

AGENDA OVERVIEW
Region 9 Meeting
Buffalo Niagara Marriott
1340 Millersport Highway
Amherst, New York
September 25, 2019

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

- 8:30** Registration Opens (breakfast available)
- 9:30-10:30** Public Feedback Breakout Sessions (*NEW*)
- 10:30-11:00** Member Networking (*NEW*)
- 11:00-11:25** Welcome and Update from Regional Councillor, Dr. Kim-Schluger
Non-Discussion Agenda (*includes 5 - 10 minutes for voting preparation*)
- 11:25-11:50** OPTN Update
- 11:50-12:30** Begin Discussion Agenda and OPTN Committee Reports
- 12:30-1:10** Lunch
- 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 Appointment Process for the Histocompatibility Vice Chair, *OPTN Histocompatibility Committee*
- Clarification of Pre-Existing Liver Disease, *OPTN Liver and Intestinal Organ Transplantation Committee*

Discussion:

- Modify Data Submission Policies, *OPTN Data Advisory Committee*
- Data Collection to Evaluate the Logistical Impact of Broader Distribution, *OPTN Operations and Safety Committee*
- Eliminate the Use of DSA and Region in Kidney Allocation Policy, *OPTN Kidney Transplantation Committee*
- Eliminate the Use of DSA and Region in Pancreas Allocation Policy, *OPTN Pancreas Transplantation Committee*
- Expedited Placement of Livers, *OPTN Organ Procurement Organization Committee*
- Continuous Distribution of Lungs Concept Paper, *OPTN Thoracic Organ Transplantation Committee*

DETAILED AGENDA
Region 9 Meeting
Buffalo Niagara Marriott
1340 Millersport Highway
Amherst, New York
September 25, 2019

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

- 8:30 Registration Opens (breakfast available)**
- 9:30-10:30 Public Feedback Breakout Sessions (NEW)**
- Kidney and Pancreas (9:30-10:45):**
- Eliminate the Use of DSA and Region in Pancreas Allocation Policy, *OPTN Pancreas Transplantation Committee*
 - Eliminate the Use of DSA and Region in Kidney Allocation Policy, *OPTN Kidney Transplantation Committee*
- Thoracic:**
- Continuous Distribution of Lungs Concept Paper, *OPTN Thoracic Organ Transplantation Committee*
 - OPTN Thoracic Committee Update
- OPO, Liver, and Operations and Safety:**
- Liver Committee Update
 - Data Collection to Evaluate the Logistical Impact of Broader Distribution, *OPTN Operations and Safety Committee*
 - Expedited Placement of Livers, *OPTN Organ Procurement Organization Committee*
- 10:30-11:00 Member Networking (NEW)**
- 11:00-11:25 Welcome and Update from Regional Councillor**
(includes 5 minutes for voting preparation)
- Leona Kim-Schluger, MD
Mount Sinai Medical Center
Region 9 Councillor

Non-Discussion Agenda (vote)

**** 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. 8).

- Modify Appointment Process for the Histocompatibility Vice Chair, *OPTN Histocompatibility Committee*
- Clarification of Pre-Existing Liver Disease, *OPTN Liver and Intestinal Organ Transplantation Committee*

- 11:25-11:50 OPTN Update**
- Brian Shepard
UNOS, Chief Executive Officer

Discussion Agenda and OPTN Committee Reports

Moderator: Dr. Kim-Schluger

- 11:50-12:10 Thoracic Organ Transplantation Committee**
- Donna Mancini, MD
Mount Sinai Medical Center

Continuous Distribution of Lungs Concept Paper (20 min.), vote

In December 2018, the OPTN Board of Directors selected continuous distribution for all organs. Continuous distribution will prioritize candidates on the match run based on a combination of points awarded for factors related to medical priority, expected post-transplant outcome, the efficient management of organ placement, and equity. Continuous distribution will eliminate hard boundaries, such as being more than 250 nautical miles from

the donor hospital, which currently preclude a patient from being prioritized ahead of patients on the other side of a boundary.

This concept paper builds upon the work by the Ad Hoc Geography Committee and establishes a framework for the replacement of our current classification-based allocation system with a points-based allocation system. This framework is built on a new composite allocation score that weighs the OPTN final rule requirements that apply to the OPTN allocation system. All final rule requirements must be satisfied. Competing factors must be weighed such that the OPTN Board of Directors is satisfied that all of the regulatory requirements are all satisfied. This framework is intended to result in more equity for patients; more transparency into the allocation system; and more efficiency in developing organ allocation policies, implementing those policies, and achieving the goals of those policies. While the OPTN Thoracic Organ Transplantation Committee (hereafter, the Committee) and this paper focus on lung allocation, this framework will ultimately apply to all organs and all transplant candidates. The development of this new framework will utilize clinical and operational analysis in addition to values and legal analysis. The process for developing continuous, points-based priorities may benefit from the use of structured, analytical approaches such as multi-criteria decision-making (MCDM) methods and mathematical optimization. The OPTN is currently exploring the value of how such methods may lend to this project. This concept paper explains the progress made by the Committee to date and the anticipated process to develop the remainder of the proposal for lungs.

This document is a concept paper and not a policy proposal. Therefore, the committee has not developed any specific scoring model or policy language. The primary purpose of this paper is to solicit feedback and ideas on the approach, including appropriate factors to account for in a points-based allocation system.

12:10-12:30 Data Advisory Committee

Eric Messick
UNOS, Policy Analyst

Modify Data Submission Policies (20 min.), vote

The National Organ Transplant Act of 1984 requires that the Organ Procurement Transplantation Network (OPTN) “collect, analyze, and publish data concerning organ donation and transplants.” *Policy 18: Data Submission Requirements* establishes the OPTN’s data requirements. OPTN members are required to complete and submit data on transplant candidates, recipients, and donors. The data are submitted electronically through UNetSM, a secure web-based data collection system, with the exception of certain data associated with Vascularized Composite Allografts (VCA). Appendix A provides a glossary of terms and meanings.

In order to collect the highest quality data, this proposal addresses some of the identified gaps in current policy and practice. For example, the OPTN Data Advisory Committee (hereafter, “Committee”) proposes clarifying when data elements collected using the Transplant Information Electronic Data Interchange® (TIEDI) are required to be submitted (Table 1). (See Appendix B for more detail regarding the TIEDI data reporting requirements.) The Committee also proposes limiting members’ ability to change data submitted through TIEDI. Finally, the proposal revises certain policy language to make it more consistent with members’ data entry experiences.

Table 1: Titles and Acronyms of TIEDI Data Collection Instruments and Responsible OPTN Member

Title	Acronym	Responsible Member
Deceased Donor Registration	DDR	Organ Procurement Organization
Donor Histocompatibility	DHS	Histocompatibility Lab
Living Donor Follow-up	LDF	Transplant Program
Living Donor Registration	LDR	Transplant Program
Recipient Histocompatibility	RHS	Histocompatibility Lab
Transplant Candidate Registration	TCR	Transplant Program
Transplant Recipient Follow-up	TRF	Transplant Program
Transplant Recipient Registration	TRR	Transplant Program

Source: OPTN Policy 18: Data Submission Requirements, Table 18-1: Data Submission Requirements.

The proposal will promote the efficient management of the OPTN in several ways. It clarifies the need for submitting accurate, high-quality data at the time of entry. It seeks to achieve this by improving the timelines for submitting data, and limiting the ability to change data after final submission. These actions improve the widespread availability of trusted, complete, and accurate data for members seeking to use it for performance improvement, and for the OPTN's evaluation of transplant system performance. In addition, researchers, such as the Scientific Registry of Transplant Recipients (SRTR), who also study and assess transplant system performance, will benefit from the proposed efforts to improve data quality. It also aligns with the Final Rule's requirement that timely and institution-specific performance data be made publicly available in order to appraise the quality of transplantation programs.

12:30-1:10 Break for Networking Lunch

1:10-1:20 Pediatric Transplantation Committee Update

Warren Zuckerman, MD
New York Presbyterian
Hospital/Columbia University
Medical Center

1:20-1:45 Kidney Transplantation Committee

Ernesto Molmenti, MD, MBA,
PhD
North Shore University
Hospital/Northwell Health

Eliminate the Use of DSA and Region in Kidney Allocation Policy (25 min.), vote

The Final Rule sets requirements for allocation policies developed by the Organ Procurement and Transplantation Network (OPTN), including the use of sound medical judgement, achieving the best use of organs, preserving the ability for transplant programs to decide whether to accept an organ offer, avoiding wasting organs (unnecessary organ loss), avoiding futile transplants, promoting patient access to transplantation 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.

OPTN Policy 8: Allocation of Kidneys currently uses DSA and region as geographic units of distribution. DSA and region are poor proxies for geographic distance between donors and transplant candidates due to variation in size, shapes, and populations resulting in an inconsistent application for all candidates. As a result, the use of DSA and region in kidney distribution presents a potential conflict with the Final Rule. The proposed solution removes DSA and region as units of distribution in kidney allocation policy, and would allocate using rationally determined units of distribution that are intended to ensure that the most urgent candidates are prioritized, thereby promoting greater equity in access to transplantation.

The OPTN Kidney Transplantation Committee (hereafter, "Committee") proposes removing DSA within kidney allocation policy in favor of a single fixed distance circle encompassing 500 nautical miles (NM) with the donor hospital at its center. Region as currently determined would be removed as a unit of distribution. The 500 NM circle would include proximity points that award candidates inside the single fixed circle a maximum of four points and award candidates outside of the fixed circle a maximum of eight points based on their distance from the donor hospital. The goal of these changes is to make kidney allocation policy more consistent with the Final Rule and to increase geographic equity in access to transplantation regardless of a candidate's place of listing, while limiting transportation costs and inefficiencies through the use of proximity points.

Also included in this policy proposal are changes that further prioritize pediatric and prior living donor candidates. Additionally, policy changes are included regarding import matches and exceptions for medical urgency that require amendment due to the removal of DSA as a distribution unit from allocation policy.

The Committee encourages all interested individuals to comment on the proposal in its entirety, but specifically asks for feedback regarding:

- What factors should be used to select a circle size that distributes kidneys broadly and efficiently?
- Should proximity points be used inside the 500 NM circle? Should they be used outside the distribution circle? How should the assigned values be weighted in relation to other kidney allocation points?
- What priority do you think is appropriate for pediatric candidates? Should prioritization be applied inside the distribution circle? Should prioritization be applied outside the distribution circle?
- What priority do you think is appropriate for prior living donor candidates? Should prioritization be applied inside the distribution circle?
- What operational concerns should the committee consider as this policy is being prepared for OPTN board action and implementation?
- Should medical urgency criteria be defined? If so, what specific conditions would qualify? Where should the new medically urgent classification be placed within allocation tables? Should placement within allocation tables vary depending on the KDPI of the donor kidney? How should two medically urgent candidates be prioritized should two appear on the same match run?
- When import back up is granted, do you support the use of an import match run for the import OPO to reallocate the kidney? Should the match run use the same size circle as the original allocation but with increased points for proximity? Should the circle size be smaller? If so, what distance will promote the efficient reallocation of kidneys?

1:45-2:05 Pancreas Transplantation Committee

Liise Kayler MD, MS, FACS
Erie County Medical Center

Eliminate the Use of DSA and Region in Pancreas Allocation Policy (20 min.), vote

The Final Rule sets requirements for allocation policies developed by the Organ Procurement and Transplantation Network (OPTN), including the use of sound medical judgement, achieving the best use of organs, preserving the ability for transplant programs to decide whether to accept an organ offer, avoiding wasting organs (unnecessary organ loss), avoiding futile transplants, promoting patient access to transplantation 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.

OPTN Policy 11: Allocation of Pancreas, Kidney-Pancreas and Islets currently uses DSA and region as geographic units of distribution. DSAs and regions are poor proxies for geographic distance between donors and transplant candidates due to variation in size, shapes and populations, resulting in an inconsistent application for all candidates. As a result, the use of DSAs and regions in pancreas distribution presents a potential conflict with the Final Rule. The use of DSAs and regions in pancreas distribution may also contribute to variation in pancreas utilization and discard rates geographically, potentially conflicting with the Final Rule requirement to promote patient access to transplant. Finally, most pancreas recipients are also kidney recipients, and DSA is the largest factor related to disparity in kidney allocation, which also indicates that DSAs and regions present a potential conflict with promoting patient access to transplant.

The OPTN Pancreas Transplantation Committee (hereafter, “Committee”) proposes removing DSA within pancreas allocation policy in favor of a single fixed distance circle encompassing 500 nautical miles (NM) with the donor hospital at its center. Region as currently determined would be removed as a unit of distribution. The 500 NM circle would include proximity points that award candidates inside the single fixed circle a maximum of four points and award candidates outside of the fixed circle a maximum of eight points based on their distance from the donor hospital.

To determine the proposed solution, the Committee used sound medical judgment, including review of kidney-pancreas simulated allocation model (KPSAM) and relevant literature, clinical and operational experience of

Committee members, input from stakeholders and feedback from public comment. The Committee considered many options before deciding on the proposed solution – these options included multiple fixed distance circles with no points, multiple fixed distance circles with points, and single circles with no points. The Committee chose the proposed solution because it reflects the Final Rule’s requirement that organ allocation not be based on a candidate’s place of residence or place of listing except as necessary. Broader distribution would indicate that geography would play less of a role than it would if initial distribution were confined to a smaller circle. At the same time, the proposed solution also fulfills Final Rule requirements for avoiding unnecessary organ loss and promoting the efficient management of organ placement by including steep proximity points inside and outside the circle to avoid organs traveling unnecessarily and to promote efficiency.

The goal of the proposed changes is to make pancreas allocation policy more consistent with the Final Rule and to increase geographic equity in access to transplantation regardless of a candidate’s place of listing, while limiting transportation costs and inefficiencies through the use of proximity points.

The Committee encourages all interested individuals to comment on the proposal in its entirety, but specifically asks for feedback regarding:

What considerations should be taken into account to select a circle size that distributes pancreata broadly and efficiently?

Proximity points are intended to contribute to efficiency in the broader distribution of pancreata. Should they be used inside the 500NM circle? Should they be used outside the 500NM circle?

What operational concerns should the committee consider as this policy is being prepared for OPTN board action and implementation?

For import back up, should the initial distance from the transplant program be 150 NM or another distance, when considering the efficient reallocation of pancreas and kidney-pancreas? Should proximity points be included outside the initial import match run circle to limit travel costs and preservation time, or should there be a secondary circle of 500 NM to address those concerns?

Should programs qualify for facilitated placement if the program performs 2 or 5 transplants in 2 years from pancreata imported beyond 500 NM from the transplant program?

2:05-2:20 Operations and Safety Committee

Phyllis Murawski, BSN, MS
Erie County Medical Center

Data Collection to Evaluate the Logistical Impact of Broader Distribution (15 min.)

The elimination of donation service areas (DSAs) and regions from OPTN policy is expanding to all organ allocation policies, and resulting in increased logistical challenges, which will impact all members in the organ donation and transplantation community. Currently, data and analysis on the impact of broader organ distribution on travel is limited. The OPTN Operations and Safety Committee (hereinafter “the Committee”) is requesting input from the community to solicit suggestions and feedback that will be considered for a potential future data collection proposal on the logistical impact of broader distribution, specifically as it pertains to transportation. This document is not a proposal, but instead a request for discussion, feedback, and suggestions on potential data elements and data source that should be considered. The input received will allow further considerations for a future data collection proposal that would support the OPTN strategic plan of promoting efficient management of the OPTN by providing information to tailor further broader distribution discussion and potential data collection requests in the future.

Expedited Placement of Livers (20 min.), vote

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 regarding broader organ distribution and system optimization, the community expressed an interest in better understanding expedited placement and its role in addressing the issue of late liver turndowns. The goal of this proposal is to address the following issues related to expedited placement:

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

The OPO Committee (hereinafter referred to as “the Committee”) submitted this proposal for public comment during the January-March 2019 cycle. The main concerns raised during public comment were that initiating expedited placement from the donor operating room (OR) is too late in the process and 20 minutes for transplant hospitals to respond to expedited liver offers is not enough time. In response to public comment, the Committee made the decision to revise the proposal and clarify the process by which livers will be allocated using expedited placement. This proposal still requires transplant hospitals to enter candidate-level acceptance criteria to opt in to receive expedited livers and allow additional screening on the liver match run for expedited offers. OPOs will have the ability to see expedited candidates on the original liver match run which will allow for advance communication and planning in the event expedited placement is necessary. However, expedited liver offers can only be sent by the host OPO once the conditions outlined in the proposal have been met. Finally, the previously proposed time limit of 20 minutes for transplant hospitals to respond to these offers has been changed to 30 minutes.

3:00 Estimated Adjournment

Appendix A

Non-Discussion Agenda Proposals

Histocompatibility Committee

Modify Appointment Process for the Histocompatibility Vice Chair

The OPTN has 21 standing and ad-hoc committees that develop policy proposals and advise the OPTN Board of Directors. The committees each have approximately 18 members, led by a Chair and Vice Chair who each serve for terms defined in OPTN bylaws. The names of potential committee leaders are proposed by existing leadership with UNOS staff input and submitted for consideration. The Vice President of the OPTN Board of Directors then appoints Chairs and Vice Chairs from a list of qualified nominees.

The OPTN Histocompatibility Committee Vice Chair is the only exception to this practice and is selected via a national election by all eligible member histocompatibility laboratory representatives.

In order to achieve efficiency in OPTN governance through consistency, the OPTN Histocompatibility Committee proposes to modify the appointment process outlined in the OPTN Bylaws, *Article 7.1: Composition of Standing Committees (Bylaws 7.1)*. This will eliminate the election of the Vice Chair and make it more consistent with the manner in which all other standing and ad-hoc committees have the Vice Chair selected.

Liver and Intestinal Organ Transplantation Committee

Clarification of Pre-Existing Liver Disease

A liver candidate with a diagnosis of fulminant liver failure may qualify to be listed as Status 1A on the liver waiting list. Status 1A is the highest medical urgency category for liver candidates, and is reserved for candidates who have the highest risk of one week mortality if they do not receive a transplant. In order to qualify for Status 1A based on this diagnosis, the candidate must not have pre-existing liver disease. There has not been a clear policy on whether pre-existing liver disease for which the candidate has already received a liver transplant would disqualify a candidate. This policy would clarify that pre-existing liver disease in a prior liver transplant recipient would not disqualify them as a candidate for Status 1A fulminant liver failure unless the candidate had a diagnosis of liver disease following that liver transplant.