**OPTN Board Policy Group**
**Meeting Summary**
**November 14, 2023**

**Maryjane Farr, Group Leader**

**Introduction**

The Board Policy Group met via Webex on 11/14/2023 to discuss the following agenda items:

1. Amend Adult Heart Status 2 Mechanical Device Requirements (Heart Transplantation Committee)
2. Deceased Donor Support Therapy Data Collection (Operations & Safety Committee)
3. Ethical Considerations of Normothermic Regional Perfusion (Ethics Committee)
4. Update Guidance on Optimizing VCA Recovery (Vascularized Composite Allograft Transplantation Committee)

Board Members met to discuss select items from the Summer 2023 Public Comment cycle to prepare for the December Board of Directors meeting. The following is a summary of the group's discussions.

Contractor staff presented the purpose of Board Policy Groups. Board Policy Group members were asked to vote on the agenda placement for proposals, on whether they should be included in the discussion or consent agenda. Board Policy Group members were also asked to vote on their recommendation to the Board to approve or decline the proposal at the December Board meeting.

**1. Amend Adult Heart Status 2 Mechanical Device Requirements**

J.D. Menteer, Vice Chair of the Heart Transplantation Committee, presented the proposal to Amend Adult Heart Status 2 Mechanical Device Requirements on behalf of the committee. Dr. Menteer noted that the proposal addresses the increase in intra-aortic balloon pump (IABP) use within status 2, properly aligns medical urgency of candidates within status 2, prevents future status 2 congestion by use of a different device, increases access for other status 2 candidates, improves waitlist outcomes, and improves patient, living donor, and transplant recipient outcomes.

Dr. Menteer explained that the proposal from the Heart Transplantation Committee would initiate and show failure of inotropic drug therapy prior to IABP, or percutaneous endovascular mechanical circulatory devices use. Dr. Menteer noted that to extend a candidate's assignment, transplant programs must demonstrate contraindication to durable device support and either: failure to wean off the device while still on inotropic therapy, or develop ventricular tachycardia (VT), or requirement of cardioversion, defibrillation, or antitachycardia pacing. He explained that candidates initially assigned to status 2 because of VT or other complications from attempting inotropic therapy qualify for extension without attempting inotropic therapy again. Dr. Menteer shared that to extend a candidates assignment, transplant programs would have to demonstrate a contra indication to a durable device and a failure to wean off the temporary device while on continued inotrope therapy to extend status 2. Dr. Menteer explained that the proposal leaves in place existing eligibility criteria addressing cardiogenic shock associated with emergency events. He explained that after public comment, the Heart Transplantation Committee added eligibility criteria for candidates experiencing arrhythmias as a result of inotropic therapy.

Dr. Menteer shared feedback received during public comment. He highlighted that more than half of the commenters were supportive of the proposal and no national stakeholder organization expressed opposition to the proposal. Dr. Menteer shared specific feedback that the committee took into consideration. This feedback included concern for patients developing arrhythmias while attempting inotrope therapy, concern that the proposal was overly prescriptive to management of care, and request for additional guidance for regional review boards.

Dr. Menteer shared that implementation for members would include reporting the use of inotropes and arrhythmias on initial and extension justification forms. Members would also have to demonstrate a failure of inotropes to stabilize cardiogenic shock prior to the use of an IABP or percutaneous mechanical circulatory support devices (MCSD) to list a candidate as status 2. Dr. Menteer explained that IT implementation for the proposal will take approximately 2900 hours. IT will need to update the Adult Heart Status 2 Justification Forms, account for the transition from current qualifying criteria, and update reference documents.

Summary of discussion:

Board Policy Group members asked specific clarifying questions on the content within the briefing paper from a cardiac perspective, and the impact the policy could have on specific patients, such as patients that may become hypertensive. A Board Policy Group member voiced their concern on the impact this policy could have on heart-kidney patients. The Board Policy Group member commented that the policy is addressing something important that is a result of a prior policy.

Board Policy Group members also asked many clarifying clinical questions that are detailed in the proposal.

Vote:

Do you recommend placement of this proposal on the consent or discussion agenda?

> With a total of 7 votes, the Board Policy Group unanimously voted to recommend the proposal to Amend Adult Heart Status 2 Mechanical Device Requirements for the discussion agenda.

Does the group recommend the Board approve or decline this policy proposal?

> With a total of 7 votes, the Board Policy Group unanimously voted to recommend approval of the proposal to Amend Adult Heart Status 2 Mechanical Device Requirements to the Board of Directors.

**2. Deceased Donor Support Therapy Data Collection**

Alden Doyle, Chair of the Operations and Safety Committee (OSC) presented the proposal for Deceased Donor Support Therapy Data Collection on behalf of the committee. The proposal aims to collect high level data on donor support therapies to promote efficient review of organ offers from donors on support therapies (e.g., CRRT, ECMO). Dr. Doyle explained that the policy would provide granular information to complement ongoing offer filter efforts, standardize reporting of these data, and allow for the evaluation of post-transplant outcomes. Dr. Doyle noted that the proposal aligns with the strategic plan goal to increase the number of transplants by promoting more efficient donor organ review. He noted that the proposal also aligns with the OPTN Data Collection Principle to fulfill the requirements of the OPTN Final Rule, and that standardizing the data can promote the efficient allocation of organs.

Dr. Doyle explained that the OSC is proposing to add six new data fields. He presented that the proposal would change the parent field in deceased donor data collection. Data would be collected in the OPTN Donor Data and Matching System, and would populate to the OPTN Data System. He explained that the

proposal would centralize extracorporeal membrane oxygenation (ECMO) data collection by deleting current data fields in Deceased Donor Registration (DDR) forms, and add ECMO data to the list of support therapy options.

Dr. Doyle shared that during public comment there was overall support for the proposal from the community. Dr. Doyle noted modifications that were made to data fields post-public comment. He noted that these modifications included a parent field question that would be included in instances when donors transfer to other hospitals and thus, not limiting data collection to the initial time of admission. Another modification the committee made was to provide more granular options to support therapy options by updating data definitions to reflect additional support therapy options. Dr. Doyle explained that clarifications that were made post-public comment were a delineation between normothermic regional perfusion (NRP) data collection efforts, and that clarification was added on collecting multiple beginning and end times for support therapies.

Dr. Doyle shared that there were also non-public comment related modifications. He explained that the committee decided to remove "on-going until cross clamp" as an option due to programming concerns with the option becoming a default and not providing accurate data. The committee also decided to modify the begin date and time and end date and time fields. The committee decided to further clarify the purpose of these data fields are to collect begin and end date and times before cross clamp date and time. This change will account for scenarios where a therapy might begin and end on the same day as cross clamp but before actual time of cross clamp. The committee reviewed these recommendations and voted in agreement on the changes.

Dr. Doyle shared that implementation efforts for OPOs will include raising awareness of the changes to the OPTN Donor Data and Matching System, Data System for the OPTN, and data definitions. Education may be needed for both OPOs and transplant hospitals on the changes.

Summary of discussion:

A group member asked if this information would be available in real-time as they are accepting offers. Dr. Doyle confirmed that this was correct. A group member asked about the IT implementation hours and the burden for members.

Vote:

Do you recommend placement of this proposal on the consent or discussion agenda?

> With a total of 7 votes, the Board Policy Group unanimously voted to recommend the proposal on Deceased Donor Support Therapy Data Collection for the consent agenda.

Does the group recommend the Board approve or decline this policy proposal?

> With a total of 6 approve, 1 undecided/abstain, 0 decline, the Board Policy Group voted to recommend approval of the proposal on Deceased Donor Support Therapy Data Collection to the Board of Directors.

**3. Ethical Considerations of Normothermic Regional Perfusion**

Andrew Flescher, Chair of the Ethics Committee, presented the white paper on the Ethical Considerations of Normothermic Regional Perfusion (NRP) on behalf of the committee. Dr. Flescher explained that the committee performed an ethical analysis on the practice of NRP according to the ethical principles of nonmaleficence (do no harm), respect for persons (including autonomy), and utility. Dr. Flescher noted that the white paper aligns with the strategic plan goal to increase the number of transplants.

Dr. Flescher shared that the Ethics Committee modified the white paper based on public comment feedback and post-public comment review. He noted that these modifications affirmed that the same principles and concerns apply to both thoracoabdominal (TA-) and abdominal (A-) NRP. He shared that based on feedback received, the community was more concerned about the principle of do no harm for TA-NRP. Dr. Flescher noted that after public comment, the committee also updated the utility section for currency and thoroughness, and the committee modified the respect for persons section to acknowledge OPO expertise regarding conversations with donor families, affirming the need for shared decision-making and engagement with donor families to clarify their preferences in learning more about NRP.

Dr. Flescher presented the modifications the committee made based on public comment feedback and post-public comment review. Dr. Flescher explained that much of the substance of the analysis was maintained and in alignment with public comment feedback. He shared that there was overall support in regional meetings and from stakeholders on the white paper, however, they received contrasting feedback in support or opposition to NRP as a practice. Dr. Flescher shared that two of the main themes during public comment were around disclosure, and around the differences between TA- and A- NRP. Dr. Flescher shared themes from public comment that were supportive of NRP and themes from public comment that were opposed to NRP as a practice.

Dr. Flescher shared that the implementation of the white paper is minimal. He shared if the white paper is approved by the Board, the white paper will be posted on the OPTN Website. There is no fiscal or IT impact on the OPTN.

Summary of discussion:

A Board Policy Group member asked if the white paper is a formal position from the OPTN on whether the practice of NRP is ethical or not. Dr. Flescher shared that the committee was diligent to ensure they were not prescriptive in the paper on whether to practice NRP or not. A Board Policy Group member commented that they believed the paper was as neutral and nonprescriptive as the Ethics Committee could have produced.

Vote:

Do you recommend placement of this proposal on the consent or discussion agenda?

> With a total of 7 votes, the Board Policy Group unanimously voted to recommend the white paper on the Ethical Analysis of Normothermic Regional Perfusion (NRP) for the discussion agenda.

Does the group recommend the Board approve or decline this policy proposal?

> With a total of 4 approve, 3 undecided/abstain, and 0 decline, the Board Policy Group voted to recommend approval of the white paper on the Ethical Analysis of Normothermic Regional Perfusion (NRP) to the Board of Directors.

**4. Update Guidance on Optimizing VCA Recovery**

Sandra Amaral, Chair of the Vascularized Composite Allograft (VCA) Committee, presented an update on the guidance document on Optimizing VCA Recovery. Dr. Amaral explained that the VCA committee aims to increase the recovery and transplantation of VCA grafts. The guidance document aims to inform the community of VCA graft recovery recommendations, provide guidance to OPOs and transplant programs pursuing VCA transplantation, and increase VCA visibility in the transplant community.

Dr. Amaral shared key themes the guidance document received during public comment. These themes included infrequency of VCA events affects member readiness to perform VCA recovery and transplant,

exclusion from CMS metrics and insurance coverage could deter OPOs from becoming involved with VCA, VCA authorization and recovery must not compromise solid organ donation and recovery, and sharing recipient experiences could educate the public and promote VCA donation and transplant. Dr. Amaral shared that the community was overall supportive of the guidance document during public comment.

Dr. Amaral shared that the guidance document provides VCA recovery recommendations based on the background of VCA, considerations for the identification and initial evaluation of the potential VCA donor, family considerations, recovery and post-recovery considerations, and media and public relations strategies. Dr. Amaral shared post-public comment changes made by the VCA committee. She explained that changes included clarification that VCA authorization and recovery must not compromise solid organ donation and recovery, recommendation for OPOs to designate a champion coordinator, and a recommendation to build awareness of VCA transplantation by sharing recipient experiences with the public after a defined waiting period.

Dr. Amaral shared that there will be no additional education or implementation associated with the guidance document. She shared that the document is to act as a resource to the community.

Summary of discussion:

Group members commended the committee's work.

Vote:

Do you recommend placement of this proposal on the consent or discussion agenda?

> With a total of 8 votes, the Board Policy Group unanimously voted to recommend the Updated Guidance on Optimizing VCA Recovery for the consent agenda.

Does the group recommend the Board approve or decline this policy proposal?

> With a total of 7 votes, the Board Policy Group unanimously voted to recommend approval of the Updated Guidance on Optimizing VCA Recovery to the Board of Directors.

The meeting adjourned.

**Attendance**

- **Group Members**
  - Andrew Kao
  - Daniel Yip
  - Emily Blumberg
  - Jerry McCauley
  - Kenneth McCurry
  - Laurel Avery
  - Linda Cendales
  - Maryjane Farr
  - Reginald Gohh
- **HRSA Representatives**
  - Christopher McLaughlin
- **UNOS Staff**
  - Anna Messmer
  - Cole Fox
  - Eric Messick
  - Jacqui O'Keefe
  - Joann White
  - Kelley Poff
  - Kieran McMahon
  - Leah Nunez
  - Morgan Jupe
  - Rebecca Murdock
  - Ross Walton
  - Susan Tlusty
  - Susie Sprinson
- **Other Attendees**
  - Alden Doyle
  - Andrew Flescher
  - JonDavid Menteer
  - Sandra Amaral