OPTN Operations and Safety Committee – Donor Testing Requirements Workgroup
Meeting Summary
August 28, 2024
Conference Call

Annemarie Lucas, MHSA, Chair

Introduction

The OPTN Operations and Safety Committee ("Committee," "OSC") Donor Testing Requirements Workgroup ("Workgroup") met via WebEx teleconference on 8/28/2024 to discuss the following agenda items:

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

1. Project Overview

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There were no action items for this agenda item.

Presentation Summary:

The Workgroup received an overview of the *Re-evaluate Deceased Donor Testing Requirements* project that included the progress to date of the project, and feedback received (to date). The Workgroup members were also provided an overview of upcoming Workgroup assignments and meeting schedule.

The purpose of the *Re-evaluate Deceased Donor Testing Requirements* project is to:

- Determine what testing requirements (if any) are outdated/no longer relevant
- Better understand processes related to donor testing and propose modifications to current policy

This project will have two components:

- Policy: Re-evaluate policies related to deceased donor testing:
    - Deceased Donor General Risk Assessment (Policy 2.8)
    - Deceased Donor Infectious Disease Testing (Policy 2.9)
    - Additional Deceased Donor Testing (Policy 2.10)
    - Required information for deceased kidney, liver, heart, and pancreas donors* (Policies 2.11 A, B, C, and E)

*The Lung Transplantation Committee is currently working on a policy proposal addressing requirements for deceased lung donors

- Data Collection: Introduce Pre/Post- Transfusion Field
    - This project was brought to the Committee as a referral from the Membership and Professional Standards Committee (MPSC).
        - Purpose: *OPTN Policy 2.6 Deceased Donor Blood Type Determination* outlines requirements for blood typing but does not specify if the donor blood draw occurs pre- or post- transfusion. This can lead to patient safety risks as this can affect patient ABO results.

- Proposal: Inclusion of a check box to indicate if the blood draw was done pre-or post-transfusion to standardize communication and reduce patient risk

The Workgroup will be cognizant of current Public Health Services (PHS) guidelines and Food and Drug Administration (FDA) regulations in their review of current OPTN policies as outlined above. If there are any modifications suggested, the Workgroup will consult with stakeholders (OPTN Ad hoc Disease Transmission Advisory Committee and the Histocompatibility Committee) to discuss those recommended modifications further. Additionally, the Workgroup was made aware of the OPO Committee's *Guidance on Requested Deceased Donor Information*[1] that will be reviewed to ensure that any modifications suggested is in alignment with the guidance document. If not, the Workgroup will make modifications to the guidance.

Summary of Discussion:

A member stated that liver biopsies should be considered as a testing requirement. Another member suggested Glasgow Comas Scale (GCS) data being collected. A member commented that neurologic status is not always helpful in reviewing for donation after cardiac death (DCD) offers. Another member replied by stating that neurologic status can sometimes be helpful but added that the challenge is reviewing information for DCD offers such as neurologic status in a standardized/centralized way. The member continued by suggesting that there be consideration in discussing better ways to communicate these data points within the system.

A member stated that on the transplant side, when there is a decline that is beginning to happen at a neurological status, this may mean that the donor is coming towards brain death. It would inform the transplant program if the offer that was previously a DCD donor would now need brain death testing.

Another member added that conversely to this, DCD donors had been accepted at their program where the GCS had been 3 or 4 and upon arrival at the hospital, would then find out the GCS was 10 or 11. There does not seem to be consistency in how this information is being reported. Just like there is criteria for brain death, there may need to be criteria for how GCS is evaluated from an OPO perspective. A member voiced agreement with this and emphasized the importance of having a way to better communicate data points in the system to have consistency in reporting this information.

Another member added challenges related to obtaining cardiac catheterization as well angiogram; there has been pushback being observed in obtaining this information in addition to obtaining echocardiogram information. A member added that the timing of unplanned or nonroutine biopsies as also being a challenge. The member continued by explaining that there had been several instances they'd experienced where a biopsy had been performed on a potentially concerning nodule or lesion that is not communicated to the transplant hospital until results are received at which point the organ has already been transplanted. This poses an issue of unintentional transmission of fungal and infectious diseases which carries a risk of malignancy transmission. It is beneficial for programs to know this information to better inform on whether to move forward for transplant or wait for results.

A member asked if there had been any analysis on donor decline codes relevant to this project. Staff replied that this would need to be looked into further as there had been previous work done on analyzing decline codes.

The Workgroup will begin their work on reviewing the policies and determining if current policies are still relevant to current practices. If policies are no longer relevant, the Workgroup will discuss what

[1] "Guidance on Requested Deceased Donor Information," OPTN, June 2018, available at https://optn.transplant.hrsa.gov/policiesbylaws/public-comment/guidance-on-requested-deceased-donor-information/.

challenges are being seen and what modifications should be recommended. The Workgroup will also be asked to identify and suggest any requirements that are not currently in policy that should be included. The modifications recommended will be discussed in detail to determine if they are better fit into policy and/or guidance.

There were no additional comments or questions. The meeting was adjourned.

Upcoming Meetings

- September 18, 2024 (Teleconference)

Attendance

- **Committee Members**
  - Annemarie Lucas
  - Ashley Cardenas
  - Christine Hwang
  - Chuck Zollinger
  - Dan DiSante
  - Lara Danzinger-Isakov
  - Elizabeth Shipman
  - Heather Miller Webb
  - Jennifer Hartman
  - Jessica Yokubeak
  - Laurine Bow
  - Malay Shah
  - Norihisa Shigemura
  - Qingyong Xu
  - Shehzad Rehman
  - Vanessa Cowan
- **FDA Representatives**
  - Brandy Clark
- **HRSA Representatives**
  - N/A
- **SRTR Staff**
  - N/A
- **UNOS Staff**
  - Joann White
  - Kayla Temple
  - Kerrie Masten
  - Laura Schmitt