**OPTN Membership and Professional Standards Committee**
**Meeting Summary**
**August 23, 2024**
**Conference Call**

**Cliff Miles, M.D., Chair**
**Scott Lindberg, M.D., Vice Chair**

## Introduction

The Membership and Professional Standards Committee (MPSC) met via Webex in both open and closed session on August 23, 2024, to discuss the following agenda items:

1. Revise Conditions for Access to the OPTN Computer System
2. Update Histocompatibility Bylaws
3. Require Reporting of HLA Critical Discrepancies and Crossmatching Events to the OPTN
4. Promote Efficiency of Lung Donor Testing
5. Membership Issues
6. Other Issues

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

## 1. Revise Conditions for Access to the OPTN Computer System

A representative of the OPTN Network Operations Oversight Committee (NOOC) provided an overview of the *Revise Conditions for Access to the OPTN Computer System* proposal, which is currently out for public comment. The purpose of the proposal is to enhance OPTN computer system security, expand accountability for system security to include business organizations who access the system, and to require all members with system interconnections to develop an Interconnection Security Agreement (ISA) with the OPTN.

Proposed policy changes include:

- Require OPTN membership as a condition of access to the OPTN Computer System
- Limit reasons for access to the OPTN Computer System to facilitating organ transplantation, fulfilling OPTN Obligations, and quality assurance and performance improvement
- Require reporting of privacy incidents involving data obtained from the OPTN Computer System
- Require all members with system interconnections to the OPTN Computer System to develop an ISA with the OPTN
- Require OPTN business members who access the OPTN Computer System to follow the same information security requirements that apply to other member types who access the OPTN Computer System

Upon implementation of the proposal, OPTN members will be required to take the following actions:

- Report privacy incidents to the OPTN
- Educate users on permissible reasons for OPTN Computer System access
- Develop ISA with the OPTN, if applicable
- Business organizations must apply for OPTN business membership

- Business members must follow the information security requirements that apply to all other member types

The NOOC representative requested Committee feedback on whether there are any potential unintended consequences of requiring business membership and whether the proposed monitoring and compliance for the proposal is sufficient.

Summary of Discussion:

Members asked whether business members will be able to serve on OPTN committees. Members acknowledged that business members do not have voting privileges, but questioned whether business participation on OPTN committees could offer an unfair advantage to a business over its competitors by way of the participating business' access to information not available to the public or influencing policies in its favor.

The presenter referenced a contracted donor evaluation vendor as an example of a potential business member who would have access to the OPTN Computer System to provide services to a transplant hospital OPTN member. The proposal targets these types of businesses to become OPTN members to ensure that they are beholden to the OPTN bylaws and system access requirements.

Members expressed concern about businesses with access to the OPTN Computer System using OPTN data for purposes other than the reason that permits their access. One member cited an example an organ offer screening business, which has access to the system for that purpose that is branching out into organ transplant aviation services. Other organ transplant aviation businesses would not typically have system access, leading to a competitive advantage for the business with access. The presenter responded that the proposal ensures business access does not fall outside of acceptable use of the OPTN computer system by specifying conditions of access.

A member asked what procedure will be used to determine whether applying business members are granted access to the OPTN Computer system, as there may be a wide range of types of businesses requesting access for novel reasons. OPTN staff answered that business members with access do not have general access to the system as a whole; the OPTN member contracting with the business determines what level of access should be granted to their member-specific data.

The Chair noted that there will be two categories of business members: those who require OPTN Computer System Access, and those who do not. This proposal will require a more nuanced MPSC review of business membership applications. Members commented on the separate need for more robust membership requirements for businesses providing services to transplant programs, regardless of whether they have access to the OPTN Computer System, which will allow the Committee to hold them accountable more broadly. A member noted the increasing use of third-party vendors emphasizing the need for thoughtful consideration of requirements.

**2. Update Histocompatibility Bylaws**

The Vice Chair of the OPTN Histocompatibility Committee presented the *Update Histocompatibility Bylaws* proposal, which is currently out for public comment. The purpose of the proposal is to update and clarify the OPTN bylaws affecting histocompatibility laboratories, particularly aligning the bylaws with upcoming Clinical Laboratory Improvement Amendments (CLIA) changes.

The proposed changes include:

- Allowance of multiple OPTN-approved laboratory directors at a histocompatibility laboratory
- Update laboratory director education and training requirements to align with CLIA
- Clarify and expand requirements for laboratory agreements with transplant programs and OPOs

- Modify required personnel and add primary data coordinator to act as OPTN point of contact
- Update laboratory subcontracting requirements, including removal of the requirement for the laboratory director to review and approve all subcontracting requirements before release
- Expand inactivation and withdrawal notification requirements
- Remove or clarify requirements that are redundant to existing regulatory requirements for labs

Upon implementation of the proposal, OPTN members will be required to take the following actions:

- Histocompatibility laboratories:
    - Must evaluate agreements with transplant hospitals and OPOs to ensure compliance with new requirements
    - May choose to submit additional laboratory director applications
- OPOs and transplant programs:
    - Must evaluate agreements with histocompatibility laboratories to ensure compliance with new requirements

The Histocompatibility Committee Vice Chair requested the Committee's feedback on:

- Potential metrics beyond those included in CLIA requirements
- The clarity of the requirements for transplant program and OPO agreements
- The impact on patient safety
- Removing OPTN bylaw requirements that are also required by other regulatory bodies

Summary of Discussion:

A member inquired if certification is required for histocompatibility laboratory technical supervisors. The presenter responded that the American Society for Histocompatibility and Immunogenetics (ASHI) accreditation is required for technical supervisors within the definitions of CLIA. Since the OPTN Bylaws are required to be in alignment with CLIA regulations, the Histocompatibility Committee opted to remove the requirements from OPTN Bylaws that were already outlined in CLIA. Despite not being explicitly listed within the bylaws, technical supervisors are required to be accredited by ASHI.

Members expressed support for the proposal, with one member commenting on the importance of ensuring that highly qualified individuals with several years of experience are not subject to unduly burdensome application documentation submission requirements.

**3. Require Reporting of HLA Critical Discrepancies and Crossmatching Events to the OPTN**

The Vice Chair of the OPTN Histocompatibility Committee presented the *Require Reporting of HLA Critical Discrepancies and Crossmatching Events to the OPTN* proposal, which is currently out for public comment. The purpose of the proposal is to require reporting of critical discrepancies in Human Leukocyte Antigen (HLA) testing to gain insight into root causes, develop prevention strategies, and uphold patient safety.

The proposed changes include:

- Require HLA critical discrepancy reporting to the OPTN Patient Safety Reporting Portal within 24 hours of discovery
- Update the definition of HLA critical discrepancy
- Require reporting of incorrect specimens or typings used for physical or virtual crossmatch

Upon implementation of the proposal, histocompatibility laboratory OPTN members will be required to take the following actions:

- Report critical discrepancies to the OPTN within 24 hours of discovery
- Review reported incidents and, as needed, perform root cause analyses, and implement corrective action plans

The Histocompatibility Committee Vice Chair requested the Committee's feedback on the appropriateness of the 24-hour reporting time frame, the modified definition of a critical HLA discrepancy, inclusion of incorrect or inappropriate samples used or provided for crossmatch in required reports, whether the proposal aligns with existing required reporting for other patient safety events, and what information labs should submit with reports to facilitate standardized and streamlined case review.

Summary of Discussion:

A member expressed support for the 24-hour time frame, noting the laboratory would only be required to report awareness of the event not resolution to the discrepancy, and inclusion of incorrect or inappropriate samples used or provided for crossmatch in reports. The member commented on the modification of the definition for a critical HLA discrepancy, advocating for a definition that considered any discrepancy to be critical, as even small differences can be clinically relevant.

Another member commented on the 24-hour reporting requirement, highlighting that the proposed language requires only reporting to the OPTN Patient Safety Reporting Portal, and does not include notification to the involved OPOs and transplant programs. The presenter commented on the unifying role of reporting to the OPTN in sharing information among relevant parties while acknowledging the lack of requirement for labs to disseminate this information and the potential benefit of clarifying this responsibility within the language. Members provided insight on their experiences learning of a discrepancy and identified that a best practice would be for a transplant program to immediately notify the OPO. Members felt that it should be required to be reported to the OPTN, but it would not be efficient for the OPTN to be responsible for notifying other potentially affected groups.

A member inquired how disagreements between labs performing testing over result discrepancies will be handled. The Histocompatibility Committee Vice Chair responded that while disagreements of this nature can typically be resolved through communication and independent investigation of results on the part of each lab, in cases where agreement cannot be reached, the MPSC could be engaged in resolution efforts with the aid of histocompatibility subject matter experts.

A member asked whether infrastructure exists to support an increase in the number of reports received. The presenter replied that the Histocompatibility Committee does anticipate an increase in the volume of reports, but not at a drastic rate that will require infrastructure changes.

**4. Promote Efficiency of Lung Donor Testing**

The Vice Chair of the Lung Transplantation Committee presented the *Promote Efficiency of Lung Donor Testing* proposal to the MPSC. The purpose of the proposal is to promote efficiency of lung donor testing by proposing changes to OPTN Policy 2.11.D and updating the associated guidance on requested lung donor information. These proposed policy changes include:

- Addition of more specific requirements for obtaining arterial blood gases
    - Ventilator settings for challenge gasses: PEEP of 5-8 cmH2O, FiO2 100%, Tidal volume of 6-8 mL/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 the organ recovery
    - Must not be drawn within 30 minutes of any recruitment maneuver
- Required reporting of
    - chest computed tomography (CT) scan, if performed
    - an echocardiogram or a right heart catheterization
    - chest x-ray images or interpretation of chest x-ray within 3 hours of initial offer
- Require chest x-rays to be updated every 24 hours
- Remove requirement for description of sputum for a sputum gram stain

The proposed guidance changes include:

- Change "mycology sputum smear" to "fungal culture results"
- Add "bacterial culture results"
- Recommend providing a chest CT within 72 hours prior to initial offer
- Suggest providing chest CT images that show the lungs
- Specify that chest x-ray images are preferred over interpretations
- If an echocardiogram has been done and there are still questions or concerns, recommend obtaining a right heart catheterization.

Summary of Discussion:

A member began by asking for clarification why there was an option for sharing an interpretation for a chest x-ray and not just requiring image sharing, given the potential for images to be more impactful to the decision-making process. The option for an interpretation was an existing requirement in policy and by having both options available, it allows for instances where imaging sharing is difficult or not possible within the time frame. It was noted by another member that the chest x-ray report is still an important requirement because it empowers coordinators who are not trained in x-ray interpretation to make a decision based on the report, instead of having to wait for a surgeon to come out of the operating room or another similar scenario that would cause delays.

Another member expressed concern that adding these testing requirements does not leave much room for transplant hospitals to request more data. This project is meant to be an improvement to the current state of lung donor testing but should not preclude further testing from being requested or performed within reason. It should also help in reducing the use of "stalling tactics" from transplant centers that are making requests and not deciding on the donor offer.

A member shared support for the proposal but has concern about some of the proposed requirements being difficult to comply with in all situations, leading to potential non-compliance even when every effort is being made to follow OPTN policy. Of particular concern was the language requiring that challenge gases not be drawn within 30 minutes of attempting a recruitment maneuver coinciding with the required repeat testing time frame. This is exacerbated in instances of donor instability or when timing is difficult, and the proposed policy may conflict with what an OPO needs to do for donor care. There was also some concern that particularly in donation after circulatory death (DCD) cases, some donor hospitals may be less inclined to deliver on the proposed expectations when OPOs are making the requests, and there needs to be some understanding in those circumstances. The proposed policy language does not account for the scenario when a donor is on ex vivo lung perfusion (EVLP), particularly in the requirements for repeat testing of ABGs and chest x-rays.

Another member was concerned about the timing requirements for the chest x-ray because they work with a donor hospital that will not release images without an interpretation, which sometimes can take up to 8 hours. That would mean that under the new proposed language the OPO would either be out of compliance, or the donor would have to be significantly delayed. It was suggested that the use of language such as "every effort will be made to" might share the spirit of the policy without resulting in members being out of compliance for circumstances they cannot control.

**5. Membership Issues**

The Committee is charged with determining whether member clinical transplant programs, organ procurement organizations, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants and applications are presented to the MPSC members as either a consent or discussion agenda during closed session. The Committee reviewed and approved the consent agenda by a vote of 21 For, 0 Against, and **0** Abstentions.

The Committee considered the applications and other actions listed below and will ask the Board of Directors to approve the following recommendations during its December 2024 meeting.

- Approve 2 New Transplant Programs
- Approve 2 New Transplant Components
- Approve 1 Transplant Program-Reactivation
- Approve 1 Transplant Component-Reactivation
- Approve 1 Transplant Component-Conditional to Full
- Approve 1 Transplant Component-Conditional
- Approve 1 Business Membership Renewal

The Committee also reviewed and approved the following personnel changes.

- 8 applications for new key personnel for Transplant Programs or Components
- 49 applications for changes in key personnel for Transplant Programs or Components
- 7 applications for changes in key personnel for Histocompatibility Laboratories

In addition, the Committee discussed one pancreas program key personnel change application that was not on the consent agenda.

**6. Other Issues**

At the July MPSC meeting, Committee members suggested actions that could address issues that had been identified with third party vendors. Committee members suggested forming a small ad hoc workgroup that could consider and develop recommendations for potential referrals. Staff requested additional volunteers for an ad hoc workgroup that would meet once or twice prior to the November MPSC meeting to develop recommendations to the Committee.

**Upcoming Meetings**

- September 27, 2024, 2-5pm, ET
- October 9, 2024, 3-6pm, ET
- November 6-8, 2024, times TBD, Virtual
- December 13, 2024, 2-5pm, ET

**Attendance**

- **Committee Members**
  - Kamyar Afshar
  - Mitzi Barker
  - Megan Bell
  - Kristine Browning
  - Christopher Curran
  - Chadrick Denlinger
  - Amishi Desai
  - Chad Ezzell
  - Sander Florman
  - Darla Granger
  - Dipankar Gupta
  - Shelley Hall
  - Kyle Herber
  - Michelle James
  - Christy Keahey
  - Lindsay King
  - Varvara Kirchner
  - Peter Lalli
  - Scott Lindberg
  - Deborah Maurer
  - Luis Mayen
  - Deborah McRann
  - Clifford Miles
  - Saeed Mohammad
  - Nirmal Sharma
  - Carrie Thiessen
  - Mark Wakefield
- **HRSA Representatives**
  - James Bowman
  - Marilyn Levi
  - Arjun Naik
- **SRTR Staff**
  - Jonathan Miller
  - Jon Snyder
  - Bryn Thompson
- **UNOS Staff**
  - Anne Ailor
  - Robert Albertson
  - Kristine Althaus
  - Sally Aungier
  - Matt Belton
  - Torry Boffo
  - Jadia Bruckner
  - Nadine Cahalan
  - Elinor Carmona

- Robyn DiSalvo
- Laureen Edwards
- Katie Favaro
- Liz Friddell
- Jasmine Gaines
- Caroline Hales
- Houlder Hudgins
- Elias Khalil
- Lee Ann Kontos
- Jessie Kunnmann
- Lindsay Larkin
- Krissy Laurie
- Jon McCue
- Amy Minkler
- Heather Neil
- Delaney Nilles
- Jacqui O'Keefe
- Jamie Panko
- Rob Patterson
- Kelley Poff
- Liz Robbins
- Laura Schmitt
- Erin Schnellinger
- Sharon Shepherd
- Courtney Skeen
- Kaitlin Swanner
- Stephon Thelwell
- Betsy Warnick
- Joann White
- Trevi Wilson
- Claudia Woisard
- Hobie Wood
- Hollie Woodcock
- Karen Wooten
- Amanda Young

- **Other Attendees**
  - Kelley Hitchman
  - Dennis Lyu
  - Daniel Yip