OPTN Operations and Safety Committee
Donor Testing Requirements Workgroup
Meeting Summary
June 18, 2025
Conference Call

Annemarie Lucas, MHSA, Chair
Kaitlyn Fitzgerald, BSN, RN, Co-Chair

Introduction

The OPTN Operations and Safety Committee's Donor Testing Requirements Workgroup (the Workgroup) met via WebEx teleconference on 06/18/2025 to discuss the following agenda items:

1. Review and Finalize Workgroup Recommendations: Review/cross referencing OPTN Policy and OPTN Donor Data and Matching System requirements
2. Closing Remarks

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

1. Review and Finalize Workgroup Recommendations: Review/cross referencing OPTN Policy and OPTN Donor Data and Matching System requirements

The Workgroup reviewed and cross-referenced Workgroup policy recommendations and OPTN Donor Data and Matching system requirements.

Summary of discussion:

Decisions for each section of the policy are delineated below.

2.11.A Required Information for Deceased Kidney Donors

Test currently not required in policy but is required in the OPTN Donor Data and Matching system:

- **Blood urea nitrogen (BUN)**

The Co-chair stated that their organ procurement organization (OPO) does not have issues obtaining BUN. Another member agreed. The Workgroup agreed to include BUN in policy.

2.11.B Required Information for Deceased Liver Donors

Tests currently required in policy but is not required in the OPTN Donor Data and Matching system:

- **Alkaline phosphate**
- **Partial thromboplastin (PTT)**

Tests currently not required in policy but is required in the OPTN Donor Data and Matching system:

- **Sodium (Na)**
- **Creatinine (Cr)**

A member stated that the policy requirements should align with requirements in the OPTN Donor Data and Matching system and recommended alkaline phosphate and PTT to be required in the OPTN Donor

Data and Matching system. The Co-Chair voiced support for this suggestion. The Co-Chair commented that in OPTN Policy 2.8: *Required Deceased Donor General Risk Assessment*, there is a requirement for electrolytes and glucose which should capture sodium. It was suggested that instead of the policy listing electrolytes, sodium and creatinine could be added to this policy.

The Chair questioned that if these tests were added to OPTN Policy 2.8 would they apply to all organs. The Chair added that if electrolytes includes sodium and creatinine, they would agree with this modification to Policy 2.8.

The Co-Chair suggested that since sodium is in Policy 2.8 already, it does not need to be outlined again in the liver policy. The Co-Chair added that they did not believe that creatinine would fall under electrolytes. A member agreed. The Chair asked if creatinine would be covered in the urinalysis outlined in Policy 2.8. The Co-Chair responded that it is not believed that creatinine is included in the urinalysis.

The OPTN contractor staff summarized the Workgroup's recommendation of requiring alkaline phosphate and PTT in the OPTN Donor Data and Matching system to align with policy. Sodium is already covered by the requirement to report electrolytes under Policy 2.8 and does not need to be included in the liver testing requirements. Creatinine should be included in the liver policy as it is currently not a requirement in policy.

A member asked for clarification of including creatinine with the liver testing requirement. If a donor happens to be a liver only donor, creatinine is not needed for just liver, therefore it may not need to be listed just in the liver policy. The Chair clarified that the reasoning is that in the system, it is required for liver and there is a need to align this in policy.

The OPTN contractor staff clarified that creatinine is not required for all donors but is required to send liver electronic notifications. The question may be whether it would be appropriate for the system to require creatinine for the deceased liver donors or if it is not needed for liver offers. The member stated that if creatinine is not needed for liver offers then the system should not be asking for it. The Co-Chair agreed with this.

The OPTN contractor staff mentioned that in 2016, there was an Electronic Organ Placement Workgroup that decided the system modifications for sodium and creatinine to be required to send liver electronic notifications.

The OPTN contractor staff clarified the Workgroup's recommendation to propose the addition of creatinine into policy and added that in public comment, there could be a question posed if there is still agreement in the 2016 decision in requiring this test for liver offers. The Co-Chair asked if it may make sense to add creatinine to Policy 2.8 instead of an organ specific requirement. A member voiced agreement with this and added that OPOs would receive this test result regardless. The Co-Chair commented on not being able to think of an instance where there would be a donor that would not have creatinine. The Co-Chair added that this could also apply to BUN in adding this to Policy 2.8.

OPTN contractor staff clarified that if creatinine and BUN were included in Policy 2.8, there will be no specific requirement especially related to liver or kidney. This would mean that the electronic notification system will not check for creatinine and BUN. If the suggested changes to Policy 2.8 are made, there will need to be system changes as well. Additionally, for the recommendation of aligning policy requirements for alkaline phosphate and PTT by making it required in the system, users would be required to enter these tests at the time of the electronic notification or there would be an error. Is this logistically possible to get all these results at the time of electronic offers?

A member commented that it seems that the system should align with what is being required in policy. The Co-Chair voiced concern that policy states that entering this information has to be done within 12

hours of the offer so if the system requires the alkaline phosphate and PTT to be entered prior, would it need to be within this timeframe? OPTN contractor staff clarified that based on the previous Workgroup's recommendation, the 12-hour timeframe is not enforced in the system.

OPTN contractor staff summarized the Workgroup's discussion that there is support of the system checking to make sure that alkaline phosphate and PTT are entered for the OPO to send liver offers, but not if the system were to enforce the 12-hour timeframe. A member agreed with this summary. The Workgroup was asked if the concern would be that the requirement would be to update these values every 12 hours or if there are times where there are values that would be more than 12 hours old.

The Co-Chair replied that there are instances where there is a need to get to allocation as soon as they start the case and run the list. The labs may have been drawn but the results may not have resulted yet. The results that are available may not be in the 12-hour timeframe and should not be a hinderance in OPOs from being able to run a list and send offers while waiting for these results in those instances.

OPTN contractor staff asked if the 12-hour requirement should be removed from policy or if those two lab test should be removed from the 12-hour requirement. The Co-Chair voiced that they did not think the 12-hour requirement is an issue; the concern is if the system will not allow an organ offer to be sent where flexibility is needed. A member agreed with this.

The Workgroup agreed to making alkaline phosphate and PTT a system requirement without a timeframe needing to be enforced in the system to send out an electronic offer, sodium not being added to the liver policy as it is already included in Policy 2.8 through the electrolytes requirement, and additional research would be needed to provide a recommendation on whether creatinine should be included in Policy 2.8 or the liver policy.

OPTN contractor staff asked if there were any logistical issues in obtaining alkaline phosphate and PTT labs. The Workgroup confirmed there were no issues seen in collecting these labs.

2.11.C Required Information for Deceased Heart Donors

Test currently not required in policy or the OPTN Donor Data and Matching system:

- **12-lead electrocardiogram (EKG) imaging (due to current language "12-lead electrocardiogram interpretation, if available")**

Test currently required in policy but is not required in the OPTN Donor Data and Matching system:

- **Arterial blood gas (ABG) results and ventilator settings**

OPTN contractor staff clarified that for the 12-lead electrocardiogram, it is very specific in the system. In the system there is an EKG category in the system – is this acceptable to have this category in the system? Additionally, the Workgroup was asked whether the 12-lead EKG imaging is the peak and lows of the heart activity or 3-dimensional imaging? If 12-lead imaging is required, there would need to be standardization in the type of imaging that is used.

A member stated that from their OPO's perspective, there is an attachment added in the OPTN Donor Data and Matching system. OPTN contractor staff summarized that it was understood that typically the imaging is an attachment added in the system. The Workgroup agreed with the system checking to ensure that an attachment is included under EKG to verify the electrocardiogram requirement.

OPTN contractor staff clarified that for the ABG and ventilator settings, it is also found in Policy 2.8. For lung and heart-lung, the system currently checks to make sure at least one ABG record is entered. Should this be applicable for heart offers as well? A member voiced agreement with this.

The Co-Chair suggested not having the requirement of a record to be entered with an FiO2 of 100 percent for heart. Workgroup members agreed with this. A member clarified that the recommendation would be to have a blood gas regardless of the settings. OPTN contractor staff stated that the language used for lung is what the system is currently doing for lung since the policy language for deceased lung donors require certain ventilator settings. Since this is not in the heart policy language, the language could just state that there needs to be at least one record for ABG. The member agreed with this language and not being specific in the ventilator settings done for lung.

OPTN contractor staff asked for clarification on entering ventilator settings for the ABG results. Currently the system documents ABG ventilator setting values. The Workgroup was asked for clarification on if the Workgroup's recommendation means the system can check any value entered, because if not, there will be an error in the system at the time of the electronic notification. A member commented that the values in the system makes sense and it should be checked by the system. There should not be a restriction of the ventilator setting being at 100 percent for heart as outlined in the lung policy.

The Workgroup reviewed a list of the ABG values. A member agreed that for heart, if the ventilator setting does not need to be FiO2 at 100 percent, entering a value should be fine since the system will not provide any hinderance in sending out an electronic offer.

2.11.E Required Information for Deceased Pancreas Donors

A Workgroup member clarified that for insulin protocol, their OPO has their own insulin protocol where they document that information in the medications. There is a section in the OPTN Donor Data and Matching system for medications that include insulin so there is nothing that is uploaded specifically. Other members agreed. A member commented that they guess this has never been enforced and it is based on an OPOs protocol where they report if insulin was administered with the begin and end date and time. The member continued by commenting that this should not be something that the system should require. If transplant programs ask for it, their OPO provides their protocol. Other members agreed with this.

The Co-Chair interpreted this requirement to being that the intent is to see if insulin has been administered versus seeing the protocol followed. A member suggested changing language to the policy to "insulin dosing"; insulin dosing is different from insulin protocol. The Co-Chair agreed with this.

OPTN contractor staff stated that the system does not enforce insulin protocol to have before sending electronic notifications for pancreas donors, but it is in the policy. A member stated that the system should not be required to send out electronic notifications for pancreas donors. There will be follow up with pancreas subject matter experts on this proposed change.

A member stated that there are times when donors are not on insulin. Another member stated that this is more of a "yes" or "no" question. The Co-Chair agreed with this. Additional research and input will be looked into for final confirmation on this recommendation.

The Workgroup looked at a proposed change in policy language that would read for item 5 "serum amylase, if available" and leave item 6 "serum lipase" as currently written. A member commented that for smaller hospitals it is a send out for these tests and it can take a long time to get the result. The Co-

Chair agreed with this and stated that their OPOs have encountered some cases where the hospital system does not do serum amylase and it is a four to five day send out test. Many times, they have already recovered the donor at that point. The Co-Chair suggested that having the ability to not have to do a workaround that results in them entering a zero and providing further explanation in donor highlights would be beneficial.

OPTN contractor staff summarized that with the recommendation of adding policy language to item 5 "if available" for serum amylase; serum amylase would no longer be a system requirement based on the policy language change.

Tests currently not required in policy but is required in the OPTN Donor Data and Matching system:

- **Glucose**
- **Serum lipase upper limit**

From the Workgroup's previous recommendation on glucose, serum glucose is outlined in Policy 2.8, therefore the Workgroup recommended not needing to include this test in the pancreas policy. The Workgroup agreed with adding serum lipase upper limit to the pancreas policy to be aligned with the system requirements.

Next steps:

The Workgroup will continue to review and finalize their recommendations on the cross reference of policy and system requirements.

2. Closing Remarks

The Workgroup will reconvene in July to review and finalize the Workgroup recommendations. Once the Workgroup recommendations have been finalized, the policy and guidance recommendations will be reviewed by the OPTN Operations and Safety Committee.

Upcoming Meeting

- July 16, 2025 (Teleconference)

Attendance

- **Workgroup Members**
  - Annemarie Lucas, Workgroup Chair
  - Kaitlyn Fitzgerald, Workgroup Co-Chair
  - Chuck Zollinger
  - Heather Miller Webb
  - Irma Sison
  - Kerri Jones
  - Kimberly Koontz
  - Norihisa Shigemura
- **UNOS Staff**
  - Kaitlin Swanner
  - Niyati Upadhyay
  - Chelsea Hawkins