

OPTN Organ Procurement Organization (OPO) Committee

Meeting Summary

January 22, 2020

Conference Call

Diane Brockmeier, Committee Chair

Kurt Shutterly, Co-Chair

Introduction

The Organ Procurement Organization (OPO) Committee (the Committee) met via Citrix GoToMeeting teleconference on 1/22/2020 to discuss the following agenda items:

1. Regional Meeting Prep
2. Centers for Medicare and Medicaid Services (CMS) Proposed Rules
3. Additional Updates

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

1. Regional Meeting Prep

The Committee reviewed the regional meeting schedule, presentation slides and discussed meeting expectations.

Summary of discussion:

The Committee members received information regarding the upcoming regional meetings and reviewed the regional meeting presentation slides.

The Committee Chair stated that there was considerable discussion by the workgroup around the host OPO being responsible for reallocation. Additionally, there was discussion about the programming implications and the need to implement the reallocation policies at the same time as the new kidney and pancreas allocation policies.

A member asked for clarification on whether the OPO has the option of reallocating the organ. For example, was the organ declined before it left the donor hospital or when it got to the original accepting transplant hospital? There could be challenges depending on if an organ is in route and declined. The Committee Chair stated that, in most cases, there is an assumption that the organ has traveled to another transplant program. However, the proposed policies allow the host OPO the discretion to either continue allocating off the original match run or using a new "reallocation" match run.

There were no additional comments or questions.

Next Steps:

- Additional information will be sent to members leading up to their regional meeting presentations.

2. Centers for Medicare and Medicaid Services (CMS) Proposed Rules

The Committee reviewed and provided feedback on the proposed CMS regulations.

Summary of discussion:

The Committee reviewed the proposed OPTN response that highlighted several areas of concerns. The Committee Chair shared the discussion points from a meeting at a recent Association of Organ Procurement Organizations (AOPO) meeting.

- Reaffirm the need for a more comprehensive “denominator” for assessing OPOs performance on converting a death to a donor.

The Committee Chair stated that AOPO preferred the CALC¹ metric to the proposed Centers for Disease Control and Prevention (CDC) metric. Additionally, if approximations are used they should include confidence intervals.

- Restate the need for death data, with sufficient clinical detail, transmitted preferably directly to donor hospitals’ electronic medical records (EMR) to the OPTN should be used to assess actual donor potential for regulatory purposes.

The Committee Chair stated that AOPO recognized that while it would be ideal for hospital source data being directly submitted to CMS, there could be challenges for hospitals if this becomes an unfunded mandate. She noted that AOPO will encourage CMS to explore this as an option to obtain data if more specificity or clarity could be provided.

- Appropriate risk adjustment is necessary to properly assess performance

The Committee Chair stated that AOPO agrees with the need for risk adjustments due to the variability across country. Elements should have a statistical impact (ex. age, cause of death) although there is dispute about whether race should be included and if it would drive a statistical impact in the data.

The Committee Vice Chair suggested adding the question “Is a 70 year old as likely to become a donor or transplant the same amount of organs as a 20 year old?” This point is as much about actual outcome as it is authorization.

- Two metrics should measure two distinctly different things

The Committee Chair commented that the proposed rule change states the metrics should be from two separate sources. AOPO will strongly recommend retaining observed vs. expected as the transplant metric.

- Is one year of data enough to truly assess the performance of an OPO?

The Committee Chair stated that AOPO did not agree with this proposal and recommended that 36 months of cumulative data be used, as is the practice today. A one year snapshot is not enough data to truly assess an OPO’s performance.

Additionally, AOPO’s concern is the practicality and timeframe for the assessment. Is year 1 of the next cycle going to serve as the denominator for subsequent years? How will this be operationalized and what does the timeframe look like to collect the data? Will this continue to be modified?

A member asked if there was any proposal for when an organization was re-certified or taken over by another OPO. Is that OPO expected to take on this evaluation as well?

¹ Goldberg D, Karp S, et al, “Importance of incorporating standardized, verifiable, objective metrics of organ procurement organization performance into discussions about organ allocation,” Am J Transplant. 2019;00:1-6.

The Committee Chair stated that it would be a broad assumption that a “high performing” OPO can get another OPO back on track within a year, which would not be practical. This reaffirms the recommendation by AOPO to have a cumulative, longer-term review period.

Another member stated that it was unclear what the process will be for covering a donation service area if an OPO gets decertified. What happens if no other OPO applies for the DSA?

- Discuss the appropriateness of proposed calculation of donor potential for regulatory purposes

The Committee Chair stated that AOPO wants to ensure that there is enough clinical detail. Some of the other concerns include determining who submits the data because there is a lack of consistency in how this information is collected.

The Committee Vice Chair stated that their program will take samples of medically unsuitable brain dead donors and compare the death certificates on file with their actual diagnosis to determine accuracy.

UNOS Research staff asked that if there was discussion or thoughts about the currency of the data due to the lag for ICD-10 codes and how this may affect the use of this information for regulation. The Committee Chair stated that a lot of discussion was on the timeliness and currency of the data. Right now, the data available is two years old so additional work needs to be done in order to obtain the data in a quicker fashion.

- Express concerns over proposed changes to the definition of “donor”

The Committee Chair stated that there was discussion about potential donors that eventually result in no organs transplanted. OPOs do a lot of the same work on the front end with getting authorization, assessing donors, and initiating donor management. The suitability of organs to be transplanted are sometimes “beyond the OPO’s control” and OPOs should not be held accountable for this. Although the proposed rules indicate that OPOs have some control by working with transplant hospitals, this does not always result in every organ being transplanted due to a variety of reasons.

- Concern over flagging methodology

The Committee Chair stated that there were some comments made that no other healthcare entity is evaluated based on a single point of failure set at the 75th percentile. Recognizing that this is not how traditional healthcare is monitored across the country, why are OPOs the only healthcare entity to be held at this standard? There was also a recommendation that instead of a finite number, there should be another statistically relevant methodology to show some range data.

There are also mitigating factors that should be included. One of the examples given: After the hurricanes in Puerto Rico, many people fled the country resulting in a loss in their population. This poses the question of whether there are other mitigating factors that should be included.

- Request clarity on intended process following decertification of ~30 OPOs

The Committee Chair stated that there is a lot of concern that donation would drop should this happen and it was not seen as particularly helpful in getting more people transplanted.

A member added that if there is no transition time identified in the proposed rules, or direction about how organizations are set up, staffed, or financially impacted by decertification.

A member asked if there was any conversation about changes in expectations for transplant center performance. The Committee Chair stated that there is hope that there would be some accountability metrics to transplant centers; however, this proposal is focused on OPOs.

A member added that there was discussion in better aligning the transplant metrics. From the transplant program perspective, there is no knowledge of any new metrics coming out that are analogous to OPOs. Members were encouraged to work with their respective organizations to review and provide feedback on the proposed regulations.

Next Steps:

- The feedback received will be shared with OPTN leadership for their review and consideration in their written response.

3. Additional Updates

The Committee were provided additional updates.

Summary of discussion:

The Committee was made aware of a new way to access meeting materials to the OPO Committee SharePoint site. Further information will be sent to members after the meeting.

The MPSC has been working on changes to the *OPTN Bylaws, Appendix B: Membership Requirements for Organ Procurement Organizations (OPO)* that will require feedback from the OPO Committee. The Committee will have the opportunity to provide feedback and this will be on the agenda for a future meeting.

There were no additional comments or questions. The meeting was adjourned.

Upcoming Meeting

- February 19, 2020 (Teleconference)