The Donation and Transplant Community Perspective: Let Our Voice be Heard

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Disclosures

• I was assigned this specific topic for the debate
• My goal is to have a system that works
• Vested interest in transplant on a personal level
  – College roommate
  – Best friend’s daughter
• I am a transplant hepatologist
  – I have biases and potential conflicts of interest like everyone else
  – My guiding principle is to minimize biases to achieve the best solution
  – Goal for our system should be minimize biases as much as possible
• Funded by NIDDK R01: DK120561; Using Ethics, Epidemiology and High-Quality Data to Optimize the Allocation of Livers for Transplantation
• Previous funded by NIDDK K08: DK098272; A Population-Based Cohort to Study Outcomes in End-Stage Liver Disease Patients
• Other research support (unrelated to topic): Gilead, Merck, AbbVie
What is the OPTN

• Public-private partnership that links all professionals involved in the U.S. donation and transplantation system

• Goals are to
  – Increase the number of and access to transplants
  – Improve survival rates after transplantation
  – Promote patient safety and efficient management of the system
Is there a problem that needs to be fixed?

- Taking a 20,000-foot view, we are in a bad situation.
Is there a problem that needs to be fixed?

Taking a 20,000 foot view, we are in a bad situation

Broader concerns than people may recognize

Issues with policy development process

Federal judge allows new liver transplant policy to take effect

Some hospitals wary as new liver transplant rules begin

*Long-delayed rules that will more broadly share scarce donated livers go into effect Tuesday*

By LAURAN NEERGAARD AP Medical Writer

February 3, 2020, 5:30 PM • 4 min read
Is there a problem that needs to be fixed?

Taking a 20,000 foot view, we are in a bad situation

• Broader concerns than people may recognize
• Issues with policy development process
• Concerns about outcomes from recent policies
Recent missteps in policy development: KAS

- Kidney Allocation System (KAS)
  - Goal: Change allocation to prioritize disadvantaged groups and focus on utility for ‘best’ kidneys
- Successes:
  - Improved equity for some (e.g., minorities)
  - Improved access for sensitized patients
  - Better donor-recipient longevity matches
- Missteps
  - Increased discards according to UNOS analysis
  - Decreased access to pediatric kidneys among pediatric recipients: “This represents the flawed application of an adult donor metric to pediatric donors, for whom the KDPI was neither derived nor tested”
- Could this have been avoided under a different policymaking process?
  - My answer: Possibly

Recent missteps in policy development: Lung

- 2017: Change from DSA-first to sharing by circles (response to lawsuit)
- Problem 1: National discard rate increased (OPTN thoracic committee)\(^1\)
- Problems 2-4: Single-center/OPO data (Wash U) \(^2\)
  - Decreased local utilization
  - Increased ischemic time
  - Doubling costs donor organs
- Could this have been avoided under a different policymaking process?
  - My answer: Yes

Recent missteps in policy development: Heart

• Change distribution and allocation in 2018
  – Distribution: Changed geographic units of sharing
    • DSA->circles
  – Allocation: Changes in waitlist prioritization
    • Super-sickest receive the highest priority (e.g., ECMO)

• Problems
  – Increased cold ischemic time\(^1\)
  – Plummeting post-transplant outcomes: 6-month survival decreased from 93.4\(^%\)\(\rightarrow\)77.9\(^%\)\(^1\)

• Could this have been avoided under a different policymaking process?
  – My answer: Yes

Recent missteps in policy development: Liver

• Acuity Circles began 2/4/2020
• Allocation circles based on distance from donor hospital: 150, 250, and 500 nautical miles
• MELD thresholds: 37-40, 33-36, 29-32, 15-28, <15
• Exception points based on MMAT-3 from transplant hospital
HCC patient in Boston: 28 MELD exception points
HCC patient in NYC: 28 MELD exception points
HCC patient in Philadelphia: 27 MELD exception points
HCC patient at UVA: 25 MELD exception points
HCC patient at Duke: 25 MELD exception points
HCC patient in Lexington, KY: 24 MELD exception points
HCC patient in Lexington, KY: 25 MELD exception points

Donor in Washington, DC
Donor in Las Vegas, NV

HCC patient at Intermountain Medical Center: 23 MELD exception points

HCC patient at Banner: 23 MELD exception points

HCC patient at Mayo Scottsdale: 23 MELD exception points

HCC patient in San Francisco: 29 MELD exception points

HCC patient in Los Angeles: 31 MELD exception points
Starting point—some rules we cannot change

• Designing a new system of policy making has some constraints

• NOTA and Final Rule
  – Established regulatory framework for operations of OPTN
    • Have a Board of Directors
      – Representatives of OPOs, transplant centers, voluntary health associations, and the general public
      – Not less than 34 nor more than 412 members
      – Have an executive committee and other committees

• HRSA/HHS Oversight
Starting point—where flexibility is allowed

- Process of choosing committee members
- Process of choosing committee leadership
- Impact of public comment and regional votes
- Transparency of process
Possible roots of the problem

- Lack of transparency
- Committee selection and composition
- Will of the people ignored: Public comments and regional meetings
- Insufficient independent external input
- Process slow to adapt (moving forward or going back)
- Governmental overreach
- Caveat
  - Cannot prove that my proposed process would avoid missteps
  - At very least would increase transparency
  - System fails if we can’t maintain public trust
OPTN/UNOS Policy Development Process

1. Committees analyze the problem as well as any potential solutions to identify the best solutions for the problems facing the transplant community

2. Committee proposal released to the community through public comment
   - OPTN holds regional, in-person meetings throughout the country during this time
     • Allows community to convene, discuss, and comment on proposals
     • Feedback is utilized by the Board and committees to refine proposed solutions to best address the problems facing the transplant community.

3. Once the committees agree upon their proposed solutions, they are reviewed and approved by Policy Oversight Committee

4. Finally reviewed and voted upon by the OPTN Board of Directors
Documented issues with transparency and behind the scenes decision making

• Conclusion of Judge Amy Totenberg, 11th Federal District Court
  – “But this is a difficult and wrenching case. As the Court has recognized from the outset, there are extraordinarily complex and compelling issues raised by the conflicts at the heart of organ transplant litigation. Unfortunately, the manner in which the liver transplant policy change was driven in this case made the capacity of the affected institutions to effectively and preemptively address these complexities and policy tensions together all the more difficult. Acrimony boiled over under these circumstances.”

Opinion, Judge Amy Totenberg, US District Judge, 1/16/2020
OPTN bylaws for standing committee assignments

• Standing committee membership (some exclusions)
  – Step 1: Regional councilor receives nominations
  – Step 2: UNOS Vice President appoints committee members from list of nominees
  – Committee Chair and Vice-Chair: Selected by UNOS Vice-President
  – Vice President can appoint person to >1 standing committee

• Policy oversight committee
  – Vice Chairs of each Committees or representative of each Committee
  – Chair and Vice Chair appointed by vice president
  – Current representation among 21 voting members: Region 1 (6), Region 4 (4), Region 2, 7, 9, 10 (1 total)

• Nominating committee
  – Appointed by the president
  – No more than 12 voting members
  – Includes: President, Immediate Past president, Past president directly preceding the Immediate Past president, Vice president
Public involvement in policymaking

• Committee proposal released to the community through public comment
  – Usually 2-month period of public comment
• OPTN holds regional meetings throughout the country during this time
  – Allows community to convene, discuss, and comment on proposals
  – Feedback is utilized by the Board and committees to refine proposed solutions to best address the problems facing the transplant community.
Limited role of public feedback in policymaking:
Liver distribution a case study

- Optimal disparity metric
- Overwhelming majority at 2014 OPTN Forum
- Regional meetings in 2018 voting on Acuity circles vs B2C
  - Acuity circles: 4 Regions (1, 4, 5, 9)
  - B2C: 7 regions (2, 3, 6, 7, 8, 10, 11)
- OPTN/UNOS President 2016 response to question about regional votes: “They’re not binding in any way, shape, or form.”
- Liver Committee vote, 11/2/2018: B2C - 11 votes; Acuity circles: 9 votes
- Limited time to review public comments (order from Judge Amy Totenberg, 1/16/2010)
Independent external input: Role of the SRTR

• Scientific Registry of Transplant Recipients (SRTR)
  – PHS Act requires the operation of SRTR to support ongoing evaluation of the scientific and clinical status of solid organ transplantation
  – Mission: To provide advanced statistical and epidemiological analyses related to solid organ allocation and transplantation in support of the Department of Health and Human Services and its agents in their oversight of the national organ transplantation system.

• SRTR Senior Staff
  – Liver transplant surgeon
  – 2 transplant hepatologists
  – 2 transplant nephrologists
  – Transplant cardiologist
  – Transplant pulmonologist

• Policy oversight committee: 3 members of SRTR staff
Process of adapting to problems or responding to unintended consequences of policies

- OPTN bylaws for “Ongoing Policy Review”
- Committees periodically evaluate OPTN policies to determine if the policies are meeting stated objectives and remain current with scientific and technological advances. Depending on the outcomes of these assessments, proposals for additional policies or changes to existing policies may be proposed.

- KAS and KDPI of pediatric kidneys
  - Paper by Nazarian et al. published in March 2018
  - No proposals to date about changing weighting pediatric kidneys

- UNOS began tracking transportation errors in 2016 for organs
12/2017: OPTN/UNOS Board of Directors approves new liver distribution policy that was DSA + 150 miles

| 12/3/2018 | OPTN/UNOS Board meeting. HRSA representatives attending the meeting reiterate to the Board HHS’s position that DSAs and Regions do not meet the requirements of the Final Rule. | HHS_00009374 |
How to let the donation and transplant community’s voices be heard

• Improve transparency
• Change process of committee assignments
• Increase weighing of public input into policymaking
• Get independent external input
• Be able to rapidly response to change/adapt
• Limit governmental over-reach
Change #1: New process of policy making

• Goals
  – Improve transparency
  – Increase weighting of public input
  – Ensure independent external input

• Step 1: Developing and moving a policy through an organ-specific committee (OPTN House of Representatives)
  – Committee member can develop idea for a policy
  – Policy idea gets discussed in subcommittee
  – Subcommittee refines and discusses merits of a bill
  – Subcommittee releases policy idea to committee
  – Committee discusses policy, amends, and votes (majority)
Change #1: New process of policy making

- **Step 2:** Policy moves to committee of councilors (OPTN Senate)
  - 11 Regional Councilors
  - OPO Representative(s)
  - General public representatives
  - Other representatives
  - Policy discussed, debated, and amended in collaboration with organ-specific committee (requires majority vote)

- **Step 3:** Policy sent out for Public Comment and Regional Meetings
  - Must obtain >50% of the ‘popular’ vote
  - Must be approved by ≥6 OPTN regions

- **Step 4:** Policy reviewed by independent external body

- **Step 5:** Policy presented to Board of Directors
  - Policy approved by simple majority
Change #2: Revise process of committee membership and leadership

- Need broader representation and transparency in process
- Committee assignments chosen democratically at regional meetings
- Self-nominations or nominations by others
  - Nominees briefly state case for their position at regional meeting
  - 1 center-1 vote
  - Liver committee: Each liver center in region has 1 vote for who should be committee
- Committee chairs and vice chairs: Voted on by committee
- Other committees (e.g., OPO)
  - Chosen by organization (AOPO)
  - Other patient groups
- Policy oversight committee: Equal representation for every region
- Guiding principle (adapted from Chief Justice Roberts): “We do not have Region 1 Committee Members or Region 3 Committee Members, Region 9 Committee Members or Region 11 Committee Members. What we should have is an extraordinary group of dedicated committee members doing their level best to do equal right to those appearing before them.”
Change #3: Develop independent external oversight committee of experts

• Government Accountability Office (GAO)
  – Independent, nonpartisan agency that works for Congress to examine how taxpayer dollars are spent and provides objective, reliable information to help the government save money and work more efficiently

• Congressional Budget Office (CBO)
  – Produce independent analyses of budgetary and economic issues to support the Congressional budget process; strictly nonpartisan
Change #3: Develop independent external oversight committee of experts

- OABO (OPTN Accountability and Budget Office)
  - Independent body of transplant experts and community members
  - Independent from transplant centers
  - Removed from all OPTN committees
  - Include external experts outside of transplant with specific expertise
    - Demographer
    - Economist
    - Population scientist/epidemiologist
    - Systems engineer/operations management
  - Limit potential inherent conflicts of interest
    - Transplant nephrologists recused from kidney proposals
      - Cannot eliminate all COIs
      - Need to be transparent about them and minimize
  - Chaired by non-clinician and expert not involved in US transplant system
How will we judge if my system is working

• John Lydgate, “You can please some of the people all of the time, you can please all of the people some of the time, but you can’t please all of the people all of the time.”

• Goals of the OPTN
  – Increase the number of and access to transplants
  – Improve survival rates after transplantation
  – Promote patient safety and efficient management of the system
How will we judge if my system is working

• Feedback from stakeholders: Do they feel included? Do they feel voice matters?
• Process review: Is policy process being followed? Is public feedback being heard?
• Committee structure: Is there appropriate representation? Are new voices given opportunity to participate in process?
• How are policies working?
  – Do predicted outcomes match observed outcomes
  – Are we ensuring no policy
    • Limits the number of transplants
    • Limits access
    • Increases discards
    • Decreases utility
    • Increases inefficiency without other gains
Phoenix Address

• These missteps in OPTN policy development shall not have occurred in vain—that this OPTN, under HHS, shall have a new birth of freedom—and that OPTN of the donation and transplantation community, by the donation and transplantation community, for the donation and transplantation community, shall not perish from the current structure of transplant policymaking in the US.