

**OPTN Policy Oversight Committee
Meeting Summary
November 5, 2020
Conference Call**

**Alexandra Glazier, JD, Chair
Nicole Turgeon, MD, Vice Chair**

Introduction

The Policy Oversight Committee (POC) met via Citrix GoTo teleconference on 11/05/2020 to discuss the following agenda items:

1. Vice Chairs: Feedback from Committees
2. Efficient Matching Recommendations
3. Multi-organ Project Sequencing
4. New Project
5. Evaluating Projects Post-Implementation
6. January 2021 Public Comment Preview

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

1. Vice Chairs: Feedback from Committees

The Vice Chairs (VCs) shared feedback from their committees related to project prioritization, the strategic policy priorities, and high priority project ideas.

Summary of discussion:

Project Prioritization

The Kidney Committee was disappointed that their pediatric project was put on hold but the Kidney VC said it is a good reminder that committee leadership should verify the priority for a project before proceeding. The Chair said it is always a judgment call to determine when to bring something to POC, since the committee has to do enough analysis to propose a solution. The POC VC said that one of the growing pains for POC is to figure out the review process when committees resume work on projects that were previously approved by POC but delayed. The kidney pediatric work was not reviewed early enough, so that is a learning experience for the POC and that feedback is appreciated. Fortunately, the kidney pediatric work was not all for naught since it will be useful moving forward.

The Pediatric Committee was also disappointed that the kidney pediatric project was put on hold. The Pediatric VC recommended that the committees contributing to these workgroups are brought into the discussions about how to categorize the projects within the strategic policy priorities. Sometimes it is not clear where a project fits in the policy priorities, and having the committees' buy-in when a project is deprioritized in terms of where it really fits in the policy priorities may help with understanding how a specific group's priorities can be part of, but not minimized by, the other priorities.

The Operations and Safety Committee (OSC) thought the committee had enough bandwidth to take on the organ packaging project. The Chair asked how the OSC felt about this project being pursued as a continuous improvement project instead of a policy project. The OSC was supportive and did not have concerns about the project prioritization, but members felt they could continue to help with this work.

Strategic Policy Priorities

Several committees expressed general support for the strategic policy priorities. The Transplant Administrators Committee (TAC) and the Transplant Coordinators Committee (TCC) appreciate being more involved in the policy development process in the early stages as workgroup members. The Ethics Committee is interested in being involved in the efficient matching projects on local recovery. The Organ Procurement Organization (OPO) Committee is focused on multi-organ transplantation (MOT).

Continuous Distribution

The Lung, Kidney, and Pancreas Committees are working on continuous distribution allocation systems for their organs. The Kidney VC said the Kidney Committee is under the impression that they should develop a continuous distribution system primarily based on the attributes currently included in the kidney allocation system, and asked if it would be in the purview of the committee to remove attributes or make other changes. UNOS staff said the Lung Committee is incorporating changes in continuous distribution that are easy to include and will not slow down the progress of the project. UNOS staff recommended that if a change will add another cycle to the development of the project, that is something that should be put aside for future work.

The Ethics Committee is interested in working on an ethical analysis of continuous distribution. The Disease Transmission Advisory Committee (DTAC) suggested considering the regional variability in risk of donor-derived infections within continuous distribution. The Histocompatibility Committee (Histo) is working on strategies to help incorporate sensitization into continuous distribution.

High Priority Project Ideas

The Liver and Intestine Committee (Liver Committee) is interested in updating the Model for End Stage Liver Disease (MELD) score to address disparities based on sex, since women are disadvantaged by how creatinine factors into the current MELD score. The Vascularized Composite Allograft (VCA) Committee is focused on the project to program VCA in UNetSM, which has posed questions about how to allocate portions of limbs and flaps. The committee's next priority will be establishing membership requirements for uterus transplant programs.

2. Efficient Matching Recommendations

The Chair shared an overview of the efficient matching recommendations prioritized by the POC on 10/14/2020. This overview was presented to the OPTN Executive Committee (ExCom) on 10/20/2020.

Summary of discussion:

The Chair reported to the ExCom that these recommendations are directional, rather than detailed descriptions of what the projects might look like once they have been handed over to committees for further work. POC leadership provided some additional feedback to UNOS staff on project sequencing. Based on the feedback from the POC, increasing offer filters was the highest priority project idea as the community continues to shift to broader distribution, and this project should be sequenced with development of a dynamic match run. Developing a "conditional yes" option would be sequenced after those projects. Communication enhancements in DonorNet[®] would be sequenced with the project to add biopsy image sharing. The project to develop a minimum set of criteria for kidney biopsy would be sequenced with the development of a standardized pathology report. The pathology report would be managed through an implementation workgroup rather than as a policy project.

Next steps:

UNOS staff will map these recommendations to a calendar so the POC can assign work to committees. UNOS staff will schedule calls with committee chairs and workgroup leads to hand off the projects.

3. Multi-organ Project Sequencing

The OPO VC presented on the first phase of the MOT policy work, which is slated for public comment in January 2021. The Chair proposed a plan for the next phase of MOT policy work.

Summary of discussion:

Phase 1 of MOT Policy Work

The proposal includes a 500 nautical mile (nm) sharing threshold and medical criteria for heart-liver, lung-liver, heart-kidney, and lung-kidney allocation. A member asked which match run the OPO will follow for heart-liver candidates. The OPO VC said that OPOs would still have to run the heart match run first, so thoracic organs take priority. The POC VC said that when policy was developed for liver-kidney allocation, there was a problem with liver candidates pulling viable kidneys out of the kidney pool, which is why the OPTN implemented a liver-kidney safety net. The POC VC said the same approach should be considered for heart-kidney.

A member said that the kidneys that are pulled for MOT are also among the better quality kidneys with a lower Kidney Donor Profile Index (KDPI). It may be appropriate to pull in the Ethics Committee and other stakeholders to think about how quality matching factors in to MOT allocation, since that has been a big concern in the nephrology community. MOT candidates generally have increased risk of mortality and morbidity, and they are pulling higher quality kidneys. The Ethics Committee wrote a white paper on this topic. The POC VC agreed these are important points that the OPTN will need to address, as well as eligibility criteria and impact on vulnerable populations. The Chair said that all of that work is part of the next phase of MOT work.

Next Phase of MOT Policy Work

The Chair said that the next phase of MOT work also needs to include transition plans for organs as they shift to continuous distribution and other organs remain in their current systems. The Chair shared a chart outlining how project work on eligibility criteria and safety nets could follow the work on continuous distribution. For example, since lung, kidney, and pancreas are the first organs to shift to continuous distribution, members from those committees would work together to consider how to handle MOT for those organs in a continuous distribution framework. A member recommended having the appropriate people from all the relevant committees involved from the beginning to streamline the work. The Chair was envisioning a series of separate workgroups rather than one overall separate steering group but asked for feedback for the POC. The Chair asked if it would make sense for members of the Heart and VCA Committees to be involved in the MOT work for lung, kidney, and pancreas.

A member said that the MOT work could collide with other work, particularly if the Phase 1 changes will not work in continuous distribution. The Chair said that is why the work will be sequenced so that the timing aligns with continuous distribution. The member said that it sounds like the current workgroup decided that OPOs should allocate based off of one list, meaning that all heart combinations would be allocated off of the heart list, instead of creating new lists, like the current kidney-pancreas list and liver-intestine list that are totally separate. The OPO VC explained that some of the allocation schemes will depend in part on the criteria developed by the Phase 1 workgroup. For example, before an OPO allocates a heart-liver to a candidate at a status lower than a status 4, the liver would first be offered to someone who urgently needs a liver alone. The workgroup focused on clarifying existing policy because from an OPO perspective, there are no rules or regulations. A member asked if the concern is more about a potential conflict of principles in terms of how organs are prioritized, or an inevitable conflict of how to manage scarce resources. The OPO VC said the next phase should iron out more of those questions, but in the interim, the workgroup felt that OPOs need some sort of guidelines.

The Chair said the OPTN does need to figure out a way to do this work that will sort through those priorities. The Chair noted that the concept of having organ-specific workgroups is supported by the POC, and said that the OPTN should think about MOT as globally as possible so that any guiding principles can be identified early and applied across organs. It will be important for VCs to share this information with the organ committees since this work will not be the sole responsibility of the OPO Committee moving forward. The OPO VC said the Phase 1 workgroup did have representatives from all of the organ committees, which worked well, and it would make sense to have similar, smaller workgroups to work through the policy details moving forward.

A member asked if the MOT work will consider guidance for backup and reallocation of organs from MOT candidates. The OPO VC said the workgroup had some recommendations for backups but thought that might fit better in the next phase of work. It is still important to have strong back-ups for MOT candidates, and OPOs should be doing that now. The Chair suggested providing some brief guidance to accompany this policy. A member suggested that the guidance clarify what to do when there are different transplant centers advocating for their patients. Another member suggested guidance or best practices for organ retrieval teams, for example, what to do if a thoracic team travels to get a liver and a lung, but does not have anyone to recover the liver.

Next steps:

The Chair suggested that the Phase 1 workgroup work on best practices while the MOT proposal goes through public comment. UNOS staff will establish workgroups to carry out the next phase of the MOT work in conjunction with continuous distribution.

4. New Project

The POC considered a new project from the Heart Committee entitled *Reporting Immediate Graft Dysfunction in Heart Transplant Recipients*.

Summary of discussion:

The purpose of the project is to collect data to better identify primary graft dysfunction in heart transplant recipients. The Heart Committee is proposing a two-phase approach. For Phase 1, the Committee would submit a request for information for public comment in January 2021 to identify the appropriate data. In Phase 2, the committee would submit a data collection proposal.

The project aligns with the strategic plan goal to improve waitlisted patient, living donor, and transplant recipient outcomes, and does not directly align with the strategic policy priorities. However, the Heart VC said this project will help inform continuous distribution. It also ties to efficient matching in that it will help identify futile transplants or avoid allocating donors where there is a very high primary graft dysfunction. The Chair said the efficient matching policy priority is more focused on process points that increase utilization. The project is small in terms of resource estimates, and the timing makes sense since the committee has a window of time before starting work on continuous distribution of hearts.

The Liver VC agreed that the project impacts utilization because if it is possible to identify patients who should not get a heart, then that heart can go to someone who can benefit from it. The Liver VC asked if primary graft dysfunction is more of a recipient problem or a donor problem for heart, since for liver, it is usually more of a patient selection problem than an issue with the organ. The Heart VC said it comes down to donor-recipient matching. For example, higher ischemic time for an older donor would not be a good decision, but right now those decisions are subjective. The Liver VC said the Heart Committee could probably identify some recipient factors that contribute to this. The Heart VC agreed and said the goal is also to clarify the definition for primary graft dysfunction. The Kidney VC said it is simpler for kidney since their graft dysfunction definitions are based on re-initiation of dialysis.

The POC voted to approve the project (19-yes, 0-no, 0-abstain).

Next steps:

The ExCom will consider the project for approval during their meeting on 12/6/2020.

5. Evaluating Projects Post-Implementation

The Chair explained that the POC's charter includes assessing the impact of implemented policy, but the POC has not done a lot of work in this area. The POC should not duplicate the work happening at the committee level, but should consider how the POC can add value in post-implementation evaluation.

Summary of discussion:

A member recommended that the POC identify the information that should be reported back to POC post-implementation when a project comes to the POC for approval. The Kidney VC recommended that committees also review post implementation monitoring as they embark on new projects to make sure that the reports are used to inform future work. For example, the Kidney VC has been reviewing monitoring of the kidney allocation system (KAS) to see if it was successful in reducing disparities so the committee can build on that in continuous distribution. A member said the POC should also reflect on why a project did not achieve intended goals, and what the OPTN should do differently moving forward.

The UNOS CEO reiterated that the POC should not repeat what the committees are doing. The POC could think more about how committees are approaching projects in terms of the philosophies or ethics underpinning how policies are created. For example, the details of how the MELD score is calculated may not be relevant to the rest of the POC, but if the Liver Committee chooses to heavily prioritize access over post-transplant outcomes in the MELD score, that is an area where the OPTN should probably be more consistent across organs. The discussion at the POC should be more about how the committee thought about the problem when developing the proposal. If a couple of committees have made decisions for their organs, the POC should consider if those decisions should apply to other organs, like how policies address pediatric candidates. The implementation of circles in organ allocation is another example where the end result is a bit different for each of the organs. During that process, the OPTN did not have a lot of conversations across organs about the best way to do this, but the POC could facilitate those conversations in the future.

The Chair said some of this discussion should be had up front rather than in post-implementation review. Ideally, the POC should have consistent principles when the projects are approved. The UNOS CEO agreed, but this framework could be helpful to start some of these conversations. For example, a circle framework was implemented in lung allocation prior to other organs, and it may have been helpful if they had shared their experience with the other organ committees. The Liver VC agreed that some best practices should be shared across organs, like safety nets and review boards.

Next steps:

The Chair asked POC members to send ideas prior to the next meeting about topics for discussion.

6. January 2021 Public Comment Preview

The Vice Chairs presented proposals slated for public comment in January 2021.

Summary of discussion:

The following proposals were discussed earlier in the meeting:

- Clarification of Multi-Organ Allocation Policy (OPO Committee) – Phase 1 of MOT work
- Reporting Immediate Graft Dysfunction in Heart Transplant Recipients (Heart Committee)

The POC heard presentations on the following proposals:

- Data Collection to Assess Socioeconomic Status & Access to Transplant (Minority Affairs Committee)
- Revision of General Considerations in Assessment for Transplant Candidacy (Ethics Committee)
- 2021-2024 OPTN Strategic Plan (ExCom)
- Required Reporting of Donor HLA Typing Changes (Histocompatibility Committee)
- Updating Median MELD at Transplant Calculation & Sorting Within Liver Allocation Classifications (Liver Committee)
- Updating National Liver Review Board Guidance Documents and Policy Clarifications (Liver Committee)
- Membership Requirements Revisions (Membership and Professional Standards Committee)
- Review Deceased Donor Registration Form (OPO Committee)

Data Collection to Assess Socioeconomic Status & Access to Transplant (Minority Affairs Committee)

The Minority Affairs Committee (MAC) VC explained that this proposal would add two data fields to the Transplant Candidate Registration (TCR): annual household income range and household size. These data fields would be optional, based on concerns raised during the winter 2020 public comment cycle. To alleviate concerns about how the data would be used, the MAC could modify the proposed data collection on salary to ask if a patient is above or below the poverty line.

The Chair suggested that MAC run a pilot to demonstrate how the data would be useful, rather than sending the proposal out for public comment again without a lot of changes, since it was heavily criticized the first time. It would be more difficult for the MAC to get the project off the ground if the proposal was released for public comment again and received the same negative response. Launching the data collection as a pilot would allow the MAC to generate some proof of concept about whether or not it really is difficult to collect this data, and to identify any barriers so it could be scaled further. A pilot may also help validate whether any proxies for this data would be useful. The Chair asked the POC for other ideas to support the MAC's work in getting more data on disparity and access that would avoid going through public comment again.

A member said that a regional demonstration project in areas where this might be a big problem, like in the Southeast, might be helpful. The Chair asked if there is a difference between a pilot and a demonstration project. UNOS staff explained that there is a demonstration project supported by a variance that went through policy, but voluntary data collection could be managed as a pilot without public comment. A member said it is possible that some programs are already collecting this data, perhaps as part of a Medicaid innovation project.

A member expressed concern about the bias of data not reported, and asked if it would be possible to get information from programs who choose not to participate as to why they are not participating. A member was concerned that a pilot might not provide enough data to do meaningful statistical analysis. The member was not sure how many hospitals would volunteer to do extra work when they are already overwhelmed. The MAC VC said that the proposal will also allow an opt-out option for programs to indicate if a patient did not respond to the questions regarding salary. The Chair said that if the POC does not recommend sending this proposal out for public comment, then the POC should have that conversation now. The MAC VC said there may be more momentum behind this proposal now if this were to go out for public comment again, but agreed to share this feedback with the MAC.

Revision of General Considerations in Assessment for Transplant Candidacy (Ethics Committee)

A member asked if inconsistency has led to varying access among specific populations, and whether this proposal is focused on racial inequities or consistency across the board. The Ethics VC said the guidance is more focused on consistency across the board, but the committee could build on this work. A member asked how granular the proposal will be. The Ethics VC said that the guidance is written in a way to encourage people to keep an open mind about transplant candidacy, rather than being narrowly proscriptive or prescriptive, or overly didactic.

The Chair said the project seems to fall within the scope of the OPTN's authority but asked if UNOS anticipates any concerns about this proposal going to public comment. UNOS staff submitted an analysis to HRSA on OPTN authority under the National Organ Transplant Act (NOTA) and the Final Rule to pursue this project, since ethics projects are receiving additional scrutiny from HRSA under the new OPTN contract. UNOS staff has not heard back from HRSA, so UNOS is prepared to move the proposal forward to public comment absent any other concerns. HRSA staff said they are reviewing the authority statement and will try to provide a response soon.

Required Reporting of Donor HLA Typing Changes (Histocompatibility Committee)

The Histo VC explained that the committee is trying to avoid human leukocyte antigen (HLA) typing errors, so this proposal would help communicate any sort of discrepancy. A member asked if there is a way to add a notification on the match run, before more offers are made, if there is a change in donor HLA typing in the middle of allocation. The Histo VC said that the committee would like for the match to be re-run any time there are HLA changes, but the committee was concerned about the unintended consequences of making this a policy requirement. The Chair said there are some efficiency concerns from the OPO perspective and suggested that the public comment document discuss these issues and possible options for addressing them. A member asked if the proposal would include programming to acknowledge receipt of notifications. The Histo VC was not sure if this would be included.

The OPO VC expressed support for the project and said it is long overdue. A member said it may make sense to identify some metrics to evaluate this issue. The Chair agreed that the Histo Committee should have a plan for post-implementation review that could look at these data. The Histo VC said that it is important to the committee to understand why and how mistakes are being made and how to avoid them. Members discussed incorporating the programming changes into the dynamic match run. The Histo VC said that would be very helpful, especially for thoracic organs, since there is no requirement to do HLA typing prior to running a match for those organs.

Updating Median MELD at Transplant Calculation & Sorting Within Liver Allocation Classifications (Liver & Intestine Committee)

The Liver Committee is combining two projects in one proposal: *Updating Median MELD at Transplant Calculation* and *Sorting within Liver Allocation Classifications*. Median MELD at Transplant (MMA_T) is calculated around a transplant program, so exception candidates listed at programs geographically located within the same circle of allocation could have different scores on the same match run. The other issue is how to sort exception candidates within classifications, and the committee proposes ranking exception candidates by time since submission of earliest approved exception and lab candidates by time at current score or higher. The proposal will rank lab candidates ahead of exception candidates in the same classification when they have the same MELD or Pediatric End-Stage Liver Disease (PELD) score and blood type compatibility.

The Chair noted that differential in MMA_T in part relates to geographic disparities that were intended to be addressed in the liver allocation policy that went into effect in February. The Chair asked if this policy

has been in effect long enough for the committee to know that a correction through policy is necessary, or if this is something that is likely to even out over time. The Chair asked if it is important to address this now, or if it would be better addressed in continuous distribution. The Liver VC said it would be hard to prove the geographic disparities even with several years of data, because surgeon behavior helps to mitigate the problem. For example, if a surgeon sees that offers are declining, then the surgeon will be more aggressive in their offer acceptance practices, but that does not mean that it is fair for one program to always have to accept lower quality livers. It does not appear that this issue will even out over time as it is more of an issue of fairness and equity than utility.

The Chair asked if there will be modeling data in the public comment proposal to explain how the proposal will increase fairness. The Liver VC explained that the geographic radius used to calculate MMat for the donor hospital would start at 150 nm, and if there were at least 10 transplant events with a MELD score in the last year and at least two transplant programs within that circle, then that circle would be used. If those criteria were not satisfied, then the circle would grow by 50 nm increments until the criteria were met. The committee evaluated different circle sizes but determined that 150 nm was the most appropriate because larger circles skewed the data. The Chair said it was strange to use a different radius than the circle used for allocation, and the public comment document should have substantive justification for changing the circle size. The Liver VC said the circle for calculating MMat has nothing to do with the acuity circle. The Chair said it does impact who gets priority in allocation.

The Pediatric VC asked how this would impact pediatric candidates. The Liver VC said the allocation will run the same way for pediatric candidates. The only difference is that all exception patients on the same match run will be assigned an exception score relative to the same MMat, since currently that varies. The pediatric representatives on the workgroup did not seem concerned about this change. A member said that proposals often say that there is no impact on pediatric candidates, but sometimes policies are inappropriately applied to pediatric patients, so the question is whether the impact on pediatrics has been considered appropriately. The Liver VC said that the proposal does not change median PELD at transplant (MPaT). The Pediatric VC suggested that the OPTN consider the impact on pediatric patients more broadly across projects. The Liver VC said that work on the PELD score is on the committee's radar. The Liver VC invited the members to follow up with the pediatric representatives on the workgroup to discuss any concerns. The Chair recommended making sure these concerns are addressed in the public comment document.

Membership Requirements Revisions (MPSC)

A member noted that one of the challenges with the pediatric membership requirements update was that surgeons needed letters from their fellowship directors, but some of the surgeons have been practicing for 30 years. The member asked how the MPSC will redefine currency, since some of the current requirements are not relevant. The MPSC VC acknowledged the concern and said that the committee is taking a hard look about whether those letters are really relevant and what should be required. The MPSC is trying to streamline the process and focus on requirements that will add value. If the letters are not adding value, then the MPSC is looking to replace it with something that is better.

Next steps:

The POC did not have questions or comments on the remaining proposals. The POC will review all of the proposals again in January 2021 and recommend to the Executive Committee whether the proposals should be approved for public comment.

Upcoming Meeting

- December 9, 2020

Attendance

- **Committee Members**
 - Alexandra Glazier, Chair
 - Nicole Turgeon, Vice Chair
 - Sandra Amaral
 - Marie Budev
 - Rocky Daly
 - Lara Danziger-Isakov
 - Alden Doyle
 - Garret Erdle
 - Andrew Flescher
 - Rachel Forbes
 - Heung Bae Kim
 - Sarah Konigsburg
 - John Lunz
 - Paulo Martins
 - Stacy McKean
 - Sumit Mohan
 - Martha Pavlakis
 - Emily Perito
 - James Pomposelli
 - Kurt Shutterly
 - Susan Zylicz
- **HRSA Representatives**
 - Marilyn Levi
 - Shannon Taitt
- **SRTR Staff**
 - Jon Snyder
- **UNOS Staff**
 - Brian Shepard, CEO
 - James Alcorn
 - Sally Aungier
 - Nicole Benjamin
 - Matt Cafarella
 - Craig Connors
 - Shannon Edwards
 - Chelsea Haynes
 - Robert Hunter
 - Courtney Jett
 - Lauren Mauk
 - Meghan McDermott
 - Eric Messick
 - Elizabeth Miller
 - Rebecca Murdock
 - Kelley Poff
 - Matt Prentice
 - Tina Rhoades

- Sharon Shepherd
- Leah Slife
- Susie Sprinson
- Kaitlin Swanner
- Susan Tlusty
- Kim Uccellini
- Ross Walton
- Amber Wilk