses were performed using SAS v9.3 (SAS Institute, Inc., Cary, NC.) and R Version 3.5.3 (R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL: https://www.R-project.org/).

A Notice on COVID

For all figures and tables, we note that the World Health Organization (WHO) declared COVID-19 a pandemic on March 11, 2020 and a national state of emergency was declared in the U.S. on March 13, 2020. Based on the WHO's declaration of the pandemic and the national state of emergency, the post-implementation monitoring for this report contains roughly 7 months of COVID-Era data (03/11/2020 - 10/17/2020). Given the impact that has been seen on the U.S. transplant and donation community (unos.org/covid) the true impact of this policy change is more difficult to determine.

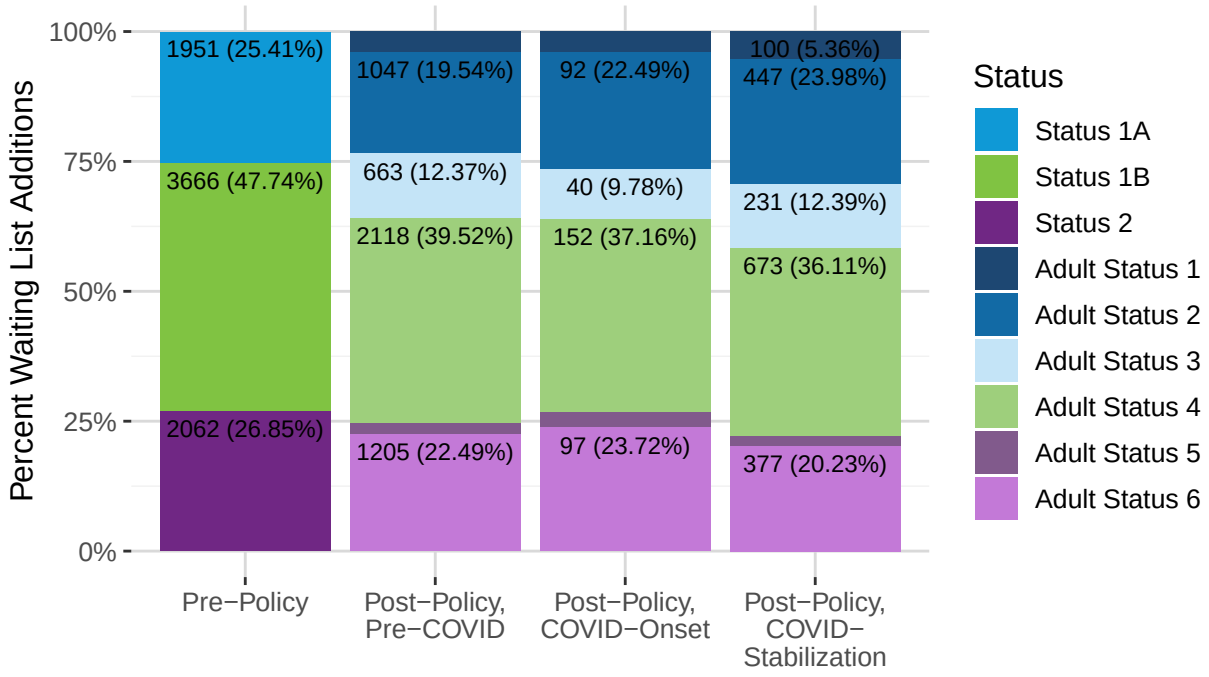
Figures are presented showing pre- post policy changes while tables include multiple COVID eras, representing the heaviest-impacted period of time from March 13, 2020 to May 09, 2020 (COVID-Onset period) and the additional period of time with continual, albeit less-dramatic, impact from May 10, 2020 to the end of the post-policy cohort (COVID-Stabilization period).

Results

Waitlist

These analyses examine differences between two waiting list cohorts: the pre-implementation cohort, composed of 7872 registrations added to the heart waiting list between October 18, 2016 and October 17, 2018; and the post-implementation cohort, composed of 7752 registrations added between October 18, 2018 and October 17, 2020.

Figure 1. Adult Heart Waiting List Additions by Medical Urgency Status and Era



Statuses representing less than 5% of the total are not labeled on the plot
Pre−Policy: October 18, 2016 − October 17, 2018;
Post−Policy, Pre−COVID: October 18, 2018 − March 12, 2020;
Post−Policy, COVID Onset: March 13, 2020 − May 09 2020;
Post−Policy COVID Stabilization: May 10, 2020 − October 17, 2020;

Pre-implementation most additions were made at Status 1B, while post-implementation Adult Status 4 predominated. Adult Statuses 2 and 6 were the next-largest groups. Adult Statuses 1 and 5 represented only a small fraction of registrations post-implementation. These trends persisted across post-implmenentation COVID-eras.

Table 1 breaks down the number and percent of registrations both by medical urgency status and by equivalent medical urgency status as defined in the Committee Request section above. Additionally, the pre and post-policy monitoring eras are shown overall and the post-implementation era is broken out by the COVID-Eras. Trends in heart waiting list additions by medical urgency status persisted across all COVID-eras.

Table 1. Adult Heart Waiting List Additions by Era and Medical Urgency Status

Era	Equivalent Status	Status	N	%
Pre-Policy	Equivalent Status 1A	Status 1A	1951	24.8%
	Equivalent Status 1B	Status 1B	3666	46.6%
	Equivalent Status 2	Status 2	2062	26.2%
	Temporarily inactive	Temporarily inactive	193	2.5%
Post-Policy, Pre-COVID	Equivalent Status 1A	Adult Status 1	213	3.9%
		Adult Status 2	1047	19.2%
		Adult Status 3	663	12.2%
	Equivalent Status 1B	Adult Status 4	2118	38.9%
		Adult Status 5	113	2.1%
	Equivalent Status 2	Adult Status 6	1205	22.1%
	Temporarily inactive	Temporarily inactive	91	1.7%
Post-Policy, COVID-Onset	Equivalent Status 1A	Adult Status 1	16	3.8%
		Adult Status 2	92	22.1%
		Adult Status 3	40	9.6%
	Equivalent Status 1B	Adult Status 4	152	36.5%
		Adult Status 5	12	2.9%
	Equivalent Status 2	Adult Status 6	97	23.3%
	Temporarily inactive	Temporarily inactive	7	1.7%
Post-Policy, COVID-Stabilization	Equivalent Status 1A	Adult Status 1	100	5.3%
		Adult Status 2	447	23.7%
		Adult Status 3	231	12.2%
	Equivalent Status 1B	Adult Status 4	673	35.7%
		Adult Status 5	36	1.9%
	Equivalent Status 2	Adult Status 6	377	20%
	Temporarily inactive	Temporarily inactive	22	1.2%
Post-Policy (overall)	Equivalent Status 1A	Adult Status 1	329	4.2%
		Adult Status 2	1586	20.5%
		Adult Status 3	934	12%
	Equivalent Status 1B	Adult Status 4	2943	38%
		Adult Status 5	161	2.1%
	Equivalent Status 2	Adult Status 6	1679	21.7%
	Temporarily inactive	Temporarily inactive	120	1.5%

Note:
Pre-Policy: October 18, 2016 - October 17, 2018;
Post-Policy, Pre-COVID: October 18, 2018 - March 12, 2020;
Post-Policy, COVID Onset: March 13, 2020 - May 09 2020;
Post-Policy COVID Stabilization: May 10, 2020 - October 17, 2020;

Figure 3. Adult Heart Waiting List Additions by Region and Era

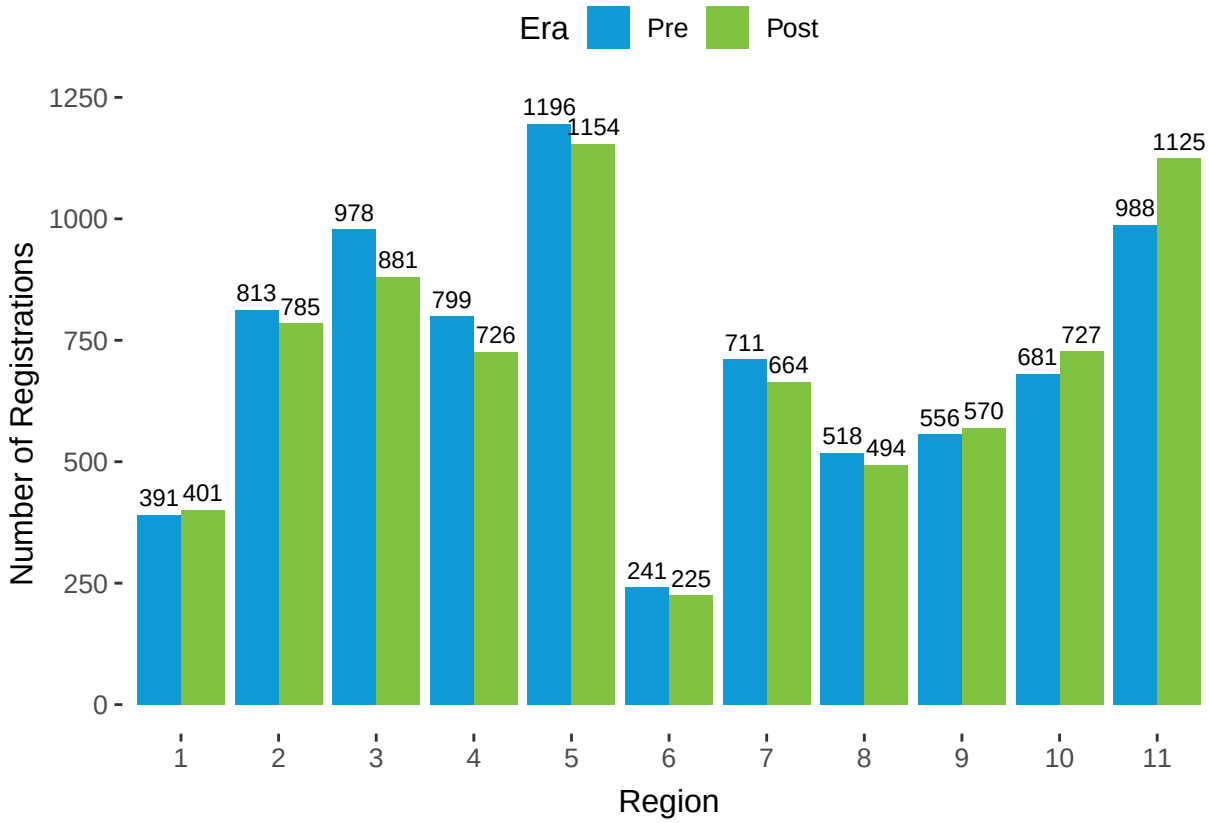
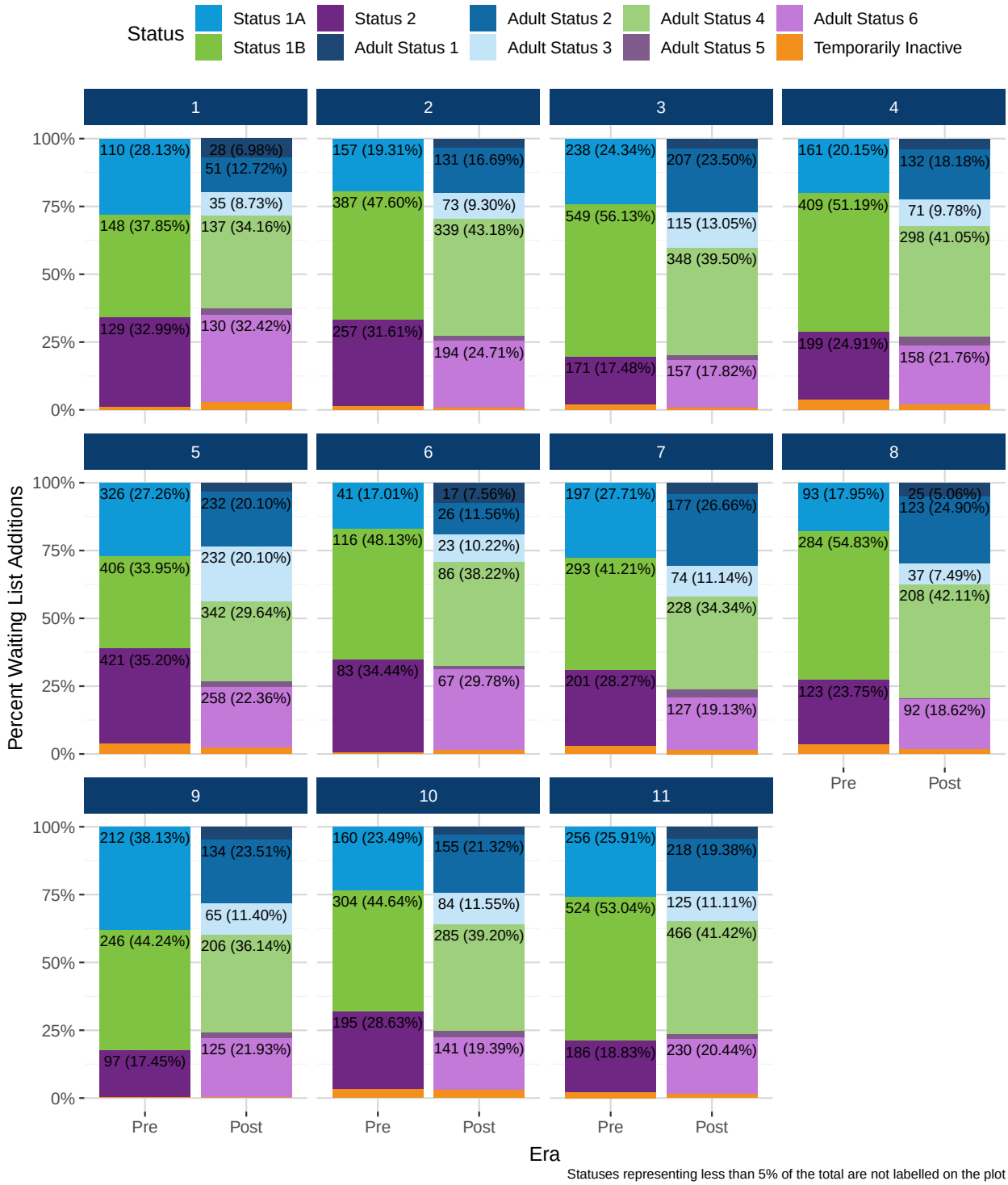


Figure 3 shows the number of adult heart waiting list registrations added by region both pre- and post-implementation. While there was little change in the number of waiting list additions for several regions, the number of registrations added increased by more than 5% in regions 10 and 11 and decreased by more than 5% in regions 3, 4, 6, and 7.

Figure 4 shows the number of adult heart waiting list registrations by region and medical urgency status. The proportion of registrations added at each status was similar across regions, with Adult Status 4 accounting for the largest number of post-implementation registrations in all regions and either Adult Status 5 or Temporarily Inactive the least. Post-implementation the greatest degree of variability was seen in the Adult Status 2 category, which represented nearly 26.7% of new post-implementation registrations in region 7 compared to 11.6% of new post-implementation registrations in region 6.

Tables A1 and A2 (see Appendix) show the count and percent of adult heart waiting list registrations by region and medical urgency status pre-implementation and post-implementation, respectively.

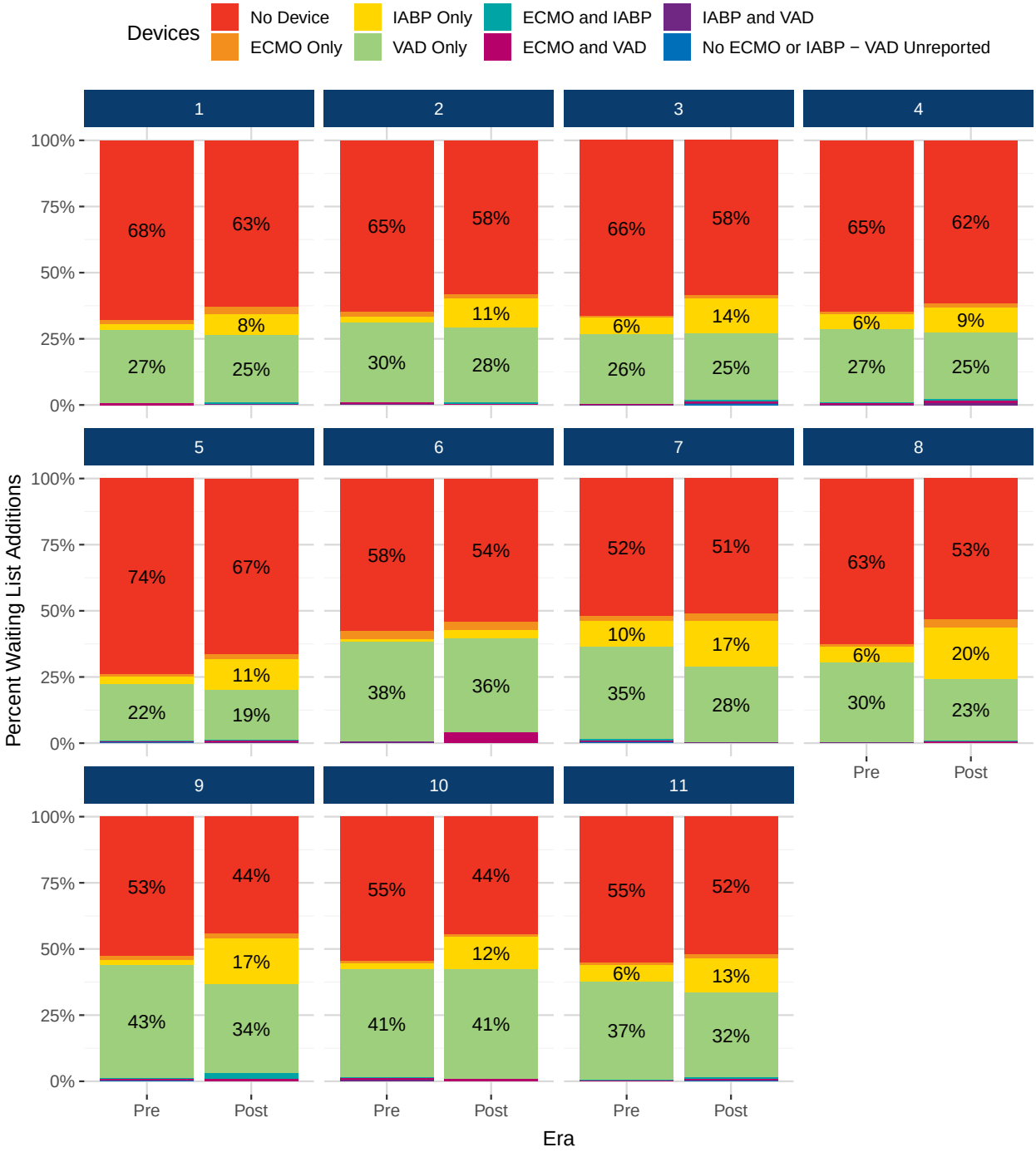
Figure 4. Adult Heart Waitlist Additions by Region, Era, and Medical Urgency Status



Statuses representing less than 5% of the total are not labelled on the plot

Figure 4 shows the adult heart waiting list additions by region, device at time of listing, and era. In each region the percent of waiting list additions for those on no devices decreased. The largest decrease occurred in region 10 where 55% of all waitlist additions were on no device in the pre era compared to 44% in the post era. In the post era as few as 44% of all waitlist additions were on no devices at time of listing and as many as 66% were on no devices at time of listing. The percent of waitlist additions in each region on IABP-only increased post-implementation.

Figure 5. Adult Heart Waitlist Additions by Region, Era, and Device



Device information exists on both the TCR and WL status justification forms and may differ;

Device information pulled from TCR for this figure.

Table 2 shows the criteria qualifying adult heart waiting list candidates for their medical urgency status at time of listing post-implementation. For Adult Status 5 and Adult Status 6, which have no qualifying criteria, the count of waiting list additions at the status is given. For Adult Status 1 the most common criterion for waiting list additions was VA ECMO, with (24.78%) or without (32.28%) hemodynamic values. For Adult Status 2 the most common criterion was intra-aortic balloon pump with hemodynamic values (46.52%); it was rare for IABP to be reported without hemodynamic values (1.75%). For Adult Status 3 the most common qualifying criterion was multiple inotropes/single high dose inotrope with hemodynamic monitoring (36.16%) followed by dischargeable LVAD for discretionary 30 days (23.86%), and for Adult Status 4 the most common was dischargeable LVAD without discretionary 30 days (43.89%).

The percent of adult heart waiting list additions qualifying by an exception at time of listing was greatest for Adult Status 2, with 33.29% of candidates qualifying under this criterion. For the other statuses the percent of candidates qualifying by an exception at listing ranged between 17.18% for Adult Status 4 and 21.31% for Adult Status 3.

Table A3 shows the criteria qualifying adult heart candidates for their medical urgency status at registration by region. Proportions of qualifying criteria for each status were broadly similar, with much of the variability coming from the proportion of registrations granted an exception for a status in each region.

Table 2. Adult Heart Waitlist Additions by Criteria Within Medical Urgency Status at Listing Post-Implementation

Status	Criteria	N	%
Adult Status 1	BIVAD/Ventricular Episodes	22	6.34%
	Exception	73	21.04%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	54	15.56%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	112	32.28%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	86	24.78%
Overall		**347**	**100%**
Adult Status 2	Exception	537	33.63%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	28	1.75%
	Intra-aortic ballon pump - Hemodynamic Values obtained	743	46.52%
	Mechanical circulatory support device(MCSD) with malfunction	35	2.19%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	19	1.19%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	20	1.25%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	120	7.51%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	47	2.94%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	48	3.01%
Overall		**1597**	**100%**
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	225	23.86%

(continued)

Status	Criteria	N	%
Adult Status 3	Exception	201	21.31%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	6	0.64%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	60	6.36%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	36	3.82%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	14	1.48%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	11	1.17%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	12	1.27%
	Mechanical circulatory support device (MCSD) with hemolysis	4	0.42%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	3	0.32%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	3	0.32%
	Mechanical circulatory support device (MCSD) with pump thrombosis	22	2.33%
	Mechanical circulatory support device (MCSD) with right heart failure	5	0.53%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	341	36.16%
Overall		**943**	**100%**
Adult Status 4	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	304	10.20%
	Congenital heart disease	215	7.21%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1308	43.89%
	Exception	512	17.18%
	Inotropes without hemodynamic monitoring	434	14.56%
	Ischemic heart disease with intractable angina	54	1.81%
	Retransplant	153	5.13%
Overall		**2980**	**100%**
Adult Status 5	None	199	100.00%
Adult Status 6	None	1689	100.00%

Note:
"%" indicates the percent of waiting list registrations within a medical urgency status

Tables 3 and 4 show the qualifying criteria for candidates on the adult heart waiting list stratified by initial or extension request as it appeared on February 29, 2020 and September 30, 2020, respectively. While Table 4 is a more recent presentation of the qualifying criteria for candidates on the adult heart waiting list it is during the COVID-Stabilization Era. Table 3 is also presented in order to determine any possible differences due to the snapshot being taken during the COVID-19 period and represents the waitinglist compostion post-implementation, pre-COVID. In general, Adult Status 1 candidates spent very little time on the waiting list with a median waiting time of 5 days (Table 10), and therefore at any given time there are few of them waiting, which makes the distribution of qualifying criteria difficult to determine.

In both tables 3 and 4 there were very few candidates waiting at Adult Status 1 making the distributions at listing and under an extension difficult to decipher; the majority overall were waiting with a non-dischargeable, surgically implanted, non-endovascular biventricular support device (37.50%). At both initial listing and extension, an exception was the most common criterion followed by intra-aortic balloon pump with hemodynamic values for Adult Status 2. For Adult Status 3, dischargeable LVAD for discretionary 30 days remained the most common criteria at listing and MCSD with bacteremic device infection remained the most common for those waiting under an extension on February 29, 2020. On September 30, 2020 exception tied MCSD with bacteremic device infection for the most common criteria for candidates waiting at Adult Status 3 under an extension. The distribution of qualifying criteria for candidates at Adult Status 4 on February 29, 2020 was similar to the distribution of qualifying criteria on September 30, 2020, with dischargeable LVAD without discretionary 30 days being the most common in both cases for candidates waiting under their initial listing as well as those waiting under an extension.

Table 3. Criteria Within Medical Urgency Status for Adult Heart Candidates Waiting on February 29, 2020

		Initial		Extension		Total	
Status	**Criteria**	**N**	**%**	**N**	**%**	**N**	**%**
Adult Status 1	BIVAD/Ventricular Episodes	2	33.33%	0	0.00%	2	25.00%
	Exception	2	33.33%	0	0.00%	2	25.00%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	1	16.67%	2	100.00%	3	37.50%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	1	16.67%	0	0.00%	1	12.50%
Overall		**6**	**100%**	**2**	**100%**	**8**	**100%**
Adult Status 2	Exception	22	39.29%	15	53.57%	37	44.05%
	Intra-aortic ballon pump - Hemodynamic Values obtained	20	35.71%	6	21.43%	26	30.95%
	Mechanical circulatory support device(MCSD) with malfunction	3	5.36%	0	0.00%	3	3.57%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	1.79%	0	0.00%	1	1.19%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	5	8.93%	0	0.00%	5	5.95%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	4	7.14%	6	21.43%	10	11.90%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	1	1.79%	1	3.57%	2	2.38%
Overall		**56**	**100%**	**28**	**100%**	**84**	**100%**
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	31	33.33%	0	0.00%	31	15.20%
	Exception	10	10.75%	22	19.82%	32	15.69%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	7	7.53%	2	1.80%	9	4.41%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	13	13.98%	30	27.03%	43	21.08%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	4	4.30%	17	15.32%	21	10.29%

(continued)

Status	Criteria	N	%	N	%	N	%
Adult Status 3	Mechanical circulatory support device (MCSD) with device infection - Erythema	2	2.15%	4	3.60%	6	2.94%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	3	3.23%	3	2.70%	6	2.94%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	0	0.00%	1	0.90%	1	0.49%
	Mechanical circulatory support device (MCSD) with hemolysis	0	0.00%	1	0.90%	1	0.49%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	3	3.23%	0	0.00%	3	1.47%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	2	2.15%	0	0.00%	2	0.98%
	Mechanical circulatory support device (MCSD) with pump thrombosis	4	4.30%	21	18.92%	25	12.25%
	Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	7	6.31%	7	3.43%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	14	15.05%	3	2.70%	17	8.33%
Overall		**93**	**100%**	**111**	**100%**	**204**	**100%**
Adult Status 4	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	44	7.09%	52	5.11%	96	5.86%
	Congenital heart disease	41	6.60%	61	5.99%	102	6.22%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	394	63.45%	774	76.03%	1168	71.26%
	Exception	75	12.08%	57	5.60%	132	8.05%
	Inotropes without hemodynamic monitoring	35	5.64%	21	2.06%	56	3.42%
	Ischemic heart disease with intractable angina	16	2.58%	19	1.87%	35	2.14%
	Retransplant	16	2.58%	34	3.34%	50	3.05%
Overall		**621**	**100%**	**1018**	**100%**	**1639**	**100%**
Adult Status 5	None	59	100.00%	41	100.00%	100	100.00%
Adult Status 6	None	308	100.00%	205	100.00%	513	100.00%

Note:
"%" indicates the percent of waiting list registrations within a medical urgency status

Table 4. Criteria Within Medical Urgency Status for Adult Heart Candidates Waiting on September 30, 2020

		Initial		Extension		Total	
Status	**Criteria**	**N**	**%**	**N**	**%**	**N**	**%**
Adult Status 1	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	2	66.67%	1	100.00%	3	75.00%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	1	33.33%	0	0.00%	1	25.00%
Overall		**3**	**100%**	**1**	**100%**	**4**	**100%**
Adult Status 2	Exception	34	52.31%	12	57.14%	46	53.49%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	1	1.54%	0	0.00%	1	1.16%
	Intra-aortic ballon pump - Hemodynamic Values obtained	23	35.38%	0	0.00%	23	26.74%
	Mechanical circulatory support device(MCSD) with malfunction	0	0.00%	1	4.76%	1	1.16%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	1.54%	0	0.00%	1	1.16%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	3	4.62%	1	4.76%	4	4.65%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	1	1.54%	7	33.33%	8	9.30%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	2	3.08%	0	0.00%	2	2.33%
Overall		**65**	**100%**	**21**	**100%**	**86**	**100%**
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	34	44.74%	0	0.00%	34	19.21%
	Exception	9	11.84%	24	23.76%	33	18.64%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	5	6.58%	4	3.96%	9	5.08%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	7	9.21%	24	23.76%	31	17.51%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	3	3.95%	17	16.83%	20	11.30%

(continued)

Status	Criteria	N	%	N	%	N	%
Adult Status 3	Mechanical circulatory support device (MCSD) with device infection - Erythema	2	2.63%	4	3.96%	6	3.39%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	3	3.95%	2	1.98%	5	2.82%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	1.32%	0	0.00%	1	0.56%
	Mechanical circulatory support device (MCSD) with hemolysis	0	0.00%	1	0.99%	1	0.56%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	1.32%	0	0.00%	1	0.56%
	Mechanical circulatory support device (MCSD) with pump thrombosis	4	5.26%	19	18.81%	23	12.99%
	Mechanical circulatory support device (MCSD) with right heart failure	1	1.32%	1	0.99%	2	1.13%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	6	7.89%	5	4.95%	11	6.21%
Overall		**76**	**100%**	**101**	**100%**	**177**	**100%**
Adult Status 4	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	31	5.60%	48	5.17%	79	5.33%
	Congenital heart disease	28	5.05%	55	5.92%	83	5.60%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	347	62.64%	692	74.49%	1039	70.06%
	Exception	82	14.80%	62	6.67%	144	9.71%
	Inotropes without hemodynamic monitoring	38	6.86%	17	1.83%	55	3.71%
	Ischemic heart disease with intractable angina	12	2.17%	19	2.05%	31	2.09%
	Retransplant	16	2.89%	36	3.88%	52	3.51%
Overall		**554**	**100%**	**929**	**100%**	**1483**	**100%**
Adult Status 5	None	72	100.00%	20	100.00%	92	100.00%
Adult Status 6	None	318	100.00%	182	100.00%	500	100.00%

Note:
"%" indicates the percent of waiting list registrations within a medical urgency status

Table 5 shows the count and percent of registrations with a mechanical circulatory support device (MCSD) at listing, based on information reported on the TCR and broken down by device type and brand. Overall, 62.11% of new registrations had an MCSD listed on the TCR pre-implementation, compared to 55.78% post-implementation. LVADs were less common post-implementation than pre-implementation, while the proportion of new registrations with an IABP increased. The proportion of registrations on ECMO at listing also increased, but ECMO still contributes a small number of the total registrations with MCSDs.

Table A4 shows the count and percent of registrations with an MCSD at listing by region as reported on the TCR. The distribution of MCSDs at listing is broadly similar across regions. The percent of registrations on an LVAD+RVAD at listing was higher in region 1 than other regions, and region 6 had the smallest decline in LVADs among registrations.

For comparison, Table A5 shows the MCSDs at listing based on information reported on justification forms in Waitlist post-implementation. While MCSDs are categorized differently in Waitlist data, reporting of MCSDs at registration is similar in Waitlist to what is reported on the TCR, with Left Dischargeable VAD the most commonly-reported device, followed by IABP.

Table 5. Mechanical Circulatory Support Devices at Listing for Adult Heart Candidates

Brand	Era	Count	Percent
ECMO			
Total ECMO	**Pre**	**144**	**4.62%**
	Post	**248**	**6.81%**
IABP			
Total IABP	**Pre**	**401**	**12.86%**
	Post	**1049**	**28.82%**
LVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	6	0.28%
Cardiac Assist Tandem Heart	Pre	4	0.17%
	Post	2	0.09%
CentriMag (Thoratec/Levitronix)	Pre	17	0.71%
	Post	18	0.85%
Evaheart	Pre	1	0.04%
	Post	1	0.05%
Heartmate II	Pre	1097	45.52%
	Post	344	16.26%
HeartMate III	Pre	58	2.41%
	Post	954	45.11%
Heartmate XVE	Pre	2	0.08%
	Post	0	0%
Heartsaver VAD	Pre	1	0.04%
	Post	3	0.14%
Heartware HVAD	Pre	714	29.63%
	Post	534	25.25%

Impella CP	Pre	2	0.08%
	Post	40	1.89%
Impella Recover 2.5	Pre	11	0.46%
	Post	3	0.14%
Impella Recover 5.0	Pre	47	1.95%
	Post	93	4.4%
Impella RP	Pre	0	0%
	Post	1	0.05%
Jarvik 2000	Pre	1	0.04%
	Post	0	0%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	3	0.14%
Terumo DuraHeart	Pre	1	0.04%
	Post	0	0%
Thoratec PVAD	Pre	1	0.04%
	Post	0	0%
Other, Specify	Pre	453	18.8%
	Post	113	5.34%
Total LVAD	**Pre**	**2410**	**77.32%**
	Post	**2115**	**58.1%**
LVAD+RVAD			
Abiomed AB5000	Pre	0	0%
	Post	1	0.53%
Cardiac Assist Protek Duo	Pre	0	0%
	Post	13	6.84%
Cardiac Assist Tandem Heart	Pre	8	6.35%
	Post	4	2.11%
CentriMag (Thoratec/Levitronix)	Pre	54	42.86%
	Post	85	44.74%
Heartmate II	Pre	7	5.56%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	27	14.21%
Heartware HVAD	Pre	31	24.6%
	Post	21	11.05%
Impella CP	Pre	0	0%
	Post	1	0.53%
Impella Recover 5.0	Pre	3	2.38%
	Post	6	3.16%

Impella RP	Pre	0	0%
	Post	1	0.53%
Maquet Jostra Rotaflow	Pre	5	3.97%
	Post	12	6.32%
Thoratec PVAD	Pre	0	0%
	Post	2	1.05%
Other, Specify	Pre	18	14.29%
	Post	17	8.95%
Total LVAD+RVAD	**Pre**	**126**	**4.04%**
	Post	**190**	**5.22%**
RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	3	17.65%
Cardiac Assist Tandem Heart	Pre	1	14.29%
	Post	1	5.88%
CentriMag (Thoratec/Levitronix)	Pre	4	57.14%
	Post	3	17.65%
Heartmate II	Pre	1	14.29%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	2	11.76%
Impella Recover 5.0	Pre	1	14.29%
	Post	3	17.65%
Impella RP	Pre	0	0%
	Post	1	5.88%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	1	5.88%
Other, Specify	Pre	0	0%
	Post	3	17.65%
Total RVAD	**Pre**	**7**	**0.22%**
	Post	**17**	**0.47%**
TAH			
SynCardia CardioWest	Pre	29	100%
	Post	19	90.48%
Other, Specify	Pre	0	0%
	Post	2	9.52%
Total TAH	**Pre**	**29**	**0.93%**
	Post	**21**	**0.58%**

Figure 6. Justification Forms at Listing by Justification Review Type and Status Requested

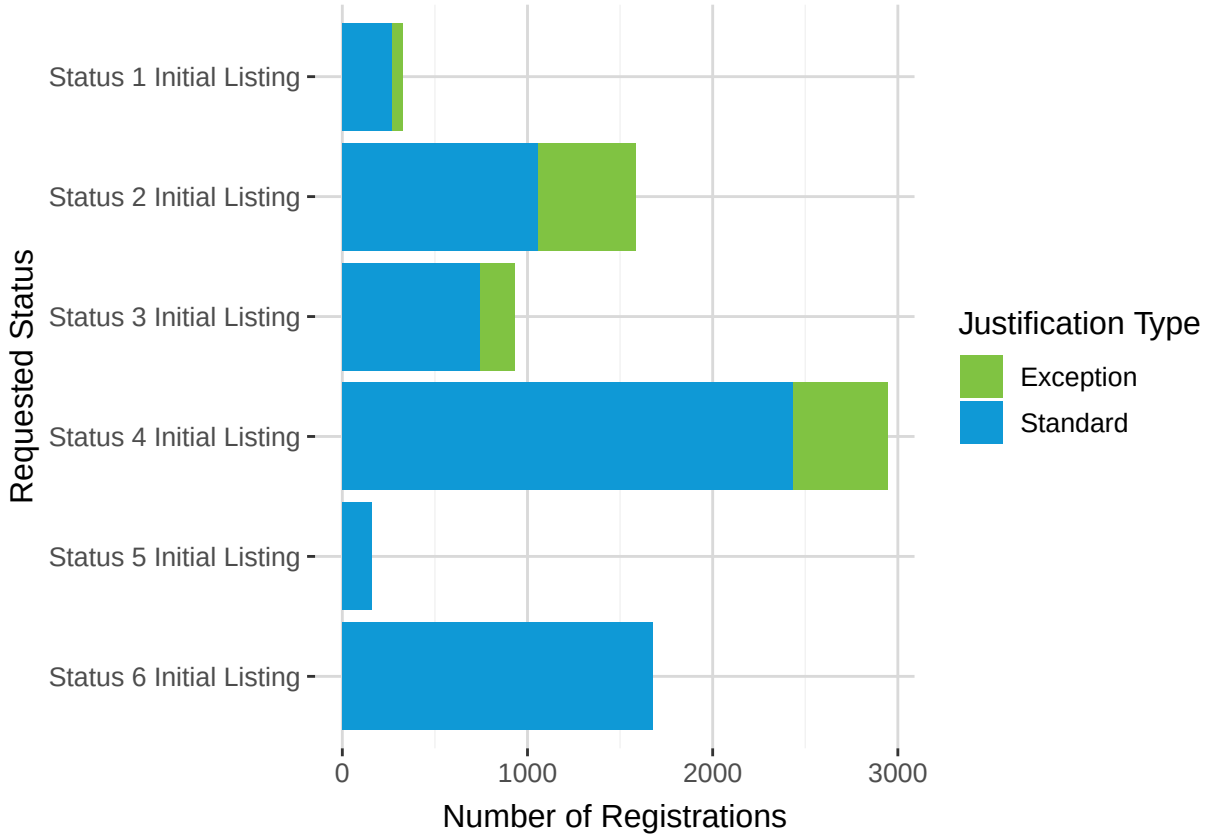


Figure 6 shows the number of justification forms at listing, the status requested, and whether the review type was standard or exception. The most-requested status at listing was Adult Status 4, followed by Adult Status 6. Exception requests were most common for candidates listing at either Adult Status 2 or Adult Status 4.

Figure 7. Candidates Ever Waiting by Era and Medical Urgency Status

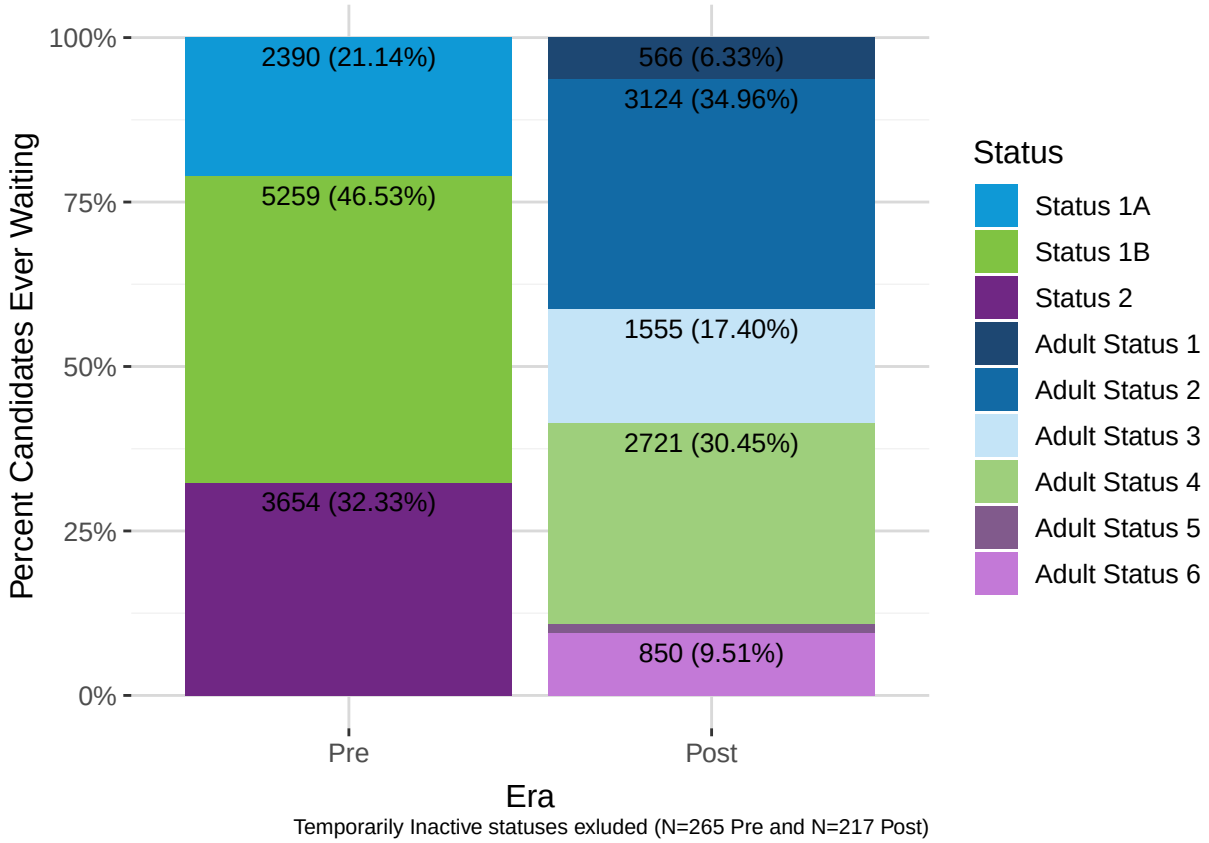
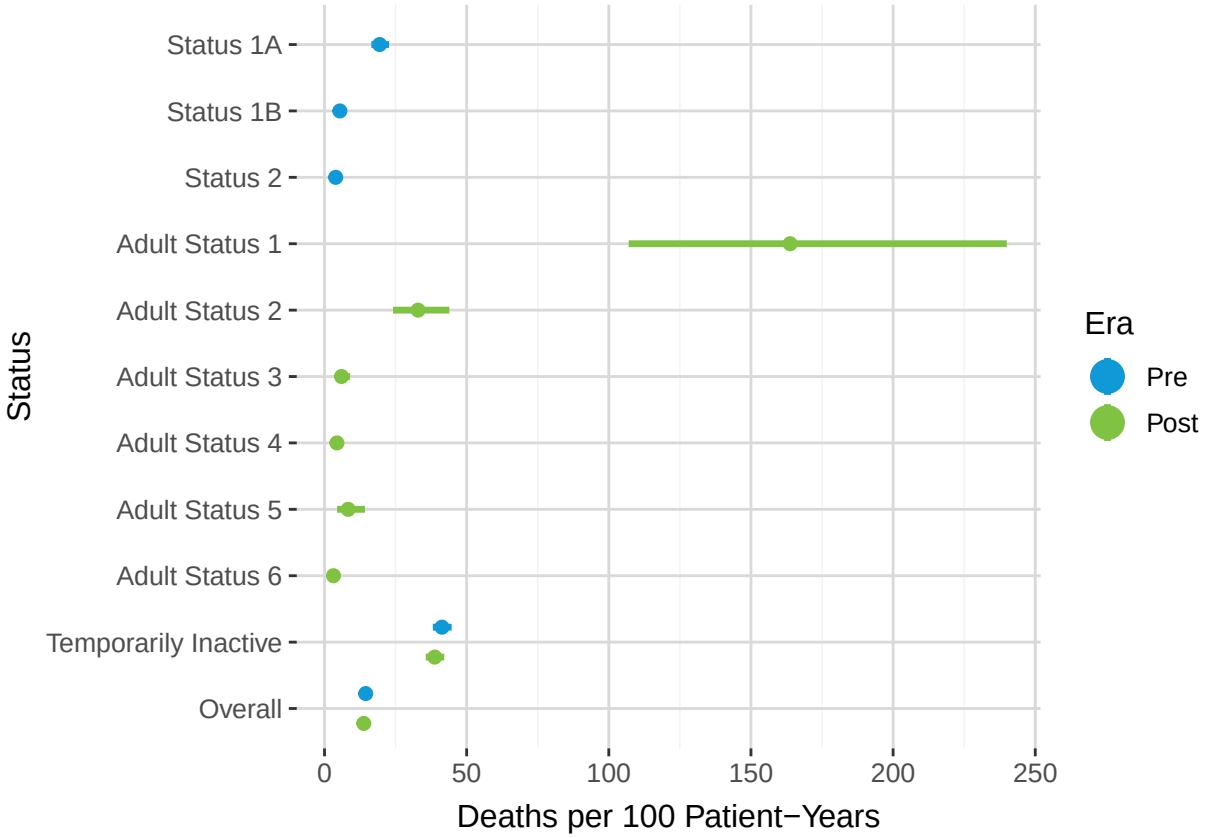


Figure 7 shows the composition of candidates ever waiting by medical urgency status both pre- and post-implementation. The statuses shown pre-implementation are the statuses candidates held when added to the waiting list; displaying the most recent candidate status would make interpretation more difficult by showing post-implementation statuses in the pre era for those candidates who were waiting in both eras. Post-implementation statuses shown are the most recent status for each candidate in order to avoid displaying pre-implementation statuses in the post era for those candidates added before the policy implementation took effect. "Temporarily inactive" is omitted because more candidates wait at this status than are added at this status, making it difficult to compare across eras.

Pre-implementation, the largest proportion of adult heart candidates waited at Status 1B, while post-implementation the largest group of waiting candidates was Adult Status 2 followed by the second-most-common status, Adult Status 4. Of the new statuses used post-implementation, Adult Status 5 had the fewest candidates ever waiting (<5%), followed by Adult Status 1.

Figure 8. Deaths per 100 Patient-Years Waiting by Medical Urgency Status and Era



Figures 7 and 8 show the number of deaths per 100 patient-years by medical urgency status and era. Although the medical urgency statuses used pre- and post-implementation are not directly comparable, the fact that Adult Status 1 has a dramatically higher number of deaths per 100 patient-years than Adult Status 2, which in turn had more deaths than Adult Status 3, indicates that the revisions to the adult heart allocation system were successful in creating medical urgency statuses that group candidates according to their risk of death while waiting, at least for the three most urgent statuses. Adult Statuses 4-6 had similar deaths per 100 patient waiting years indicated by the overlapping confidence intervals. Overall there was no significant difference in the number of deaths per 100 patient-years between the two eras.

Figure 8 zooms in on Adult statuses 3-6 in order to gain a clearer picture of what is happening in these statuses.

Figure 9. Zooming in on Adult Heart Statuses 3-6: Deaths per 100 Patient-Years Waiting by Medical Urgency Status and Era

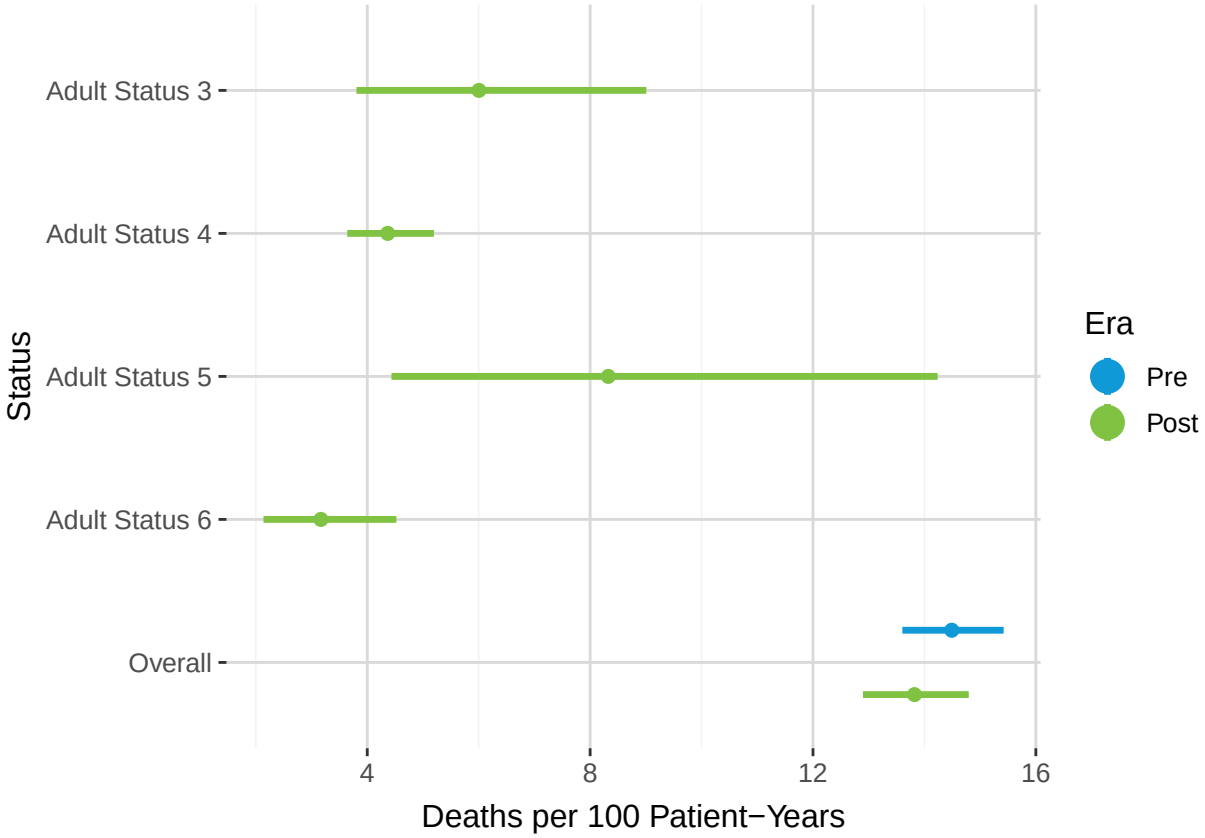
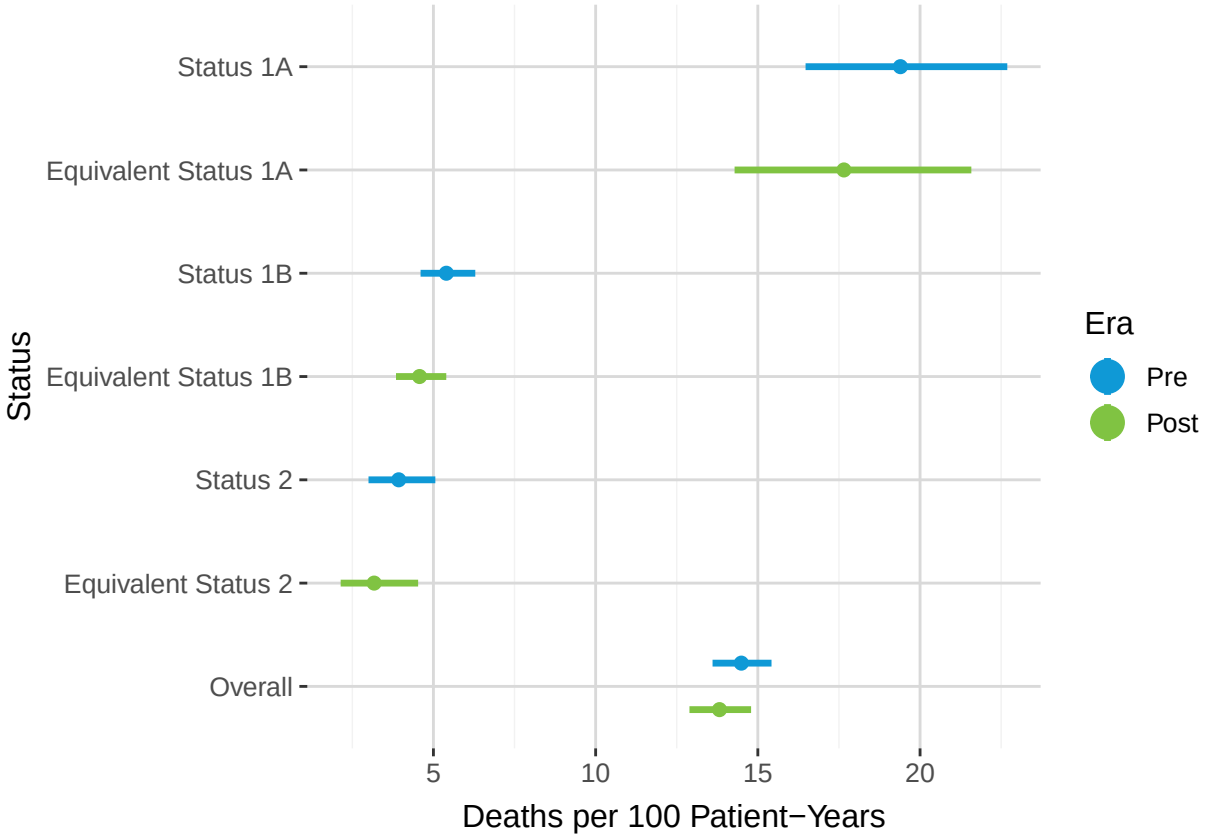


Figure 10. Deaths per 100 Patient-Years Waiting by Equivalent Medical Urgency Status



The Committee Request section defines the comparison of equivalent post-implementation statuses to old statuses as: old Status 1A compared to Adult Statuses 1-3, old Status 1B compared to Adult Statuses 4 and 5, and old Status 2 compared to Adult Status 6. Figure 11 shows the deaths per 100 patient years waiting by equivalent statuses post-implementation as compared to pre-implementation. There was no significant difference in deaths per 100 patient-years waiting between equivalent status 1A and old status 1A, equivalent status 1B and old status 1B and equivalent status 2 and old status 2.

Table A6 shows the counts of patients ever waiting by status and era, as well as the number of deaths on the waiting list and the deaths per 100 patient-years.

Figure 11 displays the deaths per 100 patient-years waiting by criteria within medical urgency status for the four most medically urgent adult statuses post-implementation. Deaths per 100 patient-years waiting could not be estimated for Adult Status 3 with criteria of VA ECMO after 7 days due to small sample size. The deaths per 100 patient-years waiting were similar across criteria within statuses suggesting that candidates, despite qualifying criteria, have similar medical urgency within each status. Table A7 shows the counts of patients ever waiting by status and era, as well as the number of deaths on the waiting list and the deaths per 100 patient-years.

Figure 11. Deaths per 100 Patient-Years Waiting by Criteria within Medical Urgency Status Post-Implementation

Figure 12. Deaths per 100 Patient-Years Waiting by Region and Era

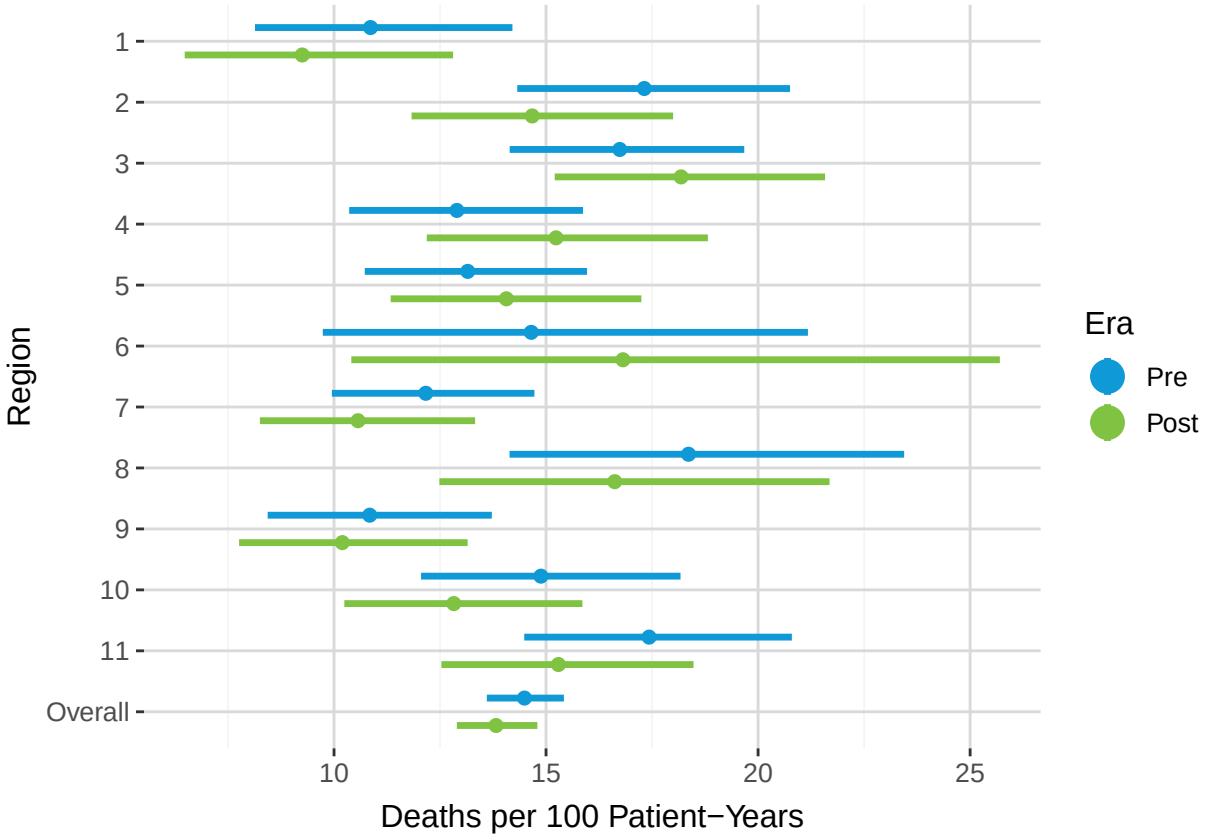


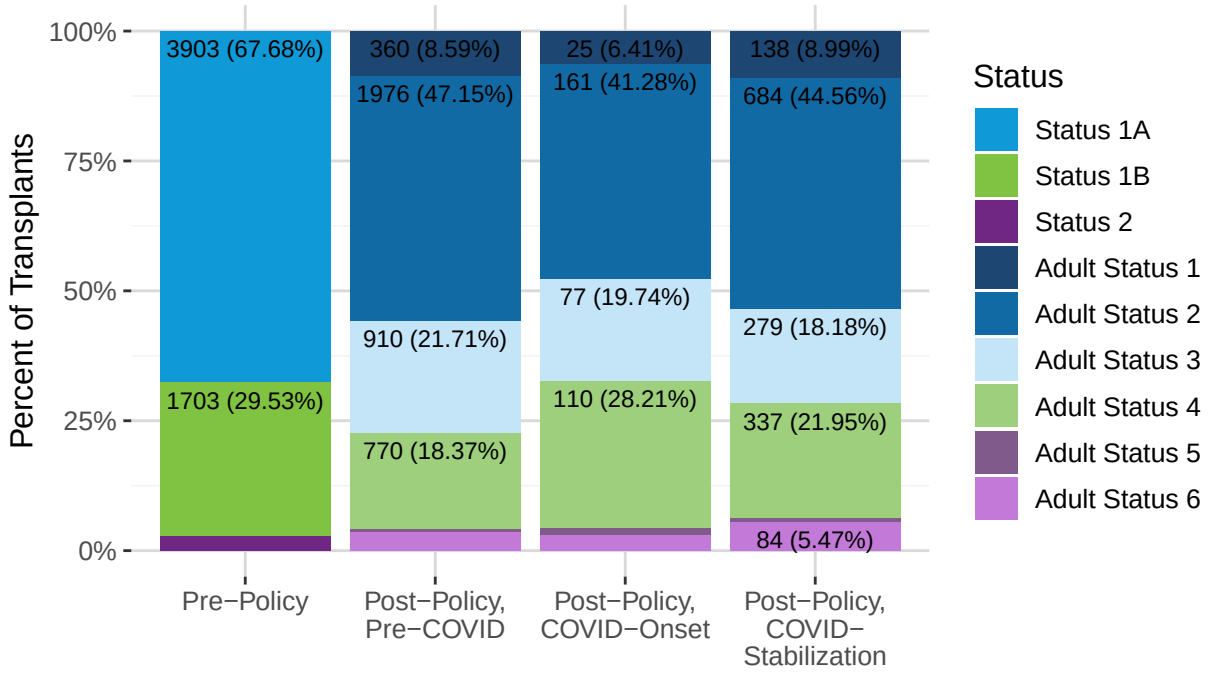
Figure 12 shows the number of deaths per 100 patient-years by region and era. There was no significant change in the number of deaths per 100 patient-years in any region pre- vs post-implementation. Although not significantly different, there were fewer deaths per 100 patient-years in a majority of the regions and overall.

Table A8 shows the number of patients ever waiting and the number of deaths for each region pre- and post-implementation, as well as the number of deaths per 100 patient-years, the relative risk of death, and the 95% confidence interval around the relative risk of death.

Transplant

These analyses examine differences in transplants between two cohorts: the pre-implementation cohort, composed of 5767 adult heart transplants performed between October 18 2016 and October 17 2018 and the post-implementation cohort, composed of 6116 adult heart transplants performed between October 18 2018 and October 17 2020. There were 349 more heart transplants performed in the post-implementation cohort than in the pre-implementation cohort.

Figure 13. Proportion of Adult Heart Transplants by Medical Urgency Status and Era



Statuses representing less than 5% of the total are not labeled on the plot
Pre−Policy: October 18, 2016 − October 17, 2018;
Post−Policy, Pre−COVID: October 18, 2018 − March 12, 2020;
Post−Policy, COVID Onset: March 13, 2020 − May 09 2020;
Post−Policy COVID Stabilization: May 10, 2020 − October 17, 2020;

Figure 13 shows the proportion of adult heart transplants performed both pre- and post-implementation by medical urgency status. Status 1A candidates received around 2/3 (67.68%) of all transplants pre-implementation, but no single status represented such a large fraction of transplants post-implementation. However, Adult Status 2 candidates received the largest fraction of all transplants followed by Adult Statuses 3 and 4. Post-implementation Adult Status 6 represented only 4.01% of transplants, while there were only 44 (0.72%) transplants to Adult Status 5 patients in the two years after the new adult heart allocation policy went into effect. For the most part, trends in percent of transplants by medical urgency status remained similar across post-implementation cohorts. During the post-policy COVID-Onset era there was a slight increase in the proportion of Adult Status 4 transplants and a slight decrease in the proportion of Adult Status 2 transplants as compared to the other post-policy eras.

Table 6 breaks down the count and percent of transplants by medical urgency status, equivalent medical urgency status as defined in the Data section above and by post-implementation COVID-eras. Post-implementation Adult Status 2 was consistently the predominant status followed statuses 3 and 4.

Table 6. Adult Heart Transplants by Era and Medical Urgency Status

Era	Equivalent Status	Status	N	%
Pre-Policy	Equivalent Status 1A	Status 1A	3903	67.7%
	Equivalent Status 1B	Status 1B	1703	29.5%
	Equivalent Status 2	Status 2	161	2.8%
Post-Policy, Pre-COVID	Equivalent Status 1A	Adult Status 1	360	8.6%
		Adult Status 2	1976	47.1%
		Adult Status 3	910	21.7%
	Equivalent Status 1B	Adult Status 4	770	18.4%
		Adult Status 5	26	0.6%
	Equivalent Status 2	Adult Status 6	149	3.6%
Post-Policy, COVID-Onset	Equivalent Status 1A	Adult Status 1	25	6.4%
		Adult Status 2	161	41.3%
		Adult Status 3	77	19.7%
	Equivalent Status 1B	Adult Status 4	110	28.2%
		Adult Status 5	5	1.3%
	Equivalent Status 2	Adult Status 6	12	3.1%
Post-Policy, COVID-Stabilization	Equivalent Status 1A	Adult Status 1	138	9%
		Adult Status 2	684	44.6%
		Adult Status 3	279	18.2%
	Equivalent Status 1B	Adult Status 4	337	22%
		Adult Status 5	13	0.8%
	Equivalent Status 2	Adult Status 6	84	5.5%
Post-Policy (overall)	Equivalent Status 1A	Adult Status 1	523	8.6%
		Adult Status 2	2821	46.1%
		Adult Status 3	1266	20.7%
	Equivalent Status 1B	Adult Status 4	1217	19.9%
		Adult Status 5	44	0.7%
	Equivalent Status 2	Adult Status 6	245	4%

Note:
Pre-Policy: October 18, 2016 - October 17, 2018;
Post-Policy, Pre-COVID: October 18, 2018 - March 12, 2020;
Post-Policy, COVID Onset: March 13, 2020 - May 09 2020;
Post-Policy COVID Stabilization: May 10, 2020 - October 17, 2020;

Figure 14. Adult Heart Transplants by Region and Era

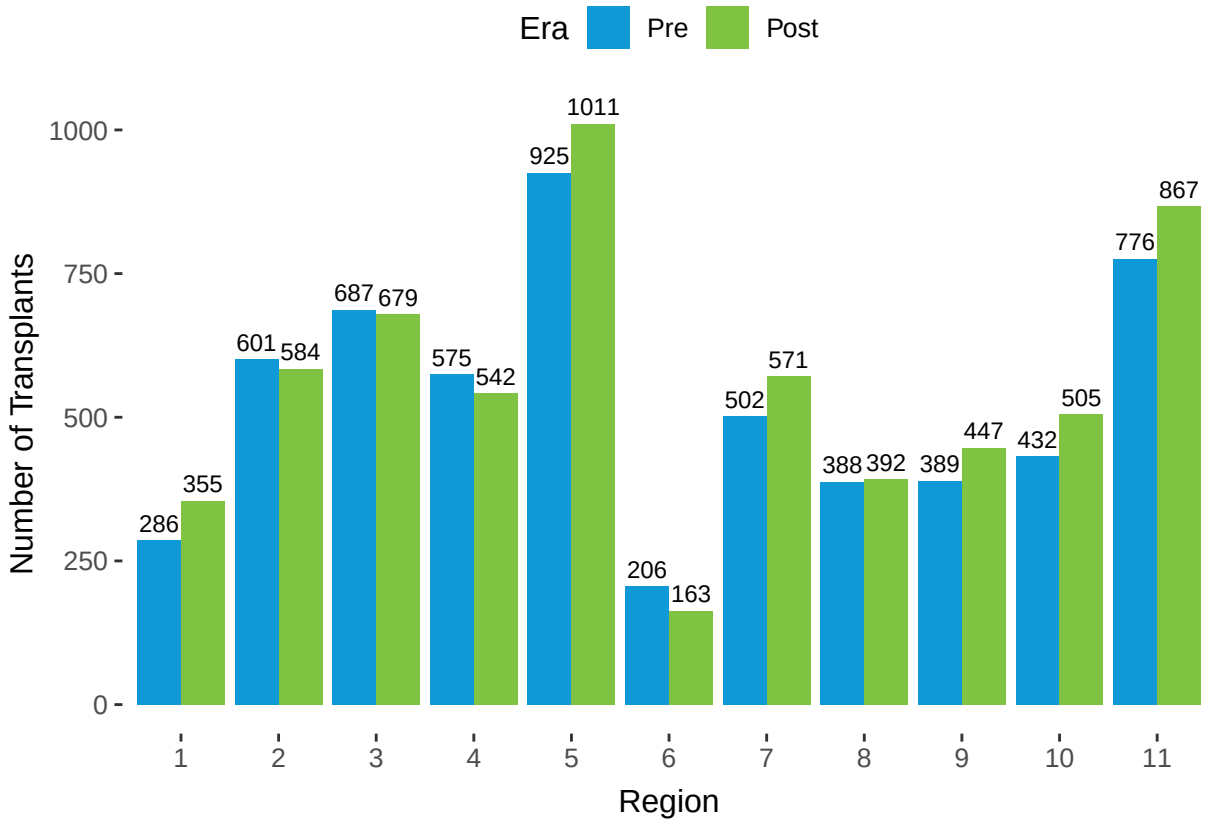
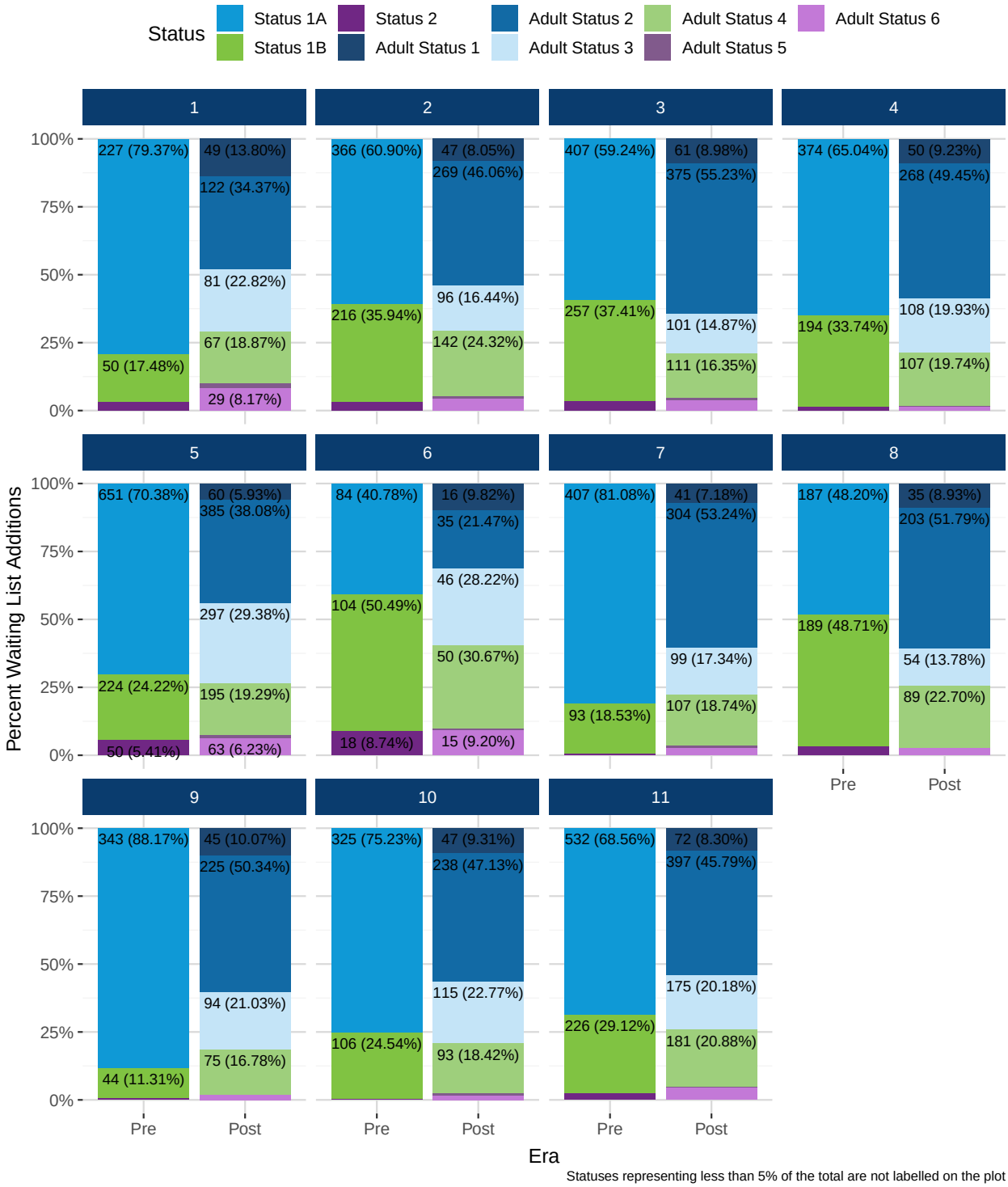


Figure 14 shows the number of adult heart transplants by era and region. The number of heart transplants rose in regions 1, 5, 7, 8, 9, 10, and 11, and decreased in regions 2, 3, 4, and 6.

Figure 15 shows the number of adult heart transplants by era, region, and medical urgency status. The distribution of statuses receiving transplants varied from region to region post-implementation, but in all but one region (region 6) Adult Status 2 candidates received the largest percent of all transplants; in region 6 Adult Status 4 (30.67%) and Adult Status 3 (28.22%) candidates received a larger percent of transplants compared to Adult Status 2 (21.47%). When comparing transplant across regions it is important to note that region 6 has the fewest number of transplant centers followed by region 1. Adult Status 5 transplants were performed in all regions except region 9 but never accounted for more than 2% of all transplants in regions where they took place. Adult Status 6 transplants were performed in all regions but only accounted for more than 5% of transplants in regions 1, 5 and 6.

Tables A9 and A10 show the count and percent of adult heart transplants by region and medical urgency status pre-implementation and post-implementation, respectively.

Figure 15. Adult Heart Transplants by Region, Era, and Medical Urgency Status



Statuses representing less than 5% of the total are not labelled on the plot

Table 7 shows the criteria allowing heart transplant recipients to qualify for their medical urgency status at time of transplant and whether they were transplanted after their initial qualification for a status or on an extension. This table only includes adult heart transplants performed during the post-implementation period. The "extension" category includes all extensions, regardless of the extension number. For Adult Status 1, it was most common for transplant recipients under their initial request to have received an exception (31.13%), while for those transplanted under an extension, non-dischargeable, surgically implanted, non-endovascular biventricular support device, exception and VA ECMO with hemodynamic values were tied for the most common criteria (24.07%). For Adult Status 2, it was most common for recipients transplanted under their initial request to qualify based on an IABP with hemodynamic values (42.56%) followed by an exception (40.22%), while it was most common for those transplanted under an extension to have an exception (48.22%). For Adult Status 3, the most common criterion for recipients transplanted under an initial request was dischargeable LVAD for discretionary 30 days (47.99%), while it was most common for recipients transplanted under an extension to have an exception (42.20%). For Adult Status 4, dischargeable LVAD without discretionary 30 days was the most common criterion both for those transplanted under their initial request (40.63%) and for those transplanted under an extension (55.95%).

Table A10 shows the criteria qualifying heart transplant recipients for their medical urgency status at time of transplant and whether they were transplanted after their initial qualification for a status or on an extension by region. The proportion of criteria for adult heart recipients in each region is fairly similar to the criteria seen for that medical urgency status at the national level, with the most variability being in the number of transplant recipients who received an exception in a region.

Table 7. Adult Heart Transplants by Criteria Within Medical Urgency Status at Transplant Post-Implementation

Status	Criteria	Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 1	BIVAD/Ventricular Episodes	40	8.53%	6	11.11%	46	8.80%
	Exception	146	31.13%	13	24.07%	159	30.40%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	63	13.43%	13	24.07%	76	14.53%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	106	22.60%	9	16.67%	115	21.99%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	114	24.31%	13	24.07%	127	24.28%
Overall		**469**	**100%**	**54**	**100%**	**523**	**100%**
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	0.04%	0	0.00%	1	0.04%
	Exception	897	40.22%	285	48.22%	1182	41.90%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	31	1.39%	3	0.51%	34	1.21%
	Intra-aortic ballon pump - Hemodynamic Values obtained	949	42.56%	171	28.93%	1120	39.70%
	Intra-aortic balloon pump after 14 days	3	0.13%	0	0.00%	3	0.11%
	Mechanical circulatory support device(MCSD) with malfunction	91	4.08%	57	9.64%	148	5.25%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	26	1.17%	1	0.17%	27	0.96%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	16	0.72%	0	0.00%	16	0.57%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	129	5.78%	18	3.05%	147	5.21%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	40	1.79%	43	7.28%	83	2.94%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	1	0.04%	0	0.00%	1	0.04%

Adult Status 2
(continued)

Status	Criteria	N	%	N	%	N	%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	3	0.13%	0	0.00%	3	0.11%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	43	1.93%	13	2.20%	56	1.99%
Overall		**2230**	**100%**	**591**	**100%**	**2821**	**100%**
	Congenital heart disease	1	0.11%	0	0.00%	1	0.08%
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	429	47.99%	0	0.00%	429	33.89%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	6	0.67%	0	0.00%	6	0.47%
	Exception	160	17.90%	157	42.20%	317	25.04%
	Intra-aortic ballon pump - Hemodynamic Values obtained	4	0.45%	0	0.00%	4	0.32%
	Intra-aortic balloon pump after 14 days	2	0.22%	1	0.27%	3	0.24%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	15	1.68%	4	1.08%	19	1.50%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	47	5.26%	44	11.83%	91	7.19%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	21	2.35%	40	10.75%	61	4.82%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	8	0.89%	10	2.69%	18	1.42%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	13	1.45%	2	0.54%	15	1.18%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	10	1.12%	3	0.81%	13	1.03%
	Mechanical circulatory support device (MCSD) with hemolysis	5	0.56%	6	1.61%	11	0.87%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	10	1.12%	1	0.27%	11	0.87%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	1	0.11%	0	0.00%	1	0.08%

Adult Status 3
(continued)

Status	Criteria	N	%	N	%	N	%
	Mechanical circulatory support device (MCSD) with pump thrombosis	3	0.34%	26	6.99%	29	2.29%
	Mechanical circulatory support device (MCSD) with right heart failure	3	0.34%	9	2.42%	12	0.95%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	155	17.34%	69	18.55%	224	17.69%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	0.11%	0	0.00%	1	0.08%
Overall		**894**	**100%**	**372**	**100%**	**1266**	**100%**
Adult Status 4	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	92	11.19%	38	9.62%	130	10.68%
	Congenital heart disease	41	4.99%	31	7.85%	72	5.92%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	334	40.63%	221	55.95%	555	45.60%
	Exception	185	22.51%	50	12.66%	235	19.31%
	Inotropes without hemodynamic monitoring	105	12.77%	21	5.32%	126	10.35%
	Intra-aortic ballon pump - Hemodynamic Values obtained	1	0.12%	0	0.00%	1	0.08%
	Ischemic heart disease with intractable angina	17	2.07%	12	3.04%	29	2.38%
	No criteria for this status	1	0.12%	0	0.00%	1	0.08%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	0.12%	0	0.00%	1	0.08%
	Retransplant	45	5.47%	22	5.57%	67	5.51%
Overall		**822**	**100%**	**395**	**100%**	**1217**	**100%**
Adult Status 5	None	37	100.00%	7	100.00%	44	100.00%
Adult Status 6	None	222	100.00%	23	100.00%	245	100.00%

Note:
"%" indicates the percent of waiting list registrations within a medical urgency status

Table 8 shows the count and percent of registrations with a mechanical circulatory support device (MCSD) at transplant, based on information reported on the TRR and broken down by device type and brand. Overall, 43.27% of transplants had an MCSD listed on the TRR pre-implementation, compared to 33.43% post-implementation. Changes in the proportion of MCSDs at transplant were similar to those observed for MCSDs reported at listing but were more dramatic, with the percent of transplants made to recipients with LVADs falling substantially and the percent recipients with an IABP or on ECMO more than doubling.

Table A12 shows the count and percent of MCSDs at transplant by region based on information reported on the TRR. The distribution of MCSDs at transplant is broadly similar across regions, although region 6 had a smaller decline in LVADs among recipients than other regions. Region 8 had the lowest proportion of transplant recipients with an LVAD at transplant post-implementation, and about half of transplant recipients in this region had an IABP at transplant. Post-implementation the percent of patients on IABP over-doubled compared to pre-implementation for all regions except 4 and 7.

For comparison, Table A13 shows the count and percent of mechanical circulatory support devices reported for adult heart transplant recipients at the time of transplant during the post-implementation era, based on the recipient's justification form history and broken down by device type and brand. The MCSDs at transplant reported on waitlist justification forms were similar to those reported on the TRR, with a higher proportion of recipients with an IABP being reported on justification forms than on the TRR and a lower proportion of recipients with some form of LVAD based on the justification form data than the proportion reported on the TRR.

Table 8. Mechanical Circulatory Support Devices at Transplant for Adult Heart Candidates

Brand	Era	Count	Percent
ECMO			
Total ECMO	**Pre**	**58**	**1.71%**
	Post	**332**	**7.59%**
IABP			
Total IABP	**Pre**	**468**	**13.8%**
	Post	**1712**	**39.12%**
LVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	3	0.15%
Cardiac Assist Tandem Heart	Pre	2	0.08%
	Post	1	0.05%
CentriMag (Thoratec/Levitronix)	Pre	10	0.38%
	Post	24	1.18%
Heartmate II	Pre	1162	43.77%
	Post	393	19.34%
HeartMate III	Pre	78	2.94%
	Post	757	37.25%
Heartmate XVE	Pre	4	0.15%
	Post	0	0%
Heartsaver VAD	Pre	12	0.45%
	Post	3	0.15%
	Pre	1031	38.83%

Heartware HVAD	Post	579	28.49%
Impella CP	Pre	1	0.04%
	Post	32	1.57%
Impella Recover 2.5	Pre	6	0.23%
	Post	6	0.3%
Impella Recover 5.0	Pre	38	1.43%
	Post	145	7.14%
Jarvik 2000	Pre	1	0.04%
	Post	0	0%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	1	0.05%
Thoratec IVAD	Pre	2	0.08%
	Post	0	0%
Other, Specify	Pre	308	11.6%
	Post	88	4.33%
Total LVAD	**Pre**	**2655**	**78.3%**
	Post	**2032**	**46.44%**
LVAD+RVAD			
Berlin Heart EXCOR	Pre	0	0%
	Post	1	0.43%
Cardiac Assist Protek Duo	Pre	0	0%
	Post	15	6.47%
Cardiac Assist Tandem Heart	Pre	4	2.7%
	Post	2	0.86%
CentriMag (Thoratec/Levitronix)	Pre	56	37.84%
	Post	120	51.72%
Heartmate II	Pre	6	4.05%
	Post	0	0%
HeartMate III	Pre	2	1.35%
	Post	40	17.24%
Heartware HVAD	Pre	50	33.78%
	Post	32	13.79%
Impella CP	Pre	0	0%
	Post	2	0.86%
Impella Recover 2.5	Pre	1	0.68%
	Post	1	0.43%
Impella Recover 5.0	Pre	3	2.03%
	Post	3	1.29%
	Pre	5	3.38%

Maquet Jostra Rotaflow	Post	6	2.59%
Other, Specify	Pre	21	14.19%
	Post	10	4.31%
Total LVAD+RVAD	**Pre**	**148**	**4.36%**
	Post	**232**	**5.3%**
RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	4	14.29%
CentriMag (Thoratec/Levitronix)	Pre	3	27.27%
	Post	7	25%
Heartmate II	Pre	2	18.18%
	Post	0	0%
Heartware HVAD	Pre	2	18.18%
	Post	3	10.71%
Impella CP	Pre	0	0%
	Post	2	7.14%
Impella Recover 2.5	Pre	0	0%
	Post	1	3.57%
Impella Recover 5.0	Pre	2	18.18%
	Post	4	14.29%
Impella RP	Pre	1	9.09%
	Post	3	10.71%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	1	3.57%
Other, Specify	Pre	1	9.09%
	Post	3	10.71%
Total RVAD	**Pre**	**11**	**0.32%**
	Post	**28**	**0.64%**
TAH			
SynCardia CardioWest	Pre	50	98.04%
	Post	37	92.5%
Other, Specify	Pre	1	1.96%
	Post	3	7.5%
Total TAH	**Pre**	**51**	**1.5%**
	Post	**40**	**0.91%**

Figure 16 shows the proportion of requested statuses for adult heart recipients at transplant, as well as the review type of the requests and whether they were initial or extension requests. The most common request at transplant was Adult Status 2 initial; this status also had the highest proportion of exception requests. Initial requests were more common than extension requests.

Figure 16. Adult Heart Transplants by Review Type and Requested Status

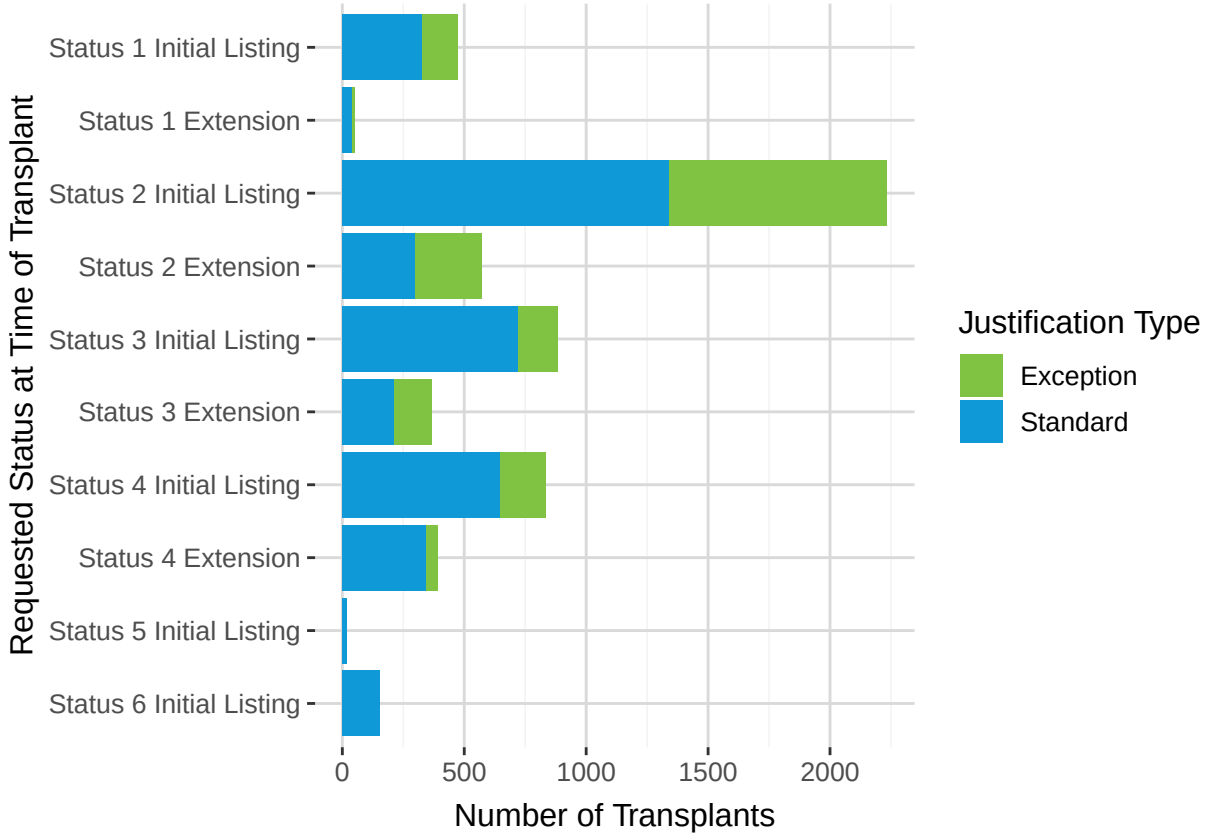
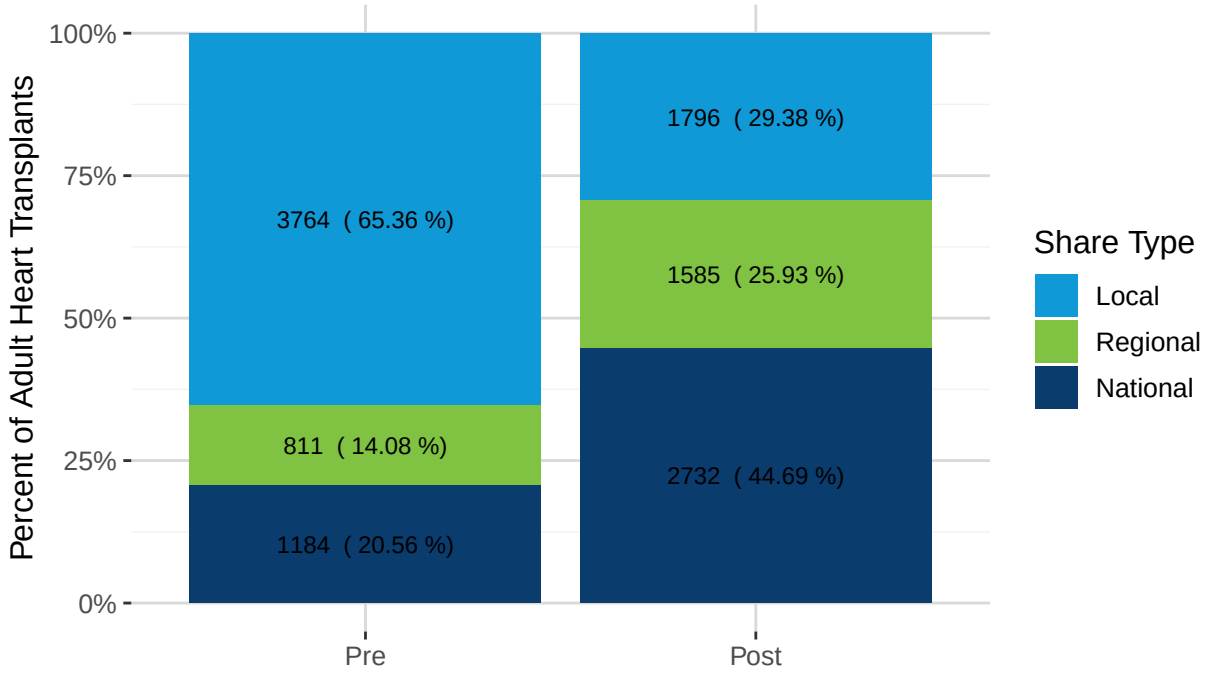


Figure 17. Adult Heart Transplants by Share Type and Era



Pre−Policy: October 18, 2016 − October 17, 2018;
Post−Policy, Pre−COVID: October 18, 2018 − March 12, 2020;
Post−Policy, COVID Onset: March 13, 2020 − May 09 2020;
Post−Policy COVID Stabilization: May 10, 2020 − October 17, 2020;
Not reported share types excluded (n=8 pre & n=3 post);

Figure 17 shows the percent of adult heart transplants by share type and era. Here, "local" refers to hearts recovered and transplanted within the same DSA and "regional" refers to hearts recovered and transplanted in different DSAs but within the same OPTN region. This report includes data from after the removal of DSA from heart allocation, implemented January 09, 2020; a separate OPTN monitoring report addresses the removal.

The number of local transplants declined substantially post-implementation while both regional and national shares increased. The increase was most dramatic for heart transplants at the national share level, which more than doubled post-implementation. Table 9 shows the proportion of heart transplants broken out by post-implementation COVID-eras. National shares were most common across all post-implementation COVID-eras followed by local and regional shares which varied slightly across post-implementation eras.

Table A14 gives the counts and percentages of adult heart transplants performed in each distance category by share type and era.

Table 9. Heart Transplants by Share Type and Era

Era	Zone	N	%
Pre-Policy	Local	3764	65.3%
	Regional	811	14.1%
	National	1184	20.5%
	Not Reported	8	0.1%
Post-Policy, Pre-COVID	Local	1324	31.6%
	Regional	1012	24.1%
	National	1853	44.2%
	Not Reported	2	0%
Post-Policy, COVID-Onset	Local	95	24.4%
	Regional	118	30.3%
	National	177	45.4%
	Not Reported	0	0%
Post-Policy, COVID-Stabilization	Local	377	24.6%
	Regional	455	29.6%
	National	702	45.7%
	Not Reported	1	0.1%
Post-Policy (overall)	Local	1796	29.4%
	Regional	1585	25.9%
	National	2732	44.7%
	Not Reported	3	0%

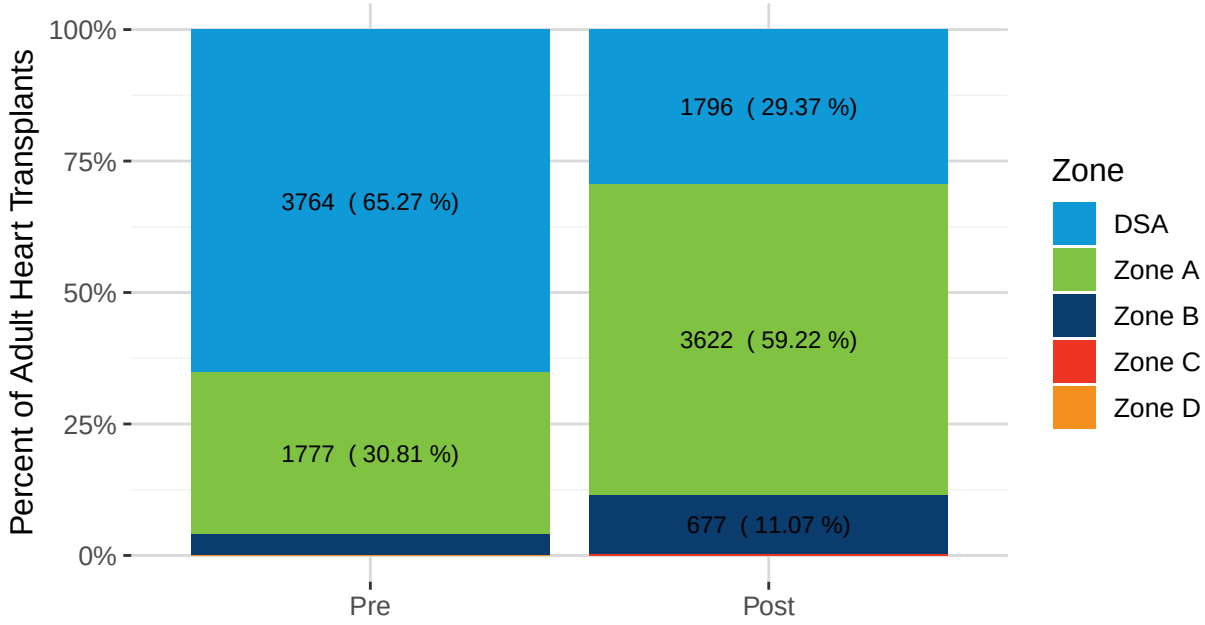
Note:
Pre-Policy: October 18, 2016 - October 17, 2018;
Post-Policy, Pre-COVID: October 18, 2018 - March 12, 2020;
Post-Policy, COVID Onset: March 13, 2020 - May 09 2020;
Post-Policy COVID Stabilization: May 10, 2020 - October 17, 2020;

Figure 18 and Table 10 show the number of adult heart transplants performed by zone and era. Transplants within the DSA decreased post-implementation but rose in Zones A, B and C. The greatest increase in the percent of transplants was in Zone A, but transplants also more than doubled in Zone B. Zone C saw only 25 adult heart transplant with 4 pre-implementation and 21 post-implementation. There was only 1 adult heart transplant in Zone D pre-implementation and none occurred post-implementation. These trends were consistent across post-implementation COVID-Eras, as shown in Table 10.

The zones are defined as follows relative to the location of the transplant hospital:

- Zone A: within 500 nautical miles of the donor hospital but outside the donor hospital's DSA
- Zone B: 500 or more nautical miles from the donor hospital but within 1000 nautical miles of the donor hospital
- Zone C: 1000 or more nautical miles from the donor hospital but within 1500 nautical miles of the donor hospital
- Zone D: 1500 or more nautical miles from the donor hospital but within 2500 nautical miles of the donor hospital

Figure 18. Adult Heart Transplants by Zone and Era



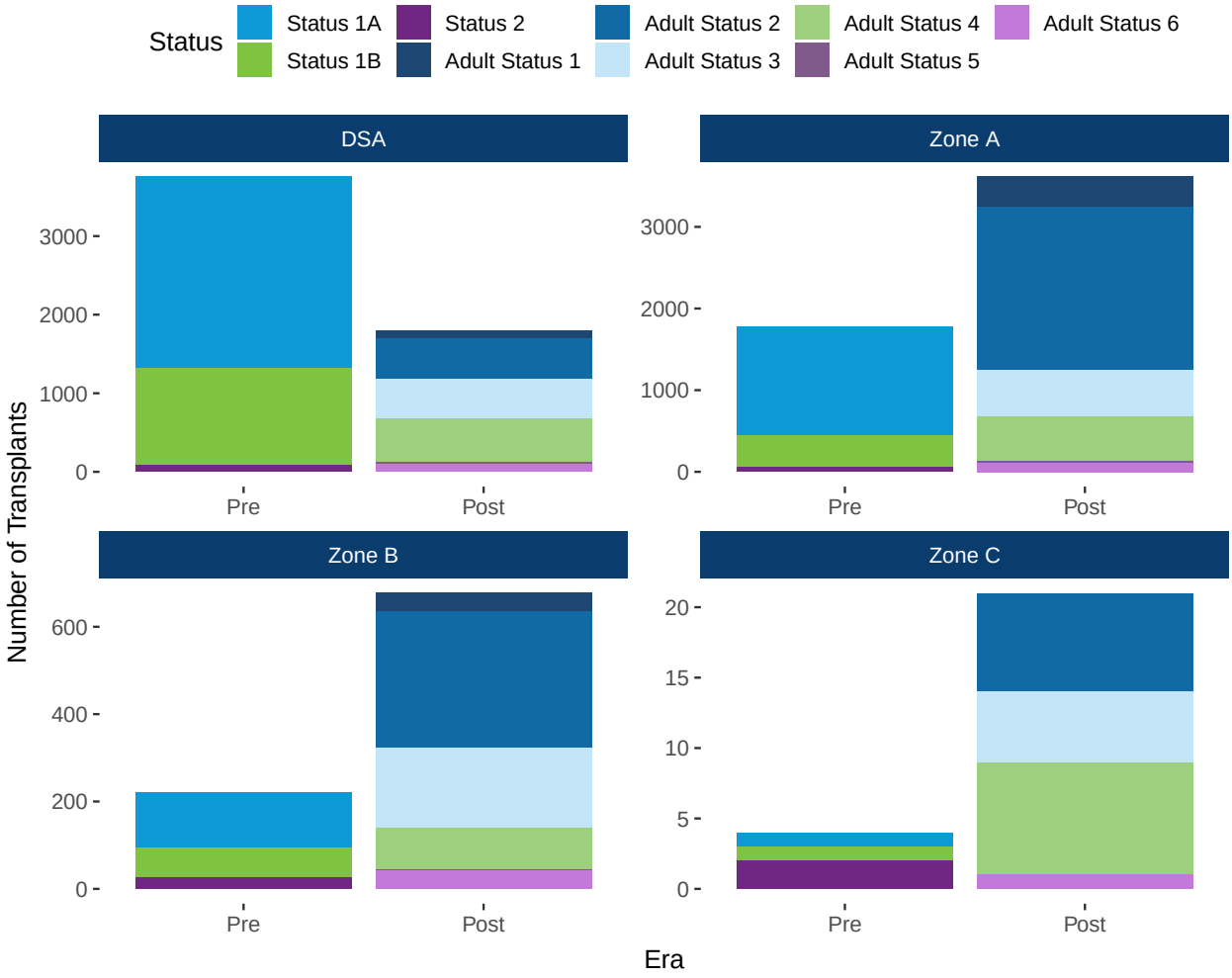
Pre−Policy: October 18, 2016 − October 17, 2018;
Post−Policy, Pre−COVID: October 18, 2018 − March 12, 2020;
Post−Policy, COVID Onset: March 13, 2020 − May 09 2020;
Post−Policy COVID Stabilization: May 10, 2020 − October 17, 2020;
Zones representing <5% of the total are not labeled on the plot;
DSA was removed as a unit of allocation from heart policy on 1/09/2020;
A separate monitoring report addresses the removal

Table 10. Heart Transplants by Zone and Era

Era	Zone	N	%
Pre-Policy	DSA	3764	65.3%
	Zone A	1777	30.8%
	Zone B	221	3.8%
	Zone C	4	0.1%
	Zone D	1	0%
Post-Policy, Pre-COVID	DSA	1324	31.6%
	Zone A	2387	57%
	Zone B	467	11.1%
	Zone C	13	0.3%
	Zone D	0	0%
Post-Policy, COVID-Onset	DSA	95	24.4%
	Zone A	255	65.4%
	Zone B	40	10.3%
	Zone C	0	0%
	Zone D	0	0%
Post-Policy, COVID-Stabilization	DSA	377	24.6%
	Zone A	980	63.8%
	Zone B	170	11.1%
	Zone C	8	0.5%
	Zone D	0	0%
Post-Policy (overall)	DSA	1796	29.4%
	Zone A	3622	59.2%
	Zone B	677	11.1%
	Zone C	21	0.3%
	Zone D	0	0%

Note:
Pre-Policy: October 18, 2016 - October 17, 2018;
Post-Policy, Pre-COVID: October 18, 2018 - March 12, 2020;
Post-Policy, COVID Onset: March 13, 2020 - May 09 2020;
Post-Policy COVID Stabilization: May 10, 2020 - October 17, 2020;
DSA was removed as a unit of allocation from heart policy on 1/09/2020;
A separate monitoring report addresses the removal;

Figure 19. Adult Heart Transplants by Zone, Era, and Medical Urgency Status

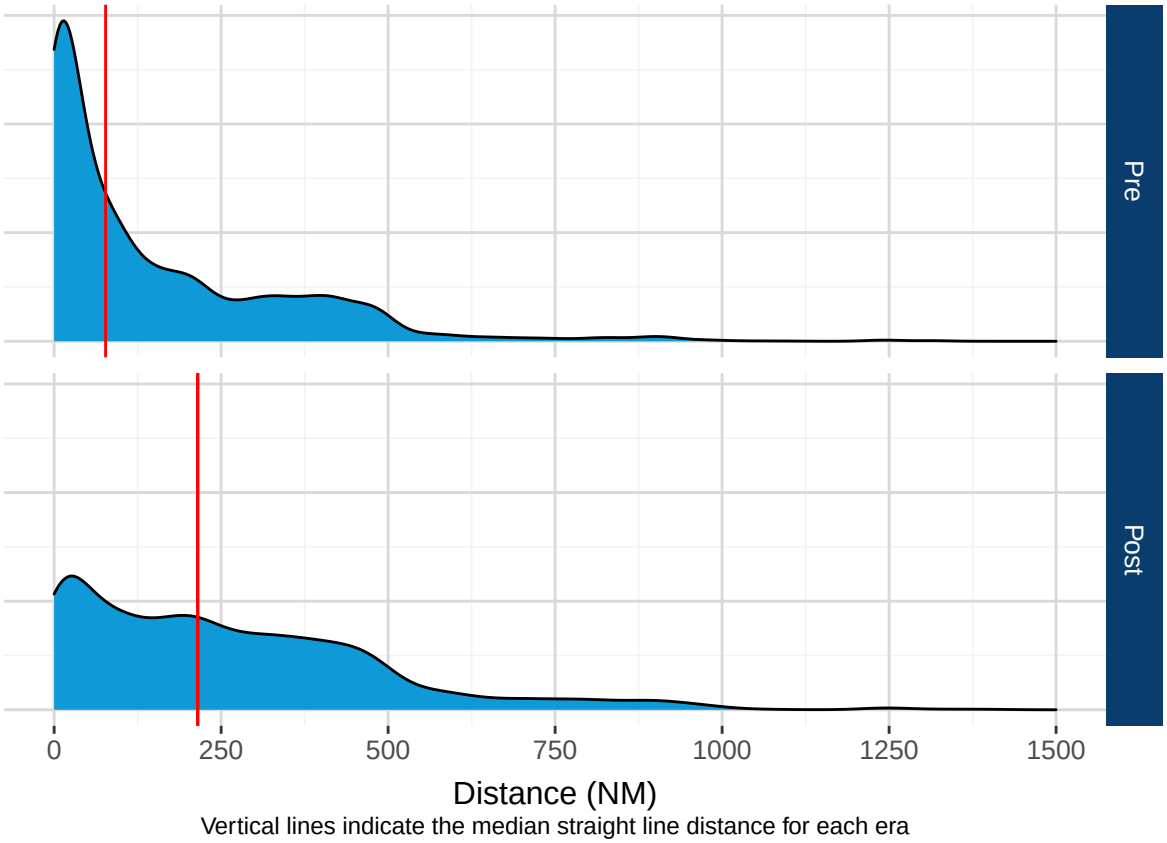


DSA was removed as a unit of allocation from heart policy on 1/09/2020
A separate monitoring report addresses the removal;

Figure 19 shows the number of adult heart transplants by zone, medical urgency status, and era. Pre-implementation, most transplants within the DSA and Zone A were Status 1A. Post-implementation, an approximately equal proportion of Adult Status 2, 3, and 4 candidates received transplants in the DSA. Post implementation, Adult Status 2 candidates received the largest proportion of transplants in Zones A and B and Adult Status 4 candidates received the largest proportion of transplants in Zone C. No Adult Status 1 transplants were performed in Zone C, likely due to the longer distance traveled.

Table A15 shows the counts and percentages of adult heart transplants by zone, era, and medical urgency status.

Figure 20. Distance Traveled at Transplant by Era



Vertical lines indicate the median straight line distance for each era

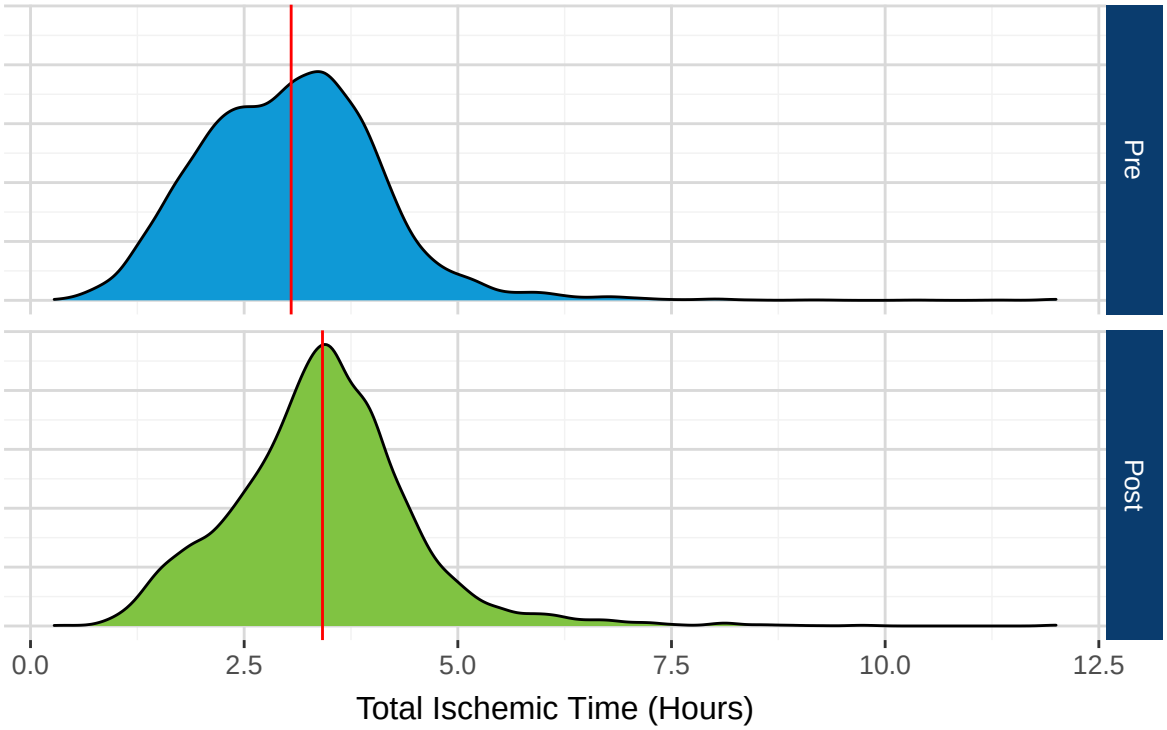
Table 11. Distance Traveled at Transplant by Era

Era	Min	IQR	Mean	Median	Max
Pre-Policy	**0**	**226.00**	**154.28**	**77**	**1851**
Post-Policy, Pre-COVID	0	324.00	262.28	217	1402
Post-Policy, COVID-Onset	0	286.75	237.87	202	989
Post-Policy, COVID-Stabilization	0	300.00	264.34	215	1414
Post-Policy (overall)	**0**	**318.00**	**261.24**	**215**	**1414**

Note:
Pre-Policy: October 18, 2016 - October 17, 2018;
Post-Policy, Pre-COVID: October 18, 2018 - March 12, 2020;
Post-Policy, COVID Onset: March 13, 2020 - May 09 2020;
Post-Policy COVID Stabilization: May 10, 2020 - October 17, 2020;

Figure 20 and Table 11 show the distribution of distance traveled by hearts pre- and post-implementation. Table 11 shows the breakdown by post-implementation COVID-eras; the results were consistent across COVID-eras although distances decreased slightly during the COVID-Onset era. While the majority of hearts traveled less than 100 nautical miles pre-implementation, post-implementation travel distances were distributed much more evenly up to about 500 nautical miles before dropping off. The median distance traveled increased significantly ($p < 0.001$) post-implementation, from a pre-implementation median of 77 nautical miles to a post-implementation median of 215 nautical miles.

Figure 21. Total Ischemic Time at Transplant by Era



DSA was removed as a unit of allocation from heart policy on 1/09/2020
A separate monitoring report addresses the removal;

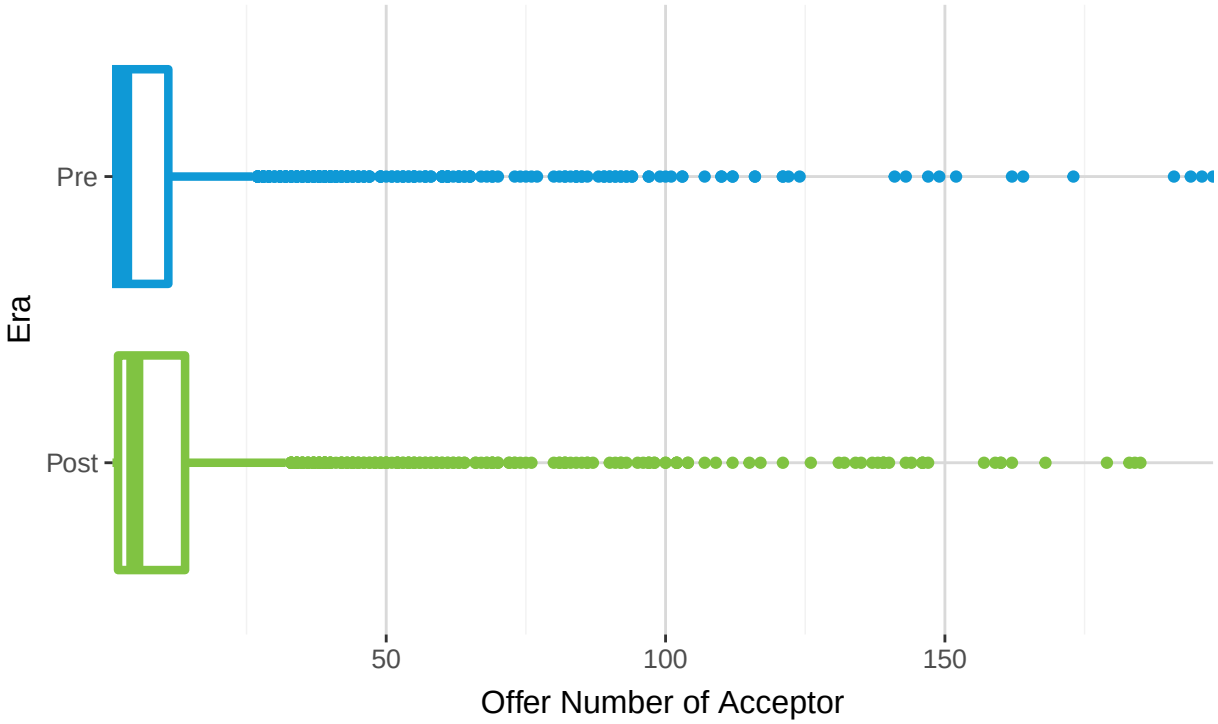
Table 12. Total Ischemic Time at Transplant by Era

Era	Min	IQR	Mean	Median	Max
Pre-Policy	**0.28**	**1.40**	**3.05**	**3.05**	**12.00**
Post-Policy, Pre-COVID	0.33	1.23	3.41	3.43	12.00
Post-Policy, COVID-Onset	0.95	1.10	3.32	3.30	7.55
Post-Policy, COVID-Stabilization	0.35	1.14	3.45	3.40	9.85
Post-Policy (overall)	**0.33**	**1.22**	**3.41**	**3.42**	**12.00**

Note:
Pre-Policy: October 18, 2016 - October 17, 2018;
Post-Policy, Pre-COVID: October 18, 2018 - March 12, 2020;
Post-Policy, COVID Onset: March 13, 2020 - May 09 2020;
Post-Policy COVID Stabilization: May 10, 2020 - October 17, 2020;

Figure 21 and Table 12 show the distribution of total ischemic times at transplant both pre- and post-implementation where total ischemic time is defined as the sum of cold ischemic time, warm ischemic time, and anastomotic time. Table 12 breaks down the post-implementation period by COVID-eras. Total ischemic times increased significantly ($p < 0.001$) post-implementation to a mean of 3.4 hours from 3 hours. The maximum ischemic time reported during the pre-implementation era was the same as the maximum ischemic time reported during the post-implementation era (12 hours). These findings were consistent across the post-implementation COVID-eras except for the maximum ischemic time which was shorter during the post-implementation COVID-stabilization and COVID-Onset eras.

Figure 22. Boxplot of the Sequence Number of the Acceptor for Adult Hearts



There were 14 acceptances with an offer number over 200 in the pre era and 12 in the post era (not shown)

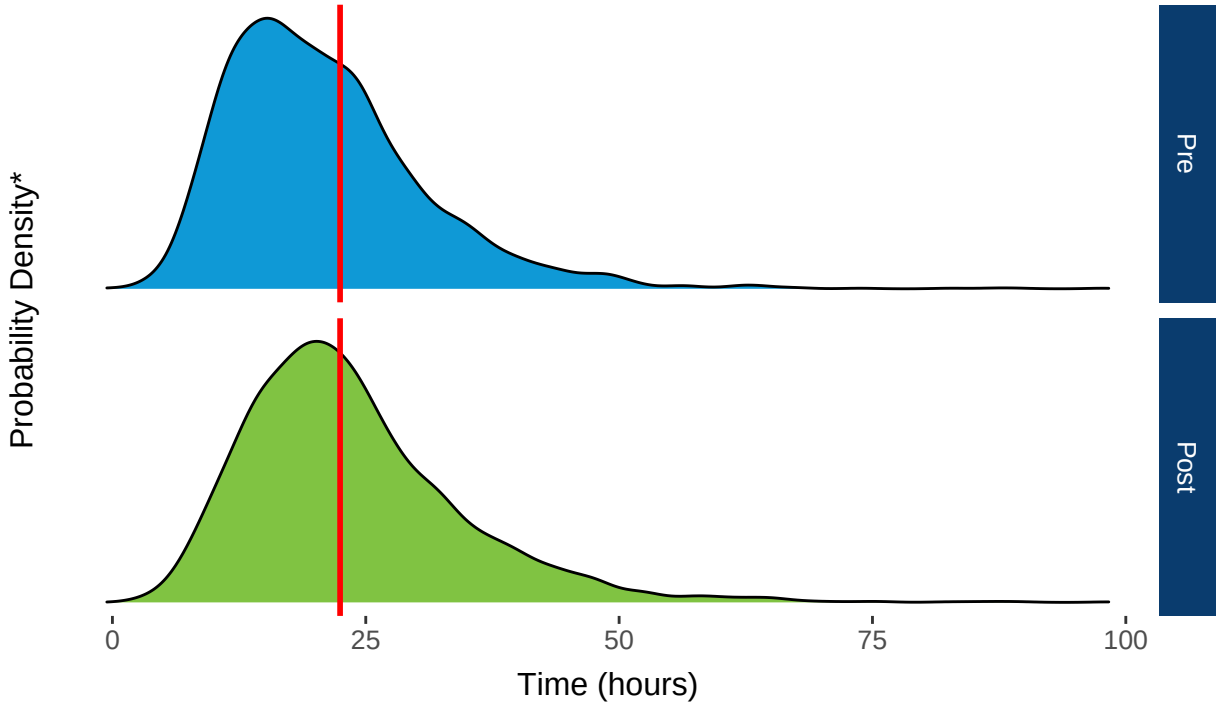
Table 13. Summary of the Sequence Number of the Final Acceptor for Adult Heart Donors

Era	Min	IQR	Mean	Median	Max
Pre-Policy	**1**	**10.00**	**14.47**	**3**	**740**
Post-Policy, Pre-COVID	1	11.00	15.61	5	660
Post-Policy, COVID-Onset	1	13.25	14.27	5	135
Post-Policy, COVID-Stabilization	1	16.00	21.11	6	499
Post-Policy (overall)	**1**	**12.00**	**16.86**	**5**	**660**

Note:
Pre-Policy: October 18, 2016 - October 17, 2018;
Post-Policy, Pre-COVID: October 18, 2018 - March 12, 2020;
Post-Policy, COVID Onset: March 13, 2020 - May 09 2020;
Post-Policy COVID Stabilization: May 10, 2020 - October 17, 2020;

Figure 22 and Table 13 show the distribution of sequence numbers for the final acceptors of adult hearts both pre-and post-implementation. Table 13 breaks out the post-implementation by COVID-Eras. The mean and median sequence number for the final acceptor increased for adult heart donors post-implementation. The largest increase in the sequence number for the final acceptor occurred Post-Policy, during the COVID-stabilization period. The maximum sequence number of the final acceptor was lower post-implementation compared to pre-implementation.

Figure 23. Time from First Electronic Offer to Cross Clamp for Deceased Heart Donors



* High probability density values mean that a high percentage of the population lies at or around the corresponding x−axis value, and vice versa
Red line indicates the mean in each corresponding era
Times > 100 were included in mean calculations but excluded from plot (n=3; 1 pre & 2 post)

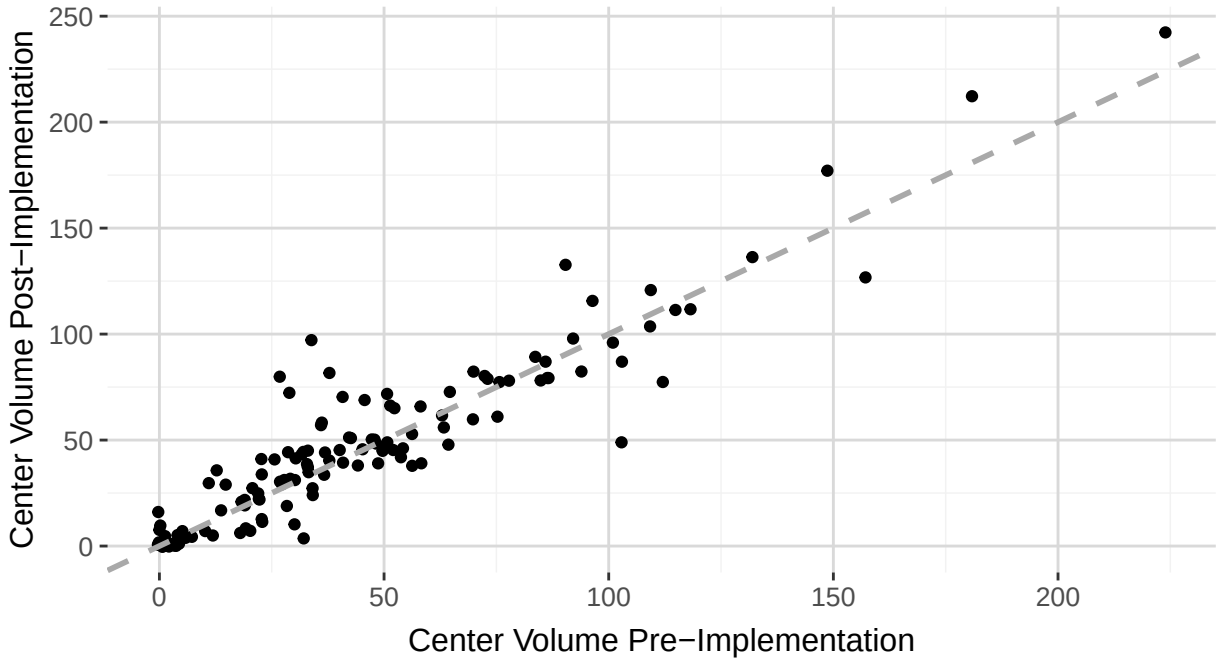
Table 14. Time from First Electronic Offer to Cross Clamp for Deceased Heart Donors

Era	Min	IQR	Mean	Median	Max
Pre-Policy	**-0.55**	**11.99**	**21.06**	**19.47**	**97.73**
Post-Policy, Pre-COVID	1.90	12.64	23.15	21.05	98.32
Post-Policy, COVID-Onset	3.90	14.86	25.30	23.72	75.93
Post-Policy, COVID-Stabilization	4.36	12.54	24.67	22.83	82.37
Post-Policy (overall)	**1.90**	**12.70**	**23.72**	**21.88**	**98.32**

Note:
Pre-Policy: October 18, 2016 - October 17, 2018;
Post-Policy, Pre-COVID: October 18, 2018 - March 12, 2020;
Post-Policy, COVID Onset: March 13, 2020 - May 09 2020;
Post-Policy COVID Stabilization: May 10, 2020 - October 17, 2020;

Figure 23 and Table 14 show the distributions of time from first electronic offer to cross clamp both pre- and post-implementation. The mean time from first electronic offer to cross clamp increased slightly post- implementation, from 21.06 hours to 23.72. The slight increase in time from first electronic offer to cross clamp was consistently seen across all post-implementation COVID-eras.

Figure 24. Center Adult Heart Transplant Volume by Era



* COVID−19 Pandemic & National State of Emergency Declared March 11−13, 2020
This figure contains roughly 4 months of COVID−era data:
Pre−Policy: October 18, 2016 − October 17, 2018;
Post−Policy, Pre−COVID: October 18, 2018 − March 12, 2020;
Post−Policy, COVID Onset: March 13, 2020 − May 09 2020;
Post−Policy COVID Stabilization: May 10, 2020 − October 17, 2020;

Figure 24 compares the number of adult heart transplants performed by transplant centers before and after modifications to the adult heart allocation system. This figure contains roughly 7 months of COVID-Era data and should be interpreted with caution as certain centers are known to have been significantly impacted by COVID. Dots that fall below the diagonal gray line represent centers where transplant volume decreased post-implementation, while those above the line performed more transplants in the two years after implementation. There were 133 transplant centers that performed at least one adult heart transplant in one of the two eras. Of those, 72 performed more adult heart transplants post-implementation than they did pre-implementation. There were 53 centers that performed fewer adult heart transplants after implementation than they did pre-implementation. Of these, 27 did more than 25% fewer transplants post-implementation than they did pre-implementation.

Figure 25. Distribution of Medical Urgency Status for Patients Ever Waiting by Change in Listing Center Volume Post Implementation

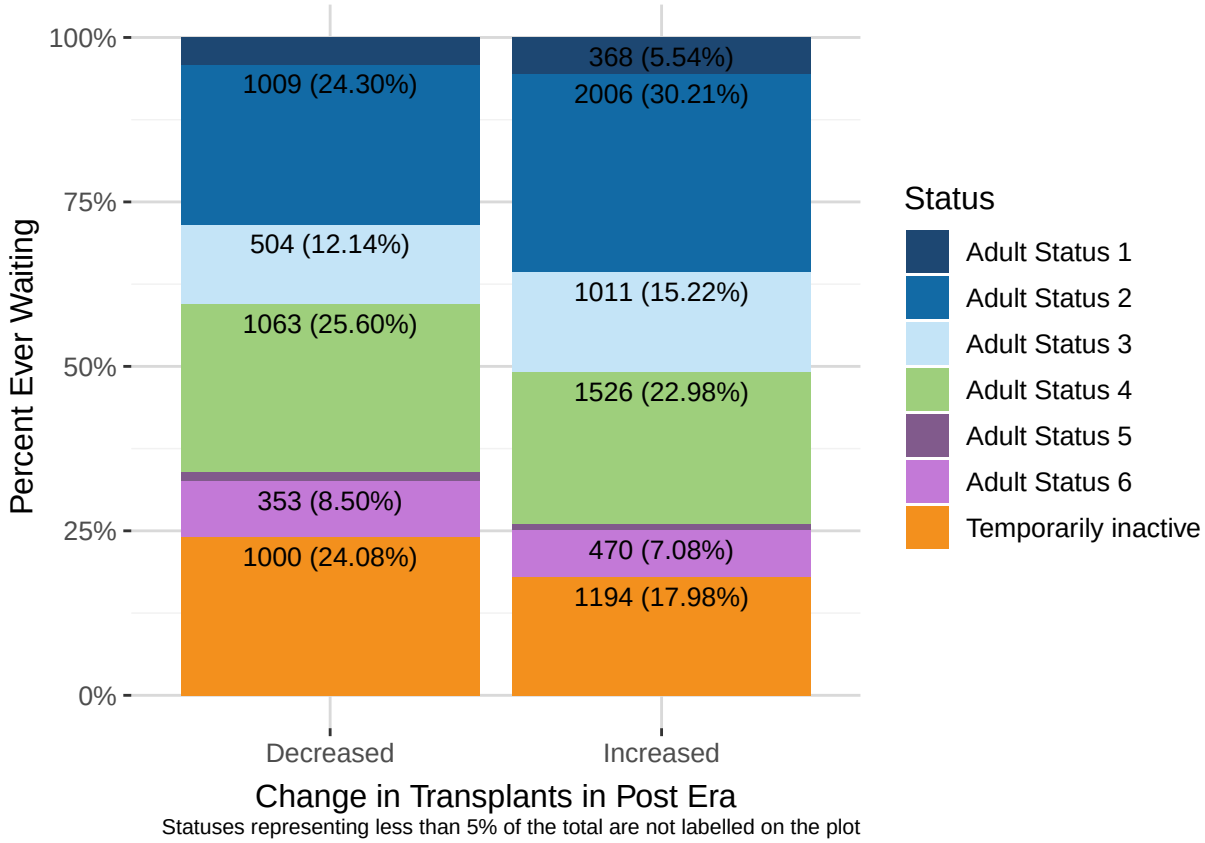


Figure 25 compares the distributions of patients ever waiting at different medical urgency statuses post-implementation at centers where the number of transplants performed post-implementation increased to the distribution at centers where the number of transplants performed post-implementation decreased. Centers where transplant volume increased tended to have a higher proportion of candidates listed at Adult Status 1-3. Centers where transplant volume decreased tended to have a higher proportion of Adult Status 6 candidates, who receive few heart offers as a result of their relatively low degree of medical urgency. There were statistically significant differences in the proportion of patients ever waiting by listing center volume post-implementation ($p < 0.001$). Differences in waitlist makeup may help to explain changes in the number of transplants performed by centers post-implementation.

Figure 26 shows the number of transplants per 100 patient-years waiting both pre- and post-implementation. The number of transplants per 100 patient years to Adult Status 1 and Adult Status 2 recipients was significantly higher than the number of transplants per 100 patient years for any other status either pre- or post-implementation. In general the number of transplants per 100 patient-years waiting declined with medical urgency status, as expected because higher priority is given to candidates in higher medical urgency statuses. Overall, there were more transplants per 100 patient waiting years post-implementation compared to pre-implementation.

Figure 27 shows the transplants per 100 patient waiting years by medical urgency status and era for Adult Heart Statuses 3-6 only in order to better understand visualize these particular statuses.

Figure 26. Transplants per 100 Patient-Years Waiting by Medical Urgency Status and Era

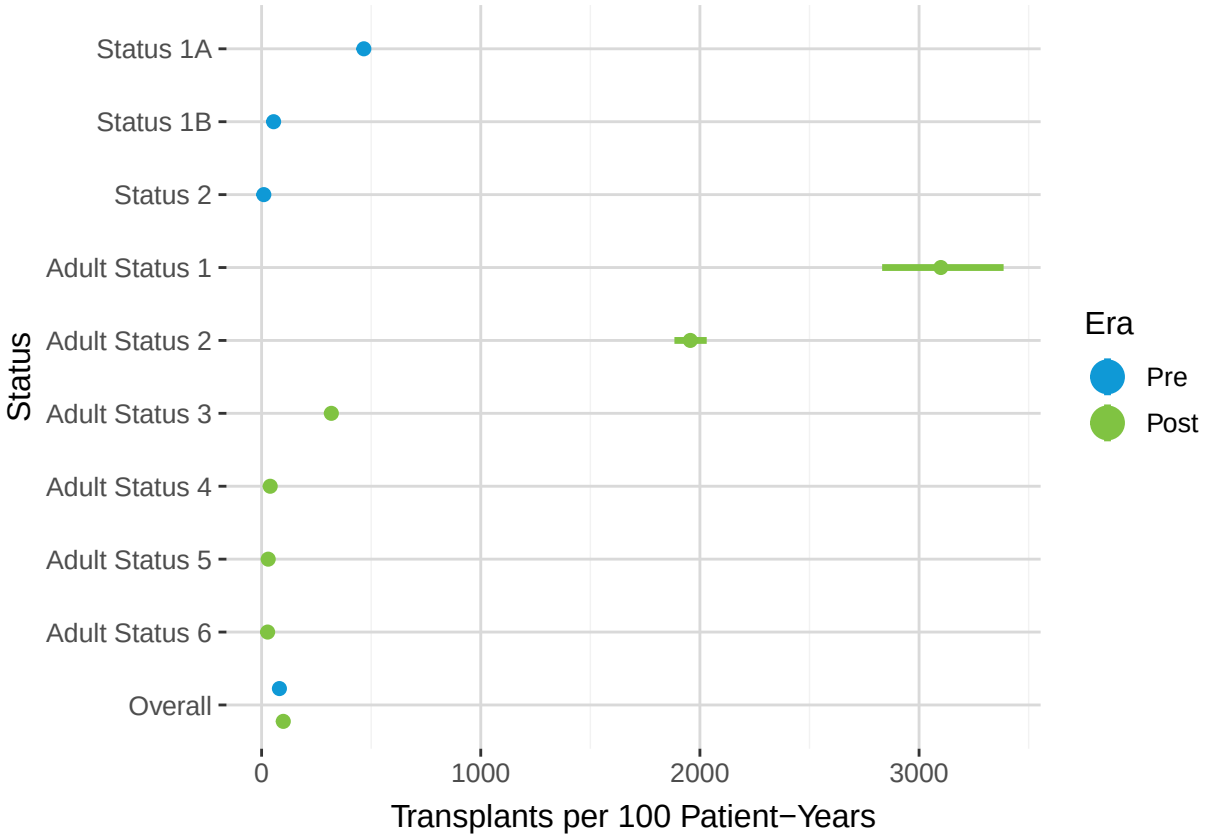


Figure 27. Zooming in on Adult Heart Statuses 3-6: Transplants per 100 Patient-Years Waiting by Medical Urgency Status and Era

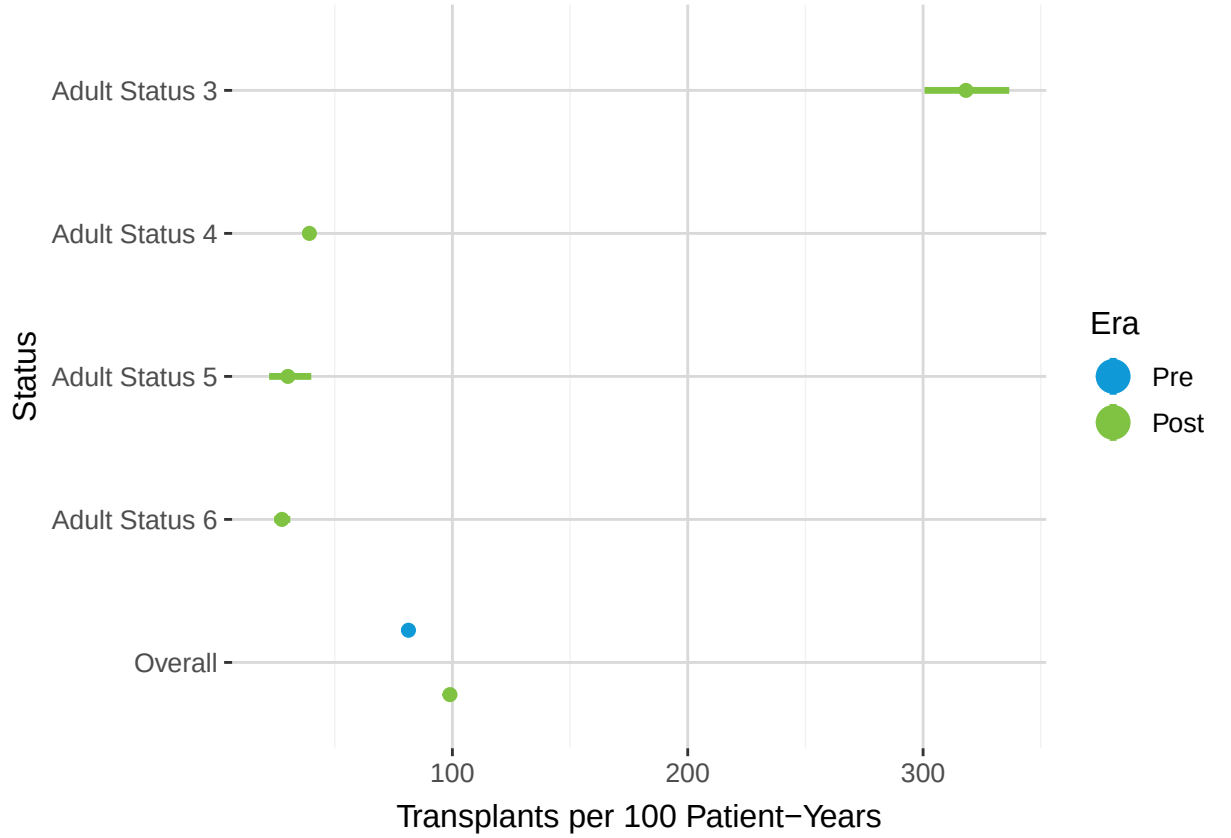


Table A16 shows the patients ever waiting, number of transplants, and transplants per 100 patient years for each medical urgency status both pre- and post-implementation.

Figure 28. Transplants per 100 Patient-Years Waiting by Equivalent Medical Urgency Status

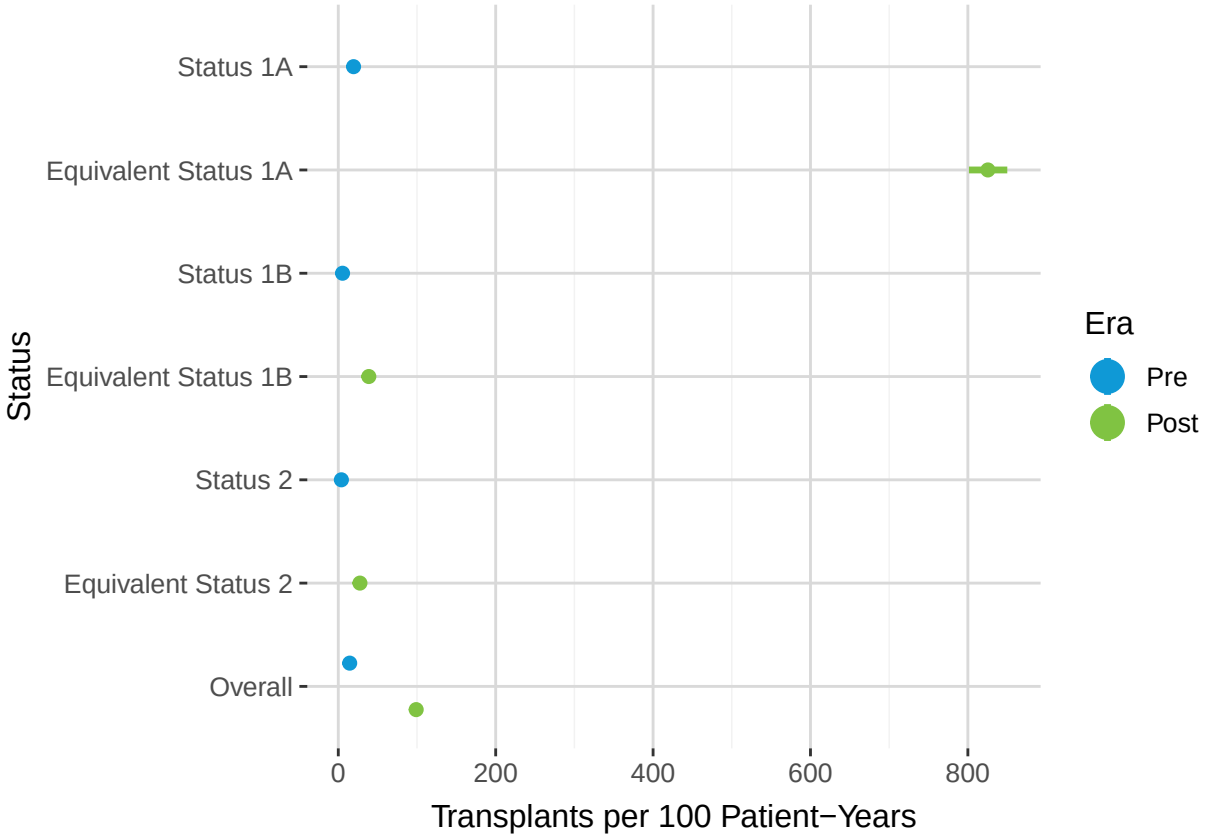


Figure 28 shows the transplants per 100 patient years by equivalent statuses post-implementation as compared to pre-implementation. The Committee Request section defines the equivalent post-implementation statuses as: old Status 1A compared to Adult Statuses 1-3, old Status 1B compared to Adult Statuses 4 and 5, and old Status 2 compared to Adult Status 6. Each of the equivalent statuses had a significantly higher transplant rate compared to their old status counterparts; the largest difference was observed between Old Status 1A and Equivalent Status 1A.

Figure 29. Transplants per 100 Patient-Years Waiting by Region, Medical Urgency Status, and Era

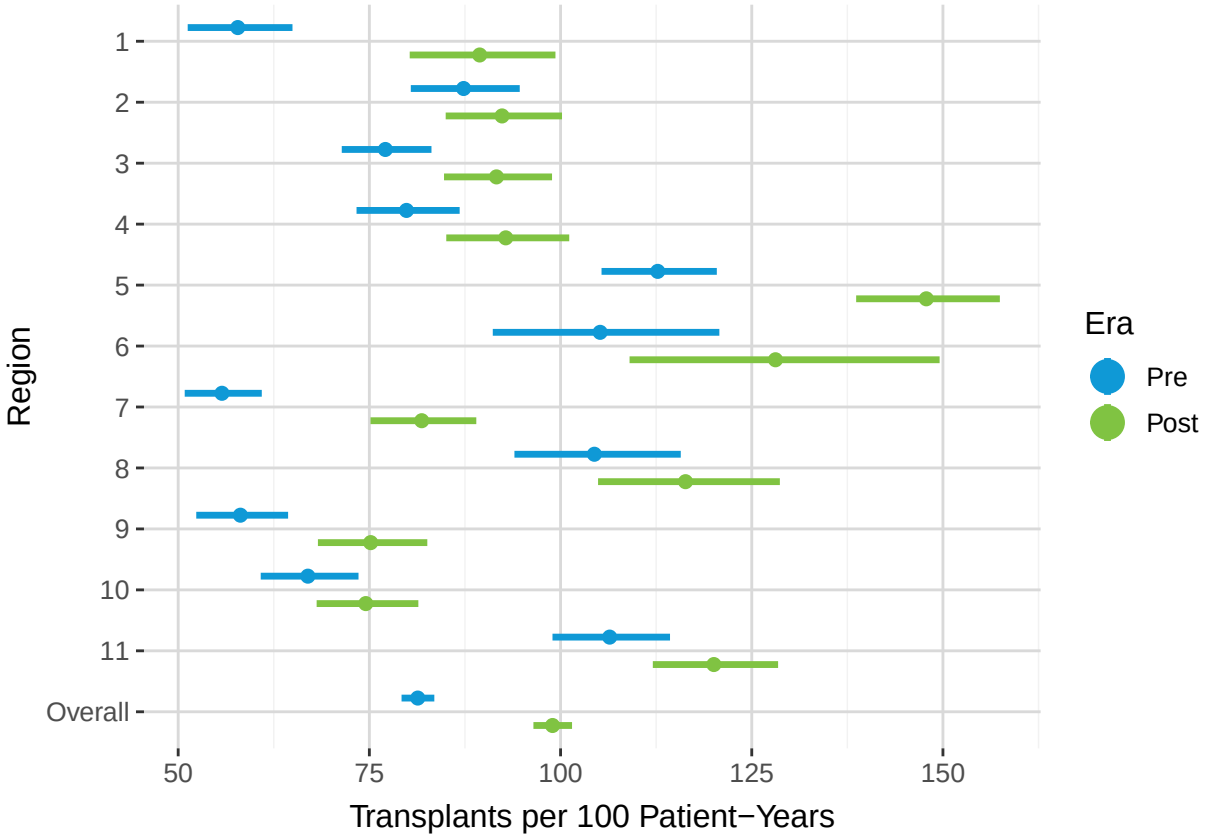


Figure 29 shows the number of transplants per 100 patient-years waiting for each region pre- and post-implementation. The number of transplants per 100 patient-years post-implementation increased for all regions. The increase in transplants per 100 patient waiting years was significant for regions 1, 3, 5, 7, 9, and overall.

Table A17 shows the number of patients ever waiting and the number of transplants for each region pre- and post-implementation, as well as the number of transplant per 100 patient-years, the relative risk of transplant, and the 95% confidence interval. The overall relative risk of transplant rose significantly to 1.22 (95% CI: (1.17, 1.26)) times what it was pre-implementation. The highest relative risk of transplant was in region 1 (1.55 (1.36, 1.77)).

Table 15. Median Days to Transplant by Medical Urgency Status and Era

Era	Status	Days Waiting
Pre	Status 1A	59
	Status 1B	216
	Status 2	564
Pre	**Total**	**226**
Post	Adult Status 1	5
	Adult Status 2	9
	Adult Status 3	26
	Adult Status 4	223
	Adult Status 5	581
	Adult Status 6	342
Post	**Total**	**85**

Tables 15 and 16 show competing risks analyses of the median days waiting before transplant by status both pre- and post-implementation, where days waiting is total days on the waiting list for all active waiting statuses. Pre-implementation, the shortest wait to transplant was for Status 1A candidates, with a median wait time of 59 days. Post-implementation all of Adult Status 1, Adult Status 2, and Adult Status 3 had shorter median wait times, at 5, 9, and 26 days, respectively, and when grouped together into Equivalent Status 1A with a median time to transplant of 12 days, compared to Status 1A candidates pre-implementation. Equivalent Status 2 also saw a significant decrease in median time to transplant from 564 days pre-implementation to 329 days post-implementation. Overall the median days waiting to transplant fell from 226 to 85, a 62% decrease.

Table 16. Median Days to Transplant by Equivalent Medical Urgency Status and Era

Era	Status	Days Waiting
Pre	Equivalent Status 1A	59
	Equivalent Status 1B	216
	Equivalent Status 2	564
Pre	**Total**	**226**
Post	Equivalent Status 1A	12
	Equivalent Status 1B	231
	Equivalent Status 2	342
Post	**Total**	**85**

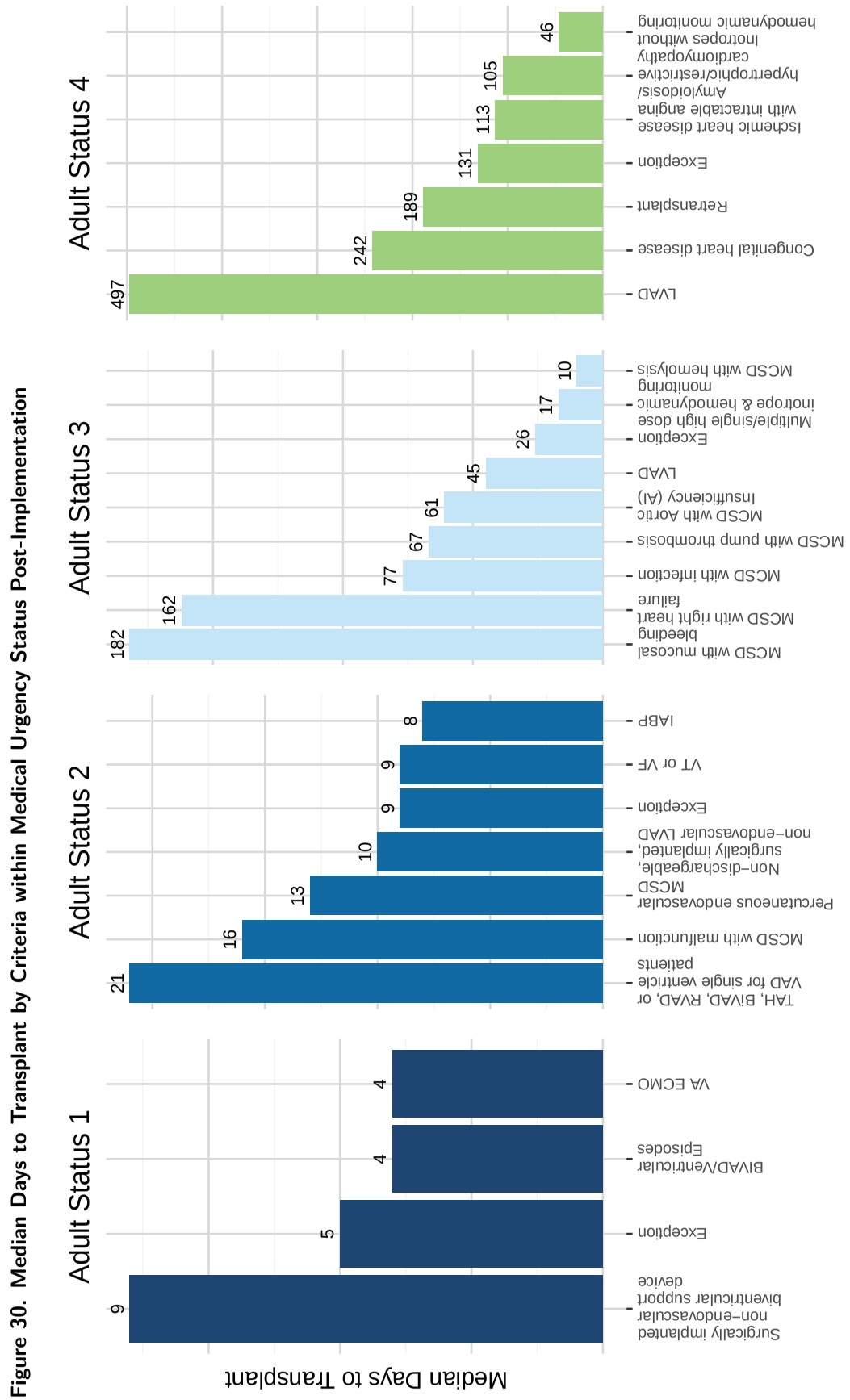


Figure 30. Median Days to Transplant by Criteria within Medical Urgency Status Post-Implementation

Table 17. Median Days to Transplant by Medical Urgency Status and Criteria Post-Implementation

Status	Criteria	Days Waiting
Adult Status 1	BIVAD/Ventricular Episodes	4
	Exception	5
	Surgically implanted non-endovascular biventricular support device	9
	VA ECMO	4
Adult Status 1	**Total**	**5**
Adult Status 2	Exception	9
	IABP	8
	MCSD with malfunction	16
	Non-dischargeable, surgically implanted, non-endovascular LVAD	10
	Percutaneous endovascular MCSD	13
	TAH, BiVAD, RVAD, or VAD for single ventricle patients	21
	VT or VF	9
Adult Status 2	**Total**	**9**
Adult Status 3	Exception	26
	LVAD	45
	MCSD with Aortic Insufficiency (AI)	61
	MCSD with hemolysis	10
	MCSD with infection	77
	MCSD with mucosal bleeding	182
	MCSD with pump thrombosis	67
	MCSD with right heart failure	162
	Multiple/single high dose inotrope & hemodynamic monitoring	17
Adult Status 3	**Total**	**26**
Adult Status 4	Amyloidosis/hypertrophic/restrictive cardiomyopathy	105
	Congenital heart disease	242
	Exception	131
	Inotropes without hemodynamic monitoring	46
	Ischemic heart disease with intractable angina	113
	LVAD	497
	Retransplant	189
Adult Status 4	**Total**	**223**
Adult Status 5	No criteria for this status	581
Adult Status 5	**Total**	**581**
Adult Status 6	No criteria for this status	342
Adult Status 6	**Total**	**342**

Note:
** indicates that median time to transplant could not be calculated
median time to transplant could not be calculated for Adult Status 5 due to sample size

Figure 30 and Table 17 show the results of the competing risks analysis of the median time to transplant by criteria within medical urgency status post-implementation. No criteria are required for Adult Statuses 5 and 6 and therefore these statuses were omitted from the figure. Adult status 4 candidates with an LVAD had the highest median days to transplant followed by candidates with congenital heart disease while candidates listed with BIVAD/Ventricular Episodes or VA ECMO in Adult Status 1 had the shortest median days to transplant. Adult Statuses 3 and 4 had the greatest variability in median days to transplant across criteria.

Figure 31. Median Days to Transplant by Exception vs. Standard Review by Status

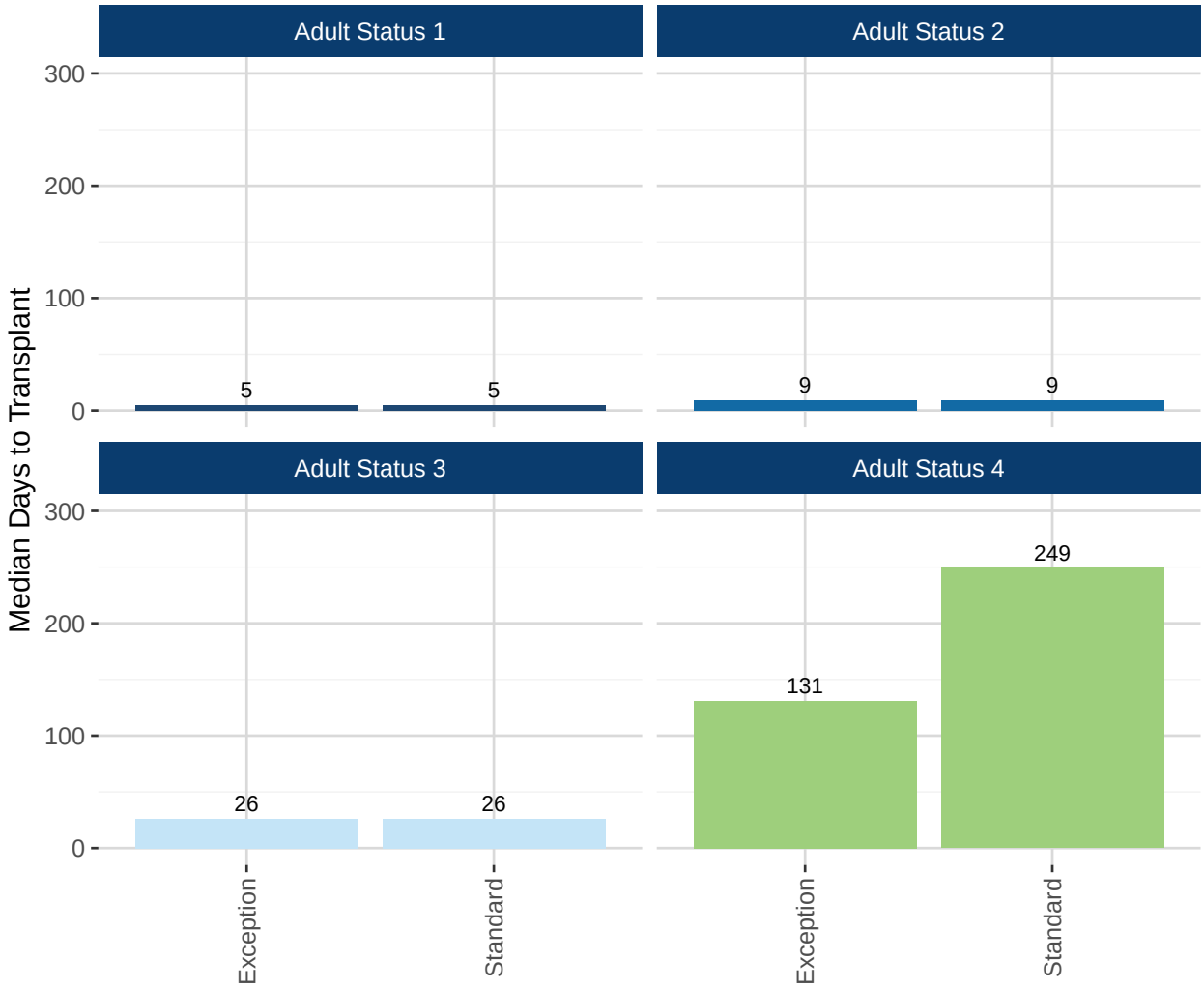


Figure 31 displays the results of the competing risks analysis of the median days to transplant for Adult Statuses 1-4 by exception versus no exception. Median days to transplant was the same between exception versus standard review for Adult Statuses 1-3. There was a larger difference between median days to transplant for those with an exception versus standard review for Adult Status 4 Candidates; Adult Status 4 candidates with an exception had noticeably lower median days to transplant.

Figure 32. Median Days to Transplant by Region and Era

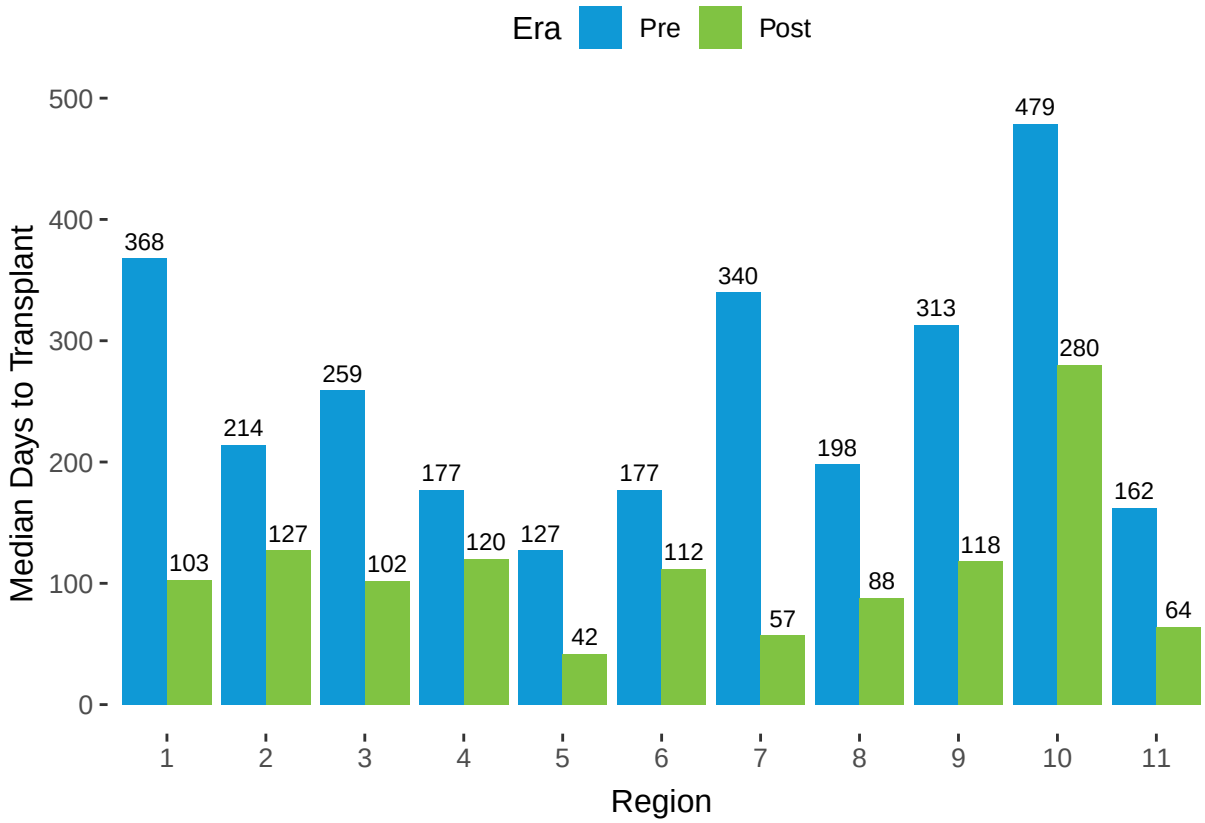


Figure 32 shows a competing risks analysis of the median days waiting before transplant by status and region. The median time to transplant declined in all regions. The largest decrease in median days waited was seen in region 7, where the median wait time decreased from 340 days to 57 days, a 72% decrease.

Utilization

This chapter examines differences in heart utilization between two donor cohorts: the 19181 deceased donors with at least one organ recovered for the purpose of transplant between October 18, 2016 and October 17, 2018 (pre-implementation); and the 22232 deceased donors with a least one organ recovered for the purpose of transplant between October 18, 2018 and October 17, 2020 (post-implementation).

Tables 18 and 19 show the utilization and discard rates for adult hearts by era both overall and for non-DCD donors. Here utilization is defined as the number of hearts recovered during a period divided by the total number of deceased donors in that period and discard is defined as one minus the number of adult deceased donor hearts transplanted in a period divided by the total number of adult deceased donor hearts recovered in that period.

As expected, heart utilization is higher among Donation after Brain Death (DBD; also referred to as non-DCD) donors with 27.65% utilization for all adult heart donors compared to 35.58% utilization in Non-DCD adult heart donors in the post-implementation period. There was a small decrease in utilization rates for all adult heart donors and for Non-DCD donors while there was a small increase in discard rates for adult hearts. These trends were largely consistent across all post-implementation COVID-eras with some differences in discard rates for Non-DCD donors across the post-implementation period. Discard rates decreased noticeably in the post-policy COVID-Onset and COVID-Stabilization periods.

Table 18. Utilization and Discard Rates for Heart Donors by Era

Era	Utilization	Discard
Pre-Policy	**29.35%**	**0.95%**
Post-Policy, Pre-COVID	27.42%	1.08%
Post-Policy, COVID-Onset	26.9%	1.02%
Post-Policy, COVID-Stabilization	28.5%	1.01%
Post-Policy (overall)	**27.65%**	**1.06%**

Note:
Pre-Policy: October 18, 2016 - October 17, 2018;
Post-Policy, Pre-COVID: October 18, 2018 - March 12, 2020;
Post-Policy, COVID Onset: March 13, 2020 - May 09 2020;
Post-Policy COVID Stabilization: May 10, 2020 - October 17, 2020;

Table 19. Utilization and Discard Rates for Non-DCD Adult Heart Donors by Era

Era	Utilization	Discard
Pre-Policy	**36.19%**	**0.95%**
Post-Policy, Pre-COVID	35.64%	1%
Post-Policy, COVID-Onset	33.93%	0.26%
Post-Policy, COVID-Stabilization	36.97%	0.53%
Post-Policy (overall)	**35.85%**	**0.84%**

Note:
Pre-Policy: October 18, 2016 - October 17, 2018;
Post-Policy, Pre-COVID: October 18, 2018 - March 12, 2020;
Post-Policy, COVID Onset: March 13, 2020 - May 09 2020;
Post-Policy COVID Stabilization: May 10, 2020 - October 17, 2020;

Figure 33. Utilization Rates for Adult Heart Donors by Region and Era

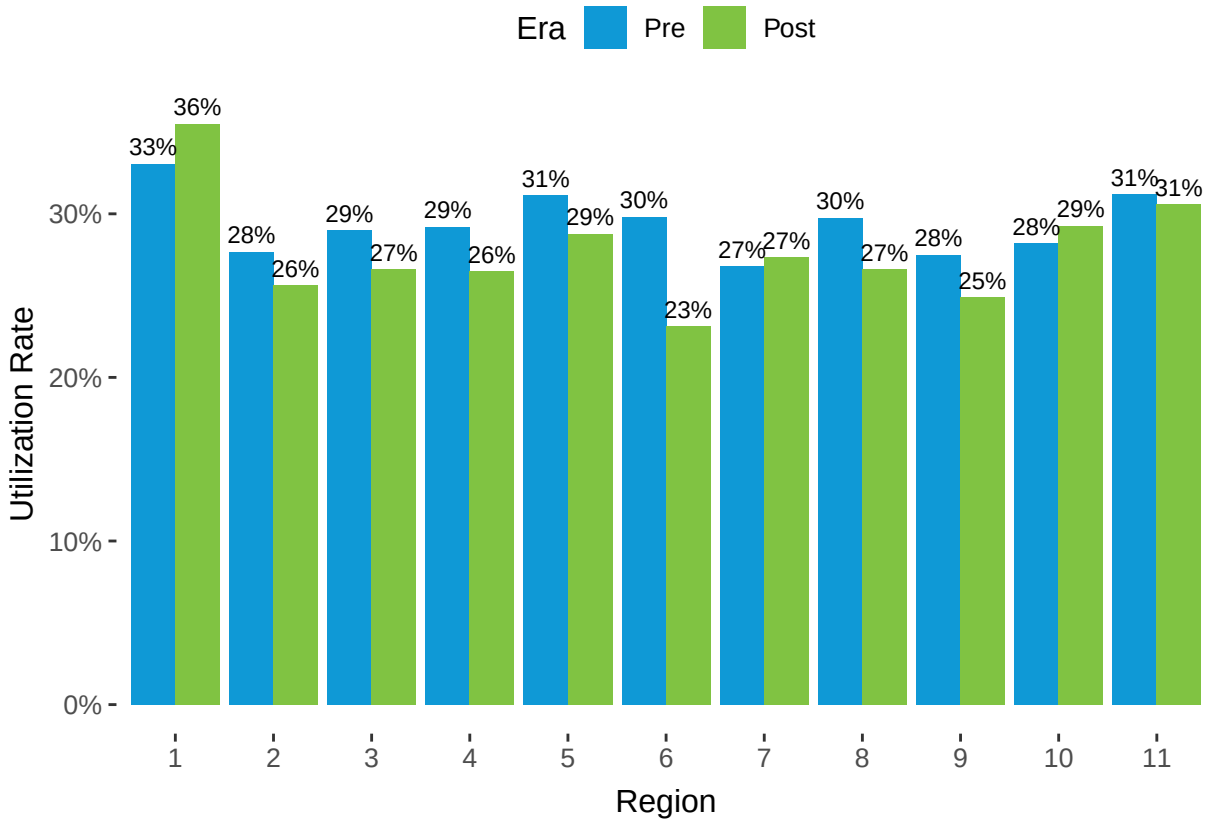


Figure 33 shows the utilization rates of adult hearts by region both pre- and post-implementation. Utilization rates decreased in the majority of the regions. Utilization rates rose in regions 1, 7, and 10 and decreased in the remaining regions.

Figure 34. Utilization Rates for Non-DCD Adult Heart Donors by Region and Era

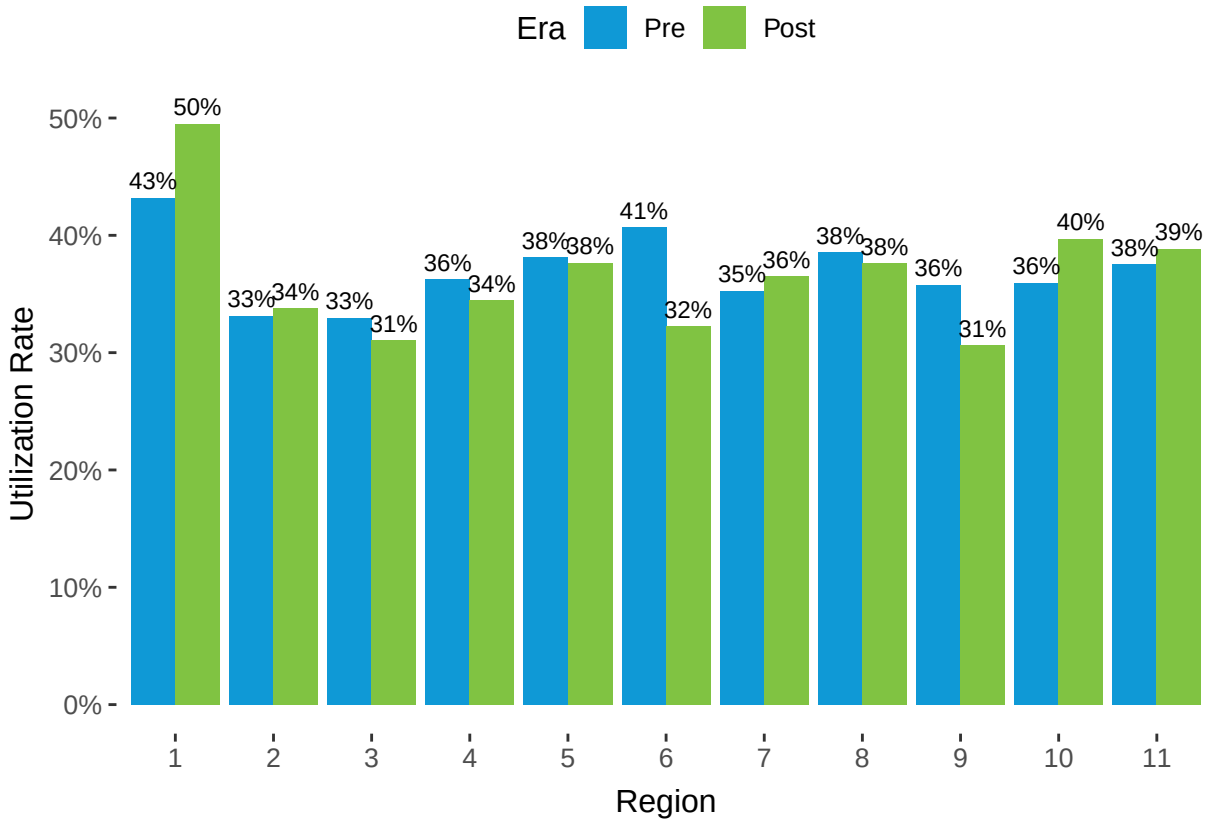


Figure 34 shows utilization rates of adult hearts by region and era for non-DCD donors only. Utilization rates are higher for non-DCD donors than for donors overall (Tables 18 and 19) and rose in regions 1, 2, 7, 10 and 11. The largest decline pre- to post-implementation was in region 6 and the largest increase was in region 1.

Figure 35. Utilization Rates for Adult Heart Donors by Donor Age and Era

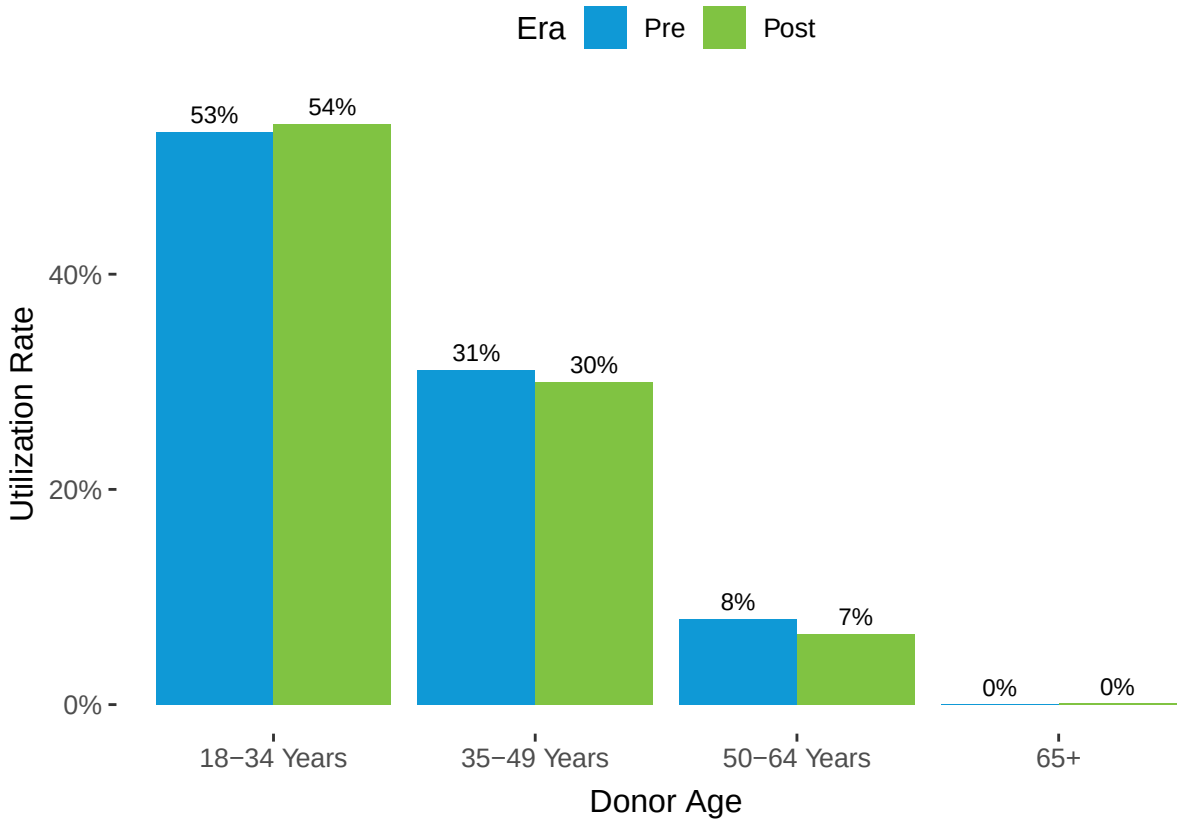


Figure 35 shows the utilization rates for adult hearts both pre- and post-implementation by donor age. There was little change in adult heart utilization in any donor age group.

Figure 36. Utilization Rates for Adult Non-DCD Heart Donors by Donor Age and Era

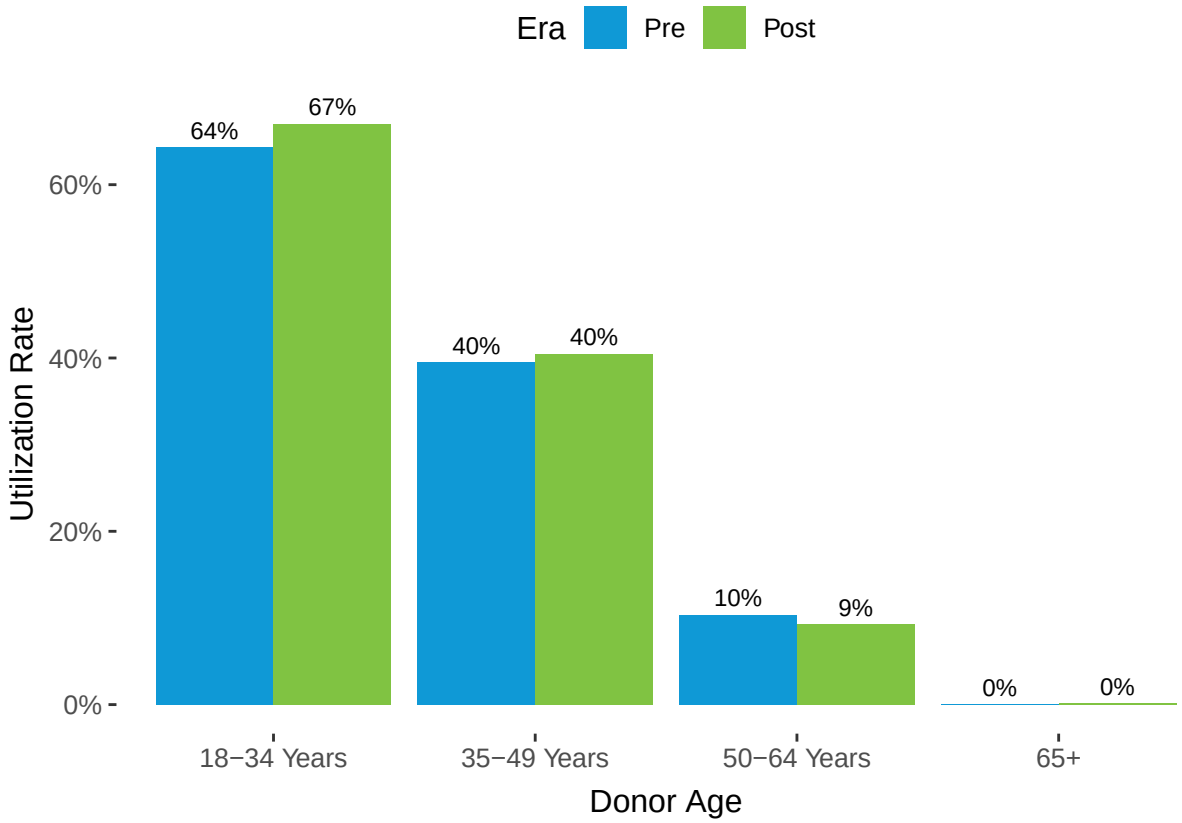


Figure 36 shows the utilization rates for adult hearts from non-DCD donors both pre- and post-implementation by donor age. The utilization rates for non-DCD donors increased slightly pre- to post-implementation for donor ages 18-34 and 35-49 years and decreased slightly for donor ages 50-64 years.

Outcomes

Heart allocation policy has traditionally been based on waiting list mortality rather than post-transplant outcomes, and the revisions to the adult heart allocation system were made with waiting list mortality rather than post-transplant survival in mind. However, in order to uncover potential unintended impacts on transplant outcomes, this chapter examines recipient outcomes data for the 2599 adult heart recipients transplanted between October 18, 2016 and October 17, 2017 (pre-implementation) and the 2793 adult heart recipients transplanted between October 18, 2018 and October 17, 2019 (post-implementation). Under the COVID-19 Amnesty Policy, the time frame for reporting deaths and graft failures for transplant recipients was extended from 14 days to 30 days of knowledge of the event. Due to the extended time frames for reporting death and the potential for increased patient censoring, survival curves are presented using the standard approach as well as an approach that assumes that recipients were alive unless their death was reported to the OPTN or external sources. Both methods are presented with the expectation that the true one-year survival rate likely lies somewhere between the two estimates. The details and rationale for these approaches are discussed in more detail in the Methods Section.

Figure 37. One-Year Patient Survival using an Assume-Alive Approach

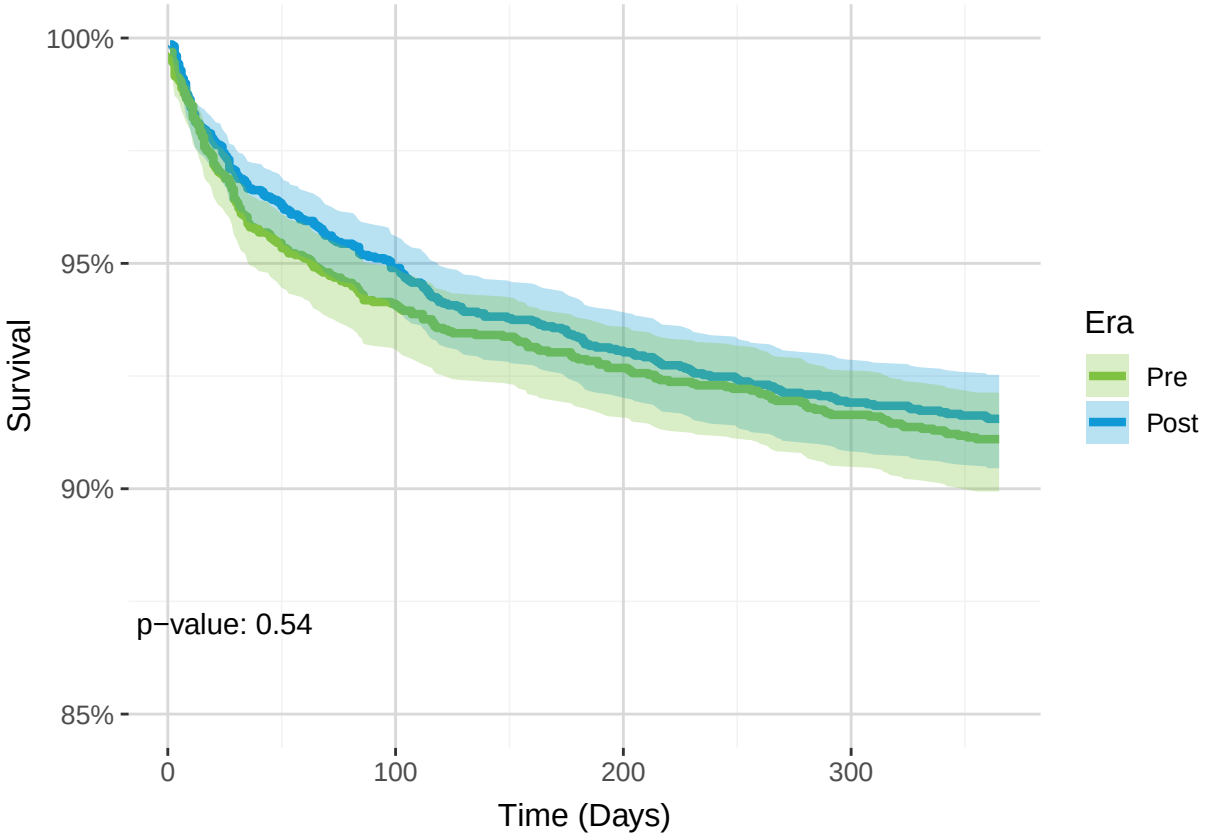


Figure 38. One-Year Patient Survival using Standard Approach

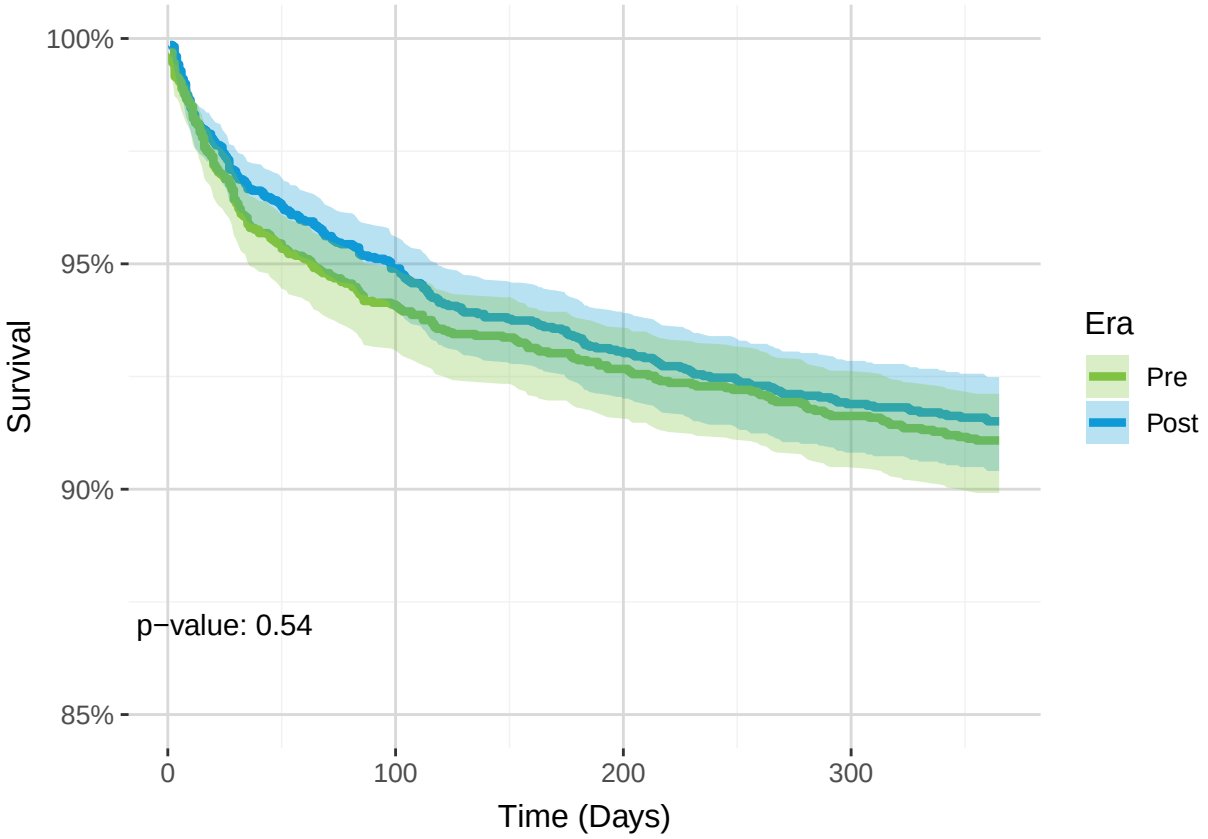


Figure 37 and Figure 38 show the one-year patient survival for adult heart recipients pre- and post-implementation using assume-alive and standard approach, respectively. There was no significant difference in patient survival between the two eras ($p = 0.54$) for either approach. Under the assume-alive approach, one-year patient survival in the pre era was 91.1% compared to 91.55% in the post era.

Figures 39 and 43 show the one-year patient survival for different medical urgency statuses pre- and post-implementation for both the standard and assume-alive approaches. The results for the standard and assume-alive approaches were very similar. Status 2 had the highest one year survival with Statuses 1B and 1A having slightly lower survival. Pre-implementation there were 60 Status 2 recipients of which 4 died before one year compared to the 161 out of 1721 and 66 out of 818 recipients in Adult Statuses 1A and 1B, respectively, who died before one year.

Post-Implementation Adult Status 1 had the lowest one-year patient survival and Adult Statuses 4 and 6 had the highest one-year patient survival. There were 236 Adult Status 1 recipients of which 28 died before one year compared to the 29 out of 508 and 8 out of 110 Adult Status 4 and 6 recipients, respectively, who died before one year. Adult statuses 2, 3 had similar patient survival rates at one year and fell between Statuses 4 and 6 and Adult Status 1. Adult Status 5 was omitted because there were only 0 recipients during the one-year survival post-implementation period.

Figure 39. One-Year Assume Alive Patient Survival by Medical Urgency Status Pre-Implementation

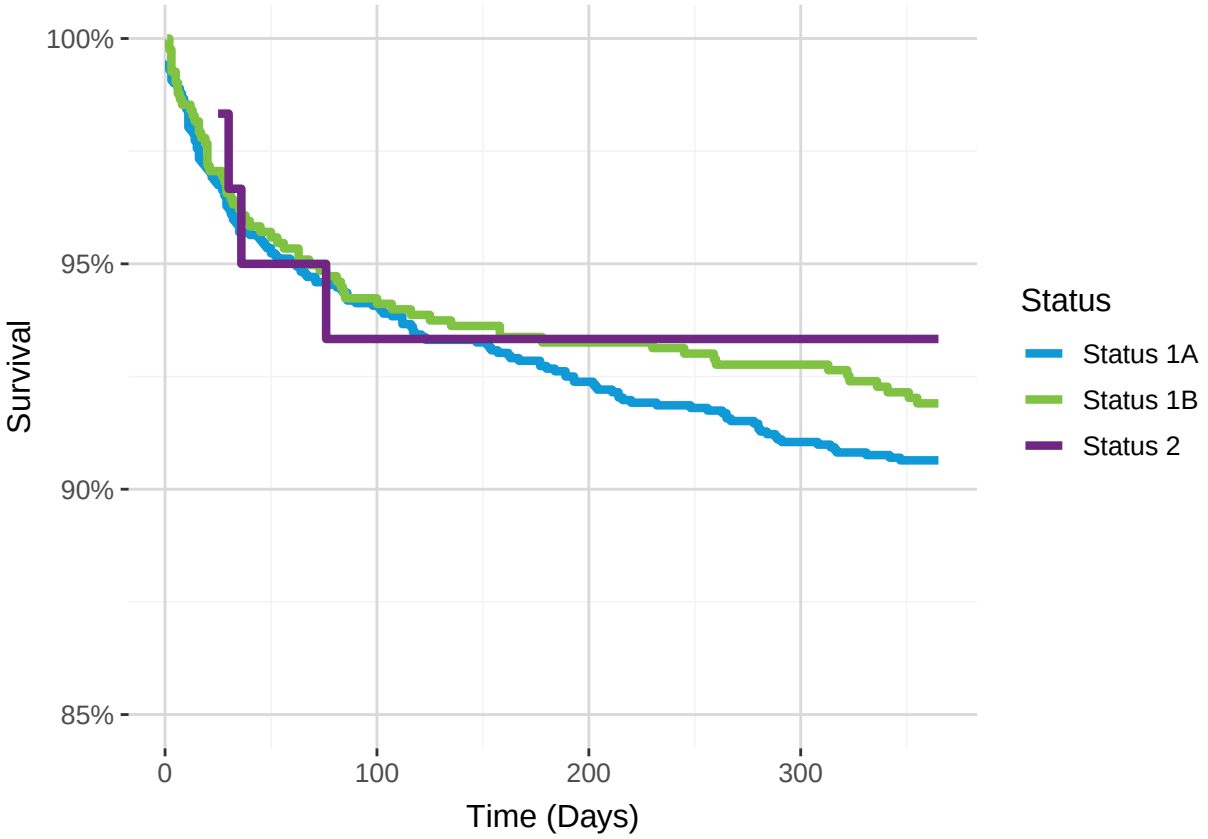


Figure 40. One-Year Standard Patient Survival by Medical Urgency Status Pre-Implementation

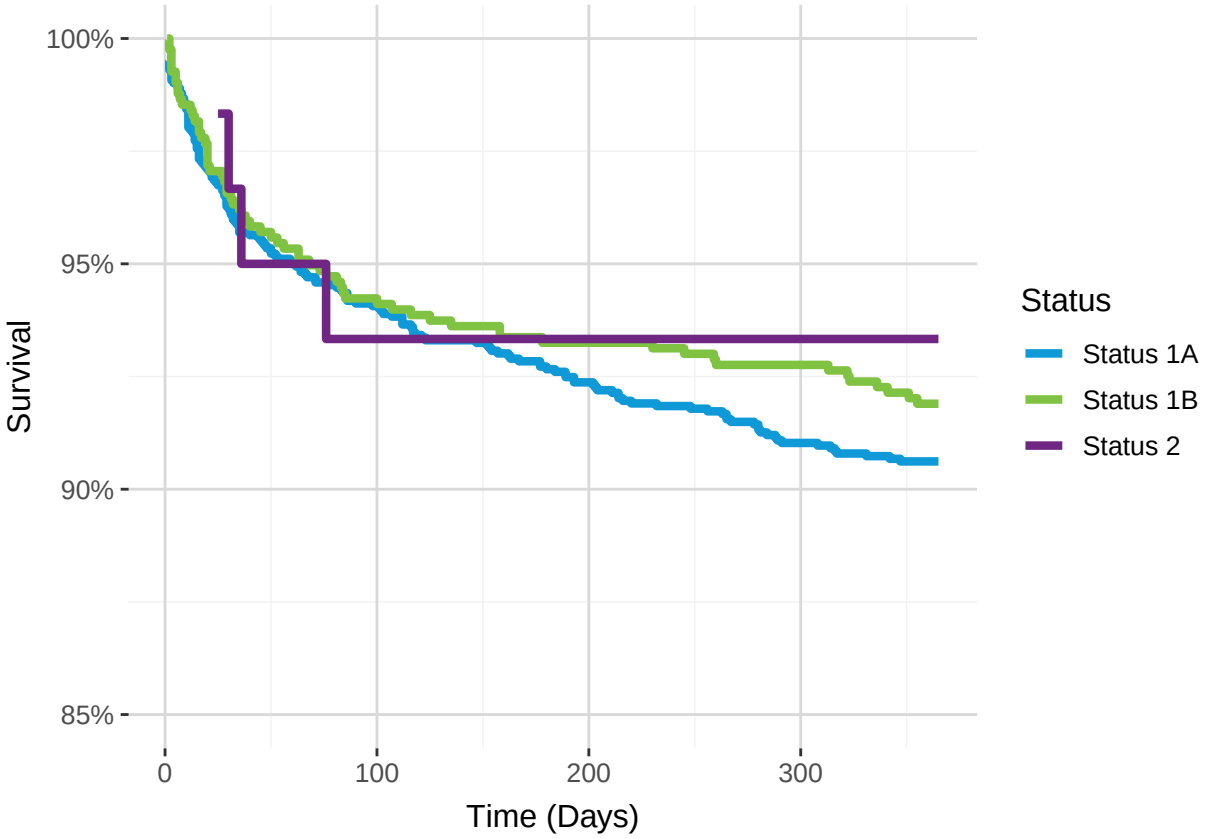


Figure 41. One-Year Assume Alive Patient Survival by Medical Urgency Status Post-Implementation

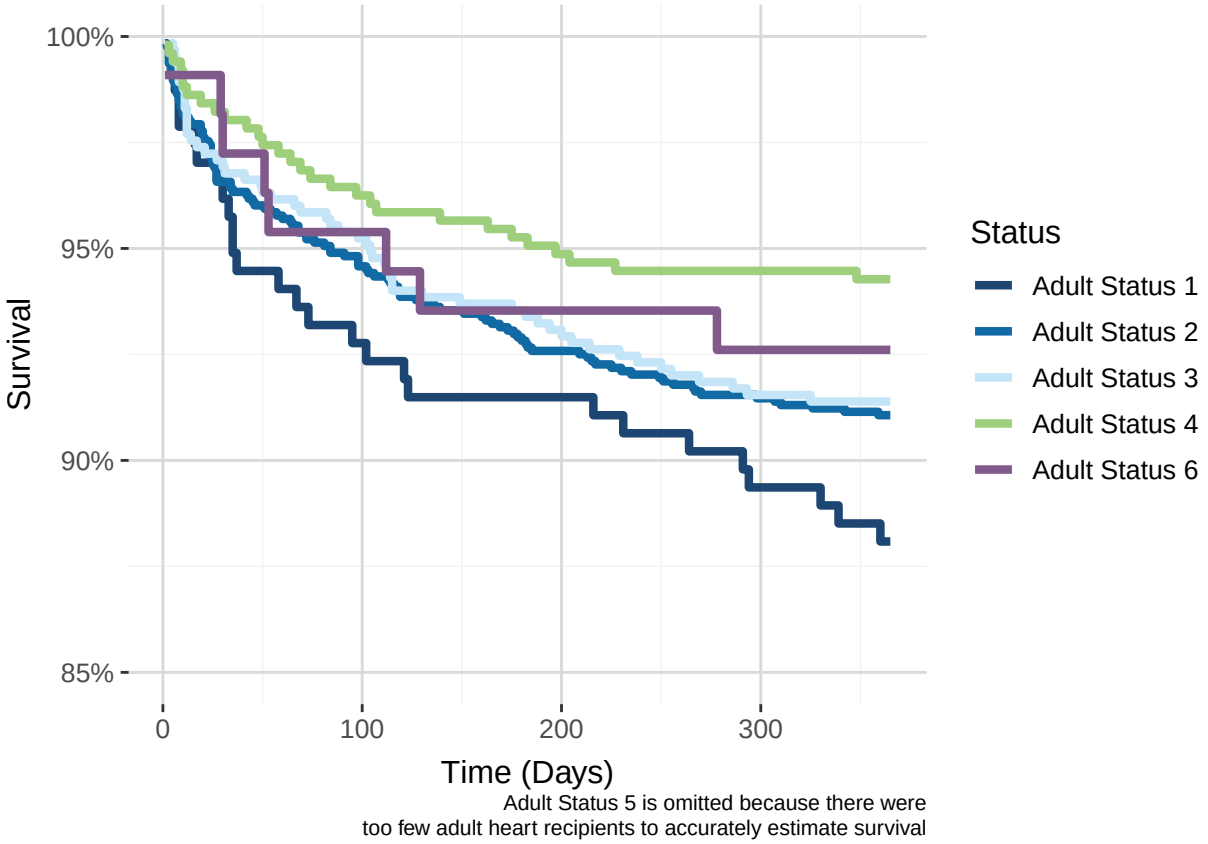
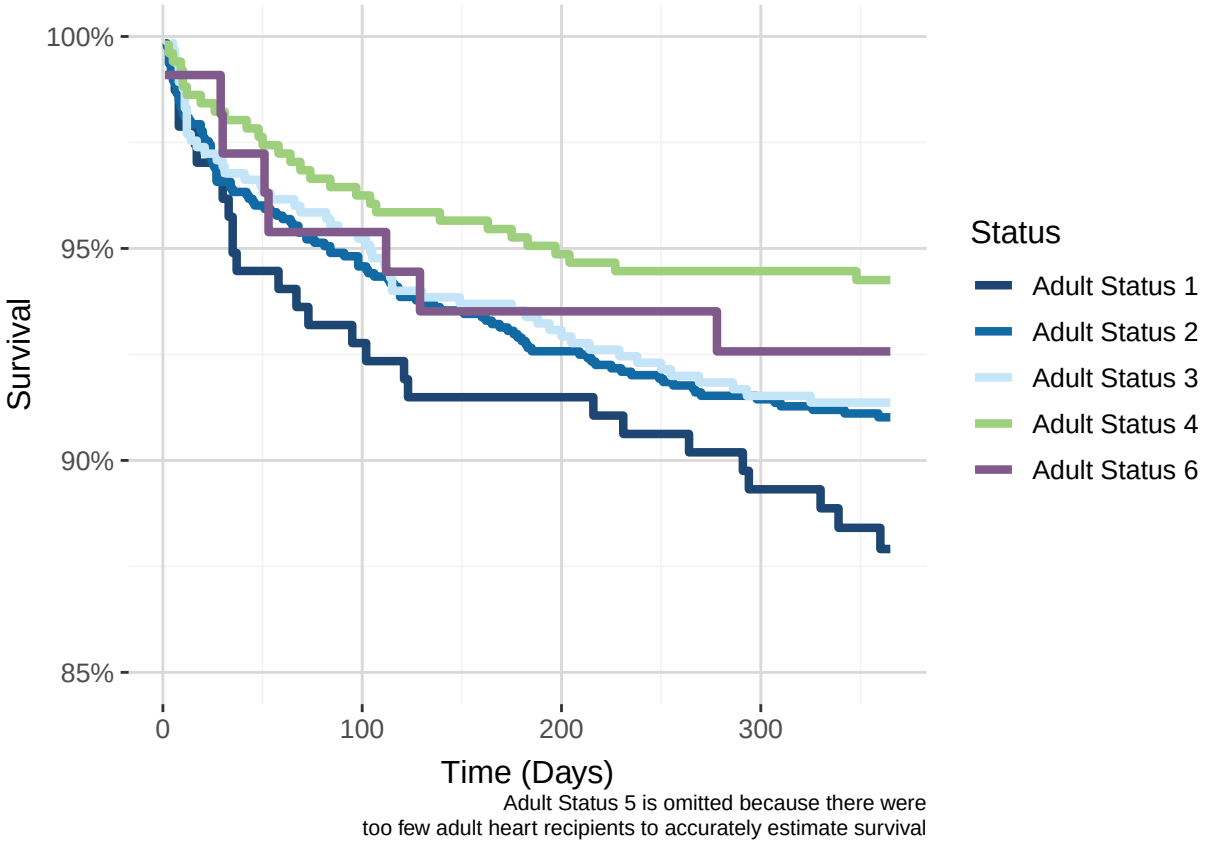


Figure 42. One-Year Standard Patient Survival by Medical Urgency Status Post-Implementation



Adult Status 5 is omitted because there were too few adult heart recipients to accurately estimate survival

Figures 43 and 44 show patient survival by zone, pre- and post-implementation using the assume-alive approach. These analyses are unadjusted and therefore do not account for medical urgency or other candidate or donor factors that could impact outcomes. Pre-implementation DSA had the lowest one-year patient survival while Zone A had the lowest patient post-implementation. Pre-implementation DSA had the largest proportion of highly medically urgent candidates while post-implementation Zone A had the highest proportion of the most medically urgent candidates. The larger proportion of transplants to more medically urgent candidates in the DSA pre-implementation and in Zone A post-implementation might explain the reduced survival.

Figure 43. One-Year Assume-Alive Patient Survival by Zone Pre-Implementation

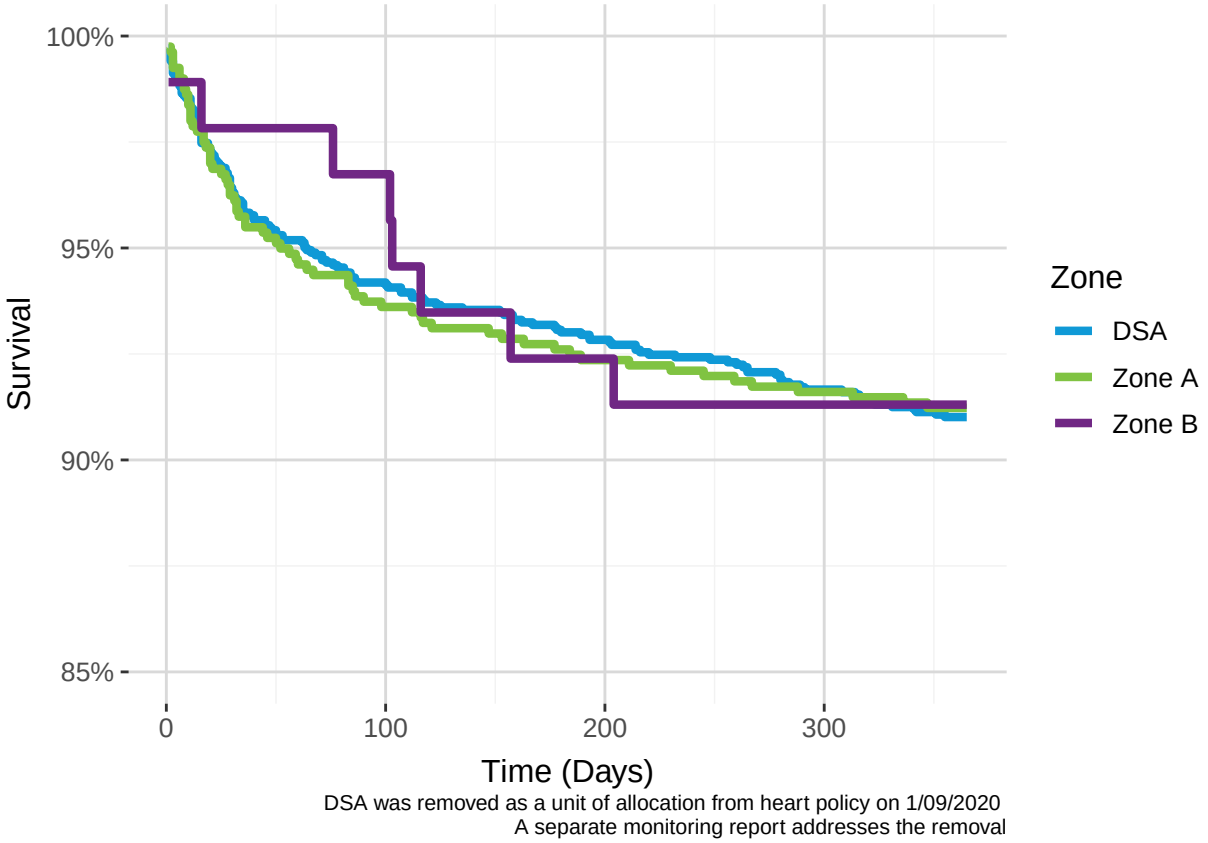
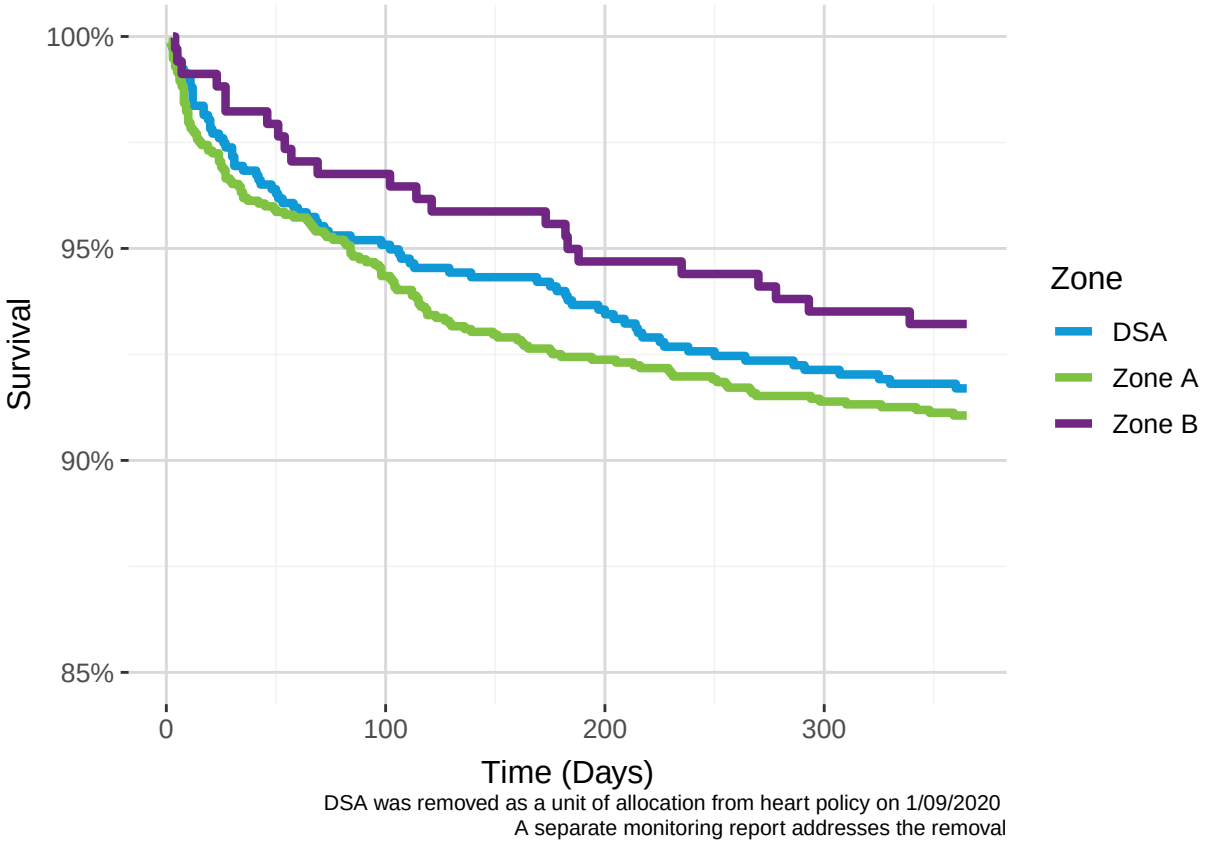


Figure 44. One-Year Assume-Alive Patient Survival by Zone Post-Implementation



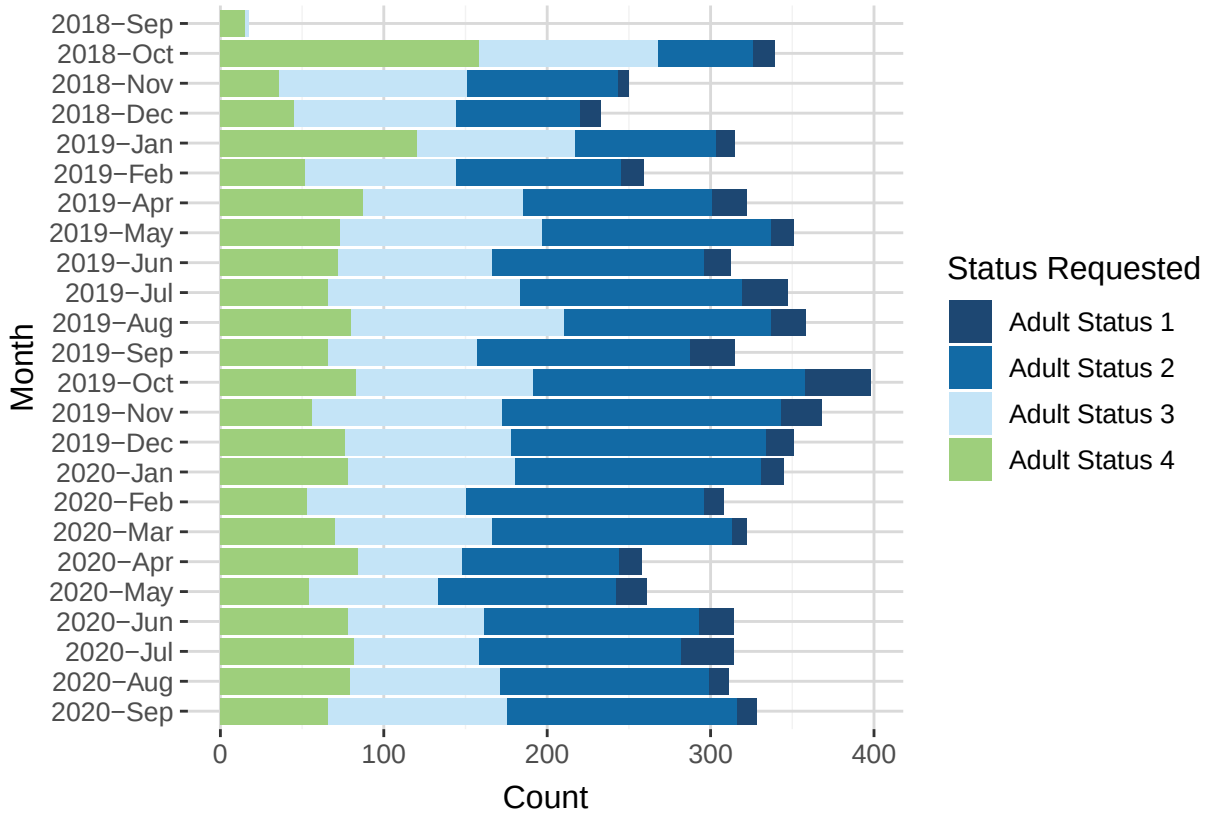
Regional Review Board

Error in get(genname, envir = envir) : object 'testthat_print' not found

This chapter summarizes adult heart justification forms submitted to the Heart Regional Review Board between September 18, 2018, when phase 1 of new adult heart allocation was implemented, and September 30, 2020 when the most recent RRB rolled off before the end of the post-implementation period. There were 7598 adult heart justification forms submitted to the Heart Regional Review Board during this time.

Figure 45 summarizes the number of distinct justification forms by adult heart medical urgency status and the month the form was submitted. The form status is the status for which the candidate was applying. Adult heart candidates can apply for multiple exceptions/extensions during their time on the waiting list, so this does not represent the number of candidates that applied for exception/extension requests.

Figure 45. Number of distinct justification forms by medical urgency status and month form was submitted



Due to the time period examined, September 2018 is not a complete month

Table 20 summarizes the number and percent of distinct justification forms submitted by medical urgency status and month of submission. Adult Status 2 represented the largest number of forms submitted, followed closely by Adult Status 3. Adult Status 1 had the lowest number of justification forms submitted.

Table 20. Number of distinct justification forms by medical urgency status and month form was submitted

Form Submission Year-Month	Adult Status 1	Adult Status 2	Adult Status 3	Adult Status 4	Total
2018-Sep	0 (0.0%)	0 (0.0%)	2 (11.8%)	15 (88.2%)	17 (100.0%)
2018-Oct	13 (3.8%)	58 (17.1%)	110 (32.4%)	158 (46.6%)	339 (100.0%)
2018-Nov	7 (2.8%)	92 (36.8%)	115 (46.0%)	36 (14.4%)	250 (100.0%)
2018-Dec	13 (5.6%)	76 (32.6%)	99 (42.5%)	45 (19.3%)	233 (100.0%)
2019-Jan	12 (3.8%)	86 (27.3%)	97 (30.8%)	120 (38.1%)	315 (100.0%)
2019-Feb	14 (5.4%)	101 (39.0%)	92 (35.5%)	52 (20.1%)	259 (100.0%)
2019-Mar	16 (5.3%)	121 (40.1%)	106 (35.1%)	59 (19.5%)	302 (100.0%)
2019-Apr	21 (6.5%)	116 (36.0%)	98 (30.4%)	87 (27.0%)	322 (100.0%)
2019-May	14 (4.0%)	140 (39.9%)	124 (35.3%)	73 (20.8%)	351 (100.0%)
2019-Jun	16 (5.1%)	130 (41.7%)	94 (30.1%)	72 (23.1%)	312 (100.0%)
2019-Jul	28 (8.1%)	136 (39.2%)	117 (33.7%)	66 (19.0%)	347 (100.0%)
2019-Aug	21 (5.9%)	127 (35.5%)	130 (36.3%)	80 (22.3%)	358 (100.0%)
2019-Sep	28 (8.9%)	130 (41.3%)	91 (28.9%)	66 (21.0%)	315 (100.0%)
2019-Oct	40 (10.1%)	167 (42.0%)	108 (27.1%)	83 (20.9%)	398 (100.0%)
2019-Nov	25 (6.8%)	171 (46.5%)	116 (31.5%)	56 (15.2%)	368 (100.0%)
2019-Dec	17 (4.8%)	156 (44.4%)	102 (29.1%)	76 (21.7%)	351 (100.0%)
2020-Jan	14 (4.1%)	151 (43.8%)	102 (29.6%)	78 (22.6%)	345 (100.0%)
2020-Feb	12 (3.9%)	146 (47.4%)	97 (31.5%)	53 (17.2%)	308 (100.0%)
2020-Mar	9 (2.8%)	147 (45.7%)	96 (29.8%)	70 (21.7%)	322 (100.0%)
2020-Apr	14 (5.4%)	96 (37.2%)	64 (24.8%)	84 (32.6%)	258 (100.0%)
2020-May	19 (7.3%)	109 (41.8%)	79 (30.3%)	54 (20.7%)	261 (100.0%)
2020-Jun	21 (6.7%)	132 (42.0%)	83 (26.4%)	78 (24.8%)	314 (100.0%)
2020-Jul	32 (10.2%)	124 (39.5%)	76 (24.2%)	82 (26.1%)	314 (100.0%)
2020-Aug	12 (3.9%)	128 (41.2%)	92 (29.6%)	79 (25.4%)	311 (100.0%)
2020-Sep	12 (3.7%)	141 (43.0%)	109 (33.2%)	66 (20.1%)	328 (100.0%)
Total	430 (5.7%)	2981 (39.2%)	2399 (31.6%)	1788 (23.5%)	7598 (100.0%)

Figure 46 and Table 21 summarize the number of initial and extension justification forms that needed to be reviewed by the RRB by medical urgency status. As the name implies, the initial request is the first request for a candidate for a particular status under a specific medical condition for the candidate. If the medical conditions of the candidates remain the same, when the initial request expires the candidate may request an extension.

The number of initial forms submitted is higher than the number of extension forms submitted for each medical urgency status except Adult Status 3. The numbers of extension and initial forms submitted were similar for Adult Status 3; larger gaps between the number of initial and extension forms submitted can be seen for the remaining Adult Statuses (1,2, and 4). For forms submitted to the RRB, adult Status 2 was the most commonly requested initial medical urgency status and Adult Status 3 was the most commonly requested extension followed closely by Adult Status 2.

Figure 46. Number of justification forms by medical urgency status and form type

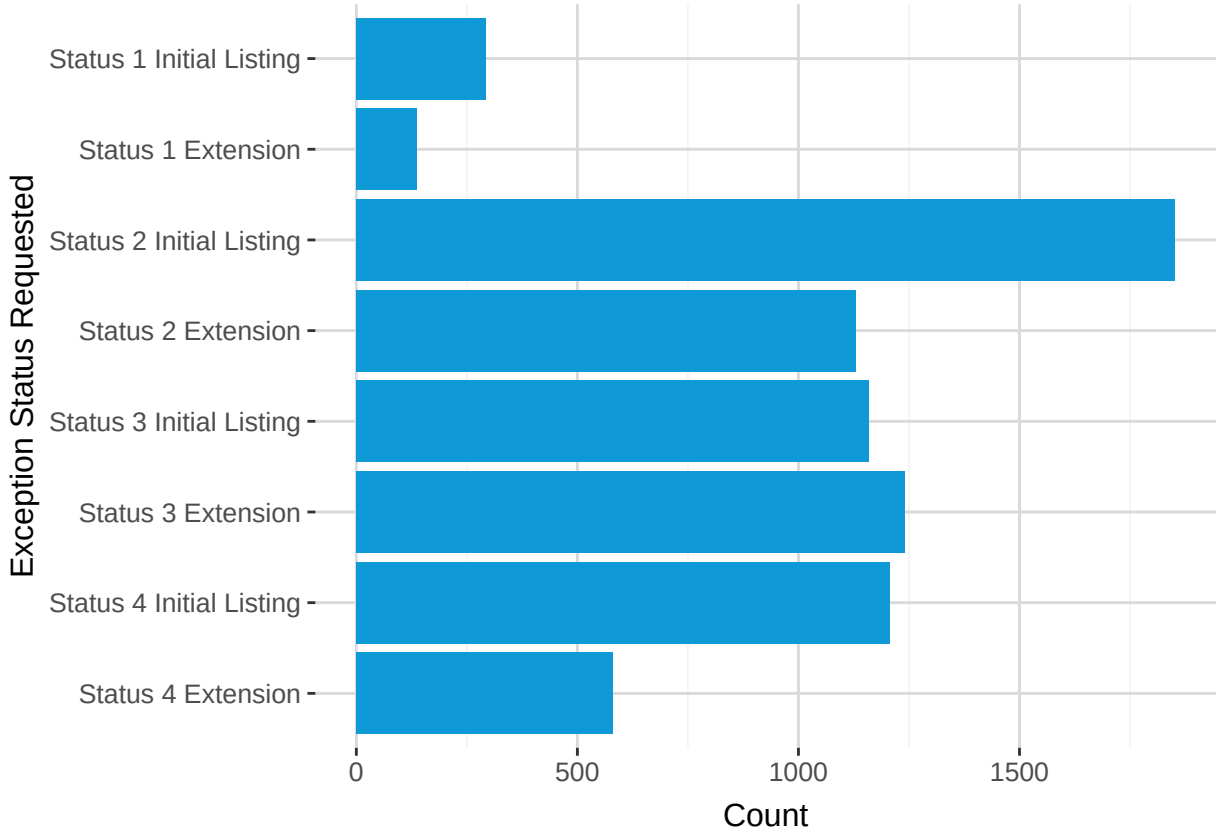


Table 21. Number of justification forms by medical urgency status and form type

Adult Heart Status and Form Type	Number of Justification Forms	Percent
Status 1 Initial Listing	294	3.9%
Status 1 Extension	136	1.8%
Status 2 Initial Listing	1852	24.4%
Status 2 Extension	1129	14.9%
Status 3 Initial Listing	1159	15.3%
Status 3 Extension	1240	16.3%
Status 4 Initial Listing	1207	15.9%
Status 4 Extension	581	7.6%
Total	7598	100.0%

Under the new adult heart allocation system some "standard" justification forms are required by policy to be reviewed by the RRB. Figure 47 and Table 22 below summarize the number of forms that have been submitted as an exception versus those that are standard and need RRB approval by medical urgency status. The majority of the forms that the Regional Review Boards are reviewing are exception requests, regardless of the status being requested. The only standard forms needing RRB approval were submitted for Adult Status 1 (per OPTN policy 6.1.A) and Adult Status 2 (per OPTN policy 6.1.B).

Figure 47. Number of justification forms by exception versus standard review and heart status

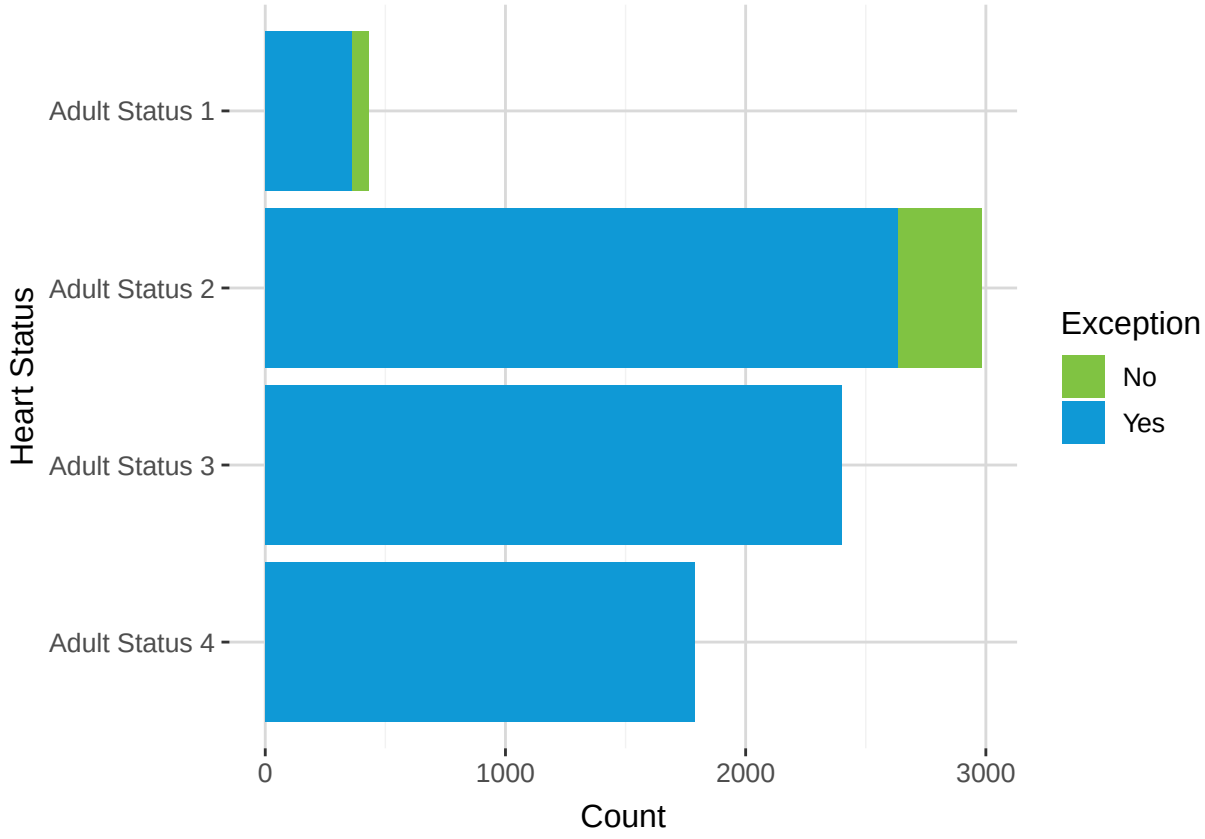


Table 22. Number of justification forms by exception versus standard review and medical urgency status

	Exception Request		
Adult Heart Status	No	Yes	Total
Adult Status 1	71 (16.5%)	359 (83.5%)	430 (100.0%)
Adult Status 2	346 (11.6%)	2635 (88.4%)	2981 (100.0%)
Adult Status 3	0 (0.0%)	2399 (100.0%)	2399 (100.0%)
Adult Status 4	0 (0.0%)	1788 (100.0%)	1788 (100.0%)
Total	417 (5.5%)	7181 (94.5%)	7598 (100.0%)

Figure 48 and Table 22 summarize form submission by the candidate's transplant center's OPTN region. A majority of the OPTN regions submitted over 500 forms that needed RRB approval (Regions 2, 3, 4, 5, 7, 9, 10, and 11). OPTN region 6 submitted the fewest forms and Region 3 submitted the most.

Figure 48. Number of justification forms by medical urgency status and OPTN region of candidate's transplant center

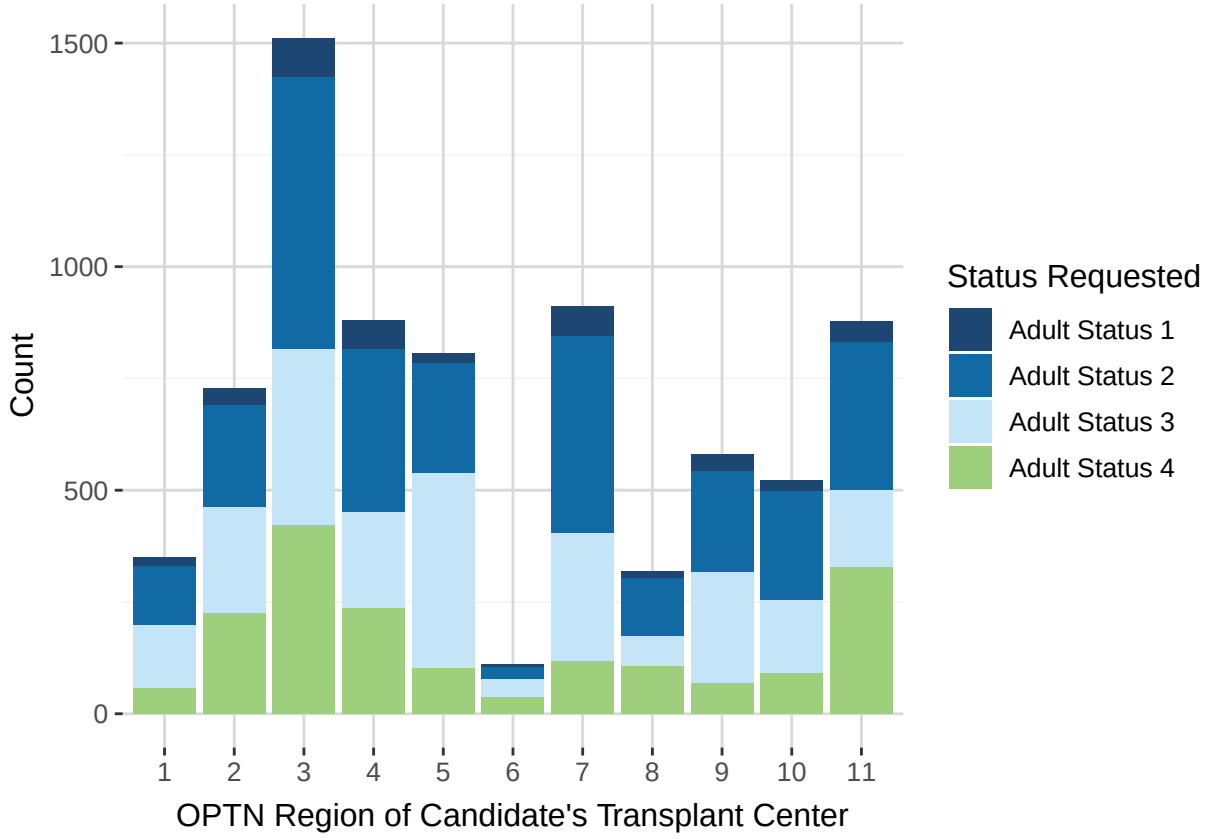


Table 23. Number of initial and extension justification forms by medical urgency status and OPTN region of candidate's transplant center

Adult Heart Status and Form Type	1	2	3	4	5	6	7	8	9	10	11	Total
Status 1 Initial Listing	14	28	62	47	17	4	20	15	30	24	33	294
Status 1 Extension	5	11	27	19	4	2	47	0	7	1	13	136
Status 2 Initial Listing	95	124	371	223	154	20	213	100	166	151	235	1852
Status 2 Extension	38	103	237	142	93	8	228	30	61	93	96	1129
Status 3 Initial Listing	56	106	179	129	203	26	104	45	112	81	118	1159
Status 3 Extension	83	133	215	84	233	14	182	22	136	83	55	1240
Status 4 Initial Listing	37	160	264	183	75	32	68	77	48	56	207	1207
Status 4 Extension	21	64	157	54	27	5	50	29	20	34	120	581
Total	349	729	1512	881	806	111	912	318	580	523	877	7598

Table 24 summarizes the form types and whether the form was approved, not approved, not required-other or not required-withdrawn. The vast majority of forms submitted were approved (93.3%), regardless of medical urgency status or form type. Status 1 justification forms at initial listing had the lowest approval rate (87.2%) while Status 3 Extensions had the highest approval rate (97.2%).

Table 24. Number of initial and extension justification forms by medical urgency status and conclusion from the form status field

Adult Heart Status and Form Type	Approved	Not Approved	Not Required - Other	Not Required - Withdrawn	Total
Status 1 Initial Listing	254 (87.3%)	16 (5.5%)	7 (2.4%)	14 (4.8%)	291 (100.0%)
Status 1 Extension	124 (96.1%)	1 (0.8%)	0 (0.0%)	4 (3.1%)	129 (100.0%)
Status 2 Initial Listing	1665 (90.1%)	121 (6.5%)	16 (0.9%)	46 (2.5%)	1848 (100.0%)
Status 2 Extension	1044 (94.3%)	35 (3.2%)	7 (0.6%)	21 (1.9%)	1107 (100.0%)
Status 3 Initial Listing	1026 (89.4%)	67 (5.8%)	16 (1.4%)	39 (3.4%)	1148 (100.0%)
Status 3 Extension	1193 (97.1%)	10 (0.8%)	1 (0.1%)	24 (2.0%)	1228 (100.0%)
Status 4 Initial Listing	1153 (96.1%)	24 (2.0%)	5 (0.4%)	18 (1.5%)	1200 (100.0%)
Status 4 Extension	557 (96.4%)	13 (2.2%)	1 (0.2%)	7 (1.2%)	578 (100.0%)
Total	7016 (93.2%)	287 (3.8%)	53 (0.7%)	173 (2.3%)	7529 (100.0%)

Under the new adult heart allocation system regions review requests from other regions. There have been two sets of RRB assignments during the period from September 18, 2018 to September 30, 2020 (https://optn.transplant.hrsa.gov/members/review-boards/#HeartReviewBoard). Table 25 summarizes the number of forms submitted from each region and the corresponding region that reviews the request by RRB assignment period. Region 3 submitted substantially more forms than any other region in both assignment periods. Region 6 submitted the smallest number of forms in both review periods.

Table 25. Number of forms by region submitting form and region reviewing form and review period

Region	N
Sept 18, 2018 - Sep 30, 2019	
Region 1, Reviewed by Region 2	179
Region 2, Reviewed by Region 5	361
Region 3, Reviewed by Region 7	739
Region 4, Reviewed by Region 10	438
Region 5, Reviewed by Region 9	396
Region 6, Reviewed by Region 8	52
Region 7, Reviewed by Region 11	468
Region 8, Reviewed by Region 4	162
Region 9, Reviewed by Region 1	242
Region 10, Reviewed by Region 6	243
Region 11, Reviewed by Region 3	440
Oct 1, 2019 - Sep 30, 2020	
Region 1, Reviewed by Region 8	170
Region 2, Reviewed by Region 7	368
Region 3, Reviewed by Region 11	773
Region 4, Reviewed by Region 5	443
Region 5, Reviewed by Region 4	410
Region 6, Reviewed by Region 1	59
Region 7, Reviewed by Region 3	444
Region 8, Reviewed by Region 6	156
Region 9, Reviewed by Region 10	338
Region 10, Reviewed by Region 9	280
Region 11, Reviewed by Region 2	437
Total	7598

Figure 49 and Table 26 summarize the the conclusions (approved/not approved/not required-other/not required- withdrawn) by OPTN region that reviewed the request, not the OPTN region from which the form originated, and RRB assignment period that requests were reviewed during. From October 1, 2019 to September 30, 2020 Region 10 approved the lowest proportion and Region 7 approved the highest proportion of requests.

Figure 49. Conclusions from justification forms by region reviewing request and review period

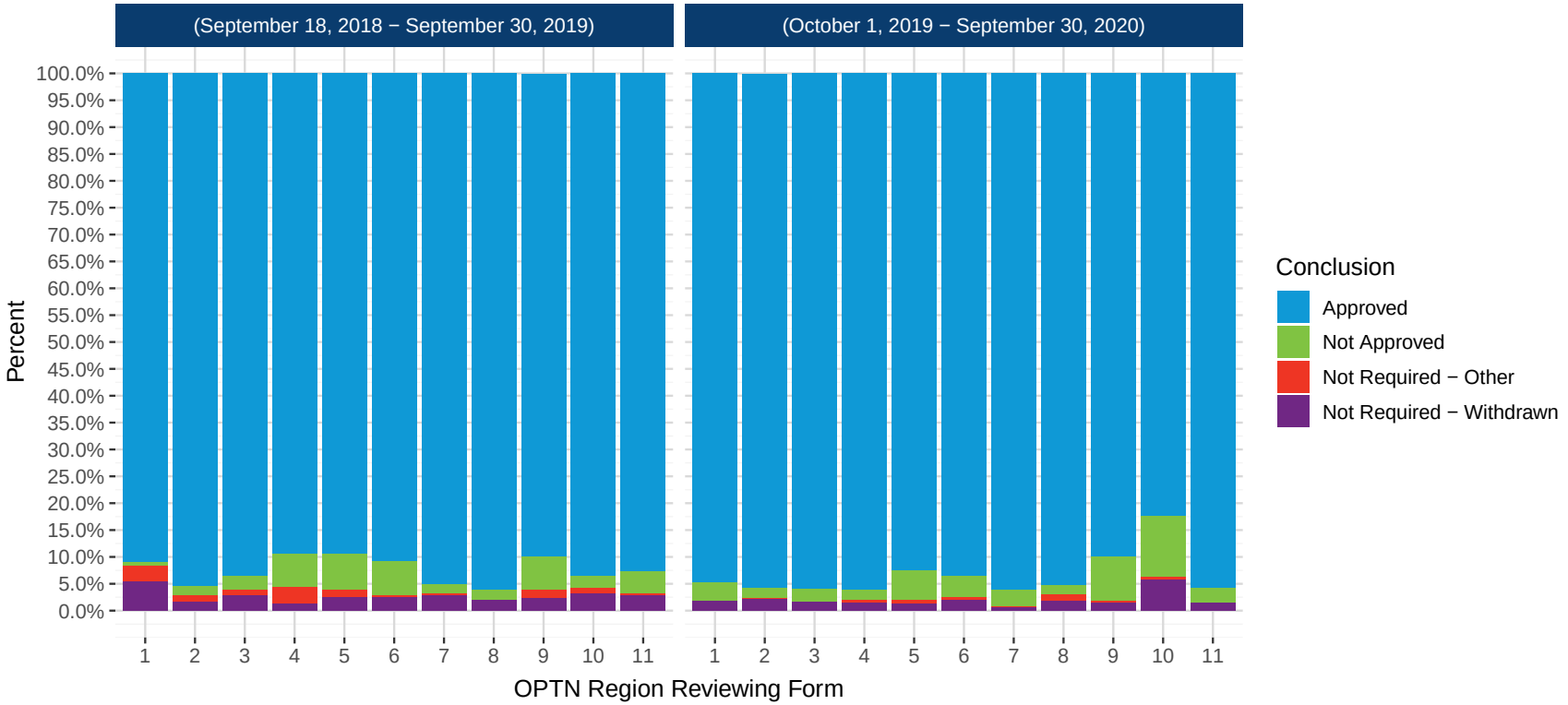


Table 26. Conclusions from justification forms by region reviewing request

OPTN Region Reviewing Form	Approved	Not Approved	Not Required - Other	Not Required - Withdrawn	Total
Sept 18, 2018 - Sep 30, 2019					
1	219 (90.9%)	2 (0.8%)	7 (2.9%)	13 (5.4%)	241 (100.0%)
2	169 (95.5%)	3 (1.7%)	2 (1.1%)	3 (1.7%)	177 (100.0%)
3	408 (93.6%)	11 (2.5%)	5 (1.1%)	12 (2.8%)	436 (100.0%)
4	144 (89.4%)	10 (6.2%)	5 (3.1%)	2 (1.2%)	161 (100.0%)
5	321 (89.4%)	24 (6.7%)	5 (1.4%)	9 (2.5%)	359 (100.0%)
6	219 (90.9%)	15 (6.2%)	1 (0.4%)	6 (2.5%)	241 (100.0%)
7	690 (95.2%)	12 (1.7%)	3 (0.4%)	20 (2.8%)	725 (100.0%)
8	50 (96.2%)	1 (1.9%)	0 (0.0%)	1 (1.9%)	52 (100.0%)
9	351 (90.0%)	24 (6.2%)	6 (1.5%)	9 (2.3%)	390 (100.0%)
10	407 (93.6%)	10 (2.3%)	4 (0.9%)	14 (3.2%)	435 (100.0%)
11	429 (92.7%)	19 (4.1%)	2 (0.4%)	13 (2.8%)	463 (100.0%)
Oct 1, 2019 - Sep 30, 2020					
1	55 (94.8%)	2 (3.4%)	0 (0.0%)	1 (1.7%)	58 (100.0%)
2	415 (95.8%)	8 (1.8%)	1 (0.2%)	9 (2.1%)	433 (100.0%)
3	422 (95.9%)	11 (2.5%)	0 (0.0%)	7 (1.6%)	440 (100.0%)
4	391 (96.1%)	8 (2.0%)	2 (0.5%)	6 (1.5%)	407 (100.0%)
5	406 (92.5%)	24 (5.5%)	3 (0.7%)	6 (1.4%)	439 (100.0%)
6	145 (93.5%)	6 (3.9%)	1 (0.6%)	3 (1.9%)	155 (100.0%)
7	351 (96.2%)	11 (3.0%)	1 (0.3%)	2 (0.5%)	365 (100.0%)
8	161 (95.3%)	3 (1.8%)	2 (1.2%)	3 (1.8%)	169 (100.0%)
9	251 (90.0%)	23 (8.2%)	1 (0.4%)	4 (1.4%)	279 (100.0%)
10	276 (82.4%)	38 (11.3%)	2 (0.6%)	19 (5.7%)	335 (100.0%)
11	736 (95.7%)	22 (2.9%)	0 (0.0%)	11 (1.4%)	769 (100.0%)
Total	7016 (93.2%)	287 (3.8%)	53 (0.7%)	173 (2.3%)	7529 (100.0%)

Note:
The number of justification forms with conclusions differs from the number of forms submitted reported in previous analyses because not all submitted forms have been resolved

Figure 50 and Table 27 show a registration-level summary of the forms that were exception requests. Previous figures have counted all forms submitted, regardless of how many were associated with a given registration; the following data includes only the first form submitted as an exception request for a particular waiting list registration.

A total of 3090 registrations applied for an exception in the given period. The most common initial request was for Adult Status 2 (n=1243, 40.2%).

Figure 50. Number of registrations with an exception by first status requested

Table 27. Number of registrations with an exception by first status requested

Status Requested	Registration Count	Percent
Status 1 Initial Listing	180	5.8%
Status 2 Initial Listing	1243	40.2%
Status 3 Initial Listing	737	23.9%
Status 4 Initial Listing	930	30.1%
Total	3090	100.0%

Figure 51 and Table 28 show the distribution of the number of exceptions requests per registration by medical urgency status. Adult Status 2 had the maximum number of exception requests per registration with 43 requests per registration followed by Adult Status 3 with 35 exception requests per registration. The median was 1 request per registration except for Adult Status 3 where the median was 2 requests.

Figure 51. Number of exception requests submitted per registration by medical urgency status

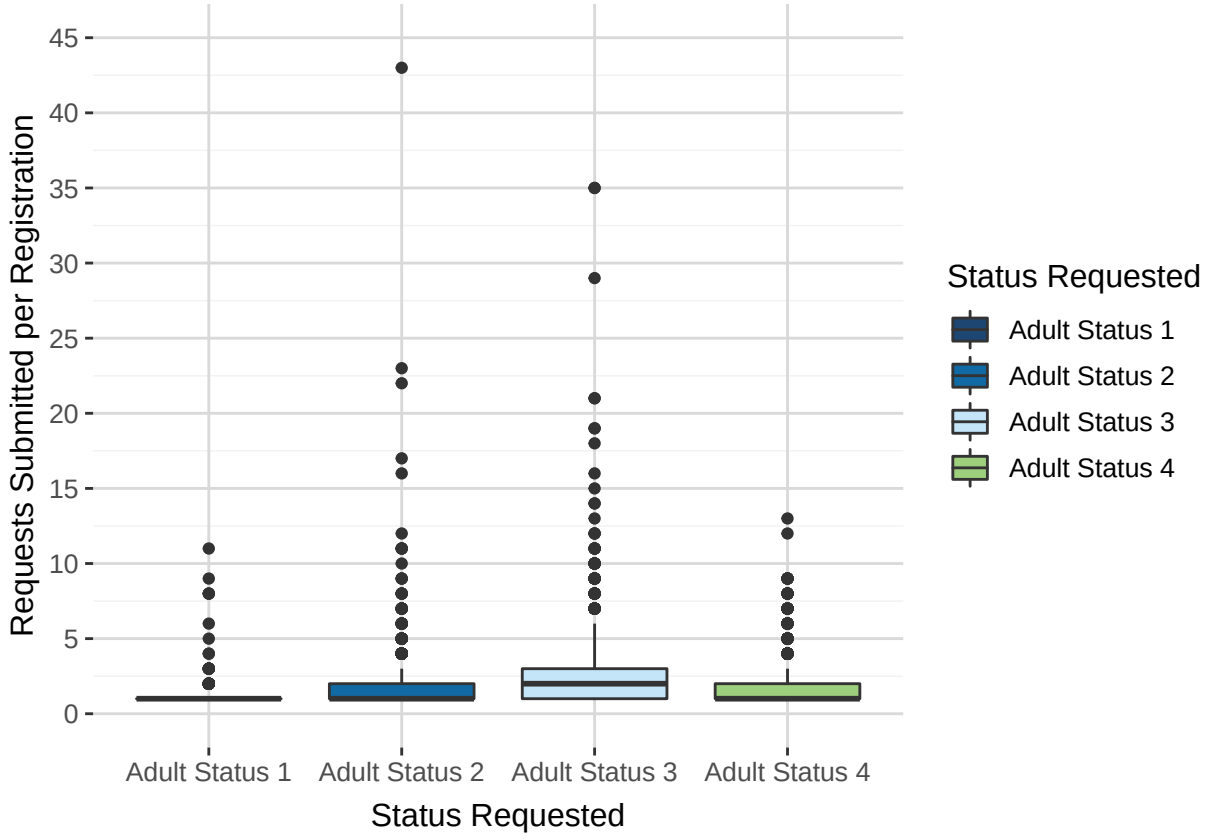


Table 28. Summary of exception requests submitted per registration by medical urgency status

Status Requested	Min	25th Percentile	Median	Mean	75th Percentile	Max
Adult Status 1	1	1	1	1	1	11
Adult Status 2	1	1	1	2	2	43
Adult Status 3	1	1	2	3	3	35
Adult Status 4	1	1	1	2	2	13

Pediatrics

This chapter provides a high-level overview of how pediatric heart candidates were impacted by changes to the adult heart allocation system. This includes 1295 pediatric heart candidates listed and 882 pediatric heart candidates transplanted between October 18, 2016 and October 17, 2018 (pre-implementation) along with 1347 pediatric heart candidates listed and 988 pediatric heart candidates transplanted between between October 18, 2018 and October 17, 2020 (post-implementation). Finally, there were 3034 pediatric candidates ever waiting.

Figure 52 Pediatric Heart Waiting List Additions by Medical Urgency Status and Era

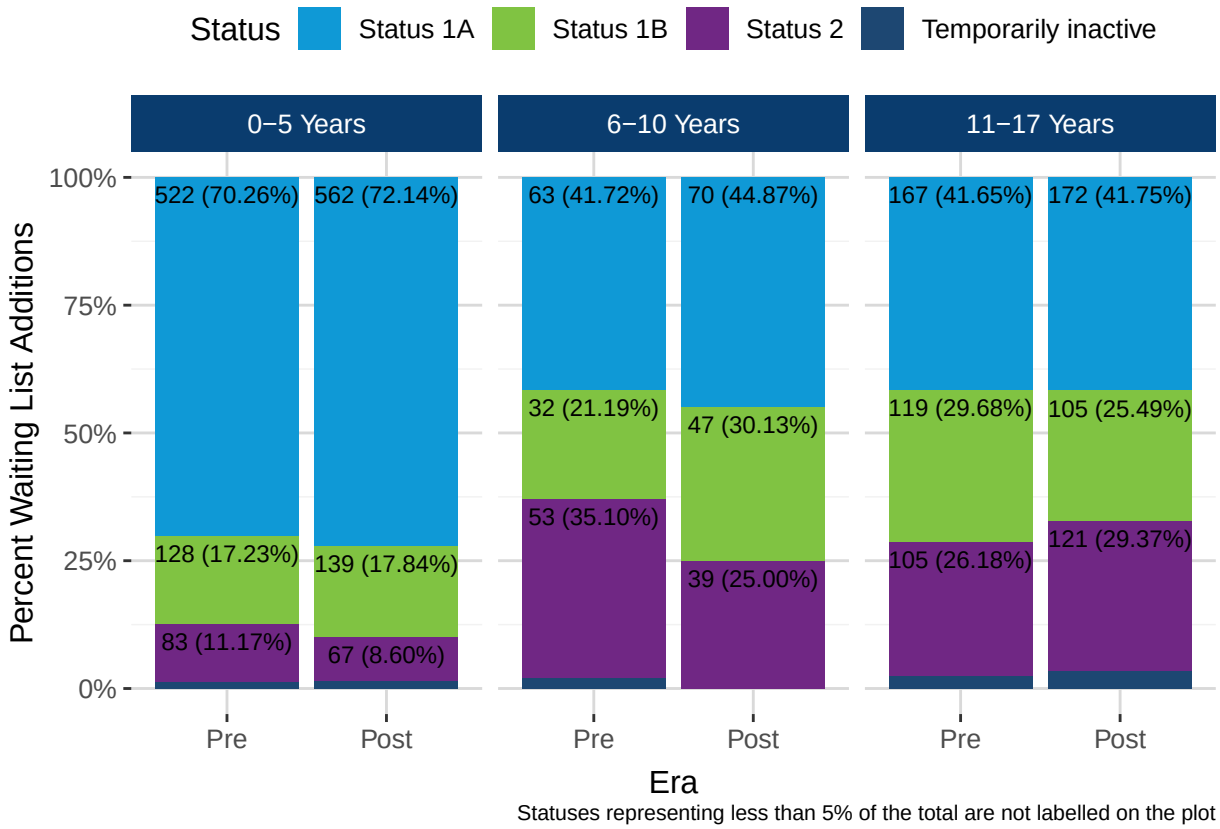


Figure 52 and Table 28 summarize the count and percent of pediatric heart waiting list registrations by status and age group. The proportion of pediatric additions did not differ substantially between eras; the largest shift was an increase in pediatric Status 1B and decrease in pediatric Status 2 candidates aged 6-10 years registering post-implementation. Table 27 further breaks down the percent of heart waiting list additions by post-implementation COVID-eras.

Table 28. Pediatric Heart Waiting List Additions by Era and Medical Urgency Status

		Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (Overall)	
Age Group	**Status**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
0-5 Years	Status 1A	522	71.2%	389	73.5%	37	74%	136	72%	562	73.2%
	Status 1B	128	17.5%	96	18.1%	11	22%	32	16.9%	139	18.1%
	Status 2	83	11.3%	44	8.3%	2	4%	21	11.1%	67	8.7%
6-10 Years	Status 1A	63	42.6%	52	44.1%	2	33.3%	16	50%	70	44.9%
	Status 1B	32	21.6%	36	30.5%	3	50%	8	25%	47	30.1%
	Status 2	53	35.8%	30	25.4%	1	16.7%	8	25%	39	25%
11-17 Years	Status 1A	167	42.7%	117	42.5%	14	41.2%	41	46.1%	172	43.2%
	Status 1B	119	30.4%	76	27.6%	6	17.6%	23	25.8%	105	26.4%
	Status 2	105	26.9%	82	29.8%	14	41.2%	25	28.1%	121	30.4%
Overall	Status 1A	752	59.1%	558	60.5%	53	58.9%	193	62.3%	804	60.8%
	Status 1B	279	21.9%	208	22.6%	20	22.2%	63	20.3%	291	22%
	Status 2	241	18.9%	156	16.9%	17	18.9%	54	17.4%	227	17.2%

Note:
Pre-Policy: October 18, 2016 - October 17, 2018;
Post-Policy, Pre-COVID: October 18, 2018 - March 12, 2020;
Post-Policy, COVID Onset: March 13, 2020 - May 09 2020;
Post-Policy COVID Stabilization: May 10, 2020 - October 17, 2020

Figure 53. Pediatric Heart Candidates Ever Waiting by Era and Most Recent Medical Urgency Status

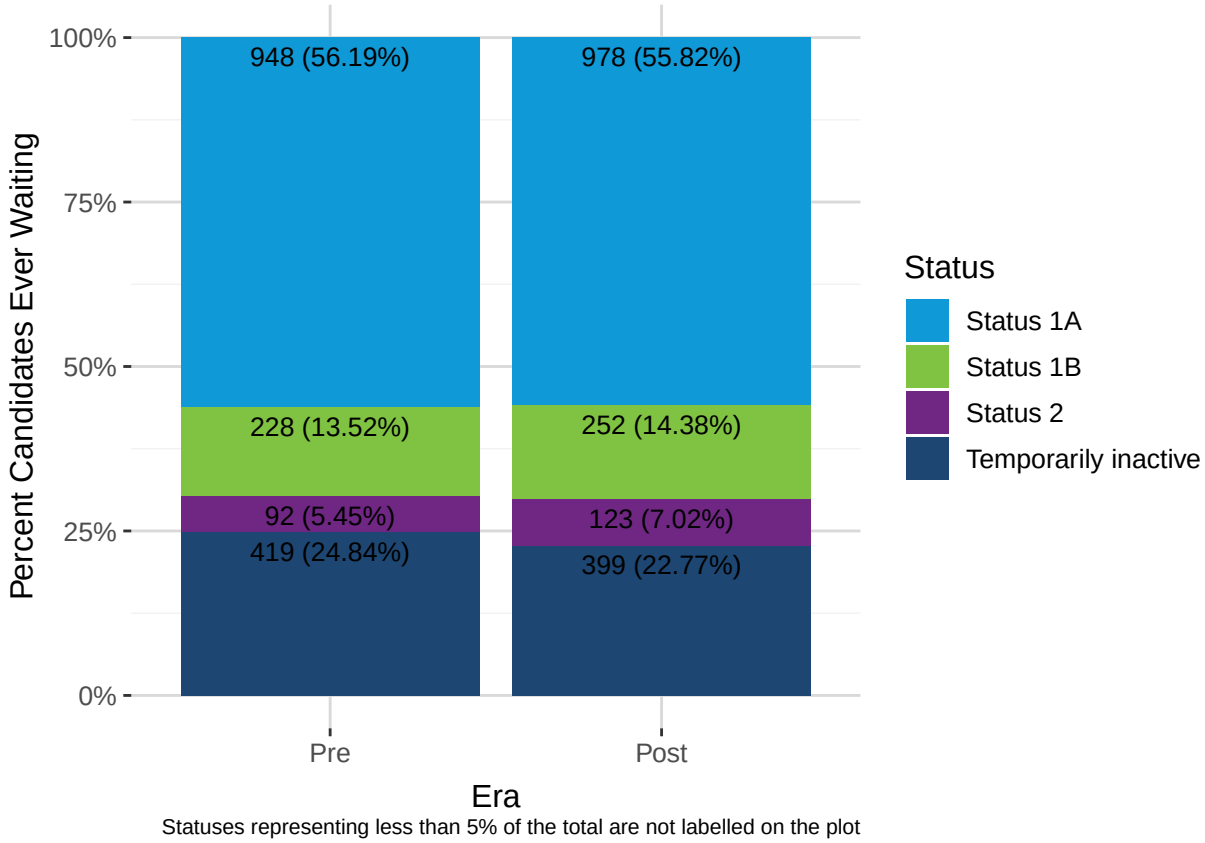


Figure 53 shows the proportion of pediatric heart candidates ever waiting by medical urgency status both pre- and post-implementation. There was very little change in the medical urgency status composition of the pediatric heart waiting list after changes to the adult heart allocation system were implemented.

Figure 54. Pediatric Heart Transplants by Medical Urgency Status and Era

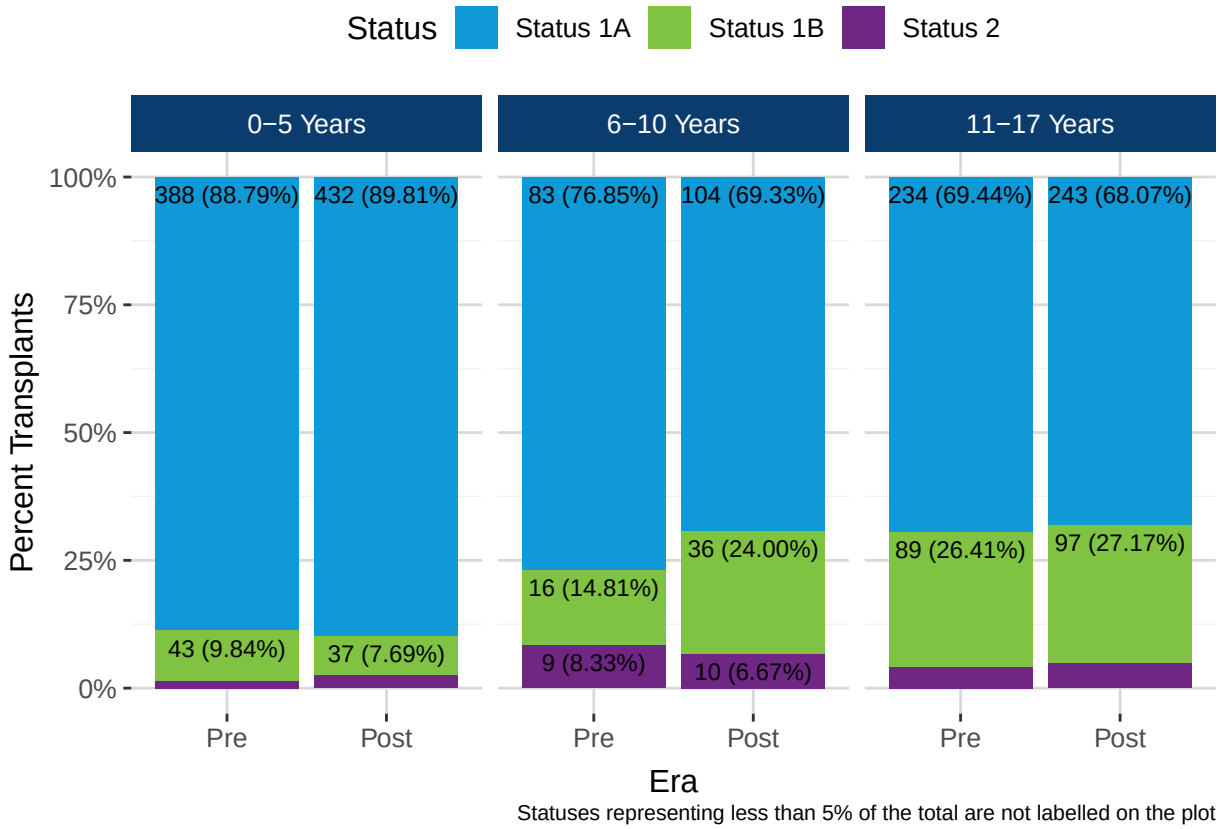


Figure 54 and Table 29 summarize the proportion of pediatric heart candidates transplanted by medical urgency status both pre- and post-implementation. There was little change in the proportion of medical urgency statuses transplanted for pediatric candidates aged 11-17 years and 0-5 years. The proportion of transplants that went to Status 1B pediatric recipients aged 6-10 years increased from 14.81% to 24.00% pre- to post-implementation.

Table 29. Pediatric Heart Transplants by Era and Medical Urgency Status

		Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (Overall)	
Age Group	**Status**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
0-5 Years	Status 1A	388	88.8%	301	90.9%	24	80%	107	89.2%	432	89.8%
	Status 1B	43	9.8%	22	6.6%	4	13.3%	11	9.2%	37	7.7%
	Status 2	6	1.4%	8	2.4%	2	6.7%	2	1.7%	12	2.5%
6-10 Years	Status 1A	83	76.9%	76	70.4%	4	57.1%	24	68.6%	104	69.3%
	Status 1B	16	14.8%	27	25%	2	28.6%	7	20%	36	24%
	Status 2	9	8.3%	5	4.6%	1	14.3%	4	11.4%	10	6.7%
11-17 Years	Status 1A	234	69.4%	175	71.1%	11	78.6%	57	58.8%	243	68.1%
	Status 1B	89	26.4%	61	24.8%	3	21.4%	33	34%	97	27.2%
	Status 2	14	4.2%	10	4.1%	0	0%	7	7.2%	17	4.8%
Overall	Status 1A	705	79.9%	552	80.6%	39	76.5%	188	74.6%	804	60.8%
	Status 1B	148	16.8%	110	16.1%	9	17.6%	51	20.2%	291	22%
	Status 2	29	3.3%	23	3.4%	3	5.9%	13	5.2%	227	17.2%

Note:
Pre-Policy: October 18, 2016 - October 17, 2018;
Post-Policy, Pre-COVID: October 18, 2018 - March 12, 2020;
Post-Policy, COVID Onset: March 13, 2020 - May 09 2020;
Post-Policy COVID Stabilization: May 10, 2020 - October 17, 2020

Figure 55. Pediatric Deaths per 100 Patient-Years Waiting by Medical Urgency Status and Era

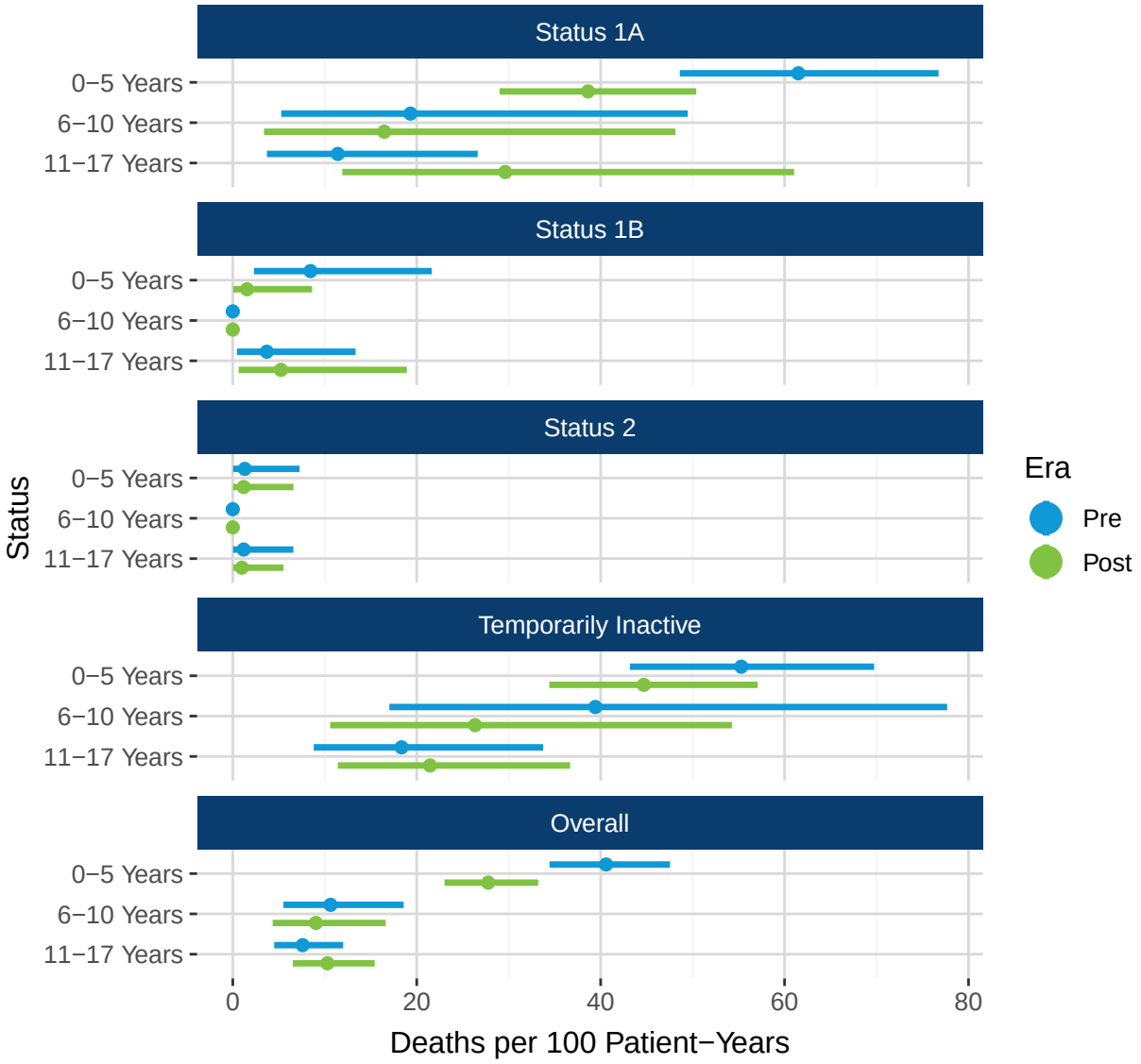


Figure 55 shows the deaths per 100 patient-years for pediatric heart candidates pre- and post-implementation by medical urgency status and era. There was a significant decrease in the number of deaths per 100 patient-years for pediatric candidates aged 0-5 years post-policy.

Table A18 shows the number of pediatric candidates ever waiting, the number of deaths for each medical urgency status and age group pre- and post-implementation, the number of deaths per 100 patient-years, the relative risk of death, and the 95% confidence interval around the relative risk of death. Relative risk of death and the confidence interval around relative risk of death are omitted if they could not be calculated due to small sample size.

Figure 56. Pediatric Transplants per 100 Patient-Years Waiting by Medical Urgency Status and Era

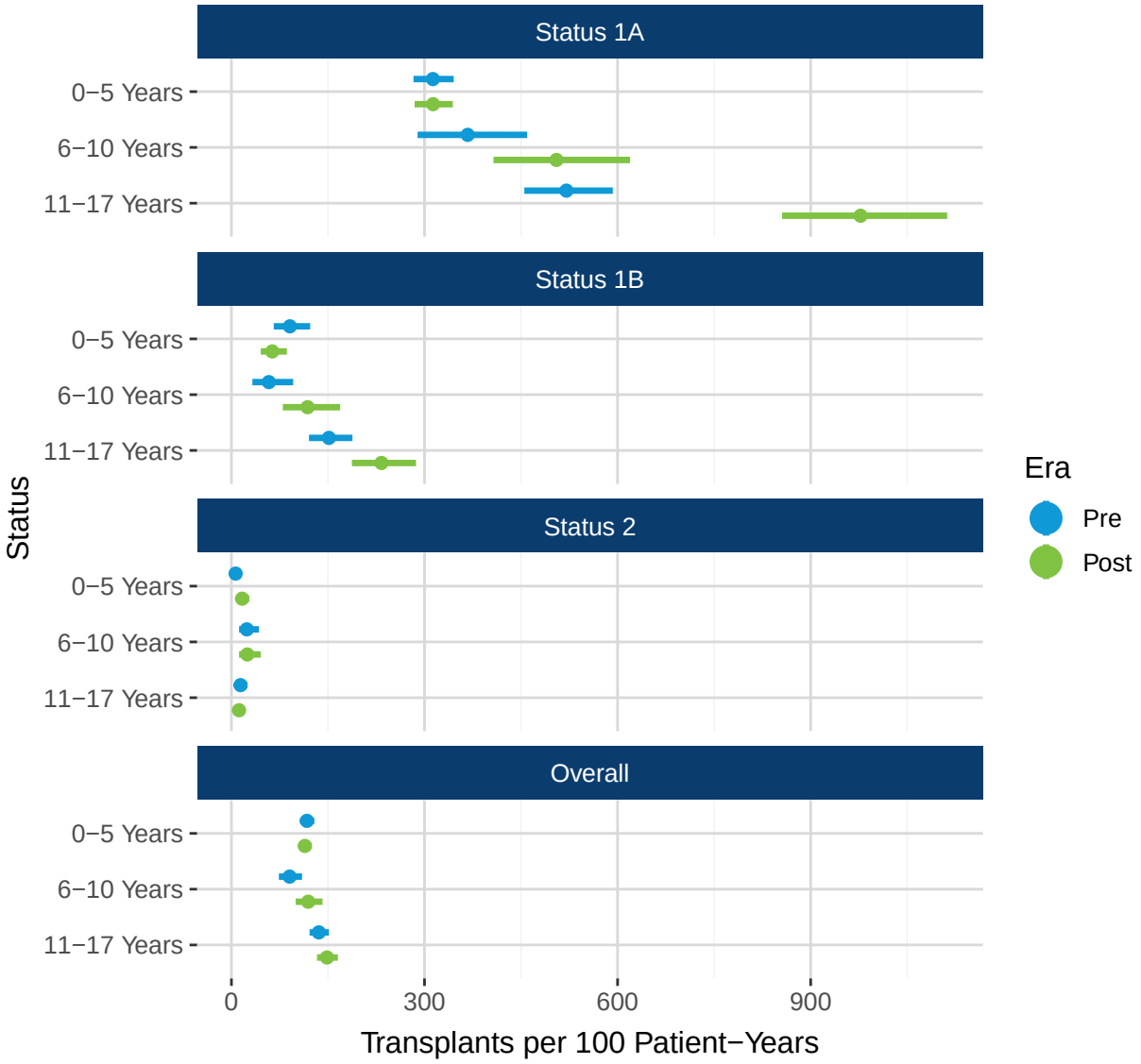


Figure 56 shows the number of transplants per 100 patient-years for pediatric heart candidates by age group, medical urgency status, and era. Post-implementation the number of transplants per 100 patient-years was significantly higher for Status 1A pediatric candidates 11-17 years old.

Table A19 shows the number of pediatric candidates ever waiting and the number of transplants for each medical urgency status and age group pre- and post-implementation, as well as the number of transplants per 100 patient-years, the relative risk of transplant, and the 95% confidence interval around the relative risk of transplant. Overall the relative risk of transplant for pediatric candidates in the 6-10 years age group was significantly higher after the implementation of changes to adult heart allocation. The relative risk of transplant was also significantly higher in the post era for pediatric candidates in the 6-10 and 11-17 years age group at Status 1A and 1B. The relative risk of transplant was significantly higher for pediatric candidates in the 0-5 year old group in Status 2.

Conclusion

Monitoring suggests that revisions to the heart allocation system resulted in broader sharing with a substantial increase in the median distance traveled, a decline in local shares and increases in regional and national shares. Hearts are traveling greater distances to be transplanted. Changes to the adult heart allocation system have also substantially reduced the median time spent waiting before a transplant, especially for the most medically urgent candidates. Transplant rates have increased, most dramatically for the most medically urgent candidates, while post-transplant outcomes have remained constant. There has been no substantial impact on the number of waiting list registrations, transplants performed, or heart utilization.

While some transplant centers have seen a decrease in transplant volume, it appears that differences in waiting list composition may explain this, rather than the change in allocation policy. In addition, changes to the adult heart allocation system have not had an noticeable impact on pediatric heart candidates.

The change in heart allocation policy also included changes to the RRB process. Since these changes went into effect, the number of justification forms submitted to the RRB has varied monthly. The majority of requests were for Adult Status 2 and were exception requests rather than standard review forms. The majority of forms were approved regardless of the region reviewing the form.

Appendix

Table A1: Adult Heart Waiting List Additions by Region and Medical Urgency Status Pre-Implementation

Region		Status 1A	Status 1B	Status 2	Temporarily Inactive	Total
1	N	110	148	129	4	391
	%	28.13%	37.85%	32.99%	1.02%	100.00%
2	N	157	387	257	12	813
	%	19.31%	47.60%	31.61%	1.48%	100.00%
3	N	238	549	171	20	978
	%	24.34%	56.13%	17.48%	2.04%	100.00%
4	N	161	409	199	30	799
	%	20.15%	51.19%	24.91%	3.75%	100.00%
5	N	326	406	421	43	1196
	%	27.26%	33.95%	35.20%	3.60%	100.00%
6	N	41	116	83	1	241
	%	17.01%	48.13%	34.44%	0.41%	100.00%
7	N	197	293	201	20	711
	%	27.71%	41.21%	28.27%	2.81%	100.00%
8	N	93	284	123	18	518
	%	17.95%	54.83%	23.75%	3.47%	100.00%
9	N	212	246	97	1	556
	%	38.13%	44.24%	17.45%	0.18%	100.00%
10	N	160	304	195	22	681
	%	23.49%	44.64%	28.63%	3.23%	100.00%
11	N	256	524	186	22	988
	%	25.91%	53.04%	18.83%	2.23%	100.00%

Table A2: Adult Heart Waitlist Additions by Region and Medical Urgency Status Post-Implementation

Region		Adult Status 1	Adult Status 2	Adult Status 3	Adult Status 4	Adult Status 5	Adult Status 6	Temporarily Inactive	Total
1	N	28	51	35	137	9	130	11	401
	%	6.98%	12.72%	8.73%	34.16%	2.24%	32.42%	2.74%	100.00%
2	N	28	131	73	339	15	194	5	785
	%	3.57%	16.69%	9.30%	43.18%	1.91%	24.71%	0.64%	100.00%
3	N	33	207	115	348	15	157	6	881
	%	3.75%	23.50%	13.05%	39.50%	1.70%	17.82%	0.68%	100.00%
4	N	30	132	71	298	24	158	13	726
	%	4.13%	18.18%	9.78%	41.05%	3.31%	21.76%	1.79%	100.00%
5	N	40	232	232	342	24	258	26	1154
	%	3.47%	20.10%	20.10%	29.64%	2.08%	22.36%	2.25%	100.00%
6	N	17	26	23	86	3	67	3	225
	%	7.56%	11.56%	10.22%	38.22%	1.33%	29.78%	1.33%	100.00%
7	N	28	177	74	228	20	127	10	664
	%	4.22%	26.66%	11.14%	34.34%	3.01%	19.13%	1.51%	100.00%
8	N	25	123	37	208	1	92	8	494
	%	5.06%	24.90%	7.49%	42.11%	0.20%	18.62%	1.62%	100.00%
9	N	28	134	65	206	11	125	1	570
	%	4.91%	23.51%	11.40%	36.14%	1.93%	21.93%	0.18%	100.00%
10	N	22	155	84	285	19	141	21	727
	%	3.03%	21.32%	11.55%	39.20%	2.61%	19.39%	2.89%	100.00%
11	N	50	218	125	466	20	230	16	1125
	%	4.44%	19.38%	11.11%	41.42%	1.78%	20.44%	1.42%	100.00%

Table A3: Adult Heart Waitlist Additions by Criteria Within Medical Urgency Status at Listing Post-Implementation by Region

	Criteria	Initial	
		N	%
Adult Status 1			
Region 1			
	BIVAD/Ventricular Episodes	1	3.45%
	Exception	2	6.90%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	14	48.28%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	9	31.03%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	3	10.34%
Overall			
		29	100%
Adult Status 1			
Region 2			
	BIVAD/Ventricular Episodes	3	9.68%
	Exception	3	9.68%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	1	3.23%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	10	32.26%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	14	45.16%
Overall			
		31	100%
Adult Status 1			
Region 3			
	BIVAD/Ventricular Episodes	2	5.56%
	Exception	12	33.33%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	6	16.67%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	6	16.67%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	10	27.78%
Overall			
		36	100%
Adult Status 1			
Region 4			
	BIVAD/Ventricular Episodes	1	3.12%
	Exception	13	40.62%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	3	9.38%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	12	37.50%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	3	9.38%
Overall			
		32	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 1 Region 5			
	BIVAD/Ventricular Episodes	1	2.33%
	Exception	7	16.28%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	3	6.98%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	18	41.86%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	14	32.56%
Overall		43	100%
Adult Status 1 Region 6			
	BIVAD/Ventricular Episodes	2	11.76%
	Exception	3	17.65%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	3	17.65%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	9	52.94%
Overall		17	100%
Adult Status 1 Region 7			
	BIVAD/Ventricular Episodes	3	10.71%
	Exception	6	21.43%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	3	10.71%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	12	42.86%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	4	14.29%
Overall		28	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 1 Region 8			
	BIVAD/Ventricular Episodes	2	8.00%
	Exception	7	28.00%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	1	4.00%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	11	44.00%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	4	16.00%
Overall		25	100%
Adult Status 1 Region 9			
	BIVAD/Ventricular Episodes	2	6.45%
	Exception	6	19.35%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	3	9.68%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	13	41.94%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	7	22.58%
Overall		31	100%
Adult Status 1 Region 10			
	BIVAD/Ventricular Episodes	2	8.33%
	Exception	5	20.83%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	3	12.50%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	9	37.50%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	5	20.83%
Overall		24	100%
Adult Status 1 Region 11			
	BIVAD/Ventricular Episodes	3	5.88%
	Exception	9	17.65%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	17	33.33%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	9	17.65%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	13	25.49%
Overall		51	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 2			
Region 1			
	Exception	17	33.33%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	4	7.84%
	Intra-aortic ballon pump - Hemodynamic Values obtained	14	27.45%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	3	5.88%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	2	3.92%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	6	11.76%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	3.92%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	3	5.88%
Overall			
		51	100%
Adult Status 2			
Region 2			
	Exception	34	25.95%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	2	1.53%
	Intra-aortic ballon pump - Hemodynamic Values obtained	74	56.49%
	Mechanical circulatory support device(MCSD) with malfunction	4	3.05%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	2	1.53%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	0.76%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	8	6.11%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	3	2.29%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	3	2.29%
Overall			
		131	100%

Table A3: *(continued)*

Criteria	Initial N	Initial %
Adult Status 2 Region 3		
Exception	97	46.41%
Intra-aortic ballon pump - Hemodynamic Values not obtained	1	0.48%
Intra-aortic ballon pump - Hemodynamic Values obtained	77	36.84%
Mechanical circulatory support device(MCSD) with malfunction	5	2.39%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	2	0.96%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	2	0.96%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	16	7.66%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	9	4.31%
Overall	209	100%
Adult Status 2 Region 4		
Exception	64	47.76%
Intra-aortic ballon pump - Hemodynamic Values not obtained	2	1.49%
Intra-aortic ballon pump - Hemodynamic Values obtained	36	26.87%
Mechanical circulatory support device(MCSD) with malfunction	3	2.24%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.75%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	3	2.24%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	18	13.43%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	1.49%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	5	3.73%
Overall	134	100%
Adult Status 2 Region 5		
Exception	46	19.83%
Intra-aortic ballon pump - Hemodynamic Values not obtained	10	4.31%
Intra-aortic ballon pump - Hemodynamic Values obtained	127	54.74%
Mechanical circulatory support device(MCSD) with malfunction	3	1.29%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.43%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	8	3.45%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	29	12.50%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	6	2.59%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	2	0.86%
Overall	232	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 2			
Region 6			
	Exception	7	26.92%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	1	3.85%
	Intra-aortic ballon pump - Hemodynamic Values obtained	5	19.23%
	Mechanical circulatory support device(MCSD) with malfunction	1	3.85%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	2	7.69%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	5	19.23%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	3	11.54%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	2	7.69%
Overall			
		26	100%
Adult Status 2			
Region 7			
	Exception	65	36.31%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	3	1.68%
	Intra-aortic ballon pump - Hemodynamic Values obtained	91	50.84%
	Mechanical circulatory support device(MCSD) with malfunction	3	1.68%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.56%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	5	2.79%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	6	3.35%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	5	2.79%
Overall			
		179	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 2			
Region 8			
	Exception	40	32.52%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	1	0.81%
	Intra-aortic ballon pump - Hemodynamic Values obtained	75	60.98%
	Mechanical circulatory support device(MCSD) with malfunction	3	2.44%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.81%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	0.81%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	1.63%
Overall			
		123	100%
Adult Status 2			
Region 9			
	Exception	44	31.88%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	1	0.72%
	Intra-aortic ballon pump - Hemodynamic Values obtained	73	52.90%
	Mechanical circulatory support device(MCSD) with malfunction	1	0.72%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	0.72%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	4	2.90%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	10	7.25%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	4	2.90%
Overall			
		138	100%
Adult Status 2			
Region 10			
	Exception	39	25.16%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	3	1.94%
	Intra-aortic ballon pump - Hemodynamic Values obtained	75	48.39%
	Mechanical circulatory support device(MCSD) with malfunction	7	4.52%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.65%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	19	12.26%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	6	3.87%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	5	3.23%
Overall			
		155	100%

Table A3: ***(continued)***

Criteria		Initial N	Initial %
Adult Status 2			
Region 11			
	Exception	84	38.36%
	Intra-aortic ballon pump - Hemodynamic Values obtained	96	43.84%
	Mechanical circulatory support device(MCSD) with malfunction	5	2.28%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	7	3.20%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	0.46%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	9	4.11%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	7	3.20%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	10	4.57%
Overall			
		219	100%
Adult Status 3			
Region 1			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	20	54.05%
	Exception	6	16.22%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	1	2.70%
	Mechanical circulatory support device (MCSD) with pump thrombosis	1	2.70%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	9	24.32%
Overall			
		37	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 3			
Region 2			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	28	38.36%
	Exception	8	10.96%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	1.37%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	4	5.48%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	1	1.37%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	1.37%
	Mechanical circulatory support device (MCSD) with right heart failure	3	4.11%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	27	36.99%
Overall		73	100%
Adult Status 3			
Region 3			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	14	12.17%
	Exception	44	38.26%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	7	6.09%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	3	2.61%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	3	2.61%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	3	2.61%
	Mechanical circulatory support device (MCSD) with pump thrombosis	3	2.61%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	38	33.04%
Overall		115	100%

Table A3: *(continued)*

Criteria	Initial N	Initial %
Adult Status 3		
Region 4		
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	4	5.63%
Exception	20	28.17%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	1.41%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	1	1.41%
Mechanical circulatory support device (MCSD) with device infection - Debridement	4	5.63%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	1.41%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	2	2.82%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	2.82%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	1.41%
Mechanical circulatory support device (MCSD) with pump thrombosis	1	1.41%
Mechanical circulatory support device (MCSD) with right heart failure	1	1.41%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	33	46.48%
Overall		
	71	100%
Adult Status 3		
Region 5		
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	35	15.02%
Exception	47	20.17%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	0.43%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	5	2.15%
Mechanical circulatory support device (MCSD) with device infection - Debridement	1	0.43%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	0.43%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	2	0.86%
Mechanical circulatory support device (MCSD) with pump thrombosis	2	0.86%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	139	59.66%
Overall		
	233	100%

Table A3: ***(continued)***

Criteria		Initial N	Initial %
Adult Status 3			
Region 6			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	1	4.35%
	Exception	7	30.43%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	3	13.04%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	4	17.39%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	4.35%
	Mechanical circulatory support device (MCSD) with hemolysis	1	4.35%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	6	26.09%
Overall		23	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 3			
Region 7			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	20	26.67%
	Exception	13	17.33%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	10	13.33%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	1	1.33%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	3	4.00%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	2	2.67%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	2.67%
	Mechanical circulatory support device (MCSD) with hemolysis	1	1.33%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	1.33%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	1	1.33%
	Mechanical circulatory support device (MCSD) with pump thrombosis	6	8.00%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	15	20.00%
Overall		75	100%
Adult Status 3			
Region 8			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	7	18.92%
	Exception	8	21.62%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	5	13.51%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	2	5.41%
	Mechanical circulatory support device (MCSD) with hemolysis	1	2.70%
	Mechanical circulatory support device (MCSD) with pump thrombosis	2	5.41%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	12	32.43%
Overall		37	100%

Table A3: *(continued)*

Criteria	Initial N	Initial %
Adult Status 3 Region 9		
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	20	28.99%
Exception	17	24.64%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	1.45%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	5	7.25%
Mechanical circulatory support device (MCSD) with device infection - Debridement	4	5.80%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	1.45%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	1.45%
Mechanical circulatory support device (MCSD) with pump thrombosis	1	1.45%
Mechanical circulatory support device (MCSD) with right heart failure	1	1.45%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	18	26.09%
Overall	69	100%
Adult Status 3 Region 10		
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	33	39.29%
Exception	12	14.29%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	2	2.38%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	10	11.90%
Mechanical circulatory support device (MCSD) with device infection - Debridement	8	9.52%
Mechanical circulatory support device (MCSD) with device infection - Erythema	2	2.38%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	2.38%
Mechanical circulatory support device (MCSD) with pump thrombosis	3	3.57%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	12	14.29%
Overall	84	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 3			
Region 11			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	43	34.13%
	Exception	19	15.08%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	9	7.14%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	8	6.35%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	4	3.17%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	4	3.17%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	0.79%
	Mechanical circulatory support device (MCSD) with hemolysis	1	0.79%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	2	1.59%
	Mechanical circulatory support device (MCSD) with pump thrombosis	3	2.38%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	32	25.40%
Overall			
		126	100%
Adult Status 4			
Region 1			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	38	27.34%
	Congenital heart disease	7	5.04%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	57	41.01%
	Exception	5	3.60%
	Inotropes without hemodynamic monitoring	25	17.99%
	Ischemic heart disease with intractable angina	2	1.44%
	Retransplant	5	3.60%
Overall			
		139	100%
Adult Status 4			
Region 2			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	28	8.16%
	Congenital heart disease	25	7.29%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	161	46.94%
	Exception	69	20.12%
	Inotropes without hemodynamic monitoring	51	14.87%
	Ischemic heart disease with intractable angina	4	1.17%
	Retransplant	5	1.46%
Overall			
		343	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 4 Region 3			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	15	4.29%
	Congenital heart disease	14	4.00%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	133	38.00%
	Exception	114	32.57%
	Inotropes without hemodynamic monitoring	57	16.29%
	Ischemic heart disease with intractable angina	5	1.43%
	Retransplant	12	3.43%
Overall		350	100%
Adult Status 4 Region 4			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	25	8.20%
	Congenital heart disease	19	6.23%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	119	39.02%
	Exception	94	30.82%
	Inotropes without hemodynamic monitoring	26	8.52%
	Ischemic heart disease with intractable angina	12	3.93%
	Retransplant	10	3.28%
Overall		305	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 4 Region 5			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	53	14.89%
	Congenital heart disease	50	14.04%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	101	28.37%
	Exception	32	8.99%
	Inotropes without hemodynamic monitoring	81	22.75%
	Ischemic heart disease with intractable angina	4	1.12%
	Retransplant	35	9.83%
Overall		356	100%
Adult Status 4 Region 6			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	10	11.63%
	Congenital heart disease	4	4.65%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	43	50.00%
	Exception	9	10.47%
	Inotropes without hemodynamic monitoring	14	16.28%
	Ischemic heart disease with intractable angina	2	2.33%
	Retransplant	4	4.65%
Overall		86	100%
Adult Status 4 Region 7			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	26	11.26%
	Congenital heart disease	23	9.96%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	108	46.75%
	Exception	27	11.69%
	Inotropes without hemodynamic monitoring	24	10.39%
	Ischemic heart disease with intractable angina	7	3.03%
	Retransplant	16	6.93%
Overall		231	100%
Adult Status 4 Region 8			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	18	8.61%
	Congenital heart disease	17	8.13%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	71	33.97%
	Exception	38	18.18%
	Inotropes without hemodynamic monitoring	50	23.92%
	Ischemic heart disease with intractable angina	3	1.44%
	Retransplant	12	5.74%
Overall		209	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 4 Region 9			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	21	10.19%
	Congenital heart disease	9	4.37%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	127	61.65%
	Exception	11	5.34%
	Inotropes without hemodynamic monitoring	21	10.19%
	Ischemic heart disease with intractable angina	3	1.46%
	Retransplant	14	6.80%
Overall			
		206	100%
Adult Status 4 Region 10			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	34	11.81%
	Congenital heart disease	19	6.60%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	178	61.81%
	Exception	17	5.90%
	Inotropes without hemodynamic monitoring	25	8.68%
	Ischemic heart disease with intractable angina	5	1.74%
	Retransplant	10	3.47%

Table A3: ***(continued)***

	Criteria	Initial N	Initial %
Overall		288	100%
Adult Status 4 Region 11			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	36	7.71%
	Congenital heart disease	28	6.00%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	210	44.97%
	Exception	96	20.56%
	Inotropes without hemodynamic monitoring	60	12.85%
	Ischemic heart disease with intractable angina	7	1.50%
	Retransplant	30	6.42%
Overall		467	100%
Adult Status 5 Region 1			
	None	10	100.00%
Adult Status 5 Region 2			
	None	18	100.00%
Adult Status 5 Region 3			
	None	22	100.00%
Adult Status 5 Region 4			
	None	30	100.00%
Adult Status 5 Region 5			
	None	35	100.00%
Adult Status 5 Region 6			
	None	3	100.00%
Adult Status 5 Region 7			
	None	23	100.00%
Adult Status 5 Region 8			
	None	1	100.00%
Adult Status 5 Region 9			
	None	14	100.00%
Adult Status 5 Region 10			
	None	22	100.00%
Adult Status 5 Region 11			
	None	21	100.00%
Adult Status 6 Region 1			
	None	130	100.00%
Adult Status 6 Region 2			
	None	198	100.00%

Table A3: ***(continued)***

Criteria		Initial N	Initial %
Adult Status 6 Region 3			
	None	158	100.00%
Adult Status 6 Region 4			
	None	159	100.00%
Adult Status 6 Region 5			
	None	258	100.00%
Adult Status 6 Region 6			
	None	67	100.00%
Adult Status 6 Region 7			
	None	128	100.00%
Adult Status 6 Region 8			
	None	92	100.00%
Adult Status 6 Region 9			
	None	128	100.00%
Adult Status 6 Region 10			
	None	141	100.00%
Adult Status 6 Region 11			
	None	230	100.00%

Table A4: Mechanical Circulatory Support Devices at Listing by Region

Brand	Era	Count	Percent
Region 1 ECMO			
Total ECMO	**Pre**	**9**	**6.52%**
	Post	**14**	**8.19%**
Region 1 IABP			
Total IABP	**Pre**	**9**	**6.52%**
	Post	**35**	**20.47%**
Region 1 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	6	6%
	Post	3	3.61%
Heartmate II	Pre	40	40%
	Post	6	7.23%
HeartMate III	Pre	5	5%
	Post	48	57.83%
Heartsaver VAD	Pre	1	1%
	Post	1	1.2%
Heartware HVAD	Pre	26	26%
	Post	20	24.1%
Impella CP	Pre	0	0%
	Post	1	1.2%
Impella Recover 2.5	Pre	1	1%
	Post	0	0%
Impella Recover 5.0	Pre	4	4%
	Post	2	2.41%
Other, Specify	Pre	17	17%
	Post	2	2.41%
Total LVAD	**Pre**	**100**	**72.46%**
	Post	**83**	**48.54%**
Region 1 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	5.26%
Cardiac Assist Tandem Heart	Pre	2	10%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	14	70%
	Post	29	76.32%
Heartmate II	Pre	1	5%
	Post	0	0%
	Pre	0	0%

HeartMate III	Post	5	13.16%
Heartware HVAD	Pre	0	0%
	Post	1	2.63%
Impella Recover 5.0	Pre	1	5%
	Post	1	2.63%
Other, Specify	Pre	2	10%
	Post	0	0%
Total LVAD+RVAD	**Pre**	**20**	**14.49%**
	Post	**38**	**22.22%**
Region 1 RVAD			
CentriMag (Thoratec/Levitronix)	Pre	0	NaN%
	Post	1	100%
Total RVAD	**Pre**	**0**	**0%**
	Post	**1**	**0.58%**
Region 2 ECMO			
Total ECMO	**Pre**	**21**	**7%**
	Post	**21**	**6.21%**
Region 2 IABP			
Total IABP	**Pre**	**24**	**8%**
	Post	**90**	**26.63%**
Region 2 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	2	0.83%
	Post	2	0.91%
Heartmate II	Pre	120	49.59%
	Post	30	13.64%
HeartMate III	Pre	5	2.07%
	Post	99	45%
Heartware HVAD	Pre	58	23.97%
	Post	50	22.73%
Impella CP	Pre	1	0.41%
	Post	4	1.82%
Impella Recover 2.5	Pre	2	0.83%
	Post	1	0.45%
Impella Recover 5.0	Pre	7	2.89%
	Post	4	1.82%
Other, Specify	Pre	47	19.42%
	Post	30	13.64%
	Pre	**242**	**80.67%**

Total LVAD	**Post**	**220**	**65.09%**
Region 2 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	25%
CentriMag (Thoratec/Levitronix)	Pre	5	50%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	1	25%
Heartware HVAD	Pre	3	30%
	Post	0	0%
Thoratec PVAD	Pre	0	0%
	Post	1	25%
Other, Specify	Pre	2	20%
	Post	1	25%
Total LVAD+RVAD	**Pre**	**10**	**3.33%**
	Post	**4**	**1.18%**
Region 2 RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	33.33%
CentriMag (Thoratec/Levitronix)	Pre	1	100%
	Post	0	0%
Impella Recover 5.0	Pre	0	0%
	Post	1	33.33%
Other, Specify	Pre	0	0%
	Post	1	33.33%
Total RVAD	**Pre**	**1**	**0.33%**
	Post	**3**	**0.89%**
Region 2 TAH			
SynCardia CardioWest	Pre	2	100%
	Post	0	NaN%
Total TAH	**Pre**	**2**	**0.67%**
	Post	**0**	**0%**
Region 3 ECMO			
Total ECMO	**Pre**	**10**	**2.92%**
	Post	**24**	**6.11%**
Region 3 IABP			
Total IABP	**Pre**	**65**	**19.01%**
	Post	**132**	**33.59%**
Region 3 LVAD			

Cardiac Assist Tandem Heart	Pre	2	0.8%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	2	0.8%
	Post	2	0.9%
Heartmate II	Pre	123	49%
	Post	38	17.19%
HeartMate III	Pre	5	1.99%
	Post	99	44.8%
Heartware HVAD	Pre	48	19.12%
	Post	52	23.53%
Impella CP	Pre	0	0%
	Post	1	0.45%
Impella Recover 2.5	Pre	1	0.4%
	Post	0	0%
Impella Recover 5.0	Pre	5	1.99%
	Post	21	9.5%
Other, Specify	Pre	65	25.9%
	Post	8	3.62%
Total LVAD	**Pre**	**251**	**73.39%**
	Post	**221**	**56.23%**
Region 3 LVAD+RVAD			
Cardiac Assist Tandem Heart	Pre	5	31.25%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	5	31.25%
	Post	9	64.29%
Heartmate II	Pre	3	18.75%
	Post	0	0%
Heartware HVAD	Pre	1	6.25%
	Post	4	28.57%
Other, Specify	Pre	2	12.5%
	Post	1	7.14%
Total LVAD+RVAD	**Pre**	**16**	**4.68%**
	Post	**14**	**3.56%**
Region 3 RVAD			
Impella Recover 5.0	Pre	0	NaN%
	Post	1	50%
Other, Specify	Pre	0	NaN%
	Post	1	50%
	Pre	**0**	**0%**

Total RVAD	**Post**	**2**	**0.51%**
Region 4 ECMO			
Total ECMO	**Pre**	**13**	**4.47%**
	Post	**21**	**7.09%**
Region 4 IABP			
Total IABP	**Pre**	**52**	**17.87%**
	Post	**78**	**26.35%**
Region 4 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	1	0.53%
Heartmate II	Pre	125	58.41%
	Post	51	26.84%
HeartMate III	Pre	0	0%
	Post	43	22.63%
Heartware HVAD	Pre	48	22.43%
	Post	60	31.58%
Impella CP	Pre	0	0%
	Post	3	1.58%
Impella Recover 2.5	Pre	4	1.87%
	Post	0	0%
Impella Recover 5.0	Pre	9	4.21%
	Post	27	14.21%
Terumo DuraHeart	Pre	1	0.47%
	Post	0	0%
Thoratec PVAD	Pre	1	0.47%
	Post	0	0%
Other, Specify	Pre	26	12.15%
	Post	5	2.63%
Total LVAD	**Pre**	**214**	**73.54%**
	Post	**190**	**64.19%**
Region 4 LVAD+RVAD			
CentriMag (Thoratec/Levitronix)	Pre	2	25%
	Post	4	66.67%
Heartware HVAD	Pre	3	37.5%
	Post	0	0%
Impella Recover 5.0	Pre	1	12.5%
	Post	1	16.67%
	Pre	2	25%

Maquet Jostra Rotaflow	Post	0	0%
Other, Specify	Pre	0	0%
	Post	1	16.67%
Total LVAD+RVAD	**Pre**	**8**	**2.75%**
	Post	**6**	**2.03%**
Region 4 TAH			
SynCardia CardioWest	Pre	4	100%
	Post	1	100%
Total TAH	**Pre**	**4**	**1.37%**
	Post	**1**	**0.34%**
Region 5 ECMO			
Total ECMO	**Pre**	**19**	**5.83%**
	Post	**35**	**8.5%**
Region 5 IABP			
Total IABP	**Pre**	**37**	**11.35%**
	Post	**136**	**33.01%**
Region 5 LVAD			
Cardiac Assist Tandem Heart	Pre	2	0.78%
	Post	1	0.47%
Heartmate II	Pre	70	27.45%
	Post	17	8.02%
HeartMate III	Pre	7	2.75%
	Post	75	35.38%
Heartmate XVE	Pre	1	0.39%
	Post	0	0%
Heartware HVAD	Pre	129	50.59%
	Post	71	33.49%
Impella CP	Pre	0	0%
	Post	13	6.13%
Impella Recover 2.5	Pre	2	0.78%
	Post	1	0.47%
Impella Recover 5.0	Pre	9	3.53%
	Post	19	8.96%
Other, Specify	Pre	35	13.73%
	Post	15	7.08%
Total LVAD	**Pre**	**255**	**78.22%**
	Post	**212**	**51.46%**
Region 5 LVAD+RVAD			
	Pre	0	0%

Cardiac Assist Tandem Heart	Post	3	12.5%
CentriMag (Thoratec/Levitronix)	Pre	3	37.5%
	Post	6	25%
HeartMate III	Pre	0	0%
	Post	1	4.17%
Heartware HVAD	Pre	4	50%
	Post	5	20.83%
Impella CP	Pre	0	0%
	Post	1	4.17%
Impella Recover 5.0	Pre	0	0%
	Post	1	4.17%
Other, Specify	Pre	1	12.5%
	Post	7	29.17%
Total LVAD+RVAD	**Pre**	**8**	**2.45%**
	Post	**24**	**5.83%**
Region 5 RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	33.33%
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	1	33.33%
Heartmate II	Pre	1	50%
	Post	0	0%
Impella Recover 5.0	Pre	1	50%
	Post	0	0%
Impella RP	Pre	0	0%
	Post	1	33.33%
Total RVAD	**Pre**	**2**	**0.61%**
	Post	**3**	**0.73%**
Region 5 TAH			
SynCardia CardioWest	Pre	5	100%
	Post	2	100%
Total TAH	**Pre**	**5**	**1.53%**
	Post	**2**	**0.49%**
Region 6 ECMO			
Total ECMO	**Pre**	**7**	**6.73%**
	Post	**16**	**14.16%**
Region 6 IABP			
Total IABP	**Pre**	**4**	**3.85%**
	Post	**7**	**6.19%**

Region 6 LVAD			
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	1	1.19%
Heartmate II	Pre	24	28.57%
	Post	11	13.1%
HeartMate III	Pre	2	2.38%
	Post	33	39.29%
Heartmate XVE	Pre	1	1.19%
	Post	0	0%
Heartware HVAD	Pre	40	47.62%
	Post	24	28.57%
Impella CP	Pre	1	1.19%
	Post	11	13.1%
Impella Recover 5.0	Pre	2	2.38%
	Post	2	2.38%
Other, Specify	Pre	14	16.67%
	Post	2	2.38%
Total LVAD	**Pre**	**84**	**80.77%**
	Post	**84**	**74.34%**
Region 6 LVAD+RVAD			
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	1	50%
CentriMag (Thoratec/Levitronix)	Pre	2	100%
	Post	0	0%
Heartware HVAD	Pre	0	0%
	Post	1	50%
Total LVAD+RVAD	**Pre**	**2**	**1.92%**
	Post	**2**	**1.77%**
Region 6 RVAD			
Cardiac Assist Protek Duo	Pre	0	NaN%
	Post	1	100%
Total RVAD	**Pre**	**0**	**0%**
	Post	**1**	**0.88%**
Region 6 TAH			
SynCardia CardioWest	Pre	7	100%
	Post	3	100%
Total TAH	**Pre**	**7**	**6.73%**
	Post	**3**	**2.65%**
Region 7 ECMO			

Total ECMO	**Pre**	**20**	**5.57%**
	Post	**22**	**6.57%**
Region 7 IABP			
Total IABP	**Pre**	**77**	**21.45%**
	Post	**118**	**35.22%**
Region 7 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	4	1.61%
	Post	0	0%
Heartmate II	Pre	95	38.15%
	Post	27	15%
HeartMate III	Pre	2	0.8%
	Post	82	45.56%
Heartsaver VAD	Pre	0	0%
	Post	1	0.56%
Heartware HVAD	Pre	89	35.74%
	Post	62	34.44%
Impella CP	Pre	0	0%
	Post	1	0.56%
Impella Recover 5.0	Pre	3	1.2%
	Post	3	1.67%
Other, Specify	Pre	56	22.49%
	Post	4	2.22%
Total LVAD	**Pre**	**249**	**69.36%**
	Post	**180**	**53.73%**
Region 7 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	16.67%
CentriMag (Thoratec/Levitronix)	Pre	3	25%
	Post	4	33.33%
HeartMate III	Pre	0	0%
	Post	1	8.33%
Heartware HVAD	Pre	8	66.67%
	Post	4	33.33%
Impella Recover 5.0	Pre	0	0%
	Post	1	8.33%
Other, Specify	Pre	1	8.33%
	Post	0	0%
Total LVAD+RVAD	**Pre**	**12**	**3.34%**
	Post	**12**	**3.58%**

Region 7 TAH			
SynCardia CardioWest	Pre	1	100%
	Post	3	100%
Total TAH	**Pre**	**1**	**0.28%**
	Post	**3**	**0.9%**
Region 8 ECMO			
Total ECMO	**Pre**	**6**	**3.06%**
	Post	**20**	**8.3%**
Region 8 IABP			
Total IABP	**Pre**	**31**	**15.82%**
	Post	**100**	**41.49%**
Region 8 LVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	0.91%
Heartmate II	Pre	86	55.13%
	Post	23	20.91%
HeartMate III	Pre	3	1.92%
	Post	53	48.18%
Heartware HVAD	Pre	41	26.28%
	Post	27	24.55%
Impella Recover 5.0	Pre	1	0.64%
	Post	1	0.91%
Other, Specify	Pre	25	16.03%
	Post	5	4.55%
Total LVAD	**Pre**	**156**	**79.59%**
	Post	**110**	**45.64%**
Region 8 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	4	40%
CentriMag (Thoratec/Levitronix)	Pre	1	50%
	Post	1	10%
HeartMate III	Pre	0	0%
	Post	2	20%
Heartware HVAD	Pre	1	50%
	Post	1	10%
Impella RP	Pre	0	0%
	Post	1	10%
Other, Specify	Pre	0	0%
	Post	1	10%

Total LVAD+RVAD	**Pre**	**2**	**1.02%**
	Post	**10**	**4.15%**
Region 8 RVAD			
Cardiac Assist Tandem Heart	Pre	1	100%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	1	100%
Total RVAD	**Pre**	**1**	**0.51%**
	Post	**1**	**0.41%**
Region 9 ECMO			
Total ECMO	**Pre**	**15**	**5.36%**
	Post	**28**	**8.12%**
Region 9 IABP			
Total IABP	**Pre**	**12**	**4.29%**
	Post	**110**	**31.88%**
Region 9 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	1	0.55%
Evaheart	Pre	1	0.43%
	Post	0	0%
Heartmate II	Pre	138	59.48%
	Post	32	17.58%
HeartMate III	Pre	10	4.31%
	Post	123	67.58%
Heartware HVAD	Pre	25	10.78%
	Post	18	9.89%
Impella CP	Pre	0	0%
	Post	1	0.55%
Impella Recover 2.5	Pre	1	0.43%
	Post	0	0%
Impella Recover 5.0	Pre	0	0%
	Post	2	1.1%
Jarvik 2000	Pre	1	0.43%
	Post	0	0%
Other, Specify	Pre	56	24.14%
	Post	5	2.75%
Total LVAD	**Pre**	**232**	**82.86%**
	Post	**182**	**52.75%**
Region 9 LVAD+RVAD			

Cardiac Assist Tandem Heart	Pre	1	5%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	8	40%
	Post	7	35%
Heartmate II	Pre	1	5%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	11	55%
Heartware HVAD	Pre	5	25%
	Post	0	0%
Thoratec PVAD	Pre	0	0%
	Post	1	5%
Other, Specify	Pre	5	25%
	Post	1	5%
Total LVAD+RVAD	**Pre**	**20**	**7.14%**
	Post	**20**	**5.8%**
Region 9 RVAD			
CentriMag (Thoratec/Levitronix)	Pre	0	NaN%
	Post	1	100%
Total RVAD	**Pre**	**0**	**0%**
	Post	**1**	**0.29%**
Region 9 TAH			
SynCardia CardioWest	Pre	1	100%
	Post	4	100%
Total TAH	**Pre**	**1**	**0.36%**
	Post	**4**	**1.16%**
Region 10 ECMO			
Total ECMO	**Pre**	**11**	**3.36%**
	Post	**16**	**3.82%**
Region 10 IABP			
Total IABP	**Pre**	**24**	**7.34%**
	Post	**90**	**21.48%**
Region 10 LVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	0.34%
CentriMag (Thoratec/Levitronix)	Pre	1	0.36%
	Post	2	0.68%
Heartmate II	Pre	117	42.7%
	Post	48	16.38%

HeartMate III	Pre	9	3.28%
	Post	141	48.12%
Heartware HVAD	Pre	84	30.66%
	Post	59	20.14%
Impella CP	Pre	0	0%
	Post	4	1.37%
Impella Recover 5.0	Pre	6	2.19%
	Post	8	2.73%
Impella RP	Pre	0	0%
	Post	1	0.34%
Other, Specify	Pre	57	20.8%
	Post	29	9.9%
Total LVAD	**Pre**	**274**	**83.79%**
	Post	**293**	**69.93%**
Region 10 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	12.5%
CentriMag (Thoratec/Levitronix)	Pre	8	50%
	Post	3	18.75%
Heartmate II	Pre	1	6.25%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	3	18.75%
Heartware HVAD	Pre	5	31.25%
	Post	4	25%
Impella Recover 5.0	Pre	1	6.25%
	Post	1	6.25%
Other, Specify	Pre	1	6.25%
	Post	3	18.75%
Total LVAD+RVAD	**Pre**	**16**	**4.89%**
	Post	**16**	**3.82%**
Region 10 RVAD			
CentriMag (Thoratec/Levitronix)	Pre	2	100%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	1	50%
Impella Recover 5.0	Pre	0	0%
	Post	1	50%
	Pre	**2**	**0.61%**

Total RVAD	**Post**	**2**	**0.48%**
Region 10 TAH			
SynCardia CardioWest	Pre	0	NaN%
	Post	1	50%
Other, Specify	Pre	0	NaN%
	Post	1	50%
Total TAH	**Pre**	**0**	**0%**
	Post	**2**	**0.48%**
Region 11 ECMO			
Total ECMO	**Pre**	**13**	**2.86%**
	Post	**31**	**5.37%**
Region 11 IABP			
Total IABP	**Pre**	**66**	**14.54%**
	Post	**153**	**26.52%**
Region 11 LVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	4	1.18%
CentriMag (Thoratec/Levitronix)	Pre	2	0.57%
	Post	7	2.06%
Evaheart	Pre	0	0%
	Post	1	0.29%
Heartmate II	Pre	159	45.04%
	Post	61	17.94%
HeartMate III	Pre	10	2.83%
	Post	158	46.47%
Heartsaver VAD	Pre	0	0%
	Post	1	0.29%
Heartware HVAD	Pre	126	35.69%
	Post	91	26.76%
Impella CP	Pre	0	0%
	Post	1	0.29%
Impella Recover 2.5	Pre	0	0%
	Post	1	0.29%
Impella Recover 5.0	Pre	1	0.28%
	Post	4	1.18%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	3	0.88%
	Pre	55	15.58%

Other, Specify	Post	8	2.35%
Total LVAD	**Pre**	**353**	**77.75%**
	Post	**340**	**58.93%**
Region 11 LVAD+RVAD			
Abiomed AB5000	Pre	0	0%
	Post	1	2.27%
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	4.55%
CentriMag (Thoratec/Levitronix)	Pre	3	25%
	Post	22	50%
Heartmate II	Pre	1	8.33%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	3	6.82%
Heartware HVAD	Pre	1	8.33%
	Post	1	2.27%
Impella Recover 5.0	Pre	0	0%
	Post	1	2.27%
Maquet Jostra Rotaflow	Pre	3	25%
	Post	12	27.27%
Other, Specify	Pre	4	33.33%
	Post	2	4.55%
Total LVAD+RVAD	**Pre**	**12**	**2.64%**
	Post	**44**	**7.63%**
Region 11 RVAD			
CentriMag (Thoratec/Levitronix)	Pre	1	100%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	1	33.33%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	1	33.33%
Other, Specify	Pre	0	0%
	Post	1	33.33%
Total RVAD	**Pre**	**1**	**0.22%**
	Post	**3**	**0.52%**
Region 11 TAH			
SynCardia CardioWest	Pre	9	100%
	Post	5	83.33%
	Pre	0	0%

Other, Specify	Post	1	16.67%
Total TAH	**Pre**	**9**	**1.98%**
	Post	**6**	**1.04%**

Table A5: Mechanical Circulatory Support Devices at Listing for Adult Heart Candidates as Entered into Waitlist, Post-Implementation

Device	Brand	Count	Percent
IABP	**Total**	**1098**	**30.37%**
Left Dischargeable VAD	Evaheart	2	0.11%
	Heartmate II	337	18.27%
	HeartMate III	939	50.89%
	Heartsaver VAD	1	0.05%
	Heartware HVAD	561	30.41%
	Worldheart Levacor	1	0.05%
	Other, Specify	4	0.22%
Left Dischargeable VAD	**Total**	**1845**	**51.02%**
Left Non-Dischargeable VAD	Abiomed AB5000	1	1.47%
	CentriMag (Thoratec/Levitronix)	50	73.53%
	Maquet Jostra Rotaflow	8	11.76%
	Other, Specify	9	13.24%
Left Non-Dischargeable VAD	**Total**	**68**	**1.88%**
Left Percutaneous Device	Cardiac Assist Protek Duo	1	0.41%
	Cardiac Assist Tandem Heart	5	2.07%
	CentriMag (Thoratec/Levitronix)	1	0.41%
	Impella CP	48	19.92%
	Impella Recover 2.5	3	1.24%
	Impella Recover 5.0	117	48.55%
	Other, Specify	66	27.39%
Left Percutaneous Device	**Total**	**241**	**6.66%**
Right Dischargeable VAD	HeartMate III	5	45.45%
	Heartware HVAD	5	45.45%
	Other, Specify	1	9.09%
Right Dischargeable VAD	**Total**	**11**	**0.3%**
Right Non-Dischargeable VAD	CentriMag (Thoratec/Levitronix)	59	78.67%
	Maquet Jostra Rotaflow	8	10.67%
	Other, Specify	8	10.67%
Right Non-Dischargeable VAD	**Total**	**75**	**2.07%**
Right Percutaneous Device	Cardiac Assist Protek Duo	11	44%
	Cardiac Assist Tandem Heart	5	20%
	CentriMag (Thoratec/Levitronix)	3	12%
	Impella Recover 5.0	3	12%
	Impella RP	2	8%
	Other, Specify	1	4%
Right Percutaneous Device	**Total**	**25**	**0.69%**
Single Dischargeable VAD	HeartMate III	2	66.67%
	Heartware HVAD	1	33.33%
Single Dischargeable VAD	**Total**	**3**	**0.08%**
Single Non-Dischargeable VAD	**Total**	**1**	**0.03%**
Single Percutaneous Device	**Total**	**1**	**0.03%**
TAH	SynCardia CardioWest	14	87.5%

Table A6: Deaths per 100 Patient-Years Waiting by Medical Urgency Status and Era

Era	Status	Patients Ever Waiting	Number of Deaths	Deaths per 100 Patient Years	CI
Pre	Status 1A	6024	156	19	[16, 23]
	Status 1B	6901	164	5	[5, 6]
	Status 2	2789	60	4	[3, 5]
	Temporarily Inactive	3963	613	41	[38, 45]
Pre	**Overall**	**10741**	**993**	**14**	**[14, 15]**
Post	Adult Status 1	641	26	164	[107, 240]
	Adult Status 2	3420	46	33	[24, 44]
	Adult Status 3	3282	23	6	[4, 9]
	Adult Status 4	5333	127	4	[4, 5]
	Adult Status 5	395	13	8	[4, 14]
	Adult Status 6	2633	30	3	[2, 5]
	Temporarily Inactive	3859	558	39	[36, 42]
Post	**Overall**	**10582**	**829**	**14**	**[13, 15]**

Table A7: Deaths per 100 Patient-Years Waiting by Criteria within Medical Urgency Status

Status	CriteriaDescription	Patients Ever Waiting	Number of Deaths	Deaths per 100 Patient Years	CI
Adult Status 1	BIVAD/Ventricular Episodes	50	1	81	[2, 449]
	Exception	172	6	127	[47, 276]
	Surgically implanted non-endovascular biventricular support device	65	3	108	[22, 316]
	Surgically implanted non-endovascular biventricular support device	65	3	108	[22, 316]
	VA ECMO	235	4	102	[28, 262]
Adult Status 2	Exception	1107	4	8	[2, 21]
	IABP	1119	4	12	[3, 30]
	MCSD with malfunction	149	0	0	-
	Non-dischargeable, surgically implanted, non-endovascular LVAD	31	2	253	[31, 912]
	Percutaneous endovascular MCSD	186	0	0	-
	TAH, BiVAD, RVAD, or VAD for single ventricle patients	102	3	22	[5, 65]
	VT or VF	74	1	42	[1, 232]
	Dischargeable LVAD for discretionary 30 days	1146	1	1	[0, 7]
	Exception	648	3	6	[1, 16]
	IABP after 14 days	26	0	0	-
	MCSD with Aortic Insufficiency	43	0	0	-
	MCSD with device infection	328	2	2	[0, 8]
	MCSD with hemolysis	42	0	0	-
	MCSD with mucosal bleeding	45	0	0	-
	MCSD with pump thrombosis	77	1	3	[0, 17]
	MCSD with right heart failure	27	1	16	[0, 92]

Adult Status 3	Multiple/single high dose inotrope & hemodynamic monitoring	576	2	8	[1, 30]
	Non-dischargeable, surgically implanted, non-endovascular LVAD >14 days	1	0	0	-
	Percutaneous endovascular circulatory support device after 14 days	3	0	0	-
	VA ECMO after 7 days	2	0		-
Adult Status 4	Amyloidosis/hypertrophic/restrictive cardiomyopathy	330	1	1	[0, 5]
	Congenital heart disease	265	5	4	[1, 9]
	Dischargeable LVAD without discretionary 30 days	2612	31	2	[1, 3]
	Exception	678	6	3	[1, 7]
	Inotropes without hemodynamic monitoring	616	4	5	[1, 13]
	Inotropes without hemodynamic monitoring	616	4	5	[1, 13]
	Ischemic heart disease with intractable angina	78	2	6	[1, 21]
	Retransplant	183	4	5	[1, 13]

Table A8: Deaths per 100 Patient-Years Waiting by Region, Medical Urgency Status, and Era

Region	Era	Patients Ever Waiting	Deaths per 100 Patient Years	Relative Risk	CI
1	Pre	612	11	Ref	-
	Post	623	9	0.85	[0.59, 1.24]
2	Pre	1147	17	Ref	-
	Post	1091	15	0.85	[0.63, 1.13]
3	Pre	1370	17	Ref	-
	Post	1261	18	1.09	[0.72, 1.63]
4	Pre	1100	13	Ref	-
	Post	1023	15	1.18	[0.85, 1.63]
5	Pre	1474	13	Ref	-
	Post	1473	14	1.07	[0.80, 1.42]
6	Pre	333	15	Ref	-
	Post	272	17	1.15	[0.74, 1.77]
7	Pre	1106	12	Ref	-
	Post	1034	11	0.87	[0.65, 1.17]
8	Pre	657	18	Ref	-
	Post	646	17	0.91	[0.65, 1.27]
9	Pre	835	11	Ref	-
	Post	866	10	0.94	[0.60, 1.47]
10	Pre	954	15	Ref	-
	Post	1033	13	0.86	[0.62, 1.19]
11	Pre	1320	17	Ref	-
	Post	1382	15	0.88	[0.67, 1.16]
Overall	Pre	10741	14	Ref	-
	Post	10582	14	0.95	[0.87, 1.05]

Table A9: Adult Heart Transplants by Region and Medical Urgency Status Pre-Implementation

Region		Status 1A	Status 1B	Status 2	Total
1	N	227	50	9	286
	%	79.37%	17.48%	3.15%	100.00%
2	N	366	216	19	601
	%	60.90%	35.94%	3.16%	100.00%
3	N	407	257	23	687
	%	59.24%	37.41%	3.35%	100.00%
4	N	374	194	7	575
	%	65.04%	33.74%	1.22%	100.00%
5	N	651	224	50	925
	%	70.38%	24.22%	5.41%	100.00%
6	N	84	104	18	206
	%	40.78%	50.49%	8.74%	100.00%
7	N	407	93	2	502
	%	81.08%	18.53%	0.40%	100.00%
8	N	187	189	12	388
	%	48.20%	48.71%	3.09%	100.00%
9	N	343	44	2	389
	%	88.17%	11.31%	0.51%	100.00%
10	N	325	106	1	432
	%	75.23%	24.54%	0.23%	100.00%
11	N	532	226	18	776
	%	68.56%	29.12%	2.32%	100.00%

Table A10: Adult Heart Transplants by Region and Medical Urgency Status Post-Implementation

Region		Adult Status 1	Adult Status 2	Adult Status 3	Adult Status 4	Adult Status 5	Adult Status 6	Total
1	N	49	122	81	67	7	29	355
	%	13.80%	34.37%	22.82%	18.87%	1.97%	8.17%	100.00%
2	N	47	269	96	142	4	26	584
	%	8.05%	46.06%	16.44%	24.32%	0.68%	4.45%	100.00%
3	N	61	375	101	111	6	25	679
	%	8.98%	55.23%	14.87%	16.35%	0.88%	3.68%	100.00%
4	N	50	268	108	107	1	8	542
	%	9.23%	49.45%	19.93%	19.74%	0.18%	1.48%	100.00%
5	N	60	385	297	195	11	63	1011
	%	5.93%	38.08%	29.38%	19.29%	1.09%	6.23%	100.00%
6	N	16	35	46	50	1	15	163
	%	9.82%	21.47%	28.22%	30.67%	0.61%	9.20%	100.00%
7	N	41	304	99	107	5	15	571
	%	7.18%	53.24%	17.34%	18.74%	0.88%	2.63%	100.00%
8	N	35	203	54	89	1	10	392
	%	8.93%	51.79%	13.78%	22.70%	0.26%	2.55%	100.00%
9	N	45	225	94	75	0	8	447
	%	10.07%	50.34%	21.03%	16.78%	0.00%	1.79%	100.00%
10	N	47	238	115	93	4	8	505
	%	9.31%	47.13%	22.77%	18.42%	0.79%	1.58%	100.00%
11	N	72	397	175	181	4	38	867
	%	8.30%	45.79%	20.18%	20.88%	0.46%	4.38%	100.00%

Table A11: Adult Heart Transplants by Criteria Within Medical Urgency Status at Transplant Post-Implementation by Region

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 1						
Region 1						
Exception	12	29.27%	1	12.50%	13	26.53%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	14	34.15%	6	75.00%	20	40.82%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	11	26.83%	0	0.00%	11	22.45%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	4	9.76%	1	12.50%	5	10.20%
Overall	41	100%	8	100%	49	100%
Adult Status 1						
Region 2						
BIVAD/Ventricular Episodes	3	7.14%	0	0.00%	3	6.38%
Exception	17	40.48%	0	0.00%	17	36.17%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	3	7.14%	0	0.00%	3	6.38%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	5	11.90%	2	40.00%	7	14.89%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	14	33.33%	3	60.00%	17	36.17%
Overall	42	100%	5	100%	47	100%
Adult Status 1						
Region 3						
BIVAD/Ventricular Episodes	4	7.41%	1	14.29%	5	8.20%
Exception	24	44.44%	5	71.43%	29	47.54%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	5	9.26%	1	14.29%	6	9.84%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	8	14.81%	0	0.00%	8	13.11%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	13	24.07%	0	0.00%	13	21.31%
Overall	54	100%	7	100%	61	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 1						
Region 4						
BIVAD/Ventricular Episodes	2	4.65%	1	14.29%	3	6.00%
Exception	24	55.81%	3	42.86%	27	54.00%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	3	6.98%	0	0.00%	3	6.00%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	10	23.26%	2	28.57%	12	24.00%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	4	9.30%	1	14.29%	5	10.00%
Overall						
	43	100%	7	100%	50	100%
Adult Status 1						
Region 5						
BIVAD/Ventricular Episodes	6	10.53%	0	0.00%	6	10.00%
Exception	5	8.77%	0	0.00%	5	8.33%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	5	8.77%	1	33.33%	6	10.00%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	19	33.33%	1	33.33%	20	33.33%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	22	38.60%	1	33.33%	23	38.33%
Overall						
	57	100%	3	100%	60	100%

Table A11: ***(continued)***

Criteria	Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 1 Region 6						
Exception	3	21.43%	0	0.00%	3	18.75%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	3	21.43%	1	50.00%	4	25.00%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	8	57.14%	1	50.00%	9	56.25%
Overall	14	100%	2	100%	16	100%
Adult Status 1 Region 7						
BIVAD/Ventricular Episodes	5	14.71%	0	0.00%	5	12.20%
Exception	10	29.41%	2	28.57%	12	29.27%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	2	5.88%	1	14.29%	3	7.32%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	11	32.35%	2	28.57%	13	31.71%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	6	17.65%	2	28.57%	8	19.51%
Overall	34	100%	7	100%	41	100%
Adult Status 1 Region 8						
BIVAD/Ventricular Episodes	4	11.76%	0	0.00%	4	11.43%
Exception	9	26.47%	0	0.00%	9	25.71%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	1	2.94%	1	100.00%	2	5.71%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	11	32.35%	0	0.00%	11	31.43%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	9	26.47%	0	0.00%	9	25.71%
Overall	34	100%	1	100%	35	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 1						
Region 9						
BIVAD/Ventricular Episodes	3	7.50%	2	40.00%	5	11.11%
Exception	10	25.00%	1	20.00%	11	24.44%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	4	10.00%	2	40.00%	6	13.33%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	13	32.50%	0	0.00%	13	28.89%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	10	25.00%	0	0.00%	10	22.22%
Overall						
	40	100%	5	100%	45	100%
Adult Status 1						
Region 10						
BIVAD/Ventricular Episodes	8	18.18%	2	66.67%	10	21.28%
Exception	15	34.09%	0	0.00%	15	31.91%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	4	9.09%	0	0.00%	4	8.51%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	8	18.18%	1	33.33%	9	19.15%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	9	20.45%	0	0.00%	9	19.15%
Overall						
	44	100%	3	100%	47	100%

Table A11: ***(continued)***

Criteria	Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 1						
Region 11						
BIVAD/Ventricular Episodes	5	7.58%	0	0.00%	5	6.94%
Exception	17	25.76%	1	16.67%	18	25.00%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	22	33.33%	1	16.67%	23	31.94%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	7	10.61%	0	0.00%	7	9.72%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	15	22.73%	4	66.67%	19	26.39%
Overall	66	100%	6	100%	72	100%
Adult Status 2						
Region 1						
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	1.04%	0	0.00%	1	0.82%
Exception	50	52.08%	18	69.23%	68	55.74%
Intra-aortic ballon pump - Hemodynamic Values not obtained	3	3.12%	0	0.00%	3	2.46%
Intra-aortic ballon pump - Hemodynamic Values obtained	23	23.96%	4	15.38%	27	22.13%
Mechanical circulatory support device(MCSD) with malfunction	5	5.21%	2	7.69%	7	5.74%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	3	3.12%	0	0.00%	3	2.46%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	1.04%	0	0.00%	1	0.82%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	6	6.25%	1	3.85%	7	5.74%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	1	1.04%	1	3.85%	2	1.64%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	3	3.12%	0	0.00%	3	2.46%
Overall	96	100%	26	100%	122	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 2						
Region 2						
Exception	60	28.99%	20	32.26%	80	29.74%
Intra-aortic ballon pump - Hemodynamic Values not obtained	4	1.93%	0	0.00%	4	1.49%
Intra-aortic ballon pump - Hemodynamic Values obtained	113	54.59%	32	51.61%	145	53.90%
Mechanical circulatory support device(MCSD) with malfunction	10	4.83%	5	8.06%	15	5.58%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	3	1.45%	0	0.00%	3	1.12%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	11	5.31%	1	1.61%	12	4.46%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	0.97%	4	6.45%	6	2.23%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	2	0.97%	0	0.00%	2	0.74%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	2	0.97%	0	0.00%	2	0.74%
Overall						
	207	100%	62	100%	269	100%

Table A11: ***(continued)***

Criteria	Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 2						
Region 3						
Exception	175	61.19%	57	64.04%	232	61.87%
Intra-aortic ballon pump - Hemodynamic Values not obtained	1	0.35%	0	0.00%	1	0.27%
Intra-aortic ballon pump - Hemodynamic Values obtained	79	27.62%	15	16.85%	94	25.07%
Mechanical circulatory support device(MCSD) with malfunction	6	2.10%	5	5.62%	11	2.93%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	4	1.40%	0	0.00%	4	1.07%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	0.35%	0	0.00%	1	0.27%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	13	4.55%	3	3.37%	16	4.27%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	1	0.35%	5	5.62%	6	1.60%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	6	2.10%	4	4.49%	10	2.67%
Overall						
	286	100%	89	100%	375	100%
Adult Status 2						
Region 4						
Exception	95	47.98%	38	54.29%	133	49.63%
Intra-aortic ballon pump - Hemodynamic Values not obtained	0	0.00%	1	1.43%	1	0.37%
Intra-aortic ballon pump - Hemodynamic Values obtained	53	26.77%	17	24.29%	70	26.12%
Intra-aortic balloon pump after 14 days	1	0.51%	0	0.00%	1	0.37%
Mechanical circulatory support device(MCSD) with malfunction	10	5.05%	5	7.14%	15	5.60%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.51%	0	0.00%	1	0.37%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	2	1.01%	0	0.00%	2	0.75%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	28	14.14%	3	4.29%	31	11.57%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	1	0.51%	6	8.57%	7	2.61%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	1	0.51%	0	0.00%	1	0.37%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	6	3.03%	0	0.00%	6	2.24%
Overall						
	198	100%	70	100%	268	100%

Table A11: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 2							
Region 5							
	Exception	81	24.55%	21	38.18%	102	26.49%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	11	3.33%	0	0.00%	11	2.86%
	Intra-aortic ballon pump - Hemodynamic Values obtained	181	54.85%	18	32.73%	199	51.69%
	Mechanical circulatory support device(MCSD) with malfunction	4	1.21%	3	5.45%	7	1.82%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.30%	0	0.00%	1	0.26%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	8	2.42%	0	0.00%	8	2.08%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	33	10.00%	4	7.27%	37	9.61%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	7	2.12%	6	10.91%	13	3.38%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	4	1.21%	3	5.45%	7	1.82%
Overall							
		330	100%	55	100%	385	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 2						
Region 6						
Exception	6	20.69%	3	50.00%	9	25.71%
Intra-aortic ballon pump - Hemodynamic Values not obtained	2	6.90%	0	0.00%	2	5.71%
Intra-aortic ballon pump - Hemodynamic Values obtained	5	17.24%	0	0.00%	5	14.29%
Mechanical circulatory support device(MCSD) with malfunction	4	13.79%	0	0.00%	4	11.43%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	3.45%	0	0.00%	1	2.86%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	3	10.34%	1	16.67%	4	11.43%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	7	24.14%	1	16.67%	8	22.86%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	1	3.45%	1	16.67%	2	5.71%
Overall						
	29	100%	6	100%	35	100%
Adult Status 2						
Region 7						
Exception	96	42.48%	33	42.31%	129	42.43%
Intra-aortic ballon pump - Hemodynamic Values not obtained	3	1.33%	0	0.00%	3	0.99%
Intra-aortic ballon pump - Hemodynamic Values obtained	104	46.02%	28	35.90%	132	43.42%
Mechanical circulatory support device(MCSD) with malfunction	10	4.42%	13	16.67%	23	7.57%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.44%	0	0.00%	1	0.33%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	6	2.65%	1	1.28%	7	2.30%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	4	1.77%	2	2.56%	6	1.97%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	2	0.88%	1	1.28%	3	0.99%
Overall						
	226	100%	78	100%	304	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 2						
Region 8						
Exception	67	38.29%	8	28.57%	75	36.95%
Intra-aortic ballon pump - Hemodynamic Values not obtained	1	0.57%	1	3.57%	2	0.99%
Intra-aortic ballon pump - Hemodynamic Values obtained	93	53.14%	15	53.57%	108	53.20%
Mechanical circulatory support device(MCSD) with malfunction	6	3.43%	3	10.71%	9	4.43%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	2	1.14%	0	0.00%	2	0.99%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	1.14%	0	0.00%	2	0.99%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	4	2.29%	1	3.57%	5	2.46%
Overall						
	175	100%	28	100%	203	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 2						
Region 9						
Exception	63	34.81%	23	52.27%	86	38.22%
Intra-aortic ballon pump - Hemodynamic Values not obtained	2	1.10%	0	0.00%	2	0.89%
Intra-aortic ballon pump - Hemodynamic Values obtained	90	49.72%	6	13.64%	96	42.67%
Mechanical circulatory support device(MCSD) with malfunction	12	6.63%	4	9.09%	16	7.11%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	2	1.10%	0	0.00%	2	0.89%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	6	3.31%	0	0.00%	6	2.67%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	1.10%	9	20.45%	11	4.89%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	1	0.55%	0	0.00%	1	0.44%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	3	1.66%	2	4.55%	5	2.22%
Overall						
	181	100%	44	100%	225	100%
Adult Status 2						
Region 10						
Exception	58	31.69%	27	49.09%	85	35.71%
Intra-aortic ballon pump - Hemodynamic Values not obtained	1	0.55%	1	1.82%	2	0.84%
Intra-aortic ballon pump - Hemodynamic Values obtained	80	43.72%	12	21.82%	92	38.66%
Intra-aortic balloon pump after 14 days	2	1.09%	0	0.00%	2	0.84%
Mechanical circulatory support device(MCSD) with malfunction	17	9.29%	9	16.36%	26	10.92%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.55%	0	0.00%	1	0.42%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	0.55%	0	0.00%	1	0.42%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	13	7.10%	3	5.45%	16	6.72%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	7	3.83%	3	5.45%	10	4.20%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	3	1.64%	0	0.00%	3	1.26%
Overall						
	183	100%	55	100%	238	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 2						
Region 11						
Exception	146	45.77%	37	47.44%	183	46.10%
Intra-aortic ballon pump - Hemodynamic Values not obtained	3	0.94%	0	0.00%	3	0.76%
Intra-aortic ballon pump - Hemodynamic Values obtained	128	40.13%	24	30.77%	152	38.29%
Mechanical circulatory support device(MCSD) with malfunction	7	2.19%	8	10.26%	15	3.78%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	10	3.13%	1	1.28%	11	2.77%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	10	3.13%	1	1.28%	11	2.77%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	6	1.88%	6	7.69%	12	3.02%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	9	2.82%	1	1.28%	10	2.52%
Overall						
	319	100%	78	100%	397	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 1						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	32	59.26%	0	0.00%	32	39.51%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	2	3.70%	0	0.00%	2	2.47%
Exception	9	16.67%	8	29.63%	17	20.99%
Intra-aortic balloon pump after 14 days	2	3.70%	0	0.00%	2	2.47%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	6	11.11%	8	29.63%	14	17.28%
Mechanical circulatory support device (MCSD) with device infection - Debridement	0	0.00%	1	3.70%	1	1.23%
Mechanical circulatory support device (MCSD) with hemolysis	0	0.00%	2	7.41%	2	2.47%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	0	0.00%	1	3.70%	1	1.23%
Mechanical circulatory support device (MCSD) with pump thrombosis	1	1.85%	3	11.11%	4	4.94%
Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	2	7.41%	2	2.47%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	2	3.70%	2	7.41%	4	4.94%
Overall						
	54	100%	27	100%	81	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 2						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	37	49.33%	0	0.00%	37	38.54%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	1.33%	0	0.00%	1	1.04%
Exception	9	12.00%	16	76.19%	25	26.04%
Intra-aortic ballon pump - Hemodynamic Values obtained	1	1.33%	0	0.00%	1	1.04%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	1.33%	0	0.00%	1	1.04%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	5	6.67%	0	0.00%	5	5.21%
Mechanical circulatory support device (MCSD) with device infection - Debridement	2	2.67%	1	4.76%	3	3.12%
Mechanical circulatory support device (MCSD) with device infection - Erythema	0	0.00%	1	4.76%	1	1.04%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	0	0.00%	1	4.76%	1	1.04%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	2	2.67%	0	0.00%	2	2.08%
Mechanical circulatory support device (MCSD) with right heart failure	2	2.67%	2	9.52%	4	4.17%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	15	20.00%	0	0.00%	15	15.62%
Overall						
	75	100%	21	100%	96	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 3						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	31	44.93%	0	0.00%	31	30.69%
Exception	12	17.39%	17	53.12%	29	28.71%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	1.45%	0	0.00%	1	0.99%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	3	4.35%	4	12.50%	7	6.93%
Mechanical circulatory support device (MCSD) with device infection - Debridement	2	2.90%	2	6.25%	4	3.96%
Mechanical circulatory support device (MCSD) with device infection - Erythema	3	4.35%	1	3.12%	4	3.96%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	2.90%	0	0.00%	2	1.98%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	1.45%	0	0.00%	1	0.99%
Mechanical circulatory support device (MCSD) with pump thrombosis	1	1.45%	4	12.50%	5	4.95%
Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	1	3.12%	1	0.99%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	13	18.84%	3	9.38%	16	15.84%
Overall						
	69	100%	32	100%	101	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 4						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	29	34.12%	0	0.00%	29	26.85%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	1.18%	0	0.00%	1	0.93%
Exception	22	25.88%	12	52.17%	34	31.48%
Intra-aortic balloon pump after 14 days	0	0.00%	1	4.35%	1	0.93%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	1.18%	0	0.00%	1	0.93%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	2	2.35%	0	0.00%	2	1.85%
Mechanical circulatory support device (MCSD) with device infection - Debridement	1	1.18%	6	26.09%	7	6.48%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	1.18%	0	0.00%	1	0.93%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	3	3.53%	0	0.00%	3	2.78%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	1.18%	0	0.00%	1	0.93%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	23	27.06%	4	17.39%	27	25.00%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	1.18%	0	0.00%	1	0.93%
Overall						
	85	100%	23	100%	108	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 5						
Congenital heart disease	1	0.51%	0	0.00%	1	0.34%
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	69	35.20%	0	0.00%	69	23.23%
Exception	41	20.92%	47	46.53%	88	29.63%
Intra-aortic ballon pump - Hemodynamic Values obtained	1	0.51%	0	0.00%	1	0.34%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	0.51%	0	0.00%	1	0.34%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	12	6.12%	3	2.97%	15	5.05%
Mechanical circulatory support device (MCSD) with device infection - Debridement	0	0.00%	2	1.98%	2	0.67%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	4	2.04%	0	0.00%	4	1.35%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	0.51%	0	0.00%	1	0.34%
Mechanical circulatory support device (MCSD) with hemolysis	0	0.00%	1	0.99%	1	0.34%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	0.51%	0	0.00%	1	0.34%
Mechanical circulatory support device (MCSD) with pump thrombosis	0	0.00%	3	2.97%	3	1.01%
Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	1	0.99%	1	0.34%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	65	33.16%	44	43.56%	109	36.70%
Overall						
	196	100%	101	100%	297	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 6						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	14	41.18%	0	0.00%	14	30.43%
Exception	7	20.59%	6	50.00%	13	28.26%
Intra-aortic ballon pump - Hemodynamic Values obtained	1	2.94%	0	0.00%	1	2.17%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	1	2.94%	1	8.33%	2	4.35%
Mechanical circulatory support device (MCSD) with device infection - Debridement	3	8.82%	3	25.00%	6	13.04%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	2.94%	0	0.00%	1	2.17%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	5.88%	0	0.00%	2	4.35%
Mechanical circulatory support device (MCSD) with hemolysis	1	2.94%	0	0.00%	1	2.17%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	4	11.76%	2	16.67%	6	13.04%
Overall						
	34	100%	12	100%	46	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 7						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	39	60.94%	0	0.00%	39	39.39%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	1.56%	0	0.00%	1	1.01%
Exception	10	15.62%	11	31.43%	21	21.21%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	0	0.00%	1	2.86%	1	1.01%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	3	4.69%	6	17.14%	9	9.09%
Mechanical circulatory support device (MCSD) with device infection - Debridement	0	0.00%	2	5.71%	2	2.02%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	1.56%	4	11.43%	5	5.05%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	2	3.12%	0	0.00%	2	2.02%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	1.56%	1	2.86%	2	2.02%
Mechanical circulatory support device (MCSD) with hemolysis	2	3.12%	0	0.00%	2	2.02%
Mechanical circulatory support device (MCSD) with pump thrombosis	0	0.00%	8	22.86%	8	8.08%
Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	1	2.86%	1	1.01%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	5	7.81%	1	2.86%	6	6.06%
Overall						
	64	100%	35	100%	99	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 8						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	24	60.00%	0	0.00%	24	44.44%
Exception	9	22.50%	4	28.57%	13	24.07%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	2.50%	0	0.00%	1	1.85%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	3	7.50%	4	28.57%	7	12.96%
Mechanical circulatory support device (MCSD) with device infection - Debridement	1	2.50%	3	21.43%	4	7.41%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	2.50%	0	0.00%	1	1.85%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	0	0.00%	1	7.14%	1	1.85%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	0	0.00%	1	7.14%	1	1.85%
Mechanical circulatory support device (MCSD) with hemolysis	0	0.00%	1	7.14%	1	1.85%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	1	2.50%	0	0.00%	1	1.85%
Overall						
	40	100%	14	100%	54	100%
Adult Status 3						
Region 9						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	36	62.07%	0	0.00%	36	38.30%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	1.72%	0	0.00%	1	1.06%
Exception	9	15.52%	21	58.33%	30	31.91%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	4	6.90%	2	5.56%	6	6.38%
Mechanical circulatory support device (MCSD) with device infection - Debridement	1	1.72%	3	8.33%	4	4.26%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	1.72%	1	2.78%	2	2.13%
Mechanical circulatory support device (MCSD) with hemolysis	0	0.00%	1	2.78%	1	1.06%
Mechanical circulatory support device (MCSD) with pump thrombosis	0	0.00%	2	5.56%	2	2.13%
Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	1	2.78%	1	1.06%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	6	10.34%	5	13.89%	11	11.70%

Table A11: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Overall							
		58	100%	36	100%	94	100%
Adult Status 3							
Region 10							
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	43	50.59%	0	0.00%	43	37.39%
	Exception	10	11.76%	2	6.67%	12	10.43%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	8	9.41%	2	6.67%	10	8.70%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	5	5.88%	1	3.33%	6	5.22%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	5	5.88%	14	46.67%	19	16.52%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	0	0.00%	3	10.00%	3	2.61%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	1.18%	0	0.00%	1	0.87%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	1.18%	0	0.00%	1	0.87%
	Mechanical circulatory support device (MCSD) with hemolysis	1	1.18%	0	0.00%	1	0.87%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	4	4.71%	0	0.00%	4	3.48%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	1	1.18%	0	0.00%	1	0.87%
	Mechanical circulatory support device (MCSD) with pump thrombosis	0	0.00%	4	13.33%	4	3.48%
	Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	1	3.33%	1	0.87%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	6	7.06%	3	10.00%	9	7.83%
Overall							
		85	100%	30	100%	115	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 11						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	75	55.97%	0	0.00%	75	42.86%
Exception	22	16.42%	13	31.71%	35	20.00%
Intra-aortic ballon pump - Hemodynamic Values obtained	1	0.75%	0	0.00%	1	0.57%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	2	1.49%	1	2.44%	3	1.71%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	3	2.24%	15	36.59%	18	10.29%
Mechanical circulatory support device (MCSD) with device infection - Debridement	6	4.48%	3	7.32%	9	5.14%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	0.75%	1	2.44%	2	1.14%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	3	2.24%	0	0.00%	3	1.71%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	0.75%	0	0.00%	1	0.57%
Mechanical circulatory support device (MCSD) with hemolysis	1	0.75%	1	2.44%	2	1.14%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	2	1.49%	0	0.00%	2	1.14%
Mechanical circulatory support device (MCSD) with pump thrombosis	1	0.75%	2	4.88%	3	1.71%
Mechanical circulatory support device (MCSD) with right heart failure	1	0.75%	0	0.00%	1	0.57%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	15	11.19%	5	12.20%	20	11.43%
Overall	134	100%	41	100%	175	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 4						
Region 1						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	17	36.17%	3	15.00%	20	29.85%
Congenital heart disease	3	6.38%	0	0.00%	3	4.48%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	21	44.68%	14	70.00%	35	52.24%
Exception	1	2.13%	1	5.00%	2	2.99%
Inotropes without hemodynamic monitoring	3	6.38%	0	0.00%	3	4.48%
Ischemic heart disease with intractable angina	1	2.13%	0	0.00%	1	1.49%
Retransplant	1	2.13%	2	10.00%	3	4.48%
Overall	47	100%	20	100%	67	100%
Adult Status 4						
Region 2						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	6	6.12%	5	11.36%	11	7.75%
Congenital heart disease	4	4.08%	3	6.82%	7	4.93%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	45	45.92%	25	56.82%	70	49.30%
Exception	25	25.51%	7	15.91%	32	22.54%
Inotropes without hemodynamic monitoring	15	15.31%	2	4.55%	17	11.97%
Ischemic heart disease with intractable angina	2	2.04%	1	2.27%	3	2.11%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	1.02%	0	0.00%	1	0.70%
Retransplant	0	0.00%	1	2.27%	1	0.70%
Overall	98	100%	44	100%	142	100%
Adult Status 4						
Region 3						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	6	7.89%	2	5.71%	8	7.21%
Congenital heart disease	2	2.63%	1	2.86%	3	2.70%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	26	34.21%	15	42.86%	41	36.94%
Exception	28	36.84%	12	34.29%	40	36.04%
Inotropes without hemodynamic monitoring	10	13.16%	2	5.71%	12	10.81%
Ischemic heart disease with intractable angina	1	1.32%	2	5.71%	3	2.70%
Retransplant	3	3.95%	1	2.86%	4	3.60%
Overall	76	100%	35	100%	111	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 4						
Region 4						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	12	15.38%	7	24.14%	19	17.76%
Congenital heart disease	2	2.56%	3	10.34%	5	4.67%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	22	28.21%	12	41.38%	34	31.78%
Exception	23	29.49%	1	3.45%	24	22.43%
Inotropes without hemodynamic monitoring	12	15.38%	3	10.34%	15	14.02%
Ischemic heart disease with intractable angina	3	3.85%	2	6.90%	5	4.67%
Retransplant	4	5.13%	1	3.45%	5	4.67%
Overall						
	78	100%	29	100%	107	100%

Table A11: ***(continued)***

Criteria	Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 4 Region 5						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	20	14.39%	10	17.86%	30	15.38%
Congenital heart disease	14	10.07%	10	17.86%	24	12.31%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	52	37.41%	24	42.86%	76	38.97%
Exception	19	13.67%	1	1.79%	20	10.26%
Inotropes without hemodynamic monitoring	16	11.51%	3	5.36%	19	9.74%
Ischemic heart disease with intractable angina	3	2.16%	3	5.36%	6	3.08%
No criteria for this status	1	0.72%	0	0.00%	1	0.51%
Retransplant	14	10.07%	5	8.93%	19	9.74%
Overall	139	100%	56	100%	195	100%
Adult Status 4 Region 6						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	3	7.89%	4	33.33%	7	14.00%
Congenital heart disease	2	5.26%	0	0.00%	2	4.00%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	21	55.26%	4	33.33%	25	50.00%
Exception	3	7.89%	1	8.33%	4	8.00%
Inotropes without hemodynamic monitoring	8	21.05%	1	8.33%	9	18.00%
Ischemic heart disease with intractable angina	0	0.00%	1	8.33%	1	2.00%
Retransplant	1	2.63%	1	8.33%	2	4.00%
Overall	38	100%	12	100%	50	100%
Adult Status 4 Region 7						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	12	17.91%	1	2.50%	13	12.15%
Congenital heart disease	2	2.99%	4	10.00%	6	5.61%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	25	37.31%	26	65.00%	51	47.66%
Exception	15	22.39%	4	10.00%	19	17.76%
Inotropes without hemodynamic monitoring	8	11.94%	1	2.50%	9	8.41%
Ischemic heart disease with intractable angina	2	2.99%	1	2.50%	3	2.80%
Retransplant	3	4.48%	3	7.50%	6	5.61%
Overall	67	100%	40	100%	107	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 4						
Region 8						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	3	5.66%	2	5.56%	5	5.62%
Congenital heart disease	4	7.55%	5	13.89%	9	10.11%
Dischargeable left ventricular assist device (LVAD) without discretionary						
30 days	17	32.08%	19	52.78%	36	40.45%
Exception	11	20.75%	4	11.11%	15	16.85%
Inotropes without hemodynamic monitoring	15	28.30%	4	11.11%	19	21.35%
Retransplant	3	5.66%	2	5.56%	5	5.62%
Overall						
	53	100%	36	100%	89	100%

Table A11: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 4 Region 9						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	1	2.70%	3	7.89%	4	5.33%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	19	51.35%	31	81.58%	50	66.67%
Exception	6	16.22%	1	2.63%	7	9.33%
Inotropes without hemodynamic monitoring	7	18.92%	1	2.63%	8	10.67%
Ischemic heart disease with intractable angina	1	2.70%	0	0.00%	1	1.33%
Retransplant	3	8.11%	2	5.26%	5	6.67%
Overall	37	100%	38	100%	75	100%
Adult Status 4 Region 10						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	4	7.55%	1	2.50%	5	5.38%
Congenital heart disease	5	9.43%	2	5.00%	7	7.53%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	32	60.38%	27	67.50%	59	63.44%
Exception	7	13.21%	3	7.50%	10	10.75%
Inotropes without hemodynamic monitoring	3	5.66%	3	7.50%	6	6.45%
Ischemic heart disease with intractable angina	0	0.00%	1	2.50%	1	1.08%
Retransplant	2	3.77%	3	7.50%	5	5.38%
Overall	53	100%	40	100%	93	100%
Adult Status 4 Region 11						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	8	5.88%	0	0.00%	8	4.42%
Congenital heart disease	3	2.21%	3	6.67%	6	3.31%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	54	39.71%	24	53.33%	78	43.09%
Exception	47	34.56%	15	33.33%	62	34.25%
Inotropes without hemodynamic monitoring	8	5.88%	1	2.22%	9	4.97%
Intra-aortic ballon pump - Hemodynamic Values obtained	1	0.74%	0	0.00%	1	0.55%
Ischemic heart disease with intractable angina	4	2.94%	1	2.22%	5	2.76%
Retransplant	11	8.09%	1	2.22%	12	6.63%
Overall	136	100%	45	100%	181	100%

Table A11: ***(continued)***

Criteria	Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 5 Region 1						
None	6	100.00%	1	100.00%	7	100.00%
Adult Status 5 Region 2						
None	2	100.00%	2	100.00%	4	100.00%
Adult Status 5 Region 3						
None	4	100.00%	2	100.00%	6	100.00%
Adult Status 5 Region 4						
None	1	100.00%	0	0.00%	1	100.00%
Adult Status 5 Region 5						
None	10	100.00%	1	100.00%	11	100.00%

Table A11: ***(continued)***

Criteria		Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 5 Region 6							
	None	1	100.00%	0	0.00%	1	100.00%
Adult Status 5 Region 7							
	None	4	100.00%	1	100.00%	5	100.00%
Adult Status 5 Region 8							
	None	1	100.00%	0	0.00%	1	100.00%
Adult Status 5 Region 10							
	None	4	100.00%	0	0.00%	4	100.00%
Adult Status 5 Region 11							
	None	4	100.00%	0	0.00%	4	100.00%
Adult Status 6 Region 1							
	None	25	100.00%	4	100.00%	29	100.00%
Adult Status 6 Region 2							
	None	25	100.00%	1	100.00%	26	100.00%
Adult Status 6 Region 3							
	None	20	100.00%	5	100.00%	25	100.00%
Adult Status 6 Region 4							
	None	8	100.00%	0	0.00%	8	100.00%
Adult Status 6 Region 5							
	None	61	100.00%	2	100.00%	63	100.00%
Adult Status 6 Region 6							
	None	13	100.00%	2	100.00%	15	100.00%
Adult Status 6 Region 7							
	None	12	100.00%	3	100.00%	15	100.00%

Table A11: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 6 Region 8							
	None	8	100.00%	2	100.00%	10	100.00%
Adult Status 6 Region 9							
	None	5	100.00%	3	100.00%	8	100.00%
Adult Status 6 Region 10							
	None	8	100.00%	0	0.00%	8	100.00%
Adult Status 6 Region 11							
	None	37	100.00%	1	100.00%	38	100.00%

Table A12: Mechanical Circulatory Support Devices at Transplant by Region

Brand	Era	Count	Percent
Region 1 ECMO			
Total ECMO	**Pre**	**4**	**1.84%**
	Post	**23**	**7.93%**
Region 1 IABP			
Total IABP	**Pre**	**3**	**1.38%**
	Post	**80**	**27.59%**
Region 1 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	2	1.06%
	Post	4	2.96%
Heartmate II	Pre	65	34.39%
	Post	22	16.3%
HeartMate III	Pre	13	6.88%
	Post	59	43.7%
Heartsaver VAD	Pre	1	0.53%
	Post	0	0%
Heartware HVAD	Pre	81	42.86%
	Post	38	28.15%
Impella Recover 5.0	Pre	3	1.59%
	Post	9	6.67%
Other, Specify	Pre	24	12.7%
	Post	3	2.22%
Total LVAD	**Pre**	**189**	**87.1%**
	Post	**135**	**46.55%**
Region 1 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	4%
Cardiac Assist Tandem Heart	Pre	2	10%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	11	55%
	Post	41	82%
HeartMate III	Pre	0	0%
	Post	5	10%
Heartware HVAD	Pre	4	20%
	Post	1	2%
Other, Specify	Pre	3	15%
	Post	1	2%
	Pre	**20**	**9.22%**

Total LVAD+RVAD	**Post**	**50**	**17.24%**
Region 1 RVAD			
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	1	50%
Impella Recover 2.5	Pre	0	0%
	Post	1	50%
Impella Recover 5.0	Pre	1	100%
	Post	0	0%
Total RVAD	**Pre**	**1**	**0.46%**
	Post	**2**	**0.69%**
Region 2 ECMO			
Total ECMO	**Pre**	**13**	**4.21%**
	Post	**32**	**7.82%**
Region 2 IABP			
Total IABP	**Pre**	**25**	**8.09%**
	Post	**168**	**41.08%**
Region 2 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	3	1.53%
Heartmate II	Pre	118	47.39%
	Post	32	16.33%
HeartMate III	Pre	6	2.41%
	Post	61	31.12%
Heartsaver VAD	Pre	1	0.4%
	Post	0	0%
Heartware HVAD	Pre	92	36.95%
	Post	69	35.2%
Impella CP	Pre	1	0.4%
	Post	4	2.04%
Impella Recover 2.5	Pre	0	0%
	Post	2	1.02%
Impella Recover 5.0	Pre	2	0.8%
	Post	19	9.69%
Other, Specify	Pre	29	11.65%
	Post	6	3.06%
Total LVAD	**Pre**	**249**	**80.58%**
	Post	**196**	**47.92%**
Region 2 LVAD+RVAD			

Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	8.33%
CentriMag (Thoratec/Levitronix)	Pre	11	61.11%
	Post	4	33.33%
Heartmate II	Pre	3	16.67%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	2	16.67%
Heartware HVAD	Pre	2	11.11%
	Post	2	16.67%
Impella Recover 5.0	Pre	0	0%
	Post	1	8.33%
Maquet Jostra Rotaflow	Pre	2	11.11%
	Post	0	0%
Other, Specify	Pre	0	0%
	Post	2	16.67%
Total LVAD+RVAD	**Pre**	**18**	**5.83%**
	Post	**12**	**2.93%**
Region 2 RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	100%
CentriMag (Thoratec/Levitronix)	Pre	1	33.33%
	Post	0	0%
Heartmate II	Pre	1	33.33%
	Post	0	0%
Heartware HVAD	Pre	1	33.33%
	Post	0	0%
Total RVAD	**Pre**	**3**	**0.97%**
	Post	**1**	**0.24%**
Region 2 TAH			
SynCardia CardioWest	Pre	1	100%
Total TAH	**Pre**	**1**	**0.32%**
Region 3 ECMO			
Total ECMO	**Pre**	**9**	**2.49%**
	Post	**32**	**6.63%**
Region 3 IABP			
Total IABP	**Pre**	**52**	**14.36%**
	Post	**218**	**45.13%**
Region 3 LVAD			

Cardiac Assist Tandem Heart	Pre	1	0.36%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	2	0.73%
	Post	1	0.5%
Heartmate II	Pre	129	46.91%
	Post	43	21.39%
HeartMate III	Pre	10	3.64%
	Post	66	32.84%
Heartsaver VAD	Pre	1	0.36%
	Post	0	0%
Heartware HVAD	Pre	90	32.73%
	Post	51	25.37%
Impella CP	Pre	0	0%
	Post	3	1.49%
Impella Recover 2.5	Pre	1	0.36%
	Post	1	0.5%
Impella Recover 5.0	Pre	2	0.73%
	Post	19	9.45%
Other, Specify	Pre	39	14.18%
	Post	17	8.46%
Total LVAD	**Pre**	**275**	**75.97%**
	Post	**201**	**41.61%**
Region 3 LVAD+RVAD			
Cardiac Assist Tandem Heart	Pre	1	4.55%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	9	40.91%
	Post	9	37.5%
Heartmate II	Pre	1	4.55%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	3	12.5%
Heartware HVAD	Pre	7	31.82%
	Post	9	37.5%
Impella Recover 2.5	Pre	0	0%
	Post	1	4.17%
Other, Specify	Pre	4	18.18%
	Post	2	8.33%
Total LVAD+RVAD	**Pre**	**22**	**6.08%**
	Post	**24**	**4.97%**

Region 3 RVAD			
Heartmate II	Pre	1	50%
	Post	0	0%
Impella CP	Pre	0	0%
	Post	1	20%
Impella Recover 5.0	Pre	0	0%
	Post	3	60%
Impella RP	Pre	1	50%
	Post	0	0%
Other, Specify	Pre	0	0%
	Post	1	20%
Total RVAD	**Pre**	**2**	**0.55%**
	Post	**5**	**1.04%**
Region 3 TAH			
SynCardia CardioWest	Pre	2	100%
	Post	3	100%
Total TAH	**Pre**	**2**	**0.55%**
	Post	**3**	**0.62%**
Region 4 ECMO			
Total ECMO	**Pre**	**4**	**1.36%**
	Post	**32**	**8.16%**
Region 4 IABP			
Total IABP	**Pre**	**83**	**28.23%**
	Post	**155**	**39.54%**
Region 4 LVAD			
Heartmate II	Pre	126	63.32%
	Post	50	26.74%
HeartMate III	Pre	3	1.51%
	Post	29	15.51%
Heartmate XVE	Pre	3	1.51%
	Post	0	0%
Heartware HVAD	Pre	51	25.63%
	Post	45	24.06%
Impella CP	Pre	0	0%
	Post	5	2.67%
Impella Recover 2.5	Pre	1	0.5%
	Post	0	0%
	Pre	5	2.51%

Impella Recover 5.0	Post	50	26.74%
Thoratec IVAD	Pre	2	1.01%
	Post	0	0%
Other, Specify	Pre	8	4.02%
	Post	8	4.28%
Total LVAD	**Pre**	**199**	**67.69%**
	Post	**187**	**47.7%**
Region 4 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	14.29%
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	7	50%
HeartMate III	Pre	0	0%
	Post	2	14.29%
Heartware HVAD	Pre	0	0%
	Post	3	21.43%
Other, Specify	Pre	2	100%
	Post	0	0%
Total LVAD+RVAD	**Pre**	**2**	**0.68%**
	Post	**14**	**3.57%**
Region 4 RVAD			
CentriMag (Thoratec/Levitronix)	Post	1	50%
Impella RP	Post	1	50%
Total RVAD	**Post**	**2**	**0.51%**
Region 4 TAH			
SynCardia CardioWest	Pre	6	100%
	Post	2	100%
Total TAH	**Pre**	**6**	**2.04%**
	Post	**2**	**0.51%**
Region 5 ECMO			
Total ECMO	**Pre**	**7**	**1.69%**
	Post	**48**	**8.76%**
Region 5 IABP			
Total IABP	**Pre**	**40**	**9.66%**
	Post	**220**	**40.15%**
Region 5 LVAD			
Heartmate II	Pre	72	22.15%
	Post	26	10.48%
	Pre	8	2.46%

HeartMate III	Post	74	29.84%
Heartsaver VAD	Pre	2	0.62%
	Post	2	0.81%
Heartware HVAD	Pre	204	62.77%
	Post	100	40.32%
Impella CP	Pre	0	0%
	Post	9	3.63%
Impella Recover 2.5	Pre	3	0.92%
	Post	2	0.81%
Impella Recover 5.0	Pre	19	5.85%
	Post	24	9.68%
Other, Specify	Pre	17	5.23%
	Post	11	4.44%
Total LVAD	**Pre**	**325**	**78.5%**
	Post	**248**	**45.26%**
Region 5 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	5.56%
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	1	5.56%
CentriMag (Thoratec/Levitronix)	Pre	3	10.71%
	Post	11	61.11%
HeartMate III	Pre	2	7.14%
	Post	2	11.11%
Heartware HVAD	Pre	14	50%
	Post	3	16.67%
Impella Recover 2.5	Pre	1	3.57%
	Post	0	0%
Impella Recover 5.0	Pre	2	7.14%
	Post	0	0%
Maquet Jostra Rotaflow	Pre	1	3.57%
	Post	0	0%
Other, Specify	Pre	5	17.86%
	Post	0	0%
Total LVAD+RVAD	**Pre**	**28**	**6.76%**
	Post	**18**	**3.28%**
Region 5 RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	16.67%

Heartware HVAD	Pre	0	0%
	Post	2	33.33%
Impella Recover 5.0	Pre	1	100%
	Post	0	0%
Impella RP	Pre	0	0%
	Post	2	33.33%
Other, Specify	Pre	0	0%
	Post	1	16.67%
Total RVAD	**Pre**	**1**	**0.24%**
	Post	**6**	**1.09%**
Region 5 TAH			
SynCardia CardioWest	Pre	13	100%
	Post	7	87.5%
Other, Specify	Pre	0	0%
	Post	1	12.5%
Total TAH	**Pre**	**13**	**3.14%**
	Post	**8**	**1.46%**
Region 6 ECMO			
Total ECMO	**Pre**	**2**	**1.53%**
	Post	**16**	**14.04%**
Region 6 IABP			
Total IABP	**Pre**	**2**	**1.53%**
	Post	**9**	**7.89%**
Region 6 LVAD			
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	1	1.23%
Heartmate II	Pre	35	29.41%
	Post	10	12.35%
HeartMate III	Pre	2	1.68%
	Post	29	35.8%
Heartmate XVE	Pre	1	0.84%
	Post	0	0%
Heartware HVAD	Pre	70	58.82%
	Post	25	30.86%
Impella CP	Pre	0	0%
	Post	9	11.11%
Impella Recover 5.0	Pre	2	1.68%
	Post	4	4.94%

Other, Specify	Pre	9	7.56%
	Post	3	3.7%
Total LVAD	**Pre**	**119**	**90.84%**
	Post	**81**	**71.05%**
Region 6 LVAD+RVAD			
Cardiac Assist Protek Duo	Post	1	50%
Impella CP	Post	1	50%
Total LVAD+RVAD	**Post**	**2**	**1.75%**
Region 6 TAH			
SynCardia CardioWest	Pre	8	100%
	Post	6	100%
Total TAH	**Pre**	**8**	**6.11%**
	Post	**6**	**5.26%**
Region 7 ECMO			
Total ECMO	**Pre**	**3**	**0.8%**
	Post	**28**	**6.32%**
Region 7 IABP			
Total IABP	**Pre**	**106**	**28.27%**
	Post	**201**	**45.37%**
Region 7 LVAD			
Heartmate II	Pre	100	39.68%
	Post	36	18.65%
HeartMate III	Pre	6	2.38%
	Post	82	42.49%
Heartware HVAD	Pre	114	45.24%
	Post	63	32.64%
Impella Recover 2.5	Pre	1	0.4%
	Post	0	0%
Impella Recover 5.0	Pre	1	0.4%
	Post	9	4.66%
Other, Specify	Pre	30	11.9%
	Post	3	1.55%
Total LVAD	**Pre**	**252**	**67.2%**
	Post	**193**	**43.57%**
Region 7 LVAD+RVAD			
Berlin Heart EXCOR	Pre	0	0%
	Post	1	5.56%
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	11.11%

Cardiac Assist Tandem Heart	Pre	1	7.14%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	2	14.29%
	Post	6	33.33%
HeartMate III	Pre	0	0%
	Post	1	5.56%
Heartware HVAD	Pre	11	78.57%
	Post	8	44.44%
Total LVAD+RVAD	**Pre**	**14**	**3.73%**
	Post	**18**	**4.06%**
Region 7 RVAD			
CentriMag (Thoratec/Levitronix)	Post	1	100%
Total RVAD	**Post**	**1**	**0.23%**
Region 7 TAH			
SynCardia CardioWest	Post	2	100%
Total TAH	**Post**	**2**	**0.45%**
Region 8 ECMO			
Total ECMO	**Post**	**22**	**7.75%**
Region 8 IABP			
Total IABP	**Pre**	**43**	**19.63%**
	Post	**139**	**48.94%**
Region 8 LVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	0.9%
Heartmate II	Pre	89	52.05%
	Post	30	27.03%
HeartMate III	Pre	3	1.75%
	Post	50	45.05%
Heartware HVAD	Pre	39	22.81%
	Post	29	26.13%
Other, Specify	Pre	40	23.39%
	Post	1	0.9%
Total LVAD	**Pre**	**171**	**78.08%**
	Post	**111**	**39.08%**
Region 8 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	20%
CentriMag (Thoratec/Levitronix)	Pre	2	100%
	Post	4	40%

HeartMate III	Pre	0	0%
	Post	3	30%
Other, Specify	Pre	0	0%
	Post	1	10%
Total LVAD+RVAD	**Pre**	**2**	**0.91%**
	Post	**10**	**3.52%**
Region 8 RVAD			
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	2	100%
Heartware HVAD	Pre	1	50%
	Post	0	0%
Other, Specify	Pre	1	50%
	Post	0	0%
Total RVAD	**Pre**	**2**	**0.91%**
	Post	**2**	**0.7%**
Region 8 TAH			
SynCardia CardioWest	Pre	1	100%
Total TAH	**Pre**	**1**	**0.46%**
Region 9 ECMO			
Total ECMO	**Pre**	**4**	**1.53%**
	Post	**35**	**9.49%**
Region 9 IABP			
Total IABP	**Pre**	**20**	**7.63%**
	Post	**147**	**39.84%**
Region 9 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	2	0.91%
	Post	6	3.59%
Heartmate II	Pre	146	66.67%
	Post	54	32.34%
HeartMate III	Pre	9	4.11%
	Post	78	46.71%
Heartware HVAD	Pre	27	12.33%
	Post	24	14.37%
Impella CP	Pre	0	0%
	Post	1	0.6%
Jarvik 2000	Pre	1	0.46%
	Post	0	0%
Other, Specify	Pre	34	15.53%
	Post	4	2.4%

Total LVAD	**Pre**	**219**	**83.59%**
	Post	**167**	**45.26%**
Region 9 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	8.33%
CentriMag (Thoratec/Levitronix)	Pre	5	35.71%
	Post	4	33.33%
Heartmate II	Pre	1	7.14%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	7	58.33%
Heartware HVAD	Pre	6	42.86%
	Post	0	0%
Other, Specify	Pre	2	14.29%
	Post	0	0%
Total LVAD+RVAD	**Pre**	**14**	**5.34%**
	Post	**12**	**3.25%**
Region 9 RVAD			
CentriMag (Thoratec/Levitronix)	Post	1	33.33%
Impella CP	Post	1	33.33%
Other, Specify	Post	1	33.33%
Total RVAD	**Post**	**3**	**0.81%**
Region 9 TAH			
SynCardia CardioWest	Pre	5	100%
	Post	5	100%
Total TAH	**Pre**	**5**	**1.91%**
	Post	**5**	**1.36%**
Region 10 ECMO			
Total ECMO	**Pre**	**4**	**1.3%**
	Post	**24**	**5.71%**
Region 10 IABP			
Total IABP	**Pre**	**17**	**5.54%**
	Post	**126**	**30%**
Region 10 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	1	0.38%
	Post	2	0.84%
Heartmate II	Pre	103	39.16%
	Post	43	17.99%
	Pre	5	1.9%

HeartMate III	Post	105	43.93%
Heartsaver VAD	Pre	2	0.76%
	Post	1	0.42%
Heartware HVAD	Pre	110	41.83%
	Post	58	24.27%
Impella CP	Pre	0	0%
	Post	1	0.42%
Impella Recover 2.5	Pre	0	0%
	Post	1	0.42%
Impella Recover 5.0	Pre	4	1.52%
	Post	7	2.93%
Other, Specify	Pre	38	14.45%
	Post	21	8.79%
Total LVAD	**Pre**	**263**	**85.67%**
	Post	**239**	**56.9%**
Region 10 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	7.69%
CentriMag (Thoratec/Levitronix)	Pre	10	55.56%
	Post	7	26.92%
HeartMate III	Pre	0	0%
	Post	8	30.77%
Heartware HVAD	Pre	4	22.22%
	Post	5	19.23%
Impella CP	Pre	0	0%
	Post	1	3.85%
Impella Recover 5.0	Pre	1	5.56%
	Post	0	0%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	2	7.69%
Other, Specify	Pre	3	16.67%
	Post	1	3.85%
Total LVAD+RVAD	**Pre**	**18**	**5.86%**
	Post	**26**	**6.19%**
Region 10 RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	50%
CentriMag (Thoratec/Levitronix)	Pre	1	100%
	Post	0	0%

Impella Recover 5.0	Pre	0	0%
	Post	1	50%
Total RVAD	**Pre**	**1**	**0.33%**
	Post	**2**	**0.48%**
Region 10 TAH			
SynCardia CardioWest	Pre	3	75%
	Post	3	100%
Other, Specify	Pre	1	25%
	Post	0	0%
Total TAH	**Pre**	**4**	**1.3%**
	Post	**3**	**0.71%**
Region 11 ECMO			
Total ECMO	**Pre**	**8**	**1.6%**
	Post	**40**	**6.41%**
Region 11 IABP			
Total IABP	**Pre**	**77**	**15.37%**
	Post	**249**	**39.9%**
Region 11 LVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	0.73%
Cardiac Assist Tandem Heart	Pre	1	0.25%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	3	0.76%
	Post	8	2.92%
Heartmate II	Pre	179	45.43%
	Post	47	17.15%
HeartMate III	Pre	13	3.3%
	Post	124	45.26%
Heartsaver VAD	Pre	5	1.27%
	Post	0	0%
Heartware HVAD	Pre	153	38.83%
	Post	77	28.1%
Impella Recover 5.0	Pre	0	0%
	Post	4	1.46%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	1	0.36%
Other, Specify	Pre	40	10.15%
	Post	11	4.01%

Total LVAD	**Pre**	**394**	**78.64%**
	Post	**274**	**43.91%**
Region 11 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	2.17%
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	1	2.17%
CentriMag (Thoratec/Levitronix)	Pre	3	30%
	Post	27	58.7%
Heartmate II	Pre	1	10%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	7	15.22%
Heartware HVAD	Pre	2	20%
	Post	1	2.17%
Impella Recover 5.0	Pre	0	0%
	Post	2	4.35%
Maquet Jostra Rotaflow	Pre	2	20%
	Post	4	8.7%
Other, Specify	Pre	2	20%
	Post	3	6.52%
Total LVAD+RVAD	**Pre**	**10**	**2%**
	Post	**46**	**7.37%**
Region 11 RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	25%
CentriMag (Thoratec/Levitronix)	Pre	1	100%
	Post	1	25%
Heartware HVAD	Pre	0	0%
	Post	1	25%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	1	25%
Total RVAD	**Pre**	**1**	**0.2%**
	Post	**4**	**0.64%**
Region 11 TAH			
SynCardia CardioWest	Pre	11	100%
	Post	9	81.82%
Other, Specify	Pre	0	0%
	Post	2	18.18%

Total TAH	**Pre**	**11**	**2.2%**
	Post	**11**	**1.76%**

Table A13: Mechanical Circulatory Support Devices at Transplant for Adult Heart Candidates as Entered into Waitlist, Post-Implementation

Device	Brand	Count	Percent
IABP	**Total**	**1605**	**45.8%**
Left Dischargeable VAD	Heartmate II	172	16.18%
	HeartMate III	545	51.27%
	Heartsaver VAD	1	0.09%
	Heartware HVAD	345	32.46%
Left Dischargeable VAD	**Total**	**1063**	**30.34%**
Left Non-Dischargeable VAD	Abiomed BVS 5000	1	1.04%
	CentriMag (Thoratec/Levitronix)	75	78.12%
	Maquet Jostra Rotaflow	5	5.21%
	Thoratec IVAD	1	1.04%
	Other, Specify	14	14.58%
Left Non-Dischargeable VAD	**Total**	**96**	**2.74%**
Left Percutaneous Device	Cardiac Assist Protek Duo	3	1.06%
	Cardiac Assist Tandem Heart	5	1.76%
	CentriMag (Thoratec/Levitronix)	1	0.35%
	Impella CP	45	15.85%
	Impella Recover 2.5	3	1.06%
	Impella Recover 5.0	150	52.82%
	Impella RP	1	0.35%
	Other, Specify	76	26.76%
Left Percutaneous Device	**Total**	**284**	**8.11%**
Right Dischargeable VAD	Heartmate II	1	7.69%
	HeartMate III	4	30.77%
	Heartware HVAD	6	46.15%
	Other, Specify	2	15.38%
Right Dischargeable VAD	**Total**	**13**	**0.37%**
Right Non-Dischargeable VAD	CentriMag (Thoratec/Levitronix)	83	81.37%
	Maquet Jostra Rotaflow	5	4.9%
	Other, Specify	14	13.73%
Right Non-Dischargeable VAD	**Total**	**102**	**2.91%**
Right Percutaneous Device	Cardiac Assist Protek Duo	15	51.72%
	Cardiac Assist Tandem Heart	2	6.9%
	CentriMag (Thoratec/Levitronix)	3	10.34%
	Impella CP	1	3.45%
	Impella Recover 5.0	2	6.9%
	Impella RP	4	13.79%
	Maquet Jostra Rotaflow	1	3.45%
	Other, Specify	1	3.45%
Right Percutaneous Device	**Total**	**29**	**0.83%**
Single Dischargeable VAD	**Total**	**1**	**0.03%**
Single Non-Dischargeable VAD	**Total**	**1**	**0.03%**
Single Percutaneous Device	**Total**	**2**	**0.06%**

	AbioCor	1	3.85%
TAH	SynCardia CardioWest	23	88.46%
	Other, Specify	2	7.69%
TAH	**Total**	**26**	**0.74%**
VA ECMO	**Total**	**282**	**8.05%**

Table A14: Adult Heart Transplants by Distance Traveled and Share Type

Distance	Share	Era	Count	Percent
< 500 NM	Local	Pre	3746	64.96%
		Post	1777	29.05%
	Regional	Pre	770	13.35%
		Post	1528	24.98%
	National	Pre	1002	17.37%
		Post	2099	34.32%
	Not Reported	Pre	6	0.1%
		Post	1	0.02%
500 NM - <1000 NM	Local	Pre	6	0.1%
		Post	3	0.05%
	Regional	Pre	39	0.68%
		Post	54	0.88%
	National	Pre	179	3.1%
		Post	615	10.06%
	Not Reported	Pre	2	0.03%
		Post	2	0.03%
1000 NM - <1500 NM	Local	Pre	12	0.21%
		Post	16	0.26%
	Regional	Pre	2	0.03%
		Post	3	0.05%
	National	Pre	2	0.03%
		Post	18	0.29%
	Not Reported	Pre	0	0%
		Post	0	0%
	Local	Pre	0	0%
	Regional	Pre	0	0%
	National	Pre	1	0.02%
	Not Reported	Pre	0	0%

Table A15: Adult Heart Transplants by Zone, Era, and Medical Urgency Status

Zone	Era	Status	Count	Percent
DSA	Pre	Status 1A	2440	42.31%
		Status 1B	1245	21.59%
		Status 2	79	1.37%
	Post	Adult Status 1	103	1.68%
		Adult Status 2	507	8.29%
		Adult Status 3	503	8.22%
		Adult Status 4	565	9.24%
		Adult Status 5	26	0.43%
		Adult Status 6	92	1.5%
Zone A	Pre	Status 1A	1335	23.15%
		Status 1B	389	6.75%
		Status 2	53	0.92%
	Post	Adult Status 1	379	6.2%
		Adult Status 2	1994	32.6%
		Adult Status 3	576	9.42%
		Adult Status 4	547	8.94%
		Adult Status 5	15	0.25%
		Adult Status 6	111	1.81%
Zone B	Pre	Status 1A	127	2.2%
		Status 1B	67	1.16%
		Status 2	27	0.47%
	Post	Adult Status 1	41	0.67%
		Adult Status 2	313	5.12%
		Adult Status 3	182	2.98%
		Adult Status 4	97	1.59%
		Adult Status 5	3	0.05%
		Adult Status 6	41	0.67%
Zone C	Pre	Status 1A	1	0.02%
		Status 1B	1	0.02%
		Status 2	2	0.03%
	Post	Adult Status 2	7	0.11%
		Adult Status 3	5	0.08%
		Adult Status 4	8	0.13%
		Adult Status 6	1	0.02%
Zone D	Pre	Status 1B	1	0.02%

Table A16: Transplants per 100 Patient-Years Waiting by Medical Urgency Status and Era

Era	Status	Patients Ever Waiting	Number of Transplants	Transplants per 100 Patient Years	CI
Pre	Status 1A	6024	3753	467	[452, 482]
	Status 1B	6901	1666	55	[52, 58]
	Status 2	2789	154	10	[9, 12]
Pre	**Overall**	**10741**	**5573**	**81**	**[79, 83]**
Post	Adult Status 1	641	492	3099	[2832, 3386]
	Adult Status 2	3420	2734	1956	[1884, 2031]
	Adult Status 3	3282	1219	318	[301, 337]
	Adult Status 4	5333	1141	39	[37, 42]
	Adult Status 5	395	47	30	[22, 40]
	Adult Status 6	2633	261	28	[24, 31]
Post	**Overall**	**10582**	**5935**	**99**	**[96, 102]**

Table A17: Transplants per 100 Patient-Years Waiting by Region, Medical Urgency Status, and Era

Region	Era	Patients Ever Waiting	Transplants per 100 Patient Years	Relative Risk	CI
1	Pre	612	58	Ref	-
	Post	623	89	1.55	[1.36, 1.77]
2	Pre	1147	87	Ref	-
	Post	1091	92	1.06	[0.94, 1.19]
3	Pre	1370	77	Ref	-
	Post	1261	92	1.19	[1.01, 1.39]
4	Pre	1100	80	Ref	-
	Post	1023	93	1.16	[1.02, 1.33]
5	Pre	1474	113	Ref	-
	Post	1473	148	1.31	[1.17, 1.47]
6	Pre	333	105	Ref	-
	Post	272	128	1.22	[1.04, 1.43]
7	Pre	1106	56	Ref	-
	Post	1034	82	1.47	[1.31, 1.65]
8	Pre	657	104	Ref	-
	Post	646	116	1.11	[0.98, 1.27]
9	Pre	835	58	Ref	-
	Post	866	75	1.29	[1.09, 1.53]
10	Pre	954	67	Ref	-
	Post	1033	75	1.11	[0.97, 1.27]
11	Pre	1320	106	Ref	-
	Post	1382	120	1.13	[1.00, 1.27]
Overall	Pre	10741	81	Ref	-
	Post	10582	99	1.22	[1.17, 1.26]

Table A18: Pediatric Deaths per 100 Patient-Years Waiting by Medical Urgency Status and Era

Status	Age Group	Era	Patients Ever Waiting	Deaths per 100 Patient Years	Relative Risk	CI
Status 1A	0-5 Years	Pre	684	61	Ref	-
		Post	732	39	0.63	[0.23, 1.73]
	6-10 Years	Pre	106	19	Ref	-
		Post	112	16	0.85	[0.27, 2.70]
	11-17 Years	Pre	307	11	Ref	-
		Post	272	30	2.6	[0.82, 8.18]
Status 1B	0-5 Years	Pre	225	8	Ref	-
		Post	261	2	0.18	-
	6-10 Years	Pre	72	0	Ref	-
		Post	81	0	-	-
	11-17 Years	Pre	216	4	Ref	-
		Post	181	5	1.42	[0.20, 10.06]
Status 2	0-5 Years	Pre	166	1	Ref	-
		Post	163	1	0.91	-
	6-10 Years	Pre	66	0	Ref	-
		Post	52	0	-	-
	11-17 Years	Pre	143	1	Ref	-
		Post	160	1	0.84	[0.05, 13.37]
Temporarily Inactive	0-5 Years	Pre	338	55	Ref	-
		Post	365	45	0.81	[0.39, 1.69]
	6-10 Years	Pre	68	39	Ref	-
		Post	58	26	0.67	[0.31, 1.45]
	11-17 Years	Pre	133	18	Ref	-
		Post	142	21	1.17	[0.51, 2.67]
Overall	0-5 Years	Pre	901	41	Ref	-
		Post	944	28	0.68	[0.38, 1.24]
	6-10 Years	Pre	184	11	Ref	-
		Post	193	9	0.85	[0.45, 1.61]
	11-17 Years	Pre	496	8	Ref	-
		Post	494	10	1.35	[0.73, 2.51]

Table A19: Pediatric Transplants per 100 Patient-Years Waiting by Medical Urgency Status and Era

Status	Age Group	Era	Patients Ever Waiting	Transplants per 100 Patient Years	Relative Risk	CI
Status 1A	0-5 Years	Pre	684	313	Ref	-
		Post	732	313	1	[0.78, 1.28]
	6-10 Years	Pre	106	367	Ref	-
		Post	112	505	1.38	[1.10, 1.73]
	11-17 Years	Pre	307	520	Ref	-
		Post	272	978	1.88	[1.56, 2.26]
Status 1B	0-5 Years	Pre	225	91	Ref	-
		Post	261	63	0.7	[0.39, 1.26]
	6-10 Years	Pre	72	58	Ref	-
		Post	81	118	2.04	[1.28, 3.25]
	11-17 Years	Pre	216	151	Ref	-
		Post	181	233	1.54	[1.14, 2.08]
Status 2	0-5 Years	Pre	166	7	Ref	-
		Post	163	17	2.54	[1.15, 5.60]
	6-10 Years	Pre	66	24	Ref	-
		Post	52	25	1.03	[0.35, 3.03]
	11-17 Years	Pre	143	14	Ref	-
		Post	160	12	0.84	[0.38, 1.86]
Overall	0-5 Years	Pre	901	117	Ref	-
		Post	944	114	0.97	[0.79, 1.20]
	6-10 Years	Pre	184	90	Ref	-
		Post	193	119	1.32	[1.09, 1.60]
	11-17 Years	Pre	496	136	Ref	-
		Post	494	148	1.09	[0.94, 1.27]