

**OPTN Board of Directors
Post-Public Comment Briefing
October 8, 2020
Conference Call**

**David Mulligan, M.D., FACS, President
Matthew Cooper, M.D., Vice President**

Introduction

The Board of Directors met via teleconference on 10/08/2020 to discuss the following agenda items:

1. Welcome, Roll Call, and Announcements
2. Incorporating COVID-19 Related Organ Failure in Candidate Listings Proposal
3. Regional Meeting Discussion Agenda Proposals
4. Regional Meeting Non-Discussion Agenda Proposals
5. Adjourn

The following is a summary of the Board's discussions.

1. Welcome, Roll Call, and Announcements

David Mulligan, Board President, welcomed all attendees to the meeting. A quorum was present. The agenda for the meeting was reviewed.

2. Incorporating COVID-19 Related Organ Failure in Candidate Listings Proposal

Erika Lease, Chair of the Lung Transplantation Committee, presented the Committee's proposal to add diagnoses for patients who are being transplanted for COVID-19-related organ failure.

This proposal would allow monitoring of waitlist survival and post-transplant survival related to COVID-19, as well as the post-transplant outcomes of these patients. The proposal is to add two new diagnoses of "COVID-19 Acute Respiratory Distress Syndrome" and "COVID-19 Pulmonary Fibrosis: Other" to Group D in UNet.

Public comment showed general support for the proposal. The Heart Transplantation Committee and other members of the heart transplant community supported incorporating COVID-19 related organ failure in heart listing. There were a fair number of comments outside the scope of the proposal, including regarding data collection on pre-transplant patients who develop COVID-19 and then recover, a question about what to do regarding a patient who gets COVID-19 and then has a severe exacerbation of underlying disease, and a fair number of comments on post-transplant patients who develop COVID-19. These questions were outside the scope of this proposal. AST and ASTS supported the proposal.

There was feedback from the heart transplant community to add new diagnosis codes in UNet for listing heart candidates: "COVID-19 dilated myopathy: active myocarditis" and "COVID-19 dilated myopathy: history of myocarditis". The UNet heart diagnosis code of "dilated myopathy: viral" will change to "dilated myopathy: viral (not COVID-19)". Because lung diagnoses are still written out in policy, this will be a policy change for lung, but diagnoses are not written in policy for heart, so it would just be a programming change.

The impact to transplant programs is that they will be able to use the new diagnoses codes as soon as they are available. They will also be able to update the diagnosis for currently-listed patients if needed. Less than 200 hours of effort for implementation is expected with a target implementation date of October 28, 2020.

Summary of discussion:

One question was asked regarding standard criteria for listing COVID-19 patients. It was clarified that the criteria for listing is something that programs themselves can determine. Groups such as ISHLT are working on guidelines for when it would be appropriate for COVID-19 patients to be listed, but formulating guidelines for diagnoses is outside the role of OPTN.

The Board President confirmed that there are currently eight patients with a lung transplant under this diagnosis so far, but currently no known heart transplants. There is some chronic injury from the virus that goes well beyond the acute phase of the disease that has been seen in lung, and heart, kidney, and liver may be susceptible as well.

One member commented on the opportunity to amend the transplant diagnoses so that they can be included in the analytics to come in the future. Dr. Lease agreed that the idea is a good one but has not been specifically examined, so it will be something for the Lung Committee to work on in the future.

There was an inquiry regarding whether the heart diagnoses could be added to this proposal or whether the Heart Transplantation Committee needs to do their own heart-specific proposal. The Chair of the Heart Transplantation Committee stated that no one has been transplanted yet for COVID-19 cardiomyopathy. The public comment for this proposal included a request for the concept of adding history of COVID-19 in the data collection for heart transplant. The Heart Committee will therefore determine if COVID-19 is involved for the future, but there is no data currently for acute indications.

Another member brought up the diagnosis of Multisystem Inflammatory Syndrome in Children (MIS-C) associated with COVID-19, and whether that would be worth tracking. In some cases these patients will have a coronary aneurysm, so it is anticipated that there might be a need for this small population.

A motion was made and seconded for the Board of Directors to change Policy 10.1.F.i: Lung Disease Diagnosis Groups, as proposed by the Lung Transplantation Committee.

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

3. Regional Meeting Discussion Agenda Proposals

Dr. Mulligan explained that the goal of this briefing is to inform the Board of the Summer 2020 public comment proposals, as well as to have the committee Chairs share next steps. Craig Connors, UNOS Director of Policy and Community Relations, explained that overall, there was widespread support for the proposals, due in part to the work and preparation that went into developing the proposals. Many Board members also attended the regional meetings and provided feedback. Feedback came through as sentiment expressed at regional meetings and as public comment, sentiments expressed by stakeholders at cross-committee meetings, and from submissions through the OPTN website. The NLRB proposal received the most comments.

Dr. Lease presented on the Update on the Continuous Distribution of Organs Project, which shares with the community some of the progress made with continuous distribution of lung. The project included summarizing attributes considered by the Lung Committee, outlining how those attributes align with NOTA and the Final Rule, explaining how the work will influence the conversation of transitioning other organs to continuous distribution, and providing an overview of the policy development approach overall. Feedback was also requested on the prioritization exercise that was provided to the community.

Regarding the continuous distribution framework, there was overall support for removing the hard boundaries associated with geography, blood type, etc; for adjusting attributes over time as technology advances; and for using post-transplant survival of longer than one year. Regarding the policy development, there was overall support for consistency of this approach across the organs and for continued education and community outreach regarding the project.

Feedback on how to create an attribute for placement efficiency was also requested. There was understanding of the complexity of travel, support for giving relatively less weight for placement efficiency, and understanding of the need to account for those factors in a way that does not slow the process and result in organ discard. There were concerns about the possibility of continuous distribution impacting multi-organ allocation and lung candidates under age 12.

The Committee will use community feedback to inform decisions on prioritizing the attributes, compare community and Committee preferences to implied weightings in current policy; and will ultimately build a continuous distribution framework to send to SRTR for modeling. The aim is to have a policy proposal out for public comment in August 2021.

There was a question regarding incorporating issues such as socioeconomic status, etc, as kidney allocation in the past was found to negatively impact disadvantaged social and racial groups in general. The Lung Committee is working with the Minority Affairs Committee to review those issues.

Dr. James Trotter presented the "Further enhancements to the National Liver Review Board (NLRB)" proposal. This proposal incorporates additional improvements to NLRB based on data and feedback. It will update NLRB policy language regarding criteria for portopulmonary hypertension (POPH) exceptions and extensions to have a more effective process for reviewing post-transplant explant pathology forms for hepatocellular carcinoma patients. It also includes guidelines for creating a separate Appeals Review Team (ART) and ART leader for pediatric cases and clarifications on MELD score for polycystic liver disease (PLD) and providing guidance for candidates requiring a kidney.

Generally, there was support for all aspects of the proposal, with some negative comments. There were comments were around PLD guidance and better-defined criteria for moderate to severe protein calorie malnutrition. AST, ASTS, AOPO, NATCO, and SPLIT support the proposal.

There was a patient-driven campaign through Change.org with about 10,000 signatures that led to comments regarding guidance on candidates with primary sclerosing cholangitis (PSC). There is sentiment among some patients and clinicians that the liver MELD score does not take PSC severity of illness into account as accurately as other diagnoses. However, there are no data showing higher mortality rate in PSC patients on the waiting list. One Board member recommended that the Board review some of the comments on the Change.org petition. The Liver Committee Chair has discussed the issue with a patient organization called PSC Partners. One comment was for the Board to be cognizant of the fact that while PSC Partners is a well-organized and well-funded group, there are other groups that should also be heard. The Liver Committee will take the public comment seriously and be data-driven in any further considerations.

The Liver Committee will consider ASTS comments on specific POPH criteria and request more specific language regarding evidence of HCC treatment prior to transplant. In response to public comments, the committee will add language stating that cases in violation can be referred to the MPSC, and the committee will consider further clarification on what constitutes evidence of HCC treatment; consider adding responsibilities of ART leader and add a pediatric ART leader; and discuss objective language regarding "moderate to severe protein calorie malnutrition" in PLD patients. They will meet to finalize the proposal on October 22.

Marian Michaels presented the Align OPTN Policy with U.S. Public Health Service Guidelines, 2020 proposal on behalf of the Ad Hoc Disease Transmission Advisory Committee (DTAC). This proposal aligns the OPTN policies with the revised U.S. 2020 Public Health Service (PHS) guidelines for assessing solid organ donors and monitoring transplant recipients for HIV, hepatitis B and hepatitis C, as required by the Final Rule. Changes to policy include risk assessment of living and deceased donors, living and deceased solid organ testing, transplant candidate informed consent, recipient testing in collection and storage of donor and recipient specimens.

The robust commentary showed general support, with opposition for a few parts of the proposal. There was an overwhelming desire to revise the 2013 PHS guidelines, as over 27% are at PHS increased risk. There was support for removal of "increased risk designation" terminology, for reduction of risk criteria timeframe, and removal of hemodilution as risk criteria for PHS. There was concern for the requirement to store living donor specimens for 10 years, for pre-transplant donor testing within 96 hours of procurement, conducting universal testing for HIV, as well as documentation of HBV assessment. There was both concern and support for removal of informed consent for PHS by itself.

HRSA feedback just received prior to this meeting included that specimen storage remain at 10 years and deceased donor collection timing will be within 96 hours. Absent or different timeframes would not align with the PHS guidelines. Although the OPTN is not authorized to require HBV vaccine, it is authorized to require documentation for the need of HBV surface antibody. HRSA agreed with the OPTN proposal to require HIV, HBV, and HCV testing to four to eight weeks and HBV NAT for liver at 11 to 13 months, which still aligns with PHS guidelines. The committee has not had a chance to review feedback from HRSA, but plans to do so soon.

One Board member asked about aligning OPTN and PHS policy, and Dr. Michaels clarified that the Final Rule requires OPTN policy alignment with PHS recommendations. Another member encouraged DTAC to speak with HRSA regarding the 10-year and 96 hours requirements. Dr. Michaels explained that the first PHS version did not define rigid recipient testing, and there are few scenarios where 10-year storage will help a case of HIV, HBV or HCV one or two years after donation. Regarding the 96 hours, the first PHS version contained differences from that stated by PHS and what was eventually put into policy. Another Board member encouraged the Committee to consider if the requirements are worth the risk of losing donors from delays due to obtaining tests within a specified timeline.

One Board member noted that there was misunderstanding amongst coordinators and administrators regarding the Hepatitis B requirement for testing versus proof of vaccination or the need for vaccination, as the information can be difficult to impossible to obtain. Dr. Michaels replied that DTAC will clarify the issue with the coordinators and administrators and take their feedback into consideration. The DTAC will meet next on 10/13/20 and 10/26/20.

Heather Hunt presented Modify Living Donor Policy to Include Vascularized Composite Allograft (VCA) Donors proposal on behalf of Living Donor Committee.

The proposal establishes safeguards for living VCA donors and creates living donor compliance standards for VCA programs. The proposal expands living donation to include VCA by adding informed consent and medical evaluation requirements specific to VCA donors. There was general support for the proposal and no corresponding commentary to understand the general opposition. There was robust discussion with the Patient Affairs Committee that supported the proposal.

There was overall support for adding VCA to living donor policy for patient safety and member compliance, general support from a number of professional organizations and other OPTN committees. Regarding informed consent requirements, the Patient Affairs Committee and AST recommended adding language around, for example, the potential loss of sense of identity and the requirement to

provide information regarding outcomes, as VCA is still largely experimental. Regarding Medical Evaluation Requirements, DTAC suggested adding timing requirements for specific tests, mainly for transmissible diseases. VCA suggested including limiting informed consent to uterus donors due to ethical considerations for other genitourinary organs. The National Catholic Bioethics Center sent a letter in opposition to VCA generally.

The Living Donor Committee will meet again before finalizing the proposal on 10/26/20. They will discuss adding language to the consent requirements, the timing requirements for some tests under the Medical Evaluation Requirements, and whether to keep informed consent requirements as proposed or to restrict to uterus at this time. There were no questions from Board members regarding this proposal.

Bohdan Pomahac, Chair of the VCA Committee presented the Modify Data Collection on VCA Living Donors proposal, which aims to improve the ability to monitor living donor patient safety and collect data on VCA living donors. The proposal aligns with all other living donor data collection that exists for other organs. In addition, there are certain VCA-specific elements that will be included in Living Donor Registration (LDR) and Living Donor Followup (LDF) forms. There was general support for the proposal with a few strongly opposed, potentially due to lack of awareness. In addition, there have been ethical sentiments regarding uterus donation.

Comments of support were related to aligning data collection similarly to other living donors, monitoring donor characteristics that may impact recipient outcomes, and for post-donation monitoring to improve safety including new-onset psychological symptoms for all VCA living donors. AST recommended adding additional data related to infectious disease testing and tracking of intraoperative anesthetic complications for VCA living donors. ASTS suggested uterus should fall under solid organ and not VCA. AOPO, DTAC, Living Donor and TCC Committees supported the proposal. The Ethics Committee was concerned about including history of induced abortion, as could be considered private information.

The VCA Committee will weigh the benefits of adding new items against the burden of data collection that is imposed on all the programs, and specifically discuss infectious disease testing, whether to add anesthetic complications for living donors, new-onset psychological symptoms, and issues related to gender dysphoria, as well as concern for tracking induced abortion history, sexually transmitted infections, and syphilis screening. There were no additional questions from Board members regarding this proposal.

Shelley Hall, Chair of the Heart Transplantation Committee, presented Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy.

The objectives of this proposal are to reduce and modify the policy for invasive procedures for measuring cardiac index for Status 4 candidacy, to align the Status 1 so they are all the same in data renewal, and a guidance document addresses a growing trend of rapid escalation of Status 2 candidate exception requests. The proposal will measure cardiac index at the start of inotrope administration for Status 4 patients and extend qualifying and extension timeframes at this status from up to 90 days to up to 180 days. Additionally, it will reduce initial qualifying and extension timeframes for certain status 1 candidates from up to 14 days to up to 7 days. The guidance document will clarify the type of information and level of detail to include in status 2 exception requests.

Overall there was very favorable response during public comment with very few negative comments for the proposal. There was support for standardization of expected information in the guidance document. There was also support for changing the timing of cardiac index measurement. Dr. Hall explained that the vast majority of centers have been using exception requests to get around that, so this change is really a correction of an oversight. AST, ASTS, NATCO showed support. The Heart Committee will review the feedback and finalize the proposal on 10/29/20.

One Board member commented that the Committee will need to evaluate the impact on patients who are using devices. There was concern from one Board member over the current heart transplant practices, as they could lead into equity concerns with some patients getting transplant and others getting VADs. There was agreement, and this guidance document is the first attempt to level the language, but stricter policies will likely be necessary to change practice in the future.

Dr. Hall then presented Guidance Addressing the Use of Pediatric Heart Exceptions.

The Pediatric Work Group created a document to provide consistent guidance for review of the following diagnoses: dilated cardiomyopathy, hypertrophic or restrictive cardiomyopathy, single-ventricle heart disease, and coronary allograft vasculopathy and re-transplantation. Similar to the adult Status 2 document, it provides standard language for what information to include in the exception request.

There was overall support for the proposal. There were comments about the appropriateness of inotrope dosing, the specificity of VAD contraindications, and Fontan patients. There was support that the guidance document was the correct step to increasing consistency in fairness. The Committee will meet on 10/29/21 to finalize the proposal. There were no additional questions from Board members regarding this proposal.

Craig Connors, UNOS Director of Policy and Community Relations, presented the COVID-19 Emergency Policies and Data Collection. These emergency policies went out for public comment retrospectively according to the Bylaws Section 11.7.

Overall, there was support over the OPTN and Executive Committee actions in response to the pandemic. There was support for use of the emergency action bylaw in this situation. Of note, there was mixed feedback on whether the data collection on COVID testing prior to donation should be a permanent and mandatory field, and on whether retrospective data entry should be required or not. There are 55,000 forms in amnesty status at this time, about 35% of all forms that met the policy timeline. Except for the first action which has an expiration of March 2021, expirations for the actions were extended to 12/31/20. Some comments suggested further extension.

The Executive Committee will meet 10/20/20 and review the monitoring report to evaluate usage of the policies, their effectiveness, and their need for continuation. The main areas to consider from public comment are around the COVID-19 testing field in DonorNet and the retrospective data entry for follow-up forms in amnesty status.

4. Regional Meeting Non-Discussion Agenda Proposals

Mr. Connors presented two non-discussion proposals that were out for public comment.

Update Cohort for Calculation of the Lung Allocation Score (LAS): This proposal from the Lung Committee is designed to improve accuracy of LAS in ranking candidates. The limited comments received revealed overall support for the proposal. There are no anticipated changes post public comment.

Modify Data Collection on Living VCA Donors: The proposal from the VCA Committee will amend policies as VCA is programmed into UNet. There was overall strong support for the proposal. There were no suggestions to amend the policy changes. The VCA Committee will finalize the proposal on 10/26/20.

Next steps:

Contact information for Committee Chairs and their staff contacts was provided to the Board for any further comments or questions on any of the proposals presented today.

5. Adjourn

The December in-person Board meeting will be held virtually with a tentative in-person meeting planned for Spring 2021. The meeting was adjourned.

Upcoming Meetings

- December 6-7, 2020, virtual meeting

Attendance

- **Committee Members**
 - David Mulligan
 - Alan Langnas
 - Alexandra Glazier
 - Amishi Desai
 - Atsi Yoshida
 - Cameron Wolfe
 - Celeste Williams
 - Denise Alveranga
 - Earnest Davis
 - James Sharrock
 - Jeffrey Orłowski
 - Joseph Ferreira
 - Joseph Hillenburg
 - Keith Wille
 - Kelly Ranum
 - Laura DePiero
 - Leona Kim Schluger
 - Leway Chen
 - Lisa Stocks
 - Luis Fernandez
 - Marian Michaels
 - Maryl Johnson
 - Matthew Cooper
 - Medhat Askar
 - Michael Moritz
 - Mindy Dison
 - Pamela Gillette
 - Patrick Healey
 - Pono Shim
 - R. Patrick Wood
 - Randee Bloom
 - Robert Goodman
 - Seth Karp
 - Stacey Lerret
 - Suzanne Conrad
 - Valinda Jones
 - William Bry
 - William Hildebrand
- **HRSA Representatives**
 - Christopher McLaughlin
 - Shannon Dunne
- **UNOS Staff**
 - Chelsea Haynes
 - Craig Connors
 - Emily Ward

- **Other Attendees**
 - Erika Lease
 - Shelley Hall
 - James Trotter
 - Bohdan Pomahac
 - Heather Hunt