

**OPTN Policy Oversight Committee
Meeting Minutes
June 25, 2019
Conference Call**

**Jennifer Milton, BSN, CCTC, MBA, Chair
Alex Glazier, JD, MPH, Vice Chair**

Introduction

The Policy Oversight Committee (POC) met via teleconference on 6/25/2019 to discuss the following agenda items:

1. Welcome and Introduction
2. Upcoming Public Comment Proposals
3. Update on Setting Strategic Policy Priorities
4. Wrap-Up

The following is a summary of the Policy Oversight Committee's (POC) discussions.

1. Welcome and Introduction

The Committee Chair welcomed members to the meeting and provided an overview of the meeting agenda.

Summary of discussion:

The Committee Chair began the meeting by welcoming members and provided an overview of the meeting agenda that included a review of the proposals that will be out for the fall 2019 public comment cycle as well as an update on the POC's new structure on setting strategic policy priorities to their rules.

2. Upcoming Public Comment Proposals

The United Network for Organ Sharing (UNOS) staff provided members with an overview of the fall 2019 public comment proposals.

Summary of discussion:

UNOS staff began by providing members with background information on the review process for the fall 2019 public comment cycle. In presenting the proposals prior to the fall public comment cycle, members will have the opportunity to identify any red flags (clinical, financial, legal, procedural, and/or political) that would prevent the OPTN from potentially adopting the proposal. If any red flags are identified, this will allow time for UNOS staff to resolve those issues before submission for public comment in August.

Pancreas Committee: Remove Donation Service Area (DSA) and Region from Pancreas Allocation Policy

UNOS staff began by providing an overview of the discussion among the Pancreas Committee on the Scientific Registry of Transplant Recipients (SRTR) data. The Pancreas Committee reviewed the Final Rule and relevant metrics, and discussed the variations that were the most appropriate change for pancreas allocation to remove DSA and region. The two variations that received the most support were the 500/500/4/8. This variation represents 500 for pancreas, 4 points inside, 8 points outside, and 500 for kidney as well under this assumption. The other run with the most support was 250/250/2/4. This

variation represents both kidney and pancreas having circle sizes of 250 nautical miles (NM) with 2 points inside, and 4 points outside.

The Pancreas Committee preferred the 500/500/4/8 option as their first choice. The Pancreas Committee felt that the limitations for ischemic time were not significant enough that pancreas should be limited in terms of the distribution as there are fewer pancreas programs and in ensuring the diabetics on the list are transplanted. By contrast, members preferred the 150 option and their second choice was the 250/250/2/4 option. UNOS staff added that this was not a final decision as the committee will discuss further.

A member asked if there was discussion among the Pancreas Committee on the legal situation that is happening with the Liver proposal and if there was any thought of letting that resolve before moving forward. UNOS staff stated that this did come up briefly and it was discussed that regardless of how the Liver Committee's proposal moves forward, the Pancreas and Kidney Committees are required to put forward something that changes the distribution to remove DSAs and regions. It is anticipated that questions will come up regarding this, but it would not change the priority of the Committee.

Another member stated that there could be some implications in terms of the policy development process and asked if the Pancreas Committee discussed the possibility that this proposal could be implicated by the result of the Liver lawsuit. UNOS staff stated that there is a potential outcome from the lawsuit where the Health Resources and Services Administration (HRSA) could decide that future significant proposals may need to be published in the Federal Register. The approach to this would be to adapt this process as necessary, with the OPTN policy process working in parallel. This would not negate the necessity of the proposal going into public comment this fall.

Kidney Committee: Remove DSA and Region from Kidney Allocation Policy

UNOS staff provided an overview of the Kidney Committee's proposal. The Kidney Committee had similar discussions as the Pancreas Committee and took a deep dive in the SRTR data. One of the conversations among members was regarding pediatric priority. The Kidney Committee included further pediatric and living donor prioritization within the kidney classification tables. There was in depth discussion about the prioritization of pediatric candidates resulting from broader sharing as opposed to what was resulting from the increase in priority within the tables. The SRTR made it clear that the increased prioritization that pediatric candidates was receiving was from the broader distribution and not as much from the increased allocation within the tables. The Kidney Committee independently arrived to the two framework variations that the Pancreas Committee arrived to as well, although the margin is slimmer than the Pancreas Committee.

The two preferred variations of the Kidney Committee were the 500/500/4/8 by a single vote of 11 to 10. The second choice was 250/250/2/4. These were informal straw polls on general preferences. UNOS and SRTR staff will develop some illustrations to show how individual metrics are effected between the two frameworks when compared to baseline. The Kidney Committee plan to vote on a framework during their July 8th or July 15th Committee call.

A member asked where the data that was modeled for the prioritization of pediatric and previous living donors is being manifested in the project proposal. UNOS staff stated that the Kidney Committee had been discussing this prioritization from the beginning but did not have the bandwidth in the first round of modeling to include this information. The decision was to include this information in the second round of modeling and not necessarily as part of the formal policy proposal for the fall. Now that it has been shown that pediatric candidates are receiving increase priority by nature of broader sharing, the

Kidney Committee could decide that broader sharing is giving enough priority to pediatric candidates and not include the increased prioritization within the kidney classification tables. The prior living donor cohort was also included, however, the number of candidates was so small that the impact was determined to be very minimal. The Kidney Committee could still decide to further prioritize those prior living donor candidates. This is all reflective of the modeling results of the Kidney-Pancreas (KP) and will be available from the slides of the recent KP meeting.

Another member asked about the concerns about timing and the anticipated reaction from stakeholders. UNOS staff stated that in working on this project from the beginning, there were two rounds of modeling as well as a concept paper. There has also been feedback from the community through public comment as well as the regional meetings. Based on the feedback received, the scope and variations were narrowed down.

Histocompatibility Committee: Modify Appointment Process for the Histocompatibility Vice Chair

UNOS staff reviewed the Histocompatibility (Histo) Committee's proposal. Currently, the Histo Committee is the only standing Committee that does not have its Vice Chair appointed by the Vice President of the OPTN Board. The process instead goes through a national election. The Histo Committee is proposing a revision of the OPTN Bylaws, specifically Article 7.1 to eliminate the election process. This would bring the Committee in consistency with the other standing Committees and would comply with the OPTN Strategic Plan to reduce administrative burden. The controversies of this proposal would be the lack of specificity in the current Bylaws of how Vice Chairs are appointed. Additionally, in the Final Rule, all of the compositions of the Committees have listed representation from transplant coordinators, OPOs, transplant hospitals, recipients, and donor families. Histocompatibility laboratory personnel is not listed in the Final Rule and is a concern the Histo Committee has expressed and anticipate this being mentioned in public comment.

Operations and Safety Committee: Data Collection to Evaluate the Logistical Impact of Broader Distribution

UNOS staff provided an overview with the Operations and Safety Committee's (OSC) public comment proposal. The proposal is in response to the OSC's feedback question during the spring 2019 public comment cycle which asked if there was support for additional data collection to further evaluate the logistical impact of broader distribution. The proposal is proposing five data elements to further evaluate the impact of travel mode in broader distribution.

A member asked if the Organ Procurement Organization (OPO) Committee was consulted. The Committee Vice Chair stated that the proposal was unable to be discussed during the procurement council at the Association of Organ Procurement Organization (AOPO) conference as planned, but there will be a listserv seeking input to provide an opportunity to get some information from AOPO. There have been conversations with members offline during the AOPO conference as well.

Liver Committee: Update to Definition of Pre-Existing Liver Disease

The Liver Committee's Vice Chair provided members with an overview of the Liver Committee's public comment proposal. The Liver Committee proposes to allow the definition of pre-existing liver disease to be reset at the time of transplant. This would allow liver transplant recipients who develop acute liver failure to receive the designation as a patient with acute liver failure because they receive the highest priority score. This is a rare event – only about 3,000 of these cases occur per year. The occurrence of this would have to be 1 in 100,000 (rate in the United States per year) and the number of liver recipients is about 80,000 who are alive. This issue was brought up by a center and it is believed this proposal would pass since it is an obvious requirement and it is uncommon that this would ever happen.

Organ Procurement Organization Committee: Expedited Placement of Livers

UNOS staff provided an overview of the Organ Procurement Organization (OPO) Committee's Expedited Placement of Livers proposal. This is a revised proposal. Two of the main themes that came from the spring 2019 public comment cycle were initiating expedited placement in the OR was too late in the process and 20 minutes to respond to expedited offers was too short of a timeframe. The OPO Committee worked to revise the proposal which included some policy modifications and programming process clarifications in an effort to address the concerns that were raised during public comment. There were no changes made to the requirements by which transplant centers opt in to receive expedited liver offers. Some of the programming changes will be made to allow OPOs to see expedited candidates on the liver match run so that communications and arrangements can be made ahead of time in the event of a late turndown. The time limit to respond to expedited offers was increased from 20 minutes to 30 minutes.

A member asked if there were concerns in public comment that the OPO Committee decided did not require any modifications to the proposal. UNOS staff stated that there were a number of comments from the last public comment cycle about the need to update DonorNet. The OPO Committee agreed that this was outside the scope of this proposal.

Another member asked if there was any modeling to demonstrate that the expedited placement of livers would increase allocation. UNOS staff stated that there was no data to evaluate in developing this proposal. This would be one of the data points that would be reviewed following the implementation of this proposal.

Another member stated that there was another expedited organ placement project with the Liver Committee as a stakeholder, and asked how it was that the expedited proposal of livers was going to public comment rather than a proposal including an overall expedited process. UNOS staff stated that the OPO Committee decided early on to start with liver to come up with an expedited system that could eventually be applied to the other organ systems. This was explained in the public comment document.

A member asked if the OPO Committee discussed how this proposal would relate to liver distribution. Would this require additional work depending on the outcome of the policy that is currently in court? UNOS staff stated that this proposed expedited system was developed to however the match run is currently being executed based on whatever current allocation policy is put in place. It is intended to be able to fit into any allocation system. This information was referenced in the public comment document.

Data Advisory Committee: Modify Data Submission Policies

UNOS staff provided an overview of the Data Advisory Committee's (DAC) proposal. The DAC's proposal is addressing two data integrity concerns. First, there is a lack of a singular requirement for timely data submission which has led to member confusion about when data is due and has raised questions about the commitment of the OPTN to data quality. The proposal is also addressing the ability for members to continue changing data values well after the data has officially been submitted. This impacts data accuracy as well as the validity of the research findings that are based on this data.

The proposed solutions are to implement a single policy addressing the data submission requirements and deadlines. The DAC is proposing to do this by eliminating *OPTN Policy 18.4: Data Submission Standard*, which will leave *OPTN Policy 18.1: Data Submission Requirements* containing the deadlines and due dates for data collection. The second part of the proposal is to implement a multistep process that would require members who submit final data to unlock that information prior to making any changes.

In terms of the potential controversies there is a slight burden added with unlocking data. Members may cite that the requirements associated with unlocking the data are potentially onerous and may also report that the proposed time frame extensions are insufficient.

Thoracic Committee: Continuous Distribution of Lungs

UNOS staff provided an overview of the Thoracic Committee's Continuous Distribution of Lungs proposal. The ad hoc Geography Committee made a recommendation to the Board of Directors to select continuous distribution as the preferred framework for all of the organs.

UNOS staff worked with HRSA and the SRTR staff to begin discussing this framework with lung. The Thoracic Committee developed a concept paper, which discusses what continuous distribution will look like in the long term. This is not just about geography, but really about moving from a classification based system to a points based allocation system. This has implications for how organs are allocated and the potential to write allocation policies moving forward. A policy proposal is expected to be developed and submitted for public comment in 2020.

A member asked for clarification that the Thoracic Committee is submitting a concept paper that will have public comment taken on. UNOS staff confirmed that this was correct and that typically this is not done for every proposal. Concept papers are usually developed during times when there is a controversial or complicated proposal, or when something new is being done. This concept paper addresses all of these points and allows the opportunity to educate the community as well as gather feedback on this project.

A member asked if there was anything specific to discuss about children in the concept paper. UNOS staff confirmed that there is a section in the concept paper on how age is used. In moving away from a classification based to a points base system, this gives the opportunity to think about age in a different setting and making sure this is consistent with not only NOTA and the Final Rule but also the Principles of Allocation in pediatrics.

There were no further comments or questions.

Next steps:

- UNOS staff will use the feedback received to incorporate or clarify as needed in the public comment proposals
- The POC will have the ability to review the full proposals before they go out to public comment

3. Update on Setting Strategic Policy Proposals

The Committee Vice Chair provided members with an update on the POC's strategic goals.

Summary of discussion:

The Committee Vice Chair provided an overview of the POC's strategic priority of setting strategic policy proposals. The focus of the Committee is in identifying strategic policy priorities to recommend to the Executive Committee to approve as the first set of strategic policy priorities. The Vice Chair reviewed the strategic policy priorities that had been discussed by the Committee and asked members for their input. During the July meeting, members will be asked to identify their top three priorities that the Committee would like to have a more facilitated discussion about the pros and cons and to make a recommendation on two of those priorities.

A member asked how the Board would want the Committee to prioritize within the broader scope of UNOS. The Vice Chair stated that this would enable a portfolio of projects that are inter related to move

forward and facilitate an opportunity for bigger change over time rather than evaluating each proposal at a time. There is acknowledgement that even with setting some policy priorities, there will be many projects that will fall outside of these priorities that would need to continue moving forward.

Next steps:

- UNOS staff will send the current list of Strategic Policy Priorities to members to review and identify their top three priorities in preparation for the next Committee meeting.
- The POC will identify at least two policy priorities, develop a portfolio around the priorities selected, and send their recommendation to the Executive Committee for approval.

4. Wrap-Up

UNOS staff thanked members who were ending their term on the POC for their time and efforts.

Upcoming events were reviewed with members that included:

- July 1st – New Committee terms
- July 29th – POC meeting
- August 1st – Executive Committee Meeting
- August 2nd – October 2nd: Fall Public Comment Cycle

here were no additional comments or questions. The meeting was adjourned.

Upcoming Meeting

- July 29, 2019