Overview of New Donor Heart Allocation Tiers

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RESOLVING THE ORGAN SHORTAGE

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Conflict of Interest Disclosure

I have no relevant financial relationships to disclose.

Background

The Heart Subcommittee was asked by the UNOS Board to explore opportunities for broader, more equitable sharing of donor hearts.

Review requested because of

1) the increase of candidates waiting without a corresponding increase in available donors

2) higher than desirable waiting list mortality rates in higher status patients and

3) changing management of heart failure patients with the increased use of VADs.

Goals

- Reduce waiting list mortality rates
- Reduce the use of exceptions by better accommodating all candidates within the system
- Ensure that qualifying criteria for the statuses are based on objective physiological indications rather than therapeutic intervention
- Improve overall access to transplantation by modifying geographic distribution to ensure maximum utilization of donor hearts

Options Considered

- Modify current 3-tiered system
- Develop heart allocation score
- Add more tiers

How was the proposal developed?

Identify patients with high waitlist mortality
- Considerations: waitlist mortality, transplant rates and post-transplant survival

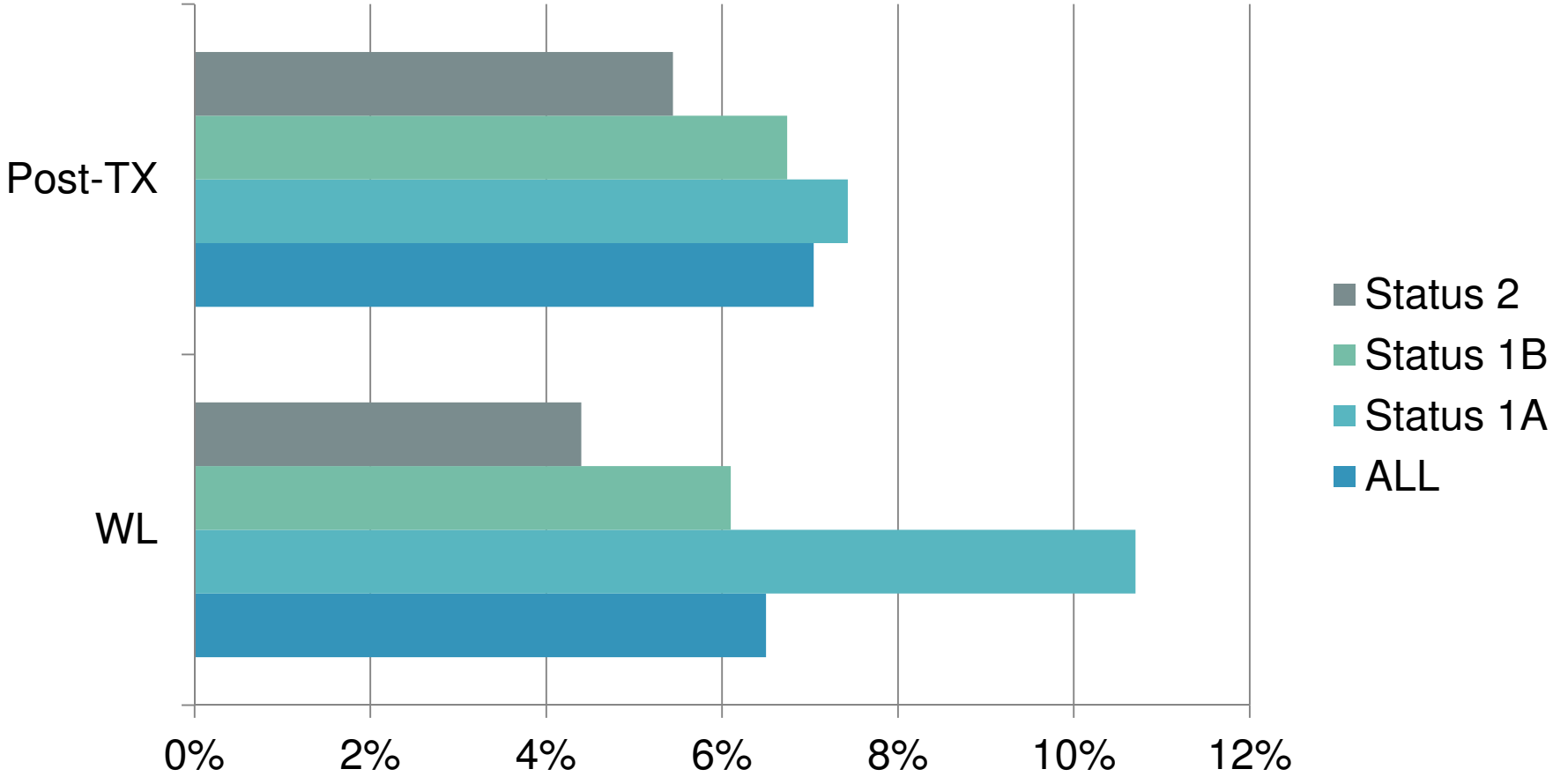
Define “criteria” for subjective decisions based upon objective data elements and physiological principles

Explore options for broader sharing for the sickest patients

Integrate pediatric allocation

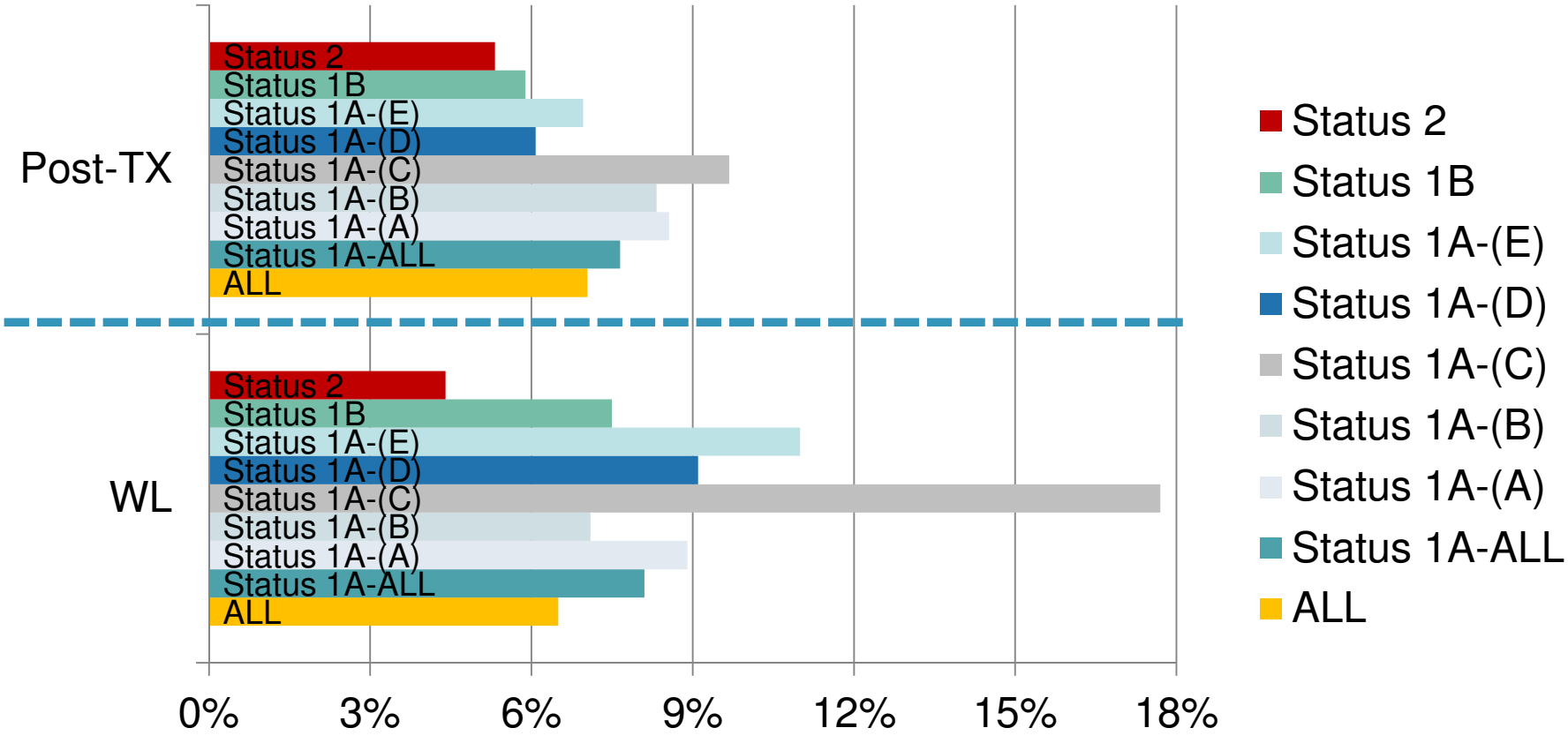
Model the above and hope/pray that the data is interpretable, accurate and explainable

% died within 6 months: medical urgency status *at* listing/transplant



UNOS Data, 2013

% died within 6 months*: ***ever waiting*** in criteria



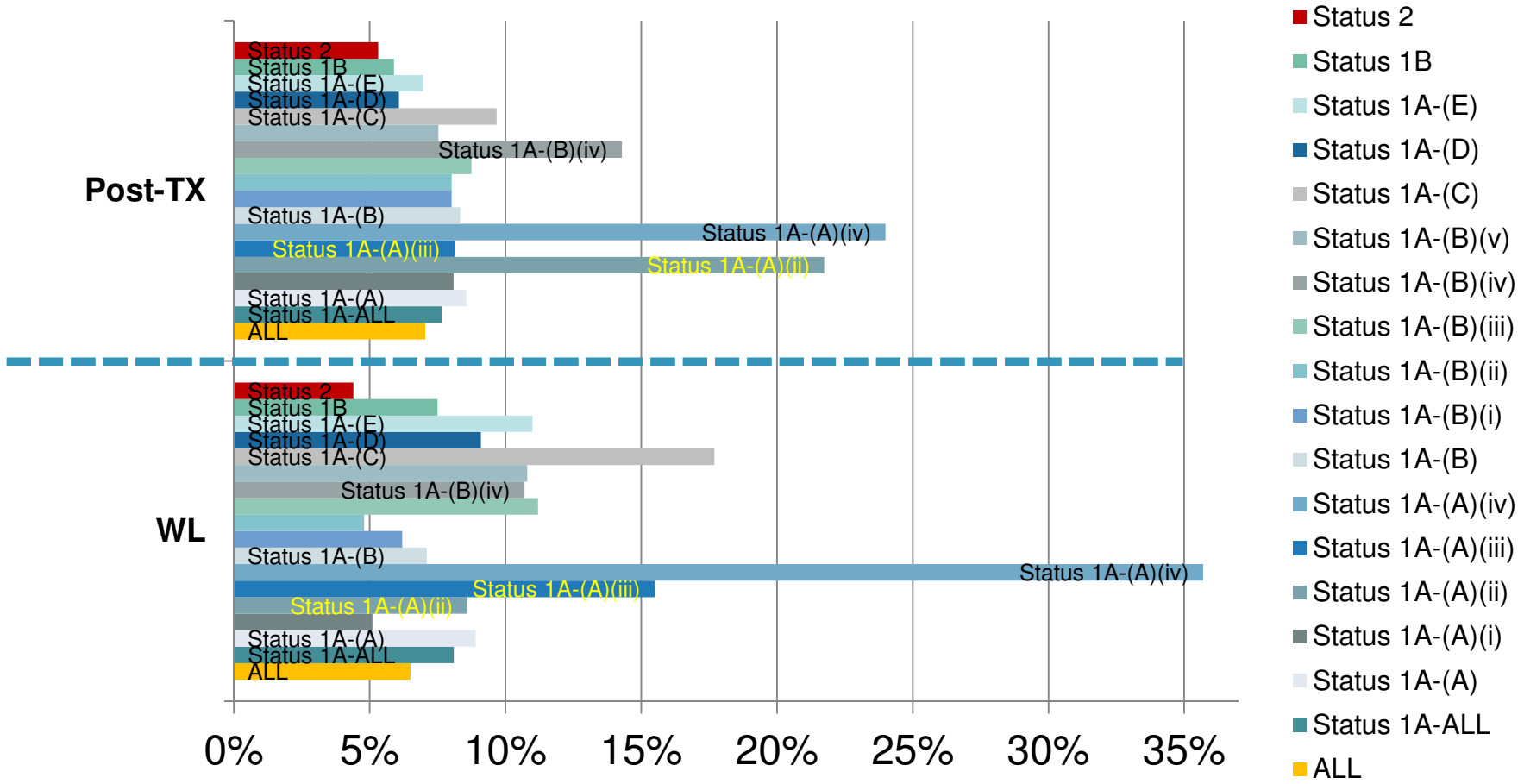
* For WL analysis, time is computed from first entry into criteria, rather than time since listing.

UNOS Data, 2013

Criteria:

A = Mechanical circulatory support (i.e., VAD for 30 days, TAH, balloon pump, ECMO)
B = Mechanical circulatory support with device complications
C = Mechanical ventilation
D = Continuous infusion of single high dose or multiple inotropes + continuous hemodynamic monitoring
E = Exception

% 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.

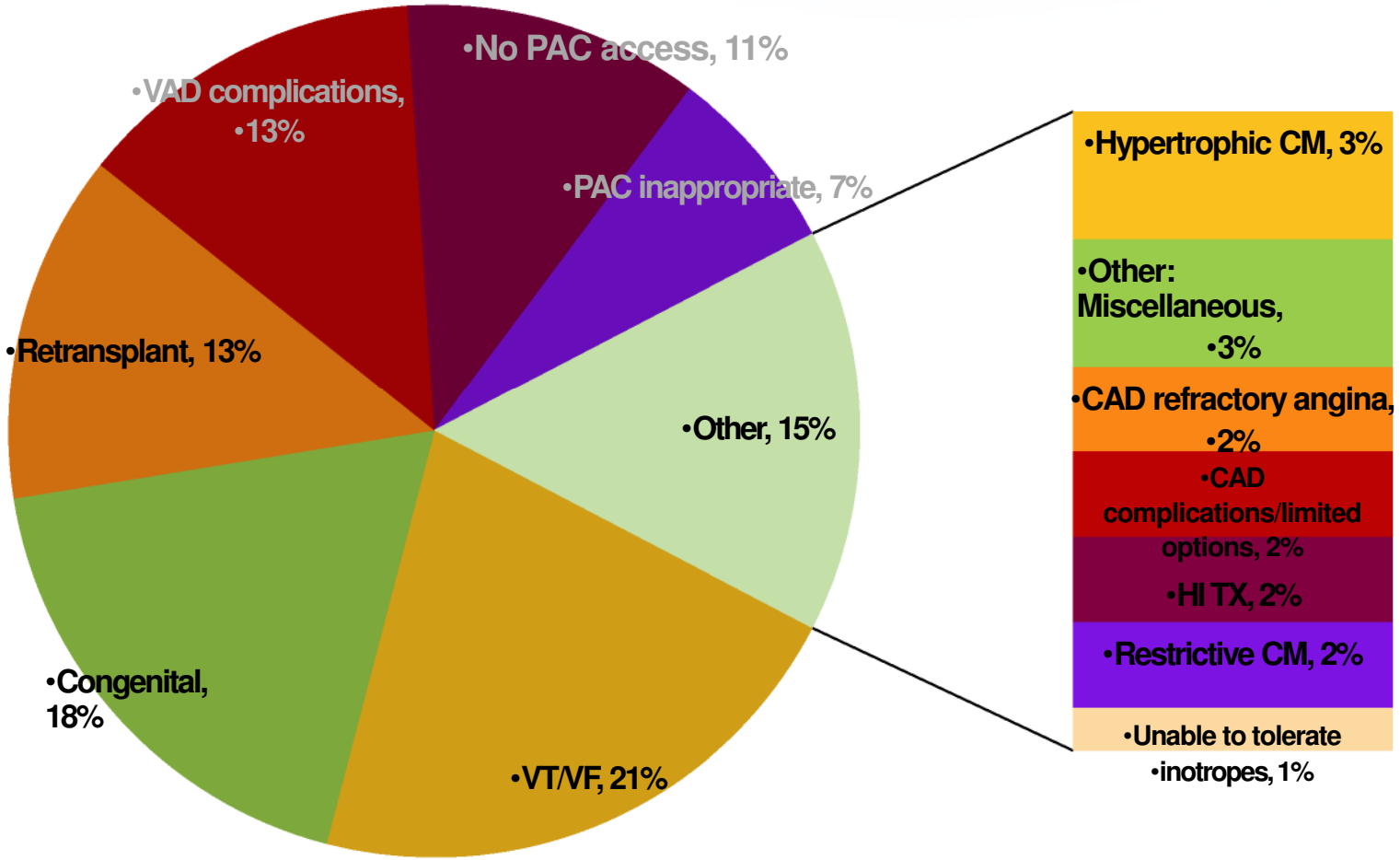
UNOS Data, 2013

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

Categories for adult status 1A exception



OPTN

Am J Transplantation 2015; 15: 44–54

UNOS DONATE LIFE


1A - Urgent
1A
1B-U
1B
ACO
2
7
Status 1A (a)
suberiteria iv - ECMO
Status 1A (a)
Suberiteria iii
IABP
Status 1A (a)
suberiteria i (VAD for 30d)
Retransplantation
Status 1A (c)
mechanical ventilation
Amyloid
Status 1A (e)
CHD
Status 1A (a)
(circulatory support device)
Status 1A (b)
(device complication)
Status 1A (d)
(IV Inotropes & continuous hemodynamic monitoring)
Ischemic Cmp
VT/VF
Status 1A (a)
Suberiteria ii
TAH
Status 1A (b)
suberiteria v
other device related complications
HOCM
Hypertrophic Cmp
Status 1A (b)
Suberiteria iv
Life-threatening Vent. arrhythmia
Status 1A (b)
Suberiteria ii
Device Infection
Restrictive Cmp
Status 1A (b)
Suberiteria iii
Device malfunction
Sensitized patient
Zonal Sharing
VAD Complxn
Unable to place lines

Table of waiting list and post-transplant outcomes by tier and criteria (1)

		Waitlist outcomes							Post-tx outcome	
Tier and subtier		Obs Days	Tx	Tx rate	Deaths	Death rate	Death/ too sick	Death/ too sick rate	Deaths	Death rate
Tier 1	1a ECMO	432	13	1099.1	18	1521.9	21	1775.5	5	26.7
	1b Mech Vent	1086	15	504.5	6	201.8	9	302.7	5	24.7
	1ci Non-disch R/BiVAD	404	15	1356.1	2	180.8	3	271.2	3	10.9
	1ci VAD+Vent Arrhy	1714	21	447.5	2	42.6	2	42.6	4	11.1
Tier 2	2a IABP	5263	168	1165.9	15	104.1	18	124.9	26	8.7
	2b VT/VT	11392	88	282.1	4	12.8	6	19.2	12	7.7
	2c Dev Malf'n/failure	6996	71	370.7	6	31.3	7	36.5	8	6.2
	2d TAH	4015	48	436.7	0	0.0	0	0.0	10	12.6
	2e Disch R/BiVAD	2076	43	756.5	0	0.0	0	0.0	5	6.2
Tier 3	3a LVAD for 30d	31563	513	593.6	15	17.4	15	17.4	65	7.0
	3b Stat 1A Exception	6863	138	734.4	7	37.3	10	53.2	24	10.0
	3c Inotropes w/Monitor	28603	700	893.9	15	19.2	24	30.6	77	5.9
	3d Oth Dev Comp	5769	74	468.5	2	12.7	2	12.7	12	9.1
	3e Dev Infection	31108	261	306.4	6	7.0	9	10.6	53	11.9
	3f Thromboembolism	5253	85	591.0	2	13.9	2	13.9	11	7.1

SRTR Data, 2/2014

Proposed Statuses 1-3

Status	Criteria
1	• ECMO • Continuous Mechanical ventilation • Non-dischargeable (surgically implanted) VAD • MCSD with life-threatening ventricular arrhythmia
2	• Intra-aortic balloon pump • Ventricular tachycardia/ventricular fibrillation, mechanical support not required • MCSD with device malfunction/mechanical failure • Total artificial heart • Dischargeable BiVAD or RVAD • Acute circulatory support
3	• Dischargeable LVAD for up to 30 days • Multiple inotropes or single high-dose inotropes with continuous hemodynamic monitoring • MCSD with device infection • MCSD with hemolysis • MCSD with pump thrombosis • MCSD with right heart failure • MCSD with mucosal bleeding • MCSD with aortic insufficiency

Proposed Statuses 4-6

Status	Criteria
4	• Stable LVAD candidates not using 30 day discretionary period • Inotropes without hemodynamic monitoring • Diagnosis of congenital heart disease (CHD) • Diagnosis of ischemic heart disease with intractable angina • Diagnosis of hypertrophic cardiomyopathy • Diagnosis of restrictive cardiomyopathy • Diagnosis of amyloidosis • Retransplant
5	Combined organ transplants
6	All remaining active candidates

Geographic Sharing Background

Problem

- DSA boundaries create inequities in access to transplant, particularly for the most urgent candidates

Goal

- Increase the number of donors available to the most critically ill patients, without increasing the number of discarded organs

Status

- TSAM request submitted for 4 different allocations sequences

Where Would You Want to Be Waiting As Status I?

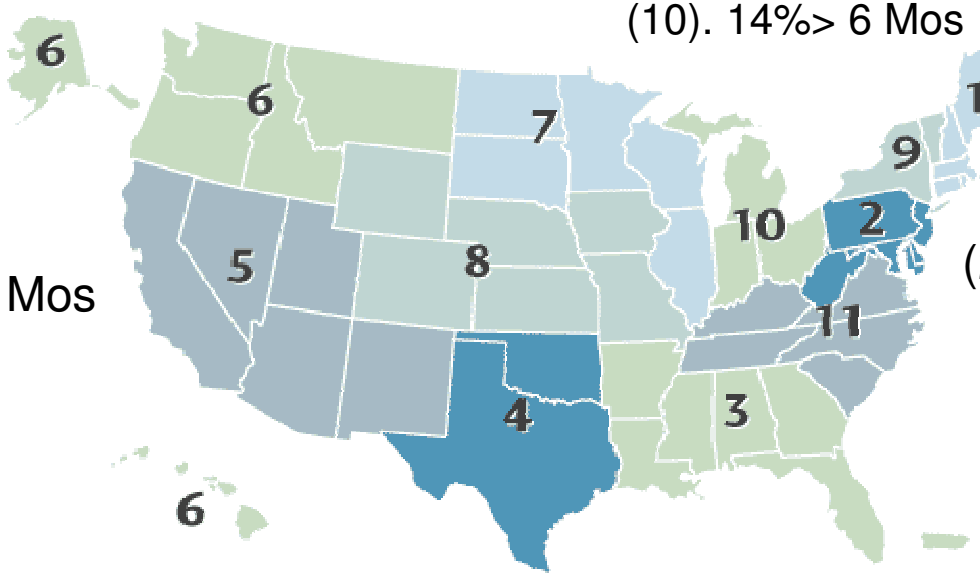
(6). 52% > 6 Mos

(10). 14%> 6 Mos

(1). 68% > 6 Mos

(5). 12% > 6 Mos

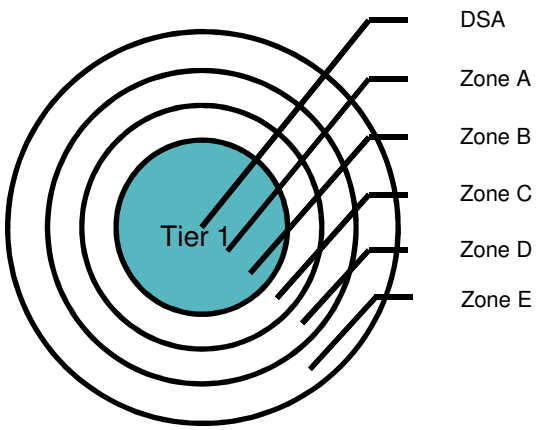
(2). 67% > 6 Mos



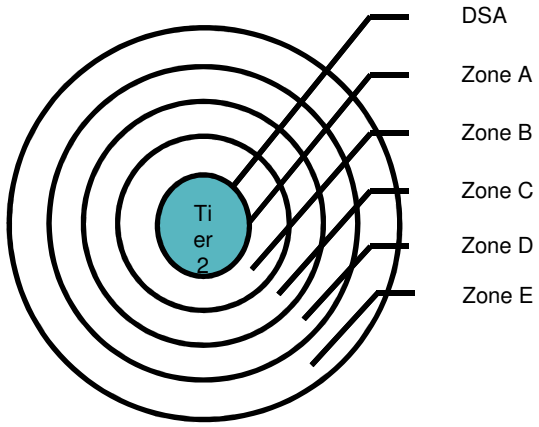
% of pts listed as Status I
who have been waiting > 6 Months

UNOS Data as of April 12, 2013

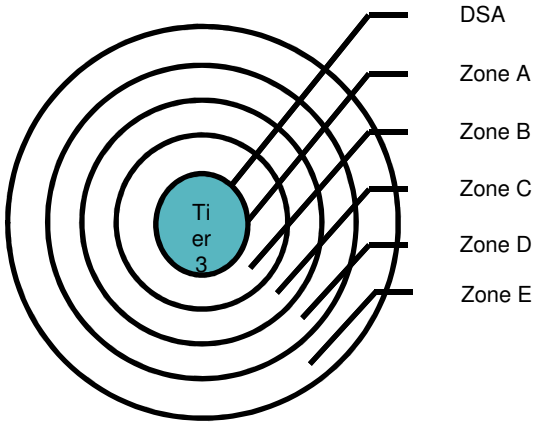
Broader Sharing For Tier 1



Offer 1 (All tier 1s in DSA + Zone A + Zone B)



Offer 2 (All Tier 2s in DSA + Zone A)



Offer 3 (All Tier 3s in DSA + Zone A)

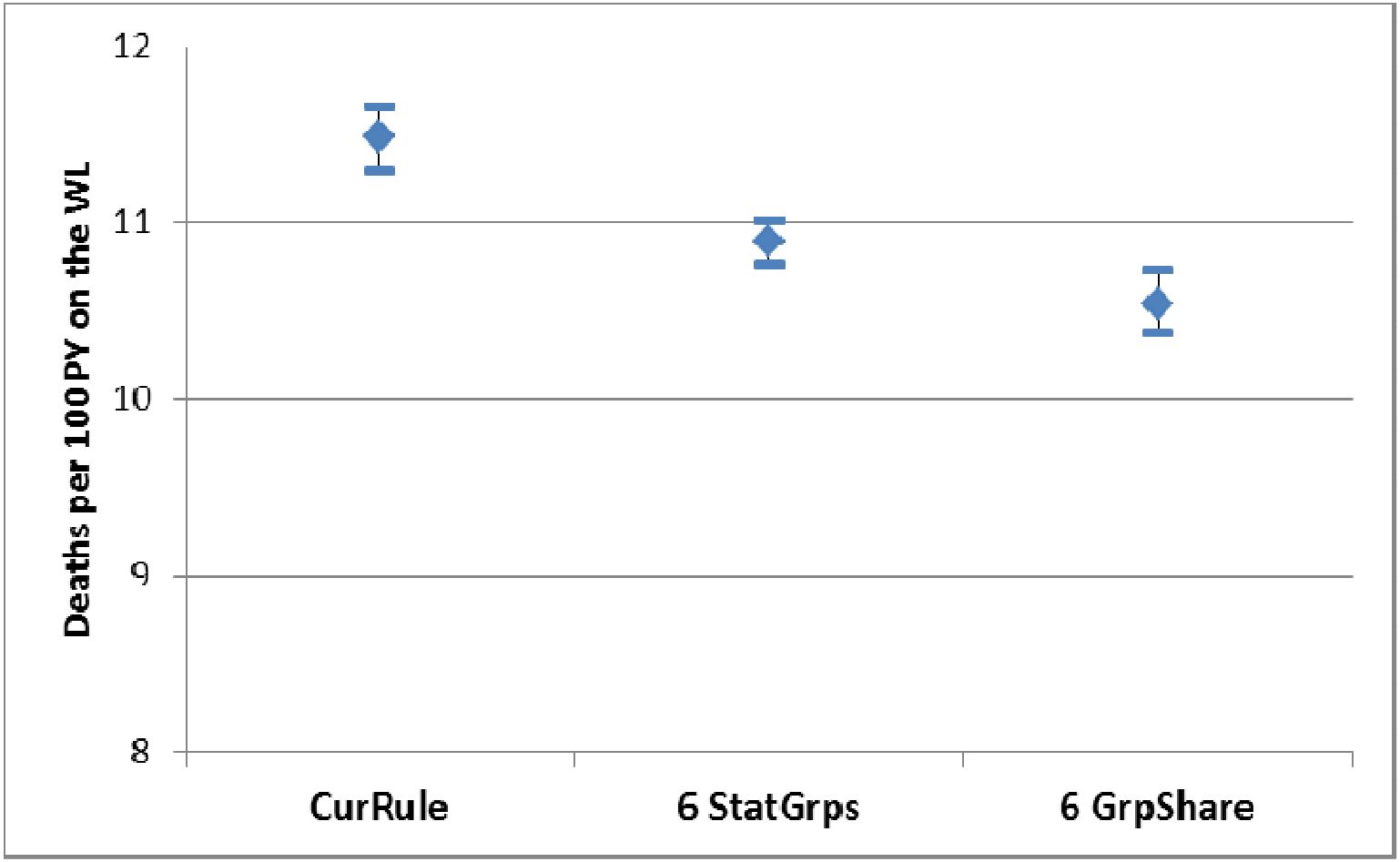
Two Preferred Modeled Sequences

Broader sharing 1/2A	
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

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

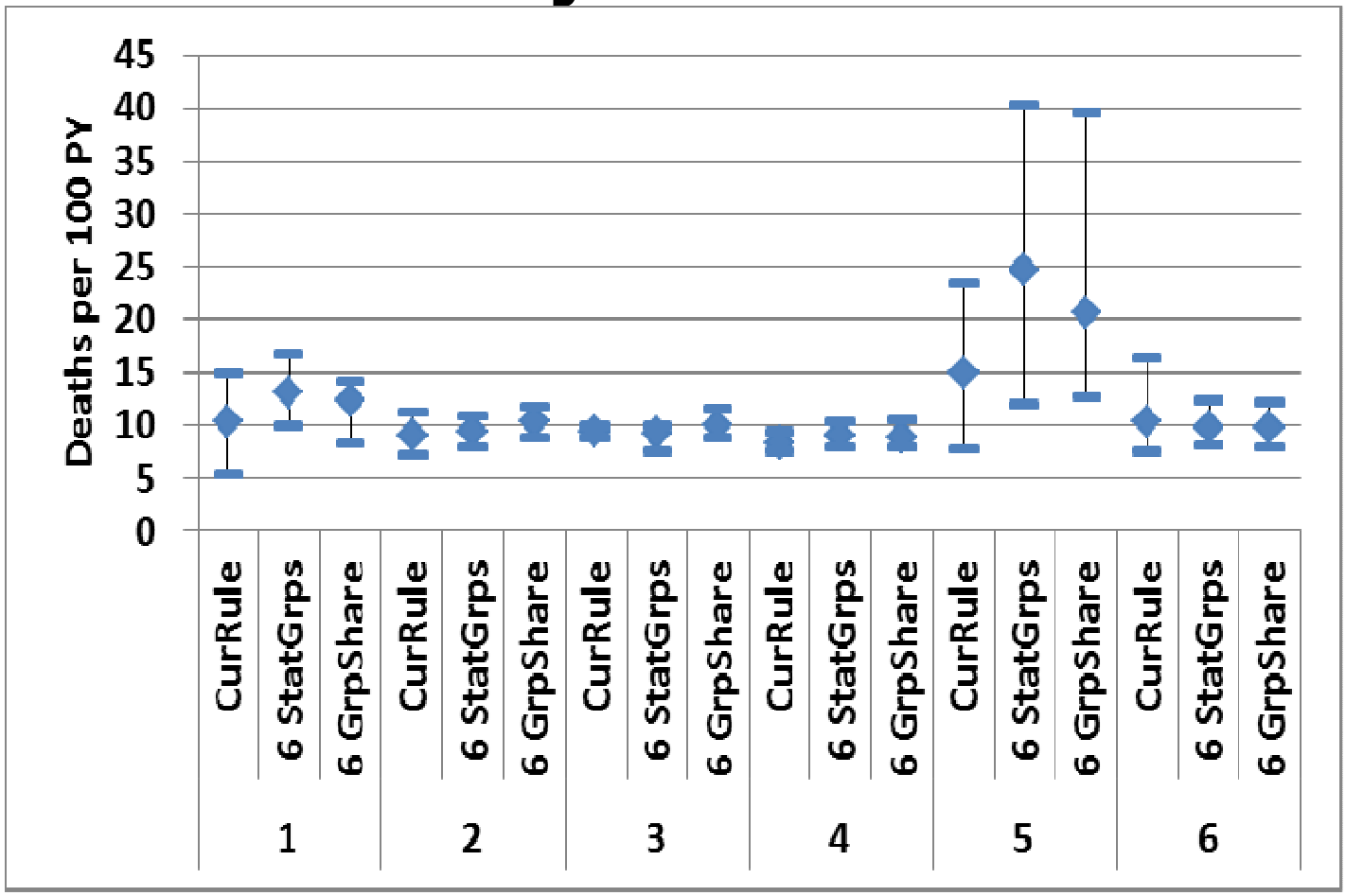
SRTR Data, 2/2014

Overall waitlist mortality rates by simulation



SRTR Data, 2/2014

Two-year post-transplant mortality rates by simulation

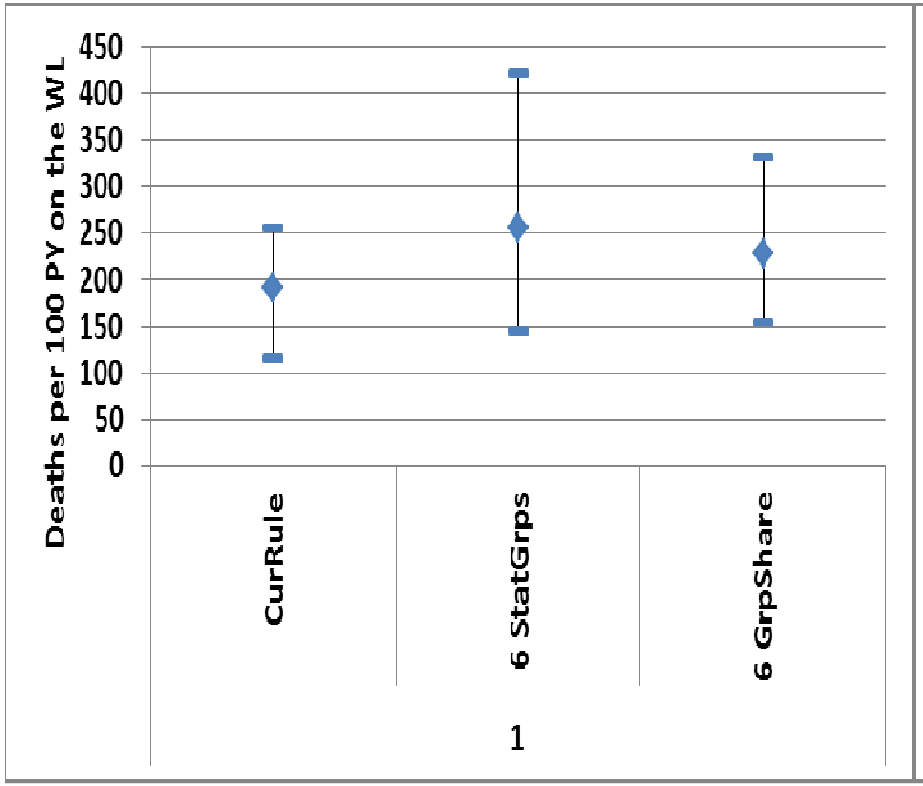


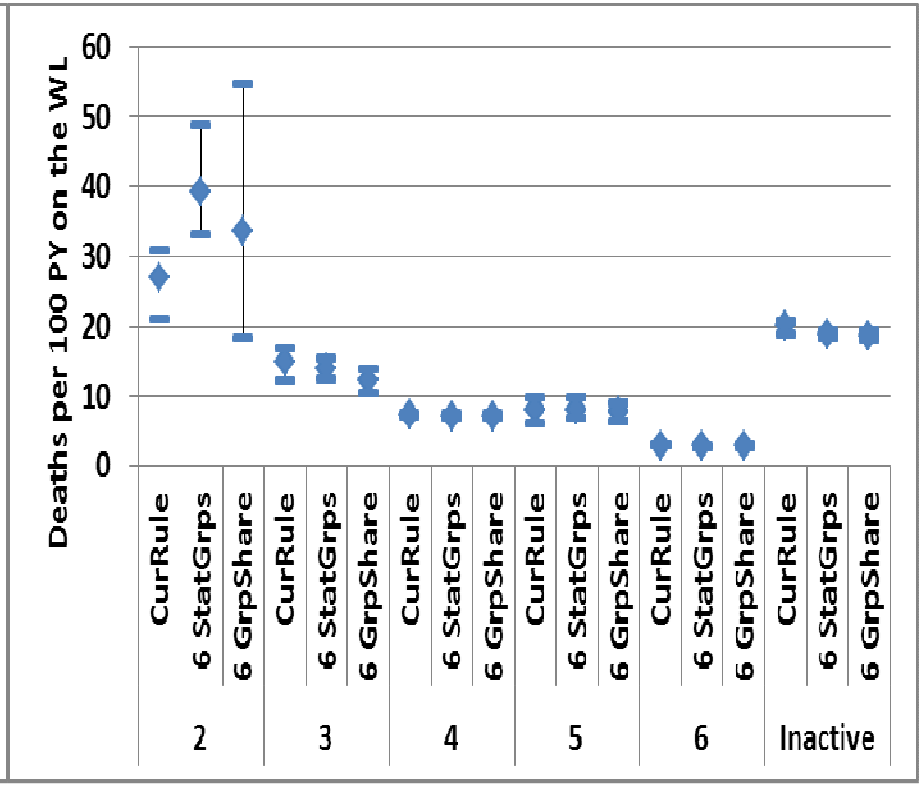
SRTR Data, 2/2014

Conclusions

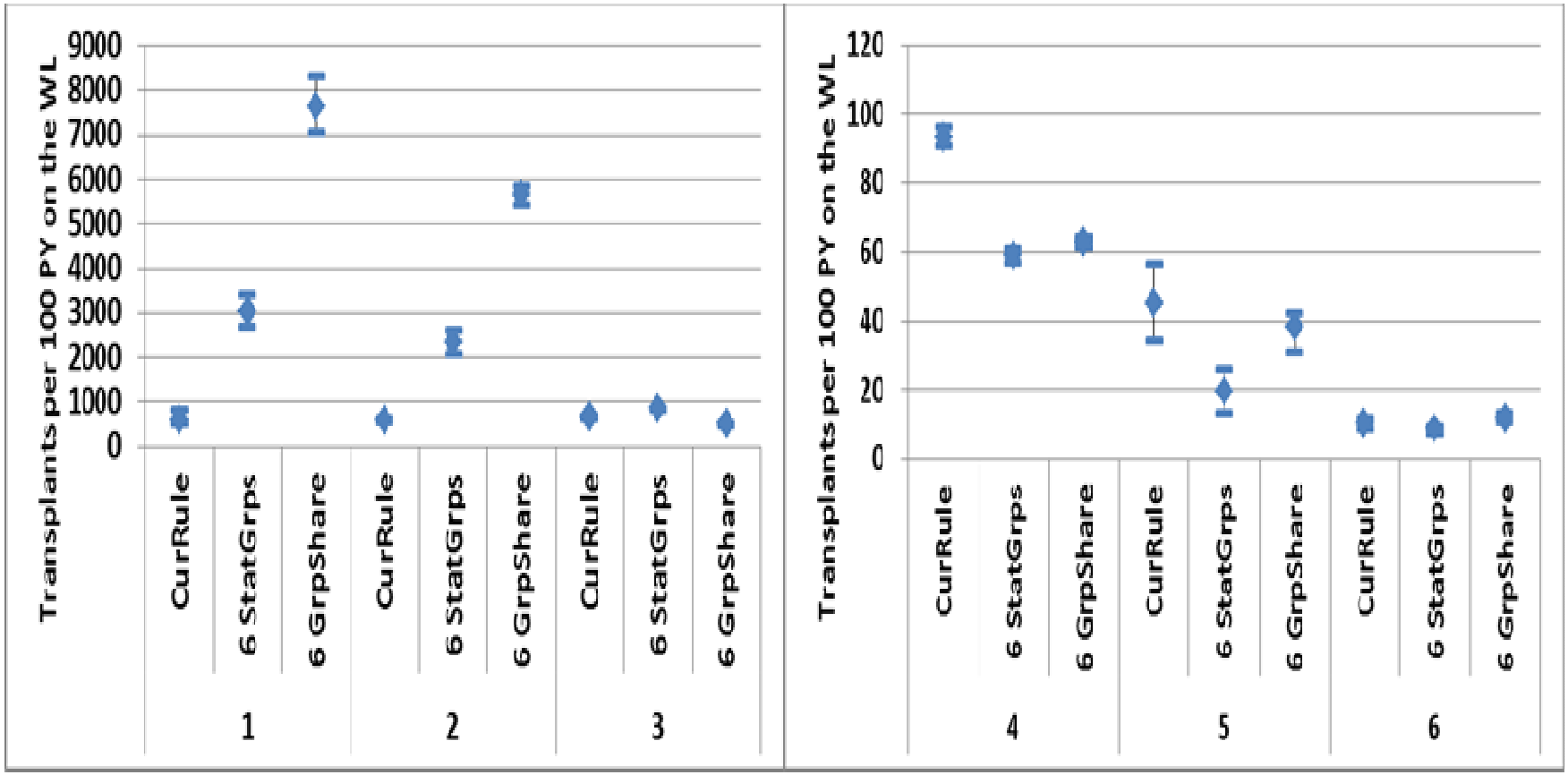
- Multi-tiered system serves to address the problems noted in the current system
  - Reduce waiting list mortality rates – allocate organs to the most critically ill candidates
  - Addresses issues with specific patients groups, some possibly disenfranchised in today's allocation system
  - Incorporates broader geographic sharing to optimize access and limit regional disparities that may exist
- Post-transplant survival - within each status, projected to remain comparable to those rates in the current system

Waitlist mortality rates by simulation





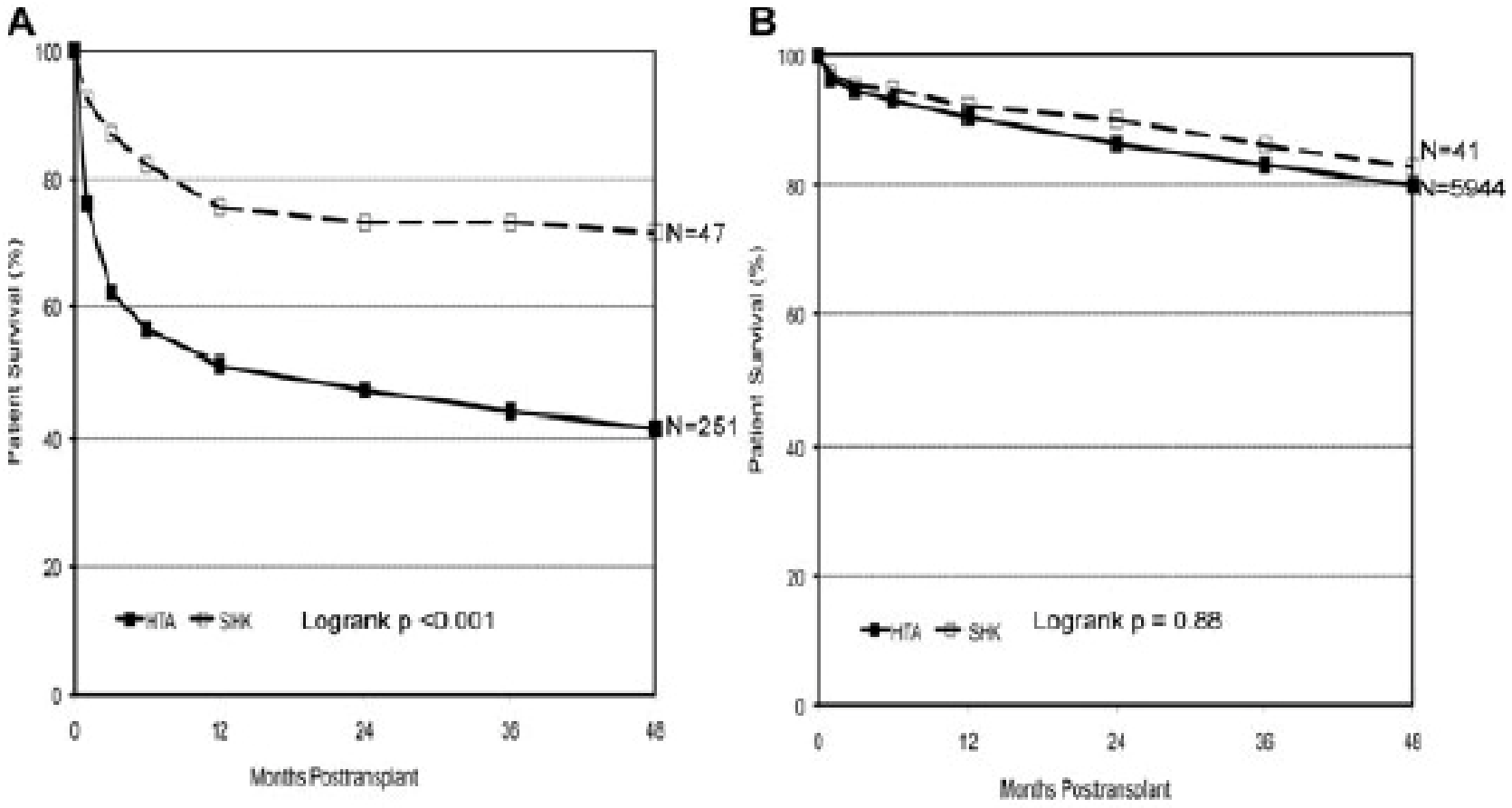
Transplant rates by simulation



Multi-Organ Transplantation

Heart-Lung

Heart + Abdominal Organ(s)

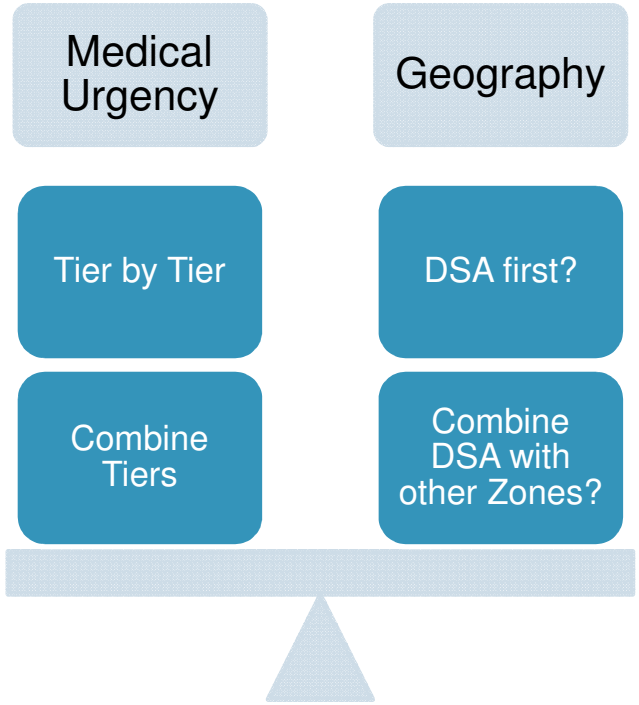


Am J Transplant 2009;9:844-52

Problems with the Current System

1. Status 1A candidates are 3x more likely to die on the waiting list than candidates in any other status
2. High # of exception requests indicates certain candidates not served well by current system
3. Policy out of date re: increased use of MCSDs and associated complications
4. Current geographic sharing scheme is inequitable and inconsistent with the Final Rule

Who gets the first offer?



Proposed New Statuses

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