OPTN Public Comment Orientation

Matt Prentice

Manager of Policy and Community Relations
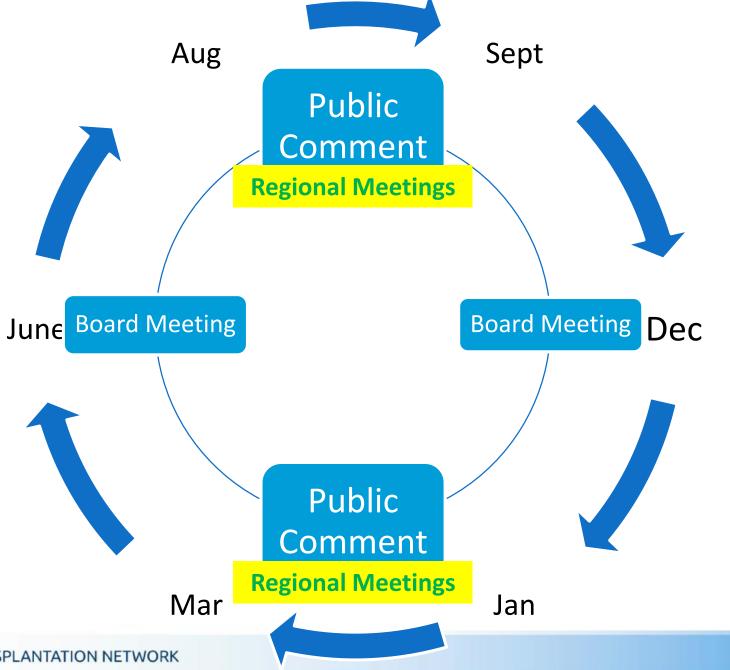
UNOS

Overview

- Policy development process

- Participating in public comment

- Regional Meetings

Policy Development Process

Two 6-Month Policy Cycles

Ongoing Committee Meetings

Aug

Sept

Public Comment

Regional Meetings

Board Meeting

June

Board Meeting

Dec

Public Comment

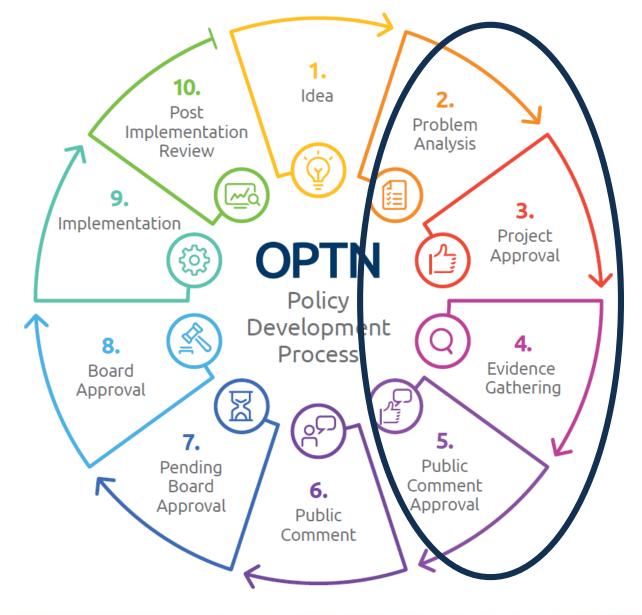Regional Meetings

Mar

Jan

Ideas Can Come From…

- OPTN members

- Committee members

- Community contributors

- Regional feedback

- Government mandates

- Professional societies

- Actually, anywhere

Send ideas for projects to member.questions@unos.org

OPTN Policy Development Process

1. Idea
2. Problem Analysis
3. Project Approval
4. Evidence Gathering
5. Public Comment Approval
6. Public Comment
7. Pending Board Approval
8. Board Approval
9. Implementation
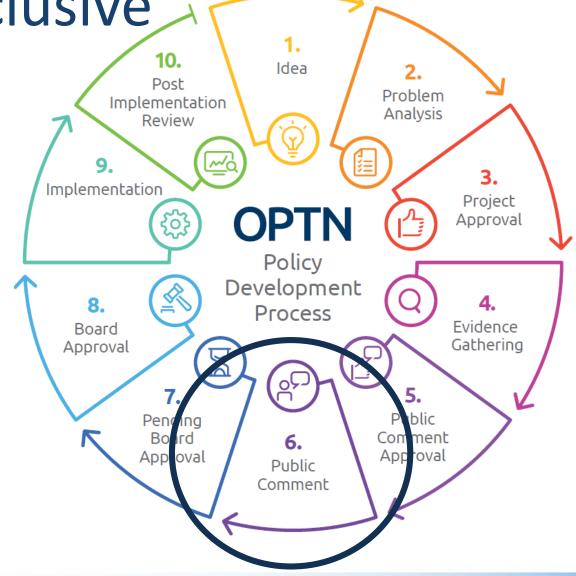10. Post Implementation Review

Project Development

- OPTN Policy Oversight Committee Role
  - Strategic Plan and Priority Alignment
  - Resource Estimates
  - Cost/Benefit Estimates
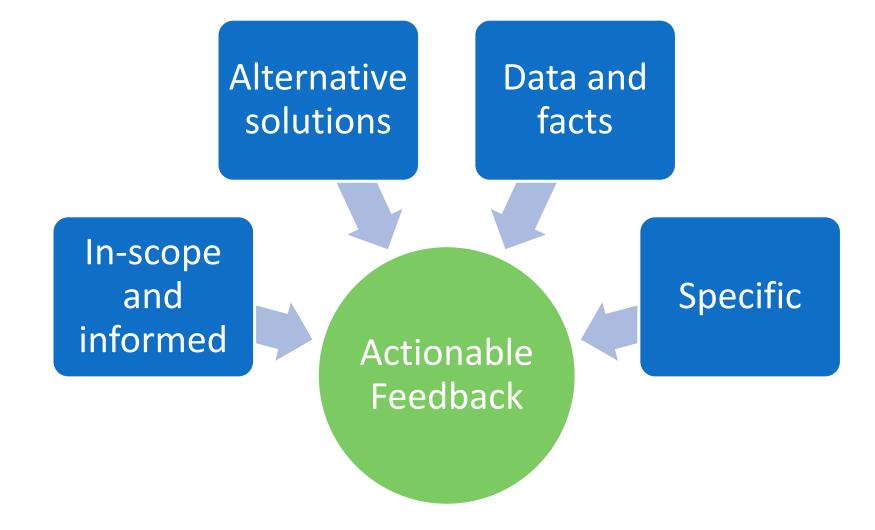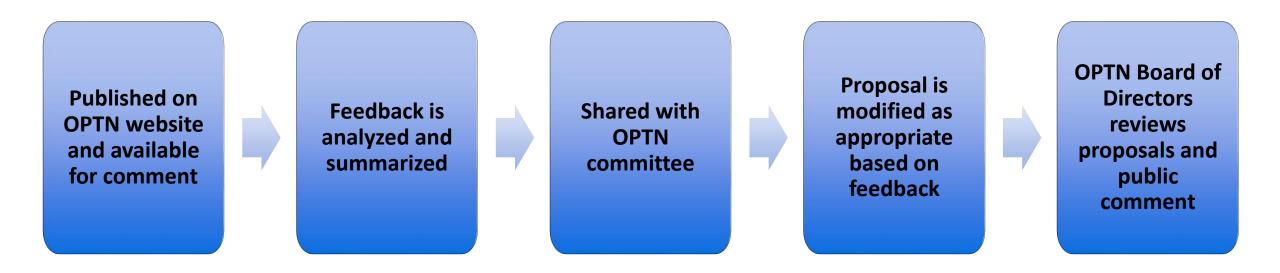- OPTN Executive Committee Review and Approval

OPTN Policy Development Process

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Public Comment is Inclusive

- Any member of the public on OPTN website
- Regional meetings
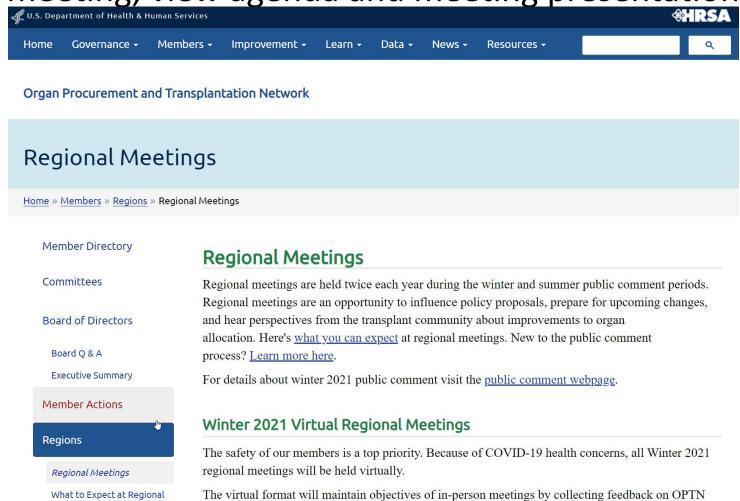- OPTN Committees
- Stakeholder organizations

OPTN
Policy Development Process

1. Idea
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Actionable Feedback

Alternative solutions

Data and facts

In-scope and informed

Specific

Actionable Feedback

What Happens with Public Comment?

Published on OPTN website and available for comment → Feedback is analyzed and summarized → Shared with OPTN committee → Proposal is modified as appropriate based on feedback → OPTN Board of Directors reviews proposals and public comment

Regional Meeting Information

Register for a meeting, view agenda and meeting presentations

Plan and Prepare for Regional Meetings

- **Register** for your meeting and review agenda

- **Read** meeting related communications

- **Review** public comment documents

- **Read** relevant items; note questions and feedback

- **Review** recordings of public comment items

- **Discuss** items with your colleagues

Public Comment – we want to hear from you!

Ongoing OPTN Policy Efforts

Continuous Distribution

What is involved in the future of MOT?

- **Eligibility Criteria**
  - Example: Qualifying GFR value for SLK candidates

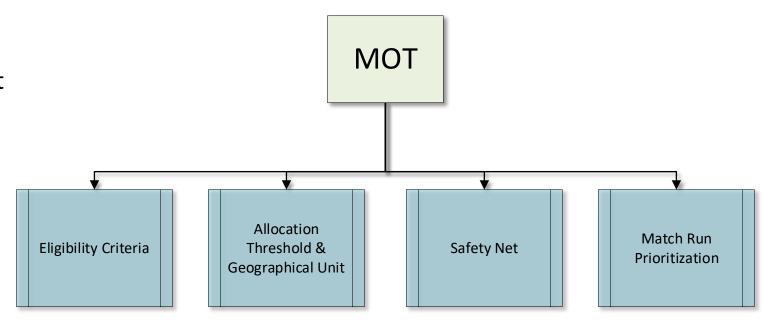- **Allocation Threshold & Geographical Unit**
  - Example: OPO Committee's proposal that Heart candidates are required to be a minimum of Status 3 and within 500NM of the donor, for OPOs to be *required* to allocate the kidney with the heart

- **Safety Net**
  - Example: Qualifying GFR or Dialysis <1 year post-transplant for increased kidney priority following a liver transplant

- **Match Run Prioritization**
  - Example: OPOs would be required to allocate a kidney to kidney candidates, before allocating to an SLK candidate, and then allocating to other multi-organ combinations involving a kidney

Match run rules workgroup

Increase offer filters

- Set adjustable default filters for more tailored screening of organ offers based on center acceptance practices

Develop a dynamic match run

- Screen candidates off the match run in real time as new information is entered regarding serology, anatomy, biopsy, etc.

Create additional acceptance codes to indicate conditional yes

- Provide more information to OPOs about a center's level of interest and desired conditions for accepting an organ offer

Technology tools workgroup

Communications Enhancements in DonorNet®

- Streamlining communication in DonorNet® would allow OPOs the ability to update status of donors and send push notifications before, during and after allocation

Image Sharing

- Develop Guidance to Maximize the Use of Image Sharing Technology across the Entire Network

Biopsy best practices workgroup

Standardized Pathology Report

- Develop a Form that Pathologists Would Complete During Biopsy Readings to Allow for Consistent Analysis across Organ Procurement Organizations (OPOs) and Transplant Programs

Minimum Set of Donor Kidney Criteria Appropriate for Biopsy

- Develop a Minimum Set of Donor Kidney Criteria Appropriate for Biopsy

Questions

UNOS Solutions

Thomas Millisor

Director of UNOS Solutions

Solutions: Who we are

We are transplant researchers, analysts, data scientists, and professionals working with the transplant community to increase transplantation, drive insights, innovation and improvements, and provide deep knowledge and analysis of data.

We are UNOS--- with almost 40 years in the transplant industry.

Who we work with:

- Members
- Corporations
- Researchers
- General Public

IT

Solutions

Member Quality

Partner

PCR and PE

OE

Research/BI

Common requests:

Experience
- Transplant
- Operations and Policy

Technical Capabilities
- Data collection and linkage

Analytics
- Complex analysis
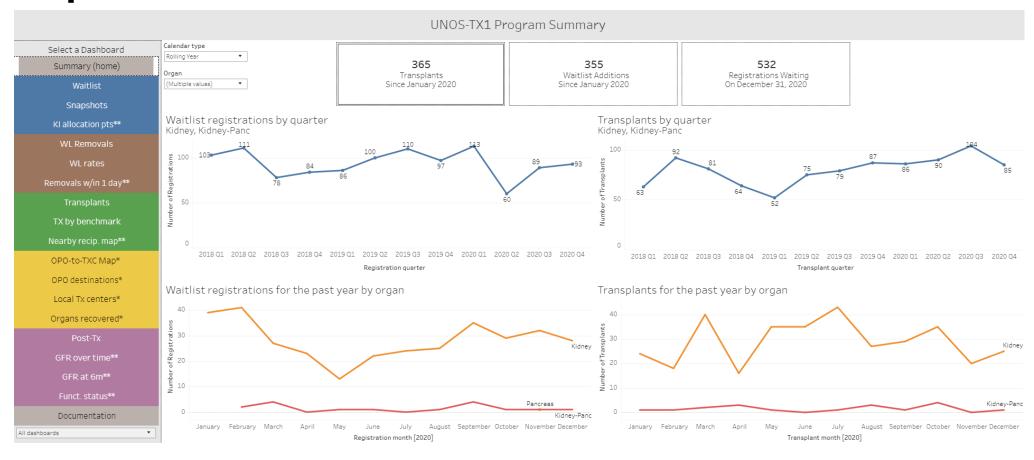- Forecasting and dynamic modeling
- Business intelligence

Products and process:

- ## Registries as a Service
  - ### Post-market FDA
  - ### Learning Networks
- ## Data Analytics and Research
- ## Consulting and Education
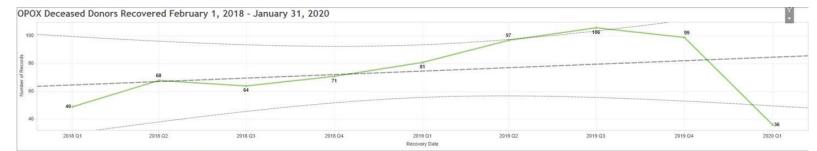- ## Technology

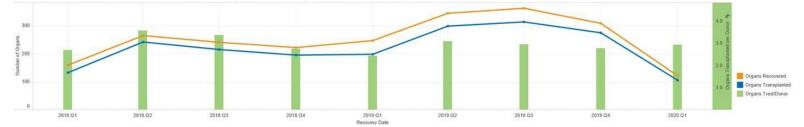# Transplant Center Dashboard 2.0

- Enhanced waitlist, transplant, and post-transplant analyses
- New recovery and destination maps
- Additional outcomes data
- Redesigned layout
- Regional, national, and self-selected benchmark programs for transplant volume analyses
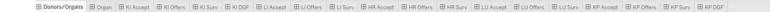
OUT summary:

Summer 2021 Updates:

- Enhanced navigation and visual aesthetic

- Movement to the Data Services Portal
  - Able to download data

- New focused visualization on Outcomes of Individual Organs (New tab) including 3 years of data

- Transplant Maps
  - Displaying geographical source of each organ.

- OPO Map
  - Displaying transplants geographical destination of each organ.

- Updating report twice a month

- Three additional tabs… More to come!

Registries as a service:

- FDA-compliant
  - Medical device companies
  - Therapeutics and Pharmaceuticals
- Learning Network
  - Designed to gather data, engage conversation, and drive best practices
  - Examples:
    - Donor Management Goals (OPOs)
    - Starzl Network for Excellence in Pediatric Transplantation (TXPs)
    - ISHLT

Contact us:

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