One-Year Monitoring Report on Revisions to the Adult Heart Allocation System

Kelsi Lindblad
Thoracic Committee Meeting
February 27, 2020
2018 Adult Heart Allocation Modifications

- Major changes:
  - New medical urgency status classifications and qualifying criteria
  - Broader sharing 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

- Changes implemented October 18, 2018
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)

- New in this presentation: outcomes data, waiting list mortality and transplant rates, median time to transplant, and electronic offer data

- See complete report for additional analyses: heart utilization, pediatrics, data stratified by region, and additional analyses as indicated in this presentation
Waiting List

3990 adult heart waiting list registrations added pre-implementation compared to 3931 added post-implementation
Waiting List Additions by Status and Era

Percent Waiting List Additions

Era

Pre Post

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
- Temporarily Inactive

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

981 (24.59%)
1865 (46.74%)
1058 (26.52%)
872 (22.18%)
717 (18.24%)
1562 (39.74%)
479 (12.19%)
<table>
<thead>
<tr>
<th>Status</th>
<th>Criterion</th>
<th>Count</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult Status 1</td>
<td>VA ECMO without hemodynamic values</td>
<td>60</td>
<td>35.71%</td>
</tr>
<tr>
<td>Adult Status 1</td>
<td>Exception</td>
<td>32</td>
<td>19.05%</td>
</tr>
<tr>
<td>Adult Status 2</td>
<td>IABP with hemodynamic values</td>
<td>342</td>
<td>47.37%</td>
</tr>
<tr>
<td>Adult Status 2</td>
<td>Exception</td>
<td>227</td>
<td>31.44%</td>
</tr>
<tr>
<td>Adult Status 3</td>
<td>Dischargeable LVAD for discretionary 30 days</td>
<td>118</td>
<td>24.43%</td>
</tr>
<tr>
<td>Adult Status 3</td>
<td>Exception</td>
<td>86</td>
<td>17.81%</td>
</tr>
<tr>
<td>Adult Status 4</td>
<td>Dischargeable LVAD without discretionary 30 days</td>
<td>709</td>
<td>44.85%</td>
</tr>
<tr>
<td>Adult Status 4</td>
<td>Exception</td>
<td>249</td>
<td>15.75%</td>
</tr>
</tbody>
</table>

For each status, only the most common criterion and the number of exceptions is shown. For complete criteria data, see full report.
# Devices at Listing 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>57</td>
<td>3.74%</td>
</tr>
<tr>
<td>ECMO</td>
<td>Post</td>
<td>119</td>
<td>6.52%</td>
</tr>
<tr>
<td>IABP</td>
<td>Pre</td>
<td>182</td>
<td>11.93%</td>
</tr>
<tr>
<td>IABP</td>
<td>Post</td>
<td>484</td>
<td>26.52%</td>
</tr>
<tr>
<td>LVAD</td>
<td>Pre</td>
<td>1204</td>
<td>78.95%</td>
</tr>
<tr>
<td>LVAD</td>
<td>Post</td>
<td>1106</td>
<td>60.60%</td>
</tr>
<tr>
<td>RVAD, LVAD+RVAD, TAH</td>
<td>Pre</td>
<td>82</td>
<td>5.38%</td>
</tr>
<tr>
<td>RVAD, LVAD+RVAD, TAH</td>
<td>Post</td>
<td>116</td>
<td>6.35%</td>
</tr>
</tbody>
</table>

For complete device data, see full report.
Waiting List Mortality

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
- Temporarily Inactive
- Overall

Era

- Pre
- Post

Deaths per 100 Patient-Years
Transplant

2954 adult heart transplants performed pre-implementation compared to 3032 adult heart transplants performed post-implementation
Transplants by Status and Era

Era

Percent Heart Transplants

Status

2018 (68.31%)
262 (8.64%)
1386 (45.71%)
835 (28.27%)
706 (23.28%)
554 (18.27%)

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

Pre
Post

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
### Status Qualification Criteria at Transplant Post-Implementation

<table>
<thead>
<tr>
<th>Status</th>
<th>Criterion</th>
<th>Count</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<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>
</tr>
</tbody>
</table>

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

<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>
<td>Post</td>
<td>159</td>
<td>7.42%</td>
</tr>
<tr>
<td>IABP</td>
<td>Pre</td>
<td>221</td>
<td>13.22%</td>
</tr>
<tr>
<td>IABP</td>
<td>Post</td>
<td>822</td>
<td>38.34%</td>
</tr>
<tr>
<td>LVAD</td>
<td>Pre</td>
<td>1328</td>
<td>79.43%</td>
</tr>
<tr>
<td>LVAD</td>
<td>Post</td>
<td>1002</td>
<td>46.74%</td>
</tr>
<tr>
<td>RVAD, LVAD+RVAD, TAH</td>
<td>Pre</td>
<td>93</td>
<td>5.57%</td>
</tr>
<tr>
<td>RVAD, LVAD+RVAD, TAH</td>
<td>Post</td>
<td>161</td>
<td>7.51%</td>
</tr>
</tbody>
</table>

For complete device data, see full report
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.
## 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>

<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

![Graph showing transplant rates by status and era. The x-axis represents Transplants per 100 Patient-Years, ranging from 0 to 3000. The y-axis lists different status categories, including Status 1A, Status 1B, Status 2, Adult Status 1, Adult Status 2, Adult Status 3, Adult Status 4, Adult Status 5, Adult Status 6, and Overall. The graph indicates varying rates across these categories, with some statuses showing higher rates than others. The era is indicated by blue and green markers, with blue representing pre and green representing post.](image-url)
Transplants by Zone and Era

<table>
<thead>
<tr>
<th>Zone</th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>DSA</td>
<td>1895</td>
<td>1015</td>
</tr>
<tr>
<td>Zone A</td>
<td>936</td>
<td></td>
</tr>
<tr>
<td>Zone B</td>
<td>122</td>
<td>360</td>
</tr>
<tr>
<td>Zone C</td>
<td>1</td>
<td>7</td>
</tr>
</tbody>
</table>

Era: Pre | Post

Number of Transplants
Transplants by Distance Traveled and Share Type

Transplants with unreported share type involved organs recovered in Canada
Transplants by Zone, Era, and Status

Era

Number of Transplants

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

Three Zone C transplants omitted from plot
Distance Traveled at Transplant by Era

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.
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
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 Era

- Survival over time for two eras: Pre and Post.
- p-value: 0.22

Graph shows decreasing survival rates with time for both eras, with the Post era generally having a slightly higher survival rate compared to the Pre era.
Six-Month Graft Survival by Status Pre-Implementation
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

Survival vs. Time (Days)

Era
- Pre
- Post

p-value: 0.4
Regional Review Board

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

Month

2018-Sep
2018-Oct
2018-Nov
2018-Dec
2019-Jan
2019-Feb
2019-Apr
2019-May
2019-Jun
2019-Jul
2019-Aug
2019-Sep
2019-Oct

Status Requested

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

Count

Due to the time period examined, October 2019 and September 2018 are not complete months.
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

Counts:
- Status 1 Initial Listing: 200
- Status 1 Extension: 50
- Status 2 Initial Listing: 600
- Status 2 Extension: 500
- Status 3 Initial Listing: 700
- Status 3 Extension: 700
- Status 4 Initial Listing: 800
- Status 4 Extension: 300

Optn
Organ Procurement and Transplantation Network
Justification Forms by Status and Exception vs Standard Review

Heart Status

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

Exception

No
Yes

Count

0 500 1000
Conclusions from Justification Forms by Reviewing Region
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
Pediatrics

- 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
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