AGENDA
Region 9 Meeting
New York Academy of Medicine
1216 Fifth Avenue, New York, NY
March 21, 2018

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

9:00  Registration (continental breakfast available)

10:00-10:20  Welcome and Update from Regional Councillor  Lewis Teperman, MD
Northwell Health/Hofstra Medical School
Region 9 Councillor

Non-Discussion Agenda (vote)  Dr. Teperman
** As a reminder, the following proposals require a vote but will not be presented or discussed**

Ethics Committee (Non-Discussion (ND))
Manipulation of the Waitlist Priority in the Organ Allocation System through the Escalation of Medical Therapies
Beginning in 1993, the Ethics Committee (the Committee) developed a series of white papers that are available through the Organ Procurement and Transplantation Network (OPTN) website. A white paper is an authoritative report or guide that informs readers concisely about a complex issue and presents the issuing body's philosophy on the matter. It is meant to help readers understand an issue, solve a problem, or make a decision.

There have been recent reports describing the manipulation of waitlist priority of the organ allocation system in both the medical literature and the lay press. To date, the OPTN and the United Network for Organ Sharing (UNOS) have not offered guidance or established a formal position statement on this issue.

This white paper will define and present an ethical analysis of manipulation or the waitlist priority of the organ allocation system through the use of medically unnecessary interventions that are used to increase a transplant candidate's priority on the waitlist. The white paper will delineate the potential harms to transplant candidates, the wait list as a whole, transplant providers, and transplant hospitals involved in the manipulation of the organ allocation system.

Operations and Safety (ND)
Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB
The OPTN/UNOS Operations and Safety Committee (the Committee) has updated the Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB, originally developed by the Committee and approved by the OPTN/UNOS Board of Directors in June 2011.

Since the original publication, the Committee sponsored major revisions to ABO policies that were approved by the OPTN/UNOS Board of Directors and implemented in June 2016. During that process, the Committee identified the need to revise the subtyping guidance, as many questions emerged related to subtyping. Questions and identified issues include lab result nomenclature, results interpretation, and incomplete knowledge of policy requirements.

In addition, the revised Kidney Allocation System (KAS) went into effect in December 2014. It eliminated variances (including subtyping variances). KAS put use of subtyped deceased donors into policy to help promote greater access to kidneys for blood type B candidates. Allocation of kidneys using subtyped
donors has increased. Pre-KAS there were 19 transplants (0.2% of all kidney transplants) using subtyped donors for blood type B candidates. Post-KAS (year 2) that number had risen to 168 (1.4% of all kidney transplants).
The revised guidance document is also part of efforts to assist members with subtyping. Nearly a quarter of OPOs had a subtyping issue cited on their last site survey. Instructional Innovations developed a subtyping e-learning module in response to these concerns. The guidance document is cited as a resource. It needs to be updated to complement the efforts aimed at improving compliant subtyping practices and reporting.

Changes made to the guidance document include:

- Updated OPTN Policy references
- Amended information about special considerations such as neonates
- Updated additional complementary resources
- Revised structure and addition of key points
- Modified language to read more as a plain language document

Organ Procurement Organization Committee (ND)
Guidance on Requested Deceased Donor Information
The OPTN/UNOS Organ Procurement Organization Committee created this guidance document to address the requested deceased donor information removed from policy as part of a recent public comment proposal. This guidance document is designed to assist members in identifying additional testing and other information needed to best evaluate potential donors.

This guidance document is intended only to provide guidance for OPOs and transplant hospitals during organ placement. The scope and content should reflect collaboration between OPOs and transplant programs, taking into consideration their needs and best practices. This is not intended to be a comprehensive list of all information necessary to evaluate organs for all donors.

Thoracic Organ Transplantation Committee (ND)
Review Board Guidance for Hypertrophic and Restrictive Cardiomyopathy Exception Requests
The OPTN/UNOS Board of Directors recently approved the Thoracic Organ Transplantation Committee’s (Committee) proposal to Modify the Adult Heart Allocation System during its December 2016 meeting. During the development of the proposal, the Committee received feedback from the heart transplant community voicing concerns that hypertrophic cardiomyopathy (HCM) and restrictive cardiomyopathy (RCM) candidates may be disadvantaged by the proposed policy.2 The Committee considered the following issues in HCM and RCM candidates:

- HCM/RCM physiology may not benefit from mechanical circulatory support devices (MCSDs), and the higher statuses are device driven
- A lack of uniform expertise in HCM/RCM physiology results in variability in Regional Review Board (RRB) decisions across the country
- Objectively quantifying the severity of illness is challenging

The Committee acknowledged that some HCM/RCM candidates may have higher mortality and may not be candidates for mechanical support options, but ultimately did not change proposed policy due to lack of objective data to support these assumptions. Instead, the exception and review process will accommodate these candidates, who can apply to the review board for an exception in any status as their medical urgency and potential for benefit would warrant. The Committee recognized that HCM/RCM expertise may be inconsistent across the review boards, thus potentially making evaluation and award of HCM/RCM exception requests vulnerable to variability. To help mitigate these potential inconsistencies, the Committee created guidance for the review boards with the goal of outlining objective criteria to standardize the evaluation and decision-making of HCM/RCM exception requests. Improved data
collection required by the new policy should result in better assessment of whether specific subpopulations of HCM/RCM are disadvantaged by the status 4 assignment and may result in future policy changes to address any disadvantages.

This proposal aligns with the OPTN strategic goal of improving equity in access to transplant by providing objective criteria to review boards, potentially making evaluation and award of exception requests for HCM/RCM candidates more consistent, especially for those boards that lack an HCM/RCM expert. In addition, developing standardized exception criteria creates an intelligible pathway for more medically urgent HCM/RCM candidates to obtain access to higher urgency statuses, under which they may be transplanted more quickly, thereby potentially reducing waitlist mortality for those candidates.

**Thoracic Organ Transplantation Committee (ND)**

**Modification of the Lung Transplant Recipient Follow-Up Form (TRF) to Better Characterize Longitudinal Change in Lung Function following Transplantation**

The current OPTN/UNOS adult and pediatric lung and heart-lung Transplant Recipient Follow-up form (TRF) collects lung graft function status limited to bronchiolitis obliterans syndrome (BOS). The Thoracic Organ Transplantation Committee (Committee) identified two issues with the way graft function data is collected on the TRF, which limits the utility of this data in the context of chronic lung rejection:

- BOS data collection is outdated, incomplete and inaccurate
- Restrictive allograft syndrome (RAS) is not collected at all

Therefore, the limited data currently collected does not capture all the prognosis possibilities for declining graft function and may not accurately describe the type of rejection a patient is exhibiting. Chronic lung allograft dysfunction (CLAD) is a broader, more contemporary definition of post-transplant lung dysfunction, encompassing both obstructive and restrictive chronic lung rejection. This proposal will modify the adult and pediatric lung and heart-lung TRF forms to align with updated professional definitions. Refining the outcomes data the OPTN collects can better inform future policy.

This proposal aligns with the OPTN strategic goal of improving transplant recipient outcomes by collecting more granular data on lung dysfunction to help inform future policies for improving lung transplant outcomes. In addition, it will more accurately characterize longitudinal change in lung function following transplantation. Finally, examining outcomes other than strictly survival (in particular, quality-of-life measures such as pulmonary function) will be important for patients and for program assessment.

**Vascularized Composite Allograft Transplantation Committee (ND)**

**Align VCA Transplant Program Membership Requirements with Requirements of Other Solid Organ Transplant Programs**

In December 2015, the OPTN/UNOS Board of Directors approved changes to the Bylaws to remove the ambiguous term “foreign equivalent” from the transplant program key personnel requirements. Members and the Membership and Professional Standards Committee found it difficult to determine if a board certification or case experience performed outside the United States should be considered equivalent. In lieu of accepting foreign board certification, the Board approved continuing education pathways in order for individuals who were foreign board certified or U.S. board ineligible to continue to be considered for key personnel positions at solid organ transplant programs. These changes were not made to the membership requirements for key personnel at vascularized composite allograft (VCA) transplant programs due to feedback from professional transplant societies concerned about the impact of such changes on the nascent developmental stage of the VCA transplant field.

The current membership requirements for VCA transplant programs in the OPTN Bylaws include a pathway for non-board certified individuals to qualify as a primary VCA transplant surgeon. However, this pathway will sunset on September 1, 2018. The VCA Committee feels the implications of this sunset would:

- be overly restrictive
• result in membership requirements that were dissimilar to the membership requirements for all other solid organ transplant programs
• prohibit a surgeon who is U.S. board ineligible, but otherwise well qualified by training and experience, to qualify as a primary VCA transplant surgeon

This proposal addresses this gap for surgeons who wish to apply to be a primary VCA transplant surgeon. This proposal is not intended to reduce the rigor of the training and experience requirements for key personnel at VCA transplant programs. Rather, it is intended to add an option for these surgeons that is consistent with the membership requirements for all other solid organ transplant programs.

The Committee feels this proposal is in keeping with Goal 4 of the OPTN Strategic Plan by ensuring consistency between the requirements between key personnel at solid organ and VCA transplant programs. It will also address a problem posed by the increased burden for individuals to qualify as a primary VCA transplant surgeon if the sunset provision is not amended.

Vascularized Composite Allograft Transplantation Committee (ND)
Guidance on Optimizing VCA Recovery from Deceased Donors
Engaging in vascularized composite allograft (VCA) recovery from deceased donors requires a significant amount of planning and development by organ procurement organizations (OPOs) and VCA transplant programs. OPOs currently recovering VCAs have reported as long as a two-year development period for standard operating procedures (SOPs) or protocols and training on the same. To assess the barriers to VCA authorization and recovery, the OPTN/UNOS VCA Committee (Committee) conducted an on-line survey of OPOs in the U.S. The Committee felt barriers identified in this survey likely contribute to low numbers of deceased VCA donors, and further delays in the development of VCA recovery SOPs/protocols at OPOs.

The Committee believes this guidance will address an unmet need for the OPO community. As a result of this proposal, OPOs without experience in VCA recovery will have access to effective practices identified by those OPOs with experience in the field. This guidance also reinforces the concept that OPOs can support VCA transplant programs outside their donation service area (DSA), and potentially even outside their region.

The Committee feels this proposal is in keeping with Goal I of the OPTN Strategic Plan. By increasing VCA awareness to OPOs that have not yet recovered VCAs, there will hopefully be an increase in deceased donors screened for VCA donation and VCA recoveries.

10:20-10:45 OPTN/UNOS Update
Yolanda Becker, MD
OPTN/UNOS President

10:45 OPTN/UNOS Committee Reports and Voting on Public Comment Proposals
Moderator: Dr. Teperman

** A working lunch will be served at 12:30**

Executive Committee

Dr. Becker

10:45-11:00 2018-2021 OPTN Strategic Plan (15 min.), vote, page 209
The new strategic plan format will list the overarching goal (i.e. increase transplants), core activities in the areas of match, data, and quality (i.e. UNOS operates a 24/7 Organ Center), new initiatives for the next three years (i.e. expand use of collaborative improvement models), and the key metrics we will use to analyze success (by 2020, an X increase in utilization of organs from participants in collaborative improvement programs).

11:00-11:20 Improving the OPTN/UNOS Committee Structure (20 min.), vote, page 214
In June 2016, the OPTN/UNOS Executive Committee endorsed formation of a two-year workgroup
The committee governance workgroup identified the current “one size fits all” structure as needing improvement because it limits opportunity for broader transplant community participation and makes it difficult to incorporate diverse perspectives on committees. In addition, the structure and current methods for collecting public comment from committees, regions, societies, and the general public does not allow the Board of Directors to fully consider the sentiment of particular groups or communities when making policy decisions, as perspectives are offered sporadically throughout the system. In this document, the Executive Committee outlines a proposed new volunteer workforce structure and requests feedback on whether this new concept better incorporates perspectives of different important constituencies (patient, living donor, donor family, transplant professionals), while also maintaining the subject matter expertise.

11:20-11:45 Thoracic Organ Transplantation Committee
Donna Mancini, MD
Mount Sinai Medical Center

Committee Update (5 min.)

Broader Distribution of Adult Donor Lungs (20 min., vote, page 229)
On November 24, 2017, the OPTN/UNOS Executive Committee approved an emergency change to lung allocation policy to remove the donation service area (DSA) as a unit of distribution and instead distribute lungs from adult donors to all lung candidates within 250 nautical miles of the donor. DSA level allocation was also removed from the pediatric donor sequence. These changes to policy were implemented immediately. Because this change was made on an emergency basis, it must be distributed for public comment within six months of the change, and will expire on November 24, 2018, if no other action is taken.

The Thoracic Organ Transplantation Committee is sponsoring this retrospective public comment proposal, which also includes two additional changes to policy that are required as a consequence of removing the DSA as a unit of distribution from lung allocation policy:

1) Modifications to Board-approved heart-lung allocation policy that has not yet been implemented
2) Modifications to policy for sensitized lung candidates

The goal of these changes is to make lung allocation policy more consistent with the OPTN Final Rule, provide more equity in access to transplantation regardless of a candidate’s geography, and to clarify and make more transparent the heart-lung allocation policy. These changes also address how implementation of the new lung allocation policy impacts heart-lung allocation policy and policy addressing sensitized lung candidates.

11:45-12:05 Ad Hoc Disease Transmission Advisory Committee
Maricar Malinas, MD
Yale New Haven Hospital

Committee Update (5 min.)

Clarify Informed Consent Policy for Transmittable Conditions (15 min., vote, page 10)
Current policy states that specific pre-transplant informed consent is required when, “The donor has a known medical condition that may, in the transplant hospital’s medical judgment, be transmissible to the recipient, including HIV.” The phrase “known medical condition” has led to questions and varying applications in practice. The Membership and Professional Standards Committee (MPSC) notes in a memo to the Ad Hoc Disease Transmission Advisory Committee (DTAC) that broad interpretation of this
policy would require specific informed consent for any positive serology, culture, or other donor test result and that this would be cumbersome without adding patient benefit.

For example, Epstein-Barr virus (EBV) and cytomegalovirus (CMV) are common conditions and typically do not impact organ use except under unusual circumstances. Requiring specific informed consent prior to surgery for those serologies or other donor culture results may not be reasonable and leads to undue burden on the program.

The DTAC has consistently maintained that the policy was not meant to include transmissions that are common in organ transplantation. The DTAC expects that these would be included as part of routine pretransplant education. Due to the interpretation concerns, the DTAC proposes changes to this policy.

This proposal specifies conditions requiring informed consent prior to transplant. The Committee proposes linking conditions that would require specific consent to those that exist in Policy 5.3.B Infectious Disease Screening Criteria. This policy specifies organ specific preferences that can be made in Waitlistsm for individual candidates on whether organ offers will be received from donors who have tested positive for certain transmittable conditions. Currently, this policy includes CMV for intestines only, as well as hepatitis B (HBV) core antibody and Nucleic Acid Test (NAT), hepatitis C (HCV) antibody and NAT for heart, intestine, kidney, liver, lung, pancreas, heart-lung, and kidney-pancreas listings. Organs from HIV positive donors may only be recovered and transplanted according to Final Rule requirements. Currently, use is only permissible for kidney and liver transplantation. Consent requirements for these organs, outlined in Policy 15.7.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs, would not change.

Linking pre-transplant informed consent requirements to existing candidate screening conditions will provide consistency and specificity. It establishes the principle that if organ offers are screened based on a specific positive infectious disease result, and then positive results for those conditions will require pre-transplant informed consent. Future changes to the screening policy would cascade to the informed consent policy. These changes also address the growing use of positive organs for conditions such as HCV as effective treatments have become available. The proposal does not change required informed consent for US Public Health Service increased risk organs.

Membership and Professional Standards Committee

12:05-12:25 Committee Update (20 min.)

12:25-1:00 Lunch

1:00-1:20 Appendix L Revisions (20 min.), vote, page 74

Appendix L of the OPTN Bylaws details actions that the OPTN, through the Membership and Professional Standards Committee (MPSC) and Board of Directors, may take when OPTN members fail to comply with OPTN Obligations. Appendix L also outlines members' rights when the MPSC or Board of Directors is considering taking certain actions. The current Bylaws require the MPSC to engage with members through predetermined steps and timelines. As a result, both the MPSC and the member are sometimes required to interact in ways that do not provide significant value. Additionally, the current Bylaws include conflicting requirements, lack consistent and sufficient detail, and are organized confusingly. The proposal improves the OPTN review process and describes the process in a way that is more detailed and easier for members to understand. With a focus on member improvement in response
to noncompliance with OPTN obligations, the rewrite of Appendix L primarily supports the OPTN strategic goal of promoting living donor and transplant recipient safety.

1:20-1:35 Liver and Intestinal Organ Transplantation Committee  
Committee Update (15 min.)  
Leona Kim-Schluger, MD  
Mount Sinai Medical Center

1:35-1:50 Organ Procurement Organization Committee  
Expedited Organ Placement Concept Paper (15 min.), vote, page 21  
Daniel DiSante  
Center for Donation and Transplant

Expedited organ placement has been an important part of organ allocation for many years. Organ procurement organizations (OPOs) utilize this method to quickly place organs that are at risk of discard. OPTN/UNOS policy does not currently address expedited placement except for Policy 11.6: Facilitated Pancreas Allocation. Consequently, during recent discussions about broader sharing and system optimization, the community has expressed a want to better understand expedited placement, understand its impact on transplant candidates, and to maximize utilization of transplantable organs. The OPO Committee (“the Committee”) is seeking feedback from the donation and transplant community. The Committee intends to use this feedback in the development of policy language intended to address the following problems:

1. Lack of transparency with the current system
2. Lack of guidance for OPOs and transplant hospitals
3. Lack of consistent practice across the country
4. Inconsistent access to organs for candidates in need of transplant

Due to the complexity of this issue, the Committee made the decision to focus on the liver allocation process during the initial phase of this project. The intent is to develop a framework for expedited placement, initially focusing on liver placement, that can eventually be applied to the other organ systems.

The Committee determined that any expedited placement system is likely to have three components:

1. A trigger – the determination to perform expedited placement
2. A mechanism – the way expedited placement gets initiated in the match system
3. A qualification – the determination of how transplant hospitals qualify to receive expedited offers on behalf of their patients

The Committee determined that separate triggers are needed to address the different scenarios that might lead OPOs to initiate expedited placement:

1. Prior to donor recovery procedure (pre-operating room)
2. In the operating room

The Committee is aware that certain transplant hospitals are more likely to accept expedited placement offers than others. Therefore, the Committee would like to outline how transplant hospitals qualify to accept expedited offers.

The Committee seeks public comment regarding the triggers for expedited placement as well as determining which transplant hospitals might qualify for such offers. The Committee is concerned that proposing a system that is too cumbersome will have a negative impact on the expedited placement process and could result in a loss of organs for transplant. The Committee plans to circulate a policy proposal during the fall 2018 public comment cycle.

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1:50-2:00 Kidney Transplantation Committee

Committee Update (10 min.)

2:00-2:15 Pancreas Transplantation Committee

Proposal to Change Waiting Time Criteria for Kidney-Pancreas Candidates (15 min.), vote, page 56

A section of the kidney pancreas (KP) waiting time criteria limits waiting time accrual to candidates on insulin that have either a C-peptide ≤ 2 ng/mL or a C-peptide 2 > ng/mL and a body mass index (BMI) below or equal to the maximum (30 kg/m2). Pancreas Committee (Committee) analysis and review of current evidence indicates that this waiting time criterion represents an unnecessary and arbitrary limitation to certain candidates’ ability to accrue waiting time. Because waiting time is an important part of pancreas allocation, it may also limit these candidates’ access to transplantation.

The waiting time criterion was included in the 2014 Pancreas Allocation System (PAS) because of concerns about outcomes for high BMI Type 2 candidates (who are identified by having a high C-peptide). However, evidence gathered by the Committee suggests this restriction for Type 2 candidates is arbitrary because Type 1 and Type 2 KP recipients may have comparable outcomes. Additionally, Type 2 high BMI simultaneous pancreas-kidney (SPK) recipients may have comparable outcomes to other SPK recipients. The KP waiting time criterion arbitrarily restricts waiting time for Type 2 high BMI candidates while allowing Type 1 high BMI candidates to accrue waiting time and have greater access to transplant. African Americans and Hispanics are also more likely to have a higher BMI within the Type 2 candidate list, indicating that the current policy may create an inequity in restricting minority KP candidate access to waiting time accrual.

Changing KP waiting time criteria aligns with the first OPTN strategic goal to increase the number of transplants. In 2015, 25% of pancreata recovered for transplant were discarded. By enhancing access for candidates currently prevented from accruing waiting time, this proposal may reduce the pancreas discard rate and increase the total number of KP transplants. By removing a barrier to waiting time accrual for minority populations, this proposal may also reduce an inequity in access to transplant in alignment with the OPTN second strategic goal. Ultimately, removing the KP waiting time criterion and maximum allowable BMI would provide certain candidates access to kidney and pancreas transplantation based on center best practices and clinical evidence rather than an arbitrary waiting time criterion.

2:15-2:30 Operations and Safety Committee

Extra Vessels: Reducing Reporting Burdens and Clarifying Policies (15 min.), vote, page 31

This proposal would change requirements when extra vessels are shared among transplant hospitals. Members would no longer need to submit a justification to the Membership and Professional Standards Committee (MPSC). Instead, they will report sharing to the OPTN Contractor through the existing extra vessels reporting system in UNetsm implemented in August 2015. The justification requirement is no longer needed. Reporting sharing through UNetsm is already occurring and assures tracking capabilities. The justification reviews have not found any associated policy violations. The requirement creates unnecessary burden without benefit for transplant hospitals, the MPSC, and staff. Proposed IT programming will allow OPOs to view extra vessel dispositions from donors that they recovered. This proposal would change extra vessels policy labeling requirements for infectious disease results by
narrowing labeling from “all” to only “HIV, hepatitis B (HBV), and hepatitis C (HCV)” results. This will facilitate aligning test results and names among OPTN Contractor IT systems (e.g. DonorNet®, TransNet®) and the label that currently have inconsistencies. A TransNet barcode will be added to the label to allow scanning and accessing all infectious disease results available in DonorNet. This proposal will align policy language with the Final Rule indicating that vessels (including extra vessels) are considered part of the organ with which they are recovered and subject to applicable requirements. Some current policies need clarifications, exclusions, or deletions to fit within the federal regulation logic and framework.

3:00 Estimated Adjournment (depending upon the amount of discussion)