

OPTN Liver and Intestinal Organ Transplantation Committee

Winter 2021

Committee Update

- Acuity Circles: Nine Month Monitoring Report Highlights
- Recent public comment proposals
- Ongoing projects

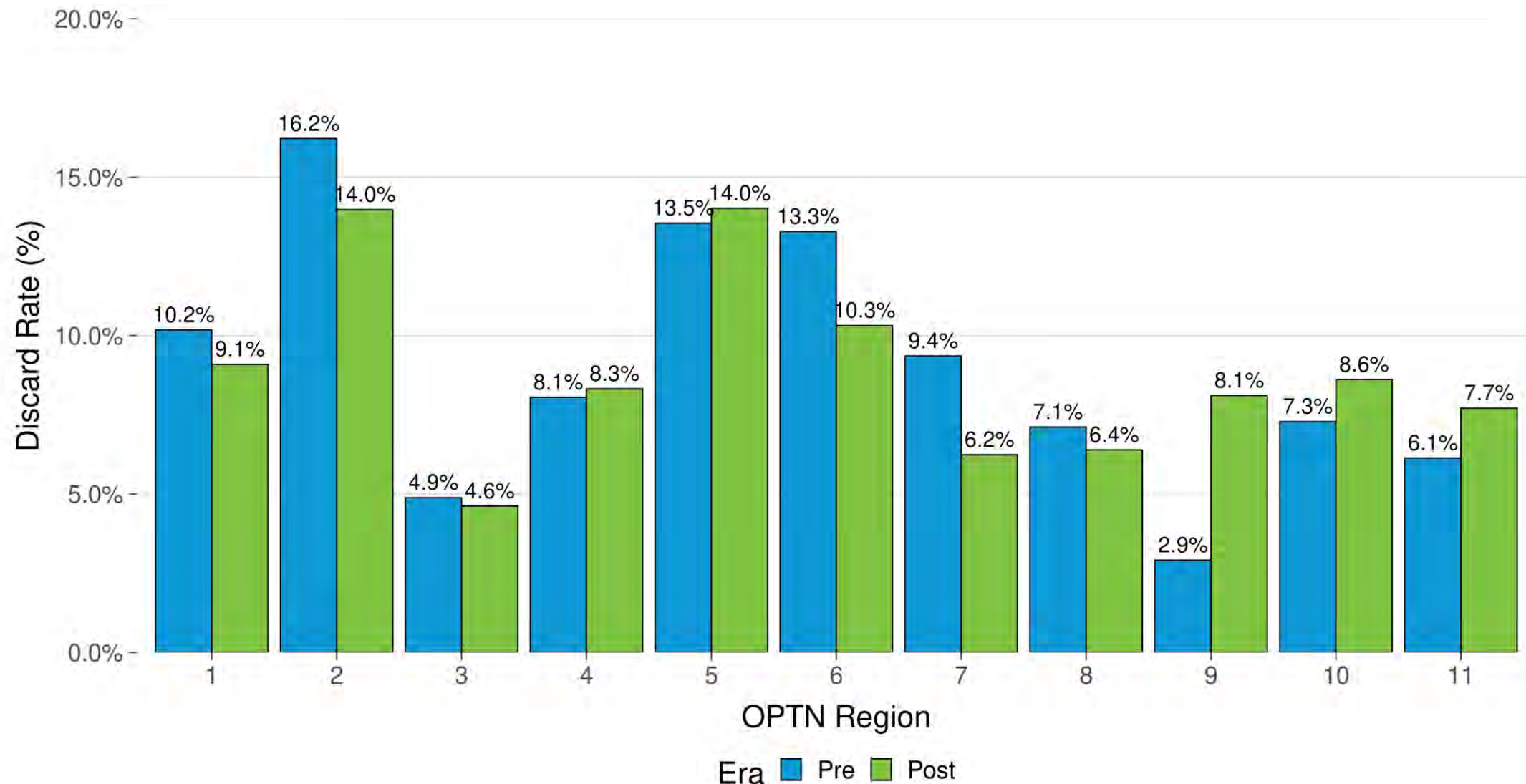
Acuity Circles

Nine Month Monitoring Report Highlights

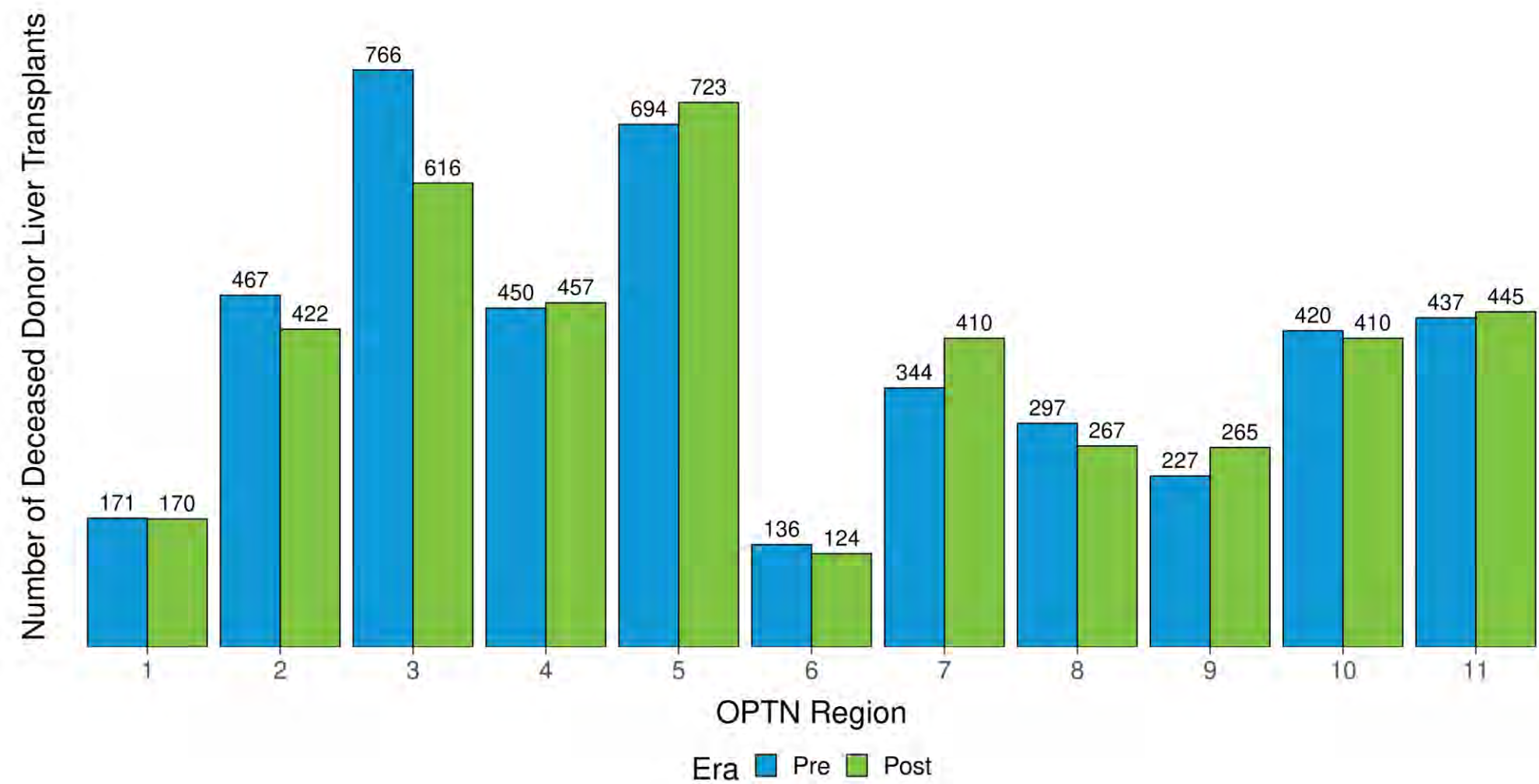
Data Cohorts

- Cohorts contain 9 months of data before and after liver policy change
- Feb. 5, 2019 – Nov. 2, 2019: Pre-Policy Era (to consider seasonal changes)
 - NLRB in place from May 14, 2019
- Feb. 4, 2020 – Oct. 31, 2020: Post-Policy Era (overall)
 - NLRB in place, changes to median MELD at transplant definition occurred
 - COVID-19 national emergency declared Mar. 13, 2020
- Deceased donor transplant cohorts defined through Sept. 2, 2019 (Pre-Policy) and Aug. 31, 2020 (Post-Policy) due to data lags

Liver Discard Rate by OPTN Region and Era



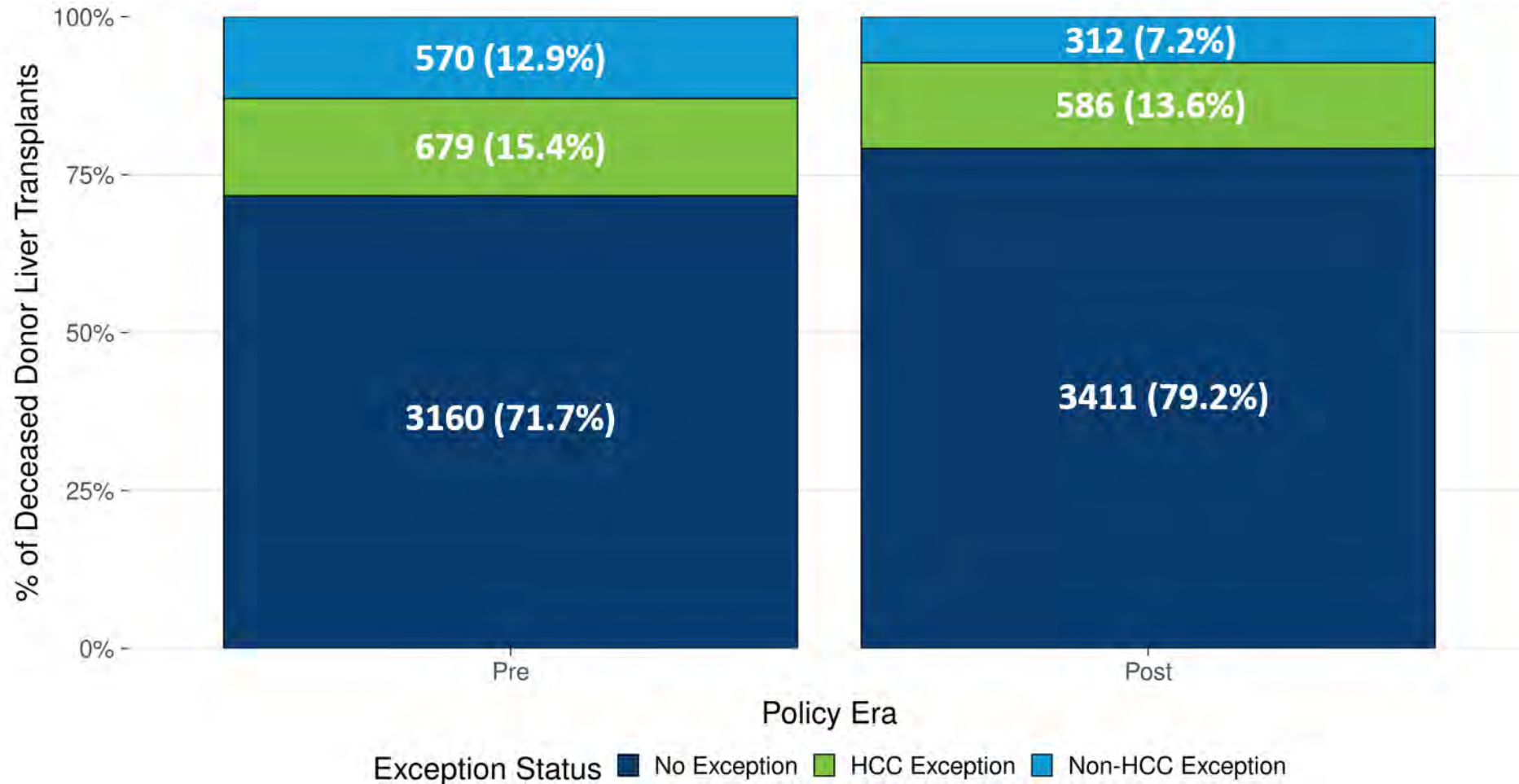
Deceased Donor Liver-Alone Transplants by OPTN Region and Era



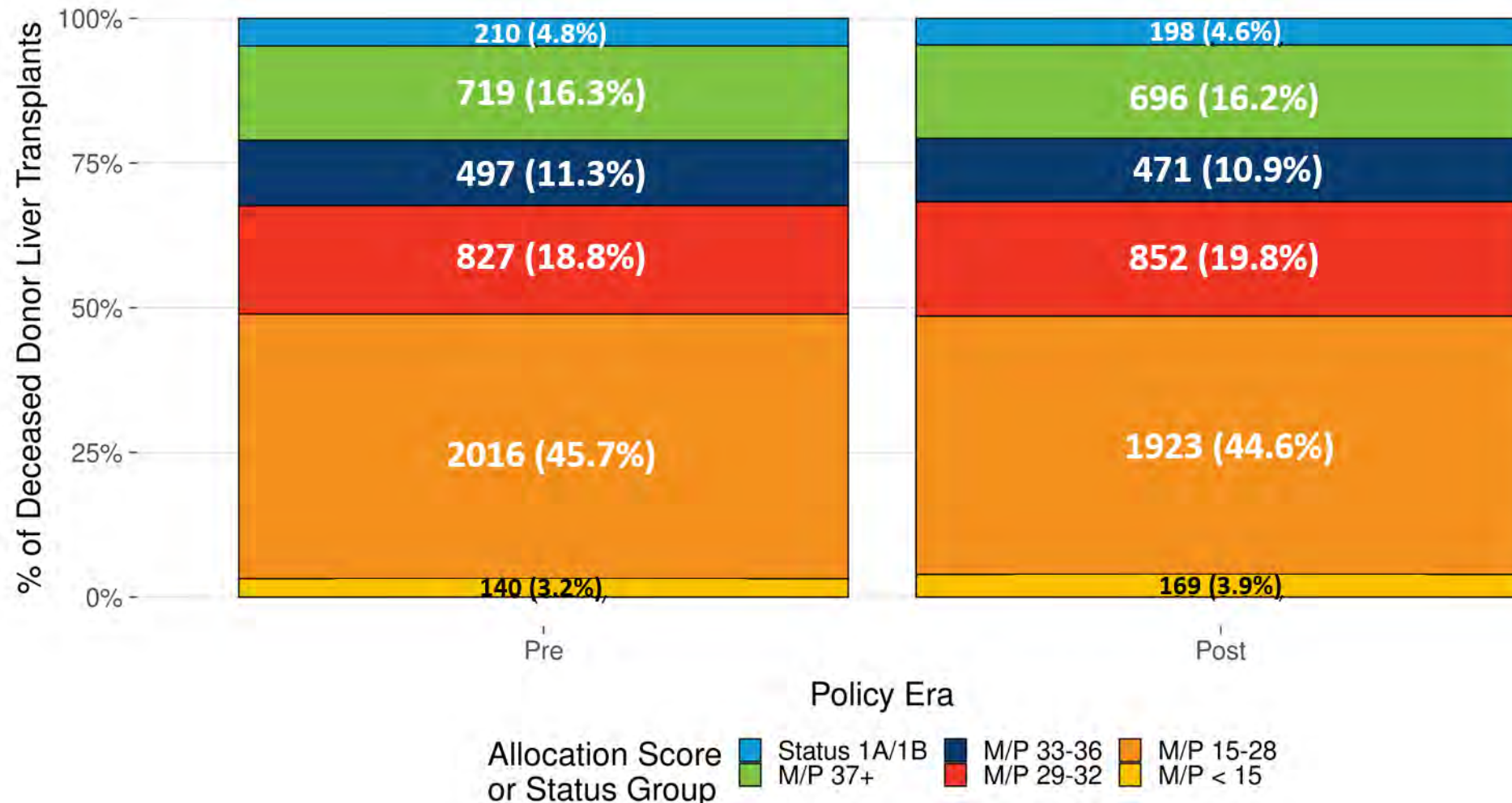
Deceased Donor Liver-Alone Transplants by Age at Transplant and Era

| Age Group | Pre-Policy N (%) | Post-Policy (overall) N (%) |
|--------------------------------|---------------------|--------------------------------|
| Pediatric (age 0-11 years) | 226 (5.1%) | 178 (4.1%) |
| Pediatric (age 12-17 years) | 33 (0.7%) | 66 (1.5%) |
| Adult (age 18+ years) | 4150 (94.1%) | 4065 (94.3%) |

Deceased Donor Liver-Alone Transplants by Exception Status and Era



Deceased Donor Liver-Alone Transplants by Allocation MELD or PELD Score or Status and Era



Deceased Donor Liver-Alone Transplant Variance and Standard Deviation in Median Allocation MELD or PELD at Transplant (MTS) By Era

| Unit of MTS | Pre-Policy Variance (SD) | Post-Policy (overall) Variance (SD) |
|-------------------|-----------------------------|--|
| OPTN Region | 8.25 (2.87) | 4.82 (2.20) |
| DSA | 14.84 (3.85) | 11.76 (3.43) |
| State | 17.93 (4.23) | 13.15 (3.63) |
| Transplant Center | 24.50 (4.95) | 24.92 (4.99) |

Summary Metrics

| Characteristic | Pre-Policy | Post-Policy (overall) |
|---|-------------|-----------------------|
| Deceased Liver Donors Recovered (N) | 6919 | 6897 |
| Discard Rate (%) | 9.2% | 9.0% |
| Utilization Rate (%) | 72.1% | 68.5% |
| Deceased Donor Liver-Alone Transplants (N) | 4409 | 4309 |
| Within 150 Nautical Miles (NM) (%) | 65.3% | 50.3% |
| Within Local DSA (%) | 62.8% | 34.6% |
| Distance Between Donor Hospital and Transplant Center (NM) (Median) | 79 NM | 148 NM |
| Deceased Donor SLK Transplants | 401 | 452 |
| Liver Waiting List Registrations* Removed Due to Death or Too Sick to Transplant | 1578 | 1497 |

* Candidates may be listed at multiple transplant programs, contributing multiple registrations and thus represent multiple deaths in this count.

Summary

- Metrics are constrained to data points that are reliably available while adhering to data submission lags required by OPTN policy
- Impact of COVID-19 pandemic will continue to be a confounding factor in analyzing this policy change
- **Full report available on the OPTN website:**
<https://optn.transplant.hrsa.gov/resources/by-organ/liver-intestine/>

Recent Public Comment Proposals

Further Enhancements to the NLRB

- Changes pending implementation
 - Standard criteria for portopulmonary hypertension (POPH)
 - *Post-transplant Explant Pathology* form review process
 - Creation of pediatric appeals review team (ART)
- Updates to guidance for polycystic liver disease (PLD) effective February 9, 2021

Ongoing Committee Projects

Updating the PELD Score and Status 1B Criteria

- **Purpose**
 - Re-calculate the pediatric end-stage liver disease (PELD) score to better predict pediatric waitlist mortality and update Status 1B criteria
- **PELD**
 - **Progress to date:**
 - Review recent literature and determine factors that predict pediatric waitlist mortality
 - Updated PELD derivation request includes: age, albumin, bilirubin, INR, growth failure, sodium, modified Schwartz Calculation of eGFR/serum creatinine
 - **Next Steps:**
 - Work group to consider: PELD trajectory variable and further calibration of updated PELD score to account for age-adjusted mortality
 - After derivation of updated PELD, new score will be modeled using LSAM to predict impact on waitlist outcomes

Updating the PELD Score and Status 1B Criteria

- Status 1B Potential Modifications:
 - **GI bleeding threshold** for candidates with chronic liver disease:

| | Current | Considered |
|-----------------|--|---|
| Liver-Alone | At least 30 mL/kg of red blood cell replacement within previous 24 hours | At least 30 mL/kg of red blood cell replacement within previous <u>96 24 hours</u> or <u>20 mL/kg in the previous 24 hours</u> |
| Liver-Intestine | At least 10 mL/kg of red blood cell replacement within the previous 24 hours | No changes |

Updating the PELD Score and Status 1B Criteria

- Status 1B Potential Modifications:
 - MELD/PELD 25 threshold for candidates with chronic liver disease
 - Stratification within Status 1B to better predict mortality and morbidity

Improving the MELD Calculation

- Purpose
 - Improve the model for end-stage liver disease (MELD) score to better predict waitlist mortality and reduce disparity for females
- Research has consistently demonstrated females are disadvantaged in current liver allocation due to:
 - Donor-recipient size mismatch
 - Higher prevalence of hepatocellular carcinoma in men
 - Use of creatinine in current MELD calculation
- Project will update the MELD score based on current research to better predict waitlist mortality and reduce sex-based disparity in liver allocation

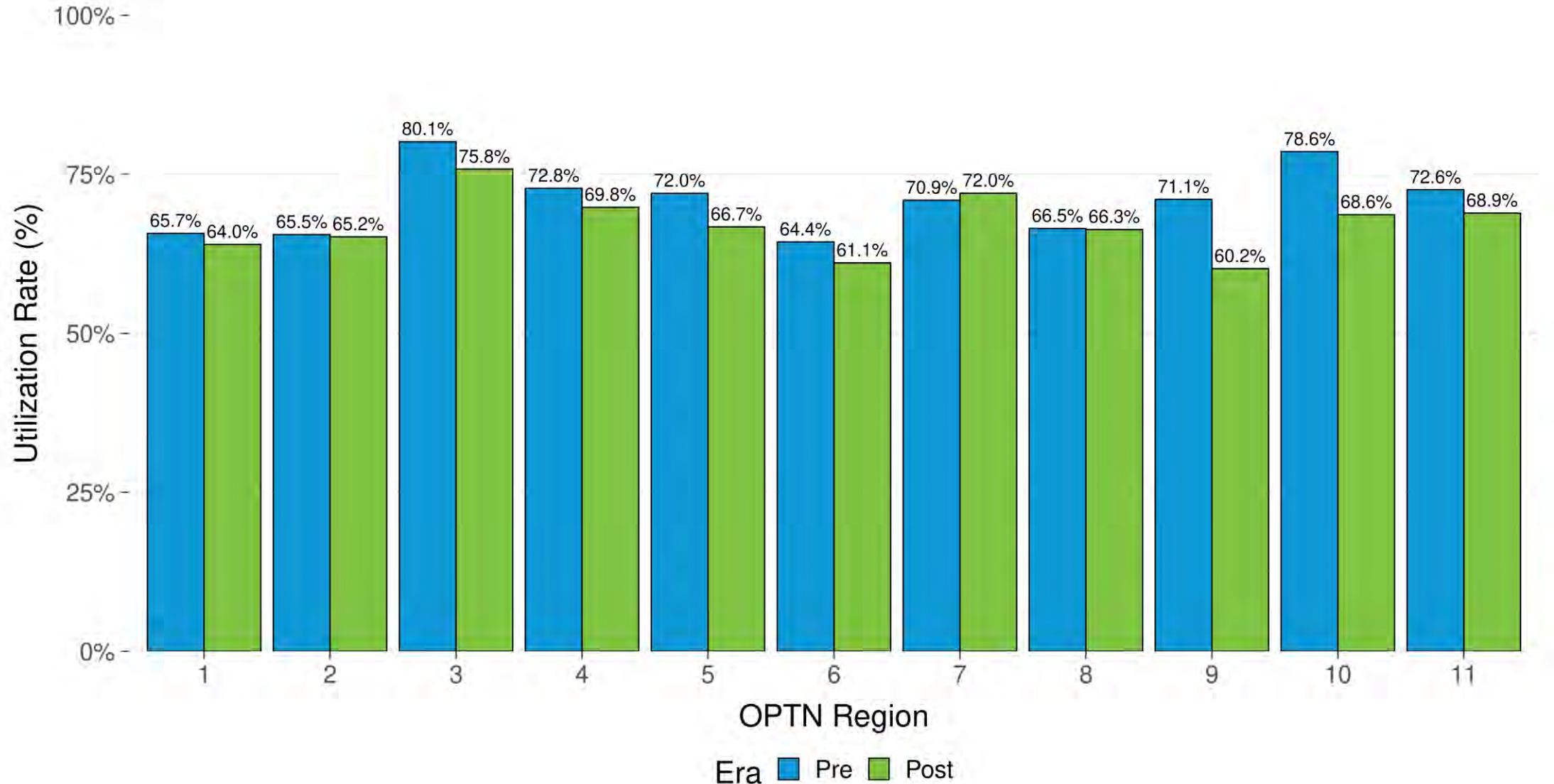
Updating Diagnoses on TCR

- Current alcohol-associated diagnoses on transplant candidate registration (TCR) form are confusing and inaccurate, leading to incorrect data entry
- Goal:
 - Update liver diagnoses on TCR to allow for more complete and accurate data collection on transplant candidates/recipients with alcohol-associated liver diseases
- Current diagnoses:
 - Alcoholic Cirrhosis
 - Alcoholic Cirrhosis with hepatitis C
 - Acute Alcoholic Hepatitis
- What alcohol-associated diagnoses should be included on the TCR?

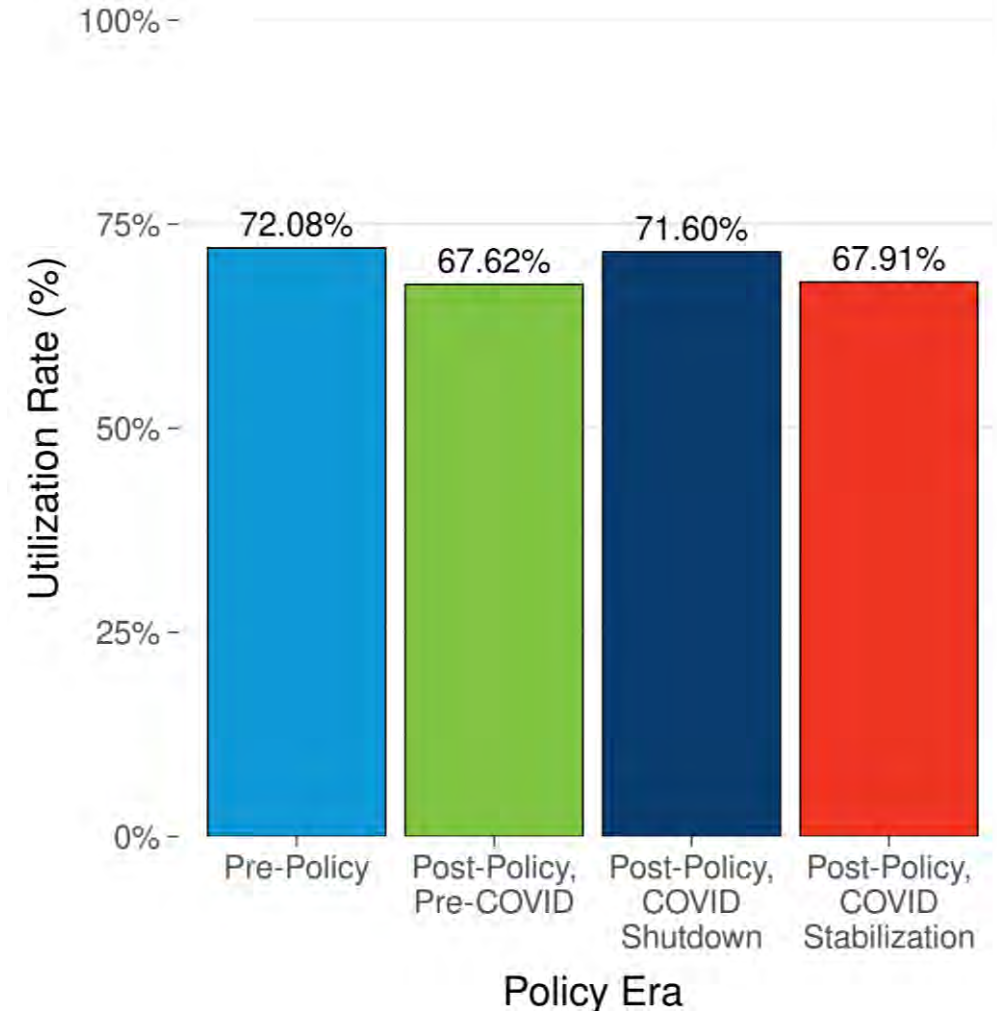
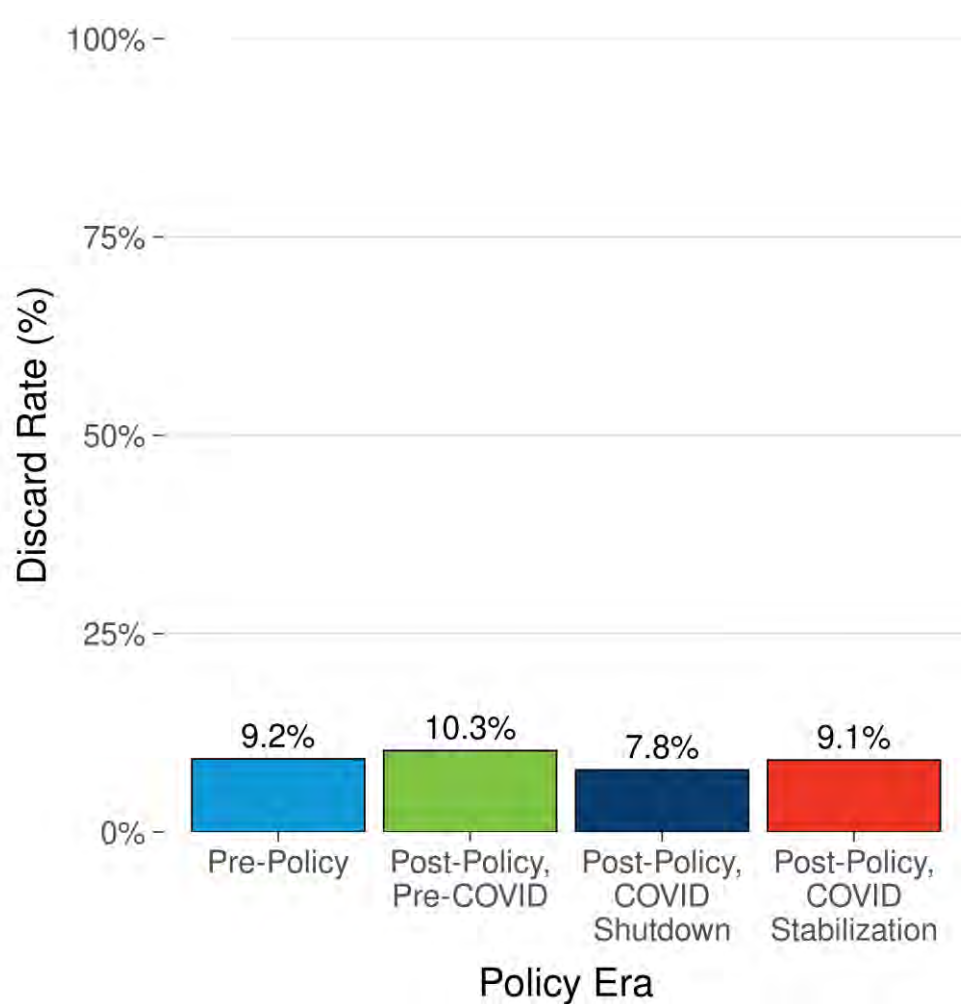
Feedback or Questions

Extra slides

Liver Utilization Rate by OPTN Region and Era

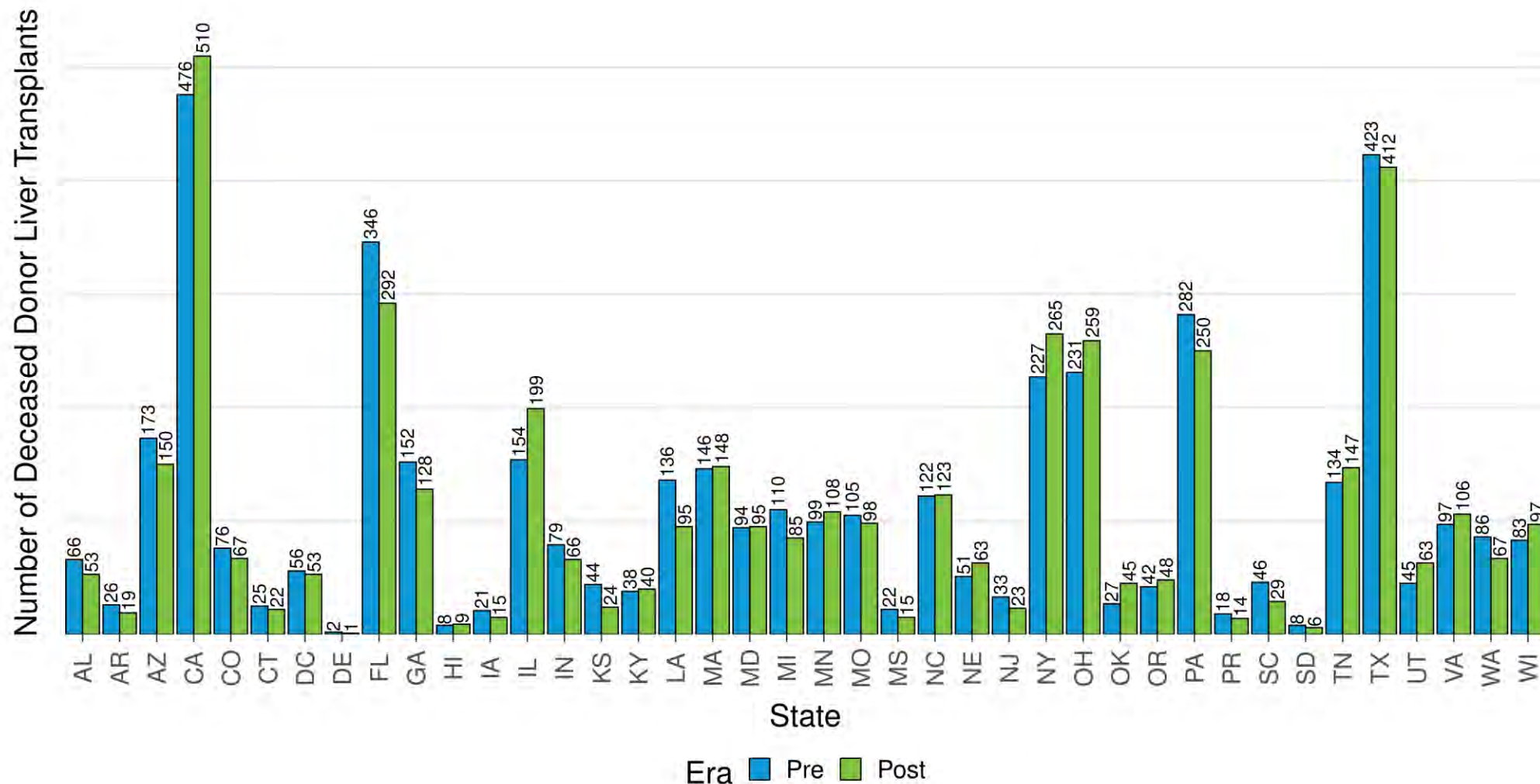


Liver Discard and Utilization Rates by COVID-19 Era

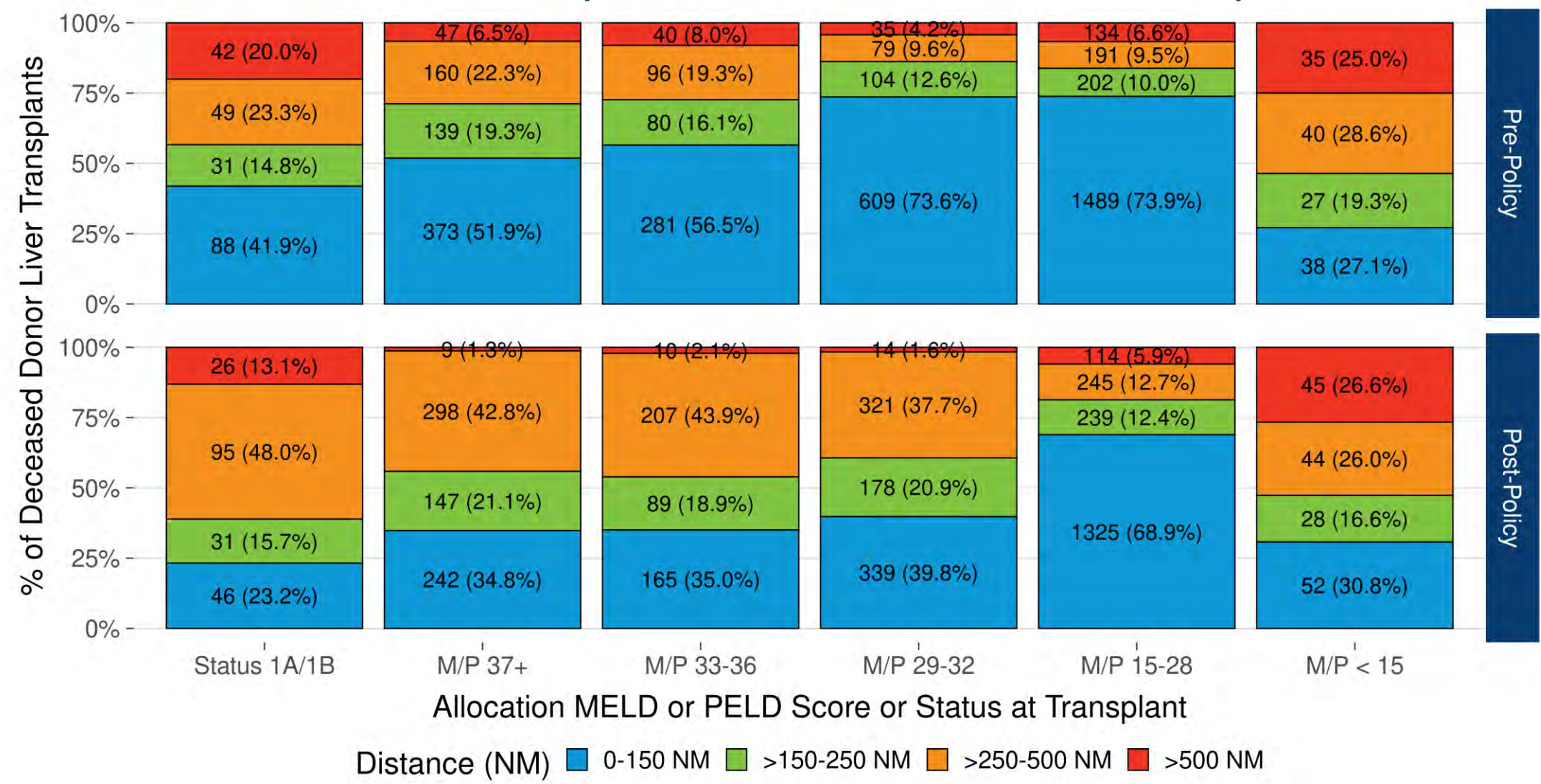


Pre-Policy: 02/05/2019-11/02/2019; Post-Policy, Pre-COVID: 02/04/2020-03/12/2020; Post-Policy, COVID Shutdown: 03/13/2020-05/09/2020; Post-Policy, COVID Stabilization: 05/10/2020-10/31/2020

Deceased Donor Liver-Alone Transplants by State and Era

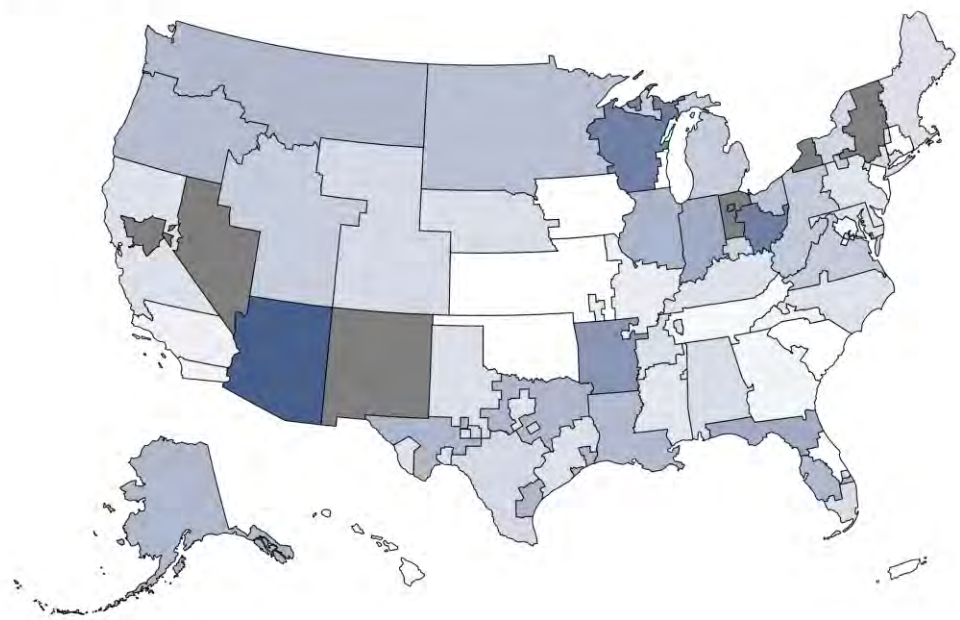


Deceased Donor Liver-Alone Transplants by Allocation MELD or PELD Score or Status, Classification Distance, and Era

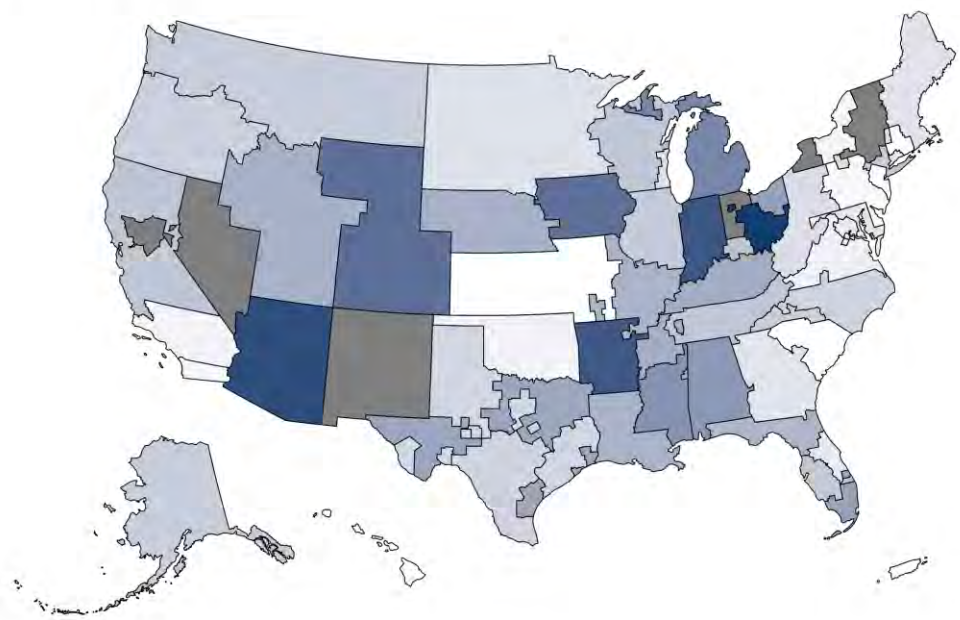


Percent of DCD Deceased Donor Liver-Alone Transplants by DSA and Era

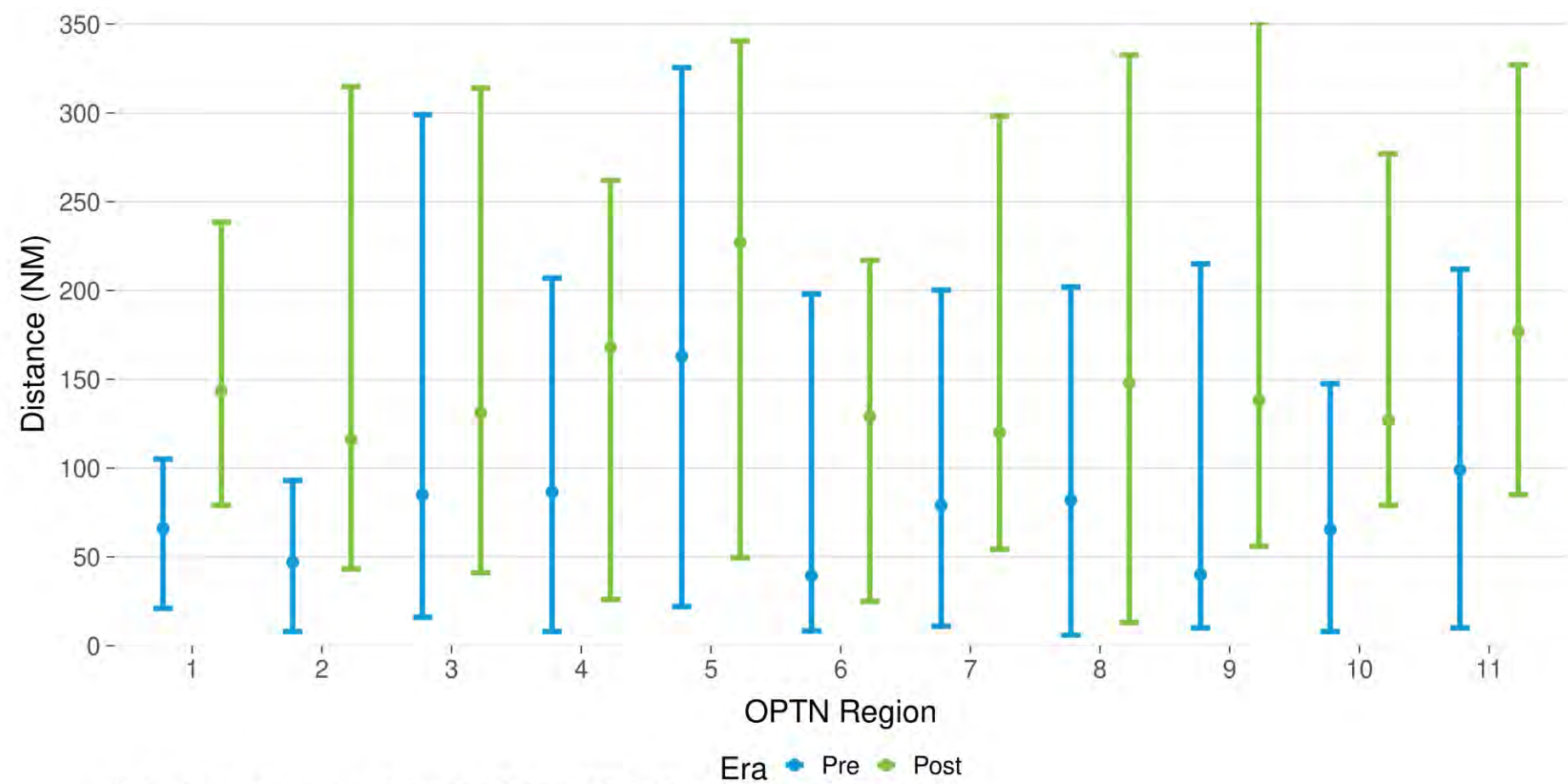
Pre-Policy



Post-Policy



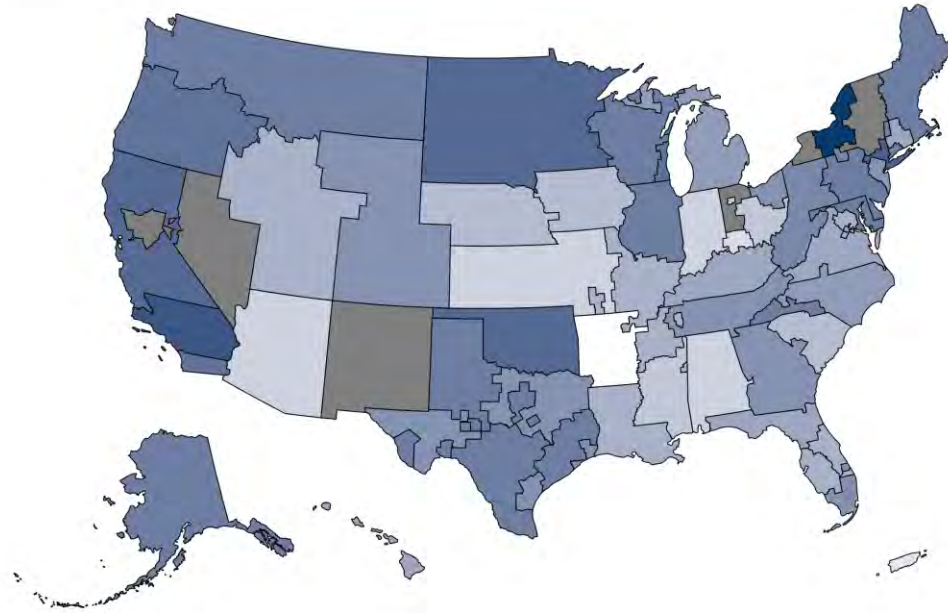
Median Distance from Donor Hospital to Transplant Center of Deceased Donor Liver-Alone Transplants by OPTN Region and Era



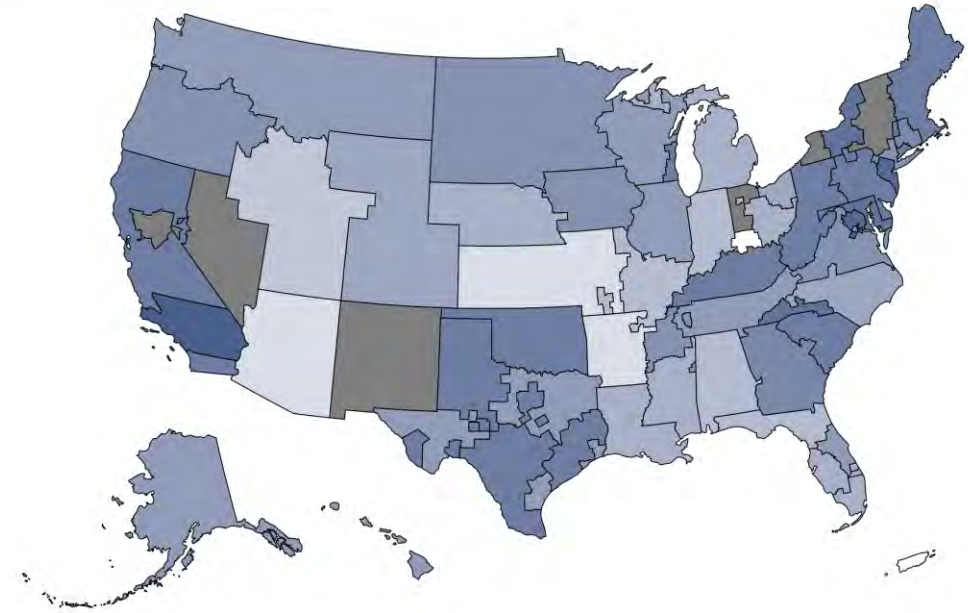
National state of emergency declared in US due to COVID-19 pandemic on March 13, 2020.
Points represent median distance, error bars denote 25th and 75th percentiles (IQR), respectively.


Deceased Donor Liver-Alone Transplant Median Allocation MELD or PELD Score at Transplant (MTS) by DSA and Era

Pre-Policy



Post-Policy



Median Transplant Score  18 21 24 27 30 33 36