AGENDA OVERVIEW

Region 2 Meeting
DoubleTree by Hilton Pittsburgh Airport
8402 University Blvd
Moon Township, PA 15108
February 1, 2019

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

8:30	**Registration (breakfast available)**	
9:00-10:00	**Liver Program Directors Meeting**	Walnut Room
	Thoracic Program Directors Meeting	Oak Room
10:00-10:30	**Welcome and Update from Regional Councillor**, Matthew Cooper, MD **Non-Discussion Agenda *(includes 5 - 10 minutes for voting preparation)***	
10:30-10:55	**OPTN/UNOS Update,** Brian Shepard, UNOS CEO	
10:55-12:00	**Begin Discussion Agenda and OPTN/UNOS Committee Reports**	
12:00-12:30	**Networking Lunch (30 min)**	
12:30-1:10	**Discussion Session**	
1:10-2:40	**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*

- Modify HOPE Act Variance to Include Other Organs, *Ad Hoc Disease Transmission Advisory Committee*
- Clarifications on Reporting Maintenance Dialysis, *Living Donor Committee*
- Guidance on Effective Practices in Broader Distribution, *Operations and Safety Committee*

Discussion

- Eliminate the Use of Donor Service Areas (DSAs) in Thoracic Distribution, *Thoracic Organ Transplantation Committee*
- Eliminate the Use of Regions in VCA Distribution, *VCA Committee*
- Removal of DSA and Region from Kidney and Pancreas Allocation, *Kidney Transplantation Committee and Pancreas Transplantation Committee*
- Expedited Placement of Livers, *Organ Procurement Organization Committee*
- Split Liver Variance, *Liver & Intestinal Organ Transplantation Committee*
- Ethical Implications of Multi-Organ Transplants, *Ethics Committee*

DETAILED AGENDA

Region 2 Meeting
DoubleTree by Hilton Pittsburgh Airport
8402 University Blvd
Moon Township, PA 15108
February 1, 2019

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

8:30	**Registration (breakfast available)**	
9:00-10:00	**Liver Program Directors Meeting** **Thoracic Program Directors Meeting**	Walnut Room Oak Room
10:00-10:30	**Welcome and Update from Regional Councillor** ***(includes 10 minutes for voting preparation)***	Matthew Cooper, MD Medstar Georgetown Transplant Institute Region 2 Councillor
Non-Discussion Agenda (vote)		Dr. Matthew Cooper

**** 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. 7).

- Modify HOPE Act Variance to Include Other Organs, *Ad Hoc Disease Transmission Advisory Committee*
- Clarifications on Reporting Maintenance Dialysis, *Living Donor Committee*
- Guidance on Effective Practices in Broader Distribution, *Operations and Safety Committee*

10:30-10:55	**OPTN/UNOS Update**	Brian Shepard UNOS Chief Executive Officer
Discussion Agenda and OPTN/UNOS Committee Reports		Moderator: Dr. Cooper
10:55-11:15	**Thoracic Organ Transplantation Committee**	Jonathan D'Cunha, MD, PhD, FACS University of Pittsburgh Medical Center

Eliminate the Use of Donor Service Areas (DSAs) in Thoracic Distribution *(20 min.), vote, page [ ]*
The Organ Procurement and Transplantation Network (OPTN) Final Rule (hereafter, Final Rule) sets requirements for allocation policies developed by the OPTN, including sound medical judgement, best use of organs, ability for transplant hospitals to decide whether to accept an organ offer, avoiding wasting organs, promoting patient access to transplant, avoiding futile transplants, and promoting efficiency. The Final Rule also includes a requirement that allocation 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 Final Rule listed above.

In the past year, the United States Secretary of Health and Human Services (HHS) received critical comments regarding compliance with the National Organ Transplant Act (NOTA) and associated regulations under the Final Rule with respect to the geographic units used in lung and liver distribution. The OPTN made rapid changes to resolve using donation service area (DSA) and OPTN regions in lung and liver distribution, respectively. Furthermore, the OPTN Executive Committee directed the organ-specific committees to analyze those distribution systems and replace DSAs and OPTN regions (Regions) with a more rational and defensible unit of distribution.

Policy 6: Allocation of Hearts and Heart-Lungs currently uses DSAs as a geographic unit of distribution. These are poor proxies for geographic distance between donors and transplant candidates because the disparate sizes, shapes, and populations of DSAs result in an inconsistent application for all candidates. This presents a potential conflict with the Final Rule.

The OPTN Thoracic Organ Transplantation Committee (hereafter, the Committee) proposes replacing DSAs with a 250 nautical mile (NM) distance from the donor hospital. The goal of this change is to make heart allocation policy more consistent with the Final Rule and provide more equity in access to transplantation regardless of a candidate's place of listing. In addition, this realigns the first units of distribution for heart and lung allocation, addresses the limited utility of the exception for sensitized heart candidates, and finally, resolves several clerical artifacts that remain as a consequence of removing DSA as a unit of distribution from heart allocation policy.

11:15-11:35 Vascularized Composite Allograft Committee — TBD, Institution/Organization

Eliminate the Use of Regions in VCA Distribution *(20 min.), vote, page [ ]*
The OPTN Final Rule (hereafter Final Rule) sets requirements for allocation polices developed by the OPTN, including sound medical judgement, best use of organs, ability for transplant programs to decide whether to accept an organ offer, avoiding wasting organs, and promoting efficient management of organ placement. The Final Rule also includes a requirement that allocation 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.

On July 31, 2018, the Secretary of Health and Human Services (HHS) found that the use of donation service areas (DSAs) or regions in organ allocation policies cannot be justified under the Final Rule. OPTN policies for vascularized composite allograft (VCA) allocation use "region" as the first geographic boundary for distribution. In response to the Secretary's letter, the OPTN Executive Committee directed the VCA Transplantation Committee (Committee) to develop a proposal that replaces "region" with another geographic boundary in VCA allocation policy. This proposal would replace use of regions in VCA allocation policies with a 750 nautical mile (NM) concentric circle around a donor hospital. This will address the Secretary's findings by allowing efficient placement of deceased donor VCAs, help achieve optimal recipient and graft outcomes, and to reduce the risk of organs being recovered but not transplanted.

This proposal is consistent with Goal Two of the OPTN Strategic Plan to increase equity in access to transplant. This project aims to implement rational units for geographic distribution that are more consistent with the requirements of the Final Rule.

11:35-12:00 Kidney and Pancreas Transplantation Committees — Stephen Guy, MD, FACS, Hahnemann Univ Hospital; Peter Abrams, MD, MedStar Georgetown Univ. Hospital

Removal of DSA and Region from Kidney and Pancreas Allocation
(25 min.), vote, page [ ]
The Organ Procurement and Transplantation Network (OPTN) Final Rule (hereafter "Final Rule") sets requirements for allocation polices developed by the OPTN, including the use of sound medical judgement, considering the best use of organs, the ability for centers to decide whether to accept an organ offer, avoid wasting organs, and promoting efficiency. The Final Rule also includes a requirement

that policies “shall not be based on the candidate’s place of residence or place of registration, except to the extent required” by the other requirements of the Final Rule.

In the past year, the United States Secretary of Health and Human Services (HHS) received critical comments regarding compliance with the National Organ Transplant Act (NOTA) and associated regulations under the Final Rule with respect to the geographic units used in lung and liver distribution. The OPTN made rapid changes to resolve using donation service area (DSA) and OPTN regions (Regions) in lung and liver distribution, respectively. Furthermore, the OPTN Executive Committee directed the organ-specific committees to analyze their distribution systems and replace DSAs and regions with a more rational and defensible unit of distribution.

Policy 8: Allocation of Kidney and Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets currently use DSA and Region as geographic units of distribution. These are not good proxies for geographic distance between donors and transplant candidates because the disparate sizes, shapes, and populations of DSAs and regions result in an inconsistent application for all candidates. This presents a potential conflict with the Final Rule.

Members of the OPTN Kidney Transplantation Committee, joined by members from the OPTN Pancreas Transplantation Committee and the OPTN Pediatric Transplantation Committee, created the Kidney/Pancreas Workgroup (hereafter “the Workgroup”) in order to remove DSA and Region from kidney and pancreas allocation policies. The Workgroup reviewed OPTN data on current distribution practices, engaged Workgroup members on their collective clinical experience, and utilized the OPTN Board of Directors’ “Geographic Organ Distribution Principles and Models” to develop five potential allocation options that eliminate DSA and Region from kidney and pancreas allocation policies.

The five variations that the workgroup chose to model are:
1. A fixed concentric circle framework with a 150 nautical mile (NM) small circle and a 300 NM large circle
2. A fixed concentric circle framework with a 250 NM small circle and a 500 NM large circle
3. A fixed concentric circle framework with a single 500 NM circle
4. A hybrid framework with a single 500 NM circle that utilizes a small number of proximity points inside and outside of the circle, and
5. A hybrid framework with a single 500 NM circle that utilizes a large number of proximity points inside and outside of the circle.

These frameworks will be more comprehensively outlined in this paper’s “What Concepts Are Being Considered?” section. The Workgroup is not limiting itself to consideration of solely these five variations, but rather used these variations as choices to model in the KPSAM in order to most strategically determine what could be the ideal variation. The Workgroup understands that, given community feedback and additional evidence gathered, it is possible that the framework ultimately selected by the Workgroup may be a combination of these variations, or perhaps a new variation, such as a single-circle hybrid with a smaller concentric circle.

The Workgroup is currently considering these five options for modifying kidney and pancreas allocation policy to be more consistent with the Final Rule and to provide more equity in access to transplantation regardless of a candidate’s place of registration, except to the extent required by §121.8 (a)(1)-(5). The Workgroup requests community feedback in order to better inform the evidence-gathering and decision-making processes.

12:00-12:30 Break for Networking Lunch

12:30-1:10 Discussion Session

1:10-1:40 Liver & Intestinal Organ Transplantation Committee

Joseph Roth
NJ Organ & Tissue Sharing Network

Committee Update *(15 min.)*

Split Liver Variance *(15 min.), vote, page [ ]*
This proposal would create a variance to permit participating liver programs to split a liver and transplant the first segment into the candidate to whom it was allocated, and then transplant the remaining segment into another candidate at the same transplant hospital or an affiliated hospital. The goal is to increase the number of livers that are split, and thereby increase the number of liver transplants available from the same donor pool. It aims at reducing the logistical and technical challenges currently associated with splitting a liver. The variance would be used to determine whether it would in fact increase the number of transplants by increasing the number of livers that are split.

This variance was initially proposed by transplant hospitals and OPOs in Region 8, who requested it as a regional variance. However, other regions expressed interest and the Committee proposes that this be an open variance that other regions can also join.

1:40-2:00 Organ Procurement Organization Committee

Carolyn Welsh
NJ Organ & Tissue Sharing Network

Expedited Placement of Livers *(20 min.), vote, page [ ]*
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 not being used for transplant. OPTN policy does not currently address expedited placement with the exception of Policy 11.6: Facilitated Pancreas Allocation. Consequently, during recent discussions about broader distribution and system optimization, the community expressed the desire to better understand expedited placement, its impact on transplant candidates, and to maximize utilization of transplantable organs.

Therefore, the goal of this proposal is to address the following issues:
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

The OPO Committee is proposing policy language that will allow for the quick identification of transplant candidates willing to accept an expedited offer when a liver has been declined late in the process. This will be accomplished by requiring transplant hospitals to enter candidate-level acceptance criteria that will allow for additional screening on an expedited liver match run. As part of this proposal, OPOs will be permitted to make expedited offers if the donor has entered the operating room and the OPO is notified of a liver turndown. These offers will be sent out with an abbreviated time limit of 20 minutes to identify those candidates willing to accept an expedited liver offer. At the end of this time limit, the liver will be placed with the candidate that appears highest on the match run.

2:00-2:10 Pediatric Transplantation Committee

Rachel Ryan, RN, BSN, CCTC
Children's Hospital of Philadelphia

Committee Update *(10 min.)*

2:10-2:30 Ethics Committee

John Entwistle III, MD, PhD
Thomas Jefferson Univ. Hospital

Ethical Implications of Multi-Organ Transplants *(20 min.), vote, page [ ]*
The allocation policies for multi-organ transplant (MOT) have the potential to create inequity in the organ distribution process, either in the rate of transplantation or in the time to transplantation. Such potential inconsistencies may affect the patients who are awaiting MOT as well as those who are awaiting single organ transplantation (SOT) because both groups depend upon available organs from the same limited donor pool. Prioritization of MOT candidates and the allocation rules for each combination have not been standardized across the different organs. As a result, the current allocation system has generated confusion in the transplant community about the rationale for differences in MOT allocation plans between different organ combinations.

The OPTN Ethics Committee (hereafter "The Committee") performed an analysis of policy and relevant literature focusing on the potential conflict in the principles of equity and utility in the allocation of multi-organ transplants. Ultimately the Committee affirmed that MOT should reflect a balance between equity and utility, with the understanding that no system can maximize both. Because the ethical issues of equity and utility that MOT raises are common with all organ combinations, the ethical principles must be carefully considered and weighed in the development and modification of MOT policy. This white paper details the ethical dilemmas that arise from conflicts between equity and utility and the recommendations of the Committee regarding the allocation of multi-organ transplants.

The 2018 OPTN Strategic Plan called for the OPTN to "measure equity in allocation, including geographic disparities and multi-organ disparities." This White Paper lays the foundation for other committees to clarify or modify existing multi-organ allocation policy and to do so in a consistent, principled manner, which aligns with the OPTN strategic goal to provide equity in access to transplant.

2:30-2:40 Ad Hoc Disease Transmission Advisory Committee

Marian Michaels, MD, MPH
UPMC Children's Hospital of Pittsburgh

Committee Update – Case Studies *(10 min.)*

3:00 Estimated Adjournment

APPENDIX A
Non-Discussion Agenda Proposals

Ad Hoc Disease Transmission Advisory Committee

Modify HOPE Act Variance to Include Other Organs

The HIV Organ Policy Equity Act was enacted on November 21, 2013, permitting use of organs from HIV- positive donors for transplantation into HIV-positive candidates under approved research protocols designed to evaluate the feasibility, effectiveness, and safety of such organ transplants. In November 2015, OPTN policies for recovery and transplantation of HIV positive livers and kidneys to HIV-positive candidates were effective, in addition to final research requirements for program participation, published by the National Institutes of Health (NIH). ,

This proposal modifies the policies enacted by the OPTN HOPE Act Variance to allow programs meeting the research and experience requirements to recover and transplant organs in addition to liver and kidney. Program participation requirements, including meeting minimum experience, operating under an approved Institutional Review Board (IRB), and adhering to the federal research protocol guidelines, remain unchanged.

No clinical outcomes that may threaten the safety of such transplants have been reported to the OPTN since 2015. Expansion of the variance to include other organs besides kidney and liver has been requested by active program participants. Federal criteria do not limit the program to specific organ transplants, and explicitly encouraged future expansion of the program upon publishing research study participation criteria in November 2015.

Living Donor Committee

Clarifications on Reporting Maintenance Dialysis

Members have raised questions regarding the meaning of the phrase “begins dialysis” in Organ Procurement and Transplantation Network (OPTN) Policy 18.6: Reporting of Living Donor Events. Currently, it is not clear whether the phrase “begins dialysis” requires reporting chronic dialysis representing end-stage renal failure (ESRD) and/or acute dialysis under OPTN Policy 18.6. In addition, there are several other areas within policy language, the Transplant Information Electronic Data Interchange (TIEDI®), and the OPTN Patient Safety Portal, which refer to the decrease or loss of renal function in a living donor using inconsistent terminology.

Clarifying when transplant hospitals should report chronic versus acute dialysis in the sections of OPTN policy and harmonizing terminology on OPTN forms will help centers accurately report living donor events. In addition, greater clarity in reporting will improve safety reviews and the understanding of clinical events after living donation.

Operations and Safety Committee

Guidance on Effective Practices in Broader Distribution

The OPTN Operations and Safety Committee created a guidance document to provide effective practices as well as operational and process recommendations. The intent of this guidance is to help OPTN members adapt to policy changes that address the broader distribution of organs. These allocation changes impact all members in the organ donation and transplantation community and will require operational changes to increase the efficiency of organ allocation, donor and recipient matching, transportation logistics, and organ recovery.

The guidance document is intended to serve as a resource for OPTN members. The scope and content should reflect collaboration between OPOs, transplant hospitals, and histocompatibility labs, taking into consideration their needs and best practices.