Consider Options for Improved Zonal or Geographic Sharing

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RESOLVING THE ORGAN SHORTAGE

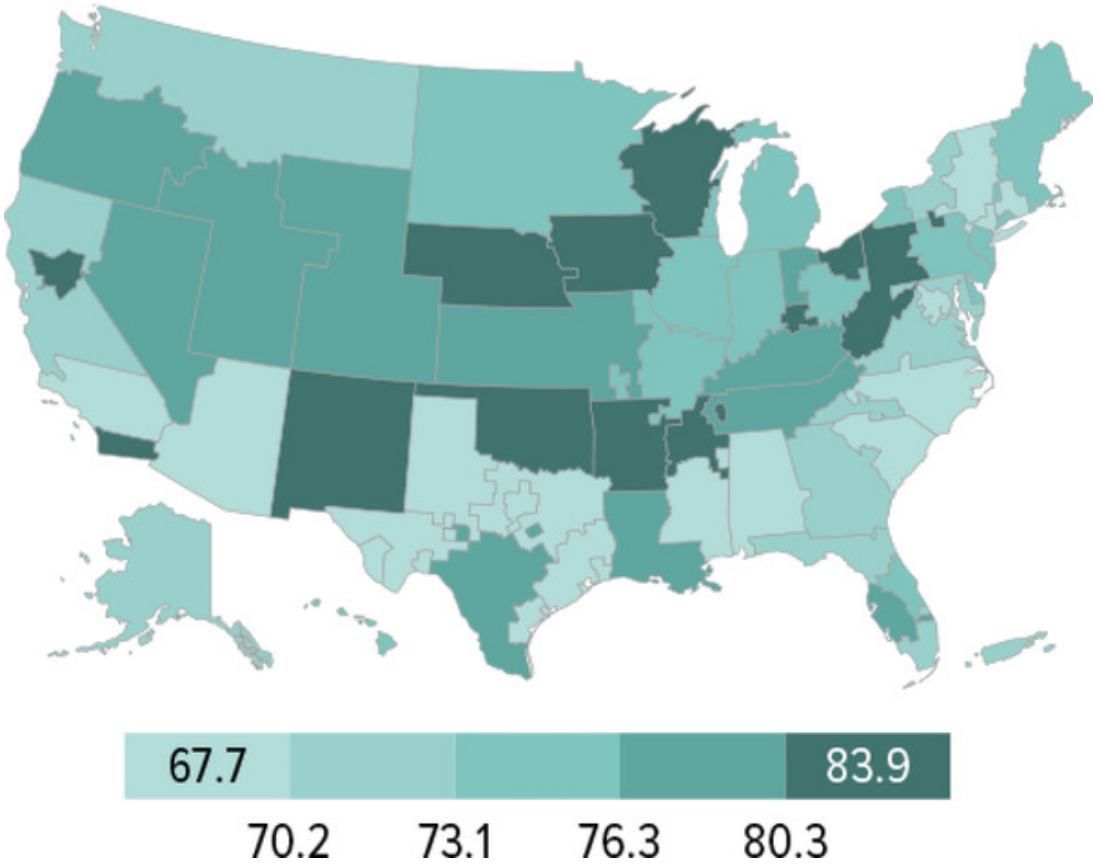
PRACTICE | POLICY | POLITICS

FEBRUARY 25-27, 2016 • PHOENIX, ARIZONA

Conflict of Interest Disclosure

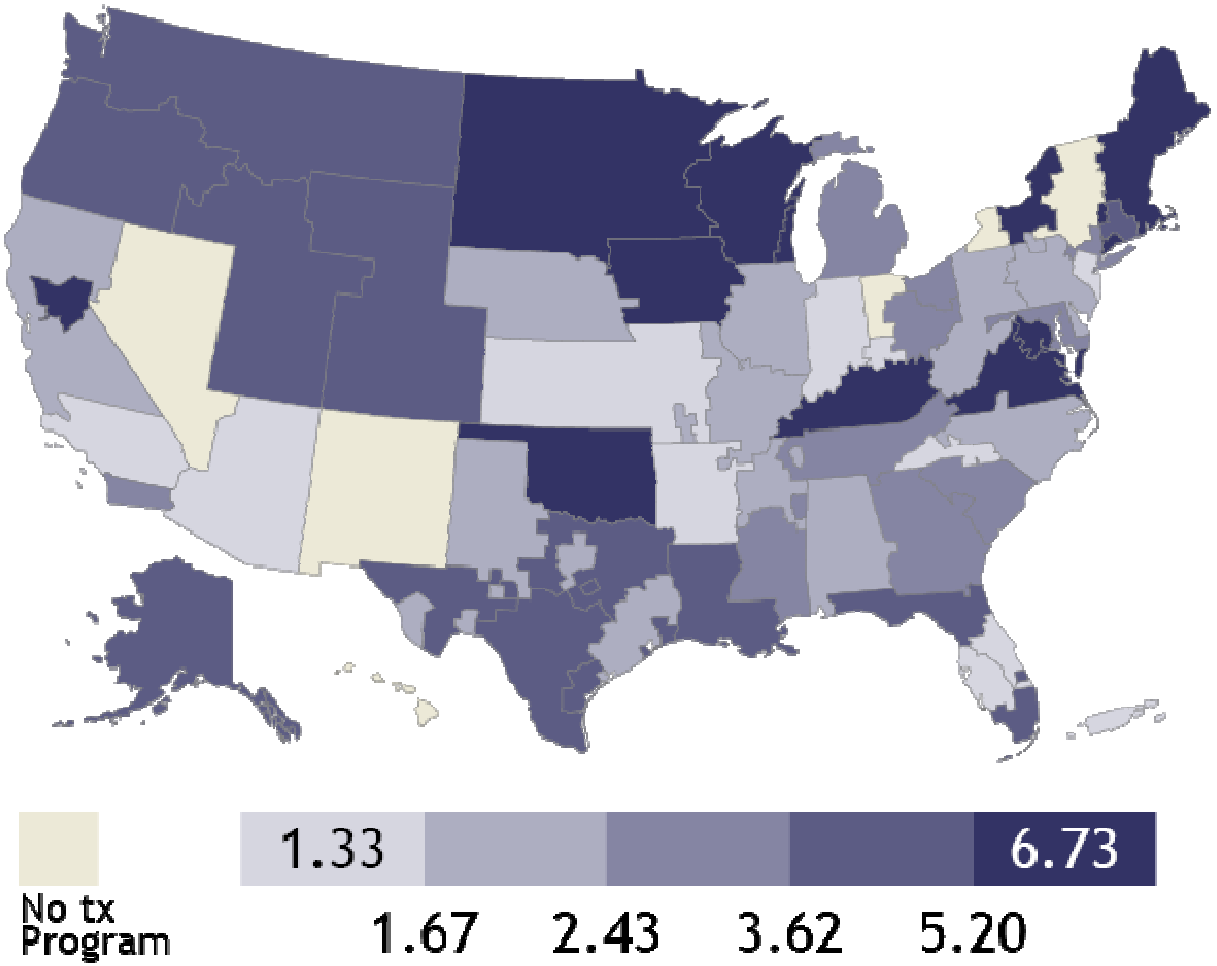
No relevant financial relationships to disclose

Deceased Organ Donation per 100 eligible deaths, by DSA, 2014



American Journal of Transplantation
pages 195-215, 11 JAN 2016 DOI: 10.1111/ajt.13673

DOD 7.1 Variation in waiting time (months) for patients receiving a deceased donor tx in 2012, by DSA: heart



Regional Differences in Percentage Cumulative Waiting Time After the 2006 UNOS Policy Changes in the Donor Heart Allocation Algorithm

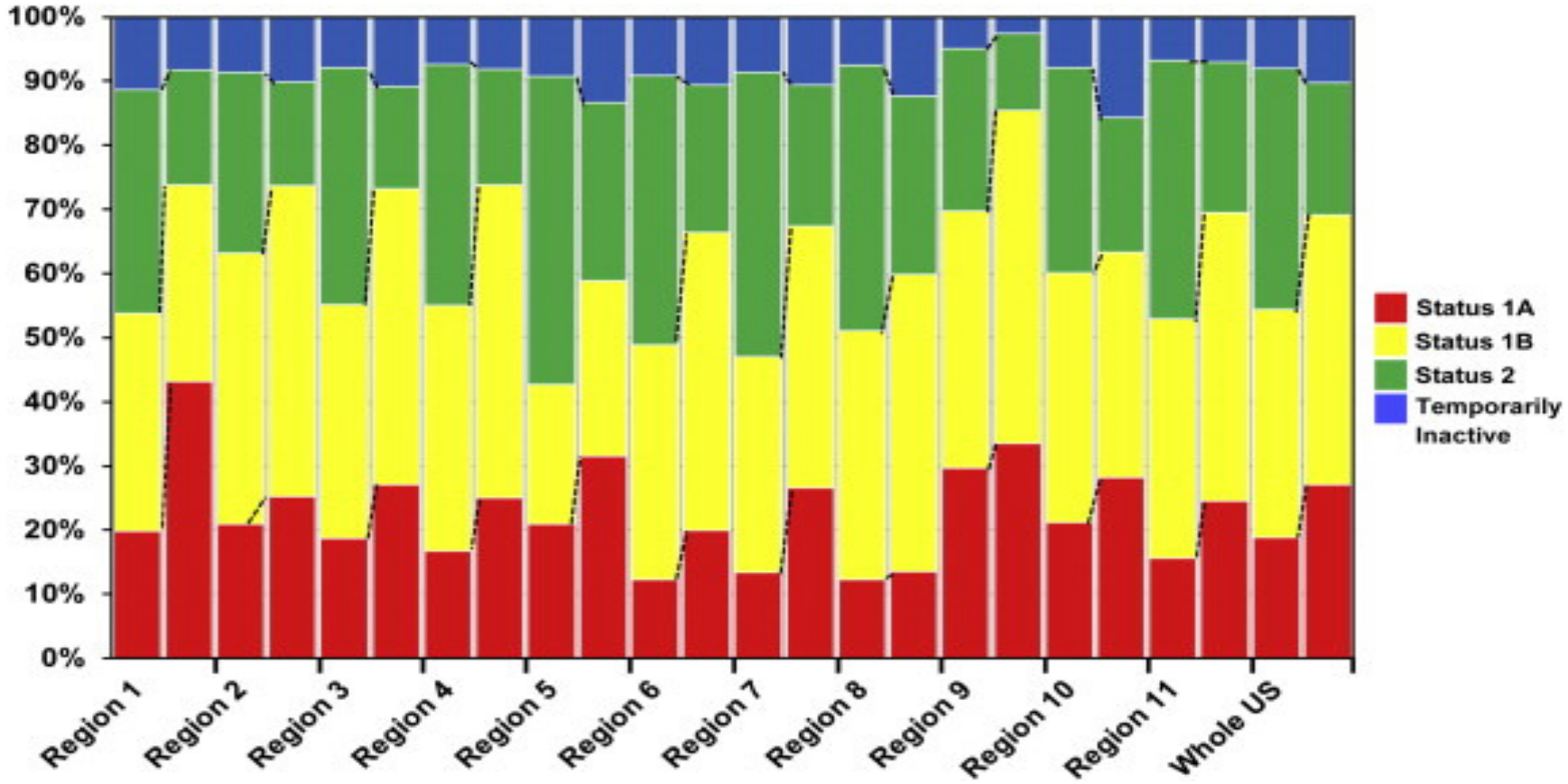
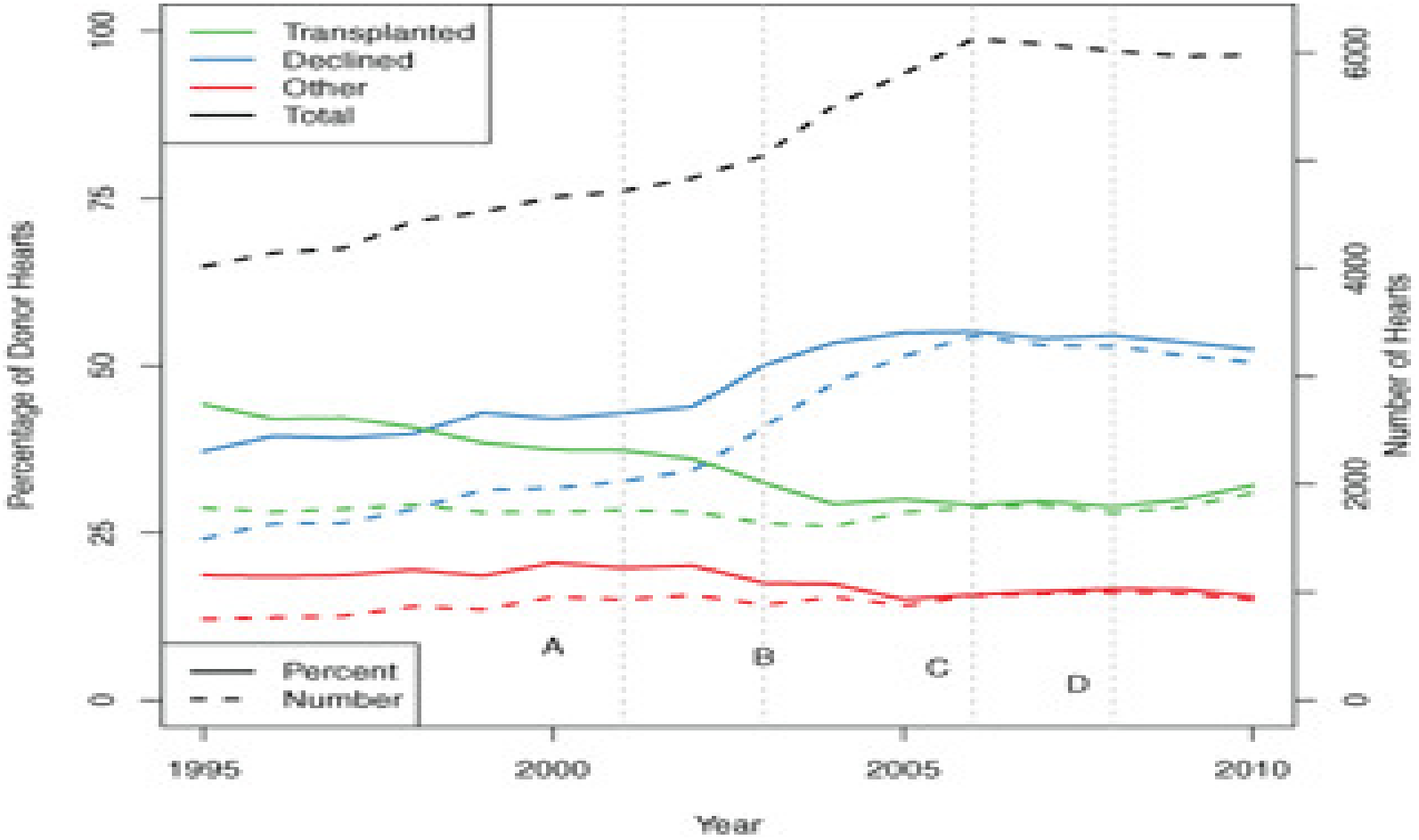


Figure 3. Percentage of Cumulative Waiting Time in Each UNOS Category The analysis revealed a uniform trend toward an increased time listed as United Network for Organ Sharing (UNOS) status 1A and 1B during the time waiting for heart transplantation. Total ...

P. Christian Schulze, Shuichi Kitada, Kevin Clerkin, Zhezhen Jin, Donna M. Mancini

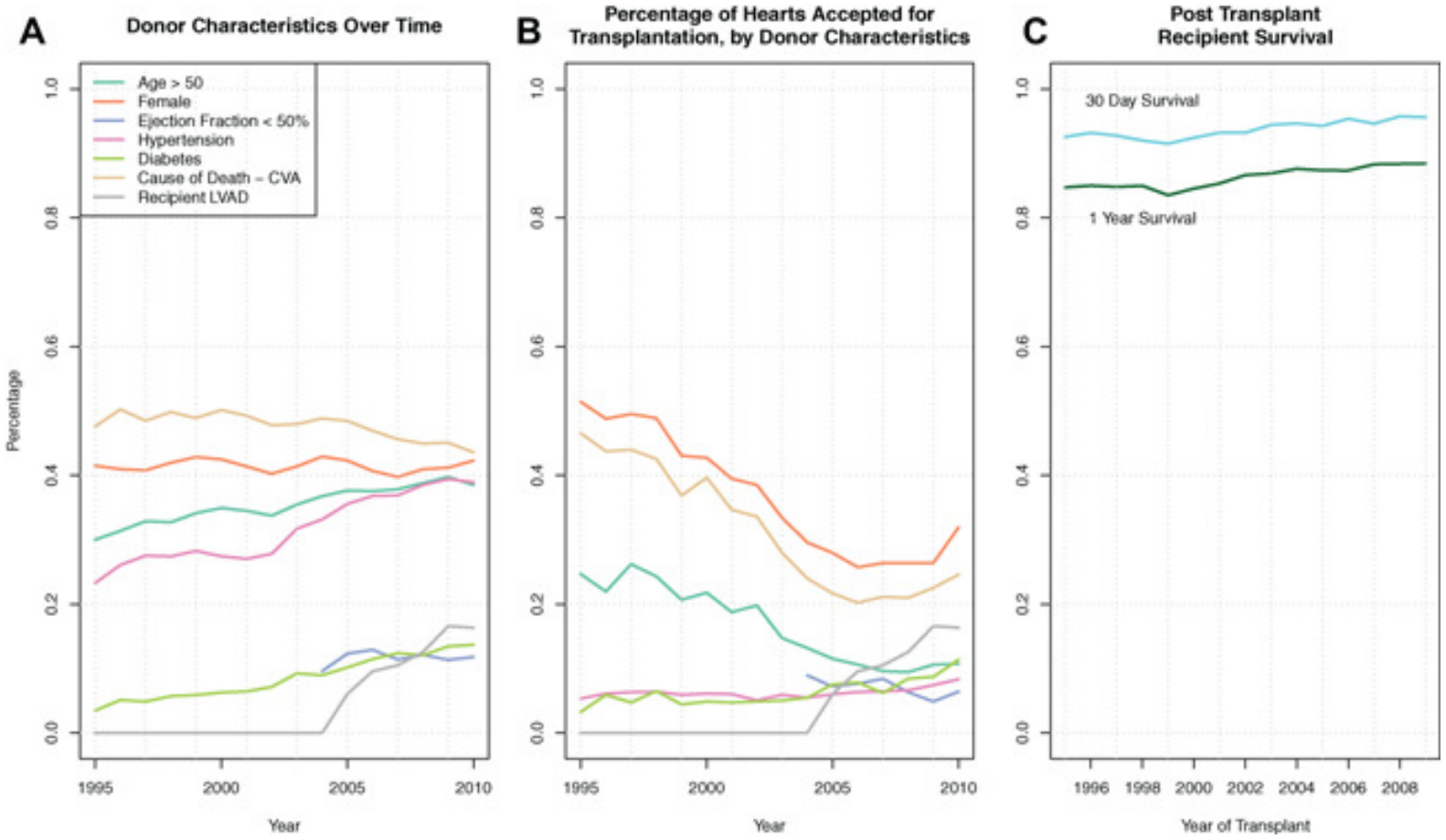
JACC: Heart Failure, Volume 2, Issue 2, 2014, 166–177

Proportion of Donor Hearts Accepted or Declined for Transplantation



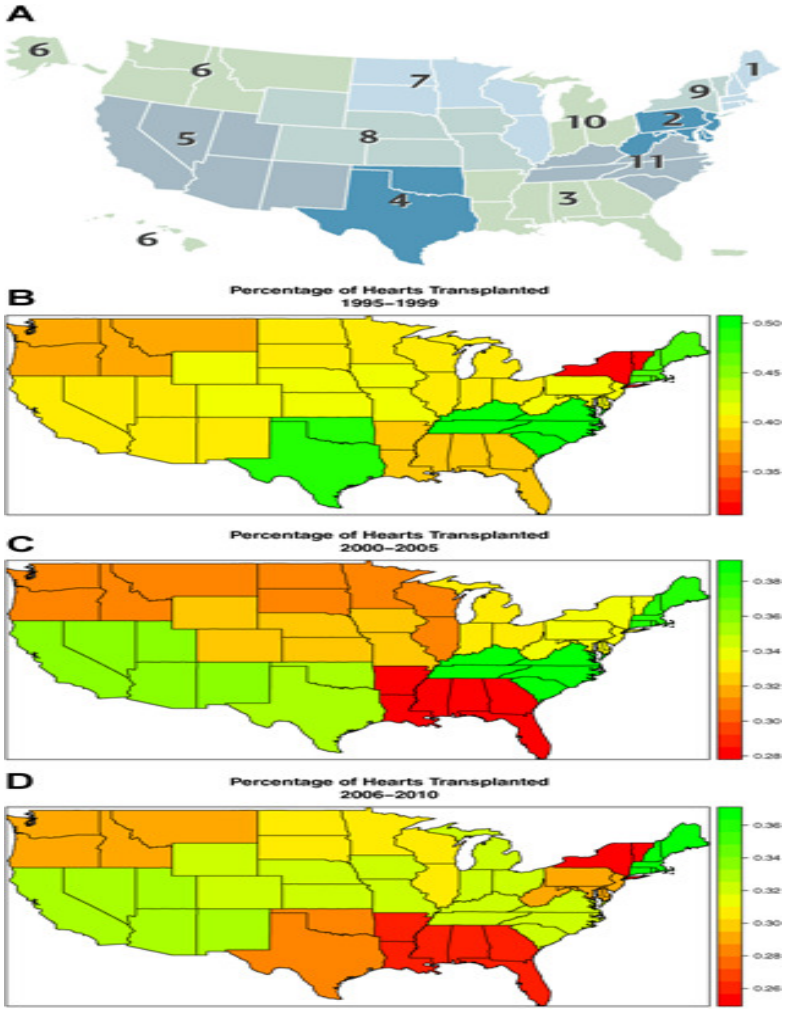
Khush, et al, American Journal of Transplantation
Volume 15, Issue 3, pages 642-649, 10 FEB 2015 DOI: 10.1111/ajt.13055

Change in the Prevalence of Donor Characteristics that Predict Heart Non-utilization



Khush, et al, American Journal of Transplantation
Volume 15, Issue 3, pages 642-649, 10 FEB 2015 DOI: 10.1111/ajt.13055

Percentage of Donor Hearts Accepted for Transplantation by UNOS Region



Khush et al, American Journal of Transplantation
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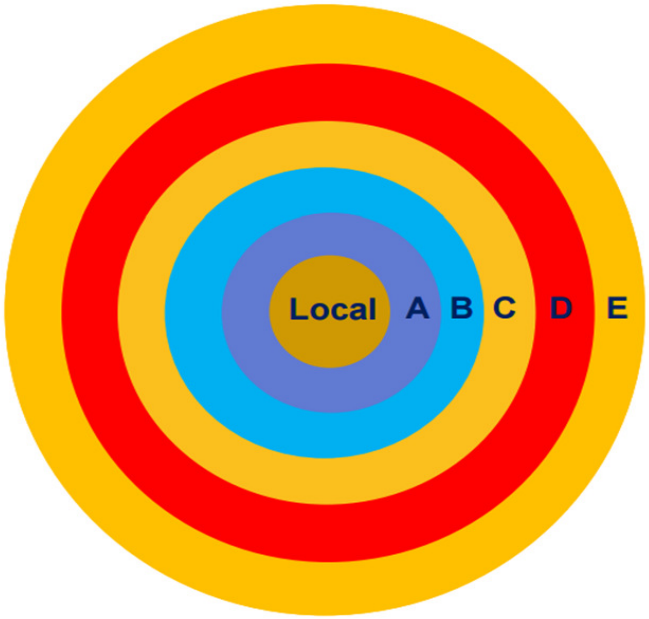
Regional Variability in Heart Donation, Waiting Time, and Utilization Rates

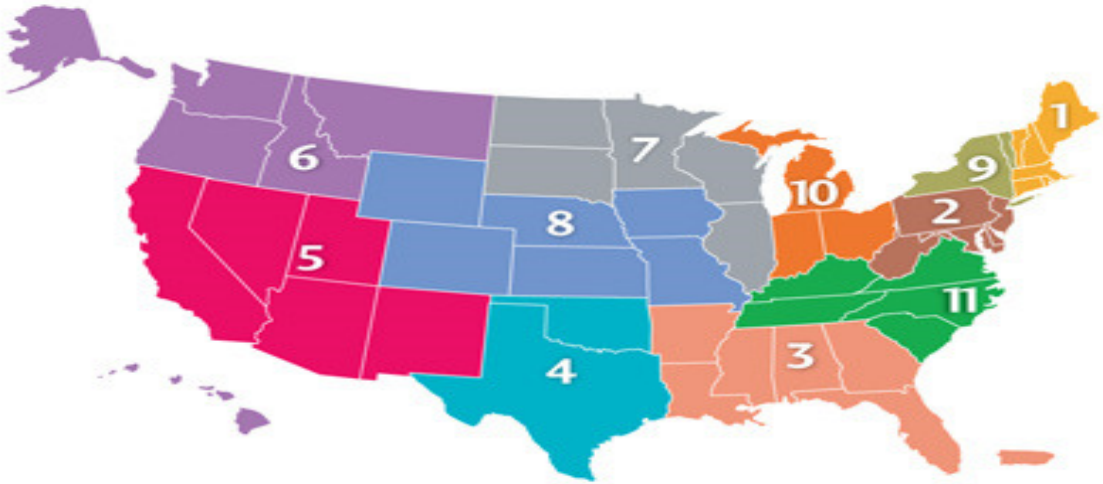
What factors should determine broader geographic sharing??

1. Wait list mortality
2. Time on the waiting list
3. “Artificial” boundaries
4. Final rule
5. Transplant outcomes?
6. Costs?



VS

Zone A – 500 miles
Zone B – 1000 miles
Zone C – 1500 miles
Zone D - 2500 miles
Zone E - >2500 miles



Sharing of adult deceased donor livers before and after Share 35

	Pre-Share35 (N = 5557)	Post-Share35 (N = 5878)	p-value
Local	4329 (77.9%)	3857 (65.6%)	
Regional	1060 (19.1%)	1805 (30.7%)	<0.001
National	168 (3.0%)	216 (3.7%)	
No MELD exception	2605 (63.0%)	2759 (63.1%)	
HCC exception	742 (18.0%)	719 (16.5%)	0.1
Non-HCC exception	786 (19.0%)	891 (20.4%)	

Massie et al, AJT 2015; 15: 659-667

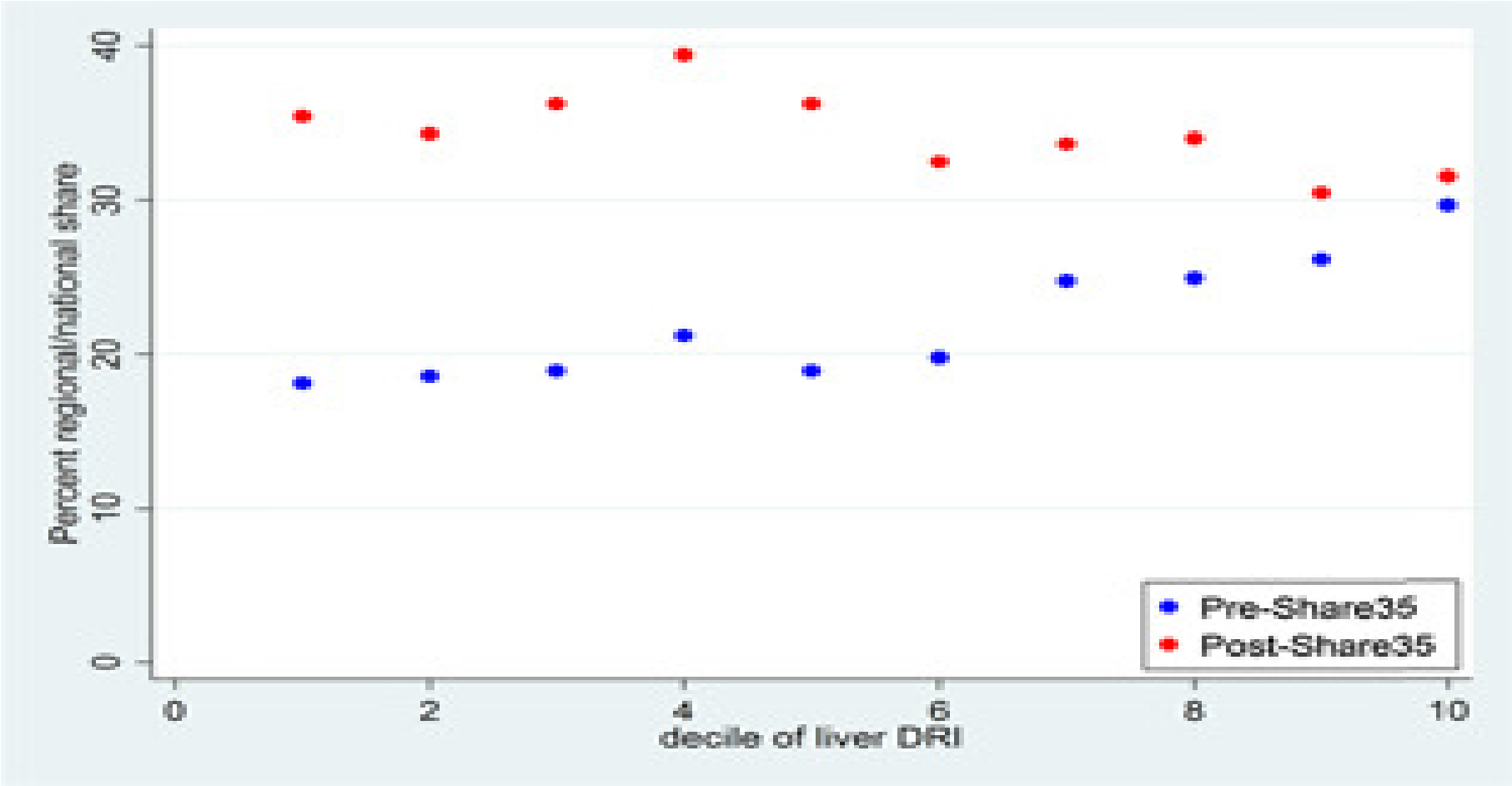
United Network for Organ Sharing

Table 2. Adult heart-alone transplants performed between January 2013 and June 2015
Stratified by medical urgency status at transplant and zone

	All		Medical urgency status at transplant					
			Status 1A		Status 1B		Status 2	
	N	%	N	%	N	%	N	%
All	***5207***	***100.0***	***3466***	***100.0***	***1546***	***100.0***	***195***	***100.0***
DSA	3337	64.1	2144	61.9	1104	71.4	89	45.6
Zone A	1608	30.9	1185	34.2	354	22.9	69	35.4
Zone B	242	4.6	131	3.8	77	5.0	34	17.4
Zone C	18	0.3	6	0.2	9	0.6	3	1.5
Zone D	2	0.0	.	.	2	0.1	.	.
Zone E	.	.	.	.	.	.	.	.

Interpretation: During this time period, no adult heart transplant recipients were transplanted with a heart from beyond Zone D (1501 miles through 2500 miles), and only 2 were transplanted in Zone D. In this cohort, 95% were transplanted with a heart from the local DSA or Zone A. The percentage was similar for the most urgent statuses (96% and 94% for status 1A and 1B, respectively). But a much higher percentage of status 2 transplants were performed using organs from Zone B and Zone C (19% combined).

Early Changes in Liver Distribution Following Implementation of Share 35 – Donor Risk Index



American Journal of Transplantation
Volume 15, Issue 3, pages 659-667, 18 FEB 2015 DOI: 10.1111/ajt.13099

United Network for Organ Sharing

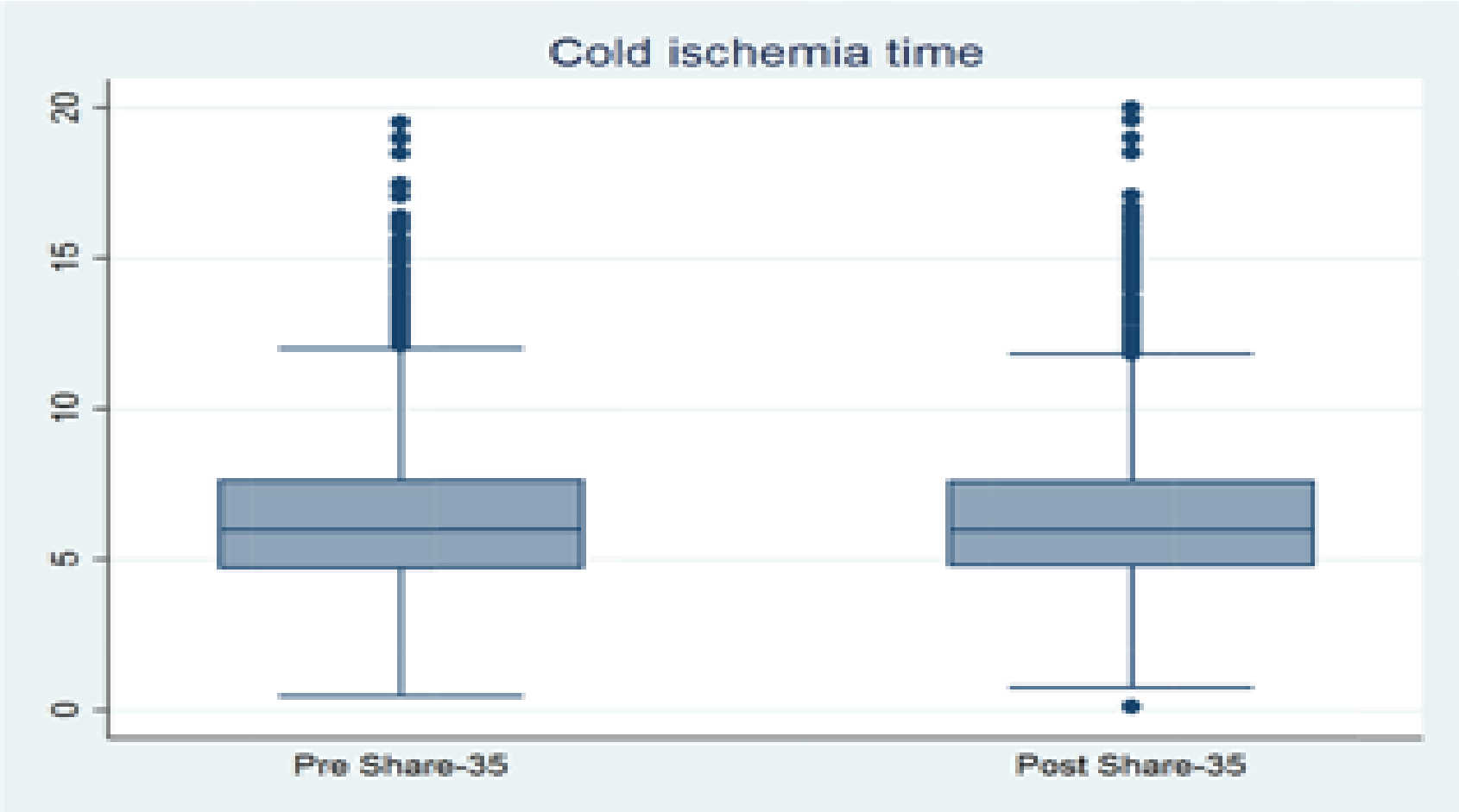
Table 1. Median offer number of acceptor
For heart-alone transplants performed between January 2013 and June 2015

Donor age group	Number of transplants with known acceptor number	Median offer number	5th %-ile	95th %-ile	25th %-ile	75th %-ile
ALL	***6232***	***3***	***1***	***56***	***1***	***9***
0-17 years	1207	2	1	19	1	5
18+ years	5025	3	1	66	1	11

Interpretation: The median offer number the transplant recipient was 3 for adult donor hearts, so half of those accepted were accepted by the first, second or third candidate to whom the heart was offered. Only 25% of adult donor hearts that were accepted were accepted beyond offer number 11.

NOTE: Analysis restricted to donors recovered in the US and heart-alone transplants.
Only offers with a refusal or acceptance were analyzed; bypasses were excluded.

Early Changes in Liver Distribution Following Implementation of Share 35



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United Network for Organ Sharing

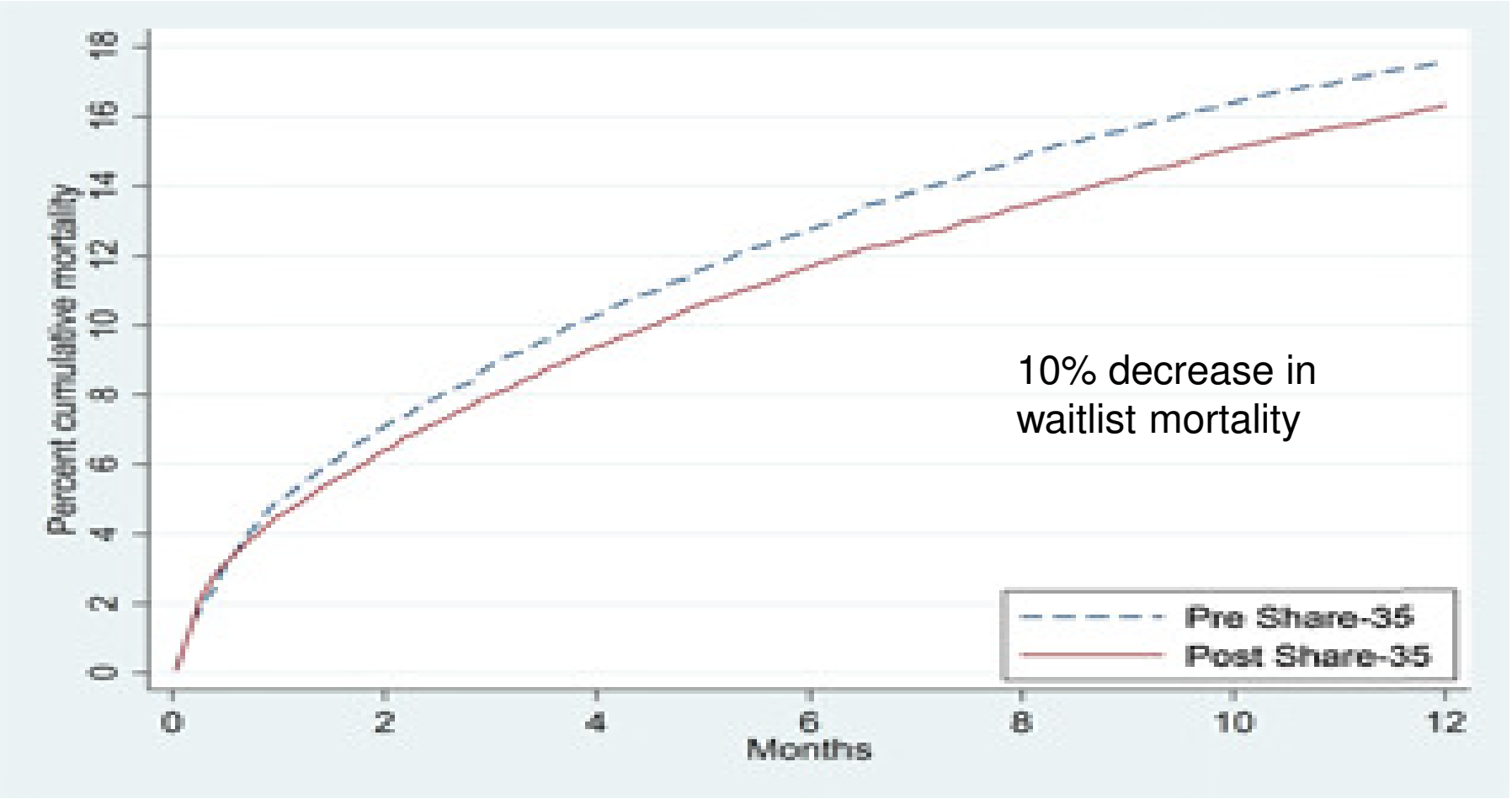
Table 3. Median ischemia time
For adult heart-alone transplants performed between January 2013 and June 2015

Medical urgency status at transplant	Geographic zone	Number of transplants	Ischemia time (hours)	5th %-ile	95th %-ile	25th %-ile	75th %-ile	P-value
Status 1A	DSA	2115	2.7	1.4	4.3	2.2	3.4	<0.0001
Status 1A	Zone A	1174	3.7	2.6	5.0	3.3	4.1	
Status 1B	DSA	1087	2.7	1.4	4.4	2.0	3.4	<0.0001
Status 1B	Zone A	350	3.6	2.4	5.1	3.2	4.1	

Interpretation: There was approximately an hour difference in ischemia time between transplants performed using organs recovered in the DSA compared to Zone A in both Status 1A transplants and Status 1B transplants. These differences were both statistically significant.

NOTE: P-values were computed using the Wilcoxon rank sum test.

Early Changes in Liver Distribution Following Implementation of Share 35 – Waitlist Mortality



American Journal of Transplantation
Volume 15, Issue 3, pages 659-667, 18 FEB 2015 DOI: 10.1111/ajt.13099

Recipient Waitlist Event Rate and Waitlist Mortality After the 2006 UNOS Policy Changes in the Donor Heart Allocation Algorithm

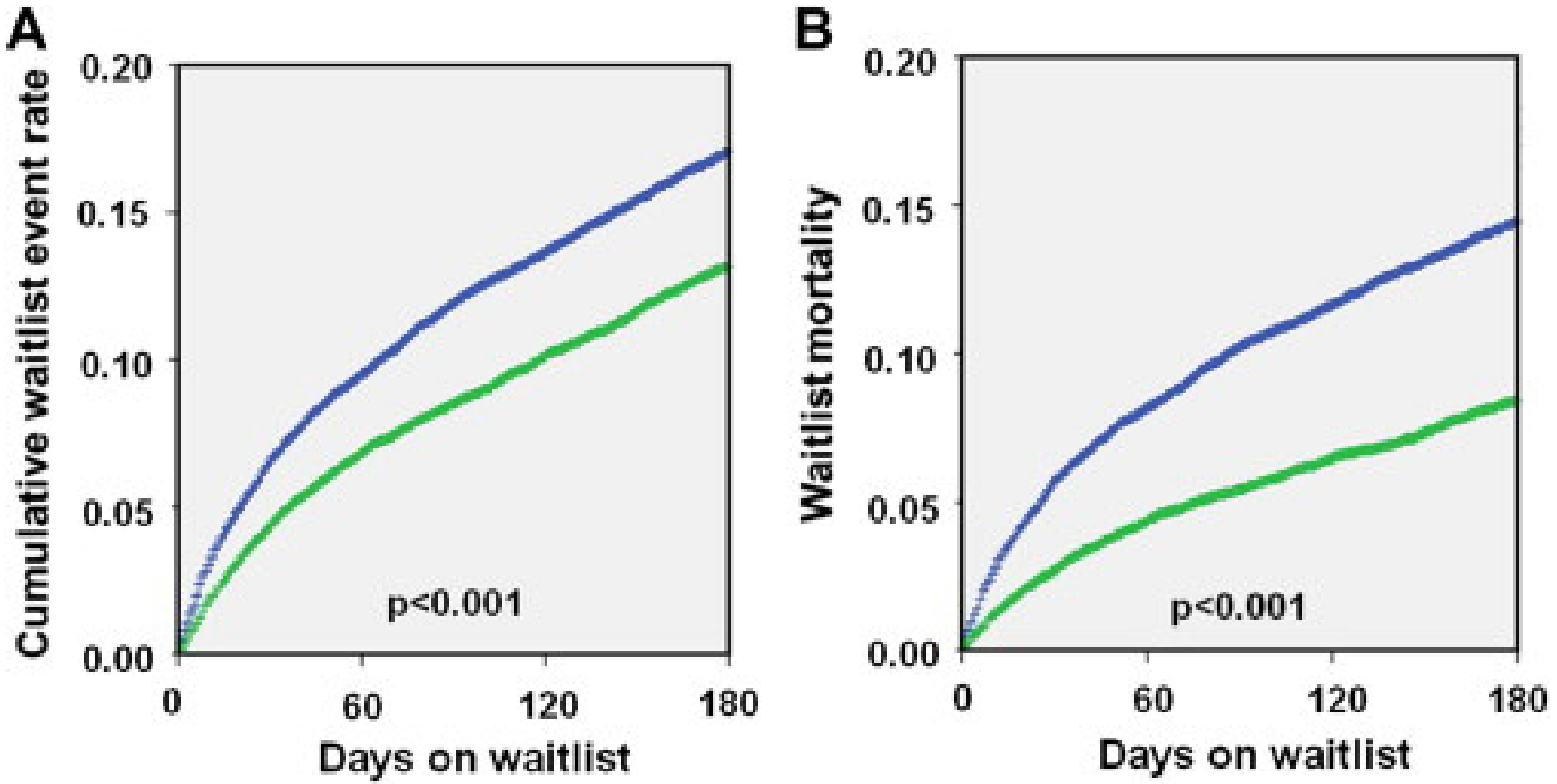


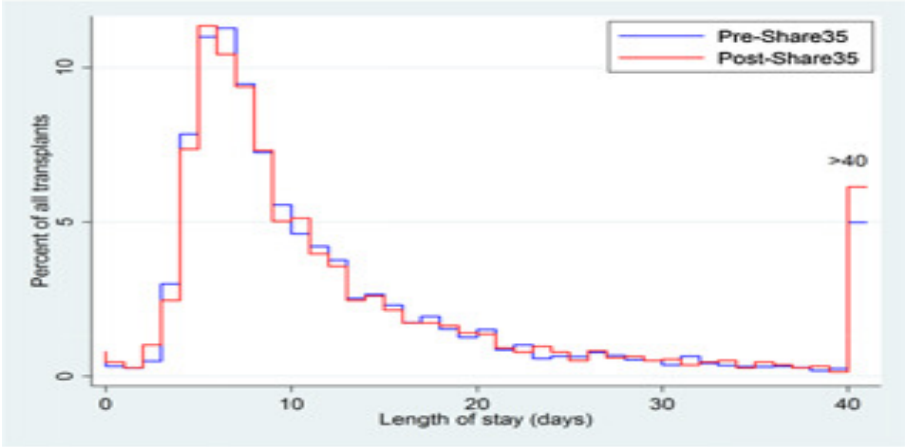
Figure 1. Comparison of 180-Day Waitlist Prognosis (A) Comparison of the cumulative event rate including death and delisting (15.3% vs. 11.6%, p < 0.001) between the 2 eras. (B) Mortality while being listed (13.3% vs. 7.9%, p < 0.001) in the 2 eras. B...

P. Christian Schulze, Shuichi Kitada, Kevin Clerkin, Zhezhen Jin, Donna M. Mancini

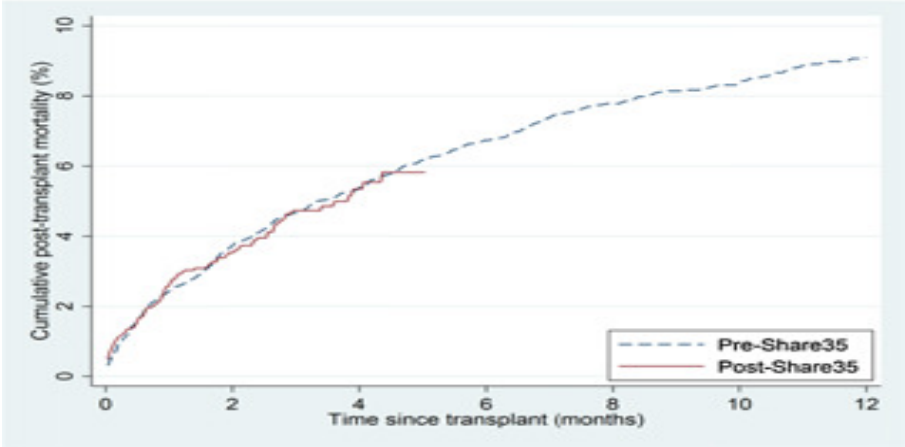
JACC: Heart Failure, Volume 2, Issue 2, 2014, 166–177

Early Changes in Liver Distribution Following Implementation of Share 35 – LOS and posttransplant mortality

A



B



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Volume 15, Issue 3, pages 659-667, 18 FEB 2015 DOI: 10.1111/ajt.13099

Post-transplant Survival After the 2006 UNOS Policy Changes in the Donor Heart Allocation Algorithm

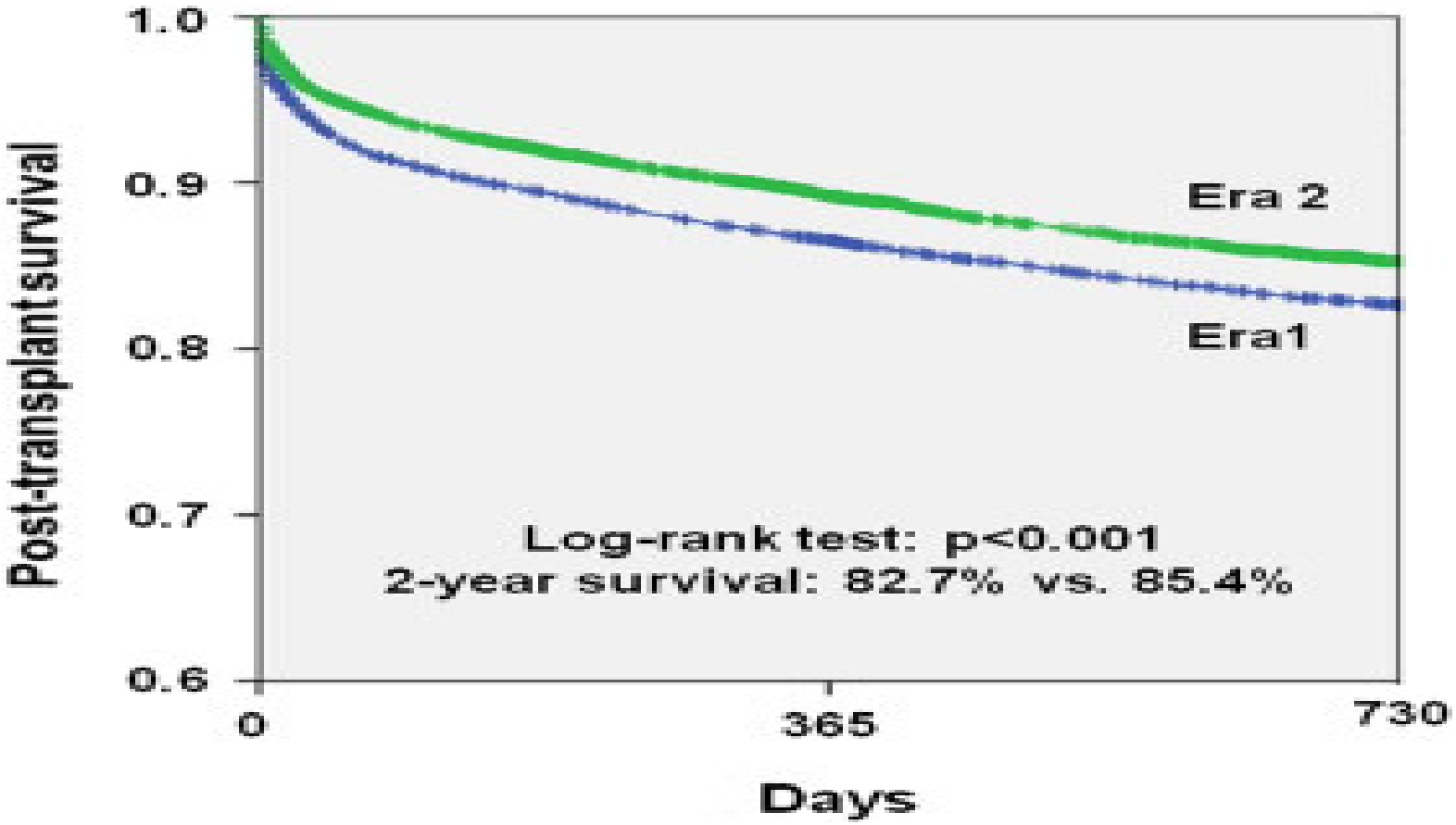

Figure 5. Comparison of Post-Transplant Mortality Analysis of outcomes after heart transplantation up to 2 years between the 2 eras. Blue = Era 1 (January 20, 1999 to July 11, 2006); green = Era 2 (July 12, 2006 to April 30, 2012).
P. Christian Schulze, Shuichi Kitada, Kevin Clerkin, Zhezhen Jin, Donna M. Mancini

JACC: Heart Failure, Volume 2, Issue 2, 2014, 166–177

United Network for Organ Sharing

Table 4. Post-transplant survival rates
For adult heart alone transplants performed between January 2013 and June 2015

Medical urgency status at transplant	Day Post-Transplant	Geographic zone	Number of Transplants	Number Alive or Still Functioning	Survival Rate	95% confidence limits	p-value
Status 1A	30	DSA	2144	2032	96.10	[95.22,96.98]	0.9999
	30	Zone A	1185	1123	96.10	[94.89,97.31]	
	365	DSA	2144	1153	90.04	[88.66,91.42]	0.5707
	365	Zone A	1185	649	89.48	[87.56,91.41]	

Medical urgency status at transplant	Day Post-Transplant	Geographic zone	Number of Transplants	Number Alive or Still Functioning	Survival Rate	95% confidence limits	p-value
Status 1B	30	DSA	1104	1034	95.53	[94.19,96.87]	0.6032
	30	Zone A	354	338	96.32	[93.99,98.66]	
	365	DSA	1104	595	91.29	[89.47,93.11]	0.1816
	365	Zone A	354	193	88.90	[85.15,92.64]	

Interpretation: There was no evidence of a statistically significant difference in survival at 30 days or at 365 days between hearts transplanted from the local DSA or from Zone A, when stratified by Status 1A or Status 1B at transplant.

Costs to Emory University Hospital (Lifelink of GA)

- Organ acquisition cost - $36,500
- King Air Twin Engine - $1350/hr
- Jet - $2150/hr
- Fuel Charge $300

Financial Impact of Share 35

	Before Share 35	After Share 35	Total change	Percent change
Imports				
Total number	208	296	88	42.3
Average cost	$47 448	$50 428	$2980	6.3
Total cost	$9 869 176	$14 926 748	$5 057 571	51.2
Surcharge total	$494 285	$1 080 406	$586 121	118.6
Total flight cost	$199 787	$456 521	$256 733	128.5
Exports				
Total number	157	334	177	112.7
Average cost	$29 756	$31 813	$2057	6.91
Surcharge total	$210 400	$419 562	$209 162	99.4
Total cost	$4 671 658	$10 625 407	$5 953 749	127.4
Total				
Total cost of liver imports	$9 869 176	$14 926 748	$5 057 572	–
Total cost of liver exports	$4 671 658	$10 625 407	$5 953 749	–
Total change in overall costs	–	–	$11 011 321	–

Nine OPOs – 17% of US population/19% of deceased donors
Extrapolating nationally – $68,820,756/yr/pop - $55,056,605/yr/organ donors
“Any alternative allocation proposal needs to account for the financial implications to the transplant infrastructure.”

Fernandez, et al, American Journal of Transplantation 2016; 16:287-291

Costs

"David, don't you know that it's cheaper to die?"

Personal communication Bud Frazier, circa 1989

Food for Thought

Number & type of organs transplanted (2011-2012) if all OPOs were performing at least as expected

Organ	Current Yield	At Least As Expected Yield	Additional Transplants
Heart	4,747	5,001	254
Intestine	233	290	57
Kidney	23,717	24,216	499
Liver	11,768	12,105	337
Lung	3,278	3,521	243
Pancreas	2,088	2,342	254
Total	**45,831**	**47,475**	**1,644**

SRTR
SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Israni, SRTR, WTC 2014

More food….

Number & type of organs transplanted (2011-2012) if all OPOs were performing at least as expected or performing as well as the highest performing OPO

Organ	Current Yield	At Least As Expected Yield	Additional Transplants	Yield as Highest OPO	Additional Transplants
Heart	4,747	5,001	254	6,514	1,767
Intestine	233	290	57	1,229	996
Kidney	23,717	24,216	499	29,152	5,435
Liver	11,768	12,105	337	14,384	2,,616
Lung	3,278	3,521	243	6,083	2,805
Pancreas	2,088	2,342	254	4,885	2,797
Total	**45,831**	**47,475**	**1,644**	**62,248**	**16,417**

SRTR

Israni, SRTR, WTC 2014

Always Read the Fine Print

Limitations of the thoracic simulated allocation model (TSAM) used for this analysis should be considered when interpreting results.

- TSAM assumes that organ acceptance behavior does not change in response to simulated policy changes; moreover, organ acceptance behavior is based on historical acceptance behavior that may or may not change under proposed sharing
- TSAM does not anticipate changes in listing behavior that allocation rule changes could precipitate.
- TSAM cannot account for center-specific practices.
- TSAM assumes that all organ offers follow the stated allocation rules, and does not allow for exceptions or expedited placements.
- TSAM models are limited by the available data during the cohort period.
- All prediction models include uncertainty.

Most Bang for the Buck

1. Education/Outreach
2. OPO performance
3. Transplant center utilization
4. Final rule – Time as a discriminating factor for allocation
5. Broader sharing – what are the unintended consequences

Acknowledgement

Leah Edwards, PhD
UNOS