OPTN Liver and Intestinal Organ Transplantation Committee Update

Agenda

- Acuity Circles and National Liver Review Board 2-year monitoring data
- Other public comment items
- Recent and upcoming implementations

Removal of DSA and Region from Liver and Intestine Allocation

2 Year Post-Implementation Acuity Circle Monitoring

Cohorts

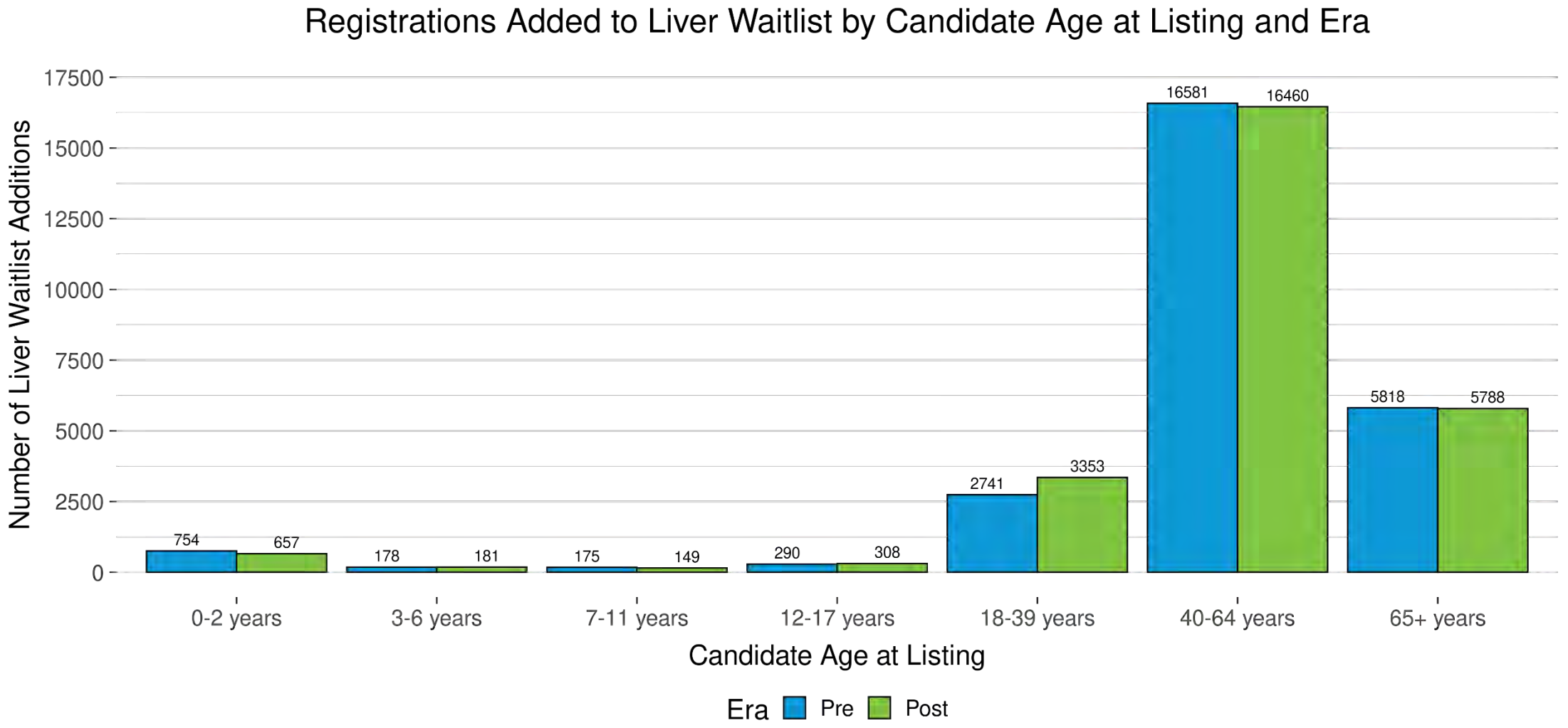
- **Two years pre- and post-AC implementation (2/4/2020)**
- **Pre-AC:** 2/3/2018-2/3/2020
- **Post-AC:** 2/4/2020-2/3/2022

- Analysis based on OPTN data as of 6/17/2022
- Data subject to change based on future data submission or correction
- **COVID-19 declared a national emergency on 3/13/2020**

National Summary

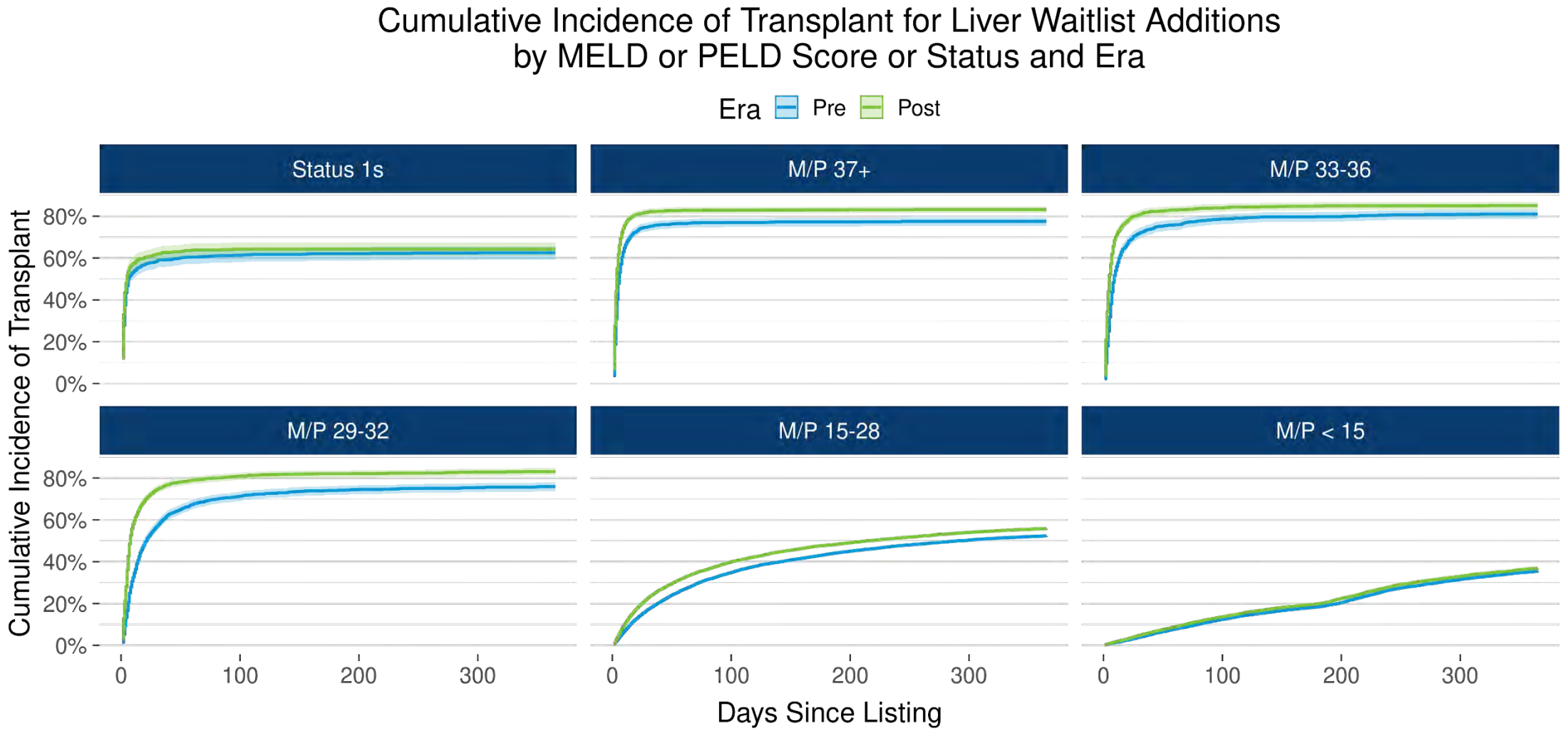
Metric	Age Group	Pre-Policy	Post-Policy	Difference (Post-Pre)
Waitlist Additions	Adult (18+ at listing)	25,140	25,601	461
	Pediatric (<18 at listing)	1,397	1,295	-102
Waitlist Removals for Death/Too Sick	Adult (18+ at listing	4,180	3,973	-201
	Pediatric (<18 at listing)	76	58	-18
Deceased Donor Liver-Alone Transplants	Adult (18+ at transplant)	13,773	14,489	716
	Pediatric (<18 at transplant)	873	789	-84
Liver Multi-Organ Transplants	All Ages	1,636	1,764	128
Liver Donors Recovered	Adult (18+ at donation)	16,449	17,454	1,005
	Pediatric (<18 at donation)	1,449	1,380	-69

There were fewer pediatric and more adult registrations added to the liver waitlist post-AC.



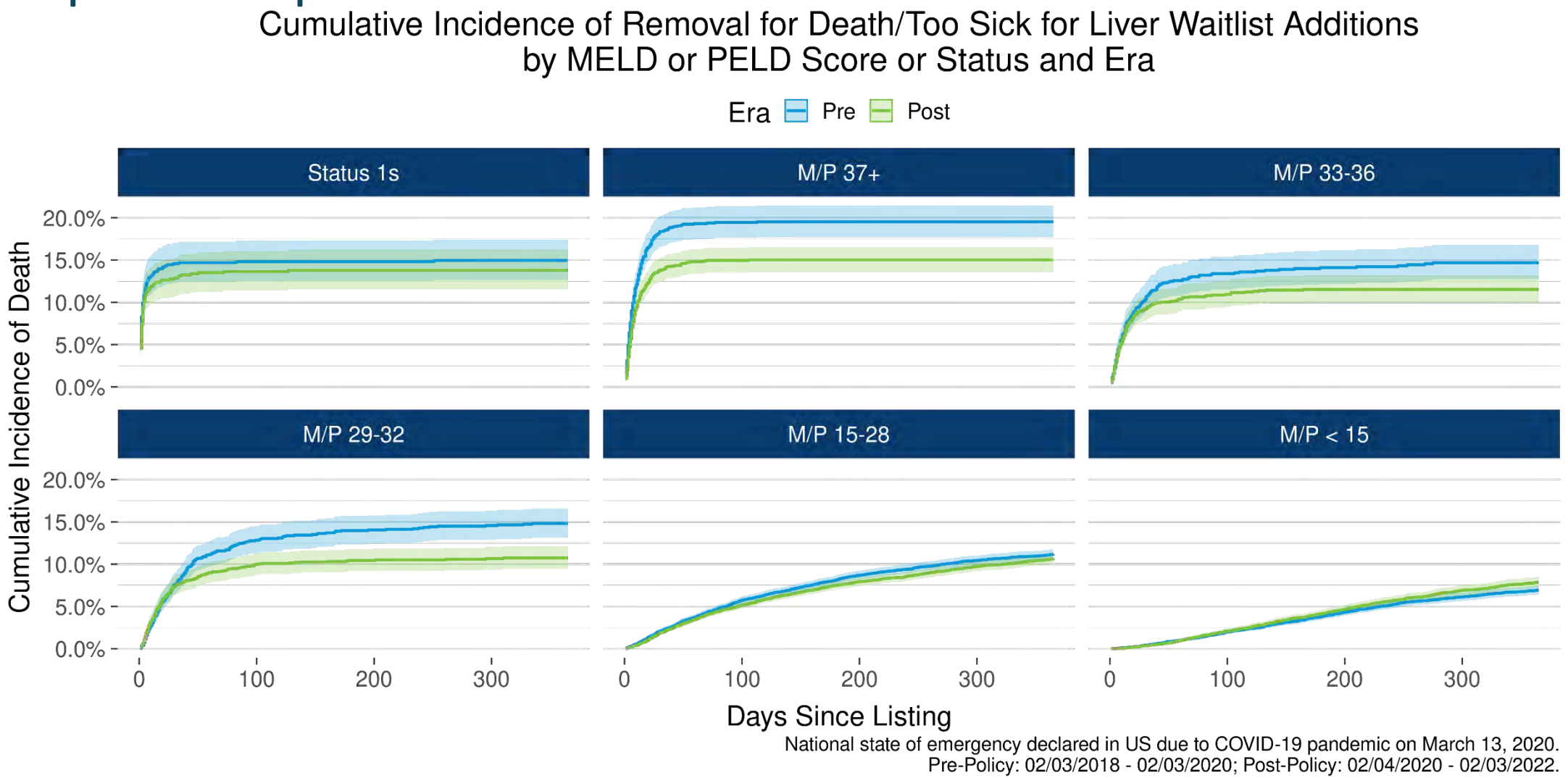
National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
Pre-Policy: 02/03/2018 - 02/03/2020; Post-Policy: 02/04/2020 - 02/03/2022.

The likelihood of transplant is higher post-AC compared to pre-AC.

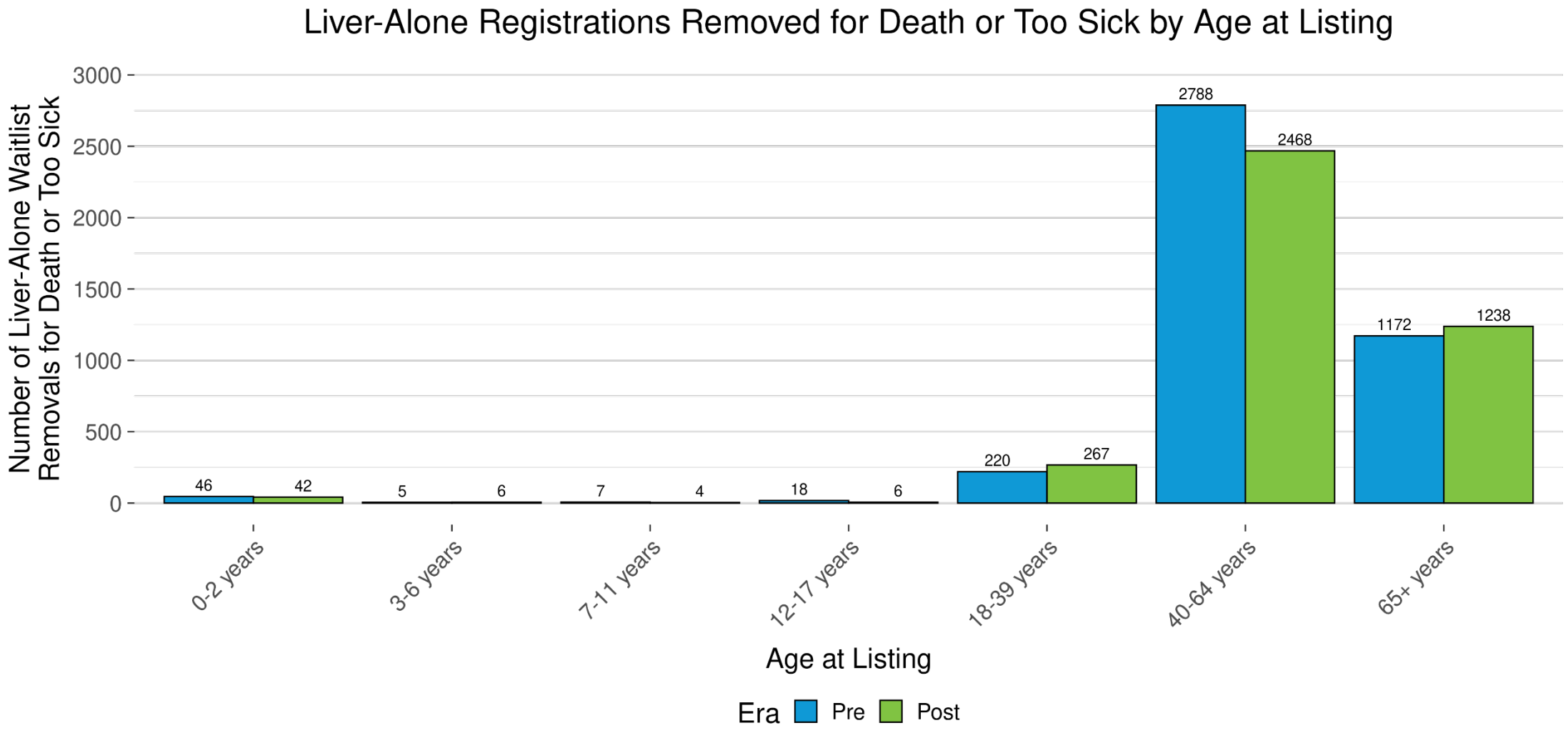


National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
Pre-Policy: 02/03/2018 - 02/03/2020; Post-Policy: 02/04/2020 - 02/03/2022.

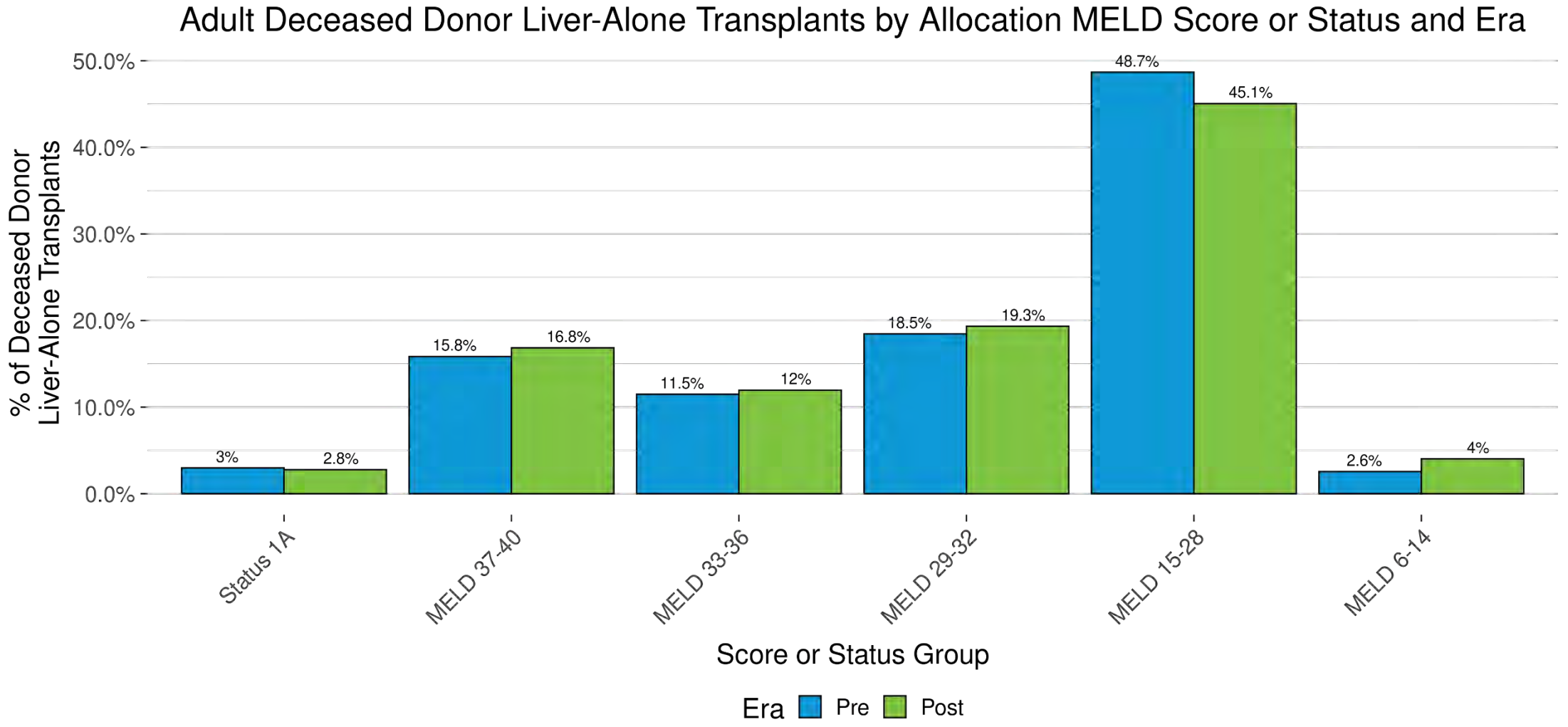
The likelihood of removal for death or too sick is lower post-AC compared to pre-AC.



There were fewer removals for death or too sick post-AC.



The proportion of adult transplants by MELD or PELD score or status group remained similar.



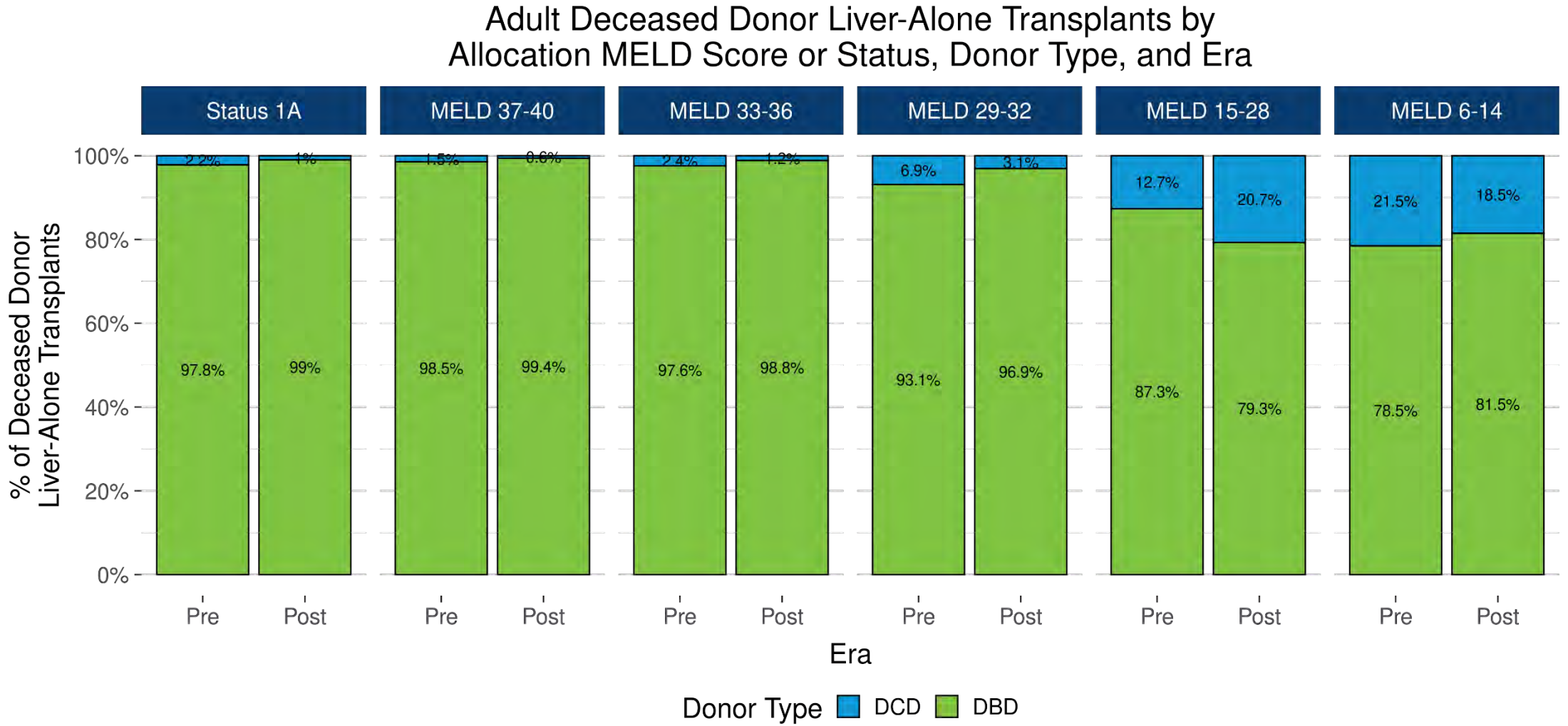
National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
Pre-Policy: 02/03/2018 - 02/03/2020; Post-Policy: 02/04/2020 - 02/03/2022.

The variance in Median MELD at Transplant (MMaT) decreased by OPTN Region, DSA, and State.

Table 30. Variance and Standard Deviation of Median Adult Deceased Donor Liver-Alone Recipient Allocation MELD Score at Transplant By Era

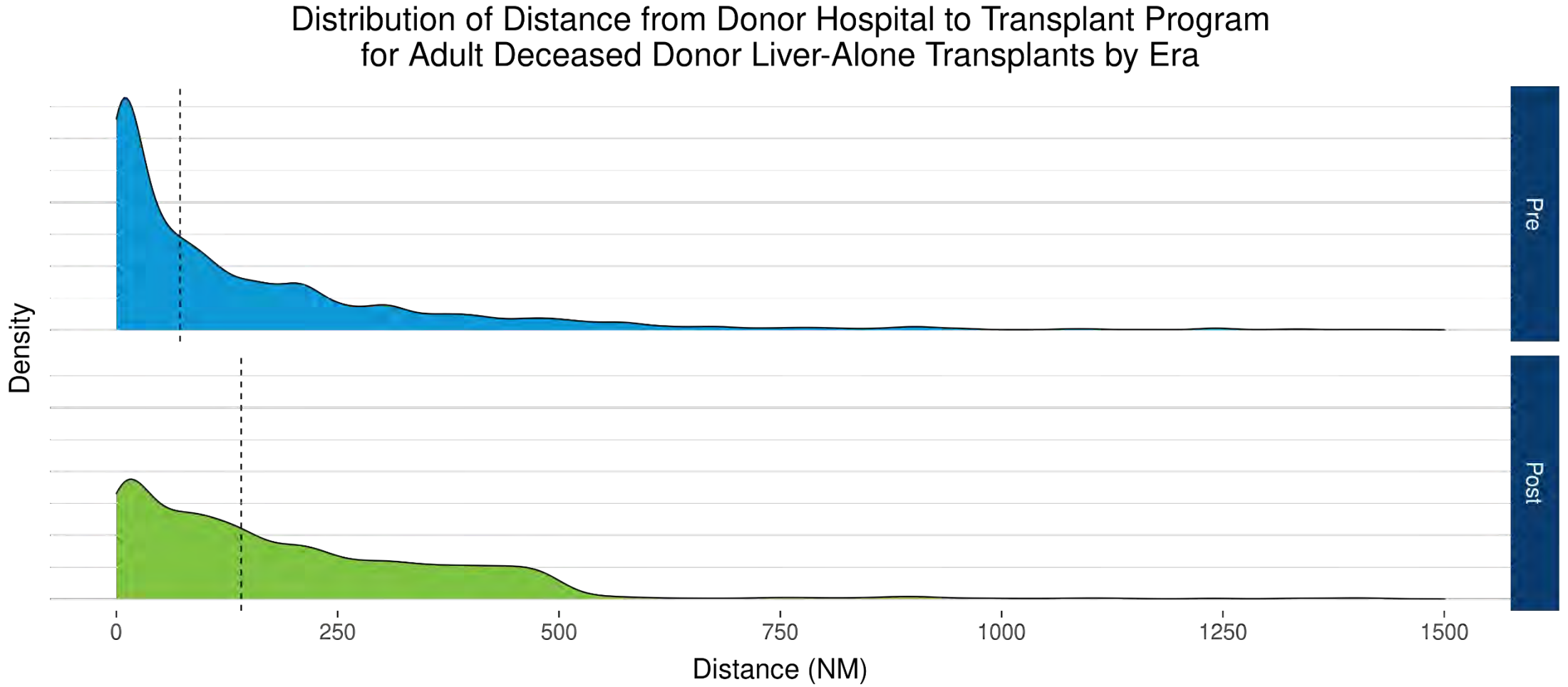
	Pre-Policy		Post-Policy	
Unit of Median Transplant Score	Variance	(SD)	Variance	(SD)
OPTN Region	6.16	2.48	5.36	2.32
DSA	14.72	3.84	11.54	3.40
State	14.84	3.85	8.89	2.98
Transplant Center	16.62	4.08	27.61	5.25

More DCD transplants were performed post-AC, with a larger proportion of DCD transplants in the MELD 15-28 group.



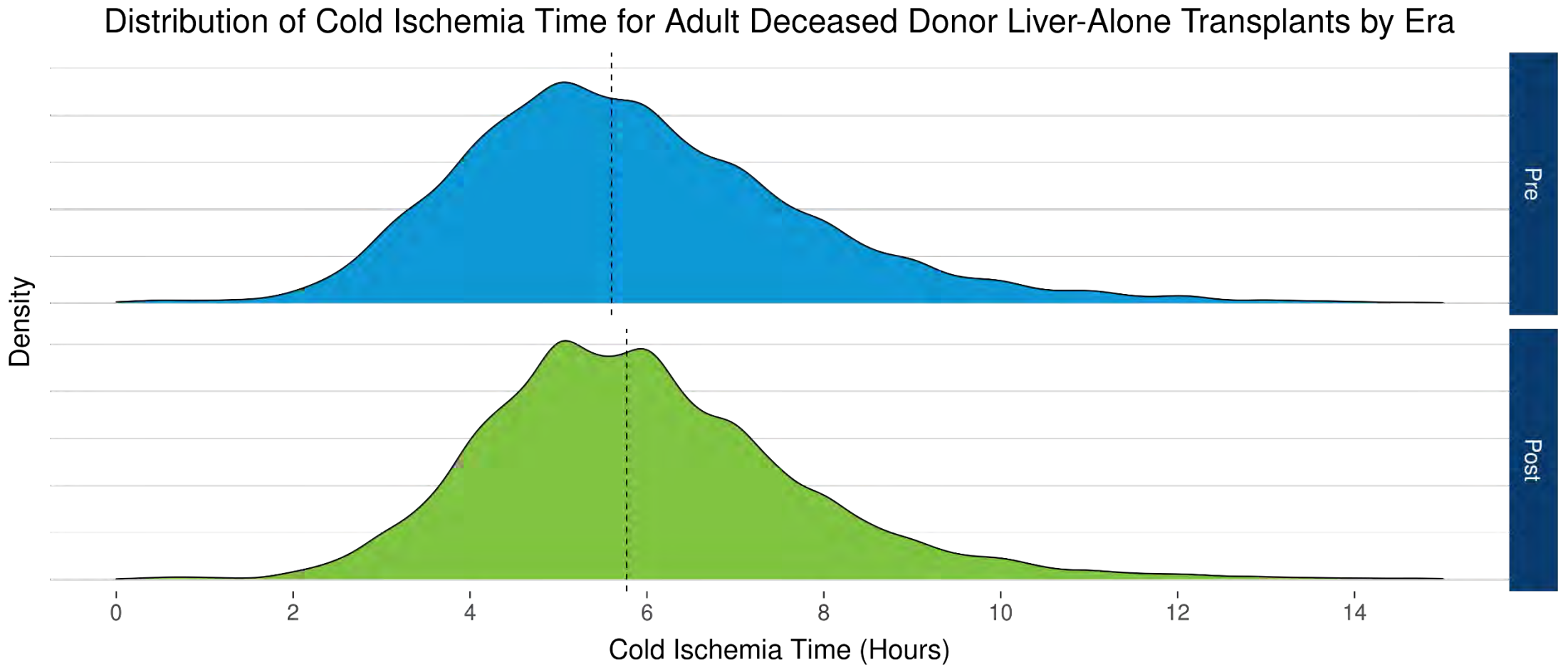
National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
Pre-Policy: 02/03/2018 - 02/03/2020; Post-Policy: 02/04/2020 - 02/03/2022.

Median distance for adult transplants increased from 72 NM to 141 NM.



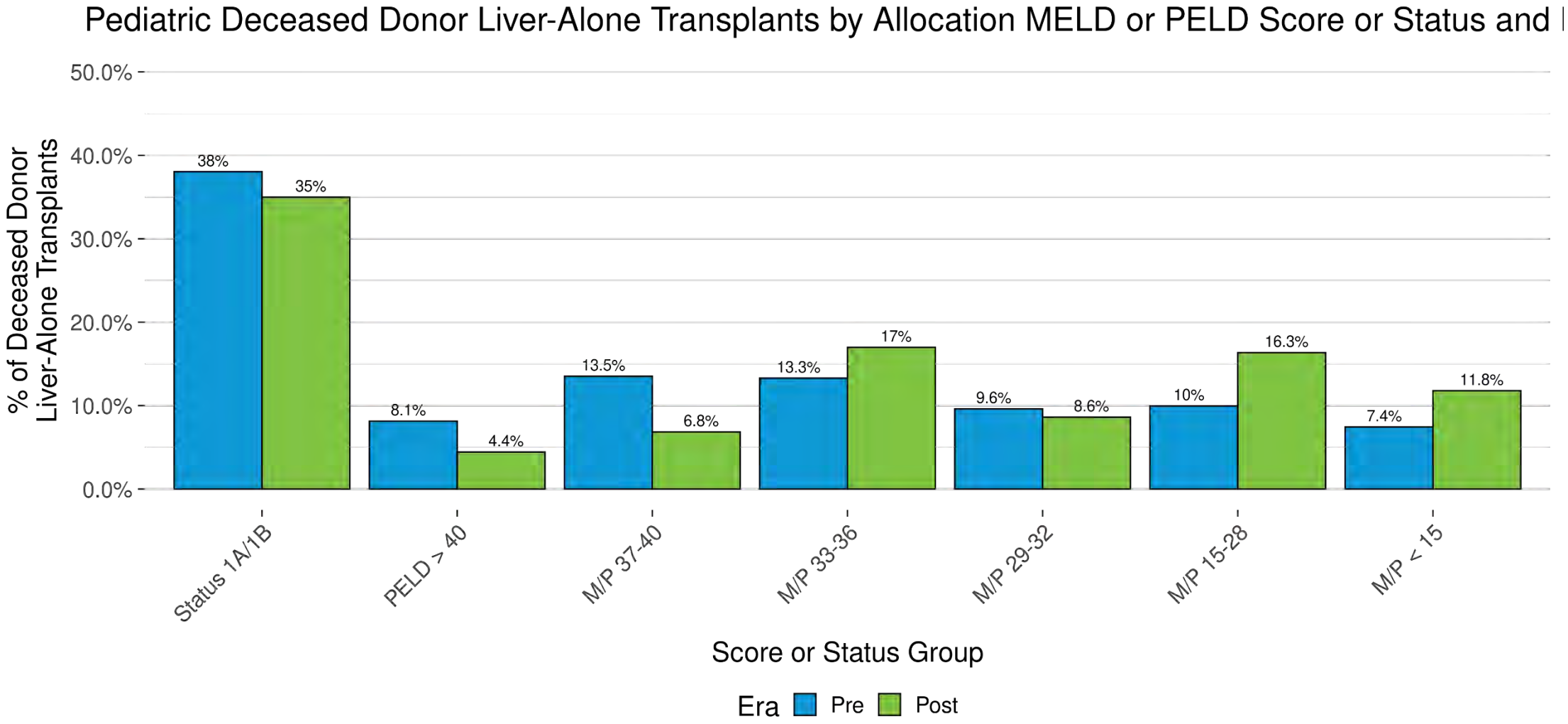
National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
Pre-Policy: 02/03/2018 - 02/03/2020; Post-Policy: 02/04/2020 - 02/03/2022.
** Dotted lines indicate median distance within each era.
*** There were 32 pre-policy and 31 post-policy transplants with distance >1500 NM not included.

Cold ischemia time for adult transplants increased by roughly 10 minutes.



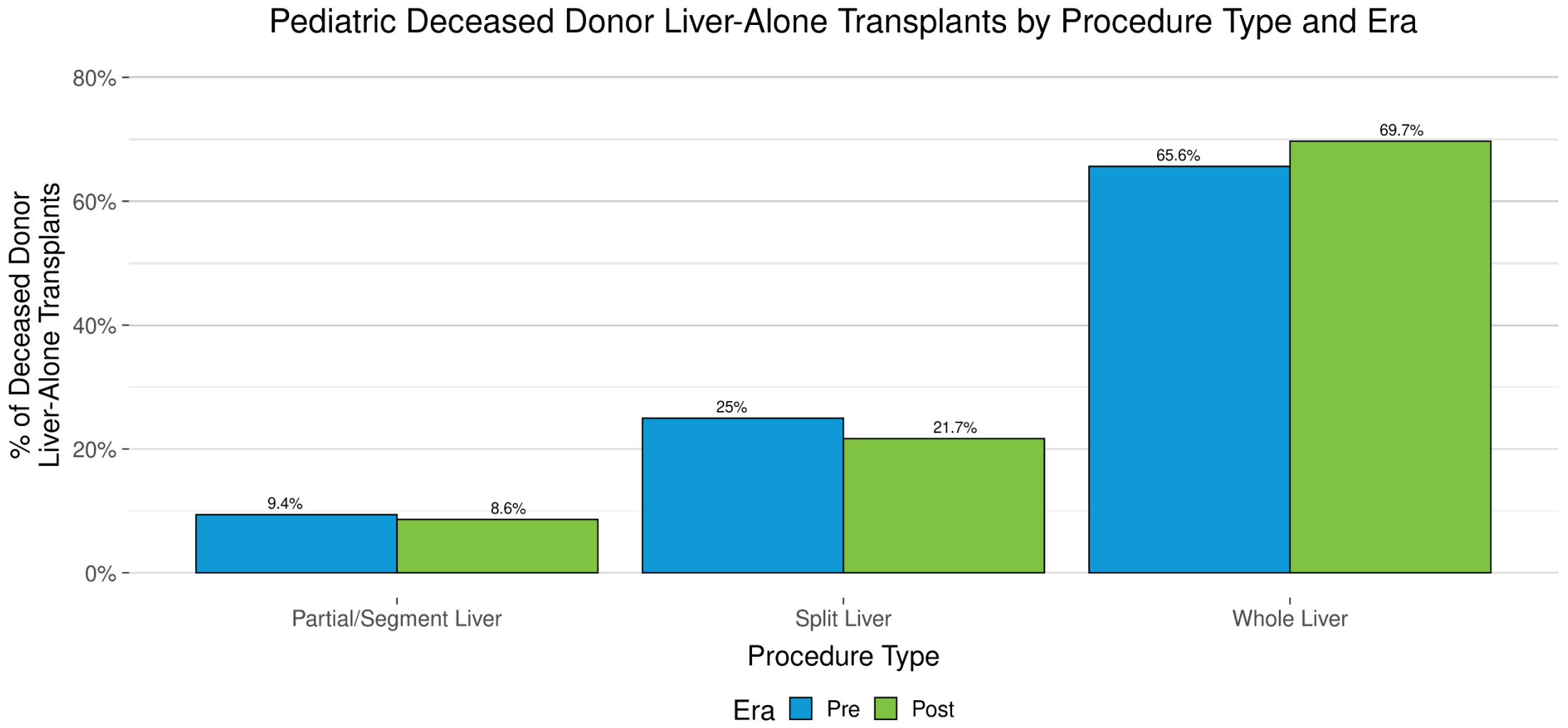
National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
Pre-Policy: 02/03/2018 - 02/03/2020; Post-Policy: 02/04/2020 - 02/03/2022.
** Dotted lines indicate median cold ischemia time within each era.
*** There were 46 pre-policy and 114 post-policy transplant recipients with missing cold ischemia time that are not included.
^ There were 27 pre-policy and 58 post-policy transplants with cold ischemia time >15 hours not included.

Post-AC, a smaller share of pediatric transplants had a MELD or PELD score greater than 36 or were Status 1A/1B.



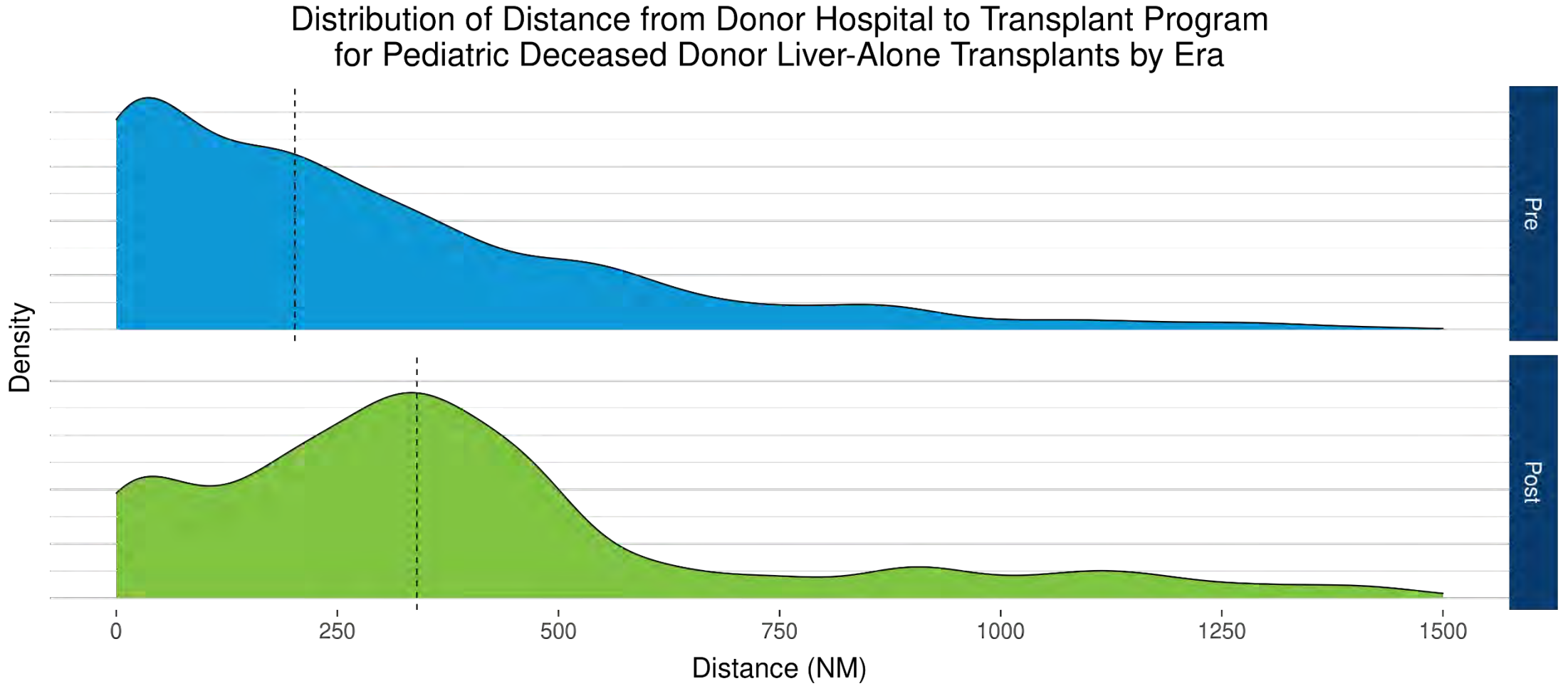
National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
Pre-Policy: 02/03/2018 - 02/03/2020; Post-Policy: 02/04/2020 - 02/03/2022.

Fewer pediatric split liver transplants were performed post-AC.



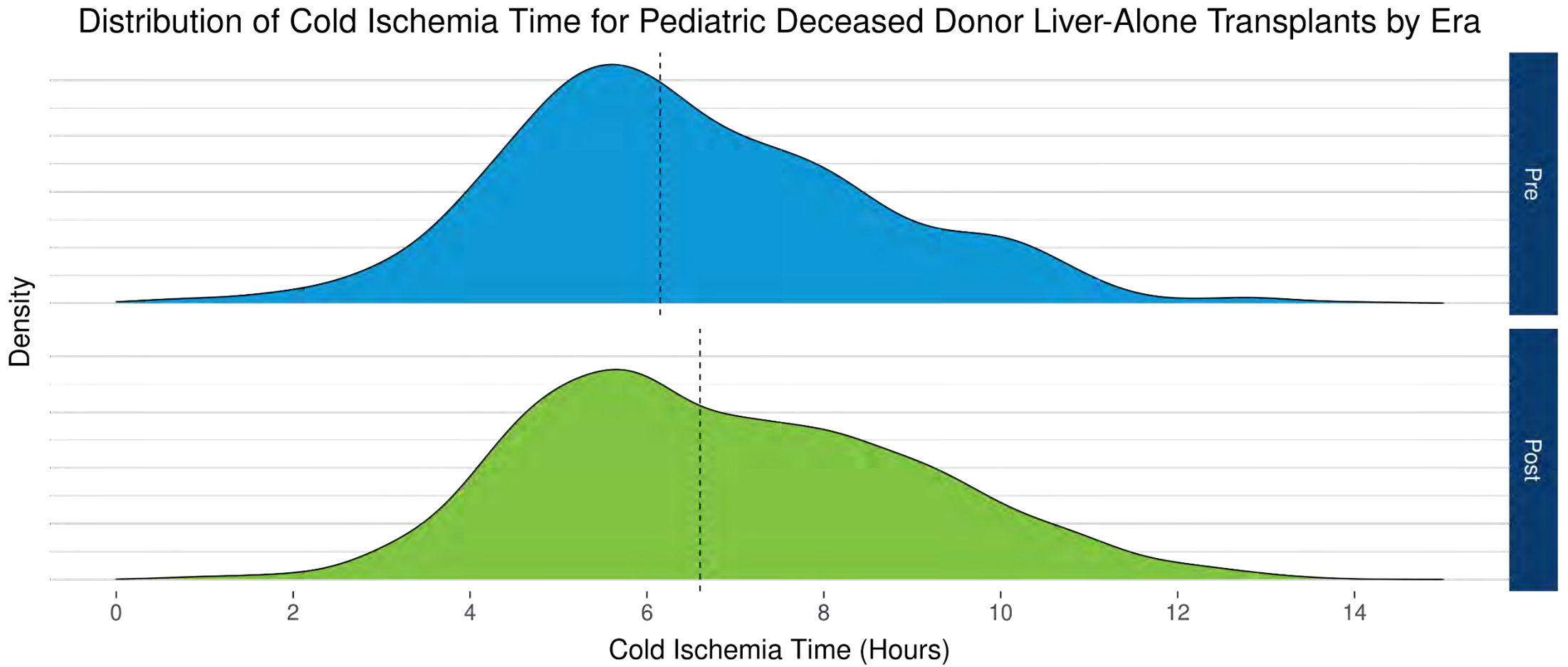
National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
Pre-Policy: 02/03/2018 - 02/03/2020; Post-Policy: 02/04/2020 - 02/03/2022.

Median distance for pediatric transplants increased from 202 NM to 340 NM.



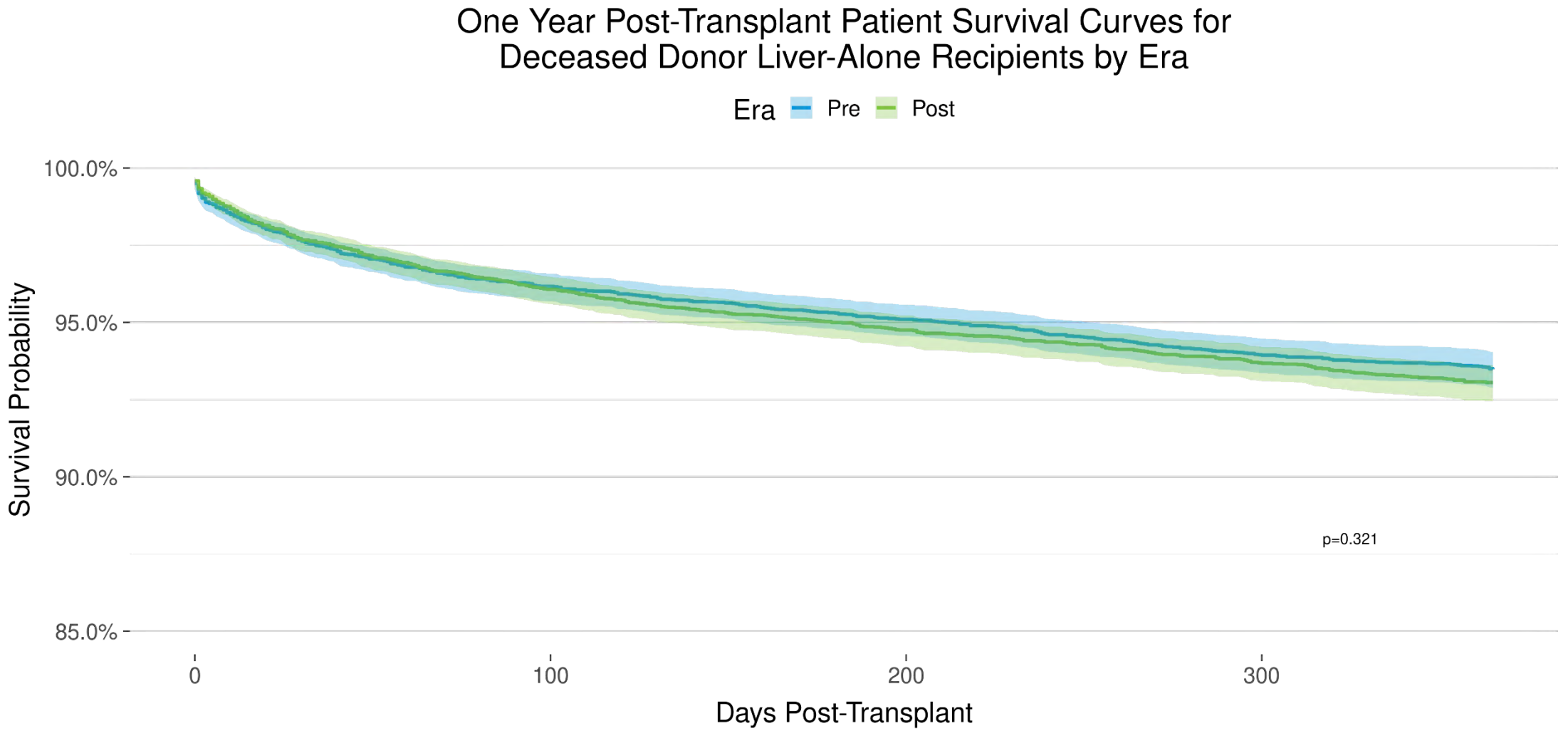
National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
Pre-Policy: 02/03/2018 - 02/03/2020; Post-Policy: 02/04/2020 - 02/03/2022.
** Dotted lines indicate median distance within each era.
*** There were 14 pre-policy and 19 post-policy transplants with distance >1500 NM not included.

Cold ischemia time for pediatric transplants increased by roughly 27 minutes.



National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
Pre-Policy: 02/03/2018 - 02/03/2020; Post-Policy: 02/04/2020 - 02/03/2022.
** Dotted lines indicate median cold ischemia time within each era.
*** There were 11 pre-policy and 6 post-policy transplant recipients with missing cold ischemia time that are not included.
^ There were 1 pre-policy and 1 post-policy transplants with cold ischemia time >15 hours not included.

There was no statistically significant change in patient survival.



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Pre-Policy: 02/03/2018 - 02/03/2020; Post-Policy: 02/04/2020 - 02/03/2022.

Donor Utilization and Efficiency of Allocation

- National liver discard rate increased from 9.0% to 9.5%
- National liver utilization rate decreased from 72.4% to 65.1%
- Offer rates increased across all allocation MELD or PELD score or status groups
- Median sequence number of final acceptor increased from 5 (IQR: 2-14) to 9 (IQR: 4-26)

Summary Findings

- Removals for death/too sick went down; transplant counts went up
- Distribution of transplants by MELD or PELD score or status remained similar
- Median distance from donor hospital to transplant program increased
- CIT went up slightly
- No statistically significant change in patient survival
- Slight increase in discard rate; decrease in utilization rate

National Liver Review Board

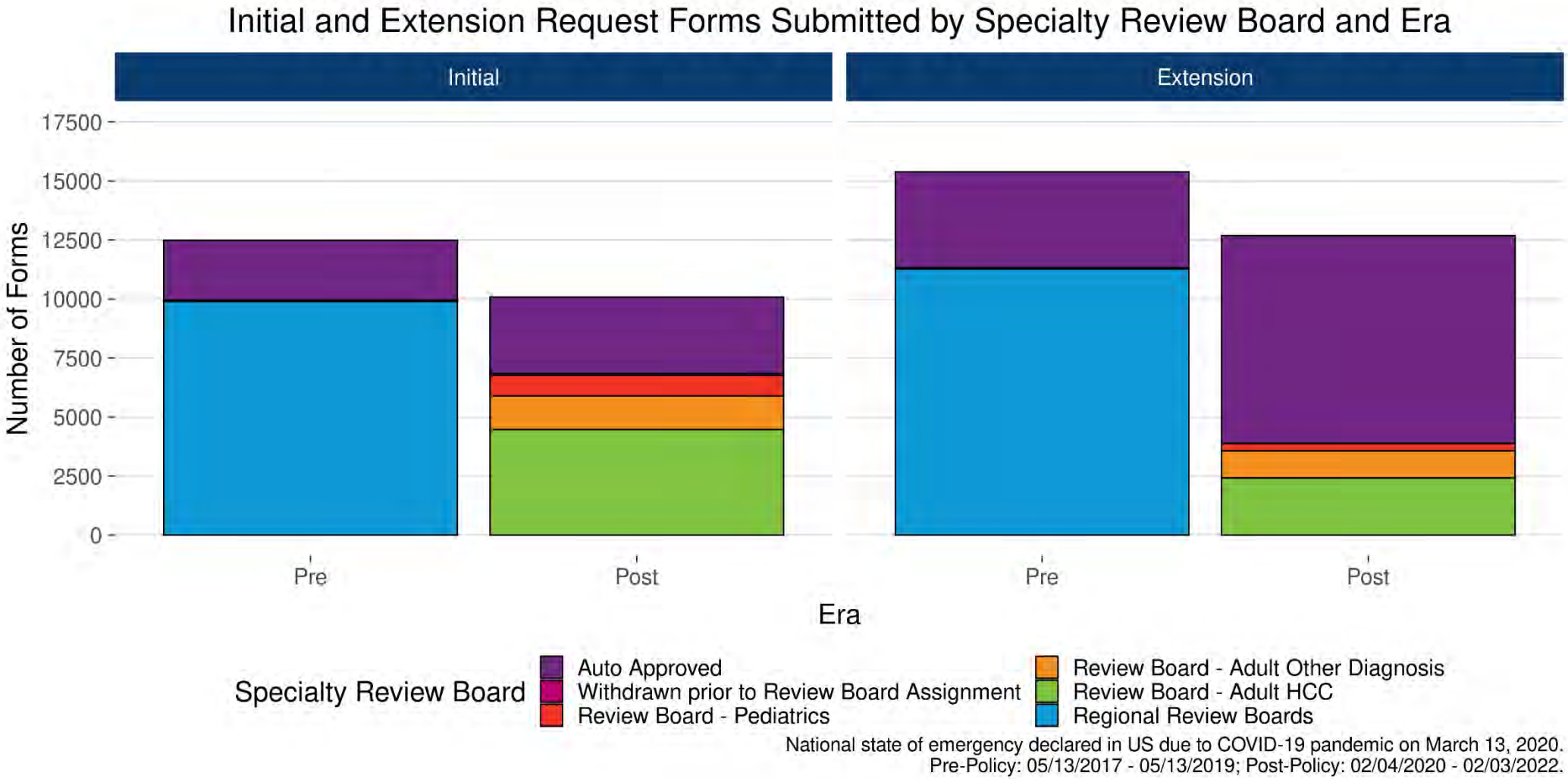
2 Year Post-Acuity Circle Implementation Monitoring

Cohorts

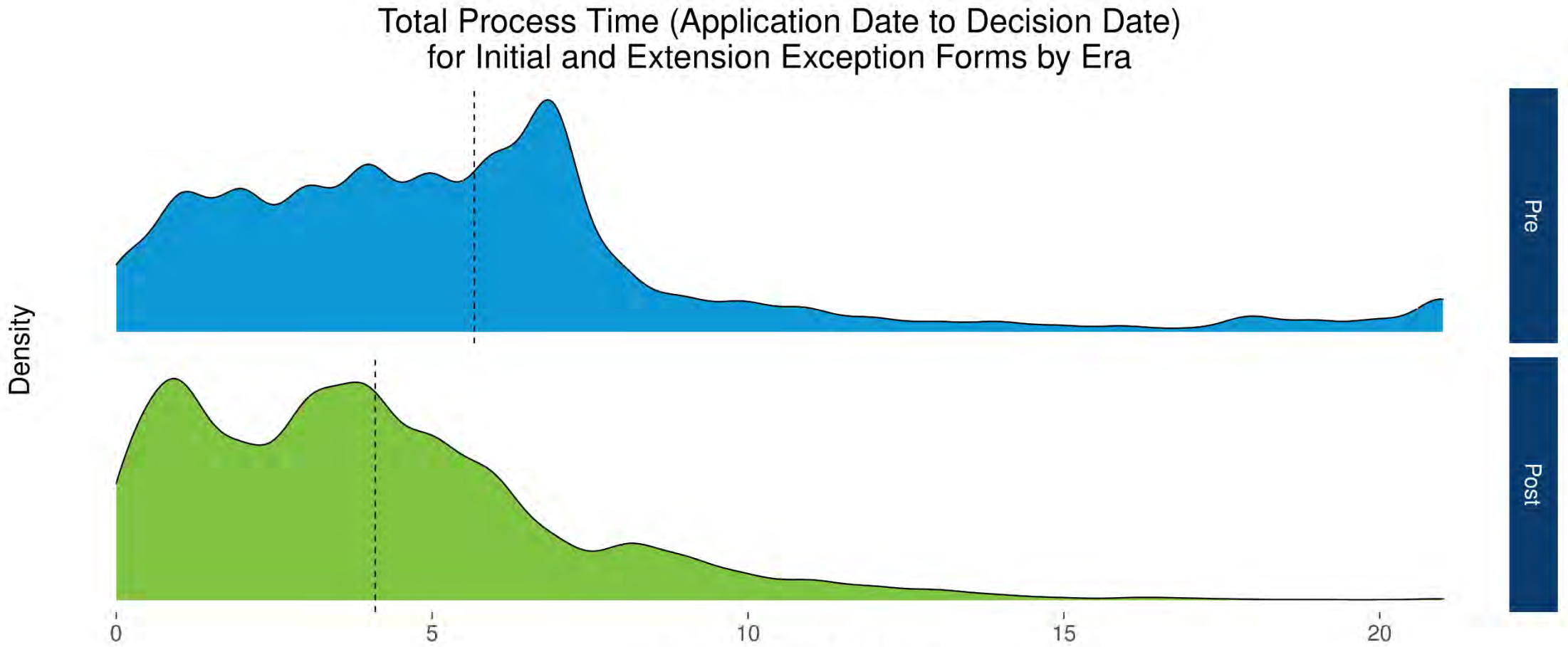
- **Two years pre-NLRB and 2 years post-Acuity Circles**
- **Pre-Policy (RRB):** 5/13/2017-5/13/2019
- **Post-Policy (NLRB):** 2/4/2020-2/3/2022
- Data from 5/14/2019-2/3/2020 are excluded

- Analysis based on OPTN data as of 6/17/2022
- Data subject to change based on future data submission or correction

Post-NLRB there was an increase in the percentage of automatically approved initial and extension forms.

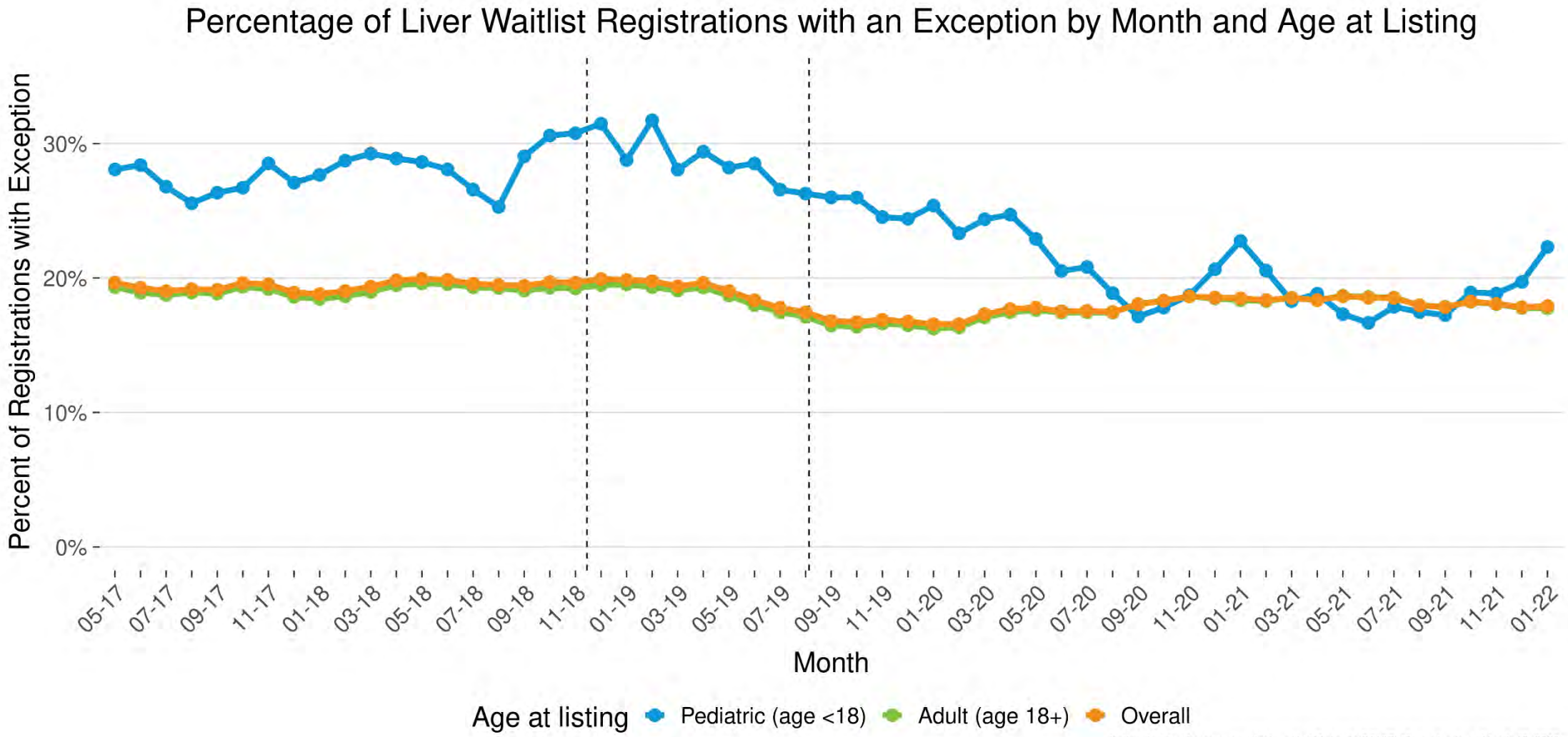


Post-NLRB the average adjudication time decreased from 6 to 4 days.

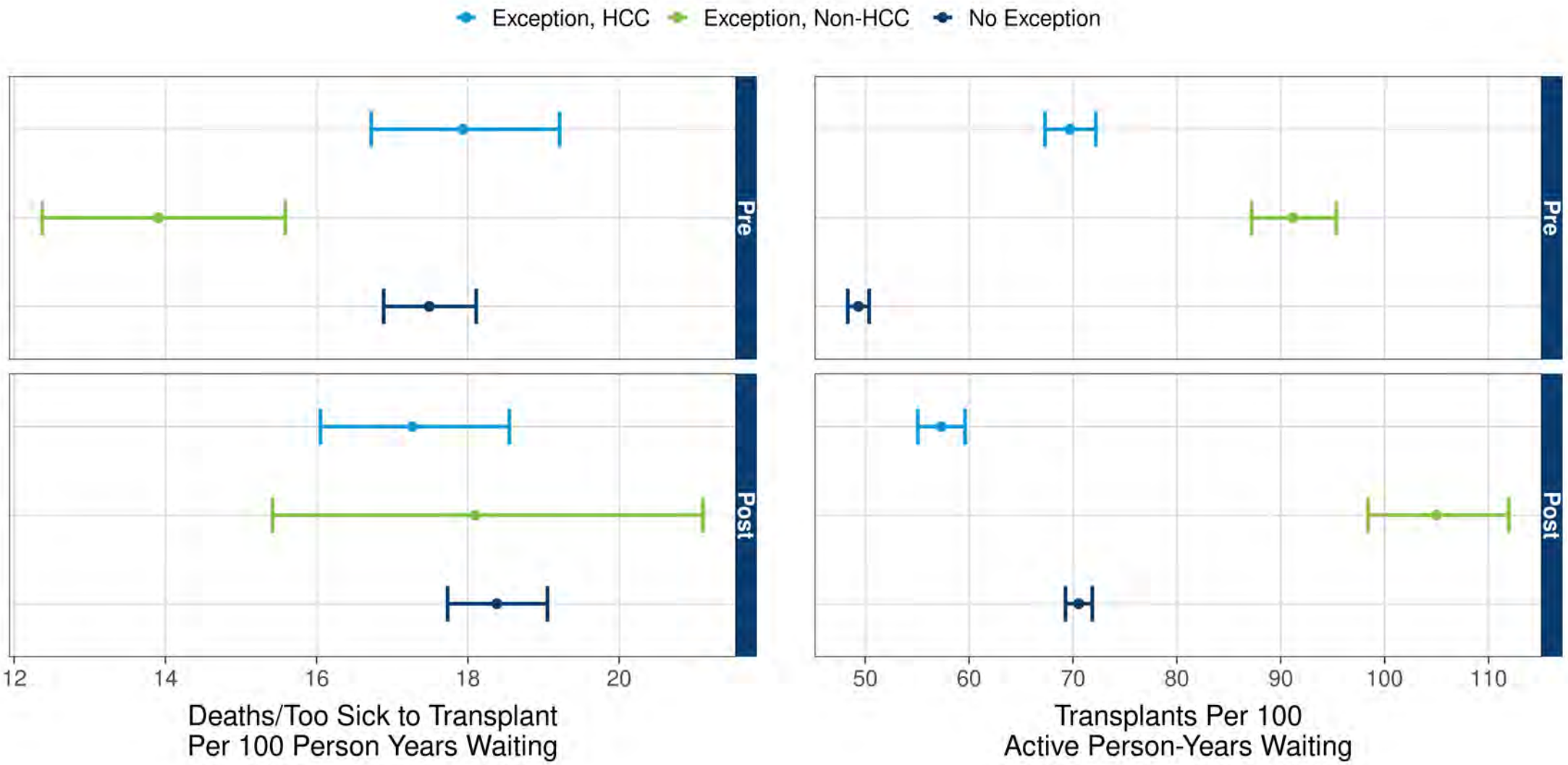


National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
Pre-Policy: 05/13/2017 - 05/13/2019; Post-Policy: 02/04/2020 - 02/03/2022.
There were N=852 forms removed for missing process time, due to being withdrawn prior to decision.
The dotted vertical lines represent mean days in each era.

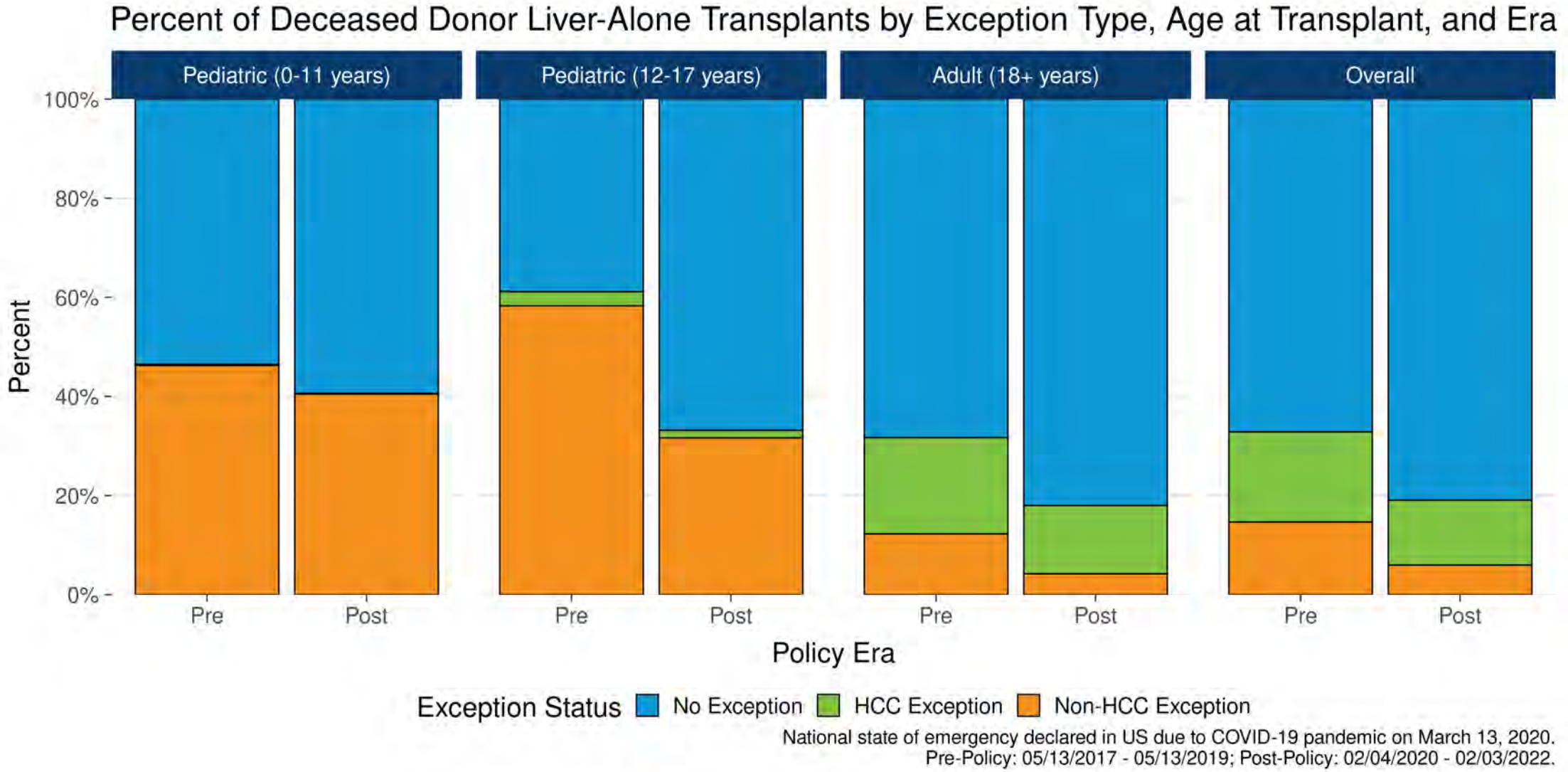
Post-NLRB the percentage of waitlist registrations with an exception decreased.



Post-NLRB, HCC exception transplant rates decreased (right) without a change in waitlist mortality rates (left).



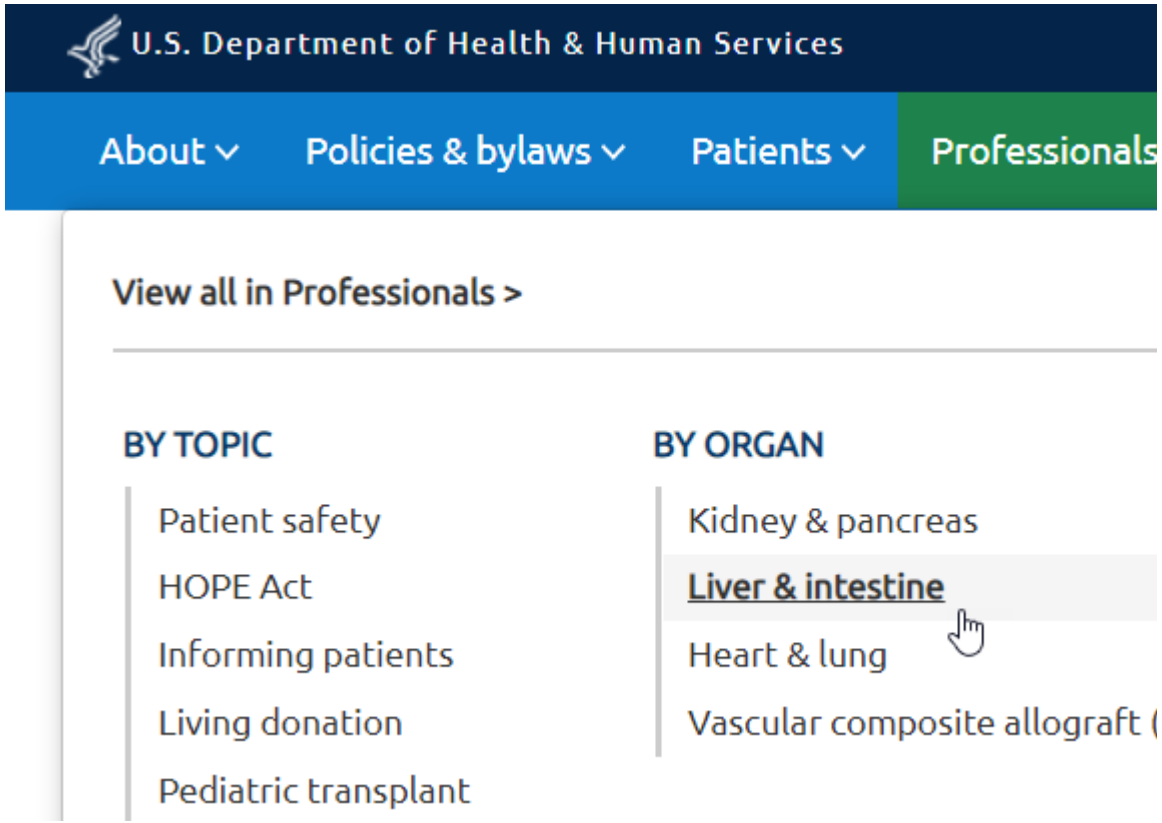
Post-NLRB the number of non-HCC exception deceased donor liver-alone transplants decreased.



Summary Findings

- Increased percentages of automatically approved initial and extension request forms, decreasing the forms requiring additional review
- Decreased time from exception request form submission to adjudication
- Decreased percentage of waitlist registrations with an exception
- Decrease in HCC exception transplant rates with no significant change in waitlist mortality rates
- Decreased number of non-HCC exception deceased donor liver-alone transplants

Questions?



Two Year Monitoring Report of Liver and Intestine Acuity Circle Allocation
Removal of DSA and Region as Units of Allocation

DHHS Contract No. 250-2019-00001C
Date Completed: August 5, 2022

Prepared for:
Liver & Intestinal Transplantation Committee
Committee Meeting
Date of Meeting: August 5, 2022

By:
Samantha Weiss, M.S.
Julia Foutz, MPH
UNOS Research Department

Contents

Other Public Comment Items

Review of Variances

- Align expiration dates of four OPTN liver allocation variances to coincide with implementation of continuous distribution
  - Hawaii/Puerto Rico: ABO blood type variance
  - Hawaii/Puerto Rico: Access for Medically Urgent Candidates
  - Split liver: Region 8 closed variance
  - Split liver: Open split liver variance
- Extending and aligning the end dates for the four variances will allow the Committee to consider how to incorporate the variances into continuous distribution as they develop the points-based framework
- Committee will continue to monitor variances and adjust if needed

Continued Review of NLRB Guidance

- Ensure guidance remains updated, clear, and aligned with current research so the appropriate candidates receive MELD or PELD exceptions
- Proposed changes:
  - Create guidance for pediatric candidates with cystic fibrosis
  - Update guidance for hepatic adenomas and Budd-Chiari syndrome

Recent and Upcoming Implementations

Recent Implementations

- **June 28, 2022**: Calculate median MELD at transplant (MMaT) around donor hospital and update sorting within liver allocation
- **July 26, 2022**: Updated NLRB guidance for ischemic cholangiopathy, polycystic liver disease, and HCC candidates who are treated and recur

Upcoming implementations

- **August 30, 2022**:
  - Updated process for reviewing HCC explant pathology forms
  - New diagnoses on transplant candidate registration form and transplant recipient registration form

Current Diagnosis	New Diagnosis
Alcoholic Cirrhosis	Alcohol-associated cirrhosis without acute alcohol-associated hepatitis
Alcoholic Cirrhosis with Hepatitis C	N/A: diagnosis will be inactivated
Acute Alcoholic Hepatitis	Acute alcohol-associated hepatitis with or without cirrhosis

Upcoming implementations

- **Slated for April 2023**: Improving Liver Allocation: MELD, PELD, Status 1A, and Status 1B
- MELD 3.0:
  - Adds two new variables: current sex and albumin
  - Updates coefficients for existing variables (sodium, bilirubin, creatinine, and international normalized ratio (INR))
  - Introduces interaction terms between bilirubin and sodium and between albumin and creatinine
  - Caps creatinine at 3.0 mg/dL

Upcoming Implementations (tentative April 2023)

- PELD Cr:
  - Adds creatinine variable as measure of renal function
  - Updates parameters for current variables (albumin, bilirubin, INR)
  - Includes continuous variables for age and growth failure instead of categorical variables
  - Incorporates age-adjusted mortality factor to align with risk of mortality in the adult population

Upcoming Implementations (tentative April 2023)

- Status 1A:
  - Create more objective way to define hepatic encephalopathy in pediatric candidates
- Status 1B:
  - Remove MELD/PELD 25 threshold for liver-alone and liver-intestine candidates
  - Update gastrointestinal bleeding threshold to match definition of persistent mild shock or moderate shock for liver-alone candidates with chronic liver disease
  - Remove Glasgow Coma Score criterion
  - Prioritize candidates with chronic liver disease, who are at highest mortality risk

Upcoming Implementations (tentative April 2023)

- For MELD 3.0 and PELD Cr, transplant programs will need to:
  - Submit creatinine for PELD candidates and albumin for MELD candidates
  - Report candidate's current sex if different than birth sex
  - Inform candidates of any changes in MELD/PELD score
- OPTN will provide additional resources and education closer to implementation

Upcoming Implementations (tentative April 2023)

- Align OPTN policy language with LI-RADS terminology
- No changes to which candidates will be auto-approved for an HCC exception

Questions?