OPTN Executive Committee
Meeting Summary
October 26, 2021
Conference Call

Matthew Cooper, Chair

Introduction

The Executive Committee (EC) met via teleconference on 10/26/2021 to discuss the following agenda items:

1. Welcome and Roll Call
2. OPTN Regional Review Project
3. OPTN Charter Revision Project
4. HOPE Act: Letter to HHS Secretary Becerra
5. SARS-CoV-2 Lower Respiratory Testing Policy
6. Proposal to Clarify Acceptable Signature Formats in OPTN Policies and Bylaws
7. COVID-19 Safety Protocols: December 2021 OPTN Board of Directors Meeting
8. Adjourn

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

1. Welcome and Roll Call

The Executive Committee Chair welcomed all attendees to the teleconference. The agenda was reviewed.

2. OPTN Regional Review Project

UNOS staff and independent consultants from EY presented the project. This Executive Committee proposal project has already gone through public comment, and EY was asked to do an independent analysis on the feedback received. During regional meetings was focused around four concepts: structure, governance, responsibility, and geography.

The EY project team created three broad themes for potential models that went out for public comment. Each model included different components of structure and governance of the OPTN, which could be mixed and matched into a new model. One significant finding was that the community supports regions and being able to gather with those in their geographic region. People have personal and professional longstanding relationships with one another, with transplant centers, and OPOs. There was some desire to combine cohorts of stakeholders in addition to regional groupings to enrich the discussion. Regional boundaries could be redrawn to create less of an imbalance that currently occurs due to density of transplant centers in the center and on the coastal regions of the country. To ensure equity and diversity of perspective, there should be Board representation for all members. It was suggested that there should be increased partnership with OPOs as an enabler to encourage equitable transplant access and enhance the voice of underrepresented minorities in the policy-making process. There was a pushback against creating communities of common interest. Regional meetings should be opportunities for education and engagement.

EY concluded that there is a desire for change to structure and governance, and changes to enhance transplants and donations and to promote equity should be at the core. The public comments were consistent with the feedback received from primary interviews and roundtable discussions held earlier in the engagement, thereby reinforcing the proposed initiatives.

A summary of the categorization of the comments was presented. An analysis was done to discover key themes. Support for the first idea of maintaining the regional structure primarily came from the regional meetings themselves and committees. Secondly, on the patient side there is still the belief that allocation equity has a role to play in the regional structure. Thirdly, the committees themselves continue to be a voice for minority members, emphasizing the idea of building cohorts to supplement the geograpy.

While there was support for regional groupings, most of the comments also supported the idea of changing the current regional boundaries. The arbitrary boundaries created years ago may not be appropriate today. One model could involve maintaining a geographic body, with the addition of interest groups or cohorts. This hybrid cohort structure was broadly supported, as it seems to offer a potential balance of regional and national resources, and the greatest potential for representation of interests and flexibility. Regarding structure, a regional grouping is useful and might be an opportunity to use interest groups and other ways of interacting as a supplement, but not a replacement to the current structure. Regarding governance, members emphasized the importance of having a Board that is representative, feeling the need to have a voice in voting and policy issues. There was no consensus as to the size of the Board.

Regarding responsibility, ensuring a voice for underrepresented communities will be important. The idea of national interest cohorts to represent communities across all regions who have like interests was supported.

Topics identified for further consideration include "Do no harm," meaning whatever is currently working should remain; and that change should be gradual. The OPTN may propose a "strawman" single map of new regional boundaries; and identify champions who support and see themselves in the new model.

A series of actions called "no regret" initiatives were identified, which could be taken regardless of any changes to boundaries or to the Board. There was general support through public comment for the recommended initiatives, which are mostly around increasing awareness, communication, understanding, and transparency. Communication should be proactive, the community should be educated in as many aspects of transplant as they could be, and the framework for going forward in building the hybrid structure with cohorts should be transparent.

Summary of discussion:

The Committee agreed with the idea of broader regions, especially when talking about continuous distribution. When a similar discussion around governance was held five or six years ago, the idea of interest groups replacing committees also came up, but there was no support for that model.

UNOS staff facilitated discussion to refine the Regional Review Project plan in terms of deciding what a proposal could look like and what changes the EC wants to pursue. Topics and recommendations from the community were presented, which EC members could break down into four categories: those to pursue now, those to pursue at a later time, requires further feedback in upcoming Winter 2022 public comment, something that is ready for change right away. One topic is clarifying the committee nomination appointment process. There was agreement that the appointment process can be difficult to understand for new members. Attempts at clarifying the process could be continued.

In the interest of time, and to allow more time for review and contemplation of the topics, EC members will be provided the remaining topics in the form of a survey following the meeting to individually identify which of the four above categories each topic fits into. The goal of the exercise is to identify which topics are supported and warrant further discussion versus which ones can be tabled or let go.

There was a lot of conversation at regional meetings about the maps outlining regions. There were clear disparities due to population differences in regions. There are 11 regions used by the OPTN today, while HHS uses 10 different defined regions in other areas of healthcare and ESRD uses 18 regions throughout the country.

Alternatively, maps could be non-contiguous by having regions mapped into clusters of similar member profiles. This has been modeled by researchers in the past. Others have created clusters based upon a network analysis, drawing maps by looking at working relationships. One EC member was concerned about non-contiguous maps since many issues shared by geographic neighbors such as a similar DCD population or shared academic environments. This can make regions rewarding to be part of. Another member agreed that there is a benefit for like kinds of programs, but contiguous maps allow for better cohorts of representatives and better public confidence. An additional benefit to contiguous maps is that there are state laws that affect transplantation.

Other mapping possibilities assessed include fewer numbers of regions or keeping the current number of regions, but balancing them out more equally. However, increasing the number of regions above 11 will make it difficult to balance the metrics due to the size of California. The EC considered which metrics are important in terms of drawing maps. UNOS staff previously determined five metrics: percent of population, percent of donors, percent of active members, percent of recipients, and percent of transplants. One EC member felt it important to take a step back and determine the problems that the current regions are not addressing and then determine the map that best addresses solving those problems. However, based on public comment the current map reveals regions that are clearly larger no matter what metrics are used, which cause equity issues in terms of representation between different areas.

Next steps:

The Committee members will complete the post-meeting survey which UNOS staff will send out regarding the topics and recommendations from public comment that the EC should further pursue. The take-way from the public comment was not to eliminate regions, but to consider redrawing the maps. EC members carefully consider how many regions there should be and what metrics should be used when considering the different maps.

3. OPTN Charter Revision Project

UNOS staff presented the concerns about the charter in its current state and subtractions and additions to the Charter that the EC will focus on. The purpose of the OPTN in the current charter is not fully accurate. It includes some, but not all functions of the OPTN required by NOTA. Clarifying the purpose will prevent inconsistencies. Secondly, in terms of membership, the Final Rule lists three categories of membership, which are not precisely reflected in the charter. Therefore, the question is whether to mirror the language from the Final Rule in the charter. Another area of concern is under the Board composition section of the charter, which is almost a word-for-word reflection of what is currently in the Final Rule, there is mention of pediatric representation. HRSA identified a similar extra provision in the charter that is not found in the Final Rule, stating that there should be a representative of HRSA on the Board. One EC member asked what overrides everything in terms of adjustments to the bylaws and the Final Rule. It was clarified that order of authority is NOTA, followed by the Final Rule, the OPTN contract or charter depending on what type of question is being asked, and finally, the bylaws. The OPTN can

only do what is authorized by NOTA. This project will be discussed further at the November EC meeting. Any further comments or questions may be emailed to UNOS Associate General Counsel.

4. HOPE Act: Letter to HHS Secretary Becerra

The UNOS Chief Medical Officer presented the draft HIV Organ Policy Equity (HOPE) Act and letter to the HHS Secretary, which is sponsored by the Disease Transmission Advisory Committee (DTAC). The HOPE Act was passed in 2013 and two years later the NIH put forth its clinical criteria by which it operates. The role of the OPTN is to evaluate the safety of the HOPE Act. What the HOPE Act does is permits the use of organs from HIV-positive donors to be transplanted into HIV-positive recipients, which was previously forbidden by NOTA. However, these transplants must be part of an Institutional Review Board-approved research study and should follow the NIH guidelines. The transplants must then be evaluated by the HHS Secretary to review the standards by which they were done within the OPTN. This was set up to be done as a research variance within the OPTN. The OPTN then annually evaluated the Data and Safety Monitoring Board (DSMB) reports.

The HOPE Act states that no later than four years after date of enactment and annually thereafter the Secretary shall review the results of the scientific research in conjunction with the OPTN. In the past, the HHS Secretary has recommended continuation of the HOPE Act research studies.

Most of the HOPE Act transplants are done in the context of two large, multicenter, NIH-sponsored trials, one for kidney and one for liver. From these, a unified DSMB reported is created that looks at kidney and liver separately and are annually evaluated by the DSMB workgroup comprised of UNOS staff and community experts, including kidney, liver, and infectious disease experts. There are other smaller single-center trials, though these have not enrolled patients for some time. No safety concerns have been found in the past that would pause or discontinue these transplants. One HOPE Act heart transplant center has been approved, but has not yet done a transplant.

In contrast to previous years, the DSMB workgroup has recommended that the research requirement be eliminated and that the Secretary consider instructing the OPTN to bring the HOPE act process within OPTN policy. It will still prohibit the transplantation of HIV-positive organs into anybody except HIV-positive recipients. The OPTN safety reporting structures, data collection, and follow-up will allow the OPTN to continue to monitor the outcomes of these transplants in the future. This will also allow the expansion of HIV-positive programs, as this population is underrepresented and has limited transplant opportunities.

The EC Chair noted that the HOPE Act allowed for identification of the number of false-positive HIV donor organs that in the past were discarded and now subsequently were transplanted. One question was whether DTAC or the EC has considered any type of monitoring of the transition from research, including removal of the IRB approval, to standard of practice monitoring, as this should be clearly described in the letter. The DTAC Work Group did discuss the criteria necessary to initiate these HIV-positive transplant protocols. They felt maintaining even partial research criteria would be an impediment to expansion of this program. Just as with hepatitis, COVID-19, and West Nile virus, the impact of HIV on donation and transplantation should continue to be monitored collaboratively between MPSC and program outcomes, but also with DTAC. One comment was that there are now four years of data demonstrating the safety of HIV-positive transplants, so they should be able to move forward to the current monitoring process for these transplants. Another Committee member commented that her center is one that has had a hard time getting access to these transplants, even though they have HIV-positive patients open to accepting HIV-positive donor organs, and agrees that these transplants should be treated like any other viral transmission. The EC discussed other possible changes to the monitoring requirements, but ultimately decided that in the absence of IRB approval, the

OPTN still has the ability to monitor these transplant outcomes and transplant protocols will still ensure safety in HIV-positive transplants.

A motion was made and seconded for the Executive Committee to approve the letter with a paragraph (to be approved by the Executive Committee Chair once completed) addressing the fact that they have considered and do not believe there are any extensive requirements beyond the current requirements for disease transmission monitoring.

The vote was 100% yes; 0 no; 0 abstained.

5. SARS-CoV2 Lower Respiratory Testing Policy

The EC Chair presented the data from the lower respiratory testing policy for lung donors. Compliance remains high.

6. Proposal to Clarify Acceptable Signature Formats in OPTN Policies and Bylaws

The EC Chair described a proposal that will allow for a new section to Policy and Bylaw regarding electronic signatures to meet the OPTN obligations. Handwritten signatures will still be accepted. The proposed language states: signatures necessary to meet OPTN obligations may be handwritten or electronically produced, including digital or electronically-imaged signatures. There were no questions or comments from the Executive Committee. A motion was made and seconded for the Executive Committee to support sending the above proposed policy language changes to the OPTN Board of Directors for approval.

The vote was 100% yes; 0 no; 0 abstained.

7. COVID-19 Safety Protocols: December 2021 OPTN Board of Directors Meeting

The plan is to have the Board of Directors meeting in person in Dallas in December 2021. Safety continues to be of utmost importance; therefore, planned safety protocols for the upcoming Board meeting were presented. All members attending in person will be expected to be vaccinated. A virtual option will be available for those who wish to attend, but are not unvaccinated or do not feel comfortable attending in person. There will be minimal contact with any other individuals who will be assisting with meeting logistics. Additional mask and social distancing requirements will remain. All Committee members were given opportunity to state any comments or concerns. Individual Board members will monitor themselves for symptoms. Proof of vaccination will be collected in advance of the meeting in a confidential manner. Safety protocol successes or challenges learned from the December meeting can be applied to future meetings. A motion was made and seconded for the Executive Committee to approve the COVID-19 Safety Protocols for the OPTN Board of Directors Meeting December 2021 as written.

The vote was 100% yes; 0 no; 0 abstained.

It was RESOLVED, that the OPTN Executive Committee adopts the following COVID-19 safety protocols for the December 6, 2021 meeting of the OPTN Board of Directors:

That technology tools be provided to allow for virtual observation, participation, and voting in the meeting;

That those Board members and staff that choose to attend the meeting in person provide evidence of vaccination in advance of booking travel arrangements;

That unvaccinated Board members and staff may only attend and participate in the meeting virtually;

That any Board member or staff, vaccinated or not, showing symptoms of COVID-19 may only participate in the meeting virtually;

That all in-person attendees wear masks in indoor public places during the meeting;

That all in-person attendees observe social distancing arrangements;

That public observation of the board meeting will take place virtually; and

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

8. Adjourn

The Executive Committee Chair adjourned the meeting.

Upcoming Meeting

- November 19, 2021 at 12-1:30 pm ET

Attendance

- **Committee Members**
  - Matt Cooper
  - Jerry McCauley
  - Lisa Stocks
  - Irene Kim
  - Richard Formica
  - David Mulligan
  - Brad Kornfeld
  - Stacee Lerret
  - Valinda Jones
  - William Hildebrand
- **HRSA Representatives**
  - Chris McLaughlin
  - Frank Holloman
  - Shannon Taitt
  - Vanessa Arriola
- **UNOS Staff**
  - Susie Sprinson
  - James Alcorn
  - Liz Robbins
  - Brian Shepard
  - David Klassen
- **Other Attendees**
  - Matthew Weiss
  - Mat Marolla