OPTN Operations and Safety Committee
Meeting Summary
August 22, 2024
Conference Call

Kim Koontz, MPH, Chair
Steven Potter, MD, Vice Chair

Introduction

The OPTN Operations and Safety Committee (the Committee) met via WebEx teleconference on 08/22/2024 to discuss the following agenda items:

1. Welcome and Announcements
2. Public Comment Presentation: Update Histocompatibility Bylaws
3. Public Comment Presentation: Promote Efficiency of Lung Donor Testing
4. Upcoming Meetings

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

1. Welcome and Announcements

The Chair and Vice Chair welcomed the Committee and introduced the meeting's objective, which include providing feedback on two public comment proposals.

Summary of discussion:

There were no questions or comments.

2. Public Comment Presentation: Update Histocompatibility Bylaws Proposal

The Vice Chair of the OPTN Histocompatibility Committee presented the *Update Histocompatibility Bylaws* proposal.

Presentation summary:

The purpose of this proposal is to clarify and update OPTN histocompatibility bylaws in order to align with upcoming Clinical Laboratory Improvement Amendments (CLIA) changes.

The proposal includes the following:

- Allow multiple OPTN-approved laboratory directors at a histocompatibility lab
- Update laboratory director education and training requirements to align with CLIA
    - Laboratory directors must already follow CLIA requirements for qualifications, and must be certified by a board approved by the US Department of Health and Human Services (HHS)
- Clarify and expand requirements for laboratory agreements with transplant programs and OPOs
    - Proposed changes organize requirements into four named categories: Human Leukocyte Antigen (HLA) typing requirements, crossmatching requirements, antibody screening, and blood type verification
- Modify required personnel and add primary data coordinator to act as OPTN point of contact (POC)

- Update laboratory subcontracting requirements
- Remove requirement for the laboratory director to review and approve all subcontracting results before release
- Expand inactivation and withdrawal notification requirements
- Remove or clarify requirements that are redundant to existing regulatory requirements for labs

In 2020, a Histocompatibility Subcommittee developed proposed changes to Bylaws, which the OPTN Histocompatibility Committee supported. The Membership and Professional Standards Committee (MPSC) endorsed initial draft language. In 2023, the Centers for Medicare and Medicaid Services (CMS) published a final rule updating CLIA. These updates will be effective on December 28, 2024.

If approved, this proposal will require histocompatibility labs will be required to evaluate their transplant hospital and OPO agreements to ensure they meet new requirements. Laboratories may choose to submit additional laboratory director applications but are not required to do so. OPOs and transplant programs may need to alter their agreements with laboratories if they do not meet the new requirements.

The OPTN Histocompatibility Committee is seeking feedback regarding metrics that should be considered beyond CLIA requirements and whether the components outlined are sufficient and clear.

Summary of discussion:

The Vice Chair remarked on concerns shared at his regional meeting, noting specifically that there is concern that if the CLIA requirements are adopted, there is a possibility that non-qualified personnel are signing off on HLA reports. The Vice Chair continued that there were several highly technical concerns raised at the regional meetings, and asked if the bylaw changes could be modified to supplement requirements and include further guardrails on CLIA requirements. The Histocompatibility Vice Chair noted that these concerns were raised at her regional meeting as well, and pointed out that the CLIA regulations to be implemented later in the year are not optional and will be required regardless of their status in OPTN bylaws. The Histocompatibility Vice Chair explained that there has been concern about the difference between the CLIA definition of laboratory director and the CLIA definition of an HLA laboratory specific technical supervisor, and the training specific to those roles. She continued, noting that CLIA does not get histocompatibility specific until describing the technical supervisor; CLIA uses the term “laboratory director” to indicate any personnel that are sufficiently trained in any high complexity or mid complexity laboratory area, not just histocompatibility. The histocompatibility specific area of CLIA describes specific training for HLA technical supervisors. The Histocompatibility Vice Chair explained that the concern seems to be that using the language “CLIA laboratory director” would be inclusive of personnel who do not have any HLA or histocompatibility specific training. The Histocompatibility Vice Chair noted that the Histocompatibility Committee could consider adopting language changes such that the requirements of a CLIA technical supervisor must be met; however, the OPTN bylaws in full require that histocompatibility key personnel include an HLA director, technical supervisor, and a clinical consultant. The Histocompatibility Vice Chair noted that a laboratory director who does not meet the technical supervisor requirements be involved in the hospital lab, but that this person may not be able to sign off on histocompatibility results because those results can only be signed off on by personnel who meet CAP and ASHI requirements. CAP and ASHI requirements are more stringent than CLIA. The Histocompatibility Vice Chair noted that the laboratory director could still apply to the OPTN, but a key personnel from that laboratory must include a technical supervisor, who must meet specific HLA training requirements.

The Operations and Safety Committee Vice Chair remarked that this makes sense, and asked if those concerns from regional meetings are substantive enough to be address by language changes, or if the

requirements and restrictions currently in place are sufficient. The Histocompatibility Vice Chair remarked that this is good feedback, and that OPTN bylaws could be more stringent than CLIA requirements. The Histocompatibility Vice Chair noted that this type of feedback could be sought at future regional meetings and cross-committee presentations, particularly regarding an additional requirement that laboratory directors must also meet the qualifications of a histocompatibility technical supervisor. The Histocompatibility Vice Chair added that this additional requirement may not be necessary based on the current requirements, which ensure the presence of a technical supervisor on staff and ensures that personnel signing off on HLA reports have specific training requirements.

One member asked about the removal of the subcontractor requirements, asking for an example. The Histocompatibility Vice Chair gave an example where during a donor typing, a histocompatibility lab's agents are not capable of resolving an unambiguous answer or goes on back order, or for some reason, the main lab cannot fulfill its functions and so sends its test to a back up laboratory. The Histocompatibility Vice Chair continued that every HLA lab is required to designate an emergency backup laboratory, for more routine and emergent needs. The Histocompatibility Vice Chair explained that this proposal will update requirements such that any laboratory subcontracted by an HLA lab for services related to the OPTN must meet AHI or CAP accreditation requirements, and must also become an OPTN member. The Histocompatibility Vice Chair explained these two requirements then render it relatively unnecessary and duplicative to have the local director for the primary HLA lab that is not performing the testing review the answer, particularly because the laboratory performing the testing is fully accredited and an OPTN member lab. The member agreed that this makes sense, noting that it is important to ensure HLA lab results are all reviewed appropriately.

3. Public Comment Proposal: Promote Efficiency of Lung Donor Testing

A representative of the OPTN Lung Transplantation Committee (the Lung Committee) presented the *Promote Efficiency of Lung Donor Testing* proposal, and the Committee provided feedback.

Presentation summary:

The purpose of this proposal is to promote efficiency of lung donor testing by proposing changes to lung donor testing requirements in OPTN *Policy 2.11.D: Required Information for Deceased Lung Donors* and the OPTN guidance on request deceased lung donor information.

Proposed changes to the policy include arterial blood gases (ABG), chest computed tomography (chest CT), chest x-rays, sputum gram stains, and echocardiogram, and right heart catheterization requirements.

Current policy requires an ABG with a ventilator setting of an FiO2 of 100% and a Positive End-Expiratory Pressure (PEEP) of 5 within two hours prior to offer. The proposed changes to ABG requirements include:

- Ventilator settings for challenge gases: PEEP of 5-8 cmH2O, FiO2 100%, Tidal Volume of 6-8mL/kg ideal body weight
- Obtained 2 hours prior to initial offer, every 4 hours between the time of the initial offer and organ offer acceptance, and at least every 8 hours between organ offer acceptance and organ recovery
- Challenge gases must not be drawn within 30 minutes of any recruitment maneuver

The proposal also includes the following information to be required for deceased lung donors:

- Chest CT scan, if performed
- Chest X-Ray, specifically:

    - Images or interpretation by a radiologist or qualified physician within 3 hours prior to the initial offer
    - Updated chest x-ray interpretation or images at least every 24 hours between the time of the initial offer and organ recovery
- Sputum gram stain
    - Proposal removes requirement for sputum description
- Either echocardiogram or right heart catheterization to screen for pulmonary hypertension

The proposal will also include the following changes to OPTN Guidance on Requested Deceased Lung Donor Information:

- Updating the name of "mycology sputum smear" to "fungal and bacterial culture results"
- Additional guidance for providing information required by OPTN Policy *2.11.D: Required Information for Deceased Lung Donors:*
    - When providing chest x-ray results, images are preferred
    - When providing a chest CT scan for lung donors, the host OPO should provide the CT within 72 hours prior to the initial offer, and the host OPO should provide images with lung windows
    - If an echocardiogram is provided, the transplant program may also request a right heart catheterization if pulmonary hypertension is suspected in the donor

Lung transplant program members have expressed concern about the quality of information on organ offers they are receiving, and the Committee noted that donor data available at the time that lung programs expected to review and respond to offers is outdated or incomplete. The availability of more relevant and timely information should make it easier for programs to say "yes" to organ offers.

If approved, OPOs would be responsible for providing required lung donor testing information. OPOs may need to modify their internal policies or processes to comply with changes to *Policy 2.11.D: Required Information for Deceased Lung Donors*. Transplant programs will need to be aware of changes to required testing for lung organ offers.

The Lung Committee is seeking feedback on the following questions:

- Do the proposed lung testing requirements strike the proper balance between requiring information transplant programs need to decide on an offer and what OPOs are reasonably able to provide?
- Are the ABG ventilator settings and timing requirements attainable for each lung donor offer?
- Are the chest x-ray timing requirements attainable for each lung donor offer?
- Should any of the proposed requirements for OPTN *Policy 2.11.D* be moved to Guidance on Requested Deceased Lung Donor Information?

<u>Summary of discussion:</u>

The Chair asked if the Lung Committee considered these requirements as it relates to smaller donor hospitals where there are limited resources or for donation after circulatory death (DCD) donors. The Lung Committee representative agreed, and noted that the Lung Committee proposed options, such as having imaging made available rather than requiring interpretation, as this allows transplant programs to interpret their own imaging.

The Vice Chair expressed support for this proposal, but noted concern for OPOs' ability to met these requirements.

One member remarked on the PEEP range requirement for ABG results, and the Lung Committee representative explained that this range is 5-8 for challenge gases and an tidal volume ranging from 6 to 8 based on the body weight. The member asked what the reasoning was for establishing the PEEP range instead of utilizing a fixed marker. The Lung Committee representative noted that this question will be taken back to the Lung Committee for consideration as well.

A member noted that some OPOs take measurements to place potential donors on prone, and how the ABGs will be taken for prone patients. The Lung Committee representative noted that these requirements are written such that ABGs cannot be drawn within 30 minutes of any recruitment maneuver. The Lung Committee representative noted that this concern will be taken back to the Lung Committee for consideration.

One member expressed concern with the requirement to perform ABG draws every four hours, especially when considering recruitment maneuvers, including proning. The member continued that having to prone and un-prone a patient in 3 hours is very unrealistic, and that the desired results of such recruitment maneuvers will not be able to be achieved in that short period of time.

Another member added that it can be difficult to perform donor testing at smaller hospitals, particularly if the testing needs to be performed at regular intervals, requiring over night testing. The member also expressed concern for donor instability and rushed cases, which are increasing in frequency and volume.

OPTN Contractor staff shared a link to the guidance this proposal aims to change, which was initially released by the OPO Committee. OPTN Contractor staff asked the Committee if there was any feedback or suggestions for modifications that may make it easier to meet the requirements. The Chair remarked that while it is important to get the information and ensure that it's timely, it's important to ensure there is flexibility in the process for OPOs trying to meet these requirements. Others agreed. One member noted that there are a number of variables that impact an OPO's ability to perform these kinds of testing, and offered that potentially the requirements could include greater time ranges or else be considered guidance rather than requirements. The Chair noted that OPOs managing donors and meeting requirements across multiple organ systems may find that allocation is held up by these requirements, particularly if there are rigid timeframes that impact offer notification. The member continued that a range, instead of a specific time frame, can reduce the impact of delays to allocation.

4. Upcoming Meetings

OPTN Contractor staff reviewed information relating to meeting logistics for the upcoming in-person Committee meeting, as well as information about the Donor Testing Requirements Workgroup.

Summary of discussion:

There were no questions or comments.

Upcoming Meetings

- September 11th – In-Person in Richmond, Virginia

Attendance

- **Committee Members**
  - Kim Koontz
  - Steven Potter
  - Annemarie Lucas
  - Anne Krueger
  - Amanda Bailey
  - Bridget Dewees
  - Elizabeth Shipman
  - Jillian Wojtowicz
  - Joe Brownlee
  - Jennifer Smith
  - Megan Roberts
  - Mony Fraer
  - Norihisa Shigemura
  - Sarah Koohmaraie
- **SRTR Staff**
  - Avery Cook
- **UNOS Staff**
  - Joann White
  - Kaitlin Swanner
  - Kelley Poff
  - Kayla Temple
  - Laura Schmitt
- **Other Attendees**
  - Kelley Hitchman
  - Joseph Tusa