“Share 35” Liver Policy: Analysis at 1 Year

OPTN Liver and Intestinal Organ Transplantation Committee Forum
September 16, 2014
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

Liver and Intestinal Organ Transplantation Committee charged with monitoring the impact of allocation changes
Data

- Data provided for 2 eras:
  - June 18, 2012 – June 17, 2013 (Pre-Era)
  - June 18, 2013 – June 17, 2014 (Post-Era)
  - OPTN data as of August 22, 2014

- Types of data
  - National and some regional/DSA data focused on:
    - Transplants by MELD/PELD, CIT, distance
    - Post-transplant outcomes
    - Waiting list mortality
    - DSA imports/exports
Counts of waiting list deaths include:

- OPTN member reported removals for death
- OPTN member reported removals for “too sick”
- SSADMF deaths (pre-removal and within 30 days of removal within the period)

Overall death rate presented as deaths per patient-year

“Intent-to-treat” analysis for MELD/PELD 35+ waiting list outcomes

- Time to transplant, death, other removal from first entry into MELD/PELD 35+ category
- Analysis accounts for competing risks

Post-transplant patient survival estimated using Kaplan-Meier
Transplants
Deceased Donor Liver Transplants by Era and Region

Overall: 6029 Pre, 6357 Post

Region

Pre-Era

Post-Era

1 2 3 4 5 6 7 8 9 10 11

693 757 1078 520 901 159 525 492 467 480 512 538

Pre-Era

Post-Era

223 222 1156 579 957 188 525 316 655 672

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Deceased Donor Liver Transplants by Era and Status/Allocation Score

Pre-Era Post-Era

% of Transplants

N=6029 N=6357


Status or MELD/PELD Score

- < 15
- 15-34
- 35+
- Status 1

- 6.3% 6.1%
- 18.7% 26.3%
- 73.1% 66.1%
- 12.6% MELD/PELD Exceptions 10.1% MELD/PELD Exceptions
- 47.5% MELD/PELD exceptions 51.6% MELD/PELD exceptions

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UNOS DONATE LIFE

United Network for Organ Sharing
Deceased Donor Liver Transplants by Era and Region – Median Allocation Score At Transplant
(Status 1s Excluded)

US Overall
Pre-Era: 27
Post-Era: 28

Pre: 6/18/2012-6/17/2013
Median Allocation MELD/PELD at Transplant, by DSA within Region and Era

Pre-Era

Post-Era

Variance across all DSAs = 14.3

Variance across all DSAs = 17.6

Median Match MELD @ Transplant

Pre: 6/18/2012-6/17/2013

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Pre: 6/18/2012-6/17/2013

UNOS DONATE LIFE
Deceased Donor Liver Transplants by Era and Share Type

Pre-Era: 6/18/2012-6/17/2013

- N=6029
  - Local: 74.7%
  - Regional: 20.4%
  - National: 4.9%

- N=6357
  - Local: 63.1%
  - Regional: 31.8%
  - National: 5.0%

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Pre: 6/18/2012-6/17/2013
Regional Shares Pre-Era and Post-Era

Pre: 6/18/2012-6/17/2013
Multi-Organ Transplants

- **Liver-Intestine:** 34 in Pre-Era, 75 in Post-Era
  - 0.6% of Pre-Era, 1.2% of Post-Era Transplants
  - 22 National Shares in Pre-Era vs. 53 in Post-Era

- **Liver-Kidney:** 504 (8.4%) in Pre, 535 (8.4%) in Post
  - 90% local, 9% Regional in Pre-Era
  - 67% local, 32% Regional in Post-Era
Organ Travel Distance, Cold Ischemia Time, Donor Risk Index
### Organ Travel Distance, Cold Ischemia Time, and Donor Risk Index

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Median Distance organs traveled (miles)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall:</td>
<td>59</td>
<td>85</td>
</tr>
<tr>
<td>Local:</td>
<td>22</td>
<td>23</td>
</tr>
<tr>
<td>Regional:</td>
<td>231</td>
<td>236</td>
</tr>
<tr>
<td>National:</td>
<td>687</td>
<td>660</td>
</tr>
<tr>
<td><strong>Median Cold Ischemia Time (CIT) (hours)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall:</td>
<td>6.1</td>
<td>6.1</td>
</tr>
<tr>
<td>Local:</td>
<td>5.9</td>
<td>5.8</td>
</tr>
<tr>
<td>Regional:</td>
<td>6.7</td>
<td>6.7</td>
</tr>
<tr>
<td>National:</td>
<td>8.1</td>
<td>7.7</td>
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<tr>
<td><strong>Median Donor Risk Index (DRI)</strong></td>
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<td></td>
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<tr>
<td>Overall:</td>
<td>1.4</td>
<td>1.4</td>
</tr>
<tr>
<td>Local:</td>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>Regional:</td>
<td>1.5</td>
<td>1.4</td>
</tr>
<tr>
<td>National:</td>
<td>1.6</td>
<td>1.7</td>
</tr>
</tbody>
</table>

Increase in Organ Travel Distance for Regions 4, 5, and 7
Median Distance Livers Traveled, by DSA within Region and Era

**Pre-Era**

Variance across all DSAs = 2723.6

**Post-Era**

Variance across all DSAs = 6009.3

Pre: 6/18/2012-6/17/2013  
Median CIT, by DSA within Region and Era

Variance across all DSAs = 1.22

Variance across all DSAs = 1.15

Pre-Era

Post-Era

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Pre: 6/18/2012-6/17/2013

## Transplant Metrics for Recipients with Match MELD/PELD at Transplant of 35+

<table>
<thead>
<tr>
<th>Factor</th>
<th>Pre-Era</th>
<th>Post-Era</th>
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</thead>
<tbody>
<tr>
<td>Distance</td>
<td>51</td>
<td>166</td>
</tr>
<tr>
<td>CIT</td>
<td>6.3</td>
<td>6.6</td>
</tr>
<tr>
<td>DRI</td>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>Length of Stay</td>
<td>16</td>
<td>15</td>
</tr>
<tr>
<td>MELD/PELD (Lab)</td>
<td>37</td>
<td>37</td>
</tr>
</tbody>
</table>

Median values reported

Livers Not Used
Livers Not Used

- Recovered for Transplant but Not Transplanted:
  - 669 in Pre-Era (10.3% of recovered)
  - 653 in Post-Era (9.5% of recovered)

- Livers Not Recovered:
  - 1149 in Pre-Era (14.1% of all donors)
  - 1099 in Post-Era (13.0% of all donors)
Livers Recovered for Transplant But Not Transplanted, by Era and Region

US Total
Pre-Era: 669
Post-Era: 653

Transplant Outcomes
Six-Month Patient Survival
Deceased Donor Liver Transplants Performed
120 Days Pre- and Post-Share 35

% Survival

Months Post-Transplant

Pre-Era: All
Post Era: All
Pre Era: 35+
Post Era: 35+

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Post-Transplant Mortality Rates

Massie et al., AJT (in revision)
### Liver Waiting List Additions, Pre-Era and Post-Era, By Status/Allocation Score

<table>
<thead>
<tr>
<th>Status</th>
<th>&lt; 15</th>
<th>15-34</th>
<th>35+</th>
<th>Inactive</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Pre-Era</td>
<td>461</td>
<td>3.9</td>
<td>5,080</td>
<td>43.4</td>
<td>5289</td>
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<tr>
<td>Post-Era</td>
<td>421</td>
<td>3.5</td>
<td>5,275</td>
<td>43.4</td>
<td>5485</td>
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<tr>
<td>Net</td>
<td>-40</td>
<td>+195</td>
<td>+196</td>
<td>+84</td>
<td>+5</td>
</tr>
</tbody>
</table>

Pre: 6/18/2012-6/17/2013
Liver Candidates With MELD/PELD Allocation Scores of 35+ at Month’s End

Candidates on the Liver Waiting List at Month End, By Status/Allocation Score

Waiting List Death Rates
Overall Liver Waiting List Death Rates: Deaths/Too Sick Per 100 Patient-Years

No significant differences

Pre-Era | Post-Era
--- | ---
 Adults: 18.8 (2967) | 18.9 (2931)
 Pediatrics: 8.9 (44) | 8.7 (43)
 Overall: 18.5 (3011) | 18.5 (2974)

Relative Risk of Waiting List Mortality, Post-Era vs. Pre-Era, By Ethnicity

Pre: 6/18/2012-6/17/2013
Relative Risk of Waiting List Mortality, Post-Era vs. Pre-Era, By Region

Crude RR

Region


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MELD/PELD 35+ Waiting List Outcomes: Competing Risks Analysis

N = 1720

N = 1998

Days Since Entry: Pre-Era

Days Since Entry: Post-Era

Death 0.32

Death 0.24

Transplant 0.58

Transplant* 0.66


*Transplant rate, Death Rate Significantly Different, p< 0.05
Imports/Exports
Net Flow of Livers, Pre-Era vs Post-Era, by DSA

Pre: 06/18/2012 – 6/17/2013

MSD=184.4
Net Flow of Livers, Pre-Era vs Post-Era, by DSA

MSD=187.4

Net Importers, Pre
Net Exporters, Post

Net Exporters Pre and Post

Net Exporters Pre, Net Importers Post

Net Importers, Pre and Post

Net Flow, Post

100 80 60 40 20 0 -20 -40 -60 -80 -100

Net Flow of Livers, Pre

100 80 60 40 20 0 -20 -40 -60 -80 -100

Pre: 06/18/2010 – 6/17/2011
Summary: Post Share 35 Era Data

- Increased number/percent of MELD/35+ transplants
- Increased regional sharing
- No impact to overall waiting list mortality
  - No impacts to waiting list mortality by age, ethnicity
- MELD/PELD 35+ waiting list candidates
  - Increased transplant rate
  - Decreased mortality rate
- Post-transplant survival (preliminary)
  - No overall change
  - No change to outcomes for MELD/PELD 35+ recipients
- No impact to overall liver discard rate
- Overall import/export dynamics similar to previous era
Reminder: 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 $\geq 35$ by descending M/P score, local candidates ranked above regional candidates at each score
4. Local candidates with MELD/PELD scores 29-34
5. National Liver-Intestine Candidates
6. Local candidates with MELD/PELD scores 15-28
7. Regional candidates with MELD/PELD scores 15-34
Algorithm (cont.)

8. National Status 1A candidates
9. National Status 1B candidates
10. National Candidates with MELD/PELD scores $\geq 15$
11. Local candidates with MELD/PELD scores $< 15$
12. Regional candidates with MELD/PELD scores $< 15$
Deceased Donor Liver Transplants by Era, Age, and Status/Allocation Score

- Adult, Pre (N=5557)
  - < 15: 76.4%
  - 15-34: 18.8%
  - 35+: 18.8%
  - Status 1: 7.3%

- Adult, Post (n=5878)
  - < 15: 63.8%
  - 15-34: 27.2%
  - 35+: 17.4%
  - Status 1: 8.7%

- Pediatric, Pre (n=472)
  - < 15: 39.8%
  - 15-34: 34.2%
  - 35+: 16.5%
  - Status 1: 7.3%

- Pediatric, Post (n=479)
  - < 15: 38.2%
  - 15-34: 38.2%
  - 35+: 16.5%
  - Status 1: 7.3%

Pre: 6/18/2012-6/17/2013
Deceased Donor Liver Transplants with MELD/PELD 35+, by Month

*June 2012/2014 are only partial months in the cohort, so were omitted

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## Transplant Metrics for Regionally Shared Livers

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<tr>
<th>Factor</th>
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<tbody>
<tr>
<td>DRI</td>
<td>1.5</td>
<td>1.4</td>
</tr>
<tr>
<td>CIT</td>
<td>6.7</td>
<td>6.7</td>
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<tr>
<td>Distance</td>
<td>231</td>
<td>236</td>
</tr>
<tr>
<td>LOS</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>M/P (Lab)</td>
<td>23</td>
<td>31</td>
</tr>
<tr>
<td>M/P (Match)</td>
<td>27</td>
<td>36</td>
</tr>
</tbody>
</table>

Liver Waiting List Additions by Month and MELD/PELD Score at Listing, July 2012-May 2014

Pre-Era: 6/18/2012-6/17/2013

Pre: Status 1, 35+
Post: Status 1, 35+, Inactive
Deceased Donor Liver-Intestine Transplants by Month

*June 2012/2014 are only partial months in the cohort, so were omitted

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Liver Waiting List Additions by Month and MELD/PELD Score at Listing, July 2012-May 2014

Pre-Era: 6/18/2012-6/17/2013

# of Additions

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Liver Candidates Waiting for an Intestine at Month’s End

Number of Candidates

OPTN