Final Report

OPTN Thoracic Committee | Descriptive Data Request

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

DHHS Contract No. 250-2019-00001C
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Background/Purpose

On October 18, 2018 the OPTN implemented modifications to the adult heart allocation system. These modifications were made on the recommendation of the Thoracic Organ Transplantation Committee (the Committee) and were intended to better stratify the most medically urgent heart transplant candidates, reflect the increased use of mechanical circulatory support devices (MCSD) and prevalence of MCSD complications, and address geographic disparities in access to donors among heart transplant candidates. The implementation involved creating new adult heart medical urgency statuses and altering how organs should be 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 should evaluate exception requests. Historically, Regional Review Boards reviewed exceptions from their own OPTN region. When the new adult heart allocation policy went into effect this was changed such that OPTN regions were assigned to review exceptions from other OPTN regions.

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

Strategic Plan Goal or Committee Project Addressed

Improve equity in access to heart transplants

Committee Request

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

- Waiting list additions stratified by:
  - Medical urgency status
  - Region
  - Medical urgency status within Region
- Transplants stratified by:
  - Medical urgency status
  - Region
  - Medical urgency status within Region
  - Zone (DSA, Zone A, Zone B, etc.)
- Utilization of deceased donor hearts stratified by:
  - Donor age
  - Region
- Exception requests stratified by:
  - Medical urgency status
  - Region
  - Medical urgency status within Region

Additional metrics specified in the monitoring plan (e.g. waiting list mortality, post-transplant survival) are omitted due to a small sample size or because insufficient time has passed to draw conclusions. They may be presented in a later report once a sufficient amount of data has been gathered.

Data

Data Sources: These analyses use data from the OPTN waitlist, the Deceased Donor Registration (DDR) form, the Transplant Candidate Registration (TCR) form, and the Transplant Recipient Registration (TRR) form. Analyses are based on OPTN data as of April 12, 2019 and are subject to change based on future data submission or correction.

Cohort:

- Adults (age >= 18) added only to the heart waiting list between October 18, 2017 and February 17, 2018 (pre) or between October 18, 2018 and February 17, 2019 (post)
- Adult (age >= 18) candidates ever waiting only on the heart waiting list between October 18, 2017 and February 17, 2018 (pre) or between October 18, 2018 and February 17, 2019 (post)
- Adult (age >=18) deceased donor heart recipients transplanted between October 18, 2017 and February 17, 2018 (pre) or between October 18, 2018 and February 17, 2019 (post)
- Adult (age >= 18) deceased donors recovered between October 18, 2017 and February 17, 2018 (pre) or between October 18, 2018 and February 17, 2019 (post)
- Adult (age >= 18) heart and heart-lung exception requests (initial or extension) submitted between September 18, 2018 and February 17, 2019. This report includes forms submitted to the RRB as well as standard extension forms that are required by policy to go to the RRB.

Waitlist

These analyses examine differences between two waiting list cohorts: the pre-implementation cohort, composed of 1313 registrations added to the heart waiting list between October 18, 2017 and February 17, 2018; and the post-implementation cohort, composed of 1252 registrations added between October 18, 2018 and February 17, 2019.

Figure 1. Adult Heart Waiting List Registrations Added by Week

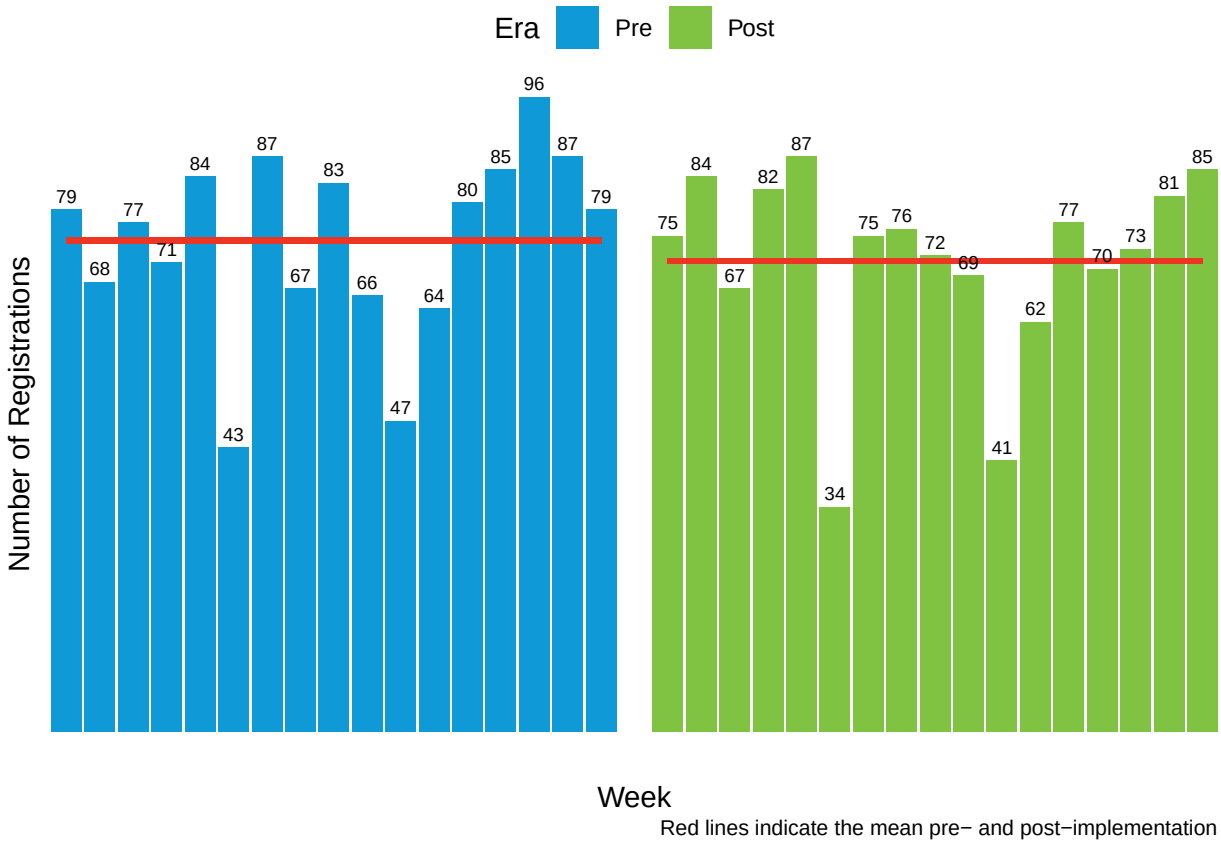


Figure 1 shows the number of registrations added to the heart waiting list by week pre- and post-implementation. While the number of registrations added varies by week, overall the number of registrations added per week fell slightly after the new allocation policy was implemented, from a mean of 74 per week pre-implementation to a mean of 71 per week post-implementation.

Figure 2. Adult Heart Waiting List Additions by Medical Urgency Status and Era

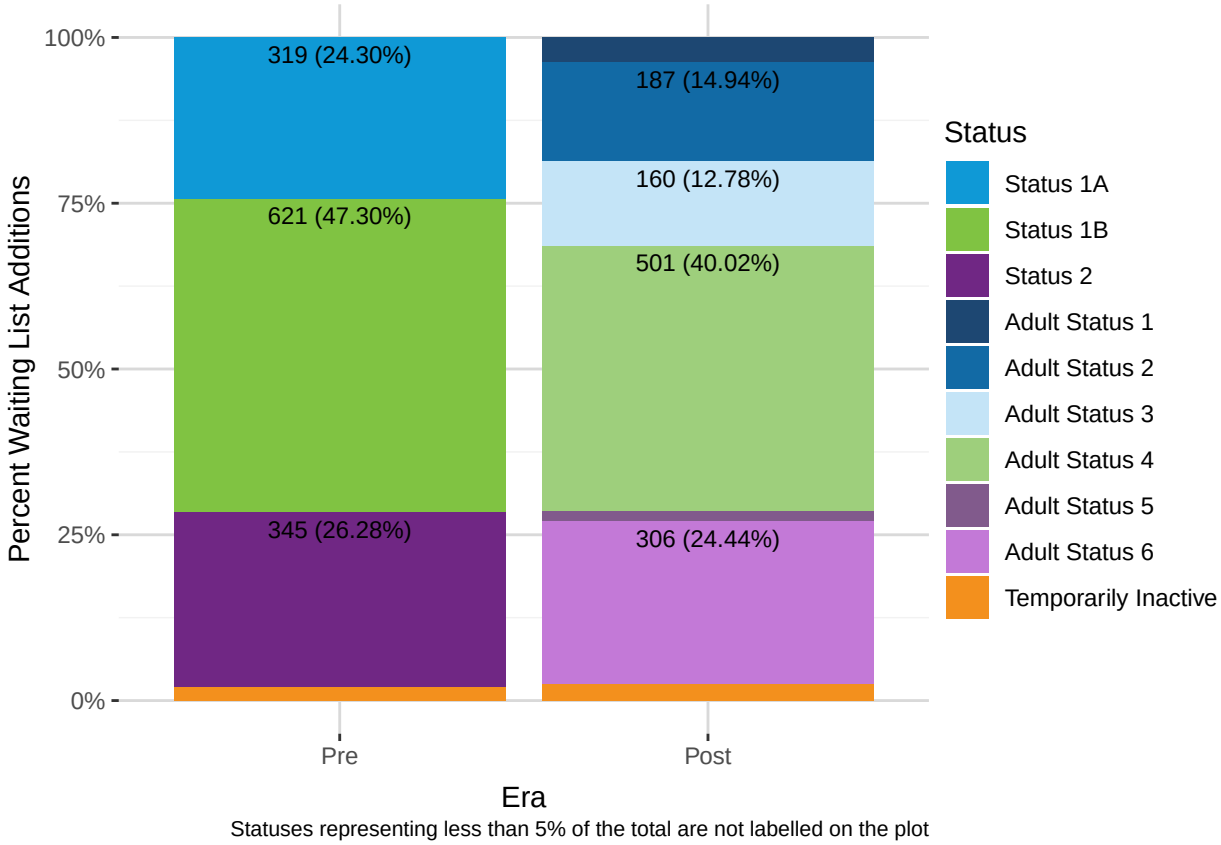


Figure 2 shows the proportion of waiting list additions pre- and post-implementation by medical urgency status. Pre-implementation most additions were made at Status 1B, while post-implementation Adult Status 4 predominated. Adult Status 6 was the second-largest group post-implementation, followed by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

Table 1 breaks down the number and percent of registrations both by medical urgency status and by equivalent medical urgency status as defined in the Data 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	319	24.30%
	Equivalent Status 1B	Status 1B	621	47.30%
	Equivalent Status 2	Status 2	345	26.28%
	Temporarily inactive	Temporarily Inactive	28	2.13%
Post	Equivalent Status 1A	Adult Status 1	46	3.67%
		Adult Status 2	187	14.94%
		Adult Status 3	160	12.78%
		Overall	393	31.39%
	Equivalent Status 1B	Adult Status 4	501	40.02%
		Adult Status 5	19	1.52%
		Overall	520	41.53%
	Equivalent Status 2	Adult Status 6	306	24.44%
		Overall	306	24.44%
	Temporarily inactive	Temporarily Inactive	33	2.64%

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

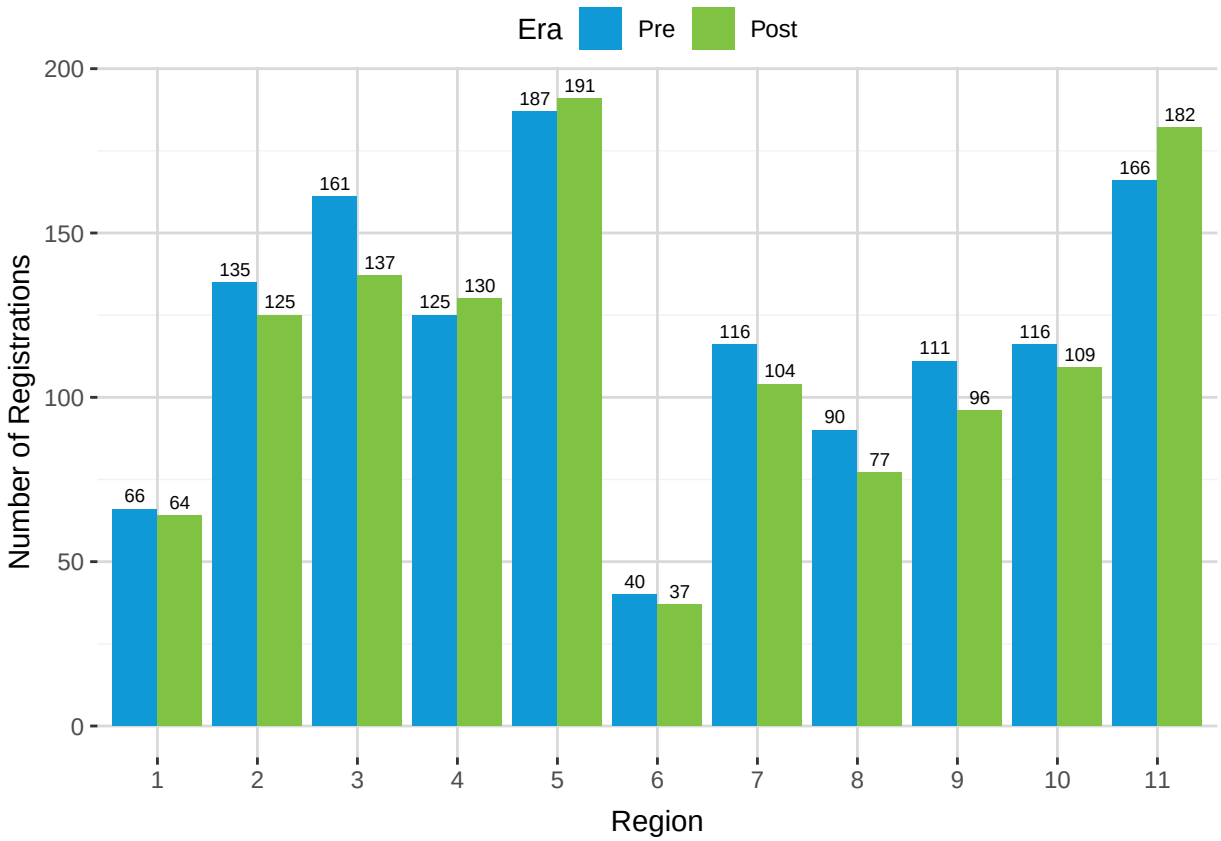
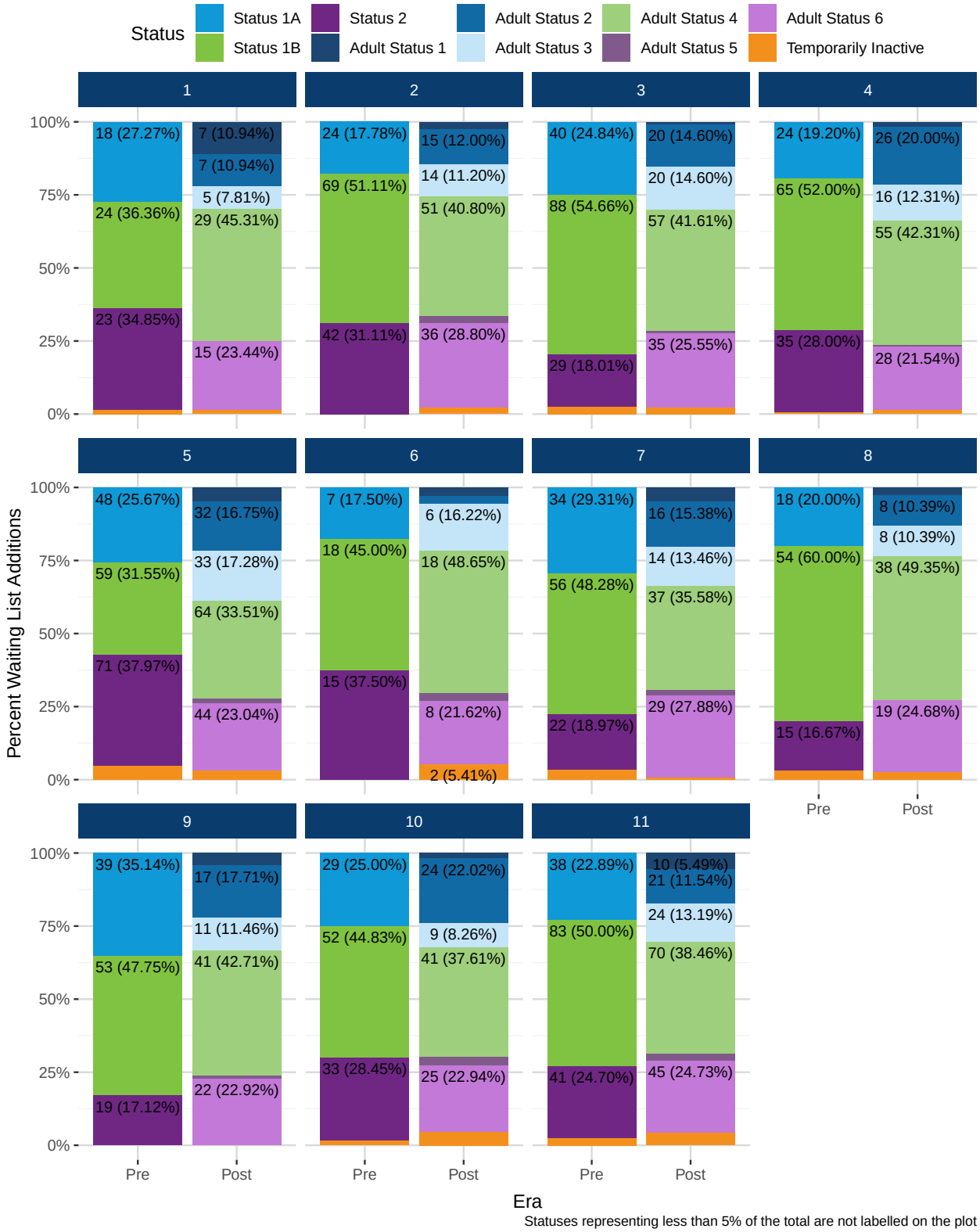


Figure 3 shows the number of adult heart waiting list registrations added by region both pre- and post-implementation. The number of waitlist additions decreased in all regions except regions 4, 5, and 11.

Figure 4 shows the number of adult heart waiting list registrations by region and medical urgency status. The proportion of registrations added at each status is similar across regions, with Adult Status 4 accounting for the largest number of post-implementation registrations in all regions and either Adult Status 5 or Temporarily Inactive the least. Post-implementation the greatest degree of variability was seen in the Adult Status 2 category, which represented over 20% of registrations in region 10 and under 5% in region 6.

Tables 2 and 3 show the count and percent of adult heart waiting list registrations by region and medical urgency status pre-implementation and post-implementation, respectively.

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



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

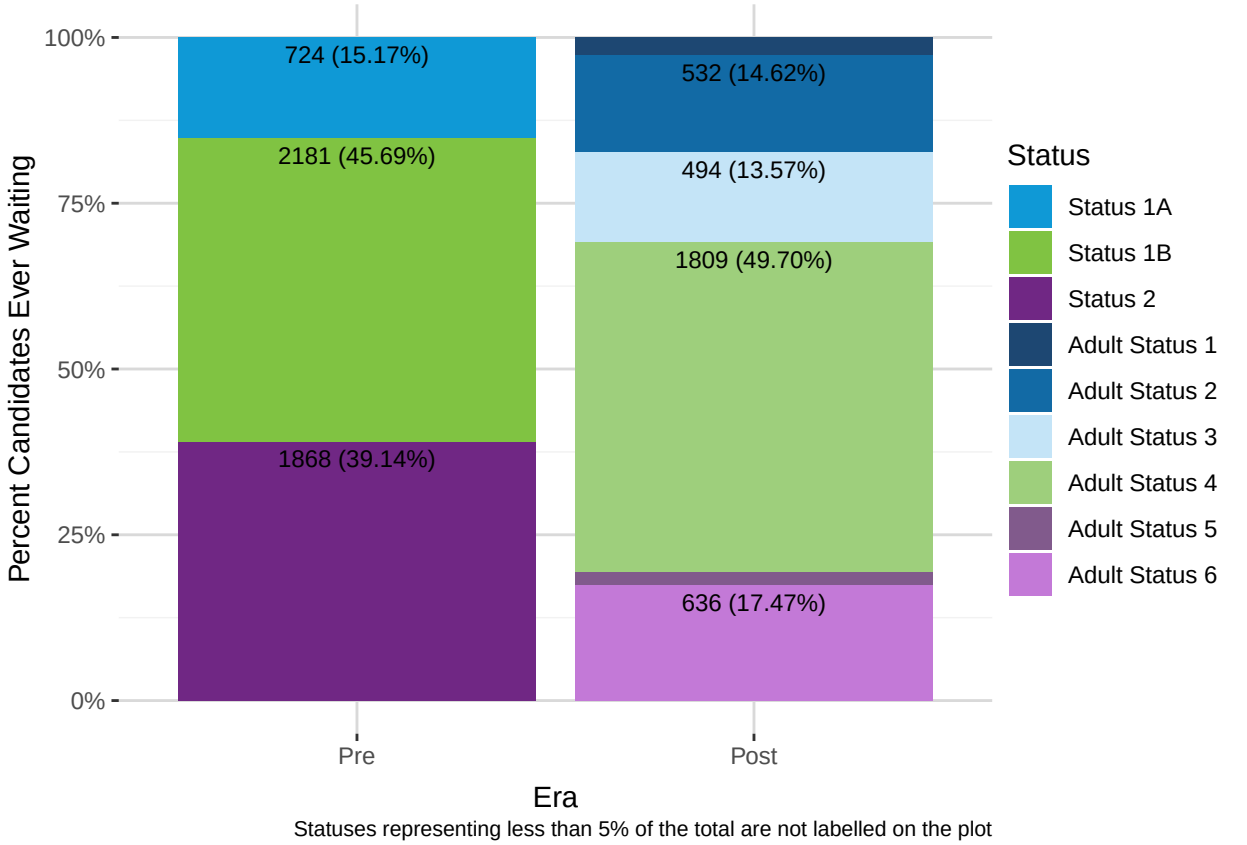
Table 2. Adult Heart Waiting List Additions by Region and Medical Urgency Status Pre-Implementation

Region		Status 1A	Status 1B	Status 2	Temporarily Inactive	Total
1	N	18	24	23	1	66
	%	27.27%	36.36%	34.85%	1.52%	100.00%
2	N	24	69	42	0	135
	%	17.78%	51.11%	31.11%	0.00%	100.00%
3	N	40	88	29	4	161
	%	24.84%	54.66%	18.01%	2.48%	100.00%
4	N	24	65	35	1	125
	%	19.20%	52.00%	28.00%	0.80%	100.00%
5	N	48	59	71	9	187
	%	25.67%	31.55%	37.97%	4.81%	100.00%
6	N	7	18	15	0	40
	%	17.50%	45.00%	37.50%	0.00%	100.00%
7	N	34	56	22	4	116
	%	29.31%	48.28%	18.97%	3.45%	100.00%
8	N	18	54	15	3	90
	%	20.00%	60.00%	16.67%	3.33%	100.00%
9	N	39	53	19	0	111
	%	35.14%	47.75%	17.12%	0.00%	100.00%
10	N	29	52	33	2	116
	%	25.00%	44.83%	28.45%	1.72%	100.00%
11	N	38	83	41	4	166
	%	22.89%	50.00%	24.70%	2.41%	100.00%

Table 3. Adult Heart Waitlist Additions by Region and Medical Urgency Status Post-Implementation

Region		Adult Status 1	Adult Status 2	Adult Status 3	Adult Status 4	Adult Status 5	Adult Status 6	Temporarily Inactive	Total
1	N	7	7	5	29	0	15	1	64
	%	10.94%	10.94%	7.81%	45.31%	0.00%	23.44%	1.56%	100.00%
2	N	3	15	14	51	3	36	3	125
	%	2.40%	12.00%	11.20%	40.80%	2.40%	28.80%	2.40%	100.00%
3	N	1	20	20	57	1	35	3	137
	%	0.73%	14.60%	14.60%	41.61%	0.73%	25.55%	2.19%	100.00%
4	N	2	26	16	55	1	28	2	130
	%	1.54%	20.00%	12.31%	42.31%	0.77%	21.54%	1.54%	100.00%
5	N	9	32	33	64	3	44	6	191
	%	4.71%	16.75%	17.28%	33.51%	1.57%	23.04%	3.14%	100.00%
6	N	1	1	6	18	1	8	2	37
	%	2.70%	2.70%	16.22%	48.65%	2.70%	21.62%	5.41%	100.00%
7	N	5	16	14	37	2	29	1	104
	%	4.81%	15.38%	13.46%	35.58%	1.92%	27.88%	0.96%	100.00%
8	N	2	8	8	38	0	19	2	77
	%	2.60%	10.39%	10.39%	49.35%	0.00%	24.68%	2.60%	100.00%
9	N	4	17	11	41	1	22	0	96
	%	4.17%	17.71%	11.46%	42.71%	1.04%	22.92%	0.00%	100.00%
10	N	2	24	9	41	3	25	5	109
	%	1.83%	22.02%	8.26%	37.61%	2.75%	22.94%	4.59%	100.00%
11	N	10	21	24	70	4	45	8	182
	%	5.49%	11.54%	13.19%	38.46%	2.20%	24.73%	4.40%	100.00%

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



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

Figure 5 shows the composition of candidates ever waiting by medical urgency status both pre- and post-implementation. The statuses shown pre-implementation are the statuses candidates held when added to the waiting list; displaying the most recent candidate status would make interpretation more difficult by showing post-implementation statuses in the pre era for those candidates who were waiting in both eras. Post-implementation statuses shown are the most recent status for each candidate in order to avoid displaying pre-implementation statuses in the post era for those candidates added before the policy implementation took effect. "Temporarily inactive" is omitted because more candidates wait at this status than are added at this status, making it difficult to compare across eras.

Pre-implementation there were a similar number of candidates waiting at Status 1B and Status 2, while post-implementation the largest group of waiting candidates was Adult Status 4, with the second-most-common status, Adult Status 6, containing substantially fewer candidates. Of the new statuses used post-implementation, Adult Status 5 had the fewest candidates ever waiting, followed by Adult Status 1.

Transplant

These analyses examine differences in transplants between two cohorts: the pre-implementation cohort, composed of 918 adult heart transplants performed between October 18, 2017 and February 17, 2018; and the post-implementation cohort, composed of 909 adult heart transplants performed between October 18, 2018 and February 17, 2019. There were 9 more heart transplants performed in the pre-implementation cohort than in the post-implementation cohort.

Figure 7. Adult Heart Transplants Performed by Week

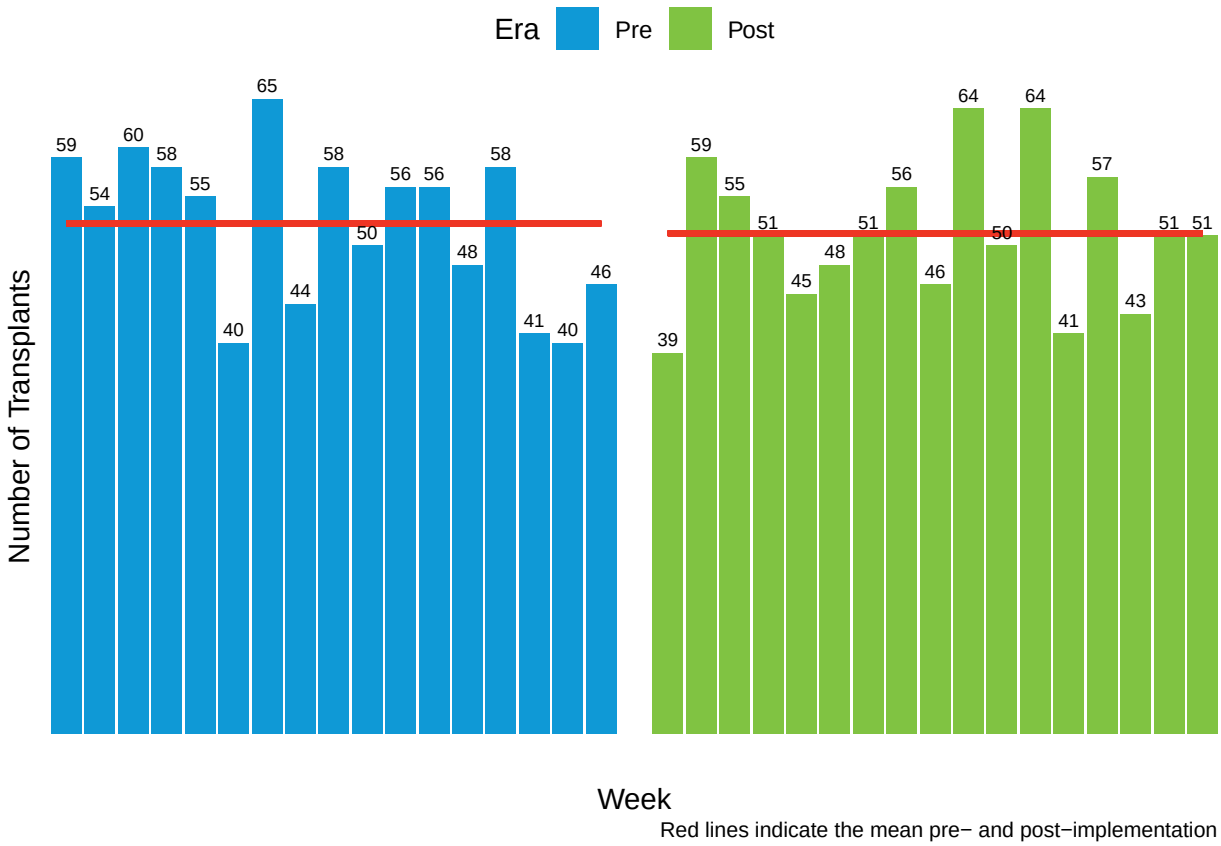
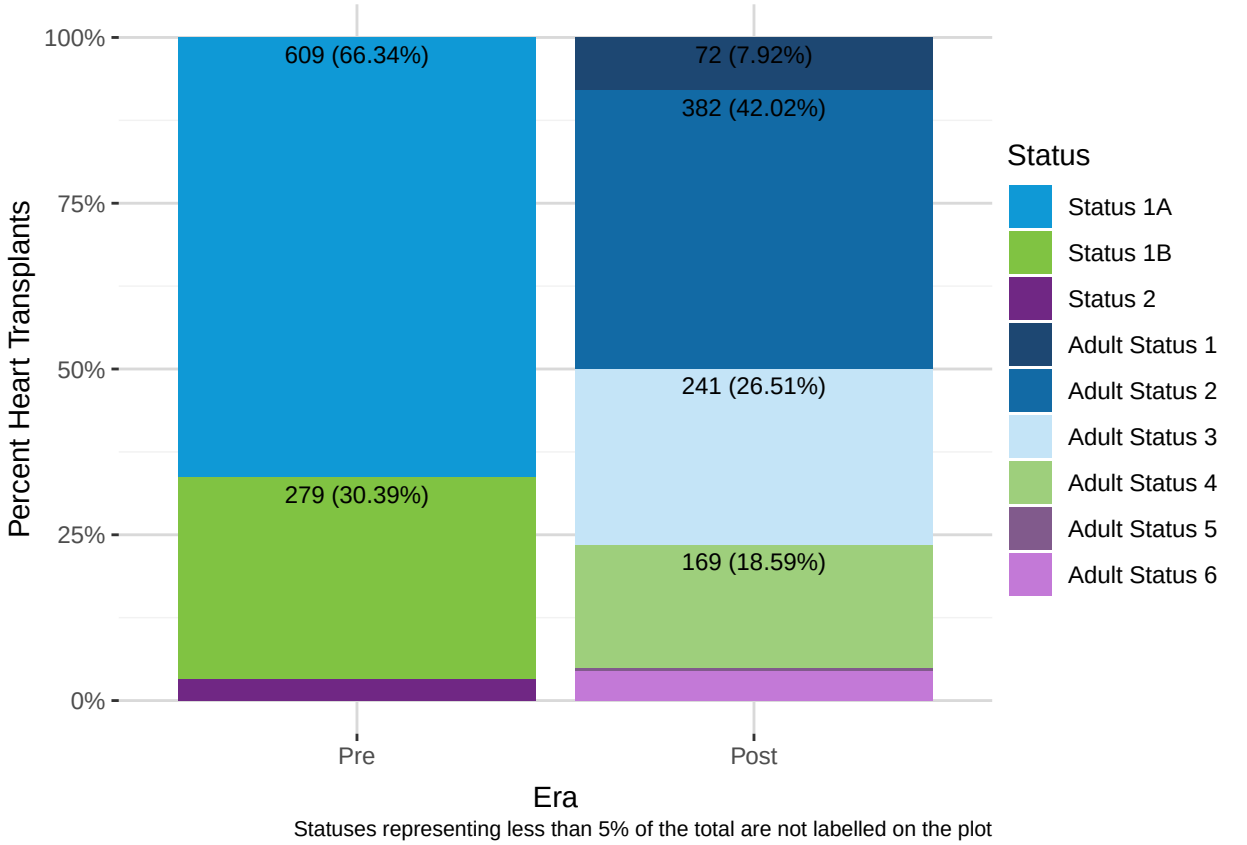


Figure 7 shows the number of adult heart transplants performed per week pre-implementation and post-implementation. The mean number of transplants was similar across the two eras, with a weekly mean of 52 pre-implementation and a weekly mean of 51 post-implementation.

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



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

Figure 8 shows the proportion of adult heart transplants performed both pre- and post-implementation by medical urgency status. Status 1A candidates received around 2/3 of all transplants pre-implementation, but no single status represented such a large fraction of transplants post-implementation. Adult Status 2 candidates received the most transplants, followed by Adult Status 3, Adult Status 4, and Adult Status 1. Post-implementation Adult Status 6 represented only 4.51% of transplants, while there were only 4 (0.44%) transplants to Adult Status 5 patients in the four months examined.

Table 4 breaks down the number and percent transplants both by medical urgency status and by equivalent medical urgency status as defined in the Data section above.

Table 4. Adult Heart Transplants by Era and Medical Urgency Status

Era	Equivalent Status	Status	N	%
Pre	Equivalent Status 1A	Status 1A	609	66.34%
	Equivalent Status 1B	Status 1B	279	30.39%
	Equivalent Status 2	Status 2	30	3.27%
Post	Equivalent Status 1A	Adult Status 1	72	7.92%
		Adult Status 2	382	42.02%
		Adult Status 3	241	26.51%
		Overall	695	76.46%
	Equivalent Status 1B	Adult Status 4	169	18.59%
		Adult Status 5	4	0.44%
		Overall	173	19.03%
	Equivalent Status 2	Adult Status 6	41	4.51%
		Overall	41	4.51%

Figure 9. Adult Heart Transplants by Region and Era

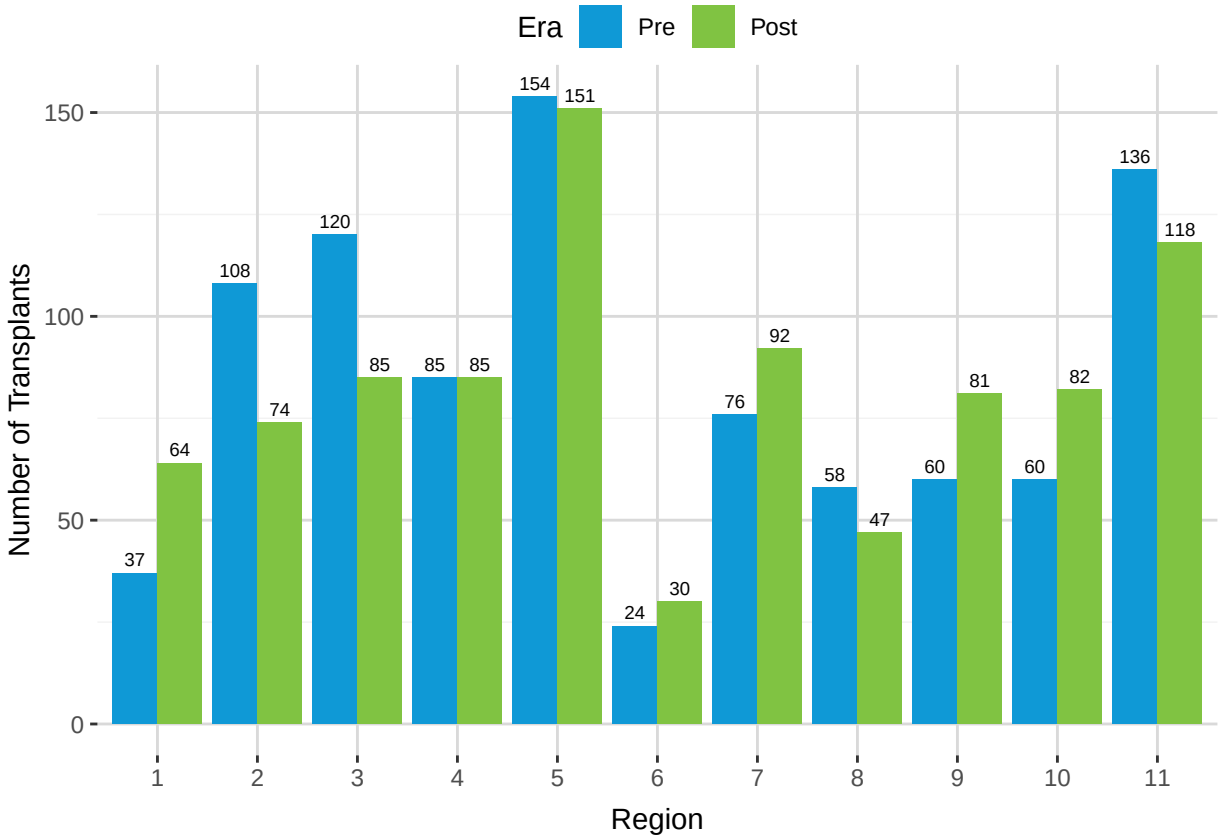
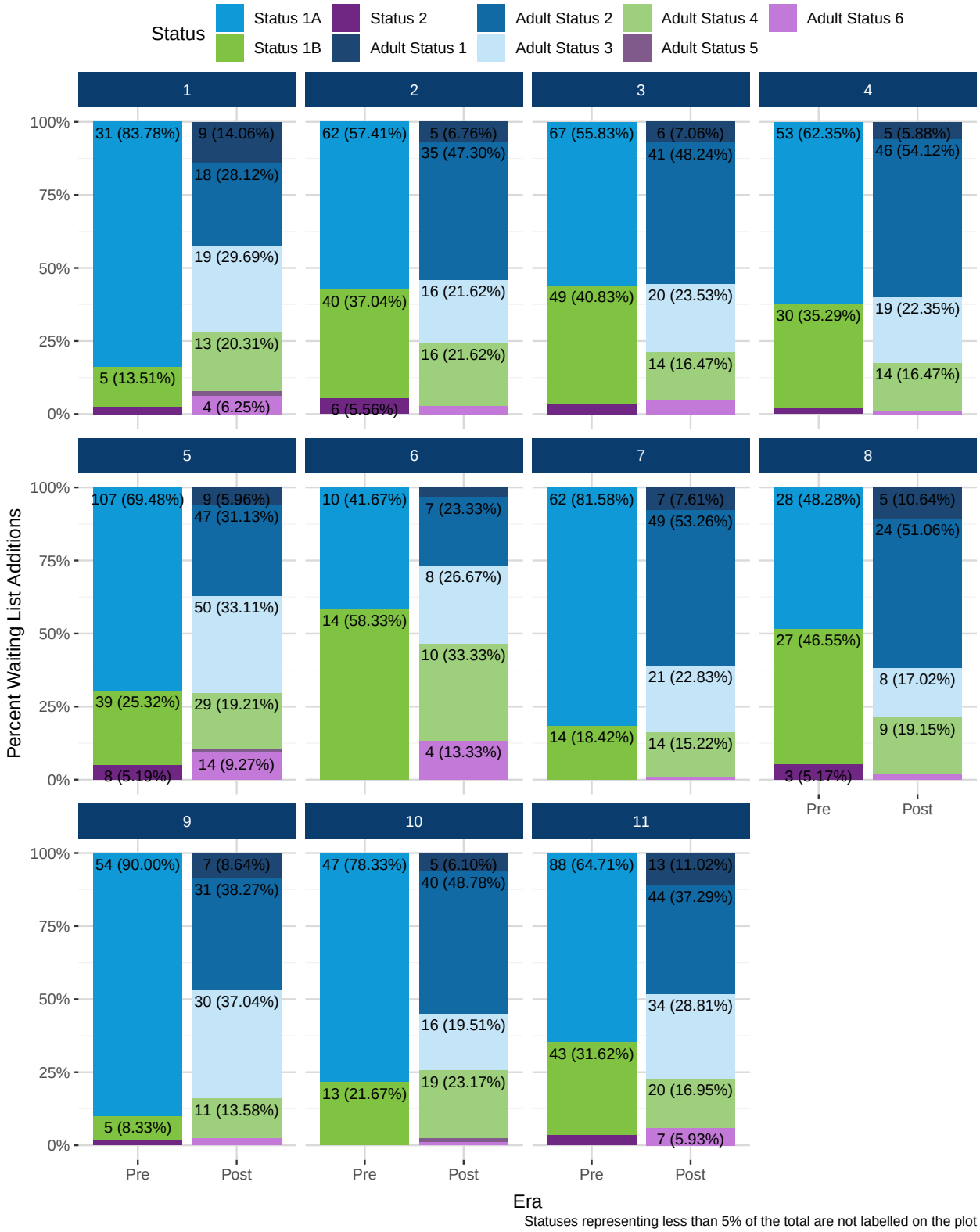


Figure 9 shows the number of adult heart transplants by era and region. The number of heart transplants rose in regions 1, 6, 7, 9, and 10, decreased in regions 2, 3, 5, 8, and 11, and remained the same in region 4.

Figure 10 shows the number of adult heart transplants by era, region, and medical urgency status. The distribution of statuses receiving transplants varied from region to region post-implementation, but in most regions Adult Status 2 candidates received the most transplants; in regions 1 and 5 Adult Status 3 candidates received the most transplants, while in region 6 Adult Status 4 candidates received the most transplants. The only Adult Status 5 transplants performed post-implementation were in regions 1, 5, and 10.

Tables 5 and 6 show the count and percent of adult heart waiting transplants by region and medical urgency status pre-implementation and post-implementation, respectively.

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



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

Table 5. Adult Heart Transplants by Region and Medical Urgency Status Pre-Implementation

Region		Status 1A	Status 1B	Status 2	Total
1	N	31	5	1	37
	%	83.78%	13.51%	2.70%	100.00%
2	N	62	40	6	108
	%	57.41%	37.04%	5.56%	100.00%
3	N	67	49	4	120
	%	55.83%	40.83%	3.33%	100.00%
4	N	53	30	2	85
	%	62.35%	35.29%	2.35%	100.00%
5	N	107	39	8	154
	%	69.48%	25.32%	5.19%	100.00%
6	N	10	14	0	24
	%	41.67%	58.33%	0.00%	100.00%
7	N	62	14	0	76
	%	81.58%	18.42%	0.00%	100.00%
8	N	28	27	3	58
	%	48.28%	46.55%	5.17%	100.00%
9	N	54	5	1	60
	%	90.00%	8.33%	1.67%	100.00%
10	N	47	13	0	60
	%	78.33%	21.67%	0.00%	100.00%
11	N	88	43	5	136
	%	64.71%	31.62%	3.68%	100.00%

Table 6. Adult Heart Transplants by Region and Medical Urgency Status Post-Implementation

Region		Adult Status 1	Adult Status 2	Adult Status 3	Adult Status 4	Adult Status 5	Adult Status 6	Total
1	N	9	18	19	13	1	4	64
	%	14.06%	28.12%	29.69%	20.31%	1.56%	6.25%	100.00%
2	N	5	35	16	16	0	2	74
	%	6.76%	47.30%	21.62%	21.62%	0.00%	2.70%	100.00%
3	N	6	41	20	14	0	4	85
	%	7.06%	48.24%	23.53%	16.47%	0.00%	4.71%	100.00%
4	N	5	46	19	14	0	1	85
	%	5.88%	54.12%	22.35%	16.47%	0.00%	1.18%	100.00%
5	N	9	47	50	29	2	14	151
	%	5.96%	31.13%	33.11%	19.21%	1.32%	9.27%	100.00%
6	N	1	7	8	10	0	4	30
	%	3.33%	23.33%	26.67%	33.33%	0.00%	13.33%	100.00%
7	N	7	49	21	14	0	1	92
	%	7.61%	53.26%	22.83%	15.22%	0.00%	1.09%	100.00%
8	N	5	24	8	9	0	1	47
	%	10.64%	51.06%	17.02%	19.15%	0.00%	2.13%	100.00%
9	N	7	31	30	11	0	2	81
	%	8.64%	38.27%	37.04%	13.58%	0.00%	2.47%	100.00%
10	N	5	40	16	19	1	1	82
	%	6.10%	48.78%	19.51%	23.17%	1.22%	1.22%	100.00%
11	N	13	44	34	20	0	7	118
	%	11.02%	37.29%	28.81%	16.95%	0.00%	5.93%	100.00%

Figure 12. Adult Heart Transplants by Share Type and Era

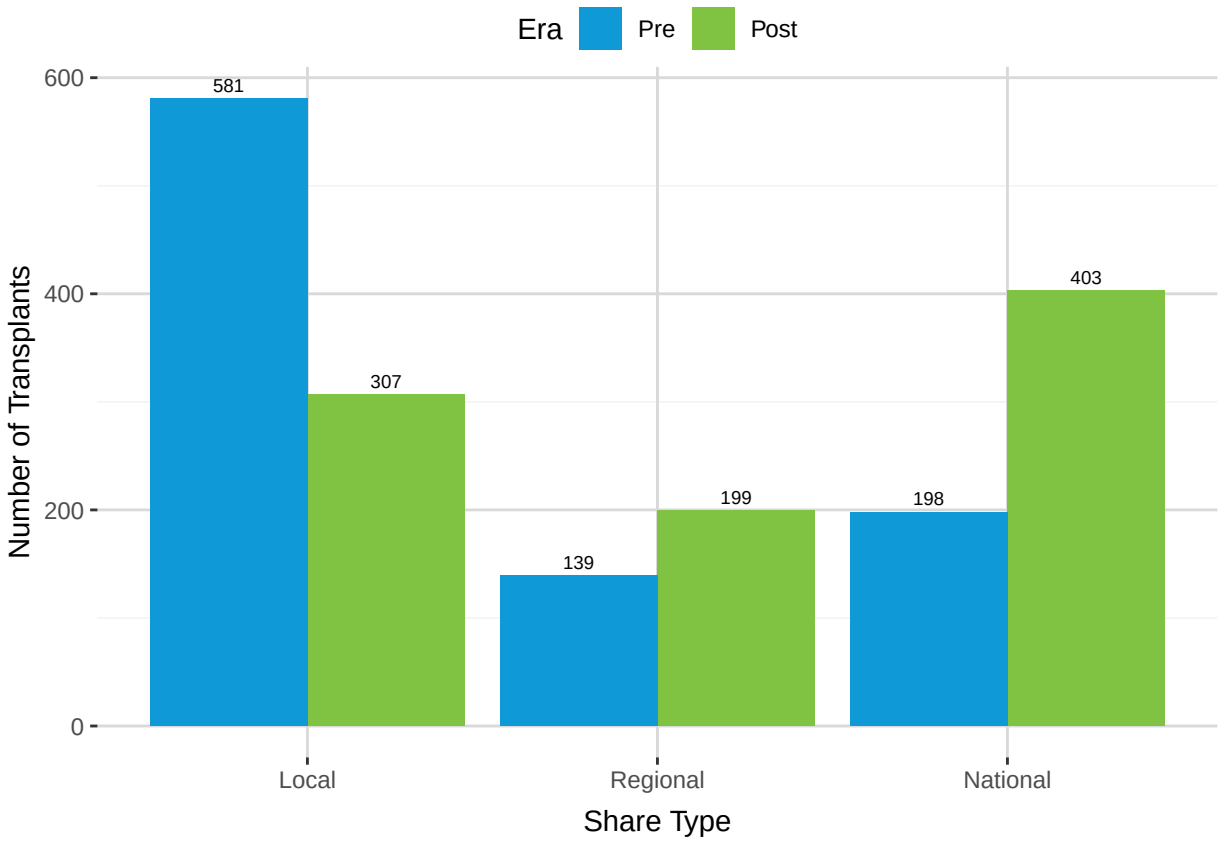


Figure 12 shows the number of adult heart transplants by share type and era. Here, "local" refers to hearts recovered and transplanted within the same DSA and "regional" refers to organs recovered and transplanted in different DSAs but within the same OPTN region. The number of local transplants declined 47.16% post-implementation, with increases in both regional and national shares. The increase was most dramatic for heart transplants at the national share level, which more than doubled post-implementation.

Figure 13. Adult Heart Transplants by Zone and Era

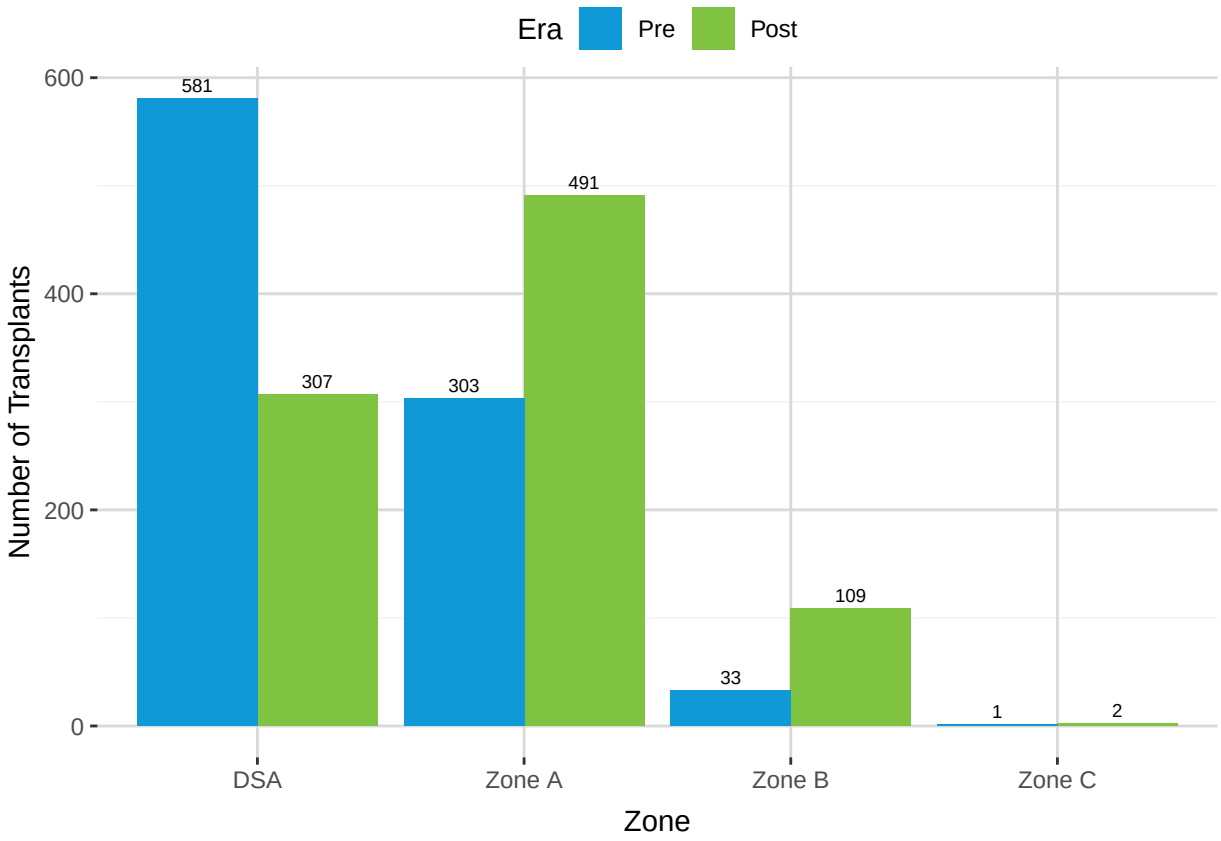


Figure 13 shows the number of adult heart transplants performed by zone and era. Transplants within the DSA decreased post-implementation but rose in all other zones. The greatest increase by absolute volume was in Zone A, but transplants also rose nearly 300% in Zone B. There were no transplants past Zone C.

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

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

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

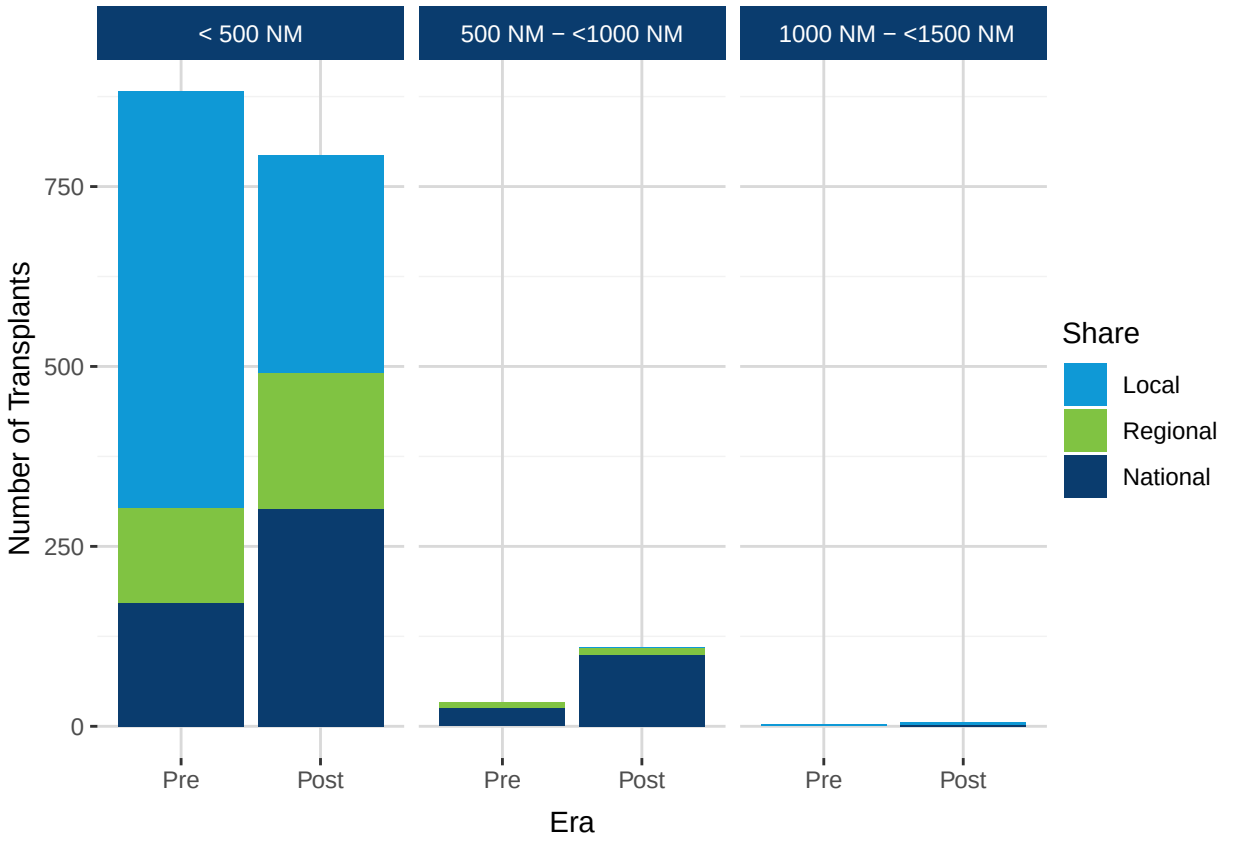


Figure 14 shows the number of transplants performed by distance traveled and share type. Local shares decreased across all distance categories, and the number of organs traveling less than 500 nautical miles but representing either a regional or national share increased post-implementation. The number and percentage of transplants for hearts that traveled more than 500 nautical miles but no more than 1000 nautical miles classified as national shares also increased post-implementation. The majority of hearts that traveled more than 1000 nautical miles up to 1500 nautical miles were classified as local shares both pre- and post-implementation; all of these long-distance local shares represent transplants performed in OPTN region 6.

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

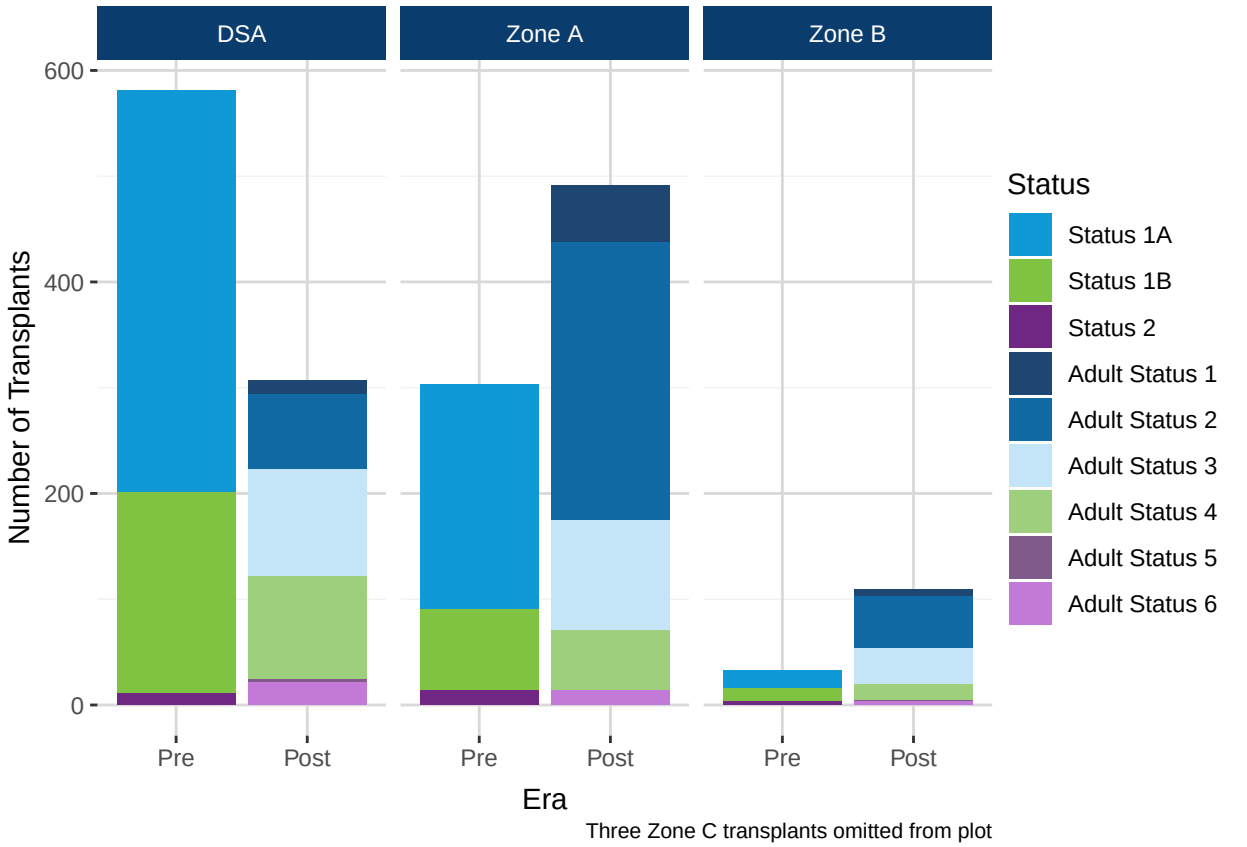


Figure 15 shows the number of adult heart transplants by zone, medical urgency status, and era. Pre-implementation most transplants within the DSA or Zone A were Status 1A, with Status 1B making up nearly as many transplants as Status 1A in Zone B. Post-implementation Adult Status 1 and Adult Status 2 were more common in Zone A than the other zones. Within the DSA most transplants were to Adult Status 4 candidates, and the proportion of transplants to this status declined across DSA, Zone A, and Zone B.

There were three transplants in Zone C, one pre-implementation and two post-implementation (not shown in Figure 15). The pre-implementation transplant went to a Status 2 candidate, and the two post-implementation transplants went to an Adult Status 3 and an Adult Status 4 candidate, respectively.

Figure 16. Distance Traveled at Transplant by Era

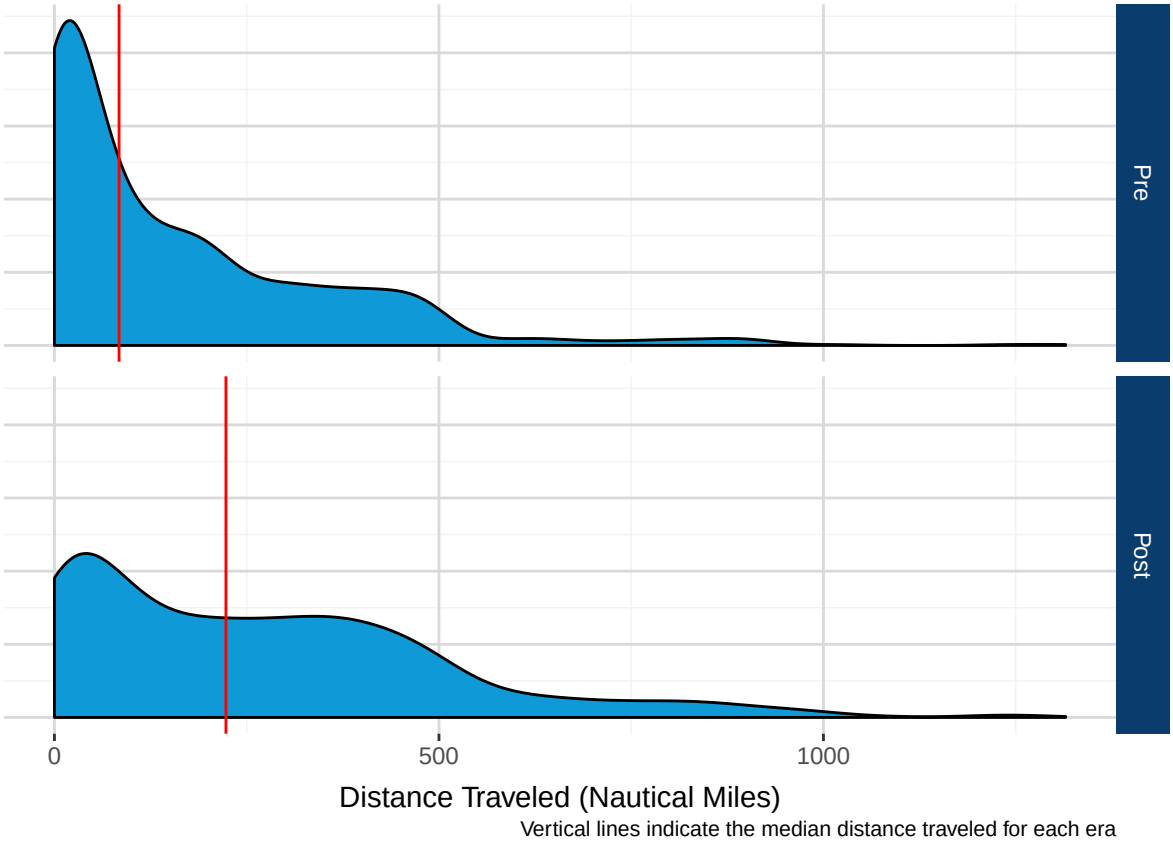


Figure 17 shows the distributions of distance traveled by hearts pre- and post-implementation. While the majority of hearts traveled less than 100 nautical miles pre-implementation, post-implementation travel distances were distributed much more equally up to about 500 nautical miles before dropping off. The median distance traveled increased substantially post-implementation, from a pre-implementation median of 84 nautical miles to a post-implementation median of 223 nautical miles.

Figure 17. Total Ischemic Time at Transplant by Era

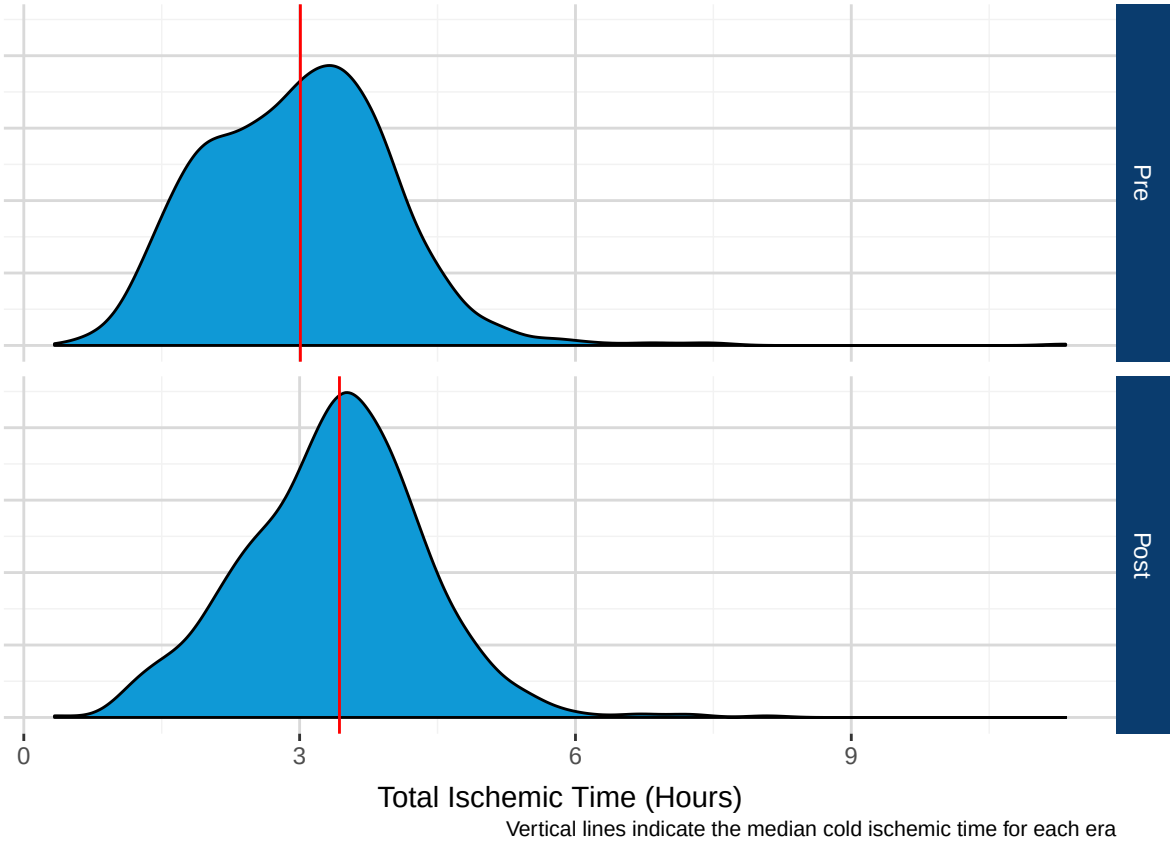


Figure 17 shows the distribution of total ischemic times at transplant both pre- and post-implementation, where total ischemic time is defined as the sum of cold ischemic time, warm ischemic time, and anastomotic time. Total ischemic times increased significantly ($p < 0.001$) post-implementation to a mean of 3.4 hours from 3 hours. Total ischemic time has not been reported for 9.02% transplants in the post-implementation era, so conclusions are subject to change.

Figure 18. Center Adult Heart Transplant Volume by Era

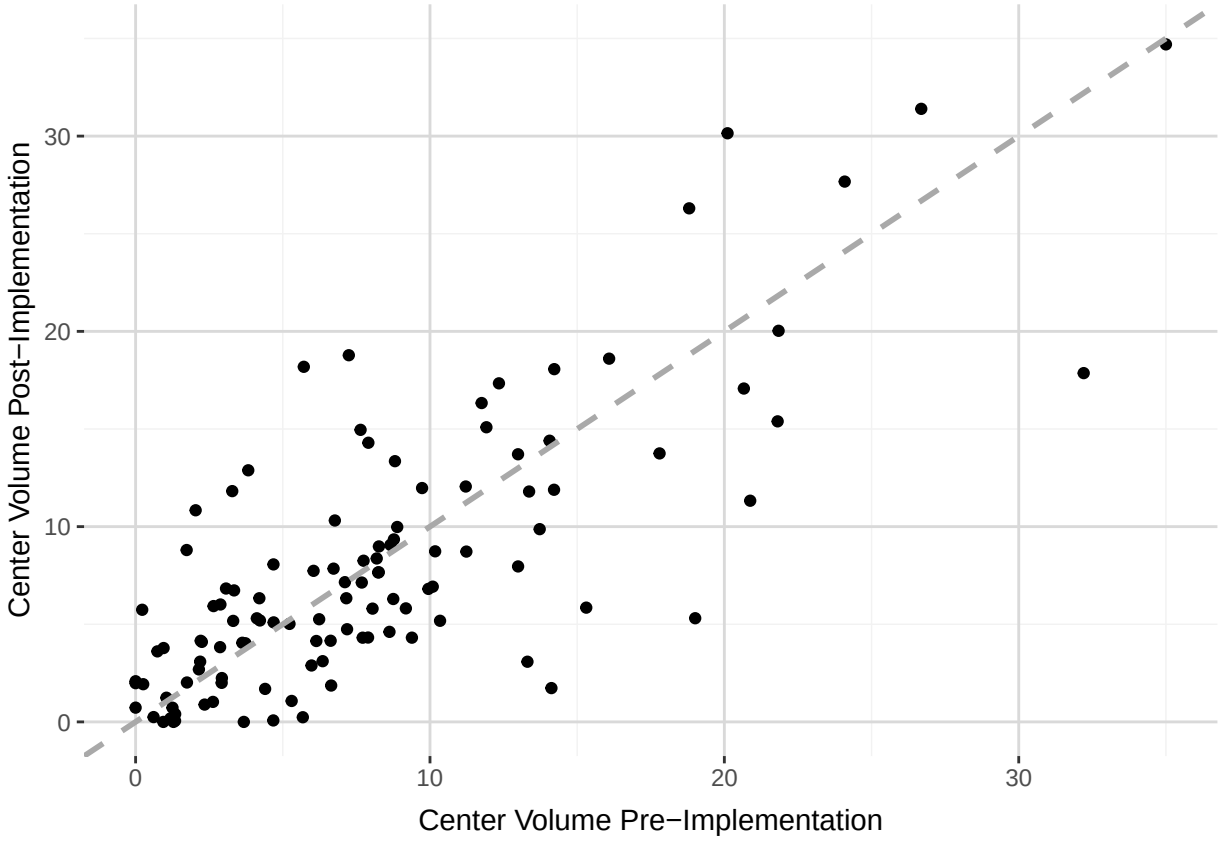


Figure 18 compares the number of adult heart transplants performed by transplant centers before and after modifications to the adult heart allocation system. Dots that fall below the diagonal gray line represent centers where transplant volume decreased post-implementation, while those above the line performed more transplants in the four months after implementation. There were 113 transplant centers that performed at least one adult heart transplant in one of the two eras. Of those, 48 performed more adult heart transplants post-implementation than they did pre-implementation.

Figure 19. Distribution of Medical Urgency Status for Patients Ever Waiting by Change in Listing Center Volume Post Implementation

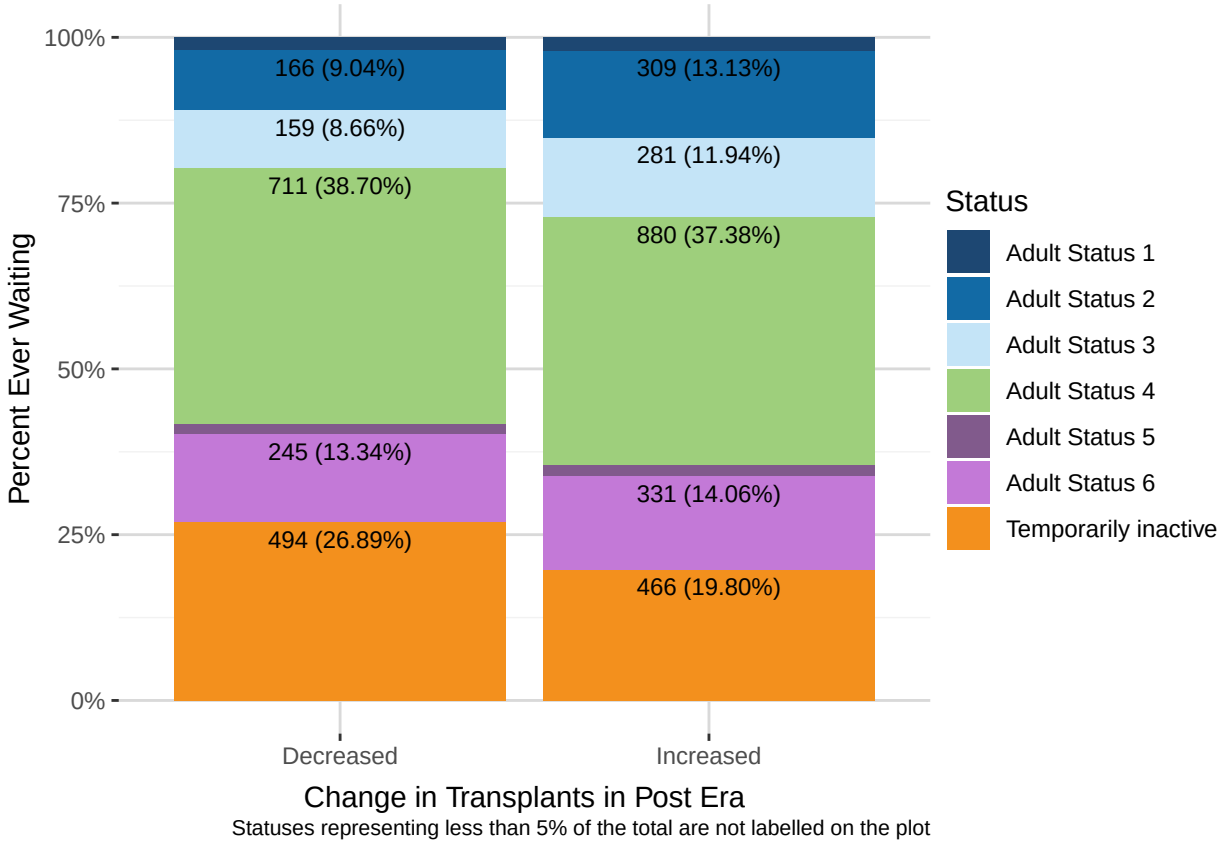


Figure 19 compares the distributions of patients ever waiting at different medical urgency statuses post-implementation at centers where the number of transplants performed post-implementation increased to the distribution at centers where the number of transplants performed post-implementation decreased. 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 temporarily inactive candidates, who do not receive heart offers. The differences between the distributions of medical urgency statuses are statistically significant ($p < 0.001$). Differences in waitlist makeup may help to explain changes in the number of transplants performed by centers post-implementation.

Utilization

These analyses examine differences in heart utilization between two donor cohorts: the 3181 deceased donors with at least one organ recovered for the purpose of transplant between October 18, 2017 and February 17, 2018 (pre-implementation); and the 3363 deceased donors donors with a least one organ recovered for the purpose of transplant between October 18, 2018 and February 17, 2019 (post-implementation).

Figure 20. Utilization Rates for Adult Heart Donors by Week

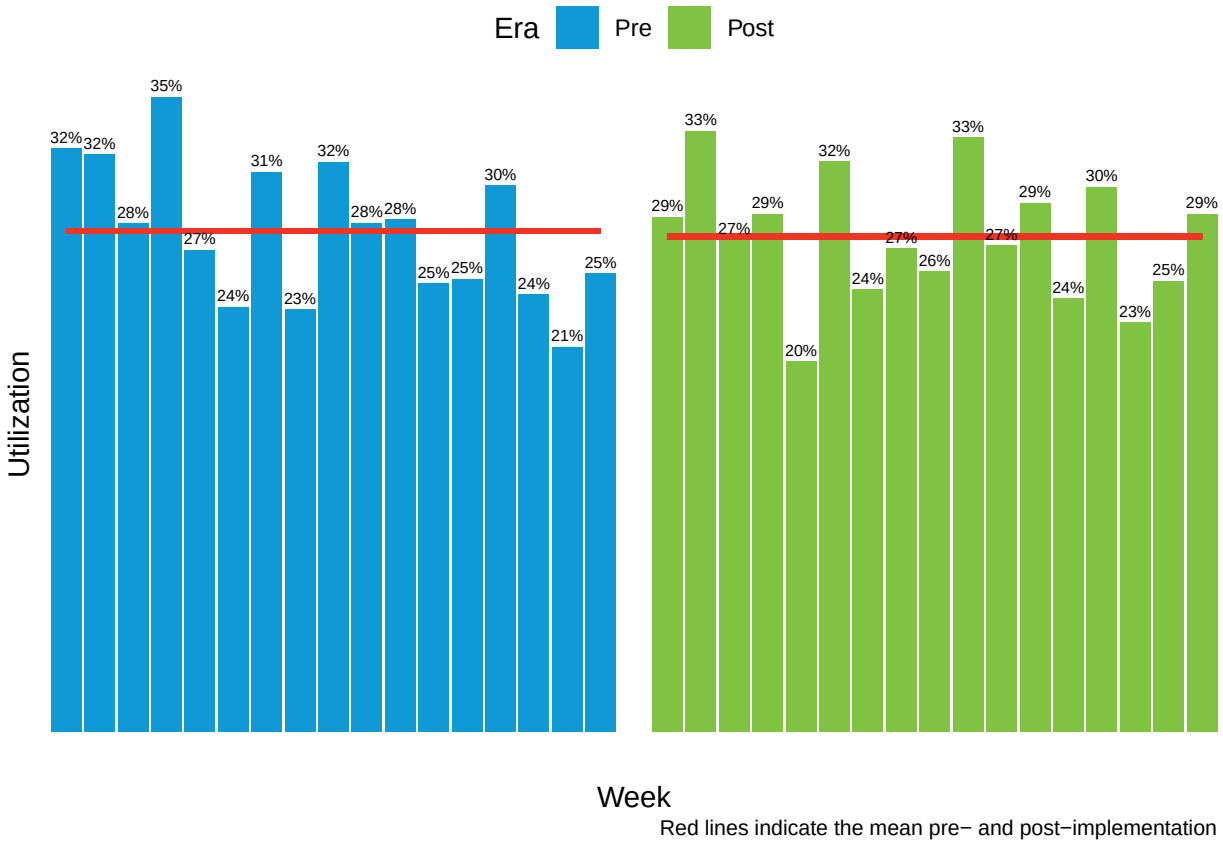


Figure 20 shows the utilization of adult hearts recovered by week both pre- and post-implementation. Utilization remained fairly constant between the two cohorts, with a pre-implementation weekly mean rate of 27.78% and a post-implementation weekly mean rate of 27.47%.

Figure 21. Utilization Rates for Non-DCD Adult Heart Donors by Week

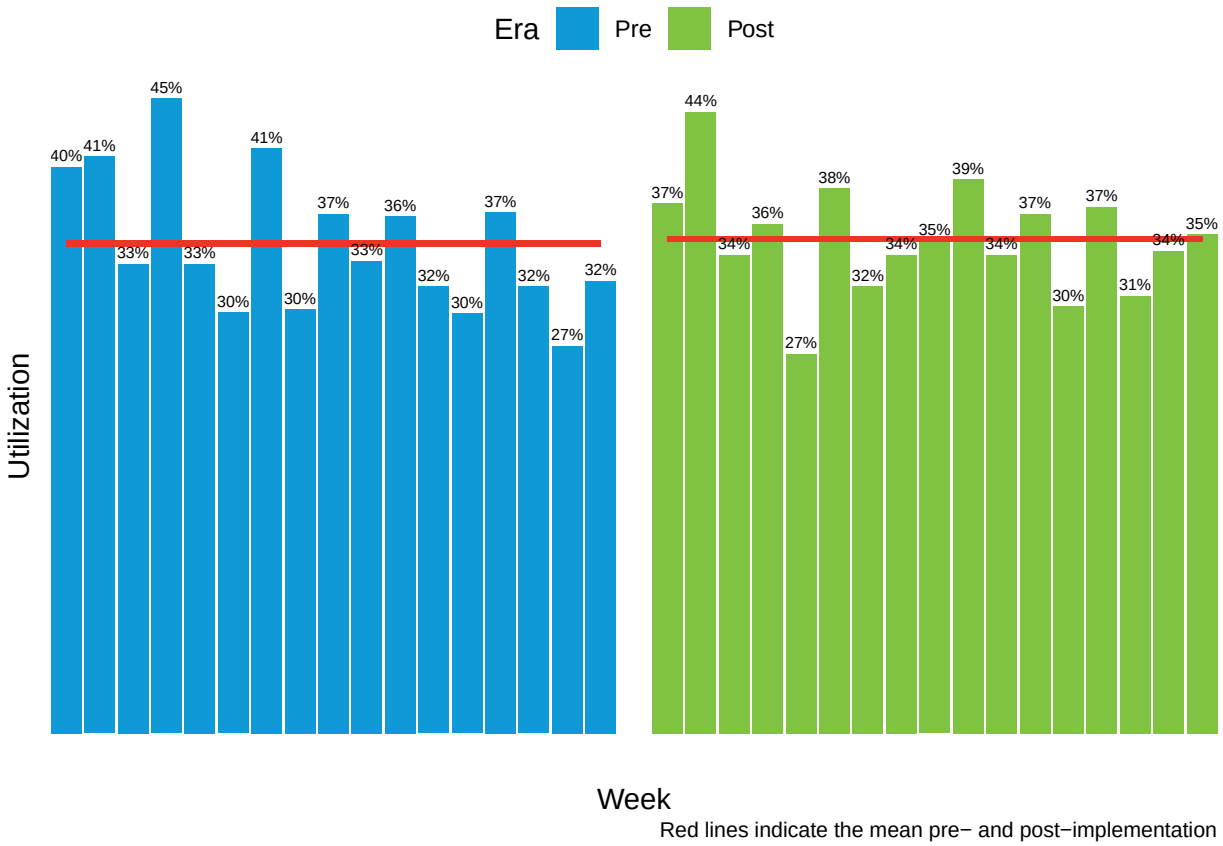


Figure 21 shows the utilization of adult hearts recovered by week for non-DCD donors only. As expected, heart utilization rates are higher among non-DCD donors than among all donors, and the mean utilization rate remained fairly constant across cohorts, with weekly mean 34.59% utilization pre-implementation and weekly mean 34.90% post-implementation.

In addition to a stable utilization rate, the discard rate for adult hearts was also fairly consistent between cohorts, with a weekly mean discard rate of 1.19% pre-implementation and a weekly mean discard rate of 0.96% post-implementation.

Figure 22. Utilization Rates for Adult Heart Donors by Region and Era

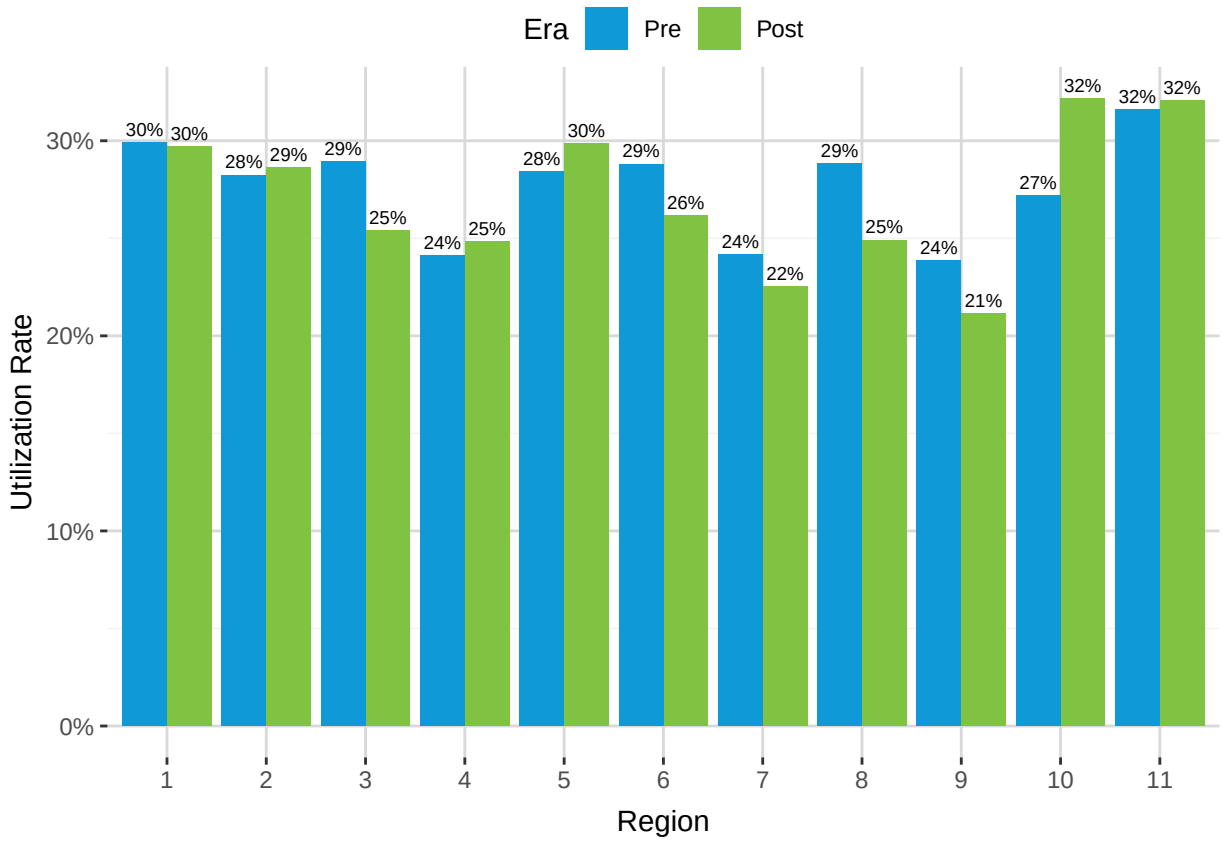


Figure 22 shows utilization rates of adult hearts by region both pre- and post-implementation. Utilization rates remained steady or rose for most regions post-implementation. In most regions the change in heart utilization between eras was small.

Figure 23. Utilization Rates for Non-DCD Adult Heart Donors by Region and Era

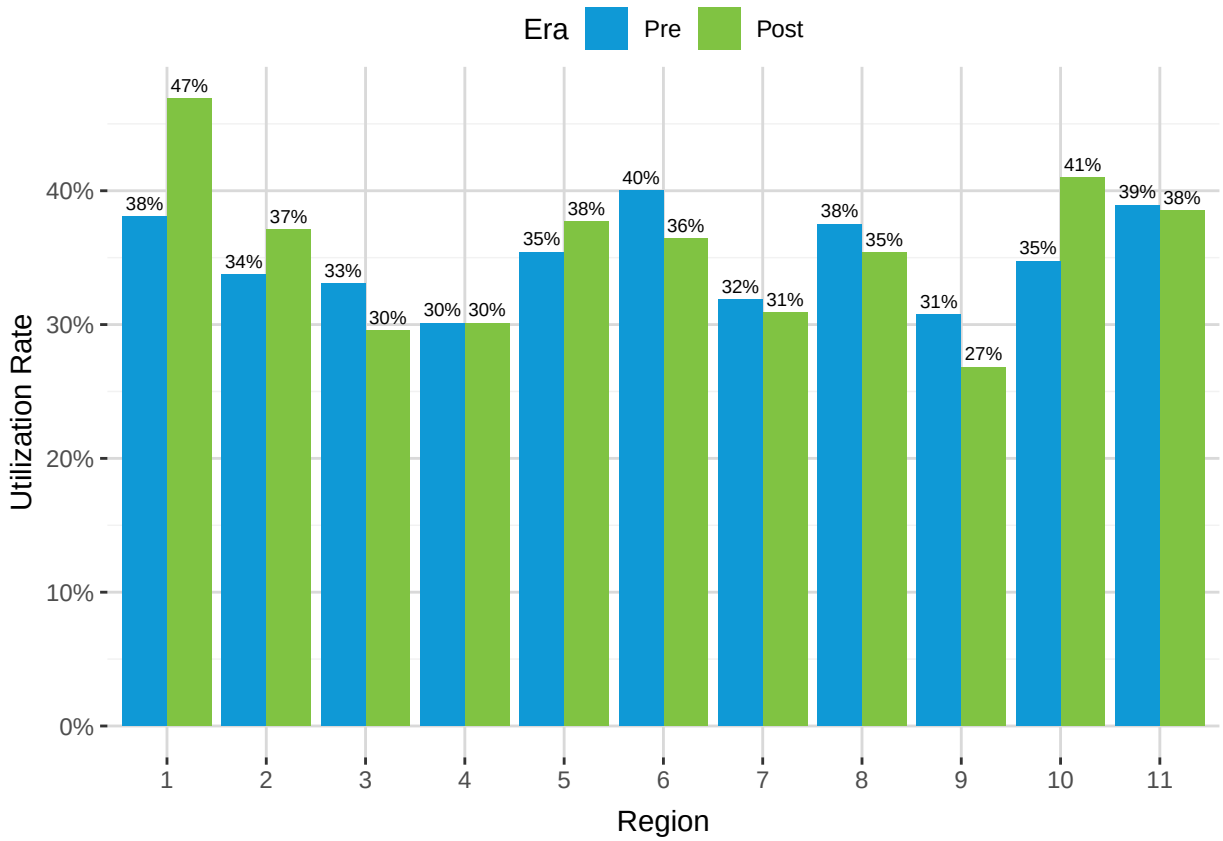


Figure 23 shows utilization rates of adult hearts by region both pre- and post-implementation for non-DCD donors only. Utilization rates are higher for non-DCD donors than for donors overall and rose in regions 1, 2, 5, and 10. The non-DCD adult heart utilization rate remained constant in region 4 post-implementation and fell in all other regions.

Figure 24. Utilization Rates for Adult Heart Donors by Donor Age and Era

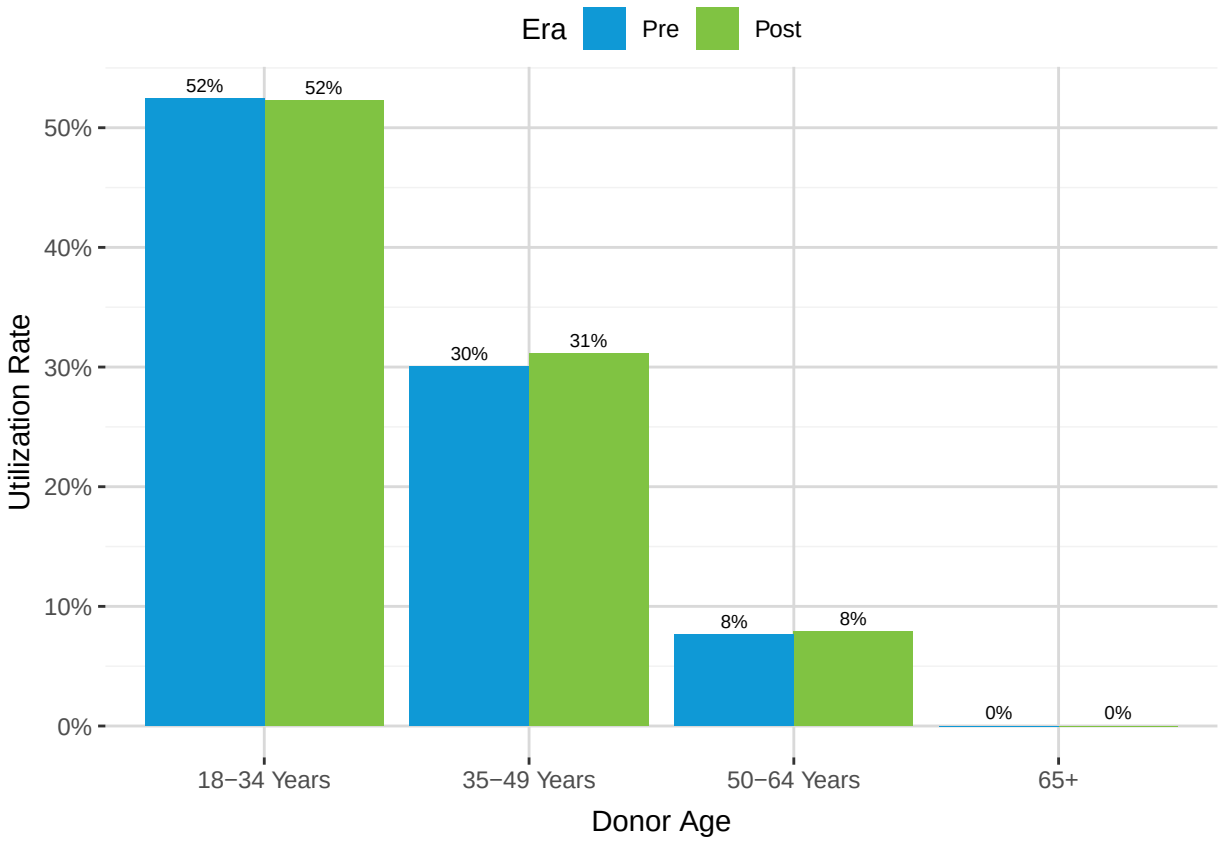


Figure 24 shows the utilization rates for adult hearts both pre- and post-implementation by donor age. There was little change in adult heart utilization in any donor age group.

Figure 25. Utilization Rates for Adult Non-DCD Heart Donors by Donor Age and Era

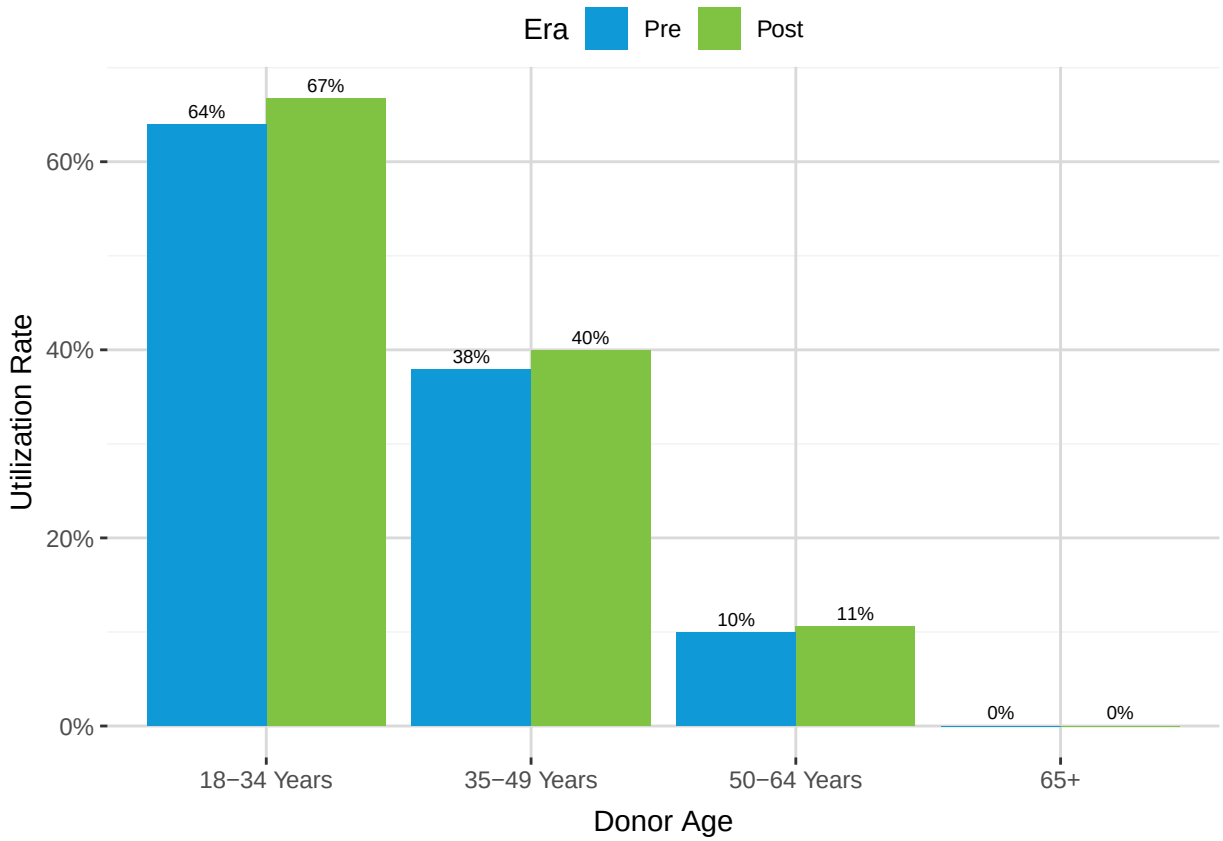


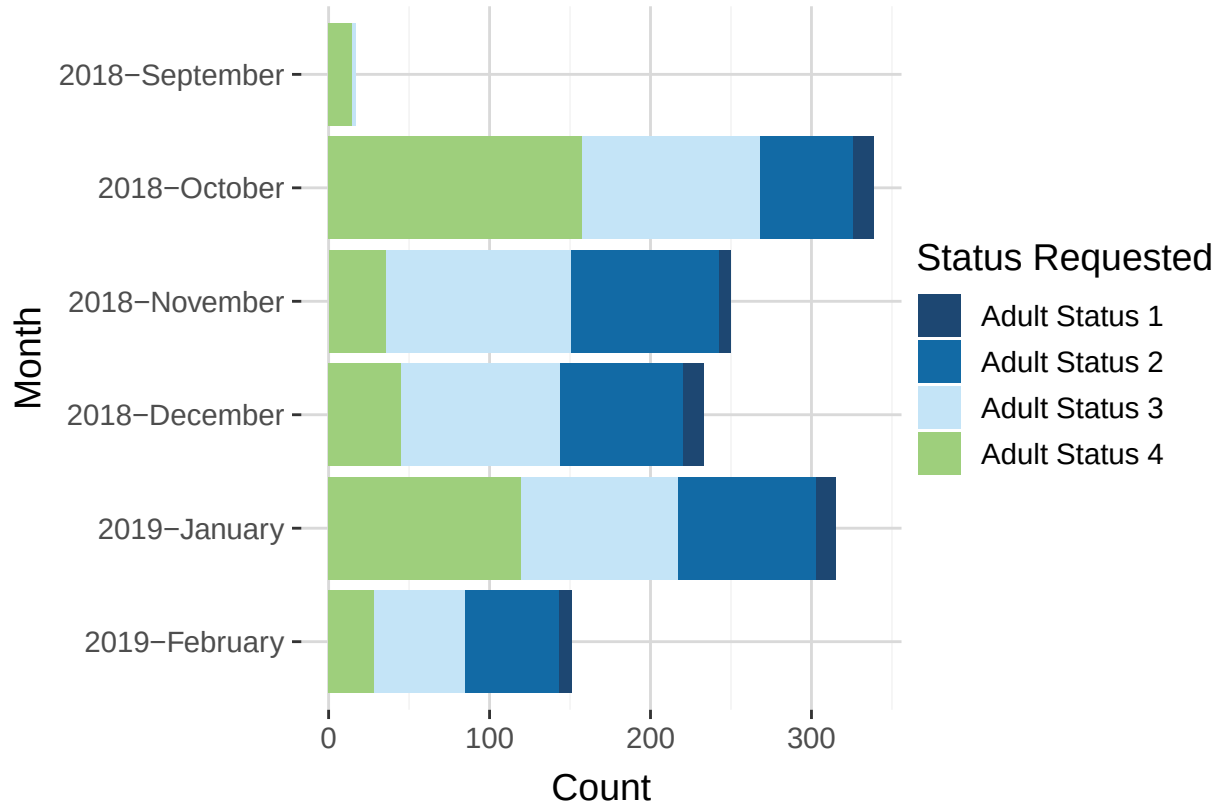
Figure 25 shows the utilization rates for adult hearts from non-DCD donors by age both pre- and post-implementation by donor age. Utilization rates rose slightly for all age groups post-implementation.

Regional Review Board

This chapter summarizes adult heart justification forms submitted to the Heart Regional Review Board between September 18, 2018, when phase 1 of new adult heart allocation was implemented, and February 17, 2019. There were 1305 adult heart justification forms submitted to the Heart Regional Review Board during this time.

Figure 26 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 is applying. Adult heart candidates can apply for multiple exceptions/extensions during their time on the waiting list, so this does not represent the number of candidates that applied for an exception/extension request.

Figure 26. Number of distinct justification forms by medical urgency status and month form was submitted



Due to the time period examined, February and September are not complete months

Table 7 summarizes the number and percent of distinct justification forms submitted by medical urgency status and month of submission. Adult Status 3 represents the largest number of forms submitted, followed closely by Adult Statuses 2 and 4.

Table 7. Number of distinct justification forms by medical urgency status and month form was submitted

Adult Heart Status	2018-September	2018-October	2018-November	2018-December	2019-January	2019-February	Total
Adult Status 1	0 (0.0%)	13 (3.8%)	7 (2.8%)	13 (5.6%)	12 (3.8%)	8 (5.3%)	53 (4.1%)
Adult Status 2	0 (0.0%)	58 (17.1%)	92 (36.8%)	76 (32.6%)	86 (27.3%)	58 (38.4%)	370 (28.4%)
Adult Status 3	2 (11.8%)	110 (32.4%)	115 (46.0%)	99 (42.5%)	97 (30.8%)	57 (37.7%)	480 (36.8%)
Adult Status 4	15 (88.2%)	158 (46.6%)	36 (14.4%)	45 (19.3%)	120 (38.1%)	28 (18.5%)	402 (30.8%)
Total	17 (100.0%)	339 (100.0%)	250 (100.0%)	233 (100.0%)	315 (100.0%)	151 (100.0%)	1305 (100.0%)

Figure 27 and Table 8 summarize the number of initial and extension justification forms that needed to be reviewed by the RRB by medical urgency status. As the name implies, the initial request is the first request for a candidate for a particular status under a specific medical condition for the candidate. If the medical condition of the candidates remains the same, when the initial request expires the candidate may request an extension.

The number of initial forms submitted is higher than the number of extension forms submitted for each medical urgency status. Adult Status 4 was the most commonly requested medical urgency status, followed by Adult Status 3. Adult Status 1 was the least common.

Figure 27. Number of justification forms by medical urgency status and form type

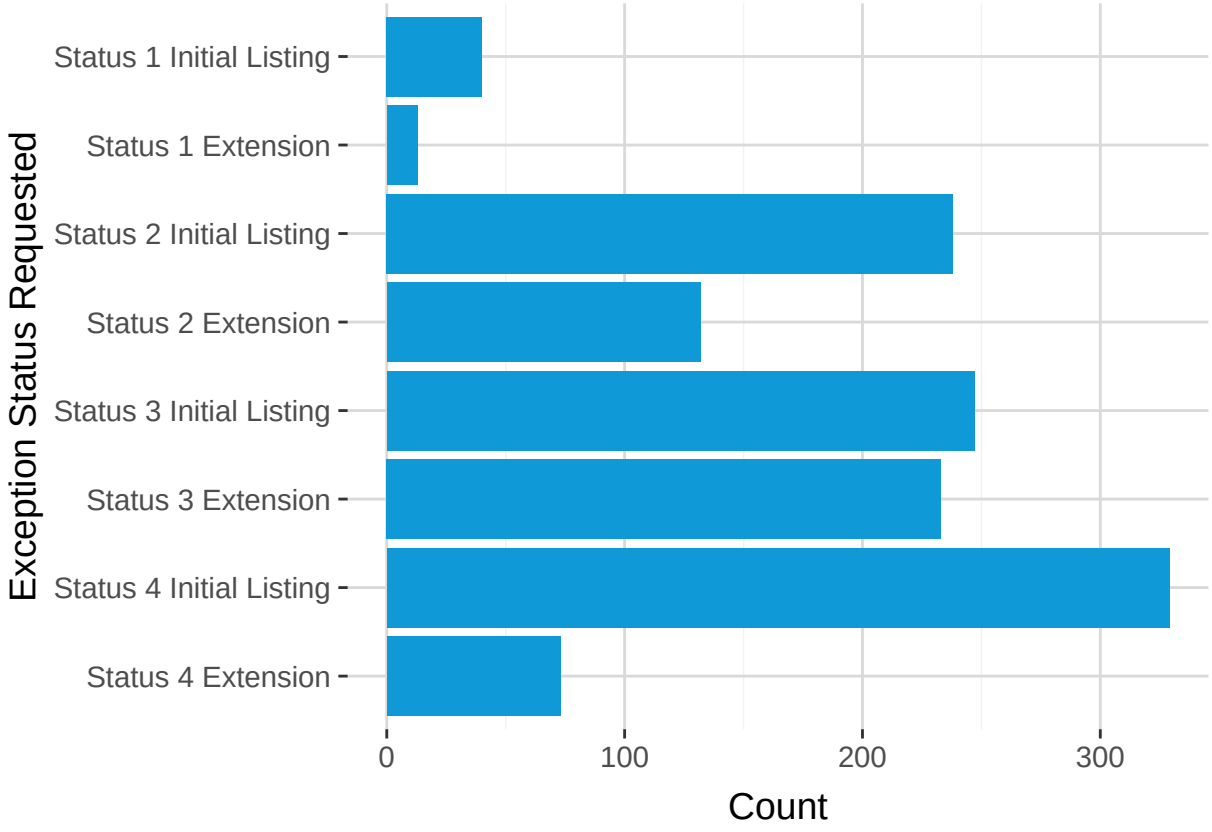


Table 8. Number of justification forms by medical urgency status and form type

Adult Heart Status and Form Type	Number of Justification Forms	Percent
Status 1 Initial Listing	40	3.1%
Status 1 Extension	13	1.0%
Status 2 Initial Listing	238	18.2%
Status 2 Extension	132	10.1%
Status 3 Initial Listing	247	18.9%
Status 3 Extension	233	17.9%
Status 4 Initial Listing	329	25.2%
Status 4 Extension	73	5.6%
Total	1305	100.0%

Under the new adult heart allocation system some "standard" justification forms are required by policy to be reviewed by the RRB. Figure 28 and Table 9 below summarize the number of forms that have been submitted as an exception versus those that are standard and need RRB approval by medical urgency status. The majority of the forms that the Regional Review Boards are reviewing are exception requests, regardless of the status being requested. The only standard forms needing RRB approval were submitted for Adult Status 1 and Adult Status 2.

Figure 28. Number of justification forms by exception versus standard review and heart status

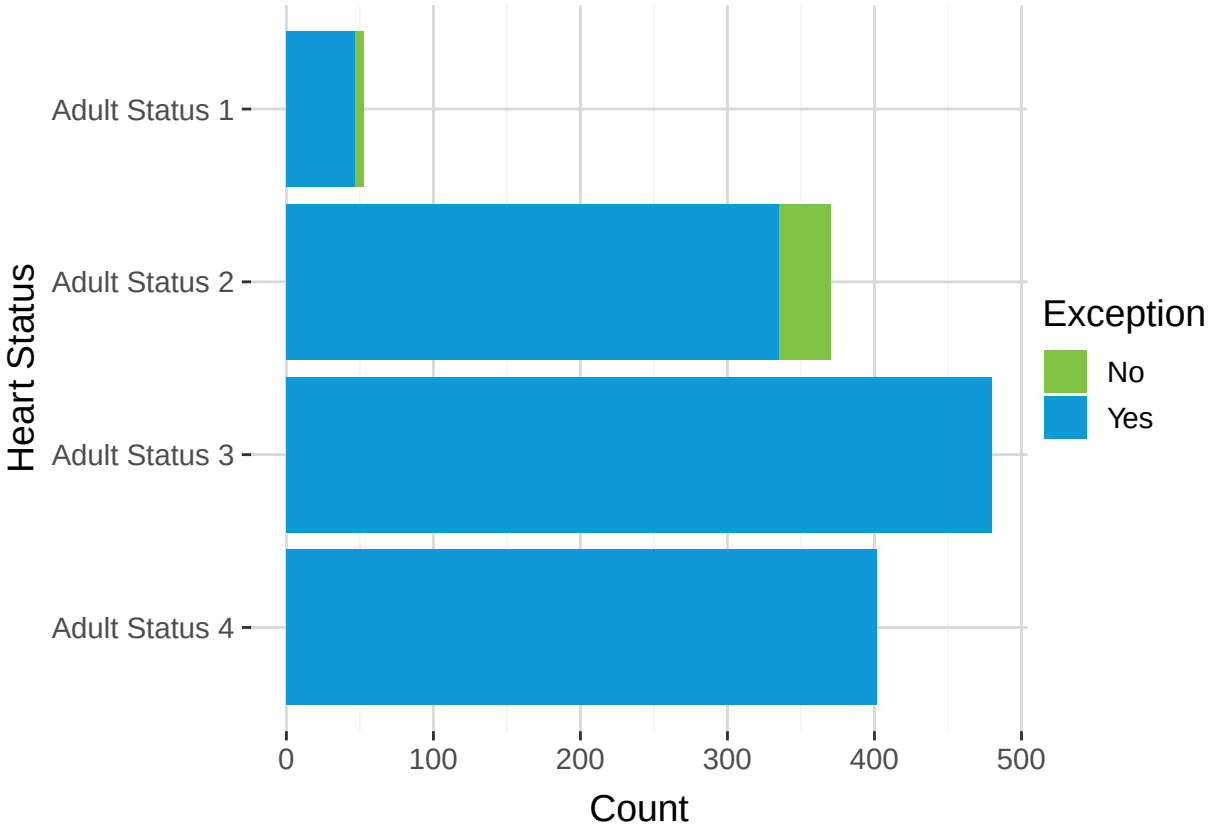


Table 9. Number of justification forms by exception versus standard review and medical urgency status

	Exception Request		
Adult Heart Status	No	Yes	Total
Adult Status 1	6 (11.3%)	47 (88.7%)	53 (100.0%)
Adult Status 2	35 (9.5%)	335 (90.5%)	370 (100.0%)
Adult Status 3	0 (0.0%)	480 (100.0%)	480 (100.0%)
Adult Status 4	0 (0.0%)	402 (100.0%)	402 (100.0%)
Total	41 (3.1%)	1264 (96.9%)	1305 (100.0%)

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

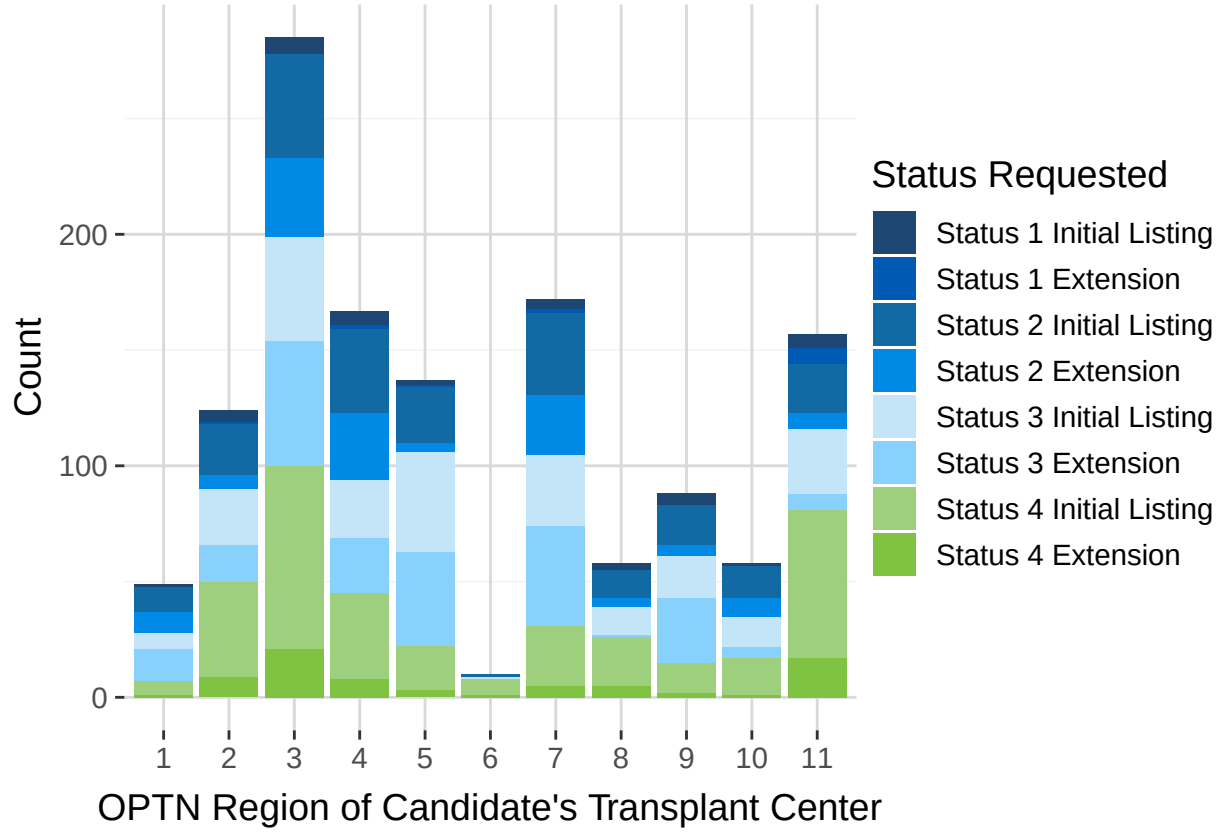


Table 10. Number of inital and extension justification forms by medical urgency status and OPTN region of candidate's transplant center

Adult Heart Status and Form Type	1	2	3	4	5	6	7	8	9	10	11	Total
Status 1 Initial Listing	1	5	7	6	2	0	4	3	5	1	6	40
Status 1 Extension	0	1	0	2	1	0	2	0	0	0	7	13
Status 2 Initial Listing	11	22	45	36	24	1	35	12	17	14	21	238
Status 2 Extension	9	6	34	29	4	0	26	4	5	8	7	132
Status 3 Initial Listing	7	24	45	25	43	1	31	12	18	13	28	247
Status 3 Extension	14	16	54	24	41	0	43	1	28	5	7	233
Status 4 Initial Listing	6	41	79	37	19	7	26	21	13	16	64	329
Status 4 Extension	1	9	21	8	3	1	5	5	2	1	17	73
Total	49	124	285	167	137	10	172	58	88	58	157	1305

Figure 29 and Table 10 summarize form submission by the candidate's transplant center's OPTN region. OPTN regions 2, 3, 4, 5, 7, and 11 each submitted over 100 forms that needed RRB approval. OPTN region 6 submitted the fewest forms.

Table 11 summarizes the form types and whether the form was approved, not approved, not required-other or not required-withdrawn. The vast majority of forms submitted are approved, regardless of medical urgency status or form type.

Table 11. Number of inital and extension justification forms by medical urgency status and conclusion from the form status field

Adult Heart Status and Form Type	Approved	Not Approved	Not Required - Other	Not Required - Withdrawn	Total
Status 1 Initial Listing	31	2	0	5	38
Status 1 Extension	11	0	0	1	12
Status 2 Initial Listing	208	19	0	9	236
Status 2 Extension	120	3	1	4	128
Status 3 Initial Listing	203	15	2	18	238
Status 3 Extension	222	3	0	6	231
Status 4 Initial Listing	299	14	2	7	322
Status 4 Extension	68	4	0	0	72
Total	1162	60	5	50	1277

Table 12. Number of forms by region submitting form and region reviewing form

Region	N
Region 1, Reviewed by Region 2	49
Region 2, Reviewed by Region 5	124
Region 3, Reviewed by Region 7	285
Region 4, Reviewed by Region 10	167
Region 5, Reviewed by Region 9	137
Region 6, Reviewed by Region 8	10
Region 7, Reviewed by Region 11	172
Region 8, Reviewed by Region 4	58
Region 9, Reviewed by Region 1	88
Region 10, Reviewed by Region 6	58
Region 11, Reviewed by Region 3	157
Total	1305

Under the new adult heart allocation system regions review requests from other regions. Table 12 summarizes the number of forms submitted from each region and the corresponding region that reviews the request. Region 3 submitted substantially more forms than any other region, followed by region 7 and region 4. Region 6 submitted the smallest number of forms.

Figure 30. Conclusions from justification forms by region reviewing request

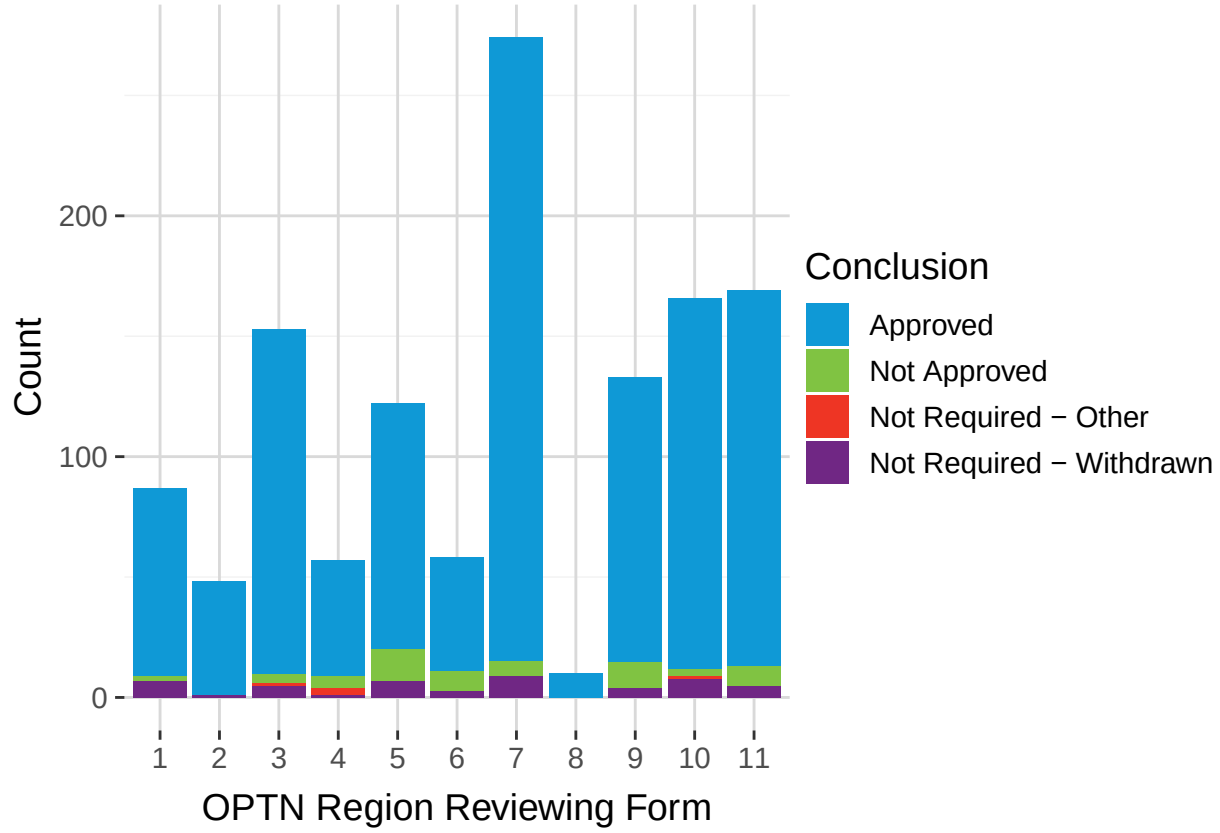


Figure 30 and Table 13 summarize the the conclusions (approved/not approved/not required-other/not required-withdrawn) by OPTN region that reviewed the request, not the OPTN region from which the form originated. Most regions approved a similar proportion of the forms submitted to them. Region 8 approved 100% of forms submitted (from region 6), but there were only 10 reviewed in total, whereas region 6, evaluating forms from region 10, had the lowest rate of approval of any region.

Table 13. Conclusions from justification forms by region reviewing request

OPTN Region Reviewing Form	Approved	Not Approved	Not Required - Other	Not Required - Withdrawn	Total
1	78 (89.7%)	2 (2.3%)	0 (0.0%)	7 (8.0%)	87 (100.0%)
2	47 (97.9%)	0 (0.0%)	0 (0.0%)	1 (2.1%)	48 (100.0%)
3	143 (93.5%)	4 (2.6%)	1 (0.7%)	5 (3.3%)	153 (100.0%)
4	48 (84.2%)	5 (8.8%)	3 (5.3%)	1 (1.8%)	57 (100.0%)
5	102 (83.6%)	13 (10.7%)	0 (0.0%)	7 (5.7%)	122 (100.0%)
6	47 (81.0%)	8 (13.8%)	0 (0.0%)	3 (5.2%)	58 (100.0%)
7	259 (94.5%)	6 (2.2%)	0 (0.0%)	9 (3.3%)	274 (100.0%)
8	10 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
9	118 (88.7%)	11 (8.3%)	0 (0.0%)	4 (3.0%)	133 (100.0%)
10	154 (92.8%)	3 (1.8%)	1 (0.6%)	8 (4.8%)	166 (100.0%)
11	156 (92.3%)	8 (4.7%)	0 (0.0%)	5 (3.0%)	169 (100.0%)
Total	1162 (91.0%)	60 (4.7%)	5 (0.4%)	50 (3.9%)	1277 (100.0%)

Figure 31 and Table 14 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 618 registrations have applied for an exception. The majority of initial requests were for Adult Status 4.

Figure 31. Number of registrations with an exception by first status requested

Table 14. Number of registrations with an exception by first status requested

Status Requested	Registration Count	Percent
Status 1 Initial Listing	27	4.4%
Status 2 Initial Listing	153	24.8%
Status 3 Initial Listing	158	25.6%
Status 4 Initial Listing	280	45.3%
Total	618	100.0%

Conclusion

Early monitoring suggests that revisions to the heart allocation system have resulted in broader sharing, with a decline in local shares and increases in regional and national shares. Hearts are traveling greater distances to be transplanted. There has been no substantial impact on the number of waiting list registrations, transplants performed, or heart utilization. While some transplant centers have seen a decrease in transplant volume, it appears that differences in waiting list composition may explain this, rather than the change in allocation policy.

The change in heart allocation policy also included changes to the RRB process. Since these changes went into effect, the number of justification forms submitted to the RRB has varied between 200 and 300 per month. The majority of these were requests for Adult Status 3 and were exception request forms rather than standard review forms. The majority of requests were approved regardless of the region reviewing the request.