OPTN Transplant Coordinators Committee
Meeting Summary
June 22, 2022
Conference Call

Stacy McKean, RN, Chair
Natalie Santiago-Blackwell, RN, MSN, Vice Chair

Introduction

The Transplant Coordinators Committee (the Committee) met via Citrix GoToMeeting teleconference on 06/22/2022 to discuss the following agenda items:

1. Recognition of Outgoing Members
2. Updates to Modify Data Submission Policy
3. Require Confirmatory HLA Typing for Deceased Donors

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

1. Recognition of Outgoing Members

The Committee recognized outgoing members, and thanked them for their Committee service.

Summary of discussion:

The Committee had no questions or comments.

2. Updates to Modify Data Submission Policy

Staff presented an update on the upcoming implementation of the Modify Data Submission Policy update.

Presentation Summary:

The purpose of the policy update is to clarify information required for submission and update the due dates for submission. This will limit OPTN members' ability to make post-submission deadline changes to the data. This update was approved by the Board of Directors in December 2019.

Submission deadlines will be clarified and extended for certain data collection. Data are "locked" after established reporting deadlines. Members can "unlock" data after the deadline with the submission of a description of the reason for the changes, and acknowledgement of the member's internal leadership's awareness of the changes. An annual report to the OPTN Board will detail the frequency of and reasons for changes following the deadlines.

These changes will impact 8 forms in the Information System for the Organ Procurement and Transplantation Network:

- Extends the due date by at least 30 days
- Locks forms once the due date is reached
- Change two labels, change validation message, collect unlocked data with reason and approver
- The currently existing Import Utility will omit records from the import if the form is past the due date, and an email with attached file of locked records will be sent to the user

Reporting changes:

- Deprecate OPTN Computer System Compliance Report associated with OPTN Policy 18.4:
- Refresh member reports in the OPTN Computer System Portal with Data Lock Dashboard and Data Lock Preview
- Two new training modules will be made available at the end of June and at the end of August

Implementation is currently scheduled for August 30, 2022. Software engineering development is complete, and will be released to the Beta Portal on June 29, with release to Production on August 30. Several communications have been sent, including a system notice of changes and an integrator notice.

Changes to final data will not be permitted unless the member reports, within the data collection system prior to making the changes, both the approval of the member's official OPTN Representative or designee and the reason for the changes.

- Transplant programs will manage their own approvers
- Transplant program staff, with appropriate access, can "unlock" the form, note the reason for the change, name the approver, and then make necessary edits
- There will be no data validation of the approver name
- To reduce confusion, the label for the OPTN Representative field will be "Approved By"

Updates to the Import Utility, specifically the decision to reject or omit changes to locked form upon impact, will be communicated at regional meetings and to transplant programs utilizing the utility. The use of new reports will be promoted, to avoid manual data entry.

New forms generated on August 30, 2022 or later will follow the new submission timelines. Upon implementation, a data script will be run to reconcile historical forms. All pre-existing forms that have an expected date due within their respective 30 or 60 day timeframe will be reconciled to include the additional time afforded by the new policy change.

Summary of discussion:

The Committee had no questions or comments.

3. Require Confirmatory HLA Typing for Deceased Donors

The Incoming Vice-Chair of Histocompatibility Committee presented an overview the Require Confirmatory HLA Typing for Deceased Donors project.

Presentation Summary:

Histocompatibility Lab Directors have recently submitted a letter expressing concern about the current lack of required redundancy for HLA typing, as compared to ABO typing. Both are considered critical to determine patient and donor compatibility.

Inclusion of incorrect HLA typing in the match run may mean offers are given to patients highly sensitized against the donor. Virtual crossmatching or assessment of immunologic risk requires correct HLA typing to determine candidate and donor matches and donor service area. This affects both acceptance and rejection of an organ offer and peri-transplant care for the recipient. Crossmatches and confirmatory typings often occur after transplant for hearts and lungs, creating potential for hyper acute or accelerated rejection.

Recommended steps to mitigate risk have included increased safeguards to ensure correct donor HLA typing, redundancy in the system of HLA typing, and requiring confirmatory typing in policy. The Histocompatibility Committee has discussed this, and recommends that deceased donors should have

two HLA samples run, drawn at two separate times, similar to ABO policy. Both samples should be typed at a molecular level for all loci. The Histocompatibility Committee recommends requiring raw HLA typing data to be uploaded for both samples into attachments in the OPTN Donor Data and Matching System. There is the possibility for further discussion on best practices for different sample types or assays. Both typing results would be required at the same reporting timeframe as current policy. It's necessary to ensure typings are not discrepant and to ensure efficiency and safety. Samples are able to run in parallel, so as not to increase turnaround time for HLA typing. The Histocompatibility Committee did not want to create requirements that would increase the time to allocation or burden on staff.

Summary of discussion:

The Vice Chair noted that this requirement seems straightforward. The Incoming Vice Chair of the Histocompatibility Committee noted that this requirement aligns with current practices, transitioning towards increased reliance on virtual crossmatch, and that there is need for a specific level of certainty.

The Committee had no other questions or comments.

4. Normothermic Regional Perfusion Workgroup Participation

Staff presented an opportunity for Committee members to join the Ethics Committee's Normothermic Regional Perfusion (NRP) Workgroup.

Presentation summary:

Ethics Committee's NRP Workgroup will have bimonthly meetings starting in mid-July

- Goal: Review ethical implications of NRP as a surgical technique in deceased donor organ recovery
  - NRP involves in situ reperfusion of organs with donation after circulatory death (DCD) donors, block recirculation to the brain
  - Consider potential for NRP to be ethically pursued, and any limitations or objections implied by the ethical principles
  - Use principles of autonomy, transparency and utility
- The OPTN Policy Oversight Committee highlighted need for coordinator perspective

Summary of discussion:

The Committee had no other questions or comments.

Upcoming Meeting

- July 21, 2022

Attendance

- **Committee Members**
  - Stacy McKean
  - Natalie Santiago-Blackwell
  - Angele Lacks
  - Ashley Cardenas
  - Ashely Anne Hamby
  - Heather Bastardi
  - Brenda Durand
  - Donna Campbell
  - Heather Miller-Webb
  - Jaime Myers
  - Jill Campbell
  - Kelsey McCauley
  - Lisa Gallagher
  - Rosa Guajardo
  - Sergio Manzano
- **HRSA Representatives**
  - Marilyn Levi
  - Raelene Skerda
- **UNOS Staff**
  - Ross Walton
  - Robert Hunter
  - Alex Carmack
  - Nadine Hoffman
  - Brooke Chenault
  - Cole Fox
  - Courtney Jett
  - Eric Messick
  - Isaac Hager
- **Other Attendees**
  - Gerald Morris