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
Region 8 Sharing Agreement
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

OPTN
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 \( \geq 29 \)
- Regional LI MELD/PELD \( \geq 29 \)
- 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

<table>
<thead>
<tr>
<th></th>
<th>HR</th>
<th>95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Region 8</td>
<td>0.94</td>
<td>0.81-1.10</td>
<td>0.46</td>
</tr>
<tr>
<td>Other Regions</td>
<td>1.01</td>
<td>0.97-1.05</td>
<td>0.65</td>
</tr>
</tbody>
</table>

1 Adjusted for MELD group, age, gender, and race.
Results: Cumulative Incidence of Death, Competing Risk Analysis, Unadjusted
## Sample Size Calculation: Results

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

*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.