Broader Sharing in Heart Allocation: Where do we draw the line?

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Disclosure

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Learning Objectives

1. Understand the rationale for broader sharing
2. Describe boundary options for broader sharing – local, regional, or national
3. Identify unintended consequences of broader sharing
4. “Translate” continuous distribution policy
Current Heart Allocation

Post-transplant survival
What should be our target?

Risk of waitlist mortality
What is an “acceptable” rate?
Father (Ischemic) Time
Broader Sharing – How Did We Get Here?

UNOS Thoracic Transplant Committee

• Believed current heart geographic sharing policies were not aligned with the spirit of the Final Rule
• Primary goal of candidate reprioritization and broader sharing was to reduce waitlist mortality and delisting for clinical deterioration
• Avoid negatively impacting post-transplant survival

Rogers, J Thorac Cardiovas Surg 2016;152:1484-6
Broader Sharing – How Did We Get Here?

UNOS Thoracic Transplant Committee

• Developed 4 separate alternatives for broader organ sharing
• Concluded that the proposal that shares hearts as far as 1000 miles was medically reasonable and would provide greatest opportunity for expedited transplant
• Supported by TSAM performed by SRTR

Rogers, J Thorac Cardiovas Surg 2016;152:1484-6
Broader Sharing – How Did We Get Here?

UNOS Thoracic Transplant Committee

• Concerns raised by transplant community
  – Lengthen cold ischemic time
  – Disenfranchise local organ donation
  – Delay organ recovery
  – Increase cost

• Revised allocation to proposal that shares hearts to 500 miles instead of 1000 for status 1 and 2

• Geographic zones of 500 miles originally created with first iteration of allocation system in 1988

Rogers, J Thorac Cardiovasc Surg 2016;152:1484-6
Broader Sharing – Conflicting Early Results

Lies, Damn Lies, and Statistics

- 83% of transplants occurred in status 1, 2, or 3 patients
- 90 day post-transplant survival 87.6% vs 94.5%
- 180 day post-transplant survival 77.9% vs 93.4%
- Ischemic time increased from 3.0 to 3.4 hours
- Each 30 minute increase in ischemic time associated with 8% increase in hazard rate of death or retransplantation
- Impact of reduction in wait list mortality is small

Cogswell, et.al, J Heart and Lung Transplant 2020;39:1-4
Broader Sharing – Conflicting Early Results

Figure 2: Six-Month Patient Survival

Figure 2 shows the six-month patient survival for adult heart recipients pre- and post-implementation. There was no significant difference in patient survival between the two eras.

Six-month graft survival in the pre era was 93.6% compared to 92.8% in the post era. This difference is not statistically significant ($p = 0.42$).

Figures 23 and 24 show the six-month patient survival for different medical urgency statuses pre- and post-implementation, respectively.
Broader Sharing – Conflicting Early Results

Figure 34: Six-Month Patient Survival by Medical Urgency Status Post-Implementation

- Adult Status 6 is omitted because there were too few adult heart recipients to accurately estimate survival.
Broader Sharing – How Did We Get Here?

“One of the great mistakes is to judge policies and programs by their intentions rather than their results.”

MILTON FRIEDMAN
(1912 - 2006)
Geographic Variation in the Treatment of US Adult Heart Transplant Candidates

Parker, et al; JACC 2018;71:1715-25
Geographic Variation in the Treatment of US Adult Heart Transplant Candidates

• For every 10% increase in the percentage of recipients who were status 1A at transplant, the odds of potential overtreatment increased 6%
• If there were 3 or more centers in the OPO, the odds of potential overtreatment were 50% higher
• Wide center-level variation in treatment and listing practices that could not be explained by variation in candidate characteristics
• The AHA cardiogenic shock criteria have not been prospectively validated in the heart transplant candidate population and may not be the best way to risk stratify candidates

Parker, et al JACC 2018;71:1715-25
Geographic Variation in Survival Benefit of Adults Undergoing Heart Transplantation in the US

Parker, et al; JAMA 2019;322(18):1789-1798
Geographic Variation in Survival Benefit of Adults Undergoing Heart Transplantation in the US

• Large group of low survival benefit centers that prioritized less medically urgent candidates who had a lower risk of death without transplant and less potential survival benefit

• These centers more likely to select stable candidates and escalate supportive therapies as needed to achieve status 1A

• Frequently treated patients with high-dose inotropes and IABP despite absence of cardiogenic shock

Parker, et al; JAMA 2019;322(18):1789-1798
Organ Distribution Characteristics

Pre – 36%  Post-66.5%

Figure 13. Adult Heart Transplants by Zone and Era

Figure 13 shows the number of adult heart transplants performed by zone and era. Transplants within the OSA decreased post-implementation but rose in all other zones. The greatest increase by absolute volume was in Zone A, but transplants also rose nearly 200% in Zone B. There were no transplants past Zone C.

The zones are defined as follows relative to the location of the transplant hospital:
- Zone A: within 500 nautical miles of the donor hospital but outside the donor hospital’s OSA
- Zone B: 500 or more nautical miles from the donor hospital but within 1000 nautical miles of the donor hospital
- Zone C: 1000 or more nautical miles from the donor hospital but within 1500 nautical miles of the donor hospital
Organ Distribution Characteristics

Figure 16. Distance Traveled at Transplant by Era

Vertical lines indicate the median distance traveled for each era.

Figure 17 shows the distributions of distance traveled by hearts pre- and post-implementation. While the majority of hearts traveled less than 100 nautical miles pre-implementation, post-implementation travel distances were distributed much more evenly up to about 500 nautical miles before dropping off. The median distance traveled increased significantly (p < 0.001) post-implementation, from a pre-implementation median of 83 nautical miles to a post-implementation median of 216 nautical miles.
Figure 17. Total Ischemic Time at Transplant by Era

Figure 17 shows the distribution of total ischemic times at transplant both pre- and post-implementation, where total ischemic time is defined as the sum of cold ischemic time, warm ischemic time, and anastomotic time. Total ischemic times increased significantly (p < 0.001) post-implementation to a median of 3.4 hours from 3 hours. The maximum ischemic time reported during the pre-implementation era was the same as the maximum ischemic time reported during the post-implementation era: 12 hours.
Figure 28 shows the utilization rates for adult hearts from non-DCD donors both pre- and post-implementation by donor age. Utilization rates rose slightly for all age groups post-implementation.
Death Rate from Heart Disease - 35+ years of age 2014-2016
Should Heart Transplantation be Regionalized in the US?

Magruder, et al; AJT 2017;17:485-495
Should Heart Transplantation be Regionalized in the US?

• Risk of 1-year mortality after transplantation was found to be independently associated with center-volume tertiles after risk adjustment

• Theoretical simulation closed low-volume centers in each region and referred their patients to region’s highest volume center

• Demonstrated improved mortality even after case-mix adjustment

Magruder et al; AJT 2017;17:485-495
Geographic Inequity in Transplant Access

FIGURE 1. Individuals’ continuum of care in organ failure and transplantation. Each step is associated with geographic differences in likelihood of progression.

Lynch et al; Curr Opin Organ Transplant 2019; 24:337-342
Geographic Inequity in Transplant Access

• Lawsuit filed by lung transplant candidate challenging geographic inequity in lung transplantation in 2017

• UNOS removed local OPO as 1st unit of allocation and changed it to 250 nautical mile circle from donor hospital within 5 days

Lynch et al; Curr Opin Organ Transplant 2019;24:337-342
Public Preferences Toward Organ Allocation

- Little public support that allocation decisions should be based solely on risk of waiting-list mortality
- Strong public support for maximizing outcomes after transplantation
- Prioritizing US citizens or residents
- Keeping organs local
- Considering cost in allocation decisions

Continuous Distribution Policy

• Approved by OPTN Board of Directors in 12/18
• Based on work by the Ad Hoc Geography Committee
• Will apply to all organ allocation systems, initiated in lung first
• Will eliminate hard boundaries
Continuous Distribution Policy – What does it mean?

Will prioritize waiting list candidates based on a combination of points:

1. Medical Severity
2. Expected post-transplant outcome
3. Efficient management of organ placement
4. Equity
Continuous Distribution Policy – Possible Scenarios

Figures 1 and 2 show how these scores could combine into a composite score. The committee will need to determine not only which components to include in a composite allocation score but also how much importance to place on each component. For example, one option would be four equally weighted components while another option could have more components with different weights.
Continuous Distribution Policy – Project Overview

OPTN Concept Paper

Figure 3: Project Overview

- Identify attributes
- Categorize attributes
- Convert attributes into points
- Prioritize attributes against each other
- Build framework
- SRTR modeling
- Public comment on policy proposal
- Board
Conclusions

Geographic considerations in organ allocation remain controversial

Geography is “in the eye of the beholder”

Is 500 miles the right distance for the first allocation zone?

The most significant hurdle to broader sharing that can not be ignored is ischemic time

Older donor age with increased ischemic time is a particularly challenging scenario – should donor age be considered in geographic allocation?
Robert Taylor MD, Director of Cardiology, captured this fiery sunset and a slice of the Atlanta skyline from the physicians’ parking deck of Emory University Hospital.