

Regulatory landscape of Transplantation: Role of OPTN's Membership and Professional Standards committee

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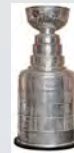
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Disclosures

- No relevant financial disclosures 😞
- Fiduciary:
 - MPSC 2017-2021
 - OPTN + UNOS BOD 2021-2023
 - Incoming Chair of MPSC, beginning July 1
- Award for longest presentation title



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Objectives

- Overview of the OPTN
- What even is the MPSC? What does it do?
- Foray into performance metrics
- Get to know a whole bunch of acronyms/abbreviations

BRB
YOLO
FYI
GOAT
FML

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Rapid growth of transplantation

- 1st kidney transplant in 1954, followed by liver, lung, heart
- 1000s of organ transplants annually by early 1980s
- Ad hoc organ exchange with inconsistent model for organ recovery
- Little oversight/regulation



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National Organ Transplant Act of 1984



- Organ Procurement & Transplantation Network (OPTN)
 - Private nonprofit entity by contract with HHS
 - Establish membership criteria and medical criteria for allocating organs
 - National policy and system; nationwide coordination
- Banned the sale of organs
- Created SRTR for data analysis
- Created the modern OPO system
 - 56 Donor Service Areas (DSA)



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OPTN contract

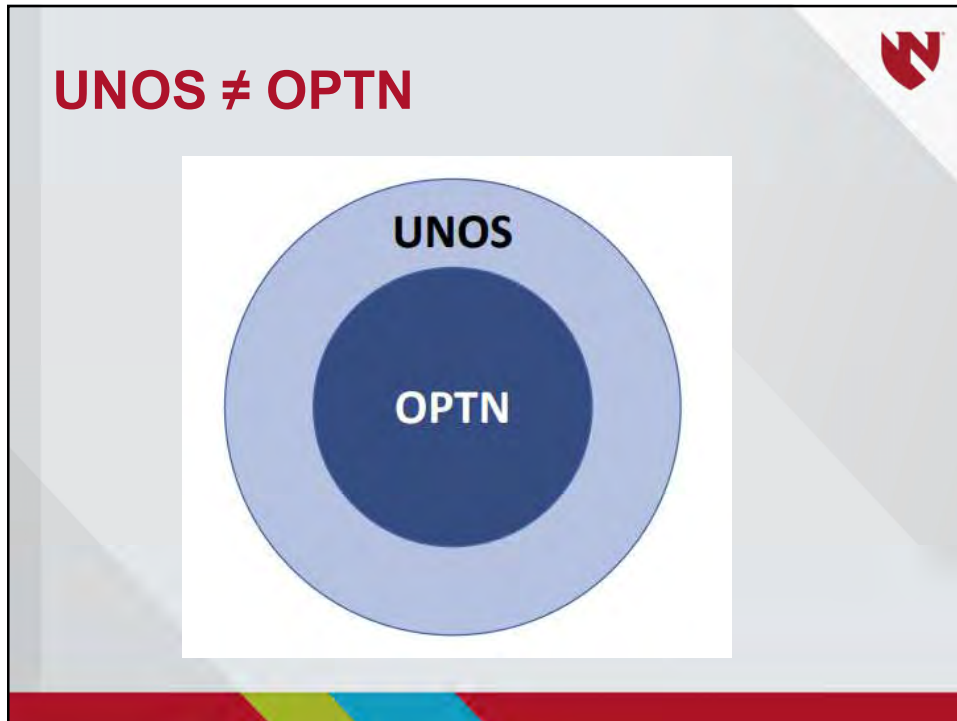


- Competitive bid process, with qualifying criteria
- Cost reimbursement contract
 - Authorized fee collection based on patient registrations on waiting list
 - Limited direct federal funding
- UNOS has held contract since 1987



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OPTN structure (“Final Rule”, 2000)

Committees – develop policies and other initiatives, seek public input, provide recommendations to Board of Directors

- Volunteers, represent areas of country and various disciplines/perspectives
- Federal government ex-officio, non-voting members

Board of Directors – acts on matters brought before it

- Volunteers; Federal government ex-officio, non-voting members
- Executive Committee can act in certain circumstances, subject to Board review/approval

CEO – directs and oversees all staff efforts

<https://www.ecfr.gov/current/title-42/chapter-I/subchapter-K/part-121>



The graphic shows the word 'VOLUNTEER' in white capital letters on a black background, with several colorful hands (yellow, orange, red, purple, green) raised behind it.

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Key OPTN responsibilities (also in “Final Rule”)



- Maintain national transplant list
- Facilitate organ distribution, transplantation
- Establish equitable policies and membership standards
- Monitor members for compliance, safety, quality
- Collect/validate/report transplant data
- Promote most/best use of available organs

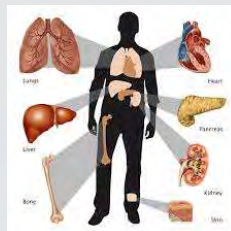


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- Maintain national transplant list
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OPTN | ORGAN PROCUREMENT AND
TRANSPLANTATION NETWORK

The Law says **that** members shall be monitored

The OPTN Bylaws state **how** members are monitored

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Membership and Professional Standards Committee (“MPSC”)



- Operating committee of the OPTN
- Volunteers from hospital, OPO, histo lab members, as well as patient/family, HHS reps
- Monitors member compliance with:
 - Membership criteria
 - Bylaws and policies
 - OPTN final Rule
- Peer review:
 - Reviews patient safety events
 - Provides performance improvement feedback

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Membership requirements

- Covered by appendices of OPTN bylaws
- Initial applications submitted to MPSC for review, recs forwarded to BOD for approval
- Appendix D covers requirements for transplant hospitals
 - Including QAPI, facilities, key personnel, other personnel



Optn.transplant.hrsa.gov

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More on Membership

Transplant program activity

“Functional inactivity” (appendix D.11)

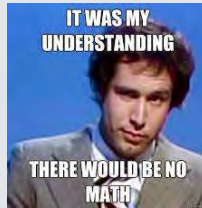
- Failure to perform at least 1 transplant in 3 months (kidney, liver, heart)
- Patients on waitlist must be notified
- Triggers review of program
- May result in recommendation that program inactivate



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And...Performance

- Historically, transplant programs monitored for 1 year patient and graft survival
- SRTR-provided risk-adjustment
 - Either of the following met:
 1. Probability is >75% that the HR is >1.2
 2. Probability is >10% that the HR is >2.5



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Shortfalls of “old” system

- Reliance on single, post-transplant metric
- Risk aversion may contribute to lower transplant volumes
- Data that programs under performance review do in fact transplant less

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OPTN Ad hoc systems performance committee, 2018

- Charge: standards for transplant system performance as a whole
- Fiduciary role under the Final Rule to monitor member performance
- Constrained by OPTN authority
- Strive to encourage performance improvement
- Goal for more holistic evaluation of transplant program performance

https://optn.transplant.hrsa.gov/media/3015/201906_spc_boardreport.pdf

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OPTN policy/bylaw development process



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New transplant program performance monitoring system



1. Organ offer acceptance
2. 90-day post-transplant graft survival
3. 1-year post transplant graft survival, conditional on 90-day survival
4. Waitlist mortality*

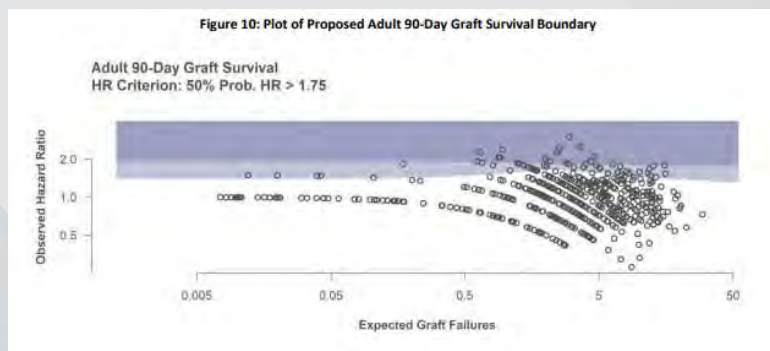
*Pending implementation

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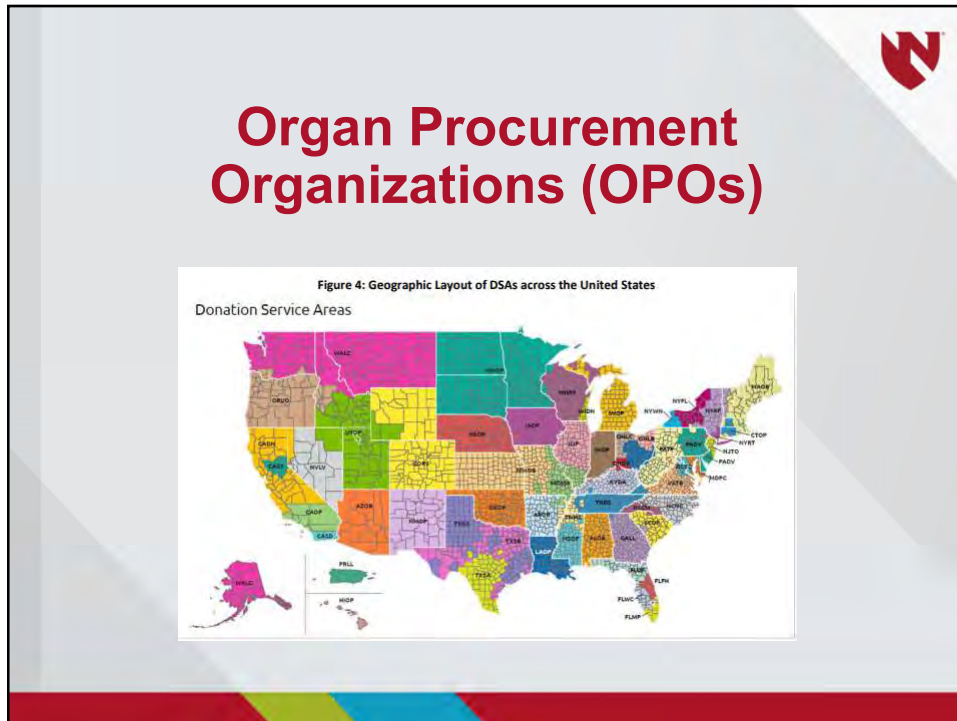
Performance boundaries (1)



- For WL mortality and graft survival metrics
 - Based on rolling 2.5 year cohorts
 - Probability >50% that HR > 1.75



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OPTN Membership

- Appendix B of OPTN bylaws cover requirements for OPOs
- Applications reviewed by MPSC, recs forwarded to BOD
 - QAPI
 - Facilities
 - Personnel
 - CMS certification

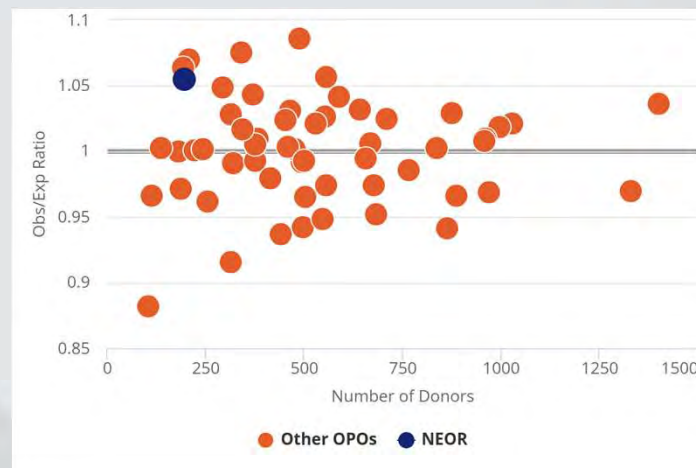
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OPO Performance

- As with hospitals, performance standards are included in membership requirements (App B.2)
- Organ yield is current metric
 - >10 fewer per 100 than expected
 - O:E < 0.90
 - P < 0.05
- Risk-adjusted by SRTR, both overall and organ-specific

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NEOR, all organs:



SRTR.org

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Day in the Life of the MPSC



- Compliance monitoring:
 - Membership applications (new organ transplant program...)
 - Key personnel change (new primary physician for...)
 - Performance “flag” (transplant program or OPO)
 - Living donor death or other patient safety event
 - Allocation violation
 - Functional inactivity

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Appendix L “Reviews and Actions”



- Framework for peer review process
 - Investigations
 - Peer visits
 - Informal discussion/Interview/Hearing
- OPTN Actions
 - Non-adverse (not public, no BOD approval)
 - Close with no action
 - Notice of Noncompliance
 - Letter of Warning
 - Adverse actions (BOD approval, Public)
 - Probation
 - Member not in good Standing



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What's on the horizon?



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The future MPSC

- OPO metrics
- Revision of membership criteria
- Transplant program metrics? (again!)
- Continued shift toward quality improvement
- Impact of OPTN restructuring?



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Summary

- Member performance monitoring is required under NOTA and the Final Rule
- MPSC composed of cross-disciplinary volunteers
- Tasked with reviewing member activity (compliance, performance)
- Emphasis is on quality improvement and patient safety

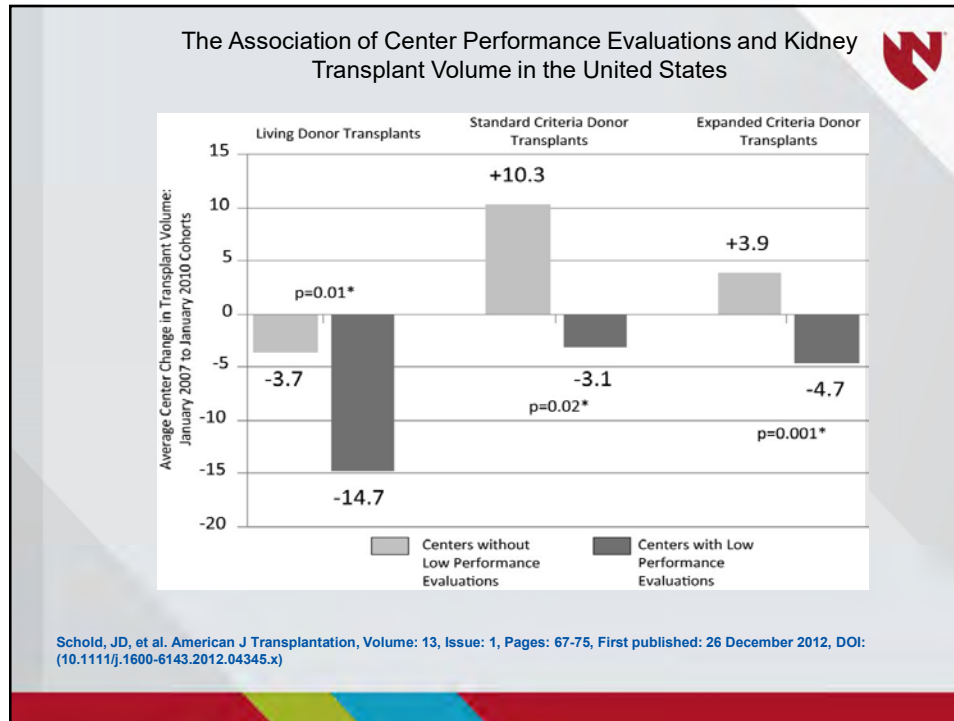


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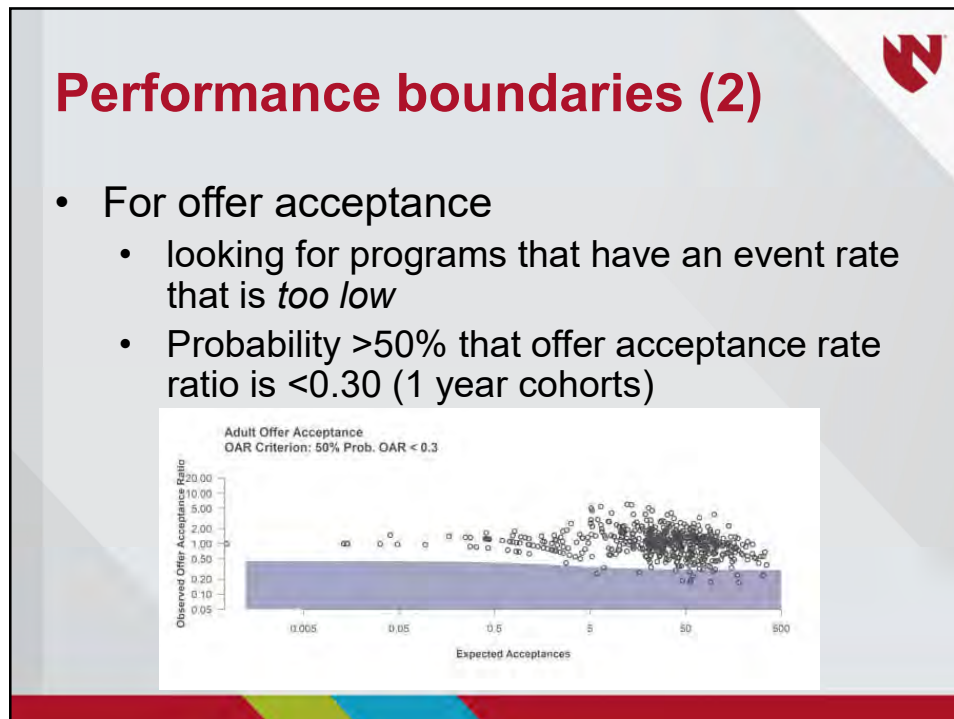


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Will more programs get 'flagged'??



SRTR modeling based on spring 2020 data:

Adult Proposed Boundaries	Heart	Kidney	Liver	Lung	Total
Waiting List Mortality - 50% Probability RR > 1.75	5	0	3	5	13
Offer Acceptance - 50% Probability RR < 0.30	1	6	5	2	14
90-day Graft Survival - 50% Probability HR > 1.75	3	10	4	2	19
Conditional 1-year Graft Survival - 50% Probability HR > 1.75	3	9	1	3	16
Total	12	25	13	12	62

Compared to average of 68.5 over previous 3 cycles...

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