

OPTN Heart Transplantation Committee

Meeting Summary

December 21, 2021

Conference Call

Shelley Hall, MD, Chair

Richard Daly, DO, Vice Chair

Introduction

The Heart Transplantation Committee met via Citrix GoTo teleconference on 12/21/2021 to discuss the following agenda items:

1. Multi-Factor Authentication in UNetSM
2. Heart and Heart-Lungs Donor Acceptance Criteria – Removing Local vs. Import Data Fields
3. Status updates: *Report Primary Graft Dysfunction* and *Amend Status Extension Requirements*
4. Future Committee Activities

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

1. Multi-Factor Authentication in UNetSM

The Committee was updated on the requirement for UNetSM users to download Authy for multi-factor authentication when accessing UNetSM for added security. In February 2022, UNetSM security administrators will be required to start using Authy authentication and the remaining UNetSM users will be required in March 2022. It was encouraged that users download and setup their Authy accounts now to ensure there are no problems after implementation. Instructions on how to link Authy accounts to UNetSM will be coming in early 2022.

2. Heart and Heart-Lungs Donor Acceptance Criteria – Removing Local vs. Import Data Fields

The Committee was asked for feedback to determine if local versus import fields can be removed from donor acceptance criteria on heart and heart-lung waitlist registration forms. This was being asked of the Committee because as lung transitions to continuous distribution allocation, which moves away from hard boundaries, there will no longer be donor acceptance criteria for local versus import which impacts heart-lung offers. Benefits of removing these acceptance criteria for heart would include increasing transparency, making candidate ranking easier to understand, and would prepare for future organ types transitioning to continuous distribution. An analysis of the current use of local versus import fields shows minimal difference between what is entered. If the criteria are removed, donor acceptance criteria would only have one field instead of the two for both local and import. Acceptance criteria entered would then apply to all donors regardless of location. A possible disadvantage of removing the local versus import criteria is that there would be approximately three years between lung and heart implementation dates of continuous distribution where heart programs would not be able to differentiate local versus import while still utilizing hard geographic boundaries. It was also noted that the updates to offer acceptance for all organs was an ongoing project and that the OPTN organ specific committees would be consulted to help inform organ specific details.

Summary of discussion:

The Chair noted that even though heart is still within hard boundaries, local versus import is not really applicable with the new allocation system implemented in October 2018 which shifted to broader sharing of 500 nautical miles. The Vice Chair voiced concern due to the new performance metric of organ turn down rates being implemented and the acceptance of older donors based on location may be relevant. The Chair mentioned that something to consider is the region you are in and how organ procurement organizations (OPO) operate in that region. It was clarified that import is either outside your OPOs donor service area (DSA) or outside of 250 nautical miles. A member asked if the Vice Chair currently differentiate. The Vice Chair stated that they did on occasion to differentiate age to screen off older donors that are further away. The Vice Chair explained that they are not opposed to removing it, but felt it needed to be discussed in light of the new performance metrics since you might get those offers you would have differentiated for with the local versus import options which may affect a program's turn down metrics. The Chair noted that the use of the local versus import granularity is not being utilized currently and a member stated they are not using them at their program, but might start based on the new performance metrics.

The Chair asked if the fields could be streamlined to local and import for age and donation after cardiac death (DCD) only. It was clarified that the removal is not a now or never thing, but it was explained that it would be easier to remove in conjunction with lung continuous distribution and recommended not splitting out the criteria for age and DCD since that would likely cause more confusion. A member stated that while they appreciate the point of being more scrutinized on turn downs in performance metrics, the acceptance of older donors is already very low and how programs operate should not change much. Another member agreed since chronological age as a single factor to make a determination on accepting or rejecting an offer is rarely used and recommended removing the fields. A member asked for clarification on the ability to have local versus import at all in continuous distribution and it was clarified that the way points are allocated for distance are gradual relative to proximity to the donor hospital. The Committee briefly discussed and requested more information on how continuous distribution would affect a program's performance metrics. After discussion, the Committee ultimately supported removing local versus import donor acceptance criteria.

Next Steps:

Follow-up with the OPTN Lung Transplantation Committee and Membership and Professional Standards Committee liaisons find out whether performance metrics for programs in continuous distribution would be impacted or would be different than current practices.

3. Status updates: *Report Primary Graft Dysfunction and Amend Status Extension Requirements*

The Committee was given an update on all of the proposals that were approved at the December 2022 Board of Directors meeting, including the two Heart Committee proposals. The *Amend Status Extension Requirements in Adult Heart Allocation* policy proposal requires programming and implementation is projected for some time in the first quarter of 2023. Implementation of the *Report Primary Graft Dysfunction (PGD) in Heart Transplant Recipients* proposal is projected for some time during the second quarter of 2023, because changes to TIEDI® data elements requires Office of Management and Budget (OMB) review and approval, in addition to the required programming. The Chair noted that while it is unfortunate that implementation takes a long time, it is positive that both proposals passed and understands that there are only so many resources to implement all of the approved projects. The Chair also mentioned that having the initial PGD Request for Feedback document was very important to the success of the final proposal.

4. Future Committee Activities

The Committee reviewed the policy/project development process and revisited the previously discussed possible new activities/projects:

- Educational emails for the community
- Data elements and definitions for Coronary Artery Disease (CAD) and Cardiac Allograft Vasculopathy (CAV)
- Heart-specific donor data fields

Summary of discussion:

The Committee was reminded that work on the continuous distribution of hearts would begin around the end of 2022 or beginning of 2023.

Educational Emails

These emails would be an opportunity to share important ideas with the transplant community and would need small teams of Committee members to identify timely topics and develop messaging. The Chair mentioned that currently most of the communication is received through the broad OPTN communications which is typically more generic, but the goal of the emails would be to focus on topics that are important to the heart community that would be isolated correspondence. An initial topic idea included more information on the level of detail expected for Heart Review Board exception requests. A member asked if this would be an opportunity to ask for feedback as a member that reviews the Heart Review Board appeals and the Chair stated that the hope would be that the communication to the community would help create standardization that the Heart Review Board could use in their decision making.

Data elements and definitions for CAD and CAV

This project would revise the definition for CAD and create a new data field and definition for CAV. This involved the created of a Heart Subcommittee specific to working on these two fields and definitions.

Heart-specific donor data fields

This project would also have a specific Heart Subcommittee to address the substantial changes that are occurring with the management and procurement of donor hearts. This project would identify and create new data collection regarding heart donor data fields. The Chair explained that there are a lot of requests for this coming from the community that came up especially during the public comment cycle for *Report Primary Graft Dysfunction in Heart Transplant Recipients*. The Chair continued explaining that this may include collaboration from multiple OPTN Committees.

Next Steps:

A follow-up email will be sent to Committee members requesting a response prioritizing their new project interests.

Upcoming Meetings

- January 18, 2022
- February 15, 2022

Attendance

- **Committee Members**
 - Shelley Hall, Chair
 - Rocky Daly, Vice Chair
 - Amrut Ambardekar
 - Cindy Martin
 - Hannah Copeland
 - Jonah Odum
 - Jondavid Menteeer
 - Kelly Newlin
 - Michael Kwan
 - Fawwaz Shaw
 - Tariq Ahmad
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Katie Audette
 - Yoon Son Ahn
- **UNOS Staff**
 - Keighly Bradbrook
 - Sara Rose Wells
 - Eric Messick
 - Krissy Laurie
 - Laura Schmitt
 - Darby Harris
 - Mike Ferguson
- **Other Attendees**
 - Samantha Taylor