OPTN Operations and Safety Committee
Meeting Summary
April 27, 2023
Conference Call

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

Introduction

The OPTN Operations and Safety Committee (the Committee) met via Citrix GoToMeeting teleconference on 04/27/2023 to discuss the following agenda items:

1. OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) Project Updates
2. Efficiency Project Update
3. Discussion/Report Outs: MPSC Referred Project Ideas

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

1. OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) Project Updates

The Committee was provided and overview of projects updates from the DTAC for the upcoming 2023 Summer Public Comment cycle.

The DTAC has two projects that will be going out for the 2023 Summer Public Comment cycle. One project will be a concept paper focused on human immunodeficiency virus (HIV) positive donors who are later deemed to be HIV uninfected. The concept paper will allow DTAC to determine the scope of the problem before providing an algorithm that would identify and clarify such situations. The paper is a request for information or feedback that is used by the OPTN to develop proposals if it is warranted. Through this process, Organ Procurement Organizations (OPO) will be able to provide feedback directly or anonymously during the public comment cycle. This will also allow DTAC to assess the community's desire for an algorithm that would help identify HIV positive donors who were actually HIV uninfected. In the concept paper, DTAC intends to introduce questions that prompt feedback during public comment.

Proposed Discussion Questions for Concept Paper:

- How often do OPOs encounter HIV positive donors that are later deemed to be HIV uninfected?
- Do OPOs need a testing algorithm to deem a donor as HIV positive, but HIV uninfected?
- Due to risk of transmission, does it make sense to create this algorithm only for pediatric donors?

The second project that DTAC is putting out for summer public comment focuses on revisions to endemic guidance documents. These documents are predominantly from the years of 2012 and 2014. The intent of the guidance is meant to be used in complex scientific or clinical situations to allow for decision-making. It is also used to address highly controversial issues and to communicate member obligations not readily apparent in policy or bylaws. DTAC will condense and update their existing guidance documents in an overall guidance document for endemic diseases and will add sections for both living and deceased donors.

Guidance Documents Revisions:

- Mycobacterium tuberculosis
  - Updates to include the changes to nomenclature (Tuberculosis Infection instead of Latent Tuberculosis Infection)
  - Update testing (language around preferred testing is slightly outdated)
  - Update report of Donor Derived Infections (DDI)
  - Refresh epidemiology
  - Add section on deceased donors
- Chagas
  - Update donor screening section if the proposal passes
- West Nile Virus
  - Updates to include deceased donors
  - Update summary section
  - Update epidemiology figures
- Living Donor
  - Revisit the detailed information for each pathogen through the lens of what we know about DDI reports and newer epidemiology
  - Update Strongyloides and Chagas to align with policy proposal

Summary of discussion:

A member suggested that it might be worthwhile to get a more concrete number of incorrectly diagnosed HIV positive donors to gain more direction. In response, UNOS staff said that the DTAC are compiling information but require more to decide. Due to the limited amount of HIV donors, the DTAC want to make sure that there is a need that can be supported and that every avenue on the matter is being explored.

The Committee member also questioned why there were only a small number of HIV positive donors recorded and whether there were only a few being referred for organ donation. The member suggests that maybe local OPOs or hospitals are crossing out these donors because of their positive status. UNOS staff state that there is still a lack of knowledge regarding who is approved under the HIV Organ Policy Equity (HOPE) Act. Staff hope that there is an increase in HIV positive donors but note that the final decision regarding acceptance of these organs is ultimately left to the discretion of the transplant center. A different Committee member also expressed the challenges that are faced with HIV positive donors. More specifically, there are potential HIV positive donors in the country that they pursue but are unable to place organs for because of the limited list. Therefore, the number of actual donors is significantly different from the number of HIV positive potential donors. The Committee member states that if there is a high percentage of false positives, an algorithm would be helpful in identifying these situations.

The member also suggests that centers should be able to treat their patients, regardless of HOPE Act approval, in cases where they have an HIV positive patient and an HIV positive donor. UNOS staff responded and said if the Secretary provides direction to remove the research initiative, DTAC would go forward with that recommendation as well. The Committee member added that the high barriers set forth by the HOPE Act discourage transplant programs from providing such services, especially for such a small group of people. This may be counterintuitive to providing equity and access to transplants.

Another Committee member also aimed to clarify whether the HIV positive donors being considered were those who had a false positive or those who were testing negative because they have been in therapy for several years and had no detectable viral load. A Committee member explained that, on this

matter, DTAC was focusing on potential donors who had false positive or conflicting results. Current policy may limit opportunities of organ donation for false positive HIV donors. Therefore, the upcoming concept paper would provide direction regarding whether an algorithm is needed to consider and conclude if a patient is HIV positive or not.

Next steps:

DTAC will finalize their Concept Paper and revise their endemic guidance documents to release them for 2023 Summer Public Comment.

2. Efficiency Project Update

A UNOS staff member provided a follow-up of previous projects focused on the enhancement of the OPTN Donor Data and Matching System which will be going before the Board in June.

The proposed project works to identify potential enhancements to the OPTN Donor Data and Matching System that may improve efficiency of organ offer allocation. In addition, this project aims to identify enhancement opportunities that would not require supporting policy, new data, or public comment. The selection process included a review of the list of previously mentioned enhancement opportunities, evaluation of existing projects to identify overlap, and one-on-one interviews with various member transplant programs. The UNOS staff member highlighted six different problem areas and potential solutions which are outlined below.

Offers Console for Transplant Programs:

- Problem: The offers console in the OPTN Donor Data and Matching System displays all organ offers for a donor. Transplant hospital staff may not be on-call for all organs so it can be challenging to navigate the list to find the offers they need to manage. The most important information used by transplant hospitals when evaluating offers is not displayed on the offers console. Both factors may contribute to the time it takes to evaluate an offer. Therefore, transplant hospital staff request more control over the display of offers for certain organ types and they want to see more data points related to case progression on the console.
- Solution: Redesign the transplant center console to allow transplant hospital staff to filter the donor organ offers that they need to see. The OPTN IT Customer Advocacy Department would also add additional fields that pertain to different evaluation stages. For example, information would include cross clamp date and time, OR date, organ placed, and top ranked patient.

Lack of Visibility into All Matches Run for a Donor:

- Problem: Transplant hospital members do not have an overall view of the organs being allocated for a donor because their view is organ specific. There is no visibility into which organs OPOs are planning to allocate.
- Solution: UNOS staff want to provide a list of all matches that have been run for a donor with pertinent information for each match. In this case, transplant hospitals can see if an organ has been placed and they would have the ability to navigate to the different organ match run lists from this screen as well.

Improve Navigation Between Different Organ Matches:

- Problem: Transplant programs have a match specific view so they cannot easily navigate to other matches for the same donor. This results in frustration and can increase the time it takes to evaluate offers.
- Solution: A solution for this would be to allow transplant centers to easily switch between matches for a donor. The dropdown on the match run list will display a list of matches and the transplant center will be able to navigate to other matches.

Transplant Center Donor Record View:

- Problem: The donor record contains a large amount of information, and the current order of sections is not optimal for transplant hospital coordinator donor evaluation. This may impact the time it takes them to review and respond to organ offers and can affect an overall allocation time.
- Solution: Rearrange the sections on the transplant hospital view of donor record based on feedback from members.

Follow Donor Alerts:

- Problem: Transplant hospitals are not notified of changes to OR times in a consistent manner.
- Solution: A solution for this would be to automate donor alerts. Whenever an OPO changes the recovery facility or OR date and time, then the system would automatically send out an alert. In addition, cross-clamp date and time may also be added to the follow donor alerts.

Remove Yellow Highlight from Match Results on Transplant Center's View:

- Problem: The yellow highlight is confusing for transplant hospitals.
- Solution: Remove the yellow highlight from the transplant hospital view of match results.

The enhancement bundle of work presented would coincide with the June 2023 Board meeting. Implementation is slated for the second quarter (Q2) of 2024.

Summary of discussion:

On the matter of offer consoles for transplant hospitals, a Committee member agreed that additional filters would be a useful tool to screen offers. Others also suggested that it may be worthwhile to display where patients are compared to other programs and to also add an interactive element for staff. The member shares that due to the volume of offers, transplant centers may mix offers up and decline the wrong ones. The interactive component may allow a transplant hospital staff member to write or leave a note next to an item on the page and avoid such mistakes. UNOS staff confirmed that this has been asked quite a bit, however, there is uncertainty whether this can be added to the current bundle of enhancements.

When discussing the lack of visibility into all matches for a donor, a Committee member expressed that a list of matches run, and related information would be valuable. One of the challenges often seen is that there may be a required share on the heart list but it will not show placement on the liver list. This solution would give some visibility into the possibility of multi-organ transplants. UNOS staff also mentioned that other solutions could be considered, however, it would require additional data collection. Another Committee member agreed that this solution would be helpful for them as transplant programs would be able to see if there is a heart-kidney in place when they are allocating a kidney. In addition, a question was posed regarding whether programs would be able to see which lists had been run or if there was a section that displayed allocation progression. UNOS staff responded and

said that this type of change would require additional data collection and would be added to the list of potential enhancements in the future.

UNOS staff asked if the navigation tool between different organ matches would be helpful. A Committee member agreed and mentioned that this function already exists for OPOs but would be new for transplant programs. On the matter of rearranging the transplant center donor record view, a Committee member commented that the change made sense and was a good idea. In relation to the confusion that transplant hospitals have with the yellow highlight, UNOS staff explained that the initial intention was to help OPOs determine the highest-ranking patient without a response. More specifically, the highlight would enable the OPO to clearly see who is next on the list to be offered the organ. However, the yellow highlight is displayed on the screen for transplant hospitals too, which may be confusing. It may make centers think they are going to get a primary offer even if the organ has already been placed.

A Committee member asked whether the proposed enhancements were a result of surveys conducted or data received. The staff member said the proposed enhancements were a result of one-on-one interviews, feedback from the OPTN Computer System user surveys, feedback from help service desk claims, and topics previously discussed in past OSC meetings or workgroups. The member responded that this project made sense, especially if this is what people wanted to see. UNOS staff acknowledged that even though all items might not benefit everyone, the enhancements aim to improve requests made across all channels.

Next steps:

UNOS staff will prepare and present proposed enhancements during June 2023 Board meeting.

3. Discussion/Report Outs: MPSC Referred Project Ideas

UNOS staff provided recommendations on two project idea referrals from the OPTN Membership & Professional Standards Committee (MPSC):

Project Idea 1: Centralized Reporting

- Purpose: *OPTN Policy 16.6.B's* 14-day limitation on vessel storage leads to:
    - Lack of available deceased donor vessels for use in transplantation, and sharing with other transplant hospitals
    - No clear delineation of when the 14-day storage period for vessel begins
- Proposal: Revisions to *OPTN Policy 16.6*: *Extra Vessels Transplant and Storage*
    - Define storage and include storage time period that is supported by clinical evidence
    - Develop a centralized system to track deceased donor vessel availability

Project Idea 2: Organ Labeling Clarification

- Purpose: Information required on organ labels are inconsistent with information required on the OPTN standardized label as incorporates into OPTN Organ Labeling, Packaging and Tracking System.
- Proposal: Review *OPTN Policy 16.3: Packaging and Labeling* to:
    - Include all required information in policy
    - Remove enumerated required information from policy and require accurate information be included for all elements of the OPTN furnished label

Summary of discussion:

A Committee member stated that it seemed like the process for sharing extra vessels is not very effective. However, they find that the proposal was sufficient. A different member asked how often vessels were shared with other centers. An MPSC representative mentioned that one of their struggles in this matter is finding a center that has extra vessels, and finding one that is willing to share them. The Committee suggested that this may be a problem that centralized reporting is not equipped to address. Potential next steps could be to understand and identify how big the scope of the problem is before they move forward with its prioritization. In addition, the Committee also agreed that requesting more data, compiling a list of questions, and analyzing and tracking data points relating to donor vessels may be a valuable next step.

A member suggested that transplant administrator groups could also spend time with the centralized reporting proposal. They may be able to provide some ideas and recommendations back to OSC, as they are more likely to be directly involved with the issue. The member also acknowledged that the revision to the policy would be relatively simple, however, the development of the tracking system would be a much heavier task. Priorities would have to be based on the data that is gathered and how often the problem occurs. A member said there could also be a problem with surveys or surveying because there is no clear delineation of when the 14-day storage period begins. Time could differ based on whether centers are starting the period based on the time the patient went into the OR or the time the cross-clamping took place. This is where clarification would be needed. Another member agreed that clarity would be beneficial, especially because it can be a challenge for centers to locate extra vessels. The Committee also voiced interested in collaborating with the OPO committee to determine if OPOs have a system for transplant programs to request extra vessels and what those policies look like.

In the context of Project Idea 2, a member stated that they thought it made sense to have "cross-clamped" on the label and that policy language should be consistent. In addition, they suggested that it may not hurt to do a review of the policy for internal and external labeling to see what the differences are. The Committee agreed that there is interest in working on this in the future. More specifically, their recommendation would be to review the policy and determine exactly what the changes would be. A member asked if this is a policy that the OSC would sponsor. UNOS staff explained that the Committee received this referral because the Committee has worked on organ labeling in the past. In addition, the OSC covers any policies related to patient safety procedures. The Committee member also questioned whether changes would align with transplant labels and whether that information would automatically populate on the label. UNOS staff replied that this is something that would need to be further considered and would require collaboration with IT staff.

Next steps:

UNOS staff will summarize the Committee's thoughts and recommendations and will submit them to the MPSC for their review.

Upcoming Meeting

- May 25, 2023 (Teleconference)

Attendance

- **Committee Members**
  - Kimberly Koontz
  - Andy Bonham
  - Christopher Curran
  - Jami Gleason
  - Jillian Wojtowicz
  - Julie Bergin
  - Norihisa Shigemura
  - Renee Morgan
  - Snehal Patel
  - Stephanie Little
  - Mony Fraer
  - Susan Stockemer
  - Laura Huckstein
  - Anja DiCesaro
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katherine Audette
- **UNOS Staff**
  - Joann White
  - Isaac Hager
  - Taylor Livelli
  - Kerrie Masten
  - Carlos Martinez
  - Kim Woodard
  - Laura Schmitt
  - Meghan McDermott
  - Sharon Shepard
  - Aneemarie Lucas