

AGENDA OVERVIEW

Region 10 Meeting
Hilton Garden Inn Dayton/Beavercreek
3520 Pentagon Boulevard, Beavercreek, OH
September 28, 2018

(Note: All times except the start time are approximate. Actual times will be determined by the amount of discussion.)

- 8:00** Registration (breakfast available)
- 8:30-10:00** Liver Program Directors meeting
- 9:00-10:00** Thoracic Program Directors meeting
- 10:00-10:35** Welcome and Update from Regional Councillor, Todd Pesavento, MD
Non-Discussion Agenda (*includes 10 – 15 minutes for voting preparation*)
- 10:35-11:00** OPTN/UNOS Update, Maryl Johnson, MD, OPTN/UNOS Vice President
- 11:00-11:45** Begin Discussion Agenda and OPTN/UNOS Committee Reports
- 11:45-12:45** Regional Discussion Session,
- 12:45-1:30** Networking Lunch (45 mins.)
- 1:30-2:45** Conclude Discussion Agenda and OPTN/UNOS Committee Reports
- 3:00** Estimated Adjournment (depending upon the amount of discussion)

Agenda Items

Non-Discussion *These items will be voted on but will not be presented/discussed*

- Membership & Professional Standards Committee, *Change to Hospital-Based OPO Voting Privileges*
- Pancreas Transplantation Committee, *Changes to Islet Bylaws*
- Pediatric Transplantation Committee, *Guidance on Pediatric Transplant Recipient Transition and Transfer*

Discussion

- Ad Hoc Geography Committee, *Frameworks for Organ Distribution*
- Histocompatibility Committee, *Addressing HLA Typing Errors*
- Pancreas Transplantation Committee, *Pancreas Program Functional Inactivity*

DETAILED AGENDA

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8:00 Registration (breakfast available)

8:30-10:00 Liver Program Directors meeting

9:00-10:00 Thoracic Program Directors meeting

10:00-10:35 **Welcome and Update from Regional Councillor**
(includes 10 - 15 minutes for voting preparation)

Todd Pesavento, MD
Ohio State University
Medical Center
Region 10 Councillor

Non-Discussion Agenda (vote)

Todd Pesavento, MD

**** As a reminder, the following proposals require a vote but will not be presented or discussed.****
Executive Summaries of Non-Discussion Agenda items can be found in Appendix A (p. 5).

- Membership & Professional Standards Committee, *Change to Hospital-Based OPO Voting Privileges*
- Pancreas Transplantation Committee, *Changes to Islet Bylaws*
- Pediatric Transplantation Committee, *Guidance on Pediatric Transplant Recipient Transition and Transfer*

10:35-11:00 **OPTN/UNOS Update**

Maryl Johnson, MD
OPTN/UNOS Vice President

Discussion Agenda and OPTN/UNOS Committee Reports

Moderator: Dr. Pesavento

11:00-11:25 Ad Hoc Geography Committee

Maryl Johnson, MD
OPTN/UNOS Vice President

Frameworks for Organ Distribution (25 min.), vote, page 6

The Ad Hoc Geography Committee was formed in December 2017 to examine the geographic distribution of organs. The Committee was charged with:

- Establishing defined guiding principles for the use of geographic constraints in organ allocation
- Reviewing and recommending models for incorporating geographic principles into allocation policies
- Identifying uniform concepts for organ specific allocation policies in light of the requirements of the OPTN Final Rule

The OPTN Final Rule sets requirements for allocation policies developed by the OPTN, including sound medical judgement, best use of organs, the ability for centers to decide whether to accept an organ offer, to avoid wasting organs, and to promote efficiency. The Final Rule also includes a requirement that policies “shall not be based on the candidate’s place of residence or place of listing, except to the extent required” by the other requirements of the Rule.

On June 11, 2018, the OPTN/UNOS Board of Directors adopted principles to guide future organ transplant policy relating to geographic aspects of organ distribution. Additionally, the Board of Directors accepted the Ad Hoc Geography Committee's recommendation to request community feedback on the recommended distribution frameworks, with a goal of identifying a single, preferred distribution framework to be used across organs. This proposal includes three distribution frameworks identified by the Ad Hoc Geography Committee as being in alignment with the adopted principles of geographic distribution and the OPTN Final Rule.

11:25-11:35 Thoracic Organ Transplantation Committee
Committee Update (10 min.)

Marie Budev, DO, MPH
Cleveland Clinic Foundation

11:35-11:45 Patient Affairs /Transplant Coordinators Committee(s)
Committee Update (10 min.)

Elizabeth Rubinstein
Patient Affairs Committee

11:45-12:45 Regional Discussion Session

Tools You Can Use – UNOS Data Services Portal (60 min.)

Sarah Taranto
Assistant Director of Data
Quality and Analytics
UNOS

12:45-1:30 Break for Networking Lunch

1:30-1:55 Liver and Intestinal Organ Transplantation Committee
Committee Update (25 min.)

Shimul Shah, MD, FACS
University of Cincinnati
Medical Center

1:55-2:15 Histocompatibility Committee

Gabriel Maine, PhD
Histocompatibility Laboratory
Beaumont Health

Addressing HLA Typing Errors (20 min.), vote, page 19

The OPTN/UNOS does not have a system for timely reporting and reviewing human leukocyte antigen (HLA) typing errors. Because HLA typing discrepancies are flagged on the donor and recipient histocompatibility forms completed after transplant, there is no timely mechanism for detecting errors in the HLA information used for generating match runs used in organ allocation.

HLA entry errors, specifically prior to match run generation, can have serious patient safety implications. These HLA typing errors can also create system inefficiencies.

Along with transcriptional errors caused by manual entry of HLA data, another cause of these data entry errors is the setup of HLA data in DonorNet®. A user can unknowingly change a donor's HLA information prior to the match run, which can result in match runs being executed with the incorrect HLA type.

The Committee is proposing changes to reduce the number of manual HLA data entry errors in UNetSM:

1. When HLA data is entered manually into UNet, it must be entered twice for verification of accurate data entry
2. When HLA data are uploaded directly into UNet, the member must have a process for verifying that the data are accurate
3. Raw HLA typing must be attached in the system for verification of lab results

The Committee believes these changes will increase patient safety by putting more verification processes in place to ensure accurate HLA data is entered into UNet.

**2:15-2:25 Membership & Professional Standards Committee
Committee Update (10 min.)**

Atsushi Yoshida, MD
Henry Ford Hospital

2:25-2:45 Pancreas Transplantation Committee

Muhammad Yaqub, MD
Indiana University Health

Pancreas Program Functional Inactivity (20 min.), vote, page 33

The majority of programs under review for functional inactivity by the OPTN/UNOS Membership and Professional Standards Committee (MPSC) are pancreas programs. At least one pancreas transplant must be performed during a six consecutive month time period or a pancreas program will be identified as “functionally inactive” according to OPTN Bylaws Appendix D.10.A: Review of Transplant Program Functional Inactivity. From January 2011 to September 2016, 61 pancreas programs have come under review for functional inactivity at least once, which is approximately 44% of currently approved pancreas programs (138).

Review of the literature and OPTN data analyses indicate that these low-volume pancreas programs may perform at a level that impacts patient safety and access to transplant. The solution proposed by the Pancreas Committee (hereafter, the Committee) seeks to reduce MPSC review of functionally inactive pancreas programs by narrowing review to programs that have longer waiting times and low volumes. The definition will be more tailored to concerns about patient safety and access to transplant by focusing on programs with longer waiting times, and avoid reviewing programs that are small volume but transplant their patients quickly. Pancreas programs will be reviewed for functional inactivity if they fail to perform two transplants in 12 consecutive months and have an average waiting time above the national average for pancreas programs.

The Committee’s solution also addresses the concerns with patient access to transplant and patient safety by increasing communication with patients waitlisted at programs reviewed for functional inactivity. These programs will need to inform patients and potential candidates about other pancreas programs in-state or within 125 miles of the program, and provide information about the program’s waiting time compared to the national average. Providing this additional information may empower patients to make informed decisions about their transplant care, and will provide an incentive to pancreas programs to increase their volume and shorten waiting time in order to avoid sending this letter.

The proposed changes will improve waitlisted patient and transplant recipient outcomes by creating new thresholds for identifying functionally inactive pancreas programs that operate below the level that is adequate for their waitlisted candidates.

3:00 Estimated Adjournment

APPENDIX A

Non-Discussion Agenda Proposals

Membership & Professional Standards Committee

Change to Hospital-Based OPO Voting Privileges

There exist multiple types of OPOs: independent OPOs and hospital-based OPOs (HOPOs). Under the current OPTN Bylaws, only independent OPOs are permitted to vote in OPTN matters; HOPOs do not have any voting privileges in OPTN elections except as a part of their supporting hospital. Recognizing that some HOPOs serve multiple transplant hospital members within their DSA and their interests may not always align with the single hospital with which they are affiliated, this proposal would grant HOPOs a vote in OPTN regional and national matters if the HOPO is able to demonstrate functional separation between the OPO and transplant programs of the transplant hospital member.

Allowing HOPOs to have a separate vote would allow a DSA's organ procurement interests to be represented in OPTN voting matters and primarily supports the OPTN strategic goal of promoting efficiency in the management of the OPTN.

Pancreas Transplantation Committee

Changes to Islet Bylaws

Current islet Bylaw personnel requirements do not reflect the need for islet transplantation experience and expertise. This may prevent qualified candidates from leading programs and could prevent the field from growing. Inappropriate requirements may be harmful to patients if personnel who are inexperienced in islet transplantation oversee islet programs and islet patient care.

The OPTN/UNOS Pancreas Transplantation Committee (the Committee) has developed new requirements for islet programs that reflect the needs particular to islet programs and their patients. Currently, the OPTN Bylaws *Appendices G.5: Primary Pancreatic Islet Transplant Surgeon Requirements* and *G.6: Primary Pancreatic Islet Transplant Physician Requirements*, specify requirements for islet program key personnel that are identical to pancreas program requirements despite significant differences in the experience and backgrounds of key islet personnel. The overarching goals in seeking to improve islet program Bylaws are to provide a simple, achievable experiential pathway for islet program leaders that facilitates the initiation and development of clinical islet transplant programs, while ensuring sufficient experience to provide for safe patient care. The proposed changes include three critical elements:

1. Require a single clinical leader of the islet program to replace the transplant surgeon and transplant physician roles. This person must have experience inclusive of pre-, peri- and post-operative care, islet isolation, and a demonstrated background in transplantation medicine, immunosuppression management, beta cell biology, or endocrinology.
2. Require four different expert medical personnel roles with defined skill sets to provide key support in the delivery of islet transplant therapy: an abdominal surgeon, portal vein access specialist, immunosuppression management specialist, and endocrinologist. A single person can fill one or all of the aforementioned roles.
3. Permit islet transplant programs to be free standing and not affiliated with an established pancreas transplant program.

The proposed changes apply only to programs that perform allogeneic islet transplants, which are under OPTN purview through the National Organ Transplantation Act.

Bylaw program requirements that provide accountability and reflect the necessary expertise and experience in program personnel promote patient safety. Changing the Bylaws to provide more flexibility

for islet programs while enhancing program accountability with more detailed islet experience requirements should contribute positively to increased transplant recipient safety.

Pediatric Transplantation Committee

Guidance on Pediatric Transplant Recipient Transition and Transfer

Suboptimal transition and transfer processes for pediatric transplant recipients have been associated with increased risk of non-adherence with their plan of care and graft loss. Breakdowns in transition and the transfer to adult medical care may contribute to “lost to follow-up” designations for pediatric transplant recipients on OPTN data collection forms. The goal of the guidance is to support improvements in transplant outcomes by reducing instances of graft loss from non-adherence, and by providing guidance to transplant hospitals to improve the transition and transfer process for pediatric recipients. A secondary goal of this guidance is to reduce the incidence of lost to follow-up designations for pediatric transplant recipients. By sharing effective practices for recipient transition and transfer from pediatric to adult medical care, transplant outcome data will be more complete and more representative of clinical practices.

This guidance aligns with the goals of the OPTN Strategic Plan to improve waitlisted patient, living donor, and transplant recipient outcomes. Long term post-transplant survival data are vital to understanding outcomes for all pediatric transplant recipients and developing healthcare policy to improve these outcomes.