

**OPTN Board of Directors
Meeting Minutes
March 30, 2020
Conference Call**

**Maryl Johnson, MD, Chair
David Mulligan, MD, Vice Chair**

Introduction

The Board of Directors (BOD) met via teleconference on 03/30/2020 to discuss the following agenda items:

1. Welcome and purpose
2. Post-Public Comment Proposal Presentations
3. Update on OPTN Response to COVID-19 pandemic

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

1. Welcome and purpose

The purpose of the meeting today is for the BOD to hear the public comment summaries, as well as discuss recommendations and comments from the community and Board Members.

2. Post-Public Comment Proposal Presentations

Seven of the project proposals will be discussed further today. The majority of the comments were collected during regional meetings. Committee members will send any questions or comments regarding proposals not on the agenda today to UNOS staff.

- Kidney Committee: Addressing Medically Urgent Candidates in New Kidney Allocation Policy

The Kidney Committee Chair presented the proposal, which creates a standard definition for medical urgency, a new classification with high priority in each of the four KDPI sequences, and a process for documentation and retrospective review by the Kidney Committee.

The public comment sentiment revealed quite a bit of support for the proposal. A summary of the comments reveals patients in imminent loss of dialysis access will be allowed urgent classification and high priority. Regions 8 and 2 showed support, but also looked at alternative approaches, mainly prospective versus retrospective review. Societies showed general support, with ASTS discussing what type of supporting documentation was needed and NATCO recommending prospective versus retrospective review.

The Kidney Committee has met to discuss some of the changes to the proposal. They are currently discussing whether they want to do a prospective review process and want to be in line with the community regarding the medically urgent definition to only include complete exhaustion of dialysis access, as many DSAs and regions approached this differently. They also want to prioritize medically urgent candidates within their classifications at the appropriate spot. The term "medical urgency" was changed to "elevated medical urgency" based on feedback and language around dialysis exhaustion and contraindications was clarified. They will meet next on 4/2/2020.

Summary of discussion:

One Committee Member asked when an individual is close to not having access whether the expertise of the center they are coming from will be considered in the medically urgent definition. It was noted that this point was brought up specifically for procedures like translumbar dialysis access, as not all centers offer that. Most transplant centers have access to/can refer to centers with these techniques. The Committee Chair commented about whether during something like COVID-19 when a center will not have access to the techniques, the individual would still get elevated. Working together will be key in situations such as with COVID-19, and a prospective process will allow for leeway on this.

The Kidney Committee originally considered a prospective review; some regions only institute this at impending loss of vascular access, but others wait for true loss and life expectancy less than one week and then prospective review becomes harder since the Organ Center administers this and does not have resources to run this over the weekend. Therefore, they felt retrospective review on a case-by-case basis was proposed.

Another Committee Member commented that in the last 20 years in the Eastern Pennsylvania area, they never approved any patient for medical urgency, with the exception of a heart/kidney recipient whose kidney could not be transplanted and needed kidney urgently. They are therefore skeptical of a retrospective review process. Other Committee Members agreed they have always been able to either create access, such as through grafting, but tentatively agreed about a retrospective review process.

- Liver & Intestine Committee: Enhancements to the National Liver Review Board

The Liver Committee Chair stated the purpose of the enhancements is to incorporate improvements to the NLRB based on 6 months of experience. The proposal will increase and standardize HCC automatic approvals, clarify MMA and MPAT at update schedule, clarify scope of NLRB review process/process for final appeals, and add guidance for secondary sclerosing cholangitis to clarify portopulmonary hypertension in candidates with prior HCC. The changes are important, but minor.

The public comment sentiment generally showed favorable response. The summary revealed very little public comment, but ideas suggested included feedback on operational aspects of NLRB, removing inactive reviewers, and comments about metabolic diseases and specific scores that are awarded to patients.

The Liver Committee is currently considering changes to guidance for documents with metabolic disease and timeframe for removing inactive reviewers, and will ensure that description of the review board scope in policy language and guidelines are in alignment. They will finalize the proposal on 4/14/2020.

Summary of discussion:

One Committee Member expressed support for evaluating inactive reviewers every 6 months. Another requested clarification on process for evaluating reviewers. One challenge is objectively measuring specific disorders, such as cholangitis or polycystic liver disease, where patients typically have very severe subjective symptoms. Another challenge is when reviewers give their personal medical opinions, rather than follow guidance. Overall, the process is much more objective than it used to be.

- Histocompatibility Committee: HLA Equivalency Tables Update 2020

The Chair of the BOD clarified the updates are not only for 2020, but an expedited pathway for future updates so that it will not have to come before the Board every time.

The Histocompatibility Committee (HC) Chair stated that it sometimes takes a while to get updates into policy due to the process for approvals and nomenclature changes. The HC is required to review the equivalency tables annually (which define the matching algorithms that are used to define O-ABDR mismatch priority for kidney recipients and look at the equivalencies for unacceptable antigens for all organs). The proposal will allow for a general review and update of the current HLA equivalency tables; basically group DPB1 epitope-based alleles to allow for more simplified definitions of unacceptable antigens; and create policy language allowing for expedition of the equivalency table updates process.

The proposal was widely favored with no negative public comment. There were a few suggestions on semantic differences in nomenclature of the DPB1 epitopes/alleles. The HC will continue with the definition in the original proposal that was supported by the American Society for Histocompatibility and Immunogenetics (ASHI). The one change made was to add one DPB1 allele that was missed in the table. The HC will meet next on 4/17/2020.

Summary of discussion:

One Committee Member further offered that the proposal was reviewed by the ASHI Board and the National Clinical Affairs Committee with general support from all the experts.

- Thoracic Committee: National Heart Review Board for Pediatrics

The Thoracic Committee Chair presented the purpose is to address an increase in pediatric heart Status 1A since the 2016 criteria update and significant variation in the expertise of members regarding pediatric transplantation on regional review boards. The proposal will create a national review board to review all pediatric heart 1A and 1B exceptions; have reviewers with pediatric heart experience make decisions for the exceptions for pediatric heart patients; and implement a short, but reasonable timeline for completions of reviews.

The public comment sentiment revealed everyone was either neutral or supportive of the proposal. There was recognition that the lack of pediatric expertise leads to pretty standard exception request approval. There were suggestions to make sure there is a spread across regions or program volume for reviewers of a particular exception.

Changes to the proposal being considered include timeliness of reviews and methodology of the primary and alternative representatives voting, continuing to discuss with UNOS IT to make this happen; metrics associated with removal for failing to vote; looking at distribution of geographic and experiential representation; and ensuring consistency with other review boards across other organs. The Thoracic Committee will meet next on 4/17/2020.

Summary of discussion:

There were no comments on this proposal from Committee Members.

- OPO Committee: Modifications to Released Kidney and Pancreas Allocation

The OPO Committee Chair stated the purpose of the proposal was to identify the next suitable transplant candidate for an organ after it had been accepted and then later declined by the original intended recipient, as well as develop policies consistent with recent policies related to the Final Rule for reallocation of kidney and pancreas. The proposal is to use the same distribution unit and same proximity points as the original match run. If utilized, the host OPO would be responsible for reallocation for delegating that work to the Organ Center.

The majority of the proposal had support, with some specific items singled out. Public comment included support for allowing the host OPO to maintain responsibility for reallocation of the organ, as the host OPO is vested in the placement of the organ. Region 5 comments were that the host OPO could delegate it to the importing OPO. Other comments expressed concern about reallocation of the pancreas specifically, as pancreas has unique logistical and cold ischemic time considerations; about the proposed size of the reallocation circle, including comments from AST and ASTS; and about the limited availability of cross matching materials to be shared.

The OPO Committee is considering a center backup or a smaller circle being permitted for pancreas reallocation and to keep the option to delegate responsibility to the OPO in the DSA of the transplant program that received the organ if it promotes greater efficiency. They will finalize the proposal at their meeting on 4/22/2020.

Summary of discussion:

One Committee Member asked if the proposal focuses on after the organ is procured and sent, but not the turn-downs prior to the shipment. It was clarified that the proposal does deal with organs post shipment.

The Region 5 representative reiterated that Region 5 unanimously suggests keeping the option of delegating to the importing OPO by the host OPO. Another Committee Member asked about the plan for implementing that option, and if the incoming OPO takes over without the consent of the designated OPO. It was clarified that the host OPO would retain responsibility and delegate to the Organ Center and importing OPO.

- VCA Committee: Update to VCA Transplant Outcomes Data Collection

The VCA Committee Chair presented the purpose of the proposal is to create data elements consistent across VCA types and to compile outcome information that can be used for future policy making. The proposal will modify existing Transplant Recipient Registration and Transplant Recipient Follow-up data for head and neck and upper limb transplants; add new data elements for uterus; remove data not relevant to specific VCA types; and request data elements be collected for other VCA types, as larynx, abdominal wall, or penis.

The public comment sentiment revealed generally strong support with one opposition at a couple of committee meetings. The summary of public comment showed general support for adding/removing specific fields, for consistent data collection to help future policy decision making, for collecting quality of life measures on VCA recipients, and for retaining hemoglobin A1c data collection. Different stakeholders supported the proposal. There was feedback to retain skin changes as monitoring tool for skin-containing VCAs.

The VCA Committee is considering retaining data collection of hemoglobin A1c and the skin changes during rejection for any skin-containing VCA. They will next meet 4/3/2020.

Summary of discussion:

There were no comments on this proposal from Committee Members.

- Minority Affairs Committee: Data Collection to Assess Socioeconomic Status (SES) and Access to Transplant

The Minority Affairs Committee (MAC) Vice Chair presented a brief summary of the proposal. Low SES status has been shown to make transplant outcomes worse, and the Final Rule states SES should not be a limiting factor for transplant access. Further SES data measures are needed

to fix the system, so the proposal is to add annual household income and household size to the Transplant Candidate Registration (TCR) form at time of listings.

The public comment sentiment revealed little support at regional meetings in the beginning, but more support later on. Public comments were related to data burden, perhaps discomfort answering the questions and the new fields on the forms; reliability of the parameters; criticism over the integrity of the data; and how the data would be used.

The MAC will propose that the questions about income be optional, use a range of income instead of actual income, and state clearly that it will not affect allocation of organs and the data will be securely stored. The proposal will not deal with data regarding SES/patient referrals to transplant. They will finalize the proposal at their meeting on 4/1/2020.

Summary of discussion:

One Committee Member asked about what the concerns are of the nonmembers and patients being strongly opposed and opposed on the public comment sentiment. In addition, sentiment at committee meetings showed Patient Affairs Committee (PAC), Transplant Administrators Committee and Transplants Coordinators Committee were all on the negative side. The MAC Vice Chair clarified that this snapshot of public sentiment is not so reliable because the public was not informed enough about the importance of the data and that the data will be secure and will not affect allocation. The MAC will work through specific concerns raised. They need to also emphasize that most centers already collect these data, but do not report on the TCR.

Another Committee Member felt that PAC would most concerned about implementing this and asked what their specific comments were. Their concerns were that patients might feel this would affect their eligibility for transplant, feel the data points are intrusive, and the security of the data.

One Committee Member was concerned whether the time of listing and not prior to listing is the right time to collect the data. Aside from what PAC addressed, the proposal needs to include stronger measures to bolster trust, as well as data segregation. This is why MAC is considering making the questions optional.

Next steps:

Questions or comments from Board Members can be addressed to the Committees prior to their meetings and prior to the finalizing the proposals.

3. Update on OPTN Response to COVID-19 pandemic

The BOD Chair reiterated that the UNOS.org/COVID website is a very up-to-date resource regarding COVID-19 information, including current statistics, recommendations for OPOs and transplant centers and for donor testing of COVID-19, as well as ways to inactivate programs and content of the COVID town hall last week. It also has a place to report any issues related to COVID and organ transplant.

UNOS staff provided further updates. HRSA is working through the federal government to get approvals for official communications, while UNOS is a little more flexible as far as linking to societies and non-government organizations.

A breakdown of donor transplant drop-off by geographic area and organ type was shown. The experiences are very different across the country. The University of Washington provided state-by-state models, suggesting for example that the New York peak may be 7 days away, while the Virginia peak is 7 or 8 weeks away. The worst-case scenarios allow for planning of support necessary for each community.

Deceased donor transplants are down about 30%, living donor transplants have fallen to nearly nothing, and inactivation of candidates is rising rapidly.

For the OPTN standpoint, the following changes have already been made. Policy changed to allow centers to recertify that the candidates' lab values are still the most recently available to maintain scores. New refusal codes related to COVID-19 were created added to the system. A tool for kidney will make it easier to inactivate multiple candidates at a time, if necessary. The national system of data is being monitored and there is a new issue-reporting tool in UNet.

Potential policy changes being considered include waiving testing requirements for listing of non-dialysis kidney candidates; continuing waiting time if a candidate is inactive due to COVID-19; adding additional COVID-19 codes; addressing liver donor follow-up requirements; requiring OPOs to assign donor hospital surgeons at donor hospitals when qualified and available, currently gathering feedback from the Board, OPO Committee and organ-specific committees; and MPSC-area discussions about adjustments needed to follow-up forms and monitoring requirements, as follow-up forms are being filled out for clinic visits that took place weeks ago.

Regarding OPTN current operations, committee meetings through the end of April will be virtual and site surveys through May will be virtual, but may also be rescheduled at member's request. The Organ Center is up and running 24/7 with staff working remotely. Member and patient questions lines are also up and running. The June Board meeting plans are under review.

There is an emergency policy process that allows the Executive Committee to adopt emergency policies without public comment that will have an expiration date of no more than a year away and that will be put out for public comment within 6 months.

Summary of discussion:

One Committee Member's comment was whether centers will be able to do data validation and cleanup prior to next SRTR data release. UNOS staff clarified they are still in discussion with HRSA, SR, MPSC regarding options for necessary adjustments to reviewing metrics and requirements. Colleagues will need to apply requirements in light of the pandemic, while still committing to patient safety and good stewardship of organs. Communication at this time will be most important.

It was also questioned whether there might be a need to put Board members rolling off on a reserve function to help support new members rolling on through the pandemic. Part of the Executive Committee will turn over at the end of June because there would be some elected from the new Board, but several officers remain the same. Therefore, not allowing new Board members to take their seats will probably not be necessary, but this can be reevaluated as time goes on.

The VCA Committee Chair was concerned about the requirement for a local surgeon to perform procurements, since for VCA the qualifications are unclear if VCA procurement is not part of their practice. In the proposal, the initial idea was that the first option be given to the donor hospital if there are qualified available surgeons. OPOs may determine who those qualified surgeons are. The Minority Affairs Committee Vice Chair felt having a qualified surgeon does not necessarily enter all the cases because there are centers that would not consider another surgeon to procure a pancreas or marginal liver, but a mandate might lead to organ discards.

Another Committee Member felt one thing underemphasized in the discussion over the weekend is that limiting travel by teams is a good goal, but there will still be large exposure to many people at the procurement, even if done by local teams. Transplant centers and OPOs will really need to make safe judgments on risk-benefit in their communities about some of the procurements.

One Committee Member questioned how the virtual site surveys are being conducted. Reviews will be conducted for centers that have already prepared their documents and medical records, but centers may also request to postpone their survey.

Next steps:

Communication with staff about any challenges pertaining to COVID-19 s will be done through email, phone calls, or the portal on the website.

Upcoming Meetings

- March 30, 2020 11am ET (Teleconference)
- June 7-8, 2020 (Richmond, VA)

Executive Director thanked committee members for convening on short notice, as well as staff working extra hours to ensure timely implementation.