

One-Year Heart Monitoring Report

Eliminate the Use of DSAs in Thoracic Distribution

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Background/Purpose

Allocation of hearts and heart-lungs historically used Donor Service Areas (DSAs) as a geographic unit of distribution for both pediatric and adult heart candidates. Due to the different sizes, shapes and populations of DSAs, this would sometimes result in hearts or heart-lungs being transplanted further away when there was a candidate of similar medical urgency closer to the donor hospital.

During the summer of 2018, the Organ Procurement and Transplantation Network (OPTN) Executive Committee directed the organ-specific committees to remove DSA and OPTN regions from their allocation systems and replace them with a rationally determined substitute that could be consistently applied and was legally defensible by way of better alignment with the Final Rule.

The OPTN Thoracic Organ Transplantation Committee proposed replacing DSAs with a 250 nautical mile (NM) distance from the donor hospital. Since this implementation, the OPTN Thoracic Organ Transplantation Committee split into the Lung Transplantation Committee and the Heart Transplantation Committee (hereafter referred to as The Committee). The Committee will continue monitoring the removal of DSA from heart allocation policy.

The goal of this change was to make heart allocation policy consistent with the Final Rule and provide improved equity in access to transplantation regardless of a candidate's place of listing. In addition, this proposal implemented on January 09, 2020 realigned the first units of distribution for heart and lung allocation, addressed the limited utility of the exception for sensitized heart candidates, and finally, resolved several clerical artifacts that remain as a consequence of removing DSA as a unit of distribution from heart allocation policy.

This report looks at the impact of the removal of DSA as a unit of allocation and will be followed by more extensive analyses annually for two 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

As outlined in the monitoring plan in the proposal, the Committee will monitor metrics as they relate to the proposed geographic changes regarding the removal of DSA from heart allocation. This includes, but is not limited to:

1. The number/% of transplants stratified by distance (NM) between donor hospital and transplant center
2. Volume of transplants by de-identified heart transplant centers
3. Distribution of the distance (NM) between donor hospital and transplant center, including range, IQR, mean, and median
4. Number and percent of transplants by geographic classification (local, regional, national) and distance (NM) between donor hospital and transplant center
5. Distribution of ischemic time (hours) for heart transplants, including range, IQR, mean, and median
6. Unadjusted post-transplant patient survival stratified by distance (NM) between donor hospital and transplant center

Metric 6, above, was omitted in the 3-month and 6-month reports due to insufficient time having passed to draw conclusions. It is presented in this report.

These reports will be presented to the Thoracic Committee as appropriate post implementation at 3-months, 6-months, and annually thereafter for two years.

Data and Methods

Data Sources: These analyses use data from the OPTN waiting list, the Deceased Donor Registration (DDR) form, the Transplant Candidate Registration (TCR) form, and the Transplant Recipient Registration (TRR) form. Analyses are based on OPTN data as of July 16, 2021 and are subject to change based on future data submission or correction.

Methods:

Adults (age ≥ 18 at listing) and pediatric (age < 18 at listing) candidates added to the heart waiting list between January 09, 2019 and January 08, 2020 (pre) or between January 09, 2020 and January 08, 2021 (post) were stratified by medical urgency status, region, and medical urgency status within region.

Snapshot data provide a summary of candidates on the waitlist on the last day of a given month. Snapshot data are provided for 4 eras (pre-policy, post-policy pre COVID, post-policy COVID Onset, and Post-Policy COVID Stabilization; See "A Notice on COVID" for more details about these eras) and summaries reflect the waitlist on the last day of the first month of the period. Snapshot data were stratified by medical urgency status.

Candidates removed from the waiting list between January 09, 2019 and January 08, 2020 (pre) or between January 09, 2020 and January 08, 2021 (post) were stratified by era, medical urgency status within era and reason for removal.

Candidates ever waiting between January 09, 2019 and January 08, 2020 (pre) or between January 09, 2020 and January 08, 2021 (post) were stratified by medical urgency status and region. The distribution of medical urgency status for candidates ever waiting was further stratified by whether the listing center performed more or fewer transplants post-implementation than pre-implementation, and the distributions were compared using the Chi-squared test.

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 between January 09, 2019 and January 08, 2020 (pre) or between January 09, 2020 and January 08, 2021 (post). Rates were calculated as the ratio of death or transplant to patient-years of exposure, and rates are displayed as deaths or transplants per 100 patient-years. The OPTN database was supplemented with deaths from verified external sources. Since candidates may be removed from the waiting list shortly prior to death as their health deteriorates, the waiting list mortality rate calculation included deaths within seven days of waiting list removal and those removed from the waiting list as a result of becoming too sick to transplant. Candidates who received any previous transplant were excluded from the waiting list mortality and transplant rate analyses.

Deceased donor heart recipients transplanted between January 09, 2019 and January 08, 2020 (pre) or between January 09, 2020 and January 08, 2021 (post) were stratified by medical urgency status, region, medical urgency status within region, zone, share type, distance traveled to transplant, and geographic region. 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.

Electronic offer data for adult (age ≥ 18) deceased donors recovered between January 09, 2019 and January 08, 2020 (pre) or between January 09, 2020 and January 08, 2021 (post) were used to assess the time between first electronic offer and cross clamp and the sequence number of the acceptor on adult heart match runs. The distribution of the offer number on heart match runs was summarized using the median, 10th percentile, and 90th percentile.

Outcomes analyses were performed on a subset of adult heart transplant recipients with the potential for at least one year of follow-up plus a two-month data lag, which included recipients transplanted between January 09, 2019 and July 08, 2019 in the pre-implementation cohort and between January 09, 2020 and July 08, 2020 in the post-implementation cohort. The COVID-19 crisis has created challenges to conducting routine outpatient activities, including clinical testing, which are needed to obtain information required for transplant candidates, recipients, and living donors. Current OPTN policy requires that transplant programs submit data for transplant recipients and living donors. The emergency policy from the OPTN Executive Committee temporarily relaxed requirements for follow-up form submission. The intent of the policy was to prevent unnecessary exposure risk to transplant recipients and living donors and to alleviate potential data burden for centers in the midst of COVID-19

crisis. The 'TRF and LDF Data Submission During COVID-19 Amnesty Period' emergency policy temporarily suspended the requirements for data collection and submission for the living donor follow-up (LDF), organ specific transplant recipient follow-up (TRF), and recipient malignancy (PTM) forms. The suspension of these requirements is backdated to forms expected between March 13, 2020 and March 31, 2021. It did not suspend the requirement to report recipient death or graft failure, but extended the time frame for reporting that information for transplant recipients from 14 days to 30 days of knowledge of the event. We expect higher rates of patient status censoring as a result of the amnesty policy. To account for this increase, survival analyses were run assuming recipients were alive unless their death was reported to the OPTN or identified in external sources. Assume-alive and standard patient survival curves are presented but graft survival was omitted due to the lack of access to external sources to verify information. Survival curves were constructed using unadjusted Kaplan-Meier methodology and compared using the log-rank test.

Utilization and discard rates were calculated for a cohort of deceased donors recovered between January 09, 2019 and January 08, 2020 (pre) or between January 09, 2020 and January 08, 2021 (post). Utilization rate was defined as the number of deceased donor hearts recovered divided by the total number of deceased donors recovered. The discard rate was defined as one minus the number of adult deceased donor hearts transplanted divided by the total number of adult deceased donor hearts recovered in that period.

Statistical analyses were performed using SAS v9.3 (SAS Institute, Inc., Cary, NC.) and R Version 4.0.2 (R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL: <https://www.R-project.org/>).

A Notice on COVID

For all figures and tables, we note that the World Health Organization (WHO) declared COVID-19 a pandemic on March 11, 2020 and a national state of emergency was declared in the U.S. on March 13, 2020. This report contains 10 months of COVID-era data in the post-policy era since the declaration of this national emergency, and given the impact that has been seen on the U.S. transplant and donation community (see data trends at unos.org/covid) the true impact of this policy change is very challenging to determine. Figures and tables include multiple COVID eras, representing the heaviest-impacted period of time from March 13, 2020 to May 09, 2020 and the additional period of time with continual, albeit less-dramatic, impact from May 10, 2020 to the end of the post-policy cohort.

Results

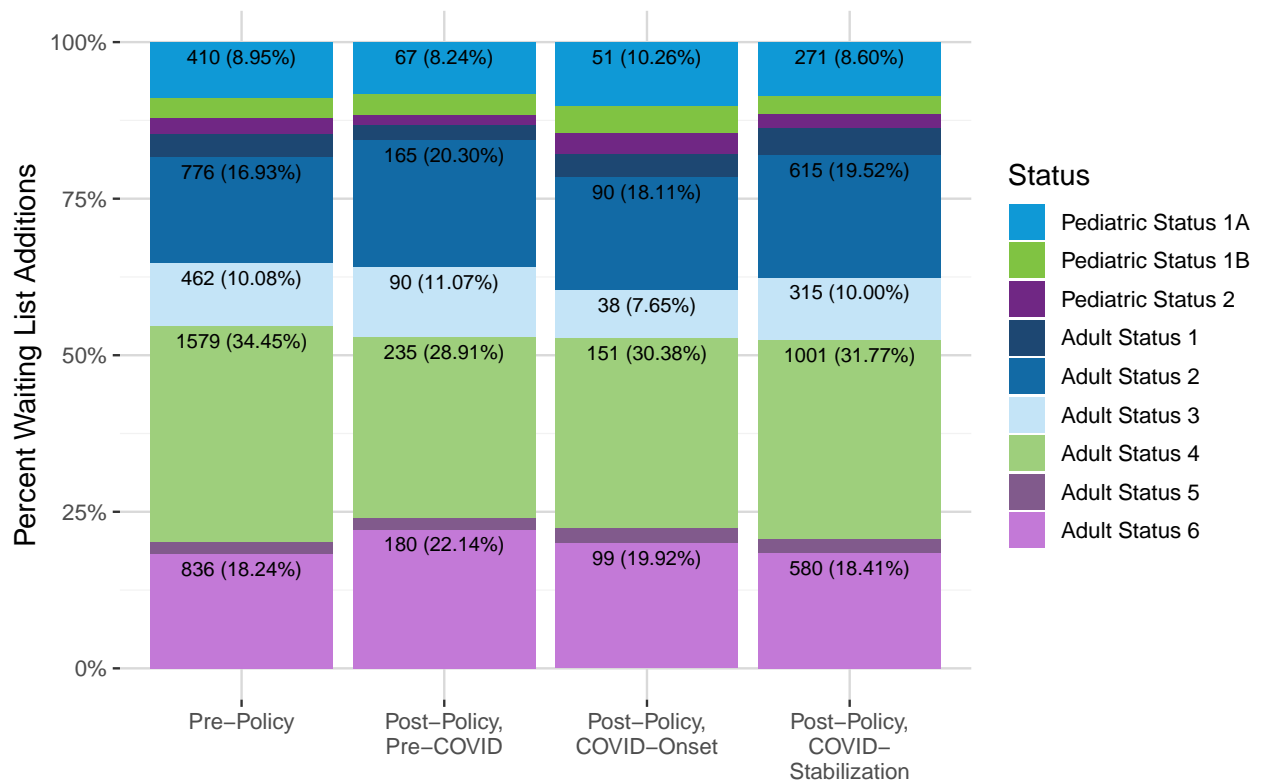
Waitlist

The analyses in this chapter describe the differences in waitlist additions and candidates ever-waiting between the pre-implementation and post-implementation cohorts. Where possible the post-implementation cohort was split into 3 COVID-related post-implementation eras (post-policy pre-COVID, post-policy COVID Onset, and post-policy COVID stabilization) and dates for these eras are marked in footnotes.

Pre-implementation there were 4657 registrations added to the heart waiting list between January 09, 2019 and January 08, 2020, and 4517 registrations added post-implementation between January 09, 2020 and January 08, 2021. Of these, 690 registrations were pediatric registrations pre-implementation and 642 were pediatric registrations post-implementation. There were 3967 adult registrations pre-implementation and 3875 adult registrations post-implementation.

Figure 1 and Table 1 show the proportion and counts of heart waitlist additions by era and medical urgency status. The proportions of waitlist additions to different medical urgency statuses were similar across eras. There was a slight decrease in the proportion of Adult Status 4 registrations and a slight increase in the proportion of Adult Status 2 registrations post-implementation. These trends were consistent across post-implementation COVID-eras.

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



Statuses representing less than 5% of the total are not labeled on the plot
 Temporarily inactive statuses excluded (n=74 Pre & n=56 Post)
 Pre-Policy: January 09, 2019 – January 08, 2020;
 Post-Policy, Pre-COVID: January 09, 2020 – March 12, 2020;
 Post-Policy, COVID Onset: March 13, 2020 – May 08 2020;
 Post-Policy COVID Stabilization: May 09 2020 – January 08, 2021

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

Status	Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
	N	%	N	%	N	%	N	%	N	%
Pediatric Status 1A	410	8.8%	67	8.1%	51	10.1%	271	8.5%	389	8.6%
Pediatric Status 1B	148	3.2%	28	3.4%	21	4.1%	89	2.8%	138	3.1%
Pediatric Status 2	118	2.5%	13	1.6%	17	3.4%	75	2.4%	105	2.3%
Adult Status 1	167	3.6%	20	2.4%	18	3.6%	136	4.3%	174	3.9%
Adult Status 2	776	16.7%	165	20%	90	17.8%	615	19.3%	870	19.3%
Adult Status 3	462	9.9%	90	10.9%	38	7.5%	315	9.9%	443	9.8%
Adult Status 4	1579	33.9%	235	28.5%	151	29.8%	1001	31.4%	1387	30.7%
Adult Status 5	87	1.9%	15	1.8%	12	2.4%	69	2.2%	96	2.1%
Adult Status 6	836	18%	180	21.8%	99	19.5%	580	18.2%	859	19%
Temporarily inactive	74	1.6%	11	1.3%	10	2%	35	1.1%	56	1.2%

Percentages may differ from Figure 1 because temporarily inactives are included in table;

Pre-Policy: January 09, 2019 - January 08, 2020;

Post-Policy, Pre-COVID: January 09, 2020 - March 12, 2020;

Post-Policy, COVID Onset: March 13, 2020 - May 08 2020;

Post-Policy COVID Stabilization: May 09 2020 - January 08, 2021;

Table 2 shows a snapshot of the heart waitlist at the end of the first month of each period. Snapshots show the makeup of the waitlist as of a particular date. The proportions of candidates waiting at each medical urgency status remained fairly similar across snapshots.

Table 2. Heart Waiting List on Last Day of First Month of Each Period by Medical Urgency Status

Status	Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization	
	N	%	N	%	N	%	N	%
Pediatric Status 1A	88	3.1%	83	3.3%	100	3.7%	86	3%
Pediatric Status 1B	70	2.4%	87	3.5%	90	3.4%	80	2.8%
Pediatric Status 2	118	4.1%	111	4.4%	117	4.4%	125	4.4%
Adult Status 1	6	0.2%	7	0.3%	9	0.3%	2	0.1%
Adult Status 2	59	2.1%	51	2%	73	2.7%	88	3.1%
Adult Status 3	218	7.6%	129	5.1%	157	5.9%	210	7.4%
Adult Status 4	1626	56.6%	1479	58.8%	1526	57.1%	1648	57.7%
Adult Status 5	82	2.9%	90	3.6%	90	3.4%	97	3.4%
Adult Status 6	606	21.1%	479	19%	509	19.1%	519	18.2%

Pre-Policy: January 31, 2019;

Post-Policy, Pre-COVID: January 31, 2020;

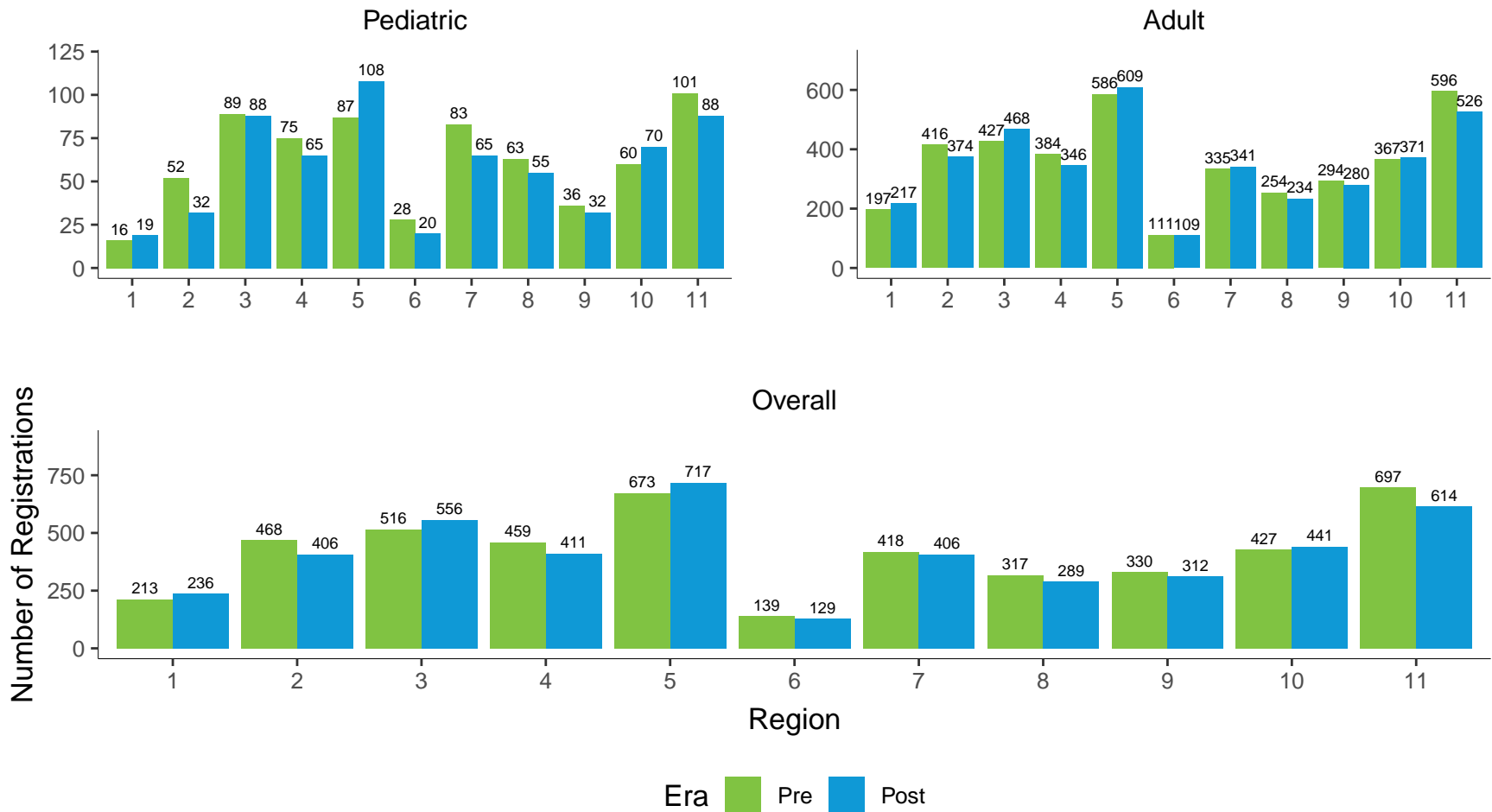
Post-Policy, COVID Onset: March 31, 2020;

Post-Policy COVID Stabilization: May 31, 2020

Figure 2 and shows the number of heart waitlist additions by region and era, overall and for pediatric and adult candidates. Overall, waitlist additions remained similar pre- to post-implementation for all regions. Table 3 shows the number of heart waiting list additions by region and era (including COVID eras).

Figure A1 shows the number of heart waitlist additions by region and medical urgency status pre- and post-implementation. Tables A1 and A2 show the number and percent of waitlist additions by region and medical urgency status pre- and post-implementation, respectively.

Figure 2. Heart Waiting List Additions by Region and Era



* COVID-19 Pandemic & National State of Emergency Declared March 11-13, 2020

Table 3. Heart Waiting List Additions by Region and Era

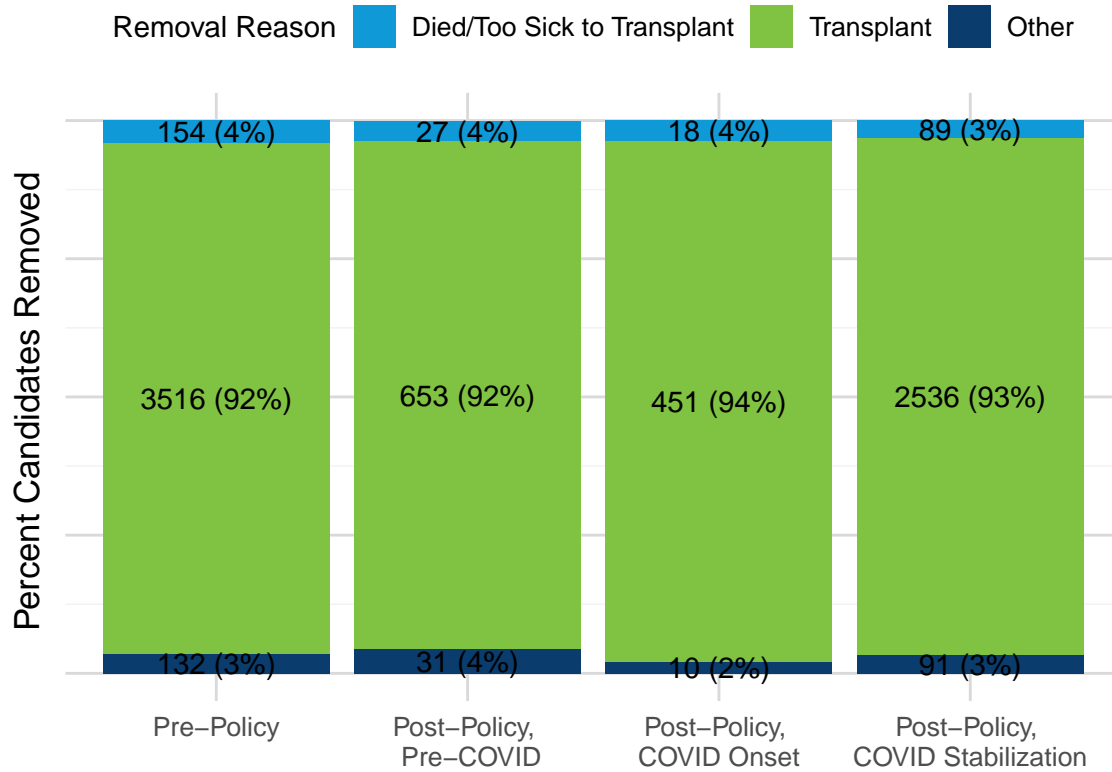
Age Group	Region	Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
		N	%	N	%	N	%	N	%	N	%
Pediatric	1	16	2.3%	3	2.7%	3	3.3%	13	3%	19	3%
	2	52	7.5%	6	5.5%	4	4.3%	22	5%	32	5%
	3	89	12.9%	20	18.2%	16	17.4%	52	11.8%	88	13.7%
	4	75	10.9%	8	7.3%	9	9.8%	48	10.9%	65	10.1%
	5	87	12.6%	19	17.3%	14	15.2%	75	17%	108	16.8%
	6	28	4.1%	2	1.8%	2	2.2%	16	3.6%	20	3.1%
	7	83	12%	12	10.9%	9	9.8%	44	10%	65	10.1%
	8	63	9.1%	11	10%	7	7.6%	37	8.4%	55	8.6%
	9	36	5.2%	4	3.6%	7	7.6%	21	4.8%	32	5%
	10	60	8.7%	13	11.8%	10	10.9%	47	10.7%	70	10.9%
	11	101	14.6%	12	10.9%	11	12%	65	14.8%	88	13.7%
Adult	1	197	5%	35	4.9%	24	5.8%	158	5.8%	217	5.6%
	2	416	10.5%	66	9.2%	45	10.8%	263	9.6%	374	9.7%
	3	427	10.8%	97	13.6%	46	11.1%	325	11.8%	468	12.1%
	4	384	9.7%	55	7.7%	51	12.3%	240	8.7%	346	8.9%
	5	586	14.8%	106	14.8%	63	15.2%	440	16%	609	15.7%
	6	111	2.8%	20	2.8%	15	3.6%	74	2.7%	109	2.8%
	7	335	8.4%	80	11.2%	28	6.7%	233	8.5%	341	8.8%
	8	254	6.4%	38	5.3%	24	5.8%	172	6.3%	234	6%
	9	294	7.4%	67	9.4%	12	2.9%	201	7.3%	280	7.2%
	10	367	9.3%	59	8.3%	36	8.7%	276	10.1%	371	9.6%
	11	596	15%	91	12.7%	71	17.1%	364	13.3%	526	13.6%
Overall	1	213	4.6%	38	4.6%	27	5.3%	171	5.4%	236	5.2%
	2	468	10%	72	8.7%	49	9.7%	285	8.9%	406	9%
	3	516	11.1%	117	14.2%	62	12.2%	377	11.8%	556	12.3%
	4	459	9.9%	63	7.6%	60	11.8%	288	9%	411	9.1%
	5	673	14.5%	125	15.2%	77	15.2%	515	16.2%	717	15.9%
	6	139	3%	22	2.7%	17	3.4%	90	2.8%	129	2.9%
	7	418	9%	92	11.2%	37	7.3%	277	8.7%	406	9%
	8	317	6.8%	49	5.9%	31	6.1%	209	6.6%	289	6.4%
	9	330	7.1%	71	8.6%	19	3.7%	222	7%	312	6.9%
	10	427	9.2%	72	8.7%	46	9.1%	323	10.1%	441	9.8%
	11	697	15%	103	12.5%	82	16.2%	429	13.5%	614	13.6%

Pre-Policy: January 09, 2019 - January 08, 2020; Post-Policy, Pre-COVID: January 09, 2020 - March 12, 2020;

Post-Policy, COVID Onset: March 13, 2020 - May 08 2020; Post-Policy COVID Stabilization: May 09, 2020 - January 08, 2021;

Figure 3 examines the number and proportion of candidates removed from the waitlist by removal reason and era. The proportion of candidates removed from the waitlist due to death or being too sick to transplant remained similar across all eras.

Figure 3. Candidates Removed from Waitlist by Removal Reason and Era



Pre-Policy: January 09, 2019 – January 08, 2020;
 Post-Policy, Pre-COVID: January 09, 2020 – March 12, 2020;
 Post-Policy, COVID Onset: March 13, 2020 – May 08 2020;
 Post-Policy COVID Stabilization: May 09 2020 – January 08, 2021;

Figure 4 displays the counts and proportions of candidates removed from the waitlist by removal reason and medical urgency status. The proportion of candidates removed for death or being too sick to transplant increased slightly in Pediatric Status 1A, decreased slightly in Pediatric Statuses 1B and remained the same for Pediatric Status 2 candidates post-implementation. The proportion of candidates removed due to death or being too sick to transplant decreased or remained the same in all adult heart statuses except for Adult Statuses 1 & 5 where there was a slight increase. Adult Statuses 4 and 6 saw the largest decrease in the proportion of candidates removed due to death or being too sick to transplant.

Figure 4. Candidates Removed by Removal Reason within Medical Urgency Status and Era

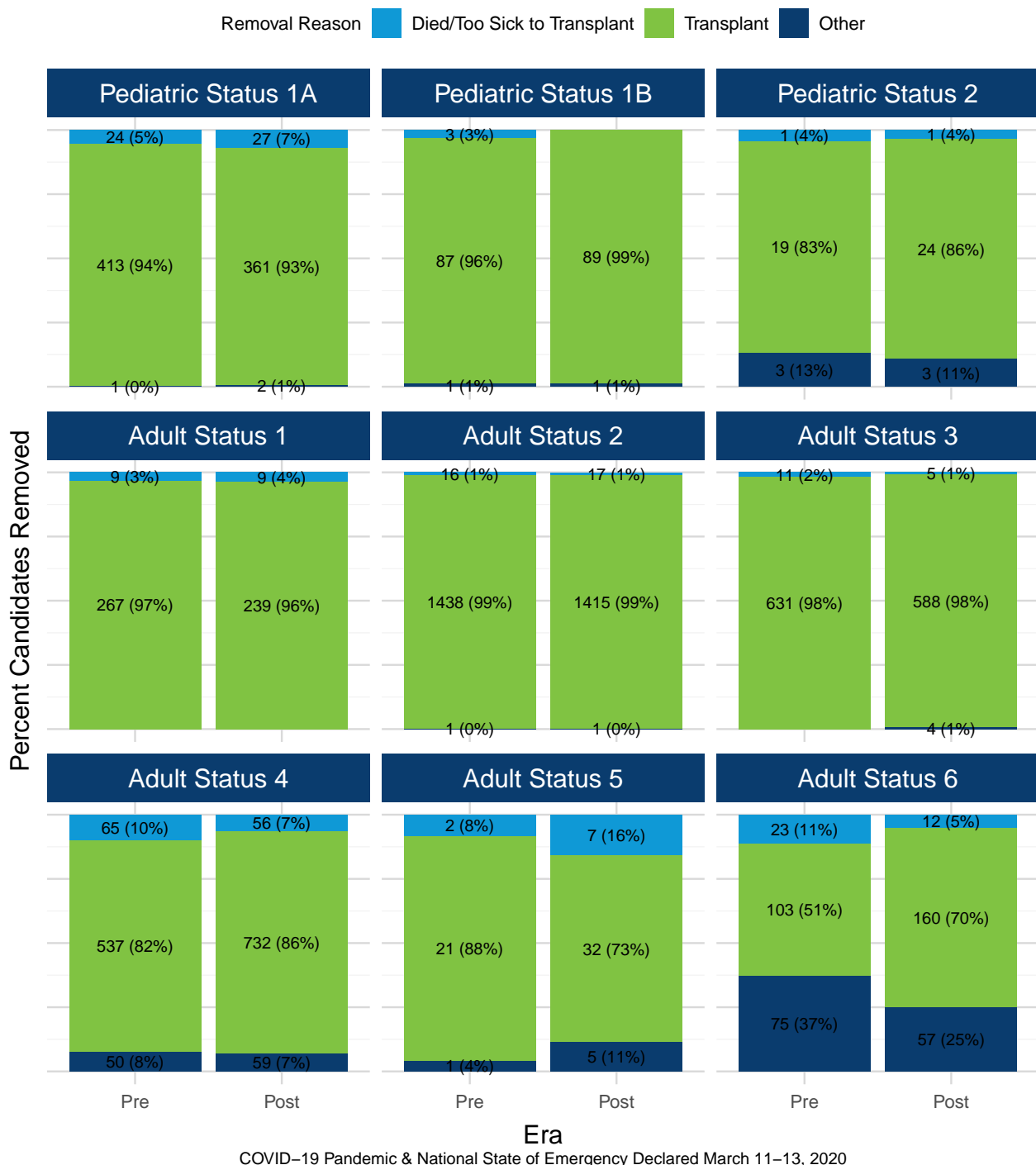


Figure 5 shows the percent of candidates ever-waiting by medical urgency status and era. Post-implementation there was an increase in the percent of Adult Status 4 and 6 candidates ever waiting and a decrease in the percent of Adult Status 2 and 3 candidates ever waiting.

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

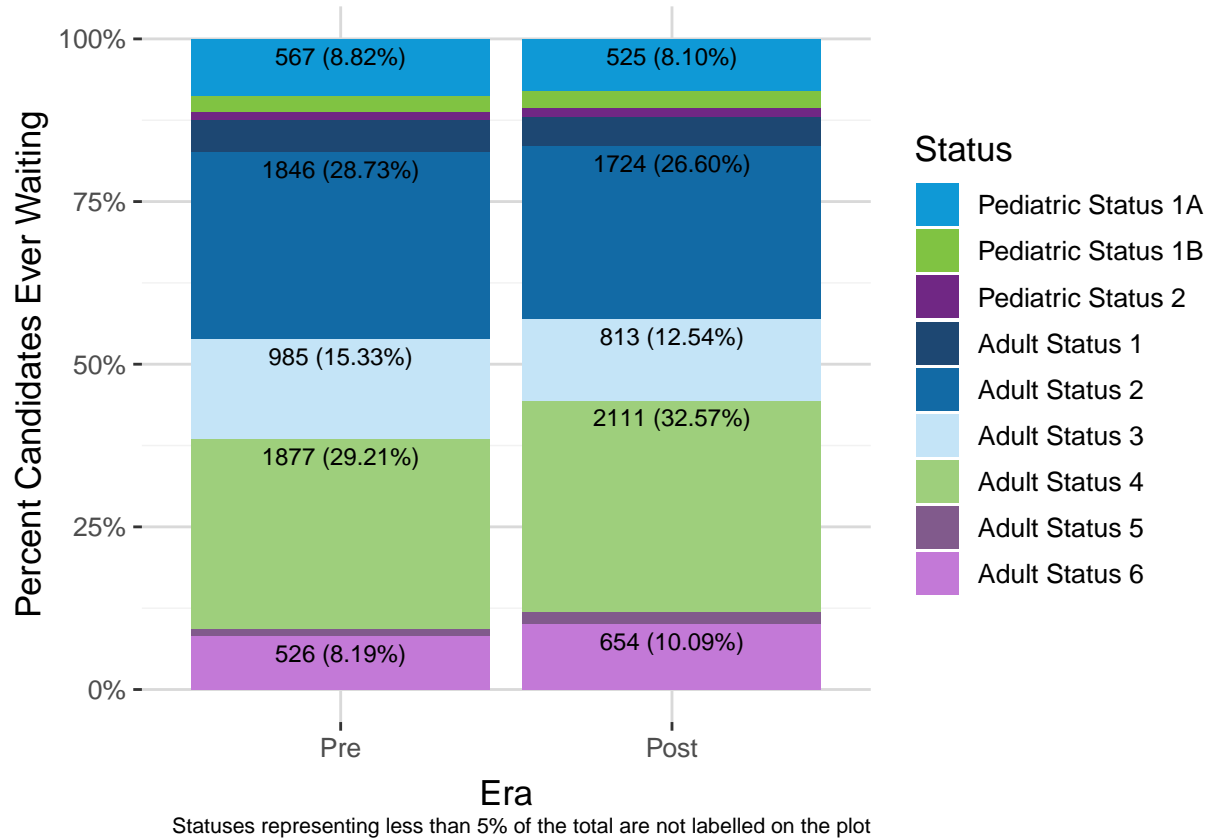


Figure 6 and Table 4 show the waitlist mortality rates by medical urgency status and era. Waitlist mortality rates were defined as the number of deaths per 100 patient years. There was no significant difference in waitlist mortality rates by era.

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

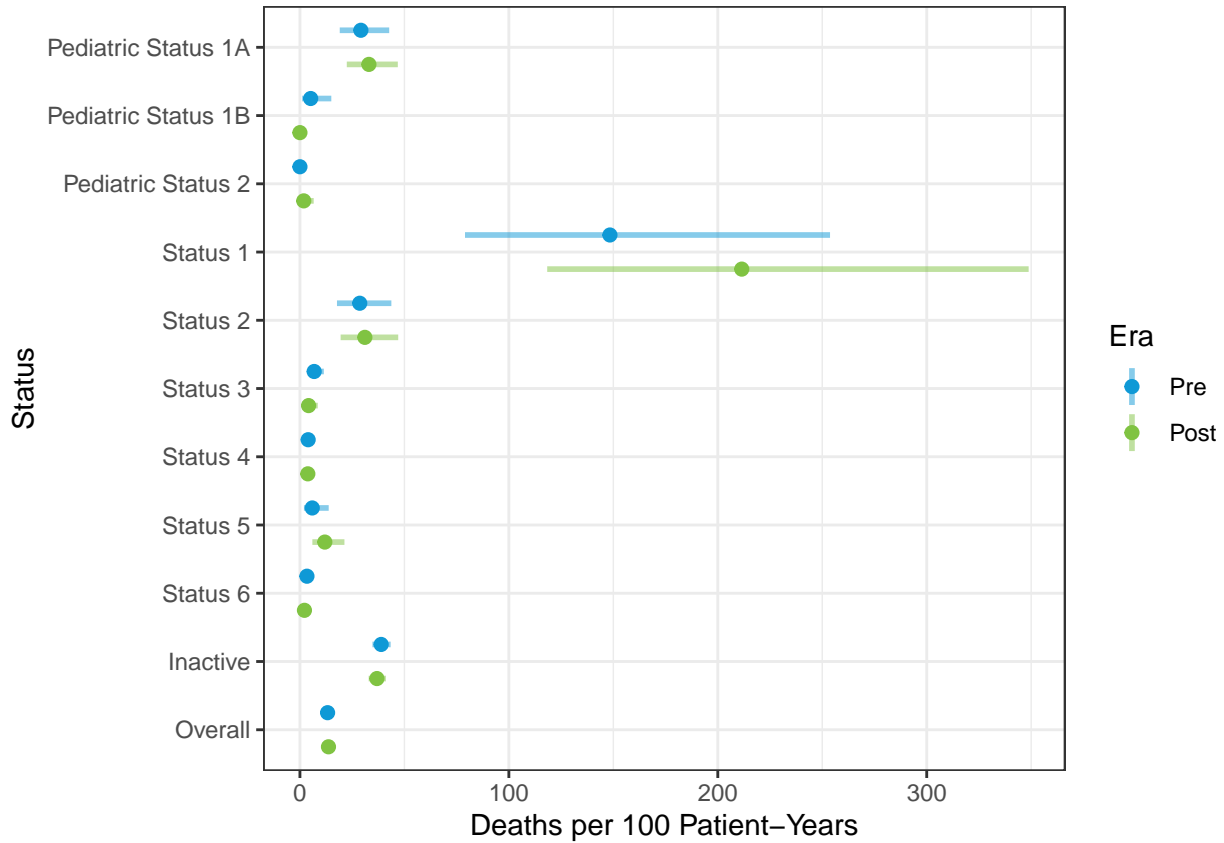


Table 4. Deaths per 100 Patient-Years Waiting by Medical Urgency Status and Era

Status	Era	Patients Ever Waiting	Deaths	Deaths per 100 Patient Years	95% CI
Pediatric Status 1A	Pre	618	26	29.16	[19.05, 42.73]
	Post	588	31	33.01	[22.43, 46.85]
Pediatric Status 1B	Pre	297	3	5.14	[1.06, 15.02]
	Post	291	0	0.00	–
Pediatric Status 2	Pre	242	0	0.00	–
	Post	246	2	1.82	[0.22, 6.58]
Status 1	Pre	344	13	148.37	[79.00, 253.72]
	Post	311	15	211.47	[118.36, 348.79]
Status 2	Pre	1800	21	28.63	[17.72, 43.76]
	Post	1766	22	31.07	[19.47, 47.04]
Status 3	Pre	1928	14	6.81	[3.72, 11.43]
	Post	1497	7	4.14	[1.66, 8.53]
Status 4	Pre	3761	63	3.93	[3.02, 5.03]
	Post	3461	55	3.78	[2.84, 4.91]
Status 5	Pre	261	5	5.90	[1.91, 13.76]
	Post	279	11	11.90	[5.94, 21.30]
Status 6	Pre	1737	19	3.35	[2.02, 5.24]
	Post	1555	11	2.16	[1.08, 3.87]
Inactive	Pre	2683	314	38.88	[34.70, 43.42]
	Post	2797	316	36.84	[32.89, 41.14]
Overall	Pre	7961	478	13.23	[12.07, 14.48]
	Post	7840	470	13.66	[12.45, 14.95]

Figure 7 shows the waitlist mortality rates by region and era. There was no significant difference in waitlist mortality by era overall. Waitlist mortality was significantly higher post-implementation in Region 8.

Figure 7. Deaths per 100 Patient-Years Waiting by Region and Era

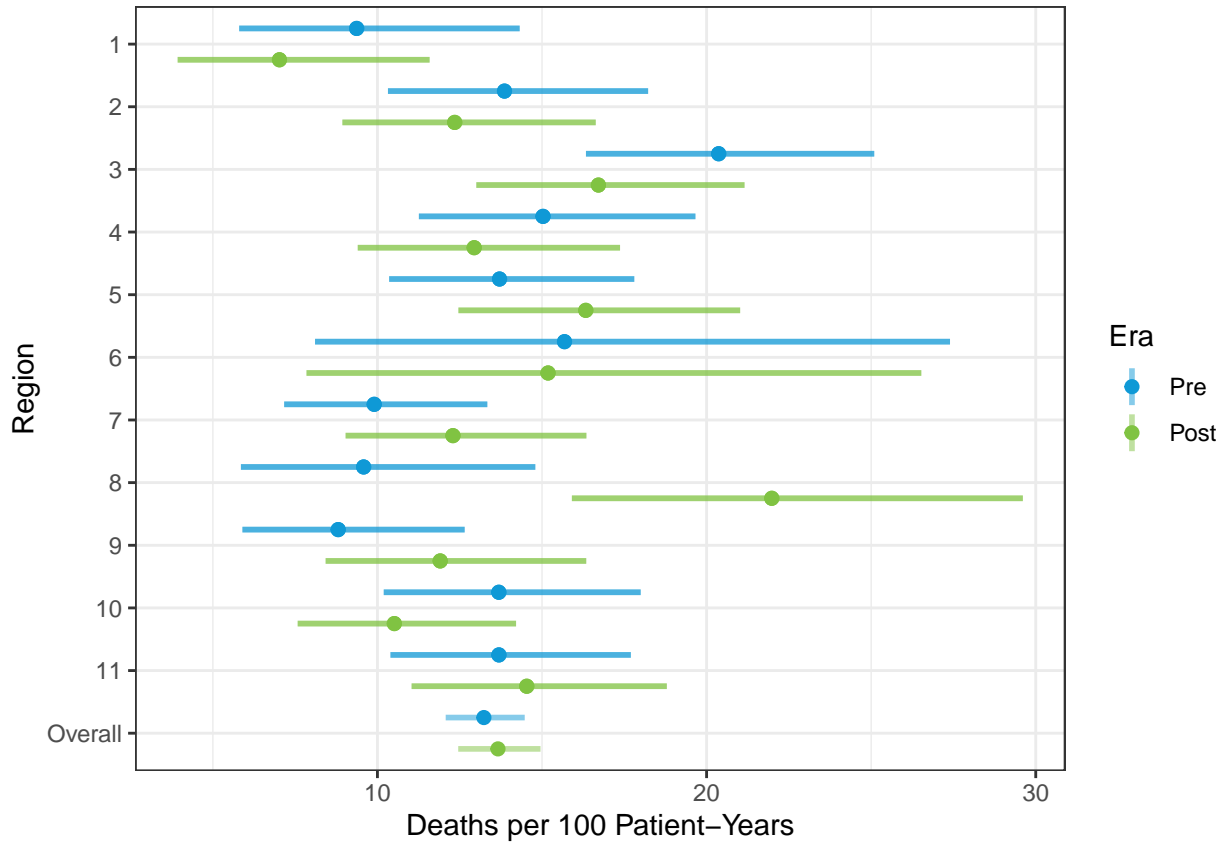


Table 5 shows the number of candidates ever waiting and the number of deaths for each region pre- and post-implementation, as well as the number of deaths per 100 patient-years, and the 95% confidence interval around the number of deaths per 100 patient-years.

Table 5. Deaths per 100 Patient-Years Waiting by Region and Era

Region	Era	Patients Ever Waiting	Deaths	Deaths per 100 Patient Years	CI
1	Pre	445	21	9.37	[5.80, 14.32]
	Post	434	15	7.02	[3.93, 11.58]
2	Pre	811	51	13.86	[10.32, 18.22]
	Post	769	43	12.35	[8.94, 16.63]
3	Pre	957	88	20.37	[16.33, 25.09]
	Post	943	69	16.71	[13.00, 21.15]
4	Pre	794	53	15.03	[11.26, 19.66]
	Post	751	44	12.94	[9.40, 17.37]
5	Pre	1073	56	13.71	[10.36, 17.80]
	Post	1069	60	16.33	[12.46, 21.02]
6	Pre	200	12	15.68	[8.10, 27.40]
	Post	194	12	15.18	[7.85, 26.52]
7	Pre	830	43	9.90	[7.17, 13.34]
	Post	795	47	12.29	[9.03, 16.35]
8	Pre	497	20	9.58	[5.85, 14.80]
	Post	492	43	21.98	[15.91, 29.61]
9	Pre	642	29	8.81	[5.90, 12.65]
	Post	630	38	11.91	[8.43, 16.34]
10	Pre	767	51	13.69	[10.19, 18.00]
	Post	810	42	10.51	[7.58, 14.21]
11	Pre	1021	58	13.69	[10.40, 17.70]
	Post	1013	58	14.54	[11.04, 18.79]
Overall	Pre	7961	478	13.23	[12.07, 14.48]
	Post	7840	470	13.66	[12.45, 14.95]

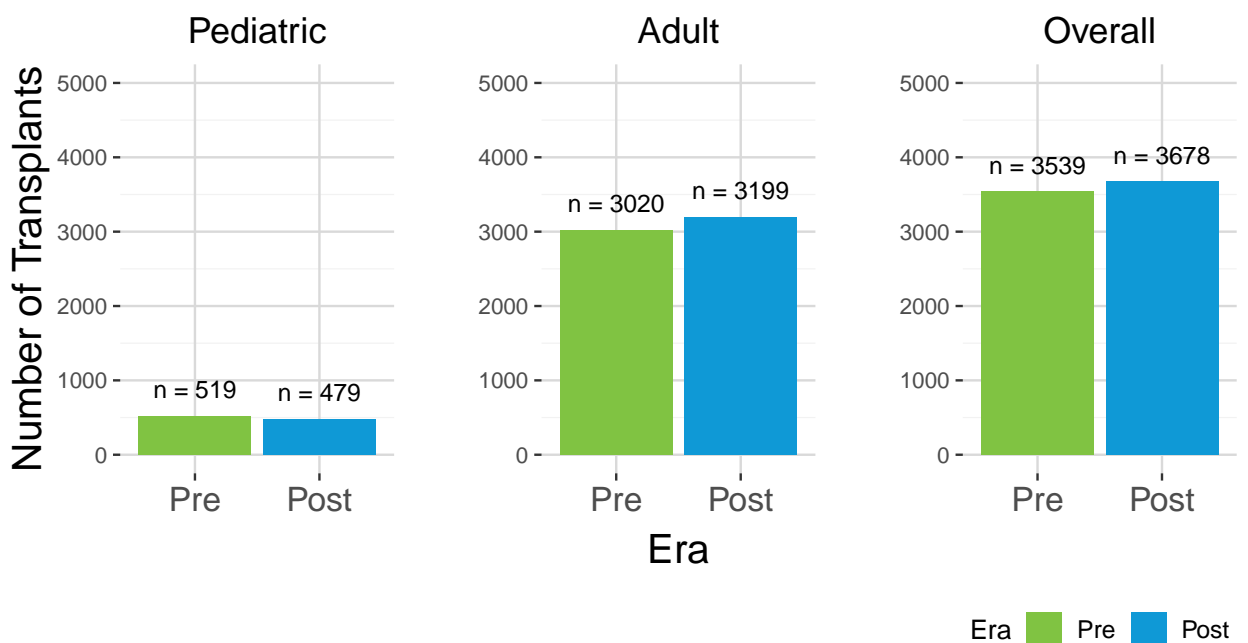
Transplant

The analyses in this chapter describe the differences in transplants between the pre-implementation and post-implementation cohorts. Where possible the post-implementation cohort was split into 3 COVID-related post-implementation eras (post-policy pre-COVID, post-policy COVID Onset, and post-policy COVID stabilization) and dates for these eras are marked in footnotes.

Overall there were 3539 heart transplants performed pre-implementation (January 09 2019 - January 08 2020) and 3678 adult heart transplant performed post-implementation (January 09 2020 - January 08 2021). There were 139 more heart transplants performed in the post-implementation cohort than in the pre-implementation cohort.

Figure 8 shows the number of adult heart transplants by era overall and for pediatric and adult recipients separately. The number of pediatric transplants decreased while the number of adult heart transplants increased marginally.

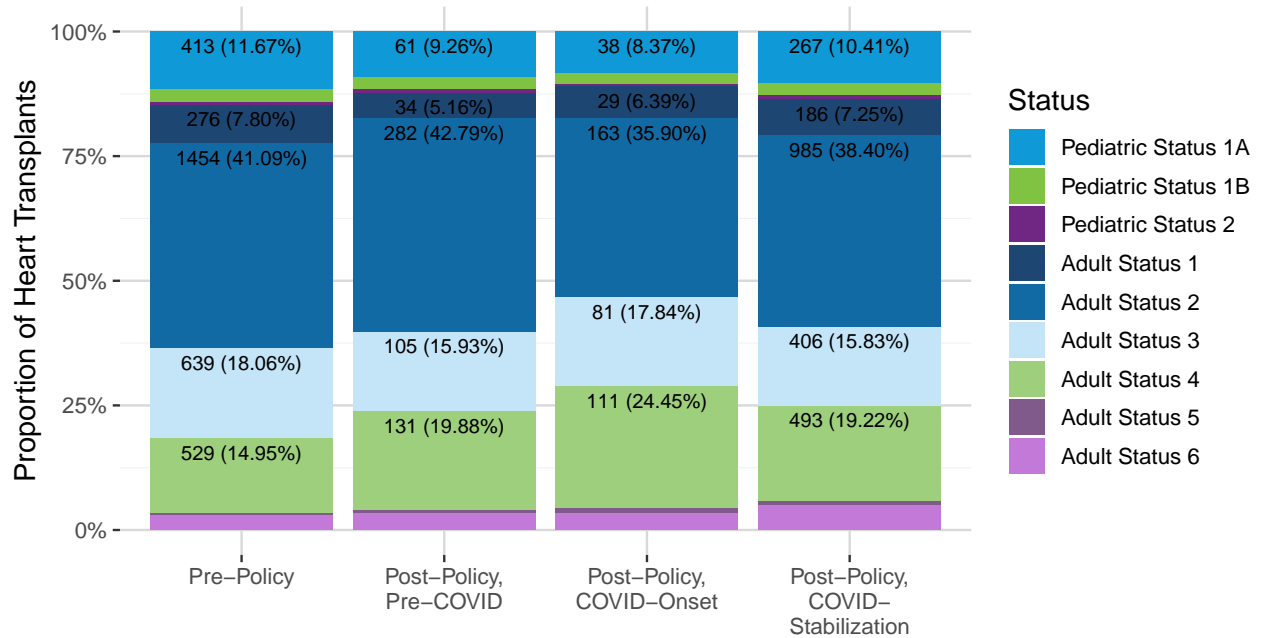
Figure 8. Number of Heart Transplants by Era



* COVID-19 Pandemic & National State of Emergency Declared

Figure 9 and Table 6 show the proportion and counts of heart transplants by era and medical urgency status. The proportion of transplants going to Adult Statuses 5 and 6 increased in all post-implementation cohorts and overall but made up less than 5% of heart transplants in each era. Post-implementation there was a smaller proportion of Adult Status 3 transplants and a larger proportion of Adult Status 4 transplants; this persisted across all COVID-eras. The proportion of Adult Status 1 and 2 transplants remained fairly similar across eras. The proportion of Pediatric Status 1A transplants decreased across all post-implementation eras. Pediatric Statuses 1B and 2 each made up less than 5% of all transplants and showed no consistent increase or decrease pre- to post-implementation.

Figure 9. Proportion of Heart Transplants by Medical Urgency Status and Era



Statuses representing less than 5% of the total are not labeled on the plot
 Pre-Policy: January 09, 2019 – January 08, 2020;
 Post-Policy, Pre-COVID: January 09, 2020 – March 12, 2020;
 Post-Policy, COVID Onset: March 13, 2020 – May 08 2020;
 Post-Policy COVID Stabilization: May 09 2020 – January 08, 2021

Table 6. Heart Transplants by Medical Urgency Status and Era

Status	Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
	N	%	N	%	N	%	N	%	N	%
Pediatric Status 1A	413	11.7%	61	9.3%	38	8.4%	267	10.4%	366	10%
Pediatric Status 1B	87	2.5%	15	2.3%	10	2.2%	64	2.5%	89	2.4%
Pediatric Status 2	19	0.5%	5	0.8%	2	0.4%	17	0.7%	24	0.7%
Adult Status 1	276	7.8%	34	5.2%	29	6.4%	186	7.3%	249	6.8%
Adult Status 2	1454	41.1%	282	42.8%	163	35.9%	985	38.4%	1430	38.9%
Adult Status 3	639	18.1%	105	15.9%	81	17.8%	406	15.8%	592	16.1%
Adult Status 4	529	14.9%	131	19.9%	111	24.4%	493	19.2%	735	20%
Adult Status 5	21	0.6%	4	0.6%	5	1.1%	23	0.9%	32	0.9%
Adult Status 6	101	2.9%	22	3.3%	15	3.3%	124	4.8%	161	4.4%

Pre-Policy: January 09, 2019 - January 08, 2020;

Post-Policy, Pre-COVID: January 09, 2020 - March 12, 2020;

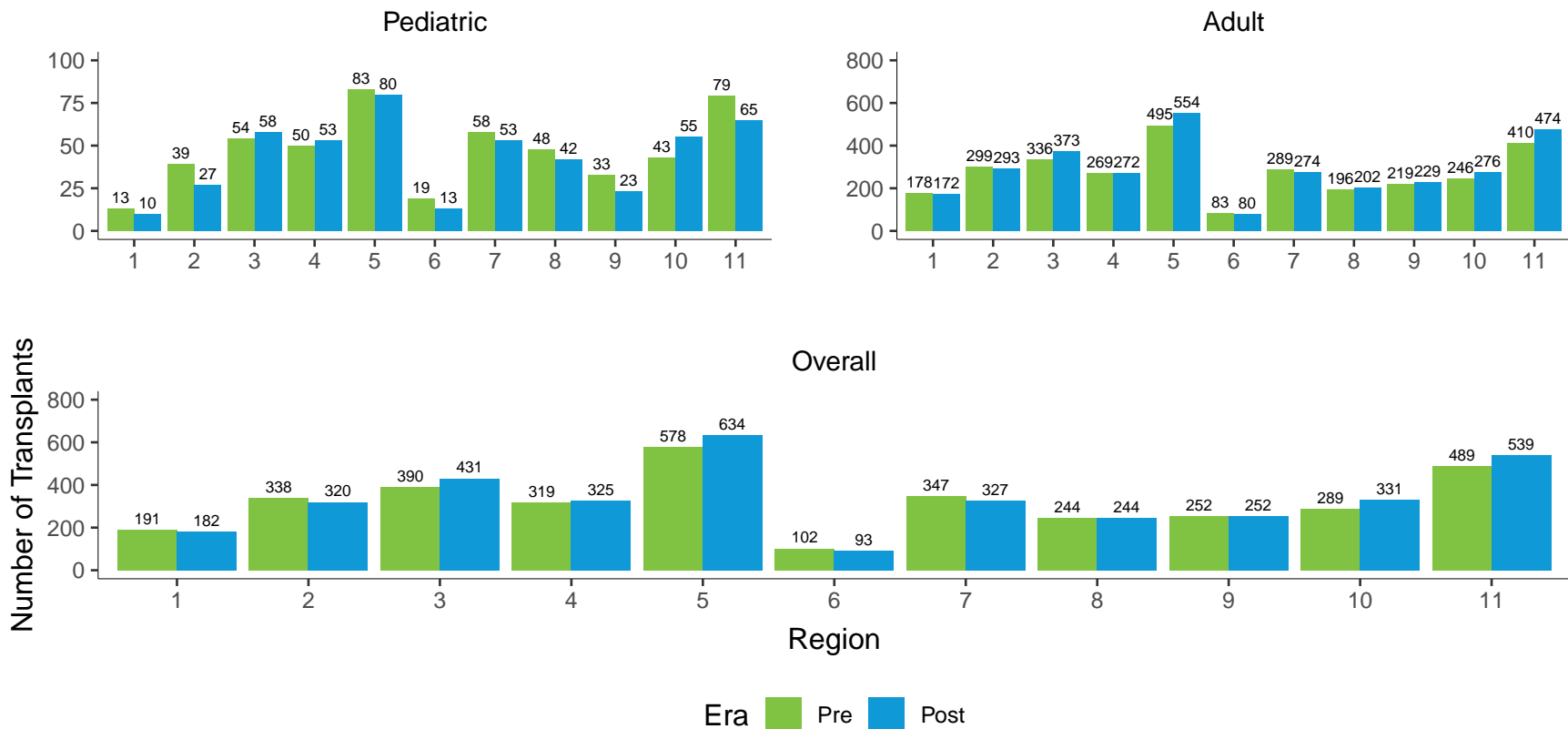
Post-Policy, COVID Onset: March 13, 2020 - May 08 2020;

Post-Policy COVID Stabilization: May 09 2020 - January 08, 2021;

Figure 10 and Table 7 show the number of heart transplants performed by OPTN region. The number of transplants performed remained fairly similar pre- to post-implementation for pediatrics, adults and overall. Table 7 further breaks down the count and percent of adult, pediatric and overall transplants by region and COVID-eras.

Figure A2 shows the number of adult heart transplants performed by region, medical urgency status and era. Adult statuses 5 and 6 each made up less than 5% of all transplants in each region pre- and post-implementation. The percent of Adult Status 4 transplants increased in every region while the percent of Adult Status 3 transplants decreased in all Regions or remained (within 1%) except for Regions 4, 5, 8 and 10. Tables A3 and A4 show the number and percent of heart transplants by region and medical urgency status pre- and post-implementation respectively.

Figure 10. Heart Transplants by Region and Era



* COVID-19 Pandemic & National State of Emergency Declared March 11-13, 2020

Table 7. Heart Transplants by Region and Era

Age Group	Region	Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
		N	%	N	%	N	%	N	%	N	%
Pediatric	1	13	2.5%	0	0%	3	6%	7	2%	10	2.1%
	2	39	7.5%	5	6.2%	2	4%	20	5.7%	27	5.6%
	3	54	10.4%	11	13.6%	7	14%	40	11.5%	58	12.1%
	4	50	9.6%	9	11.1%	5	10%	39	11.2%	53	11.1%
	5	83	16%	13	16%	9	18%	58	16.7%	80	16.7%
	6	19	3.7%	2	2.5%	1	2%	10	2.9%	13	2.7%
	7	58	11.2%	15	18.5%	5	10%	33	9.5%	53	11.1%
	8	48	9.2%	7	8.6%	5	10%	30	8.6%	42	8.8%
	9	33	6.4%	1	1.2%	2	4%	20	5.7%	23	4.8%
	10	43	8.3%	8	9.9%	1	2%	46	13.2%	55	11.5%
	11	79	15.2%	10	12.3%	10	20%	45	12.9%	65	13.6%
Adult	1	178	5.9%	27	4.7%	23	5.7%	122	5.5%	172	5.4%
	2	299	9.9%	54	9.3%	48	11.9%	191	8.6%	293	9.2%
	3	336	11.1%	71	12.3%	47	11.6%	255	11.5%	373	11.7%
	4	269	8.9%	53	9.2%	30	7.4%	189	8.5%	272	8.5%
	5	495	16.4%	97	16.8%	72	17.8%	385	17.4%	554	17.3%
	6	83	2.7%	10	1.7%	12	3%	58	2.6%	80	2.5%
	7	289	9.6%	52	9%	37	9.2%	185	8.3%	274	8.6%
	8	196	6.5%	31	5.4%	22	5.4%	149	6.7%	202	6.3%
	9	219	7.3%	51	8.8%	17	4.2%	161	7.3%	229	7.2%
	10	246	8.1%	47	8.1%	24	5.9%	205	9.2%	276	8.6%
	11	410	13.6%	85	14.7%	72	17.8%	317	14.3%	474	14.8%
Overall	1	191	5.4%	27	4.1%	26	5.7%	129	5%	182	4.9%
	2	338	9.6%	59	9%	50	11%	211	8.2%	320	8.7%
	3	390	11%	82	12.4%	54	11.9%	295	11.5%	431	11.7%
	4	319	9%	62	9.4%	35	7.7%	228	8.9%	325	8.8%
	5	578	16.3%	110	16.7%	81	17.8%	443	17.3%	634	17.2%
	6	102	2.9%	12	1.8%	13	2.9%	68	2.7%	93	2.5%
	7	347	9.8%	67	10.2%	42	9.3%	218	8.5%	327	8.9%
	8	244	6.9%	38	5.8%	27	5.9%	179	7%	244	6.6%
	9	252	7.1%	52	7.9%	19	4.2%	181	7.1%	252	6.9%
	10	289	8.2%	55	8.3%	25	5.5%	251	9.8%	331	9%
	11	489	13.8%	95	14.4%	82	18.1%	362	14.1%	539	14.7%

Pre-Policy: January 09, 2019 - January 08, 2020;

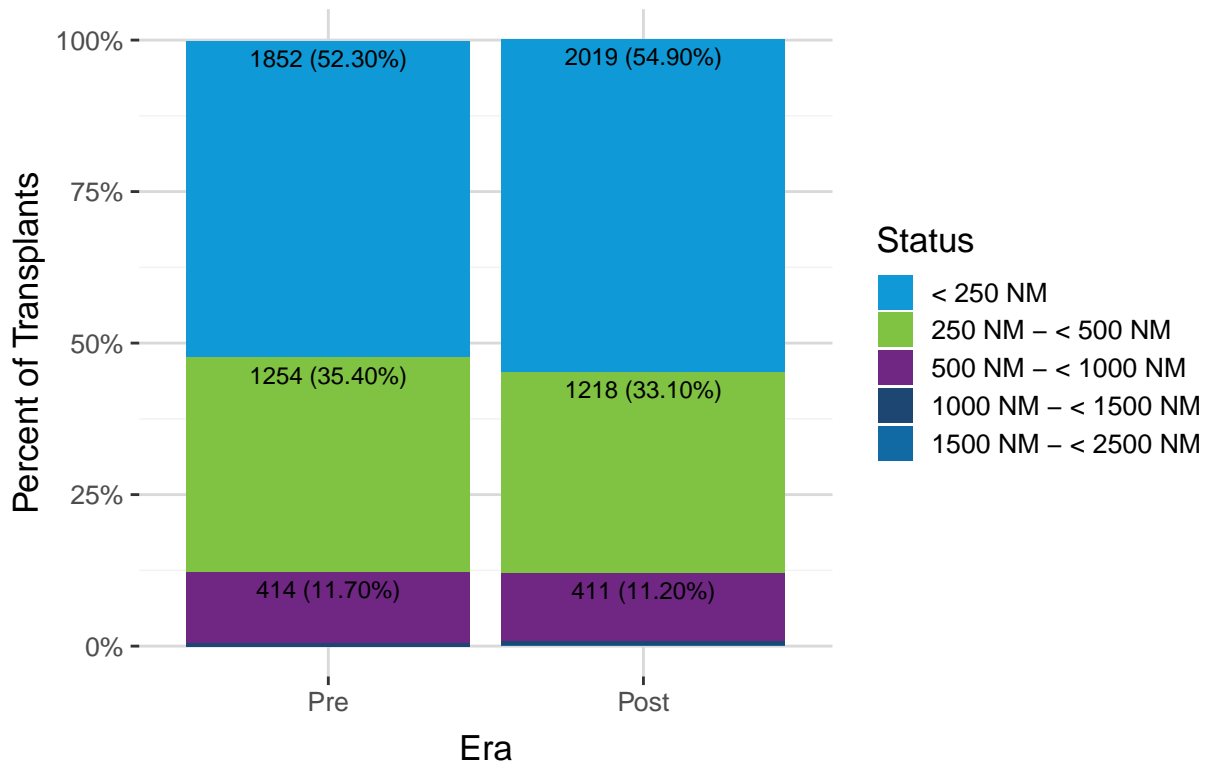
Post-Policy, Pre-COVID: January 09, 2020 - March 12, 2020;

Post-Policy, COVID Onset: March 13, 2020 - May 08 2020;

Post-Policy COVID Stabilization: May 09 2020 - January 08, 2021;

Figure 11 shows heart transplants by distance traveled and era. Only a small number of transplants occurred within 1000-<1500 NM and only 2 transplants occurred over 1500 NM in the post-implementation era. Overall there was a small decrease in the percent of transplants 250-<500 NM and a small increase in the percent of transplants <250 NM. Trends in pediatric transplants by distance traveled were less consistent across COVID-eras and therefore harder to decipher.

Figure 11. Heart Transplants by Distance Traveled and Era



Distance groups representing less than 5% of the total are not labelled on the plot;
 There were n=19 and n=28 transplants within 1000-<1500NM pre- and post, respectively;
 There were n=2 transplants within 1500-<2500 NM post-implementation;

Table 8. Heart Transplants by Distance Traveled and Era

Age Group	Distance Group	Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
		N	%	N	%	N	%	N	%	N	%
Pediatric	< 250 NM	220	42.4%	26	32.1%	19	38%	148	42.5%	193	40.3%
	250 NM - < 500 NM	229	44.1%	40	49.4%	21	42%	154	44.3%	215	44.9%
	500 NM - < 1000 NM	67	12.9%	13	16%	9	18%	42	12.1%	64	13.4%
	1000 NM - < 1500 NM	3	0.6%	2	2.5%	1	2%	4	1.1%	7	1.5%
Adult	< 250 NM	1632	54%	333	57.6%	252	62.4%	1241	56%	1826	57.1%
	250 NM - < 500 NM	1025	33.9%	190	32.9%	113	28%	700	31.6%	1003	31.4%
	500 NM - < 1000 NM	347	11.5%	50	8.7%	39	9.7%	258	11.6%	347	10.8%
	1000 NM - < 1500 NM	16	0.5%	5	0.9%	0	0%	16	0.7%	21	0.7%
	1500 NM - < 2500 NM	0	0%	0	0%	0	0%	2	0.1%	2	0.1%
Overall	< 250 NM	1852	52.3%	359	54.5%	271	59.7%	1389	54.2%	2019	54.9%
	250 NM - < 500 NM	1254	35.4%	230	34.9%	134	29.5%	854	33.3%	1218	33.1%
	500 NM - < 1000 NM	414	11.7%	63	9.6%	48	10.6%	300	11.7%	411	11.2%
	1000 NM - < 1500 NM	19	0.5%	7	1.1%	1	0.2%	20	0.8%	28	0.8%
	1500 NM - < 2500 NM	0	0%	0	0%	0	0%	2	0.1%	2	0.1%

Pre-Policy: January 09, 2019 - January 08, 2020;

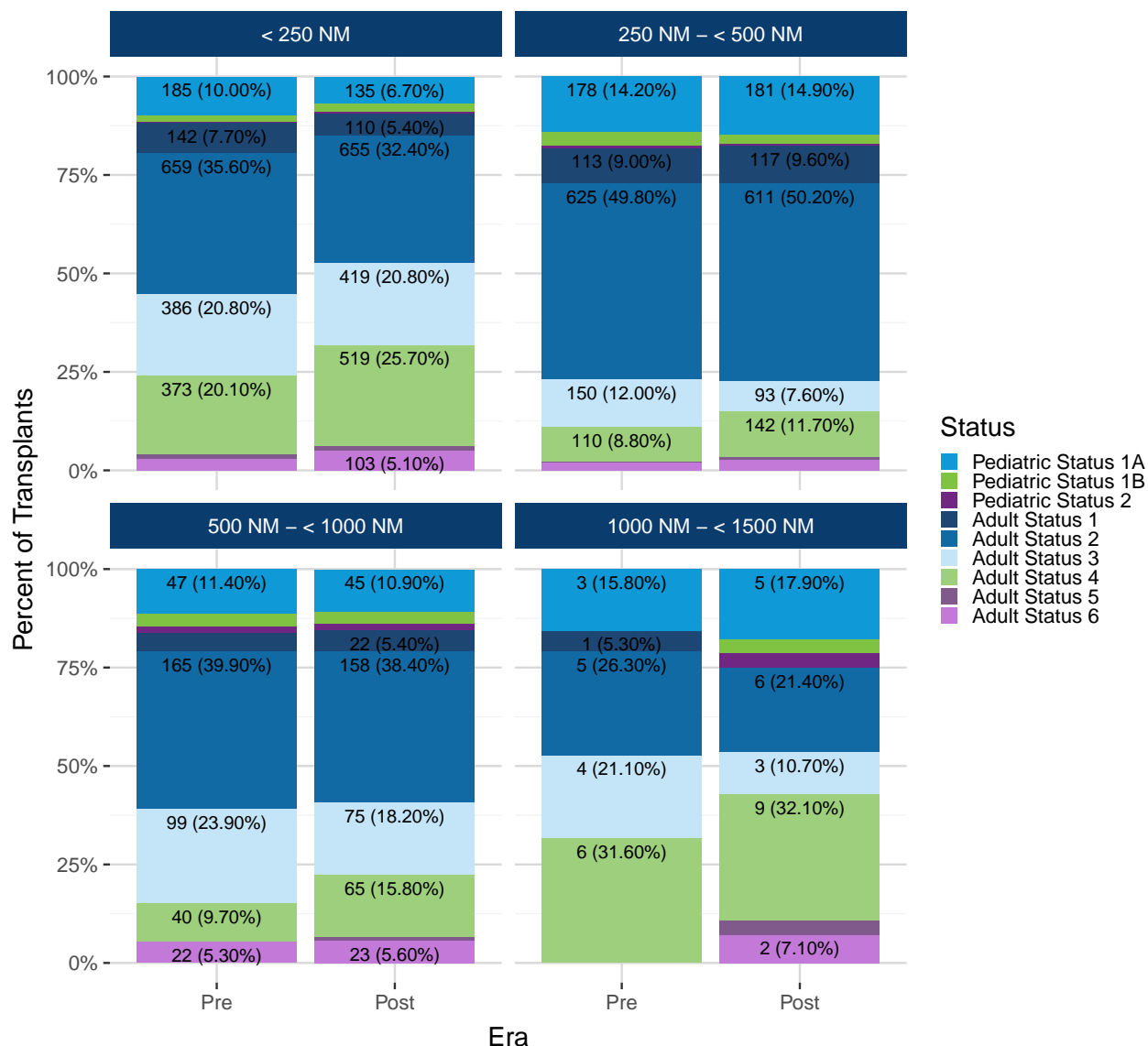
Post-Policy, Pre-COVID: January 09, 2020 - March 12, 2020;

Post-Policy, COVID Onset: March 13, 2020 - May 08 2020;

Post-Policy COVID Stabilization: May 09 2020 - January 08, 2021

Figure 12 and Table 9 shows the percent of heart transplants by distance traveled and medical urgency status. Hearts traveling <250 NM were fairly evenly distributed between adult status 1, 2 and 3 recipients in both eras while the majority of hearts traveling between 250 and 500 NM went adult status 2 candidates in both eras. Post-removal of DSA from heart allocation, a larger percentage of hearts traveling 500 - <1000NM went to adult status 4 candidates and a smaller percent to adult status 3. Only a small number of hearts traveled 1000-<1500 NM but there did appear to be an increase in the proportion of less medical urgent candidates (pediatric status 1B and 2 and adult statuses 5 & 6) in the post era.

Figure 12. Heart Transplants by Distance Traveled, Medical Urgency Status and Era



Medical urgency statuses representing less than 5% of the total are not labelled on the plot;
Transplants within 1500-<2500 NM were excluded (n=2 post-implementation);

Table 9. Heart Transplants by Distance Traveled, Medical Urgency Status and Era

Distance Group	Status	Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
		N	%	N	%	N	%	N	%	N	%
< 250 NM	Pediatric Status 1A	185	10%	17	4.7%	13	4.8%	105	7.6%	135	6.7%
	Pediatric Status 1B	29	1.6%	8	2.2%	4	1.5%	35	2.5%	47	2.3%
	Pediatric Status 2	6	0.3%	1	0.3%	2	0.7%	8	0.6%	11	0.5%
	Adult Status 1	142	7.7%	9	2.5%	16	5.9%	85	6.1%	110	5.4%
	Adult Status 2	659	35.6%	133	37%	81	29.9%	441	31.7%	655	32.4%
	Adult Status 3	386	20.8%	74	20.6%	59	21.8%	286	20.6%	419	20.8%
	Adult Status 4	373	20.1%	100	27.9%	83	30.6%	336	24.2%	519	25.7%
	Adult Status 5	18	1%	3	0.8%	3	1.1%	14	1%	20	1%
	Adult Status 6	54	2.9%	14	3.9%	10	3.7%	79	5.7%	103	5.1%
250 NM - < 500 NM	Pediatric Status 1A	178	14.2%	33	14.3%	18	13.4%	130	15.2%	181	14.9%
	Pediatric Status 1B	44	3.5%	5	2.2%	3	2.2%	21	2.5%	29	2.4%
	Pediatric Status 2	7	0.6%	2	0.9%	0	0%	3	0.4%	5	0.4%
	Adult Status 1	113	9%	24	10.4%	11	8.2%	82	9.6%	117	9.6%
	Adult Status 2	625	49.8%	121	52.6%	66	49.3%	424	49.6%	611	50.2%
	Adult Status 3	150	12%	19	8.3%	10	7.5%	64	7.5%	93	7.6%
	Adult Status 4	110	8.8%	19	8.3%	20	14.9%	103	12.1%	142	11.7%
	Adult Status 5	2	0.2%	1	0.4%	2	1.5%	4	0.5%	7	0.6%
	Adult Status 6	25	2%	6	2.6%	4	3%	23	2.7%	33	2.7%
500 NM - < 1000 NM	Pediatric Status 1A	47	11.4%	9	14.3%	7	14.6%	29	9.7%	45	10.9%
	Pediatric Status 1B	14	3.4%	2	3.2%	2	4.2%	8	2.7%	12	2.9%
	Pediatric Status 2	6	1.4%	2	3.2%	0	0%	5	1.7%	7	1.7%
	Adult Status 1	20	4.8%	1	1.6%	2	4.2%	19	6.3%	22	5.4%
	Adult Status 2	165	39.9%	28	44.4%	16	33.3%	114	38%	158	38.4%
	Adult Status 3	99	23.9%	11	17.5%	12	25%	52	17.3%	75	18.2%
	Adult Status 4	40	9.7%	9	14.3%	8	16.7%	48	16%	65	15.8%
	Adult Status 5	1	0.2%	0	0%	0	0%	4	1.3%	4	1%
	Adult Status 6	22	5.3%	1	1.6%	1	2.1%	21	7%	23	5.6%
1000 NM - < 1500 NM	Pediatric Status 1A	3	15.8%	2	28.6%	0	0%	3	15%	5	17.9%
	Pediatric Status 1B	0	0%	0	0%	1	100%	0	0%	1	3.6%
	Pediatric Status 2	0	0%	0	0%	0	0%	1	5%	1	3.6%
	Adult Status 1	1	5.3%	0	0%	0	0%	0	0%	0	0%
	Adult Status 2	5	26.3%	0	0%	0	0%	6	30%	6	21.4%
	Adult Status 3	4	21.1%	1	14.3%	0	0%	2	10%	3	10.7%
	Adult Status 4	6	31.6%	3	42.9%	0	0%	6	30%	9	32.1%
	Adult Status 5	0	0%	0	0%	0	0%	1	5%	1	3.6%
	Adult Status 6	0	0%	1	14.3%	0	0%	1	5%	2	7.1%
1500 NM - < 2500 NM	Adult Status 3	0	0%	0	0%	0	0%	2	100%	2	100%

Pre-Policy: January 09, 2019 - January 08, 2020;

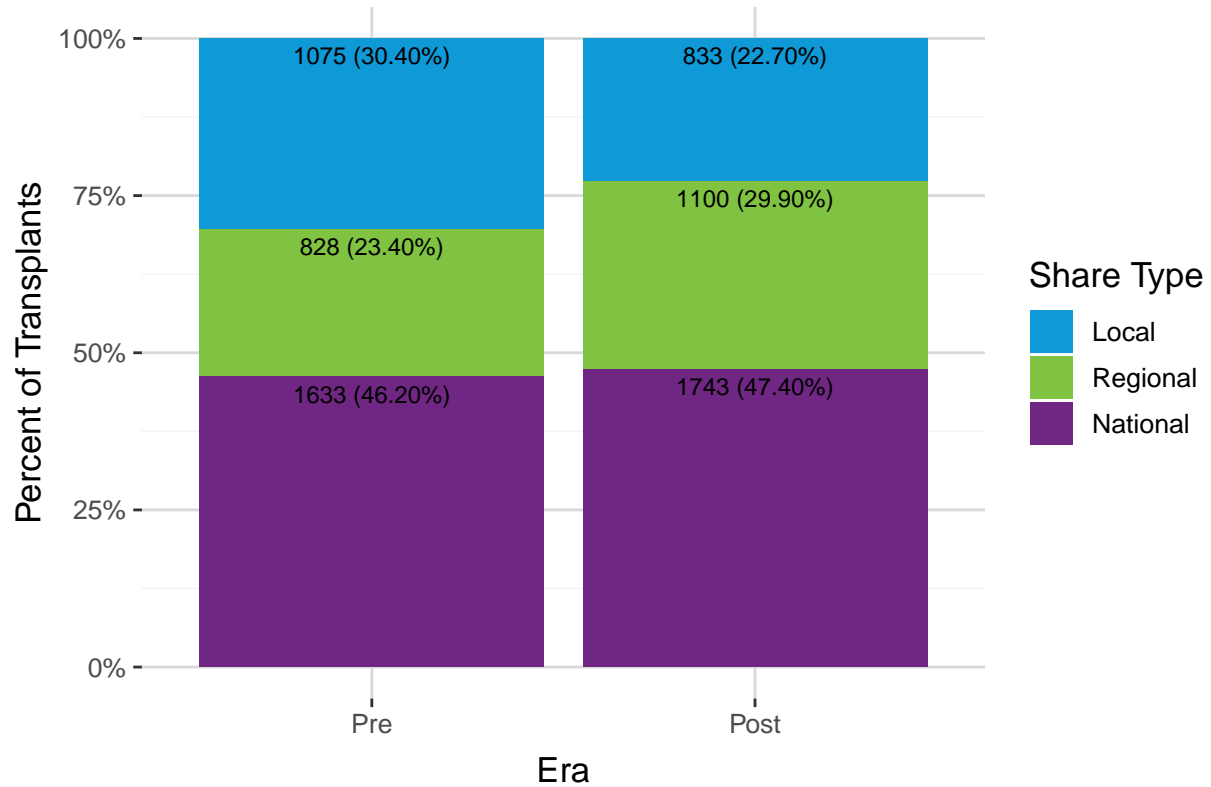
Post-Policy, Pre-COVID: January 09, 2020 - March 12, 2020;

Post-Policy, COVID Onset: March 13, 2020 - May 08 2020;

Post-Policy COVID Stabilization: May 09 2020 - January 08, 2021;

Figure 13 and Table 10 show the proportion and number of heart transplants by share type and era. Here, “local” refers to hearts recovered and transplanted within the same DSA, “regional” refers to hearts recovered and transplanted in different DSAs but within the same OPTN region and “national” refers to hearts recovered and transplanted in different OPTN regions. Overall, the number of local transplants decreased post-implementation while regional shares increased. The proportion of national shares remained similar pre- to post-implementation. These findings were consistent across age groups and COVID-eras.

Figure 13. Heart Transplants by Share Type



Share types representing less than 5% of the total are not labelled on the plot;
Foreign Canadian shares excluded (n=3 Pre-Policy, n=2 Post-Policy);

Table 10. Heart Transplants by Share Type

Age Group	Share Type	Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
		N	%	N	%	N	%	N	%	N	%
Pediatric	Local	92	17.8%	8	9.9%	6	12%	50	14.4%	64	13.4%
	Regional	127	24.5%	23	28.4%	14	28%	108	31%	145	30.3%
	National	299	57.7%	50	61.7%	30	60%	190	54.6%	270	56.4%
Adult	Local	983	32.6%	141	24.4%	99	24.5%	529	23.9%	769	24.1%
	Regional	701	23.2%	174	30.1%	125	30.9%	656	29.6%	955	29.9%
	National	1334	44.2%	263	45.5%	180	44.6%	1030	46.5%	1473	46.1%
Overall	Local	1075	30.4%	149	22.6%	105	23.1%	579	22.6%	833	22.7%
	Regional	828	23.4%	197	29.9%	139	30.6%	764	29.8%	1100	29.9%
	National	1633	46.2%	313	47.5%	210	46.3%	1220	47.6%	1743	47.4%

Foreign Canadian Shares Excluded (n=3 Pre-Policy, n=2 Post-Policy);

Pre-Policy: January 09, 2019 - January 08, 2020;

Post-Policy, Pre-COVID: January 09, 2020 - March 12, 2020;

Post-Policy, COVID Onset: March 13, 2020 - May 08 2020;

Post-Policy COVID Stabilization: May 09 2020 - January 08, 2021

Figure 14 and Table 11 show the number and percent of heart transplants by geographic area. Regions 5 and 6 were considered to be in the West, Regions 1, 2, and 9 in the Northeast, Regions 3, 4, and 11 in the South or Southeast and Regions 7, 8, and 10 were considered to be in the Midwest. There were similar proportions of heart transplants pre- to post-implementation for all geographic areas.

Figure 14. Heart Transplants by Geographic Area

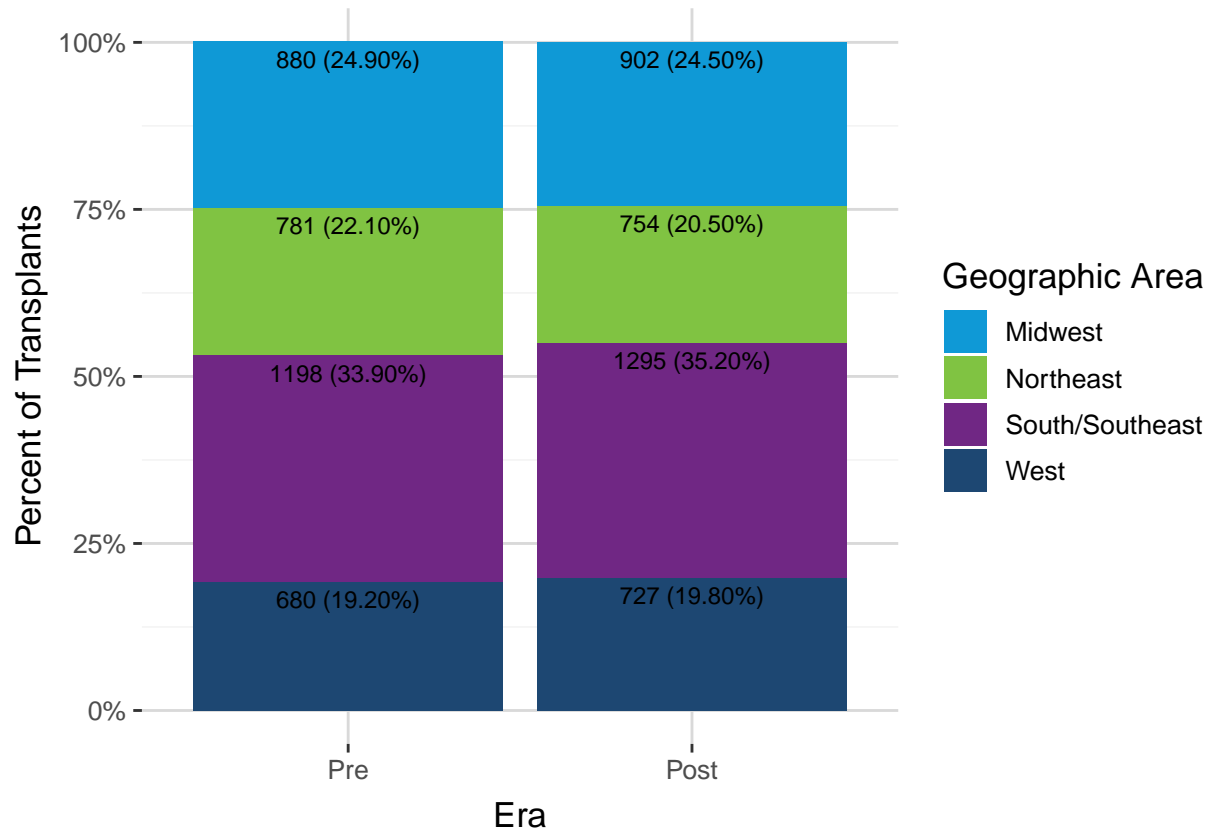


Table 11. Heart Transplants by Geographic Area

Age Group	Geographic Area	Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
		N	%	N	%	N	%	N	%	N	%
Pediatric	Midwest	149	28.7%	30	37%	11	22%	109	31.3%	150	31.3%
	Northeast	85	16.4%	6	7.4%	7	14%	47	13.5%	60	12.5%
	South/Southeast	183	35.3%	30	37%	22	44%	124	35.6%	176	36.7%
	West	102	19.7%	15	18.5%	10	20%	68	19.5%	93	19.4%
Adult	Midwest	731	24.2%	130	22.5%	83	20.5%	539	24.3%	752	23.5%
	Northeast	696	23%	132	22.8%	88	21.8%	474	21.4%	694	21.7%
	South/Southeast	1015	33.6%	209	36.2%	149	36.9%	761	34.3%	1119	35%
	West	578	19.1%	107	18.5%	84	20.8%	443	20%	634	19.8%
Overall	Midwest	880	24.9%	160	24.3%	94	20.7%	648	25.3%	902	24.5%
	Northeast	781	22.1%	138	20.9%	95	20.9%	521	20.3%	754	20.5%
	South/Southeast	1198	33.9%	239	36.3%	171	37.7%	885	34.5%	1295	35.2%
	West	680	19.2%	122	18.5%	94	20.7%	511	19.9%	727	19.8%

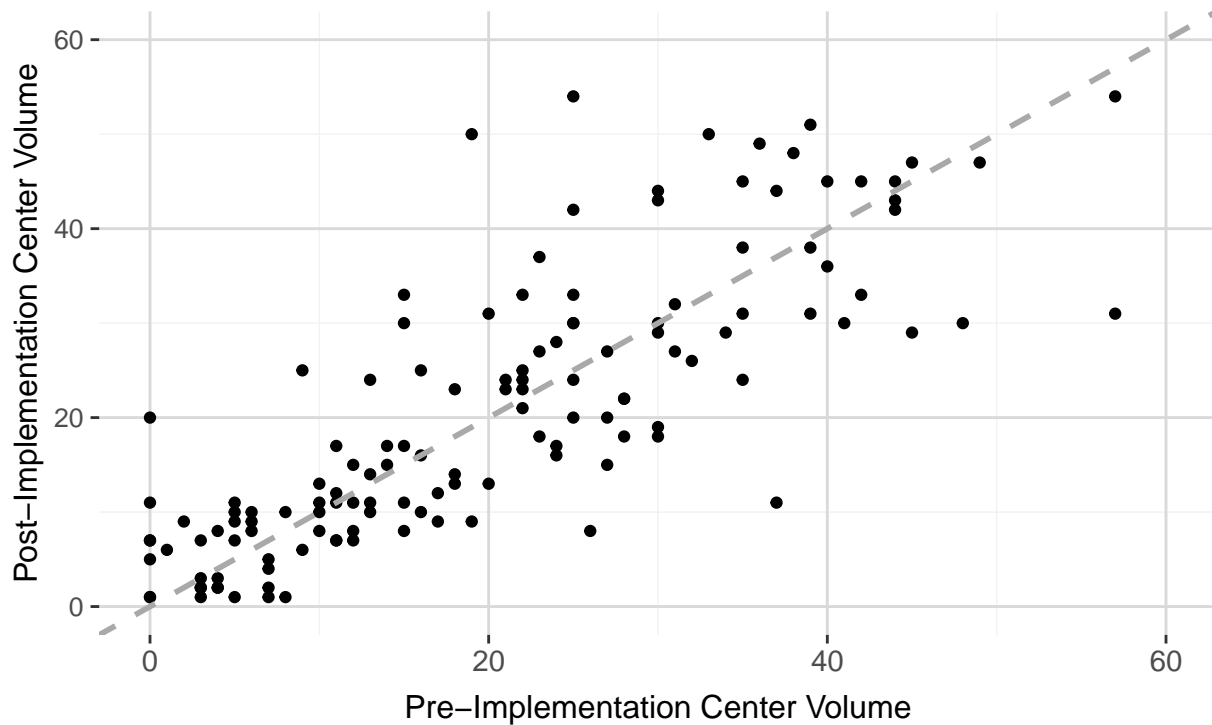
Pre-Policy: January 09, 2019 - January 08, 2020;

Post-Policy, Pre-COVID: January 09, 2020 - March 12, 2020;

Post-Policy, COVID Onset: March 13, 2020 - May 08 2020;

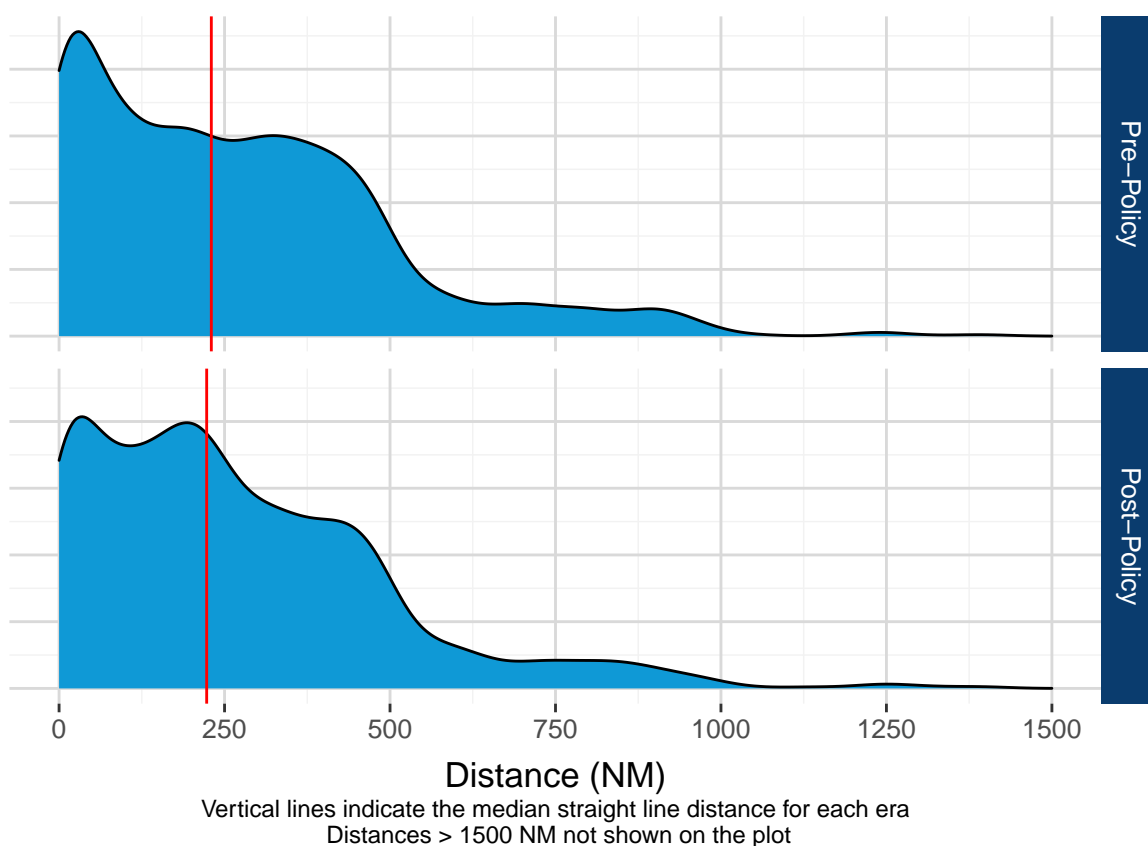
Post-Policy COVID Stabilization: May 09 2020 - January 08, 2021

Figure 15. Center Heart Transplant Volume by Era



* COVID-19 Pandemic & National State of Emergency Declared March 11-13, 2020
 This figure contains roughly 10 months of COVID-era data:
 Post-Policy, Pre-COVID: January 09, 2020 – March 12, 2020;
 Post-Policy, COVID Onset: March 13, 2020 – May 08 2020;
 Post-Policy COVID Stabilization: May 09 2020 – January 08, 2021

Figure 15 compares the number of heart transplants performed by transplant centers pre-policy and post-policy. This figure contains roughly 10 months of COVID-Era data and should be interpreted with caution as certain centers are known to have been significantly impacted by COVID-19. 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 year post-implementation. There were 144 transplant centers that performed at least one heart transplant in one of the two eras. Of those, 77 performed the same number or more heart transplants post-implementation than they did pre-implementation. There were 67 centers that performed fewer heart transplants post-implementation. Of these, 38 did more than 25% fewer transplants post-implementation.

Figure 16. Distribution of Distance Between Donor Hospital and Transplant Center**Table 12. Distance Between Donor Hospital and Transplant Center**

Era	Min	IQR	Mean	Median	Max
Pre-Policy	0	326.00	270.46	230	1402
Post-Policy, Pre-COVID	0	288.00	267.57	223	1368
Post-Policy, COVID-Onset	0	282.50	247.40	207	1212
Post-Policy, COVID-Stabilization	0	308.00	277.60	227	1761
Post-Policy (overall)	0	304.75	272.08	223	1761

Pre-Policy: January 09, 2019 - January 08, 2020;

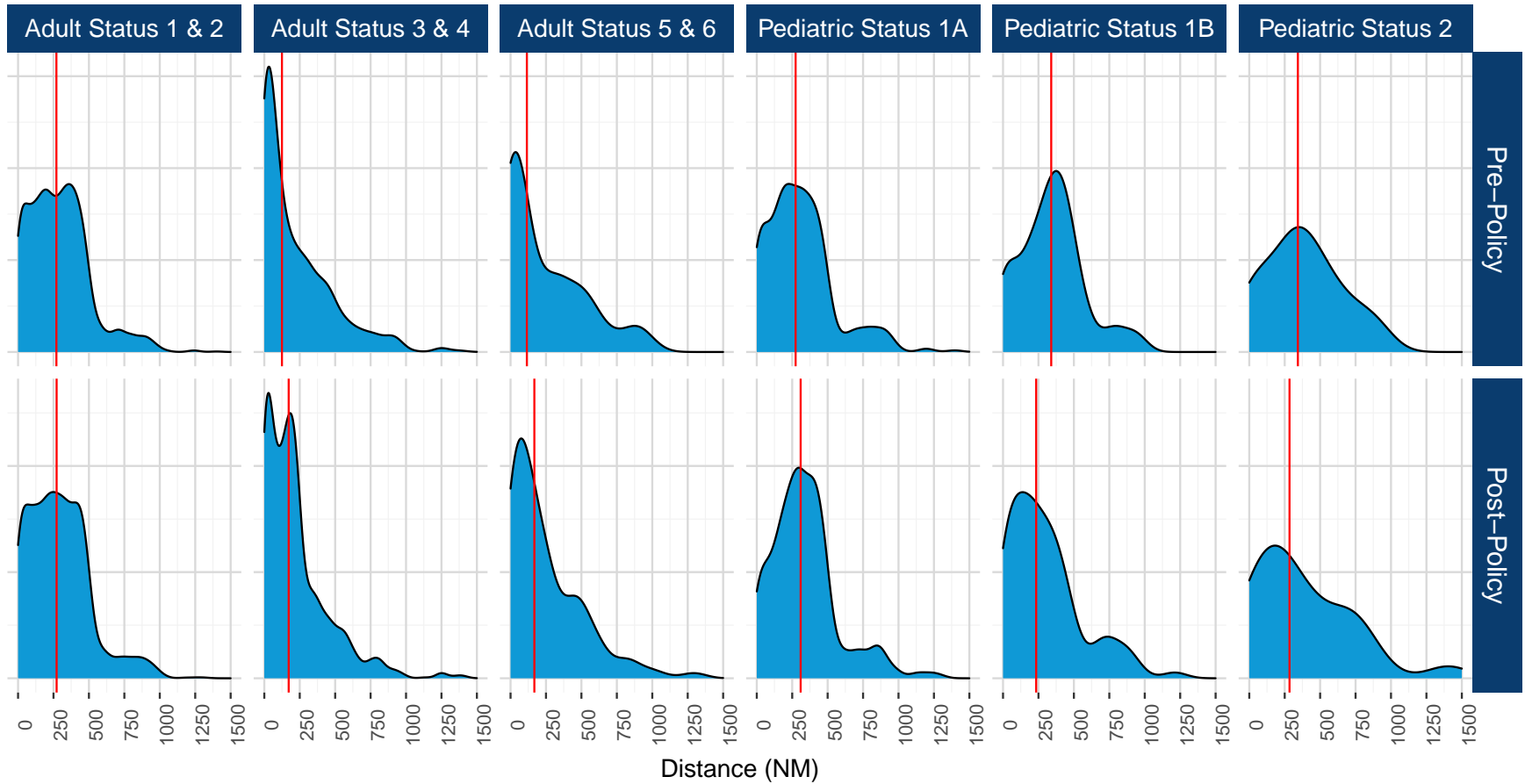
Post-Policy, Pre-COVID: January 09, 2020 - March 12, 2020;

Post-Policy, COVID Onset: March 13, 2020 - May 08, 2020;

Post-Policy COVID Stabilization: May 09, 2020 - January 08, 2021

Figure 16 and Table 12 show the distributions of distance traveled by era. Here, distance refers to the total straight line distance between the donor hospital and the transplant center in nautical miles. The median distance traveled decreased slightly from 230 pre-implementation to 223 post-implementation. More hearts were shared between 125 and 250 nautical miles post-implementation. The inter-quartile range (IQR) is the difference between the 75th percentile and the 25th percentile and represents the middle 50% of the observations. The IQR decreased from 326 pre-implementation to 304.75 post-implementation. This indicates the middle 50% of observations are closer together post-implementation compared to pre-implementation. These results were consistent across COVID-eras.

Figure 17. Distribution of Distance Between Donor Hospital and Transplant Center by Medical Urgency Status



Distance (NM)

Vertical lines indicate the median straight line distance for each era

Table 13. Distribution of Distance Between Donor Hospital and Transplant Center by Medical Urgency Status

Status	Pre-Policy		Post-Policy, Pre-COVID		Post-Policy, COVID Onset		Post-Policy, COVID Stabilization		Post-Policy (overall)	
	Median	IQR	Median	IQR	Median	IQR	Median	IQR	Median	IQR
Pediatric Status 1A	274.0	275.0	350.0	295.0	309.0	242.5	303	246.5	309.5	253.5
Pediatric Status 1B	340.0	267.0	203.0	319.0	385.0	423.8	211	263.8	234.0	304.0
Pediatric Status 2	343.0	342.0	347.0	501.0	103.5	103.5	314	382.0	284.0	416.5
Adult Status 1 & 2	270.5	279.0	275.5	271.5	246.0	297.2	278	300.0	272.0	293.5
Adult Status 3 & 4	124.5	321.2	167.0	203.5	158.0	213.8	177	257.5	172.0	251.5
Adult Status 5 & 6	115.0	420.2	197.0	209.5	183.5	324.0	155	369.0	168.0	339.0

Pre-Policy: January 09, 2019 - January 08, 2020;

Post-Policy, Pre-COVID: January 09, 2020 - March 12, 2020;

Post-Policy, COVID Onset: March 13, 2020 - May 09 2020;

Post-Policy COVID Stabilization: May 09 2020 - January 08, 2021

Figure 17 and Table 13 show the distributions of distances traveled by hearts pre- and post-implementation by medical urgency statuses. Adult medical urgency statuses 1 & 2, 3 & 4 and 5 & 6 were grouped together. Median distance traveled increased for pediatric status 1A and adult statuses 3&4 and 5&6 and decreased for pediatric status 1B and 2. Median distance traveled remained similar for adult statuses 1&2. Post-implementation there was broader sharing of pediatric status 2 hearts as can be seen by the much wider IQR.

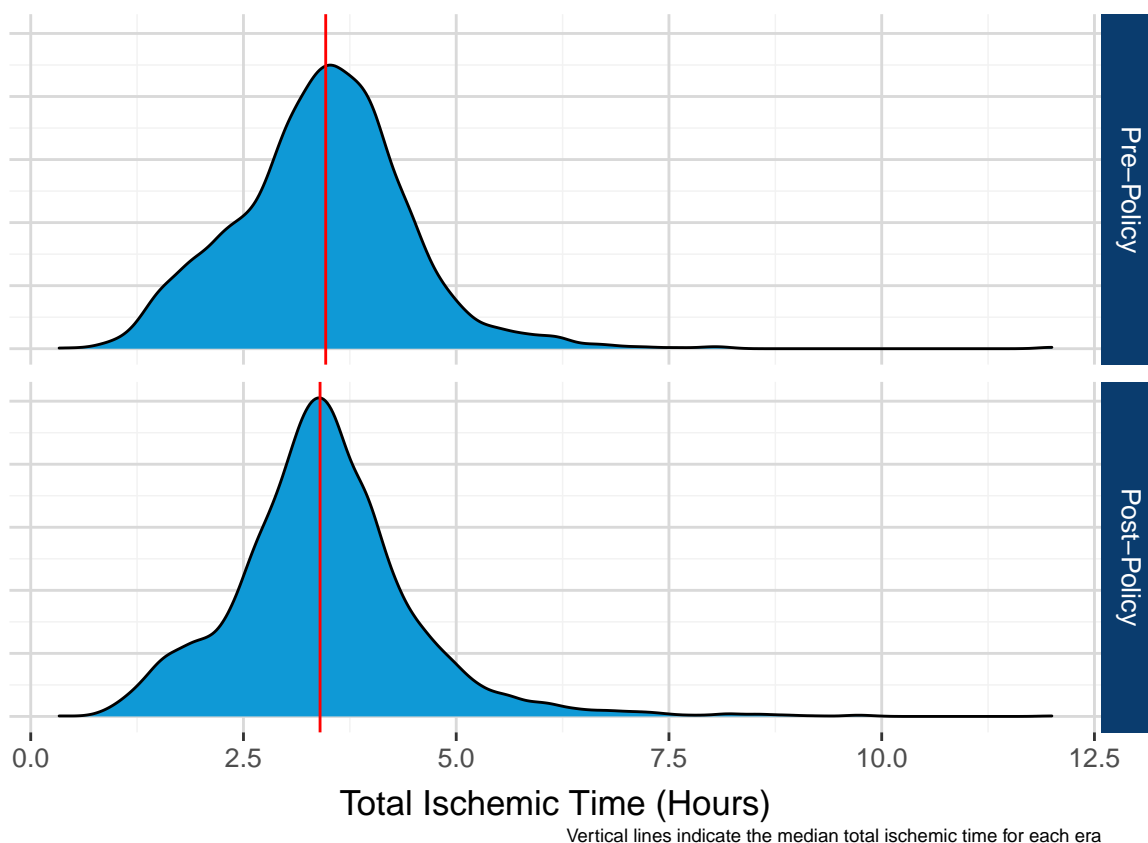
Figure 18. Total Ischemic Time at Transplant by Era

Table 14. Total Ischemic Time at Transplant by Era

Era	Min	IQR	Mean	Median	Max
Pre-Policy	0.33	1.20	3.43	3.47	12.00
Post-Policy, Pre-COVID	0.88	1.10	3.47	3.43	9.70
Post-Policy, COVID-Onset	0.95	1.12	3.33	3.30	7.55
Post-Policy, COVID-Stabilization	0.35	1.13	3.46	3.42	12.00
Post-Policy (overall)	0.35	1.13	3.44	3.40	12.00

Note:

Pre-Policy: January 09, 2019 - January 08, 2020;

Post-Policy, Pre-COVID: January 09, 2020 - March 12, 2020;

Post-Policy, COVID Onset: March 13, 2020 - May 08 2020;

Post-Policy COVID Stabilization: May 09 2020 - January 08, 2021

Figure 18 and Table 14 show the distribution of total ischemic times at transplant both pre- and post-implementation, where total ischemic time is defined as the sum of cold ischemic time, warm ischemic time, and anastomotic time. Total ischemic times stayed roughly the same, with a median ischemic time of 3.47 hours pre-implementation, compared to a median ischemic time of 3.4 hours post-implementation. The IQR decreased slightly from 1.2 pre-implementation, compared to 1.13 post-implementation meaning that the middle 50% of ischemic times were closer together post-implementation. This can be seen by the sharper, more distinguished peak in the post-implementation distributions compared to the pre-implementation distribution.

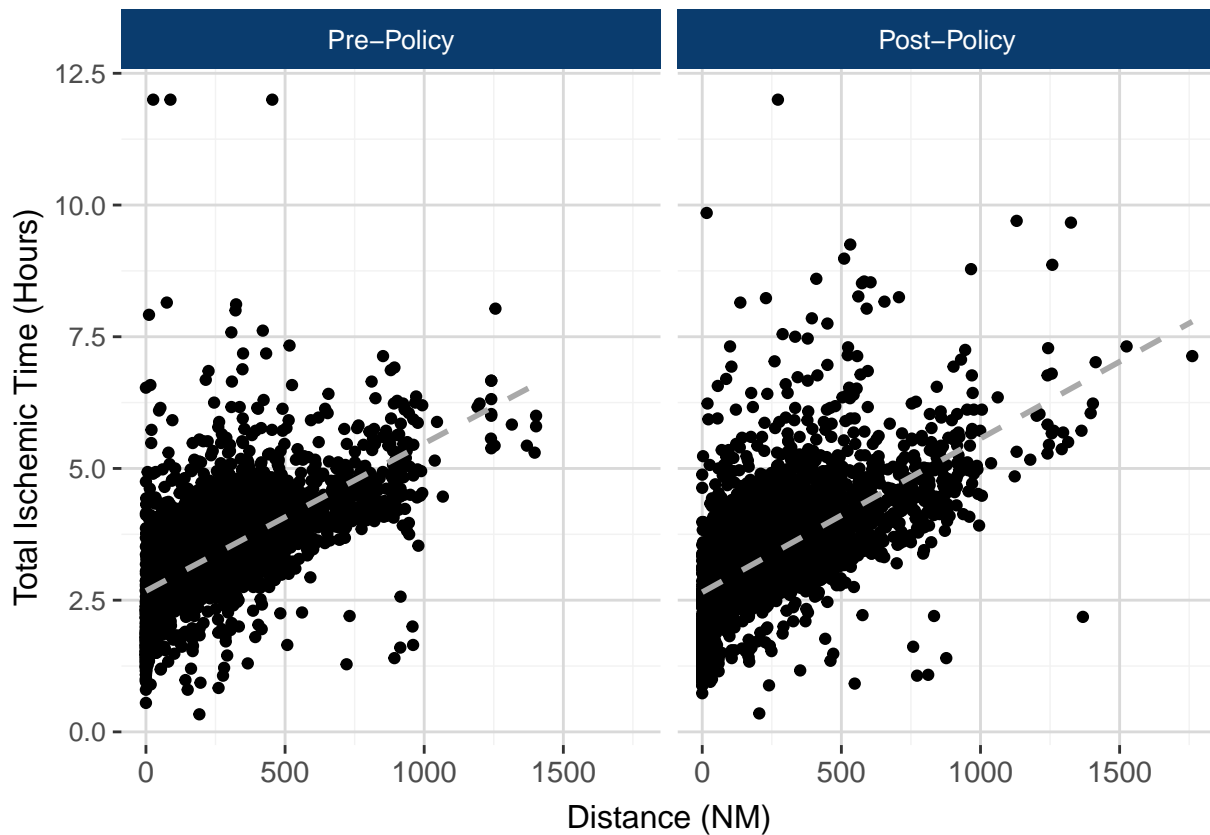
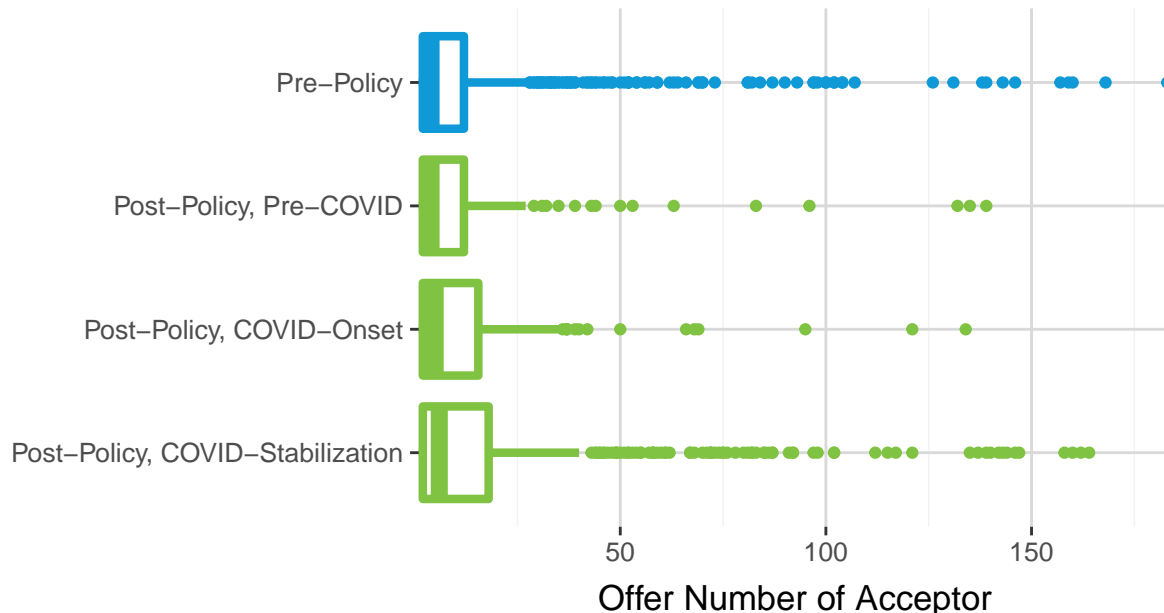
Figure 19. Ischemic Time by Distance Traveled Pre- and Post-Implementation

Figure 19 shows the total ischemic time by distance traveled pre- and post-implementation. Ischemic time increased at approximately the same rate pre- and post-implementation as distance increased. The Pearson correlation between distance and ischemic time was 0.64 pre-implementation and 0.63 post-implementation.

Figure 20. Boxplot of the Sequence Number of the Acceptor for Adult Hearts

Sequence Numbers >200 excluded from graphic (Pre=6, Post=9)
 Pre-Policy: January 09, 2019 – January 08, 2020;
 Post-Policy, Pre-COVID: January 09, 2020 – March 12, 2020;
 Post-Policy, COVID Onset: March 13, 2020 – May 08 2020;
 Post-Policy COVID Stabilization: May 09 2020 – January 08, 2021;

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

Era	Min	IQR	Mean	Median	Max
Pre-Policy	1	11.00	15.58	4	660
Post-Policy, Pre-COVID	1	10.00	13.42	4	204
Post-Policy, COVID-Onset	1	13.50	13.58	5	134
Post-Policy, COVID-Stabilization	1	16.75	22.55	6	499
Post-Policy (overall)	1	15.00	19.79	5	499

Note:

Pre-Policy: January 09, 2019 - January 08, 2020;

Post-Policy, Pre-COVID: January 09, 2020 - March 12, 2020;

Post-Policy, COVID Onset: March 13, 2020 - May 08 2020;

Post-Policy COVID Stabilization: May 09 2020 - January 08, 2021

Figure 20 and Table 15 show the distribution of sequence numbers for the final acceptors of hearts both pre- and post-implementation. The median for sequence number was higher post-implementation but the maximum decreased substantially. In addition, the IQR was larger indicating that the middle 50% of sequence numbers were farther apart as can be seen Figure 20 in the post-implementation periods. These trends were seen for all post-implementation COVID-eras.

Figure 21 and Table 16 show the transplant rate overall and by medical urgency status. Overall there was a significant increase in the transplant rate in the post-era as can be seen by the non-overlapping confidence intervals in Table 16. There were no significant differences in pediatric transplant rates for any status. Transplant rates were significantly higher in the post-era for adult statuses 4 and 6.

Figure 21. Transplants per 100 Patient-Years Waiting by Medical Urgency Status and Era

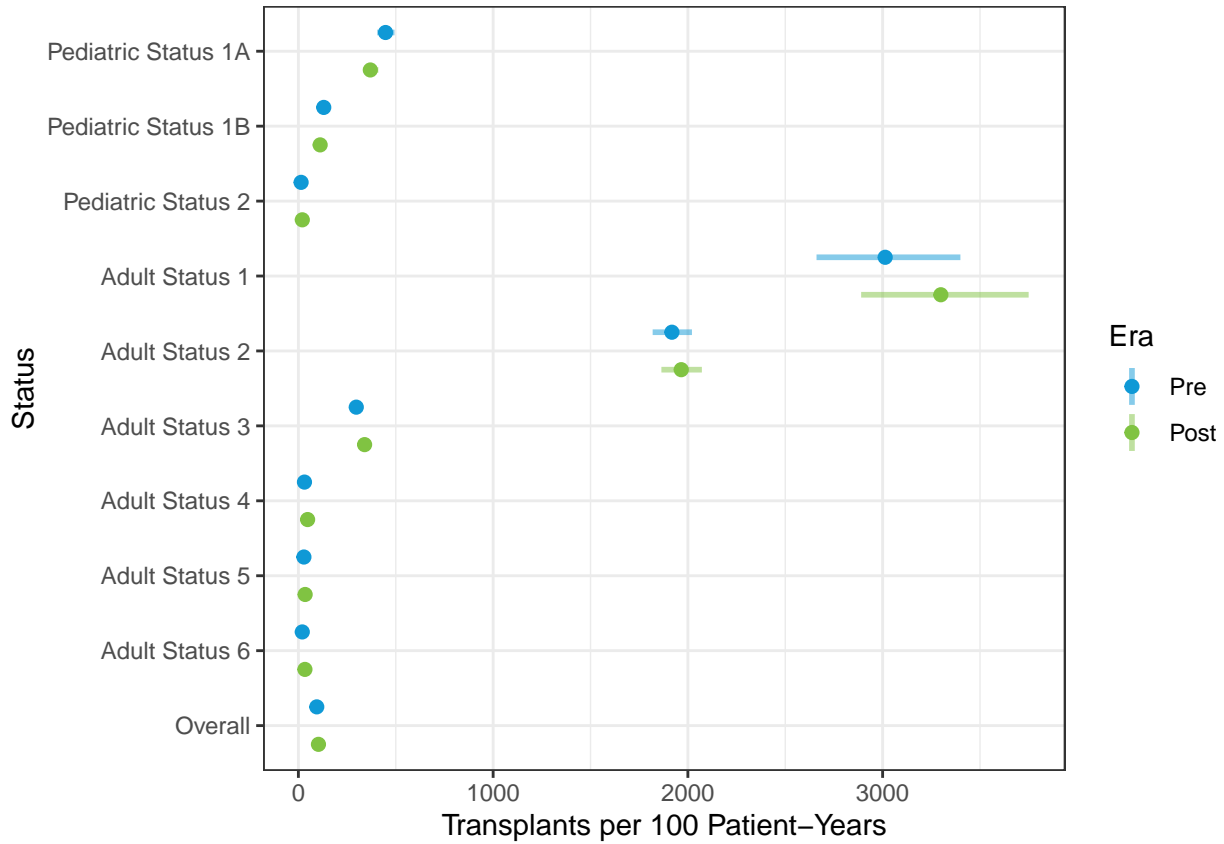


Table 16. Transplants per 100 Patient-Years Waiting by Medical Urgency Status and Era

Status	Era	Patients Ever Waiting	Transplants	Transplants per 100 Patient Years	95% CI
Pediatric Status 1A	Pre	618	399	447.50	[404.66, 493.64]
	Post	588	347	369.46	[331.61, 410.45]
Pediatric Status 1B	Pre	297	76	130.20	[102.58, 162.96]
	Post	291	82	111.71	[88.85, 138.66]
Pediatric Status 2	Pre	242	16	13.90	[7.94, 22.57]
	Post	246	22	20.05	[12.56, 30.35]
Adult Status 1	Pre	344	264	3013.13	[2660.59, 3399.39]
	Post	311	234	3298.96	[2889.78, 3749.83]
Adult Status 2	Pre	1800	1407	1917.97	[1819.05, 2020.87]
	Post	1766	1392	1965.87	[1863.95, 2071.93]
Adult Status 3	Pre	1928	611	297.27	[274.16, 321.80]
	Post	1497	575	339.92	[312.70, 368.88]
Adult Status 4	Pre	3761	499	31.14	[28.47, 34.00]
	Post	3461	690	47.36	[43.89, 51.03]
Adult Status 5	Pre	261	24	28.31	[18.14, 42.12]
	Post	279	32	34.63	[23.68, 48.88]
Adult Status 6	Pre	1737	113	19.94	[16.43, 23.97]
	Post	1555	171	33.59	[28.74, 39.02]
Overall	Pre	7961	3409	94.38	[91.24, 97.60]
	Post	7840	3545	103.04	[99.68, 106.49]

Figure 21 and Table 17 show the transplant rate overall and by region. Overall there was a significant increase in the transplant rate in the post-era. Transplant rates were significantly higher in the post-era for region 5.

Figure 21. Transplants per 100 Patient-Years Waiting by Region and Era

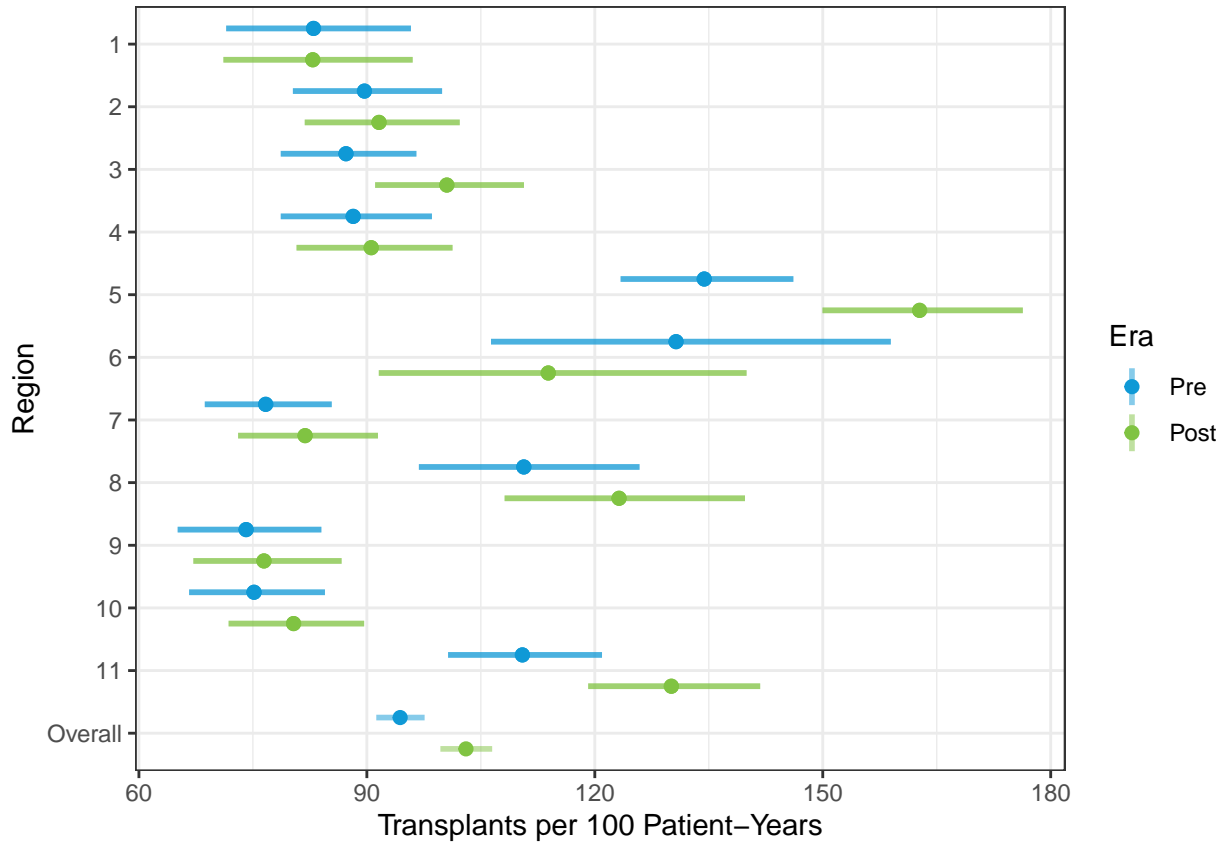


Table 17. Transplants per 100 Patient-Years Waiting by Region and Era

Region	Era	Patients Ever Waiting	Transplants	Transplants per 100 Patient Years	CI
1	Pre	445	186	82.98	[71.48, 95.80]
	Post	434	177	82.88	[71.12, 96.03]
2	Pre	811	330	89.68	[80.27, 99.90]
	Post	769	319	91.60	[81.82, 102.22]
3	Pre	957	377	87.25	[78.67, 96.52]
	Post	943	415	100.53	[91.09, 110.68]
4	Pre	794	311	88.20	[78.67, 98.57]
	Post	751	308	90.58	[80.74, 101.28]
5	Pre	1073	549	134.40	[123.40, 146.13]
	Post	1069	598	162.75	[149.97, 176.33]
6	Pre	200	100	130.69	[106.34, 158.96]
	Post	194	90	113.88	[91.57, 139.97]
7	Pre	830	333	76.69	[68.67, 85.38]
	Post	795	313	81.87	[73.05, 91.46]
8	Pre	497	231	110.66	[96.85, 125.89]
	Post	492	241	123.19	[108.13, 139.77]
9	Pre	642	244	74.11	[65.10, 84.01]
	Post	630	244	76.46	[67.16, 86.68]
10	Pre	767	280	75.15	[66.61, 84.49]
	Post	810	321	80.35	[71.80, 89.64]
11	Pre	1021	468	110.47	[100.69, 120.95]
	Post	1013	519	130.08	[119.13, 141.76]
Overall	Pre	7961	3409	94.38	[91.24, 97.60]
	Post	7840	3545	103.04	[99.68, 106.49]

The following set of figures examines six-month post-transplant patient survival for heart-alone transplant recipients. Figure 22 displays the six-month assume-alive post-transplant patient survival for candidates transplanted between 01/09/2019 - 07/08/2019 (pre) and between 01/09/2020 - 07/08/2020 (post). There was no significant difference in post-transplant patient survival between the two eras ($p=0.28$).

Figure 22. Six-Month Post-Transplant Patient Survival by Era

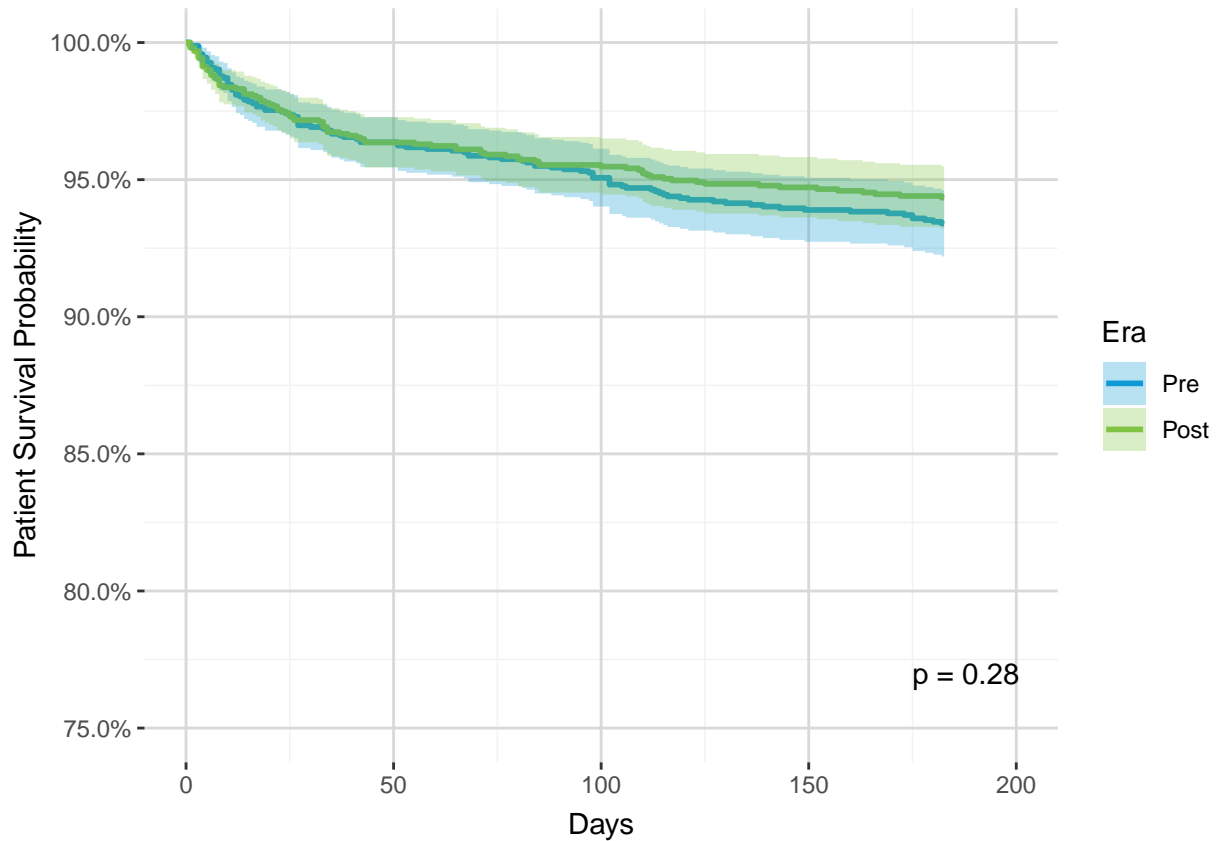
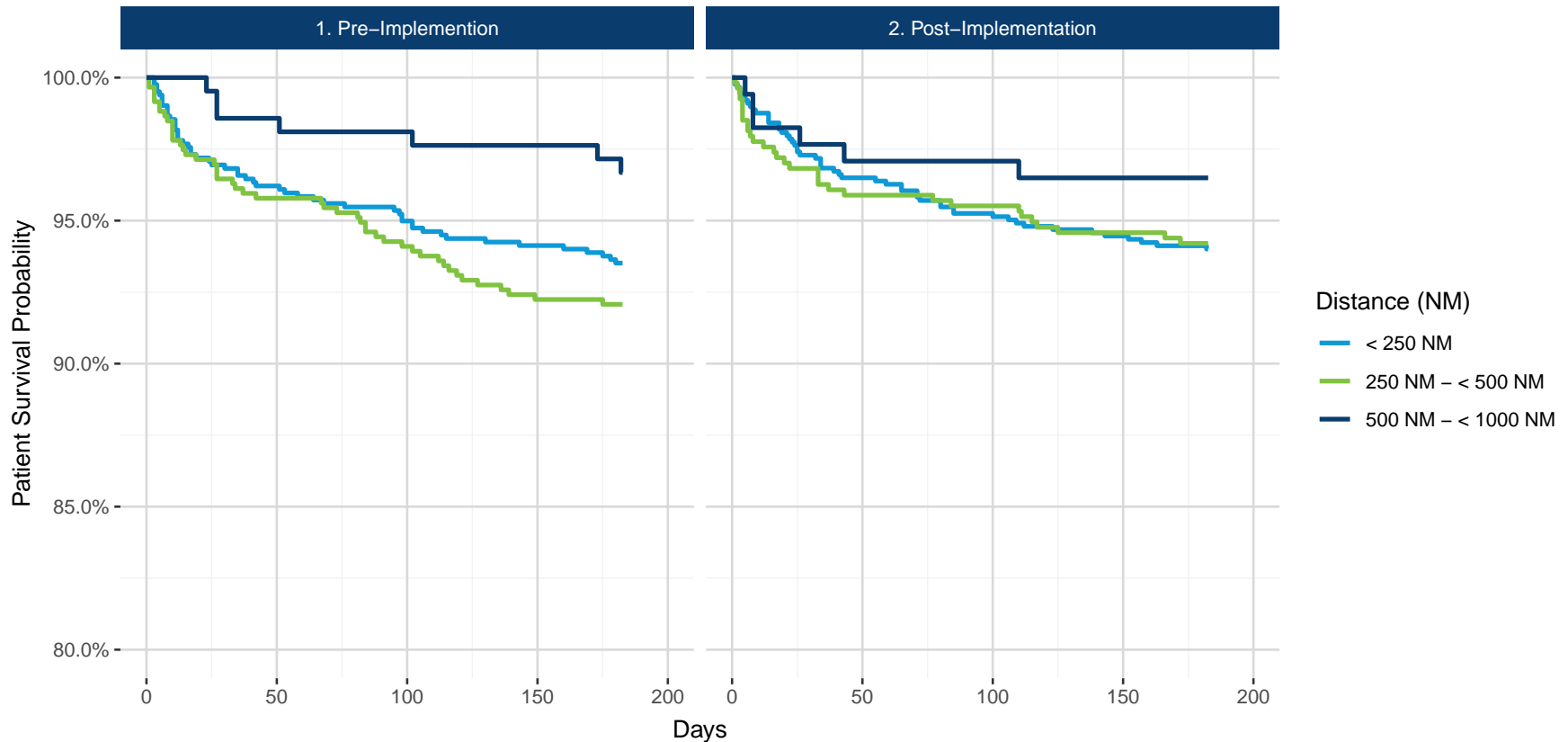


Figure 23 shows the six-month post-transplant assume-alive patient survival by distance traveled. It is important to note that the post-transplant survival estimates do not adjust for factors like medical urgency status which may differ between distance groups (Figure 12). Pre-implementation recipients who received hearts that traveled 250-<500 NM had the lowest survival while recipients who received hearts traveling 500-<1000NM had the highest post-transplant survival. Post-implementation the differences in post-transplant survival between the distance groups were less dramatic. Specifically, recipients receiving hearts traveling <250 and 250-<500 NM had similar six-month post-transplant survival, just below 95%, while hearts traveling 500-<1000NM had slightly higher six-month post-transplant survival at a little over 95%.

Figure 23. Six-Month Post-Transplant Patient Survival by Distance Group and Era



Transplants traveling 1000-<1500 NM and 1500-<2500 NM were excluded due to insufficient sample size (see Table 8);

Utilization

This chapter examines differences in heart utilization between two donor cohorts: the 11878 deceased donors with at least one organ recovered for the purpose of transplant between January 09, 2019 and January 08, 2020 (pre-implementation); and the 12597 deceased donors with a least one organ recovered for the purpose of transplant between January 09, 2020 and January 08, 2021 (post-implementation).

Table 18 shows the utilization and discard rates by era overall and for pediatrics and adults. The utilization rate remained similar across eras and the discard rate remained very low across all eras.

Table 18. Utilization and Discard Rates for Heart Donors by Era

Era	Ped/Adult	Utilization	Discard
Pre-Policy	Overall	30.29%	0.85%
	Adult	27.58%	0.95%
	Peds	62.87%	0.35%
Post-Policy, Pre-COVID	Overall	28.41%	1.78%
	Adult	26.09%	2.09%
	Peds	57.23%	0%
Post-Policy, COVID-Onset	Overall	29.78%	0.85%
	Adult	27.72%	0.74%
	Peds	57.94%	1.59%
Post-Policy, COVID-Stabilization	Overall	29.99%	0.84%
	Adult	27.73%	0.88%
	Peds	61.12%	0.55%
Post-Policy (overall)	Overall	29.67%	1.01%
	Adult	27.5%	1.02%
	Peds	61.45%	0.45%

Pre-Policy: January 09, 2019 - January 08, 2020;

Post-Policy, Pre-COVID: January 09, 2020 - March 12, 2020;

Post-Policy, COVID Onset: March 13, 2020 - May 08 2020;

Post-Policy COVID Stabilization: May 09 2020 - January 08, 2021

Figure 24 shows the utilization rates by region and era. The largest decrease in utilization occurred in Region 1 with a roughly 20% decrease.

Figure 24. Utilization Rates for Heart Donors by Region and Era

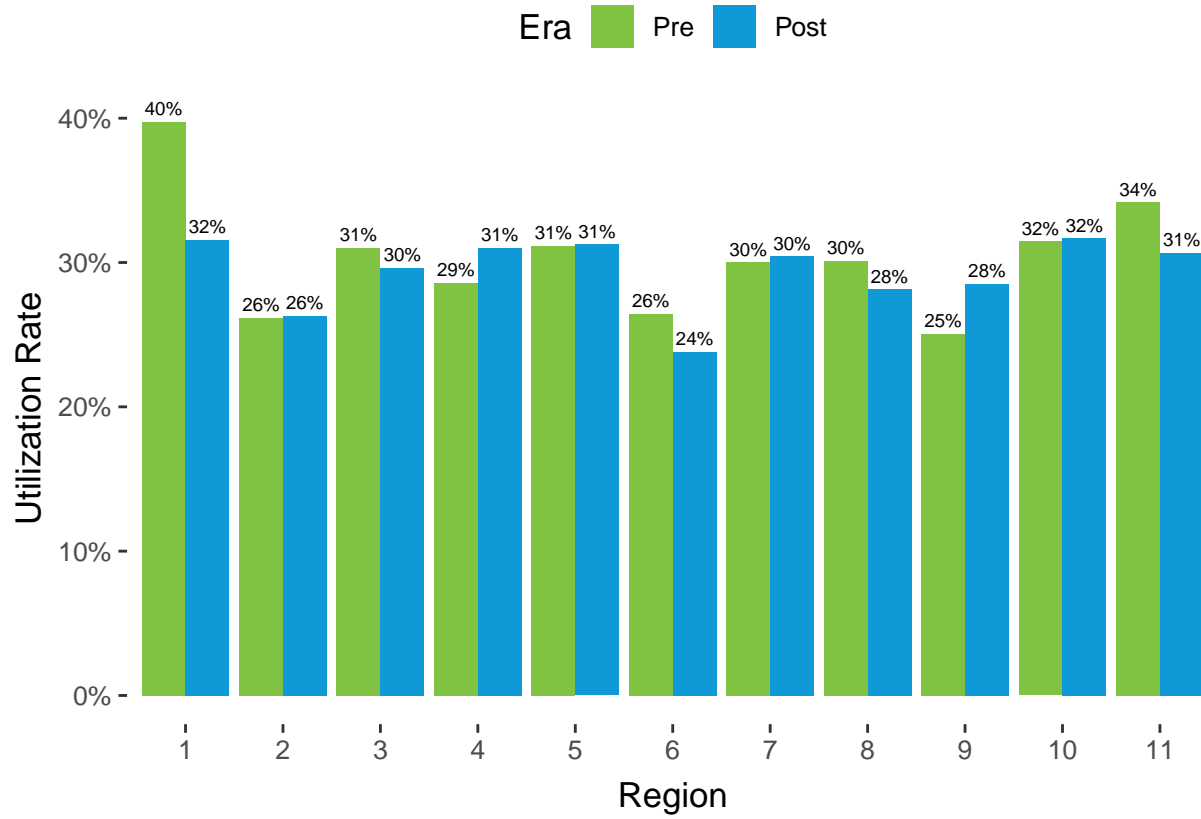
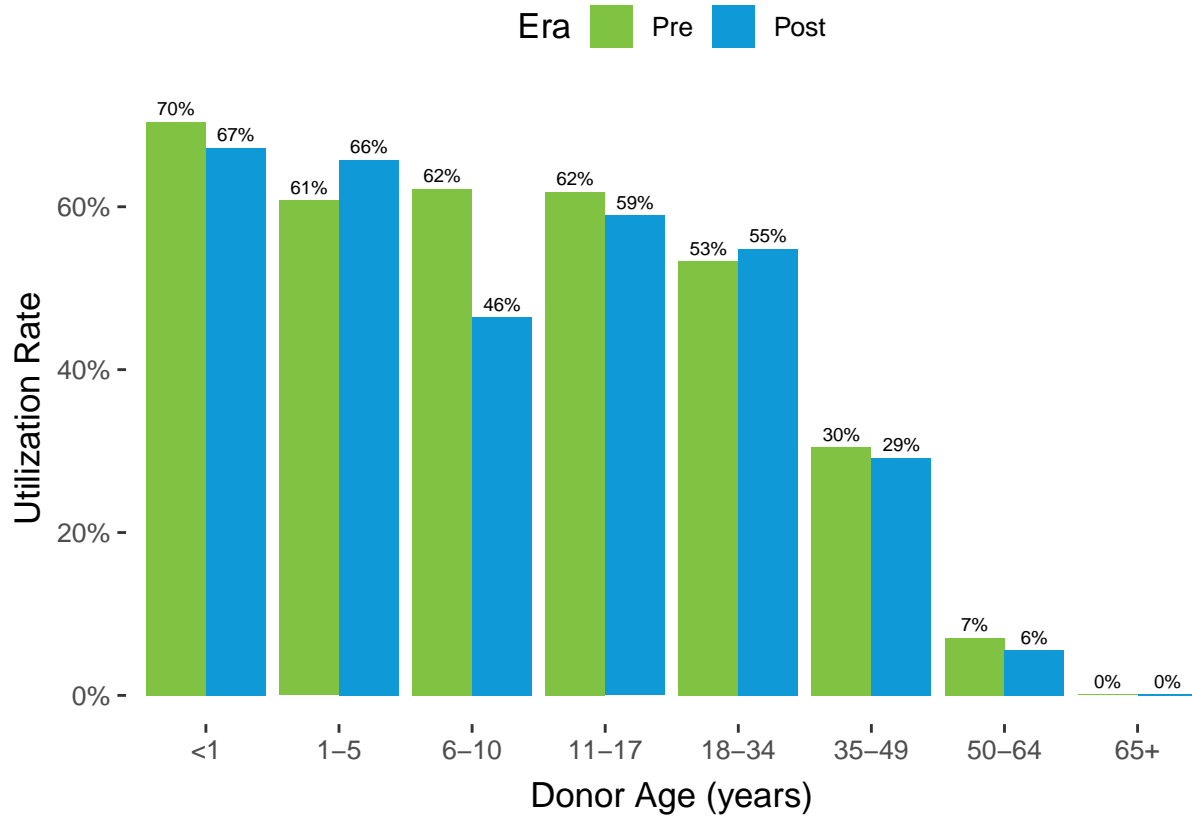


Figure 25 shows the utilization rates by donor age and era. Utilization was highest in ages <1 year pre- and post-implementation and lowest in the over 50 groups. Utilization remained similar pre- to post-implementation in all age groups except for ages 6-10 where it decreased by roughly 25%.

Figure 25. Utilization Rates for Heart Donors by Donor Age and Era

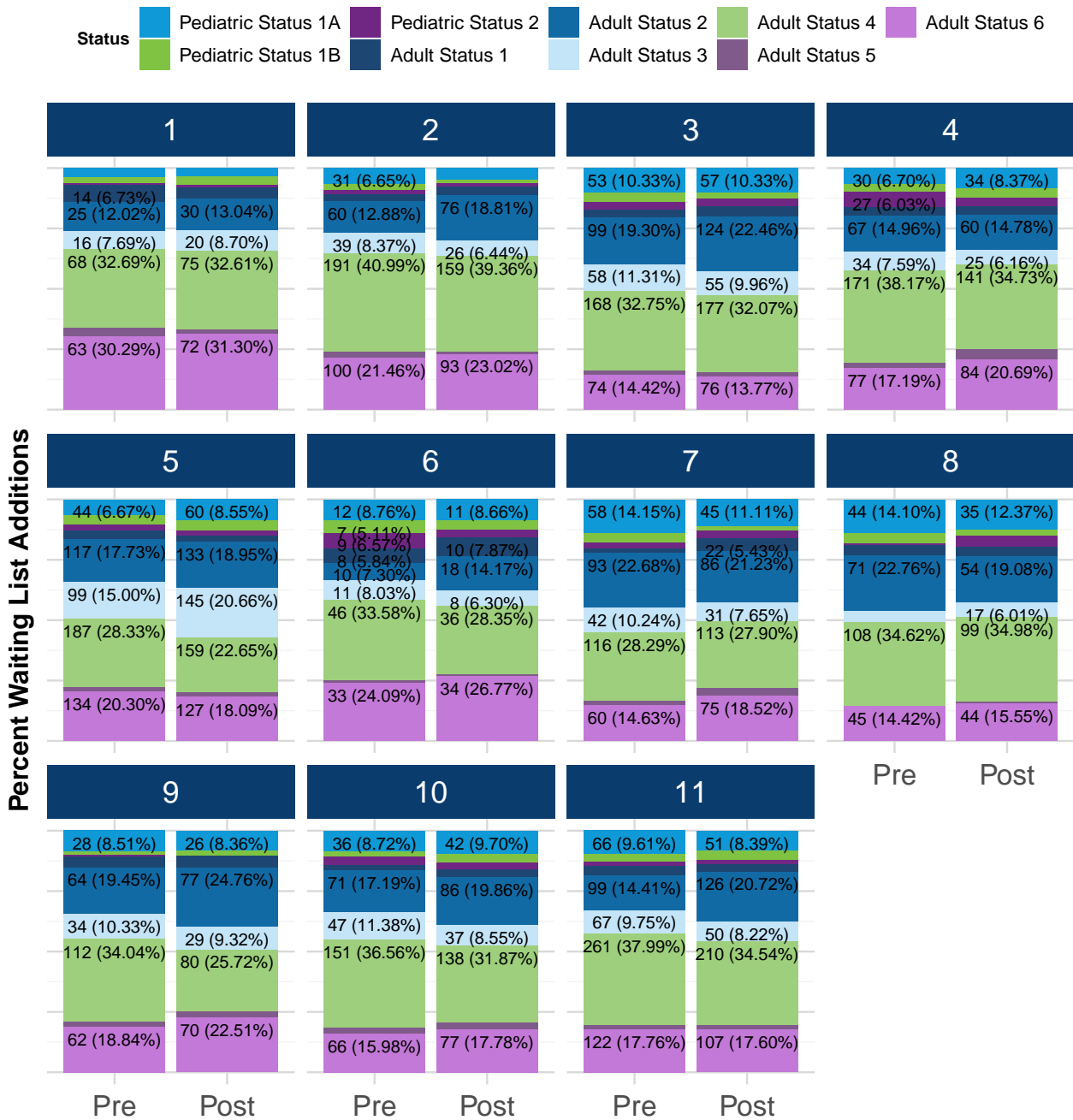


Summary

One year of monitoring the removal of DSA from heart allocation suggests that there were no major unintended impacts of the policy to heart allocation. More heart transplants were performed between 125-250 NM from the donor hospital. As expected, slightly fewer heart transplants occurred locally (within the same DSA) and more occurred regionally (different DSAs but the same region). Post-implementation, the median distance traveled decreased slightly overall but, increased for the less medically urgent adult heart candidates and more medically urgent pediatric candidates. While the removal of DSA from heart allocation appears to have affected the distances hearts are traveling, the removal did not appear to significantly affect total ischemic time nor has there been an increase in candidates removed from the waitlist due to death or being too sick to transplant. Waitlist mortality rates did not differ between eras and transplants rates increased significantly post-implementation. Finally, there were no significant differences in six-month post-transplant survival overall. The committee will continue to monitor these metrics in addition to other metrics as more data are made available.

Appendix

Figure A1. Waiting List Additions by Region, Medical Urgency Status and Era



Era
 COVID-19 Pandemic & National State of Emergency Declared March 11-13, 2020
 This figure contains roughly 10 months of COVID-era data
 Statuses representing <5% of the total are not labeled on the plot
 Temporarily Inactive Statuses Excluded

Table A1: Waitlist Additions by Region and Medical Urgency Status Pre-Implementation

Region		Adult Status 1	Adult Status 2	Adult Status 3	Adult Status 4	Adult Status 5	Adult Status 6	Pediatric Status 1A	Pediatric Status 1B	Pediatric Status 2	Temporarily Inactive	Total
1	N %	14 6.57%	25 11.74%	16 7.51%	68 31.92%	7 3.29%	63 29.58%	8 3.76%	5 2.35%	2 0.94%	5 2.35%	201 94.37%
2	N %	14 2.99%	60 12.82%	39 8.33%	191 40.81%	11 2.35%	100 21.37%	31 6.62%	11 2.35%	9 1.92%	2 0.43%	446 95.30%
3	N %	17 3.29%	99 19.19%	58 11.24%	168 32.56%	9 1.74%	74 14.34%	53 10.27%	20 3.88%	15 2.91%	3 0.58%	478 92.64%
4	N %	17 3.70%	67 14.60%	34 7.41%	171 37.25%	10 2.18%	77 16.78%	30 6.54%	15 3.27%	27 5.88%	11 2.40%	406 88.45%
5	N %	24 3.57%	117 17.38%	99 14.71%	187 27.79%	13 1.93%	134 19.91%	44 6.54%	25 3.71%	17 2.53%	13 1.93%	618 91.83%
6	N %	8 5.76%	10 7.19%	11 7.91%	46 33.09%	1 0.72%	33 23.74%	12 8.63%	7 5.04%	9 6.47%	2 1.44%	121 87.05%
7	N %	8 1.91%	93 22.25%	42 10.05%	116 27.75%	8 1.91%	60 14.35%	58 13.88%	15 3.59%	10 2.39%	8 1.91%	385 92.11%
8	N %	14 4.42%	71 22.40%	15 4.73%	108 34.07%	0 0.00%	45 14.20%	44 13.88%	13 4.10%	2 0.63%	5 1.58%	297 93.69%
9	N %	15 4.55%	64 19.39%	34 10.30%	112 33.94%	7 2.12%	62 18.79%	28 8.48%	5 1.52%	2 0.61%	1 0.30%	322 97.58%
10	N %	9 2.11%	71 16.63%	47 11.01%	151 35.36%	10 2.34%	66 15.46%	36 8.43%	9 2.11%	14 3.28%	14 3.28%	390 91.33%
11	N %	27 3.87%	99 14.20%	67 9.61%	261 37.45%	11 1.58%	122 17.50%	66 9.47%	23 3.30%	11 1.58%	10 1.43%	653 93.69%

Note:

COVID-19 Pandemic & National State of Emergency Declared March 11-13, 2020

This table contains roughly 10 months of COVID-era data

Table A2: Waitlist Additions by Region and Medical Urgency Status Post-Implementation

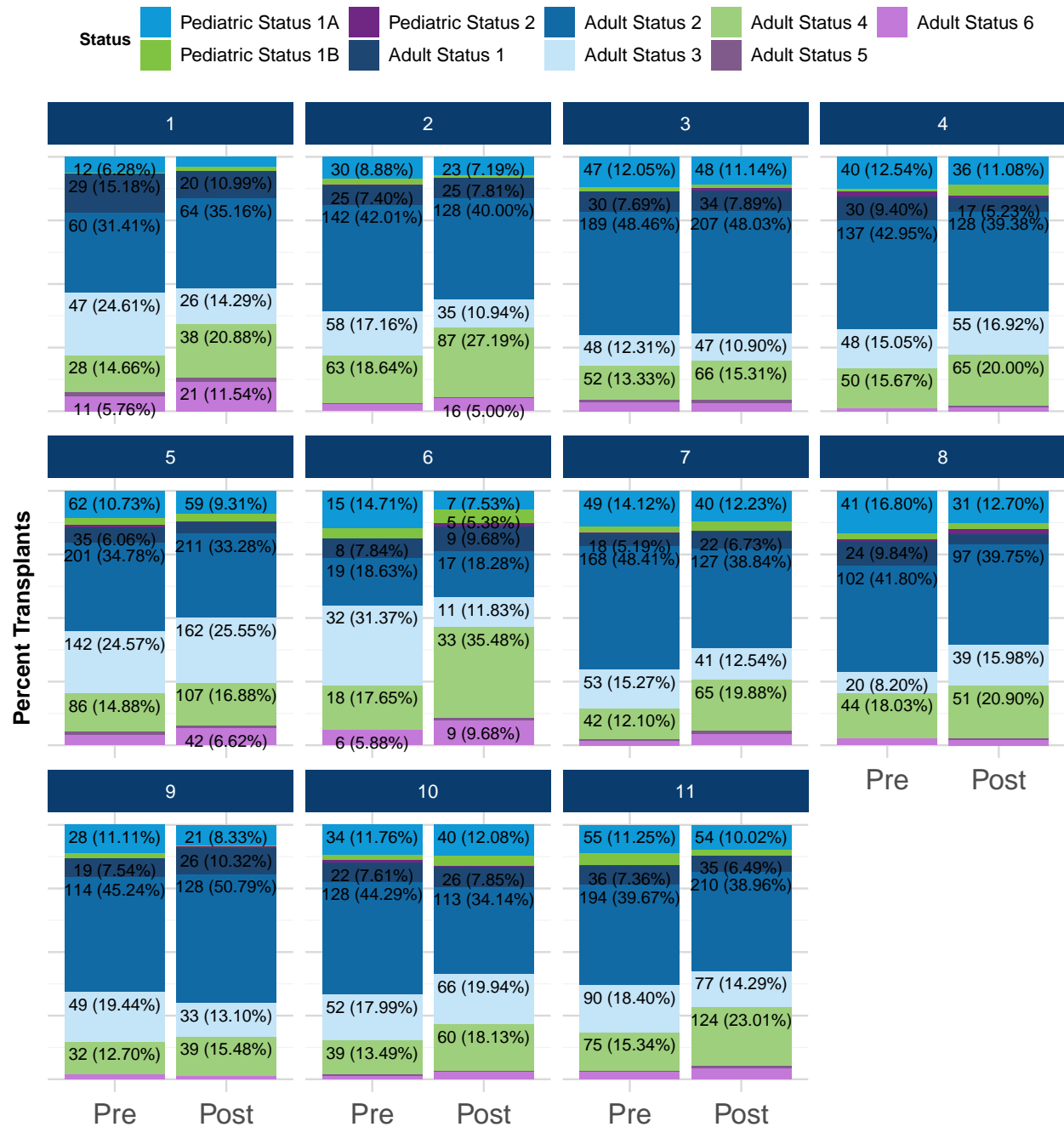
Region		Adult Status 1	Adult Status 2	Adult Status 3	Adult Status 4	Adult Status 5	Adult Status 6	Pediatric Status 1A	Pediatric Status 1B	Pediatric Status 2	Temporarily Inactive	Total
1	N	10	30	20	75	4	72	8	8	3	6	219
	%	4.24%	12.71%	8.47%	31.78%	1.69%	30.51%	3.39%	3.39%	1.27%	2.54%	92.80%
2	N	15	76	26	159	4	93	20	6	5	2	393
	%	3.69%	18.72%	6.40%	39.16%	0.99%	22.91%	4.93%	1.48%	1.23%	0.49%	96.80%
3	N	24	124	55	177	8	76	57	12	19	4	521
	%	4.32%	22.30%	9.89%	31.83%	1.44%	13.67%	10.25%	2.16%	3.42%	0.72%	93.71%
4	N	14	60	25	141	18	84	34	17	13	5	376
	%	3.41%	14.60%	6.08%	34.31%	4.38%	20.44%	8.27%	4.14%	3.16%	1.22%	91.48%
5	N	19	133	145	159	14	127	60	31	14	15	657
	%	2.65%	18.55%	20.22%	22.18%	1.95%	17.71%	8.37%	4.32%	1.95%	2.09%	91.63%
6	N	10	18	8	36	1	34	11	5	4	2	118
	%	7.75%	13.95%	6.20%	27.91%	0.78%	26.36%	8.53%	3.88%	3.10%	1.55%	91.47%
7	N	22	86	31	113	13	75	45	8	12	1	385
	%	5.42%	21.18%	7.64%	27.83%	3.20%	18.47%	11.08%	1.97%	2.96%	0.25%	94.83%
8	N	12	54	17	99	2	44	35	7	13	6	263
	%	4.15%	18.69%	5.88%	34.26%	0.69%	15.22%	12.11%	2.42%	4.50%	2.08%	91.00%
9	N	15	77	29	80	8	70	26	6	0	1	305
	%	4.81%	24.68%	9.29%	25.64%	2.56%	22.44%	8.33%	1.92%	0.00%	0.32%	97.76%
10	N	14	86	37	138	12	77	42	15	12	8	406
	%	3.17%	19.50%	8.39%	31.29%	2.72%	17.46%	9.52%	3.40%	2.72%	1.81%	92.06%
11	N	19	126	50	210	12	107	51	23	10	6	575
	%	3.09%	20.52%	8.14%	34.20%	1.95%	17.43%	8.31%	3.75%	1.63%	0.98%	93.65%

Note:

COVID-19 Pandemic & National State of Emergency Declared March 11-13, 2020

This table contains roughly 10 months of COVID-era data

Figure A2. Waiting Transplants by Region, Medical Urgency Status and Era



Era

COVID-19 Pandemic & National State of Emergency Declared March 11-13, 2020
 This figure contains roughly 10 months of COVID-era data;
 Statuses representing <5% of the total are not labeled on the plot
 Temporarily Inactive Statuses Excluded

Table A3: Heart Transplants by Region and Medical Urgency Status Pre-Implementation

Region		Pediatric Status 1A	Pediatric Status 1B	Pediatric Status 2	Adult Status 1	Adult Status 2	Adult Status 3	Adult Status 4	Adult Status 5	Adult Status 6	Total
1	N %	12 6.28%	1 0.52%	0 0.00%	29 15.18%	60 31.41%	47 24.61%	28 14.66%	3 1.57%	11 5.76%	149 78.01%
2	N %	30 8.88%	7 2.07%	2 0.59%	25 7.40%	142 42.01%	58 17.16%	63 18.64%	2 0.59%	9 2.66%	264 78.11%
3	N %	47 12.05%	7 1.79%	0 0.00%	30 7.69%	189 48.46%	48 12.31%	52 13.33%	3 0.77%	14 3.59%	321 82.31%
4	N %	40 12.54%	4 1.25%	6 1.88%	30 9.40%	137 42.95%	48 15.05%	50 15.67%	0 0.00%	4 1.25%	265 83.07%
5	N %	62 10.73%	17 2.94%	4 0.69%	35 6.06%	201 34.78%	142 24.57%	86 14.88%	8 1.38%	23 3.98%	461 79.76%
6	N %	15 14.71%	4 3.92%	0 0.00%	8 7.84%	19 18.63%	32 31.37%	18 17.65%	0 0.00%	6 5.88%	78 76.47%
7	N %	49 14.12%	8 2.31%	1 0.29%	18 5.19%	168 48.41%	53 15.27%	42 12.10%	2 0.58%	6 1.73%	297 85.59%
8	N %	41 16.80%	6 2.46%	1 0.41%	24 9.84%	102 41.80%	20 8.20%	44 18.03%	0 0.00%	6 2.46%	194 79.51%
9	N %	28 11.11%	5 1.98%	0 0.00%	19 7.54%	114 45.24%	49 19.44%	32 12.70%	0 0.00%	5 1.98%	215 85.32%
10	N %	34 11.76%	6 2.08%	3 1.04%	22 7.61%	128 44.29%	52 17.99%	39 13.49%	2 0.69%	3 1.04%	245 84.78%
11	N %	55 11.25%	22 4.50%	2 0.41%	36 7.36%	194 39.67%	90 18.40%	75 15.34%	1 0.20%	14 2.86%	399 81.60%

Note:

COVID-19 Pandemic & National State of Emergency Declared March 11-13, 2020

This table contains roughly 10 months of COVID-era data

Table A4: Heart Transplants by Region and Medical Urgency Status Post-Implementation

Region		Pediatric Status 1A	Pediatric Status 1B	Pediatric Status 2	Adult Status 1	Adult Status 2	Adult Status 3	Adult Status 4	Adult Status 5	Adult Status 6	Total
1	N %	7 3.85%	3 1.65%	0 0.00%	20 10.99%	64 35.16%	26 14.29%	38 20.88%	3 1.65%	21 11.54%	120 65.93%
2	N %	23 7.19%	3 0.94%	1 0.31%	25 7.81%	128 40.00%	35 10.94%	87 27.19%	2 0.62%	16 5.00%	215 67.19%
3	N %	48 11.14%	5 1.16%	5 1.16%	34 7.89%	207 48.03%	47 10.90%	66 15.31%	5 1.16%	14 3.25%	346 80.28%
4	N %	36 11.08%	14 4.31%	3 0.92%	17 5.23%	128 39.38%	55 16.92%	65 20.00%	2 0.62%	5 1.54%	253 77.85%
5	N %	59 9.31%	17 2.68%	4 0.63%	26 4.10%	211 33.28%	162 25.55%	107 16.88%	6 0.95%	42 6.62%	479 75.55%
6	N %	7 7.53%	5 5.38%	1 1.08%	9 9.68%	17 18.28%	11 11.83%	33 35.48%	1 1.08%	9 9.68%	50 53.76%
7	N %	40 12.23%	11 3.36%	2 0.61%	22 6.73%	127 38.84%	41 12.54%	65 19.88%	5 1.53%	14 4.28%	243 74.31%
8	N %	31 12.70%	6 2.46%	5 2.05%	9 3.69%	97 39.75%	39 15.98%	51 20.90%	1 0.41%	5 2.05%	187 76.64%
9	N %	21 8.33%	1 0.40%	1 0.40%	26 10.32%	128 50.79%	33 13.10%	39 15.48%	0 0.00%	3 1.19%	210 83.33%
10	N %	40 12.08%	13 3.93%	2 0.60%	26 7.85%	113 34.14%	66 19.94%	60 18.13%	2 0.60%	9 2.72%	260 78.55%
11	N %	54 10.02%	11 2.04%	0 0.00%	35 6.49%	210 38.96%	77 14.29%	124 23.01%	5 0.93%	23 4.27%	387 71.80%

Note:

COVID-19 Pandemic & National State of Emergency Declared March 11-13, 2020

This table contains roughly 10 months of COVID-era data