What Has Happened to Undermine the Public-Private Partnership

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Disclosure

• No financial disclosures relevant to this presentation

• I’m Not a Lawyer

• I’ve held various leadership positions with the OPTN/UNOS

• Washington University is a party to the most recent lawsuit involving the OPTN/UNOS
Learning Objectives

• Understand the legislative and regulatory framework that serves as the foundation for the OPTN with particular reference to the organ allocation policy development process

• Understand the factors that have prevented the OPTN from fully realizing the goals envisioned by those who developed NOTA and the OPTN Final Rule with particular reference to the legal challenges to OPTN policy development.
Media and Judicial Influence - Overview

- Legal Background
- Lung Allocation Challenges
- Liver Allocation Challenges
Federal Legal Framework

**Established:**
- Organ Procurement and Transplantation Network (OPTN)
- Scientific Registry of Transplant Recipients (SRTR)
- Organ Procurement Organizations (OPOs)
- Prohibits sale or purchase of human organs

**Federal Law:** NOTA (1984)

**Established:**
- OPTN Board and Committee structure
- Process for OPTN membership
- Listing Requirements and Procurement Principles
- Principles and Process for Allocation Policy Development and Review

**HHS Regulation:** OPTN Final Rule (2000)
UNOS and the OPTN

- The federal contract for the OPTN has been held by the United Network for Organ Sharing (UNOS) since 1984.
- Since that time UNOS has been responsible for governing development of US organ allocation policy.
- The process has evolved over time but is intended to be data driven, consensus based and iterative.
Secretarial Review. Under § 121.4(d):

Any interested individual or entity may submit to the Secretary in writing critical comments related to the manner in which the OPTN is carrying out its duties ... The Secretary will consider the comments in light of the National Organ Transplant Act and the regulations under this part and may consult with the Advisory Committee on Organ Transplantation established under §121.12. After this review, the Secretary may:

• (1) Reject the comments;
• (2) Direct the OPTN to revise the policies or practices consistent with the Secretary's response to the comments; or
• (3) Take such other action as the Secretary determines appropriate.
Courts adjudicate challenges to OPTN Policies under the framework provided by the Administrative Procedures Act.

Courts typically defer to Agency rules if there is a reasonable basis supporting the rule: (the “Chevron doctrine”).

Standard of Review – Agency Rules are upheld unless determined to be “Arbitrary and Capricious”.

The US Supreme Court, in *Kisor v. Wilkie*, recently reinforced the deference to Agency rules as long as the Agency’s construction is deemed reasonable.
Media and Judicial Influence- Overview

Legal Background

Lung Allocation Challenges

Liver Allocation Challenges
Sara is a young girl with Cystic Fibrosis who was listed for lung transplant at CHOP (age 9) 12/2011

Height range increased in order to access adult lungs (for lobar transplant) 11/2012

Admitted to CHOP for further care 2/2013

Transferred to PICU for BiPap 5/2013

CHOP Requests Exception to Allow SM to have an LAS and compete with adolescents/adults 5/23/13
# Pediatric Lung Background

<table>
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<th>Recipient Age</th>
<th>Donor Age</th>
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<tr>
<td>1st</td>
<td>&lt; 12</td>
<td>12 - 17</td>
<td>12 +</td>
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<tr>
<td>2nd</td>
<td>12 - 17</td>
<td>&lt; 12</td>
<td>&lt; 12</td>
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<tr>
<td>3rd</td>
<td>18 +</td>
<td>18 +</td>
<td>18 +</td>
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</tbody>
</table>

Figure 1: Zones Used for Thoracic Organ Allocation

- DSA
- Zone A
- Zone B
- Zone C
- Zone D
- Zone E

**AST** AMERICAN SOCIETY OF TRANSPLANTATION

**CEDT** CUTTING EDGE of TRANSPLANTATION
Sara is a young girl with Cystic Fibrosis who was listed for lung transplant at CHOP (age 9)

11/2012
Height range increased in order to access adult lungs (for lobar transplant)

2/2013
Admitted to CHOP for further care

5/2013
Transferred to PICU for BiPap

5/23/13
CHOP Requests Exception to Allow SM to have an LAS and compete with adolescents/adults

5/24/13
Family makes public and social media appeal
Sarah murnaghan
1 petition

Follow

Most recent

VICTORY This petition won 6 years ago

Petition to John Roberts, Kathleen Sebelius
Allow transplants of adult lungs to children

Ten-year-old Sarah Murnaghan has end-stage Cystic Fibrosis and has been on the lung transplant list for 18 months. Too sick to leave Children’s Hospital of Philadelphia for three months, she has

Maureen Garrity

⚠️ 371,277 supporters

RELATED TOPICS

- Lung transplant
- Cystic fibrosis
- Organ procurement and trans...
- Child health
- Organ transplant
- Organ donation
- Health
- Children
Pediatric Lung Timeline

- **5/29-30/13**: HHS Secretary requests information about Pediatric Lung Allocation, OPTN responds.
- **6/3/13**: SM Attorney sends “Critical Comments” Letter to HHS Secretary.
- **6/5/13**: Federal Lawsuit filed requesting a TRO. OPTN Ordered to “immediately cease application of the Under 12 Rule as to [SM]”.
- **6/6-10/13**: OPTN/UNOS Pediatric, Thoracic, Ethics and Executive Committees review case.
OPTN/UNOS Committee Opinions

**Thoracic and Pediatric Committees**
- Concluded that there was insufficient data to justify an urgent change to allocation policy.
- Made plans to review the pediatric lung allocation policies in upcoming meetings.

**Ethics Committee**
- Expressed concerns about the appropriateness of judicial intervention.
- Expressed concerns that lawsuits as a mechanism to effect change in the allocation system may disrupt the public trust.
Cumulative probability of death/too sick by age for lung additions during 9/12/10-3/11/13
**Number of lung registrations with offers or acceptance by age, 9/12/10-3/11/13**

<table>
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<tr>
<th>Age</th>
<th>REGs Ever Active</th>
<th>REGs with at Least 1 Offer</th>
<th>REGs with 3+ Offers or Acceptance</th>
<th>REGs with an Acceptance</th>
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<tr>
<td></td>
<td>N</td>
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<tr>
<td>0 - 5</td>
<td>54</td>
<td>29</td>
<td>53.7</td>
<td>27</td>
</tr>
<tr>
<td>6-11</td>
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<td>34</td>
<td>69.4</td>
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<td>12-17</td>
<td>115</td>
<td>100</td>
<td>87.0</td>
<td>88</td>
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<tr>
<td>18+</td>
<td>7,323</td>
<td>6,826</td>
<td>93.2</td>
<td>6,262</td>
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</table>

**Notes:**
- Included lung registrations with or without any other organ(s)
- Age was determined based on maximum of age at listing or age at start of period
Pediatric Lung Timeline

OPTN Executive Committee creates LRB exception for Lung Transplant Candidates aged 0-11 to be listed as adolescents (sunset 6/14)

6/10/13

SM discharged home

8/26/13

6/12/13

SM undergoes transplant (subsequent retransplant on 6/15)

6/25/14

OPTN Board makes exception path permanent

6/25/14
OPTN Executive Committee creates LRB exception for Lung Transplant Candidates aged 0-11 to be listed as adolescents (sunset 6/14)

6/10/13

SM undergoes transplant (subsequent retransplant on 6/15)

6/12/13

SM discharged home

8/26/13

OPTN Board approves prioritizing distribution of pediatric donor lungs to pediatric candidates within 1000 mi of donor hospital

12/2/15 (implemented 3/17)

OPTN Board makes exception path permanent

6/25/14
Summary - Pediatric Lung

**Precedents**
- Media / Social Media campaign triggers Secretarial review
- Critical Comments as a path for Legal Action
- Federal Court Grants a TRO leading to OPTN Policy change

**Factors constraining precedent**
- Difficult to defend allocation groupings (age boundary) without lung review board appeal path
- Inconclusive data regarding equitable access to donor lungs for candidates aged 0-11 compared to adolescents and adults
- NOTA requires the OPTN to address unique health care needs of children
Local Allocation of Lung Donors Results in Transplanting Lungs in Lower Priority Transplant Recipients

Mark J. Russo, MD, MS,* David Meltzer, MD, PhD, Aurelie Merlo, AB, Elizabeth Johnson, MA, Nazly M. Shariati, MD, MS, Joshua R. Sonett, MD, and Robert Gibbons, PhD

- Locally allocated donor lungs bypassed a potential higher LAS candidate within the same region 82.8% of the time.
- 16.1% of these events involved a candidate who ultimately died waiting.
OPTN Final Rule

- **Policy development.** The Board of Directors established under § 121.3 shall develop, in accordance with the policy development process described in § 121.4, policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies:
  - (1) Shall be based on sound medical judgment;
  - (2) Shall seek to achieve the best use of donated organs;
  - (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with § 121.7(b)(4)(d) and (e);
  - (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;
  - (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;
  - (8) Shall not be based on the candidate’s place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.
Adult Lung Timeline

11/16/17

“Critical Comment” submitted to HHS requesting removal of DSA from lung allocation policy making initial distribution a 500 NM circle (Zone A)

11/20/17

Lawsuit Filed in Federal Court, including request for TRO. Court requests emergency review of lung policy
Plaintiff’s Argument & HRSA Questions

Using DSA Boundaries is Arbitrary and Capricious:

• No correlation to organ viability
• Not created for organ distribution
• Not consistent in size
• Results in wide variation
• Results in allocation inconsistent with the mandates of the final rule

HRSA Asks OPTN:

• Is the use of DSAs in the lung allocation policy consistent with the requirements of the OPTN Final Rule?
• Is the use of DSAs more consistent with the Final Rule than an alternative policy in which Zone A would be the first unit of allocation?
11/24/17: OPTN/HRSA Communications

OPTN (via ExCom) to HRSA:

• Lung allocation policy contained an over-reliance on DSA as primary unit of allocation
• A revised policy that does not depend on DSA as primary unit of allocation of lungs is more consistent with Final Rule
• Replacing DSA with a 250-mile circle from donor hospital as first element of lung allocation is a reasonable geographic constraint

HRSA directs the OPTN to:

• Remove DSA from lung allocation policy and make a 250 NM circle the first unit of distribution
Adult Lung Timeline

“Critical Comment” submitted to HHS requesting removal of DSA from lung allocation policy making initial distribution a 500 NM circle (Zone A)

11/16/17

Lawsuit Filed in Federal Court, including request for TRO. Court requests emergency review of lung policy

11/20/17

Revised Policy Implemented under OPTN Emergency Policy Pathway

11/24/2017
Summary - Lung Geography

Key Points
- Executive Committee action likely avoided a more drastic policy change (500 NM vs. 250 NM)
- Difficult to defend DSA as the primary unit of distribution

Precedent
- Judicial intervention influences the OPTN to make a rapid and significant change to allocation policy.

Implications
- Established a need for reevaluation of DSA use in all policies
- Unintended consequences?
Media and Judicial Influence - Overview

- Legal Background
- Lung Allocation Challenges
- Liver Allocation Challenges
Geography: Liver Txp Rates, by OPO

MELD 38-39: 18% to 86%

Massie/Segev, AJT 2011
Liver Distribution - Background

**OPTN Board 2012**
- Reviewed data showing a 60% difference in 90 day liver waiting list mortality for patients with MELD/PELD 38-39
- Concluded current geographic disparity is unacceptable
- Requested evaluation of optimized systems utilizing overlapping vs. non-overlapping geographic boundaries

**Activity Through 2016**
- Concept Document released in June 2014
- Public Forums September 2014, June 2015, much work in between
- Public Comment Proposal Fall 2016
Public Comment Themes

- Related to Modeling/Methodology/Policy Development Process
- Impact on Access to Transplant
- Unintended Consequences/Worse Outcomes
- OPO Performance
- Costs/Logistics
Liver Allocation Timeline

**OPTN Board Poised to Adopt New Liver Policy (culmination of years of debate)**

11/15/17

**“Critical Comments” Letter sent to HHS Secretary regarding Liver policy (same law firm)**

12/1/17

**OPTN Removes DSA from Lung Policy in response to Lawsuit, ad hoc Geography Committee formed**

11/24/17
12/4/17 Liver Policy

• After Multiple Amendments / Robust Debate
  OPTN Board Accepted Liver/Intestine Committee
  Recommendation

• Decision Balanced Equity (MELD variance) with
  Efficiency (percent organs flown)
Liver Allocation Timeline

• 5/30/18 – A Revised “Critical Comments” letter sent to HHS Secretary Asserting that Current and Pending Liver Policy, NLRB violate the OPTN Final Rule

• 6/8/18 – HRSA Administrator Requests OPTN input in relation to the liver policies:
  • DSAs as units of distribution
  • OPTN regions as units of distribution
  • Proximity points in relation to DSAs
  • Using median MELD in DSAs in granting MELD exceptions
Liver Allocation Timeline

- **6/25/18** – OPTN Response to Secretary:
  - Revised Liver Policy does not include an over-reliance on DSA - prioritizes medically urgent candidates irrespective of location (contrast lung allocation policy)
  - OPTN reconfirms that DSAs/Regions are neither rationally determined nor consistently applied
  - OPTN commits to a deliberative, multi-step plan to eliminate use of DSAs/Regions in liver distribution within a timeframe to minimize unintended consequences
Liver Allocation Timeline

- **7/13/18** – Lawsuit Filed – Requests that Court:
  - Declare that DSA and Region in liver distribution violates NOTA and the Final Rule
  - Require Secretary to direct the OPTN to implement a “zone-based” liver distribution policy within 6 months
  - Enjoin HHS Secretary to prevent OPTN implementation of new liver policy

- **7/31/18** – HRSA directs OPTN to adopt revised liver policy by December 2018 and develop plan to remove DSA/regions from remaining organ allocation policies
Liver Allocation Timeline

OPTN Liver/Intestine Committee Begins Considering DSA/Region-Free Liver Policy Alternatives

7/31/18

10/8 – 11/1/18
Abbreviated Public Comment Period
DSA Free Liver Allocation Proposals

- The committee modeled two allocation frameworks: Acuity circle (150/250/500nm by MELD 37/33/29/15) and Broader 2 Circles (share MELD at least 32 to 250 nm)

- Both models followed the geography committee’s proposed framework of fixed distances from the donor hospital and use 150, 250 and 500 nautical miles from the donor hospital as units of allocation
## Impact of Proposals

<table>
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<tr>
<th>Scenario</th>
<th>Variance in Median Allocation MELD/PELD at Transplant</th>
<th>Median Transport Time (hours)</th>
<th>Median Transport Distance (miles)</th>
<th>Percent of Organs Flown</th>
<th>Waitlist Mortality Count/Rate</th>
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<td>117.1</td>
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</table>
Liver Allocation Timeline

OPTN Liver/Intestine Committee Begins Considering DSA/Region-Free Liver Policy Alternatives

7/31/18

Liver/Intestine Committee Narrowly Votes to Advance “Broader 2-Circle” Model

11/2/18

10/8 – 11/1/18

Abbreviated Public Comment Period
Liver Allocation Timeline

• **12/3/18** – OPTN Board Debates Liver Policy Proposal.
  • Reviewed Modeling Data and Public Comment
  • Limited Discussion of Prior Board Decision
  • Board Opted to set aside Liver/Intestine Committee Recommendation and approve “Acuity Circle” Model
• The Board Prioritized Equity (MELD variance) and Utility (lower waiting list mortality) over Efficiency (percent organs flown)
Liver Allocation Timeline

- **2/13/19** – Coalition of 11 Transplant Centers sends “Critical Comments” letter to HHS Secretary
- **4/22/19** – Coalition of 15 Institutions Files Lawsuit arguing:
  - HHS has not independently determined Policy compliance with the Final Rule (per §121.4(b)(2) Secretarial review and appeals)
  - HHS has not referred the “Significant” Policy Proposal to the Advisory Committee on Transplantation (ibid.)
  - The Policy fails to comply with NOTA in multiple ways (related to socioeconomic inequities and efficient management of organs)
  - Plaintiffs requested the court prohibit implementation of the new liver policy
Liver Allocation Timeline

5/13/19 District court denies Plaintiffs request for a TRO

5/14/19 Acuity circles liver policy implemented by the OPTN

5/20/19 District court grants injunctive relief pending Plaintiff’s appeal, mentioning SCOTUS Case

5/24/19 The OPTN reverts to the old liver policy
Liver Allocation Timeline

- After SCOTUS ruling, appeals court remands case back to District Court: 9/25/19
- District Court Denies Plaintiffs Request for Injunction: 1/16/20
- Acuity Circles Policy Re-implemented: 2/3/20
Summary – Liver Geography

Broader Distribution of Livers Remains a Contentious Issue

Current Lawsuit

- Raised substantial challenges to OPTN autonomy in Policy development
- Precedent: Federal Court willing to overturn OPTN Policy pending review
- Overall, the court supported the OPTN policy development process

In the Meantime

- OPTN Board actively pursuing “DSA-Free” policies for Kidney, Heart and Pancreas

To be Continued...
Comment

• The precedent that Federal Courts will intervene in organ allocation policies is now well established

• Unless the Donation and Transplant Community addresses the underlying tensions, the ambiguities and nuances within the OPTN Final Rule make further Federal Court intervention an ongoing risk

• This sequence of events raises the inevitable question: How can the OPTN Public/Private partnership be improved to address these challenges?
Perspective

- Develop clarity/consensus on metrics and targets before discussing specific policy changes
- Leverage technology to provide increased transparency and objective input
- Evaluate OPTN structure / function / HRSA relationship for improvement opportunities
Thanks!
Unadjusted relative risk of death/too sick and transplant by age group for lung alone candidates ever waiting during 9/12/10-3/11/13

Squares represent the relative risk; lines represent the 95% confidence limits

Relative Risk of Death/Too Sick

Relative Risk of Transplant

Note: Age was determined based on maximum of age at listing or age at start of period
# Broader Sharing of Pediatric Donor Lungs

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Transplants per 100 PY on the WL

- **Observed**: Actual number of transplants.
- **Curr Rules**: Current rules for allocation.
- **Share Child**: Sharing between children.
- **Share Both**: Sharing between both.
- **Child Prior.**: Child priority.

The graph shows the comparison of transplants under different allocation strategies across different age groups, with a focus on enhancing pediatric donor lung sharing.
Impact – WUSM Adult Program

• Evaluated transplants pre (N=77) and post (N=50) policy change
• Significant increases noted in:
  • Median Ischemic Time (209 vs 244 min)
  • Median Organ Cost ($34K vs $70.2K)
• Commented on increased travel overall
• Also noted increased costs related to “negative fly outs” and reduced daytime transplants

Puri et al. AJT 2019;19:2164-2167
Continuous Distribution

Advantages
• Two patients who are similar in suitability would be treated much the same way
• Priority would consider specific clinical characteristics about the candidate
• More likely that organ offers would be matched efficiently with candidates in highest medical need

Disadvantages
• Less easy to understand and explain
• May not produce predictable matches
Liver Transplantation Redistricting Concepts

Gentry et al., AJT 2013
Variance in transplant rate
% organs flying