OPTN Operations and Safety Committee – Donor Testing Requirements Workgroup
Meeting Summary
September 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 9/18/2024 to discuss the following agenda items:

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

1. Policy Review/Discussion
    a. Policy 2.8: *Required Deceased Donor General Risk Assessment*
    b. Policy 2.9: *Required Deceased Donor Infectious Disease Testing*

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 2.8: *Required Deceased Donor General Risk Assessment*
- Policy 2.9: *Required Deceased Donor Infectious Disease Testing*

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 2.8: *Required Deceased Donor General Risk Assessment*

A member commented that requirement 7, "urinalysis (UA), within 24 hours before cross clamp", can be challenging, especially for those donors on dialysis. Given that there donors that are end stage renal failure, it may be helpful to have a caveat (maybe a 7a) that states "the host OPO will make a reasonable effort to obtain on a donor with renal disease". The member further explained that the challenges faced with item 7 in policy is that if a donor is on dialysis and has no urine output or if there is a donor with minimal urine output. The host OPO would then have to determine what is the highest priority for that minimal urine output – is this sent out for a UA, urine culture, or to the medical examiner. Workgroup members agreed with this.

Another member suggested moving this requirement from the general assessment policy to the kidney donor testing requirement policy (OPTN Policy 2.11). A member agreed with this and stated the

importance of this information for kidney donors. A member agreed with this and stated that many donors these days may have acute renal injuries but may still be a donor for liver.

Another member added to this point by inquiring while it may be difficult to obtain on a donor with minimal urine output and may not end up not being a kidney donor, is it important for every donor to have a UA? A member commented that from a transplant program perspective, if there is any evidence of pyuria, this may be relevant. It appears urinalysis should be sent at some point. A member suggested to this case that this requirement should stay in the general risk assessment policy as it is currently. Another member agreed with this and added that most donors have foleys which presents high risk urinary tract infections (UTIs); something may be missed if urinalysis were removed for all donors.

The Workgroup Chair summarized the discussion in that the Workgroup agrees to keep urinalysis as a requirement in the general risk assessment policy. Additionally, the Workgroup recommends including language that provides a caveat for reasonableness in obtaining the sample. A member added that the 24 hours requirement is an issue as well; maybe the donor has minimal urine output for 48 hours at which point the host OPO could start obtaining the sample for UA. How the timeframe impacts the validity of the UA should be considered as well.

Another member agreed with the Workgroup's recommendation and added that within 24 hours, there should still be a sample available that can be sent off if needed. The Workgroup Chair asked how item 7 is addressed now if no sample is available. A member stated that it is documented in their system that there is no sample available for testing. The Workgroup Chair asked if there was a need to further clarify/add a caveat in policy since OPOs document that a sample is not available. A member responded that the challenge remains for a donor with renal disease having minimal to no urine output; rather than putting a note in the system (which is not meeting policy) there should still be a caveat in policy as suggested. Another member added that to reduce the administrative burden, it would be helpful to have further clarification in policy.

A member noted that in a previous discussion with other Committees, there had been discussion in removing item 1, "arterial blood gas (ABG) results" to another section, but added their thoughts of keeping this requirement as is as the same principles discussed for urinalysis applies for the requirement for ABG. It was further explained that access to an arterial line or timing in having hospital staff drawing an ABG prior to going to the OR can be challenging, however, it was agreed that this would be nothing that would impact current policy.

Another member asked when OPOs obtain lipase for potential pancreas donors. It was discussed that lipase is usually not drawn until after authorization is obtained, since it is not a lab that is generally drawn on the typical work up for a donor. The member continued by stating that this can sometimes be challenging to obtain and can take some time; for smaller programs, these samples can sometimes be sent out externally.

Review of Policy 2.9: *Required Deceased Donor Infectious Disease Testing*

A member asked regarding item K, "Toxoplasma Immunoglobulin G (IgG) antibody test", if this is required by the heart programs and why this information is obtained. Another member confirmed this was the case and added that this is helpful for all donors based on the reporting of potential events that have occurred. A member asked if abdominal organ or transplant recipients had adverse infection positive toxoplasma. Another member asked if this was regarding disease transmissions or non-use of organs. A member

further explained that it doesn't seem relevant for abdominal, but it is always reported. The member continued by asking if there has been any disease transmission of toxoplasma to the recipient from the donor as it relates to abdominal organs. Another member explained that this information is potentially important for donors because it could potentially have implications especially as people are using alternative prophylaxis and using Pneumocystis jirovecii pneumonia (PJP) prophylaxis that is not Bactrim. If there was a positive toxoplasmosis antibody, batrum would be recommended to used to prevent potential transmission. The member stated that she could take a look at the (10-year data outside of heart to see if other organs are affected. Another member stated that from a kidney program, they developed a protocol when toxoplasma started getting reported in coordination with infectious disease (ID). The member continued by explaining that they use Trimethoprim-sulfamethoxazole (TMP-SMZ) or as a preferred alternative for the Toxoplasma positive donor recipients a Atovaquone rather than Pentamidine. For the donor positive/recipient negatives, the duration is extended at the recommendation of their ID colleagues for mismatches for Toxoplasma. The member added that although there is scant evidence on this, there is not a huge risk in terms of a longer duration of Bactrim.

Another member followed up by stating that based on the data report mentioned, it appears that there were some toxoplasma cases that were not all isolated to the heart as far as potential transmissions in the past, which is why this testing requirement is extended beyond heart donors.

A member asked if hemodilution would be addressed and if not, if it should be included in this section of the policy as far as defining a pre- versus (vs) a post- transfusion. Staff confirmed that the Workgroup would discuss this and is in regard to the pre-/post- transfusion data field component of the project; the proposed data field would provide indication of hemodilution. Staff added that the Workgroup would be reviewing OPTN Policy 2.6 which corresponds with this topic; the OPTN Operations and Safety Committee previously implemented *Guidance on Blood Type Determination*[1] addresses this as well and would be updated (as needed) to ensure any recommendations made by the Workgroup is in alignment with the guidance.

Another member asked for the OPOs representatives if the 96-hour requirement presents any challenges. A member stated that this can sometimes be challenging depending on the timing of the OR and the added expenses for transportation, however, they have been able to work through it. Another member agreed with this and emphasized that it is really nothing more than a financial challenge from their perspective, especially in the setting of late declines where they have to repeat testing prior to the OR or a scenario where they are delayed by a hospital resource. It then becomes nothing more than repeat testing and additional courier expense.

A member asked if the policy being reviewed is the most up to date as there are additional policies that have not been implemented yet that include Chagas and Strongyloides testing. Staff will make a note of

[1] "Guidance on Blood Type Determination," OPTN, June 2020, available at https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/guidance-for-addressing-blood-type-determination/.

this and will follow up with this policy with updated language for additional review. The member stated that something important to note is that the additional testing requirements are not time dependent to offer or procurement in comparison to the other testing requirements listed in this policy. Staff confirmed that this policy is targeted for implementation in December 2024.

The Workgroup agreed and recommended there being no changes made to this policy at this time. The Workgroup will follow up with the pending policy language that will be implemented in December for review and discussion.

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

Upcoming Meetings

- October 16, 2024 (Teleconference)

Attendance

- **Committee Members**
  - Annemarie Lucas
  - Chuck Zollinger
  - Dan DiSante
  - Lara Danzinger-Isakov
  - Elizabeth Shipman
  - Heather Miller Webb
  - Jennifer Hartman
  - Jessica Yokubeak
  - Kerri Jones
  - Dean Kim
  - Luis Mayen
  - Malay Shah
  - Norihisa Shigemura
  - Qingyong Xu
  - Shehzad Rehman
  - Tamas Alexy
- **FDA Representatives**
  - Brandy Clark
  - Irma Sison
- **HRSA Representatives**
  - N/A
- **SRTR Staff**
  - N/A
- **UNOS Staff**
  - Joann White
  - Kayla Temple
  - Kerrie Masten
  - Laura Schmitt
  - Kaitlin Swanner