OPTN Executive Committee
Meeting Summary
April 25, 2022
Chicago, Illinois

Matthew Cooper, MD, Chair
Jerry McCauley, MD, Vice-Chair

Introduction

The Executive Committee (the Committee) met in Chicago, IL and via WebEx on 04/25/2022 to discuss the following agenda items:

1. New Projects from the Policy Oversight Committee
2. Non-Substantive Changes to OPTN Policies and Bylaws
3. Cross-Organ Data Alignment
4. Updated SARS-CoV-2 Summary of Evidence
5. OPTN Response to NASEM Report
6. Policy 1.4.F Reinstatement Monitoring
7. In-Person Meeting Safety Protocol
8. Report from Patient Engagement and Regional Nominations Work Group
9. Public Comment Review and Discussion of Next Steps: Redesign Map of OPTN Regions

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

1. New Projects from the Policy Oversight Committee

The Committee reviewed projects recommended for approval by the OPTN Policy Oversight Committee (POC), as well as reviewed the OPTN portfolio and research allocation presented by the chair of the POC.

Data summary:

The Committee reviewed the following presentations:

- *Apply Transplant Program Notification Requirements for VCA Program Inactivation - Vascularized Composite Allograft (VCA) Committee*
    - This project will require VCA programs to notify patients when they inactivate. It does not create functional inactivity requirements for VCA programs. This is expected to improve waitlisted patient, living donor, and transplant recipient outcomes by ensuring VCA candidates are aware when they will not be able to receive offers.
- *Continued Review of NLRB Policies and Guidance – Liver Committee*
    - This project will update policy and guidance documents for the National Liver Review Board (NLRB) to reflect current clinical standards, experience with the NLRB, and updated research. This is expected to increase equity in access to transplants by decreasing appeal requests.
- *Improve Deceased Donor Evaluation for Endemic Diseases – Disease Transmission Advisory Committee (DTAC)*
    - This project develops and updates policy addressing the type, timing, and regionality of evaluation and testing of donors for endemic diseases. This is expected to improve

transplant recipient safety by decreasing the number of potential disease transmission events.

- *Require Confirmatory HLA Typing for Deceased Donors – Histocompatibility Committee*
    - This project will require confirmatory Human Leukocyte Antigen (HLA) typing of deceased donors to occur at the time of initial HLA typing, modeled after blood type confirmatory typing. This is expected to improve transplant recipient safety by decreasing the number of critical HLA discrepancies that are not detected until after the match run or transplant.

The Committee also reviewed committee resource allocation. At present, there are 15,000 technical implementation hours available per board cycle. The most recent technical implementation cycle will require over 30,000 hours. The POC is working to create a metric that defines project benefit and rates various project attributes. In addition, they are discussing how best to monitor the overall OPTN technical implementation budget in conjunction with approving critical work that can be accomplished in a timely manner.

The OPTN Network Oversight Operations Committee (NOOC) also discussed an increase in both the technical hours allocated per board cycle, as well as additional IT staff necessary for supporting this increase. NOOC was supportive of this request, and noted it may take up to 2 years to approach this capacity; furthermore, this increase in capacity may also require more support across other departments.

Summary of discussion:

Apply Transplant Program Notification Requirements for VCA Program Inactivation

A member inquired whether this is likely to change practices currently done by VCA programs, and whether this is going to increase regulatory burden. The presenter responded that the VCA Committee felt that this was a requirement for other organs that should be extended to include VCA, and it would not increase regulatory burden. This proposal was supported unanimously by a vote of 100% yes, 0 no, 0 abstain.

Continued Review of NLRB Policies and Guidance

A member suggested that, similar to a 2006 panel reviewing liver exception points, it may be prudent for the OPTN to host another in which subject experts provide input on liver exception points. This proposal was supported unanimously by a vote of 100% yes, 0 no, 0 abstain.

Improve Deceased Donor Evaluation for Endemic Diseases

The Chair suggested this could also benefit the DTAC's proposal addressing the 2020 update to the Public Health Service (PHS) guidelines. This proposal was supported unanimously by a vote of 100% yes, 0 no, 0 abstain.

Require Confirmatory HLA Typing for Deceased Donors

A member wondered how requiring confirmatory typing would not slow down the allocation process. The presenter replied that, similar to ABO testing, two samples would be testing simultaneously, rather than sequentially, so there should be no increase to sample test time. A member present on the DTAC noted that the committee felt very strongly that confirmatory HLA testing was necessary. This proposal was supported unanimously by a vote of 100% yes, 0 no, 0 abstain.

OPTN Portfolio and Resource Review

A member asked how the OTPN capacity is calculated, noting that members will likely have concerns with a fee raise if there is not quantitative data to support the change. A second member noted that the fully implemented cost ($6.7 million) is the cost of the 15,000 requested technical implementation hours. This incorporates increases to IT staff, Research staff, Communication staff, and Policy & Community Relations staff. A member noted that these costs are approximations based on fiscal year 2022 estimates and track a "ramp up" to fully implemented capacity. This statement was supported by a member of the Finance Committee.

A member wondered how much project cost factored into POC approval of a project. The POC Chair noted that it has been a factor for consideration, but part of the project benefit scoring system update is to better capture the cost vs. value add ratio. They added that, even with their early evaluation, the POC is on pace to surpass the allotted budget for projects. Another member suggested that this could considered like a funnel, in which many projects start at the top and are slowly filtered as they move through the review process, ultimately resulting in their order of development. They inquired how many projects were approved by the POC and would be moving forward in development. The POC Chair responded that there were certainly more projects approved than rejected; part of the reason to develop a structured tool to evaluate projects is to have more of a basis upon which to reject proposals. However, they added that there are a large number of projects that are important to undertake that the OPTN does not have the resources to support currently.

It was asked whether the staffing increase is a temporary response to the rollout of continuous distribution, or whether this is expected to be a permanent change. The POC Chair responded that there will continue to be a need for the increased resources even once continuous distribution is implemented. This point was furthered by another member who added that part of the budget increase request is to proactively prevent Committees from falling behind on necessary projects as the number of projects and scale of projects increase. It was also suggested that this price increase could be visualized adjacent to the number of registrations programs have in order to determine how impactful this price increase would be. A member supported this, noting that there will need to be communication and education surrounding why this increase is necessary.

A member contributed that an increase in appropriations fee would help offset the amount that the registration fee had to be raised.

Next steps:

The Executive Committee will consider the implications of a raising the registration fee.

2. Non-Substantive Changes to OPTN Policies and Bylaws

The Committee reviewed upcoming non-substantive changes to OPTN Policies. This is pursuant to OPTN Bylaws 10.3 and 11.5.

Data summary:

The Committee reviewed changes to *OPTN Policy 4.10: Reference Tables of HLA Antigen Values and Split Equivalences, OPTN Policy 8.5.H: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%, OPTN Policy 8.5.I: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 20% but less than 35%, OPTN Policy 8.5.J: Allocation of Kidneys from Donors with KDPI Greater than 35% but less than or equal to 85%, OPTN Policy 8.5.K: Allocation of Kidneys from Donors with KDPI Scores Greater than 85%,* and *OPTN Policy 9.4: MELD or PELD Exceptions, OPTN Policy 10.1.F: The LAS Calculation*.

Summary of discussion:

There was no discussion surrounding any of the proposed changes. The Committee voted unanimously 100% yes, 0 no, 0 abstain in support of the changes.

Next steps:

The proposed changes will be made.

3. Cross-Organ Data Alignment

This proposal will add discrete date fields for donor height and weight for each organ in order to more accurately track measurements. This change was initially implemented only for Lung, but it is being proposed for all organs.

Summary of discussion:

A member inquired how Body Mass Index (BMI) would be calculated if there were measurements collected on different dates. The presenter replied that the calculation would be performed off the two most recent reports of height and weight. The Committee voted unanimously 100% yes, 0 no, 0 abstain to sponsor the proposal for the Board of Directors meeting.

Next steps:

The Committee will sponsor the proposal for the Board of Directors meeting.

4. Updated SARS-CoV-2 Summary of Evidence

This document update will bring up-to-date the current Summary of Evidence on COVID-19 with information gathered in the past quarter. The Summary of Evidence document reviews information on COVID-19 relevant to minimizing risk of donor-derived transmission while maximizing donor utilization.

Data summary:

The updates include:

- Updated Omicron section to reflect BA2 subvariants prevalence
- Updated data on lung donor with lower respiratory tests
- Unknown long term outcomes includes possibility of thrombotic events
- Workgroup voted unanimously to approve the document

Summary of discussion:

There was no discussion surrounding this item. The Committee voted unanimously 100% yes, 0 no, 0 abstain in support of updating the Summary of Evidence.

Next steps:

The Summary of Evidence will be updated.

5. OPTN Response to NASEM Report

The Committee reviewed the OPTN letter written in response to the National Academies of Sciences, Engineering, and Medicine (NASEM) report*, Realizing the Promise of Equity in the Organ Transplantation System*. This review was delivered by the Executive Director of the OPTN.

Data summary:

The NASEM report's recommendations are holistic and many align with existing OPTN work:

- Acceleration of the continuous distribution framework
- Need to better understand access to the waitlist

- Enhanced data collection
- Improve OPTN policy development process

Summary of discussion:

A member suggested that access to the waitlist from a waitlisting perspective could potentially be outside the scope of the committees, given that each program controls their own waitlisting practices. The presenter agreed, but noted that an investigation into it may facilitate change from those programs.

A second member contributed that an investigation could better link pre-transplant data from the Centers for Medicare and Medicaid (CMS) and post-transplant data from the Health Resources and Human Services Administration (HRSA). This was supported by another member, who added this will contribute to the conversation that candidate data tracking should begin at the diagnosis of organ failure rather than waitlisting. A third member added that this could encourage programs to develop policies surrounding how a candidate's estimated Glomerular Filtration Rate (eGFR) trending should inform the program's waitlisting practices (i.e. if their eGFR is not low enough to list for transplant but has been continuously trending downwards, they should be listed for transplant).

The presenter noted that there is disagreement with some of the recommendations within the report; notably, the OPTN IT function should exist as a separate entity than its policy development function. In addition, they noted an area in which it was quoted that 20% of kidney offers are offered to deceased candidates. They clarified that this statistic was from a report over a five year period in which it was noted that 20% of all kidney matches contained at least one deceased donor. The actual percentage of deceased candidates that kidneys were offered to is approximately .5%.

A member asked whether the letter reviewed was in its final state, as well as whether it would be open for the public to read. The presenter replied that the letter was public, but the contents within it are subject to change before final submission.

With no further discussion, the Committee voted unanimously in favor of submitting the OPTN letter in response to the NASEM report by a vote of 100% yes, 0 no, 0 abstain.

Next steps:

The Committee will submit the OPTN letter in response to the NASEM report pending any non-substantive edits by the OPTN President.

6. Policy 1.4.F Reinstatement Monitoring

The Committee reviewed the data report for the reinstatement of *OPTN Policy 1.4.F.* This policy was approved by emergency action and requires Committee review monthly. As of April 11, 2022, the policy has sunset.

Summary of discussion:

There was no discussion surrounding this item.

Next steps:

No further action will be taken with the reinstatement of *OPTN Policy: 1.4.F*.

7. In-Person Meeting Safety Protocol

The Committee reviewed the safety protocols for OPTN meetings as approved from November 2021.

Summary of discussion:

A member suggested that mask wearing be changed to optional rather than mandatory. The Vice-Chair contributed that, given the constantly changing state of COVID-19, whatever resolutions are passed should be subject to change at a later date. They concluded by agreeing that the rigidity of existing language should be relaxed due to current COVID-19 data. Another member also agreed with this sentiment, noting that it may not be feasible to enforce strict mask wearing, and that the area of greatest risk likely is not the Committee meeting itself, but the travel to get there. In addition, these guidelines should take into account that immunocompromised patients may be present at these gatherings.

It was suggested that the requirements should move away from a bulleted list. A bulleted list does not accurately reflect the dynamic safety needs for in-person gatherings at varying stages of COVID-19 severity. In addition, a member contributed that simply being vaccinated, as stipulated in the guidelines, may not be specific enough as requirements change for different age demographics and different COVID-19 vaccines.

A member suggested that the guidelines could be to follow local public health and CDC guidelines. The Vice-Chair responded that the problem there is the rate at which these guidelines change. In addition, it was reiterated that these in-person meetings have a higher likelihood of containing vulnerable populations.

It was then proposed that the overarching principle should be the ability of the individual to attend meetings either virtually or in-person, in response to their personal comfort levels, and still be able to meaningfully contribute. The Chair reiterated that the guidelines established in November have worked well because they outlined rules for individuals to follow. The Committee agreed, and proposed that the list should remain, but become more flexible in its guidance; for example, strongly encouraging individuals who attend to be vaccinated and spacing individuals whenever possible. These should exist not only to protect individuals who attend, but also patients who may be treated by attendees of the meeting.

The Vice-Chair advocated against requiring proof of vaccination to attend, noting that vaccination is not wholly effective at preventing contraction and transmission and it would put burden on staff to determine vaccine status. Two Committee members supported this statement, adding that it should be strongly recommended rather than required.

The OPTN Executive Director asked whether there should be limitations on in-person attendance for the general public for the Board of Directors meeting in June. A member and the Vice-Chair supported limiting in-person attendance. It was also suggested that a “catch all” bullet be added which allows decisions to be made in accordance with epidemic severity at that time.

With no further discussion, the Committee voted unanimously to approve the updated COVID-19 safety protocols. By a vote of 100% yes, 0 no, 0 abstain it was

RESOLVED, that the OPTN Executive Committee adopts the following COVID-19 safety protocols for meetings of OPTN Board of Directors, Regions, and Committees:

- That technology tools be provided to allow for virtual observation, participation, and voting in the meetings;
- That those who choose to attend the meetings in person are encouraged to be vaccinated;
- That anyone showing symptoms of COVID-19 may only participate in the meeting virtually;
- That in person attendees are encouraged to wear masks and observe social distancing in indoor public places during the meeting;
- That public observation of the meetings is encouraged to take place virtually; and

- That the OPTN President and OPTN Executive Director are authorized to take all steps reasonably necessary to implement this Resolution.

Next steps:

The Committee will distribute the finalized draft of the updated COVID-19 safety protocols to be used for upcoming in-person meetings.

8. Report from Patient Engagement and Regional Nominations Work Group

The Committee reviewed progress to date from sponsored workgroups.

Data summary:

Patient Engagement Workgroup

This Workgroup develops recommendations and clarifies the role of patient representatives in OPTN governance and policy development. They were tasked with determining if committees should change the number of patient representatives. They developed the following recommendations:

- Continue to grow the volunteer pipeline
    - Establish roles for patients to engage outside of committee service
    - Use policy committees as an opportunity to develop patient volunteers for continued OPTN involvement
- Continue to enhance the volunteer experience
    - Increase number of patient representatives on committees to a minimum of two
- Strengthen the patient voice in policy development
    - Provide hybrid meeting options

Regional Nominations Workgroup

This Workgroup assesses the current regional nomination process and develops recommendations for consistency across regions. They were tasked with improving the regional meeting experience by promoting consistency and incorporating positive elements specific to certain regions. The developed the following recommendations:

- OPTN should promote consistency, transparency, and fairness by providing recommendations to regional nominating committees (RNCs)
- RNC Composition should consider:
    - OPO Committee Regional Rep as OPO Rep on RNC
    - PAC Regional Rep as patient rep on RNC
    - RNC should be 4-6 people
- RNC should continue to evaluate the geographic distribution of their representatives and consider rotating the Associate Councilor position
- RNC should continue to use the OPTN Committee Needs Assessment, historic and current geographic representation, and information on first-time and returning volunteers to recommend nominees
- Regional representatives and RNCs should take an active role in recruiting new volunteers

Summary of discussion:

Patient Engagement Workgroup

A member asked why there had not been a call to use stakeholder organizations who have contact with patients to recommend volunteers. The Workgroup Chair presenting noted that this does currently exist. A member supported increasing the visibility of OPTN volunteer options. In addition, they liked the stipulation that committees should have to explain their policies going out for public comment to a patient such that they can understand how graspable it is. A second member supported having patients provide input on how necessary a policy seems.

The presenter inquired how feasible it would be for transplant program members to educate their patients on volunteer opportunities with the OPTN. The Vice-Chair stated that they felt it would not be very difficult. The Vice-Chair went on to note that getting volunteers involved prior to committee service could be how the OPTN engages transplant affinity groups. This would help create a pipeline for committee service, and would engage a larger number of interested patients or individuals.

The Committee broadly supported raising the minimum number of patients present on OTPN committees to two. The Chair added that this would also bring the patient perspective more to the forefront for regional and committee leadership. A member also voiced support for patient specific engagement activities at regional meetings, again to bring the patient perspective to the forefront. They suggested transplant programs could nominate patients to attend regional meetings to increase patient participation. Another member supported this, but advocated that travel costs should either be covered or not be covered uniformly to maintain consistency.

A member speculated that there may be more engagement from post-transplant patients, as pre-transplant patients are both sick and focused much more on receiving their transplant.

The Chair inquired whether there was a timeline for the proposed changes from the Workgroup. The Chair of the Workgroup responded that there was not a timeline yet. The Workgroup Chair contributed that increasing patient involvement with the OPTN improves the selection of patients for Board of Directors placement, and increasing the number of patients on committees would help create a pipeline.

Regional Nominations Workgroup

A member asked how the size of the RNC is currently determined. The Workgroup lead replied that it is currently determined based off the RNC leadership's discretion of regional needs.

It was suggested that feedback should be given to candidates not nominated to serve on a committee to promote transparency in the nomination process. A second member agreed with this suggestion, adding that this would encourage younger members to stay involved in the nomination process.

A member inquired how the nominees submitted for committee assignment are considered by OPTN Vice-President. The Vice-Chair responded that almost always the primary or secondary nominee is chosen, but each evaluation is done on a case-by-case basis; there is no structured formula for review. They noted that rejections may sometimes be because they feel the nominee does not reflect the makeup of the committee. It was suggested that the reasons for rejection could be distributed.

The Chair suggested that the historic list of committee appointments could be distributed, such that interested candidates can approach past member to gain a better understanding of the committee.

A member added that it seems like a relatively easy change for RNCs to deliberately make sure they have an OPO and patient/donor representative on their committee, even if it is not required. This would both help standardize the makeup of RNCs and ensure that their perspective is present.

The Chair stated that one problem with virtual meetings is the difficulty in junior members networking with more senior members. In addition, programs may be more willing to send senior members to

regional meetings, while junior members are passed over. They proposed reaching out to transplant programs' senior administrators to ensure they are aware of the importance of junior staff involvement at regional meetings. A member added that a benefit of the virtual meetings is the ability to provide their opinion in the meeting chat, which may be more appealing for junior members.

Another member advocated for having a specific number of committee members that must be new to the OPTN each term, such that new perspectives are continuously brought in. However, a second member noted that one of the challenges currently is maintaining enough members to acclimate the new members to the functions of the committee. The Chair agreed and added that some committees working on certain projects may not be the best starting point for new members (e.g. the Liver Committee undergoing the development of continuous distribution). They considered that this may not be as obvious as it could be and is an area for greater transparency.

9. Public Comment Review and Discussion of Next Steps: Redesign Map of OPTN Regions

The Committee reviewed the public comment feedback from their concept paper *Redesign Map of OPTN Regions*.

Data summary:

The Committee viewed the summary of public comment feedback themes. In addition, the Committee considered a resolution to monitor the existing regional structure and evaluate it again no later than three years after this meeting date. This approach recognizes the value of existing bonds between programs, and it acknowledges that continuous distribution may create new challenges for regional structuring that can be better addressed post-implementation.

Summary of discussion:

A member considered that there was not conclusive evidence to support redesigning the map OPTN regions, and stated that continuing with this approach might cause consternation amongst members. This was supported by another member, who added that this investigation may have come too early with the upcoming implementation of continuous distribution. The incoming Vice-Chair agreed, saying that broader sharing of organs will naturally bear with it its own new questions and challenges. Once these have been brought to light, the OPTN may be better situated to consider whether there is a better structure than the existing 11 regions.

A second member noted that a theme amongst the comments was fostering better representation and participation at the regional level, which could be considered outside the context of a regional redesign.

The Vice-Chair noted that the investigation in this project has primarily been focused on geography; in the future, the investigation could focus instead on the function of regions if the matter is considered again. The Chair contributed that continuous distribution may help determine what regions could look like by addressing some of the geographic distance concerns brought up in the public comment feedback.

The Committee unanimously voted to approve the resolution proposed to reevaluate the regional structure in at most three years from April 25, 2022. By a vote of 100% yes, 0 no, 0 abstain:

Whereas, the Executive Committee recognizes that regional meetings are an opportunity for collaboration and relationship building among professionals from many different organizations who work together to increase donations and transplants, and

Whereas, the current regional maps are based on historical patterns and interactions that may change as allocation policies change, and data about the effects of circle-based policies and continuous distribution policies are not yet available, therefore be it

RESOLVED, that the OPTN Executive Committee commits to regular review of the regional map boundaries based on the most current available data, the first review to take place no more than three years from today, April 25, 2022.

Next steps:

The Executive Committee will not produce a paper for public comment on regional redesign. The Committee will reevaluate the regional structure at a later date.

Upcoming Meeting

- June 26, 2022

Attendance

- **Committee Members**
  - Matthew Cooper
  - Jerry McCauley
  - Mindy Dison
  - Rich Formica
  - Pat Healey
  - William Hildebrand
  - Valinda Jones
  - Irene Kim
  - Brad Kornfeld
  - Lisa Stocks
  - Stacee Lerret
  - David Mulligan
- **HRSA Representatives**
  - Frank Holloman
  - Chris McLaughlin
  - Shannon Taitt
- **SRTR Staff**
  - Ryo Hirose
  - Jon Snyder
- **UNOS Staff**
  - Carrie Caumont
  - Susie Sprinson
  - Kaitlin Swanner
- **Other Attendees**
  - Nicole Turgeon