

2 Year Monitoring Report Pediatric National Heart Review Board

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Background/Purpose

Before the implementation of the pediatric National Heart Review Board (NHRB) on June 15, 2021, Regional Review Boards (RRBs) handled and reviewed exception cases for pediatric candidates listed before their 18th birthday. The purpose the NHRB was to improve quality and consistency in evaluating exceptions for heart candidates listed before their 18th birthday. Pediatric heart candidates can be listed as Status 1A, Status 1B, Status 2 or Inactive. Active pediatric candidates not meeting the criteria for Statuses 1A and 1B are put in Status 2 by default. The NHRB is comprised of representatives from pediatric heart programs from across the country. Reviewers are randomly assigned to review exception requests.

Strategic Plan Goal or Committee Project Addressed

1. Improve equity in access to transplants.
2. Improve waitlisted patient, living donor, and transplant recipient outcomes.

Committee Request

As outlined in the monitoring plan in the board briefing report, the Committee will monitor metrics as they relate to the pediatric NHRB. This includes, but is not limited to:

- Examine changes in the number and percent of pediatric candidates by status, exception, age group, OPTN region, and diagnosis
- Examine changes in the number and percent of pediatric transplant recipients by status, exception, age group, OPTN region, and diagnosis
- Evaluate changes in waiting list mortality rate for pediatric candidates by status and exception
- Evaluate changes in transplant rate for pediatric candidates by status and exception
- Report the percent of approvals and denials for exception requests by status
- Examine changes in post-transplant patient survival rates overall and stratified by status

This policy will be formally evaluated approximately 6 months, 1 year, and 2 years post-implementation. The aforementioned metrics, and any subsequently requested by the committee, will be evaluated as data become available (Appropriate lags will be applied, per typical UNOS conventions, to account for time delay in institutions reporting data to UNetSM)

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 December 08, 2023 and are subject to change based on future data submission or correction.

Methods:

Pediatric (age < 18 at listing) candidates added to the heart waiting list between June 15, 2019 and June 14, 2021 (pre) or between June 15, 2021 and June 14, 2023 (post) were stratified by medical urgency status, exception vs standard criteria, age group, OPTN region, and diagnosis. For the diagnosis section, the other category contains valvular heart disease, muscular dystrophy: other specify, arrhythmogenic right ventricular dysplasia, COVID-19: dilated myopathy, cancer, and the other category. The acronym CHD stands for coronary heart disease and CAD stands for coronary artery disease.

Pediatric (age < 18 at transplant) heart recipients transplanted between June 15, 2019 and June 14, 2021 (pre) or between June 15, 2021 and June 14, 2023 (post) were stratified by medical urgency status, exception vs standard criteria, age group, OPTN region, and diagnosis. For the diagnosis section, the other category contains valvular

heart disease, muscular dystrophy: other specify, arrhythmogenic right ventricular dysplasia, COVID-19: dilated myopathy, cancer, and the other category. The acronym CHD stands for coronary heart disease and CAD stands for coronary artery disease.

Waiting list mortality rates and transplant rates were calculated based on a cohort of pediatric (age < 18) candidates ever waiting between June 15, 2019 and June 14, 2021 (pre) or between June 15, 2021 and June 14, 2023 (post). Rates were calculated as the ratio of death or transplant to patient-years of exposure, and 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. Exceptions were calculated by whether the candidate ever had an exception in each policy era. Candidates who received any previous transplant were excluded from the waiting list mortality and transplant rate analyses.

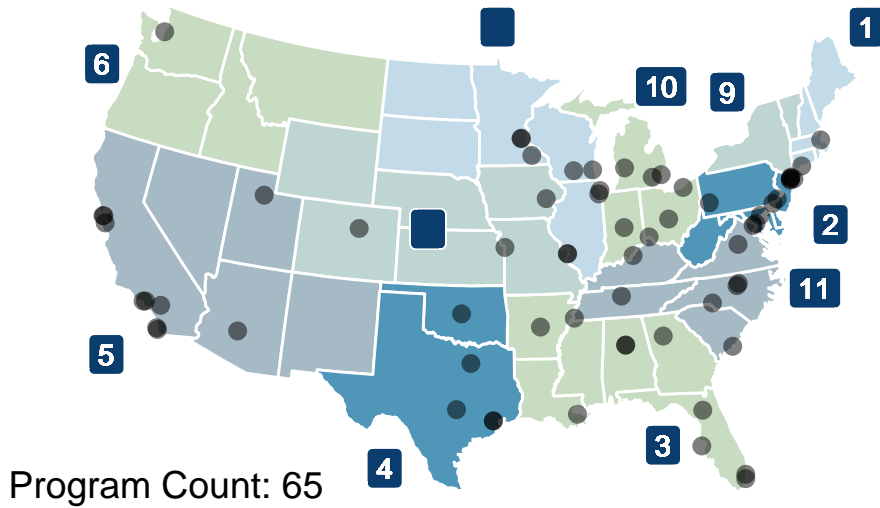
Outcomes analyses were performed on a subset of pediatric (age < 18 at transplant) heart transplant recipients with the potential for at least 1 year of follow-up plus a two-month data lag, which included recipients transplanted between June 14, 2020 and June 14, 2021 in the pre-implementation cohort and between June 15, 2021 and June 14, 2022 in the post-implementation cohort. 1 year survival curves were constructed using unadjusted Kaplan-Meier methodology and compared using the log-rank test.

Statistical analyses were performed using SAS v9.3 (SAS Institute, Inc., Cary, NC.) and R Version 4.1.3 (R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL: <https://www.R-project.org/>).

Results

At the same time that the Pediatric NHRB was implemented, the pediatric bylaws also went into effect. The bylaws established requirements for pediatric components and minimum qualifications for primary pediatric transplant surgeons and physicians for kidney, liver, pancreas, heart and lung programs. Figure 1 shows all programs with an approved pediatric program per the OPTN pediatric bylaws. There are a total of 65 active programs with approved pediatric components as of December 08, 2023.

Figure 1. Map of Active Heart Programs with an Approved Pediatric Component

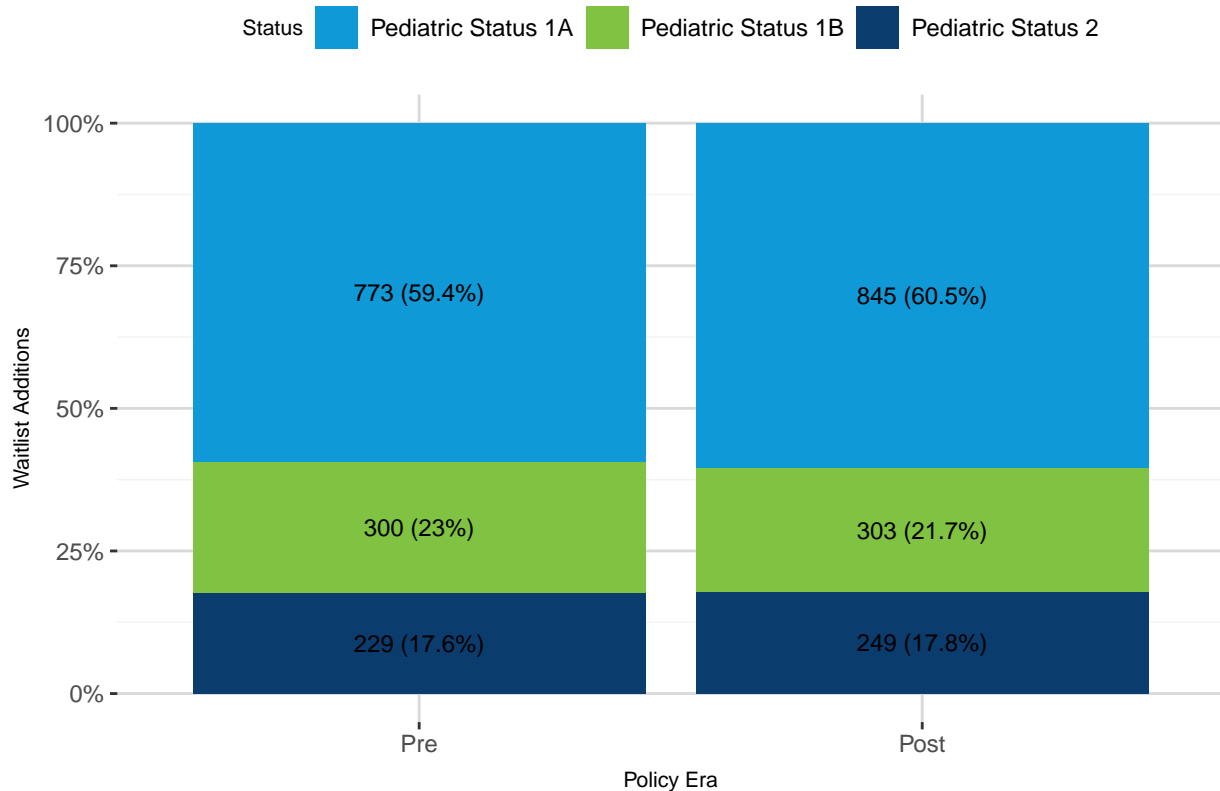


Waiting List

The following metrics summarize waiting list additions by medical urgency status, exception vs. standard criteria, age group, OPTN region, and diagnosis.

Figure 2 shows pediatric waitlist additions by medical urgency status and era. There is slight variation between the statuses in the pre and post-policy eras. There was an increase in the percent of status 1A waitlist additions from 59.4% (n=773) in the pre-policy era to 60.5% (n=845) in the post-policy era. There was a decrease in the percent of status 1B waitlist additions from 23% (n=300) in the pre-policy era to 21.7% (n=303) in the post-policy era.

Figure 2. Waitlist additions by medical urgency status and era



Note: Temporarily inactive medical urgency status was removed from this figure (n=34)

Figure 3 shows the pediatric waitlist additions by age at listing and era. The pre and post-policy eras had a similar distribution across the age groups. Compared to the pre-policy era, post-policy there was an increase in the percent of waitlist additions for candidates ages 6-10 from 11.3% (n=149) to 14.7% (n=207), as well as an increase in the percent of waitlist additions for candidates ages 11-17 from 32.7% (n=432) to 34.6% (n=488).

Conversely, there was a decrease in the percent of candidates younger than 1 year old from 35.7% (n=471) to 31.9% (n=450), as well as a decrease in candidates ages 1-5 from 20.4% (n=269) to 18.9% (n=267).

Figure 3. Waitlist additions by age at listing and era

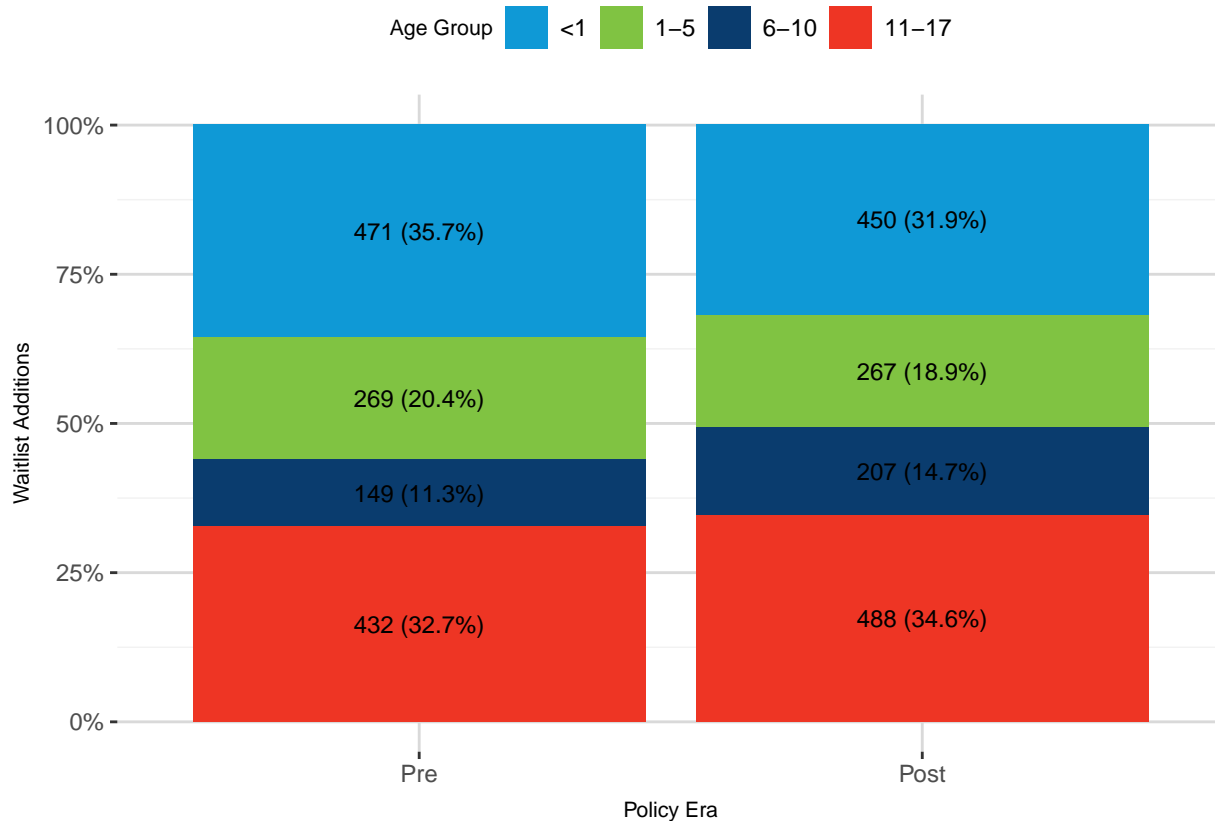
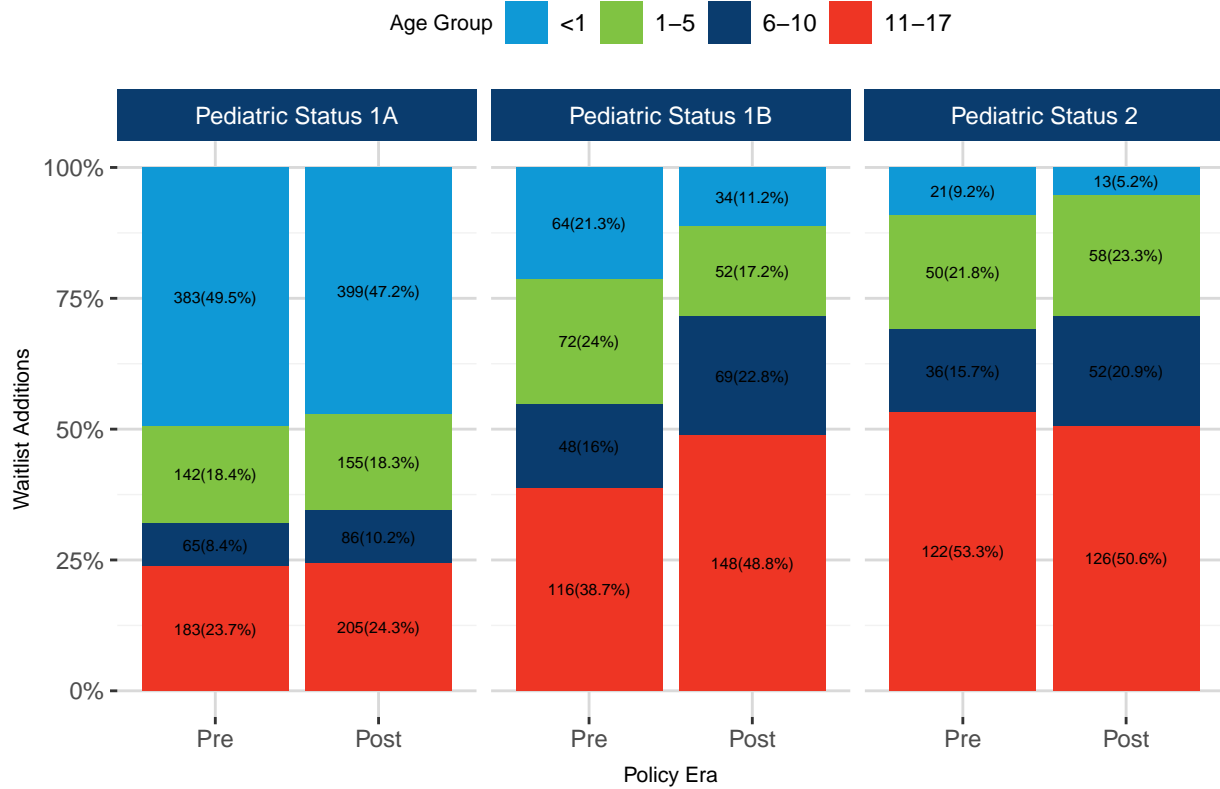


Figure 4 and table 1 show pediatric waitlist additions by medical urgency status, age at listing, and era. Pediatric status 1A candidates were more likely to be in the <1 age group, while pediatric status 1B and status 2 candidates were more likely to be in the 11-17 age group. In the post-policy era, there was a slightly higher percent of candidates in the 6-10 age group in status 1A, from 8.4% (n=65) in the pre-policy era to 10.2% (n=86) in the post-policy era. Pediatric status 1B had higher percentages of waitlist additions in the 6-10 and 11-17 age groups in the post-policy era. Pediatric status 2 had a slightly higher percent of waitlist additions in the 1-5 and 6-10 age groups in the post-policy era.

Figure 4. Waitlist additions by medical urgency status, age at listing and era



Note: Temporarily inactive medical urgency status was removed from this figure (n=34)

Table 1. Waitlist additions by medical urgency status, age at listing and era

Status	Age Group	Pre	Post
Pediatric Status 1A	<1	383 (49.5%)	399 (47.2%)
	1-5	142 (18.4%)	155 (18.3%)
	6-10	65 (8.4%)	86 (10.2%)
	11-17	183 (23.7%)	205 (24.3%)
Pediatric Status 1B	<1	64 (21.3%)	34 (11.2%)
	1-5	72 (24%)	52 (17.2%)
	6-10	48 (16%)	69 (22.8%)
	11-17	116 (38.7%)	148 (48.8%)
Pediatric Status 2	<1	21 (9.2%)	13 (5.2%)
	1-5	50 (21.8%)	58 (23.3%)
	6-10	36 (15.7%)	52 (20.9%)
	11-17	122 (53.3%)	126 (50.6%)

Note:

Temporarily inactive medical urgency status was removed from this table (n=34)

Figure 5 shows the pediatric waitlist additions by OPTN region and era. Most regions recorded a positive change between eras. Region 9 had the largest positive percent change in pediatric waitlist additions from pre-policy to post-policy with a difference of 39.4%. Region 3 had the largest negative percent change in pediatric waitlist additions from pre-policy to post-policy with a difference of -18%.

Figure 5. Waitlist additions by OPTN region and era

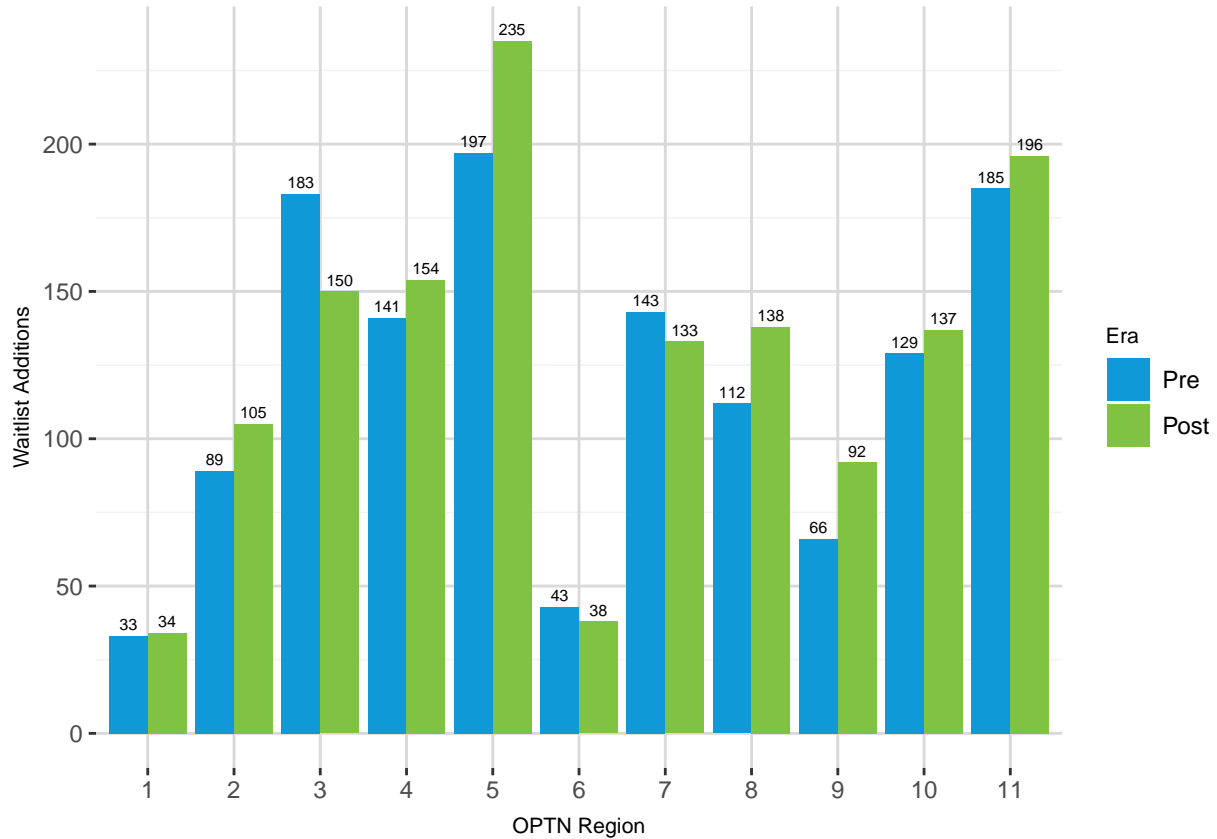
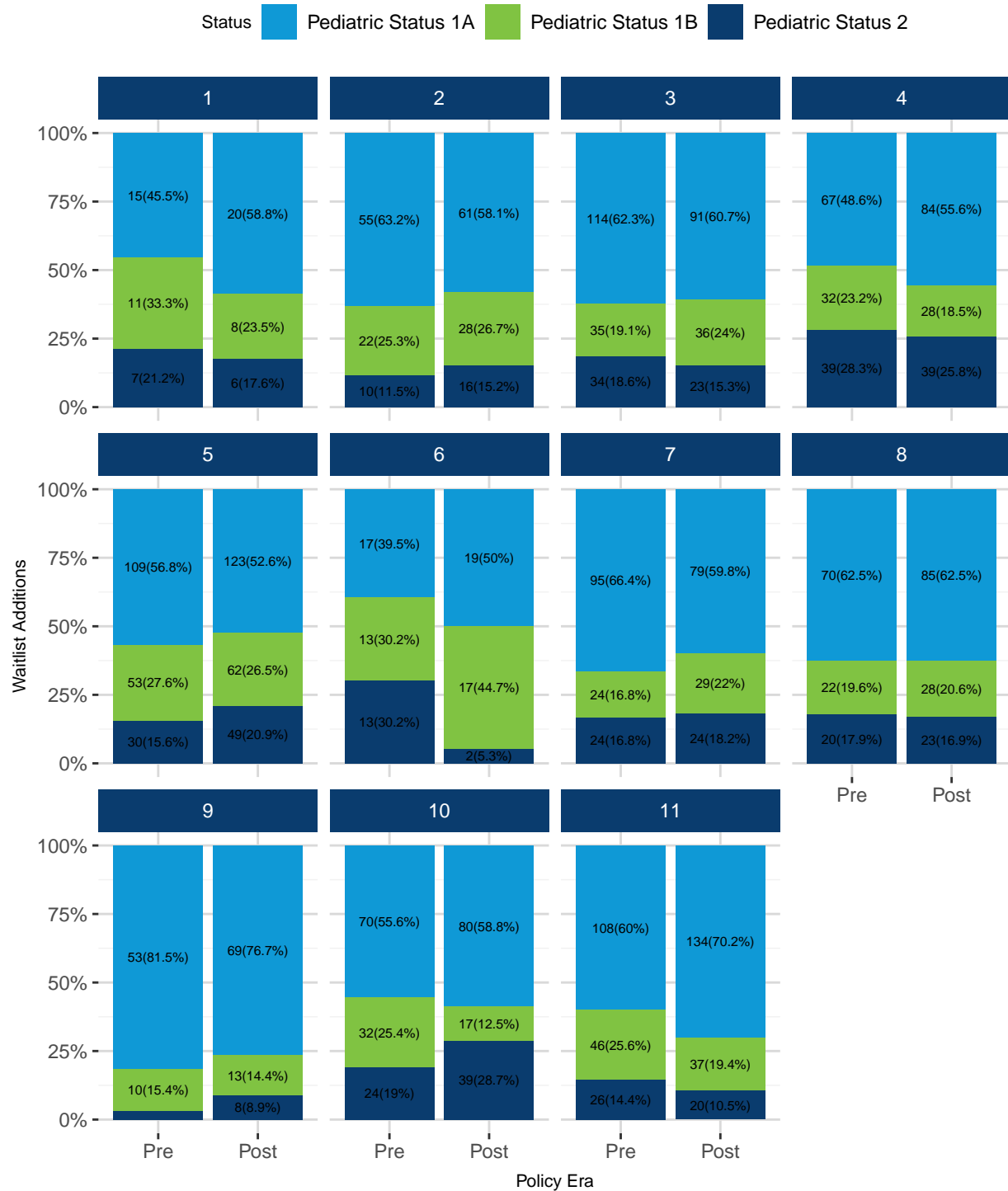


Figure 6 and table 2 show pediatric waitlist additions by medical urgency status and OPTN region. Region 7 had the greatest percent decrease in Pediatric 1A candidates, while Region 1 had the greatest percent increase in Pediatric 1A candidates. Region 10 had the greatest percent decrease in Pediatric 1B candidates, and Region 6 had the greatest percent decrease in Pediatric 2 candidates.

Figure 6. Waitlist additions by medical urgency status, OPTN region, and era



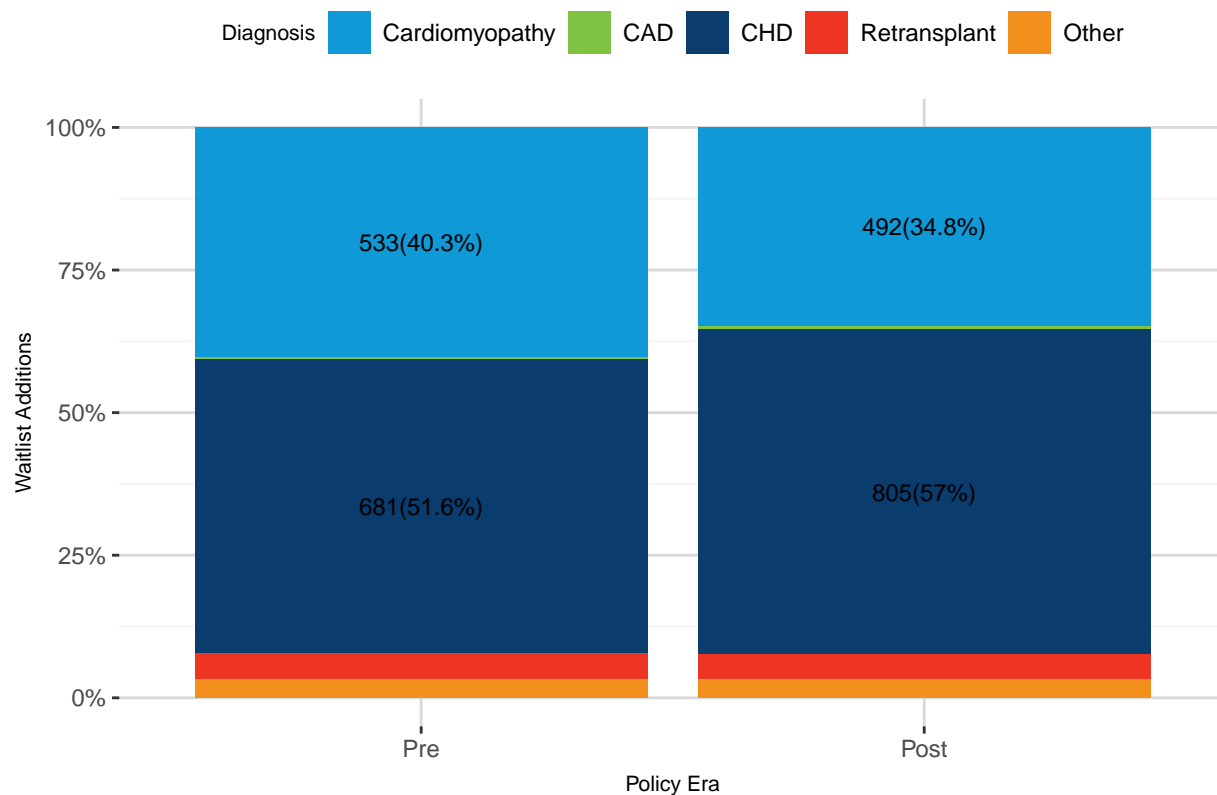
Note: Categories representing less than 5% of the total are not labeled on the plot. Temporarily inactive medical urgency status was removed from this figure (n=34)

Table 2. Waitlist additions by medical urgency status and OPTN region

OPTN Region	Status	Pre	Post
1	Pediatric Status 1A	15(45.5%)	20(58.8%)
	Pediatric Status 1B	11(33.3%)	8(23.5%)
	Pediatric Status 2	7(21.2%)	6(17.6%)
2	Pediatric Status 1A	55(63.2%)	61(58.1%)
	Pediatric Status 1B	22(25.3%)	28(26.7%)
	Pediatric Status 2	10(11.5%)	16(15.2%)
3	Pediatric Status 1A	114(62.3%)	91(60.7%)
	Pediatric Status 1B	35(19.1%)	36(24%)
	Pediatric Status 2	34(18.6%)	23(15.3%)
4	Pediatric Status 1A	67(48.6%)	84(55.6%)
	Pediatric Status 1B	32(23.2%)	28(18.5%)
	Pediatric Status 2	39(28.3%)	39(25.8%)
5	Pediatric Status 1A	109(56.8%)	123(52.6%)
	Pediatric Status 1B	53(27.6%)	62(26.5%)
	Pediatric Status 2	30(15.6%)	49(20.9%)
6	Pediatric Status 1A	17(39.5%)	19(50%)
	Pediatric Status 1B	13(30.2%)	17(44.7%)
	Pediatric Status 2	13(30.2%)	2(5.3%)
7	Pediatric Status 1A	95(66.4%)	79(59.8%)
	Pediatric Status 1B	24(16.8%)	29(22%)
	Pediatric Status 2	24(16.8%)	24(18.2%)
8	Pediatric Status 1A	70(62.5%)	85(62.5%)
	Pediatric Status 1B	22(19.6%)	28(20.6%)
	Pediatric Status 2	20(17.9%)	23(16.9%)
9	Pediatric Status 1A	53(81.5%)	69(76.7%)
	Pediatric Status 1B	10(15.4%)	13(14.4%)
	Pediatric Status 2	2(3.1%)	8(8.9%)
10	Pediatric Status 1A	70(55.6%)	80(58.8%)
	Pediatric Status 1B	32(25.4%)	17(12.5%)
	Pediatric Status 2	24(19%)	39(28.7%)
11	Pediatric Status 1A	108(60%)	134(70.2%)
	Pediatric Status 1B	46(25.6%)	37(19.4%)
	Pediatric Status 2	26(14.4%)	20(10.5%)

Figure 7 and table 3 show the pediatric waitlist additions by diagnosis and era. There was a decrease in waitlist additions reporting a primary diagnosis of cardiomyopathy from 40.3%(n=533) in the pre-policy era to 34.8%(n=492) in the post-policy era. There was an increase in waitlist additions reporting a primary diagnosis of CHD from 51.6%(n=681) in the pre-policy era to 57%(n=805) in the post-policy era.

Figure 7. Waitlist additions by diagnosis and era



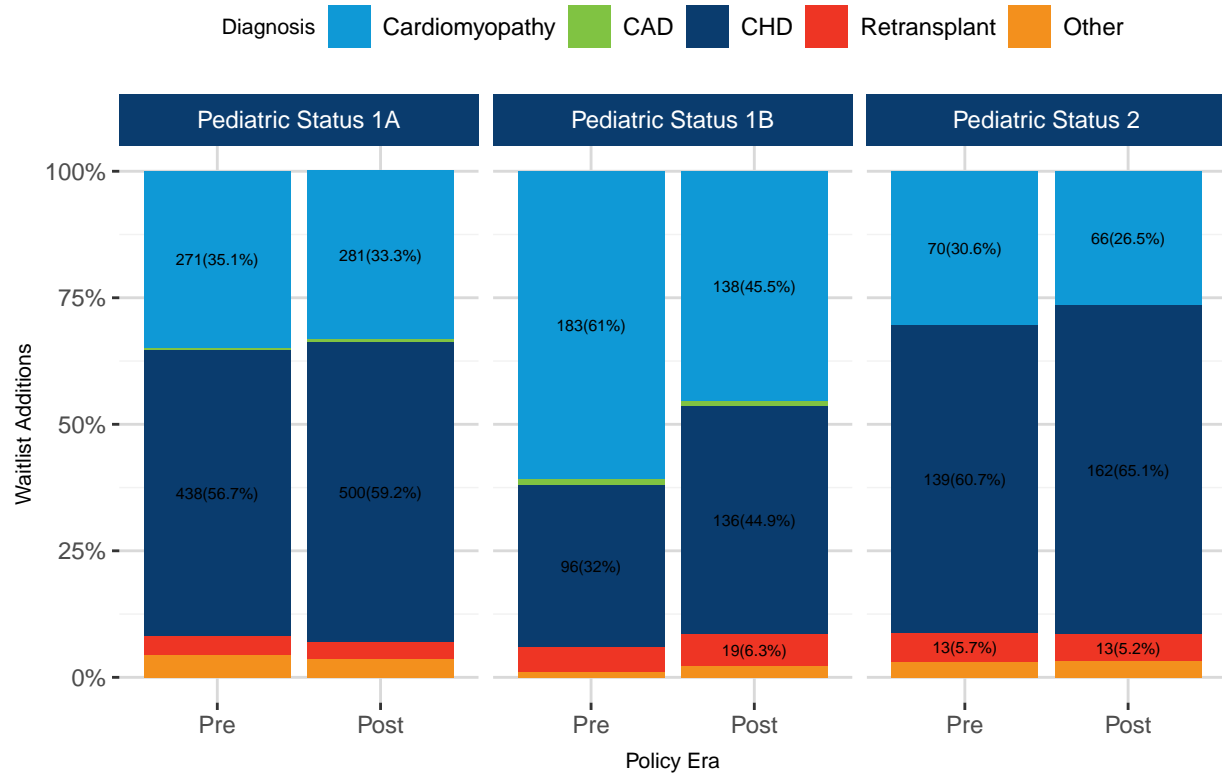
Note: Categories representing less than 5% of the total are not labeled on the plot.

Table 3. Waitlist additions by diagnosis and era

Diagnosis	Pre	Post
Cardiomyopathy	533(40.3%)	492(34.8%)
CAD	5(0.4%)	8(0.6%)
CHD	681(51.6%)	805(57%)
Retransplant	58(4.4%)	62(4.4%)
Other	44(3.3%)	45(3.2%)

Figure 8 and table 4 show pediatric waitlist additions by medical urgency status, diagnosis, and era. Between the two eras, the pediatric status 1A additions were similarly distributed across the diagnoses. There was a decrease in pediatric status 1B cardiomyopathy diagnoses from 61%(n=183) to 45.5%(n=138), a decrease in pediatric status 2 cardiomyopathy diagnoses from 30.6%(n=70) to 26.5%(n=66), an increase in pediatric status 1B CHD diagnoses from 32%(n=96) to 44.9%(n=136), and an increase in pediatric status 2 CHD diagnoses from 60.7%(n=139) to 65.1%(n=162).

Figure 8. Waitlist additions by medical urgency status, diagnosis and era



Note: Categories representing less than 5% of the total are not labeled on the plot. Temporarily inactive medical urgency status was removed from this figure (n=34)

Table 4. Waitlist additions by medical urgency status, diagnosis and era

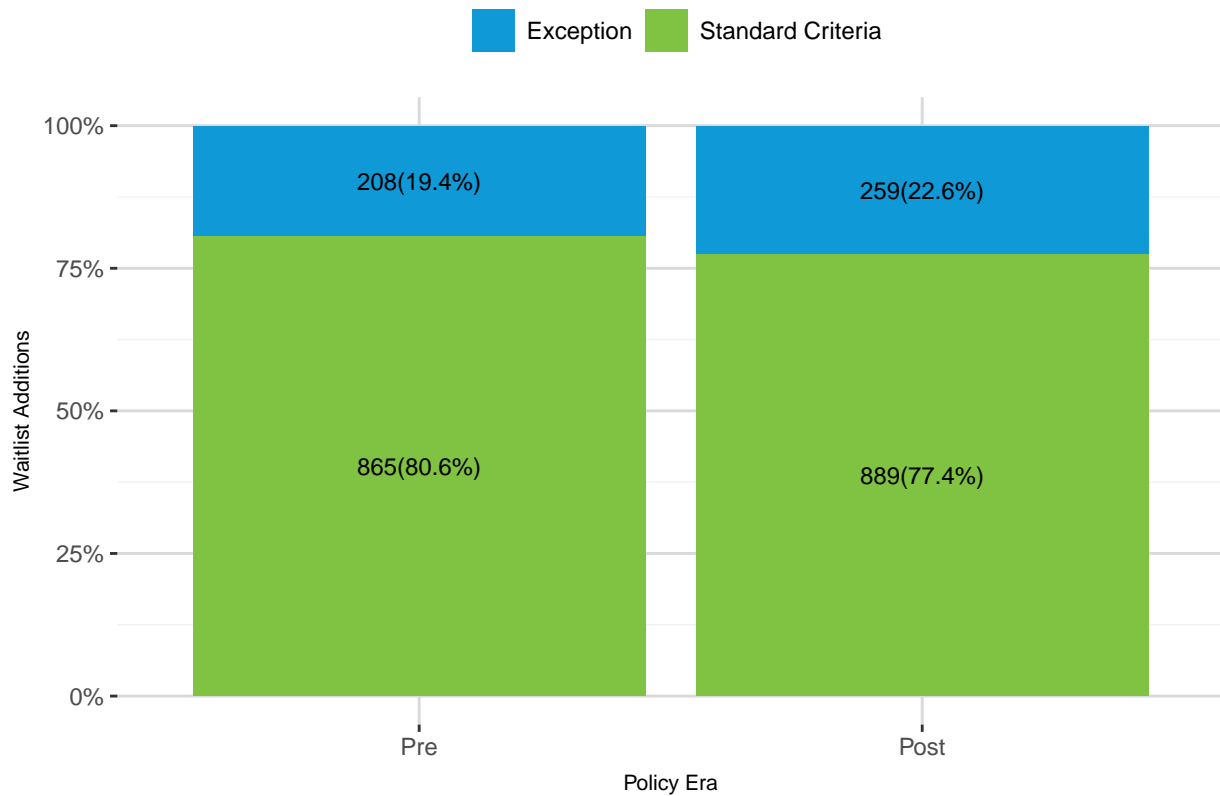
Status	Diagnosis	Pre	Post
Pediatric Status 1A	Cardiomyopathy	271(35.1%)	281(33.3%)
	CAD	2(0.3%)	5(0.6%)
	CHD	438(56.7%)	500(59.2%)
	Retransplant	28(3.6%)	29(3.4%)
	Other	34(4.4%)	30(3.6%)
	Not Reported	0(0%)	0(0%)
Pediatric Status 1B	Cardiomyopathy	183(61%)	138(45.5%)
	CAD	3(1%)	3(1%)
	CHD	96(32%)	136(44.9%)
	Retransplant	15(5%)	19(6.3%)
	Other	3(1%)	7(2.3%)
	Not Reported	0(0%)	0(0%)
Pediatric Status 2	Cardiomyopathy	70(30.6%)	66(26.5%)
	CAD	0(0%)	0(0%)
	CHD	139(60.7%)	162(65.1%)
	Retransplant	13(5.7%)	13(5.2%)
	Other	7(3.1%)	8(3.2%)
	Not Reported	0(0%)	0(0%)

Note:

Temporarily inactive medical urgency status was removed from this table (n=14)

Figure 9 shows pediatric waitlist additions by exception vs. standard criteria at listing and era. The exceptions were similarly distributed across eras.

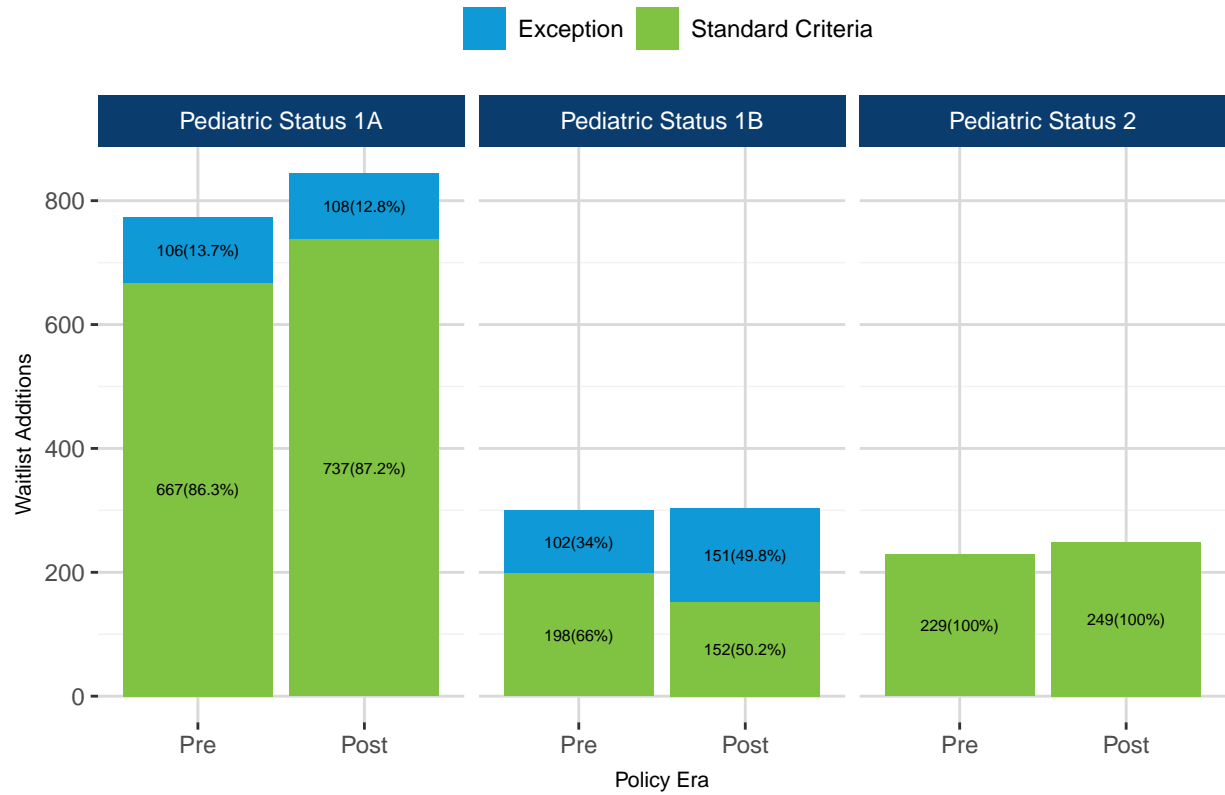
Figure 9. Waitlist additions by exception vs. standard criteria at listing and era



Note: Both the temporarily inactive and pediatric status 2 waitlist additions were removed from the figure (n=512)

Figure 10 shows pediatric waitlist additions by medical urgency status, exception vs. standard criteria, and era. Pediatric status 1A exceptions are similarly distributed across era. Pediatric status 1B exceptions rose from 34%(n=102) in the pre-policy era to 49.8%(n=151) in the post-policy era. Pediatric status 2 is not eligible for exception, so 100% of those waitlist additions were standard criteria.

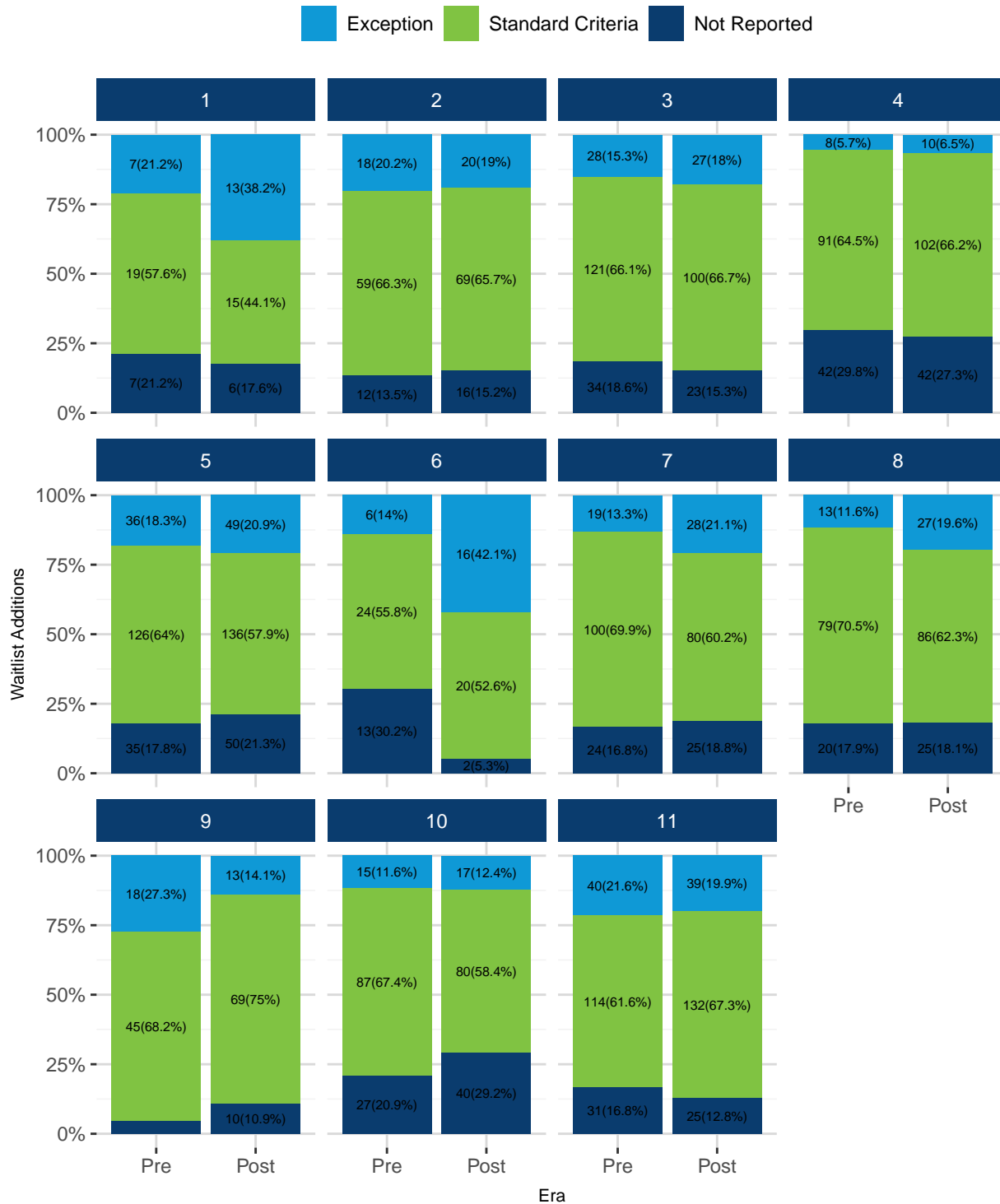
Figure 10. Waitlist additions by medical urgency status, exception vs. standard criteria and era



Temporarily inactive medical urgency status was removed from this figure (n=34)

Figure 11 and table 5 show the breakdown of waitlist additions by exception vs. standard criteria stratified by OPTN region. The majority of regions saw an increase in waitlist additions with exceptions. Region 6 had the biggest percent increase in exceptions from 14% in the pre-policy era to 42.1% in the post-policy era.

Figure 11. Waitlist additions by exception vs. standard criteria and OPTN region



Note: Categories representing less than 5% of the total are not labeled on the plot.

Table 5. Waitlist additions by exception vs. standard criteria and OPTN region

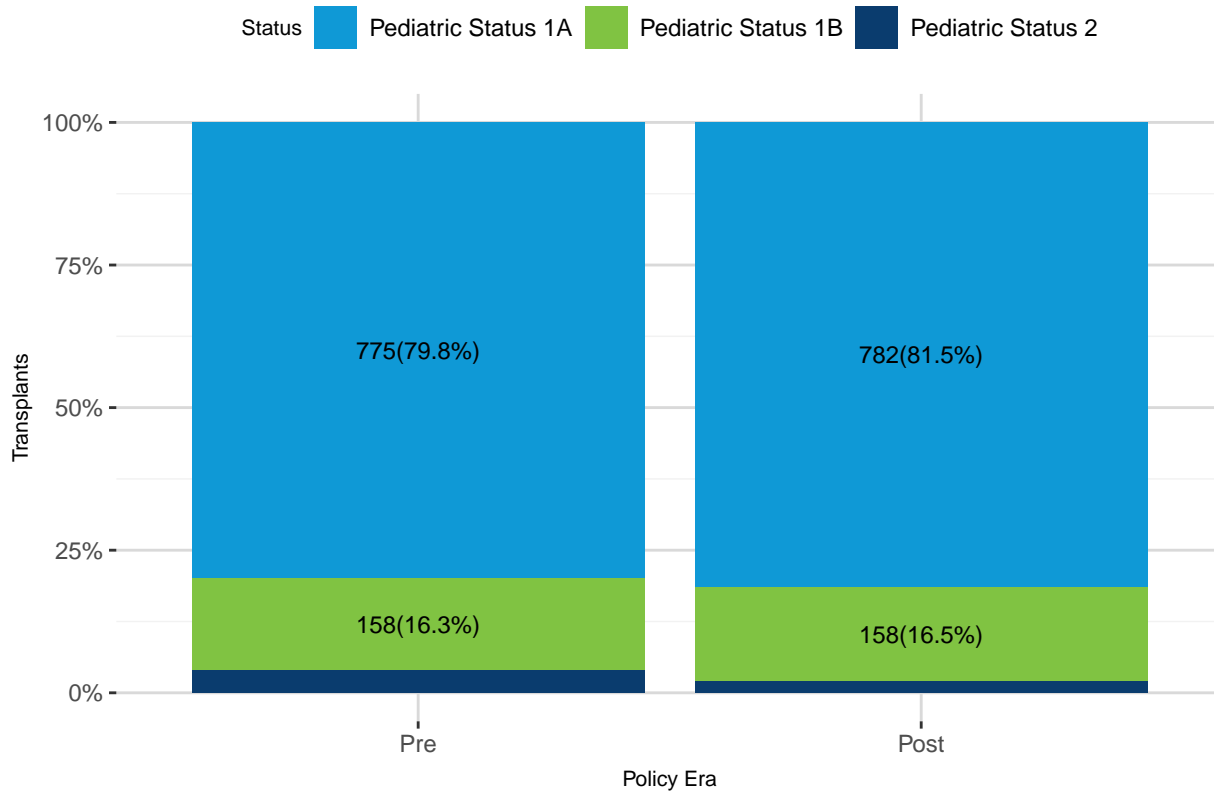
OPTN Region	Exception vs. Standard Criteria	Pre	Post
1	Exception	7(21.2%)	13(38.2%)
	Standard Criteria	19(57.6%)	15(44.1%)
	Not Reported	7(21.2%)	6(17.6%)
2	Exception	18(20.2%)	20(19%)
	Standard Criteria	59(66.3%)	69(65.7%)
	Not Reported	12(13.5%)	16(15.2%)
3	Exception	28(15.3%)	27(18%)
	Standard Criteria	121(66.1%)	100(66.7%)
	Not Reported	34(18.6%)	23(15.3%)
4	Exception	8(5.7%)	10(6.5%)
	Standard Criteria	91(64.5%)	102(66.2%)
	Not Reported	42(29.8%)	42(27.3%)
5	Exception	36(18.3%)	49(20.9%)
	Standard Criteria	126(64%)	136(57.9%)
	Not Reported	35(17.8%)	50(21.3%)
6	Exception	6(14%)	16(42.1%)
	Standard Criteria	24(55.8%)	20(52.6%)
	Not Reported	13(30.2%)	2(5.3%)
7	Exception	19(13.3%)	28(21.1%)
	Standard Criteria	100(69.9%)	80(60.2%)
	Not Reported	24(16.8%)	25(18.8%)
8	Exception	13(11.6%)	27(19.6%)
	Standard Criteria	79(70.5%)	86(62.3%)
	Not Reported	20(17.9%)	25(18.1%)
9	Exception	18(27.3%)	13(14.1%)
	Standard Criteria	45(68.2%)	69(75%)
	Not Reported	3(4.5%)	10(10.9%)
10	Exception	15(11.6%)	17(12.4%)
	Standard Criteria	87(67.4%)	80(58.4%)
	Not Reported	27(20.9%)	40(29.2%)
11	Exception	40(21.6%)	39(19.9%)
	Standard Criteria	114(61.6%)	132(67.3%)
	Not Reported	31(16.8%)	25(12.8%)

Transplants

The following metrics summarize transplant recipients by medical urgency status, exception vs. standard criteria, age group, OPTN region, and diagnosis.

Figure 12 and table 6 show pediatric heart transplants by medical urgency status and era. The medical urgency statuses are similarly distributed across era.

Figure 12. Transplants by medical urgency status and era



Note: Categories representing less than 5% of the total are not labeled on the plot.

Table 6. Transplants by medical urgency status and era

Status	Pre	Post
Pediatric Status 1A	775(79.8%)	782(81.5%)
Pediatric Status 1B	158(16.3%)	158(16.5%)
Pediatric Status 2	38(3.9%)	19(2%)

Figure 13 shows the pediatric transplants by age at transplant an era. The pre and post-policy eras had a similar distribution across the age groups.

Figure 13. Transplants by age at transplant and era

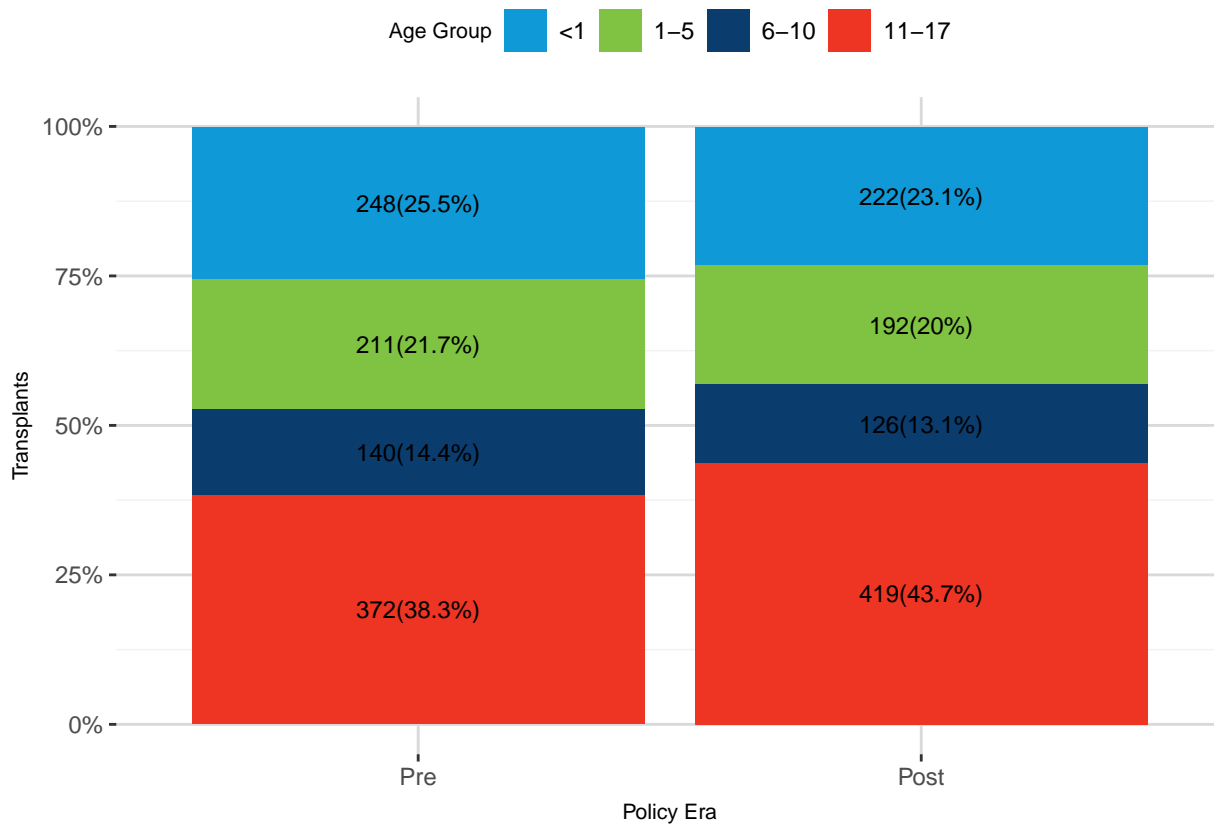
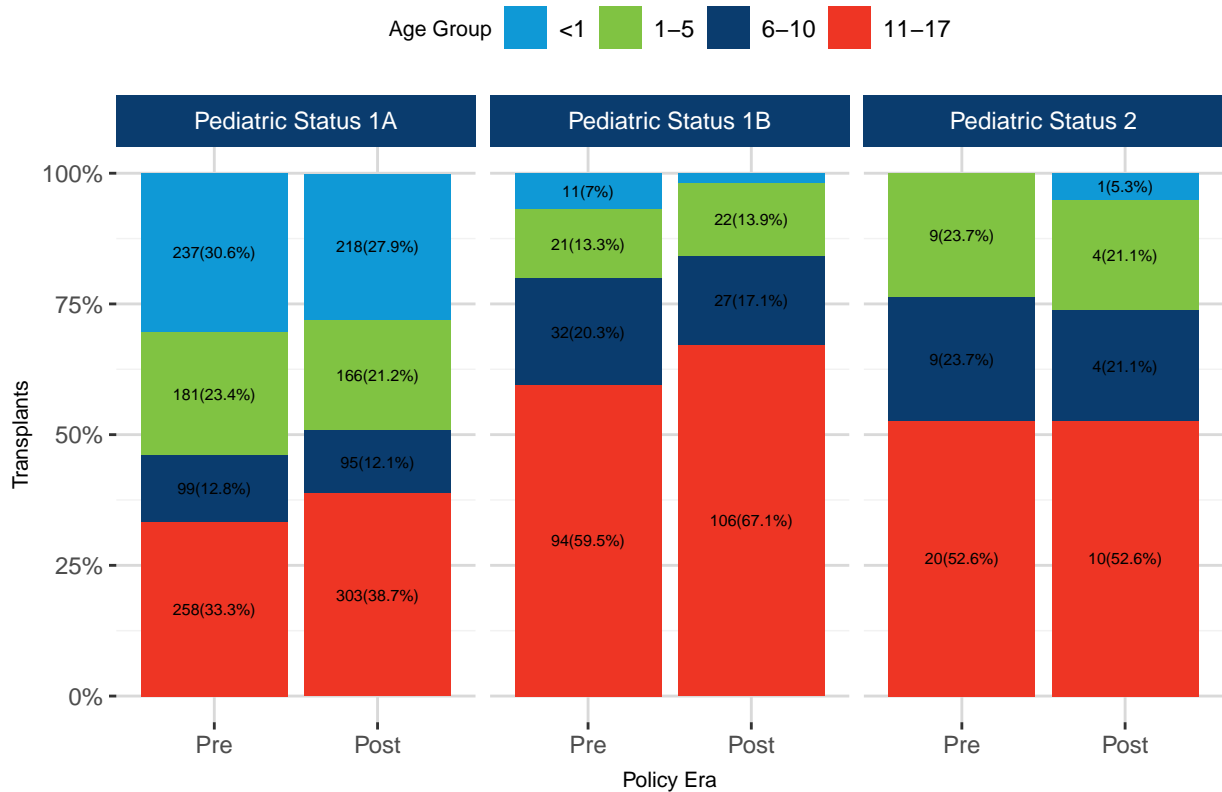


Figure 14 shows pediatric heart transplants by medical urgency status, age at transplant, and era. Pediatric status 1A transplants decreased within the <1 age group from 30.6%(n=237) to 27.9%(n=218) and increased within the 11-17 age group from 33.3%(n=258) to 38.7%(n=303). Pediatric status 1B had a decrease in transplants within the <1 age group from 7%(n=11) to 1.9%(n=3) and an increase in transplants within the 11-17 age group from 59.5%(n=94) to 67.1%(n=106).

Figure 14. Transplants by medical urgency status, age at transplant, and era



Note: Categories representing less than 5% of the total are not labeled on the plot.

Figure 15 shows pediatric heart transplants by OPTN region and era. Region 9 had the greatest positive percent change in pediatric transplants from pre-policy to post-policy with a difference of 26%. Region 7 had the greatest negative percent change in pediatric transplants from pre-policy to post-policy with a difference of -28.8%.

Figure 15. Transplants by OPTN region and era

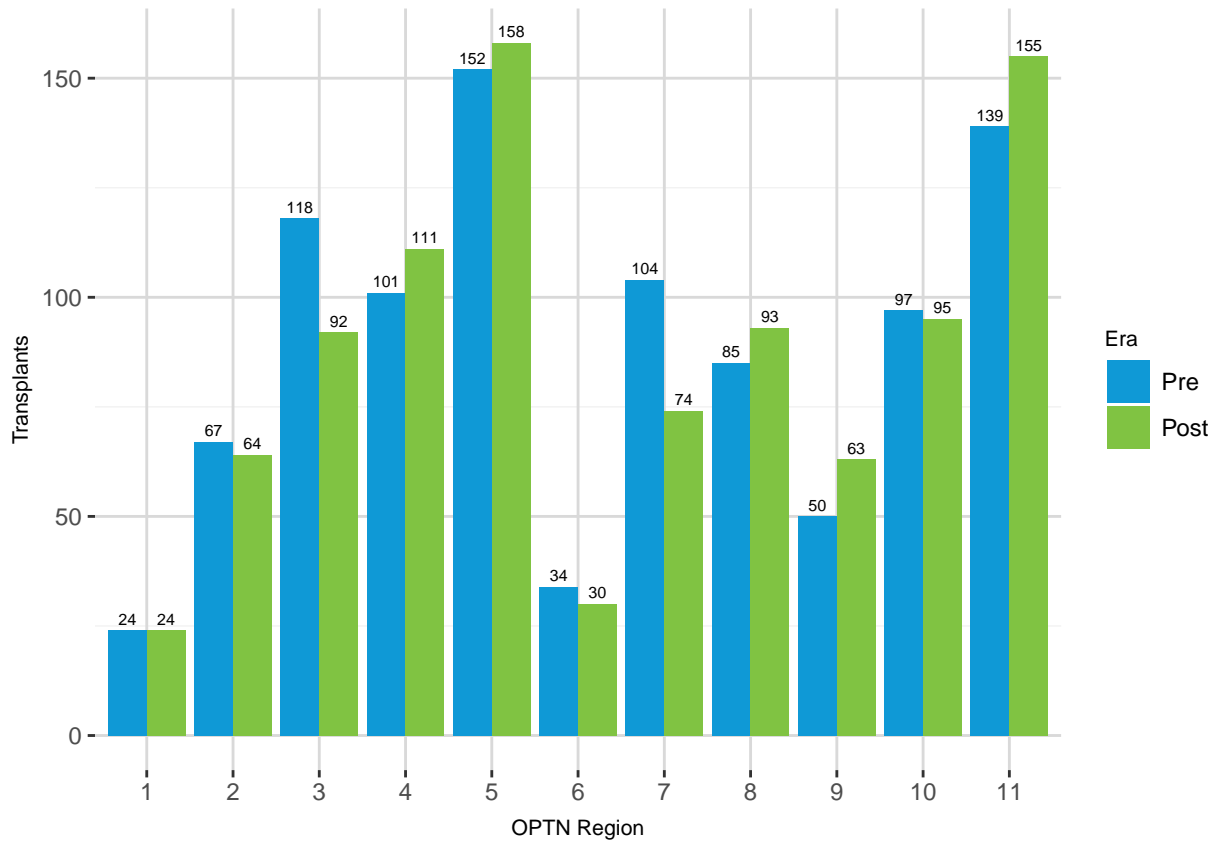
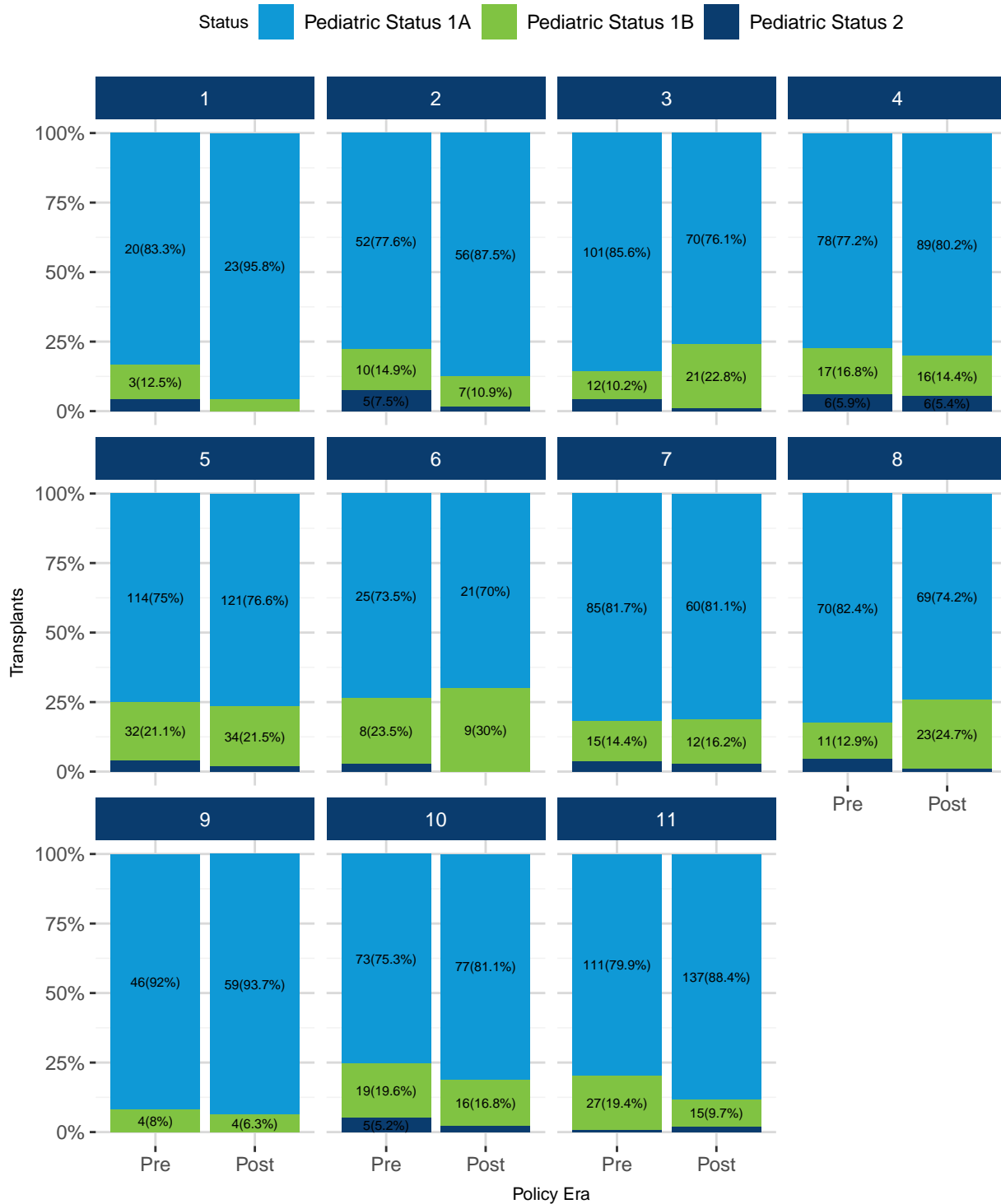


Figure 16 and table 7 show pediatric heart transplants by medical urgency status and OPTN region. The majority of regions saw a percent increase in pediatric status 1A transplants, as well as a percent decrease in pediatric status 2 transplants.

Figure 16. Transplants by medical urgency status and OPTN region



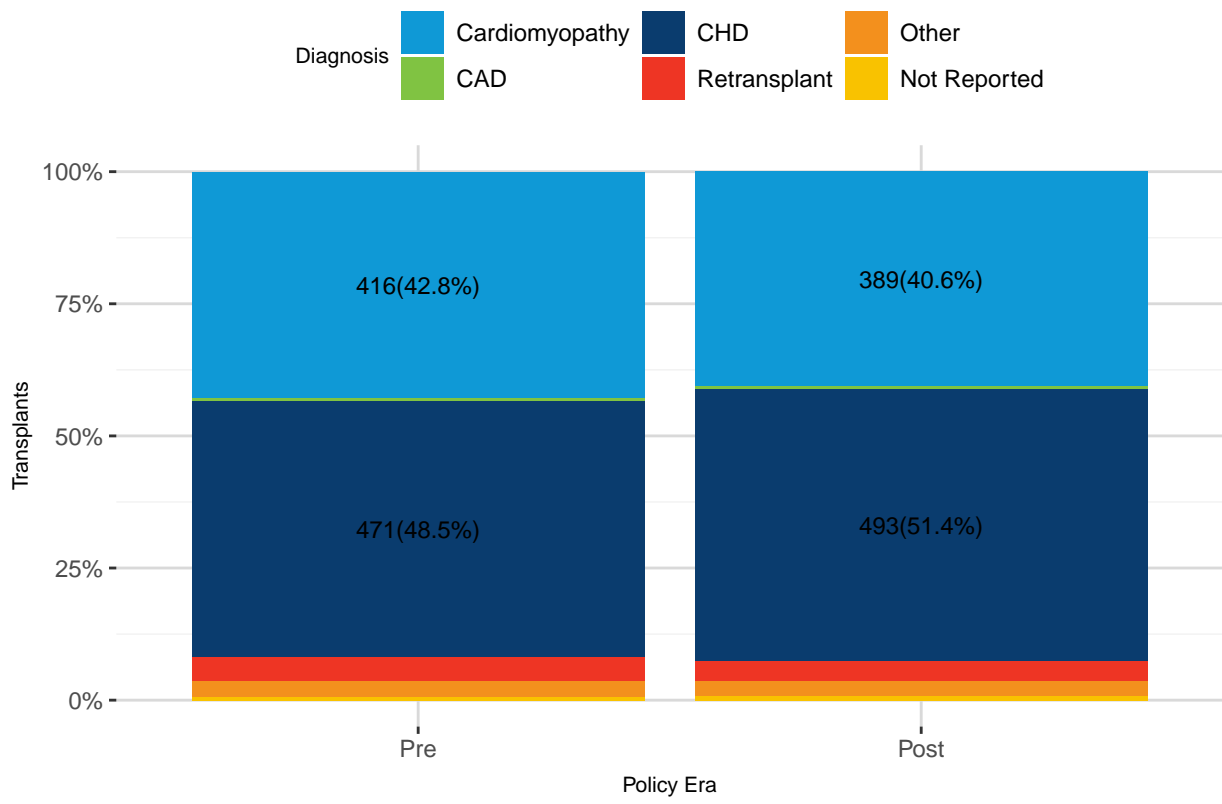
Note: Categories representing less than 5% of the total are not labeled on the plot.

Table 7. Transplants by medical urgency status and OPTN region

Region	Status	Pre	Post
1	Pediatric Status 1A	20(83.3%)	23(95.8%)
	Pediatric Status 1B	3(12.5%)	1(4.2%)
	Pediatric Status 2	1(4.2%)	0(0%)
2	Pediatric Status 1A	52(77.6%)	56(87.5%)
	Pediatric Status 1B	10(14.9%)	7(10.9%)
	Pediatric Status 2	5(7.5%)	1(1.6%)
3	Pediatric Status 1A	101(85.6%)	70(76.1%)
	Pediatric Status 1B	12(10.2%)	21(22.8%)
	Pediatric Status 2	5(4.2%)	1(1.1%)
4	Pediatric Status 1A	78(77.2%)	89(80.2%)
	Pediatric Status 1B	17(16.8%)	16(14.4%)
	Pediatric Status 2	6(5.9%)	6(5.4%)
5	Pediatric Status 1A	114(75%)	121(76.6%)
	Pediatric Status 1B	32(21.1%)	34(21.5%)
	Pediatric Status 2	6(3.9%)	3(1.9%)
6	Pediatric Status 1A	25(73.5%)	21(70%)
	Pediatric Status 1B	8(23.5%)	9(30%)
	Pediatric Status 2	1(2.9%)	0(0%)
7	Pediatric Status 1A	85(81.7%)	60(81.1%)
	Pediatric Status 1B	15(14.4%)	12(16.2%)
	Pediatric Status 2	4(3.8%)	2(2.7%)
8	Pediatric Status 1A	70(82.4%)	69(74.2%)
	Pediatric Status 1B	11(12.9%)	23(24.7%)
	Pediatric Status 2	4(4.7%)	1(1.1%)
9	Pediatric Status 1A	46(92%)	59(93.7%)
	Pediatric Status 1B	4(8%)	4(6.3%)
10	Pediatric Status 1A	73(75.3%)	77(81.1%)
	Pediatric Status 1B	19(19.6%)	16(16.8%)
	Pediatric Status 2	5(5.2%)	2(2.1%)
11	Pediatric Status 1A	111(79.9%)	137(88.4%)
	Pediatric Status 1B	27(19.4%)	15(9.7%)
	Pediatric Status 2	1(0.7%)	3(1.9%)

Figure 17 and Table 8 show pediatric heart transplants by diagnosis at transplant and era. The diagnosis groups are similarly distributed across era.

Figure 17. Transplants by diagnosis at transplant and era



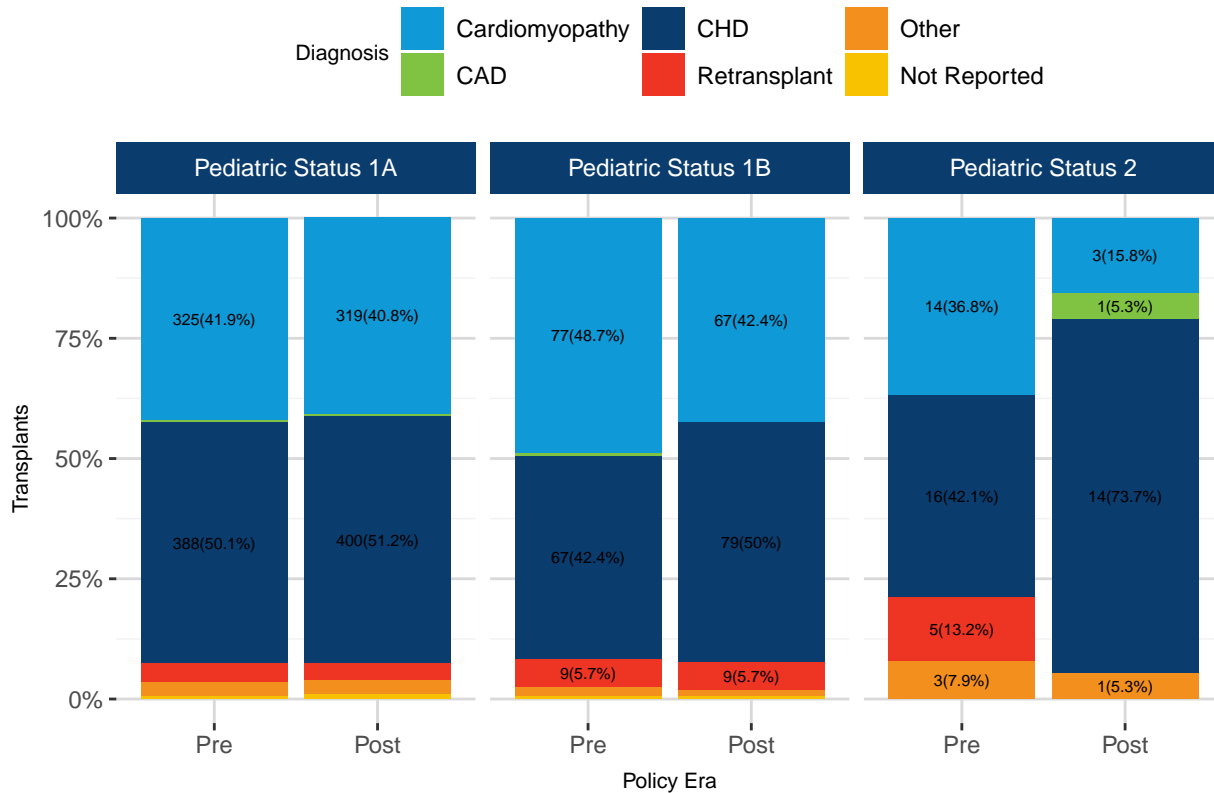
Note: Categories representing less than 5% of the total are not labeled on the plot.

Table 8. Transplants by diagnosis at transplant and era

Diagnosis	Pre	Post
Cardiomyopathy	416(42.8%)	389(40.6%)
CAD	5(0.5%)	6(0.6%)
CHD	471(48.5%)	493(51.4%)
Retransplant	45(4.6%)	36(3.8%)
Other	28(2.9%)	27(2.8%)
Not Reported	6(0.6%)	8(0.8%)

Figure 18 shows pediatric heart transplants by medical urgency status, diagnosis at transplant, and era. Pediatric status 1A transplants were similarly distributed across diagnoses and eras. A smaller percent of pediatric status 1B transplants reported primary diagnosis of cardiomyopathy at transplant from 48.7%(n=77) in the pre-policy era to 42.4%(n=67) in the post policy era. Moreover, there was a percent increase in pediatric status 1B transplants reporting a primary diagnosis of CHD from 42.4%(n=67) in the pre-policy era to 50%(n=79) in the post-policy era. Pediatric status 2 had a very small sample size.

Figure 18. Transplants by medical urgency status, diagnosis at transplant and era



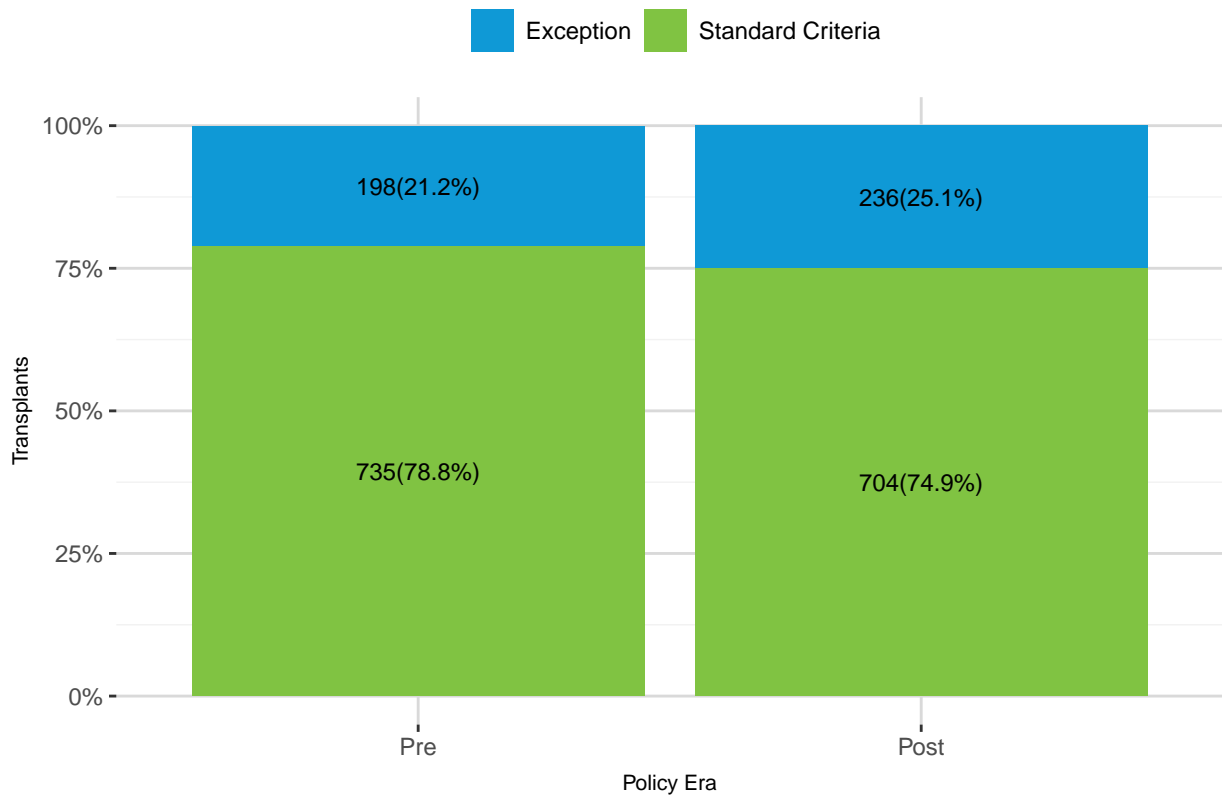
Note: Categories representing less than 5% of the total are not labeled on the plot.

Table 9. Transplants by medical urgency status, diagnosis at transplant and era

Status	Diagnosis	Pre	Post
Pediatric Status 1A	Cardiomyopathy	325(41.9%)	319(40.8%)
	CAD	4(0.5%)	5(0.6%)
	CHD	388(50.1%)	400(51.2%)
	Retransplant	31(4%)	27(3.5%)
	Other	22(2.8%)	24(3.1%)
	Not Reported	5(0.6%)	7(0.9%)
	Pediatric Status 1B	Cardiomyopathy	77(48.7%)
CAD		1(0.6%)	0(0%)
CHD		67(42.4%)	79(50%)
Retransplant		9(5.7%)	9(5.7%)
Other		3(1.9%)	2(1.3%)
Not Reported		1(0.6%)	1(0.6%)
Pediatric Status 2	Cardiomyopathy	14(36.8%)	3(15.8%)
	CAD	0(0%)	1(5.3%)
	CHD	16(42.1%)	14(73.7%)
	Retransplant	5(13.2%)	0(0%)
	Other	3(7.9%)	1(5.3%)
	Not Reported	0(0%)	0(0%)

Figure 19 shows pediatric heart transplants by exception vs. standard criteria at transplant and era. The number and percent of exceptions increased in the post-policy period compared to the pre-policy period.

Figure 19. Transplants by exception vs. standard criteria at transplant and era



Pediatric status 2 were removed from the figure (n= 57)

Figure 20 shows pediatric heart transplants by medical urgency status, exception vs. standard criteria, and era. Both pediatric status 1A and 1B exceptions increased from the pre-policy era to the post-policy era. Pediatric status 2 is not eligible for exception, so 100% of those transplants were standard criteria.

Figure 20. Transplants by medical urgency status, exception vs. standard criteria and era

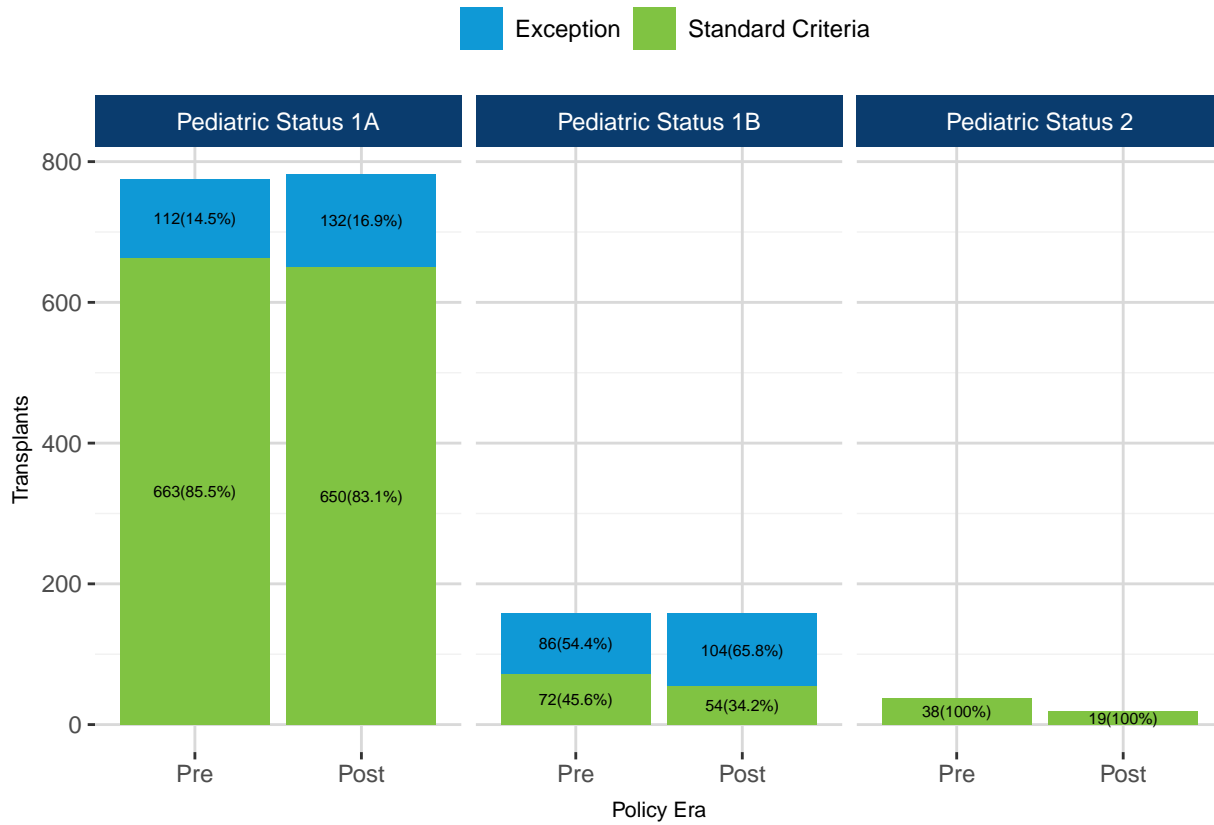
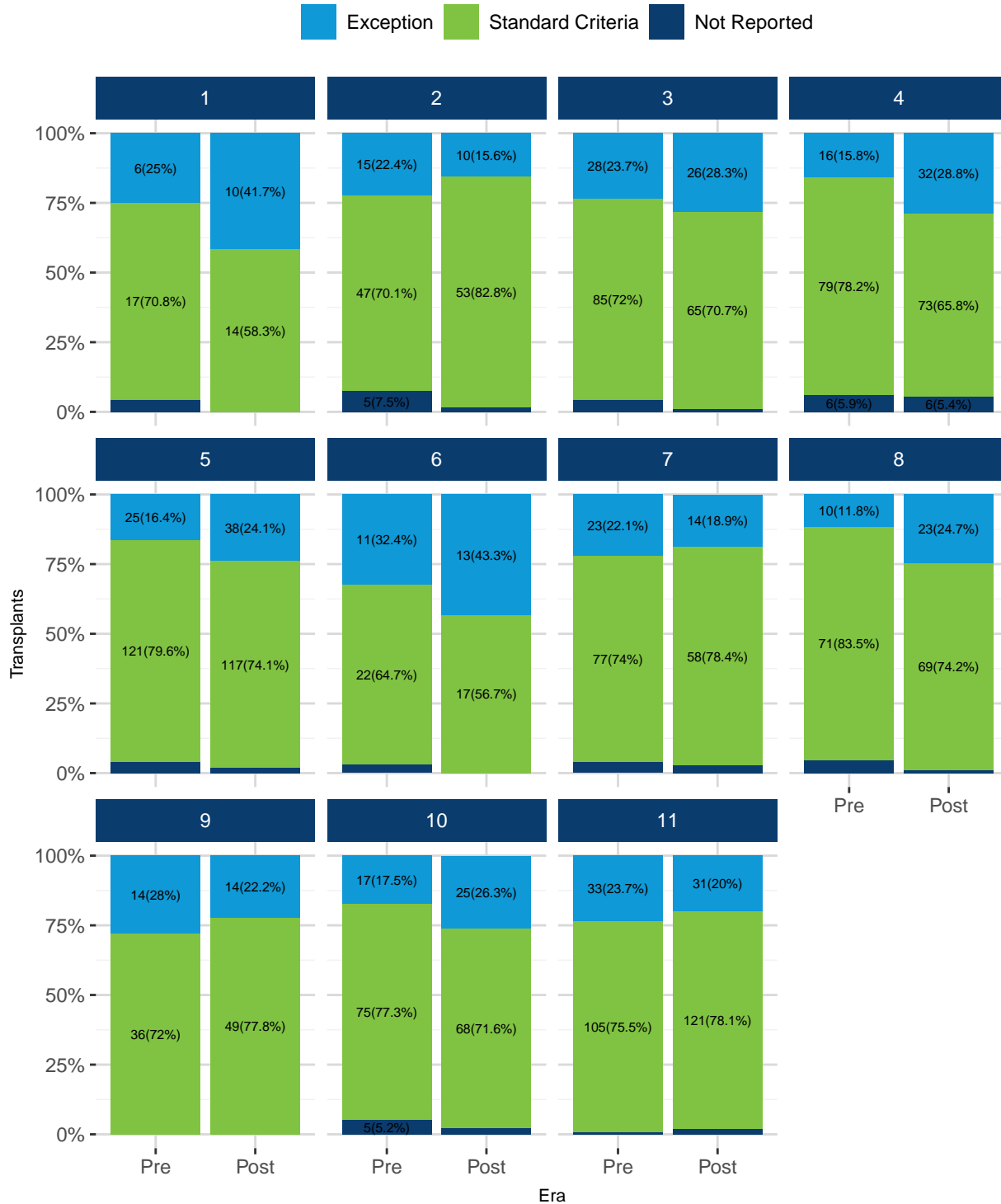


Figure 21 and table 10 show pediatric heart transplants by exception vs. standard criteria at transplant and OPTN region. The majority of regions saw an increase in transplants to patients with exceptions. The greatest increase in transplants to patients with exceptions was in Region 1 from 25% (n=6) in the pre-policy era to 41.7% (n=10) in the post-policy era.

Figure 21. Transplants by exception vs. standard criteria at Transplant and OPTN region



Note: Categories representing less than 5% of the total are not labeled on the plot.

Table 10. Transplants by exception vs. standard criteria at Transplant and OPTN region

OPTN Region	Exception vs. Standard Criteria	Pre	Post
1	Exception	6(25%)	10(41.7%)
	Standard Criteria	17(70.8%)	14(58.3%)
	Not Reported	1(4.2%)	0(0%)
2	Exception	15(22.4%)	10(15.6%)
	Standard Criteria	47(70.1%)	53(82.8%)
	Not Reported	5(7.5%)	1(1.6%)
3	Exception	28(23.7%)	26(28.3%)
	Standard Criteria	85(72%)	65(70.7%)
	Not Reported	5(4.2%)	1(1.1%)
4	Exception	16(15.8%)	32(28.8%)
	Standard Criteria	79(78.2%)	73(65.8%)
	Not Reported	6(5.9%)	6(5.4%)
5	Exception	25(16.4%)	38(24.1%)
	Standard Criteria	121(79.6%)	117(74.1%)
	Not Reported	6(3.9%)	3(1.9%)
6	Exception	11(32.4%)	13(43.3%)
	Standard Criteria	22(64.7%)	17(56.7%)
	Not Reported	1(2.9%)	0(0%)
7	Exception	23(22.1%)	14(18.9%)
	Standard Criteria	77(74%)	58(78.4%)
	Not Reported	4(3.8%)	2(2.7%)
8	Exception	10(11.8%)	23(24.7%)
	Standard Criteria	71(83.5%)	69(74.2%)
	Not Reported	4(4.7%)	1(1.1%)
9	Exception	14(28%)	14(22.2%)
	Standard Criteria	36(72%)	49(77.8%)
10	Exception	17(17.5%)	25(26.3%)
	Standard Criteria	75(77.3%)	68(71.6%)
	Not Reported	5(5.2%)	2(2.1%)
11	Exception	33(23.7%)	31(20%)
	Standard Criteria	105(75.5%)	121(78.1%)
	Not Reported	1(0.7%)	3(1.9%)

Exception Requests

In the pre-policy era, there were a total of 409 exceptions filed. Of those, 406 were approved/completed, 0 were withdrawn or not required, and 3 were denied.

In the post-policy era, pediatric status 1A had 88.6% (n = 194) of exceptions approved and 10.5% (n = 23) of exceptions denied. Pediatric status 1B had 97.7% (n = 258) of exceptions approved and 2.3% (n = 6) of exceptions denied.

Survival Analysis

The following figures examine changes in post-transplant patient survival rates overall and stratified by status. The cohort for these analyses are patients transplanted 1 year prior to implementation for the pre-policy era, June 14, 2020 to June 14, 2021, and 1 year after implementation for the post-policy era, June 15, 2021 to June 14, 2022. All survival analyses reflect 1 year survival.

Figure 22 and table 11 show post-transplant patient survival rates overall by era. Overall patient survival was higher post-policy at 93.4% when compared to pre-policy at 90.9%.

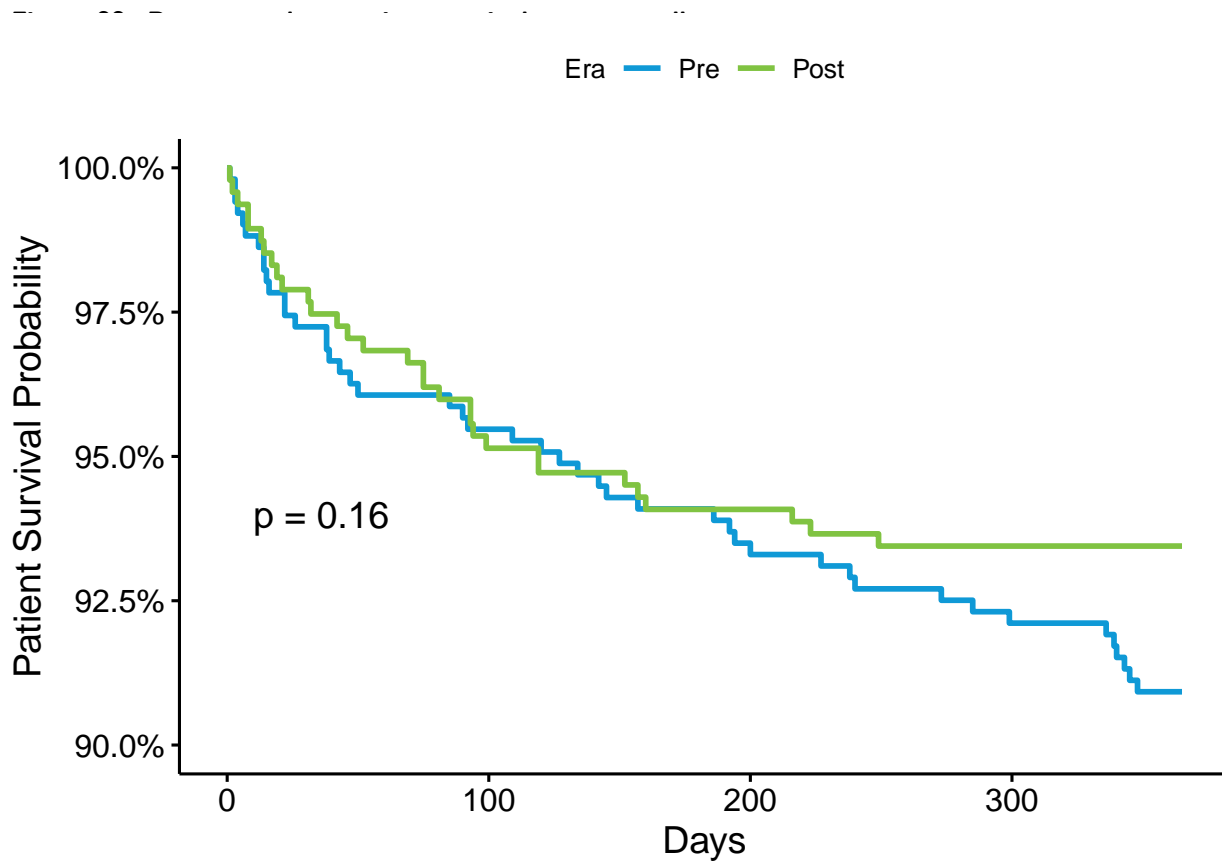


Table 11. Post-transplant patient survival rates overall

Era	N at Risk	N Events	Estimate	95% Confidence Interval	
				Lower CL	Upper CL
Pre	457	46	0.909	0.881	0.931
Post	348	31	0.934	0.908	0.953

Figure 23 and table 12 show post-transplant patient survival rates stratified by status and by era. Post-transplant survival for pediatric status 1A patients was higher post policy (93.5%) than pre-policy (90.9%). Post-transplant survival for pediatric status 1B patients was also higher post policy (95.1%) than pre-policy (90.7%).

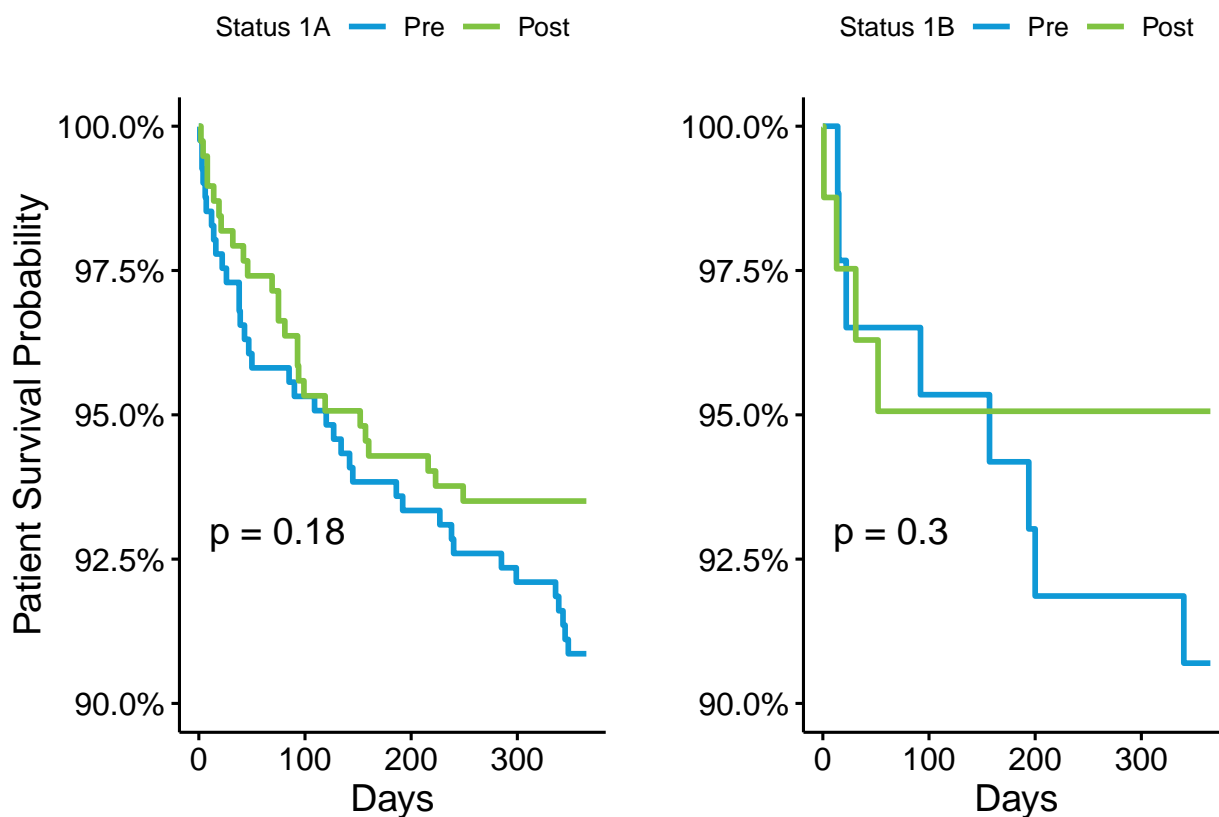


Table 12. Post-transplant patient survival rates stratified by status

Era	Status	N at Risk	N Events	Estimate	95% Confidence Interval	
					Lower CL	Upper CL
Pre	Pediatric Status 1A	364	37	0.909	0.876	0.933
	Pediatric Status 1B	78	8	0.907	0.823	0.952
Post	Pediatric Status 1A	284	25	0.935	0.905	0.956
	Pediatric Status 1B	62	4	0.951	0.874	0.981

Rates

Figure 24 and table 13 show the waitlist mortality rate for pediatric heart candidates stratified by pediatric heart status and whether the candidate ever had an exception in each era. Compared to the pre-policy era, the mortality rate for candidates with an exception in the post-policy era increased across statuses, and decreased for status 1A and status 2 candidates without an exception.

Figure 24. Waitlist mortality rate

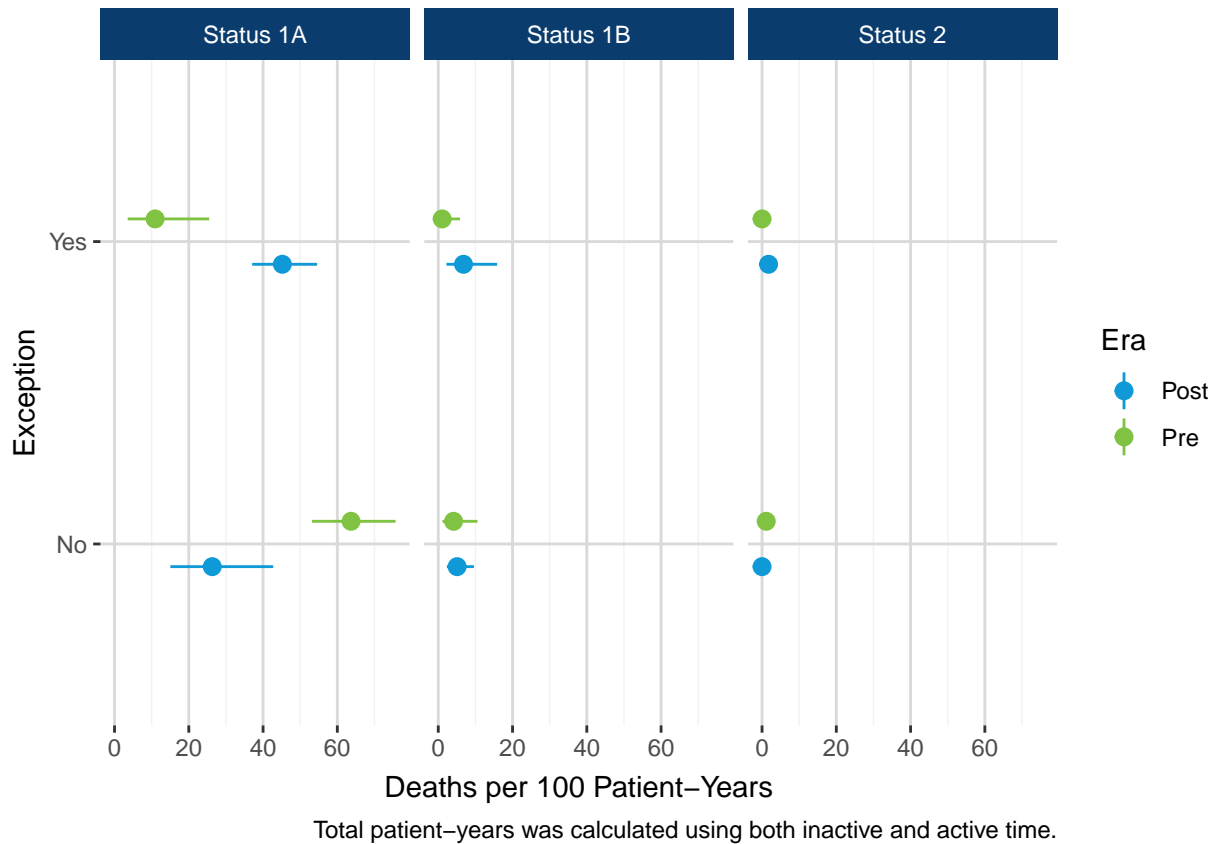


Table 13 Waitlist mortality rate

Era	Status	Exception	N Patients	N Events	Total Patient-Years	Deaths per 100 Patient-Years	95% Confidence Interval	
							Lower CL	Upper CL
Pre	Status 1A	Yes	223	5	45.756	10.927	3.548	25.501
	Status 1A	No	884	129	202.523	63.696	53.179	75.684
	Status 1B	Yes	263	1	95.501	1.047	0.027	5.834
	Status 1B	No	290	4	97.055	4.121	1.123	10.552
	Status 2	Yes	133	0	81.942	0.000	0.000	0.000
	Status 2	No	289	3	266.534	1.126	0.232	3.289
	Overall	-	1597	142	792.836	17.910	15.086	21.110
	Status 1A	No	273	16	60.797	26.317	15.042	42.737
Post	Status 1A	Yes	915	108	238.967	45.195	37.074	54.565
	Status 1B	No	365	9	177.800	5.062	2.315	9.609
	Status 1B	Yes	251	5	73.649	6.789	2.204	15.843
	Status 2	No	131	0	58.781	0.000	0.000	0.000
	Status 2	Yes	305	5	284.268	1.759	0.571	4.105
	Overall	-	1713	143	893.340	16.007	13.491	18.856

Note:

Total patient-years was calculated using both inactive and active time.

Figure 25 and table 14 shows the waitlist transplant rate for pediatric heart candidates stratified by pediatric heart status and whether the candidate ever had an exception in each era. Overall, the transplant rate for all candidates decreased from pre-policy to post-policy.

Figure 25. Waitlist transplant rate

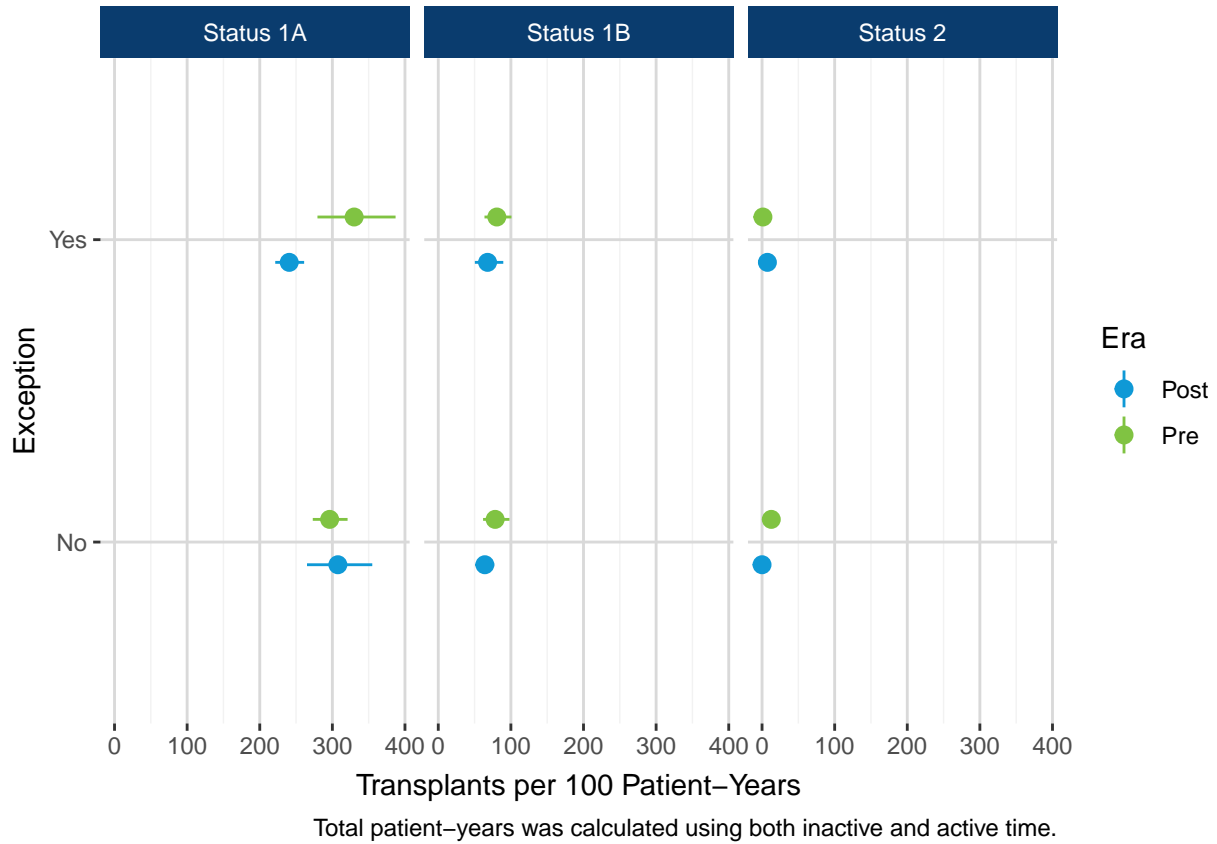


Table 14. Waitlist transplant rate

Era	Status	Exception	N Patients	N Events	Total Patient-Years	Transplants per 100 Patient-Years	95% Confidence Interval	
							Lower CL	Upper CL
Pre	Status 1A	Yes	223	151	45.756	330.010	279.473	387.045
	Status 1A	No	884	600	202.523	296.262	273.028	320.945
	Status 1B	Yes	263	77	95.501	80.627	63.630	100.770
	Status 1B	No	290	76	97.055	78.306	61.696	98.012
	Status 2	Yes	133	1	81.942	1.220	0.031	6.799
	Status 2	No	289	34	266.534	12.756	8.834	17.826
	Overall	-	1597	939	792.836	118.436	110.981	126.260
Post	Status 1A	No	273	187	60.797	307.580	265.073	354.963
	Status 1A	Yes	915	575	238.967	240.619	221.351	261.115
	Status 1B	No	365	114	177.800	64.117	52.889	77.024
	Status 1B	Yes	251	50	73.649	67.889	50.389	89.504
	Status 2	No	131	0	58.781	0.000	0.000	0.000
	Status 2	Yes	305	21	284.268	7.387	4.573	11.292
	Overall	-	1713	947	893.340	106.007	99.362	112.979

Note:

Total patient-years was calculated using both inactive and active time.

Summary

Waitlist additions and transplants by medical urgency status were similarly distributed across eras. Age and exceptions were also similarly distributed across eras in both waitlist additions and transplants. Overall, post-transplant patient survival increased. The overall mortality rate and transplant rate for pediatric heart candidates decreased from pre-policy to post-policy.