OPTN Organ Procurement Organization (OPO) Committee
In-Person Meeting Minutes
October 10, 2019
Richmond, VA

Diane Brockmeier, RN, BSN, MHA, Chair
Kurt Shutterly, RN, CPTC, Vice Chair

Introduction

The OPO Committee met in Richmond, VA on 10/10/2019 to discuss the following agenda items:

1. Expedited Placement of Livers
2. Donation after Circulatory Death (DCD) Policy Review Project Update
3. Data Advisory Committee and Enterprise Data Management
4. Deceased Donor Registration (DDR) Review Project Update
5. Policy Oversight Committee Update, Strategic Priorities, Project Ideas
6. Kidney and Pancreas Allocation – Logistics and Efficiency
7. Committee Charge
8. Improving the Efficiency of Organ Placement – Time Limit and Acceptance Limit Policy Review (1 Year Data)
9. Notification Limits Project

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

1. Expedited Placement of Livers

Members reviewed the public comment data and response themes for this proposal.

Summary of discussion:

Overall, the proposal was widely supported. All eleven regions supported the proposal with Regions 2 and 3 having the most votes in opposition of the proposal. The overall votes from the regional meetings were 52 strongly support, 139 support, 25 neutral/abstain, 12 oppose, and 13 strongly oppose. All thirteen transplant organizations that provided comment supported the proposal as did the seven OPTN committees that reviewed the proposal. The Committee reviewed the common themes from public comment:

- *Monitoring policy change* – The most frequent comment was that the OPO Committee should actively monitor how the system is working. The commenters stated that members should be monitored to ensure that both OPOs and transplant hospitals are complying with the new requirements. Examples include "the OPTN should monitor liver programs that are not accepting livers but have opted to participate in expedited placement" and when "OPOs are initiating expedited placement to ensure viable backup recipients are not disadvantaged." Committee leadership noted that the Committee included a detailed monitoring plan in the proposal and will review initial data at 6 and 12 months post-implementation.
- *Opting in* – There were several public comments expressing concern that every transplant hospital will opt in to receive expedited liver offers and this will impact the efficiency of organ placement. The Committee previously discussed placing limits on the number of candidates each transplant hospital could opt in to receive expedited offers but ultimately decided to take

the approach of requiring the opt-in for every candidate for both DCD and DBD donors. UNOS staff clarified that there would be a functionality in DonorNet® that will allow the Committee to collect data in order to monitor transplant hospitals that opt in but never accept offers.

- *Logistics* – There were several comments about logistics, including delaying cross clamp and expedited offers being sent directly to "decision makers." The Committee did not want to mandate delaying cross clamp in order to allow for individual processes. The Committee is working with UNOS Information Technology staff to potentially create a separate "contact" for expedited placement.
- *Transparency, consistency, and equity* – Several commenters appreciated the Committee's effort to create a transparent system that provides consistency in practice and more equitable access to expedited liver offers.
- *DonorNet improvements* – Several commenters recommended DonorNet changes that will allow for more transparency about transplant centers accepting multiple organs and to monitor centers not responding within the 30-minute timeframe. Additionally, there was a recommendation to create more descriptive decline codes in DonorNet. The Committee understands to need to make improvements to DonorNet but agreed that this falls outside the scope of this proposal.
- *Initiating expedited placement* – There were two comments noting that initiating expedited placement in the donor OR was too late in the process. The Committee discussed this comment following the Spring 2019 public comment period and agreed that it would be difficult to establish an arbitrary timeframe (e.g. 2 hours) prior to entering the donor OR. The Committee believes that making programming changes to allow for the identification of expedited candidates on the liver match run will allow for advanced planning in the event of a late turndown.

One member stated that there might be challenges for some candidates, particularly those that do not live close to the transplant hospitals. The Committee Chair noted that these individuals would not be ideal candidates for expedited offers and should not opt into the system. She also noted that it is imperative that transplant hospitals consider distance and other factors outlined in the requirements for opting in to receive expedited liver offers. A member commented that the percentage of centers that would accept these organs might be small but it is something the Committee can monitor since the data will be collected following implementation.

The Committee briefly discussed the programming for this project. UNOS Information Technology staff explained that host OPOs would have the ability to document when the donor entered the operating room and when they were notified by the primary transplant hospital of a turndown. Once this information is entered, the host OPO will have the ability to use the expedited placement system.

Another member stated that there should be a standard to allow centers to see images. The Committee Chair stated that if an offer is accepted by a transplant hospital, it would be the responsibility of the OPO to provide the information if there is time. A member stated that in most hospitals provide images, such as a CT scan, would be available. However, the Committee Chair noted that since this is an expedited situation, there might not be time for additional testing prior to making a decision on the offer. The Committee Chair stated that this would be a request to take to the Liver Committee for further discussion.

Finally, a member stated that consideration should be given to donor families because delays have an impact on them.

The Committee Chair called for a vote to approve the policy language as written. The policy language will be submitted to the Board of Directors in December 2019.

Vote: 17 Support, 0 Neutral, 0 Oppose

Next Steps:

- OPTN Board of Directors Meeting: December 2-3, 2019 in Dallas, TX
- Programming and educational efforts will begin pending approval by the Board.

2. DCD Policy Review Project Update

The Committee received an update on this project.

Summary of discussion:

UNOS staff provided the background information on this project. The current policy language was initially distributed for public comment during the March – June 2012 cycle. However, prior to the Board of Directors meeting in November 2012, several organizations submitted letters opposing the policy language as written. The focus of the opposition centered on the timing of the donation discussions and the fact that they were unaware of the proposal. The Executive Committee directed the OPO Committee to review the comments outlined in letters, revise the proposal if necessary, and re-distribute the proposal for public comment during the March – June 2013 cycle.

The OPTN Ethics Committee provided the following input to the OPO Committee prior to the second public comment period:

- Supported the donor evaluation prior to decision to withdraw support
- Supported the separation between decision to withdraw care and decision to donate
- Families should "generally be approached" about organ donation *after* the evaluation and the decision to withdraw support has occurred
- It would not be prudent for OPTN policy to flatly prohibit donation discussions prior to the decision to withdraw support

Committee leadership recently received information from several OPO leaders stating that there are OPOs who have been having the donation conversations earlier and found a way to operationalize their processes around the policy language. There was a request for the OPO Committee to review and update the language to allow for earlier discussions when appropriate.

The Committee formed a subcommittee to begin work on this project in August 2019. The subcommittee has held two conference calls to identify a path forward to address the concerns. The subcommittee identified two central issues:

1. When OPOs initiate donation discussions
2. When OPOs provide donation information

Currently, OPTN policy prevents OPOs from "initiating" donation discussions prior to the decision to withdraw life sustaining medical support. The policy does not prohibit donation discussions if initiated by the donor family or the healthcare team. The subcommittee developed two options for policy language changes.

- Option #1: "Prior to discussing donation opportunities with the legal authorizing individual, the host OPO must confirm with the healthcare team that end of life discussions and decisions are being held with the legal authorizing individual."

- Option #2: "Prior to initiating any discussion with the legal authorizing person about organ donation for a potential DCD donor, the OPO must confirm that the authorizing person intends to withdraw life sustaining medical treatment."

One member stated that it is important for families to understand the process. There are safeguards in healthcare independent of organ donation and families deserve to have all of the information available so they can make informed decisions. A member stated that one of the disadvantages is that palliative care is not available at all institutions. She noted that, as part of the decision on the policy language, there should also be education for those institutions that do not have palliative care resources.

A member noted that there should be a way to outline this process without being too prescriptive. For example, distinguishing between OPO staff providing information versus offering donation. A member noted that sometimes the donor hospitals are a barrier to the discussion and it would be important to have policy language as a way to justify the discussion. The Committee Chair noted that the real struggle is the inconsistency with how this occurs at the hospital and patient level; there is really no standard of care on how these discussions are conducted. Some donor hospitals with palliative care departments already have processes in place. The intent is to make sure that the option is under consideration – not making the decision. This is similar to the different levels of do not resuscitate orders.

Another member asked how members are monitored for compliance with the current policy language? A member stated that when auditors review their records, the time of the documented discussion is compared to the time of the decision to withdraw life-sustaining treatment.

One member asked if there were data to determine when the discussions occur and how that affects the authorization rate. A member noted that anecdotally if all the decisions about care have already been made, the likelihood of getting authorization from the family is probably less than if they had been provided information early on in the process. Another member noted that if the Committee reviewed the timing of authorization refusals they are probably late because the request came late in the process, regardless of whether it was a DBD or DCD donor. It would be beneficial to know if "80% of time, if the family had been educated prior to that we would have made a donation." However, a member noted that it would be difficult data to collect.

One member commented that the Centers for Medicare and Medicaid Services (CMS) regulations allow OPOs the opportunity to talk to the family when a physician brings up donation. However, she also noted that CMS has rules about who can be a "designated requester" and that some physicians do not meet that requirement.

There was a question raised about whether the timing of the donation discussion should be in OPTN policy. One member noted that the CMS regulation is easier to work with than the OPTN policies, but acknowledged that it does not address the timing of the discussion. She noted that the Committee should also take into account advanced directives, palliative care, and other considerations. One member noted that it would be beneficial to have OPTN policy because any absence puts OPOs in the position of relying on CMS regulations and individual hospital policies. One member noted that donor hospitals do not routinely ask to see CMS or OPTN policies during these discussions. However, whatever language the Committee comes up with should align with CMS regulations.

The Committee reviewed the CMS guidelines[1] that states "if an OPO recovers from donors after cardiac death, the OPO must have protocols that address the following: Criteria for evaluating patients for DCD, withdrawal of support including the relationship between the time of consent to donation and the

[1] https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/Downloads/cms3064f.pdf

withdrawal of support." The Committee Chair noted that the CMS regulations are probably easier to work with because they only require OPOs to have protocols. Additionally, the "time of consent" does not address the timing of the donation discussion.
The Committee Chair asked members for a vote on the options for how the subcommittee should move forward on this project. The Committee unanimously agreed that OPTN policy should be aligned with CMS regulations. The Committee agreed the language could also clarify the differences in donation discussions or options, end of life decisions, and the time of authorization.

Next Steps:

The subcommittee will use the feedback to further develop a path forward. One member suggested that it might be helpful to reach out to those OPOs that have operationalized their processes in order to help inform some potential policy language. The Committee agreed that it would be better to adopt the CMS regulation language and recommended that the subcommittee discuss this path forward.

3. Data Advisory Committee and Enterprise Data Management

The Committee was provided with an overview of the Data Advisory Committee and Enterprise Data Management.

4. Summary of discussion:

Currently, the Data Advisory Committee is working on a policy proposal for data submission that will be submitted to the Board of Directors in December 2019. As an operating committee of the Board, the DAC will have an expanded role and be accountable to the Board for all OPTN data collection, including assessing data collection needs and making annual recommendations about what data elements to add, modify, or delete. The DAC will be collaborating with sponsoring Committees on all data policies. Additionally, on a quarterly basis, the DAC will review and provide an annual report to the Board of Directors (BOD) with recommendations on data collection.

A member asked if there has been any discussion about how to integrate data that is collected in various locations such as electronic medical record (EMRs), DonorNet, and TIEDI (Transplant Information Electronic Data Interchange). UNOS staff noted that in working to standardize new data collection, the OPTN would review how the data collected could be more interoperable with the EHRs so it supports the API work within the various data systems. The intent is to reduce the redundant entry of data in multiple locations.

A member asked if there is a way for members to access their own data in real time. UNOS staff stated that it is a great example of an enhancement request that committee members can submit through the UNet^{sm} data portal.

5. DDR Review Project Update

The Committee was provided an update on the Deceased Donor Registration (DDR) Review Project.

Summary of discussion:

The DDR Review Workgroup is a joint workgroup with the Data Advisory Committee. There have been three conference calls to date and the workgroup has helped develop a data element standard review checklist. The checklist includes the following:

- Purpose, relevancy, and face validity
- Reliability
- Definition
- Availability, (member) burden, and interoperability

- Alternative data sources
- Usability and conformity

The workgroup has also developed a review worksheet and tested it using the clinical information section of the DDR. This process will also include an evaluation of the purpose for collecting the data element. UNOS staff noted that there would be a process for making recommendations to remove data elements. This will include reaching out to various stakeholders to ensure that removing the data element does not have a negative impact.

A member asked why there is a need to collect educational level in the data collection forms. UNOS staff noted that the question highlights the gap that we have with data collection. The DAC has started to address this by working with sponsoring committees to ensure the purpose of the data collection is clear and that the data definitions allow for consistent reporting.

A member asked if there are initiatives to evaluate data submitted by transplant hospitals. UNOS staff clarified that there will be a similar process with the transplant hospitals. The work has started with the DDR and will eventually include the data collection forms submitted by transplant hospitals.

Finally, a member stated that if the EMRs could communicate with DonorNet, it would make it easier to transfer this information.

Next Steps:

- The Workgroup will have their next conference call on Tuesday, October 15, 2019.

6. Policy Oversight Committee (POC) Update, Strategic Priorities, Project Ideas

The Committee Vice Chair provided members with a Policy Oversight Committee (POC) update.

Summary of discussion:

The purpose of the POC is to advise the Committees and Board of Directors on:

- Strategic planning activities
- Prioritization of OPTN policy development activities
- Evaluating policy proposals prior to public comment
- Coordinating policy issues that have broad implications across OPTN committees; and
- Ensuring that all OPTN governance groups consider and justify compliance with the requirements of the final rule as part of the policy development process.

The POC's work to identify potential strategic policy priorities has led to the identification of the following three themes:

- Continuous distribution
- More efficient donor/recipient matching to increase utilization
- Improved equity for multi-organ and single organ candidates

The goal is to maximize benefit to the transplant community and provide recommendations to the Board of Directors. Individual committees will sponsor specific projects.

The Committee was asked to brainstorm on projects the OPTN should pursue in relation to the themes that were selected. A member asked a question about how this might affect current projects. UNOS staff clarified that this would not affect the current projects that are in progress.

Another member stated that in working on themes is a great opportunity to have Committee projects more aligned.

A member stated that with liver allocation, there should be a system in place that would help in effectively allocating marginal organs. One member noted that if we could understand what certain members have done to accept marginal organs and what systems they use for those decisions, we could better incorporate that into the global structure and potentially reduce the barriers for all members. The Committee members acknowledged that there is variability in how transplant hospitals accept marginal organs and that should be part of the discussion. The Committee Chair noted that the Ad Hoc Systems Performance Committee also discussed this. UNOS staff noted that the goal of the POC work is to identify policy projects that can improve the system.

Another member added that it is frustrating for OPOs when transplant hospitals enter a provisional yes for every offer end up declining it once a center becomes the primary center. He noted that there should be data available that illustrates the extent of this problem. This is particularly troublesome when centers have multiple candidates on the list and take one hour to make a decision for each candidate.

The Committee Chair stated that the challenges with multi-organ allocation is also a challenge that should be addressed. A member stated that multi-organ offers can result in delays because there are no policies around which list to use to allocate multi-organ combinations.

Another member stated that another issue has been rural/smaller transplant programs. The Executive Order is attempting to get patients off dialysis but those patients who live in rural areas do not want to travel to larger programs to receive transplant services. She noted that broader distribution models put rural programs at a disadvantage for organ offers because now they are competing with larger transplant programs. Those patients could end up not being transplanted because they are not willing to travel for services.

Next Steps:

Committee members were urged to continue to evaluate ideas that can be brought forward to the POC for consideration.

7. Kidney and Pancreas Allocation – Logistics and Efficiency

The Committee was provided with a brief overview of the proposed changes to kidney and pancreas allocation. The Committee was asked to provide additional feedback on the following questions:

1. What specific concerns do you have about cross matching and tissue-typing logistics that might result from the kidney geography proposal and specifically the 500 nautical miles (nm) circle as the first unit of allocation? Would those concerns be significantly reduced if that first circle were 250 nm? How so?
2. In your experience, do you foresee problems with capacity as it concerns domestic commercial air travel within the current kidney geography proposal? If the allocation circle were reduced to 250 nm, modeling shows slightly less organs would fly than we see in current practice. Would this alleviate some of those concerns?
3. What alternatives to commercial air flights (e.g., charter, private, “for hire”, contracts with Fed Ex, UPS, DHL, etc) might be explored to mitigate some of the anticipated need for additional capacity for air transport with the Kidney Allocation proposal? How should OPTN approach these challenges in the future with more extensive broader geographic sharing?
4. Do you have concerns about an increased need for local procurement that may result from the current kidney proposal? Would those concerns be alleviated by reducing the allocation circle to a distance of 250 nm?

Summary of discussion:

The Committee provided the following comments:

Cross matching and tissue typing logistics

- There was a question about how many organizations are performing virtual cross matches and if this was becoming a standard practice. A member stated that their organization does not rely on virtual cross matching. A member stated that it is hard to prescribe for HLA labs and that there could be a different approach to this.
- There is concern about not having enough blood to perform a cross match, especially with pediatric or small donors.
- There are times when the blood is drawn and the cross match is not run. One reason could be the cost. There are a number of OPOs unable to send blood ahead of time due to costs.
- The change to local backup could compound the lack of tissue typing material available.

Commercial air travel

Challenges

- Organs lost to the airlines.
- Some airlines will no longer take kidney pumps (size, lithium batteries, etc) and this could affect outcomes.
- Lack of data showing how many kidneys are refused due to travel issues since the OPTN does not collect data on travel and logistics.
- Some airlines refuse to transport kidneys and blood samples because of the biohazard label. A member stated that getting better clarity on what the label must include should be discussed.
- Comment about the importance of working with the Federal Aviation Administration in order to bypass some of the cargo processes and provide guidance due to the variability among airlines.
- Recommendation to consult with a logistics company to better understand how these processes could be improved.
- The issue with flights could be mitigated with 250nm so that ground transportation is a viable option.
- Air travel is not always linear since there are stops along the way.
- Even OPOs that own planes will not use them for transporting kidneys, especially when they start transporting significantly more livers.
- There is concern with the closing times of regional airports.
- Many OPOs are not located near a hub airport so many are using ground transportation. There is the potential for more organs lost with broader distribution.

Alternatives to commercial airlines

- Potential opportunity to work with other vendors such as UPS, FedEx etc.
- What is the status of drones?
- FedEx and ground transportation can sometimes fails.
- Is there a portal available to view the UPS and Fed Ex flights since these do not show up during normal travel search? OPOs need visibility of travel routes for transporting organs.
- Is there a way to use the military as a resource since they are required to have flight training hours?

Distance

- Impact on donor families should be considered due to the potential increase in donor case times.
- Is it acceptable to have a slight decrease in equity with 250nm in order to help with logistics and costs?

- For 500nm, there is concern about time constraints and the potential increase in organ discards which could be mitigated with 250nm.
- For 500nm, some OPOs do everything via ground transportation and the increased distance would create logistical challenges.
- 250nm will always be better than 500nm because it is reasonable to use ground transportation.
- Broader distribution could disadvantage rural candidates, consider extra points for candidates at rural programs where there are fewer hospitals within 250 nm. UNOS staff clarified that this is not currently addressed in the policies but would be brought back to the Pancreas and Kidney Committees for further discussion.

Local procurement

- This is a real problem and will get more challenging, although 250nm vs 500nm will not have an impact.
- At the national level, the kidney reimbursement has not changed in many years so it does not cover the costs, therefore creating no financial incentive to provide recovery services.
- Some organizations have their own procurement teams, which put costs back into the system.

Import/Backup

- Only 50% of OPOs currently manage imports. The host OPO should always manage allocation because the importing OPO does not have a stake in the organ.
- Recommendation to consider a center-specific backup although one concern was to ensure equity stays in the system. For HLA and tissue typing, there may be a need to review the local backup policies and outlining the requirements needed.
- Larger circle will create more import back-up situations, which could cause more non-utilization. Host OPO could potentially get organ back to re-allocate with smaller circle.

Pancreas specific:

- There are not many opportunities to reallocate the pancreas due to CIT.
- Pancreas moving to center backups: Concern raised about centers accepting for primary candidate with no intention of using it for that candidate.
- We need to get the pancreas placed and transplanted.

Next Steps:

- Feedback received will be incorporated into Kidney and Pancreas Committee discussions

8. Notification Limits Project

The Committee reviewed and provided feedback on the Allocation Based Notification Limits project.

Summary of discussion:

A member asked if there was a limit provided with the expedited placement proposal. The Committee Chair clarified that the expedited placement proposal includes the ability to send an unlimited number of offers without the current limit restrictions.

The proposed solution for the notification limits project is to:

- Replace local/non-local limits with fixed limited defined by the OPTN
- Limits will be based on match type/allocation (higher limits based on donor criteria)
- Program limits only (no candidate limits)
- Remove pre versus post recovery limits
- Balance organ placement efficiency versus notification volumes

The benefits of these changes would:

- Allows for different limits across organ types
- Consistent with allocation policy so more transparent for members
- Easier to incorporate into continuous distribution

A member asked that if there could be a functionality created that would send a notification to programs and alert them that there may be a potential offer. This would allow visibility for users where the system would send an automatic offer to the first three programs on the list. The other programs that are within the list would be alerted when they are next should the offer be declined. UNOS staff stated that although this suggestion is not within the scope of the notification limits project, this was a good idea and encouraged the members to submit ideas like this to the Customer Innovation Department. UNOS staff regularly review the ideas submitted to determine what can be worked on to help promote efficiencies within the system.

A member stated that the model seems to be more straightforward but the process would still be slow. Another member asked what the Organ Center thought about the model since they facilitate the majority of the national offers. UNOS staff clarified that the project was developed with collaboration and input from the Organ Center.

Next Steps:

The Committee was encouraged to provide any additional feedback.

9. Committee Charge

The Committee reviewed the revised committee charge and voted to move it forward for Board approval.

Summary of discussion:

The Committee members were provided with an opportunity to review the current charge by email in July 2019. The Committee briefly reviewed the change during its August 2019 conference call with no additional changes. There were several additional changes made prior to the meeting and the committee voted to approve the following language by a vote of 17 in support, O opposed, and 0 abstentions.

> *The OPO Committee considers issues relating to organ procurement organizations and their role in increasing the number of organs recovered and ~~placed~~ allocated efficiently and effectively. It considers medical, scientific, and ethical aspects of organ procurement as they pertain to the purview and responsibilities of the OPTN. It creates policy proposals and collaborates with other OPTN Committees to ensure the impact on OPOs is considered.*

Next Steps:

- The Committee Charge will go to the Board for review and vote during the BOD meeting in December.

1. Improving the Efficiency of Organ Placement – Time Limit and Acceptance Limit Policy Review (1 Year Data)

UNOS Research staff provided an update on the 1-year data for this project.

Summary of discussion:

The Committee provided the following comments on the data:

- The biggest impact appears to be on liver and lung placement
- A member stated that the impact of multiple acceptances for one candidate would be that it prolongs the allocation process.
- A member asked if time intervals were measured. UNOS staff stated that this was not included in the data. The member continued by noting that it would be interesting to review the intervals for cold time.
- Another member stated that with broader sharing, this process would become more challenging.
- A member stated that for concurrent acceptances, it does not appear that livers are being allocated faster through this process.
- A member stated that there is not transparency to see where the offers are being sent. If this information were visible, it would allow the opportunity for OPOs to set up their backups.

Next Steps:

- UNOS staff will review the feedback received and will do additional research and will present updated information at a future meeting.
- The Committee was encouraged to provide any additional feedback.

Upcoming Meetings

- November 20, 2019 (Teleconference)
- December 18, 2019 (Teleconference)