Final Report

OPTN OPTN Liver and Intestine Committee | Descriptive Data Request

MELD 3.0 and PELD-CR
Three Month Monitoring Report

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By:
Erin Schnellinger, PhD
Katrina Gauntt, MS
UNOS Research Department

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Executive Summary

This report provides a review of the first three months under the Improving Liver Allocation: MELD, PELD, Status 1A, Status 1B policy. After three months of implementation of this policy:

MELD 3.0:

- Deceased donor transplant was the most common reason for removal from the waiting list among liver candidates aged 12 years and older at removal. The proportion of females removed for deceased donor transplant increased pre- to post-policy.
- There were no statistically significant changes in waiting list removal rates due to death or too sick pre- to post-policy.
- Overall transplant rates significantly increased post-policy. When examined by sex, the transplant rate for females increased significantly pre- to post-policy, whereas the transplant rate for males remained roughly the same pre- to post-policy.
- The number and proportion of Status 1A/1B transplant recipients decreased slightly pre- to post-policy for both female and male transplant recipients. Within each sex, the median allocation MELD score at transplant remained the same pre- to post-policy, although it was higher for females compared to males.

PELD-Cr:

- Deceased donor transplant was the most common reason for removal from the waiting list among liver candidates aged 0-11 years at removal.
- There were no statistically significant changes in transplant rates and waiting list removal rates due to death or too sick pre- to post-policy.
- The number and proportion of Status 1A/1B transplant recipients decreased pre- to post-policy. The median PELD score at transplant remained the same across policy eras, but the interquartile range, which captures the middle 50% of PELD scores at transplant, decreased pre to post-policy.

Status 1A and 1B:

- Deceased donor transplant was the most common reason for removal from the waiting list among pediatric (age $<$18 years at removal) liver candidates with Status 1A or 1B, both overall and by diagnosis (chronic liver disease, hepatoblastoma, metabolic disease, other).
- The number of pediatric Status 1A and 1B liver transplants decreased pre- to post-policy, both overall and by diagnosis.
- Recipients with chronic liver disease made up the largest proportion of transplants, followed by metabolic disease, hepatoblastoma, and other diagnosis.
- The number of pediatric Status 1B cases that did not meet standard criteria decreased pre- to post-policy, and the number of those cases that were not approved decreased as well.

Background/Purpose

The Model for End Stage Liver Disease (MELD) score is used to prioritize liver transplant candidates who are 12 years of age or older, while the Pediatric End Stage Liver Disease (PELD) score prioritizes liver transplant candidates who are less than 12 years old. MELD and PELD are measures of medical urgency that are calculated based on clinical data. The original MELD and PELD scores were incorporated into OPTN policy in 2002. MELD was subsequently updated in 2016 to include serum sodium in the calculation (MELD-Na), whereas PELD was never updated.

Research suggests that MELD-Na disadvantages female candidates because MELD-Na uses creatinine to predict waiting list mortality. More specifically, creatinine tends to be underestimated among female candidates due to their lower muscle mass, which implies that MELD-Na might not capture their medical urgency accurately. Similarly, research also suggests that PELD tends to under-predict pediatric candidates' risk of waiting list mortality. There were also concerns about how PELD handles pediatric candidates who have growth failure as measured by the Centers for Disease Control and Prevention's (CDC) growth failure charts but who do not meet the growth failure criteria in PELD to warrant additional PELD points. Finally, some concerns arose regarding the criteria used to identify Status 1A and 1B candidates.

To address these concerns, on July 13, 2023, the OPTN implemented the "Improving Liver Allocation: MELD, PELD, Status 1A, Status 1B" policy. This policy:

- Updated the coefficients of the existing MELD score variables, added albumin, sex, and interaction terms to the MELD model, and lowered the maximum creatinine value from 4.0 to 3.0 mg/dL. The new model is hereafter referred to as MELD 3.0.
- Updated the coefficients of the existing PELD score variables, converted the age and growth failure variables from categorical to continuous, added creatinine to the model, adjusted the model so that the risk of waiting list mortality at a given PELD score aligns with the risk of waiting list mortality for an 18-year-old candidate with an equivalent MELD score, and floored the PELD score at 6. The new model is hereafter referred to as PELD-Cr.
- Updated the Status 1A criteria for pediatric candidates with fulminant liver failure by aligning the definiton for hepatic encephalopathy with the definition developed by the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition.
- Removed the MELD/PELD 25 threshold from Status 1B criteria for liver-intestine and liver-alone candidates with chronic liver disease; updated the gastro-intestinal bleeding threshold for liver-alone candidates to align with the definition for persistent mild shock or moderate shock; removed the Glasgow Coma Score (GCS) criteria from the Status 1B definition for liver-alone and liver-intestine candidates; and improved the sorting of Status 1B candidates by assigning diagnosis points so that candidates with diagnoses that have the highest risk of waiting list mortality receive better priority.

For more details on this policy change, please see the Improving Liver Allocation: MELD, PELD, Status 1A, Status 1B briefing paper .

The purpose of this report is to assess the impact of MELD 3.0, PELD-Cr, and the updated Status 1A/1B criteria on waiting list mortality and transplant rates. More specifically, this report aims to determine whether MELD 3.0 reduced the disparity in waiting list removal rates for death or too sick to transplant and liver transplant rates between males and females; and whether PELD-Cr and the Status 1A and 1B changes reduced pediatric waiting list mortality.

Monitoring Plan

Monitoring of the effect of the Improving Liver Allocation: MELD, PELD, Status 1A, Status 1B policy implemented on July 13, 2023 will be performed at approximately 3 months, 6 months, 1 year, and 2 years post-implementation. Overall results will be provided and some analyses will be stratified by candidate or recipient sex, age group (i.e., 0-2, 3-11, 12-17, 18+ years old), and other features (e.g., height, exception type) as appropriate.

Part 1: To monitor if MELD 3.0 reduced the disparity in waitlist removal rates for death or too sick to transplant and liver transplant rates between males and females, a pre- and post-policy implementation analysis of liver candidates and transplant recipients (age 12 years and older) will include:

- Changes in the number and percent of liver transplants, overall and by recipient sex
- Changes in the median allocation Model for End-Stage Liver Disease (MELD) score at transplant, overall and by recipient sex
- Changes in the number of liver candidates removed from the waitlist by reported removal reason, overall and by candidate sex
- Changes in waitlist removal rates for death or too sick to transplant, overall and by recipient sex (as sample size allows)
- Changes in transplant rates, overall and by recipient sex (as sample size allows)
- The above metrics will be stratified by age group (12-17 years vs. 18+ years), as appropriate
- The above metrics will be stratified by height and/or exception type (no exception, HCC exception, non-HCC exception), as appropriate.

Part 2: To monitor if PELD Cr reduced pediatric waitlist mortality, a pre- and post-policy implementation analysis of liver candidates and transplant recipients (age 0-11 years) will include:

- Changes in the number and percent of liver transplants, overall and by age group
- Changes in the median allocation Pediatric End-Stage Liver Disease (PELD) score at transplant, overall and by age group
- Changes in the number of liver candidates removed from the waitlist by reported removal reason, overall and by candidate age group
- Changes in waitlist removal rates for death or too sick to transplant, overall and by age group (as sample size allows)
- Changes in transplant rates, overall and by age group (as sample size allows)
- The above metrics will be stratified by exception type as appropriate.

Part 3: To monitor if the Status 1A and 1B policy changes reduced pediatric waitlist mortality, a pre- and post-policy implementation analysis will include:

- Changes in the number of pediatric Status 1A and 1B transplants, overall and by diagnosis
- Changes in the number of pediatric liver candidates with Status 1A and 1B removed from the waitlist by reported removal reason, overall and by diagnosis
- Changes in the number of pediatric Status 1B cases that did not meet standard criteria by case outcome and turndown reason

Key results can be found in the main report. Supporting figures and tables can be found in the Appendix.

Data and Methods

Data Sources:

These analyses use data from the OPTN Waiting List, Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), Transplant Recipient Followup (TRF), and Deceased Donor Registration (DDR) forms. The report also includes liver MELD and PELD exception request forms submitted during the time frames noted below. Analyses are based on OPTN data as of February 16, 2024 and are subject to change based on future data submission or correction.

Cohorts

This report includes cohorts of liver-alone registrations ever waiting during 04/12/2023 - 07/12/2023 (pre-policy) and 07/13/2023 - 10/12/2023 (post-policy) for waiting list removal due to death or too sick to transplant and transplant rates. Multi-organ listings are excluded.

The report also includes liver MELD and PELD exception request forms submitted during 04/12/2023 - 07/12/2023 (pre-policy) and 07/13/2023 - 10/12/2023 (post-policy).

Deceased donor, liver-alone transplant cohorts are defined based on transplant date as 04/12/2023 - 07/12/2023 (pre-policy) and 07/13/2023 - 10/12/2023 (post-policy).

Waiting list removal cohorts are defined based on removal date as 04/12/2023 - 07/12/2023 (pre-policy) and 07/13/2023 - 10/12/2023 (post-policy).

Analyses are based on OPTN data as of February 16, 2024 and are subject to change based on future data submission or correction.

Methods

Counts and percentages were used to summarize categorical variables or characteristics, while density curves and distribution summaries (minimum, maximum, mean, median, percentiles) were provided for continuous characteristics. If statistical tests of comparison were performed, Chi-Square tests were used for categorical comparisons pre- versus post-policy, and either t-tests or Kolmogorov-Smirnov tests were used for continuous variable comparisons pre- versus post-policy, as appropriate for differences in mean values or full distributions.

Removal rates as expressed by removals per 100 person-years were calculated by dividing the number of removals for death or too sick to transplant by the number of years patients spent waiting (expressed per 100 person-years). Dividing by the number of person-years serves to normalize the rates to account for differences in the number of candidates and duration of time waited within each era by different patient characteristics. For each time interval, all waiting time (active and inactive) within the interval analyzed was used for the person-years calculation. Since some candidates may spend several months or years on the waiting list, a candidate may contribute waiting time to both eras, but a removal is attributed only to the era and characteristic group in which it occurred. Some candidates may also be multi-listed at a number of transplant programs and thus have multiple registrations. Waiting time for each registration is contributed for each candidate, but only one removal per candidate is included in the calculation.

Transplant rates as expressed by transplants per 100 active person-years were calculated by dividing the number of deceased donor liver-alone transplants by the number of active years patients spent waiting (expressed per 100 person-years). For each time interval, only active waiting time within the interval analyzed was used for the person-years calculation since candidates may only receive offers and thus transplants when in an active status. Since some candidates may spend several months or years on the waiting list, a candidate may contribute waiting time to both eras, but a transplant is attributed only to the era and characteristic group in which it occurred.

Note that this policy introduced a new field, "Sex for the purposes of adult MELD calculation", to the TCR form for calculating MELD scores. This field is required for candidates who are at least 18 years of age at the time of registration, and should be filled out in consultation with the candidate and consistent with the following: a) select Female if the candidate's sex recorded at birth is female, or if the candidate's sex recorded at birth was male, and, for example, the candidate is currently taking feminizing gender affirming hormone therapy to align with their gender identity; b) select Male if the candidate's sex recorded at birth is male, or if the candidate's sex recorded at birth was female, and, for example, the candidate is currently taking masculinizing gender affirming hormone therapy to align with their gender identity. This field was optional for candidates who were registered on the waiting list prior to the implementation of this policy, and is optional for pediatric candidates. Some of the MELD 3.0 analyses are stratified by sex. For these analyses, the "Sex for the purposes of adult MELD calculation" field is used when available; when this field is missing, candidates' birth sex is used, consistent with how the OPTN Computer System computes MELD scores. If PELD-Cr analyses are stratified by sex, birth sex is used, consistent with the fact that birth sex is used to calculate PELD scores.

Note that when rates were stratified by exception type, the associated waiting time from a candidate registration was attributed to the person-years under "HCC exception" if there was ever an approved liver MELD or PELD exception request for an HCC diagnosis within that era. Similarly, associated waiting time for a candidate registration was attributed to the person-years under "non-HCC exception" if an approved liver MELD or PELD exception request for a diagnosis other than HCC occurred within that era. If a registration had multiple forms submitted within an era for both HCC and non-HCC exception types, the first submitted form was used. All other candidates' person-years waiting was attributed to the non-exception group. This exception type definition differs from that used in counts of transplants, where group membership is defined as the exception status at the time of event rather than ever during the policy period; thus, counts may not align with events from rates based on these definitions.

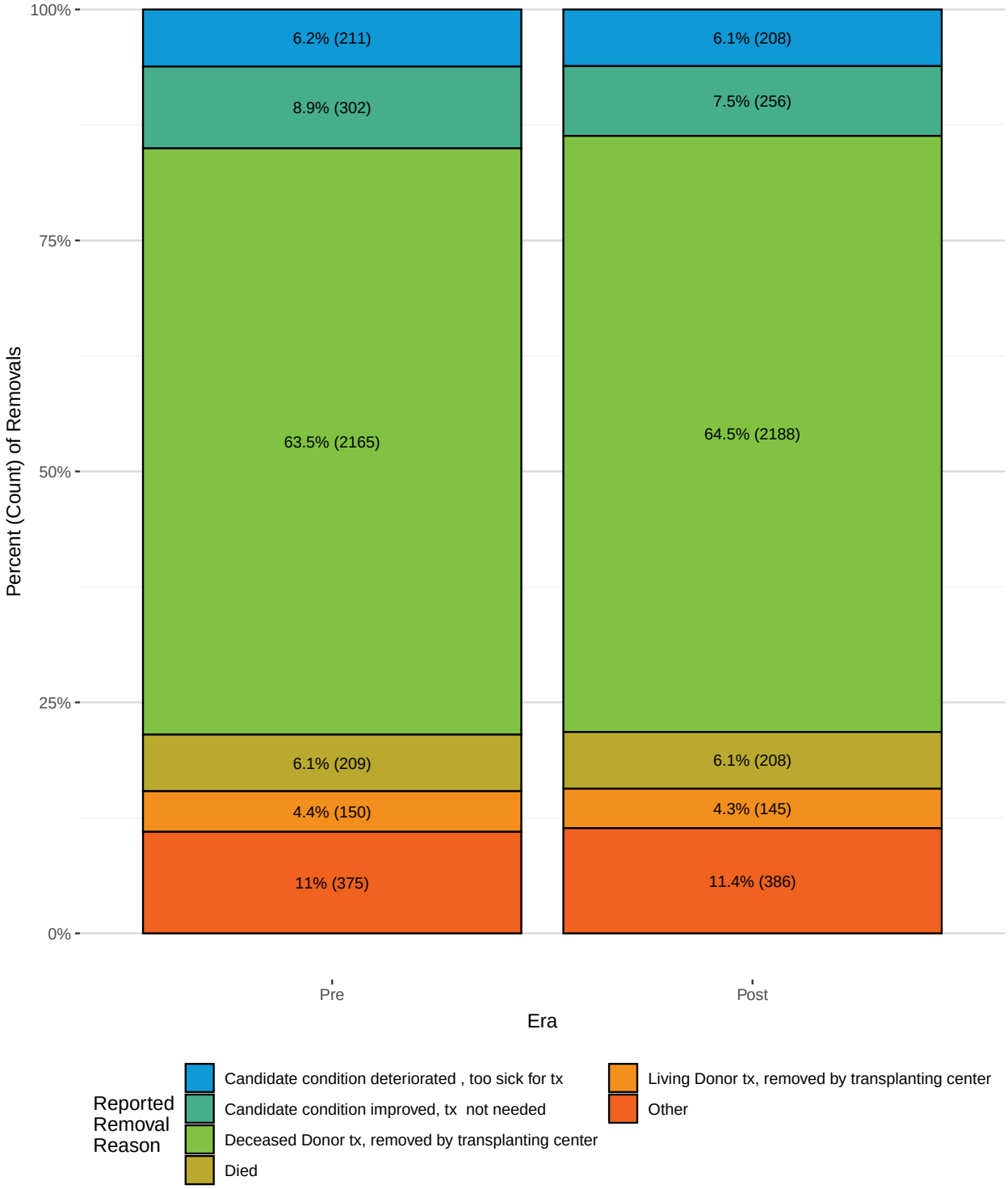
MELD 3.0 Results

This section of the report monitors whether MELD 3.0 reduced the disparity in waiting list removal rates for death or too sick to transplant and liver transplant rates between males and females. All analyses in this section include liver candidates and transplant recipients aged 12 years and older; liver candidates and transplant recipients less than 12 years old appear in the PELD-Cr section below.

Waiting List

Figure 1 and **Table 1** show the number of liver candidates aged 12 years and older who were removed from the waiting list by reported removal reason and policy era. 3412 candidates were removed in the pre-policy era and 3391 candidates were removed in the post-policy era. Deceased donor transplant made up the largest number and proportion of removal reasons (Pre: 302 (31.7%); Post: 256 (32.3%)), followed by "Candidate condition improved, transplant not needed" (Pre: 2 (4.4%); Post: 0 (3.8%)); "Candidate condition deteriorated, too sick for transplant" (Pre: 2165 (3.1%); Post: 2188 (3.1%)); and waiting list death (Pre: 209 (3.1%); Post: 209 (3.1%)).

Figure 1. Count and Percent of Liver Candidates Aged 12 Years and Older Removed from the Waiting List by Reported Removal Reason and Era



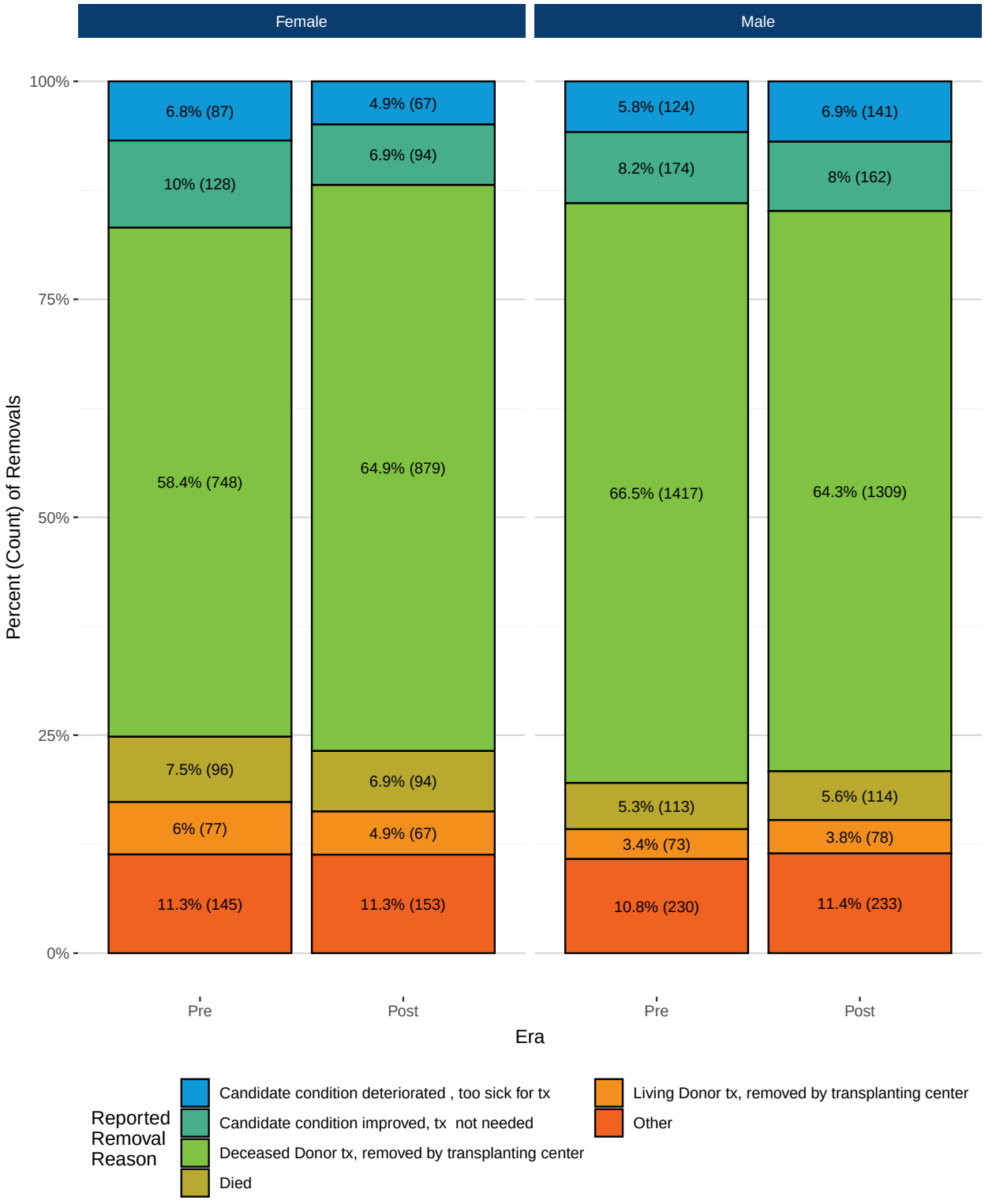
*Removal reasons containing <3% of forms were combined with the Other category for plotting purposes, but appear in the corresponding table.

Table 1. Count and Percent of Liver Candidates Aged 12 Years and Older Removed from the Waiting List by Reported Removal Reason and Era

Reported Removal Reason	Pre	Post
Deceased Donor tx, removed by transplanting center	2165 (63.5%)	2188 (64.5%)
Candidate condition improved, tx not needed	302 (8.9%)	256 (7.5%)
Candidate condition deteriorated , too sick for tx	211 (6.2%)	208 (6.1%)
Died	209 (6.1%)	208 (6.1%)
Other	204 (6.0%)	218 (6.4%)
Living Donor tx, removed by transplanting center	150 (4.4%)	145 (4.3%)
Transplant at another center (multi-listed)	66 (1.9%)	70 (2.1%)
Refused transplant	35 (1.0%)	41 (1.2%)
Unable to contact candidate	34 (1.0%)	37 (1.1%)
Transferred to another center	28 (0.8%)	14 (0.4%)
Patient died during TX procedure	4 (0.1%)	6 (0.2%)
Candidate Removed in Error	2 (0.1%)	0 (0.0%)
Transplanted in another country	2 (0.1%)	0 (0.0%)
Total	3412 (100.0%)	3391 (100.0%)

Figure 2 and **Table 2** show the number of liver candidates removed from the waiting list by reported removal reason, candidate sex for the purposes of adult MELD calculation, and policy era. For females, the top three reasons for removal were deceased donor transplant, removed by transplanting center; candidate condition improved, transplant not needed; and waiting list death. For males, the top three reasons for removal were deceased donor transplant, removed by transplanting center; candidate condition improved, transplant not needed; and candidate condition deteriorated, too sick for transplant. The proportion of females removed for deceased donor transplant increased pre- to post-policy (Pre: 748 (58.4%); Post: 879 (64.9%)), whereas the proportion of males removed for deceased donor transplant decreased slightly pre- to post-policy (Pre: 1417 (66.5%); Post: 1309 (64.3%)).

Figure 2. Count and Percent of Liver Candidates Aged 12 Years and Older Removed from the Waiting List by Reported Removal Reason, Candidate Sex for the Purposes of Adult MELD Calculation, and Era



*Removal reasons containing <3% of forms were combined with the Other category for plotting purposes, but appear in the corresponding table.

Table 2. Count and Percent of Liver Candidates Aged 12 Years and Older Removed from the Waiting List by Reported Removal Reason, Candidate Sex for the Purposes of Adult MELD Calculation, and Era

	Female		Male	
Reported Removal Reason	Pre	Post	Pre	Post
Deceased Donor tx, removed by transplanting center	748 (58.4%)	879 (64.9%)	1417 (66.5%)	1309 (64.3%)
Candidate condition improved, tx not needed	128 (10.0%)	94 (6.9%)	174 (8.2%)	162 (8.0%)
Died	96 (7.5%)	94 (6.9%)	113 (5.3%)	114 (5.6%)
Other	91 (7.1%)	89 (6.6%)	113 (5.3%)	129 (6.3%)
Candidate condition deteriorated , too sick for tx	87 (6.8%)	67 (4.9%)	124 (5.8%)	141 (6.9%)
Living Donor tx, removed by transplanting center	77 (6.0%)	67 (4.9%)	73 (3.4%)	78 (3.8%)
Transplant at another center (multi-listed)	22 (1.7%)	24 (1.8%)	44 (2.1%)	46 (2.3%)
Transferred to another center	13 (1.0%)	6 (0.4%)	15 (0.7%)	8 (0.4%)
Unable to contact candidate	11 (0.9%)	18 (1.3%)	23 (1.1%)	19 (0.9%)
Refused transplant	6 (0.5%)	14 (1.0%)	29 (1.4%)	27 (1.3%)
Patient died during TX procedure	2 (0.2%)	2 (0.1%)	2 (0.1%)	4 (0.2%)
Candidate Removed in Error	0 (0.0%)	0 (0.0%)	2 (0.1%)	0 (0.0%)
Transplanted in another country	0 (0.0%)	0 (0.0%)	2 (0.1%)	0 (0.0%)
Total	1281 (100.0%)	1354 (100.0%)	2131 (100.0%)	2037 (100.0%)

Figure 3 and **Table 4** show the rate of waiting list removal due to death or too sick to transplant per 100 person-years waiting for liver-alone candidates aged 12 years and older by era. The overall waiting list removal rate increased slightly from 18.24 (16.51, 20.10) removals per 100 person-years waiting pre-policy to 20.18 (18.24, 22.27) removals per 100 person-years waiting post-policy. This difference was not statistically significant.

Figure 3. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Person-Years Waiting among Candidates Aged 12 Years and Older by Era

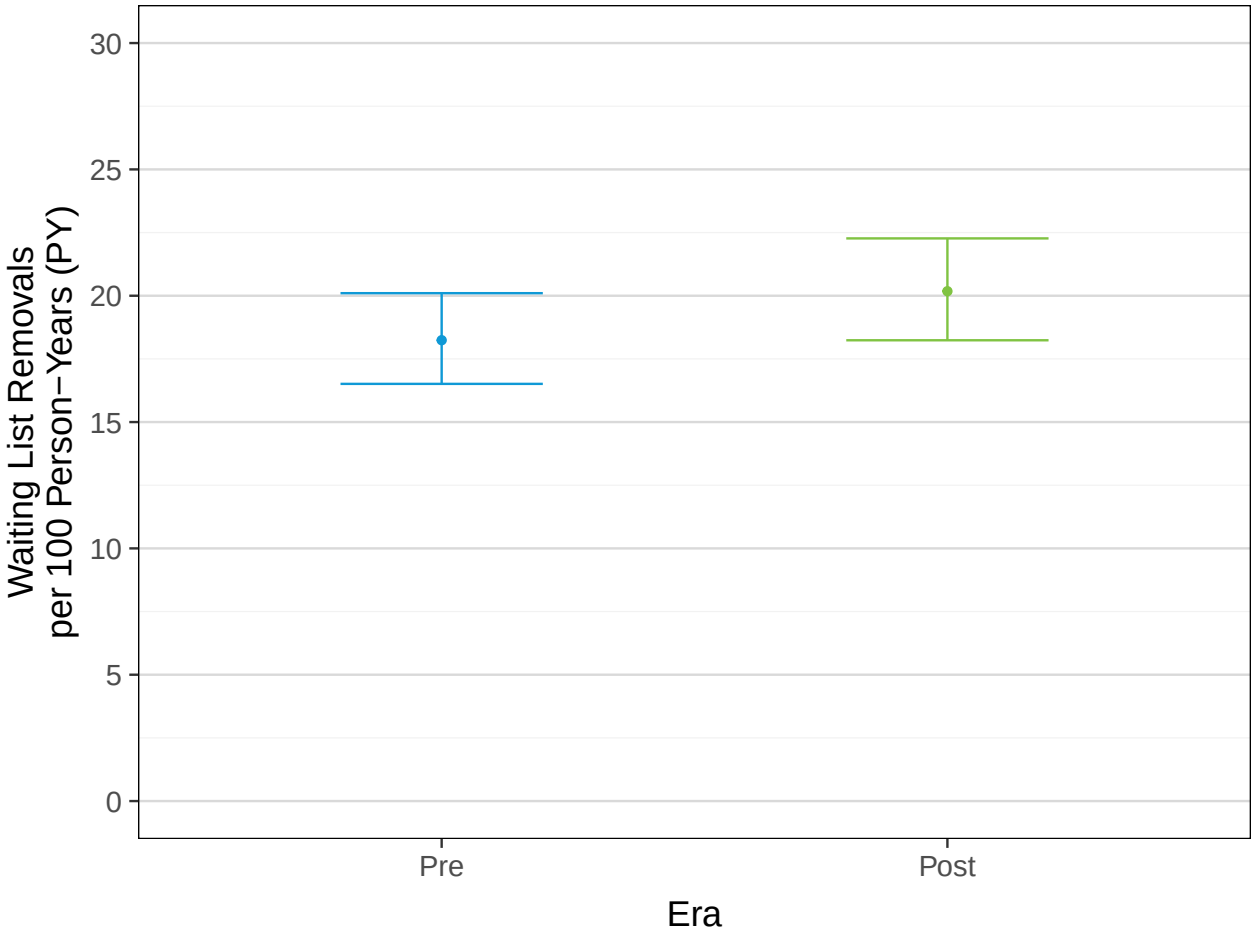


Table 4. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Person-Years Waiting among Candidates Aged 12 Years and Older by Era

	Ever Waiting	Death/Too Sick Events	Person-Years (PY)	Removals per 100 PY	
Era	N	N	PY	Estimate	95% CI
Pre	11973	407	2231.4	18.24	(16.51, 20.10)
Post	11864	395	1957.6	20.18	(18.24, 22.27)

Figure 4 and **Table 5** show the rate of waiting list removal due to death or too sick to transplant per 100 person-years waiting for liver-alone candidates aged 12 years and older by candidate sex for the purposes of adult MELD calculation and era. In both policy eras, waiting list removal rates were higher for females compared to males, although these differences were not statistically significant. Within each sex, waiting list removal rates tended to increase pre- to post-policy, although these increases were not statistically significant.

Figure 4. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Person-Years Waiting among Candidates Aged 12 Years and Older by Candidate Sex for the Purposes of Adult MELD Calculation and Era

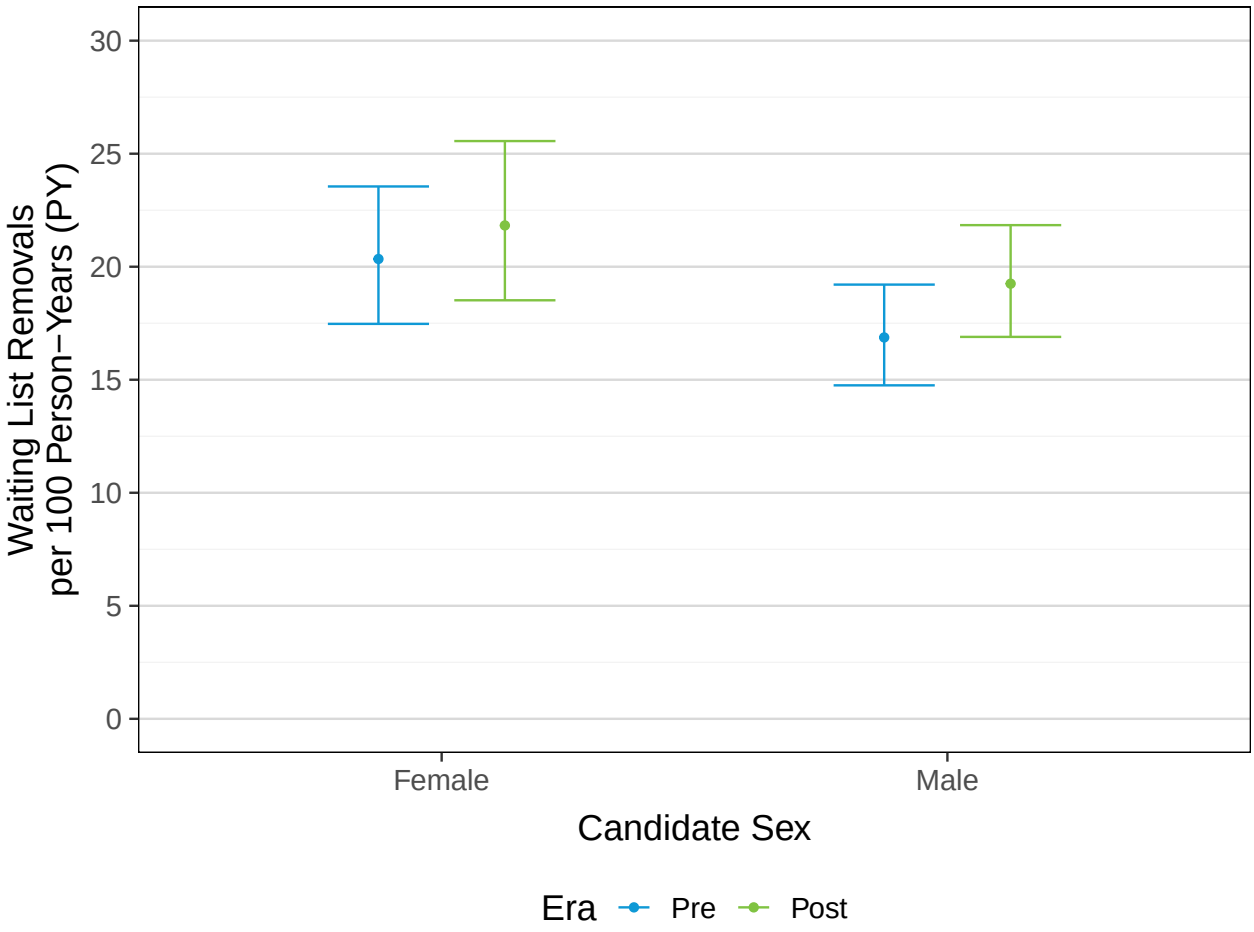


Table 5. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Person-Years Waiting among Candidates Aged 12 Years and Older by Candidate Sex for the Purposes of Adult MELD Calculation and Era

		Ever Waiting	Death/Too Sick Events	Person-Years (PY)	Removals per 100 PY	
Era	Candidate Sex	N	N	PY	Estimate	95% CI
Pre	Female	4677	179	880.0	20.34	(17.47, 23.55)
	Male	7296	228	1351.4	16.87	(14.75, 19.21)
Post	Female	4730	154	705.6	21.83	(18.51, 25.56)
	Male	7134	241	1252.0	19.25	(16.90, 21.84)

Figure 5 and **Table 7** show liver-alone transplant rates per 100 active person-years waiting among candidates aged 12 years and older by era. The overall transplant rate increased from 95.23 (91.23, 99.37) transplants per 100 active person-years waiting pre-policy to 110.49 (105.89, 115.25) transplants per 100 active person-years waiting post-policy. This increase was statistically significant.

Figure 5. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting among Candidates Aged 12 Years and Older by Era

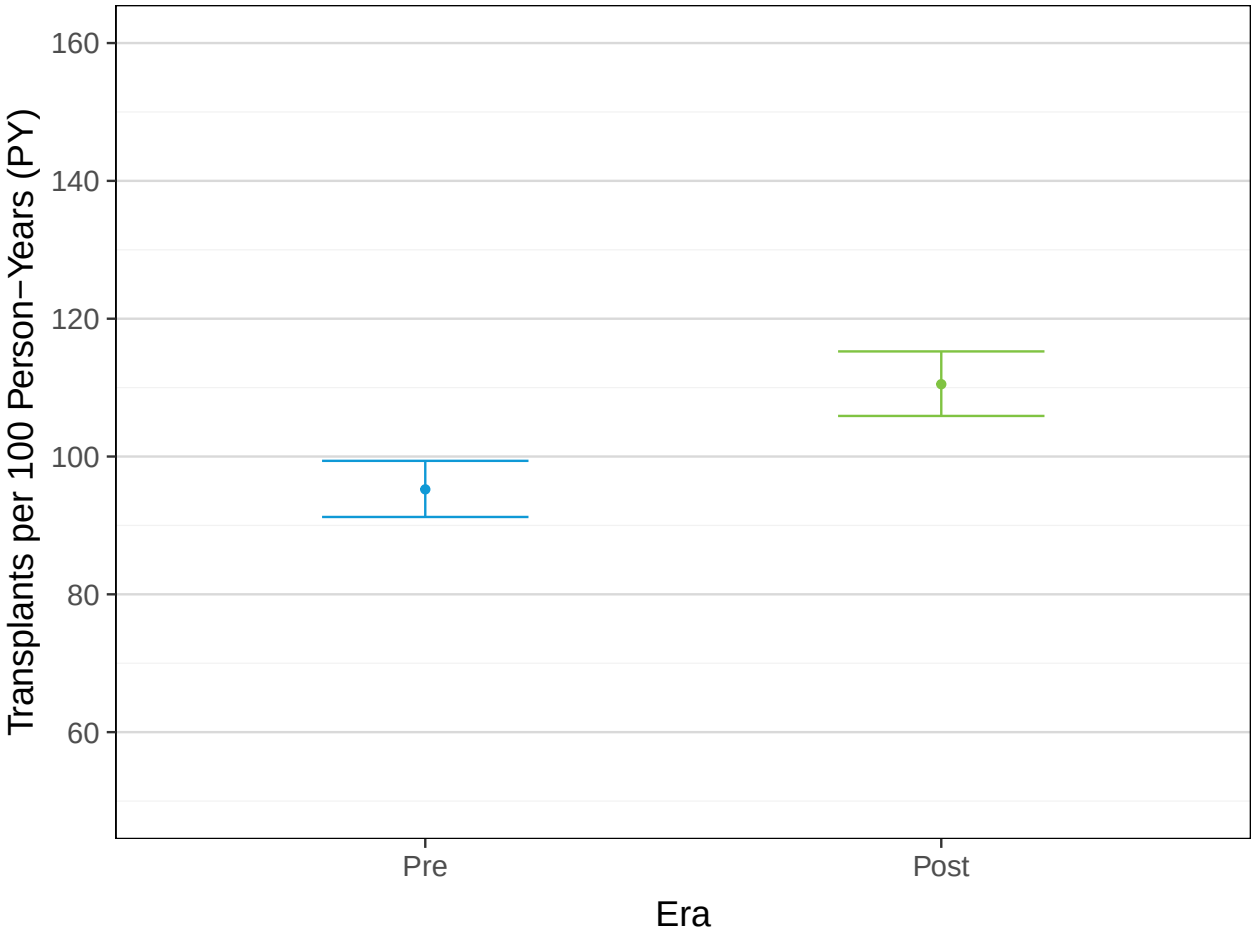


Table 7. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting among Candidates Aged 12 Years and Older by Era

	Ever Waiting	Transplant Events	Active Person-Years (PY)	Transplants per 100 Active PY	
Era	N	N	PY	Estimate	95% CI
Pre	11973	2125	2231.4	95.23	(91.23, 99.37)
Post	11864	2163	1957.6	110.49	(105.89, 115.25)

Figure 6 and **Table 8** show liver-alone transplant rates per 100 active person-years waiting among candidates aged 12 years and older by candidate sex for the purposes of adult MELD calculation and era. The transplant rate for males remained very similar pre- and post-policy, whereas the transplant rate for females significantly increased in the post-policy era. Note that within each sex, the number of candidates ever waiting remained fairly similar across policy eras.

Figure 6. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting among Candidates Aged 12 Years and Older by Candidate Sex for the Purposes of Adult MELD Calculation and Era

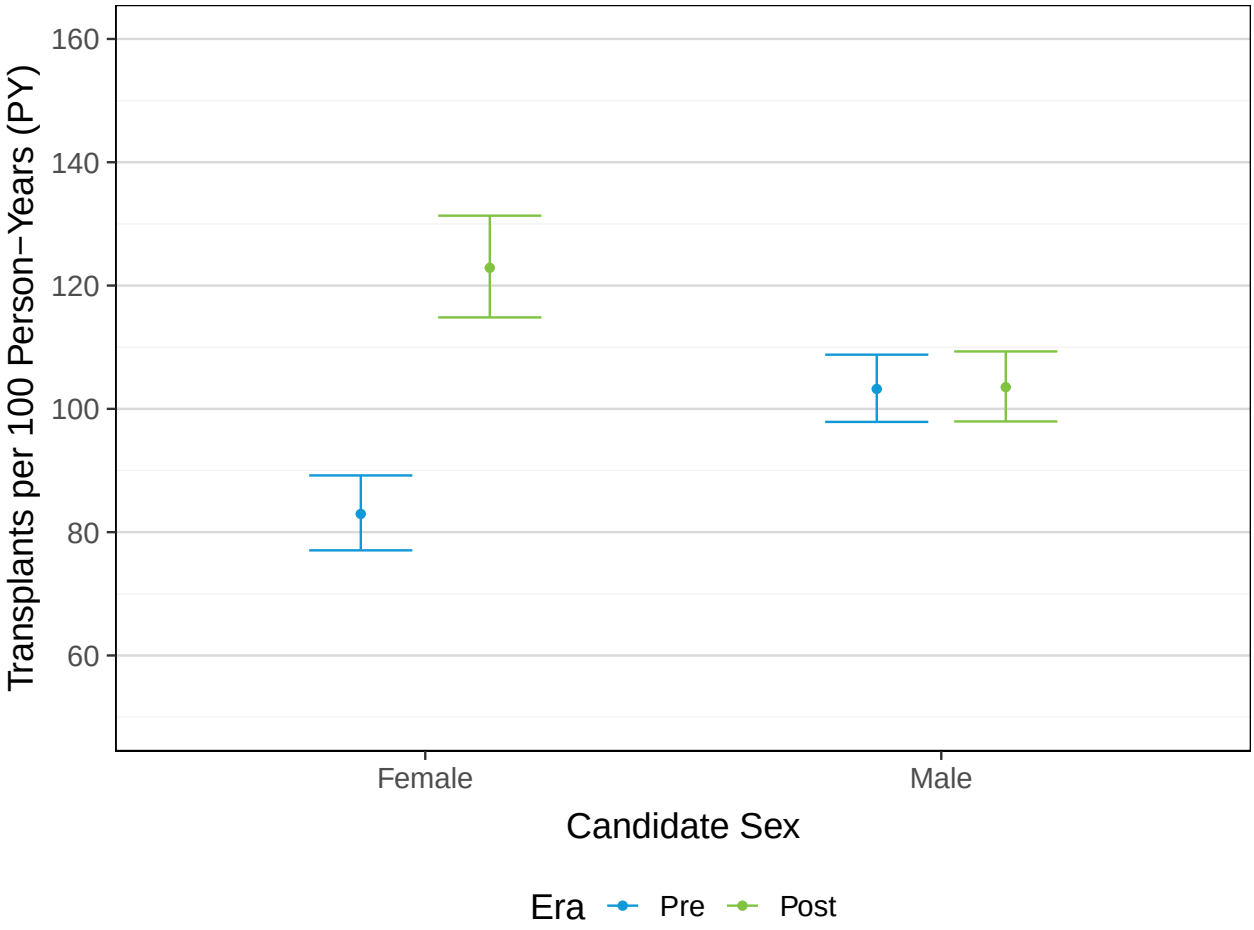


Table 8. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting among Candidates Aged 12 Years and Older by Candidate Sex for the Purposes of Adult MELD Calculation and Era

		Ever Waiting	Transplant Events	Active Person-Years (PY)	Transplants per 100 Active PY	
Era	Candidate Sex	N	N	PY	Estimate	95% CI
Pre	Female	4677	730	880.0	82.96	(77.05, 89.20)
	Male	7296	1395	1351.4	103.23	(97.88, 108.79)
Post	Female	4730	867	705.6	122.88	(114.83, 131.34)
	Male	7134	1296	1252.0	103.52	(97.96, 109.31)

Transplant

Figure 7 and **Table 10** show the number of liver transplants among recipients aged 12 years and older by policy era. There were 4411 total transplants among recipients aged 12 years and older in the study period. 2192 of these transplants occurred in the pre-policy era and 2219 occurred in the post-policy era.

Figure 7. Count of Liver Transplants among Recipients Aged 12 Years and Older by Era

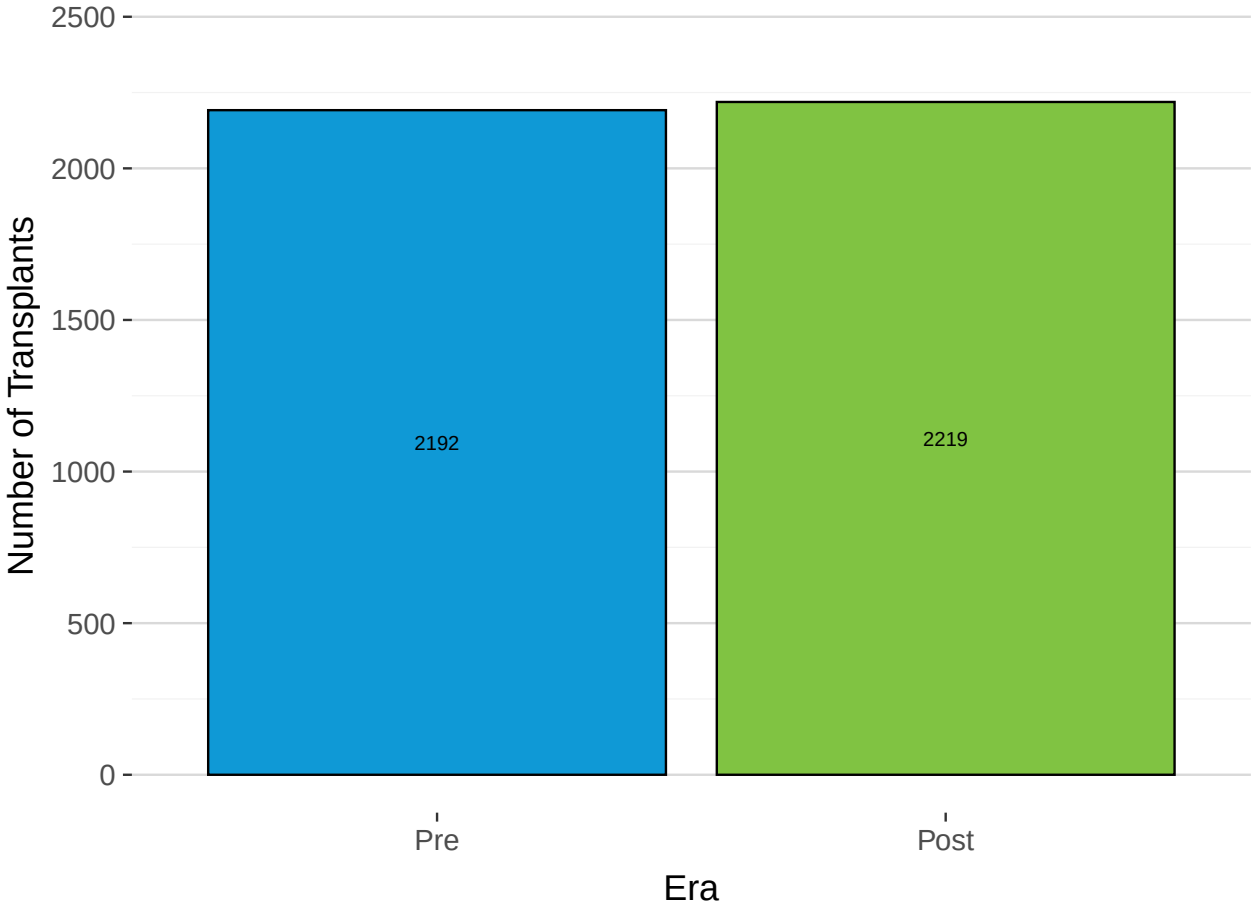


Table 10. Count and Percent of Liver Transplants among Recipients Aged 12 Years and Older by Era

Era	N (%)
Pre	2192 (49.7%)
Post	2219 (50.3%)
Total	4411 (100.0%)

Figure 8 and **Table 12** show the number of liver transplants among recipients aged 12 years and older by recipient sex for the purposes of adult MELD calculation and policy era. The number of female transplant recipients aged 12 years and older increased from 758 (34.6%) pre-policy to 895 (40.3%) post-policy.

Figure 8. Count and Percent of Liver Transplants among Recipients Aged 12 Years and Older by Recipient Sex for the Purposes of Adult MELD Calculation and Era

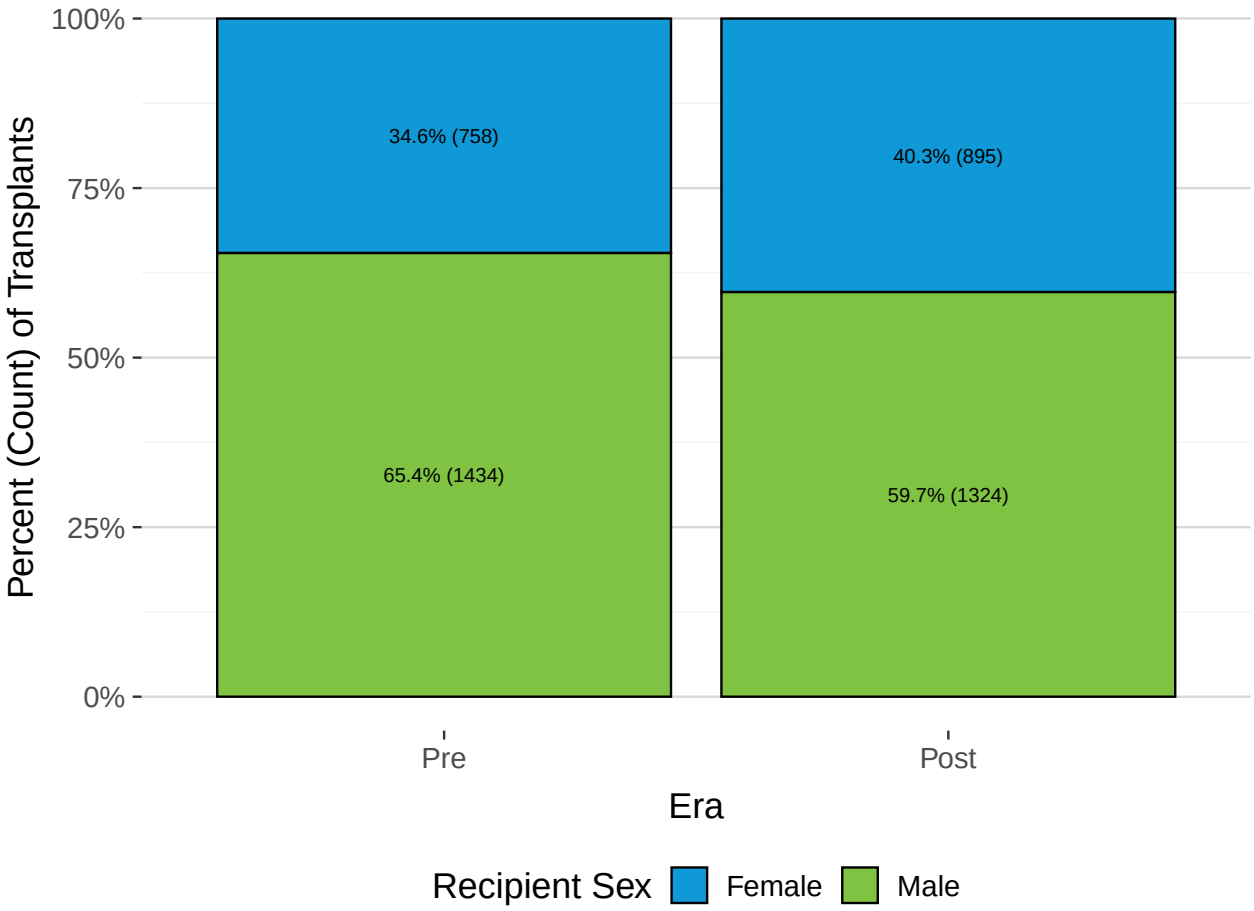


Table 12. Count and Percent of Liver Transplants among Recipients Aged 12 Years and Older by Recipient Sex for the Purposes of Adult MELD Calculation and Era

Recipient Sex	Pre	Post
Female	758 (34.6%)	895 (40.3%)
Male	1434 (65.4%)	1324 (59.7%)
Total	2192 (100.0%)	2219 (100.0%)

Figure 9, **Figure 10**, and **Table 14** show the distribution of allocation MELD score at transplant for liver-alone transplant recipients aged 12 years and older by era. The number and proportion of Status 1A/1B transplant recipients decreased slightly from pre- to post-policy. The distribution of allocation MELD scores at transplant remained similar across policy eras, although the median did increase slightly from 27 pre-policy to 28 post-policy.

Figure 9. Distribution of Allocation MELD Score or Status at Transplant for Liver-Alone Transplant Recipients Aged 12 Years and Older by Era

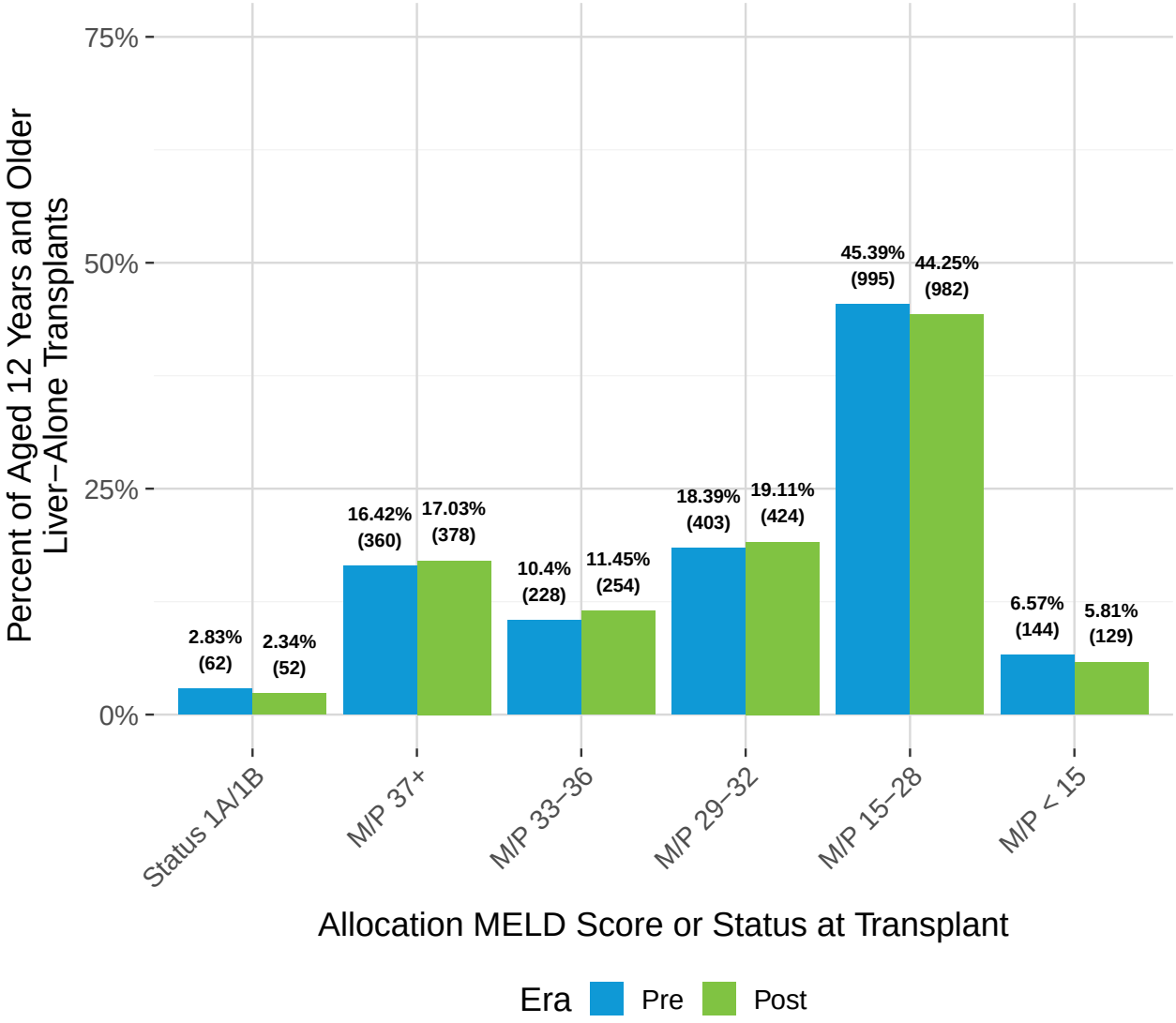
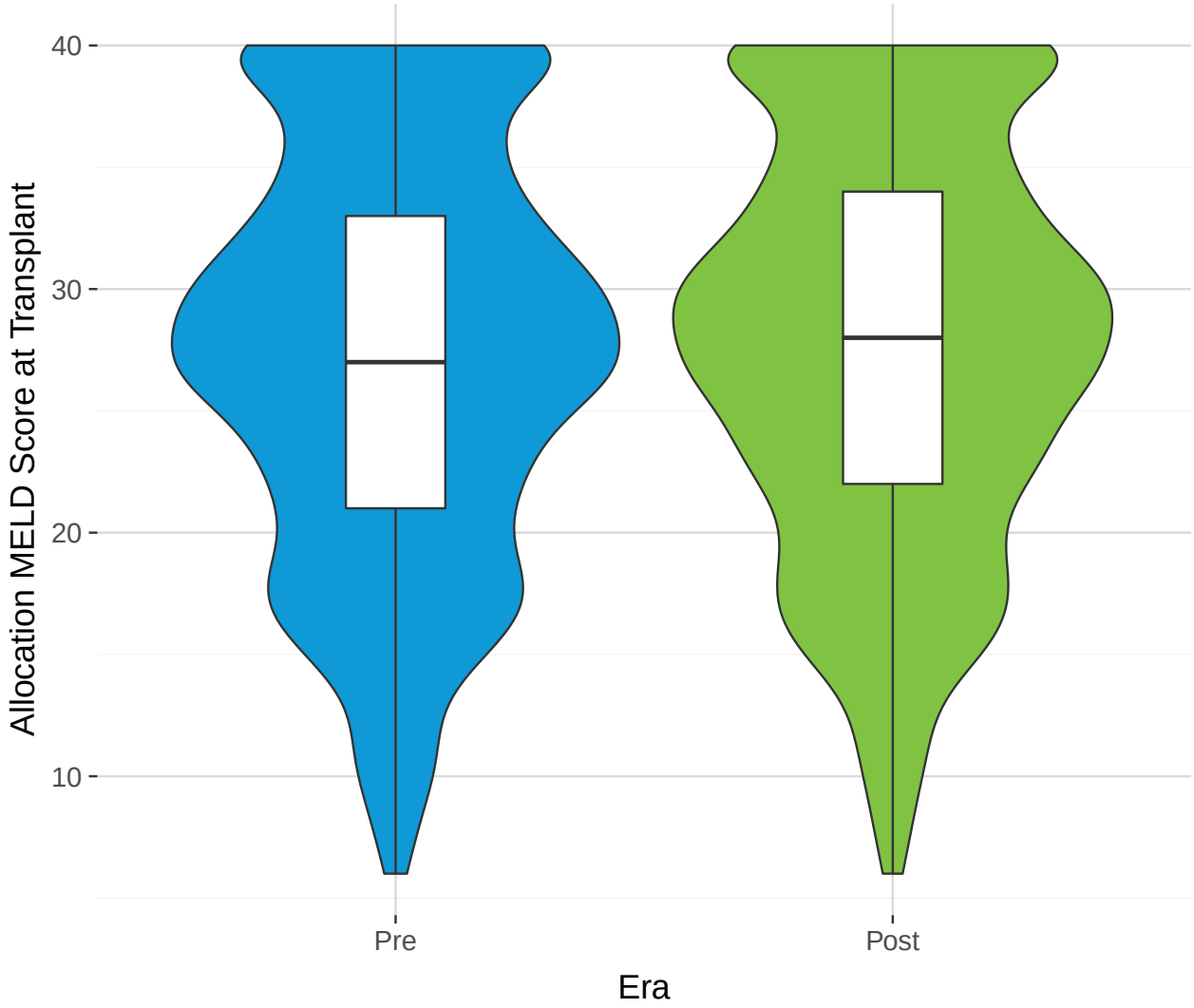


Figure 10. Distribution of Allocation MELD Score at Transplant for Liver-Alone Transplant Recipients Aged 12 Years and Older by Era



Status 1A/1B candidates do not have allocation MELD scores at transplant. As a result, 62 (2.83%) pre−policy recipients and 52 (2.34%) post−policy recipients were excluded.

Table 14. Summary of Allocation MELD Score at Transplant for Liver-Alone Transplant Recipients Aged 12 Years and Older by Era

Era	Transplants	Minimum	25th Percentile	Median	75th Percentile	Maximum	Interquartile Range
Pre	2130	6	21	27	33	40	12
Post	2167	6	22	28	34	40	12

Status 1A/1B candidates do not have allocation MELD scores at transplant. As a result, 62 (2.83%) pre-policy recipients and 52 (2.34%) post-policy recipients were excluded.

Figure 11, **Figure 12**, and **Table 16** show the distribution of allocation MELD score at transplant for liver-alone transplant recipients aged 12 years and older by recipient sex and era. The number and proportion of Status 1A/1B transplant recipients decreased slightly pre- to post-policy for both female and male transplant recipients. Within each sex, the median allocation MELD score at transplant remained the same pre- to post-policy, although it was higher for females (29) compared to males (27). The interquartile range, which captures the middle 50% of allocation MELD scores at transplant, decreased slightly for females pre- to post-policy (Pre: 22-35; Post: 23-35), and increased slightly for males pre- to post-policy (Pre: 21-32.2; Post: 21-33).

Figure 11. Distribution of Allocation MELD Score or Status at Transplant for Liver-Alone Transplant Recipients Aged 12 Years and Older by Recipient Sex and Era

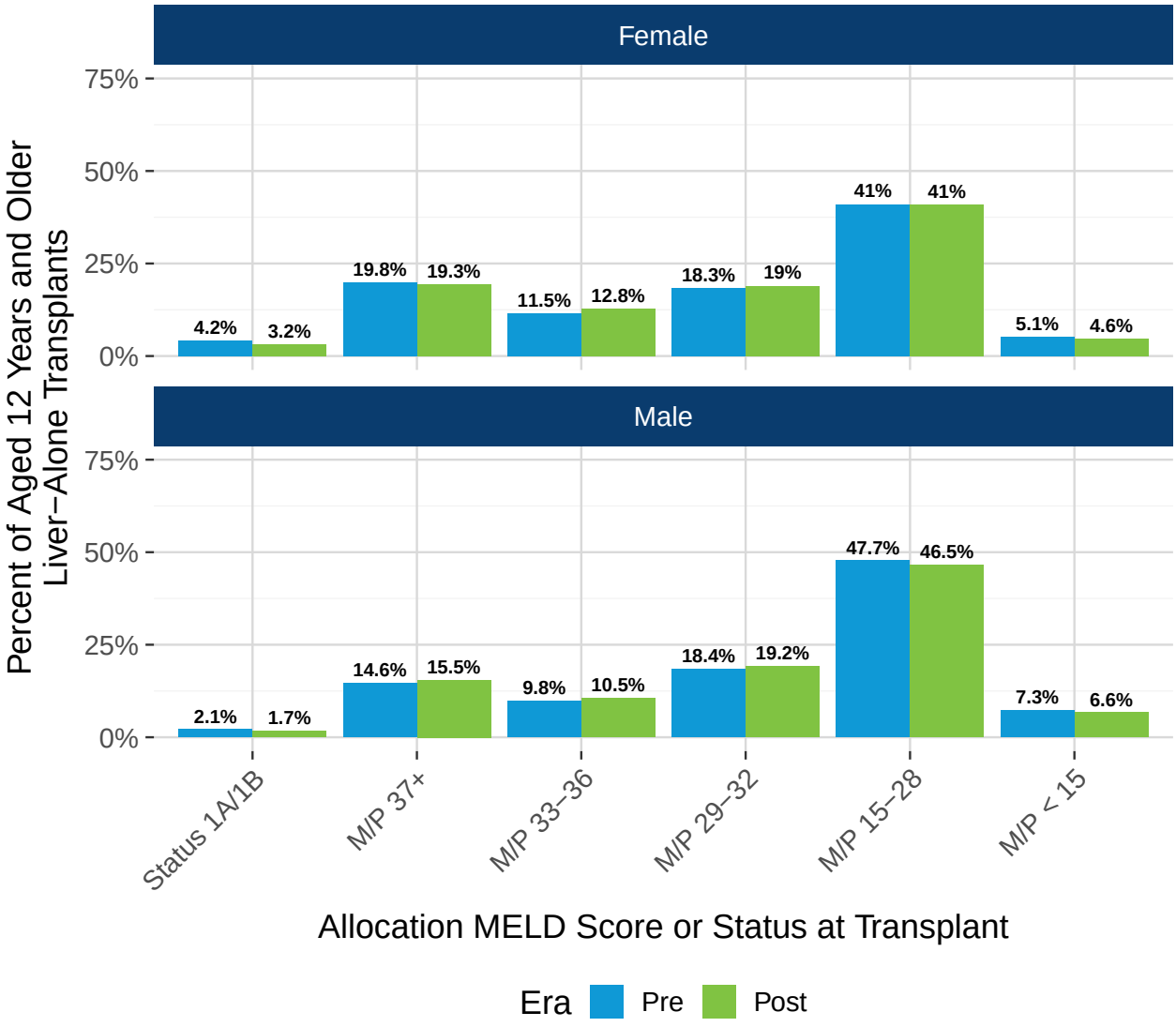
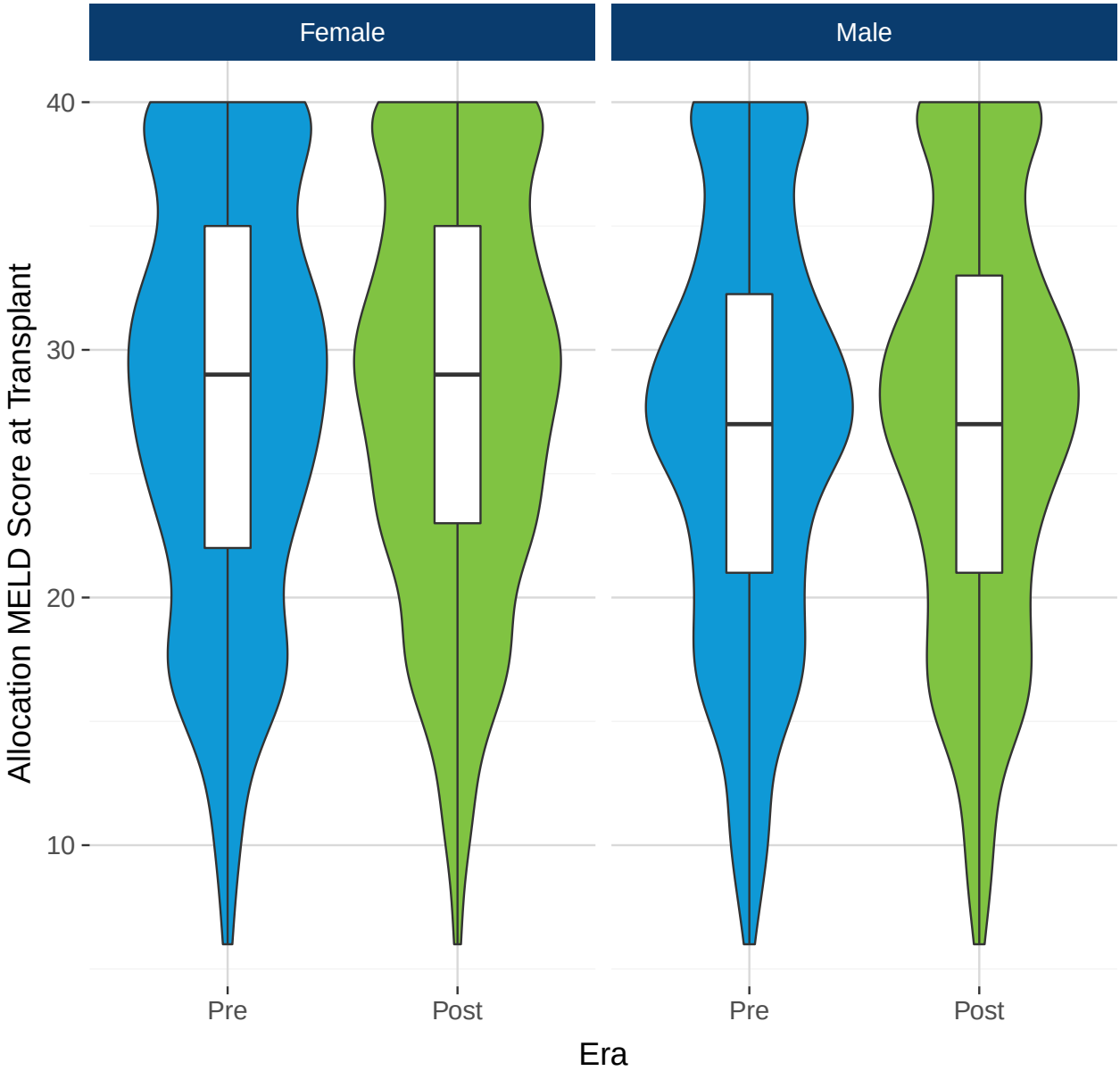


Figure 12. Distribution of Allocation MELD Score at Transplant for Liver-Alone Transplant Recipients Aged 12 Years and Older by Recipient Sex and Era



Status 1A/1B candidates do not have allocation MELD scores at transplant. As a result, 32 (4.22%) female pre−policy recipients, 29 (3.24%) female post−policy recipients, 30 (2.09%) male pre−policy recipients, and 23 (1.74%) male post−policy recipients were excluded.

Table 16. Summary of Allocation MELD Score at Transplant for Liver-Alone Transplant Recipients Aged 12 Years and Older by Recipient Sex and Era

Recipient Sex	Policy Era	Transplants	Minimum	25th Percentile	Median	75th Percentile	Maximum	Interquartile Range
Female	Pre	726	6	22	29	35.0	40	13.0
	Post	866	6	23	29	35.0	40	12.0
Male	Pre	1404	6	21	27	32.2	40	11.2
	Post	1301	6	21	27	33.0	40	12.0

Status 1A/1B candidates do not have allocation MELD scores at transplant. As a result,
32 (4.22%) female pre-policy recipients, 29 (3.24%) female post-policy recipients,
30 (2.09%) male pre-policy recipients, and 23 (1.74%) male post-policy recipients were excluded.

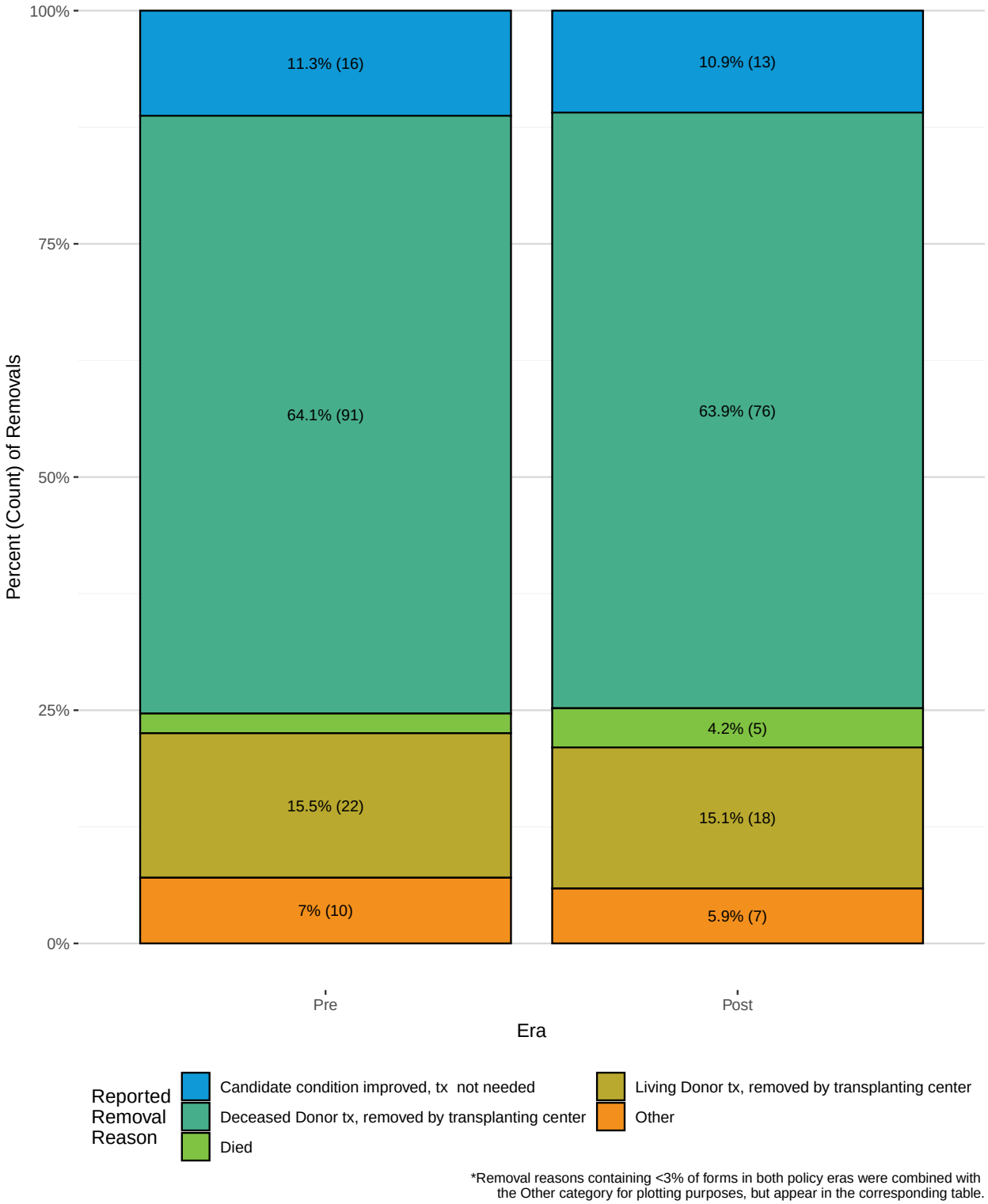
PELD-Cr Results

This section of the report monitors whether PELD-Cr reduced pediatric waiting list mortality. The analyses in this section include liver candidates and transplant recipients between 0-11 years old; note that throughout this section, age is taken at transplant or removal from the waiting list, as appropriate. Liver candidates and transplant recipients 12 years and older appear in the MELD 3.0 section above.

Waiting List

Figure 13 and **Table 17** show the number of liver candidates aged 0-11 years who were removed from the waiting list by reported removal reason and policy era. 142 candidates were removed in the pre-policy era and 119 candidates were removed in the post-policy era. Deceased donor transplant made up the largest number and proportion of removal reasons (Pre: 91 (64.1%); Post: 76 (63.9%)), followed by living donor transplant (Pre: 22 (15.5%); Post: 18 (15.1%)) and "Candidate condition improved, transplant not needed" (Pre: 16 (11.3%); Post: 13 (10.9%)).

Figure 13. Count and Percent of Liver Candidates Aged 0-11 Years Removed from the Waiting List by Reported Removal Reason and Era



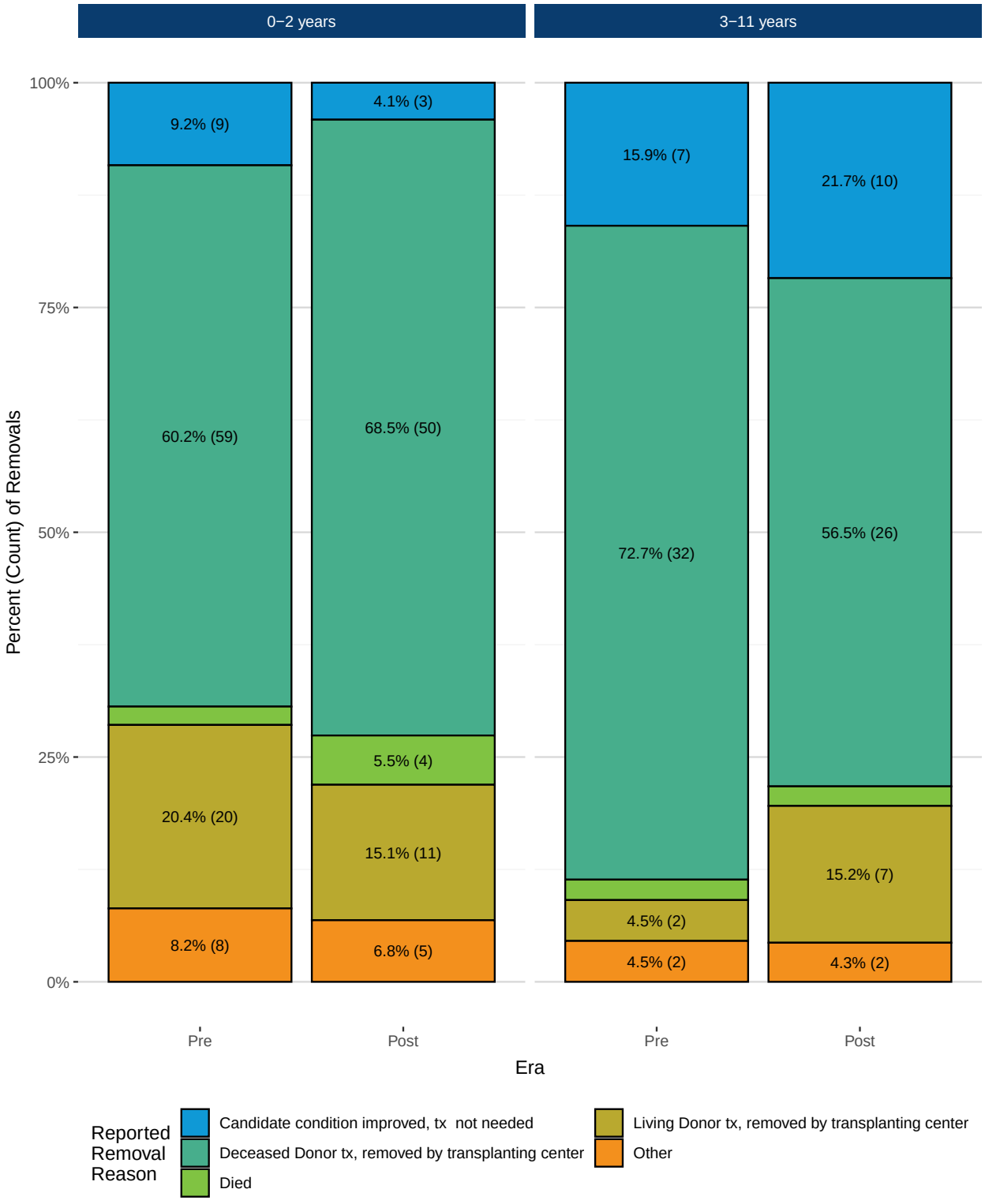
*Removal reasons containing <3% of forms in both policy eras were combined with the Other category for plotting purposes, but appear in the corresponding table.

Table 17. Count and Percent of Liver Candidates Aged 0-11 Years Removed from the Waiting List by Reported Removal Reason and Era

Reported Removal Reason	Pre	Post
Deceased Donor tx, removed by transplanting center	91 (64.1%)	76 (63.9%)
Living Donor tx, removed by transplanting center	22 (15.5%)	18 (15.1%)
Candidate condition improved, tx not needed	16 (11.3%)	13 (10.9%)
Transplant at another center (multi-listed)	5 (3.5%)	3 (2.5%)
Candidate condition deteriorated , too sick for tx	3 (2.1%)	1 (0.8%)
Died	3 (2.1%)	5 (4.2%)
Transferred to another center	2 (1.4%)	0 (0.0%)
Other	0 (0.0%)	3 (2.5%)
Total	142 (100.0%)	119 (100.0%)

Figure 14 and **Table 18** show the number of liver candidates aged 0-11 years at removal who were removed from the waiting list by reported removal reason, candidate age group at time of removal (0-2 years vs. 3-11 years) and policy era. Care should be taken when interpreting changes in the other removal categories, as sample sizes are small. Regardless of age group, the top three reasons for removal were deceased donor transplant, removed by transplanting center; living donor transplant, removed by transplanting center; and candidate condition improved, transplant not needed. Although the number of candidates aged 0-2 years old at time of removal who were removed for deceased donor transplant decreased pre- to post-policy, the proportion of candidates aged 0-2 years old at time of removal who were removed for deceased donor transplant increased pre- to post-policy (Pre: 59 (60.2%); Post: 50 (68.5%)). Both the number and proportion of candidates aged 3-11 years old at time of removal who were removed for deceased donor transplant decreased pre- to post-policy (Pre: 32 (72.7%); Post: 26 (56.5%)).

Figure 14. Count and Percent of Liver Candidates Aged 0-11 Years Removed from the Waiting List by Reported Removal Reason, Candidate Age Group at Time of Removal, and Era



*Removal reasons containing <4% of forms in both policy eras were combined with the Other category for plotting purposes, but appear in the corresponding table.

Table 18. Count and Percent of Liver Candidates Aged 0-11 Years Removed from the Waiting List by Reported Removal Reason, Candidate Age Group at Time of Removal, and Era

	0-2 Years		3-11 Years	
Reported Removal Reason	Pre	Post	Pre	Post
Deceased Donor tx, removed by transplanting center	59 (60.2%)	50 (68.5%)	32 (72.7%)	26 (56.5%)
Living Donor tx, removed by transplanting center	20 (20.4%)	11 (15.1%)	2 (4.5%)	7 (15.2%)
Candidate condition improved, tx not needed	9 (9.2%)	3 (4.1%)	7 (15.9%)	10 (21.7%)
Transplant at another center (multi-listed)	4 (4.1%)	2 (2.7%)	1 (2.3%)	1 (2.2%)
Candidate condition deteriorated , too sick for tx	2 (2.0%)	1 (1.4%)	1 (2.3%)	0 (0.0%)
Died	2 (2.0%)	4 (5.5%)	1 (2.3%)	1 (2.2%)
Transferred to another center	2 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	0 (0.0%)	2 (2.7%)	0 (0.0%)	1 (2.2%)
Total	98 (100.0%)	73 (100.0%)	44 (100.0%)	46 (100.0%)

Figure 15 and **Table 20** show the rate of waiting list removal due to death or too sick to transplant per 100 person-years waiting for liver-alone candidates aged 0-11 years at listing by era. The overall waiting list removal rate increased slightly from 9.72 (3.57, 21.17) removals per 100 person-years waiting pre-policy to 12.04 (4.42, 26.21) removals per 100 person-years waiting post-policy. This difference was not statistically significant.

Figure 15. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Person-Years Waiting among Candidates Aged 0-11 Years at Listing by Era

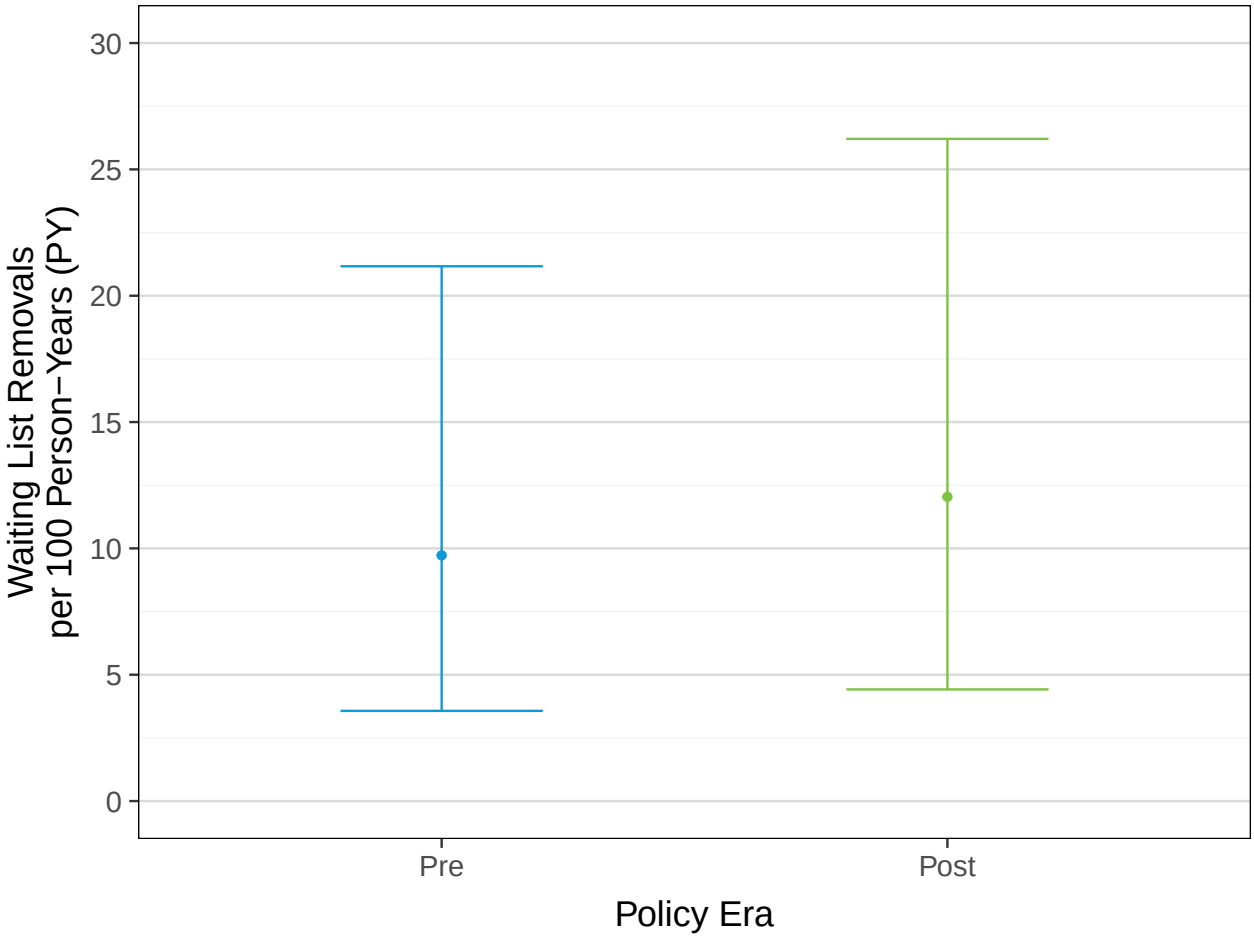


Table 20. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Person-Years Waiting among Candidates Aged 0-11 Years at Listing by Era

	Ever Waiting	Death/Too Sick Events	Person-Years (PY)	Removals per 100 PY	
Era	N	N	PY	Estimate	95% CI
Pre	375	6	61.7	9.72	(3.57, 21.17)
Post	345	6	49.8	12.04	(4.42, 26.21)

Figure 16 and **Table 21** show the rate of waiting list removal due to death or too sick to transplant per 100 person-years waiting for liver-alone candidates aged 0-11 years at listing by age group and era. In both policy eras, waiting list removal rates were higher for candidates 0-2 years old compared to candidates between 3-11 years old, although these differences were not statistically significant. Within each age group, waiting list removal rates increased post-policy, although this increase was not statistically significant.

Figure 16. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Person-Years Waiting among Candidates Aged 0-11 Years at Listing by Age Group and Era

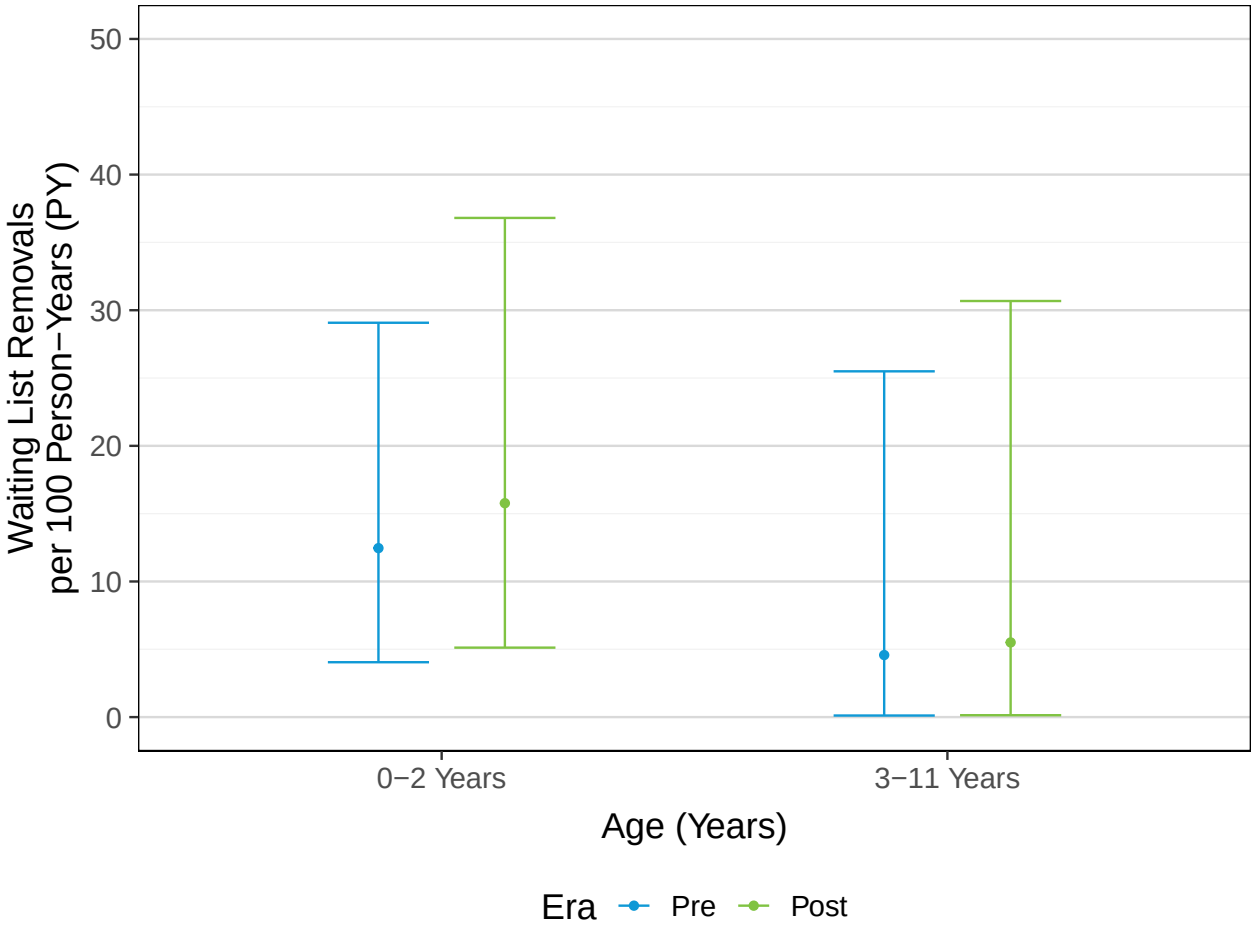


Table 21. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Person-Years Waiting among Candidates Aged 0-11 Years at Listing by Age Group and Era

		Ever Waiting	Death/Too Sick Events	Person-Years (PY)	Removals per 100 PY	
Era	Age (Years)	N	N	PY	Estimate	95% CI
Pre	0-2 Years	258	5	40.1	12.46	(4.05, 29.08)
	3-11 Years	123	1	21.9	4.58	(0.12, 25.49)
Post	0-2 Years	224	5	31.7	15.77	(5.12, 36.80)
	3-11 Years	125	1	18.2	5.51	(0.14, 30.68)

Figure 17 and **Table 23** show liver-alone transplant rates per 100 person-years waiting among candidates aged 0-11 years at listing by era. The overall transplant rate increased from 145.86 (117.29, 179.29) transplants per 100 active person-years waiting pre-policy to 156.53 (123.73, 195.36) transplants per 100 active person-years waiting post-policy. This increase was not statistically significant.

Figure 17. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting among Candidates Aged 0-11 Years at Listing by Era

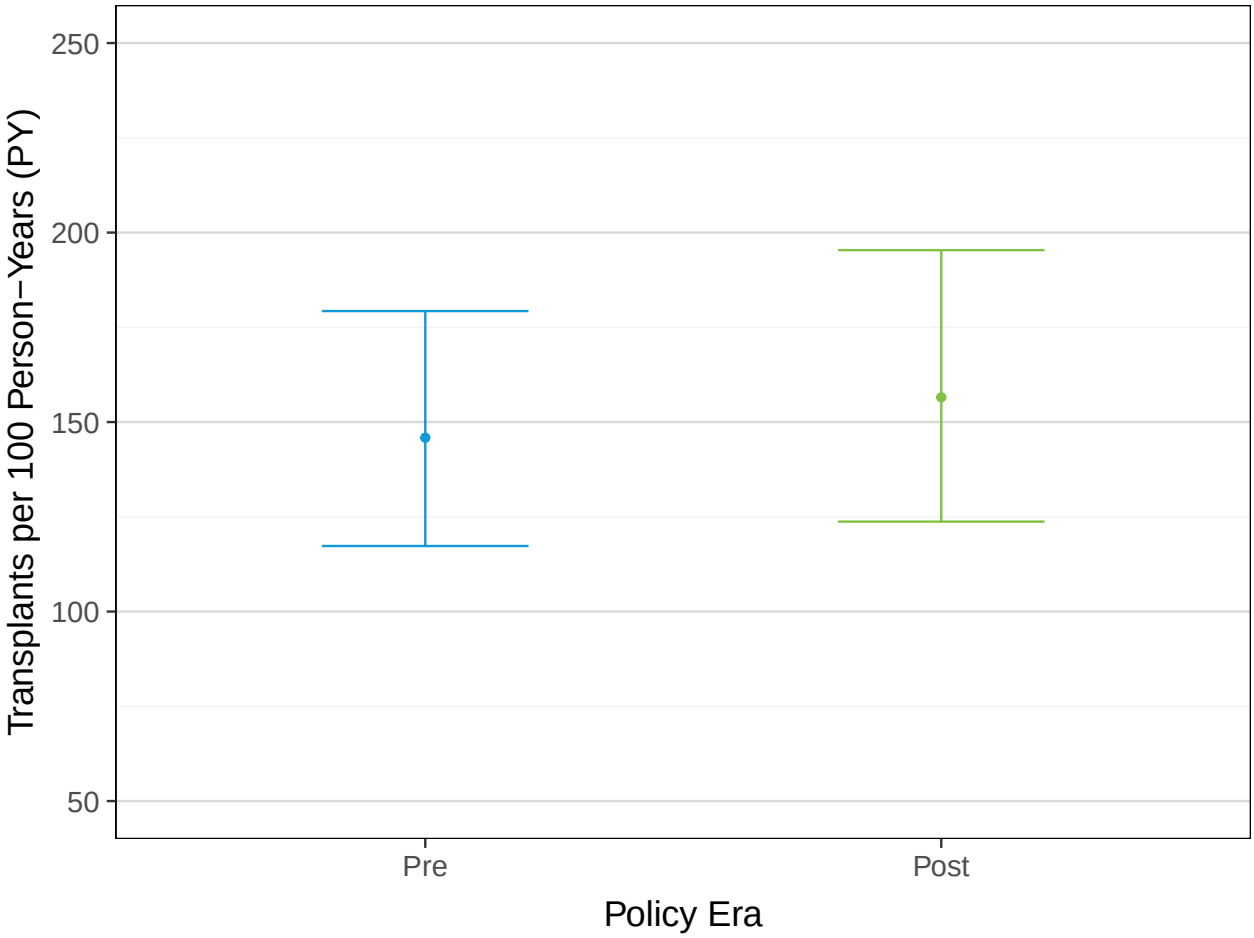


Table 23. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting among Candidates Aged 0-11 Years at Listing by Era

	Ever Waiting	Transplant Events	Active Person-Years (PY)	Transplants per 100 Active PY	
Era	N	N	PY	Estimate	95% CI
Pre	375	90	61.7	145.86	(117.29, 179.29)
Post	345	78	49.8	156.53	(123.73, 195.36)

Figure 18 and **Table 24** show liver-alone transplant rates per 100 active person-years waiting among candidates aged 0-11 years at listing by age group and era. The transplant rate among candidates 0-2 years old remained higher than that among candidates 3-11 years old, regardless of policy era. Within each age group, the transplant rate increased pre- to post-policy although these increases were not statistically significant.

Figure 18. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting among Candidates Aged 0-11 Years at Listing by Age Group and Era

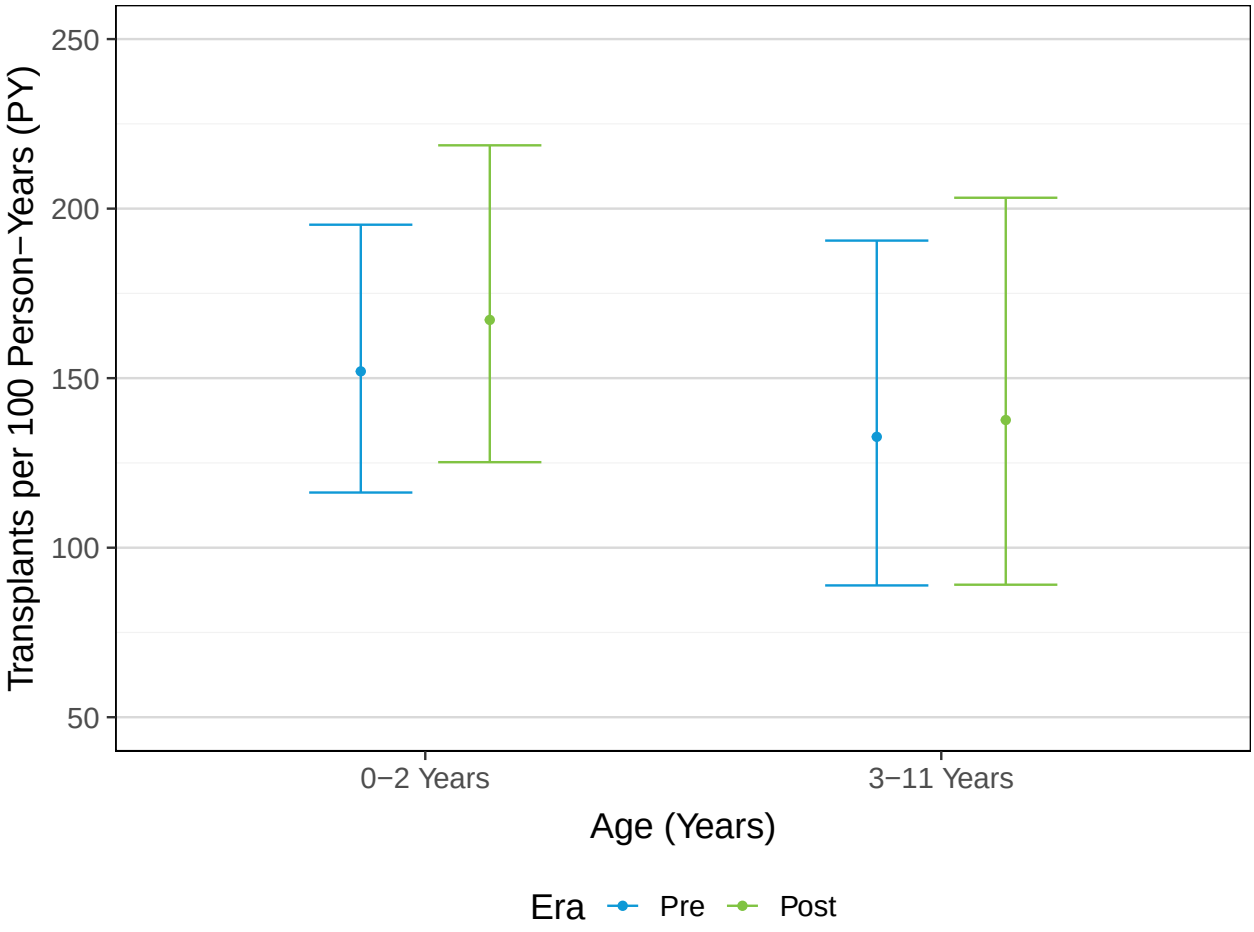


Table 24. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting among Candidates Aged 0-11 Years at Listing by Age Group and Era

		Ever Waiting	Transplant Events	Active Person-Years (PY)	Transplants per 100 Active PY	
Era	Age (Years)	N	N	PY	Estimate	95% CI
Pre	0-2 Years	258	61	40.1	152.00	(116.27, 195.25)
	3-11 Years	123	29	21.9	132.69	(88.87, 190.57)
Post	0-2 Years	224	53	31.7	167.17	(125.22, 218.66)
	3-11 Years	125	25	18.2	137.65	(89.08, 203.20)

Transplant

Figure 19 and **Table 26** show the number of liver transplants among recipients aged 0-11 years at time of transplant by policy era. There were 168 total transplants among recipients aged 12 years and older in the study period. 91 of these transplants occurred in the pre-policy era and 77 occurred in the post-policy era.

Figure 19. Number of Liver Transplants among Recipients Aged 0-11 Years at Time of Transplant by Era

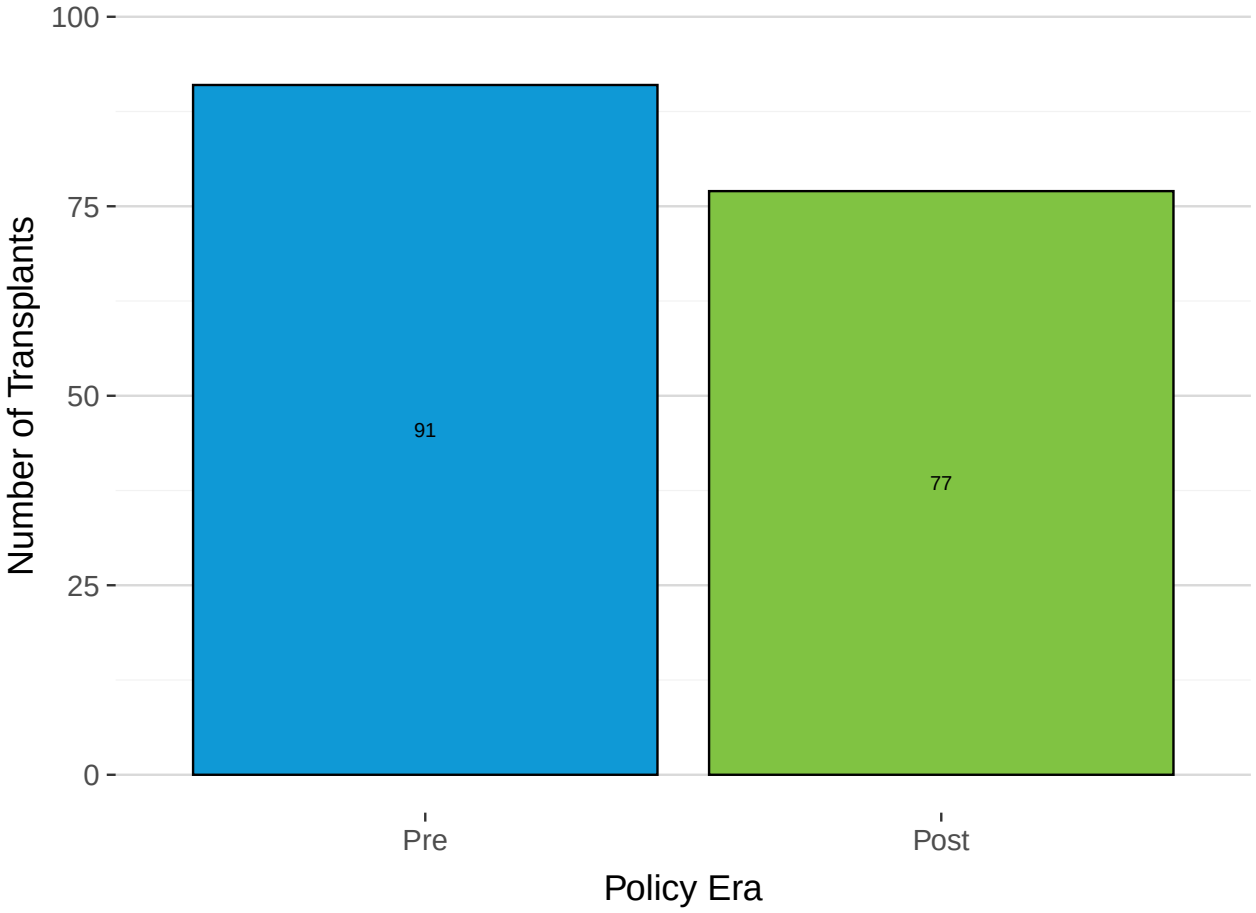


Table 26. Count and Percent of Liver Transplants among Recipients Aged 0-11 Years at Time of Transplant by Era

Era	N (%)
Pre	91 (54.2%)
Post	77 (45.8%)
Total	168 (100.0%)

Figure 20 and **Table 28** show the number of liver transplants among recipients aged 0-11 years by age group at time of transplant (0-2 years vs. 3-11 years) and policy era. The number and proportion of transplant recipients 0-2 years old decreased from 58 (63.7%) pre-policy to 51 (66.2%) post-policy.

Figure 20. Count and Percent of Liver Transplants among Recipients Aged 0-11 Years by Recipient Age Group at Time of Transplant and Era

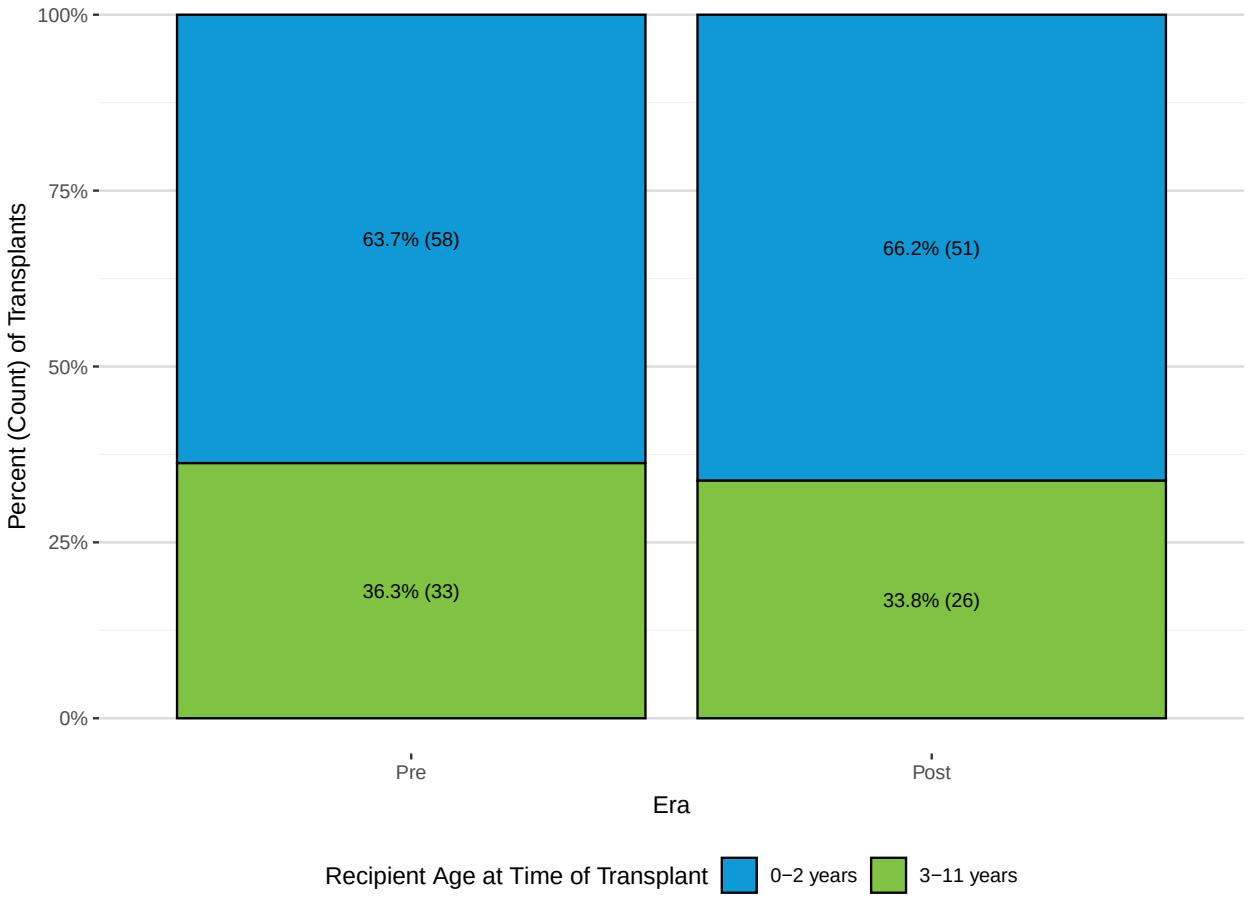


Table 28. Count and Percent of Liver Transplants among Recipients Aged 0-11 Years by Recipient Age Group at Time of Transplant and Era

Recipient Age at Time of Transplant	Pre	Post
0-2 years	58 (63.7%)	51 (66.2%)
3-11 years	33 (36.3%)	26 (33.8%)
Total	91 (100.0%)	77 (100.0%)

Figure 21, **Figure 22**, and **Table 30** show the distribution of allocation PELD score at transplant for liver-alone transplant recipients aged 0-11 years by era. Note that in the pre-policy era, PELD scores could range between -99 and 99, whereas in the post-policy era, PELD scores were floored at 6; thus, PELD scores in the post-policy era can only range between 6 and 99.

The number and proportion of Status 1A/1B transplant recipients decreased from 39 (42.86%) pre-policy to 28 (36.36%) post-policy. The median PELD score at transplant remained the same across policy eras, but the interquartile range, which captures the middle 50% of PELD scores at transplant, decreased from 22-33 pre-policy to 28-35 post-policy. Moreover, the overall distribution became less skewed post-policy compared to pre-policy.

Figure 21. Distribution of Allocation PELD Score or Status at Transplant for Liver-Alone Transplant Recipients Aged 0-11 Years at Time of Transplant by Era

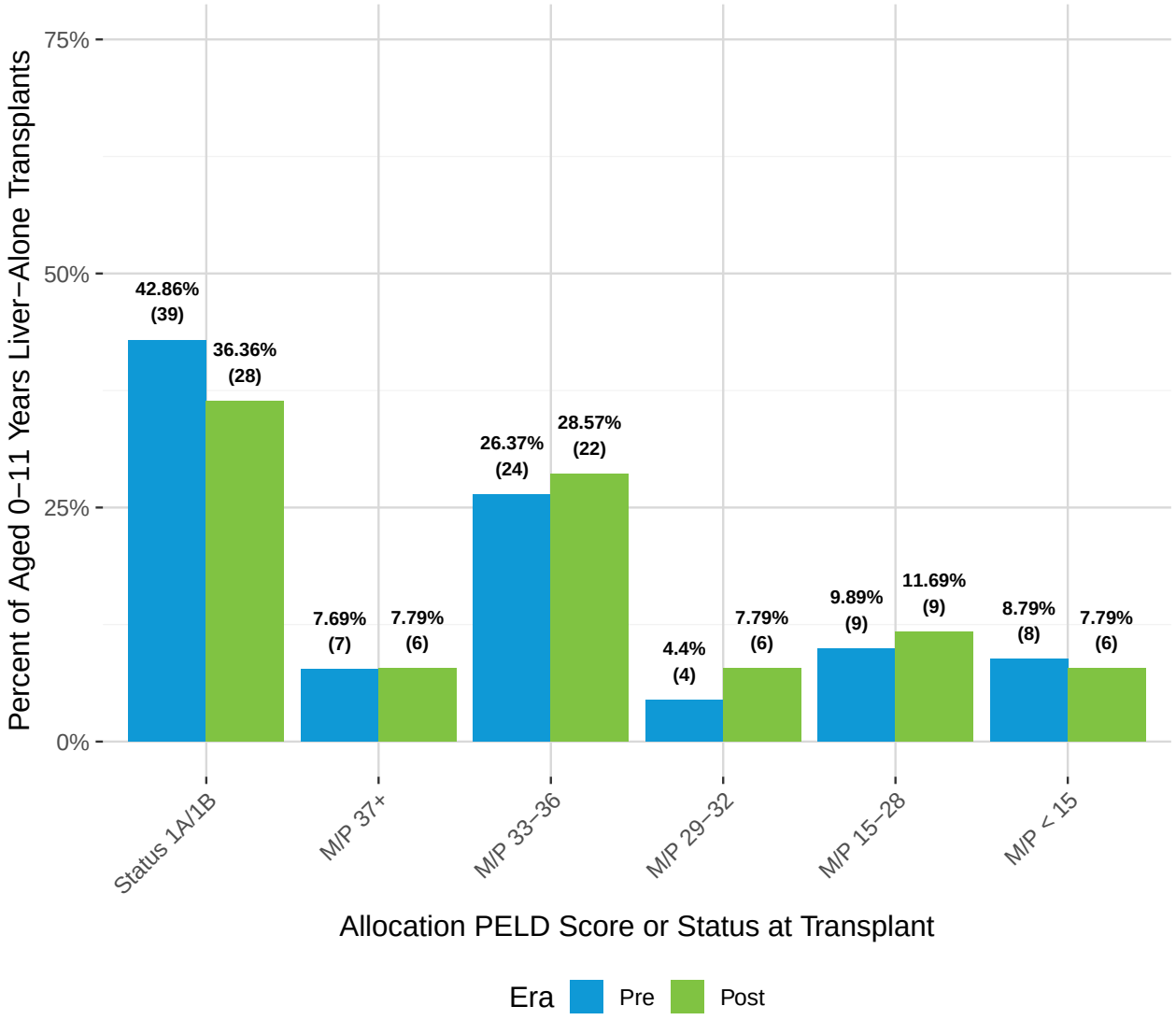
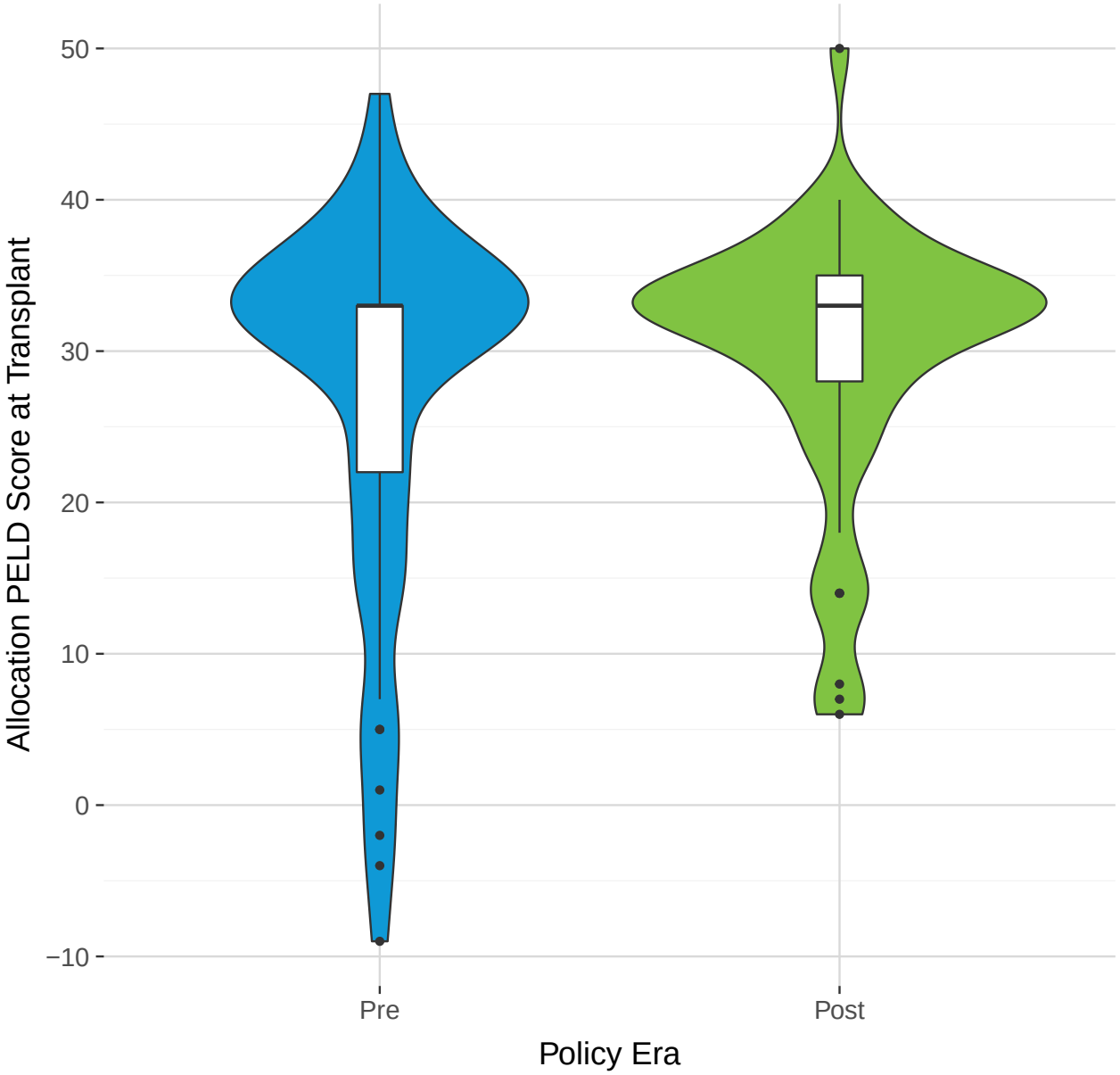


Figure 22. Distribution of Allocation PELD Score at Transplant for Liver-Alone Transplant Recipients Aged 0-11 Years at Time of Transplant by Era



Status 1A/1B candidates do not have allocation PELD scores at transplant. As a result, 39 (42.86%) pre−policy recipients and 28 (36.36%) post−policy recipients were excluded. Pre−policy, PELD could range between −99 and 99; post−policy, PELD ranges between 6 and 99.

Table 30. Summary of Allocation PELD Score at Transplant for Liver-Alone Transplant Recipients Aged 0-11 Years at Time of Transplant by Era

Policy Era	N	Minimum	25th Percentile	Median	75th Percentile	Maximum	Interquartile Range
Pre	52	-9	22	33	33	47	11
Post	49	6	28	33	35	50	7

Status 1A/1B candidates do not have allocation PELD scores at transplant. As a result, 39 (42.86%) pre-policy recipients and 28 (36.36%) post-policy recipients were excluded.
Pre-policy, PELD could range between -99 and 99; post-policy, PELD ranges between 6 and 99.

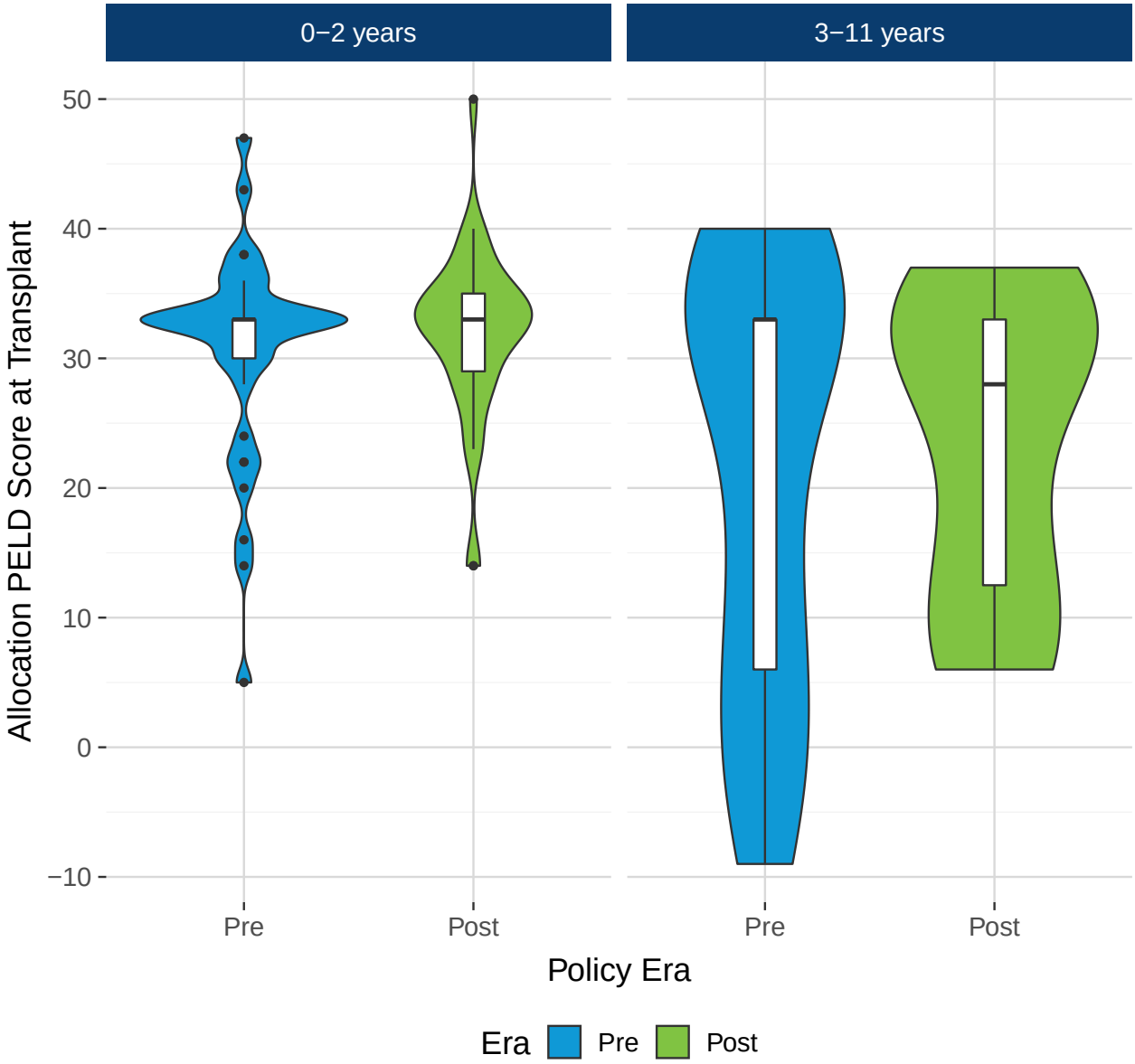
Figure 23, **Figure 24**, and **Table 32** show the distribution of allocation PELD score at transplant for liver-alone transplant recipients aged 0-11 years at time of transplant by age group and era. Among transplant recipients 0-2 years old at the time of transplant, the number and proportion of Status 1A/1B transplant recipients decreased from 25 (43.1%) pre- to 14 (27.45%) post-policy. The median PELD score at transplant among recipients 0-2 years old remained the same pre- to post-policy (33), but the interquartile range, which captures the middle 50% of allocation PELD scores at transplant, increased slightly (Pre: 30-33; Post: 29-35).

Among transplant recipients 3-11 years old at the time of transplant, the number of Status 1A/1B transplant recipients remained the same, but the proportion of Status 1A/1B transplant recipients increased from 14 (42.42%) pre- to 14 (53.85%) post-policy. The median PELD score at transplant among recipients 3-11 years old at the time of transplant decreased from 33 pre-policy to 28 pre-policy. The interquartile range of allocation PELD scores at transplant for recipients 3-11 years old decreased as well (Pre: 6-33; Post: 12.5-33).

Regardless of policy era, the median allocation PELD score at transplant was the same or higher for recipients 0-2 years old than for recipients 3-11 years old; the interquartile range of allocation PELD scores at transplant was narrower for recipients 0-2 years old than for recipients 3-11 years old. Overall, the distribution of allocation PELD scores at transplant was less skewed post-policy compared to pre-policy.

Figure 23. Distribution of Allocation PELD Score or Status at Transplant for Liver-Alone Transplant Recipients Aged 0-11 Years by Recipient Age Group at Time of Transplant and Era

Figure 24. Distribution of Allocation PELD Score at Transplant for Liver-Alone Transplant Recipients Aged 0-11 Years by Recipient Age Group at Time of Transplant and Era



Status 1A/1B candidates do not have allocation PELD scores at transplant. As a result, 25 (43.1%) pre−policy recipients aged 0−2 years, 14 (27.45%) post−policy recipients aged 0−2 years, 14 (42.42%) pre−policy recipients aged 3−11 years, and 14 (53.85%) post−policy recipients aged 3−11 years were excluded. Pre−policy, PELD could range between −99 and 99; post−policy, PELD ranges between 6 and 99.

Table 32. Summary of Allocation PELD Score at Transplant for Liver-Alone Transplant Recipients Aged 0-11 Years by Recipient Age Group at Time of Transplant and Era

Recipient Age at Time of Transplant	Policy Era	Transplants	Minimum	25th Percentile	Median	75th Percentile	Maximum	Interquartile Range
0-2 years	Pre	33	5	30.0	33	33	47	3.0
	Post	37	14	29.0	33	35	50	6.0
3-11 years	Pre	19	-9	6.0	33	33	40	27.0
	Post	12	6	12.5	28	33	37	20.5

Status 1A/1B candidates do not have allocation PELD scores at transplant. As a result,
25 (43.1%) pre-policy recipients aged 0-2 years, 14 (27.45%) post-policy recipients aged 0-2 years,
14 (42.42%) pre-policy recipients aged 3-11 years, and 14 (53.85%) post-policy recipients aged 3-11 years were excluded.
Pre-policy, PELD could range between -99 and 99; post-policy, PELD ranges between 6 and 99.

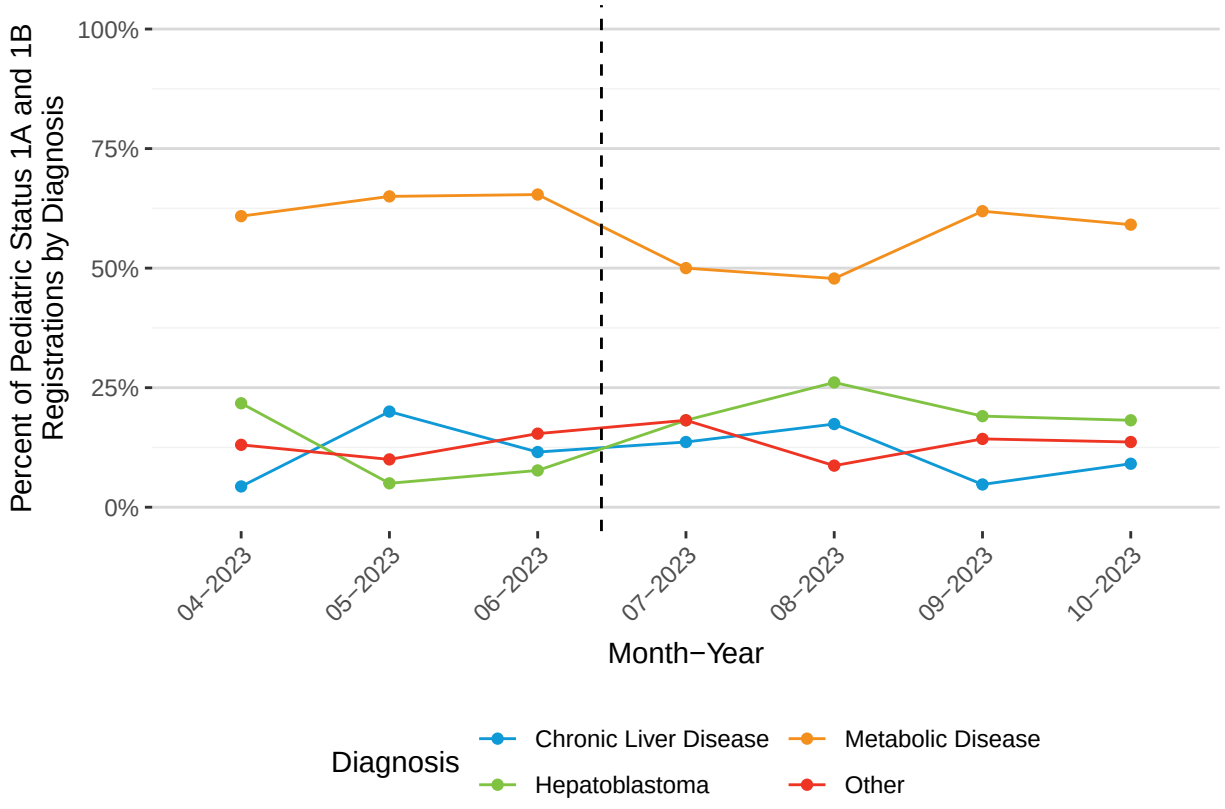
Status 1A and 1B Results

This section of the report monitors whether the Status 1A and 1B policy changes reduced pediatric waiting list mortality. The analyses in this section include liver candidates and transplant recipients with Status 1A or 1B who were less than 18 years old at listing.

Waiting List

Figure 25 and **Table 33** show the percent of pediatric (<18 years old) Status 1A/1B liver-alone waiting list registrations with Status 1B at the end of each month by diagnosis (chronic liver disease, hepatoblastoma, metabolic disease, other). At the end of each month, the majority of pediatric Status 1A and 1B registrations had metabolic disease. Counts and percents remained fairly consistent pre- and post-policy, although results should be interpreted cautiously due to small sample size.

Figure 25. Percent of Pediatric (Age <18) Status 1A and 1B Liver Waiting List Registrations each Month by Diagnosis



Dotted line represents implemention of MELD 3.0, PELD−Cr, Status 1A and 1B policy on July 13, 2023.

Table 33. Count and Percent of Pediatric (Age <18) Status 1A and 1B Liver Waiting List Registrations each Month by Diagnosis

	Chronic Liver Disease		Hepatoblastoma		Metabolic Disease		Other	
Month-Year	N	%	N	%	N	%	N	%
04-2023	1	4.3	5	21.7	14	60.9	3	13.0
05-2023	4	20.0	1	5.0	13	65.0	2	10.0
06-2023	3	11.5	2	7.7	17	65.4	4	15.4
07-2023	3	13.6	4	18.2	11	50.0	4	18.2
08-2023	4	17.4	6	26.1	11	47.8	2	8.7
09-2023	1	4.8	4	19.0	13	61.9	3	14.3
10-2023	2	9.1	4	18.2	13	59.1	3	13.6

Figure 26 and **Table 34** show the number of pediatric liver candidates with Status 1A and 1B who were removed from the waiting list by reported removal reason and policy era. 42 candidates were removed in the pre-policy era and 31 candidates were removed in the post-policy era. Deceased donor transplant made up the largest number and proportion of removal reasons (Pre: 36 (85.7%); Post: 26 (83.9%)).

Figure 26. Count and Percent of Pediatric (Age <18) Liver Candidates with Status 1A and 1B who were Removed from the Waiting List by Reported Removal Reason and Era

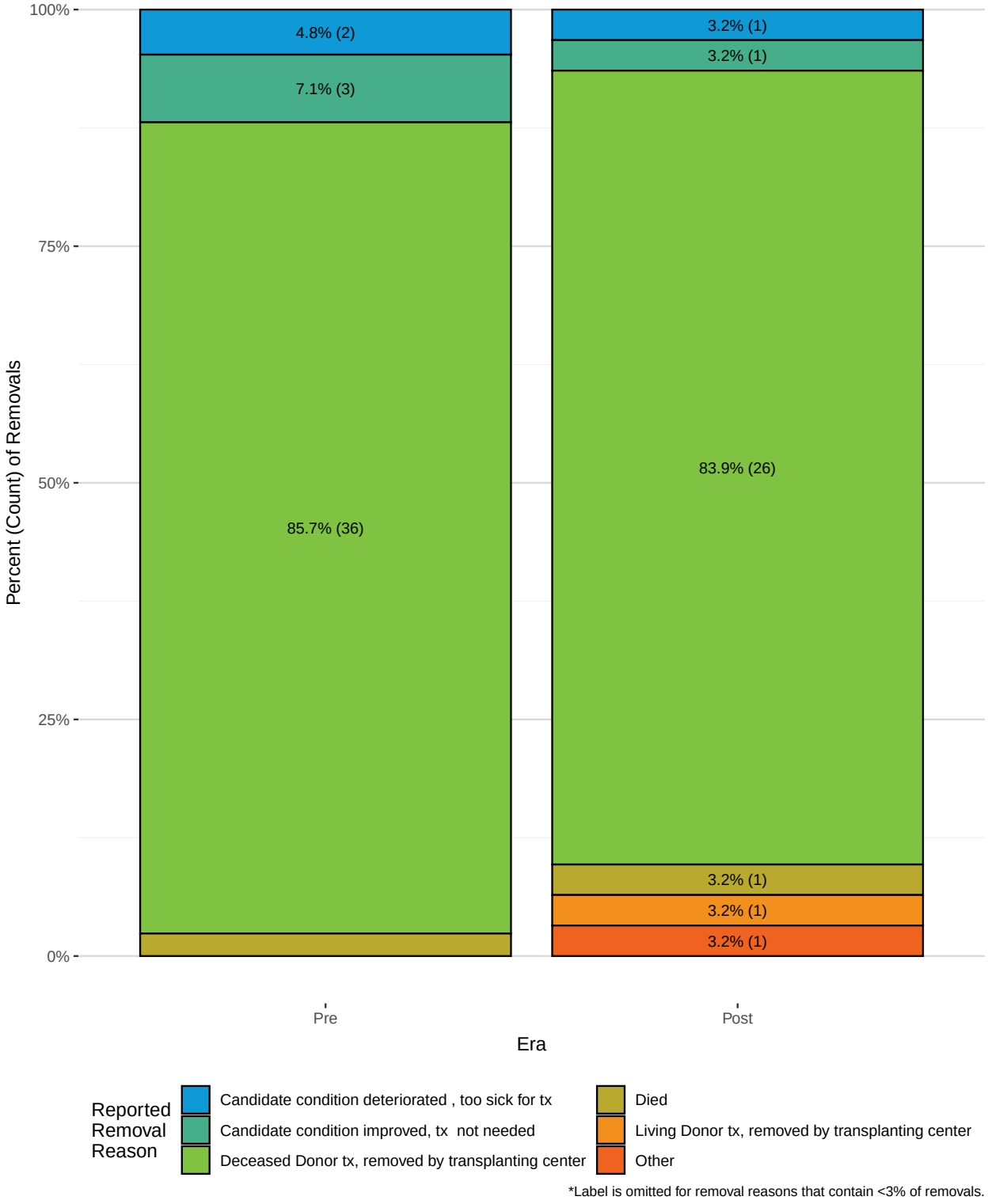
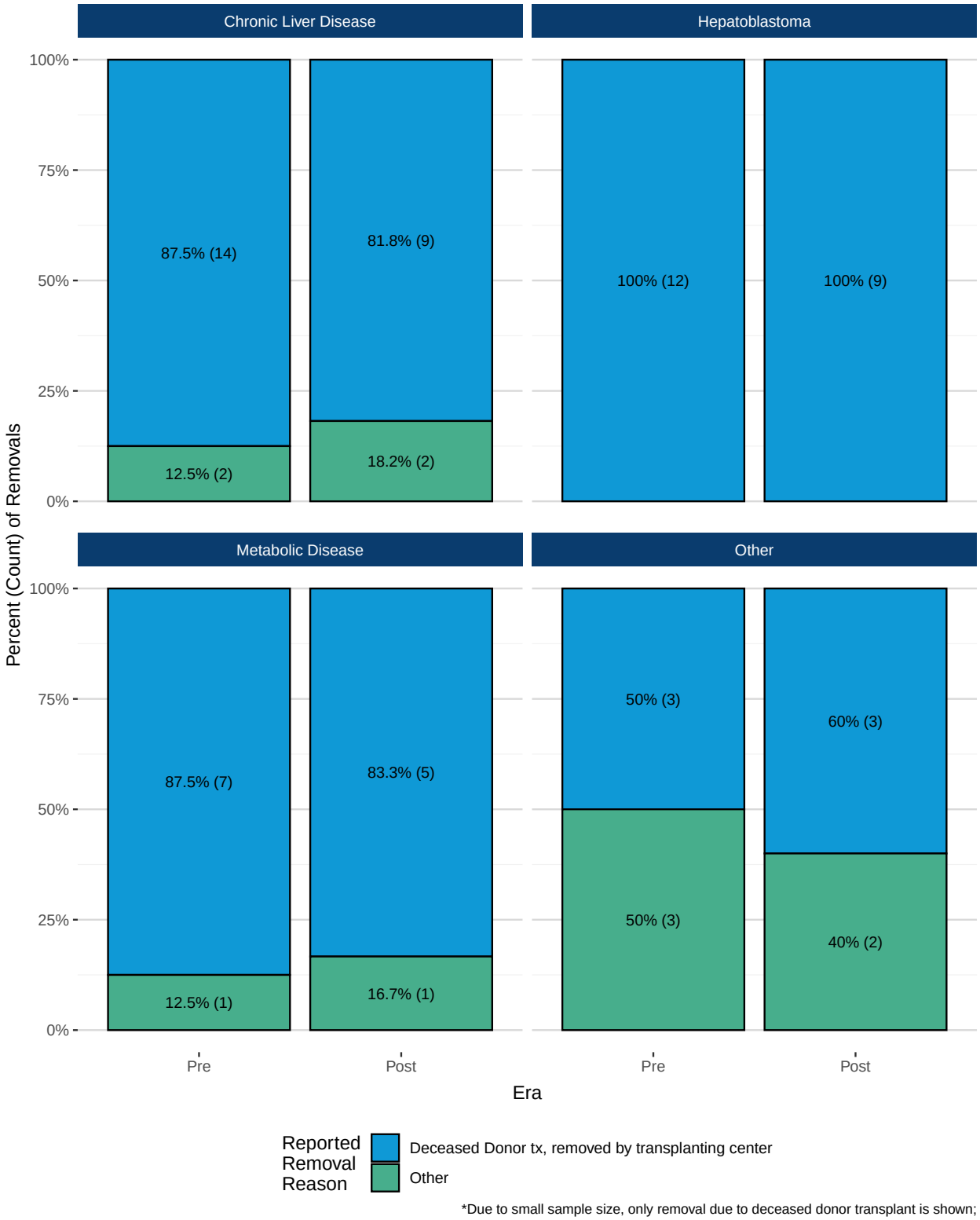


Table 34. Count and Percent of Pediatric (Age <18) Liver Candidates with Status 1A and 1B who were Removed from the Waiting List by Reported Removal Reason and Era

Reported Removal Reason	Pre	Post
Deceased Donor tx, removed by transplanting center	36 (85.7%)	26 (83.9%)
Candidate condition improved, tx not needed	3 (7.1%)	1 (3.2%)
Candidate condition deteriorated , too sick for tx	2 (4.8%)	1 (3.2%)
Died	1 (2.4%)	1 (3.2%)
Living Donor tx, removed by transplanting center	0 (0.0%)	1 (3.2%)
Other	0 (0.0%)	1 (3.2%)
Total	42 (100.0%)	31 (100.0%)

Figure 27 and **Table 35** show the number of pediatric liver candidates with Status 1A and 1B who were removed from the waiting list by reported removal reason, diagnosis (chronic liver disease, hepatoblastoma, metabolic disease, other), and policy era. Care should be taken when interpreting changes in the other removal categories, as sample sizes are small. Regardless of diagnosis, the top reason for removal was deceased donor transplant. The number of removals for deceased donor transplant decreased pre- to post-policy for Status 1B candidates in the "Chronic Liver Disease" (Pre: 14 (87.5%); Post: 9 (81.8%)), "Hepatoblastoma" (Pre: 12 (100.0%); Post: 9 (100.0%)), and "Metabolic Disease" diagnosis categories (Pre: 7 (87.5%); Post: 5 (83.3%)).

Figure 27. Count and Percent of Pediatric (Age <18) Liver Candidates with Status 1A and 1B who were Removed from the Waiting List by Reported Removal Reason, Diagnosis, and Era



*Due to small sample size, only removal due to deceased donor transplant is shown;

Table 35. Count and Percent of Pediatric (Age <18) Liver Candidates with Status 1A and 1B who were Removed from the Waiting List by Reported Removal Reason, Diagnosis, and Era

	Chronic Liver Disease		Hepatoblastoma		Metabolic Disease		Other	
Reported Removal Reason	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Deceased Donor tx, removed by transplanting center	14 (87.5%)	9 (81.8%)	12 (100.0%)	9 (100.0%)	7 (87.5%)	5 (83.3%)	3 (50.0%)	3 (60.0%)
Other	2 (12.5%)	2 (18.2%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	1 (16.7%)	3 (50.0%)	2 (40.0%)
Total	16 (100.0%)	11 (100.0%)	12 (100.0%)	9 (100.0%)	8 (100.0%)	6 (100.0%)	6 (100.0%)	5 (100.0%)

Due to small sample size, only removal due to deceased donor transplant is shown;
all other removal reasons are grouped into the Other category.

Transplant

Figure 28 and **Table 37** show the number of pediatric (age <18 at time of transplant) Status 1A and 1B liver transplants by policy era. There were 83 total transplants among pediatric Status 1A and 1B recipients in the study period. 48 of these transplants occurred in the pre-policy era and 35 occurred in the post-policy era.

Figure 28. Number of Pediatric (Age <18 at Transplant) Status 1A and 1B Liver Transplants by Era

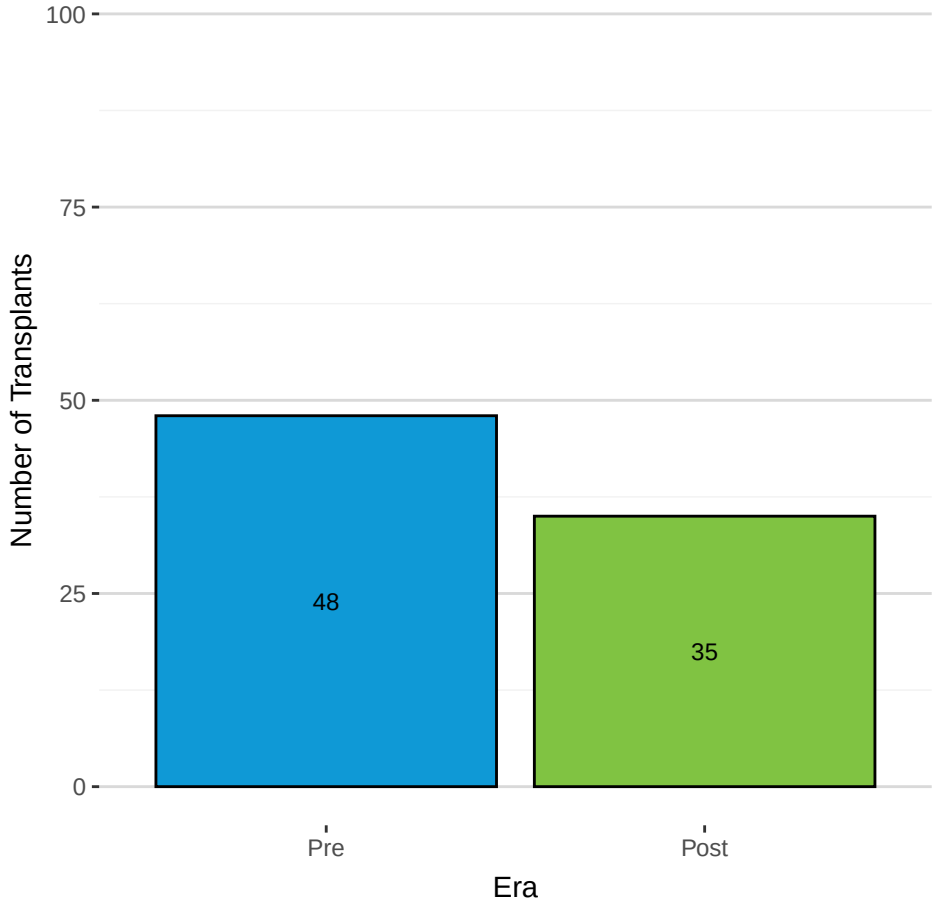


Table 37. Count and Percent of Pediatric (Age <18 at Transplant) Status 1A and 1B Liver Transplants by Era

Era	N (%)
Pre	48 (57.8%)
Post	35 (42.2%)
Total	83 (100.0%)

Figure 29 and **Table 39** show the number and proportion of liver transplants among pediatric (age <18 at time of transplant) Status 1A and 1B recipients by diagnosis (chronic liver disease, hepatoblastoma, metabolic disease, other) and policy era. The number of transplant recipients decreased pre- to post-policy regardless of diagnosis. However, the proportions remained relatively similar across policy eras. Recipients with chronic liver disease made up the largest proportion of transplants (Pre: 18 (37.5%); Post: 14 (40.0%)), followed by metabolic disease (Pre: 15 (31.2%); Post: 11 (31.4%)), hepatoblastoma (Pre: 12 (25.0%); Post: 9 (25.7%)), and other diagnosis (Pre: 3 (6.2%); Post: 1 (2.9%)).

Figure 29. Count and Percent of Pediatric (Age <18 at Transplant) Status 1A and 1B Liver Transplants by Diagnosis and Era

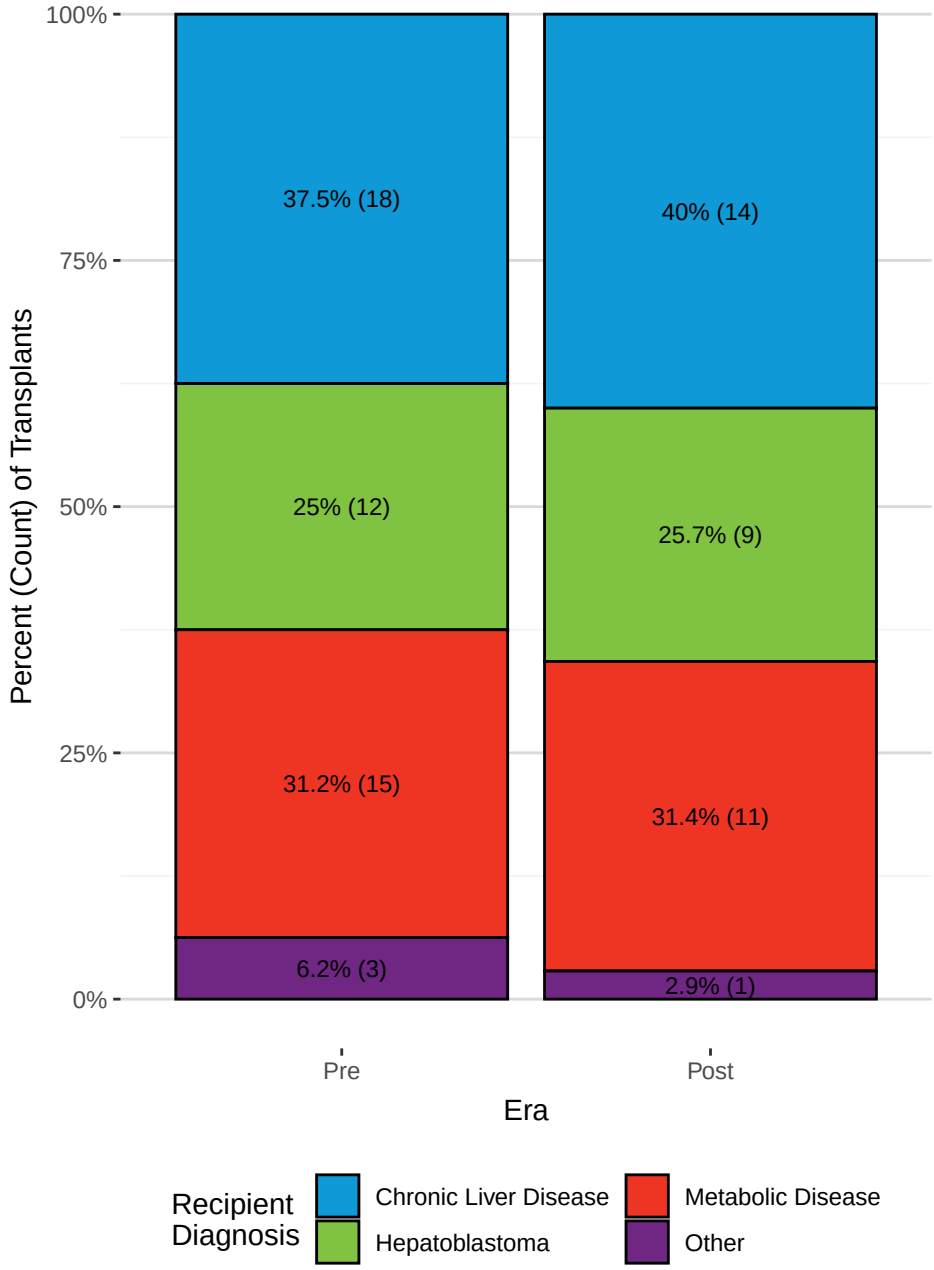


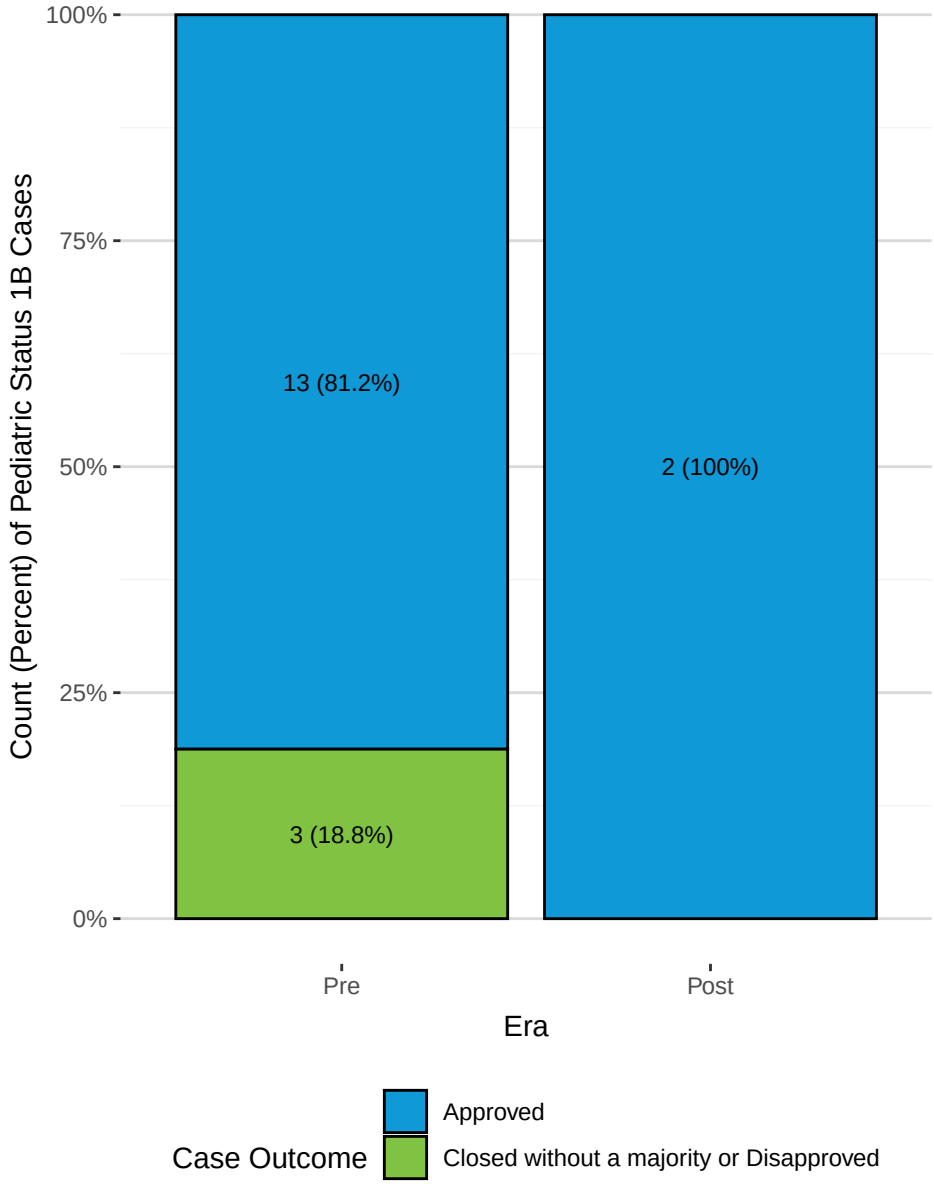
Table 39. Count and Percent of Pediatric (Age <18 at Transplant) Status 1A and 1B Liver Transplants by Diagnosis and Era

Recipient Diagnosis	Pre	Post
Chronic Liver Disease	18 (37.5%)	14 (40.0%)
Hepatoblastoma	12 (25.0%)	9 (25.7%)
Metabolic Disease	15 (31.2%)	11 (31.4%)
Other	3 (6.2%)	1 (2.9%)
Total	48 (100.0%)	35 (100.0%)

Case Outcomes for Forms Submitted in the Pre- and Post-Policy Eras

Figure 30 and **Table 41** show the number and percent of pediatric Status 1B cases that did not meet standard criteria by case outcome and policy era. 16 pediatric Status 1B cases did not meet standard criteria pre-policy, whereas only 2 pediatric Status 1B cases did not meet standard criteria post-policy. In both policy eras, the majority of pediatric Status 1B cases that did not meet standard criteria were approved (Pre: 13 (81.2%); Post: 2 (100.0%)).

Figure 30. Count and Percent of Pediatric Status 1B Cases by Case Outcome and Era



*Due to small sample sizes, cases that closed without a majority or that were disapproved are combined into one category.

Table 41. Count and Percent of Pediatric Status 1B Cases by Case Outcome and Era

Case Outcome	Pre	Post
Approved	13 (81.2%)	2 (100.0%)
Closed without a majority or Disapproved	3 (18.8%)	0 (0.0%)
Total	16 (100.0%)	2 (100.0%)

Due to small sample sizes, cases that closed without a majority or that were disapproved are combined into one category.

Due to the small number of pediatric Status 1B cases that closed without a majority or that were disapproved (i.e., Pre: 3 (18.8%); Post: 0 (0.0%)), turndown reasons for these cases are not summarized in this report. However, **Table 42** shows the criteria not met for Status 1B requests that did not meet standard criteria but were subsequently approved by era. The most common reason why these Status 1B requests did not meet standard criteria in the pre-policy era was that the candidate had chronic liver disease but the calculated MELD or PELD score was less than or equal to 25. There were too few Status 1B requests that did not meet standard criteria in the post-policy era but were subsequently approved to draw many conclusions.

Table 42. Number and Percent of Criteria Not Met for Pediatric Status 1B Requests that Do Not Meet Standard Criteria by Case Outcome and Era

	Approved	
Criteria Not Met for Status 1B Requests that Do Not Meet Standard Critera	Pre	Post
Chronic liver disease BUT calculated MELD/PELD score is less than or equal to 25	9 (69.2%)	0 (0.0%)
Candidate does not have chronic liver disease, non-metastatic hepatoblastoma, or metabolic disease	2 (15.4%)	1 (50.0%)
Chronic Liver Disease with MELD/PELD greater than 25 and GI bleeding requiring red blood cell replacement BUT amount indicated is less than 30 mL/kg for initial forms or less than 1 mL/kg for extensions (for Liver Only candidate)	1 (7.7%)	0 (0.0%)
Chronic Liver Disease with MELD/PELD greater than 25 BUT Candidate is not on a mechanical ventilator, dialysis, CVVH, or CVVHD, does not have a GI Bleed requiring at least 30 mL/kg of red blood cell replacement, and does not have a Glasgow coma score less than 10 (for Liver Only candidate)	1 (7.7%)	0 (0.0%)
Metabolic disease BUT candidate does not have an approved MELD/PELD Exception meeting standard criteria for metabolic disease for at least 30 days	0 (0.0%)	1 (50.0%)
Total	13 (100.0%)	2 (100.0%)

Due to small sample sizes, cases that closed without a majority or that were disapproved are not shown.

Conclusion

During the 3-months after implementation of the Improving Liver Allocation: MELD, PELD, Status 1A, Status 1B policy, deceased donor transplant was the most common reason for removal from the waiting list for MELD, PELD, and Status 1A/1B candidates. Under MELD 3.0, transplant rates increased significantly post-policy both overall and for females, whereas the transplant rate for males remained roughly the same across policy eras; waiting list removal rates due to death or too sick increased slightly (but not significantly) both overall and by sex, with removal rates being higher for females compared to males; the number and proportion of Status 1A/1B transplant recipients decreased slightly pre- to post-policy for both female and male transplant recipients; and the median allocation MELD score at transplant remained the same across policy eras.

Under PELD-Cr, there were no significant changes in transplant rates and waiting list removal rates, likely due to small sample sizes. The median PELD score at transplant remained the same across policy eras, while the interquartile range and extent of skewness decreased. These metrics will continue to be monitored in future reports, and as sample sizes increase, more telling insights may be able to be gleaned.

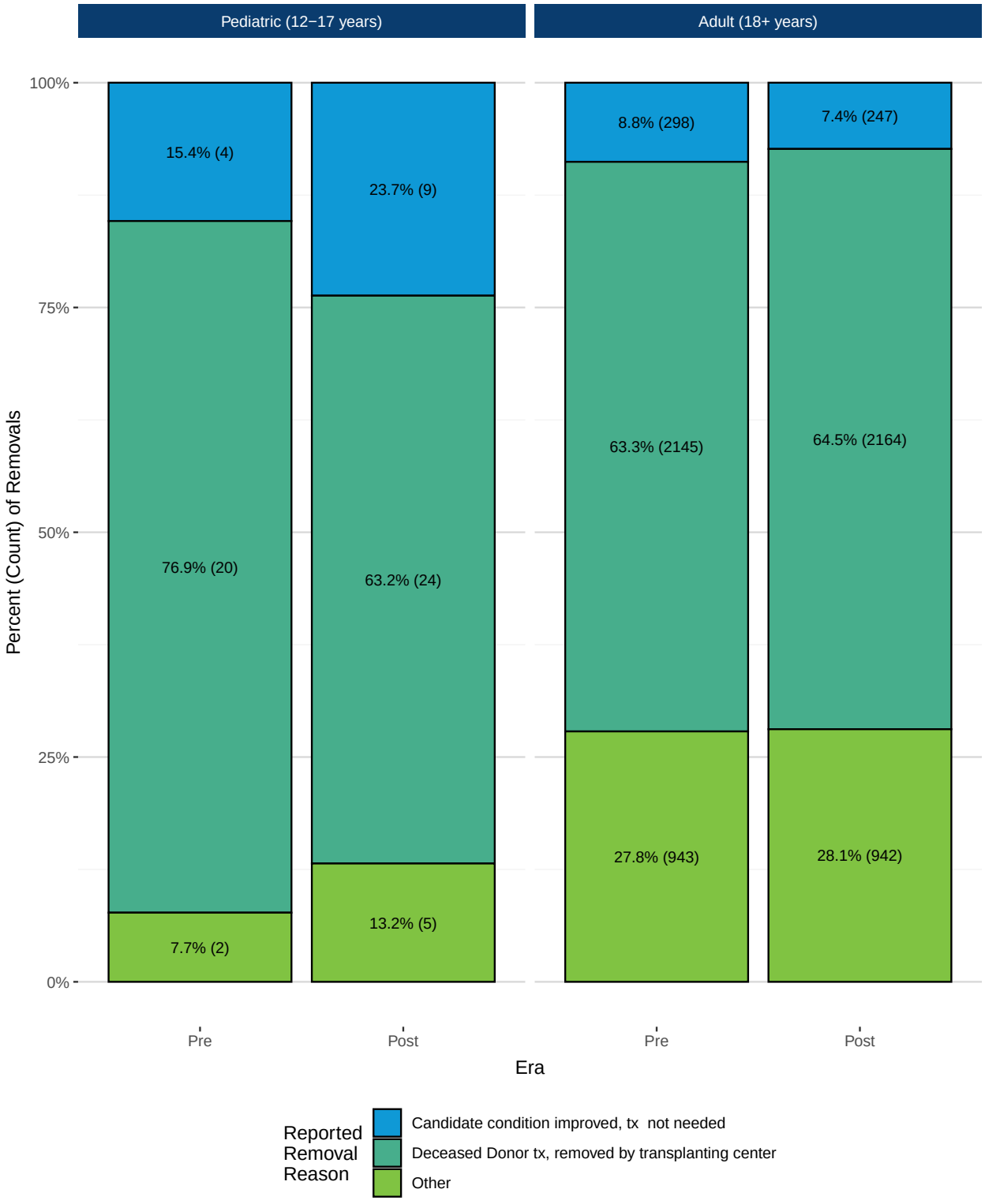
Under the Status 1A and 1B modifications, the number of pediatric Status 1A and 1B liver transplants decreased pre- to post-policy, both overall and by diagnosis; recipients with chronic liver disease made up the largest proportion of transplants, followed by metabolic disease, hepatoblastoma, and other diagnosis; the number of pediatric Status 1B cases that did not meet standard criteria decreased, and the number of those cases that were not approved decreased as well.

Appendix

Additional MELD 3.0 Results

This section stratifies the analyses shown in the main "MELD 3.0 Results" section by age group (12-17 years vs. 18+ years), height, and exception type (no exception, HCC exception, non-HCC exception), as appropriate. Note that these results should be interpreted cautiously, as some subgroups have small sample sizes.

Appendix Figure 1. Count and Percent of Liver Candidates 12 Years and Older Removed from the Waiting List by Reported Removal Reason, Age at Removal, and Era

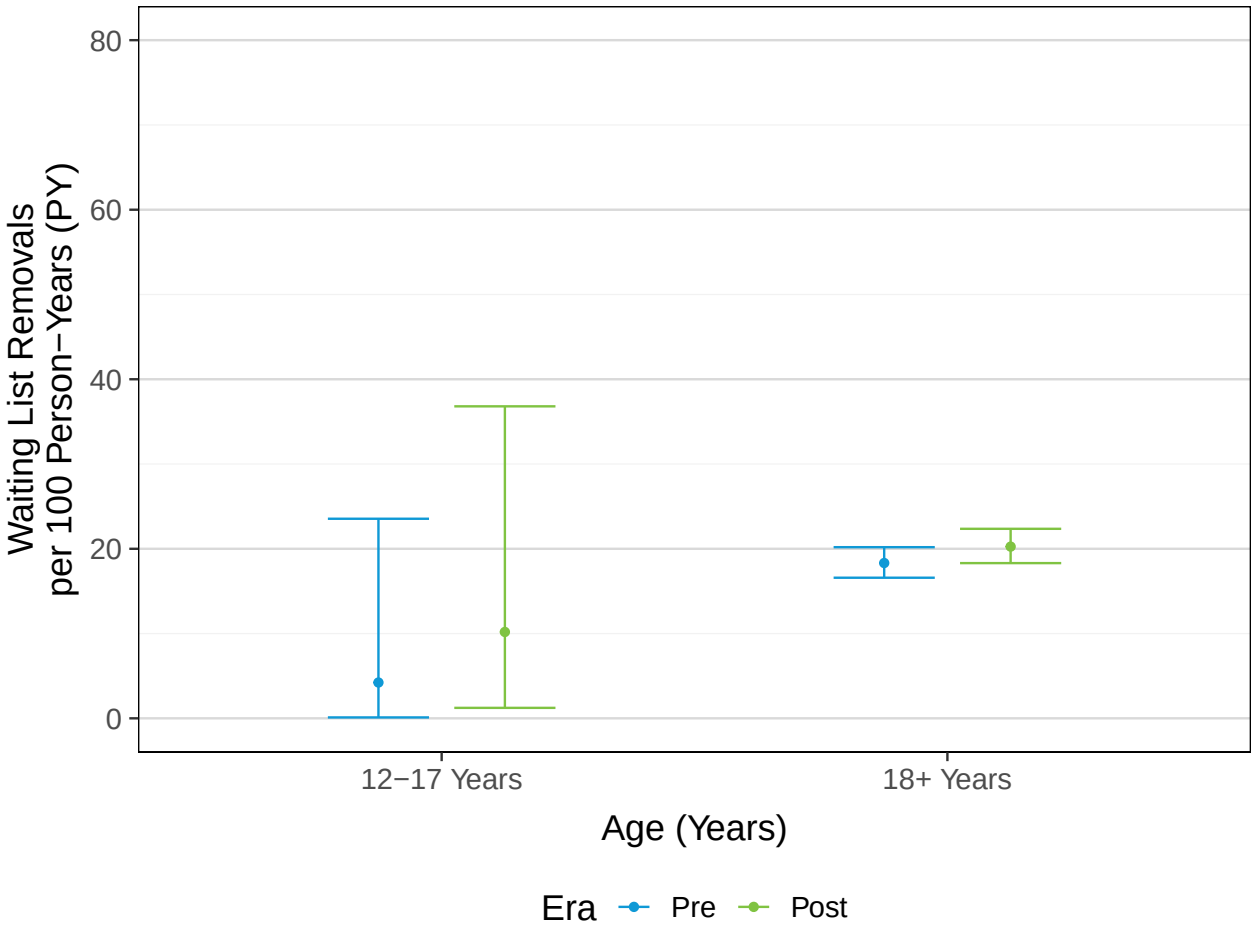


*Removal reasons containing <7% of forms in each policy era were combined with the Other category for plotting purposes, but appear in the corresponding table.

Appendix Table 1. Count and Percent of Liver Candidates Aged 12 Years and Older Removed from the Waiting List by Reported Removal Reason, Age at Removal, and Era

	Pediatric (12-17 years)		Adult (18+ years)	
Reported Removal Reason	Pre	Post	Pre	Post
Deceased Donor tx, removed by transplanting center	20 (76.9%)	24 (63.2%)	2145 (63.3%)	2164 (64.5%)
Candidate condition improved, tx not needed	4 (15.4%)	9 (23.7%)	298 (8.8%)	247 (7.4%)
Candidate condition deteriorated , too sick for tx	1 (3.8%)	2 (5.3%)	210 (6.2%)	206 (6.1%)
Died	0 (0.0%)	1 (2.6%)	209 (6.2%)	207 (6.2%)
Other	0 (0.0%)	0 (0.0%)	204 (6.0%)	218 (6.5%)
Living Donor tx, removed by transplanting center	0 (0.0%)	2 (5.3%)	150 (4.4%)	143 (4.3%)
Transplant at another center (multi-listed)	1 (3.8%)	0 (0.0%)	65 (1.9%)	70 (2.1%)
Refused transplant	0 (0.0%)	0 (0.0%)	35 (1.0%)	41 (1.2%)
Unable to contact candidate	0 (0.0%)	0 (0.0%)	34 (1.0%)	37 (1.1%)
Transferred to another center	0 (0.0%)	0 (0.0%)	28 (0.8%)	14 (0.4%)
Patient died during TX procedure	0 (0.0%)	0 (0.0%)	4 (0.1%)	6 (0.2%)
Candidate Removed in Error	0 (0.0%)	0 (0.0%)	2 (0.1%)	0 (0.0%)
Transplanted in another country	0 (0.0%)	0 (0.0%)	2 (0.1%)	0 (0.0%)
Total	26 (100.0%)	38 (100.0%)	3386 (100.0%)	3353 (100.0%)

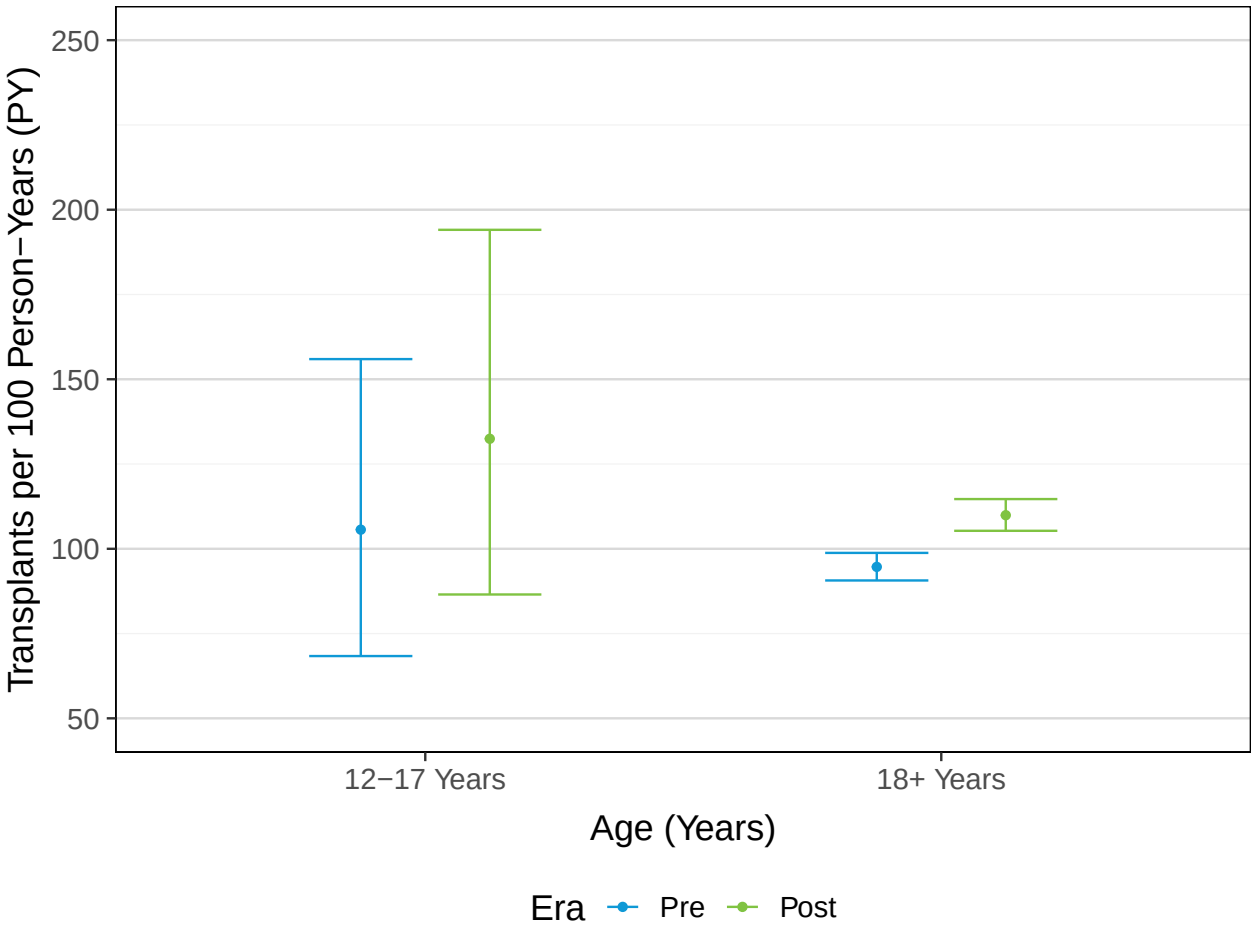
Appendix Figure 2. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Person-Years Waiting among Candidates Aged 12 Years and Older by Age and Era



Appendix Table 2. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Person-Years Waiting among Candidates Aged 12 Years and Older by Age and Era

		Ever Waiting	Death/Too Sick Events	Person-Years (PY)	Removals per 100 PY	
Era	Age (Years)	N	N	PY	Estimate	95% CI
Pre	12-17 Years	126	1	23.7	4.23	(0.11, 23.54)
	18+ Years	11989	408	2226.9	18.32	(16.59, 20.19)
Post	12-17 Years	126	2	19.6	10.19	(1.23, 36.80)
	18+ Years	11868	395	1949.8	20.26	(18.31, 22.36)

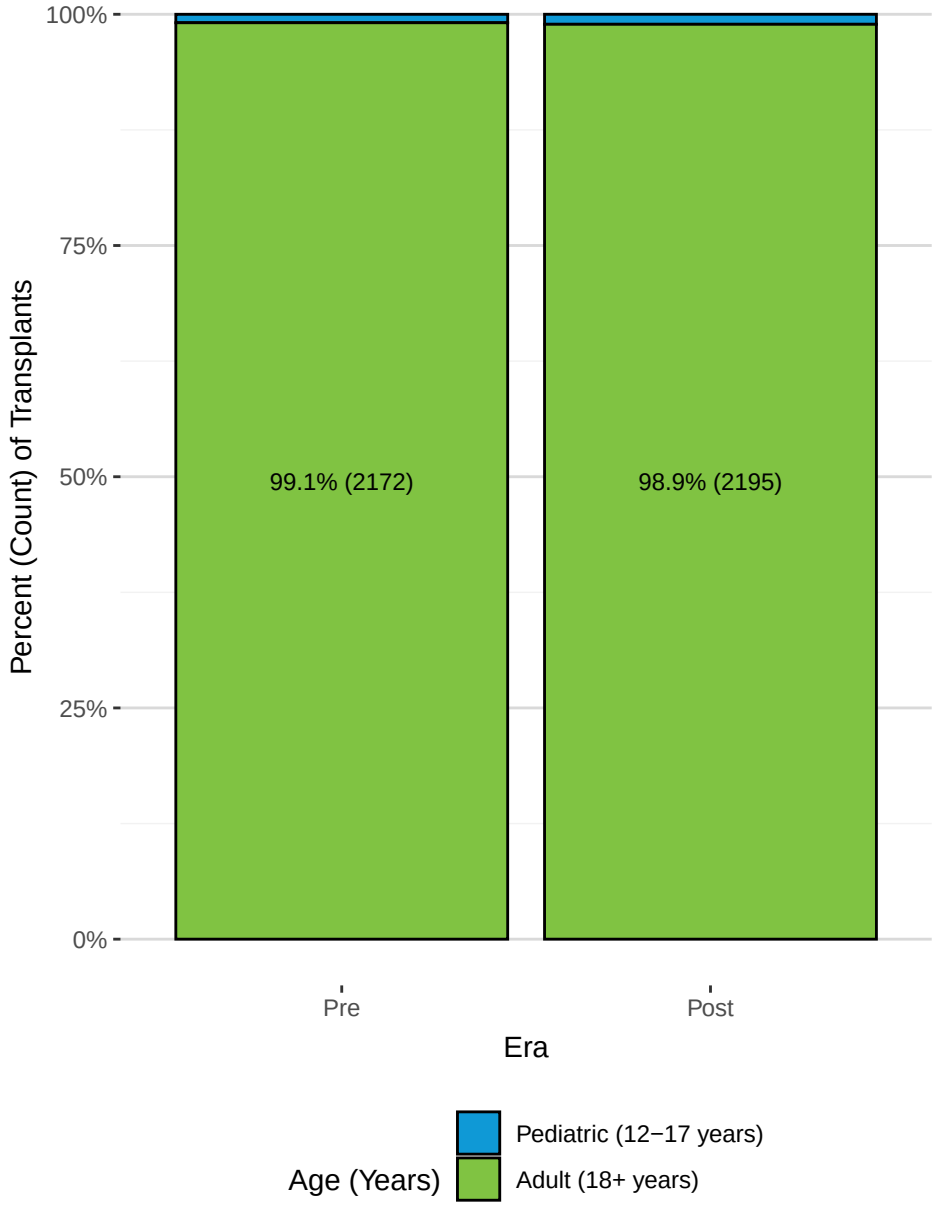
Appendix Figure 3. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting among Candidates Aged 12 Years and Older by Age and Era



Appendix Table 3. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting among Candidates Aged 12 Years and Older by Age and Era

		Ever Waiting	Transplant Events	Active Person-Years (PY)	Transplants per 100 Active PY	
Era	Age (Years)	N	N	PY	Estimate	95% CI
Pre	12-17 Years	126	25	23.7	105.64	(68.36, 155.94)
	18+ Years	11989	2108	2226.9	94.66	(90.66, 98.79)
Post	12-17 Years	126	26	19.6	132.45	(86.52, 194.07)
	18+ Years	11868	2143	1949.9	109.91	(105.30, 114.66)

Appendix Figure 4. Count and Percent of Liver Transplants among Recipients Aged 12 Years and Older by Age at Transplant and Era

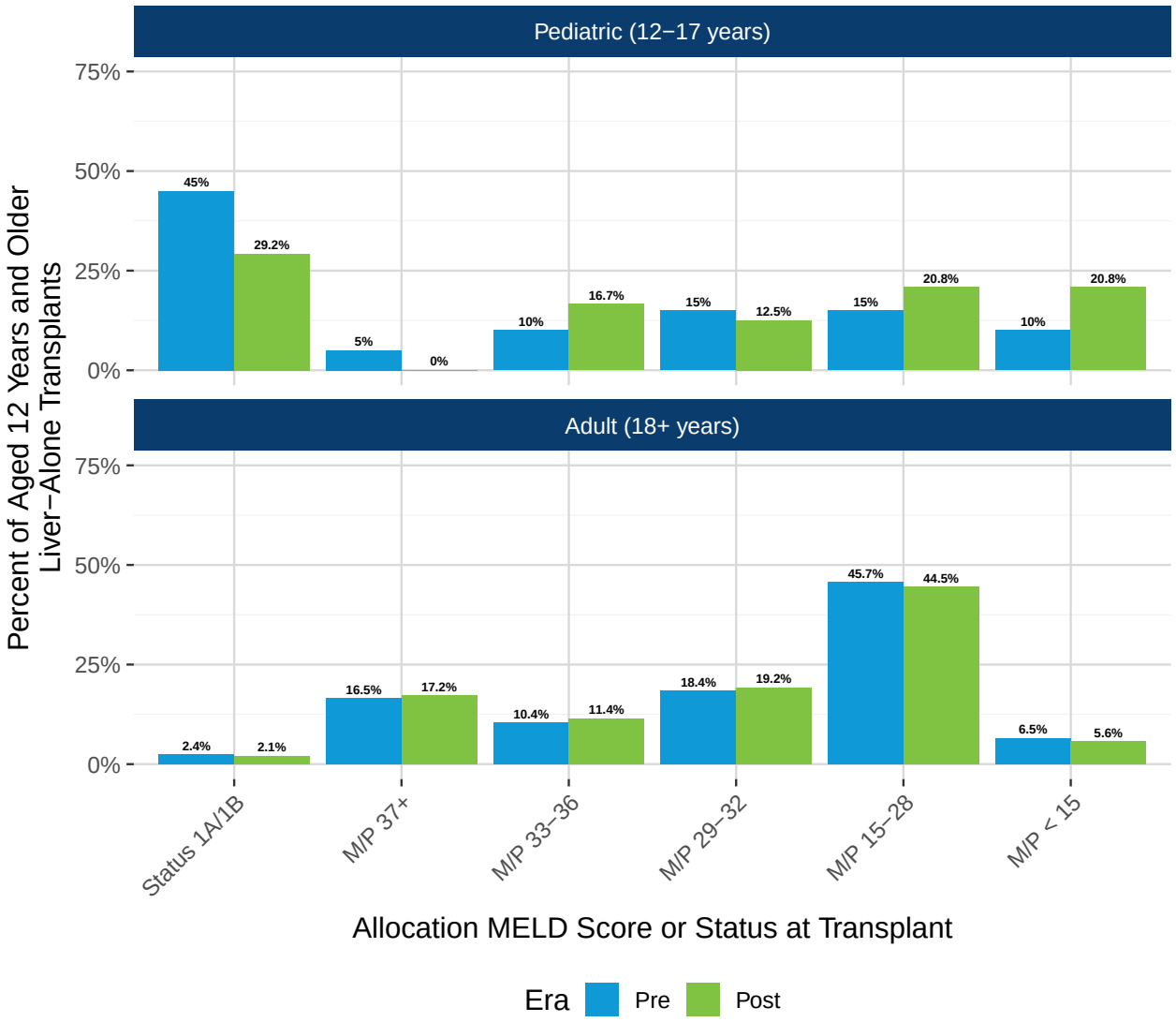


*Label is omitted for age groups that contain <2% of transplants.

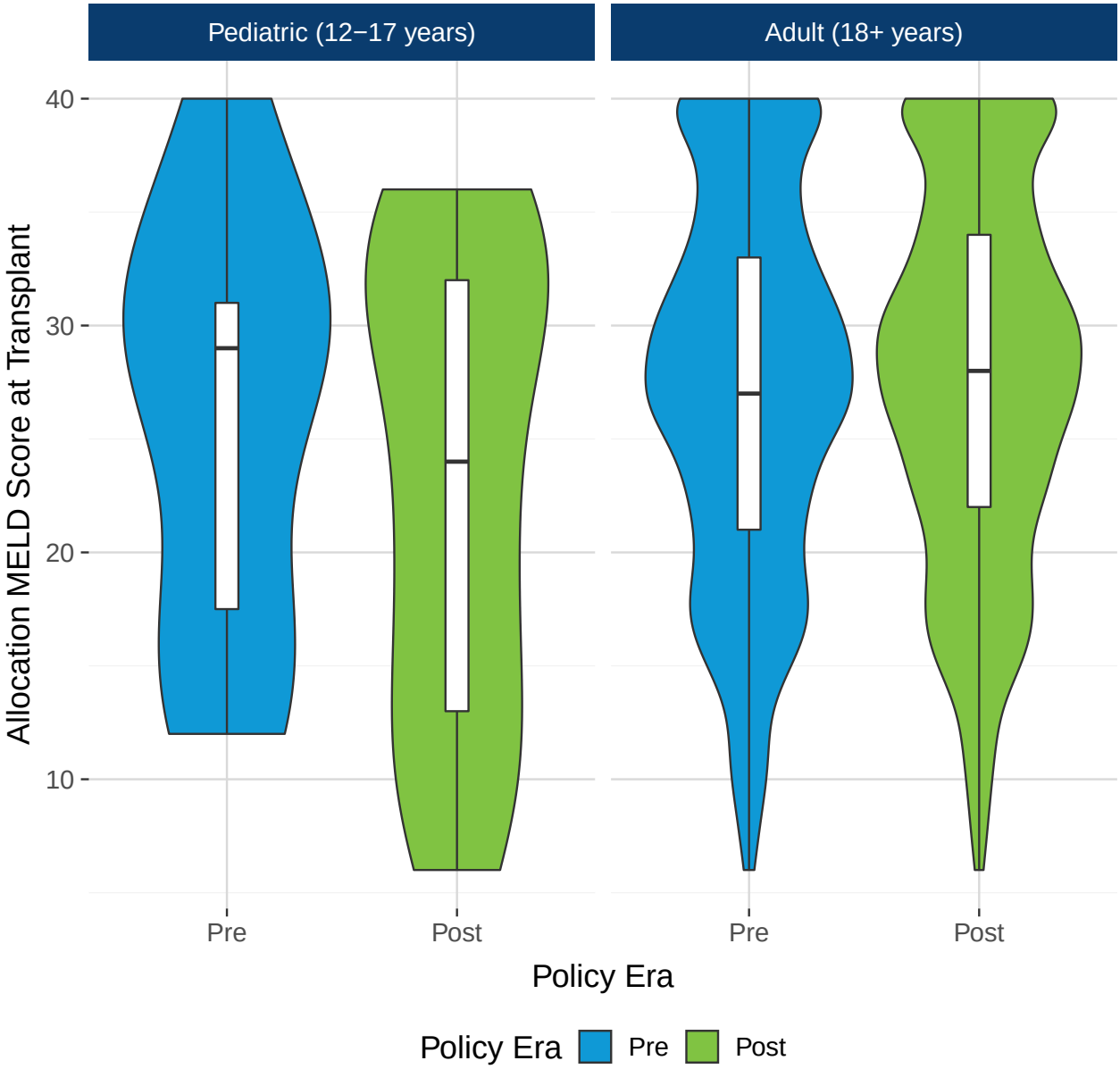
Appendix Table 4. Count and Percent of Liver Transplants among Recipients Aged 12 Years and Older by Age at Transplant and Era

Age (Years)	Pre	Post
Pediatric (12-17 years)	20 (0.9%)	24 (1.1%)
Adult (18+ years)	2172 (99.1%)	2195 (98.9%)
Total	2192 (100.0%)	2219 (100.0%)

Appendix Figure 5. Distribution of Allocation MELD Score or Status at Transplant for Liver-Alone Transplant Recipients Aged 12 Years and Older by Age at Transplant and Era



Appendix Figure 6. Distribution of Allocation MELD Score at Transplant for Liver-Alone Transplant Recipients Aged 12 Years and Older by Age at Transplant and Era



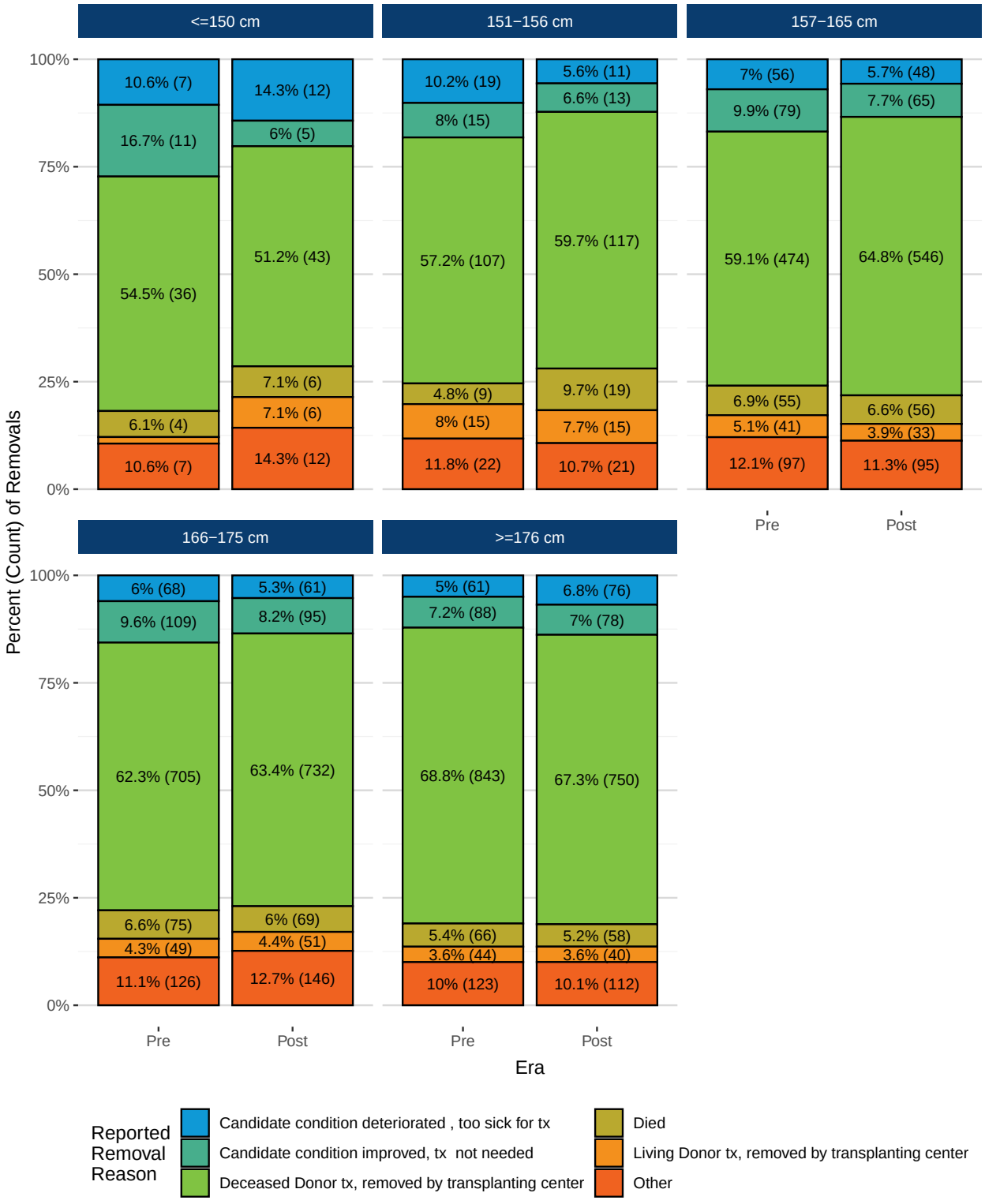
Status 1A/1B recipients were excluded because they do not have allocation MELD scores at transplant.
Pre−policy, 9 (45%) and 53 (2.44%) Status 1A/1B recipients were in the Pediatric (12−17 years) and Adult (18+ years) age groups, respectively.
Post−policy, 7 (29.17%) and 45 (2.05%) Status 1A/1B recipients were in the Pediatric (12−17 years) and Adult (18+ years) age groups, respectively.

Appendix Table 5. Summary of Allocation PELD Score at Transplant for Liver-Alone Transplant Recipients Aged 12 Years and Older by Age at Transplant and Era

Age (Years)	Policy Era	N	Minimum	25th Percentile	Median	75th Percentile	Maximum	Interquartile Range
Pediatric (12-17 years)	Pre	11	12	17.5	29	31	40	13.5
	Post	17	6	13.0	24	32	36	19.0
Adult (18+ years)	Pre	2119	6	21.0	27	33	40	12.0
	Post	2150	6	22.0	28	34	40	12.0

Status 1A/1B recipients were excluded because they do not have allocation MELD scores at transplant
Pre-policy, 9 (45%) and 53 (2.44%) Status 1A/1B recipients were in the Pediatric (12-17 years) and Adult (18+ years) age groups, respectively. Post-policy, 7 (29.17%) and 45 (2.05%) Status 1A/1B recipients were in the Pediatric (12-17 years) and Adult (18+ years) age groups, respectively.

Appendix Figure 7. Count and Percent of Liver Candidates 12 Years and Older Removed from the Waiting List by Reported Removal Reason, Height at Removal, and Era

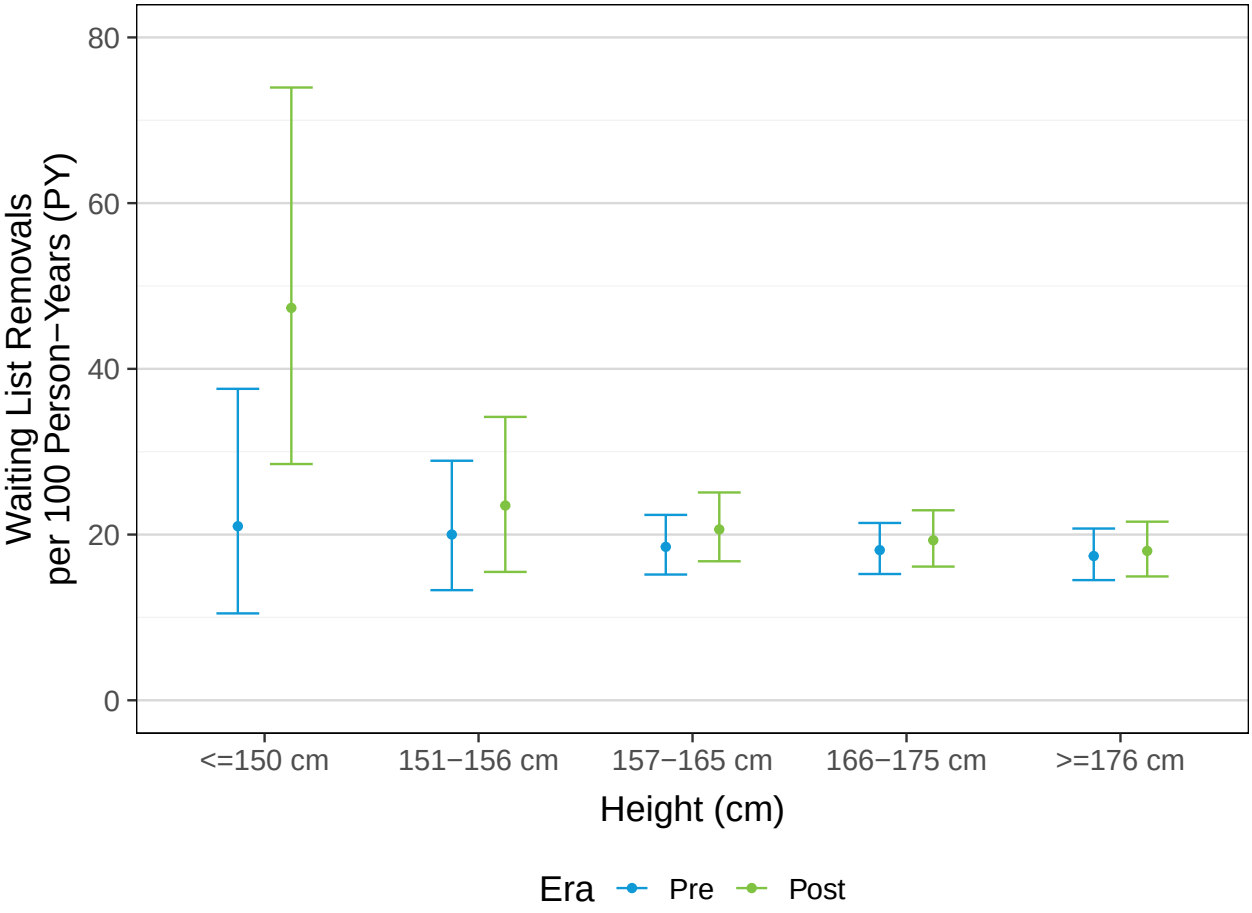


*Removal reasons containing <3% of forms in both policy eras were combined with the Other category for plotting purposes, but appear in the corresponding table.

Appendix Table 6. Count and Percent of Liver Candidates Aged 12 Years and Older Removed from the Waiting List by Reported Removal Reason, Height at Removal, and Era

	<=150 cm		151-156 cm		157-165 cm		166-175 cm		>=176 cm	
Reported Removal Reason	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Candidate condition deteriorated , too sick for tx	7 (10.6%)	12 (14.3%)	19 (10.2%)	11 (5.6%)	56 (7.0%)	48 (5.7%)	68 (6.0%)	61 (5.3%)	61 (5.0%)	76 (6.8%)
Candidate condition improved, tx not needed	11 (16.7%)	5 (6.0%)	15 (8.0%)	13 (6.6%)	79 (9.9%)	65 (7.7%)	109 (9.6%)	95 (8.2%)	88 (7.2%)	78 (7.0%)
Candidate Removed in Error	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)	0 (0.0%)
Deceased Donor tx, removed by transplanting center	36 (54.5%)	43 (51.2%)	107 (57.2%)	117 (59.7%)	474 (59.1%)	546 (64.8%)	705 (62.3%)	732 (63.4%)	843 (68.8%)	750 (67.3%)
Died	4 (6.1%)	6 (7.1%)	9 (4.8%)	19 (9.7%)	55 (6.9%)	56 (6.6%)	75 (6.6%)	69 (6.0%)	66 (5.4%)	58 (5.2%)
Living Donor tx, removed by transplanting center	1 (1.5%)	6 (7.1%)	15 (8.0%)	15 (7.7%)	41 (5.1%)	33 (3.9%)	49 (4.3%)	51 (4.4%)	44 (3.6%)	40 (3.6%)
Other	5 (7.6%)	5 (6.0%)	17 (9.1%)	16 (8.2%)	54 (6.7%)	51 (6.0%)	67 (5.9%)	89 (7.7%)	61 (5.0%)	57 (5.1%)
Patient died during TX procedure	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	1 (0.1%)	2 (0.2%)	2 (0.2%)	3 (0.3%)	0 (0.0%)	1 (0.1%)
Refused transplant	0 (0.0%)	0 (0.0%)	1 (0.5%)	3 (1.5%)	10 (1.2%)	12 (1.4%)	11 (1.0%)	12 (1.0%)	13 (1.1%)	14 (1.3%)
Transferred to another center	0 (0.0%)	1 (1.2%)	0 (0.0%)	0 (0.0%)	9 (1.1%)	6 (0.7%)	10 (0.9%)	3 (0.3%)	9 (0.7%)	4 (0.4%)
Transplant at another center (multi-listed)	1 (1.5%)	5 (6.0%)	2 (1.1%)	0 (0.0%)	15 (1.9%)	15 (1.8%)	24 (2.1%)	24 (2.1%)	24 (2.0%)	26 (2.3%)
Transplanted in another country	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)	0 (0.0%)
Unable to contact candidate	1 (1.5%)	1 (1.2%)	1 (0.5%)	2 (1.0%)	8 (1.0%)	9 (1.1%)	10 (0.9%)	15 (1.3%)	14 (1.1%)	10 (0.9%)
Total	66 (100.0%)	84 (100.0%)	187 (100.0%)	196 (100.0%)	802 (100.0%)	843 (100.0%)	1132 (100.0%)	1154 (100.0%)	1225 (100.0%)	1114 (100.0%)

Appendix Figure 8. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Person-Years Waiting among Candidates Aged 12 Years and Older by Height and Era



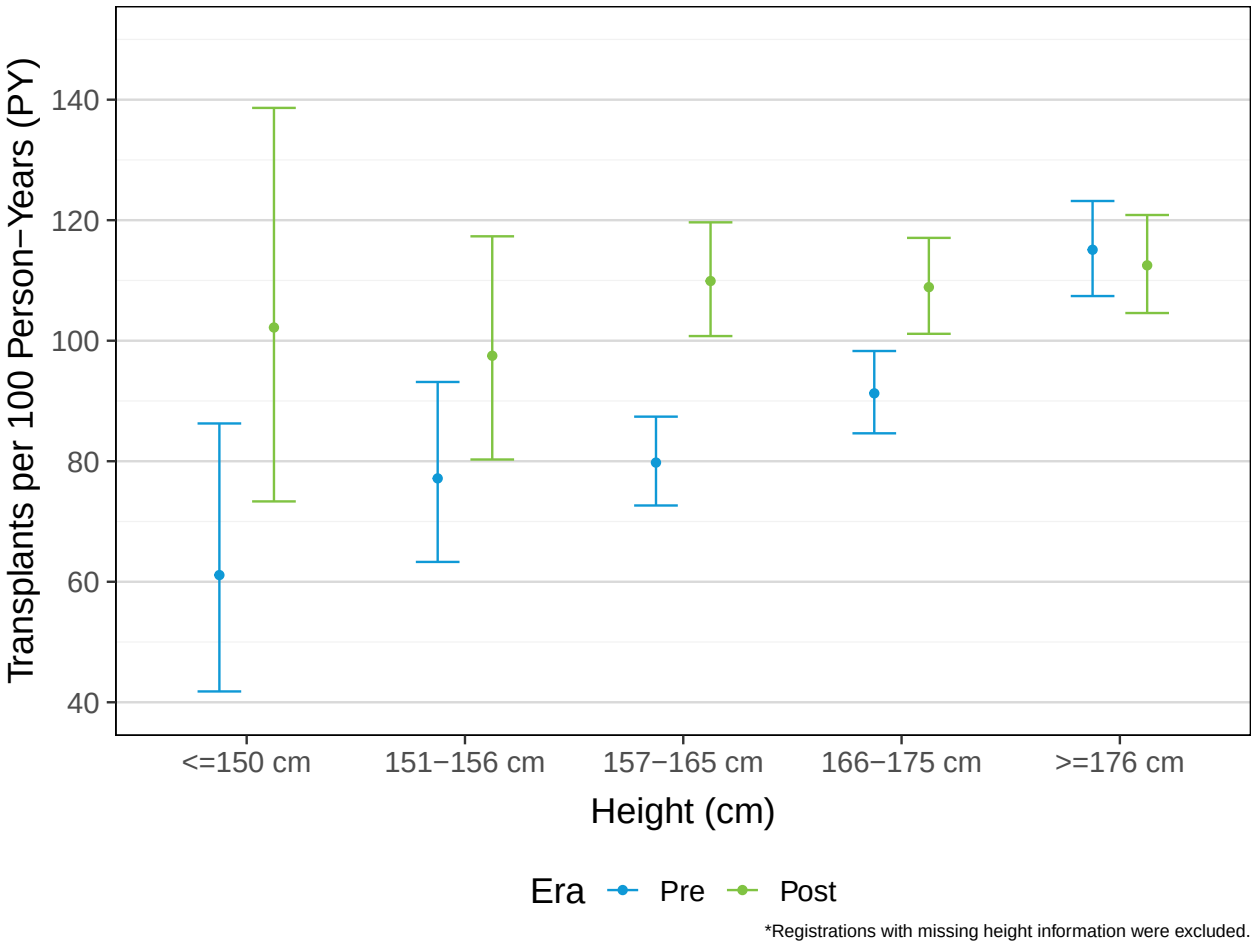
*Registrations with missing height information were excluded.

Appendix Table 7. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Person-Years Waiting among Candidates Aged 12 Years and Older by Height and Era

		Ever Waiting	Death/Too Sick Events	Person-Years (PY)	Removals per 100 PY	
Era	Height (cm)	N	N	PY	Estimate	95% CI
Pre	<=150 cm	270	11	52.4	21.01	(10.49, 37.59)
	151-156 cm	740	28	140.0	20.00	(13.29, 28.91)
	157-165 cm	3025	107	577.9	18.52	(15.17, 22.37)
	166-175 cm	4113	139	767.0	18.12	(15.24, 21.40)
	>=176 cm	4023	126	723.8	17.41	(14.50, 20.73)
Post	<=150 cm	283	19	40.1	47.36	(28.51, 73.95)
	151-156 cm	742	27	114.9	23.51	(15.49, 34.20)
	157-165 cm	3113	100	485.0	20.62	(16.78, 25.08)
	166-175 cm	4064	130	673.2	19.31	(16.13, 22.93)
	>=176 cm	3864	120	665.7	18.03	(14.94, 21.55)

Registrations with missing height information were excluded.

Appendix Figure 9. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting among Candidates Aged 12 Years and Older by Height and Era



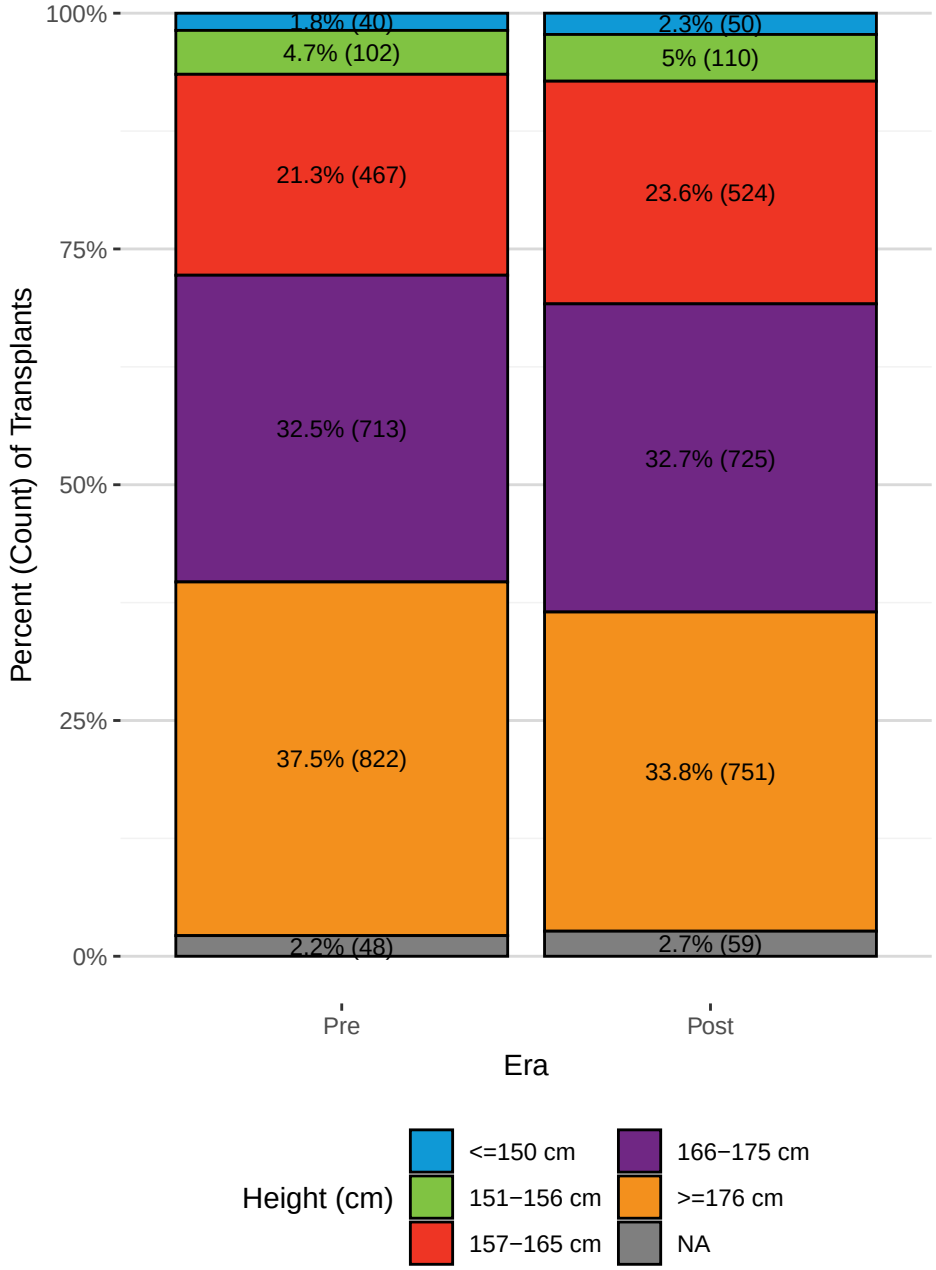
*Registrations with missing height information were excluded.

Appendix Table 8. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting among Candidates Aged 12 Years and Older by Height and Era

		Ever Waiting	Transplant Events	Active Person-Years (PY)	Transplants per 100 Active PY	
Era	Height (cm)	N	N	PY	Estimate	95% CI
Pre	<=150 cm	270	32	52.4	61.11	(41.80, 86.27)
	151-156 cm	740	108	140.0	77.15	(63.29, 93.15)
	157-165 cm	3025	461	577.9	79.77	(72.66, 87.40)
	166-175 cm	4113	700	767.0	91.27	(84.63, 98.29)
	>=176 cm	4023	833	723.8	115.09	(107.41, 123.18)
Post	<=150 cm	283	41	40.1	102.19	(73.33, 138.64)
	151-156 cm	742	112	114.9	97.51	(80.29, 117.32)
	157-165 cm	3113	533	485.0	109.91	(100.77, 119.64)
	166-175 cm	4064	733	673.2	108.89	(101.15, 117.06)
	>=176 cm	3864	749	665.7	112.51	(104.59, 120.86)

Registrations with missing height information were excluded.

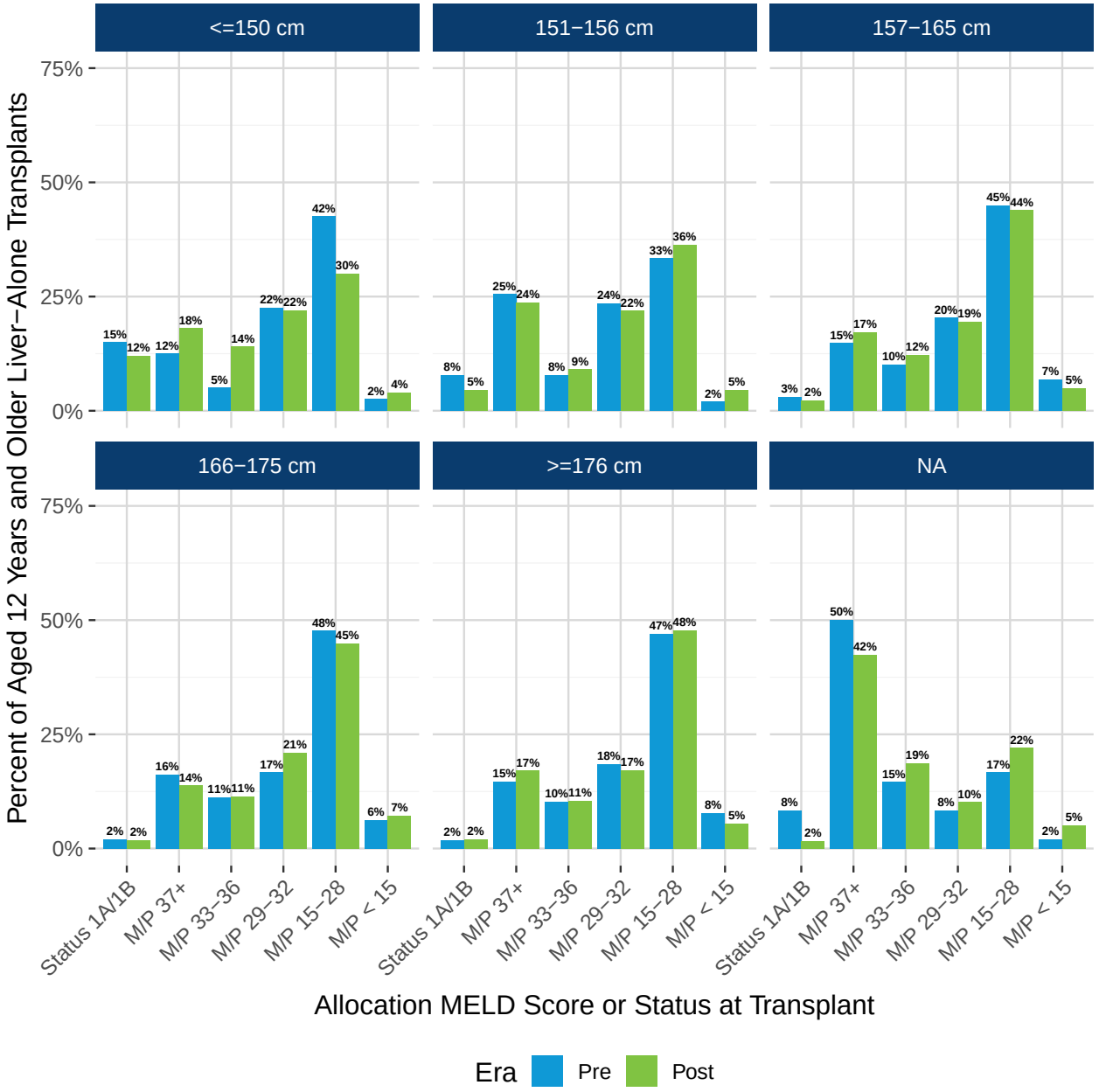
Appendix Figure 10. Count and Percent of Liver Transplants among Recipients Aged 12 Years and Older by Height at Transplant and Era



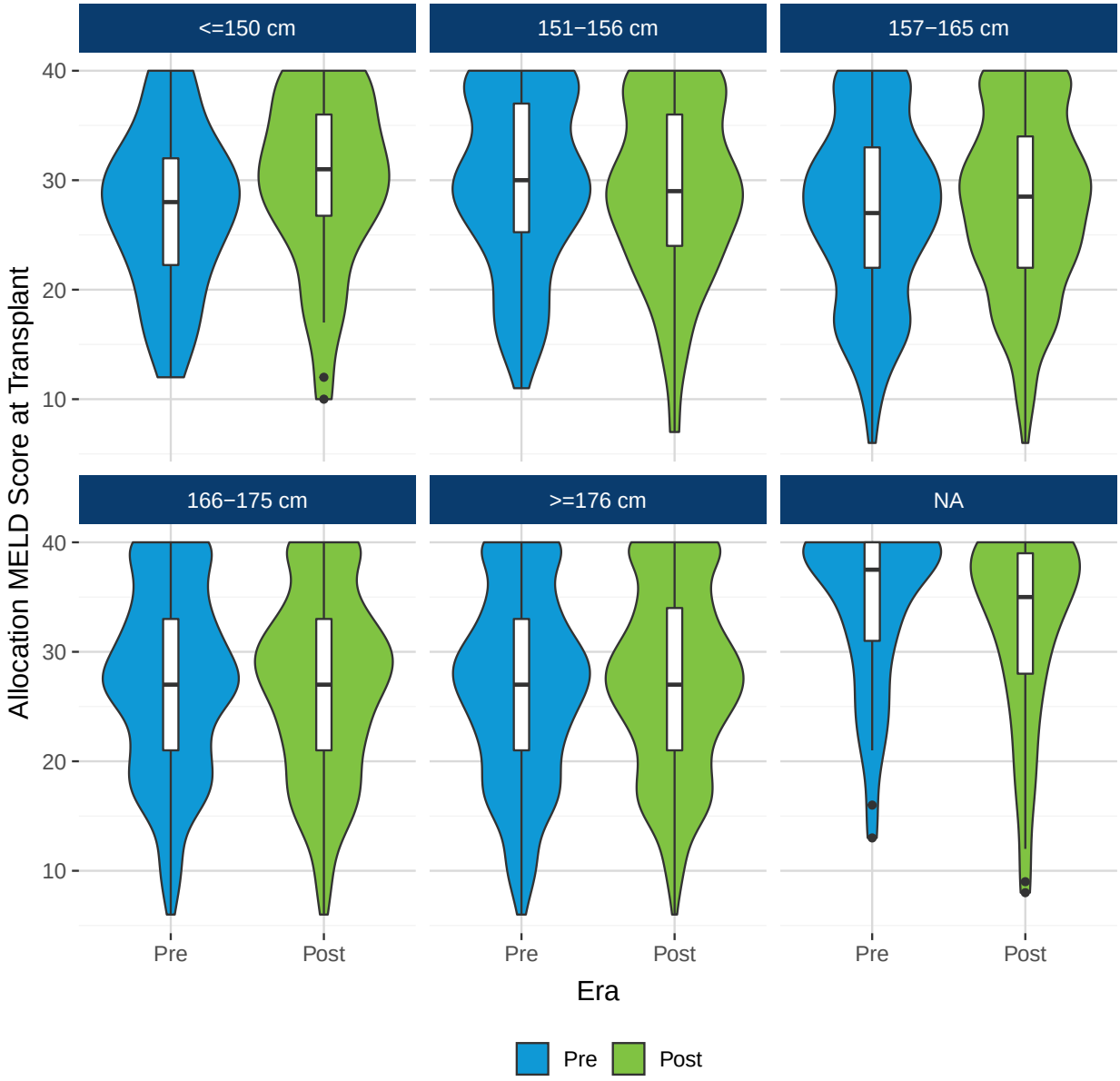
Appendix Table 9. Count and Percent of Liver Transplants among Recipients Aged 12 Years and Older by Height at Transplant and Era

Height (cm)	Pre	Post
<=150 cm	40 (1.8%)	50 (2.3%)
151-156 cm	102 (4.7%)	110 (5.0%)
157-165 cm	467 (21.3%)	524 (23.6%)
166-175 cm	713 (32.5%)	725 (32.7%)
>=176 cm	822 (37.5%)	751 (33.8%)
NA	48 (2.2%)	59 (2.7%)
Total	2192 (100.0%)	2219 (100.0%)

Appendix Figure 11. Distribution of Allocation MELD Score or Status at Transplant for Liver-Alone Transplant Recipients Aged 12 Years and Older by Height at Transplant and Era



Appendix Figure 12. Distribution of Allocation MELD Score at Transplant for Liver-Alone Transplant Recipients Aged 12 Years and Older by Height at Transplant and Era



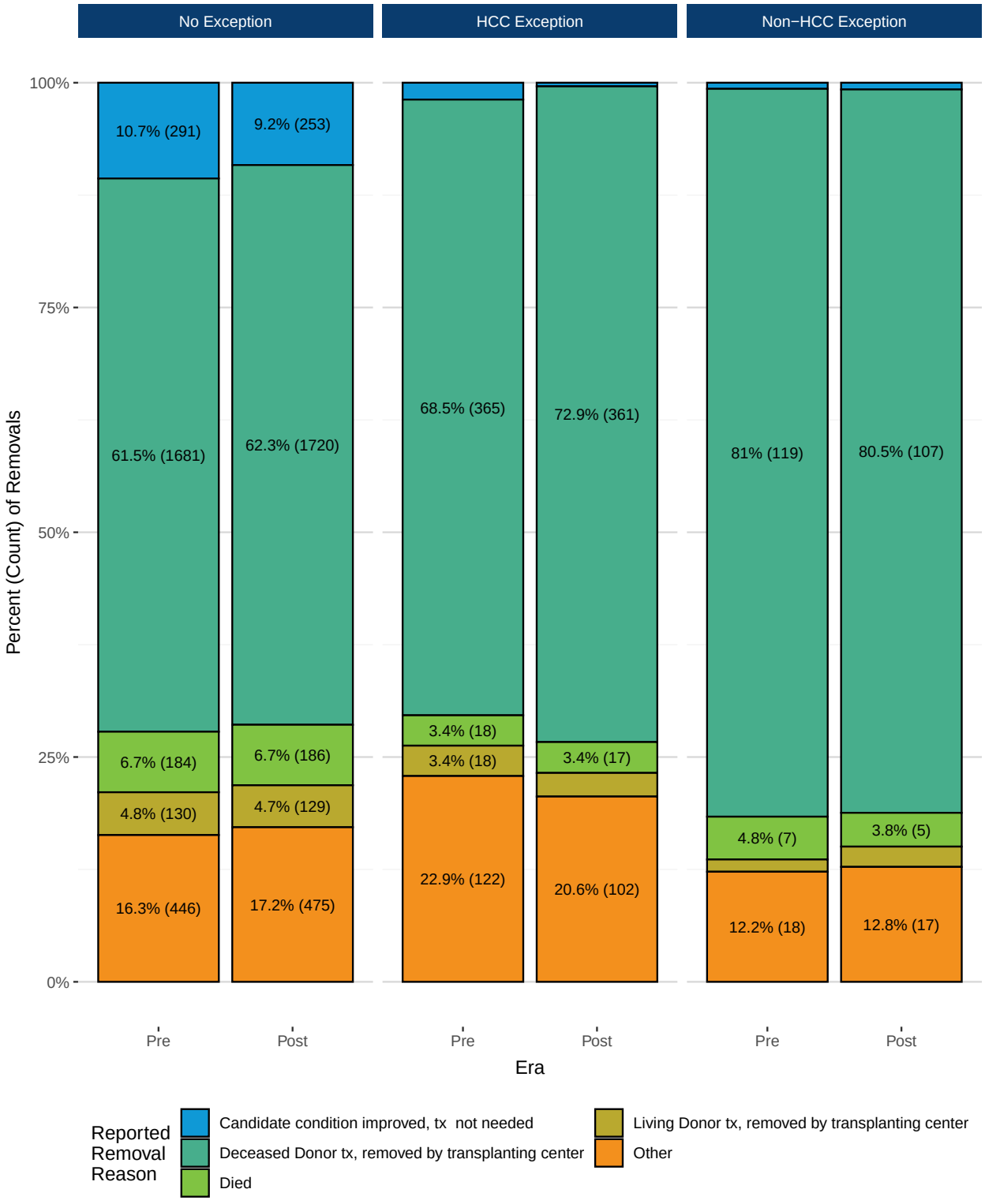
ecipients who received transplant while in Status 1A/1B were excluded because they do not have allocation MELD scores at transplant. Pre−policy, 6 (15%), 8 (7.84%), 14 (3%), 15 (2.1%), 15 (1.82%), and 4 (8.33%) Status 1A/1B recipients were in the <150 cm, 151−156 cm, 157−165 cm, 166−175 cm, >176 cm, and missing height groups, respectively. Post−policy, 6 (12%), 5 (4.55%), 12 (2.29%), 13 (1.79%), 15 (2%), and 1 (1.69%) Status 1A/1B recipients were in the <150 cm, 151−156 cm, 157−165 cm, 166−175 cm, >176 cm, and missing height groups, respectively.

Appendix Table 10. Summary of Allocation PELD Score at Transplant for Liver-Alone Transplant Recipients Aged 12 Years and Older by Height at Transplant and Era

Height (cm)	Policy Era	N	Minimum	25th Percentile	Median	75th Percentile	Maximum	Interquartile Range
<=150 cm	Pre	34	12	22.2	28.0	32	40	9.8
	Post	44	10	26.8	31.0	36	40	9.2
151-156 cm	Pre	94	11	25.2	30.0	37	40	11.8
	Post	105	7	24.0	29.0	36	40	12.0
157-165 cm	Pre	453	6	22.0	27.0	33	40	11.0
	Post	512	6	22.0	28.5	34	40	12.0
166-175 cm	Pre	698	6	21.0	27.0	33	40	12.0
	Post	712	6	21.0	27.0	33	40	12.0
>=176 cm	Pre	807	6	21.0	27.0	33	40	12.0
	Post	736	6	21.0	27.0	34	40	13.0
NA	Pre	44	13	31.0	37.5	40	40	9.0
	Post	58	8	28.0	35.0	39	40	11.0

Recipients who received transplant while in Status 1A/1B were excluded because they do not have allocation MELD scores at transplant. Pre-policy, 6 (15%) , 8 (7.84%) , 14 (3%) , 15 (2.1%) , 15 (1.82%) , and 4 (8.33%) Status 1A/1B recipients were in the <150 cm, 151-156 cm, 157-165 cm, 166-175 cm, >176 cm, and missing height groups, respectively. Post-policy, 6 (12%) , 5 (4.55%) , 12 (2.29%) , 13 (1.79%) , 15 (2%) , and 1 (1.69%) Status 1A/1B recipients were in the <150 cm, 151-156 cm, 157-165 cm, 166-175 cm, >176 cm, and missing height groups, respectively.

Appendix Figure 13. Count and Percent of Liver Candidates 12 Years and Older Removed from the Waiting List by Reported Removal Reason, Exception Type, and Era

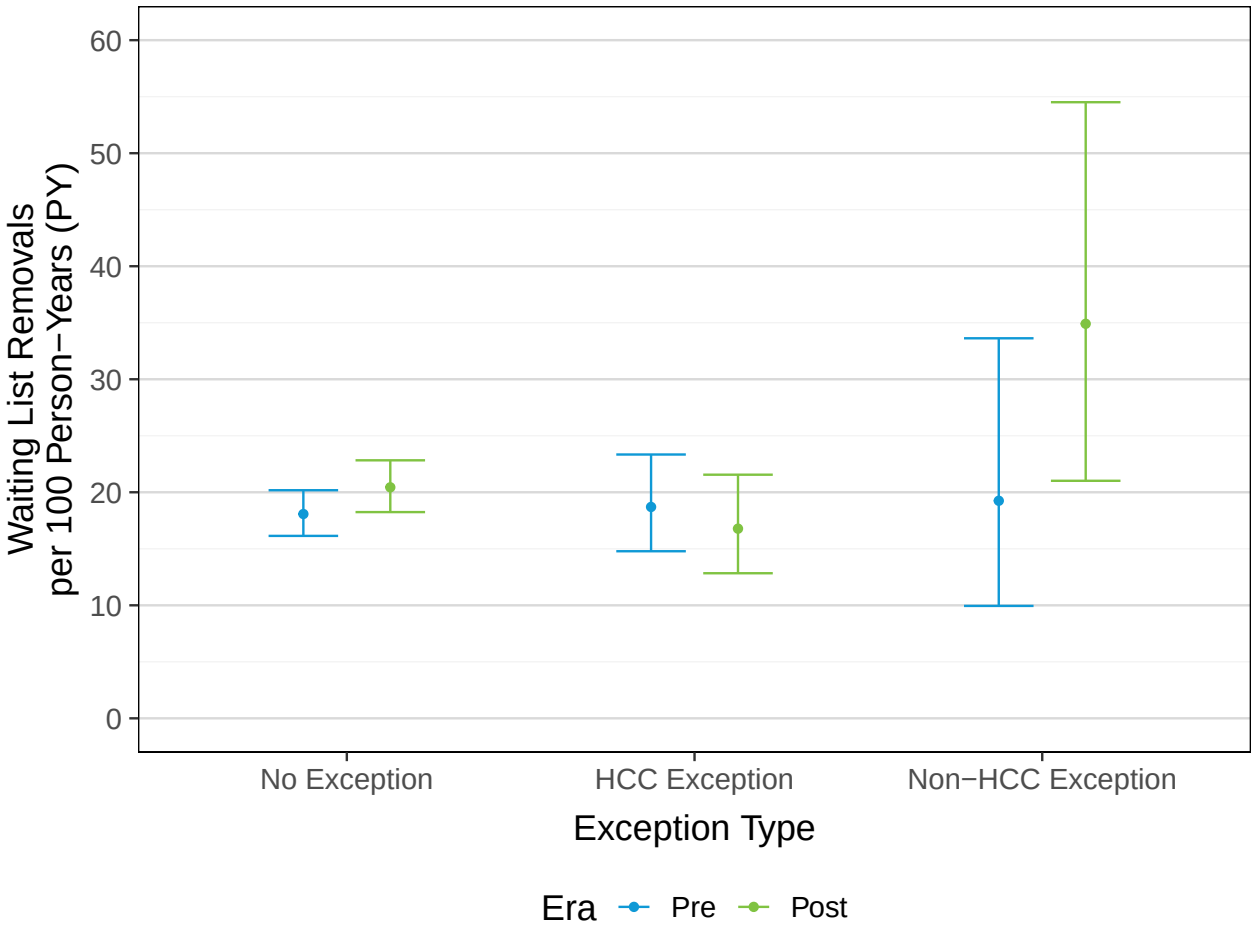


*Removal reasons containing <3% of forms in both policy eras were combined with the Other category for plotting purposes, but appear in the corresponding table.

Appendix Table 11. Count and Percent of Liver Candidates Aged 12 Years and Older Removed from the Waiting List by Reported Removal Reason, Exception Type, and Era

	No Exception		HCC Exception		Non-HCC Exception	
Reported Removal Reason	Pre	Post	Pre	Post	Pre	Post
Deceased Donor tx, removed by transplanting center	1681 (61.5%)	1720 (62.3%)	365 (68.5%)	361 (72.9%)	119 (81.0%)	107 (80.5%)
Candidate condition improved, tx not needed	291 (10.7%)	253 (9.2%)	10 (1.9%)	2 (0.4%)	1 (0.7%)	1 (0.8%)
Died	184 (6.7%)	186 (6.7%)	18 (3.4%)	17 (3.4%)	7 (4.8%)	5 (3.8%)
Other	169 (6.2%)	185 (6.7%)	29 (5.4%)	33 (6.7%)	6 (4.1%)	0 (0.0%)
Candidate condition deteriorated , too sick for tx	157 (5.7%)	157 (5.7%)	49 (9.2%)	38 (7.7%)	5 (3.4%)	13 (9.8%)
Living Donor tx, removed by transplanting center	130 (4.8%)	129 (4.7%)	18 (3.4%)	13 (2.6%)	2 (1.4%)	3 (2.3%)
Transplant at another center (multi-listed)	44 (1.6%)	55 (2.0%)	19 (3.6%)	13 (2.6%)	3 (2.0%)	2 (1.5%)
Unable to contact candidate	33 (1.2%)	37 (1.3%)	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Refused transplant	19 (0.7%)	28 (1.0%)	16 (3.0%)	13 (2.6%)	0 (0.0%)	0 (0.0%)
Transferred to another center	17 (0.6%)	11 (0.4%)	8 (1.5%)	2 (0.4%)	3 (2.0%)	1 (0.8%)
Patient died during TX procedure	4 (0.1%)	2 (0.1%)	0 (0.0%)	3 (0.6%)	0 (0.0%)	1 (0.8%)
Transplanted in another country	2 (0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Candidate Removed in Error	1 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.7%)	0 (0.0%)
Total	2732 (100.0%)	2763 (100.0%)	533 (100.0%)	495 (100.0%)	147 (100.0%)	133 (100.0%)

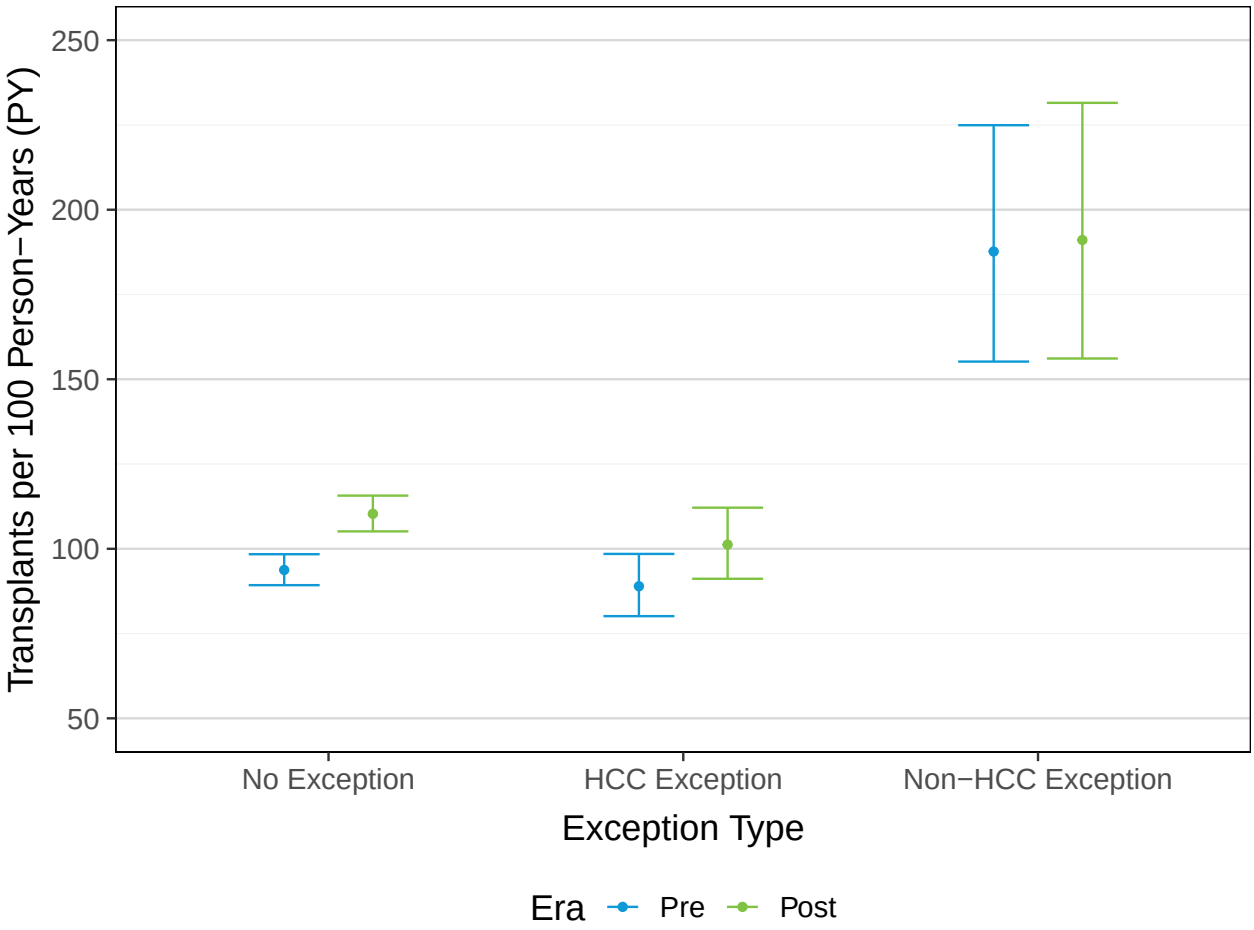
Appendix Figure 14. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Person-Years Waiting among Candidates Aged 12 Years and Older by Exception Type and Era



Appendix Table 12. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Person-Years Waiting among Candidates Aged 12 Years and Older by Exception Type and Era

		Ever Waiting	Death/Too Sick Events	Person-Years (PY)	Removals per 100 PY	
Era	Exception Type	N	N	PY	Estimate	95% CI
Pre	No Exception	9550	317	1753.6	18.08	(16.14, 20.18)
	HCC Exception	2088	78	417.1	18.70	(14.78, 23.34)
	Non-HCC Exception	363	12	62.3	19.25	(9.95, 33.62)
Post	No Exception	9515	315	1541.0	20.44	(18.25, 22.83)
	HCC Exception	2022	61	363.5	16.78	(12.84, 21.56)
	Non-HCC Exception	364	19	54.4	34.91	(21.02, 54.51)

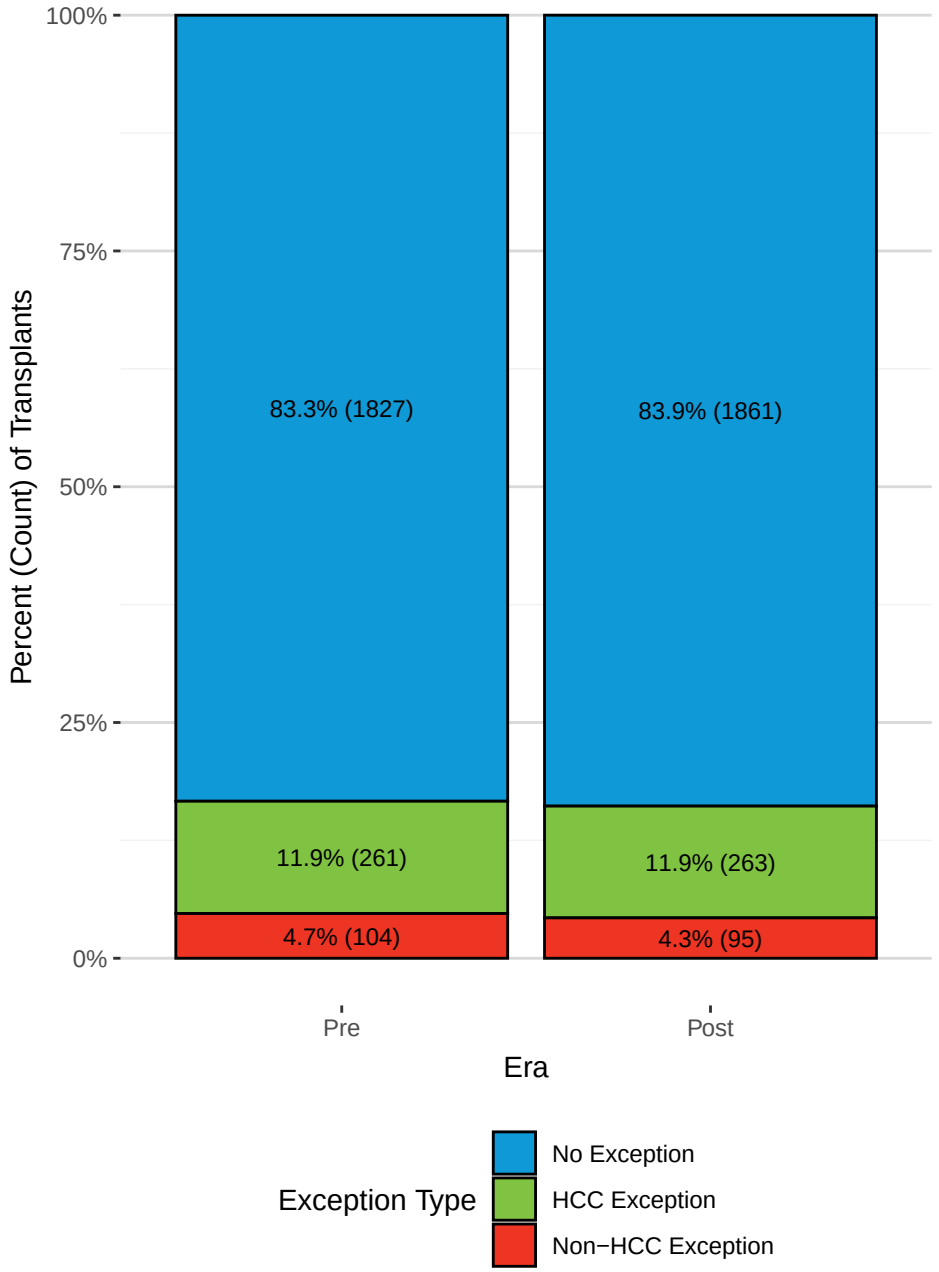
Appendix Figure 15. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting among Candidates Aged 12 Years and Older by Exception Type and Era



Appendix Table 13. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting among Candidates Aged 12 Years and Older by Exception Type and Era

		Ever Waiting	Transplant Events	Active Person-Years (PY)	Transplants per 100 Active PY	
Era	Exception Type	N	N	PY	Estimate	95% CI
Pre	No Exception	9550	1644	1753.6	93.75	(89.27, 98.40)
	HCC Exception	2088	371	417.1	88.95	(80.13, 98.48)
	Non-HCC Exception	363	117	62.3	187.67	(155.21, 224.92)
Post	No Exception	9515	1700	1541.0	110.32	(105.13, 115.69)
	HCC Exception	2022	368	363.5	101.23	(91.15, 112.12)
	Non-HCC Exception	364	104	54.4	191.07	(156.12, 231.51)

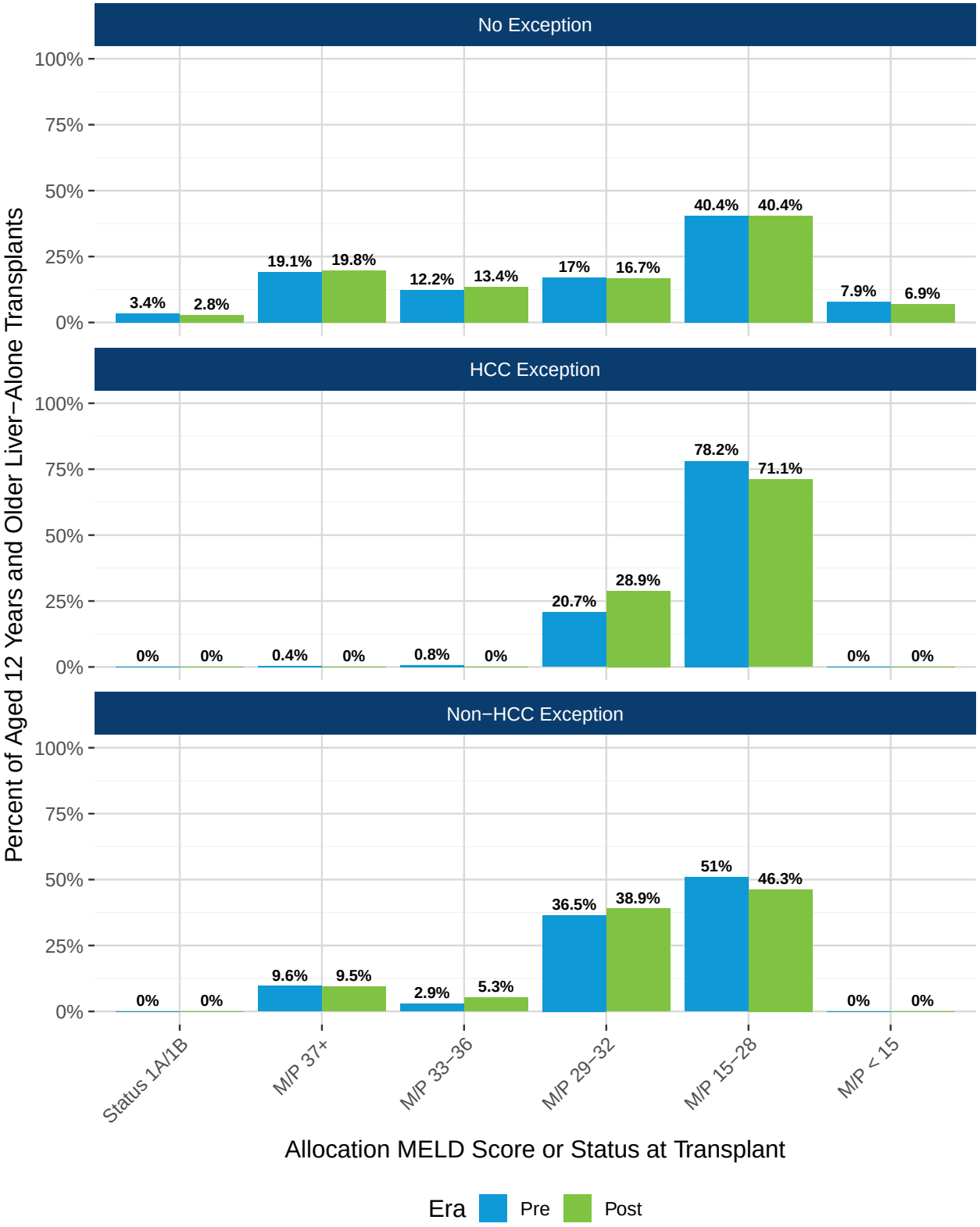
Appendix Figure 16. Count and Percent of Liver Transplants among Recipients Aged 12 Years and Older by Exception Type and Era



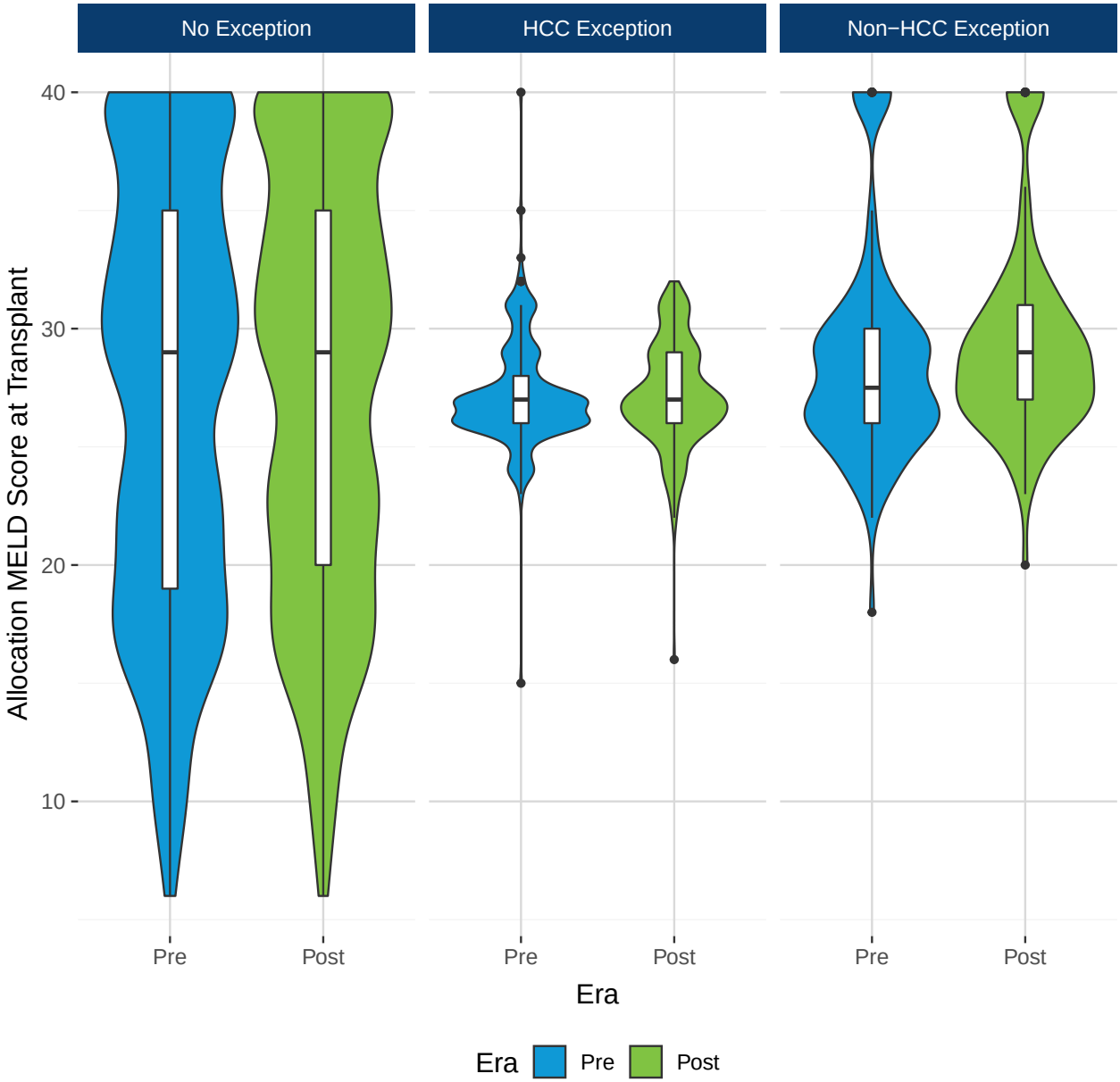
Appendix Table 14. Count and Percent of Liver Transplants among Recipients Aged 12 Years and Older by Exception Type and Era

Exception Type	Pre	Post
No Exception	1827 (83.3%)	1861 (83.9%)
HCC Exception	261 (11.9%)	263 (11.9%)
Non-HCC Exception	104 (4.7%)	95 (4.3%)
Total	2192 (100.0%)	2219 (100.0%)

Appendix Figure 17. Distribution of Allocation MELD Score or Status at Transplant for Liver-Alone Transplant Recipients Aged 12 Years and Older by Exception Type and Era



Appendix Figure 18. Distribution of Allocation MELD Score at Transplant for Liver-Alone Transplant Recipients Aged 12 Years and Older by Exception Type and Era



Status 1A/1B recipients do not have allocation MELD scores at transplant. As a result, 62 (3.39%) pre−policy recipients and 52 (2.79%) post−policy recipients were excluded.

Appendix Table 15. Summary of Allocation MELD Score at Transplant for Liver-Alone Transplant Recipients Aged 12 Years and Older by Exception Type and Era

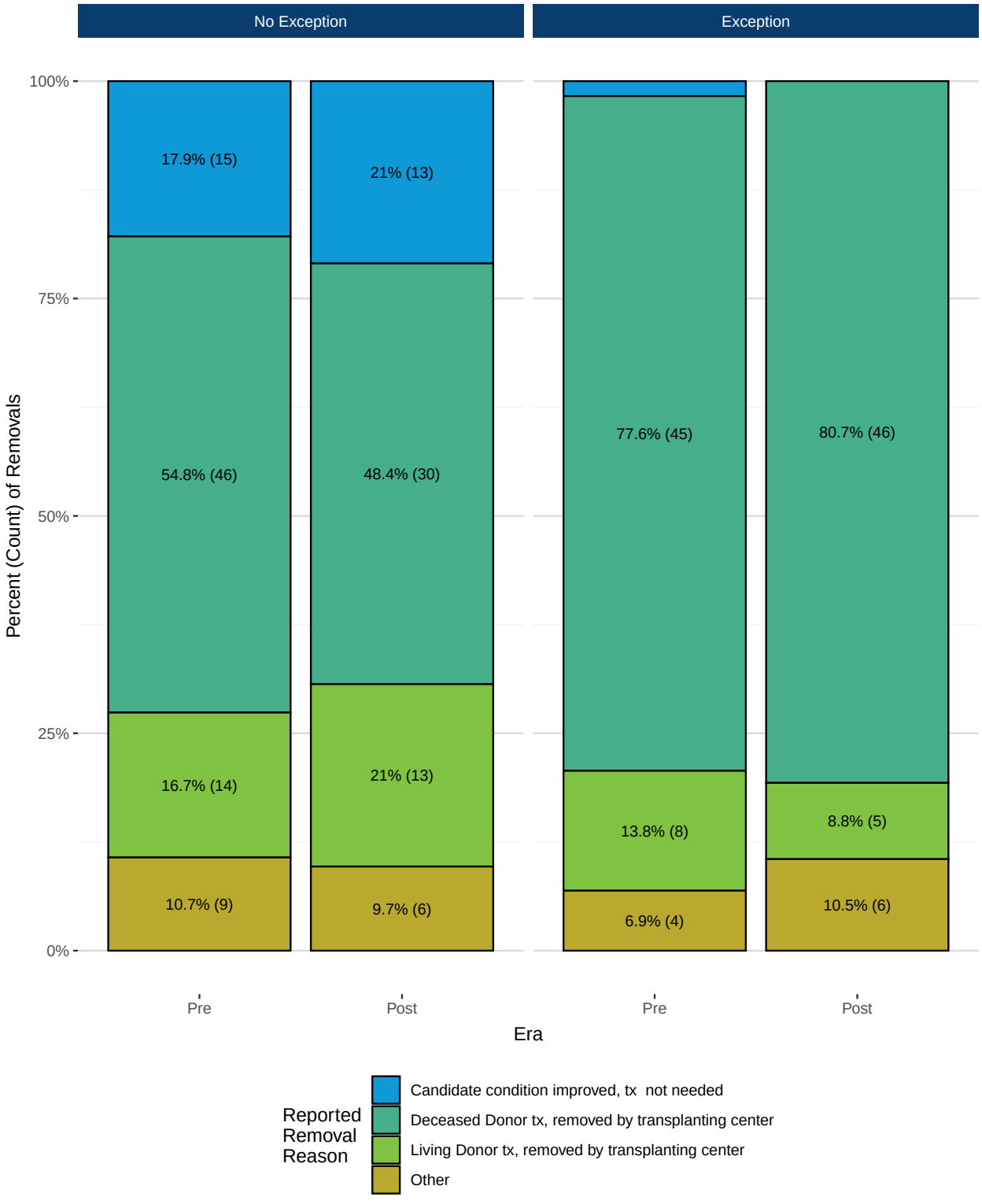
Exception Type	Policy Era	N	Minimum	25th Percentile	Median	75th Percentile	Maximum	Interquartile Range
No Exception	Pre	1765	6	19	29.0	35	40	16
	Post	1809	6	20	29.0	35	40	15
HCC Exception	Pre	261	15	26	27.0	28	40	2
	Post	263	16	26	27.0	29	32	3
Non-HCC Exception	Pre	104	18	26	27.5	30	40	4
	Post	95	20	27	29.0	31	40	4

Status 1A/1B recipients do not have allocation MELD scores. As a result,
62 (3.39%) pre-policy recipients and 52 (2.79%) post-policy recipients were excluded.

Additional PELD-Cr Results

This section stratifies the analyses shown in the main "PELD-Cr Results" section by exception type (no exception vs. exception). Note that exceptions are not further stratified into HCC exceptions vs. non-HCC exceptions here due to the fact that there are very few pediatric candidates with HCC exceptions. Results should still be interpreted cautiously as some subgroups have small sample sizes.

Appendix Figure 19. Count and Percent of Liver Candidates Aged 0-11 Years Removed from the Waiting List by Reported Removal Reason, Exception Type, and Era

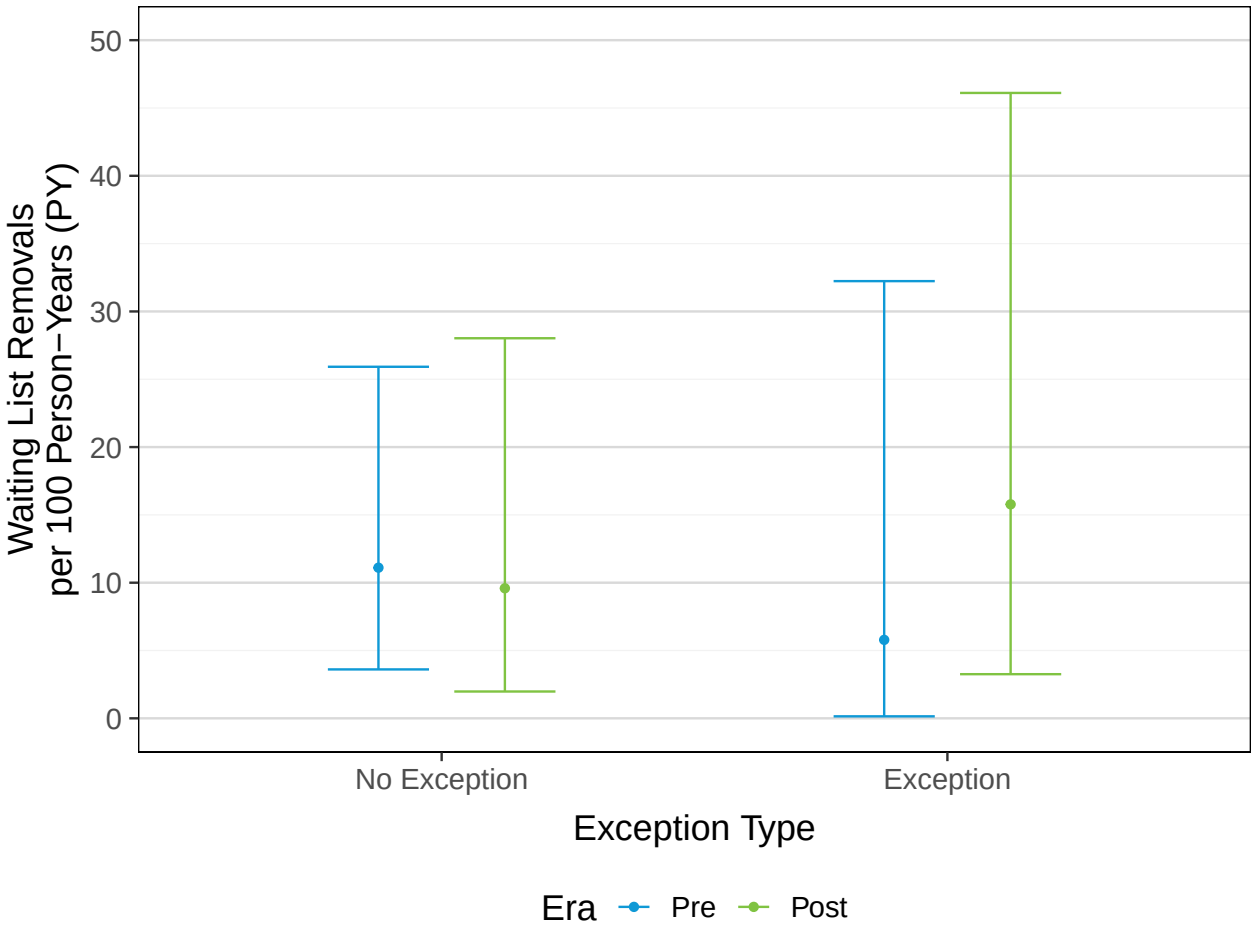


*Removal reasons containing <4 forms in both policy eras were combined with the Other category for plotting purposes, but appear in the corresponding table.

Appendix Table 16. Count and Percent of Liver Candidates Aged 0-11 Years Removed from the Waiting List by Reported Removal Reason, Exception Type, and Era

	No Exception		Exception	
Reported Removal Reason	Pre	Post	Pre	Post
Deceased Donor tx, removed by transplanting center	46 (54.8%)	30 (48.4%)	45 (77.6%)	46 (80.7%)
Candidate condition improved, tx not needed	15 (17.9%)	13 (21.0%)	1 (1.7%)	0 (0.0%)
Living Donor tx, removed by transplanting center	14 (16.7%)	13 (21.0%)	8 (13.8%)	5 (8.8%)
Candidate condition deteriorated , too sick for tx	3 (3.6%)	1 (1.6%)	0 (0.0%)	0 (0.0%)
Transplant at another center (multi-listed)	3 (3.6%)	0 (0.0%)	2 (3.4%)	3 (5.3%)
Died	2 (2.4%)	2 (3.2%)	1 (1.7%)	3 (5.3%)
Transferred to another center	1 (1.2%)	0 (0.0%)	1 (1.7%)	0 (0.0%)
Other	0 (0.0%)	3 (4.8%)	0 (0.0%)	0 (0.0%)
Total	84 (100.0%)	62 (100.0%)	58 (100.0%)	57 (100.0%)

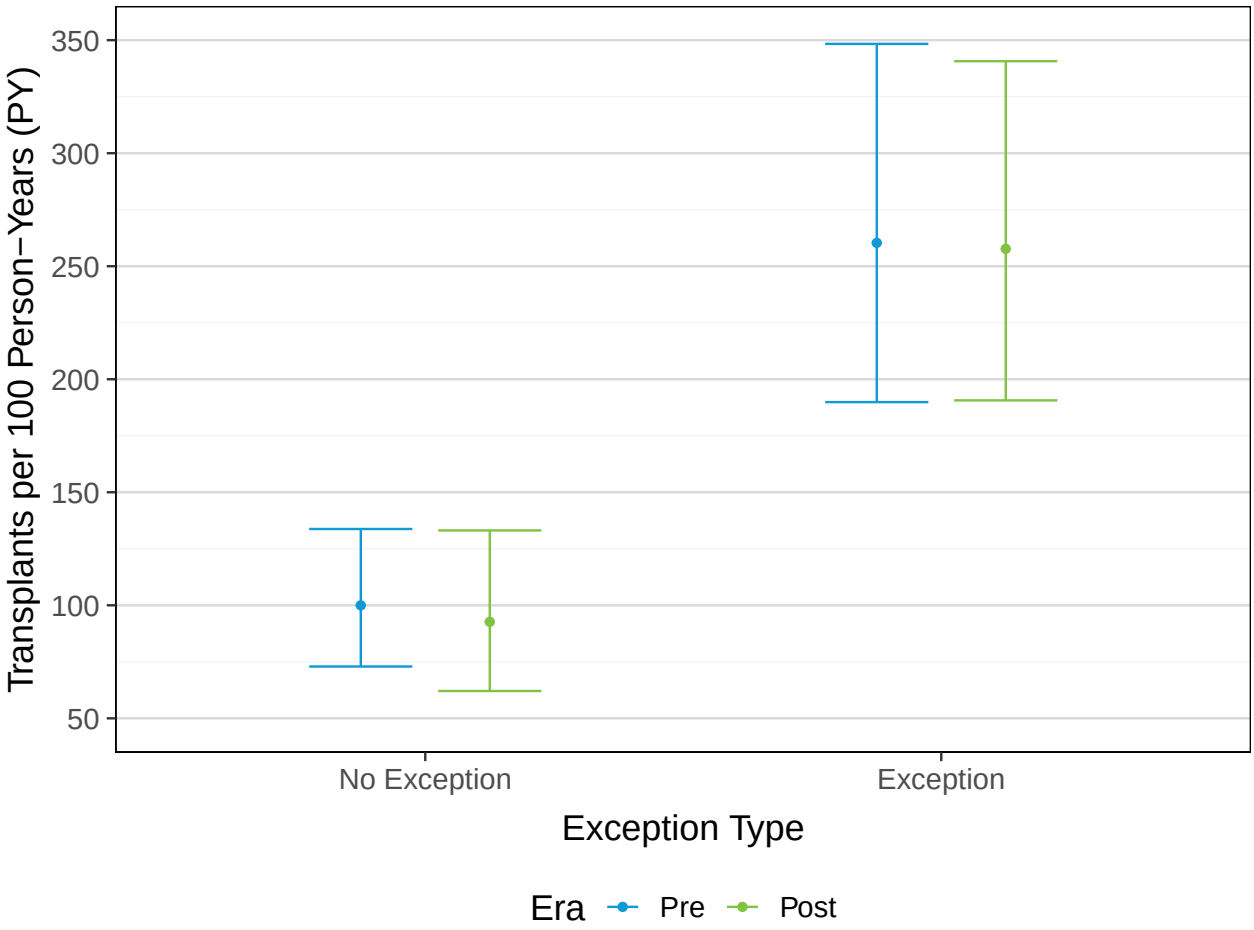
Appendix Figure 20. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Person-Years Waiting among Candidates Aged 0-11 Years by Exception Type and Era



Appendix Table 17. Liver-Alone Waiting List Deaths or Removals for Too Sick Per 100 Person-Years Waiting among Candidates Aged 0-11 Years by Exception Type and Era

		Ever Waiting	Death/Too Sick Events	Person-Years (PY)	Removals per 100 PY	
Era	Exception Type	N	N	PY	Estimate	95% CI
Pre	No Exception	269	5	45.0	11.11	(3.61, 25.92)
	Exception	114	1	17.3	5.79	(0.15, 32.23)
Post	No Exception	223	3	31.3	9.59	(1.98, 28.02)
	Exception	127	3	19.0	15.78	(3.25, 46.11)

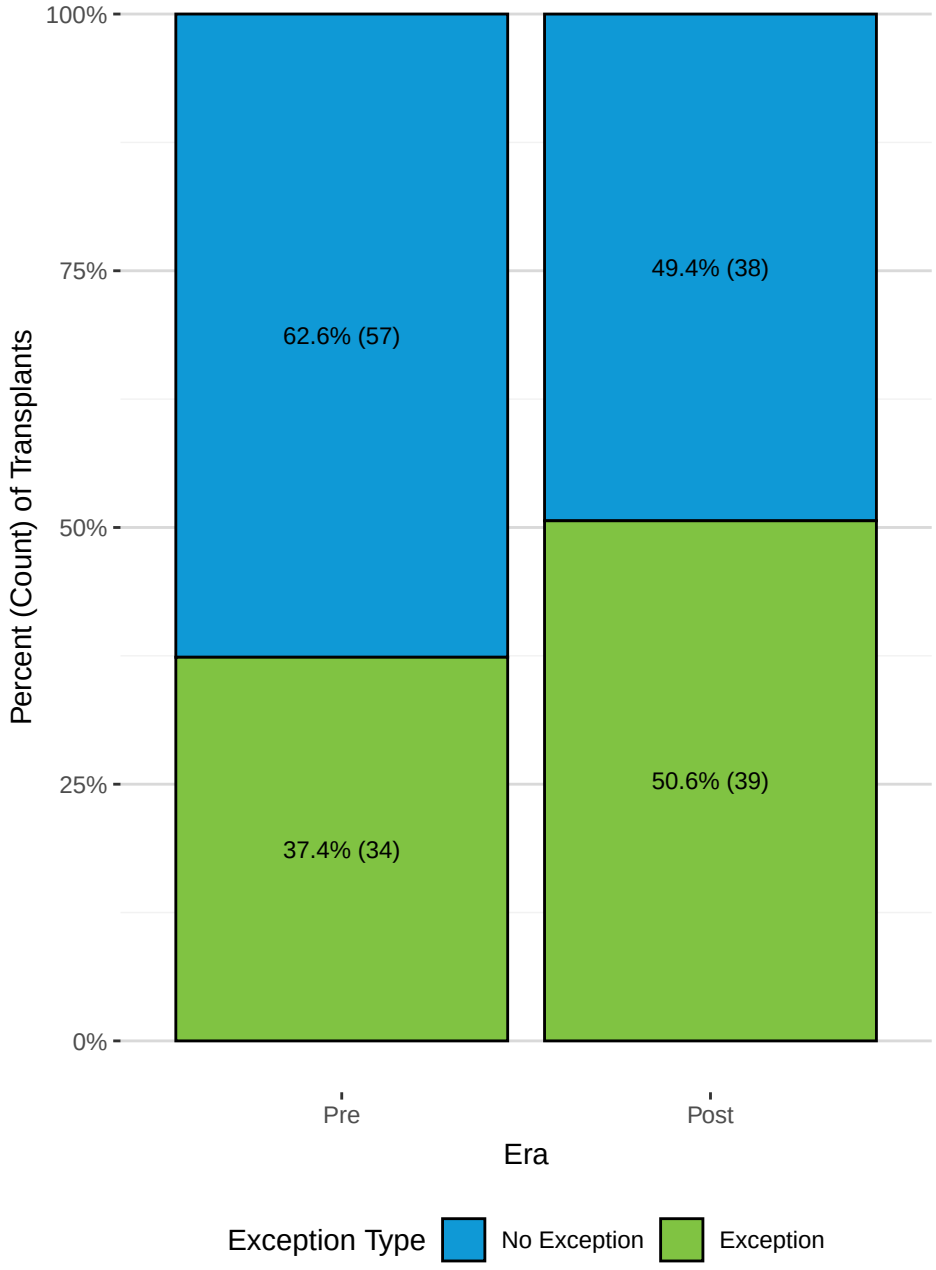
Appendix Figure 21. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting among Candidates Aged 0-11 Years by Exception Type and Era



Appendix Table 18. Liver-Alone Transplant Rates Per 100 Active Person-Years Waiting among Candidates Aged 0-11 Years by Exception Type and Era

		Ever Waiting	Transplant Events	Active Person-Years (PY)	Transplants per 100 Active PY	
Era	Exception Type	N	N	PY	Estimate	95% CI
Pre	No Exception	269	45	45.0	99.96	(72.91, 133.76)
	Exception	114	45	17.3	260.34	(189.90, 348.36)
Post	No Exception	223	29	31.3	92.70	(62.08, 133.13)
	Exception	127	49	19.0	257.71	(190.65, 340.70)

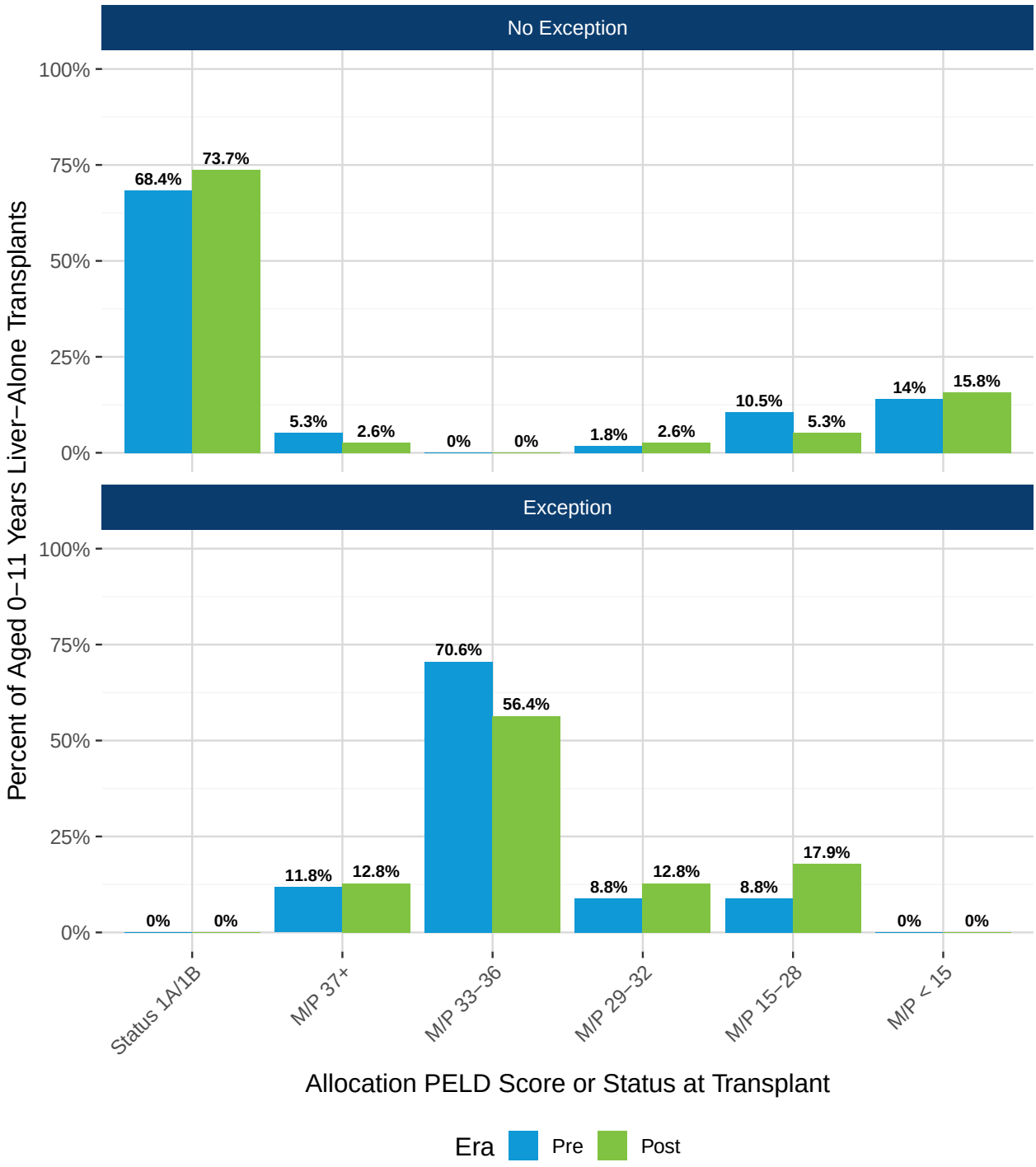
Appendix Figure 22. Count and Percent of Liver Transplants among Recipients Aged 0-11 Years by Exception Type and Era



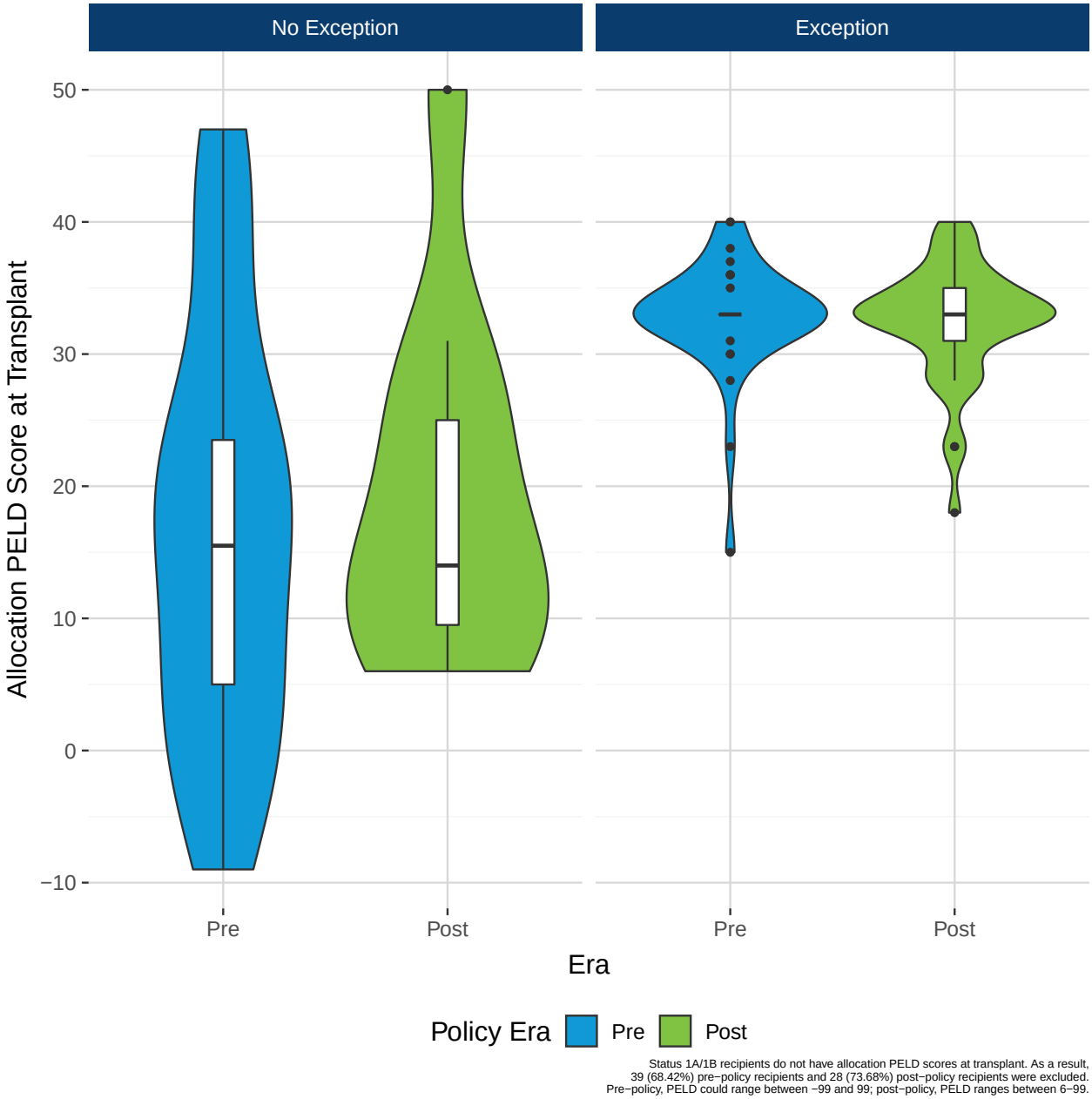
Appendix Table 19. Count and Percent of Liver Transplants among Recipients Aged 0-11 Years by Exception Type and Era

Exception Type	Pre	Post
No Exception	57 (62.6%)	38 (49.4%)
Exception	34 (37.4%)	39 (50.6%)
Total	91 (100.0%)	77 (100.0%)

Appendix Figure 23. Distribution of Allocation PELD Score or Status at Transplant for Liver-Alone Transplant Recipients Aged 0-11 Years by Exception Type and Era



Appendix Figure 24. Distribution of Allocation PELD Score at Transplant for Liver-Alone Transplant Recipients Aged 0-11 Years by Exception Type and Era



Status 1A/1B recipients do not have allocation PELD scores at transplant. As a result, 39 (68.42%) pre−policy recipients and 28 (73.68%) post−policy recipients were excluded. Pre−policy, PELD could range between −99 and 99; post−policy, PELD ranges between 6−99.

Appendix Table 20. Summary of Allocation PELD Score at Transplant for Liver-Alone Transplant Recipients Aged 0-11 Years by Exception Type and Era

Exception Type	Policy Era	N	Minimum	25th Percentile	Median	75th Percentile	Maximum	Interquartile Range
No Exception	Pre	18	-9	5.0	15.5	23.5	47	18.5
	Post	10	6	9.5	14.0	25.0	50	15.5
Exception	Pre	34	15	33.0	33.0	33.0	40	0.0
	Post	39	18	31.0	33.0	35.0	40	4.0

Status 1A/1B recipients do not have allocation PELD scores at transplant. As a result, 39 (68.42%) pre-policy recipients and 28 (73.68%) post-policy recipients were excluded.
Pre-policy, PELD could range between -99 and 99; post-policy, PELD ranges between 6 and 99.