

## OPTN Operations and Safety Committee – Donor Testing Requirements Workgroup

### Meeting Summary

November 20, 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 11/20/2024 to discuss the following agenda items:

1. Policy Review/Discussion
  - a. Policy 2.9: *Required Deceased Donor Infectious Disease Testing* (continued from 9/18)
  - b. Policy 2.11.A: *Required Information for Deceased Kidney Donors*
  - c. Policy 2.11.B: *Required Information for Deceased Liver Donors*

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

### 1. Policy Review/Discussion

The Committee will continue review and discussions on policies for this project.

### Presentation Summary:

The Workgroup reviewed the following OPTN policies:

- Policy 2.9: *Required Deceased Donor Infectious Disease Testing* (continued from 9/18)
- Policy 2.11.A: *Required Information for Deceased Kidney Donors*
- Policy 2.11.B: *Required Information for Deceased Liver Donors*

In their review of the above-mentioned policies, the Workgroup discussed the following:

- Are the current requirements outlined still relevant to current practices?
  - If no, what challenges are being seen? What modifications would you suggest?
- Are there any requirements not mentioned that should be added?

### Summary of Discussion:

Review of Policy 2.9: *Required Deceased Donor Infectious Disease Testing* (continued from 9/18)

Members continued a previous discussion as there is an update to OPTN Policy 2.9 pending implementation. It was clarified that while the testing is mandatory, the results do not need to be returned before an organ offer or transplant, ensuring the process is not delayed.

One member highlighted that coordinating with the Centers for Disease Control and Prevention (CDC) for confirmatory testing presents a significant operational challenge. A member assented, adding that the number of tests performed is relatively small, with positive results being exceptionally rare. This minimal occurrence helps reduce the overall burden on transplant centers and organ procurement organizations (OPOs). From the OPO perspective, members did not identify any major issues or concerns with the policy changes. However, one member noted that West Nile Virus testing is no longer explicitly

listed as a requirement and questioned whether it was still necessary. Another member explained that while West Nile Virus testing is not currently required, it is under consideration for inclusion as part of a future seasonal testing policy.

Members agreed that most OPOs are already performing the tests or can do so on an as-needed basis, meaning any additional requirements would not pose a significant operational burden. The group concluded that no changes to the current guidance or additional language are needed at this time.

*Review of Policy 2.11.A: Required Information for Deceased Kidney Donors*

A member brought up requirement #6, relating to biopsy:

6. Biopsy results, if performed. The host OPO must make reasonable efforts to perform a biopsy on deceased donor kidneys from donors that meet at least one of the following criteria, excluding donors less than 18 years old:

- Anuria, or a urine output of less than 100ml in 24 hours during current hospital admission or in the course of donor management
- Donor has received hemodialysis or other renal replacement therapy during current hospital admission or in the course of donor management
- History of diabetes, or HbA1C of 6.5 or greater during donor evaluation or management
- KDPI greater than 85% at the time of original match run.
- Donor age 60 years or older
- Donor age 50-59 years, and meets at least two of the following criteria:
  - History of hypertension
  - Manner of death: Cerebrovascular Accident (CVA)
  - Terminal serum creatinine greater than or equal to 1.5mg/dl

If the biopsy is not performed, the host OPO must document the reason and make this documentation available to the OPTN on request.

Members discussed the current exclusionary language applied for biopsies for donors less than 18 years of age. One member suggested that, in certain clinical situations, OPOs should have the option to perform biopsies on younger donors. A member offered that OPOs will do biopsies upon request but added that the existing exclusionary language presents challenges. Members agreed on adding guidance around this topic to clarify when and why biopsies might be appropriate. Another member suggested that removing the exclusion entirely could be considered, though this would require further input from the broader OPO community.

To support the use of guidance documents, members proposed including hyperlinks to guidance within policies, making it easier for OPOs to access relevant information during allocation. OPTN Contractor staff noted this for potential updates in the future, highlighting that sometimes hyperlinks change though and that could present some issues.

The conversation then shifted to blood transfusions, with a suggestion to ensure recent blood transfusions are documented. It was confirmed that a proposed data collection field would address this issue, providing a more generalized approach to tracking transfusions.

The group also discussed high-resolution imaging of biopsy slides. Members agreed that including language to encourage high-resolution imaging as a best practice would be beneficial, though it may not be feasible for all OPOs due to varying resources and technology. To address this, it was suggested that the language be added to specify “if performed” or “if available” to avoid creating an unnecessary burden. This approach was supported as reasonable and applicable across all organ types, not just kidney.

### Review of Policy 2.11.B: *Required Information for Deceased Liver Donors*

Members continued discussions on aligning language and requirements for kidney and liver policies, specifically focusing on biopsy, imaging, and lab tests.

It was agreed that the liver biopsy and imaging language should mirror what was previously discussed for kidney, including the “if not available, document why” requirement. This would also apply to computed tomography (CT) images for consistency across policies.

Regarding lab tests, members debated whether specific tests should be explicitly listed for kidneys, similar to how they are delineated for liver. A member raised the point that labs such as creatinine and urinalysis are called out for liver but not for kidneys. The Workgroup Chair noted that some of these are captured in general testing requirements, which may already provide adequate coverage.

A member expressed concerns about being overly prescriptive but acknowledged the value of uniformity. They suggested including creatinine and blood urea nitrogen (BUN) for kidneys, as these are essential markers, while sodium remains critical for liver and could be explicitly added. Other members agreed that some tests, like creatine phosphokinase (CPK), are unnecessary unless donor history indicates a need. One member also pointed out that obtaining direct bilirubin within 12 hours could be challenging for OPOs, and it may not need to be a policy requirement unless bilirubin levels are abnormal. Adding such requirements increases the compliance burden without significant clinical relevance.

Members agreed on the need to avoid redundancy in policy and ensure that any additions provide meaningful clinical value without creating unnecessary burdens for OPO staff.

Staff summarized the recommendations as follows:

- Mirror biopsy and imaging language for liver, aligning with the previously discussed approach for kidney.
- Remove direct bilirubin as a requirement unless further compliance issues are identified.
- Potentially include sodium in the required tests for liver, pending follow-up on its necessity.
- Potentially include creatinine and BUN for kidney to ensure clarity and uniformity in testing requirements.

#### Next steps:

The Workgroup will continue working on reviewing donor testing policy requirements.

#### **Upcoming Meetings**

- December 18, 2024 (Teleconference)

## Attendance

- **Committee Members**
  - Annemarie Lucas
  - Christine Hwang
  - Chuck Zollinger
  - Lara Danziger-Isakov
  - Elizabeth Shipman
  - Heather Miller Webb
  - Jessica Youkubek
  - Dean Kim
  - Laurine Bow
  - Malay Shah
  - Norihisa Shigemura
  - Qingyong Xu
  - Tamas Alexy
- **FDA Representatives**
  - Brandy Clark
  - Irma Sison
- **HRSA Representatives**
  - N/A
- **SRTR Staff**
  - N/A
- **UNOS Staff**
  - Joann White
  - Houlder Hudgins
  - Kaitlin Swanner
  - Kayla Temple
  - Kerrie Masten
  - Stryker-Ann Vosteen
  - Rob McTier