Final Report

OPTN Heart Committee | Descriptive Data Request

# 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 (MCSD) and prevalence of MCSD complications, and address geographic disparities in access to donors. The implementation involved creating new adult heart medical urgency statuses and altering how organs were shared based on medical urgency and distance from the donor hospital. On October 18, 2018, new guidelines also went into effect governing how Regional Review Boards (RRBs) evaluated exception requests. Historically, RRBs reviewed exceptions from their own OPTN region. Under the new guidelines, OPTN regions are assigned to review exceptions from other OPTN regions.

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

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

# Data and Methods

**Data Sources:** These analyses use data from the OPTN waiting list, the Deceased Donor Registration (DDR) form, the Transplant Candidate Registration (TCR) form, the Transplant Recipient Registration (TRR) form, and the Transplant Recipient Followup (TRF) form. Analyses are based on OPTN data as of 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.

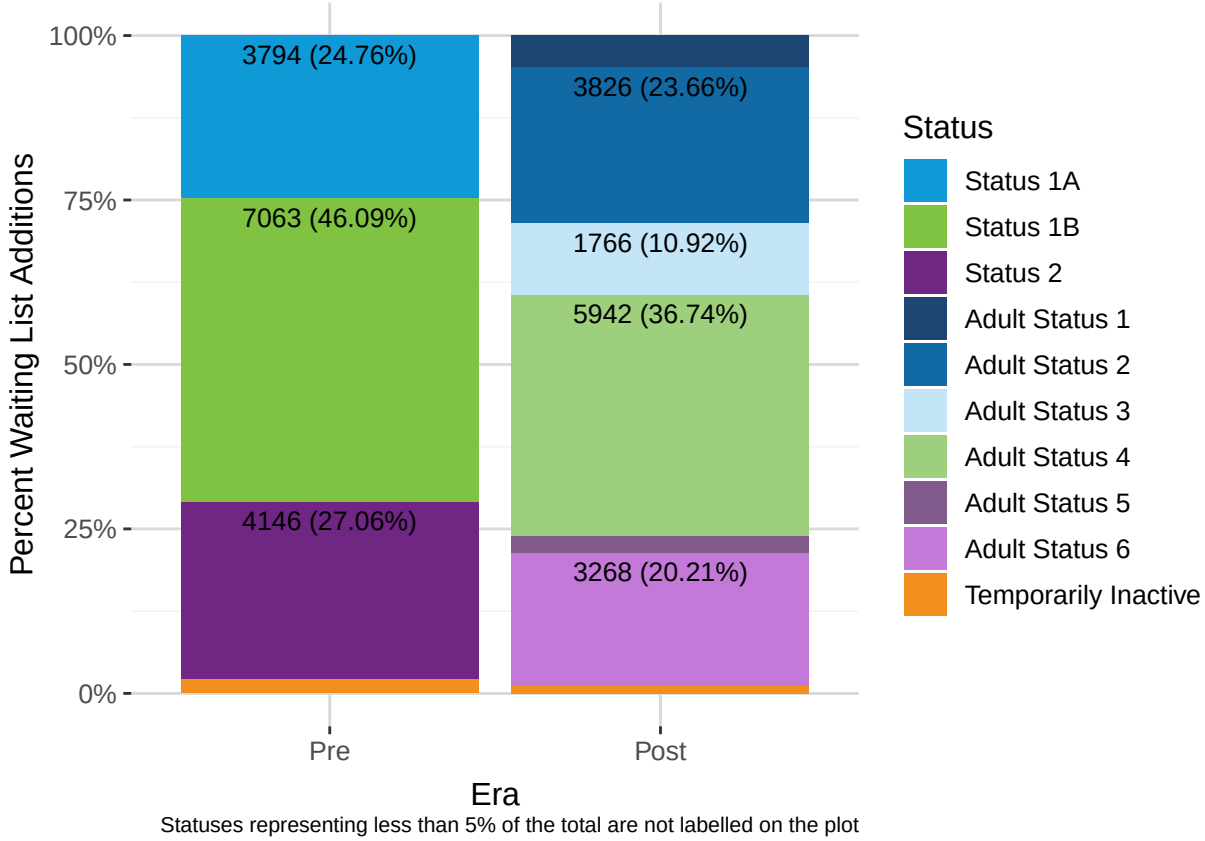
Statistical analyses were performed using SAS v9.4 (SAS Institute, Inc., Cary, NC.) and R Version 4.1.3 (R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL: https://www.R-project.org/).

# 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**




Statuses 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**

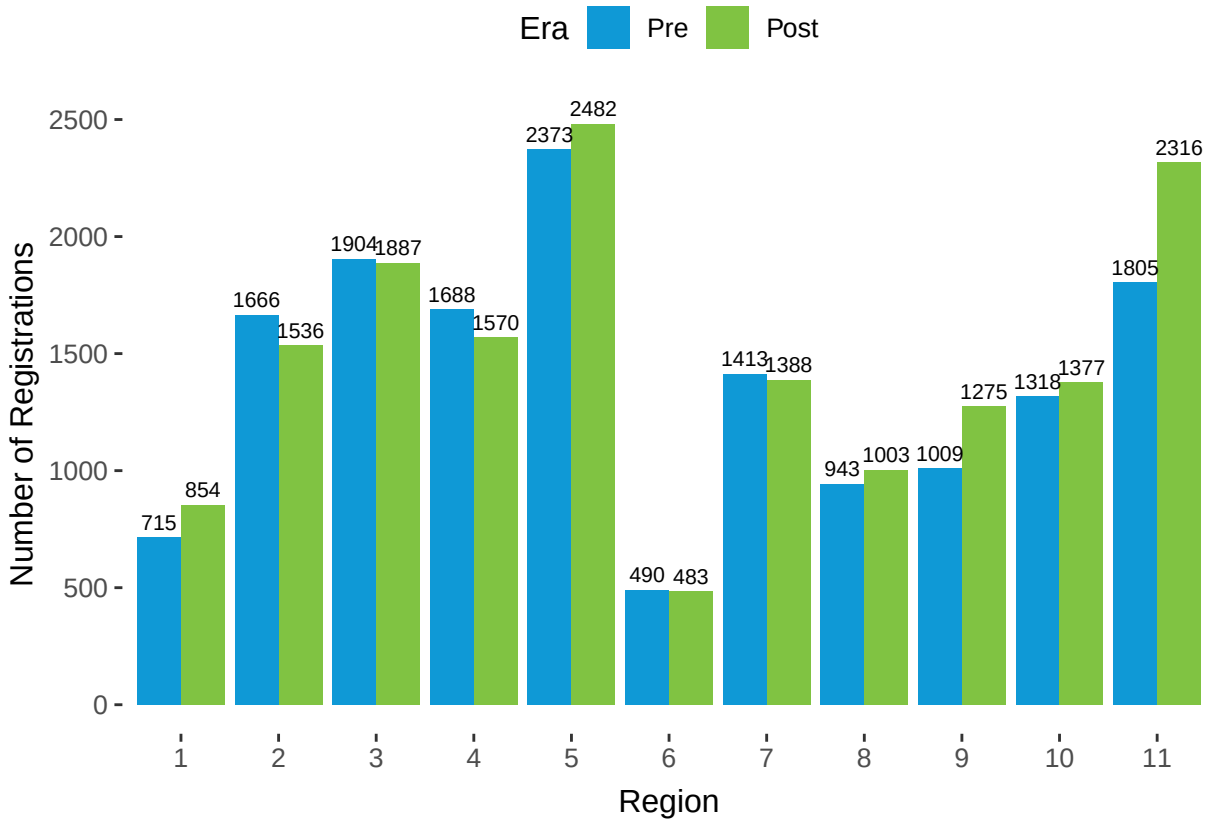



Figure 2 shows the number of adult heart waiting list registrations added by region both pre- and post-implementation. Compared to pre-implementation, the number of registrations added post-implementation increased by more than 5% in regions 1, 8, 9, and 11, decreased by more than 5% in regions 2 and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

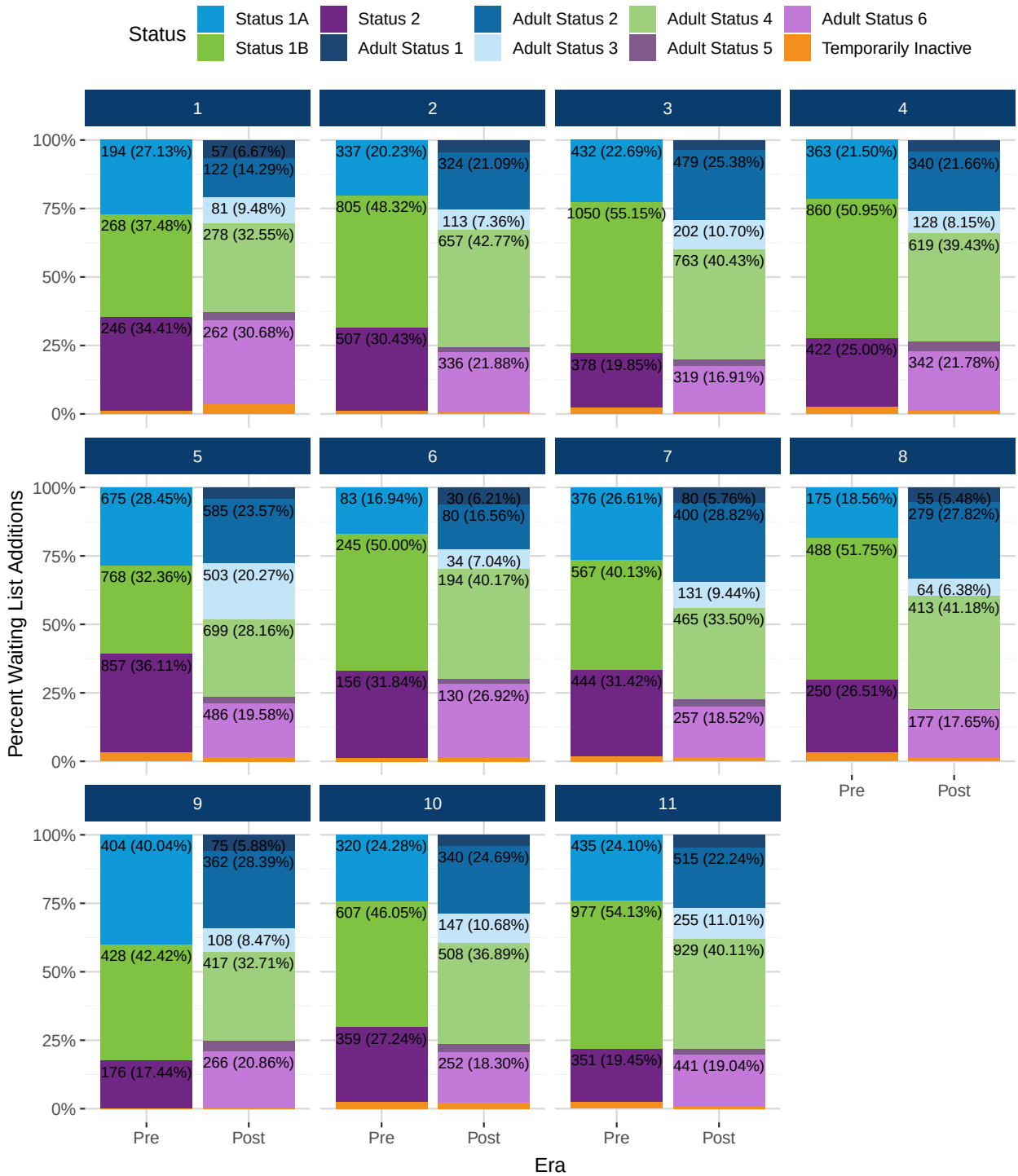


Figure 4 shows the adult heart waiting list additions by region, device at time of listing, and era. The percent of waiting list additions for those on no devices decreased in all regions except in region 6. The largest decrease occurred in regions 3 and 5. In the post-policy era as few as 47% of all 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**

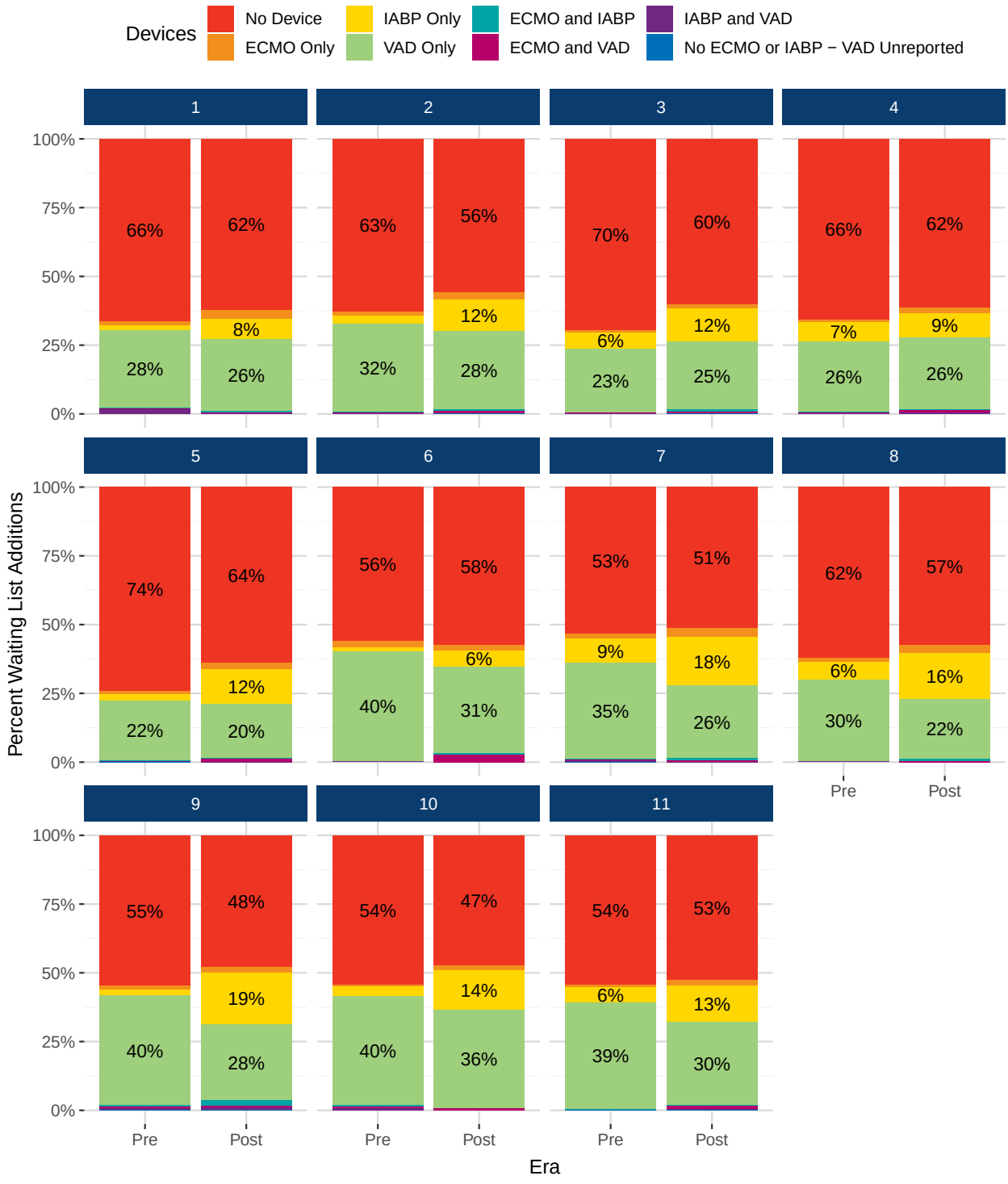


Table 2 shows the criteria qualifying adult heart waiting list candidates for their medical urgency status at time of listing post-implementation. For Adult Status 5 and Adult Status 6, which have no qualifying criteria, the count of waiting list additions at the status is given. For Adult Status 1 the 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 artifical heart(TAH), BiVAD, right ventricular assist device(RVAD), or ventricular assist device(VAD) for single ventricle patients | 88 | 2.28% |
| | Ventricluar tachycardia(VT) or ventricular fibrilation(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)**

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

*(continued)*

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

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

**Table 4. Criteria Within Medical Urgency Status for Adult Heart Candidates Waiting on September 30, 2022 (Post-Guidance)**

| | | Initial | | Extension | | Total | |
|---|---|---|---|---|---|---|---|
| **Status** | **Criteria** | **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 artifical 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 (MCSD) 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 MCSD 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 MCSDs.

**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**

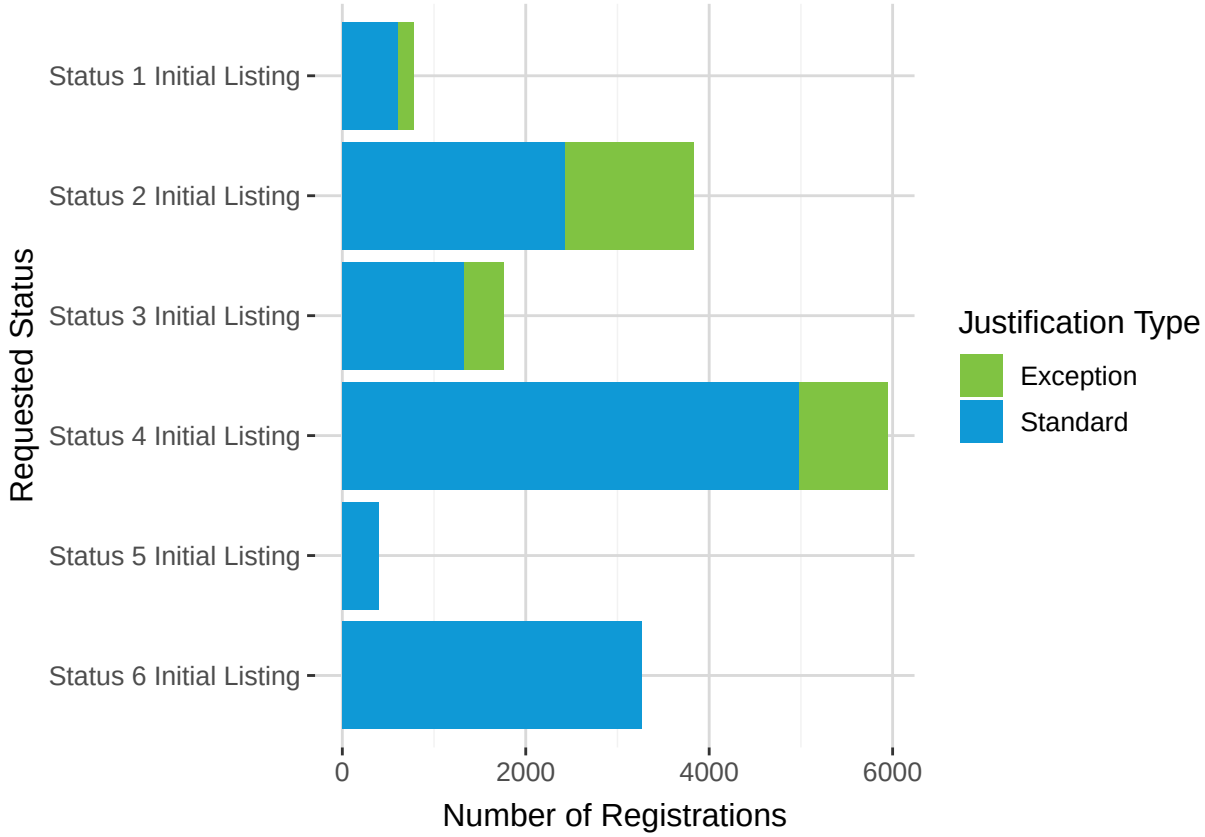



Figure 5 shows the number of justification forms at listing, the status requested, and whether the review type was standard or exception. The most-requested status at listing was Adult Status 4, followed by Adult Status 2. Exception requests were most common for candidates listing at either Adult Status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

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

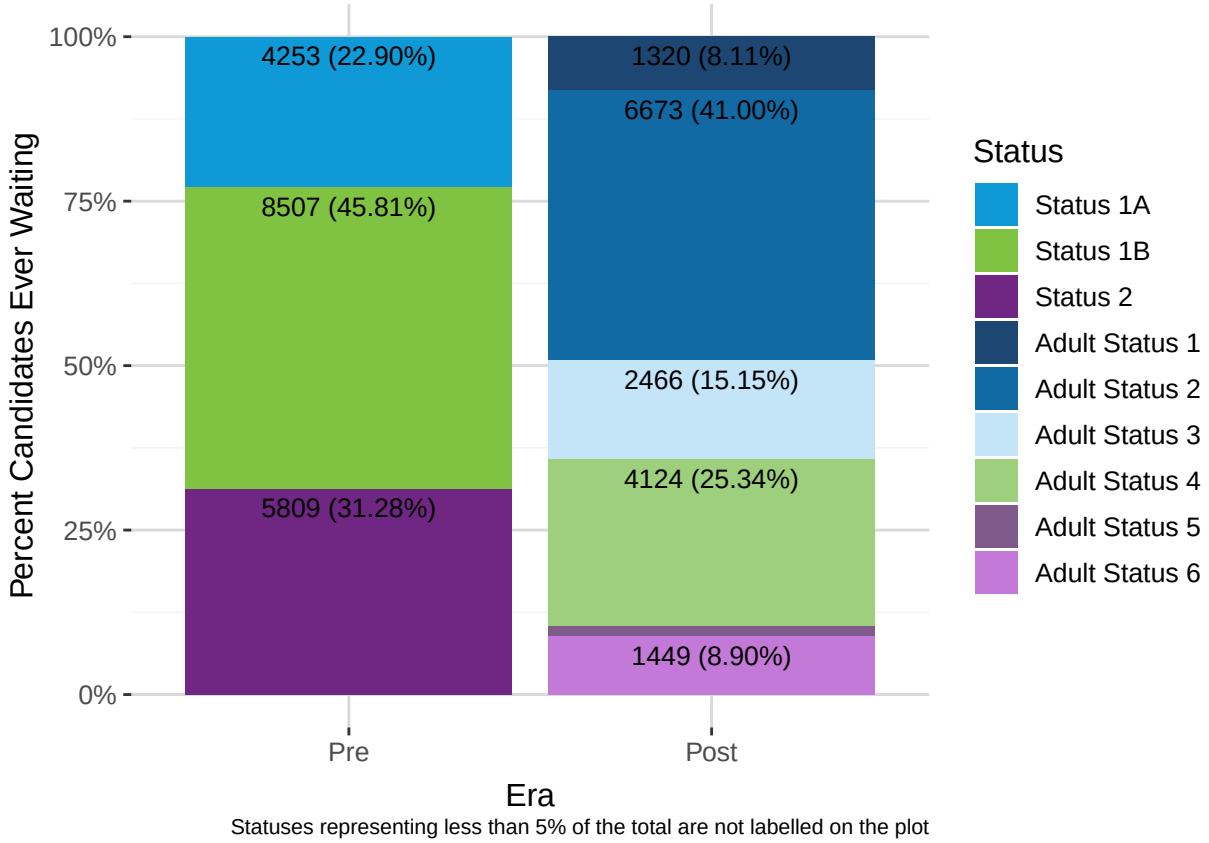
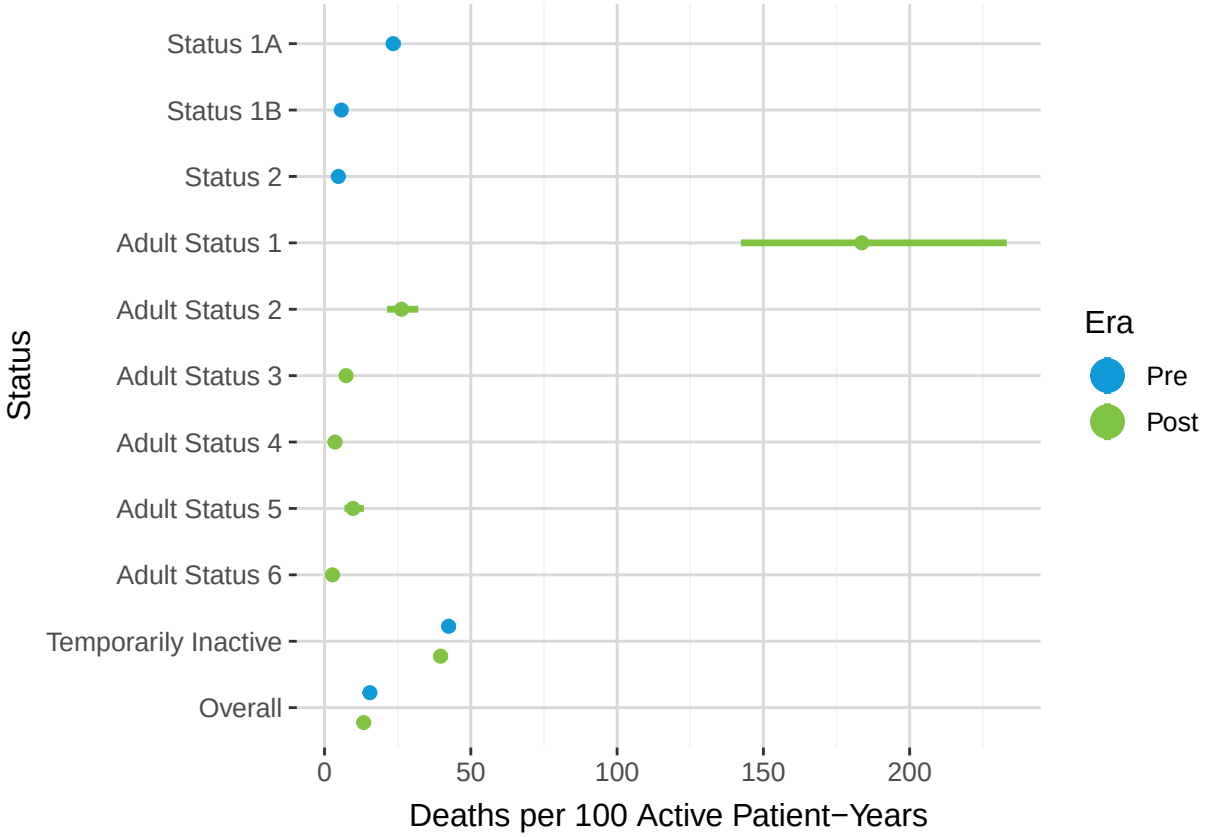



Figure 6 shows the composition of candidates ever waiting by medical urgency status both pre- and post-implementation. The statuses shown pre-implementation are the statuses candidates held when added to the waiting list; displaying the most recent candidate status would make interpretation more difficult,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

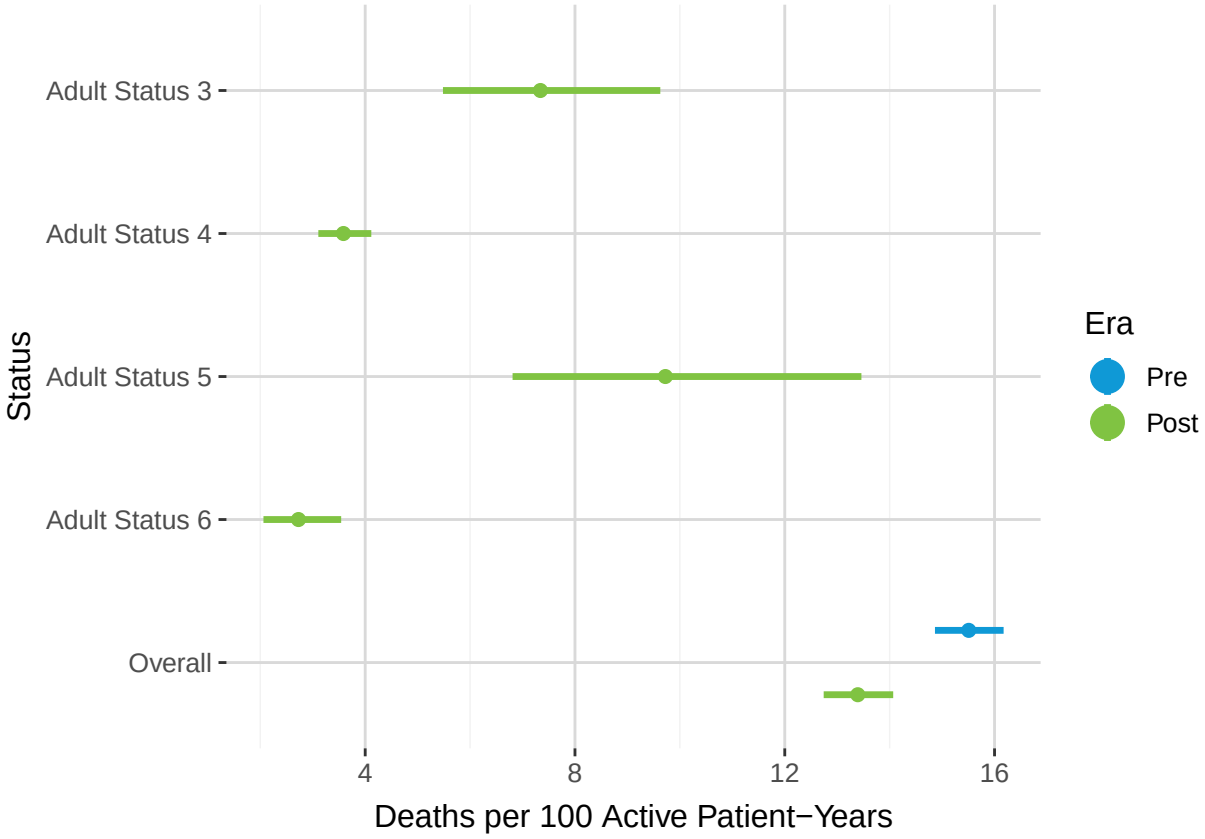
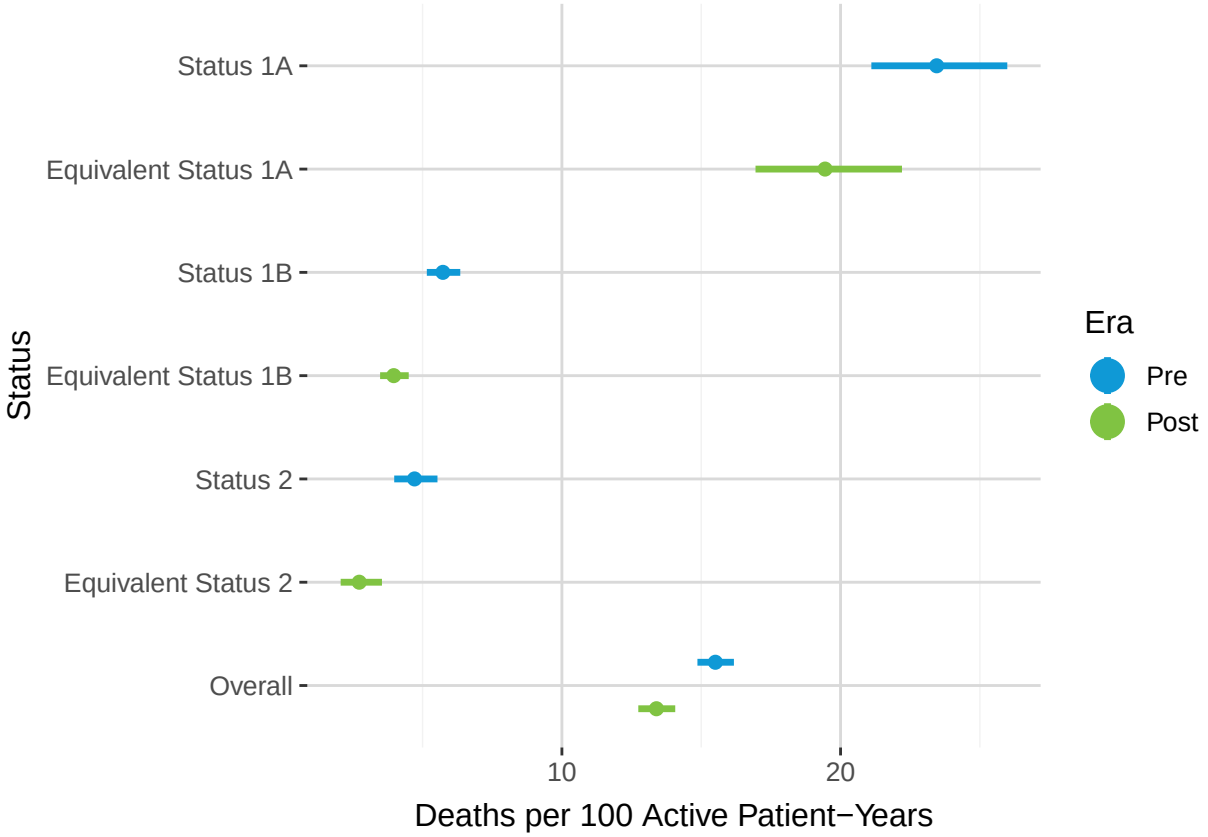


**Table 6. Deaths per 100 Active Patient-Years Waiting by Medical Urgency Status and Era**

| 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** | **[13, 14]** |

**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**

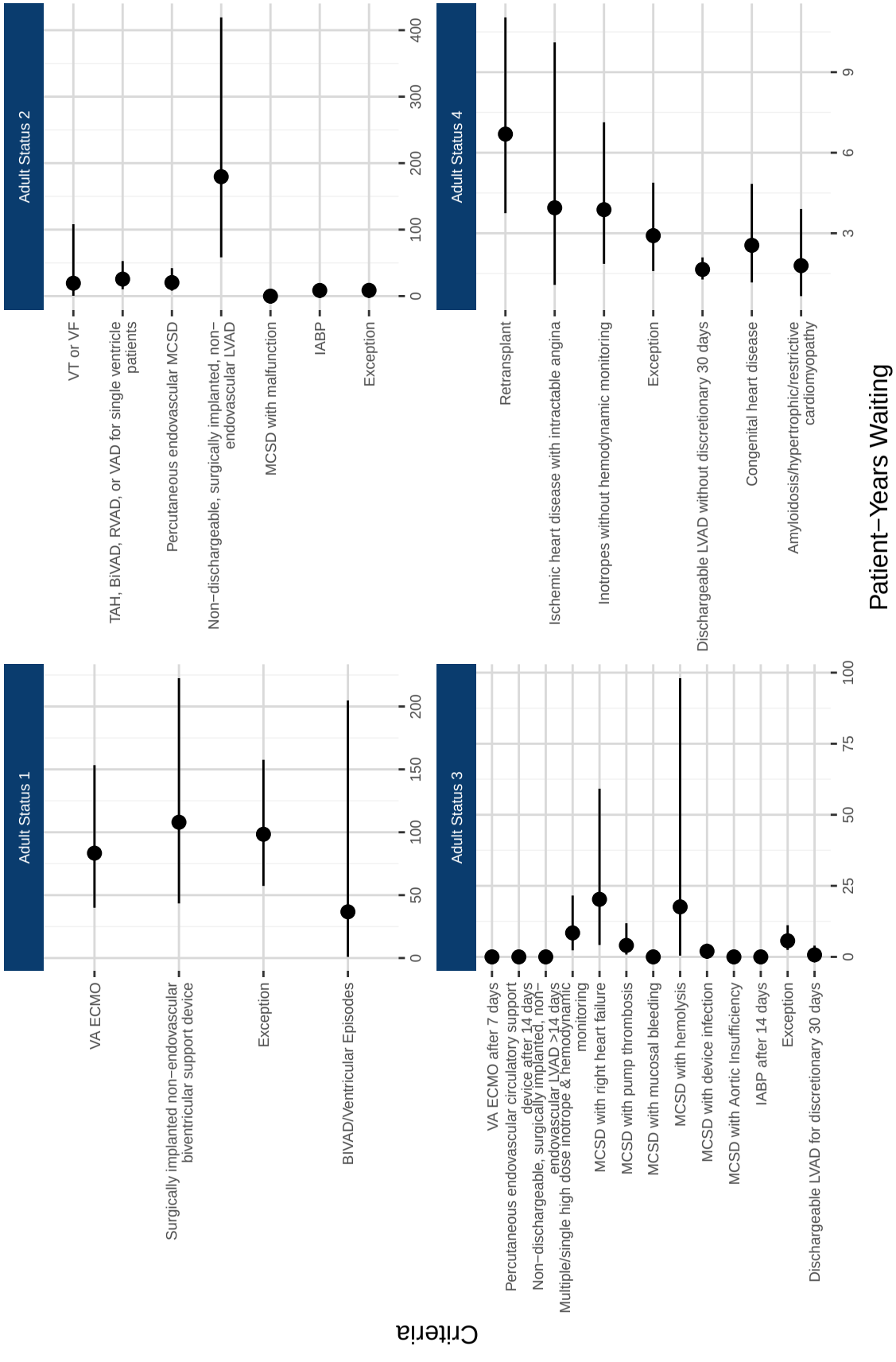


Figure 11 displays the deaths per 100 patient-years waiting by criteria within medical urgency status for Status 2 and 3 only to facilitate comparisons among these criteria.

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

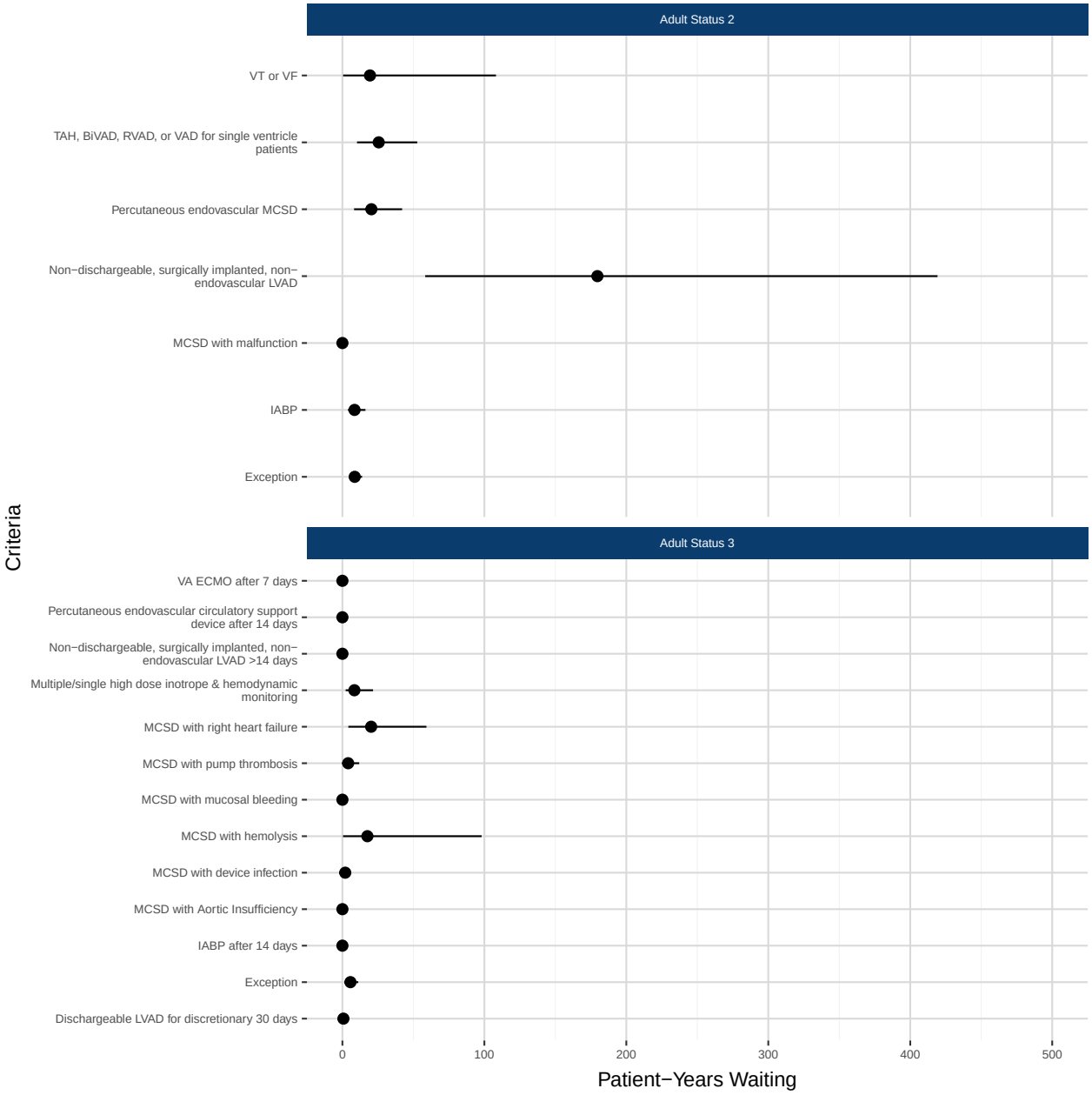


**Table 7. Deaths per 100 Active Patient-Years Waiting by Criteria within Medical Urgency Status Post-Implementation**

| 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] |
| | MCSD with malfunction | 324 | 0 | 0 | - |
| | Non-dischargeable, surgically implanted, non-endovascular LVAD | 92 | 5 | 180 | [58, 419] |
| | Percutaneous endovascular MCSD | 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 | - |
| | MCSD with Aortic Insufficiency | 95 | 0 | 0 | - |
| | MCSD with device infection | 714 | 5 | 2 | [1, 5] |
| | MCSD with hemolysis | 57 | 1 | 18 | [0, 98] |
| | MCSD with mucosal bleeding | 75 | 0 | 0 | - |
| | MCSD with pump thrombosis | 140 | 3 | 4 | [1, 12] |
| | MCSD 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] |

| | | | | | |
|---|---|---|---|---|---|
| **Adult Status 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] |
| | 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**

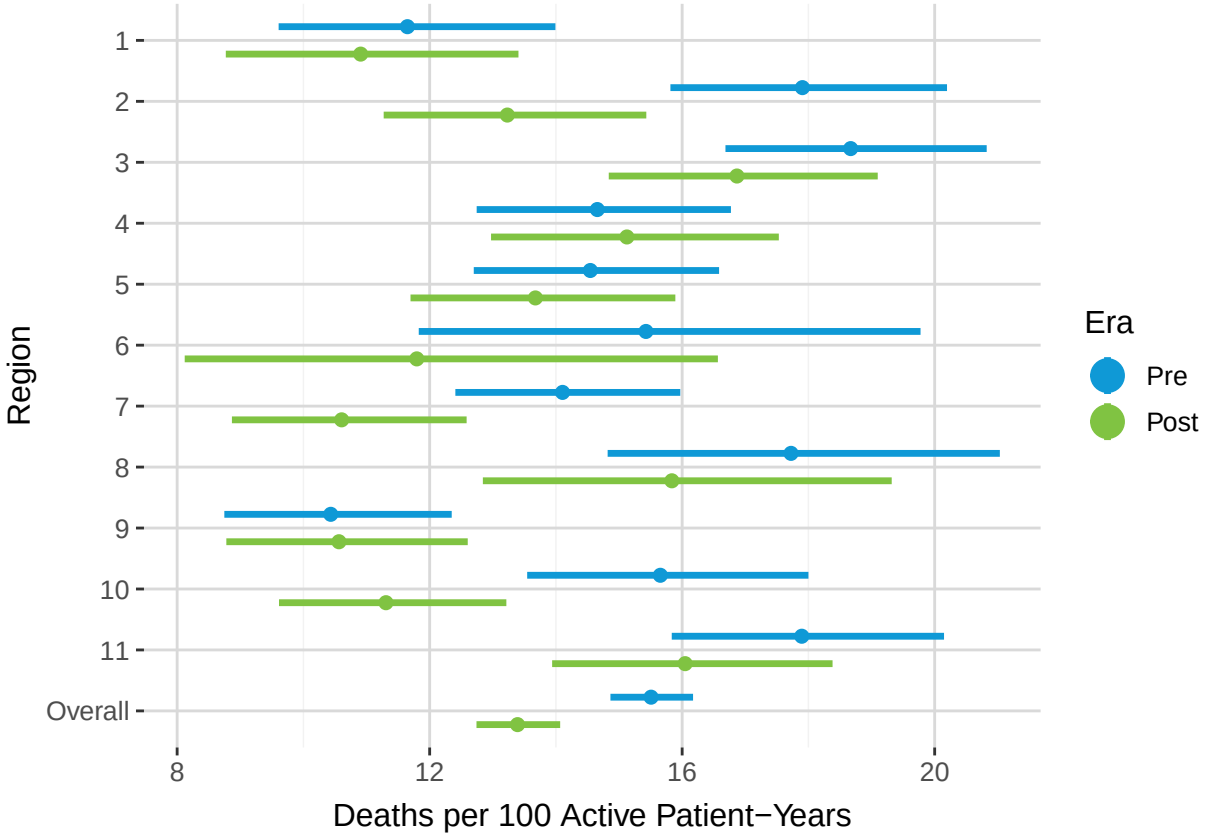



Figure 12 shows the number of deaths per 100 patient-years by region and era. The number of deaths per 100 patient-years waiting was significantly lower post-implementation in regions 2 and 10, and there was no significant change in the number of deaths per 100 patient-years in any other region pre- 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**

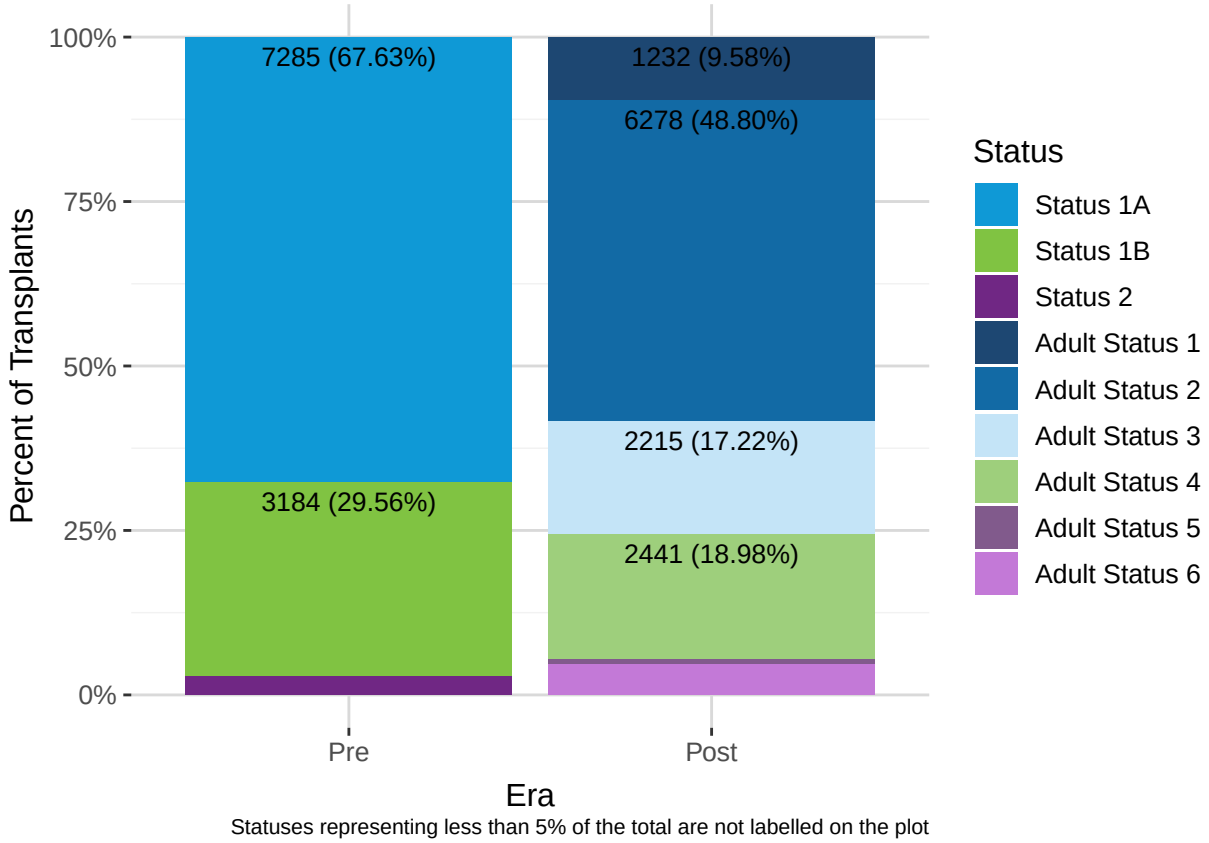



Figure 13 shows the proportion of adult heart transplants performed both pre- and post-implementation by medical urgency status. Status 1A candidates received around two-thirds (67.64%) of all transplants pre-implementation, but no single status represented such a large fraction of transplants post-implementation. 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**

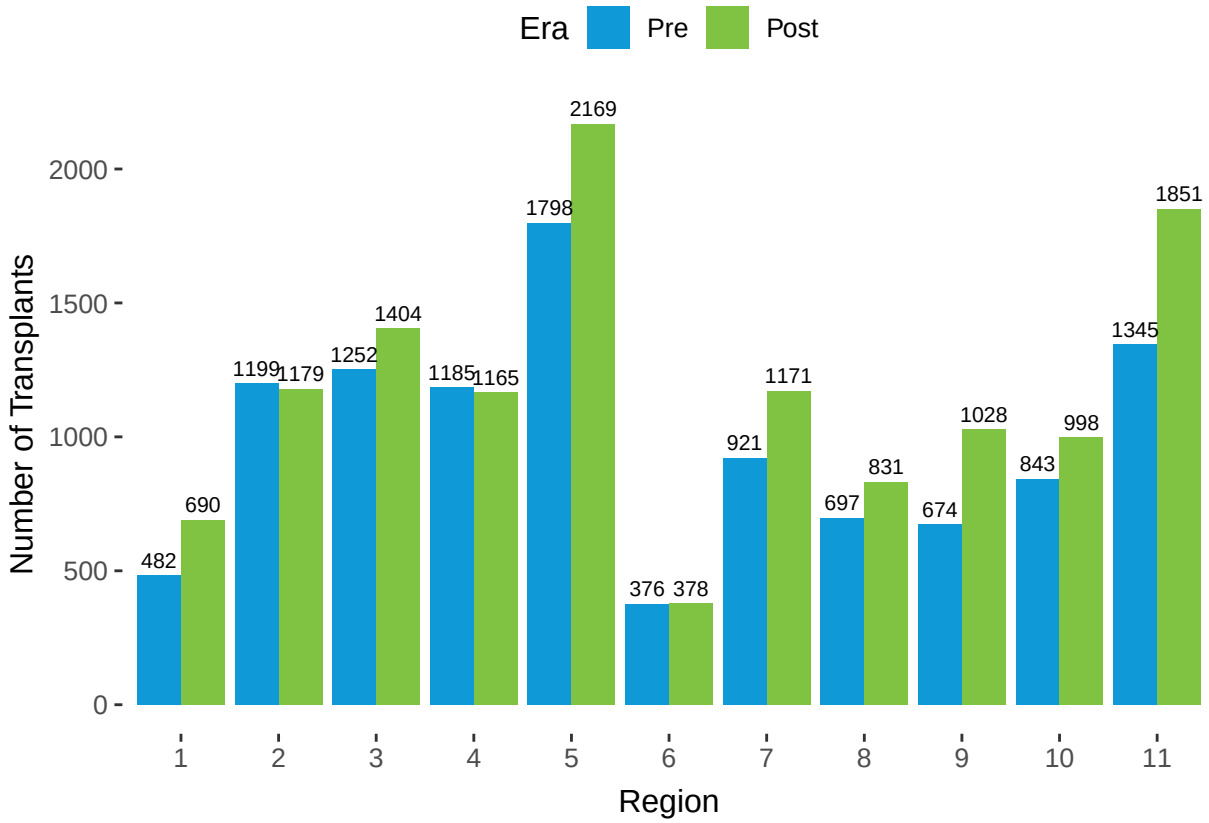
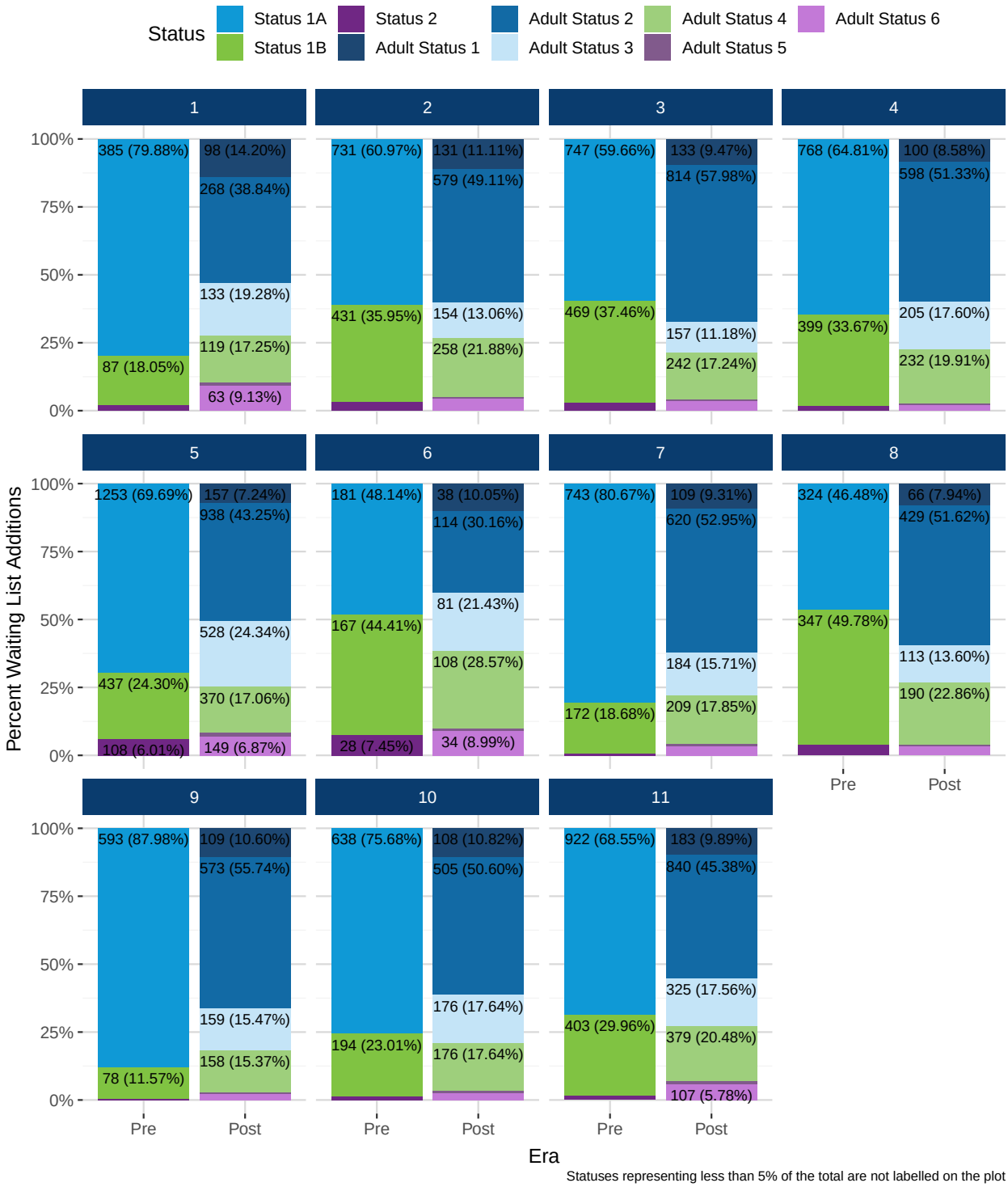



Figure 14 shows the number of adult heart transplants by era and region. The number of heart transplants rose in regions 1, 3, 5, 6, 7, 8, 9, 10, and 11, and decreased in regions 2 and 4.

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**




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

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**

| | | Initial | | Extension | | Total | |
|---|---|---|---|---|---|---|---|
| **Status** | **Criteria** | **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 artifical 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% |
| | Ventricluar tachycardia(VT) or ventricular fibrilation(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** | **100%** |
| | 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**

| | | Initial | | Extension | | Total | |
|---|---|---|---|---|---|---|---|
| **Status** | **Criteria** | **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 artifical 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% |
| | Ventricluar tachycardia(VT) or ventricular fibrilation(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** | **100%** |
| | 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**

| | | Initial | | Extension | | Total | |
|---|---|---|---|---|---|---|---|
| **Status** | **Criteria** | **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 artifical 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% |
| | Ventricluar tachycardia(VT) or ventricular fibrilation(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 (MCSD) at transplant, based on information reported on the TRR and broken down by device type and brand. Overall, 43.07% of transplants had an MCSD listed on the TRR pre-implementation, compared to 34.8% post-implementation. Changes in the proportion of MCSDs at transplant were similar to those observed for MCSDs reported at listing but were more dramatic, with the percent of transplants made to recipients with LVADs falling substantially and the percent recipients with an IABP or on ECMO more than doubling.

**Table 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**

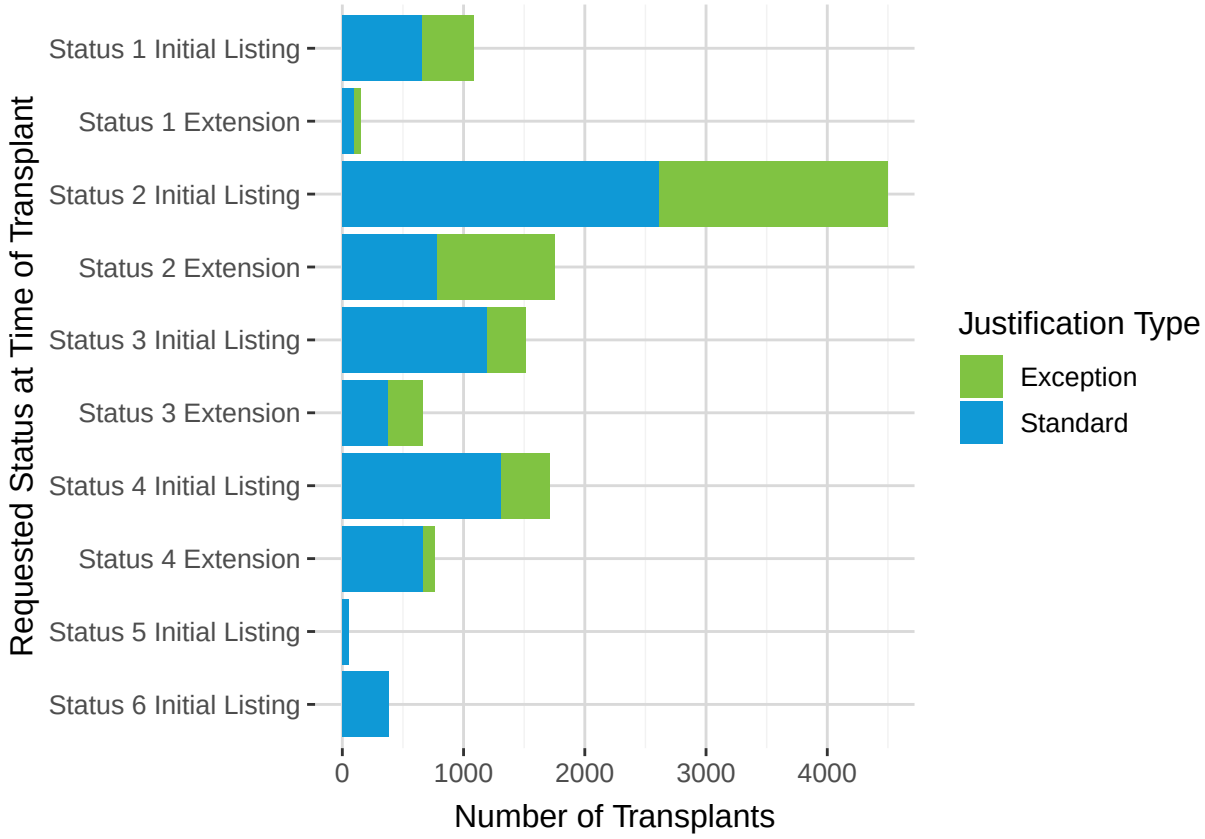


**Figure 17. Adult Heart Transplants by Review Type, Requested Status, and Guidance Period**

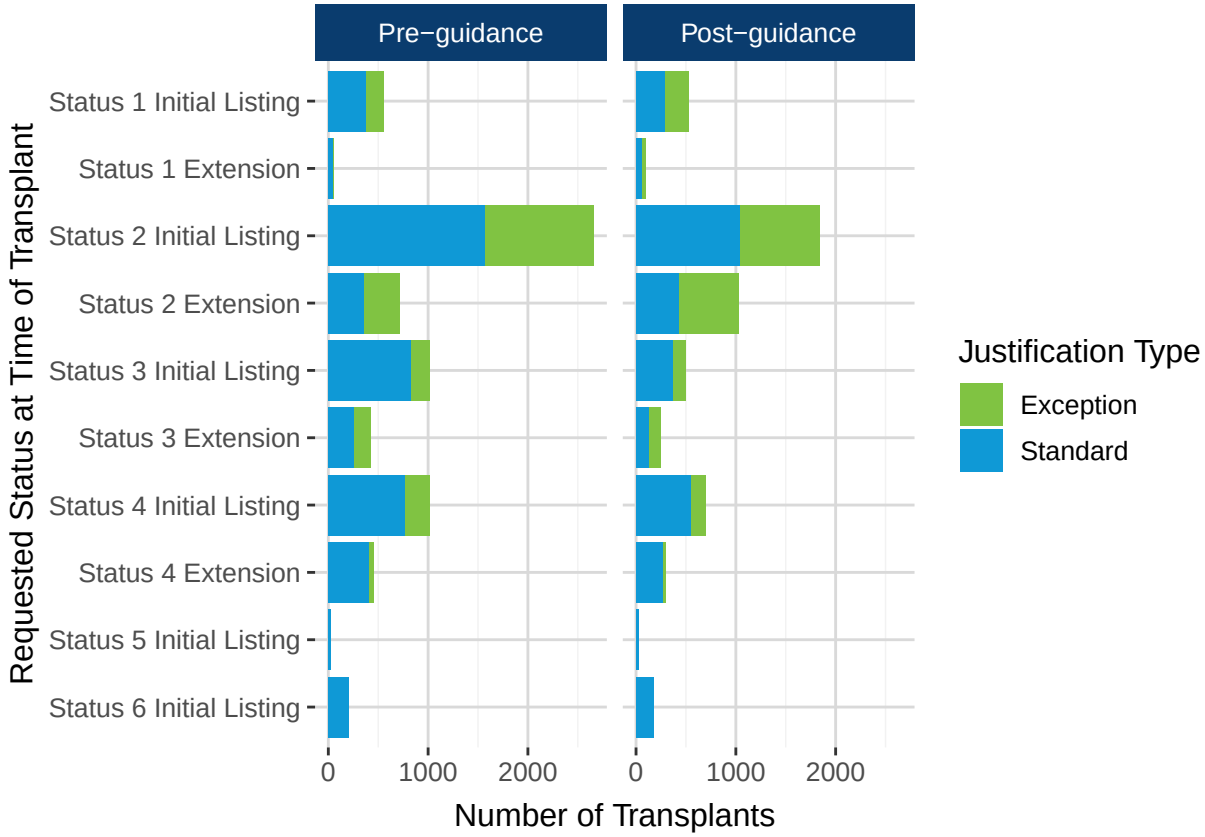


**Figure 18. Adult Heart Transplants by Share Type and Era**

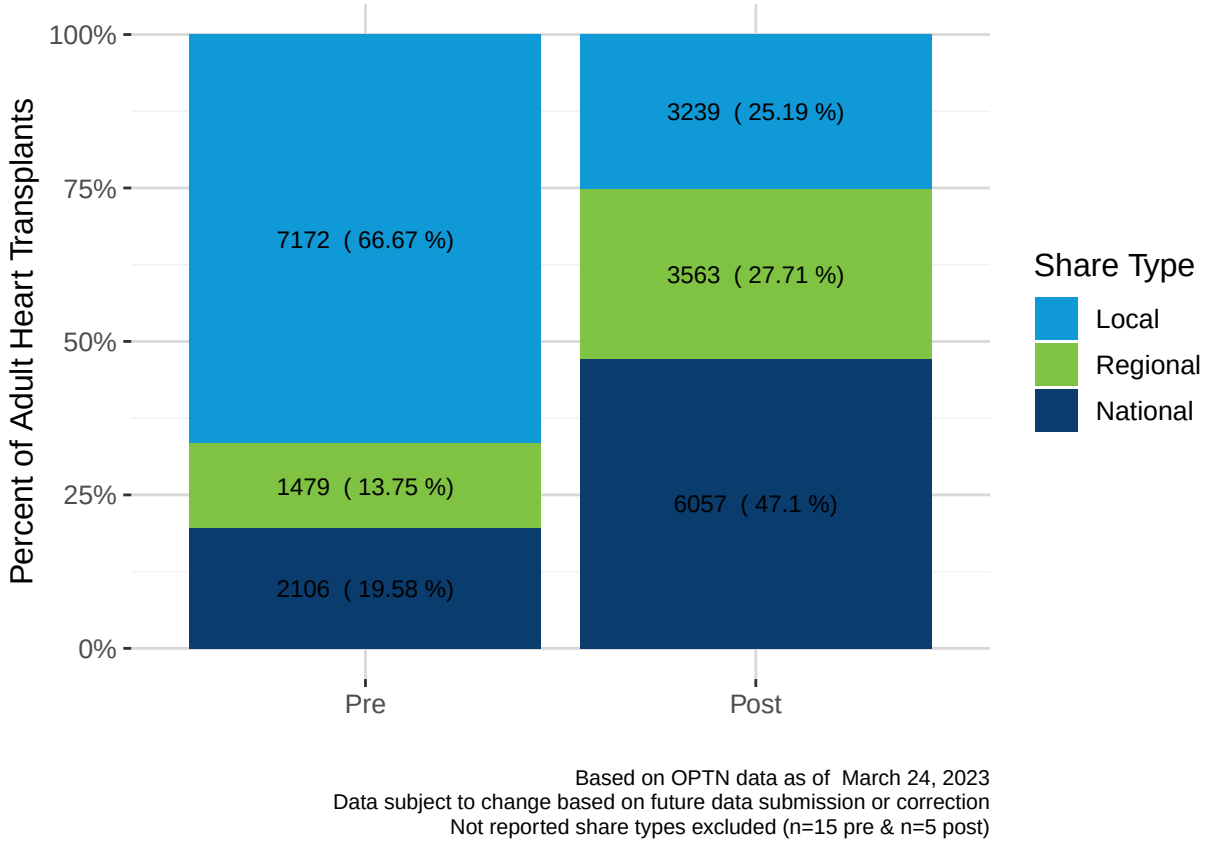



Figure 18 shows the percent of adult heart transplants by share type and era. Here, "local" refers to hearts recovered and transplanted within the same DSA and "regional" refers to hearts recovered and transplanted in different DSAs but within the same OPTN region. This report includes data from after 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**

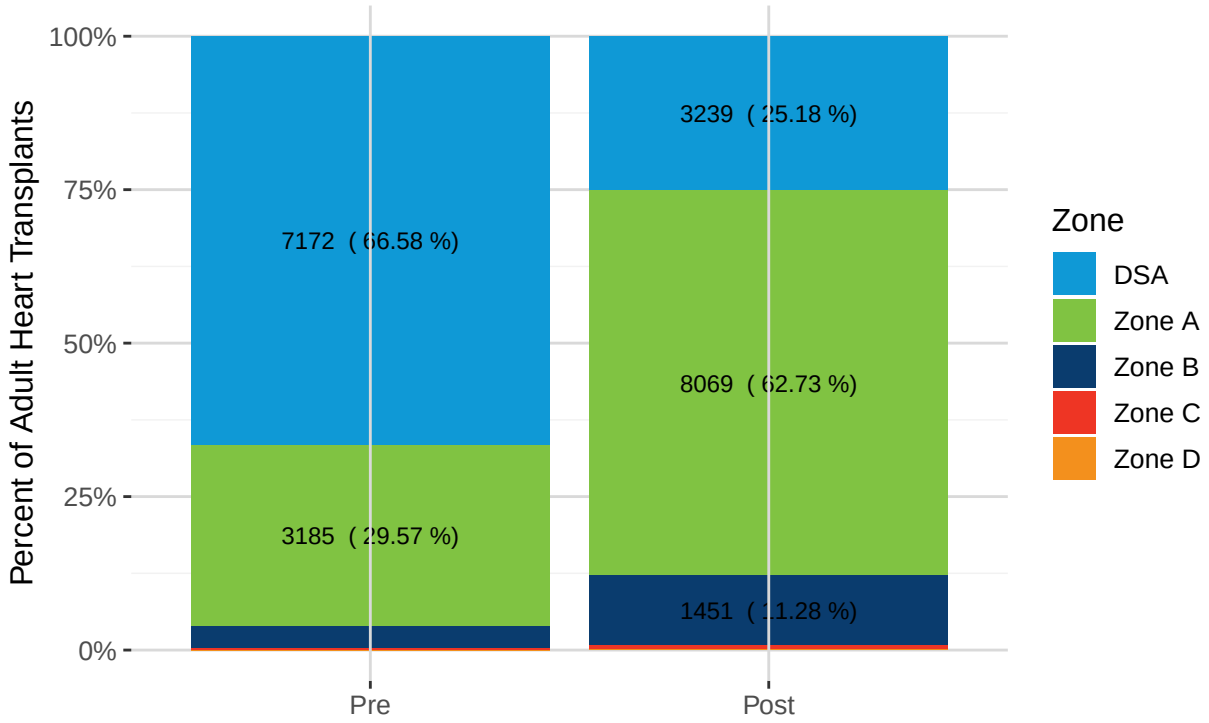
| Era | Zone | N | % |
|---|---|---|---|
| Pre | Local | 7172 | 66.6% |
| | Regional | 1479 | 13.7% |
| | National | 2106 | 19.6% |
| | Not Reported | 15 | 0.1% |
| Post | Local | 3239 | 25.2% |
| | Regional | 3563 | 27.7% |
| | National | 6057 | 47.1% |
| | Not Reported | 5 | 0% |

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**



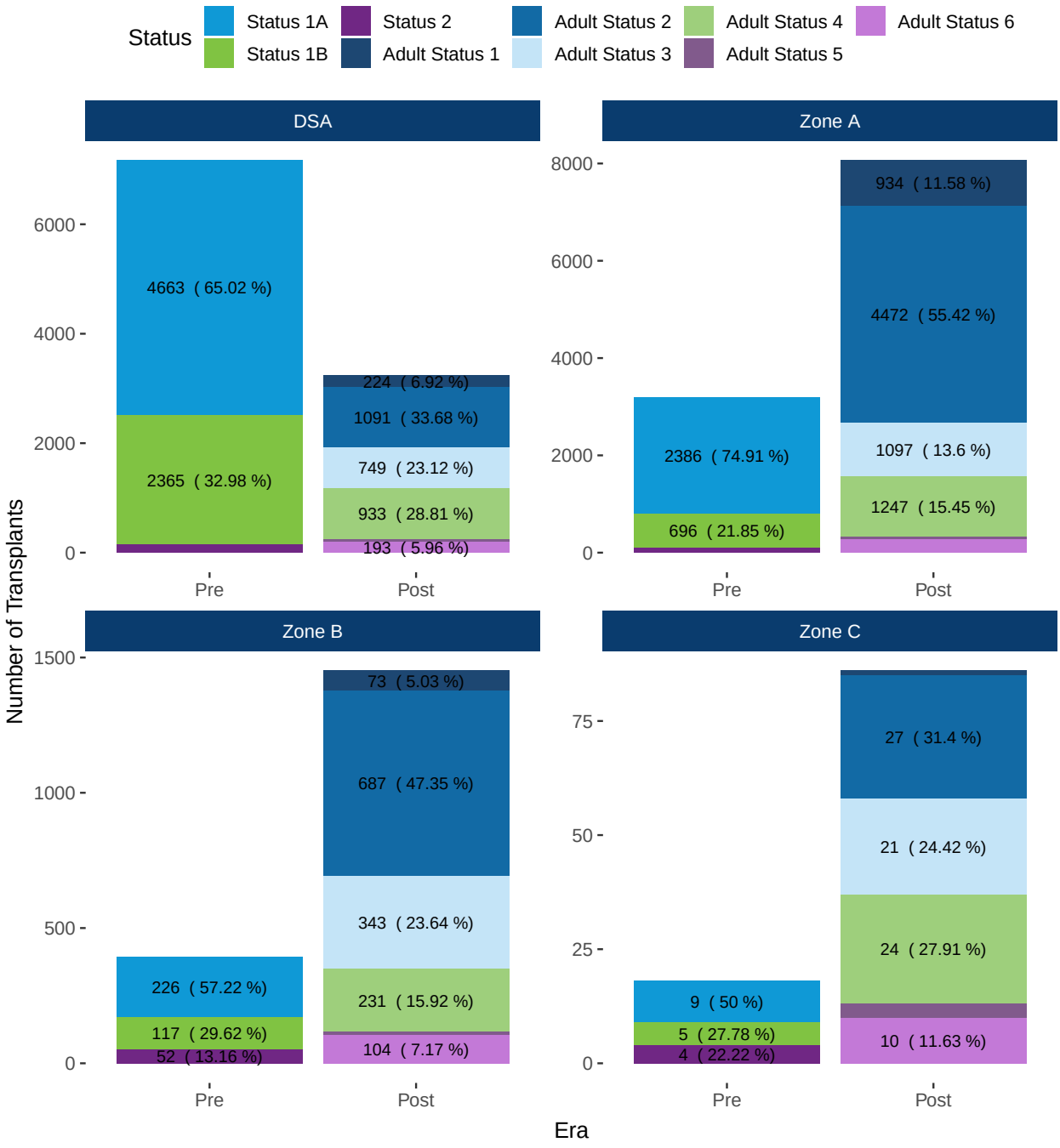

Zones representing <5% of the total are not labeled on the plot;
DSA was removed as a unit of allocation from heart policy on 1/09/2020;
a separate monitoring report addresses that removal

**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**

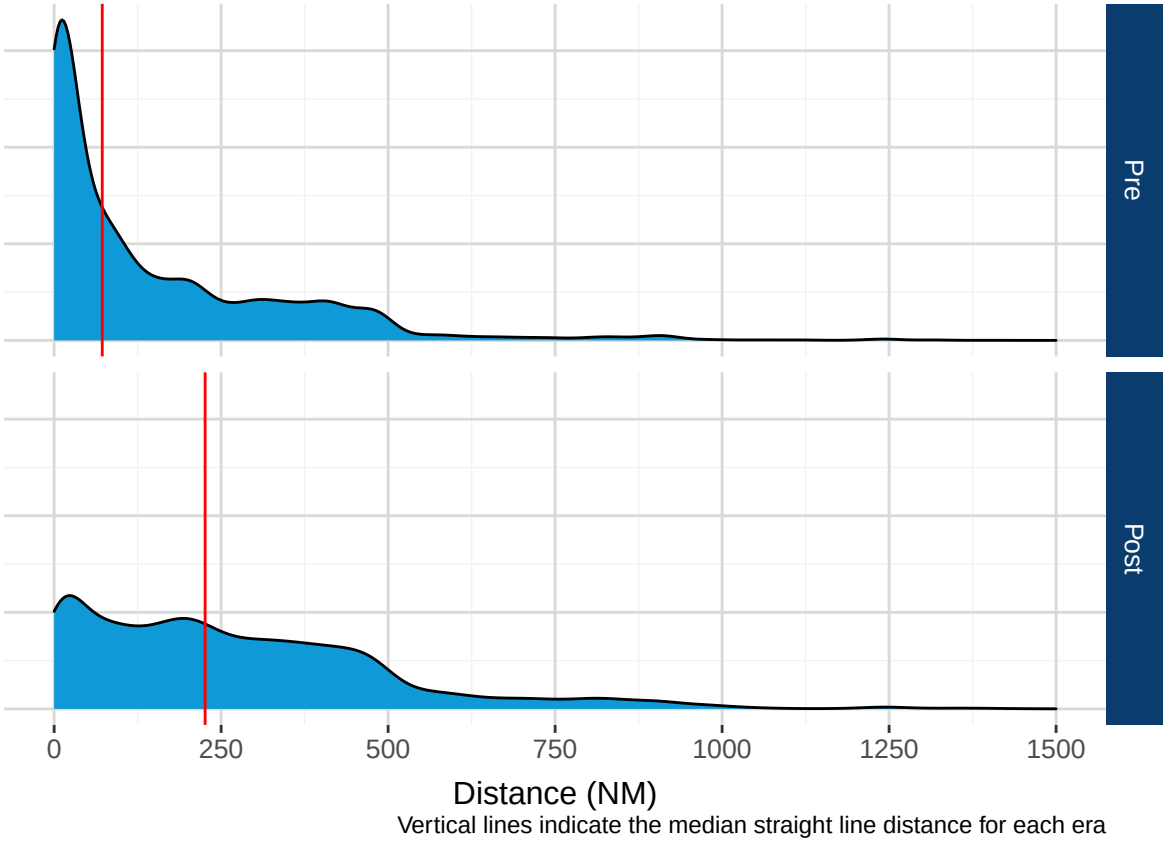
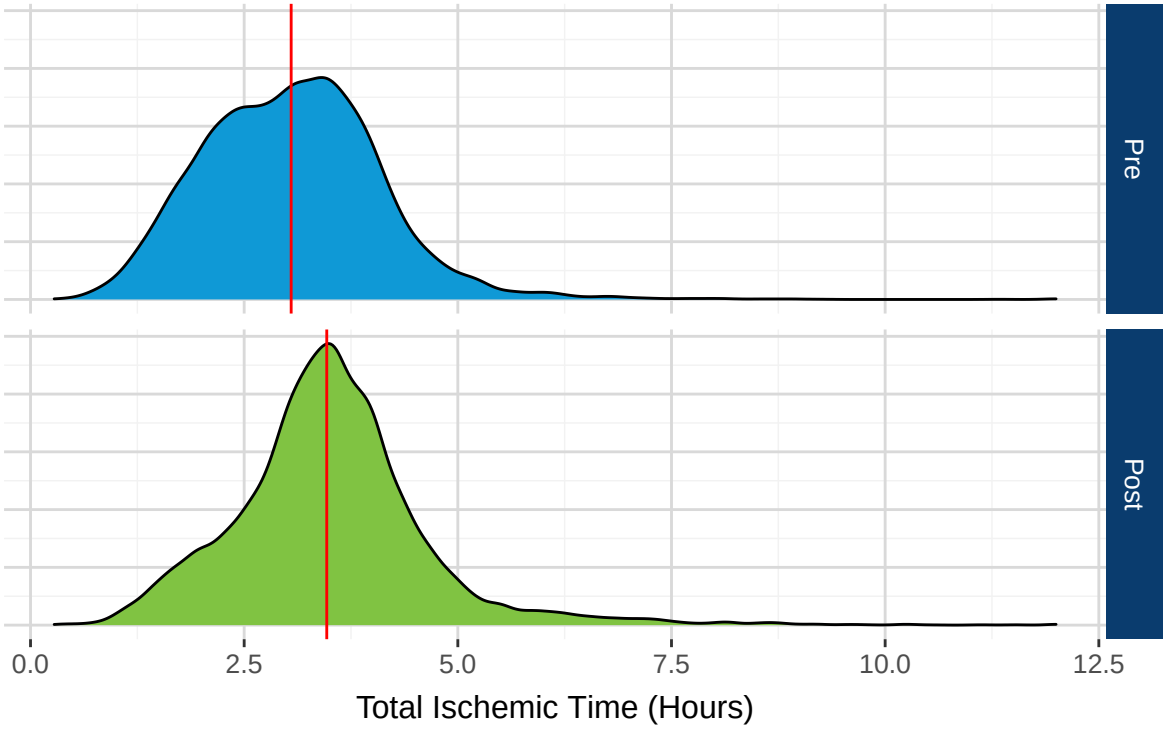



**Table 15. Distance Traveled at Transplant by Era**

| 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**



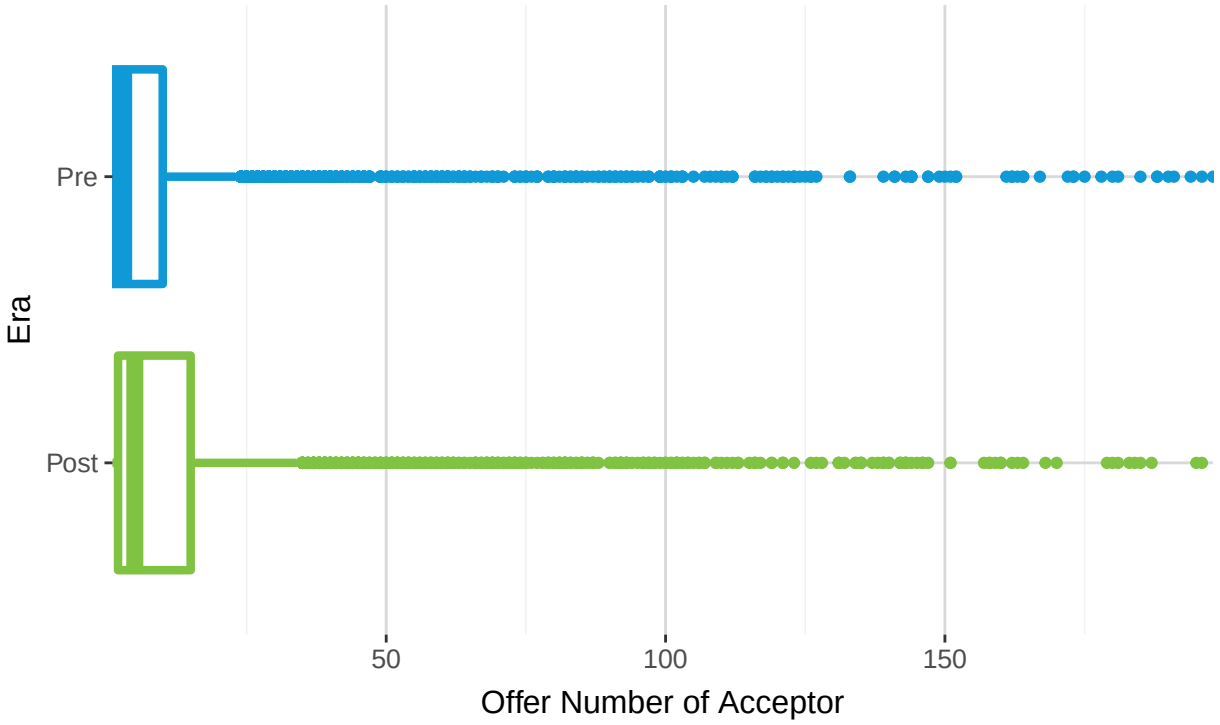

Vertical lines indicate the median cold ischemic time for each era
DSA was removed as a unit of allocation from heart policy on 1/09/2020
a separate monitoring report addresses the removal

**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**



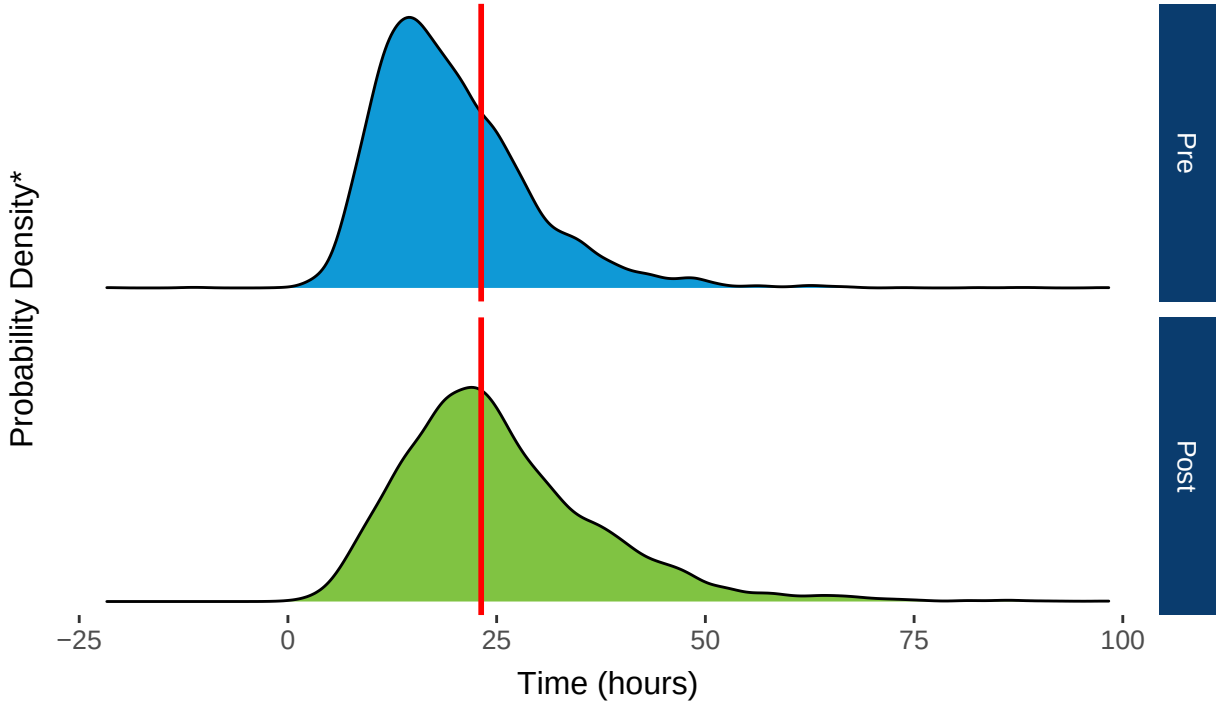

There were 38 acceptances with an offer number over 200 in the pre era and 57 in the post era (not shown)

**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**

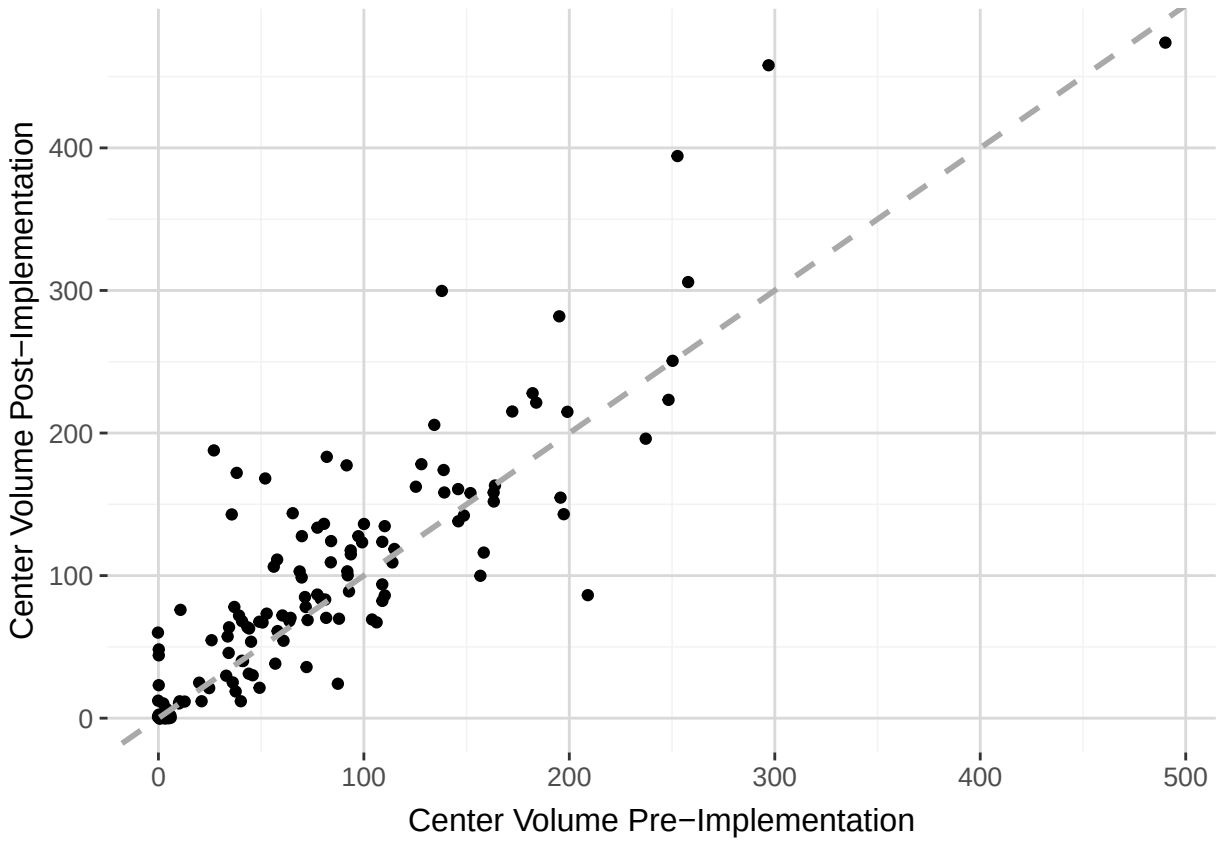



Figure 25 compares the number of adult heart transplants performed by transplant centers before and after modifications to the adult heart allocation system. This figure contains roughly 32 months of COVID-Era data and should be interpreted with caution as certain centers are known to have been significantly 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**

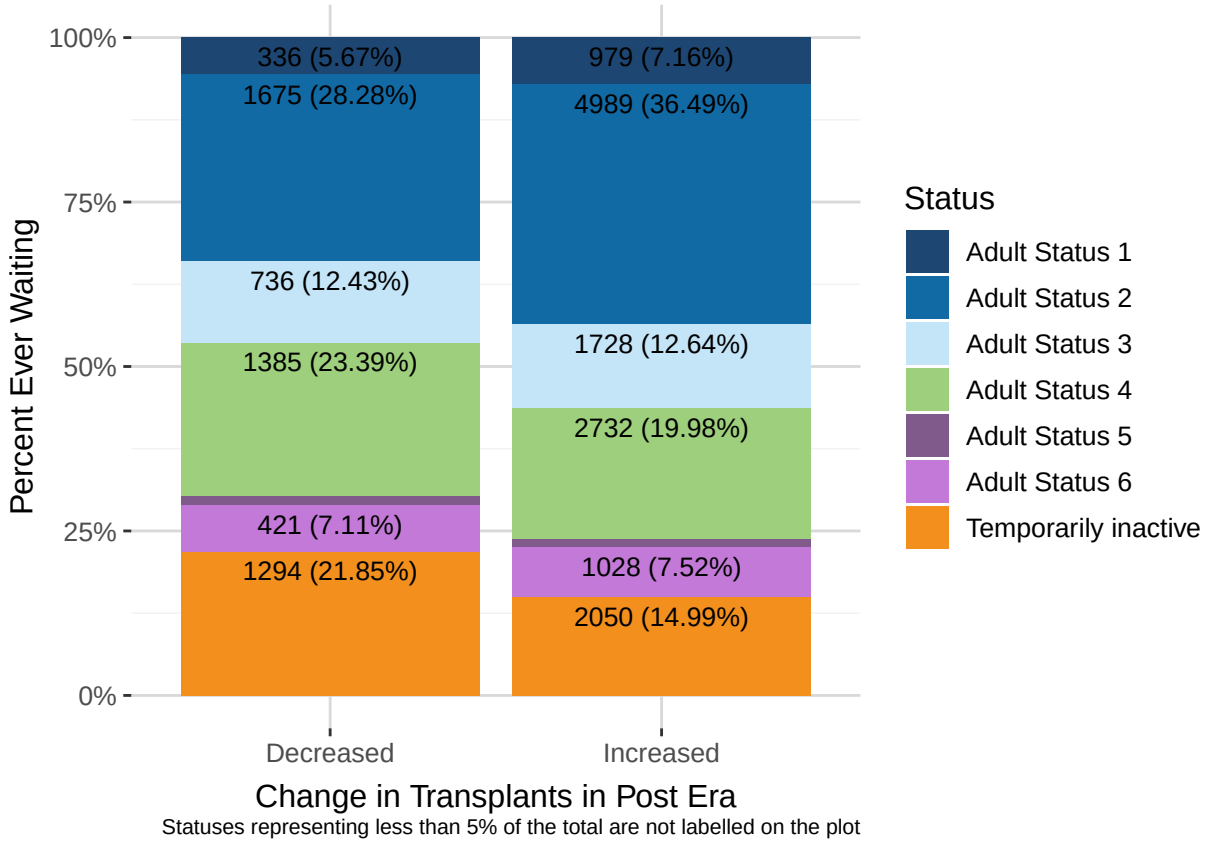



Figure 26 compares the distributions of patients ever waiting at different medical urgency statuses post-implementation at centers where the number of transplants performed post-implementation increased to the distribution at centers where the number of transplants performed post-implementation decreased. 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 proprotion of inactive candidates. There were statistically significant differences in the proportion of patients ever waiting by listing center volume post-implementation ($p < 0.001$). Differences in waitlist makeup may help to explain changes in the number of transplants performed by centers post-implementation.

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

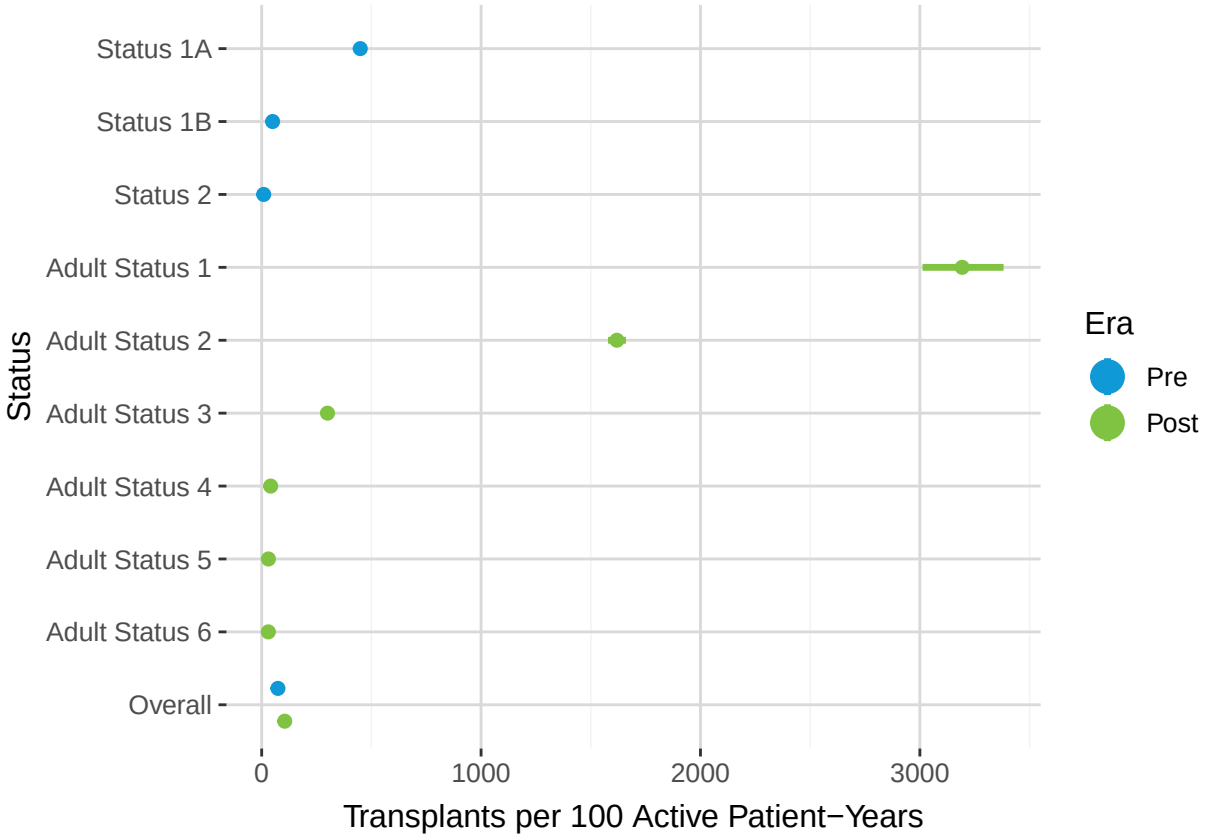


**Figure 28. Zooming in on Adult Heart Statuses 3-6: Transplants per 100 Active Patient-Years Waiting by Medical Urgency Status and Era**

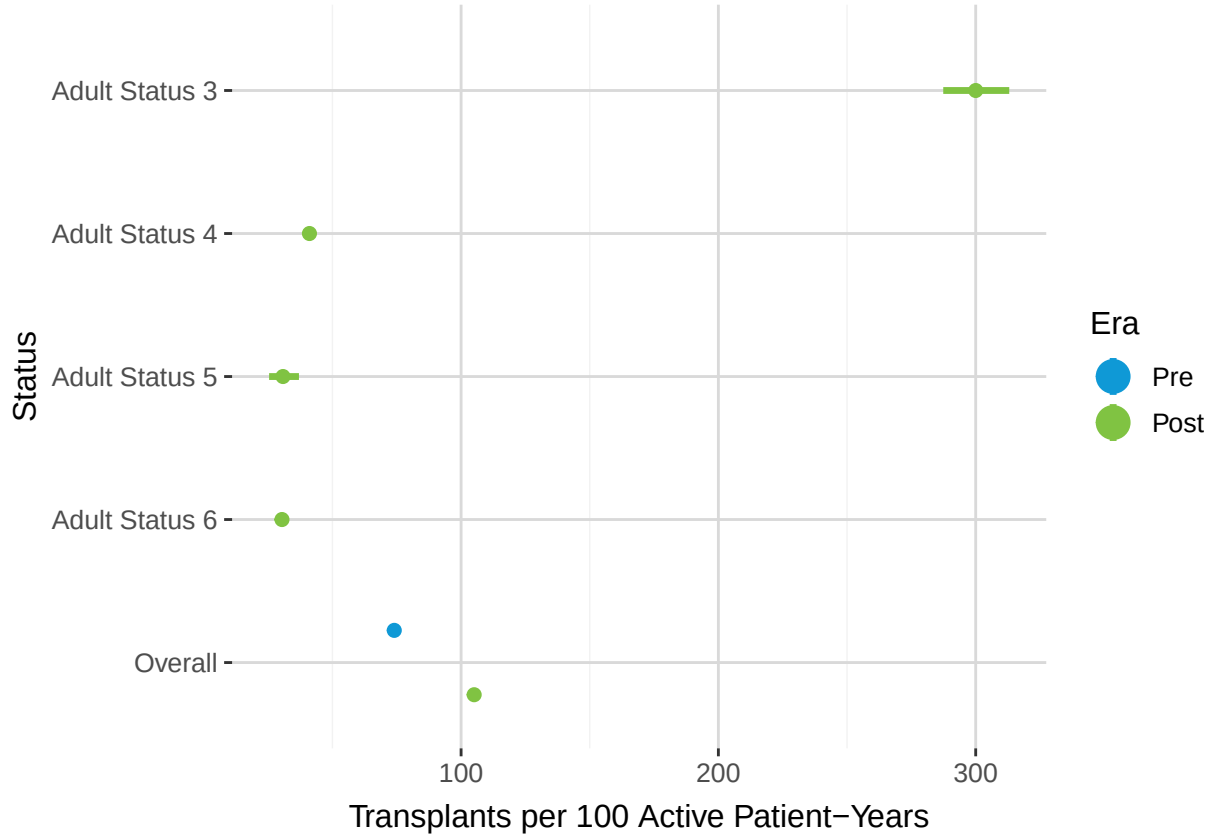


**Table 19. Transplants per 100 Active Patient-Years Waiting by Medical Urgency Status and Era**

| 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**

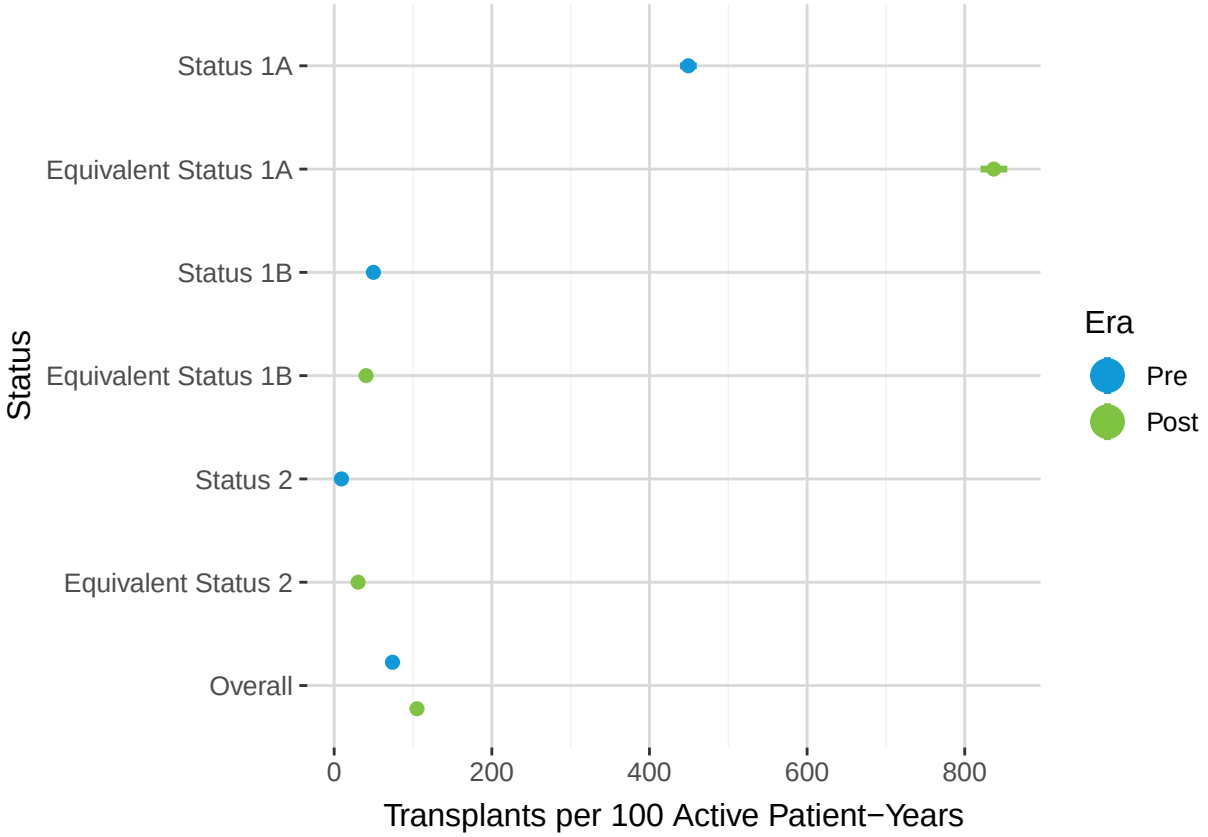



Figure 29 shows the transplants per 100 patient years by equivalent statuses post-implementation as compared to pre-implementation. The Committee Request section defines the equivalent post-implementation statuses as: old Status 1A compared to Adult Statuses 1-3, old Status 1B compared to Adult Statuses 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**

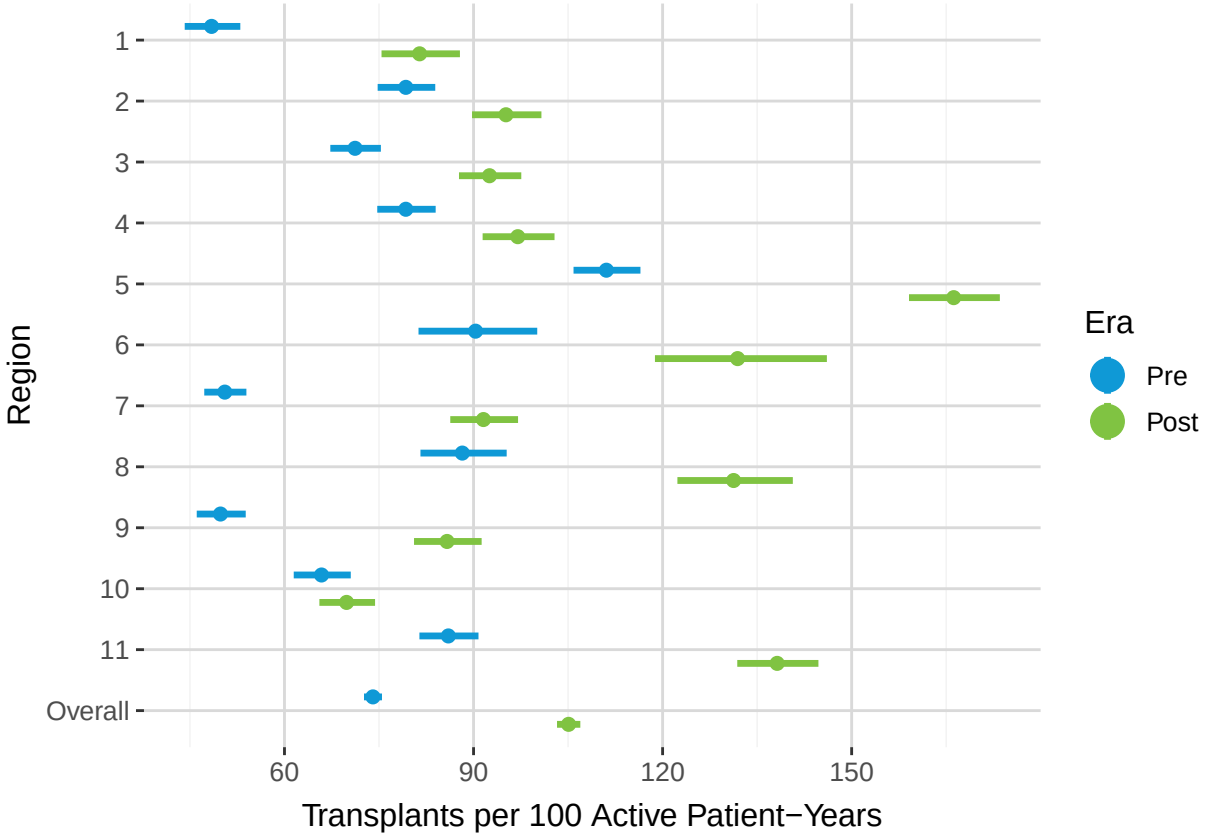



Figure 30 shows the number of transplants per 100 patient-years waiting for each region pre- and post-implementation. The number of transplants per 100 patient-years post-implementation increased for all regions. This increase was statistically significant for all regions except region 10. The overall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

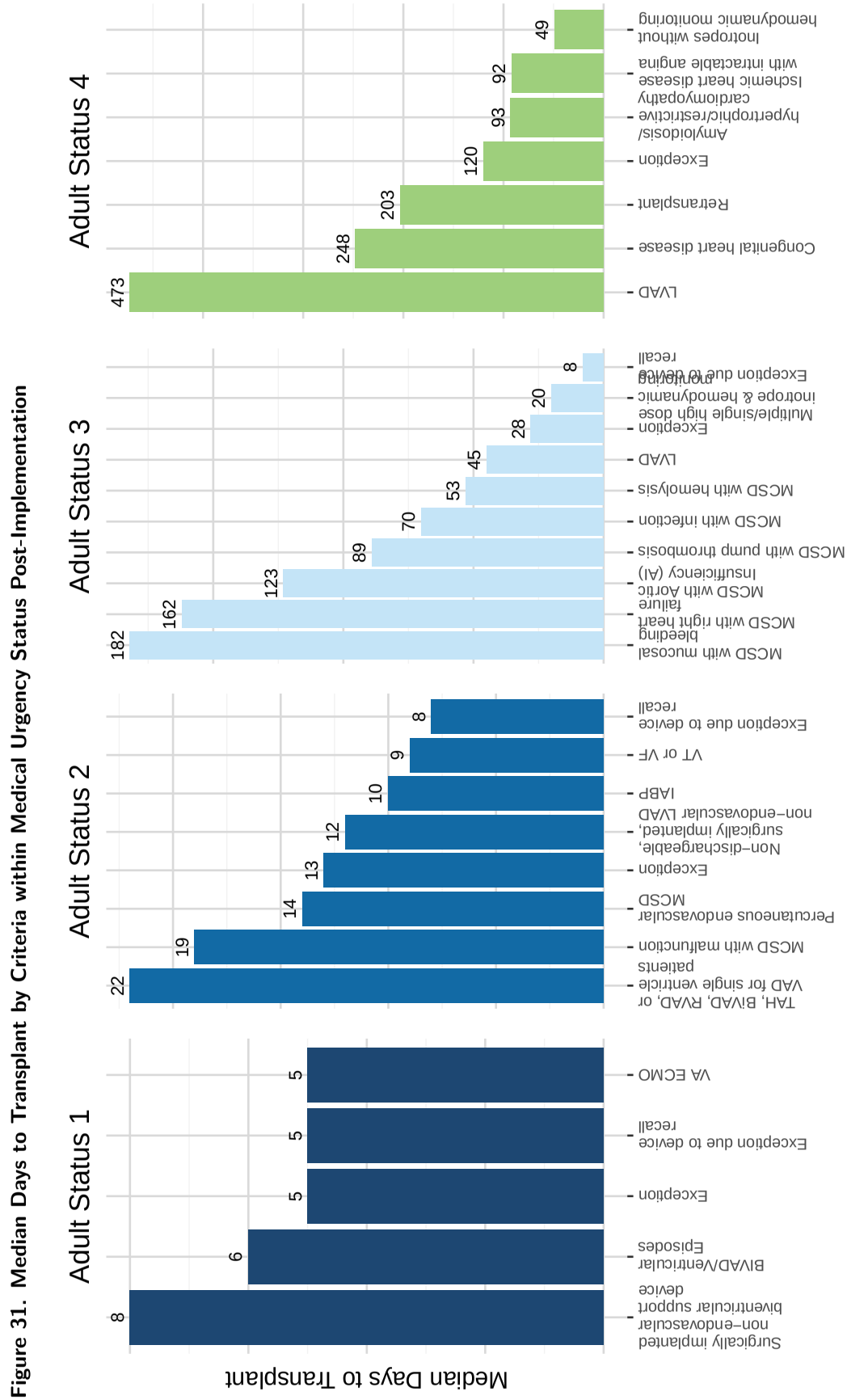



**Figure 31. Median Days to Transplant by Criteria within Medical Urgency Status Post-Implementation**

**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 |
| | MCSD with malfunction | 19 |
| | Non-dischargeable, surgically implanted, non-endovascular LVAD | 12 |
| | Percutaneous endovascular MCSD | 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 |
| | MCSD with Aortic Insufficiency (AI) | 123 |
| | MCSD with hemolysis | 53 |
| | MCSD with infection | 70 |
| | MCSD with mucosal bleeding | 182 |
| | MCSD with pump thrombosis | 89 |
| | MCSD 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**

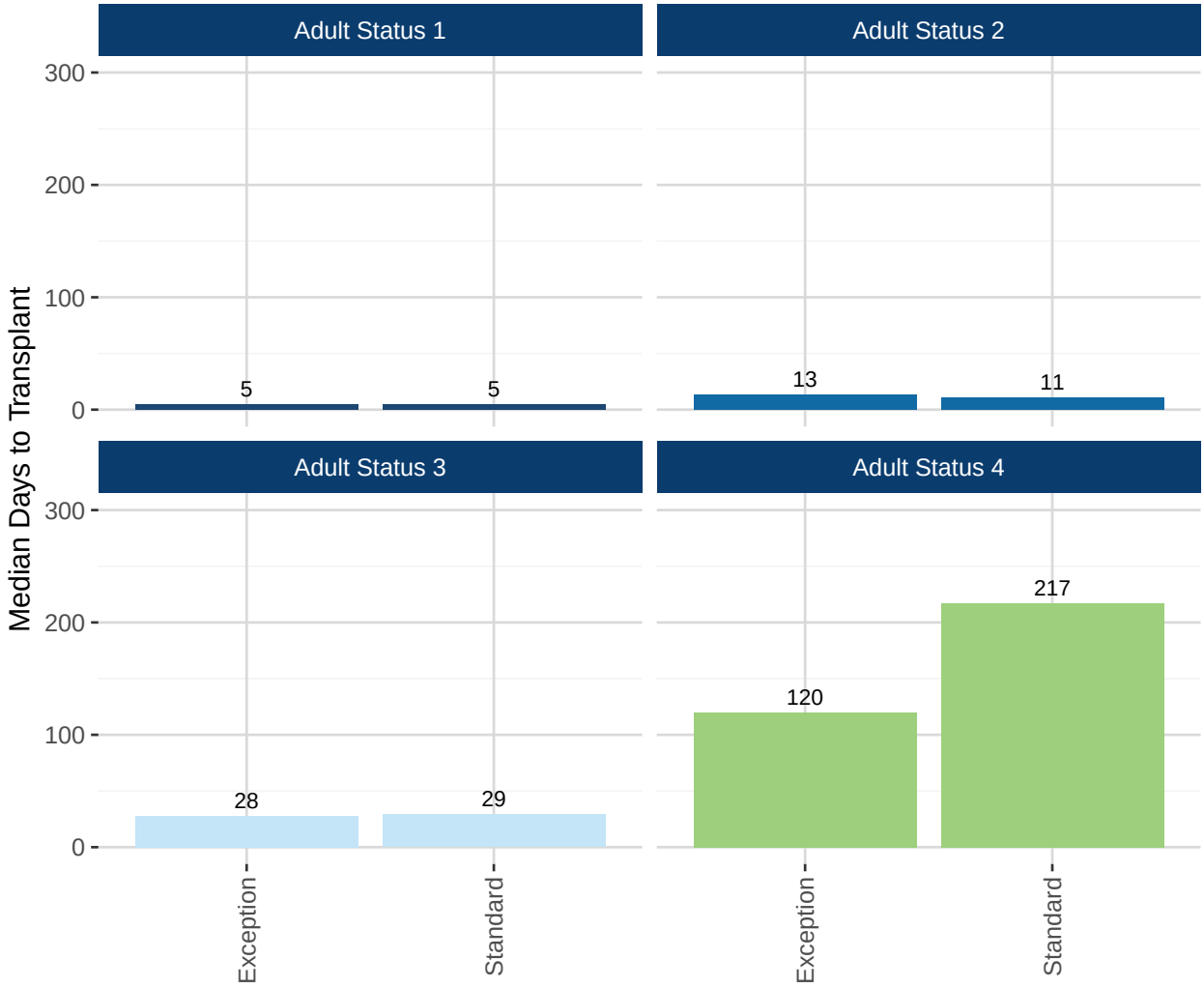



Figure 32 displays the results of the competing risks analysis of the median days to transplant for Adult Statuses 1-4 by exception versus no exception. Median days to transplant was the same between exception versus standard review for Adult Status 1. For Adult Status 2 the median days to transplant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

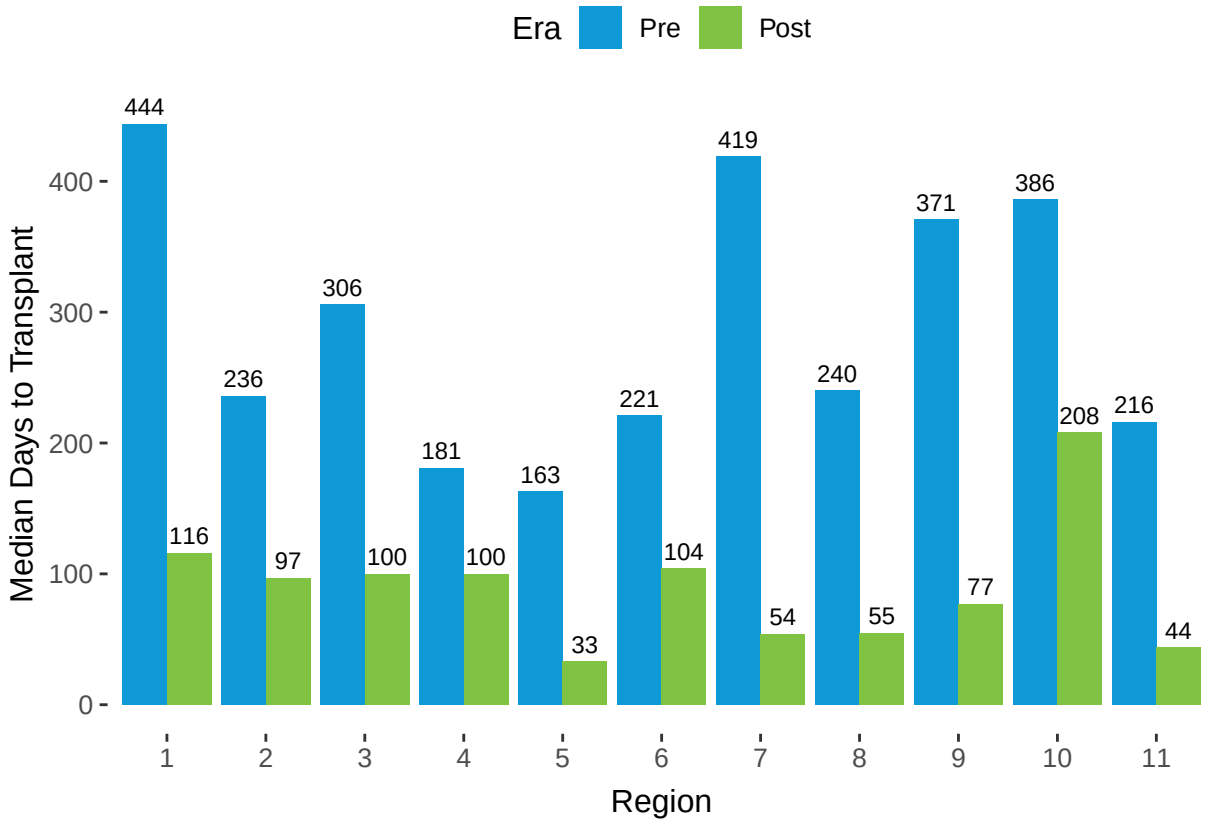



Figure 33 shows a competing risks analysis of the median days waiting before transplant by status and region. The median time to transplant declined in all regions. The largest decrease in median days waited was seen in region 7, where the median wait time decreased from 419 days to 54 days, a decrease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

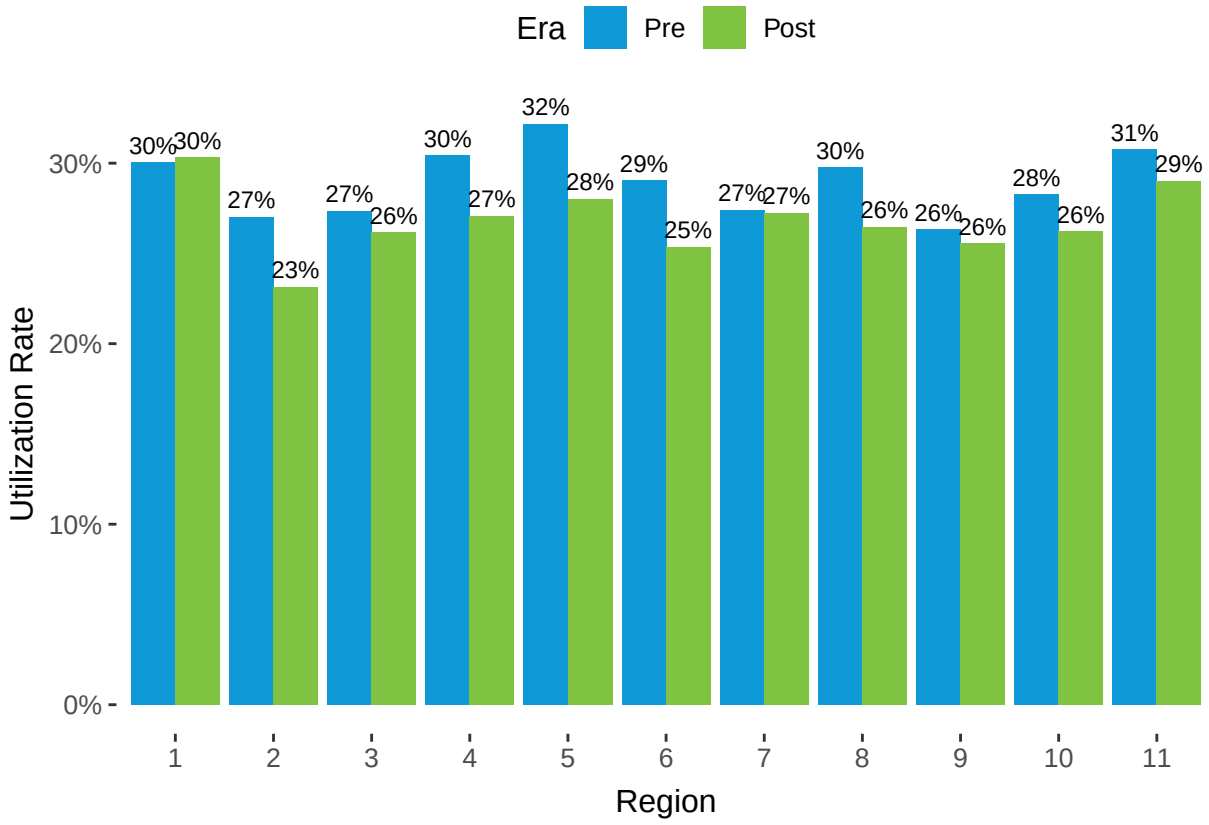



Figure 34 shows the utilization rates of adult hearts by region both pre- and post-implementation. Utilization rates decreased in the majority of the regions. Utilization rates remained the same in region 1 and decreased in the remaining regions.

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

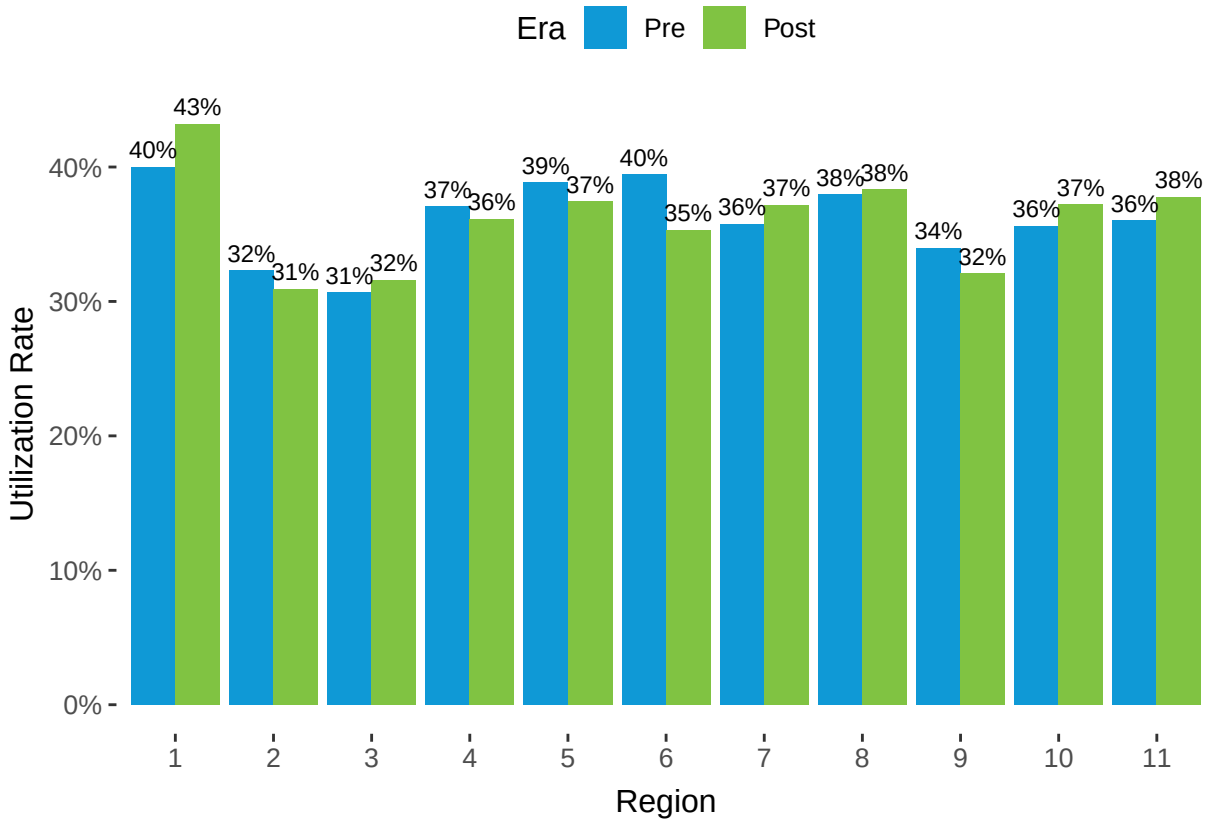



Figure 35 shows utilization rates of adult hearts by region and era for non-DCD donors only. Utilization rates are higher for non-DCD donors than for donors overall (Tables 23 and 24) and rose in regions 1, 3, 7, 10, and 11. The largest decline pre- to post-implementation was in region 6 and the largest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

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

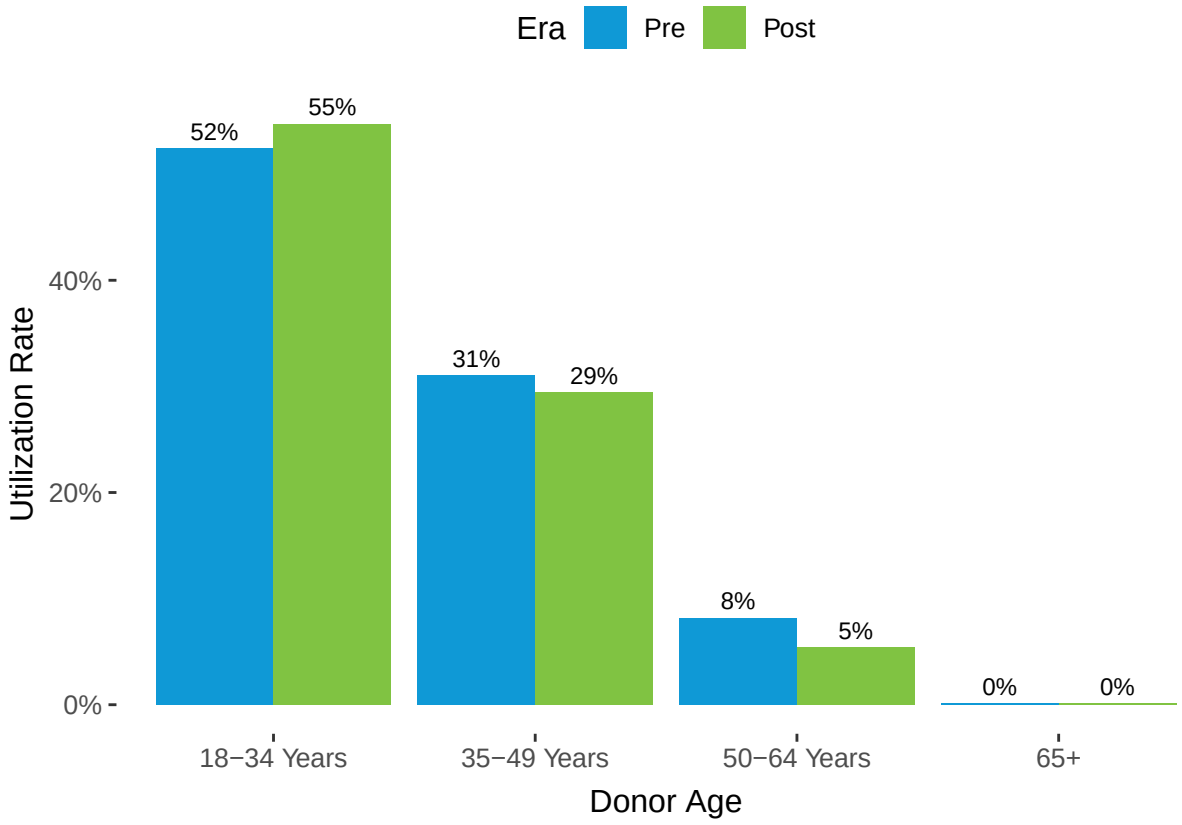



Figure 36 shows the utilization rates for adult hearts both pre- and post-implementation by donor age. There was little change in adult heart utilization in any donor age group.

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

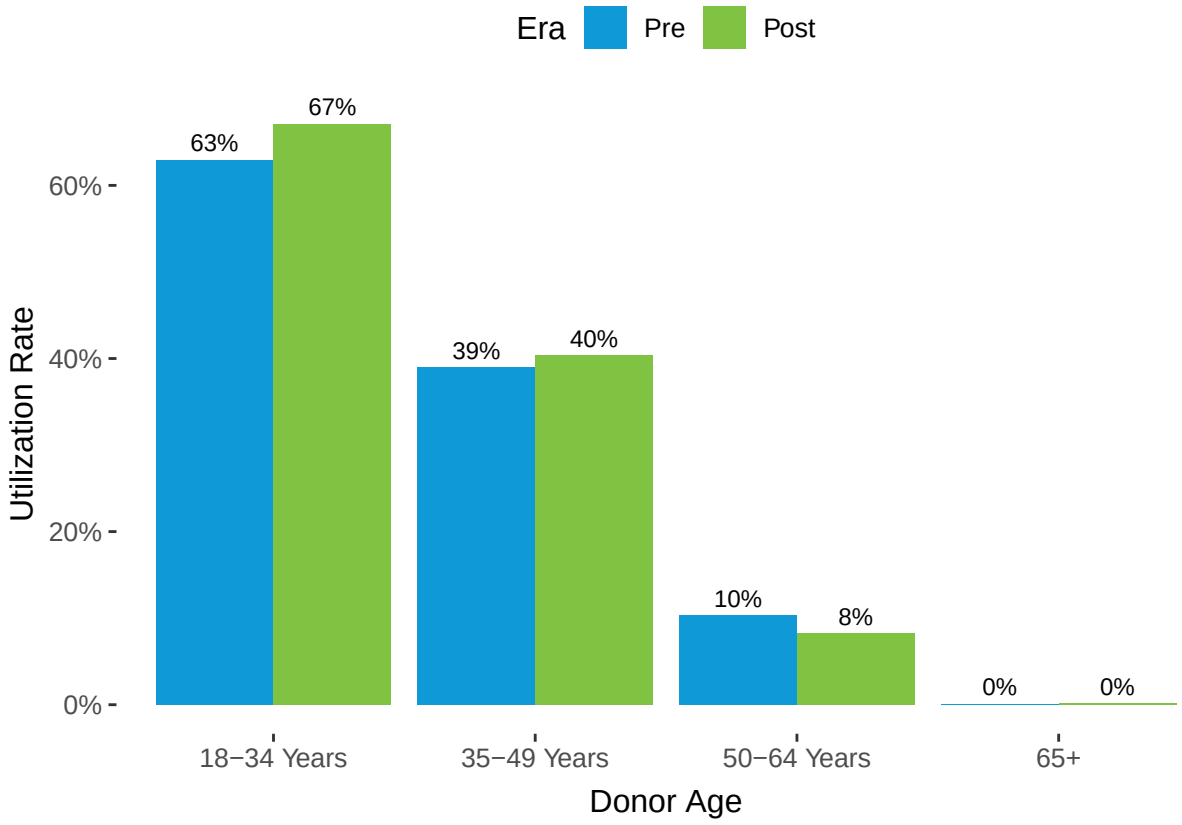



Figure 37 shows the utilization rates for adult hearts from non-DCD donors both pre- and post-implementation by donor age. The utilization rates for non-DCD donors increased slightly pre- to post-implementation for donor age groups 18-34 years and 35-49 years, and decreased slightly for donor ages 50-64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

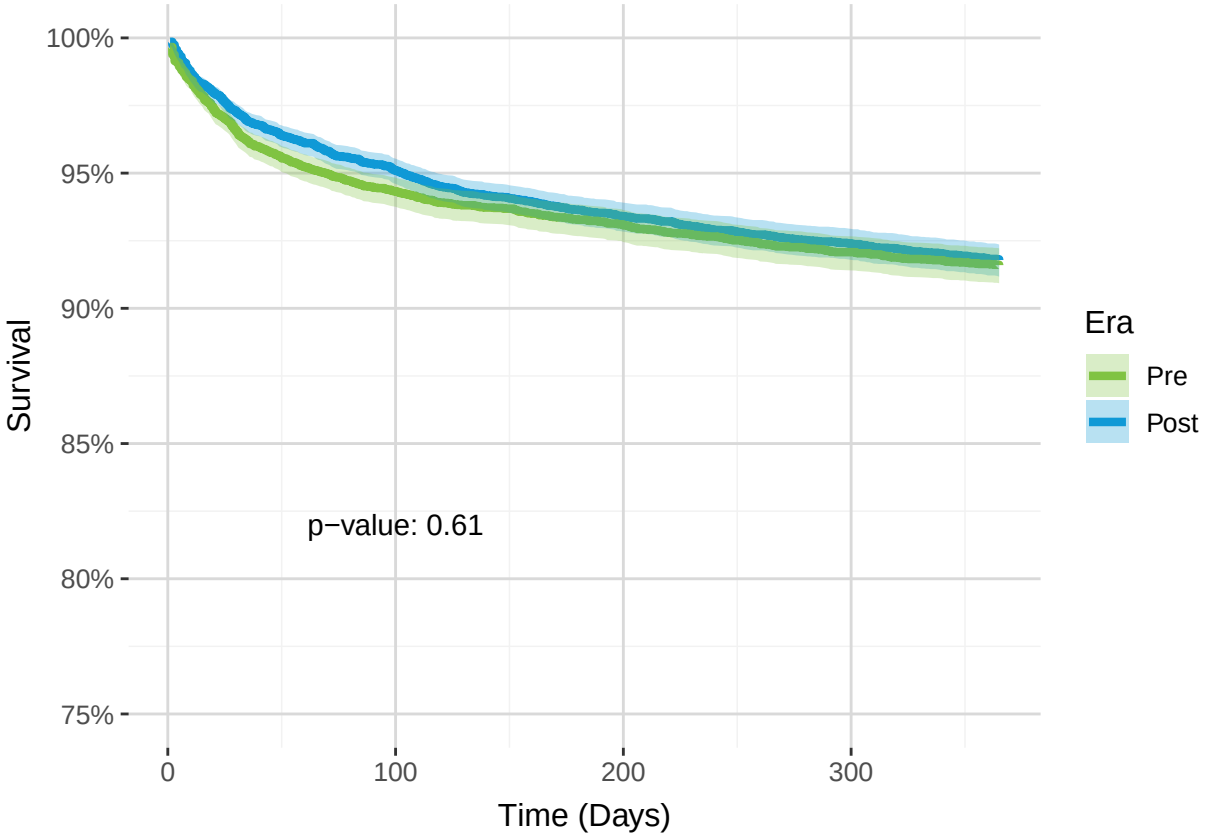



Figure 38 shows the one-year patient survival for adult heart recipients pre- and post-implementation. There was no significant difference in patient survival between the two eras ($p = 0.61$). One-year patient survival in the pre era was 91.6% compared to 91.79% in the post era.

**Figure 39. Three-Year Patient Survival**

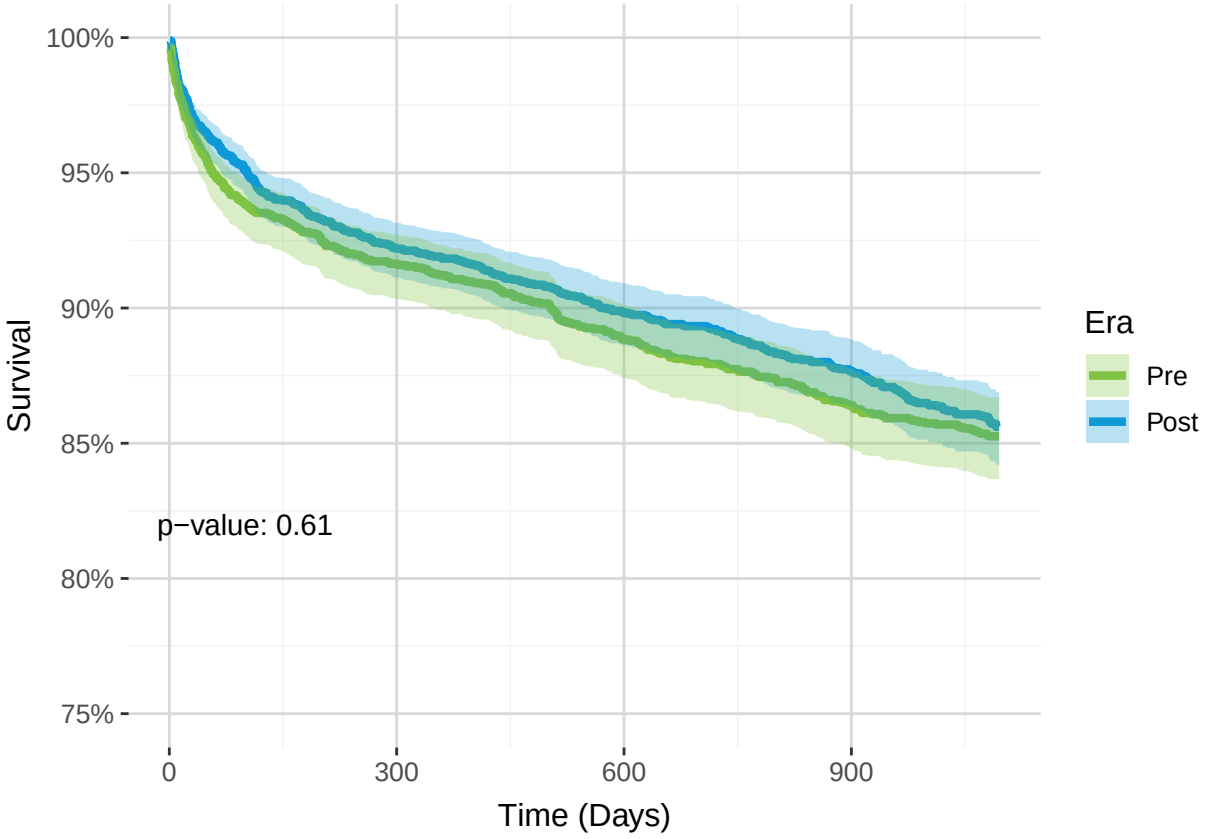



Figure 39 shows the three-year patient survival for adult heart recipients pre- and post-implementation. As with one-year patient survival, there was no significant difference in three-year patient survival between the two eras (p = 0.61). Three-year patient survival in the pre era was 85.26% compared 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**

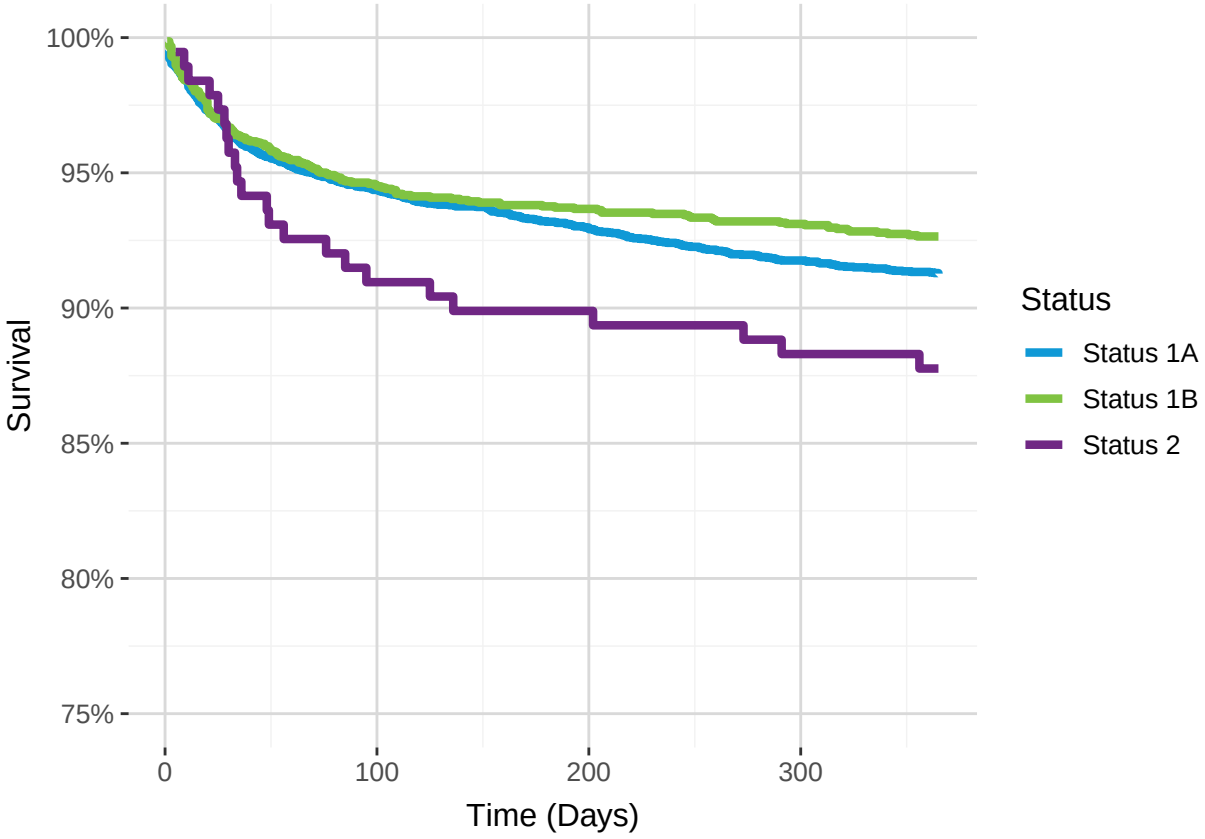
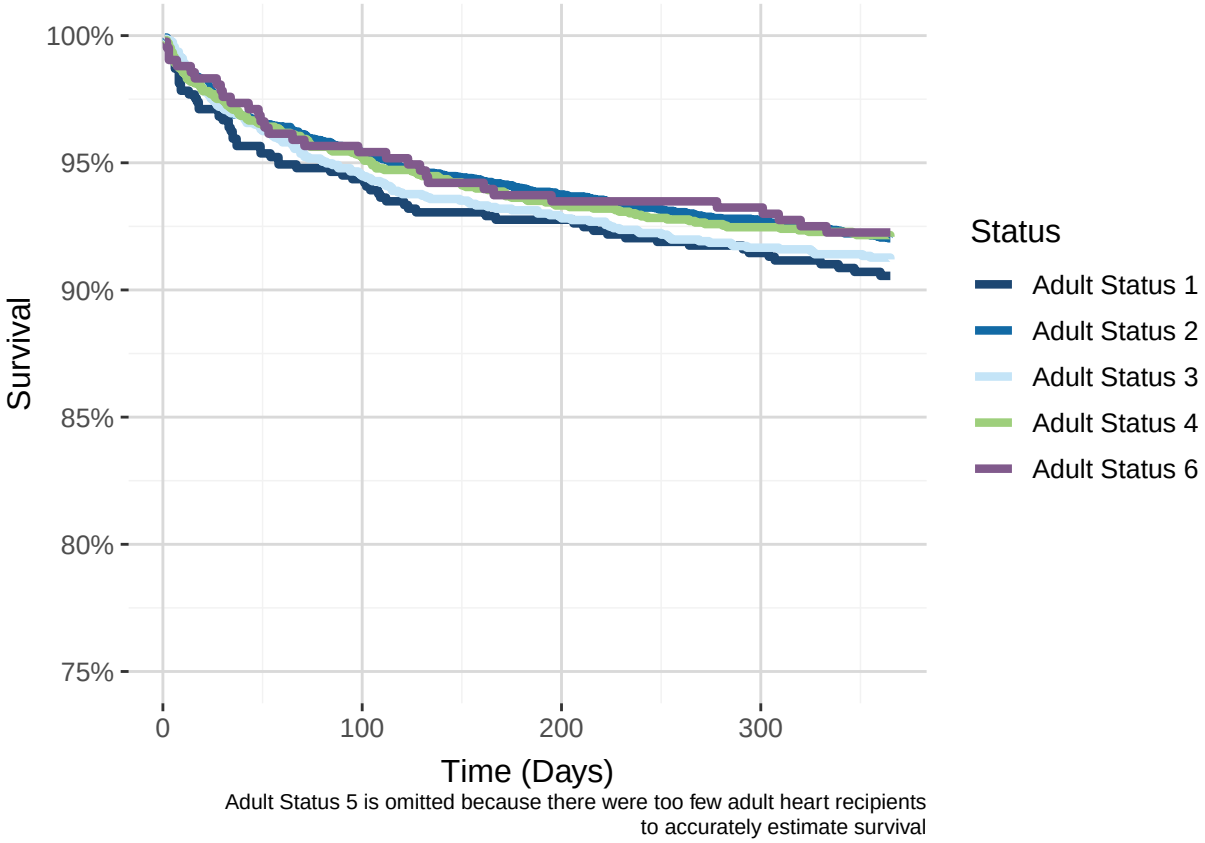


**Figure 41. One-Year Patient Survival by Medical Urgency Status Post-Implementation**




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**

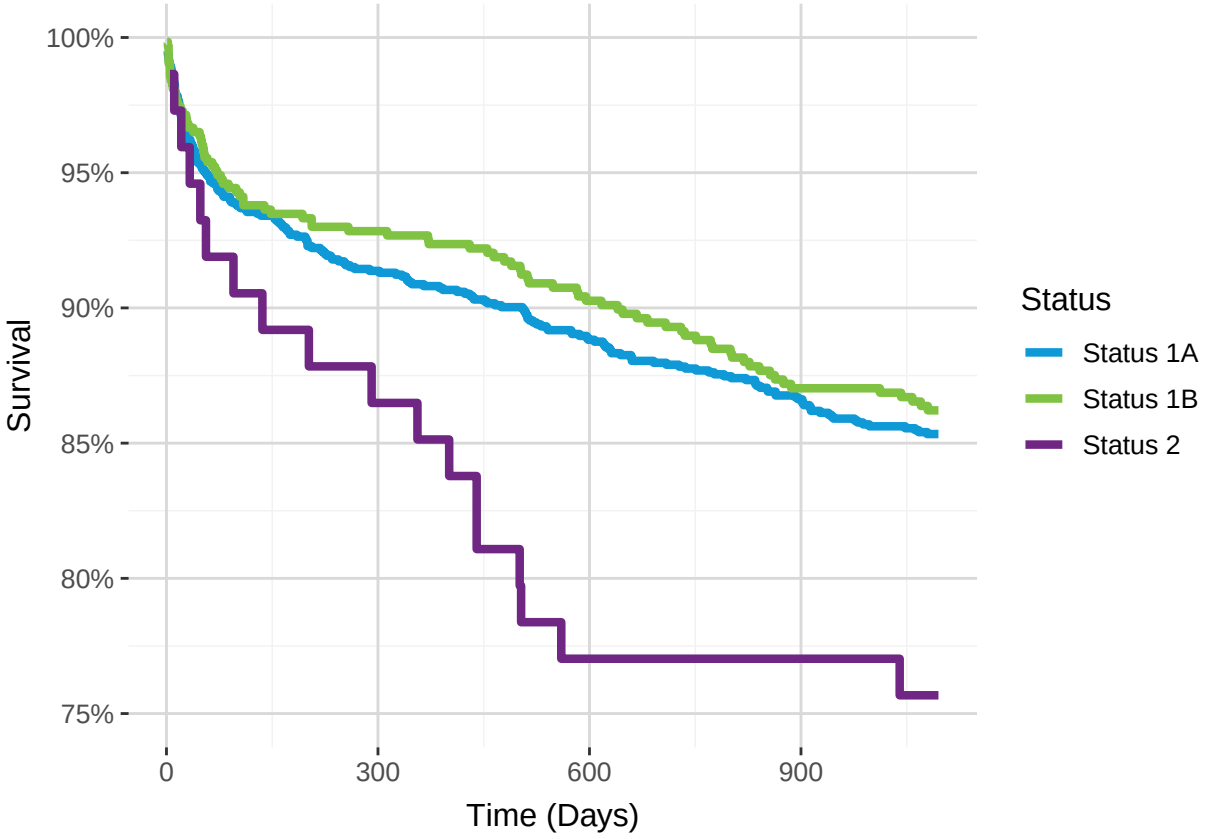
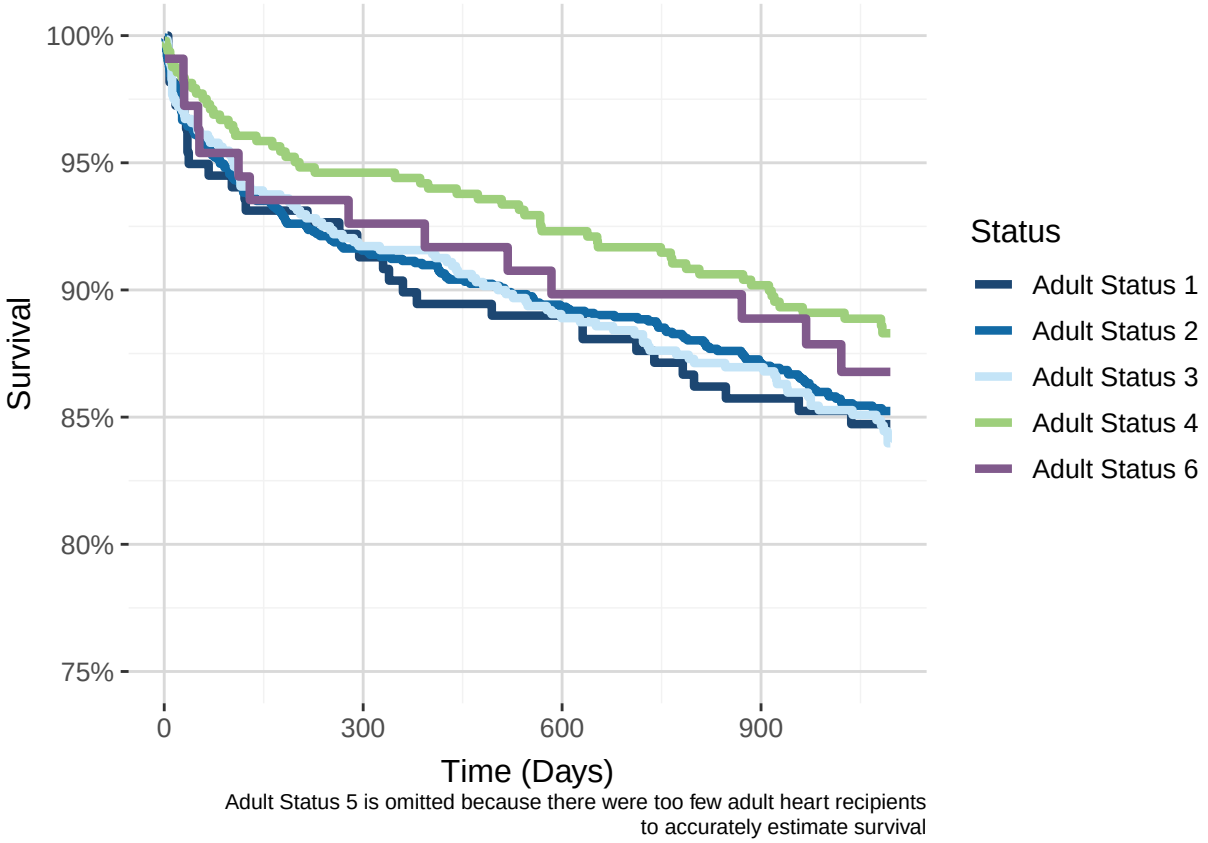


**Figure 43. Three-year Patient Survival by Medical Urgency Status Post-Implementation**




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**

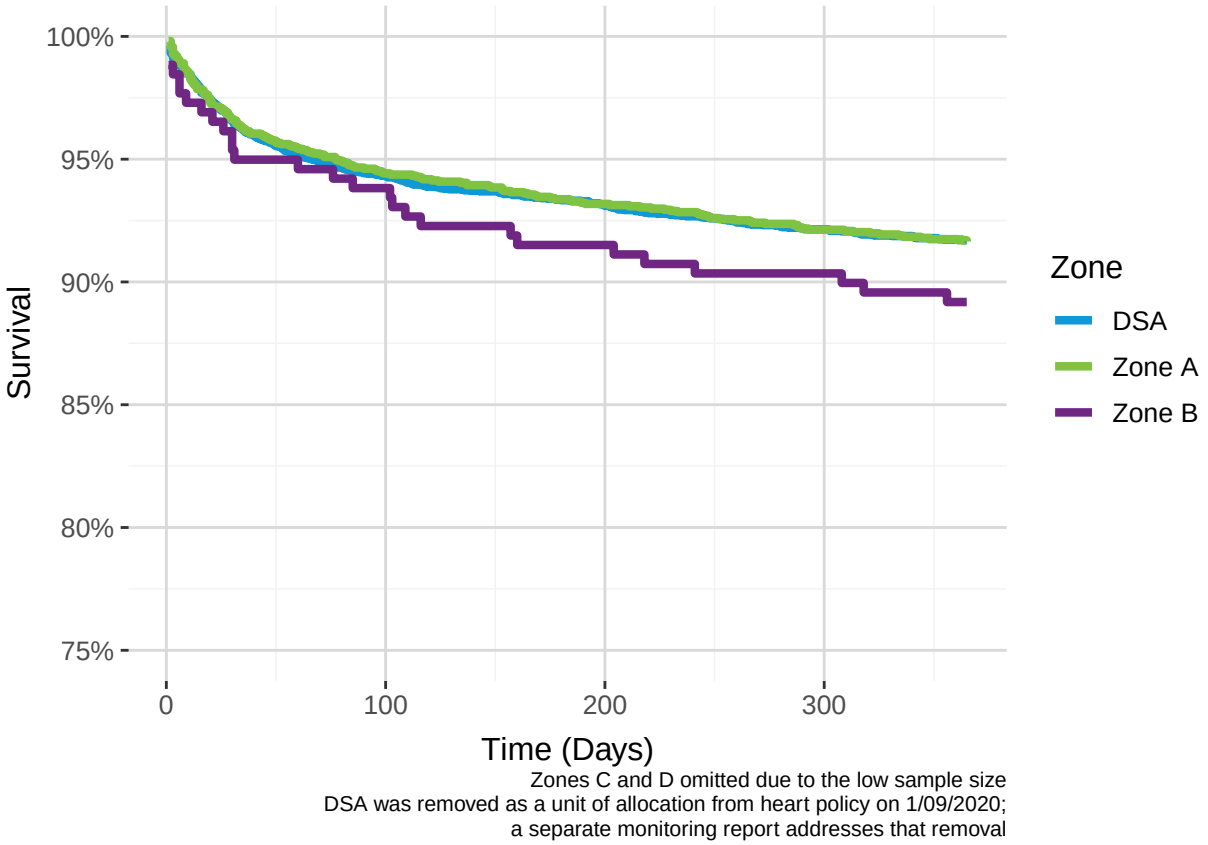
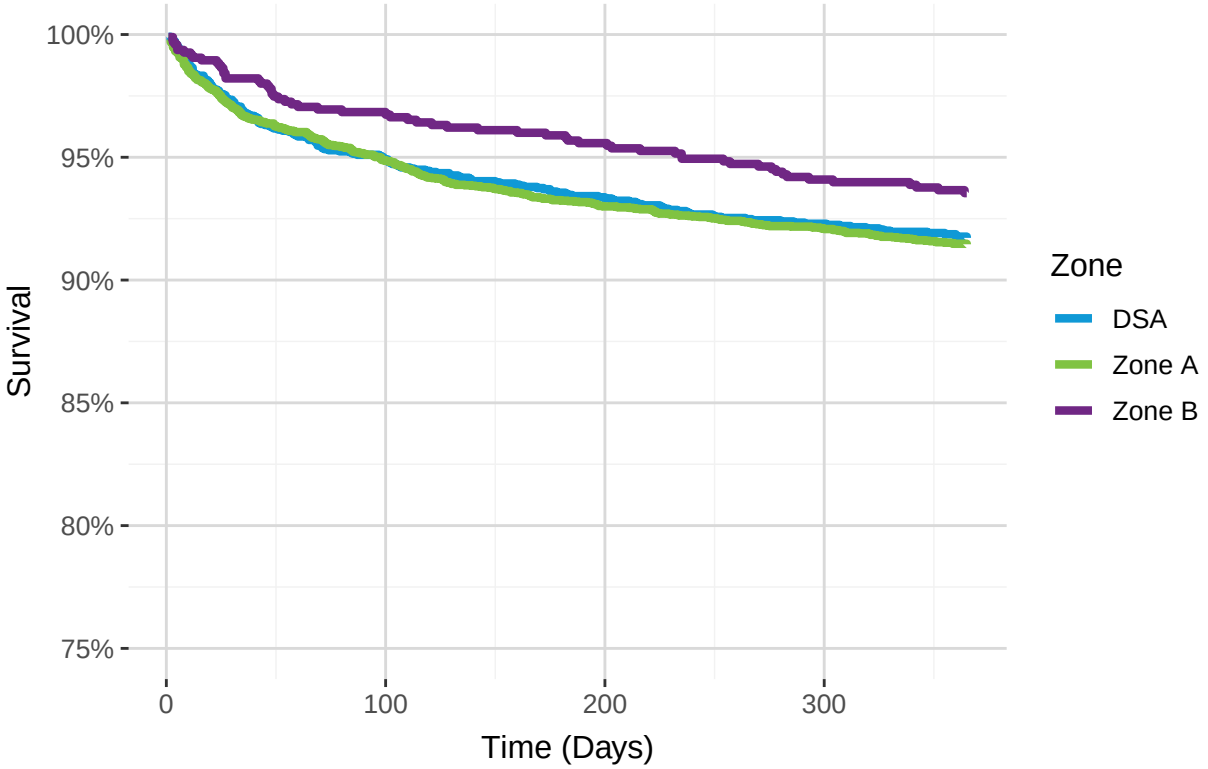


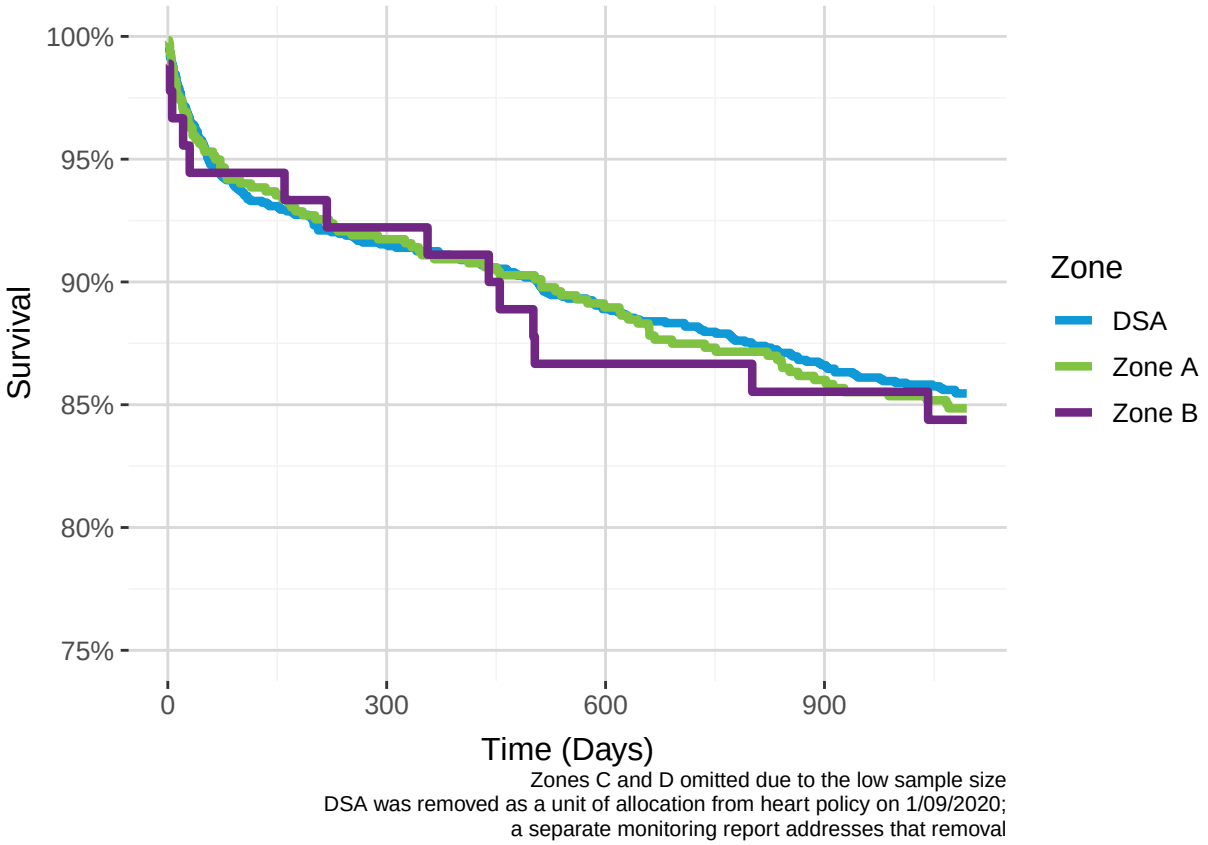
**Figure 45. One-Year Patient Survival by Zone Post-Implementation**




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

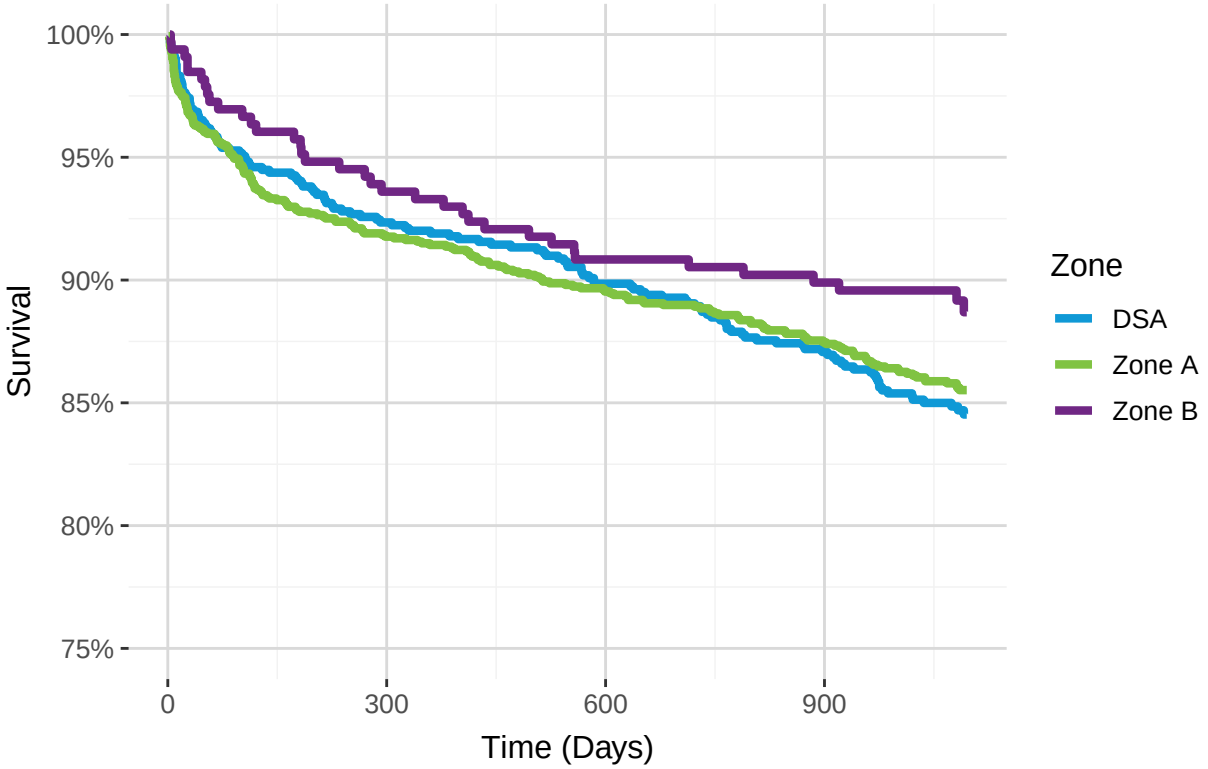
Figures 46 and 47 show three-year patient survival by zone, pre- and post-implementation. These analyses are unadjusted and therefore do not account for medical urgency or other candidate or donor factors that could impact outcomes. Zone B had the lowest three-year patient survival pre-implementation,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



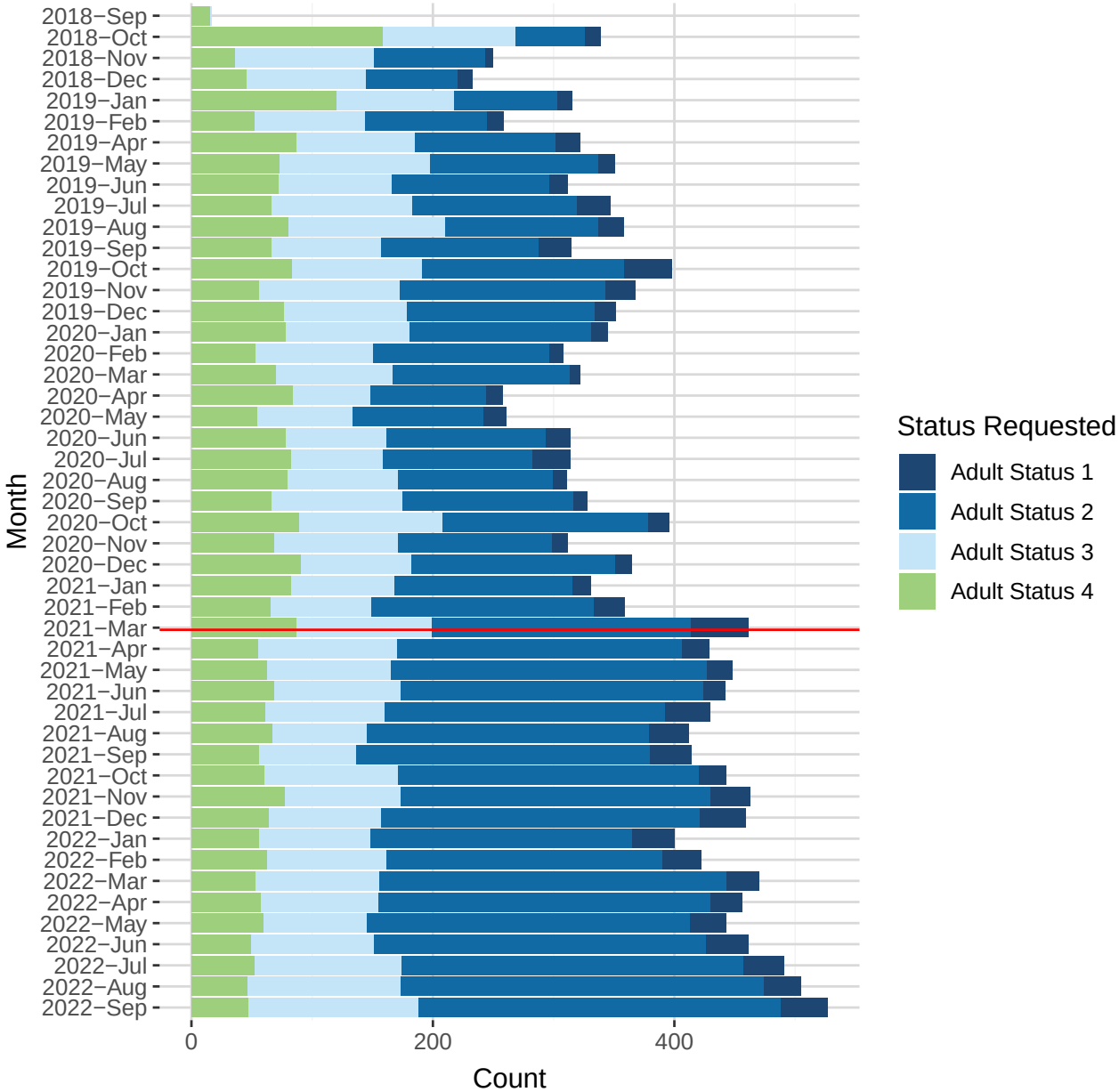

Zones C and D omitted due to the low sample size
DSA was removed as a unit of allocation from heart policy on 1/09/2020;
a separate monitoring report addresses that removal

## 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-** | 2021-Dec | 38 (8.3%) | 264 (57.5%) | 93 (20.3%) | 64 (13.9%) | 459 (100.0%) |
| **guidance** | 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**

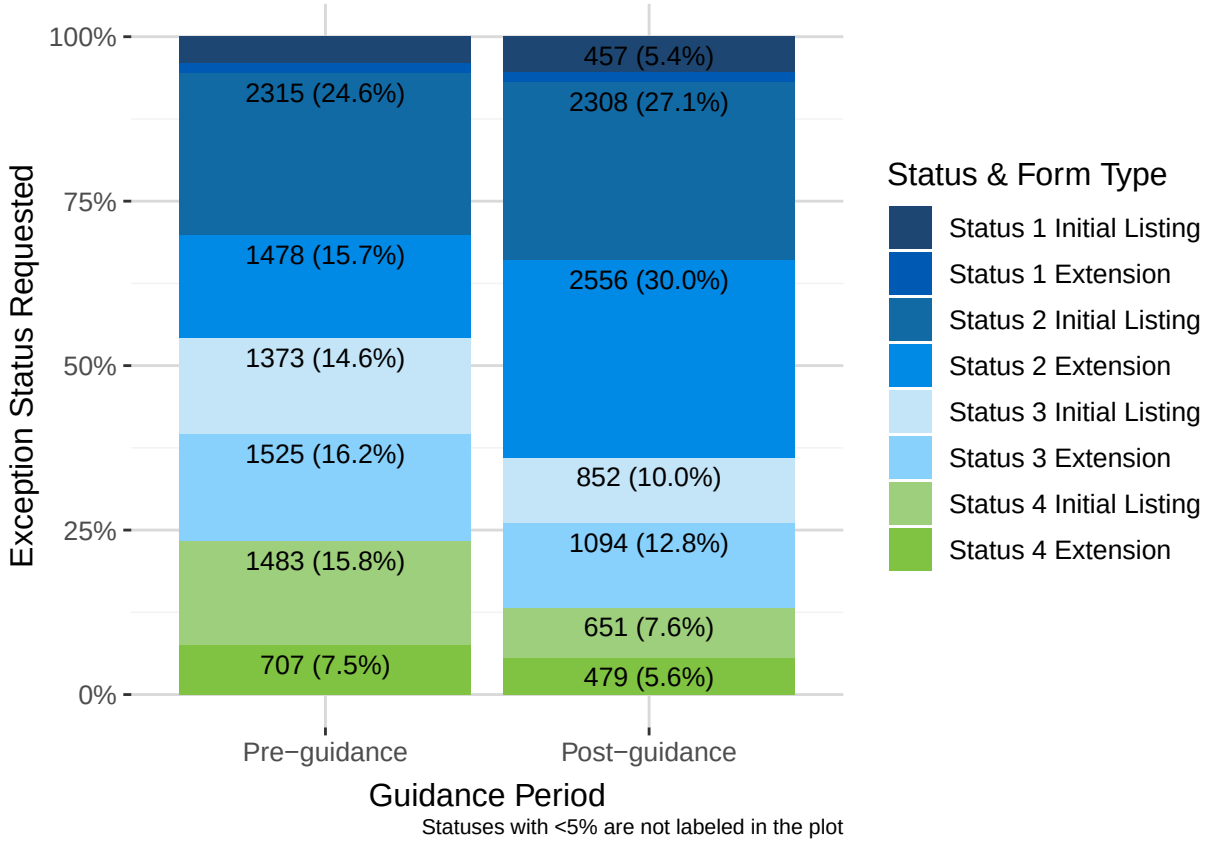


**Figure 50. Number of justification forms by medical urgency status, form type, and guidance period**

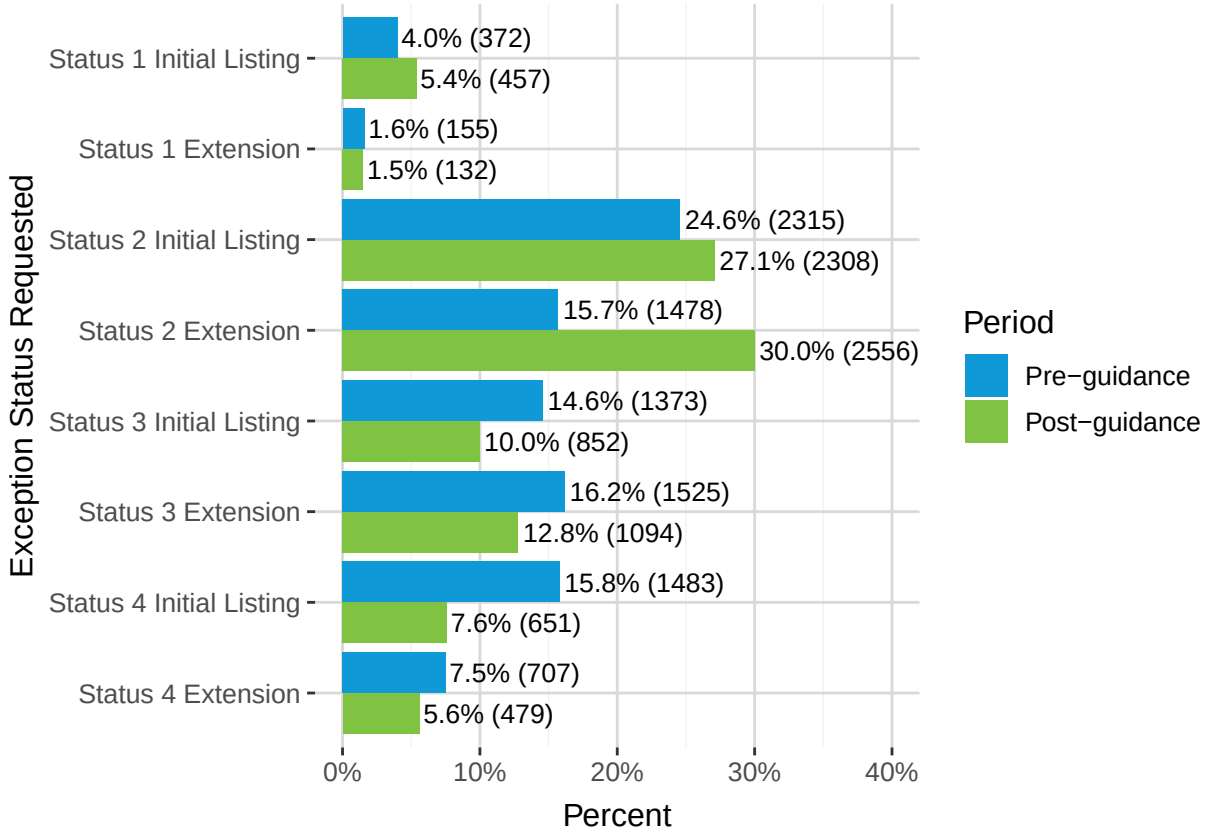



**Table 26. Number of justification forms by medical urgency status, form type, and guidance period**

| | Number of Justification Forms | | | | | |
|---|---|---|---|---|---|---|
| | Pre-guidance | | Post-guidance | | Overall | |
| **Adult Heart Status and Form Type** | **N** | **%** | **N** | **%** | **N** | **%** |
| Status 1 Initial Listing | 372 | 4.0% | 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**

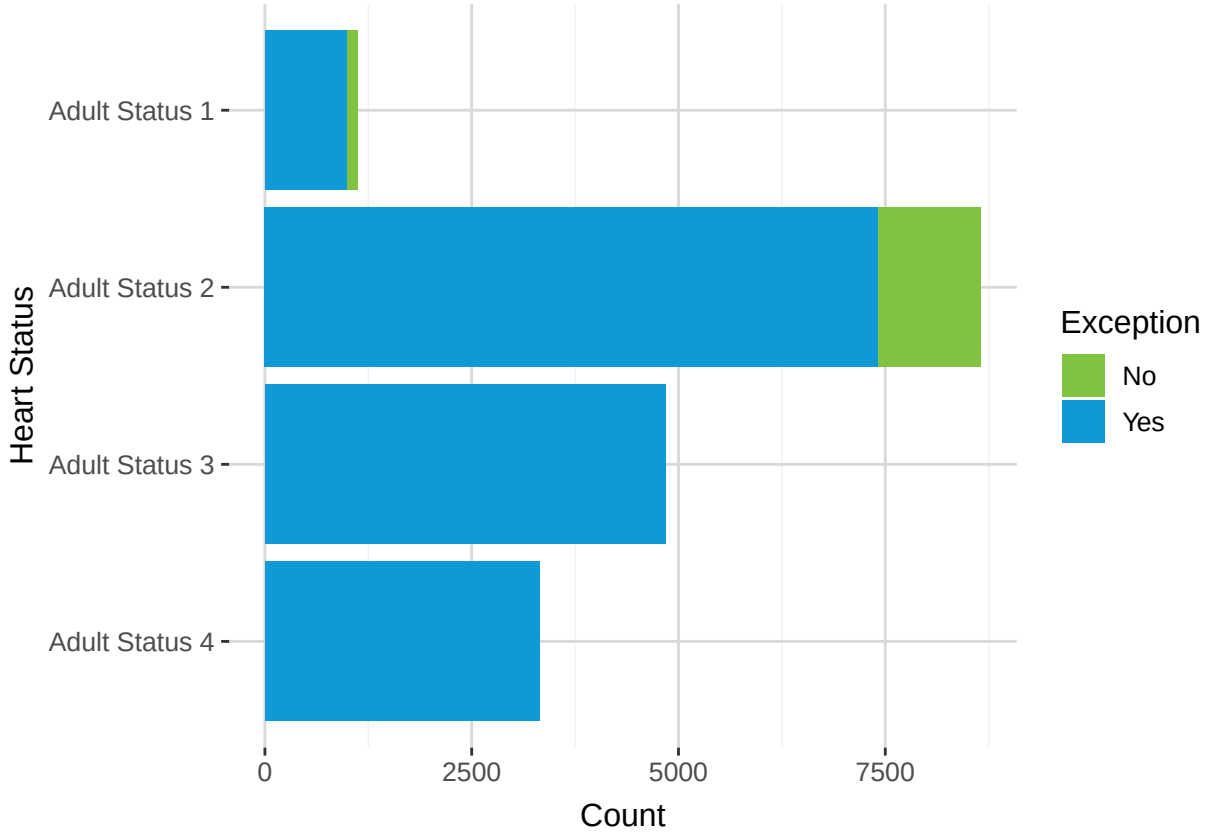


**Figure 52. Number of justification forms by exception versus standard review, heart status, and guidance period**

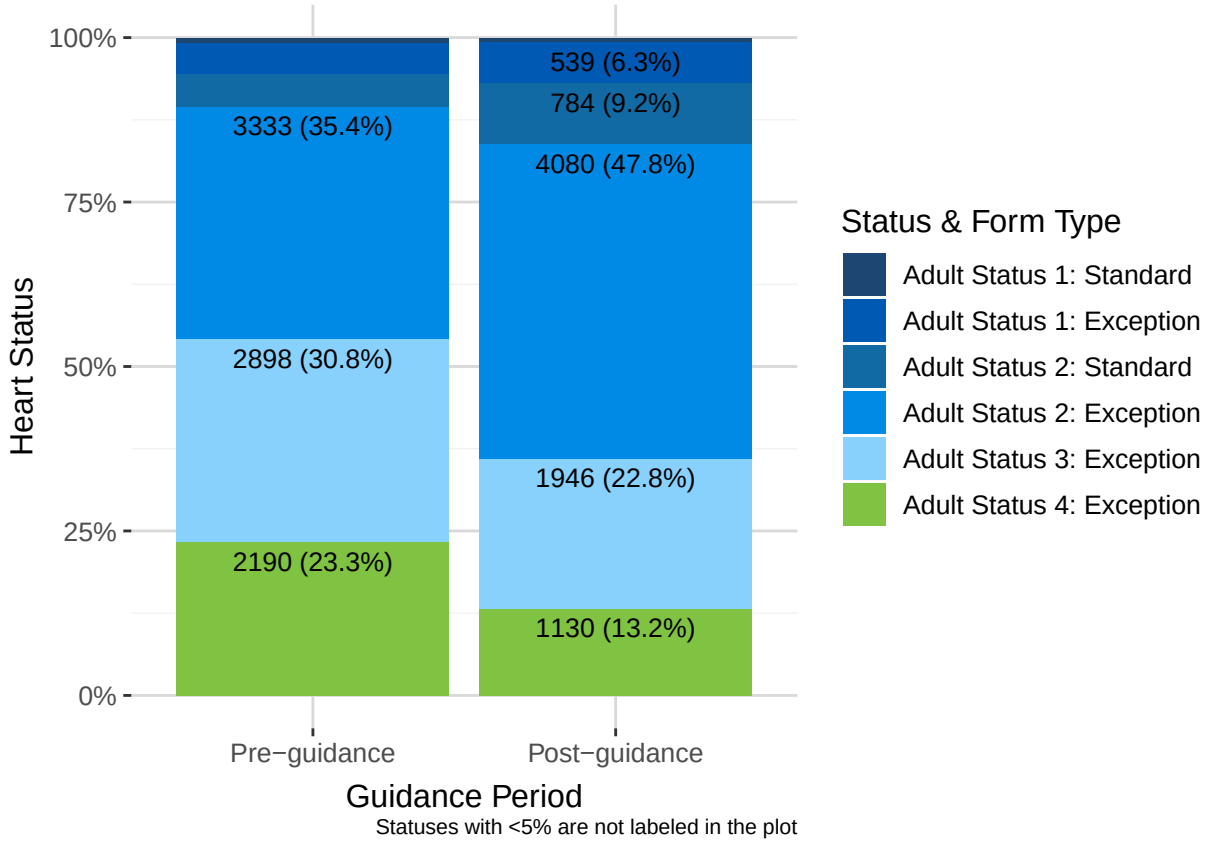


**Figure 53. Number of justification forms by exception versus standard review, heart status, and guidance period**

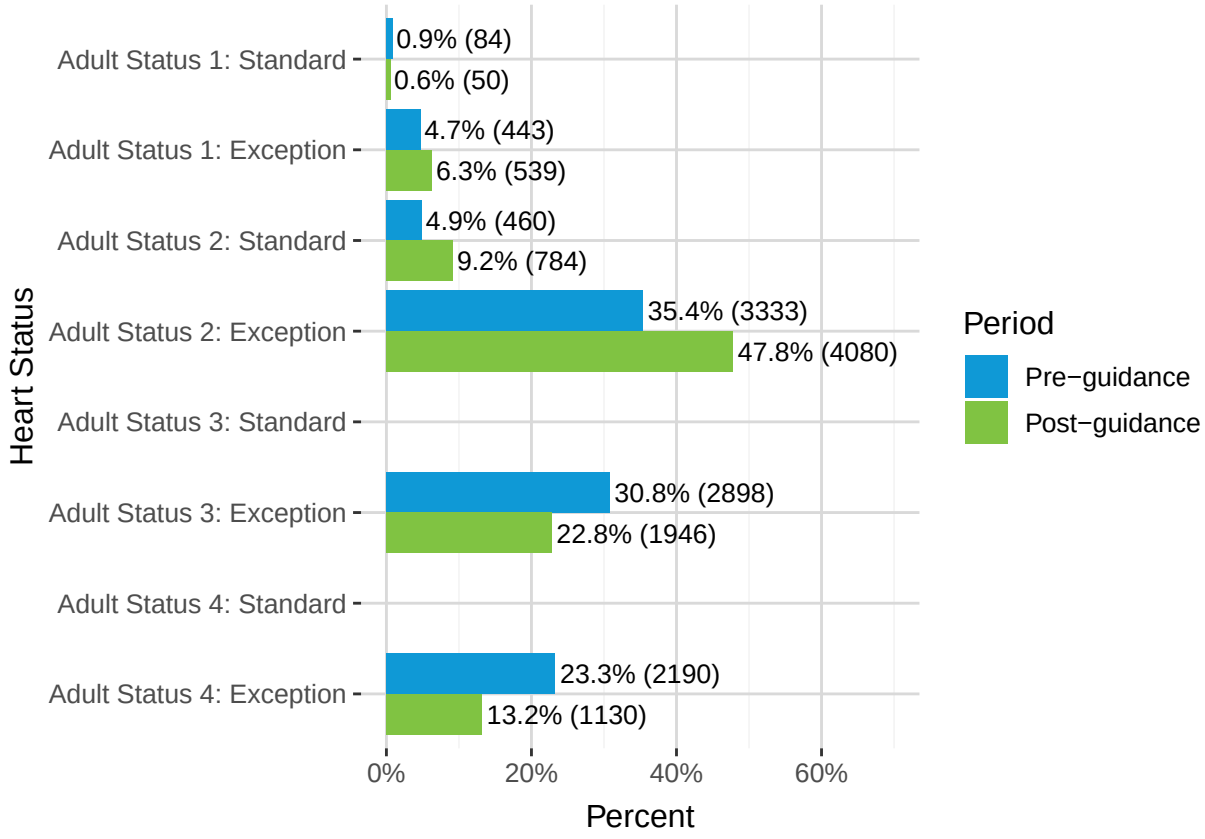



**Table 27. Number of justification forms by exception versus standard review and medical urgency status**

| | Exception Request | | |
|---|---|---|---|
| **Adult Heart Status** | **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**

| | | Exception Request | | |
|---|---|---|---|---|
| **Guidance Period** | **Adult Heart Status** | **No** | **Yes** | **Total** |
| **Pre-guidance** | Adult Status 1 | 84 (15.9%) | 443 (84.1%) | 527 (100.0%) |
| | Adult Status 2 | 460 (12.1%) | 3333 (87.9%) | 3793 (100.0%) |
| | Adult Status 3 | 0 (0.0%) | 2898 (100.0%) | 2898 (100.0%) |
| | Adult Status 4 | 0 (0.0%) | 2190 (100.0%) | 2190 (100.0%) |
| | **Total** | **544 (5.8%)** | **8864 (94.2%)** | **9408 (100.0%)** |
| **Post-guidance** | Adult Status 1 | 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**

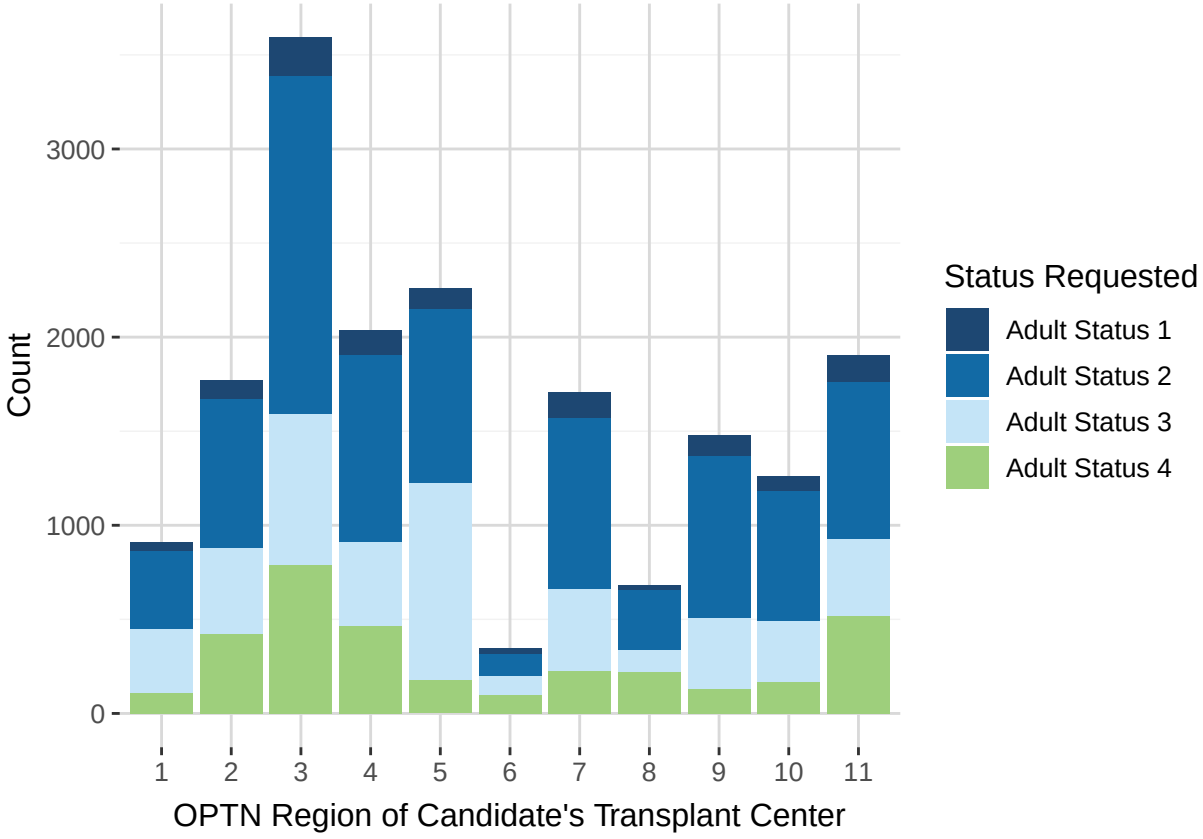



**Table 29. Number of initial and extension justification forms by medical urgency status and OPTN region of candidate's transplant center**

| 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**

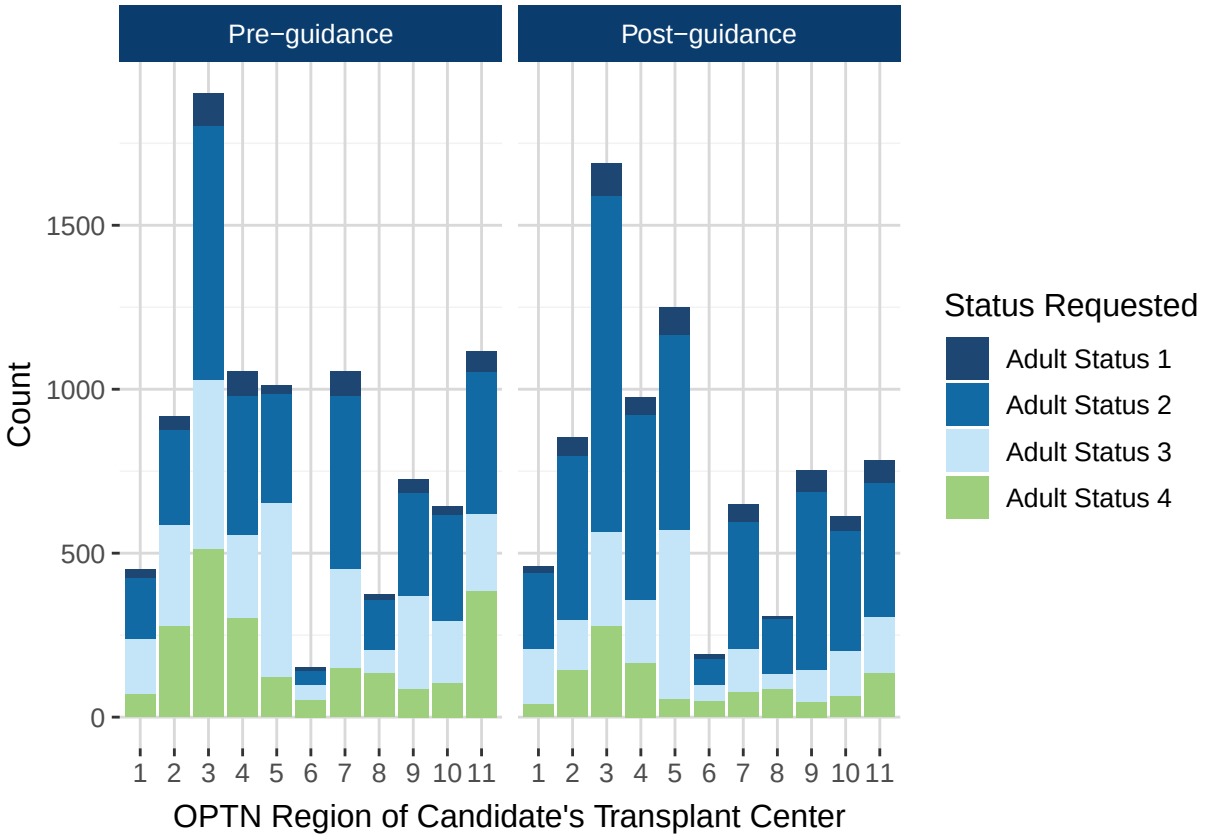


**Table 30. Number of initial and extension justification forms by medical urgency status, OPTN region of candidate's transplant center, and guidance period**

| 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%) | 829 (100.0%) |
| | 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**

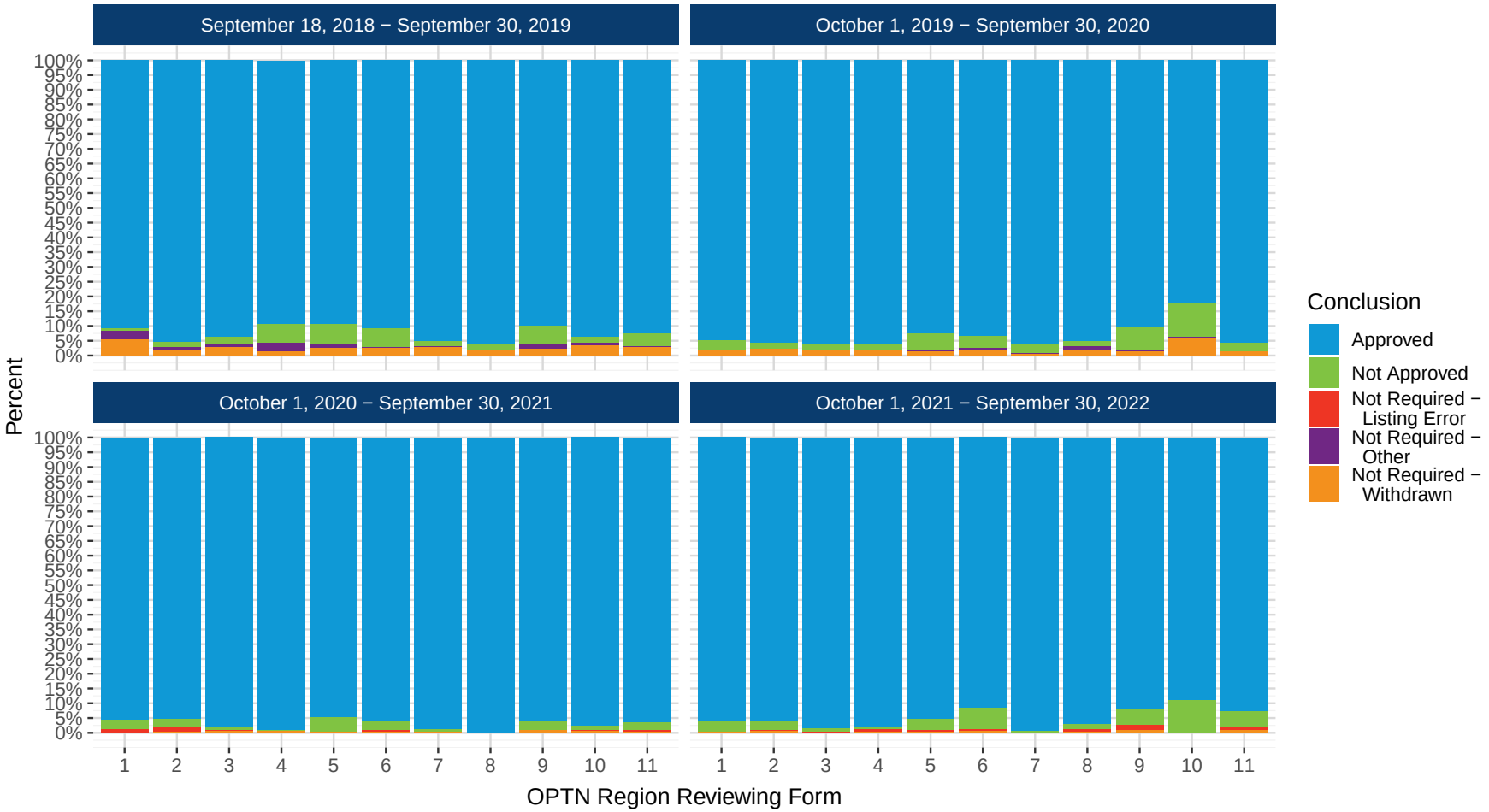


**Table 34. Conclusions from justification forms by region reviewing request**

| 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**

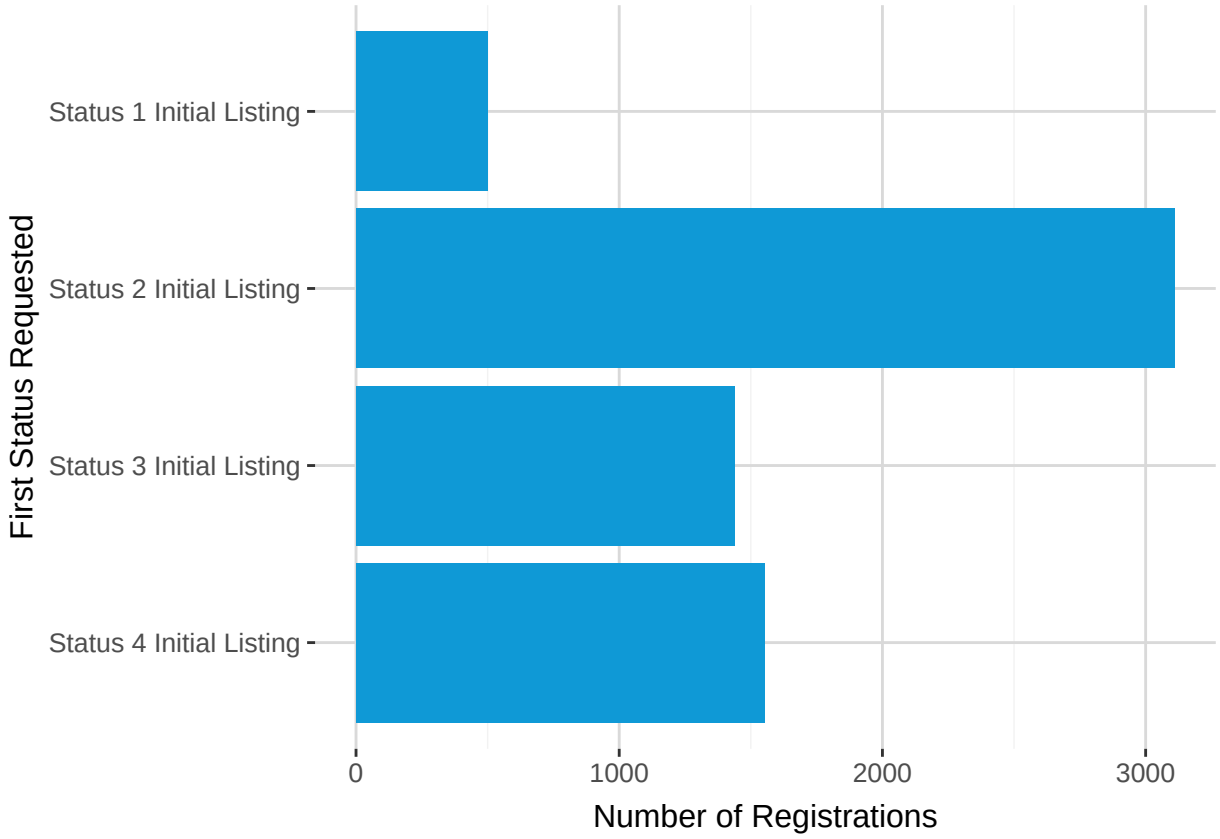



**Table 35. Number of registrations with an exception by first status requested**

| 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**

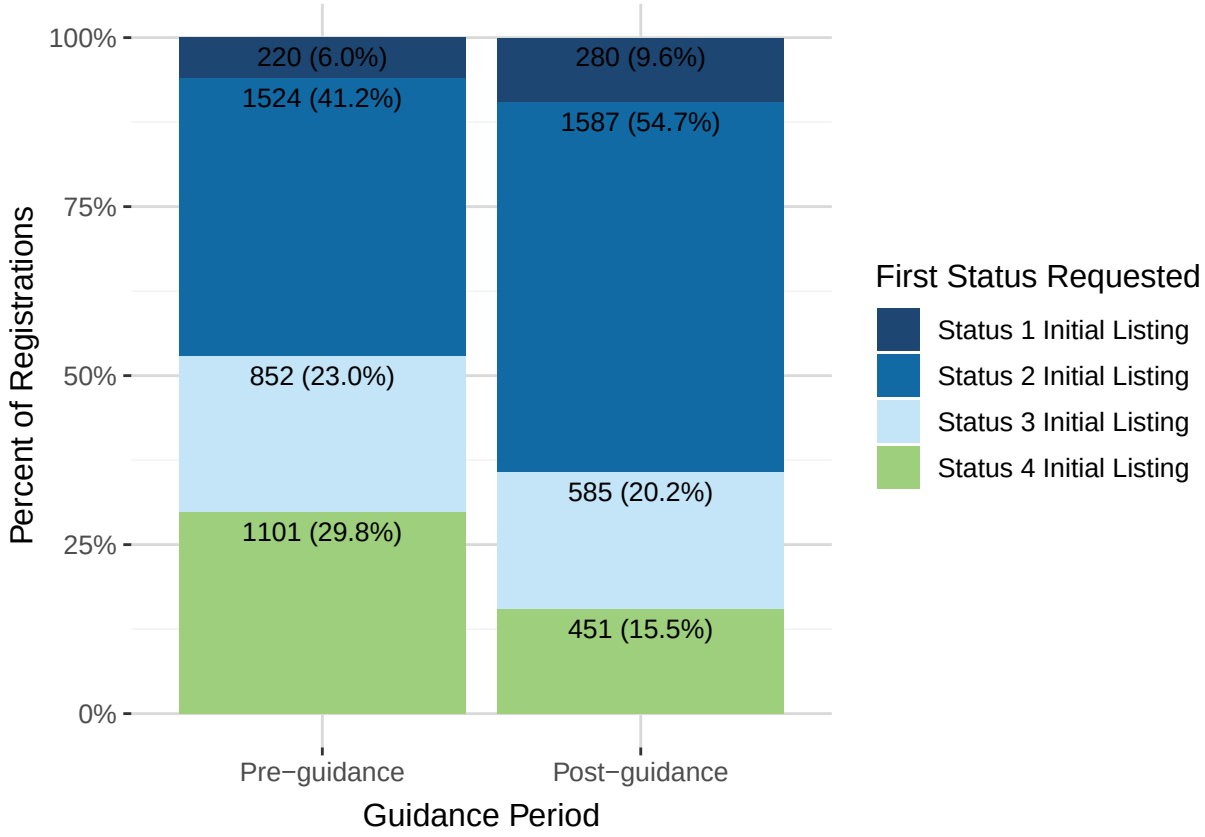


**Figure 59. Number of registrations with an exception by first status requested and guidance period**

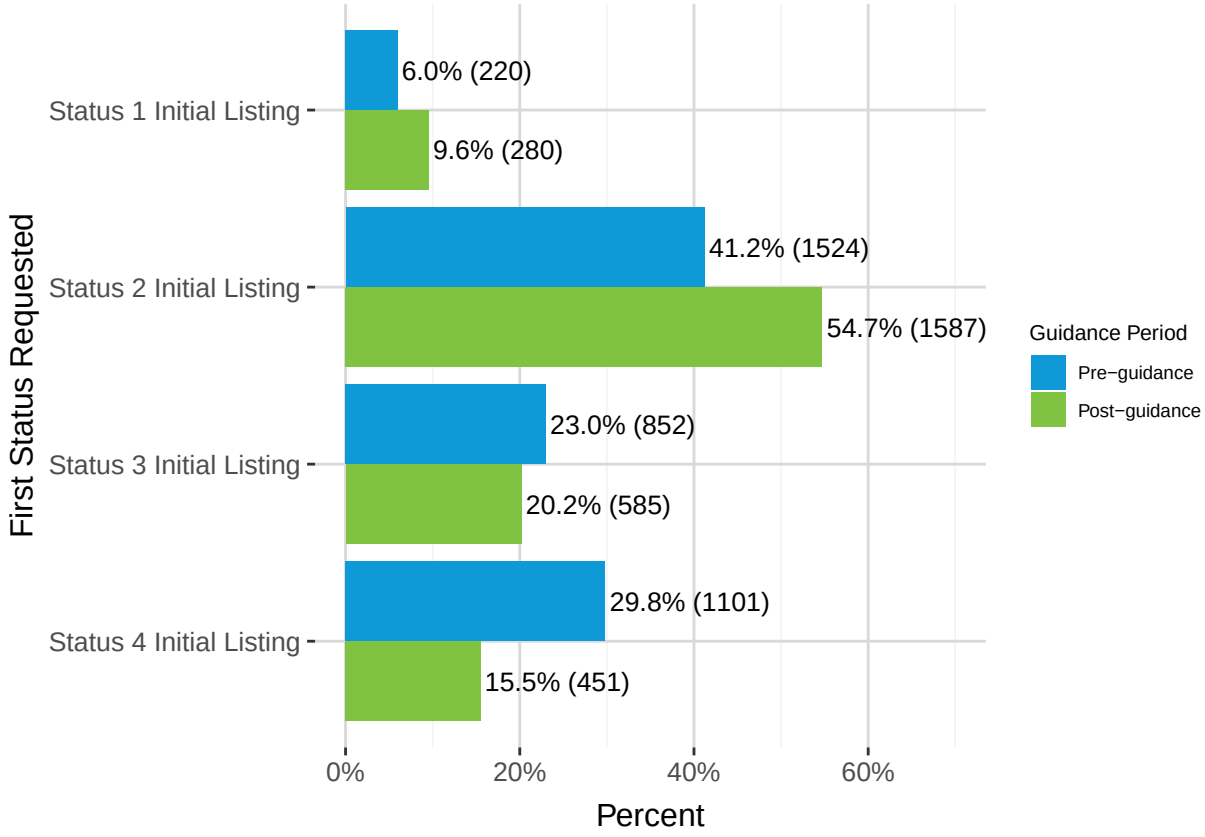



**Table 36. Number of registrations with an exception by first status requested and guidance period**

| | Number and Percent of Registrations | | | | | |
|---|---|---|---|---|---|---|
| | Pre-guidance | | Post-guidance | | Overall | |
| **Status Requested** | **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**

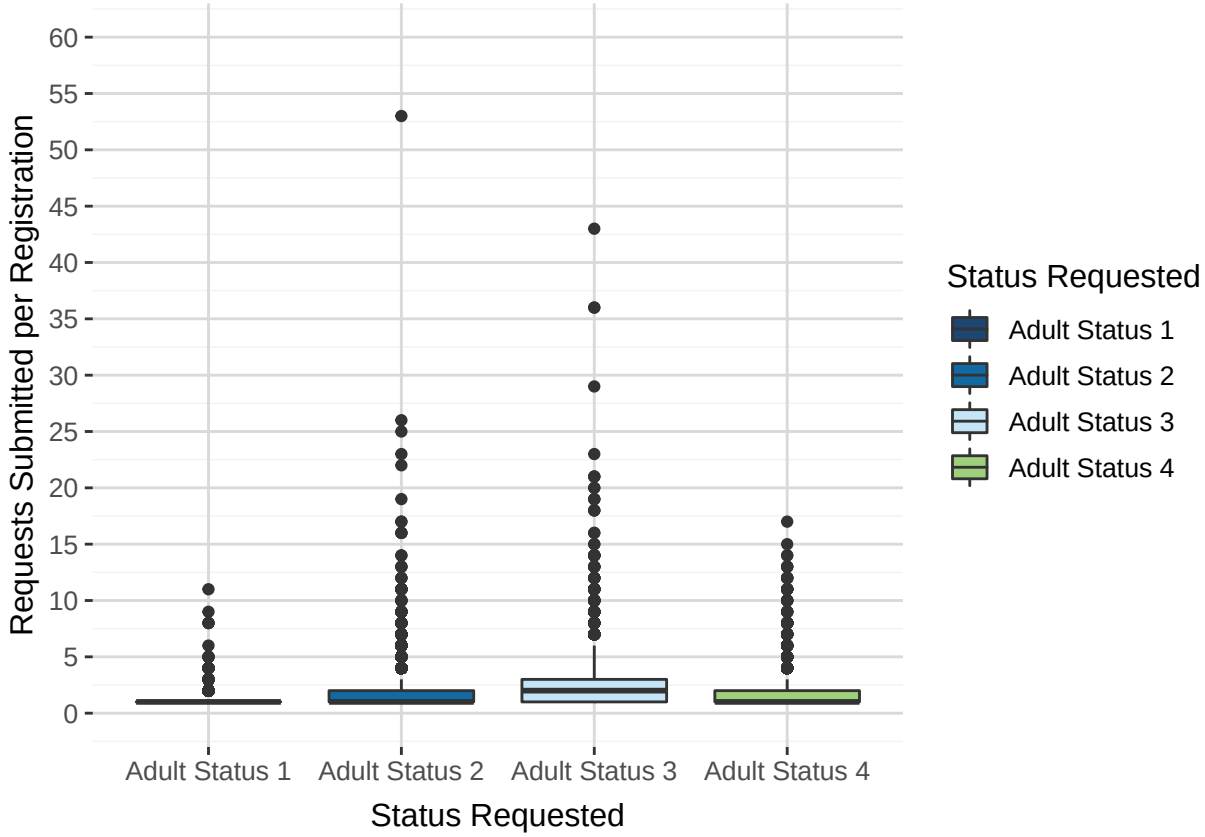



**Table 37. Summary of exception requests submitted per registration by medical urgency status**

| 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**

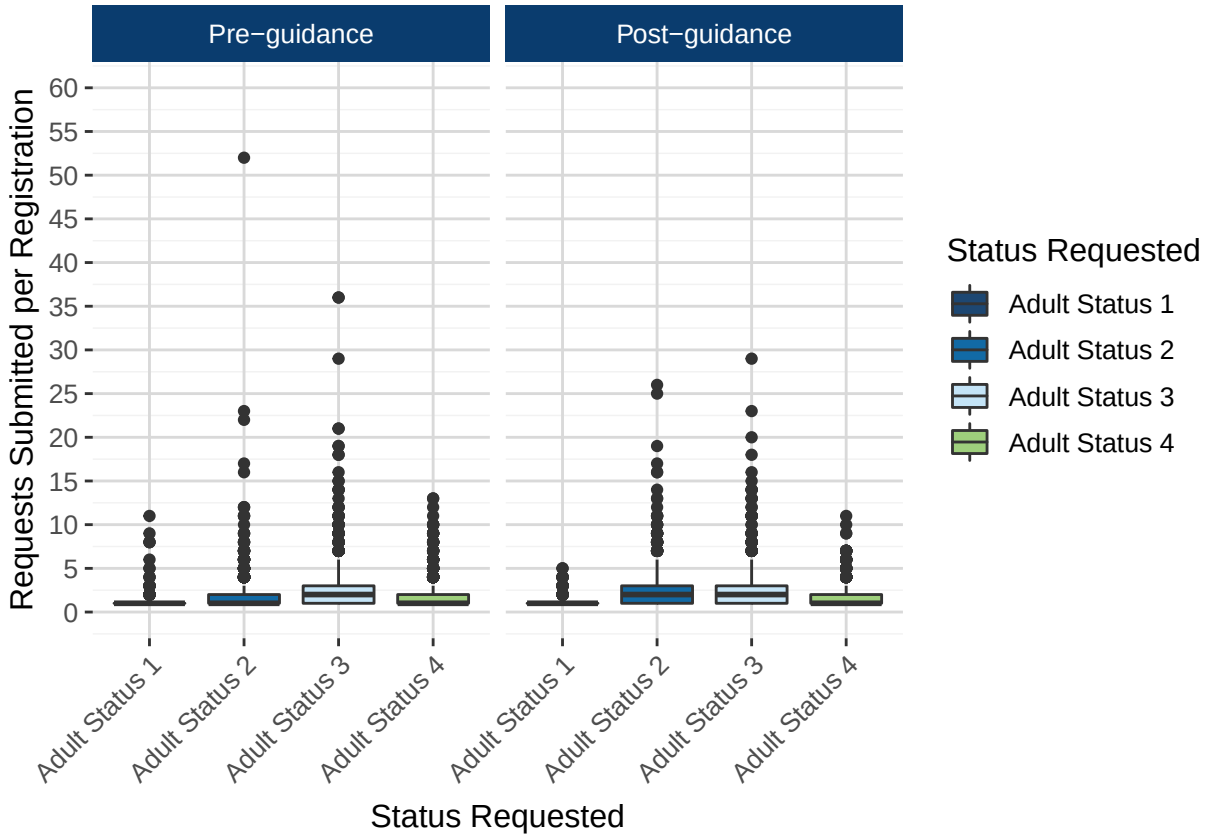



**Table 38. Summary of exception requests submitted per registration by medical urgency status and guidance period**

| 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**

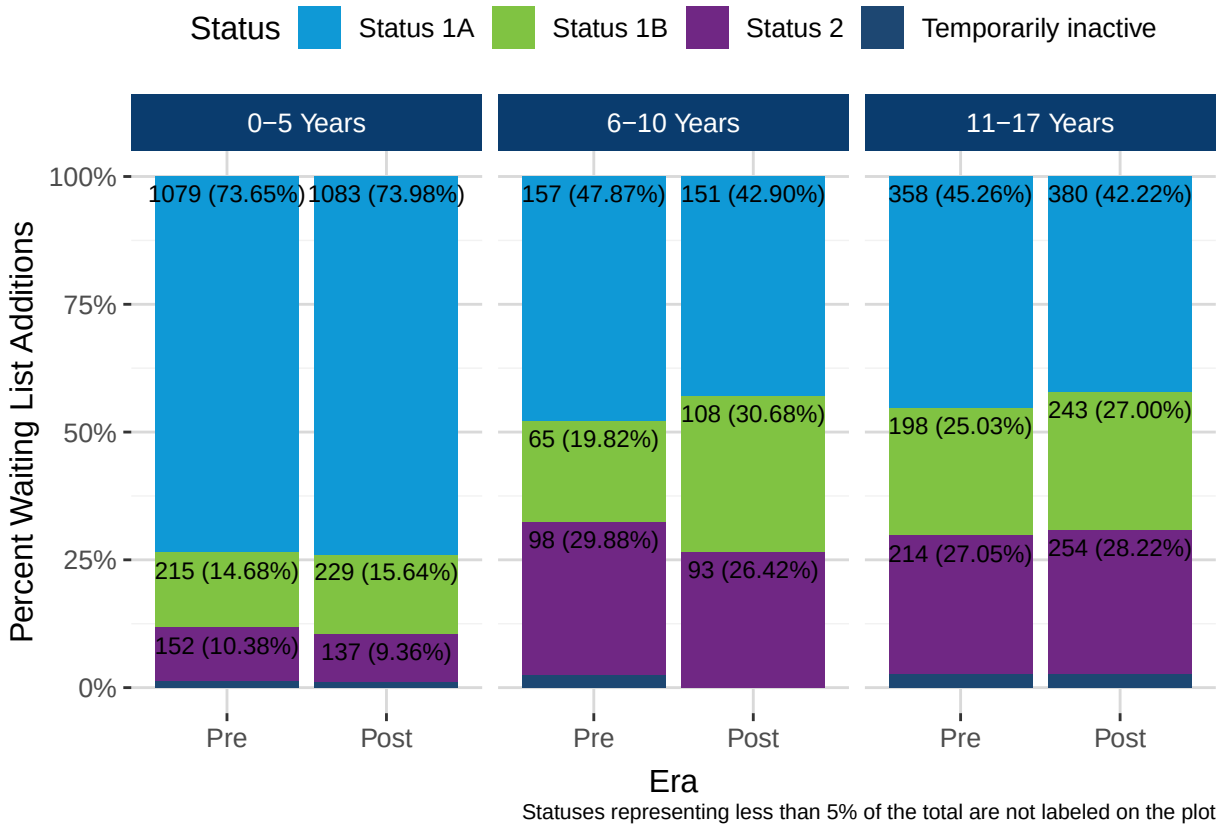



Figure 62 and Table 39 summarize the count and percent of pediatric heart waiting list registrations by status and age group. The proportion of pediatric additions did not differ substantially between eras; the largest shift was an increase in pediatric Status 1B and decrease in pediatric Status 2 candidates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

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

| | | Pre-Policy | | Post-Policy | |
|---|---|---|---|---|---|
| **Age Group** | **Status** | **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**

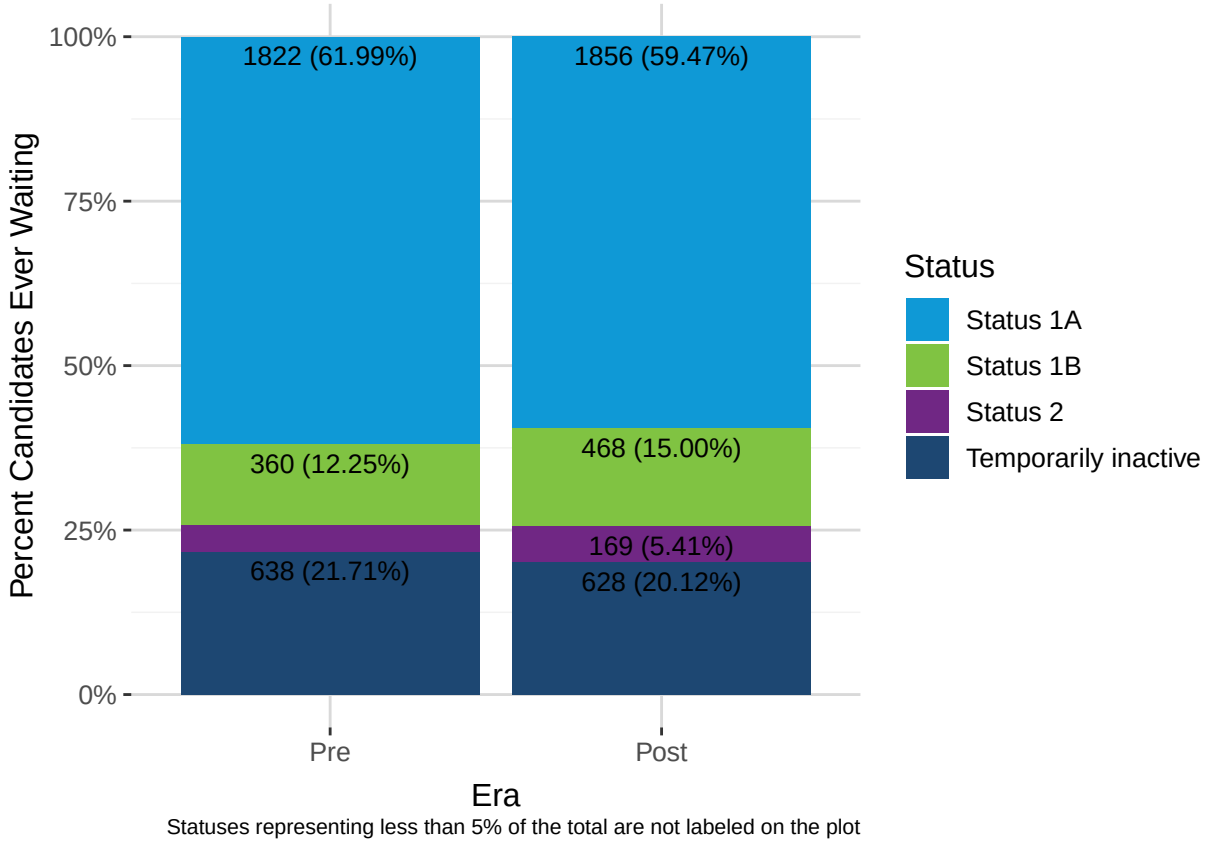



Figure 63 shows the proportion of pediatric heart candidates ever waiting by medical urgency status both pre- and post-implementation. There was very little change in the medical urgency status composition of the pediatric heart waiting list after changes to the adult heart allocation system were implemented.

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

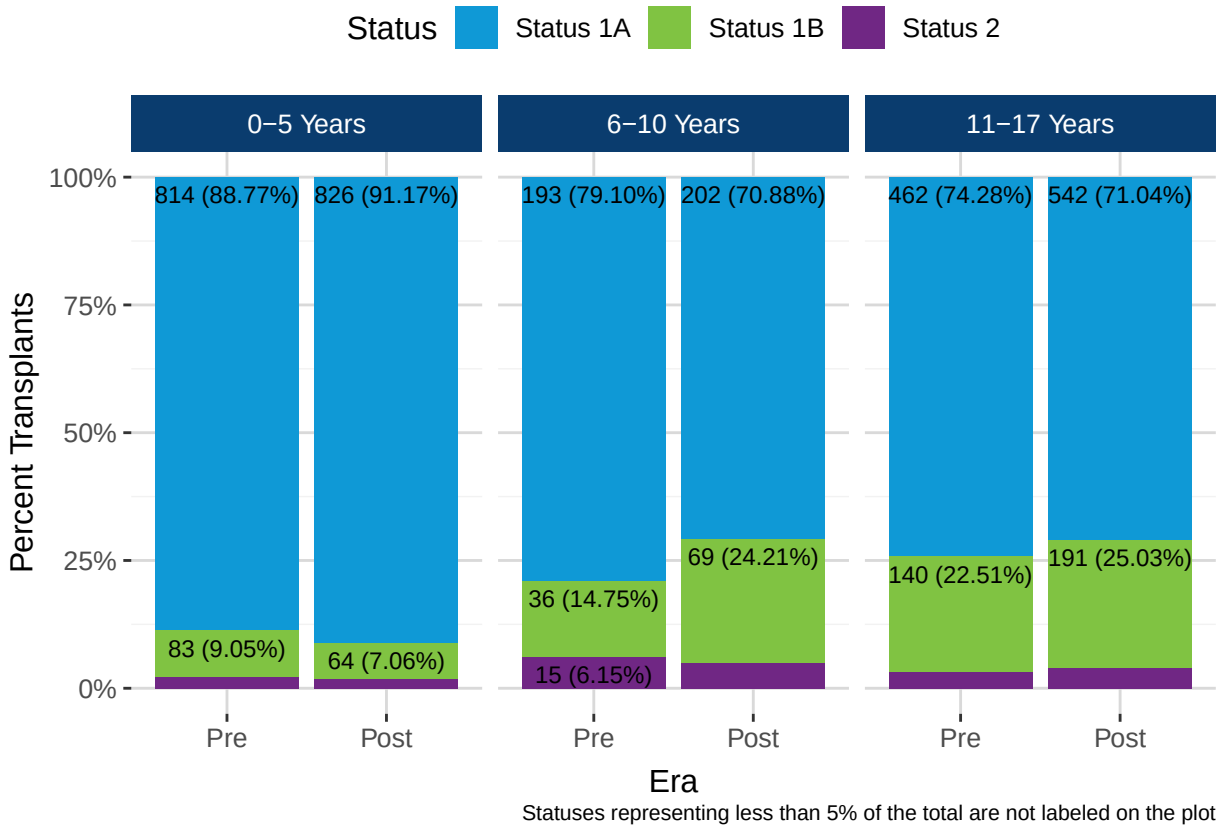



Figure 64 and Table 40 summarize the proportion of pediatric heart candidates transplanted by medical urgency status both pre- and post-implementation. There was little change in the proportion of medical urgency statuses transplanted for pediatric candidates aged 0-5 years and 11-17 years. The proportion 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**

| | | Pre-Policy | | Post-Policy | |
|---|---|---|---|---|---|
| **Age Group** | **Status** | **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**

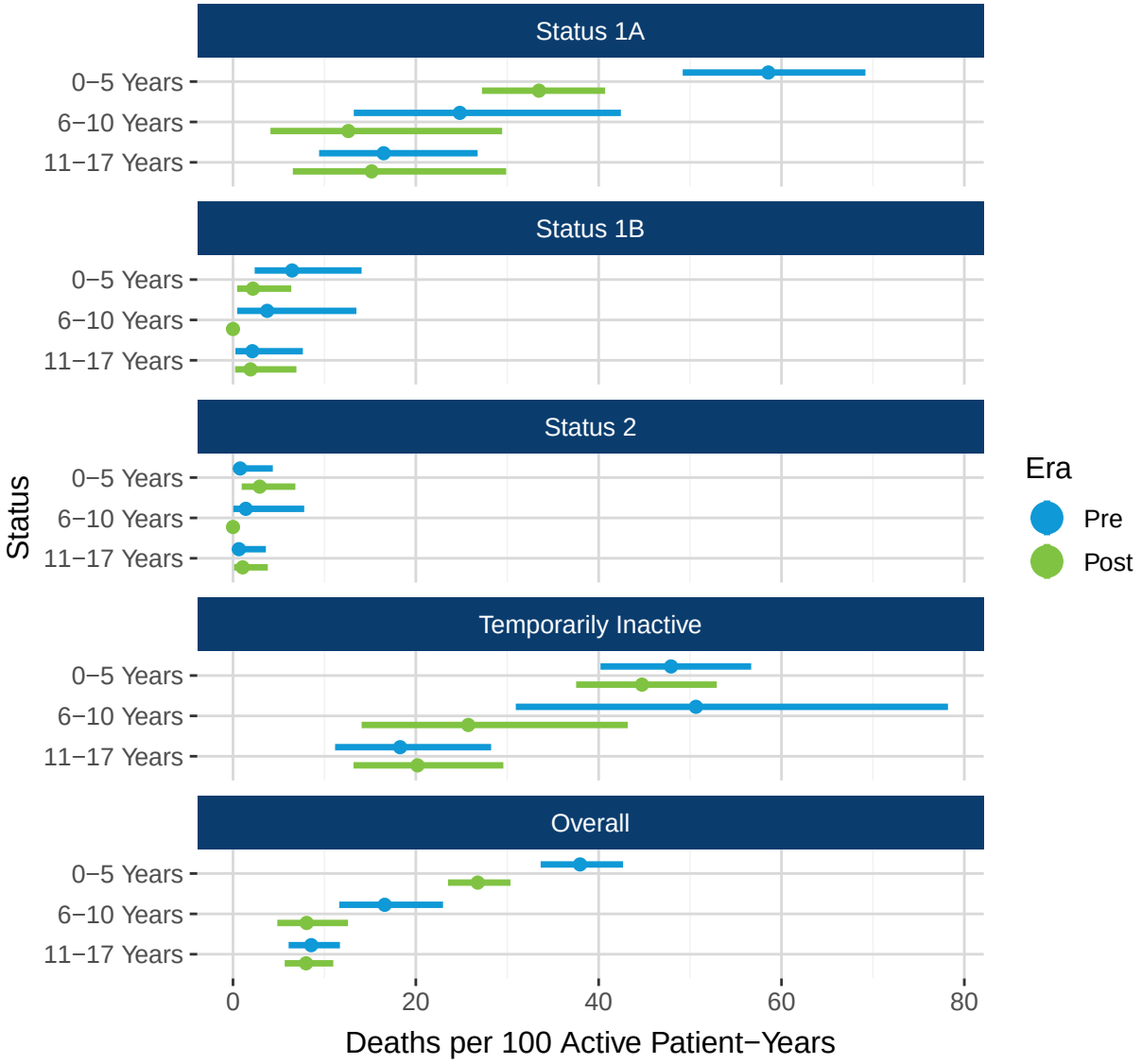



Figure 65 shows the deaths per 100 patient-years for pediatric heart candidates pre- and post-implementation by medical urgency status and era. There was a significant decrease in the number of deaths per 100 patient-years for pediatric candidates aged 0-5 years post-policy.

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**

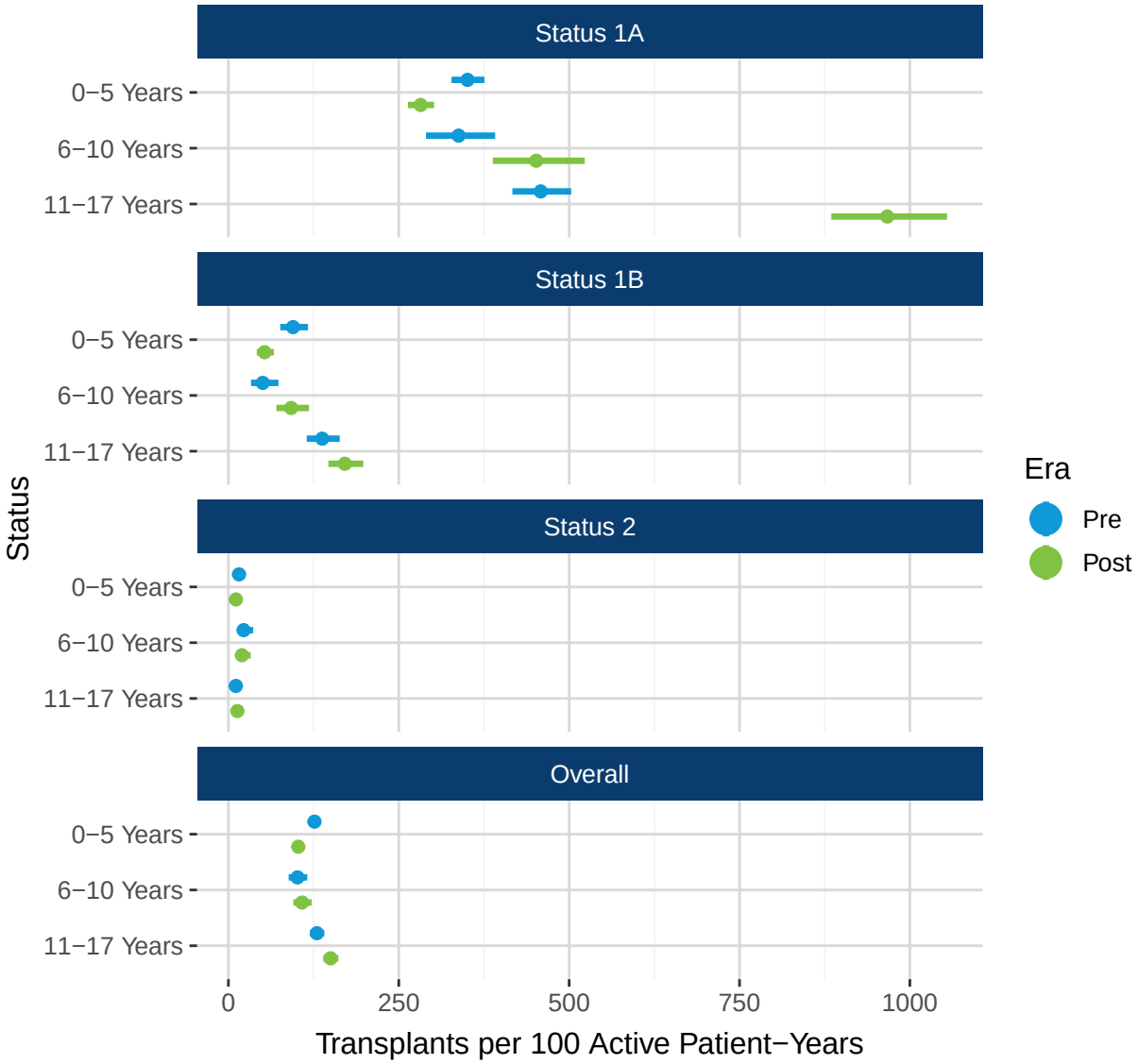



Figure 66 shows the number of transplants per 100 patient-years for pediatric heart candidates by age group, medical urgency status, and era. Post-implementation, the number of transplants per 100 patient-years was significantly higher for Status 1A pediatric candidates 11-17 years old. Conversely, the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