OPTN Operations and Safety Committee – Donor Testing Requirements Workgroup
Meeting Summary
October 16, 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 10/16/2024 to discuss the following agenda items:

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

1. Policy Review/Discussion
    a. Policy 2.10: *Additional Deceased Donor Testing*
    b. Policy 2.11: *Required Deceased Donor Information*

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 2.10: *Additional Deceased Donor Testing*
- Policy 2.11: *Required Deceased Donor Information*

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 2.10: *Additional Deceased Donor Testing*

A member voiced no issues reporting within 24 hours after receiving the test result but commented that there should be clarification on what is meant by "received". Is it when the program is called and notified of the test result? There is a gray area and a need to define this further.

Another member agreed with this and added that there is a challenge in determining when the report is received, which can be challenging from the perspective of compliance. The member further explained that, for example, when an autopsy is performed, the organ procurement organization (OPO) may know the results but not receive the official report until weeks after.

Another member agreed with this and added (in reference to the example of autopsy results) that it may look like it took a month to report results. The member stated that it is not just autopsy but the minor reports that might take longer than 24hrs for a report to be official; the unofficial results might be

there earlier. Technically, reporting would be in compliance with policy but the issue is the "receiving" part of policy.

A member suggested clarifying the language by modifying it to "24 hours of the OPO being made aware of the test result".

The Workgroup agreed with this modification.

Review of Policy 2.11: *Required Deceased Donor Information*

A member stated that their electronic medical records (EMR) labels and reports sex as birth sex. This is also how it is referenced in the OPTN Donor Data and Matching System. The member suggested modifying "sex" to "birth sex" for uniformity in how it is currently documented.

Another member commented that the list of required information to be reported is reasonable. The member added that the challenge is there being no standard way of this information being reported in the OPTN Donor Data and Matching System by OPOs.

The Workgroup Chair agreed with this and stated that some of this information is put into donor highlights and there are some fields that go unused. For radiology, the images are not always uploaded but instead include links. The Workgroup Chair added that if a donor is being moved to a recovery site, for standard operational information, the fields that are not available all go into donor highlights with an asterisk.

A member commented that many of the OPOs have their own EMR systems that have discrete data that does not currently have a place in the OPTN Donor Data and Matching System or the OPTN system. Relying on the free text causes variation and inconsistencies in how information is documented.

The Workgroup was encouraged to share all ideas but were advised that system enhancements would need to be discussed further internally for resource purposes and may not necessarily be included with this project.

A member questioned if there was redundancy in the requirement of reporting organ anatomy and recovery information. It was pointed out that this information may be in the organ specific requirements and if so, the member suggested removing this requirement from this policy. This was noted; the Workgroup agreed to be re-evaluated once the policy review was completed of the organ specific policies.

The Workgroup Chair asked if the coronavirus disease 2019 (COVID-19) status still needed on this list? Would it more qualify as infectious disease?

A member stated that COVID-19 status is still needed and necessary to be documented and made aware of. The Workgroup was asked if there were any thoughts on removing this requirement in this policy and instead including it in the infectious disease testing requirements. The member voiced uncertainty in how this would be incorporated with the infectious disease requirements in terms of how it is tested. The Workgroup agreed to maintain the COVID-19 requirement as it is currently in policy.

The member continued by asking if there was a possibility in including more requirements to this policy. The member stated that for item 6, *Donor evaluation information to include all laboratory testing, radiologic results, and injury to the organ,* many OPOs upload images, however, some do not. From an abdominal organ transplant perspective, having those images is helpful to have for the implanting surgeons. The member suggested strongly encouraging images being uploaded when possible.

Another member agreed with this and suggested developing policy that would require all cross-sectional images be uploaded and viewable. The Workgroup Chair also agreed with this and added that this was a complaint shared with her staff at her program.

A member voiced agreement with this in general, but voiced concern in developing policy language around this. The member continued by explaining that this may be a challenge for rural hospitals, who may not have the resources or ability to get imaging in a usable timeframe. The member agreed with the notion that programs should strive to have images available for every case, but this may not be feasible. It was suggested that rather than create policy language around this, it may be better placed in guidance. Another member agreed with this sentiment and added that their OPO tries to obtain images every time but can not always get a disc of a computed tomography (CT) image or upload the images.

Another member asked if it would be feasible to obtain a less vague report from the radiologists if images are unavailable. A member replied that this would be a ideal as well as having the ability to have radiologists speak with the transplant hospital directly. The member continued by stating that the issue is that from an OPO perspective, they find themselves limited to hours and are unable to obtain the images in time. The member suggested putting something in guidance around this.

Staff asked if there was anywhere written or notated that there were limitations making it difficult to input imaging. A member commented not seeing documentation related to no imaging being available in the OPTN Donor Data and Matching System. Another member agreed with this and stated that there is not a section in the OPTN Donor Data and Matching System to document this. Instead, this would be communicated with the transplant team.

Staff stated that following public comment, the OPTN Lung Transplantation Committee (Lung Committee) and its Workgroup agreed on language stating “the host OPO must make reasonable efforts to obtain” chest CT scans and the OPO must document the reason if it cannot obtain the information. The guidance requests lung windows for the chest CT scans. This language is slated to go to the Board in December is not yet approved.

A member commented that it seems that operational barriers can become part of the issue. The member suggested adding language to item 6 in the policy stating, “radiologic images when available" to address this concern. The member stated that many OPOs already have access to these images and will upload them, however, there are some OPOs that do not upload images. From an abdominal organ transplant perspective, it would be helpful to upload all of the images into the test section so that the implanting surgeons can review the organ. Another member agreed with this and suggested a requirement being that all cross-sectional images (or all imaging obtained) to be uploaded and viewable by the transplant hospital. The member agreed that the CT scans are crucial for the abdominal surgeons.

A member commented that in general, OPOs do well with making sure those images are uploaded for review. The member continued by explaining that the challenge with policy language here is that images may not always be available. Primarily, small rural hospitals may have difficulty to access imaging in a timeframe that would be useful pre-recovery. The member provided another example of server access issues or time of day that can attribute to delays in this information being obtained. The member continued by suggesting consideration for including something related to access to imaging in guidance rather than policy. Another member agreed with this and added that their OPO makes every effort to upload/share images for every case, but there are some hospitals where they are unable to get a disk of a CT; putting this in policy may be challenging.

A member suggested having language in policy that would say if there is a scenario where it is impossible to obtain imaging, the radiologist would need to give a brief report like “liver normal” or “no

abnormalities”; something more descriptive than unremarkable. Another member replied that this is the intent but not always feasible.

Staff asked if there was anywhere that a researcher three months later could understand that there were limitations that made it difficult to upload images. Members voiced uncertainty. A member stated never seeing any documentation explaining why there is no imaging in the OPTN Donor Data and Matching System. The member continued that if there is no imaging shown, they usually will ask for it and then would be told that it is not available for whatever reason, however, the member stated that not seeing the reasoning being documented anywhere in the OPTN Donor Data and Matching System. Another member stated that when asking for that information, it would be a matter of their OPO speaking with the transplant surgeon to explain why that information is not available.

Staff mentioned that the OPTN Lung Transplantation Committee agreed to language that stated that “the host OPO must make reasonable efforts to obtain chest CT scans and the OPO must document the reason if it cannot obtain the information. The guidance requests long windows for the chest CT scans. This language will go to the Board of Directors in December for review and approval.

A member suggested potentially using this language for the organ specific policies. For example, if an abdominal CT for a liver with imaging is unavailable, the reason should be documented. The Workgroup was in agreement with this.

The Workgroup Chair asked that in thinking about DCD cases, would this fall under item 4 of this policy or would it fall under recover information. The member continued by explaining that there are times when they have to follow cases for 3-4 days an then have to call OPOs to get a status update on the DCD case.

Another member asked is this was in relation to the neurological exam or general management of how they are doing the DCDs. Usually, for all donors (DCDs included), there are vent settings, pressers, drips and other information like this listed in the OPTN Donor Data and Matching System. The Workgroup Chair stated that for their program, they’ve experienced not being updated on DCD cases they are following and not knowing the final disposition.

Another member asked in follow-up if this is in relation to before the operating room (OR) is set or, for example, after the final disposition when the program does not happen to receive the kidneys. The Workgroup Chair clarified that their program stops receiving information after a certain time about potential DCD recovery and they’re still tracking it.

A member stated that sometimes they get DCD offers where the donor doesn't progress and they aren’t updated on this. The member added that unless their coordinators reach out to the OPO, they may never know the donor status. The member suggested the possibility of there being a button to alert programs that could be added. The Workgroup Chair agreed with this and commented that this may be more of an operational issue than reporting to the OPTN. The Workgroup Chair stated that she believes this is most likely reported to the OPTN, but that there is a need to ensure that the programs are aware of this issue as well.

A member commented that in these situations, if the donor organs are not recovered, they close out the disposition that no organs recovered. It seems like it might be a background OPTN Donor Data and Matching System issue. It would be much easier for an electronic notification to go out to the transplant programs when the case gets closed due to the disposition code. Workgroup members agreed with this. Another member added a suggestion that this might be as simple as a bypass code such as “donor did not pass” or “donor timed out”.

A member commented that for item 1 in the policy, they have had several un-identified donors, but there is no option for them to put "estimated age" and for item 12, there may need to be another section for DCD donors and commented there being a need to document neurological status with a timeframe for those updates.

Another member replied that for age, they have run into OPOs that document age in months. The member suggested there being guidance on this as adults should not have age documented in months. The member voiced their hesitancy to comment on DCD neurological status, but agreed that this should be ongoing documentation that is timed. The member stated that they did not find the neurological exam reflective or whether the person will pass. If it is documented, there will be a need for time stamps and ongoing updates of this information.

A member commented that at their OPO, they used to include neurologic status but stopped because the response seen for declines were "donor not expected to expire in time". They discovered that by removing this information, they were able to convey the information better with direct discussion with transplant program staff.

Staff stated that in going back to the comment about the adult age in months, they came across a patient with a BMI of 37,500 document because the units were off. Staff suggested that could be validation checks on input for the Workgroup to consider.

Staff stated that the Lung Committee/Workgroup considered adding a field for Glasgow Coma Scale but declined to move it forward due to concerns that the test wouldn't be performed consistently. There was discussion from some members that reflexes are reported twice a day in Donor Highlights. Additionally, members discussed hesitancy in including neurological status due to assumptions about a donor progressing.

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

Upcoming Meetings

- November 20, 2024 (Teleconference)

Attendance

- **Committee Members**
  - Annemarie Lucas
  - Dan DiSante
  - Elizabeth Shipman
  - Jessica Yokubeak
  - Kaitlyn Fitzgerald
  - Dean Kim
  - Laurine Bow
  - Malay Shah
  - Norihisa Shigemura
  - Qingyoung Xu
  - Shehzad Rehman
  - Vanessa Cowan
- **FDA Representatives**
  - Brandy Clark
- **HRSA Representatives**
  - Shelley Tims Grant
- **SRTR Staff**
  - N/A
- **UNOS Staff**
  - Joann White
  - Betsy Gans
  - Cass McCharen
  - Heather Miller Webb
  - Kaitlin Swanner
  - Kayla Temple
  - Kerrie Masten
  - Laura Schmitt
  - Stryker-Ann Vosteen
  - Rob McTier