

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

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Background/Purpose

On October 18, 2018 the Organ Procurement and Transplantation Network (OPTN) implemented modifications to the adult heart allocation system. Since this implementation, the OPTN Thoracic Organ Transplantation Committee split into the Lung Transplantation Committee and the Heart Transplantation Committee. The Heart Transplantation Committee (The Committee) will continue 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 (MCS) and prevalence of MCS 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 four years post-implementation, and will be followed by one more annual report at 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 (MCS) and MCS 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 (MCS) and MCS 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 March 24, 2023 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, 2014 and October 17, 2018 (pre) or between October 18, 2018 and October 17, 2022 (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, 2022 (post). Rates were assessed based on the ratio of death or transplant to active patient-years of exposure, and rates are displayed as deaths or transplants per 100 active 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, 2022 (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, 2022 (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, 2022 (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 three years of follow-up plus a two-month data lag, which included recipients transplanted between October 18, 2014 and October 17, 2015 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, 2022 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, 2022). 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, 2022 (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, 2022 (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, 2022 (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.

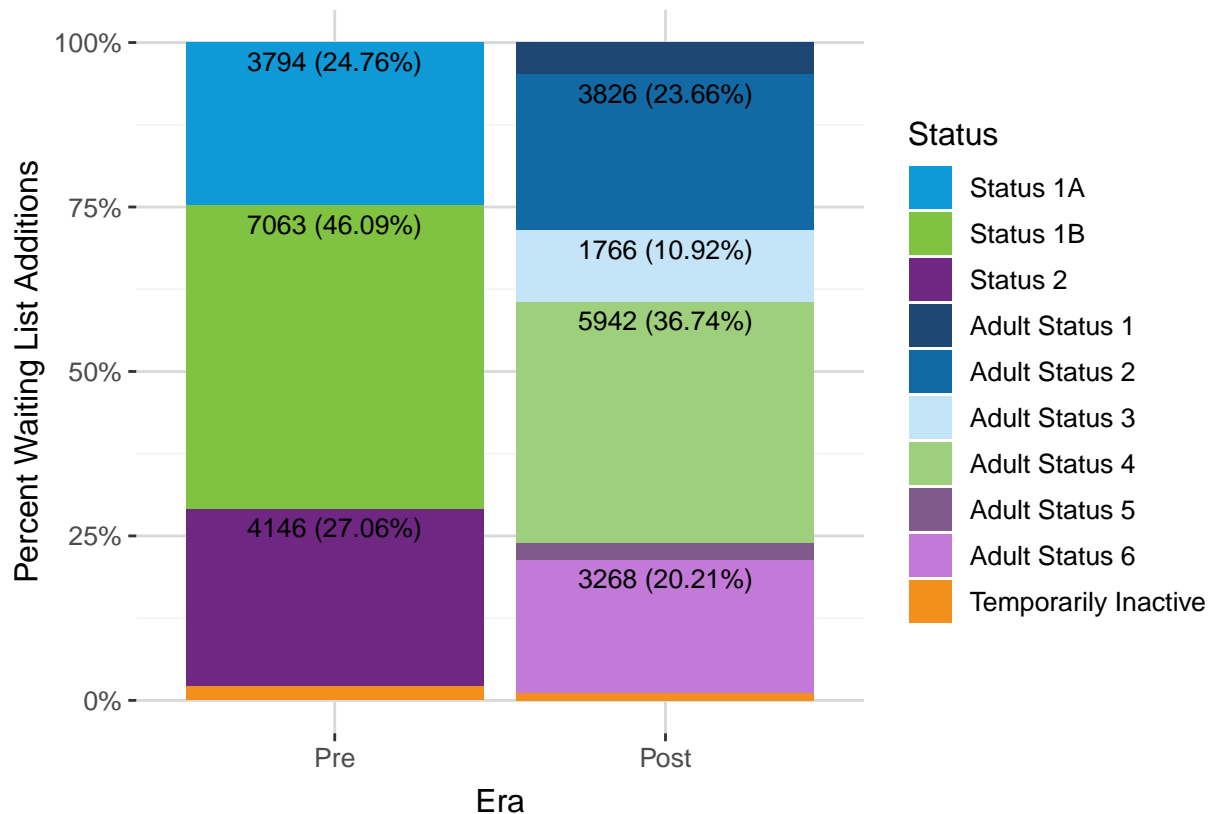
Statistical analyses were performed using SAS v9.4 (SAS Institute, Inc., Cary, NC.) and R Version 4.1.3 (R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL: <https://www.R-project.org/>).

Results

Waitlist

These analyses examine differences between two waiting list cohorts: the pre-implementation cohort, composed of 15324 registrations added to the heart waiting list between October 18, 2014 and October 17, 2018; and the post-implementation cohort, composed of 16171 registrations added between October 18, 2018 and October 17, 2022.

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



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

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	3794	24.8%
	Equivalent Status 1B	Status 1B	7063	46.1%
	Equivalent Status 2	Status 2	4146	27.1%
	Temporarily inactive	Temporarily inactive	321	2.1%
Post	Equivalent Status 1A	Adult Status 1	778	4.8%
		Adult Status 2	3826	23.7%
		Adult Status 3	1766	10.9%
	Equivalent Status 1B	Adult Status 4	5942	36.7%
		Adult Status 5	401	2.5%
	Equivalent Status 2	Adult Status 6	3268	20.2%
	Temporarily inactive	Temporarily inactive	190	1.2%

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

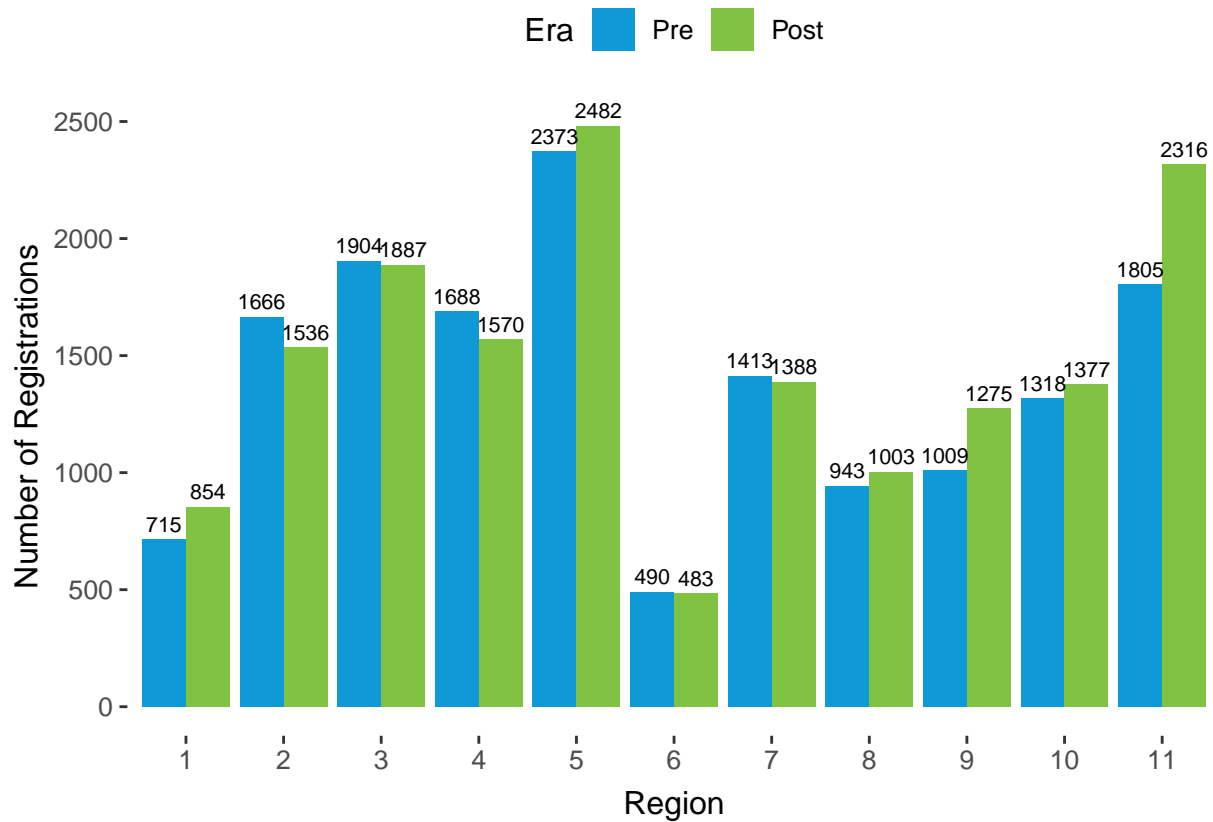


Figure 2 shows the number of adult heart waiting list registrations added by region both pre- and post-implementation. Compared to pre-implementation, the number of registrations added post-implementation increased by more than 5% in regions 1, 8, 9, and 11, decreased by more than 5% in regions 2 and 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.

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

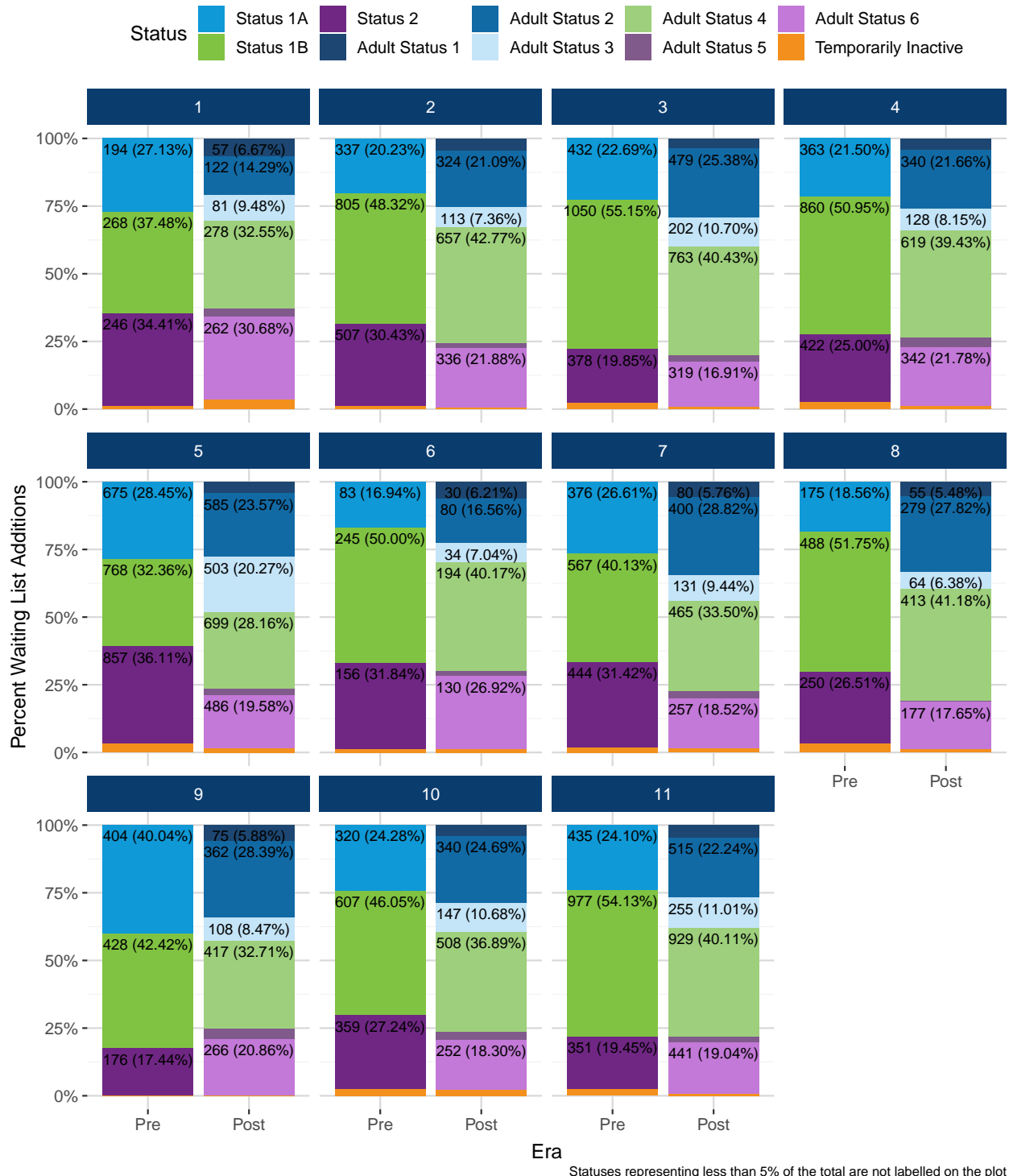


Figure 4 shows the adult heart waiting list additions by region, device at time of listing, and era. The percent of waiting list additions for those on no devices decreased in all regions except in region 6. The largest decrease occurred in regions 3 and 5. In the post-policy era as few as 47% of all waitlist additions were on no devices at time of listing (region 10) and as many as 64% were on no device (region 5). The percent of waitlist additions in each region on IABP-only increased. Conversely, the percent on VAD-only decreased or remained the same except in region 3 post-implementation.

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

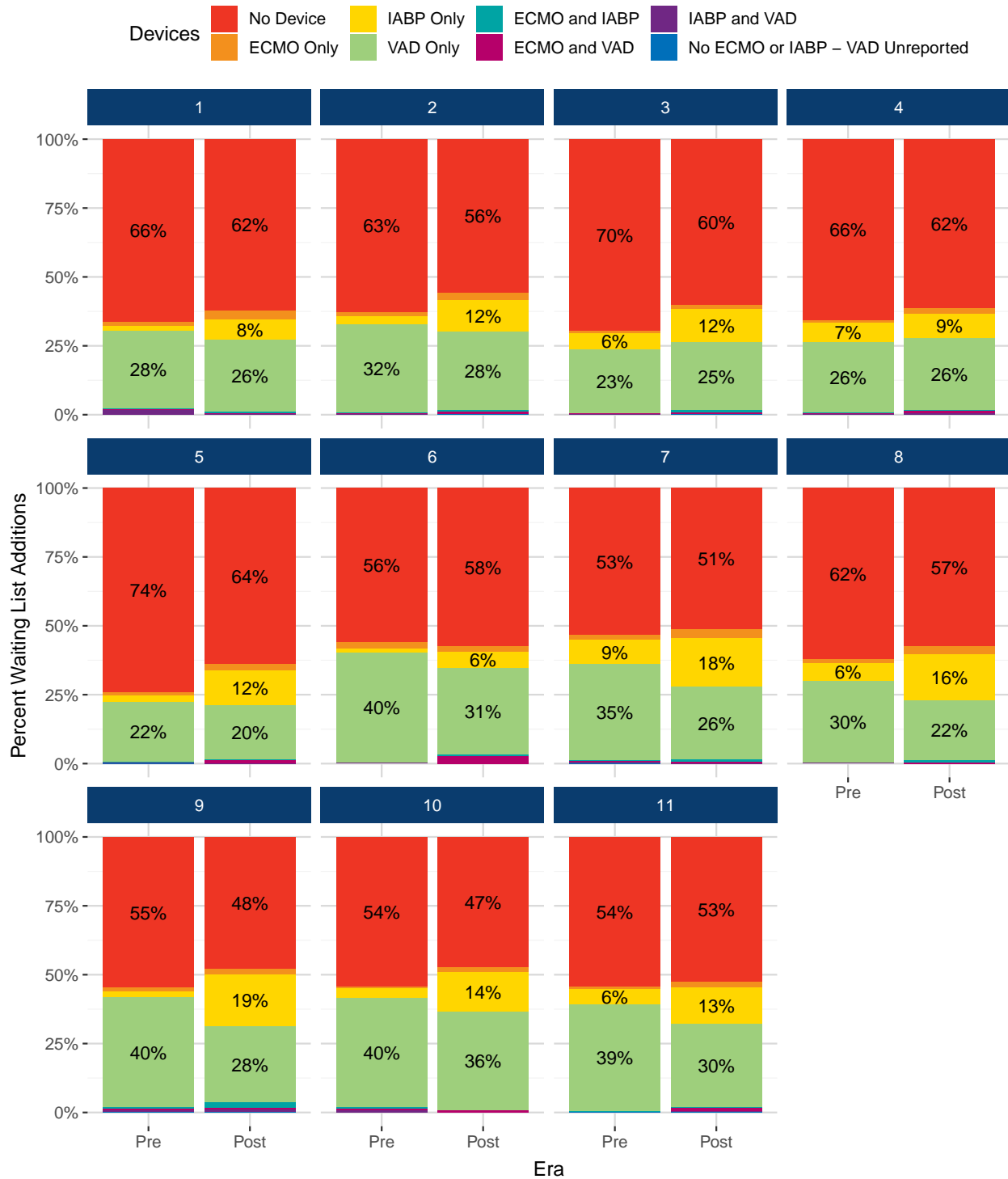


Table 2 shows the criteria qualifying adult heart waiting list candidates for their medical urgency status at time of listing post-implementation. For Adult Status 5 and Adult Status 6, which have no qualifying criteria, the count of waiting list additions at the status is given. For Adult Status 1 the most common criterion for waiting list additions was VA ECMO, with (25.70%) or without (32.44%) hemodynamic values. For Adult Status 2 the most common criterion was intra-aortic balloon pump with hemodynamic values (41.23%); it was rare for IABP to be reported without hemodynamic values (1.50%). For Adult Status 3 the most common qualifying criterion was multiple inotropes/single high dose inotrope with hemodynamic monitoring (34.06%), followed by exception (25.66%) and dischargeable LVAD for discretionary 30 days (22.24%). For Adult Status 4 the most common was dischargeable LVAD without discretionary 30 days (41.43%).

The percent of adult heart waiting list additions qualifying by an exception at time of listing was greatest for Adult Status 2, with 36.88% of candidates qualifying under this criterion. For the other statuses the percent of candidates qualifying by an exception at listing ranged between 16.08% for Adult Status 4 and 25.66% for Adult Status 3.

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	47	5.75%
	Exception	195	23.87%
	Exception due to device recall	1	0.12%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	99	12.12%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	265	32.44%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	210	25.70%
Overall		817	100%
Adult Status 2	Exception	1424	36.88%
	Exception due to device recall	2	0.05%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	58	1.50%
	Intra-aortic ballon pump - Hemodynamic Values obtained	1592	41.23%
	Mechanical circulatory support device(MCSD) with malfunction	68	1.76%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	51	1.32%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	62	1.61%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	423	10.96%
	Total artificial heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	88	2.28%
	Ventricular tachycardia(VT) or ventricular fibrillation(VF)	93	2.41%
Overall		3861	100%
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	397	22.24%

(continued)

Status	Criteria	N	%
Adult Status 3	Exception	458	25.66%
	Exception due to device recall	1	0.06%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	12	0.67%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	115	6.44%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	75	4.20%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	21	1.18%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	22	1.23%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	18	1.01%
	Mechanical circulatory support device (MCSD) with hemolysis	8	0.45%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	5	0.28%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	4	0.22%
	Mechanical circulatory support device (MCSD) with pump thrombosis	35	1.96%
	Mechanical circulatory support device (MCSD) with right heart failure	6	0.34%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	608	34.06%
Overall		1785	100%
Adult Status 4	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	604	10.06%
	Congenital heart disease	439	7.31%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	2488	41.43%
	Exception	966	16.08%
	Inotropes without hemodynamic monitoring	1065	17.73%
	Ischemic heart disease with intractable angina	116	1.93%
Retransplant	328	5.46%	
Overall		6006	100%
Adult Status 5	None	480	100.00%
Adult Status 6	None	3283	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, 2022, 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 20), 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 most common criteria for Adult Status 1 candidates was an exception due to device recall (n=4, 28.57%), 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 the same in the post-guidance period (n=3, 21.43%), 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, an exception was the most common criterion at listing postguidance. An exception and MCSD with bacteremic device infection were the most common for those waiting at Adult Status 3 under an extension pre-guidance, while an exception and MCSD with debridement device infection were the most common gpost-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.

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

Status	Criteria	Initial		Extension		Total	
		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 artificial 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%
	Ventricular tachycardia(VT) or ventricular fibrillation(VF)	2	3.08%	0	0.00%	2	2.33%
Overall		65	100%	21	100%	86	100%
Adult Status 3	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, 2022 (Post-Guidance)

Status	Criteria	Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 1	BIVAD/Ventricular Episodes	1	10.00%	0	0.00%	1	7.14%
	Exception	3	30.00%	1	25.00%	4	28.57%
	Exception due to device recall	1	10.00%	1	25.00%	2	14.29%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	2	20.00%	1	25.00%	3	21.43%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	1	10.00%	0	0.00%	1	7.14%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	2	20.00%	1	25.00%	3	21.43%
Overall		10	100%	4	100%	14	100%
Adult Status 2	Exception	50	51.55%	34	61.82%	84	55.26%
	Exception due to device recall	3	3.09%	4	7.27%	7	4.61%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	0	0.00%	1	1.82%	1	0.66%
	Intra-aortic ballon pump - Hemodynamic Values obtained	28	28.87%	7	12.73%	35	23.03%
	Mechanical circulatory support device(MCSD) with malfunction	2	2.06%	1	1.82%	3	1.97%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	1	1.03%	1	1.82%	2	1.32%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	2	2.06%	0	0.00%	2	1.32%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	9	9.28%	5	9.09%	14	9.21%
	Total artificial heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	2	2.06%	2	3.64%	4	2.63%
Overall		97	100%	55	100%	152	100%
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	7	12.73%	0	0.00%	7	4.17%

(continued)

Status	Criteria	N	%	N	%	N	%
Adult Status 3	Exception	12	21.82%	23	20.35%	35	20.83%
	Exception due to device recall	5	9.09%	19	16.81%	24	14.29%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	6	10.91%	4	3.54%	10	5.95%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	11	20.00%	21	18.58%	32	19.05%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	5	9.09%	23	20.35%	28	16.67%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	2	3.64%	8	7.08%	10	5.95%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	1	1.82%	1	0.88%	2	1.19%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	1	1.82%	1	0.88%	2	1.19%
	Mechanical circulatory support device (MCSD) with pump thrombosis	1	1.82%	8	7.08%	9	5.36%
	Mechanical circulatory support device (MCSD) with right heart failure	0	0.00%	2	1.77%	2	1.19%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	4	7.27%	3	2.65%	7	4.17%
Overall		55	100%	113	100%	168	100%
Adult Status 4	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	36	7.02%	44	5.28%	80	5.94%
	Congenital heart disease	35	6.82%	63	7.56%	98	7.28%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	285	55.56%	607	72.87%	892	66.27%
	Exception	41	7.99%	48	5.76%	89	6.61%
	Inotropes without hemodynamic monitoring	75	14.62%	16	1.92%	91	6.76%
	Ischemic heart disease with intractable angina	11	2.14%	17	2.04%	28	2.08%
	Retransplant	30	5.85%	38	4.56%	68	5.05%
Overall		513	100%	833	100%	1346	100%

(continued)

Status	Criteria	N	%	N	%	N	%
Adult Status 5	None	68	100.00%	36	100.00%	104	100.00%
Adult Status 6	None	319	100.00%	248	100.00%	567	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 (MCS) at listing, based on information reported on the TCR and broken down by device type and brand. Overall, 62.52% of new registrations had an MCS listed on the TCR pre-implementation, compared to 56.46% 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 MCSs.

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

Brand	Era	Count	Percent
ECMO			
Total ECMO	Pre	274	4.52%
	Post	596	7.96%
IABP			
Total IABP	Pre	804	13.28%
	Post	2243	29.95%
LVAD			
Abiomed AB5000	Pre	1	0.02%
	Post	0	0%
Cardiac Assist Protek Duo	Pre	0	0%
	Post	12	0.28%
Cardiac Assist Tandem Heart	Pre	10	0.22%
	Post	6	0.14%
CentriMag (Thoratec/Levitronix)	Pre	36	0.79%
	Post	33	0.78%
Evaheart	Pre	1	0.02%
	Post	3	0.07%
Heartmate II	Pre	2442	53.62%
	Post	468	11.05%
HeartMate III	Pre	61	1.34%
	Post	2144	50.63%
Heartmate XVE	Pre	7	0.15%
	Post	0	0%
Heartsaver VAD	Pre	3	0.07%
	Post	5	0.12%
Heartware HVAD	Pre	1316	28.9%
	Post	833	19.67%
Impella CP	Pre	2	0.04%
	Post	86	2.03%
Impella Recover 2.5	Pre	18	0.4%
	Post	4	0.09%

Impella Recover 5.0	Pre	72	1.58%
	Post	205	4.84%
Impella RP	Pre	0	0%
	Post	4	0.09%
Jarvik 2000	Pre	8	0.18%
	Post	0	0%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	3	0.07%
Terumo DuraHeart	Pre	2	0.04%
	Post	0	0%
Thoratec IVAD	Pre	0	0%
	Post	2	0.05%
Thoratec PVAD	Pre	4	0.09%
	Post	0	0%
Other, Specify	Pre	571	12.54%
	Post	427	10.08%
Total LVAD	Pre	4554	75.2%
	Post	4235	56.56%
LVAD+RVAD			
Abiomed AB5000	Pre	0	0%
	Post	1	0.29%
Cardiac Assist Protek Duo	Pre	0	0%
	Post	24	7.06%
Cardiac Assist Tandem Heart	Pre	13	3.92%
	Post	7	2.06%
CentriMag (Thoratec/Levitronix)	Pre	151	45.48%
	Post	160	47.06%
Heartmate II	Pre	32	9.64%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	49	14.41%
Heartware HVAD	Pre	80	24.1%
	Post	28	8.24%
Impella CP	Pre	0	0%
	Post	2	0.59%
Impella Recover 2.5	Pre	2	0.6%
	Post	0	0%
Impella Recover 5.0	Pre	5	1.51%
	Post	8	2.35%

Impella RP	Pre	0	0%
	Post	1	0.29%
Maquet Jostra Rotaflow	Pre	10	3.01%
	Post	19	5.59%
Thoratec PVAD	Pre	17	5.12%
	Post	2	0.59%
Other, Specify	Pre	22	6.63%
	Post	39	11.47%
Total LVAD+RVAD	Pre	332	5.48%
	Post	340	4.54%
RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	8	23.53%
Cardiac Assist Tandem Heart	Pre	2	11.11%
	Post	1	2.94%
CentriMag (Thoratec/Levitronix)	Pre	7	38.89%
	Post	7	20.59%
Heartmate II	Pre	2	11.11%
	Post	0	0%
HeartMate III	Pre	0	0%
	Post	2	5.88%
Heartware HVAD	Pre	3	16.67%
	Post	1	2.94%
Impella CP	Pre	0	0%
	Post	2	5.88%
Impella Recover 5.0	Pre	1	5.56%
	Post	5	14.71%
Impella RP	Pre	0	0%
	Post	2	5.88%
Maquet Jostra Rotaflow	Pre	1	5.56%
	Post	1	2.94%
Thoratec PVAD	Pre	1	5.56%
	Post	0	0%
Other, Specify	Pre	1	5.56%
	Post	5	14.71%
Total RVAD	Pre	18	0.3%
	Post	34	0.45%

TAH

SynCardia CardioWest	Pre	74	100%
	Post	35	87.5%
Other, Specify	Pre	0	0%
	Post	5	12.5%
Total TAH	Pre	74	1.22%
	Post	40	0.53%

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

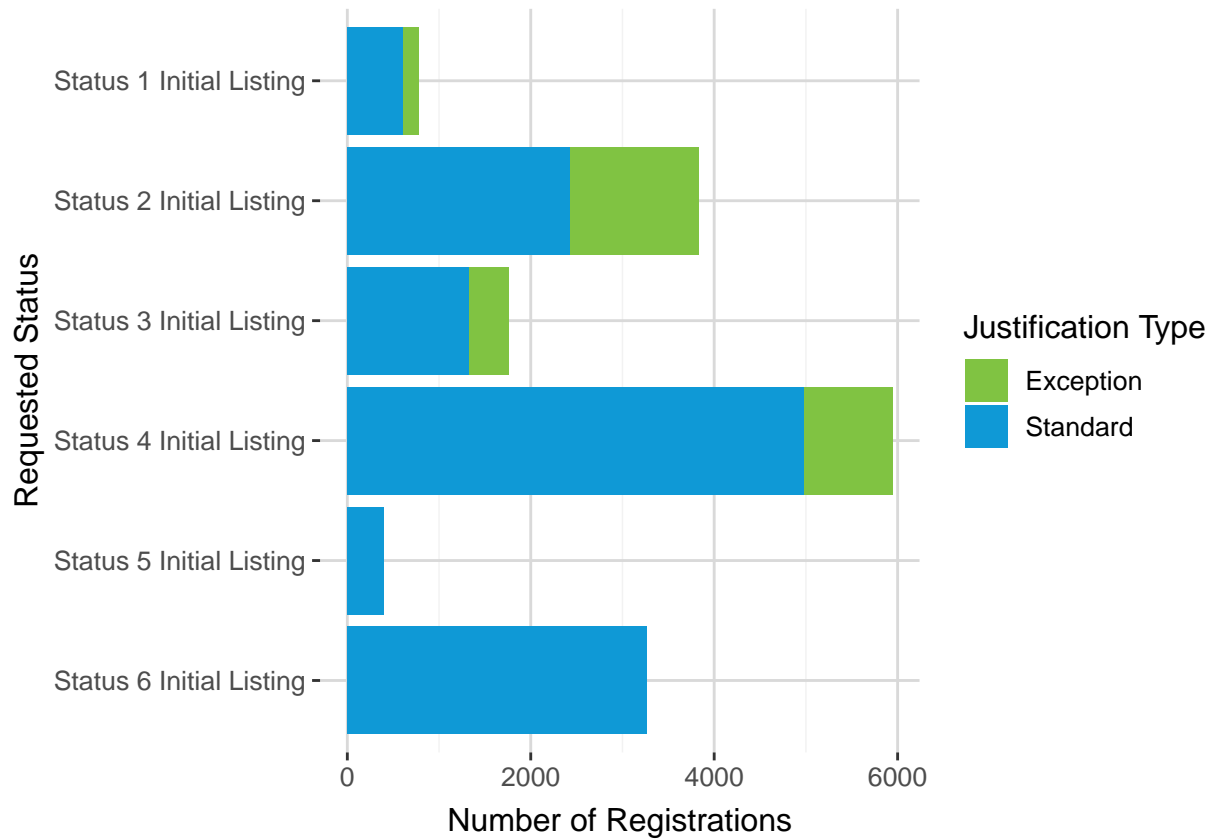


Figure 5 shows the number of justification forms at listing, the status requested, and whether the review type was standard or exception. The most-requested status at listing was Adult Status 4, followed by Adult Status 2. Exception requests were most common for candidates listing at either Adult Status 2 or Adult Status 4.

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

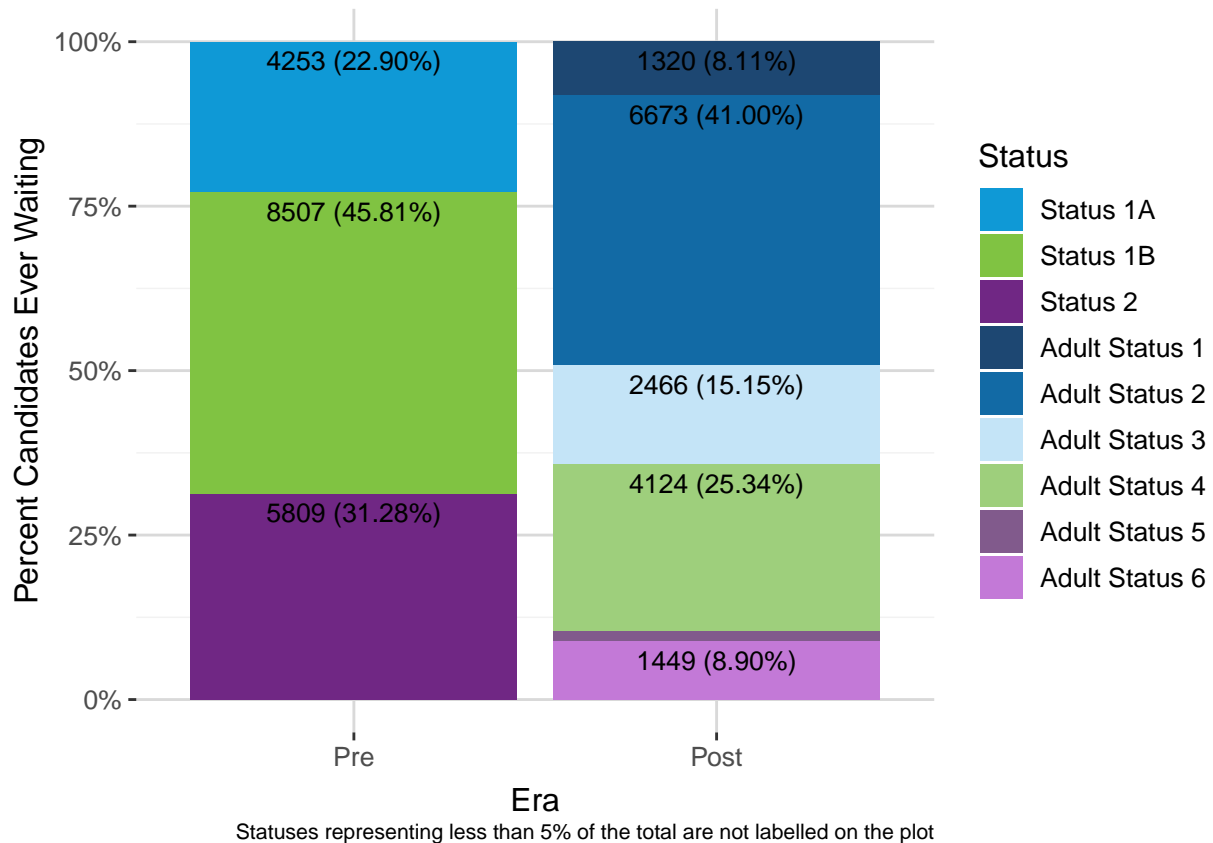
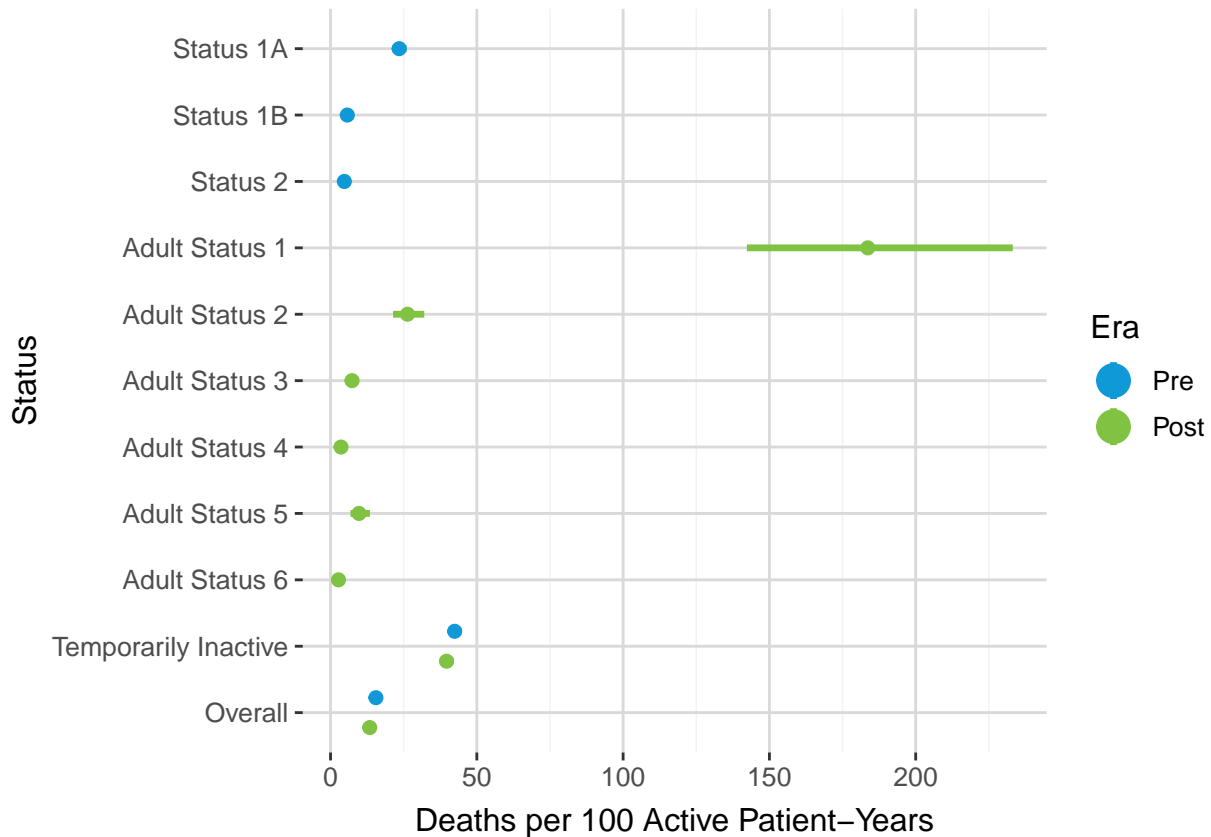


Figure 6 shows the composition of candidates ever waiting by medical urgency status both pre- and post-implementation. The statuses shown pre-implementation are the statuses candidates held when added to the waiting list; displaying the most recent candidate status would make interpretation more difficult, 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 Active Patient-Years Waiting by Medical Urgency Status and Era



Figures 7 and 8 show the number of deaths per 100 patient-years waiting 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 the number of deaths per 100 patient-years waiting was significantly lower post-implementation than pre-implementation.

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

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

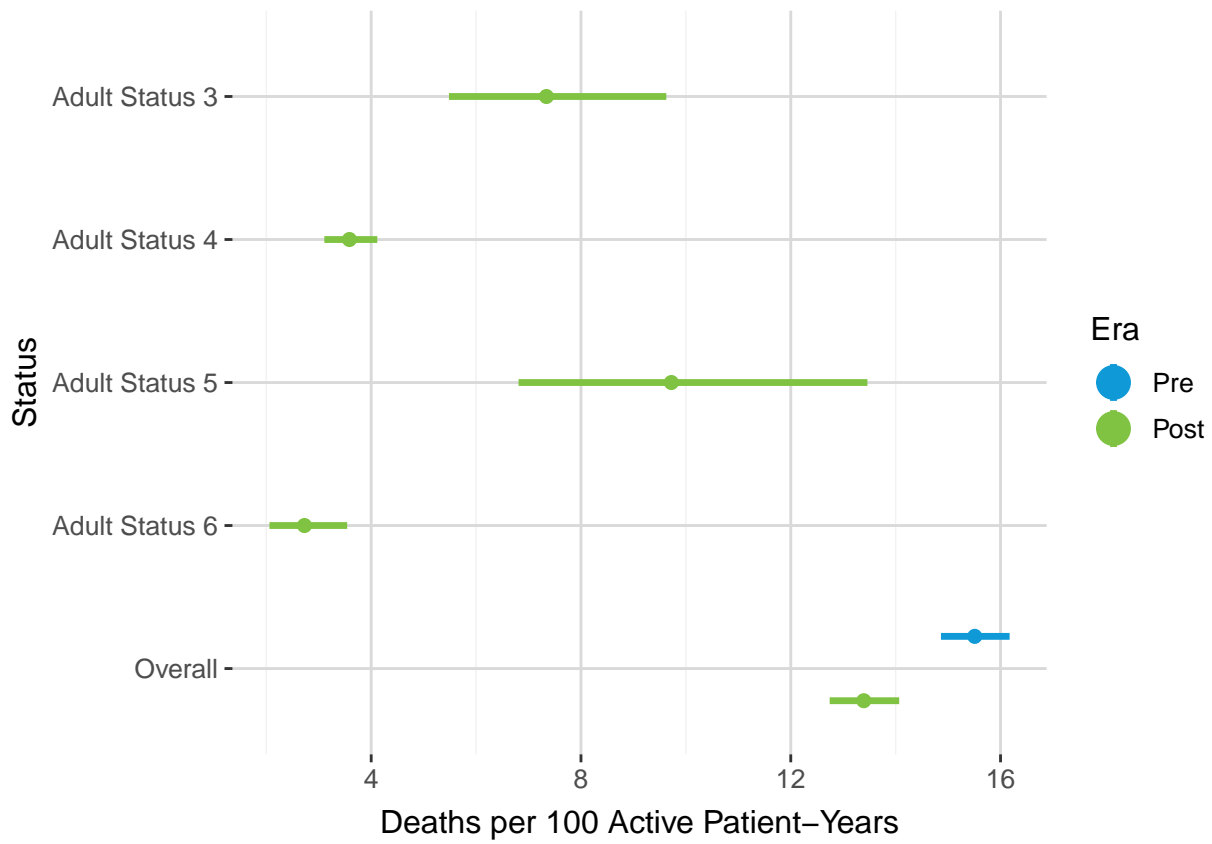
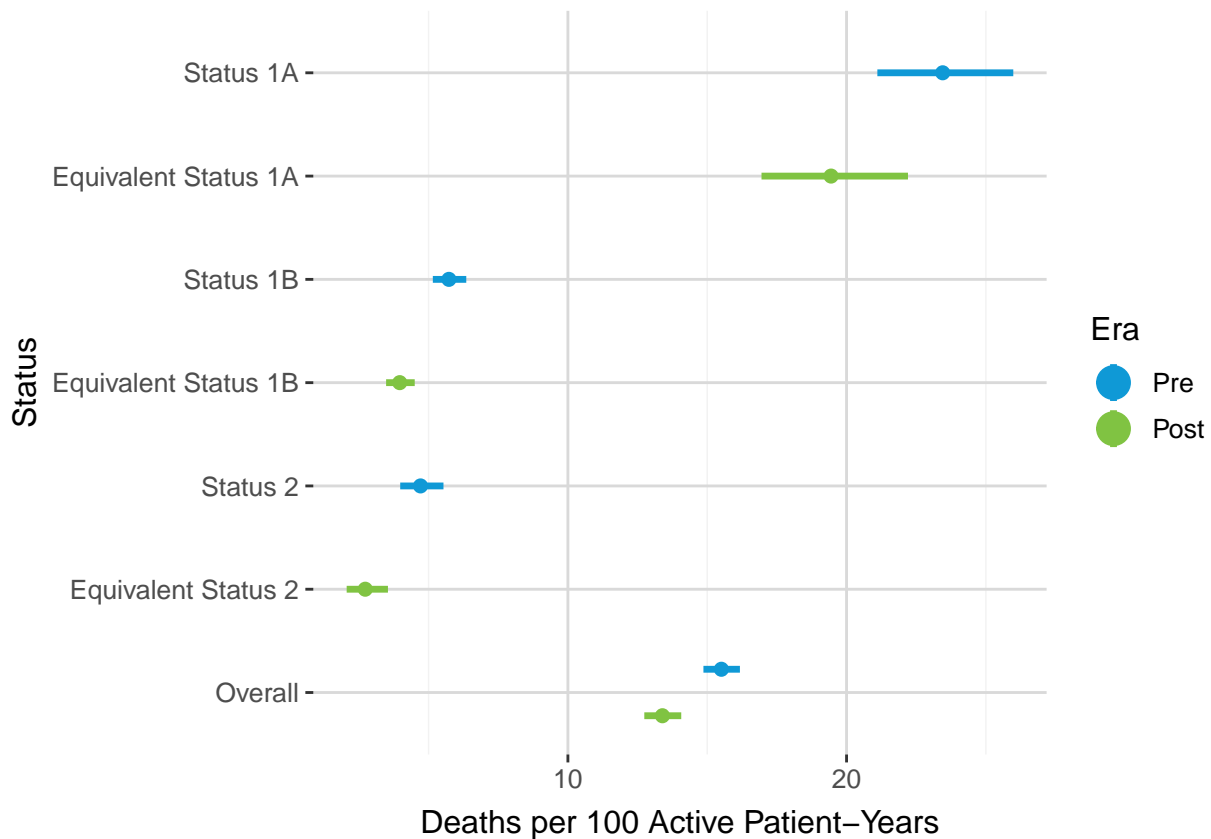


Table 6. Deaths per 100 Active Patient-Years Waiting by Medical Urgency Status and Era

Era	Status	Patients Ever Waiting	Number of Deaths	Deaths per 100 Patient Years	CI
Pre	Status 1A	10844	365	23	[21, 26]
	Status 1B	11705	360	6	[5, 6]
	Status 2	4885	148	5	[4, 6]
	Temporarily Inactive	6870	1308	42	[40, 45]
Pre	Overall	17461	2181	16	[15, 16]
Post	Adult Status 1	1514	67	184	[142, 233]
	Adult Status 2	7646	99	26	[21, 32]
	Adult Status 3	5406	52	7	[5, 10]
	Adult Status 4	8734	201	4	[3, 4]
	Adult Status 5	781	36	10	[7, 13]
	Adult Status 6	4497	56	3	[2, 4]
	Temporarily Inactive	6266	1072	40	[37, 42]
	Post	Overall	18488	1589	13

Figure 9. Deaths per 100 Active 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, but the number of deaths per 100 patient-years waiting was significantly lower for equivalent status 1B than old status 1B and significantly lower for equivalent status 2 than old status 2.

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. The number of deaths per 100 patient-years waiting was similar across criteria within most statuses, suggesting that candidates, despite qualifying criteria, have similar medical urgency within each status. Table 7 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. Confidence intervals could not be calculated for criteria without any waiting list deaths.

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

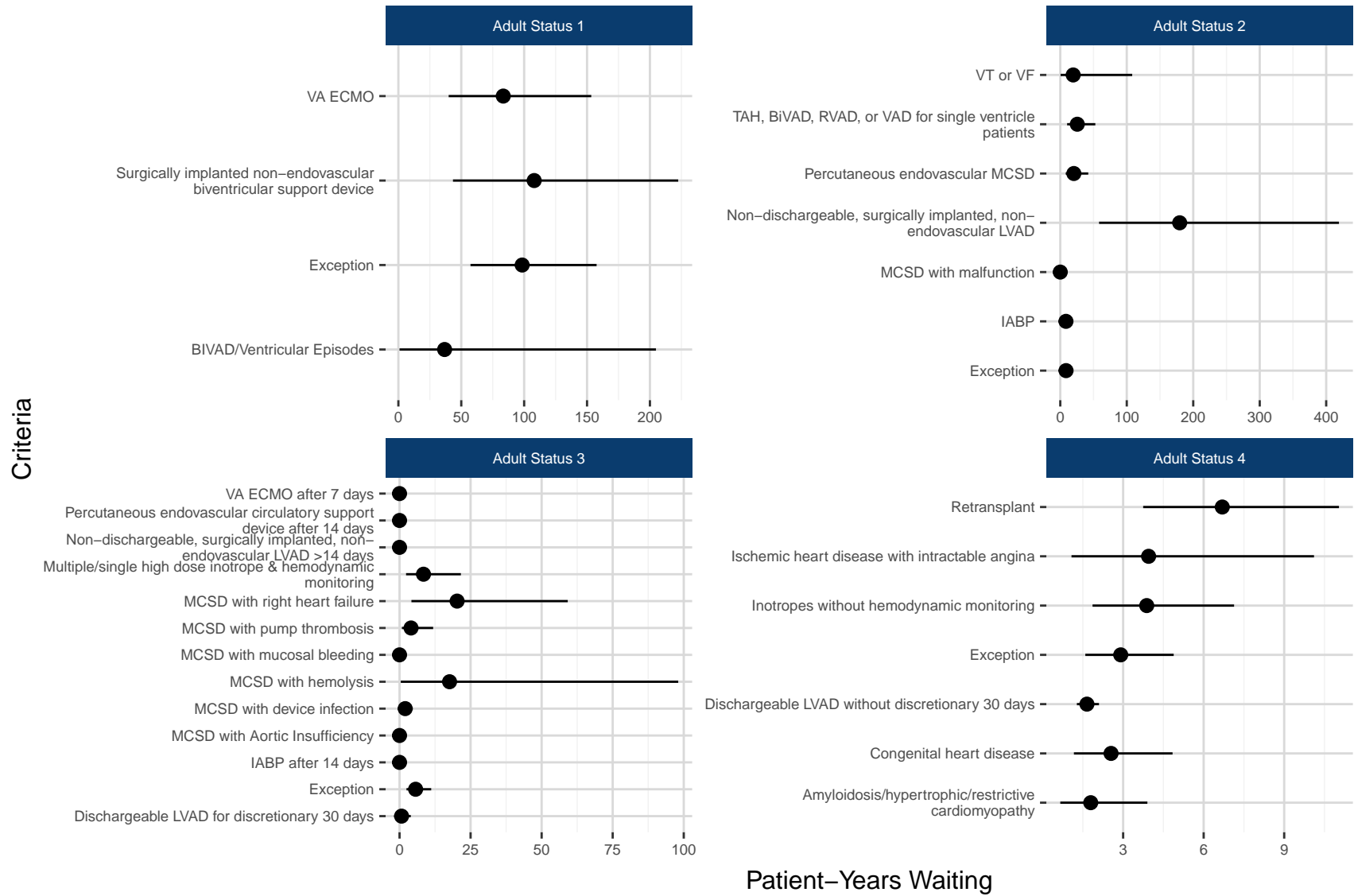


Figure 11 displays the deaths per 100 patient-years waiting by criteria within medical urgency status for Status 2 and 3 only to facilitate comparisons among these criteria.

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

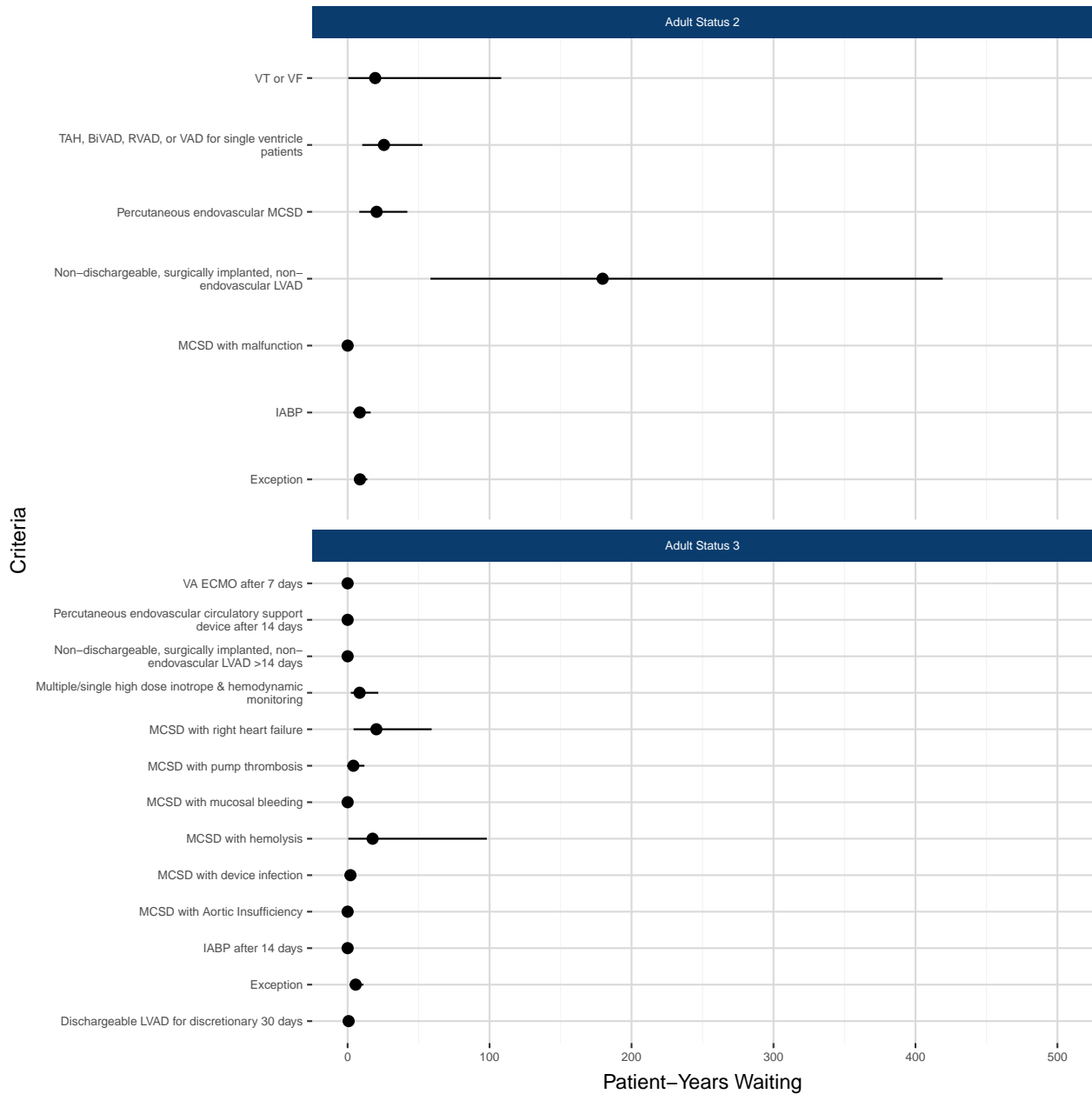


Table 7. Deaths per 100 Active Patient-Years Waiting by Criteria within Medical Urgency Status Post-Implementation

Status	CriteriaDescription	Patients Ever Waiting	Number of Deaths	Deaths per 100 Patient Years	CI
Adult Status 1	BIVAD/Ventricular Episodes	125	1	37	[1, 205]
	Exception	656	17	98	[57, 158]
	Surgically implanted non-endovascular biventricular support device	169	7	108	[43, 222]
	VA ECMO	737	10	83	[40, 153]
Adult Status 2	Exception	3660	17	9	[5, 14]
	IABP	3141	9	9	[4, 16]
	MCS D with malfunction	324	0	0	-
	Non-dischargeable, surgically implanted, non-endovascular LVAD	92	5	180	[58, 419]
	Percutaneous endovascular MCS D	884	7	20	[8, 42]
	TAH, BiVAD, RVAD, or VAD for single ventricle patients	191	7	26	[10, 53]
	VT or VF	149	1	19	[0, 108]
Adult Status 3	Dischargeable LVAD for discretionary 30 days	2167	1	1	[0, 4]
	Exception	1602	8	6	[2, 11]
	IABP after 14 days	62	0	0	-
	MCS D with Aortic Insufficiency	95	0	0	-
	MCS D with device infection	714	5	2	[1, 5]
	MCS D with hemolysis	57	1	18	[0, 98]
	MCS D with mucosal bleeding	75	0	0	-
	MCS D with pump thrombosis	140	3	4	[1, 12]
	MCS D with right heart failure	53	3	20	[4, 59]
	Multiple/single high dose inotrope & hemodynamic monitoring	1214	4	8	[2, 22]
	Non-dischargeable, surgically implanted, non-endovascular LVAD >14 days	3	0	0	-
	Percutaneous endovascular circulatory support device after 14 days	16	0	0	-
	VA ECMO after 7 days	4	0	0	-
Amyloidosis/hypertrophic/restrictive cardiomyopathy	742	6	2	[1, 4]	

	Congenital heart disease	548	9	3	[1, 5]
	Dischargeable LVAD without discretionary 30 days	4390	66	2	[1, 2]
	Exception	1498	14	3	[2, 5]
	Inotropes without hemodynamic monitoring	1700	10	4	[2, 7]
Adult Status 4	Ischemic heart disease with intractable angina	185	4	4	[1, 10]
	Retransplant	392	15	7	[4, 11]

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

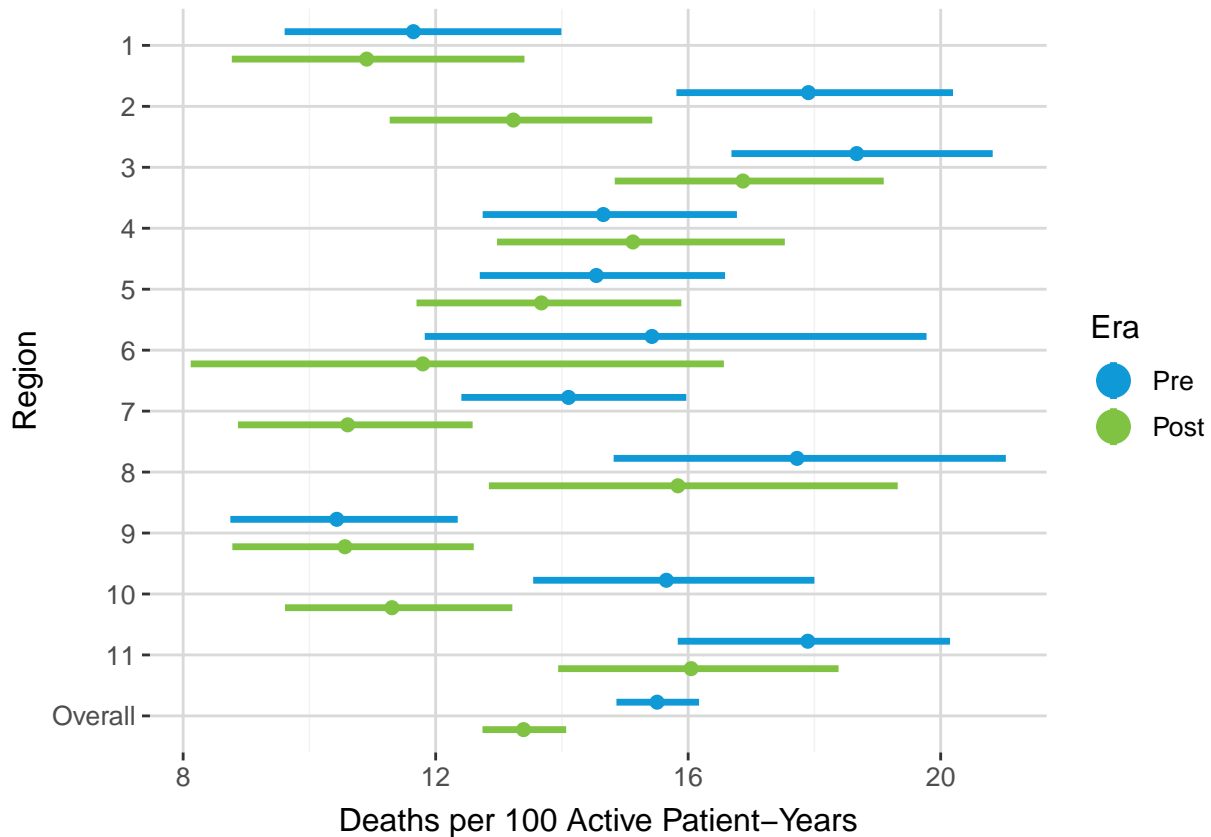


Figure 12 shows the number of deaths per 100 patient-years by region and era. The number of deaths per 100 patient-years waiting was significantly lower post-implementation in regions 2 and 10, and there was no significant change in the number of deaths per 100 patient-years in any other region pre- vs post-implementation. Although not always significantly different, there were fewer deaths per 100 patient-years post-implementation in a majority of the regions.

Transplant

These analyses examine differences in transplants between two cohorts: the pre-implementation cohort, composed of 10772 adult heart transplants performed between October 18, 2014 and October 17, 2018, and the post-implementation cohort, composed of 12864 adult heart transplants performed between October 18, 2018 and October 17, 2022. There were 2092 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

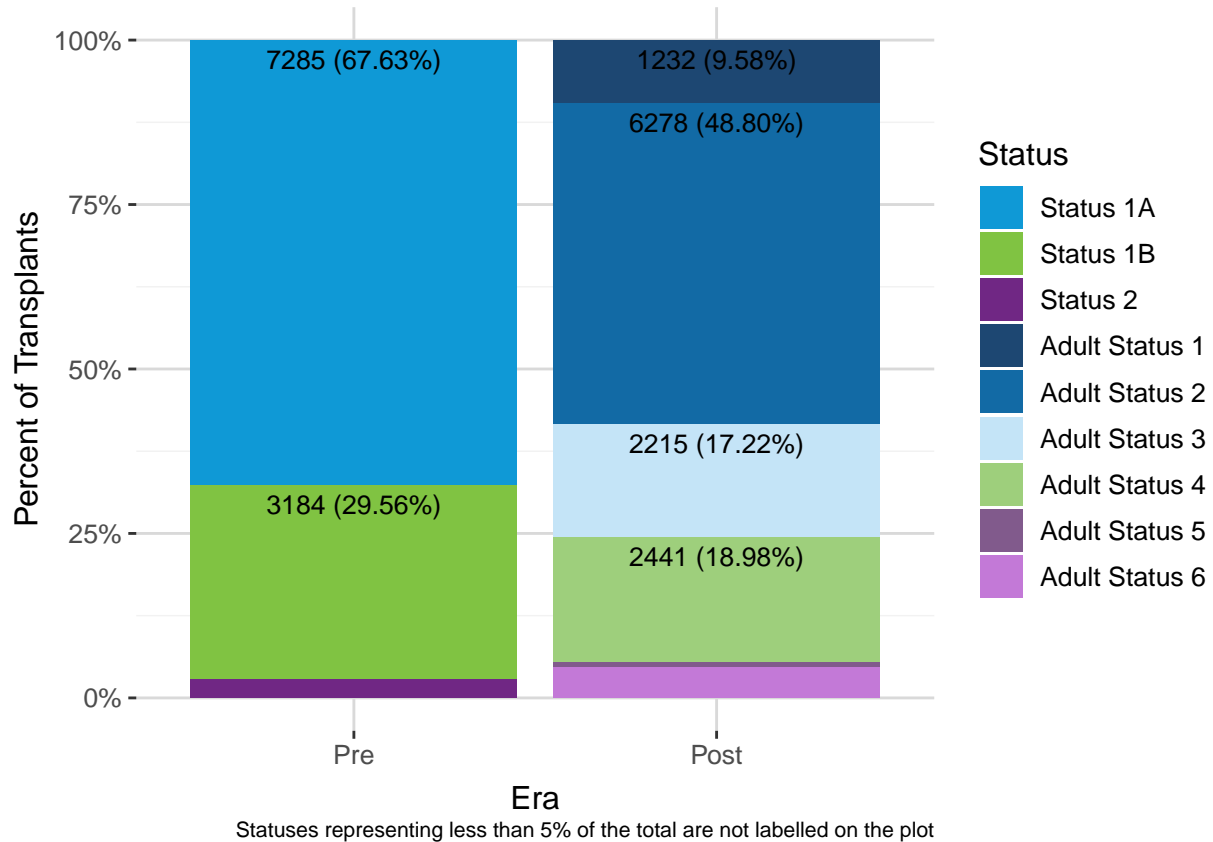


Figure 13 shows the proportion of adult heart transplants performed both pre- and post-implementation by medical urgency status. Status 1A candidates received around two-thirds (67.64%) of all transplants pre-implementation, but no single status represented such a large fraction of transplants post-implementation. 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 4.6% of transplants, and only 110 (0.9%) transplants went to Adult Status 5 patients in the four years after the new adult heart allocation policy went into effect.

Table 8 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 8. Adult Heart Transplants by Era and Medical Urgency Status

Era	Equivalent Status	Status	N	%
Pre	Equivalent Status 1A	Status 1A	7285	67.6%
	Equivalent Status 1B	Status 1B	3184	29.6%
	Equivalent Status 2	Status 2	303	2.8%
Post	Equivalent Status 1A	Adult Status 1	1232	9.6%
		Adult Status 2	6278	48.8%
		Adult Status 3	2215	17.2%
	Equivalent Status 1B	Adult Status 4	2441	19%
		Adult Status 5	110	0.9%
	Equivalent Status 2	Adult Status 6	588	4.6%

Figure 14. Adult Heart Transplants by Region and Era

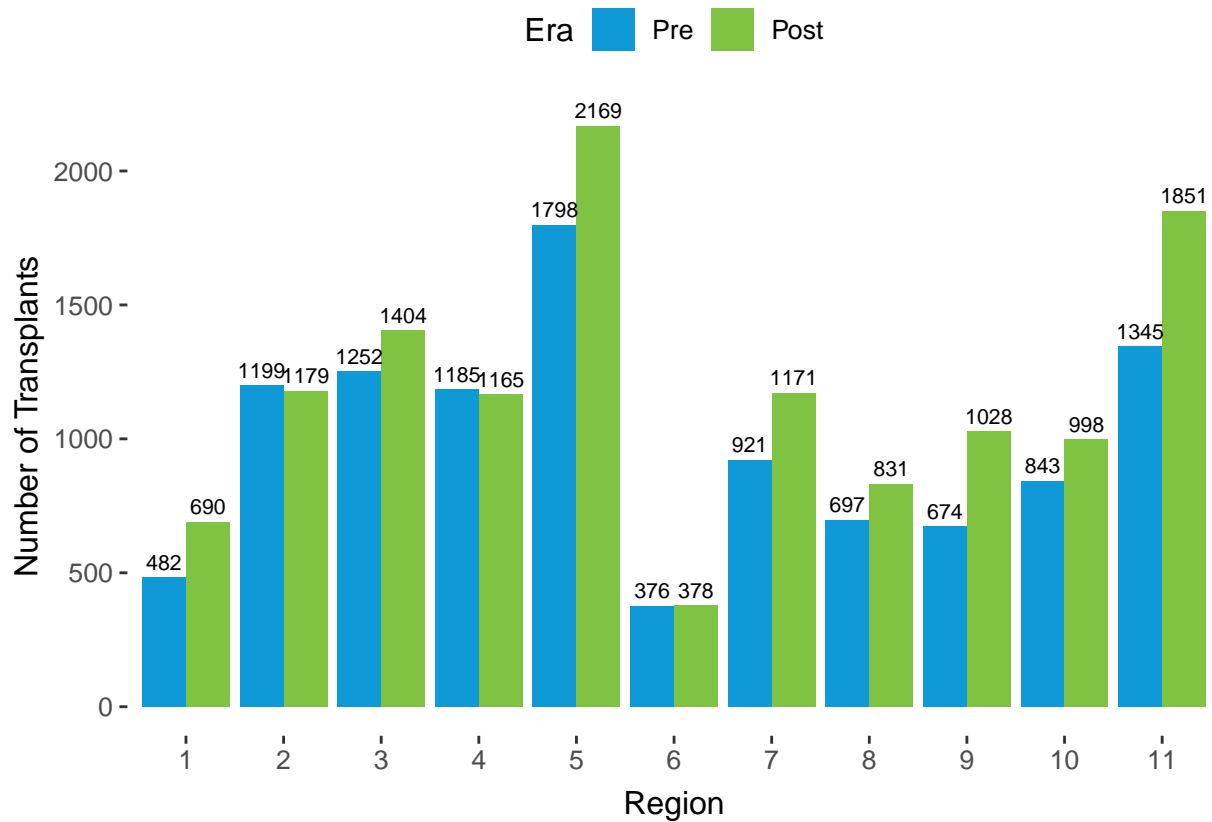


Figure 14 shows the number of adult heart transplants by era and region. The number of heart transplants rose in regions 1, 3, 5, 6, 7, 8, 9, 10, and 11, and decreased in regions 2 and 4.

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. In all regions, Adult Status 2 candidates received the largest percent of all transplants. 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

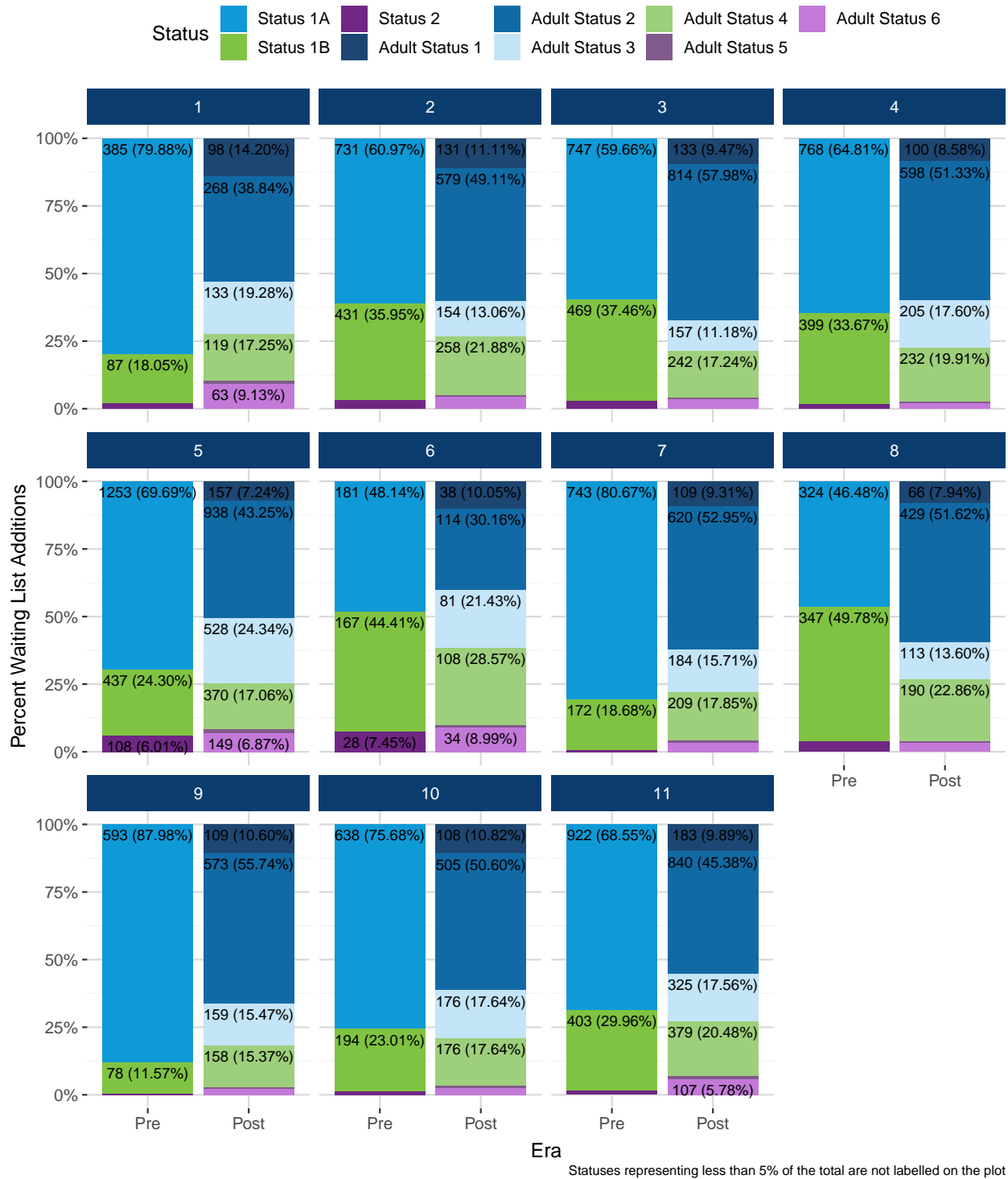


Table 9 shows the criteria allowing heart transplant recipients to qualify for their medical urgency status at time of transplant and whether they were transplanted after their initial qualification for a status or on an extension. This table only includes adult heart transplants performed during the post-implementation period. Tables 10 and 11 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, 2022). 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 (38.93%). It was also common for Adult Status 1 candidates transplanted under an extension to have received an exception (34.04%), followed by non-dischargeable, surgically implanted, non-endovascular biventricular support device (29.79%) and VA ECMO with hemodynamic values (19.15%). For Adult Status 2, it was most common for recipients transplanted under their initial request to qualify by exception (41.81%) followed closely by IABP with hemodynamic values (40.24%), while it was most common for those transplanted under an extension to have an exception (54.57%). For Adult Status 3, the most common criterion for recipients transplanted under an initial request was dischargeable LVAD for discretionary 30 days (45.71%), while it was most common for recipients transplanted under an extension to have an exception (43.40%). For Adult Status 4, dischargeable LVAD without discretionary 30 days was the most common criterion both for those transplanted under their initial request (35.98%) and for those transplanted under an extension (57.52%).

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: 12.64% vs. Post: 4.67%) and overall (Pre: 13.84% vs. Post: 8.51%), and increased for those transplanted under extension (Pre: 26.42% vs. Post: 31.82%). 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: 12.53% vs. Post: 22.30%) and overall (Pre: 10.32% vs. Post: 16.63%), and decreased for those transplanted under extension (Pre: 5.62% vs. Post: 3.12%).

Table 9. 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	87	7.99%	7	4.96%	94	7.64%
	Exception	424	38.93%	48	34.04%	472	38.37%
	Exception due to device recall	3	0.28%	1	0.71%	4	0.33%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	95	8.72%	42	29.79%	137	11.14%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	232	21.30%	16	11.35%	248	20.16%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	248	22.77%	27	19.15%	275	22.36%
Overall		1089	100%	141	100%	1230	100%
Adult Status 2	Exception	1913	41.81%	926	54.57%	2839	45.26%
	Exception due to device recall	9	0.20%	14	0.82%	23	0.37%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	52	1.14%	9	0.53%	61	0.97%
	Intra-aortic ballon pump - Hemodynamic Values obtained	1841	40.24%	413	24.34%	2254	35.94%
	Mechanical circulatory support device(MCSD) with malfunction	150	3.28%	110	6.48%	260	4.15%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	45	0.98%	7	0.41%	52	0.83%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	42	0.92%	9	0.53%	51	0.81%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	381	8.33%	127	7.48%	508	8.10%
	Total artificial heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	67	1.46%	62	3.65%	129	2.06%
	Ventricular tachycardia(VT) or ventricular fibrillation(VF)	75	1.64%	20	1.18%	95	1.51%
Overall		4575	100%	1697	100%	6272	100%
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	709	45.71%	0	0.00%	709	32.08%

(continued)

Status	Criteria	N	%	N	%	N	%
Adult Status 3	Exception	336	21.66%	286	43.40%	622	28.14%
	Exception due to device recall	0	0.00%	2	0.30%	2	0.09%
	Intra-aortic balloon pump after 14 days	4	0.26%	0	0.00%	4	0.18%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	30	1.93%	9	1.37%	39	1.76%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	93	6.00%	74	11.23%	167	7.56%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	42	2.71%	75	11.38%	117	5.29%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	15	0.97%	19	2.88%	34	1.54%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	21	1.35%	6	0.91%	27	1.22%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	15	0.97%	3	0.46%	18	0.81%
	Mechanical circulatory support device (MCSD) with hemolysis	6	0.39%	6	0.91%	12	0.54%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	11	0.71%	1	0.15%	12	0.54%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	2	0.13%	2	0.30%	4	0.18%
	Mechanical circulatory support device (MCSD) with pump thrombosis	8	0.52%	54	8.19%	62	2.81%
	Mechanical circulatory support device (MCSD) with right heart failure	6	0.39%	15	2.28%	21	0.95%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	252	16.25%	107	16.24%	359	16.24%
	Percutaneous endovascular circulatory support device after 14 days	1	0.06%	0	0.00%	1	0.05%
	Overall		1551	100%	659	100%	2210
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	191	11.40%	74	9.85%	265	10.92%
	Congenital heart disease	78	4.65%	51	6.79%	129	5.32%

(continued)

Status	Criteria	N	%	N	%	N	%
Adult Status 4	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	603	35.98%	432	57.52%	1035	42.65%
	Exception	395	23.57%	87	11.58%	482	19.86%
	Inotropes without hemodynamic monitoring	277	16.53%	35	4.66%	312	12.86%
	Ischemic heart disease with intractable angina	46	2.74%	26	3.46%	72	2.97%
	Retransplant	86	5.13%	46	6.13%	132	5.44%
Overall		1676	100%	751	100%	2427	100%
Adult Status 5	None	88	100.00%	19	100.00%	107	100.00%
Adult Status 6	None	511	100.00%	75	100.00%	586	100.00%

Note:

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

Table 10. Adult Heart Transplants by Criteria Within Medical Urgency Status at Transplant Post-Implementation, Pre-Guidance

Status	Criteria	Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 1	BIVAD/Ventricular Episodes	48	8.66%	5	9.43%	53	8.73%
	Exception	181	32.67%	13	24.53%	194	31.96%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	70	12.64%	14	26.42%	84	13.84%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	121	21.84%	8	15.09%	129	21.25%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	134	24.19%	13	24.53%	147	24.22%
Overall		554	100%	53	100%	607	100%
Adult Status 2	Exception	1107	41.18%	348	49.64%	1455	42.93%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	34	1.26%	4	0.57%	38	1.12%
	Intra-aortic ballon pump - Hemodynamic Values obtained	1142	42.49%	193	27.53%	1335	39.39%
	Mechanical circulatory support device(MCSD) with malfunction	103	3.83%	64	9.13%	167	4.93%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	28	1.04%	3	0.43%	31	0.91%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	17	0.63%	1	0.14%	18	0.53%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	161	5.99%	27	3.85%	188	5.55%
	Total artificial heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	50	1.86%	46	6.56%	96	2.83%
	Ventricular tachycardia(VT) or ventricular fibrillation(VF)	46	1.71%	15	2.14%	61	1.80%
Overall		2688	100%	701	100%	3389	100%
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	502	48.22%	0	0.00%	502	34.43%
	Exception	198	19.02%	169	40.53%	367	25.17%
	Intra-aortic balloon pump after 14 days	3	0.29%	0	0.00%	3	0.21%

(continued)

Status	Criteria	N	%	N	%	N	%
Adult Status 3	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	17	1.63%	4	0.96%	21	1.44%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	58	5.57%	54	12.95%	112	7.68%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	27	2.59%	45	10.79%	72	4.94%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	9	0.86%	11	2.64%	20	1.37%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	14	1.34%	3	0.72%	17	1.17%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	10	0.96%	3	0.72%	13	0.89%
	Mechanical circulatory support device (MCSD) with hemolysis	6	0.58%	6	1.44%	12	0.82%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	10	0.96%	1	0.24%	11	0.75%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	1	0.10%	1	0.24%	2	0.14%
	Mechanical circulatory support device (MCSD) with pump thrombosis	3	0.29%	33	7.91%	36	2.47%
	Mechanical circulatory support device (MCSD) with right heart failure	3	0.29%	10	2.40%	13	0.89%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	180	17.29%	77	18.47%	257	17.63%
	Overall		1041	100%	417	100%	1458
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	103	10.40%	44	9.50%	147	10.12%
	Congenital heart disease	50	5.05%	34	7.34%	84	5.78%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	392	39.60%	260	56.16%	652	44.87%
	Exception	243	24.55%	58	12.53%	301	20.72%
	Inotropes without hemodynamic monitoring	124	12.53%	26	5.62%	150	10.32%
	Ischemic heart disease with intractable angina	22	2.22%	13	2.81%	35	2.41%

(continued)
Adult Status 4

Status	Criteria	N	%	N	%	N	%
	Retransplant	56	5.66%	28	6.05%	84	5.78%
Overall		990	100%	463	100%	1453	100%
Adult Status 5	None	46	100.00%	10	100.00%	56	100.00%
Adult Status 6	None	286	100.00%	35	100.00%	321	100.00%

Note:

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

Table 11. Adult Heart Transplants by Criteria Within Medical Urgency Status at Transplant Post-Implementation, Post-Guidance

Status	Criteria	Initial		Extension		Total	
		N	%	N	%	N	%
Adult Status 1	BIVAD/Ventricular Episodes	39	7.29%	2	2.27%	41	6.58%
	Exception	243	45.42%	35	39.77%	278	44.62%
	Exception due to device recall	3	0.56%	1	1.14%	4	0.64%
	Non-dischargeable, surgically implanted, non-endovascular biventricular support device	25	4.67%	28	31.82%	53	8.51%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values not obtained	111	20.75%	8	9.09%	119	19.10%
	Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) - Hemodynamic Values obtained	114	21.31%	14	15.91%	128	20.55%
Overall		535	100%	88	100%	623	100%
Adult Status 2	Exception	806	42.71%	578	58.03%	1384	48.01%
	Exception due to device recall	9	0.48%	14	1.41%	23	0.80%
	Intra-aortic ballon pump - Hemodynamic Values not obtained	18	0.95%	5	0.50%	23	0.80%
	Intra-aortic ballon pump - Hemodynamic Values obtained	699	37.04%	220	22.09%	919	31.88%
	Mechanical circulatory support device(MCSD) with malfunction	47	2.49%	46	4.62%	93	3.23%
	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device(LVAD)	17	0.90%	4	0.40%	21	0.73%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values not obtained	25	1.32%	8	0.80%	33	1.14%
	Percutaneous endovascular mechanical circulatory support device - Hemodynamic Values obtained	220	11.66%	100	10.04%	320	11.10%
	Total artificial heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients	17	0.90%	16	1.61%	33	1.14%
	Ventricular tachycardia(VT) or ventricular fibrillation(VF)	29	1.54%	5	0.50%	34	1.18%
Overall		1887	100%	996	100%	2883	100%
	Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	207	40.59%	0	0.00%	207	27.53%

(continued)

Status	Criteria	N	%	N	%	N	%
	Exception	138	27.06%	117	48.35%	255	33.91%
	Exception due to device recall	0	0.00%	2	0.83%	2	0.27%
	Intra-aortic balloon pump after 14 days	1	0.20%	0	0.00%	1	0.13%
	Mechanical circulatory support device (MCSD) with Aortic Insufficiency (AI)	13	2.55%	5	2.07%	18	2.39%
	Mechanical circulatory support device (MCSD) with device infection - Bacteremia	35	6.86%	20	8.26%	55	7.31%
	Mechanical circulatory support device (MCSD) with device infection - Debridement	15	2.94%	30	12.40%	45	5.98%
	Mechanical circulatory support device (MCSD) with device infection - Erythema	6	1.18%	8	3.31%	14	1.86%
	Mechanical circulatory support device (MCSD) with device infection - Positive culture	7	1.37%	3	1.24%	10	1.33%
	Mechanical circulatory support device (MCSD) with device infection - Recurrent bacteremia	5	0.98%	0	0.00%	5	0.66%
	Mechanical circulatory support device (MCSD) with mucosal bleeding - Three or more hospitalizations	1	0.20%	0	0.00%	1	0.13%
Adult Status 3	Mechanical circulatory support device (MCSD) with mucosal bleeding - Two hospitalizations	1	0.20%	1	0.41%	2	0.27%
	Mechanical circulatory support device (MCSD) with pump thrombosis	5	0.98%	21	8.68%	26	3.46%
	Mechanical circulatory support device (MCSD) with right heart failure	3	0.59%	5	2.07%	8	1.06%
	Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	72	14.12%	30	12.40%	102	13.56%
	Percutaneous endovascular circulatory support device after 14 days	1	0.20%	0	0.00%	1	0.13%
Overall		510	100%	242	100%	752	100%
	Amyloidosis, or hypertrophic or restrictive cardiomyopathy	88	12.83%	30	10.42%	118	12.11%
	Congenital heart disease	28	4.08%	17	5.90%	45	4.62%
	Dischargeable left ventricular assist device (LVAD) without discretionary 30 days	211	30.76%	172	59.72%	383	39.32%

(continued)

Status	Criteria	N	%	N	%	N	%
Adult Status 4	Exception	152	22.16%	29	10.07%	181	18.58%
	Inotropes without hemodynamic monitoring	153	22.30%	9	3.12%	162	16.63%
	Ischemic heart disease with intractable angina	24	3.50%	13	4.51%	37	3.80%
	Retransplant	30	4.37%	18	6.25%	48	4.93%
Overall		686	100%	288	100%	974	100%
Adult Status 5	None	42	100.00%	9	100.00%	51	100.00%
Adult Status 6	None	225	100.00%	40	100.00%	265	100.00%

Note:

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

Table 12 shows the count and percent of registrations with a mechanical circulatory support device (MCS) at transplant, based on information reported on the TRR and broken down by device type and brand. Overall, 43.07% of transplants had an MCS listed on the TRR pre-implementation, compared to 34.8% post-implementation. Changes in the proportion of MCSs at transplant were similar to those observed for MCSs 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 12. Mechanical Circulatory Support Devices at Transplant for Adult Heart Candidates

Brand	Era	Count	Percent
ECMO			
Total ECMO	Pre	103	1.62%
	Post	753	8.29%
IABP			
Total IABP	Pre	822	12.9%
	Post	3613	39.78%
LVAD			
Abiomed AB5000	Pre	0	0%
	Post	1	0.02%
Cardiac Assist Protek Duo	Pre	0	0%
	Post	4	0.1%
Cardiac Assist Tandem Heart	Pre	3	0.06%
	Post	3	0.07%
CentriMag (Thoratec/Levitronix)	Pre	21	0.42%
	Post	40	0.96%
Evaheart	Pre	2	0.04%
	Post	1	0.02%
Heartmate II	Pre	2497	50.2%
	Post	546	13.11%
HeartMate III	Pre	78	1.57%
	Post	1667	40.03%
Heartmate XVE	Pre	6	0.12%
	Post	0	0%
Heartsaver VAD	Pre	17	0.34%
	Post	8	0.19%
Heartware HVAD	Pre	1891	38.02%
	Post	965	23.17%
Impella CP	Pre	1	0.02%
	Post	102	2.45%
Impella Recover 2.5	Pre	9	0.18%
	Post	7	0.17%

Impella Recover 5.0	Pre	50	1.01%
	Post	323	7.76%
Impella RP	Pre	0	0%
	Post	1	0.02%
Jarvik 2000	Pre	9	0.18%
	Post	0	0%
Maquet Jostra Rotaflow	Pre	0	0%
	Post	1	0.02%
Terumo DuraHeart	Pre	1	0.02%
	Post	0	0%
Thoratec IVAD	Pre	2	0.04%
	Post	0	0%
Thoratec PVAD	Pre	3	0.06%
	Post	0	0%
Other, Specify	Pre	384	7.72%
	Post	495	11.89%
Total LVAD	Pre	4974	78.06%
	Post	4164	45.84%
LVAD+RVAD			
Abiomed AB5000	Pre	1	0.31%
	Post	0	0%
Berlin Heart EXCOR	Pre	0	0%
	Post	1	0.23%
Cardiac Assist Protek Duo	Pre	0	0%
	Post	35	8.1%
Cardiac Assist Tandem Heart	Pre	7	2.15%
	Post	4	0.93%
CentriMag (Thoratec/Levitronix)	Pre	114	34.97%
	Post	215	49.77%
Heartmate II	Pre	24	7.36%
	Post	0	0%
HeartMate III	Pre	2	0.61%
	Post	73	16.9%
Heartsaver VAD	Pre	1	0.31%
	Post	0	0%
Heartware HVAD	Pre	110	33.74%
	Post	37	8.56%
Impella CP	Pre	0	0%
	Post	3	0.69%

Impella Recover 2.5	Pre	1	0.31%
	Post	2	0.46%
Impella Recover 5.0	Pre	5	1.53%
	Post	6	1.39%
Maquet Jostra Rotaflow	Pre	5	1.53%
	Post	9	2.08%
Thoratec IVAD	Pre	1	0.31%
	Post	0	0%
Thoratec PVAD	Pre	24	7.36%
	Post	0	0%
Other, Specify	Pre	31	9.51%
	Post	47	10.88%
Total LVAD+RVAD	Pre	326	5.12%
	Post	432	4.76%
RVAD			
Cardiac Assist Protek Duo	Pre	0	0%
	Post	6	10.53%
CentriMag (Thoratec/Levitronix)	Pre	4	22.22%
	Post	12	21.05%
Heartmate II	Pre	2	11.11%
	Post	0	0%
Heartware HVAD	Pre	4	22.22%
	Post	3	5.26%
Impella CP	Pre	0	0%
	Post	11	19.3%
Impella Recover 2.5	Pre	0	0%
	Post	1	1.75%
Impella Recover 5.0	Pre	3	16.67%
	Post	10	17.54%
Impella RP	Pre	1	5.56%
	Post	5	8.77%
Maquet Jostra Rotaflow	Pre	1	5.56%
	Post	1	1.75%
Other, Specify	Pre	3	16.67%
	Post	8	14.04%
Total RVAD	Pre	18	0.28%
	Post	57	0.63%

TAH

SynCardia CardioWest	Pre	127	98.45%
	Post	57	89.06%
Other, Specify	Pre	2	1.55%
	Post	7	10.94%
Total TAH	Pre	129	2.02%
	Post	64	0.7%

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.

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

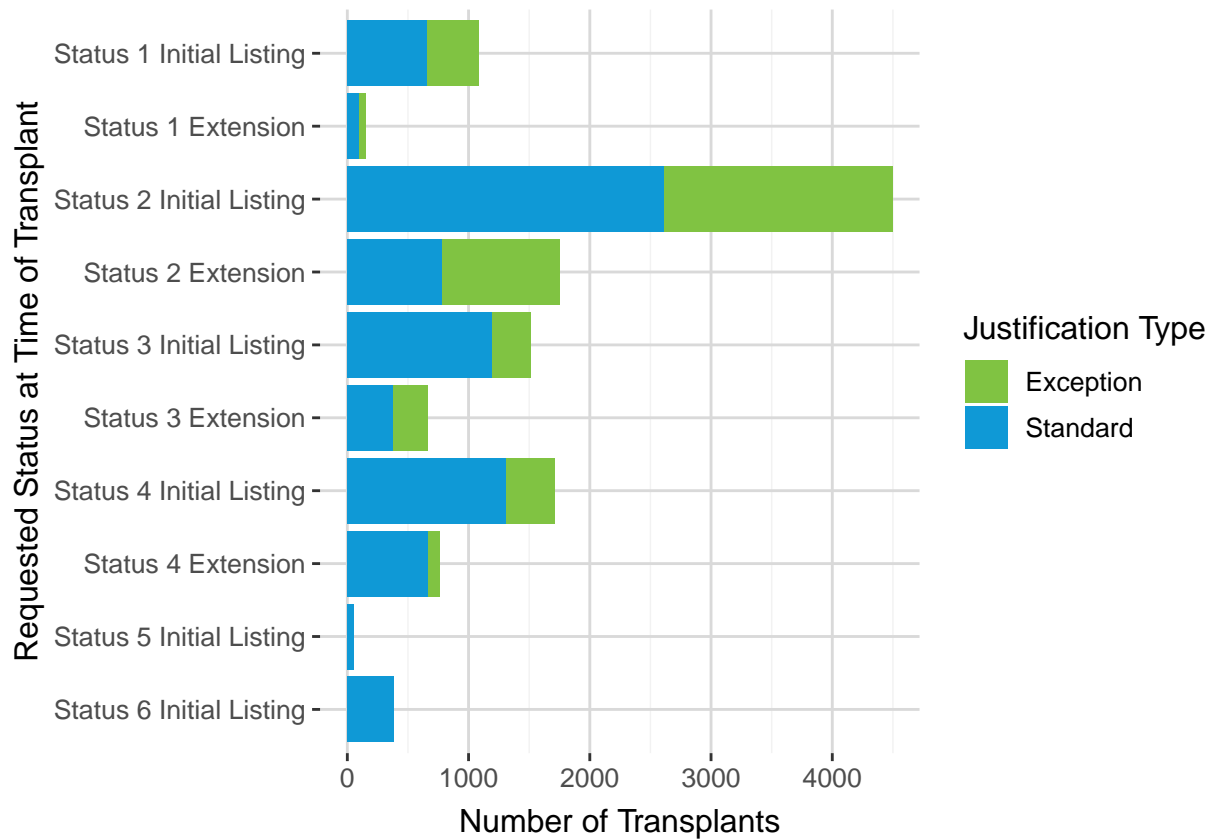
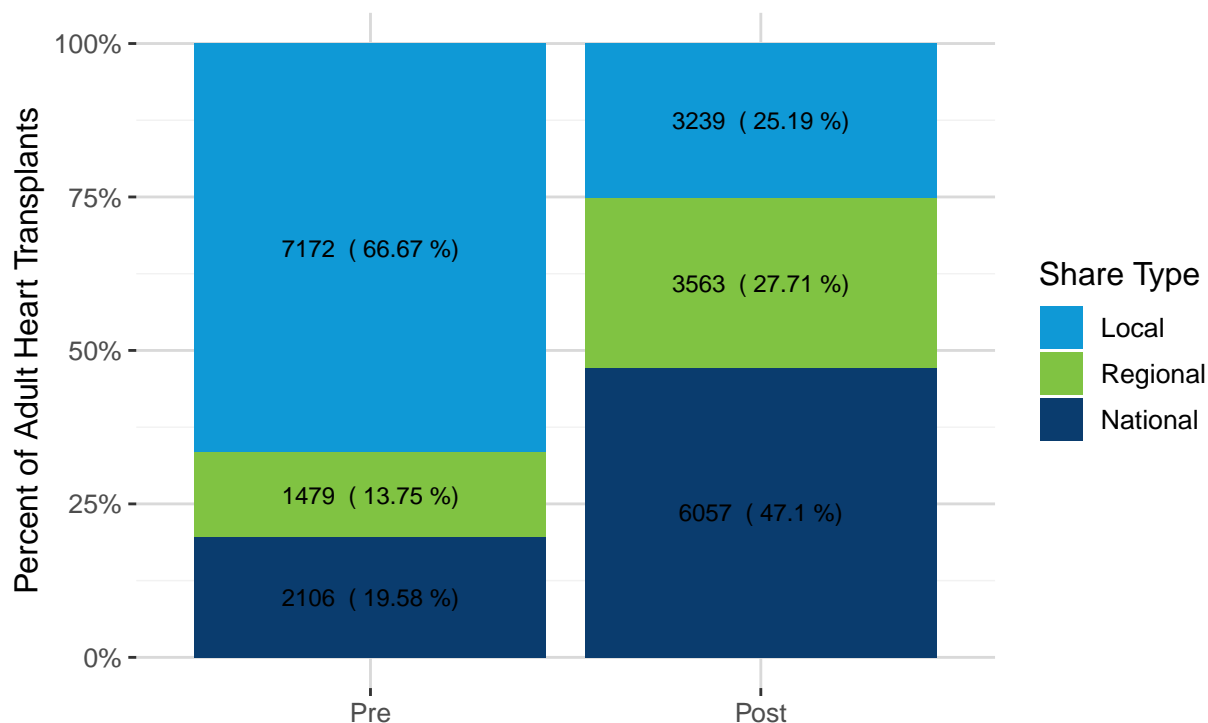


Figure 17. Adult Heart Transplants by Review Type, Requested Status, and Guidance Period



Figure 18. Adult Heart Transplants by Share Type and Era

Based on OPTN data as of March 24, 2023
 Data subject to change based on future data submission or correction
 Not reported share types excluded (n=15 pre & n=5 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 13 shows the proportion of heart transplants by share type and era.

Table 13. Heart Transplants by Share Type and Era

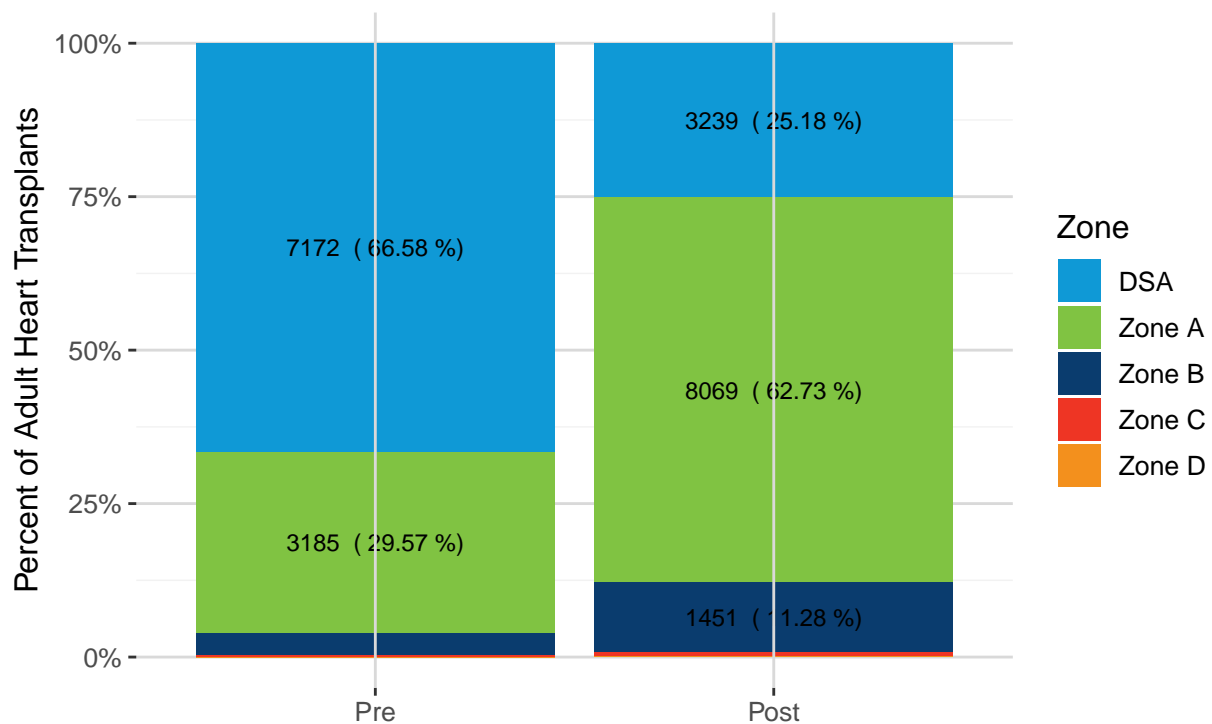
Era	Zone	N	%
Pre	Local	7172	66.6%
	Regional	1479	13.7%
	National	2106	19.6%
	Not Reported	15	0.1%
Post	Local	3239	25.2%
	Regional	3563	27.7%
	National	6057	47.1%
	Not Reported	5	0%

Figure 19 and Table 14 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 104 adult heart transplants with 18 pre-implementation and 86 post-implementation. There were only 2 adult heart transplants in Zone D pre-implementation, and 19 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



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

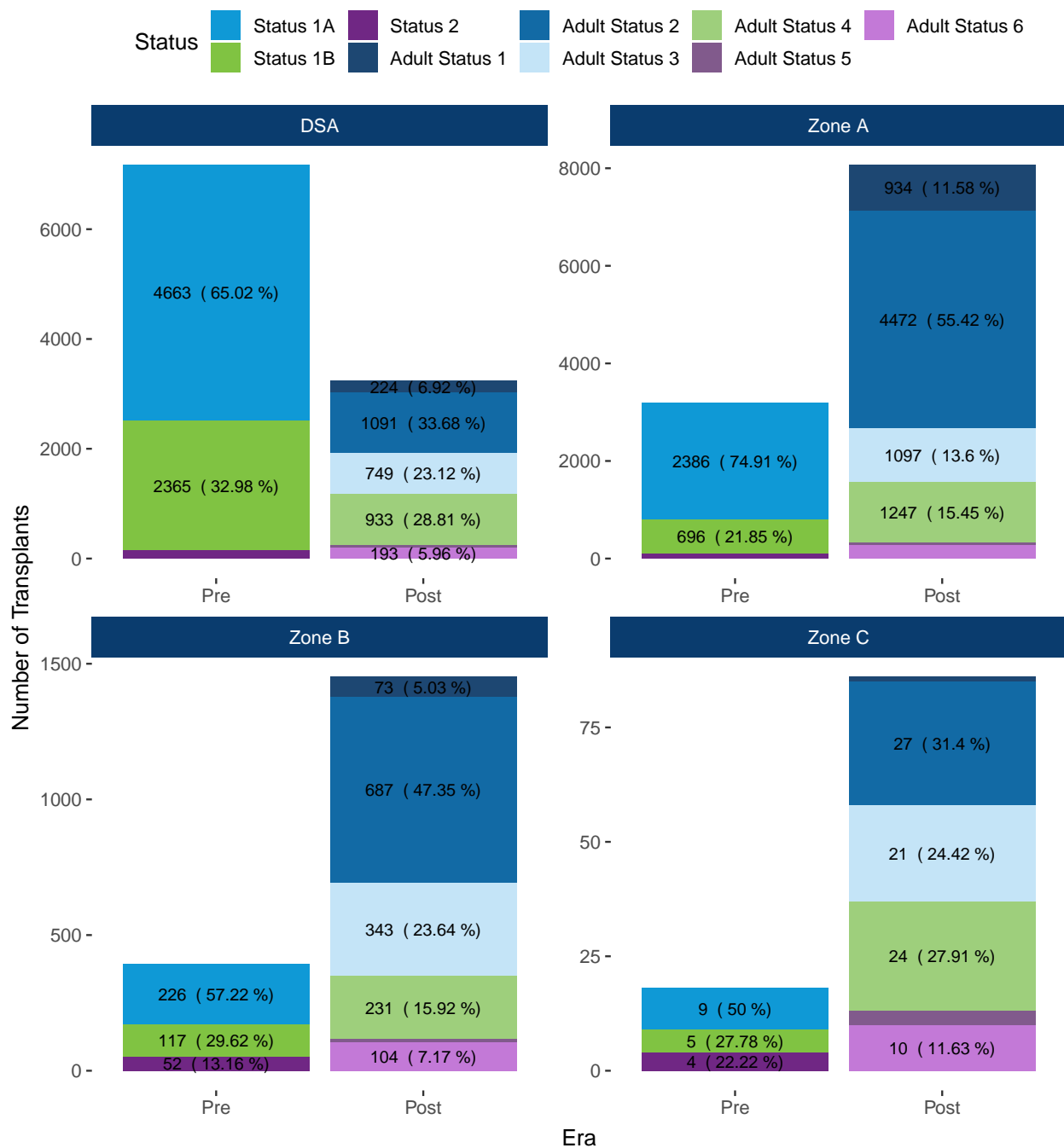
Table 14. Heart Transplants by Zone and Era

Era	Zone	N	%
Pre	DSA	7172	66.6%
	Zone A	3185	29.6%
	Zone B	395	3.7%
	Zone C	18	0.2%
	Zone D	2	0%
Post	DSA	3239	25.2%
	Zone A	8069	62.7%
	Zone B	1451	11.3%
	Zone C	86	0.7%
	Zone D	19	0.1%

Note:

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



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, B and C. Only one Adult Status 1 transplant was performed in Zone C, likely due to the longer distance traveled.

Figure 21. Distance Traveled at Transplant by Era

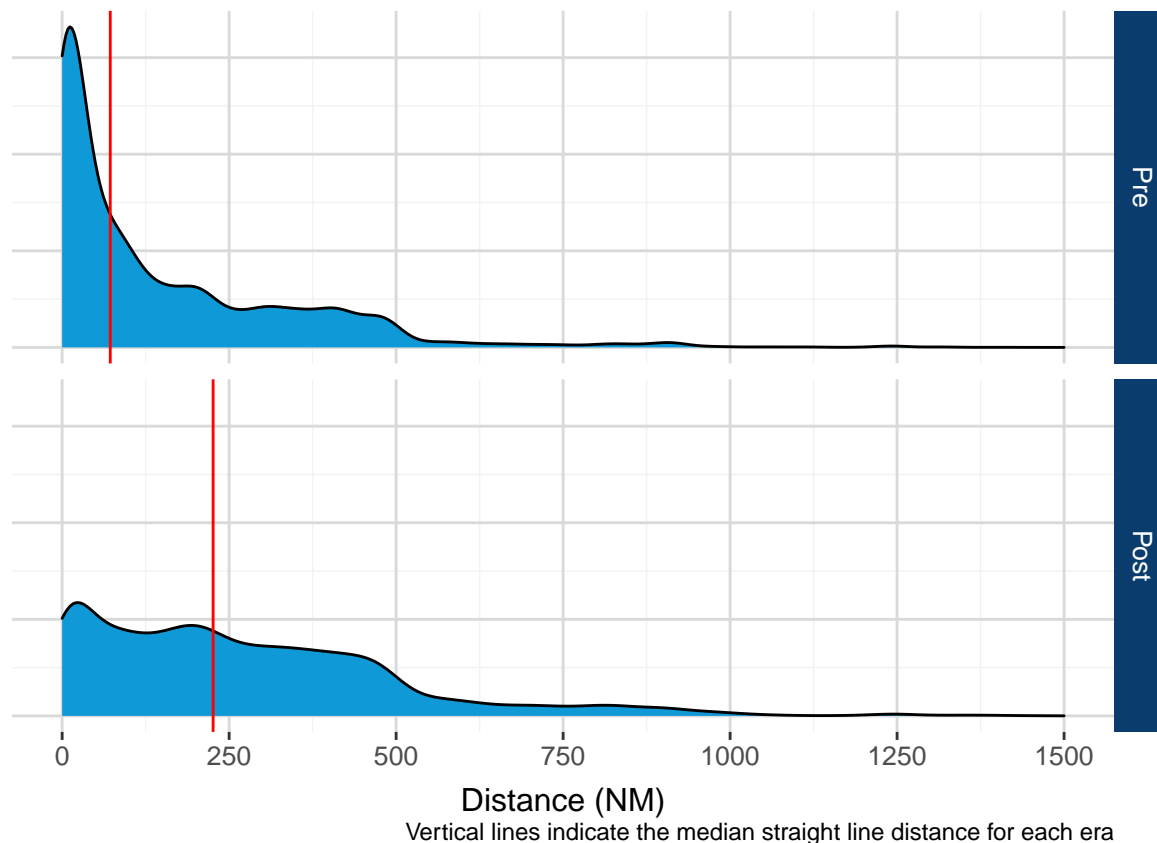
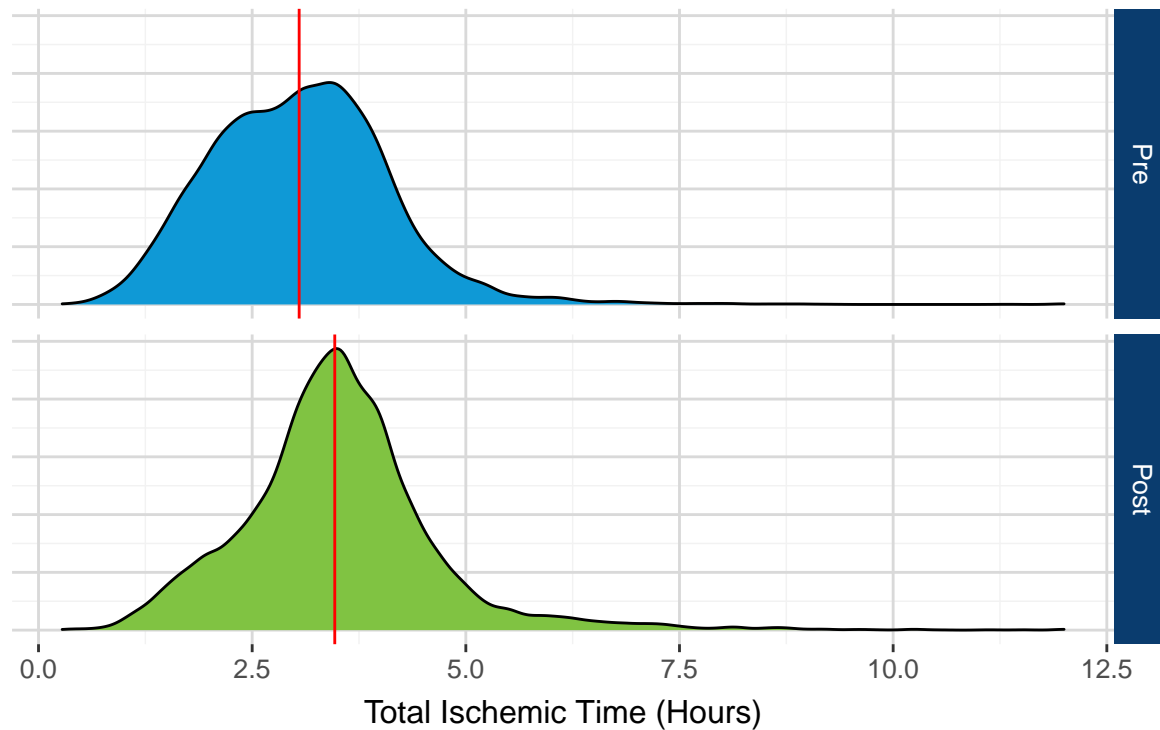


Table 15. Distance Traveled at Transplant by Era

Era	Min	IQR	Mean	Median	Max
Pre	0	223	152.10	72	2157
Post	0	315	274.53	226	2215

Figure 21 and Table 15 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 72 nautical miles to a post-implementation median of 226 nautical miles.

Figure 22. Total Ischemic Time at Transplant by Era

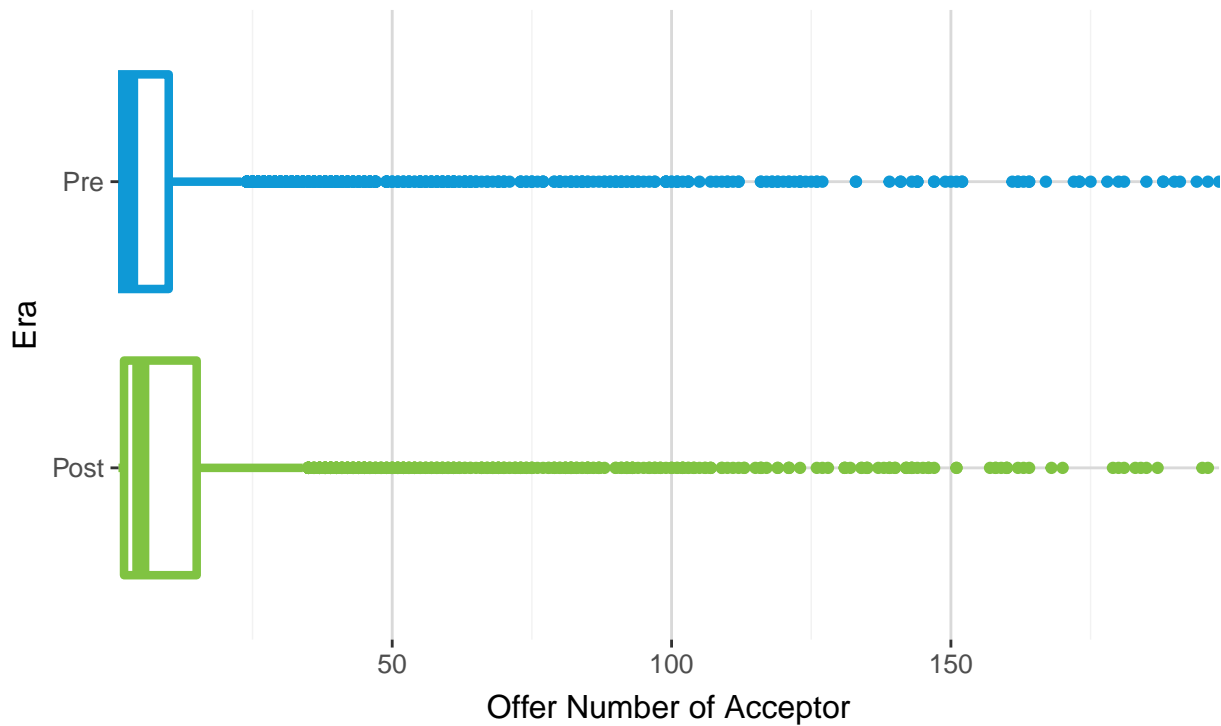
Vertical lines indicate the median cold ischemic time for each era
 DSA was removed as a unit of allocation from heart policy on 1/09/2020
 a separate monitoring report addresses the removal

Table 16. Total Ischemic Time at Transplant by Era

Era	Min	IQR	Mean	Median	Max
Pre	0.28	1.38	3.06	3.05	12
Post	0.33	1.15	3.50	3.47	12

Figure 22 and Table 16 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



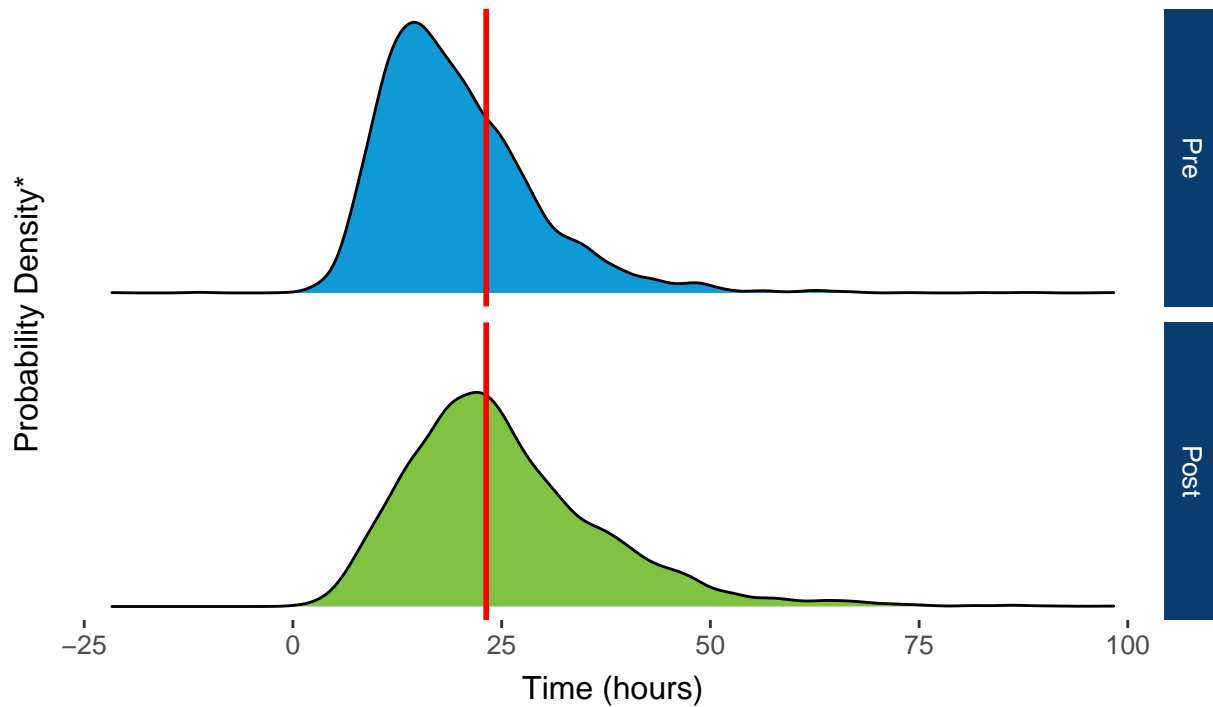
There were 38 acceptances with an offer number over 200 in the pre era and 57 in the post era (not shown)

Table 17. Summary of the Sequence Number of the Final Acceptor for Adult Heart Donors

Era	Min	IQR	Mean	Median	Max
Pre-Policy	1	10	17.47	3	1723
Post-Policy	1	14	20.86	6	1245

Figure 23 and Table 17 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=7; 2 pre & 5 post)

Table 18. Time from First Electronic Offer to Cross Clamp for Deceased Heart Donors

Era	Min	IQR	Mean	Median	Max
Pre-Policy	-21.69	11.29	19.85	18.05	512.77
Post-Policy	-0.09	14.04	25.57	23.43	305.57

Figure 24 and Table 18 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 19.85 hours to 25.57.

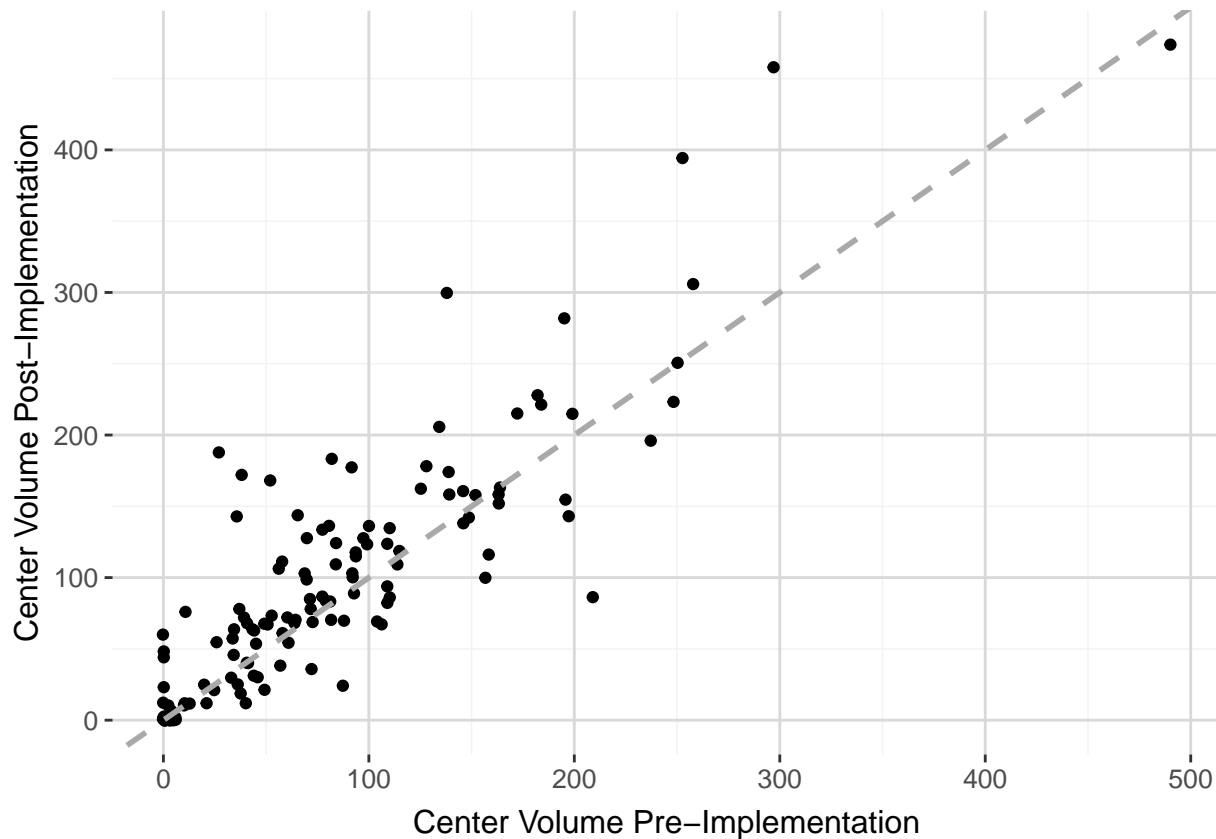
Figure 25. Center Adult Heart Transplant Volume by Era

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 32 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 three years after implementation. There were 140 transplant centers that performed at least one adult heart transplant in one of the two eras. Of those, 83 performed more adult heart transplants post-implementation than they did pre-implementation. There were 53 centers that performed fewer adult heart transplants after implementation than they did pre-implementation. Of these, 30 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

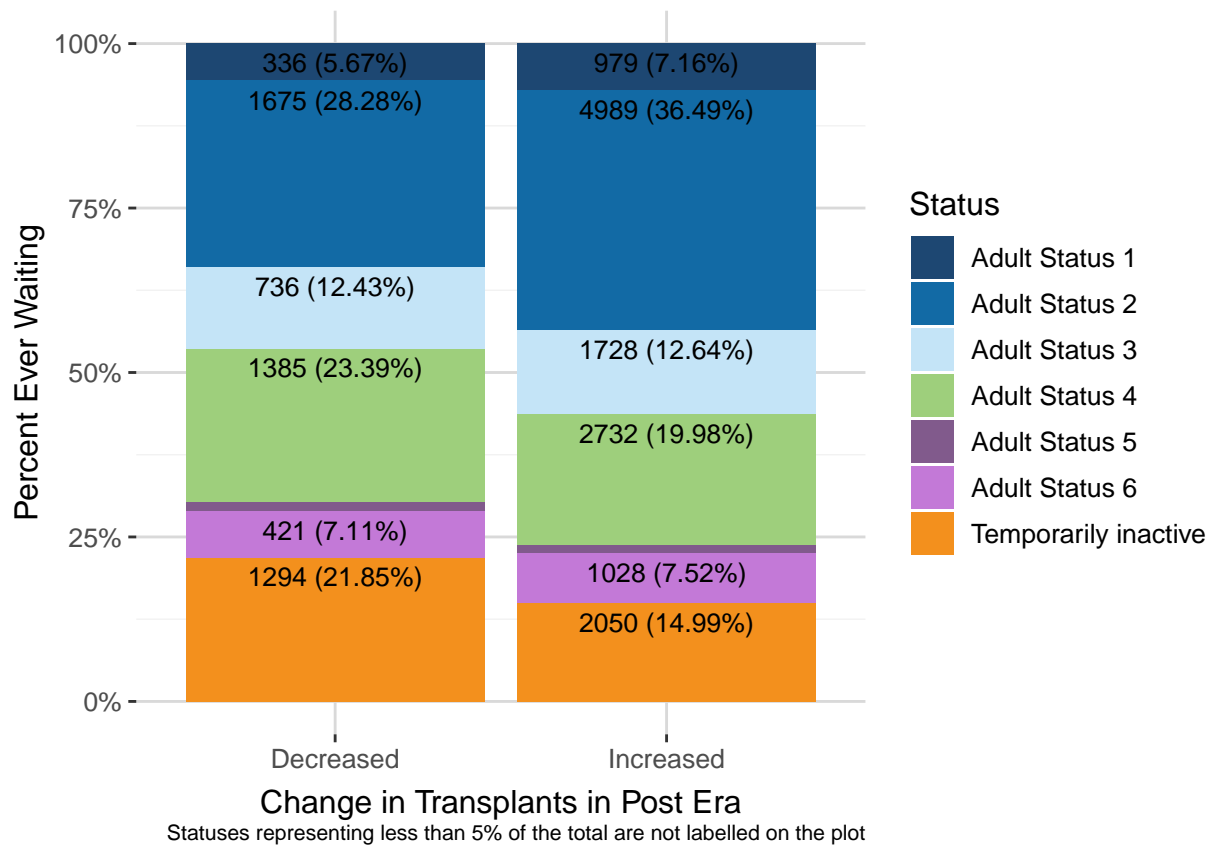


Figure 26 compares the distributions of patients ever waiting at different medical urgency statuses post-implementation at centers where the number of transplants performed post-implementation increased to the distribution at centers where the number of transplants performed post-implementation decreased. 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 proportion 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 significantly 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 in order to better visualize these particular statuses.

Table 19 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 27. Transplants per 100 Active Patient-Years Waiting by Medical Urgency Status and Era

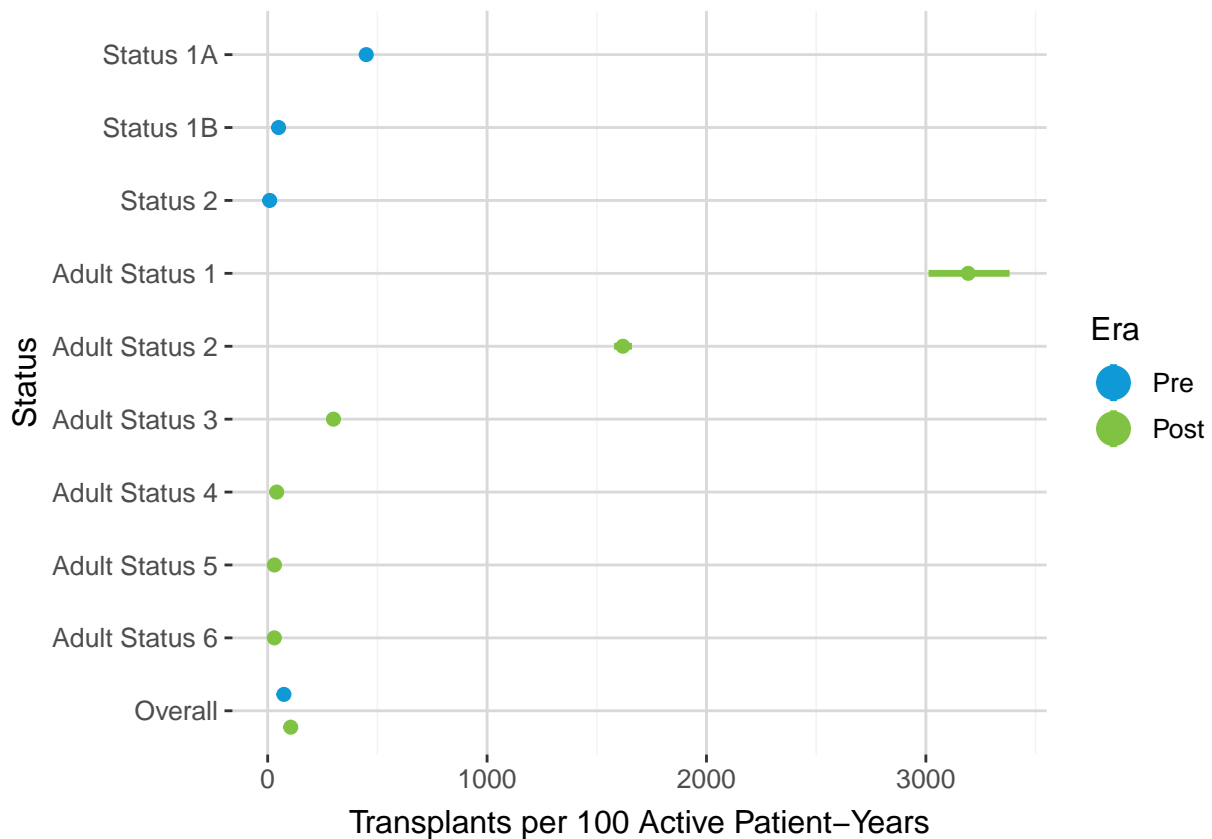


Figure 28. Zooming in on Adult Heart Statuses 3-6: Transplants per 100 Active Patient-Years Waiting by Medical Urgency Status and Era

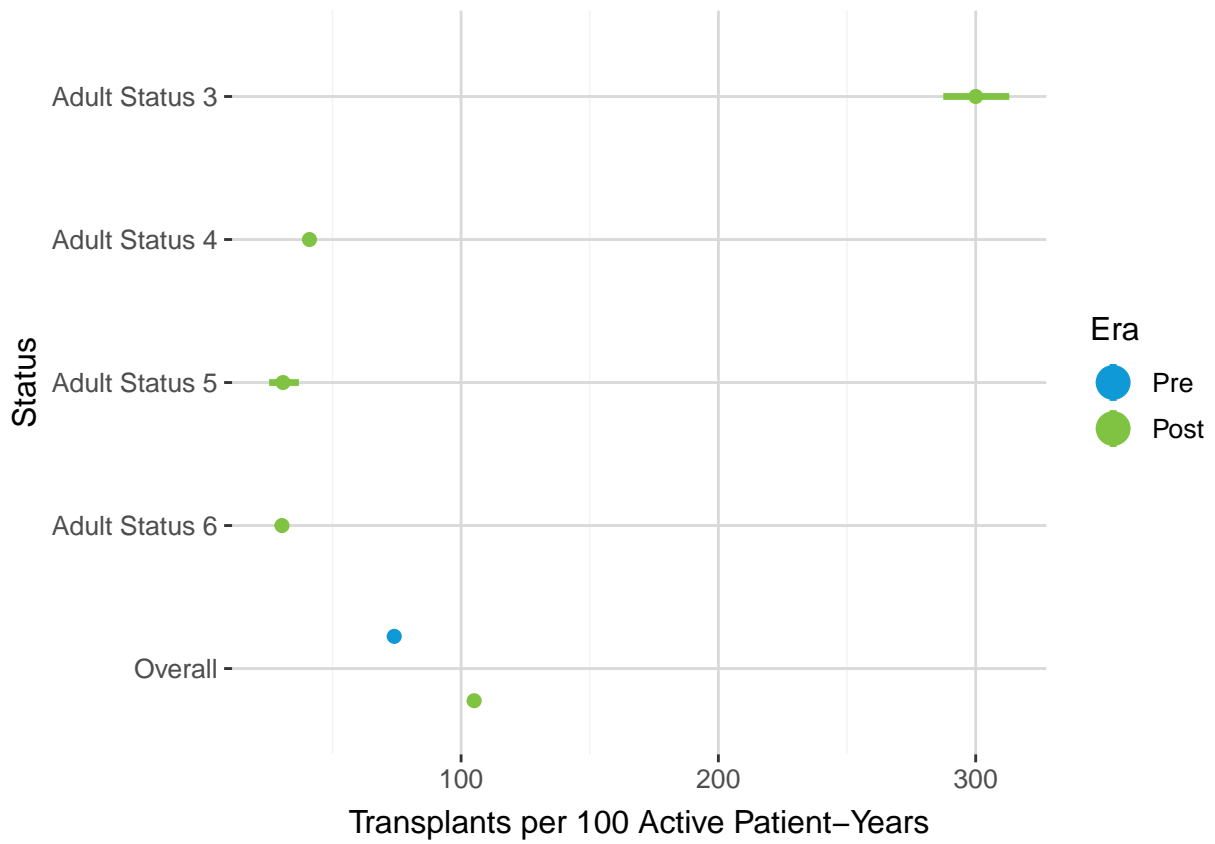


Table 19. Transplants per 100 Active Patient-Years Waiting by Medical Urgency Status and Era

Era	Status	Patients Ever Waiting	Number of Transplants	Transplants per 100 Patient Years	CI
Pre	Status 1A	10844	6994	449	[439, 460]
	Status 1B	11705	3128	50	[48, 52]
	Status 2	4885	290	9	[8, 10]
Pre	Overall	17461	10412	74	[73, 75]
Post	Adult Status 1	1514	1165	3193	[3012, 3382]
	Adult Status 2	7646	6093	1619	[1579, 1660]
	Adult Status 3	5406	2125	300	[287, 313]
	Adult Status 4	8734	2303	41	[39, 43]
	Adult Status 5	781	114	31	[25, 37]
	Adult Status 6	4497	624	30	[28, 33]
Post	Overall	18488	12468	105	[103, 107]

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

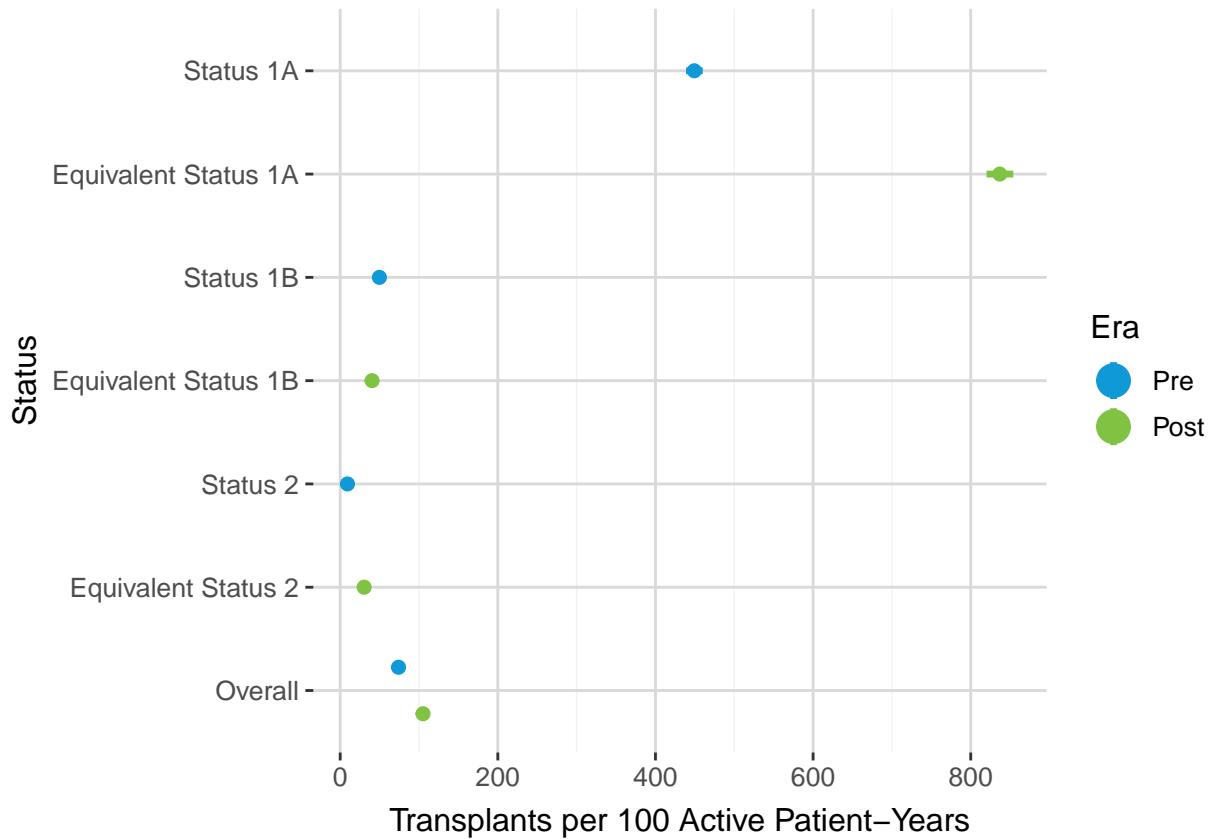


Figure 29 shows the transplants per 100 patient years by equivalent statuses post-implementation as compared to pre-implementation. The Committee Request section defines the equivalent post-implementation statuses as: old Status 1A compared to Adult Statuses 1-3, old Status 1B compared to Adult Statuses 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 Active Patient-Years Waiting by Region, Medical Urgency Status, and Era

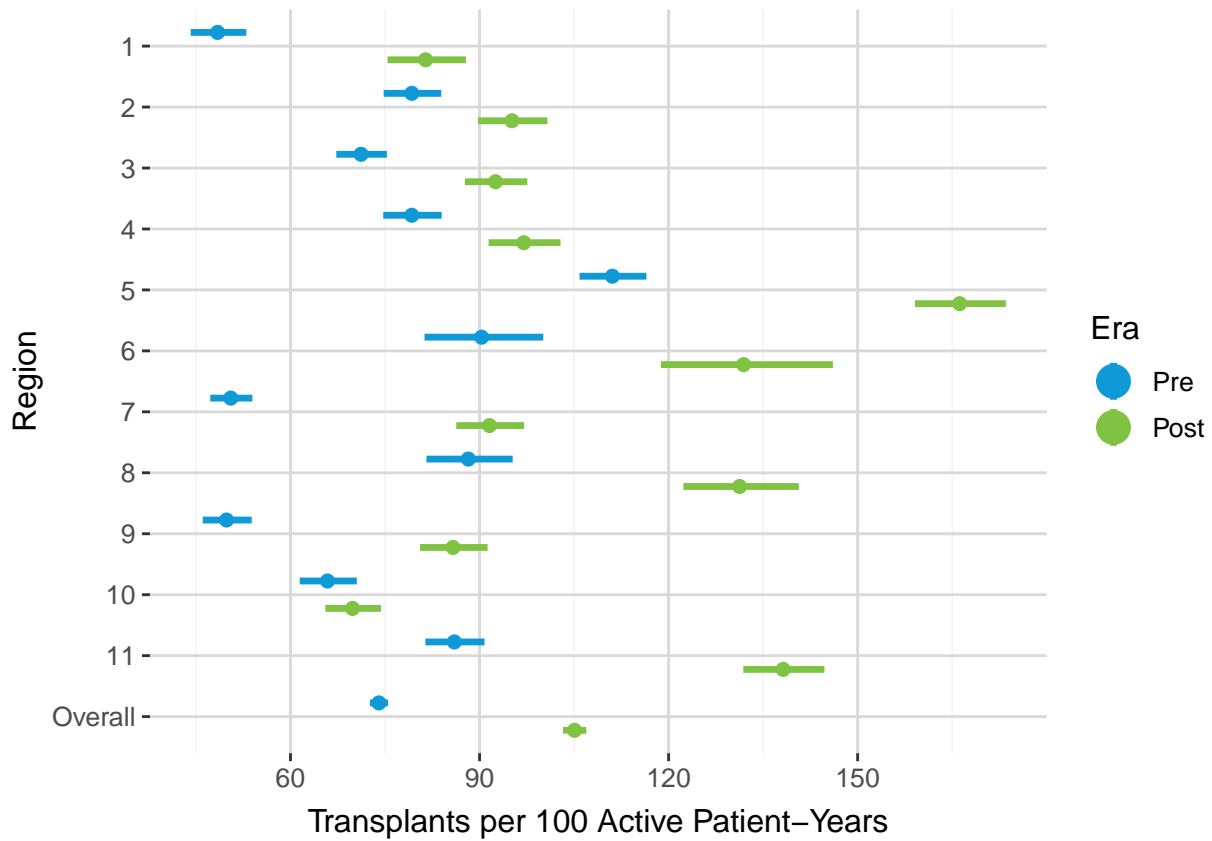


Figure 30 shows the number of transplants per 100 patient-years waiting for each region pre- and post-implementation. The number of transplants per 100 patient-years post-implementation increased for all regions. This increase was statistically significant for all regions except region 10. The overall number of transplants per 100 patient-years increased significantly from 74 (95% CI: (73, 75)) to 105 (95% CI: (103, 107)).

Table 20. Median Days to Transplant by Medical Urgency Status and Era

Era	Status	Days Waiting
Pre	Status 1A	70
	Status 1B	246
	Status 2	686
Pre	Total	263
Post	Adult Status 1	5
	Adult Status 2	12
	Adult Status 3	29
	Adult Status 4	195
	Adult Status 5	503
	Adult Status 6	277
Post	Total	69

Tables 20 and 21 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 70 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, 12, 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 686 days pre-implementation to 277 days post-implementation. Overall the median days waiting to transplant fell from 263 to 69, a 74% decrease.

Table 21. Median Days to Transplant by Equivalent Medical Urgency Status and Era

Era	Status	Days Waiting
Pre	Equivalent Status 1A	70
	Equivalent Status 1B	246
	Equivalent Status 2	686
Pre	Total	263
Post	Equivalent Status 1A	13
	Equivalent Status 1B	204
	Equivalent Status 2	277
Post	Total	69

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

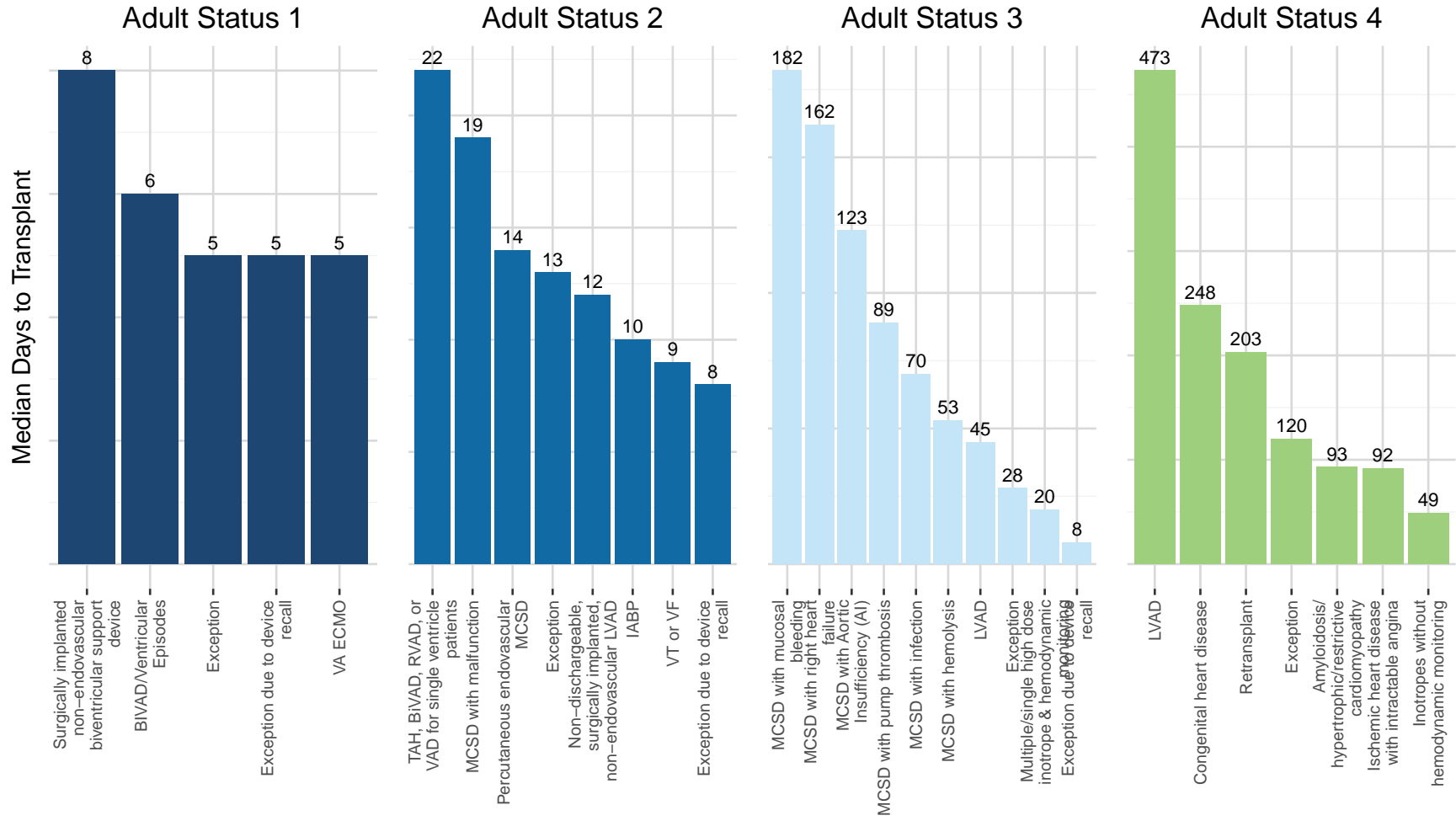


Table 22. Median Days to Transplant by Medical Urgency Status and Criteria Post-Implementation

Status	Criteria	Days Waiting
Adult Status 1	BIVAD/Ventricular Episodes	6
	Exception	5
	Exception due to device recall	5
	Surgically implanted non-endovascular biventricular support device	8
	VA ECMO	5
Adult Status 1	Total	5
Adult Status 2	Exception	13
	Exception due to device recall	8
	IABP	10
	MCS D with malfunction	19
	Non-dischargeable, surgically implanted, non-endovascular LVAD	12
	Percutaneous endovascular MCS D	14
	TAH, BiVAD, RVAD, or VAD for single ventricle patients	22
VT or VF	9	
Adult Status 2	Total	12
Adult Status 3	Exception	28
	Exception due to device recall	8
	LVAD	45
	MCS D with Aortic Insufficiency (AI)	123
	MCS D with hemolysis	53
	MCS D with infection	70
	MCS D with mucosal bleeding	182
	MCS D with pump thrombosis	89
	MCS D with right heart failure	162
Multiple/single high dose inotrope & hemodynamic monitoring	20	
Adult Status 3	Total	29
Adult Status 4	Amyloidosis/hypertrophic/restrictive cardiomyopathy	93
	Congenital heart disease	248
	Exception	120
	Inotropes without hemodynamic monitoring	49
	Ischemic heart disease with intractable angina	92
	LVAD	473
Retransplant	203	
Adult Status 4	Total	195
Adult Status 5	No criteria for this status	503
Adult Status 5	Total	503
Adult Status 6	No criteria for this status	277
Adult Status 6	Total	277

Figure 31 and Table 22 show the results of the competing risks analysis of the median time to transplant by criteria within medical urgency status post-implementation. Adult Statuses 5 and 6 have only one qualifying criterion each; 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, exception, and exception due to device recall 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

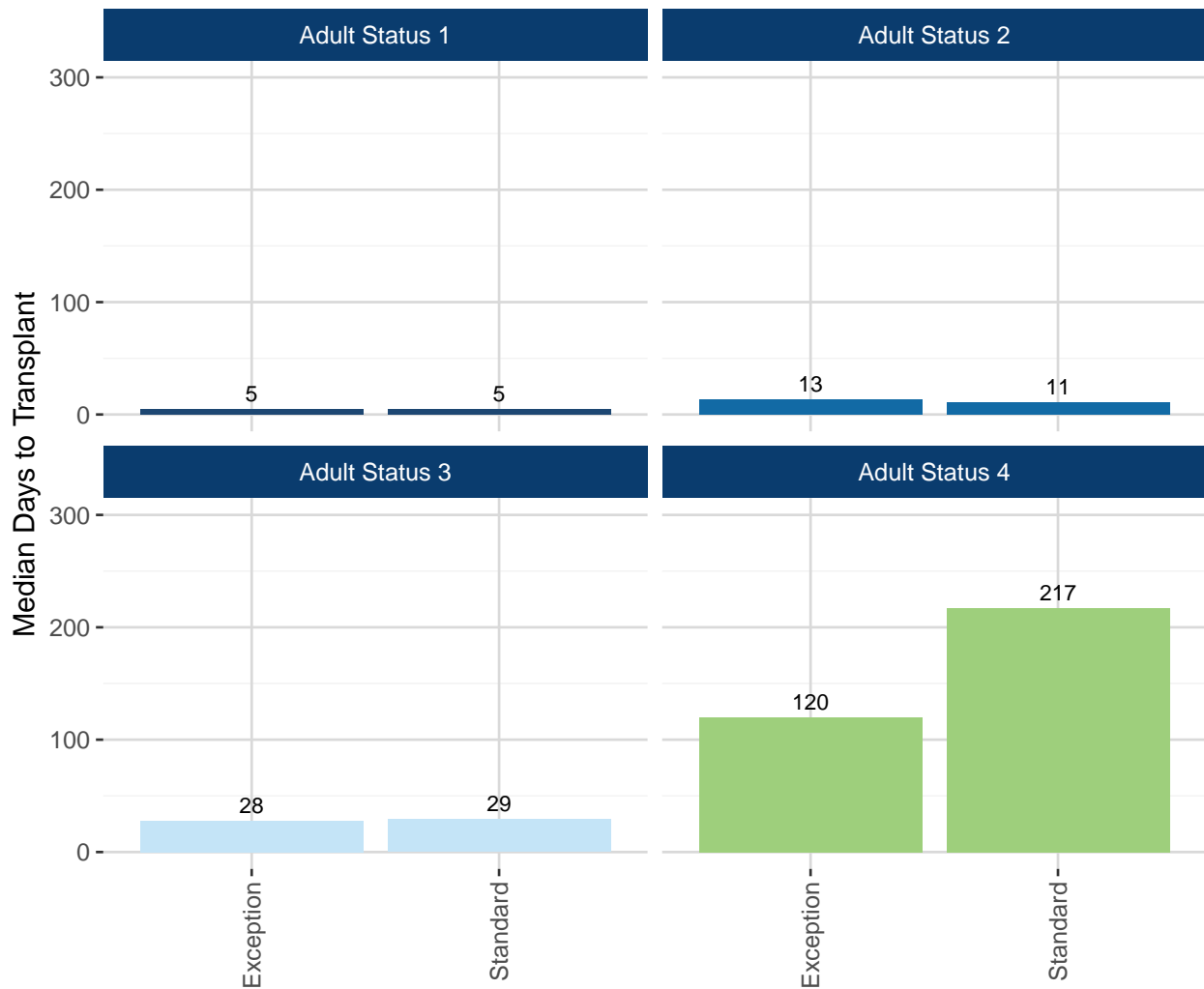


Figure 32 displays the results of the competing risks analysis of the median days to transplant for Adult Statuses 1-4 by exception versus no exception. Median days to transplant was the same between exception versus standard review for Adult Status 1. For Adult Status 2 the median days to transplant 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

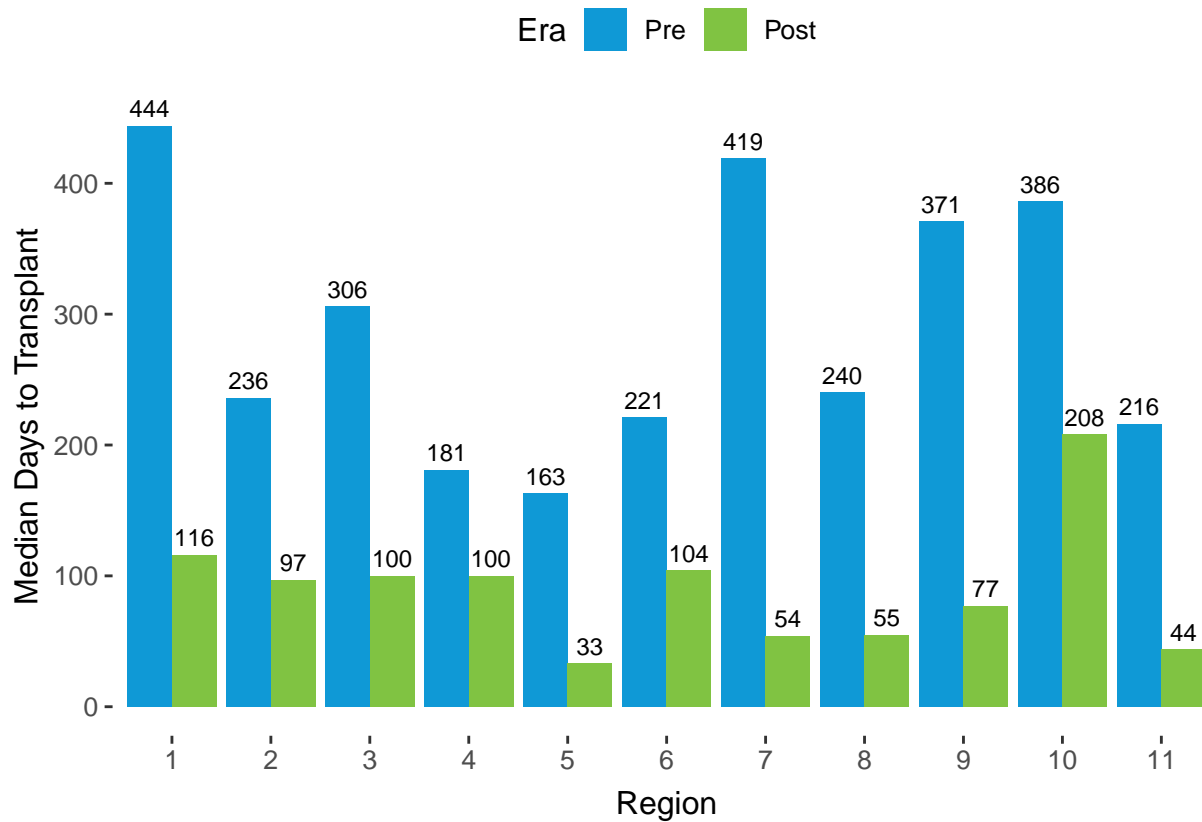


Figure 33 shows a competing risks analysis of the median days waiting before transplant by status and region. The median time to transplant declined in all regions. The largest decrease in median days waited was seen in region 7, where the median wait time decreased from 419 days to 54 days, a decrease of 87.11%.

Utilization

This chapter examines differences in heart utilization between two donor cohorts: the 36056 deceased donors with at least one organ recovered for the purpose of transplant between October 18, 2014 and October 17, 2018 (pre-implementation); and the 48509 deceased donors with a least one organ recovered for the purpose of transplant between October 18, 2018 and October 17, 2022 (post-implementation).

Tables 23 and 24 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 35.46% utilization in Non-DCD adult heart donors compared to 26.7% utilization for all adult heart donors in the post-implementation period. There was a small increase in utilization rates during the post-implementation period compared to the pre-implementation period for Non-DCD donors, and a decrease in utilization rates for all adult heart donors. Discard rates increased for all adult heart donors in the post-implementation period, whereas they decreased for Non-DCD donors.

Table 23. Heart Utilization and Discard Rates by Era

Era	Utilization	Discard
Pre	29.1%	1.01%
Post	26.7%	1.15%

Table 24. Heart Utilization and Discard Rates for Non-DCD Adult Donors by Era

Era	Utilization	Discard
Pre	35.45%	1.01%
Post	35.46%	0.8%

Figure 34. Heart Utilization Rates by Region and Era

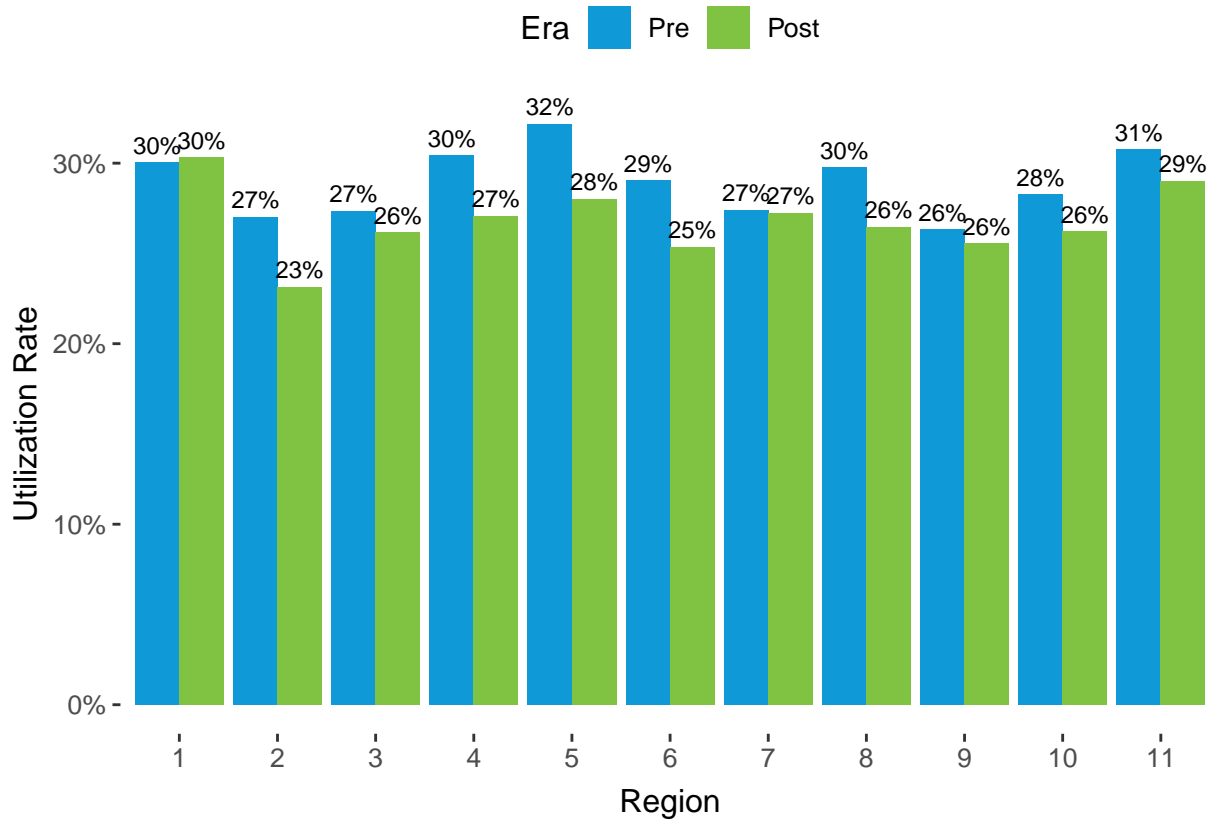


Figure 34 shows the utilization rates of adult hearts by region both pre- and post-implementation. Utilization rates decreased in the majority of the regions. Utilization rates remained the same in region 1 and decreased in the remaining regions.

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

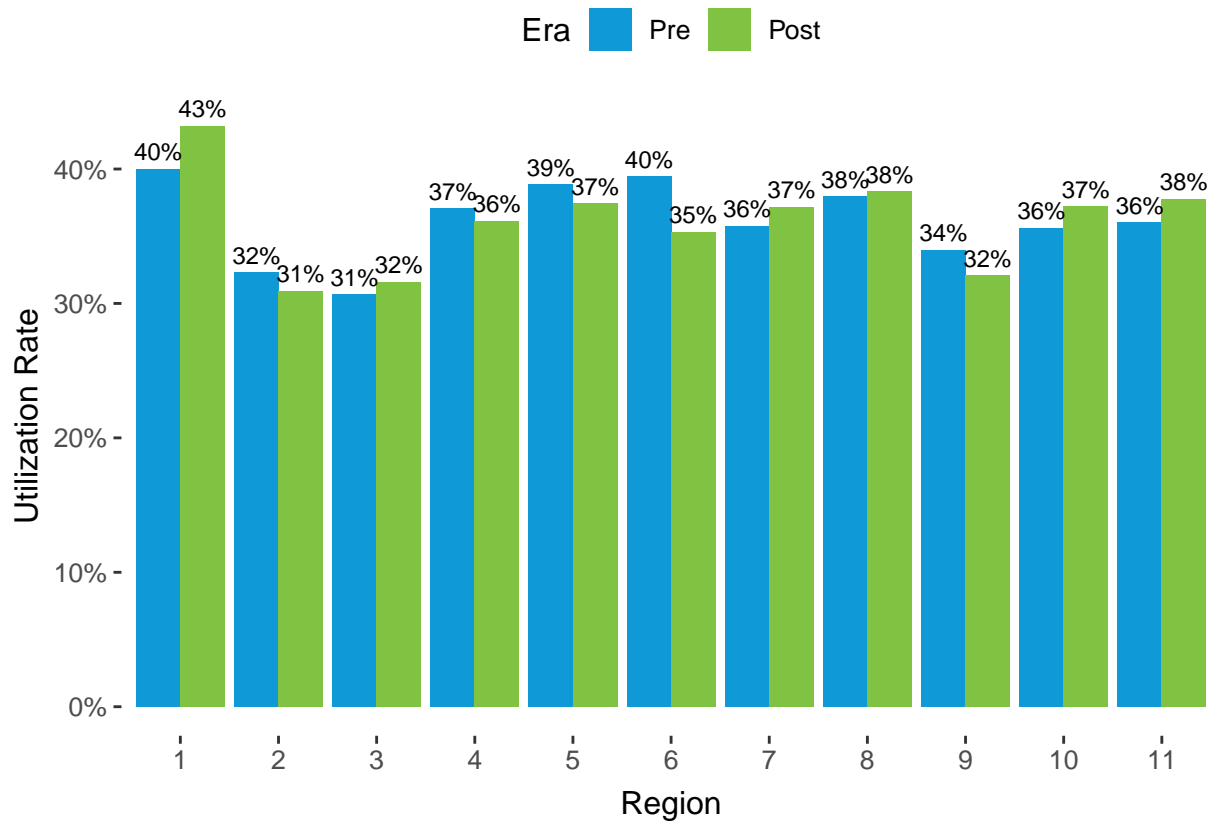


Figure 35 shows utilization rates of adult hearts by region and era for non-DCD donors only. Utilization rates are higher for non-DCD donors than for donors overall (Tables 23 and 24) and rose in regions 1, 3, 7, 10, and 11. The largest decline pre- to post-implementation was in region 6 and the largest increase occurred in region 1.

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

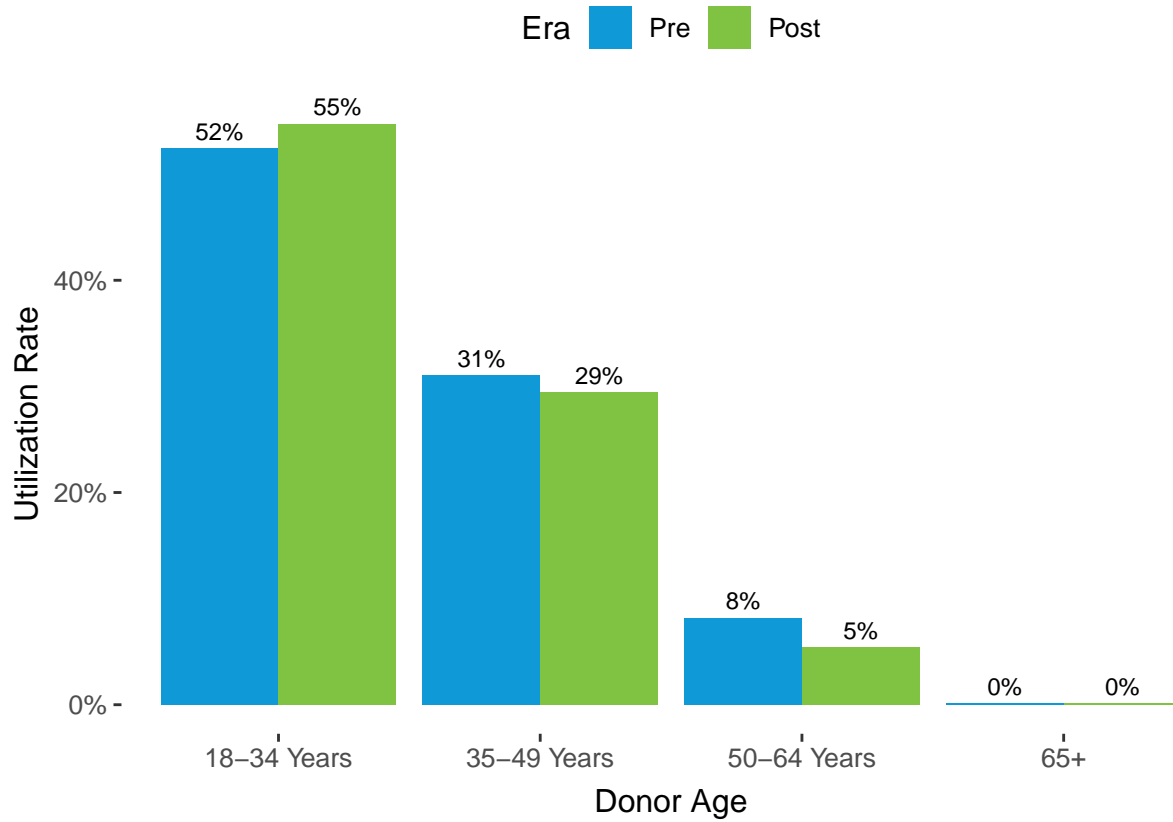


Figure 36 shows the utilization rates for adult hearts both pre- and post-implementation by donor age. There was little change in adult heart utilization in any donor age group.

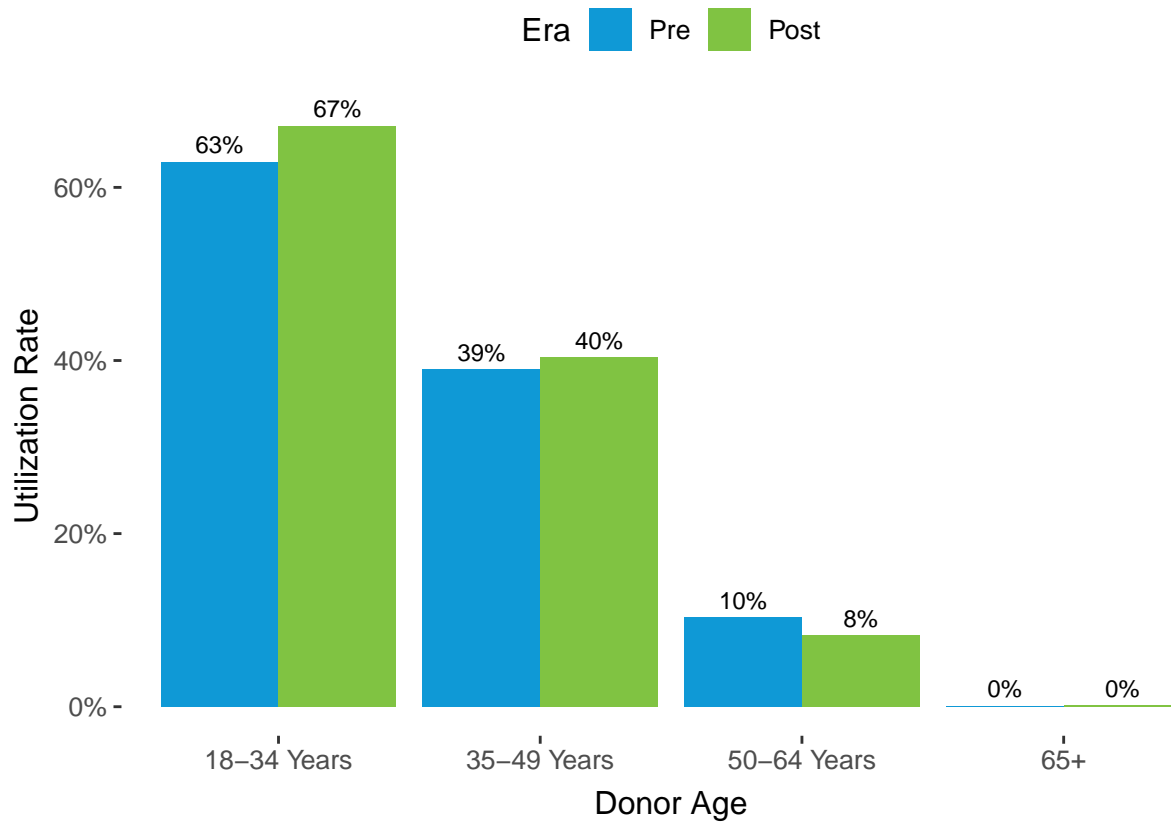
Figure 37. Heart Utilization Rates for Adult Non-DCD Donors by Donor Age and Era

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 age groups 18-34 years and 35-49 years, and decreased slightly for donor ages 50-64 years.

Outcomes

Heart allocation policy has traditionally been based on waiting list mortality rather than post-transplant outcomes, and the revisions to the adult heart allocation system were made with waiting list mortality rather than post-transplant survival in mind. However, in order to uncover potential unintended impacts on transplant outcomes, this chapter examines one-year recipient outcomes data for the 7124 adult heart recipients transplanted between October 18, 2014 and October 17, 2017 (pre-implementation) and the 8294 adult heart recipients transplanted between October 18, 2018 and October 17, 2021 (post-implementation). Three-year outcomes data were drawn from the 2134 adult heart recipients transplanted between October 18, 2014 and October 17, 2015 (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

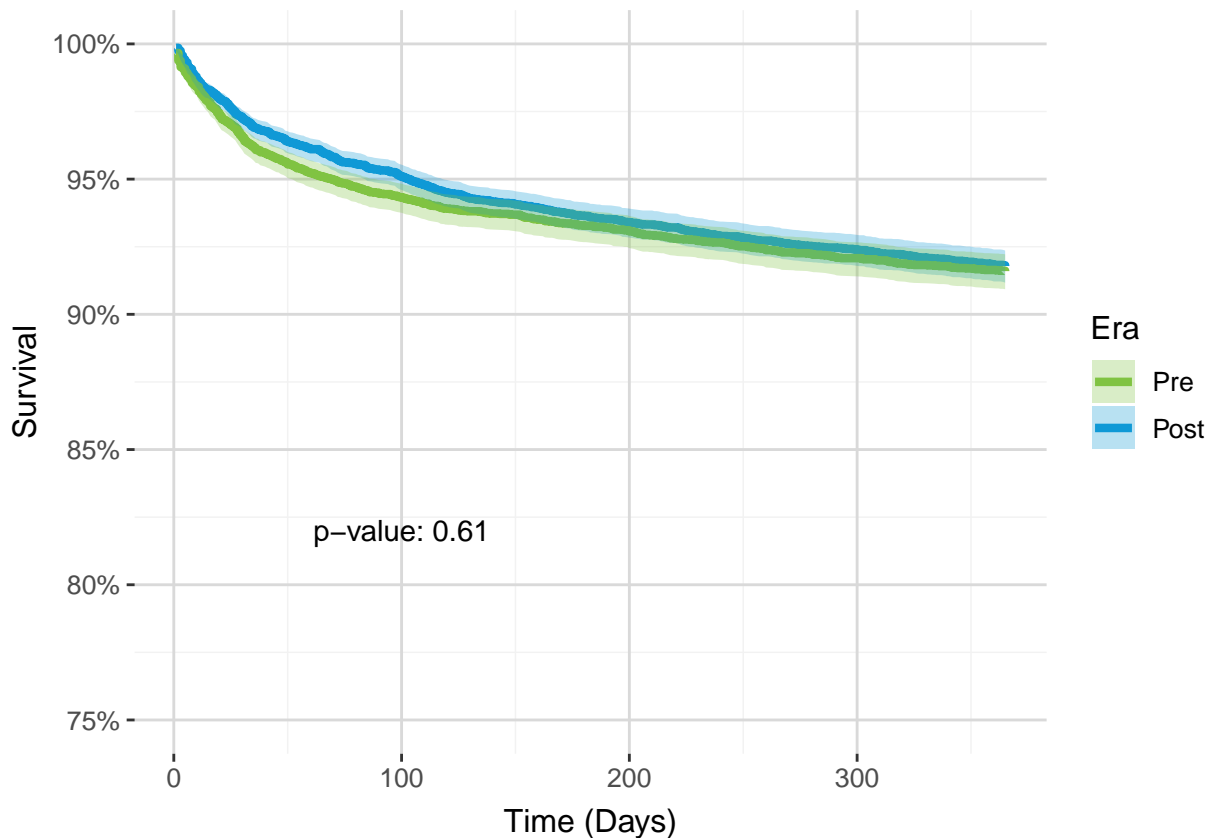


Figure 38 shows the one-year patient survival for adult heart recipients pre- and post-implementation. There was no significant difference in patient survival between the two eras ($p = 0.61$). One-year patient survival in the pre era was 91.6% compared to 91.79% in the post era.

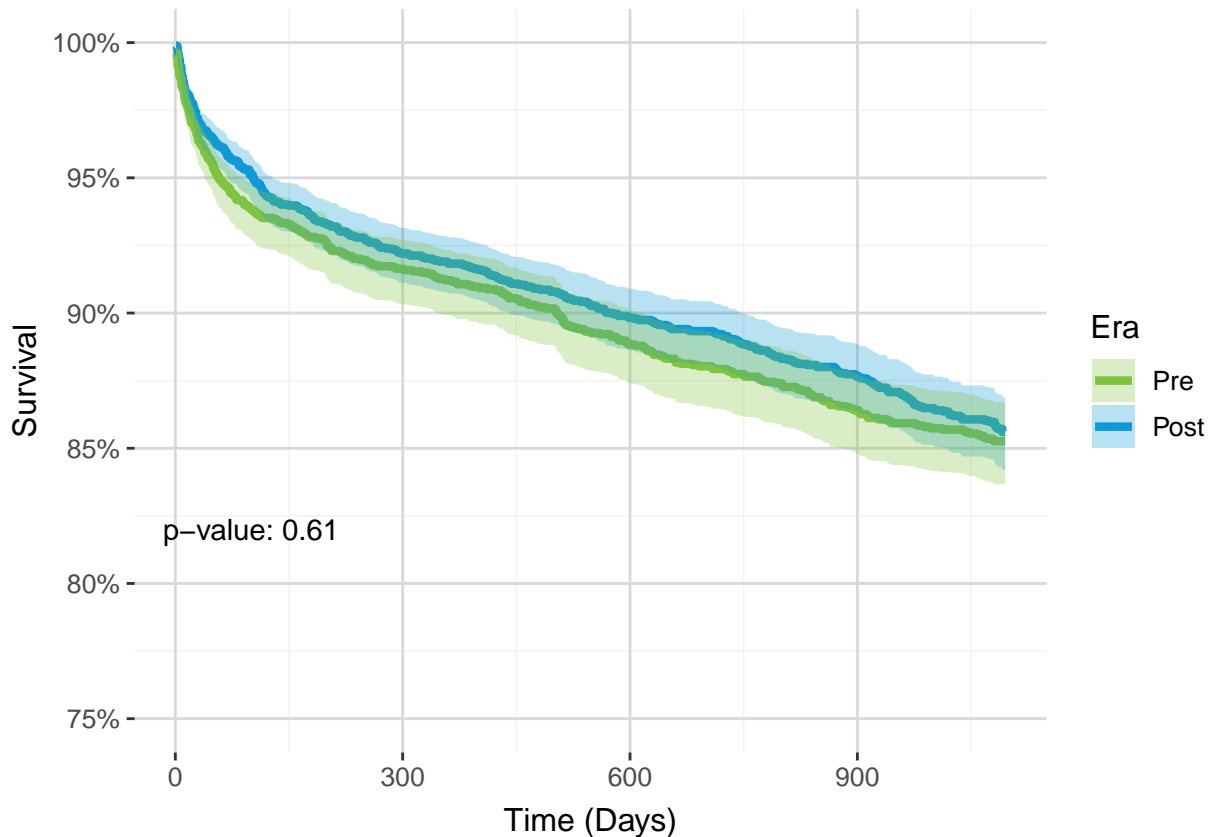
Figure 39. Three-Year Patient Survival

Figure 39 shows the three-year patient survival for adult heart recipients pre- and post-implementation. As with one-year patient survival, there was no significant difference in three-year patient survival between the two eras ($p = 0.61$). Three-year patient survival in the pre era was 85.26% compared to 85.61% 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 188 Status 2 recipients of which 23 died before one year compared to the 414 out of 4768 and 159 out of 2168 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 6 had the best one-year patient survival. There were 693 Adult Status 1 recipients of which 65 died before one year compared to the 32 out of 418 Adult Status 6 recipients who died before one year. Adult Status 4 had lower one-year survival than Adult Status 6, but higher one-year survival than Adult Statuses 2, 3, and 1. Adult Status 5 was omitted from this plot because there were 2 recipients during the one-year survival post-implementation period. These Adult Status 5 transplants were made to recipients who were waiting for multiple organs but only received a heart and therefore were not excluded by the heart-alone transplant requirement for this analysis.

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

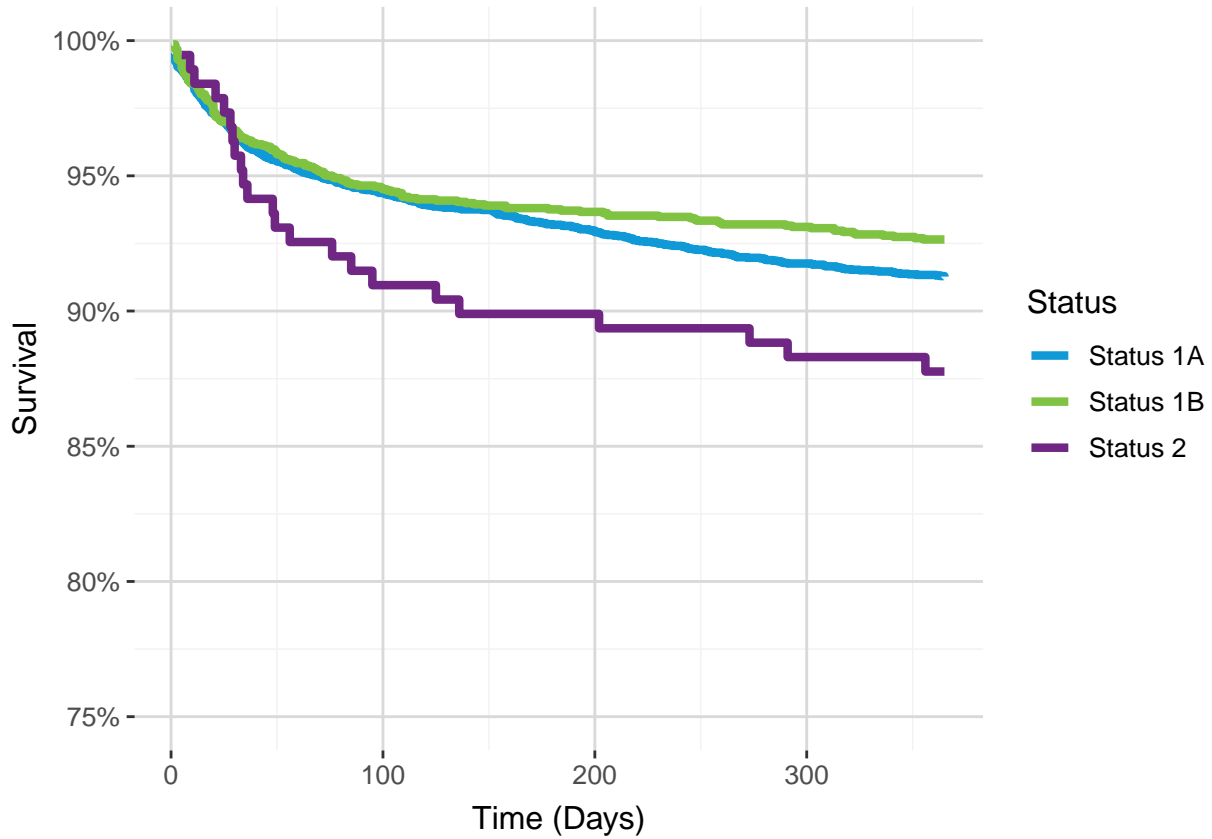
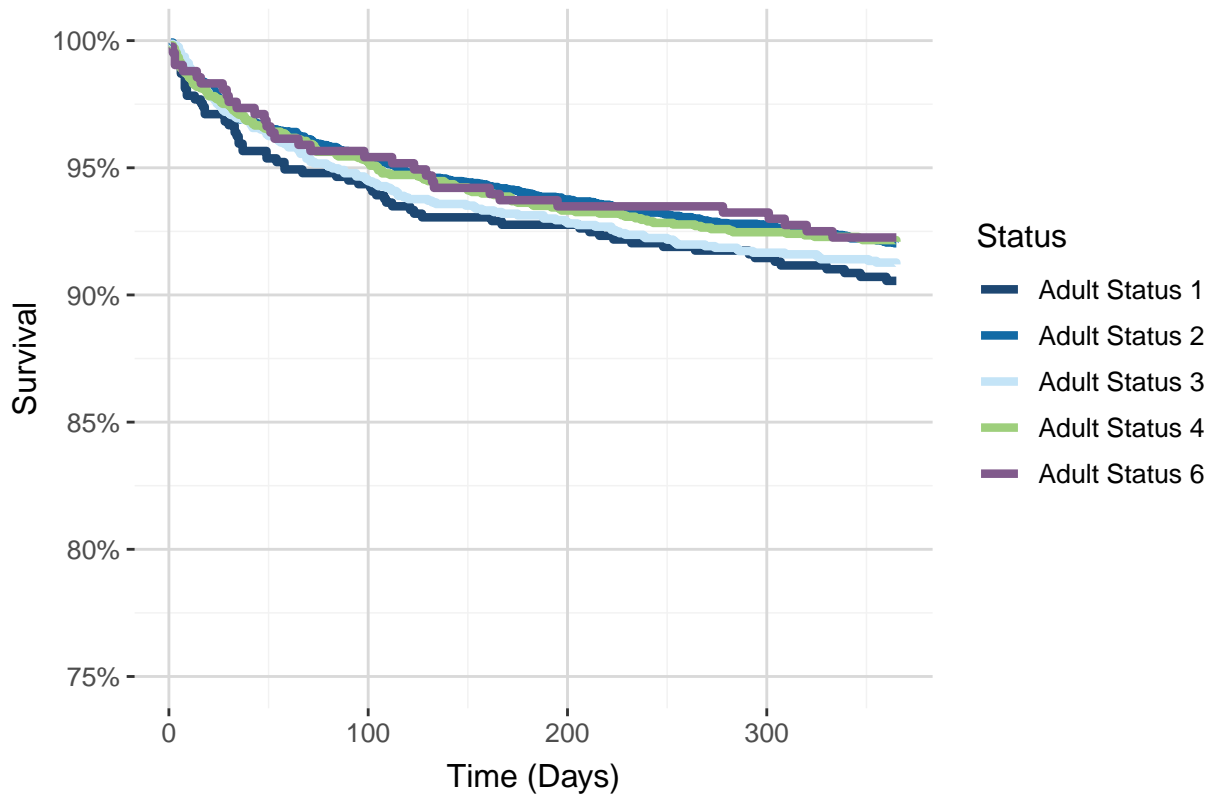


Figure 41. One-Year Patient Survival by Medical Urgency Status Post-Implementation



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

Figures 42 and 43 show the three-year patient survival for different medical urgency statuses pre- and post-implementation. As with one-year patient survival, Status 1B had the best three year survival, followed by Status 1A. Status 2 had the worst three year survival. Pre-implementation there were 74 Status 2 recipients of which 17 died before three years compared to the 173 out of 1430 and 67 out of 630 recipients in Adult Statuses 1A and 1B, respectively, who died before three years.

Post-implementation Adult Status 3 had the worst three-year patient survival and Adult Status 4 had the best three-year patient survival. There were 643 Adult Status 3 recipients of which 78 died before three years compared to the 40 out of 484 Adult Status 4 recipients who died before three years. Adult Status 6 had lower three-year survival than Adult Status 4, but higher three-year survival than Adult Statuses 1, 2, and 3. Adult statuses 1 and 2 had similar patient survival rates at three years; these rates fell between those for Adult Status 4 and Adult Status 3. Adult Status 5 was omitted from this plot because there were 0 recipients during the three-year survival post-implementation period.

Figure 42. Three-year Patient Survival by Medical Urgency Status Pre-Implementation

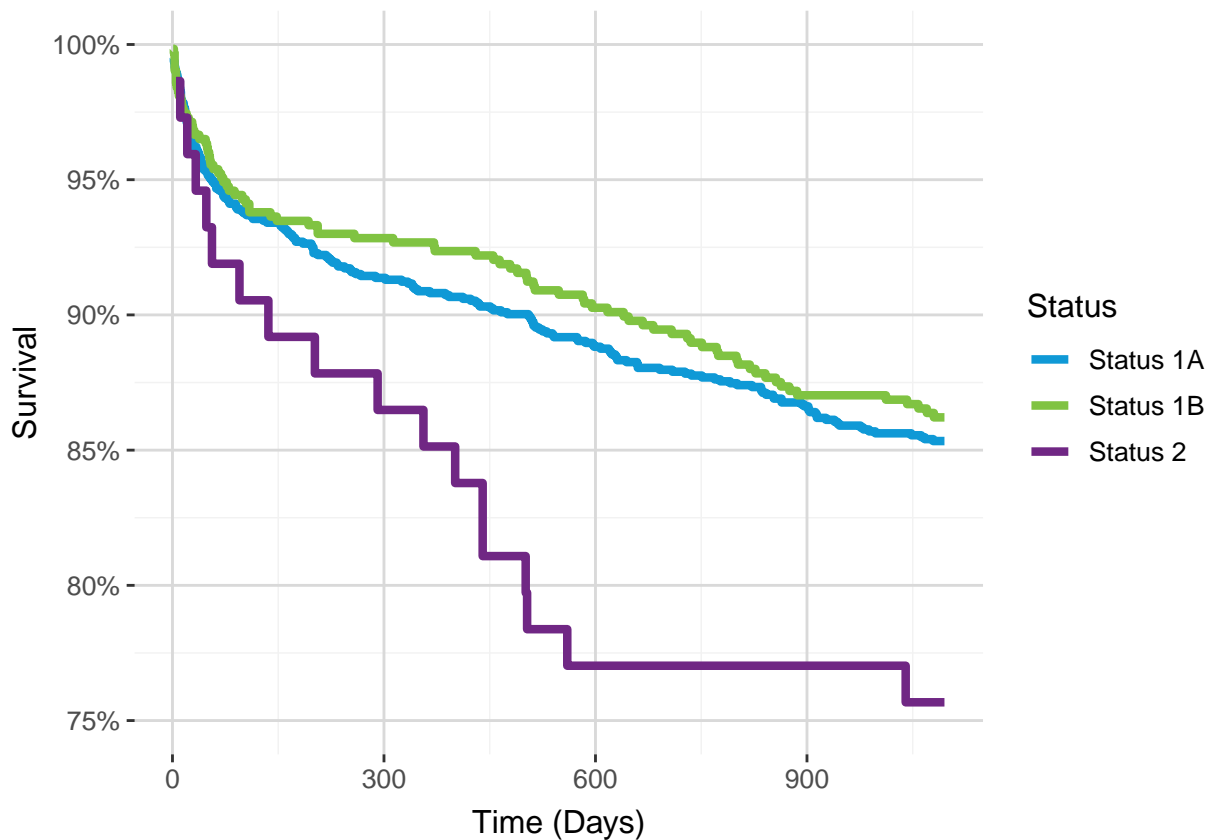
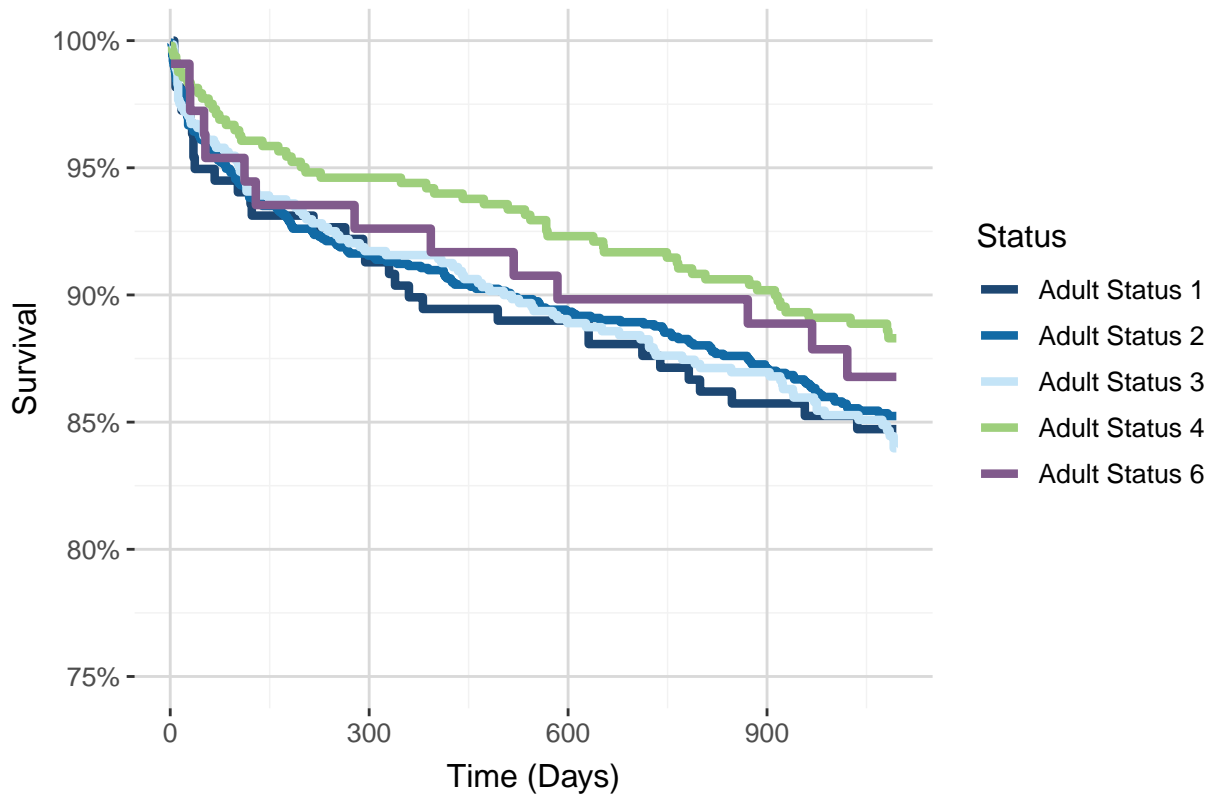


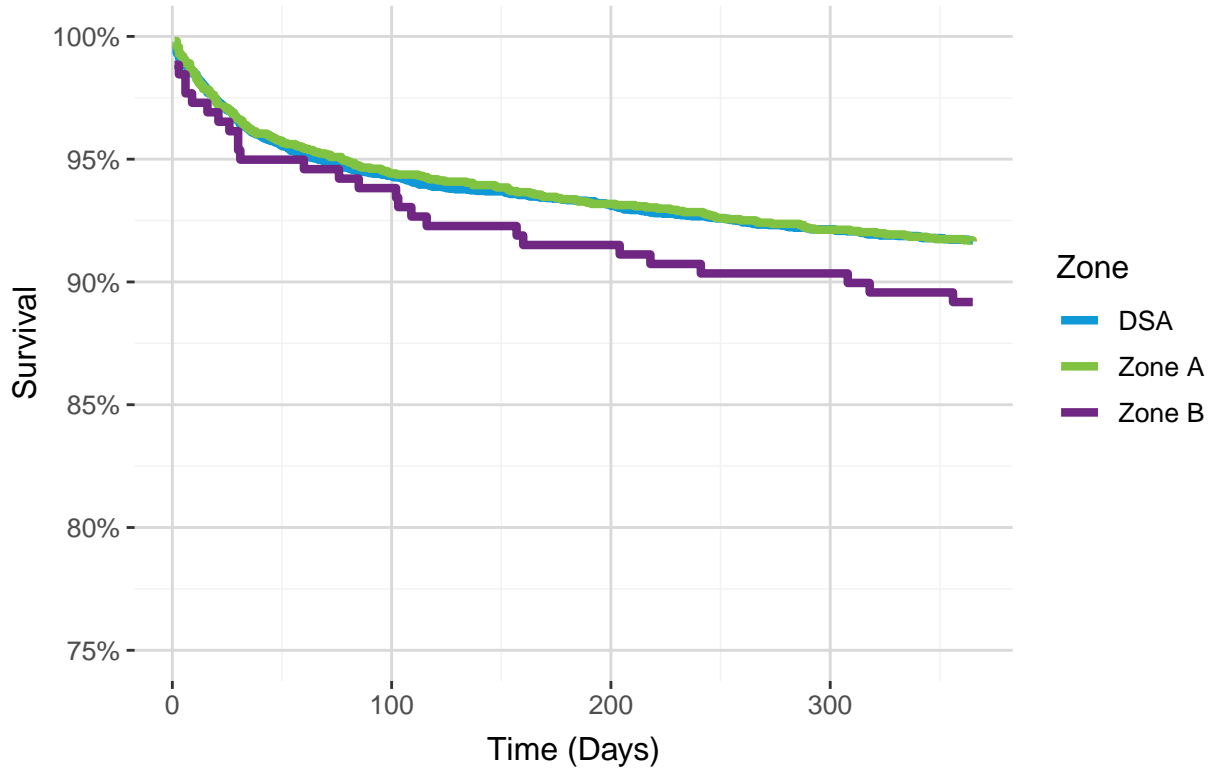
Figure 43. Three-year Patient Survival by Medical Urgency Status Post-Implementation



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

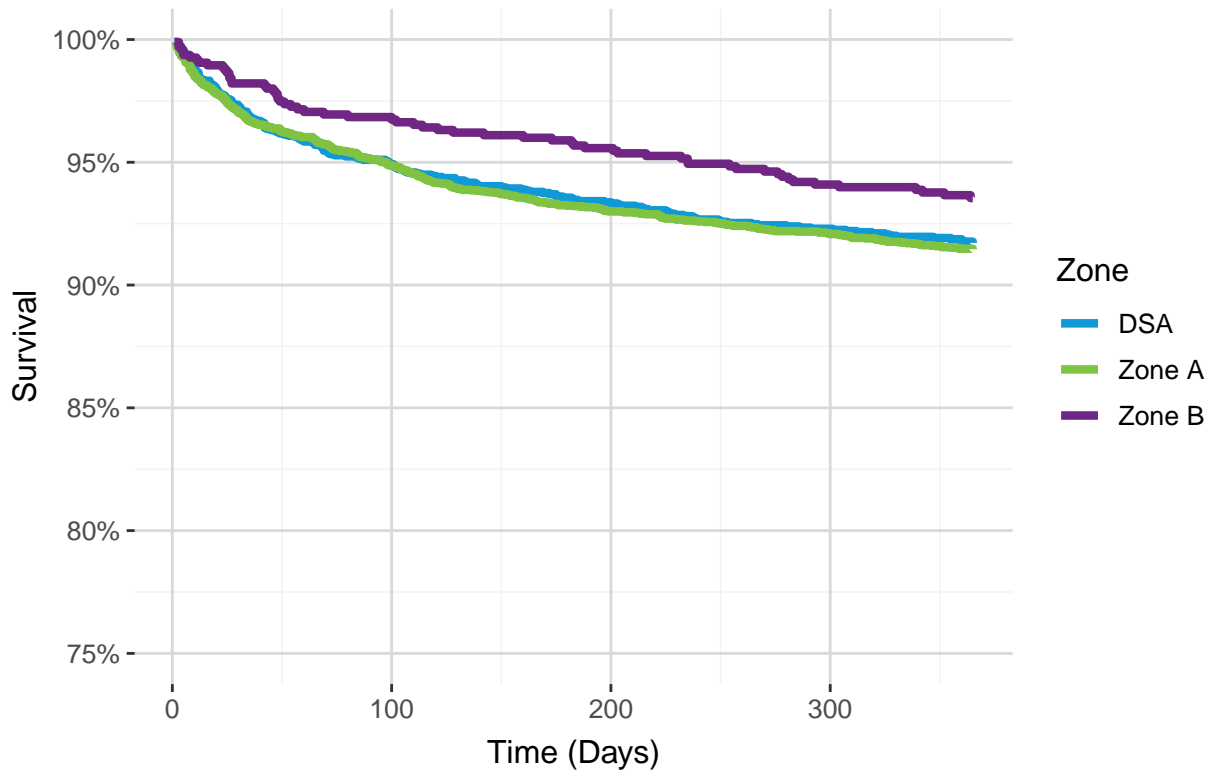
Figures 44 and 45 show one-year patient survival by zone, pre- and post-implementation. These analyses are unadjusted and therefore do not account for medical urgency or other candidate or donor factors that could impact outcomes. Pre-implementation Zone B had the lowest one-year patient survival while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

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



Zones C and D omitted due to the low sample size
 DSA was removed as a unit of allocation from heart policy on 1/09/2020;
 a separate monitoring report addresses that removal

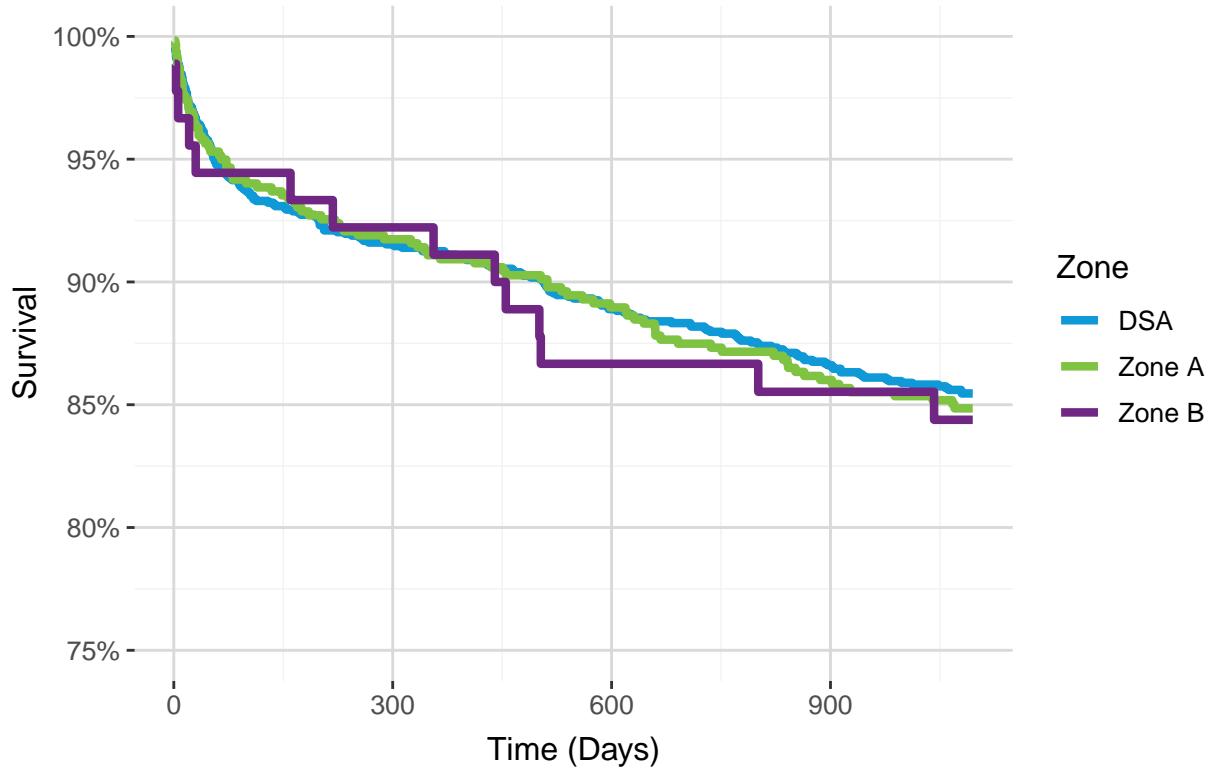
Figure 45. One-Year Patient Survival by Zone Post-Implementation



Zones C and D omitted due to the low sample size
DSA was removed as a unit of allocation from heart policy on 1/09/2020;
a separate monitoring report addresses that removal

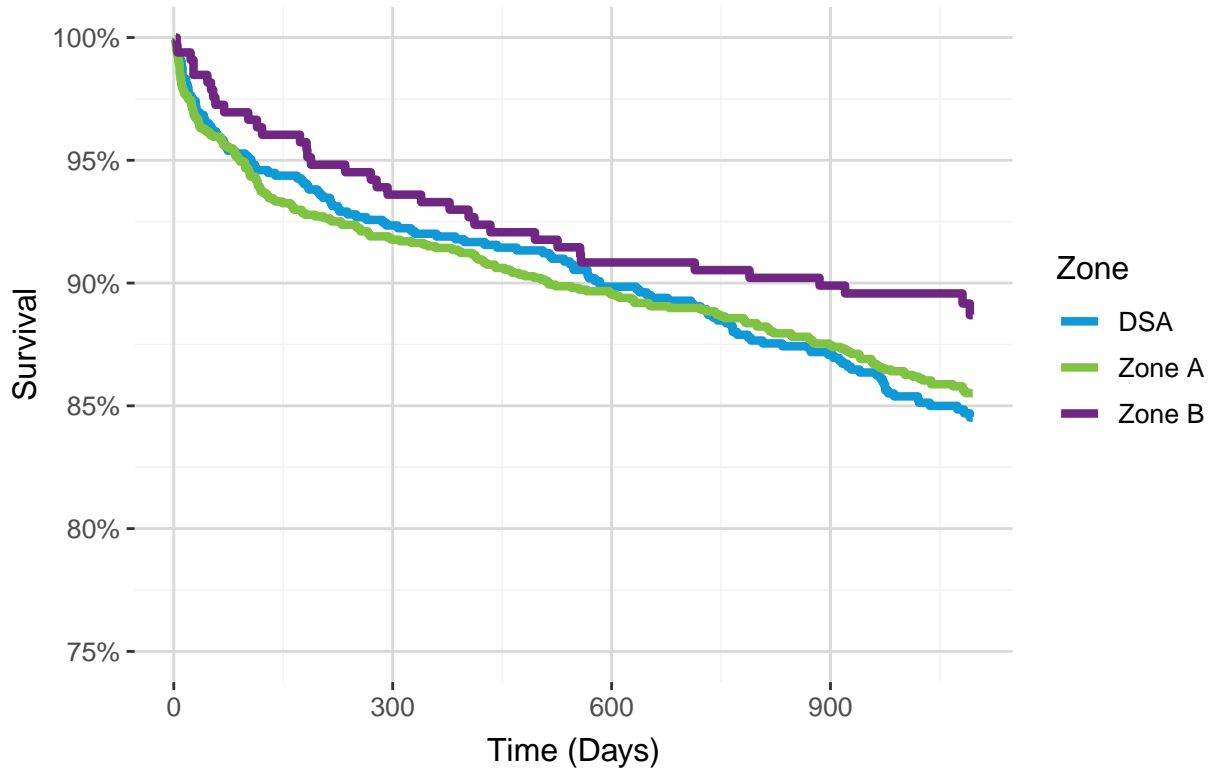
Figures 46 and 47 show three-year patient survival by zone, pre- and post-implementation. These analyses are unadjusted and therefore do not account for medical urgency or other candidate or donor factors that could impact outcomes. Zone B had the lowest three-year patient survival pre-implementation,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

Figure 46. Three-year Patient Survival by Zone Pre-Implementation



Zones C and D omitted due to the low sample size
 DSA was removed as a unit of allocation from heart policy on 1/09/2020;
 a separate monitoring report addresses that removal

Figure 47. Three-year Patient Survival by Zone Post-Implementation



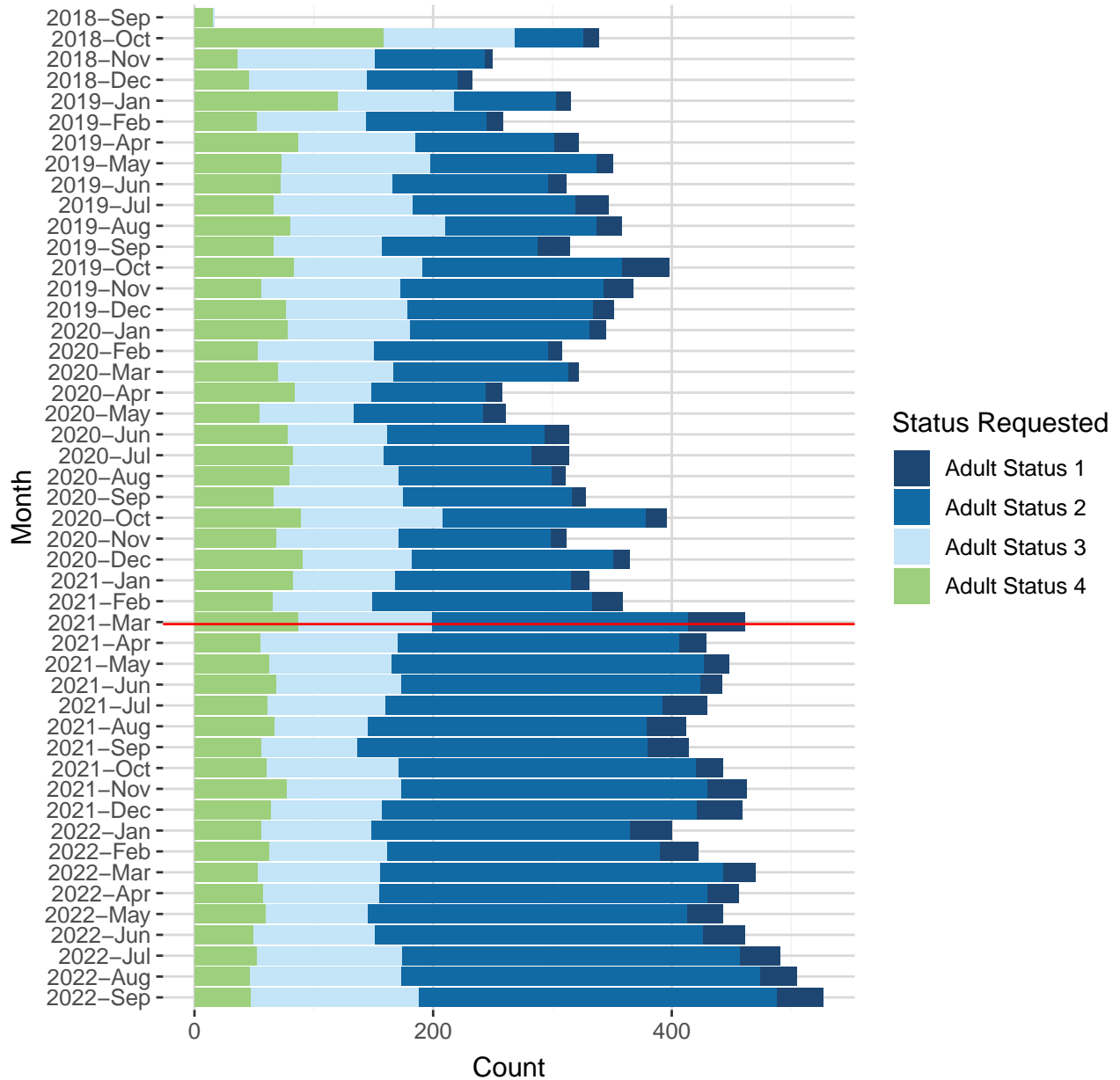
Zones C and D omitted due to the low sample size
DSA was removed as a unit of allocation from heart policy on 1/09/2020;
a separate monitoring report addresses that removal

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, 2022 when the most recent RRB rolled off before the end of the post-implementation period. 17937 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



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 25 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 25. 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%)

	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%)
	2021-Oct	23 (5.2%)	249 (56.2%)	111 (25.1%)	60 (13.5%)	443 (100.0%)
	2021-Nov	33 (7.1%)	257 (55.5%)	96 (20.7%)	77 (16.6%)	463 (100.0%)
Post-guidance	2021-Dec	38 (8.3%)	264 (57.5%)	93 (20.3%)	64 (13.9%)	459 (100.0%)
	2022-Jan	35 (8.8%)	217 (54.2%)	92 (23.0%)	56 (14.0%)	400 (100.0%)
	2022-Feb	32 (7.6%)	229 (54.3%)	99 (23.5%)	62 (14.7%)	422 (100.0%)
	2022-Mar	27 (5.7%)	288 (61.3%)	102 (21.7%)	53 (11.3%)	470 (100.0%)
	2022-Apr	26 (5.7%)	275 (60.3%)	98 (21.5%)	57 (12.5%)	456 (100.0%)
	2022-May	30 (6.8%)	268 (60.5%)	86 (19.4%)	59 (13.3%)	443 (100.0%)
	2022-Jun	35 (7.6%)	275 (59.7%)	102 (22.1%)	49 (10.6%)	461 (100.0%)
	2022-Jul	34 (6.9%)	283 (57.6%)	122 (24.8%)	52 (10.6%)	491 (100.0%)
	2022-Aug	31 (6.1%)	301 (59.6%)	127 (25.1%)	46 (9.1%)	505 (100.0%)
	2022-Sep	39 (7.4%)	300 (56.9%)	141 (26.8%)	47 (8.9%)	527 (100.0%)
	Total	589 (6.9%)	4864 (57.0%)	1946 (22.8%)	1130 (13.2%)	8529 (100.0%)
Overall	Total	1116 (6.2%)	8657 (48.3%)	4844 (27.0%)	3320 (18.5%)	17937 (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 26 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 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 2 was the most common exception request both pre-guidance and post-guidance.

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

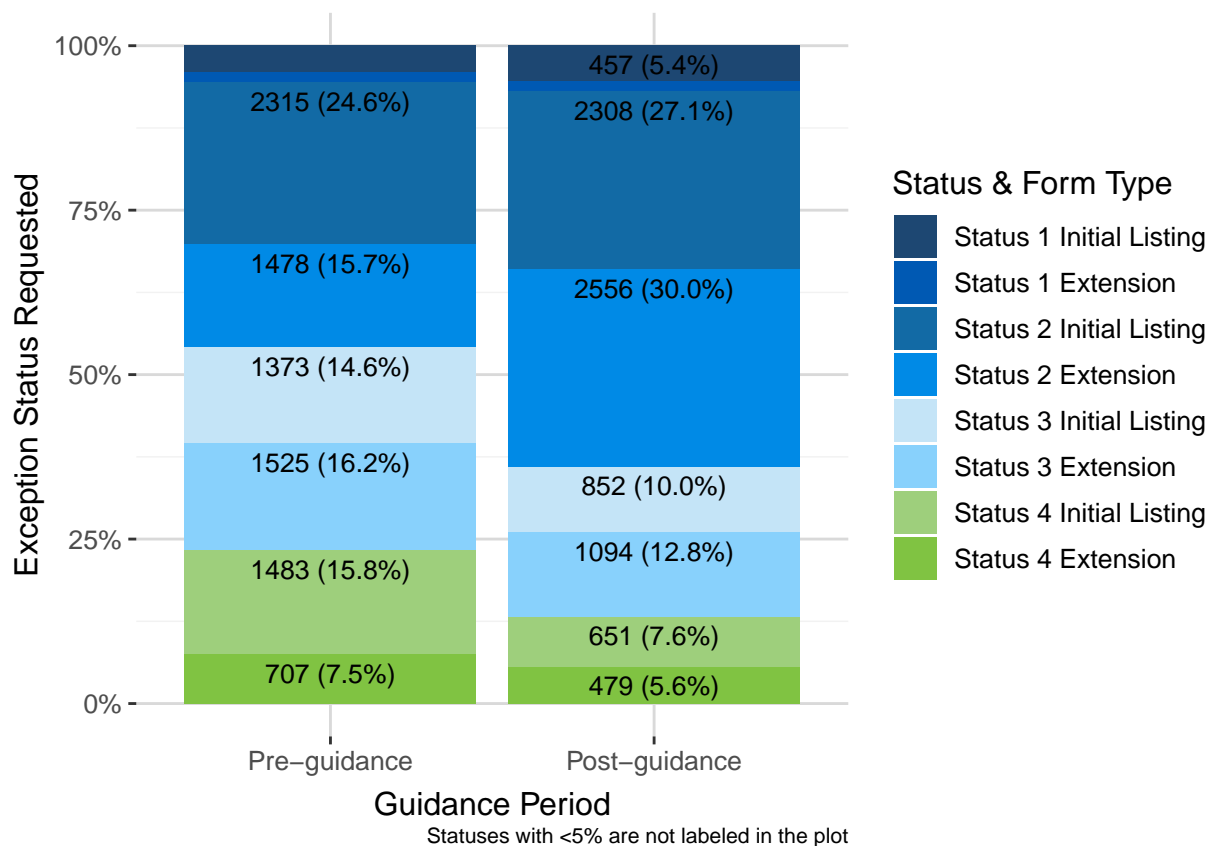


Figure 50. Number of justification forms by medical urgency status, form type, and guidance period

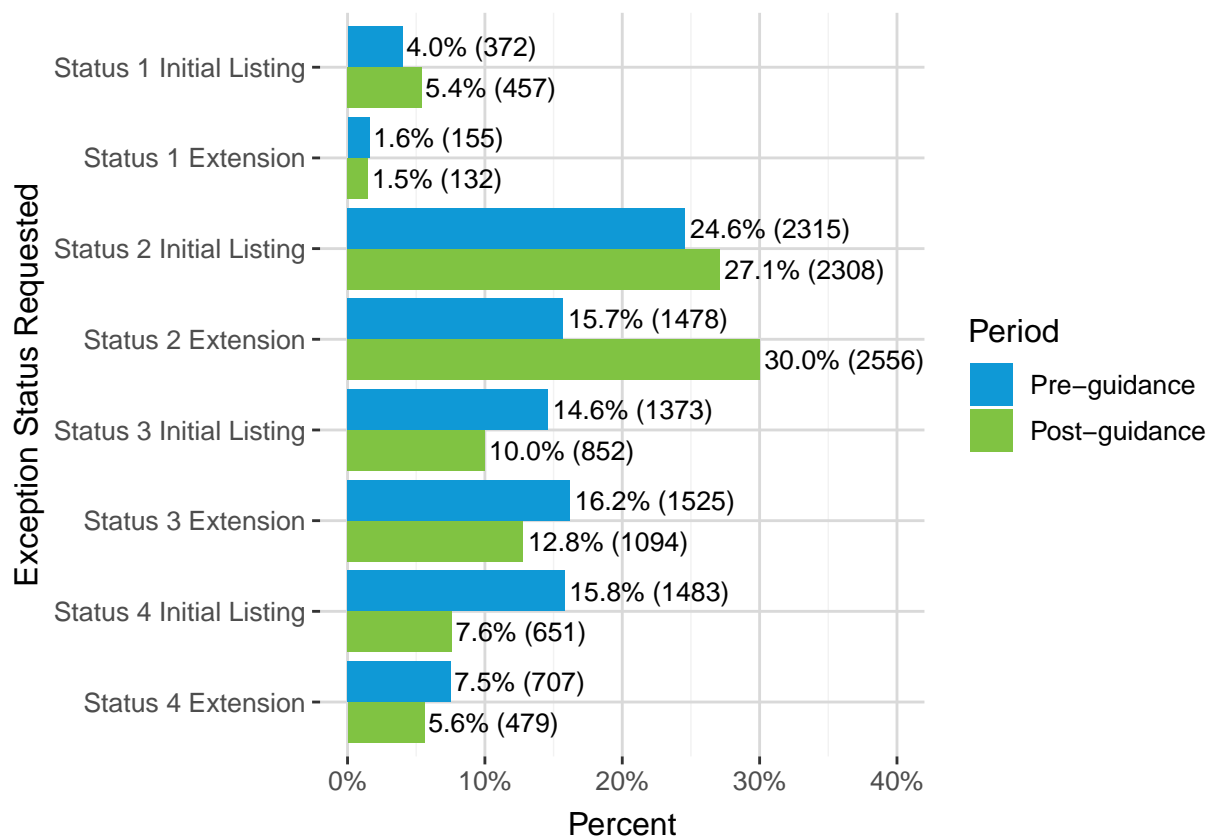


Table 26. Number of justification forms by medical urgency status, form type, and guidance period

Adult Heart Status and Form Type	Number of Justification Forms					
	Pre-guidance		Post-guidance		Overall	
	N	%	N	%	N	%
Status 1 Initial Listing	372	4.0%	457	5.4%	829	4.6%
Status 1 Extension	155	1.6%	132	1.5%	287	1.6%
Status 2 Initial Listing	2315	24.6%	2308	27.1%	4623	25.8%
Status 2 Extension	1478	15.7%	2556	30.0%	4034	22.5%
Status 3 Initial Listing	1373	14.6%	852	10.0%	2225	12.4%
Status 3 Extension	1525	16.2%	1094	12.8%	2619	14.6%
Status 4 Initial Listing	1483	15.8%	651	7.6%	2134	11.9%
Status 4 Extension	707	7.5%	479	5.6%	1186	6.6%
Total	9408	100.0%	8529	100.0%	17937	100.0%

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 27 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 28). Conversely, a larger proportion of Status 2 Standard and Status 2 Exception forms were submitted post-guidance (Figure 52 and Table 28).

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

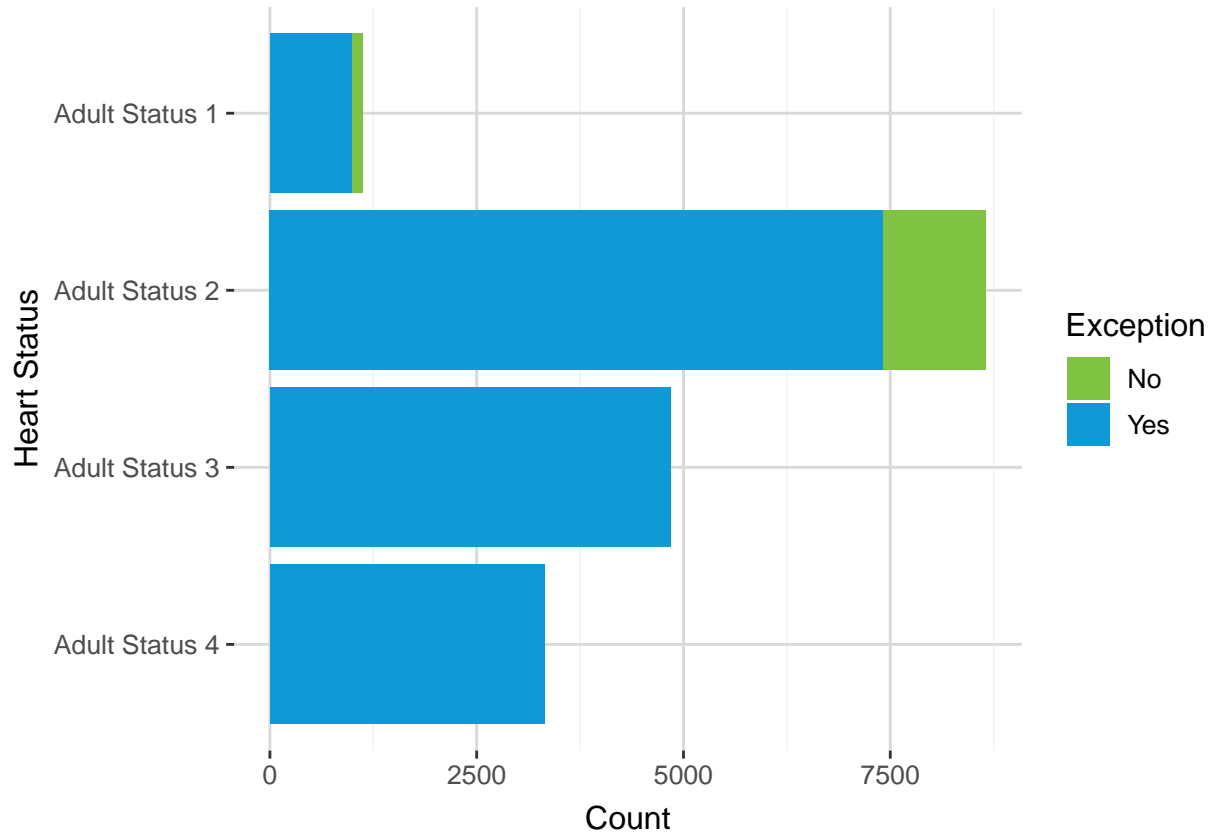


Figure 52. Number of justification forms by exception versus standard review, heart status, and guidance period

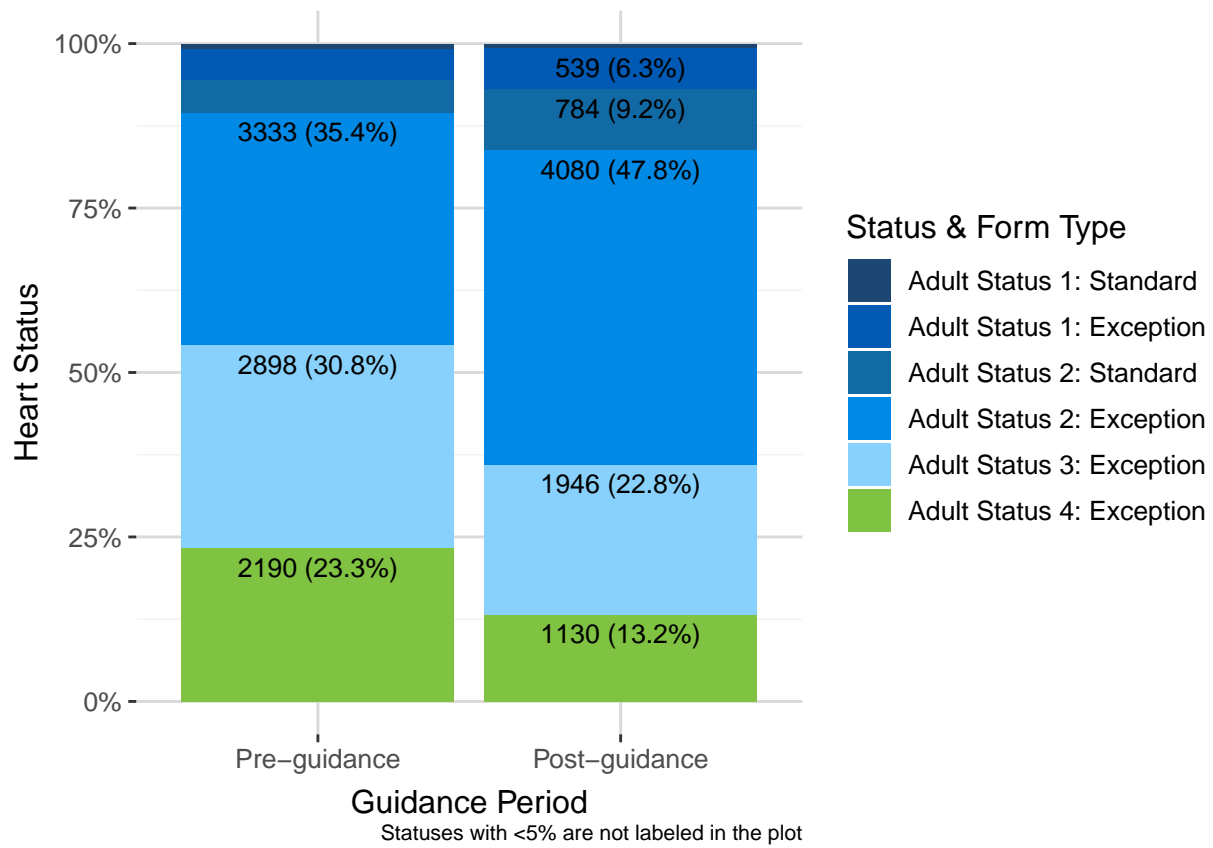
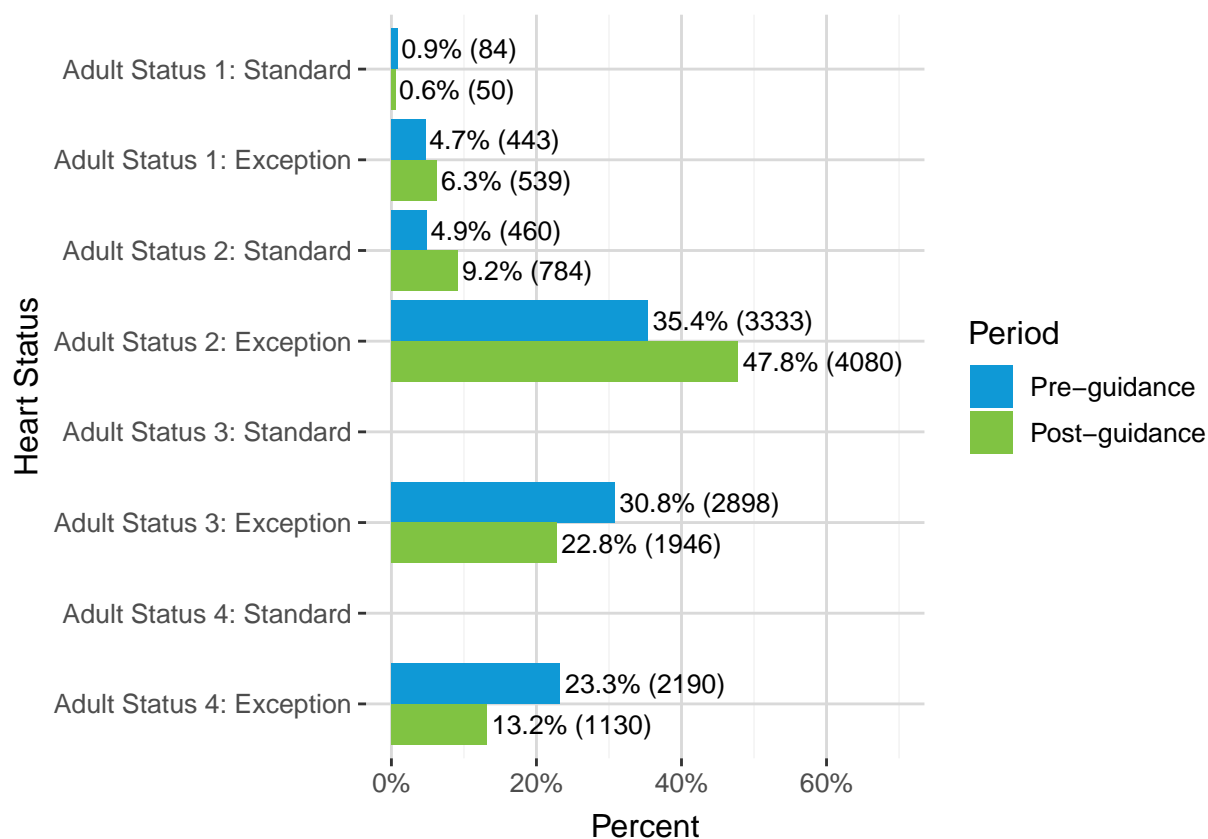


Figure 53. Number of justification forms by exception versus standard review, heart status, and guidance period**Table 27. Number of justification forms by exception versus standard review and medical urgency status**

Adult Heart Status	Exception Request		
	No	Yes	Total
Adult Status 1	134 (12.0%)	982 (88.0%)	1116 (100.0%)
Adult Status 2	1244 (14.4%)	7413 (85.6%)	8657 (100.0%)
Adult Status 3	0 (0.0%)	4844 (100.0%)	4844 (100.0%)
Adult Status 4	0 (0.0%)	3320 (100.0%)	3320 (100.0%)
Total	1378 (7.7%)	16559 (92.3%)	17937 (100.0%)

Table 28. Number of justification forms by exception versus standard review, medical urgency status, and guidance period

Guidance Period	Adult Heart Status	Exception Request		
		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	50 (8.5%)	539 (91.5%)	589 (100.0%)
	Adult Status 2	784 (16.1%)	4080 (83.9%)	4864 (100.0%)
	Adult Status 3	0 (0.0%)	1946 (100.0%)	1946 (100.0%)
	Adult Status 4	0 (0.0%)	1130 (100.0%)	1130 (100.0%)
	Total	834 (9.8%)	7695 (90.2%)	8529 (100.0%)
Overall	Adult Status 1	134 (12.0%)	982 (88.0%)	1116 (100.0%)
	Adult Status 2	1244 (14.4%)	7413 (85.6%)	8657 (100.0%)
	Adult Status 3	0 (0.0%)	4844 (100.0%)	4844 (100.0%)
	Adult Status 4	0 (0.0%)	3320 (100.0%)	3320 (100.0%)
	Total	1378 (7.7%)	16559 (92.3%)	17937 (100.0%)

Figure 54 and Table 29 summarize form submission by the candidate's transplant center's OPTN region. 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 and Table 30).

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

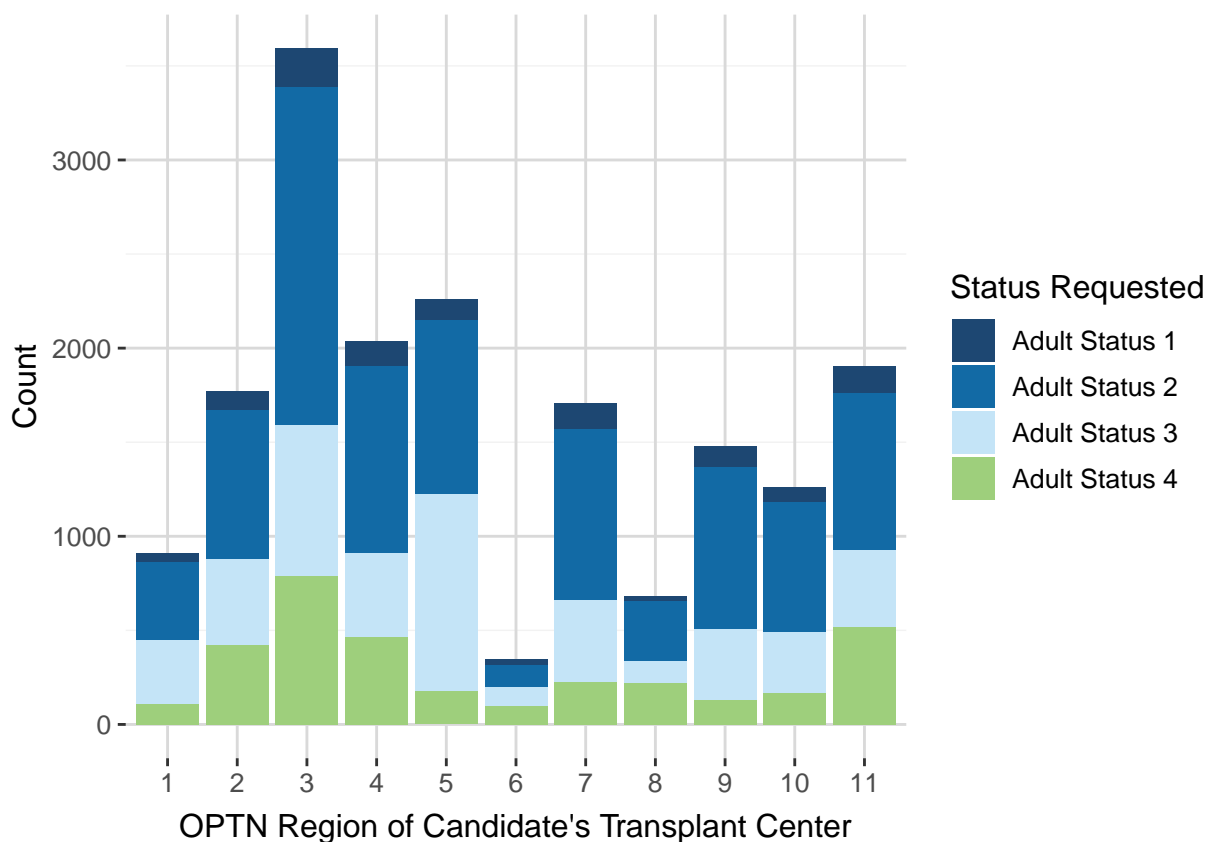


Table 29. Number of initial and extension justification forms by medical urgency status and OPTN region of candidate's transplant center

Adult Heart Status and Form Type	1	2	3	4	5	6	7	8	9	10	11	Total
Status 1 Initial Listing	41	68	157	98	88	22	62	28	87	67	111	829
Status 1 Extension	8	34	47	35	24	6	71	1	25	8	28	287
Status 2 Initial Listing	246	398	894	546	500	73	430	228	444	342	522	4623
Status 2 Extension	172	390	902	443	425	47	482	93	415	349	316	4034
Status 3 Initial Listing	136	197	337	248	443	64	173	73	181	151	222	2225
Status 3 Extension	199	263	469	197	605	32	261	40	196	172	185	2619
Status 4 Initial Listing	65	277	444	358	114	78	133	144	74	112	335	2134
Status 4 Extension	44	143	343	108	61	22	92	76	58	56	183	1186
Total	911	1770	3593	2033	2260	344	1704	683	1480	1257	1902	17937

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

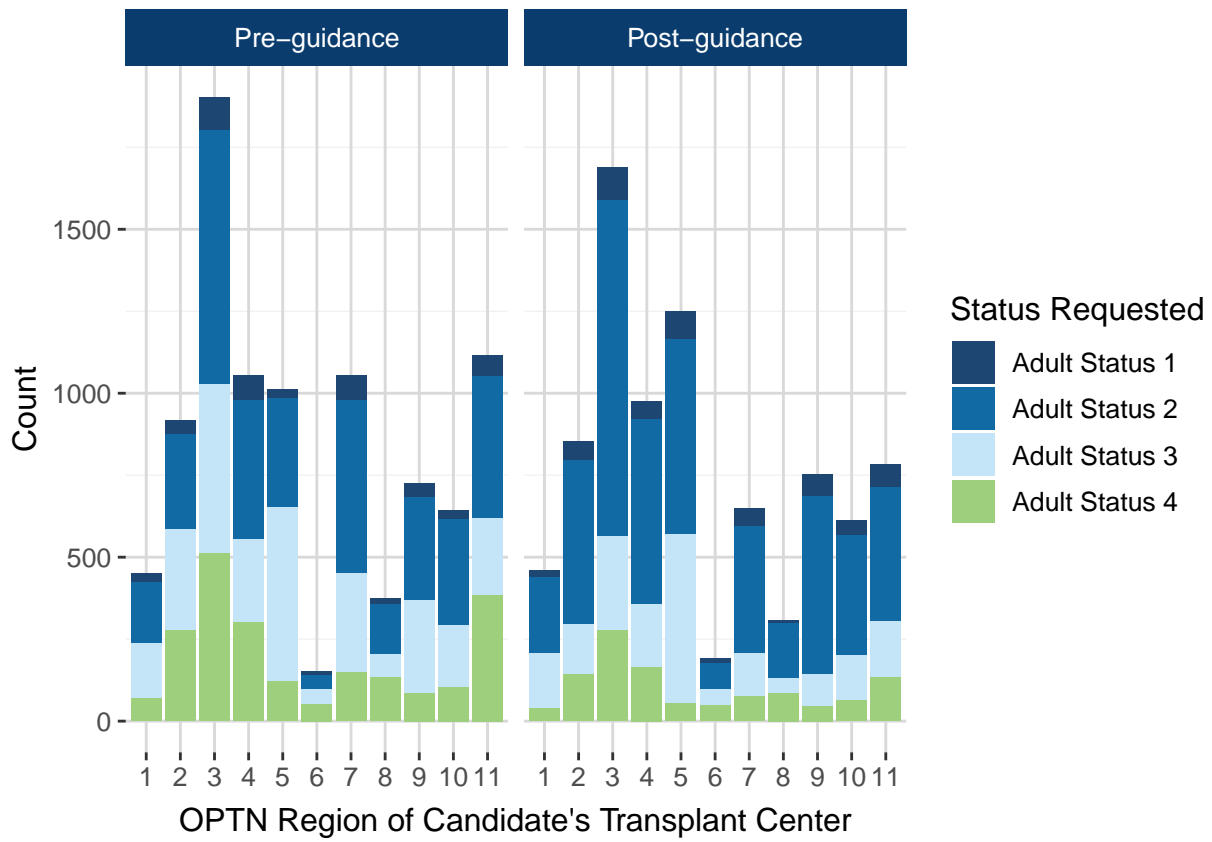


Table 30. Number of initial and extension justification forms by medical urgency status, OPTN region of candidate's transplant center, and guidance period

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	19 (4.2%)	37 (8.1%)	84 (18.4%)	46 (10.1%)	64 (14.0%)	13 (2.8%)	37 (8.1%)	10 (2.2%)	51 (11.2%)	39 (8.5%)	57 (12.5%)	457 (100.0%)
	Status 1 Extension	2 (1.5%)	21 (15.9%)	17 (12.9%)	11 (8.3%)	20 (15.2%)	3 (2.3%)	18 (13.6%)	1 (0.8%)	17 (12.9%)	7 (5.3%)	15 (11.4%)	132 (100.0%)
	Status 2 Initial Listing	119 (5.2%)	236 (10.2%)	432 (18.7%)	279 (12.1%)	295 (12.8%)	44 (1.9%)	183 (7.9%)	106 (4.6%)	233 (10.1%)	156 (6.8%)	225 (9.7%)	2308 (100.0%)
	Status 2 Extension	114 (4.5%)	265 (10.4%)	591 (23.1%)	284 (11.1%)	300 (11.7%)	33 (1.3%)	204 (8.0%)	62 (2.4%)	311 (12.2%)	211 (8.3%)	181 (7.1%)	2556 (100.0%)
	Status 3 Initial Listing	67 (7.9%)	70 (8.2%)	113 (13.3%)	92 (10.8%)	199 (23.4%)	33 (3.9%)	60 (7.0%)	26 (3.1%)	55 (6.5%)	60 (7.0%)	77 (9.0%)	852 (100.0%)
	Status 3 Extension	100 (9.1%)	81 (7.4%)	176 (16.1%)	100 (9.1%)	317 (29.0%)	18 (1.6%)	71 (6.5%)	18 (1.6%)	41 (3.7%)	76 (6.9%)	96 (8.8%)	1094 (100.0%)
	Status 4 Initial Listing	21 (3.2%)	83 (12.7%)	125 (19.2%)	122 (18.7%)	27 (4.1%)	33 (5.1%)	45 (6.9%)	49 (7.5%)	15 (2.3%)	49 (7.5%)	82 (12.6%)	651 (100.0%)
	Status 4 Extension	18 (3.8%)	60 (12.5%)	151 (31.5%)	43 (9.0%)	27 (5.6%)	15 (3.1%)	31 (6.5%)	37 (7.7%)	31 (6.5%)	15 (3.1%)	51 (10.6%)	479 (100.0%)
	Total	460 (5.4%)	853 (10.0%)	1689 (19.8%)	977 (11.5%)	1249 (14.6%)	192 (2.3%)	649 (7.6%)	309 (3.6%)	754 (8.8%)	613 (7.2%)	784 (9.2%)	8529 (100.0%)
	Overall	Status 1 Initial Listing	41 (4.9%)	68 (8.2%)	157 (18.9%)	98 (11.8%)	88 (10.6%)	22 (2.7%)	62 (7.5%)	28 (3.4%)	87 (10.5%)	67 (8.1%)	111 (13.4%)
Status 1 Extension		8 (2.8%)	34 (11.8%)	47 (16.4%)	35 (12.2%)	24 (8.4%)	6 (2.1%)	71 (24.7%)	1 (0.3%)	25 (8.7%)	8 (2.8%)	28 (9.8%)	287 (100.0%)
Status 2 Initial Listing		246 (5.3%)	398 (8.6%)	894 (19.3%)	546 (11.8%)	500 (10.8%)	73 (1.6%)	430 (9.3%)	228 (4.9%)	444 (9.6%)	342 (7.4%)	522 (11.3%)	4623 (100.0%)
Status 2 Extension		172 (4.3%)	390 (9.7%)	902 (22.4%)	443 (11.0%)	425 (10.5%)	47 (1.2%)	482 (11.9%)	93 (2.3%)	415 (10.3%)	349 (8.7%)	316 (7.8%)	4034 (100.0%)
Status 3 Initial Listing		136 (6.1%)	197 (8.9%)	337 (15.1%)	248 (11.1%)	443 (19.9%)	64 (2.9%)	173 (7.8%)	73 (3.3%)	181 (8.1%)	151 (6.8%)	222 (10.0%)	2225 (100.0%)
Status 3 Extension		199 (7.6%)	263 (10.0%)	469 (17.9%)	197 (7.5%)	605 (23.1%)	32 (1.2%)	261 (10.0%)	40 (1.5%)	196 (7.5%)	172 (6.6%)	185 (7.1%)	2619 (100.0%)
Status 4 Initial Listing		65 (3.0%)	277 (13.0%)	444 (20.8%)	358 (16.8%)	114 (5.3%)	78 (3.7%)	133 (6.2%)	144 (6.7%)	74 (3.5%)	112 (5.2%)	335 (15.7%)	2134 (100.0%)
Status 4 Extension		44 (3.7%)	143 (12.1%)	343 (28.9%)	108 (9.1%)	61 (5.1%)	22 (1.9%)	92 (7.8%)	76 (6.4%)	58 (4.9%)	56 (4.7%)	183 (15.4%)	1186 (100.0%)
Total		911 (5.1%)	1770 (9.9%)	3593 (20.0%)	2033 (11.3%)	2260 (12.6%)	344 (1.9%)	1704 (9.5%)	683 (3.8%)	1480 (8.3%)	1257 (7.0%)	1902 (10.6%)	17937 (100.0%)

Table 31 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 (94.9%), regardless of medical urgency status or form type. Status 1 justification forms at initial listing had the lowest approval rate (90.6%) while Status 3 Extensions had the highest approval rate (97.7%). Similar patterns were seen in the pre- and post-guidance periods (Table 32).

Table 31. 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	748 (90.6%)	48 (5.8%)	4 (0.5%)	7 (0.8%)	19 (2.3%)	826 (100.0%)
Status 1 Extension	270 (97.1%)	3 (1.1%)	0 (0.0%)	0 (0.0%)	5 (1.8%)	278 (100.0%)
Status 2 Initial Listing	4256 (92.2%)	270 (5.8%)	23 (0.5%)	16 (0.3%)	52 (1.1%)	4617 (100.0%)
Status 2 Extension	3825 (96.6%)	96 (2.4%)	1 (0.0%)	7 (0.2%)	31 (0.8%)	3960 (100.0%)
Status 3 Initial Listing	2040 (92.1%)	102 (4.6%)	16 (0.7%)	16 (0.7%)	40 (1.8%)	2214 (100.0%)
Status 3 Extension	2545 (97.7%)	19 (0.7%)	0 (0.0%)	1 (0.0%)	39 (1.5%)	2604 (100.0%)
Status 4 Initial Listing	2065 (97.2%)	30 (1.4%)	5 (0.2%)	5 (0.2%)	20 (0.9%)	2125 (100.0%)
Status 4 Extension	1148 (97.5%)	13 (1.1%)	1 (0.1%)	1 (0.1%)	14 (1.2%)	1177 (100.0%)
Total	16897 (94.9%)	581 (3.3%)	50 (0.3%)	53 (0.3%)	220 (1.2%)	17801 (100.0%)

Table 32. 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	681 (96.9%)	12 (1.7%)	1 (0.1%)	1 (0.1%)	8 (1.1%)	703 (100.0%)
Total	8771 (94.1%)	312 (3.3%)	7 (0.1%)	53 (0.6%)	182 (2.0%)	9325 (100.0%)	
Post-guidance	Status 1 Initial Listing	424 (92.8%)	29 (6.3%)	3 (0.7%)	0 (0.0%)	1 (0.2%)	457 (100.0%)
	Status 1 Extension	127 (97.7%)	2 (1.5%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	130 (100.0%)
	Status 2 Initial Listing	2149 (93.2%)	134 (5.8%)	19 (0.8%)	0 (0.0%)	5 (0.2%)	2307 (100.0%)
	Status 2 Extension	2443 (97.2%)	59 (2.3%)	1 (0.0%)	0 (0.0%)	10 (0.4%)	2513 (100.0%)
	Status 3 Initial Listing	803 (94.2%)	32 (3.8%)	16 (1.9%)	0 (0.0%)	1 (0.1%)	852 (100.0%)
	Status 3 Extension	1073 (98.2%)	7 (0.6%)	0 (0.0%)	0 (0.0%)	13 (1.2%)	1093 (100.0%)
	Status 4 Initial Listing	640 (98.5%)	5 (0.8%)	4 (0.6%)	0 (0.0%)	1 (0.2%)	650 (100.0%)
	Status 4 Extension	467 (98.5%)	1 (0.2%)	0 (0.0%)	0 (0.0%)	6 (1.3%)	474 (100.0%)
Total	8126 (95.9%)	269 (3.2%)	43 (0.5%)	0 (0.0%)	38 (0.4%)	8476 (100.0%)	
Overall	Status 1 Initial Listing	748 (90.6%)	48 (5.8%)	4 (0.5%)	7 (0.8%)	19 (2.3%)	826 (100.0%)
	Status 1 Extension	270 (97.1%)	3 (1.1%)	0 (0.0%)	0 (0.0%)	5 (1.8%)	278 (100.0%)
	Status 2 Initial Listing	4256 (92.2%)	270 (5.8%)	23 (0.5%)	16 (0.3%)	52 (1.1%)	4617 (100.0%)
	Status 2 Extension	3825 (96.6%)	96 (2.4%)	1 (0.0%)	7 (0.2%)	31 (0.8%)	3960 (100.0%)
	Status 3 Initial Listing	2040 (92.1%)	102 (4.6%)	16 (0.7%)	16 (0.7%)	40 (1.8%)	2214 (100.0%)
	Status 3 Extension	2545 (97.7%)	19 (0.7%)	0 (0.0%)	1 (0.0%)	39 (1.5%)	2604 (100.0%)
	Status 4 Initial Listing	2065 (97.2%)	30 (1.4%)	5 (0.2%)	5 (0.2%)	20 (0.9%)	2125 (100.0%)
	Status 4 Extension	1148 (97.5%)	13 (1.1%)	1 (0.1%)	1 (0.1%)	14 (1.2%)	1177 (100.0%)
Total	16897 (94.9%)	581 (3.3%)	50 (0.3%)	53 (0.3%)	220 (1.2%)	17801 (100.0%)	

Under the new adult heart allocation system regions review requests from other regions. There have been four sets of RRB assignments during the period from September 18, 2018 to September 30, 2022 (<https://optn.transplant.hrsa.gov/members/review-boards/#HeartReviewBoard>). Table 33 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 four assignment periods. Region 6 submitted the fewest number of forms in all four review periods.

Table 33. 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
Oct 1, 2021 - Sep 30, 2022	
Region 1, Reviewed by Region 9	294
Region 2, Reviewed by Region 6	545
Region 3, Reviewed by Region 5	1086
Region 4, Reviewed by Region 3	603
Region 5, Reviewed by Region 11	858
Region 6, Reviewed by Region 10	137
Region 7, Reviewed by Region 1	415
Region 8, Reviewed by Region 7	205
Region 9, Reviewed by Region 2	486
Region 10, Reviewed by Region 8	426
Region 11, Reviewed by Region 4	485
Total	17937

Figure 56 and Table 34 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, 2022, Region 10 approved the lowest proportion and Region 7 approved the highest proportion of requests.

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

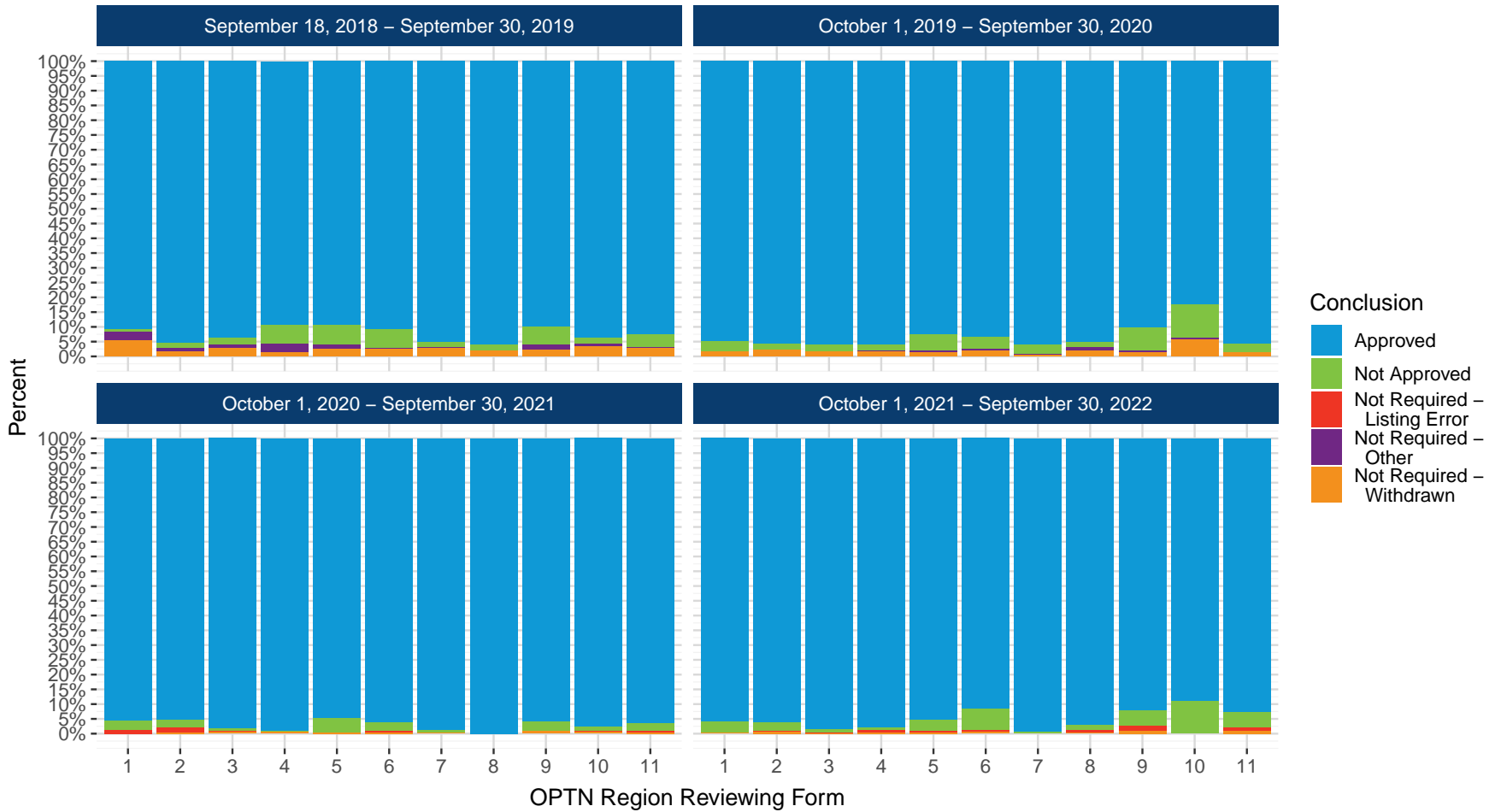


Table 34. Conclusions from justification forms by region reviewing request

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	252 (90.3%)	22 (7.9%)	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	366 (97.6%)	5 (1.3%)	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%)
Oct 1, 2021 - Sep 30, 2022						
1	395 (95.9%)	16 (3.9%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	412 (100.0%)
2	465 (96.3%)	14 (2.9%)	1 (0.2%)	0 (0.0%)	3 (0.6%)	483 (100.0%)
3	594 (98.7%)	6 (1.0%)	1 (0.2%)	0 (0.0%)	1 (0.2%)	602 (100.0%)
4	473 (97.9%)	4 (0.8%)	4 (0.8%)	0 (0.0%)	2 (0.4%)	483 (100.0%)
5	1028 (95.4%)	41 (3.8%)	5 (0.5%)	0 (0.0%)	4 (0.4%)	1078 (100.0%)
6	497 (91.5%)	39 (7.2%)	4 (0.7%)	0 (0.0%)	3 (0.6%)	543 (100.0%)
7	200 (99.5%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	201 (100.0%)
8	412 (97.2%)	7 (1.7%)	4 (0.9%)	0 (0.0%)	1 (0.2%)	424 (100.0%)
9	270 (92.2%)	15 (5.1%)	5 (1.7%)	0 (0.0%)	3 (1.0%)	293 (100.0%)
10	122 (89.1%)	15 (10.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	137 (100.0%)
11	789 (92.8%)	45 (5.3%)	8 (0.9%)	0 (0.0%)	8 (0.9%)	850 (100.0%)
Total	16897 (94.9%)	581 (3.3%)	50 (0.3%)	53 (0.3%)	220 (1.2%)	17801 (100.0%)

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 35 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 6600 registrations applied for an exception between September 18, 2018 and September 30, 2022. The most common initial request was for Adult Status 2 ($n=3111$, 47.1%). 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 58 and Table 36).

Figure 57. Number of registrations with an exception by first status requested

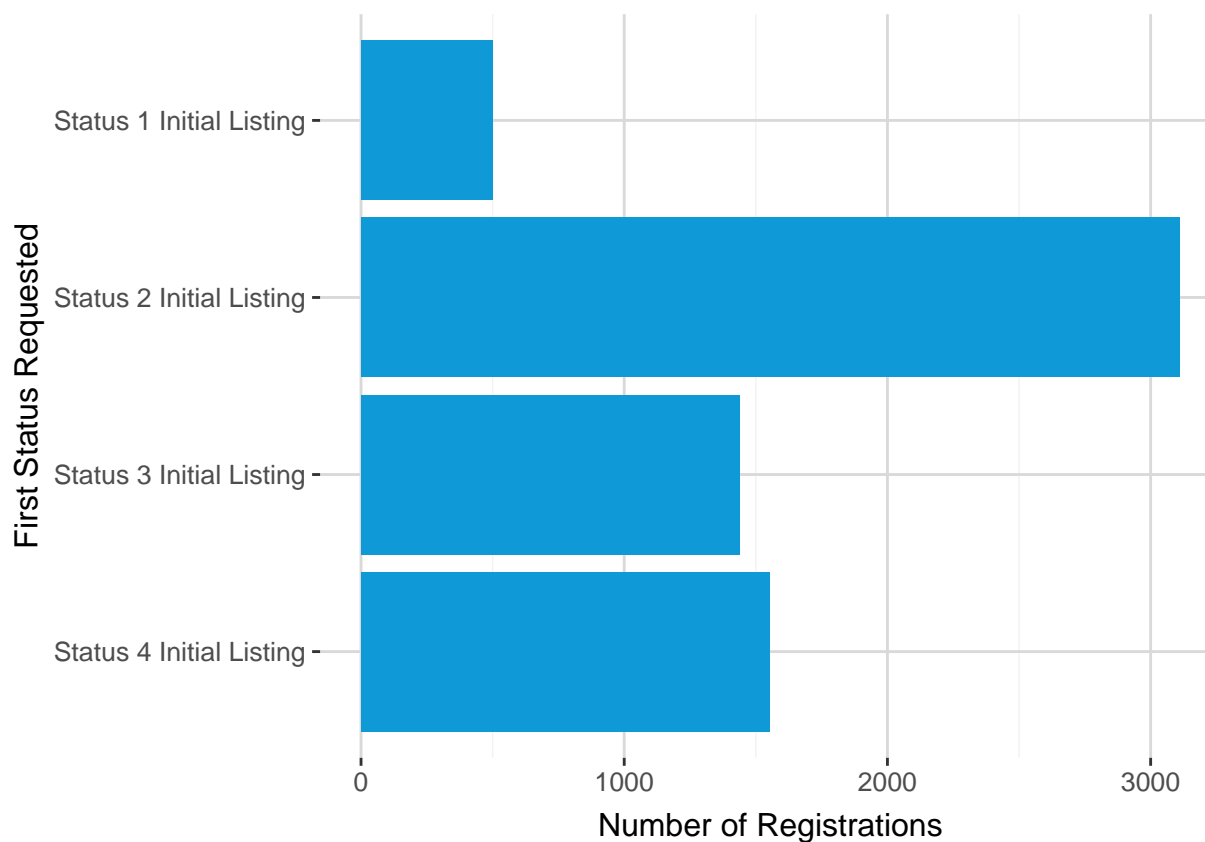


Table 35. Number of registrations with an exception by first status requested

Status Requested	Registration Count	Percent
Status 1 Initial Listing	500	7.6%
Status 2 Initial Listing	3111	47.1%
Status 3 Initial Listing	1437	21.8%
Status 4 Initial Listing	1552	23.5%
Total	6600	100.0%

Figure 58. Percent of registrations with an exception by first status requested and guidance period

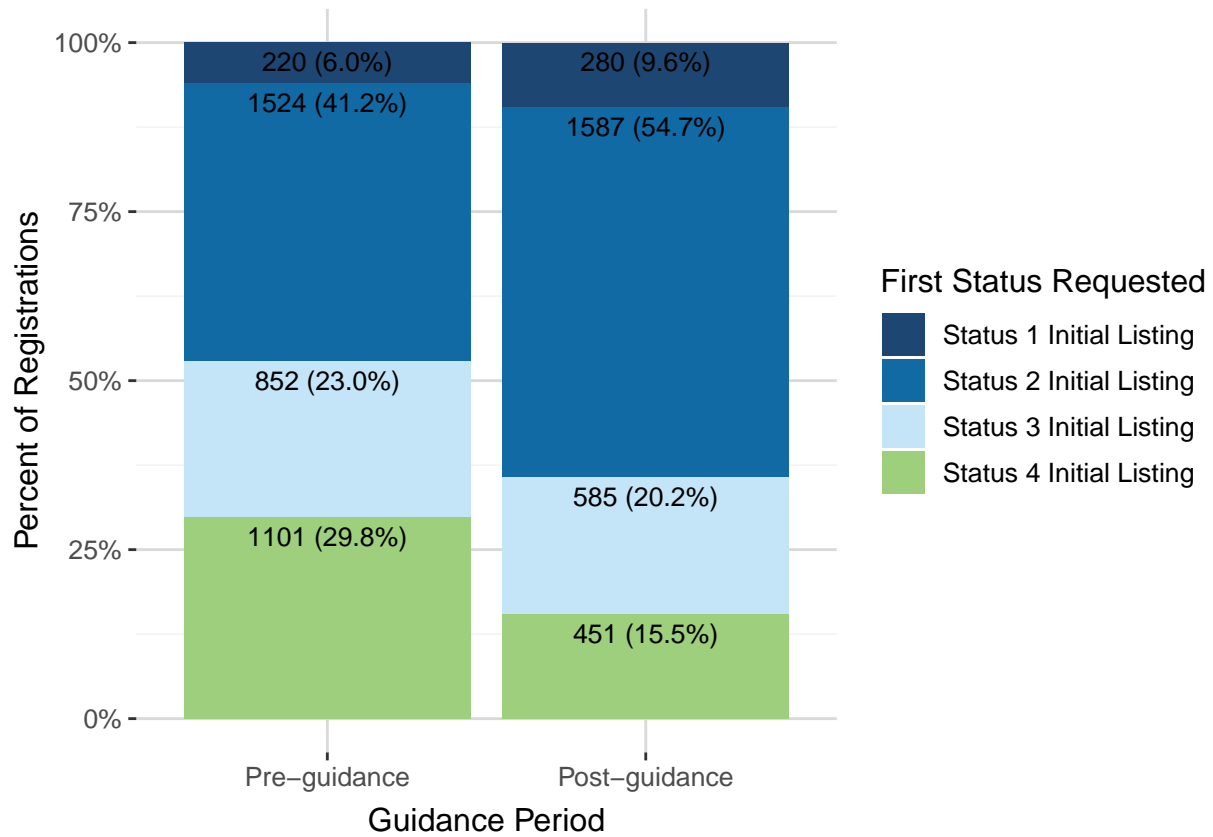
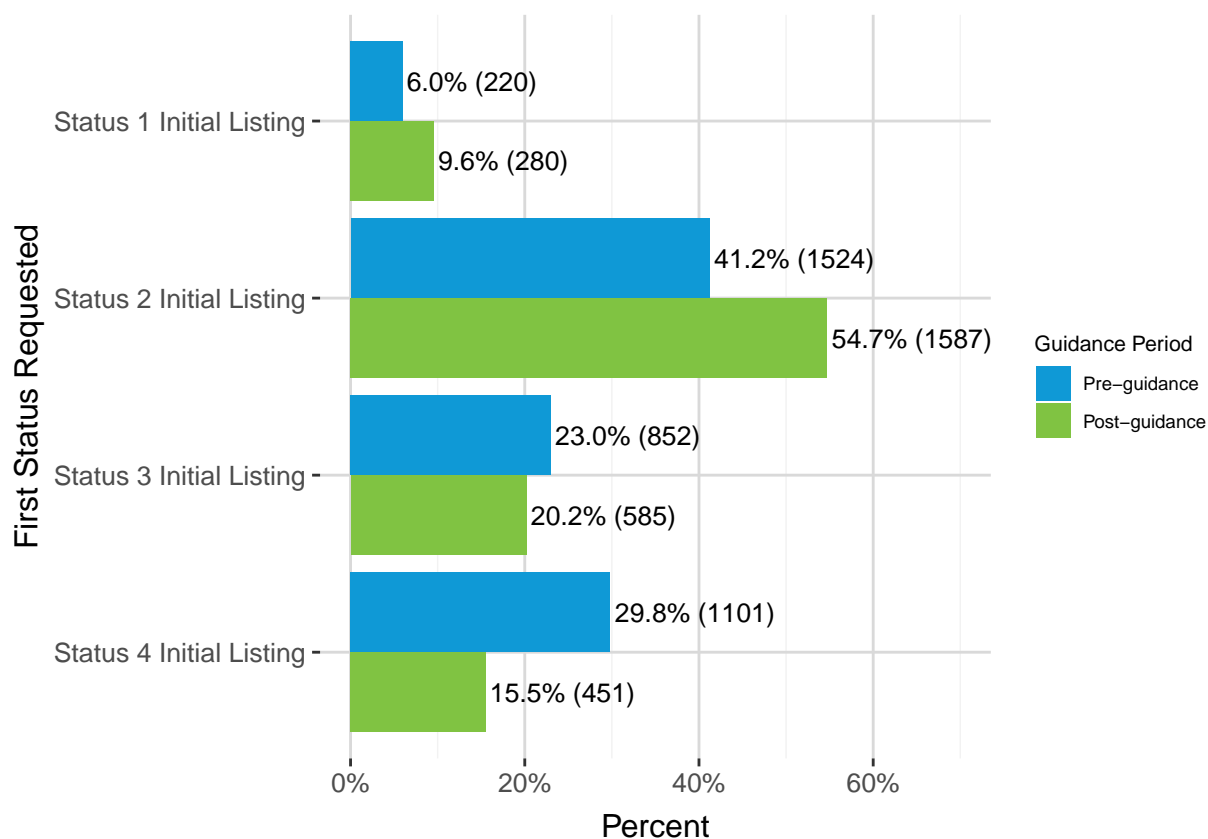


Figure 59. Number of registrations with an exception by first status requested and guidance period**Table 36. Number of registrations with an exception by first status requested and guidance period**

Status Requested	Number and Percent of Registrations					
	Pre-guidance		Post-guidance		Overall	
	N	%	N	%	N	%
Status 1 Initial Listing	220	6.0%	280	9.6%	500	7.6%
Status 2 Initial Listing	1524	41.2%	1587	54.7%	3111	47.1%
Status 3 Initial Listing	852	23.0%	585	20.2%	1437	21.8%
Status 4 Initial Listing	1101	29.8%	451	15.5%	1552	23.5%
Total	3697	100.0%	2903	100.0%	6600	100.0%

Figure 60 and Table 37 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 43 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 61 and Table 38).

Figure 60. Number of exception requests submitted per registration by medical urgency status

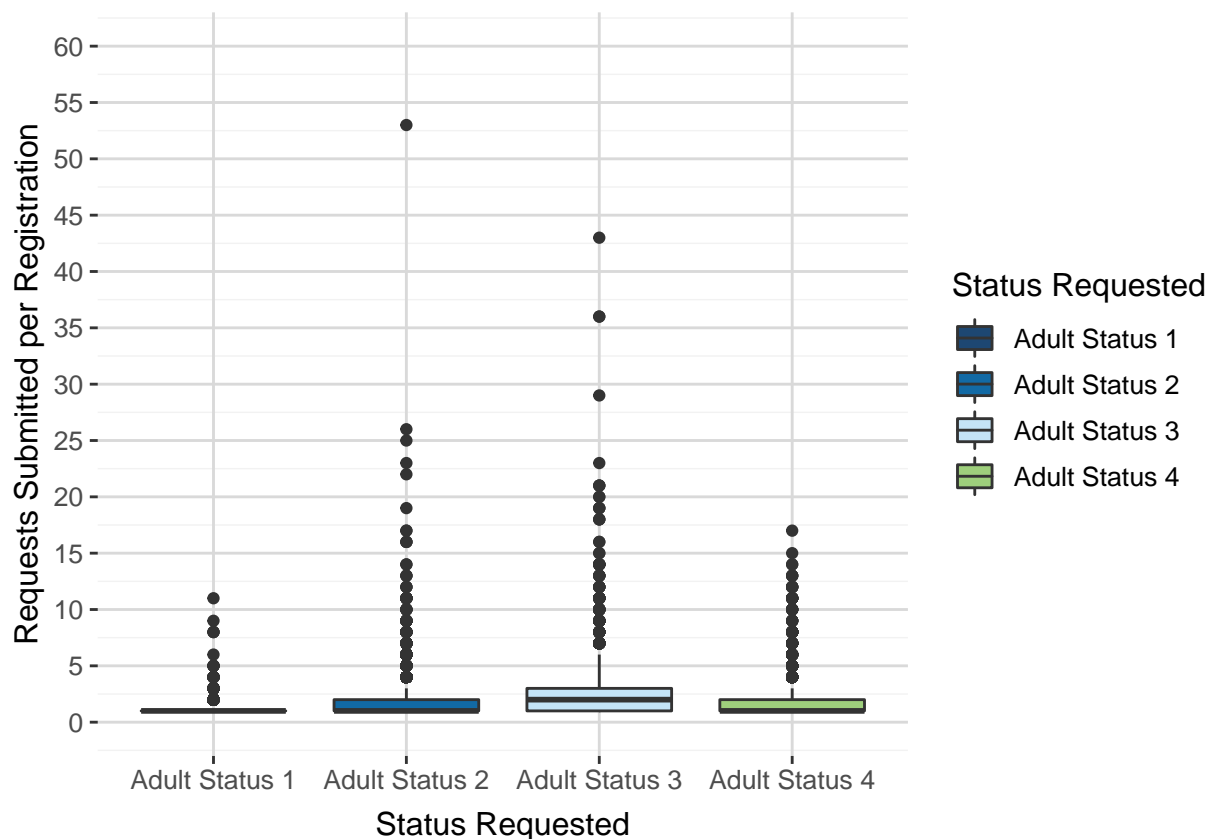


Table 37. Summary of exception requests submitted per registration by medical urgency status

Status Requested	Min	25th Percentile	Median	Mean	75th Percentile	Max	N
Adult Status 1	1	1	1	1	1	11	997
Adult Status 2	1	1	1	2	2	53	7581
Adult Status 3	1	1	2	3	3	43	4923
Adult Status 4	1	1	1	2	2	17	3354

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

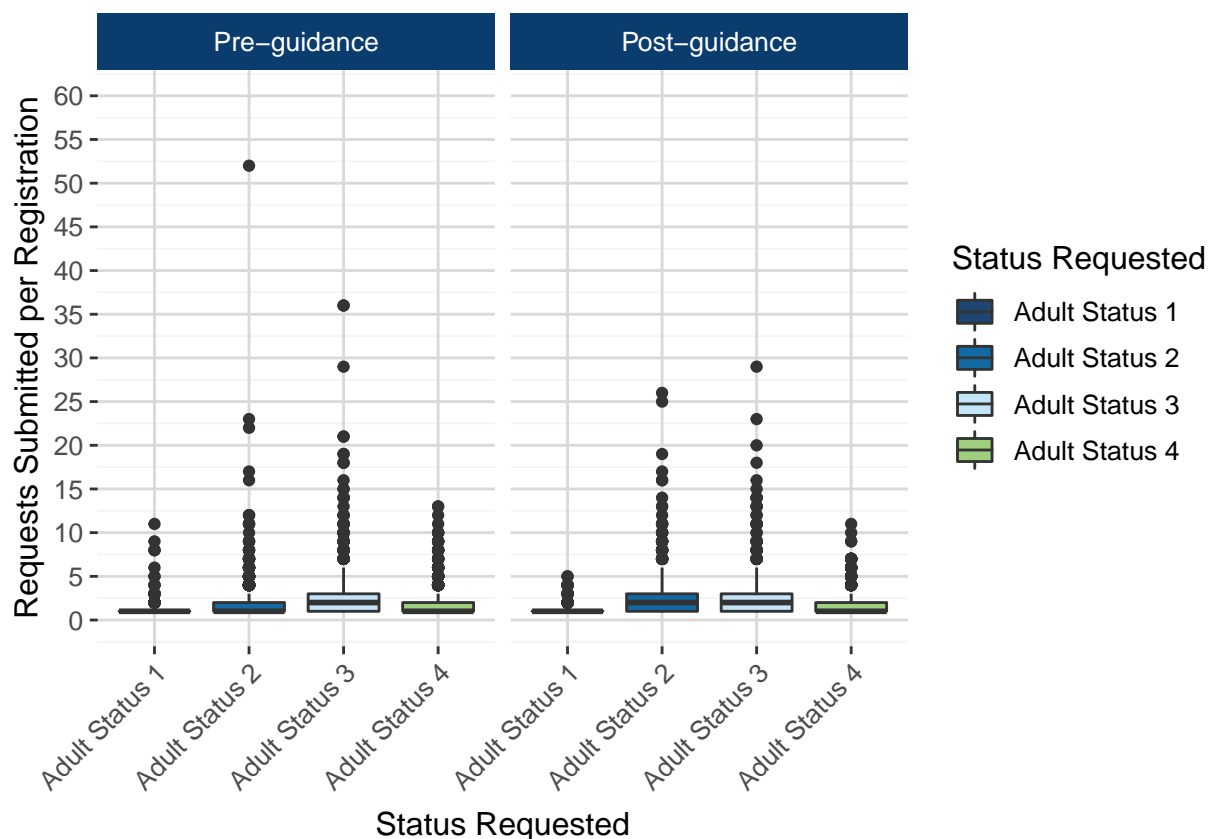


Table 38. Summary of exception requests submitted per registration by medical urgency status and guidance period

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	554
	Adult Status 2	1	1	2	2	3	26	4242
	Adult Status 3	1	1	2	3	3	29	2020
	Adult Status 4	1	1	1	2	2	11	1157

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 2584 pediatric heart candidates listed and 1783 pediatric heart candidates transplanted between October 18, 2014 and October 17, 2018 (pre-implementation) along with 2716 pediatric heart candidates listed and 1954 pediatric heart candidates transplanted between between October 18, 2018 and October 17, 2022 (post-implementation). Finally, there were 5655 pediatric candidates ever waiting.

Figure 62 Pediatric Heart Waiting List Additions by Medical Urgency Status and Era

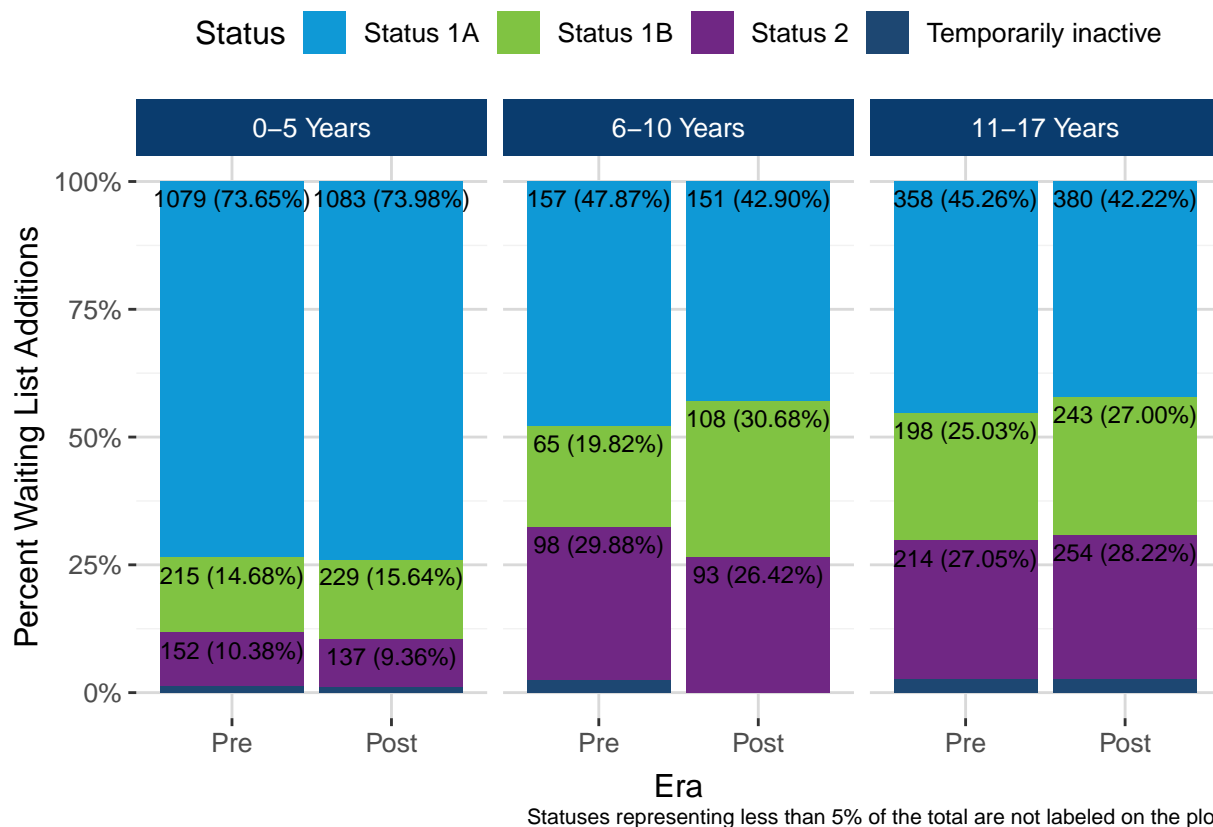


Figure 62 and Table 39 summarize the count and percent of pediatric heart waiting list registrations by status and age group. The proportion of pediatric additions did not differ substantially between eras; the largest shift was an increase in pediatric Status 1B and decrease in pediatric Status 2 candidates aged 6-10 years registering post-implementation.

Table 39. Pediatric Heart Waiting List Additions by Era and Medical Urgency Status

Age Group	Status	Pre-Policy		Post-Policy	
		N	%	N	%
0-5 Years	Status 1A	1079	74.6%	1083	74.7%
	Status 1B	215	14.9%	229	15.8%
	Status 2	152	10.5%	137	9.5%
6-10 Years	Status 1A	157	49.1%	151	42.9%
	Status 1B	65	20.3%	108	30.7%
	Status 2	98	30.6%	93	26.4%
11-17 Years	Status 1A	358	46.5%	380	43.3%
	Status 1B	198	25.7%	243	27.7%
	Status 2	214	27.8%	254	29%
Overall	Status 1A	1594	62.9%	1614	60.3%
	Status 1B	478	18.8%	580	21.7%
	Status 2	464	18.3%	484	18.1%

Figure 63. Pediatric Heart Candidates Ever Waiting by Era and Most Recent Medical Urgency Status

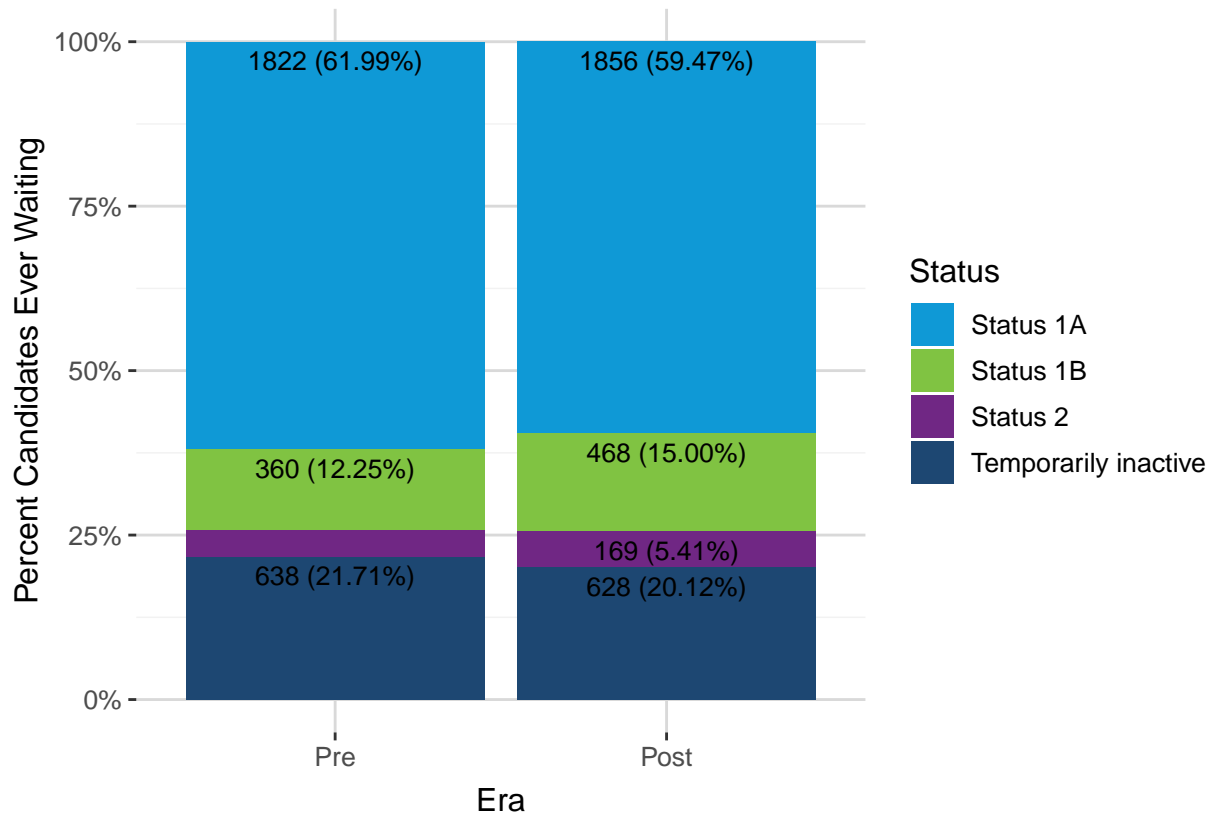


Figure 63 shows the proportion of pediatric heart candidates ever waiting by medical urgency status both pre- and post-implementation. There was very little change in the medical urgency status composition of the pediatric heart waiting list after changes to the adult heart allocation system were implemented.

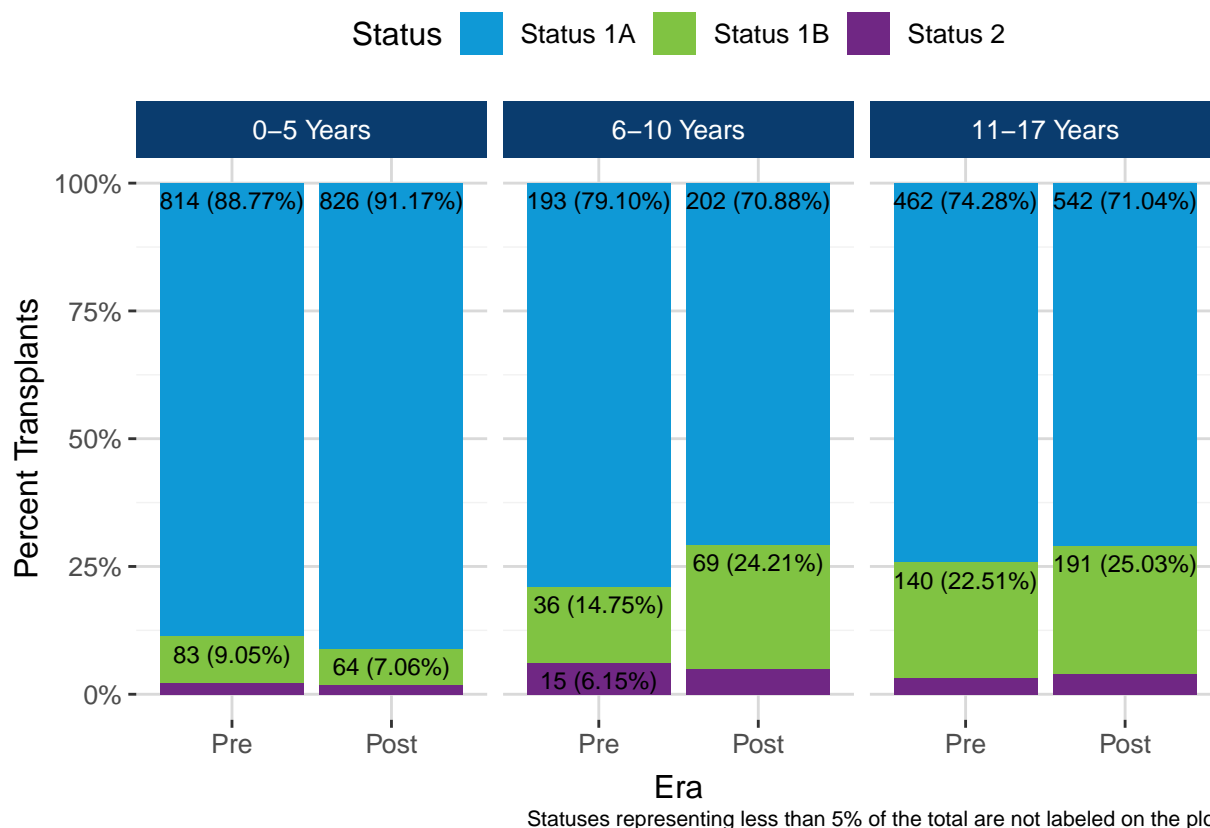
Figure 64. Pediatric Heart Transplants by Medical Urgency Status and Era

Figure 64 and Table 40 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 14.75% to 24.21% pre- to post-implementation.

Table 40. Pediatric Heart Transplants by Era and Medical Urgency Status

Age Group	Status	Pre-Policy		Post-Policy	
		N	%	N	%
0-5 Years	Status 1A	814	88.8%	826	91.2%
	Status 1B	83	9.1%	64	7.1%
	Status 2	20	2.2%	16	1.8%
6-10 Years	Status 1A	193	79.1%	202	70.9%
	Status 1B	36	14.8%	69	24.2%
	Status 2	15	6.1%	14	4.9%
11-17 Years	Status 1A	462	74.3%	542	71%
	Status 1B	140	22.5%	191	25%
	Status 2	20	3.2%	30	3.9%
Overall	Status 1A	1469	82.4%	1570	80.3%
	Status 1B	259	14.5%	324	16.6%
	Status 2	55	3.1%	60	3.1%

Figure 65. Pediatric Deaths per 100 Active Patient-Years Waiting by Medical Urgency Status and Era

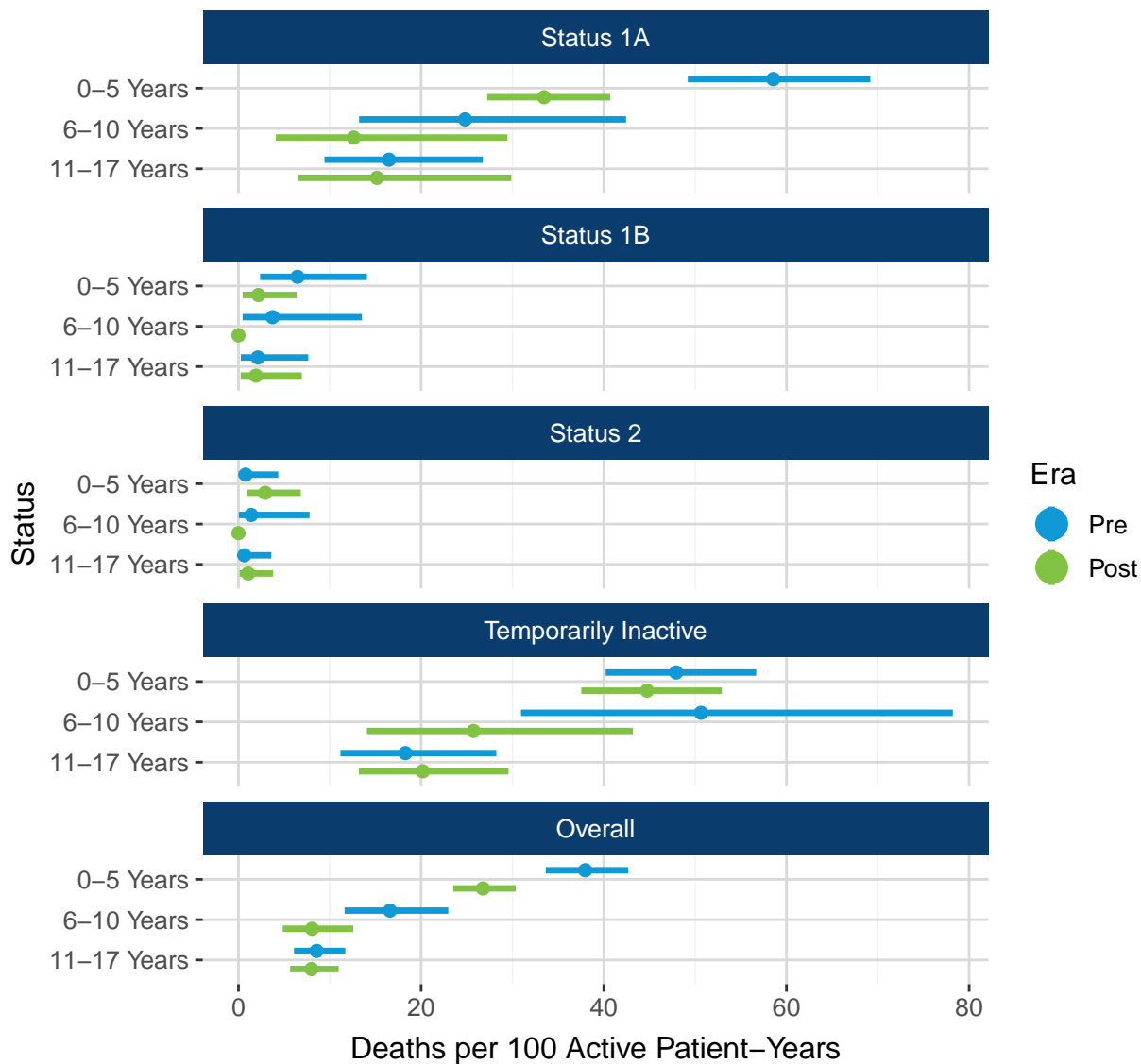


Figure 65 shows the deaths per 100 patient-years for pediatric heart candidates pre- and post-implementation by medical urgency status and era. There was a significant decrease in the number of deaths per 100 patient-years for pediatric candidates aged 0-5 years post-policy.

Table 41 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.

Table 41. Pediatric Deaths per 100 Active 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	1301	59	Ref	-
		Post	1328	33	0.57	[0.32, 1.02]
	6-10 Years	Pre	234	25	Ref	-
		Post	231	13	0.51	[0.21, 1.24]
	11-17 Years	Pre	575	16	Ref	-
		Post	587	15	0.92	[0.39, 2.15]
Status 1B	0-5 Years	Pre	398	6	Ref	-
		Post	428	2	0.34	[0.06, 2.02]
	6-10 Years	Pre	120	4	Ref	-
		Post	178	0	0	-
	11-17 Years	Pre	340	2	Ref	-
		Post	398	2	0.91	[0.13, 6.44]
Status 2	0-5 Years	Pre	262	1	Ref	-
		Post	271	3	3.74	[0.44, 32.00]
	6-10 Years	Pre	105	1	Ref	-
		Post	100	0	0	-
	11-17 Years	Pre	232	1	Ref	-
		Post	278	1	1.63	[0.15, 18.00]
Temporarily Inactive	0-5 Years	Pre	589	48	Ref	-
		Post	633	45	0.93	[0.58, 1.49]
	6-10 Years	Pre	113	51	Ref	-
		Post	105	26	0.51	[0.29, 0.88]
	11-17 Years	Pre	205	18	Ref	-
		Post	264	20	1.1	[0.62, 1.98]
Overall	0-5 Years	Pre	1601	38	Ref	-
		Post	1601	27	0.71	[0.50, 1.00]
	6-10 Years	Pre	334	17	Ref	-
		Post	369	8	0.49	[0.31, 0.77]
	11-17 Years	Pre	808	9	Ref	-
		Post	948	8	0.93	[0.60, 1.46]

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

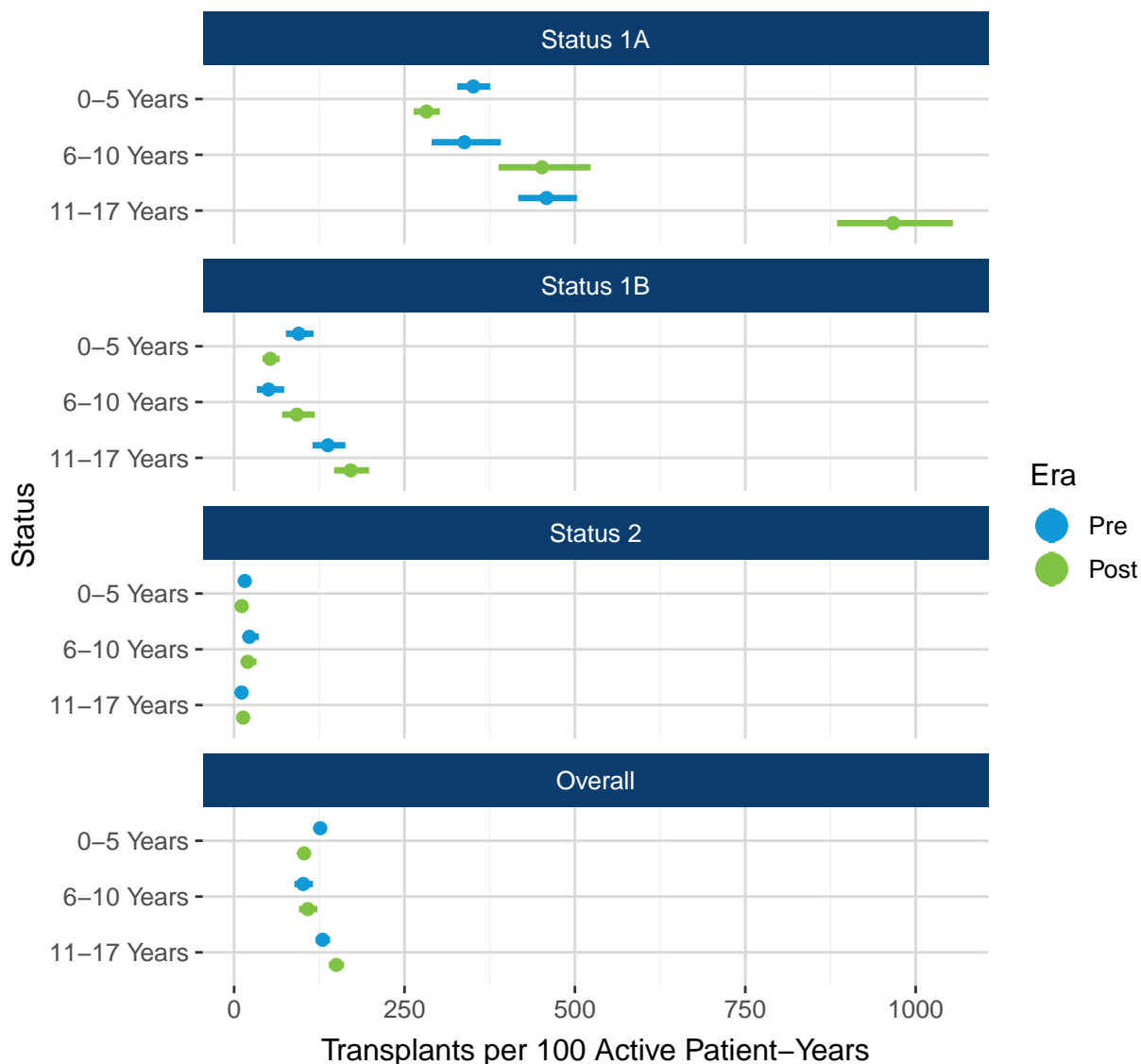


Figure 66 shows the number of transplants per 100 patient-years for pediatric heart candidates by age group, medical urgency status, and era. Post-implementation, the number of transplants per 100 patient-years was significantly higher for Status 1A pediatric candidates 11-17 years old. Conversely, the number of transplants per 100 patient-years was significantly lower post-implementation for Status 1A and Status 1B pediatric candidates 0-5 years old.

Table 42 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.

Table 42. Pediatric Transplants per 100 Active 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	1301	351	Ref	-	
		Post	1328	282	0.8	[0.68, 0.95]	
	6-10 Years	Pre	234	338	Ref	-	
		Post	231	452	1.34	[1.14, 1.57]	
	11-17 Years	Pre	575	458	Ref	-	
		Post	587	967	2.11	[1.86, 2.40]	
	Status 1B	0-5 Years	Pre	398	95	Ref	-
			Post	428	53	0.56	[0.36, 0.87]
6-10 Years		Pre	120	50	Ref	-	
		Post	178	92	1.83	[1.32, 2.53]	
11-17 Years		Pre	340	138	Ref	-	
		Post	398	171	1.24	[0.99, 1.56]	
Status 2		0-5 Years	Pre	262	16	Ref	-
			Post	271	11	0.71	[0.37, 1.38]
	6-10 Years	Pre	105	22	Ref	-	
		Post	100	20	0.89	[0.45, 1.73]	
	11-17 Years	Pre	232	11	Ref	-	
		Post	278	13	1.2	[0.65, 2.22]	
	Overall	0-5 Years	Pre	1601	126	Ref	-
			Post	1601	103	0.81	[0.70, 0.94]
6-10 Years		Pre	334	101	Ref	-	
		Post	369	108	1.07	[0.93, 1.22]	
11-17 Years		Pre	808	130	Ref	-	
		Post	948	150	1.15	[1.04, 1.29]	

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.