

OPTN Executive Committee

Meeting Summary

January 16, 2020

Conference Call

Maryl Johnson, M.D., Chair

David Mulligan, M.D., FACS, Vice Chair

Introduction

The Executive Committee (EC) met via teleconference on 01/16/2020 to discuss the following agenda items:

1. Action Items
 - Projects Recommended for Spring 2020 Public Comment
 - New Project Recommended for Approval Requirements Revisions and Simplification (MPSC)
 - Special Public Comment Proposal: Access for Urgent Liver Candidates in Hawaii and Puerto Rico
2. Update on Board Resolution on Efficient Matching
3. OPTN Response to HRSA Request for Public Comment: Removing Financial Disincentives to Living Organ Donation
4. OPTN Response to CMS Request for Public Comment: OPO Conditions for Medicare/Medicaid Coverage: Revisions to the Outcome Measure Requirements for OPOs

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

1. Action Items

- Projects Recommended for Spring 2020 Public Comment

The Policy Oversight Committee (POC) Chair presented twelve public documents recommended by POC for EC approval. There are two guidance documents and one request for feedback.

For the data collection on uterus transplantation outcome (VCA) document, the POC requested that the document more explicitly ask for feedback related to institutional considerations such as whether IRB approval would be required, and regarding collection of data from non-transplant recipients and non-research subjects. Staff discussed with the POC that there had been review of the proposal with preliminary determination that limiting the data collection could be within OPTN's authority.

One committee member inquired as to data collection on the mothers, women who receive the uterus transplants. It was clarified that the routine data collection for transplant recipients will continue. This request for feedback was part of the outcomes assessment in regard to children born to uterus transplant recipients.

POC asked for clarity on the data collection on socioeconomic status and access to transplant (MAC) document. POC felt that since the data collection would be on listed candidates, the idea of "access to transplantation," was for access to organs for those that are already listed. Access

to transplantation starts with getting listed, but this data collection would be on patients who are not listed.

A staff member acknowledged that UNOS made the above clarification requests, and that the changes have been made. In addition, candidate and uterus recipient data collection is actually part of the VCA proposal that will go out for public comment.

A government representative laid out HRSA's three key concerns regarding the guidance document on the use of social media by individual transplant candidates to find living donors, the main one being the question of OPTN authority over limiting social media use. HRSA recommends withholding release of the document in its current form at this time. However, HRSA would be interested in working with the living donor community to further review and discuss possible ways to do something similar, but perhaps not directly through the OPTN in the future.

The Living Donor Committee representative responded that the document was meant for the donor hospital audience, and not to be used as a patient resource. The hope was that the document would be an educational resource to the transplant community to be used to help identify pros and cons of social media use in conversations between the hospital and patients.

The Executive Committee agreed to exclude the guidance document from the bloc vote at today's meeting. There were no questions from the Committee Members regarding any of the eleven remaining projects.

The Executive Committee voted to approve the release of eleven projects as presented for spring 2020 public comment, as recommended by the POC.

Results were as follows: 100% yes; 0% no; 0% abstained.

The Executive Committee voted to send the "Guidance for Transplant Hospitals on Transplant Candidate Use of Social Media to Find Living Donors" guidance document out for spring 2020 public comment, as recommended by the POC.

Results were as follows: 0% yes; 100% no; 0% abstained.

- New Project Recommended for Approval Requirements Revisions and Simplification (MPSC)

The POC Chair presented a new simplification project from the MPSC. Due to the new OPTN contract requiring review of the membership requirements bylaws, the MPSC found areas for improvement. The project was supported unanimously by POC.

The Executive Committee voted to approve the new project, "Membership Requirements Revisions and Simplification" from the MPSC, as recommended by the POC.

Results were as follows: 100% yes; 0% no; 0% abstained.

- Special Public Comment Proposal: Access for Urgent Liver Candidates in Hawaii and Puerto Rico

A representative from the Liver and Intestinal Organ Transplantation Committee presented to the Board proposal addresses the unique geography of the islands under acuity circles distribution, and would allow for status 1 and MELD/PELD of 37 or higher candidates in Hawaii and Puerto Rico to access organs prior to national offers of organs. It would add a unit of distribution to include a proportion of the contiguous states when the donor is on the mainland and the candidate is on the island. The added circles would be a 1,100 NM for candidates in Puerto Rico and a 2,400 NM circle for candidates in Hawaii, which would touch a sufficient

amount of mainland to service these urgent liver candidates. The numbers of patients with high priority in these transplant programs are small, so the number of organs being moved would be about one per year for Hawaii and perhaps slightly larger for Puerto Rico.

The Hawaii and Puerto Rico transplant community provided their input during the creation of the proposal, and it was approved unanimously by the Liver Committee. Public comment on the proposal thus far has been favorable. There were no questions from the EC members.

The Executive Committee voted to approve the policy changes as set forth regarding changes to allocation of livers and liver-intestines from non-DCD deceased donors and the closed variance for liver transplantation in Hawaii and Puerto Rico.

Results were as follows: 100% yes; 0% no; 0% abstained.

2. Update on Board Resolution on Efficient Matching

The POC Chair updated the EC on the proposal made at the last Board Meeting by Dr. Moritz, which was approved as a resolution to send to POC. It included ideas that fall within the efficient matching strategic policy priority. POC went through the resolution and had discussion on ways to direct the ideas in the resolution into the work plan for this strategic priority. POC asked leadership from the OPO and Operations and Safety Committees to consider the areas identified in the resolution and to report back to the POC on how the work will be facilitated and prioritized within their workflow. There were no questions from the Executive Committee Members.

3. OPTN Response to HRSA Request for Public Comment: Removing Financial Disincentives to Living Organ Donation

The Chair of the Living Donor Committee (LDC) presented on a rules proposal from HRSA in response to the Executive Order from July 2019 on advancing American kidney health. They propose a regulation allowing living organ donors to be reimbursed for related lost wages, child care expenses, and elder care expenses. The reimbursed expenses would be included in the current NLDAC process that offers financial support for living donors. The proposal does not change criteria eligibility based on income of donor and recipient. This will be separately addressed by HRSA in the future.

The LDC were asked to identify any other potential financial barriers to organ donation, including the challenges related to employer-provided medical insurance benefits while out of work during donation and recovery. These include foregone medical insurance benefits and loss-of-wage supplements funding medical insurance premiums provided by employer. The LDC is committed to helping in any effort that reduces financial barriers to donation. They will also continue to work on the response, which will be submitted on behalf of the OPTN, but approved by the Executive Committee.

One Committee Member asked if any of the other expenses needing reimbursement should be addressed in the proposal, other than the three areas identified. It was clarified that the three areas of expense were specifically identified by HRSA in the proposed rule change, and therefore, the response focuses on these three alone. The LDC is open to feedback from EC in asking for other considerations.

Next Steps:

The EC members may continue to provide feedback on the response to HRSA, as the letter is not due until 2/18/2020.

4. OPTN Response to CMS Request for Public Comment: OPO Conditions for Medicare/Medicaid Coverage: Revisions to the Outcome Measure Requirements for OPOs

The UNOS liaison provided a brief background. The EC approved a letter of response from OPTN to the first public comment in September 2019, followed by the CMS release of proposed changes to conditions for Medicaid/Medicare coverage (CfCs) for OPOs, and a second round of public comment. UNOS and OPTN stakeholders gathered the feedback to present to the EC today.

A UNOS Principal Research Scientist presented the two new metrics as proposed by CMS. They are the donation rate (donors divided by donor potential) and organ transplant rate (number of organs transplanted divided by donor potential). The donation rate redefines “donor” will change to “having at least one organ transplanted” or the “pancreas recovered for research or islet cells.” The donor potential data will be based on death certificate data from CDC with exclusions for causes of death that are absolute contraindications to donation, looking at in-hospital deaths of age less than 76.

With the two new metrics, no risk adjustment is proposed, there will be no flagging on one year of data, and methodology will compare the top 25% of OPOs to create a confidence interval for data for the OPO’s metric and if the confidence level is below the threshold, they would fail. Based on the flagging methodology on the 2017 data, 37 of the 58 OPOs would fail to make the measure.

Based on early feedback, the response will include the following:

- The need for a more comprehensive denominator for assessing converting a death to a donor is acknowledged.
- Reiteration of the OPTN’s original stance that death data with sufficient clinical data preferably from donor hospital EMRs should be used to assess donor potential for regulatory purposes.
- Risk adjustment is necessary to properly assess performance.
- The two metrics should measure distinctly different things
- One year of data may not be enough to truly assess the performance of an OPO due to the lack of year-over-year data.
- There should be discussion of appropriateness of proposed calculation of donor potential for regulatory purposes using these data.
- Concern over the proposed changes to the definition of “donor.”
- Concern over the flagging methodology.
- Request for clarity is needed on intended processes following decertification of 37 of 58 OPOs based on 2017 data.

The Executive Directors are continuing to create a list of answers to the requests noted in the proposal, but most fall within the feedback as summarized above.

The POC Chair agreed that an unadjusted metric is a concern because it is not accurate and because there is no defined process or system improvement agreement to improve performance. POC is aware SRTR has not been able to validate all the calculations thus far and there are some errors in the CMS data. They also agree with concerns over the decertification cycle being based on 1 year of data in a 4-year cycle, the lack of risk adjustment for age, the issue of not having zero-organ donors counted, and the lack of two clearly-independent metrics.

Next Steps:

The response document will be finalized and addressed at an additional Executive Committee call to be scheduled prior to the response due 2/21/2020.

Upcoming Meetings

- February 11th, 2020
- February 25th, 2020
- April 20, 2020 (Chicago, IL)