

## **OPTN Policy Oversight Committee**

### **Meeting Summary**

**May 20, 2020**

**Conference Call**

**Alexandra Glazier, JD, Chair**

**Nicole Turgeon, MD, Vice Chair**

### **Introduction**

The Policy Oversight Committee (POC) met via Citrix GoTo teleconference on 05/20/2020 to discuss the following agenda items:

1. Strategic Policy Priorities: Continuous Distribution
2. Strategic Policy Priorities: Efficient Placement
3. Strategic Policy Priorities: Multi-organ
4. Policy Portfolio and Project Prioritization
5. August 2020 Public Comment Preview
6. New Project Approval
7. Other Committee Business

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

### **1. Strategic Policy Priorities: Continuous Distribution**

The Vice Chair of the Thoracic Committee presented an update on the continuous distribution of lungs project, and UNOS staff discussed POC members' results from the analytical hierarchy process (AHP) prioritization exercise associated with this project. The Vice Chair of the Kidney Committee presented an update on the continuous distribution of kidneys project.

#### Summary of discussion:

#### *Continuous Distribution of Lungs*

There were no questions or comments on this project.

#### *POC Member Results from the AHP Exercise*

The Chair said it is not surprising that people placed a higher priority on equity over utility because the exercise poses questions at the level of an individual candidate. However, the exercise does not get at the overall result in a system of scarcity, where the end result is that there are not enough organs for everyone, even in the top priorities (e.g. the most medically urgent). UNOS staff agreed to take this question back to the consultant team supporting the AHP exercise to see if there is a better way to pose these questions, given that the typical use case for AHP involves evaluating individual projects with the intent of achieving the goals of a larger system. The Chair said if the question posed was whether it is more or less important for the overall system to save the most lives possible, the results might show a different spread between equity and utility. Another member agreed that the whole leads to a different conclusion than the sum of the individually weighted parts.

A member asked if the AHP exercise replaces public comment. UNOS staff explained that the exercise is a different way to get input on the project earlier in the process. The AHP exercise does not replace

public comment for the policy proposal, though the exercise will likely be released to the public during public comment this fall. The Chair noted that it is the responsibility of the OPTN to clearly articulate the basis for a policy proposal in terms of how it ties back to the requirements of the OPTN Final Rule, and the AHP exercise is a tool to help clarify those concepts.

A member asked whether collecting data on candidates not on the waitlist is something that the OPTN or UNOS is pursuing in order to improve patient access, noting that this has previously not been considered to be within the scope of OPTN work. UNOS staff explained that the OPTN focuses on access to transplant for those who are already on the waiting list, and the patient access attributes included in the continuous distribution framework are centered around those candidates.

The Chair asked about the Thoracic Committee's experience with the AHP exercise tool. The Thoracic Committee Vice Chair said it has been helpful in thinking about different perspectives on each of these issues and how the committee moves forward with the community on this project.

A member asked how the pediatric priority fits in with the other attributes, since it spans several categories, including equity, utility, and reducing biological disadvantages in patient access. UNOS staff explained that while pediatric priority is both a utility and an equity measure, and there are lots of different reasons why pediatric candidates are prioritized, pediatric priority was included under equity for simplicity instead of trying to split up pediatric priority between the equity and utility measures.

The Chair said that it is really important for the POC to feel comfortable with how the OPTN moves forward with continuous distribution and the tools that the OPTN is using since this remains a top strategic policy priority, and all of the other organs will subsequently move through this process.

A member asked how nimble this process is, for example, for situations like the COVID-19 pandemic, which affects travel, efficiency and utility. The member asked if safety should be another attribute. The Chair noted that these are frameworks for developing policy projects, and the advantage of a framework like continuous distribution is the potential for it to be a dynamic model that can adapt to situations like the pandemic. This framework should be more responsive than the current framework since different factors can be titrated up or down. Safety is factored into attributes like travel efficiency and post-transplant survival, and the attributes and their relative weights that can change over time. UNOS staff explained that by compartmentalizing the different factors that feed into allocation, it will be easier to update each individual attribute over time.

A member noted the gap in priority between prior living donors and pediatrics and asked if there is a way to account for that gap since waiting list numbers might go up as a result of COVID-19. The member asked what would be accurate to convey to living donors regarding their priority for an organ in the future, if needed. UNOS staff explained that the weights of different attributes have not yet been finalized. Based on current data, there are not many prior living donors that need lungs, but at this point the Thoracic Committee has opted to give priority for all living donors.

UNOS staff explained that the OPTN is considering renaming the continuous distribution framework. The Chair said that the name probably will not matter once the OPTN has established a consistent framework across all organs because then it will just be the standard allocation policy. UNOS staff said to expect an email in the next day requesting input in relation to the re-branding effort.

### *Continuous Distribution of Kidneys*

The Chair asked how the Kidney Committee is feeling about this project, given that the Committee expressed both excitement and trepidation about proceeding relatively early in the sequencing for continuous distribution after wrapping up another large project related to geography. The Vice Chair of the Kidney Committee (Kidney VC) said that this project has not been opened up for broad comment yet

but some of the trepidation was based on concern that the geography project was not pulling to a close, and that the Kidney Committee had just updated the allocation system. However, the Kidney VC feels that the committee has done a good job of communicating that the geography project was always a work in progress moving towards continuous distribution. The Kidney VC said that the committee will be more ready to take on continuous distribution now that they have implementation dates for the geography project.

The Chair asked if there is anything the POC can do at this point to assist the Kidney Committee with the project map. The Kidney VC said that feedback would be helpful, as well as the recognition that there are a lot of unknowns, noting that it would be helpful for committee leaders to build some general community support around continuous distribution.

## **2. Strategic Policy Priorities: Efficient Placement**

The Chair presented an update on new workgroups sponsored by POC focused on three topics: provisional yes, local recovery, and biopsy practices. These workgroups were established in response to a resolution passed at the December 2019 OPTN Board meeting that directed the POC to evaluate the potential for a collection of new projects related to efficient placement. The workgroups will make a recommendation to POC as to whether the OPTN should pursue a project in these topics areas.

### Summary of discussion:

A member asked if the local recovery workgroup could have something added to their charter related to the finances of local recovery and consistency of charges across organ procurement organizations (OPOs). The Chair said that payment issues would not be included in the charter because the workgroup is focused on the efficiency of the process to arrange for local recovery as well as expectations for local recovery. The Chair agreed that local recovery payment practices is an area that needs work but that it does not fit under the strategic policy priorities of the OPTN. The Chair noted that OPO practices regarding local recovery surgeon payment and billing are highly variable. The OPTN does not have authority over OPO financial or business practices so the POC would have to think further about how this issue could be addressed, and whether it would be through UNOS or other stakeholder organizations. One approach could be an education effort as surgeons are having more organs recovered in different areas and are learning about different practices. The UNOS CEO agreed that this is out of the scope of the OPTN but there could be an opportunity to clarify practices. UNOS cannot set prices or fees for services but UNOS can consider other approaches to help in this area.

## **3. Strategic Policy Priorities: Multi-Organ**

The Vice Chair of the OPO Committee presented an update on the multi-organ allocation project. The Workgroup has held initial discussion on multi-organ allocation involving kidneys and sought confirmation from the POC that the Workgroup can move forward on those topics, since kidney multi-organ policies were originally sequenced later in the project timeline by the POC.

### Summary of discussion:

The Chair asked how the Workgroup received feedback from POC to focus on kidney. The OPO Vice Chair said that the smaller Workgroup received the feedback well and there will be additional discussion with the full Workgroup next week.

The Pediatrics Vice Chair asked if the Pediatric Committee could be involved in the project since there is concern that multi-organ policies may disadvantage pediatric candidates. The OPO Vice Chair confirmed that some of the Workgroup members have pediatric expertise and have provided great feedback.

The Vice Chair asked for more clarification on the Workgroup's kidney focus. The OPO Vice Chair said the Workgroup is focused on heart-kidney and lung-kidney, and noted that the project scope does not include the SLK (simultaneous liver-kidney). The Vice Chair asked if they are looking at the possibility of allocating to vulnerable populations, like pediatric kidney candidates or 100% CPRA candidates, rather than a multi-organ candidate, as that was another important question raised by the community. The OPO Vice Chair affirmed that the Workgroup is evaluating those questions and making sure that vulnerable populations are prioritized over multi-organ candidates with less medical urgency.

The Chair confirmed that the POC does not have any concerns about the Workgroup going out of sequence and focusing on kidney earlier in the project timeline.

#### **4. Policy Portfolio and Project Prioritization**

UNOS staff presented an overview of the current policy portfolio and led a discussion with POC on how to prioritize OPTN projects.

##### Summary of discussion:

UNOS staff asked POC what criteria members would recommend to define value in a policy project. The Chair noted that POC has typically focused on identifying priorities that can drive larger systematic change and have an impact across multiple organs, and clarified that this question is focused on how to prioritize projects at the committee level, outside of the strategic policy priority portfolio. The Chair noted that some committees, like Thoracic and Kidney, are generating huge volumes of ideas, and asked the POC for feedback on that. A member asked how old these ideas are. UNOS staff said that some of the ideas are a few years old and have not been worked on. If the POC identifies some criteria, then UNOS can apply those criteria to the existing ideas and evaluate if they should be brought forward.

A member asked if any of these projects will change in light of the COVID-19 pandemic, given that stakeholders have different mindsets and financial restraints. The Chair said that the POC can have the conversation about how priorities are changing in light of the COVID-19 pandemic, but thought that the pandemic does not change the POC's focus in terms of looking at long-term, high-value projects. UNOS staff agreed, noting that the goal is not to mechanize policy prioritization, since projects go through the POC so that the POC can provide a critical look at projects in light of current circumstances.

A member said that it would be helpful to know which ideas are truly active and which have been dormant for several years. UNOS staff offered to follow up with more information. Another member asked if the thoracic organ ideas will be split for the new Heart and Lung committees. UNOS staff affirmed that they will support this effort.

A member said it would be great if UNOS could be nimbler about considering ideas and moving on from ideas that are not worth pursuing, saying that the OPTN needs to be somewhat reactive to current times. UNOS staff agreed it is important to maintain the currency of the portfolio and not just let ideas die over time, but noted that no one wants to kill the ideas. The Chair said it is fine for the OPTN to have a large pool of ideas, and what matters is ensuring there is a good process for taking the ideas that should be projects while setting expectations that not every idea should become a project. The Chair said that the OPTN should be moving towards the most coordinated path possible to ensure work is being completed as a system instead of committee by committee. UNOS staff agreed, saying UNOS would appreciate feedback on how to standardize the process.

A member asked how many of these ideas move forward as projects that are implemented. The member asked if some committees are putting forward bad ideas, and whether the POC can help make them more effective, or if some committees are not being heard. The Chair suggested that UNOS look at the conversion rate from idea to actual project. The Chair said the POC should also consider

expectations regarding timing and sequencing, for example, if there are projects that were approved before the current process, and whether it makes sense for a committee to return to that project later. UNOS staff said that part of this effort will include clarifying the process for projects that have slowed.

UNOS staff asked if there are other cost elements that should be considered when prioritizing projects. Currently, UNOS looks at member fiscal impact and UNOS resource utilization (staff, hardware, travel and meetings, vendor) but does not necessarily take into account committee member time and expense. POC members did not offer additional suggestions.

UNOS staff asked the POC for feedback on using AHP to prioritize OPTN projects. The Chair agreed that this is the right approach, but noted that the POC is focused at the level of the whole system, and getting too granular with the prioritization of individual projects may lead the POC to lose the big picture. However, the Chair acknowledged the value of AHP and the opportunity it provides to assign values for project prioritization and keep the full portfolio in alignment. UNOS staff agreed, noting that use of these tools would be advisory to help the POC to look at the portfolio in different ways.

UNOS left the POC with the following process questions:

- Who establishes the criteria and who sets the relative ratings?
- When and how often are benefit and cost estimates revised?
- Should in-progress projects be suspended to achieve better overall portfolio benefit?

#### Next steps:

UNOS staff encouraged POC members to discuss this process with their committees and support staff and offered to share an update during upcoming POC meetings.

### **5. August 2020 Public Comment Preview**

Vice Chairs presented updates from their committees on the projects slated for public comment in August 2020:

- Enhancements to the National Liver Review Board (NLRB), Part Two (Liver Committee)
- Adult Heart Exception Review (Thoracic Committee)
- Pediatric Heart Guidance (Thoracic Committee)
- Updated Cohort for Calculation of the LAS (Thoracic Committee)
- Membership Requirements Revisions (Membership and Professional Standards Committee)
- Programming VCA (Vascularized Composite Allograft) Allocation in UNet<sup>SM</sup> (VCA Committee)
- Modify Data Collection on VCA Living Donors (VCA Committee)
- Update Policy 14 to Include Living VCA Donors (Living Donor Committee)
- Resource for Transplant Hospitals on Transplant Candidate Use of Social Media to Find Living Donors (Living Donor Committee)
- COVID Emergency Actions (Executive Committee)

#### Summary of discussion:

The Chair asked if the Liver Committee's proposal would be one proposal including both policy and non-policy components of the NLRB project. UNOS staff affirmed that the public comment proposal will have changes to policy, guidance, and guidelines, which is consistent with the Liver Committee's proposal that is going to the board for approval in June 2020.

Following the presentations on the heart guidance proposals, the Chair asked HRSA staff and UNOS staff if there are any concerns about the OPTN issuing guidance documents. UNOS staff said that HRSA considers this type of guidance to be an acceptable type of OPTN work. For any policy proposal,

including guidance documents, the OPTN must affirm their regulatory authority to issue the proposal, and the OPTN has the authority to prepare this guidance.

Following the presentation on proposed changes to membership requirements, the Chair noted that OPOs are required by law and regulation to be members of the OPTN, so the OPTN membership application is not really discretionary. The Chair asked if the public comment proposal aligns existing regulatory requirements with those of the OPTN. The MPSC Vice Chair affirmed that a major part of the proposal is to align membership requirements with current federal regulations and clinical practice.

Regarding the proposals related to living VCA donation, the Chair asked if there is anything unique to living uterus donors that differs from the standard approach for other living donors. The Living Donor Committee (LDC) Vice Chair affirmed that there were some specific requirements added for uterus donors, including psychosocial evaluation criteria, informed consent information, and medical evaluation requirements, noting that the changes are modest but directly relevant to uterus. The LDC Vice Chair noted that no specific ethical concerns were raised regarding this proposal.

Regarding the resource for transplant hospitals on candidate use of social media to find living donors, the Chair asked if there were any concerns with this proposal given that it had previously been held up by HRSA. UNOS staff explained that the LDC changed the name of the project from “guidance” to “resource” to reflect that it is not directive, based on HRSA’s feedback. HRSA’s concern was based not in the type of work but the authority, and UNOS is still working with HRSA on this proposal. The Chair said it raises the question whether a resource document needs to go through the OPTN public comment process. UNOS staff affirmed that is part of ongoing conversations with HRSA, and explained that since there has not been a delineation at this point for a committee-sponsored, OPTN-endorsed product, the decision for now is to release it for public comment. UNOS hopes to gain more clarity and consistency on this process. The Chair said it should not go both ways. If it is not policy or guidance, it should not have to go through the public comment process so that these products can be developed faster, released to the community faster, and updated more frequently. Another member agreed with the Chair that it would be better for the OPTN to release these products faster to respond to the patient community. The member is a living donor advocate and noted that the Ethics Committee has started another subcommittee entitled Facilitating Patient Navigation. The purpose of the subcommittee is to find out what resources would be useful from the patient perspective, with the idea that they could be delivered to the patient community quickly.

## **6. New Project Approval**

Members presented three new projects for the POC to consider for approval:

- Pediatric Heart Guidance (Thoracic Committee)
- Updating Median MELD at Transplant Calculation (Liver Committee)
- Sorting Within Liver Allocation Classifications (Liver Committee)

### Summary of discussion:

The Vice Chair of the Pediatric Committee expressed support for the Pediatric Heart Guidance project and said that the Pediatric Committee is pleased to be involved with this project.

The Chair expressed concerns regarding the projects proposed by the Liver Committee. The Vice Chair of the Liver Committee (Liver VC) explained that the two liver projects are separate but related, and primarily relate to exception candidates based on issues identified following implementation of the acuity circles liver allocation policy in February 2020. Some transplant programs have expressed concern that exception candidates with a lower MELD (Model for End Stage Liver Disease) score based on the transplant program’s MMat (Median MELD at Transplant) are disadvantaged relative to exception

candidates in close geographic proximity that have a higher MELD score based on their program's MMaT. The Liver Committee had thought that some of these centers may be able to pull organs from other locations but that may not be practical due to population density. The Liver VC said that it is possible that the MMaT scores will stabilize over time, but that may take a long time, if it occurs at all.

The Liver Committee considered increasing the size of the circle for calculating MMaT to 500 nautical miles (nm) for every program. This change smoothed out some of the disparity but did not solve the problem. The Liver Committee considered the idea of a national MMaT but rejected it because it would lead to inequitable allocation across the country. One approach is to assign every exception candidate a score of 22, and with candidates earning more points over time. Another approach is to assign the same MELD score to all exception candidates within a certain circle of distribution.

The second project idea is how to sort candidates within that circle since they would all be assigned the same MELD score. The Liver Committee does not want to return to the previous allocation system as they believe it would exacerbate geographic disparity. The Liver Committee is also considering where to place exception candidates relative to non-exception candidates with the same MELD score. The Liver VC noted that exception candidates have a much lower waitlist mortality relative to non-exception candidates. The Liver VC said that the median-MELD-minus-three policy and the 6-month pause for hepatocellular carcinoma (HCC) candidates help to mitigate those differences, but this is still an issue the Liver Committee plans to consider further.

The UNOS CEO asked the POC to provide feedback to help the Liver Committee. The UNOS CEO noted that the Liver Committee took one approach to try to give more candidates a more equal opportunity for transplant. Now the Liver Committee is wrestling with the possibility that candidates have different level of opportunity for particular organ offers, which is not necessarily the same thing. It is possible that the OPTN could go back and forth on projects like this, by trying to adjust the system for disparities at the candidate level and creating new disparities at the system level. The Liver VC said that a fundamental question is whether two people in the same circle with the same diagnosis should have two different scores based on the median MELD of their transplant programs.

A member said that the Liver Committee should consider situations where a candidate is listed at multiple transplant programs and therefore has the opportunity to get assigned multiple scores. The Liver VC said that gets back to people chasing the organs, since geography is dictating who will get the organ, and the Liver Committee is trying to avoid that.

The Chair expressed concern about how this project fits into the long-term move to continuous distribution. The Chair asked if the cost/benefit analysis warrant moving forward with this project at this time, and suggested that the Liver Committee consider that further before POC approves the project. The Liver VC said that addressing this issue fits with continuous distribution because it seeks to avoid the geographic issues described previously, and determine how people with the same diagnosis should be prioritized. The Liver VC said that this is a problem in areas with high population density and multiple transplant programs in a small area.

A member said that it seems like exception points should be scalable based on where the donor organ is offered, and asked if that was the point of this project. The Liver VC affirmed that the purpose is to assign the same score for the same diagnosis for everyone within some distance of the donor. The second project is focused on how to sort between those candidates. Previously, there was an escalator system in place. Exception candidates earned additional points over time, based on how long they were on the waiting list and how long they held an exception, and there were a number of tiebreakers in place. With the new system, where all exception candidates are assigned to a score of median MELD minus three, there are now lots of exception candidates with the same score and waiting time does not

really work as a tiebreaker. The Liver VC said that all exception candidates should be sorted by time at exception instead of time at MELD score.

A member asked whether the Liver VC was suggesting placing exception MELD candidates over true MELD candidates, or placing an exception MELD candidate who has had the exception for a longer time over another exception candidate. The Liver VC said it is controversial to say that non-exception candidates should always be placed over exception candidates score for score, but the other checks in place may allow the Committee to adjust the liver exception process so that all non-exception candidates are not automatically ranked over exception candidates. The Liver VC said that exception candidates have received too much priority historically and the Liver Committee is trying to balance this out through the median-MELD-minus-three approach and the 6-month pause for HCC candidates.

The Chair expressed concern about approving this project if it is side-stepping the larger issue of whether the exception scoring process is working appropriately. The Vice Chair asked about the Liver Committee's experience with acuity circles and the extent of this problem. The Liver VC said that acuity circles have not been in effect very long, but they received a formal complaint from a transplant program. Upon review, the Liver Committee discovered four other places in the country where this occurs. Some Liver Committee members recommended waiting to see how this plays out but other Liver Committee members recommended addressing this immediately. The Vice Chair recommended that the Liver Committee wait to gather some data from acuity circles before moving forward, because sometimes letting systems percolate helps to inform the process with more data. The Vice Chair said that reacting immediately may lead to policy approaches that have unintended consequences, and it may be better to think more broadly about how to handle liver allocation in a continuous distribution framework instead of addressing this one issue. The Liver VC said that the Liver Committee felt compelled to address this issue now based on concerns about fairness. The Chair noted that the acuity circles went into effect just before the COVID-19 pandemic so it may be worth waiting for more data as the situation might look quite different six months from now.

POC voted to approve all three projects:

- Pediatric Heart Guidance – 14 yes, 0 no, 0 abstain
- Updating Median MELD at Transplant Calculation – 12 yes, 2 no, 1 abstain
- Sorting Within Liver Allocation Classifications – 10 yes, 3 no, 2 abstain

#### Next steps:

The Chair asked that the Liver VC relay the POC's feedback and that the Liver Committee provide more information to the POC to discuss sequencing for the projects. The Chair also asked that the Liver Committee leadership narrow the scope of the project further.

### **7. Other Committee Business**

The Chair asked that POC members provide feedback on the meeting to the Chair, Vice Chair, or any of the UNOS support staff, and noted that the next meeting will be in June.

#### **Upcoming Meetings**

- June 25, 2020
- July 29, 2020