OPTN Operations and Safety Committee
Meeting Summary
August 24, 2023
Conference Call

Alden Doyle, MD, MPH, Chair
Kim Koontz, MPH, Vice Chair

Introduction

The OPTN Operations and Safety Committee (henceforth the Committee) met via Citrix GoTo teleconference on 08/24/2023 to discuss the following agenda items:

1. Offer Filters in Continuous Distribution
2. Require Reporting of Patient Safety Events
3. Modify Organ Offer Acceptance Limit
4. Ethical Considerations of Normothermic Regional Perfusion (NRP)
5. Efficiency and Utilization in Kidney and Pancreas Continuous Distribution

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

1. Offer Filters in Continuous Distribution

Decision: The Committee provided feedback on offer filters popup window and agreed that more information/education needs to be provided to the community so they are aware that it can be used to enter data such as cross clamp time and biopsy results.

Summary of Presentation:

Research staff noted that as the OPTN Kidney and Pancreas Transplantation Committees have been working on continuous distribution, they have discussed how to incorporate some of the offer filter data collection into their efficiency discussions. Research staff noted that the Committee had previous discussions to address some of the questions but wanted to get feedback on the Offer Filters data entry window that allows for the entry of cross clamp time and kidney biopsy information. The question for the Committee was how often data is entered within this popup window.

Summary of Discussion:

A member noted that her staff was unsure if they could enter information in the window and went back into the OPTN Donor Data and Matching System (DDMS) to enter the information. Another member commented that they don't use this window for data collection because they send out kidney offers prior to cross clamp. Research staff noted that cross clamp time was entered in this popup window 1.5% of the time (98.5% in the DDMS) and glomerulosclerosis (biopsy) results were entered only 13.8% of the time (83% in the OPTN Computer System).

A member commented that they also allocate kidneys pre-recovery but will enter any additional information in the fields as it is received as they are working through the match run. Another member responded that it is good to know that information can be entered if needed.

A member asked for clarification that organ procurement organizations (OPOs) can enter the information and then have it applied to matches that have already been executed. Staff responded that it will be applied to any current matches and will be applied if an OPO is sending multiple batches of notifications. Staff also noted that this popup window is not the only place to enter the information – OPOs can always enter the information into the donor record, and it will apply to the offer filters.

Committee leadership agreed that some form of communication or education might be helpful so members are aware of the ability to enter data that can be applied to the match run. Several members commented that the popup window is a great tool for entering data.

A member asked about how to apply offer filters to the match run. Staff responded that members need to click on the "electronically notify" button before the option to apply offer filters becomes available. The member asked if the filters get updated when information is entered after cross clamp. Staff noted that the filters will be applied to those programs without a response but not those programs that have entered a provisional yes. Staff requested that the member contact staff after the meeting to address additional questions.

A new member asked about the allocation process and how to mitigate inefficiencies. Another member provided an example of how their OPO does not send out a lot of offers, instead using the approach of evaluating interest to ensure that transplant programs that enter provisional yes responses are truly interested in the offer. Then once they get additional information, such as biopsy results or cross clamp time, they will apply the filters and send offers.

Research staff presented potential changes to the kidney minimum acceptance criteria (KiMAC) for continuous distribution and how it could work with offer filters. Some options being considered include:

- No changes to Offer Filters data collection screen
- Offer Filters data collection screen changes to a read-only list of criteria for OPO awareness
- Removal of Offer Filters data collection screen

Research staff explained the difference between screening criteria such as the KiMAC and offer filters. Screening criteria prevents candidates from showing up on the match run while offer filters allows candidates to appear on the match run but provide kidney transplant programs the ability to filter organ offers that they would normally not accept.

Next Steps:

Staff will develop a plan to provide the community with further information/education on the offer filters tool.

2. Require Reporting of Patient Safety Events

The Committee reviewed the OPTN Membership and Professional Standards Committee's (MPSC) *Required Reporting of Patient Safety Events* proposal.

Decision: The Committee will provide feedback to the sponsoring committee.

Summary of Discussion:

The Chair expressed support for required reporting of certain events. He noted that the Operations and Safety Committee reviews patient safety data every six months, however, the data provided is voluntary. Lastly, the Chair commented that the transportation data might be challenging due to broader distribution because the number of transportation events has increased significantly.

The Vice-Chair asked for clarification about the process for reporting ABO subtyping discrepancies after the ABO verification process. The MPSC representative responded that it is typically the scenario where an OPO performs ABO subtyping, the organ is shipped to a transplant program where subtyping is repeated, and there is a different result. This can have clinical implications and collecting data will allow the MPSC to work with OPOs to understand the reason why that would happen.

A member asked why it would be the responsibility of the OPO to report the discrepancy and not the transplant center. The MPSC representative responded that ideally both would report the discrepancy as the transplant center communicates with the OPO.

A member added that OPOs often get discrepant subtyping results because the serology lab and histocompatibility lab will do testing and come up with different results. In that case, the OPO will move forward with the primary ABO results. The member provided an example of both labs having the same result and then the transplant program will get a different result and she worried about the increase in discrepant subtyping results. The MPSC member noted that the reporting would only be required if the organs have been allocated. However, several members expressed concern about the reporting burden as more and more subtyping is being performed.

A member asked about capturing late declines that result in non-use. The MPSC member responded that the challenge is how to define a late decline and how it could be a different definition for each organ type. Additionally, late declines can occur for a variety of reasons and additional discussion would be required to determine what exactly would need to be reported.

The Chair asked about limiting late decline reporting based on information that was provided earlier in the allocation process. For example, if a transplant program declines an organ for hepatitis C or biopsy results that were provided earlier, and not declining for something like organ visualization in the operating room.

A member commented that late declines are like transportation issues in that a lot of times it is beyond the control of the members – such as weather or other circumstances. However, it would be beneficial to collect data to better understand why issues occur when they shouldn't. The member expressed support for adding late declines if a specific definition is identified. A member asked if there could be an update to the patient safety portal to allow for specification for reason, if known, for delay or non-arrival of an organ. That will allow for identification of key information to figure out the real issue instead of trying to identify every delay when there is a rationale reason for it.

A member asked about the proposed requirement for recovery hospitals to report a living donor if they get listed for a transplant within two years. If the organ is recovered at the donor hospital, then sent to another location, it might be difficult for the donor hospital to be aware of the listing. The MPSC member clarified that the requirement calls for reporting "if the donor hospital becomes aware" of the listing.

A member asked about the requirements to report sanctions taken by a professional or state board against a medical professional. For example, if the OPO, transplant hospital, and lab all become aware of a sanction against a recovery surgeon, will all the organizations need to report the sanction. The MPSC member responded that it would be the organization where the sanctioned individual is employed.

<u>Next steps:</u>

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

3. Modify Organ Offer Acceptance Limit

The Committee reviewed the OPTN Organ Procurement Organization Committee's *Modify Organ Offer Acceptance Limits* proposal.

Decision: The Committee will provide feedback to the sponsoring committee.

Summary of Discussion:

A member asked how often the second liver that is declined goes to a lower status patient at the same center. The member added that the liver transplant community is outspoken about the need to accept two offers, but that has a salutary effect on multi-organ allocation where the kidney is being held while waiting to see if a SLK patient with the MELD score of 40 is going to accept the kidney.

A member commented about the last-minute declines and the need for a time limit. If an OPO is waiting for a recovery team to arrive and then they accept another offer, there needs to be a time limit for transplant programs to decide on which offer to accept. The OPO Committee member responded that there was discussion about establishing a timeframe, but it is so complex because it doesn't just impact the liver patients, there is an impact to all the organs when a recovery needs to be delayed due to a late turndown. There is also a transparency component and the need for communication between the OPO and transplant programs.

A member added to the previous comment about whether the declined liver is placed at the same center. If this happens often, it is a behavioral issue that needs to be tracked. The member added that this situation is why backup offers exist because if an OPO requests a transplant center to be a backup for this scenario, that center should take it seriously.

The member also commented on the donation after circulatory death (DCD) option and how the number of DCD donors is increasing enough to consider an exception. Lastly, the member recommended an exception for high model for end-stage liver disease (MELD) patients because those patients benefit from having two acceptances. She added that this is a behavioral issue for certain transplant centers and if the community can better understand why it is happening, then other centers won't have to be penalized by having policies that might be detrimental to their patients.

Next steps:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

4. Ethical Analysis of Normothermic Regional Perfusion (NRP)

The Committee reviewed the OPTN Ethics Committee *Ethical Analysis of Normothermic Regional Perfusion (NRP)* proposal.

Decision: The Committee will provide feedback to the sponsoring committee.

Summary of Discussion:

A member asked about the rationale for broadly stating NRP instead of addressing the specific ethical concerns related to thoracoabdominal NRP (TA-NRP) and the reperfusion of the brain. The Ethics Committee member noted that similar concerns have been raised that might lead to a modification of the white paper. He further acknowledged that TA-NRP is the challenging part of NRP and from an

anatomical perspective, collateral circulation through the abdominal spine may provide ascending blood to the brain stem.

A member asked a question about the general process for white papers and how the OPTN Board of Directors approves them. For example, if the Board approves a white paper, does that mean the OPTN approves the conclusion reached by the Ethics Committee or should white papers be used as a framework for thought and discussion on specific topics. The Ethics Committee member noted that a white paper is not intended to be a consensus document, it is an ethical analysis that starts with a problem and there is a deliberative process and analysis that is used to develop the white paper.

A member commented about a recent publication about TA-NRP case studies where there was no activity on the inter-cranial doppler. The Ethics Committee member mentioned that in Spain they use bi-spectral analysis to ensure no oxygenation to the brain. He added that the Uniform Declaration of Death Act (UDDA) does not address perfusion to the brain or brain stem and the Ethics Committee conducted an ethical analysis based on the UDDA.

Next steps:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

5. Efficiency and Utilization in Kidney and Pancreas Continuous Distribution

The Committee reviewed the OPTN Kidney and Pancreas Transplantation Committee's *Efficiency and Utilization in Kidney and Pancreas Continuous Distribution* request for feedback:

Decision: The Committee will provide feedback to the sponsoring committee.

Summary of Discussion:

Dual Kidney

A member expressed appreciation for this work and understands the issue of hard-to-place kidneys, with the main issue being that it takes too long to make offers which leads to declines from transplant programs that would have accepted the offers if made earlier. He added that dual kidneys should be considered "hard-to-place" and OPOs should have the flexibility to offer them earlier. This could provide incentive for transplant centers to have separate criteria and identify candidates that are appropriate for dual kidney transplants. He suggested a hybrid where option 2 could be offered out early and another subset of kidneys that for some reason, such as unusual anatomy, are in class 1 and can't be offered as single kidneys and therefore get offered as part of a dual.

A member supported donor criteria over a percentage of the match run because, with complex donors or marginal organs, time is the most important consideration so OPOs should not be required to work down the match run.

A member suggested using a data-based approach and evaluating which patients are successfully transplanted as duals and developing criteria based on those patients. He added that most of them are probably KDPI of 85 or greater. Staff noted that data reviewed showed a greater number of DCD donors, diabetes and other risk factors and those trends stick out a little more with KDPIs of 35-85 group. The donor characteristics were less severe for the successful dual kidney transplants for the KDPI of 85-100. Staff noted that this might be due to tolerance levels changing for higher KDPI donors.

Mandatory Kidney-Pancreas Offers

A member noted that there is a strong push from the pancreas and pediatric community to change multi-organ allocation so that only one kidney goes with any double-organ combination and that should be factored into the analysis. Additionally, any time you consider kidney-pancreas allocation you need to be aware of the challenges of recovering pancreata and how a high percentage of them cannot be transplanted. Lastly, the kidneys often allocated with the pancreas are higher quality kidneys and if the pancreas is not transplanted, the kidney might go to a local candidate and not the original pediatric or other multi-organ candidate. Staff acknowledged previous feedback from the OPTN Ad Hoc Multi-Organ Transplantation Committee and how kidney-pancreas patients are essentially kidney patients who also need a pancreas based on qualifying criteria.

Staff asked about how allocating one kidney to kidney alone candidates and the second kidney to multi-organ candidates would impact mandatory kidney-pancreas offers in the continuous distribution framework. A member responded that the ongoing multi-organ discussions are complex and how a kidney-pancreas transplant can save lives because the patients listed for that combination have higher mortality. He added that there is also the issue of whether they are on dialysis and how that can cause differential mortality. It is challenging to balance equity and utility with multi-organ transplants.

Next steps:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

Upcoming Meetings

- September 28, 2023 (in-person)
- October 26, 2023 (teleconference)

Attendance

- **Committee Members**
  - Alden Doyle
  - Kimberly Koontz
  - Anne Krueger
  - Snehal Patel
  - Jennifer Smith
  - Jami Gleason
  - Julie Bergin
  - Jillian Wojtowicz
  - Jill Campbell
  - Kaitlyn Fitzgerald
  - Laura Huckestein
  - Sarah Koohmaraie
  - Stephanie Little
  - Mony Fraer
  - Nicole Toran
  - Norihisa Shigemura
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Katie Audette
  - Avery Cook
- **UNOS Staff**
  - Joann White
  - Carlos Martinez
  - Cole Fox
  - Kerrie Masten
  - Kayla Temple
  - Katrina Gauntt
  - Lauren Mauk
  - Lindsay Larkin
  - Lauren Motley
  - Laura Schmitt
  - Elena Liberatore
  - Robert Hunter
- **Other Attendees**
  - Zoe Stewart Lewis
  - Lori Markham
  - Sanjay Kulkarni