OPTN/UNOS Membership and Professional Standards Committee (MPSC)
Meeting Minutes
February 26-27, 2019
Chicago, Illinois

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Introduction

The Membership and Professional Standards Committee met in Chicago, Illinois, on February 26-27, 2019, to discuss the following agenda items:

1. Data Portal 2.0
2. Systems Performance Committee Update
3. Survey Evaluation Tool Implementation Update
4. Expedited Placement of Livers Proposal
5. Organ Center Kidney Accelerated Placement Concept (KAP)
6. Member Related Actions
7. Living Donor Events
8. OPO Performance
9. ABO Incompatible Transplants
10. Committee Actions

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

1. Data Portal 2.0

In the Fall 2018, UNOS rolled out many updates to the interface and functionality of the UNOS Data Portal and has historically received feedback regarding members being unaware of the opportunities available to create and request reports using the portal. During the meeting, UNOS Staff presented on a number of changes implemented in the UNOS Data Portal, including the introduction of several new member-specific visualizations, "quality-of-life" features, and the Custom Report Builder.

Special mention was made to highlight opportunities for members to provide feedback on further development of the data portal (e.g., features to add/modify/remove, general impressions about ease-of-use). Additionally, members were given the opportunity to acquaint themselves with the data portal on their own computers and ask specific questions about how to use and access it.

2. Systems Performance Committee Update

MPSC representatives on the Ad Hoc Systems Performance Committee (SPC) provided an update on its charge to define and measure the relative effectiveness of the transplant system as a whole. The committee is looking at systems performance, and ways to improve both transplant hospitals and OPOs, and the system in general.

The SPC has three work groups: System Dynamics, OPO and Transplant Hospitals. The three groups are charged with working together to identify specific metrics, tools, projects, and efforts that measure or support system performance. They are considering options that do not just layer on more regulation or monitoring on top of what currently exists, but rather taking a clean slate approach. The workgroups will share recommendations and gather input from members during a public meeting on March 11-12, 2019, and will report to the Board of Directors in June.

3. Survey Evaluation Tool Implementation Update

On November 1, 2018, Site Survey implemented a scorecard alternative that aims to shift the workload of the MPSC to focus on members that truly need help, reduce the amount of time between and survey to follow-up and/or close, and further shift the perception of Site Survey and the MPSC. The Survey Evaluation Tool (SET) is an internal decision making tool that categorizes policies bases on risk, stresses the importance of the requirement, and includes information about the thoroughness of the members corrective action plan. The SET aligns the process for all survey types and is more agile for monitoring changes. After a routine survey, Site Survey will evaluate the survey findings in conjuction with any corrective action plans submitted by the member to either close the survey or conduct a follow up desk review in six months. If a member is unable to show proof of sustainable improvement after six months, Site Survey will refer the member to the MPSC for additional guidance and help. The MPSC will review follow up surveys with no/minimal improvement, surveys with identified patient safety risks, and MPSC directed surveys. The changes will be evaluated in phase two through member feedback, amount of case load reduction, and number of follow up surveys.

4. Expedited Placement of Livers Proposal

The OPO Committee Chair presented the proposal to the MPSC. Members asked questions about the implications of intra-operative expedited placement of livers and had a few comments for consideration when drafting the final policy language.

- What happens when the initial recovery team wants to leave after declining the liver? Why doesn't policy require them to stay and help with the procurement in order to protect the procurement process?
  The policy's current language does not require the initial recovery team to stay and procure the liver for the accepting transplant hospital of the expedited liver. The OPO committee felt that if the donor became unstable or other circumstances arose that would require cross clamp to occur, the OPO needs to have the ability to do so without breaking policy. They were also unsure if they could make this mandatory and were concerned that this requirement would not make it through the policy-drafting phase. However, the OPO Committee felt that making a recommendation or training document with the following, would be appropriate:
  - Recommend that cross-clamp be held for up to one hour if the donor and recipient are stable
  - Transportation be in process by the OPO during the expedited placement process
  - The local team to hold and be available for the accepting hospital
- When identifying expedited placement recipients, will there be a new match run or is the original match run used? The transplant hospital may not be familiar with the case and donor prior to receiving the offer and 20 minutes is a very short turnaround time.
  This project will require programming prior to implementation and discussions surrounding requirements are ongoing. Re-executing the match run, from an OPO perspective, is not appropriate logistically. Discussions have been around programming an expedited placement button in the match run that would gray out PTRs that previously declined as well as recipients that are not listed as willing to accept an expedited placement liver. OPOs are still able to utilize backup offers from the original match run.
- Acceptance of marginal livers or turndowns in the OR has nothing to do with the patients in most cases; it is largely a hospital issue. Most hospitals say they are willing to accept these organs and later decline. In order to utilize these livers, we should identify the 10 hospitals that actually utilize these organs and make direct offers to them.

The policy is a culmination of 24 months of work for the committee and early on, the data reviewed showed that only five hospitals were receiving 60% of these livers from the OR, which is a very small number. The challenge of reaching out to only those select hospitals is that it creates no transparency. Other hospitals may use these organs but are not getting the offers because we do not have a system in place to allow this.

- Is there a cap on how many offers an OPO can push out at once?
  Once the expedited placement pathway is chosen, there is no cap for the OPO on how many hospitals can receive the offer. That design is intentional since the liver is at risk of not being transplanted.

The MPSC offered two additional comments about the proposal:

- The OPO Committee should gather data quickly on which programs are accepting and transplanting these organs in order to start refining the criteria for which programs can accept expedited offers. This has to be an iterative process where hospitals are re-evaluated to receive these offers on an on-going basis.
- There need to be guidelines on when the OPO should move to the expedited list versus offering down the original run.

5. Organ Center Kidney Accelerated Placement Concept (KAP)

UNOS staff presented on the concept of kidney accelerated placement through the UNOS Organ Center. This is a non-policy project presented to this Committee as in their role as a potential stakeholder in this work. The concept presented is partially based on findings from the National Kidney Foundation Consensus Conference on Decreasing Kidney Discards that convened in May 2017. This conference noted and recommended that system level changes be made to reduce organ discard and improve placement of high-risk kidneys.

The goal of this project is to test the implementation of accelerated placement of deceased donor kidneys by the Organ Center to increase the number kidney transplants, and to improve the efficiency of Organ Center organ placement processes. First, Research staff analyzed the Organ Center's current process of allocating national kidneys according to the match run sequence to identify patterns in which kidney transplants are not happening that possibly could occur. Then, Research and Organ Center staff created an algorithm/decision tree to identify which transplant programs are most likely to accept the national kidney offer, with the objective of succeeding with placement more quickly so as not to waste time on that match/organ. This could result in increased transplants in two ways: 1) kidneys that may not have resulted in a transplant if allocated according to the traditional match run may now end up transplanted because a placement can occur more quickly; and 2) Organ Center staff can more quickly move on to the next match that could possibly result in transplants.

All OPOs are currently required to transfer kidney matches that reach allocation classification tiers at the national level to the Organ Center. Through a series of organ refusals both locally and regionally, the community has already deemed kidneys 'hard to use' or 'marginal' if the Organ Center is attempting national placement for them.

A low-risk cohort of kidneys that can be used for this project was identified. Potential use-cases have been identified, and strict thresholds and protocol have been outlined in order to effectively, safely, and consistently study the effects of such an accelerated placement practice for the Organ Center. There is potential to increase the number of transplants by effectively re-ordering the match run sequence to allow for offers to reach patients at centers that have a higher probability of accepting a "hard to place" kidney, similar to one that the center has previously accepted, before other centers that have not and likely would not, eliminating the

buildup of cold ischemic time due to the ongoing process of offers and time allowed for centers to consider these offers. The Organ Center provides a unique opportunity, given that a large portion of the their donor portfolio is made up of high-KDPI donors that have been refused at both the local and regional level, with less than half of these donors' expected kidney yield less than one. This would also serve as a pilot to inform future expedited placement projects and concepts.

6. Member Related Actions

The Committee is charged with determining whether member clinical transplant programs, organ procurement organizations, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants.

The Committee reviewed the applications and status changes listed below and will recommend that the Board of Directors take the following actions when it meets in December:

- Approve 1 New transplant program in an existing member hospital
- Approve 1 New non-institutional member
- Approve 1 Reactivation of a living donor component
- Approve 1 Renewal for non-institutional member

In addition, the Committee also reviewed and approved the following actions:

- 18 Changes in transplant program and living donor component personnel
- 3 Changes in histocompatibility lab personnel

The Committee also received notice of the following membership changes:

- 1 Change in OPO personnel

The Committee reviewed and approved the membership consent agenda. The Committee also discussed and approved a key person change application for a primary heart transplant surgeon.

7. Living Donor Events

The Committee reviewed 10 total living donor events at its February meeting, including eight aborted procedures and two living donor deaths. The Committee closed issues with no action, issued a Notice of Noncompliance, and offered an informal discussion to gather additional information. The Committee also closed two ongoing cases.

8. OPO Performance

The Committee approved sending an initial inquiry to one OPO newly identified for lower than expected organ yield and the continuation of monitoring of two OPOs that were under review for lower than expected organ yield.

9. ABO Incompatible Transplants

During routine monitoring of members brought to the attention of the MPSC for reasons related to ABO verification and/or compliance, the MPSC requested additional data to help support a thorough discussion and understanding of current trends in the ABO data reported to the OPTN. UNOS staff presented an analysis focusing on determining the number of discrepant ABO results that are submitted. The analysis highlighted three primary findings:

- That current data collection protocols do not permit a direct approach to discovering discrepant ABO results. Specifically, members are not allowed to input discrepant ABO

values into a donor record at all; instead, they are required to initiate a new –separate-donor record to contain the “new” ABO result. This has the consequence of meaning that, before two discrepant ABO values can be discovered in the OPTN database, the old and new donor records must be able to be matched to one another using the records’ individual identifiers (such as the donor’s name, date of birth, hospital at which the donor was recovered, etc.). Since no perfect procedure exists to match old and new donor records, only a subset of all discrepant ABO results are discoverable, implying that the “apparent” number of discrepant ABO results should be interpreted as an underestimate of the true number.

- Discrepant ABO results are rarely reported: during 2013-2017, 106,655 deceased-donor records were submitted to the OPTN, of which 616 were “new” records for a donor already appearing on an earlier record. Among the 616 “duplicated” records submitted, only 225 corresponded to donors who had organs recovered for transplant. Ninety-three of those donors had one or more discrepant ABO results recorded, of which 85 were changes of subtype while the remaining 8 involved a change of primary AB.
- These discrepant results represented a very small minority in terms of the number of deceased donors recovered during the same period. Eight discrepant primary ABO results in the context of 46,201 deceased donors recovered during 2013-2017 implied approximately 1.7 discrepant primary ABO results per 10,000 deceased donors, though this estimate likely underestimates the true prevalence.

In response to this presentation, MPSC members identified questions to include in a referral to the Operations and Safety Committee for a project they are undertaking. This discussion took place as the major discussion of potential education referrals for members. Some topics include:

- Definition of mass transfusion.
- Information OPOs need to provide to transplant hospitals in these situations.
- Current protocols.
- Recommendations from the American Academy of Trauma Professionals or Emergency Medicine regarding guidance on ABO determination in patients with mass transfusion or hemodilution.
- Scientific education regarding mass transfusion and considerations of what to expect in mass transfusion cases.
- Other methods of typing donors in these situations.
- Protocol/policy for when to retest ABO.
- Consider possible solutions such as genotyping.

10. Committee Actions

The Committee unanimously agreed that actions regarding Bylaws, Policy, and program-specific decisions made during the OPTN session would be accepted as UNOS actions.

RESOLVED, that the Committee accepts those program specific determinations made during the meeting as UNOS recommendations.

FURTHER RESOLVED, that the Committee also accepts the recommendations made relative to Bylaw and Policy changes.

The Committee voted 34 Yes, 0 No, 1 Abstention

Upcoming Meetings

- April 16, 2019, Conference Call
- May 23, 2019, Conference Call
- June 27, 2019, Conference Call
- July 16-18, 2019, Chicago
- November 5-7, 2019, Chicago