

Liver and Intestinal Transplantation Committee Report

*OPTN/UNOS Board of Directors Meeting
David Mulligan, Chair
June 23-24, 2014*

1. National Review Board
2. Share 15/35 /
National LI-IN Share Analysis
3. Redesigning Liver Distribution

National Review Board (NRB) for MELD/PELD Exceptions

OPTN

2004 NRB Proposal

- Regions 2, 3, 4, 6, 8, 9, 11 opposed, 1, 5, 7 in favor
- Pediatric, Patient Affairs, and TAC opposed
 - “Current RRB system works very well”
 - National process would lengthen review time
 - Premature
 - Would take away ability to work out discrepancies locally
 - Need more standardized guidelines

RESOLVED, that the Liver Committee recommends that the National Review Board should be **DEFERRED** for a period of 12 months, until the standardized guidelines can be refined.

19 in favor, 0 opposed, 1 abstention

2012 Board Resolution

In November 2013, the Board approved the following resolution by a vote of 34 in favor, 1 opposed, and 0 abstentions:

RESOLVED, that the Liver and Intestinal Organ Transplantation Committee is directed to develop a plan to include a conceptual basis and a proposed timeline for implementation of a National Liver Review Board to be presented to the Board of Directors in June 2014.

2014 Construct (Based on 2004 Model)

1. National Review Board Composition:

a. Board members:

- i. One board will be elected for both pediatrics and adults.
- ii. Board members will be active transplant surgeons or physicians, preferably with >3 years experience.
- iii. Each region will select 10 representatives.
- iv. Appointed members will indicate whether their practice includes children and/or adults.
- v. Board members may not designate alternates.
- vi. Board members will sign an agreement of understanding regarding the expectations of board members.
- vii. Terms: 2-3 years, 2 term limit, 20-30% turnover per year

2014 Construct

b. Voting

- i. Cases submitted for review will be assigned randomly to 7 members of the board.
- ii. The case will be closed when 4 members have voted to either support or reject the exception request.
- iii. If a board member requests to abstain from voting, the case will be automatically reassigned to another board member.
- iv. Cases cannot be assigned to board members from the requesting center.

c. Pediatric cases

- i. Pediatric cases will be assigned such that the board will consist of practitioners who care for children (+/- adults).

2014 Construct

2. Assignment of priority:

- a. Review board members are provided with the mean and median MELD and PELD scores, at transplantation in the recipient's blood type for the OPO and where the recipient is listed and the standard deviation for these values. These cumulative values are to be updated monthly based upon the last year of data. Review board members then consider the requested MELD/PELD score in light of the relevance of a particular MELD/PELD score in the area of organs where they are listed.
 - b. All priority requests include information on previous requests for priority submitted by the center on this patient.
3. Standard guidelines for approving exception cases will be developed to be used by the NRB. These guidelines will be reviewed and approved by the Liver and Intestinal Committee as they are produced.

2014 Construct

4. Appeals:

- a. If the request for exception is denied by the NRB, the center has 4 choices:
 - i. Take no further action; the patient remains listed at the calculated MELD/PELD score
 - ii. Submit an appeal with new information or arguments for elevated priority
 - iii. Request a conference call with the NRB panel, if 4.a.ii results in denial
 - iv. Direct UNETSM to list the patient at the requested MELD/PELD score. All patients transplanted under protest of the NRB will be referred to the Liver and Intestinal Committee for review and possible action.

NRB

PROS	CONS
Could reduce regional variation	Difficult to implement because of regional variation
Random, objective reviewers	Invested reviewers
Could apply methods of efficient RRBs to other RRBs	Many RRBs work efficiently and well
Potentially faster turnaround	Potentially longer turnaround
More flexible manpower	Could require more volunteers
Regional agreements lead to inconsistent results	Regional agreements allow new methods
More consistent data collection and review	

NRB Manpower Estimate

- 7200
- 1200 (if MELD-Na passes)
- 6000
- 1000 (if specific criteria accepted for NET/PCLD/PSC (programming \$\$))
- 5000
- 860 (for all others with * (programming \$\$))

4140 cases/yr

4140/365 = 11.3 cases per day, every day

4140/260 = 16 cases per day, weekday

16 x 7 = 112 NRB members needed per day

110 members

1-3 reviews every weekday for 2-3 years

	Initial, Appeal, or Extension						Total N
	Appeal		Extension		Initial		
	N	%	N	%	N	%	
Exc. Case Dx							
Familial Amyloidosis	4	5.1	53	67.1	22	27.8	79*
HCC (not meeting criteria)	23	0.9	1400	53.7	1185	45.4	2608
Hepatopulmonary Syndrome	16	3.3	223	45.7	249	51.0	488*
Portopulmonary Hypertension	9	5.4	78	46.4	81	48.2	168*
Primary Oxaluria	3	7.0	17	39.5	23	53.5	43*
Other specify*	246	6.8	1299	35.7	2098	57.6	3643
Hepatic Artery Thrombosis (HAT)	4	5.1	12	15.2	63	79.7	79**
Metabolic Disease	2	2.0	31	31.3	66	66.7	99*
Non-metastatic hepatoblastoma	0	0	0	0	5	100.0	5*
Total	307	4.3	3113	43.2	3792	52.6	7212

NRB

Expressed Concerns

- Standardized MELD exceptions **MUST** be in place prior to NRB creation
- Consider delay until redistricting to minimize regional variations in MELD exception points
- Programming costs
- Workload for NRB members
 - Delay in response times
- UNOS Committee and Public Response

Committee Response

The Committee approved the following motion by a vote of 22 in favor, 0 opposed, and 0 abstentions:

Motion: The Committee will present the NRB construct to the Board in June 2014, noting that the Committee has significant concerns about the timing and logistics of implementation.

Next Steps

- Committee requests feedback from the Board
- Earliest Public Comment, Fall 2014
 - Wait and pair with Redesigning Liver Distribution?

Share 15/35 / National LI-IN Share Analysis

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

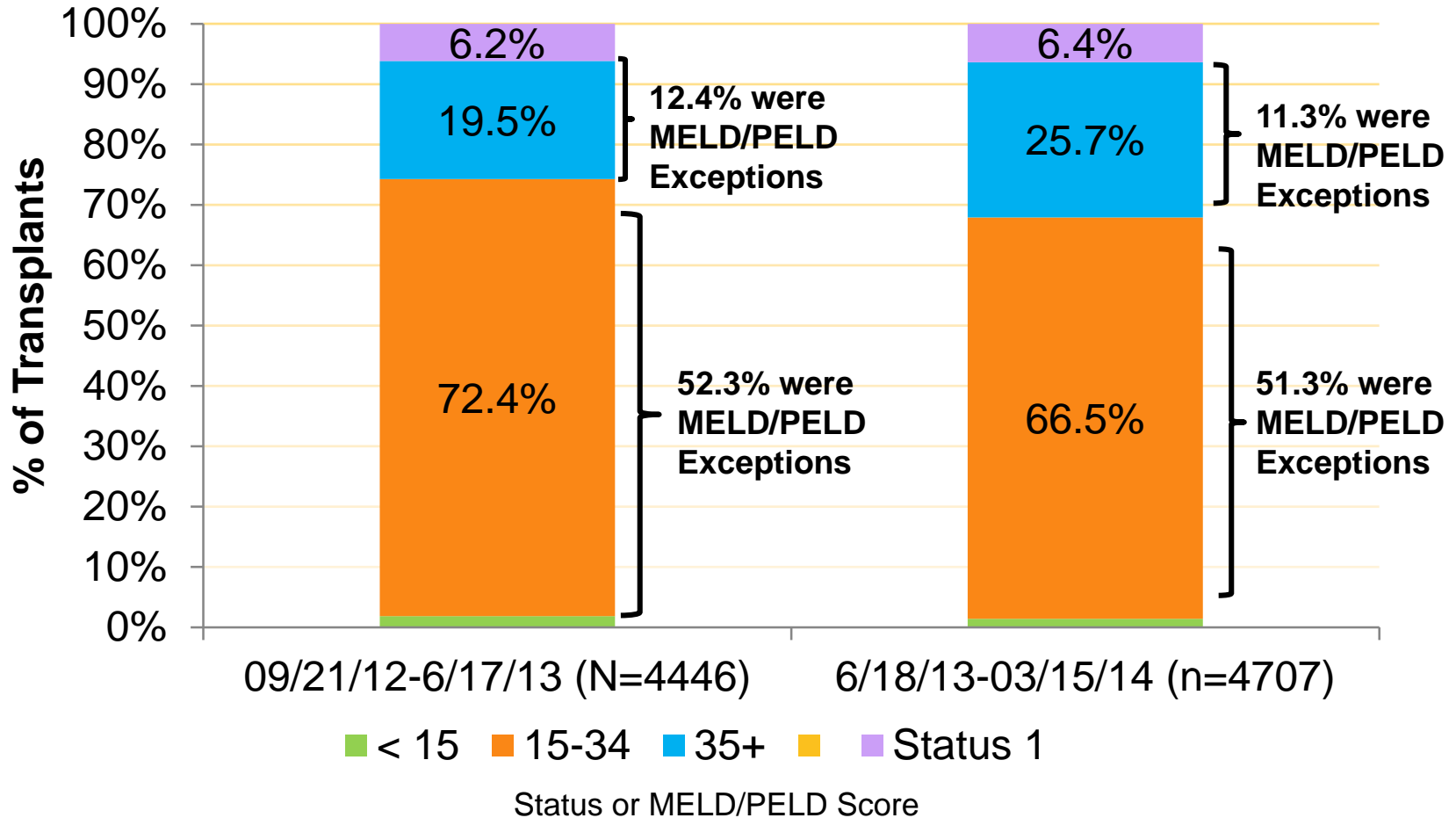
Share 15/35/LI-IN Algorithm

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 score 29-34
5. National Liver-Intestine candidates
6. Local candidates with MELD/PELD score 15-28
7. Regional candidates with MELD/PELD score 15-28
8. National Status 1A candidates
9. National Status 1B candidates
10. National candidates with MELD/PELD score ≥ 15
11. Local candidates with MELD/PELD < 15
12. Regional candidates with MELD/PELD scores < 15

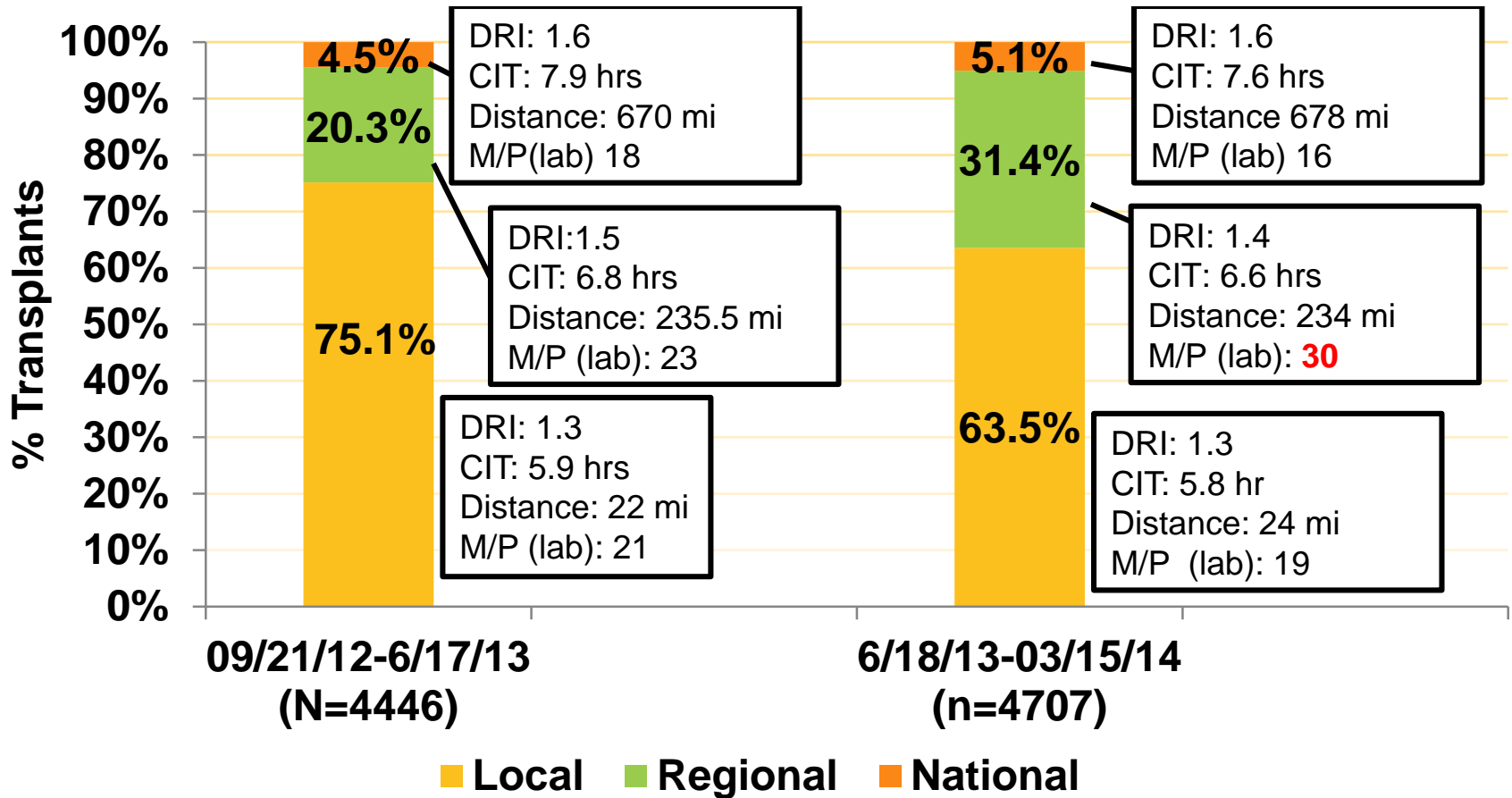
Data

- Data provided for 2 eras:
 - September 21, 2012 – June 17, 2013 (“Pre”)
 - June 18, 2013 – March 15, 2014 (“Post”)
 - Each Era 270 days
 - OPTN data as of June 6, 2014
- Types of data
 - National and some regional data focused on:
 - Transplants by MELD/PELD, age, CIT, distance
 - Waiting List Snapshot Data
 - DSA imports/exports
 - *Still a little too early for reporting of post-transplant outcomes (6-months outcomes of first 3 months)*

Deceased Donor Liver Transplants by Era and Status/Allocation Score

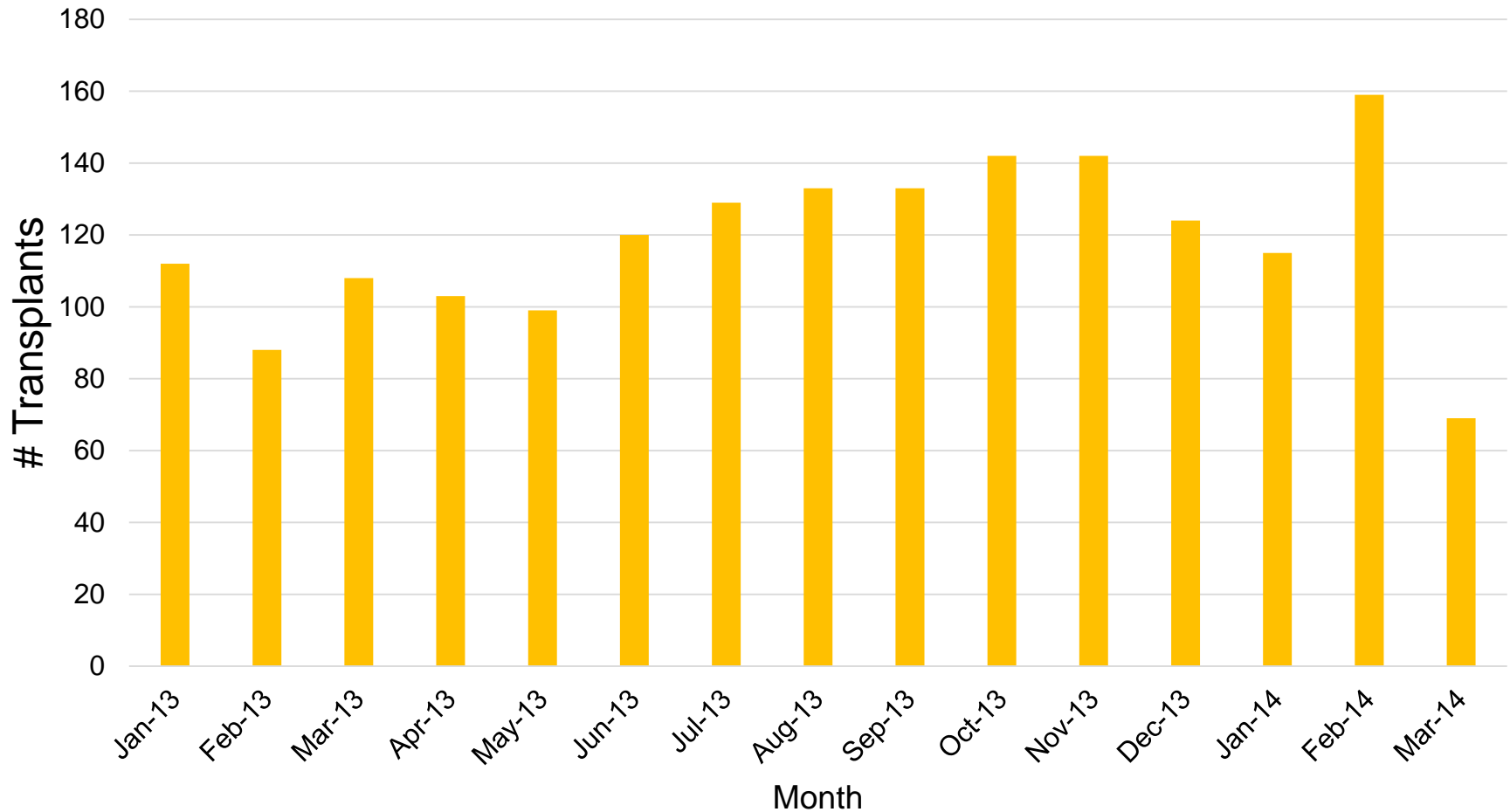


Deceased Donor Liver Transplants by Era and Share Type

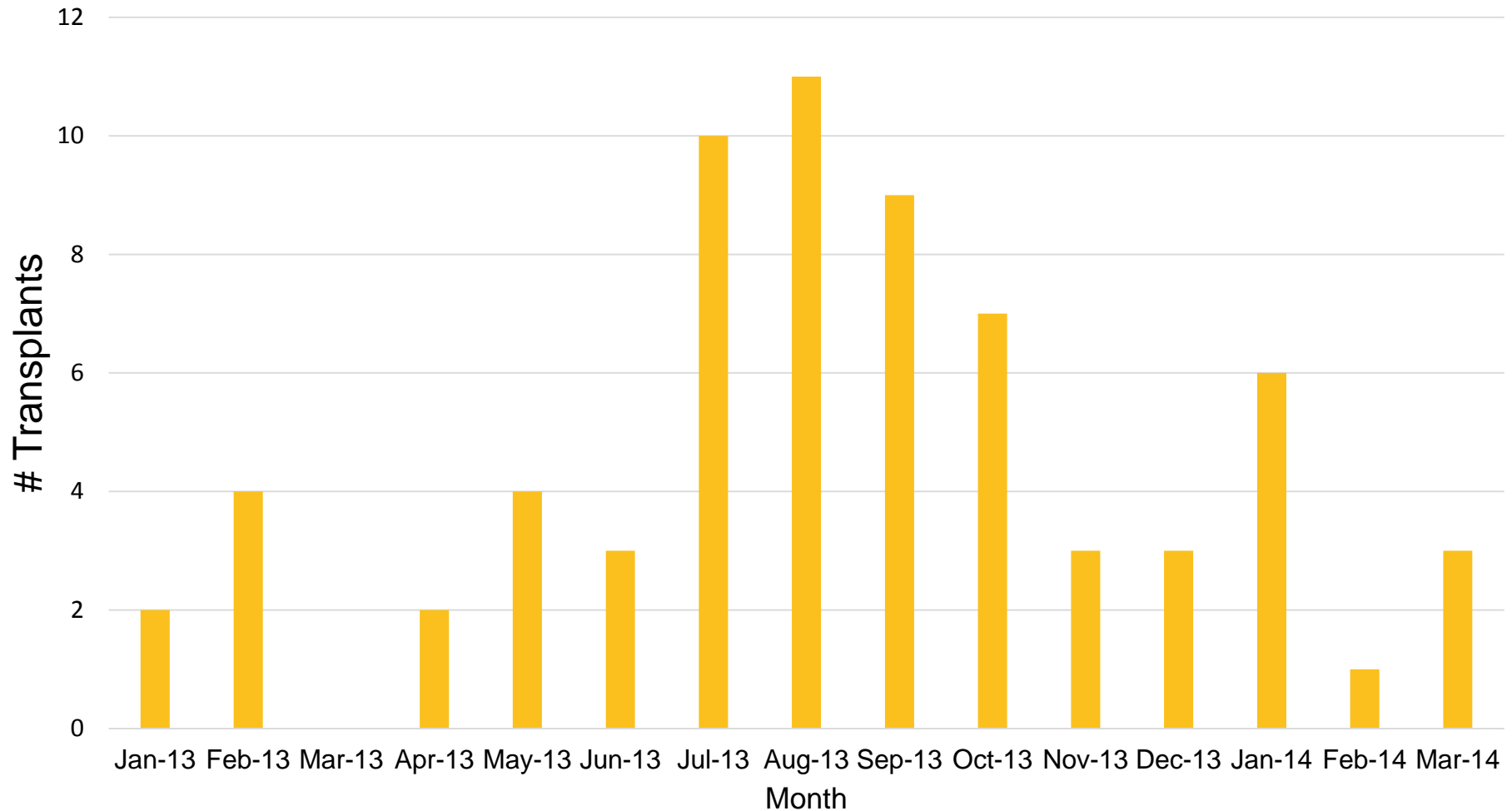


Median Values Shown

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



Deceased Donor Liver-Intestine Transplants, by Month



Multi-Organ Transplants

- Liver-Intestine: 23 in Pre-Era, 56 in Post-Era
 - 15 National Shares in Era 1, 39 in Era 2
- Liver-Kidney: 378 (8.5%) in Pre, 387 (8.2%) in Post
 - 32 Regional Shares in Era 1, 116 in Era 2

Discards

- Livers Recovered for Transplant but Not Transplanted:
 - 506 in Pre-Era (10.5 % of recovered)
 - 475 in Post-Era (9.4% of recovered)
- Livers Not Recovered:
 - 819 in Pre-Era (13.7% of all donors)
 - 811 in Post-Era (13.0 % of all donors)

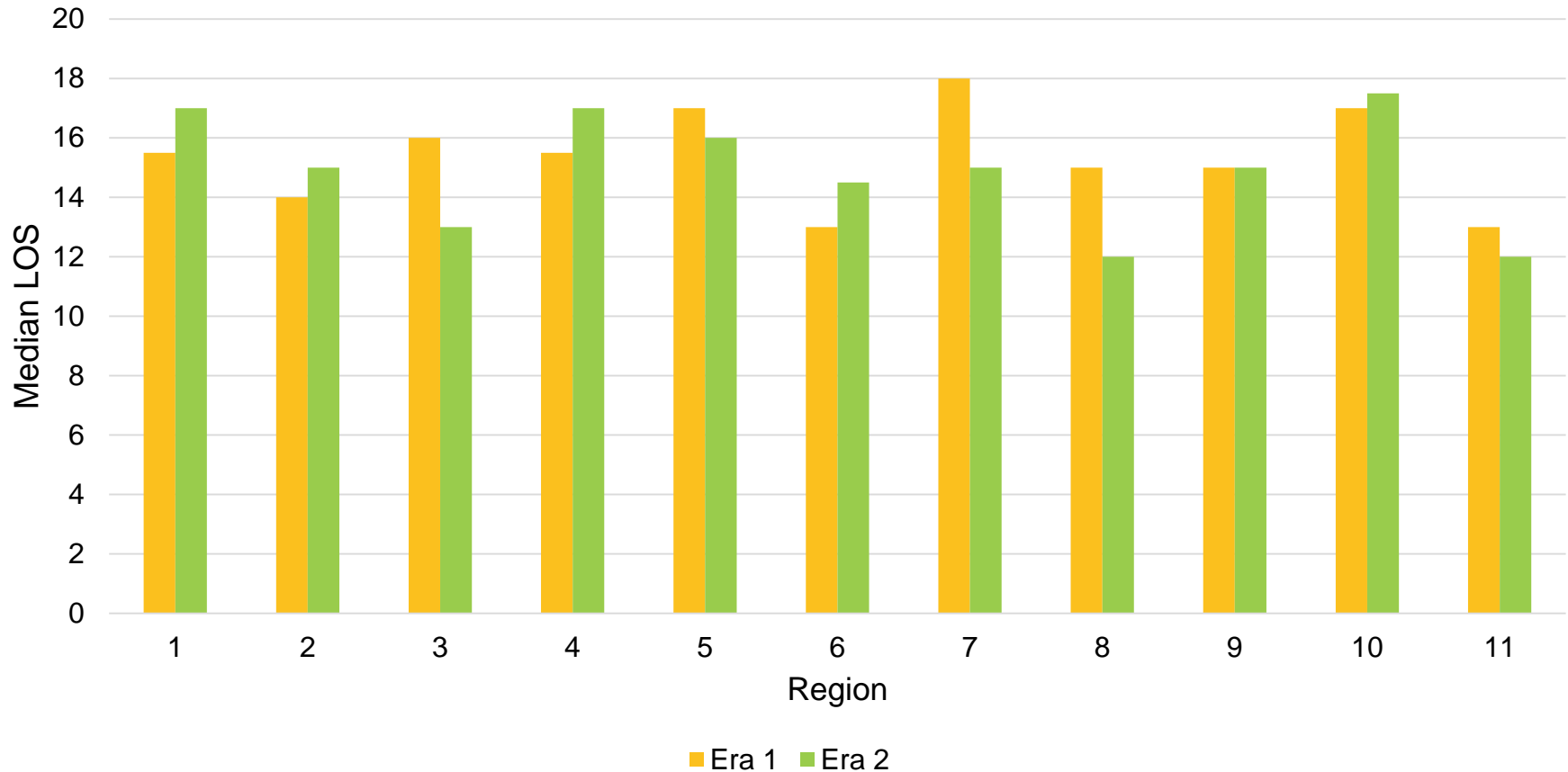
Discards by Region

Region	Era 1	Era 2	Difference
1	13	18	+5
2	137	119	-18
3	47	40	-7
4	28	49	+21
5	83	70	-13
6	30	18	-12
7	30	26	-4
8	34	34	0
9	14	10	-4
10	32	42	+10
11	58	49	-9
Total	506	475	-31

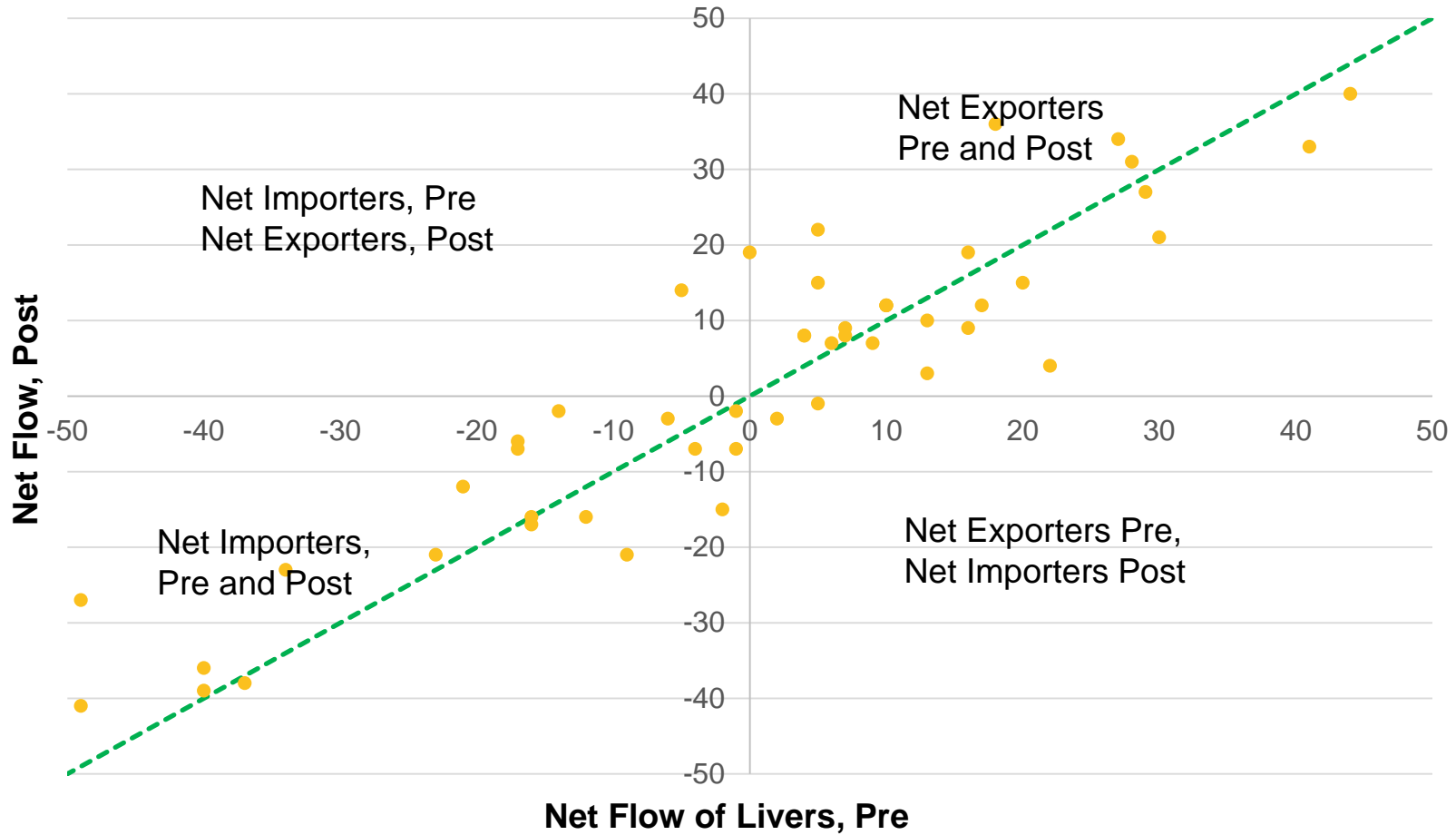
Deceased Donor Transplants by Region

Region	Era 1	Era 2	Difference
1	166	168	2
2	510	570	60
3	801	855	54
4	390	442	52
5	675	705	30
6	120	131	11
7	375	360	-15
8	354	363	9
9	211	227	16
10	368	399	31
11	476	487	11
Total	4446	4707	261

Median LOS Post-Transplant, by Era and Region, MELD/PELD Scores 35+



Net Flow of Livers, Pre vs Post by DSA



Questions?

Redesigning Liver Distribution

OPTN

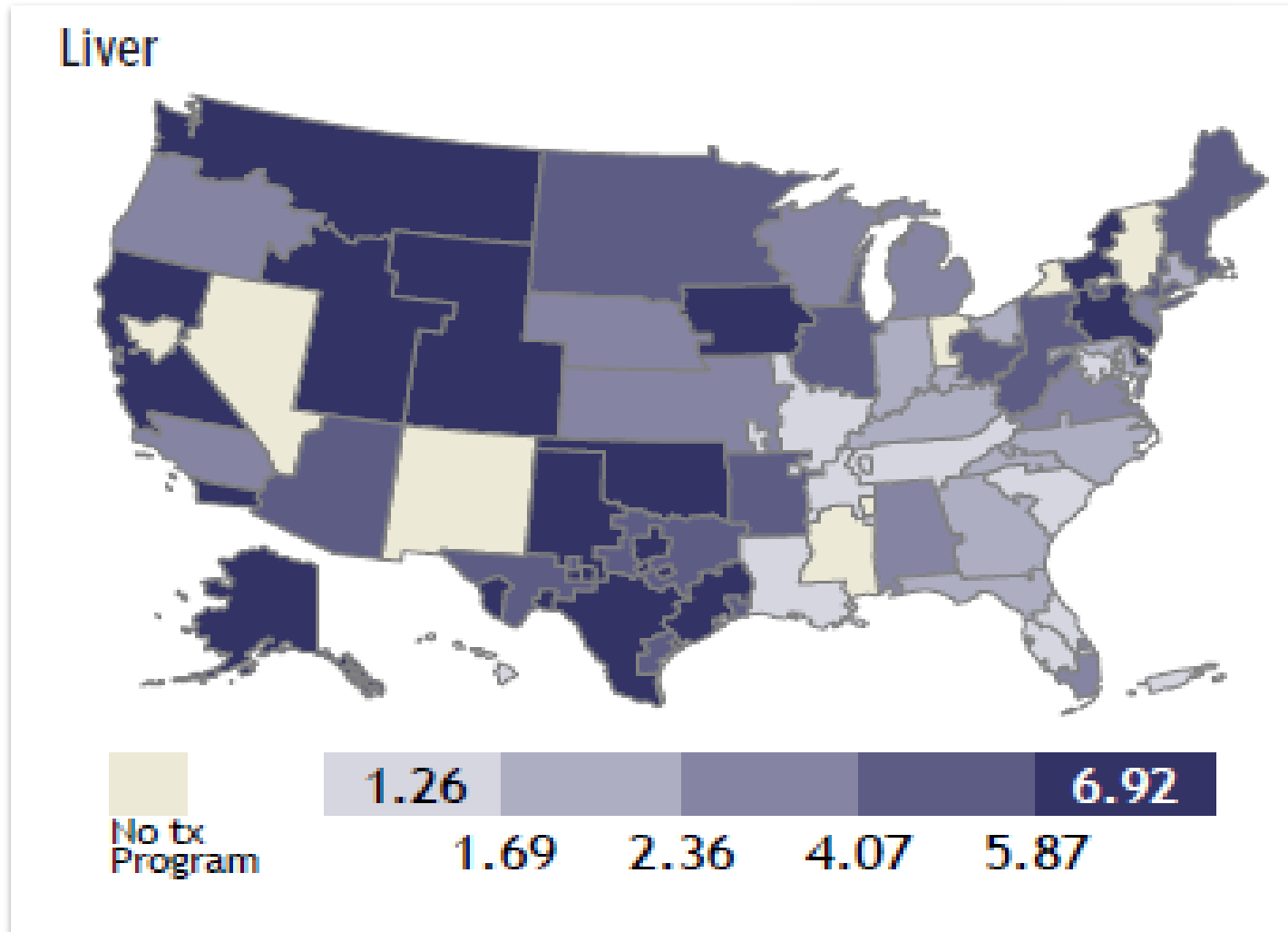
The Current System

- Based on the model for end-stage liver disease (MELD) and pediatric end-stage liver disease (PELD) scores since 2002.
- Prioritizes candidates based on the risk of death while awaiting liver transplantation.

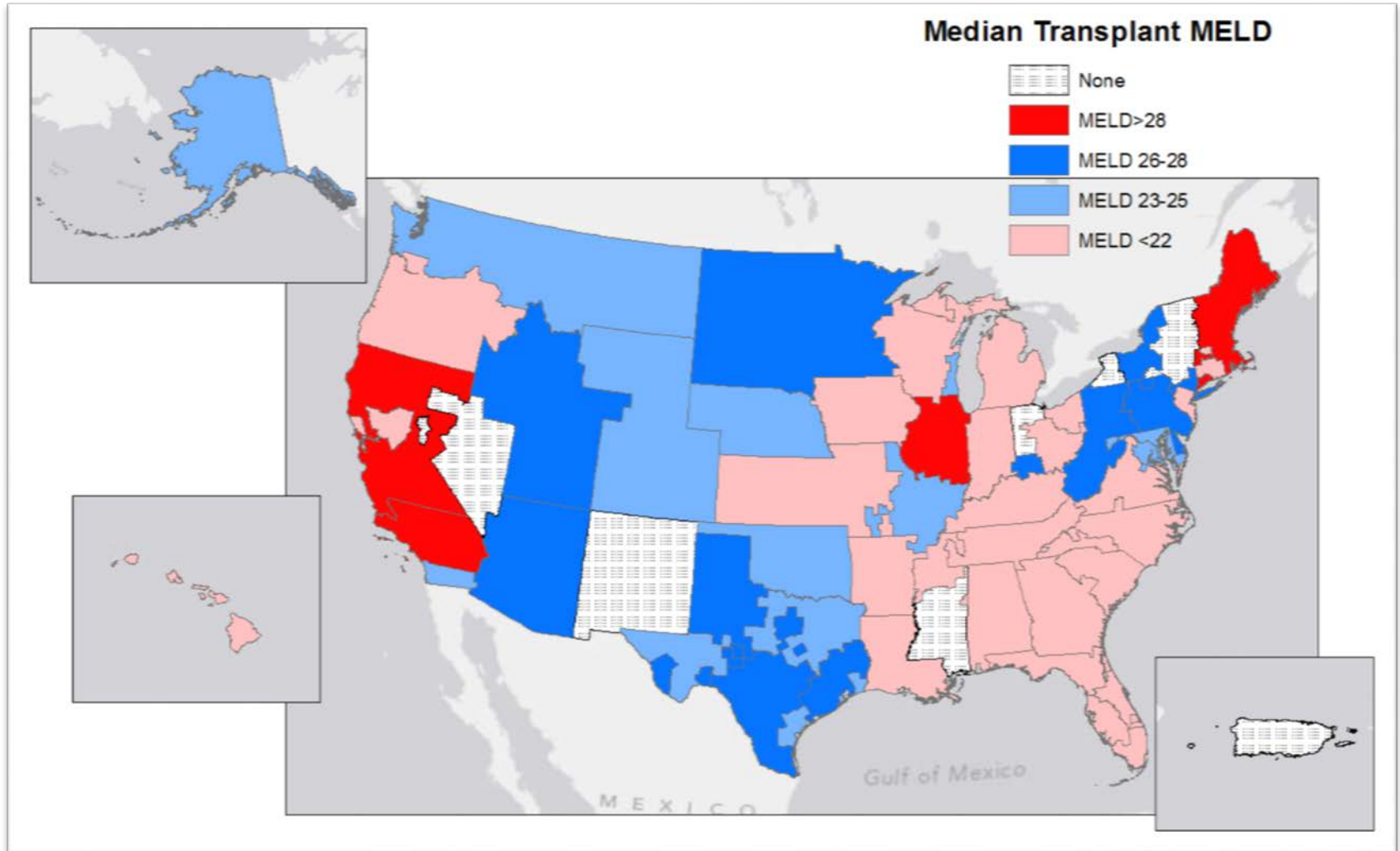
Challenges Liver Candidates Face

- Despite improvements in liver allocation and distribution, waitlist mortality remains high for patients with higher MELD scores
- Significant disparity exists between OPOs and regions with regard to mean MELD at transplant and waitlist mortality
- **How can we direct livers to those most in need?**

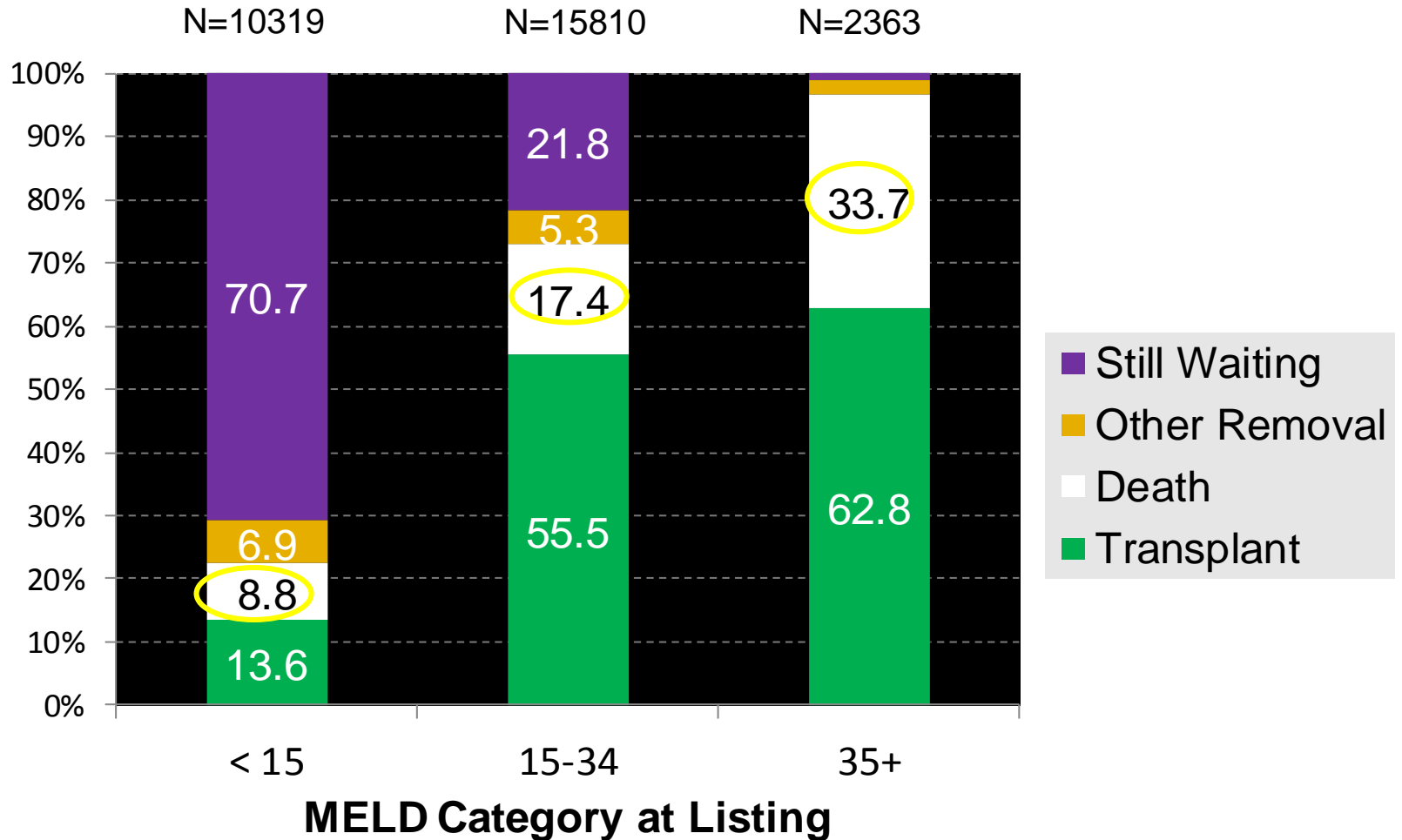
Variation in liver transplant wait time by DSA (months from listing)



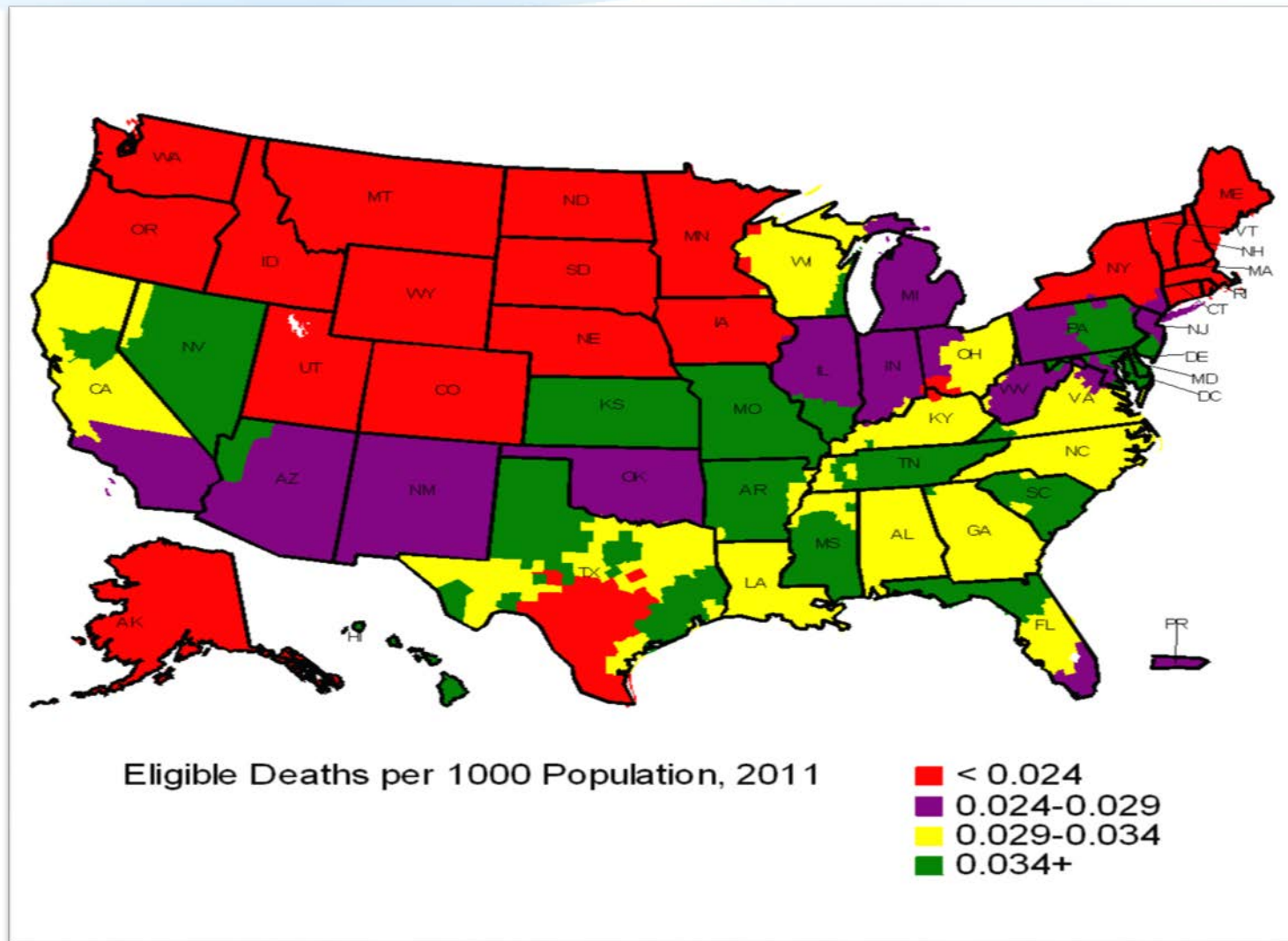
Existing Geographic Disparities



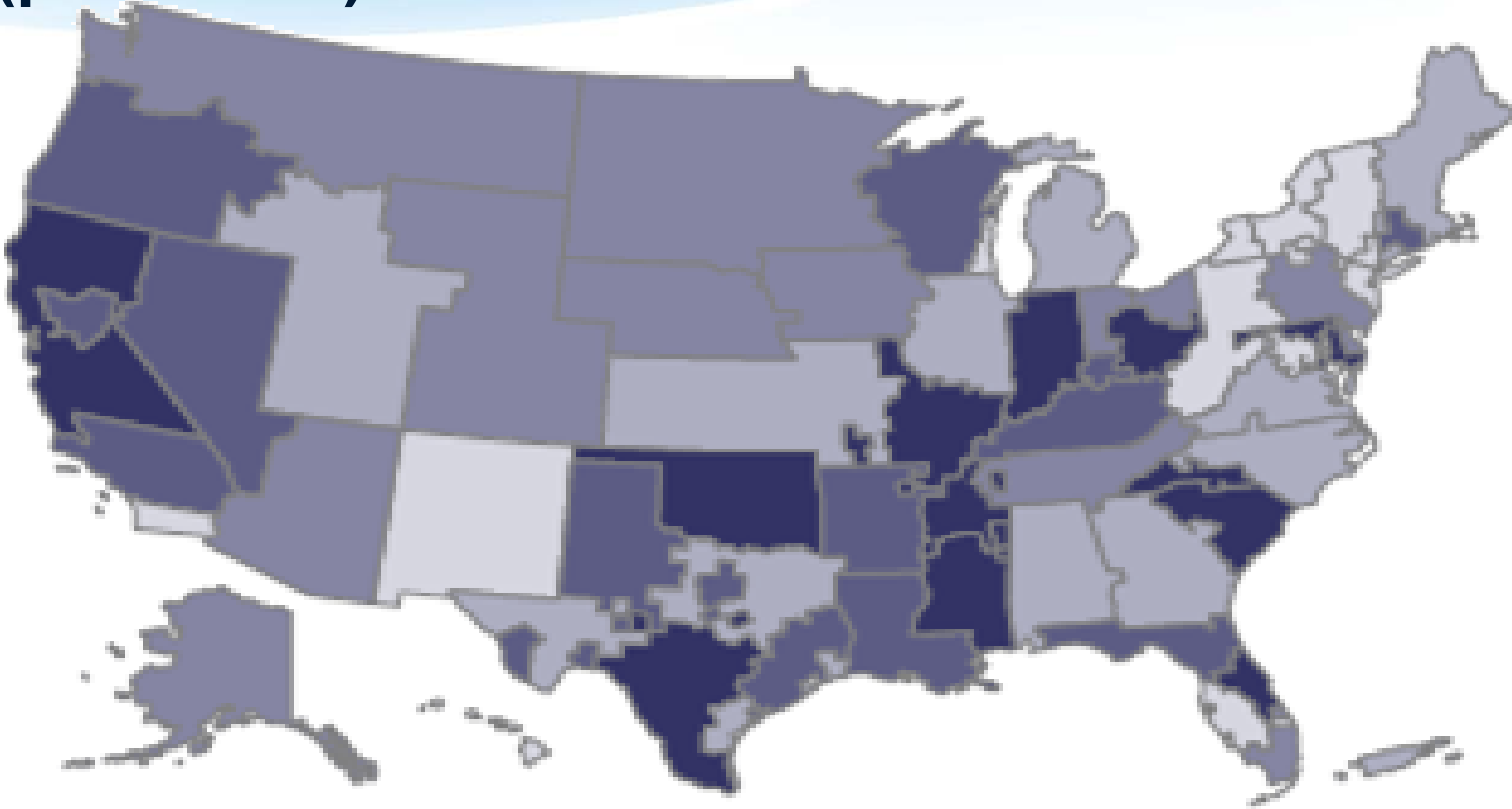
Liver Waiting List Outcome Probabilities at 1 Year: Candidates Added 2007-2010



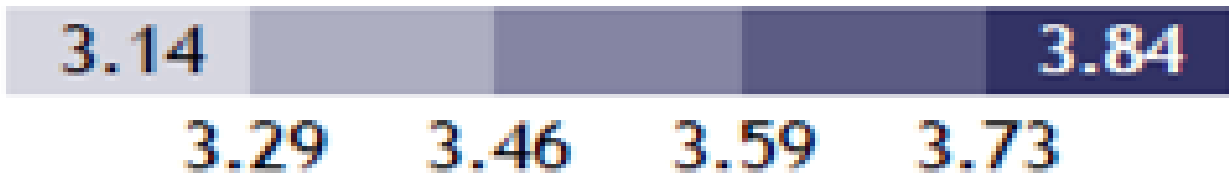
Variation in Death Rates by DSA, 2011



Variation in number of organs recovered by DSA (per donor)



SRTR
Annual
Report 2012



November 2012 OPTN Board Resolution

- The existing geographic disparity in allocation of organs for transplant is unacceptably high
- The Board directs the organ-specific committees to define the measurement of fairness and any constraints for each organ system.
- The Board requests that optimized systems utilizing overlapping v. non-overlapping geographic boundaries be compared

Redistricting as a Potential Solution

Statistical modeling strongly suggests that using fewer geographical allocation districts would likely result in reduced waitlist deaths and a reduced variation in the MELD or PELD scores at transplant.

Redistricting as a Potential Solution

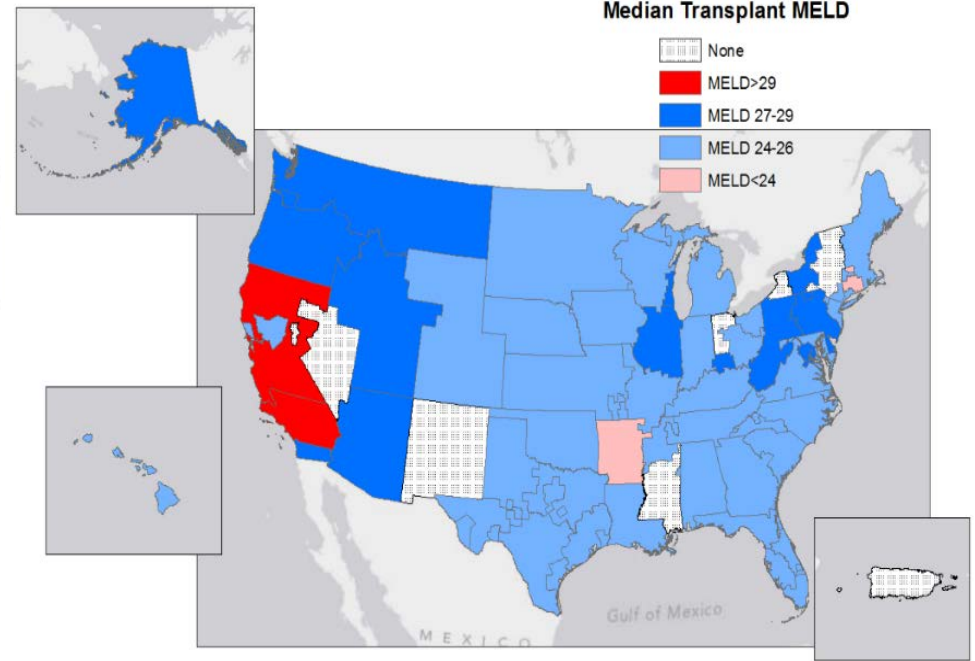
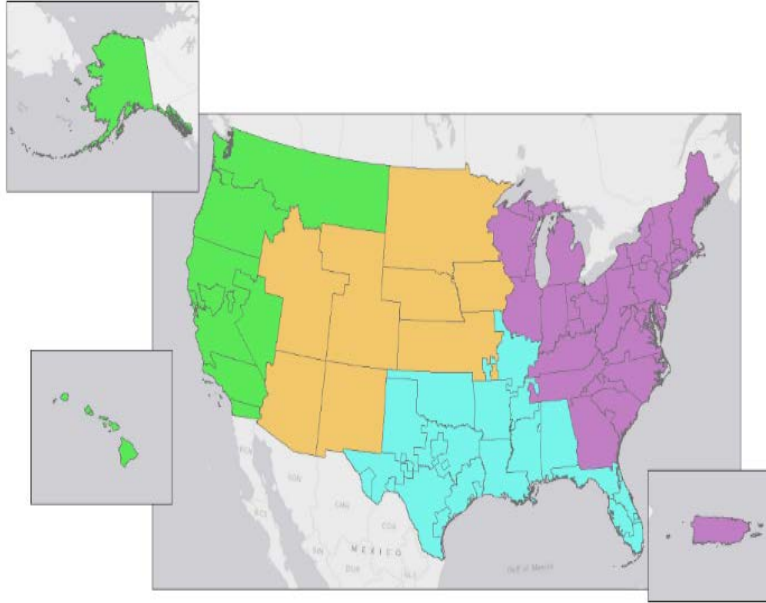
The Committee agreed upon the following parameters for these optimized maps:

- The number of districts should be at least 4 and no more than 8;
- The minimum number of transplant centers per district is 6;
- The maximum median travel time between DSAs placed in the same district is 3 hours; and
- The number of waitlist deaths under redistricting must not be statistically significantly higher than in the current system.
- The districts should be contiguous.

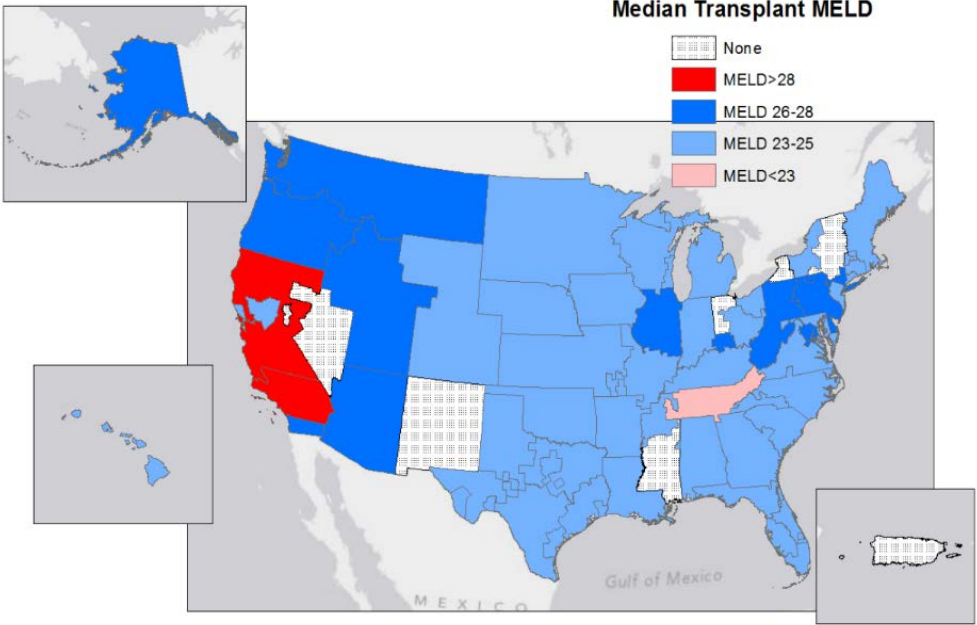
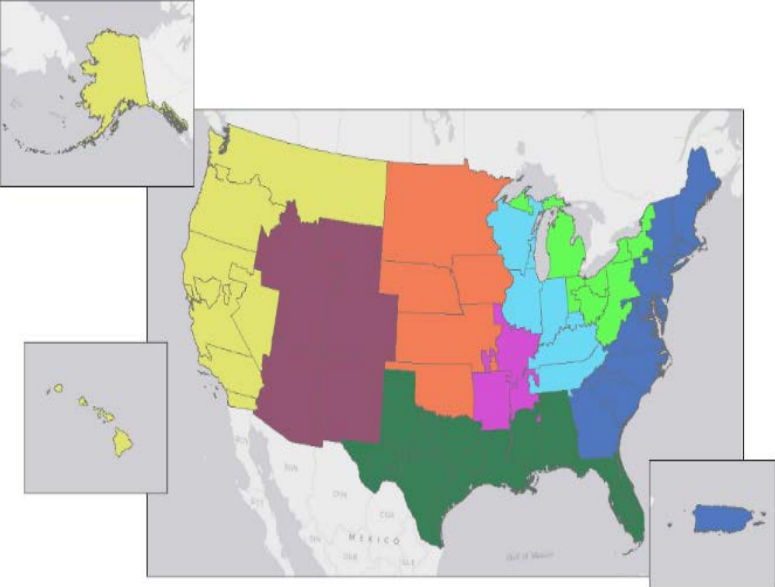
Optimized Redistribution Plan Based on Statistical Evidence

Districts	Standard deviation, MELD @ Transplant	% of Transplants with MELD scores <15	% of Transplants with MELD scores >25	% Pediatric	Net total deaths	Net waitlist deaths
4	1.87	2.5%	64.3%	8.7%	-553.8	-581.1
8	2.08	3.7%	59.6%	8.1%	-332.4	-342.1
Current System	3.01	5.8%	50.1%	7.5%	0	0
Regional	3.26	5.5%	54.3%	7.7%	-164.6	-122.4
National	1.66	1.9%	83.3%	10.4%	-343.6	-509.9

4 District Distribution Model & Reduction in Disparity



8 District Distribution Model & Reduction in Disparity



Our next steps

- Concept Document was released June 16, 2014
- Collect community responses today - July 11, 2014
- Public Forum in Chicago September 16th, 2014
- Earliest policy proposal could be circulated for Public Comment Spring 2015

Alternative concepts that emerge from the community will be considered by the Committee

The Committee requests any feedback from the Board on the Concept Document