SESSION V
CONTROVERSIES IN ADVANCED HEART DISEASE

The New UNOS Donor Heart Allocation Proposal is NOT Fair!

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What are the goals of the proposal?

- **Reduce waiting list mortality rates**
  - Active heart transplant candidates have doubled since 2006
  - 548% increase of Status 1A candidates
  - Status 1A candidates are 3x more likely to die on the waiting list
    - Mortality risks are vastly disparate

- **Reduce the use of exceptions to qualify for a status**
What are the goals of the proposal?

• Accommodate increased use of mechanical circulatory support devices

• Improve overall access to transplantation by modifying geographical distribution
  – OPTN Final Rule: Organ allocation policies “[s]hall not be based on the candidate’s place of residence or place of listing…”
# Proposed New Statuses

<table>
<thead>
<tr>
<th>Current Status</th>
<th>Proposed Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>3</td>
</tr>
<tr>
<td>1B</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>6</td>
</tr>
</tbody>
</table>
## Proposed Statuses

<table>
<thead>
<tr>
<th>Status</th>
<th>Criteria</th>
</tr>
</thead>
</table>
| 1      | ECMO (14 days)  
Non-dischargeable (surgically implanted) VAD  
MCS with life-threatening ventricular arrhythmia |
| 2      | IABP  
Ventricular tachycardia/ventricular fibrillation, mechanical support not required  
Total artificial heart  
Dischargeable BiVAD, RVAD, or single ventricle patients with LVAD  
Percutaneous endovascular mechanical circulatory devices  
MCS with device malfunction/mechanical failure |
| 3      | Dischargeable LVAD for up to 30 days  
Multiple inotropes or single high dose inotropes with continuous hemodynamic monitoring  
MCS with device related complications |
## Proposed Statuses

<table>
<thead>
<tr>
<th>Status</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Stable LVAD Inotropes without Hemodynamic Monitoring Diagnosis exceptions: Congenital heart disease, Amyloidosis, Hypertrophic cardiomyopathy, Restrictive cardiomyopathy Re-transplant</td>
</tr>
<tr>
<td>5</td>
<td>Combined organ transplants</td>
</tr>
<tr>
<td>6</td>
<td>All remaining active candidates</td>
</tr>
</tbody>
</table>
ECMO as Bridge to Transplant

Kaplan-Meier survival estimates

log rank, p < 0.0001

Months of Follow Up

0 12 24 36 48 60 72 84 96 108 120 132 144

No ECMO  ECMO Support

DePasquale, EC et al., The Journal of Heart and Lung Transplantation April 2013; Vol 32, Issue 4
ECMO as Bridge to MCS

Artificial Organs 2016

Cedars-Sinai
ECMO

- Salvage therapy

- ECMO patients are high risk and usually portend worse survival
  - Scarcity of donor hearts

- 14 days may be too late to effectively transition patients to another support
“Gaming”

- Incentivizes usage of ECMO
- Incentivizes usage of IABP
- Incentivizes usage of temporary mechanical support instead of durable devices

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Current Allocation Policy

Geographic Allocation
Local: Status 1A, Status 1B
Zone A: Status 1A, Status 1B
Local: Status 2
Zone B: Status 1A, Status 1B
Zone A: Status 2
Zone B: Status 2
OPO Donation Service Areas

58 OPO Donation Service Areas in the U.S.

OPO Data

Population Bases ranged from 1.2 Million to 18.9 Million
Deceased Donors Recovered ranged from 32 to 439 Donors
Donors per million (dpm) ranged from 17 to 44 DPM: 26.5 mean
### Proposed Broader Sharing Sequence

<table>
<thead>
<tr>
<th>Candidate Status</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status 1 Adult + Status 1A Pediatric</td>
<td>Local + Zone A</td>
</tr>
<tr>
<td>Status 2 Adult</td>
<td>Local + Zone A</td>
</tr>
<tr>
<td>Status 3 Adult + Status 1B Pediatric</td>
<td>Local</td>
</tr>
<tr>
<td>Status 1 Adult + Status 1A Pediatric</td>
<td>Zone B</td>
</tr>
<tr>
<td>Status 2 Adult</td>
<td>Zone B</td>
</tr>
<tr>
<td>Status 4 Adult</td>
<td>Local</td>
</tr>
<tr>
<td>Status 3 Adult + Status 1B Pediatric</td>
<td>Zone A</td>
</tr>
<tr>
<td>Status 5 Adult + Status 2 Pediatric</td>
<td>Local</td>
</tr>
<tr>
<td>Status 3 Adult + Status 1B Pediatric</td>
<td>Zone B</td>
</tr>
<tr>
<td>Status 6 Adult + Status 2 Pediatric</td>
<td>Local</td>
</tr>
<tr>
<td>Status 1 Adult + Status 1A Pediatric</td>
<td>Zone C</td>
</tr>
<tr>
<td>Status 2 Adult</td>
<td>Zone C</td>
</tr>
<tr>
<td>Status 3 Adult + Status 1B pediatric</td>
<td>Zone C</td>
</tr>
<tr>
<td>Status 4 Adult</td>
<td>Zone A</td>
</tr>
</tbody>
</table>
Broader Sharing

- Increased travel time increases longer ischemic times which can worsen outcomes
  - Compounds risk factor with high risk recipients
- Increased costs
  - Transportation
  - Benefits large transplant centers
- Benefit/Hurt coastal region programs and those who do not share a central location
- Zones do not account for population density
- The waitlist in larger programs can potentially increase
- Back up centers may be necessary
Conclusion

• The new UNOS heart allocation proposal will...

  – decrease wait list mortality vs increase post transplant morbidity and mortality

  – Broader sharing will benefit sicker patients however may compromise outcomes due to increased ischemic time

  – Benefit small transplant centers/OPO DSA vs benefit large transplant centers