Final Report

OPTN Thoracic Committee | Descriptive Data Request

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

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Background/Purpose

On October 18, 2018 the OPTN implemented modifications to the adult heart allocation system. These modifications were made on the recommendation of the Thoracic Organ Transplantation Committee (the Committee) and 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. Data presented in this report were gathered prior to this allocation change, and all references to DSA, zone, and region throughout this report refer to these concepts as they were used in allocation prior to January 9, 2020.

This report serves as an early look at the impact of the modifications to adult heart allocation and will be followed by 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 early 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: 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 and medical urgency status within region
- 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 and medical urgency status within region
- 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
- 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, and the Transplant Recipient Registration (TRR) form. Analyses are based on OPTN data as of February 21, 2020 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, 2017 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2019 (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, 2017 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2019 (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 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, 2017 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2019 (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, 2017 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2019 (post) were used to assess the 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, 2017 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2019 (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 six months of follow-up, which included recipients transplanted between October 18, 2017 and May 17, 2018 in the pre-implementation cohort and between October 18, 2018 and May 17, 2019 in the post-implementation cohort. 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 October 18, 2017 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2019 (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, 2017 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2019 (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, 2017 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2019 (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 3.5.0 (R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL: https://www.R-project.org/).

Results

Waitlist

These analyses examine differences between two waiting list cohorts: the pre-implementation cohort, composed of 3990 registrations added to the heart waiting list between October 18, 2017 and October 17, 2018; and the post-implementation cohort, composed of 3931 registrations added between October 18, 2018 and October 17, 2019.

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

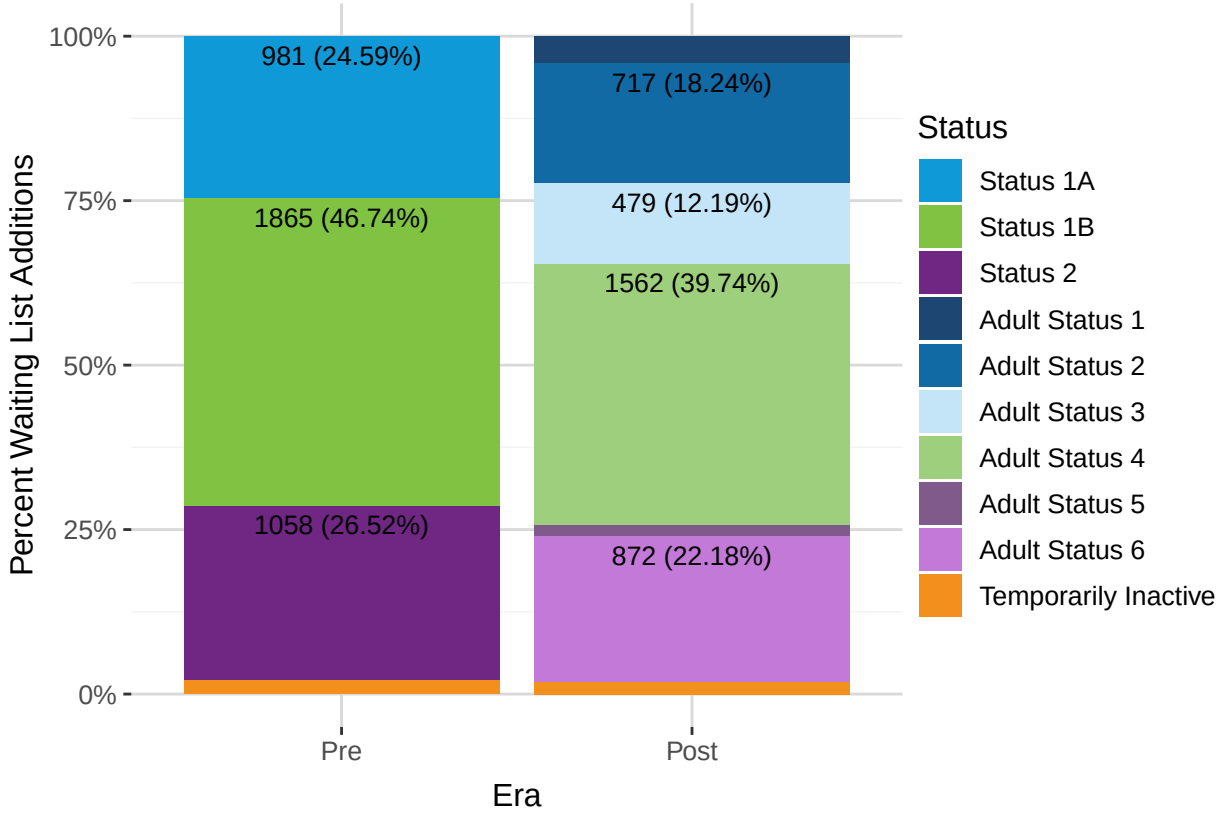


Figure 1 shows the proportion of waiting list additions pre- and post-implementation by medical urgency status. Pre-implementation most additions were made at Status 1B, while post-implementation Adult Status 4 predominated. Adult Status 6 was the second-largest group post-implementation, followed by Adult Status 2 and Adult Status 3. Adult Status 1 and Adult Status 5 represented only a small fraction of registrations post-implementation.

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.

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

Era	Equivalent Status	Status	N	%
Pre	Equivalent Status 1A	Status 1A	981	24.59%
	Equivalent Status 1B	Status 1B	1865	46.74%
	Equivalent Status 2	Status 2	1058	26.52%
	Temporarily inactive	Temporarily Inactive	86	2.16%
Post	Equivalent Status 1A	Adult Status 1	161	4.10%
		Adult Status 2	717	18.24%
		Adult Status 3	479	12.19%
		Overall	1357	34.52%
	Equivalent Status 1B	Adult Status 4	1562	39.74%
		Adult Status 5	68	1.73%
		Overall	1630	41.47%
	Equivalent Status 2	Adult Status 6	872	22.18%
		Overall	872	22.18%
	Temporarily inactive	Temporarily Inactive	72	1.83%

Figure 2. Adult Heart Waiting List Additions by Region and Era

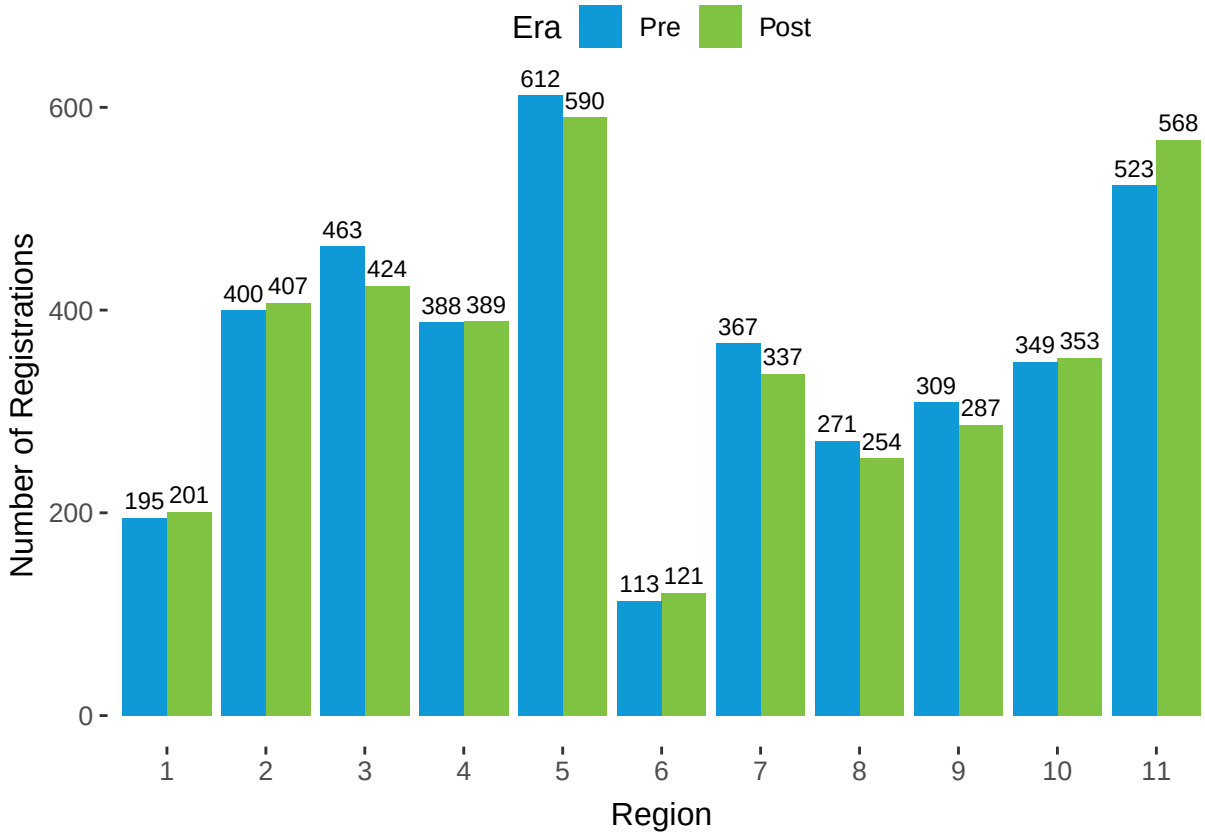
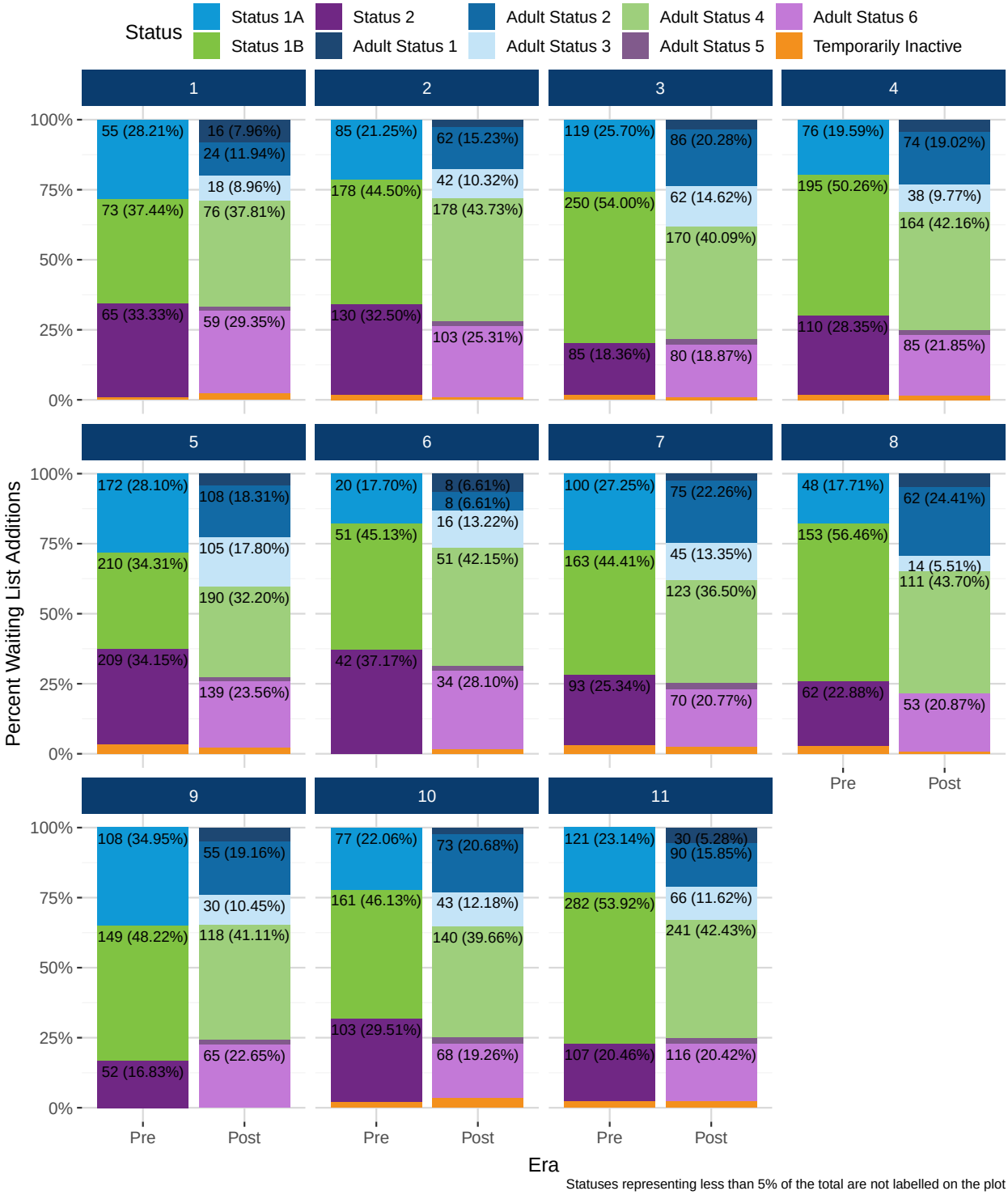


Figure 2 shows the number of adult heart waiting list registrations added by region both pre- and post-implementation. There was little change in the number of waiting list additions for most regions, but the number of registrations added increased by more than 5% in regions 6 and 11 and decreased by more than 5% in regions 3, 7, 8, and 9.

Figure 3 shows the number of adult heart waiting list registrations by region and medical urgency status. The proportion of registrations added at each status is 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 25% of new post-implementation registrations in region 8 compared to 6.6% 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 3. 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

Table 2 shows the criteria qualifying adult heart waiting list candidates for their medical urgency status at time of listing. 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 or without hemodynamic values. For Adult Status 2 the most common criterion was intra-aortic balloon pump with hemodynamic values; it was rare for IABP to be reported without hemodynamic values. For Adult Status 3 the most common qualifying criterion was multiple inotropes/single high dose inotrope with hemodynamic monitoring, and for Adult Status 4 the most common was dischargeable LVAD without discretionary 30 days.

The percent of adult heart waiting list additions qualifying by an exception at time of listing was greatest for Adult Status 2, with 31.4% of candidates qualifying under this criterion. For the other statuses the percent of candidates qualifying by an exception at listing ranged between 15.8% for Adult Status 4 and 19.1% for Adult Status 1.

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. The region with the highest proportion of candidates qualifying under an exception was region 4, with 25.75% of adult heart candidates qualifying with an exception at time of listing, closely followed by region 3, which had 23.91% of candidates qualifying under an exception at time of listing. The region with the lowest proportion of candidates qualfying under an exception at time of listing was region 1 at 6.86%.

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	12	7.14%
	Exception	32	19.05%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	22	13.10%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	60	35.71%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	42	25.00%
Overall		**168**	**100%**
Adult Status 2	Exception	227	31.44%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	13	1.80%
	Intra-aortic ballon pump - Hemodynamic Values obtained	342	47.37%
	Mechanical circulatory support device(MCSD) with malfunction	21	2.91%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	9	1.25%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	6	0.83%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	49	6.79%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	26	3.60%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	29	4.02%
Overall		**722**	**100%**

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Status	Criteria	N	%
Adult Status 3	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	118	24.43%
	Exception	86	17.81%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	4	0.83%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	35	7.25%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	14	2.90%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	11	2.28%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	4	0.83%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	6	1.24%
	Mechanical circulatory support device (MCSD) with hemolysis	4	0.83%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	0.21%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	1	0.21%
	Mechanical circulatory support device (MCSD) with pump thrombosis	11	2.28%
	Mechanical circulatory support device (MCSD) with right heart failure	2	0.41%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	186	38.51%
Overall		**483**	**100%**
Adult Status 4	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	160	10.12%
	Congenital heart disease	112	7.08%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	709	44.85%
	Exception	249	15.75%
	Inotropes without hemodynamic monitoring	240	15.18%
	Ischemic heart disease with intractable angina	33	2.09%
	Retransplant	78	4.93%
Overall		**1581**	**100%**
Adult Status 5	None	82	100.00%
Adult Status 6	None	880	100.00%

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

Table 3 shows the qualifying criteria for candidates on the adult heart waiting list as it appeared on December 31, 2019, stratified by initial or extension request. Adult Status 1 candidates spend very little time on the waiting list, and therefore at any given time there are few of them waiting, which makes the distribution of qualifying criteria difficult to determine. For Adult Status 2, half of candidates were waiting with an exception and, among those who were not, the most common criterion was intra-aortic balloon pump with hemodynamic values. For Adult Status 3, dischargeable LVAD for discretionary 30 days was the most common criterion for candidates waiting under their initial status request, while MCSD with bacteremic device infection was the most common for those waiting under an extension. The distribution of qualifying criteria for candidates waiting at Adult Status 4 on December 31, 2019 was similar to the distribution of qualifying criteria for this status at listing, with dischargeable LVAD without discretionary 30 days being the most common in both cases. For candidates waiting at Adult Status 4 under an extension, there were fewer exceptions and more candidates waiting under the dischargeable LVAD without discretionary 30 days criterion.

Table 3. Criteria Within Medical Urgency Status for Adult Heart Candidates Waiting on December 31, 2019

		Initial		Extension		Total	
Status	**Criteria**	**N**	**%**	**N**	**%**	**N**	**%**
Adult Status 1	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	1	16.67%	1	100.00%	2	28.57%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	1	16.67%	0	0.00%	1	14.29%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	4	66.67%	0	0.00%	4	57.14%
Overall		**6**	**100%**	**1**	**100%**	**7**	**100%**
Adult Status 2	Exception	14	50.00%	12	50.00%	26	50.00%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	1	3.57%	0	0.00%	1	1.92%
	Intra-aortic ballon pump - Hemodynamic Values obtained	10	35.71%	5	20.83%	15	28.85%
	Mechanical circulatory support device(MCSD) with malfunction	1	3.57%	2	8.33%	3	5.77%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	2	7.14%	0	0.00%	2	3.85%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	0	0.00%	5	20.83%	5	9.62%
Overall		**28**	**100%**	**24**	**100%**	**52**	**100%**
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	47	47.96%	0	0.00%	47	21.76%

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Status	Criteria	N	%	N	%	N	%
Adult Status 3	Exception	13	13.27%	21	17.80%	34	15.74%
	Intra-aortic balloon pump after 14 days	1	1.02%	0	0.00%	1	0.46%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	4	4.08%	2	1.69%	6	2.78%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	15	15.31%	29	24.58%	44	20.37%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	3	3.06%	17	14.41%	20	9.26%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	1	1.02%	5	4.24%	6	2.78%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	0	0.00%	3	2.54%	3	1.39%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	2.04%	1	0.85%	3	1.39%
	Mechanical circulatory support device (MCSD) with hemolysis	0	0.00%	1	0.85%	1	0.46%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	3	3.06%	0	0.00%	3	1.39%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	1	1.02%	0	0.00%	1	0.46%
	Mechanical circulatory support device (MCSD) with pump thrombosis	3	3.06%	23	19.49%	26	12.04%
	Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	10	8.47%	10	4.63%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	5	5.10%	6	5.08%	11	5.09%
Overall		**98**	**100%**	**118**	**100%**	**216**	**100%**
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	47	7.00%	53	5.16%	100	5.89%
	Congenital heart disease	40	5.96%	62	6.04%	102	6.01%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	411	61.25%	787	76.63%	1198	70.55%

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Status	Criteria	N	%	N	%	N	%
Adult Status 4	Exception	79	11.77%	56	5.45%	135	7.95%
	Inotropes without hemodynamic monitoring	42	6.26%	18	1.75%	60	3.53%
	Ischemic heart disease with intractable angina	20	2.98%	16	1.56%	36	2.12%
	Retransplant	32	4.77%	35	3.41%	67	3.95%
Overall		**671**	**100%**	**1027**	**100%**	**1698**	**100%**
Adult Status 5	None	59	100.00%	35	100.00%	94	100.00%
Adult Status 6	None	278	100.00%	223	100.00%	501	100.00%

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

Table 4 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, 63.11% of new registrations had an MCSD listed on the TCR pre-implementation, compared to 56.02% 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 nearly doubled, 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 number of registrations on an LVAD+RVAD at listing was much higher in region 1 than other regions, and region 6 had the smallest decline in LVADs among registrations, with over 78% of registrations having an LVAD at listing post-implementation.

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 4. Mechanical Circulatory Support Devices at Listing for Adult Heart Candidates

Brand	Era	Count	Percent
ECMO			
Total ECMO	**Pre**	**57**	**3.74%**
	Post	**119**	**6.52%**
IABP			
Total IABP	**Pre**	**182**	**11.93%**
	Post	**484**	**26.52%**
LVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	3	0.27%
Cardiac Assist Tandem Heart	Pre	2	0.17%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	8	0.66%
	Post	9	0.81%
Evaheart	Pre	1	0.08%
	Post	1	0.09%
Heartmate II	Pre	433	35.96%
	Post	234	21.16%
HeartMate III	Pre	57	4.73%
	Post	435	39.33%
Heartmate XVE	Pre	2	0.17%
	Post	0	0%
Heartsaver VAD	Pre	1	0.08%
	Post	2	0.18%

Heartware HVAD	Pre	361	29.98%
	Post	319	28.84%
Impella CP	Pre	2	0.17%
	Post	20	1.81%
Impella Recover 2.5	Pre	8	0.66%
	Post	3	0.27%
Impella Recover 5.0	Pre	28	2.33%
	Post	45	4.07%
Impella RP	Pre	0	0%
	Post	1	0.09%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	2	0.18%
Other, Specify	Pre	301	25%
	Post	32	2.89%
Total LVAD	**Pre**	**1204**	**78.95%**
	Post	**1106**	**60.6%**
LVAD+RVAD			
Abiomed AB5000	Pre	0	0%
	Post	1	1.09%
Cardiac Assist Protek Duo	Pre	0	0%
	Post	5	5.43%
Cardiac Assist Tandem Heart	Pre	4	6.25%
	Post	2	2.17%
CentriMag (Thoratec/Levitronix)	Pre	31	48.44%
	Post	36	39.13%
Heartmate II	Pre	3	4.69%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	13	14.13%
Heartware HVAD	Pre	11	17.19%
	Post	15	16.3%
Impella Recover 5.0	Pre	1	1.56%
	Post	2	2.17%
Maquet Jostra Rotaflow	Pre	2	3.12%
	Post	6	6.52%
Thoratec PVAD	Pre	0	0%
	Post	2	2.17%
	Pre	12	18.75%

Other, Specify	Post	10	10.87%
Total LVAD+RVAD	**Pre**	**64**	**4.2%**
	Post	**92**	**5.04%**
RVAD			
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	1	14.29%
CentriMag (Thoratec/Levitronix)	Pre	1	50%
	Post	2	28.57%
Impella Recover 5.0	Pre	1	50%
	Post	1	14.29%
Impella RP	Pre	0	0%
	Post	1	14.29%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	1	14.29%
Other, Specify	Pre	0	0%
	Post	1	14.29%
Total RVAD	**Pre**	**2**	**0.13%**
	Post	**7**	**0.38%**
TAH			
SynCardia CardioWest	Pre	16	100%
	Post	15	88.24%
Other, Specify	Pre	0	0%
	Post	2	11.76%
Total TAH	**Pre**	**16**	**1.05%**
	Post	**17**	**0.93%**

Figure 4. Justification Forms at Listing by Justification Review Type and Status Requested

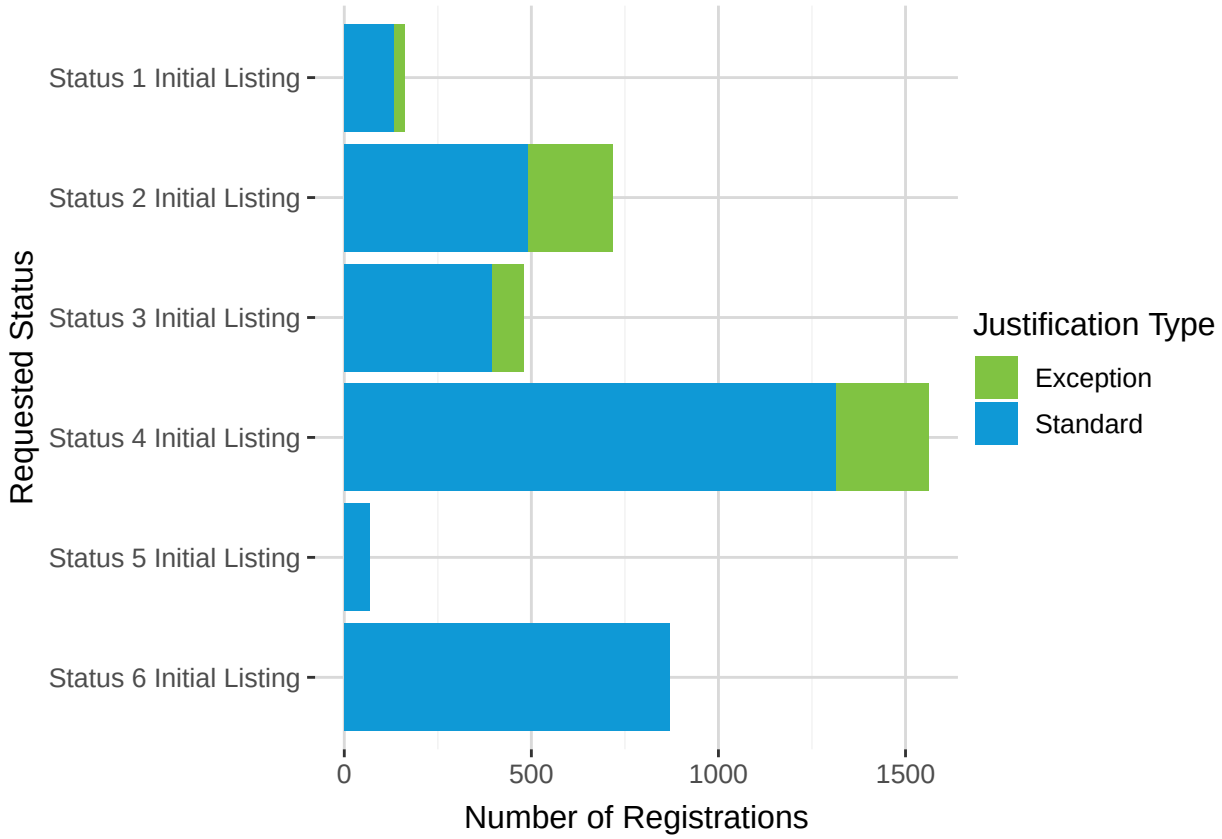
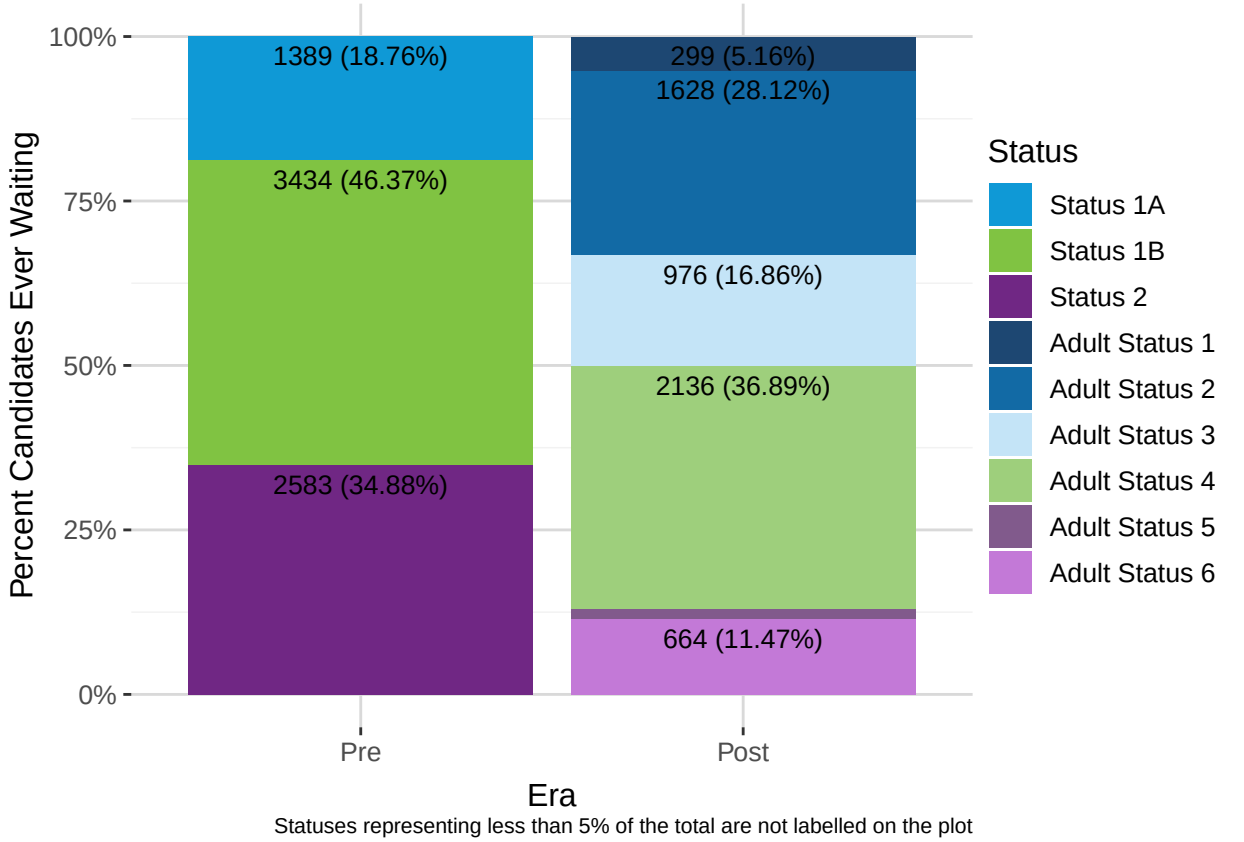


Figure 4 shows the number of justification forms at listing, the status requested, and whether the review type was standard or exception. The most-requested status at listing was Adult Status 4, followed by Adult Status 6. Exception requests were most common for candidates listing at either Adult Status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

Figure 5. Candidates Ever Waiting by Era and Medical Urgency Status



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

Figure 5 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 majority of adult heart candidates waited at Status 1B, while post-implementation the largest group of waiting candidates was Adult Status 4, with the second-most-common status, Adult Status 2, containing substantially fewer candidates. Of the new statuses used post-implementation, Adult Status 5 had the fewest candidates ever waiting, followed by Adult Status 1.

Figure 6. Deaths per 100 Patient-Years Waiting by Medical Urgency Status and Era

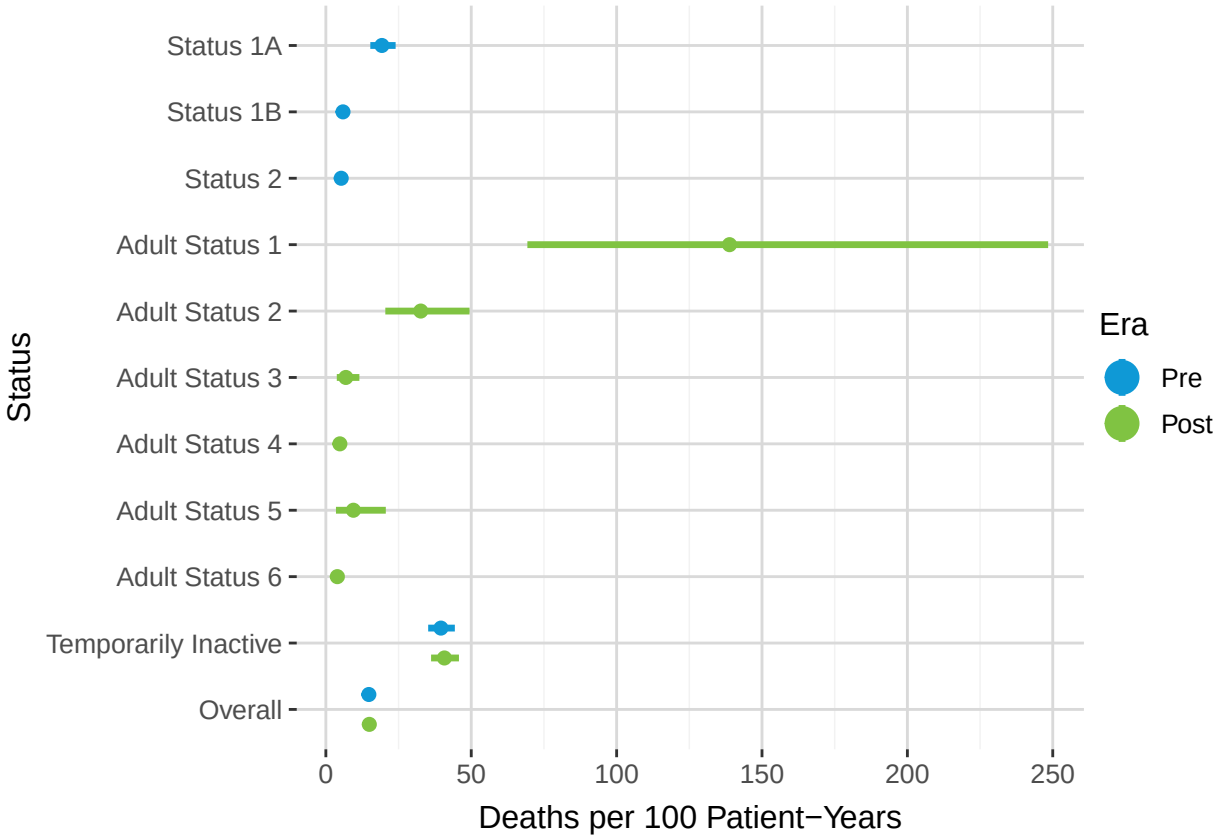


Figure 6 shows the number of deaths per 100 patient-years by medical urgency status and era. Although the medical urgency statuses used pre- and post-implementation are not directly comparable, the fact that Adult Status 1 has a dramatically higher number of deaths per 100 patient-years than Adult Status 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. Overall there was no significant difference in the number of deaths per 100 patient-years between the two eras.

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 7. Deaths per 100 Patient-Years Waiting by Region, Medical Urgency Status, and Era

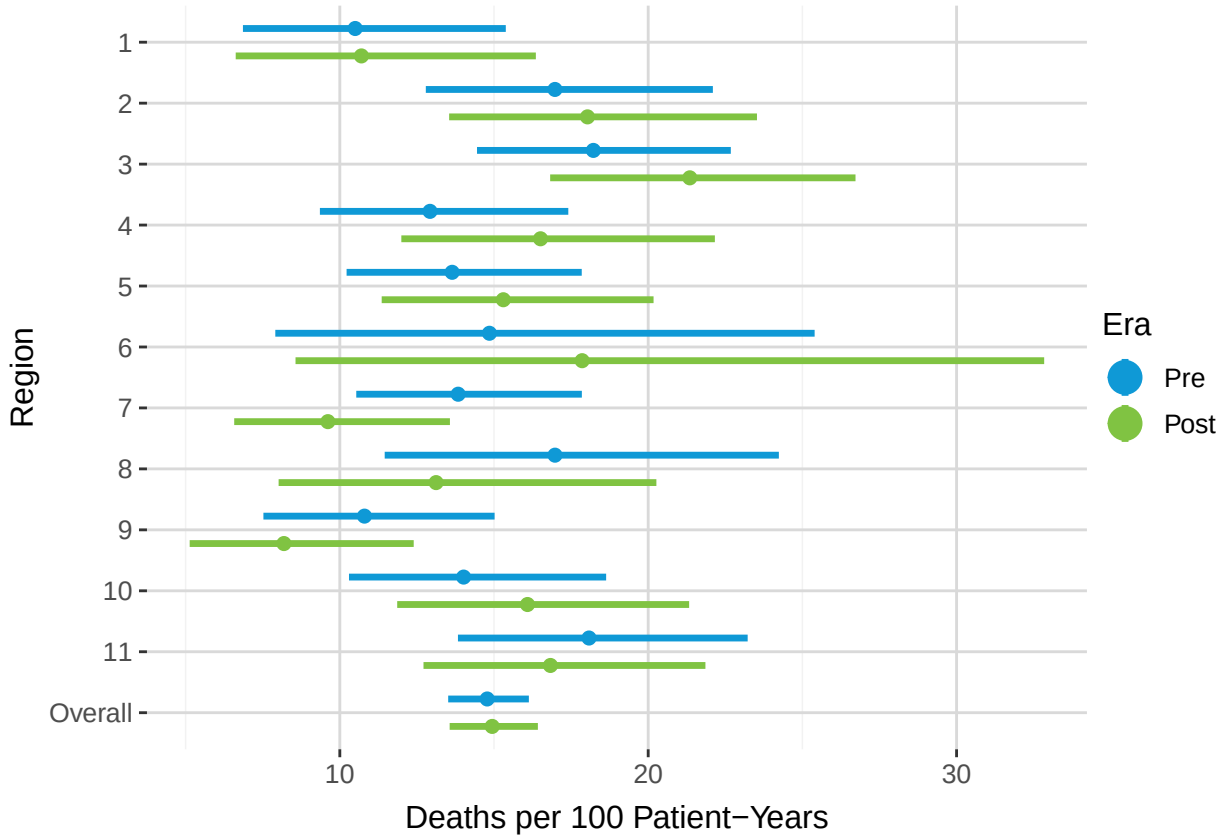


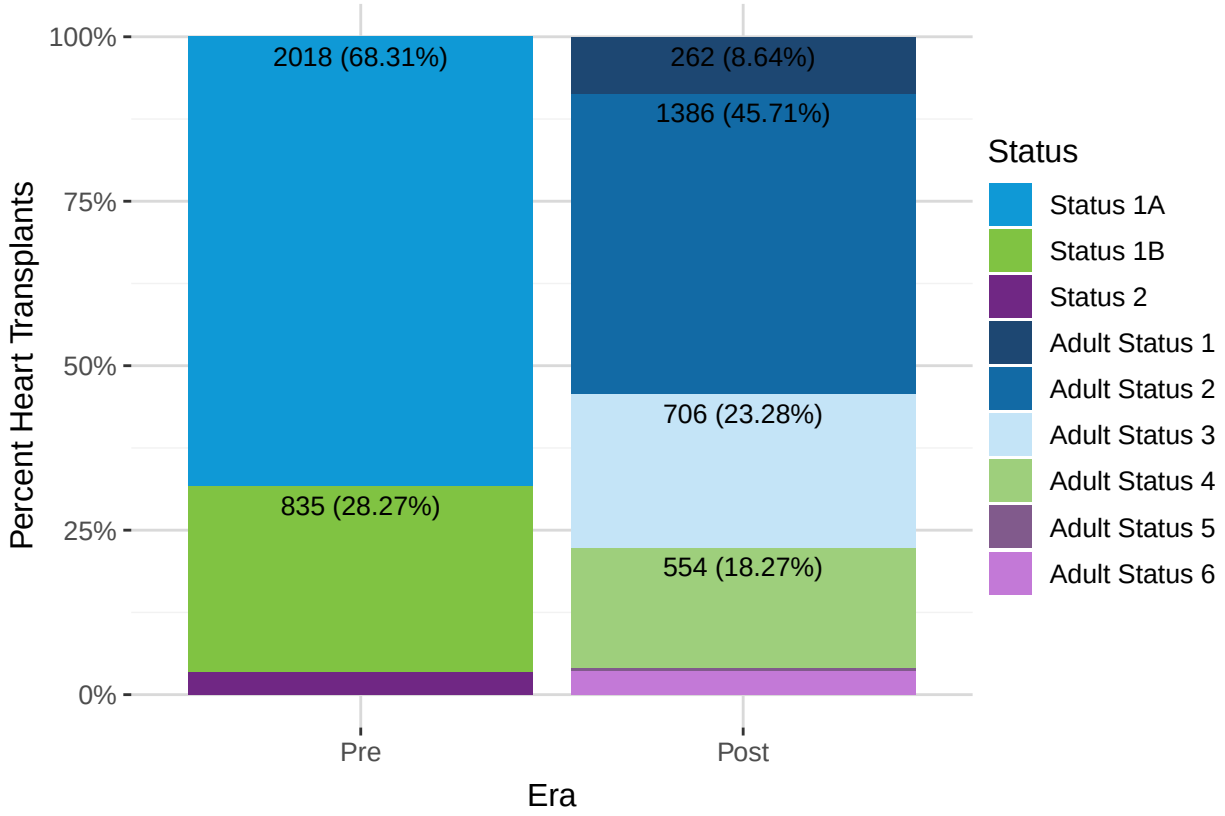
Figure 7 shows the number of deaths per 100 patient-years by region and era. There was no significant change in the number of deaths per 100 patient-years in any region pre- vs post-implementation.

Table A7 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 2954 adult heart transplants performed between October 18, 2017 and October 17, 2018; and the post-implementation cohort, composed of 3032 adult heart transplants performed between October 18, 2018 and October 17, 2019. There were 78 more heart transplants performed in the post-implementation cohort than in the pre-implementation cohort.

Figure 8. Proportion of Adult Heart Transplants by Medical Urgency Status and Era



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

Figure 8 shows the proportion of adult heart transplants performed both pre- and post-implementation by medical urgency status. Status 1A candidates received around 2/3 of all transplants pre-implementation, but no single status represented such a large fraction of transplants post-implementation. Adult Status 2 candidates received the most transplants, followed by Adult Status 3, Adult Status 4, and Adult Status 1. Post-implementation Adult Status 6 represented only 3.63% of transplants, while there were only 14 (0.46%) transplants to Adult Status 5 patients in the first year after the new adult heart allocation policy went into effect.

Table 5 breaks down the count and percent of transplants both by medical urgency status and by equivalent medical urgency status as defined in the Data section above.

Table 5. Adult Heart Transplants by Era and Medical Urgency Status

Era	Equivalent Status	Status	N	%
Pre	Equivalent Status 1A	Status 1A	2018	68.31%
	Equivalent Status 1B	Status 1B	835	28.27%
	Equivalent Status 2	Status 2	101	3.42%
Post	Equivalent Status 1A	Adult Status 1	262	8.64%
		Adult Status 2	1386	45.71%
		Adult Status 3	706	23.28%
		Overall	2354	77.64%
	Equivalent Status 1B	Adult Status 4	554	18.27%
		Adult Status 5	14	0.46%
		Overall	568	18.73%
	Equivalent Status 2	Adult Status 6	110	3.63%
		Overall	110	3.63%

Figure 9. Adult Heart Transplants by Region and Era

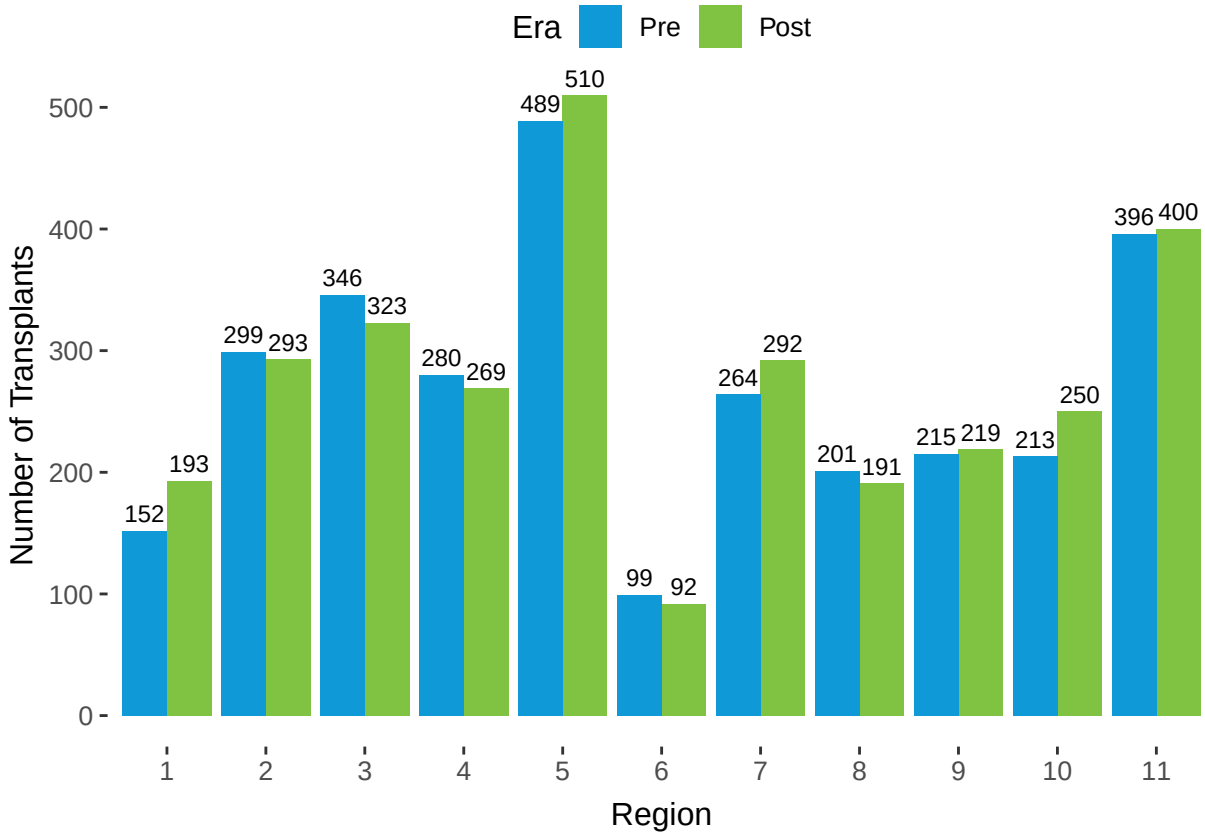


Figure 9 shows the number of adult heart transplants by era and region. The number of heart transplants rose in regions 1, 5, 7, and 10, decreased in regions 2, 3, 4, 6, and 8, and remained similar in regions 9 and 11.

Figure 10 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 most regions Adult Status 2 candidates received the most transplants; in region 6 Adult Status 3 candidates received the most transplants. The only Adult Status 5 transplants performed post-implementation were in regions 1, 2, 3, 5, and 10.

Tables A8 and A9 show the count and percent of adult heart waiting transplants by region and medical urgency status pre-implementation and post-implementation, respectively.

Figure 10. Adult Heart Transplants by Region, Era, and Medical Urgency Status

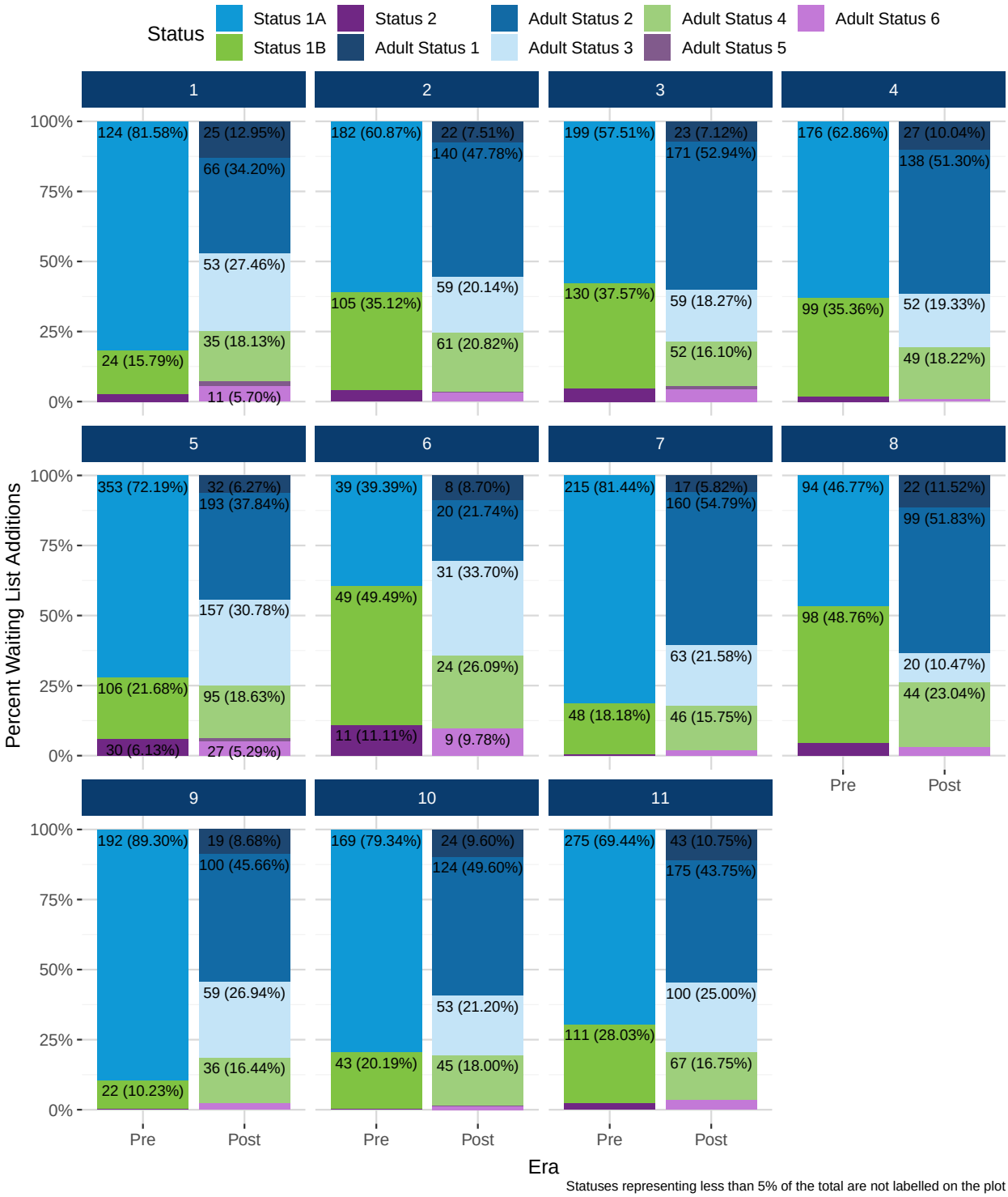


Table 6 shows the criteria qualifying heart transplant recipients for their medical urgency status at time of transplant and whether they were transplanted after their initial qualification for a status or on an extension. This table only includes adult heart transplants performed during the post-implementation 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, while for those transplanted under an extension, the most common criterion was non-dischargeable, surgically implanted, non-endovascular biventricular support device. For Adult Status 2, it was most common for recipients transplanted under their initial request to qualify based on an IABP with hemodynamic values, while it was most common for those transplanted under an extension to have an exception. For Adult Status 3, the most common criterion for recipients transplanted under an initial request was dischargeable LVAD for discretionary 30 days, while it was most common for recipients transplanted under an extension to have an exception. For Adult Status 4, dischargeable LVAD without discretionary 30 days was the most common criterion both for those transplanted under their initial request and for those transplanted under an extension.

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 typically 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 6. Adult Heart Transplants by Criteria Within Medical Urgency Status at Transplant Post-Implementation

		Initial		Extension		Total	
Status	**Criteria**	**N**	**%**	**N**	**%**	**N**	**%**
Adult Status 1	BIVAD/Ventricular Episodes	22	9.32%	4	15.38%	26	9.92%
	Exception	77	32.63%	4	15.38%	81	30.92%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	31	13.14%	7	26.92%	38	14.50%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	56	23.73%	5	19.23%	61	23.28%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	50	21.19%	6	23.08%	56	21.37%
Overall		**236**	**100%**	**26**	**100%**	**262**	**100%**
Adult Status 2	Exception	422	38.36%	126	44.06%	548	39.54%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	18	1.64%	2	0.70%	20	1.44%
	Intra-aortic ballon pump - Hemodynamic Values obtained	471	42.82%	80	27.97%	551	39.75%
	Intra-aortic balloon pump after 14 days	1	0.09%	0	0.00%	1	0.07%
	Mechanical circulatory support device(MCSD) with malfunction	57	5.18%	30	10.49%	87	6.28%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	14	1.27%	0	0.00%	14	1.01%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	7	0.64%	0	0.00%	7	0.51%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	58	5.27%	6	2.10%	64	4.62%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	22	2.00%	32	11.19%	54	3.90%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	2	0.18%	0	0.00%	2	0.14%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	28	2.55%	10	3.50%	38	2.74%
Overall		**1100**	**100%**	**286**	**100%**	**1386**	**100%**

(continued)

Status	Criteria	N	%	N	%	N	%
Adult Status 3	Congenital heart disease	1	0.19%	0	0.00%	1	0.14%
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	254	49.42%	0	0.00%	254	35.98%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	3	0.58%	0	0.00%	3	0.42%
	Exception	82	15.95%	87	45.31%	169	23.94%
	Intra-aortic ballon pump - Hemodynamic Values obtained	2	0.39%	0	0.00%	2	0.28%
	Intra-aortic balloon pump after 14 days	1	0.19%	1	0.52%	2	0.28%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	8	1.56%	0	0.00%	8	1.13%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	27	5.25%	25	13.02%	52	7.37%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	10	1.95%	13	6.77%	23	3.26%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	5	0.97%	6	3.12%	11	1.56%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	8	1.56%	1	0.52%	9	1.27%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	6	1.17%	1	0.52%	7	0.99%
	Mechanical circulatory support device (MCSD) with hemolysis	4	0.78%	4	2.08%	8	1.13%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	7	1.36%	1	0.52%	8	1.13%
	Mechanical circulatory support device (MCSD) with pump thrombosis	2	0.39%	8	4.17%	10	1.42%
	Mechanical circulatory support device (MCSD) with right heart failure	1	0.19%	3	1.56%	4	0.57%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	93	18.09%	42	21.88%	135	19.12%
Overall		**514**	**100%**	**192**	**100%**	**706**	**100%**

(continued)

Status	Criteria	N	%	N	%	N	%
Adult Status 4	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	38	9.38%	18	12.08%	56	10.11%
	Congenital heart disease	21	5.19%	15	10.07%	36	6.50%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	166	40.99%	72	48.32%	238	42.96%
	Exception	93	22.96%	22	14.77%	115	20.76%
	Inotropes without hemodynamic monitoring	49	12.10%	10	6.71%	59	10.65%
	Intra-aortic ballon pump - Hemodynamic Values obtained	1	0.25%	0	0.00%	1	0.18%
	Ischemic heart disease with intractable angina	11	2.72%	3	2.01%	14	2.53%
	No criteria for this status	1	0.25%	0	0.00%	1	0.18%
	Retransplant	25	6.17%	9	6.04%	34	6.14%
Overall		**405**	**100%**	**149**	**100%**	**554**	**100%**
Adult Status 5	None	11	100.00%	3	100.00%	14	100.00%
Adult Status 6	None	102	100.00%	8	100.00%	110	100.00%

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

Table 7 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, 45.06% of new registrations had an MCSD listed on the TRR pre-implementation, compared to 34.37% 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 by more than 20% and the percent recipients with an IABP or on ECMO more than doubling.

Table A11 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 the number of recipients on an LVAD+RVAD is much higher in region 1 than other regions, and region 6 had a much smaller decline in LVADs among recipients than other regions, with over 75% of recipients having an LVAD post-implementation. Region 8 had the lowest proportion of transplant recipients with an LVAD at transplant, and over half of transplant recipients in this region had an IABP at transplant. Region 8 also went from zero transplants to recipients on ECMO pre-implementation to 12 post-implementation, 9.02% of the devices listed for transplant recipients at transplant in the post-implementation era in that region.

For comparison, Table A12 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 slightly smaller proportion of recipients with an IABP being reported on justification forms than on the TRR and a higher proportion of recipients with some form of LVAD based on the justification form data than the proportion reported on the TRR.

Table 7. Mechanical Circulatory Support Devices at Transplant for Adult Heart Candidates

Brand	Era	Count	Percent
ECMO			
Total ECMO	**Pre**	**30**	**1.79%**
	Post	**160**	**7.45%**
IABP			
Total IABP	**Pre**	**221**	**13.22%**
	Post	**822**	**38.27%**
LVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	0.1%
Cardiac Assist Tandem Heart	Pre	1	0.08%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	6	0.45%
	Post	8	0.8%
Heartmate II	Pre	488	36.75%
	Post	231	23.03%
HeartMate III	Pre	76	5.72%
	Post	318	31.7%
Heartmate XVE	Pre	1	0.08%
	Post	0	0%

Heartsaver VAD	Pre	5	0.38%
	Post	1	0.1%
Heartware HVAD	Pre	520	39.16%
	Post	339	33.8%
Impella CP	Pre	1	0.08%
	Post	15	1.5%
Impella Recover 2.5	Pre	5	0.38%
	Post	5	0.5%
Impella Recover 5.0	Pre	29	2.18%
	Post	68	6.78%
Other, Specify	Pre	196	14.76%
	Post	17	1.69%
Total LVAD	**Pre**	**1328**	**79.43%**
	Post	**1003**	**46.69%**
LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	3	2.59%
Cardiac Assist Tandem Heart	Pre	2	3.33%
	Post	2	1.72%
CentriMag (Thoratec/Levitronix)	Pre	26	43.33%
	Post	64	55.17%
HeartMate III	Pre	2	3.33%
	Post	20	17.24%
Heartware HVAD	Pre	16	26.67%
	Post	19	16.38%
Impella Recover 2.5	Pre	0	0%
	Post	1	0.86%
Impella Recover 5.0	Pre	1	1.67%
	Post	1	0.86%
Maquet Jostra Rotaflow	Pre	2	3.33%
	Post	0	0%
Other, Specify	Pre	11	18.33%
	Post	6	5.17%
Total LVAD+RVAD	**Pre**	**60**	**3.59%**
	Post	**116**	**5.4%**
RVAD			
	Pre	0	0%

Cardiac Assist Protek Duo	Post	4	28.57%
CentriMag (Thoratec/Levitronix)	Pre	1	12.5%
	Post	3	21.43%
Heartware HVAD	Pre	3	37.5%
	Post	2	14.29%
Impella Recover 5.0	Pre	2	25%
	Post	1	7.14%
Impella RP	Pre	1	12.5%
	Post	2	14.29%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	1	7.14%
Other, Specify	Pre	1	12.5%
	Post	1	7.14%
Total RVAD	**Pre**	**8**	**0.48%**
	Post	**14**	**0.65%**
TAH			
SynCardia CardioWest	Pre	24	96%
	Post	30	90.91%
Other, Specify	Pre	1	4%
	Post	3	9.09%
Total TAH	**Pre**	**25**	**1.5%**
	Post	**33**	**1.54%**

Figure 11 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, and exceptions were more common for initial requests than extension requests for all statuses except Adult Status 3.

Figure 11. Adult Heart Transplants by Review Type and Requested Status

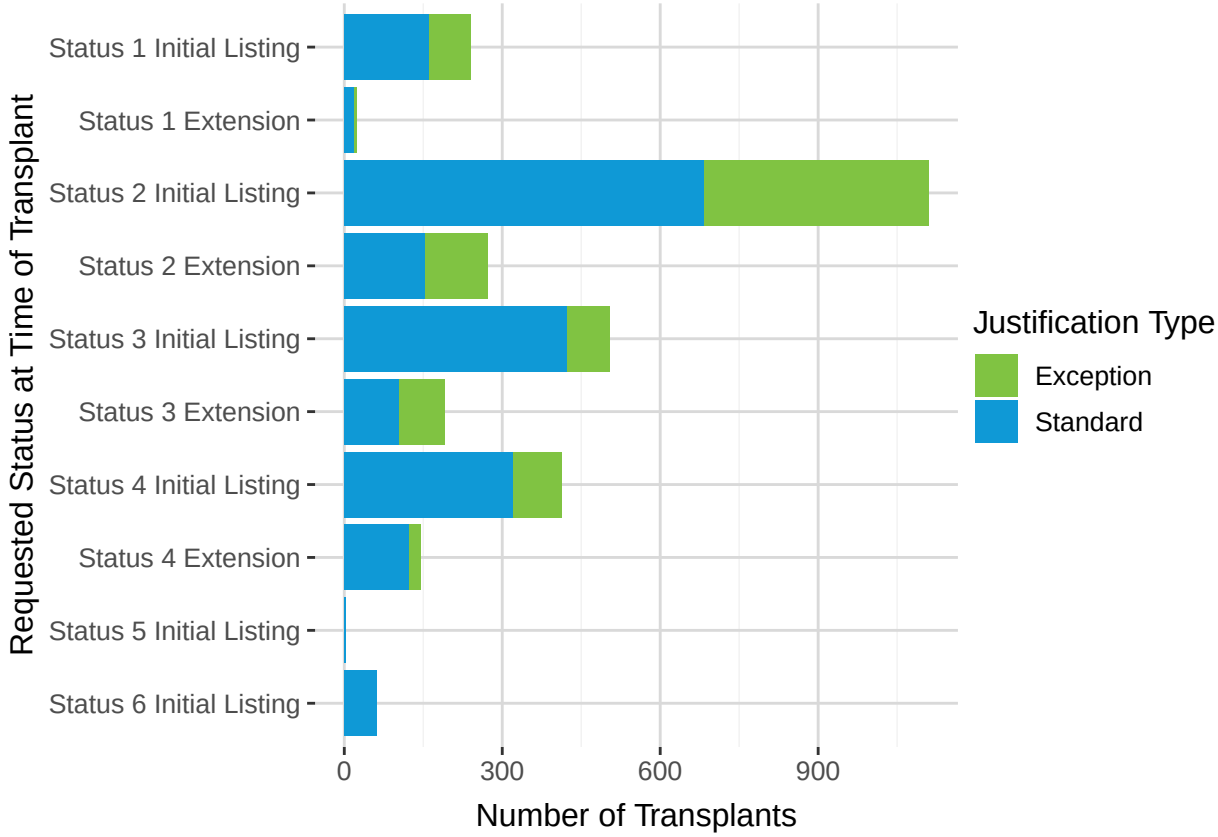


Figure 12. Adult Heart Transplants by Share Type and Era

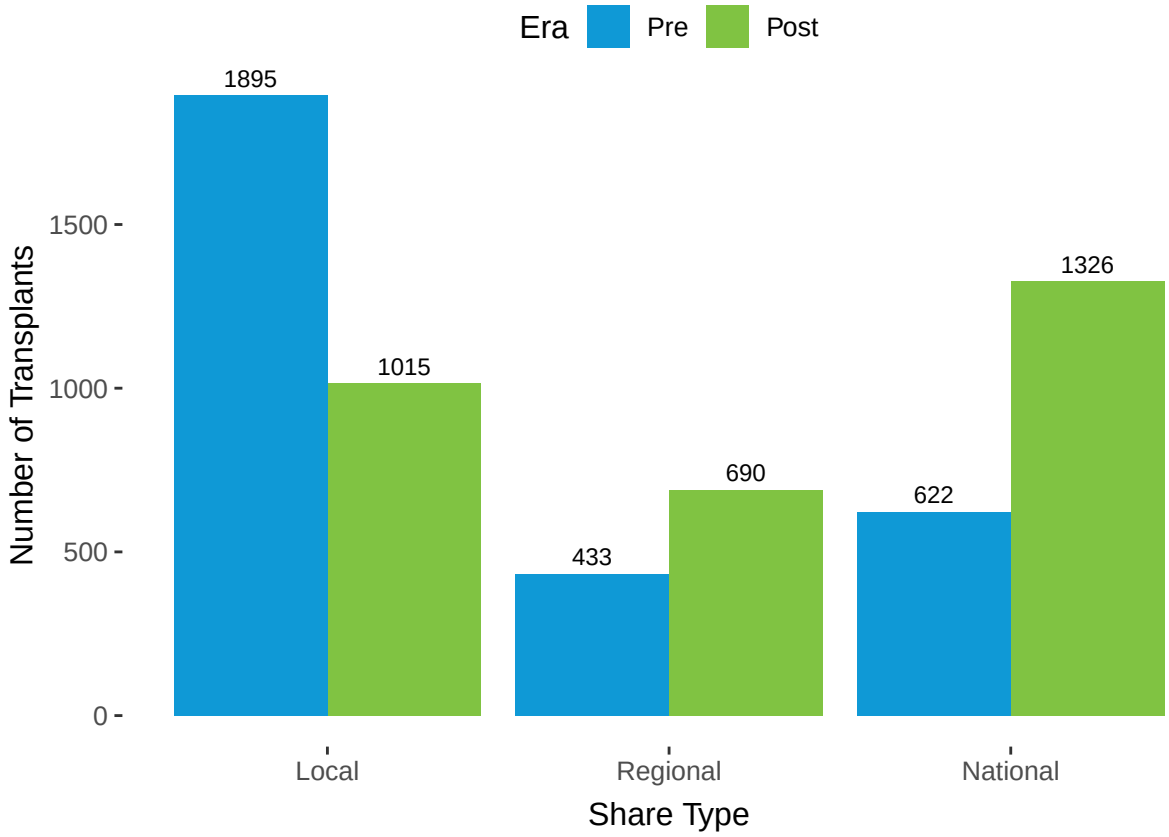


Figure 12 shows the number of adult heart transplants by share type and era. Here, "local" refers to hearts recovered and transplanted within the same DSA and "regional" refers to organs recovered and transplanted in different DSAs but within the same OPTN region. This report does not include any data from after the removal of DSA from heart allocation.

The number of local transplants declined 46.44% post-implementation, with increases in both regional and national shares. The increase was most dramatic for heart transplants at the national share level, which more than doubled post-implementation.

Figure 13. Adult Heart Transplants by Zone and Era

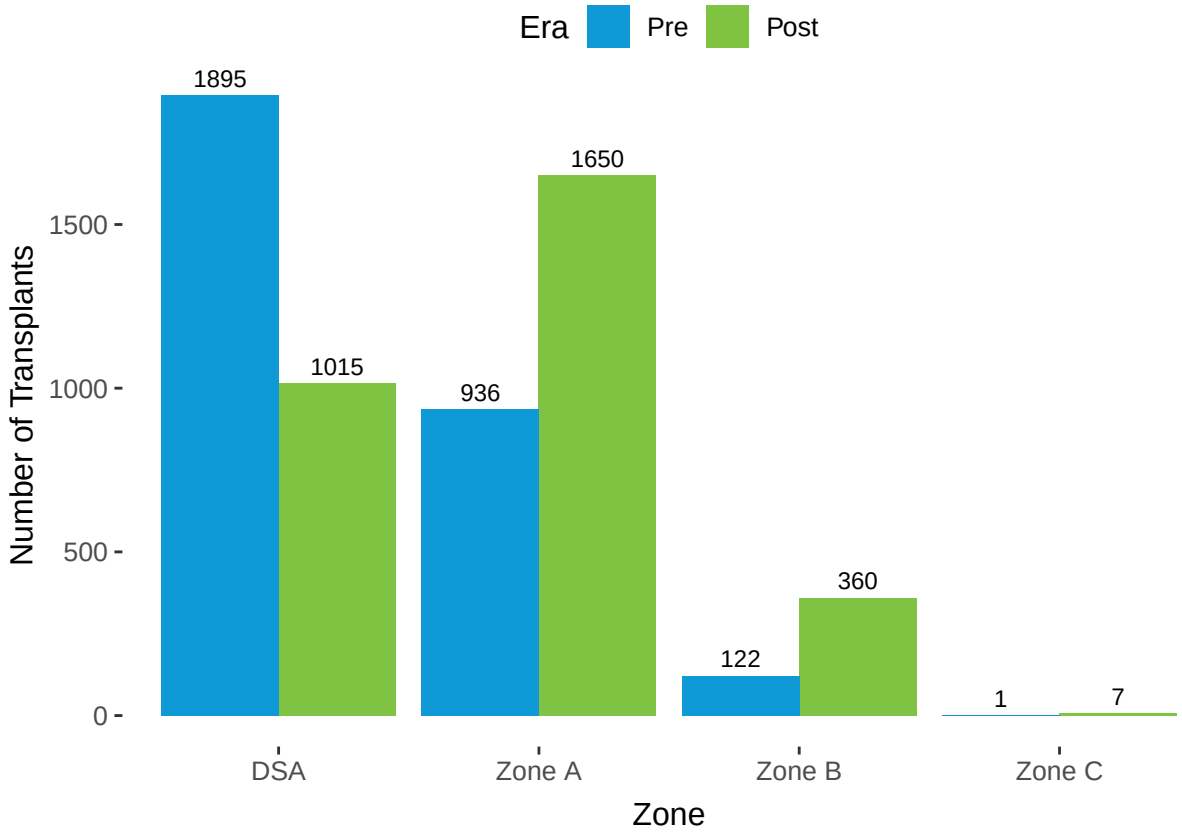
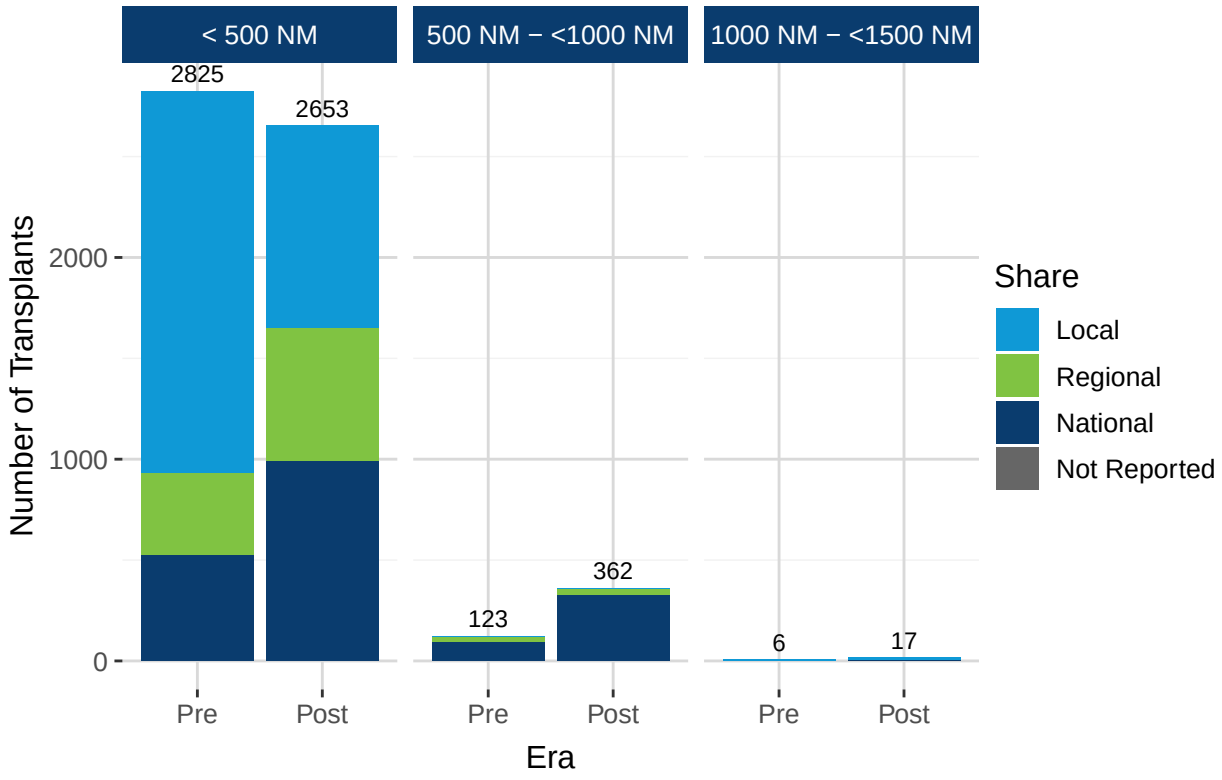


Figure 13 shows the number of adult heart transplants performed by zone and era. Transplants within the DSA decreased post-implementation but rose in all other zones. The greatest increase by absolute volume was in Zone A, but transplants also rose nearly 200% in Zone B. There were no transplants past Zone C.

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

Figure 14. Adult Heart Transplants by Distance Traveled and Share Type



Transplants with unreported share type involved organs recovered in Canada

Figure 14 shows the number of adult heart transplants performed by distance traveled and share type. Local shares decreased across all distance categories except the 1000 NM - <1500 NM distance category, where they increased. The number of organs traveling less than 500 nautical miles but representing either a regional or national share increased post-implementation. The number and percentage of transplants for hearts that traveled at least 500 nautical miles but less than 1000 nautical miles classified as national shares also increased post-implementation. The majority of hearts that traveled more than 1000 nautical miles up to 1500 nautical miles were classified as local shares both pre- and post-implementation; all of these long-distance local shares represent transplants performed in OPTN region 6.

Table A13 gives the counts and percentages of adult heart transplants performed in each distance category by share type and era.

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

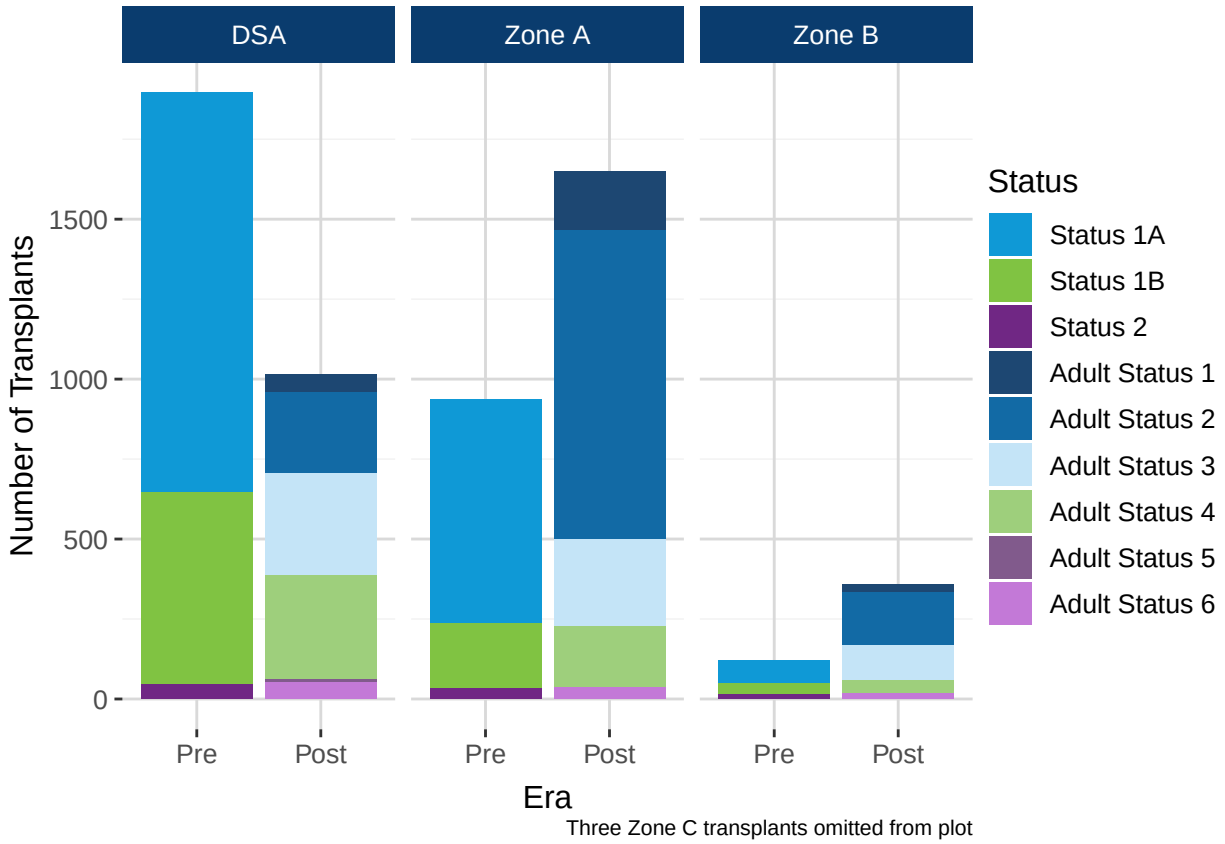


Figure 15 shows the number of adult heart transplants by zone, medical urgency status, and era. Pre-implementation most transplants within the DSA or Zone A were Status 1A. Post-implementation Adult Status 1 and Adult Status 2 were more common in Zone A than the other zones, likely as a result of the most medically urgent patients being prioritized in Zone A as well as DSA under the new adult heart allocation system. Within the DSA a similar number of transplants went to Adult Status 3, Adult Status 4, and Adult Status 2 candidates, while the proportion of Adult Status 3 and Adult Status 4 transplants declined across DSA, Zone A, and Zone B.

There were 8 transplants in Zone C, 1 pre-implementation and 7 post-implementation (not shown in Figure 15). The pre-implementation transplant went to a Status 2 candidate, and the majority of the post-implementation transplants went to Adult Status 3 candidates, with one Adult Status 2 recipient and two Adult Status 4 recipients.

Table A14 shows the counts and percentages of adult heart transplants by zone, era, and medical urgency status.

Figure 16. Distance Traveled at Transplant by Era

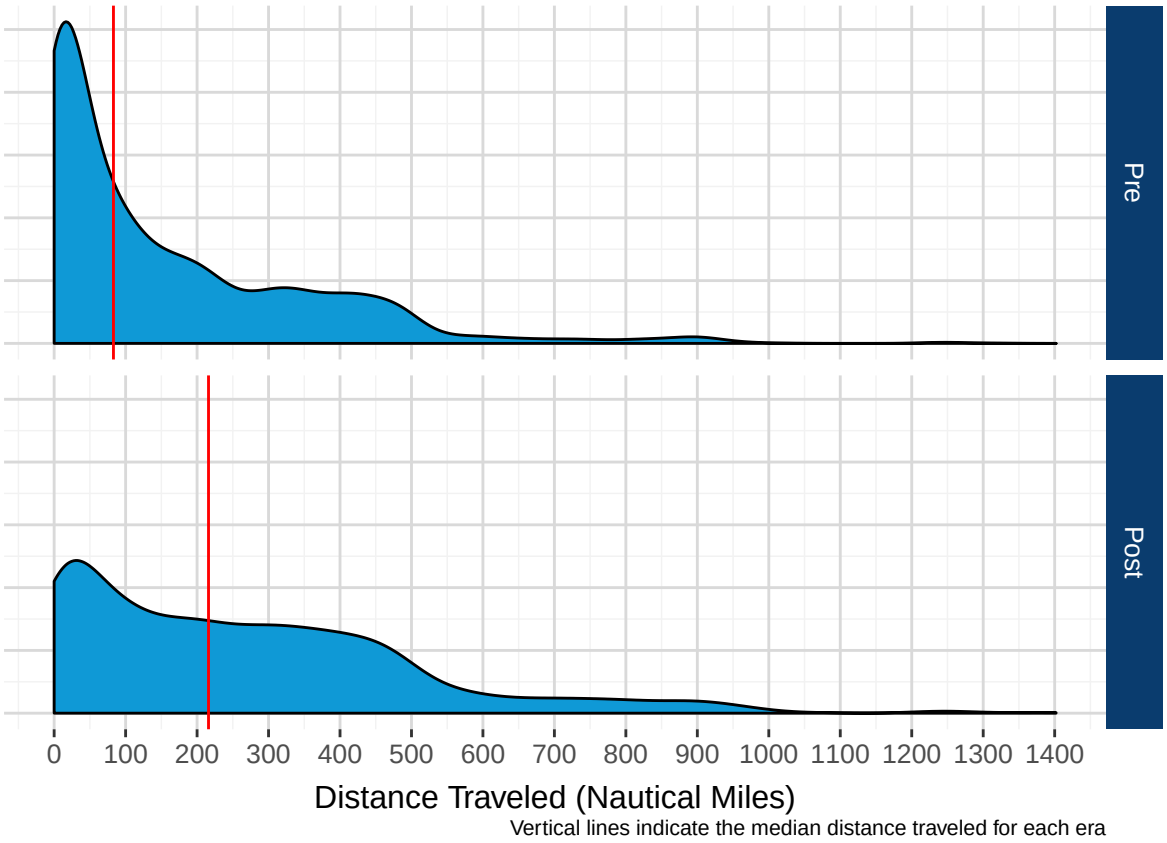


Figure 17 shows the distributions of distance traveled by hearts pre- and post-implementation. While the majority of hearts traveled less than 100 nautical miles pre-implementation, post-implementation travel distances were distributed much more evenly up to about 500 nautical miles before dropping off. The median distance traveled increased significantly ($p < 0.001$) post-implementation, from a pre-implementation median of 83 nautical miles to a post-implementation median of 216 nautical miles.

Figure 17. Total Ischemic Time at Transplant by Era

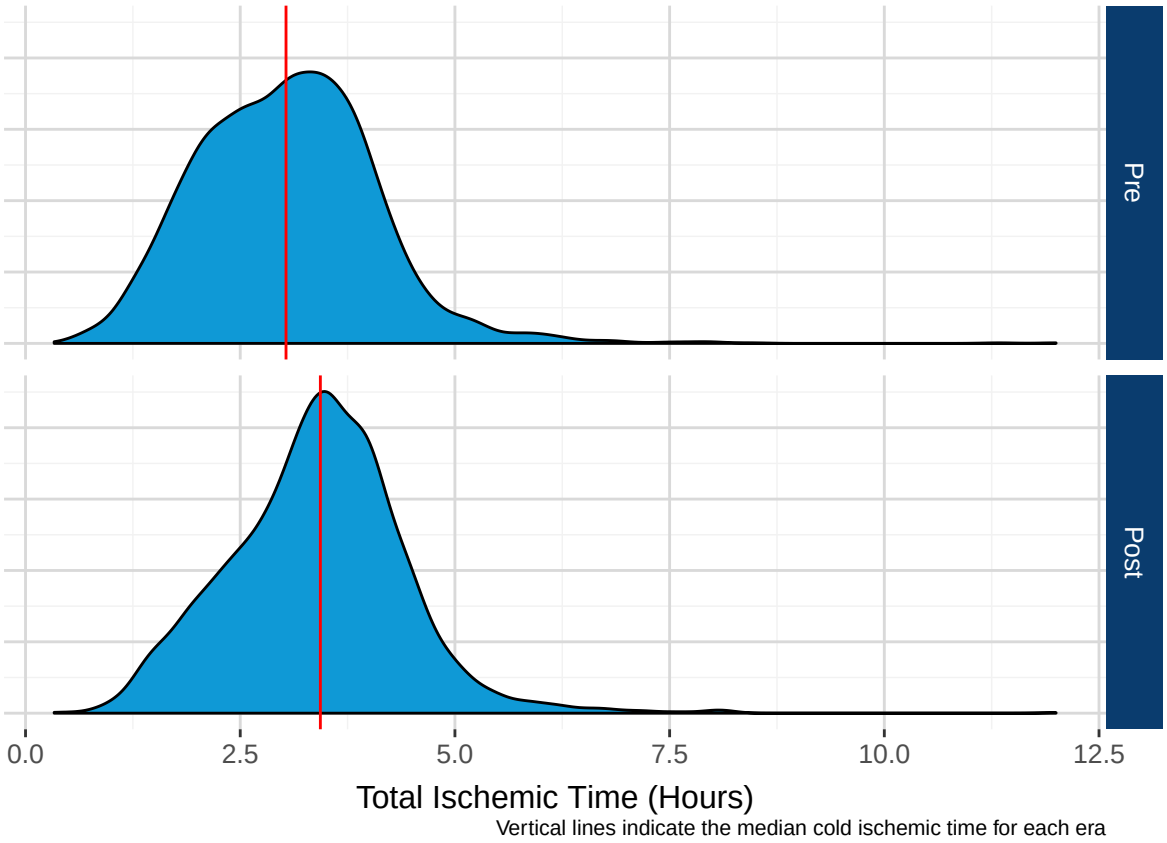
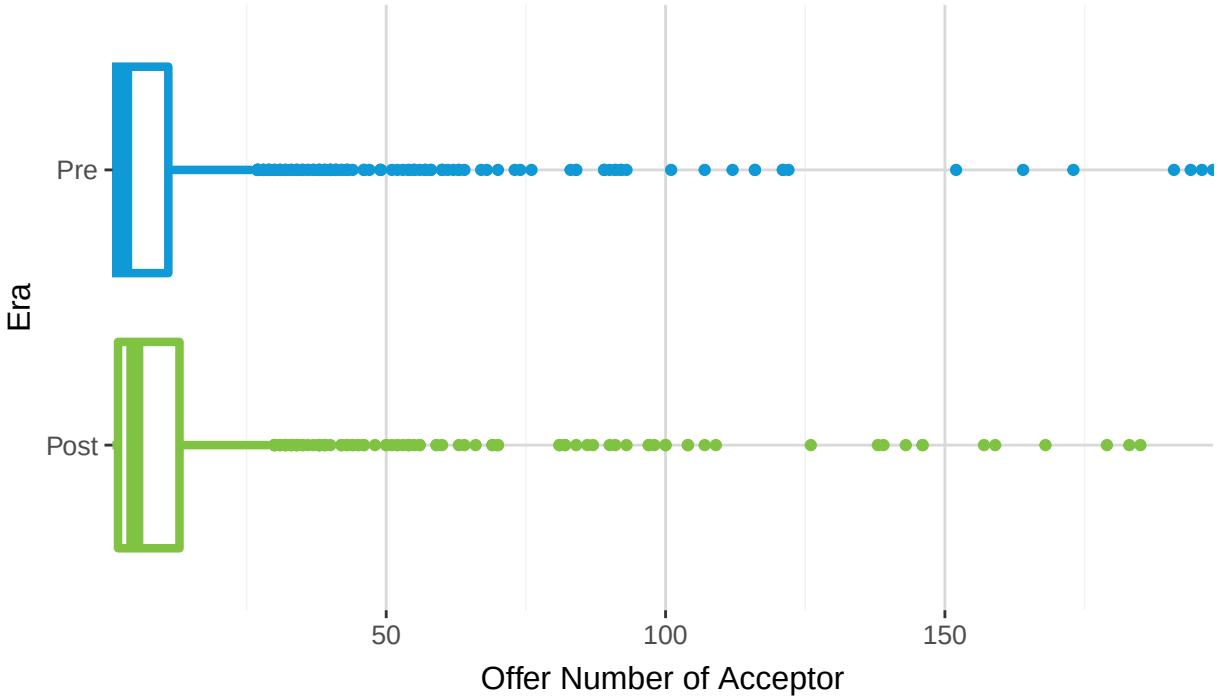


Figure 17 shows the distribution of total ischemic times at transplant both pre- and post-implementation, where total ischemic time is defined as the sum of cold ischemic time, warm ischemic time, and anastomotic time. Total ischemic times increased significantly ($p < 0.001$) post-implementation to 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.

Figure 18. Boxplot of the Sequence Number of the Acceptor for Adult Hearts



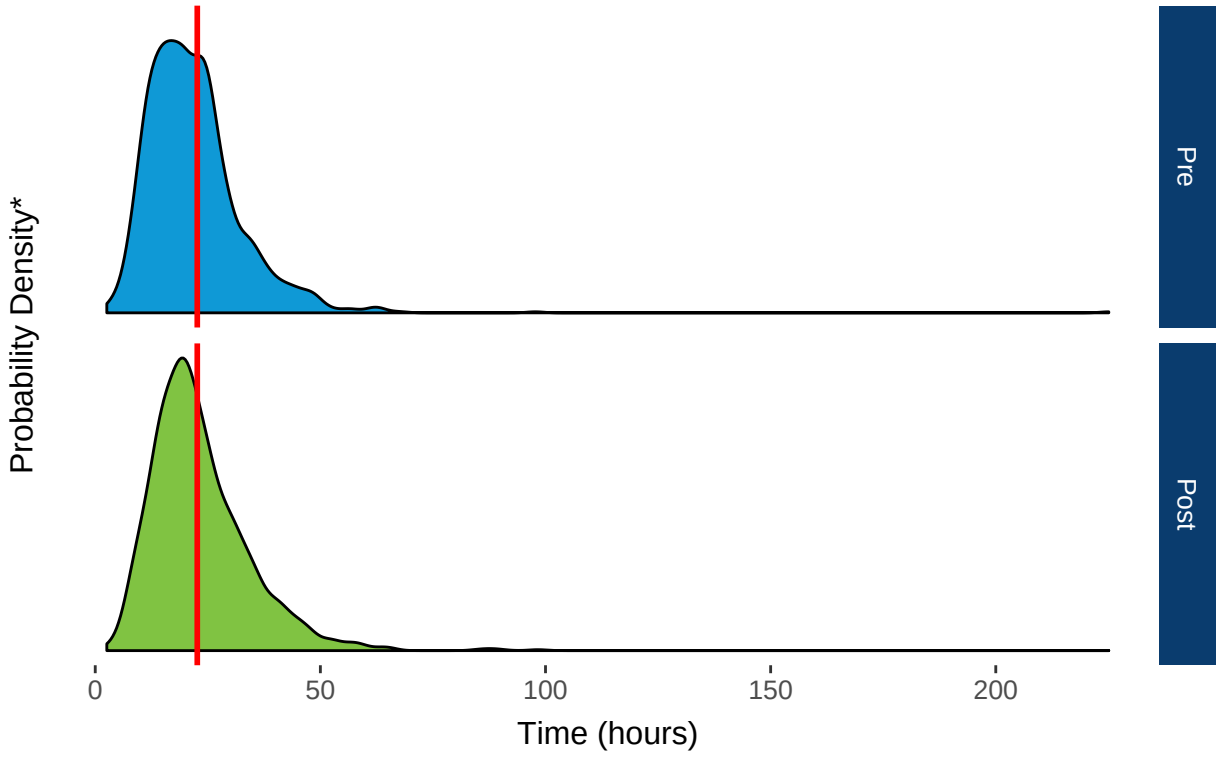
There were 8 acceptances with an offer number over 200 in the pre era and 7 in the post era (not shown)

Figure 18 shows the distribution of sequence numbers for the final acceptors of adult hearts both pre-and post-implementation. The median sequence number of the final acceptor increased slightly post-implementation (Table 8), which may have contributed to the increase in ischemic time observed post-implementation.

Table 8. Summary of the Sequence Number of the Final Acceptor for Adult Heart Donors

Era	Median	10th Percentile	90th Percentile
Pre	3	1	37
Post	5	1	34

Figure 19. 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.

Figure 19 shows 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 changed little after implementation, from 21.98 hours to 23.31.

Figure 20. Center Adult Heart Transplant Volume by Era

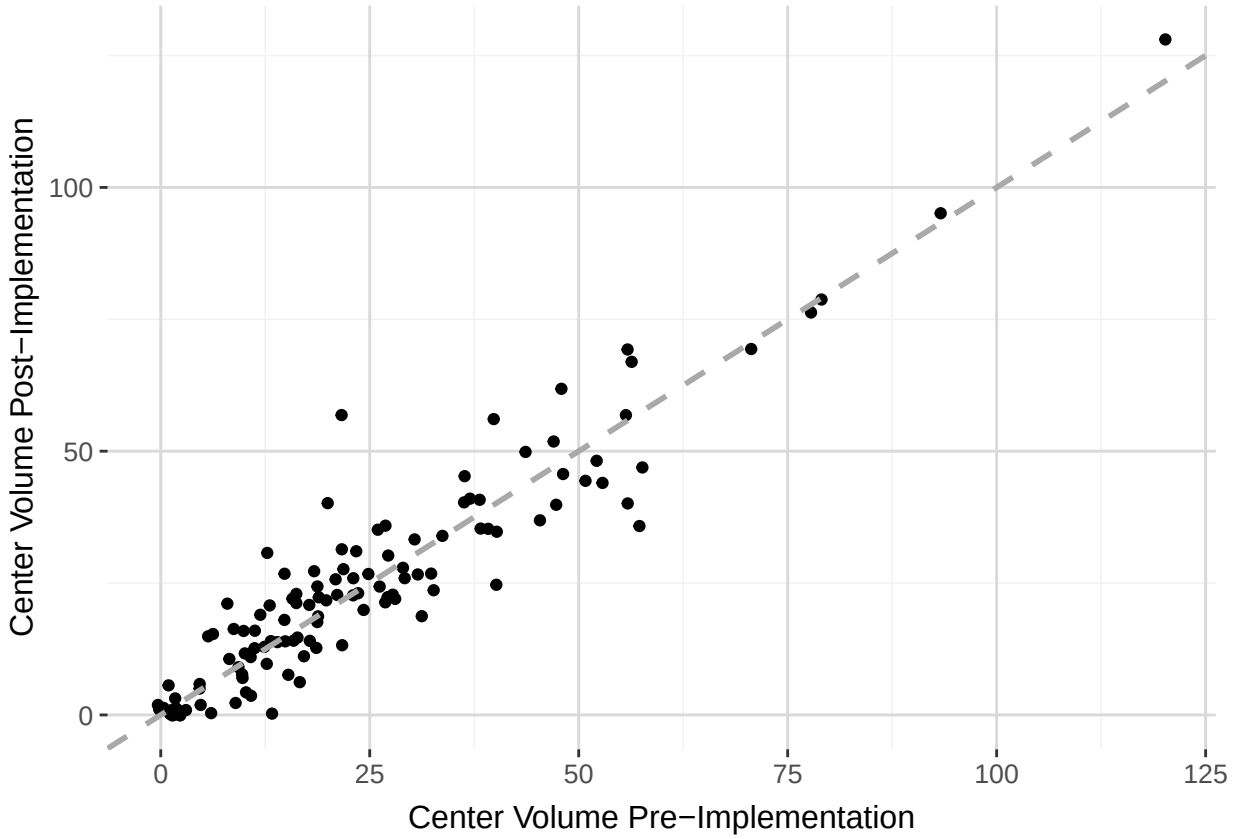


Figure 20 compares the number of adult heart transplants performed by transplant centers before and after modifications to the adult heart allocation system. Dots that fall below the diagonal gray line represent centers where transplant volume decreased post-implementation, while those above the line performed more transplants in the first year after implementation. There were 124 transplant centers that performed at least one adult heart transplant in one of the two eras. Of those, 58 performed more adult heart transplants post-implementation than they did pre-implementation. There were 56 centers that performed fewer adult heart transplants after implementation than they did pre-implementation. Of these, 26 did more than 25% fewer transplants post-implementation than they did pre-implementation.

Figure 21. Distribution of Medical Urgency Status for Patients Ever Waiting by Change in Listing Center Volume Post Implementation

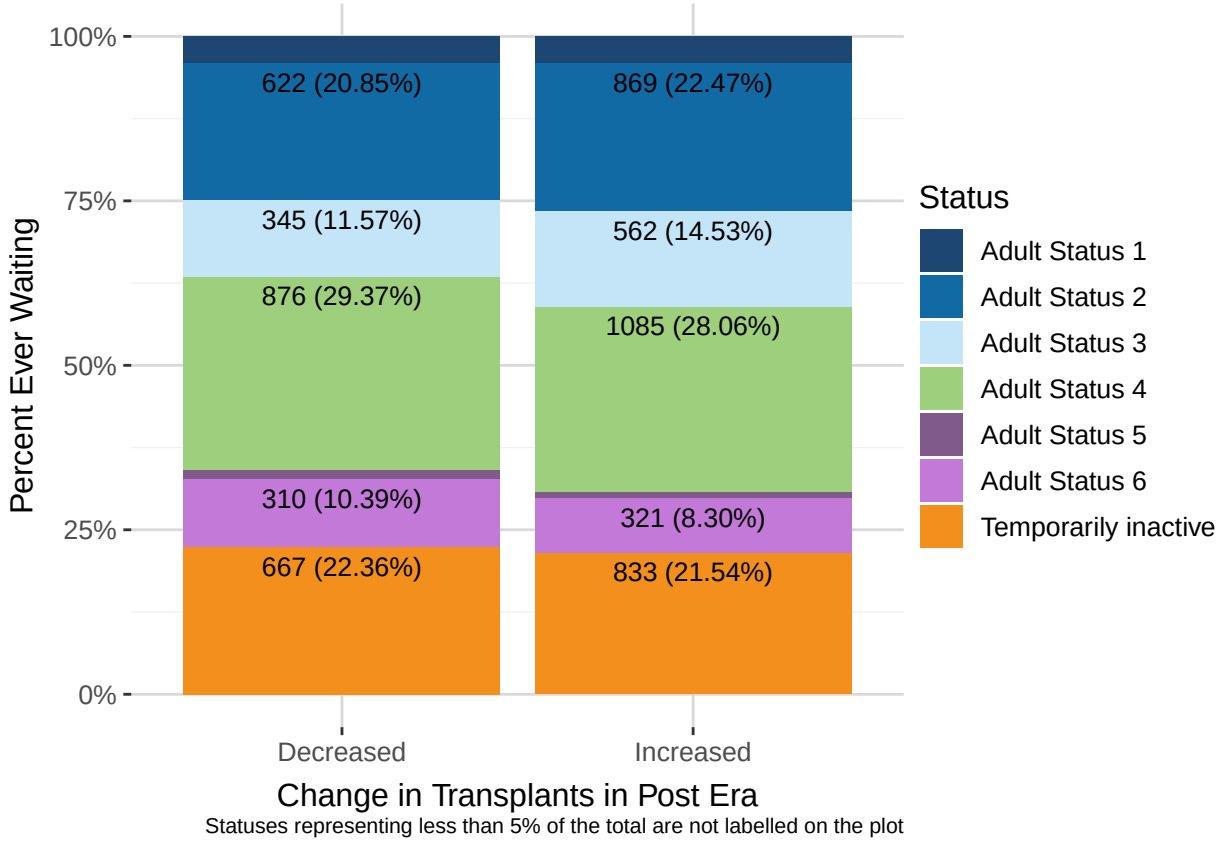


Figure 21 compares the distributions of patients ever waiting at different medical urgency statuses post-implementation at centers where the number of transplants performed post-implementation increased to the distribution at centers where the number of transplants performed post-implementation decreased. 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. The differences between the distributions of medical urgency statuses are statistically significant ($p < 0.001$). Differences in waitlist makeup may help to explain changes in the number of transplants performed by centers post-implementation.

Figure 22. Transplants per 100 Patient-Years Waiting by Medical Urgency Status and Era

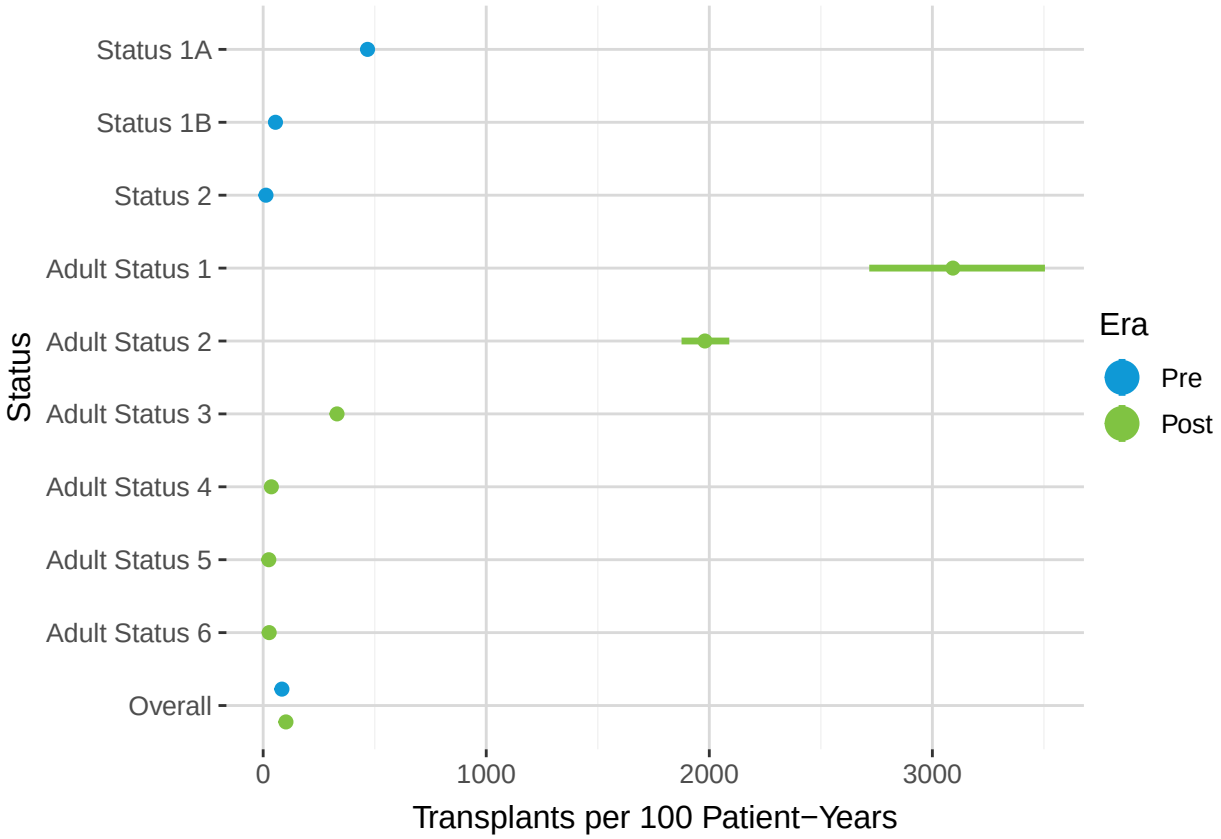


Figure 22 shows the number of transplants per 100 patient-years waiting both pre- and post-implementation. The number of transplants per 100 patient years to Adult Status 1 and Adult Status 2 recipients was significantly higher than the number of transplants per 100 patient years for any other status 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 the number of transplants per 100 patient-years waiting significantly increased post-implementation.

Table A15 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 23. Transplants per 100 Patient-Years Waiting by Region, Medical Urgency Status, and Era

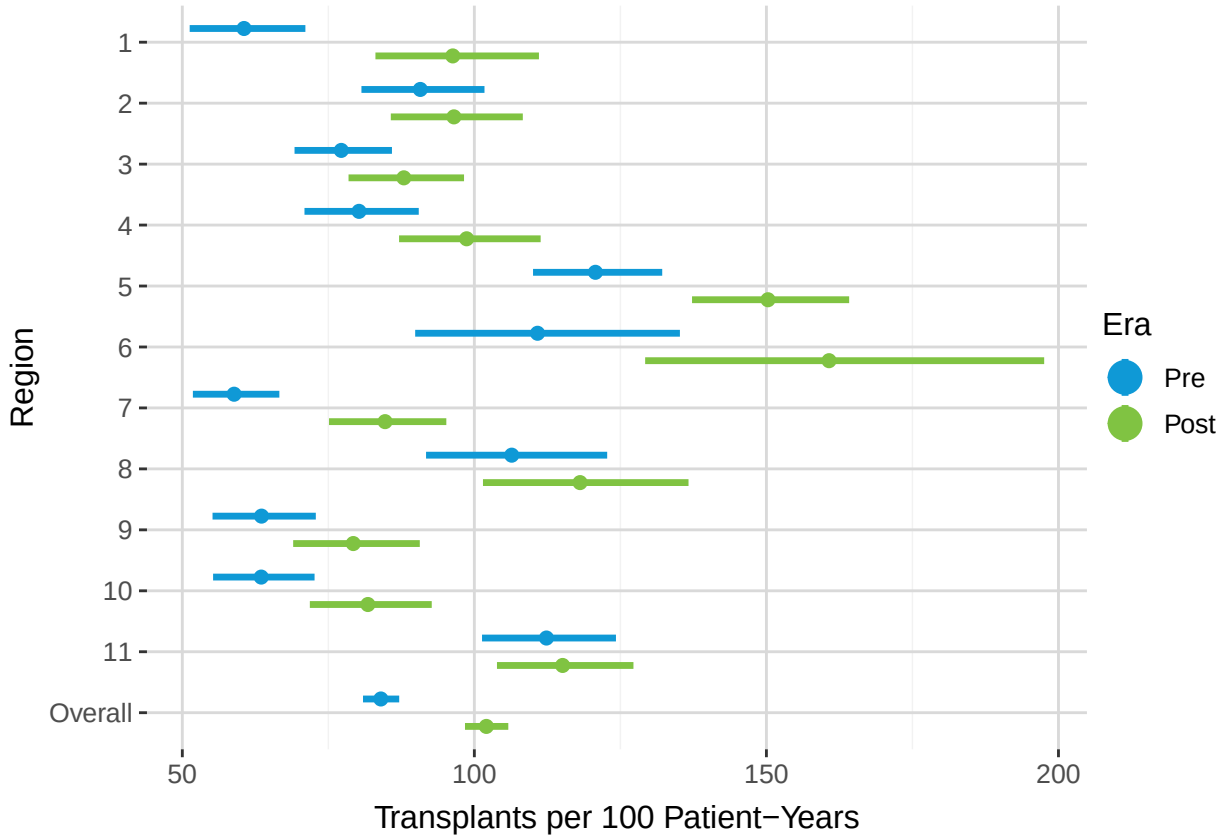


Figure 23 shows the number of transplants per 100 patient-years waiting for each region pre- and post-implementation. The number of transplants per 100 patient-years rose significantly for regions 1, 5, and 7.

Table A16 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 deaths per 100 patient-years, the relative risk of death, and the 95% confidence interval around the relative risk of death. The relative risk of transplant rose significantly for regions 1, 4, 5, 6, 7, and 10. The overall relative risk of transplant also rose significantly to 1.22 times what it was pre-implementation.

Table 9. Median Days to Transplant by Medical Urgency Status and Era

Era	Status	Days Waiting
Pre	Status 1A	56
	Status 1B	201
	Status 2	**
Pre	**Overall**	**198**
Post	Adult Status 1	4
	Adult Status 2	9
	Adult Status 3	27
	Adult Status 4	262
	Adult Status 5	**
	Adult Status 6	**
Post	**Overall**	**111**

Note:
"**" indicates that median time to transplant could not be calculated because fewer than 50% of candidate registrations at this status had received a transplant within one year

Figure 9 shows a competing risks analysis of the median days waiting before transplant by status both pre- and post-implementation, where days waiting is total days on the waiting list, regardless of active status. Pre-implementation the shortest wait to transplant was for Status 1A candidates, with a median wait time of 56 days. Post-implementation all of Adult Status 1, Adult Status 2, and Adult Status 3 had shorter median wait times, at 4, 9, and 27 days, respectively. Overall the median days waiting before transplant fell from 198 to 111, a 44% decrease.

Figure 24. Median Days to Transplant by Region and Era

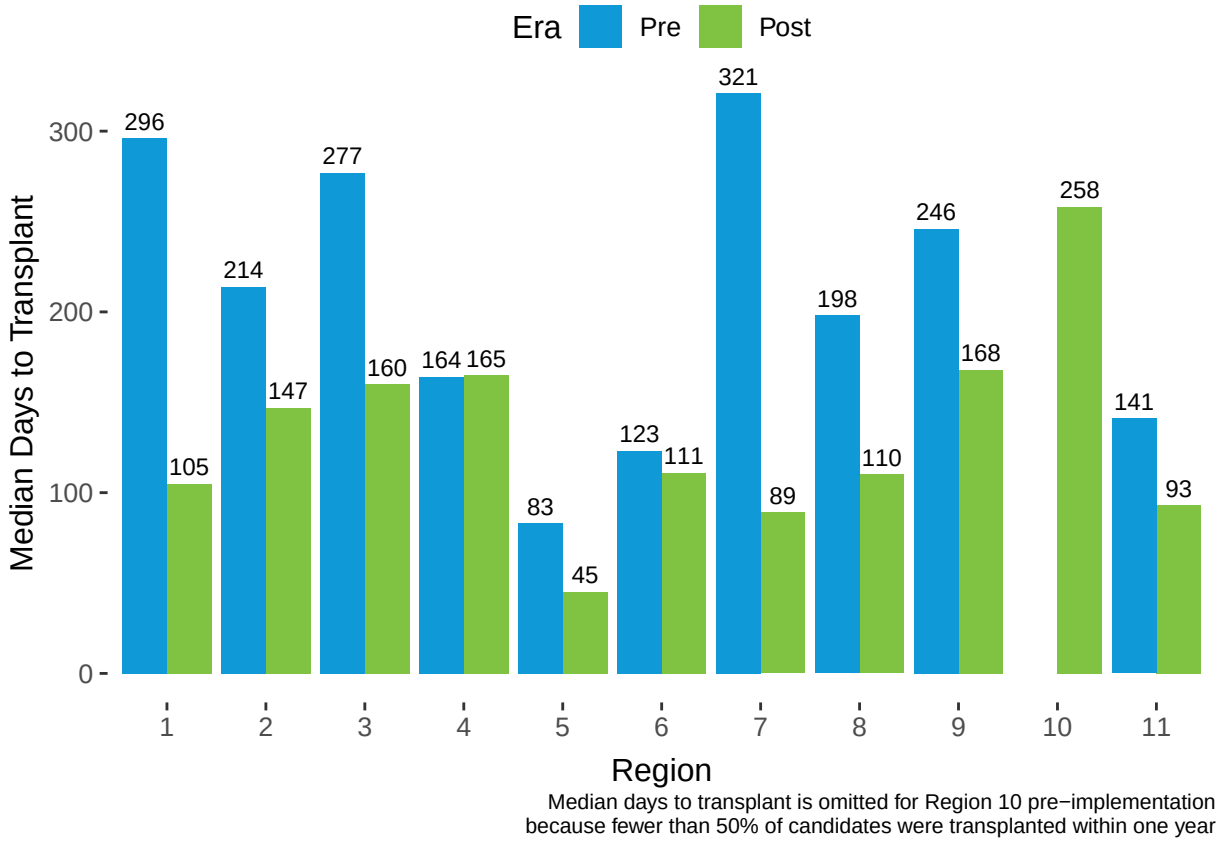


Figure 24 shows a competing risks analysis of the median days waiting before transplant by status and region. The median time to transplant declined in all regions except region 4, where it was similar both pre- and post-implementation. The largest decrease in median days waited to transplant was seen in region 7, where the median wait time decreased from 321 days to 89 days.

Utilization

This chapter examines differences in heart utilization between two donor cohorts: the 9771 deceased donors with at least one organ recovered for the purpose of transplant between October 18, 2017 and October 17, 2018 (pre-implementation); and the 10685 deceased donors with a least one organ recovered for the purpose of transplant between October 18, 2018 and October 17, 2019 (post-implementation).

Tables 10 and 11 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 recovered 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 non-DCD donors. There was little change in utilization or discard in the post-implementation era.

Table 10. Utilization and Discard Rates for Adult Heart Donors by Era

Era	Utilization	Discard
Pre	29.58%	0.79%
Post	28.49%	0.94%

Table 11. Utilization and Discard Rates for Non-DCD Adult Heart Donors by Era

Era	Utilization	Discard
Pre	36.96%	0.79%
Post	36.76%	0.91%

Figure 25. Utilization Rates for Adult Heart Donors by Region and Era

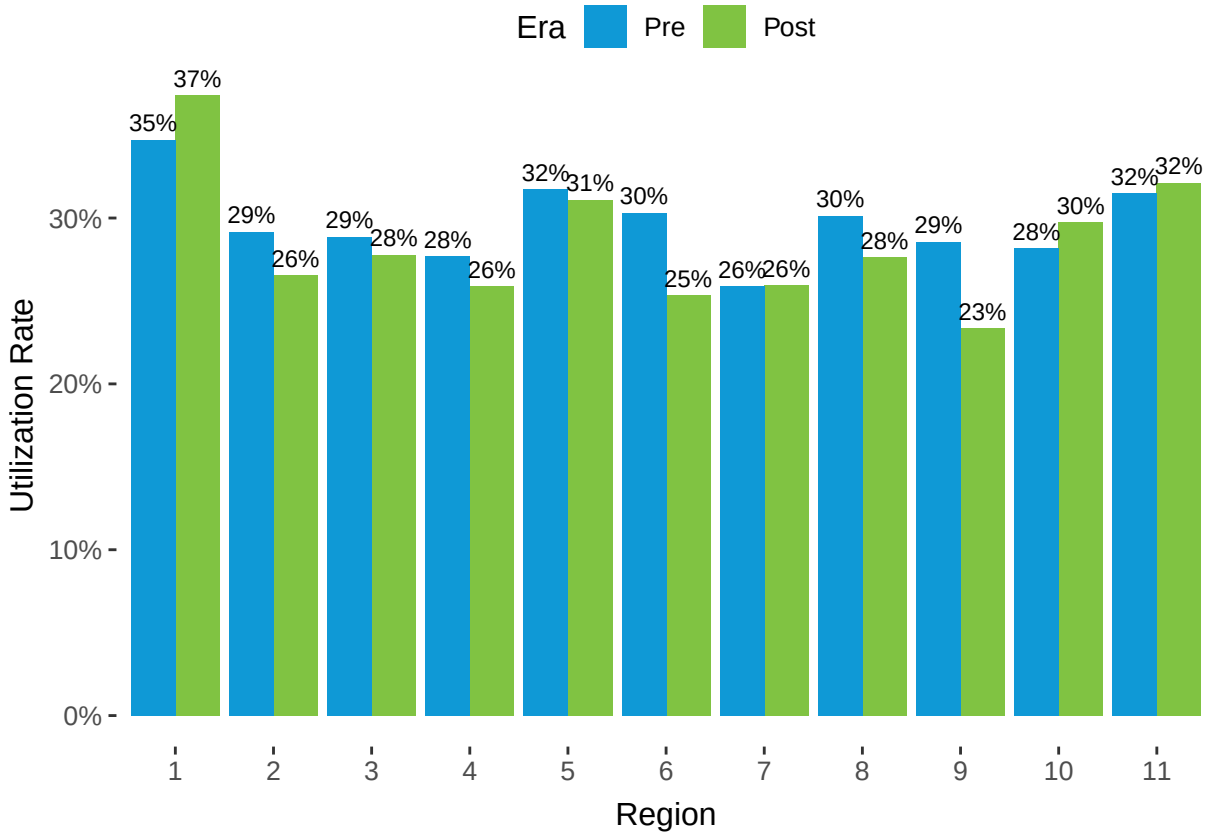


Figure 25 shows utilization rates of adult hearts by region both pre- and post-implementation. Utilization rates rose in region 1, fell in rgions 2, 6, and 9, and remained similar in other regions.

Figure 26. Utilization Rates for Non-DCD Adult Heart Donors by Region and Era

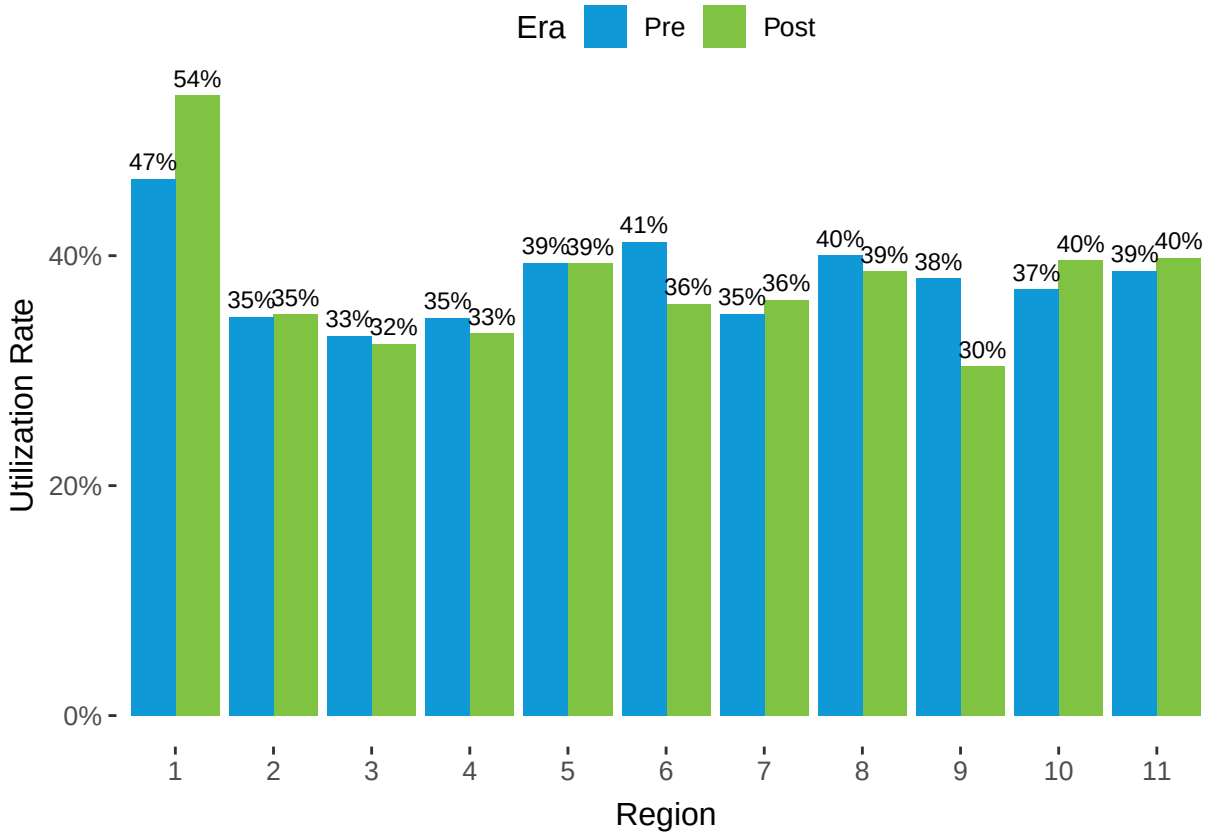


Figure 26 shows utilization rates of adult hearts by region both pre- and post-implementation for non-DCD donors only. Utilization rates are higher for non-DCD donors than for donors overall and rose in regions 1 and 10 while falling in region 6 and region 9. The non-DCD adult heart utilization rate remained similar across eras in all other regions.

Figure 27. Utilization Rates for Adult Heart Donors by Donor Age and Era

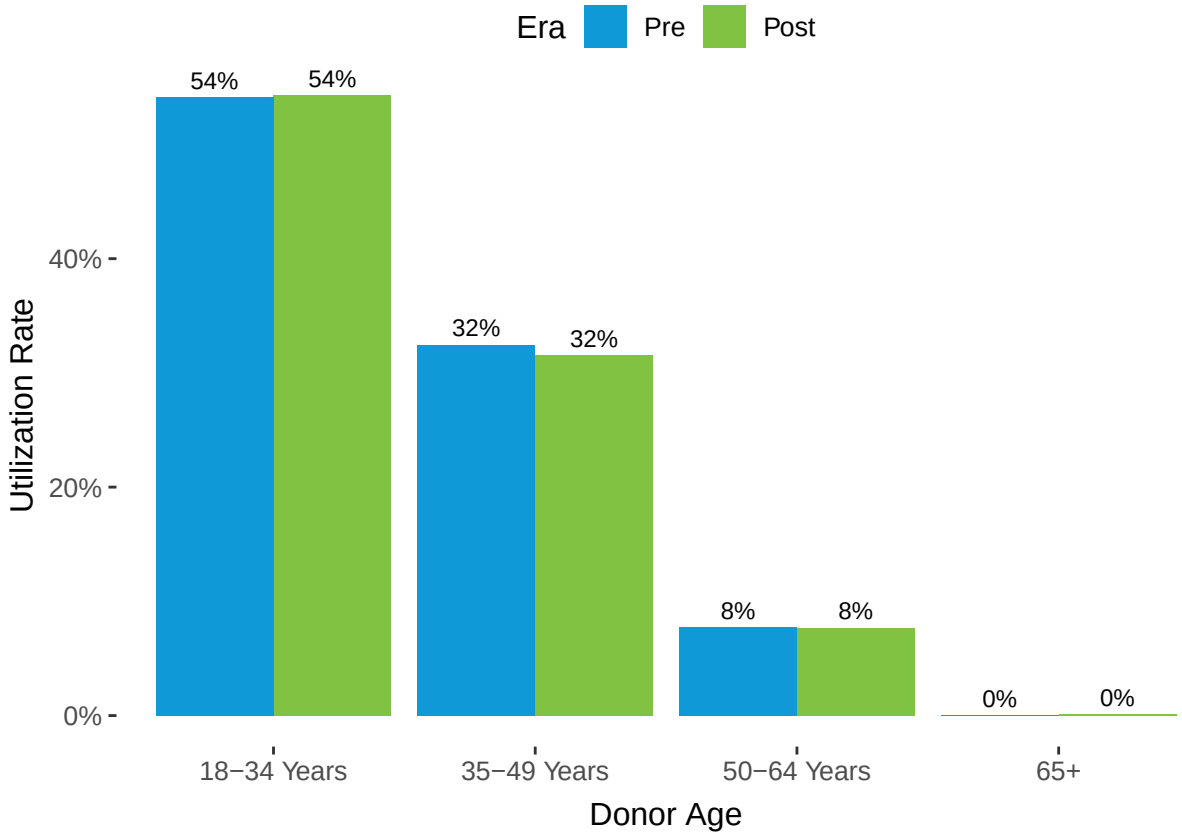


Figure 27 shows the utilization rates for adult hearts both pre- and post-implementation by donor age. There was little change in adult heart utilization in any donor age group.

Figure 28. Utilization Rates for Adult Non-DCD Heart Donors by Donor Age and Era

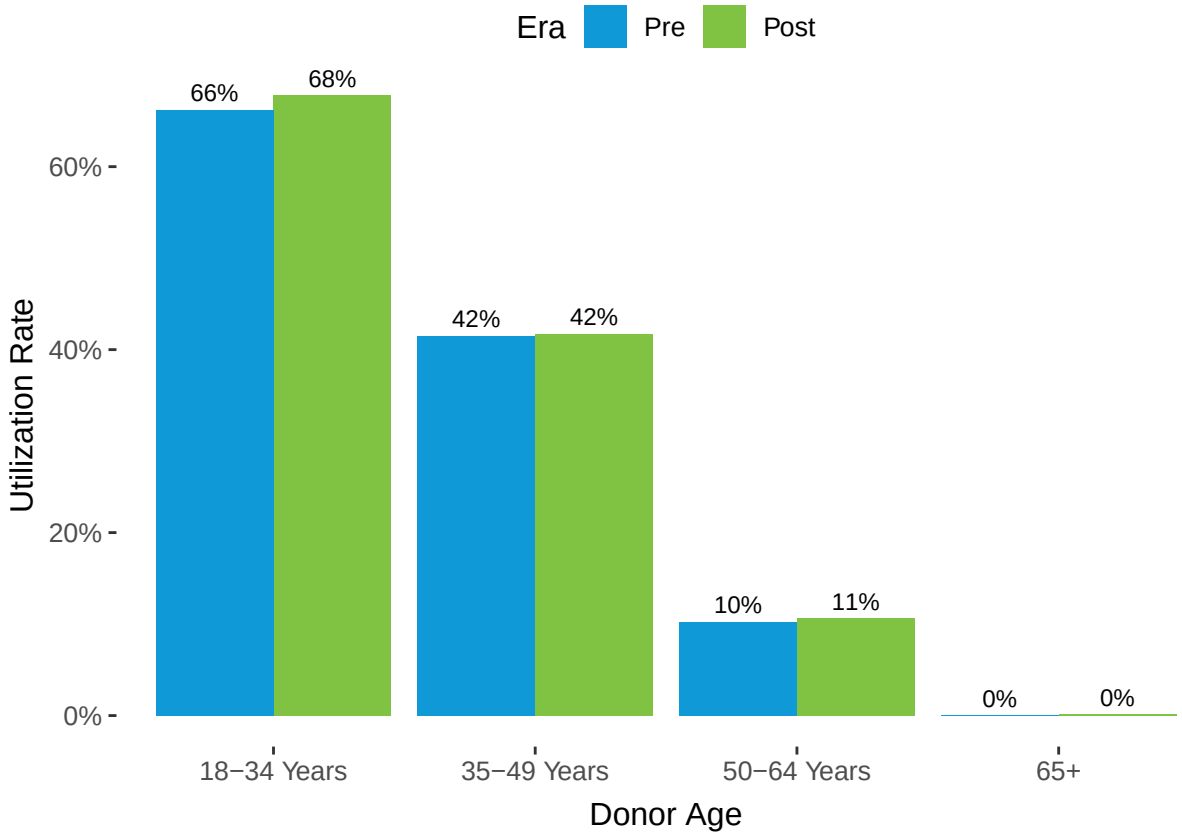


Figure 28 shows the utilization rates for adult hearts from non-DCD donors both pre- and post-implementation by donor age. Utilization rates rose slightly for all age groups post-implementation.

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 1658 adult heart recipients transplanted between October 18, 2017 and May 17, 2018 (pre-implementation) and the 1689 adult heart recipients transplanted between October 18, 2018 and May 17, 2019 (post-implementation).

Figure 29. Six-Month Graft Survival

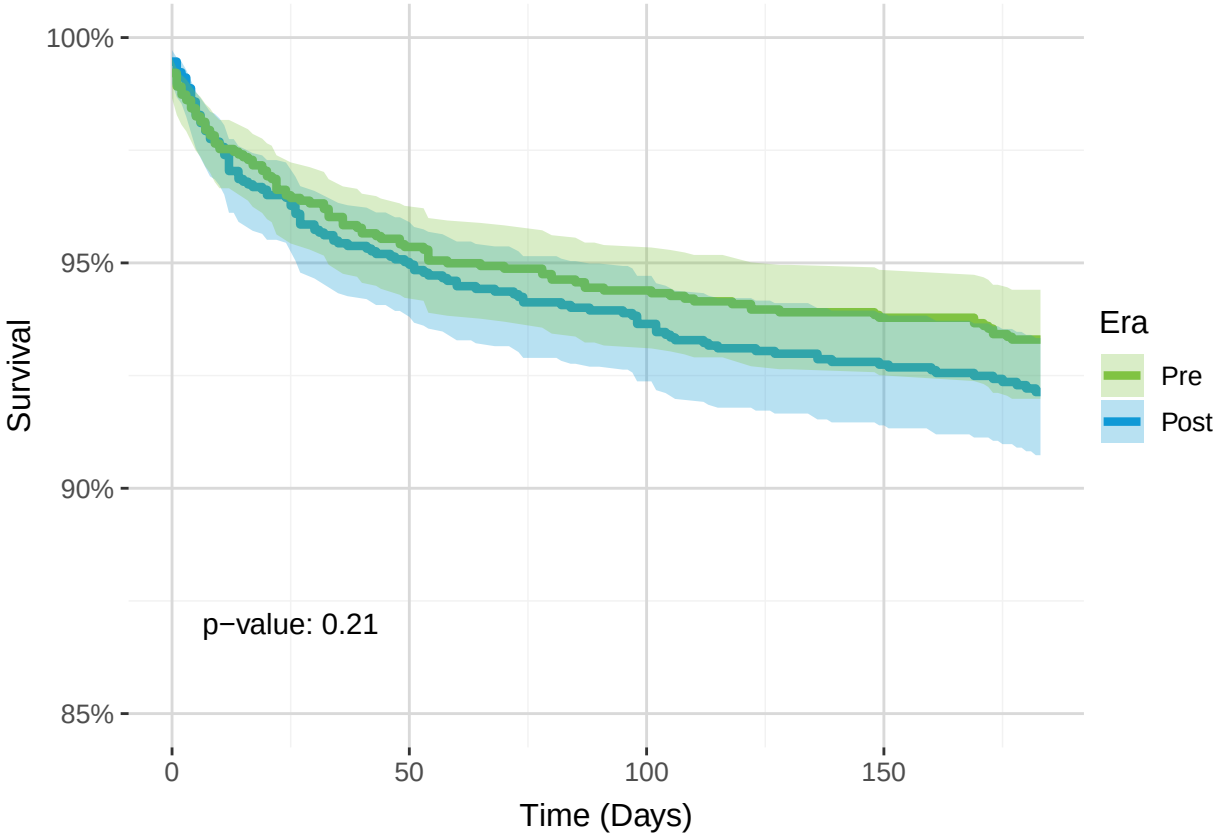


Figure 29 shows the six-month graft survival for adult heart recipients pre- and post-implementation. There was no significant difference in graft survival between the two eras.

Six-month graft survival in the pre era was 93.3% compared to 92.14% in the post era. The difference is not statistically significant ($p = 0.21$).

Figures 30 and 31 show the six-month graft survival for different medical urgency statuses pre- and post-implementation, respectively.

Figure 30. Six-Month Graft Survival by Medical Urgency Status Pre-Implementation

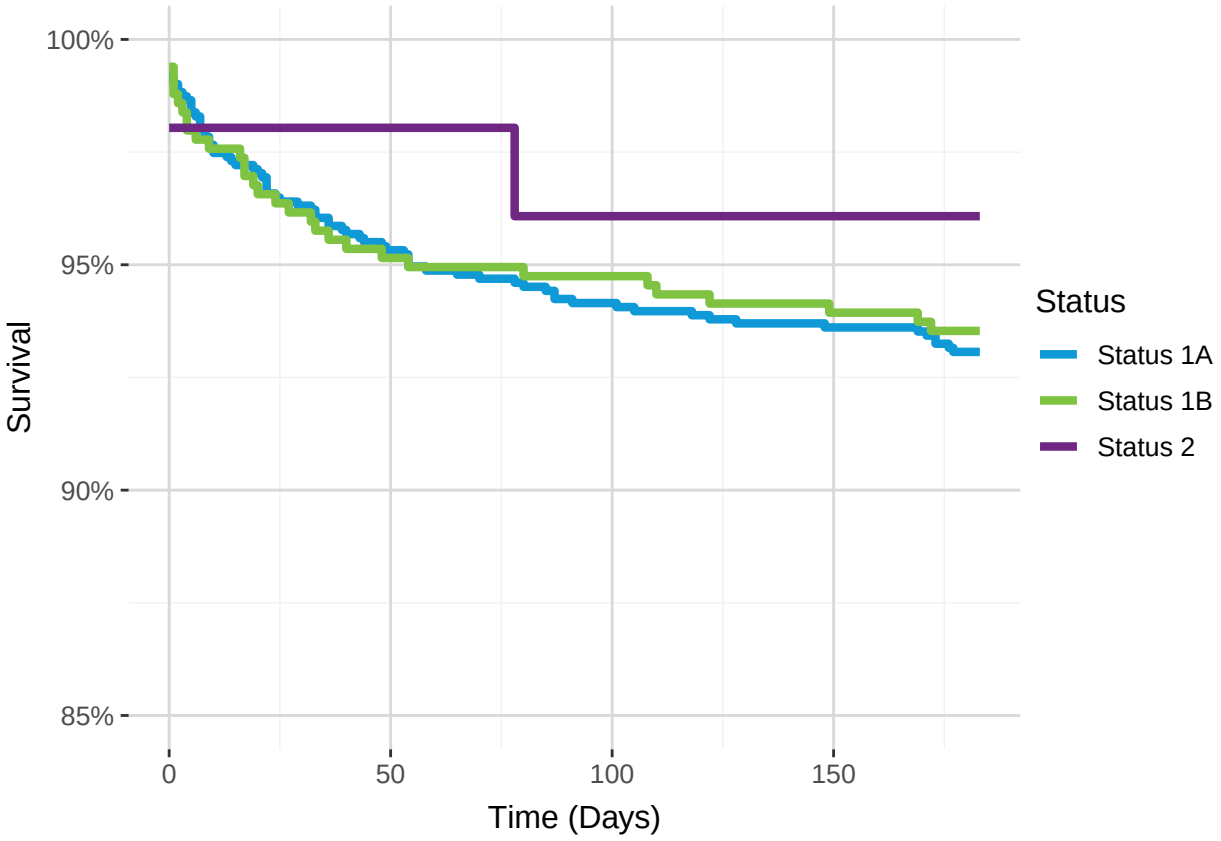
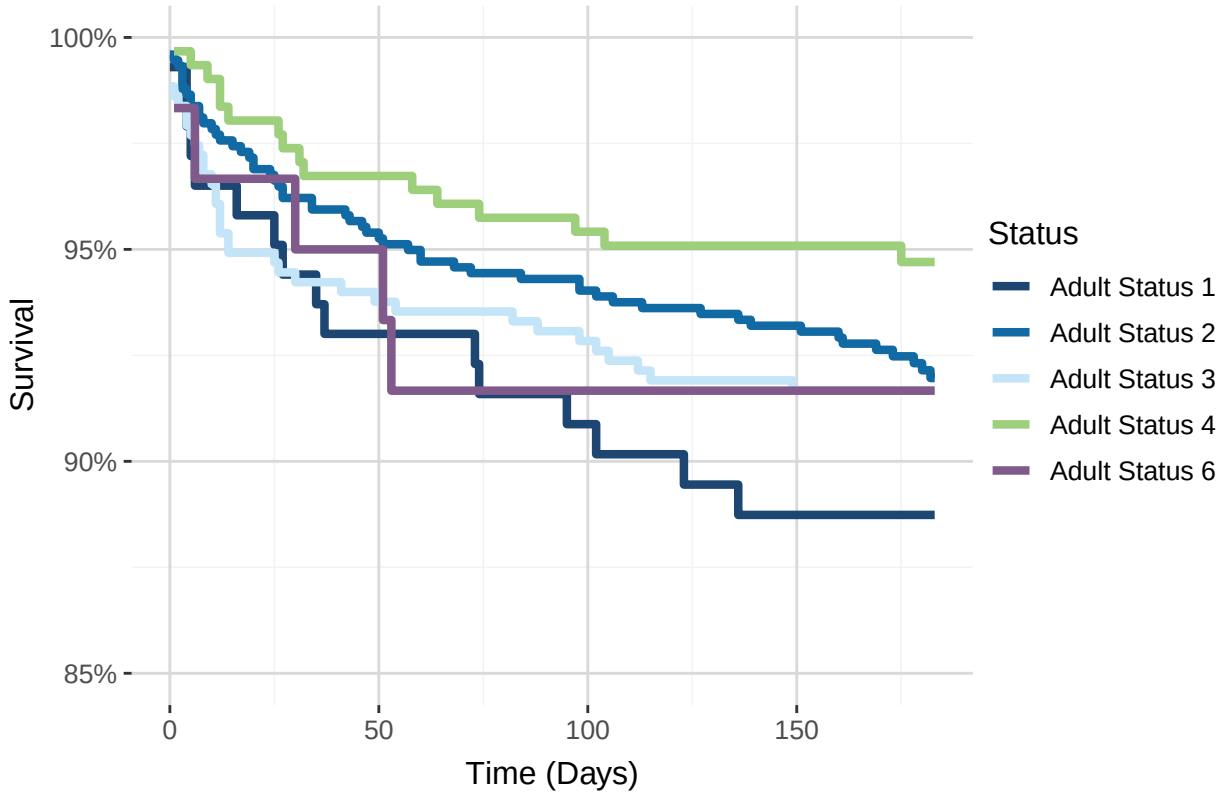


Figure 31. Six-Month Graft Survival by Medical Urgency Status Post-Implementation



After 149 days waiting, survival for Adult Status 3 is the same as for Adult Status 6
Adult Status 5 is omitted because there were too few adult heart recipients to accurately estimate survival

Figure 32. Six-Month Patient Survival

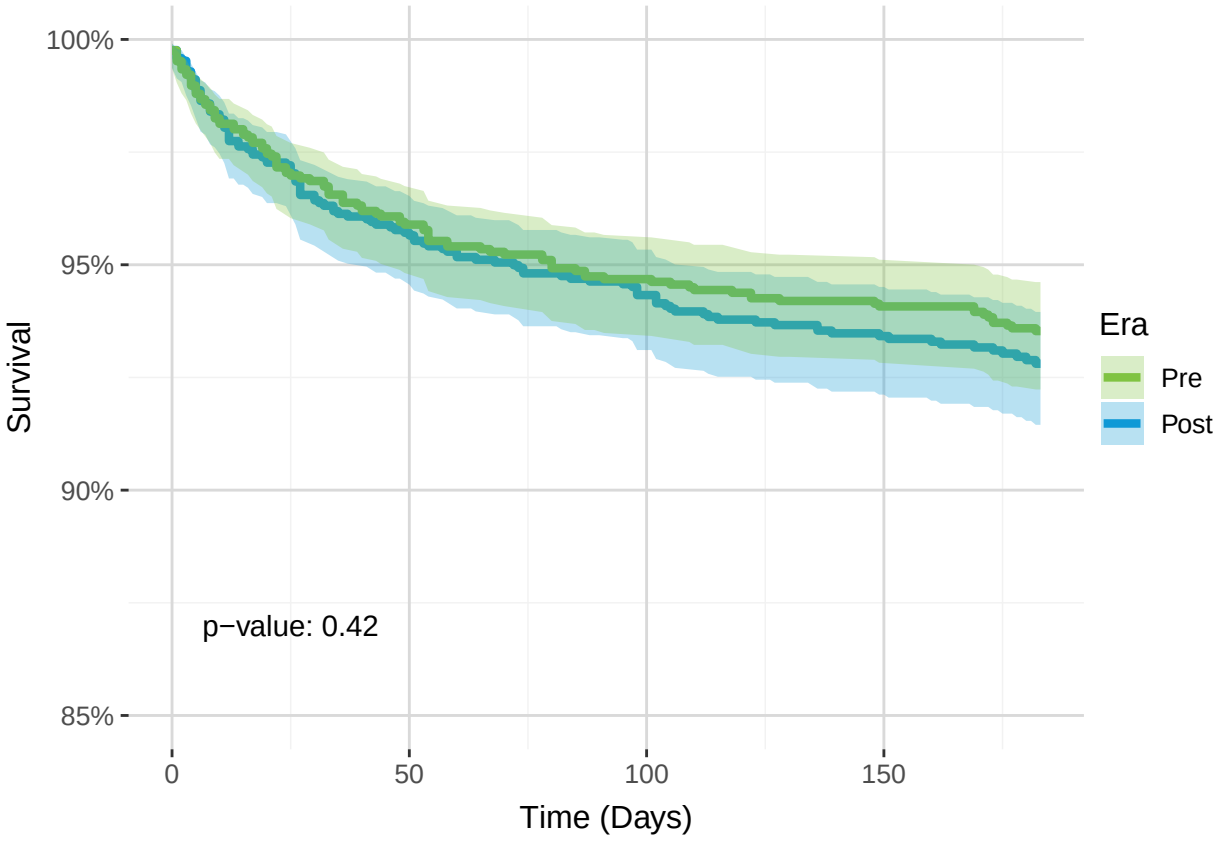


Figure 32 shows the six-month patient survival for adult heart recipients pre- and post-implementation. There was no significant difference in patient survival between the two eras.

Six-month graft survival in the pre era was 93.53% compared to 92.81% in the post era. The difference is not statistically significant ($p = 0.42$).

Figures 33 and 34 show the six-month patient survival for different medical urgency statuses pre- and post-implementation, respectively.

Figure 33. Six-Month Patient Survival by Medical Urgency Status Pre-Implementation

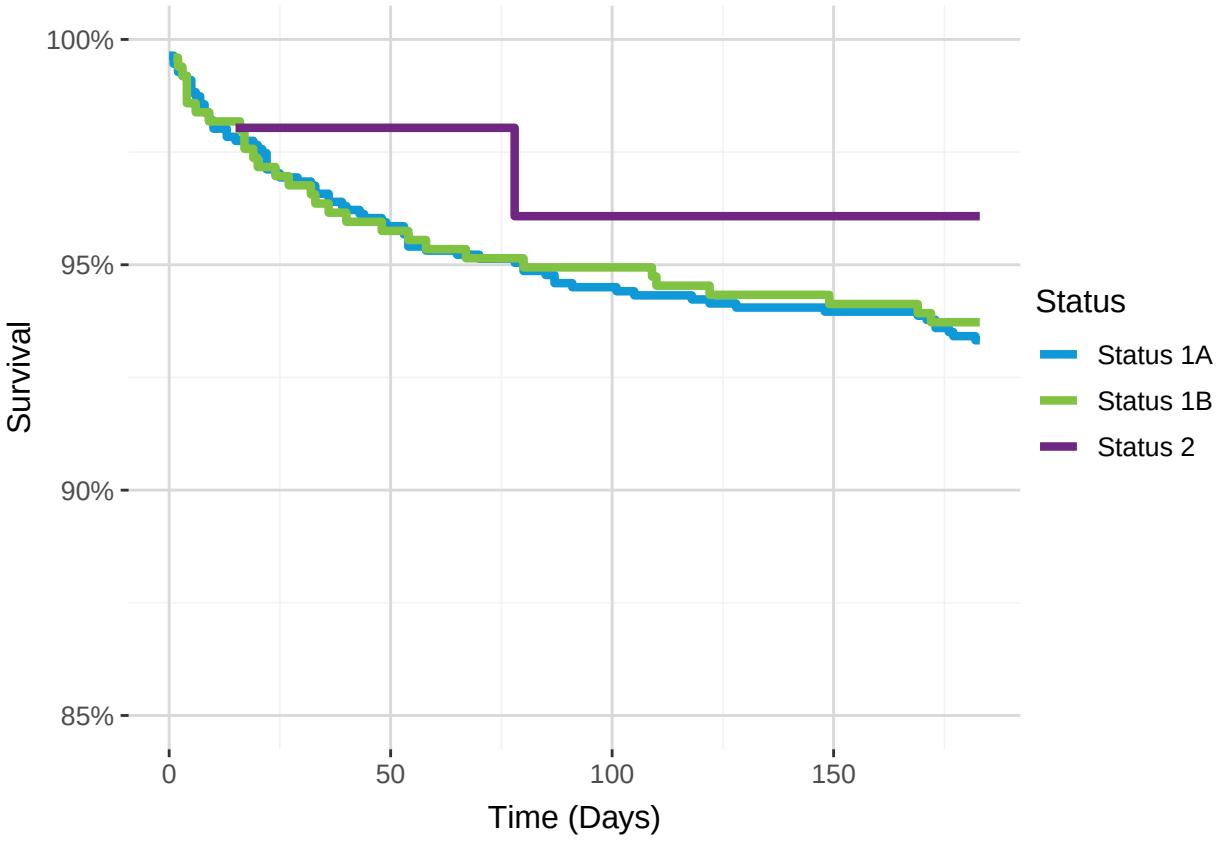
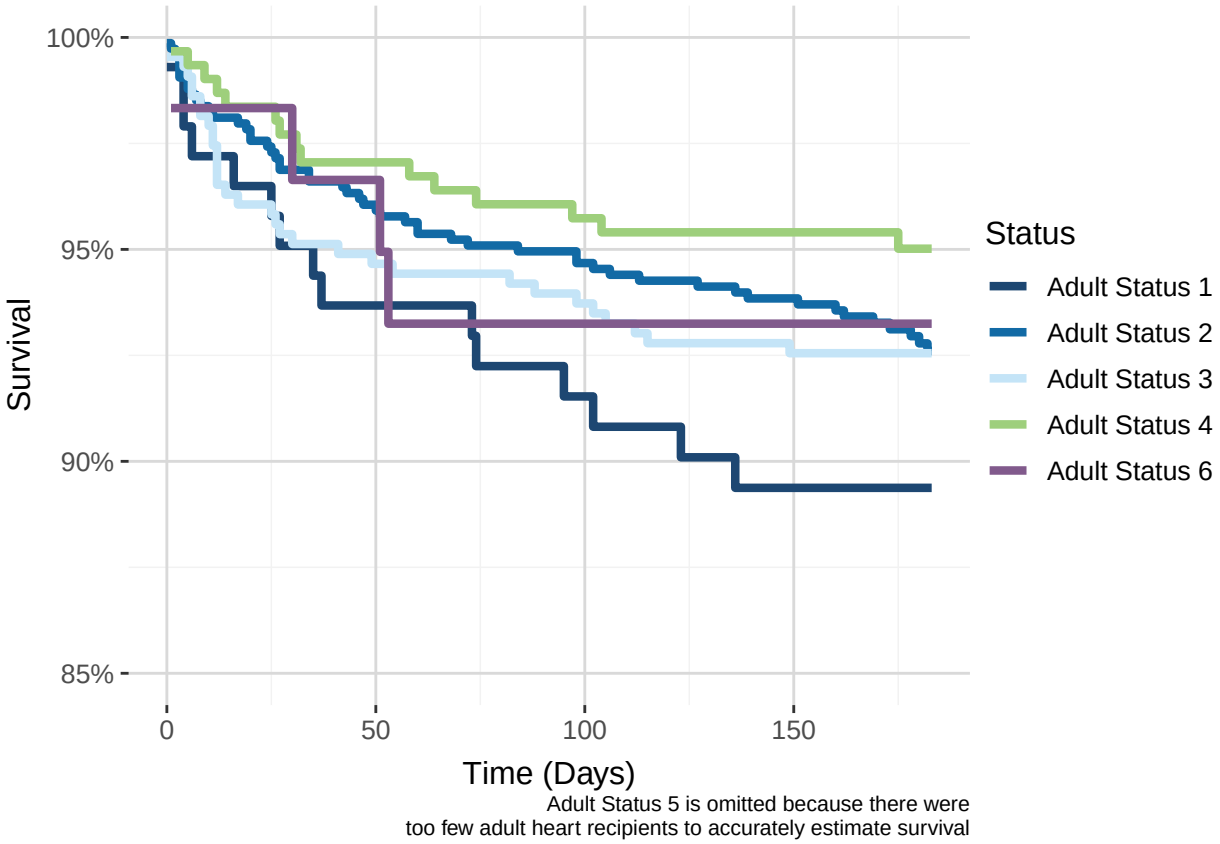


Figure 34. Six-Month Patient Survival by Medical Urgency Status Post-Implementation



Regional Review Board

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 October 17, 2019. There were 3921 adult heart justification forms submitted to the Heart Regional Review Board during this time.

Figure 35 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 an exception/extension request.

Figure 35. Number of distinct justification forms by medical urgency status and month form was submitted

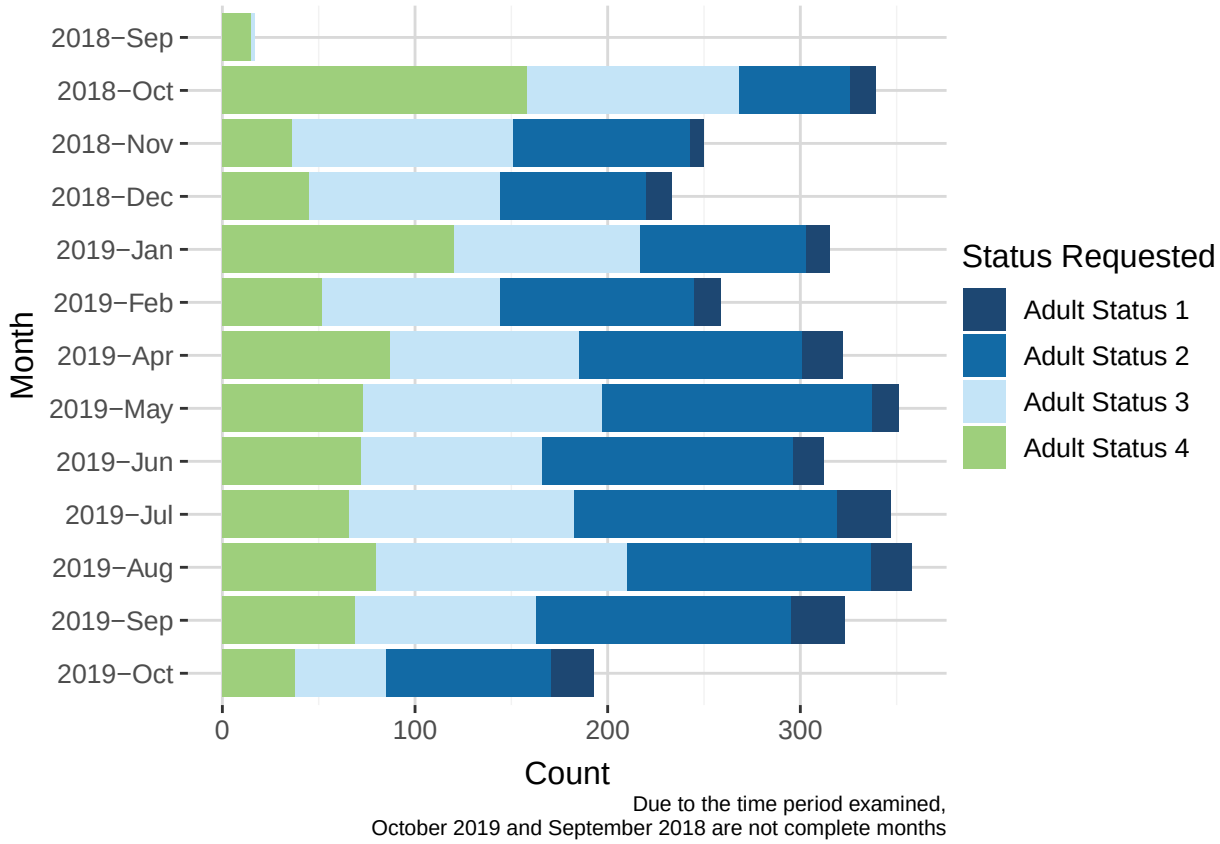


Table 12 summarizes the number and percent of distinct justification forms submitted by medical urgency status and month of submission. Adult Status 2 represents the largest number of forms submitted, followed closely by Adult Statuses 3 and 4.

Table 12. Number of distinct justification forms by medical urgency status and month form was submitted

Adult Heart Status	2018-Sep	2018-Oct	2018-Nov	2018-Dec	2019-Jan	2019-Feb	2019-Mar	2019-Apr	2019-May	2019-Jun	2019-Jul	2019-Aug	2019-Sep	2019-Oct	Total
Adult Status 1	0 (0.0%)	13 (3.8%)	7 (2.8%)	13 (5.6%)	12 (3.8%)	14 (5.4%)	16 (5.3%)	21 (6.5%)	14 (4.0%)	16 (5.1%)	28 (8.1%)	21 (5.9%)	28 (8.7%)	22 (11.4%)	225 (5.7%)
Adult Status 2	0 (0.0%)	58 (17.1%)	92 (36.8%)	76 (32.6%)	86 (27.3%)	101 (39.0%)	121 (40.1%)	116 (36.0%)	140 (39.9%)	130 (41.7%)	136 (39.2%)	127 (35.5%)	132 (40.9%)	86 (44.6%)	1401 (35.7%)
Adult Status 3	2 (11.8%)	110 (32.4%)	115 (46.0%)	99 (42.5%)	97 (30.8%)	92 (35.5%)	106 (35.1%)	98 (30.4%)	124 (35.3%)	94 (30.1%)	117 (33.7%)	130 (36.3%)	94 (29.1%)	47 (24.4%)	1325 (33.8%)
Adult Status 4	15 (88.2%)	158 (46.6%)	36 (14.4%)	45 (19.3%)	120 (38.1%)	52 (20.1%)	59 (19.5%)	87 (27.0%)	73 (20.8%)	72 (23.1%)	66 (19.0%)	80 (22.3%)	69 (21.4%)	38 (19.7%)	970 (24.7%)
Total	17 (100.0%)	339 (100.0%)	250 (100.0%)	233 (100.0%)	315 (100.0%)	259 (100.0%)	302 (100.0%)	322 (100.0%)	351 (100.0%)	312 (100.0%)	347 (100.0%)	358 (100.0%)	323 (100.0%)	193 (100.0%)	3921 (100.0%)

Figure 36 and Table 13 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 condition of the candidates remains 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. Adult Status 2 was the most commonly requested medical urgency status, followed by Adult Status 3. Adult Status 1 was the least common.

Figure 36. Number of justification forms by medical urgency status and form type

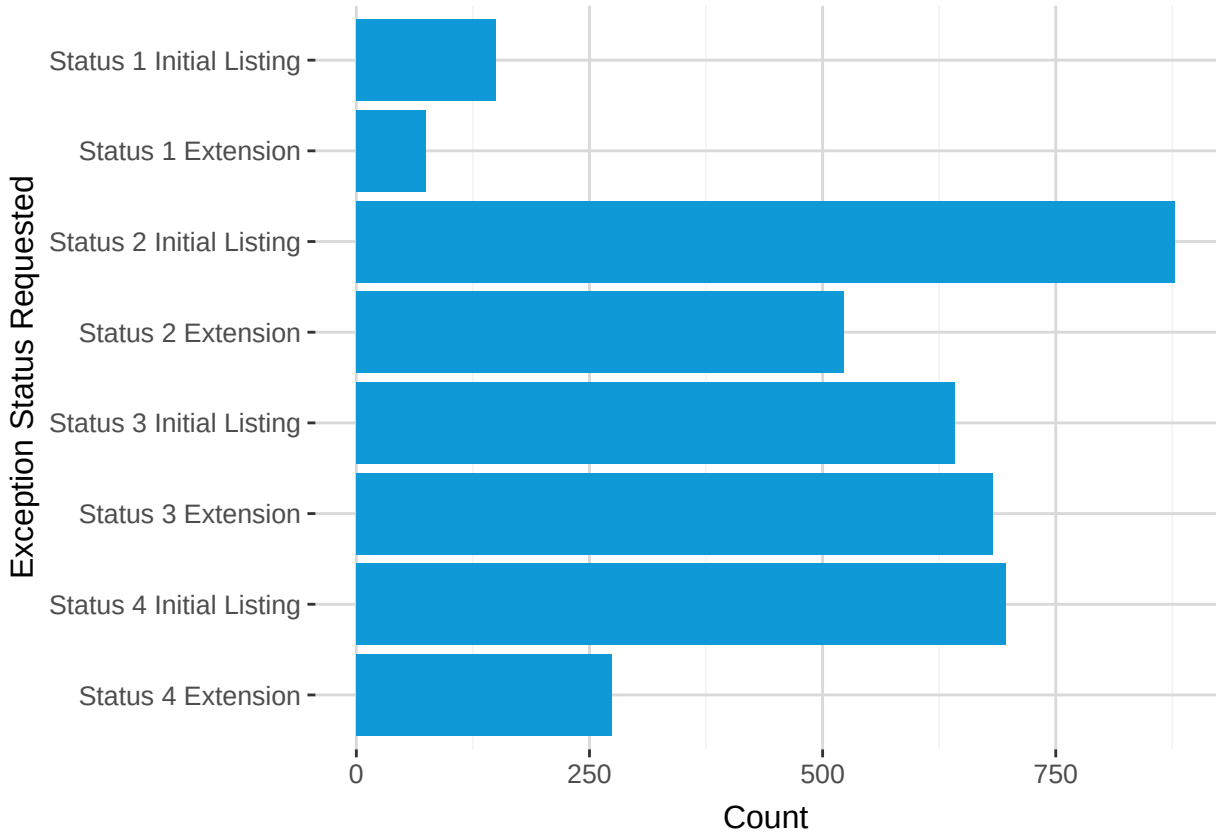


Table 13. Number of justification forms by medical urgency status and form type

Adult Heart Status and Form Type	Number of Justification Forms	Percent
Status 1 Initial Listing	150	3.8%
Status 1 Extension	75	1.9%
Status 2 Initial Listing	878	22.4%
Status 2 Extension	523	13.3%
Status 3 Initial Listing	642	16.4%
Status 3 Extension	683	17.4%
Status 4 Initial Listing	696	17.8%
Status 4 Extension	274	7.0%
Total	3921	100.0%

Under the new adult heart allocation system some "standard" justification forms are required by policy to be reviewed by the RRB. Figure 37 and Table 14 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 37. Number of justification forms by exception versus standard review and heart status

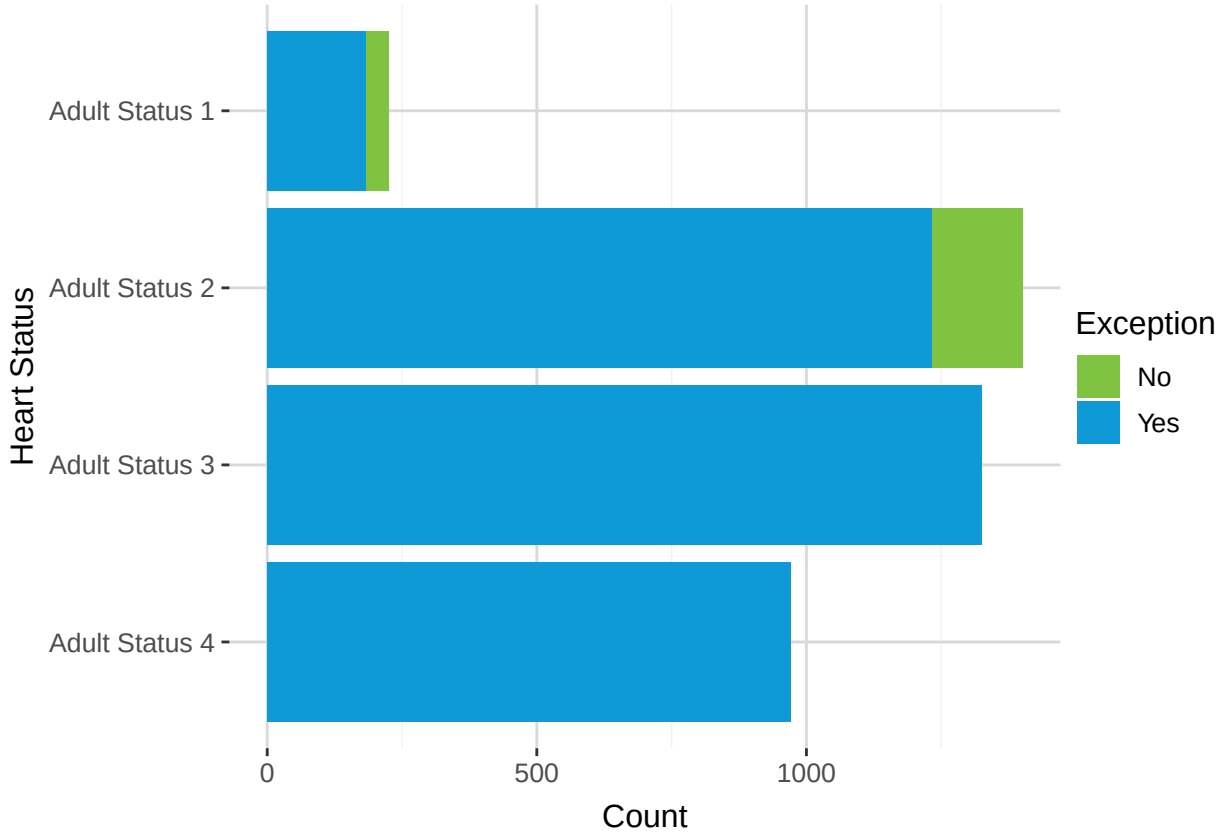


Table 14. Number of justification forms by exception versus standard review and medical urgency status

	Exception Request		
Adult Heart Status	No	Yes	Total
Adult Status 1	42 (18.7%)	183 (81.3%)	225 (100.0%)
Adult Status 2	168 (12.0%)	1233 (88.0%)	1401 (100.0%)
Adult Status 3	0 (0.0%)	1325 (100.0%)	1325 (100.0%)
Adult Status 4	0 (0.0%)	970 (100.0%)	970 (100.0%)
Total	210 (5.4%)	3711 (94.6%)	3921 (100.0%)

Figure 38. Number of justification forms by medical urgency status and OPTN region of candidate's transplant center

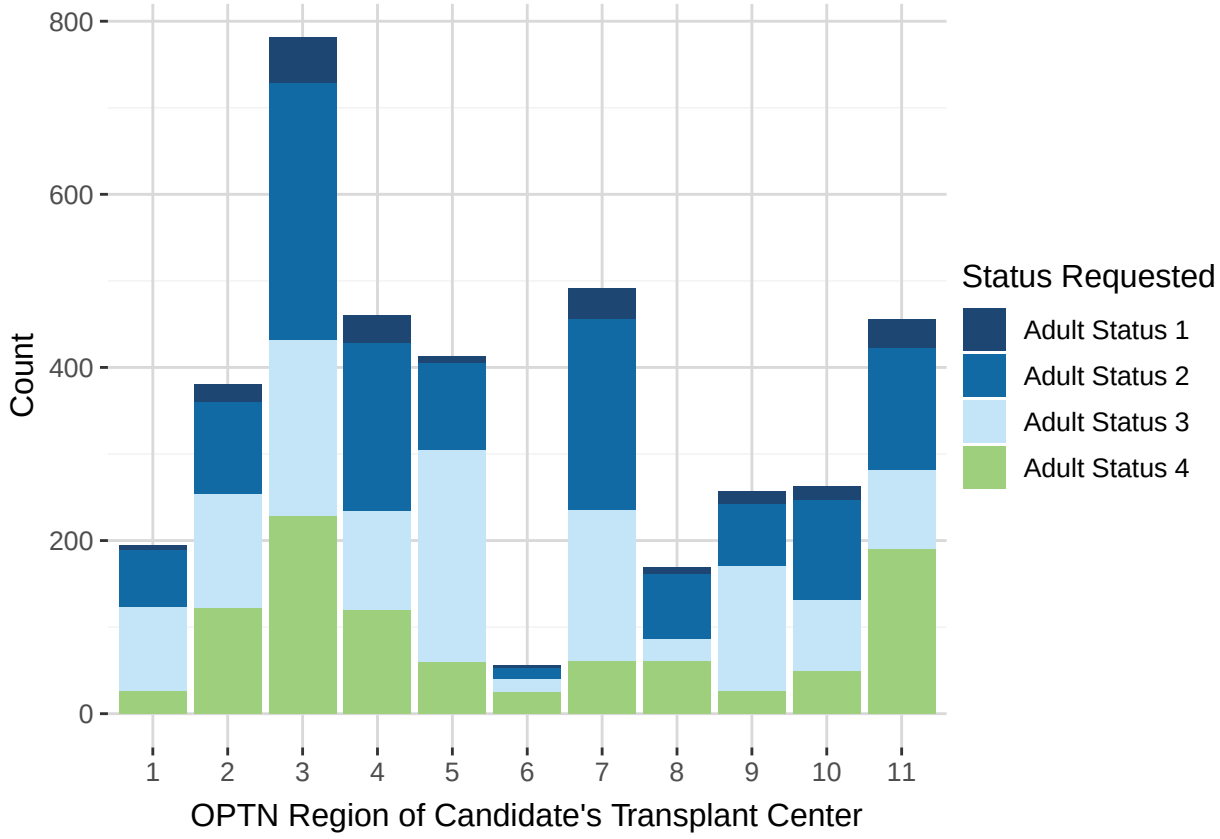


Table 15. Number of initial and extension justification forms by medical urgency status and OPTN region of candidate's transplant center

Adult Heart Status and Form Type	1	2	3	4	5	6	7	8	9	10	11	Total
Status 1 Initial Listing	4	18	31	26	5	2	9	8	9	15	23	150
Status 1 Extension	1	2	21	6	2	1	26	0	5	1	10	75
Status 2 Initial Listing	49	67	164	105	77	11	115	56	60	70	104	878
Status 2 Extension	16	40	133	89	24	2	105	19	12	45	38	523
Status 3 Initial Listing	38	65	95	68	114	12	71	22	54	41	62	642
Status 3 Extension	60	66	108	46	131	3	104	3	91	42	29	683
Status 4 Initial Listing	20	92	159	95	46	22	39	44	21	31	127	696
Status 4 Extension	6	31	70	25	14	3	22	17	5	18	63	274
Total	194	381	781	460	413	56	491	169	257	263	456	3921

Figure 38 and Table 15 summarize form submission by the candidate's transplant center's OPTN region. OPTN regions 3, 4, 5, 7, and 11 each submitted over 400 forms that needed RRB approval. OPTN region 6 submitted the fewest forms.

Table 16 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 are approved, regardless of medical urgency status or form type.

Table 16. 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	123 (83.1%)	9 (6.1%)	6 (4.1%)	10 (6.8%)	148 (100.0%)
Status 1 Extension	68 (94.4%)	0 (0.0%)	0 (0.0%)	4 (5.6%)	72 (100.0%)
Status 2 Initial Listing	785 (89.8%)	54 (6.2%)	11 (1.3%)	24 (2.7%)	874 (100.0%)
Status 2 Extension	483 (94.7%)	13 (2.5%)	4 (0.8%)	10 (2.0%)	510 (100.0%)
Status 3 Initial Listing	552 (87.3%)	38 (6.0%)	13 (2.1%)	29 (4.6%)	632 (100.0%)
Status 3 Extension	657 (97.3%)	5 (0.7%)	1 (0.1%)	12 (1.8%)	675 (100.0%)
Status 4 Initial Listing	652 (94.6%)	18 (2.6%)	4 (0.6%)	15 (2.2%)	689 (100.0%)
Status 4 Extension	257 (94.1%)	11 (4.0%)	1 (0.4%)	4 (1.5%)	273 (100.0%)
Total	3577 (92.4%)	148 (3.8%)	40 (1.0%)	108 (2.8%)	3873 (100.0%)

Table 17. Number of forms by region submitting form and region reviewing form

Region	N
Region 1, Reviewed by Region 2	194
Region 2, Reviewed by Region 5	381
Region 3, Reviewed by Region 7	781
Region 4, Reviewed by Region 10	460
Region 5, Reviewed by Region 9	413
Region 6, Reviewed by Region 8	56
Region 7, Reviewed by Region 11	491
Region 8, Reviewed by Region 4	169
Region 9, Reviewed by Region 1	257
Region 10, Reviewed by Region 6	263
Region 11, Reviewed by Region 3	456
Total	3921

Under the new adult heart allocation system regions review requests from other regions. Table 17 summarizes the number of forms submitted from each region and the corresponding region that reviews the request. Region 3 submitted substantially more forms than any other region, followed by region 7 and region 4. Region 6 submitted the smallest number of forms.

Figure 39. Conclusions from justification forms by region reviewing request

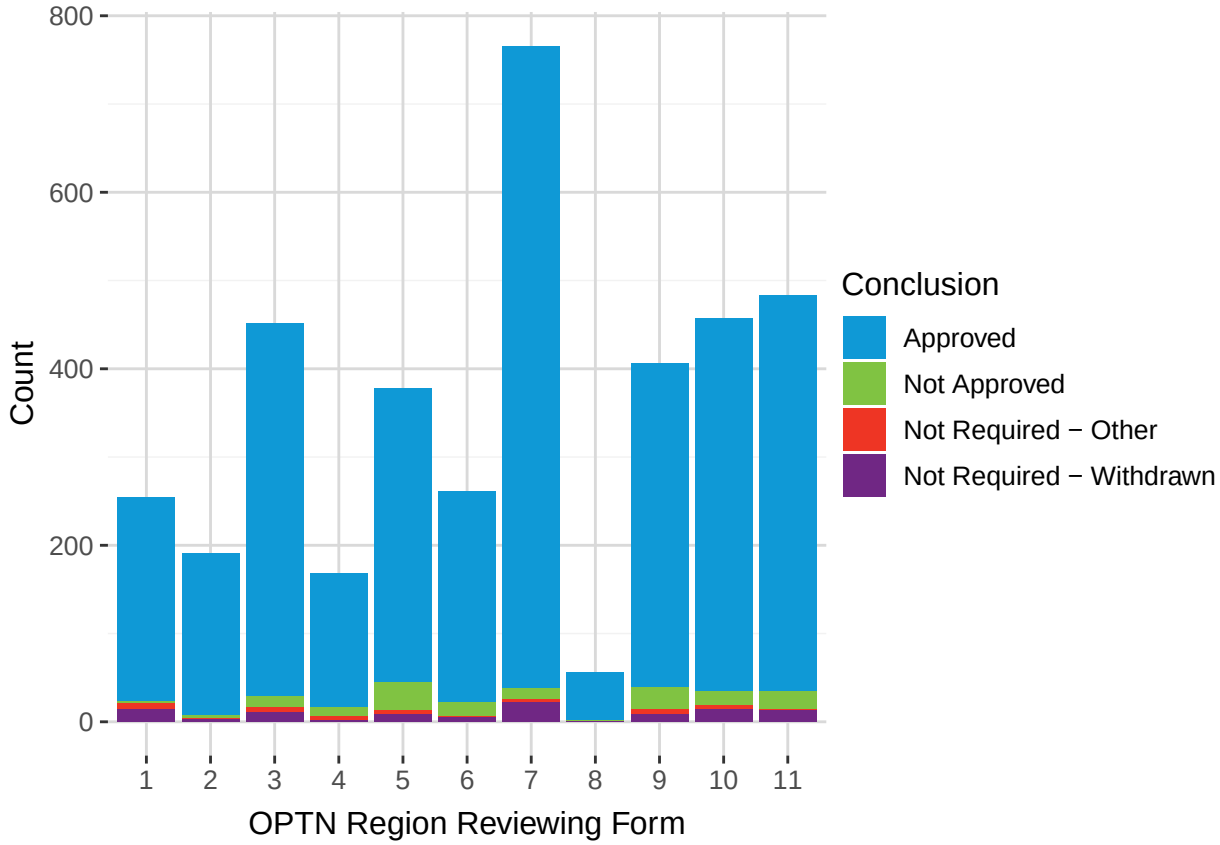


Figure 39 and Table 18 summarize the the conclusions (approved/not approved/not required-other/not required-withdrawn) by OPTN region that reviewed the request, not the OPTN region from which the form originated. Most regions approved a similar proportion of the forms submitted to them. Region 8 had the highest approval rate, approving 96.4% of forms submitted (from region 6), whereas region 5, evaluating forms from region 2, had the lowest rate of approval of any region.

Table 18. Conclusions from justification forms by region reviewing request

OPTN Region Reviewing Form	Approved	Not Approved	Not Required - Other	Not Required - Withdrawn	Total
1	231 (90.6%)	2 (0.8%)	7 (2.7%)	15 (5.9%)	255 (100.0%)
2	183 (95.8%)	3 (1.6%)	2 (1.0%)	3 (1.6%)	191 (100.0%)
3	422 (93.4%)	13 (2.9%)	5 (1.1%)	12 (2.7%)	452 (100.0%)
4	151 (89.9%)	10 (6.0%)	5 (3.0%)	2 (1.2%)	168 (100.0%)
5	333 (88.1%)	31 (8.2%)	5 (1.3%)	9 (2.4%)	378 (100.0%)
6	239 (91.6%)	15 (5.7%)	1 (0.4%)	6 (2.3%)	261 (100.0%)
7	727 (94.9%)	13 (1.7%)	3 (0.4%)	23 (3.0%)	766 (100.0%)
8	54 (96.4%)	1 (1.8%)	0 (0.0%)	1 (1.8%)	56 (100.0%)
9	367 (90.4%)	24 (5.9%)	6 (1.5%)	9 (2.2%)	406 (100.0%)
10	422 (92.3%)	16 (3.5%)	4 (0.9%)	15 (3.3%)	457 (100.0%)
11	448 (92.8%)	20 (4.1%)	2 (0.4%)	13 (2.7%)	483 (100.0%)
Total	3577 (92.4%)	148 (3.8%)	40 (1.0%)	108 (2.8%)	3873 (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 40 and Table 19 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 1636 registrations have applied for an exception. The most common initial request was for Adult Status 2.

Figure 40. Number of registrations with an exception by first status requested

Table 19. Number of registrations with an exception by first status requested

Status Requested	Registration Count	Percent
Status 1 Initial Listing	88	5.4%
Status 2 Initial Listing	586	35.8%
Status 3 Initial Listing	414	25.3%
Status 4 Initial Listing	548	33.5%
Total	1636	100.0%

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 1368 pediatric heart candidates listed, 1757 pediatric heart candidates ever waiting, and 976 pediatric heart candidates transplanted between October 18, 2017 and October 17, 2018 (pre-implementation) or between October 18, 2018 and October 17, 2019 (post-implementation).

Figure 41. Pediatric Heart Waiting List Additions by Medical Urgency Status and Era

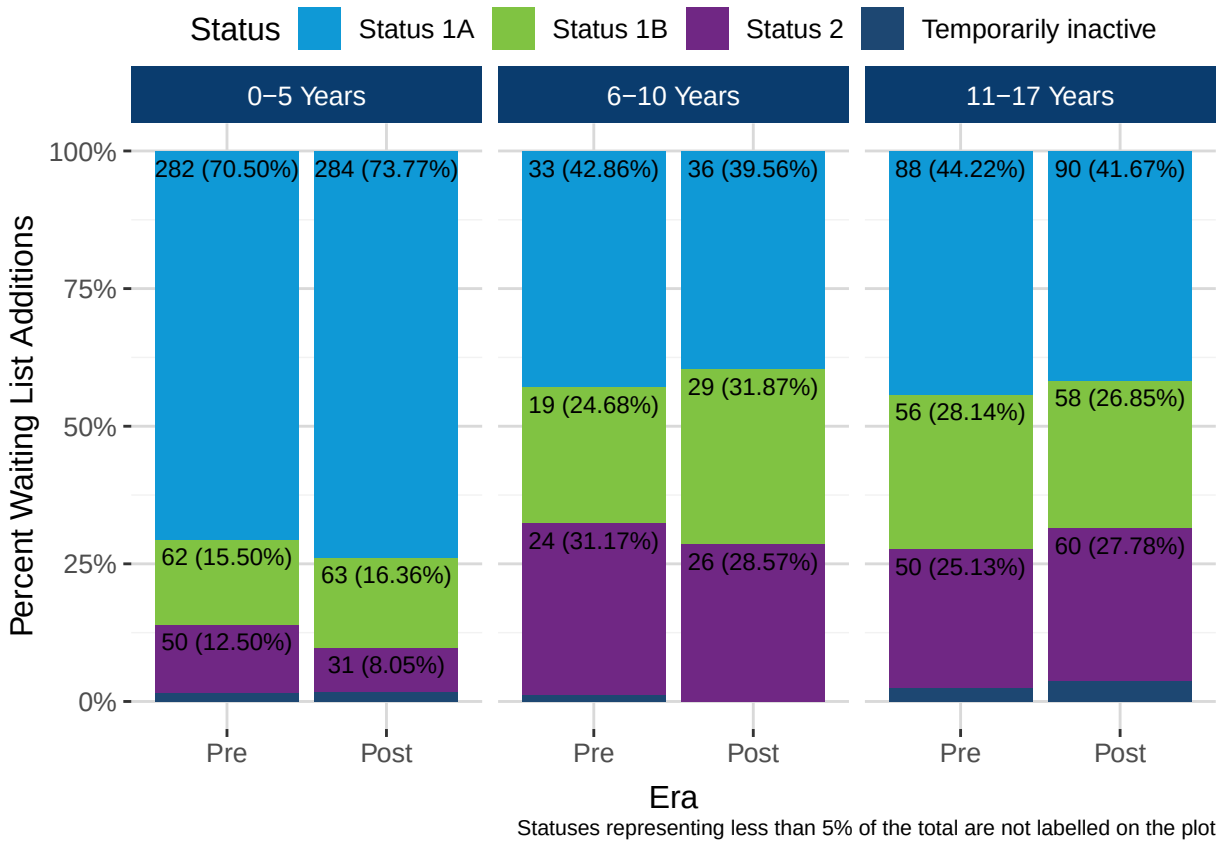


Figure 41 and Table 20 summarize the count and percent of pediatric heart waiting list registrations by status and age group. The proportion of pediatric additions did not differ substantially between eras; the largest shift was an increase in pediatric Status 1B candidates aged 6-10 years registering post-implementation. Overall there were fewer pediatric candidates aged 0-5 added to the waiting list post-implementation than there were pre-implementation.

Table 20. Pediatric Heart Waiting List Additions by Era and Medical Urgency Status

Age Group	Status	Era	Count	Percent
0-5 Years	Status 1A	Pre	282	70.5%
		Post	284	73.77%
	Status 1B	Pre	62	15.5%
		Post	63	16.36%
	Status 2	Pre	50	12.5%
		Post	31	8.05%
	Temporarily Inactive	Pre	6	1.5%
		Post	7	1.82%
0-5 Years	**Total**	**Pre**	**400**	**59.17%**
		Post	**385**	**55.64%**
6-10 Years	Status 1A	Pre	33	42.86%
		Post	36	39.56%
	Status 1B	Pre	19	24.68%
		Post	29	31.87%
	Status 2	Pre	24	31.17%
		Post	26	28.57%
	Temporarily Inactive	Pre	1	1.3%
6-10 Years	**Total**	**Pre**	**77**	**11.39%**
		Post	**91**	**13.15%**
11-17 Years	Status 1A	Pre	88	44.22%
		Post	90	41.67%
	Status 1B	Pre	56	28.14%
		Post	58	26.85%
	Status 2	Pre	50	25.13%
		Post	60	27.78%
	Temporarily Inactive	Pre	5	2.51%
		Post	8	3.7%
11-17 Years	**Total**	**Pre**	**199**	**29.44%**
		Post	**216**	**31.21%**

Figure 42. Pediatric Heart Candidates Ever Waiting by Era and Most Recent Medical Urgency Status

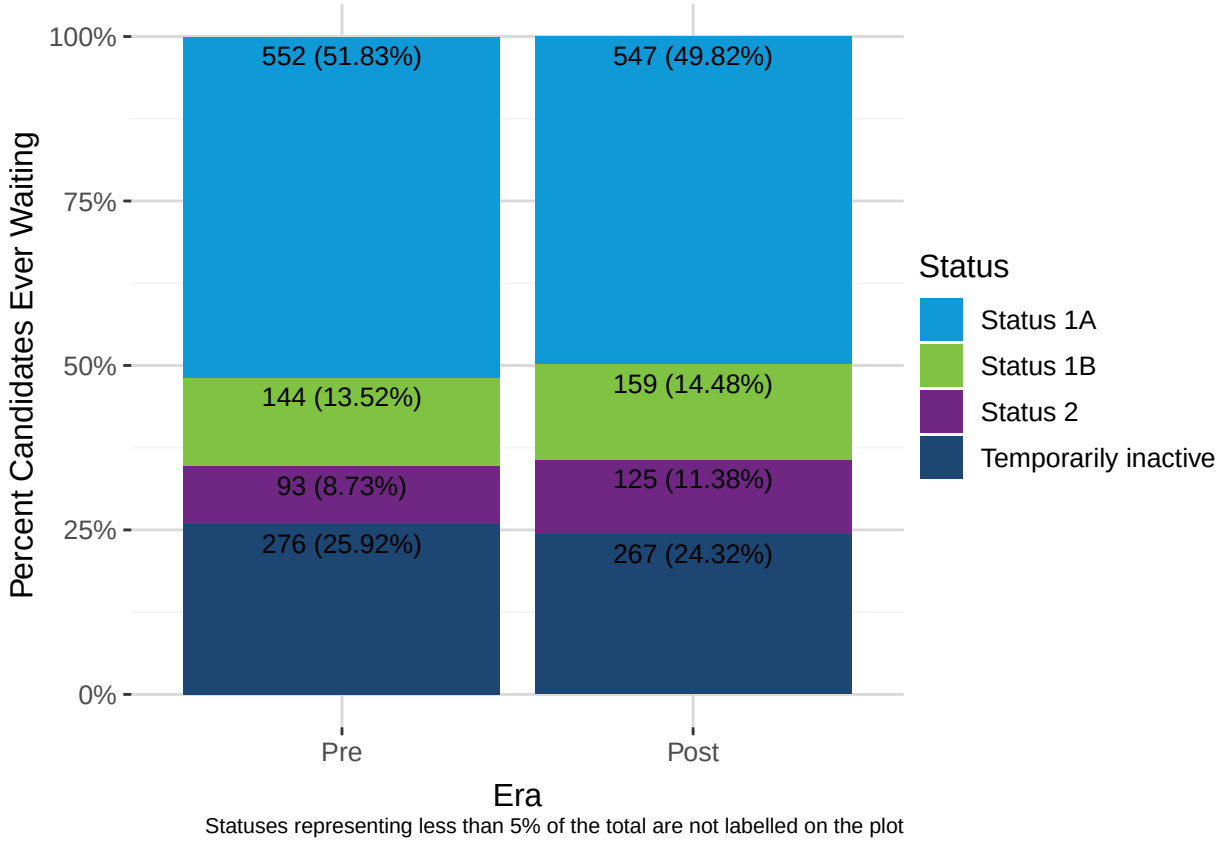


Figure 42 shows the proportion of pediatric heart candidates ever waiting by medical urgency status both pre- and post-implementation. There was very little change in the medical urgency status composition of the pediatric heart waiting list after changes to the adult heart allocation system were implemented.

Figure 43. Pediatric Heart Transplants by Medical Urgency Status and Era

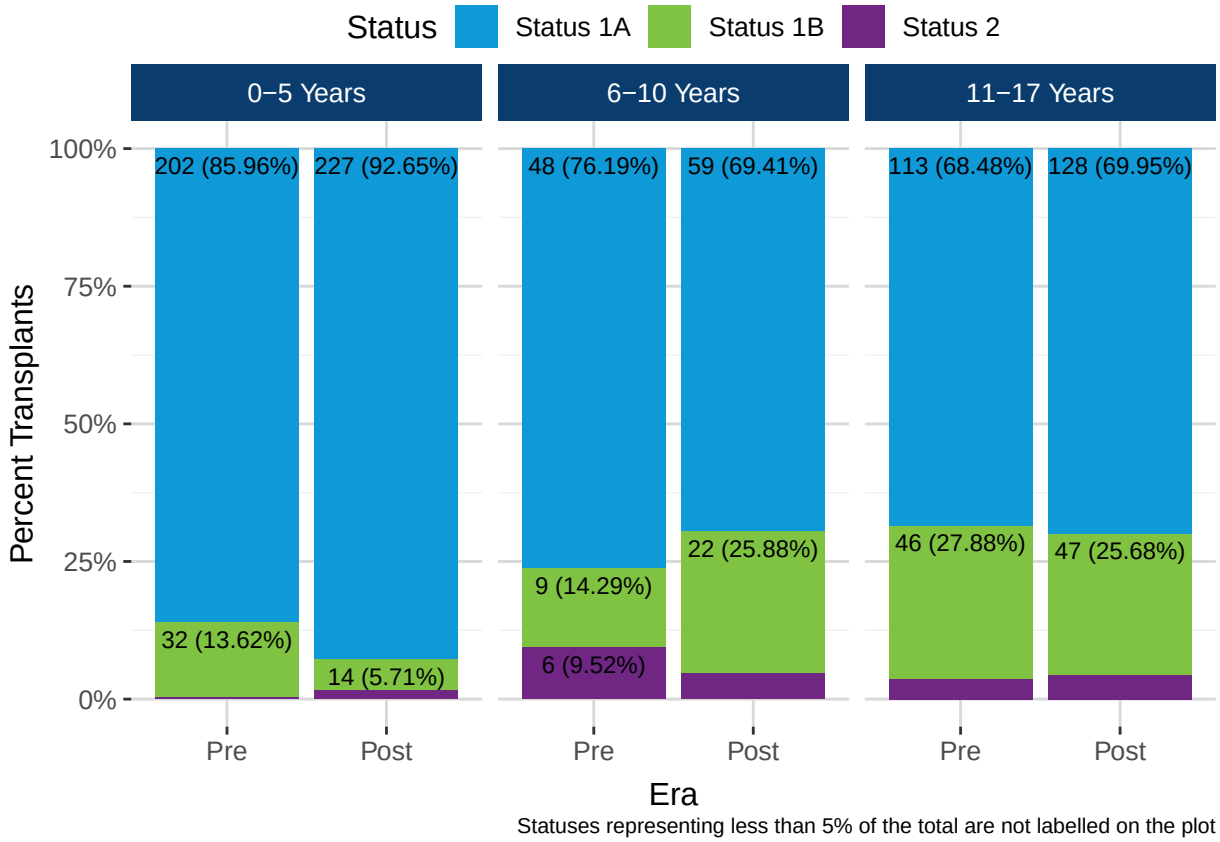


Figure 43 and table 21 summarize the proportion of pediatric heart candidates transplanted by medical urgency status both pre- and post-implementation. There was little change in the proportion of medical urgency statuses transplanted for pediatric candidates aged 11-17 years, but the proportion of transplants that went to Status 1A pediatric recipients aged 0-5 years decreased post-implementation. For pediatric recipients aged 6-10 years the proportion of transplants made to Status 2 recipients decreased post-implementation, while the proportion of transplants made to Status 1B recipients went up.

Table 21. Pediatric Heart Transplants by Era and Medical Urgency Status

Age Group	Status	Era	Count	Percent
0-5 Years	Status 1A	Pre	202	85.96%
		Post	227	92.65%
	Status 1B	Pre	32	13.62%
		Post	14	5.71%
	Status 2	Pre	1	0.43%
		Post	4	1.63%
0-5 Years	**Total**	**Pre**	**235**	**50.76%**
		Post	**245**	**47.76%**
6-10 Years	Status 1A	Pre	48	76.19%
		Post	59	69.41%
	Status 1B	Pre	9	14.29%
		Post	22	25.88%
	Status 2	Pre	6	9.52%
		Post	4	4.71%
6-10 Years	**Total**	**Pre**	**63**	**13.61%**
		Post	**85**	**16.57%**
11-17 Years	Status 1A	Pre	113	68.48%
		Post	128	69.95%
	Status 1B	Pre	46	27.88%
		Post	47	25.68%
	Status 2	Pre	6	3.64%
		Post	8	4.37%
11-17 Years	**Total**	**Pre**	**165**	**35.64%**
		Post	**183**	**35.67%**

Figure 44. Pediatric Deaths per 100 Patient-Years Waiting by Medical Urgency Status and Era

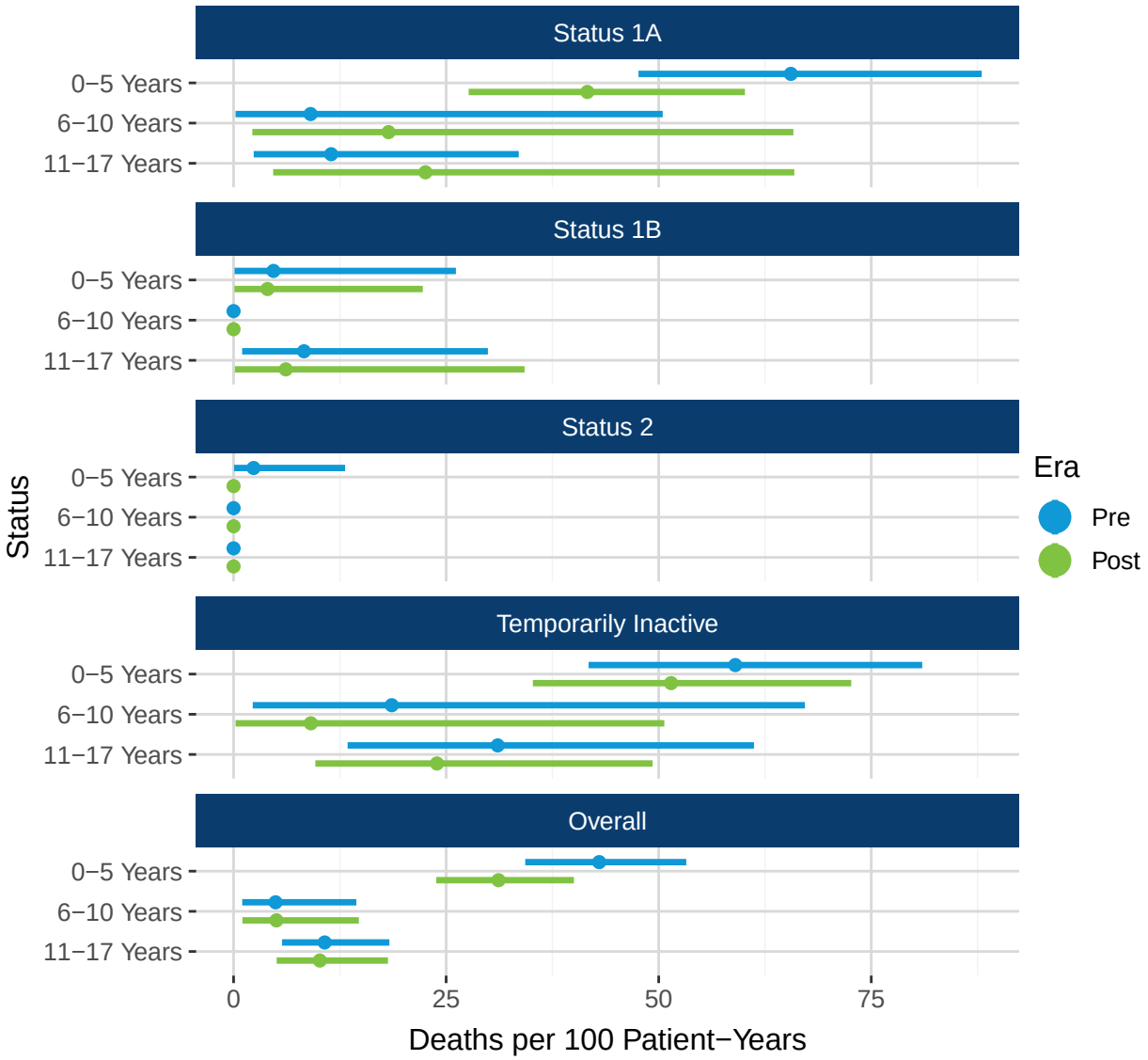


Figure 44 shows the deaths per 100 patient-years for pediatric heart candidates pre- and post-implementation by medical urgency status and era. There was no significant change in the number of deaths per 100 patient-years for any medical urgency status or age group between the two eras.

Table A17 shows the number of pediatric candidates ever waiting and the number of deaths for each medical urgency status and age group 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. 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 45. Pediatric Transplants per 100 Patient-Years Waiting by Medical Urgency Status and Era

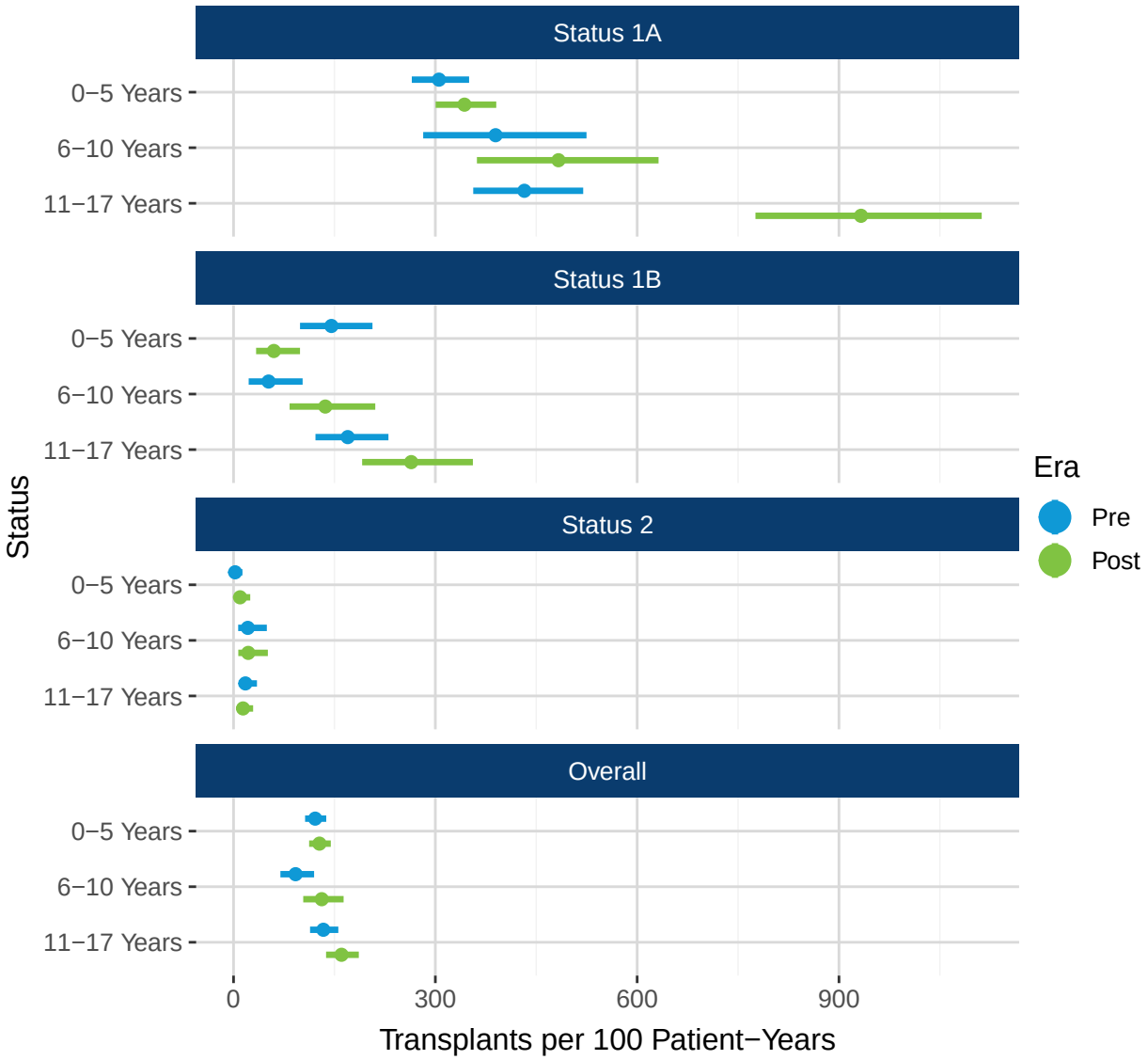


Figure 45 shows the number of transplants per 100 patient-years for pediatric heart candidates by age group, medical urgency status, and era. Post-implementation the number of transplants per 100 patient-years was significantly higher for Status 1A pediatric candidates 11-17 years old and significantly lower for Status 1B pediatric candidates 0-5 years old. However, young pediatric candidates do not compete with adults for small donor hearts, and the decrease in the transplant rate for pediatrics age 0-5 may be a result of factors other than revisions to adult heart allocation.

Table A18 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 greater in the post era for pediatric candidates in the 11-17 years age group at Status 1A, pediatric candidates in the 6-10 years age group at Status 1B, and pediatric candidates in the 0-5 years age group at Status 2. The relative risk of transplant was significantly lower for pediatric candidates in the 0-5 years age group at Status 1B.

Conclusion

Early monitoring suggests that revisions to the heart allocation system have resulted in broader sharing, with 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 receiving a transplant, especially for the most medically urgent candidates. Transplant rates have increased, most dramatically for the most medically urgent candidates, while the rate of death on the waiting list and 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, the changes to the adult heart allocation system have not had a clear 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 between 200 and 400 per month. The majority of these were requests for Adult Status 2 and were exception request forms rather than standard review forms. The majority of requests were approved regardless of the region reviewing the request.

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	55	73	65	2	195
	%	28.21%	37.44%	33.33%	1.03%	100.00%
2	N	85	178	130	7	400
	%	21.25%	44.50%	32.50%	1.75%	100.00%
3	N	119	250	85	9	463
	%	25.70%	54.00%	18.36%	1.94%	100.00%
4	N	76	195	110	7	388
	%	19.59%	50.26%	28.35%	1.80%	100.00%
5	N	172	210	209	21	612
	%	28.10%	34.31%	34.15%	3.43%	100.00%
6	N	20	51	42	0	113
	%	17.70%	45.13%	37.17%	0.00%	100.00%
7	N	100	163	93	11	367
	%	27.25%	44.41%	25.34%	3.00%	100.00%
8	N	48	153	62	8	271
	%	17.71%	56.46%	22.88%	2.95%	100.00%
9	N	108	149	52	0	309
	%	34.95%	48.22%	16.83%	0.00%	100.00%
10	N	77	161	103	8	349
	%	22.06%	46.13%	29.51%	2.29%	100.00%
11	N	121	282	107	13	523
	%	23.14%	53.92%	20.46%	2.49%	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	16	24	18	76	3	59	5	201
	%	7.96%	11.94%	8.96%	37.81%	1.49%	29.35%	2.49%	100.00%
2	N	10	62	42	178	8	103	4	407
	%	2.46%	15.23%	10.32%	43.73%	1.97%	25.31%	0.98%	100.00%
3	N	14	86	62	170	8	80	4	424
	%	3.30%	20.28%	14.62%	40.09%	1.89%	18.87%	0.94%	100.00%
4	N	16	74	38	164	6	85	6	389
	%	4.11%	19.02%	9.77%	42.16%	1.54%	21.85%	1.54%	100.00%
5	N	25	108	105	190	9	139	14	590
	%	4.24%	18.31%	17.80%	32.20%	1.53%	23.56%	2.37%	100.00%
6	N	8	8	16	51	2	34	2	121
	%	6.61%	6.61%	13.22%	42.15%	1.65%	28.10%	1.65%	100.00%
7	N	8	75	45	123	8	70	8	337
	%	2.37%	22.26%	13.35%	36.50%	2.37%	20.77%	2.37%	100.00%
8	N	12	62	14	111	0	53	2	254
	%	4.72%	24.41%	5.51%	43.70%	0.00%	20.87%	0.79%	100.00%
9	N	14	55	30	118	5	65	0	287
	%	4.88%	19.16%	10.45%	41.11%	1.74%	22.65%	0.00%	100.00%
10	N	8	73	43	140	8	68	13	353
	%	2.27%	20.68%	12.18%	39.66%	2.27%	19.26%	3.68%	100.00%
11	N	30	90	66	241	11	116	14	568
	%	5.28%	15.85%	11.62%	42.43%	1.94%	20.42%	2.46%	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	6.25%
	Exception	1	6.25%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	6	37.50%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	6	37.50%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	2	12.50%
Overall			
		16	100%
Adult Status 1			
Region 2			
	BIVAD/Ventricular Episodes	2	18.18%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	1	9.09%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	2	18.18%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	6	54.55%
Overall			
		11	100%
Adult Status 1			
Region 3			
	Exception	3	17.65%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	2	11.76%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	5	29.41%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	7	41.18%
Overall			
		17	100%
Adult Status 1			
Region 4			
	BIVAD/Ventricular Episodes	1	5.88%
	Exception	8	47.06%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	1	5.88%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	5	29.41%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	2	11.76%
Overall			
		17	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 1 Region 5			
	Exception	3	12.00%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	2	8.00%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	13	52.00%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	7	28.00%
Overall		25	100%
Adult Status 1 Region 6			
	Exception	1	12.50%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	2	25.00%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	5	62.50%
Overall		8	100%
Adult Status 1 Region 7			
	BIVAD/Ventricular Episodes	2	25.00%
	Exception	2	25.00%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	1	12.50%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	3	37.50%
Overall		8	100%
Adult Status 1 Region 8			
	BIVAD/Ventricular Episodes	2	16.67%
	Exception	3	25.00%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	6	50.00%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	1	8.33%
Overall		12	100%

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

Criteria		Initial N	Initial %
Adult Status 1			
Region 9			
	BIVAD/Ventricular Episodes	1	6.67%
	Exception	3	20.00%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	7	46.67%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	4	26.67%
Overall			
		15	100%
Adult Status 1			
Region 10			
	BIVAD/Ventricular Episodes	2	22.22%
	Exception	2	22.22%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	4	44.44%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	1	11.11%
Overall			
		9	100%
Adult Status 1			
Region 11			
	BIVAD/Ventricular Episodes	1	3.33%
	Exception	6	20.00%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	9	30.00%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	7	23.33%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	7	23.33%
Overall			
		30	100%
Adult Status 2			
Region 1			
	Exception	8	33.33%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	1	4.17%
	Intra-aortic ballon pump - Hemodynamic Values obtained	6	25.00%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	4.17%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	4.17%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	3	12.50%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	8.33%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	2	8.33%
Overall			
		24	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 2			
Region 2			
	Exception	13	20.97%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	2	3.23%
	Intra-aortic ballon pump - Hemodynamic Values obtained	36	58.06%
	Mechanical circulatory support device(MCSD) with malfunction	3	4.84%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	1.61%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	3	4.84%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	1	1.61%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	3	4.84%
Overall			
		62	100%
Adult Status 2			
Region 3			
	Exception	27	30.68%
	Intra-aortic ballon pump - Hemodynamic Values obtained	44	50.00%
	Mechanical circulatory support device(MCSD) with malfunction	2	2.27%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	1.14%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	7	7.95%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	7	7.95%
Overall			
		88	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 2 Region 4			
	Exception	40	53.33%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	1	1.33%
	Intra-aortic ballon pump - Hemodynamic Values obtained	23	30.67%
	Mechanical circulatory support device(MCSD) with malfunction	2	2.67%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	6	8.00%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	3	4.00%
Overall		75	100%
Adult Status 2 Region 5			
	Exception	20	18.52%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	4	3.70%
	Intra-aortic ballon pump - Hemodynamic Values obtained	58	53.70%
	Mechanical circulatory support device(MCSD) with malfunction	3	2.78%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	3	2.78%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	16	14.81%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	3	2.78%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	1	0.93%
Overall		108	100%
Adult Status 2 Region 6			
	Exception	3	37.50%
	Intra-aortic ballon pump - Hemodynamic Values obtained	1	12.50%
	Mechanical circulatory support device(MCSD) with malfunction	1	12.50%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	12.50%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	1	12.50%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	1	12.50%
Overall		8	100%
Adult Status 2 Region 7			
	Exception	24	31.58%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	2	2.63%
	Intra-aortic ballon pump - Hemodynamic Values obtained	36	47.37%
	Mechanical circulatory support device(MCSD) with malfunction	2	2.63%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	1.32%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	4	5.26%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	3	3.95%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	4	5.26%
Overall		76	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 2 Region 8			
	Exception	22	35.48%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	1	1.61%
	Intra-aortic ballon pump - Hemodynamic Values obtained	36	58.06%
	Mechanical circulatory support device(MCSD) with malfunction	2	3.23%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	1.61%
Overall		62	100%
Adult Status 2 Region 9			
	Exception	12	21.43%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	1	1.79%
	Intra-aortic ballon pump - Hemodynamic Values obtained	31	55.36%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	1.79%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	8	14.29%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	3	5.36%
Overall		56	100%

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

Criteria		Initial N	Initial %
Adult Status 2			
Region 10			
	Exception	22	30.14%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	1	1.37%
	Intra-aortic ballon pump - Hemodynamic Values obtained	34	46.58%
	Mechanical circulatory support device(MCSD) with malfunction	4	5.48%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	1.37%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	7	9.59%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	2.74%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	2	2.74%
Overall			
		73	100%
Adult Status 2			
Region 11			
	Exception	36	40.00%
	Intra-aortic ballon pump - Hemodynamic Values obtained	37	41.11%
	Mechanical circulatory support device(MCSD) with malfunction	2	2.22%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	4	4.44%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	1.11%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	1.11%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	6	6.67%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	3	3.33%
Overall			
		90	100%
Adult Status 3			
Region 1			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	10	52.63%
	Exception	2	10.53%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	1	5.26%
	Mechanical circulatory support device (MCSD) with pump thrombosis	1	5.26%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	5	26.32%
Overall			
		19	100%
Adult Status 3			
Region 2			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	17	40.48%
	Exception	4	9.52%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	2.38%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	1	2.38%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	1	2.38%
	Mechanical circulatory support device (MCSD) with right heart failure	1	2.38%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	17	40.48%

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

Criteria		Initial N	Initial %
Overall			
		42	100%
Adult Status 3			
Region 3			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	9	14.52%
	Exception	17	27.42%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	5	8.06%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	2	3.23%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	2	3.23%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	1.61%
	Mechanical circulatory support device (MCSD) with pump thrombosis	1	1.61%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	25	40.32%
Overall			
		62	100%

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

Criteria	Initial N	Initial %
Adult Status 3 Region 4		
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	4	10.53%
Exception	9	23.68%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	2.63%
Mechanical circulatory support device (MCSD) with device infection - Debridement	1	2.63%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	2.63%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	2.63%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	2.63%
Mechanical circulatory support device (MCSD) with right heart failure	1	2.63%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	19	50.00%
Overall	38	100%
Adult Status 3 Region 5		
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	18	17.14%
Exception	20	19.05%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	2	1.90%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	0.95%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	64	60.95%
Overall	105	100%
Adult Status 3 Region 6		
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	1	6.25%
Exception	5	31.25%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	2	12.50%
Mechanical circulatory support device (MCSD) with device infection - Debridement	3	18.75%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	6.25%
Mechanical circulatory support device (MCSD) with hemolysis	1	6.25%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	3	18.75%
Overall	16	100%

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

Criteria	Initial N	Initial %
Adult Status 3		
Region 7		
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	7	15.56%
Exception	6	13.33%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	7	15.56%
Mechanical circulatory support device (MCSD) with device infection - Erythema	2	4.44%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	2.22%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	4.44%
Mechanical circulatory support device (MCSD) with hemolysis	1	2.22%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	2.22%
Mechanical circulatory support device (MCSD) with pump thrombosis	4	8.89%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	14	31.11%
Overall		
	45	100%
Adult Status 3		
Region 8		
Exception	3	21.43%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	3	21.43%
Mechanical circulatory support device (MCSD) with hemolysis	1	7.14%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	7	50.00%
Overall		
	14	100%
Adult Status 3		
Region 9		
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	10	30.30%
Exception	9	27.27%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	3.03%
Mechanical circulatory support device (MCSD) with device infection - Debridement	1	3.03%
Mechanical circulatory support device (MCSD) with pump thrombosis	1	3.03%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	11	33.33%
Overall		
	33	100%

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

Criteria	Initial N	Initial %
Adult Status 3		
Region 10		
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	19	44.19%
Exception	4	9.30%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	2.33%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	7	16.28%
Mechanical circulatory support device (MCSD) with device infection - Debridement	1	2.33%
Mechanical circulatory support device (MCSD) with device infection - Erythema	2	4.65%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	2.33%
Mechanical circulatory support device (MCSD) with pump thrombosis	3	6.98%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	5	11.63%
Overall		
	43	100%
Adult Status 3		
Region 11		
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	23	34.85%
Exception	7	10.61%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	7	10.61%
Mechanical circulatory support device (MCSD) with device infection - Debridement	5	7.58%
Mechanical circulatory support device (MCSD) with device infection - Erythema	4	6.06%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	1.52%
Mechanical circulatory support device (MCSD) with hemolysis	1	1.52%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	1	1.52%
Mechanical circulatory support device (MCSD) with pump thrombosis	1	1.52%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	16	24.24%
Overall		
	66	100%
Adult Status 4		
Region 1		
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	17	22.08%
Congenital heart disease	3	3.90%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	34	44.16%
Exception	3	3.90%
Inotropes without hemodynamic monitoring	15	19.48%
Ischemic heart disease with intractable angina	2	2.60%
Retransplant	3	3.90%
Overall		
	77	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 4 Region 2			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	13	7.18%
	Congenital heart disease	13	7.18%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	86	47.51%
	Exception	32	17.68%
	Inotropes without hemodynamic monitoring	33	18.23%
	Ischemic heart disease with intractable angina	2	1.10%
	Retransplant	2	1.10%
Overall		181	100%
Adult Status 4 Region 3			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	11	6.40%
	Congenital heart disease	4	2.33%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	66	38.37%
	Exception	57	33.14%
	Inotropes without hemodynamic monitoring	25	14.53%
	Ischemic heart disease with intractable angina	2	1.16%
	Retransplant	7	4.07%
Overall		172	100%

Table A3: *(continued)*

Criteria	Initial N	Initial %
Adult Status 4 Region 4		
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	16	9.47%
Congenital heart disease	13	7.69%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	65	38.46%
Exception	46	27.22%
Inotropes without hemodynamic monitoring	18	10.65%
Ischemic heart disease with intractable angina	8	4.73%
Retransplant	3	1.78%
Overall	169	100%
Adult Status 4 Region 5		
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	27	13.78%
Congenital heart disease	28	14.29%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	54	27.55%
Exception	18	9.18%
Inotropes without hemodynamic monitoring	52	26.53%
Ischemic heart disease with intractable angina	2	1.02%
Retransplant	15	7.65%
Overall	196	100%
Adult Status 4 Region 6		
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	8	15.69%
Congenital heart disease	3	5.88%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	25	49.02%
Exception	4	7.84%
Inotropes without hemodynamic monitoring	8	15.69%
Ischemic heart disease with intractable angina	1	1.96%
Retransplant	2	3.92%
Overall	51	100%
Adult Status 4 Region 7		
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	10	8.13%
Congenital heart disease	11	8.94%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	71	57.72%
Exception	8	6.50%
Inotropes without hemodynamic monitoring	10	8.13%
Ischemic heart disease with intractable angina	4	3.25%
Retransplant	9	7.32%
Overall	123	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 4 Region 8			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	10	8.93%
	Congenital heart disease	9	8.04%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	38	33.93%
	Exception	20	17.86%
	Inotropes without hemodynamic monitoring	24	21.43%
	Ischemic heart disease with intractable angina	2	1.79%
	Retransplant	9	8.04%
Overall		112	100%
Adult Status 4 Region 9			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	16	13.56%
	Congenital heart disease	5	4.24%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	78	66.10%
	Exception	5	4.24%
	Inotropes without hemodynamic monitoring	7	5.93%
	Retransplant	7	5.93%
Overall		118	100%

Table A3: *(continued)*

	Criteria	Initial N	Initial %
Adult Status 4 Region 10			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	16	11.35%
	Congenital heart disease	9	6.38%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	83	58.87%
	Exception	9	6.38%
	Inotropes without hemodynamic monitoring	16	11.35%
	Ischemic heart disease with intractable angina	4	2.84%
	Retransplant	4	2.84%
Overall		141	100%
Adult Status 4 Region 11			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	16	6.64%
	Congenital heart disease	14	5.81%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	109	45.23%
	Exception	47	19.50%
	Inotropes without hemodynamic monitoring	32	13.28%
	Ischemic heart disease with intractable angina	6	2.49%
	Retransplant	17	7.05%
Overall		241	100%
Adult Status 5 Region 1			
	None	4	100.00%
Adult Status 5 Region 2			
	None	9	100.00%
Adult Status 5 Region 3			
	None	11	100.00%
Adult Status 5 Region 4			
	None	9	100.00%
Adult Status 5 Region 5			
	None	13	100.00%
Adult Status 5 Region 6			
	None	2	100.00%
Adult Status 5 Region 7			
	None	9	100.00%
Adult Status 5 Region 9			
	None	5	100.00%
Adult Status 5 Region 10			
	None	8	100.00%
Adult Status 5 Region 11			
	None	12	100.00%

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

Criteria		Initial N	Initial %
Adult Status 6 Region 1			
	None	59	100.00%
Adult Status 6 Region 2			
	None	105	100.00%
Adult Status 6 Region 3			
	None	81	100.00%
Adult Status 6 Region 4			
	None	86	100.00%
Adult Status 6 Region 5			
	None	139	100.00%
Adult Status 6 Region 6			
	None	34	100.00%
Adult Status 6 Region 7			
	None	71	100.00%
Adult Status 6 Region 8			
	None	53	100.00%
Adult Status 6 Region 9			
	None	68	100.00%

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

Criteria	Initial N	Initial %
Adult Status 6 Region 10		
None	68	100.00%
Adult Status 6 Region 11		
None	116	100.00%

Table A4: Mechanical Circulatory Support Devices at Listing by Region

Brand	Era	Count	Percent
Region 1 ECMO			
Total ECMO	**Post**	**8**	**9.09%**
Region 1 IABP			
Total IABP	**Pre**	**6**	**8.11%**
	Post	**17**	**19.32%**
Region 1 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	5	9.26%
	Post	1	2.27%
Heartmate II	Pre	16	29.63%
	Post	6	13.64%
HeartMate III	Pre	5	9.26%
	Post	18	40.91%
Heartsaver VAD	Pre	1	1.85%
	Post	0	0%
Heartware HVAD	Pre	14	25.93%
	Post	18	40.91%
Impella CP	Pre	0	0%
	Post	1	2.27%
Impella Recover 5.0	Pre	2	3.7%
	Post	0	0%
Other, Specify	Pre	11	20.37%
	Post	0	0%
Total LVAD	**Pre**	**54**	**72.97%**
	Post	**44**	**50%**
Region 1 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	5.56%
Cardiac Assist Tandem Heart	Pre	2	14.29%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	9	64.29%
	Post	14	77.78%
HeartMate III	Pre	0	0%
	Post	2	11.11%
Impella Recover 5.0	Pre	1	7.14%
	Post	1	5.56%

Other, Specify	Pre	2	14.29%
	Post	0	0%
Total LVAD+RVAD	**Pre**	**14**	**18.92%**
	Post	**18**	**20.45%**
Region 1 RVAD			
CentriMag (Thoratec/Levitronix)	Post	1	100%
Total RVAD	**Post**	**1**	**1.14%**
Region 2 ECMO			
Total ECMO	**Pre**	**12**	**9.6%**
	Post	**7**	**4%**
Region 2 IABP			
Total IABP	**Pre**	**8**	**6.4%**
	Post	**52**	**29.71%**
Region 2 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	1	0.88%
Heartmate II	Pre	29	29.59%
	Post	22	19.3%
HeartMate III	Pre	4	4.08%
	Post	46	40.35%
Heartware HVAD	Pre	33	33.67%
	Post	27	23.68%
Impella CP	Pre	1	1.02%
	Post	0	0%
Impella Recover 2.5	Pre	1	1.02%
	Post	1	0.88%
Impella Recover 5.0	Pre	5	5.1%
	Post	1	0.88%
Other, Specify	Pre	25	25.51%
	Post	16	14.04%
Total LVAD	**Pre**	**98**	**78.4%**
	Post	**114**	**65.14%**
Region 2 LVAD+RVAD			
CentriMag (Thoratec/Levitronix)	Pre	3	50%
	Post	0	0%
Heartware HVAD	Pre	1	16.67%
	Post	0	0%

Thoratec PVAD	Pre	0	0%
	Post	1	50%
Other, Specify	Pre	2	33.33%
	Post	1	50%
Total LVAD+RVAD	**Pre**	**6**	**4.8%**
	Post	**2**	**1.14%**
Region 2 TAH			
SynCardia CardioWest	Pre	1	100%
Total TAH	**Pre**	**1**	**0.8%**
Region 3 ECMO			
Total ECMO	**Pre**	**5**	**2.99%**
	Post	**10**	**5.46%**
Region 3 IABP			
Total IABP	**Pre**	**29**	**17.37%**
	Post	**61**	**33.33%**
Region 3 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	1	0.78%
	Post	0	0%
Heartmate II	Pre	50	38.76%
	Post	22	20.75%
HeartMate III	Pre	5	3.88%
	Post	44	41.51%
Heartware HVAD	Pre	25	19.38%
	Post	31	29.25%
Impella CP	Pre	0	0%
	Post	1	0.94%
Impella Recover 2.5	Pre	1	0.78%
	Post	0	0%
Impella Recover 5.0	Pre	5	3.88%
	Post	8	7.55%
Other, Specify	Pre	42	32.56%
	Post	0	0%
Total LVAD	**Pre**	**129**	**77.25%**
	Post	**106**	**57.92%**
Region 3 LVAD+RVAD			
Cardiac Assist Tandem Heart	Pre	1	25%
	Post	0	0%

CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	2	33.33%
Heartmate II	Pre	1	25%
	Post	0	0%
Heartware HVAD	Pre	0	0%
	Post	3	50%
Other, Specify	Pre	2	50%
	Post	1	16.67%
Total LVAD+RVAD	**Pre**	**4**	**2.4%**
	Post	**6**	**3.28%**

Region 4 ECMO

Total ECMO	**Pre**	**4**	**3.17%**
	Post	**11**	**7.01%**

Region 4 IABP

Total IABP	**Pre**	**22**	**17.46%**
	Post	**47**	**29.94%**

Region 4 LVAD

CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	1	1.04%
Heartmate II	Pre	46	48.94%
	Post	33	34.38%
HeartMate III	Pre	0	0%
	Post	16	16.67%
Heartsaver VAD	Pre	0	0%
	Post	1	1.04%
Heartware HVAD	Pre	21	22.34%
	Post	34	35.42%
Impella CP	Pre	0	0%
	Post	2	2.08%
Impella Recover 2.5	Pre	4	4.26%
	Post	0	0%
Impella Recover 5.0	Pre	4	4.26%
	Post	9	9.38%
Other, Specify	Pre	19	20.21%
	Post	0	0%
Total LVAD	**Pre**	**94**	**74.6%**
	Post	**96**	**61.15%**

Region 4 LVAD+RVAD			
CentriMag (Thoratec/Levitronix)	Pre	2	50%
	Post	2	100%
Heartware HVAD	Pre	2	50%
	Post	0	0%
Total LVAD+RVAD	**Pre**	**4**	**3.17%**
	Post	**2**	**1.27%**
Region 4 TAH			
SynCardia CardioWest	Pre	2	100%
	Post	1	100%
Total TAH	**Pre**	**2**	**1.59%**
	Post	**1**	**0.64%**
Region 5 ECMO			
Total ECMO	**Pre**	**5**	**2.94%**
	Post	**20**	**10%**
Region 5 IABP			
Total IABP	**Pre**	**21**	**12.35%**
	Post	**55**	**27.5%**
Region 5 LVAD			
Cardiac Assist Tandem Heart	Pre	2	1.47%
	Post	0	0%
Heartmate II	Pre	29	21.32%
	Post	10	9.17%
HeartMate III	Pre	7	5.15%
	Post	35	32.11%
Heartmate XVE	Pre	1	0.74%
	Post	0	0%
Heartware HVAD	Pre	62	45.59%
	Post	39	35.78%
Impella CP	Pre	0	0%
	Post	8	7.34%
Impella Recover 2.5	Pre	2	1.47%
	Post	1	0.92%
Impella Recover 5.0	Pre	5	3.68%
	Post	15	13.76%
Other, Specify	Pre	28	20.59%
	Post	1	0.92%
	Pre	**136**	**80%**

Total LVAD	**Post**	**109**	**54.5%**
Region 5 LVAD+RVAD			
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	1	8.33%
CentriMag (Thoratec/Levitronix)	Pre	2	50%
	Post	2	16.67%
HeartMate III	Pre	0	0%
	Post	1	8.33%
Heartware HVAD	Pre	1	25%
	Post	3	25%
Other, Specify	Pre	1	25%
	Post	5	41.67%
Total LVAD+RVAD	**Pre**	**4**	**2.35%**
	Post	**12**	**6%**
Region 5 RVAD			
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	1	50%
Impella Recover 5.0	Pre	1	100%
	Post	0	0%
Impella RP	Pre	0	0%
	Post	1	50%
Total RVAD	**Pre**	**1**	**0.59%**
	Post	**2**	**1%**
Region 5 TAH			
SynCardia CardioWest	Pre	3	100%
	Post	2	100%
Total TAH	**Pre**	**3**	**1.76%**
	Post	**2**	**1%**
Region 6 ECMO			
Total ECMO	**Pre**	**1**	**1.96%**
	Post	**8**	**12.31%**
Region 6 IABP			
Total IABP	**Pre**	**4**	**7.84%**
	Post	**2**	**3.08%**
Region 6 LVAD			
	Pre	11	26.83%

Heartmate II	Post	8	15.69%
HeartMate III	Pre	2	4.88%
	Post	18	35.29%
Heartmate XVE	Pre	1	2.44%
	Post	0	0%
Heartware HVAD	Pre	15	36.59%
	Post	18	35.29%
Impella CP	Pre	1	2.44%
	Post	6	11.76%
Impella Recover 5.0	Pre	1	2.44%
	Post	1	1.96%
Other, Specify	Pre	10	24.39%
	Post	0	0%
Total LVAD	**Pre**	**41**	**80.39%**
	Post	**51**	**78.46%**
Region 6 LVAD+RVAD			
Cardiac Assist Tandem Heart	Post	1	50%
Heartware HVAD	Post	1	50%
Total LVAD+RVAD	**Post**	**2**	**3.08%**
Region 6 TAH			
SynCardia CardioWest	Pre	5	100%
	Post	2	100%
Total TAH	**Pre**	**5**	**9.8%**
	Post	**2**	**3.08%**
Region 7 ECMO			
Total ECMO	**Pre**	**8**	**4.52%**
	Post	**5**	**2.98%**
Region 7 IABP			
Total IABP	**Pre**	**38**	**21.47%**
	Post	**47**	**27.98%**
Region 7 LVAD			
Heartmate II	Pre	39	30.95%
	Post	20	18.52%
HeartMate III	Pre	2	1.59%
	Post	42	38.89%
Heartsaver VAD	Pre	0	0%
	Post	1	0.93%

Heartware HVAD	Pre	42	33.33%
	Post	41	37.96%
Impella Recover 5.0	Pre	0	0%
	Post	2	1.85%
Other, Specify	Pre	43	34.13%
	Post	2	1.85%
Total LVAD	**Pre**	**126**	**71.19%**
	Post	**108**	**64.29%**
Region 7 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	16.67%
CentriMag (Thoratec/Levitronix)	Pre	1	25%
	Post	1	16.67%
Heartware HVAD	Pre	2	50%
	Post	4	66.67%
Other, Specify	Pre	1	25%
	Post	0	0%
Total LVAD+RVAD	**Pre**	**4**	**2.26%**
	Post	**6**	**3.57%**
Region 7 TAH			
SynCardia CardioWest	Pre	1	100%
	Post	2	100%
Total TAH	**Pre**	**1**	**0.56%**
	Post	**2**	**1.19%**
Region 8 ECMO			
Total ECMO	**Pre**	**4**	**4.3%**
	Post	**11**	**9.02%**
Region 8 IABP			
Total IABP	**Pre**	**14**	**15.05%**
	Post	**53**	**43.44%**
Region 8 LVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	1.79%
Heartmate II	Pre	31	41.33%
	Post	15	26.79%
HeartMate III	Pre	3	4%
	Post	26	46.43%

Heartware HVAD	Pre	22	29.33%
	Post	10	17.86%
Impella Recover 5.0	Pre	1	1.33%
	Post	1	1.79%
Other, Specify	Pre	18	24%
	Post	3	5.36%
Total LVAD	**Pre**	**75**	**80.65%**
	Post	**56**	**45.9%**
Region 8 LVAD+RVAD			
Cardiac Assist Protek Duo	Post	1	50%
Heartware HVAD	Post	1	50%
Total LVAD+RVAD	**Post**	**2**	**1.64%**
Region 9 ECMO			
Total ECMO	**Pre**	**3**	**1.96%**
	Post	**13**	**7.65%**
Region 9 IABP			
Total IABP	**Pre**	**4**	**2.61%**
	Post	**46**	**27.06%**
Region 9 LVAD			
Evaheart	Pre	1	0.75%
	Post	0	0%
Heartmate II	Pre	70	52.24%
	Post	23	23.23%
HeartMate III	Pre	10	7.46%
	Post	65	65.66%
Heartware HVAD	Pre	17	12.69%
	Post	11	11.11%
Other, Specify	Pre	36	26.87%
	Post	0	0%
Total LVAD	**Pre**	**134**	**87.58%**
	Post	**99**	**58.24%**
Region 9 LVAD+RVAD			
Cardiac Assist Tandem Heart	Pre	1	8.33%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	6	50%
	Post	1	12.5%
	Pre	1	8.33%

Heartmate II	Post	0	0%
HeartMate III	Pre	0	0%
	Post	6	75%
Thoratec PVAD	Pre	0	0%
	Post	1	12.5%
Other, Specify	Pre	4	33.33%
	Post	0	0%
Total LVAD+RVAD	**Pre**	**12**	**7.84%**
	Post	**8**	**4.71%**
Region 9 RVAD			
CentriMag (Thoratec/Levitronix)	Post	1	100%
Total RVAD	**Post**	**1**	**0.59%**
Region 9 TAH			
SynCardia CardioWest	Post	3	100%
Total TAH	**Post**	**3**	**1.76%**
Region 10 ECMO			
Total ECMO	**Pre**	**7**	**4.12%**
	Post	**7**	**3.52%**
Region 10 IABP			
Total IABP	**Pre**	**7**	**4.12%**
	Post	**43**	**21.61%**
Region 10 LVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	0.72%
CentriMag (Thoratec/Levitronix)	Pre	1	0.69%
	Post	2	1.45%
Heartmate II	Pre	50	34.48%
	Post	33	23.91%
HeartMate III	Pre	9	6.21%
	Post	57	41.3%
Heartware HVAD	Pre	44	30.34%
	Post	31	22.46%
Impella CP	Pre	0	0%
	Post	1	0.72%
Impella Recover 5.0	Pre	4	2.76%
	Post	5	3.62%
	Pre	0	0%

Impella RP	Post	1	0.72%
Other, Specify	Pre	37	25.52%
	Post	7	5.07%
Total LVAD	**Pre**	**145**	**85.29%**
	Post	**138**	**69.35%**
Region 10 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	12.5%
CentriMag (Thoratec/Levitronix)	Pre	5	50%
	Post	2	25%
Heartmate II	Pre	1	10%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	1	12.5%
Heartware HVAD	Pre	4	40%
	Post	2	25%
Impella Recover 5.0	Pre	0	0%
	Post	1	12.5%
Other, Specify	Pre	0	0%
	Post	1	12.5%
Total LVAD+RVAD	**Pre**	**10**	**5.88%**
	Post	**8**	**4.02%**
Region 10 RVAD			
CentriMag (Thoratec/Levitronix)	Pre	1	100%
	Post	0	0%
Impella Recover 5.0	Pre	0	0%
	Post	1	100%
Total RVAD	**Pre**	**1**	**0.59%**
	Post	**1**	**0.5%**
Region 10 TAH			
SynCardia CardioWest	Post	1	50%
Other, Specify	Post	1	50%
Total TAH	**Post**	**2**	**1.01%**
Region 11 ECMO			
Total ECMO	**Pre**	**8**	**3.65%**
	Post	**19**	**6.38%**

Region 11 IABP			
Total IABP	**Pre**	**29**	**13.24%**
	Post	**61**	**20.47%**
Region 11 LVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	0.54%
CentriMag (Thoratec/Levitronix)	Pre	1	0.58%
	Post	4	2.16%
Evaheart	Pre	0	0%
	Post	1	0.54%
Heartmate II	Pre	62	36.05%
	Post	42	22.7%
HeartMate III	Pre	10	5.81%
	Post	68	36.76%
Heartware HVAD	Pre	66	38.37%
	Post	59	31.89%
Impella CP	Pre	0	0%
	Post	1	0.54%
Impella Recover 2.5	Pre	0	0%
	Post	1	0.54%
Impella Recover 5.0	Pre	1	0.58%
	Post	3	1.62%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	2	1.08%
Other, Specify	Pre	32	18.6%
	Post	3	1.62%
Total LVAD	**Pre**	**172**	**78.54%**
	Post	**185**	**62.08%**
Region 11 LVAD+RVAD			
Abiomed AB5000	Pre	0	0%
	Post	1	3.85%
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	3.85%
CentriMag (Thoratec/Levitronix)	Pre	3	50%
	Post	12	46.15%
HeartMate III	Pre	0	0%
	Post	3	11.54%
	Pre	1	16.67%

Heartware HVAD	Post	1	3.85%
Maquet Jostra Rotaflow	Pre	2	33.33%
	Post	6	23.08%
Other, Specify	Pre	0	0%
	Post	2	7.69%
Total LVAD+RVAD	**Pre**	**6**	**2.74%**
	Post	**26**	**8.72%**
Region 11 RVAD			
Maquet Jostra Rotaflow	Post	1	50%
Other, Specify	Post	1	50%
Total RVAD	**Post**	**2**	**0.67%**
Region 11 TAH			
SynCardia CardioWest	Pre	4	100%
	Post	4	80%
Other, Specify	Pre	0	0%
	Post	1	20%
Total TAH	**Pre**	**4**	**1.83%**
	Post	**5**	**1.68%**

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

Device	Brand	Count	Percent
IABP	**Total**	**496**	**27.71%**
Left Dischargeable VAD	Evaheart	2	0.2%
	Heartmate II	224	22.6%
	HeartMate III	422	42.58%
	Heartware HVAD	339	34.21%
	Worldheart Levacor	1	0.1%
	Other, Specify	3	0.3%
Left Dischargeable VAD	**Total**	**991**	**55.36%**
Left Non-Dischargeable VAD	CentriMag (Thoratec/Levitronix)	21	70%
	Maquet Jostra Rotaflow	5	16.67%
	Other, Specify	4	13.33%
Left Non-Dischargeable VAD	**Total**	**30**	**1.68%**
Left Percutaneous Device	Cardiac Assist Protek Duo	1	1.11%
	Cardiac Assist Tandem Heart	1	1.11%
	CentriMag (Thoratec/Levitronix)	1	1.11%
	Impella CP	25	27.78%
	Impella Recover 2.5	2	2.22%
	Impella Recover 5.0	60	66.67%
Left Percutaneous Device	**Total**	**90**	**5.03%**
Right Dischargeable VAD	HeartMate III	3	50%
	Heartware HVAD	3	50%
Right Dischargeable VAD	**Total**	**6**	**0.34%**
Right Non-Dischargeable VAD	CentriMag (Thoratec/Levitronix)	23	69.7%
	Maquet Jostra Rotaflow	4	12.12%
	Other, Specify	6	18.18%
Right Non-Dischargeable VAD	**Total**	**33**	**1.84%**
Right Percutaneous Device	Cardiac Assist Protek Duo	6	40%
	Cardiac Assist Tandem Heart	4	26.67%
	CentriMag (Thoratec/Levitronix)	1	6.67%
	Impella Recover 5.0	2	13.33%
	Impella RP	2	13.33%
Right Percutaneous Device	**Total**	**15**	**0.84%**
TAH	**Total**	**13**	**0.73%**
VA ECMO	**Total**	**116**	**6.48%**

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	3473	80	19	[15, 24]
	Status 1B	4251	87	6	[5, 7]
	Status 2	1837	40	5	[4, 7]
	Temporarily Inactive	2491	295	40	[35, 44]
Pre	**Overall**	**7118**	**502**	**15**	**[14, 16]**
Post	Adult Status 1	329	11	139	[69, 248]
	Adult Status 2	1725	22	33	[20, 49]
	Adult Status 3	2028	14	7	[4, 12]
	Adult Status 4	3626	67	5	[4, 6]
	Adult Status 5	224	6	9	[3, 21]
	Adult Status 6	1687	17	4	[2, 6]
	Temporarily Inactive	2344	287	41	[36, 46]
Post	**Overall**	**7003**	**430**	**15**	**[14, 16]**

Table A7: 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	437	10	Ref	-
	Post	426	11	1.02	[0.62, 1.69]
2	Pre	738	17	Ref	-
	Post	722	18	1.06	[0.71, 1.59]
3	Pre	897	18	Ref	-
	Post	830	21	1.17	[0.65, 2.11]
4	Pre	697	13	Ref	-
	Post	707	17	1.28	[0.80, 2.03]
5	Pre	961	14	Ref	-
	Post	941	15	1.12	[0.75, 1.67]
6	Pre	204	15	Ref	-
	Post	177	18	1.2	[0.64, 2.25]
7	Pre	773	14	Ref	-
	Post	723	10	0.69	[0.45, 1.07]
8	Pre	425	17	Ref	-
	Post	418	13	0.77	[0.45, 1.31]
9	Pre	595	11	Ref	-
	Post	591	8	0.76	[0.38, 1.50]
10	Pre	645	14	Ref	-
	Post	672	16	1.15	[0.73, 1.81]
11	Pre	836	18	Ref	-
	Post	866	17	0.93	[0.63, 1.37]
Overall	Pre	7118	15	Ref	-
	Post	7003	15	1.01	[0.89, 1.15]

Table A8: Adult Heart Transplants by Region and Medical Urgency Status Pre-Implementation

Region		Status 1A	Status 1B	Status 2	Total
1	N	124	24	4	152
	%	81.58%	15.79%	2.63%	100.00%
2	N	182	105	12	299
	%	60.87%	35.12%	4.01%	100.00%
3	N	199	130	17	346
	%	57.51%	37.57%	4.91%	100.00%
4	N	176	99	5	280
	%	62.86%	35.36%	1.79%	100.00%
5	N	353	106	30	489
	%	72.19%	21.68%	6.13%	100.00%
6	N	39	49	11	99
	%	39.39%	49.49%	11.11%	100.00%
7	N	215	48	1	264
	%	81.44%	18.18%	0.38%	100.00%
8	N	94	98	9	201
	%	46.77%	48.76%	4.48%	100.00%
9	N	192	22	1	215
	%	89.30%	10.23%	0.47%	100.00%
10	N	169	43	1	213
	%	79.34%	20.19%	0.47%	100.00%
11	N	275	111	10	396
	%	69.44%	28.03%	2.53%	100.00%

Table A9: 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	25	66	53	35	3	11	193
	%	12.95%	34.20%	27.46%	18.13%	1.55%	5.70%	100.00%
2	N	22	140	59	61	1	10	293
	%	7.51%	47.78%	20.14%	20.82%	0.34%	3.41%	100.00%
3	N	23	171	59	52	3	15	323
	%	7.12%	52.94%	18.27%	16.10%	0.93%	4.64%	100.00%
4	N	27	138	52	49	0	3	269
	%	10.04%	51.30%	19.33%	18.22%	0.00%	1.12%	100.00%
5	N	32	193	157	95	6	27	510
	%	6.27%	37.84%	30.78%	18.63%	1.18%	5.29%	100.00%
6	N	8	20	31	24	0	9	92
	%	8.70%	21.74%	33.70%	26.09%	0.00%	9.78%	100.00%
7	N	17	160	63	46	0	6	292
	%	5.82%	54.79%	21.58%	15.75%	0.00%	2.05%	100.00%
8	N	22	99	20	44	0	6	191
	%	11.52%	51.83%	10.47%	23.04%	0.00%	3.14%	100.00%
9	N	19	100	59	36	0	5	219
	%	8.68%	45.66%	26.94%	16.44%	0.00%	2.28%	100.00%
10	N	24	124	53	45	1	3	250
	%	9.60%	49.60%	21.20%	18.00%	0.40%	1.20%	100.00%
11	N	43	175	100	67	0	15	400
	%	10.75%	43.75%	25.00%	16.75%	0.00%	3.75%	100.00%

Table A10: 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	4	18.18%	0	0.00%	4	16.00%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	9	40.91%	3	100.00%	12	48.00%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	7	31.82%	0	0.00%	7	28.00%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	2	9.09%	0	0.00%	2	8.00%
Overall	22	100%	3	100%	25	100%
Adult Status 1						
Region 2						
BIVAD/Ventricular Episodes	2	10.00%	0	0.00%	2	9.09%
Exception	10	50.00%	0	0.00%	10	45.45%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	2	10.00%	0	0.00%	2	9.09%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	2	10.00%	1	50.00%	3	13.64%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	4	20.00%	1	50.00%	5	22.73%
Overall	20	100%	2	100%	22	100%
Adult Status 1						
Region 3						
BIVAD/Ventricular Episodes	2	10.00%	1	33.33%	3	13.04%
Exception	10	50.00%	1	33.33%	11	47.83%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	0	0.00%	1	33.33%	1	4.35%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	3	15.00%	0	0.00%	3	13.04%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	5	25.00%	0	0.00%	5	21.74%
Overall	20	100%	3	100%	23	100%

Table A10: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 1						
Region 4						
BIVAD/Ventricular Episodes	0	0.00%	1	20.00%	1	3.70%
Exception	16	72.73%	1	20.00%	17	62.96%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	1	4.55%	0	0.00%	1	3.70%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	3	13.64%	2	40.00%	5	18.52%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	2	9.09%	1	20.00%	3	11.11%
Overall	22	100%	5	100%	27	100%
Adult Status 1						
Region 5						
BIVAD/Ventricular Episodes	4	12.90%	0	0.00%	4	12.50%
Exception	3	9.68%	0	0.00%	3	9.38%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	2	6.45%	0	0.00%	2	6.25%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	11	35.48%	0	0.00%	11	34.38%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	11	35.48%	1	100.00%	12	37.50%
Overall	31	100%	1	100%	32	100%

Table A10: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 1						
Region 6						
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	2	28.57%	1	100.00%	3	37.50%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	5	71.43%	0	0.00%	5	62.50%
Overall	7	100%	1	100%	8	100%
Adult Status 1						
Region 7						
BIVAD/Ventricular Episodes	4	28.57%	0	0.00%	4	23.53%
Exception	4	28.57%	1	33.33%	5	29.41%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	0	0.00%	1	33.33%	1	5.88%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	4	28.57%	0	0.00%	4	23.53%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	2	14.29%	1	33.33%	3	17.65%
Overall	14	100%	3	100%	17	100%
Adult Status 1						
Region 8						
BIVAD/Ventricular Episodes	4	19.05%	0	0.00%	4	18.18%
Exception	6	28.57%	0	0.00%	6	27.27%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	0	0.00%	1	100.00%	1	4.55%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	6	28.57%	0	0.00%	6	27.27%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	5	23.81%	0	0.00%	5	22.73%
Overall	21	100%	1	100%	22	100%

Table A10: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 1						
Region 9						
BIVAD/Ventricular Episodes	2	11.11%	1	100.00%	3	15.79%
Exception	3	16.67%	0	0.00%	3	15.79%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	9	50.00%	0	0.00%	9	47.37%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	4	22.22%	0	0.00%	4	21.05%
Overall	18	100%	1	100%	19	100%
Adult Status 1						
Region 10						
BIVAD/Ventricular Episodes	3	13.64%	1	50.00%	4	16.67%
Exception	10	45.45%	0	0.00%	10	41.67%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	2	9.09%	0	0.00%	2	8.33%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	3	13.64%	1	50.00%	4	16.67%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	4	18.18%	0	0.00%	4	16.67%
Overall	22	100%	2	100%	24	100%

Table A10: *(continued)*

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 1						
Region 11						
BIVAD/Ventricular Episodes	1	2.56%	0	0.00%	1	2.33%
Exception	11	28.21%	1	25.00%	12	27.91%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	15	38.46%	1	25.00%	16	37.21%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	6	15.38%	0	0.00%	6	13.95%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	6	15.38%	2	50.00%	8	18.60%
Overall	39	100%	4	100%	43	100%
Adult Status 2						
Region 1						
Exception	30	53.57%	7	70.00%	37	56.06%
Intra-aortic ballon pump - Hemodynamic Values not obtained	1	1.79%	0	0.00%	1	1.52%
Intra-aortic ballon pump - Hemodynamic Values obtained	11	19.64%	2	20.00%	13	19.70%
Mechanical circulatory support device(MCSD) with malfunction	3	5.36%	1	10.00%	4	6.06%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	3	5.36%	0	0.00%	3	4.55%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	1.79%	0	0.00%	1	1.52%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	3	5.36%	0	0.00%	3	4.55%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	1	1.79%	0	0.00%	1	1.52%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	3	5.36%	0	0.00%	3	4.55%
Overall	56	100%	10	100%	66	100%

Table A10: ***(continued)***

Criteria	Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 2						
Region 2						
Exception	27	23.89%	9	33.33%	36	25.71%
Intra-aortic ballon pump - Hemodynamic Values not obtained	3	2.65%	0	0.00%	3	2.14%
Intra-aortic ballon pump - Hemodynamic Values obtained	64	56.64%	12	44.44%	76	54.29%
Mechanical circulatory support device(MCSD) with malfunction	6	5.31%	2	7.41%	8	5.71%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.88%	0	0.00%	1	0.71%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	6	5.31%	1	3.70%	7	5.00%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	1.77%	3	11.11%	5	3.57%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	2	1.77%	0	0.00%	2	1.43%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	2	1.77%	0	0.00%	2	1.43%
Overall						
	113	100%	27	100%	140	100%

Table A10: ***(continued)***

Criteria	Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 2						
Region 3						
Exception	69	53.91%	21	48.84%	90	52.63%
Intra-aortic ballon pump - Hemodynamic Values not obtained	1	0.78%	0	0.00%	1	0.58%
Intra-aortic ballon pump - Hemodynamic Values obtained	44	34.38%	10	23.26%	54	31.58%
Mechanical circulatory support device(MCSD) with malfunction	3	2.34%	3	6.98%	6	3.51%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.78%	0	0.00%	1	0.58%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	0.78%	0	0.00%	1	0.58%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	5	3.91%	1	2.33%	6	3.51%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	1	0.78%	4	9.30%	5	2.92%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	3	2.34%	4	9.30%	7	4.09%
Overall	128	100%	43	100%	171	100%
Adult Status 2						
Region 4						
Exception	43	45.74%	23	52.27%	66	47.83%
Intra-aortic ballon pump - Hemodynamic Values obtained	28	29.79%	12	27.27%	40	28.99%
Mechanical circulatory support device(MCSD) with malfunction	7	7.45%	1	2.27%	8	5.80%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	1.06%	0	0.00%	1	0.72%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	11	11.70%	3	6.82%	14	10.14%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	0	0.00%	5	11.36%	5	3.62%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	4	4.26%	0	0.00%	4	2.90%
Overall	94	100%	44	100%	138	100%

Table A10: ***(continued)***

Criteria	Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 2						
Region 5						
Exception	44	24.72%	6	40.00%	50	25.91%
Intra-aortic ballon pump - Hemodynamic Values not obtained	5	2.81%	0	0.00%	5	2.59%
Intra-aortic ballon pump - Hemodynamic Values obtained	97	54.49%	3	20.00%	100	51.81%
Mechanical circulatory support device(MCSD) with malfunction	2	1.12%	3	20.00%	5	2.59%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	4	2.25%	0	0.00%	4	2.07%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	18	10.11%	0	0.00%	18	9.33%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	5	2.81%	3	20.00%	8	4.15%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	3	1.69%	0	0.00%	3	1.55%
Overall						
	178	100%	15	100%	193	100%

Table A10: *(continued)*

Criteria	Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 2						
Region 6						
Exception	5	31.25%	2	50.00%	7	35.00%
Intra-aortic ballon pump - Hemodynamic Values not obtained	1	6.25%	0	0.00%	1	5.00%
Intra-aortic ballon pump - Hemodynamic Values obtained	2	12.50%	0	0.00%	2	10.00%
Mechanical circulatory support device(MCSD) with malfunction	4	25.00%	0	0.00%	4	20.00%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	6.25%	0	0.00%	1	5.00%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	3	18.75%	1	25.00%	4	20.00%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	0	0.00%	1	25.00%	1	5.00%
Overall	16	100%	4	100%	20	100%
Adult Status 2						
Region 7						
Exception	47	39.50%	17	41.46%	64	40.00%
Intra-aortic ballon pump - Hemodynamic Values not obtained	2	1.68%	0	0.00%	2	1.25%
Intra-aortic ballon pump - Hemodynamic Values obtained	54	45.38%	14	34.15%	68	42.50%
Mechanical circulatory support device(MCSD) with malfunction	7	5.88%	7	17.07%	14	8.75%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.84%	0	0.00%	1	0.62%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	4	3.36%	0	0.00%	4	2.50%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	3	2.52%	2	4.88%	5	3.12%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	1	0.84%	1	2.44%	2	1.25%
Overall	119	100%	41	100%	160	100%
Adult Status 2						
Region 8						
Exception	32	38.55%	6	37.50%	38	38.38%
Intra-aortic ballon pump - Hemodynamic Values not obtained	1	1.20%	1	6.25%	2	2.02%
Intra-aortic ballon pump - Hemodynamic Values obtained	42	50.60%	7	43.75%	49	49.49%
Mechanical circulatory support device(MCSD) with malfunction	4	4.82%	1	6.25%	5	5.05%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	2	2.41%	0	0.00%	2	2.02%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	2	2.41%	1	6.25%	3	3.03%

Table A10: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Overall						
	83	100%	16	100%	99	100%
Adult Status 2						
Region 9						
Exception	26	32.10%	6	31.58%	32	32.00%
Intra-aortic ballon pump - Hemodynamic Values obtained	41	50.62%	4	21.05%	45	45.00%
Mechanical circulatory support device(MCSD) with malfunction	9	11.11%	1	5.26%	10	10.00%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	3	3.70%	0	0.00%	3	3.00%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	0	0.00%	6	31.58%	6	6.00%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	2	2.47%	2	10.53%	4	4.00%
Overall						
	81	100%	19	100%	100	100%

Table A10: *(continued)*

Criteria	Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 2						
Region 10						
Exception	31	33.33%	13	41.94%	44	35.48%
Intra-aortic ballon pump - Hemodynamic Values not obtained	1	1.08%	1	3.23%	2	1.61%
Intra-aortic ballon pump - Hemodynamic Values obtained	39	41.94%	7	22.58%	46	37.10%
Intra-aortic balloon pump after 14 days	1	1.08%	0	0.00%	1	0.81%
Mechanical circulatory support device(MCSD) with malfunction	10	10.75%	7	22.58%	17	13.71%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	1.08%	0	0.00%	1	0.81%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	6	6.45%	1	3.23%	7	5.65%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	2.15%	2	6.45%	4	3.23%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	2	2.15%	0	0.00%	2	1.61%
Overall						
	93	100%	31	100%	124	100%
Adult Status 2						
Region 11						
Exception	68	48.92%	16	44.44%	84	48.00%
Intra-aortic ballon pump - Hemodynamic Values not obtained	3	2.16%	0	0.00%	3	1.71%
Intra-aortic ballon pump - Hemodynamic Values obtained	49	35.25%	9	25.00%	58	33.14%
Mechanical circulatory support device(MCSD) with malfunction	2	1.44%	4	11.11%	6	3.43%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	5	3.60%	0	0.00%	5	2.86%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	0.72%	0	0.00%	1	0.57%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	5	3.60%	6	16.67%	11	6.29%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	6	4.32%	1	2.78%	7	4.00%
Overall						
	139	100%	36	100%	175	100%

Table A10: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 3							
Region 1							
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	20	58.82%	0	0.00%	20	37.74%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	2.94%	0	0.00%	1	1.89%
	Exception	5	14.71%	6	31.58%	11	20.75%
	Intra-aortic balloon pump after 14 days	1	2.94%	0	0.00%	1	1.89%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	4	11.76%	7	36.84%	11	20.75%
	Mechanical circulatory support device (MCSD) with hemolysis	0	0.00%	2	10.53%	2	3.77%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	0	0.00%	1	5.26%	1	1.89%
	Mechanical circulatory support device (MCSD) with pump thrombosis	1	2.94%	2	10.53%	3	5.66%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	2	5.88%	1	5.26%	3	5.66%
Overall		34	100%	19	100%	53	100%

Table A10: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 2						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	24	52.17%	0	0.00%	24	40.68%
Exception	6	13.04%	9	69.23%	15	25.42%
Intra-aortic ballon pump - Hemodynamic Values obtained	1	2.17%	0	0.00%	1	1.69%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	3	6.52%	0	0.00%	3	5.08%
Mechanical circulatory support device (MCSD) with device infection - Debridement	0	0.00%	1	7.69%	1	1.69%
Mechanical circulatory support device (MCSD) with device infection - Erythema	0	0.00%	1	7.69%	1	1.69%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	0	0.00%	1	7.69%	1	1.69%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	2.17%	0	0.00%	1	1.69%
Mechanical circulatory support device (MCSD) with right heart failure	1	2.17%	1	7.69%	2	3.39%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	10	21.74%	0	0.00%	10	16.95%
Overall	46	100%	13	100%	59	100%
Adult Status 3						
Region 3						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	19	44.19%	0	0.00%	19	32.20%
Exception	8	18.60%	6	37.50%	14	23.73%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	2	4.65%	3	18.75%	5	8.47%
Mechanical circulatory support device (MCSD) with device infection - Debridement	2	4.65%	1	6.25%	3	5.08%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	2.33%	0	0.00%	1	1.69%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	2.33%	0	0.00%	1	1.69%
Mechanical circulatory support device (MCSD) with pump thrombosis	1	2.33%	3	18.75%	4	6.78%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	9	20.93%	3	18.75%	12	20.34%
Overall	43	100%	16	100%	59	100%

Table A10: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 3							
Region 4							
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	16	35.56%	0	0.00%	16	30.77%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	2.22%	0	0.00%	1	1.92%
	Exception	10	22.22%	3	42.86%	13	25.00%
	Intra-aortic balloon pump after 14 days	0	0.00%	1	14.29%	1	1.92%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	2	4.44%	0	0.00%	2	3.85%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	1	2.22%	0	0.00%	1	1.92%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	2	4.44%	0	0.00%	2	3.85%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	2.22%	0	0.00%	1	1.92%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	12	26.67%	3	42.86%	15	28.85%
Overall		45	100%	7	100%	52	100%

Table A10: *(continued)*

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 5						
Congenital heart disease	1	0.99%	0	0.00%	1	0.64%
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	37	36.63%	0	0.00%	37	23.57%
Exception	19	18.81%	28	50.00%	47	29.94%
Intra-aortic ballon pump - Hemodynamic Values obtained	1	0.99%	0	0.00%	1	0.64%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	0.99%	0	0.00%	1	0.64%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	6	5.94%	1	1.79%	7	4.46%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	2	1.98%	0	0.00%	2	1.27%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	0.99%	0	0.00%	1	0.64%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	0.99%	0	0.00%	1	0.64%
Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	1	1.79%	1	0.64%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	32	31.68%	26	46.43%	58	36.94%
Overall	101	100%	56	100%	157	100%
Adult Status 3						
Region 6						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	11	42.31%	0	0.00%	11	35.48%
Exception	5	19.23%	3	60.00%	8	25.81%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	0	0.00%	1	20.00%	1	3.23%
Mechanical circulatory support device (MCSD) with device infection - Debridement	2	7.69%	1	20.00%	3	9.68%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	3.85%	0	0.00%	1	3.23%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	7.69%	0	0.00%	2	6.45%
Mechanical circulatory support device (MCSD) with hemolysis	1	3.85%	0	0.00%	1	3.23%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	4	15.38%	0	0.00%	4	12.90%
Overall	26	100%	5	100%	31	100%

Table A10: *(continued)*

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 7						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	28	65.12%	0	0.00%	28	44.44%
Exception	5	11.63%	7	35.00%	12	19.05%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	1	2.33%	4	20.00%	5	7.94%
Mechanical circulatory support device (MCSD) with device infection - Debridement	0	0.00%	2	10.00%	2	3.17%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	2.33%	3	15.00%	4	6.35%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	2.33%	0	0.00%	1	1.59%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	2.33%	0	0.00%	1	1.59%
Mechanical circulatory support device (MCSD) with hemolysis	2	4.65%	0	0.00%	2	3.17%
Mechanical circulatory support device (MCSD) with pump thrombosis	0	0.00%	2	10.00%	2	3.17%
Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	1	5.00%	1	1.59%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	4	9.30%	1	5.00%	5	7.94%
Overall						
	43	100%	20	100%	63	100%

Table A10: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 8						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	8	53.33%	0	0.00%	8	40.00%
Exception	4	26.67%	1	20.00%	5	25.00%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	3	20.00%	2	40.00%	5	25.00%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	0	0.00%	1	20.00%	1	5.00%
Mechanical circulatory support device (MCSD) with hemolysis	0	0.00%	1	20.00%	1	5.00%
Overall	15	100%	5	100%	20	100%
Adult Status 3						
Region 9						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	23	65.71%	0	0.00%	23	38.98%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	2.86%	0	0.00%	1	1.69%
Exception	4	11.43%	16	66.67%	20	33.90%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	2	5.71%	1	4.17%	3	5.08%
Mechanical circulatory support device (MCSD) with device infection - Debridement	0	0.00%	3	12.50%	3	5.08%
Mechanical circulatory support device (MCSD) with hemolysis	0	0.00%	1	4.17%	1	1.69%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	5	14.29%	3	12.50%	8	13.56%
Overall	35	100%	24	100%	59	100%

Table A10: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 3							
Region 10							
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	21	45.65%	0	0.00%	21	39.62%
	Exception	5	10.87%	1	14.29%	6	11.32%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	6	13.04%	0	0.00%	6	11.32%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	2	4.35%	1	14.29%	3	5.66%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	2	4.35%	2	28.57%	4	7.55%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	0	0.00%	1	14.29%	1	1.89%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	2.17%	0	0.00%	1	1.89%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	2.17%	0	0.00%	1	1.89%
	Mechanical circulatory support device (MCSD) with hemolysis	1	2.17%	0	0.00%	1	1.89%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	3	6.52%	0	0.00%	3	5.66%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	4	8.70%	2	28.57%	6	11.32%
Overall		46	100%	7	100%	53	100%

Table A10: *(continued)*

Criteria	Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 3						
Region 11						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	47	58.75%	0	0.00%	47	47.00%
Exception	11	13.75%	7	35.00%	18	18.00%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	1.25%	0	0.00%	1	1.00%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	2	2.50%	5	25.00%	7	7.00%
Mechanical circulatory support device (MCSD) with device infection - Debridement	4	5.00%	3	15.00%	7	7.00%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	1.25%	1	5.00%	2	2.00%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	2	2.50%	0	0.00%	2	2.00%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	1.25%	0	0.00%	1	1.00%
Mechanical circulatory support device (MCSD) with pump thrombosis	0	0.00%	1	5.00%	1	1.00%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	11	13.75%	3	15.00%	14	14.00%
Overall	80	100%	20	100%	100	100%
Adult Status 4						
Region 1						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	9	37.50%	2	18.18%	11	31.43%
Congenital heart disease	2	8.33%	0	0.00%	2	5.71%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	11	45.83%	8	72.73%	19	54.29%
Ischemic heart disease with intractable angina	1	4.17%	0	0.00%	1	2.86%
Retransplant	1	4.17%	1	9.09%	2	5.71%
Overall	24	100%	11	100%	35	100%

Table A10: *(continued)*

Criteria	Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 4						
Region 2						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	3	7.32%	3	15.00%	6	9.84%
Congenital heart disease	0	0.00%	2	10.00%	2	3.28%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	18	43.90%	6	30.00%	24	39.34%
Exception	9	21.95%	6	30.00%	15	24.59%
Inotropes without hemodynamic monitoring	9	21.95%	2	10.00%	11	18.03%
Ischemic heart disease with intractable angina	2	4.88%	0	0.00%	2	3.28%
Retransplant	0	0.00%	1	5.00%	1	1.64%
Overall	41	100%	20	100%	61	100%
Adult Status 4						
Region 3						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	3	8.11%	1	6.67%	4	7.69%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	9	24.32%	5	33.33%	14	26.92%
Exception	18	48.65%	6	40.00%	24	46.15%
Inotropes without hemodynamic monitoring	4	10.81%	0	0.00%	4	7.69%
Ischemic heart disease with intractable angina	1	2.70%	2	13.33%	3	5.77%
Retransplant	2	5.41%	1	6.67%	3	5.77%
Overall	37	100%	15	100%	52	100%

Table A10: *(continued)*

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 4						
Region 4						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	5	11.90%	2	28.57%	7	14.29%
Congenital heart disease	1	2.38%	1	14.29%	2	4.08%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	15	35.71%	3	42.86%	18	36.73%
Exception	10	23.81%	0	0.00%	10	20.41%
Inotropes without hemodynamic monitoring	8	19.05%	0	0.00%	8	16.33%
Ischemic heart disease with intractable angina	1	2.38%	1	14.29%	2	4.08%
Retransplant	2	4.76%	0	0.00%	2	4.08%
Overall	42	100%	7	100%	49	100%
Adult Status 4						
Region 5						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	10	13.89%	3	13.04%	13	13.68%
Congenital heart disease	8	11.11%	6	26.09%	14	14.74%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	28	38.89%	9	39.13%	37	38.95%
Exception	10	13.89%	1	4.35%	11	11.58%
Inotropes without hemodynamic monitoring	7	9.72%	1	4.35%	8	8.42%
Ischemic heart disease with intractable angina	2	2.78%	0	0.00%	2	2.11%
No criteria for this status	1	1.39%	0	0.00%	1	1.05%
Retransplant	6	8.33%	3	13.04%	9	9.47%
Overall	72	100%	23	100%	95	100%
Adult Status 4						
Region 6						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	1	5.00%	2	50.00%	3	12.50%
Congenital heart disease	2	10.00%	0	0.00%	2	8.33%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	13	65.00%	1	25.00%	14	58.33%
Exception	2	10.00%	1	25.00%	3	12.50%
Inotropes without hemodynamic monitoring	2	10.00%	0	0.00%	2	8.33%
Overall	20	100%	4	100%	24	100%

Table A10: *(continued)*

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 4						
Region 7						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	3	9.09%	1	7.69%	4	8.70%
Congenital heart disease	1	3.03%	3	23.08%	4	8.70%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	13	39.39%	7	53.85%	20	43.48%
Exception	8	24.24%	1	7.69%	9	19.57%
Inotropes without hemodynamic monitoring	5	15.15%	1	7.69%	6	13.04%
Ischemic heart disease with intractable angina	1	3.03%	0	0.00%	1	2.17%
Retransplant	2	6.06%	0	0.00%	2	4.35%
Overall						
	33	100%	13	100%	46	100%

Table A10: *(continued)*

Criteria	Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 4 Region 8						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	0	0.00%	2	12.50%	2	4.55%
Congenital heart disease	3	10.71%	1	6.25%	4	9.09%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	7	25.00%	7	43.75%	14	31.82%
Exception	8	28.57%	1	6.25%	9	20.45%
Inotropes without hemodynamic monitoring	8	28.57%	3	18.75%	11	25.00%
Retransplant	2	7.14%	2	12.50%	4	9.09%
Overall	28	100%	16	100%	44	100%
Adult Status 4 Region 9						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	0	0.00%	2	13.33%	2	5.56%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	14	66.67%	12	80.00%	26	72.22%
Exception	3	14.29%	1	6.67%	4	11.11%
Inotropes without hemodynamic monitoring	2	9.52%	0	0.00%	2	5.56%
Retransplant	2	9.52%	0	0.00%	2	5.56%
Overall	21	100%	15	100%	36	100%
Adult Status 4 Region 10						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	2	7.14%	0	0.00%	2	4.44%
Congenital heart disease	2	7.14%	2	11.76%	4	8.89%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	18	64.29%	11	64.71%	29	64.44%
Exception	4	14.29%	1	5.88%	5	11.11%
Inotropes without hemodynamic monitoring	1	3.57%	2	11.76%	3	6.67%
Retransplant	1	3.57%	1	5.88%	2	4.44%
Overall	28	100%	17	100%	45	100%

Table A10: ***(continued)***

Criteria		Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 4							
Region 11							
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	2	3.39%	0	0.00%	2	2.99%
	Congenital heart disease	2	3.39%	0	0.00%	2	2.99%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	20	33.90%	3	37.50%	23	34.33%
	Exception	21	35.59%	4	50.00%	25	37.31%
	Inotropes without hemodynamic monitoring	3	5.08%	1	12.50%	4	5.97%
	Intra-aortic ballon pump - Hemodynamic Values obtained	1	1.69%	0	0.00%	1	1.49%
	Ischemic heart disease with intractable angina	3	5.08%	0	0.00%	3	4.48%
	Retransplant	7	11.86%	0	0.00%	7	10.45%
Overall		59	100%	8	100%	67	100%
Adult Status 5							
Region 1							
	None	3	100.00%	0	0.00%	3	100.00%
Adult Status 5							
Region 2							
	None	0	0.00%	1	100.00%	1	100.00%

Table A10: ***(continued)***

Criteria		Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 5 Region 3	None	2	100.00%	1	100.00%	3	100.00%
Adult Status 5 Region 5	None	5	100.00%	1	100.00%	6	100.00%
Adult Status 5 Region 10	None	1	100.00%	0	0.00%	1	100.00%
Adult Status 6 Region 1	None	10	100.00%	1	100.00%	11	100.00%
Adult Status 6 Region 2	None	10	100.00%	0	0.00%	10	100.00%
Adult Status 6 Region 3	None	12	100.00%	3	100.00%	15	100.00%
Adult Status 6 Region 4	None	3	100.00%	0	0.00%	3	100.00%
Adult Status 6 Region 5	None	27	100.00%	0	0.00%	27	100.00%
Adult Status 6 Region 6	None	9	100.00%	0	0.00%	9	100.00%
Adult Status 6 Region 7	None	5	100.00%	1	100.00%	6	100.00%
Adult Status 6 Region 8	None	5	100.00%	1	100.00%	6	100.00%
Adult Status 6 Region 9	None	4	100.00%	1	100.00%	5	100.00%

Table A10: ***(continued)***

Criteria	Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 6 Region 10						
None	3	100.00%	0	0.00%	3	100.00%
Adult Status 6 Region 11						
None	14	100.00%	1	100.00%	15	100.00%

Table A11: Mechanical Circulatory Support Devices at Transplant by Region

Brand	Era	Count	Percent
Region 1 ECMO			
Total ECMO	**Pre**	**3**	**2.54%**
	Post	**14**	**8.64%**
Region 1 IABP			
Total IABP	**Pre**	**2**	**1.69%**
	Post	**43**	**26.54%**
Region 1 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	1	1.02%
	Post	3	3.95%
Heartmate II	Pre	26	26.53%
	Post	17	22.37%
HeartMate III	Pre	13	13.27%
	Post	26	34.21%
Heartware HVAD	Pre	43	43.88%
	Post	27	35.53%
Impella Recover 5.0	Pre	2	2.04%
	Post	3	3.95%
Other, Specify	Pre	13	13.27%
	Post	0	0%
Total LVAD	**Pre**	**98**	**83.05%**
	Post	**76**	**46.91%**
Region 1 LVAD+RVAD			
Cardiac Assist Tandem Heart	Pre	2	14.29%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	7	50%
	Post	26	92.86%
HeartMate III	Pre	0	0%
	Post	1	3.57%
Heartware HVAD	Pre	4	28.57%
	Post	0	0%
Other, Specify	Pre	1	7.14%
	Post	1	3.57%
Total LVAD+RVAD	**Pre**	**14**	**11.86%**
	Post	**28**	**17.28%**

Region 1 RVAD			
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	1	100%
Impella Recover 5.0	Pre	1	100%
	Post	0	0%
Total RVAD	**Pre**	**1**	**0.85%**
	Post	**1**	**0.62%**
Region 2 ECMO			
Total ECMO	**Pre**	**7**	**4.9%**
	Post	**14**	**7.11%**
Region 2 IABP			
Total IABP	**Pre**	**11**	**7.69%**
	Post	**85**	**43.15%**
Region 2 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	2	2.22%
Heartmate II	Pre	42	35%
	Post	15	16.67%
HeartMate III	Pre	4	3.33%
	Post	24	26.67%
Heartware HVAD	Pre	49	40.83%
	Post	38	42.22%
Impella CP	Pre	1	0.83%
	Post	0	0%
Impella Recover 2.5	Pre	0	0%
	Post	1	1.11%
Impella Recover 5.0	Pre	1	0.83%
	Post	7	7.78%
Other, Specify	Pre	23	19.17%
	Post	3	3.33%
Total LVAD	**Pre**	**120**	**83.92%**
	Post	**90**	**45.69%**
Region 2 LVAD+RVAD			
CentriMag (Thoratec/Levitronix)	Pre	2	50%
	Post	4	50%
HeartMate III	Pre	0	0%
	Post	1	12.5%
	Pre	1	25%

Heartware HVAD	Post	2	25%
Maquet Jostra Rotaflow	Pre	1	25%
	Post	0	0%
Other, Specify	Pre	0	0%
	Post	1	12.5%
Total LVAD+RVAD	**Pre**	**4**	**2.8%**
	Post	**8**	**4.06%**
Region 2 RVAD			
Heartware HVAD	Pre	1	100%
Total RVAD	**Pre**	**1**	**0.7%**
Region 3 ECMO			
Total ECMO	**Pre**	**6**	**3.31%**
	Post	**8**	**3.7%**
Region 3 IABP			
Total IABP	**Pre**	**18**	**9.94%**
	Post	**95**	**43.98%**
Region 3 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	2	1.32%
	Post	0	0%
Heartmate II	Pre	59	39.07%
	Post	26	26.26%
HeartMate III	Pre	10	6.62%
	Post	27	27.27%
Heartsaver VAD	Pre	1	0.66%
	Post	0	0%
Heartware HVAD	Pre	51	33.77%
	Post	29	29.29%
Impella CP	Pre	0	0%
	Post	3	3.03%
Impella Recover 2.5	Pre	1	0.66%
	Post	1	1.01%
Impella Recover 5.0	Pre	2	1.32%
	Post	9	9.09%
Other, Specify	Pre	25	16.56%
	Post	4	4.04%
Total LVAD	**Pre**	**151**	**83.43%**
	Post	**99**	**45.83%**

Region 3 LVAD+RVAD			
CentriMag (Thoratec/Levitronix)	Pre	1	25%
	Post	1	8.33%
HeartMate III	Pre	0	0%
	Post	3	25%
Heartware HVAD	Pre	3	75%
	Post	6	50%
Impella Recover 2.5	Pre	0	0%
	Post	1	8.33%
Other, Specify	Pre	0	0%
	Post	1	8.33%
Total LVAD+RVAD	**Pre**	**4**	**2.21%**
	Post	**12**	**5.56%**
Region 3 RVAD			
Impella RP	Pre	1	100%
Total RVAD	**Pre**	**1**	**0.55%**
Region 3 TAH			
SynCardia CardioWest	Pre	1	100%
	Post	2	100%
Total TAH	**Pre**	**1**	**0.55%**
	Post	**2**	**0.93%**
Region 4 ECMO			
Total ECMO	**Post**	**13**	**7.22%**
Region 4 IABP			
Total IABP	**Pre**	**36**	**27.91%**
	Post	**73**	**40.56%**
Region 4 LVAD			
Heartmate II	Pre	53	60.23%
	Post	26	30.95%
HeartMate III	Pre	3	3.41%
	Post	12	14.29%
Heartmate XVE	Pre	1	1.14%
	Post	0	0%
Heartware HVAD	Pre	22	25%
	Post	23	27.38%
	Pre	0	0%

Impella CP	Post	2	2.38%
Impella Recover 2.5	Pre	1	1.14%
	Post	0	0%
Impella Recover 5.0	Pre	4	4.55%
	Post	20	23.81%
Other, Specify	Pre	4	4.55%
	Post	1	1.19%
Total LVAD	**Pre**	**88**	**68.22%**
	Post	**84**	**46.67%**
Region 4 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	16.67%
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	2	33.33%
HeartMate III	Pre	0	0%
	Post	1	16.67%
Heartware HVAD	Pre	0	0%
	Post	2	33.33%
Other, Specify	Pre	2	100%
	Post	0	0%
Total LVAD+RVAD	**Pre**	**2**	**1.55%**
	Post	**6**	**3.33%**
Region 4 RVAD			
CentriMag (Thoratec/Levitronix)	Post	1	50%
Impella RP	Post	1	50%
Total RVAD	**Post**	**2**	**1.11%**
Region 4 TAH			
SynCardia CardioWest	Pre	3	100%
	Post	2	100%
Total TAH	**Pre**	**3**	**2.33%**
	Post	**2**	**1.11%**
Region 5 ECMO			
Total ECMO	**Pre**	**3**	**1.44%**
	Post	**27**	**10.07%**
Region 5 IABP			
Total IABP	**Pre**	**22**	**10.53%**
	Post	**101**	**37.69%**

Region 5 LVAD			
Heartmate II	Pre	27	16.46%
	Post	16	12.7%
HeartMate III	Pre	8	4.88%
	Post	33	26.19%
Heartsaver VAD	Pre	2	1.22%
	Post	1	0.79%
Heartware HVAD	Pre	95	57.93%
	Post	55	43.65%
Impella CP	Pre	0	0%
	Post	4	3.17%
Impella Recover 2.5	Pre	2	1.22%
	Post	2	1.59%
Impella Recover 5.0	Pre	16	9.76%
	Post	15	11.9%
Other, Specify	Pre	14	8.54%
	Post	0	0%
Total LVAD	**Pre**	**164**	**78.47%**
	Post	**126**	**47.01%**
Region 5 LVAD+RVAD			
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	1	25%
CentriMag (Thoratec/Levitronix)	Pre	1	10%
	Post	2	50%
HeartMate III	Pre	2	20%
	Post	1	25%
Heartware HVAD	Pre	3	30%
	Post	0	0%
Maquet Jostra Rotaflow	Pre	1	10%
	Post	0	0%
Other, Specify	Pre	3	30%
	Post	0	0%
Total LVAD+RVAD	**Pre**	**10**	**4.78%**
	Post	**4**	**1.49%**
Region 5 RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	33.33%
	Pre	1	50%

Heartware HVAD	Post	1	33.33%
Impella Recover 5.0	Pre	1	50%
	Post	0	0%
Impella RP	Pre	0	0%
	Post	1	33.33%
Total RVAD	**Pre**	**2**	**0.96%**
	Post	**3**	**1.12%**
Region 5 TAH			
SynCardia CardioWest	Pre	8	100%
	Post	6	85.71%
Other, Specify	Pre	0	0%
	Post	1	14.29%
Total TAH	**Pre**	**8**	**3.83%**
	Post	**7**	**2.61%**
Region 6 ECMO			
Total ECMO	**Post**	**9**	**13.04%**
Region 6 IABP			
Total IABP	**Pre**	**2**	**3.33%**
	Post	**5**	**7.25%**
Region 6 LVAD			
Heartmate II	Pre	13	25%
	Post	8	15.38%
HeartMate III	Pre	2	3.85%
	Post	15	28.85%
Heartware HVAD	Pre	27	51.92%
	Post	21	40.38%
Impella CP	Pre	0	0%
	Post	6	11.54%
Impella Recover 5.0	Pre	2	3.85%
	Post	2	3.85%
Other, Specify	Pre	8	15.38%
	Post	0	0%
Total LVAD	**Pre**	**52**	**86.67%**
	Post	**52**	**75.36%**
Region 6 TAH			
SynCardia CardioWest	Pre	6	100%
	Post	3	100%

Total TAH	**Pre**	**6**	**10%**
	Post	**3**	**4.35%**
Region 7 ECMO			
Total ECMO	**Pre**	**2**	**1.03%**
	Post	**9**	**3.9%**
Region 7 IABP			
Total IABP	**Pre**	**54**	**27.84%**
	Post	**101**	**43.72%**
Region 7 LVAD			
Heartmate II	Pre	35	25.74%
	Post	20	18.69%
HeartMate III	Pre	6	4.41%
	Post	41	38.32%
Heartware HVAD	Pre	69	50.74%
	Post	41	38.32%
Impella Recover 2.5	Pre	1	0.74%
	Post	0	0%
Impella Recover 5.0	Pre	0	0%
	Post	5	4.67%
Other, Specify	Pre	25	18.38%
	Post	0	0%
Total LVAD	**Pre**	**136**	**70.1%**
	Post	**107**	**46.32%**
Region 7 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	16.67%
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	3	25%
Heartware HVAD	Pre	2	100%
	Post	7	58.33%
Total LVAD+RVAD	**Pre**	**2**	**1.03%**
	Post	**12**	**5.19%**
Region 7 TAH			
SynCardia CardioWest	Post	2	100%
Total TAH	**Post**	**2**	**0.87%**
Region 8 ECMO			
Total ECMO	**Post**	**12**	**9.02%**

Region 8 IABP			
Total IABP	**Pre**	**18**	**16.98%**
	Post	**68**	**51.13%**
Region 8 LVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	2.04%
Heartmate II	Pre	41	48.81%
	Post	17	34.69%
HeartMate III	Pre	3	3.57%
	Post	15	30.61%
Heartware HVAD	Pre	17	20.24%
	Post	15	30.61%
Other, Specify	Pre	23	27.38%
	Post	1	2.04%
Total LVAD	**Pre**	**84**	**79.25%**
	Post	**49**	**36.84%**
Region 8 LVAD+RVAD			
CentriMag (Thoratec/Levitronix)	Pre	2	100%
	Post	3	75%
HeartMate III	Pre	0	0%
	Post	1	25%
Total LVAD+RVAD	**Pre**	**2**	**1.89%**
	Post	**4**	**3.01%**
Region 8 RVAD			
Heartware HVAD	Pre	1	50%
Other, Specify	Pre	1	50%
Total RVAD	**Pre**	**2**	**1.89%**
Region 9 ECMO			
Total ECMO	**Pre**	**3**	**2.17%**
	Post	**19**	**10.73%**
Region 9 IABP			
Total IABP	**Pre**	**12**	**8.7%**
	Post	**62**	**35.03%**
Region 9 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	1	0.86%
	Post	0	0%

Heartmate II	Pre	79	68.1%
	Post	32	37.65%
HeartMate III	Pre	9	7.76%
	Post	38	44.71%
Heartware HVAD	Pre	11	9.48%
	Post	15	17.65%
Other, Specify	Pre	16	13.79%
	Post	0	0%
Total LVAD	**Pre**	**116**	**84.06%**
	Post	**85**	**48.02%**
Region 9 LVAD+RVAD			
CentriMag (Thoratec/Levitronix)	Pre	3	50%
	Post	2	33.33%
HeartMate III	Pre	0	0%
	Post	4	66.67%
Heartware HVAD	Pre	1	16.67%
	Post	0	0%
Other, Specify	Pre	2	33.33%
	Post	0	0%
Total LVAD+RVAD	**Pre**	**6**	**4.35%**
	Post	**6**	**3.39%**
Region 9 RVAD			
Other, Specify	Post	1	100%
Total RVAD	**Post**	**1**	**0.56%**
Region 9 TAH			
SynCardia CardioWest	Pre	1	100%
	Post	4	100%
Total TAH	**Pre**	**1**	**0.72%**
	Post	**4**	**2.26%**
Region 10 ECMO			
Total ECMO	**Pre**	**1**	**0.62%**
	Post	**10**	**4.85%**
Region 10 IABP			
Total IABP	**Pre**	**7**	**4.32%**
	Post	**70**	**33.98%**

Region 10 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	1	0.88%
Heartmate II	Pre	43	31.62%
	Post	28	24.56%
HeartMate III	Pre	5	3.68%
	Post	44	38.6%
Heartware HVAD	Pre	60	44.12%
	Post	31	27.19%
Impella Recover 2.5	Pre	0	0%
	Post	1	0.88%
Impella Recover 5.0	Pre	2	1.47%
	Post	5	4.39%
Other, Specify	Pre	26	19.12%
	Post	4	3.51%
Total LVAD	**Pre**	**136**	**83.95%**
	Post	**114**	**55.34%**

Region 10 LVAD+RVAD			
CentriMag (Thoratec/Levitronix)	Pre	8	57.14%
	Post	4	66.67%
HeartMate III	Pre	0	0%
	Post	1	16.67%
Heartware HVAD	Pre	2	14.29%
	Post	1	16.67%
Impella Recover 5.0	Pre	1	7.14%
	Post	0	0%
Other, Specify	Pre	3	21.43%
	Post	0	0%
Total LVAD+RVAD	**Pre**	**14**	**8.64%**
	Post	**6**	**2.91%**

Region 10 RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	66.67%
CentriMag (Thoratec/Levitronix)	Pre	1	100%
	Post	0	0%
Impella Recover 5.0	Pre	0	0%
	Post	1	33.33%
	Pre	**1**	**0.62%**

Total RVAD	**Post**	**3**	**1.46%**
Region 10 TAH			
SynCardia CardioWest	Pre	2	66.67%
	Post	3	100%
Other, Specify	Pre	1	33.33%
	Post	0	0%
Total TAH	**Pre**	**3**	**1.85%**
	Post	**3**	**1.46%**
Region 11 ECMO			
Total ECMO	**Pre**	**5**	**2.16%**
	Post	**25**	**8.09%**
Region 11 IABP			
Total IABP	**Pre**	**39**	**16.81%**
	Post	**119**	**38.51%**
Region 11 LVAD			
Cardiac Assist Tandem Heart	Pre	1	0.55%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	2	1.09%
	Post	2	1.65%
Heartmate II	Pre	70	38.25%
	Post	26	21.49%
HeartMate III	Pre	13	7.1%
	Post	43	35.54%
Heartsaver VAD	Pre	2	1.09%
	Post	0	0%
Heartware HVAD	Pre	76	41.53%
	Post	44	36.36%
Impella Recover 5.0	Pre	0	0%
	Post	2	1.65%
Other, Specify	Pre	19	10.38%
	Post	4	3.31%
Total LVAD	**Pre**	**183**	**78.88%**
	Post	**121**	**39.16%**
Region 11 LVAD+RVAD			
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	1	3.33%
	Pre	2	100%

CentriMag (Thoratec/Levitronix)	Post	17	56.67%
HeartMate III	Pre	0	0%
	Post	7	23.33%
Heartware HVAD	Pre	0	0%
	Post	1	3.33%
Impella Recover 5.0	Pre	0	0%
	Post	1	3.33%
Other, Specify	Pre	0	0%
	Post	3	10%
Total LVAD+RVAD	**Pre**	**2**	**0.86%**
	Post	**30**	**9.71%**

Region 11 RVAD

Cardiac Assist Protek Duo	Post	1	25%
CentriMag (Thoratec/Levitronix)	Post	1	25%
Heartware HVAD	Post	1	25%
Maquet Jostra Rotaflow	Post	1	25%
Total RVAD	**Post**	**4**	**1.29%**

Region 11 TAH

SynCardia CardioWest	Pre	3	100%
	Post	8	80%
Other, Specify	Pre	0	0%
	Post	2	20%
Total TAH	**Pre**	**3**	**1.29%**
	Post	**10**	**3.24%**

Table A12: Mechanical Circulatory Support Devices at Transplant for Adult Heart Candidates as Entered into Waitlist, Post-Implementation

Device	Brand	Count	Percent
IABP	**Total**	**722**	**47.72%**
Left Dischargeable VAD	Heartmate II	80	19.14%
	HeartMate III	174	41.63%
	Heartware HVAD	164	39.23%
Left Dischargeable VAD	**Total**	**418**	**27.63%**
Left Non-Dischargeable VAD	CentriMag (Thoratec/Levitronix)	36	83.72%
	Maquet Jostra Rotaflow	2	4.65%
	Other, Specify	5	11.63%
Left Non-Dischargeable VAD	**Total**	**43**	**2.84%**
Left Percutaneous Device	Cardiac Assist Protek Duo	3	2.73%
	Cardiac Assist Tandem Heart	2	1.82%
	CentriMag (Thoratec/Levitronix)	1	0.91%
	Impella CP	19	17.27%
	Impella Recover 2.5	2	1.82%
	Impella Recover 5.0	81	73.64%
	Impella RP	1	0.91%
	Other, Specify	1	0.91%
Left Percutaneous Device	**Total**	**110**	**7.27%**
Right Dischargeable VAD	Heartmate II	1	20%
	HeartMate III	2	40%
	Heartware HVAD	2	40%
Right Dischargeable VAD	**Total**	**5**	**0.33%**
Right Non-Dischargeable VAD	CentriMag (Thoratec/Levitronix)	36	78.26%
	Maquet Jostra Rotaflow	2	4.35%
	Other, Specify	8	17.39%
Right Non-Dischargeable VAD	**Total**	**46**	**3.04%**
Right Percutaneous Device	Cardiac Assist Protek Duo	8	47.06%
	Cardiac Assist Tandem Heart	2	11.76%
	CentriMag (Thoratec/Levitronix)	1	5.88%
	Impella Recover 5.0	2	11.76%
	Impella RP	3	17.65%
	Other, Specify	1	5.88%
Right Percutaneous Device	**Total**	**17**	**1.12%**
TAH	AbioCor	1	5%
	SynCardia CardioWest	18	90%
	Other, Specify	1	5%
TAH	**Total**	**20**	**1.32%**
VA ECMO	**Total**	**132**	**8.72%**

Table A13: Adult Heart Transplants by Distance Traveled and Share Type

Distance	Share	Era	Count	Percent
< 500 NM	Local	Pre	1889	63.95%
		Post	1003	33.08%
	Regional	Pre	408	13.81%
		Post	660	21.77%
	National	Pre	527	17.84%
		Post	993	32.75%
	Not Reported	Pre	2	0.07%
		Post	1	0.03%
500 NM - <1000 NM	Local	Pre	1	0.03%
		Post	2	0.07%
	Regional	Pre	25	0.85%
		Post	29	0.96%
	National	Pre	94	3.18%
		Post	327	10.78%
	Not Reported	Pre	2	0.07%
		Post	0	0%
1000 NM - <1500 NM	Local	Pre	5	0.17%
		Post	10	0.33%
	Regional	Pre	0	0%
		Post	1	0.03%
	National	Pre	1	0.03%
		Post	6	0.2%
	Not Reported	Pre	0	0%
		Post	0	0%

Table A14: Adult Heart Transplants by Zone, Era, and Medical Urgency Status

Zone	Era	Status	Count	Percent
DSA	Pre	Status 1A	1248	42.25%
		Status 1B	599	20.28%
		Status 2	48	1.62%
	Post	Adult Status 1	55	1.81%
		Adult Status 2	252	8.31%
		Adult Status 3	320	10.55%
		Adult Status 4	324	10.69%
		Adult Status 5	12	0.4%
		Adult Status 6	52	1.72%
Zone A	Pre	Status 1A	699	23.66%
		Status 1B	202	6.84%
		Status 2	35	1.18%
	Post	Adult Status 1	183	6.04%
		Adult Status 2	965	31.83%
		Adult Status 3	274	9.04%
		Adult Status 4	189	6.23%
		Adult Status 5	1	0.03%
		Adult Status 6	38	1.25%
Zone B	Pre	Status 1A	71	2.4%
		Status 1B	34	1.15%
		Status 2	17	0.58%
	Post	Adult Status 1	24	0.79%
		Adult Status 2	168	5.54%
		Adult Status 3	108	3.56%
		Adult Status 4	39	1.29%
		Adult Status 5	1	0.03%
		Adult Status 6	20	0.66%
Zone C	Pre	Status 2	1	0.03%
	Post	Adult Status 2	1	0.03%
		Adult Status 3	4	0.13%
		Adult Status 4	2	0.07%

Table A15: 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	3473	1942	468	[447, 489]
	Status 1B	4251	816	55	[52, 59]
	Status 2	1837	95	13	[10, 15]
Pre	**Overall**	**7118**	**2853**	**84**	**[81, 87]**
Post	Adult Status 1	329	245	3092	[2717, 3505]
	Adult Status 2	1725	1335	1980	[1875, 2089]
	Adult Status 3	2028	675	331	[307, 357]
	Adult Status 4	3626	510	37	[34, 40]
	Adult Status 5	224	16	25	[14, 41]
	Adult Status 6	1687	116	27	[22, 32]
Post	**Overall**	**7003**	**2937**	**102**	**[98, 106]**

Table A16: 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	437	61	Ref	-
	Post	426	96	1.59	[1.32, 1.91]
2	Pre	738	91	Ref	-
	Post	722	97	1.06	[0.90, 1.26]
3	Pre	897	77	Ref	-
	Post	830	88	1.14	[0.91, 1.43]
4	Pre	697	80	Ref	-
	Post	707	99	1.23	[1.02, 1.48]
5	Pre	961	121	Ref	-
	Post	941	150	1.24	[1.06, 1.46]
6	Pre	204	111	Ref	-
	Post	177	161	1.45	[1.18, 1.79]
7	Pre	773	59	Ref	-
	Post	723	85	1.44	[1.22, 1.69]
8	Pre	425	106	Ref	-
	Post	418	118	1.11	[0.92, 1.34]
9	Pre	595	64	Ref	-
	Post	591	79	1.25	[0.98, 1.59]
10	Pre	645	64	Ref	-
	Post	672	82	1.29	[1.06, 1.56]
11	Pre	836	112	Ref	-
	Post	866	115	1.02	[0.87, 1.21]
Overall	Pre	7118	84	Ref	-
	Post	7003	102	1.22	[1.15, 1.28]

Table A17: 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	400	66	Ref	-
		Post	400	42	0.63	[0.09, 4.67]
	6-10 Years	Pre	63	9	Ref	-
		Post	72	18	2.01	[0.49, 8.30]
	11-17 Years	Pre	169	11	Ref	-
		Post	153	23	1.97	[0.40, 9.74]
Status 1B	0-5 Years	Pre	130	5	Ref	-
		Post	133	4	0.85	-
	6-10 Years	Pre	47	0	Ref	-
		Post	59	0	-	-
	11-17 Years	Pre	116	8	Ref	-
		Post	99	6	0.74	[0.07, 8.18]
Status 2	0-5 Years	Pre	110	2	Ref	-
		Post	102	0	0	-
	6-10 Years	Pre	48	0	Ref	-
		Post	41	0	-	-
	11-17 Years	Pre	95	0	Ref	-
		Post	102	0	-	-
Temporarily Inactive	0-5 Years	Pre	200	59	Ref	-
		Post	205	51	0.87	[0.21, 3.64]
	6-10 Years	Pre	39	19	Ref	-
		Post	34	9	0.49	[0.07, 3.56]
	11-17 Years	Pre	79	31	Ref	-
		Post	91	24	0.77	[0.28, 2.12]
Overall	0-5 Years	Pre	564	43	Ref	-
		Post	557	31	0.72	[0.23, 2.31]
	6-10 Years	Pre	122	5	Ref	-
		Post	138	5	1.02	[0.32, 3.23]
	11-17 Years	Pre	311	11	Ref	-
		Post	317	10	0.95	[0.42, 2.11]

Table A18: 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	400	305	Ref	-
		Post	400	343	1.12	[0.81, 1.56]
	6-10 Years	Pre	63	390	Ref	-
		Post	72	483	1.24	[0.92, 1.68]
	11-17 Years	Pre	169	432	Ref	-
		Post	153	933	2.16	[1.67, 2.78]
Status 1B	0-5 Years	Pre	130	145	Ref	-
		Post	133	60	0.41	[0.17, 0.97]
	6-10 Years	Pre	47	52	Ref	-
		Post	59	136	2.62	[1.49, 4.59]
	11-17 Years	Pre	116	170	Ref	-
		Post	99	264	1.56	[1.01, 2.39]
Status 2	0-5 Years	Pre	110	2	Ref	-
		Post	102	10	4.12	[1.11, 15.34]
	6-10 Years	Pre	48	21	Ref	-
		Post	41	22	1.03	[0.12, 8.83]
	11-17 Years	Pre	95	18	Ref	-
		Post	102	14	0.8	[0.29, 2.20]
Overall	0-5 Years	Pre	564	121	Ref	-
		Post	557	128	1.05	[0.79, 1.41]
	6-10 Years	Pre	122	92	Ref	-
		Post	138	131	1.42	[1.10, 1.84]
	11-17 Years	Pre	311	134	Ref	-
		Post	317	161	1.2	[0.97, 1.49]