OPTN Executive Committee
Meeting Summary
September 16, 2019
Teleconference

Maryl Johnson, M.D., Chair
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Introduction

The Executive Committee (EC) met via teleconference on 09/16/2019 to discuss the following agenda items:

1. Committee Charter Rewrite Update
2. Response to Centers for Medicare & Medicaid Services (CMS) Proposed Rule Change to Organ Procurement Organizations (OPO) Conditions for Coverage
3. Response to Health and Human Services (HHS) Proposed Revisions to 2013 Public Health Service (PHS) Guidelines on Increased Risk Organs
4. Other Significant Items

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

1. Committee Charter Rewrite Update

The UNOS Director of Policy and Community Relations presented the Committee Charters Rewrite Project. The Committee's discussion today will be the initiation of the process of evaluating any necessary rewrites or updates to charters of the various OPTN committees, as well any necessary changes to the committees themselves. Several committees have already proposed adjustments to their charges. At the Board meeting in December, the Board will be asked to ratify or re-ratify all committee charters.

Summary of discussion:

The reason for this Rewrite Project is that under the new OPTN contract, which required updates to OPTN governance and operations, part of the plan was to go through and validate the committees and their charges. The contract was informed by past activities.

The Chair commented that there are some committees whose roles have changed, such as the Data Advisory Committee is a committee of the Board and will be reporting to the Board. In addition, Network Operations Oversight Committee is a newly-formed committee.

One Committee member noted there are three or so committees that have a public component to them. In a couple of cases, there are references to transplant recipients and donors with detailed descriptions of what those are in each case. The suggestion was made to gravitate towards the term "transplant public" or something similar to indicate anyone involved in transplant, a transplant stakeholder, who is not a professional. Perhaps some kind of glossary to create consistency of language is needed.

Next steps:

Committee members will share any further feedback on the project to the EC Chair or the UNOS Director of Policy and Community Relations.

2. Response to Centers for Medicare & Medicaid Services (CMS) Proposed Rule Change to Organ Procurement Organizations (OPO) Conditions for Coverage

A UNOS Principal Research Scientist presented the proposed rule change following the President's Executive Order in July and CMS's proposed changes to rules governing OPO outcome measures. The Executive Committee received the CMS rule change document and proposed response prior to the meeting for review.

Data summary:

CMS proposed changes include:

- Correction to outdated SRTR risk adjusters written out in regulation for their expected donation rate metric. In order to use that information, they recommend a one-time 12-month cycle for identifying OPOs that are failing that measure, rather than the usual 36-month cycle.
- Two new metrics would use inpatient deaths 75 years of age or younger with a cause of death consistent with organ donation.
    1. Donation metric - actual deceased numbers as a percent of inpatient deaths
    2. Yield Metric - actual organs transplanted as a percentage of inpatient deaths

OPTN's response to the rule changes include:

- The 36-month cycle should remain due to fluctuation in donor activity quarter to quarter. The 12-month cycle could potentially lead to OPOs being identified as failing the metric, which is more a fluctuation of the data as opposed to performance.
- CDC mortality data source is independent and publicly available, and would be beneficial for evaluating national trends and opportunities for improvement, but lack sufficient clinical detail, such as whether patients are ventilated during their terminal stays. There is also question of the timeliness of the data, with most recent data available being from 2017.
- OPTN recommends risk adjusted donation metric based on independently-reported ventilated death data that would be collected directly from donor hospital. The detailed data could then help to identify whether the candidate was actually a potential donor and be able to risk adjust properly for that.
- Use of the current Observed to Expected Yield metric produced by SRTR should continue.

OPTN's responses are in alignment with a draft of the Association of Organ Procurement Organization's (AOPO) comments. A letter of OPTN's response will be submitted to CMS once approved.

Summary of discussion:

The Chair requested feedback from EC members especially with OPO responsibilities or donor families is requested.

Recent edits to the response document oppose the 12-month metric due the variability in donor activity. There was agreement with this from an OPO perspective.

As a community, OPOs have long recognized the need for improved metrics. Patient-level hospital data is best, so there has been much discussion on the best way to obtain that. What is needed is a more timely denominator of ventilated deaths with granular data, but the defensibility of the new metrics will be crucial. The eligible donor metric is a subset of actual donors and is not a very good assessment of performance.

One comment was that the response should include that CMS request all donor hospitals be responsible for independently informing OPTN with the clinical detail of every ventilated patient death. Therefore, the responsibility to obtain the data would not lie solely on the OPTN. There are many OPOs that currently receive automated reports from donor hospitals with a defined data set, so this would be feasible.

From the AOPO perspective, AOPO asked CMS to clarify questions regarding use of the CDC data set. This is in alignment with the OPTN response, which focuses on four components of what is considered important for the data set that is used for the denominator of the donation rate. 1) Data should be independently reported. 2) Data source needs to be consistent and available throughout the country. 3) Data needs to be available in a timely manner. 4) Data needs to be sufficiently granular to develop the denominator in a way that will accurately assess donor potential.

From a donor family perspective, one comment was that donor families and recipients are the ones getting caught in the middle of different organizations gathering their own data from different sources, causing confusion. It is important that the voices of both donor families and recipients are being heard.

Scientific Registry of Transplant Recipients (SRTR) staff agreed with the concerns discussed today. SRTR will not be making its own response to CMS, but their concerns align with the OPTN response. There is an approved use agreement with the CDC for data and SRTR is waiting for the delivery of the files to begin analyses to support the discussion. Potential analyses with the CDC data are currently limited, so SRTR will look forward to being able to evaluate the data in more detail.

Following the discussion, the Committee agreed that the revised content of the response is understandable, especially with the consistency with the AOPO letter.

The Executive Committee voted to approve the principles within the response to CMS as drafted for submission on behalf of the OPTN.

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

The Committee authorized the letter as presented and following today's discussion, but will allow the Committee Chair to approve any necessary minor adjustments that do not change the sense of the letter.

3. Response to Health and Human Services (HHS) Proposed Revisions to 2013 Public Health Service (PHS) Guidelines on Increased Risk Organs

The Chairman of DTAC presented a brief background of the proposal. The Committee received the proposed changes document and proposed response prior to the meeting for review.

<u>Data summary:</u>

Proposed revisions include:

- All organ donors need to have HIV, hepatitis B, hepatitis C with serology, as well as nucleic acid test.
- Specific testing or decease donors will be done regardless of donor profile.

- Updated medical and social risk factors will go from 12 months to 30 days prior to recovery.
- Remove "increased risk" labeling.
- No specific requirement for individual specific informed consent and instead, information for those individuals with risk factors in the last 30 days will be incorporated into the main consent.

OPTN's response to the increased guideline changes include:

- Support removal of several PHS recommendations, particularly removal of risk factors including hemodialysis and hemodilution, as well as going from 12 months to 1 month.
- Oppose requirement of additional nucleic acid testing within 24 hours prior to organ recovery. Blood is drawn within 24 hours, but many physicians wait for the results, causing potential discrepancies leading to transplant delays or organ loss.
- Oppose living donor testing be repeated within the 7-day period prior to organ recovery, which would be difficult logistically, especially for those who must travel long distances to transplant centers. The current requirement is 30 days.
- There is support for the majority of the changes.
- There was a lack of clarity of data collection in terms of what risk factors were being used to classify a deceased donor as increased risk with the 2013 guidelines. Being able to track data in the future will guide future revisions.

Summary of discussion:

From the OPO perspective, the response is consistent with AOPO's comments, particularly the concern about duplicative testing without any benefit.

One Committee member has observed that patient families (especially families of pediatric patients) may respond to the guidelines with a different perspective of the risks than those patients who make the calculations for themselves. Perhaps increased education or different education would be required for these families. The DTAC Chair, a pediatrician, gave reassurance that education will be focused for different populations, including the pediatric population. Modeling has been done by the CDC showing that the risk for even the highest-risk category was infinitesimally low, so must be weighed in context of the true risk of dying on the waiting list. One case mentioned by one of the pediatric committees was that of a teenager who refused an organ following discussion of increased risk, who then did not did not survive to the next organ offer.

Regarding the opioid epidemic and first-time use of IV drugs, although current testing may not capture a new exposure, the emphasis should be on the fact that these diseases are currently very treatable compared to the risk of death while on the waiting list. One of the changes is to do universal testing of all recipients. There was agreement that particularly with deceased donors, the full history is not always known, so universal testing is critical post-transplant.

One Committee member asked what informed consent would then look like. The OPTN will have to help provide education and guidance once the PHS Guidelines come out. Some centers may opt to still have a separate informed consent, but at minimum, the main consent will include information on donor's increased risk factors and then they would have to do more education.

One comment was that relative risk in the context of how many thousands of transplants occurred over that time period might be added to the OPTN response to help clarify how very remote the risks are.

Following the discussion, there was agreement that the response to the HHS proposed changes makes sense, particularly the informed consent section, and would improve the utility of organs.

The Executive Committee voted to approve the principles in the response to HHS as drafted for submission on behalf of the OPTN.

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

4. Other Significant Items

Assignments not completed from the August EC meeting will be resent to Committee members for review. In addition, feedback is requested on the proposed SPC project portfolio presented at the December Board meeting is requested, as well as the project initiated over the summer which will review the Conflict of Interest Policy. The results will be presented and discussed at the October EC meeting.

Upcoming Meetings

- October 8th, 2019 - 11:00AM EST/8:00AM PST (Teleconference)
- Monday, December 2, 2019 - Dallas
- Monday, April 20, 2019 - Chicago

Executive Director thanked committee members for convening on short notice, as well as staff working extra hours to ensure timely implementation.