

OPTN Membership and Professional Standards Committee (MPSC)

Meeting Summary

August 29, 2023

Virtual Meeting

Zoe Stewart Lewis, M.D., Chair

Scott Lindberg, M.D., Vice Chair

Introduction

The Membership and Professional Standards Committee (MPSC) met via Webex in both open and closed session on August 29, 2023. The Committee discussed the following agenda items during the open session of the meeting:

1. Clarification of OPO and Living Donor Recovery Hospital Requirements for Organ Donors with HIV Positive Test Results (DTAC)
2. Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation (DTAC)
3. Modify Organ Offer Acceptance Limits (OPO)
4. Concepts for a Collaborative Approach to Living Donor Data Collection (LDC)
5. Ethical Analysis of Normothermic Regional Perfusion (Ethics Committee)

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

1. Clarification of OPO and Living Donor Recovery Hospital Requirements for Organ Donors with HIV Positive Test Results (DTAC)

The OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) Chair presented their concept paper *Clarification of OPO and Living Donor Recovery Hospital Requirements for Organ Donors with HIV positive Test Results* and asked for the MPSC's feedback. This concept paper considers developing an algorithm that would account for situations where a donor may have a positive Human Immunodeficiency Virus (HIV) test but does not have an HIV infection. The purpose of this concept paper was to gather supporting evidence from the community to justify and inform future work, as well as gauge the community's interest in proceeding with this project.

Summary of Discussion:

Members inquired about specifics of the potential algorithm and supporting evidence, such as the breakdown of serology and nucleic acid testing (NAT) or the definition of confirmatory and whether confirmatory testing would be conducted on a separate sample. At this time, the DTAC does not have the information on existing testing since this is conducted by histocompatibility labs and organ procurement organizations (OPOs) and it is not required to be reported to the OPTN. The DTAC is looking to gather more information regarding existing data that these member types have to determine how to proceed with developing an algorithm. Members acknowledged the existing variability in testing practices and lack of confirmatory testing to distinguish between HIV-positive and HIV-infected, which this project hopes to fill that gap. The presenter noted that the DTAC hopes to gain supplemental information from the community that would determine the volume and scope of the issue so their

committee can provide a reasonable recommendation for this scenario. A member inquired if the transmission risk for HIV differs based on the organ. The presenter responded that theoretically, it should be similar, however, there is no evidence to provide a definitive answer to this.

A member inquired if the information the DTAC is requesting could be gathered directly from histocompatibility labs and OPOs as either a directive or through a survey. Unfortunately, a survey or required reporting of future data would require review and approval by the Office of Management and Budget (OMB) who could determine this is too burdensome and prevent the work from proceeding. The best option for the DTAC to gather this information is through a public comment request soliciting voluntary submissions from groups with this information. The presenter also clarified the DTAC is looking to understand what percentage of donors with a positive test ended up not being pursued as donors for whatever reason, such as donors who were abandoned and later tested negative. The presenter also noted that they are hoping to obtain general large swathes of data, and not patient-specific information. A HRSA representative added that there is only one box to enter the HIV response on the OPTN Computer System so if a patient tests positive and negative there is variability in which test result is entered into the system or which test type was used.

2. Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation (DTAC)

The OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) Chair informed the MPSC of their new guidance document *Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation*. This guidance document does not change MPSC workflow, but it is strongly related to the MPSC's patient safety work. The Committee members are encouraged to review the guidance document and provide feedback.

3. Modify Organ Offer Acceptance Limits (OPO)

The OPTN Organ Procurement Organization Committee past Chair presented their policy proposal *Modify Organ Acceptance Limit* and asked for the MPSC's feedback. This proposal reduces the number of concurrent organ offer acceptances from two to one. The purpose is to reduce late turns which lead to allocations out of sequence and ensure that organs are going to the most in-need patients. The proposal does not impact a transplant program's ability to receive organ offers and can accept a second offer in place of their current offer.

Summary of Discussion:

Members voiced varied support for this proposal, with more leaning toward support overall. Members were in general agreement that reducing late turn-downs is important as it makes it difficult for organ procurement organizations (OPOs) to place organs and transplant hospitals to be ready to transplant a patient. A member vocalized their support for this proposal, noting that it does not limit a transplant program from selecting a better offer, only limiting the number of offers they are able to hold onto at a given time. The MPSC continuously reviews allocation out of sequence (AOOS) and is supportive of proposals that will reduce this practice prioritizing the sickest patients who need a transplant. Limiting late turndowns and MPSC review of AOOS will create more system efficiency and reduce the burden on the system as a whole.

Members voiced opposition for two main reasons, with the first being that oftentimes they will accept an organ without a donor procurement time set. Members noted that without an operating room (OR) time set, they often feel as if it is not a 'firm' acceptance. Since there can be a lot of variability in the time between organ offer and organ procurement, it is possible for the transplant program to accept a second organ that has an OR time set and receive that organ before the initially accepted organ. The

presenter countered that transplant hospitals will still be able to accept an offer that has an OR time set over their existing offer and will discuss the potential to set an OR time prior to offers with the OPO Committee. Alternatively, the member suggested that potential liver recipients who have a high model for end-stage liver disease (MELD) score or are Status 1A should be permitted to accept two liver offers.

A member shared that in a region with a small donor population, reducing the number of organ acceptances could limit access for the sickest patients. The member acknowledged that communication has been a substantial challenge and that improving communication could lead to changed behavior as other transplant programs would be able to prepare for receiving an offer from a potential late turn-down. Members discussed the functionality of the system in permitting them to see what patients have an organ offer acceptance. Members identified that while OPOs are able to see when a patient has an accepted offer, other transplant hospitals are unable to see the acceptance on the match run. Adding this function for transplant hospitals could change their behavior when they know they are secondary to a patient who has two organ acceptances.

A member noted their surprise at not seeing any data reported for the kidney population, given their personal experience handling late turndowns and subsequent AOOS. Members hypothesized that it could be possible that these transplant programs are not entering their organ offer acceptance into the system until the final acceptance is determined.

4. Concepts for a Collaborative Approach to Living Donor Data Collection (LDC)

The OPTN Living Donor Committee Chair presented their concept paper *Concepts for a Collaborative Approach to Living Donor Data Collection* and asked for the MPSC's feedback. This concept paper has been developed in collaboration with the Scientific Registry of Transplant Recipients (SRTR) and their work developing the Living Donor Collective as a pilot project. This paper conceptualizes a future state of living donor data collection which includes the OPTN requiring collection and reporting of living donor candidate and donation decision data, which would be shared with the Living Donor Collective to establish a foundation that enables the Living Donor Collective to directly follow-up with living donor candidates and living donors long-term on a national level.

Summary of Discussion:

A member recommended expanding data collection to include information that could be considered controversial now, such as genetic testing, but would provide valuable insights to better understand the long-term impacts of living donation. The member acknowledged that between the development of the new policy and implementation of the system, it would likely be a decade before there was enough data to draw substantial conclusions from and could see this as a missed opportunity if the Living Donor Committee were to be conservative in their data collection. SRTR colleagues noted that the concept outlines more than just post-transplant follow-up data, but instead begins collecting data upstream to identify potential barriers to living donation. The presenter emphasized that this is about collecting contemporary data and aligning with the long-term calls from the living donor community to collect additional follow-up data. The presenter also acknowledged that there could be potential down the road to evaluate this data in more novel ways, but it is important for the OPTN to begin the project now.

A member who has participated in the Living Donor Collective with the SRTR voiced their support for the pilot program recognizing the value added to their program through the additional data and noted the benefit of utilizing the follow-up data. The member inquired how the follow-up would address potential living donors who became a noncandidate due to a psychological issue, emphasizing their concern for potentially retraumatizing the patient. The Living Donor Committee has not gotten into that level of detail yet as their focus has been on developing the concept for community feedback. The Committee

plans to discuss this level of detail during the next phases of development once they have support from the community to proceed with this new concept.

A member shared their experience at a very large living donor program, noting their challenges with collecting follow-up data. The member was supportive of utilizing people who have expertise in data collection and follow-up to collect this information for all patients. The member recommended integrating data collection with the hospital's existing electronic medical record (EMR) to ease the data submission process upon implementation. The member highlighted the importance of data transfer to reduce additional manual data entry.

A few members commented that without obligatory follow-up by the transplant program, there could be less buy-in from transplant programs on data collection if the OPTN were not to be monitoring or enforcing this. The Living Donor Committee has not yet discussed how the OPTN and the MPSC's role in monitoring and enforcing policy and program requirements would change in this conceptualized future state.

5. Ethical Analysis of Normothermic Regional Perfusion (Ethics Committee)

Staff informed the MPSC of the Ethics Committee's white paper *Ethical Analysis of Normothermic Regional Perfusion*. This white paper does not change MPSC's workflow, but it is a relevant topic to the community. Committee members are encouraged to review the white paper and provide feedback.

Upcoming Meetings

- September 27, 2023, 2-4:00pm, ET, Conference Call
- November 1-3, 2023, Chicago, IL
- December 6, 2023, 2-4:00pm, ET, Conference Call
- March 5-7, 2024, Detroit,
- July 23-25, 2024, Detroit, MI

Attendance

- **Committee Members**
 - Alan Betensley
 - Anil Chandraker
 - Hannah Copeland
 - Chad Ezzell
 - Robert Fontana
 - Roshan George
 - Darla Granger
 - Lafaine Grant
 - Dipankar Gupta
 - Shelley Hall
 - Robert Harland
 - Rich Hasz
 - Kyle Herber
 - Victoria Hunter
 - Michelle James
 - Peter Kennealey
 - Catherine Kling
 - Peter Lalli
 - Raymond Lee
 - Carolyn Light
 - Scott Lindberg
 - Melinda Locklear
 - Maricar Malinas
 - Deborah McRann
 - Nancy Metzler
 - Saeed Mohammad
 - Regina Palke
 - Deirdre Sawinski
 - Malay Shah
 - J. David Vega
 - Mark Wakefield
 - Candy Wells
 - James Yun
- **HRSA Representatives**
 - Jim Bowman
 - Shannon Dunne
 - Marilyn Levi
 - Arjun Naik
 - Daniel Thompson
- **SRTR Staff**
 - Ryutaro Hirose
 - Jonathan Miller
 - Jon Snyder
- **UNOS Staff**

- Robert Albertson
- Sally Aungier
- Kayla Balfour
- Matt Belton
- Rebecca Brookman
- Robyn DiSalvo
- Katie Favaro
- Liz Friddell
- Michelle Furjes
- Jasmine Gaines
- Caroline Hales
- Asia Harden
- Rachel Hippchen
- Madeline Holder
- Robert Hunter
- Lee Ann Kontos
- Ann-Marie Leary
- Taylor Livelli
- Jason Livingston
- Carlos Martinez
- Jon McCue
- Meghan McDermott
- Amy Minkler
- Samantha Noreen
- Rob Patterson
- Michelle Rabold
- Melissa Santos
- Laura Schmitt
- Sharon Shepherd
- Tynisha Smith
- Mike Stanley
- Juanita Street
- Stephon Thelwell
- Marta Waris
- Betsy Warnick
- Trevi Wilson
- Claudia Woisard
- Emily Womble
- Karen Wooten
- Amanda Young
- **Other Attendees**
 - Lara Danziger-Isakov, Chair, OPTN Disease Transmission Advisory Committee
 - Nahel Elias, Chair, OPTN Living Donor Committee
 - Krista Lentine, SRTR Representative to OPTN Living Donor Committee
 - Kurt Shutterly, Past Chair, OPTN OPO Committee