OPTN/UNOS Organ Procurement Organization Committee
Meeting Minutes
October 4, 2018
Chicago, Illinois

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Introduction

The OPO Committee met in Chicago, Illinois on 10/04/2018 to discuss the following agenda items:

1. Expedited Organ Placement Work Group Update
2. Guidance on Effective Practices in Broader Distribution
3. Geography Update
4. Improving the Efficiency of Organ Placement
5. Donor Hospital Location Project
6. Ad Hoc System Performance Committee
7. DCD Project
8. Patient Affairs Constituent Council
9. Deceased Donor Registration Form

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

1. Expedited Organ Placement Work Group Update

The Committee was provided with an update on this project and the timeline for finalizing a policy proposal. This work group has been evaluating both "in-OR" and "pre-OR" triggers for initiating expedited liver placement. The goal of this project is to develop a transparent expedited placement system that allows for equitable access to organs and avoids organ discards. The Committee was reminded that there are currently no policies that address expedited placement.

The Committee reviewed data that outlined the number of expedited placements across all organs. Between January 1, 2015 and December 31, 2016, there were 462 matches identified as expedited placement. Expedited placement is defined as any match that had at least one candidate prior to the final acceptor that was bypassed for an "expedited" reason. Those reasons include any of the following bypass codes:

- 861: Operational – OPO
- 862: Donor medical urgency
- 863: Offer not made due to expedited placement attempt.

The Committee briefly discussed the issue of late turndowns in the OR. The Committee members acknowledged that it is difficult to analyze the extent of the problem because the OPTN does not collect information on late turndowns. Committee leadership noted that the Association of Organ Procurement Organizations (AOPO) is collecting data on late turndowns. Informal discussions with AOPO representatives indicate that the number of late turndowns within an 18 month period exceeded 500 based on data collected from 38 OPOs.

One Committee member asked how this process would impact allocation of organs to Canada. The Committee chair noted that the work group has not discussed this issue and it will be added to the list of discussion items for the work group.

Pre-OR Expedited Placement

The work group has explored various options for a pre-OR trigger. These include a specific time period prior to the scheduled OR time, a specific point on the match run, and donor characteristics. The work group agreed that using donor characteristics was the best approach. They discussed the donor profiles that were created by the Liver and Intestinal Organ Transplantation Committee ("Liver Committee") as well as "probability of transplant" and "probability of discard" models to help determine the best pre-OR trigger.

During the August 23, 2018, work group conference call, the SRTR provided an analysis based on the probability of transplant model. After a discussion of the results, the work group recommended a revised data request. This revised request will evaluate a DDR[1]-based prediction model based on donor characteristics that predict the probability that a liver will be transplanted from a recovered donor (regardless of whether or not the liver was recovered) prior to national allocation. The work group will assess this model's use as a pre-OR trigger. The model will be based on demographic and clinical data that are likely to be known by the OPO prior to the match run (or as offers are being made) so that the model has to potential to be implemented in DonorNet®. The work group will provide guidance on the data (donor clinical and demographic data) to be considered as the starting point for the model.

The Committee discussed the status of this aspect of the project and determined that the Committee should focus on in-OR expedited placement for the initial proposal. The Committee agreed that pre-OR expedited placement is extremely complex and would be difficult to explain and build consensus within the community. One of the key components of an efficient pre-OR expedited placement system is that the list would have to be determined by past acceptance history for a particular type of donor. The Committee asked for specific feedback on this issue when they distributed the concept paper in early 2018. Every region and numerous individual commenters expressed concern with using past acceptance history to screen candidates off an expedited list.

In-OR Expedited Placement

The Committee discussed and supported the criteria developed by the work group that would trigger expedited placement:

> The host OPO or the Organ Center is permitted to make expedited liver offers if *both* the following conditions are met:
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> 1. The host OPO or Organ Center is notified by the primary transplant hospital that they can no longer accept the liver offer for the primary potential transplant recipient.
> 2. The deceased donor has entered the operating room. For DCD donors, the donor has entered the operating room or withdrawal of support has been initiated.

The Committee also briefly discussed the requirements for transplant hospitals to "opt-in" to receive expedited offers. The work group is still evaluating the required candidate level acceptance information for expedited offers. These include such information as:

- Distance from donor hospital
- DCD and/or DBD
- Age

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[1] Deceased Donor Registration Form

- BMI
- Macrosteatosis

The Committee discussed the process for making expediting offers once the conditions outlined above are met. The plan is to allow OPOs to send electronic expedited offers to a specified number of transplant hospitals and allow all the transplant hospitals within the "blast offer" twenty minutes to enter an acceptance or refusal. If there are no acceptances after that initial time period, the OPO would send offers to the next group of transplant hospitals with an additional twenty minutes to enter acceptances or refusals. If necessary, a third group of offers can be sent out. If there are acceptances within any of the time periods, the liver would be allocated to the transplant hospital with the highest ranked candidate according to the match run. The Committee Chair noted that the current match run would be used for these offers and not require a re-execution of the match run. One Committee member asked if it was acceptable to place the organ if a center higher on the list has not responded. The Committee Chair noted that the intent of this system is to move quickly and a "no response" within the time limits would eliminate a transplant hospital from receiving the liver.

The Committee discussed how many transplant hospitals should be included in each "blast offer." The work group had previously discussed sending the offers to twenty transplant centers. The Committee discussed the impact of the geography discussions and questioned how many transplant centers are located within each geographic area. This could help determine the number of transplant hospitals by making sure that all the transplant hospitals within the initial allocation distance are included in the initial set of expedited offers. For example, if the initial allocation unit is 500 nautical miles, the system could send blast offers to all the centers within that distance. If there are not twenty transplant hospitals within that initial allocation unit, additional transplant hospitals could be added so that a total of twenty transplant hospitals can be included in the initial blast offer. The work group will continue to discuss this issue.

One Committee member asked if this system would prevent OPOs from using their current process for expediting offers. The Committee Chair noted that it would not prevent that practice, but it might impact the level of scrutiny when OPOs expedite offers outside of policy requirements. One of the goals of this project is to encourage more consistent practices across OPOs. The Committee members acknowledged that there will be certain situations where a turndown in the OR will not require expedited placement. For example, if the primary candidate can no longer accept a liver from an "ideal donor" it might be easier to place the liver without initiating expedited placement. The Committee Chair noted that the intent is not to mandate expedited placement, but instead provide a tool for OPOs to use in order to get a liver quickly placed.

The Committee discussed the donor information available at the time of expedited liver offers. The work group agreed that the offers and responses need to be made based on "as is" information. This is due to the urgency of getting livers placed in order to prevent discards. The Committee discussed the possibility of providing a "snapshot" of important donor information that is available when the expedited offers are sent out. One Committee member noted that it will also be important for transplant hospitals to know why the organ was turned down.

The Committee briefly discussed the potential negative effects of creating an expedited placement system. The Committee members agreed that the main concern from both the OPO and transplant hospital perspective is that the process will be too slow. However, the Committee members agreed that an expedited placement system needs to be developed so candidates in need have access to these offers in a fair and transparent way. Committee members agreed that we need to start with something since there is currently no OPTN policy addressing expedited placement.

The Committee discussed the potential challenges for those transplant hospitals that use call centers. One Committee member noted that we need to clearly define "acceptance" of expedited offers. These responses will not be a placeholder, such as the use of a provisional yes, because of the urgency of getting these livers placed. Additionally, transplant hospitals will need to be aware that a "yes" response does not necessarily mean they will be receiving the liver. As previously discussed, at the end of the designated time period, the liver will be allocated to the candidate with the highest priority on the match run. Finally, the Committee discussed the need to monitor expedited offer acceptance practices so that transplant hospitals are not accepting for one candidate then using the organ for another candidate. One Committee member made a recommendation that if transplant hospital use the organ in a different candidate, then only the transplant hospital should be required to provide a justification for that action.

The Committee discussed the need to develop a guidance document to address several issues that will not be included as part of the proposed policy language. These include:

- Delay cross clamp, if possible
- Transportation logistics – Recommend that OPOs collaborate with transplant hospital on transportation logistics.
- Organ recovery – Recommend that if a recovery team turns down the liver in the OR, they still remove the organ.
- OPOs indicate the reason the liver is turned down in the donor highlights section in DonorNet.
- Use of third party call centers for expedited offers.

The Committee members were provided with an overview of the timeline for finalizing proposals for the January-March 2019 public comment period.

2. Guidance on Effective Practices in Broader Distribution

The Operations and Safety Committee leadership provided an update on this effort to provide guidance to the transplant community. As organ allocation policies move towards broader distribution, there have been concerns raised about the impact on costs and logistics for both OPOs and transplant hospitals. The Operations and Safety Committee has developed a questionnaire and are currently conducting interviews with all 58 OPOs in order to analyze the current status and capacity for increased air travel. The Committee is also working on a comprehensive guidance document that will address the following topics:

- Building relationships to optimize operations
- Organ allocation procedures
- Staffing
- Streamlining communication
- Metrics to evaluate issues and monitor the system
- Setting operating room times
- Specimen sharing and cross matching

The Committee was also provided with an update on the Operations and Safety Committee's evaluation of transportation costs and logistics. One Committee member noted that due to Federal Aviation Administration (FAA) rules, her OPO can only use their plane to transport their own staff and kidneys; they are not allowed to charter the plane. An Operations and Safety Committee representative with expertise in aviation explained the various FAA regulations that could be applied when transporting recovery teams and organs. The main goal of this data collection is to provide a summary to the Ad Hoc Geography Committee and organ-specific committees so they will have the information as they move forward with policy proposals.

3. Geography Update

UNOS staff provided an update on the status of the organ-specific committee geography projects as well as the Ad Hoc Geography Committee proposal.

- *Liver Committee* – Distributing a proposal during a special public comment period that will be open from Oct. 8 – Nov. 1, 2018. The Committee is seeking input on the MELD sharing threshold, the size of the fixed distance circles, and whether the community favors a broader 2-circle model or the acuity circles model. The Liver Committee will review comments and make a recommendation to the Board of Directors in December 2018.
- *Ad Hoc Geography Committee* – Distributed a proposal during the Aug. 3 – Oct. 3, 2018 public comment period. This proposal requested feedback on three distribution frameworks. UNOS staff noted that a majority of commenters favored the continuous distribution model. The Geography Committee will be reviewing comments and sending a recommendation to the Board of Directors in December 2018.

The following committees are developing proposals for the January-March 2019 public comment period:

- *Kidney Committee* – Submitted data request to model two allocation frameworks: Concentric circle distribution (150/250 nautical miles, 300/500 nautical miles) and a hybrid using fixed concentric circles and continuous distribution.
- *Thoracic Committee* – Submitted data request to model the following distances: 150, 250, and two variations of 500 nautical miles.
- *VCA Committee* – Developing a proposal based on a 500 or 750 nautical mile radius from the donor hospital.

UNOS staff reminded the Committee of the importance of providing feedback from the OPO perspective. The Committee will meet by conference call on October 31, 2018, to discuss the liver proposal.

4. Improving the Efficiency of Organ Placement

UNOS staff reminded the Committee members of the implementation dates for this proposal.

- March 1, 2018 - 2.2 (OPO Responsibilities), 2.11 (Required Deceased Donor Information), and 2.12 (Requested Deceased Donor Information)
- May 2, 2018 - 1.2 (Definitions) and 5.6.B (Time Limit for Review and Acceptance of Organ Offers)
- June 13, 2018 - 5.6.C (Organ Offer Acceptance Limit)

The Committee is scheduled to assess the impact of these policy changes at six and twelve months post implementation. The analysis will be provided to the Committee during its April 2019 meeting. However, UNOS staff solicited feedback from the Committee members on the following questions:

1. Managing acceptances in real time
    - Did you have to change practice or were you already doing that?
    - Did you encounter any challenges?
    - Any best practices to share?

2. Time limits for responding to offers and final decision for primary
    - Any other concerns or problems?

The Committee members were in general agreement that transplant hospitals and OPOs have adjusted to these changes without many issues. One Committee member noted that she did not recall information about the guidance document on requested deceased donor information being distributed to the community. UNOS staff agreed to check on how this information was distributed.

One Committee member noted that there was discussion at a recent regional meeting about the limit on organ offer acceptances. The discussion focused on how long OPOs should give transplant hospitals to make a decision to decline a previous acceptance in order to accept the third offer. She noted that the general consensus at the meeting was that 15 minutes was enough time to make that decision.

One Committee member raised the question about how many OPOs are enforcing the time limits. UNOS Research staff noted that it is something that can be analyzed as long as OPOs are entering the "exceeded time limit" bypass code.

5. Donor Hospital Location Project

UNOS Research staff provided an overview of the September 25, 2018 release of phase 1. This release switched the match system from using zip codes to hospital addresses. Additionally, the street address and city have been added to the dropdown list when adding a donor, which allows for improved accuracy of donor hospital selection. UNOS staff noted that future phases will include adding street address information to the monthly referral report, modifying UNet^{sm} to use a UNOS assigned unique identifier for hospitals, and creating a method for adding and tracking the recovery facility on the donor record independent of the donor hospital facility.

UNOS Research staff noted that in order to add a field for the recovery facility there needs to be a clear definition for each donor location and how each would be used in the system. For example, would they be used to define allocation circles, used for screening, or simply for informational purposes?

One Committee member commented that it is important to know the name of the referring hospital if that is where death is declared. The donor hospital should be defined as where death is declared, not necessarily where the donor was initially admitted. He also noted that it is important to know where the organs are recovered. UNOS Research staff noted that if a DCD donor is transferred to another hospital for the recovery, then we would not collect information on the referral hospital. The Committee members agreed that when a DCD donor is transferred to another hospital for organ recovery, it is usually not far away.

UNOS Research staff noted that if recovery centers are added, there will need to be a determination about how to populate the information. This could be provided by the OPOs but then OPOs would be responsible for keeping the information up to date. One Committee member noted that it should not be a problem for OPOs to provide the address of their recovery facility, even for those OPOs with multiple recovery centers.

One Committee member recommended that there be a check box to indicate if the recovery site is the same as the donor hospital.

UNOS Research staff noted that the recovery center location will not be used for allocation but could potentially provide information for future allocation decisions. The Committee agreed that the two fields should be added: 1) Where death is declared and 2) Where the organ(s) were recovered.

6. Ad Hoc System Performance Committee

The Committee Chair provided an overview of this ad hoc committee of the Board of Directors. The goal of this effort is to identify and prioritize new and existing tools and strategies that allow

the OPTN, transplant hospitals, and OPOs to drive improved system performance and collaborative improvement. There are three work groups (OPO, Transplant Program, and System Dynamics) that will meet on a regular basis and full in-person committee meetings are scheduled for October 28-29, 2018 and March 11-12, 2019.

7. DCD Project

UNOS staff informed the Committee that this project is still on hold until resources become available.

8. Patient Affairs Constituent Council

UNOS staff provided an update on this proof of concept. This effort was initiated following the committee restructure concept paper that was distributed during the January-March 2018 public comment period. During public comment there was a lot of concern raised about changing the current committee structure. However, there was support for the goal of increasing engagement and testing different approaches.

UNOS staff noted that the Patient Affairs Committee (PAC) and Transplant Coordinators Committee (TCC) agreed to participate in the constituent council proof of concept that will run from July 1 to December 31, 2018. Both committees will assess data collected during this time period, provide a report to the Board of Directors, and assist in identifying the next steps.

The OPO Committee provided two representatives to the PAC Constituent Council. The representatives provided an overview of their experience working with this group. One member noted that the donor family perspective is still lacking compared to the candidate and recipient perspective. Another member noted that some of the patient representatives on the council did not have a clear understanding of how the OPTN process works. This can be an issue as patient representatives are being considered for service on the Board of Directors.

9. Deceased Donor Registration Form

UNOS Research staff presented the following questions for consideration:

- *Cross Clamp Time for DCD* – There was a member question about how to report cross clamp time when an OPO flushes prior to cross clamp. There was general agreement that the cross clamp time recorded in the DDR should be when there is an actual cross clamp or compression. The Committee discussed how this information is used and its impact on the ischemia time data and other reports generated by the SRTR. One Committee member raised concern about how the Committee can make a decision on this without feedback from the broader community, such as the organ-specific committees. The Committee agreed that the current definitions for cross clamp and core cooling are acceptable but there might need to be additional education provided to the community.

  One Committee member commented that her OPO's expected donation after circulatory death (DCD) organ yield had increased since the addition of DCD downtime to the model. She noted that it was added in an effort to collect information about the time after which livers are no longer accepted by a transplant hospital. UNOS Research staff agreed to develop a data request to analyze this question.

- *Date/Time Authorization Obtained for Organ Donation* – Questions: 1) If a registered donor, should this be the date and time of brain death or the date and time the registry was accessed? 2) If time registry was accessed, what if the time registry accessed is before death?

One Committee member noted that her OPO uses the "time of disclosure with family" for both DCD and donation after brain death (DBD). The Committee agreed to keep the current definition for DBD. For DCD donors, the Committee agreed to use the legal definition that authorization become effective at the date and time of pronouncement of death. The Committee Chair suggested that UNOS staff confirm this with legal counsel.

- *Other Drug Use (Non-IV) Ever* – This member question centered on how an OPO answers this question when they know the donor used drugs but not the route? One Committee member noted that the word "ever" is misleading because the help documentation states "ever abused or had a dependency." This inconsistency leaves it up to the interpretation of each OPO. Another member suggested that it align with the PHS guideline.

- *Heavy Alcohol Use* – The member commented that this question is subjective based on the number of drinks per day. They noted that an individual can still be a heavy drinker and not drink daily. They suggested that "heavy alcohol use" would be better defined by drinks per week. Finally, they suggested that the definition be modified to align with the definitions determined by professional organizations that study alcohol consumption.

  The Committee discussed the fact that the question on the DDR really addresses addiction when the important information is how the history of alcohol use impacts the organs. One Committee member asked if there was any definition of the number of drinks that increases the risk for liver disease. There was a suggestion to consult with the Liver Committee when the Committee conducts a comprehensive review of the DDR.

- *Chest X-Ray* – The member question was "Is the chest x-ray result relative to only the lungs or to the lungs, pleura and affiliated vascular?" The Committee agreed that the help documentation should be updated to state that chest x-rays results are only relative to the lungs.

- *Left/Right Lung Bronchoscopy* – The member concern was that there was no answer choice for "abnormal inflammation." The Committee recommended that an additional response be added to the dropdown options. (Bronchoscopy Results – Abnormal-inflammation) SRTR staff noted that in the yield model they only use "normal/abnormal." However, the Committee noted that changing the DDR to align with the SRTR model will need to be made as part of the larger review project.

- *Medical Examiner/Coroner* – The member question was "If an OPO routinely reports all deaths to the medical examiner (ME) and the ME states that they don't need to review the case, should the OPO respond "No" to this question since it was not a case that needed to be reported?" The Committee agreed that a no response is acceptable and the help documentation should be updated. One Committee member noted that her OPO notifies the medical examiner on all cases and enter no if there is no medical examiner jurisdiction in the case. However, UNOS site surveyors discovered that for some of the no responses, there was evidence of her OPO contacting the medical examiner. Her OPO changed their processes and enter yes although it now appears that all their cases are medical examiner cases.

The Committee agreed that a review of the DDR should be submitted as a project idea. There was also a recommendation to include site surveyor staff in this future project.

Upcoming Meeting

- Oct. 31, 2018 (Conference Call)