Update on the New Heart Allocation Policy - Is It Performing as Expected?

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Disclosures

- President UNOS/OPTN Board of Directors
- Consultant to CVS/Caremark, OPTUM Health Care
- Chair, DSMB for Medtronics Mechanical Circulatory Support Device Trials
Learning Objectives

• To describe the reasons a new heart allocation policy was developed
• To review heart allocation using the new heart allocation policy compared to a similar time period in the prior year
• To recognize concerns regarding the new heart allocation policy
1500 deaths per 100 PY

5 deaths per 100 PY

Status Criteria:
- MCSD
- Thrombosis
- MCSO Infection
- Device Complication
- Infection
- 1A EXC
- LVAD (3rd)
- MCSO Failure
- VT/VE
- IABP
- VAD/IVAD
- Mech/Non
- ECMO

Source: SRTR data presentation to the OPTN/UNOS Thoracic Organ Transplantation Committee (3/17/2014)
2018 Adult Heart Allocation Modifications

- Major changes:
  - New medical urgency status classifications and qualifying criteria
  - Broader distribution for critically ill candidates
  - Exception requests reviewed by other region’s board rather than own region’s board

- Primary goals:
  - Better stratify candidates according to waiting list mortality
  - Improve access to donor hearts for critically ill candidates
  - Reduce burden of exception requests
In This Presentation

- October 18, 2018 – October 17, 2019 (one year, “post-implementation”)
  - Comparison period: October 18, 2017 – October 17, 2018 (“pre-implementation”)
  - Does NOT include data relating to the removal of DSA from allocation (happened January 9, 2020)
Waiting List

3990 adult heart waiting list registrations pre-implementation

3931 adult heart waiting list registrations post-implementation
Waiting List Additions by Status and Era

Era

Pre | Post

Status

Status 1A: 717 (18.24%)
Status 1B: 479 (12.19%)
Status 2: 1562 (39.74%)
Adult Status 1: 1058 (26.52%)
Adult Status 2: 872 (22.18%)

Percent Waiting List Additions

Statuses representing less than 5% of the total are not labelled on the plot.
Waiting List Mortality

![Graph showing Waiting List Mortality]

- Status 1A
- Status 1B
- Status 2
- Adult Status 1
- Adult Status 2
- Adult Status 3
- Adult Status 4
- Adult Status 5
- Adult Status 6
- Temporarily Inactive
- Overall

Deaths per 100 Patient-Years

Era
- Pre
- Post
Transplants

2954 adult heart transplants performed pre-implementation

3032 adult heart transplants performed post-implementation
Transplants by Status and Era

Era
Pre
Post

Percent Heart Transplants
0%
25%
50%
75%
100%

Status
Status 1A
Status 1B
Status 2
Adult Status 1
Adult Status 2
Adult Status 3
Adult Status 4
Adult Status 5
Adult Status 6

2018 (68.31%)
835 (28.27%)
1386 (45.71%)
706 (23.28%)
554 (18.27%)

Statuses representing less than 5% of the total are not labelled on the plot.
## Devices at Transplant by Era

<table>
<thead>
<tr>
<th>Device</th>
<th>Era</th>
<th>Count</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECMO</td>
<td>Pre</td>
<td>30</td>
<td>1.79%</td>
</tr>
<tr>
<td>ECMO</td>
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</tbody>
</table>

For complete device data, see full report
# Median Days to Transplant

<table>
<thead>
<tr>
<th>Era</th>
<th>Status</th>
<th>Days Waiting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre</td>
<td>Status 1A</td>
<td>56</td>
</tr>
<tr>
<td>Pre</td>
<td>Status 1B</td>
<td>201</td>
</tr>
<tr>
<td>Pre</td>
<td>Status 2</td>
<td>**</td>
</tr>
<tr>
<td>Pre</td>
<td>Overall</td>
<td>198</td>
</tr>
</tbody>
</table>

- **Median Days to Transplant:** 13

<table>
<thead>
<tr>
<th>Era</th>
<th>Status</th>
<th>Days Waiting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post</td>
<td>Adult Status 1</td>
<td>4</td>
</tr>
<tr>
<td>Post</td>
<td>Adult Status 2</td>
<td>9</td>
</tr>
<tr>
<td>Post</td>
<td>Adult Status 3</td>
<td>27</td>
</tr>
<tr>
<td>Post</td>
<td>Adult Status 4</td>
<td>262</td>
</tr>
<tr>
<td>Post</td>
<td>Adult Status 5</td>
<td>**</td>
</tr>
<tr>
<td>Post</td>
<td>Adult Status 6</td>
<td>**</td>
</tr>
<tr>
<td>Post</td>
<td>Overall</td>
<td>111</td>
</tr>
</tbody>
</table>
Transplant Rates

Transplants per 100 Patient-Years

Status
- Status 1A
- Status 1B
- Status 2
- Adult Status 1
- Adult Status 2
- Adult Status 3
- Adult Status 4
- Adult Status 5
- Adult Status 6
- Overall

Era
- Pre
- Post
Distance Traveled at Transplant by Era

Distance Traveled (Nautical Miles)

Vertical lines indicate the median distance traveled for each era
Total Ischemic Time at Transplant by Era

Vertical lines indicate the median cold ischemic time for each era

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Outcomes

Six-month survival for 1658 adult heart recipients transplanted pre-implementation compared to 1689 adult heart recipients transplanted post-implementation
Six-Month Graft Survival by Status Pre-Implementation

![Graph showing survival rates over time for different statuses.](image-url)
Six-Month Graft Survival by Status Post-Implementation

After 149 days waiting, survival for Adult Status 3 is the same as for Adult Status 6. Adult Status 5 is omitted because there were too few adult heart recipients to accurately estimate survival.
Six-Month Patient Survival by Era

\[ p\text{-value: } 0.4 \]
Regional Review Board

3921 adult heart justification forms submitted September 18, 2018-October 17, 2019
Justification Forms by Status and Form Type

- Status 1 Initial Listing
- Status 1 Extension
- Status 2 Initial Listing
- Status 2 Extension
- Status 3 Initial Listing
- Status 3 Extension
- Status 4 Initial Listing
- Status 4 Extension

Count

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Takeaways

- Increase in use of VA ECMO and especially IABPs
  - IABP use greatest for candidates in Adult Status 2
- No significant change in waiting list mortality
  - But new statuses do more accurately stratify medically urgent candidates
- Dramatic decrease in median waiting time for medically urgent candidates
- Transplant rates increased for medically urgent candidates
  - Overall rate significantly higher than pre-implementation
- No significant difference in six-month graft or patient survival
- 300-400 exception requests per month; almost all are approved
- No clear impact on pediatric heart candidates
New Heart Allocation Policy - Is It Performing as Expected?

- Primary goals:
  - Better stratify candidates according to waiting list mortality: **yes!**
  - Improve access to donor hearts for critically ill candidates: **yes!**
  - Reduce burden of exception requests: **no**
New Heart Status/Criteria

1

2
New Status/Criteria (Cont.)

3

i. Dischargeable LVAD for up to 30 days

N 30

N

ii. Subsets of status 1A

ii. Multiple inotropes or single high-dose inotropes with continuous hemodynamic monitoring

Y 14

Y

iii. Mechanical circulatory support with hemolysis, pump thrombosis, right heart failure, device infection, bleeding, AI bleeding; rest

Y 14-90

Y

iv. VA ECMO >7 days; non-dischargeable surgically implanted non-endovascular LVAD, percutaneous support device, or IABP >14 days

Y 7-14

Y

4

i. Dischargeable LVAD

N 90

Y

ii. Inotropes without hemodynamic monitoring

N 90

Y

iii. Congenital heart disease (CHD) eg:

N 90

Y

a. Unrepaired/incompletely repaired complex CHD

b. Repaired CHD with two ventricles (e.g., TOF, TOGV)

c. Single ventricle repaired with Fontan or modifications

iv. Ischemic heart disease with intractable angina

N 90

Y

v. Amyloidosis, hypertrophic cardiomyopathy or restrictive cardiomyopathy (with clinical qualifiers)

N 90

Y

vi. Retransplant

N 90

Y
<table>
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<th>New Status/Criteria (Cont.)</th>
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<tbody>
<tr>
<td><strong>5</strong> Combined organ transplants: heart - lung; heart - liver; heart - kidney</td>
</tr>
<tr>
<td><strong>6</strong> All remaining active candidates</td>
</tr>
<tr>
<td><strong>Status 2</strong></td>
</tr>
<tr>
<td><strong>Inactive</strong></td>
</tr>
<tr>
<td>Inactive/unable to undergo transplant</td>
</tr>
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### Status Qualification Criteria at Transplant Post-Implementation

<table>
<thead>
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<th>Criterion</th>
<th>Count</th>
<th>Percent</th>
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<tr>
<td>Adult Status 1</td>
<td>VA ECMO without hemodynamic values</td>
<td>61</td>
<td>23.28%</td>
</tr>
<tr>
<td></td>
<td>Exception</td>
<td>81</td>
<td>30.92%</td>
</tr>
<tr>
<td>Adult Status 2</td>
<td>IABP with hemodynamic values</td>
<td>551</td>
<td>39.75%</td>
</tr>
<tr>
<td></td>
<td>Exception</td>
<td>548</td>
<td>39.54%</td>
</tr>
<tr>
<td>Adult Status 3</td>
<td>Dischargeable LVAD for discretionary 30 days</td>
<td>254</td>
<td>35.98%</td>
</tr>
<tr>
<td></td>
<td>Exception</td>
<td>169</td>
<td>23.94%</td>
</tr>
<tr>
<td>Adult Status 4</td>
<td>Dischargeable LVAD without discretionary 30 days</td>
<td>238</td>
<td>42.96%</td>
</tr>
<tr>
<td></td>
<td>Exception</td>
<td>115</td>
<td>20.76%</td>
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For each status, only the most common criterion and the number of exceptions is shown. For complete criteria data, see full report.
## Devices at Transplant by Era

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Median Days to Transplant by Region

Median days to transplant is omitted for Region 10 pre-implementation because fewer than 50% of candidates were transplanted within one year.
Transplants by Share Type and Era

Number of Transplants

<table>
<thead>
<tr>
<th>Share Type</th>
<th>Era</th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local</td>
<td>Pre</td>
<td>1895</td>
<td>1015</td>
</tr>
<tr>
<td>Regional</td>
<td>Pre</td>
<td>433</td>
<td>690</td>
</tr>
<tr>
<td>National</td>
<td>Pre</td>
<td>622</td>
<td>1326</td>
</tr>
</tbody>
</table>

Era: Pre, Post

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Transplants by Zone and Era

Number of Transplants

<table>
<thead>
<tr>
<th>Zone</th>
<th>Era</th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>DSA</td>
<td></td>
<td>1895</td>
<td>1015</td>
</tr>
<tr>
<td>Zone A</td>
<td>936</td>
<td>1650</td>
<td></td>
</tr>
<tr>
<td>Zone B</td>
<td>122</td>
<td>360</td>
<td>1</td>
</tr>
<tr>
<td>Zone C</td>
<td>7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Sequence Number of Acceptor by Era

There were 8 acceptances with an offer number over 200 in the pre era and 7 in the post era (not shown).
Time from First Electronic Offer to Cross Clamp

* High probability density values mean that a high percentage of the population lies at or around the corresponding x-axis value, and vice versa. Red line indicates the mean in each corresponding era.
Center-Level Heart Transplant Volume by Era
**Freedom From Death or Retransplantation: Prior System vs. New System**

<table>
<thead>
<tr>
<th>Analysis Time (Days)</th>
<th>Prior System</th>
<th>New System</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6001</td>
<td>539</td>
</tr>
<tr>
<td>50</td>
<td>5704</td>
<td>125</td>
</tr>
<tr>
<td>100</td>
<td>5607</td>
<td>45</td>
</tr>
<tr>
<td>150</td>
<td>5520</td>
<td>37</td>
</tr>
<tr>
<td>200</td>
<td>4734</td>
<td>2</td>
</tr>
</tbody>
</table>

Hazard ratio 2.1, 95% CI 1.4-2.9, log rank p<0.0001

Cogswell, et al.
JHLT 2020; 39:1-4
Freedom From Death or Retransplantation: Prior System vs. New System (cont.)

Hazard ratio 2.1, 95% CI 1.4-3.2, log rank p<0.0001

Cogswell, et al.
JHLT 2020; 39:1-4
Justification Forms by Status and Exception vs Standard Review

- Adult Status 1
- Adult Status 2
- Adult Status 3
- Adult Status 4

Count

Exception
- No
- Yes

Heart Status
Justification Forms by Status and Form Type

- Status 1 Initial Listing
- Status 1 Extension
- Status 2 Initial Listing
- Status 2 Extension
- Status 3 Initial Listing
- Status 3 Extension
- Status 4 Initial Listing
- Status 4 Extension

Count

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Justification Forms by Status and Month Submitted

Due to the time period examined, October 2019 and September 2018 are not complete months.
Conclusions from Justification Forms by Reviewing Region

![Bar chart showing conclusions by OPTN Region Reviewing Form.]
Heart Utilization and Discard

- Little change in utilization/discard rates pre vs post
  - For non-DCD donors, utilization was 36.96% pre-implementation vs 36.76% post-implementation
  - For non-DCD donors, the discard rate was 0.79% pre-implementation vs 0.91% post-implementation
- No difference in utilization pre vs post when stratifying by donor age
No significant change in:
- Waiting list additions
- Waiting list composition
- Number of transplants
- Waiting list mortality

Significant increase in transplant rates for Status 1A candidates aged 11-17
- 432 per 100 patient-years pre vs 933 per 100 patient-years post

Significant decrease in transplant rates for Status 1B candidates aged 0-5
- 145 per 100 patient-years pre vs 60 per 100 patient-years post