Regulatory Impact of Donor Acceptance: Incentivizing Innovation

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No disclosures
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 COINN 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

<table>
<thead>
<tr>
<th>Post-transplant Outcomes (07/01/2006-12/31/2008)</th>
<th>1 Year</th>
<th>Statistical Significance of Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Observed</td>
<td>Expected</td>
</tr>
<tr>
<td>Adult graft survival (based on 172 transplants) (%)</td>
<td>83.86</td>
<td>86.27</td>
</tr>
<tr>
<td>Adult patient survival (based on 163 transplants) (%)</td>
<td>84.24</td>
<td>87.68</td>
</tr>
<tr>
<td>Pediatric graft survival (based on 49 transplants) (%)</td>
<td>92.80</td>
<td>90.00</td>
</tr>
<tr>
<td>Pediatric patient survival (based on 46 transplants) (%)</td>
<td>92.24</td>
<td>88.87</td>
</tr>
</tbody>
</table>

Another program with similar attributes
2019 Data

86.6% 91.3% Significantly Different
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 ≥ 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
COINN “Heart Network”

- Exempt from SRTR
- Collaborative
- Focus on goal
- Highly sensitized patients
- Use the same HLA lab
- Same desensitization protocol
- Same perioperative protocol
- Same post transplant protocol
- Referring centers credit for participation
- Other examples
  - Increased risk donors (define)
  - DCD heart transplant
  - Complex ACHD patients
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%
Thank you, Shelley Hall

You are welcome, Mary Jane Farr