

**OPTN Executive Committee Meeting
Meeting Minutes
April 20, 2020
Teleconference**

**Dr. Maryl Johnson, MD, FACC, Chair
Dr. David Mulligan, MD, FACS, Vice Chair**

Introduction

The OPTN Executive Committee met via teleconference on April 20, 2020 to discuss the following agenda items:

1. Closed Session Criteria
2. OPTN Conflicts of Interest Policy and Procedure
3. POC Update: Recommended New Projects
4. Strategic Policy Priority Update: Efficient Matching
5. Proposed Response to HRSA Request for Public Comment
6. 2021-2024 Strategic Planning Process
7. Other Significant Items

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

1. Closed Session Criteria

The UNOS staff attorney reviewed criteria for closed sessions. Current procedures have been documented with no substantive changes and are presented for approval.

Summary of discussion:

Both due process and peer reviews are completed in closed sessions, as well as any other matters of privacy that aren't appropriate for an open public session where discretion should be used. None of the operational criteria are new. Staff should consult either the Board President or the Committee Chair for a final determination as to whether the session should be open or closed. The criteria are non-exhaustive and are meant to be informative and help to make the decision. When in doubt, error on the side of transparency, and the issue should be presented in an open meeting. The only people that should attend a closed-session meeting are people who are expressly permitted or expressly invited to be there; those who are actually on the committee, staff that are specifically needed to support that meeting, HRSA and HHS reps, and anyone who is expressly invited, such as a witness. A resolution slide was provided. The Executive Committee approved the closed session criteria with no opposition and no abstention.

2. OPTN Conflicts of Interest Policy and Procedures

The UNOS staff attorney presented language changes for the Conflict of Interest Policy and Procedure.

Summary of discussion:

The actual language of the Bylaws that will be presented to the Board was discussed. No changes have been suggested regarding the Conflict of Interest Policy and Procedure since the February meeting; however, cleanups were found and addressed so that standards are applied equally across all position

levels. The standard for what a conflict is, and that it would apply to all committee members, was added to the Committee section. The same process is to be adopted for determination of Conflict of Interest. That determination is to be assigned to the Chair of the Committee, rather than having a closed-session meeting of the Executive Committee. If the committee member further disputes whether they have a conflict, they can request a closed-session meeting of the Executive Committee for review. A slide of the resolution was provided. The motion was approved, with no opposition and no abstention. A flow chart was provided and reviewed to assist with conflict of interest identification. Positive feedback was received on the flow chart.

Next steps:

The Bylaw changes will be presented at the June 2020 full board meeting for a vote. Other operational changes in regard to collecting the actual conflict, storage, and making sure the committee members all disclose their conflicts on an annual basis the same way the board members do, will be added.

3. POC Update: Recommended New Projects

The Chair of the Policy Oversight Committee presented newly recommended projects for approval.

Summary of discussion:

The new projects that were presented included a revision of U.S. Public Health Service Increased Risk Criteria and programming VCA Allocations in UNet. Some delays are anticipated related to the pandemic. The first project is revisions of the Increased Risk Criteria, and they should meet the new revised PHS criteria. The revisions can be approved in anticipation of the release of new guidelines, so that work can commence immediately upon release of the new guidelines. The second project is a VCA project related to allocation programming. This work should be integrated into UNet without further delay, and it is a necessary piece that needs to move forward. No questions or concerns were expressed.

A request was made for improved educational and informational material to be presented with the Increase Risk Criteria for pediatric parents, which will be addressed further offline.

The motion for both projects was approved without opposition or abstention.

4. Strategic Policy Priority Update: Efficient Matching

The Chair of the Policy Oversight Committee provided an update on the Efficient Placement projects that resulted from a board member proposal at the December board meeting.

Summary of discussion:

Three strategic policy priorities are going on, one of which is in regard to efficient matching. In alignment with that priority, a previous resolution had provided a number of ideas. All of which really fit well within the portfolio of work that this strategic policy priority is focused on. The directive was that the POC needed to evaluate the following ideas. Some of these ideas were already under way as possible projects, so those were moved forward in terms of value and priority. Specific areas were prioritized according to policy or guidance projects, non-policy projects, and then ideas to further evaluate. The POC is forming workgroups to evaluate the "provisional yes," and is helping to develop that project. Guidelines and policy development areas are possibilities. Ways to provide more clarity on the expectations when there is a "provisional yes," are also possibilities, as to ensure the most efficient process possible for OPOs and transplant programs.

The other two workgroups are more in the evaluation stage, one of which is in regard to local recovery. The need for efficient matching has been highlighted in the COVID environment, due to its challenging

conditions. While challenging conditions are a normal day-to-day occurrence, these pieces and ideas are being amplified in today's environment but are necessary given the especially broader distribution. There should be no mandate with regard to local recovery, but rather potential guidelines and policy development to provide clarity on the expectations if there is to be local recovery, and how that could be orchestrated most efficiently for the whole system, rather than everyone having their own series of expectations which are not aligned, or even in conflict. That project is in the beginning stage of evaluation. There has not been approval of any new project in that regard, but taking the board resolution, a workgroup will be formed. The other workgroup is biopsy requests. There is a really wide range of practice on biopsy requests both for liver and kidney, and those have significant implications to the efficiency of the system running as smoothly as possible at the time of allocation. An evaluation is needed to determine what could possibly be done there, or if that is a project that would be doable and add value.

Workgroups are being put together and committees have been identified that would be instrumental in making sure that ideas are fully evaluated. Possible solutions should take into account the wide range of interests that are implicated for each of these and should be moved forward. Many committees are involved in all of these workgroups, which means it's a lot of work. The POC wants to help sequence this by taking a look at the other work that these committees are focused on and ensuring that the work plan can be spaced out to maximize the ability to accomplish all this, without overloading those committees. The Policy Oversight Committee is in the process of sorting that all out. There is clear support for these last two being on the new projects development track. The POC is expecting the workgroup for the "provisional yes" to result in a new project proposal. Another that didn't need a workgroup, but should be set in motion soon, is the idea of trying to track some performance on backup centers that end up turning down offers. More data is needed to fully understand this picture. Further information should be available by the June board meeting.

Positive feedback was received on the projects, along with a request that new technology be considered for inclusion in these projects, especially the biopsies. The Histo Committee is to identify a couple of representatives to be part of that particular workgroup. Pulsatile perfusion and Ex vivo perfusion to be visited further down the line by the Policy Oversight Committee. New Project Development to look at policy language and performance, and the tracking of backup centers who decline offers.

5. Proposed Response to HRSA Request for Public Comment

Public comment was elicited for the changes in the guidelines for living organ donation by the UNOS representative.

Summary of discussion:

The notice that was released was a follow-up to what was discussed in February, which added lost wages, childcare, and elder care expenses as eligible non-medical expenses covered by the National Living Donor Assistance Program. In that notice, the income eligibility guidelines for the program were to be expanded with three updates. The household income eligibility threshold was to increase to 350% of the HHS poverty guidelines, versus the current 300%. The second proposed change is to clarify the use of existing preference categories in relation to the proposed income eligibility threshold. The proposed clarification is that applicants would be chosen primarily from the existing Preference Category 1, and other current Preference Categories will be considered as budget allows. The third proposed change would allow the program to reimburse eligible non-directed donors. Currently, the program does not allow for reimbursement without having an identified recipient. The Living Donor Committee and the Patient Affairs Committee leadership support increasing the household eligibility

threshold; however, they endorse the Advisory Committee on Organ Transplantation's recommendation to increase the threshold to 500% of the federal poverty limit.

In regard to the second feedback item, the committees believe there should be less emphasis on the recipient's income when determining a donor's eligibility. The Committees also recommend that there should be special consideration for donors and recipients relying on the same household income, such as spouse-to-spouse, or parent-to-child donation, as well as special consideration for donors serving as the recipient's caregiver. Lastly, the committees support expanding eligibility to non-directed donors.

After a discussion, the request for adult donor to a pediatric recipient was added specifically to the second proposed change. No further questions or concerns were presented. The motion was approved with no oppositions and no abstentions with the above noted change and clerical repairs.

6. 2021-2024 Strategic Planning Process

The OPTN Executive Director provided the status of the current plan as a thumbnail presentation. A report will be produced that includes metrics for the June board meeting. The structure of the plan, the calendar, and what is hoped to be accomplished in the June board meeting step were discussed.

Data summary:

The NOTA statutory requirements and the OPTN Final Rule were reviewed to ensure that appropriate authority is had for the projects that are chosen and that plans have been indicated for fulfilling all of the requirements that exist in NOTA and the Final Rule.

Summary of discussion:

The projects that were in the OPTN plan are organized around five key goals: increasing the number of transplants; making transplants more equitable, improving outcomes, making transplants more efficient and safer. With the current status being two years into the plan, metrics will be included in the formal report. The number of transplants has certainly gone up. New tools have been developed for offer filters that will speed the match process. Some collaborative improvement work has been done and is the basis for future work in that area. The metrics have been discussed and evaluated extensively, and there have been no new proposals from the MPSC, but the discussions and sharing information about effective practices is an ongoing activity. There is a project underway to change the dropdown menu for refusal reasons that should help make it easier to look back and learn about reasons for organ turn-downs.

Under the equity goal, there's a series of projects going on and a schedule for projects that started with the ethics and multi-organ transplant. There has been a lot of policy work regarding geographic disparity and designing new geographic models for the allocations systems. The board and nominating committee have improved how their needs analysis is created and how members of the board and committees are recruited and appointed to ensure diversity in those. There has been a lot more discussion at regional meetings with explanations on how to get involved, how to be part of the committees, as well as how to run for the board.

There is an equity benchmark for every organ that is a trackable metric. Those metrics will be included in the report. Ways to collect additional data on vulnerable populations is currently being discussed and that was sent out for public comment. The feedback will be forthcoming.

Calculators and other tools are being looked at to assist with tracking outcomes. This is a challenging area to work with from a policy or systems perspective. With the increase in the number of transplants and with some of the work behind us on geographic issues, maybe this will be an opportunity to spend a

little more time in the future working on outcomes. Some of this is inherently more difficult because it is clinical, but there are opportunities that have not been fully explored.

There have been some HLA changes related to safety issues. Extensive work has been done talking to the community about how their peers evaluate them and making it clear to people that the MPSC is an improvement body, not a sanctioning body. Their goal is to help members improve their processes, not to simply assign blame or to assign consequences. Communication tools are being worked on to share safety events and other issues without identifying people who have come forward through peer review. Significant changes have been made in the two years of this strategic plan, about the safety portal and clarifying the information and segregating those types of events into different things and making that more useable information for members in the future.

The last of the five big goals is efficiency. Some of that information may be invisible to the UNet architecture; although, the speed at which new policies get implemented does have a very tangible impact. UNet is a 24/7 system and the ability to keep that up and running is still very high. Some changes have been made in policy development, as well as the way that those processes are moved through in recent years. The committee process is generally quicker. New ideas should not be held up for process reasons, only necessary evaluation steps. Significant progress has been made, and by the end of this year, 90% of all the data elements in UNet that are received electronically should be entered.

Those are the five big goals of the OPTN plan. For each of those, as the current plan was developed, and as the new plan is proposed and developed, there are four pieces to each of these. Beginning with one of the five key goals of the network, the core activities of the OPTN are described in delivering on that goal. There are items that are done well, that should be continued; whereas strategic plans in the past had been related to the new shiny object. A comprehensive picture of what the OPTN was to deliver was not presented because in the planning process the things that should be continued were taken for granted. Core activities are what should be started with. These activities are already done well and are intended to continue. New initiatives can then be added, those being additional items for development or improvement in the future. Metrics have been identified so that progress to each of these goals can be evaluated. The formal report to the board at the upcoming meeting will include those metrics.

Next steps:

Going forward, this is the discussion of the process and those five key goals. These goals have been adapted over the years. The current plan now presents a more integrated approach to living donation. Tweaks are made from year-to-year and plan-to-plan. All of the goals look very similar over the years and are mostly consistent, trying to achieve similar things year in and year out, but still have the ability to make tweaks. Those key goals should be described, and a brainstorming discussion should be had with the board. At the upcoming meeting, this discussion is designed to walk away with a thousand ideas, that might eventually go into a draft. There is a good chance that the upcoming board meeting will not be in-person, and alternative ways are being looked at. Board members will have an opportunity for input related to goals over the next three years. Between June and December board meetings, the Policy Oversight Committee will present first, because all other committees are represented on the POC. They can do some triage of the results of the brainstorm, for items that fit our purpose the most cleanly, and the most effective things to put into the strategic plan. Those items will then be brought back to the Executive Committee and shaped into a draft to be offered to the board in December. Feedback will be requested from the December board meeting. The Executive Committee will consider that feedback and make any further revisions necessary and put the plan out for public comment in next winter's round of regional meetings and public comment period. That feedback will be then considered, and a final three-year strategic plan will be submitted to the June 2021 board of directors meeting. One year from now, we'll have completed this process.

The five key goals are the highest level of organization for the strategic plan. Feedback from the committee is requested. Goals do not need to be approved officially today, but if there are other big goals, starting that discussion will help to frame the discussion at the board meeting, and confirm that the right high-level issues are being addressed.

The feedback received indicated that the plan and goals presented are appropriate. One additional goal was presented to end the pediatric waitlist. Although a lofty goal, that concept is in the minds of many.

7. Other Significant Items

The appropriate type of discussion, or facilitation, is to be figured out for the upcoming board meeting, depending on whether the meeting is in person or virtually. Those items that are already geared up for will be described, as goals are more easily expanded and achieved when the skill set is matched. Those items can be delivered the easiest and therefore, the fastest and most efficiently. An attempt will be made to get all ideas on the table. There may be real or virtual breakout discussions. The right tools will be figured out to host this, regardless of what format the meeting occurs in.

Upcoming Meetings

- June, 2020
- December, 2020