NEW ALLOCATION AND POLICY CHANGES IN LIVER TRANSPLANTATION

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DISCLOSURES

- I have no conflicts of interest.

OBJECTIVES

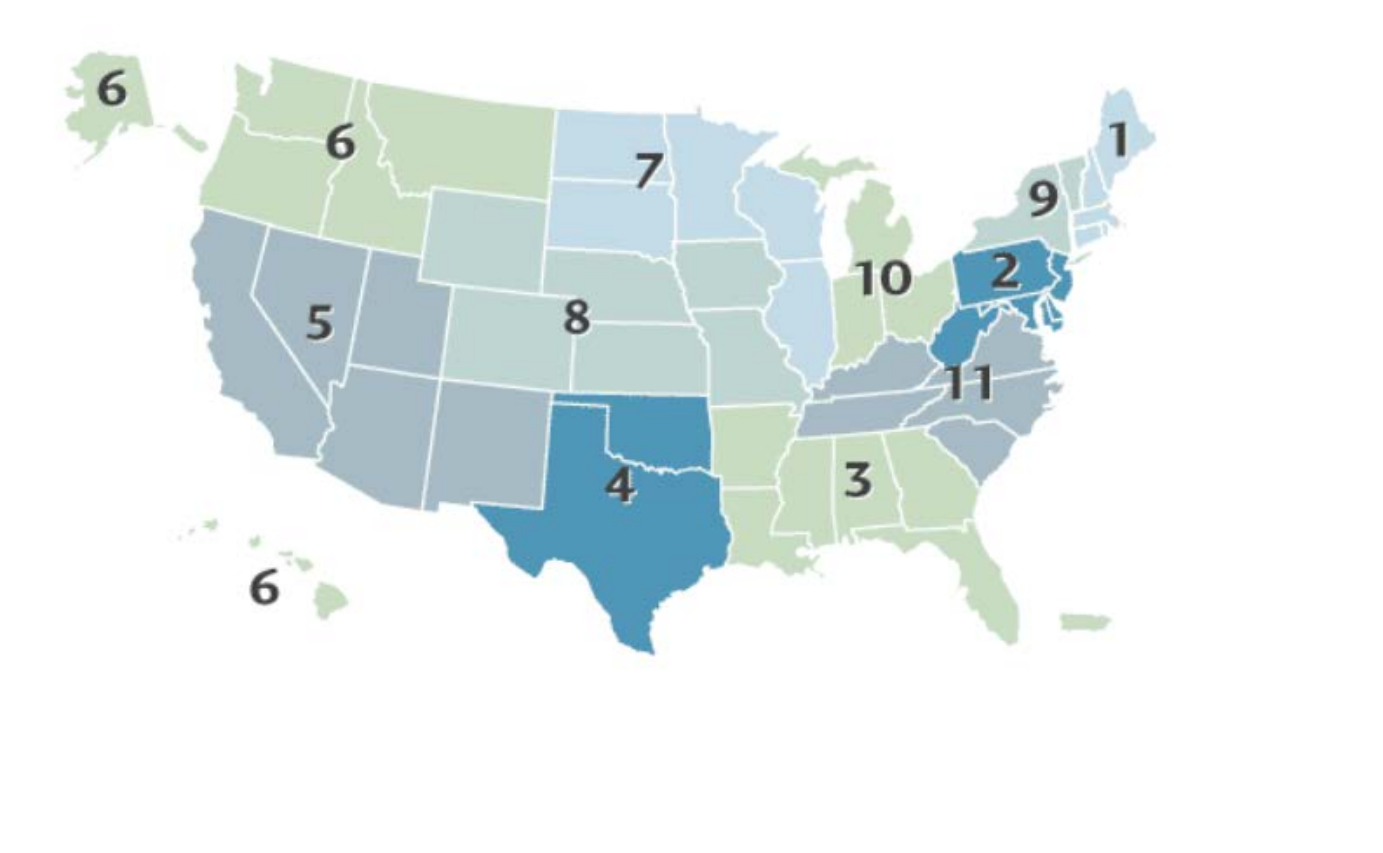
- Where we were in liver allocation
- Where we are now in liver allocation
- Where we are going in the future with liver allocation

THE FINAL RULE

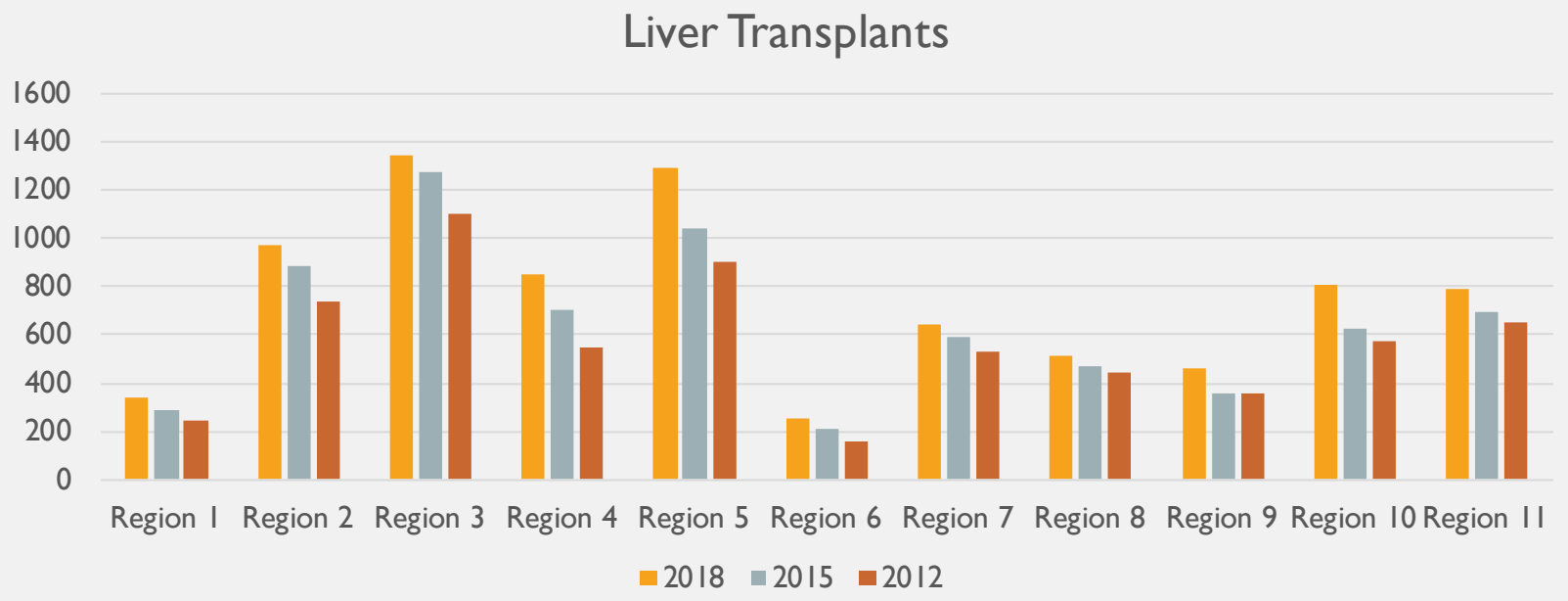
- The Department of Health and Human Services established the rule in March 2000 to replace local and regional organ allocation systems into 1 national distribution protocol.

- Organ Procurement and Transplantation Network (OPTN) allocation policies must, among other factors, be based on sound medical judgment, seek to achieve the best use of donated organs, and shall not be based on a candidate's place of residence or listing except to the extent required to satisfy other factors. The OPTN and transplant community must always balance these factors as organ allocation policies are created and changed.

GEOGRAPHIC REGIONS

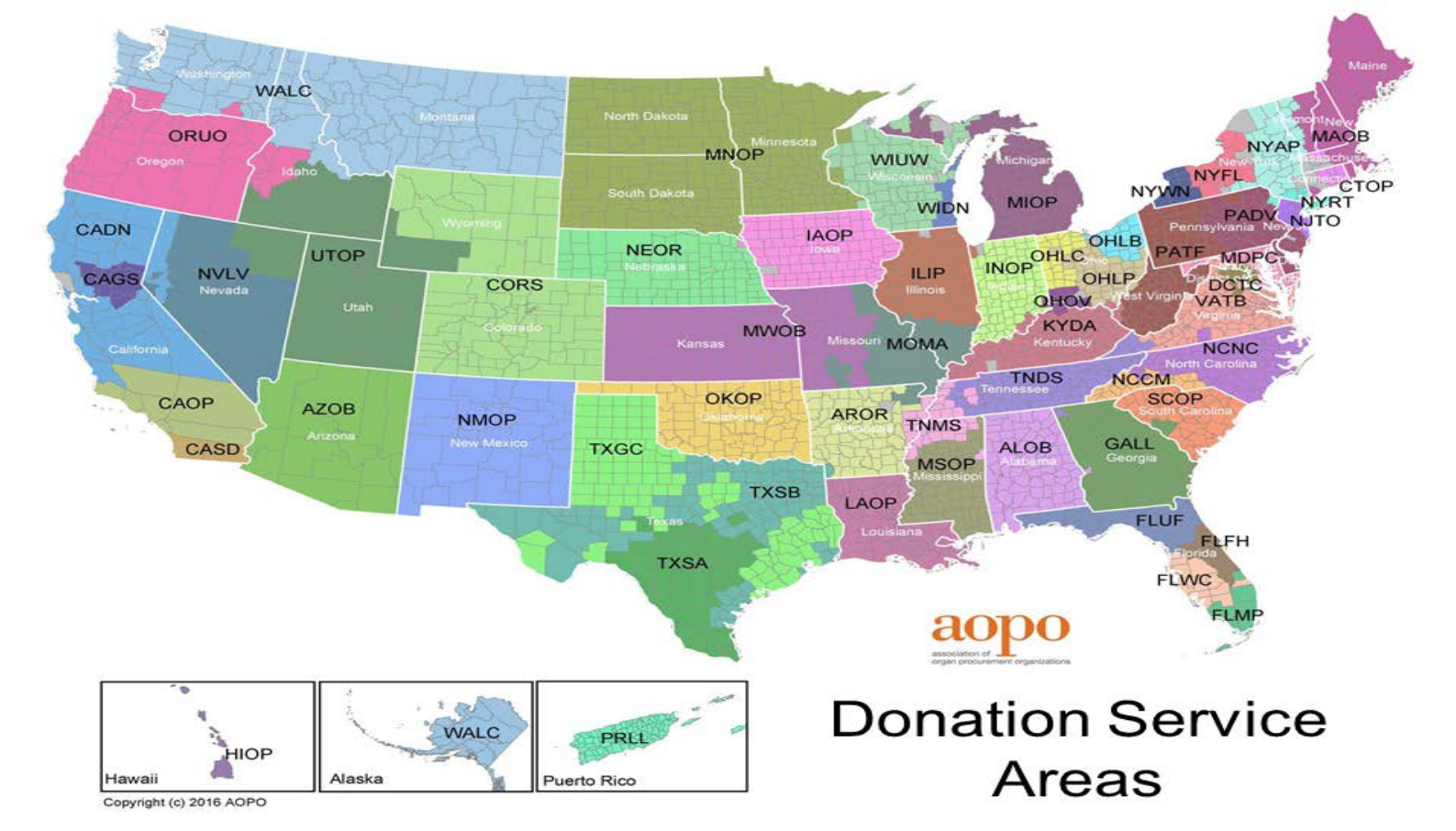


LIVER TRANSPLANTATION PER REGION

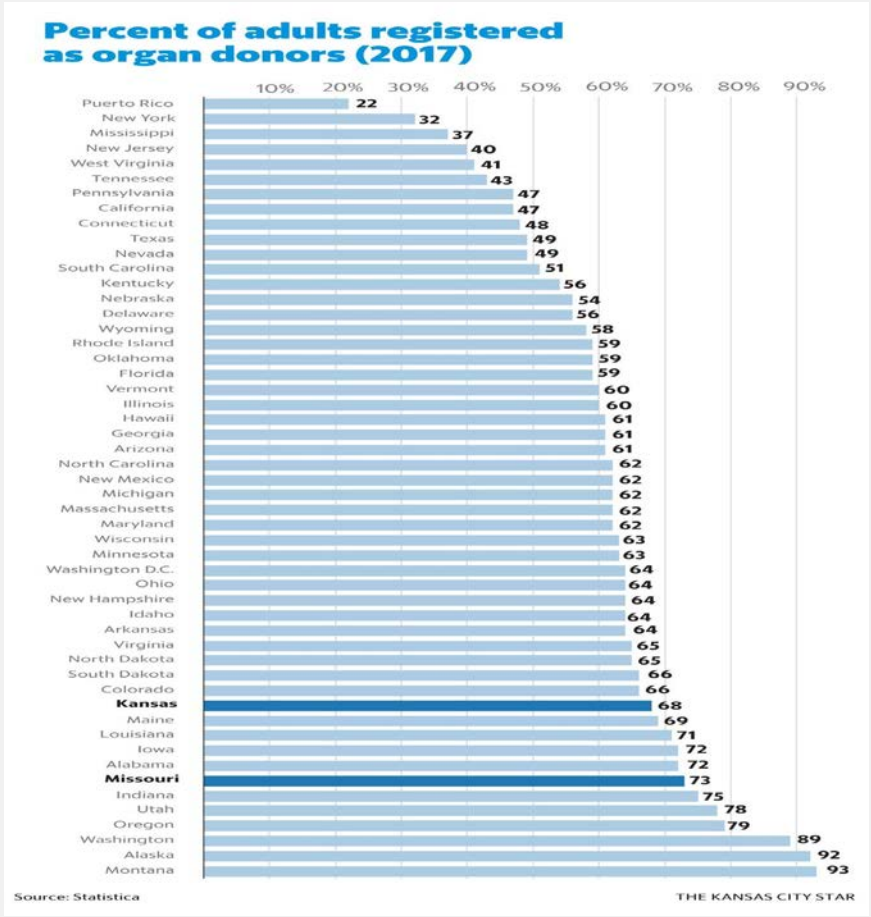


-Data derived from UNOS

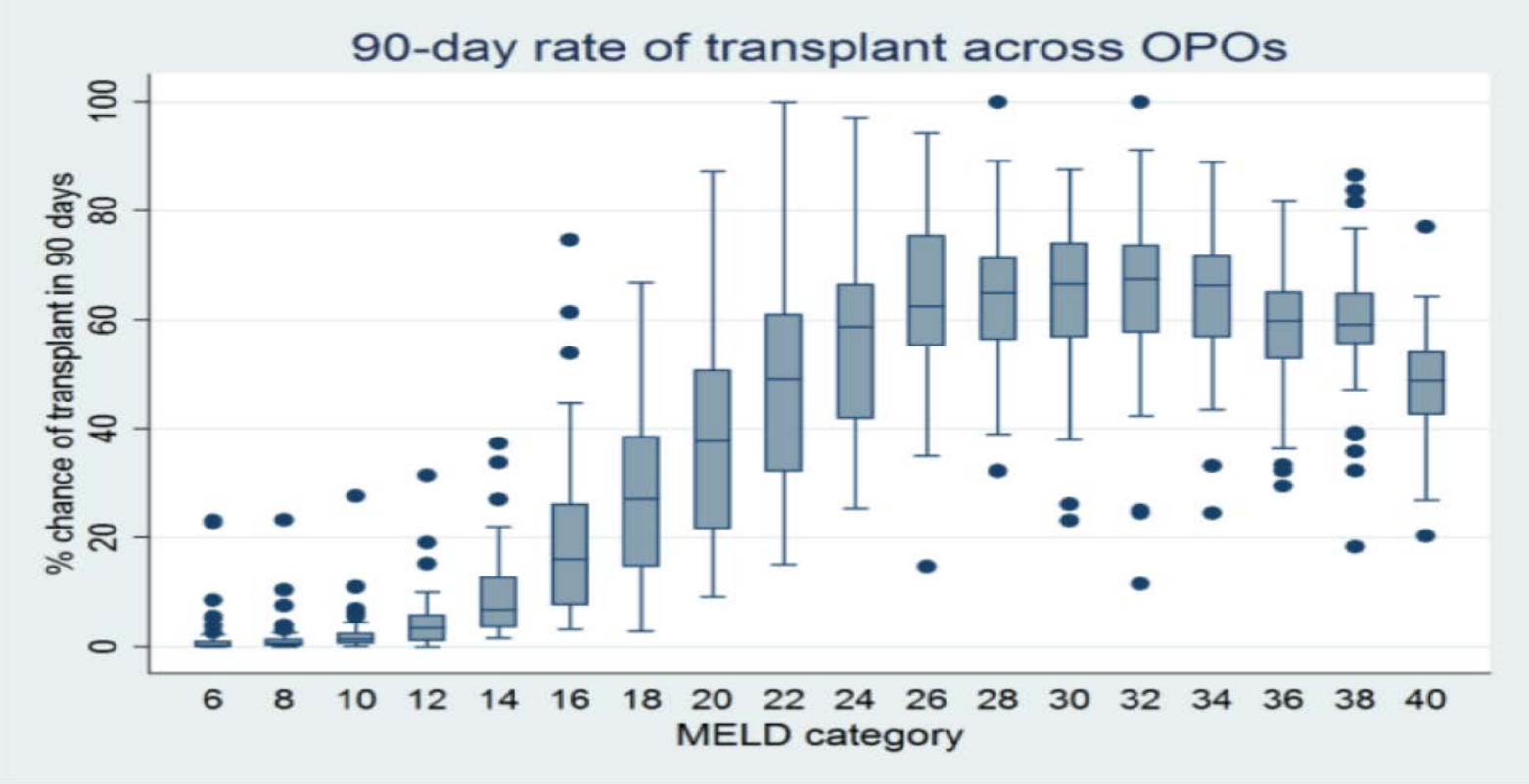
DONOR SERVICE AREA (58)



DONATION

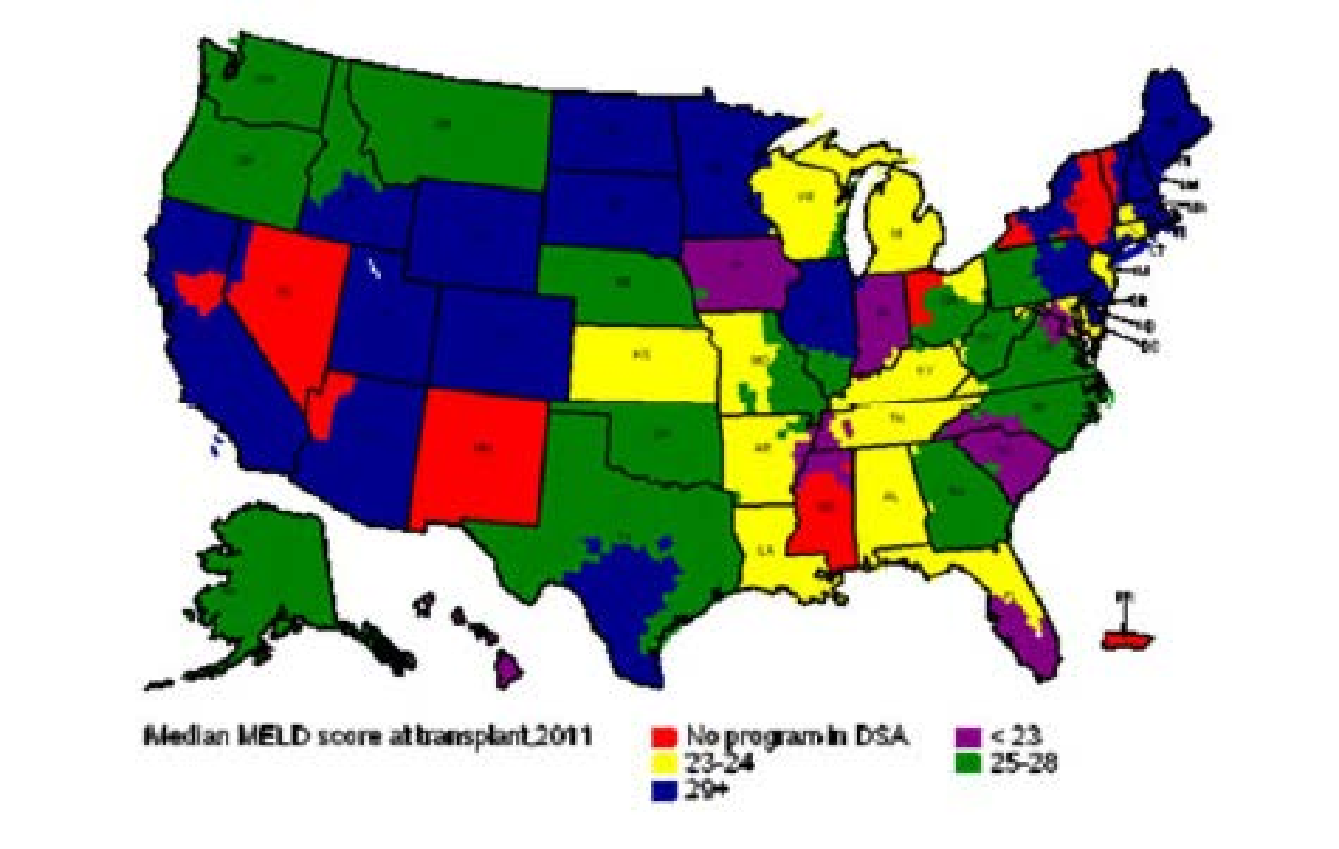

Percent of adults registered as organ donors (2017)
10%
20%
30%
40%
50%
60%
70%
80%
90%
Puerto Rico 22
New York 32
Mississippi 37
New Jersey 40
West Virginia 41
Tennessee 43
Pennsylvania 47
California 47
Connecticut 48
Texas 49
Nevada 49
South Carolina 51
Kentucky 56
Nebraska 54
Delaware 56
Wyoming 58
Rhode Island 59
Oklahoma 59
Florida 59
Vermont 60
Illinois 60
Hawaii 61
Georgia 61
Arizona 61
North Carolina 62
New Mexico 62
Michigan 62
Massachusetts 62
Maryland 62
Wisconsin 63
Minnesota 63
Washington D.C. 64
Ohio 64
New Hampshire 64
Idaho 64
Arkansas 64
Virginia 65
North Dakota 65
South Dakota 66
Colorado 66
Kansas 68
Maine 69
Louisiana 71
Iowa 72
Alabama 72
Missouri 73
Indiana 75
Utah 78
Oregon 79
Washington 89
Alaska 92
Montana 93
Source: Statistica
THE KANSAS CITY STAR

DISPARITIES IN LIVER ALLOCATION



Massie, A. B., et. al. (2011), American Journal of Transplantation, 11: 2362–2371

DISPARITIES IN LIVER ALLOCATION



Redesigning liver distribution to reduce variation in access to liver transplantation: a concept paper from the OPTN/UNOS Liver and Intestinal Organ Transplantati
Committee. Circulated June–July 2014. [Accessed 8 February 2016]

CHANGES TO CREATE EQUITY

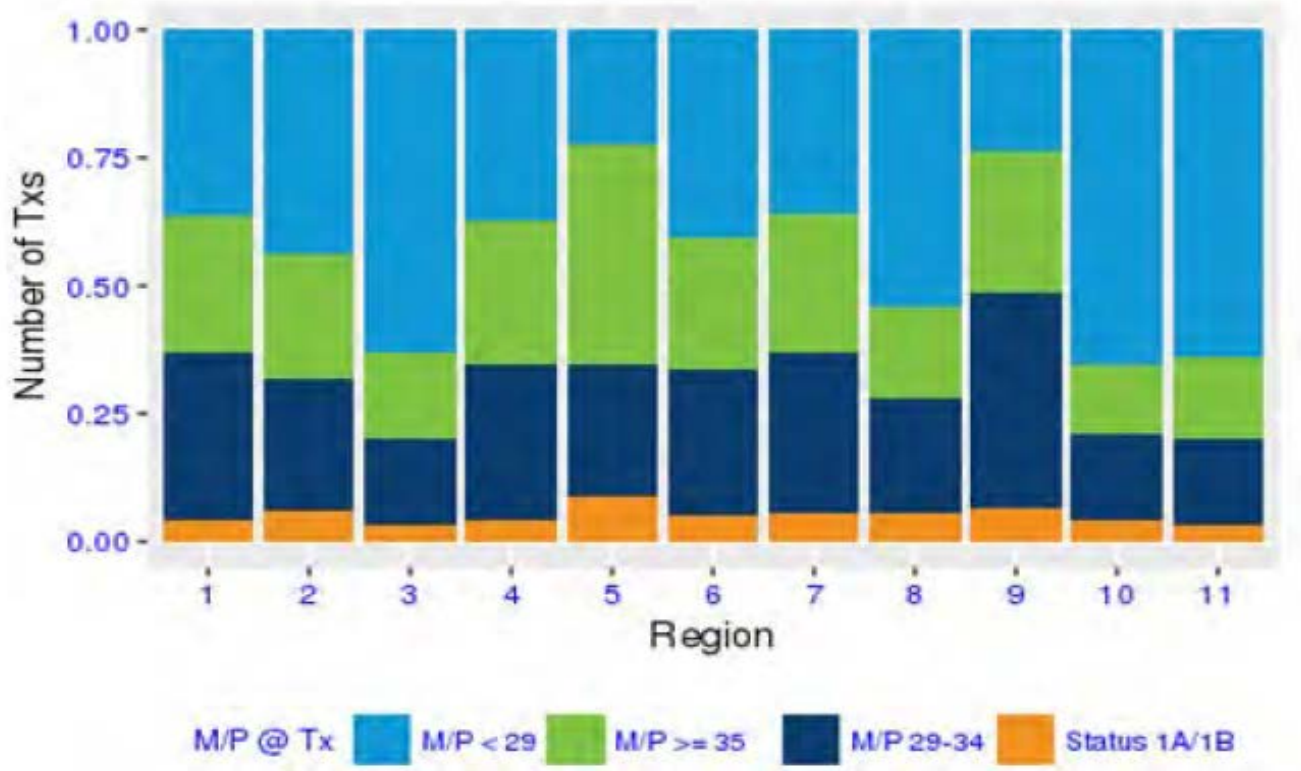
Year	Allocation Policy
1998	Final Rule Mandate from Health Resources and Services Admin
2002	Prioritization based on MELD score
2002-2005	Revisions to Exception Scoring for Hepatocellular Cancer
2009	Standardized Exceptions for Various Conditions
2015	“Cap” on HCC at 34 points, initiated after 6 months of listing
2016	Incorporation of the MELD-Na

CHANGES TO CREATE EQUITY

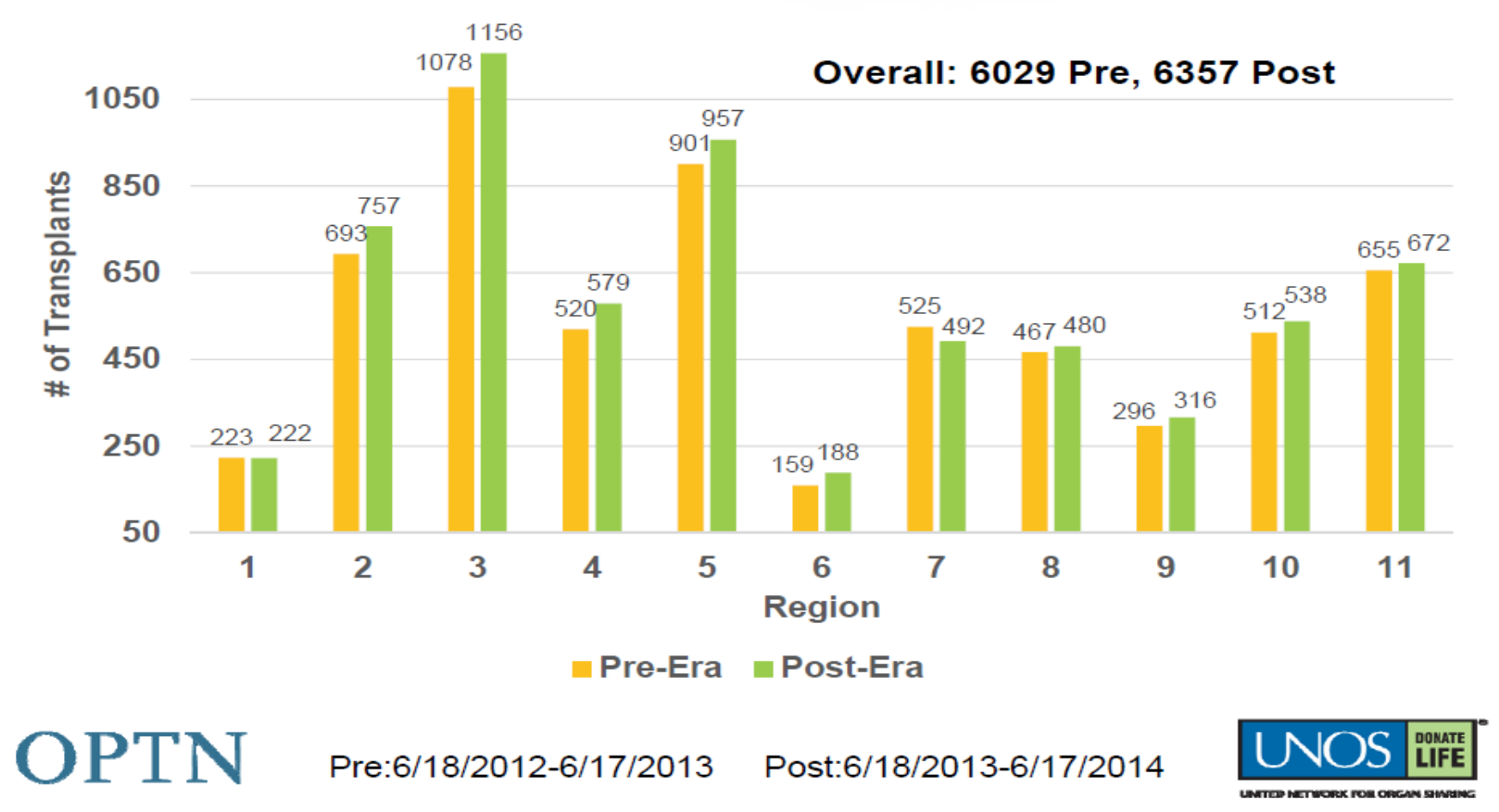
Year	Distribution Policies
2005	"Share 15" –regional candidates with MELD>15 prioritized over local candidates with MELD < 15
2010	Full regional sharing of adult donor livers for all Status 1A and Status 1B liver candidates on December 15, 2010
2013	"Share 35": livers are first offered to both local and regional candidates with a MELD above 35 in a tiered fashion before local candidates with a MELD below 35

SHARE 35

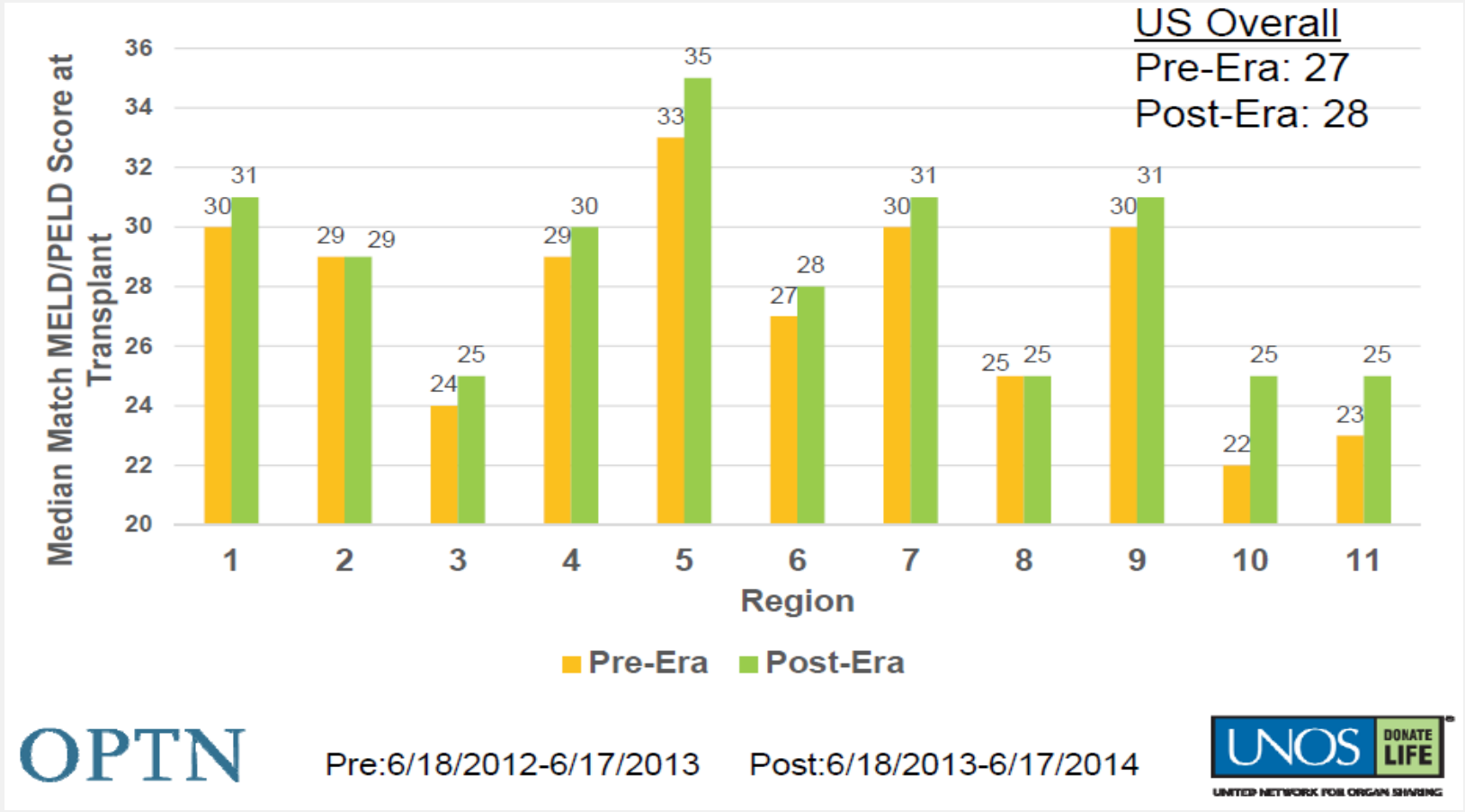
Figure 4. Deceased donor transplants in 2016, by allocation MELD or PELD score and region



SHARE 35


Overall: 6029 Pre, 6357 Post
# of Transplants
1050
850
650
450
250
50
223 222
693 757
1078 1156
520 579
901 957
159 188
525 492
467 480
296 316
512 538
655 672
1 2 3 4 5 6 7 8 9 10 11
Region
Pre-Era
Post-Era
OPTN
Pre:6/18/2012-6/17/2013
Post:6/18/2013-6/17/2014
UNOS
DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

SHARE 35


US Overall
Pre-Era: 27
Post-Era: 28
Median Match MELD/PELD Score at Transplant
36
34
32
30
28
26
24
22
20
30 31
29 29
24 25
29 30
33 35
27 28
30 31
25 25
30 31
22 25
23 25
1 2 3 4 5 6 7 8 9 10 11
Region
Pre-Era
Post-Era
OPTN
Pre:6/18/2012-6/17/2013
Post:6/18/2013-6/17/2014
UNOS
DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

DISPARITIES IN LIVER ALLOCATION

- Waitlist mortality decreased; however, MELD to transplant increased
- Despite these changes disparities persisted
- Lawsuits were filed to create a new liver allocation system

NEW LIVER ALLOCATION SYSTEM

- DHHS placed a mandate to create a new allocation system by December 2018

- Changes:
  - Use of median MELD at transplant (MMaT)
  - HCC MELD exceptions
  - Regional review boards to national review board
  - Removal of OPTN regions and DSA

MEDIAN MELD AT TRANSPLANT

Median MELD at transplant (MMaT) is calculated by using the median of the MELD scores at the time of transplant of all recipients at least 12 years old who were transplanted at hospitals within 250 nautical miles of the candidate's listing hospital in the last 365 days.

Median PELD at transplant (MPaT) is calculated by using the median of the PELD scores at the time of transplant of all recipients less than 12 years old in the nation.

The MMaT and MPaT calculations exclude recipients who are either of the following:

1. Transplanted with livers from living donors, DCD donors, and donors from donor hospitals more than 500 nautical miles away from the transplant hospital
2. Status 1A or 1B at the time of transplant.

HEPATOCELLULAR CARCINOMA

Prior to applying for a standardized MELD or PELD exception, the candidate must undergo a thorough assessment that includes *all* of the following:

1. An evaluation of the number and size of lesions before local-regional therapy that meet Class 5 criteria using a dynamic contrast enhanced computed tomography (CT) or magnetic resonance imaging (MRI)
2. A CT of the chest to rule out metastatic disease
3. A CT or MRI to rule out any other sites of extrahepatic spread or macrovascular involvement
4. An indication that the candidate is not eligible for resection
5. An indication whether the candidate has undergone local-regional therapy
6. The candidate's alpha-fetoprotein (AFP) level

The transplant hospital must maintain documentation of the radiologic images and assessments of all OPTN Class 5 lesions in the candidate's medical record. If growth criteria are used to classify a lesion as HCC, the radiology report must contain the prior and current dates of imaging, type of imaging, and measurements of the lesion.

OPTN policy

HEPATOCELLULAR CARCINOMA

Age	Age at registration	Exception Request	Score
At least 18 years old	At least 18 years old	Initial and first extension	6
At least 18 years old	At least 18 years old	Any extension after the first extension	3 points below MMaT
At least 12 years old	Less than 18 years old	Any	40
Less than 12 years old	Less than 12 years old	Any	40

OPTN policy

NATIONAL REVIEW BOARD

- Created to standardized MELD exceptions despite regions
- Formalized appeals process for non-standard exceptions

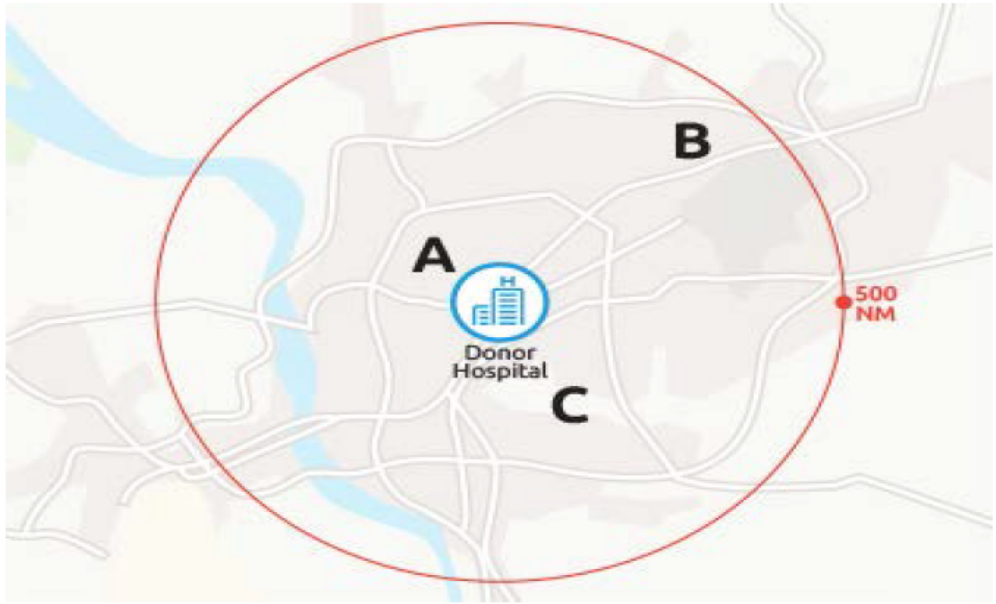
REMOVAL OF DSA AND REGIONS

- Based on **donor hospital** within 150, 250, and 500 nautical miles (1 **nautical mile** = 1.1508 statute miles)

- The policy will replace fixed, irregular local and regional geographic boundaries historically used to match liver candidates based on the donor location.

NEW LIVER ALLOCATION SYSTEM

Under the new policy, livers from all deceased donors would be offered for compatible Status 1A and 1B candidates listed at transplant hospitals within a radius of 500 nautical miles of the donor hospital. In the example below, transplant hospitals A, B and C all have Status 1A or 1B candidates compatible with the donor and are located within a 500 nautical-mile radius of the donor hospital.



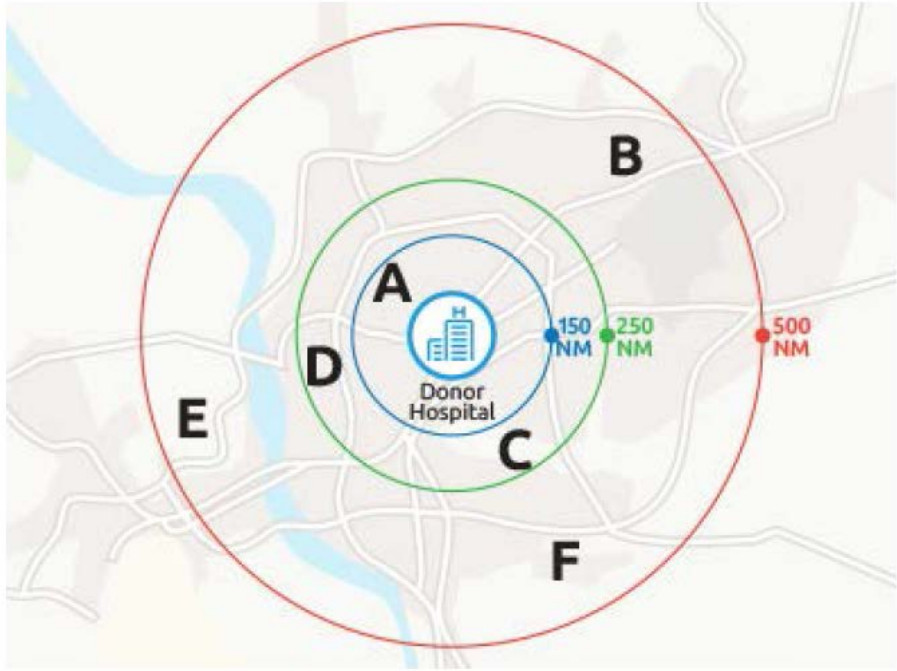
OPTN policy

NEW LIVER ALLOCATION SYSTEM

Organ distribution for adult, non-DCD donors younger than age 70

The majority of deceased liver donors are adults who are under age 70 and who are not donating upon cardiorespiratory death (also known as DCD donation). For livers from these donors, after initial offers to Status 1A and 1B candidates as above, the next steps in distribution are as follows:

- candidates with a MELD or PELD score of 37 or higher listed at transplant hospitals within a radius of 150 nautical miles from the donor hospital
- candidates with a MELD or PELD score of 37 or higher listed at transplant hospitals within a radius of 250 nautical miles from the donor hospital
- candidates with a MELD or PELD score of 37 or higher listed at transplant hospitals within a radius of 500 nautical miles from the donor hospital
- a continuing sequence of progressive offers, from more local to more distant (at transplant hospitals within 150, 250 and 500 nautical miles of the donor hospital), for candidates with ranges of MELD or PELD scores from 33 to 36, from 29 to 32, and from 15 to 28



OPTN policy

NEW LIVER ALLOCATION SYSTEM

Organ distribution for adult donors age 70 or older and/or DCD donors

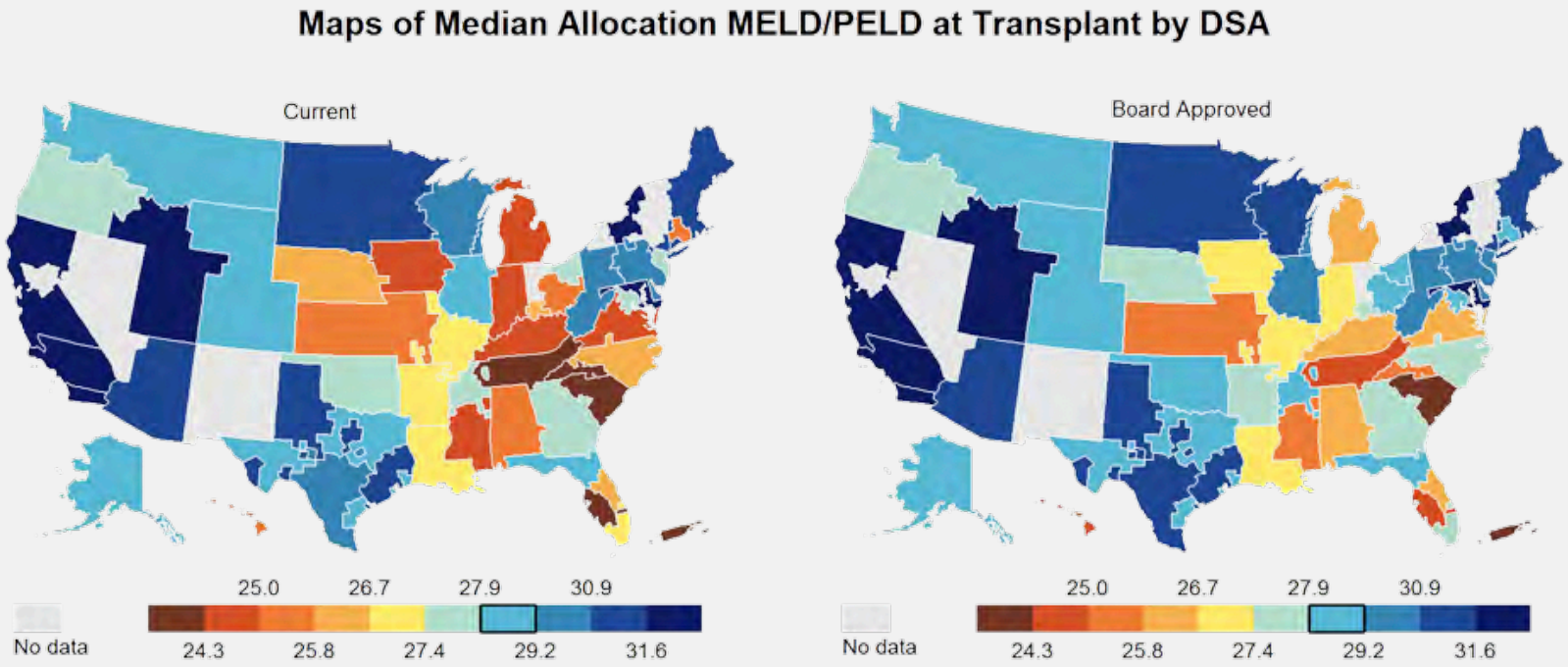
For deceased donors older than age 70, and/or who die as a result of cardiorespiratory failure, the distribution sequence will provide earlier access for candidates more local to the donor hospital. Most livers from these donors are accepted for local candidates, since they are most viable when the preservation time between recovery and transplantation is brief.

For livers from these donors, after initial offers to Status 1A and 1B candidates as above, the initial distribution sequence is as follows:

- compatible candidates with a MELD or PELD of 15 or higher, listed at transplant hospitals within a 150 nautical-mile radius of the donor hospital
- compatible candidates with a MELD or PELD of 15 or higher, listed at transplant hospitals within a 250 nautical-mile radius of the donor hospital
- compatible candidates with a MELD or PELD of 15 or higher, listed at transplant hospitals within a 500 nautical-mile radius of the donor hospital

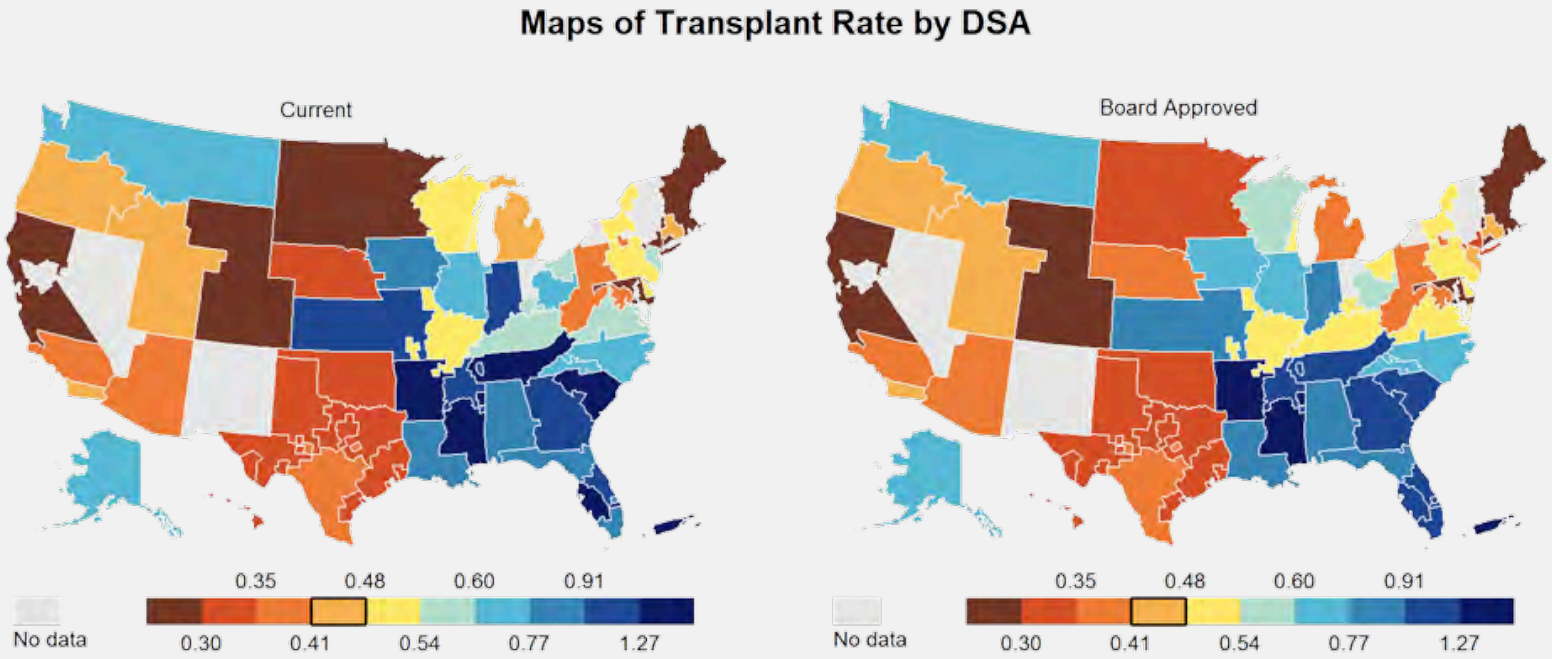
OPTN policy

NEW LIVER ALLOCATION SYSTEM



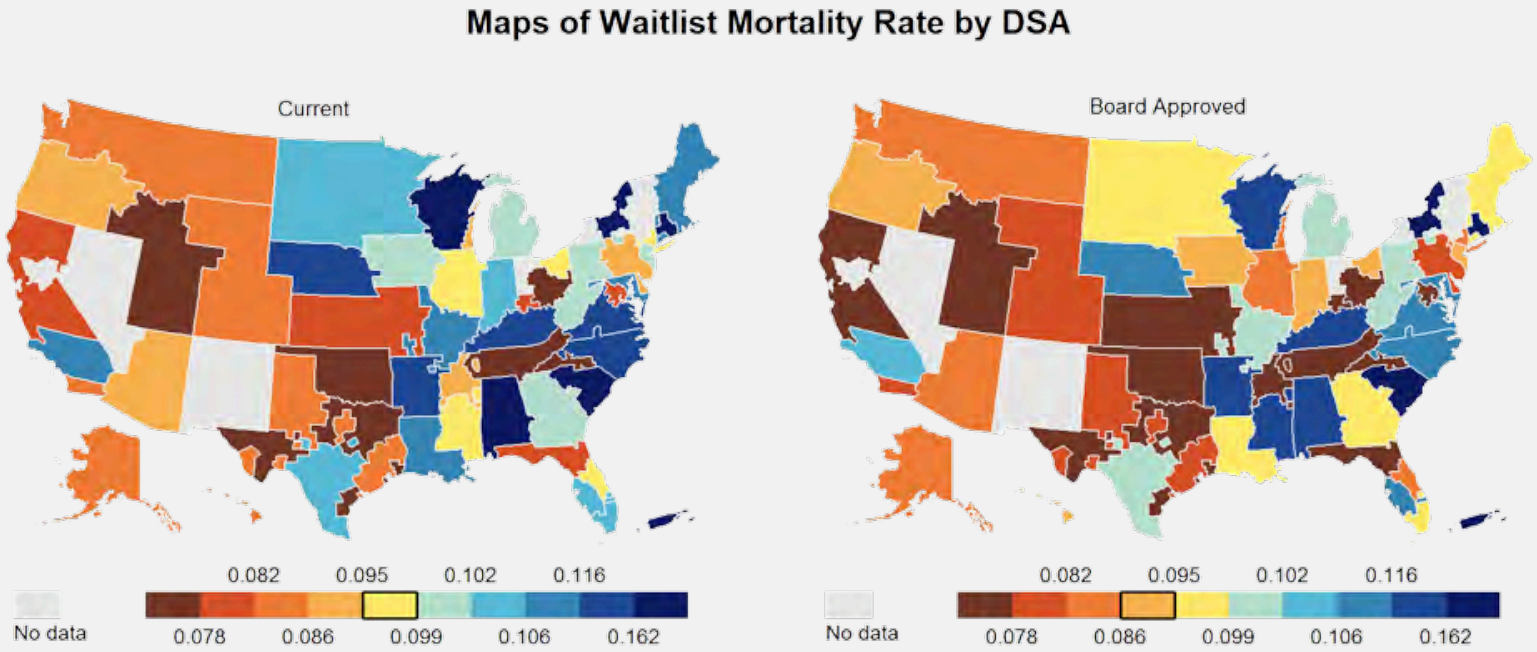
SRTR

NEW LIVER ALLOCATION SYSTEM



SRTR

NEW LIVER ALLOCATION SYSTEM



SRTR

NEW LIVER ALLOCATION SYSTEM

Scenario	Variance in Median Allocation MELD/PELD at Transplant	Median Allocation MELD/PELD at Transplant	Median Transport Time (hours)	Median Transport Distance (miles)	Percent of Organs Flown
Current	9.97 (8.74,11.9)	29 (29,29)	1.7 (1.7,1.7)	88.5 (86.9,90)	50.7 (50.2,51.1)
Board Approved	7.41 (6.36,8.47)	29.1 (29,30)	1.7 (1.7,1.7)	100.4 (98.7,101.9)	54.4 (53.8,54.9)
Acuity 250+500	4.33 (3.23,6.27)	31 (31,31)	1.9 (1.9,1.9)	183.5 (180.4,187)	71.4 (70.6,71.9)
Acuity 300+600	4.07 (3.13,6.18)	31 (31,31)	2 (2,2)	211.3 (207.5,217)	74 (73.6,74.4)
Broader 2-Circle MELD 35	6.74 (5.85,8.83)	29 (29,29)	1.8 (1.7,1.8)	107.7 (106.1,110.2)	58.4 (58,59.1)
Broader 2-Circle MELD 32	6.54 (5.37,8)	29.5 (29,30)	1.8 (1.8,1.8)	117.1 (115.8,118.6)	60.8 (60.3,61.5)

All metrics reported as *mean (min, max)* across the 10 simulation iterations.

SRTR

NEW LIVER ALLOCATION SYSTEM

Scenario	Transplant Rate	Transplant Count	Waitlist Mortality Rate	Waitlist Mortality Count	Post-Transplant Mortality Rate	Post-Transplant Mortality Count
Current	0.443 (0.435,0.451)	6651 (6575,6727)	0.097 (0.095,0.1)	1455 (1425,1504)	0.077 (0.075,0.08)	686 (666,721)
Board Approved	0.438 (0.43,0.448)	6643 (6561,6728)	0.091 (0.09,0.093)	1386 (1358,1419)	0.077 (0.075,0.079)	684 (662,712)
Acuity 250+500	0.428 (0.422,0.436)	6594 (6491,6672)	0.087 (0.085,0.088)	1341 (1310,1364)	0.078 (0.076,0.08)	687 (664,718)
Acuity 300+600	0.426 (0.419,0.434)	6583 (6492,6662)	0.085 (0.083,0.086)	1318 (1278,1346)	0.079 (0.078,0.08)	688 (676,719)
Broader 2-Circle MELD 35	0.438 (0.432,0.448)	6620 (6543,6706)	0.095 (0.093,0.096)	1433 (1404,1463)	0.077 (0.073,0.08)	676 (647,717)
Broader 2-Circle MELD 32	0.437 (0.43,0.446)	6616 (6556,6692)	0.094 (0.092,0.095)	1423 (1391,1442)	0.077 (0.076,0.08)	682 (661,721)

All metrics reported as *mean (min, max)* across the 10 simulation iterations.

SRTR

QUESTIONS

Thank you!