OPTN/UNOS Committee Orientation

Welcome & Opening Remarks
President Charlie Alexander
National Organ Procurement and Transplantation Network (OPTN)

HRSA Division of Transplantation

National Organ Transplantation Act

- Passed in 1984
- Created the current OPO system
- Established the OPTN
- Established the Scientific Registry of Transplant Recipients (SRTR)
- Prohibits the buying and selling of human organs
OPTN Final Rule

■ Effective March 16, 2000
■ Establishes regulatory framework for the structure and operations of the OPTN

Federal Involvement

■ Department of Health and Human Services
  • Centers for Medicare and Medicaid Services
  • Health Resources and Services Administration
  • Food and Drug Administration
  • Centers for Disease Control and Prevention

Among others
HRSA Division of Transplantation
Contacts

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Tynisha S. Robinson
OPTN Committee
System Coordinator
Why Committee Orientation?

The OPTN is a unique entity

The Problem
The U.S. Organ Shortage
National Organ Transplant Act of 1984

- Prohibited buying & selling organs
- Organ Procurement & Transplantation Network (OPTN)
  - Private nonprofit entity by contract with HHS
  - National policy board
  - National policy and system
  - Nationwide coordination
- Created the modern OPO system

NOTA Allocation Framework

- OPOs must have a system to allocate organs
  - equitably among transplant patients (not centers)
  - according to “established medical criteria”
- OPTN shall establish medical criteria for allocating organs and assist OPOs in nationwide equitable distribution among patients
  - medical criteria, not social or economic criteria
- OPO service area of sufficient size to assure equitable distribution of organs
- Special consideration for children and highly sensitized
Why do Committees need to be aware of the Final Rule?

- It provides specific requirements for many areas of OPTN activity, including Policy Development by OPTN Committees.
- With staff assistance, chairs are responsible for seeing that policy development is done according to requirements of the Rule.

OPTN Final Rule - Overview

- Describes definitions, OPTN, its membership, corporate status
- Addresses requirements for policies and policy development
- Provides certain requirements for wait listing, procurement, matching
- Specifies policy criteria, performance goals
- Requires processes for designating programs, program review & evaluation
- Addresses record keeping, and reporting
OPTN Policies (FR)

- OPTN Board responsible for developing policies regarding
  - Equitable allocation of deceased donor organs
  - Donor testing to prevent spread of infectious diseases
  - Reduction of inequities resulting from socioeconomic status
  - MD training and experience requirements for designated programs
  - As Secretary directs

Allocation Policy Criteria (FR)

- Organ-specific
- Sound medical judgment
- Best use of organs
- Give programs the right to refuse
- Avoid wastage and futile transplants
- Promote patient access
- Promote efficient organ placement
- Not to be based on candidate’s location unless to do otherwise would result in inefficient placement, wasted organs, poor use of organs...
Policy Performance Goals (FR)

- Objective, measurable listing and wait list removal criteria
- Ranking by urgency
  - Avoid groupings with substantially different urgency
- Distribution over as large an area as feasible in order of decreasing urgency
- Reduce inter-program performance indicator variance as reasonable

Policy Performance Assessment (FR)

- Organ procurement & allocation
- Multiple variables
  - E.g., life-years, survival rates, risk-adjusted waiting time, and transplant rates
- Patient access to transplantation
- Effects of OPTN policies on transplant centers by volume
- OPO & OPTN contractor performance
Policy Enforcement (FR)

- Board advises HHS of noncompliance and makes recommendations
- Recommendations may include
  - Loss of designation to receive organs
  - Termination of Medicare participation
  - Other measures developed by OPTN
- Secretary may take action as appropriate
**Relationship with Government**

**Contracts**

- Two-year contract (started Sept 30, 2005) with five 1-year renewals
- Cost-sharing arrangement
  - currently averages about 9% Federal funds ($2,500,000 per year +$800,000 for DDPS),
  - 91% OPTN patient registration fee plus corp. funds
- Specific tasks and deliverables
OPTN Tasks

- Board and committees
- Membership criteria & policies
- Monitor compliance
- Waiting list & match runs
- Assist with placement
- Collect and provide data
- Computer security
- Provide staff support to HRSA Collaborative
- Communicating with membership and public
- Planning and Annual Goals
- Living donor follow-up data collection for 2 years
- Living donation-related policy development

OPTN

Unifying Themes

- Goal setting and performance measurement
  - OPTN as a network (Program Goals and other network goals)
  - Board and Committees (Strategic Planning and Annual Goals)
  - Individual allocation policies
  - Internal OPTN operations
- Clinical focus – what’s best for patients?
- Evidence based policies
- Continuous process improvement
- Broad participation in OPTN
- System and contractor effectiveness and efficiency

OPTN
Strategic Planning and Key Goals of the OPTN

Framework Basics

4-5 Key Goals

National indicators to monitor progress

Evaluate projects for high impact

Prioritize on basis of available resources
To restore health and longevity to patients with end-stage organ disease

OPTN Key Goals

- Increase access to transplants
- Increase # transplants
- Longer lives for patients with organ failure
- Improve post-transplant survival
- Promote transplant safety
- Promote safety for living donors
Framework Basics

4-5 Key Goals
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National indicators to monitor progress
Evaluate projects for high impact
Prioritize on basis of available resources

OPTN

Examine Desired Allocation of Committee Work Across Key Goals

Living Donor Safety
Equitable Access
# of Transplants
Post-tx survival
Recipient Safety
Committee System

Committee Composition

- 11 regional reps
- At-large members
  - 2-3 tx patients/donors
  - 2-3 OPO reps
  - special content expertise

How do people get on committees?

- Regional reps are suggested by regional councillors
- At large members are selected from database of interested and individuals
- All are subject to approval by president
OPTN/UNOS Committees

- Ad Hoc Disease Transmission Advisory
- Ad Hoc International Relations
- Ethics
- Histocompatibility
- Kidney
- Liver/Intestine
- Living Donation
- Minority Affairs
- MPSC
- Organ Availability
- OPO
- Pancreas
- Patient Affairs
- Pediatrics
- Policy Oversight
- Thoracic
- Transplant Administrators
- Transplant Coordinators
- Operations and Safety
- Nominating
- Finance
- Executive

Information about committees
Committee Member Roles and Responsibilities

What Are Committee Responsibilities?

- Consider high-leverage improvements to the OPTN, with guidance from leadership
- Develop and make recommendations to the OPTN/UNOS Board regarding:
  - New policies and bylaws; revisions to current ones
  - Information the OPTN should communicate to
    - Clinical communities, patients, governmental agencies (e.g., CDC, CMS, NIH, HRSA), members of Congress, the public
    - Recommended improvements to the OPTN data system
Expectations for All Members

- Attend all committee meetings
- Participate in subcommittees as needed
- Participate in discussion of agenda items
- Maintain communication with constituents
- Review materials for presentation to full committee
THANK YOU!

Questions?
Brian Shepard
UNOS Director of Policy

Policy Development
Policy Development

- State the problem
- Consider your capability
- Develop alternatives
- Evaluate and choose
- Make your case
- Observe and re-evaluate

Questions?
Maureen McBride
UNOS Director of Research

EFFECTIVE USE OF DATA BY OPTN COMMITTEES
Data Requests During Policy Development Process

- Policy development generally includes the need to review various data analyses in order to generate sufficient evidence that a policy action is required.

- Analytic staff from OPTN and SRTR are prepared to help!

As you consider a data request, think about context

- Data requests must be relevant to your Committee’s activities.
- Do they align with specific items on your committee’s annual work plan?
- What specific question(s) will they help answer?
  
  - Develop an “evidence question” for each request.
Develop an evidence question

- Evidence question: the central question or hypothesis for which we are requesting evidence to evaluate

- The “evidence question” must guide the policy development process and be clearly articulated.

- Examples:
  - Will altering the kidney allocation algorithm result in an unacceptably large shift in access to transplant for sensitized candidates?
  - Will there be enough extra vessels available for vascular revision procedures in recipients of seropositive organs, if storage of seropositive vessels is prohibited?

Evidence Generation and Data Analysis

- Various types of data may be generated in response to an evidence question
  - Descriptive data analysis
  - Inferential data analysis
  - Simulation modeling
  - Surveys
  - Review of scientific/medical literature
Descriptive Data Analysis

- Provided by OPTN Research Staff
- What “actually” happened
- Examples:
  - How many Status 1A liver candidates were transplanted in 2010?
  - What was the death rate in Status 1A liver candidates in 2010?
  - Usually does not involve a multivariable model

Inferential Data Analysis

- Provided by SRTR Staff
- What would we “expect” to happen
- Examples:
  - What was the expected transplant rate for a Status 1A candidate in 2010?
  - What is the expected death rate for a Status 1A liver candidate in 2010?
  - Usually involves a multivariable model
- SRTR also responsible for simulation modeling
Additional Comments

- Requests should be generated through the Committee’s discussions rather than reflecting individual interests
- If Committee members wish to present other analyses or publications at the meeting, this should be coordinated in advance with the liaison
- After the Committee meeting, the data reports are considered public information
- If manuscripts based on activities of the Committee are to be submitted for publication then they may need to be reviewed. The Research liaison will assist you in determining which manuscripts will need review.

Subcommittee/Working Group Data Requests: Process Cycle
Important Things to Remember...

- Policy proposals must be evidence-based
- Requests for data must align with committee goals/work plan
- Hypothesis being evaluated are to be clearly stated ("evidence question")
- OPTN and SRTR fulfill these requests by following a formal process with timelines
- Impact of implemented policy changes must be evaluated empirically

Questions?
Jeff Schmid
Assistant Director
UNOS Meeting Partners

Get There Demo
Traveling to Committee Meetings

- The Process:
  - 6-8 weeks prior to the meeting date, you receive an email from your travel representative which will contain meeting information as well as the link to access our online booking tool: GetThere. Please book your travel within a week of receiving that email for reasonable cost and seating choices. Flight costs are billed directly to UNOS.
  - Once booked, your flight will be reviewed and your E-ticket will be issued. You will receive a link to access your online itinerary from meetings@unos.org. Please review this document carefully.
  - Your hotel reservation will be booked by your travel representative based on your itinerary. Hotel room and tax is billed directly to UNOS.
  - You will be asked to present a credit card at hotel check in for any other incidental charges billed to your room.

- The Process continued:
  - Reasonable expenses are reimbursed (see travel policy for details). You will be emailed a travel reimbursement form. Please fill out and sign the form then mail with all original receipts.
  - The travel policy, reimbursement forms and some travel resources can be found on the Resources page of the Committee SharePoint site: https://sts.unos.org/Resources/Pages/Travel.aspx
Traveling to Committee Meetings

Changes to Confirmed Flights:

- If you need to make a change to a ticketed reservation, please email or call the planner who booked your original travel.
- If the change is directly related to a transplant or if you have to change for a UNOS related meeting, we will cover the costs of the change.
- If you have to change for a non-UNOS meeting or for a personal reason or preference, you will be asked for a credit card to pay for any change that results in an additional collection. Emergencies are reviewed on a case-by-case basis.

UNOS maintains a 24-hour Travel Hotline which can be accessed after business hours for emergency situations only. Please call 1-800-787-0588 and tell them you are traveling for UNOS.

Traveling to Regional Meetings

- Please note that with the exception of regional representatives serving on the Patient Affairs Committee, UNOS does not reimburse travel costs incurred by regional representatives to attend regional meetings.

- If there is an issue with covering the costs incurred to attend regional meetings, please contact your Regional Administrator.
Questions?