

# Regulatory Impact of Donor Acceptance: Incentivizing Innovation

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**No disclosures**



**CUTTING EDGE** OF TRANSPLANTATION

**TRANSPLANT SUMMIT 2020**  
**BALANCING** EQUITY AND UTILITY IN THE FACE OF AN ORGAN SHORTAGE

# Learning Objectives

- Describe historical practice of donor selection (briefly)
- Describe existing data on donor risk (briefly)
- Discuss the intersection between donor acceptance practices and organ stewardship in the context of broader sharing
- Mention innovative strategies to increase the organ donor pool e.g. OPTN/UNOS sponsored COIIN Projects
- Collaborative Innovation and Improvement Network for HT?

# 50 years of Selecting Donor Hearts

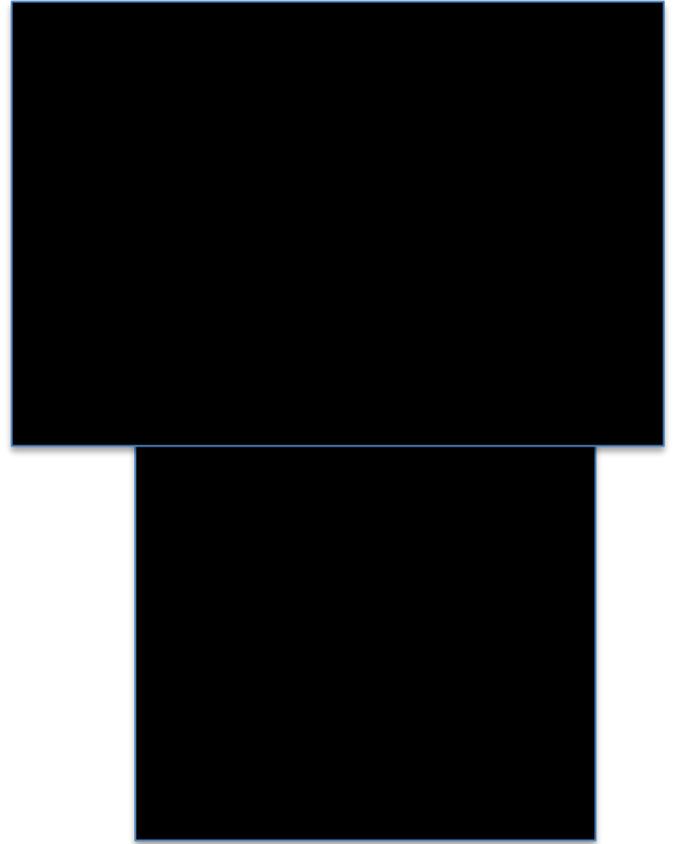
- First U.S. adult HT 1968 Stanford
- Donation after Brain Death, young, MVA mostly
- Local Hospitals with potential donors would contact the few centers doing heart transplant
- HT as a highly selective therapy, restricted to few areas of the country to few patients

# Organization of identifying donors for recipients

- National Transplant Act 1984
- Creation of federally funded centralized waiting list
- Federal Organization and Management of Donor Offers
- United Network for Organ Sharing
- Outlawing buying/selling organs
- Organ Procurement Organizations are established
- 1985 laws created to approach families
- 1986 Federal mandate to require hospitals to identify donors

# Early 2000's Perspective on HT

- Far fewer centers
- Limited program competition
- High volume center experience
- Patient-centered outcomes
- Wide margins for performance
- Donor shortage a major problem



# Early SRTR PSR Cohort 7/1/06-12/31/08

## Large volume heart transplant center

Post-transplant Outcomes ( 07/01/2006-12/31/2008)	1 Year		Statistical Significance of Difference
	Observed	Expected	
Adult graft survival (based on 172 transplants) (%)	83.86	86.27	Not Significantly Different (a)
Adult patient survival (based on 163 transplants) (%)	84.24	87.68	Not Significantly Different (a)
Pediatric graft survival (based on 49 transplants) (%)	92.80	90.00	Not Significantly Different (a)
Pediatric patient survival (based on 46 transplants) (%)	92.24	88.87	Not Significantly Different (a)

Another program with similar attributes 2019 Data	86.6%	91.3%	Significantly Different
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# 2001 Crystal City (VA) Conference

- Consensus conference on how to maximize use of all solid organs given severe organ shortages
- Key stakeholders: AST/ASTS/ISHLT/UNOS/OPOS
- Suboptimal utilization of donor hearts
- Average use 39% across all OPOs

# Crystal City Heart Work Group

- Aggressive donor management – hormonal/hemodynamic
- Focus on heart assessment
- Expand use criteria:
  - > 55 years in selective cases
  - Broader use of a standard size donor male >70 kg
  - Repair of valve lesions
  - Use of donors with mild CAD for urgent recipients
- Alternate listing proposed as a way to increase donor utilization and transplant more patients

# Alternate Lists: UCLA, Duke, Temple, Columbia

- Increased risk recipient
- Out of criteria donor hearts
- All standard recipients exhausted first
- Or highest listing status 1B if  $\geq 65$  years old
- Emphasis on individual patient benefit in the context of organ stewardship
- No emphasis on program statistics
- Outcomes acceptable and results met the Crystal City Consensus goals
- **But then things changed**

# Regulatory oversight impacts donor (and recipient) selection

- Significant regional variability in donor acceptance
- Donor shortage or donor aversion?
- Center-specific risk aversion to avoid penalty
- SRTR O/E data on survival for individual programs penalize centers that take on high risk patients – models don't capture all the risk (MCS, sensitized)
- More program competition
- Patients may now be less informed of risks taken or not taken

# AST Consensus Conference on Donor Selection

Kobashigawa et al AJT 2017

- Attempt to standardize donor selection
  - Donor age – increased risk for CAV
  - LVH but combined with older age or long ischemic time
  - LV dysfunction after resuscitation
- Donor risk scores exist, but not so much in MCS cohort
- Goal is to develop a donor risk score – what is risk metric
- Similar to KDPI – could patients prospectively consent to higher DRS (Donor Risk Score) hearts



- Large program
- Small program
- Different reasons for waitlist mortality
- Different time to transplant
- Different donor selection practices
- Different risks regarding survival outcomes



# Organ acceptance practices during a time of broader sharing

- Organ free fall is time consuming for OPOs
- Transplant Center-OPO interactions and miscommunications are key problems for MPSC.
- There are so many more offers to review
- There are likely organs being lost or nearly lost because of allocation issues and “planes in the air”
- Could we be more uniform and simple in our acceptance practices e.g. more UNET filters

# COIIN (Collaborative Innovation and Improvement Network)

- OPTN implemented COIIN 2016
- Total of 58 kidney programs across US
- Goal was to increase use of KDPI >50% kidneys
- Reduce risk aversion through collaborative approach to performance improvement



# COIIN Project brainstorming

- Heart donors with a “KDPI > 70%” exempt from regulatory scrutiny (what would be our DRS equivalent)
  - Heart recipients with cPRA > 90% exempt from scrutiny if enrolled in a national desensitization and post-transplant intensive regimen program.
  - Return of alternate listing – make it a national program

# What would a HT COIIN look like?

- Cohort of HT programs selected by OPTN/UNOS
- Collaborative website to share best practices
- Active data dashboard (shared) to record in real time transplant volumes, use of moderate-high donors (define) and organ offer acceptance rates.
- Monthly collaborative conferences to discuss other best practices to improve survival – shared QAPI



# Alternate Heart Transplant Lists: Back to the Future

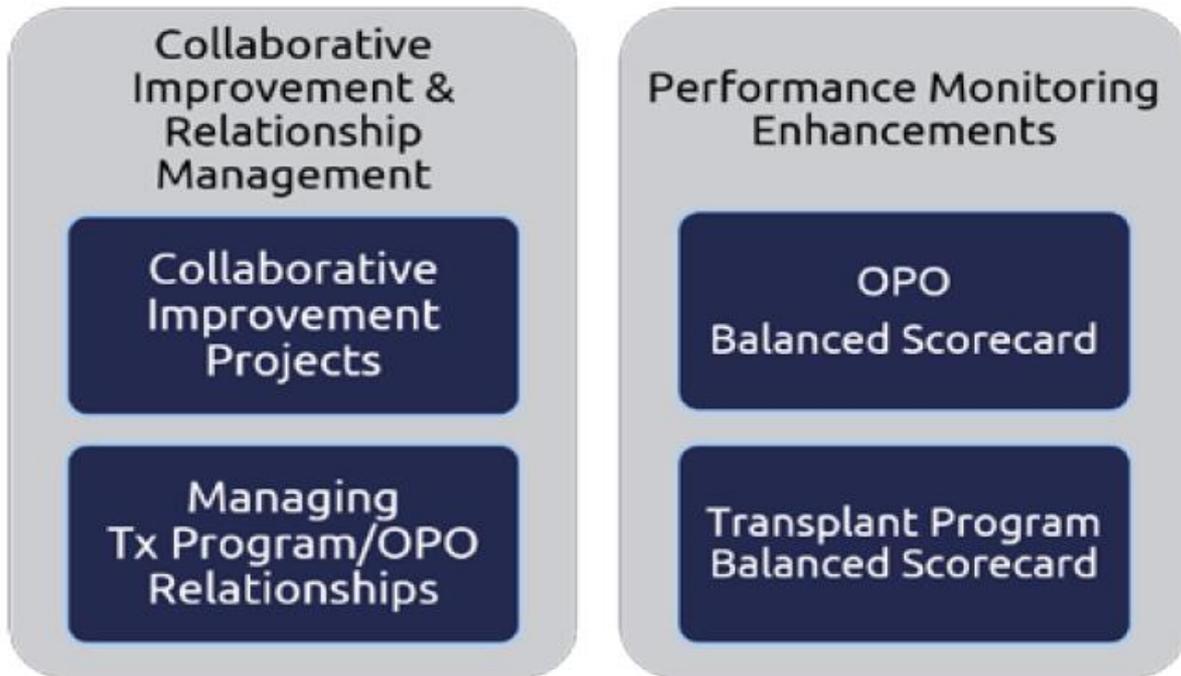
- Transplant Center-level interest in exercising organ stewardship while offering life-saving therapy to high risk patients
- Research on better understanding outcomes with these donor-recipient pairs
- Feasible during a time of less regulatory scrutiny...but now?



# Other Performance Improvement Initiatives

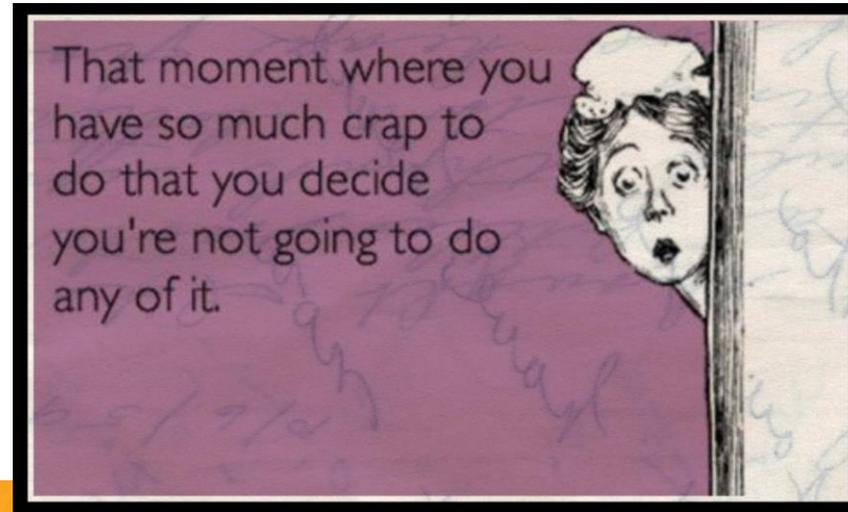
- Transplant Programs and OPOs are interdependent
  - Maximizing donor yield is a shared task
- Increased partnerships or sharing of best practices across programs to share best practices and work toward common goals
  - What if all e.g. HT programs in one Region agreed to the same listing criteria and donor acceptance criteria.
  - Focus would then be outreach to offer HT to as many patients as needed it
  - Might remove any candidate selection bias – not the select few, but cast a wide net

# OPTN Ad Hoc Systems Performance Committee Report 2019



# Why do we need to bother?

- 2001, donor acceptance 39%
- 2018, donor acceptance 39%





You are welcome, Mary Jane Farr



Thank you, Shelley Hall