

OPTN Operations and Safety Committee Donor Testing Requirements Workgroup Meeting Summary May 21, 2025 Conference Call

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Introduction

The OPTN Operations and Safety Committee's Donor Testing Requirements Workgroup (the Workgroup) met via WebEx teleconference on 05/21/2025 to discuss the following agenda items:

- 1. Welcome/Announcements
- 2. Review and Finalize Workgroup Recommendations
- 3. Closing Remarks

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

1. Welcome/Announcements

The Chair welcomed the members and introduced a new Co-Chair for the Workgroup.

2. Review and Finalize Workgroup Recommendations

The Workgroup reviewed draft policy and guidance language based on the recommendations developed by the Workgroup to date.

Summary of discussion:

Decisions for each section of the policy are delineated below.

2.11 Required Deceased Donor Information

The Workgroup considered whether to add imaging to the existing policy requirement for the host organ procurement organization (OPO) to report "donor evaluation information to include all laboratory testing, radiologic results, and injury to the organ" to the OPTN upon receipt for each potential deceased donor. A member suggested adding imaging "when available" to account for varying access to imaging at different donor hospitals. Members discussed whether "imaging" is the right term or whether a more specific term is needed, given that radiologic results could be considered "imaging." A member noted that this is currently described as "image study" in the OPTN Donor Data and Matching System and suggested using "image studies" in the policy language. A member said this could result in organ procurement organizations uploading a lot of imaging that is not relevant for offer evaluation for specific organs. The Workgroup agreed to leave the policy as is and keep requirements for imaging in the organ-specific sections of the policy.

2.11.B Required Information for Deceased Liver Donors

A member shared that the Liver & Intestine Committee felt strongly that imaging should be available for all liver donors in order for transplant programs to be able to assess the organ prior to organ recovery in

the operating room. The member said it is crucial to look at imaging to assess if the liver will fit into the abdomen of the intended recipient. Completing this assessment via imaging will help to avoid situations in which transplant programs travel to recover a liver for a specific recipient and then determine that the liver is not a good size match for the patient. The Liver & Intestine Committee recommended requiring imaging in policy. The Workgroup agreed that biopsies are not needed for all livers and should not be required in policy, but that requiring images in policy is reasonable. A member said their OPO image about 90% of their offers but that an OPO should not be deterred from allocating a liver in rare circumstances in which they are prohibited from obtaining imaging. A member recommended requiring OPOs to document those instances in which imaging cannot be obtained. The Co-Chair agreed the policy could specify that OPOs must make reasonable efforts to obtain the imaging and report the reason why if the imaging cannot be obtained. The Workgroup supported removing "if performed" from the policy language to emphasize that OPOs must obtain the imaging if possible. Members agreed reviewing the actual imaging and not just reports regarding the imaging is important for organ offer evaluation. Members noted that the policy should specify that cross-sectional imaging with a computed tomography (CT) scan is preferred.

2.11.C Required Information for Deceased Heart Donors

OPTN contractor staff will follow up with the Heart Committee representative on the workgroup on questions regarding data collection for troponin.

2.11.E Required Information for Deceased Pancreas Donors

The Workgroup considered if any changes were needed to the policy to align with changes to other sections of Policy 2.11 Required Deceased Donor Information. A member supported maintaining the current policy language requiring "hemoglobin A1C, if performed" if there are not concerns about current practices. A member said they have never seen a donor without an A1C. A member said they could not imagine accepting a pancreas without an A1C. A member suggested the Workgroup could propose requiring an A1C but noted that a hospital can take 6 to 12 hours to obtain an A1C and there may not be time to obtain that. Members agreed hemoglobin A1C should be provided. A member said they supported keeping "if performed" as their hospitals may take 24-48 hours to get a hemoglobin A1C result. The member did not support the language saying "if requested by the transplant program" because it would take too long to get the test result if it is not being ordered until the transplant program makes the request. Members did not support requiring hemoglobin A1C to run a pancreas match. The Workgroup noted that OPOs typically provide the hemoglobin A1C but that the absence of a hemoglobin A1C value should not prevent an OPO from running a pancreas match or sending pancreas offers. A member suggested changing the language to "make reasonable efforts to obtain" the hemoglobin A1C. The Workgroup supported that change. A member commented that if it would clarify things better, it would make sense to include this language, however this practice appears to be commonplace among OPOs and does not need to be clarified further. The Workgroup agreed on modifying the language to "if requested by the transplant program" to capture those instances when the A1C is not provided.

A Co-Chair noted that a local donor hospital no longer provides serum amylase so those tests need to be sent out to a separate laboratory and can take three days to result. The Co-Chair said they are not sure if this is an isolated issue or if it is more widespread. Other Workgroup members did not report experiencing this change in practice. The Workgroup considered whether OPOs should be able to send pancreas offers prior to reporting serum amylase. A member suggested requiring either serum amylase or serum lipase in the event one is not available, or having the language require "serum amylase and/or serum lipase" since some transplant programs review both values. OPTN contractor staff noted that "serum lipase upper normal limit" is currently required by the system as well.

OPTN Guidance

The Workgroup reviewed proposed changes to OPTN guidance on deceased donor information. There were no questions or comments. OPTN contractor staff requested volunteers to draft the guidance language changes.

Next steps:

OPTN contractor staff will provide updated materials to the Workgroup outlining their proposed changes to policy and guidance, and will follow up with the Workgroup members assisting with drafting the guidance language.

3. Closing Remarks

The Workgroup will reconvene in June to cross reference system requirements with the policy. Once the Workgroup recommendations have been finalized, the policy and guidance recommendations will be reviewed by the OPTN Operations and Safety Committee.

Upcoming Meeting

• June 18, 2025

Attendance

• Workgroup Members

- Annemarie Lucas, Workgroup Co-Chair
- o Kaitlyn Fitzgerald, Workgroup Co-Chair
- o Vanessa Cowan
- o Dan DiSante
- o Christine Hwang
- o Kerri Jones
- o Dean Kim
- o Kimberly Koontz
- o Luis Mayen
- o Heather Miller Webb
- o Malay Shah
- Norihisa Shigemura
- o Jessica Yokubeak
- HRSA Staff
 - o Marilyn Levi
- UNOS Staff
 - o Betsy Gans
 - o Chelsea Hawkins
 - o Cass McCharen
 - o Laura Schmitt
 - o Kaitlin Swanner
 - o Niyati Upadhyay
 - o Joann White