Polling Question?

How is Share 35R affecting your program?

1. **Positively** – Sick patients receiving more organs & fewer waitlist deaths
2. **Negatively** – Fewer transplants & more waitlist deaths
3. **No change** – no difference

Polling Question?

Are you in favor of Redistricting?

1. **YES**
2. **NO**

Polling Question?

Your preferred redistricting option would be?

1. **11**
2. **8**
3. **4**
4. **Concentric Circles**

Share 35 and Redistricting
Benefits

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CEOT
CUTTING EDGE OF TRANSPLANTATION
RESOLVING THE ORGAN SHORTAGE
PRACTICE | POLICY | POLITICS
FEBRUARY 25-27, 2016 • PHOENIX, ARIZONA

AST | AMERICAN SOCIETY OF TRANSPLANTATION

Conflict of Interest Disclosure

No relevant financial disclosures.

Allocation and Distribution of Organs

- **Efficiency**
  - Achieve efficiency in organ offers, acceptances, procurements, distribution, transport
- **Maximize utility and benefit**
  - Direct organs to those most in need
  - Avoiding Futility
- **Fairness and justice**
  - Equity in access to organs for patients with similar degrees of illness and urgency
  - Regardless of race, gender, geography

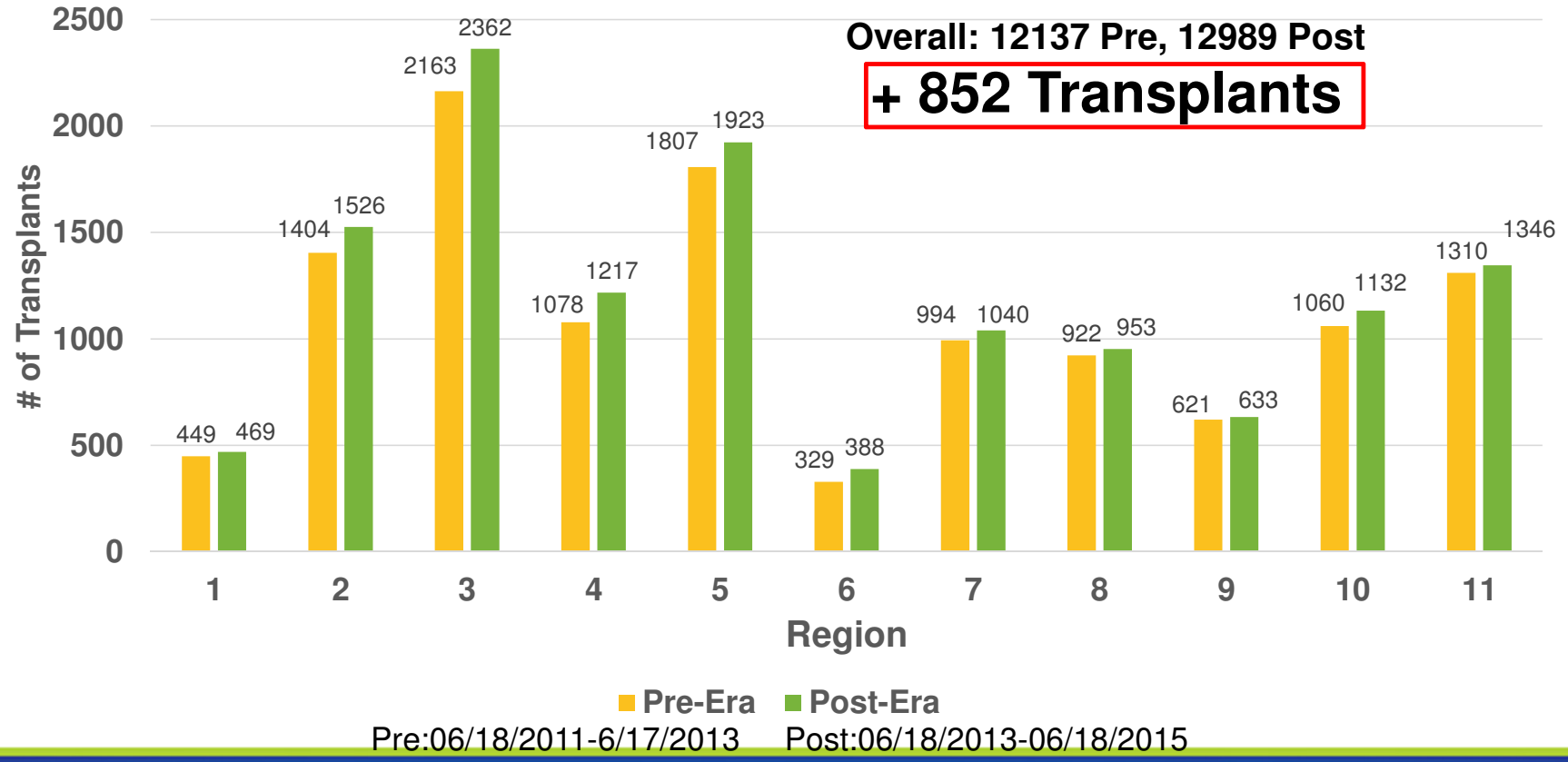
History of U.S. liver allocation changes

- On June 18, 2013, the OPTN implemented a number of changes to adult donor liver allocation:
  - National Share 15: Extend regional sharing of livers to MELD/PELD 15+ candidates on a national basis
  - Regional Share 35: Livers to MELD/PELD 35+ candidates
  - National Sharing of livers & intestines: to candidates MELD/PELD 29

Data

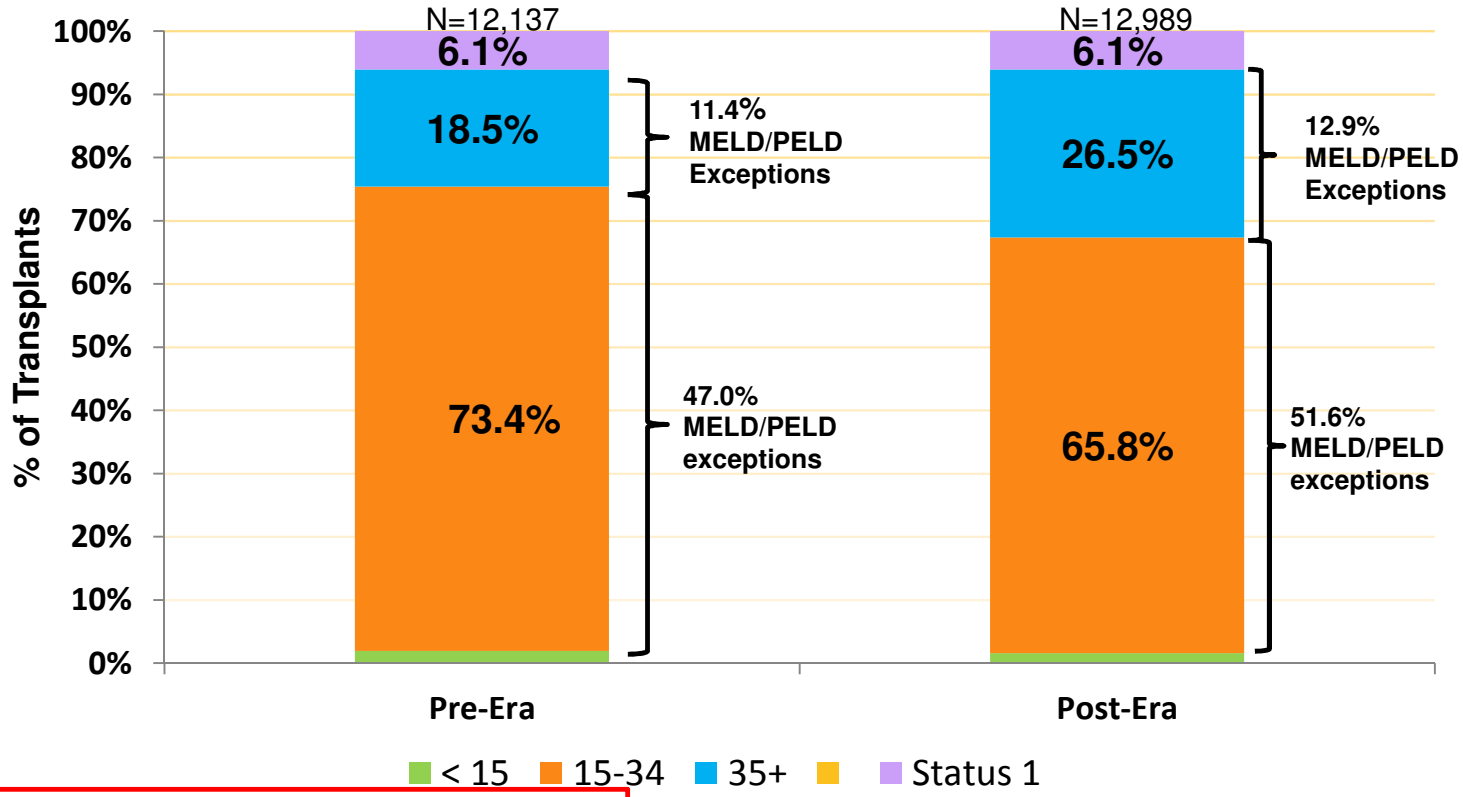
- 2 eras:
  - June 2011 – June 2013 (**Pre-Era**)
  - June 2013 – June 2015 (**Post-Era**)
  - OPTN data - September 4, 2015

DD Liver Transplants by Era and Region



Pre:06/18/2011-6/17/2013 Post:06/18/2013-06/18/2015

DD Liver Transplants by Era

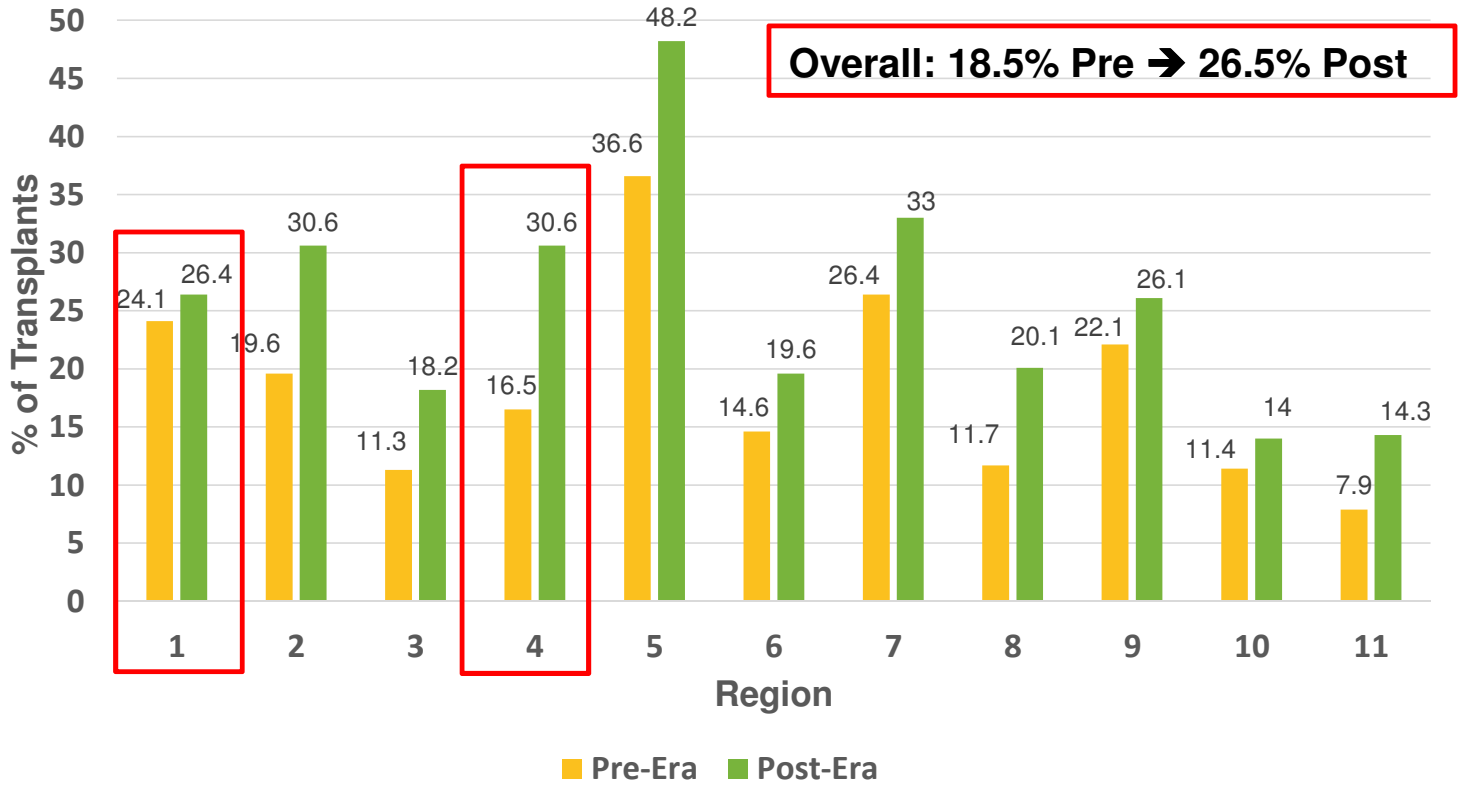


- 8% ↑ in MELD ≥35
- 6% ↑ in MELD/PELD exceptions

Status or MELD/PELD Score

Pre:6/18/2011-6/17/2013 Post:6/18/2013-6/18/2015

% of DD Liver Transplants in MELD/PELD ≥35

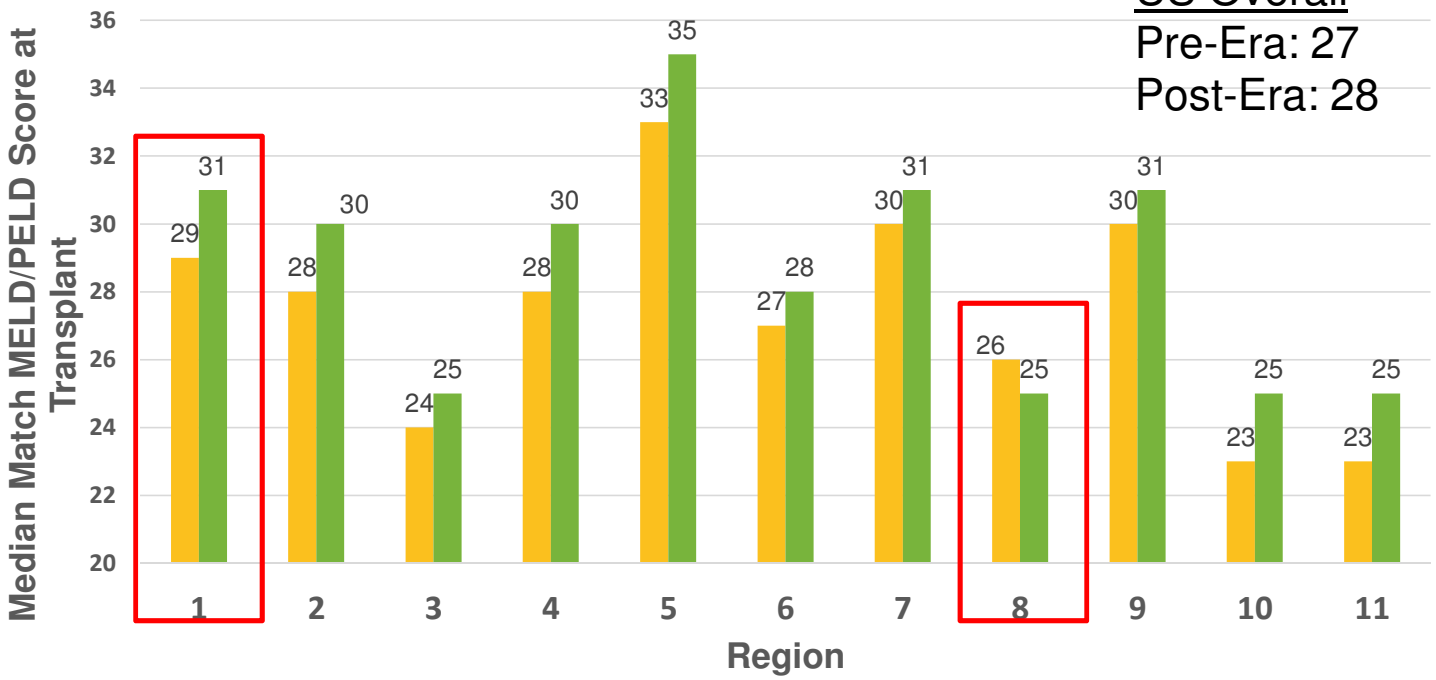


Pre:6/18/2011-6/17/2013 Post:6/18/2013-6/18/2015

DD Liver Transplants by Era and Region

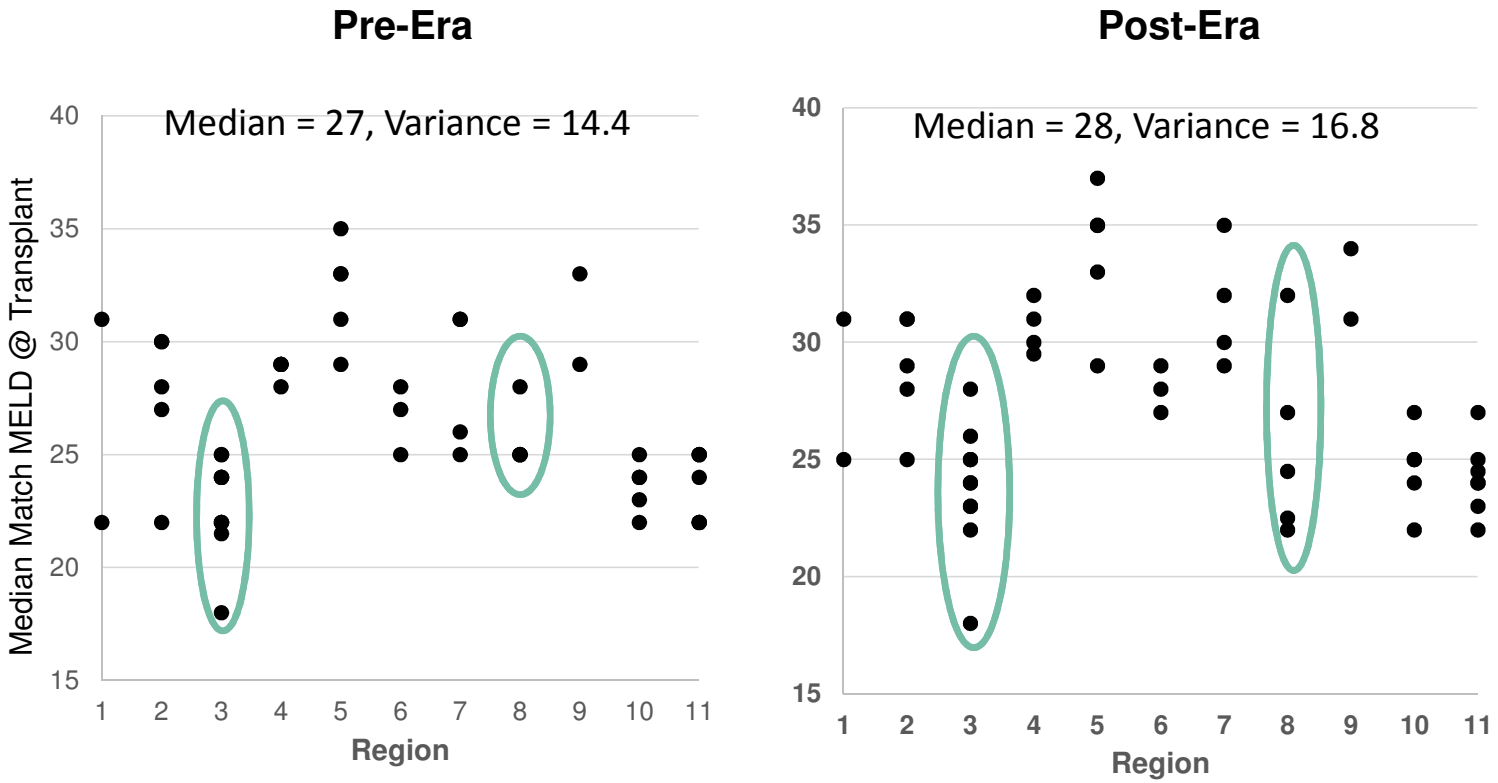
Median Allocation Score At Transplant

(Status 1s Excluded)



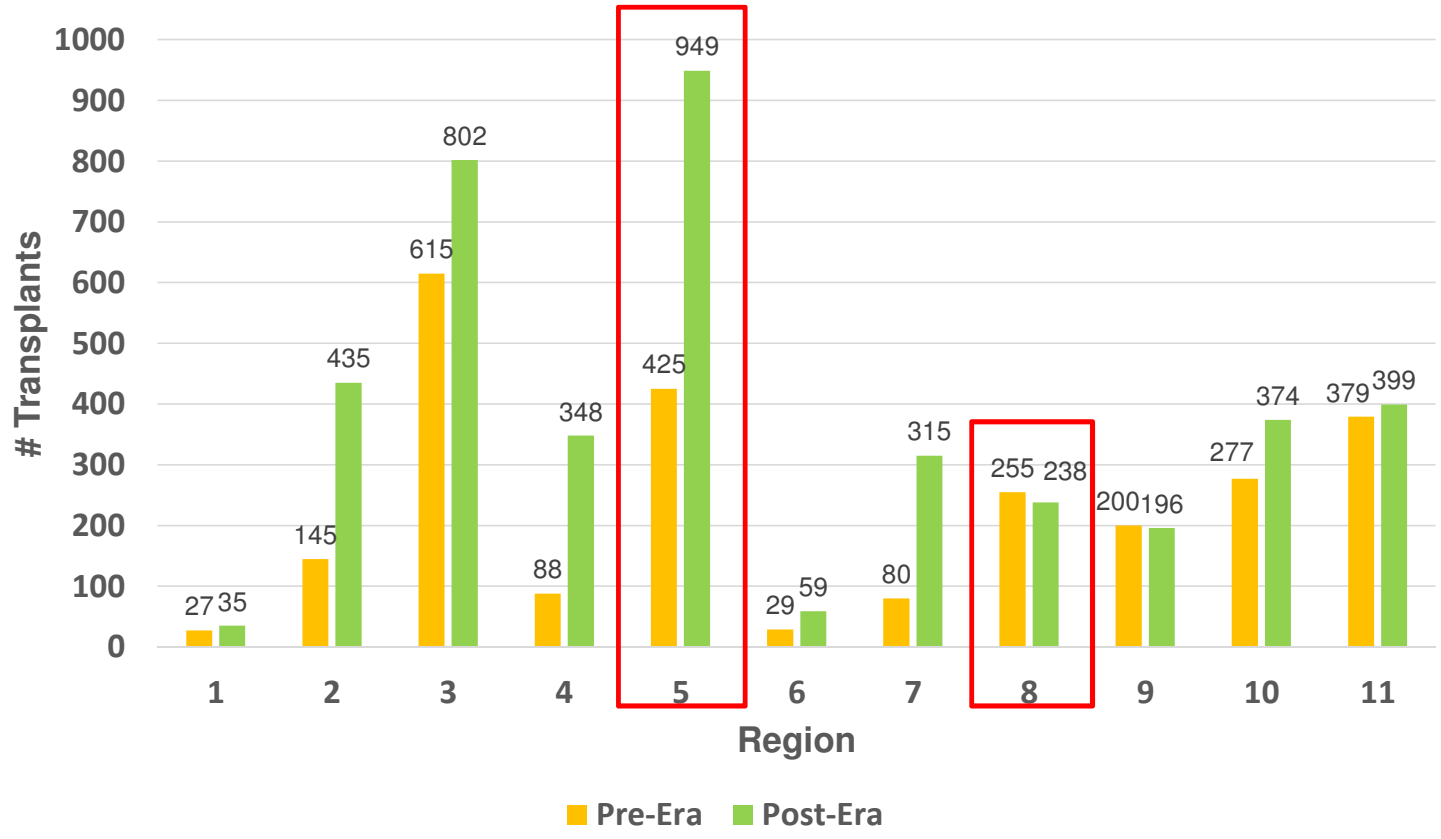
Pre:6/18/2011-6/17/2013 Post:6/18/2013-12/17/2015

Median Allocation MELD/PELD at Transplant



Pre:06/18/2011-6/17/2013 Post:06/18/2013-06/18/2015

Regional Shares Pre-Era and Post-Era



Pre:6/18/2011-6/17/2013 Post:6/18/2013-6/18/2015

Deceased Donor Transplants: Organ Travel Distance, Cold Ischemia Time, Donor Risk Index

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

	Pre	Post
Median Distance organs traveled (miles)		
Overall:	58	82
Local:	22	22
Regional:	231	238
National:	671	633
Median Cold Ischemia Time (CIT) (hours)		
Overall:	6.1	6.1
Local:	5.9	5.7
Regional:	6.7	6.6
National:	8.0	7.6
Median Donor Risk Index (DRI)		
Overall:	1.3	1.3
Local:	1.3	1.3
Regional :	1.5	1.4
National:	1.6	1.6

Pre:6/18/2011-6/17/2013 Post:6/18/2013-6/18/2015

Livers Not Used

– Livers Recovered for Transplant but Not Transplanted:

P=0.036

- 1355 in Pre-Era (10.3 % of recovered)
- 1338 in Post-Era (9.5% of recovered)

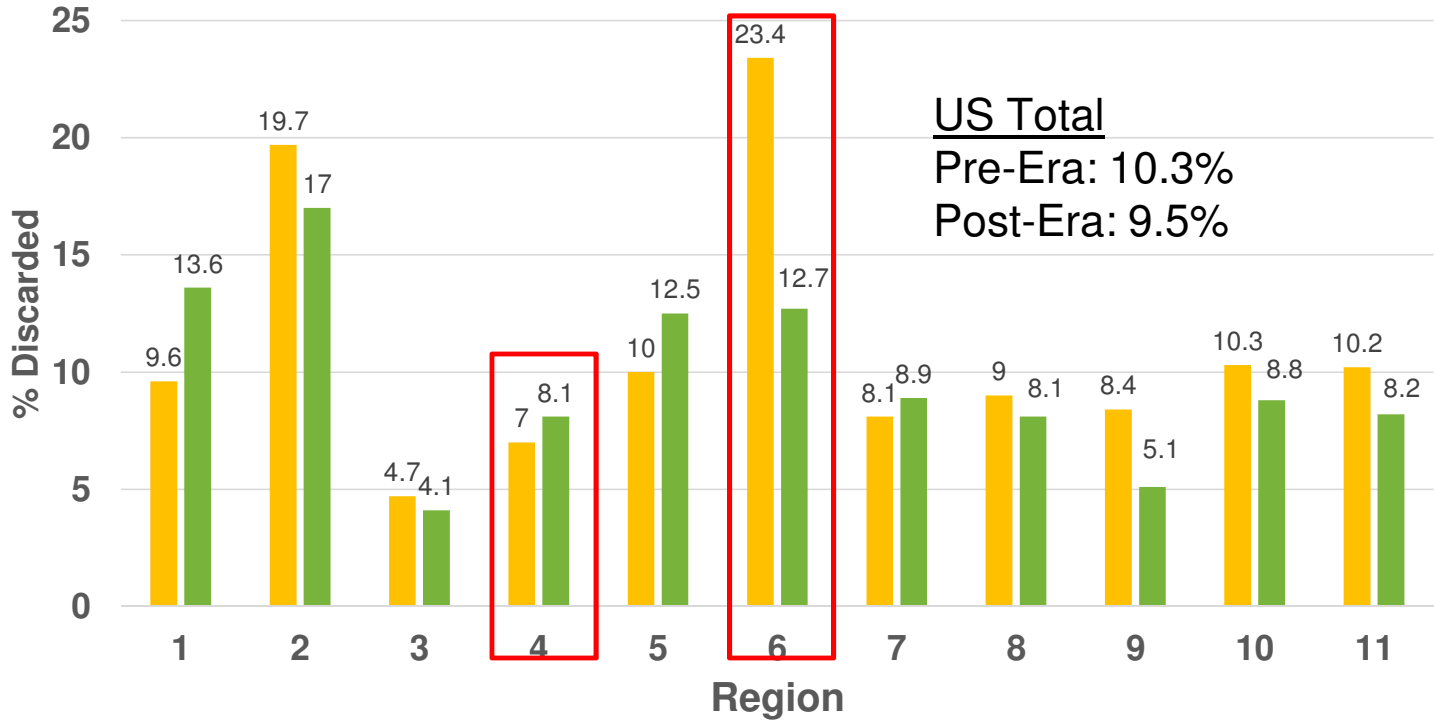
– Livers Not Recovered:

P=0.045

- 2235 in Pre-Era (13.7% of all donors)
- 2235 in Post-Era (12.9 % of all donors)

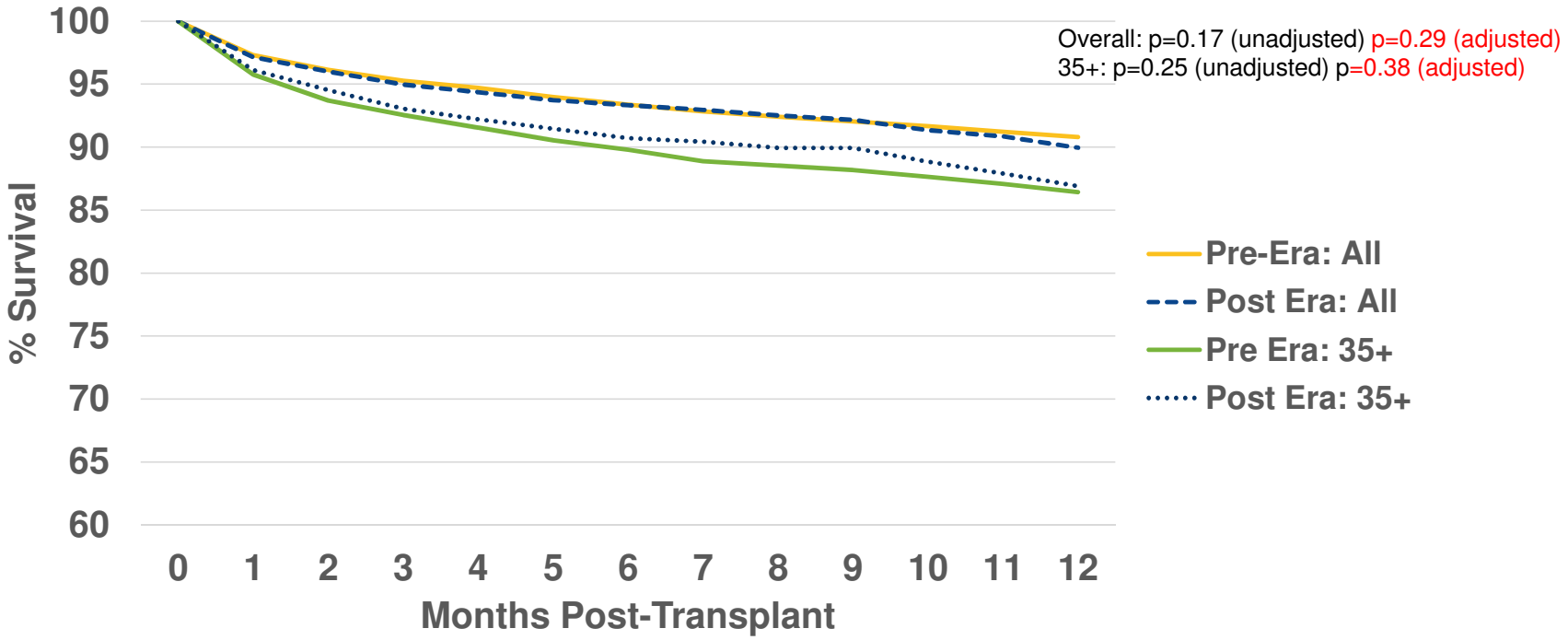
Pre:6/18/2011-6/17/2013 Post:6/18/2013-6/18/2015

Percentage of Livers Recovered for Transplant But Not Transplanted



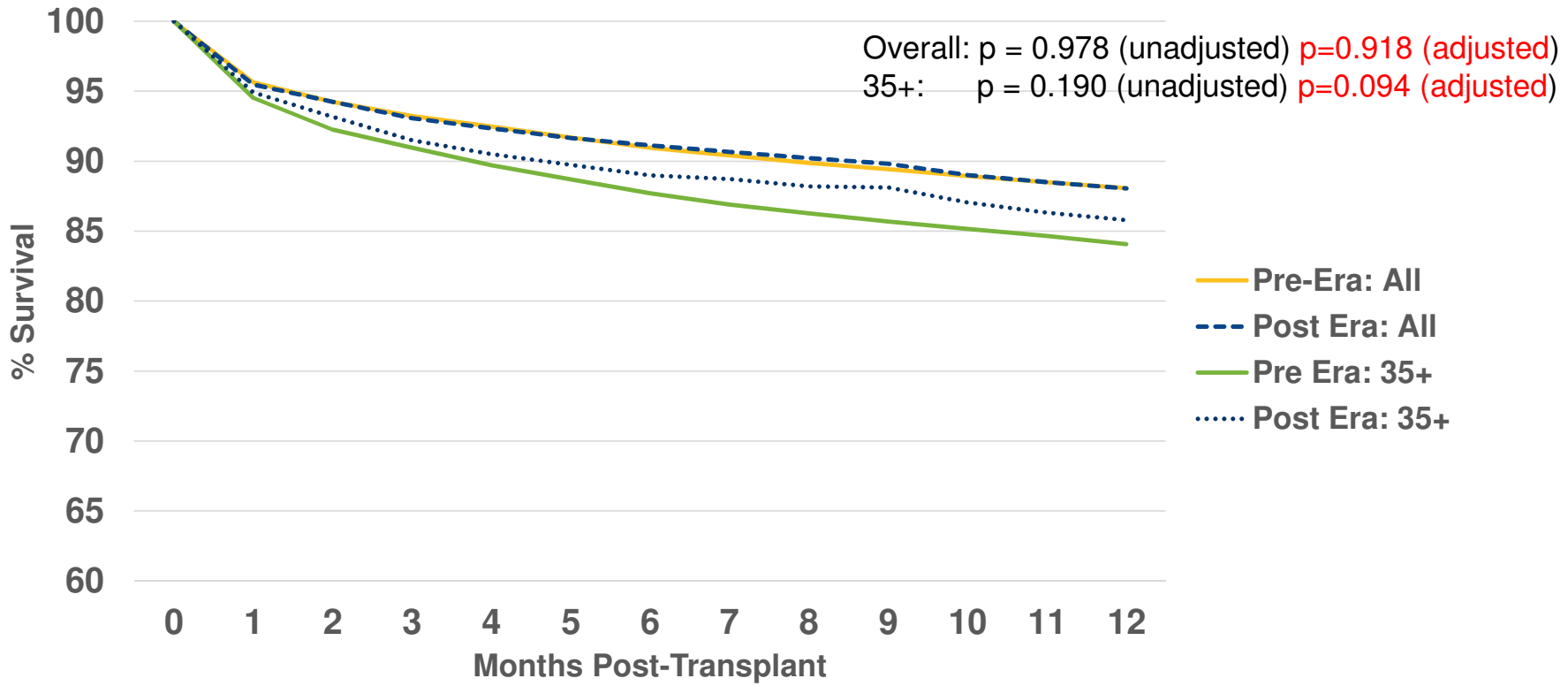
Pre:06/18/2011-6/17/2013 Post:06/18/2013-06/18/2015

Patient Survival: Primary Deceased Donor Liver Transplants by Era



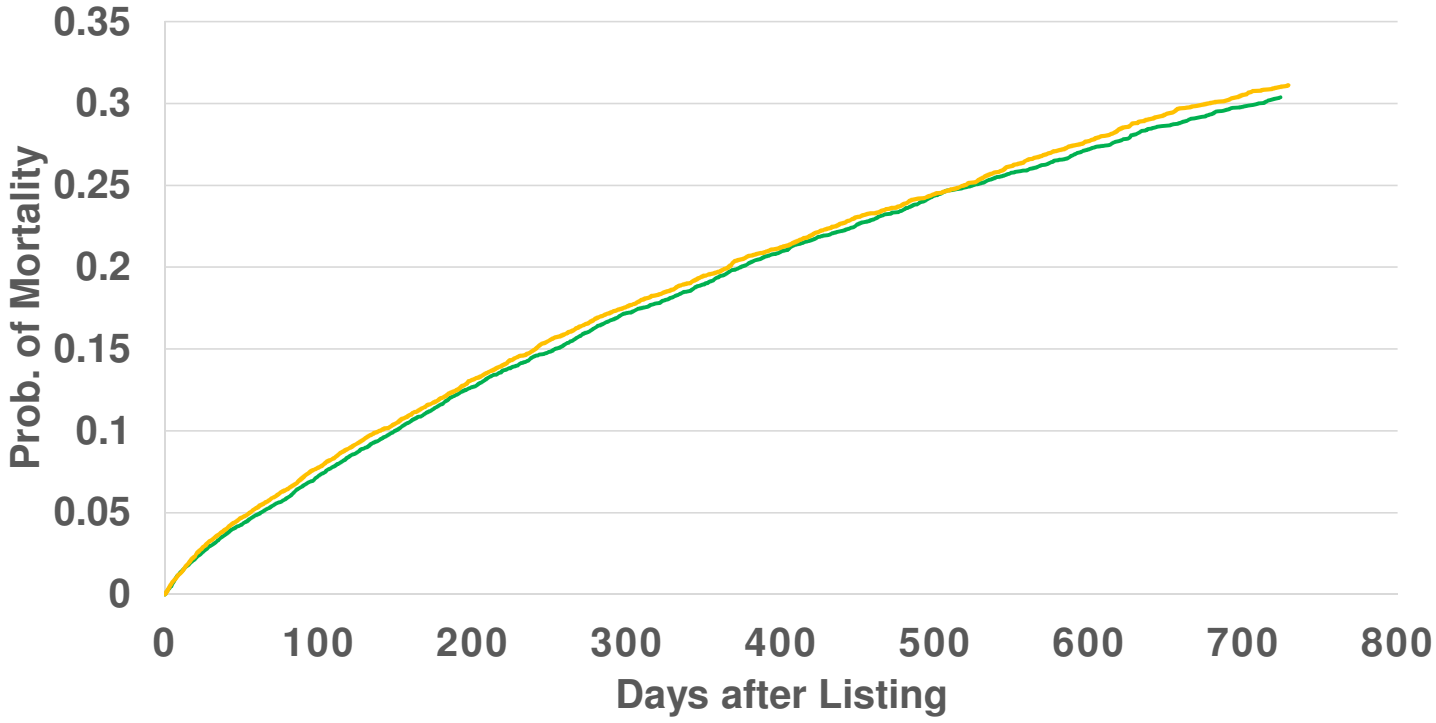
Pre:06/18/2011-6/17/2013 Post:06/18/2013-03/13/2014

Graft Survival
Deceased Donor Liver Transplants by Era



Pre:06/18/2011-6/17/2013 Post:06/18/2013-03/13/2014

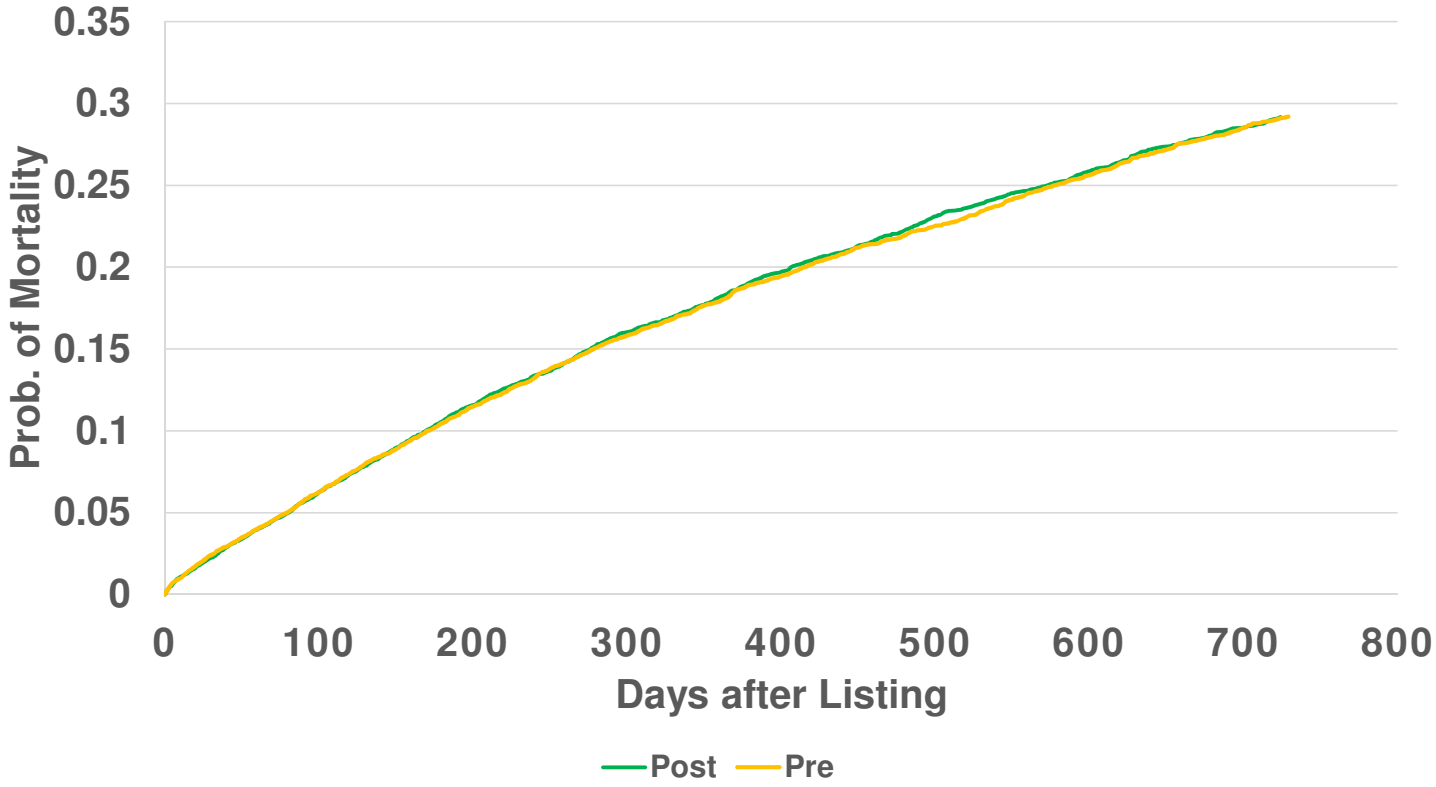
Waiting List Mortality Rates, Pre and Post Share 35 All Candidates



Competing risk framework, adjusted for MELD at start of period

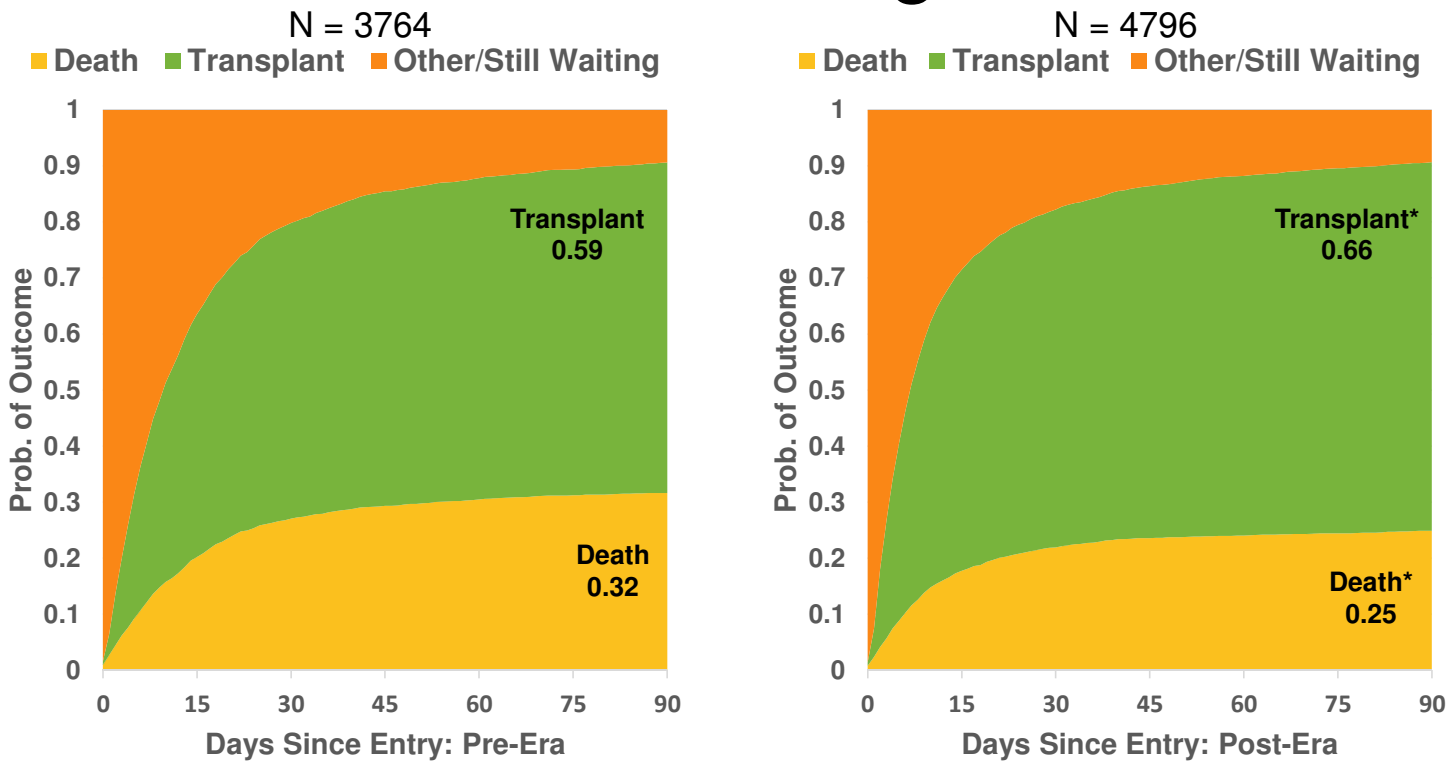
Pre: 12/18/2011-6/17/2013 Post: 6/18/2013-6/18/2015

Waiting List Mortality Rates, Pre and Post Share 35 MELD/PELD 35+ Candidates Excluded



Pre:06/18/2011-6/17/2013 Post:06/18/2013-06/18/2015

MELD/PELD 35+ Waiting List Outcomes



7% ↓ in waiting list mortality

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

Pre: 6/18/2011-6/17/2013 Post: 6/18/2013-6/18/2015

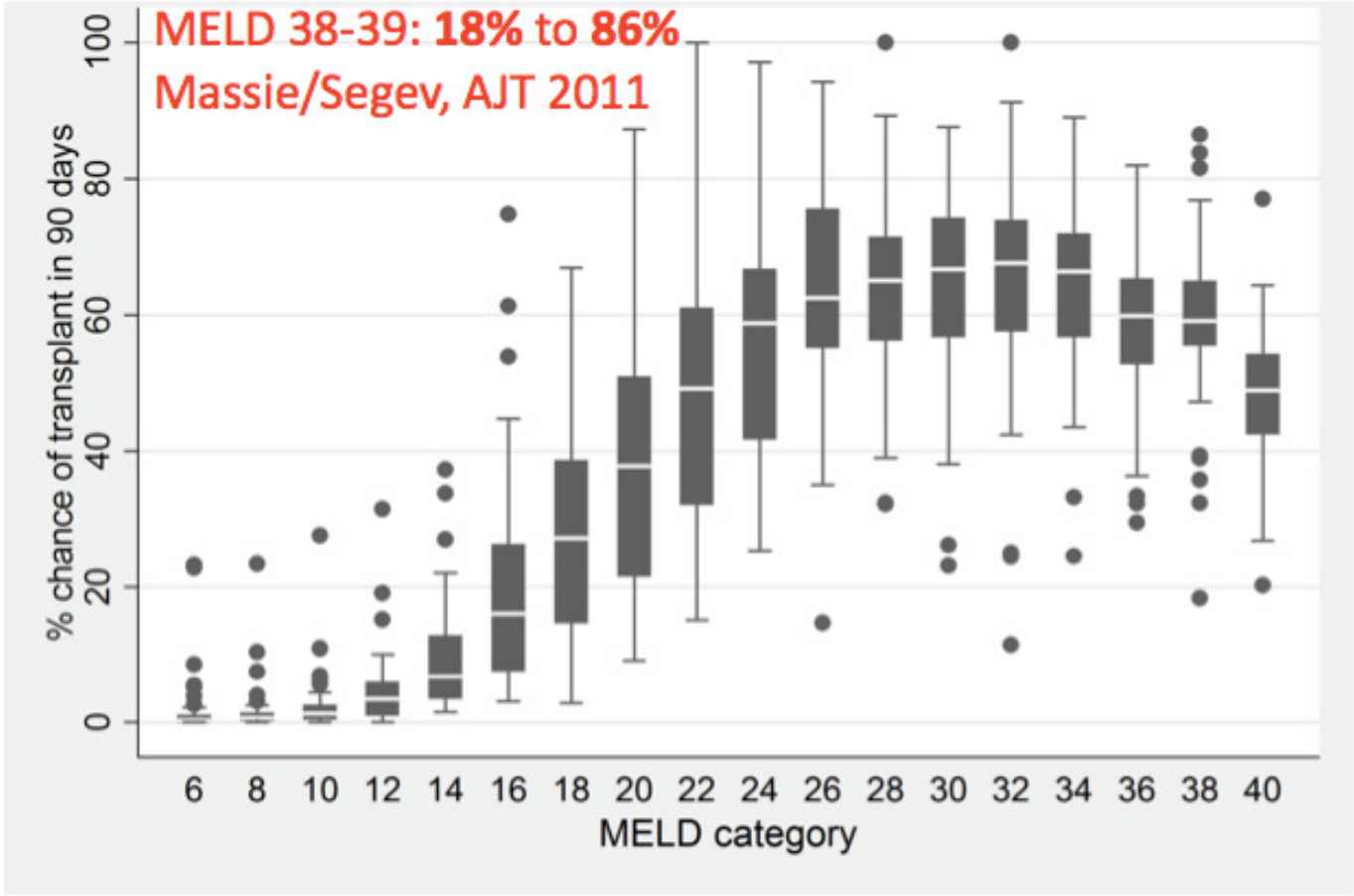
Summary: Post Share 35 Era

- ✓ Increased #/% of MELD/35+ transplants
- ✓ Increased regional sharing
- ✓ No impact to overall liver discard rate
- ✓ No impact to overall waiting list mortality
- ✓ MELD/PELD 35+ waiting list candidates
  - ✧ Increased transplant rate
  - ✧ Decreased mortality rate
- ✓ Post-transplant survival
  - ✧ No overall change
  - ✧ No change to outcomes for MELD/PELD 35+ recipients

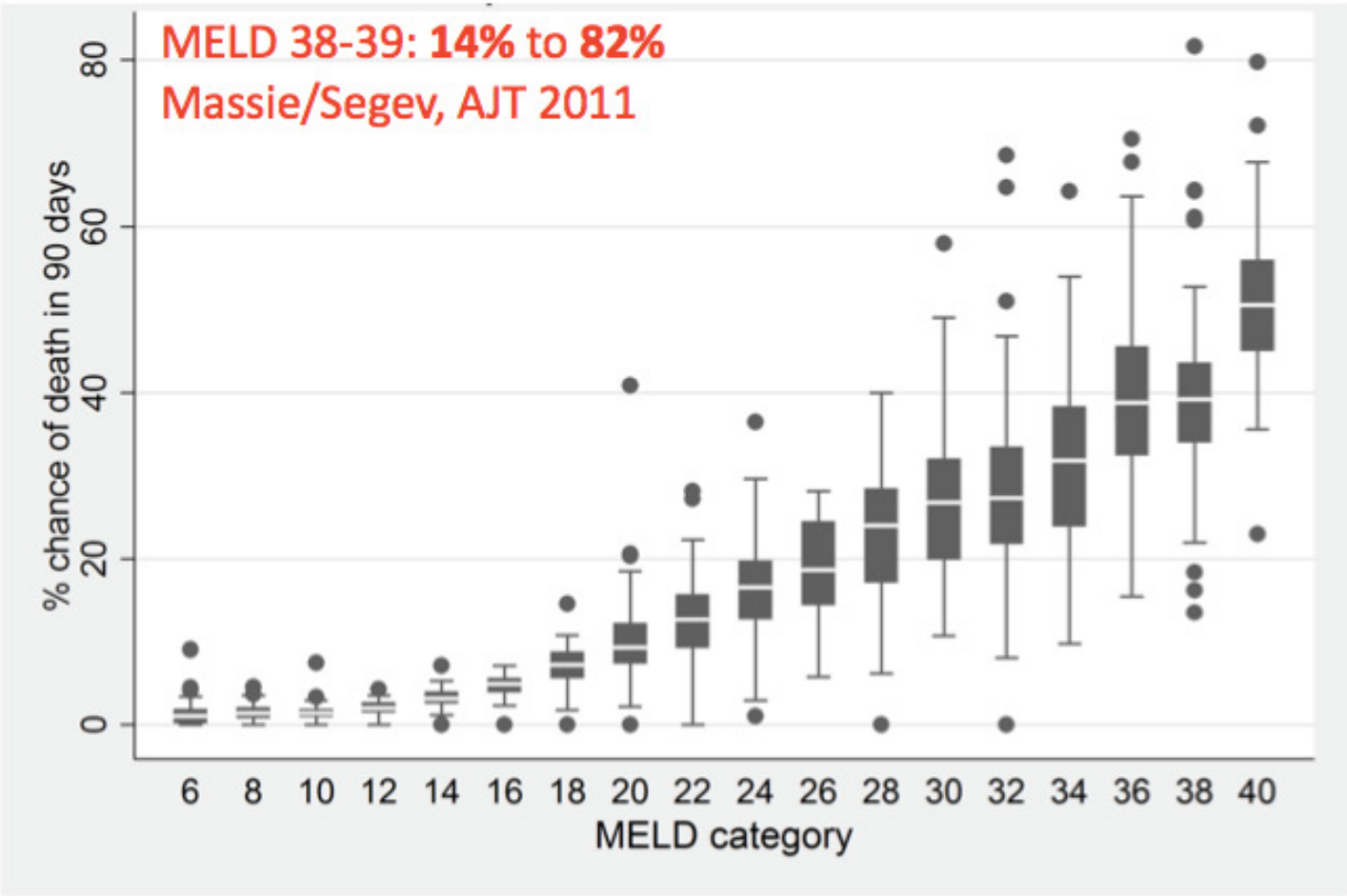
Redistricting:

How can we achieve greater balance?

Motivation: Transplant Rates, by OPO



Motivation: Death Rates, by OPO



Redistricting – progress


© Can Stock Photo

- Concept paper circulated - redistricting
- September 2014 – Liver Forum Chicago
  - Concerns expressed, ad hoc committees and workgroups formed
    - Cost
    - Logistics
    - Data
      Metrics
  - Modelling requested to reduce cold time & crisscrossing for small MELD differences
    - 150 miles and 250 miles
    - 3 and 5 MELD point advantage
- July 2015 – Liver Forum Chicago
  - Multiple supply/demand metrics presented
    - Actual donors, eligible donors, all deaths
    - Wait listed patients, WL pts > 15 MELD
  - LSAM modelling results presented with proximity circles
    - Data shows proximity circles decreased transport, flyouts
    - Disparity gains were NOT lost by giving advantage to candidates proximal to donor

LIVER FORUM II

- Request to examine candidates without MELD exceptions, lab MELD disparity
  - Data summary
    - Geographic disparity disproportionately disadvantages LAB MELD patients (vs exception MELD patients)
    - Disparity is worse than outlined for patients WITHOUT exception points
- Modelling of concentric circles- March 2016

Optimization

Based on 3 things:

1. **Supply:** # of donors recovered in each DSA (*actual data*)
2. **Demand:** # and match MELD of candidates in each DSA (*actual data*)
3. **Constraints:** determined by the Committee
   - 6 transplant centers in every district
   - Transport time—median 3 max 5
   - Can not increase wait list or post-transplant mortality

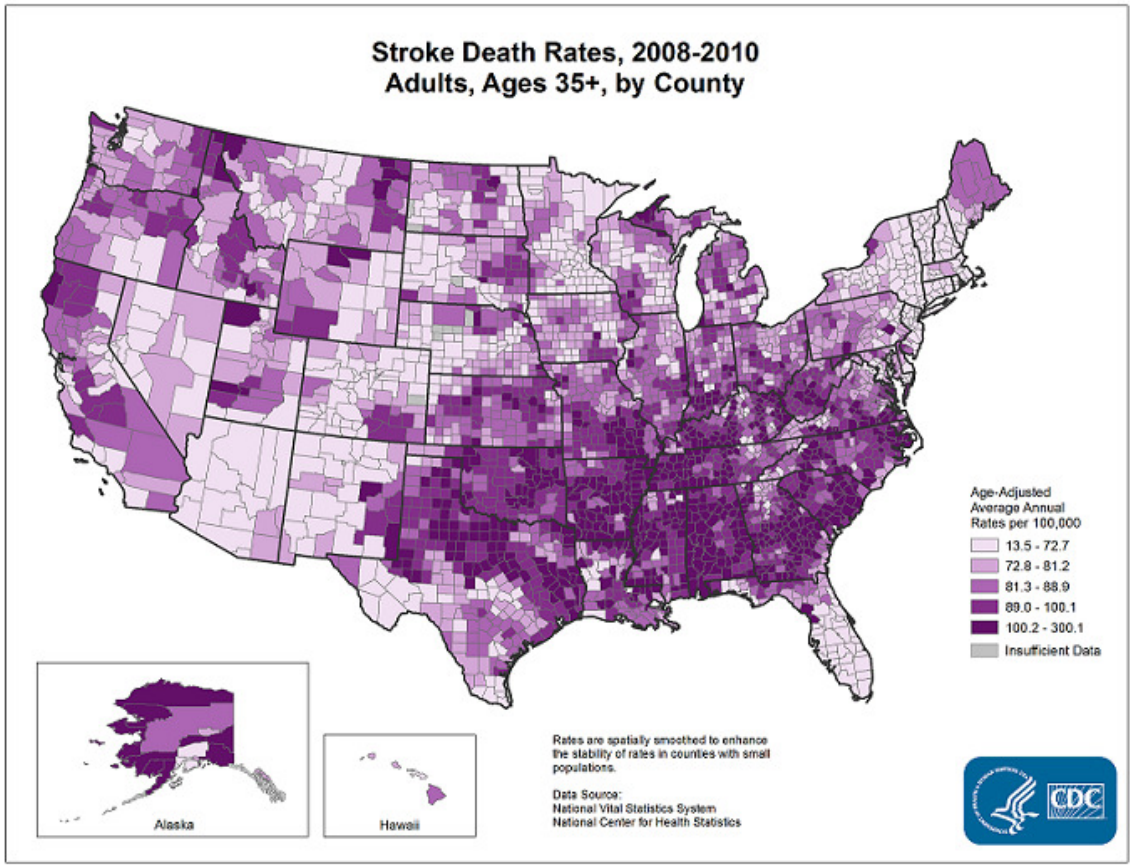
When the Committee chooses another disparity metric, the maps do not change.

What determines local supply of livers?

- **OPO performance: conversion rates?**
  - In 58 OPO's : Conversion rate ranges from 58.1-90.9 donors/100 eligible deaths
  - 1.5x fold difference between lowest and highest
- **Death rates?**
  - To a much larger degree

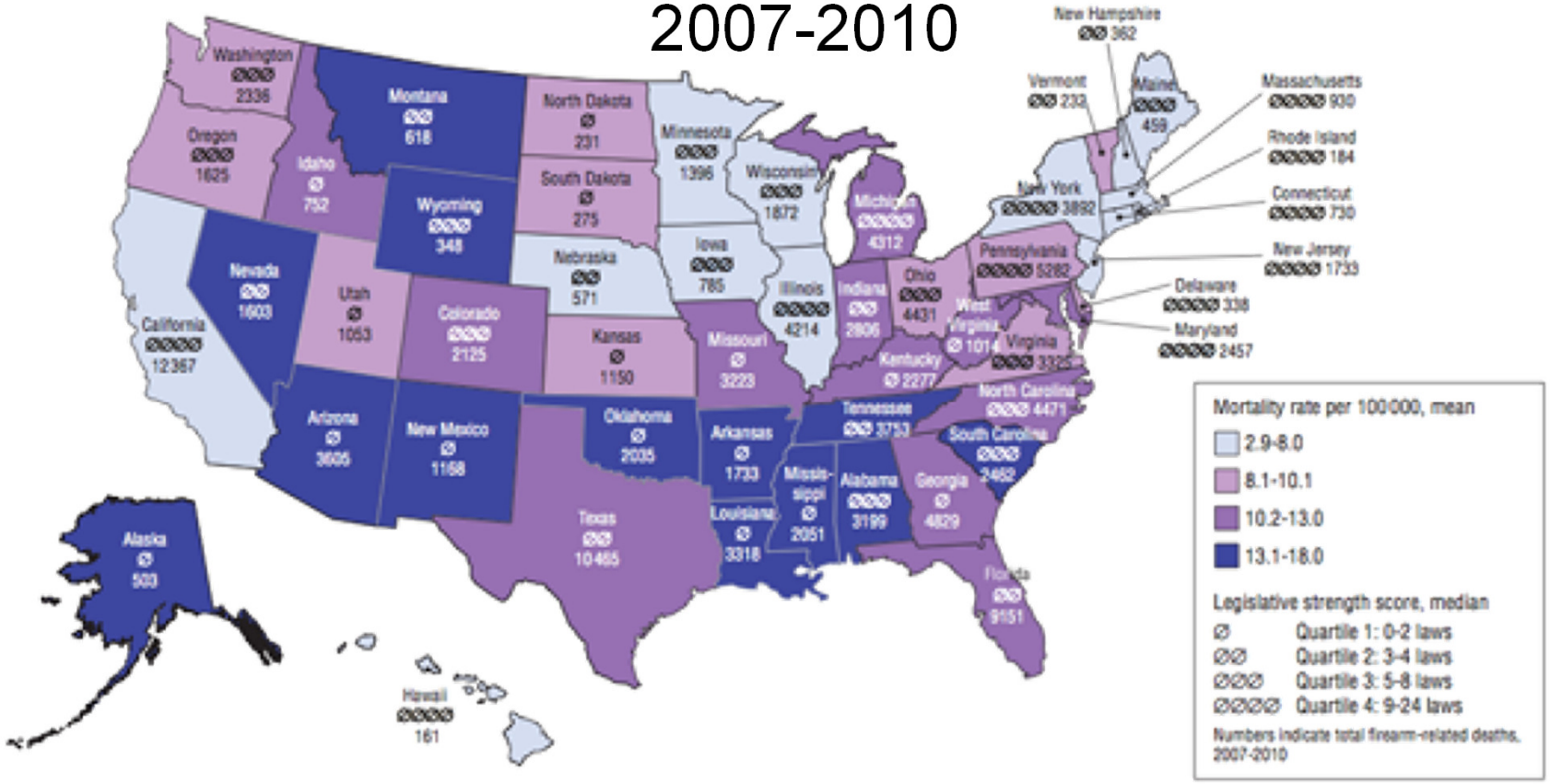
Stroke Rates

Range 13.5-300 stroke deaths/yr/100k

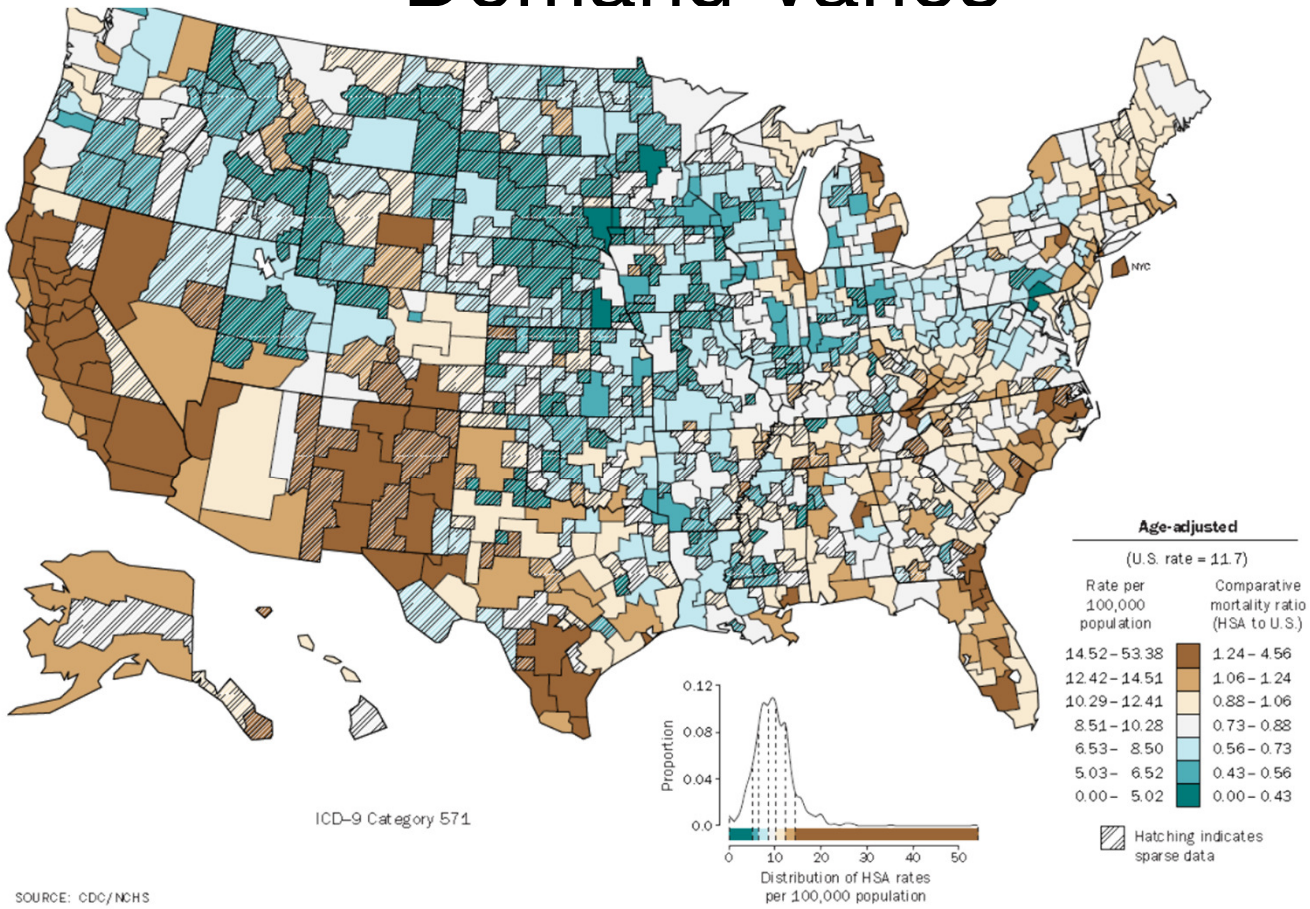


Deaths From Firearms

2007-2010



Demand Varies



Supply/Demand ratios of areas depends on borders

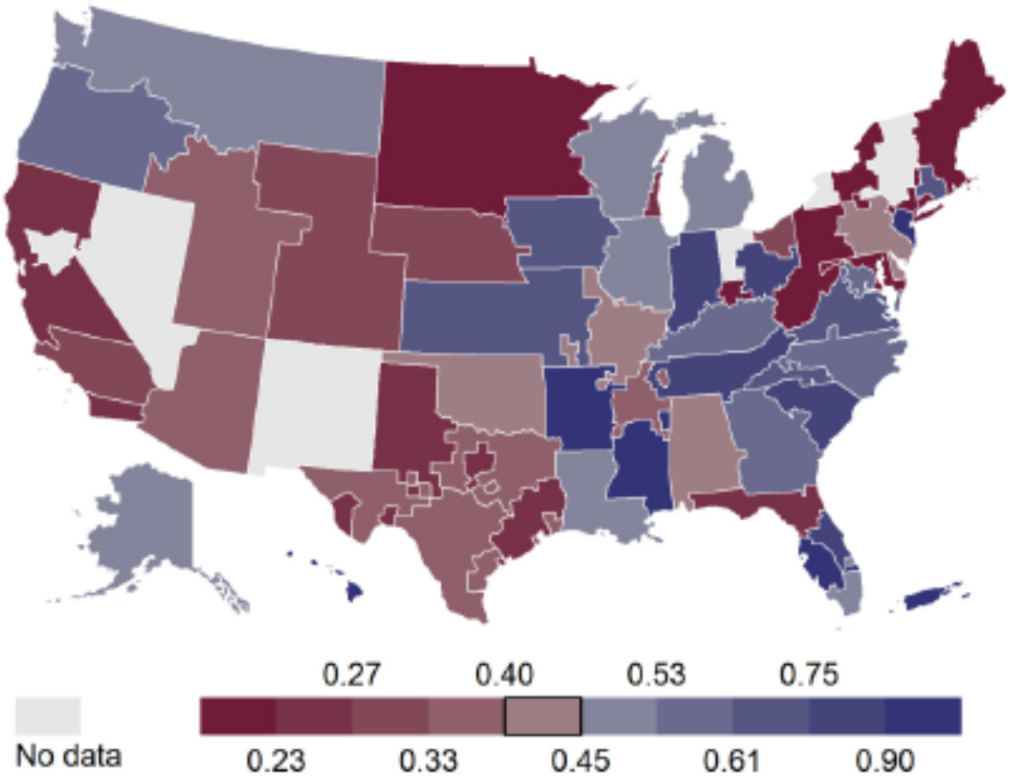
- ACTUAL DATA (2013)
- Current borders results in physical separation of HIGH SUPPLY and HIGH DEMAND areas.
- Compare supply/demand ratios

ALL DSA's with liver transplant programs vs

  - 11 UNOS regions
  - 8 districts
  - 4 districts

Supply/Demand Current Ratios

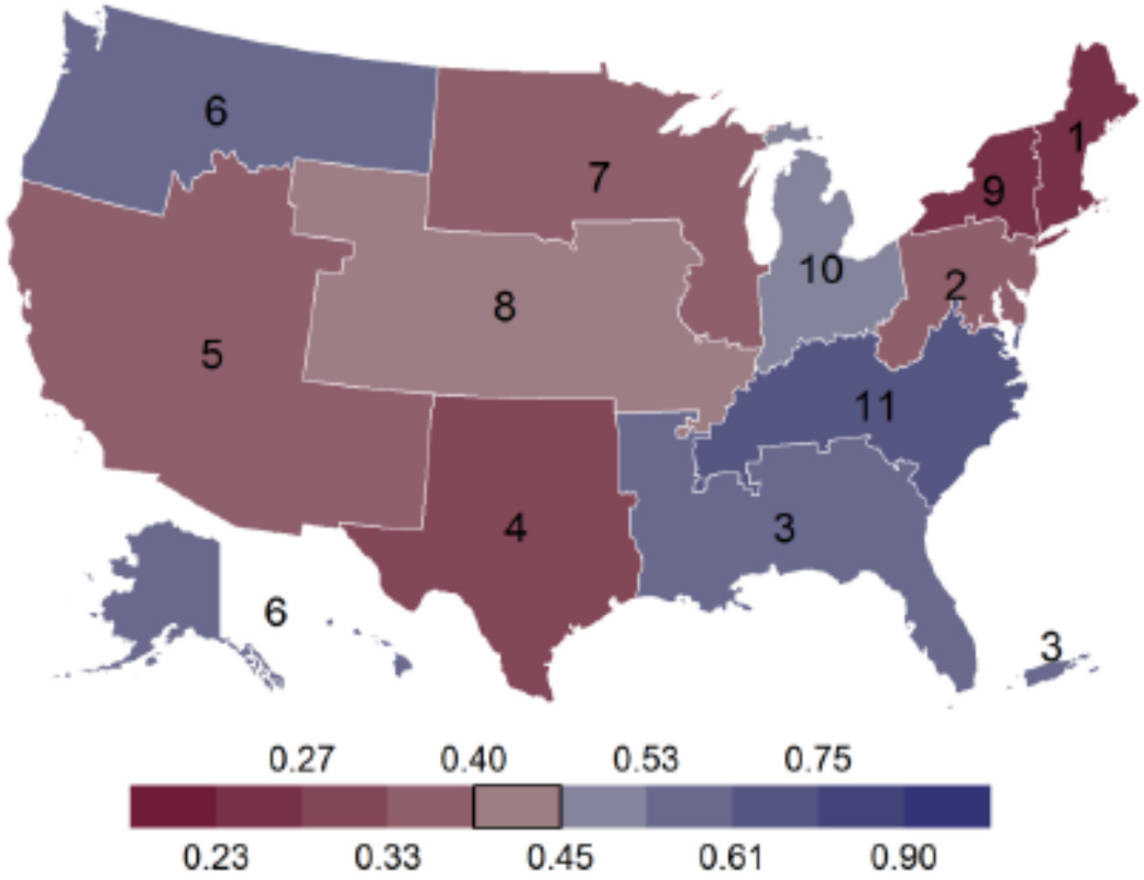
Figure 11. Ratio of eligible deaths/waitlisted candidates with allocation MELD/PELD > 15, by DSAs.



Supply/Demand by DSA - 2013

DSA	Eligible/WL	Deaths/WL	Median MELD
ALOB	0.35	179.28	**22**
AROR	0.94	385.76	25
CADN	0.18	61.28	35
CAOP	0.20	63.36	**37**
CTOP	0.55	483.71	24
FLWC	0.99	356.96	22
MSOP	2.14	**838.82**	31
HIOP	0.66	197.12	26
NYFL	0.18	119.81	34
NYRT	**0.11**	**52.61**	31
U.S.	0.27	102.03	27

Figure 12. Ratio of eligible deaths/waitlisted candidates with allocation MELD/PELD > 15, by 11 regions.



Eligible deaths/WL> 15 11 Regions

Figure 4. Ratio of eligible deaths/waitlisted candidates with allocation MELD/PELD > 15, 2013, by 11 regions.

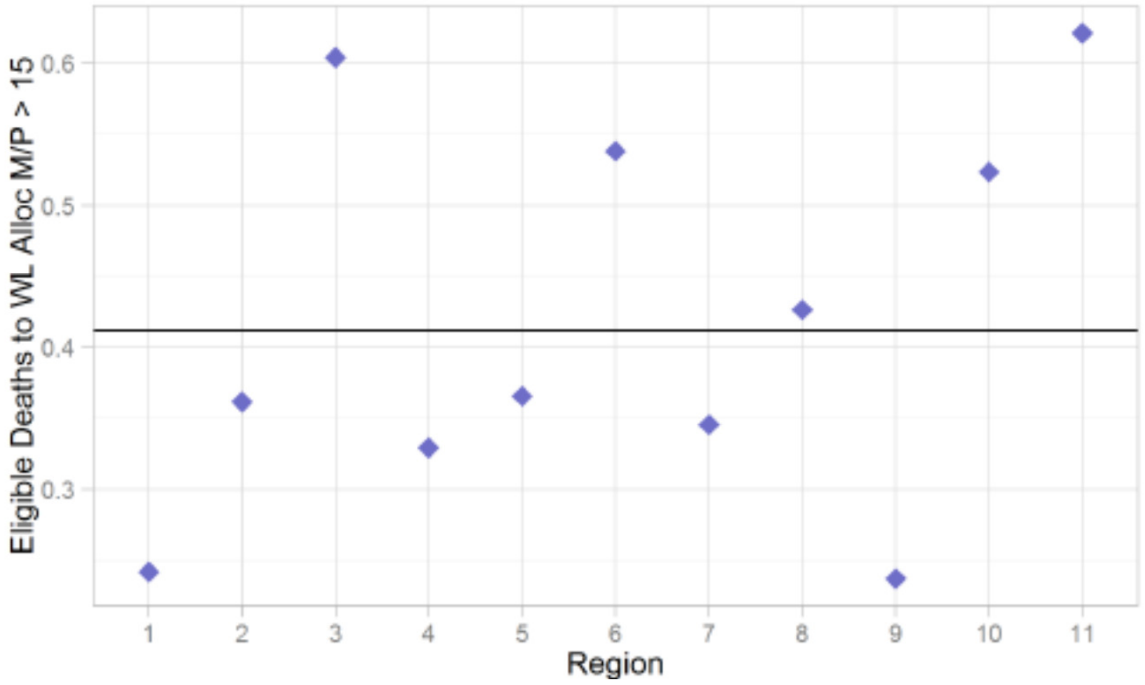
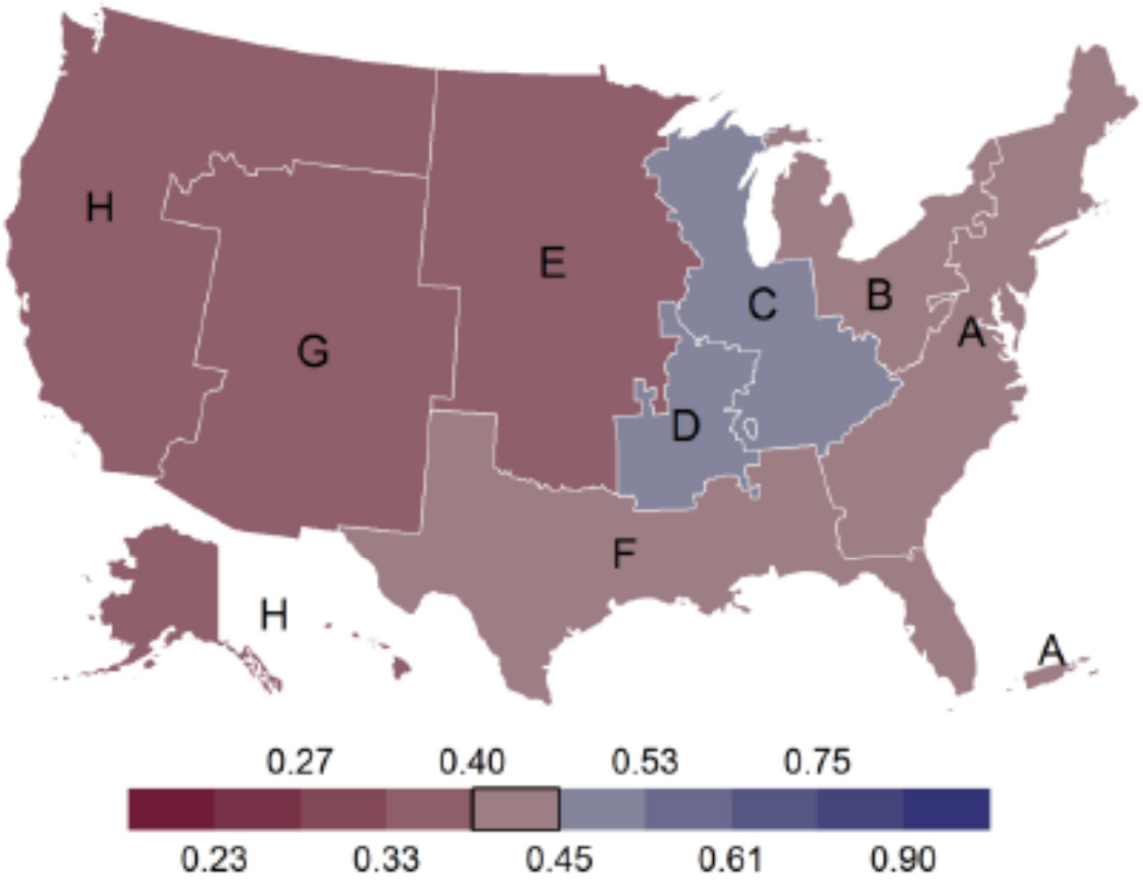


Figure 13. Ratio of eligible deaths/waitlisted candidates with allocation MELD/PELD > 15, by 8 districts.



Eligible deaths/WL pt>15 (8 districts)

Figure 5. Ratio of eligible deaths/waitlisted candidates with allocation MELD/PELD >15, 2013, by 8 districts.

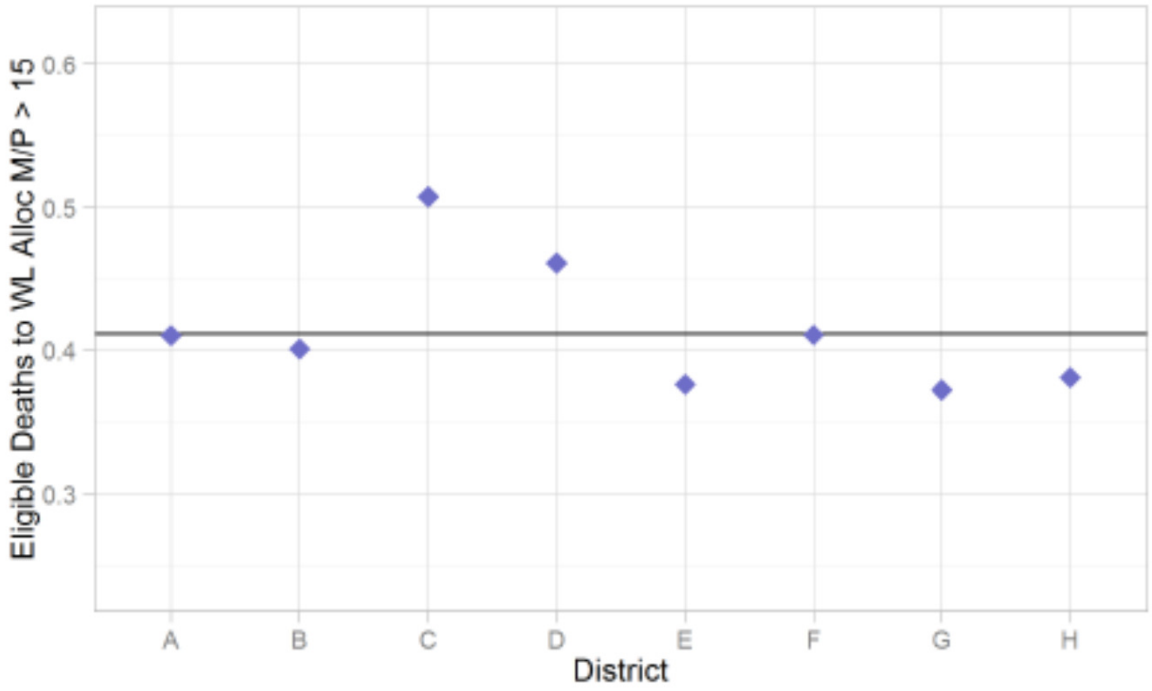
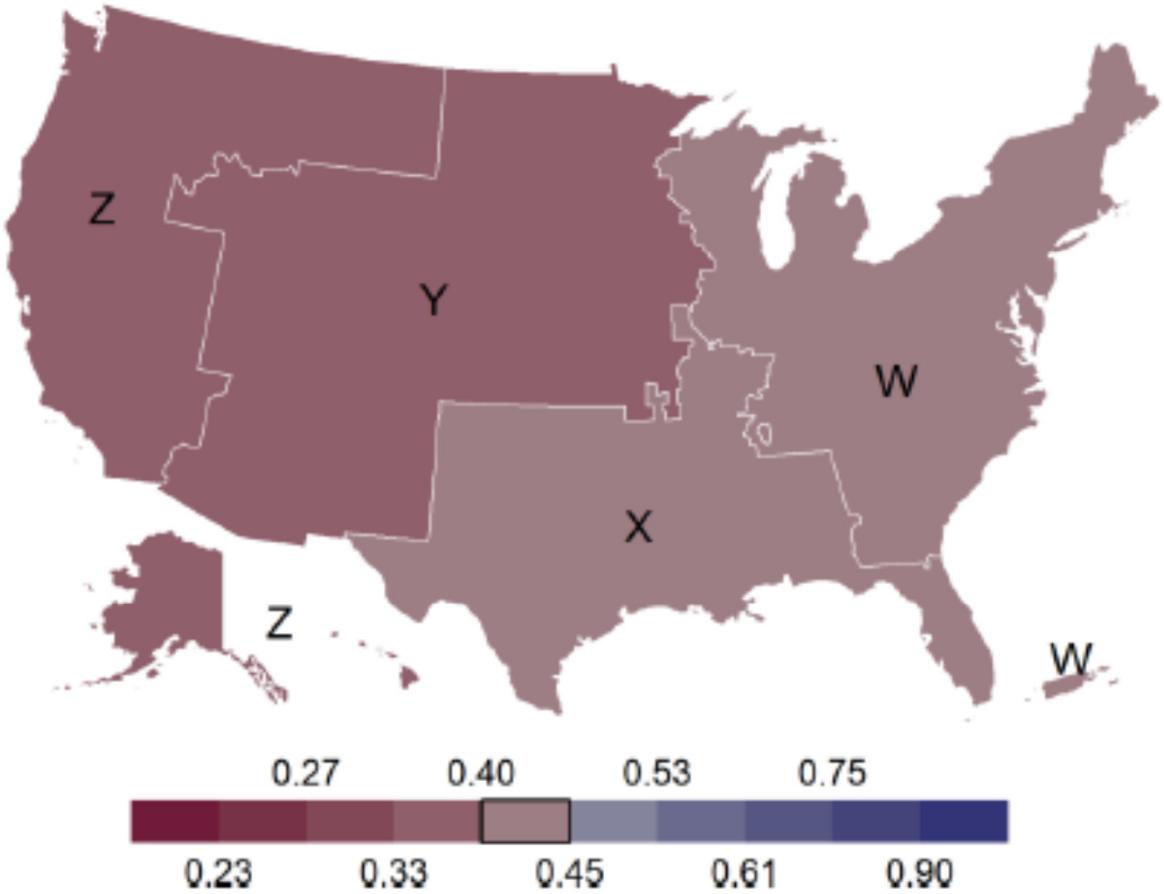
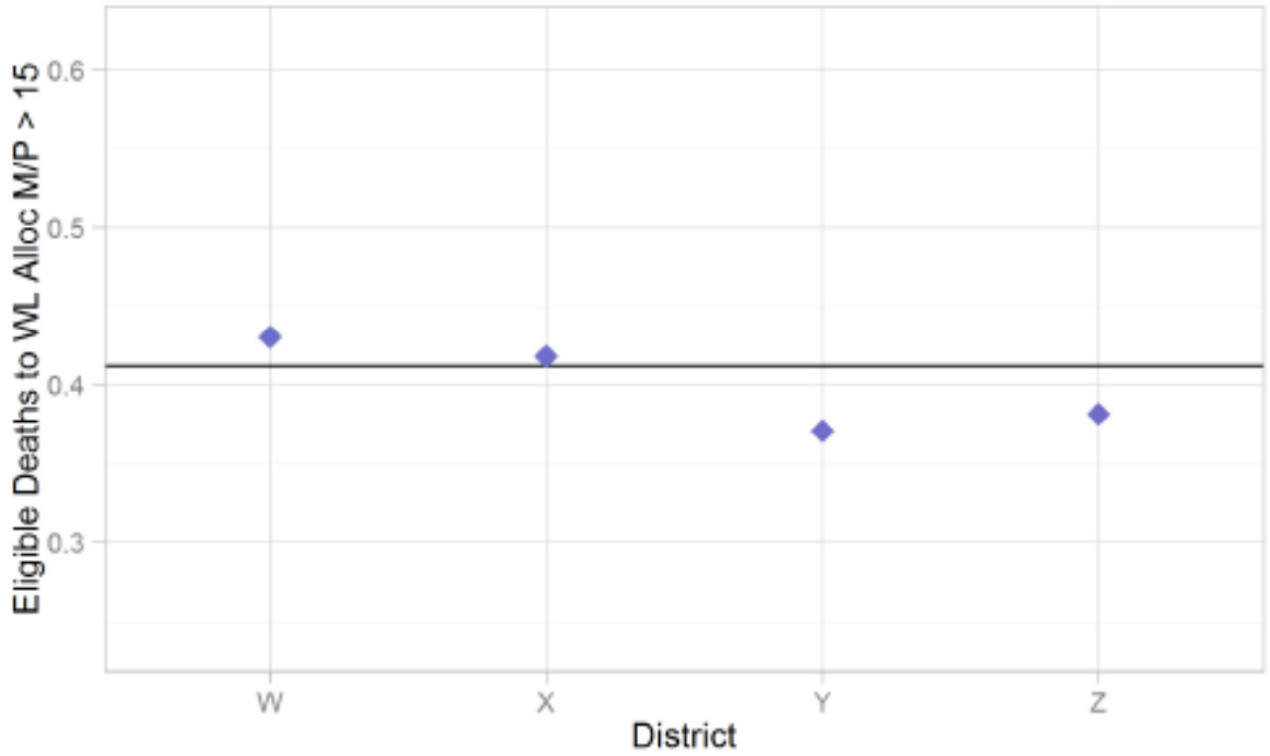


Figure 14. Ratio of eligible deaths/waitlisted candidates with allocation MELD/PELD > 15, by 4 districts.



Eligible deaths/WL>15 (4 districts)

Figure 6. Ratio of eligible deaths/waitlisted candidates with allocation MELD/PELD > 15, 2013, by 4 districts.



Potential effects of wider sharing

- Decreases disparity of supply/demand
- Decrease costs of care for the sickest pre-patients
- Equalize pressures to use all donors:
  - LDLT
  - Incentivizes more aggressive use of suboptimal donors

- Increase costs associated with transportation
- Increase transplant of sicker patients
  - Increased post op-costs
  - Worsen long-term outcomes ?

What can transplant surgeons/programs influence?

- OPO pursuit of suboptimal donors?
- Waitlist management:
  - Status 7
  - Updated and accurate acceptance criteria
- Organ acceptance practices:
  - There is currently uneven pressure to accept certain donors
- Cold ischemia time
  - Starting cases in the middle of the night, starting before organ arrives
  - **Avoiding late reallocations**
- Cost
  - Avoid futile transplants
  - Utilizing local recovery teams

Redistricting

- Will minimize disparities directly caused by DSA borders & UNOS regions
- Will not fix disparities caused by other reasons
- Fixing inequitable organ allocation may ↓ waitlist mortality caused by lower access to liver transplant.
- Will not fix waitlist mortality due to other causes (some areas of the country have ↑ transplant rates, shorter waiting time, yet still have ↑ waitlist mortality)
  - ↑ access to transplant may not Δ waitlist mortality if it caused by other comorbid conditions

References

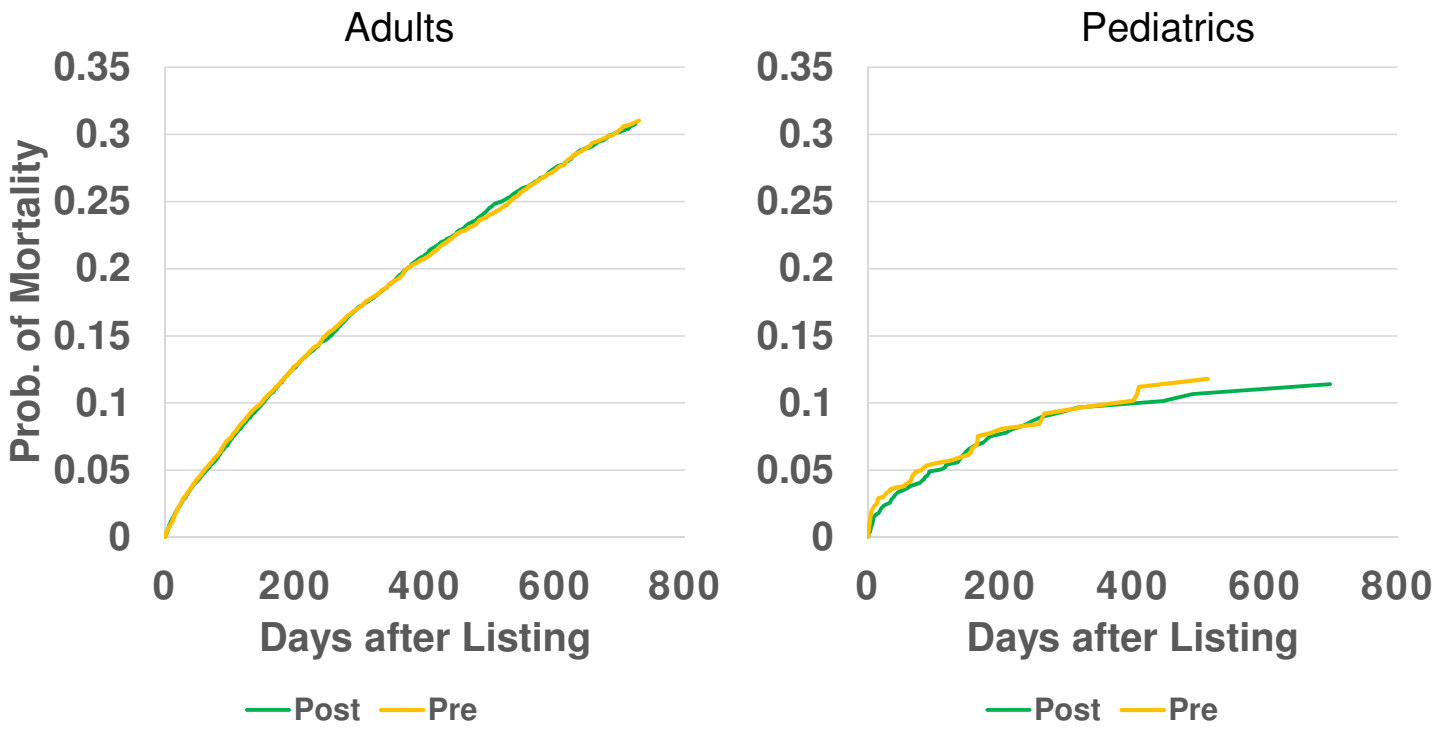
Data sourced from the SRTR: http://srtr.transplant.hrsa.gov and https://www.unos.org

What have we observed after Share 35?

- More liver transplants performed
- Higher % of MELD 35+ transplanted
- Wait list mortality for MELD 35+ ↓ significantly
- Wait list mortality ↓ slightly
- Post transplant graft and patient survival unchanged
- Increased regional sharing (20.8% to 32.0%)

- Variance in median MELD at transplant increased
- Variance in transport time increased
- Decreased overall discard rates

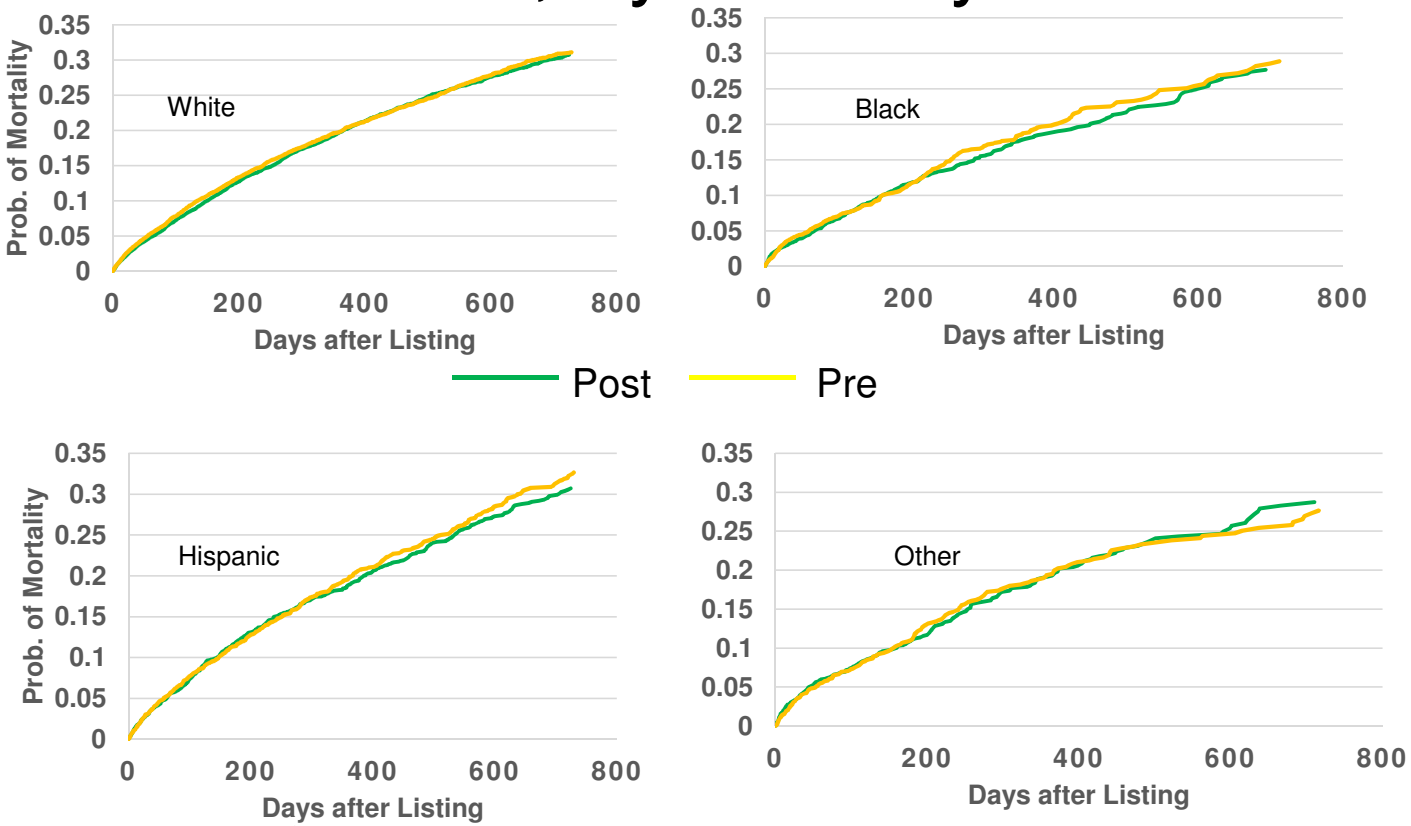
Waiting List Mortality Rates, Pre and Post Share 35, By Age Category



Competing risk framework, adjusted for MELD at start of period

Pre: 12/18/2011-6/17/2013 Post: 6/18/2013-6/18/2015

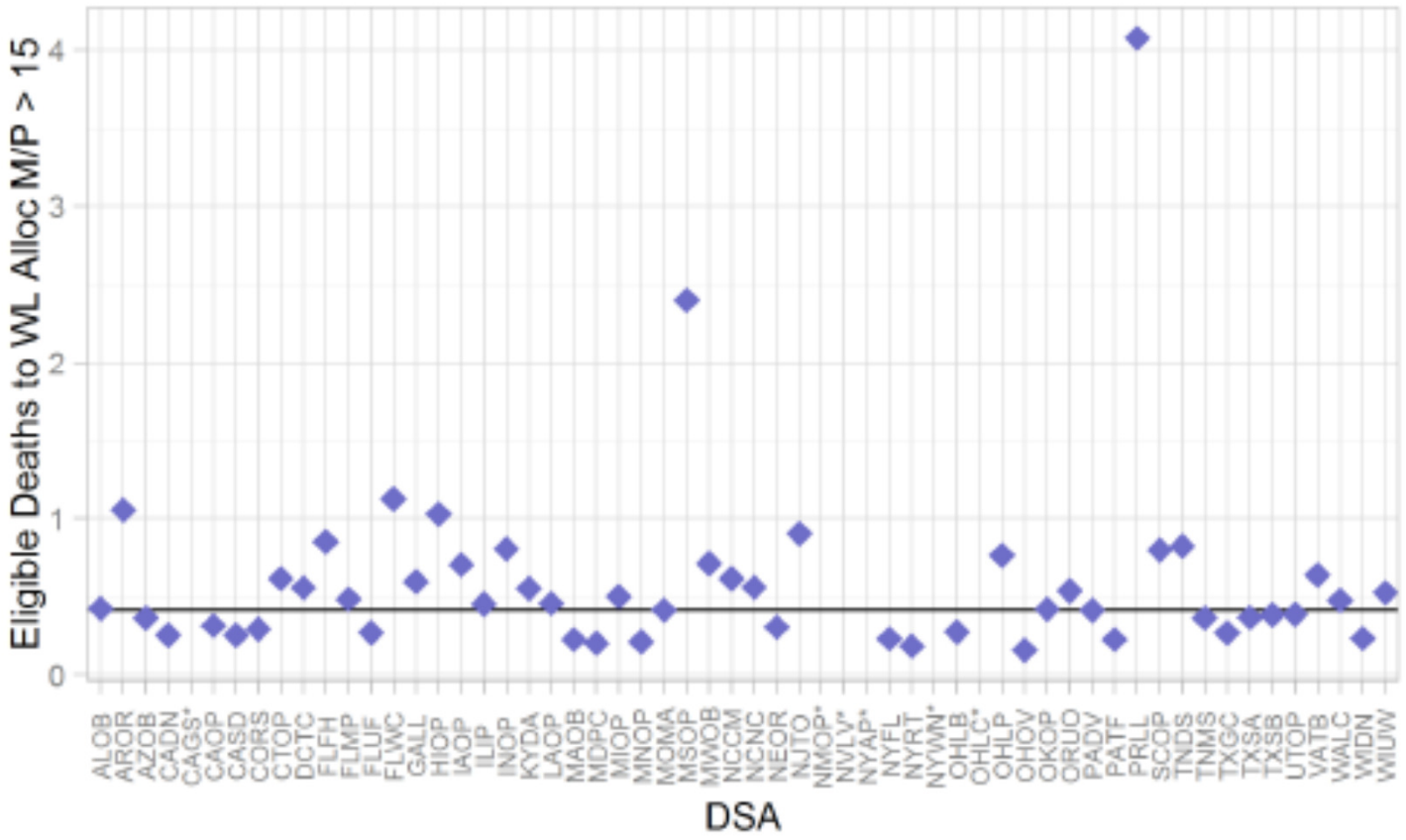
Waiting List Mortality Rates, Pre and Post Share 35, By Ethnicity



Competing risk framework, adjusted for MELD at start of period

Pre: 12/18/2011-6/17/2013 Post: 6/18/2013-6/18/2015

Figure 3. Ratio of eligible deaths/waitlisted candidates with allocation MELD/PELD > 15, 2013, by 58 DSAs*



U.S.: Eligible deaths/WL>15 = 0.42