

AGENDA
Region 1 Meeting
Beechwood Hotel
363 Plantation St, Worcester, MA
October 2, 2017

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

9:00 Registration and Continental Breakfast

10:00 Welcome/Opening Remarks

Stefan Tullius, MD
Region 1 Councillor

Non-Discussion Agenda

Dr. Tullius

**** As a reminder, the following proposals require a vote but will not be presented or discussed****

Ethics Committee

Living Donation by Persons with Certain Fatal Diseases Who Meet the Criteria to Be Living Organ Donors

Beginning in 1993, the Ethics Committee (the Committee) developed a series of white papers that are available through the 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.

In 2013, the OPTN implemented new informed consent policies (*Policy 14.3, Informed Consent Requirements*) for living kidney donors. New informed consent policies for other types of living donors followed in 2014. These new policies included absolute contraindications (Living Donor Exclusion Criteria) to living donation.

Some terminally ill patients may desire to be living donors but may not be afforded the opportunity to donate based on confusion with existing OPTN policies for living donor informed consent, medical evaluation, and post-donation reporting policy requirements. If a potential living donor patient is competent and can provide informed consent, a terminal disease should not preclude organ donation and would not violate existing policy. Based on published and anecdotal reports, members may need guidance regarding how to handle potential living donors with certain fatal diseases who meet the criteria to be living donors.

Histocompatibility Committee

Equivalency Tables Update

The Histocompatibility Committee (the Committee) is charged with reviewing the equivalency tables in *Policy 4.10: Reference Tables of HLA Antigen Values and Split Equivalences* and recommending any updates as needed. During the 2016-2017 review of the equivalency tables, the Committee identified a need to include HLA-DPB1 equivalences in policy. The Committee created a DPB1 unacceptable antigen equivalency table that includes G allele equivalences, and also made updates the existing tables to reflect advancements in HLA testing since the last comprehensive update. This proposal also updates the nomenclature in all equivalency tables in policy. By updating the equivalency tables, members have a current resource to use when performing and interpreting final crossmatches and considering organ offers. For candidates with antibodies to newly added antigens, these updates can help improve graft survival. The table updates in this proposal will provide members with new antigen equivalences that can help them make more informed transplantation decisions.

Membership & Professional Standards Committee **Addressing Approved Transplant Fellowship Training Programs**

A number of abdominal key personnel training pathways in the Bylaws require that the training occurred at a fellowship program “approved by the MPSC,” and that the Membership and Professional Standards Committee (MPSC) will review training programs “every five years or any time the program director changes.” The MPSC does not regularly review or formally approve transplant training programs, nor has it done so historically. This proposal recommends deleting Bylaws that reference the MPSC’s “approval” and routine review of transplant fellowship programs to address this discrepancy, while retaining language that validates the rigor of the training program cited by a key personnel applicant applying through one of the Bylaws’ “training pathways.” The proposal also recommends some clerical changes to simplify these Bylaws sections. Making these proposed changes to the Bylaws supports the OPTN strategic plan goal of promoting the efficient management of the OPTN.

Minority Affairs Committee **Guidance for Transplant Program Participation in the Transplantation of non-A1/non-A1B (A2/A2B)**

Blood type B candidates, a blood group more common in underrepresented minorities, have longer kidney waiting times. In December 2014, the new Kidney Allocation System (KAS) became effective, including *Policy 8.5.D: Allocation of Kidneys by Blood Type*, which allows for blood types A, non-A₁ and AB, non-A₁B kidneys to be transplanted to blood type B recipients who meet certain criteria.¹ Allocation of deceased donor kidneys from blood group A, non-A₁ and AB, non-A₁B to blood group B kidney recipients has improved transplant rates among disadvantaged blood group B patients with equivalent long-term graft outcomes compared to blood type compatible transplants.^{2,3} However, the 18 month KAS post-implementation data analysis revealed that an overwhelming majority of transplant programs (82 percent) do not perform any non-A₁/non-A₁B (A₂/A₂B) transplants and that overall transplant programs have not taken advantage of this policy change, which provides greater access to deceased donor kidneys for disadvantaged blood group B candidates.⁴ Further, a 2016 OPTN/UNOS Minority Affairs Committee (MAC) survey to all active U.S. kidney transplant programs revealed that many programs cited difficulty in establishing a protocol for patient enrollment as the major barrier to performing these transplants. Specifically, the transplant programs identified the following obstacles when developing the required protocols to participate in non-A₁ transplants:

- Difficulty establishing titer thresholds (32 percent)
- Difficulty developing an informed consent policy (21 percent)
- Difficulty determining patient eligibility (18 percent)

OPTN/UNOS policy allows each transplant program to develop and implement protocols for determining candidate eligibility, but many established programs follow similar practices for protocol. Based on the survey findings, these best practices are offered in a guidance document as an effort to increase the number of kidney transplant programs that perform non-A₁/non-A₁B (A₂/A₂B) transplants. An increase in the number of programs using this provision can increase equity in access to transplants for disadvantaged blood group B candidates, due to a greater number of potential donor matches.

Pancreas Transplantation Committee **Guidance on Increasing Pancreas After Kidney (PAK) Transplants**

There has been a substantial decline in Pancreas After Kidney (PAK) transplants for more than a decade. PAK transplants have dropped steadily each year, with a 55% decrease from 2004 to 2011, even while 2-year pancreas graft survival increased for PAKs from 69% to 81% for the same time period.¹ PAK transplantation has historically been associated with inferior pancreas allograft survival compared with Simultaneous Pancreas and Kidney (SPK) transplantation. The Pancreas Committee sought to compare PAK transplants with SPK candidates and kidney alone recipients waiting for a pancreas to examine what characteristics resulted in improved outcomes for PAK recipients and to address an influential previous study that demonstrated poor outcomes for PAK recipients.

UNOS research analysis showed that PAK transplant recipients have an increased survival advantage compared to SPK waiting list candidates who receive neither a pancreas nor a kidney. Moreover, compared to uremic diabetic waitlist candidates, SPK and PAK recipients showed similar patient survival benefits. Finally, the analysis showed that both living and deceased donor kidney recipients who subsequently receive a pancreas transplant have better kidney graft survival than those recipients who just received a kidney alone. While the analysis does not include recipients that had a kidney graft loss before the pancreas transplant, which can bias the results to those healthy enough to get a PAK that are included in the PAK group, the results still indicate that PAK transplants are appropriate for certain diabetic uremic candidates, especially those with long SPK waiting list times. The Committee seeks to provide guidance to the community on the benefits of PAK transplants for these candidates.

Pediatric Transplantation Committee

Revisions to Pediatric Emergency Membership Exception

In December 2015, the OPTN/UNOS Board of Directors (Board) approved minimum training and experience requirements for key personnel at pediatric heart, kidney, and liver transplant programs. An emergency membership exception pathway (pathway) was included in the proposal for adult heart and liver transplant programs that did not meet the pediatric key personnel requirements, but wanted to register a patient less than 18 years old on the waiting list. The intent of this pathway was to allow a one-time membership exception for the identified patient under certain exigent circumstances. Members of the Board recognized opportunities for improvement and requested the OPTN/UNOS Pediatric Transplantation Committee (Committee) work on amendments to the pathway.

The Committee collaborated with the OPTN/UNOS Membership and Professional Standards Committee (MPSC) to amend the pathway in 2016. The proposed changes include objective requirements for heart and liver transplant programs that want to register a candidate less than 18 years old. These changes will address concerns over:

- the OPTN's ability to monitor and enforce the requirements,
- subjective and ill-defined language in the prior version of the pathway,
- how the pathways will work operationally, and
- what objective criteria will be used to determine when it is acceptable to transplant a pediatric candidate using one of the pathways.

The scope of this proposal only includes modifications to the emergency membership exception pathways for heart and liver transplant programs. Modifications to the minimum training and experience requirements approved by the Board in 2015 are not being made.

Thoracic Organ Transplantation Committee

Congenital Heart Disease Exception Request Guidance for Review Boards

The OPTN Board of Directors recently approved the Thoracic Organ Transplantation Committee's (Committee) Modification to the Adult Heart Allocation proposal during their December 2016. During the development of the proposal, the Committee received feedback from the heart transplant community during both rounds of public comment voicing concerns that adult congenital heart disease (ACHD) candidates may be disadvantaged by the proposed policy.¹ The Committee considered the following issues in congenital heart disease (CHD) candidates:

- Higher urgency statuses are device-driven
- Variability in review board decision-making for ACHD exception requests
- Challenging to objectively quantify severity of illness

The Committee acknowledged that some ACHD candidates may have higher mortality and may not be candidates for mechanical support options, but ultimately did not change proposed policy. Short-term, the exception and review process will accommodate these candidates, who can apply for an exception in any status as their medical urgency and potential for benefit would warrant. The Committee recognized that CHD expertise may be inconsistent across the regional review boards (RRBs), thus potentially

making evaluation and award of ACHD exception requests vulnerable to variability. To help mitigate these inconsistencies, the Committee created guidance for the RRBs with the goal of outlining objective criteria to standardize the evaluation and decision-making of ACHD exception requests.

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

10:20 OPTN/UNOS Update

Yolanda Becker, MD
OPTN/UNOS President

10:45 OPTN/UNOS Committee Reports and Voting on Public Comment Proposals

Moderator: Dr. Tullius

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

Thoracic Organ Transplantation Committee Update (10 min.) Jonathan Hammond, JR, MD

Kidney Transplantation Committee Committee Update (15 min.)

Martha Pavlakis, MD

Improving Allocation of En Bloc Kidneys (20 min.)

Kidney transplantation is the preferred treatment for end stage renal disease (ESRD), yet demand for kidneys far exceeds supply. One strategy to increase the donor pool is to use kidneys from small, pediatric donors. However, programs may be reluctant to transplant single kidneys from small pediatric donors due to technical challenges, which may result in inferior outcomes.

To mitigate the complications associated with transplanting kidneys from small pediatric donors singly, both kidneys, including the vena cava and aorta, can be transplanted en bloc into a single recipient. However, there are currently several challenges to allocating en bloc kidneys:

- There is currently no OPTN policy regarding allocation of en bloc kidneys
- The Kidney Donor Profile Index (KDPI) programmed into DonorNet[®] doesn't consider how kidneys will be used (en bloc or single) or acknowledge the improved function of en bloc kidneys, which could screen medically suitable candidates off the match run. In addition, there are other programming limitations that make en bloc kidney allocation a challenge

The proposed policy resolves these problems by providing explicit direction to organ procurement organizations (OPOs) on when to allocate en bloc kidneys. The policy includes donor criteria regarding the type of kidneys that can be allocated en bloc and mandates that programs must indicate in WaitListSM that they accept en bloc kidneys, thus expediting placement of en bloc kidneys to programs that will transplant them. In addition, the Kidney Transplantation Committee (Committee) proposes masking the KDPI score for en bloc kidney offers to prevent potentially eligible candidates from being screened off the match run for kidneys from high KDPI donors.

This proposal aligns with three OPTN strategic goals. First, it should increase the number of transplants by utilizing kidneys previously left unrecovered or discarded. Second, it should improve outcomes for waitlisted kidney candidates and transplant recipients as studies indicate when kidneys from a small pediatric donor are transplanted into a recipient en bloc versus singly, they confer comparable to superior outcomes. In addition, accepting kidneys en bloc may shorten a candidate's time on the waitlist, conferring not only a survival advantage, but also several other additional benefits. Finally, this proposal should increase efficiency in management of the OPTN as OPOs should no longer have to contact the

Organ Center for guidance or assistance in allocating en bloc kidneys.

Improving Allocation of Dual Kidneys (15 min.)

By the conclusion of 2016, a record-setting 12,245 deceased donor kidney transplants were performed nationwide.¹ However, there were still 98,962 candidates waiting for a kidney transplant.² One strategy to increase the number of kidney transplants is to reduce the number of discards of high Kidney Donor Profile Index (KDPI) kidneys through double kidney transplantation. The OPTN/UNOS Kidney Transplantation Committee (“the Committee”) is proposing amendments to OPTN policy to improve dual kidney allocation. Dual transplants and high KDPI transplants are disproportionately performed more often in older recipients; expanding the use of dual transplantation of high KDPI kidneys could serve to counterbalance the modest decline in access for older patients post-KAS.³ Amending current OPTN policy and enhancing programming could increase usage of high KDPI kidneys that are currently at increased risk for discard.

Members say that current policy is ambiguous, out-of-date, and does not enable them to identify and allocate dual kidneys in a timely manner. As a result, dual kidneys are often offered only after the wait list has been exhausted, leading to longer cold ischemia. Transplant programs, especially those with high dual transplantation volume, say that they would prefer to receive dual kidney offers earlier (ideally before organ recovery), to allow time for logistical planning and to minimize cold ischemia. Likewise, OPOs tell us that they favor pre-recovery criteria to facilitate allocation more efficiently.

The Committee distributed a concept paper during the spring 2017 public comment period in order to seek public input on three proposed concepts that aim to address the above problems. This initial round of public comment revealed support for a modification to the allocation tables that incorporate dual kidney allocation to centers that have opted in to receive these offers. The Committee now seeks additional community feedback on the selected policy solution.

Pancreas Transplantation Committee

Jean Francis, MD

Broadened Allocation of Pancreas Transplants Across Compatible ABO Blood Types

(15 min.)

Pancreas transplants continue to decline and the majority of pancreata that are transplanted are done so as part of a simultaneous pancreas-kidney (SPK) transplant. Current blood type restrictions on kidney-pancreas allocation prevent clinically compatible SPK transplants from occurring. Preventing clinically compatible SPK transplants results in many of these pancreata being discarded or not recovered. Modifying current blood type restrictions could lead to an increase in the utilization of pancreata, an overall increase in SPK transplants, and could promote a more efficient allocation system.

This proposal modifies Policy 11.4.D *Blood Type for Kidney-Pancreas Allocation* to loosen restrictions on blood type compatibility for kidney-pancreas (KP) and pancreas alone (PA) allocation: allowing blood type A, non-A₁ and AB, non-A₁B kidney-pancreas and pancreas offers to B candidates, allowing blood type B kidney-pancreas and pancreas offers to AB candidates, and removing restrictions on blood type O compatibility. The proposal also modifies allocation to prioritize high-cPRA ABO-identical candidates above high-cPRA ABO-compatible candidates, then among candidates with cPRA < 80%, prioritize ABO-identical candidates above ABO-compatible candidates.

The Pancreas Committee is pursuing an allocation change that maximizes the increase of KP transplants and minimizes negative impacts on blood type, age, or ethnicity. While the modeling by the Scientific Registry of Transplant Recipients (SRTR) did not project that candidates would be disadvantaged based on age or ethnicity, the modeling projected that blood type O candidates would be disadvantaged by a reduced access to transplant, including a simulated 2% decrease for blood type O kidney transplants. There was also a decrease for KP blood type O transplants but an increase of KPs overall. However, the modeling projected a significant increase in the number of SPKs, an increase in the number of median years of benefit, and a net increase in transplants if the blood type restrictions were loosened. The simulation chosen by the Committee predicts the least impact on blood type O candidates except one (Run 6), which showed a smaller increase in the median years of benefit and life years from transplant

(LYFT). The increase in SPKs and net increase in transplants projected by the proposal aligns with OPTN Goal 1, to increase the number of transplants.

OPO Committee

Jennifer Vazquez, MSN, RN,
CPTC

Improving the Efficiency of Organ Allocation (20 min.)

On April 30, 2007, mandatory use of DonorNet[®] began with the goal to facilitate and expedite organ placement using an electronic organ placement system. This system allows organ procurement organizations (OPOs) to electronically notify transplant hospitals about organ offers and provide donor information. During recent discussions and proposals that seek to increase the broader sharing of organs, the transplant community has acknowledged the need to make improvements to the organ placement system in order to place organs more efficiently.

Many factors lead to inefficiencies in the organ allocation process. Some of these, such as logistical issues, are difficult to control while OPOs and transplant programs can control other issues, such as communication. This proposal is the first step to improve the organ placement process by proposing the following:

- Reduce the current time limits for responding to organ offers
- Establish a new time limit for the primary transplant hospital to make a final decision on organ offers
- Limit the number of organ acceptances for one candidate at any given time
- Require OPOs to manage organ acceptances in real time.

This proposal will also address the required deceased donor information by simplifying the language and reducing redundancies and inconsistencies in *Policy 2.11: Required Deceased Donor Information*.

This proposal primarily supports OPTN/UNOS Strategic Goal 1: Increasing the number of transplants by improving the placement of organs and potentially reducing organ discards, leading to an overall increase in the number of transplants.

Liver and Intestinal Organ Transplantation Committee Committee Update (5 min.)

Parsia Vagefi, MD

Liver Enhancing Liver Distribution (25 min.)

Over a 5-year period during the 1990's, the OPTN tried and failed to reach consensus on liver allocation policy revisions aimed at broader sharing for liver allografts, particularly for the most urgent patients. The Secretary of Health and Human Services became involved and one result was implementation of federal transplant regulations, the OPTN Final Rule in March 2000. The Rule stipulates that OPTN allocation policies must, among other factors, be based on sound medical judgment, seek to achieve the best use of donated organs, and shall not be based on the candidate's place of residence or place of listing except to the extent needed to satisfy other regulatory requirements. The Rule stipulates additional OPTN requirements and restrictions that previously did not exist.

During the years immediately following Final Rule implementation, the MELD and PELD disease severity scoring systems were developed, seen as the first necessary step before readdressing broader liver sharing. Additional liver allocation policies followed, with the understanding that the OPTN was moving toward broader sharing to reduce the observed geographic inequity in access to liver transplant for the sickest candidates. On November 13th, 2012, the OPTN/UNOS Board of Directors directed all OPTN organ-specific committees to identify allocation equity metrics appropriate to their organ types. The Liver and Intestinal Organ Transplantation Committee (hereafter called "the Committee") selected variance in median MELD at time of transplant (for exception and non-exception candidates), among other metrics, and observed continued and significant variance in this metric across regions. The Board instructed the Committee to develop evidence-based policy proposals aimed at reducing this variance in accordance with the Final Rule.

The OPTN recognizes that there are not enough organs for patients in need of lifesaving transplants

and is invested in increasing the number of transplants each year by increasing donation, reducing organ discards, and improving OPO performance. However, these efforts will not change the fact that current regional boundaries often physically separate urgent candidates from donors in close proximity. The result is that in some areas of the United States, candidates must reach a higher MELD or PELD score in order to get a transplant.

In progress for the last 5 years, the current proposal strives to balance equity in access while limiting the impact on travel and logistics. The Committee proposes a solution that implements a 150 nautical mile radius sharing circle around the donor hospital and increased sharing within the region. The 150 mile circle may include candidates outside of the region. Candidates at transplant hospitals within the circle will receive 5 additional MELD or PELD points. The Committee proposes sharing in the initial broader classification to be limited to candidates with a calculated MELD of at least 29 (candidate age greater than 18 at time of registration) and allocation MELD or PELD of at least 29 (candidate age less than 18). The Committee also proposes a separate allocation classification for DCD donors or donors at least 70years old. The new allocation for these donors is expected to increase utilization and address concerns with the broader sharing of specific donor livers.

2:30 Estimated Adjournment