

**OPTN/UNOS Executive Committee
Meeting Minutes
January 16, 2019
Teleconference**

Sue Dunn, Chair

Introduction

The Executive Committee met via teleconference on 01/16/2019 to discuss the following agenda items:

1. Mini-Brief: Amending Unacceptable Antigens Used for CPRA Calculations (Policy 4.10)
2. Mini-Brief: Clarification to NLRB (Policy 9.5)
3. Amendment to the 2019-2020 Board of Directors Slate of Nominees
4. Projects Recommended for Spring Public Comment
5. Project Recommended for Approval
6. Other Significant Items

The President welcomed attendees to the open session.

1. Mini-Brief: Amending Unacceptable Antigens Used for CPRA Calculations in Policy 4.10

Changes were made to the Histocompatibility program implemented December 2018. UNOS staff and Histocompatibility leadership became aware of the fact that the CPRA calculator was yielding higher-than-expected results. After evaluation, the issue was the policy language that was upstream, meaning if a candidate has certain selected alleles for DR51, 52, or 53, it would have an artificially inflated CPRA that would in turn potentially change the waiting time. Changes were made to correct this, including removing the first 3 lines for DR51, removing the first 4 lines for DR52, and removing the first 2 lines of DR53.

Histocompatibility leadership confirmed that this was technically accurate and agreed the changes needed to be made. The change will go into effect on January 17, 2019. The correction to the CPRA calculator will be made and outreach will be done in two tiers, first to the entire transplant community and then to programs that may have affected patients on their kidney/KP/KPD lists. A lot of this was due to the clinical relevance of changing the CPRA and potentially their waiting times.

A motion to approve the policy language clarification to OPTN policy 4.10 as proposed by the Histocompatibility Committee was made and seconded.

A vote was taken and the results were as follows: 100% yes; 0 no; 0 abstained.

2. Mini-Brief: Clarification to NLRB (Policy 9.5)

The National Liver Review Board (NLRB) Policy 9.5 was passed at the June 2017 Board meeting as part of liver allocation policy approved at the December 2018 Board meetings. Some of the updates made to policy language pertaining to NLRB need to be clarified at this time.

The first issue was that in several instances, phrases and sections that needed to be removed from policy were not presented to the Board in 2018, and so were not stricken through. Therefore, they were not technically removed from policy, causing coexisting policies. The changes include the language that was struck through and removed from the proposal.

A second change was to one use of "extension" instead of exception.

Finally, the proposal that was passed in December 2018 included an effective date at least 3 months after implementation of NLRB, which is January 31, 2019. Not included was a separate effective date allowing the dates to the NLRB to be implemented on January 31st, so the mini brief includes allowing NLRB-related changes to be implemented at the correct time.

A motion to approve the policy language clarification in OPTN policy 9.5 as proposed by Liver and Intestinal Committee was made and seconded.

A vote was taken and the results were as follows: 100% yes; 0 no; 0 abstained.

3. Amendment to the 2019-2020 Board of Directors Slate of Nominees

The Board approved the slate of nominees that would go before open election on February 4th, for the 2019-2020 cycle. The transplant coordinator representative is an uncontested ballot. The custom is to place the president-elect on the ballot for the transplant coordinator representative. NATCO nominated their current president from Region 2 on the ballot. Election opens in February.

A motion to approve the NATCO's nomination to the slate of candidates for the Transplant Coordinator Representative for the 2019-2020 Board of Directors election was made and seconded.

A vote was taken and the results were as follows: 100% yes; 0 no; 0 abstained.

4. Recommendations from the POC— Public comment proposals

They reviewed 8 projects on their last call. The Policy Oversight Committee (POC) evaluates whether the project proposals meet OPTN/UNOS standards for policy development and whether they are ready to go out for public comment.

The POC looks at the project's alignment with the OPTN/UNOS goals. Although there is overage in Goal #2 (Increase Equity in Access to Transplants), but what is more important is that there is distribution in alignment with what the goals are. The Transplant Recipient Safety goal was overrepresented in the past, but currently there are zero projects under that category, so going forward the hope is to see some proposals under that goal.

The POC voted and unanimously recommended all 8 proposals to proceed to public comment.

The POC Vice Chair raised a concern that about the Split Liver Proposal from the Liver Committee, as it is a proposal for an allocation variance based on region. It should be verified whether or not that is even implementable before sending it out for public comment, as much effort was taken explaining to the community that region is not permissible as distribution policy. In addition, in less than 6 months, liver distribution will no longer include region. This issue was not discussed by the POC in their evaluation. Staff clarified that the proposal was an open variance and is not tied to any one region.

The Executive Committee's options are to send the policy back to the Liver Committee with considerations for changes to the policy; send it out for public comment (with specific questions such as whether the boundary should be different, etc.); or reverse the proposal and send it out as an open variance and ask for specific comment on whether it should be geographically restricted in any way.

If specific references to geography were removed, with a request for the public's opinion on how to consider how to enter the variance, they would get that feedback and combine it with a more rigorous legal review before it goes to the Board of Directors. Implementation is the main concern, so asking for input on how it could be implemented is recommended.

Another member agreed that this is in line with increasing transplants and figuring out how to do it in a better way, so should go out for public comment.

One question was in regard to the Living Donor policy proposal and why it was not placed under the "Promote Living Donor and Transplant Recipient Safety" category. It indicates that this would require record keeping on living donors who might require extended dialysis after donation and it that monitoring living donors, in which case something would be done for living donor maintenance. It was clarified that the underlying data has to do with living donor safety, but the proposal itself is under the efficiency category because it is more of a clarification about how to collect that data.

A motion to approve the release of the below slate of projects for spring 2019 public comment was made and seconded.

1. Clarifications on Reporting Maintenance Dialysis – Living Donor Committee
2. Effective Practices in Broader Organ Sharing – Operations & Safety Committee
3. Eliminate the Use of DSAs and Regions in Thoracic Distribution – Thoracic Committee
4. Eliminate the Use of Regions in VCA Distribution – Vascular Composite Allograft Committee
5. Ethical Implications of Multi-Organ Transplants White Paper– Ethics Committee
6. Expedited Organ Placement – Organ Procurement Organization Committee
7. Modify HOPE Act Variance to Include Other Organs – Ad Hoc Disease Transmission Advisory Committee

A vote was taken and the results were as follows: 100% yes; 0 no; 0 abstained.

A motion to approve the Split Liver Variance with reference to "region" removed was made and seconded.

A vote was taken and the results were as follows: All but 1 yes; 0 no; 1 abstained.

5. Recommendations from the POC – New Project Approval

A proposal from the Ethics Committee is a review and revision of an existing white paper related to eligibility, particularly focusing on individuals who have intellectual disabilities. It falls under Goal #2 (Increase Equity in Access to Transplants). Ethics Committee papers are not resource intensive, other than Committee members' time, so even though it falls under Goal #2, it will not pull on any resources in any way that would be concerning. With the organ paper going out from the Ethics Committee, this would be a new and needed project.

A motion to approve the Eligibility of Intellectually Disabled Individuals for Transplant White Paper" from the Ethics Committee was made and seconded.

A vote was taken and the results were as follows: 100% yes; 0 no; 0 abstained.

6. Other Significant Items

The official release date for liver distribution will be April 30th.

The new UNOS Director of Policy and Community Relations was introduced to the Committee.

The meeting was adjourned.