OPTN Operations and Safety Committee
Meeting Summary
May 23, 2024
Conference Call

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

Introduction

The OPTN Operations and Safety Committee ("Committee," "OSC") met via WebEx teleconference on 5/23/2024 to discuss the following agenda items:

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

1. Follow Up: Re-evaluation of Deceased Donor Testing Requirements
2. Task Force Update: Rescue Pathways

1. Follow Up: Re-evaluation of Deceased Donor Testing Requirements

The Committee will continue discussions in the development of this project once approved.

The Committee reconvened their discussions on the outline of the Re-evaluation of Deceased Donor Testing Requirements project. Committee members were tasked with asking their colleagues at their respective institutions the following question(s):

- For organ procurement organizations (OPOs): What testing is most challenging to obtain?
- For transplant programs: What test results are needed/are you waiting for to better inform a decision on an organ offer?

Additionally, the Committee solicited feedback on the above-mentioned questions from the following OPTN Committees: OPO, Transplant Coordinators (TCC), and Transplant Administrators (TAC). The themes of those discussions were as follows:

Feedback from OPOs:

- Imaging (standardizing processes and accessibility within system)
- Timing of tests (and instances where tests need to be repeated) should be accounted for
- Biopsy slides (standardizing processes and accessibility within system)

Feedback from transplant programs:

- These policies should be evaluated regularly
- Consideration for processes related to testing that may not be readily available (i.e., Chagas and Strongyloides)
- DCD offers (standardizing reporting of neurologic status)
- Lung offers (standardizing reporting of ventilator settings, bronchoscopy)
- Serologies
- Imaging – computed tomography (CT) scan, biopsies

The Committee reviewed and discussed the feedback received.

Summary of Discussion:

The Committee Vice Chair added that for the OPO feedback, there were also comments related to having the ability to lock entry if subtype is not reported when documenting blood type. It was explained that if the field is not blocked, it becomes a safety issue. In reference to imaging, the comments were specifically related to standardizing the presentation of slides.

The Committee Chair asked if there were any comments related to some tests being harder to get due to technologies only being accessible in certain areas. The Vice Chair stated that there were some discussions related to accessibility to certain tests, but it was in the context of challenges of obtaining testing after hours as well as the timing of the tests. The Vice Chair added that in speaking with their staff, the oxygen (O_2) and chest x-ray, the timeframes of obtaining these tests are difficult with hospital staff post-coronavirus infectious disease (COVID). The requirement for repeating certain tests can also present challenges.

A member stated that at their program, they often encounter challenges with pathology reads. The member continued by explaining that at their local donor hospital are either unable or unwilling to do a pathology read for them to rule out malignancy and to do liver biopsies. Their program recently implemented frozen section biopsies in house for kidneys, but if there is a node or nodule on a donor, there is a challenge to have this read by donor pathology.

The Committee chair asked the member what a potential solution to this may be. The member stated that their solution is to bring a microscope to the donor hospital. The member continued by explaining that there are challenges to courier specimens back and forth to read; there is a reliance on the donor hospital for this service. There is a challenge for pathology to rule out malignancy to make sure transplant is safe to proceed. Another member stated that there are telepathology services available that could help with this process.

A member agreed with the challenges related to pathology readings and added that their program stores a microscope at their donor hospitals so the donor hospital can read the slides for their program (specifically kidney slides). Otherwise, the donor hospitals would make the slides for them, but would not read the slides.

Feedback from the OPO Committee shared similar sentiment and commented on the variation of accessibility to the imaging (slides being available vs not). An OPO member suggested consideration in potentially developing policy requiring one to two slides at minimum that should be available to a transplant program. The Vice Chair agreed with this summary and added that there is one OPO program that said they partner with their transplant program to do their biopsy slides and they will only do one slide and would not release it. Additionally, there are many options for imaging and some of the technology used is outdated (ex. burning disc for echocardiogram (Echo)). There was a suggestion of having an improved ability to do image sharing from this perspective.

A member agreed with the comments made related to the challenges of receiving results for biopsies. The Committee Chair suggested there being messaging to donor hospitals on the national expectation and importance of preparing slides. A member agreed with this and added that from their experience, they are often told that the pathologies would not be read. If there were some guidance on this, it may be helpful. The Committee Chair stated that one of the six pillars of the OPTN Expeditious Task Force (Task Force) is to do commitments, which is directed at hospital leadership. The Committee Chair suggested that if the Committee agrees, this may be something that could be brought to the Task Force Subcommittee and be a part of the conversation to help with messaging and bringing awareness to this topic.

In response to the transplant program feedback, the Committee Chair stated that regarding the comments related to having the images available, the technology exists in general in electronic medical records (EMRs). The Committee Chair continued that this information should be available especially for biopsies and scans; so often there are nuances especially for medically complex donors where this information is critical.

A member reported that the feedback they received was similar to what was addressed and added that from a liver standpoint, having a Gamma-glutamyl Transferase (GGT) at time of offer would be helpful. Another member stated that they received comments about neurological status and that currently, there is nowhere in the OPTN Donor Data and Matching System to document this which creates challenges in communicating this information. The member suggested a way of standardizing the way of reporting this information. Additionally, it would be helpful to have information related to sedation, pressors that were going at the time of neurological status as well as bed settings. For arterial blood gases (ABGs) and challenged gases, there needs to be an ability to document the donor physician whether they are prone or supine with every ABG obtained; there is currently no ability to document this information in the OPTN Donor Data and Matching System.

A member agreed with this and added that up to date urine output (not just a 24-hour block) for donation after cardiac death (DCD) kidney offers, CT with viewable images for liver/abdominal, timely echo with left-ventricle (LV) and intact ventricular septum (IVS) measurements for hearts, timely ABGs for lung, and updated culture results and pressor information for all organs.

The Vice Chair commented that their staff noted that for ABG and ventilator settings, an error shows up and zero offers can be sent until there is a 100 percent gas. There was a question as to why this was the case. A member asked if this was a policy requirement. The Vice Chair voiced uncertainty on whether this was a policy requirement or if this is the way OPTN Donor Data and Matching System is programmed. A member confirmed that this was a policy requirement.

Another member added that an immediate (STAT) Echo should be done in a timely manner. The member continued to elaborate that since COVID, staffing and resourcing has been a challenge at OPOs. There tends to be a pushback in getting a STAT Echo done in a timely manner due to this and/or on-call staff would have to come in to do the testing. The member continued by asking if other OPO members have had challenges with preparing for implementation of the Chagas and Strongyloides testing requirements. The Vice Chair stated that the TCC commented on this and was inquiring if OPOs were prepared for these requirements as well.

The Committee Chair asked if there was a standard platform/process for this type of testing. A member stated that this is part of the challenge with this new requirement. The member continued by stating that their lab would most likely need to do follow up testing to do a send out to another laboratory to do the testing which would create a delay in getting the results back in time. The Committee Chair stated that this should be paid attention to once the policy is implemented and suggested guidance for this process.

The member stated that there is not much detail for the type of testing, but instead states that it should be FDA approved. The Committee Chair responded that the Committee could investigate this further and provide guidance with the goal of promoting successful transplants and avoiding further delay in the allocation process.

Staff shared report outs from members who sent their feedback prior to the meeting which included: from the OPO perspective - bedside biopsies and cardiac catheterization being the most challenging to obtain after business hours; from the transplant program perspective – abdominal ultrasounds and/or CTs and bedside biopsies are critical to the evaluation outside of trending lab values.

A member reported from their outreach a suggestion of having a policy for requests for additional testing should be made in a specified timeframe within one hour of the primary offer. The member explained that their program receives many requests for retests that can take 5-6 hours after a primary offer has been sent which can create delays in allocation.

The Committee Chair stated that this topic was similar to the Committee's previous discussions in the Committee's past work on provisional yes. There was discussion about way for transplant programs to notify the OPOs within a certain timeframe of what additional information is needed to further review and provide a response on an offer. The goal of that project was similar in wanting to decrease the time in allocation.

Staff continued by sharing additional report outs: one member reported that their program has encountered challenges in NAT testing as their program has to send it out to have done. Additionally, TB testing, amylase and lipase can also be hard to obtain as these tests also have to be sent out which can be challenging in getting completed within certain timeframes. Another member reported that from an OPO consideration, logistical considerations can create challenges with processes and streamlined communications, especially when coordinating with multiple stakeholders dispersed over wide geographic areas. The member also noted challenges due to resource limitations, recipient center requirements, viability assessment challenges, timeliness and accuracy that can further complicate testing processes for OPOs. The member also reported out that from a transplant program perspective, tests that are need for their evaluation of organ offers are cross-matching results, viral serology tests, histocompatibility testing, donor organ function tests, imaging studies, and donor medical history. From a patient perspective, the member advocated for transparency of patients and this being in consideration in the development of this project. The member included emphasis in coordinating and having a collaborative approach with OPOs and transplant programs for these processes.

Staff stated that additional discussion and review of this feedback would be forthcoming once the project is approved.

Key Metrics

The Committee reviewed potential key metrics for this project which included the following:

Monitoring

- Offer Acceptance Rates – impact on transplant hospital behavior
- Organ Utilization Rates – impact on everyone
- Rate of turndowns related to testing

Increase Efficiency

- Time from donor added to first non-bypass response – impact on OPO behavior
- Evaluation Times – impact on transplant hospital behavior
- Rate of missing essential tests – impact on OPO behavior
- Proportion of critical test results post-acceptance

The Committee Chair stated that the monitoring aspect of the metrics to ensure there are no unintended consequences and evaluating what the impact of the policy changes. The Committee Chair continued by stating that the goal is to ensure that the data being collected is what the Committee is looking for in understanding the results. The Committee Chair stated that this is a starting point but there would be further discussion to determine if further refinement is needed to the potential key metrics.

The Committee Vice Chair agreed with this and stated that the question leadership discussed was "what would be the impact to improve donor testing?". The thought was to decrease the time that OPOs are able to get organ offers out and that the best way to measure this was from the time the donor was added to the first offer sent and observing whether or not there is a reduction in that time. From the transplant center, the evaluation time was thought of looking at from a primary notification to an acceptance observing if this time would be reduced. The Committee Vice Chair added that with this reduction in time, it would be the hope that the reduction in time is not due to organs being declined faster. The Committee was asked their thoughts.

It was reiterated that the key metrics presented is a first step and that in the development of the project may result in the key metrics being re-evaluated and modified to ensure they reflect the impact of the policy changes the Committee would like to evaluate.

A member asked for clarification on monitoring the organ utilization rates, specifically if this included recipients and how successful they are post-transplantation or if this stops once the organ is received. The Committee Chair responded by stating that this would not stop once the organ received, however for the purposes of this project, this may not have a measurable impact here. The member clarified that the metrics is more focused on speed and cycle time versus (vs) quality of the testing. The Committee Chair confirmed that was the case for now and added that in this iterative approach, would want to ensure that the testing requirements are also still relevant for the timeframes that are needed timing of the organ offer processes.

A member voiced agreement in the feedback on the testing challenges and echoed the comments on bronchoscopy testing for their diagnostic and therapeutic purpose.

Another member asked how the rate of turndowns related to testing would be measured. The Committee Chair agreed that this was a good question to ask and something that would need further discussion. The Committee Chair continued that the current work on late decline work is an effort to collect additional information to be able to investigate the factors related to late declines further. The Committee Vice Chair added that regarding late declines, there was some discussion in potentially utilizing the donor testing code in OPTN Donor Data and Matching System in listing. Currently, it is uncertain if there is a clear practice in how that code is used – is it because the testing wasn't available or because of the testing result itself? Currently, it is uncertain how to gather this information consistently.

There were no further comments or questions.

Next Steps:

The Committee will continue discussions in the development of this project once approved.

2. Task Force Update: Rescue Pathways

The Committee will be updated on the progress of the Rescue Pathways project and provide feedback as needed.

Presentation Summary:

The Committee received a presentation on the OPTN Expeditious Task Force's (Task Force) Rescue Pathways project. The project is specifically focused on a protocol that addresses accelerated placement

of hard-to-place kidneys. This protocol was developed in response to the implementation of the variance proposal that was implemented on April 2, 2024.[1]

Summary of Discussion:

The Committee Chair commented that much of the work of the Task Force would result in collaboration with the Committee. Much of the efforts of the Task Force will have collaborative efforts from a number of Committees. The Committee will have an important role in this work as it is anticipated that there will be various nuances that will need to be addressed.

Next Steps:

The Committee will be updated on the progress of the Rescue Pathways project and provide feedback as needed.

Upcoming Meetings

- June 27, 2024 (Teleconference)

[1] *Expedited Placement Variance*. Executive Committee. December 22, 2023.

Attendance

- **Committee Members**
  - Alden Doyle
  - Kim Koontz
  - Anja DiCesaro
  - Annemarie Lucas
  - Jami Gleason
  - Jillian Wojtowicz
  - Kaitlyn Fitzgerald
  - Laurel Avery
  - Megan Roberts
  - Sarah Koohmaraie
  - Norihisa Shigemura
  - Snehal Patel
  - Mony Fraer
- **HRSA Representatives**
  - Arjun Naik
- **SRTR Staff**
  - Avery Cook
- **UNOS Staff**
  - Joann White
  - Betsy Gans
  - Jadia Bruckner
  - Kaitlin Swanner
  - Kayla Temple
  - Kerrie Masten
  - Laura Schmitt
- **Other Attendees**
  - Bridget Dewees
  - Elizabeth Shipman