

Thoracic Simulation Allocation Modeling (TSAM) of a 6-Tier Allocation Strategy for Heart Transplant

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Disclosures

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I have no financial relationships to disclose within the past 12 months relevant to my presentation. The ACCME defines 'relevant' financial relationships as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

AND

My presentation does not include discussion of off-label or investigational use

This work was supported wholly or in part by HRSA contract HHS-250-2015-00009C. The content is the responsibility of the authors alone and does not necessarily reflect the views or policies of the Department of HHS, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.

Background

- The OPTN/UNOS Thoracic Committee is currently revising the heart allocation policy (OPTN Policy 6)
- Current policy does not adequately stratify risk
- Policy out of date re: increased use of mechanical circulatory support devices (MCSD) and associated complications
- Large number of exception requests
- **Study objective: Evaluate the effect of a 6-tier urgency stratification system on waitlist and post-transplant outcomes**

Methods: Development of Tiers

- The UNOS/OPTN Thoracic Committee evaluated waitlist and post transplant mortality of all listing criteria/sub criteria and diagnoses
 - Among current Status 1A candidates, observed six-month waitlist mortality ranged from 4.8% to 35.7%
 - Probability of transplant varied and lowest among those with highest waitlist mortality
- Exceptions reviewed: common reason for exceptions included VT/VF (28%), congenital heart disease (14%), VAD complications (9%), and retransplant (7%)
- Tiers based on stratification by waitlist mortality, clinical factors identified through review of exceptions, and existing status 1A and 1B criteria

Current status and corresponding tiers

Status	Tier
1A	1 (most urgent) 2 3
1B	4
2	5 6

- Tiers 1-3 are generally defined by current status 1A criteria.
- Tier 4 is generally defined by current status 1B criteria.
- Tiers 5-6 includes those currently at status 2.
- Each tier is defined in detail in the full report. (page 10, Table 3)
https://optn.transplant.hrsa.gov/media/1244/08_adult_heart_allocation_part1.pdf

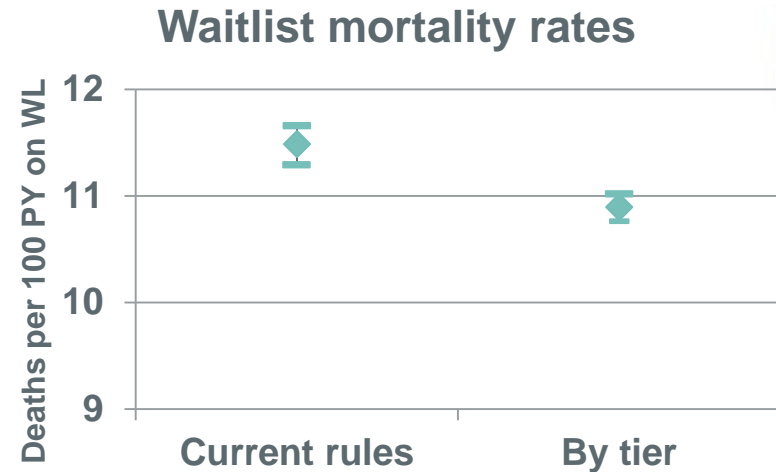
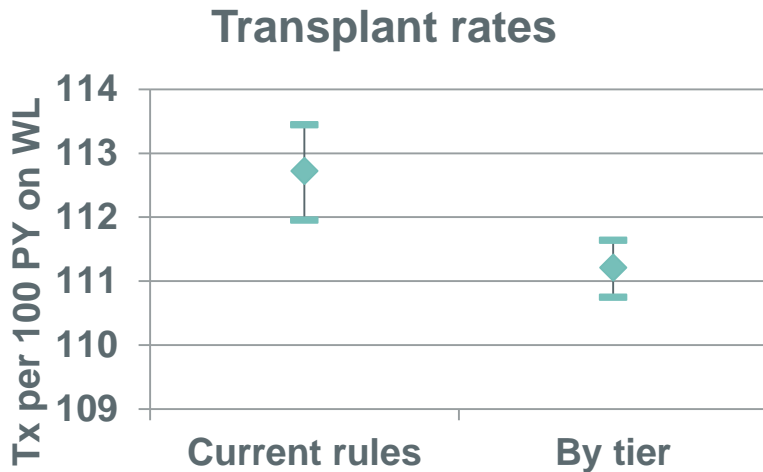
Tier Definitions Used in Modeling

Tier	Criteria	Tier	Criteria
Tier 1	1a ECMO	Tier 4	4ai Congenital Unrepaired CHD
	1b Mechanical Ventilation		4aii Congenital Repaired CHD, 2 Ventricles
	1ci Non-dischargeable VAD		4aiii Cong Repaired CHD, 1 Ventricle
	1cii MCS+Ventricular Arrhythmia		4b IHD/Intractable Angina
Tier 2	2a IABP		4c Hypertrophic Cardiomyopathy
	2b VT/VT		4d Restrictive Cardiomyopathy
	2c Device Malfunction/failure		4e LVAD after 30 days
	2d TAH		4f Inotropes w/o Monitor
	2e Dischargeable VAD		4g Amyloidosis
	2f Acute circulatory support		4h Re-transplant
Tier 3	3a LVAD for 30 days	4i Current Status 1B Exception	
	3b Current Status 1A Exception	4j Other downgrade	
	3c Inotropes w/Monitoring	Tier 5	
	3d Other Device Comp	5a Heart-lung	
	3e Device Infection	5b Heart-liver	
	3f Thromboembolism	5c Heart-kidney	
		Tier 6	Current Status 2
		Tier 7	Inactive

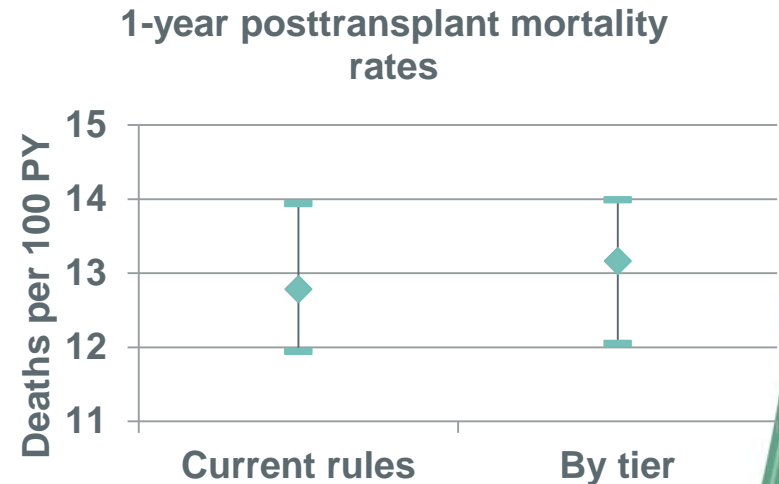
Analysis

- We evaluated the effect of a 6-tier system using Thoracic Simulation Allocation Modeling software (TSAM)
- Cohort included 9725 heart transplant and 188 heart-lung transplant candidates listed July 1, 2009-June 30, 2011
- Simulated match runs performed under tiers and current rules, i.e. current status system
- Outcomes
 - Transplant counts and rates
 - Waitlist mortality counts and rates
 - Posttransplant mortality counts and rates

Results: Overall outcomes

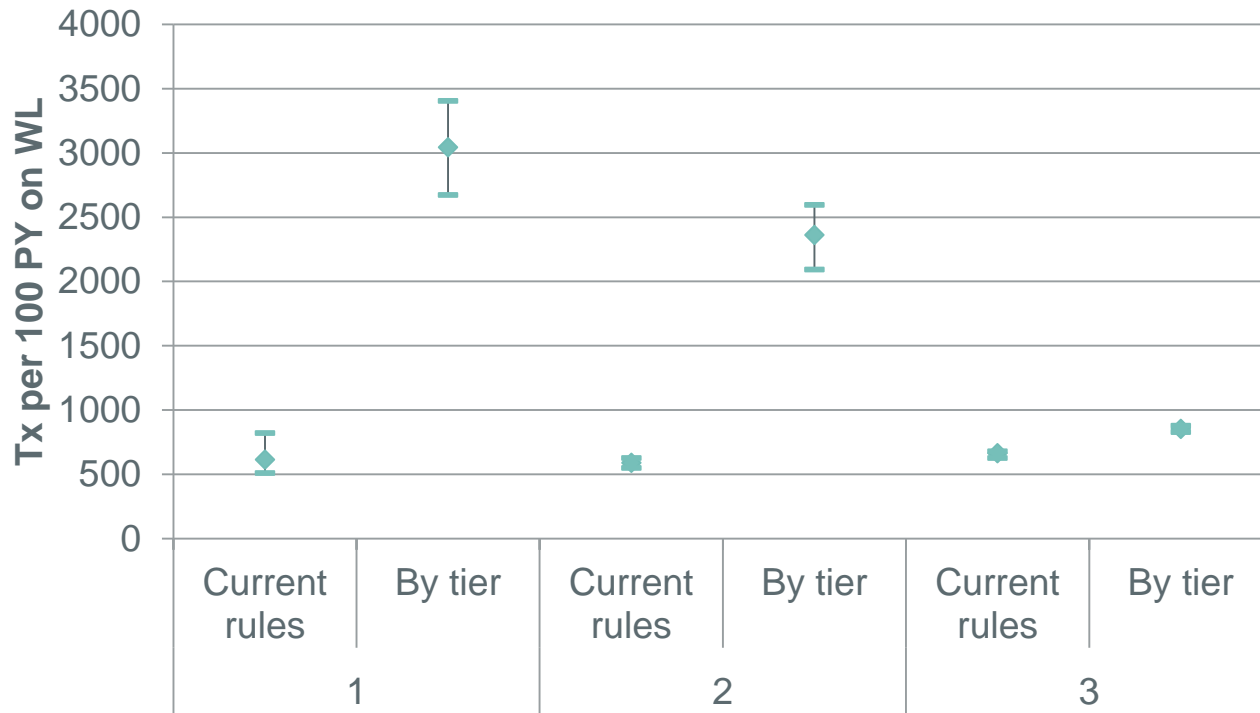


- Transplant rates declined from 112 to 110 per 100 PY
- Waitlist mortality rates declined from 11.3 to 10.8 per 100 PY
- Post-transplant mortality rates were similar 112 and 110 per 100 PY



Data are shown with ranges of the 10 simulations runs. Bars are not 95% confidence limits.

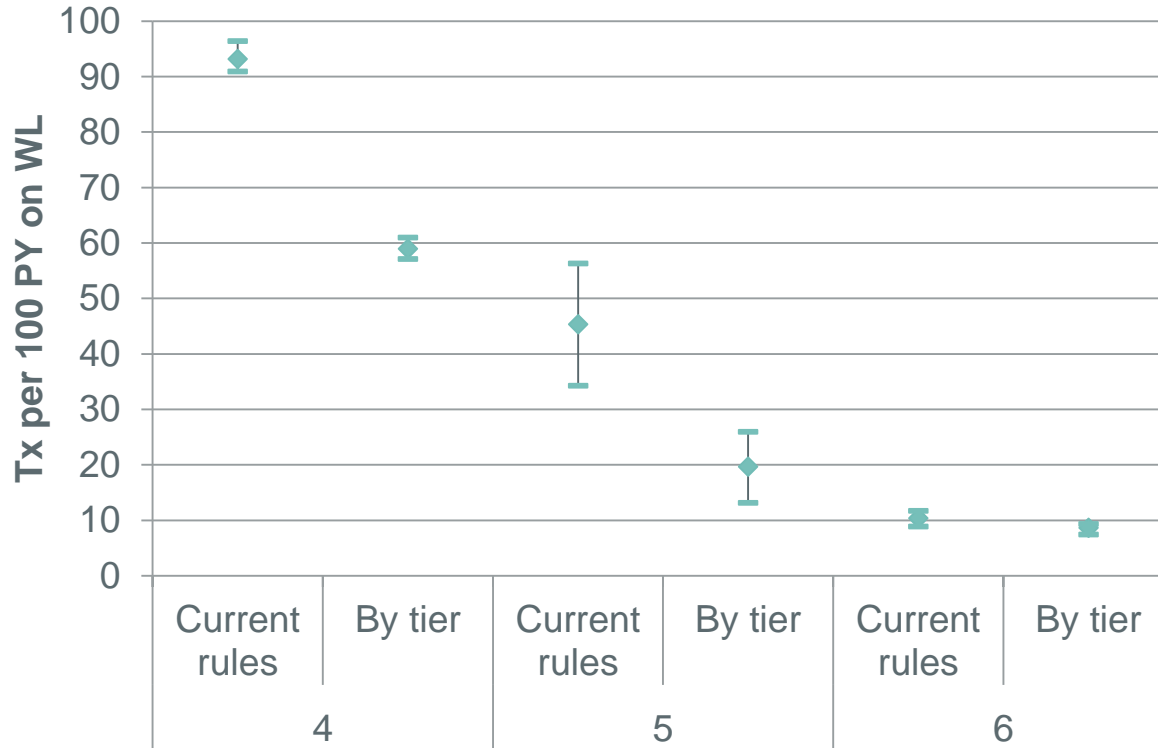
Results: Transplant rates, Tiers 1-3



Data are shown with ranges of the 10 simulations runs. Bars are not 95% confidence limits.

- Under current rules transplant rates similar between tiers 1-3
- Tier 1: Transplant rates increased from 615 to 3044 tx per 100 PY under simulation by tiers
- Tier 2: Increased from 589 to 2363 tx per 100 PY
- Tier 3: Increased from 663 to 853 tx per 100 PY

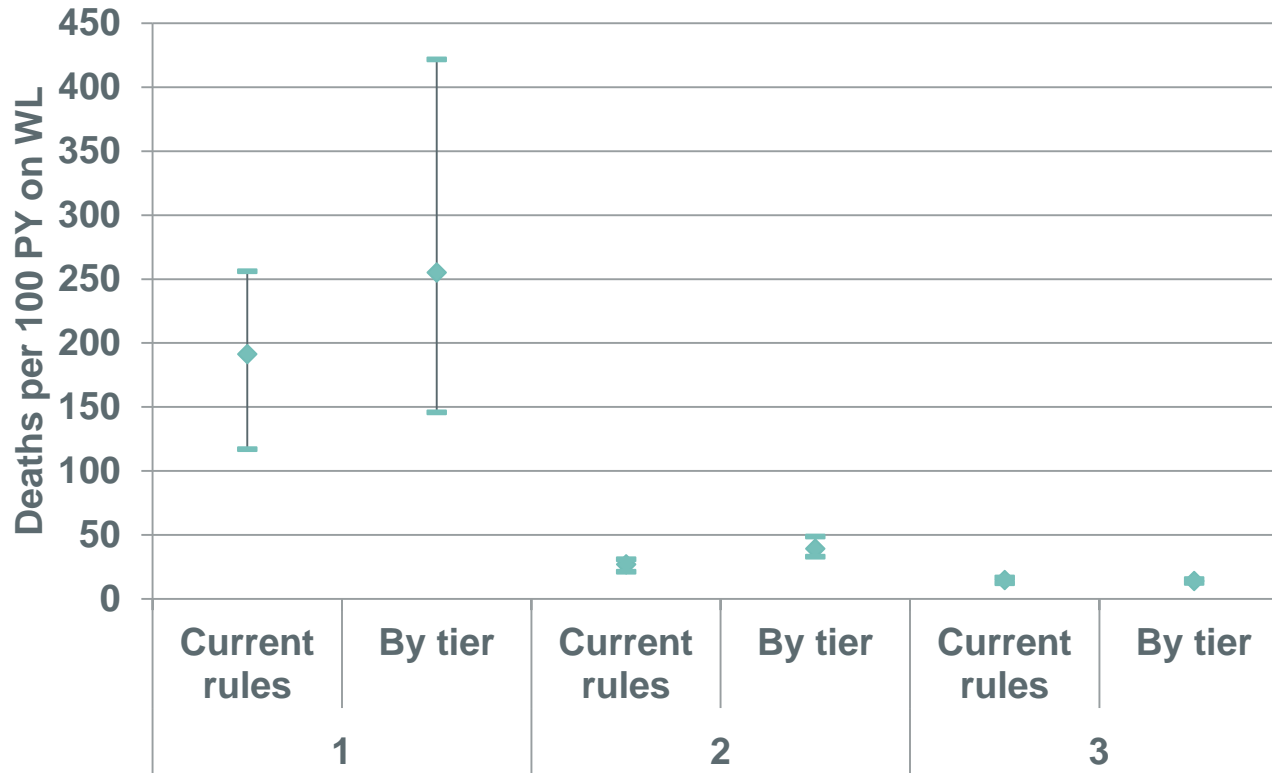
Results: Transplant rates, Tiers 4-6



Data are shown with ranges of the 10 simulations runs. Bars are not 95% confidence limits.

- Tier 4: Transplant rates decreased from 93 to 59 tx per 100 PY under simulation by tiers
- Tier 5: Decreased from 45 to 20 tx per 100 PY
- Tier 6: Transplant rates are similar in both groups, 9 to 10 tx per 100 PY

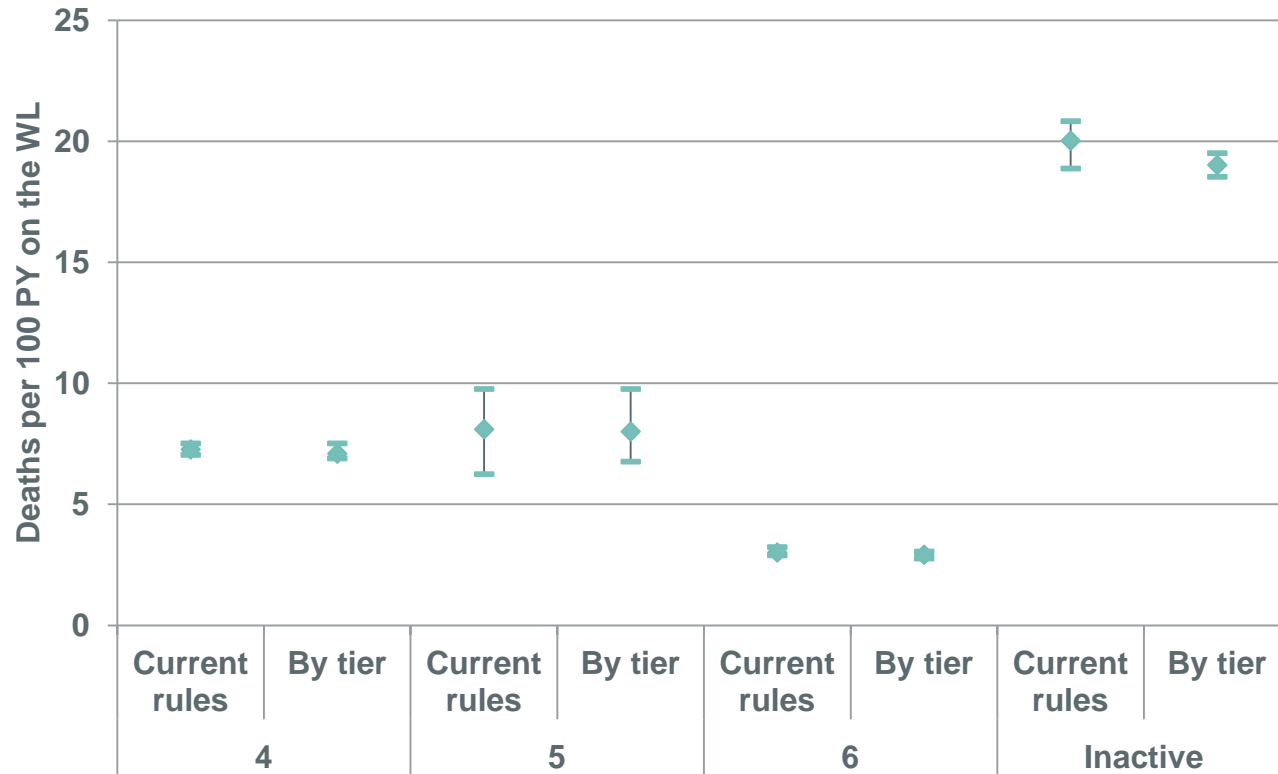
Results: Waitlist mortality rates, tiers 1-3



Data are shown with ranges of the 10 simulations runs. Bars are not 95% confidence limits.

- Tiers 1 and 2: Mortality rates overlapped in the simulations, suggesting no detectable difference.
- Point estimate increased from 191/100py to 255/100py in tier 1, 27/100py to 39/100py in tier 2.
- Death counts decreased from 16 to 10 and 16 to 11 in Tiers 1 and 2, respectively, suggesting that some candidates died shortly after listing
- Tier 3: Rates were similar in both simulations.

Results: Waitlist mortality rates, tiers 4-6 and inactive



Data are shown with ranges of the 10 simulations runs. Bars are not 95% confidence limits.

- No impact on waitlist mortality in tiers 4-6
- Number of deaths among inactive candidates declined from 349 to 332

Results: One-year post-transplant mortality rates



Data are shown with ranges of the 10 simulation runs. Bars are not 95% confidence limits.

- Within a tier, post-transplant mortality rates were similar under simulation by current rules and tiers.
- Across tiers, post-transplant mortality rates were largely similar to each other.

Conclusion

- Allocation by 6-tiered system resulted in large increases in transplant rates among the most urgent patients
- No negative impact on waitlist mortality or post-transplant outcomes
- Reduction in overall transplant rate likely due to less urgent patients awaiting transplant longer
- No systematic disparity in access to transplant by age, sex, race, or blood type was detected
- 6-tier system useful in differentiating among the most critically ill patients currently listed as Status 1A
- Evaluation of broader sharing strategies is ongoing

Limitations

- TSAM assumes that organ acceptance behavior does not change in response to simulated policy changes; moreover, it is based on historical acceptance behavior.
- TSAM does not anticipate changes in listing behavior that allocation rule changes could precipitate.
- TSAM cannot account for center-specific practices.
- TSAM assumes that all organ offers follow the stated allocation rules, and does not allow for exceptions or expedited placements.
- TSAM models are limited by the available data during the cohort period.
- All prediction models include uncertainty.

Acknowledgements

- UNOS/OPTN Thoracic Committee and the Heart Subcommittee
- Katherine Audette, SRTR Research and Policy Liaison
- Charlotte Bolch, SRTR Biostatistician
- SRTR Support Staff
- Bert Kasiske, Director, SRTR

Thank you!