OPTN Histocompatibility Committee Discrepant HLA Typings Subcommittee Meeting Summary December 4, 2020 Conference Call

Peter Lalli, Ph.D., D(ABHI), Chair John Lunz, Ph.D., D(ABHI), Vice Chair

Introduction

The Discrepant HLA Typings Workgroup met via Citrix GoToMeeting teleconference on 12/04/2020 to discuss the following agenda items:

1. Policy Language Review

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

1. Policy Language Review

Histocompatibility Committee Chair and UNOS liaison discussed the proposed changes and asked for policy language clarifications.

Data summary:

Proposed policy language attached.

Summary of discussion:

The OPO that a lab should notify would be the host OPO, or allocating OPO. There likely wouldn't be another OPO involved, unless a kidney needed to be re-transplanted for some reason into a different recipient. While extremely rare, the original allocating OPO would need to be contacted if there was a discrepancy noted from the original donor's typing. Members mentioned that the first call a histocompatibility lab would make would be to the original OPO, and the original OPO would handle further coordination with any other involved OPOs or transplant programs. That would be the case even if the donor organs are "imported" from another OPO.

The workgroup discussed the event of discovery of the discrepancy. They agreed there was no standard way that discrepancies are discovered, and that it often takes time for labs to determine which typing is correct. They agreed that formal notification before determining which typing is correct would not be helpful, and so "discovery" of the discrepancy would be discovery of which of the discrepant typings is accurate. In addition, the OPO would not formally notify accepting transplant programs until they receive the correct documentation, to ensure that the information given is accurate.

The workgroup also agreed that candidate and recipient discrepancies did not have the same level of urgency as donor typings. While accurate candidate and recipient HLA typings are necessary to monitor donor-specific antibodies, an inaccurate typing will not cause a hyperacute rejection event, and as such a week would still be an appropriate timeline.

The workgroup proposed that the previous policy language on the HLA typings discrepancy report be modified to extend from 30 to 60 days, to mirror the data submission policy changes for the Donor and Recipient Histocompatibility Forms approved by the OPTN Board of Directors in December 2019. That

timeframe allows for donor and recipient confirmatory typing if needed, in order to verify the results being reported in the patient's records.

The workgroup agreed that 12 hours from receipt of documentation was an appropriate timeframe for the OPO to be required to notify all transplant programs, either before or after procurement. If they receive the documentation prior to procurement, the notification would also be required to be prior to procurement. The workgroup discussed the scenario of a post-procurement and pre-transplant notification, but were conflicted. While it would be urgent information for the OPO to convey, they will likely not know the exact timing of transplantation into the recipient. The workgroup confirmed that the OPO should only be required to notify programs once they receive documentation of the correct HLA typing. While frequent communication between the OPO and transplant program is necessary, communication of preliminary suspicions of incorrect typing would not provide useful information.

The workgroup also discussed removal of the requirement for the Histocompatibility Committee to review discrepant typings quarterly. The UNOS liaison explained that the committee is able to request and review reports as often as they would like, and that policy language doesn't need to include what data the committee is to use to create future policy. The workgroup had no questions or comments.

Next steps:

UNOS liaison will distribute the revised policy language for a full Histocompatibility Committee vote to send to public comment in January.

Upcoming Meetings

• TBD

Attendance

• Workgroup Members

- Alejandro Diez
- o Cathi Murphey
- o Idoia Gimferrer
- o Jennifer Schiller
- o John Lunz
- o Karl Schillinger
- o Larry Suplee
- o Peter Lalli
- o Phyllis Weech
- o Reut Hod Dvorai

• HRSA Representatives

- Marilyn Levi
 - o Raelene Skerda
- UNOS Staff
 - o Adel Husayni
 - o Courtney Jett
 - o Kelsi Lindblad
 - o Leah Slife
 - o Nicole Benjamin
 - o Susan Tlusty