

Liver and Intestinal Organ Transplantation Committee

W. Kenneth Washburn, MD, Chair
Kim M. Olthoff, MD, Vice-chair

Report to the Board of Directors
June 28-29, 2011
Richmond, Virginia

ITEM FOR BOARD CONSIDERATION

OPTN

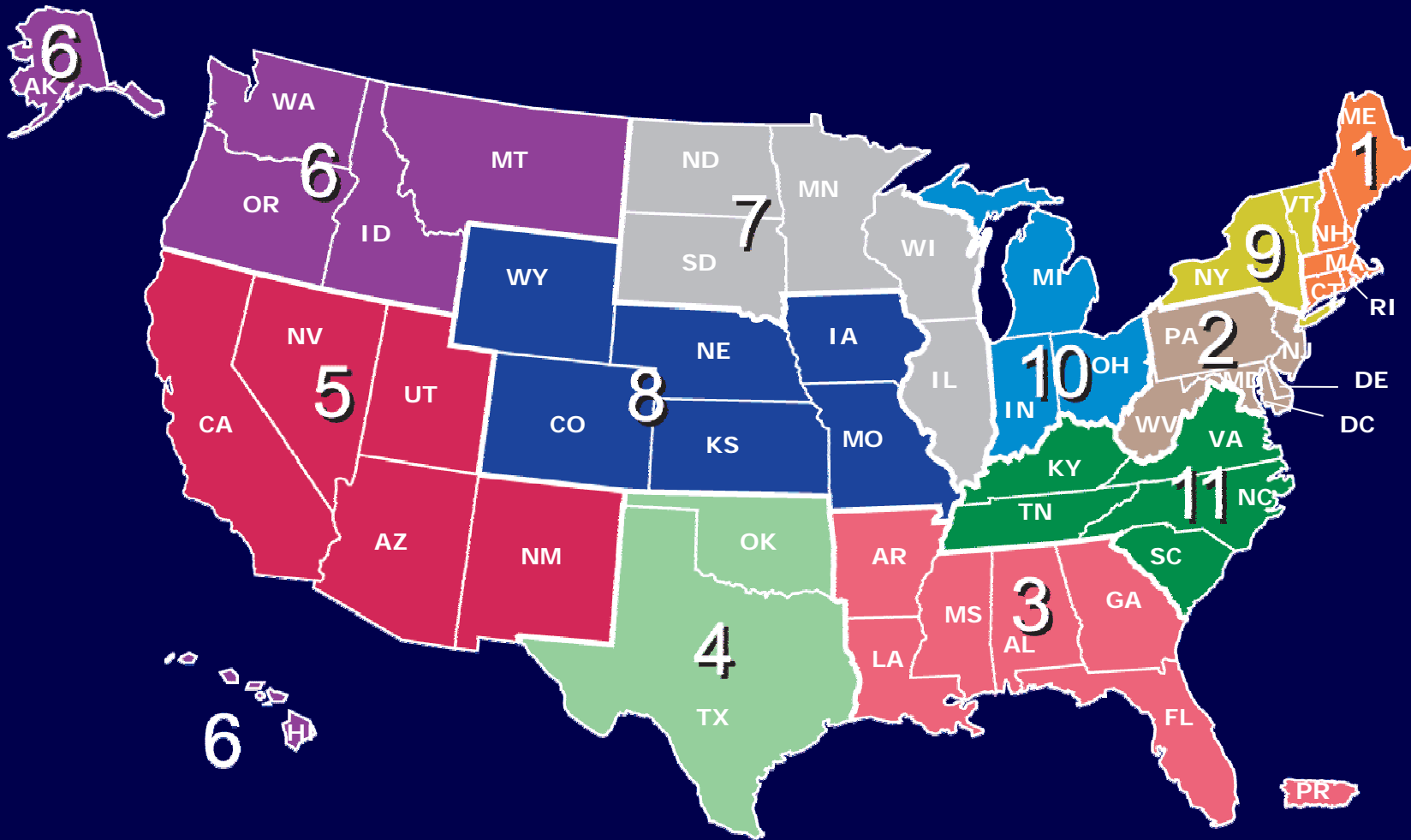
UNOS DONATE
LIFE

Region 8 Sharing Agreement

OPTN

UNOS DONATE
LIFE

REGIONAL MAP



OPTN

UNOS **DONATE LIFE**

Brief History - I

- Began in 2004 as a dispute over MO statewide ALU approved 6/04
- Liver Committee asked for delay in implementation
- Back and forth between Committee and Board
- November 2005: Board directs Liver Committee to work with Region 8 to develop a plan for broader sharing of livers

History - 2

- May 2006 Region 8 submits proposal for “Share 29” (unanimously approved) to Committee
- Proposal circulates for public comment in August 2006
- December 2006, Approved by Board
- Implemented 5/9/2007

History - 3

- Initial ending date: 05/09/2009
 - Extended until 11/8/2009
- May 2010: Regional Vote to Dissolve
 - 11 in support, 4 opposed, 1 abstention
- Data Reviewed at Forum and ATC – additional review requested in 10/2010

Adult Donor Liver Allocation Sequence

Region 8

- OPO LI Status 1A
- Regional LI Status 1A
- OPO LI Status 1B
- Regional LI Status 1B
- OPO LI MELD/PELD ≥ 29
- Regional LI MELD/PELD ≥ 29
- OPO LI MELD/PELD 15-28
- Regional LI MELD/PELD 15-28
- OPO LI MELD/PELD < 15
- Regional LI MELD/PELD < 15

National

- OPO LI Status 1A
- Regional LI Status 1A
- OPO LI Status 1B
- Regional LI Status 1B
- OPO LI MELD/PELD ≥ 15
- Regional LI MELD/PELD ≥ 15
- OPO LI MELD/PELD < 15
- Regional LI MELD/PELD < 15

Regional sharing for 29+ applies for adult donors only, includes adult and pediatric candidates, and does NOT include liver-kidneys, HCC and other exceptional cases

Summary of 3-year Analyses

- Univariate Analyses
- Overall pre-transplant death rate was lower ~6% (but not statistically significant) despite and increase in demand
- Committee requested risk-adjusted analyses

Committee / Board Deliberations 2010

- Resolution to Board, November 2010
“RESOLVED, that the Region 8 “Share 29” AAS shall be continued until June 30, 2011, pending further risk-adjusted analyses of the impact of the AAS.
- Board tabled motion
- Committee to review SRTR risk-adjusted analysis in March 2011

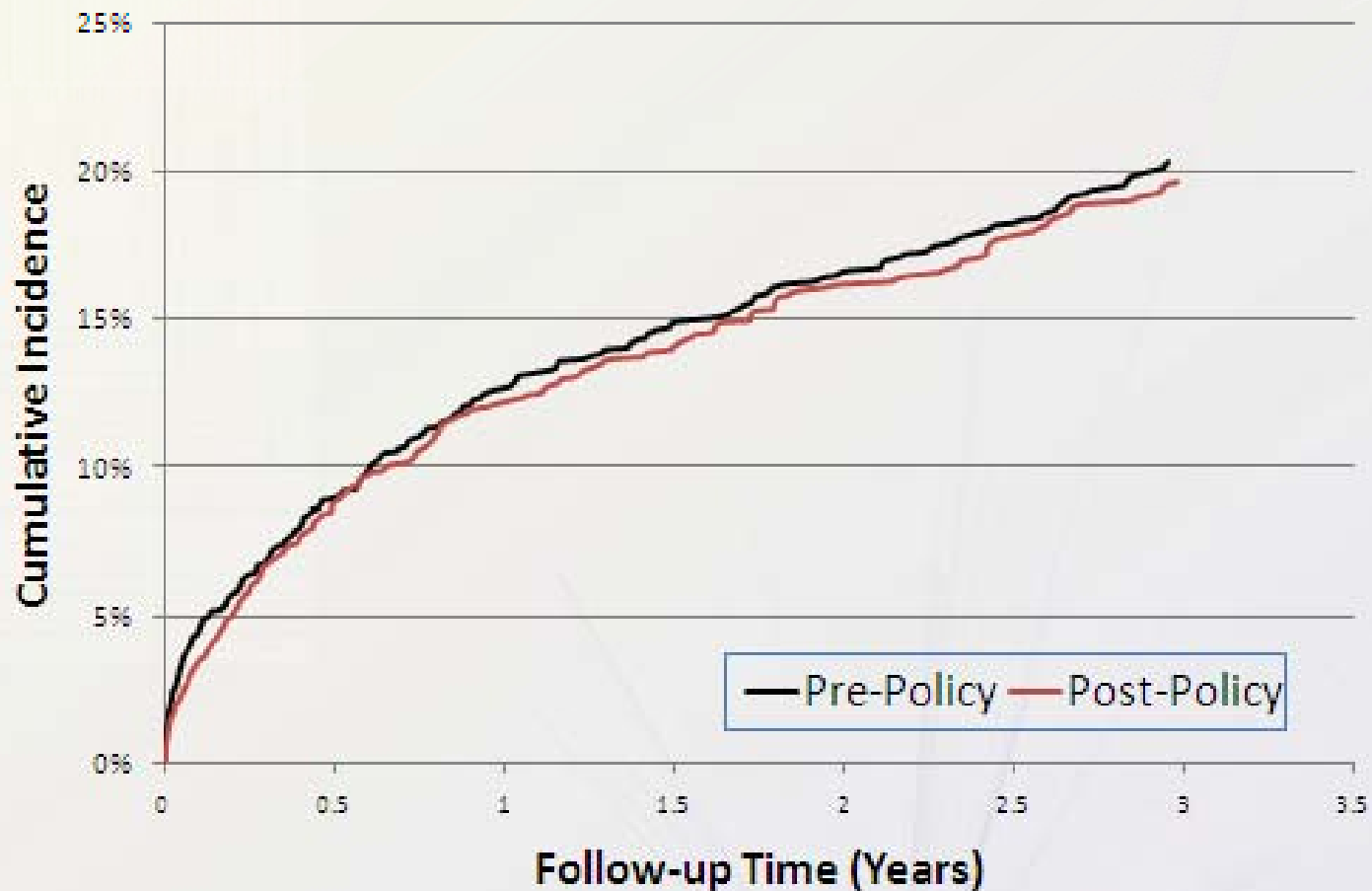
Results: Adjusted Hazard Ratio

Adjusted¹ Hazard Ratio (post- vs. pre-) from Competing Risk Models

	HR	95% CI	P-Value
Region 8	0.94	0.81-1.10	0.46
Other Regions	1.01	0.97-1.05	0.65

¹Adjusted for MELD group, age, gender, and race.

Results: Cumulative Incidence of Death, Competing Risk Analysis, Unadjusted



Sample Size Calculation: Results

Hazard Ratios Post v. Pre AAS	Number Needed in Each Group
0.98	253,634
0.96	62,692
0.94	27,545
0.92	15,315
0.91	12,030
0.90	9,687
0.88	6,648
0.86	4,826
0.84	3,650

*Region 8 contained approximately 2,000 patients in each group

Summary / Conclusions

- There was no significant difference in waiting list mortality temporally associated with the adoption of the Region 8 AAS.
- There was inadequate statistical power to detect a difference.
- It should not be concluded from this analysis that a similar change in allocation policy would or would not reduce waiting list mortality in other regions.

Liver Committee – March 2011

- Reviewed SRTR Data / Power Calculations
- AAS never designed as an experiment
- Uncomfortable requiring participation in an AAS
- Committee not currently proposing this level of sharing for the national system

**** RESOLVED, that Region 8's request to dissolve its Alternative Allocation system for regional sharing of livers shall be approved, effective pending notice and programming in UNetSM.**

Committee vote: 16 in favor, 1 opposed, and 3 abstentions.