UNOS Update

Yolanda Becker, MD
OPTN/UNOS President

Region 7
March 9, 2018
10,281 Donors in 2017 – a 3.1 % increase over 2016
Emergency Changes to Lung Allocation Policy

November 2017
### Nine Days in November: A Cautionary Tale

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Lung candidate argues that the use of DSA as the first unit of allocation contravenes NOTA, Final Rule, Medical Judgment

- Seeks removal of Classifications 1-6
- States effective result would be to share first with Zone A (500 mile circle)
- Similar argument repeated in Court filing on November 19 (Sunday)
Court Case: November 20

- Same argument from letter made in Federal Court
- Judge asked HHS to review and report by deadline
- While OPTN review was officially directed by critical comments process, content and timing were connected to judge’s requirement for HHS to review
HHS directed OPTN to review use of DSA in lung allocation policy, with particular attention to these regulatory requirements:

42 CFR 121.8 establishes a performance goal of:

“Distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency.”
HHS Questions to 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?
Executive Committee Deliberations

- Met twice week of Thanksgiving (11/22 & 11/24) to review Secretary directive and options
  - Thoracic Committee calls to discuss

- Determined:
  - current 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

- Concluded that lung allocation policy could be revised by replacing DSA as first element of lung allocation, with 250 mile circle measured from donor hospital in order to apply a reasonable geographic constraint
Current Situation

- 250 Nautical Miles Circle effective November 24
- Current process expires November 23, 2018 per procedure
- Proposal currently out for Public Comment
Ad Hoc Committee on Geography

- Chairs or co-chairs of organ specific committees, Transplant Administrators, and OPO representatives
- Several current Board members
- AOPO, AST, ASTS representatives
Ad Hoc Committee on Geography Charge

- Establish defined guiding principles for the use of geographic constraints in organ allocation
- Review and recommend frameworks/models for incorporating geographic principles into allocation policies
- Identify uniform concepts for organ specific allocation policies in light of the requirements of the OPTN Final Rule
Ad Hoc Committee on Geography

- Kevin O’Connor, M.S., PA, Chairman; president and chief executive officer of LifeCenter Northwest.
- Adam Bingaman, M.D., Ph.D.; Methodist Specialty and Transplant Hospital
- Lewis Teperman, M.D.; North Shore University Hospital
- Kenneth Washburn, M.D.; Ohio State University Medical Center
- Akinlolu Ojo, M.B.B.S., Ph.D., M.B.A.; University of Arizona Health Sciences
- Charles Alexander, RN, M.S.N., M.B.A., CPTC; The Living Legacy Foundation of Maryland
- Alexandra Glazier, J.D., M.P.H.; New England Donor Services
- Deanna Santana, B.S.; Sierra Donor Services
- Kenyon Murphy, J.D.; Vice President for Patient and Donor Affairs, OPTN/UNOS Board of Directors
- Richard Formica, M.D.; Yale New Haven Hospital
- Charles Miller, M.D.; Cleveland Clinic Foundation
- Nicole Turgeon, M.D.; Emory University Hospital
- Julie Heimbach, M.D.; Mayo Clinic, Rochester, Minn.
- Kevin Chan, M.D.; University of Michigan Medical Center
- Ryan Davies, M.D.; Children’s Medical Center of Dallas
- Silke Niederhaus, M.D.; University of Maryland Medical System
- Jennifer Prinz, RN, B.S.N., M.P.H., CPTC; Donor Alliance
- James Pittman, RN, M.S.N.; HCA Healthcare
- Elisa Gordon, Ph.D., M.P.H.; Northwestern Memorial Hospital
1/16 Call #1
- Introduction to topics
- Committee charge

2/12 Call #2
- Organ distribution principles discussion

2/26 Call #3
- Framework and models discussion

3/20 Call #4
- Further framework and models discussion

In-person Meeting
- Align organ distribution principles and framework

4/13 Call #5
- Finalize report to Board of Directors
System Assessment
System Improvement Work Group

- Three workgroups:
  - OPO Metrics
  - Transplant Program Metrics
  - System/Interaction Metrics

- System workgroup to look at new ways to measure how OPOs and Transplant Programs work effectively together, in DSAs or regions or localities

- Diane Brockmeier and Matt Cooper MD will Co-chair
  - Summit Q3-4 2018
Sample Dashboard
Process Improvement Journey

- Baldrige Criteria
- Seven critical aspects of performance
  - Leadership
  - Strategy
  - Customers
  - Knowledge Management
  - Workforce
  - Operations
  - Results
MORE TRANSPLANTS
Fair · Effective · Safe · Efficient

MATCH
Data analysis
Group facilitation
Public comment
Policy writing
Software development
Web design/Hosting
IT security
24-7 customer assistance

DATA
Collection
Provision
Analysis
Visualization
Interpretation

QI
Data interpretation
Compliance auditing
Benchmarking
Process improvement
Web-based training
In-person training
Effective practice sharing
Relational coordination
Peer coaching
Collaborative learning
Facilitation
Three Areas of Focus

Customers: OPTN/UNOS Members

Operations: Internal processes/work systems

Workforce: Internal and Volunteers (Committee Members)
Board of Directors

Vice President/
President-Elect

Other Region 7 Members of the Board for 2018-2019:
Yolanda Becker, MD – Immediate Past President
Srinath Chinnakotla MD, MCh, MBA – Region 7 Councillor
Kathy Schwab RN, CTCC – General Public Representative
Sharon Bartosh, MD – Medical Scientific Organization Representative
Joseph Hillenburg – Patient and Donor Affairs Representative
Mary Francois RN, M.S., CCTC – Transplant Coordinator Representative

Maryl R. Johnson, M.D
Pilot for Collecting Public Comment Feedback

Spring 2018
Feedback
Pilot Project
Improved Public Comment Input

- From each source that provides public comment, will collect demographic info, sentiment, and substantive feedback on four current proposals
  - Strategic Plan
  - Committee on Committees Concept Paper
  - Expedited Placement Concept Paper
  - Appendix L Rewrite
2018-2021
OPTN/UNOS Strategic Plan
How is the plan being developed?

- Strategic Planning session with Committee Chairs and Board Members at June 2017 Board Meeting
- Direct feedback from the Executive Committee
- Feedback from Board members
- Out now for public comment
Plan structure

- Same plan for OPTN and UNOS
  - Shared, high-level goals
- Description of current activities
- Opportunities for growth
- Metrics

OPTN/UNOS

2018-2021 STRATEGIC GOALS

Goal: Increase the number of transplants

Core activities:

- UNOS maintains the national transplant candidate waiting list and operates a 24/7 electronic matching system accessible to every OPO and transplant center in the country. UNOS also operates a 24/7 Organ Center, a live call center to assist OPOs and transplant centers with questions, transportation arrangements, and with placing organs. UNOS also runs a kidney paired donation program, providing a transplant option for kidney candidates who have a living donor who is medically able but cannot donate a kidney to their intended candidate because they are incompatible.

New initiatives:

- Pursue policies and system tools for more dynamic donor/recipient matching.
- Increase the number of kidney transplants arranged through kidney paired exchange programs.
- Expand the use of collaborative improvement methodologies and models.
- Evaluate metrics and monitoring approaches for increased collaboration and performance improvement activities when assessing transplant program and OPO performance.
- Decrease knowledge of and increase implementation of effective donation and procurement practices.
- Improve ability to perform analysis of refusal reasons.

Key metrics:

- By 2020, an x% decrease in amount of time of OPO first notification to OPO/Organ Center final notification (in cases clamped at x and timer)
- By 2020, an x% increase in actual acceptance of first offer (as within X offers)
- By 2020, at least a X% increase in transplants performed through kidney paired donation
- By 2020, an increase in utilization of organs from participants in collaborative improvement programs.
Mission: To advance organ availability & transplantation by uniting and supporting our communities for the benefit of patients through education, technology and policy development.

Vision: To promote long, healthy and productive lives for person with organ failure by promoting maximized organ supply, effective and safe care and equitable organ allocation and access to transplantation.

Values: Stewardship, Unity, Trust, Excellence, Accountability
## Strategic Plan Resource Allocation

### Current

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<tr>
<th>Goal</th>
<th>Benchmark</th>
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<tr>
<td>Increase the number of transplants</td>
<td>40%</td>
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<tr>
<td>Provide equity in access to transplants</td>
<td>30%</td>
</tr>
<tr>
<td>Improve waitlisted patient, living donor and transplant recipient outcomes</td>
<td>15%</td>
</tr>
<tr>
<td>Promote living donor and transplant recipient safety</td>
<td>10%</td>
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<tr>
<td>Promote efficient management of the OPTN</td>
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### Proposed

<table>
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<tr>
<th>Goal</th>
<th>Benchmark</th>
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<tr>
<td>Increase the number of transplants</td>
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<tr>
<td>Provide equity in access to transplants</td>
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<td>Promote efficiency in donation and transplant</td>
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</tr>
<tr>
<td>Promote living donor and transplant recipient safety</td>
<td>10%</td>
</tr>
<tr>
<td>Improve waitlisted patient, living donor and transplant recipient outcomes</td>
<td>10%</td>
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</table>
Strategic Plan Goals

- Equity
- Efficiency
- Safety
- Outcomes

Increase Transplants
Increase Transplants – Initiatives

- Improve donor/recipient matching
- Expand use of collaborative improvement methodologies/models
- Examine monitoring approaches for tx programs/OPOs for increased collaboration and performance improvement
- Increase txs arranged through KPD
- Promote knowledge of effective donation/procurement practices
- Improve ability to perform analysis of refusals
Promote Equity – Initiatives

- Develop equity benchmark for each organ
- Improve equity in opportunities for multi-organ and single-organ candidates
- Reduce geographic disparity
- Increase diversity on Board/Committees to ensure variety of perspectives in policy development
- Increase opportunities for volunteer engagement and awareness of OPTN/UNOS volunteer opportunities
- Collect additional data on vulnerable populations
Promote Efficiency – Initiatives

- Provide seamless data exchange between members and Unet
- Automate data reports for members
- Modularize and simplify UNetSM architecture to expedite system changes and improve quality
- Achieve continuous level of UNet accessibility
- Improve efficiency in policy development and implementation process
Improve Outcomes – Initiatives

- Improve longevity of organ transplants
- Evaluate effective methods for assessing living donor outcomes
- Enhance transplant program tools and education in selection and follow up of living donors
- Expand use of collaborative improvement models to promote effective donor management practices impacting transplant outcomes
- Develop transplant program tools to calculate survival benefit
Promote Safety – Initiatives

- Reduce number of safety incidents related to logistics/transport
- Improve perception of UNOS and MPSC as focused on process improvement
- Enhance knowledge-sharing about safety events, near misses, and effective practices
- Improve accuracy in HLA reporting
- Enhance system capability for reporting elements of data related to safety
Specific Requests for Feedback

- Does the proposed plan address the priorities for the donation and transplant community for the next three years?
- Do you think the OPTN strategic plan contains the right measures to assess progress on the strategic goals?
Questions?

Thank You for Giving the Gift of Life!

Sincerely,

UChicago Medicine

Transplantation Institute

[Image of hands holding a heart]

[Image of soccer players]
Workgroup on Committee Structure

Concept Paper – Seeking feedback
In June 2016, Executive Committee endorsed formation of two-year working group to assess and make recommendations on the following:

- OPTN/UNOS committee structure, number, and types
- Improvements to committee recruitment, selection, development, and engagement
- How to increase Committee and Board alignment
Trial Balloon

A tentative measure, or statement made, to see how a new policy might be received, so that adjustments can be made.
What are the Goals of this Concept Paper?

- Describe a participation structure that:
  - Provides opportunities to more participants
  - Increases minority representation on the committees
  - Ensures diversity in perspectives on committees
  - Strengthens connections between the Board and committees
Committees

- “one-size fits all”, regardless of function
- Committees have 18 members
  - Chair & Vice-Chair
  - 11 regional reps
  - 5 At-Large members

Other input

- Regional meetings
- PC website
- Societies
# Theories of Design

<table>
<thead>
<tr>
<th>Subjects</th>
<th>Perspectives</th>
<th>Tasks</th>
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<tr>
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<td>• medicine</td>
<td>• allocation policy</td>
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<td>• organ transplant</td>
<td>• surgery</td>
<td>• safety requirements</td>
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<td>• pediatrics</td>
<td>• OPO</td>
<td>• key data identification</td>
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<td>• administration</td>
<td>• system evaluation</td>
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<td>• finance (member)</td>
<td>• other professions</td>
<td>• member evaluation</td>
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<td>• staffing</td>
<td>• patients: candidates, recipients</td>
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<td>• donors families, and living donors</td>
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<td>• logistics</td>
<td>• ethics</td>
<td>• community engagement</td>
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<td>• gender</td>
<td>• education</td>
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New Framework: A Concept for Consideration
Two-way communication

Subject Committees
- new policy ideas
- community needs
- comments on drafts
- future committee members

Expert Councils
- draft policy language
- future work plans
- post-implementation evaluations
Two Tasks, Two Models

Subject Committees
- Single subject
- Frequently propose specific policies
- Debate specific policy language – needs smaller working group
- Send proposals to Board – needs balanced regional representation

Expert Councils
- Multiple subjects
- Weighs in on the work of many others
- Identifies gaps and opportunities – needs as many participants as possible
- Comments to Board on current and future issues
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<th>Subject Committees</th>
<th>Expert Councils/SME</th>
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<td>Chair and Vice-Chair</td>
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<td>Chairs would attend Board meeting</td>
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<td>Vice-Chair serves on POC</td>
<td>Vice-Chair serves on POC</td>
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<tr>
<td>Can suggest project ideas to the POC</td>
<td>Can suggest project ideas to the POC</td>
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<tr>
<td>Assist in UNOS educational, IT, or communications projects</td>
<td>Assist in UNOS educational, IT, or communications projects</td>
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<td>Leaders are identified for Board service</td>
<td>Leaders are identified for Board service</td>
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<tr>
<td>Have UNOS staff support***</td>
<td>Have UNOS staff support***</td>
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<tr>
<td>Reps speak with Regional voice</td>
<td>Reps speak with subject voice</td>
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<tr>
<td>Set membership appointed by OPTN President</td>
<td>Open membership to anybody in that community (Similar to communities of practice)</td>
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<tr>
<td>Sponsor public comment and Board proposals</td>
<td>Suggest ideas and a subset would participate with traditional architecture to sponsor public comment or Board proposals</td>
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<td>Chairs would present proposals to the Board and Board policy groups</td>
<td>Representatives from the Board would participate on Expert councils</td>
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<td>Meet in person and online</td>
<td>Consider new formats for large group</td>
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Feedback from Regions and Societies

- Appreciate and like the desire for increased community engagement
- Concept is sound, but more thought should be given to who is a Committee and who is a Council
- The options that Councils have for putting new ideas forward appears restrictive
- Technology and the skill set required to manage large councils is a concern
Subject Committees

- Heart
- Histocompatibility
- Kidney
- Liver/Intestine
- Lung
- Pancreas
- Operations
  - Disease Transmission
- Organ Procurement (or Donation)
- Quality Improvement (MPSC)
- VCA

Expert Councils

- Bioethicists
- Candidate and Recipient Affairs
- Deceased Donor Family
- Living Donors
- Minority Affairs and Vulnerable Populations
- OPO Executives
- Procurement Coordinators
- Transplant Administrators
- Transplant Coordinators
- Transplant Pediatric Specialists
Specific Requests for Feedback

- Will the proposed change in OPTN committee structure allow for greater opportunity for participation by the transplant/donation community?

- Will the proposed change in OPTN committee structure strengthen your voice in the policy making process?

- Do the proposed expert councils and subject committees capture all perspectives needed in the policy making process?
UNOS Update

Region 7
March 9, 2018

Stewardship ● Unity ● Trust ● Excellence ● Accountability