

“Share 35” Liver Policy: Analysis at 1 Year

*OPTN Liver and Intestinal Organ Transplantation Committee Forum
September 16, 2014*

OPTN



Background

- On June 18, 2013, the OPTN implemented a number of changes to adult donor liver allocation:
 - Extend regional sharing of livers to MELD/PELD 15+ candidates on a national basis (“Share 15”)
 - Regional sharing of livers to MELD/PELD 35+ candidates (“Share 35”)
 - National sharing of livers and intestines to liver-intestine candidates
- Liver and Intestinal Organ Transplantation Committee charged with monitoring the impact of allocation changes

Data

- Data provided for 2 eras:
 - June 18, 2012 – June 17, 2013 (Pre-Era)
 - June 18, 2013 – June 17, 2014 (Post-Era)
 - OPTN data as of August 22, 2014
- Types of data
 - National and some regional/DSA data focused on:
 - Transplants by MELD/PELD, CIT, distance
 - Post-transplant outcomes
 - Waiting list mortality
 - DSA imports/exports

Methods

- Counts of waiting list deaths include:
 - OPTN member reported removals for death
 - OPTN member reported removals for “too sick”
 - SSADMF deaths (pre-removal and within 30 days of removal within the period)
- Overall death rate presented as deaths per patient-year
- “Intent-to-treat” analysis for MELD/PELD 35+ waiting list outcomes
 - Time to transplant, death, other removal from first entry into MELD/PELD 35+ category
 - Analysis accounts for competing risks
- Post-transplant patient survival estimated using Kaplan-Meier

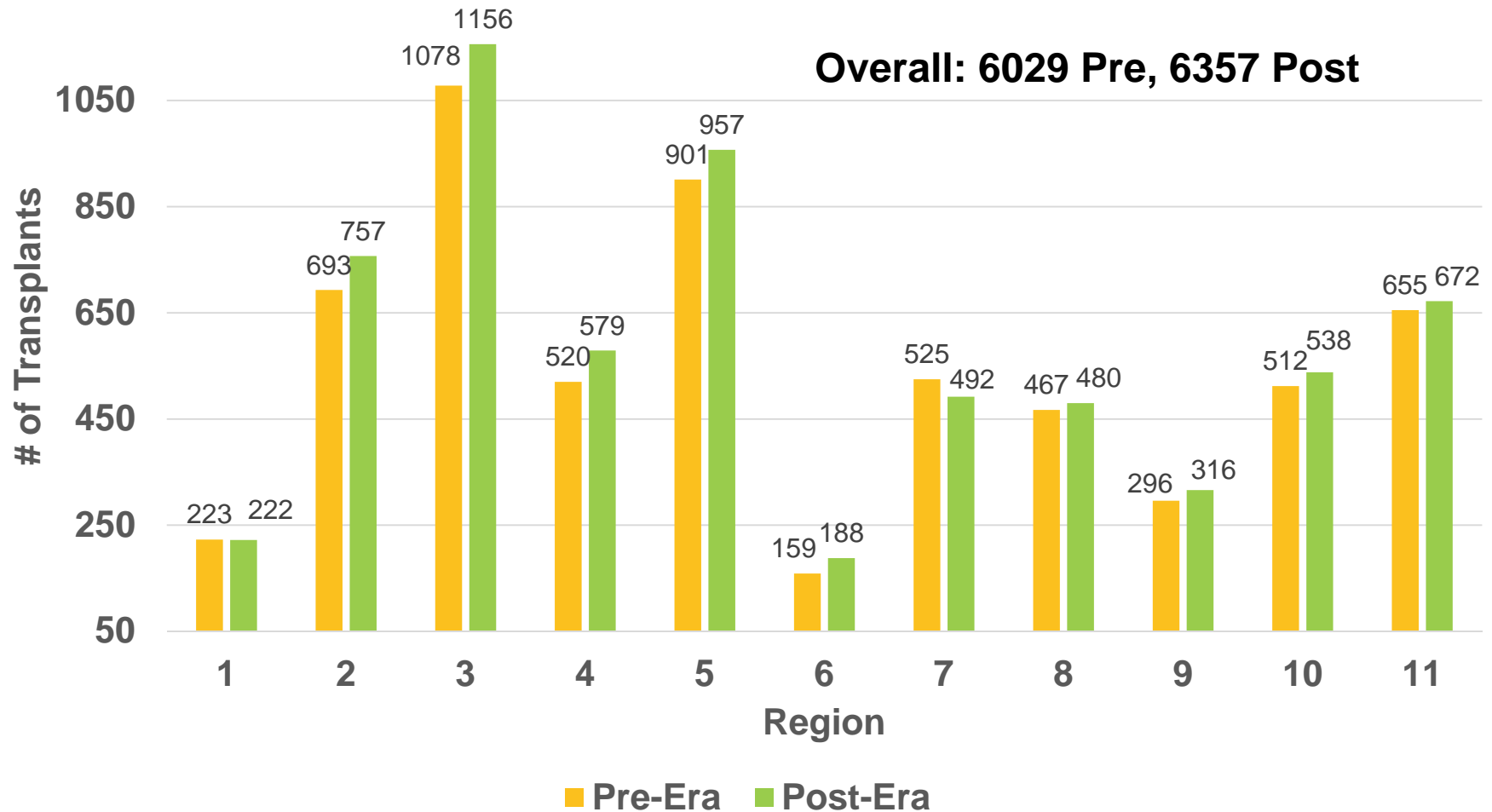


Transplants

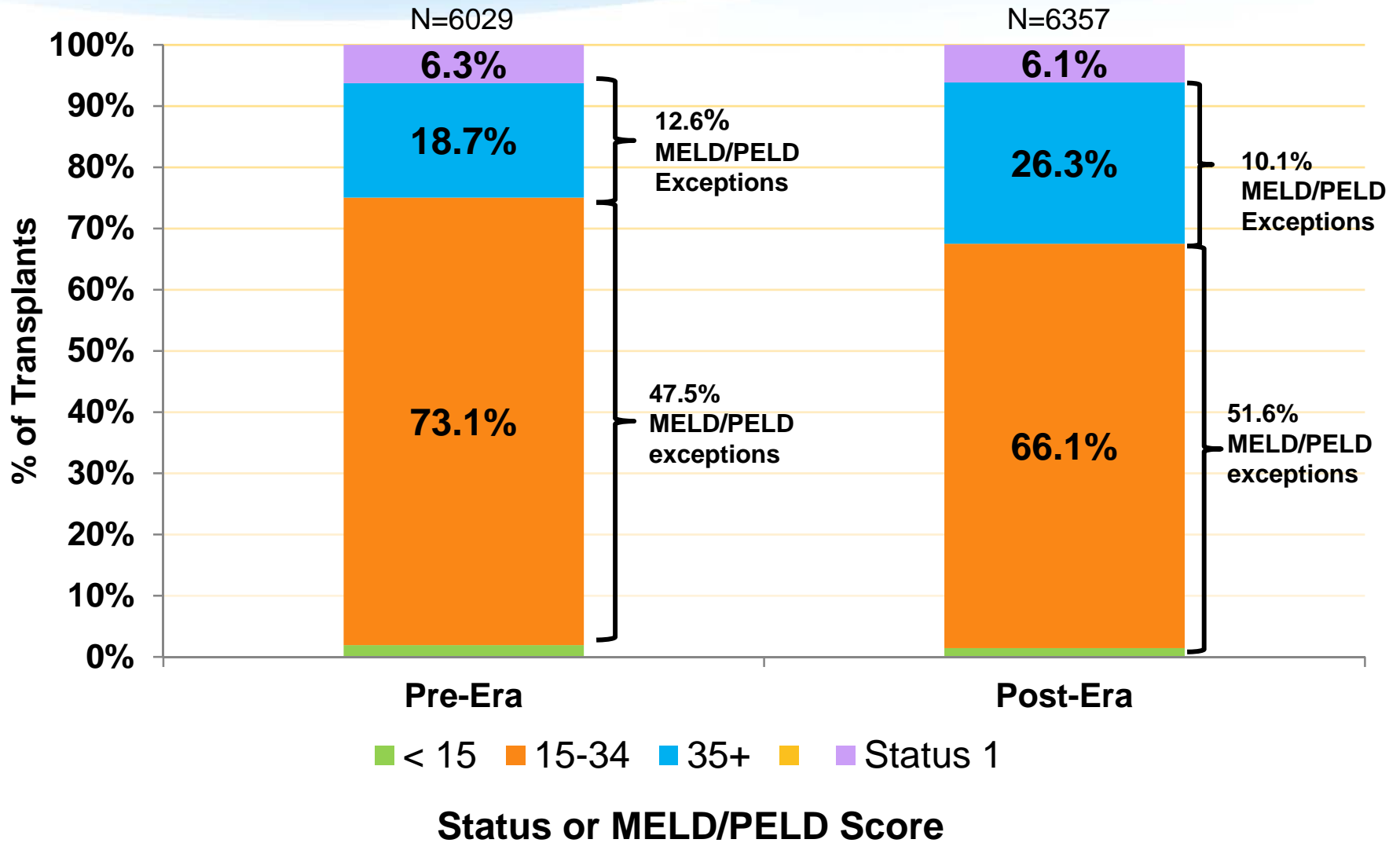
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Deceased Donor Liver Transplants by Era and Region

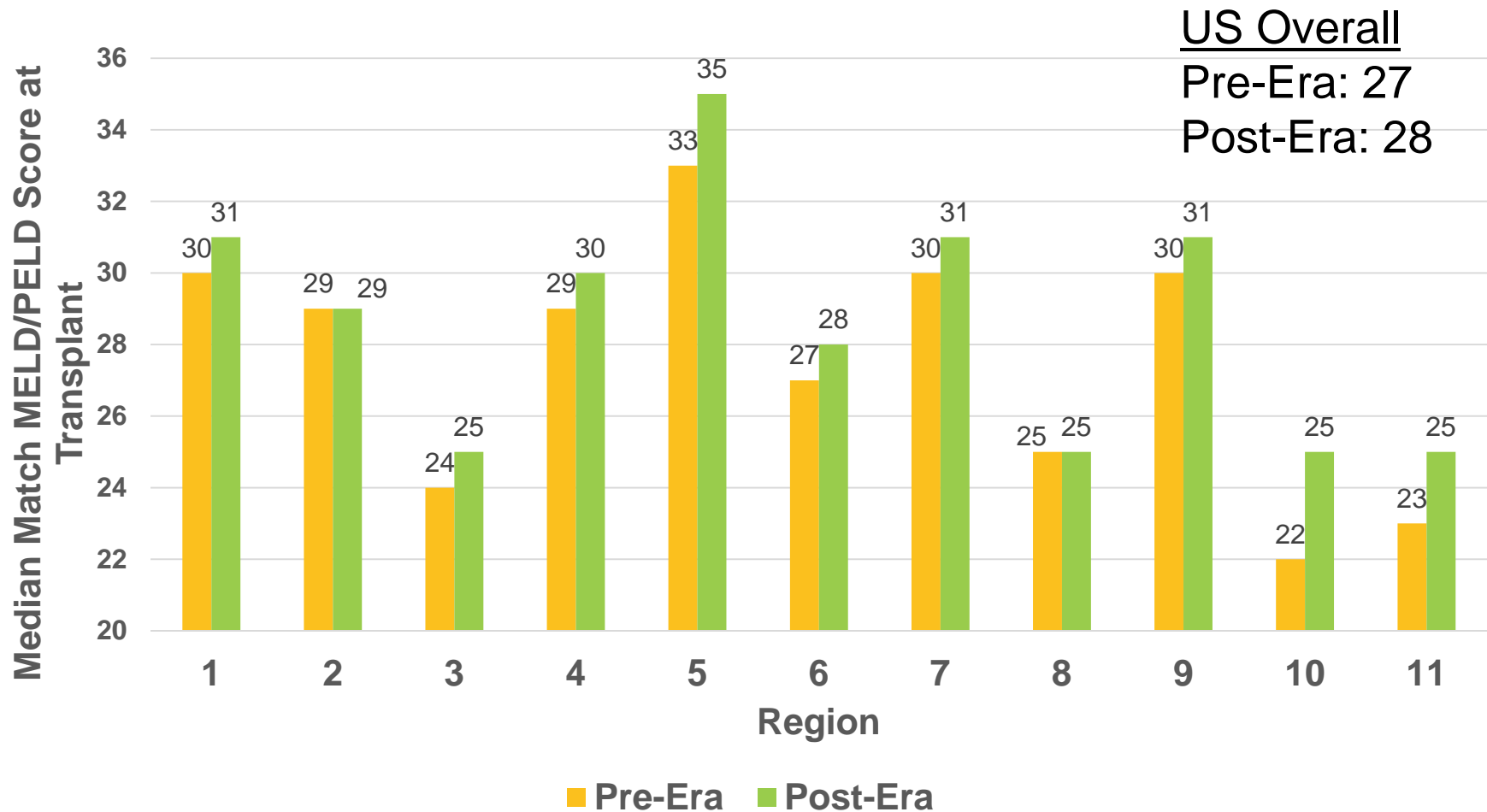


Deceased Donor Liver Transplants by Era and Status/Allocation Score



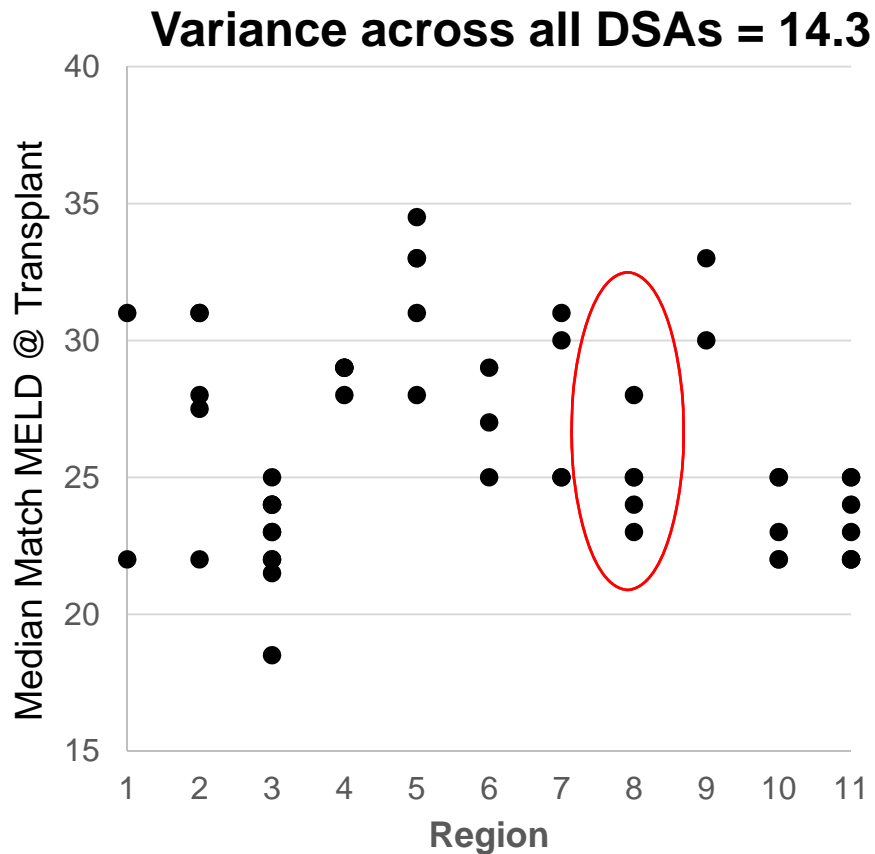
Deceased Donor Liver Transplants by Era and Region – Median Allocation Score At Transplant

(Status 1s Excluded)

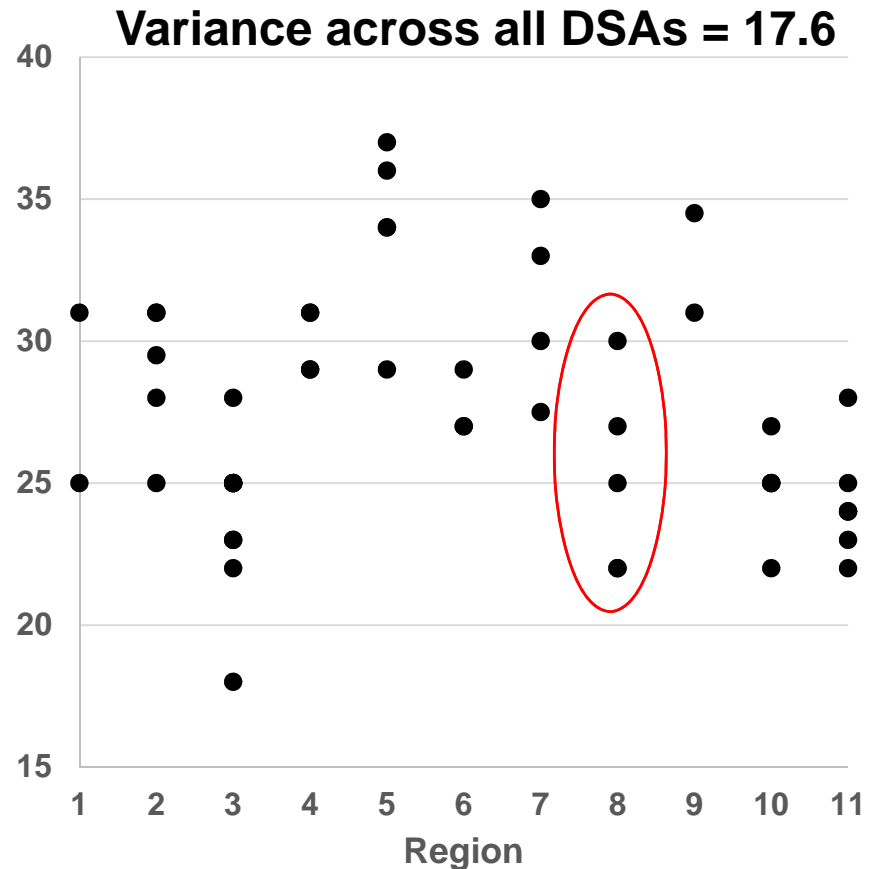


Median Allocation MELD/PELD at Transplant, by DSA within Region and Era

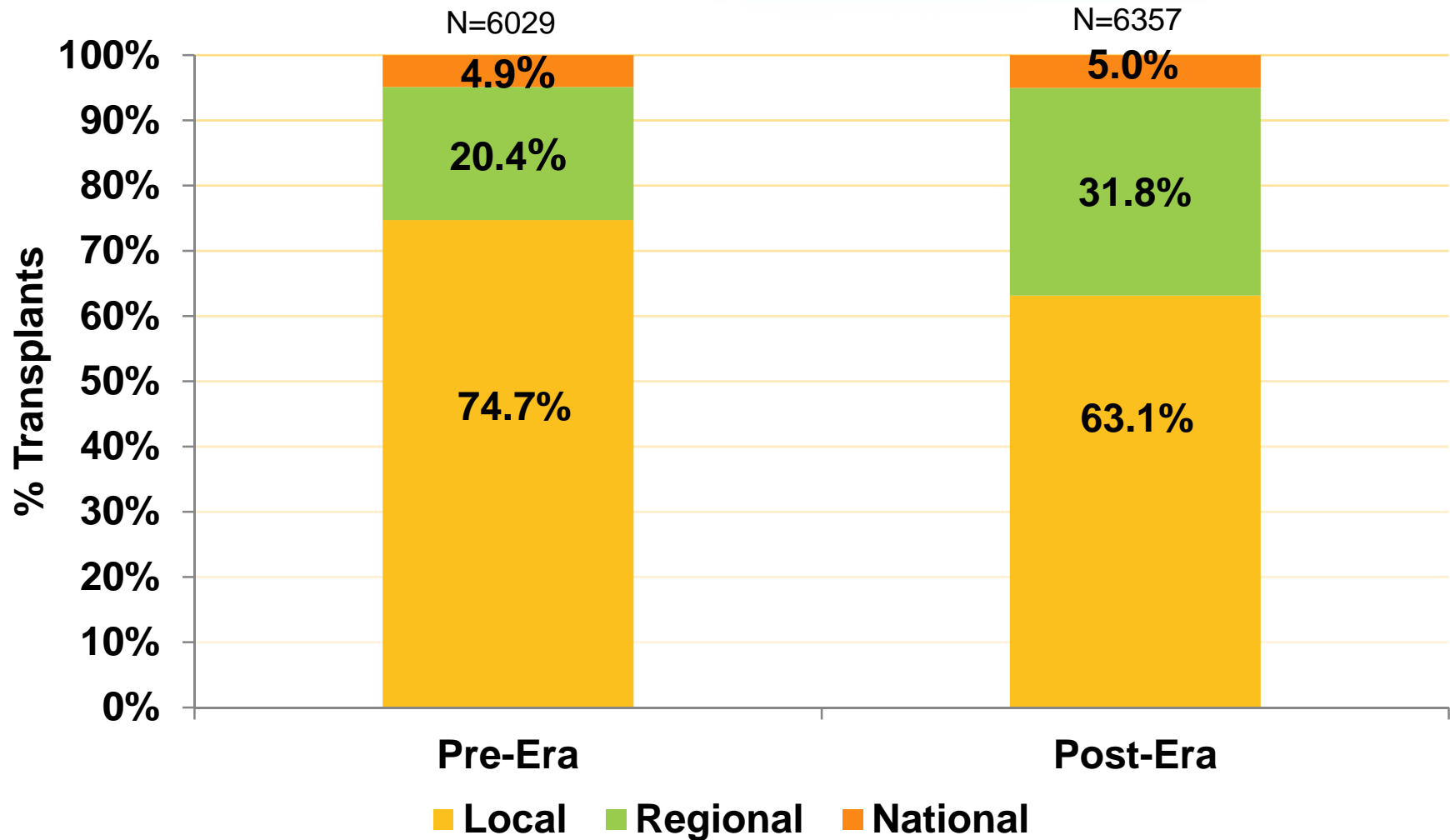
Pre-Era



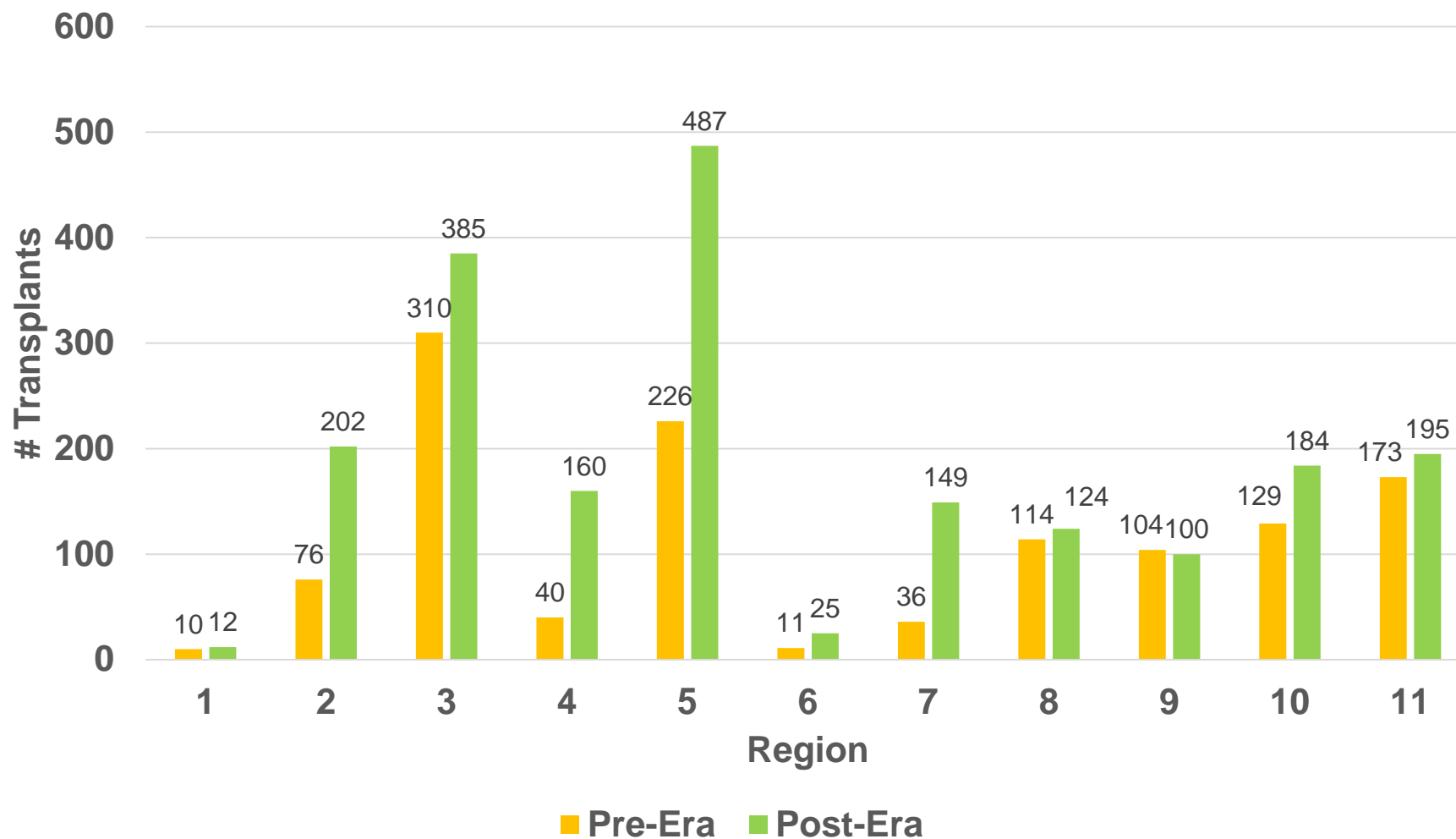
Post-Era



Deceased Donor Liver Transplants by Era and Share Type



Regional Shares Pre-Era and Post-Era



Multi-Organ Transplants

- *Liver-Intestine*: 34 in Pre-Era, 75 in Post-Era
 - 0.6% of Pre-Era, 1.2% of Post-Era Transplants
 - 22 National Shares in Pre-Era vs. 53 in Post-Era

- *Liver-Kidney*: 504 (8.4%) in Pre, 535 (8.4%) in Post
 - 90% local, 9% Regional in Pre-Era
 - 67% local, 32% Regional in Post-Era



Organ Travel Distance, Cold Ischemia Time, Donor Risk Index

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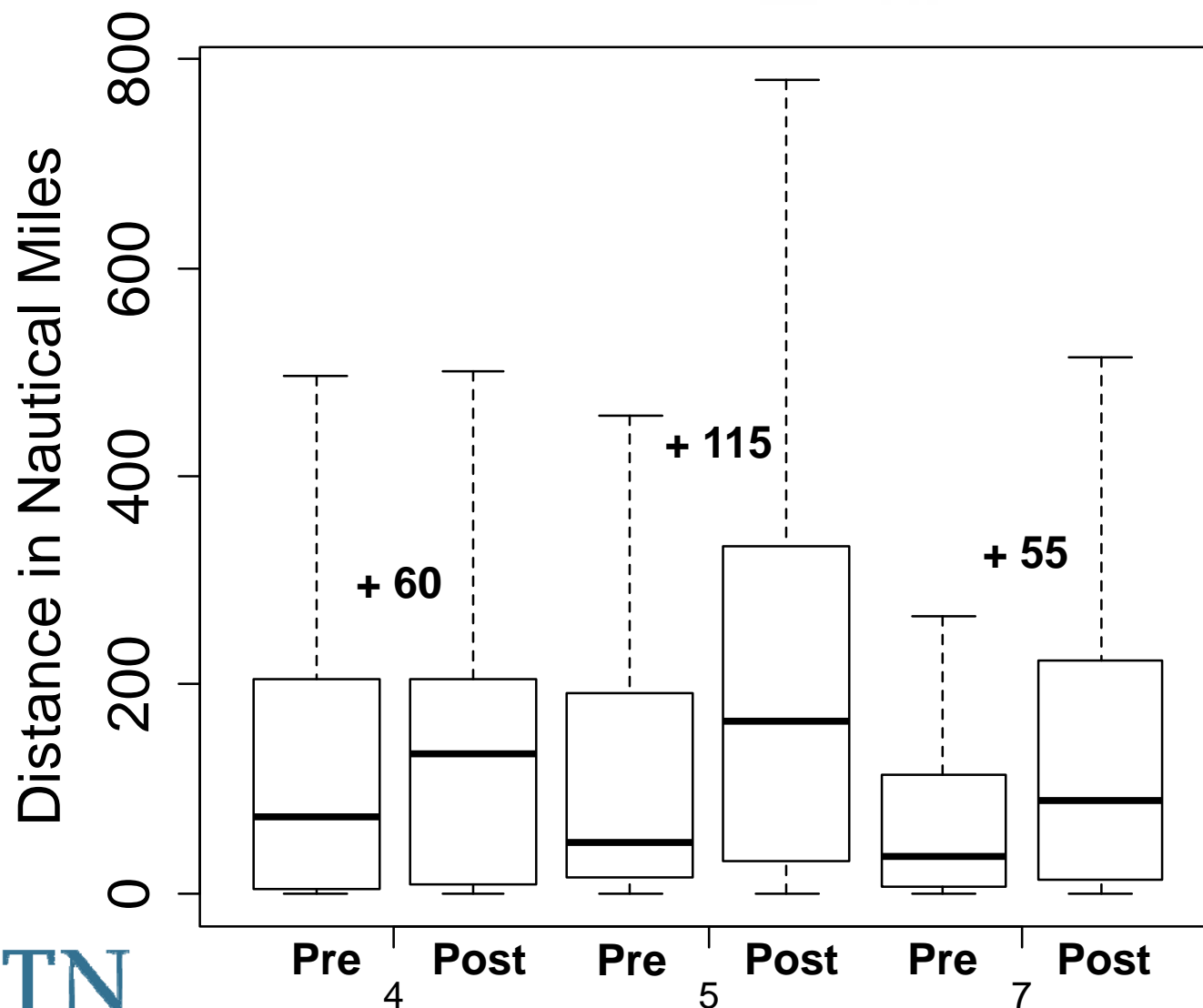


Organ Travel Distance, Cold Ischemia Time, and Donor Risk Index

	Pre	Post
Median Distance organs traveled (miles)		
Overall:	59	85
Local:	22	23
Regional:	231	236
National:	687	660
Median Cold Ischemia Time (CIT) (hours)		
Overall:	6.1	6.1
Local:	5.9	5.8
Regional:	6.7	6.7
National:	8.1	7.7
Median Donor Risk Index (DRI)		
Overall:	1.4	1.4
Local:	1.3	1.3
Regional :	1.5	1.4
National:	1.6	1.7



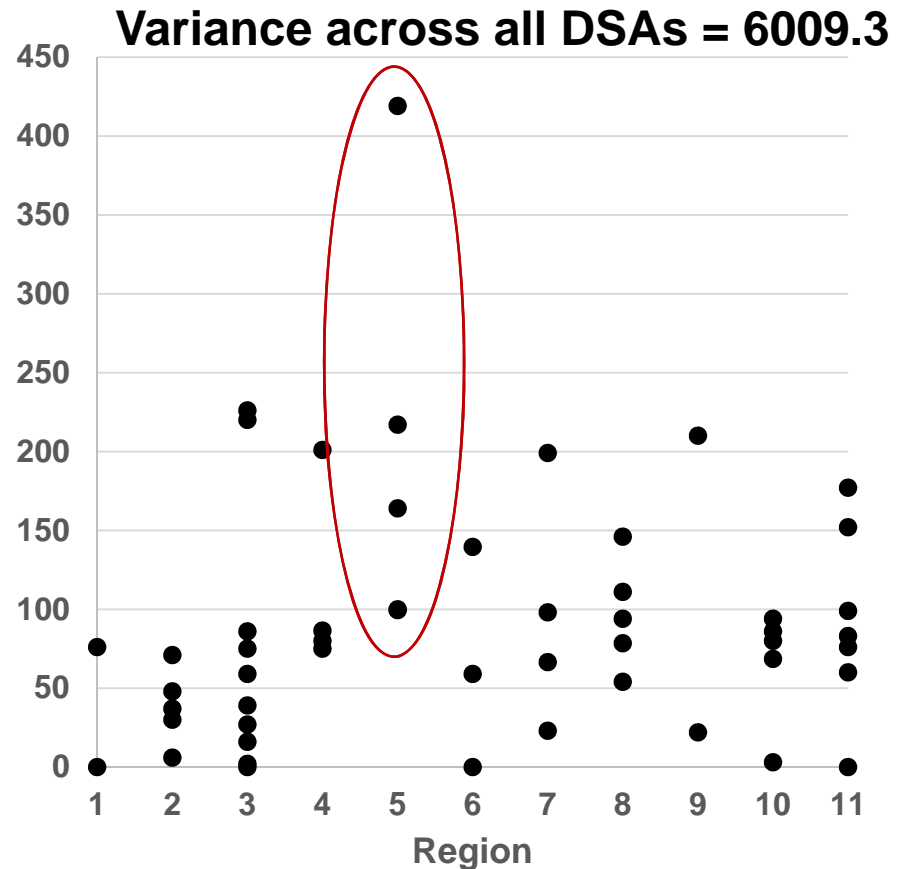
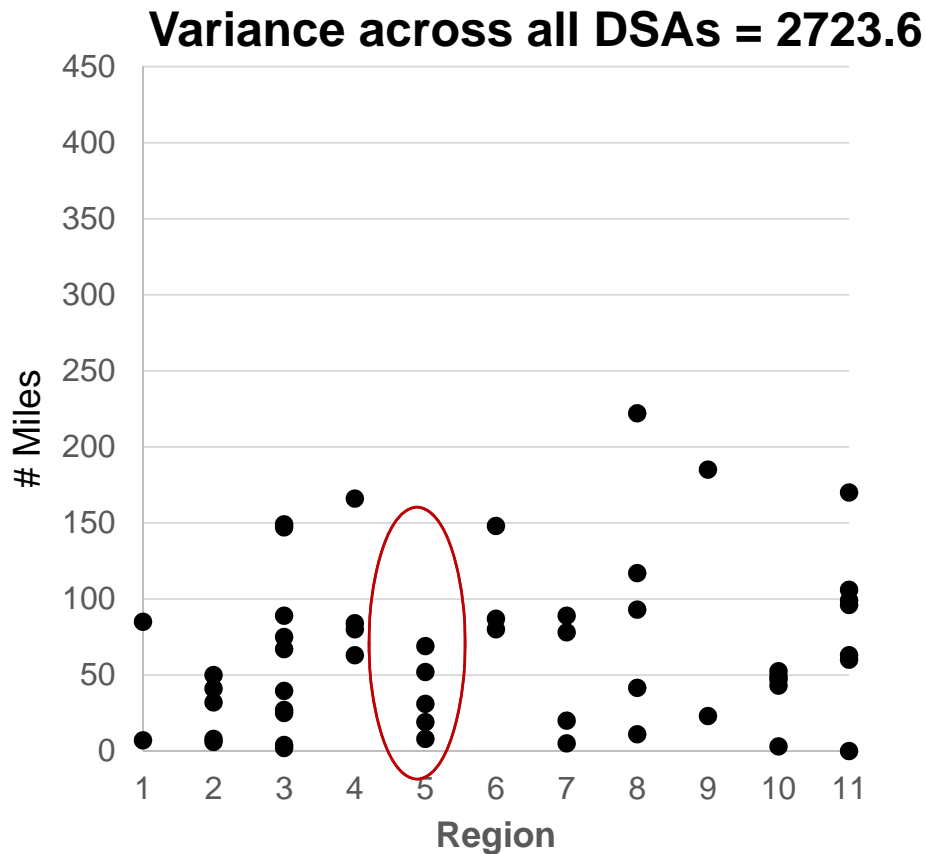
Increase in Organ Travel Distance for Regions 4, 5, and 7



Median Distance Livers Traveled, by DSA within Region and Era

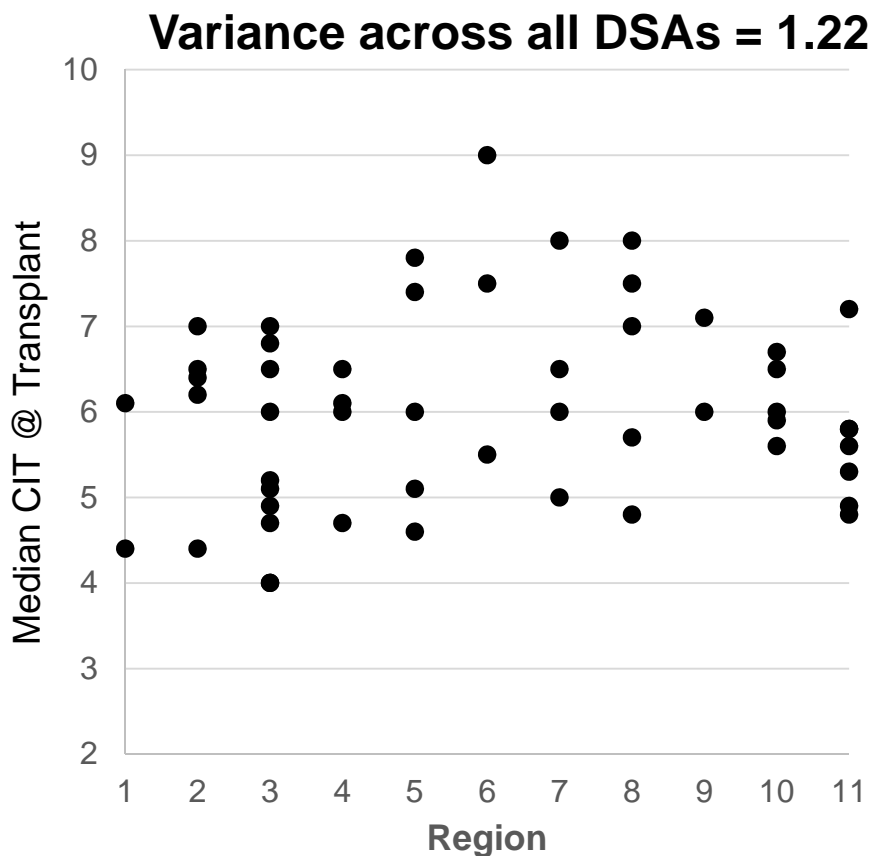
Pre-Era

Post-Era

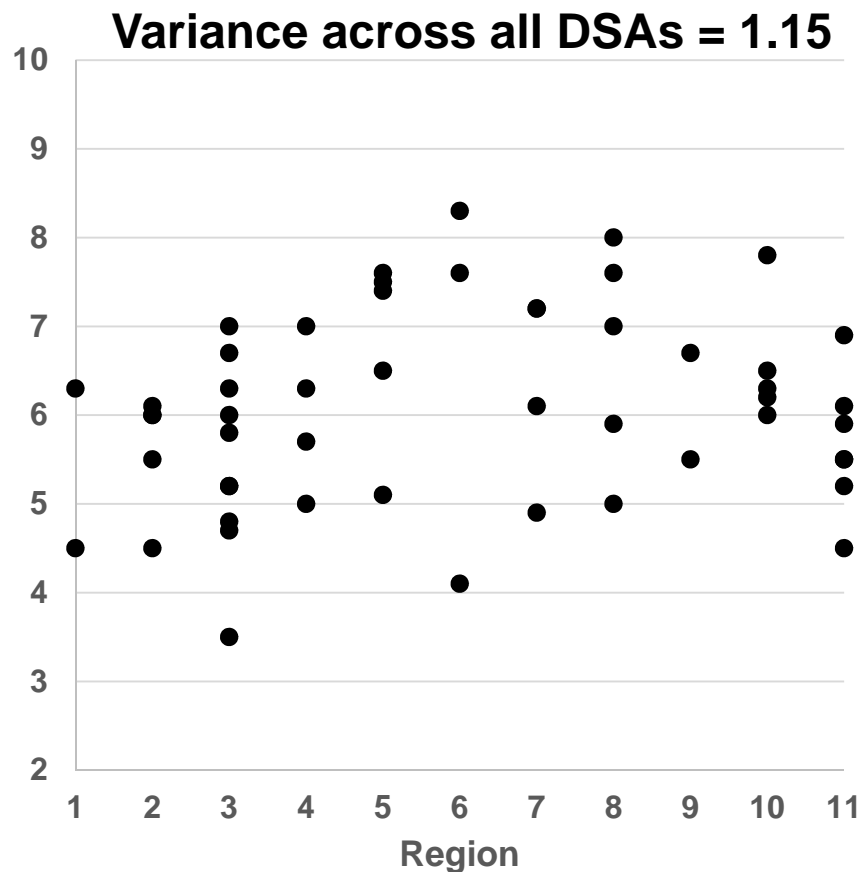


Median CIT, by DSA within Region and Era

Pre-Era



Post-Era



Transplant Metrics for Recipients with Match MELD/PELD at Transplant of 35+

Factor	Pre-Era	Post-Era
Distance	51	166
CIT	6.3	6.6
DRI	1.3	1.3
Length of Stay	16	15
MELD/PELD (Lab)	37	37



Median values reported



Livers Not Used

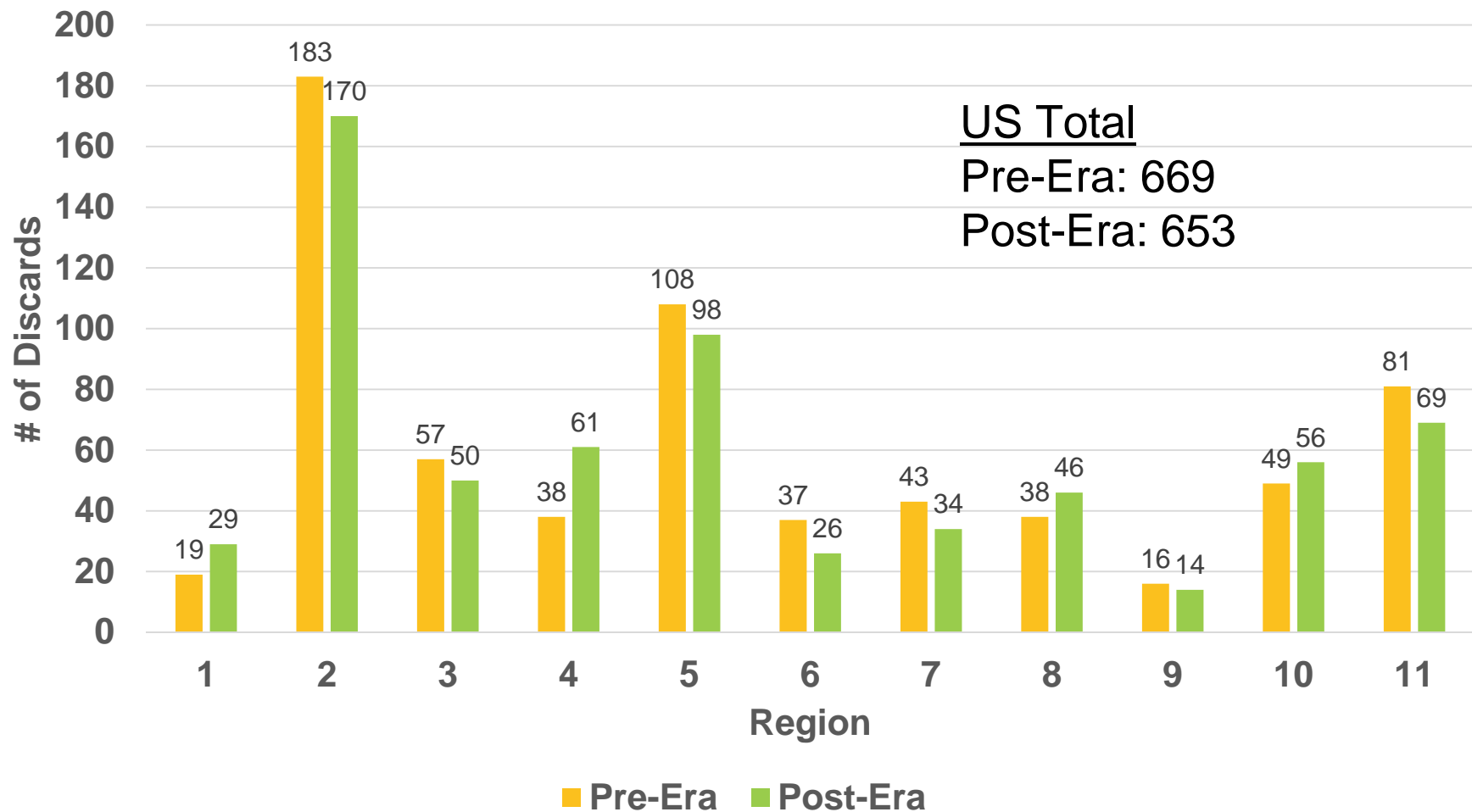
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Livers Not Used

- Recovered for Transplant but Not Transplanted:
 - 669 in Pre-Era (10.3 % of recovered)
 - 653 in Post-Era (9.5% of recovered)
- Livers Not Recovered:
 - 1149 in Pre-Era (14.1% of all donors)
 - 1099 in Post-Era (13.0 % of all donors)

Livers Recovered for Transplant But Not Transplanted, by Era and Region



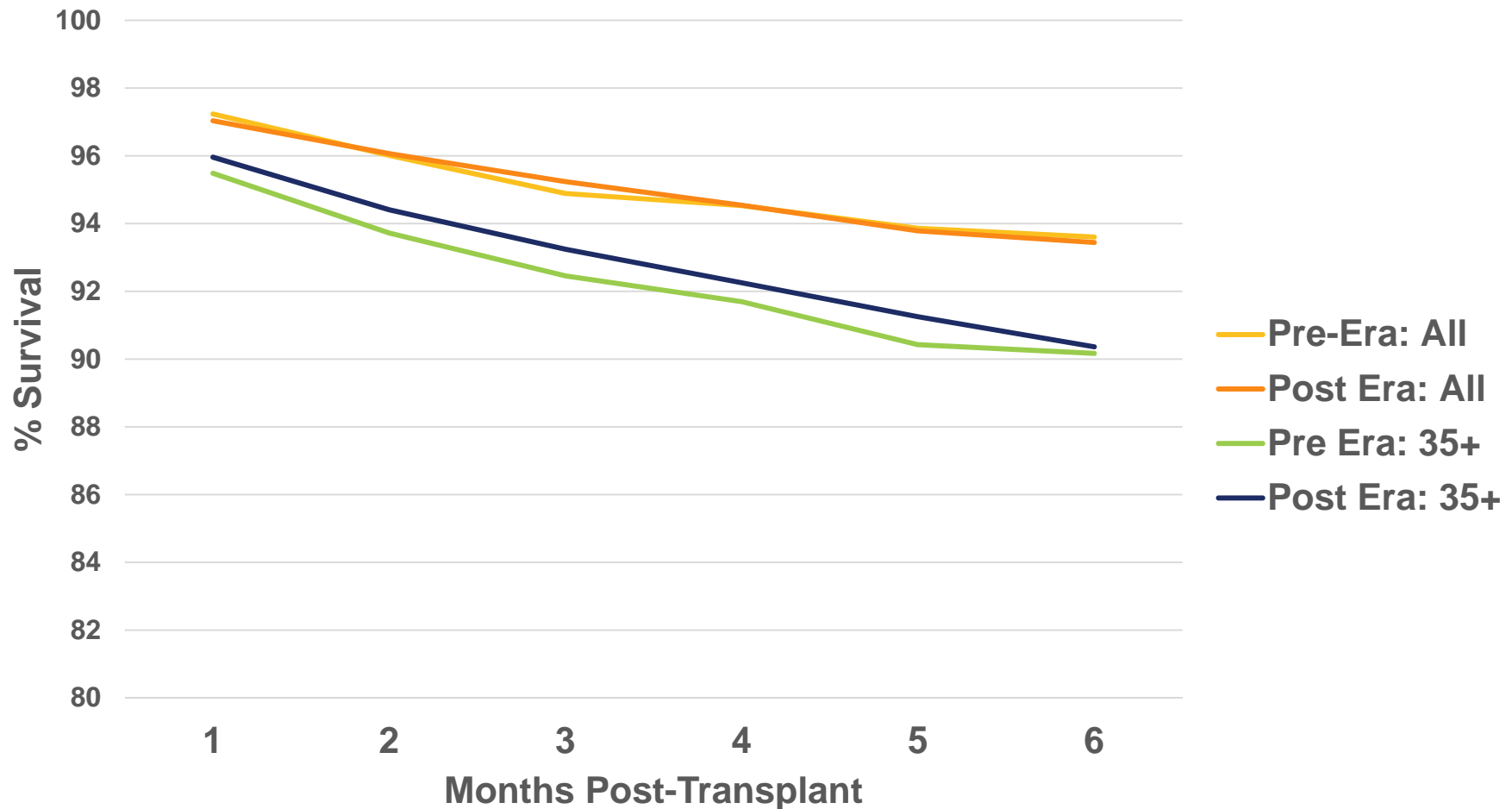


Transplant Outcomes

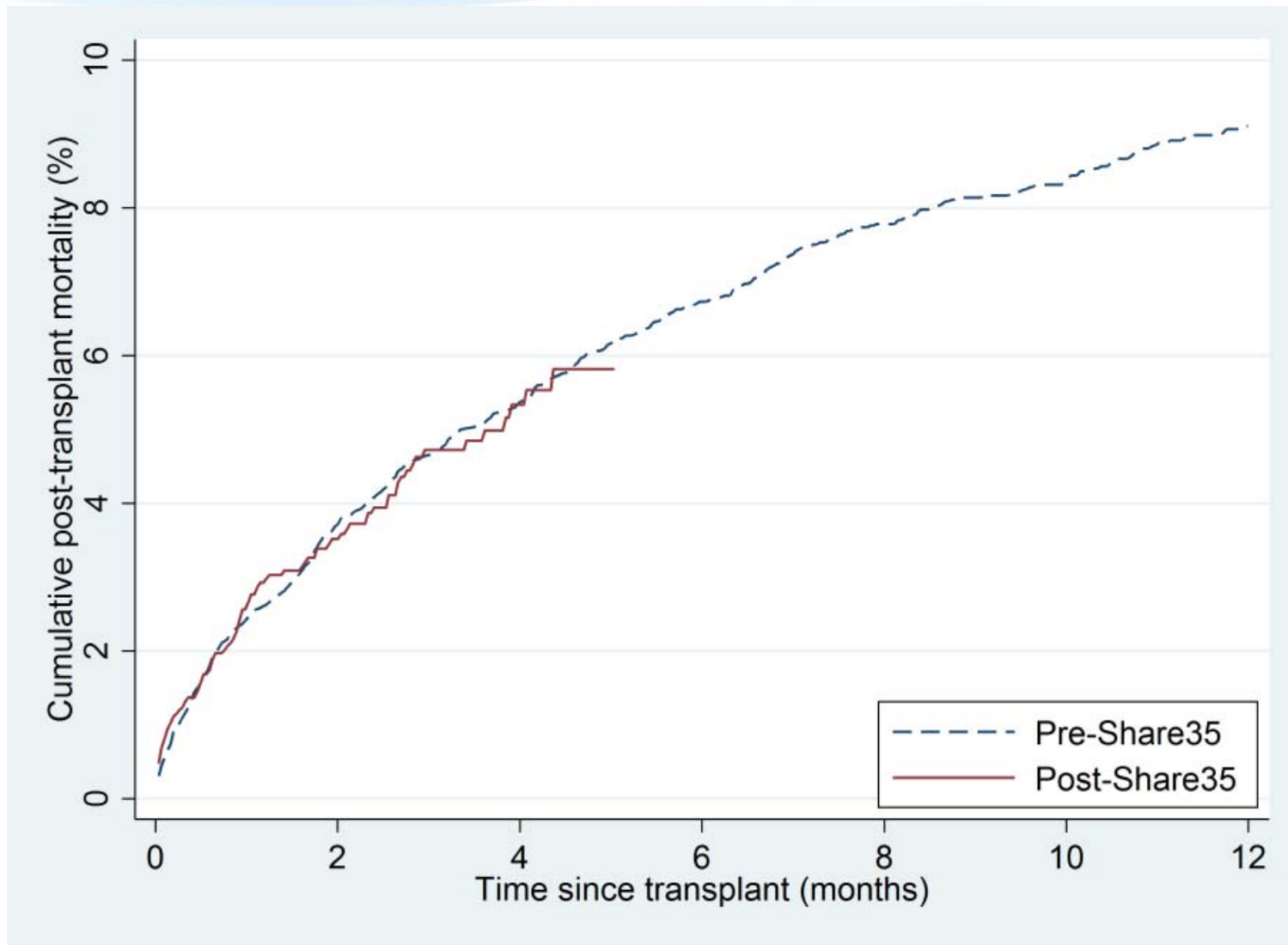
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Six-Month Patient Survival Deceased Donor Liver Transplants Performed 120 Days Pre- and Post-Share 35



Post-Transplant Mortality Rates



Massie et al., AJT (in revision)



Waiting List Dynamics

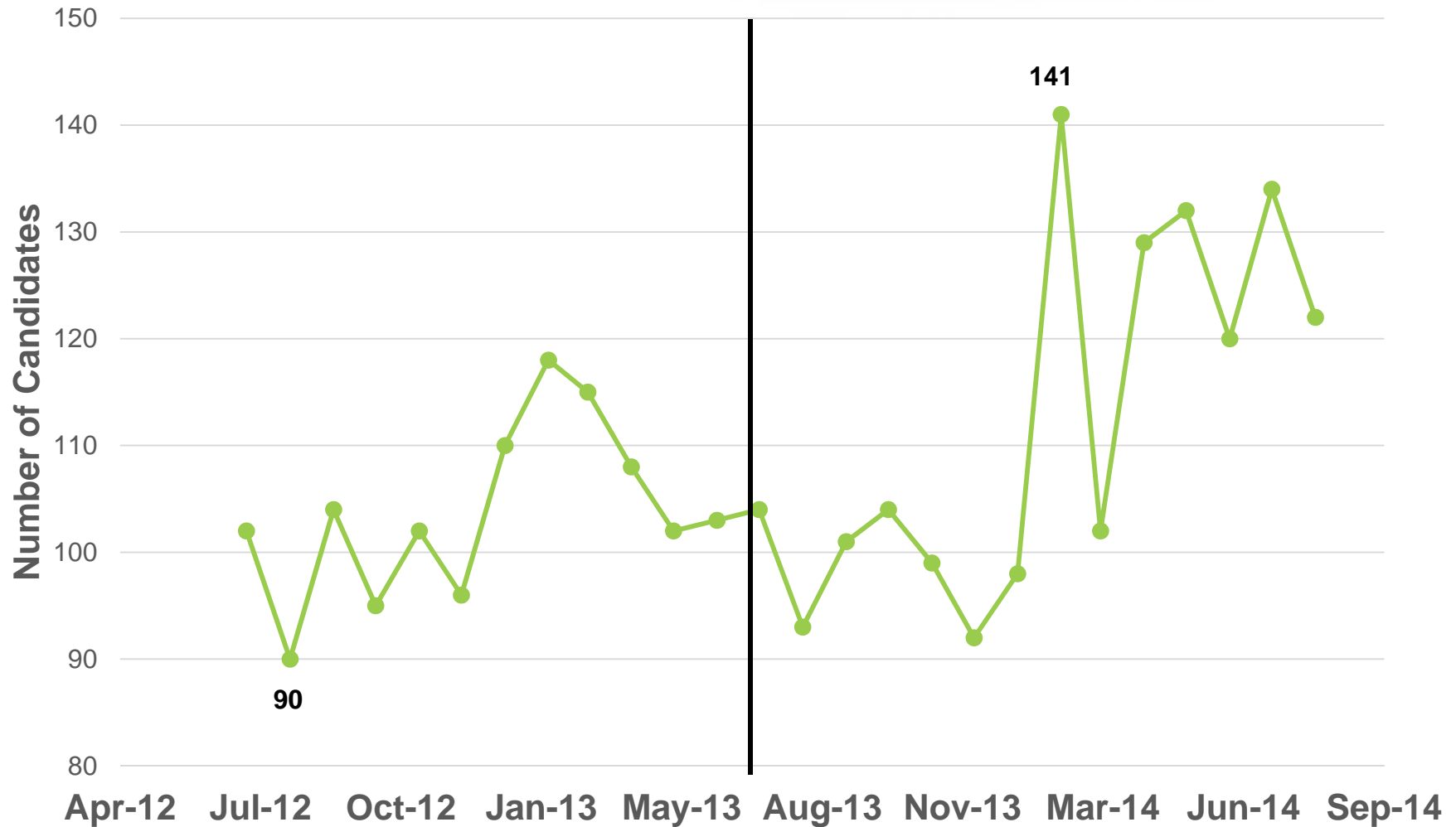
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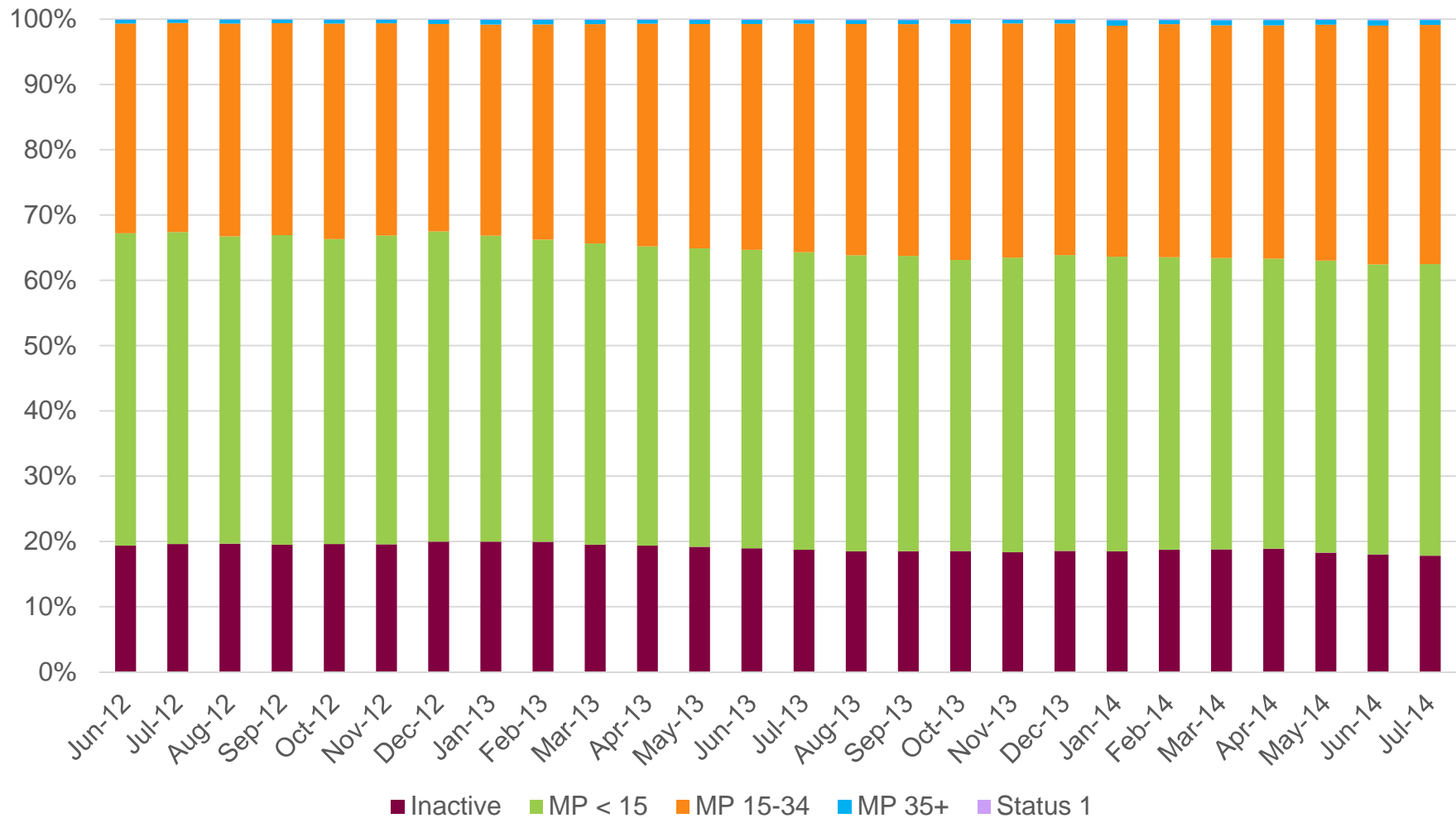
Liver Waiting List Additions, Pre-Era and Post-Era, By Status/Allocation Score

	Status 1		< 15		15-34		35+		Inactive		Total
	N	%	N	%	N	%	N	%	N	%	N
Pre-Era	461	3.9	5,080	43.4	5289	45.1	730	6.2	155	1.3	11,715
Post-Era	421	3.5	5,275	43.4	5485	45.1	814	6.7	160	1.3	12,155
Net	-40		+195		+196		+84		+5		+440

Liver Candidates With MELD/PELD Allocation Scores of 35+ at Month's End



Candidates on the Liver Waiting List at Month End, By Status/Allocation Score



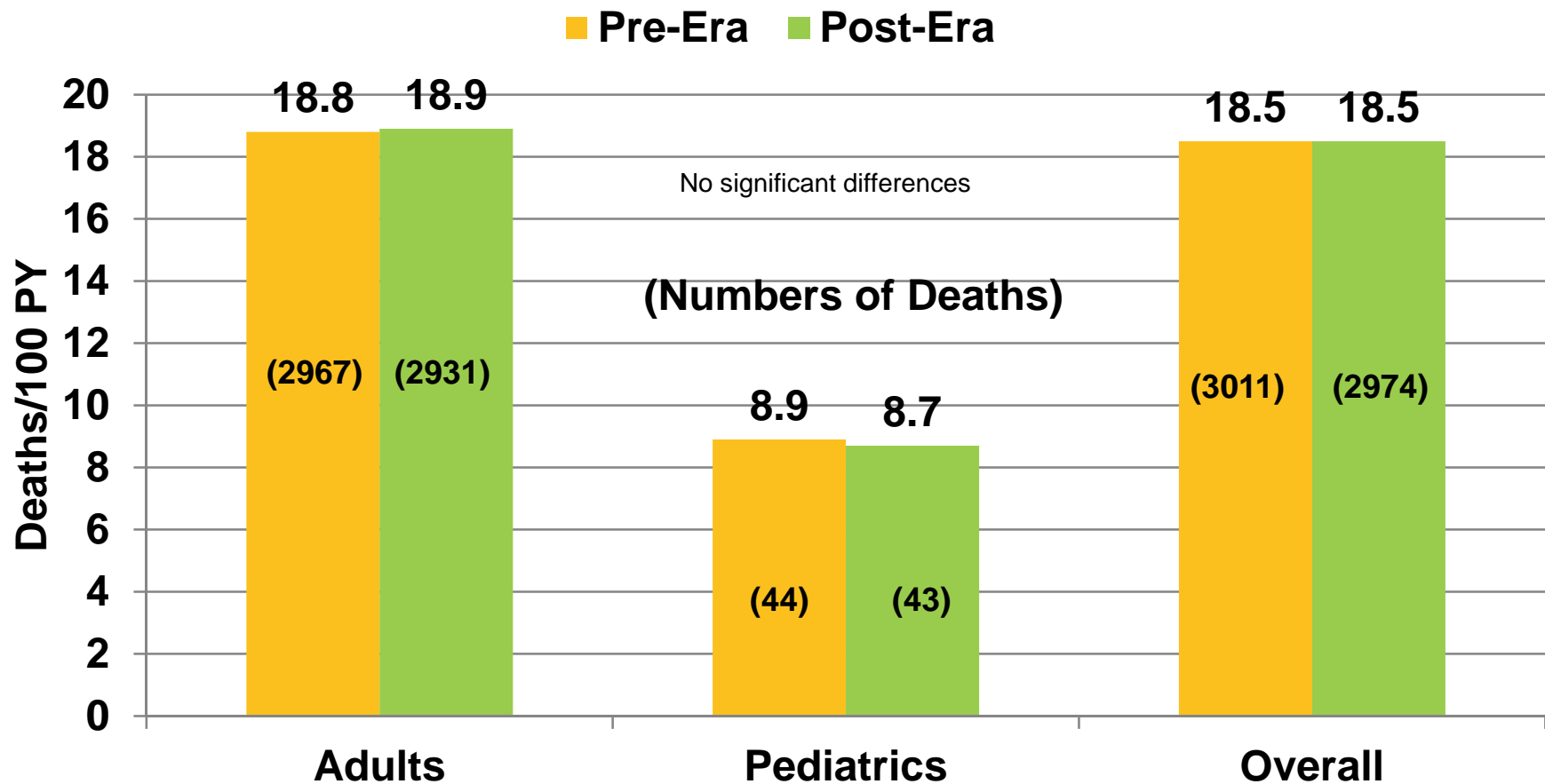


Waiting List Death Rates

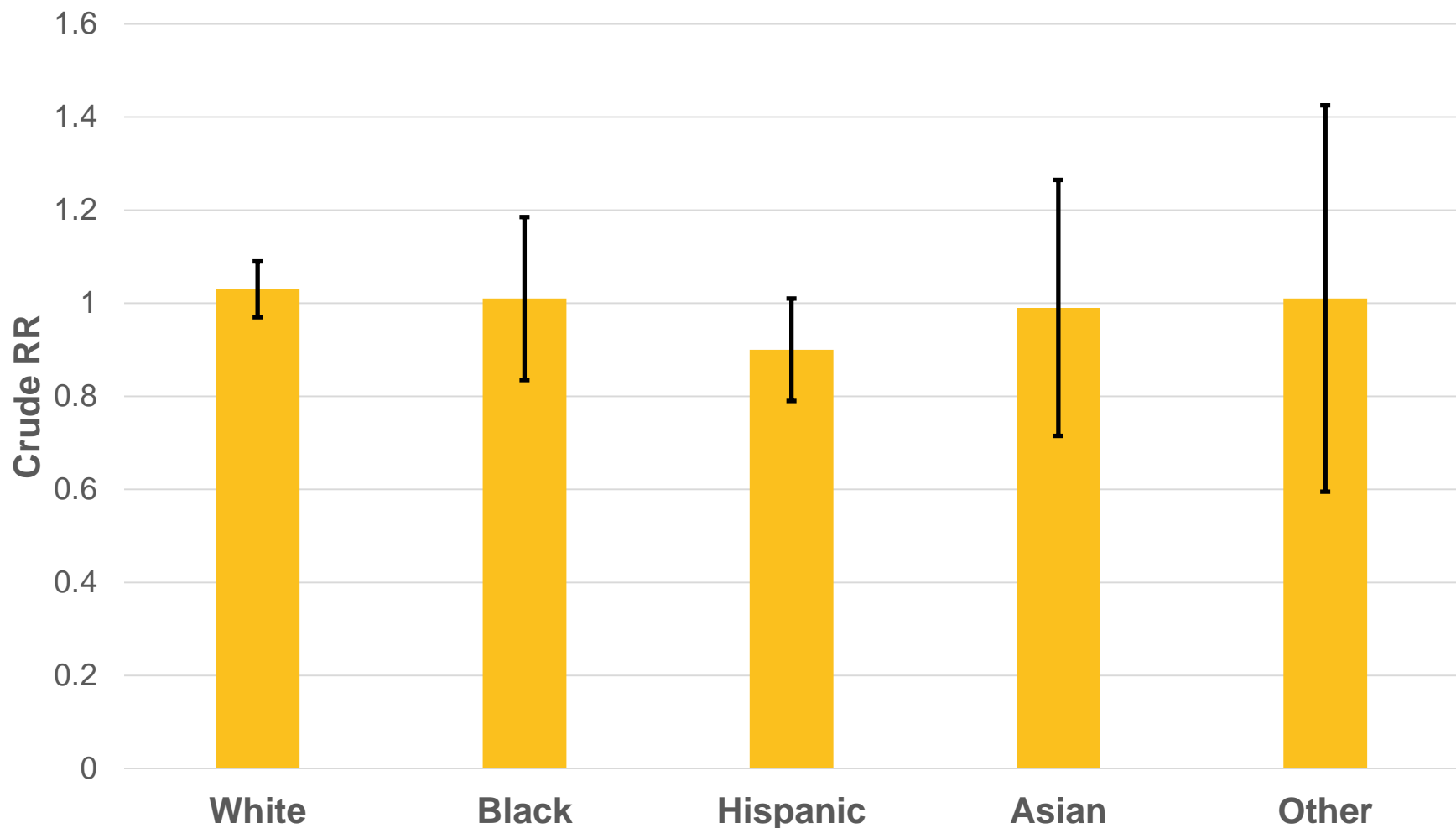
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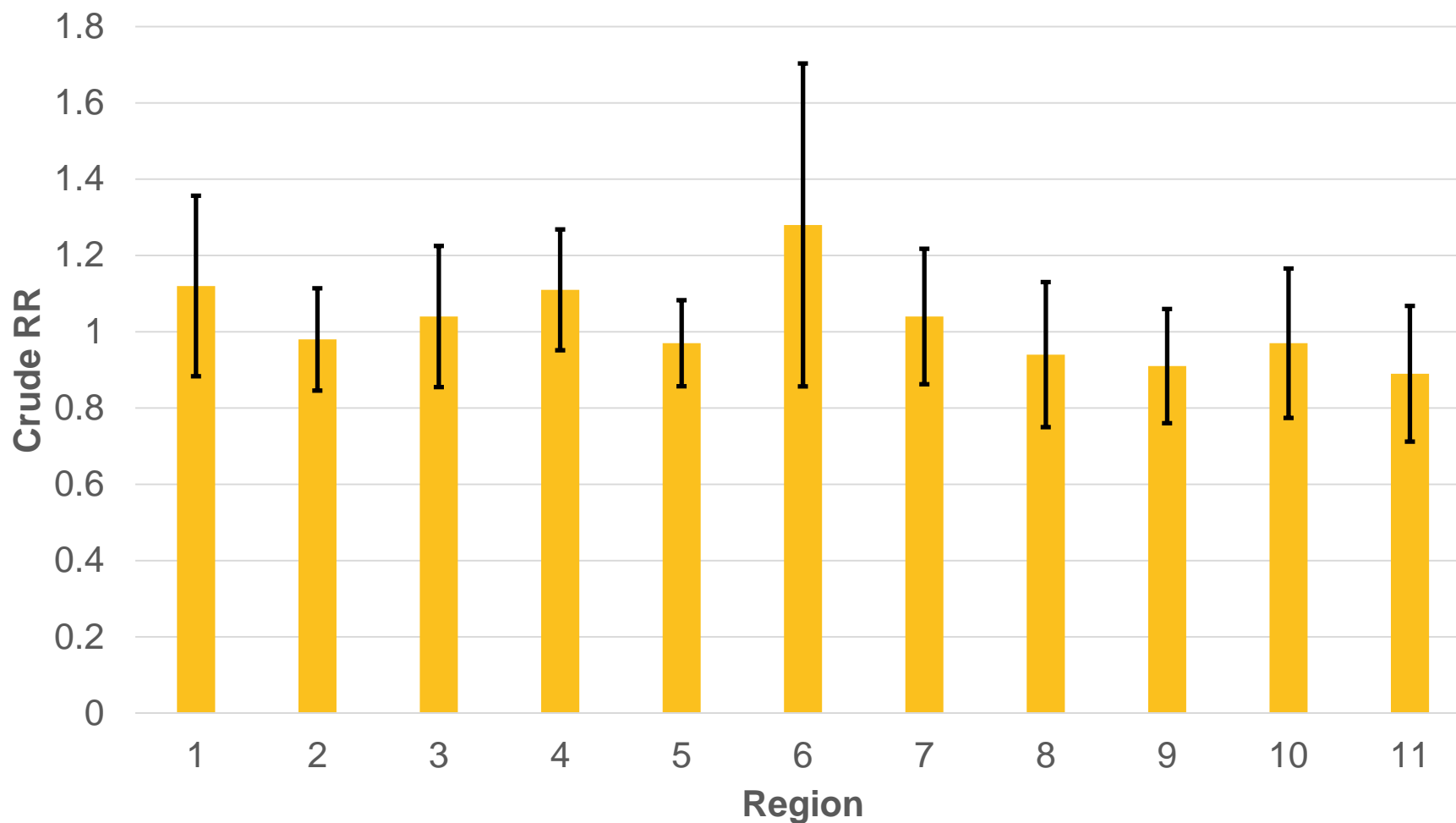
Overall Liver Waiting List Death Rates: Deaths/Too Sick Per 100 Patient-Years



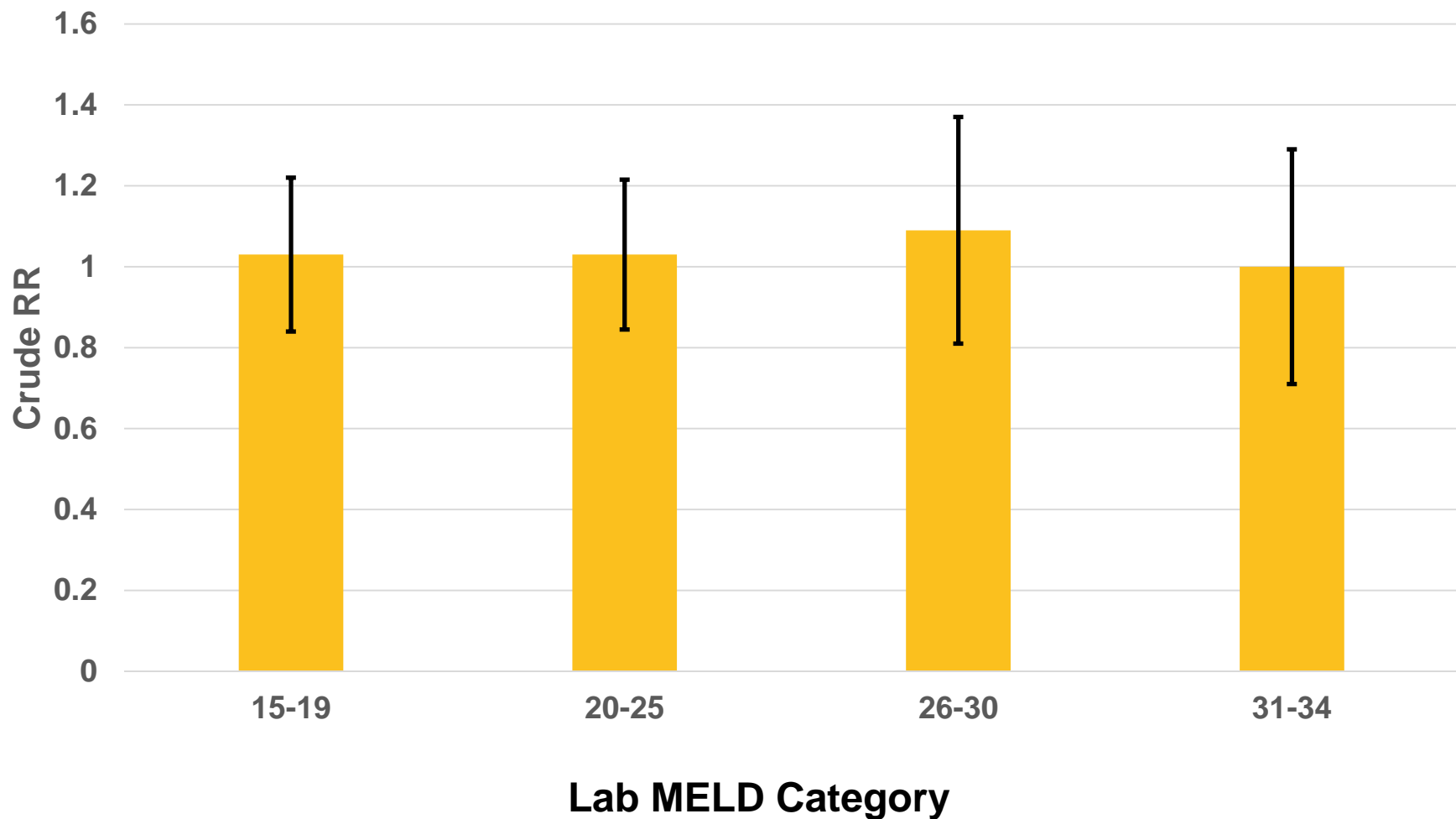
Relative Risk of Waiting List Mortality, Post-Era vs. Pre-Era, By Ethnicity



Relative Risk of Waiting List Mortality, Post-Era vs. Pre-Era, By Region



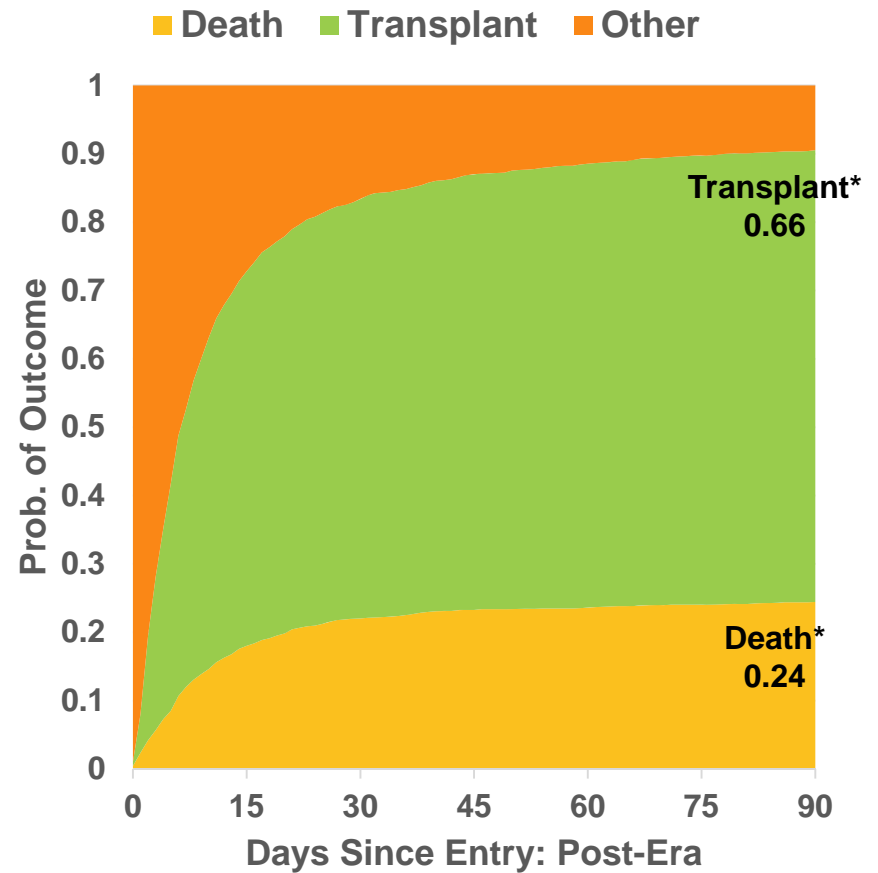
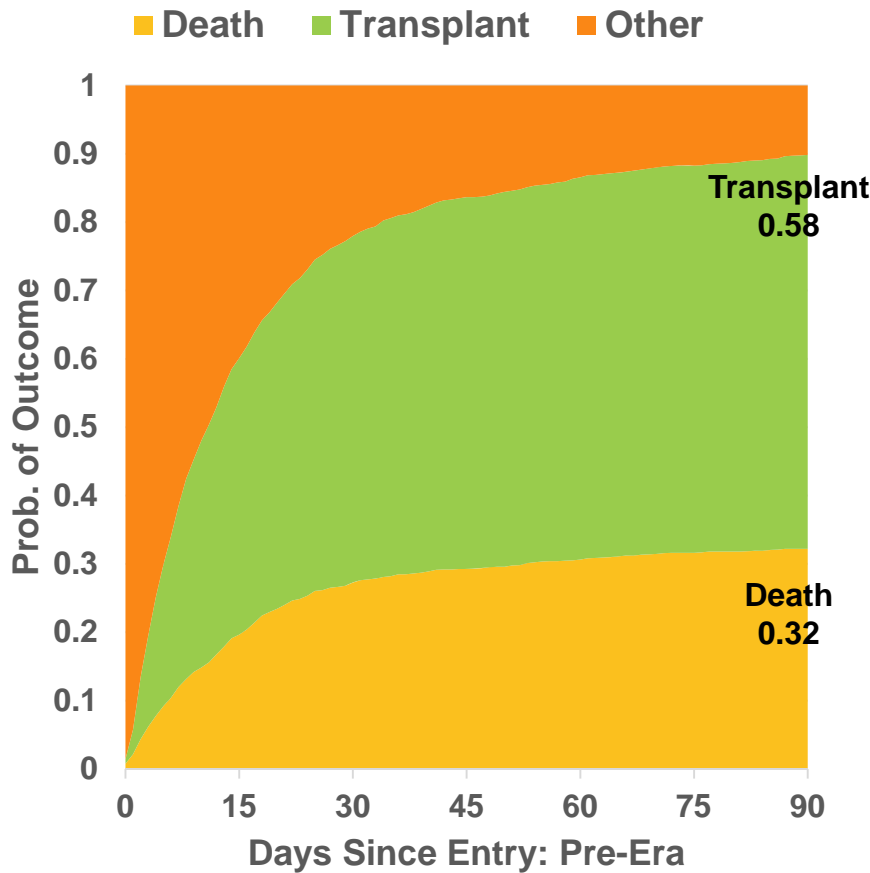
Relative Risk of Waiting List Mortality, Post-Era vs. Pre-Era



MELD/PELD 35+ Waiting List Outcomes: Competing Risks Analysis

N = 1720

N = 1998



Pre:6/18/2012-6/17/2013 Post:6/18/2013-6/17/2014



*Transplant rate, Death Rate Significantly Different, $p < 0.05$



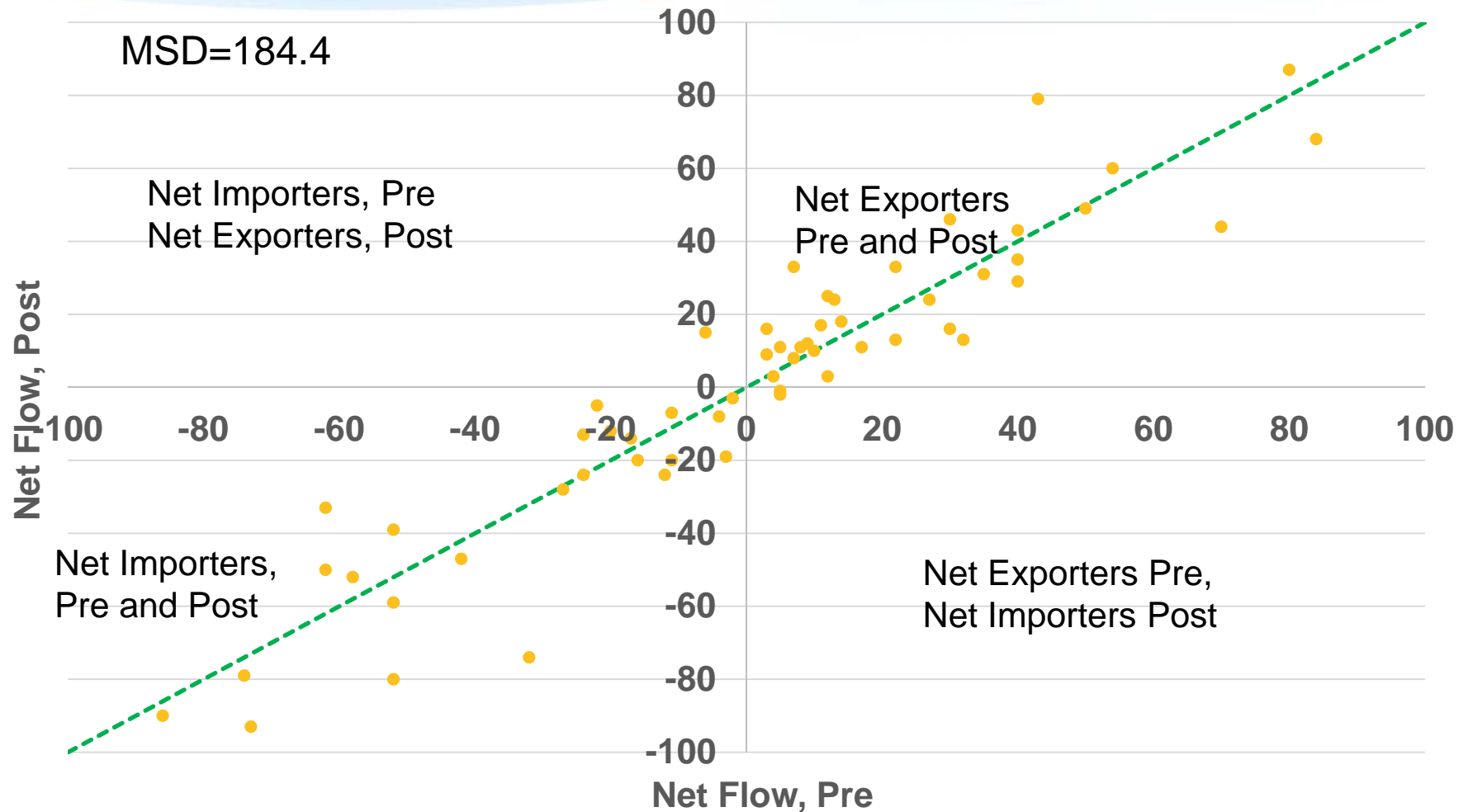


Imports/Exports

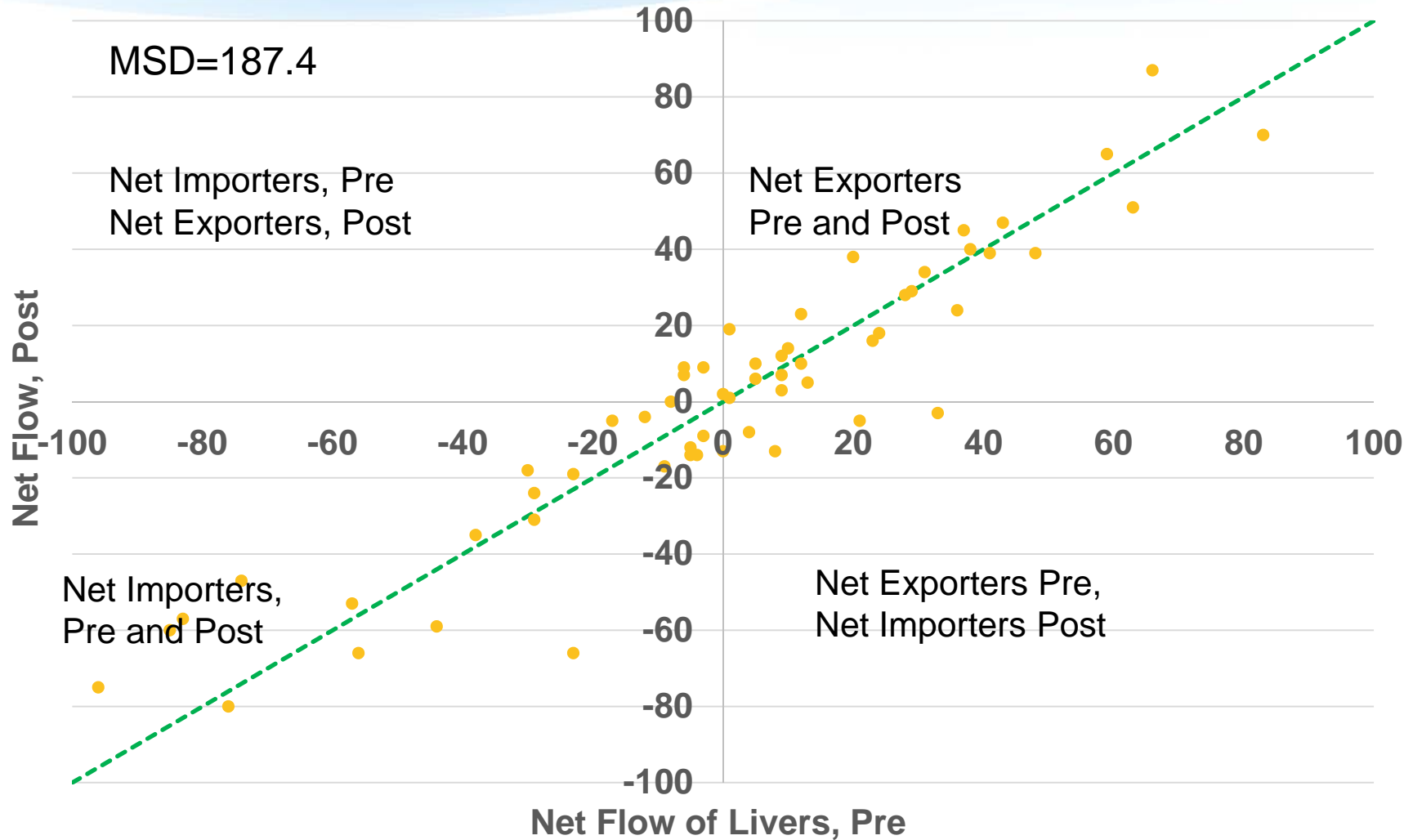
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Net Flow of Livers, Pre-Era vs Post-Era, by DSA



Net Flow of Livers, Pre-Era vs Post-Era, by DSA



Summary: Post Share 35 Era Data

- Increased number/percent of MELD/35+ transplants
- Increased regional sharing
- **No impact to overall waiting list mortality**
 - No impacts to waiting list mortality by age, ethnicity
- **MELD/PELD 35+ waiting list candidates**
 - Increased transplant rate
 - Decreased mortality rate
- **Post-transplant survival (preliminary)**
 - No overall change
 - No change to outcomes for MELD/PELD 35+ recipients
- **No impact to overall liver discard rate**
- **Overall import/export dynamics similar to previous era**



Extras

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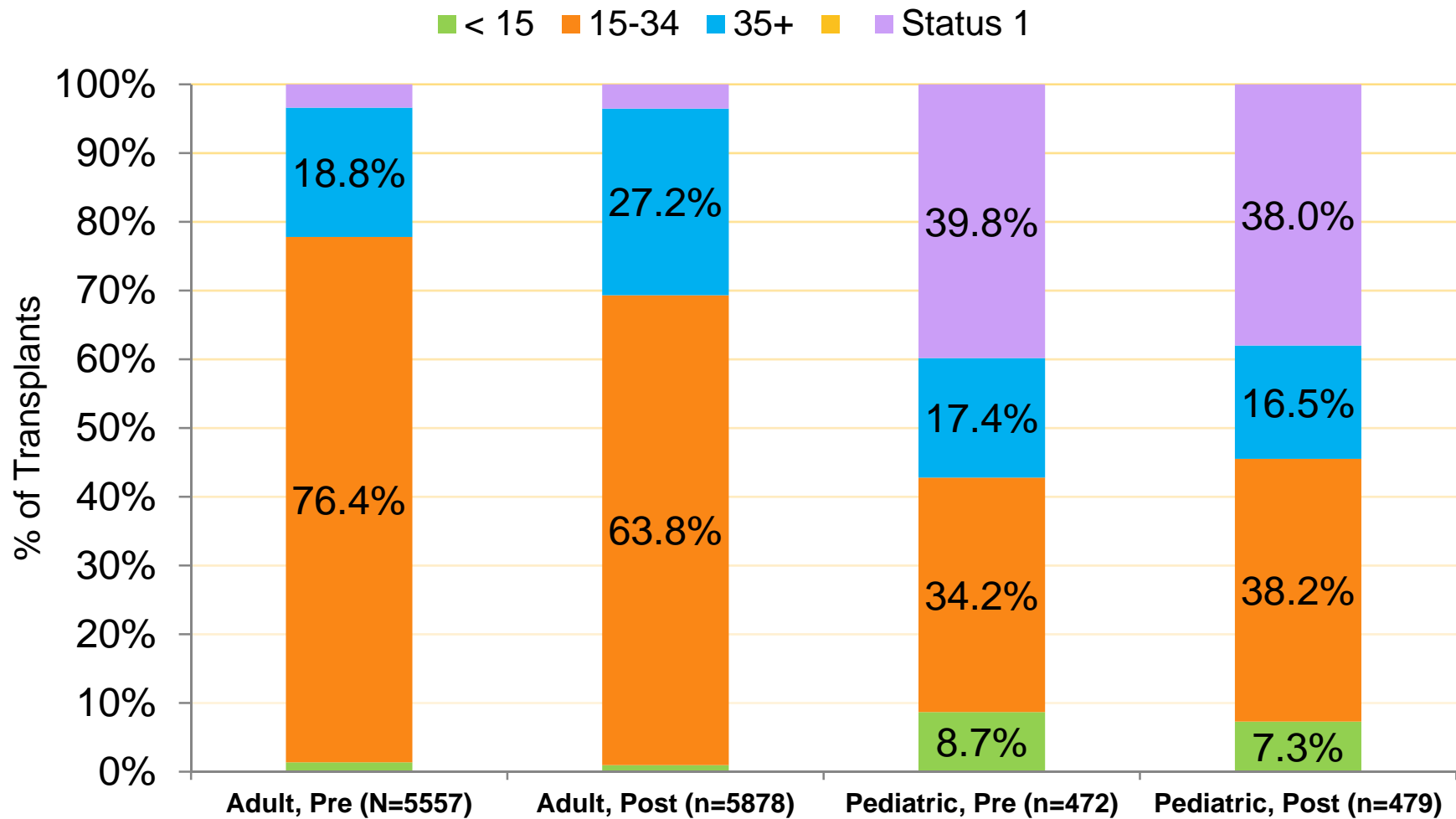
Reminder: Share 15/35/LI-IN Algorithm

1. Combined local and regional status 1A candidates
2. Combined local and regional status 1B candidates
3. Local and regional candidates with M/P Scores ≥ 35 by descending M/P score, local candidates ranked above regional candidates at each score
4. Local candidates with MELD/PELD scores 29-34
5. National Liver-Intestine Candidates
6. Local candidates with MELD/PELD scores 15-28
7. Regional candidates with MELD/PELD scores 15-34

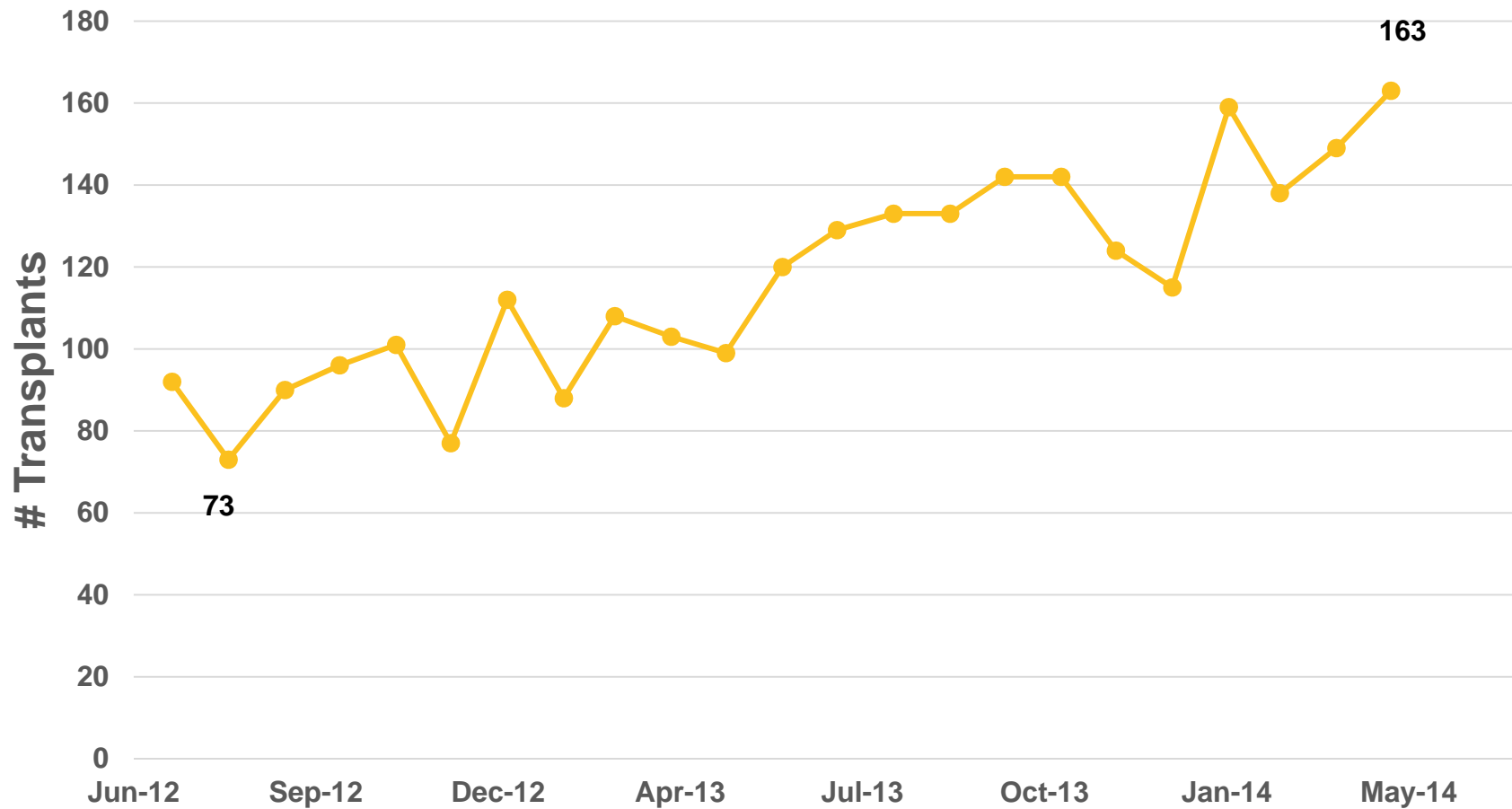
Algorithm (cont.)

8. National Status 1A candidates
9. National Status 1B candidates
10. National Candidates with MELD/PELD scores ≥ 15
11. Local candidates with MELD/PELD scores < 15
12. Regional candidates with MELD/PELD scores < 15

Deceased Donor Liver Transplants by Era, Age, and Status/Allocation Score



Deceased Donor Liver Transplants with MELD/PELD 35+, by Month

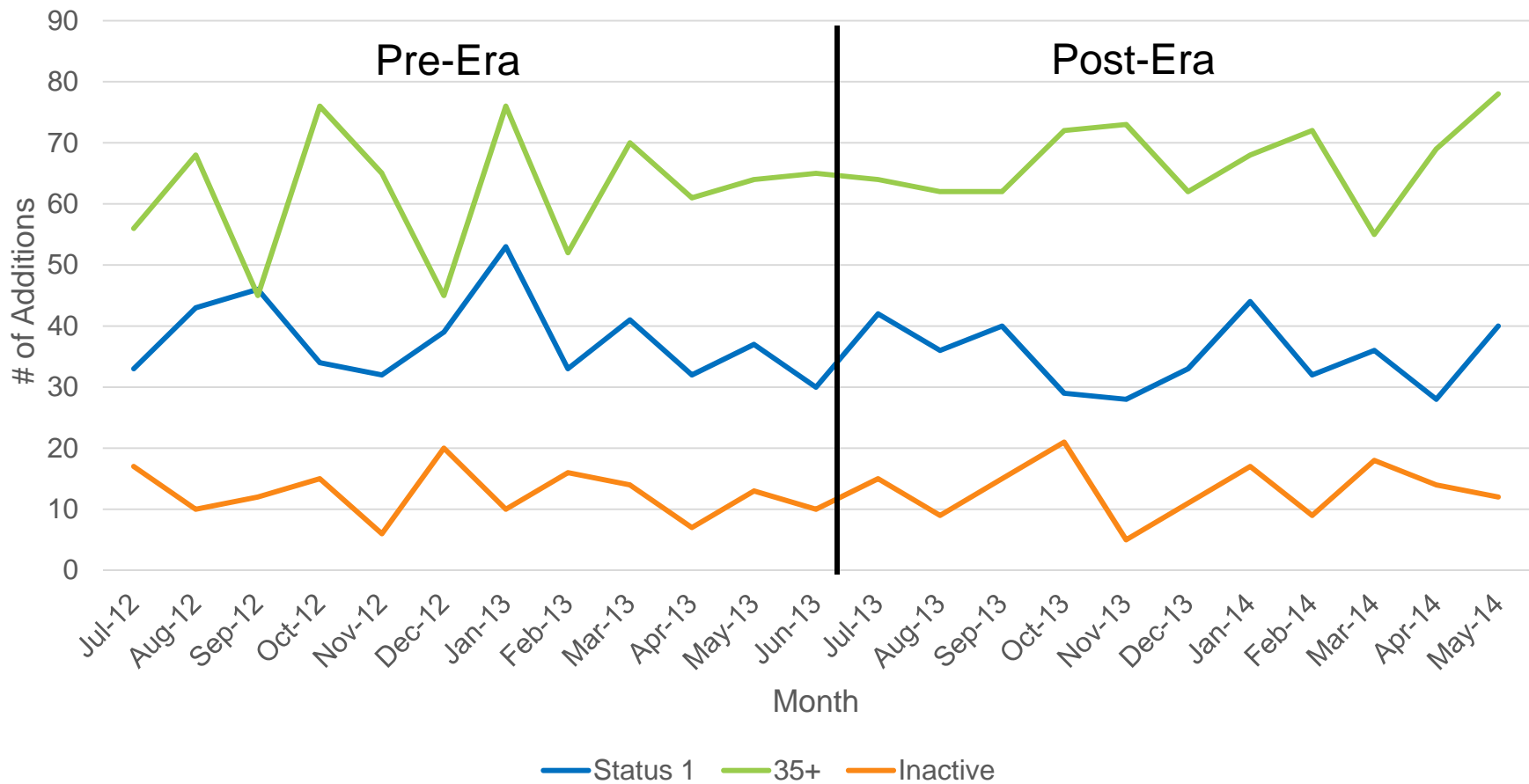


*June 2012/2014 are only partial months in the cohort, so were omitted

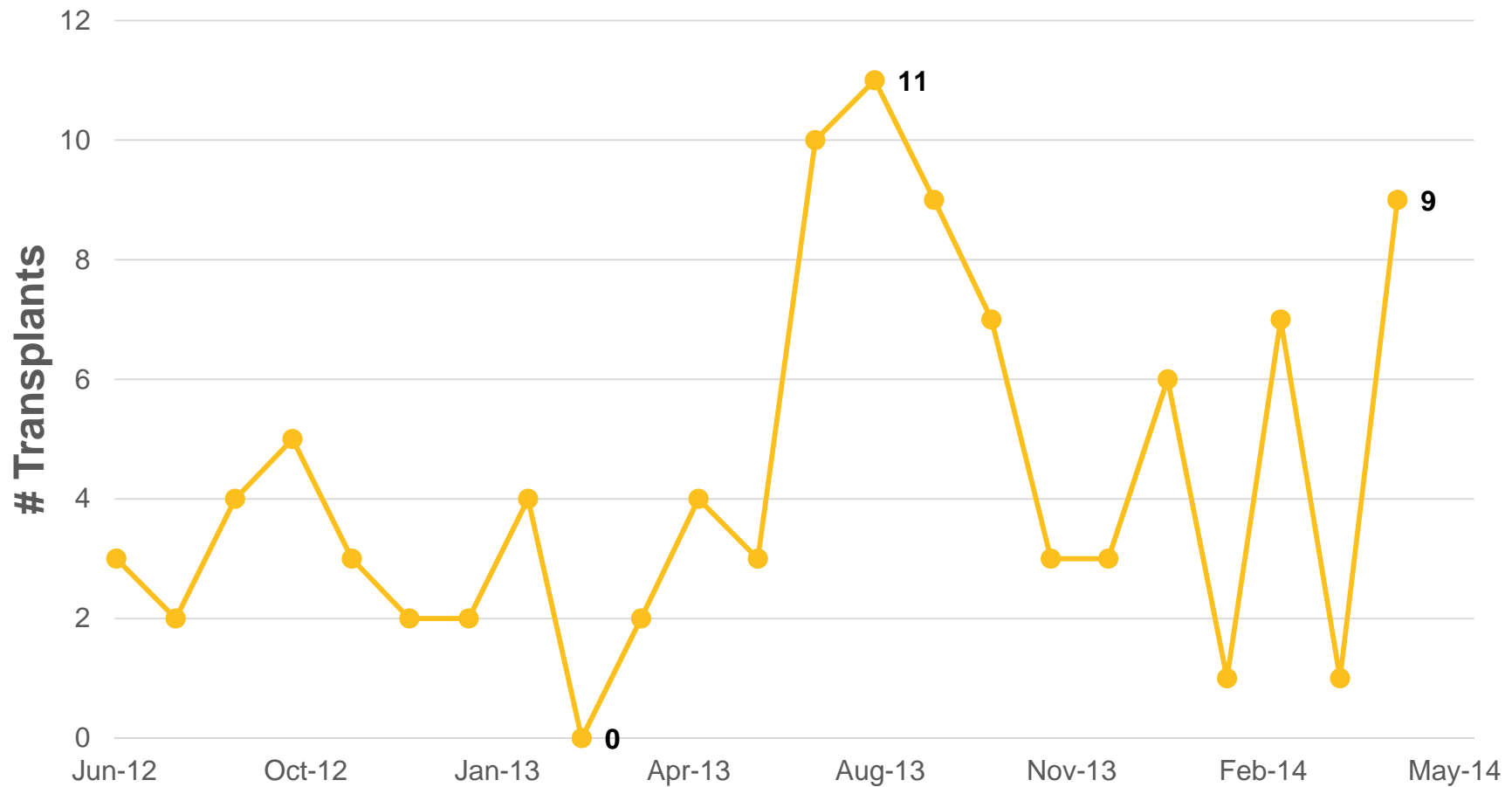
Transplant Metrics for Regionally Shared Livers

Factor	Pre-Era	Post-Era
DRI	1.5	1.4
CIT	6.7	6.7
Distance	231	236
LOS	11	12
M/P (Lab)	23	31
M/P (Match)	27	36

Liver Waiting List Additions by Month and MELD/PELD Score at Listing, July 2012-May 2014

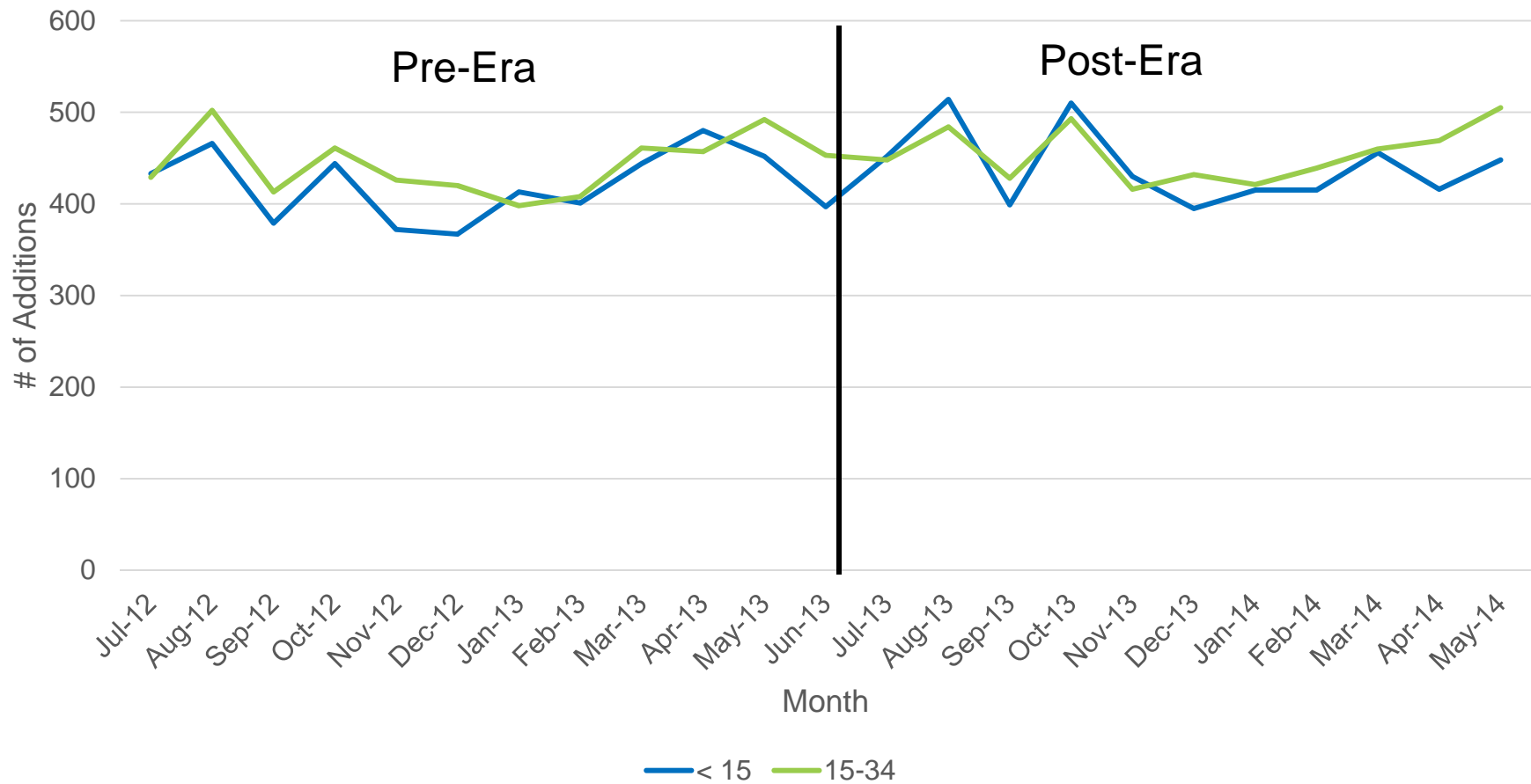


Deceased Donor Liver-Intestine Transplants by Month



*June 2012/2014 are only partial months in the cohort, so were omitted

Liver Waiting List Additions by Month and MELD/PELD Score at Listing, July 2012-May 2014



Liver Candidates Waiting for an Intestine at Month's End

