Final Report

OPTN Heart Committee | Descriptive Data Request

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

DHHS Contract No. 250-2019-00001C
Submitted: September 12, 2022

Prepared for:
Heart Committee
Committee Meeting
October 11, 2022

By:
Erin Schnellinger, PhD, MS
Keighly Bradbrook, PhD and Kelsi Lindblad, PhD
UNOS Research Department

Contents

Background/Purpose

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

This report does not address the removal of donation service area (DSA) from thoracic organ allocation, a change implemented on January 9, 2020. Although this report contains data from the DSA removal post-implementation period, a separate report addresses the monitoring of that change.

This report examines the impact of the modifications to adult heart allocation at three years post-implementation, and will be followed by two more annual reports at four and five years post-implementation. This reporting timeline is subject to change based on the results.

Strategic Plan Goal or Committee Project Addressed

Improve equity in access to heart transplants

Committee Request

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

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

Data and Methods

Data Sources: These analyses use data from the OPTN waiting list, the Deceased Donor Registration (DDR) form, the Transplant Candidate Registration (TCR) form, the Transplant Recipient Registration (TRR) form, and the Transplant Recipient Followup (TRF) form. Analyses are based on OPTN data as of September 30, 2022 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, 2015 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2021 (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, 2015 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2021 (post). Rates were assessed based on the ratio of death or transplant to patient-years of exposure, and rates are displayed as deaths or transplants per 100 patient-years. The OPTN database was supplemented with deaths from verified external sources. Since candidates may be removed from the waiting list shortly prior to death as their health deteriorates, the waiting list mortality rate calculation included deaths within seven days of waiting list removal and those removed from the waiting list as a result of becoming too sick to transplant. Candidates who had received any previous transplant were excluded from the waiting list mortality and transplant rate analyses.

Candidates ever waiting were also stratified by medical urgency status. The distribution of medical urgency status for candidates ever waiting was further stratified by whether the listing center performed a greater or lesser number of 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, 2015 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2021 (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, 2015 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2021 (post) were used to assess the time between first electronic offer and cross clamp and the sequence number of the acceptor on adult heart match runs. The distribution of the offer number of the acceptor on heart match runs was summarized using the median, 10th percentile, and 90th percentile.

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

Utilization and discard rates were calculated based on a cohort of adult (age >= 18) deceased donors recovered between October 18, 2015 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2021 (post). For the purposes of this report, the utilization rate is defined as the number of adult deceased donor hearts transplanted 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 two years of follow-up plus a two-month data lag, which included recipients transplanted between October 18, 2015 and October 17, 2016 in the pre-implementation cohort and between October 18, 2018 and October 17, 2019 in the post-implementation cohort. Candidates who received any previous transplant were excluded from the analysis, as were multi-organ transplant candidates. Standard Kaplan-Meier survival analyses were conducted, as 1) the OPTN Executive Committee's amnesty policy that temporarily relaxed reporting requirements for follow-up form submission during the height of COVID-19 is no longer in effect, and 2) we expect that any outcomes censoring that may have been seen as a result of this policy have been resolved. 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, 2021 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. On March 4, 2021, a guidance was implemented to "clarify the types and amount of information that should be provided to the heart Regional Review Board (RRB) members to assist them with objectively evaluating an exception request for a candidate being supported by the temporary therapies of a Percutaneous Endovascular Mechanical Circulatory Support Device or an Intra-Aortic Balloon Pump (IABP)". Thus, for the exception request analyses described here, the post-policy period was subdivided into two cohorts: 1) post-policy, pre-guidance (October 18, 2018 - March 3, 2021); and 2) post-policy, post-guidance (March 4, 2021 - October 17, 2021). Waiting list mortality rates for Status 1, 2, and 4 candidates pre- versus post-guidance were not computed in this report due to insufficient follow-up time post-guidance. These analyses may be added in subsequent reports.

Pediatric (age $<$ 18) candidates added only to the heart waiting list between October 18, 2015 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2021 (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, 2015 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2021 (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, 2015 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2021 (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 v9.4 (SAS Institute, Inc., Cary, NC.) and R Version 4.1.3 (R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL: https://www.R-project.org/).

A Notice on COVID

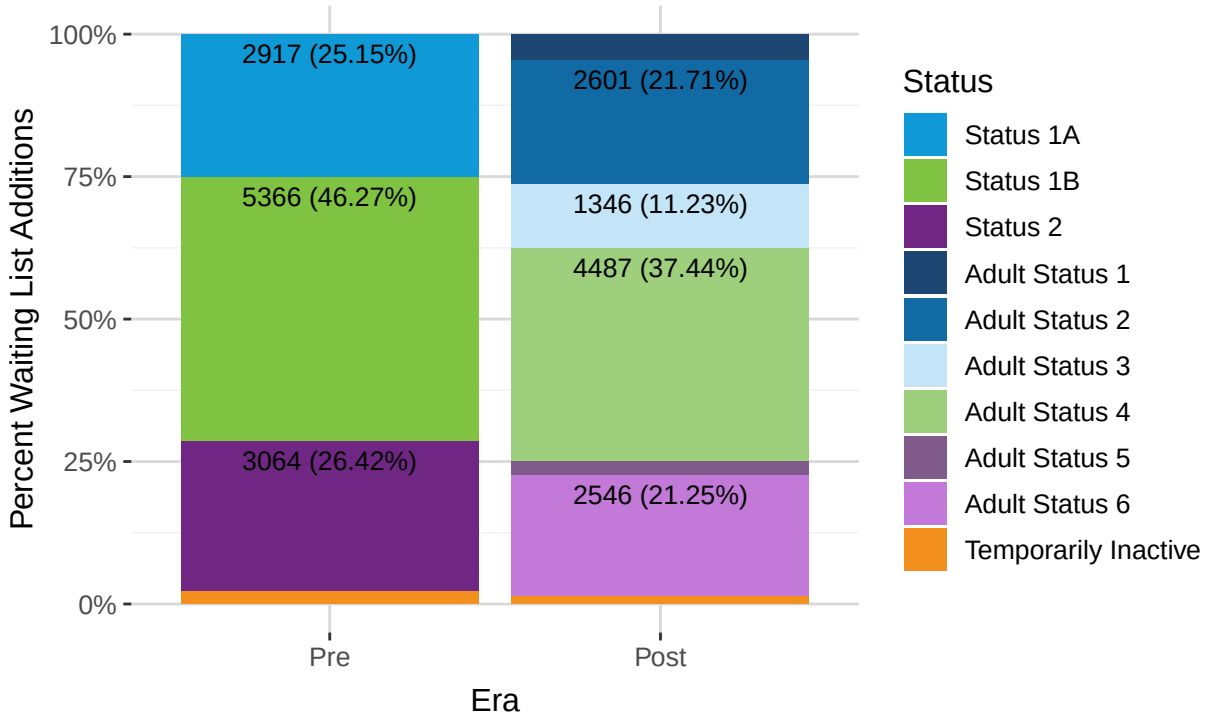
For all figures and tables, we note that the World Health Organization (WHO) declared COVID-19 a pandemic on March 11, 2020 and a national state of emergency was declared in the U.S. on March 13, 2020. Based on the WHO's declaration of the pandemic and the national state of emergency, the post-implementation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

Results

Waitlist

These analyses examine differences between two waiting list cohorts: the pre-implementation cohort, composed of 11597 registrations added to the heart waiting list between October 18, 2015 and October 17, 2018; and the post-implementation cohort, composed of 11983 registrations added between October 18, 2018 and October 17, 2021.

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



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Statuses representing less than 5% of the total are not labeled on the plot
Pre−Policy: October 18, 2015 − October 17, 2018
Post−Policy: October 18, 2018 − October 17, 2021

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

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	2917	25.2%
	Equivalent Status 1B	Status 1B	5366	46.3%
	Equivalent Status 2	Status 2	3064	26.4%
	Temporarily inactive	Temporarily inactive	250	2.2%
Post	Equivalent Status 1A	Adult Status 1	553	4.6%
		Adult Status 2	2601	21.7%
		Adult Status 3	1346	11.2%
	Equivalent Status 1B	Adult Status 4	4487	37.4%
		Adult Status 5	295	2.5%
	Equivalent Status 2	Adult Status 6	2546	21.2%
	Temporarily inactive	Temporarily inactive	155	1.3%

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre-Policy: October 18, 2015 - October 17, 2018
Post-Policy: October 18, 2018 - October 17, 2021

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

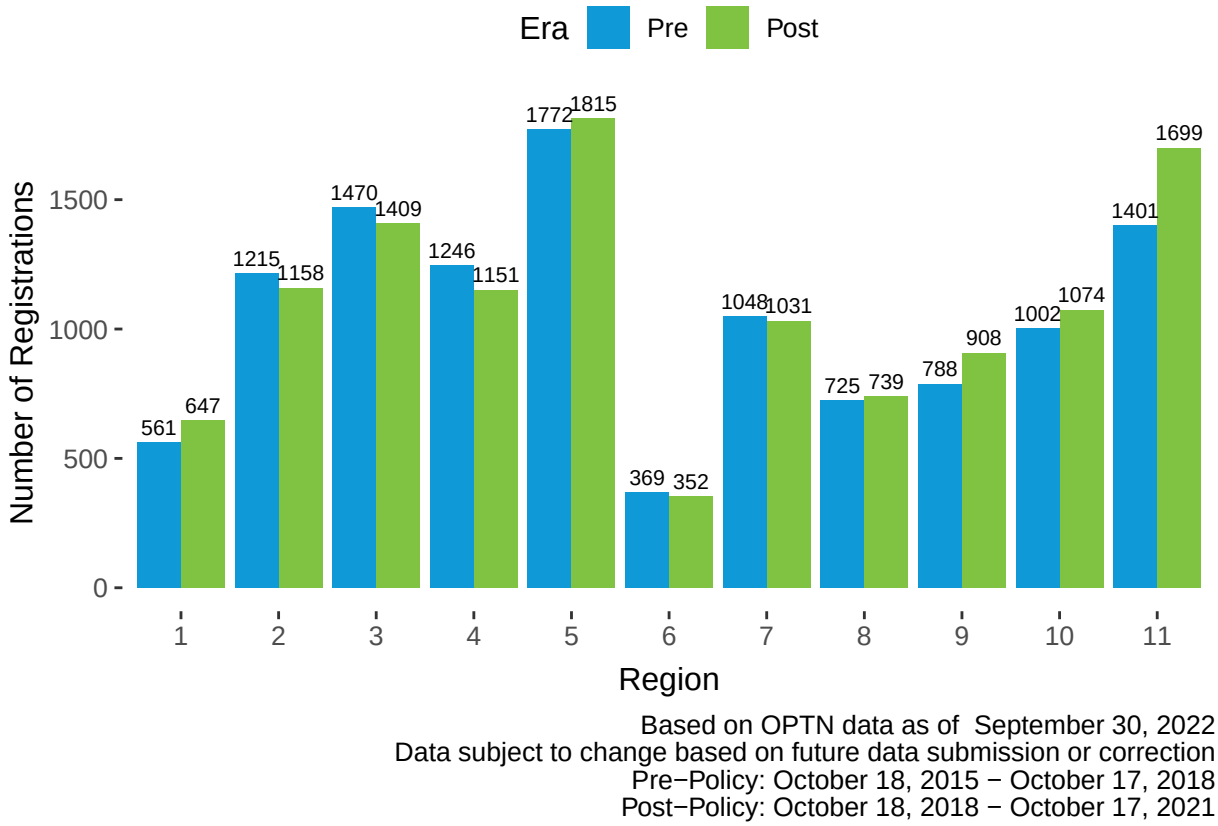
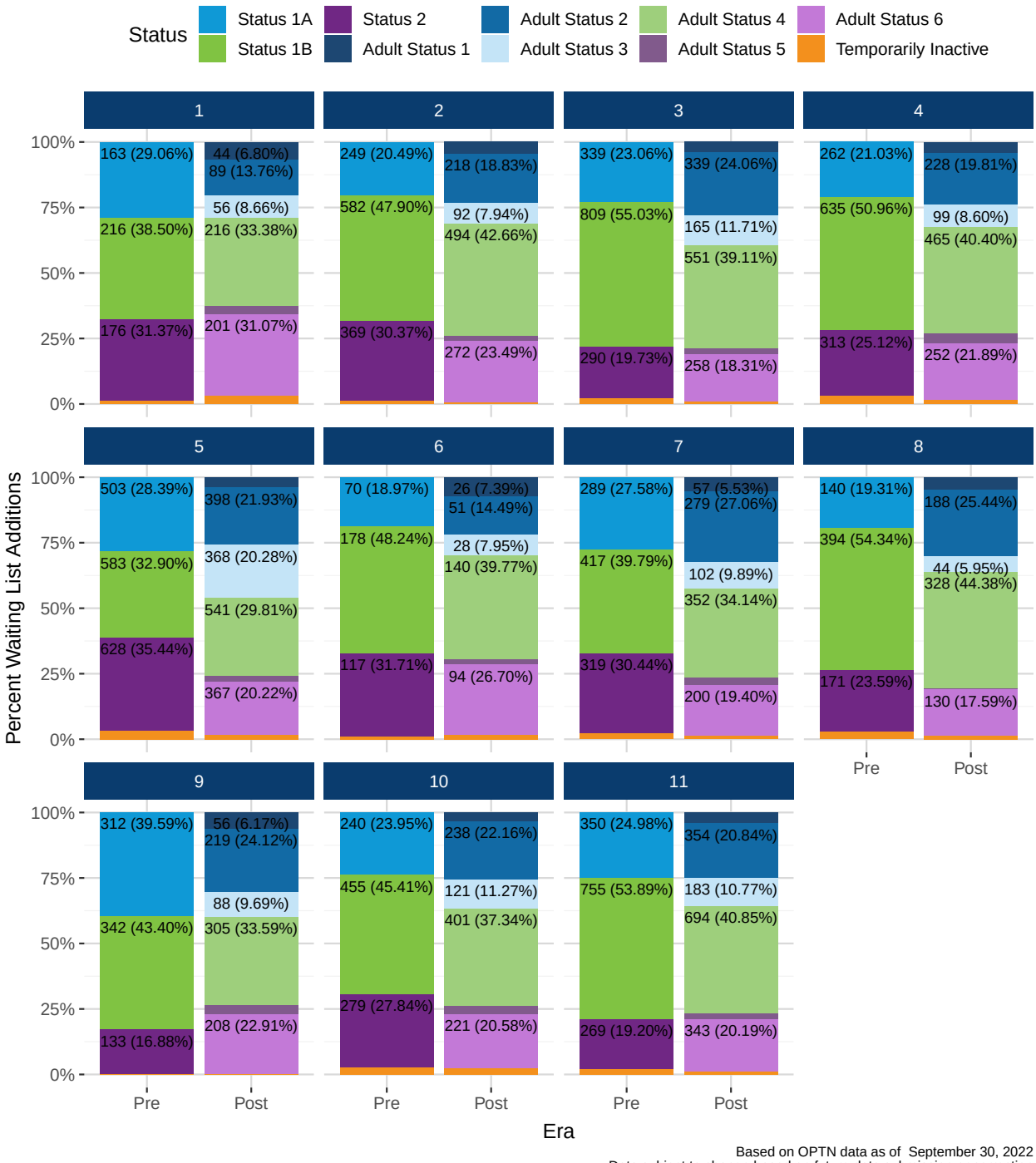


Figure 2 shows the number of adult heart waiting list registrations added by region both pre- and post-implementation. Compared to pre-implementation, the number of registrations added post-implementation increased by more than 5% in regions 1, 9, 10 and 11, decreased by more than 5% in region 4, and remained similar in the other regions.

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 was similar across regions, with Adult Status 4 accounting for the largest number of post-implementation registrations in all regions and either Adult Status 5 or Temporarily Inactive the least.

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

Figure 3. Adult Heart Waitlist Additions by Region, Era, and Medical Urgency Status



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Statuses representing less than 5% of the total are not labeled on the plot
Pre−Policy: October 18, 2015 − October 17, 2018
Post−Policy: October 18, 2018 − October 17, 2021

Figure 4 shows the adult heart waiting list additions by region, device at time of listing, and era. In each region the percent of waiting list additions for those on no devices decreased or stayed the same. The largest decrease occurred in region 3 where 69% of all waitlist additions were on no device in the pre-policy era compared to 60% in the post-policy era. In the post-policy era as few as 47% of all waitlist additions were on no devices at time of listing (region 10) and as many as 65% were on no device (region 5). The percent of waitlist additions in each region on IABP-only increased and the percent on VAD-only decreased post-implementation.

Figure 4. Adult Heart Waitlist Additions by Region, Era, and Device

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre−Policy: October 18, 2015 − October 17, 2018
Post−Policy: October 18, 2018 − October 17, 2021
Device information exists on both the TCR and WL status justification forms and may differ;
Device information pulled from TCR for this figure.

Table 2 shows the criteria qualifying adult heart waiting list candidates for their medical urgency status at time of listing post-implementation. For Adult Status 5 and Adult Status 6, which have no qualifying criteria, the count of waiting list additions at the status is given. For Adult Status 1 the most common criterion for waiting list additions was VA ECMO, with (25.73%) or without (31.73%) hemodynamic values. For Adult Status 2 the most common criterion was intra-aortic balloon pump with hemodynamic values (43.58%); it was rare for IABP to be reported without hemodynamic values (1.57%). For Adult Status 3 the most common qualifying criterion was multiple inotropes/single high dose inotrope with hemodynamic monitoring (35.05%), followed by exception (23.51%) and dischargeable LVAD for discretionary 30 days (23.37%). For Adult Status 4 the most common was dischargeable LVAD without discretionary 30 days (42.19%).

The percent of adult heart waiting list additions qualifying by an exception at time of listing was greatest for Adult Status 2, with 35.98% of candidates qualifying under this criterion. For the other statuses the percent of candidates qualifying by an exception at listing ranged between 17.30% for Adult Status 4 and 23.51% for Adult Status 3.

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

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

Status	Criteria	N	%
Adult Status 1	BIVAD/Ventricular Episodes	29	4.97%
	Exception	136	23.33%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	83	14.24%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	185	31.73%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	150	25.73%
Overall		**583**	**100%**
Adult Status 2	Exception	942	35.98%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	41	1.57%
	Intra-aortic ballon pump - Hemodynamic Values obtained	1141	43.58%
	Mechanical circulatory support device(MCSD) with malfunction	51	1.95%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	34	1.30%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	34	1.30%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	238	9.09%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	66	2.52%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	71	2.71%
Overall		**2618**	**100%**
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	318	23.37%

(continued)

Status	Criteria	N	%
Adult Status 3	Exception	320	23.51%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	9	0.66%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	88	6.47%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	53	3.89%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	16	1.18%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	16	1.18%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	15	1.10%
	Mechanical circulatory support device (MCSD) with hemolysis	7	0.51%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	4	0.29%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	4	0.29%
	Mechanical circulatory support device (MCSD) with pump thrombosis	29	2.13%
	Mechanical circulatory support device (MCSD) with right heart failure	5	0.37%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	477	35.05%
Overall		**1361**	**100%**
Adult Status 4	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	457	10.09%
	Congenital heart disease	328	7.24%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1912	42.20%
	Exception	784	17.30%
	Inotropes without hemodynamic monitoring	728	16.07%
	Ischemic heart disease with intractable angina	83	1.83%
	Retransplant	239	5.27%
Overall		**4531**	**100%**
Adult Status 5	None	357	100.00%
Adult Status 6	None	2559	100.00%

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

Tables 3 and 4 show the qualifying criteria for candidates on the adult heart waiting list stratified by initial or extension request as it appeared on September 30, 2020 or September 30, 2021, respectively. These dates were chosen to reflect waiting list composition before and after the implementation of the guidance to clarify supporting information for extension requests. In general, Adult Status 1 candidates spent very little time on the waiting list with a median waiting time of 5 days (Table 17), and therefore at any given time there are few of them waiting, which makes the distribution of qualifying criteria difficult to determine.

In both tables 3 and 4 there were very few candidates waiting at Adult Status 1 making the distributions at listing and under an extension difficult to decipher. In the post-guidance period, the majority of Adult Status 1 candidates were waiting with an exception (n=8, 57.14%), whereas in the pre-guidance period, the majority were waiting with a non-dischargeable, surgically implanted, non-endovascular biventricular support device (n=3, 75.00%). The absolute number of candidates waiting in Status 1 with a non-dischargeable, surgically implanted, non-endovascular biventricular support device remained similar in the post-guidance period (n=2, 14.29%), although the percentage decreased, likely due to the increase in Status 1 exceptions post-guidance. In both the pre- and post-guidance periods for Adult Status 2, an exception was the most common criterion at both initial listing and extension, followed by intra-aortic balloon pump with hemodynamic values. For Adult Status 3, dischargeable LVAD for discretionary 30 days was the most common criterion at listing and an exception was the most common for those waiting under an extension post-guidance (September 30, 2021). Conversely, on September 30, 2020, exception and MCSD with bacteremic device infection were the most common criteria for candidates waiting at Adult Status 3 under an extension pre-guidance. For Adult Status 4, dischargeable LVAD without discretionary 30 days was the most common at initial listing and under extension in both the pre- and post-guidance periods. The proportion of Status 4 candidates on inotropes without hemodynamic monitoring at initial listing increased post-guidance, while the proportion of these candidates under extension decreased post-guidance. Overall, these changes resulted in a doubling of the proportion of Status 4 candidates on inotropes without hemodynamic monitoring post-guidance compared to pre-guidance (7.13% vs. 3.71%).

Table 3. Criteria Within Medical Urgency Status for Adult Heart Candidates Waiting on September 30, 2020 (Pre-Guidance)

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

(continued)

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

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

Table 4. Criteria Within Medical Urgency Status for Adult Heart Candidates Waiting on September 30, 2021 (Post-Guidance)

		Initial		Extension		Total	
Status	**Criteria**	**N**	**%**	**N**	**%**	**N**	**%**
Adult Status 1	BIVAD/Ventricular Episodes	2	25.00%	1	16.67%	3	21.43%
	Exception	4	50.00%	4	66.67%	8	57.14%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	1	12.50%	1	16.67%	2	14.29%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	1	12.50%	0	0.00%	1	7.14%
Overall		**8**	**100%**	**6**	**100%**	**14**	**100%**
Adult Status 2	Exception	43	56.58%	31	64.58%	74	59.68%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	1	1.32%	0	0.00%	1	0.81%
	Intra-aortic ballon pump - Hemodynamic Values obtained	23	30.26%	8	16.67%	31	25.00%
	Mechanical circulatory support device(MCSD) with malfunction	2	2.63%	2	4.17%	4	3.23%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	1.32%	0	0.00%	1	0.81%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	3	3.95%	0	0.00%	3	2.42%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	2.63%	7	14.58%	9	7.26%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	1	1.32%	0	0.00%	1	0.81%
Overall		**76**	**100%**	**48**	**100%**	**124**	**100%**
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	30	44.78%	0	0.00%	30	18.40%
	Exception	14	20.90%	21	21.88%	35	21.47%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	1.49%	6	6.25%	7	4.29%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	6	8.96%	19	19.79%	25	15.34%

(continued)

Status	Criteria	N	%	N	%	N	%
Adult Status 3	Mechanical circulatory support device (MCSD) with device infection - Debridement	4	5.97%	19	19.79%	23	14.11%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	2	2.99%	7	7.29%	9	5.52%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	1.49%	1	1.04%	2	1.23%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	2.99%	0	0.00%	2	1.23%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	1	1.49%	0	0.00%	1	0.61%
	Mechanical circulatory support device (MCSD) with pump thrombosis	2	2.99%	15	15.62%	17	10.43%
	Mechanical circulatory support device (MCSD) with right heart failure	1	1.49%	3	3.12%	4	2.45%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	3	4.48%	5	5.21%	8	4.91%
Overall		**67**	**100%**	**96**	**100%**	**163**	**100%**
Adult Status 4	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	33	6.06%	51	5.76%	84	5.87%
	Congenital heart disease	31	5.69%	59	6.66%	90	6.29%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	304	55.78%	653	73.70%	957	66.88%
	Exception	56	10.28%	60	6.77%	116	8.11%
	Inotropes without hemodynamic monitoring	96	17.61%	6	0.68%	102	7.13%
	Ischemic heart disease with intractable angina	8	1.47%	16	1.81%	24	1.68%
	Retransplant	17	3.12%	41	4.63%	58	4.05%
Overall		**545**	**100%**	**886**	**100%**	**1431**	**100%**
Adult Status 5	None	77	100.00%	35	100.00%	112	100.00%
Adult Status 6	None	302	100.00%	256	100.00%	558	100.00%

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

Table 5 shows the count and percent of registrations with a mechanical circulatory support device (MCSD) at listing, based on information reported on the TCR and broken down by device type and brand. Overall, 61.89% of new registrations had an MCSD listed on the TCR pre-implementation, compared to 56.86% post-implementation. LVADs were less common post-implementation than pre-implementation, while the proportion of new registrations with an IABP increased post-implementation. The proportion of registrations on ECMO at listing also increased post-implementation, 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.

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

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

Brand	Era	Count	Percent
ECMO			
Total ECMO	**Pre**	**208**	**4.48%**
	Post	**424**	**7.7%**
IABP			
Total IABP	**Pre**	**613**	**13.21%**
	Post	**1621**	**29.42%**
LVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	12	0.38%
Cardiac Assist Tandem Heart	Pre	7	0.2%
	Post	5	0.16%
CentriMag (Thoratec/Levitronix)	Pre	25	0.7%
	Post	28	0.89%
Evaheart	Pre	1	0.03%
	Post	1	0.03%
Heartmate II	Pre	1791	50.48%
	Post	418	13.34%
HeartMate III	Pre	59	1.66%
	Post	1517	48.4%
Heartmate XVE	Pre	4	0.11%
	Post	0	0%
Heartsaver VAD	Pre	2	0.06%
	Post	5	0.16%
Heartware HVAD	Pre	1033	29.11%
	Post	703	22.43%
	Pre	2	0.06%

Impella CP	Post	63	2.01%
Impella Recover 2.5	Pre	13	0.37%
	Post	3	0.1%
Impella Recover 5.0	Pre	63	1.78%
	Post	143	4.56%
Impella RP	Pre	0	0%
	Post	1	0.03%
Jarvik 2000	Pre	4	0.11%
	Post	0	0%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	3	0.1%
Terumo DuraHeart	Pre	1	0.03%
	Post	0	0%
Thoratec IVAD	Pre	0	0%
	Post	2	0.06%
Thoratec PVAD	Pre	2	0.06%
	Post	0	0%
Other, Specify	Pre	541	15.25%
	Post	230	7.34%
Total LVAD	**Pre**	**3548**	**76.43%**
	Post	**3134**	**56.89%**
LVAD+RVAD			
Abiomed AB5000	Pre	0	0%
	Post	1	0.36%
Cardiac Assist Protek Duo	Pre	0	0%
	Post	16	5.76%
Cardiac Assist Tandem Heart	Pre	10	4.72%
	Post	6	2.16%
CentriMag (Thoratec/Levitronix)	Pre	89	41.98%
	Post	138	49.64%
Heartmate II	Pre	18	8.49%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	36	12.95%
Heartware HVAD	Pre	58	27.36%
	Post	25	8.99%
Impella CP	Pre	0	0%
	Post	1	0.36%
	Pre	2	0.94%

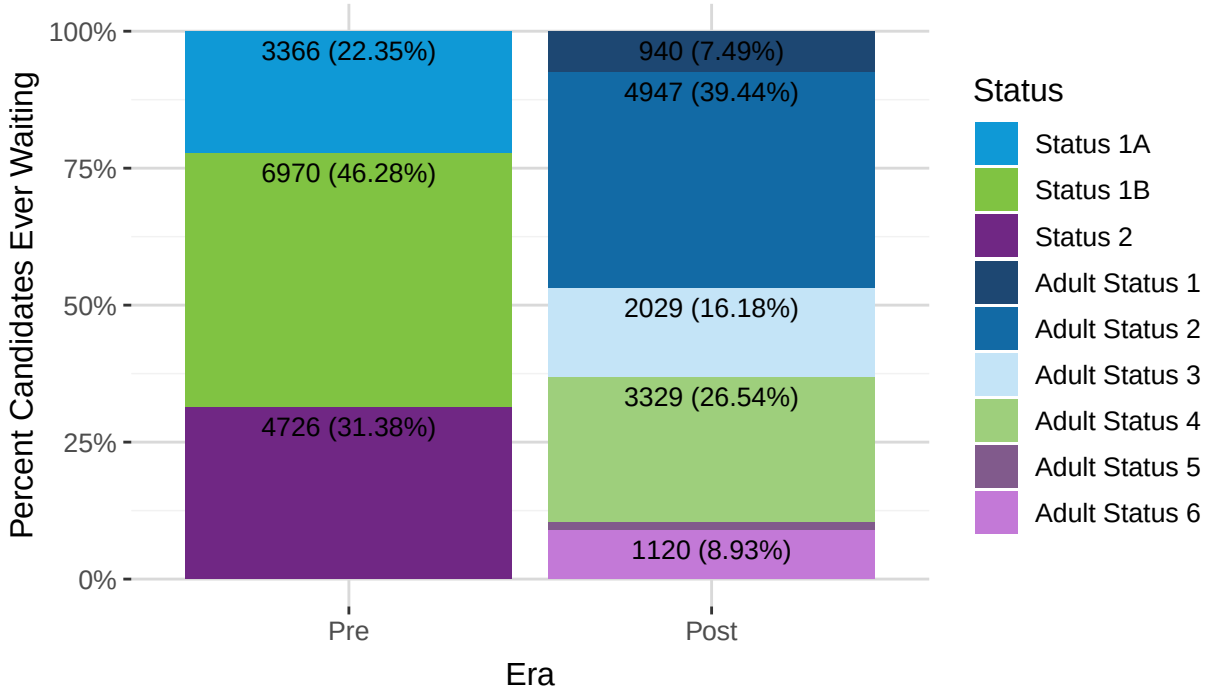
Impella Recover 2.5	Post	0	0%
Impella Recover 5.0	Pre	3	1.42%
	Post	7	2.52%
Impella RP	Pre	0	0%
	Post	1	0.36%
Maquet Jostra Rotaflow	Pre	7	3.3%
	Post	16	5.76%
Thoratec PVAD	Pre	5	2.36%
	Post	2	0.72%
Other, Specify	Pre	20	9.43%
	Post	29	10.43%
Total LVAD+RVAD	**Pre**	**212**	**4.57%**
	Post	**278**	**5.05%**
RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	3	13.64%
Cardiac Assist Tandem Heart	Pre	1	9.09%
	Post	1	4.55%
CentriMag (Thoratec/Levitronix)	Pre	6	54.55%
	Post	5	22.73%
Heartmate II	Pre	1	9.09%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	2	9.09%
Heartware HVAD	Pre	1	9.09%
	Post	0	0%
Impella CP	Pre	0	0%
	Post	1	4.55%
Impella Recover 5.0	Pre	1	9.09%
	Post	4	18.18%
Impella RP	Pre	0	0%
	Post	1	4.55%
Maquet Jostra Rotaflow	Pre	1	9.09%
	Post	1	4.55%
Other, Specify	Pre	0	0%
	Post	4	18.18%
Total RVAD	**Pre**	**11**	**0.24%**
	Post	**22**	**0.4%**

TAH			
SynCardia CardioWest	Pre	50	100%
	Post	26	86.67%
Other, Specify	Pre	0	0%
	Post	4	13.33%
Total TAH	**Pre**	**50**	**1.08%**
	Post	**30**	**0.54%**

Figure 5. Justification Forms at Listing by Justification Review Type and Status Requested

Figure 5 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 2. Exception requests were most common for candidates listing at either Adult Status 2 or Adult Status 4.

Figure 6. Candidates Ever Waiting by Era and Medical Urgency Status

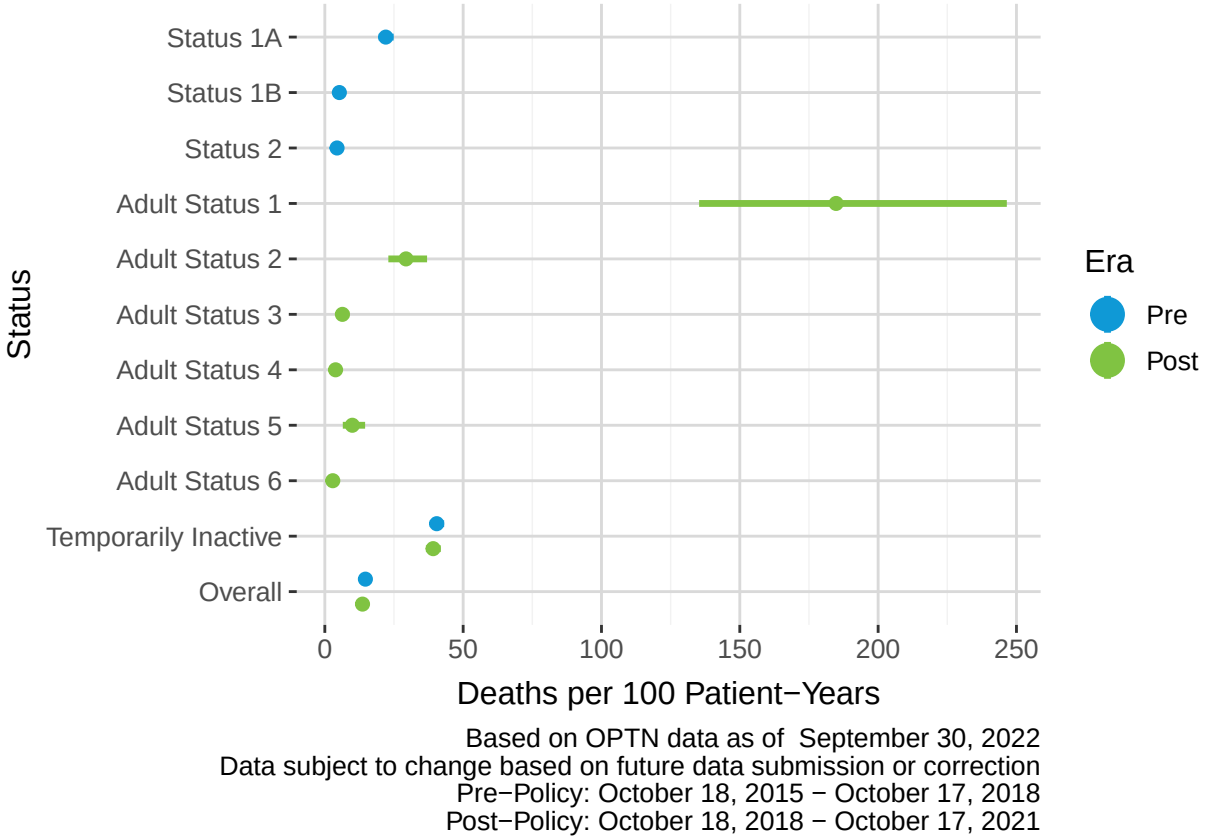


Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Temporarily Inactive statuses exluded (N=328 Pre and N=252 Post)
Statuses representing less than 5% of the total are not labeled on the plot
Pre−Policy: October 18, 2015 − October 17, 2018
Post−Policy: October 18, 2018 − October 17, 2021

Figure 6 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, as the most recent candidate status may have occurred post-implementation for candidates who were waiting in both policy eras. Post-implementation statuses shown are the most recent status for each candidate in order to avoid displaying pre-implementation statuses in the post era for those candidates added before the policy implementation took effect. "Temporarily inactive" is omitted because more candidates wait at this status than are added at this status, making it difficult to compare across eras.

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

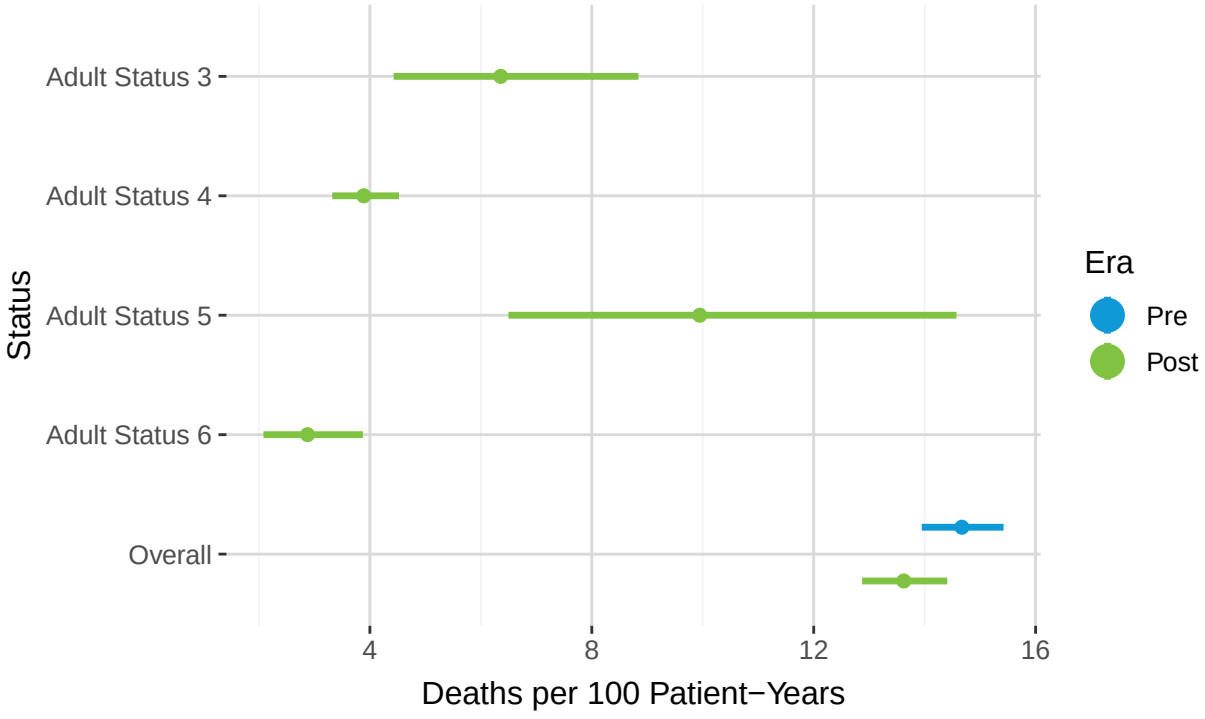
Figure 7. Deaths per 100 Patient-Years Waiting by Medical Urgency Status and Era



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

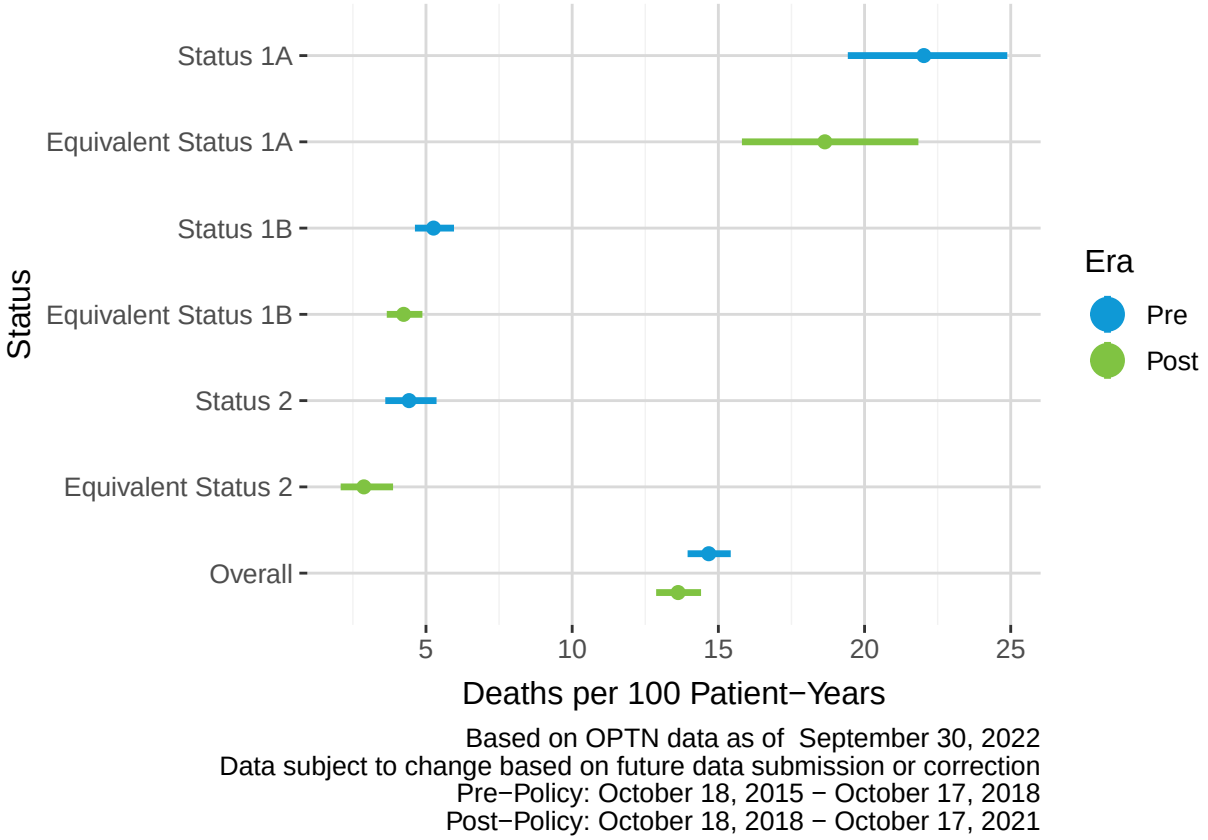
Figure 8 zooms in on Adult statuses 3-6 in order to gain a clearer picture of what is happening in these statuses.

Figure 8. Zooming in on Adult Heart Statuses 3-6: Deaths per 100 Patient-Years Waiting by Medical Urgency Status and Era



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre−Policy: October 18, 2015 − October 17, 2018
Post−Policy: October 18, 2018 − October 17, 2021

Figure 9. Deaths per 100 Patient-Years Waiting by Equivalent Medical Urgency Status



The Committee Request section defines the comparison of equivalent post-implementation statuses to old statuses as: old Status 1A compared to Adult Statuses 1-3, old Status 1B compared to Adult Statuses 4 and 5, and old Status 2 compared to Adult Status 6. Figure 9 shows the number of deaths per 100 patient-years waiting by equivalent statuses post-implementation as compared to pre-implementation. There was no significant difference in deaths per 100 patient-years waiting between equivalent status 1A and old status 1A, equivalent status 1B and old status 1B, and equivalent status 2 and old status 2.

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

Figure 10 displays the deaths per 100 patient-years waiting by criteria within medical urgency status for the four most medically urgent adult statuses post-implementation. Deaths per 100 patient-years waiting could not be estimated for Adult Status 3 with VA ECMO after 7 days due to small sample size. The number of deaths per 100 patient-years waiting was similar across criteria within statuses, suggesting that candidates, despite qualifying criteria, have similar medical urgency within each status. Table A7 shows the counts of patients ever waiting by status and era, as well as the number of deaths on the waiting list and the deaths per 100 patient-years.

Figure 10. Deaths per 100 Patient-Years Waiting by Criteria within Medical Urgency Status Post-Implementation

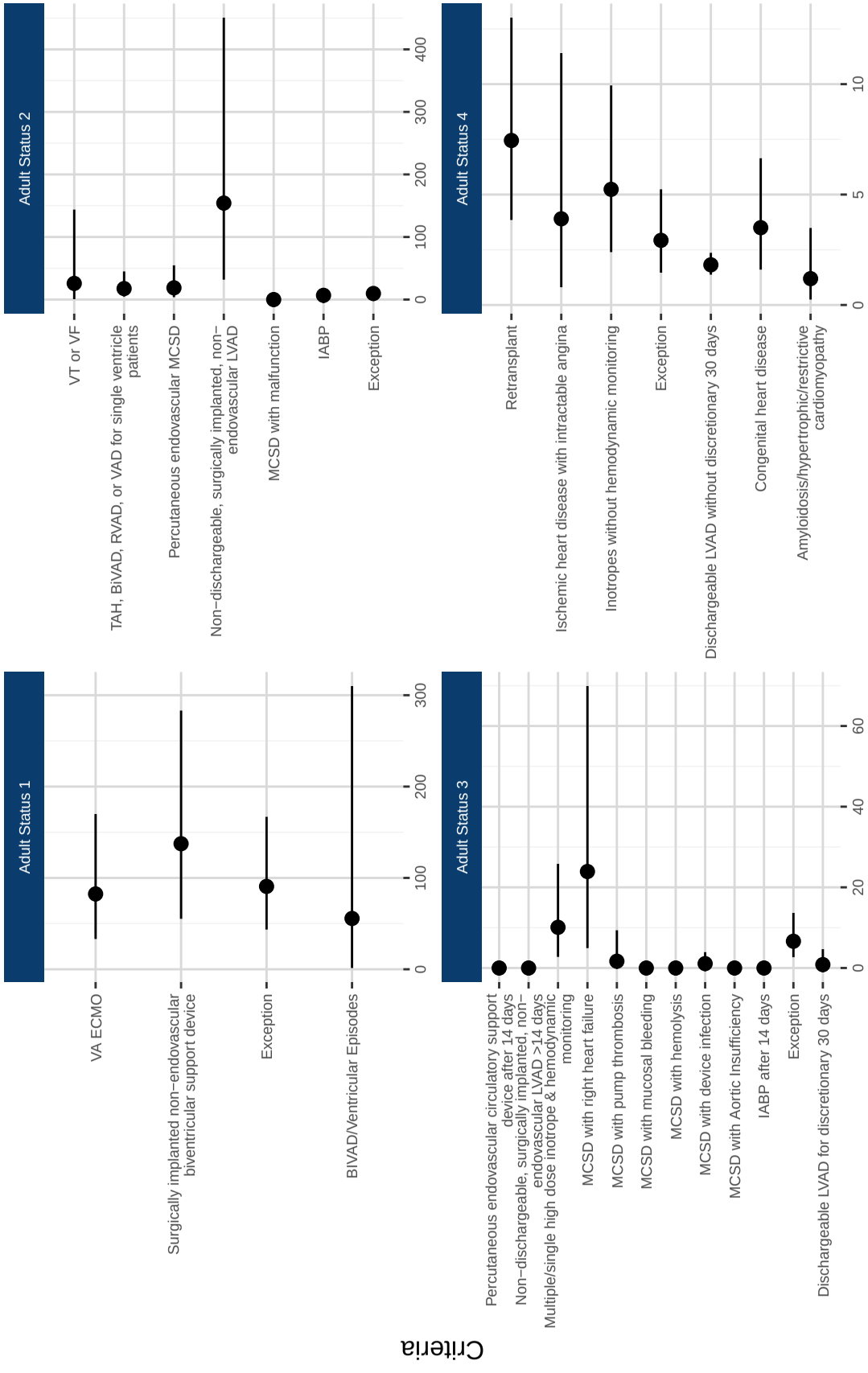


Figure 11 displays the deaths per 100 patient-years waiting by criteria within medical urgency status for Status 2 and 3 only to facilitate comparisons among these criteria.

Figure 11. Deaths per 100 Patient-Years Waiting by Criteria within Medical Urgency Status Post-Implementation for Status 2 and 3

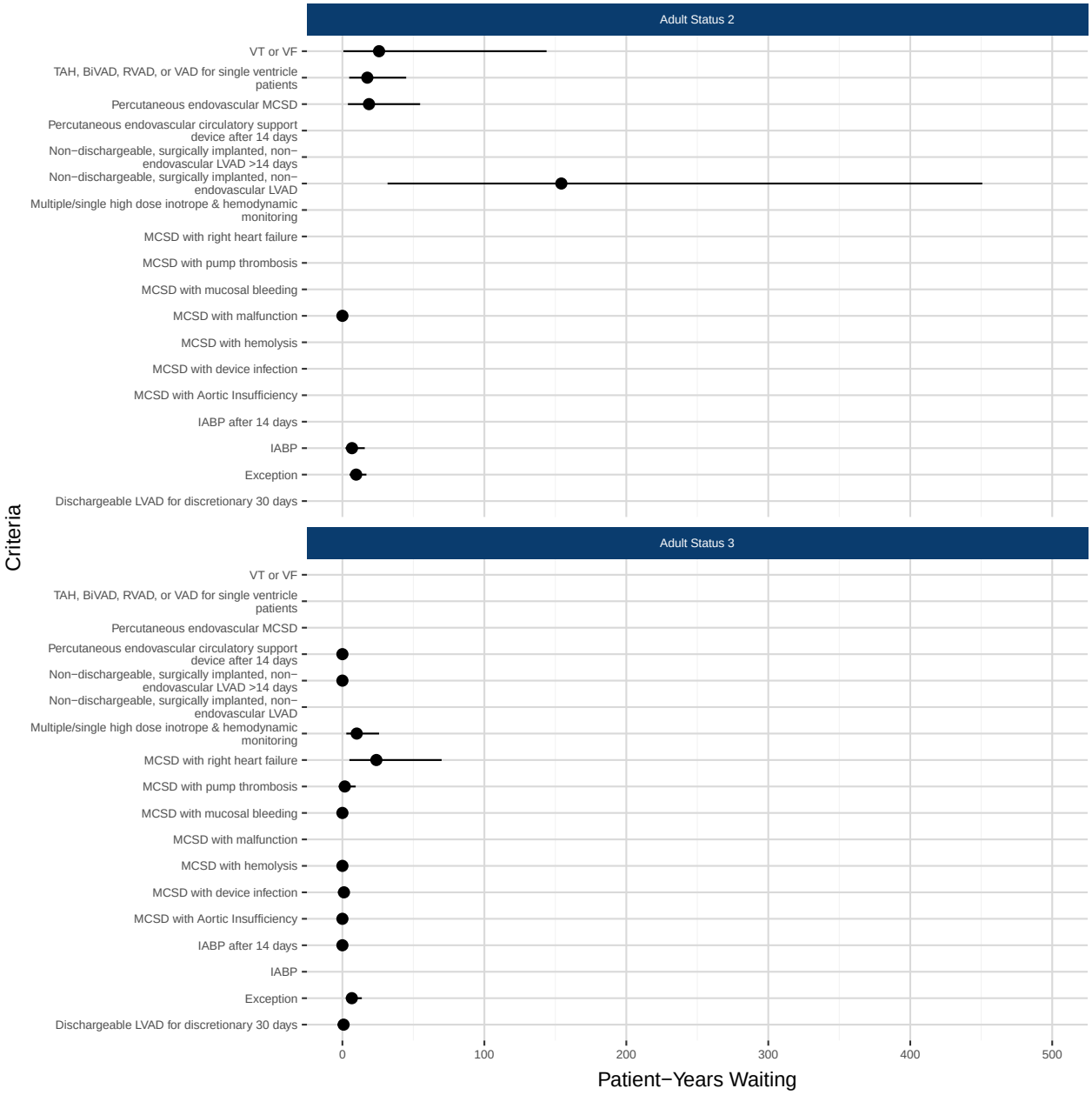


Figure 12. Deaths per 100 Patient-Years Waiting by Region and Era

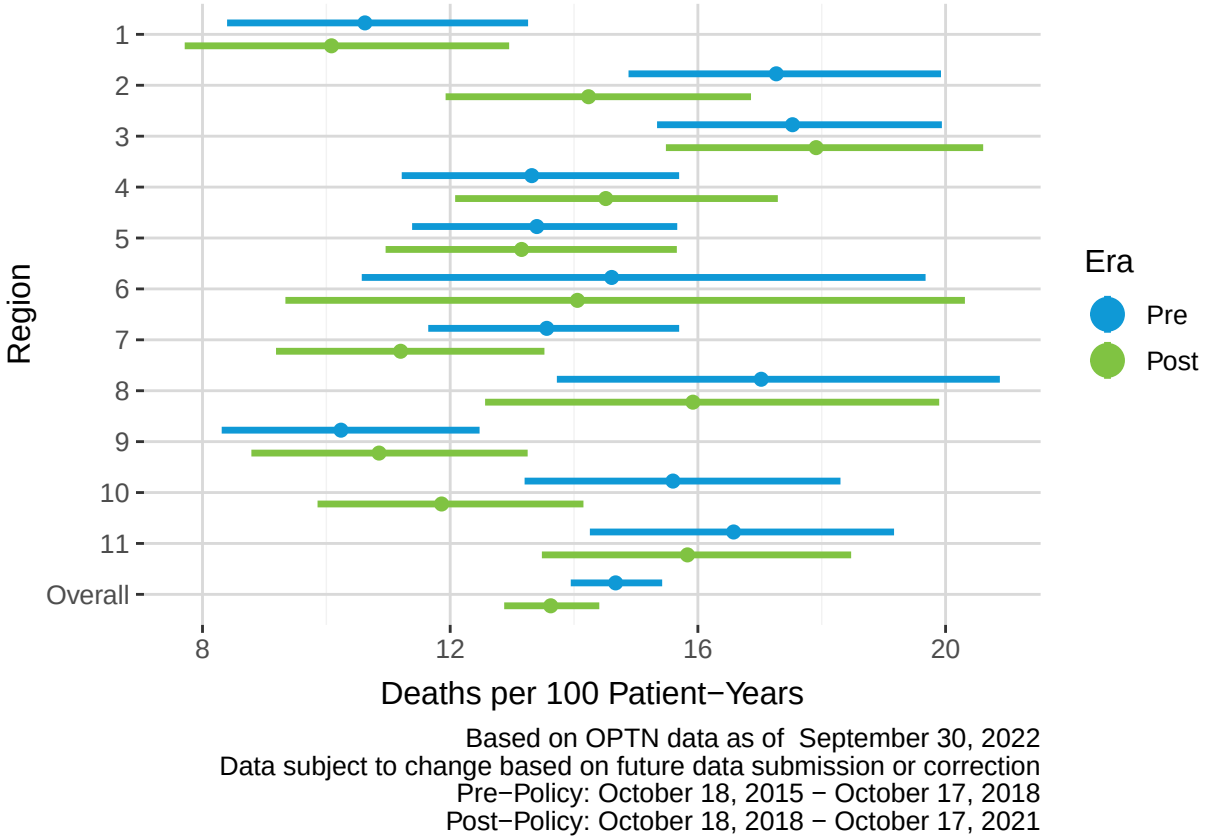


Figure 12 shows the number of deaths per 100 patient-years by region and era. There was no significant change in the number of deaths per 100 patient-years in any region pre- vs post-implementation. Although not significantly different, there were fewer deaths per 100 patient-years in a majority of the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

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

Transplant

These analyses examine differences in transplants between two cohorts: the pre-implementation cohort, composed of 8423 adult heart transplants performed between October 18, 2015 and October 17, 2018, and the post-implementation cohort, composed of 9422 adult heart transplants performed between October 18, 2018 and October 17, 2021. There were 999 more heart transplants performed in the post-implementation cohort than in the pre-implementation cohort.

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

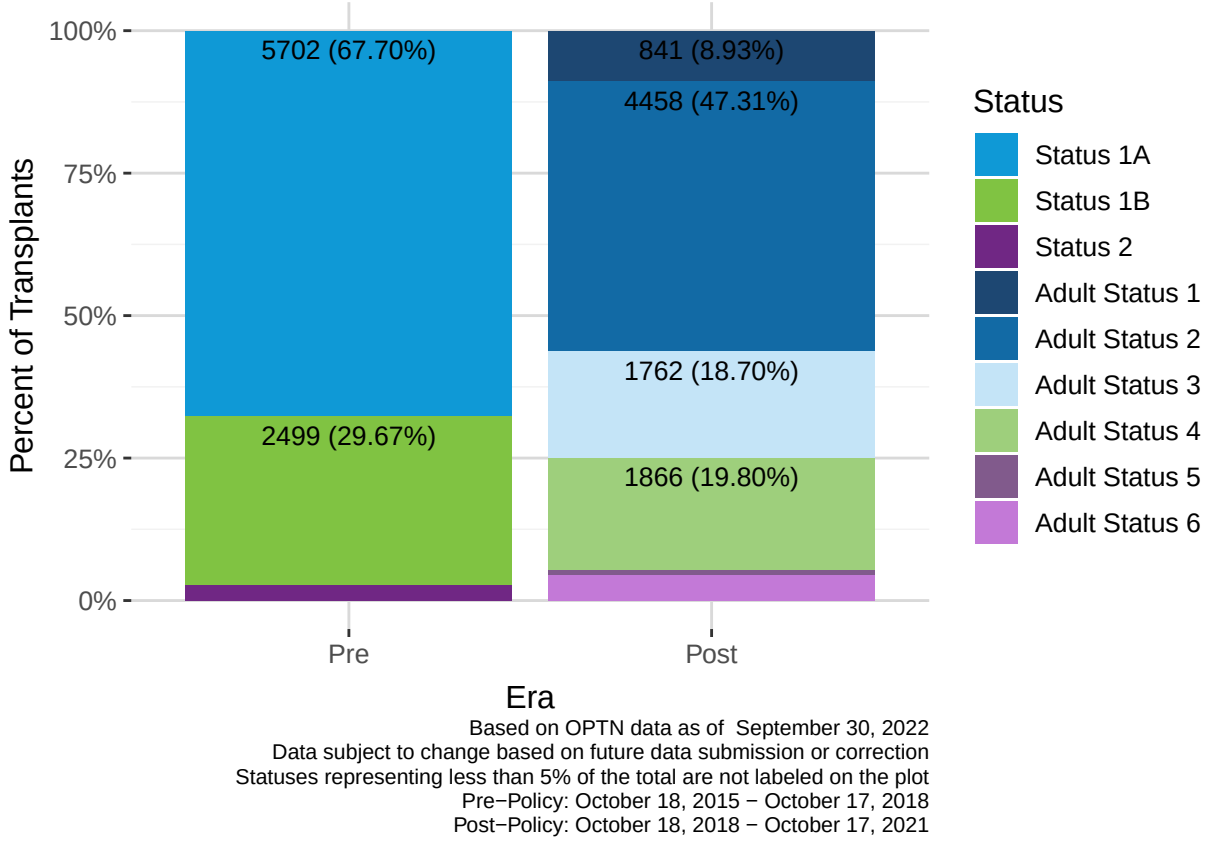


Figure 13 shows the proportion of adult heart transplants performed both pre- and post-implementation by medical urgency status. Status 1A candidates received around two-thirds (67.70%) of all transplants pre-implementation, but no single status represented such a large fraction of transplants post-implementation. Adult Status 2 candidates received the largest fraction of all transplants post-implementation, followed by Adult Statuses 3 and 4. Post-implementation, Adult Status 6 represented only 4.44% of transplants, and only 77 (0.82%) transplants went to Adult Status 5 patients in the three years after the new adult heart allocation policy went into effect.

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

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

Era	Equivalent Status	Status	N	%
Pre	Equivalent Status 1A	Status 1A	5702	67.7%
	Equivalent Status 1B	Status 1B	2499	29.7%
	Equivalent Status 2	Status 2	222	2.6%
Post	Equivalent Status 1A	Adult Status 1	841	8.9%
		Adult Status 2	4458	47.3%
		Adult Status 3	1762	18.7%
	Equivalent Status 1B	Adult Status 4	1866	19.8%
		Adult Status 5	77	0.8%
	Equivalent Status 2	Adult Status 6	418	4.4%

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre-Policy: October 18, 2015 - October 17, 2018
Post-Policy: October 18, 2018 - October 17, 2021

Figure 14. Adult Heart Transplants by Region and Era

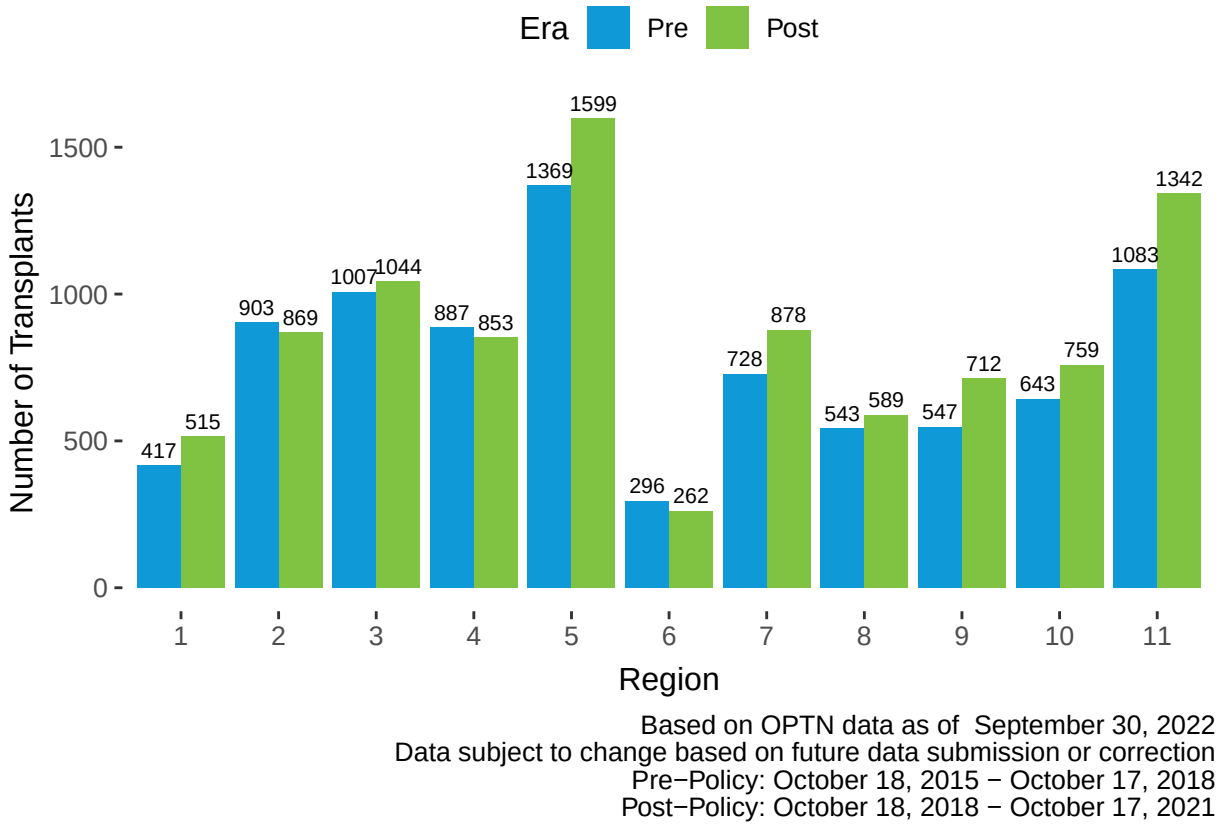
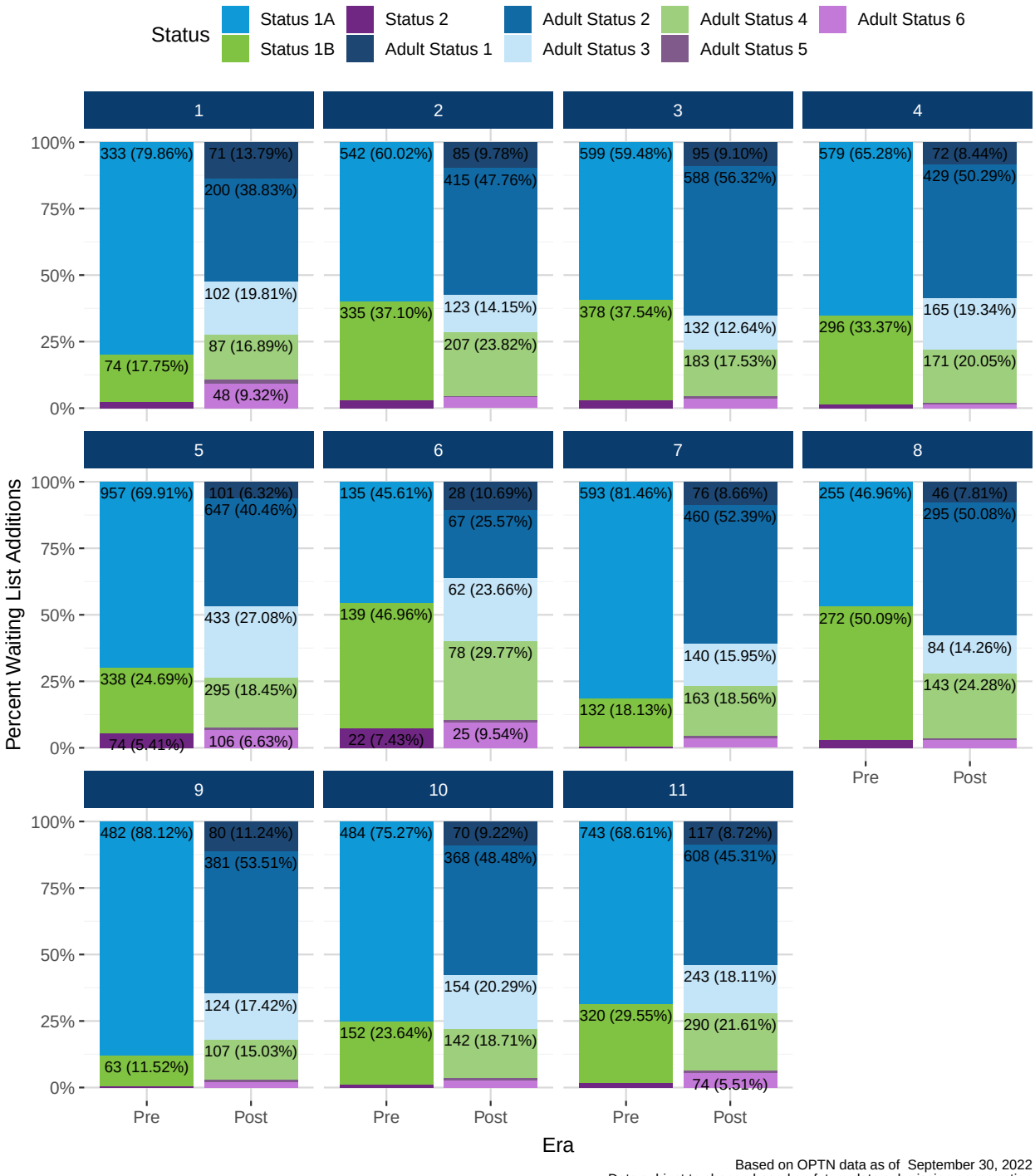


Figure 14 shows the number of adult heart transplants by era and region. The number of heart transplants rose in regions 1, 3, 5, 7, 8, 9, 10, and 11, and decreased in regions 2, 4, and 6.

Figure 15 shows the number of adult heart transplants by era, region, and medical urgency status. The distribution of statuses receiving transplants varied from region to region post-implementation, but in all but one region (region 6), Adult Status 2 candidates received the largest percent of all transplants; in region 6 Adult Status 4 (29.77%) candidates received a larger percent of transplants compared to Adult Status 2 (25.57%). When comparing transplant across regions it is important to note that region 6 has the fewest number of transplant centers followed by region 1. Adult Status 5 transplants were performed in all regions, but never accounted for more than 2% of all transplants in each region. Adult Status 6 transplants were performed in all regions but only accounted for more than 5% of transplants in regions 1, 5, 6, and 11.

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



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre−Policy: October 18, 2015 − October 17, 2018
Post−Policy: October 18, 2018 − October 17, 2021

Table 7 shows the criteria allowing heart transplant recipients to qualify for their medical urgency status at time of transplant and whether they were transplanted after their initial qualification for a status or on an extension. This table only includes adult heart transplants performed during the post-implementation period. Tables 8 and 9 display this same information separately for the pre- and post-guidance periods, respectively (i.e., October 18, 2018 - March 3, 2021 and March 4, 2021 - October 17, 2021). In all three tables, the "extension" category includes all extensions, regardless of the extension number.

Overall, for Adult Status 1, it was most common for transplant recipients under their initial request to have received an exception (36.12%). It was also common for Adult Status 1 candidates transplanted under an extension to have received an exception (28.41%), followed by non-dischargeable, surgically implanted, non-endovascular biventricular support device (26.14%) and VA ECMO with hemodynamic values (23.86%). For Adult Status 2, it was most common for recipients transplanted under their initial request to qualify by exception (41.42%) followed closely by IABP with hemodynamic values (41.18%), while it was most common for those transplanted under an extension to have an exception (54.00%). For Adult Status 3, the most common criterion for recipients transplanted under an initial request was dischargeable LVAD for discretionary 30 days (46.56%), while it was most common for recipients transplanted under an extension to have an exception (42.67%). For Adult Status 4, dischargeable LVAD without discretionary 30 days was the most common criterion both for those transplanted under their initial request (37.64%) and for those transplanted under an extension (56.80%).

Similar patterns were seen in the pre- and post-guidance periods. However, the proportion of transplant recipients in Status 1 with non-dischargeable, surgically implanted, non-endovascular biventricular support device decreased post-guidance compared to pre-guidance for initial requests (Pre: 12.77% vs. Post: 7.32%) and overall (Pre: 13.79% vs. Post: 10.34%), and increased for those transplanted under extension (Pre: 22.95% vs. Post: 33.33%). Conversely, the proportion of transplant recipients in Status 4 on inotropes without hemodynamic monitoring increased post-guidance compared to pre-guidance for initial requests (Pre: 12.34% vs. Post: 22.42%) and overall (Pre: 10.18% vs. Post: 15.92%), and decreased for those transplanted under extension (Pre: 5.57% vs. Post: 0.83%).

Table A9 shows the criteria qualifying heart transplant recipients for their medical urgency status at time of transplant and whether they were transplanted after their initial qualification for a status or on an extension by region. The proportion of criteria for adult heart recipients in each region is fairly similar to the criteria seen for that medical urgency status at the national level, with the most variability being in the number of transplant recipients who received an exception in a region.

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

Status	Criteria	Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 1	BIVAD/Ventricular Episodes	53	7.04%	7	7.95%	60	7.13%
	Exception	272	36.12%	25	28.41%	297	35.32%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	85	11.29%	23	26.14%	108	12.84%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	164	21.78%	12	13.64%	176	20.93%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	179	23.77%	21	23.86%	200	23.78%
Overall		**753**	**100%**	**88**	**100%**	**841**	**100%**
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	1	0.03%	0	0.00%	1	0.02%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	0.03%	0	0.00%	1	0.02%
	Exception	1380	41.42%	608	54.00%	1988	44.59%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	38	1.14%	7	0.62%	45	1.01%
	Intra-aortic ballon pump - Hemodynamic Values obtained	1372	41.18%	293	26.02%	1665	37.35%
	Intra-aortic balloon pump after 14 days	4	0.12%	0	0.00%	4	0.09%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	0.03%	0	0.00%	1	0.02%
	Mechanical circulatory support device(MCSD) with malfunction	121	3.63%	87	7.73%	208	4.67%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	32	0.96%	5	0.44%	37	0.83%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	24	0.72%	3	0.27%	27	0.61%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	238	7.14%	54	4.80%	292	6.55%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	53	1.59%	53	4.71%	106	2.38%

(continued)

Adult Status 2

Status	Criteria	N	%	N	%	N	%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	1	0.03%	0	0.00%	1	0.02%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	4	0.12%	0	0.00%	4	0.09%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	62	1.86%	16	1.42%	78	1.75%
Overall		**3332**	**100%**	**1126**	**100%**	**4458**	**100%**
	Congenital heart disease	1	0.08%	0	0.00%	1	0.06%
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	576	46.56%	0	0.00%	576	32.69%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	8	0.65%	0	0.00%	8	0.45%
	Exception	244	19.73%	224	42.67%	468	26.56%
	Intra-aortic ballon pump - Hemodynamic Values obtained	4	0.32%	0	0.00%	4	0.23%
	Intra-aortic balloon pump after 14 days	2	0.16%	1	0.19%	3	0.17%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	25	2.02%	8	1.52%	33	1.87%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	71	5.74%	58	11.05%	129	7.32%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	31	2.51%	56	10.67%	87	4.94%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	11	0.89%	13	2.48%	24	1.36%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	18	1.46%	3	0.57%	21	1.19%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	13	1.05%	3	0.57%	16	0.91%
	Mechanical circulatory support device (MCSD) with hemolysis	6	0.49%	6	1.14%	12	0.68%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	10	0.81%	1	0.19%	11	0.62%

(continued)

Status	Criteria	N	%	N	%	N	%
Adult Status 3	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	2	0.16%	2	0.38%	4	0.23%
	Mechanical circulatory support device (MCSD) with pump thrombosis	5	0.40%	41	7.81%	46	2.61%
	Mechanical circulatory support device (MCSD) with right heart failure	5	0.40%	13	2.48%	18	1.02%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	204	16.49%	96	18.29%	300	17.03%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	0.08%	0	0.00%	1	0.06%
Overall		**1237**	**100%**	**525**	**100%**	**1762**	**100%**
Adult Status 4	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	139	10.88%	57	9.69%	196	10.50%
	Congenital heart disease	59	4.62%	43	7.31%	102	5.47%
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	1	0.08%	0	0.00%	1	0.05%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	481	37.64%	334	56.80%	815	43.68%
	Exception	312	24.41%	74	12.59%	386	20.69%
	Inotropes without hemodynamic monitoring	186	14.55%	27	4.59%	213	11.41%
	Intra-aortic ballon pump - Hemodynamic Values obtained	1	0.08%	0	0.00%	1	0.05%
	Ischemic heart disease with intractable angina	30	2.35%	21	3.57%	51	2.73%
	No criteria for this status	1	0.08%	0	0.00%	1	0.05%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	0.08%	0	0.00%	1	0.05%
	Retransplant	67	5.24%	32	5.44%	99	5.31%
Overall		**1278**	**100%**	**588**	**100%**	**1866**	**100%**
Adult Status 5	None	64	100.00%	13	100.00%	77	100.00%
Adult Status 6	None	371	100.00%	47	100.00%	418	100.00%

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

Table 8. Adult Heart Transplants by Criteria Within Medical Urgency Status at Transplant Post-Implementation, Pre-Guidance

		Initial		Extension		Total	
Status	**Criteria**	**N**	**%**	**N**	**%**	**N**	**%**
Adult Status 1	BIVAD/Ventricular Episodes	47	8.58%	6	9.84%	53	8.70%
	Exception	181	33.03%	15	24.59%	196	32.18%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	70	12.77%	14	22.95%	84	13.79%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	119	21.72%	10	16.39%	129	21.18%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	131	23.91%	16	26.23%	147	24.14%
Overall		**548**	**100%**	**61**	**100%**	**609**	**100%**
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	0.04%	0	0.00%	1	0.03%
	Exception	1084	40.87%	374	50.47%	1458	42.97%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	34	1.28%	4	0.54%	38	1.12%
	Intra-aortic ballon pump - Hemodynamic Values obtained	1122	42.31%	205	27.67%	1327	39.11%
	Intra-aortic balloon pump after 14 days	3	0.11%	0	0.00%	3	0.09%
	Mechanical circulatory support device(MCSD) with malfunction	102	3.85%	65	8.77%	167	4.92%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	29	1.09%	3	0.40%	32	0.94%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	18	0.68%	1	0.13%	19	0.56%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	162	6.11%	27	3.64%	189	5.57%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	48	1.81%	47	6.34%	95	2.80%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	1	0.04%	0	0.00%	1	0.03%

Adult Status 2
(continued)

Status	Criteria	N	%	N	%	N	%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	3	0.11%	0	0.00%	3	0.09%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	45	1.70%	15	2.02%	60	1.77%
Overall		**2652**	**100%**	**741**	**100%**	**3393**	**100%**
	Congenital heart disease	1	0.10%	0	0.00%	1	0.07%
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	496	48.02%	0	0.00%	496	33.93%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	8	0.77%	0	0.00%	8	0.55%
	Exception	192	18.59%	176	41.03%	368	25.17%
	Intra-aortic ballon pump - Hemodynamic Values obtained	4	0.39%	0	0.00%	4	0.27%
	Intra-aortic balloon pump after 14 days	2	0.19%	1	0.23%	3	0.21%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	17	1.65%	4	0.93%	21	1.44%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	58	5.61%	54	12.59%	112	7.66%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	25	2.42%	47	10.96%	72	4.92%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	9	0.87%	11	2.56%	20	1.37%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	14	1.36%	3	0.70%	17	1.16%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	11	1.06%	3	0.70%	14	0.96%
	Mechanical circulatory support device (MCSD) with hemolysis	6	0.58%	6	1.40%	12	0.82%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	10	0.97%	1	0.23%	11	0.75%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	1	0.10%	1	0.23%	2	0.14%

Adult Status 3
(continued)

Status	Criteria	N	%	N	%	N	%
	Mechanical circulatory support device (MCSD) with pump thrombosis	3	0.29%	33	7.69%	36	2.46%
	Mechanical circulatory support device (MCSD) with right heart failure	3	0.29%	10	2.33%	13	0.89%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	172	16.65%	79	18.41%	251	17.17%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	0.10%	0	0.00%	1	0.07%
Overall		**1033**	**100%**	**429**	**100%**	**1462**	**100%**
Adult Status 4	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	103	10.33%	45	9.64%	148	10.11%
	Congenital heart disease	49	4.91%	35	7.49%	84	5.74%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	394	39.52%	261	55.89%	655	44.74%
	Exception	248	24.87%	59	12.63%	307	20.97%
	Inotropes without hemodynamic monitoring	123	12.34%	26	5.57%	149	10.18%
	Intra-aortic ballon pump - Hemodynamic Values obtained	1	0.10%	0	0.00%	1	0.07%
	Ischemic heart disease with intractable angina	22	2.21%	13	2.78%	35	2.39%
	No criteria for this status	1	0.10%	0	0.00%	1	0.07%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	0.10%	0	0.00%	1	0.07%
	Retransplant	55	5.52%	28	6.00%	83	5.67%
Overall		**997**	**100%**	**467**	**100%**	**1464**	**100%**
Adult Status 5	None	49	100.00%	10	100.00%	59	100.00%
Adult Status 6	None	288	100.00%	35	100.00%	323	100.00%

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

Table 9. Adult Heart Transplants by Criteria Within Medical Urgency Status at Transplant Post-Implementation, Post-Guidance

		Initial		Extension		Total	
Status	**Criteria**	**N**	**%**	**N**	**%**	**N**	**%**
Adult Status 1	BIVAD/Ventricular Episodes	6	2.93%	1	3.70%	7	3.02%
	Exception	91	44.39%	10	37.04%	101	43.53%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	15	7.32%	9	33.33%	24	10.34%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	45	21.95%	2	7.41%	47	20.26%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	48	23.41%	5	18.52%	53	22.84%
Overall		**205**	**100%**	**27**	**100%**	**232**	**100%**
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	1	0.15%	0	0.00%	1	0.09%
	Exception	296	43.53%	234	60.78%	530	49.77%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	4	0.59%	3	0.78%	7	0.66%
	Intra-aortic ballon pump - Hemodynamic Values obtained	250	36.76%	88	22.86%	338	31.74%
	Intra-aortic balloon pump after 14 days	1	0.15%	0	0.00%	1	0.09%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	0.15%	0	0.00%	1	0.09%
	Mechanical circulatory support device(MCSD) with malfunction	19	2.79%	22	5.71%	41	3.85%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	3	0.44%	2	0.52%	5	0.47%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	6	0.88%	2	0.52%	8	0.75%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	76	11.18%	27	7.01%	103	9.67%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	5	0.74%	6	1.56%	11	1.03%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	1	0.15%	0	0.00%	1	0.09%

(continued)

Status	Criteria	N	%	N	%	N	%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	17	2.50%	1	0.26%	18	1.69%
Overall		**680**	**100%**	**385**	**100%**	**1065**	**100%**
Adult Status 3	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	80	39.22%	0	0.00%	80	26.67%
	Exception	52	25.49%	48	50.00%	100	33.33%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	8	3.92%	4	4.17%	12	4.00%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	13	6.37%	4	4.17%	17	5.67%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	6	2.94%	9	9.38%	15	5.00%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	2	0.98%	2	2.08%	4	1.33%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	4	1.96%	0	0.00%	4	1.33%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	0.98%	0	0.00%	2	0.67%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	1	0.49%	1	1.04%	2	0.67%
	Mechanical circulatory support device (MCSD) with pump thrombosis	2	0.98%	8	8.33%	10	3.33%
	Mechanical circulatory support device (MCSD) with right heart failure	2	0.98%	3	3.12%	5	1.67%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	32	15.69%	17	17.71%	49	16.33%
Overall		**204**	**100%**	**96**	**100%**	**300**	**100%**
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	36	12.81%	12	9.92%	48	11.94%
	Congenital heart disease	10	3.56%	8	6.61%	18	4.48%
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	1	0.36%	0	0.00%	1	0.25%

(continued)

Status	Criteria	N	%	N	%	N	%
Adult Status 4	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	87	30.96%	73	60.33%	160	39.80%
	Exception	64	22.78%	15	12.40%	79	19.65%
	Inotropes without hemodynamic monitoring	63	22.42%	1	0.83%	64	15.92%
	Ischemic heart disease with intractable angina	8	2.85%	8	6.61%	16	3.98%
	Retransplant	12	4.27%	4	3.31%	16	3.98%
Overall		**281**	**100%**	**121**	**100%**	**402**	**100%**
Adult Status 5	None	15	100.00%	3	100.00%	18	100.00%
Adult Status 6	None	83	100.00%	12	100.00%	95	100.00%

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

Table 10 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, 42.72% of transplants had an MCSD listed on the TRR pre-implementation, compared to 34.41% post-implementation. Changes in the proportion of MCSDs at transplant were similar to those observed for MCSDs reported at listing but were more dramatic, with the percent of transplants made to recipients with LVADs falling substantially and the percent recipients with an IABP or on ECMO more than doubling.

Table A10 shows the count and percent of MCSDs at transplant by region based on information reported on the TRR. The distribution of MCSDs at transplant is broadly similar across regions, although region 6 had a smaller decline in LVADs among recipients than other regions. Region 9 had the lowest proportion of transplant recipients with an LVAD at transplant post-implementation, followed closely by regions 7 and 8. These three regions also had the highest proportion of transplant recipients with an IABP post-implementation. Post-implementation the percent of patients on IABP increased substantially compared to pre-implementation for all regions.

For comparison, Table A11 shows the count and percent of mechanical circulatory support devices reported for adult heart transplant recipients at the time of transplant during the post-implementation era, based on the recipient's justification form history and broken down by device type and brand. The MCSDs at transplant reported on waitlist justification forms were similar to those reported on the TRR, with a higher proportion of recipients with an IABP being reported on justification forms than on the TRR and a lower proportion of recipients with some form of LVAD based on the justification form data than the proportion reported on the TRR.

Table 10. Mechanical Circulatory Support Devices at Transplant for Adult Heart Candidates

Brand	Era	Count	Percent
ECMO			
Total ECMO	**Pre**	**87**	**1.74%**
	Post	**539**	**8.09%**
IABP			
Total IABP	**Pre**	**656**	**13.13%**
	Post	**2643**	**39.65%**
LVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	4	0.13%
Cardiac Assist Tandem Heart	Pre	3	0.08%
	Post	3	0.1%
CentriMag (Thoratec/Levitronix)	Pre	18	0.46%
	Post	36	1.17%
Evaheart	Pre	0	0%
	Post	1	0.03%
Heartmate II	Pre	1861	47.28%
	Post	491	15.98%
HeartMate III	Pre	78	1.98%
	Post	1184	38.54%
Heartmate XVE	Pre	5	0.13%
	Post	0	0%
	Pre	16	0.41%

Heartsaver VAD	Post	5	0.16%
Heartware HVAD	Pre	1529	38.85%
	Post	799	26.01%
Impella CP	Pre	1	0.03%
	Post	71	2.31%
Impella Recover 2.5	Pre	7	0.18%
	Post	7	0.23%
Impella Recover 5.0	Pre	45	1.14%
	Post	245	7.98%
Jarvik 2000	Pre	5	0.13%
	Post	0	0%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	1	0.03%
Terumo DuraHeart	Pre	1	0.03%
	Post	0	0%
Thoratec IVAD	Pre	2	0.05%
	Post	0	0%
Thoratec PVAD	Pre	1	0.03%
	Post	0	0%
Other, Specify	Pre	364	9.25%
	Post	225	7.32%
Total LVAD	**Pre**	**3936**	**78.78%**
	Post	**3072**	**46.09%**
LVAD+RVAD			
Berlin Heart EXCOR	Pre	0	0%
	Post	1	0.31%
Cardiac Assist Protek Duo	Pre	0	0%
	Post	19	5.9%
Cardiac Assist Tandem Heart	Pre	7	3.18%
	Post	3	0.93%
CentriMag (Thoratec/Levitronix)	Pre	78	35.45%
	Post	168	52.17%
Heartmate II	Pre	10	4.55%
	Post	0	0%
HeartMate III	Pre	2	0.91%
	Post	54	16.77%
Heartsaver VAD	Pre	1	0.45%
	Post	0	0%
	Pre	84	38.18%

Heartware HVAD	Post	34	10.56%
Impella CP	Pre	0	0%
	Post	2	0.62%
Impella Recover 2.5	Pre	1	0.45%
	Post	1	0.31%
Impella Recover 5.0	Pre	5	2.27%
	Post	5	1.55%
Maquet Jostra Rotaflow	Pre	5	2.27%
	Post	8	2.48%
Thoratec PVAD	Pre	6	2.73%
	Post	0	0%
Other, Specify	Pre	21	9.55%
	Post	27	8.39%
Total LVAD+RVAD	**Pre**	**220**	**4.4%**
	Post	**322**	**4.83%**
RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	6	16.22%
CentriMag (Thoratec/Levitronix)	Pre	3	23.08%
	Post	10	27.03%
Heartmate II	Pre	2	15.38%
	Post	0	0%
Heartware HVAD	Pre	2	15.38%
	Post	3	8.11%
Impella CP	Pre	0	0%
	Post	3	8.11%
Impella Recover 2.5	Pre	0	0%
	Post	1	2.7%
Impella Recover 5.0	Pre	3	23.08%
	Post	5	13.51%
Impella RP	Pre	1	7.69%
	Post	3	8.11%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	1	2.7%
Other, Specify	Pre	2	15.38%
	Post	5	13.51%
Total RVAD	**Pre**	**13**	**0.26%**
	Post	**37**	**0.56%**

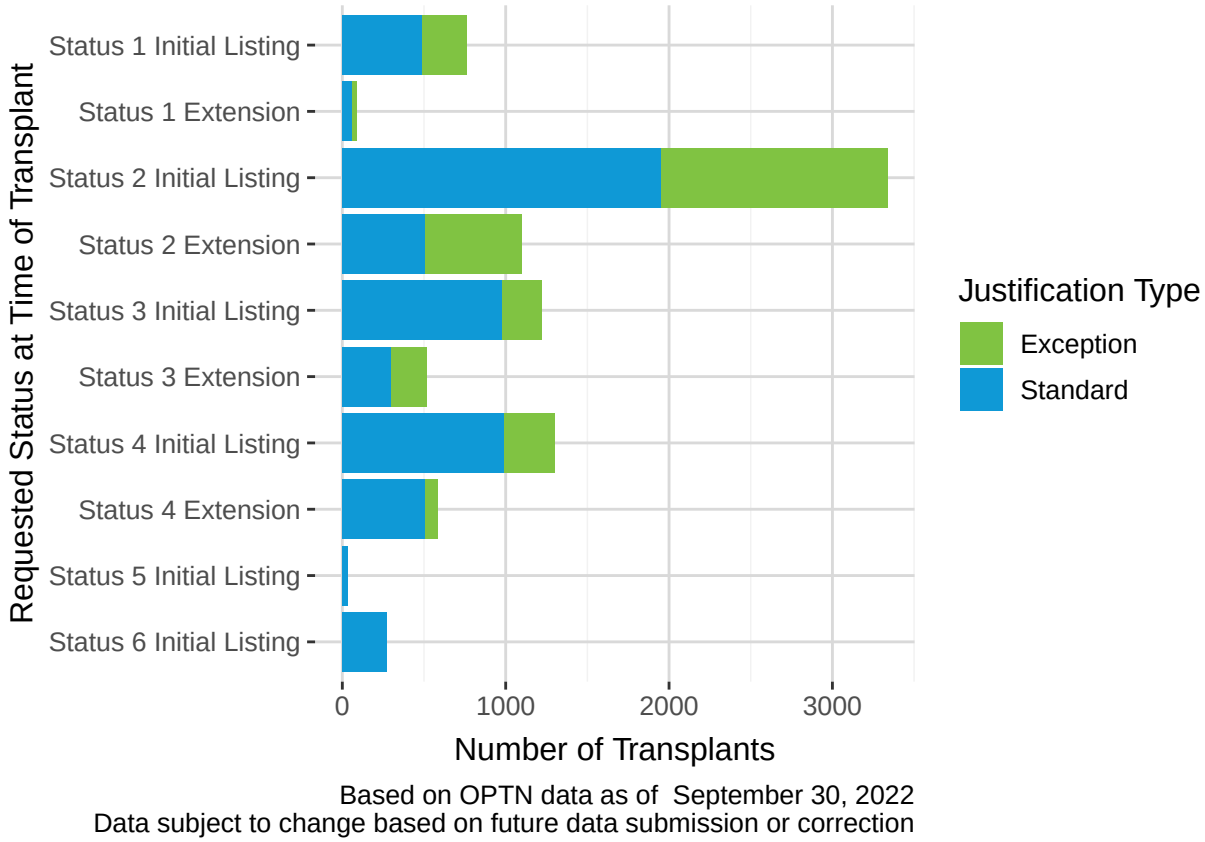
TAH

SynCardia CardioWest	Pre	83	98.81%
	Post	47	90.38%
Other, Specify	Pre	1	1.19%
	Post	5	9.62%
Total TAH	**Pre**	**84**	**1.68%**
	Post	**52**	**0.78%**

Figure 16 shows the proportion of requested statuses for adult heart recipients at transplant, as well as the review type of the requests and whether they were initial or extension requests. Figure 17 shows the same information post-implementation, stratified by pre- vs. post-guidance.

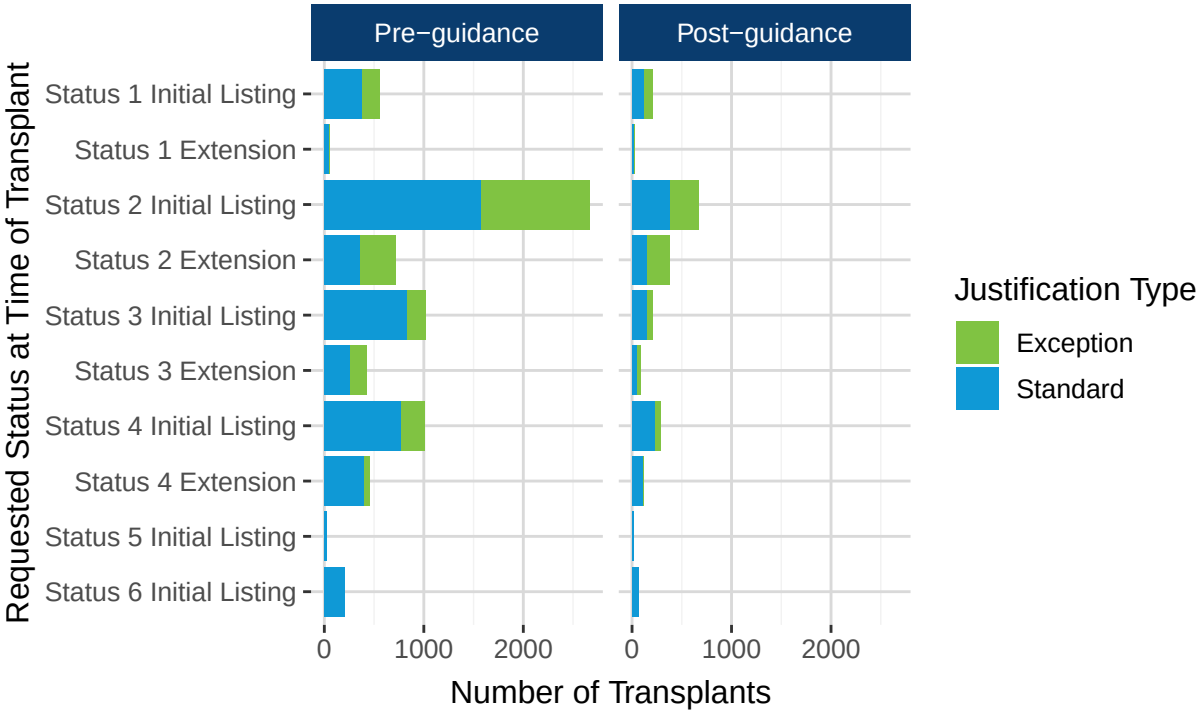
Overall, the most common request at transplant was Adult Status 2 initial; this status also had the highest proportion of exception requests. Initial requests were more common than extension requests. A similar pattern was seen in the pre- and post-guidance periods, although the number of transplants was smaller in the post-guidance period due to its shorter duration.

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



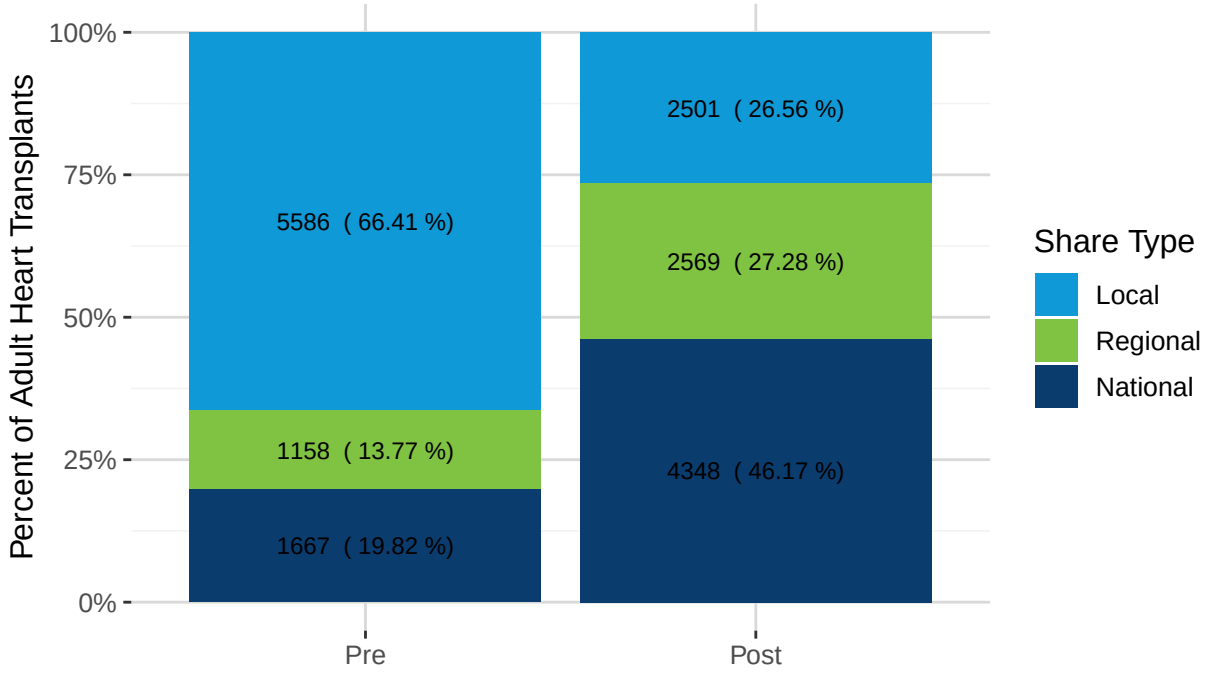
Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction

Figure 17. Adult Heart Transplants by Review Type, Requested Status, and Guidance Period



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre−Guidance: October 18, 2018 − March 3, 2021
Post−Guidance: March 4, 2021 − October 17, 2021

Figure 18. Adult Heart Transplants by Share Type and Era



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre−Policy: October 18, 2015 − October 17, 2018
Post−Policy: October 18, 2018 − October 17, 2021
Not reported share types excluded (n=12 pre & n=4 post)

Figure 18 shows the percent of adult heart transplants by share type and era. Here, "local" refers to hearts recovered and transplanted within the same DSA and "regional" refers to hearts recovered and transplanted in different DSAs but within the same OPTN region. This report includes data from after the removal of DSA from heart allocation, implemented January 09, 2020; a separate OPTN monitoring report addresses that removal.

The number of local transplants declined substantially post-implementation while both regional and national shares increased. The increase was most dramatic for heart transplants at the national share level, which more than doubled post-implementation. Table 11 shows the proportion of heart transplants by share type and era.

Table A12 gives the counts and percentages of adult heart transplants performed in each distance category by share type and era.

Table 11. Heart Transplants by Share Type and Era

Era	Zone	N	%
Pre	Local	5586	66.3%
	Regional	1158	13.7%
	National	1667	19.8%
	Not Reported	12	0.1%
Post	Local	2501	26.5%
	Regional	2569	27.3%
	National	4348	46.1%
	Not Reported	4	0%

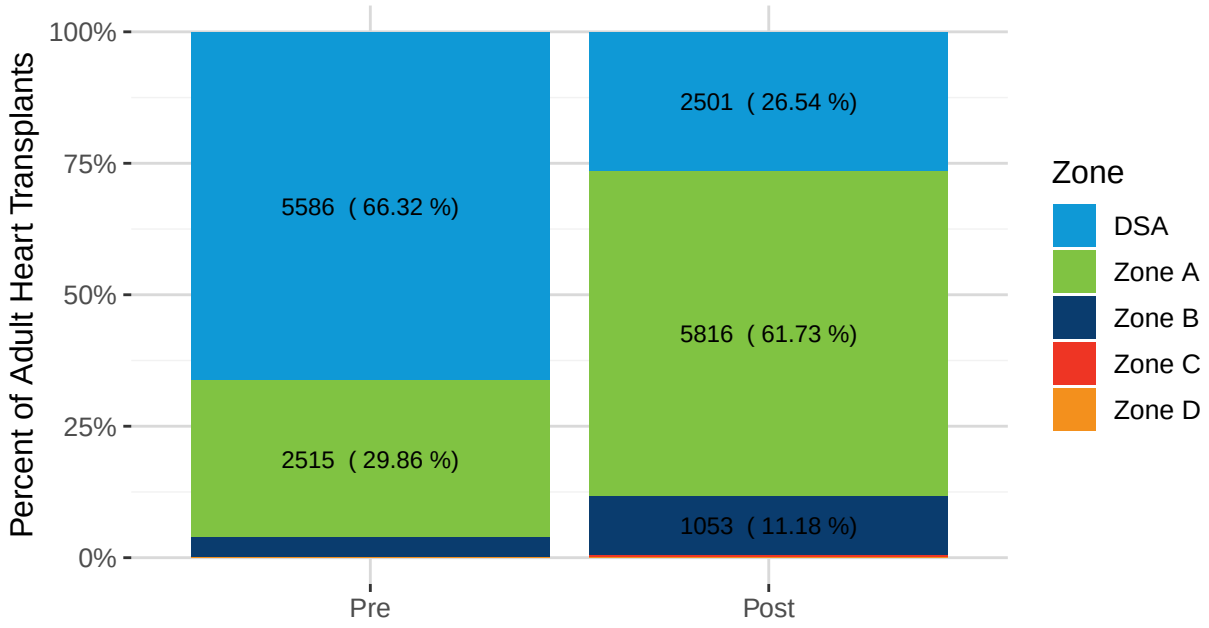
Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre-Policy: October 18, 2015 - October 17, 2018
Post-Policy: October 18, 2018 - October 17, 2021

Figure 19 and Table 12 show the number of adult heart transplants performed by zone and era. Transplants within the DSA decreased post-implementation but rose in Zones A, B, C, and D. The greatest increase in the percent of transplants was in Zone A, but transplants also more than doubled in Zone B. Zone C saw only 61 adult heart transplants with 13 pre-implementation and 48 post-implementation. There were only 2 adult heart transplants in Zone D pre-implementation and 4 occurred post-implementation.

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

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

Figure 19. Adult Heart Transplants by Zone and Era



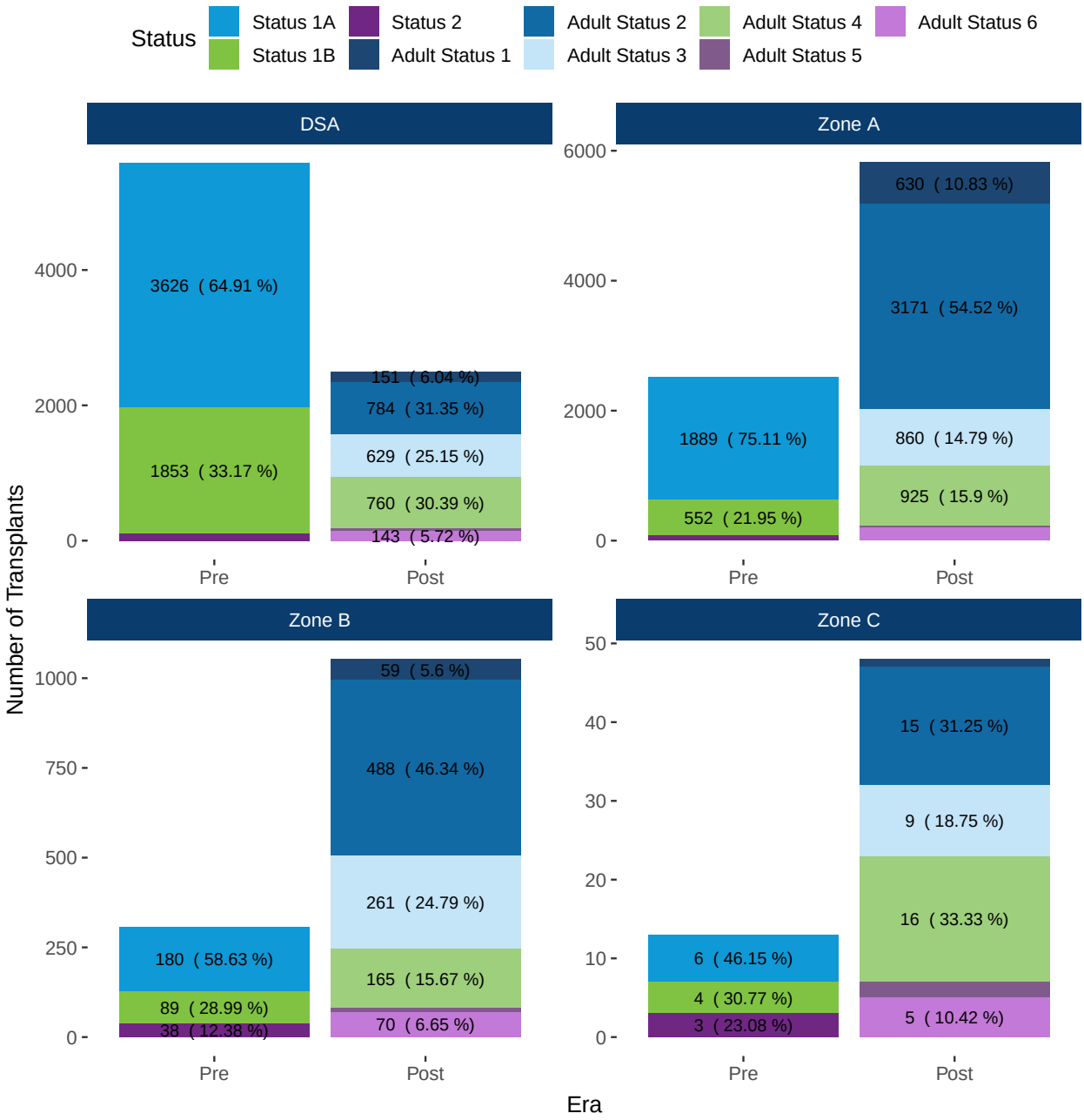
Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre−Policy: October 18, 2015 − October 17, 2018
Post−Policy: October 18, 2018 − October 17, 2021
Zones representing <5% of the total are not labeled on the plot;
DSA was removed as a unit of allocation from heart policy on 1/09/2020;
a separate monitoring report addresses that removal

Table 12. Heart Transplants by Zone and Era

Era	Zone	N	%
Pre	DSA	5586	66.3%
	Zone A	2515	29.9%
	Zone B	307	3.6%
	Zone C	13	0.2%
	Zone D	2	0%
Post	DSA	2501	26.5%
	Zone A	5816	61.7%
	Zone B	1053	11.2%
	Zone C	48	0.5%
	Zone D	4	0%

Note:
Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre-Policy: October 18, 2015 - October 17, 2018
Post-Policy: October 18, 2018 - October 17, 2021
DSA was removed as a unit of allocation from heart policy on 1/09/2020;
a separate monitoring report addresses that removal

Figure 20. Adult Heart Transplants by Zone, Era, and Medical Urgency Status

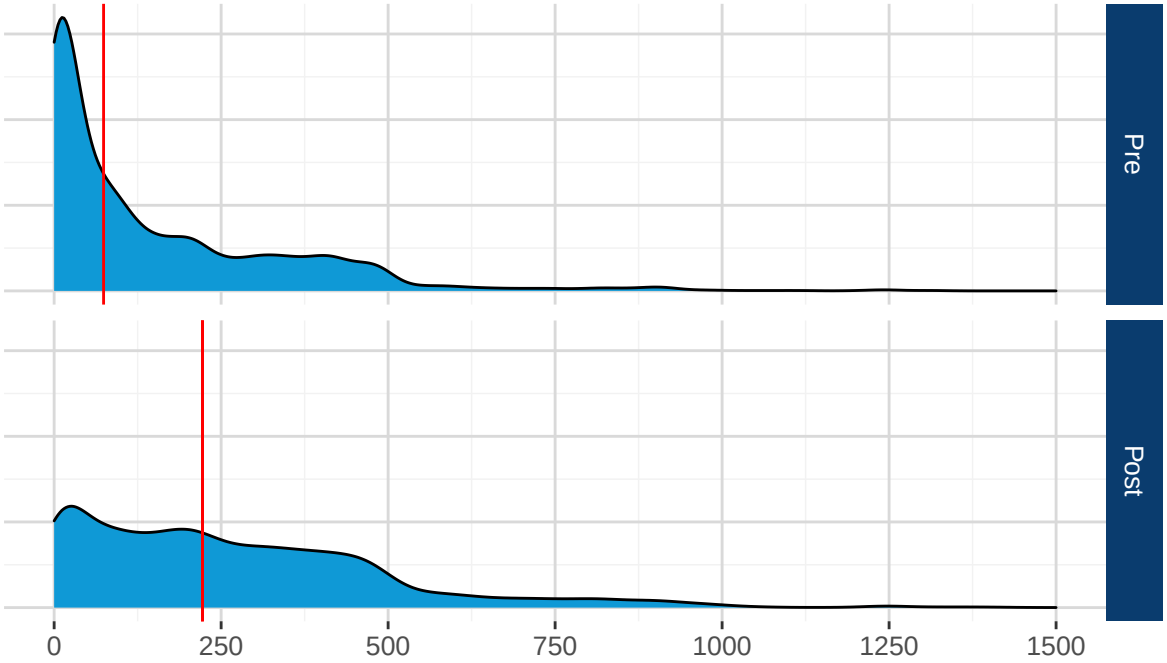


Based on OPTN data as of September 30, 2022; data subject to change based on future data submission or correction.
Pre−Policy: October 18, 2015 − October 17, 2018; Post−Policy: October 18, 2018 − October 17, 2021
Six Zone D transplants (2 pre, 4 post) omitted from plot.
DSA was removed as a unit of allocation from heart policy on 1/09/2020; a separate monitoring report addresses the removal

Figure 20 shows the number of adult heart transplants by zone, medical urgency status, and era. Pre-implementation, most transplants within the DSA and Zone A were Status 1A. Post-implementation, an approximately equal proportion of Adult Status 2, 3, and 4 candidates received transplants in the DSA. Post implementation, Adult Status 2 candidates received the largest proportion of transplants in Zones A and B and Adult Status 4 candidates received the largest proportion of transplants in Zone C. Only one Adult Status 1 transplant was performed in Zone C, likely due to the longer distance traveled.

Table A13 shows the counts and percentages of adult heart transplants by zone, era, and medical urgency status.

Figure 21. Distance Traveled at Transplant by Era



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre−Policy: October 18, 2015 − October 17, 2018
Post−Policy: October 18, 2018 − October 17, 2021
Vertical lines indicate the median straight line distance for each era

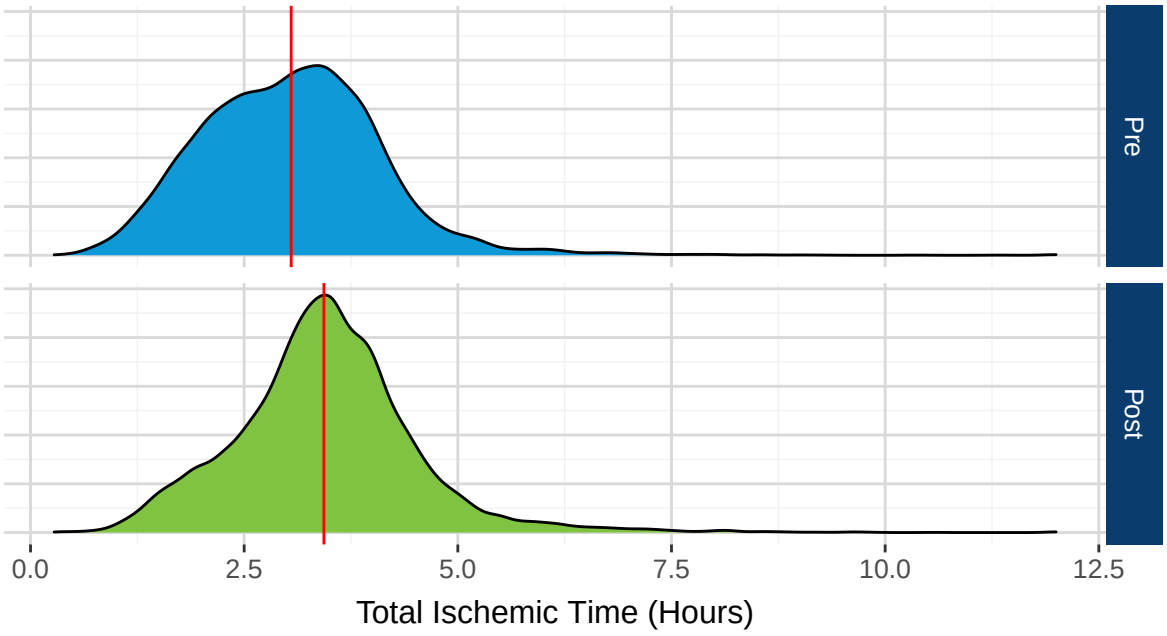
Table 13. Distance Traveled at Transplant by Era

Era	Min	IQR	Mean	Median	Max
Pre	0	221.5	152.18	74	2157
Post	0	312.0	268.36	222	2215

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre-Policy: October 18, 2015 - October 17, 2018
Post-Policy: October 18, 2018 - October 17, 2021

Figure 21 and Table 13 show the distribution 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 74 nautical miles to a post-implementation median of 222 nautical miles.

Figure 22. Total Ischemic Time at Transplant by Era



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre−Policy: October 18, 2015 − October 17, 2018
Post−Policy: October 18, 2018 − October 17, 2021
Vertical lines indicate the median cold ischemic time for each era
DSA was removed as a unit of allocation from heart policy on 1/09/2020
a separate monitoring report addresses the removal

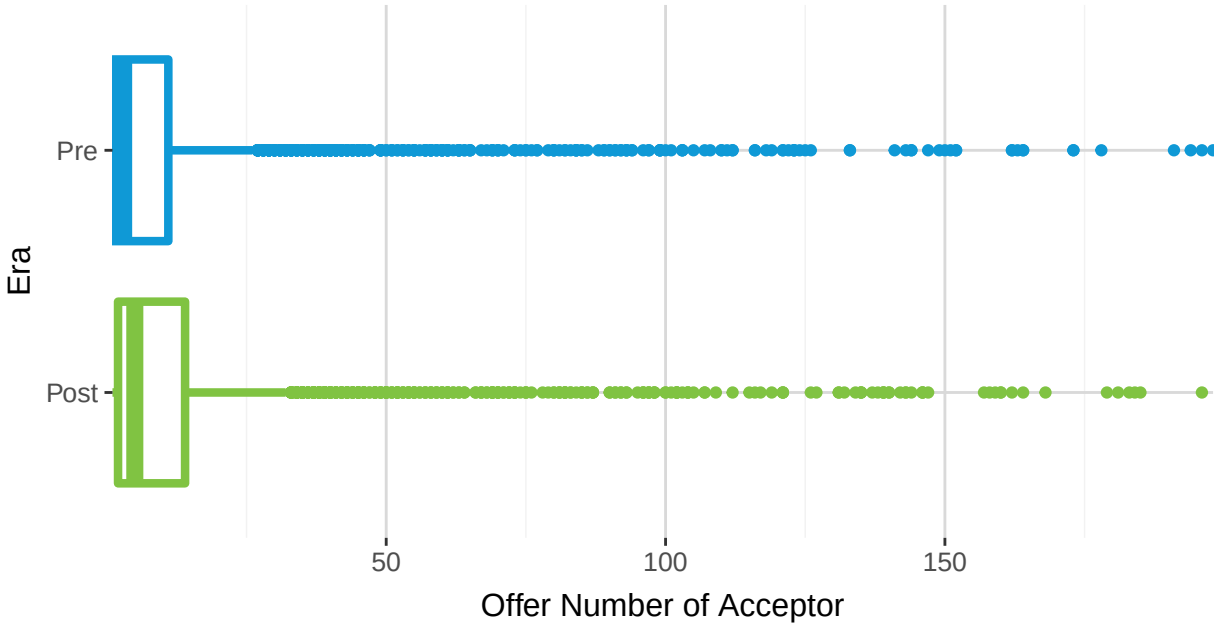
Table 14. Total Ischemic Time at Transplant by Era

Era	Min	IQR	Mean	Median	Max
Pre	0.28	1.38	3.05	3.05	12
Post	0.33	1.17	3.45	3.43	12

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre-Policy: October 18, 2015 - October 17, 2018
Post-Policy: October 18, 2018 - October 17, 2021

Figure 22 and Table 14 show the distribution of total ischemic times at transplant both pre- and post-implementation where total ischemic time is defined as the sum of cold ischemic time, warm ischemic time, and anastomotic time. Total ischemic times increased significantly ($p < 0.001$) post-implementation to a mean of 3.5 hours from 3.1 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 23. Boxplot of the Sequence Number of the Acceptor for Adult Hearts



There were 23 acceptances with an offer number over 200 in the pre era and 36 in the post era (not shown)
Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre−Policy: October 18, 2015 − October 17, 2018
Post−Policy: October 18, 2018 − October 17, 2021

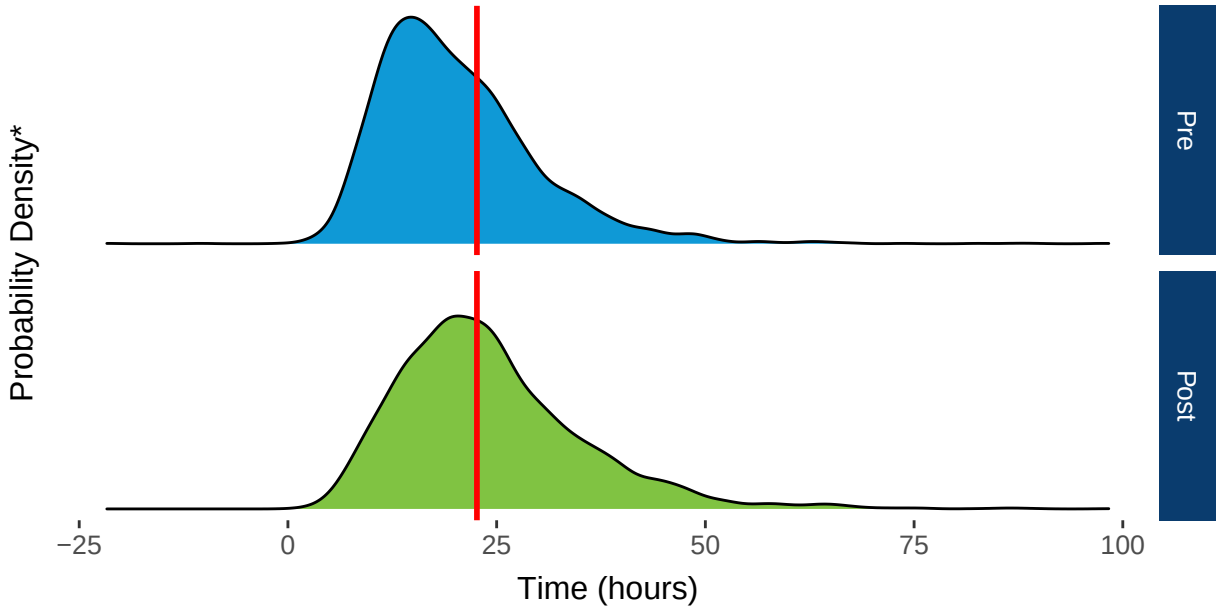
Table 15. Summary of the Sequence Number of the Final Acceptor for Adult Heart Donors

Era	Min	IQR	Mean	Median	Max
Pre-Policy	1	10	15.91	3	1723
Post-Policy	1	13	19.79	5	1245

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre-Policy: October 18, 2015 - October 17, 2018
Post-Policy: October 18, 2018 - October 17, 2021

Figure 23 and Table 15 show the distribution of sequence numbers for the final acceptors of adult hearts both pre- and post-implementation. The mean and median sequence number for the final acceptor increased for adult heart donors post-implementation. The maximum sequence number of the final acceptor was lower post-implementation compared to pre-implementation.

Figure 24. Time from First Electronic Offer to Cross Clamp for Deceased Heart Donors



* High probability density values mean that a high percentage of the population lies at or around the corresponding x−axis value, and vice versa
Red line indicates the mean in each corresponding era
Times > 100 were included in mean calculations but excluded from plot (n=5; 2 pre & 3 post)
Pre−Policy: October 18, 2015 − October 17, 2018
Post−Policy: October 18, 2018 − October 17, 2021
Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction

Table 16. Time from First Electronic Offer to Cross Clamp for Deceased Heart Donors

Era	Min	IQR	Mean	Median	Max
Pre-Policy	-21.69	11.59	20.53	18.62	512.77
Post-Policy	0.87	13.32	24.31	22.46	207.41

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre-Policy: October 18, 2015 - October 17, 2018
Post-Policy: October 18, 2018 - October 17, 2021

Figure 24 and Table 16 show the distributions of time from first electronic offer to cross clamp both pre- and post-implementation. The mean time from first electronic offer to cross clamp increased slightly post- implementation, from 20.53 hours to 24.31.

Figure 25. Center Adult Heart Transplant Volume by Era

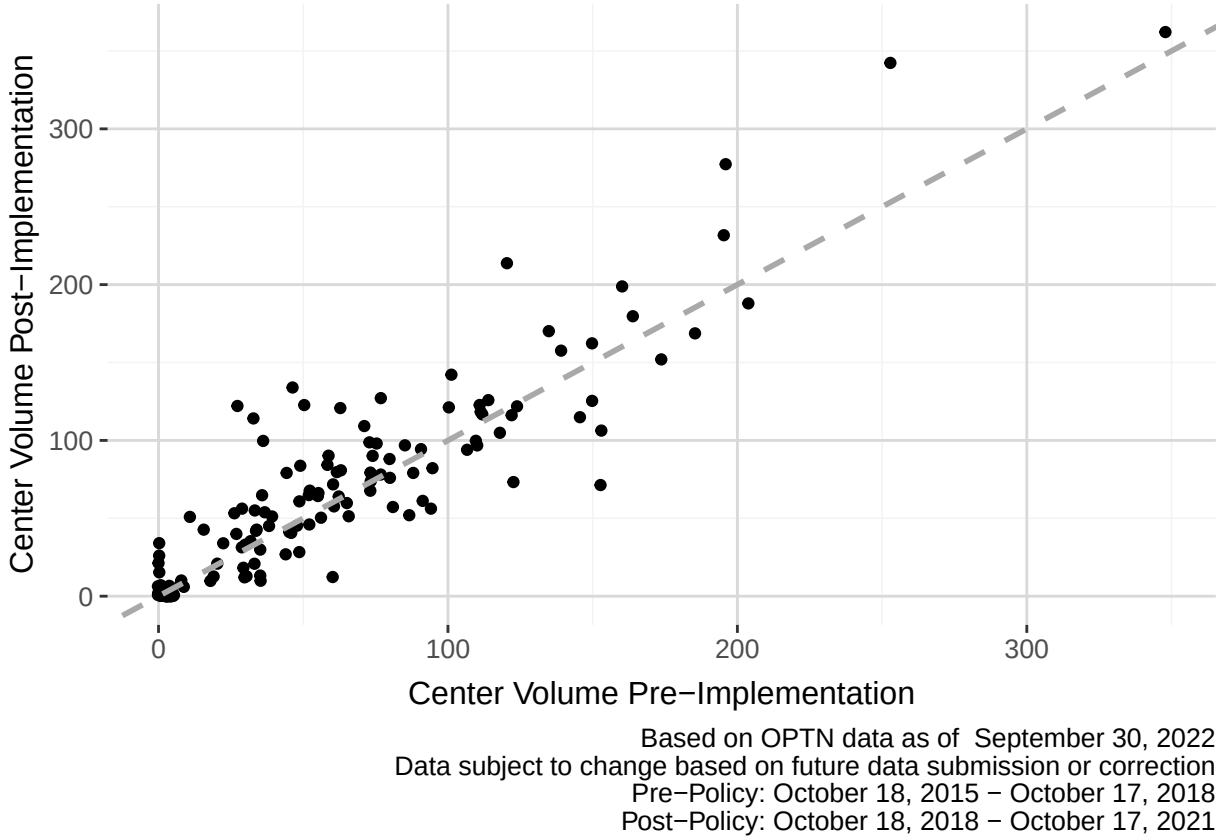


Figure 25 compares the number of adult heart transplants performed by transplant centers before and after modifications to the adult heart allocation system. This figure contains roughly 20 months of COVID-Era data and should be interpreted with caution as certain centers are known to have been significantly impacted by COVID. Dots that fall below the diagonal gray line represent centers where transplant volume decreased post-implementation, while those above the line performed more transplants in the two years after implementation. There were 138 transplant centers that performed at least one adult heart transplant in one of the two eras. Of those, 77 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, 32 did more than 25% fewer transplants post-implementation than they did pre-implementation.

Figure 26. Distribution of Medical Urgency Status for Patients Ever Waiting by Change in Listing Center Volume Post Implementation

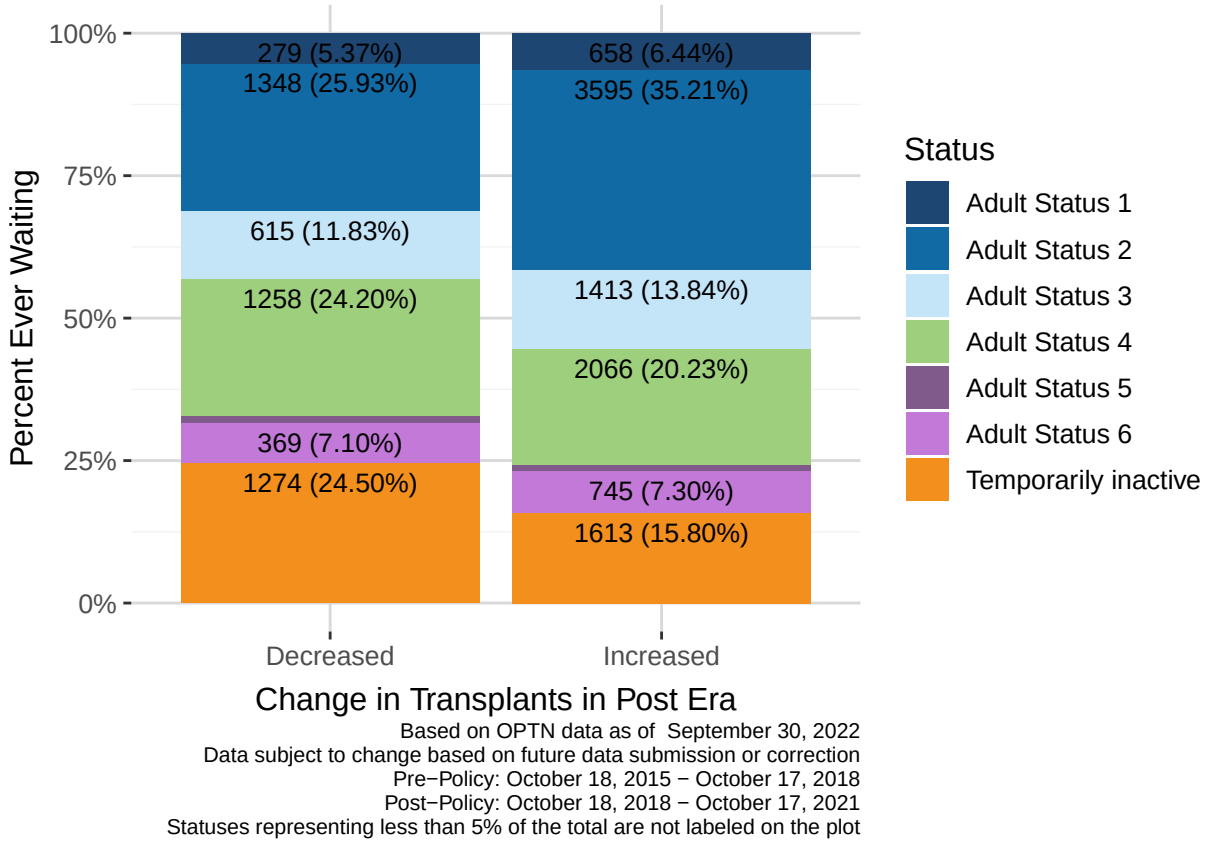


Figure 26 compares the distributions of patients ever waiting at different medical urgency statuses post-implementation at centers where the number of transplants performed post-implementation increased to the distribution at centers where the number of transplants performed post-implementation decreased. 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 4 candidates, who receive fewer heart offers as a result of their lower degree of medical urgency. Centers where transplant volume decreased also tended to have a higher proprotion of inactive candidates. There were statistically significant differences in the proportion of patients ever waiting by listing center volume post-implementation ($p < 0.001$). Differences in waitlist makeup may help to explain changes in the number of transplants performed by centers post-implementation.

Figure 27 shows the number of transplants per 100 patient-years waiting both pre- and post-implementation. The number of transplants per 100 patient years to Adult Status 1 and Adult Status 2 recipients was significantly higher than the number of transplants per 100 patient years for any other status either pre- or post-implementation. In general, the number of transplants per 100 patient-years waiting declined with medical urgency status, as expected, because higher priority is given to candidates in higher medical urgency statuses. Overall, there were more transplants per 100 patient waiting years post-implementation compared to pre-implementation.

Figure 28 shows the transplants per 100 patient waiting years by medical urgency status and era for Adult Heart Statuses 3-6 only in order to better understand visualize these particular statuses.

Figure 27. Transplants per 100 Patient-Years Waiting by Medical Urgency Status and Era

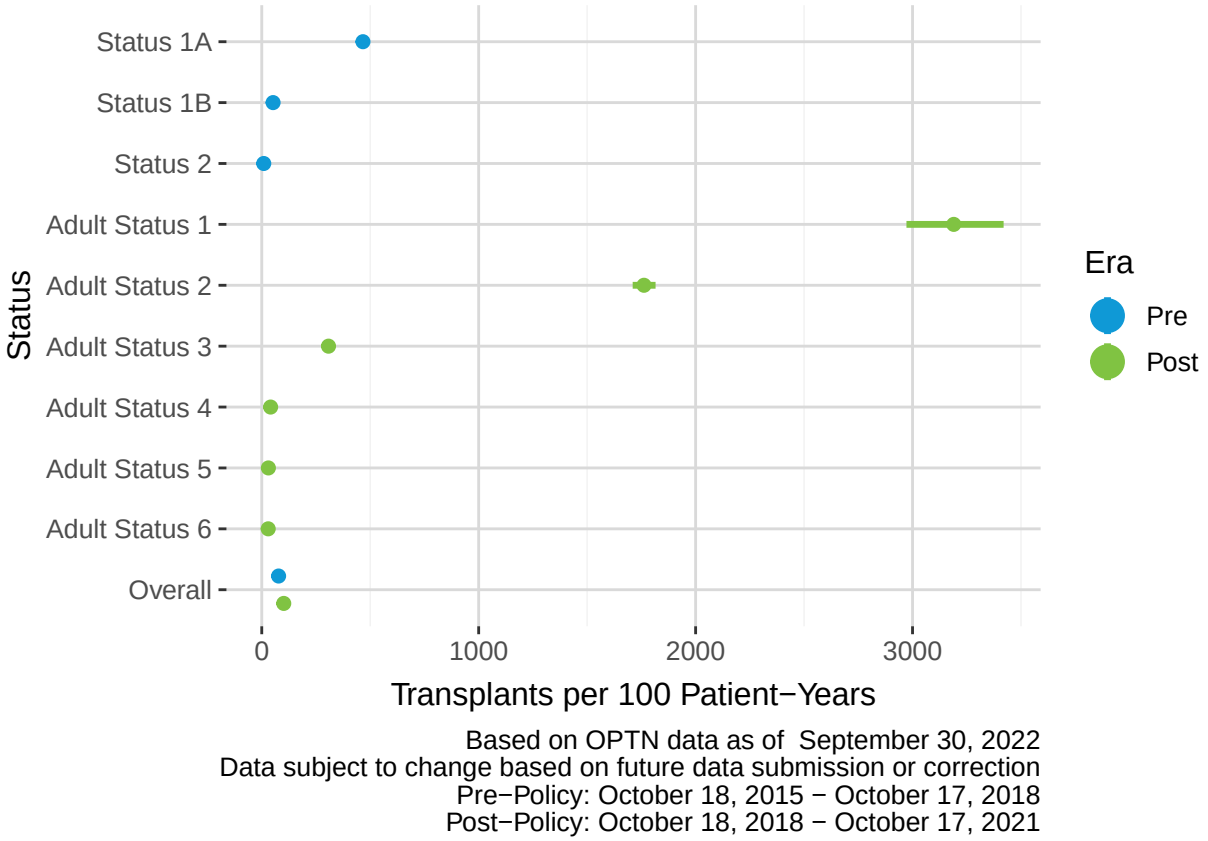


Figure 28. Zooming in on Adult Heart Statuses 3-6: Transplants per 100 Patient-Years Waiting by Medical Urgency Status and Era

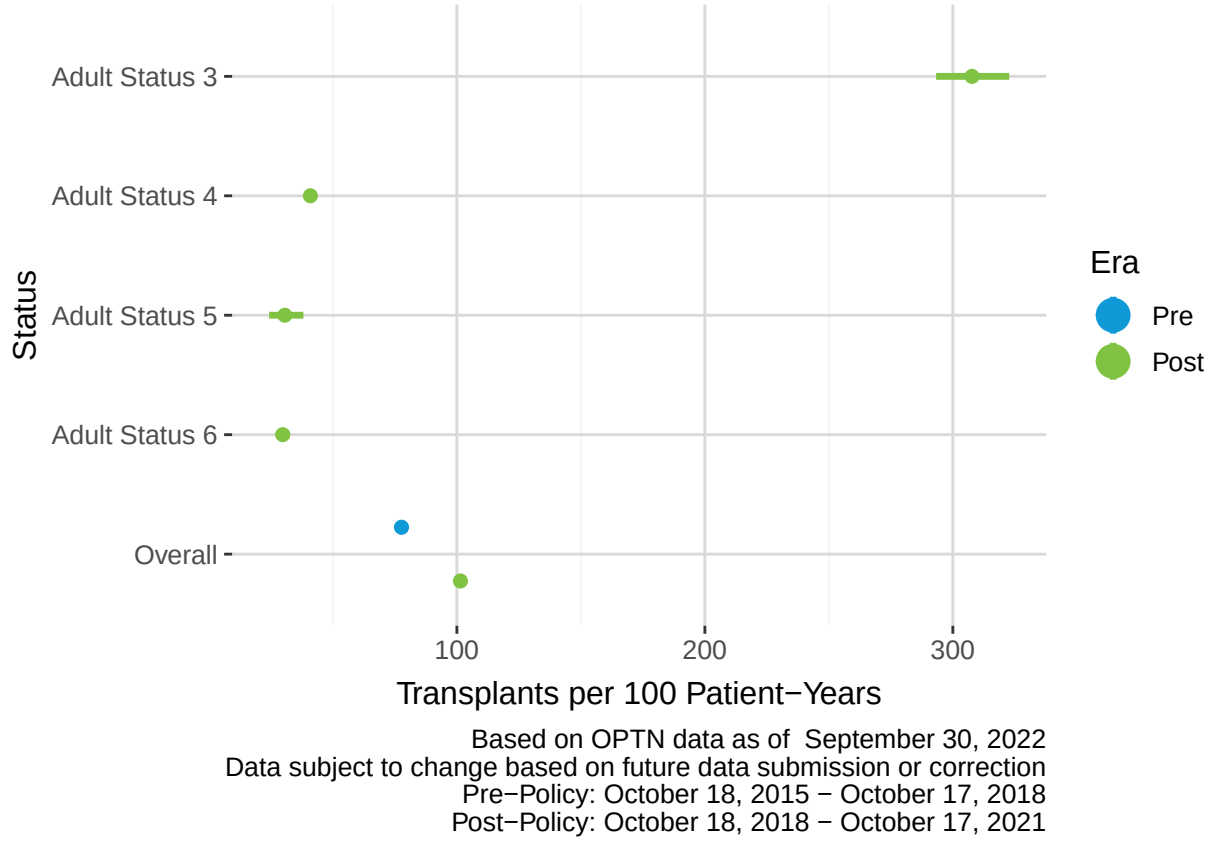


Table A14 shows the patients ever waiting, number of transplants, and transplants per 100 patient years for each medical urgency status both pre- and post-implementation.

Figure 29. Transplants per 100 Patient-Years Waiting by Equivalent Medical Urgency Status

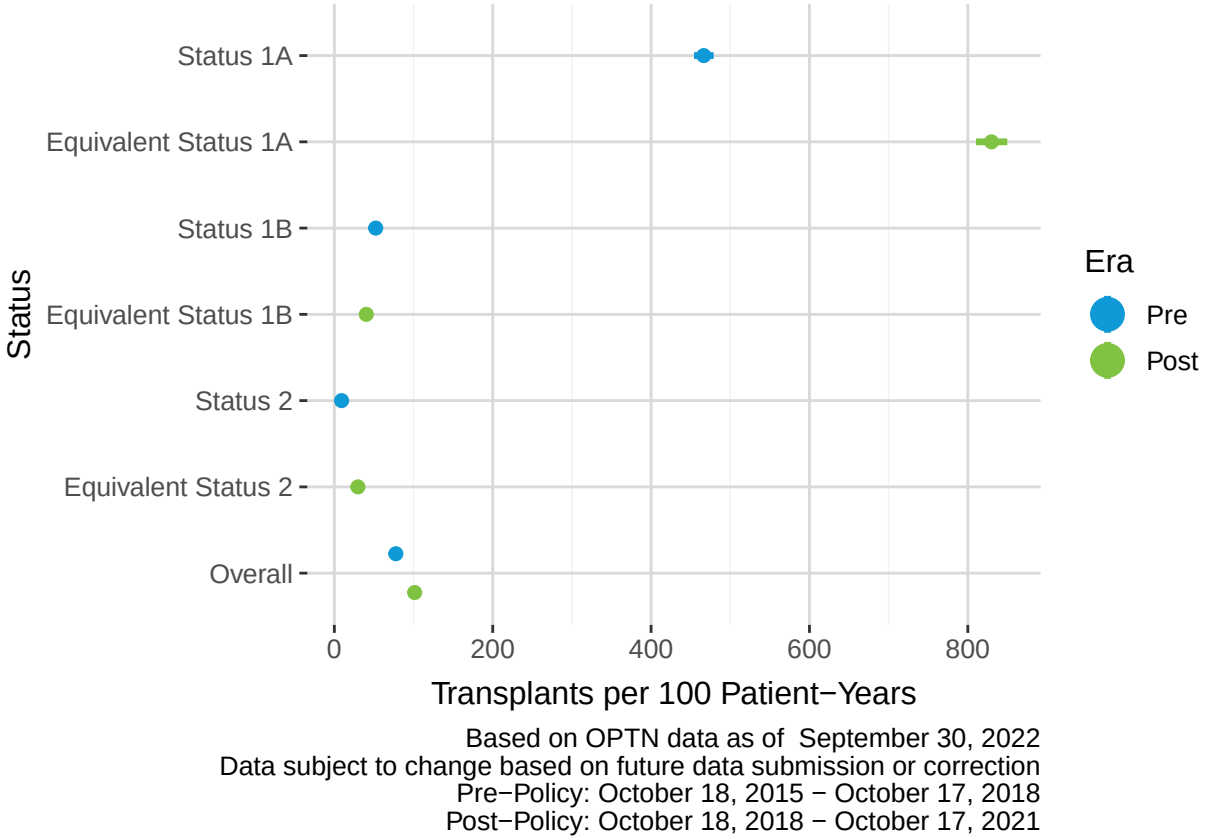


Figure 29 shows the transplants per 100 patient years by equivalent statuses post-implementation as compared to pre-implementation. The Committee Request section defines the equivalent post-implementation statuses as: old Status 1A compared to Adult Statuses 1-3, old Status 1B compared to Adult Statuses 4 and 5, and old Status 2 compared to Adult Status 6. Equivalent Status 1A and Equivalent Status 2 had significantly higher transplant rates compared to their old status counterparts. Conversely, the transplant rate for Equivalent Status 1B was significantly lower than that for old Status 1B.

Figure 30. Transplants per 100 Patient-Years Waiting by Region, Medical Urgency Status, and Era

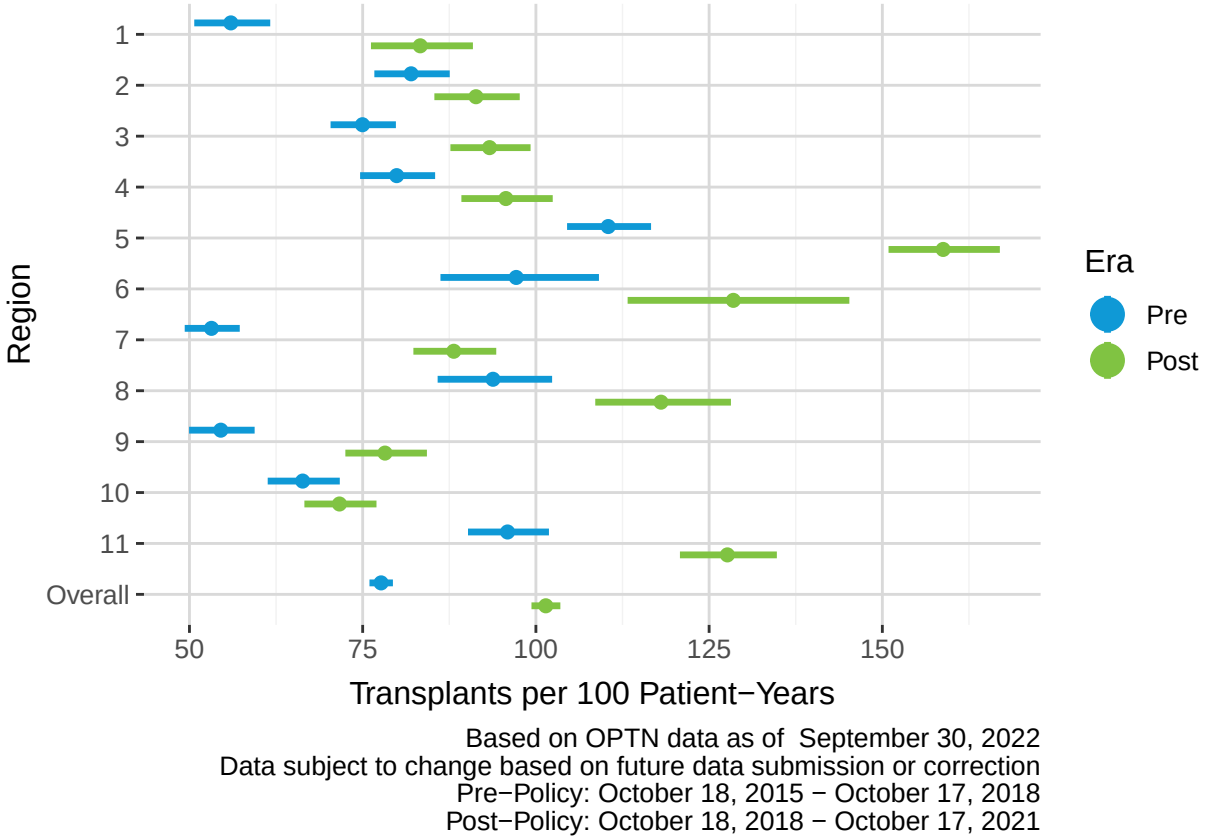


Figure 30 shows the number of transplants per 100 patient-years waiting for each region pre- and post-implementation. The number of transplants per 100 patient-years post-implementation increased for all regions. This increase was statistically significant for all regions except regions 2 and 10.

Table A15 shows the number of patients ever waiting and the number of transplants per 100 patient-years for each region pre- and post-implementation, along with the relative risk of transplant and the corresponding 95% confidence interval. The overall relative risk of transplant rose significantly to 1.31 (95% CI: (1.27, 1.47)) times what it was pre-implementation. The highest relative risk of transplant was in region 7 (1.66 (1.51, 1.82)).

Table 17. Median Days to Transplant by Medical Urgency Status and Era

Era	Status	Days Waiting
Pre	Status 1A	64
	Status 1B	228
	Status 2	604
Pre	**Total**	**242**
Post	Adult Status 1	5
	Adult Status 2	10
	Adult Status 3	29
	Adult Status 4	204
	Adult Status 5	562
	Adult Status 6	320
Post	**Total**	**78**

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre-Policy: October 18, 2015 - October 17, 2018
Post-Policy: October 18, 2018 - October 17, 2021

Tables 17 and 18 show competing risks analyses of the median days waiting until transplant by status both pre- and post-implementation, where days waiting is total days on the waiting list for all active waiting statuses. Pre-implementation, the shortest wait to transplant was for Status 1A candidates, with a median wait time of 64 days. Post-implementation, Adult Status 1, Adult Status 2, and Adult Status 3 had shorter median wait times compared to Status 1A candidates pre-implementation, with median wait times of 5, 10, and 29 days, respectively. This observation held when these three statuses were grouped together into Equivalent Status 1A (median time to transplant of 13 days). Equivalent Status 2 also saw a significant decrease in median time to transplant from 604 days pre-implementation to 320 days post-implementation. Overall the median days waiting to transplant fell from 242 to 78, a 68% decrease.

Table 18. Median Days to Transplant by Equivalent Medical Urgency Status and Era

Era	Status	Days Waiting
Pre	Equivalent Status 1A	64
	Equivalent Status 1B	228
	Equivalent Status 2	604
Pre	**Total**	**242**
Post	Equivalent Status 1A	13
	Equivalent Status 1B	218
	Equivalent Status 2	320
Post	**Total**	**78**

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre-Policy: October 18, 2015 - October 17, 2018
Post-Policy: October 18, 2018 - October 17, 2021

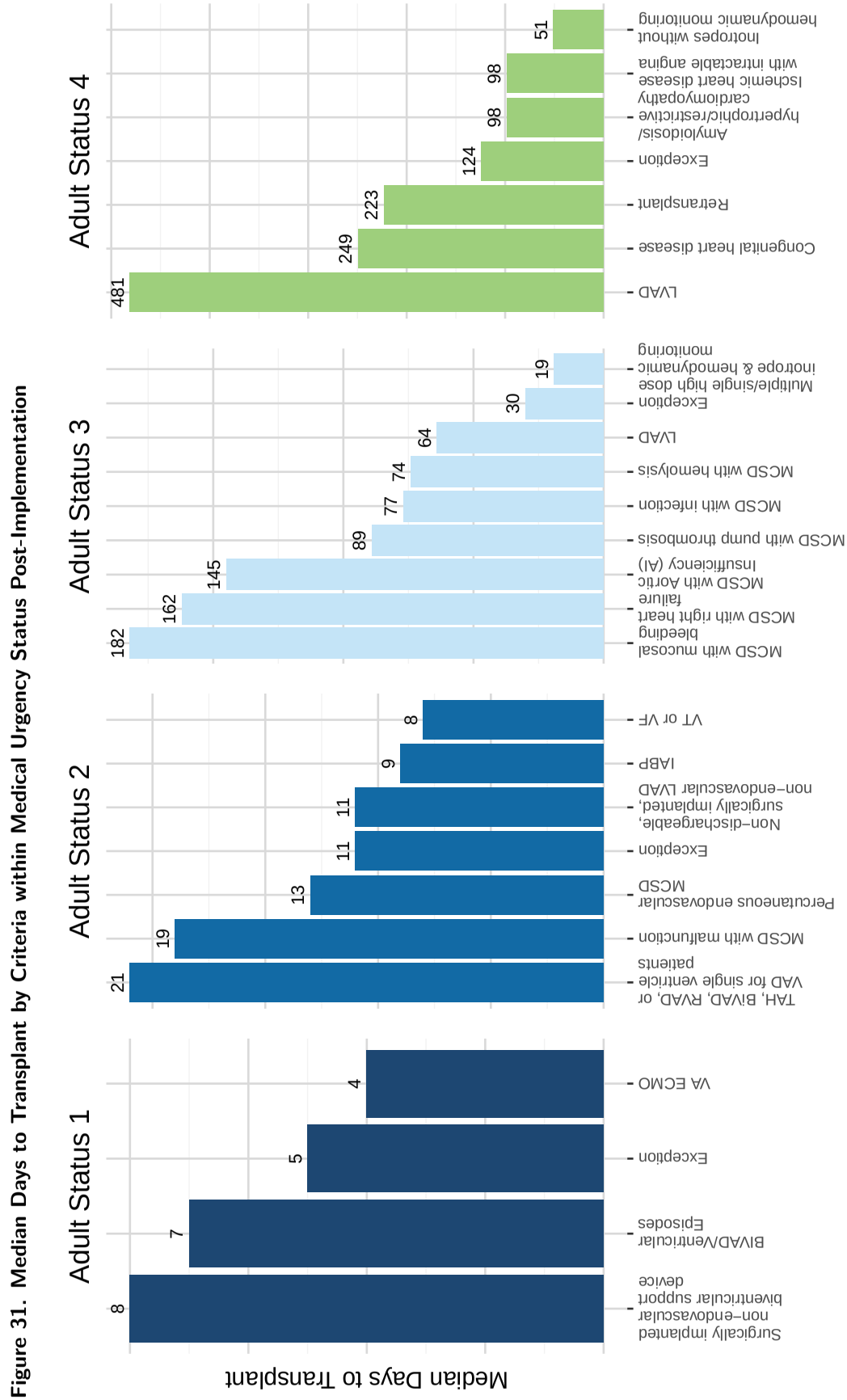


Figure 31. Median Days to Transplant by Criteria within Medical Urgency Status Post-Implementation

Table 19. Median Days to Transplant by Medical Urgency Status and Criteria Post-Implementation

Status	Criteria	Days Waiting
Adult Status 1	BIVAD/Ventricular Episodes	7
	Exception	5
	Surgically implanted non-endovascular biventricular support device	8
	VA ECMO	4
Adult Status 1	**Total**	**5**
Adult Status 2	Exception	11
	IABP	9
	MCSD with malfunction	19
	Non-dischargeable, surgically implanted, non-endovascular LVAD	11
	Percutaneous endovascular MCSD	13
	TAH, BiVAD, RVAD, or VAD for single ventricle patients	21
	VT or VF	8
Adult Status 2	**Total**	**10**
Adult Status 3	Exception	30
	LVAD	64
	MCSD with Aortic Insufficiency (AI)	145
	MCSD with hemolysis	74
	MCSD with infection	77
	MCSD with mucosal bleeding	182
	MCSD with pump thrombosis	89
	MCSD with right heart failure	162
	Multiple/single high dose inotrope & hemodynamic monitoring	19
Adult Status 3	**Total**	**29**
Adult Status 4	Amyloidosis/hypertrophic/restrictive cardiomyopathy	98
	Congenital heart disease	249
	Exception	124
	Inotropes without hemodynamic monitoring	51
	Ischemic heart disease with intractable angina	98
	LVAD	481
	Retransplant	223
Adult Status 4	**Total**	**204**
Adult Status 5	No criteria for this status	562
Adult Status 5	**Total**	**562**
Adult Status 6	No criteria for this status	320
Adult Status 6	**Total**	**320**

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction

Figure 31 and Table 19 show the results of the competing risks analysis of the median time to transplant by criteria within medical urgency status post-implementation. No criteria are required for Adult Statuses 5 and 6; consequently, these statuses were omitted from the figure. Adult status 4 candidates with an LVAD had the longest median days to transplant, followed by candidates with congenital heart disease. Candidates listed with VA ECMO in Adult Status 1 had the shortest median days to transplant. Adult Statuses 3 and 4 had the greatest variability in median days to transplant across criteria.

Figure 32. Median Days to Transplant by Exception vs. Standard Review by Status

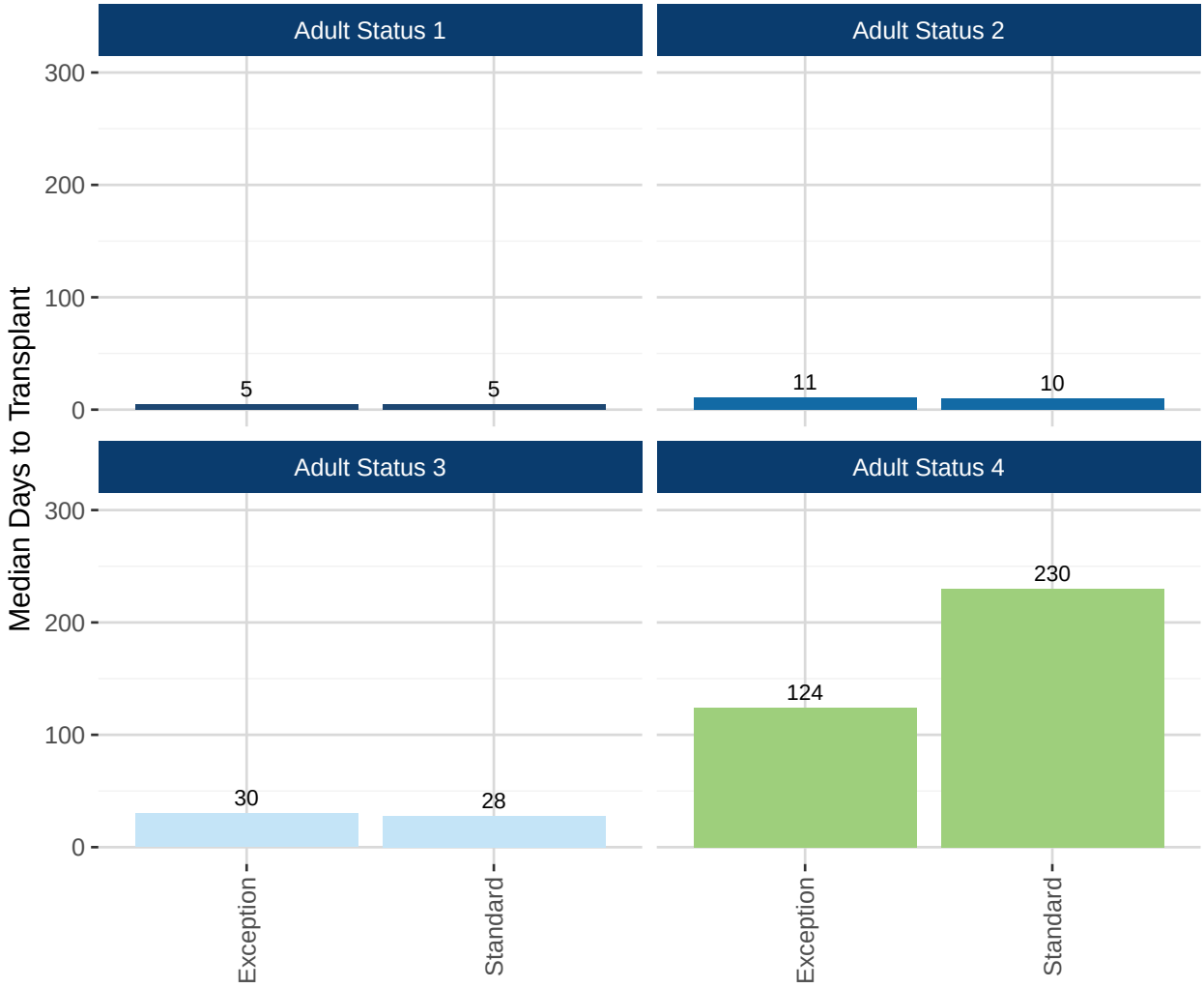
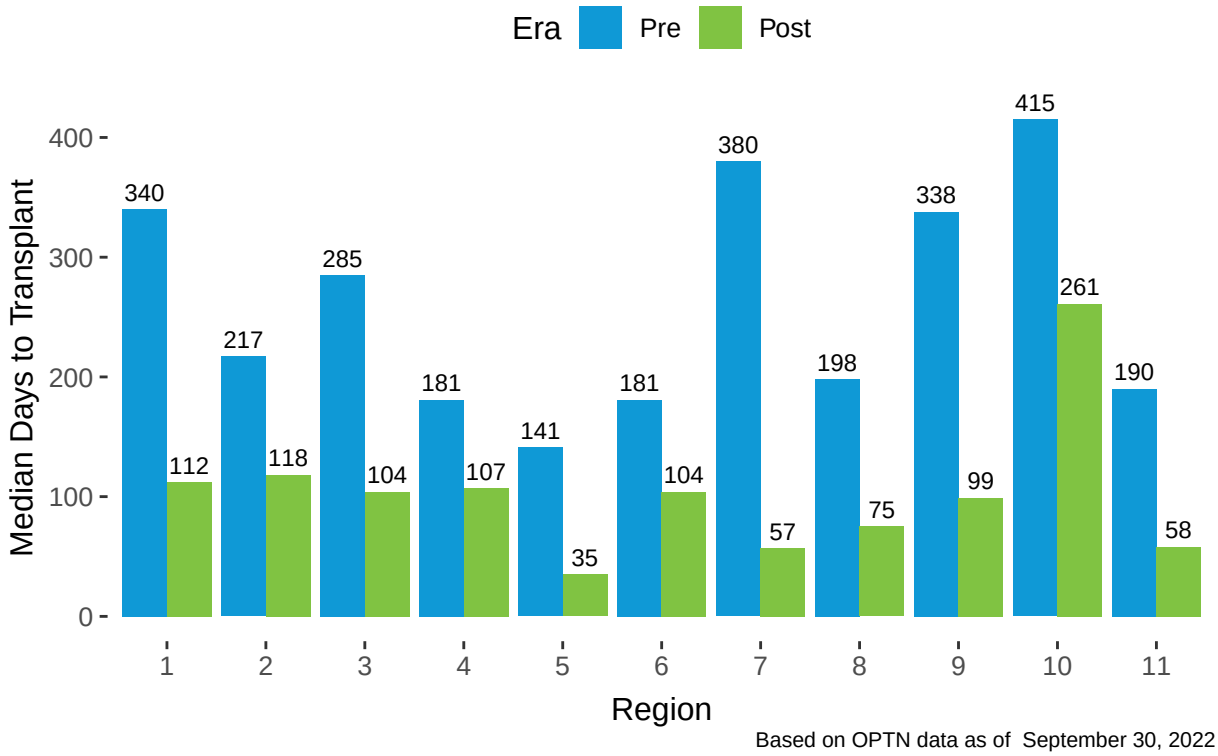


Figure 32 displays the results of the competing risks analysis of the median days to transplant for Adult Statuses 1-4 by exception versus no exception. Median days to transplant was the same between exception versus standard review for Adult Status 1. For Adult Statuses 2 and 3, the median days to transplant was higher for individuals with an exception compared to standard review. Conversely, Adult Status 4 candidates with an exception had noticeably lower median days to transplant compared to standard review.

Figure 33. Median Days to Transplant by Region and Era



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre−Policy: October 18, 2015 − October 17, 2018
Post−Policy: October 18, 2018 − October 17, 2021

Figure 33 shows a competing risks analysis of the median days waiting before transplant by status and region. The median time to transplant declined in all regions. The largest decrease in median days waited was seen in region 7, where the median wait time decreased from 380 days to 57 days, a decrease of 85%.

Utilization

This chapter examines differences in heart utilization between two donor cohorts: the 27900 deceased donors with at least one organ recovered for the purpose of transplant between October 18, 2015 and October 17, 2018 (pre-implementation); and the 35047 deceased donors with a least one organ recovered for the purpose of transplant between October 18, 2018 and October 17, 2021 (post-implementation).

Tables 20 and 21 show the utilization and discard rates for adult hearts by era both overall and for non-DCD donors. Here, utilization is defined as the number of hearts recovered during a period divided by the total number of deceased donors in that period, and discard is defined as one minus the number of adult deceased donor hearts transplanted in a period divided by the total number of adult deceased donor hearts recovered in that period.

As expected, heart utilization is higher among Donation after Brain Death (DBD; also referred to as non-DCD) donors with 35.63% utilization in Non-DCD adult heart donors compared to 27.08% utilization for all adult heart donors in the post-implementation period. There was a small decrease in utilization rates in the post-implementation period compared to the pre-implementation period for all adult heart donors and for Non-DCD donors. Discard rates increased for all adult heart donors in the post-implementation period, whereas they decreased for Non-DCD donors.

Table 20. Heart Utilization and Discard Rates by Era

Era	Utilization	Discard
Pre	29.34%	0.97%
Post	27.08%	1.06%

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre-Policy: October 18, 2015 - October 17, 2018
Post-Policy: October 18, 2018 - October 17, 2021

Table 21. Heart Utilization and Discard Rates for Non-DCD Adult Donors by Era

Era	Utilization	Discard
Pre	35.96%	0.97%
Post	35.63%	0.72%

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre-Policy: October 18, 2015 - October 17, 2018
Post-Policy: October 18, 2018 - October 17, 2021

Figure 34. Heart Utilization Rates by Region and Era

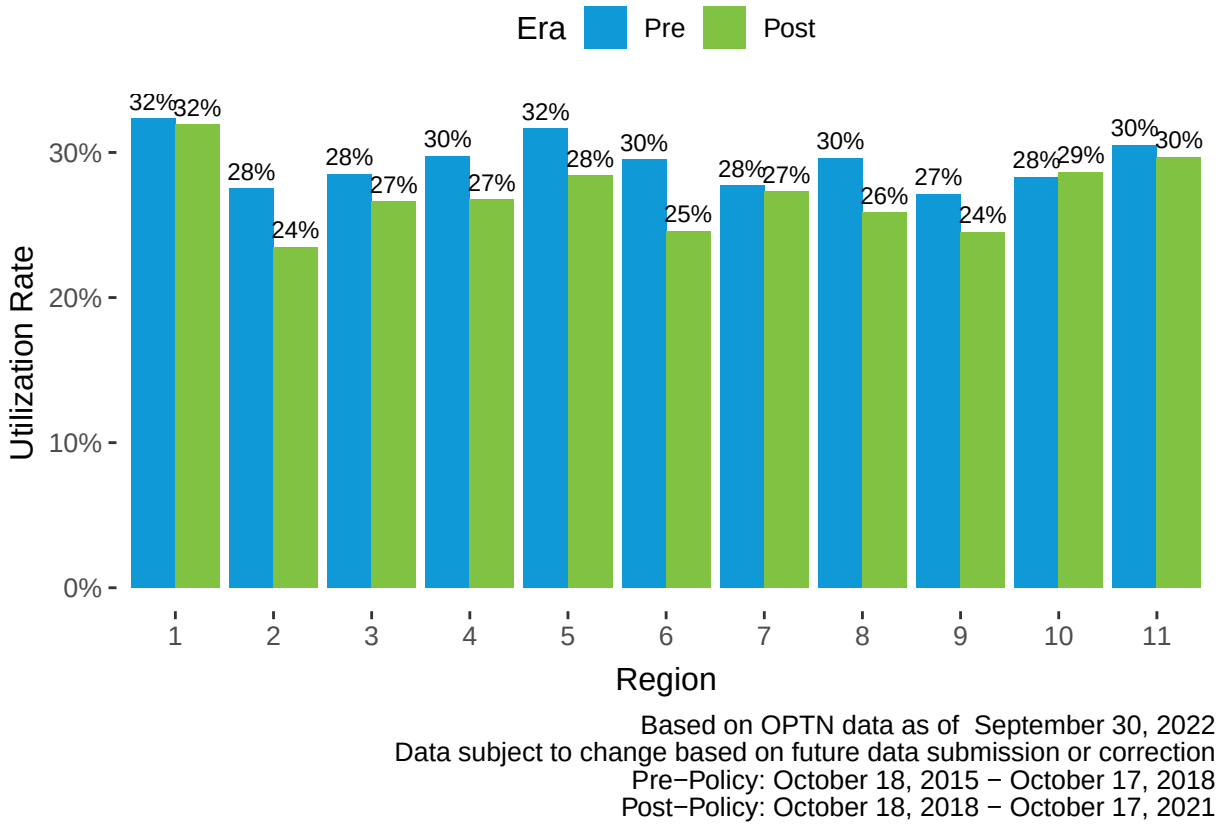


Figure 34 shows the utilization rates of adult hearts by region both pre- and post-implementation. Utilization rates decreased in the majority of the regions. Utilization rates rose in region 10 and decreased in the remaining regions.

Figure 35. Heart Utilization Rates for Adult Non-DCD Donors by Region and Era

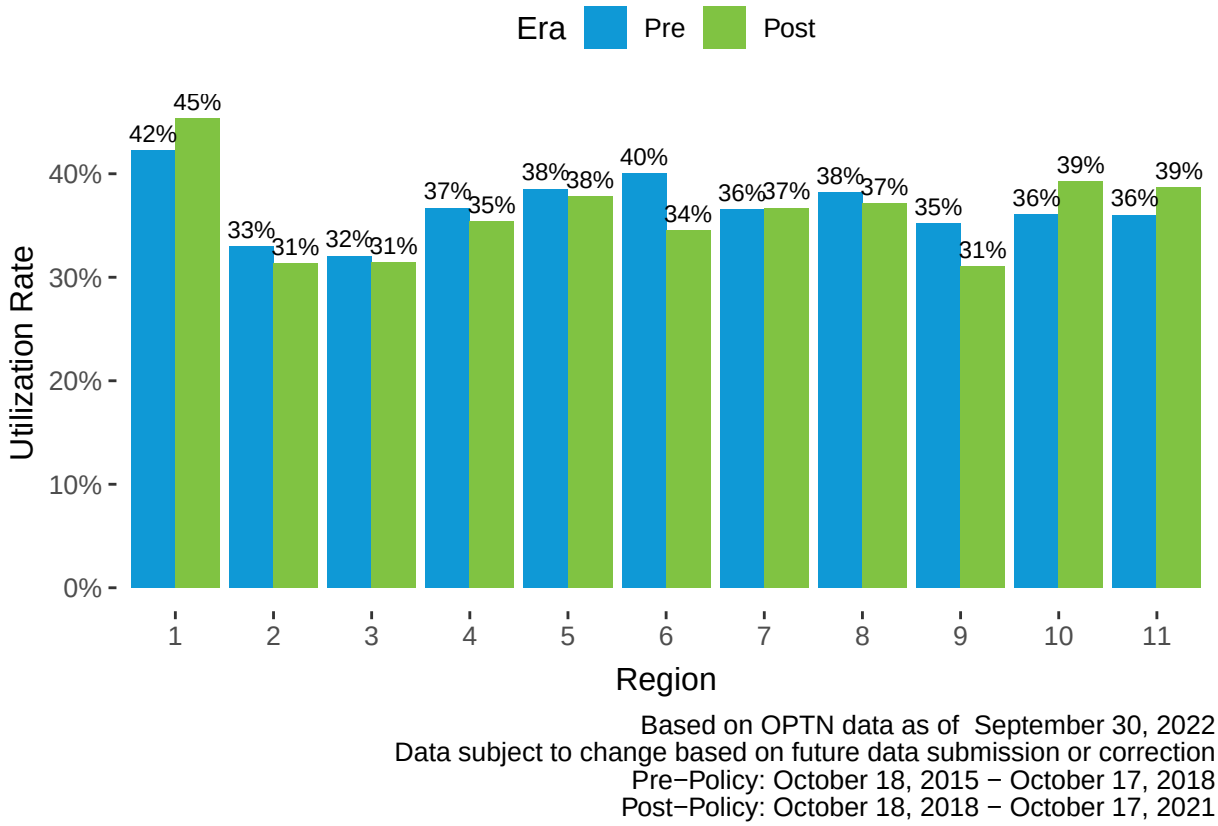


Figure 35 shows utilization rates of adult hearts by region and era for non-DCD donors only. Utilization rates are higher for non-DCD donors than for donors overall (Tables 18 and 19) and rose in regions 1, 7, 10, and 11. The largest decline pre- to post-implementation was in region 6 and the largest increase occurred in regions 1, 10, and 11.

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

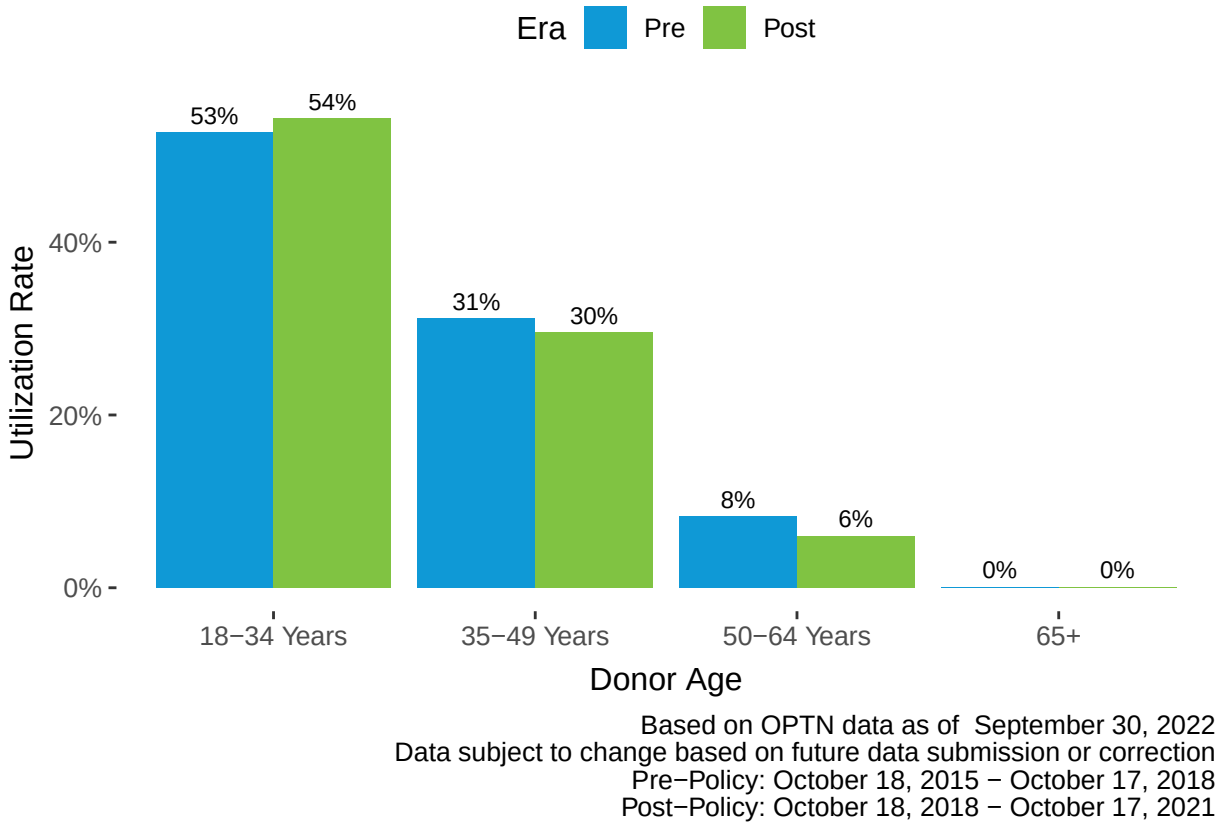


Figure 36 shows the utilization rates for adult hearts both pre- and post-implementation by donor age. There was little change in adult heart utilization in any donor age group.

Figure 37. Heart Utilization Rates for Adult Non-DCD Donors by Donor Age and Era

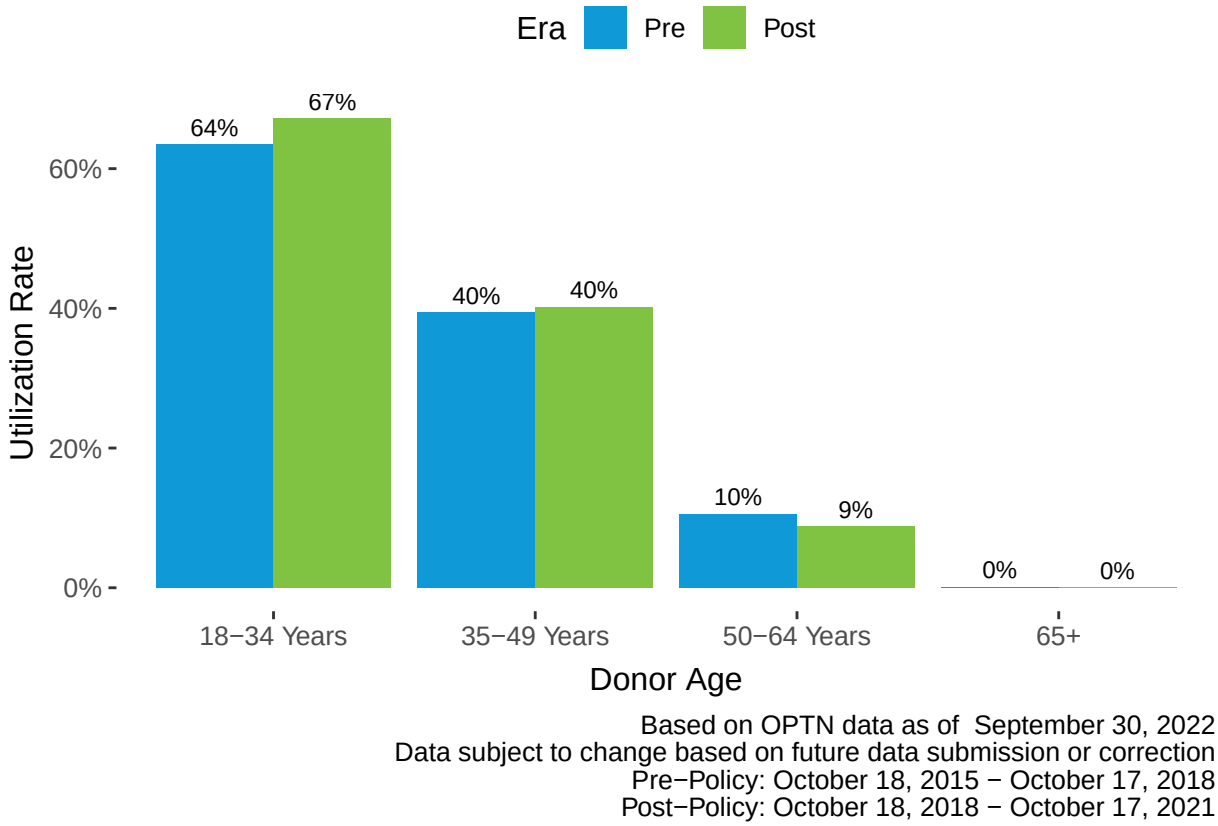


Figure 37 shows the utilization rates for adult hearts from non-DCD donors both pre- and post-implementation by donor age. The utilization rates for non-DCD donors increased slightly pre- to post-implementation for donor ages 18-34 years, remained the same for donor ages 35-49 years, and decreased slightly for donor ages 50-64 years.

Outcomes

Heart allocation policy has traditionally been based on waiting list mortality rather than post-transplant outcomes, and the revisions to the adult heart allocation system were made with waiting list mortality rather than post-transplant survival in mind. However, in order to uncover potential unintended impacts on transplant outcomes, this chapter examines recipient outcomes data for the 2447 adult heart recipients transplanted between October 18, 2015 and October 17, 2016 (pre-implementation) and the 2715 adult heart recipients transplanted between October 18, 2018 and October 17, 2019 (post-implementation). Candidates who received any previous transplant were excluded from the analysis, as were multi-organ transplant candidates. Standard Kaplan-Meier survival analyses were conducted, as 1) the OPTN Executive Committee's amnesty policy that temporarily relaxed reporting requirements for follow-up form submission during the height of COVID-19 is no longer in effect, and 2) we expect that any outcomes censoring that may have been seen previously as a result of this policy have been resolved. Survival curves were constructed using unadjusted Kaplan-Meier methodology and compared using the log-rank test.

Figure 38. One-Year Patient Survival

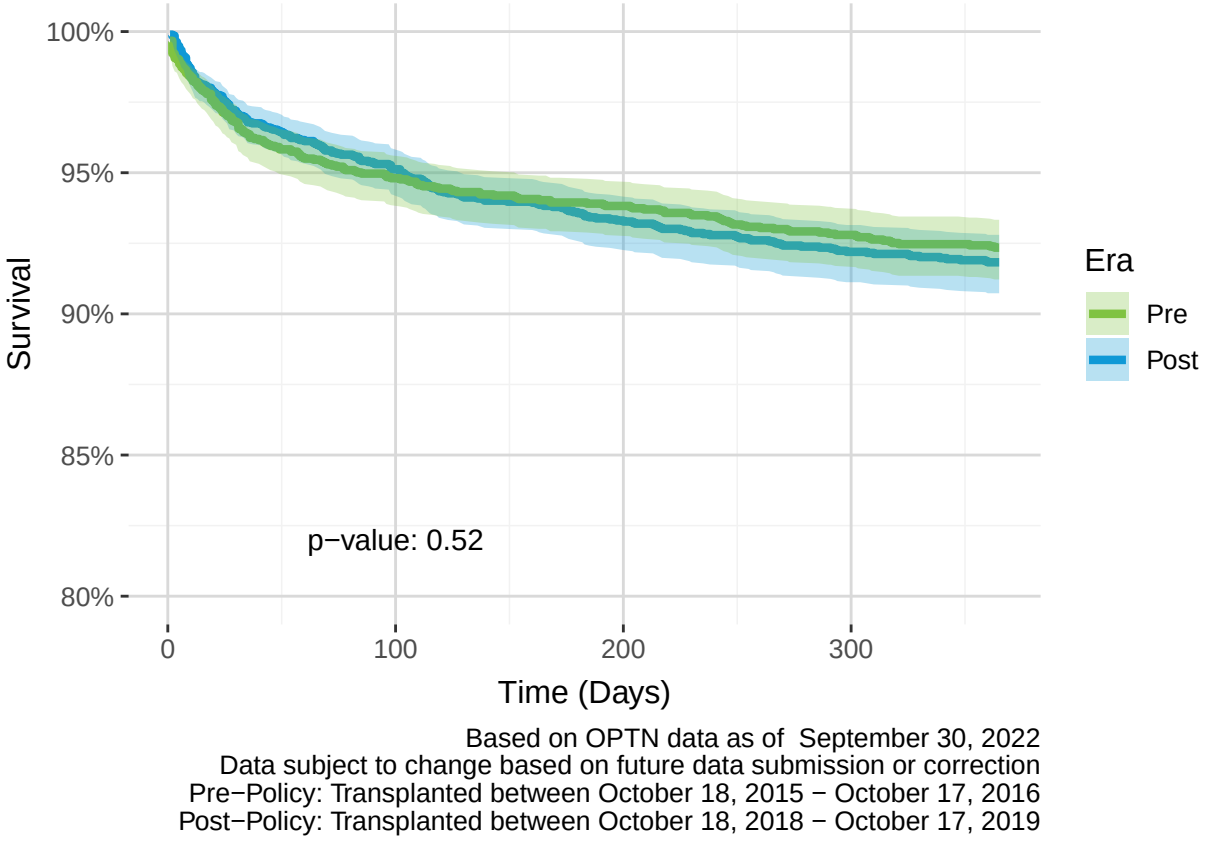


Figure 38 shows the one-year patient survival for adult heart recipients pre- and post-implementation. There was no significant difference in patient survival between the two eras ($p = 0.52$). One-year patient survival in the pre era was 92.35% compared to 91.83% in the post era.

Figure 39. Two-Year Patient Survival

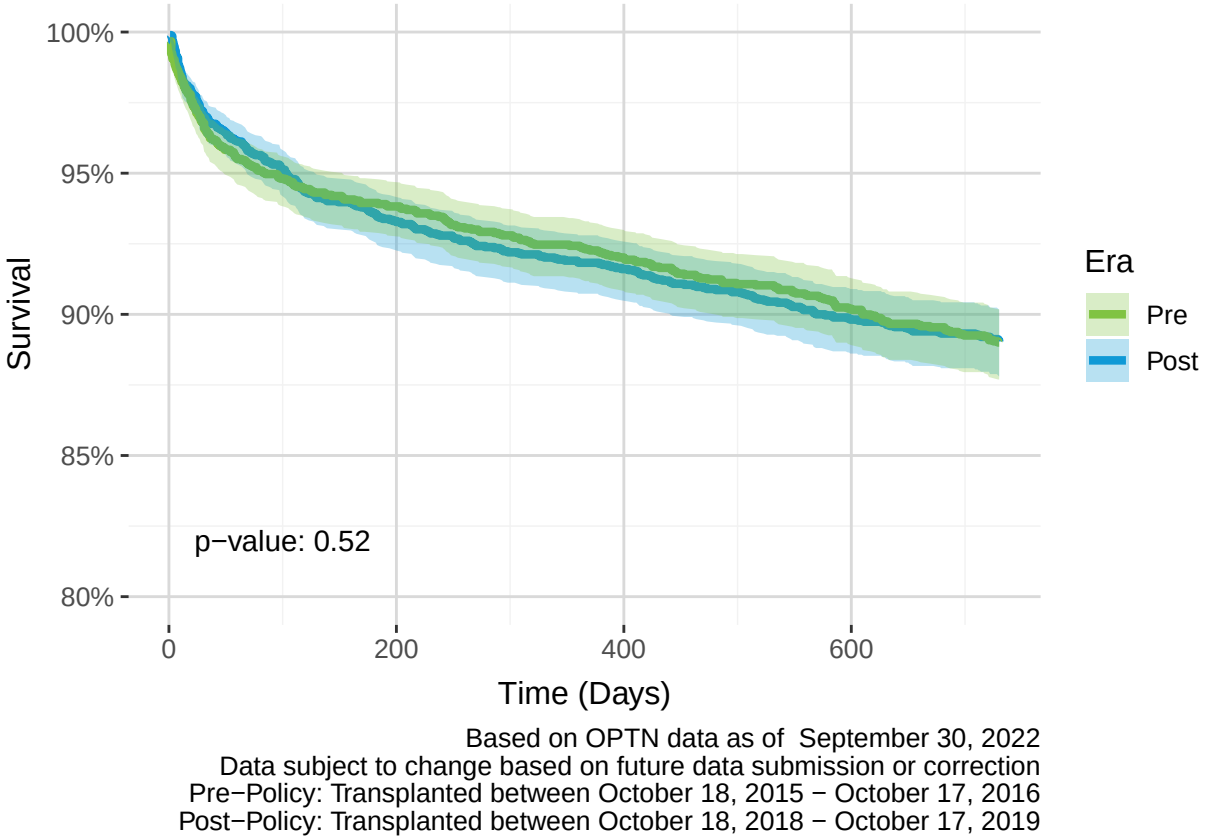
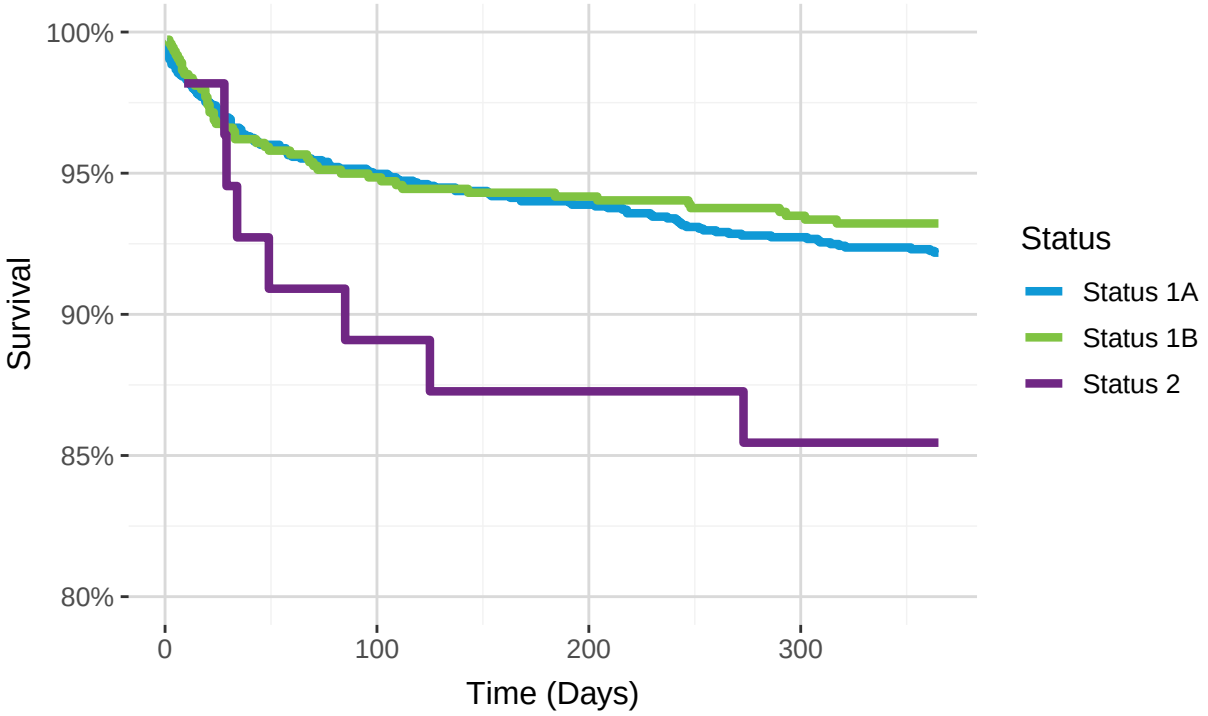


Figure 39 shows the two-year patient survival for adult heart recipients pre- and post-implementation. As with one-year patient survival, there was no significant difference in two-year patient survival between the two eras ($p = 0.52$). Two-year patient survival in the pre era was 89% compared to 89.04% in the post era.

Figures 40 and 41 show the one-year patient survival for different medical urgency statuses pre- and post-implementation. Status 1B had the best one year survival, followed by Status 1A. Status 2 had the worst one year survival. Pre-implementation there were 55 Status 2 recipients of which 8 died before one year compared to the 129 out of 1654 and 50 out of 738 recipients in Adult Statuses 1A and 1B, respectively, who died before one year.

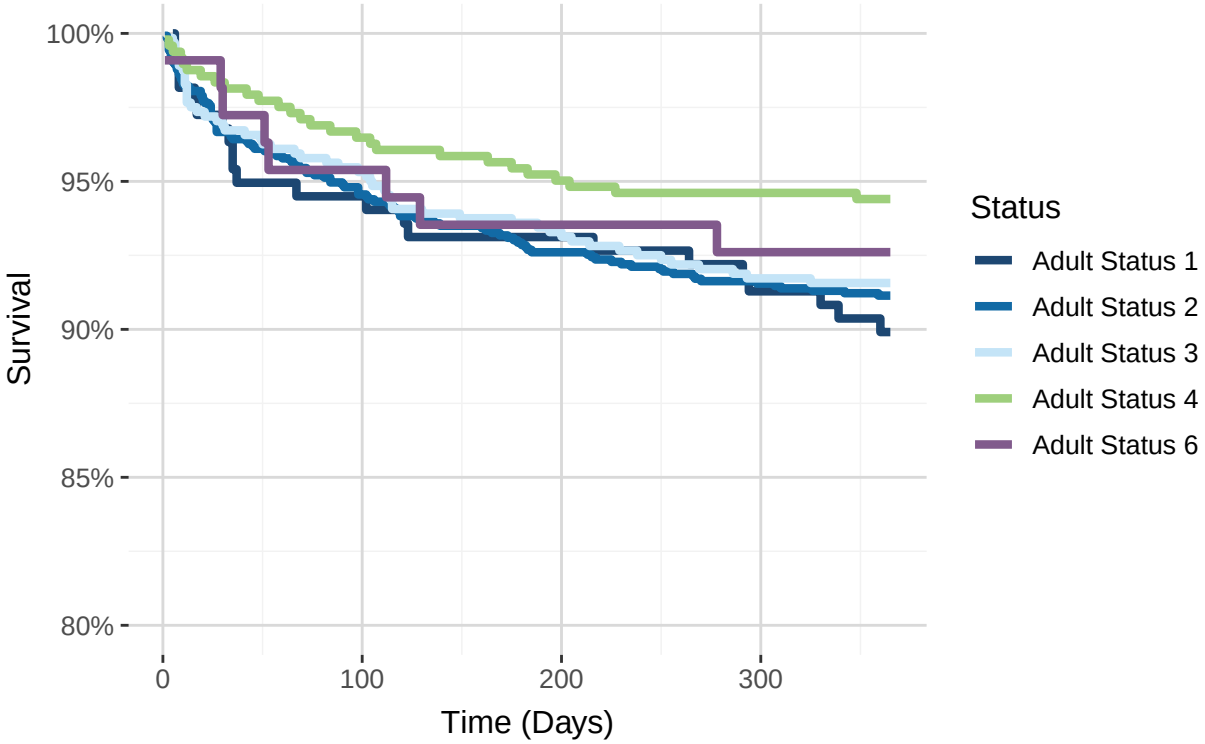
Post-implementation Adult Status 1 had the worst one-year patient survival and Adult Status 4 had the best one-year patient survival. There were 219 Adult Status 1 recipients of which 22 died before one year compared to the 27 out of 484 Adult Status 4 recipients who died before one year. Adult Status 4 had lower one-year survival than Adult Status 1, but higher one-year survival than Adult Statuses 2, 3, and 6. Adult statuses 2 and 3 had similar patient survival rates at one year; these rates fell between those for Adult Status 6 and Adult Status 1. Adult Status 5 was omitted from this plot because there were 0 recipients during the one-year survival post-implementation period.

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



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre−Policy: Transplanted between October 18, 2015 − October 17, 2016
Post−Policy: Transplanted between October 18, 2018 − October 17, 2019

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

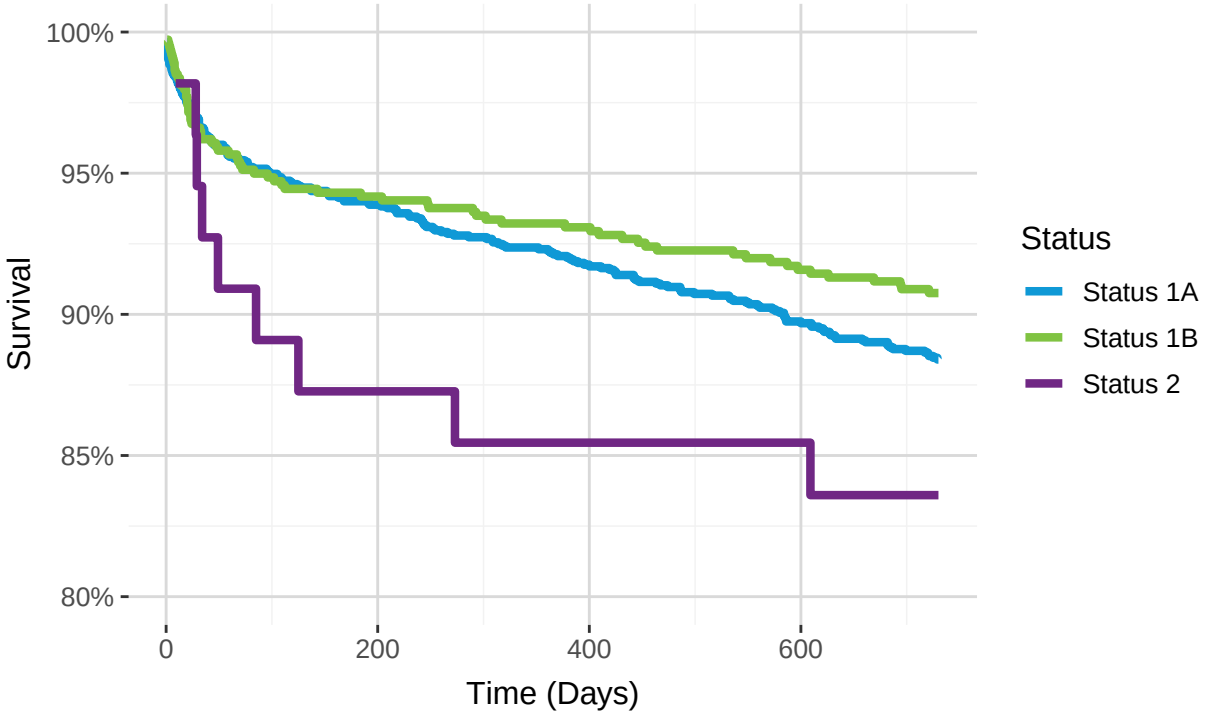


Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Adult Status 5 is omitted because there were too few adult heart recipients to accurately estimate survival

Figures 42 and 43 show the two-year patient survival for different medical urgency statuses pre- and post-implementation. As with one-year patient survival, Status 1B had the best two year survival, followed by Status 1A. Status 2 had the worst two year survival. Pre-implementation there were 55 Status 2 recipients of which 9 died before two years compared to the 191 out of 1654 and 68 out of 738 recipients in Adult Statuses 1A and 1B, respectively, who died before two years.

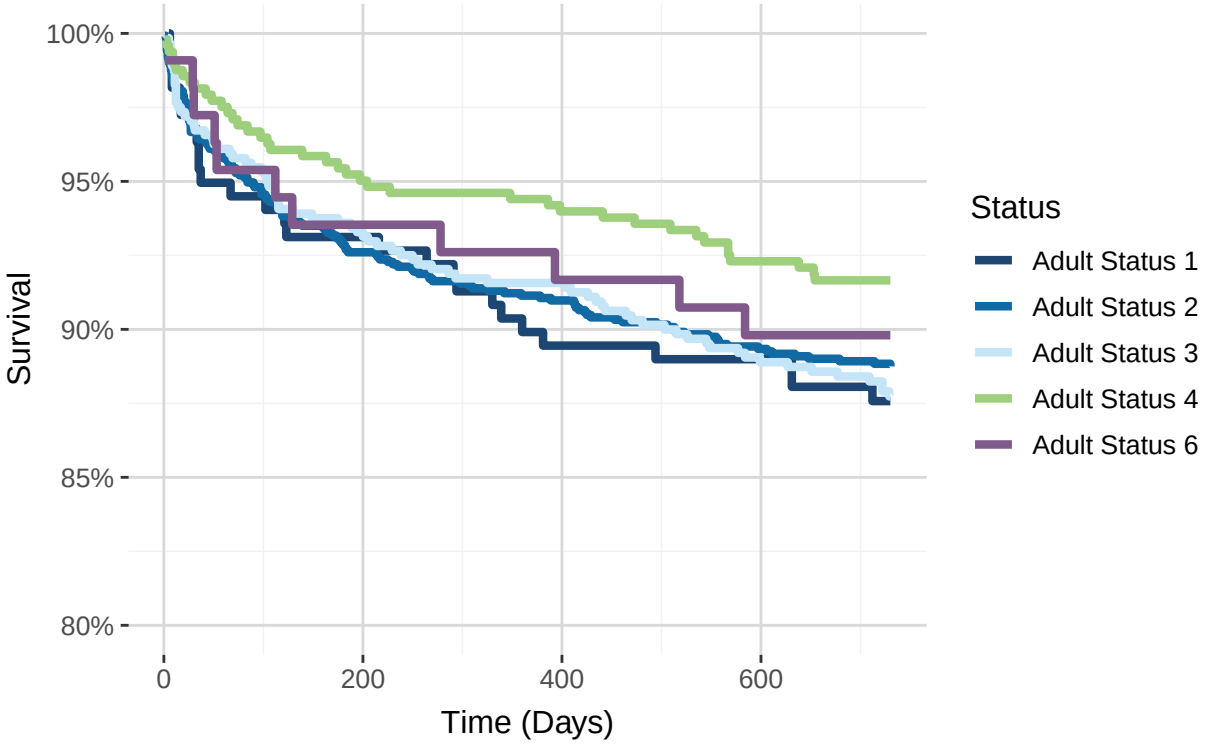
Post-implementation Adult Status 1 had the worst two-year patient survival and Adult Status 4 had the best two-year patient survival. There were 219 Adult Status 1 recipients of which 27 died before two years compared to the 40 out of 484 Adult Status 4 recipients who died before two years. Adult Status 4 had lower one-year survival than Adult Status 1, but higher one-year survival than Adult Statuses 2, 3, and 6. Adult statuses 2 and 3 had similar patient survival rates at two years; these rates fell between those for Adult Status 6 and Adult Status 1. Adult Status 5 was omitted from this plot because there were 0 recipients during the two-year survival post-implementation period.

Figure 42. Two-Year Patient Survival by Medical Urgency Status Pre-Implementation



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre−Policy: Transplanted between October 18, 2015 − October 17, 2016
Post−Policy: Transplanted between October 18, 2018 − October 17, 2019

Figure 43. Two-Year Patient Survival by Medical Urgency Status Post-Implementation



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Adult Status 5 is omitted because there were too few adult heart recipients to accurately estimate survival

Figures 44 and 45 show one-year patient survival by zone, pre- and post-implementation. These analyses are unadjusted and therefore do not account for medical urgency or other candidate or donor factors that could impact outcomes. Pre-implementation Zone B had the lowest one-year patient survival while Zone A had the lowest patient survival post-implementation.

Figure 44. One-Year Patient Survival by Zone Pre-Implementation

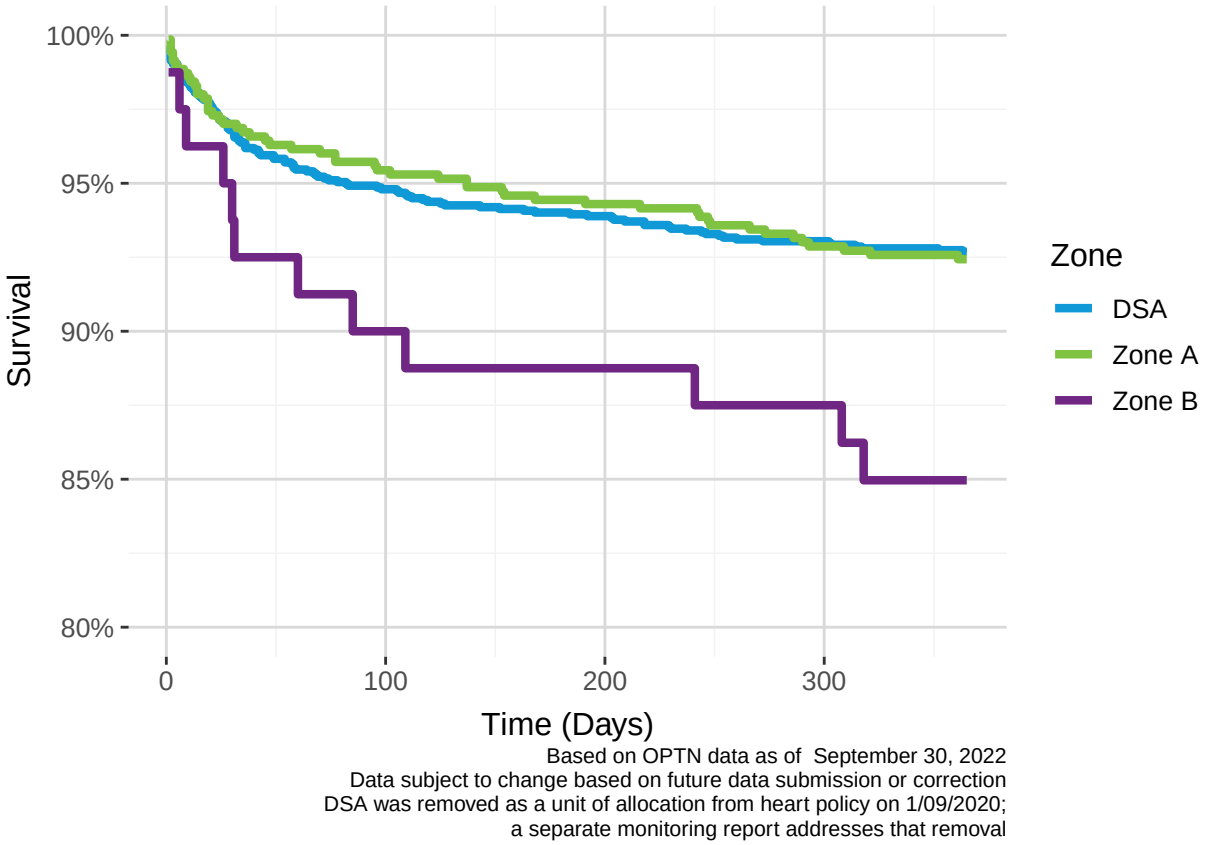
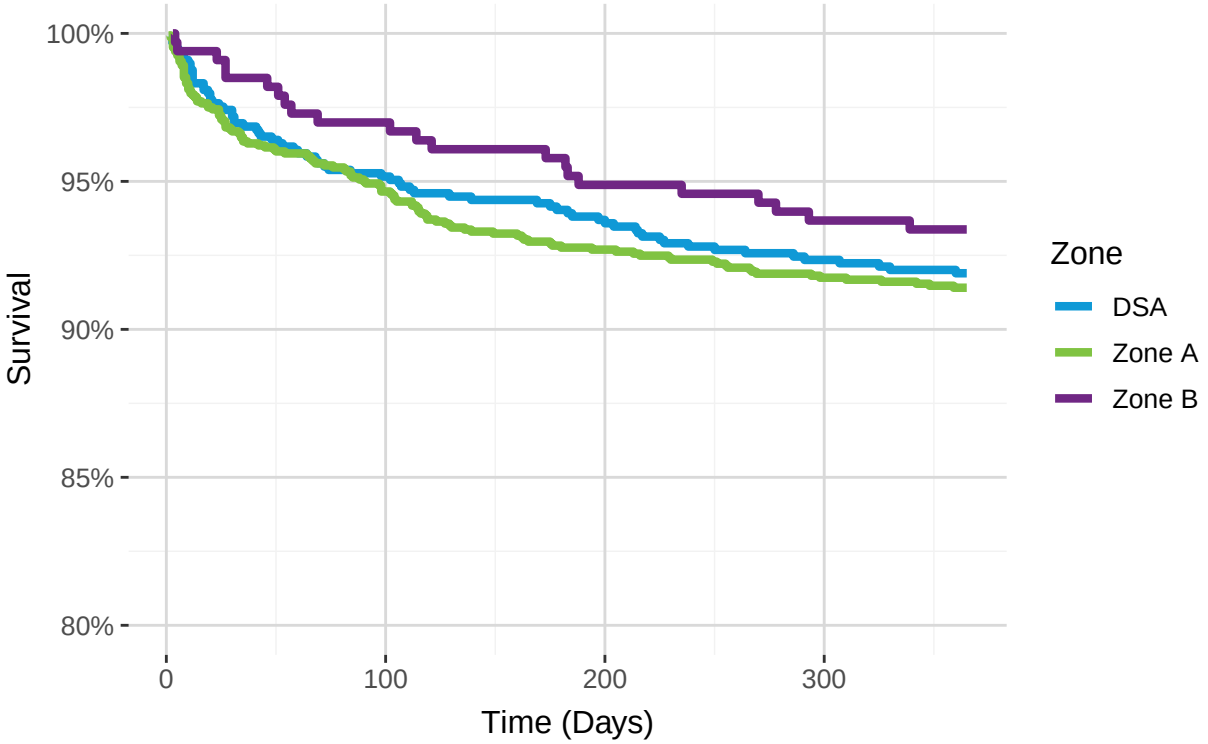


Figure 45. One-Year Patient Survival by Zone Post-Implementation



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
DSA was removed as a unit of allocation from heart policy on 1/09/2020;
a separate monitoring report addresses that removal

Figures 46 and 47 show two-year patient survival by zone, pre- and post-implementation. These analyses are unadjusted and therefore do not account for medical urgency or other candidate or donor factors that could impact outcomes. Zone B had the lowest two-year patient survival pre-implementation, while DSA and Zone A had the lowest two-year patient survival post-implementation.

Figure 46. Two-Year Patient Survival by Zone Pre-Implementation

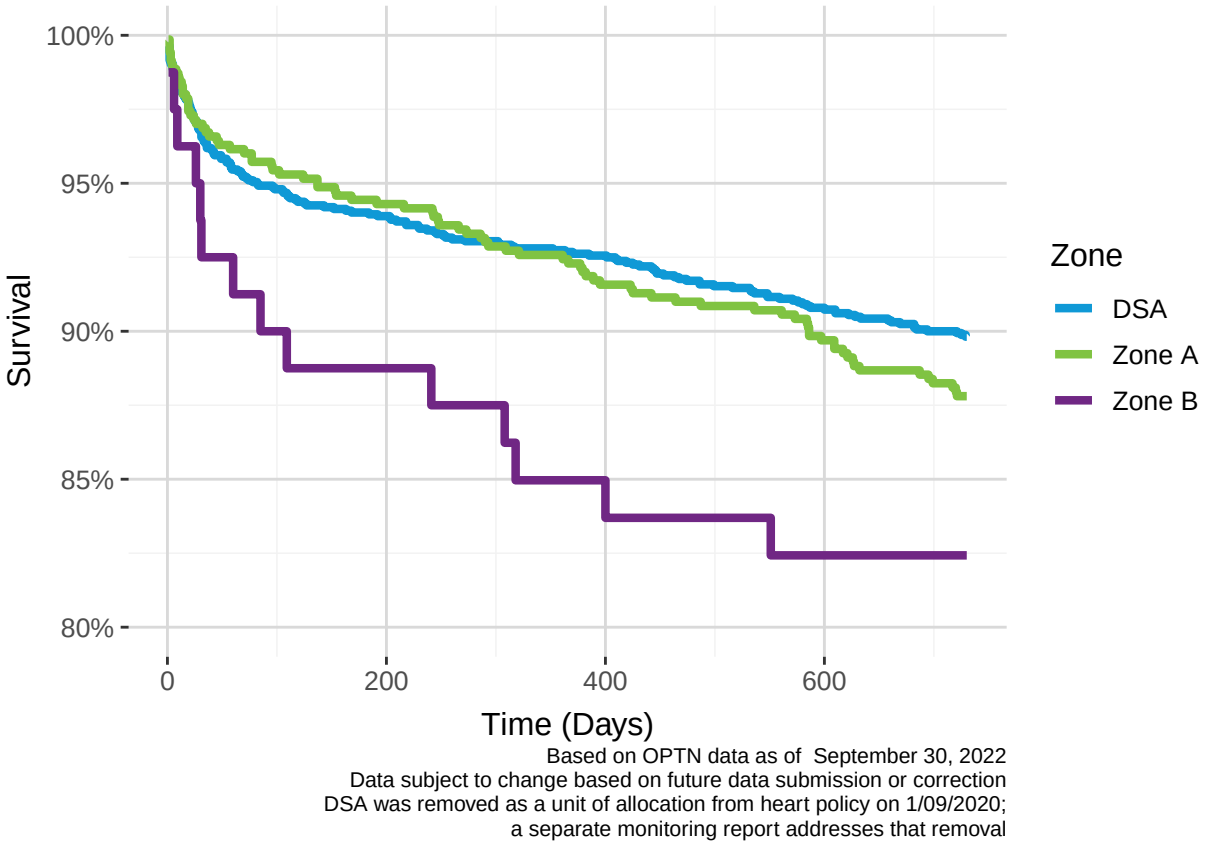
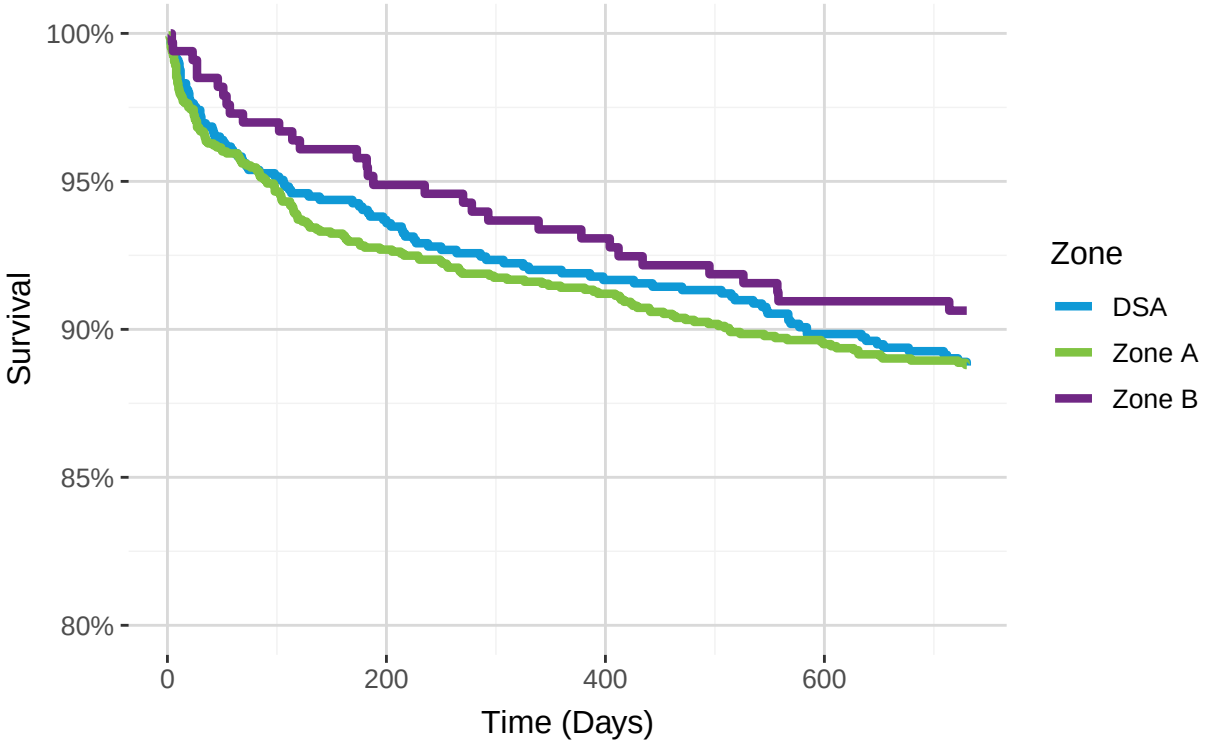


Figure 47. Two-Year Patient Survival by Zone Post-Implementation



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
DSA was removed as a unit of allocation from heart policy on 1/09/2020;
a separate monitoring report addresses that removal

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 September 30, 2021 when the most recent RRB rolled off before the end of the post-implementation period. 12397 adult heart justification forms were submitted to the Heart Regional Review Board during this time. Note that the guidance to clarify supporting information for exception requests was implemented on March 4, 2021.

Figure 48 summarizes the number of distinct justification forms by adult heart medical urgency status and the month the form was submitted. The form status is the status for which the candidate was applying. Adult heart candidates can apply for multiple exceptions/extensions during their time on the waiting list, so this does not represent the number of candidates that applied for exception/extension requests.

Figure 48. Number of distinct justification forms by medical urgency status and month form was submitted

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Justification forms submitted between September 18, 2018 − September 30, 2021
Due to the time period examined, September 2018 is not a complete month
Guidance was implemented on March 4, 2021, as indicated by the red reference line.

Table 22 summarizes the number and percent of distinct justification forms submitted by medical urgency status and month of submission. Overall, Adult Status 2 represented the largest number of forms submitted, followed by Adult Status 3; Adult Status 1 had the lowest number of justification forms submitted. Similar patterns were seen in both the pre- and post-guidance periods.

Table 22. Number of distinct justification forms by medical urgency status and month form was submitted

Guidance Period	Form Submission	Adult Status 1	Adult Status 2	Adult Status 3	Adult Status 4	Total
Pre-guidance	2018-Sep	0 (0.0%)	0 (0.0%)	2 (11.8%)	15 (88.2%)	17 (100.0%)
	2018-Oct	13 (3.8%)	58 (17.1%)	110 (32.4%)	158 (46.6%)	339 (100.0%)
	2018-Nov	7 (2.8%)	92 (36.8%)	115 (46.0%)	36 (14.4%)	250 (100.0%)
	2018-Dec	13 (5.6%)	76 (32.6%)	99 (42.5%)	45 (19.3%)	233 (100.0%)
	2019-Jan	12 (3.8%)	86 (27.3%)	97 (30.8%)	120 (38.1%)	315 (100.0%)
	2019-Feb	14 (5.4%)	101 (39.0%)	92 (35.5%)	52 (20.1%)	259 (100.0%)
	2019-Mar	16 (5.3%)	121 (40.1%)	106 (35.1%)	59 (19.5%)	302 (100.0%)
	2019-Apr	21 (6.5%)	116 (36.0%)	98 (30.4%)	87 (27.0%)	322 (100.0%)
	2019-May	14 (4.0%)	140 (39.9%)	124 (35.3%)	73 (20.8%)	351 (100.0%)
	2019-Jun	16 (5.1%)	130 (41.7%)	94 (30.1%)	72 (23.1%)	312 (100.0%)
	2019-Jul	28 (8.1%)	136 (39.2%)	117 (33.7%)	66 (19.0%)	347 (100.0%)
	2019-Aug	21 (5.9%)	127 (35.5%)	130 (36.3%)	80 (22.3%)	358 (100.0%)
	2019-Sep	28 (8.9%)	130 (41.3%)	91 (28.9%)	66 (21.0%)	315 (100.0%)
	2019-Oct	40 (10.1%)	167 (42.0%)	108 (27.1%)	83 (20.9%)	398 (100.0%)
	2019-Nov	25 (6.8%)	171 (46.5%)	116 (31.5%)	56 (15.2%)	368 (100.0%)
	2019-Dec	17 (4.8%)	156 (44.4%)	102 (29.1%)	76 (21.7%)	351 (100.0%)
	2020-Jan	14 (4.1%)	151 (43.8%)	102 (29.6%)	78 (22.6%)	345 (100.0%)
	2020-Feb	12 (3.9%)	146 (47.4%)	97 (31.5%)	53 (17.2%)	308 (100.0%)
	2020-Mar	9 (2.8%)	147 (45.7%)	96 (29.8%)	70 (21.7%)	322 (100.0%)
	2020-Apr	14 (5.4%)	96 (37.2%)	64 (24.8%)	84 (32.6%)	258 (100.0%)
	2020-May	19 (7.3%)	109 (41.8%)	79 (30.3%)	54 (20.7%)	261 (100.0%)
	2020-Jun	21 (6.7%)	132 (42.0%)	83 (26.4%)	78 (24.8%)	314 (100.0%)
	2020-Jul	32 (10.2%)	124 (39.5%)	76 (24.2%)	82 (26.1%)	314 (100.0%)
	2020-Aug	12 (3.9%)	128 (41.2%)	92 (29.6%)	79 (25.4%)	311 (100.0%)
	2020-Sep	12 (3.7%)	141 (43.0%)	109 (33.2%)	66 (20.1%)	328 (100.0%)
	2020-Oct	18 (4.5%)	170 (42.9%)	119 (30.1%)	89 (22.5%)	396 (100.0%)
	2020-Nov	14 (4.5%)	127 (40.7%)	103 (33.0%)	68 (21.8%)	312 (100.0%)
	2020-Dec	14 (3.8%)	169 (46.3%)	92 (25.2%)	90 (24.7%)	365 (100.0%)
	2021-Jan	16 (4.8%)	147 (44.4%)	86 (26.0%)	82 (24.8%)	331 (100.0%)
	2021-Feb	26 (7.2%)	184 (51.3%)	84 (23.4%)	65 (18.1%)	359 (100.0%)
	2021-Mar	9 (19.1%)	15 (31.9%)	15 (31.9%)	8 (17.0%)	47 (100.0%)
	Total	**527 (5.6%)**	**3793 (40.3%)**	**2898 (30.8%)**	**2190 (23.3%)**	**9408 (100.0%)**
Post-guidance	2021-Mar	39 (9.4%)	199 (48.1%)	97 (23.4%)	79 (19.1%)	414 (100.0%)
	2021-Apr	23 (5.4%)	236 (55.0%)	115 (26.8%)	55 (12.8%)	429 (100.0%)
	2021-May	21 (4.7%)	262 (58.5%)	103 (23.0%)	62 (13.8%)	448 (100.0%)
	2021-Jun	18 (4.1%)	251 (56.8%)	105 (23.8%)	68 (15.4%)	442 (100.0%)
	2021-Jul	38 (8.8%)	232 (54.0%)	99 (23.0%)	61 (14.2%)	430 (100.0%)
	2021-Aug	33 (8.0%)	234 (56.8%)	78 (18.9%)	67 (16.3%)	412 (100.0%)
	2021-Sep	34 (8.2%)	244 (58.9%)	80 (19.3%)	56 (13.5%)	414 (100.0%)
	Total	**206 (6.9%)**	**1658 (55.5%)**	**677 (22.6%)**	**448 (15.0%)**	**2989 (100.0%)**
Overall	**Total**	**733 (5.9%)**	**5451 (44.0%)**	**3575 (28.8%)**	**2638 (21.3%)**	**12397 (100.0%)**

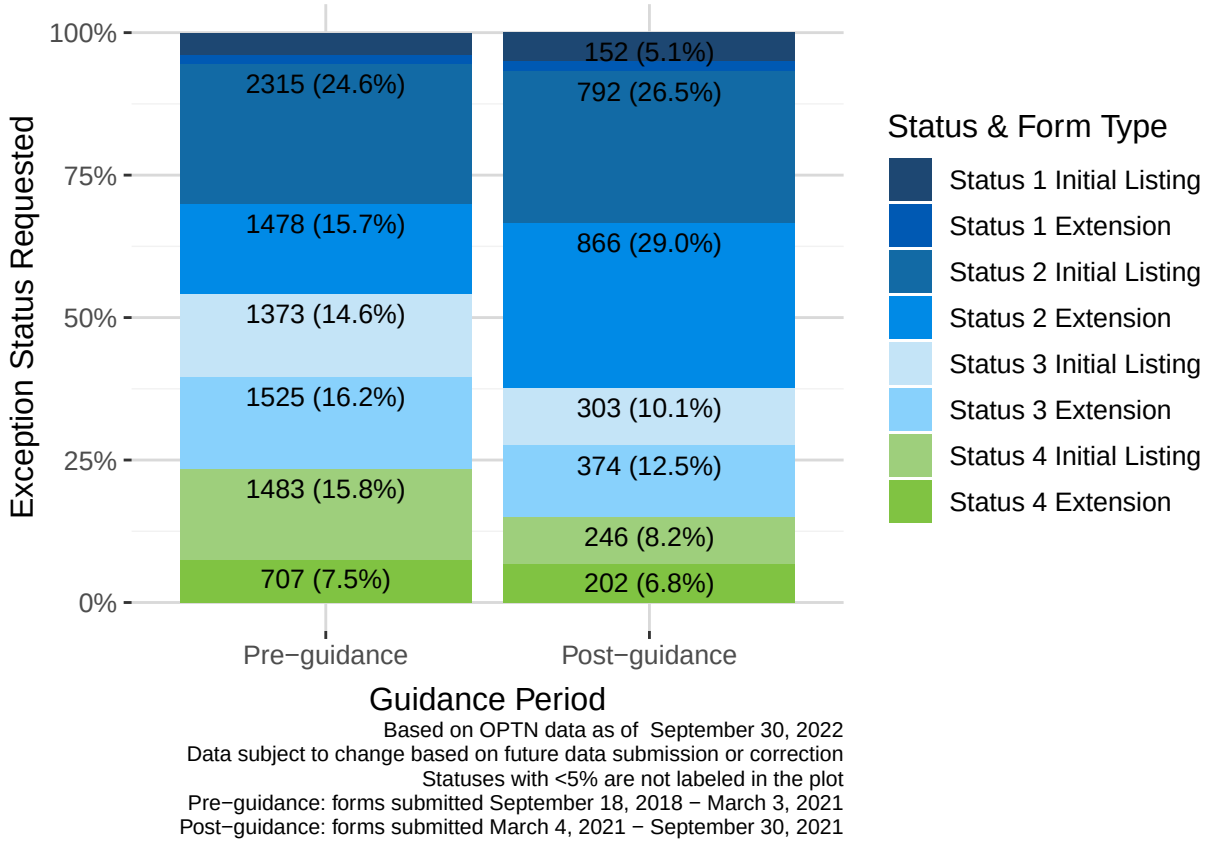
Due to the time period examined, September 2018 is not a complete month

March 2021 appears as an incomplete month in both periods due to the timing of guidance implementation

Figure 49 and Table 23 summarize the number of initial and extension justification forms that needed to be reviewed by the RRB by medical urgency status and whether the requests were submitted before or after the guidance was implemented. As the name implies, the initial request is the first request for a candidate for a particular status under a specific medical condition. If the medical condition of the candidate remains the same, when the initial request expires the candidate may request an extension.

The number of initial forms submitted was usually higher than the number of extension forms submitted for each medical urgency status, except for Adult Status 3 pre-guidance and Adult Statuses 2 and 3 post-guidance. In fact, the number of initial and extension forms submitted for Adult Status 2 increased post-guidance. Conversely, the number of initial and extension forms submitted for Statuses 3 and 4 decreased post-guidance. Adult Status 2 was the most commonly requested initial listing status in both guidance periods. Adult Status 3 was the most common exception request pre-guidance, whereas Adult Status 2 was the most common exception request post-guidance.

Figure 49. Number of justification forms by medical urgency status, form type, and guidance period



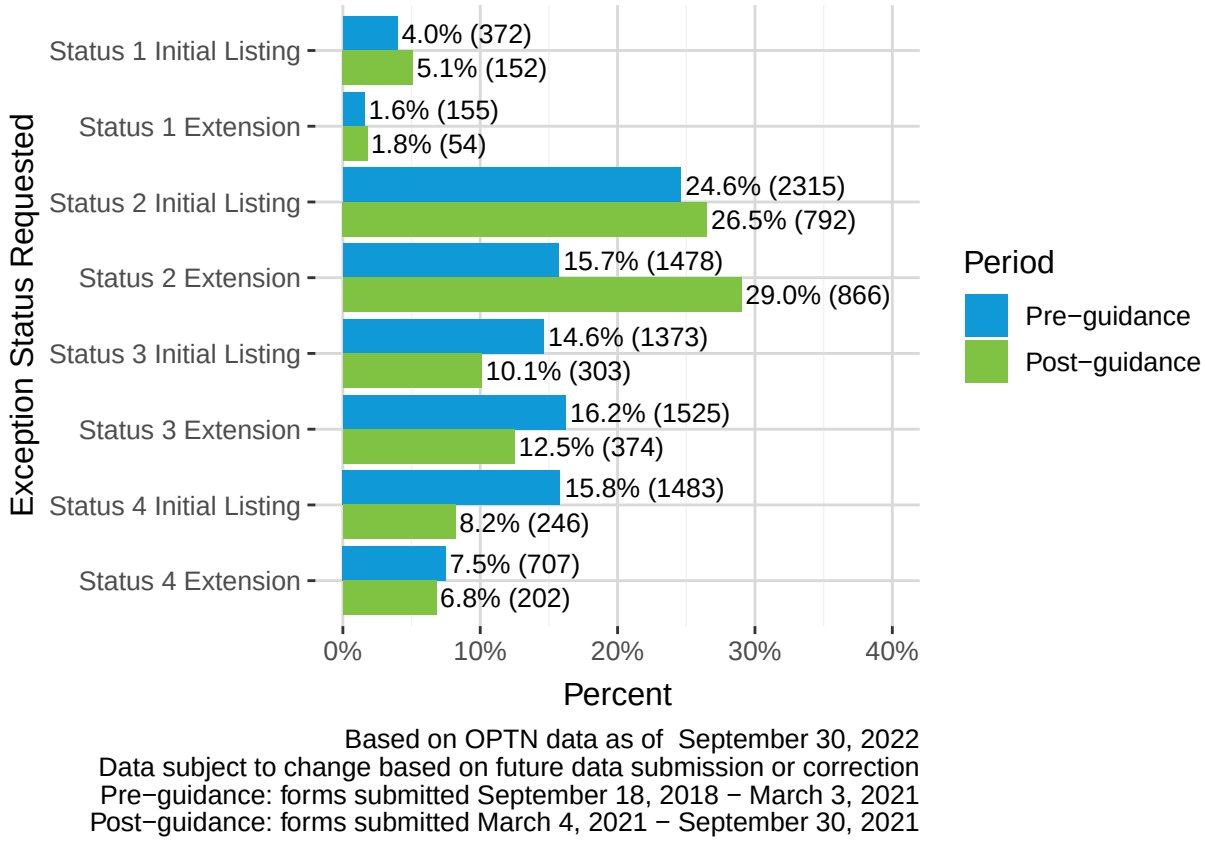


Table 23. Number of justification forms by medical urgency status, form type, and guidance period

	Number of Justification Forms					
	Pre-guidance		Post-guidance		Overall	
Adult Heart Status and Form Type	**N**	**%**	**N**	**%**	**N**	**%**
Status 1 Initial Listing	372	4.0%	152	5.1%	524	4.2%
Status 1 Extension	155	1.6%	54	1.8%	209	1.7%
Status 2 Initial Listing	2315	24.6%	792	26.5%	3107	25.1%
Status 2 Extension	1478	15.7%	866	29.0%	2344	18.9%
Status 3 Initial Listing	1373	14.6%	303	10.1%	1676	13.5%
Status 3 Extension	1525	16.2%	374	12.5%	1899	15.3%
Status 4 Initial Listing	1483	15.8%	246	8.2%	1729	13.9%
Status 4 Extension	707	7.5%	202	6.8%	909	7.3%
Total	**9408**	**100.0%**	**2989**	**100.0%**	**12397**	**100.0%**

Based on OPTN data as of September 30, 2022

Data subject to change based on future data submission or correction

Pre-guidance: justification forms submitted between September 18, 2018 - March 3, 2021

Post-guidance: justification forms submitted between March 4, 2021 - September 30, 2021

Under the new adult heart allocation system some "standard" justification forms are required by policy to be reviewed by the RRB. Figure 51 and Table 24 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 and whether the requests were submitted before or after the guidance was implemented. 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). A smaller proportion of Status 1 Standard, Status 3 Exception, and Status 4 Exception forms were submitted post-guidance compared to pre-guidance (Figure 52 and Table 25). Conversely, a larger proportion of Status 2 Standard and Status 2 Exception forms were submitted post-guidance (Figure 52 and Table 25).

Figure 51. Number of justification forms by exception versus standard review and heart status

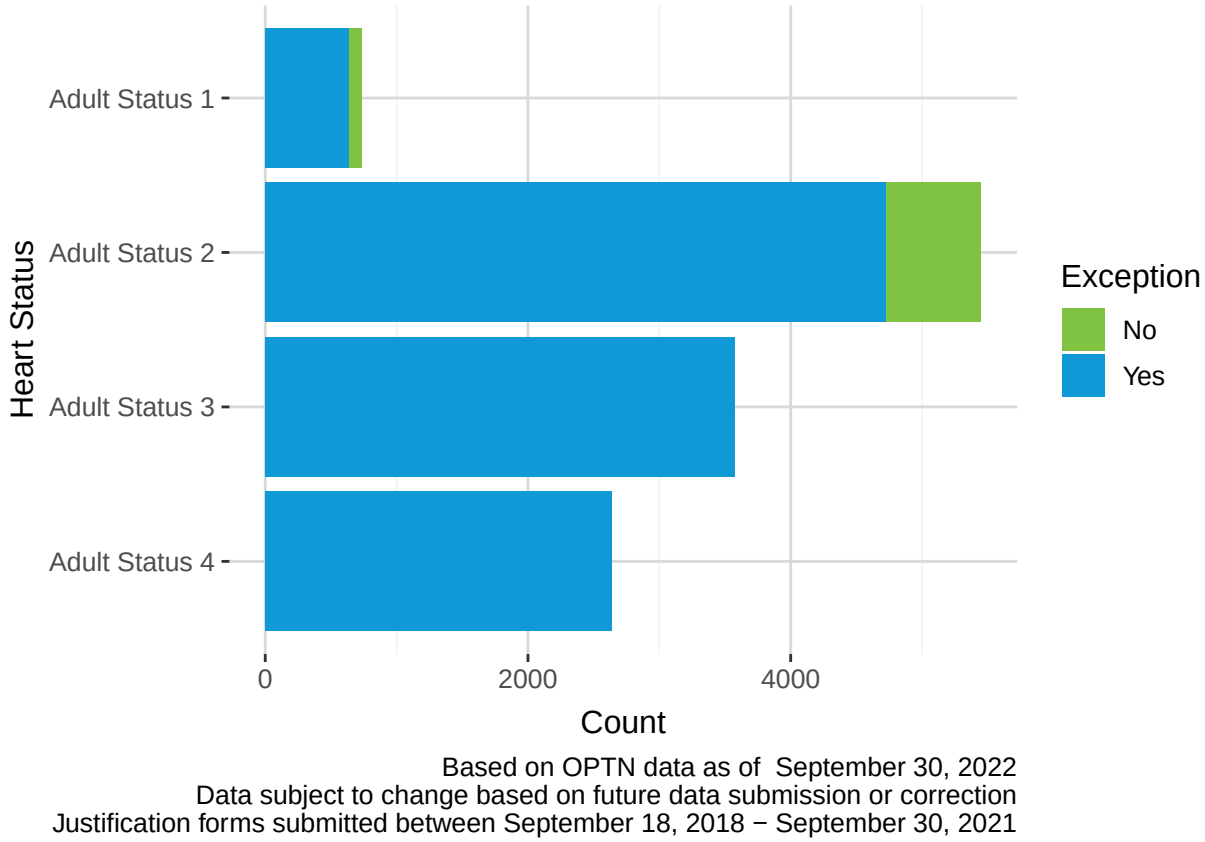
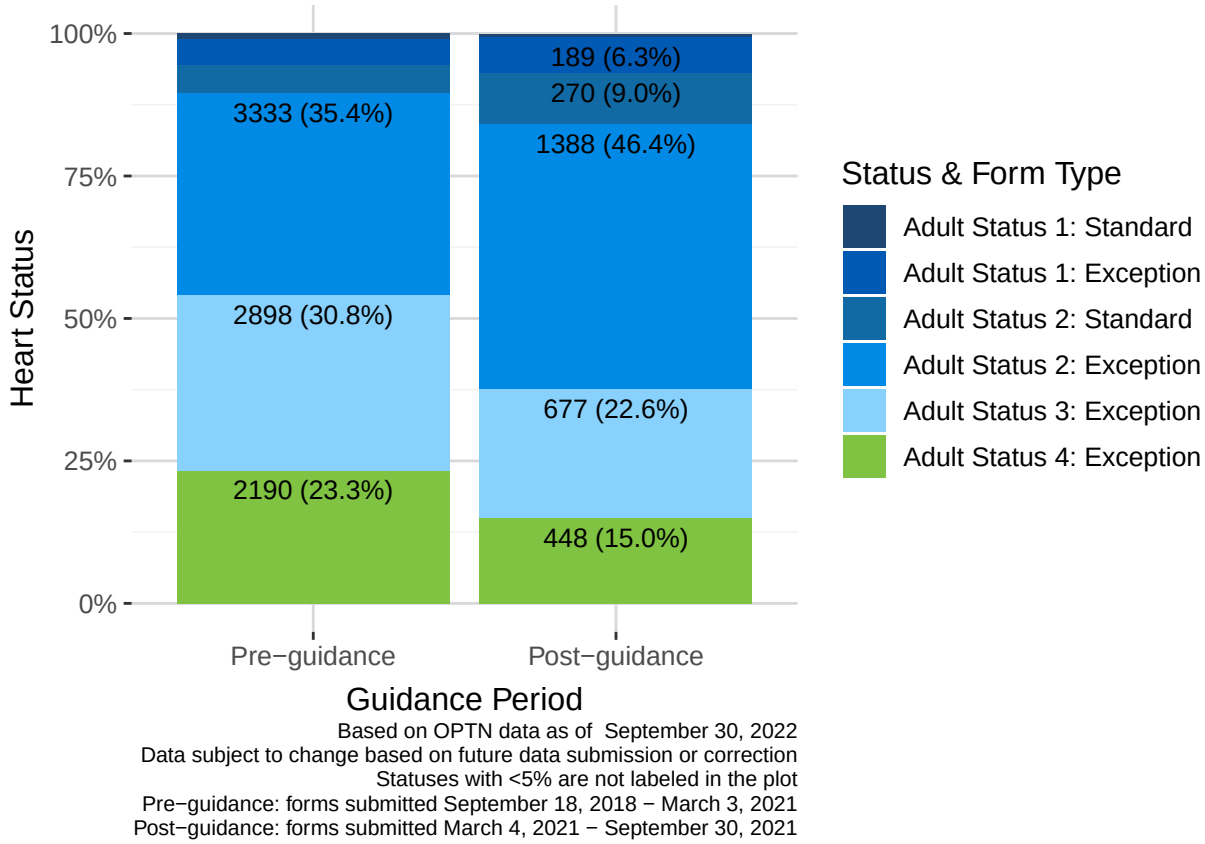


Figure 52. Number of justification forms by exception versus standard review, heart status, and guidance period



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Statuses with <5% are not labeled in the plot
Pre−guidance: forms submitted September 18, 2018 − March 3, 2021
Post−guidance: forms submitted March 4, 2021 − September 30, 2021

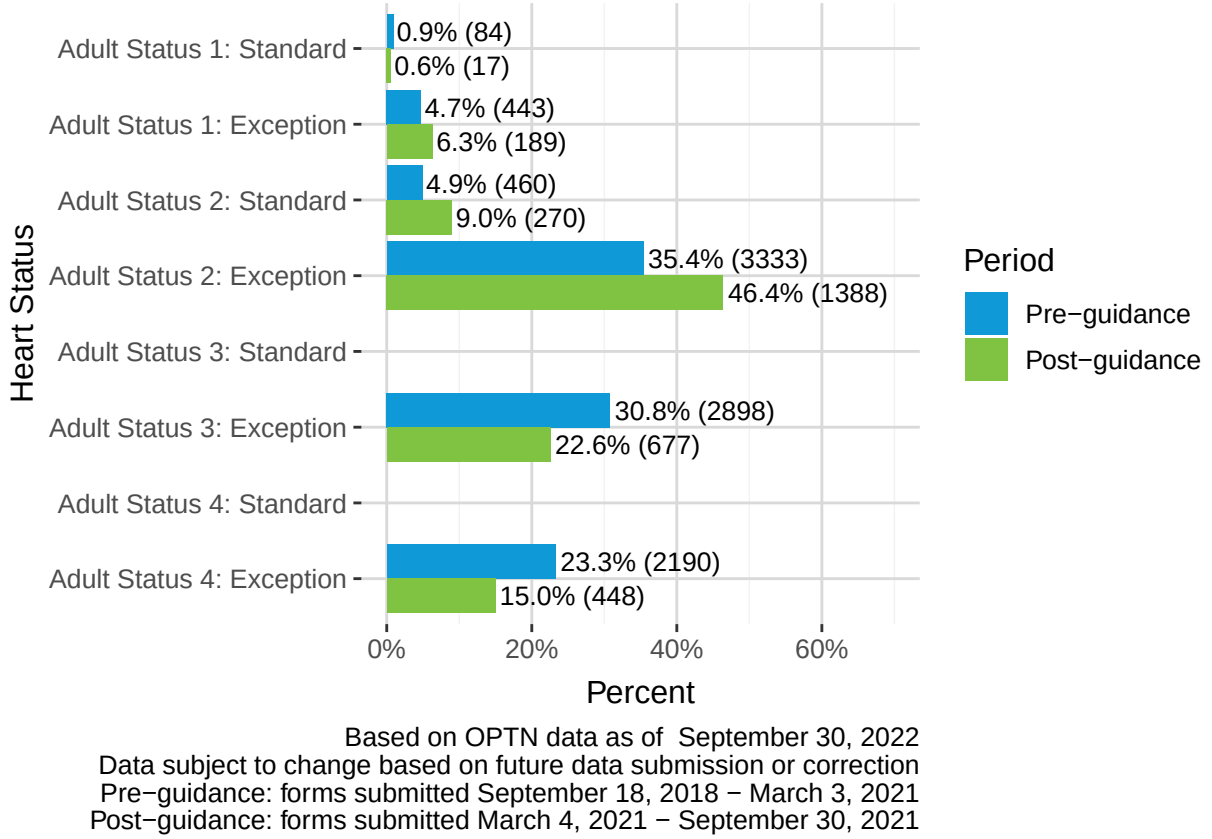


Table 24. Number of justification forms by exception versus standard review and medical urgency status

	Exception Request		
Adult Heart Status	**No**	**Yes**	**Total**
Adult Status 1	101 (13.8%)	632 (86.2%)	733 (100.0%)
Adult Status 2	730 (13.4%)	4721 (86.6%)	5451 (100.0%)
Adult Status 3	0 (0.0%)	3575 (100.0%)	3575 (100.0%)
Adult Status 4	0 (0.0%)	2638 (100.0%)	2638 (100.0%)
Total	**831 (6.7%)**	**11566 (93.3%)**	**12397 (100.0%)**

Based on OPTN data as of September 30, 2022

Data subject to change based on future data submission or correction

Justification forms submitted September 18, 2018 - September 30, 2021

Table 25. Number of justification forms by exception versus standard review, medical urgency status, and guidance period

		Exception Request		
Guidance Period	**Adult Heart Status**	**No**	**Yes**	**Total**
Pre-guidance	Adult Status 1	84 (15.9%)	443 (84.1%)	527 (100.0%)
	Adult Status 2	460 (12.1%)	3333 (87.9%)	3793 (100.0%)
	Adult Status 3	0 (0.0%)	2898 (100.0%)	2898 (100.0%)
	Adult Status 4	0 (0.0%)	2190 (100.0%)	2190 (100.0%)
	Total	**544 (5.8%)**	**8864 (94.2%)**	**9408 (100.0%)**
Post-guidance	Adult Status 1	17 (8.3%)	189 (91.7%)	206 (100.0%)
	Adult Status 2	270 (16.3%)	1388 (83.7%)	1658 (100.0%)
	Adult Status 3	0 (0.0%)	677 (100.0%)	677 (100.0%)
	Adult Status 4	0 (0.0%)	448 (100.0%)	448 (100.0%)
	Total	**287 (9.6%)**	**2702 (90.4%)**	**2989 (100.0%)**
Overall	Adult Status 1	101 (13.8%)	632 (86.2%)	733 (100.0%)
	Adult Status 2	730 (13.4%)	4721 (86.6%)	5451 (100.0%)
	Adult Status 3	0 (0.0%)	3575 (100.0%)	3575 (100.0%)
	Adult Status 4	0 (0.0%)	2638 (100.0%)	2638 (100.0%)
	Total	**831 (6.7%)**	**11566 (93.3%)**	**12397 (100.0%)**

Based on OPTN data as of September 30, 2022

Data subject to change based on future data submission or correction

Pre-guidance: forms submitted September 18, 2018 - March 3, 2021

Post-guidance: forms submitted March 4, 2021 - September 30, 2021

Figure 54 and Table 26 summarize form submission by the candidate's transplant center's OPTN region. Overall, a majority of the OPTN regions submitted over 500 forms that needed RRB approval (Regions 2, 3, 4, 5, 7, 9, 10, and 11). OPTN region 6 submitted the fewest forms and Region 3 submitted the most. Similar patterns were seen in the pre- and post-guidance periods, although the number of forms submitted was smaller in the post-guidance period due to its shorter duration. (Figure 55 Table 27).

Figure 54. Number of justification forms by medical urgency status and OPTN region of candidate's transplant center

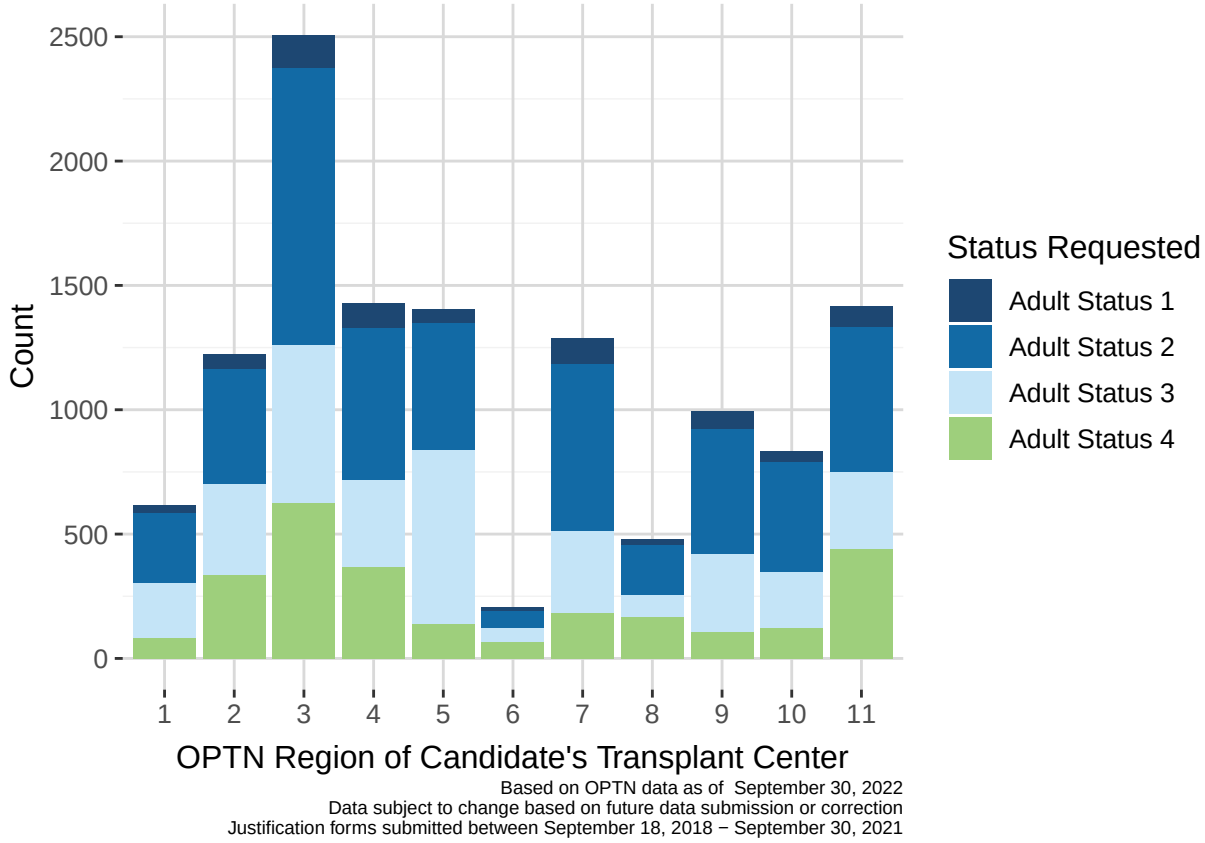


Table 26. Number of initial and extension justification forms by medical urgency status and OPTN region of candidate's transplant center

Adult Heart Status and Form Type	1	2	3	4	5	6	7	8	9	10	11	Total
Status 1 Initial Listing	28	42	103	73	42	14	42	21	52	39	68	524
Status 1 Extension	6	20	32	30	15	4	65	0	19	3	15	209
Status 2 Initial Listing	177	237	607	370	290	39	317	155	289	242	384	3107
Status 2 Extension	105	226	507	241	217	27	355	49	215	200	202	2344
Status 3 Initial Listing	85	151	261	201	312	41	130	59	144	114	178	1676
Status 3 Extension	135	212	371	147	387	15	198	26	168	111	129	1899
Status 4 Initial Listing	49	227	370	287	97	55	104	115	68	76	281	1729
Status 4 Extension	32	110	256	81	42	12	78	53	39	46	160	909
Total	**617**	**1225**	**2507**	**1430**	**1402**	**207**	**1289**	**478**	**994**	**831**	**1417**	**12397**

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Justification forms submitted September 18, 2018 - September 30, 2021

Figure 55. Number of justification forms by medical urgency status, OPTN region of candidate's transplant center, and guidance period

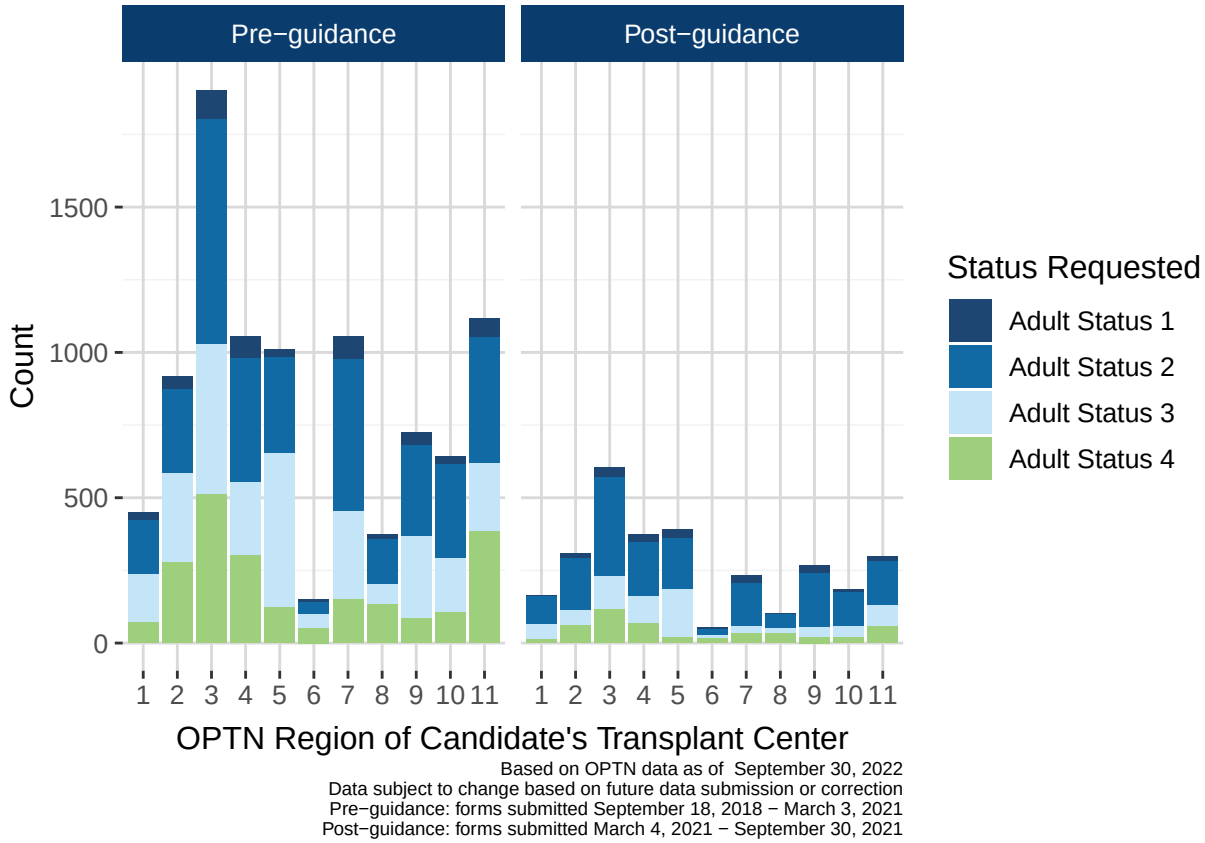


Table 27. Number of initial and extension justification forms by medical urgency status, OPTN region of candidate's transplant center, and guidance period

Guidance Period	Adult Heart Status and Form Type	1	2	3	4	5	6	7	8	9	10	11	Total
Pre-guidance	Status 1 Initial Listing	22 (5.9%)	31 (8.3%)	73 (19.6%)	52 (14.0%)	24 (6.5%)	9 (2.4%)	25 (6.7%)	18 (4.8%)	36 (9.7%)	28 (7.5%)	54 (14.5%)	372 (100.0%)
	Status 1 Extension	6 (3.9%)	13 (8.4%)	30 (19.4%)	24 (15.5%)	4 (2.6%)	3 (1.9%)	53 (34.2%)	0 (0.0%)	8 (5.2%)	1 (0.6%)	13 (8.4%)	155 (100.0%)
	Status 2 Initial Listing	127 (5.5%)	162 (7.0%)	462 (20.0%)	267 (11.5%)	205 (8.9%)	29 (1.3%)	247 (10.7%)	122 (5.3%)	211 (9.1%)	186 (8.0%)	297 (12.8%)	2315 (100.0%)
	Status 2 Extension	58 (3.9%)	125 (8.5%)	311 (21.0%)	159 (10.8%)	125 (8.5%)	14 (0.9%)	278 (18.8%)	31 (2.1%)	104 (7.0%)	138 (9.3%)	135 (9.1%)	1478 (100.0%)
	Status 3 Initial Listing	69 (5.0%)	127 (9.2%)	224 (16.3%)	156 (11.4%)	244 (17.8%)	31 (2.3%)	113 (8.2%)	47 (3.4%)	126 (9.2%)	91 (6.6%)	145 (10.6%)	1373 (100.0%)
	Status 3 Extension	99 (6.5%)	182 (11.9%)	293 (19.2%)	97 (6.4%)	288 (18.9%)	14 (0.9%)	190 (12.5%)	22 (1.4%)	155 (10.2%)	96 (6.3%)	89 (5.8%)	1525 (100.0%)
	Status 4 Initial Listing	44 (3.0%)	194 (13.1%)	319 (21.5%)	236 (15.9%)	87 (5.9%)	45 (3.0%)	88 (5.9%)	95 (6.4%)	59 (4.0%)	63 (4.2%)	253 (17.1%)	1483 (100.0%)
	Status 4 Extension	26 (3.7%)	83 (11.7%)	192 (27.2%)	65 (9.2%)	34 (4.8%)	7 (1.0%)	61 (8.6%)	39 (5.5%)	27 (3.8%)	41 (5.8%)	132 (18.7%)	707 (100.0%)
	Total	**451 (4.8%)**	**917 (9.7%)**	**1904 (20.2%)**	**1056 (11.2%)**	**1011 (10.7%)**	**152 (1.6%)**	**1055 (11.2%)**	**374 (4.0%)**	**726 (7.7%)**	**644 (6.8%)**	**1118 (11.9%)**	**9408 (100.0%)**

Post-guidance	Status 1 Initial Listing	6 (3.9%)	11 (7.2%)	30 (19.7%)	21 (13.8%)	18 (11.8%)	5 (3.3%)	17 (11.2%)	3 (2.0%)	16 (10.5%)	11 (7.2%)	14 (9.2%)	152 (100.0%)
	Status 1 Extension	0 (0.0%)	7 (13.0%)	2 (3.7%)	6 (11.1%)	11 (20.4%)	1 (1.9%)	12 (22.2%)	0 (0.0%)	11 (20.4%)	2 (3.7%)	2 (3.7%)	54 (100.0%)
	Status 2 Initial Listing	50 (6.3%)	75 (9.5%)	145 (18.3%)	103 (13.0%)	85 (10.7%)	10 (1.3%)	70 (8.8%)	33 (4.2%)	78 (9.8%)	56 (7.1%)	87 (11.0%)	792 (100.0%)
	Status 2 Extension	47 (5.4%)	101 (11.7%)	196 (22.6%)	82 (9.5%)	92 (10.6%)	13 (1.5%)	77 (8.9%)	18 (2.1%)	111 (12.8%)	62 (7.2%)	67 (7.7%)	866 (100.0%)
	Status 3 Initial Listing	16 (5.3%)	24 (7.9%)	37 (12.2%)	45 (14.9%)	68 (22.4%)	10 (3.3%)	17 (5.6%)	12 (4.0%)	18 (5.9%)	23 (7.6%)	33 (10.9%)	303 (100.0%)
	Status 3 Extension	36 (9.6%)	30 (8.0%)	78 (20.9%)	50 (13.4%)	99 (26.5%)	1 (0.3%)	8 (2.1%)	4 (1.1%)	13 (3.5%)	15 (4.0%)	40 (10.7%)	374 (100.0%)
	Status 4 Initial Listing	5 (2.0%)	33 (13.4%)	51 (20.7%)	51 (20.7%)	10 (4.1%)	10 (4.1%)	16 (6.5%)	20 (8.1%)	9 (3.7%)	13 (5.3%)	28 (11.4%)	246 (100.0%)
	Status 4 Extension	6 (3.0%)	27 (13.4%)	64 (31.7%)	16 (7.9%)	8 (4.0%)	5 (2.5%)	17 (8.4%)	14 (6.9%)	12 (5.9%)	5 (2.5%)	28 (13.9%)	202 (100.0%)
	Total	**166 (5.6%)**	**308 (10.3%)**	**603 (20.2%)**	**374 (12.5%)**	**391 (13.1%)**	**55 (1.8%)**	**234 (7.8%)**	**104 (3.5%)**	**268 (9.0%)**	**187 (6.3%)**	**299 (10.0%)**	**2989 (100.0%)**
Overall	Status 1 Initial Listing	28 (5.3%)	42 (8.0%)	103 (19.7%)	73 (13.9%)	42 (8.0%)	14 (2.7%)	42 (8.0%)	21 (4.0%)	52 (9.9%)	39 (7.4%)	68 (13.0%)	524 (100.0%)
	Status 1 Extension	6 (2.9%)	20 (9.6%)	32 (15.3%)	30 (14.4%)	15 (7.2%)	4 (1.9%)	65 (31.1%)	0 (0.0%)	19 (9.1%)	3 (1.4%)	15 (7.2%)	209 (100.0%)
	Status 2 Initial Listing	177 (5.7%)	237 (7.6%)	607 (19.5%)	370 (11.9%)	290 (9.3%)	39 (1.3%)	317 (10.2%)	155 (5.0%)	289 (9.3%)	242 (7.8%)	384 (12.4%)	3107 (100.0%)
	Status 2 Extension	105 (4.5%)	226 (9.6%)	507 (21.6%)	241 (10.3%)	217 (9.3%)	27 (1.2%)	355 (15.1%)	49 (2.1%)	215 (9.2%)	200 (8.5%)	202 (8.6%)	2344 (100.0%)
	Status 3 Initial Listing	85 (5.1%)	151 (9.0%)	261 (15.6%)	201 (12.0%)	312 (18.6%)	41 (2.4%)	130 (7.8%)	59 (3.5%)	144 (8.6%)	114 (6.8%)	178 (10.6%)	1676 (100.0%)
	Status 3 Extension	135 (7.1%)	212 (11.2%)	371 (19.5%)	147 (7.7%)	387 (20.4%)	15 (0.8%)	198 (10.4%)	26 (1.4%)	168 (8.8%)	111 (5.8%)	129 (6.8%)	1899 (100.0%)
	Status 4 Initial Listing	49 (2.8%)	227 (13.1%)	370 (21.4%)	287 (16.6%)	97 (5.6%)	55 (3.2%)	104 (6.0%)	115 (6.7%)	68 (3.9%)	76 (4.4%)	281 (16.3%)	1729 (100.0%)
	Status 4 Extension	32 (3.5%)	110 (12.1%)	256 (28.2%)	81 (8.9%)	42 (4.6%)	12 (1.3%)	78 (8.6%)	53 (5.8%)	39 (4.3%)	46 (5.1%)	160 (17.6%)	909 (100.0%)
	Total	**617 (5.0%)**	**1225 (9.9%)**	**2507 (20.2%)**	**1430 (11.5%)**	**1402 (11.3%)**	**207 (1.7%)**	**1289 (10.4%)**	**478 (3.9%)**	**994 (8.0%)**	**831 (6.7%)**	**1417 (11.4%)**	**12397 (100.0%)**

Pre-guidance: forms submitted September 18, 2018 - March 3, 2021

Post-guidance: forms submitted March 4, 2021 - September 30, 2021

Table 28 summarizes the form types and whether the form was approved, not approved, not required-listing error, not required-other, or not required-withdrawn. Overall, the majority of forms submitted were approved (94.8%), regardless of medical urgency status or form type. Status 1 justification forms at initial listing had the lowest approval rate (89.4%) while Status 3 Extensions had the highest approval rate (97.6%). Similar patterns were seen in the pre- and post-guidance periods (Table 29).

Table 28. 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 - Listing Error	Not Required - Other	Not Required - Withdrawn	Total
Status 1 Initial Listing	466 (89.4%)	27 (5.2%)	2 (0.4%)	7 (1.3%)	19 (3.6%)	521 (100.0%)
Status 1 Extension	193 (96.5%)	2 (1.0%)	0 (0.0%)	0 (0.0%)	5 (2.5%)	200 (100.0%)
Status 2 Initial Listing	2860 (92.2%)	168 (5.4%)	10 (0.3%)	16 (0.5%)	48 (1.5%)	3102 (100.0%)
Status 2 Extension	2223 (96.7%)	46 (2.0%)	0 (0.0%)	7 (0.3%)	23 (1.0%)	2299 (100.0%)
Status 3 Initial Listing	1525 (91.6%)	81 (4.9%)	4 (0.2%)	16 (1.0%)	39 (2.3%)	1665 (100.0%)
Status 3 Extension	1840 (97.6%)	15 (0.8%)	0 (0.0%)	1 (0.1%)	29 (1.5%)	1885 (100.0%)
Status 4 Initial Listing	1667 (96.9%)	28 (1.6%)	1 (0.1%)	5 (0.3%)	19 (1.1%)	1720 (100.0%)
Status 4 Extension	876 (97.0%)	13 (1.4%)	1 (0.1%)	1 (0.1%)	12 (1.3%)	903 (100.0%)
Total	**11650 (94.8%)**	**380 (3.1%)**	**18 (0.1%)**	**53 (0.4%)**	**194 (1.6%)**	**12295 (100.0%)**

Based on OPTN data as of September 30, 2022

Data subject to change based on future data submission or correction

Justification forms submitted between September 18, 2018 - September 30, 2021

Table 29. Number of initial and extension justification forms by medical urgency status, conclusion from the form status field, and guidance period

Guidance Period	Adult Heart Status and Form Type	Approved	Not Approved	Not Required - Listing Error	Not Required - Other	Not Required - Withdrawn	Total
Pre-guidance	Status 1 Initial Listing	324 (87.8%)	19 (5.1%)	1 (0.3%)	7 (1.9%)	18 (4.9%)	369 (100.0%)
	Status 1 Extension	143 (96.6%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	4 (2.7%)	148 (100.0%)
	Status 2 Initial Listing	2107 (91.2%)	136 (5.9%)	4 (0.2%)	16 (0.7%)	47 (2.0%)	2310 (100.0%)
	Status 2 Extension	1382 (95.5%)	37 (2.6%)	0 (0.0%)	7 (0.5%)	21 (1.5%)	1447 (100.0%)
	Status 3 Initial Listing	1237 (90.8%)	70 (5.1%)	0 (0.0%)	16 (1.2%)	39 (2.9%)	1362 (100.0%)
	Status 3 Extension	1472 (97.4%)	12 (0.8%)	0 (0.0%)	1 (0.1%)	26 (1.7%)	1511 (100.0%)
	Status 4 Initial Listing	1425 (96.6%)	25 (1.7%)	1 (0.1%)	5 (0.3%)	19 (1.3%)	1475 (100.0%)
	Status 4 Extension	680 (96.7%)	13 (1.8%)	1 (0.1%)	1 (0.1%)	8 (1.1%)	703 (100.0%)
	Total	**8770 (94.0%)**	**313 (3.4%)**	**7 (0.1%)**	**53 (0.6%)**	**182 (2.0%)**	**9325 (100.0%)**
Post-guidance	Status 1 Initial Listing	142 (93.4%)	8 (5.3%)	1 (0.7%)	0 (0.0%)	1 (0.7%)	152 (100.0%)
	Status 1 Extension	50 (96.2%)	1 (1.9%)	0 (0.0%)	0 (0.0%)	1 (1.9%)	52 (100.0%)
	Status 2 Initial Listing	753 (95.1%)	32 (4.0%)	6 (0.8%)	0 (0.0%)	1 (0.1%)	792 (100.0%)
	Status 2 Extension	841 (98.7%)	9 (1.1%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	852 (100.0%)
	Status 3 Initial Listing	288 (95.0%)	11 (3.6%)	4 (1.3%)	0 (0.0%)	0 (0.0%)	303 (100.0%)
	Status 3 Extension	368 (98.4%)	3 (0.8%)	0 (0.0%)	0 (0.0%)	3 (0.8%)	374 (100.0%)
	Status 4 Initial Listing	242 (98.8%)	3 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	245 (100.0%)
	Status 4 Extension	196 (98.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (2.0%)	200 (100.0%)
	Total	**2880 (97.0%)**	**67 (2.3%)**	**11 (0.4%)**	**0 (0.0%)**	**12 (0.4%)**	**2970 (100.0%)**
Overall	Status 1 Initial Listing	466 (89.4%)	27 (5.2%)	2 (0.4%)	7 (1.3%)	19 (3.6%)	521 (100.0%)
	Status 1 Extension	193 (96.5%)	2 (1.0%)	0 (0.0%)	0 (0.0%)	5 (2.5%)	200 (100.0%)
	Status 2 Initial Listing	2860 (92.2%)	168 (5.4%)	10 (0.3%)	16 (0.5%)	48 (1.5%)	3102 (100.0%)
	Status 2 Extension	2223 (96.7%)	46 (2.0%)	0 (0.0%)	7 (0.3%)	23 (1.0%)	2299 (100.0%)
	Status 3 Initial Listing	1525 (91.6%)	81 (4.9%)	4 (0.2%)	16 (1.0%)	39 (2.3%)	1665 (100.0%)
	Status 3 Extension	1840 (97.6%)	15 (0.8%)	0 (0.0%)	1 (0.1%)	29 (1.5%)	1885 (100.0%)
	Status 4 Initial Listing	1667 (96.9%)	28 (1.6%)	1 (0.1%)	5 (0.3%)	19 (1.1%)	1720 (100.0%)
	Status 4 Extension	876 (97.0%)	13 (1.4%)	1 (0.1%)	1 (0.1%)	12 (1.3%)	903 (100.0%)
	Total	**11650 (94.8%)**	**380 (3.1%)**	**18 (0.1%)**	**53 (0.4%)**	**194 (1.6%)**	**12295 (100.0%)**

Based on OPTN data as of September 30, 2022

Data subject to change based on future data submission or correction

Pre-guidance: forms submitted September 18, 2018 - March 3, 2021

Post-guidance: forms submitted March 4, 2021 - September 30, 2021

Under the new adult heart allocation system regions review requests from other regions. There have been three sets of RRB assignments during the period from September 18, 2018 to September 30, 2021 (https://optn.transplant.hrsa.gov/members/review-boards/#HeartReviewBoard). Table 30 summarizes the number of forms submitted from each region and the corresponding region that reviews the request by RRB assignment period. Region 3 submitted substantially more forms than any other region in all three assignment periods. Region 6 submitted the fewest number of forms in all three review periods.

Table 30. Number of forms by region submitting form and region reviewing form and review period

Region	N
Sept 18, 2018 - Sep 30, 2019	
Region 1, Reviewed by Region 2	179
Region 2, Reviewed by Region 5	361
Region 4, Reviewed by Region 10	438
Region 7, Reviewed by Region 11	468
Region 11, Reviewed by Region 3	440
Region 3, Reviewed by Region 7	739
Region 5, Reviewed by Region 9	396
Region 6, Reviewed by Region 8	52
Region 8, Reviewed by Region 4	162
Region 9, Reviewed by Region 1	242
Region 10, Reviewed by Region 6	243
Oct 1, 2019 - Sep 30, 2020	
Region 1, Reviewed by Region 8	170
Region 2, Reviewed by Region 7	368
Region 3, Reviewed by Region 11	773
Region 4, Reviewed by Region 5	443
Region 5, Reviewed by Region 4	410
Region 6, Reviewed by Region 1	59
Region 7, Reviewed by Region 3	444
Region 8, Reviewed by Region 6	156
Region 9, Reviewed by Region 10	338
Region 10, Reviewed by Region 9	280
Region 11, Reviewed by Region 2	437
Oct 1, 2020 - Sep 30, 2021	
Region 1, Reviewed by Region 6	268
Region 2, Reviewed by Region 9	496
Region 3, Reviewed by Region 4	995
Region 4, Reviewed by Region 11	549
Region 5, Reviewed by Region 3	596
Region 6, Reviewed by Region 8	96
Region 7, Reviewed by Region 10	377
Region 8, Reviewed by Region 1	160
Region 9, Reviewed by Region 7	414
Region 10, Reviewed by Region 2	308
Region 11, Reviewed by Region 5	540
Total	**12397**

Based on OPTN data as of September 30, 2022

Data subject to change based on future data submission or correction

Table 31 further stratifies the number of forms submitted from each region and the corresponding region that reviewed the request during the October 1, 2020 - September 30, 2021 review period by whether the forms were submitted before or after implementation of the guidance. Region 3 submitted substantially more forms than any other region both before and after the guidance was implemented. Region 6 submitted the fewest number of forms both before and after the guidance was implemented.

Table 31. Number of forms by region submitting form, region reviewing form, and guidance period for October 1, 2020 - September 30, 2021 review period

Guidance	Region	N
Pre-guidance	Region 1, Reviewed by Region 6	102
	Region 2, Reviewed by Region 9	188
	Region 3, Reviewed by Region 4	392
	Region 4, Reviewed by Region 11	175
	Region 5, Reviewed by Region 3	205
	Region 6, Reviewed by Region 8	41
	Region 7, Reviewed by Region 10	143
	Region 8, Reviewed by Region 1	56
	Region 9, Reviewed by Region 7	146
	Region 10, Reviewed by Region 2	121
	Region 11, Reviewed by Region 5	241
	Total	**1810**
Post-guidance	Region 1, Reviewed by Region 6	166
	Region 2, Reviewed by Region 9	308
	Region 3, Reviewed by Region 4	603
	Region 4, Reviewed by Region 11	374
	Region 5, Reviewed by Region 3	391
	Region 6, Reviewed by Region 8	55
	Region 7, Reviewed by Region 10	234
	Region 8, Reviewed by Region 1	104
	Region 9, Reviewed by Region 7	268
	Region 10, Reviewed by Region 2	187
	Region 11, Reviewed by Region 5	299
	Total	**2989**
Overall	**Total**	**4799**

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre-guidance: forms submitted October 1, 2020 - March 3, 2021
Post-guidance: forms submitted March 4, 2021 - September 30, 2021

Figure 56 and Table 32 summarize the conclusions (approved, not approved, not required-listing error, not required-other, not required-withdrawn) by OPTN region that reviewed the request (not the OPTN region from which the form originated) and RRB assignment period. From October 1, 2020 to September 30, 2021 Region 5 approved the lowest proportion and Region 8 approved the highest proportion of requests.

Figure 56. Conclusions from justification forms by region reviewing request and review period

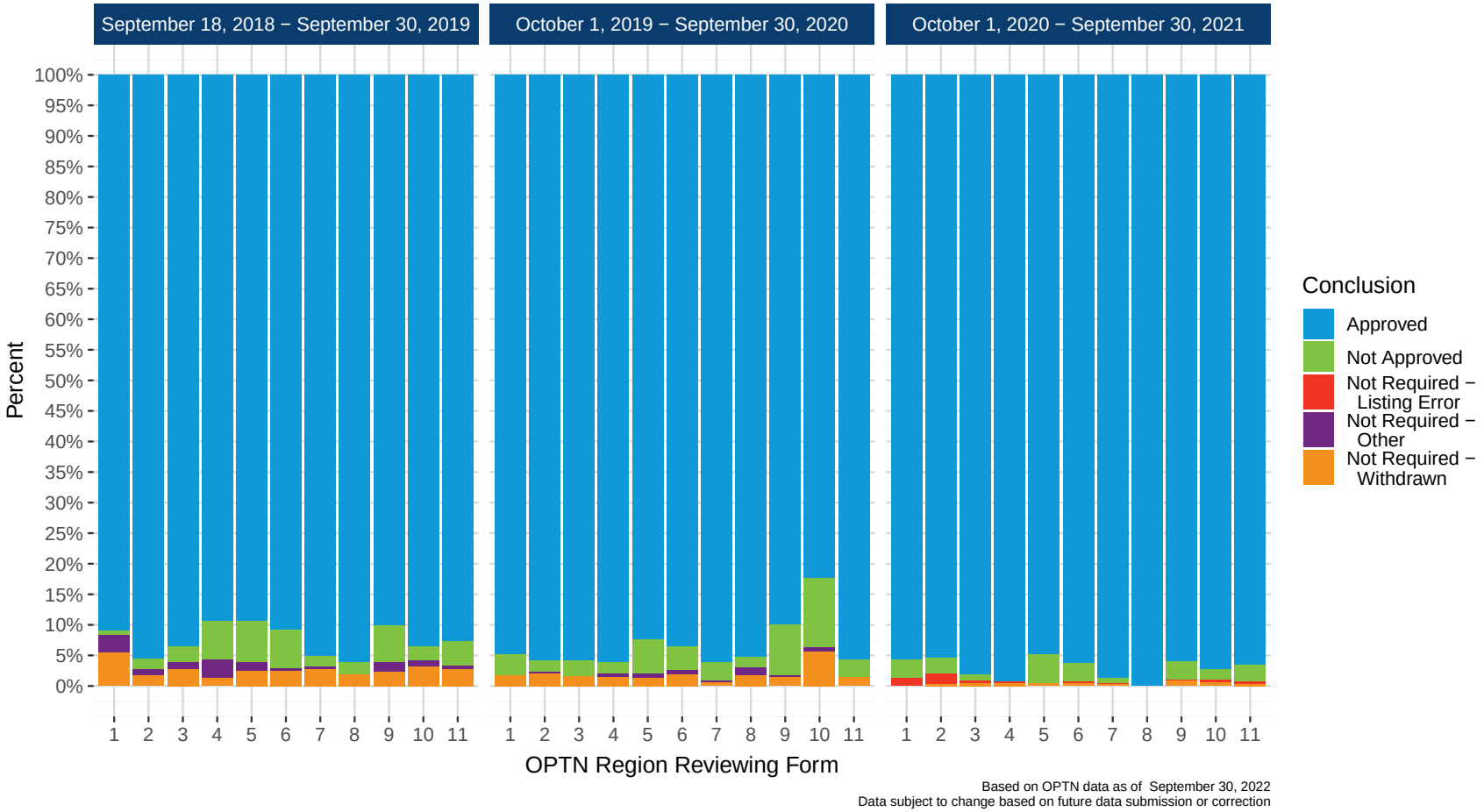


Table 32. Conclusions from justification forms by region reviewing request

OPTN Region Reviewing Form	Approved	Not Approved	Not Required - Listing Error	Not Required - Other	Not Required - Withdrawn	Total
Sept 18, 2018 - Sep 30, 2019						
1	219 (90.9%)	2 (0.8%)	0 (0.0%)	7 (2.9%)	13 (5.4%)	241 (100.0%)
2	169 (95.5%)	3 (1.7%)	0 (0.0%)	2 (1.1%)	3 (1.7%)	177 (100.0%)
3	408 (93.6%)	11 (2.5%)	0 (0.0%)	5 (1.1%)	12 (2.8%)	436 (100.0%)
4	144 (89.4%)	10 (6.2%)	0 (0.0%)	5 (3.1%)	2 (1.2%)	161 (100.0%)
5	321 (89.4%)	24 (6.7%)	0 (0.0%)	5 (1.4%)	9 (2.5%)	359 (100.0%)
6	219 (90.9%)	15 (6.2%)	0 (0.0%)	1 (0.4%)	6 (2.5%)	241 (100.0%)
7	690 (95.2%)	12 (1.7%)	0 (0.0%)	3 (0.4%)	20 (2.8%)	725 (100.0%)
8	50 (96.2%)	1 (1.9%)	0 (0.0%)	0 (0.0%)	1 (1.9%)	52 (100.0%)
9	351 (90.0%)	24 (6.2%)	0 (0.0%)	6 (1.5%)	9 (2.3%)	390 (100.0%)
10	407 (93.6%)	10 (2.3%)	0 (0.0%)	4 (0.9%)	14 (3.2%)	435 (100.0%)
11	429 (92.7%)	19 (4.1%)	0 (0.0%)	2 (0.4%)	13 (2.8%)	463 (100.0%)
Oct 1, 2019 - Sep 30, 2020						
1	55 (94.8%)	2 (3.4%)	0 (0.0%)	0 (0.0%)	1 (1.7%)	58 (100.0%)
2	415 (95.8%)	8 (1.8%)	0 (0.0%)	1 (0.2%)	9 (2.1%)	433 (100.0%)
3	422 (95.9%)	11 (2.5%)	0 (0.0%)	0 (0.0%)	7 (1.6%)	440 (100.0%)
4	391 (96.1%)	8 (2.0%)	0 (0.0%)	2 (0.5%)	6 (1.5%)	407 (100.0%)
5	406 (92.5%)	24 (5.5%)	0 (0.0%)	3 (0.7%)	6 (1.4%)	439 (100.0%)
6	145 (93.5%)	6 (3.9%)	0 (0.0%)	1 (0.6%)	3 (1.9%)	155 (100.0%)
7	351 (96.2%)	11 (3.0%)	0 (0.0%)	1 (0.3%)	2 (0.5%)	365 (100.0%)
8	161 (95.3%)	3 (1.8%)	0 (0.0%)	2 (1.2%)	3 (1.8%)	169 (100.0%)
9	251 (90.0%)	23 (8.2%)	0 (0.0%)	1 (0.4%)	4 (1.4%)	279 (100.0%)
10	276 (82.4%)	38 (11.3%)	0 (0.0%)	2 (0.6%)	19 (5.7%)	335 (100.0%)
11	736 (95.7%)	22 (2.9%)	0 (0.0%)	0 (0.0%)	11 (1.4%)	769 (100.0%)
Oct 1, 2020 - Sep 30, 2021						
1	152 (95.6%)	5 (3.1%)	2 (1.3%)	0 (0.0%)	0 (0.0%)	159 (100.0%)
2	288 (95.4%)	8 (2.6%)	5 (1.7%)	0 (0.0%)	1 (0.3%)	302 (100.0%)
3	580 (98.1%)	6 (1.0%)	2 (0.3%)	0 (0.0%)	3 (0.5%)	591 (100.0%)
4	983 (99.2%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	5 (0.5%)	991 (100.0%)
5	507 (94.8%)	26 (4.9%)	0 (0.0%)	0 (0.0%)	2 (0.4%)	535 (100.0%)
6	256 (96.2%)	8 (3.0%)	1 (0.4%)	0 (0.0%)	1 (0.4%)	266 (100.0%)
7	407 (98.8%)	3 (0.7%)	1 (0.2%)	0 (0.0%)	1 (0.2%)	412 (100.0%)
8	96 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	96 (100.0%)
9	472 (95.9%)	15 (3.0%)	1 (0.2%)	0 (0.0%)	4 (0.8%)	492 (100.0%)
10	365 (97.3%)	6 (1.6%)	2 (0.5%)	0 (0.0%)	2 (0.5%)	375 (100.0%)
11	528 (96.5%)	15 (2.7%)	2 (0.4%)	0 (0.0%)	2 (0.4%)	547 (100.0%)
Total	**11650 (94.8%)**	**380 (3.1%)**	**18 (0.1%)**	**53 (0.4%)**	**194 (1.6%)**	**12295 (100.0%)**

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
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 57 and Table 33 summarize the conclusions (approved, not approved, not required-listing error, not required-other, not required-withdrawn) by OPTN region that reviewed the request during October 1, 2020 to September 30, 2021 and whether the request was reviewed before or after the guidance was implemented. This analysis was restricted to the most recent review period to mitigate potential confounding from changes in review board assignments. During this review period, Region 2 approved the lowest proportion and Region 8 approved the highest proportion of requests before the guidance was implemented; Region 9 approved the lowest proportion and Region 8 approved the highest proportion of requests after the guidance was implemented.

Figure 57. Conclusions from justification forms by region reviewing request during October 1, 2020 - September 30, 2021 and guidance period

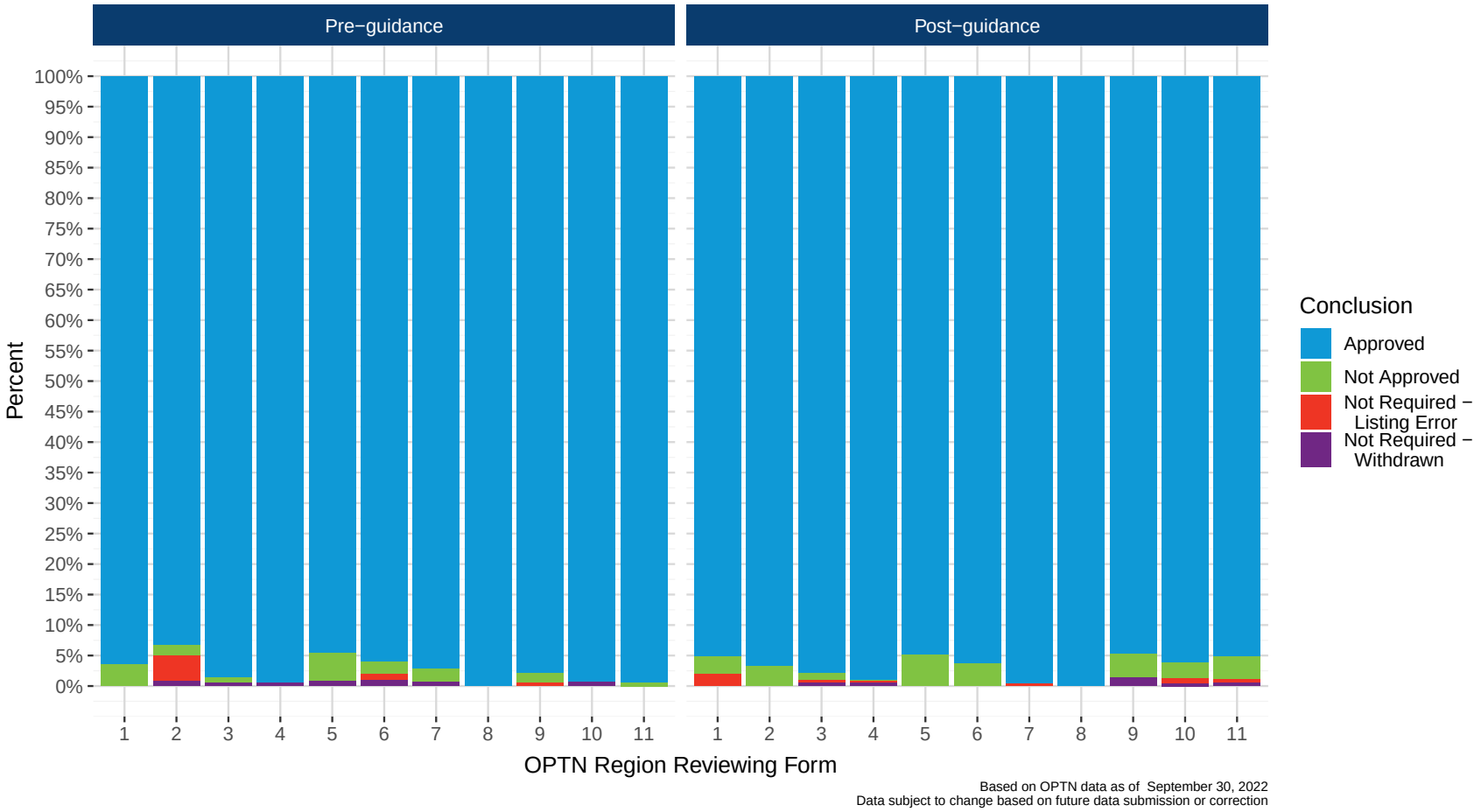


Table 33. Conclusions from justification forms by region reviewing request during October 1, 2020 - September 30, 2021 and guidance period

Guidance Period	OPTN Region Reviewing Form	Approved	Not Approved	Not Required - Listing Error	Not Required - Other	Not Required - Withdrawn	Total
Pre-guidance	1	54 (96.4%)	2 (3.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	56 (100.0%)
	2	112 (93.3%)	2 (1.7%)	5 (4.2%)	0 (0.0%)	1 (0.8%)	120 (100.0%)
	3	200 (98.5%)	2 (1.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	203 (100.0%)
	4	387 (99.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)	389 (100.0%)
	5	225 (94.5%)	11 (4.6%)	0 (0.0%)	0 (0.0%)	2 (0.8%)	238 (100.0%)
	6	97 (96.0%)	2 (2.0%)	1 (1.0%)	0 (0.0%)	1 (1.0%)	101 (100.0%)
	7	140 (97.2%)	3 (2.1%)	0 (0.0%)	0 (0.0%)	1 (0.7%)	144 (100.0%)
	8	41 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	41 (100.0%)
	9	183 (97.9%)	3 (1.6%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	187 (100.0%)
	10	142 (99.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.7%)	143 (100.0%)
	11	173 (99.4%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	174 (100.0%)
	Total	**1754 (97.7%)**	**26 (1.4%)**	**7 (0.4%)**	**0 (0.0%)**	**9 (0.5%)**	**1796 (100.0%)**
Post-guidance	1	98 (95.1%)	3 (2.9%)	2 (1.9%)	0 (0.0%)	0 (0.0%)	103 (100.0%)
	2	176 (96.7%)	6 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	182 (100.0%)
	3	380 (97.9%)	4 (1.0%)	2 (0.5%)	0 (0.0%)	2 (0.5%)	388 (100.0%)
	4	596 (99.0%)	1 (0.2%)	2 (0.3%)	0 (0.0%)	3 (0.5%)	602 (100.0%)
	5	282 (94.9%)	15 (5.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	297 (100.0%)
	6	159 (96.4%)	6 (3.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	165 (100.0%)
	7	267 (99.6%)	0 (0.0%)	1 (0.4%)	0 (0.0%)	0 (0.0%)	268 (100.0%)
	8	55 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	55 (100.0%)
	9	289 (94.8%)	12 (3.9%)	0 (0.0%)	0 (0.0%)	4 (1.3%)	305 (100.0%)
	10	223 (96.1%)	6 (2.6%)	2 (0.9%)	0 (0.0%)	1 (0.4%)	232 (100.0%)
	11	355 (95.2%)	14 (3.8%)	2 (0.5%)	0 (0.0%)	2 (0.5%)	373 (100.0%)
	Total	**2880 (97.0%)**	**67 (2.3%)**	**11 (0.4%)**	**0 (0.0%)**	**12 (0.4%)**	**2970 (100.0%)**

Overall	1	152 (95.6%)	5 (3.1%)	2 (1.3%)	0 (0.0%)	0 (0.0%)	159 (100.0%)
	2	288 (95.4%)	8 (2.6%)	5 (1.7%)	0 (0.0%)	1 (0.3%)	302 (100.0%)
	3	580 (98.1%)	6 (1.0%)	2 (0.3%)	0 (0.0%)	3 (0.5%)	591 (100.0%)
	4	983 (99.2%)	1 (0.1%)	2 (0.2%)	0 (0.0%)	5 (0.5%)	991 (100.0%)
	5	507 (94.8%)	26 (4.9%)	0 (0.0%)	0 (0.0%)	2 (0.4%)	535 (100.0%)
	6	256 (96.2%)	8 (3.0%)	1 (0.4%)	0 (0.0%)	1 (0.4%)	266 (100.0%)
	7	407 (98.8%)	3 (0.7%)	1 (0.2%)	0 (0.0%)	1 (0.2%)	412 (100.0%)
	8	96 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	96 (100.0%)
	9	472 (95.9%)	15 (3.0%)	1 (0.2%)	0 (0.0%)	4 (0.8%)	492 (100.0%)
	10	365 (97.3%)	6 (1.6%)	2 (0.5%)	0 (0.0%)	2 (0.5%)	375 (100.0%)
	11	528 (96.5%)	15 (2.7%)	2 (0.4%)	0 (0.0%)	2 (0.4%)	547 (100.0%)
	Total	**4634 (97.2%)**	**93 (2.0%)**	**18 (0.4%)**	**0 (0.0%)**	**21 (0.4%)**	**4766 (100.0%)**

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre-guidance: forms submitted October 1, 2020 - March 3, 2021
Post-guidance: forms submitted March 4, 2021 - September 30, 2021

Figure 58 and Table 34 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 4797 registrations applied for an exception between September 18, 2018 and September 30, 2021. The most common initial request was for Adult Status 2 (n=2103, 43.8%). Similar patterns were seen in the pre- and post-guidance periods, although the proportion of Adult Status 2 initial requests increased by more than 10% and the proportion of Adult Status 4 initial requests decreased by more than 10% post-guidance relative to pre-guidance (Figure 59 and Table 35).

Figure 58. Number of registrations with an exception by first status requested

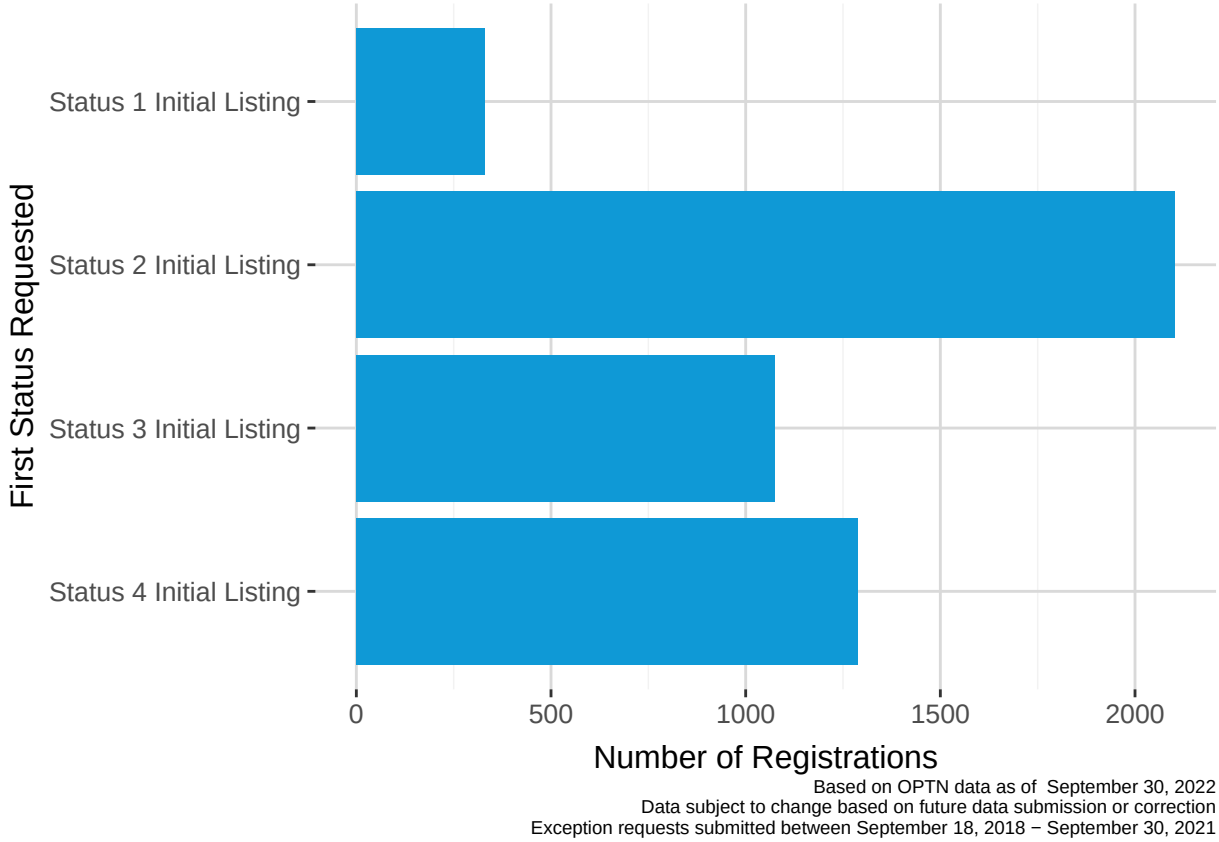
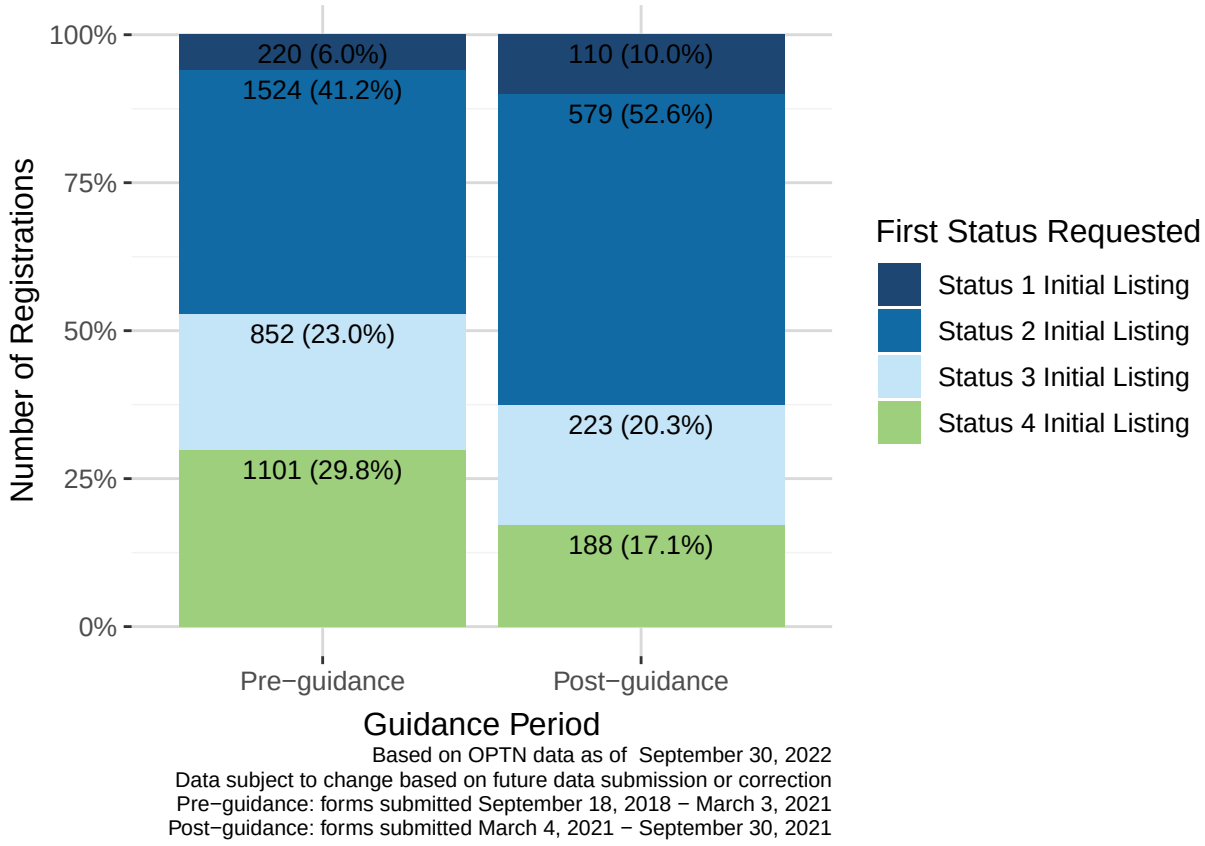


Table 34. Number of registrations with an exception by first status requested

Status Requested	Registration Count	Percent
Status 1 Initial Listing	330	6.9%
Status 2 Initial Listing	2103	43.8%
Status 3 Initial Listing	1075	22.4%
Status 4 Initial Listing	1289	26.9%
Total	**4797**	**100.0%**

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Exception requests submitted between September 18, 2018 - September 30, 2021

Figure 59. Number of registrations with an exception by first status requested and guidance period



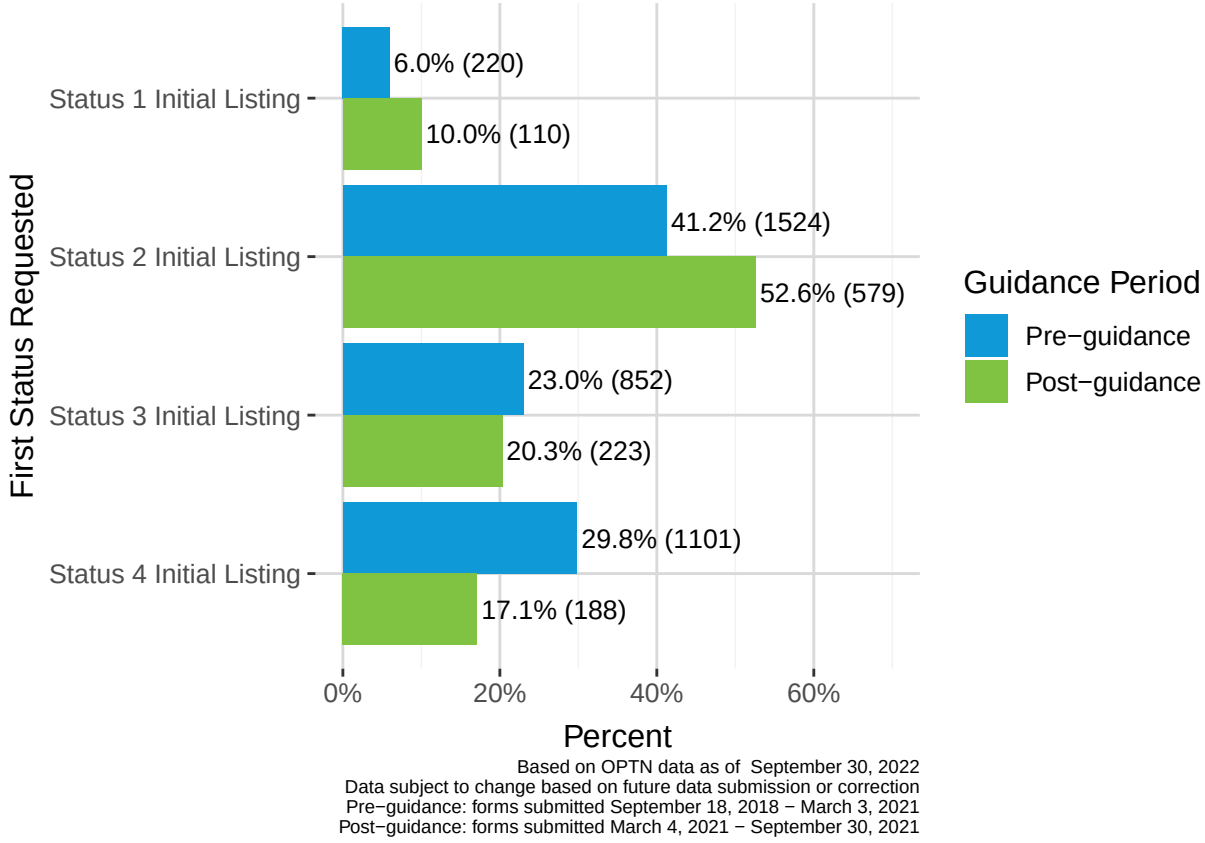


Table 35. Number of registrations with an exception by first status requested and guidance period

	Number and Percent of Registrations					
	Pre-guidance		Post-guidance		Overall	
Status Requested	**N**	**%**	**N**	**%**	**N**	**%**
Status 1 Initial Listing	220	6.0%	110	10.0%	330	6.9%
Status 2 Initial Listing	1524	41.2%	579	52.6%	2103	43.8%
Status 3 Initial Listing	852	23.0%	223	20.3%	1075	22.4%
Status 4 Initial Listing	1101	29.8%	188	17.1%	1289	26.9%
Total	**3697**	**100.0%**	**1100**	**100.0%**	**4797**	**100.0%**

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre-guidance: forms submitted September 18, 2018 - March 3, 2021
Post-guidance: forms submitted March 4, 2021 - September 30, 2021

Figure 61 and Table 36 show the distribution of the number of exception requests per registration by medical urgency status. Adult Status 2 had the maximum number of exception requests per registration with 53 requests per registration, followed by Adult Status 3 with 36 exception requests per registration. The median was 1 request per registration for Adult Status 1, 2, and 4; for Adult Status 3, the median was 2 requests per registration. Similar patterns were seen in the pre- and post-guidance periods, although the maximum number of exception requests per registration was smaller for all statuses post-guidance compared to pre-guidance due to the shorter duration of the post-guidance period (Figure 62 and Table 37).

Figure 61. Number of exception requests submitted per registration by medical urgency status

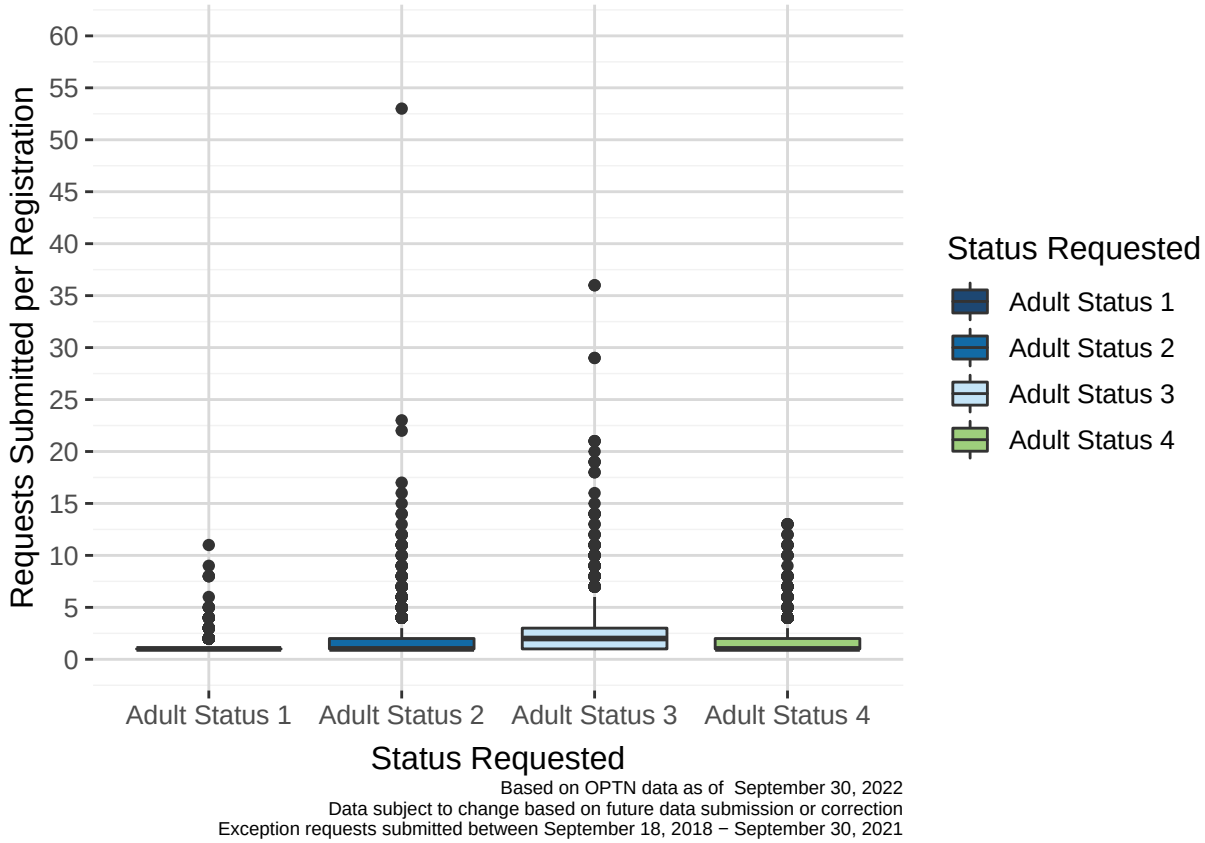


Table 36. Summary of exception requests submitted per registration by medical urgency status

Status Requested	Min	25th Percentile	Median	Mean	75th Percentile	Max	N
Adult Status 1	1	1	1	1	1	11	652
Adult Status 2	1	1	1	2	2	53	4858
Adult Status 3	1	1	2	3	3	36	3646
Adult Status 4	1	1	1	2	2	13	2678

Based on OPTN data as of September 30, 2022

Data subject to change based on future data submission or correction

Exception requests submitted between September 18, 2018 - September 30, 2021

Figure 62. Number of exception requests submitted per registration by medical urgency status and guidance period

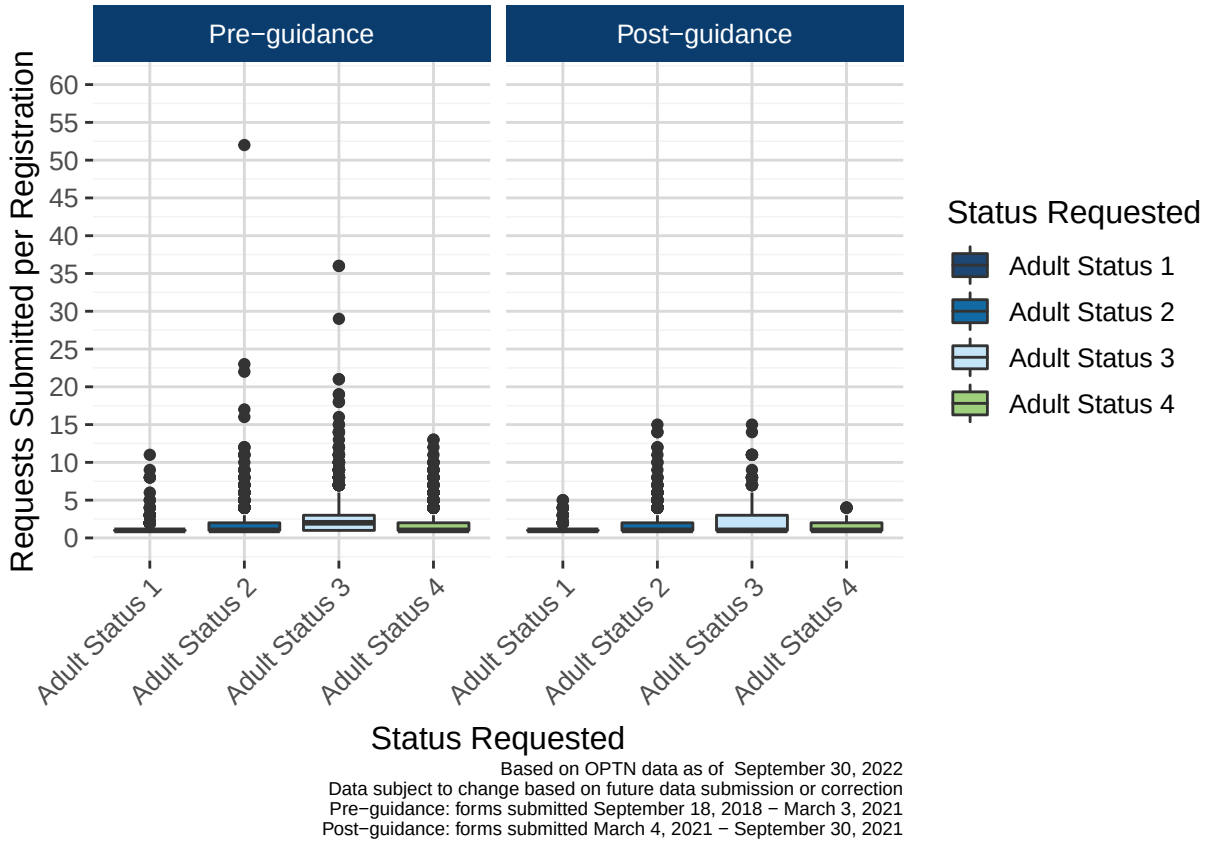


Table 37. Summary of exception requests submitted per registration by medical urgency status and guidance period

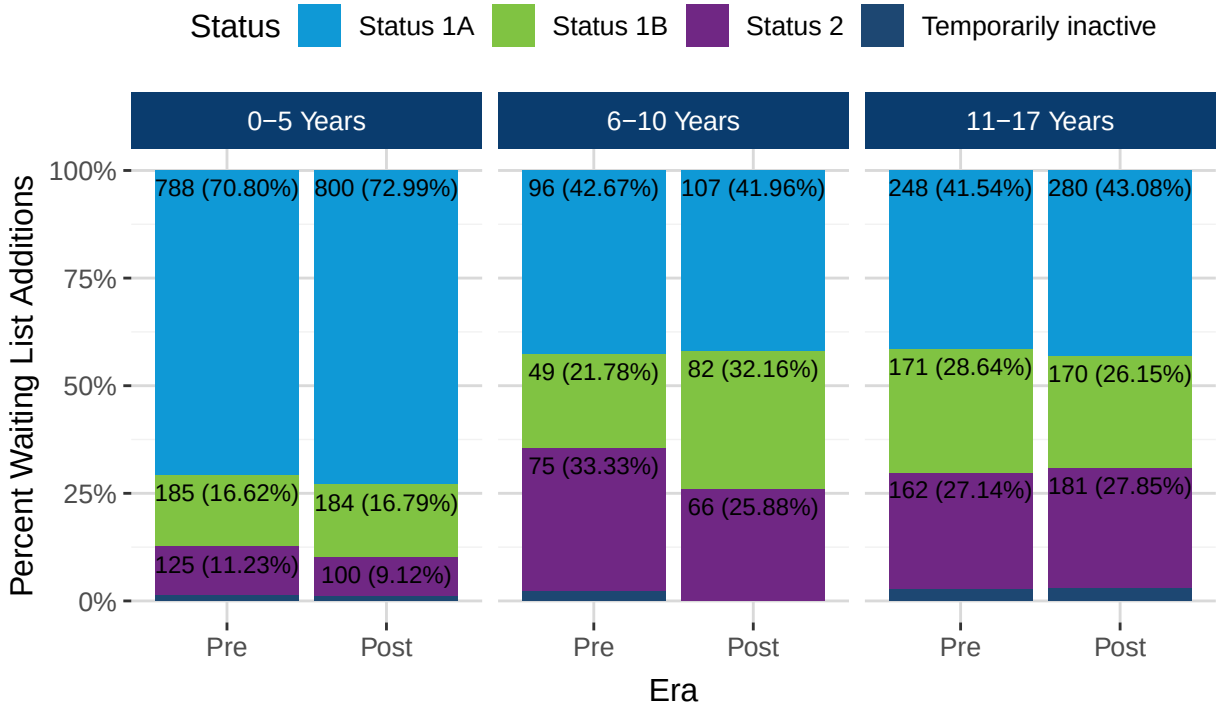
Guidance Period	Status Requested	Min	25th Percentile	Median	Mean	75th Percentile	Max	N
Pre-guidance	Adult Status 1	1	1	1	1	1	11	443
	Adult Status 2	1	1	1	2	2	52	3339
	Adult Status 3	1	1	2	3	3	36	2903
	Adult Status 4	1	1	1	2	2	13	2197
Post-guidance	Adult Status 1	1	1	1	1	1	5	209
	Adult Status 2	1	1	1	2	2	15	1519
	Adult Status 3	1	1	1	2	3	15	743
	Adult Status 4	1	1	1	2	2	4	481

Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Pre-guidance: forms submitted September 18, 2018 - March 3, 2021
Post-guidance: forms submitted March 4, 2021 - September 30, 2021

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 1935 pediatric heart candidates listed and 1332 pediatric heart candidates transplanted between October 18, 2015 and October 17, 2018 (pre-implementation) along with 2001 pediatric heart candidates listed and 1472 pediatric heart candidates transplanted between between October 18, 2018 and October 17, 2021 (post-implementation). Finally, there were 4312 pediatric candidates ever waiting.

Figure 63 Pediatric Heart Waiting List Additions by Medical Urgency Status and Era



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Statuses representing less than 5% of the total are not labeled on the plot
Pre−Policy: October 18, 2015 − October 17, 2018
Post−Policy: October 18, 2018 − October 17, 2021

Figure 63 and Table 38 summarize the count and percent of pediatric heart waiting list registrations by status and age group. The proportion of pediatric additions did not differ substantially between eras; the largest shift was an increase in pediatric Status 1B and decrease in pediatric Status 2 candidates aged 6-10 years registering post-implementation.

Table 38. Pediatric Heart Waiting List Additions by Era and Medical Urgency Status

		Pre-Policy		Post-Policy	
Age Group	**Status**	**N**	**%**	**N**	**%**
0-5 Years	Status 1A	788	71.8%	800	73.8%
	Status 1B	185	16.8%	184	17%
	Status 2	125	11.4%	100	9.2%
6-10 Years	Status 1A	96	43.6%	107	42%
	Status 1B	49	22.3%	82	32.2%
	Status 2	75	34.1%	66	25.9%
11-17 Years	Status 1A	248	42.7%	280	44.4%
	Status 1B	171	29.4%	170	26.9%
	Status 2	162	27.9%	181	28.7%
Overall	Status 1A	1132	59.6%	1187	60.3%
	Status 1B	405	21.3%	436	22.1%
	Status 2	362	19.1%	347	17.6%

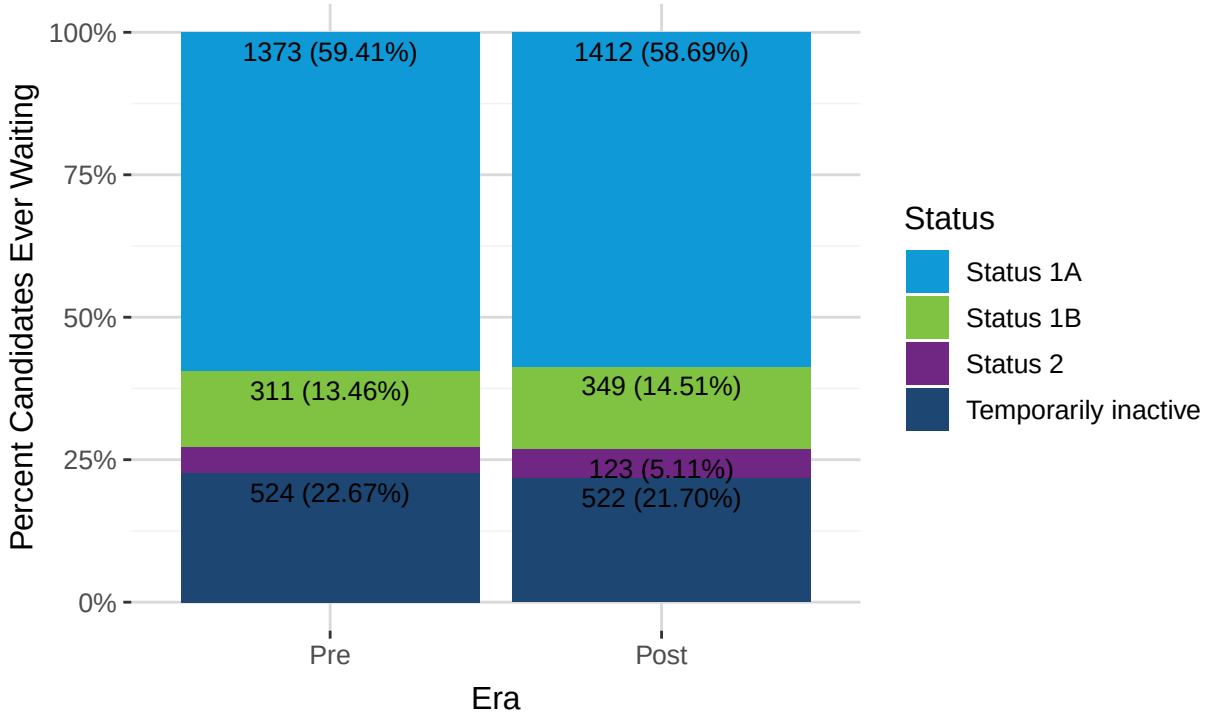
Based on OPTN data as of September 30, 2022

Data subject to change based on future data submission or correction

Pre-Policy: October 18, 2015 - October 17, 2018

Post-Policy: October 18, 2018 - October 17, 2021

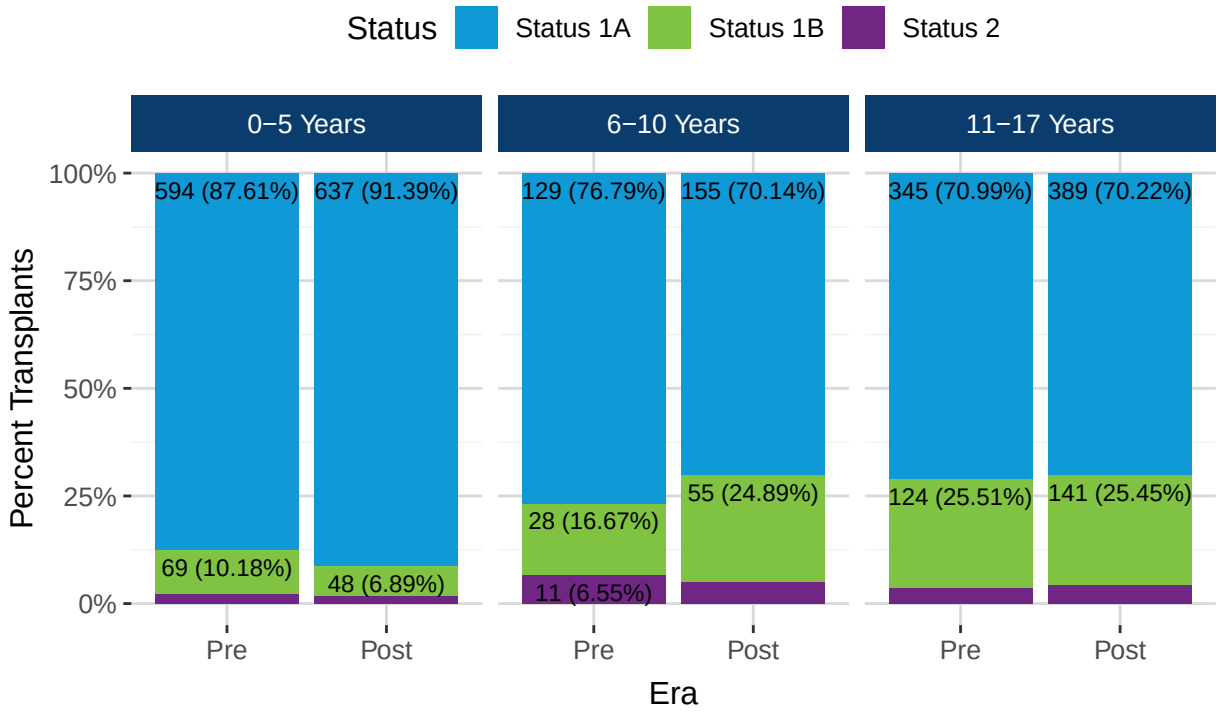
Figure 64. Pediatric Heart Candidates Ever Waiting by Era and Most Recent Medical Urgency Status



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Statuses representing less than 5% of the total are not labeled on the plot
Pre−Policy: October 18, 2015 − October 17, 2018
Post−Policy: October 18, 2018 − October 17, 2021

Figure 64 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 65. Pediatric Heart Transplants by Medical Urgency Status and Era



Based on OPTN data as of September 30, 2022
Data subject to change based on future data submission or correction
Statuses representing less than 5% of the total are not labeled on the plot
Pre−Policy: October 18, 2015 − October 17, 2018
Post−Policy: October 18, 2018 − October 17, 2021

Figure 65 and Table 39 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 0-5 years and 11-17 years. The proportion of transplants that went to Status 1B pediatric recipients aged 6-10 years increased from 16.67% to 24.89% pre- to post-implementation.

Table 39. Pediatric Heart Transplants by Era and Medical Urgency Status

		Pre-Policy		Post-Policy	
Age Group	**Status**	**N**	**%**	**N**	**%**
0-5 Years	Status 1A	594	87.6%	637	91.4%
	Status 1B	69	10.2%	48	6.9%
	Status 2	15	2.2%	12	1.7%
6-10 Years	Status 1A	129	76.8%	155	70.1%
	Status 1B	28	16.7%	55	24.9%
	Status 2	11	6.5%	11	5%
11-17 Years	Status 1A	345	71%	389	70.2%
	Status 1B	124	25.5%	141	25.5%
	Status 2	17	3.5%	24	4.3%
Overall	Status 1A	1068	80.2%	1181	80.2%
	Status 1B	221	16.6%	244	16.6%
	Status 2	43	3.2%	47	3.2%

Based on OPTN data as of September 30, 2022

Data subject to change based on future data submission or correction

Pre-Policy: October 18, 2015 - October 17, 2018

Post-Policy: October 18, 2018 - October 17, 2021

Figure 66. Pediatric Deaths per 100 Patient-Years Waiting by Medical Urgency Status and Era

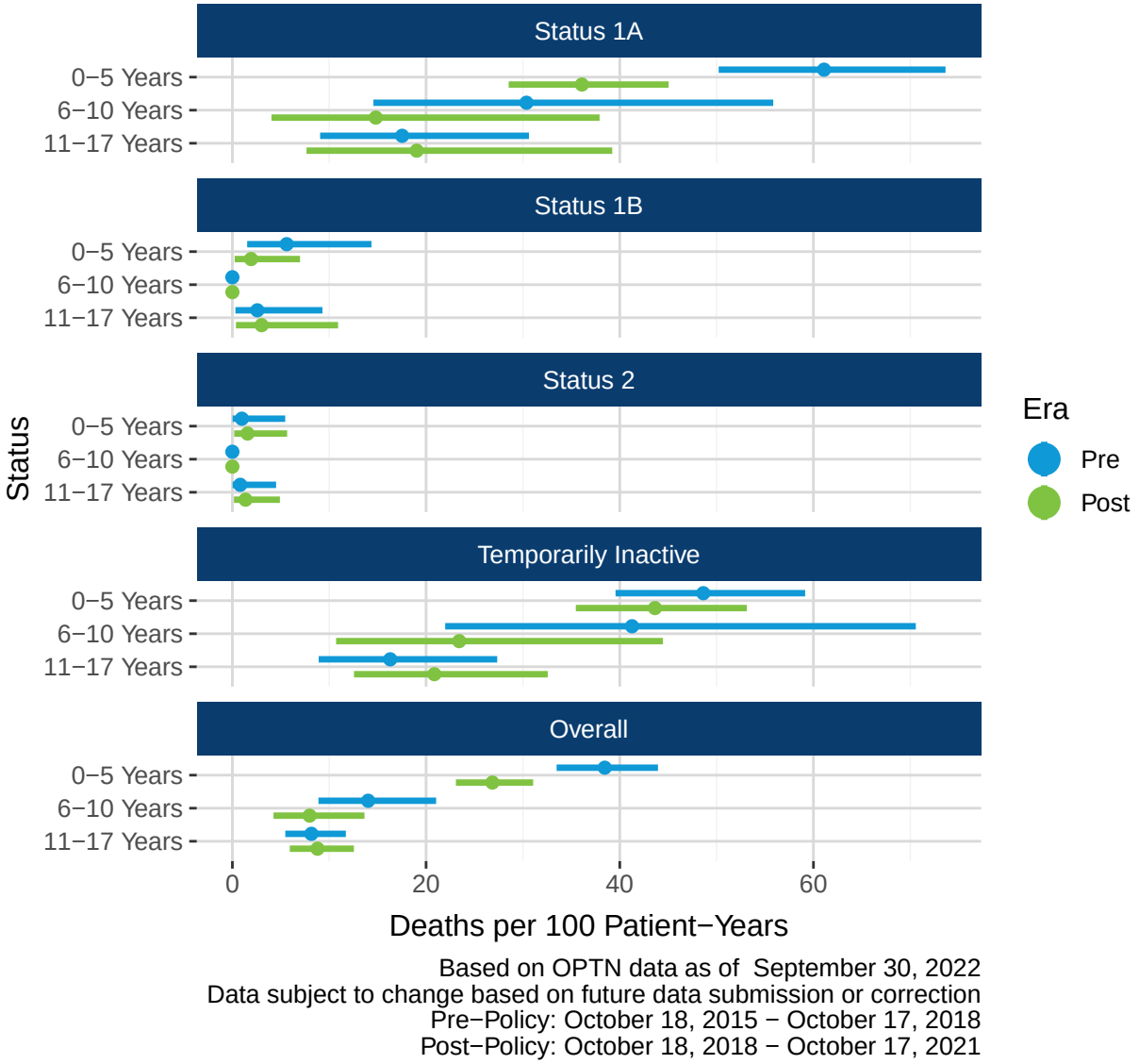


Figure 66 shows the deaths per 100 patient-years for pediatric heart candidates pre- and post-implementation by medical urgency status and era. There was a significant decrease in the number of deaths per 100 patient-years for pediatric candidates aged 0-5 years post-policy.

Table A16 shows the number of pediatric candidates ever waiting, the number of deaths per 100 patient-years for each medical urgency status and age group pre- and post-implementation, 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 67. Pediatric Transplants per 100 Patient-Years Waiting by Medical Urgency Status and Era

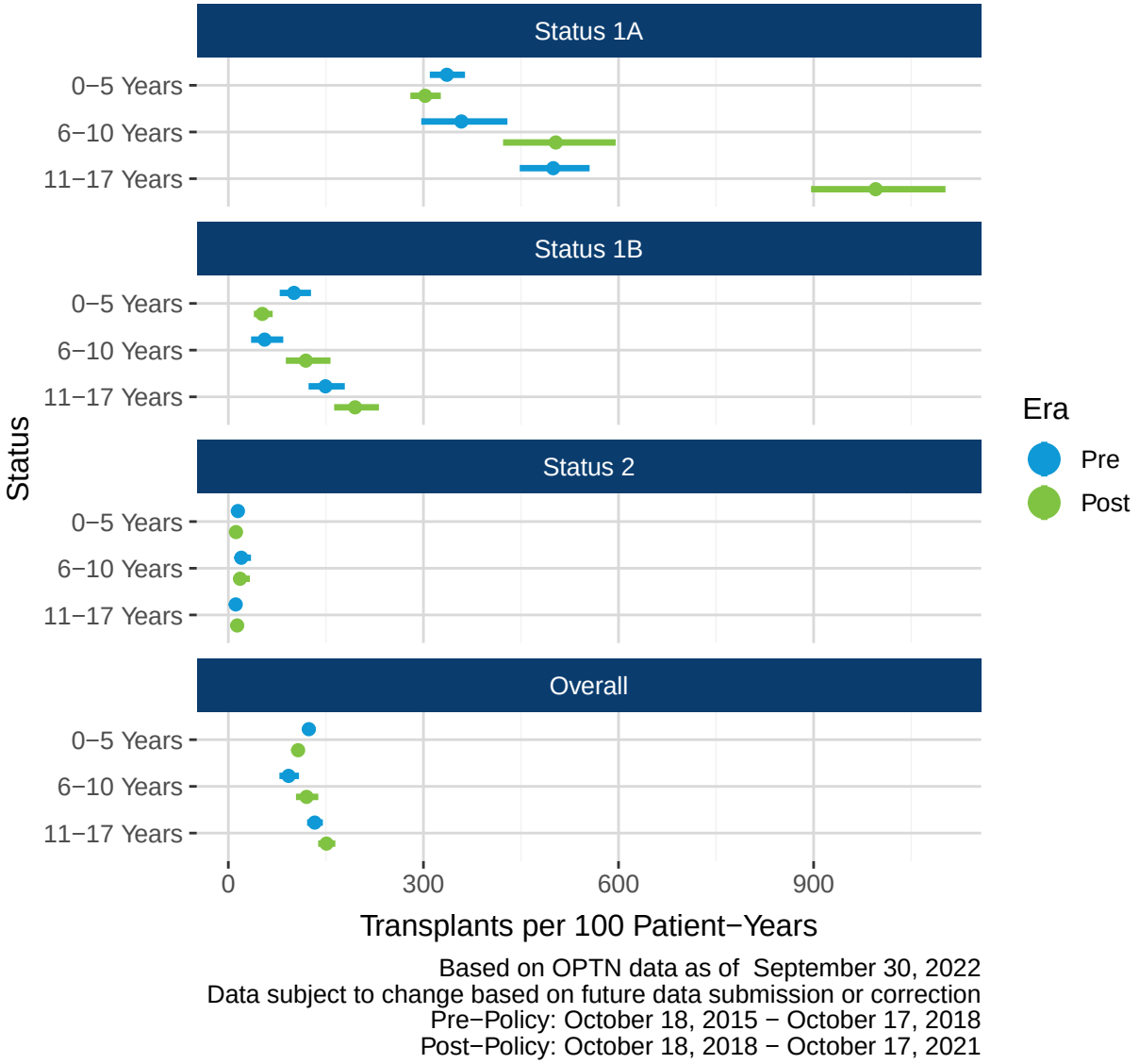


Figure 67 shows the number of transplants per 100 patient-years for pediatric heart candidates by age group, medical urgency status, and era. Post-implementation the number of transplants per 100 patient-years was significantly higher for Status 1A pediatric candidates 11-17 years old and for Status 1B pediatric candidates 6-10 years old. Conversely, the number of transplants per 100 patient-years was significantly lower post-implementation for Status 1B pediatric candidates 0-5 years old.

Table A17 shows the number of pediatric candidates ever waiting and the number of transplants per 100 patient-years for each medical urgency status and age group pre- and post-implementation, along with the relative risk of transplant and the corresponding 95% confidence interval. Overall the relative risk of transplant for pediatric candidates in the 6-10 years age group was significantly higher after the implementation of changes to adult heart allocation. The relative risk of transplant was also significantly higher in the post era for pediatric candidates in the 6-10 and 11-17 years age group at Statuses 1A and 1B.

Conclusion

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

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

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

Appendix

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

Region		Status 1A	Status 1B	Status 2	Temporarily Inactive	Total
1	N	163	216	176	6	561
	%	1.41%	1.86%	1.52%	0.05%	4.84%
2	N	249	582	369	15	1215
	%	2.15%	5.02%	3.18%	0.13%	10.48%
3	N	339	809	290	32	1470
	%	2.92%	6.98%	2.50%	0.28%	12.68%
4	N	262	635	313	36	1246
	%	2.26%	5.48%	2.70%	0.31%	10.74%
5	N	503	583	628	58	1772
	%	4.34%	5.03%	5.42%	0.50%	15.28%
6	N	70	178	117	4	369
	%	0.60%	1.53%	1.01%	0.03%	3.18%
7	N	289	417	319	23	1048
	%	2.49%	3.60%	2.75%	0.20%	9.04%
8	N	140	394	171	20	725
	%	1.21%	3.40%	1.47%	0.17%	6.25%
9	N	312	342	133	1	788
	%	2.69%	2.95%	1.15%	0.01%	6.79%
10	N	240	455	279	28	1002
	%	2.07%	3.92%	2.41%	0.24%	8.64%
11	N	350	755	269	27	1401
	%	3.02%	6.51%	2.32%	0.23%	12.08%

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	44	89	56	216	21	201	20	647
	%	0.37%	0.74%	0.47%	1.80%	0.18%	1.68%	0.17%	5.40%
2	N	52	218	92	494	24	272	6	1158
	%	0.43%	1.82%	0.77%	4.12%	0.20%	2.27%	0.05%	9.66%
3	N	55	339	165	551	31	258	10	1409
	%	0.46%	2.83%	1.38%	4.60%	0.26%	2.15%	0.08%	11.76%
4	N	49	228	99	465	42	252	16	1151
	%	0.41%	1.90%	0.83%	3.88%	0.35%	2.10%	0.13%	9.61%
5	N	71	398	368	541	40	367	30	1815
	%	0.59%	3.32%	3.07%	4.51%	0.33%	3.06%	0.25%	15.15%
6	N	26	51	28	140	7	94	6	352
	%	0.22%	0.43%	0.23%	1.17%	0.06%	0.78%	0.05%	2.94%
7	N	57	279	102	352	28	200	13	1031
	%	0.48%	2.33%	0.85%	2.94%	0.23%	1.67%	0.11%	8.60%
8	N	36	188	44	328	3	130	10	739
	%	0.30%	1.57%	0.37%	2.74%	0.03%	1.08%	0.08%	6.17%
9	N	56	219	88	305	31	208	1	908
	%	0.47%	1.83%	0.73%	2.55%	0.26%	1.74%	0.01%	7.58%
10	N	36	238	121	401	31	221	26	1074
	%	0.30%	1.99%	1.01%	3.35%	0.26%	1.84%	0.22%	8.96%
11	N	71	354	183	694	37	343	17	1699
	%	0.59%	2.95%	1.53%	5.79%	0.31%	2.86%	0.14%	14.18%

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	2.22%
	Exception	7	15.56%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	19	42.22%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	13	28.89%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	5	11.11%
Overall		45	100%
Adult Status 1 Region 2			
	BIVAD/Ventricular Episodes	3	5.45%
	Exception	6	10.91%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	3	5.45%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	15	27.27%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	28	50.91%
Overall		55	100%
Adult Status 1 Region 3			
	BIVAD/Ventricular Episodes	2	3.33%
	Exception	24	40.00%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	8	13.33%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	11	18.33%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	15	25.00%
Overall		60	100%
Adult Status 1 Region 4			
	BIVAD/Ventricular Episodes	4	7.69%
	Exception	19	36.54%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	3	5.77%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	18	34.62%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	8	15.38%
Overall		52	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 1 Region 5			
	BIVAD/Ventricular Episodes	2	2.60%
	Exception	17	22.08%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	4	5.19%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	34	44.16%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	20	25.97%
Overall		77	100%
Adult Status 1 Region 6			
	BIVAD/Ventricular Episodes	2	7.69%
	Exception	5	19.23%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	7	26.92%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	12	46.15%
Overall		26	100%
Adult Status 1 Region 7			
	BIVAD/Ventricular Episodes	4	6.90%
	Exception	15	25.86%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	8	13.79%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	22	37.93%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	9	15.52%
Overall		58	100%

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

	Criteria	Initial N	Initial %
Adult Status 1 Region 8			
	BIVAD/Ventricular Episodes	2	5.56%
	Exception	9	25.00%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	2	5.56%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	13	36.11%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	10	27.78%
Overall		36	100%
Adult Status 1 Region 9			
	BIVAD/Ventricular Episodes	2	3.23%
	Exception	12	19.35%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	9	14.52%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	24	38.71%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	15	24.19%
Overall		62	100%
Adult Status 1 Region 10			
	BIVAD/Ventricular Episodes	4	10.53%
	Exception	7	18.42%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	4	10.53%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	12	31.58%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	11	28.95%
Overall		38	100%
Adult Status 1 Region 11			
	BIVAD/Ventricular Episodes	3	4.05%
	Exception	15	20.27%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	23	31.08%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	16	21.62%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	17	22.97%
Overall		74	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 2			
Region 1			
	Exception	34	38.20%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	5	5.62%
	Intra-aortic ballon pump - Hemodynamic Values obtained	25	28.09%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	3	3.37%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	3	3.37%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	10	11.24%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	4	4.49%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	5	5.62%
Overall			
		89	100%
Adult Status 2			
Region 2			
	Exception	71	32.57%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	2	0.92%
	Intra-aortic ballon pump - Hemodynamic Values obtained	107	49.08%
	Mechanical circulatory support device(MCSD) with malfunction	6	2.75%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	5	2.29%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	0.46%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	20	9.17%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	3	1.38%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	3	1.38%
Overall			
		218	100%

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

Criteria		Initial N	Initial %
Adult Status 2			
Region 3			
	Exception	162	47.37%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	4	1.17%
	Intra-aortic ballon pump - Hemodynamic Values obtained	113	33.04%
	Mechanical circulatory support device(MCSD) with malfunction	9	2.63%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	4	1.17%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	2	0.58%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	36	10.53%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	12	3.51%
Overall			
		342	100%
Adult Status 2			
Region 4			
	Exception	119	51.29%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	2	0.86%
	Intra-aortic ballon pump - Hemodynamic Values obtained	52	22.41%
	Mechanical circulatory support device(MCSD) with malfunction	5	2.16%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.43%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	5	2.16%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	35	15.09%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	4	1.72%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	9	3.88%
Overall			
		232	100%
Adult Status 2			
Region 5			
	Exception	97	24.25%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	15	3.75%
	Intra-aortic ballon pump - Hemodynamic Values obtained	193	48.25%
	Mechanical circulatory support device(MCSD) with malfunction	5	1.25%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	3	0.75%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	15	3.75%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	56	14.00%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	12	3.00%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	4	1.00%
Overall			
		400	100%

Table A3: *(continued)*

	Criteria	Initial N	Initial %
Adult Status 2			
Region 6			
	Exception	14	27.45%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	1	1.96%
	Intra-aortic ballon pump - Hemodynamic Values obtained	14	27.45%
	Mechanical circulatory support device(MCSD) with malfunction	1	1.96%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	2	3.92%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	11	21.57%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	3	5.88%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	5	9.80%
Overall			
		51	100%
Adult Status 2			
Region 7			
	Exception	103	36.52%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	3	1.06%
	Intra-aortic ballon pump - Hemodynamic Values obtained	144	51.06%
	Mechanical circulatory support device(MCSD) with malfunction	3	1.06%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	3	1.06%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	13	4.61%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	7	2.48%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	6	2.13%
Overall			
		282	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 2			
Region 8			
	Exception	67	35.64%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	1	0.53%
	Intra-aortic ballon pump - Hemodynamic Values obtained	108	57.45%
	Mechanical circulatory support device(MCSD) with malfunction	3	1.60%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.53%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	4	2.13%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	1.06%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	2	1.06%
Overall			
		188	100%
Adult Status 2			
Region 9			
	Exception	76	34.08%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	4	1.79%
	Intra-aortic ballon pump - Hemodynamic Values obtained	119	53.36%
	Mechanical circulatory support device(MCSD) with malfunction	2	0.90%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.45%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	0.45%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	5	2.24%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	11	4.93%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	4	1.79%
Overall			
		223	100%
Adult Status 2			
Region 10			
	Exception	64	26.89%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	3	1.26%
	Intra-aortic ballon pump - Hemodynamic Values obtained	123	51.68%
	Mechanical circulatory support device(MCSD) with malfunction	8	3.36%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.42%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	2	0.84%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	24	10.08%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	7	2.94%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	6	2.52%
Overall			
		238	100%

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

Criteria		Initial N	Initial %
Adult Status 2			
Region 11			
	Exception	135	38.03%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	1	0.28%
	Intra-aortic ballon pump - Hemodynamic Values obtained	143	40.28%
	Mechanical circulatory support device(MCSD) with malfunction	9	2.54%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	12	3.38%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	3	0.85%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	24	6.76%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	13	3.66%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	15	4.23%
Overall			
		355	100%
Adult Status 3			
Region 1			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	35	60.34%
	Exception	7	12.07%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	1	1.72%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	1	1.72%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	1.72%
	Mechanical circulatory support device (MCSD) with pump thrombosis	1	1.72%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	12	20.69%
Overall			
		58	100%

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

	Criteria	Initial N	Initial %
Adult Status 3			
Region 2			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	31	33.70%
	Exception	12	13.04%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	1.09%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	7	7.61%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	3	3.26%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	1.09%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	1.09%
	Mechanical circulatory support device (MCSD) with right heart failure	3	3.26%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	33	35.87%
Overall		92	100%
Adult Status 3			
Region 3			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	20	12.12%
	Exception	61	36.97%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	9	5.45%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	4	2.42%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	4	2.42%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	4	2.42%
	Mechanical circulatory support device (MCSD) with hemolysis	1	0.61%
	Mechanical circulatory support device (MCSD) with pump thrombosis	3	1.82%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	59	35.76%
Overall		165	100%

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

	Criteria	Initial N	Initial %
Adult Status 3			
Region 4			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	8	7.92%
	Exception	32	31.68%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	0.99%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	3	2.97%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	6	5.94%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	1	0.99%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	3	2.97%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	1.98%
	Mechanical circulatory support device (MCSD) with hemolysis	1	0.99%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	0.99%
	Mechanical circulatory support device (MCSD) with pump thrombosis	2	1.98%
	Mechanical circulatory support device (MCSD) with right heart failure	1	0.99%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	40	39.60%
Overall		101	100%
Adult Status 3			
Region 5			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	53	14.25%
	Exception	88	23.66%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	0.27%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	9	2.42%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	4	1.08%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	1	0.27%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	2	0.54%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	0.27%
	Mechanical circulatory support device (MCSD) with hemolysis	1	0.27%
	Mechanical circulatory support device (MCSD) with pump thrombosis	4	1.08%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	208	55.91%
Overall		372	100%

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

Criteria	Initial N	Initial %
Adult Status 3		
Region 6		
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	1	3.57%
Exception	8	28.57%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	4	14.29%
Mechanical circulatory support device (MCSD) with device infection - Debridement	4	14.29%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	3.57%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	7.14%
Mechanical circulatory support device (MCSD) with hemolysis	1	3.57%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	7	25.00%
Overall		
	28	100%
Adult Status 3		
Region 7		
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	28	27.18%
Exception	20	19.42%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	2	1.94%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	16	15.53%
Mechanical circulatory support device (MCSD) with device infection - Debridement	1	0.97%
Mechanical circulatory support device (MCSD) with device infection - Erythema	3	2.91%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	2	1.94%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	1.94%
Mechanical circulatory support device (MCSD) with hemolysis	1	0.97%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	0.97%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	1	0.97%
Mechanical circulatory support device (MCSD) with pump thrombosis	7	6.80%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	19	18.45%
Overall		
	103	100%

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

	Criteria	Initial N	Initial %
Adult Status 3			
Region 8			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	9	20.45%
	Exception	9	20.45%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	7	15.91%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	2	4.55%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	2.27%
	Mechanical circulatory support device (MCSD) with hemolysis	1	2.27%
	Mechanical circulatory support device (MCSD) with pump thrombosis	3	6.82%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	12	27.27%
Overall		44	100%
Adult Status 3			
Region 9			
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	25	27.17%
	Exception	26	28.26%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	1.09%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	8	8.70%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	6	6.52%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	2	2.17%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	1.09%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	1.09%
	Mechanical circulatory support device (MCSD) with pump thrombosis	1	1.09%
	Mechanical circulatory support device (MCSD) with right heart failure	1	1.09%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	20	21.74%
Overall		92	100%

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

Criteria	Initial N	Initial %
Adult Status 3		
Region 10		
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	50	41.32%
Exception	19	15.70%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	2	1.65%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	12	9.92%
Mechanical circulatory support device (MCSD) with device infection - Debridement	11	9.09%
Mechanical circulatory support device (MCSD) with device infection - Erythema	2	1.65%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	1.65%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	1	0.83%
Mechanical circulatory support device (MCSD) with pump thrombosis	4	3.31%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	18	14.88%
Overall		
	121	100%
Adult Status 3		
Region 11		
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	58	31.35%
Exception	38	20.54%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	0.54%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	12	6.49%
Mechanical circulatory support device (MCSD) with device infection - Debridement	11	5.95%
Mechanical circulatory support device (MCSD) with device infection - Erythema	4	2.16%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	4	2.16%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	0.54%
Mechanical circulatory support device (MCSD) with hemolysis	1	0.54%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	2	1.08%
Mechanical circulatory support device (MCSD) with pump thrombosis	4	2.16%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	49	26.49%
Overall		
	185	100%
Adult Status 4		
Region 1		
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	49	22.48%
Congenital heart disease	14	6.42%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	85	38.99%
Exception	9	4.13%
Inotropes without hemodynamic monitoring	45	20.64%
Ischemic heart disease with intractable angina	5	2.29%
Retransplant	11	5.05%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Overall			
		218	100%
Adult Status 4			
Region 2			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	36	7.20%
	Congenital heart disease	37	7.40%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	218	43.60%
	Exception	106	21.20%
	Inotropes without hemodynamic monitoring	80	16.00%
	Ischemic heart disease with intractable angina	8	1.60%
	Retransplant	15	3.00%
Overall			
		500	100%
Adult Status 4			
Region 3			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	27	4.87%
	Congenital heart disease	25	4.51%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	200	36.10%
	Exception	171	30.87%
	Inotropes without hemodynamic monitoring	106	19.13%
	Ischemic heart disease with intractable angina	7	1.26%
	Retransplant	18	3.25%
Overall			
		554	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 4 Region 4			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	32	6.78%
	Congenital heart disease	27	5.72%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	186	39.41%
	Exception	152	32.20%
	Inotropes without hemodynamic monitoring	47	9.96%
	Ischemic heart disease with intractable angina	14	2.97%
	Retransplant	14	2.97%
Overall		472	100%
Adult Status 4 Region 5			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	93	16.76%
	Congenital heart disease	67	12.07%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	160	28.83%
	Exception	43	7.75%
	Inotropes without hemodynamic monitoring	131	23.60%
	Ischemic heart disease with intractable angina	6	1.08%
	Retransplant	55	9.91%
Overall		555	100%
Adult Status 4 Region 6			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	20	14.29%
	Congenital heart disease	6	4.29%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	63	45.00%
	Exception	17	12.14%
	Inotropes without hemodynamic monitoring	26	18.57%
	Ischemic heart disease with intractable angina	4	2.86%
	Retransplant	4	2.86%
Overall		140	100%
Adult Status 4 Region 7			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	37	10.39%
	Congenital heart disease	36	10.11%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	164	46.07%
	Exception	48	13.48%
	Inotropes without hemodynamic monitoring	39	10.96%
	Ischemic heart disease with intractable angina	9	2.53%
	Retransplant	23	6.46%
Overall		356	100%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 4 Region 8			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	27	8.21%
	Congenital heart disease	24	7.29%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	109	33.13%
	Exception	63	19.15%
	Inotropes without hemodynamic monitoring	79	24.01%
	Ischemic heart disease with intractable angina	9	2.74%
	Retransplant	18	5.47%
Overall		329	100%
Adult Status 4 Region 9			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	38	12.46%
	Congenital heart disease	12	3.93%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	180	59.02%
	Exception	14	4.59%
	Inotropes without hemodynamic monitoring	37	12.13%
	Ischemic heart disease with intractable angina	3	0.98%
	Retransplant	21	6.89%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Overall		305	100%
Adult Status 4 Region 10			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	44	10.84%
	Congenital heart disease	38	9.36%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	240	59.11%
	Exception	27	6.65%
	Inotropes without hemodynamic monitoring	32	7.88%
	Ischemic heart disease with intractable angina	8	1.97%
	Retransplant	17	4.19%
Overall		406	100%
Adult Status 4 Region 11			
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	54	7.76%
	Congenital heart disease	42	6.03%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	307	44.11%
	Exception	134	19.25%
	Inotropes without hemodynamic monitoring	106	15.23%
	Ischemic heart disease with intractable angina	10	1.44%
	Retransplant	43	6.18%
Overall		696	100%
Adult Status 5 Region 1			
	None	22	100.00%
Adult Status 5 Region 2			
	None	28	100.00%
Adult Status 5 Region 3			
	None	40	100.00%
Adult Status 5 Region 4			
	None	54	100.00%
Adult Status 5 Region 5			
	None	53	100.00%
Adult Status 5 Region 6			
	None	8	100.00%
Adult Status 5 Region 7			
	None	35	100.00%
Adult Status 5 Region 8			
	None	3	100.00%
Adult Status 5 Region 9			
	None	39	100.00%

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

Criteria		Initial N	Initial %
Adult Status 5 Region 10			
	None	36	100.00%
Adult Status 5 Region 11			
	None	39	100.00%
Adult Status 6 Region 1			
	None	201	100.00%
Adult Status 6 Region 2			
	None	276	100.00%
Adult Status 6 Region 3			
	None	259	100.00%
Adult Status 6 Region 4			
	None	254	100.00%
Adult Status 6 Region 5			
	None	367	100.00%
Adult Status 6 Region 6			
	None	94	100.00%
Adult Status 6 Region 7			
	None	202	100.00%

Table A3: *(continued)*

Criteria		Initial N	Initial %
Adult Status 6 Region 8			
	None	130	100.00%
Adult Status 6 Region 9			
	None	212	100.00%
Adult Status 6 Region 10			
	None	221	100.00%
Adult Status 6 Region 11			
	None	343	100.00%

Table A4: Mechanical Circulatory Support Devices at Listing by Region

Brand	Era	Count	Percent
Region 1 ECMO			
Total ECMO	**Pre**	**12**	**5.56%**
	Post	**26**	**9.39%**
Region 1 IABP			
Total IABP	**Pre**	**18**	**8.33%**
	Post	**56**	**20.22%**
Region 1 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	6	3.8%
	Post	3	2.13%
Heartmate II	Pre	72	45.57%
	Post	9	6.38%
HeartMate III	Pre	5	3.16%
	Post	90	63.83%
Heartsaver VAD	Pre	1	0.63%
	Post	1	0.71%
Heartware HVAD	Pre	43	27.22%
	Post	22	15.6%
Impella CP	Pre	0	0%
	Post	1	0.71%
Impella Recover 2.5	Pre	1	0.63%
	Post	0	0%
Impella Recover 5.0	Pre	5	3.16%
	Post	2	1.42%
Other, Specify	Pre	25	15.82%
	Post	13	9.22%
Total LVAD	**Pre**	**158**	**73.15%**
	Post	**141**	**50.9%**
Region 1 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	3	5.77%
Cardiac Assist Tandem Heart	Pre	2	7.14%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	19	67.86%
	Post	39	75%
Heartmate II	Pre	4	14.29%
	Post	0	0%
	Pre	0	0%

HeartMate III	Post	7	13.46%
Heartware HVAD	Pre	0	0%
	Post	2	3.85%
Impella Recover 5.0	Pre	1	3.57%
	Post	1	1.92%
Other, Specify	Pre	2	7.14%
	Post	0	0%
Total LVAD+RVAD	**Pre**	**28**	**12.96%**
	Post	**52**	**18.77%**
Region 1 RVAD			
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	1	50%
Other, Specify	Pre	0	0%
	Post	1	50%
Total RVAD	**Pre**	**0**	**0%**
	Post	**2**	**0.72%**
Region 2 ECMO			
Total ECMO	**Pre**	**30**	**6.38%**
	Post	**41**	**8.07%**
Region 2 IABP			
Total IABP	**Pre**	**35**	**7.45%**
	Post	**150**	**29.53%**
Region 2 LVAD			
Cardiac Assist Tandem Heart	Pre	1	0.26%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	4	1.05%
	Post	4	1.31%
Heartmate II	Pre	198	52.11%
	Post	37	12.09%
HeartMate III	Pre	5	1.32%
	Post	148	48.37%
Heartsaver VAD	Pre	1	0.26%
	Post	0	0%
Heartware HVAD	Pre	96	25.26%
	Post	61	19.93%
Impella CP	Pre	1	0.26%
	Post	8	2.61%
	Pre	2	0.53%

Impella Recover 2.5	Post	1	0.33%
Impella Recover 5.0	Pre	10	2.63%
	Post	7	2.29%
Thoratec PVAD	Pre	1	0.26%
	Post	0	0%
Other, Specify	Pre	61	16.05%
	Post	40	13.07%
Total LVAD	**Pre**	**380**	**80.85%**
	Post	**306**	**60.24%**
Region 2 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	12.5%
CentriMag (Thoratec/Levitronix)	Pre	11	55%
	Post	4	50%
HeartMate III	Pre	0	0%
	Post	1	12.5%
Heartware HVAD	Pre	7	35%
	Post	0	0%
Thoratec PVAD	Pre	0	0%
	Post	1	12.5%
Other, Specify	Pre	2	10%
	Post	1	12.5%
Total LVAD+RVAD	**Pre**	**20**	**4.26%**
	Post	**8**	**1.57%**
Region 2 RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	33.33%
CentriMag (Thoratec/Levitronix)	Pre	1	100%
	Post	0	0%
Impella Recover 5.0	Pre	0	0%
	Post	1	33.33%
Other, Specify	Pre	0	0%
	Post	1	33.33%
Total RVAD	**Pre**	**1**	**0.21%**
	Post	**3**	**0.59%**
Region 2 TAH			
SynCardia CardioWest	Pre	4	100%
	Post	0	0%
	Pre	**4**	**0.85%**

Total TAH	**Post**	**0**	**0%**
Region 3 ECMO			
Total ECMO	**Pre**	**16**	**3.29%**
	Post	**38**	**6.31%**
Region 3 IABP			
Total IABP	**Pre**	**104**	**21.4%**
	Post	**192**	**31.89%**
Region 3 LVAD			
Cardiac Assist Tandem Heart	Pre	2	0.59%
	Post	1	0.29%
CentriMag (Thoratec/Levitronix)	Pre	2	0.59%
	Post	3	0.88%
Heartmate II	Pre	180	53.41%
	Post	48	14.04%
HeartMate III	Pre	5	1.48%
	Post	158	46.2%
Heartmate XVE	Pre	1	0.3%
	Post	0	0%
Heartware HVAD	Pre	64	18.99%
	Post	67	19.59%
Impella CP	Pre	0	0%
	Post	2	0.58%
Impella Recover 2.5	Pre	1	0.3%
	Post	0	0%
Impella Recover 5.0	Pre	8	2.37%
	Post	27	7.89%
Jarvik 2000	Pre	1	0.3%
	Post	0	0%
Other, Specify	Pre	73	21.66%
	Post	36	10.53%
Total LVAD	**Pre**	**337**	**69.34%**
	Post	**342**	**56.81%**
Region 3 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	7.14%
Cardiac Assist Tandem Heart	Pre	5	19.23%
	Post	1	3.57%
CentriMag (Thoratec/Levitronix)	Pre	7	26.92%
	Post	15	53.57%

Heartmate II	Pre	3	11.54%
	Post	0	0%
Heartware HVAD	Pre	6	23.08%
	Post	4	14.29%
Thoratec PVAD	Pre	1	3.85%
	Post	0	0%
Other, Specify	Pre	4	15.38%
	Post	6	21.43%
Total LVAD+RVAD	**Pre**	**26**	**5.35%**
	Post	**28**	**4.65%**
Region 3 RVAD			
CentriMag (Thoratec/Levitronix)	Pre	2	100%
	Post	0	0%
Impella Recover 5.0	Pre	0	0%
	Post	1	50%
Other, Specify	Pre	0	0%
	Post	1	50%
Total RVAD	**Pre**	**2**	**0.41%**
	Post	**2**	**0.33%**
Region 4 ECMO			
SynCardia CardioWest	Pre	1	100%
	Post	0	0%
Region 4 IABP			
Total TAH	**Pre**	**1**	**0.21%**
	Post	**0**	**0%**
Region 4 LVAD			
Total ECMO	**Pre**	**20**	**4.35%**
	Post	**35**	**7.74%**
Total IABP	**Pre**	**95**	**20.65%**
	Post	**112**	**24.78%**
Cardiac Assist Tandem Heart	Pre	1	0.31%
	Post	1	0.34%
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	1	0.34%
Heartmate II	Pre	205	64.06%
	Post	58	19.53%
HeartMate III	Pre	0	0%
	Post	84	28.28%
	Pre	1	0.31%

Heartmate XVE	Post	0	0%
Heartware HVAD	Pre	63	19.69%
	Post	91	30.64%
Impella CP	Pre	0	0%
	Post	6	2.02%
Impella Recover 2.5	Pre	5	1.56%
	Post	0	0%
Impella Recover 5.0	Pre	12	3.75%
	Post	43	14.48%
Jarvik 2000	Pre	1	0.31%
	Post	0	0%
Terumo DuraHeart	Pre	1	0.31%
	Post	0	0%
Thoratec PVAD	Pre	1	0.31%
	Post	0	0%
Region 4 LVAD+RVAD			
Other, Specify	Pre	30	9.38%
	Post	13	4.38%
Total LVAD	**Pre**	**320**	**69.57%**
	Post	**297**	**65.71%**
Cardiac Assist Tandem Heart	Pre	2	11.11%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	6	33.33%
	Post	4	66.67%
Heartmate II	Pre	2	11.11%
	Post	0	0%
Heartware HVAD	Pre	5	27.78%
	Post	0	0%
Impella Recover 5.0	Pre	1	5.56%
	Post	1	16.67%
Maquet Jostra Rotaflow	Pre	2	11.11%
	Post	0	0%
Region 4 TAH			
Other, Specify	Pre	0	0%
	Post	1	16.67%
Total LVAD+RVAD	**Pre**	**18**	**3.91%**
	Post	**6**	**1.33%**
Region 5 ECMO			
	Pre	7	100%

SynCardia CardioWest	Post	2	100%
Region 5 IABP			
Total TAH	**Pre**	**7**	**1.52%**
	Post	**2**	**0.44%**
Region 5 LVAD			
Total ECMO	**Pre**	**29**	**5.84%**
	Post	**66**	**9.66%**
Total IABP	**Pre**	**51**	**10.26%**
	Post	**228**	**33.38%**
Cardiac Assist Tandem Heart	Pre	3	0.78%
	Post	2	0.57%
Heartmate II	Pre	123	31.78%
	Post	27	7.74%
HeartMate III	Pre	7	1.81%
	Post	126	36.1%
Heartmate XVE	Pre	1	0.26%
	Post	0	0%
Heartware HVAD	Pre	199	51.42%
	Post	109	31.23%
Impella CP	Pre	0	0%
	Post	19	5.44%
Impella Recover 2.5	Pre	2	0.52%
	Post	1	0.29%
Impella Recover 5.0	Pre	11	2.84%
	Post	28	8.02%
Region 5 LVAD+RVAD			
Other, Specify	Pre	41	10.59%
	Post	37	10.6%
Total LVAD	**Pre**	**387**	**77.87%**
	Post	**349**	**51.1%**
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	4	12.5%
CentriMag (Thoratec/Levitronix)	Pre	5	27.78%
	Post	10	31.25%
Heartmate II	Pre	1	5.56%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	1	3.12%
	Pre	9	50%

Heartware HVAD	Post	7	21.88%
Impella CP	Pre	0	0%
	Post	1	3.12%
Impella Recover 2.5	Pre	2	11.11%
	Post	0	0%
Impella Recover 5.0	Pre	0	0%
	Post	2	6.25%
Region 5 RVAD			
Other, Specify	Pre	1	5.56%
	Post	7	21.88%
Total LVAD+RVAD	**Pre**	**18**	**3.62%**
	Post	**32**	**4.69%**
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	33.33%
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	1	33.33%
Heartmate II	Pre	1	50%
	Post	0	0%
Impella Recover 5.0	Pre	1	50%
	Post	0	0%
Region 5 TAH			
Impella RP	Pre	0	0%
	Post	1	33.33%
Total RVAD	**Pre**	**2**	**0.4%**
	Post	**3**	**0.44%**
Region 6 ECMO			
SynCardia CardioWest	Pre	10	100%
	Post	5	100%
Region 6 IABP			
Total TAH	**Pre**	**10**	**2.01%**
	Post	**5**	**0.73%**
Region 6 LVAD			
Total ECMO	**Pre**	**9**	**5.49%**
	Post	**22**	**13.02%**
Total IABP	**Pre**	**9**	**5.49%**
	Post	**20**	**11.83%**
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	1	0.83%
	Pre	54	40.91%

Heartmate II	Post	13	10.74%
HeartMate III	Pre	2	1.52%
	Post	49	40.5%
Heartmate XVE	Pre	1	0.76%
	Post	0	0%
Heartware HVAD	Pre	55	41.67%
	Post	31	25.62%
Impella CP	Pre	1	0.76%
	Post	14	11.57%
Impella Recover 5.0	Pre	2	1.52%
	Post	2	1.65%
Region 6 LVAD+RVAD			
Other, Specify	Pre	17	12.88%
	Post	11	9.09%
Total LVAD	**Pre**	**132**	**80.49%**
	Post	**121**	**71.6%**
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	1	50%
CentriMag (Thoratec/Levitronix)	Pre	4	66.67%
	Post	0	0%
Heartmate II	Pre	1	16.67%
	Post	0	0%
Region 6 RVAD			
Heartware HVAD	Pre	1	16.67%
	Post	1	50%
Total LVAD+RVAD	**Pre**	**6**	**3.66%**
	Post	**2**	**1.18%**
Region 6 TAH			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	100%
Total RVAD	**Pre**	**0**	**0%**
	Post	**1**	**0.59%**
Region 7 ECMO			
SynCardia CardioWest	Pre	8	100%
	Post	3	100%
Region 7 IABP			
Total TAH	**Pre**	**8**	**4.88%**
	Post	**3**	**1.78%**
Region 7 LVAD			

Total ECMO	**Pre**	**26**	**4.9%**
	Post	**42**	**8.09%**
Total IABP	**Pre**	**108**	**20.34%**
	Post	**179**	**34.49%**
CentriMag (Thoratec/Levitronix)	Pre	6	1.61%
	Post	2	0.75%
Heartmate II	Pre	164	44.09%
	Post	32	11.94%
HeartMate III	Pre	2	0.54%
	Post	132	49.25%
Heartsaver VAD	Pre	0	0%
	Post	2	0.75%
Heartware HVAD	Pre	127	34.14%
	Post	84	31.34%
Impella CP	Pre	0	0%
	Post	2	0.75%
Impella Recover 5.0	Pre	5	1.34%
	Post	5	1.87%
Thoratec IVAD	Pre	0	0%
	Post	1	0.37%
Region 7 LVAD+RVAD			
Other, Specify	Pre	68	18.28%
	Post	8	2.99%
Total LVAD	**Pre**	**372**	**70.06%**
	Post	**268**	**51.64%**
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	8.33%
CentriMag (Thoratec/Levitronix)	Pre	9	37.5%
	Post	13	54.17%
HeartMate III	Pre	0	0%
	Post	4	16.67%
Heartware HVAD	Pre	14	58.33%
	Post	4	16.67%
Impella Recover 5.0	Pre	0	0%
	Post	1	4.17%
Region 7 TAH			
Other, Specify	Pre	1	4.17%
	Post	0	0%
	Pre	**24**	**4.52%**

Total LVAD+RVAD	**Post**	**24**	**4.62%**
Region 8 ECMO			
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	2	66.67%
Region 8 IABP			
Impella Recover 5.0	Pre	0	0%
	Post	1	33.33%
Region 8 LVAD			
Total RVAD	**Pre**	**0**	**0%**
	Post	**3**	**0.58%**
SynCardia CardioWest	Pre	1	100%
	Post	3	100%
Total TAH	**Pre**	**1**	**0.19%**
	Post	**3**	**0.58%**
Total ECMO	**Pre**	**9**	**3.21%**
	Post	**28**	**8.31%**
Total IABP	**Pre**	**46**	**16.43%**
	Post	**135**	**40.06%**
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	0.63%
Heartmate II	Pre	132	60.55%
	Post	29	18.12%
Region 8 LVAD+RVAD			
HeartMate III	Pre	3	1.38%
	Post	83	51.88%
Heartware HVAD	Pre	47	21.56%
	Post	36	22.5%
Impella Recover 5.0	Pre	1	0.46%
	Post	3	1.87%
Other, Specify	Pre	35	16.06%
	Post	8	5%
Total LVAD	**Pre**	**218**	**77.86%**
	Post	**160**	**47.48%**
Cardiac Assist Protek Duo	Pre	0	0%
	Post	4	33.33%
CentriMag (Thoratec/Levitronix)	Pre	3	50%
	Post	1	8.33%
	Pre	2	33.33%

Heartmate II	Post	0	0%
Region 8 RVAD			
HeartMate III	Pre	0	0%
	Post	2	16.67%
Heartware HVAD	Pre	1	16.67%
	Post	2	16.67%
Impella RP	Pre	0	0%
	Post	1	8.33%
Other, Specify	Pre	0	0%
	Post	2	16.67%
Region 9 ECMO			
Total LVAD+RVAD	**Pre**	**6**	**2.14%**
	Post	**12**	**3.56%**
Region 9 IABP			
Cardiac Assist Tandem Heart	Pre	1	100%
	Post	0	0%
Region 9 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	1	50%
Impella CP	Pre	0	0%
	Post	1	50%
Total RVAD	**Pre**	**1**	**0.36%**
	Post	**2**	**0.59%**
Total ECMO	**Pre**	**25**	**6.28%**
	Post	**47**	**9.11%**
Total IABP	**Pre**	**21**	**5.28%**
	Post	**176**	**34.11%**
CentriMag (Thoratec/Levitronix)	Pre	1	0.31%
	Post	1	0.39%
Evaheart	Pre	1	0.31%
	Post	0	0%
Heartmate II	Pre	213	65.34%
	Post	35	13.62%
HeartMate III	Pre	11	3.37%
	Post	185	71.98%
Heartware HVAD	Pre	34	10.43%
	Post	24	9.34%
Impella CP	Pre	0	0%
	Post	3	1.17%

Region 9 LVAD+RVAD			
Impella Recover 2.5	Pre	1	0.31%
	Post	0	0%
Impella Recover 5.0	Pre	0	0%
	Post	3	1.17%
Jarvik 2000	Pre	2	0.61%
	Post	0	0%
Other, Specify	Pre	63	19.33%
	Post	6	2.33%
Total LVAD	**Pre**	**326**	**81.91%**
	Post	**257**	**49.81%**
Cardiac Assist Tandem Heart	Pre	1	4.17%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	10	41.67%
	Post	14	46.67%
Heartmate II	Pre	3	12.5%
	Post	0	0%
Region 9 RVAD			
HeartMate III	Pre	0	0%
	Post	12	40%
Heartware HVAD	Pre	5	20.83%
	Post	0	0%
Region 9 TAH			
Thoratec PVAD	Pre	0	0%
	Post	1	3.33%
Other, Specify	Pre	5	20.83%
	Post	3	10%
Region 10 ECMO			
Total LVAD+RVAD	**Pre**	**24**	**6.03%**
	Post	**30**	**5.81%**
Region 10 IABP			
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	1	100%
Region 10 LVAD			
Total RVAD	**Pre**	**0**	**0%**
	Post	**1**	**0.19%**
SynCardia CardioWest	Pre	2	100%
	Post	5	100%
	Pre	**2**	**0.5%**

Total TAH	**Post**	**5**	**0.97%**
Total ECMO	**Pre**	**15**	**3.12%**
	Post	**27**	**4.59%**
Total IABP	**Pre**	**39**	**8.13%**
	Post	**144**	**24.49%**
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	0.25%
CentriMag (Thoratec/Levitronix)	Pre	2	0.5%
	Post	2	0.51%
Heartmate II	Pre	191	47.39%
	Post	57	14.5%
HeartMate III	Pre	9	2.23%
	Post	206	52.42%
Heartsaver VAD	Pre	0	0%
	Post	1	0.25%
Heartware HVAD	Pre	128	31.76%
	Post	71	18.07%
Impella CP	Pre	0	0%
	Post	5	1.27%
Impella Recover 2.5	Pre	1	0.25%
	Post	0	0%
Region 10 LVAD+RVAD			
Impella Recover 5.0	Pre	8	1.99%
	Post	11	2.8%
Impella RP	Pre	0	0%
	Post	1	0.25%
Thoratec IVAD	Pre	0	0%
	Post	1	0.25%
Other, Specify	Pre	64	15.88%
	Post	37	9.41%
Total LVAD	**Pre**	**403**	**83.96%**
	Post	**393**	**66.84%**
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	10%
CentriMag (Thoratec/Levitronix)	Pre	9	45%
	Post	6	30%
Heartmate II	Pre	1	5%
	Post	0	0%
Region 10 RVAD			

HeartMate III	Pre	0	0%
	Post	4	20%
Heartware HVAD	Pre	8	40%
	Post	4	20%
Impella Recover 5.0	Pre	1	5%
	Post	1	5%
Other, Specify	Pre	1	5%
	Post	3	15%
Total LVAD+RVAD	**Pre**	**20**	**4.17%**
	Post	**20**	**3.4%**
Region 10 TAH			
CentriMag (Thoratec/Levitronix)	Pre	2	66.67%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	1	50%
Heartware HVAD	Pre	1	33.33%
	Post	0	0%
Region 11 ECMO			
Impella Recover 5.0	Pre	0	0%
	Post	1	50%
Region 11 IABP			
Total RVAD	**Pre**	**3**	**0.63%**
	Post	**2**	**0.34%**
Region 11 LVAD			
SynCardia CardioWest	Pre	0	0%
	Post	1	50%
Other, Specify	Pre	0	0%
	Post	1	50%
Total TAH	**Pre**	**0**	**0%**
	Post	**2**	**0.34%**
Total ECMO	**Pre**	**17**	**2.58%**
	Post	**52**	**6.06%**
Total IABP	**Pre**	**87**	**13.18%**
	Post	**229**	**26.69%**
Cardiac Assist Protek Duo	Pre	0	0%
	Post	10	2%
CentriMag (Thoratec/Levitronix)	Pre	4	0.78%
	Post	12	2.4%
	Pre	0	0%

Evaheart	Post	1	0.2%
Heartmate II	Pre	259	50.29%
	Post	73	14.6%
HeartMate III	Pre	10	1.94%
	Post	256	51.2%
Heartsaver VAD	Pre	0	0%
	Post	1	0.2%
Heartware HVAD	Pre	177	34.37%
	Post	107	21.4%
Impella CP	Pre	0	0%
	Post	3	0.6%
Region 11 LVAD+RVAD			
Impella Recover 2.5	Pre	0	0%
	Post	1	0.2%
Impella Recover 5.0	Pre	1	0.19%
	Post	12	2.4%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	3	0.6%
Other, Specify	Pre	64	12.43%
	Post	21	4.2%
Total LVAD	**Pre**	**515**	**78.03%**
	Post	**500**	**58.28%**
Abiomed AB5000	Pre	0	0%
	Post	1	1.56%
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	3.12%
CentriMag (Thoratec/Levitronix)	Pre	6	27.27%
	Post	32	50%
Heartmate II	Pre	1	4.55%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	5	7.81%
Heartware HVAD	Pre	2	9.09%
	Post	1	1.56%
Region 11 RVAD			
Impella Recover 5.0	Pre	0	0%
	Post	1	1.56%
Maquet Jostra Rotaflow	Pre	5	22.73%
	Post	16	25%

Thoratec PVAD	Pre	4	18.18%
	Post	0	0%
Other, Specify	Pre	4	18.18%
	Post	6	9.38%
Total LVAD+RVAD	**Pre**	**22**	**3.33%**
	Post	**64**	**7.46%**
Region 11 TAH			
CentriMag (Thoratec/Levitronix)	Pre	1	50%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	1	33.33%
Maquet Jostra Rotaflow	Pre	1	50%
	Post	1	33.33%
Other, Specify	Pre	0	0%
	Post	1	33.33%
Total RVAD	**Pre**	**2**	**0.3%**
	Post	**3**	**0.35%**
SynCardia CardioWest	Pre	17	100%
	Post	7	70%
Other, Specify	Pre	0	0%
	Post	3	30%
Total TAH	**Pre**	**17**	**2.58%**
	Post	**10**	**1.17%**

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

Device	Brand	Count	Percent
IABP	**Total**	**1762**	**31.59%**
Left Dischargeable VAD	Evaheart	2	0.08%
	Heartmate II	411	15.43%
	HeartMate III	1505	56.49%
	Heartsaver VAD	1	0.04%
	Heartware HVAD	740	27.78%
	Worldheart Levacor	1	0.04%
	Other, Specify	4	0.15%
Left Dischargeable VAD	**Total**	**2664**	**47.76%**
Left Non-Dischargeable VAD	Abiomed AB5000	1	0.93%
	CentriMag (Thoratec/Levitronix)	83	76.85%
	Maquet Jostra Rotaflow	9	8.33%
	Other, Specify	15	13.89%

Left Non-Dischargeable VAD	**Total**	**108**	**1.94%**
Left Percutaneous Device	Cardiac Assist Protek Duo	1	0.22%
	Cardiac Assist Tandem Heart	7	1.53%
	CentriMag (Thoratec/Levitronix)	1	0.22%
	Impella CP	79	17.25%
	Impella Recover 2.5	4	0.87%
	Impella Recover 5.0	161	35.15%
	Other, Specify	205	44.76%
Left Percutaneous Device	**Total**	**458**	**8.21%**
Right Dischargeable VAD	HeartMate III	6	46.15%
	Heartware HVAD	6	46.15%
	Other, Specify	1	7.69%
Right Dischargeable VAD	**Total**	**13**	**0.23%**
Right Non-Dischargeable VAD	CentriMag (Thoratec/Levitronix)	93	81.58%
	Maquet Jostra Rotaflow	10	8.77%
	Other, Specify	11	9.65%
Right Non-Dischargeable VAD	**Total**	**114**	**2.04%**
Right Percutaneous Device	Cardiac Assist Protek Duo	12	41.38%
	Cardiac Assist Tandem Heart	5	17.24%
	CentriMag (Thoratec/Levitronix)	3	10.34%
	Impella CP	1	3.45%
	Impella Recover 5.0	3	10.34%
	Impella RP	2	6.9%
	Other, Specify	3	10.34%
Right Percutaneous Device	**Total**	**29**	**0.52%**
Single Dischargeable VAD	HeartMate III	3	60%
	Heartware HVAD	2	40%
Single Dischargeable VAD	**Total**	**5**	**0.09%**
Single Non-Dischargeable VAD	**Total**	**1**	**0.02%**
Single Percutaneous Device	Cardiac Assist Tandem Heart	1	50%
	Other, Specify	1	50%
Single Percutaneous Device	**Total**	**2**	**0.04%**
TAH	SynCardia CardioWest	21	84%
	Other, Specify	4	16%
TAH	**Total**	**25**	**0.45%**
VA ECMO	**Total**	**397**	**7.12%**

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	8510	259	22	[19, 25]
	Status 1B	9366	246	5	[5, 6]
	Status 2	3818	103	4	[4, 5]
	Temporarily Inactive	5433	930	40	[38, 43]
Pre	**Overall**	**14224**	**1538**	**15**	**[14, 15]**
Post	Adult Status 1	1034	46	185	[135, 247]
	Adult Status 2	5409	72	29	[23, 37]
	Adult Status 3	4393	35	6	[4, 9]
	Adult Status 4	7102	167	4	[3, 5]
	Adult Status 5	614	26	10	[6, 15]
	Adult Status 6	3638	43	3	[2, 4]
	Temporarily Inactive	5069	832	39	[37, 42]
Post	**Overall**	**14566**	**1227**	**14**	**[13, 14]**

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

Status	CriteriaDescription	Patients Ever Waiting	Number of Deaths	Deaths per 100 Patient Years	CI
Adult Status 1	BIVAD/Ventricular Episodes	81	1	56	[1, 310]
	Exception	416	10	91	[44, 167]
	Surgically implanted non-endovascular biventricular support device	133	7	137	[55, 283]
	VA ECMO	530	7	82	[33, 170]
Adult Status 2	Exception	2539	12	10	[5, 17]
	IABP	2306	5	7	[2, 16]
	MCSD with malfunction	257	0	0	-
	Non-dischargeable, surgically implanted, non-endovascular LVAD	67	3	154	[32, 451]
	Percutaneous endovascular MCSD	496	3	19	[4, 55]
	TAH, BiVAD, RVAD, or VAD for single ventricle patients	157	4	18	[5, 45]
	VT or VF	123	1	26	[1, 144]
	Dischargeable LVAD for discretionary 30 days	1836	1	1	[0, 5]
	Exception	1229	7	7	[3, 14]
	IABP after 14 days	45	0	0	-
	MCSD with Aortic Insufficiency	78	0	0	-
	MCSD with device infection	557	2	1	[0, 4]
	MCSD with hemolysis	52	0	0	-
	MCSD with mucosal bleeding	67	0	0	-
	MCSD with pump thrombosis	119	1	2	[0, 9]
	MCSD with right heart failure	48	3	24	[5, 70]
	Multiple/single high dose inotrope & hemodynamic monitoring	979	4	10	[3, 26]

Adult Status 3					
	Non-dischargeable, surgically implanted, non-endovascular LVAD >14 days	2	0	0	-
	Percutaneous endovascular circulatory support device after 14 days	9	0	0	-
	VA ECMO after 7 days	2	0		-
Adult Status 4	Amyloidosis/hypertrophic/restrictive cardiomyopathy	574	3	1	[0, 3]
	Congenital heart disease	428	9	4	[2, 7]
	Dischargeable LVAD without discretionary 30 days	3715	56	2	[1, 2]
	Exception	1238	11	3	[1, 5]
	Inotropes without hemodynamic monitoring	1250	9	5	[2, 10]
	Ischemic heart disease with intractable angina	136	3	4	[1, 11]
	Retransplant	303	12	7	[4, 13]

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

Region	Era	Patients Ever Waiting	Deaths per 100 Patient Years	Relative Risk	CI
1	Pre	791	11	Ref	-
	Post	857	10	0.95	[0.71, 1.27]
2	Pre	1562	17	Ref	-
	Post	1444	14	0.82	[0.65, 1.04]
3	Pre	1835	18	Ref	-
	Post	1771	18	1.02	[0.73, 1.42]
4	Pre	1511	13	Ref	-
	Post	1434	15	1.09	[0.83, 1.43]
5	Pre	1990	13	Ref	-
	Post	2096	13	0.98	[0.77, 1.24]
6	Pre	443	15	Ref	-
	Post	394	14	0.96	[0.66, 1.40]
7	Pre	1451	14	Ref	-
	Post	1382	11	0.83	[0.65, 1.05]
8	Pre	850	17	Ref	-
	Post	876	16	0.94	[0.71, 1.23]
9	Pre	1050	10	Ref	-
	Post	1196	11	1.06	[0.74, 1.52]
10	Pre	1256	16	Ref	-
	Post	1363	12	0.76	[0.58, 1.00]
11	Pre	1729	17	Ref	-
	Post	1920	16	0.96	[0.76, 1.19]
Overall	**Pre**	**14224**	**15**	**Ref**	-
	Post	**14566**	**14**	**0.93**	**[0.86, 1.00]**

Table A9: 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	22	36.67%	1	9.09%	23	32.39%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	17	28.33%	9	81.82%	26	36.62%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	13	21.67%	0	0.00%	13	18.31%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	8	13.33%	1	9.09%	9	12.68%
Overall	60	100%	11	100%	71	100%
Adult Status 1 Region 2						
BIVAD/Ventricular Episodes	6	8.00%	0	0.00%	6	7.06%
Exception	24	32.00%	3	30.00%	27	31.76%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	5	6.67%	0	0.00%	5	5.88%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	11	14.67%	2	20.00%	13	15.29%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	29	38.67%	5	50.00%	34	40.00%
Overall	75	100%	10	100%	85	100%
Adult Status 1 Region 3						
BIVAD/Ventricular Episodes	5	6.10%	2	15.38%	7	7.37%
Exception	45	54.88%	8	61.54%	53	55.79%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	5	6.10%	2	15.38%	7	7.37%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	10	12.20%	1	7.69%	11	11.58%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	17	20.73%	0	0.00%	17	17.89%
Overall	82	100%	13	100%	95	100%

Table A9: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 1						
Region 4						
BIVAD/Ventricular Episodes	4	6.45%	1	10.00%	5	6.94%
Exception	36	58.06%	4	40.00%	40	55.56%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	3	4.84%	0	0.00%	3	4.17%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	12	19.35%	3	30.00%	15	20.83%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	7	11.29%	2	20.00%	9	12.50%
Overall						
	62	100%	10	100%	72	100%
Adult Status 1						
Region 5						
BIVAD/Ventricular Episodes	6	6.32%	0	0.00%	6	5.94%
Exception	18	18.95%	2	33.33%	20	19.80%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	6	6.32%	2	33.33%	8	7.92%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	35	36.84%	1	16.67%	36	35.64%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	30	31.58%	1	16.67%	31	30.69%
Overall						
	95	100%	6	100%	101	100%

Table A9: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 1						
Region 6						
Exception	9	37.50%	1	25.00%	10	35.71%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	4	16.67%	2	50.00%	6	21.43%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	11	45.83%	1	25.00%	12	42.86%
Overall	24	100%	4	100%	28	100%
Adult Status 1						
Region 7						
BIVAD/Ventricular Episodes	7	10.94%	0	0.00%	7	9.21%
Exception	26	40.62%	2	16.67%	28	36.84%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	4	6.25%	4	33.33%	8	10.53%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	17	26.56%	2	16.67%	19	25.00%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	10	15.62%	4	33.33%	14	18.42%
Overall	64	100%	12	100%	76	100%
Adult Status 1						
Region 8						
BIVAD/Ventricular Episodes	4	8.89%	0	0.00%	4	8.70%
Exception	11	24.44%	0	0.00%	11	23.91%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	2	4.44%	1	100.00%	3	6.52%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	14	31.11%	0	0.00%	14	30.43%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	14	31.11%	0	0.00%	14	30.43%
Overall	45	100%	1	100%	46	100%

Table A9: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 1						
Region 9						
BIVAD/Ventricular Episodes	4	5.56%	2	25.00%	6	7.50%
Exception	22	30.56%	2	25.00%	24	30.00%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	9	12.50%	3	37.50%	12	15.00%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	22	30.56%	0	0.00%	22	27.50%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	15	20.83%	1	12.50%	16	20.00%
Overall	72	100%	8	100%	80	100%
Adult Status 1						
Region 10						
BIVAD/Ventricular Episodes	11	16.92%	2	40.00%	13	18.57%
Exception	28	43.08%	1	20.00%	29	41.43%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	4	6.15%	0	0.00%	4	5.71%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	11	16.92%	1	20.00%	12	17.14%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	11	16.92%	1	20.00%	12	17.14%
Overall	65	100%	5	100%	70	100%

Table A9: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 1						
Region 11						
BIVAD/Ventricular Episodes	6	5.50%	0	0.00%	6	5.13%
Exception	31	28.44%	1	12.50%	32	27.35%
Non-dischargeable, surgically implanted, non-endovascular biventricular support device	30	27.52%	2	25.00%	32	27.35%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	15	13.76%	0	0.00%	15	12.82%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	27	24.77%	5	62.50%	32	27.35%
Overall	109	100%	8	100%	117	100%
Adult Status 2						
Region 1						
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	0.70%	0	0.00%	1	0.50%
Exception	77	54.23%	43	74.14%	120	60.00%
Intra-aortic ballon pump - Hemodynamic Values not obtained	5	3.52%	0	0.00%	5	2.50%
Intra-aortic ballon pump - Hemodynamic Values obtained	32	22.54%	8	13.79%	40	20.00%
Mechanical circulatory support device(MCSD) with malfunction	5	3.52%	2	3.45%	7	3.50%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	3	2.11%	0	0.00%	3	1.50%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	0.70%	0	0.00%	1	0.50%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	10	7.04%	2	3.45%	12	6.00%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	3	2.11%	2	3.45%	5	2.50%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	5	3.52%	1	1.72%	6	3.00%
Overall	142	100%	58	100%	200	100%

Table A9: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 2						
Region 2						
Exception	98	32.24%	46	41.44%	144	34.70%
Intra-aortic ballon pump - Hemodynamic Values not obtained	4	1.32%	0	0.00%	4	0.96%
Intra-aortic ballon pump - Hemodynamic Values obtained	155	50.99%	47	42.34%	202	48.67%
Intra-aortic balloon pump after 14 days	1	0.33%	0	0.00%	1	0.24%
Mechanical circulatory support device(MCSD) with malfunction	12	3.95%	7	6.31%	19	4.58%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	5	1.64%	0	0.00%	5	1.20%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	23	7.57%	7	6.31%	30	7.23%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	0.66%	4	3.60%	6	1.45%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	2	0.66%	0	0.00%	2	0.48%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	2	0.66%	0	0.00%	2	0.48%
Overall						
	304	100%	111	100%	415	100%

Table A9: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 2						
Region 3						
Exception	246	60.29%	128	71.11%	374	63.61%
Intra-aortic ballon pump - Hemodynamic Values not obtained	2	0.49%	0	0.00%	2	0.34%
Intra-aortic ballon pump - Hemodynamic Values obtained	110	26.96%	19	10.56%	129	21.94%
Mechanical circulatory support device(MCSD) with malfunction	10	2.45%	10	5.56%	20	3.40%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	5	1.23%	2	1.11%	7	1.19%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	0.25%	0	0.00%	1	0.17%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	26	6.37%	11	6.11%	37	6.29%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	1	0.25%	5	2.78%	6	1.02%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	7	1.72%	5	2.78%	12	2.04%
Overall						
	408	100%	180	100%	588	100%
Adult Status 2						
Region 4						
Exception	149	48.85%	72	58.06%	221	51.52%
Intra-aortic ballon pump - Hemodynamic Values not obtained	0	0.00%	2	1.61%	2	0.47%
Intra-aortic ballon pump - Hemodynamic Values obtained	76	24.92%	26	20.97%	102	23.78%
Intra-aortic balloon pump after 14 days	1	0.33%	0	0.00%	1	0.23%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	0.33%	0	0.00%	1	0.23%
Mechanical circulatory support device(MCSD) with malfunction	14	4.59%	9	7.26%	23	5.36%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.33%	0	0.00%	1	0.23%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	5	1.64%	0	0.00%	5	1.17%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	48	15.74%	7	5.65%	55	12.82%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	1	0.33%	7	5.65%	8	1.86%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	1	0.33%	0	0.00%	1	0.23%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	8	2.62%	1	0.81%	9	2.10%
Overall						
	305	100%	124	100%	429	100%

Table A9: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 2							
Region 5							
	Exception	153	28.71%	48	42.11%	201	31.07%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	14	2.63%	1	0.88%	15	2.32%
	Intra-aortic ballon pump - Hemodynamic Values obtained	269	50.47%	33	28.95%	302	46.68%
	Mechanical circulatory support device(MCSD) with malfunction	9	1.69%	5	4.39%	14	2.16%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.19%	1	0.88%	2	0.31%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	9	1.69%	3	2.63%	12	1.85%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	60	11.26%	12	10.53%	72	11.13%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	11	2.06%	8	7.02%	19	2.94%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	7	1.31%	3	2.63%	10	1.55%
Overall							
		533	100%	114	100%	647	100%

Table A9: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 2							
Region 6							
	Exception	18	34.62%	9	60.00%	27	40.30%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	2	3.85%	0	0.00%	2	2.99%
	Intra-aortic ballon pump - Hemodynamic Values obtained	10	19.23%	1	6.67%	11	16.42%
	Mechanical circulatory support device(MCSD) with malfunction	5	9.62%	0	0.00%	5	7.46%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	1.92%	0	0.00%	1	1.49%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	6	11.54%	3	20.00%	9	13.43%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	8	15.38%	1	6.67%	9	13.43%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	2	3.85%	1	6.67%	3	4.48%
Overall		52	100%	15	100%	67	100%
Adult Status 2							
Region 7							
	Exception	138	41.82%	61	46.92%	199	43.26%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	3	0.91%	0	0.00%	3	0.65%
	Intra-aortic ballon pump - Hemodynamic Values obtained	152	46.06%	46	35.38%	198	43.04%
	Mechanical circulatory support device(MCSD) with malfunction	13	3.94%	18	13.85%	31	6.74%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	2	0.61%	0	0.00%	2	0.43%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	13	3.94%	2	1.54%	15	3.26%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	6	1.82%	2	1.54%	8	1.74%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	3	0.91%	1	0.77%	4	0.87%
Overall		330	100%	130	100%	460	100%

Table A9: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 2							
Region 8							
	Exception	97	39.27%	19	39.58%	116	39.32%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	1	0.40%	1	2.08%	2	0.68%
	Intra-aortic ballon pump - Hemodynamic Values obtained	131	53.04%	21	43.75%	152	51.53%
	Mechanical circulatory support device(MCSD) with malfunction	6	2.43%	6	12.50%	12	4.07%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	2	0.81%	0	0.00%	2	0.68%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	2	0.81%	0	0.00%	2	0.68%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	0.81%	0	0.00%	2	0.68%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	6	2.43%	1	2.08%	7	2.37%
Overall							
		247	100%	48	100%	295	100%

Table A9: ***(continued)***

Criteria	Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 2						
Region 9						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	1	0.37%	0	0.00%	1	0.26%
Exception	102	38.06%	65	57.52%	167	43.83%
Intra-aortic ballon pump - Hemodynamic Values not obtained	2	0.75%	2	1.77%	4	1.05%
Intra-aortic ballon pump - Hemodynamic Values obtained	131	48.88%	25	22.12%	156	40.94%
Mechanical circulatory support device(MCSD) with malfunction	13	4.85%	6	5.31%	19	4.99%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.37%	0	0.00%	1	0.26%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	4	1.49%	0	0.00%	4	1.05%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	7	2.61%	1	0.88%	8	2.10%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	0.75%	12	10.62%	14	3.67%
Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	2	0.75%	0	0.00%	2	0.52%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	3	1.12%	2	1.77%	5	1.31%
Overall						
	268	100%	113	100%	381	100%
Adult Status 2						
Region 10						
Exception	91	33.21%	51	54.26%	142	38.59%
Intra-aortic ballon pump - Hemodynamic Values not obtained	1	0.36%	1	1.06%	2	0.54%
Intra-aortic ballon pump - Hemodynamic Values obtained	125	45.62%	23	24.47%	148	40.22%
Intra-aortic balloon pump after 14 days	2	0.73%	0	0.00%	2	0.54%
Mechanical circulatory support device(MCSD) with malfunction	20	7.30%	11	11.70%	31	8.42%
Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	0.36%	0	0.00%	1	0.27%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	2	0.73%	0	0.00%	2	0.54%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	19	6.93%	4	4.26%	23	6.25%
Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	10	3.65%	4	4.26%	14	3.80%
Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	3	1.09%	0	0.00%	3	0.82%
Overall						
	274	100%	94	100%	368	100%

Table A9: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 2							
Region 11							
	Exception	211	44.99%	66	47.48%	277	45.56%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	4	0.85%	0	0.00%	4	0.66%
	Intra-aortic ballon pump - Hemodynamic Values obtained	181	38.59%	44	31.65%	225	37.01%
	Mechanical circulatory support device(MCSD) with malfunction	14	2.99%	13	9.35%	27	4.44%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	11	2.35%	2	1.44%	13	2.14%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	1	0.21%	0	0.00%	1	0.16%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	24	5.12%	5	3.60%	29	4.77%
	Total artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	7	1.49%	8	5.76%	15	2.47%
	Ventricluar tachycardia(VT) or ventricular fibrilation(VF)	16	3.41%	1	0.72%	17	2.80%
Overall							
		469	100%	139	100%	608	100%

Table A9: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 1						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	41	62.12%	0	0.00%	41	40.20%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	2	3.03%	0	0.00%	2	1.96%
Exception	11	16.67%	11	30.56%	22	21.57%
Intra-aortic balloon pump after 14 days	2	3.03%	0	0.00%	2	1.96%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	6	9.09%	11	30.56%	17	16.67%
Mechanical circulatory support device (MCSD) with device infection - Debridement	0	0.00%	3	8.33%	3	2.94%
Mechanical circulatory support device (MCSD) with hemolysis	0	0.00%	2	5.56%	2	1.96%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	0	0.00%	1	2.78%	1	0.98%
Mechanical circulatory support device (MCSD) with pump thrombosis	2	3.03%	4	11.11%	6	5.88%
Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	2	5.56%	2	1.96%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	2	3.03%	2	5.56%	4	3.92%
Overall						
	66	100%	36	100%	102	100%

Table A9: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 2						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	44	48.89%	0	0.00%	44	35.77%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	1.11%	0	0.00%	1	0.81%
Exception	13	14.44%	26	78.79%	39	31.71%
Intra-aortic ballon pump - Hemodynamic Values obtained	1	1.11%	0	0.00%	1	0.81%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	2	2.22%	0	0.00%	2	1.63%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	6	6.67%	0	0.00%	6	4.88%
Mechanical circulatory support device (MCSD) with device infection - Debridement	3	3.33%	2	6.06%	5	4.07%
Mechanical circulatory support device (MCSD) with device infection - Erythema	0	0.00%	2	6.06%	2	1.63%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	0	0.00%	1	3.03%	1	0.81%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	2	2.22%	0	0.00%	2	1.63%
Mechanical circulatory support device (MCSD) with right heart failure	2	2.22%	2	6.06%	4	3.25%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	16	17.78%	0	0.00%	16	13.01%
Overall						
	90	100%	33	100%	123	100%

Table A9: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 3							
Region 3							
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	39	44.32%	0	0.00%	39	29.55%
	Exception	17	19.32%	24	54.55%	41	31.06%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	1.14%	0	0.00%	1	0.76%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	4	4.55%	6	13.64%	10	7.58%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	2	2.27%	2	4.55%	4	3.03%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	3	3.41%	1	2.27%	4	3.03%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	3	3.41%	0	0.00%	3	2.27%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	1.14%	0	0.00%	1	0.76%
	Mechanical circulatory support device (MCSD) with pump thrombosis	1	1.14%	5	11.36%	6	4.55%
	Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	3	6.82%	3	2.27%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	17	19.32%	3	6.82%	20	15.15%
Overall							
		88	100%	44	100%	132	100%

Table A9: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 4						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	39	30.71%	0	0.00%	39	23.64%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	0.79%	0	0.00%	1	0.61%
Exception	38	29.92%	21	55.26%	59	35.76%
Intra-aortic balloon pump after 14 days	0	0.00%	1	2.63%	1	0.61%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	2	1.57%	0	0.00%	2	1.21%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	4	3.15%	0	0.00%	4	2.42%
Mechanical circulatory support device (MCSD) with device infection - Debridement	2	1.57%	9	23.68%	11	6.67%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	0.79%	0	0.00%	1	0.61%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	4	3.15%	0	0.00%	4	2.42%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	1.57%	0	0.00%	2	1.21%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	1	0.79%	0	0.00%	1	0.61%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	32	25.20%	7	18.42%	39	23.64%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	0.79%	0	0.00%	1	0.61%
Overall						
	127	100%	38	100%	165	100%

Table A9: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 3							
Region 5							
	Congenital heart disease	1	0.35%	0	0.00%	1	0.23%
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	97	33.68%	0	0.00%	97	22.40%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	0.35%	0	0.00%	1	0.23%
	Exception	66	22.92%	66	45.52%	132	30.48%
	Intra-aortic ballon pump - Hemodynamic Values obtained	1	0.35%	0	0.00%	1	0.23%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	4	1.39%	2	1.38%	6	1.39%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	18	6.25%	4	2.76%	22	5.08%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	2	0.69%	3	2.07%	5	1.15%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	0	0.00%	1	0.69%	1	0.23%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	4	1.39%	0	0.00%	4	0.92%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	0.69%	0	0.00%	2	0.46%
	Mechanical circulatory support device (MCSD) with hemolysis	1	0.35%	1	0.69%	2	0.46%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	0.35%	0	0.00%	1	0.23%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	0	0.00%	1	0.69%	1	0.23%
	Mechanical circulatory support device (MCSD) with pump thrombosis	1	0.35%	4	2.76%	5	1.15%
	Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	1	0.69%	1	0.23%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	89	30.90%	62	42.76%	151	34.87%
Overall		288	100%	145	100%	433	100%

Table A9: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 6						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	20	43.48%	0	0.00%	20	32.26%
Exception	9	19.57%	7	43.75%	16	25.81%
Intra-aortic ballon pump - Hemodynamic Values obtained	1	2.17%	0	0.00%	1	1.61%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	1	2.17%	2	12.50%	3	4.84%
Mechanical circulatory support device (MCSD) with device infection - Debridement	4	8.70%	3	18.75%	7	11.29%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	2.17%	0	0.00%	1	1.61%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	2	4.35%	0	0.00%	2	3.23%
Mechanical circulatory support device (MCSD) with hemolysis	1	2.17%	0	0.00%	1	1.61%
Mechanical circulatory support device (MCSD) with pump thrombosis	0	0.00%	1	6.25%	1	1.61%
Mechanical circulatory support device (MCSD) with right heart failure	1	2.17%	0	0.00%	1	1.61%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	6	13.04%	3	18.75%	9	14.52%
Overall						
	46	100%	16	100%	62	100%

Table A9: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 7						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	54	58.06%	0	0.00%	54	38.57%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	1.08%	0	0.00%	1	0.71%
Exception	13	13.98%	13	27.66%	26	18.57%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	2	2.15%	2	4.26%	4	2.86%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	7	7.53%	9	19.15%	16	11.43%
Mechanical circulatory support device (MCSD) with device infection - Debridement	0	0.00%	2	4.26%	2	1.43%
Mechanical circulatory support device (MCSD) with device infection - Erythema	2	2.15%	4	8.51%	6	4.29%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	3	3.23%	0	0.00%	3	2.14%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	1.08%	1	2.13%	2	1.43%
Mechanical circulatory support device (MCSD) with hemolysis	2	2.15%	0	0.00%	2	1.43%
Mechanical circulatory support device (MCSD) with pump thrombosis	0	0.00%	13	27.66%	13	9.29%
Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	1	2.13%	1	0.71%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	8	8.60%	2	4.26%	10	7.14%
Overall						
	93	100%	47	100%	140	100%

Table A9: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 8						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	41	64.06%	0	0.00%	41	48.81%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	1.56%	0	0.00%	1	1.19%
Exception	13	20.31%	4	20.00%	17	20.24%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	1.56%	0	0.00%	1	1.19%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	3	4.69%	5	25.00%	8	9.52%
Mechanical circulatory support device (MCSD) with device infection - Debridement	1	1.56%	5	25.00%	6	7.14%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	1.56%	0	0.00%	1	1.19%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	2	3.12%	1	5.00%	3	3.57%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	0	0.00%	1	5.00%	1	1.19%
Mechanical circulatory support device (MCSD) with hemolysis	0	0.00%	1	5.00%	1	1.19%
Mechanical circulatory support device (MCSD) with pump thrombosis	0	0.00%	2	10.00%	2	2.38%
Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	1	5.00%	1	1.19%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	1	1.56%	0	0.00%	1	1.19%
Overall						
	64	100%	20	100%	84	100%

Table A9: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 9						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	47	58.75%	0	0.00%	47	37.90%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	1	1.25%	0	0.00%	1	0.81%
Exception	13	16.25%	26	59.09%	39	31.45%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	1	1.25%	0	0.00%	1	0.81%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	7	8.75%	2	4.55%	9	7.26%
Mechanical circulatory support device (MCSD) with device infection - Debridement	3	3.75%	5	11.36%	8	6.45%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	1.25%	0	0.00%	1	0.81%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	1.25%	1	2.27%	2	1.61%
Mechanical circulatory support device (MCSD) with hemolysis	0	0.00%	1	2.27%	1	0.81%
Mechanical circulatory support device (MCSD) with pump thrombosis	0	0.00%	3	6.82%	3	2.42%
Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	1	2.27%	1	0.81%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	6	7.50%	5	11.36%	11	8.87%
Overall						
	80	100%	44	100%	124	100%

Table A9: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 3						
Region 10						
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	55	49.55%	0	0.00%	55	35.71%
Exception	14	12.61%	4	9.30%	18	11.69%
Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	10	9.01%	3	6.98%	13	8.44%
Mechanical circulatory support device (MCSD) with device infection - Bacteremia	8	7.21%	3	6.98%	11	7.14%
Mechanical circulatory support device (MCSD) with device infection - Debridement	7	6.31%	16	37.21%	23	14.94%
Mechanical circulatory support device (MCSD) with device infection - Erythema	1	0.90%	3	6.98%	4	2.60%
Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	0.90%	0	0.00%	1	0.65%
Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	0.90%	0	0.00%	1	0.65%
Mechanical circulatory support device (MCSD) with hemolysis	1	0.90%	0	0.00%	1	0.65%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	4	3.60%	0	0.00%	4	2.60%
Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	1	0.90%	1	2.33%	2	1.30%
Mechanical circulatory support device (MCSD) with pump thrombosis	0	0.00%	6	13.95%	6	3.90%
Mechanical circulatory support device (MCSD) with right heart failure	1	0.90%	2	4.65%	3	1.95%
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	7	6.31%	5	11.63%	12	7.79%
Overall						
	111	100%	43	100%	154	100%

Table A9: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 3							
Region 11							
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	99	53.80%	0	0.00%	99	40.74%
	Exception	37	20.11%	22	37.29%	59	24.28%
	Intra-aortic ballon pump - Hemodynamic Values obtained	1	0.54%	0	0.00%	1	0.41%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	2	1.09%	1	1.69%	3	1.23%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	7	3.80%	16	27.12%	23	9.47%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	7	3.80%	6	10.17%	13	5.35%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	2	1.09%	2	3.39%	4	1.65%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	3	1.63%	1	1.69%	4	1.65%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	0.54%	0	0.00%	1	0.41%
	Mechanical circulatory support device (MCSD) with hemolysis	1	0.54%	1	1.69%	2	0.82%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	2	1.09%	0	0.00%	2	0.82%
	Mechanical circulatory support device (MCSD) with pump thrombosis	1	0.54%	3	5.08%	4	1.65%
	Mechanical circulatory support device (MCSD) with right heart failure	1	0.54%	0	0.00%	1	0.41%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	20	10.87%	7	11.86%	27	11.11%
Overall		184	100%	59	100%	243	100%
Adult Status 4							
Region 1							
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	18	30.51%	5	17.86%	23	26.44%
	Congenital heart disease	4	6.78%	2	7.14%	6	6.90%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	23	38.98%	18	64.29%	41	47.13%
	Exception	4	6.78%	1	3.57%	5	5.75%
	Inotropes without hemodynamic monitoring	8	13.56%	0	0.00%	8	9.20%
	Ischemic heart disease with intractable angina	1	1.69%	0	0.00%	1	1.15%
	Retransplant	1	1.69%	2	7.14%	3	3.45%
Overall		59	100%	28	100%	87	100%

Table A9: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 4						
Region 2						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	8	5.59%	6	9.38%	14	6.76%
Congenital heart disease	5	3.50%	5	7.81%	10	4.83%
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	1	0.70%	0	0.00%	1	0.48%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	64	44.76%	35	54.69%	99	47.83%
Exception	38	26.57%	11	17.19%	49	23.67%
Inotropes without hemodynamic monitoring	21	14.69%	4	6.25%	25	12.08%
Ischemic heart disease with intractable angina	5	3.50%	2	3.12%	7	3.38%
Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	1	0.70%	0	0.00%	1	0.48%
Retransplant	0	0.00%	1	1.56%	1	0.48%
Overall						
	143	100%	64	100%	207	100%

Table A9: *(continued)*

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 4 Region 3						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	10	7.30%	3	6.52%	13	7.10%
Congenital heart disease	4	2.92%	1	2.17%	5	2.73%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	49	35.77%	21	45.65%	70	38.25%
Exception	45	32.85%	16	34.78%	61	33.33%
Inotropes without hemodynamic monitoring	23	16.79%	2	4.35%	25	13.66%
Ischemic heart disease with intractable angina	2	1.46%	2	4.35%	4	2.19%
Retransplant	4	2.92%	1	2.17%	5	2.73%
Overall	137	100%	46	100%	183	100%
Adult Status 4 Region 4						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	14	11.57%	8	16.00%	22	12.87%
Congenital heart disease	2	1.65%	4	8.00%	6	3.51%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	33	27.27%	25	50.00%	58	33.92%
Exception	47	38.84%	5	10.00%	52	30.41%
Inotropes without hemodynamic monitoring	15	12.40%	3	6.00%	18	10.53%
Ischemic heart disease with intractable angina	5	4.13%	4	8.00%	9	5.26%
Retransplant	5	4.13%	1	2.00%	6	3.51%
Overall	121	100%	50	100%	171	100%
Adult Status 4 Region 5						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	37	17.62%	17	20.00%	54	18.31%
Congenital heart disease	16	7.62%	12	14.12%	28	9.49%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	67	31.90%	33	38.82%	100	33.90%
Exception	26	12.38%	4	4.71%	30	10.17%
Inotropes without hemodynamic monitoring	34	16.19%	5	5.88%	39	13.22%
Ischemic heart disease with intractable angina	4	1.90%	3	3.53%	7	2.37%
No criteria for this status	1	0.48%	0	0.00%	1	0.34%
Retransplant	25	11.90%	11	12.94%	36	12.20%
Overall	210	100%	85	100%	295	100%

Table A9: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 4							
Region 6							
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	6	10.34%	5	25.00%	11	14.10%
	Congenital heart disease	2	3.45%	0	0.00%	2	2.56%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	29	50.00%	8	40.00%	37	47.44%
	Exception	8	13.79%	2	10.00%	10	12.82%
	Inotropes without hemodynamic monitoring	12	20.69%	1	5.00%	13	16.67%
	Ischemic heart disease with intractable angina	0	0.00%	2	10.00%	2	2.56%
	Retransplant	1	1.72%	2	10.00%	3	3.85%
Overall							
		58	100%	20	100%	78	100%

Table A9: ***(continued)***

Criteria	Initial		Extension		Total	
	N	%	N	%	N	%
Adult Status 4 Region 7						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	12	11.54%	3	5.08%	15	9.20%
Congenital heart disease	2	1.92%	5	8.47%	7	4.29%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	35	33.65%	35	59.32%	70	42.94%
Exception	29	27.88%	9	15.25%	38	23.31%
Inotropes without hemodynamic monitoring	19	18.27%	2	3.39%	21	12.88%
Ischemic heart disease with intractable angina	3	2.88%	1	1.69%	4	2.45%
Retransplant	4	3.85%	4	6.78%	8	4.91%
Overall	104	100%	59	100%	163	100%
Adult Status 4 Region 8						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	5	5.38%	3	6.00%	8	5.59%
Congenital heart disease	8	8.60%	5	10.00%	13	9.09%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	27	29.03%	28	56.00%	55	38.46%
Exception	24	25.81%	4	8.00%	28	19.58%
Inotropes without hemodynamic monitoring	23	24.73%	5	10.00%	28	19.58%
Ischemic heart disease with intractable angina	3	3.23%	1	2.00%	4	2.80%
Retransplant	3	3.23%	4	8.00%	7	4.90%
Overall	93	100%	50	100%	143	100%
Adult Status 4 Region 9						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	2	4.17%	3	5.08%	5	4.67%
Congenital heart disease	0	0.00%	3	5.08%	3	2.80%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	27	56.25%	48	81.36%	75	70.09%
Exception	8	16.67%	2	3.39%	10	9.35%
Inotropes without hemodynamic monitoring	7	14.58%	1	1.69%	8	7.48%
Ischemic heart disease with intractable angina	1	2.08%	0	0.00%	1	0.93%
Retransplant	3	6.25%	2	3.39%	5	4.67%
Overall	48	100%	59	100%	107	100%

Table A9: ***(continued)***

Criteria	Initial N	Initial %	Extension N	Extension %	Total N	Total %
Adult Status 4						
Region 10						
Amyloidosis, or hypertrophic or restrictive cardiomyopathy	12	13.95%	3	5.36%	15	10.56%
Congenital heart disease	6	6.98%	3	5.36%	9	6.34%
Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	45	52.33%	40	71.43%	85	59.86%
Exception	14	16.28%	3	5.36%	17	11.97%
Inotropes without hemodynamic monitoring	6	6.98%	3	5.36%	9	6.34%
Ischemic heart disease with intractable angina	1	1.16%	1	1.79%	2	1.41%
Retransplant	2	2.33%	3	5.36%	5	3.52%
Overall	86	100%	56	100%	142	100%

Table A9: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 4 Region 11							
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	15	6.85%	1	1.41%	16	5.52%
	Congenital heart disease	10	4.57%	3	4.23%	13	4.48%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	82	37.44%	43	60.56%	125	43.10%
	Exception	69	31.51%	17	23.94%	86	29.66%
	Inotropes without hemodynamic monitoring	18	8.22%	1	1.41%	19	6.55%
	Intra-aortic ballon pump - Hemodynamic Values obtained	1	0.46%	0	0.00%	1	0.34%
	Ischemic heart disease with intractable angina	5	2.28%	5	7.04%	10	3.45%
	Retransplant	19	8.68%	1	1.41%	20	6.90%
Overall		219	100%	71	100%	290	100%
Adult Status 5 Region 1							
	None	6	100.00%	1	100.00%	7	100.00%
Adult Status 5 Region 2							
	None	2	100.00%	2	100.00%	4	100.00%
Adult Status 5 Region 3							
	None	8	100.00%	2	100.00%	10	100.00%
Adult Status 5 Region 4							
	None	5	100.00%	0	0.00%	5	100.00%
Adult Status 5 Region 5							
	None	13	100.00%	4	100.00%	17	100.00%
Adult Status 5 Region 6							
	None	2	100.00%	0	0.00%	2	100.00%
Adult Status 5 Region 7							
	None	7	100.00%	2	100.00%	9	100.00%
Adult Status 5 Region 8							
	None	2	100.00%	1	100.00%	3	100.00%

Table A9: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 5 Region 9							
	None	4	100.00%	1	100.00%	5	100.00%
Adult Status 5 Region 10							
	None	5	100.00%	0	0.00%	5	100.00%
Adult Status 5 Region 11							
	None	10	100.00%	0	0.00%	10	100.00%
Adult Status 6 Region 1							
	None	42	100.00%	6	100.00%	48	100.00%
Adult Status 6 Region 2							
	None	33	100.00%	2	100.00%	35	100.00%
Adult Status 6 Region 3							
	None	30	100.00%	6	100.00%	36	100.00%
Adult Status 6 Region 4							
	None	11	100.00%	0	0.00%	11	100.00%

Table A9: ***(continued)***

Criteria		Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 6 Region 5							
	None	96	100.00%	10	100.00%	106	100.00%
Adult Status 6 Region 6							
	None	23	100.00%	2	100.00%	25	100.00%
Adult Status 6 Region 7							
	None	24	100.00%	6	100.00%	30	100.00%
Adult Status 6 Region 8							
	None	12	100.00%	6	100.00%	18	100.00%
Adult Status 6 Region 9							
	None	11	100.00%	4	100.00%	15	100.00%
Adult Status 6 Region 10							
	None	20	100.00%	0	0.00%	20	100.00%
Adult Status 6 Region 11							
	None	69	100.00%	5	100.00%	74	100.00%

Table A10: Mechanical Circulatory Support Devices at Transplant by Region

Brand	Era	Count	Percent
Region 1 ECMO			
Total ECMO	**Pre**	**4**	**1.22%**
	Post	**35**	**8.84%**
Region 1 IABP			
Total IABP	**Pre**	**7**	**2.13%**
	Post	**114**	**28.79%**
Region 1 LVAD			
CentriMag (Thoratec/Levitronix)	Pre	2	0.71%
	Post	4	2.21%
Heartmate II	Pre	102	36.43%
	Post	25	13.81%
HeartMate III	Pre	13	4.64%
	Post	78	43.09%
Heartsaver VAD	Pre	1	0.36%
	Post	0	0%
Heartware HVAD	Pre	131	46.79%
	Post	45	24.86%
Impella CP	Pre	0	0%
	Post	1	0.55%
Impella Recover 5.0	Pre	3	1.07%
	Post	16	8.84%
Other, Specify	Pre	28	10%
	Post	12	6.63%
Total LVAD	**Pre**	**280**	**85.37%**
	Post	**181**	**45.71%**
Region 1 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	3.23%
Cardiac Assist Tandem Heart	Pre	2	5.56%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	19	52.78%
	Post	51	82.26%
Heartmate II	Pre	2	5.56%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	7	11.29%
	Pre	8	22.22%

Heartware HVAD	Post	1	1.61%
Thoratec PVAD	Pre	2	5.56%
	Post	0	0%
Other, Specify	Pre	3	8.33%
	Post	1	1.61%
Total LVAD+RVAD	**Pre**	**36**	**10.98%**
	Post	**62**	**15.66%**
Region 1 RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	25%
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	1	25%
Impella Recover 2.5	Pre	0	0%
	Post	1	25%
Impella Recover 5.0	Pre	1	100%
	Post	0	0%
Other, Specify	Pre	0	0%
	Post	1	25%
Total RVAD	**Pre**	**1**	**0.3%**
	Post	**4**	**1.01%**
Region 2 ECMO			
Total ECMO	**Pre**	**19**	**3.83%**
	Post	**59**	**9.5%**
Region 2 IABP			
Total IABP	**Pre**	**35**	**7.06%**
	Post	**260**	**41.87%**
Region 2 LVAD			
Cardiac Assist Tandem Heart	Pre	1	0.25%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	4	0.98%
	Post	5	1.77%
Heartmate II	Pre	197	48.28%
	Post	35	12.37%
HeartMate III	Pre	6	1.47%
	Post	103	36.4%
Heartsaver VAD	Pre	1	0.25%
	Post	0	0%
	Pre	160	39.22%

Heartware HVAD	Post	86	30.39%
Impella CP	Pre	1	0.25%
	Post	7	2.47%
Impella Recover 2.5	Pre	0	0%
	Post	2	0.71%
Impella Recover 5.0	Pre	3	0.74%
	Post	27	9.54%
Jarvik 2000	Pre	1	0.25%
	Post	0	0%
Terumo DuraHeart	Pre	1	0.25%
	Post	0	0%
Thoratec PVAD	Pre	1	0.25%
	Post	0	0%
Other, Specify	Pre	32	7.84%
	Post	18	6.36%
Total LVAD	**Pre**	**408**	**82.26%**
	Post	**283**	**45.57%**
Region 2 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	11.11%
CentriMag (Thoratec/Levitronix)	Pre	13	46.43%
	Post	8	44.44%
Heartmate II	Pre	3	10.71%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	2	11.11%
Heartware HVAD	Pre	10	35.71%
	Post	2	11.11%
Impella Recover 5.0	Pre	0	0%
	Post	1	5.56%
Maquet Jostra Rotaflow	Pre	2	7.14%
	Post	0	0%
Other, Specify	Pre	0	0%
	Post	3	16.67%
Total LVAD+RVAD	**Pre**	**28**	**5.65%**
	Post	**18**	**2.9%**
Region 2 RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	100%

CentriMag (Thoratec/Levitronix)	Pre	1	33.33%
	Post	0	0%
Heartmate II	Pre	1	33.33%
	Post	0	0%
Heartware HVAD	Pre	1	33.33%
	Post	0	0%
Total RVAD	**Pre**	**3**	**0.6%**
	Post	**1**	**0.16%**
Region 2 TAH			
SynCardia CardioWest	Pre	3	100%
Total TAH	**Pre**	**3**	**0.6%**
Region 3 ECMO			
Total ECMO	**Pre**	**13**	**2.5%**
	Post	**48**	**6.52%**
Region 3 IABP			
Total IABP	**Pre**	**80**	**15.38%**
	Post	**321**	**43.61%**
Region 3 LVAD			
Cardiac Assist Tandem Heart	Pre	1	0.25%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	2	0.51%
	Post	2	0.62%
Heartmate II	Pre	201	51.02%
	Post	55	16.98%
HeartMate III	Pre	10	2.54%
	Post	103	31.79%
Heartsaver VAD	Pre	2	0.51%
	Post	1	0.31%
Heartware HVAD	Pre	126	31.98%
	Post	70	21.6%
Impella CP	Pre	0	0%
	Post	6	1.85%
Impella Recover 2.5	Pre	2	0.51%
	Post	1	0.31%
Impella Recover 5.0	Pre	2	0.51%
	Post	26	8.02%
Jarvik 2000	Pre	1	0.25%
	Post	0	0%

Other, Specify	Pre	47	11.93%
	Post	60	18.52%
Total LVAD	**Pre**	**394**	**75.77%**
	Post	**324**	**44.02%**
Region 3 LVAD+RVAD			
Cardiac Assist Tandem Heart	Pre	1	3.57%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	11	39.29%
	Post	12	35.29%
Heartmate II	Pre	1	3.57%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	4	11.76%
Heartware HVAD	Pre	11	39.29%
	Post	9	26.47%
Impella Recover 2.5	Pre	0	0%
	Post	1	2.94%
Other, Specify	Pre	4	14.29%
	Post	8	23.53%
Total LVAD+RVAD	**Pre**	**28**	**5.38%**
	Post	**34**	**4.62%**
Region 3 RVAD			
Heartmate II	Pre	1	50%
	Post	0	0%
Impella CP	Pre	0	0%
	Post	1	20%
Impella Recover 5.0	Pre	0	0%
	Post	3	60%
Impella RP	Pre	1	50%
	Post	0	0%
Other, Specify	Pre	0	0%
	Post	1	20%
Total RVAD	**Pre**	**2**	**0.38%**
	Post	**5**	**0.68%**
Region 3 TAH			
SynCardia CardioWest	Pre	3	100%
	Post	3	75%
Other, Specify	Pre	0	0%
	Post	1	25%

Total TAH	**Pre**	**3**	**0.58%**
	Post	**4**	**0.54%**
Region 4 ECMO			
Total ECMO	**Pre**	**13**	**2.86%**
	Post	**45**	**7.43%**
Region 4 IABP			
Total IABP	**Pre**	**132**	**29.01%**
	Post	**245**	**40.43%**
Region 4 LVAD			
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	1	0.34%
Heartmate II	Pre	188	63.95%
	Post	62	21.16%
HeartMate III	Pre	3	1.02%
	Post	53	18.09%
Heartmate XVE	Pre	3	1.02%
	Post	0	0%
Heartsaver VAD	Pre	0	0%
	Post	1	0.34%
Heartware HVAD	Pre	77	26.19%
	Post	69	23.55%
Impella CP	Pre	0	0%
	Post	13	4.44%
Impella Recover 2.5	Pre	1	0.34%
	Post	0	0%
Impella Recover 5.0	Pre	7	2.38%
	Post	82	27.99%
Jarvik 2000	Pre	1	0.34%
	Post	0	0%
Thoratec IVAD	Pre	2	0.68%
	Post	0	0%
Other, Specify	Pre	12	4.08%
	Post	12	4.1%
Total LVAD	**Pre**	**294**	**64.62%**
	Post	**293**	**48.35%**
Region 4 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	4	22.22%
	Pre	2	33.33%

Cardiac Assist Tandem Heart	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	1	16.67%
	Post	7	38.89%
Heartmate II	Pre	1	16.67%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	2	11.11%
Heartware HVAD	Pre	0	0%
	Post	4	22.22%
Impella Recover 5.0	Pre	0	0%
	Post	1	5.56%
Other, Specify	Pre	2	33.33%
	Post	0	0%
Total LVAD+RVAD	**Pre**	**6**	**1.32%**
	Post	**18**	**2.97%**
Region 4 RVAD			
CentriMag (Thoratec/Levitronix)	Post	1	50%
Impella RP	Post	1	50%
Total RVAD	**Post**	**2**	**0.33%**
Region 4 TAH			
SynCardia CardioWest	Pre	10	100%
	Post	3	100%
Total TAH	**Pre**	**10**	**2.2%**
	Post	**3**	**0.5%**
Region 5 ECMO			
Total ECMO	**Pre**	**9**	**1.46%**
	Post	**81**	**9.04%**
Region 5 IABP			
Total IABP	**Pre**	**45**	**7.32%**
	Post	**361**	**40.29%**
Region 5 LVAD			
Heartmate II	Pre	132	27.1%
	Post	32	7.82%
HeartMate III	Pre	8	1.64%
	Post	124	30.32%
Heartmate XVE	Pre	1	0.21%
	Post	0	0%
Heartsaver VAD	Pre	2	0.41%
	Post	2	0.49%

Heartware HVAD	Pre	301	61.81%
	Post	145	35.45%
Impella CP	Pre	0	0%
	Post	23	5.62%
Impella Recover 2.5	Pre	3	0.62%
	Post	3	0.73%
Impella Recover 5.0	Pre	22	4.52%
	Post	47	11.49%
Other, Specify	Pre	18	3.7%
	Post	33	8.07%
Total LVAD	**Pre**	**487**	**79.19%**
	Post	**409**	**45.65%**
Region 5 LVAD+RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	3.57%
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	2	7.14%
CentriMag (Thoratec/Levitronix)	Pre	7	15.91%
	Post	16	57.14%
HeartMate III	Pre	2	4.55%
	Post	4	14.29%
Heartware HVAD	Pre	24	54.55%
	Post	4	14.29%
Impella Recover 2.5	Pre	1	2.27%
	Post	0	0%
Impella Recover 5.0	Pre	4	9.09%
	Post	1	3.57%
Maquet Jostra Rotaflow	Pre	1	2.27%
	Post	0	0%
Other, Specify	Pre	5	11.36%
	Post	0	0%
Total LVAD+RVAD	**Pre**	**44**	**7.15%**
	Post	**28**	**3.12%**
Region 5 RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	16.67%
Heartware HVAD	Pre	0	0%
	Post	2	33.33%
	Pre	2	100%

Impella Recover 5.0	Post	0	0%
Impella RP	Pre	0	0%
	Post	2	33.33%
Other, Specify	Pre	0	0%
	Post	1	16.67%
Total RVAD	**Pre**	**2**	**0.33%**
	Post	**6**	**0.67%**
Region 5 TAH			
SynCardia CardioWest	Pre	28	100%
	Post	10	90.91%
Other, Specify	Pre	0	0%
	Post	1	9.09%
Total TAH	**Pre**	**28**	**4.55%**
	Post	**11**	**1.23%**
Region 6 ECMO			
Total ECMO	**Pre**	**2**	**1.06%**
	Post	**21**	**11.67%**
Region 6 IABP			
Total IABP	**Pre**	**2**	**1.06%**
	Post	**25**	**13.89%**
Region 6 LVAD			
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	2	1.6%
Heartmate II	Pre	57	32.76%
	Post	12	9.6%
HeartMate III	Pre	2	1.15%
	Post	39	31.2%
Heartmate XVE	Pre	1	0.57%
	Post	0	0%
Heartware HVAD	Pre	99	56.9%
	Post	39	31.2%
Impella CP	Pre	0	0%
	Post	13	10.4%
Impella Recover 5.0	Pre	2	1.15%
	Post	4	3.2%
Other, Specify	Pre	13	7.47%
	Post	16	12.8%
	Pre	**174**	**92.55%**

Total LVAD	**Post**	**125**	**69.44%**
Region 6 LVAD+RVAD			
Cardiac Assist Protek Duo	Post	1	50%
Impella CP	Post	1	50%
Total LVAD+RVAD	**Post**	**2**	**1.11%**
Region 6 TAH			
Other, Specify	Pre	1	100%
Total RVAD	**Pre**	**1**	**0.53%**
SynCardia CardioWest	Pre	9	100%
	Post	7	100%
Region 7 ECMO			
Total TAH	**Pre**	**9**	**4.79%**
	Post	**7**	**3.89%**
Region 7 IABP			
Total ECMO	**Pre**	**4**	**0.72%**
	Post	**51**	**7.53%**
Region 7 LVAD			
Total IABP	**Pre**	**143**	**25.86%**
	Post	**304**	**44.9%**
Heartmate II	Pre	172	44.79%
	Post	46	16.55%
HeartMate III	Pre	6	1.56%
	Post	112	40.29%
Heartware HVAD	Pre	166	43.23%
	Post	97	34.89%
Impella CP	Pre	0	0%
	Post	3	1.08%
Impella Recover 2.5	Pre	1	0.26%
	Post	0	0%
Impella Recover 5.0	Pre	1	0.26%
	Post	15	5.4%
Other, Specify	Pre	38	9.9%
	Post	5	1.8%
Region 7 LVAD+RVAD			
Total LVAD	**Pre**	**384**	**69.44%**
	Post	**278**	**41.06%**
Berlin Heart EXCOR	Pre	0	0%
	Post	1	2.78%
	Pre	0	0%

Cardiac Assist Protek Duo	Post	3	8.33%
Cardiac Assist Tandem Heart	Pre	2	9.09%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	2	9.09%
	Post	17	47.22%
Heartmate II	Pre	1	4.55%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	6	16.67%
Heartware HVAD	Pre	17	77.27%
	Post	8	22.22%
Other, Specify	Pre	0	0%
	Post	1	2.78%
Region 7 RVAD			
Total LVAD+RVAD	**Pre**	**22**	**3.98%**
	Post	**36**	**5.32%**
Cardiac Assist Protek Duo	Post	1	20%
CentriMag (Thoratec/Levitronix)	Post	3	60%
Region 7 TAH			
Other, Specify	Post	1	20%
Total RVAD	**Post**	**5**	**0.74%**
Region 8 ECMO			
SynCardia CardioWest	Post	3	100%
Total TAH	**Post**	**3**	**0.44%**
Region 8 IABP			
Total ECMO	**Pre**	**4**	**1.26%**
	Post	**31**	**7.51%**
Region 8 LVAD			
Total IABP	**Pre**	**60**	**18.93%**
	Post	**199**	**48.18%**
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	0.58%
Heartmate II	Pre	146	59.11%
	Post	39	22.81%
HeartMate III	Pre	3	1.21%
	Post	82	47.95%
Heartware HVAD	Pre	53	21.46%
	Post	44	25.73%
	Pre	0	0%

Impella Recover 5.0	Post	4	2.34%
Other, Specify	Pre	45	18.22%
	Post	1	0.58%
Region 8 LVAD+RVAD			
Total LVAD	**Pre**	**247**	**77.92%**
	Post	**171**	**41.4%**
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	20%
CentriMag (Thoratec/Levitronix)	Pre	2	100%
	Post	4	40%
HeartMate III	Pre	0	0%
	Post	3	30%
Other, Specify	Pre	0	0%
	Post	1	10%
Region 8 RVAD			
Total LVAD+RVAD	**Pre**	**2**	**0.63%**
	Post	**10**	**2.42%**
CentriMag (Thoratec/Levitronix)	Pre	0	0%
	Post	2	100%
Heartware HVAD	Pre	1	50%
	Post	0	0%
Other, Specify	Pre	1	50%
	Post	0	0%
Region 8 TAH			
Total RVAD	**Pre**	**2**	**0.63%**
	Post	**2**	**0.48%**
Region 9 ECMO			
SynCardia CardioWest	Pre	2	100%
Total TAH	**Pre**	**2**	**0.63%**
Region 9 IABP			
Total ECMO	**Pre**	**5**	**1.36%**
	Post	**64**	**10.7%**
Region 9 LVAD			
Total IABP	**Pre**	**27**	**7.34%**
	Post	**255**	**42.64%**
CentriMag (Thoratec/Levitronix)	Pre	2	0.64%
	Post	10	4.08%
Heartmate II	Pre	223	71.02%
	Post	69	28.16%

HeartMate III	Pre	9	2.87%
	Post	126	51.43%
Heartware HVAD	Pre	40	12.74%
	Post	31	12.65%
Impella CP	Pre	0	0%
	Post	1	0.41%
Impella Recover 5.0	Pre	0	0%
	Post	2	0.82%
Jarvik 2000	Pre	2	0.64%
	Post	0	0%
Other, Specify	Pre	38	12.1%
	Post	6	2.45%
Region 9 LVAD+RVAD			
Total LVAD	**Pre**	**314**	**85.33%**
	Post	**245**	**40.97%**
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	4.17%
CentriMag (Thoratec/Levitronix)	Pre	7	43.75%
	Post	13	54.17%
Heartmate II	Pre	1	6.25%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	10	41.67%
Heartware HVAD	Pre	6	37.5%
	Post	0	0%
Other, Specify	Pre	2	12.5%
	Post	0	0%
Region 9 RVAD			
Total LVAD+RVAD	**Pre**	**16**	**4.35%**
	Post	**24**	**4.01%**
CentriMag (Thoratec/Levitronix)	Post	1	25%
Impella CP	Post	2	50%
Region 9 TAH			
Other, Specify	Post	1	25%
Total RVAD	**Post**	**4**	**0.67%**
SynCardia CardioWest	Pre	6	100%
	Post	6	100%
Region 10 ECMO			
	Pre	**6**	**1.63%**

Total TAH	**Post**	**6**	**1%**
Region 10 IABP			
Total ECMO	**Pre**	**5**	**1.14%**
	Post	**36**	**5.9%**
Region 10 LVAD			
Total IABP	**Pre**	**21**	**4.77%**
	Post	**199**	**32.62%**
CentriMag (Thoratec/Levitronix)	Pre	3	0.78%
	Post	3	0.88%
Heartmate II	Pre	169	43.78%
	Post	52	15.2%
HeartMate III	Pre	5	1.3%
	Post	158	46.2%
Heartsaver VAD	Pre	2	0.52%
	Post	1	0.29%
Heartware HVAD	Pre	151	39.12%
	Post	79	23.1%
Impella CP	Pre	0	0%
	Post	1	0.29%
Impella Recover 2.5	Pre	0	0%
	Post	1	0.29%
Impella Recover 5.0	Pre	5	1.3%
	Post	12	3.51%
Other, Specify	Pre	51	13.21%
	Post	35	10.23%
Region 10 LVAD+RVAD			
Total LVAD	**Pre**	**386**	**87.73%**
	Post	**342**	**56.07%**
Cardiac Assist Protek Duo	Pre	0	0%
	Post	2	7.69%
CentriMag (Thoratec/Levitronix)	Pre	12	54.55%
	Post	7	26.92%
HeartMate III	Pre	0	0%
	Post	8	30.77%
Heartsaver VAD	Pre	1	4.55%
	Post	0	0%
Heartware HVAD	Pre	5	22.73%
	Post	5	19.23%
	Pre	0	0%

Impella CP	Post	1	3.85%
Impella Recover 5.0	Pre	1	4.55%
	Post	0	0%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	2	7.69%
Other, Specify	Pre	3	13.64%
	Post	1	3.85%
Region 10 RVAD			
Total LVAD+RVAD	**Pre**	**22**	**5%**
	Post	**26**	**4.26%**
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	33.33%
CentriMag (Thoratec/Levitronix)	Pre	1	100%
	Post	1	33.33%
Impella Recover 5.0	Pre	0	0%
	Post	1	33.33%
Region 10 TAH			
Total RVAD	**Pre**	**1**	**0.23%**
	Post	**3**	**0.49%**
SynCardia CardioWest	Pre	4	80%
	Post	3	75%
Other, Specify	Pre	1	20%
	Post	1	25%
Region 11 ECMO			
Total TAH	**Pre**	**5**	**1.14%**
	Post	**4**	**0.66%**
Region 11 IABP			
Total ECMO	**Pre**	**9**	**1.26%**
	Post	**68**	**7.3%**
Region 11 LVAD			
Total IABP	**Pre**	**104**	**14.53%**
	Post	**360**	**38.63%**
Cardiac Assist Protek Duo	Pre	0	0%
	Post	3	0.71%
Cardiac Assist Tandem Heart	Pre	1	0.18%
	Post	0	0%
CentriMag (Thoratec/Levitronix)	Pre	5	0.88%
	Post	12	2.85%
	Pre	0	0%

Evaheart	Post	1	0.24%
Heartmate II	Pre	274	48.24%
	Post	64	15.2%
HeartMate III	Pre	13	2.29%
	Post	206	48.93%
Heartsaver VAD	Pre	8	1.41%
	Post	0	0%
Heartware HVAD	Pre	225	39.61%
	Post	94	22.33%
Impella CP	Pre	0	0%
	Post	3	0.71%
Impella Recover 5.0	Pre	0	0%
	Post	10	2.38%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	1	0.24%
Other, Specify	Pre	42	7.39%
	Post	27	6.41%
Region 11 LVAD+RVAD			
Total LVAD	**Pre**	**568**	**79.33%**
	Post	**421**	**45.17%**
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	1.56%
Cardiac Assist Tandem Heart	Pre	0	0%
	Post	1	1.56%
CentriMag (Thoratec/Levitronix)	Pre	4	25%
	Post	33	51.56%
Heartmate II	Pre	1	6.25%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	8	12.5%
Heartware HVAD	Pre	3	18.75%
	Post	1	1.56%
Impella Recover 5.0	Pre	0	0%
	Post	2	3.12%
Maquet Jostra Rotaflow	Pre	2	12.5%
	Post	6	9.38%
Thoratec PVAD	Pre	4	25%
	Post	0	0%
	Pre	2	12.5%

Other, Specify	Post	12	18.75%
Region 11 RVAD			
Total LVAD+RVAD	**Pre**	**16**	**2.23%**
	Post	**64**	**6.87%**
Cardiac Assist Protek Duo	Pre	0	0%
	Post	1	20%
CentriMag (Thoratec/Levitronix)	Pre	1	100%
	Post	1	20%
Heartware HVAD	Pre	0	0%
	Post	1	20%
Impella Recover 5.0	Pre	0	0%
	Post	1	20%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	1	20%
Region 11 TAH			
Total RVAD	**Pre**	**1**	**0.14%**
	Post	**5**	**0.54%**
SynCardia CardioWest	Pre	18	100%
	Post	12	85.71%
Other, Specify	Pre	0	0%
	Post	2	14.29%
Total TAH	**Pre**	**18**	**2.51%**
	Post	**14**	**1.5%**

Table A11: Mechanical Circulatory Support Devices at Transplant for Adult Heart Candidates as Entered into Waitlist, Post-Implementation

Device	Brand	Count	Percent
IABP	**Total**	**2531**	**44.45%**
Left Dischargeable VAD	Heartmate II	234	13.68%
	HeartMate III	951	55.61%
	Heartsaver VAD	2	0.12%
	Heartware HVAD	523	30.58%
Left Dischargeable VAD	**Total**	**1710**	**30.03%**
Left Non-Dischargeable VAD	Abiomed BVS 5000	1	0.71%
	Biomedicus	1	0.71%
	CentriMag (Thoratec/Levitronix)	105	74.47%
	Maquet Jostra Rotaflow	8	5.67%
	Thoratec IVAD	1	0.71%
	Other, Specify	25	17.73%
Left Non-Dischargeable VAD	**Total**	**141**	**2.48%**
Left Percutaneous Device	Cardiac Assist Protek Duo	3	0.5%
	Cardiac Assist Tandem Heart	6	1%
	CentriMag (Thoratec/Levitronix)	1	0.17%
	Impella CP	79	13.19%
	Impella Recover 2.5	4	0.67%
	Impella Recover 5.0	209	34.89%
	Impella RP	2	0.33%
	Other, Specify	295	49.25%
Left Percutaneous Device	**Total**	**599**	**10.52%**
Right Dischargeable VAD	Heartmate II	1	6.67%
	HeartMate III	6	40%
	Heartware HVAD	6	40%
	Other, Specify	2	13.33%
Right Dischargeable VAD	**Total**	**15**	**0.26%**
Right Non-Dischargeable VAD	Biomedicus	1	0.67%
	CentriMag (Thoratec/Levitronix)	122	81.33%
	Maquet Jostra Rotaflow	8	5.33%
	Other, Specify	19	12.67%
Right Non-Dischargeable VAD	**Total**	**150**	**2.63%**
Right Percutaneous Device	Cardiac Assist Protek Duo	20	47.62%
	Cardiac Assist Tandem Heart	5	11.9%
	CentriMag (Thoratec/Levitronix)	4	9.52%
	Impella CP	2	4.76%
	Impella Recover 5.0	2	4.76%
	Impella RP	4	9.52%
	Maquet Jostra Rotaflow	1	2.38%
	Other, Specify	4	9.52%
Right Percutaneous Device	**Total**	**42**	**0.74%**
Single Dischargeable VAD	Heartmate II	1	33.33%
	HeartMate III	2	66.67%
Single Dischargeable VAD	**Total**	**3**	**0.05%**

Single Non-Dischargeable VAD	**Total**	**1**	**0.02%**
Single Percutaneous Device	Cardiac Assist Tandem Heart	1	25%
	Impella Recover 5.0	1	25%
	Other, Specify	2	50%
Single Percutaneous Device	**Total**	**4**	**0.07%**
TAH	AbioCor	1	2.63%
	SynCardia CardioWest	34	89.47%
	Other, Specify	3	7.89%
TAH	**Total**	**38**	**0.67%**
VA ECMO	**Total**	**460**	**8.08%**

Table A12: Adult Heart Transplants by Distance Traveled and Share Type

Distance	Share	Era	Count	Percent
< 500 NM	Local	Pre	5564	66.06%
		Post	2475	26.27%
	Regional	Pre	1095	13%
		Post	2467	26.18%
	National	Pre	1414	16.79%
		Post	3356	35.62%
	Not Reported	Pre	9	0.11%
		Post	2	0.02%
500 NM - <1000 NM	Local	Pre	6	0.07%
		Post	3	0.03%
	Regional	Pre	60	0.71%
		Post	92	0.98%
	National	Pre	242	2.87%
		Post	951	10.09%
	Not Reported	Pre	2	0.02%
		Post	2	0.02%
1000 NM - <1500 NM	Local	Pre	16	0.19%
		Post	23	0.24%
	Regional	Pre	3	0.04%
		Post	10	0.11%
	National	Pre	9	0.11%
		Post	37	0.39%
	Not Reported	Pre	1	0.01%
		Post	0	0%
1500+ NM	Local	Pre	0	0%
		Post	0	0%
	Regional	Pre	0	0%
		Post	0	0%
	National	Pre	2	0.02%
		Post	4	0.04%
	Not Reported	Pre	0	0%
		Post	0	0%

Table A13: Adult Heart Transplants by Zone, Era, and Medical Urgency Status

Zone	Era	Status	Count	Percent
DSA	Pre	Status 1A	3626	43.05%
		Status 1B	1853	22%
		Status 2	107	1.27%
	Post	Adult Status 1	151	1.6%
		Adult Status 2	784	8.32%
		Adult Status 3	629	6.68%
		Adult Status 4	760	8.07%
		Adult Status 5	34	0.36%
		Adult Status 6	143	1.52%
Zone A	Pre	Status 1A	1889	22.43%
		Status 1B	552	6.55%
		Status 2	74	0.88%
	Post	Adult Status 1	630	6.69%
		Adult Status 2	3171	33.66%
		Adult Status 3	860	9.13%
		Adult Status 4	925	9.82%
		Adult Status 5	31	0.33%
		Adult Status 6	199	2.11%
Zone B	Pre	Status 1A	180	2.14%
		Status 1B	89	1.06%
		Status 2	38	0.45%
	Post	Adult Status 1	59	0.63%
		Adult Status 2	488	5.18%
		Adult Status 3	261	2.77%
		Adult Status 4	165	1.75%
		Adult Status 5	10	0.11%
		Adult Status 6	70	0.74%
Zone C	Pre	Status 1A	6	0.07%
		Status 1B	4	0.05%
		Status 2	3	0.04%
	Post	Adult Status 1	1	0.01%
		Adult Status 2	15	0.16%
		Adult Status 3	9	0.1%
		Adult Status 4	16	0.17%
		Adult Status 5	2	0.02%
		Adult Status 6	5	0.05%

Zone D	Pre	Status 1A	1	0.01%
		Status 1B	1	0.01%
	Post	Adult Status 3	3	0.03%
		Adult Status 6	1	0.01%

Table A14: 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	8510	5485	467	[454, 479]
	Status 1B	9366	2443	52	[50, 54]
	Status 2	3818	213	9	[8, 10]
Pre	**Overall**	**14224**	**8141**	**78**	**[76, 79]**
Post	Adult Status 1	1034	794	3190	[2972, 3420]
	Adult Status 2	5409	4323	1762	[1710, 1815]
	Adult Status 3	4393	1694	308	[293, 323]
	Adult Status 4	7102	1757	41	[39, 43]
	Adult Status 5	614	80	31	[24, 38]
	Adult Status 6	3638	445	30	[27, 33]
Post	**Overall**	**14566**	**9135**	**101**	**[99, 104]**

Table A15: 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	791	56	Ref	-
	Post	857	83	1.49	[1.33, 1.66]
2	Pre	1562	82	Ref	-
	Post	1444	91	1.11	[1.01, 1.22]
3	Pre	1835	75	Ref	-
	Post	1771	93	1.24	[1.09, 1.42]
4	Pre	1511	80	Ref	-
	Post	1434	96	1.2	[1.07, 1.34]
5	Pre	1990	110	Ref	-
	Post	2096	159	1.44	[1.31, 1.58]
6	Pre	443	97	Ref	-
	Post	394	128	1.32	[1.17, 1.50]
7	Pre	1451	53	Ref	-
	Post	1382	88	1.66	[1.51, 1.82]
8	Pre	850	94	Ref	-
	Post	876	118	1.26	[1.13, 1.40]
9	Pre	1050	55	Ref	-
	Post	1196	78	1.43	[1.25, 1.65]
10	Pre	1256	66	Ref	-
	Post	1363	72	1.08	[0.96, 1.21]
11	Pre	1729	96	Ref	-
	Post	1920	128	1.33	[1.21, 1.46]
Overall	Pre	14224	78	Ref	-
	Post	14566	101	1.31	[1.27, 1.35]

Table A16: 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	985	61	Ref	-
		Post	1017	36	0.59	[0.31, 1.14]
	6-10 Years	Pre	162	30	Ref	-
		Post	167	15	0.49	[0.18, 1.32]
	11-17 Years	Pre	453	18	Ref	-
		Post	432	19	1.09	[0.43, 2.76]
Status 1B	0-5 Years	Pre	332	6	Ref	-
		Post	336	2	0.34	-
	6-10 Years	Pre	96	0	Ref	-
		Post	133	0	-	-
	11-17 Years	Pre	292	3	Ref	-
		Post	284	3	1.17	[0.17, 8.33]
Status 2	0-5 Years	Pre	219	1	Ref	-
		Post	212	2	1.6	-
	6-10 Years	Pre	86	0	Ref	-
		Post	75	0	-	-
	11-17 Years	Pre	191	1	Ref	-
		Post	214	1	1.68	[0.15, 18.49]
Temporarily Inactive	0-5 Years	Pre	456	49	Ref	-
		Post	491	44	0.9	[0.50, 1.60]
	6-10 Years	Pre	91	41	Ref	-
		Post	74	23	0.57	[0.29, 1.12]
	11-17 Years	Pre	172	16	Ref	-
		Post	200	21	1.28	[0.64, 2.55]
Overall	0-5 Years	Pre	1243	38	Ref	-
		Post	1251	27	0.7	[0.45, 1.08]
	6-10 Years	Pre	249	14	Ref	-
		Post	283	8	0.57	[0.33, 1.00]
	11-17 Years	Pre	673	8	Ref	-
		Post	717	9	1.08	[0.65, 1.80]

Table A17: 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	985	336	Ref	-
		Post	1017	303	0.9	[0.74, 1.10]
	6-10 Years	Pre	162	358	Ref	-
		Post	167	503	1.41	[1.17, 1.69]
	11-17 Years	Pre	453	500	Ref	-
		Post	432	995	1.99	[1.72, 2.31]
Status 1B	0-5 Years	Pre	332	101	Ref	-
		Post	336	52	0.52	[0.32, 0.85]
	6-10 Years	Pre	96	56	Ref	-
		Post	133	119	2.14	[1.49, 3.06]
	11-17 Years	Pre	292	149	Ref	-
		Post	284	195	1.31	[1.02, 1.68]
Status 2	0-5 Years	Pre	219	15	Ref	-
		Post	212	12	0.8	[0.37, 1.71]
	6-10 Years	Pre	86	20	Ref	-
		Post	75	18	0.9	[0.41, 2.01]
	11-17 Years	Pre	191	11	Ref	-
		Post	214	14	1.2	[0.61, 2.37]
Overall	0-5 Years	Pre	1243	124	Ref	-
		Post	1251	107	0.87	[0.73, 1.03]
	6-10 Years	Pre	249	93	Ref	-
		Post	283	120	1.3	[1.11, 1.52]
	11-17 Years	Pre	673	133	Ref	-
		Post	717	151	1.14	[1.00, 1.29]