Issues in Organ Donor Intervention Research: UNOS/OPTN Perspectives

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December 14, 2016
Deceased Donor Research: OPTN Goals

- Improve organ quality and supply
  - Pre-procurement management
  - Post-procurement perfusion
  - Organ repair or therapy and modification
- Allocation equity
- OPTN system efficiency and oversight
Waitlist / Supply: Demand

- 120,000 people on the various organ specific lists
- 9000 deceased donors this year
- 32,000 organ transplants this year
- 3.5 organs transplanted per donor
- 88 transplants per day
- 22 deaths on the lists per day
Organ Procurement and Transplantation Act (NOTA): Legal Framework

- **NOTA:** Passed by Congress in 1986, established the Organ Procurement and Transplantation Network (OPTN)
- **Final Rule:** Issued by HHS in 1999: Operational requirements for OPTN followed IOM report
- **OPTN required to balance equity with outcomes in OPTN operations**
OPTN: Structural Constraints

- Organ Procurement Organizations (OPOs) or Donor Service Areas (DSAs): 58, the local geographical unit of allocation
- Regions: 11, the next largest unit of allocation, also has an administrative function
- National: the largest unit of allocation
- These geographical boundaries are not designed to optimize allocation, largely political and historical in nature
- Allocation proceeds from local to regional to national
Organ allocation policies are “local” (OPO), then regional then national – and are patient specific (not transplant center)
Allocation: organ specific systems

- **Kidney**: utility and equity, recipient health, organ quality
- **Liver**: sickest first, varied sharing by MELD score
- **Heart**: sickest first, geography by zones
- **Lung**: Lung allocation score, a balance of pre and post transplant survival, geography DSA, then zones
- **Pancreas**: largely waiting time
Rank order on waiting list

- Driven by the organ available
- Donor factors: donor research has the potential to affect organ quality
- Recipient factors
  - Typical match-run may have thousands of recipient candidates
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Donor research is not new
Transplantation as standard of care

背景：对在移植和透析患者中进行比较的移植或透析作为标准治疗的患者，与终末期肾病的生存率和移植术的死亡率之间的关系是受争议的，因为那些接受透析的患者有更高的慢性肾病的风险。

方法：在一项研究中，我们对透析和移植的患者进行了一项长期的前瞻性研究，其中包含了这些患者在透析和移植治疗期间的各种数据。通过使用多变量回归分析，我们评估了透析和移植之间的关系。

结果：在透析和移植组中，透析组的生存率明显高于移植组。透析组的生存率在透析开始后3个月达到峰值，然后逐渐下降。移植组的生存率在移植后3个月达到峰值，然后逐渐下降。

结论：透析和移植之间的关系是复杂的，需要进一步的研究来确定最佳的治疗方案。
Issues to address: Consent

- Is recipient consent required?
- When is recipient consent required?
- At what level of risk is consent required?
- How and when is consent obtained?
- Global consent for research versus study specific consent?
- Logistical issues of consent and allocation equity?
Issues to address: Allocation equity

- Donor research creates a separate population of donor organs and may limit allocation to a subset of recipients
- Limiting the pool of organs available for transplantation to a portion of the waitlist population creates inequity
- How much inequity inherent in the OPTN system is tolerable?
Issues to address: Research oversight

- How is study risk assessment determined?
- How is study validity addressed?
- How is transplant program oversight addressed?
- Carve-outs for research outcomes?
- How is public data and clinical outcome transparency maintained in the context of research confidentiality?