



# Issues with the New Donor Heart Allocation Proposal

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**RESOLVING THE ORGAN SHORTAGE**



PRACTICE |



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POLITICS

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# Do we have Issues?



# Conflict of Interest Disclosure

I have no relevant financial relationships to disclose.

# Background

## Problems

- Too many candidates waiting as Status 1A (3x more likely to die on waiting list)
- Changing landscape of HF management – LVAD usage
- Specific patient groups may be disenfranchised
- Inequities in access to organs because of artificial geographic boundaries

## Goals

- Reduce waiting list mortality
- Better stratify candidates based on medical urgency
- Expand access to donor organs for the most critically ill patients

# Proposed New Statuses: High Level

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

- Proposed statuses 1-3 are generally defined by current status 1A criteria
- Proposed status 4 is generally defined by current status 1B criteria
- Proposed status 5-6 are generally defined by current status 2 criteria

# Proposed Statuses 1-3

Status	Criteria
1	<ul style="list-style-type: none"> <li>• ECMO</li> <li>• Continuous Mechanical ventilation</li> <li>• Non-dischargeable (surgically implanted) VAD</li> <li>• MCSD with life-threatening ventricular arrhythmia</li> </ul>
2	<ul style="list-style-type: none"> <li>• Intra-aortic balloon pump</li> <li>• Ventricular tachycardia/ventricular fibrillation, mechanical support not required</li> <li>• MCSD with device malfunction/mechanical failure</li> <li>• Total artificial heart</li> <li>• Dischargeable BiVAD or RVAD</li> <li>• Acute circulatory support</li> </ul>
3	<ul style="list-style-type: none"> <li>• Dischargeable LVAD for up to 30 days</li> <li>• Multiple inotropes or single high-dose inotropes with continuous hemodynamic monitoring</li> <li>• MCSD with device infection</li> <li>• MCSD with hemolysis</li> <li>• MCSD with pump thrombosis</li> <li>• MCSD with right heart failure</li> <li>• MCSD with mucosal bleeding</li> <li>• MCSD with aortic insufficiency</li> </ul>

# Proposed Statuses 4-6

Status	Criteria
4	<ul style="list-style-type: none"><li>• Stable LVAD candidates not using 30 day discretionary period</li><li>• Inotropes without hemodynamic monitoring</li><li>• Diagnosis of congenital heart disease (CHD)</li><li>• Diagnosis of ischemic heart disease with intractable angina</li><li>• Diagnosis of hypertrophic cardiomyopathy</li><li>• Diagnosis of restrictive cardiomyopathy</li><li>• Diagnosis of amyloidosis</li><li>• Retransplant</li></ul>
5	Combined organ transplants
6	All remaining active candidates



# Do we have Issues?

- Preference for HAS
- Should ECMO be in the highest status?
- Should TAH be in Tier 2?
- Should we eliminate or extend the 30 day elective VAD times?
- Where should percutaneous VADS be placed in the system?



# Do we have More Issues?

- How should inotrope-dependent patients be categorized?
- Potentially disenfranchised groups
  - The highly sensitized individual
  - Congenital heart disease/restrictive CMP
  - Amyloid patients
- Broader geographic sharing
- Transition from the current to new system

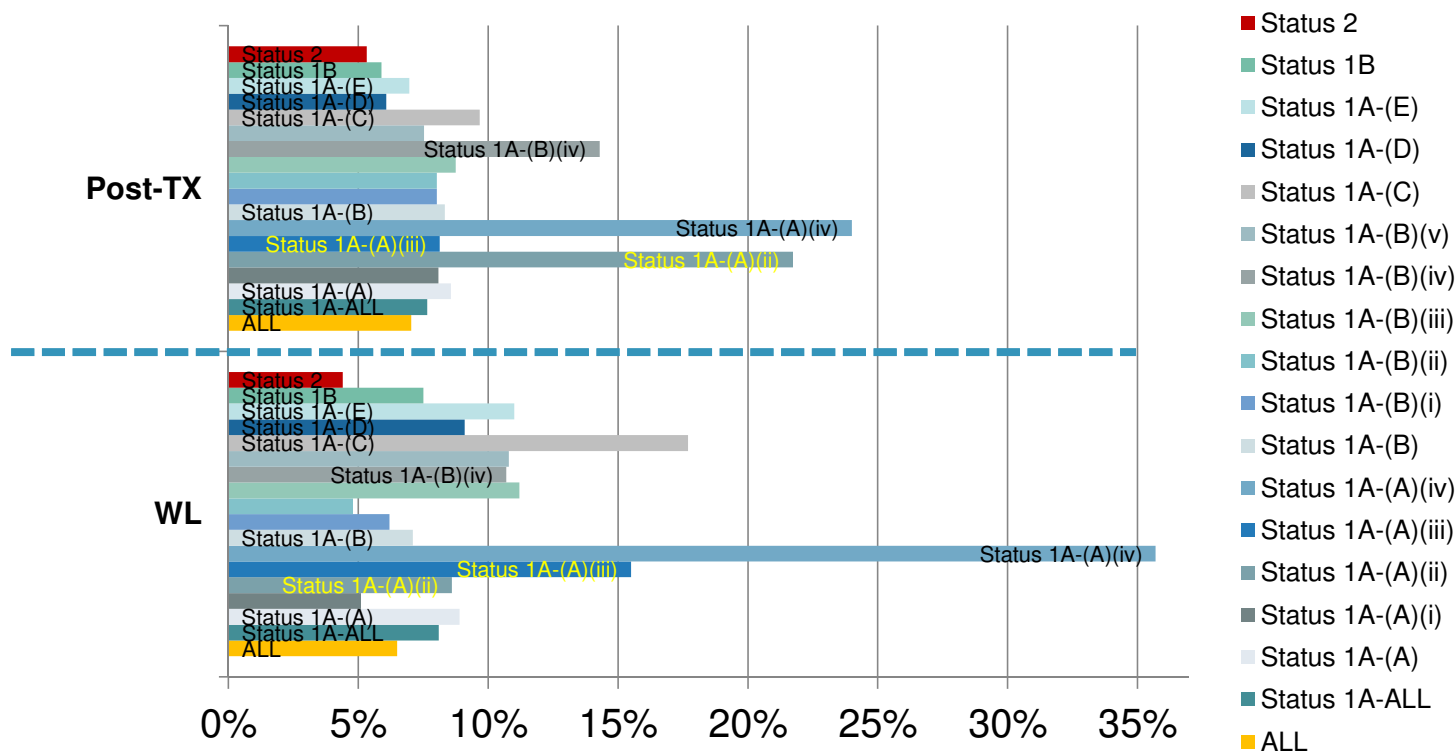
# Heart Allocation Score

- OPTN does not collect enough the data necessary to develop a score
- Inflexible solution
- Changes in heart transplant technology occurring too quickly
- Proposal includes prospective collection of key data elements in preparation for the future HAS

# ECMO Priority

- Will ECMO in highest priority incentivize increased use of ECMO?
- If so, will post-transplant outcomes be worse?
- Is there potential for outcomes to be better if ECMO patients are transplanted quicker?
- Assessment of net transplant benefit

## % died within 6 months\*: ever waiting in criteria or sub-criteria



\* For WL analysis, time is computed from first entry into criteria/sub-criteria, rather than time since listing.

### Sub-criteria:

A(i) = VAD for 30 days  
 A(ii) = TAH  
 A(iii) = Intra-aortic balloon pump  
 A(iv) = ECMO

B(i) = Thromboembolism  
 B(ii) = Device infection  
 B(iii) = Device malfunction  
 B(iv) = Life-threatening ventricular arrhythmia  
 B(v) = Other device related complication

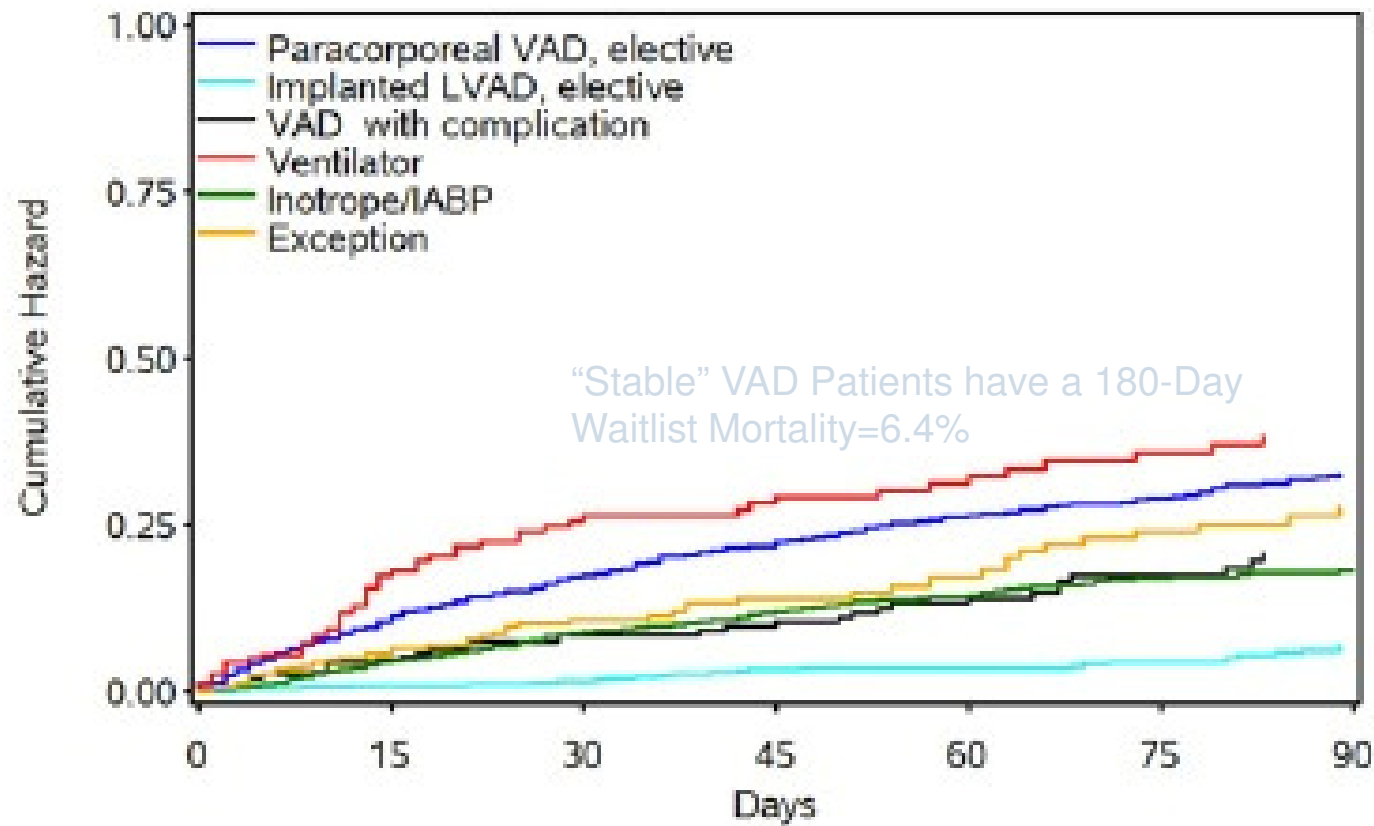
# Total Artificial Heart (TAH)

- Proposal: all TAH candidates grouped together in status 2 (hospitalized and not hospitalized)
- Debate about whether outpatient TAH are more stable (should they be in a lower status?)
- Debate about whether inpatient TAH are less stable (should they be in a higher status?)

# VAD for 30 Days

- Debate:
  - Eliminate 30 day time
    - Candidates are at lower risk of developing adverse events when using this criterion
    - Candidates using this criterion have lower WL mortality risk than others in same status
  - Retain 30 day time
    - Candidates should not have to risk becoming unstable to get priority for transplant
- Proposal: retains elective 30 day time for stable LVAD patients in status 3 - compromise

# The Waitlist Mortality for “Stable” VAD Patients

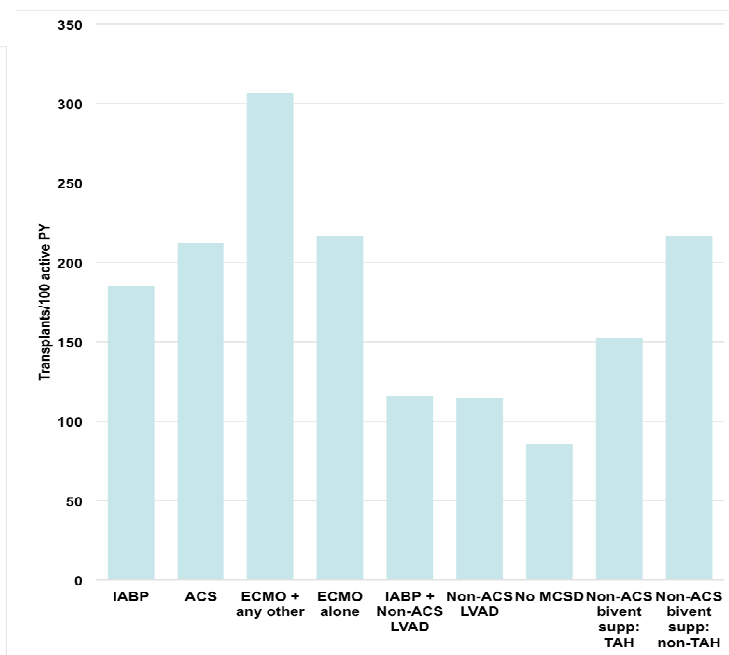
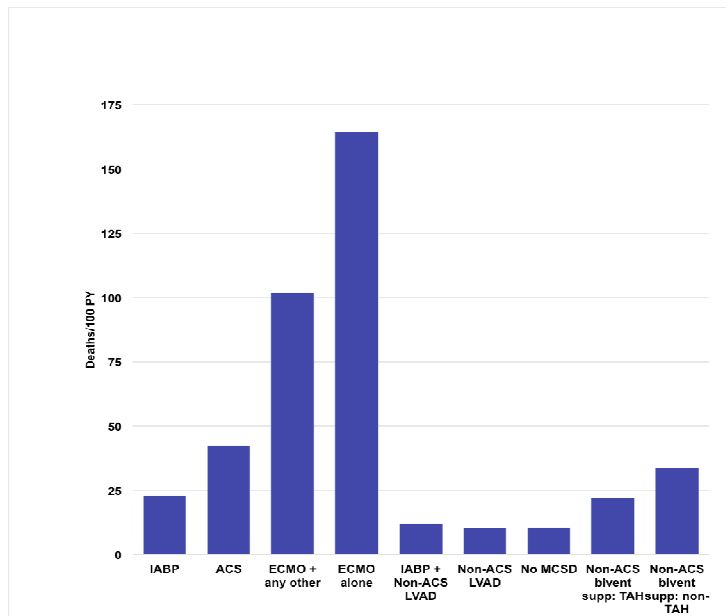


J Am Coll Cardiol 2012;60:36-43



# Percutaneous VAD

## Waiting list death rates and transplant rates by detailed device grouping at listing



# PAC + 1 high-dose or multiple inotropes

- Requirements for  $CI \leq 2.2$  L/min/m<sup>2</sup>
- Options for hemodynamic monitoring
  - Cardiac output
  - LVEDP
  - Future technologies
- Physiologic indication for inotropic support

# Sensitization Challenges

## Identifying Sensitized Candidates

Low percentage (14%) of waitlist registrations have UAs reported

Significant # of heart transplant programs reported UAs for 0 registrations

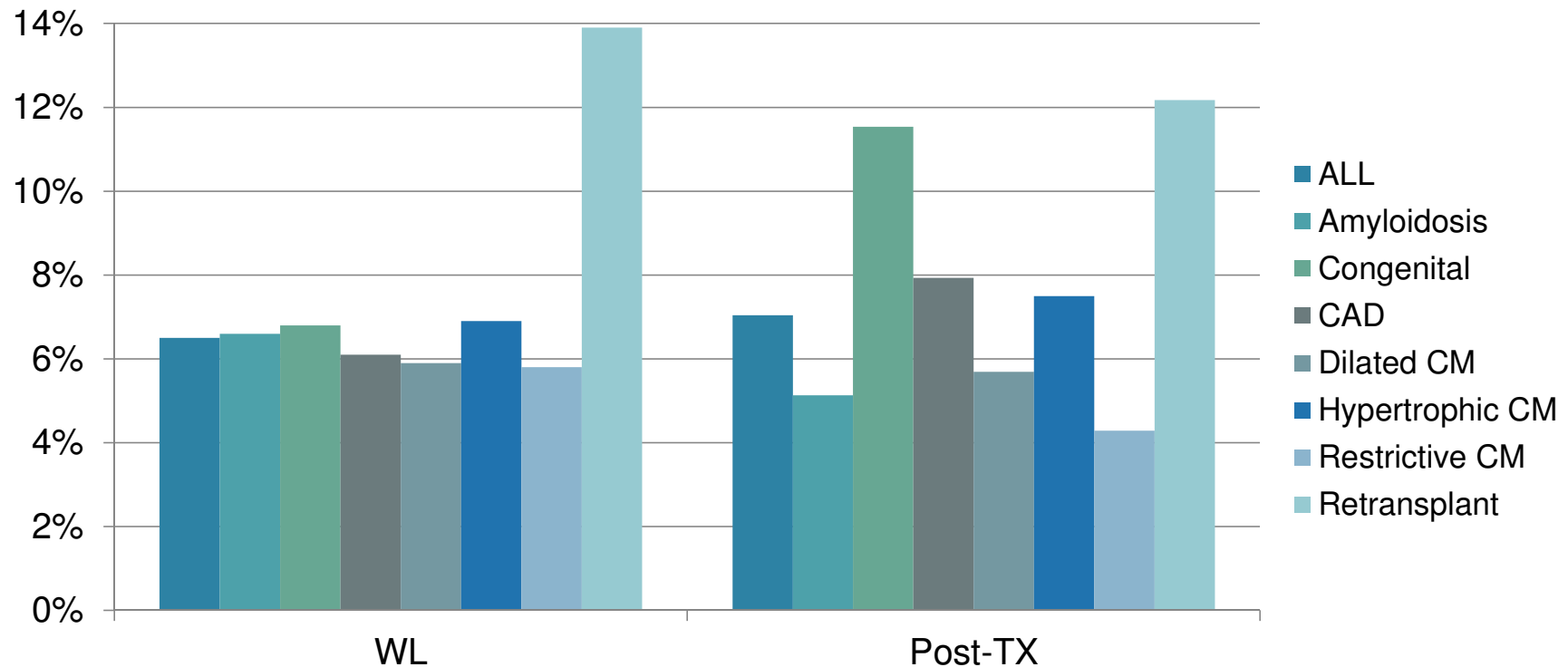
UAs reported in WL not complete enough to compute CPRA

## Prioritizing Sensitized Candidates

Add # days waiting time

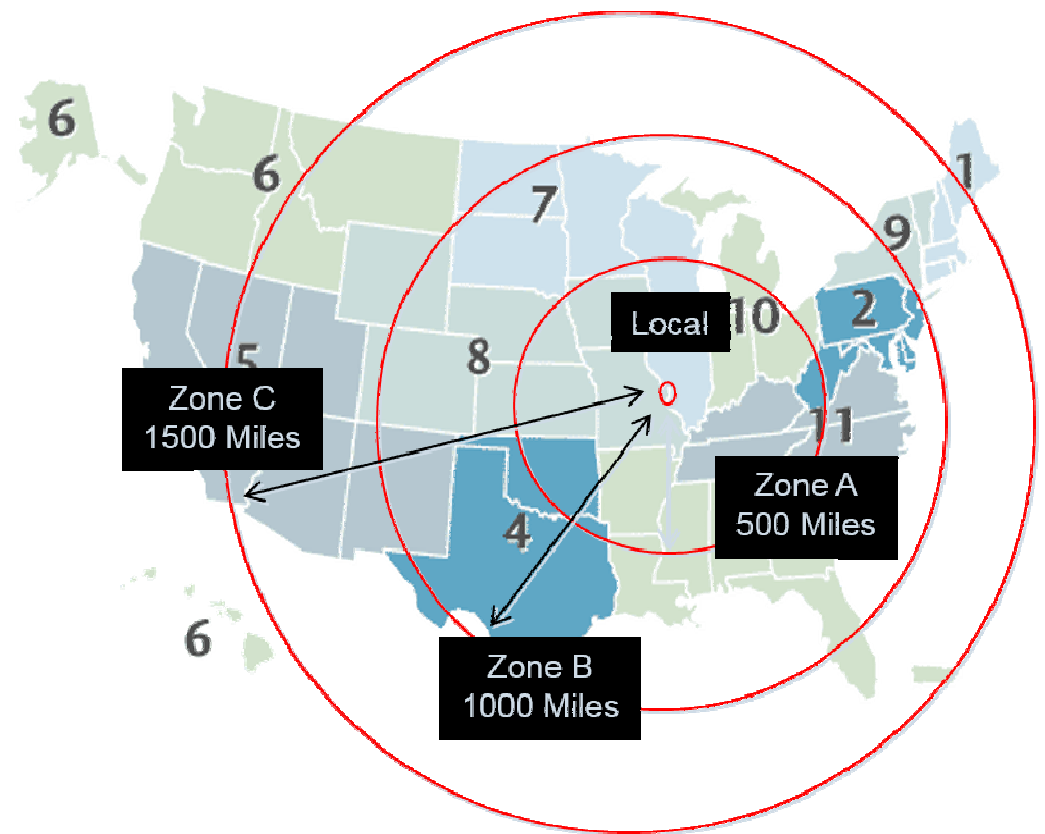
Move up to a different tier

# % died within 6 months: diagnosis



# Current Allocation Policy

- 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
- Etc...

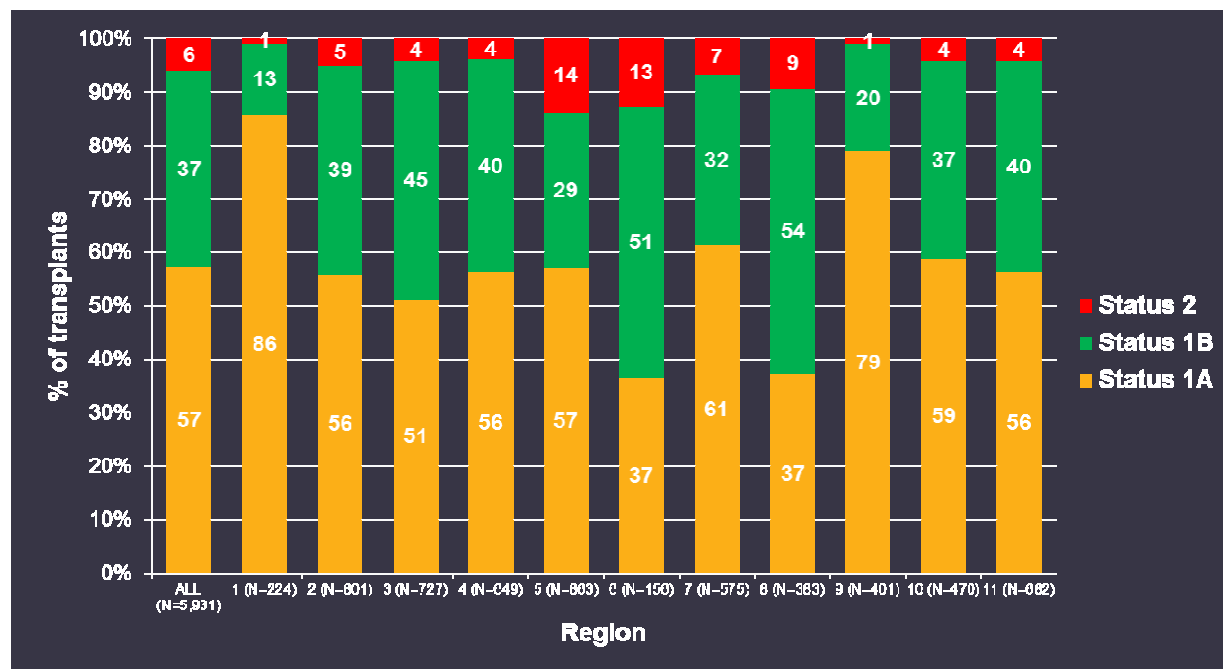


# Geographical Challenges in Heart Allocation



A status 1B patient in NYC would be transplanted before a status 1A patient 15 miles away in Newark

# Regional Status Disparities





# Proposed Broader Sharing Sequence

Candidate Status	Location
Status 1 adult + Status 1A ped	DSA + Zone A
Status 1 adult + Status 1A ped	Zone B
Status 2 adult	DSA + Zone A
Status 2 adult	Zone B
Status 3 adult + Status 1B ped	DSA
Status 4 adult	DSA
Status 3 adult + Status 1B ped	Zone A

# Plan to Transition Adult Heart Candidates

## Proposal for:

Transferring  
statuses from old  
system to new

Transferring  
waiting time from  
old system to  
new

Handling  
approved and “in  
flight” exception  
requests

# Conclusions

- Reduce waiting list mortality rates – allocate organs to the most critically ill candidates
- Post-transplant survival - within each status, projected to remain comparable to those rates in the current system
- Broader geographic sharing to improve access and decrease regional disparities that may exist
- Address potentially disenfranchised patient groups
- Prospective data collection to optimize future allocation system



# Two Preferred Modeled Sequences

Broader sharing 1/2A		Broader sharing 1/2B	
Candidate status	Location	Candidate status	Location
Status 1 adult + Status 1A ped	DSA + Zone A	Status 1 adult + Status 1A ped	DSA + Zone A
Status adult + Status 1A ped	Zone B	Status 1 adult + Status 1A ped	Zone B
Status 2 adult	DSA + Zone A	Status 2 adult	DSA + Zone A
Status 2 adult	Zone B	Status 2 adult	Zone B
Status 3 adult + Status 1B ped	DSA	Status 3 adult + Status 1B ped	DSA
Status 4 adult	DSA	Status 3 adult + Status 1B ped	Zone A
Status 3 adult + Status 1B ped	Zone A	Status 4 adult	DSA

# Adult Heart Allocation Proposal: Waiting Time Transition Plan

New Status	Waiting Time Calculated As	New Status	Waiting Time Calculated As
Status 1	Accumulated time at New Status 1 Plus accumulated time at Status 1A*	Status 4	Accumulated time at New Status 4 Plus accumulated time at New Status 3 Plus accumulated time at New Status 2 Plus accumulated time at New Status 1 Plus accumulated time at Status 1A* Plus accumulated time at Status 1B
Status 2	Accumulated time at New Status 2 Plus accumulated time at New Status 1 Plus accumulated Time at Status 1A*	Status 5	Accumulated time at New Status 5 Plus accumulated time at New Status 4 Plus accumulated time at New Status 3 Plus accumulated time at New Status 2 Plus accumulated time at New Status 1 Plus accumulated time at Status 1A* Plus accumulated time at Status 1B
Status 3	Accumulated time at New Status 3 Plus accumulated time at New Status 2 Plus accumulated time at New Status 1 Plus accumulated time at Status 1A*	Status 6	Plus accumulated Time at Old Status 2 Accumulated time at New Status 6 Plus accumulated time at New Status 5 Plus accumulated time at New Status 4 Plus accumulated time at New Status 3 Plus accumulated time at New Status 2 Plus accumulated time at New Status 1 Plus accumulated time at Status 1A* Plus accumulated time at Status 1B Plus accumulated Time at Old Status 2