OPTN Operations and Safety Committee – Donor Testing Requirements Workgroup
Meeting Summary
December 18, 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 12/18/2024 to discuss the following agenda items:

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

1. Policy Review/Discussion
    a. Policy 2.11.C: *Required Information for Deceased Heart Donors*
    b. Policy 2.11.E: *Required Information for Deceased Pancreas Donors* 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 2.11.C: *Required Information for Deceased Heart Donors*
- Policy 2.11.E: *Required Information for Deceased Pancreas 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 2.11.C: *Required Information for Deceased Heart Donors*

A member suggested that for the first requirement, "12-lead electrocardiogram (ECG) interpretation, if available" the language "if available" should be removed. The member voiced uncertainty as to what "if available" means and stated that every patient would need at least one ECG; surgeons would need to see the actual ECG tracings in their assessment of the heart.

The Workgroup Chair clarified that an interpretation of the imaging is not enough; there is a need to see the actual ECG tracing. The Workgroup Chair continued that this should be explicitly clear in language. The member agreed with this and suggested rewording of the language of the first requirement to say "12-lead ECG tracings". The member clarified that physicians like to see the actual ECG because oftentimes the interpretation is a machine generated interpretation; although the interpretation is not bad, physicians always like to review the imagining themselves.

The member stated that the other requirements currently listed in policy are needed. The member suggested including troponin as a requirement. The member stated that they would need to see troponin ascension on every patient and trends, if possible, if available. The member stated that they receive creatinine kinase (CK) and creatinine kinase – MB (CK-MB) which the do not use anymore as a lot of times there are trauma patients who are getting the CKs which are not of relevance in their assessment.

The member concluded by reiterating their suggestion of including troponin trends. The member added that the organ procurement organizations (OPOs) should add a cut off value for the troponin because it is institutional dependent, and the various assays used have different cut offs. This results in transplant programs constantly having to go back to the OPO to ask what the actual cut off value is for the troponin. The member stated that when the assay is run, the upper normal range should be included.

Another member asked if this was in reference to a specific troponin – is it Troponin I? A member replied that various OPOs and various hospitals use different troponins. The member continued by stating that they only use the high sensitivity now while other programs use the old lower sensitivity with different cut off values, which is fine but they need to know what that cut off is. Another member stated that they run into this same issue locally and this would be important to get this standardized. A member agreed with this and added that it may not be realistic to standardize a troponin test as it would be dependent on the institution; the actual cut off values should be standardized.

The member continued by stating that there should be an age cut off for catheterizations (cath) for donors. In their practice, typically, if a donor male is 30 years of age, they would like to see a cath. By 40 years of age, it should be necessary to obtain a coronary angiogram with the right heart cath. The member stated that there should be discussion and agreement on what the lower age cut off should be.

The Workgroup Chair asked for clarification on if the recommendation is to be age 30 and greater for donor males or age 40 and greater for all donors? The member stated that this is (accepting) institutional and surgical practice dependent for when they want a cath. The member stated that their surgeons like for there to be an angiogram for donor males age 30+ and for donor females age 35+. It is uncertain if this is true across the country, so the member suggested caths being required for all donors at age 35+ or somewhere in that range.

Another member voiced agreement and stated that some guidelines for when a cath should be done would be helpful. The member continued by stating that from an OPO perspective, it would be ideal to somewhat mimic the way the kidney biopsy language looks stating that the OPO will make every reasonable effort to obtain a cath in these situations. Other information such as donor age (30 for male, over 35 for females), drug use, history of hypertension, and additional information of this nature would be helpful for OPOs.

A member agreed with this and stated that even if the age were 35+, this would be acceptable. The member agreed that guidance would be helpful to outline this. The member added that in addition to the angiogram, their surgeons are interested in the right heart cath. Ther should be a recommendation that if an angiogram is done, there should be a right heart cath. If there is a cath without a cardiac output, this is not helpful.

The Workgroup agreed to move forward with a recommendation for donor age 35+ for cath for every patient.

A member stated that similar to previous discussions on imaging, if there is any opportunity to obtain digital imaging to support the report (not just the report), this should be encouraged. Another member agreed with this as they always look at the imaging. The Workgroup discussed and agreed to the same

recommendation as made previously for imaging that states, “The host OPO must make reasonable efforts to obtain the following information for all deceased donors. If the host OPO obtains any of the following information, it must be provided with the donor offer. If the host OPO cannot obtain this information, the host OPO must document the reason and make this documentation available to the OPTN on request." The Workgroup also agreed to include a recommendation related to high resolution imagining in guidance; these recommendations were agreed to be included for all organs.

A member stated that they sometimes run into an issue when they receive echocardiogram images, and the valves are not visible. It is important that these valves are visible for review, especially for substance use donors. This results in them having to go back to the OPOs to ask for additional imaging where they typically are told no; this brings challenges with their review. The member suggested putting something in guidance to include this for heart.

OPTN Contractor staff shared language used for lung policy for consideration:

> “The host OPO must make reasonable efforts to obtain the following information for all deceased donors. If the host OPO obtains any of the following information, it must be provided with the donor offer. If the host OPO cannot obtain this information, the host OPO must document the reason and make this documentation available to the OPTN on request. This would include either echocardiogram or right heart catheterization to screen for pulmonary hypertension.”

A member stated that the reason behind this would be different because it is specific to pulmonary hypertension. Therefore, the language would apply but not as it pertains to the latter part of the language. Another member agreed with this and stated that this would not be done for pulmonary hypertension screening; the purpose for heart (in contrast to the lung language) would be specific for hemodynamics and cardiac input.

The Workgroup’s discussion and recommendations were summarized as follows:

- 12-lead ECG tracing needed for every donor; removal of language stating “if available” for this requirement
- Troponin level with trends and cutoff value for institution as different for different tests
- Right heart cath needed for every patient age 35+ with complete hemodynamics
- High resolution digital images of cath and echo when available (use lung policy language)
    - Add valve visibility language to the guidance document

The Workgroup agreed with this. There were no additional comments or questions.

Review of Policy 2.11.E: *Required Information for Deceased Pancreas Donors*

A member stated from their review of the policy, there were no recommended changes to the current policy.

Another member asked if any of the pancreas programs feel that A1C should be required based upon certain donor characteristics. The member continued by stating that OPOs should be able to obtain this. Current policy states “if performed”; it was suggested that there could be stronger language that states that this should be performed.

A member responded that it can be challenging because of how difficult it is to interpret. This test is often done as an inpatient during an acute phase. The member voiced uncertainty in changing the current language to require A1C testing be performed, and stated that from their perspective it is not as useful for them in their assessment of the donor.

The Workgroup recommended no changes this time.

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

Upcoming Meetings

- Wednesday, January 15, 2025 (Teleconference)

Attendance

- **Committee Members**
  - Annemarie Lucas
  - Chuck Zollinger
  - Lara Danzinger-Isakov
  - Jennifer Hartman
  - Kaitlyn Fitzgerald
  - Malay Shah
  - Norihisa Shigemura
  - Shehzad Rehman
  - Tamas Alexy
- **FDA Representatives**
  - Brandy Clark
  - Irma Sison
- **HRSA Representatives**
  - N/A
- **SRTR Staff**
  - N/A
- **UNOS Staff**
  - Joann White
  - Kaitlin Swanner
  - Kerrie Masten
  - Laura Schmitt
  - Stryker-Ann Vosteen