OPTN Board of Directors
Meeting Summary
January 20, 2021
Conference Call

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

Introduction

The Board of Directors met via teleconference on 01/20/21 to discuss the following agenda items:

1. Welcome, Roll Call, and Announcements
2. Regional Meeting Agenda Overview and Board Member Engagement
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

The Board President welcomed all attendees to the meeting. A quorum was present.

2. Regional Meeting Agenda Overview and Board Member Engagement

The UNOS Director of Policy and Community Relations presented an overview of the proposals that will be released for January 2021 Public Comment.

Comments may be submitted through the OPTN website beginning 1/21/21. The schedule of upcoming regional meetings was reviewed. The agenda will follow a similar structure to the most recent Public Comment cycle, using the virtual format with a few minor changes. Board members are encouraged to attend their respective regional meetings, collaborate with fellow Board members, Committee chairs and staff, and submit public comment to the OPTN website.

3. Regional Meeting Discussion Agenda Proposals

OPTN Committee Chairs presented their committee's proposals that will be going out for Winter 2021 public comment. There are also two non-sentiment items presented by the corresponding Committee Chairs.

a) 2021-2024 OPTN Strategic Plan - Executive Committee

The Chair of the Executive Committee (EC), Dr. David Mulligan, presented the 2021-2024 OPTN Strategic Plan proposal. The new proposed plan is narrowed down to four major goals, with the previous efficiency goal #3 being merged into goal #1, Increase the Number of Transplants, which is now 50% of resource efforts. The 2021-2024 plan includes a new initiative specific to increasing the number of DCD donor organs recovered and transplanted, as well as a new initiative to examine differences in access to transplant. As part of developing the proposal, the EC hosted virtual prioritization exercises with the Board and Committee leadership, and Board members are encouraged to continue to share their feedback throughout public comment and

regional meetings. Board members were specifically asked to provide feedback on any goals or initiatives that might be missing from the plan.

b) Develop Measures for Primary Graft Dysfunction in Hearts - Heart Transplantation Committee

The first non-sentiment item (request for feedback) comes from the Heart Committee, and was presented by Dr. Shelley Hall. The Committee developed this request for feedback due to a growing concern in the new allocation system with the increased emphasis on temporary mechanical support, there may be more primary graft dysfunction (PGD). In order to fully understand the extent of the issue, the Heart Committee wanted to engage the community at the beginning of the effort prior to developing a policy proposal.

Dr. Hall explained that PGD is when the heart does not survive the preservation process in transplant. The ISHLT came up with a definition in 2013, but it was more of a scientific, rather than a practical definition. In addition, the OPTN has not collected any post-transplant data specific to PGD, so it is difficult to conduct more detailed analyses as what factors contribute to PGD. Therefore, the goal of the request for feedback is to gain input about what potential data elements should be collected to answer questions about PGD.

Key data elements could include which side (left, right or both ventricles), if there is mechanical support being utilized, and what the drips are, but more detailed elements could include whether a DCD donor is involved, procurement team type, preservation solution, etc., as well as timeframes of the data collection. In addition to identifying appropriate data elements, key questions for public comment are: what challenges programs might have in collecting the data and what information might be helpful in developing future policy response.

c) Calculate Median MELD at Transplant Around the Donor Hospital and Update Sorting within Liver Allocation - Liver and Intestinal Transplantation Committee

Two proposals were presented by Dr. James Trotter. Dr. Trotter explained that Region 2 and Region 5 sent letters to the OPTN describing how the continuous distribution policy may disadvantage particular patients in their regions. The first part of the proposal addresses this by increasing equity by assigning MELD exception scores relative to the median MELD at transplant (MMaT) of the donor hospital instead of the transplant program. This would align geographic areas around the donor hospital and used in the calculation of MMaT with the geographic units used in liver allocation. The second part of the proposal is to update sorting within liver allocation to align with the proposed changes and increase equity between exception and non-exception candidates.

The current policy states that exception candidates are assigned an exception score relative to the MMaT of the transplant program they are listed. Transplant programs in close geographic proximity can have different MMaT scores, so candidates with the same exception diagnosis can have different exception scores.

The proposal will change how the MMaT is calculated to be based on number of transplants performed within 150 NM of the donor hospital in the past year. That cohort must include two programs and at least 10 transplants, but if that threshold is not met, the circle will expand by 50 NM increments until met. Exception candidates on the match run are assigned exception scores relative to the MMaT at the donor hospital where the match is run.

The proposal is to have exception candidates ranked by time since the submission of the first approved exception. Lab candidates will be ranked by time at score or higher and ahead of

exception candidates who have the same MELD/PELD score and the same blood type compatibility.

The proposed calculation is intended to change equity in access to specific donor offers based on the initial experience with acuity circles policy. The sorting update is to sort based on historical data that has shown better waitlist outcomes for exception and lab candidates.

Transplant programs should consider the following: exception candidates will not have a static exception score, exception requests will be for a specific score, exception requests will be for a number of points higher or lower than MMaT of MPaT, and request for MELD or PELD over 40 can be specifically requested. Implementation is estimated to require 6,100 hours of programming, communication, and education. This proposal was supported unanimously by the Liver Committee. The Liver Committee Chair offered to have additional in-depth discussions with the Board members as needed.

One Member asked why exception candidates are ranked lower than those with labs. It was clarified that waitlist mortality for patients with exception scores have been historically about 80% lower, so when exception patients and lab patients have the same MELD, the lab patients will be prioritized higher. With the move to continuous distribution, there will be creation of a new way to allocate livers that goes beyond mortality at 90 days and takes other factors into account. Another Board member asked that with the increase exceptions of hepatocellular carcinoma patients, if there are any data to suggest that they are still prioritized over the lab MELD patients. Dr. Trotter confirmed there are no current data on the changes with acuity circles. This is why the decision was made on historical data.

One Board member noted that the acuity circle model took 10 years to implement. With the continuous distribution only in place for nine months and with COVID happening in a similar timeframe, it seems premature to say that the current acuity circles system is not equitable. Dr. Trotter noted that it is anticipated that this topic will come up in public comment. The Liver Committee will take the public comment supporting all sides into consideration. One Board member asked how this will impact pediatric patients, and Dr. Trotter explained that this proposal does not impact pediatric patients.

One Board member noted that the resource estimate for implementation was too high. UNOS staff clarified that the estimates are accurate, as changing the basis for MMaT and how candidates are sorted on each match run is a significant programming effort.

d) Update National Liver Review Board (NLRB) Guidance Documents and Policy Clarification - Liver and Intestinal Transplantation Committee

The NLRB, implemented in May of 2019, is a way to more equitably adjudicate patients for lab MELD exception scores. The proposal makes minor improvements based on feedback and experience, including clarifying standard criteria in policy for cholangiocarcinoma (CCA) exceptions, updating pediatric NLRB guidance, removing guidance for candidates under age 60 with neuroendocrine tumors (NET), and updating primary and secondary sclerosing cholangitis candidates to recommend they be admitted to the hospital two or more times in a previous year.

The proposal aligns policy with established diagnostic criteria for CCA; published literature were reviewed for pediatric guidance with feedback from the pediatric transplant community and Pediatric Transplantation Committee; NET guidance is based on data showing favorable post-

transplant outcomes for recipients over 60; sclerosing cholangitis guidance is based on data that patients with higher MELD scores have a higher waitlist dropout rate.

Implementation considerations include program familiarity with change in guidance when submitting exception requests. The OPTN resource estimate is 150 hours for programming changes, and 180 hours for implementation and ongoing support. There were no questions from the Board regarding this proposal.

e) Revise General Considerations in Assessment for Transplant Candidacy - Ethics Committee

The proposal is the revision of an existing document that reviews general considerations in the assessment of transplant candidates. The purpose is to address an ethical analysis of the concerns related to the use of psychosocial and non-medical criteria in listing evaluations.

The white paper encourages transplant programs using psychosocial/non-medical criteria to be clear with candidates about use of these criteria, while adhering to ethical principles. It addresses life expectancy, potentially injurious behaviors, history of nonadherence, repeat transplantation, incarceration status, immigration status, and social support.

One Board member noted that the document does not specifically mention marijuana, and was also curious about incarceration status. The Ethics Chair clarified that while marijuana specifically is not addressed in this paper, it does address the use of potentially injurious behaviors, including the use of a range of drugs. This white paper references an existing ethics white paper on the topic of incarceration status, which concludes that people should not to be prohibited from access to transplantation on the grounds of their incarceration status.

f) Update Transplant Program Key Personnel Training and Experience Requirements – Membership and Professional Standards Committee (MPSC)

This is a not a proposal, but rather a request for feedback on a topic that generates a lot of discussion with MPSC. The MPSC is conducting a holistic review of OPTN membership requirements. The feedback received will be used when examining the framework for developing training and experience requirements for primary surgeons and physicians. The MPSC will work with program-specific committees when considering changes to the framework that would then be applied to organ-specific requirements in future proposals.

Feedback will be requested on the improvements under consideration, which include simplifying the requirements through consolidation of the multiple pathways into one comprehensive pathway that would accept fellowship and clinical experience of potential primary physicians and surgeons; focusing on the creation of certain exemptions for surgeons or physicians serving as primaries in the last 10 years; replacing some requirements for overly-specific experience with broader language; and replacing current requirements for letters of reference and letters of recommendation with a single OPTN-provided certification form that can be completed online.

The MPSC is considering expanding conditional approval pathways to surgeons when programs experience unexpected vacancies. In the past 12 months, the frequency of this has been high. Additional improvements may include requiring OPTN orientation for new primaries. The responsibilities of primaries is to ensure program compliance with OPTN obligations, so the OPTN is requesting feedback on ideas for the curriculum that would be helpful to surgeons who have not been primaries.

Other key questions for public comment include whether there are any unintended consequences to the changes, what should be considered equivalent training to a board-certified practitioner, whether primaries should have some experience in the U.S., as well as feedback on other suggested options and on a future project around expectations for the surgeon/physician availability and responsibilities.

One Board member, who was previously on the MPSC Committee, expressed his support for the project, stating these changes are long overdue and that he is very comfortable with the direction in which the work is headed. There was agreement that this proposal gets to the original intent of the OPTN Bylaws. There were no further questions or comments.

g) Clarify Multi-organ Allocation - Organ Procurement Organization (OPO) Committee

The purpose of this proposal is to take the initial step in addressing multi-organ allocation by attempting to clarify the language in Policy 5.10.C. Eleven OPTN committees participated in creation of the proposal. The proposal itself establishes requirements for when OPOs must offer a second organ to the same candidate when allocating to a heart or lung match run candidate, but the candidate must be heart adult Status 1, 2 or 3, or pediatric Status 1A or 1B; or lung allocation score greater than 35. It will also increase the distance from the current 250 NM range for heart and lung/150 NM for liver to 500 NM for all these candidates.

The rationale is to create parameters for OPOs when allocating certain multi-organ combinations and to ensure that the multi-organ allocation geographically aligns with heart and lung policy. The goal is to increase OPO consistency and practice.

Key questions for public comment include whether the proposed status thresholds are appropriate for when the OPO is required to share a liver or kidney from the same donor, and whether the 500 NM range is an appropriate distance for multi-organ offers to be classified as requiring the second organ.

One Board member noted concern about the relationship between adult multi-organ transplant (MOT) candidates and children who are not MOT. The OPO Chair did confirm that a very small number of candidates will be impacted by these policy clarifications, but input from the Pediatric Committee has been taken into consideration.

Next steps:

The Board will have a Post-Public Comment briefing on 3/29/21 to review the results of public comment.

4. Regional Meeting Non-Discussion Agenda Proposals

Two non-discussion items going out for Winter 2021 public comment were presented by the corresponding Committee Chairs.

Summary of discussion:

a) Modify the Deceased Donor Registration (DDR) Form - OPO Committee

The purpose of the proposal is to ensure more consistent and accurate data collection, and to provide OPO staff with improved direction and clarity when entering deceased donor data into the DDR form. The Committee conducted an extensive review of the entire DDR, which has not been done since 2011. As a result, the policy will modify several data elements, update data definitions, and relocate and remove some data elements. Feedback will be requested on data elements that the OPO Committee could not reach a consensus on, such as data regarding

recovery date versus collection of cross-plant date, citizenship, medication specifics, drug use history, and transfusion volume specifics. The changes come as a result of increased questions to the OPO Committee for review and clarification, as well as the charge from the Data Advisory Committee to review all data collection forms.

Key questions for public comment include whether or not the proposed changes improve the actual data collection process and whether the changes will provide OPO staff with improved and clear direction when entering the deceased donor data. There were no questions from the Board regarding this proposal.

b) Require Notification of Human Leukocyte Antigen (HLA) Typing Changes - Histocompatibility Committee Adjourn

The proposal will ensure better patient safety through early notification in any circumstances where critical HLA typing changes could potentially lead to incorrectly-placed organs resulting in acute rejection or death. It also addresses incorrect candidate, recipient, and donor HLA typings that lead to these events.

The proposal would require immediate reporting of critical HLA typing changes. Should any of the histocompatibility labs identify an error, the lab must notify the OPO of any donor changes within one hour of identification and confirmation that the typing was entered into DonorNet incorrectly. For any circumstances where the lab identifies a recipient typing error, the lab has five days to notify the transplant program. When an OPO has been notified by the lab, the OPO must notify the transplant programs that have accepted or are evaluating organs within 12 hours of their notification.

The proposal defines what would be described as a critical HLA discrepancy where a change in typing could lead to adverse events. There were 27 patient safety reports related to HLA typing in the past two years in which many cited delayed notifications of incorrect typings.

Key questions for public comment include whether an automated electronic notification should be included when in implementation; whether it is feasible to create policies for cases where the incorrect typing is identified between procurement and before transplant; if there are points requiring re-execution of a match run; and whether the timeframe is reasonable.

One Board member asked whether the proposed notification process is addressing communication between HLA labs and the accepting centers, or DonorNet, or individuals. The Board member noted that allocation might be a distant center the lab does not normally communicate with. The proposal is connected to how the errors tend to be identified, which is usually through the laboratory at an accepting center that recognizes something has gone wrong. Generally, the OPO responsible for the donor allocation is notified and is then responsible for disseminating that information. Whether the error would impact things like allocation order has been discussed with the leadership of other organ committees. There is a balance to deciding whether or not to redo a match run and whether the process is far enough along that it risks the possibility of multiple organs lost.

5. Adjourn

For the Board's information, the Director of the Organ Center will be stepping in as the interim UNOS Director of Policy and Community Relations next month. The Board President also thanked the Board members for their time and effort. The meeting was adjourned.

Upcoming Meeting

- March 29, 2021, 2-3:30 p.m. ET

Attendance

- **Committee Members**
    - David Mulligan
    - Matthew Cooper
    - Maryl Johnson
    - Lisa Stocks
    - Robert Goodman
    - Mindy Dison
    - Denise Alveranga
    - Keith Wille
    - Randee Bloom
    - Celeste Williams
    - Stacee Lerret
    - Medhat Askar
    - Marian Michaels
    - Earnest Davis
    - Amishi Desai
    - Merry Smith
    - Leona Kim-Schluger
    - Seth Karp
    - James Sharrock
    - Pamela Gillette
    - William Bry
    - Patrick Healey
    - Joseph Hillenburg
    - Kelly Ranum
    - Joseph Ferreira
    - Jeffrey Orlowski
    - Suzanne Conrad
    - Leway Chen
    - Laura DePiero
    - Michael Moritz
    - R. Patrick Wood
- **HRSA Representatives**
    - Christopher McLaughlin
    - Shannon Taitt
- **UNOS Staff**
    - Chelsea Haynes
    - Craig Connors
- **Other Attendees**
    - Diane Brockmeier
    - Peter Lalli
    - Ian Jamieson
    - Shelley Hall
    - James Trotter
    - Keren Ladin