

SESSION V
CONTROVERIES 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

Current Status	Proposed Status
1 A	1
	2
	3
1 B	4
2	5
	6



Proposed Statuses

Status	Criteria
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

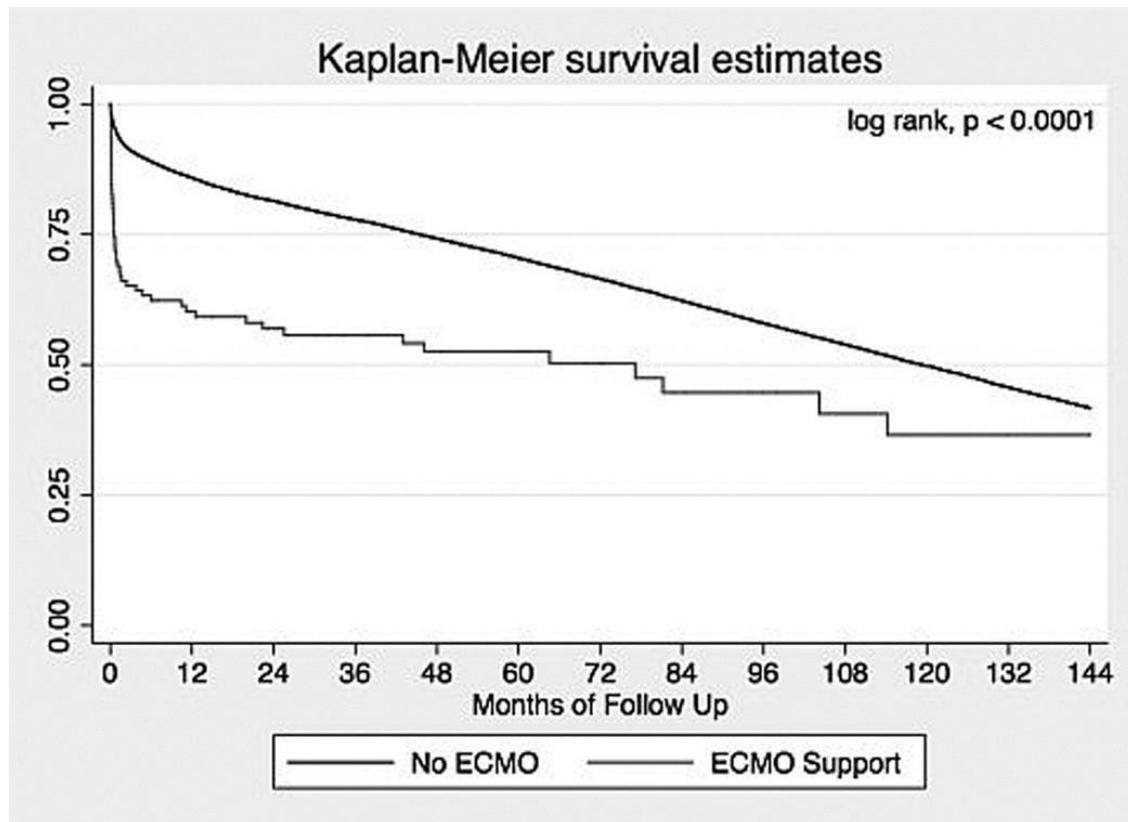


Proposed Statuses

Status	Criteria
4	Stable LVAD Inotropes without Hemodynamic Monitoring Diagnosis exceptions: Congenital heart disease, Amyloidosis, Hypertrophic cardiomyopathy, Restrictive cardiomyopathy Re-transplant
5	Combined organ transplants
6	All remaining active candidates



ECMO as Bridge to Transplant

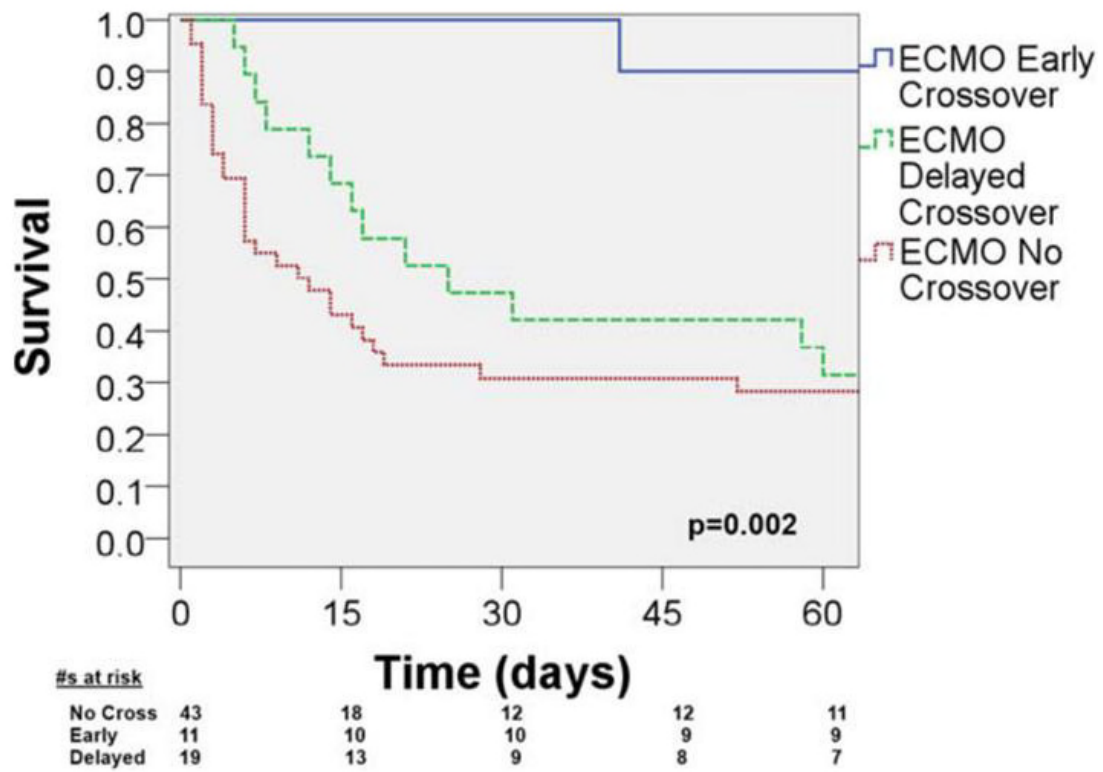


DePasquale, EC et al., The Journal of Heart and Lung Transplantation April 2013; Vol 32, Issue 4



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ECMO as Bridge to MCS



Cheng R, et al. Device Strategies for Patients in INTERMACS Profiles 1 and 2 Cardiogenic Shock: Double Bridge with Extracorporeal Membrane Oxygenation and Initial Implant of More Durable Devices Artificial Organs 2016



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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

Status	Criteria
1	ECMO (14 days) Non-dischargeable (surgically implanted) VAD MCS with life-threatening ventricular arrhythmia
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Current Allocation Policy



Geographic Allocation

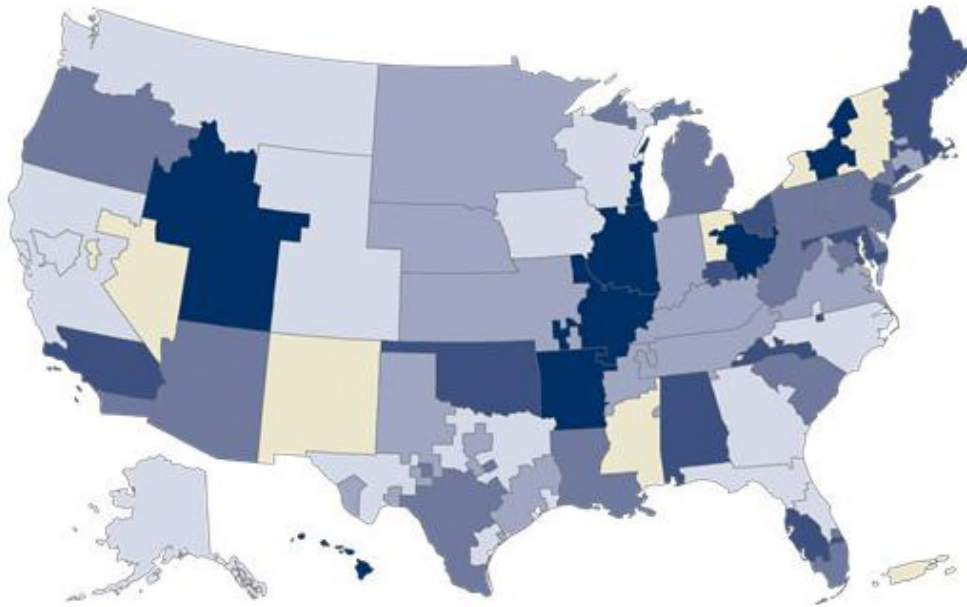
- Local: Status 1A, Status 1B
- Zone A: Status 1A, Status 1B
- Local: Status 2
- Zone B: Status 1A, Status 1B
- Zone A: Status 2
- Zone B: Status 2



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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

Candidate Status	Location
Status 1 Adult + Status 1 A Pediatric	Local + Zone A
Status 2 Adult	Local + Zone A
Status 3 Adult + Status 1 B Pediatric	Local
Status 1 Adult + Status 1 A Pediatric	Zone B
Status 2 Adult	Zone B
Status 4 Adult	Local
Status 3 Adult + Status 1 B Pediatric	Zone A
Status 5 Adult + Status 2 Pediatric	Local
Status 3 Adult + Status 1 B Pediatric	Zone B
Status 6 Adult + Status 2 Pediatric	Local
Status 1 Adult + Status 1 A Pediatric	Zone C
Status 2 Adult	Zone C
Status 3 Adult + Status 1 B pediatric	Zone C
Status 4 Adult	Zone A



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

