

**OPTN Heart Transplantation Committee
Meeting Summary
February 15, 2021
Conference Call**

**Shelley Hall, MD, Chair
Richard Daly, DO, Vice Chair**

Introduction

The Heart Transplantation Committee met via Citrix GoTo teleconference on 02/15/2021 to discuss the following agenda items:

1. Public comment presentation: *Histocompatibility Committee: Change Calculated Panel Reactive Antibody (CPRA) Calculation*
2. Presentation of Quarterly Regional Review Board results for October – December 2021
3. Updates on status of Committee activities and other business

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

1. Public comment presentation: Histocompatibility Committee: *Change Calculated Panel Reactive Antibody (CPRA) Calculation*

The OPTN Histocompatibility (Histo) Committee Chair presented their public comment proposal and asked for the Committee's feedback. The purpose of the proposal is to revise the current CPRA calculator to include additional human leukocyte antigen (HLA) loci and use higher resolution typing data from a significantly larger data set. This revised CPRA will better reflect actual sensitization and improve access to transplant for the highly sensitized and minority candidates.

Summary of discussion:

A member asked if allele specific information is entered to get a CPRA, would programs only be able to get that CPRA? In heart transplantation, only low resolution DNA typing is available for donors, so programs will want to know how many donors will be excluded. The Histo Chair clarified that the histocompatibility equivalency tables in OPTN Policy are used to screen off donors, but unacceptable antigens will only exclude donors that have high resolution typing for that allele. The member countered that this would impact the perception of the pool of available donors which impacts programs when they are counseling their patients. The Histo Chair added that as part of typing methodology the laboratories are providing slightly higher resolution data that in most cases can provide more distinctions so all donors are not going to get screened off automatically using those inputted unacceptable antigens.

The Chair noted that having CPRA viewable for all candidates does not mean much in the heart community because of the variability in reporting, but added that transparency changes behavior so could change what programs report. They added that heart does not see highly sensitized patients nearly as often as other organ types do.

The Vice Chair stated that when a program chooses to list unacceptable antigens they are told what percentage of the population is being excluded as donors. After that, programs screen donors based on general quality and whether or not they are willing to accept certain antigens that are within a medium

range. The Vice Chair added that at their program, they end up looking up the CPRA so felt it would be helpful for it to be viewable. A member explained that many cardiologists and cardiovascular surgeons do not look at CPRA and would not know how to interpret a lot of immunology. The Chair added that it would be more beneficial to see CPRA reporting independent of what is entered as unacceptable since the combination of the two is the most valuable and a member agreed. The Histo Chair noted that this conversation may be more relevant for the Committee when they start work on continuous distribution. Members added there are a number of large programs that do consider this information and that it would not hurt to have it viewable. Overall, the Committee supported having CPRA viewable for all candidates.

2. Presentation of Quarterly Regional Review Board results for October – December 2021

The Committee reviewed the quarterly regional review board report for the last quarter of 2021. The quarterly reports contain the number of distinct justification forms submitted to review boards by pediatric and adult status for the last three months. The report also shows the process time for the forms and notably the time to process adult forms has been increasing slightly over the past few quarters, which is being monitored.

Summary of discussion:

The Chair asked if the report contained the process times broken down by OPTN Region and it was clarified that those data are not a part of the report, but could be requested by the Committee. A member agreed that it would be helpful to know how long the process time is by Region, because there are instances where a candidate is being transplanted at a then denied status which could be avoided if the Regional Review Board response times were less than 10 days. The Chair clarified that they would want to know the response time of the reviewing Region, not the transplanting Region. The Chair also added that there may be a need for reeducation or improvements, but if there are transplants occurring at an ultimately denied status, there is no way of correcting the program.

A member asked if the data on percent accepted was available to the individual review boards since it may be helpful to give the reviewers more feedback on how they are performing. The member added that it would be helpful if the reviewers could see if their denials were consistently overturned. It was clarified that it is not currently done, but it is something that could potentially be added as part of continuous distribution. A member agreed that having more transparency on the outcomes would be helpful for reviewers.

A member stated that the major issue is while a large portion of reviews happen within a day, the distribution curve shows that there are still a lot that get reviewed between four to 10 days. They added that many of those patients are transplanted, especially at Status 1 or 2, and the Committee reviewers end up denying the status after transplant occurs. It was clarified the current timeframe is three to five days, and members agreed that it should be made shorter. The Vice Chair added that there is no option to request an exception for a higher status and not list the candidate at that status until it is approved. Members discussed that it is not necessarily gaming of the system when programs submit exceptions and the candidate is transplanted at a subsequently denied status; since programs believe their patient is at imminent risk of death, they utilized the appropriate process to revise their patient's status to reflect this medical urgency. The Chair clarified that while the listing process was modified in 2016, the review process was not so the Committee will need to address this issues in continuous distribution.

A member noted that the review board members are volunteers and sometimes getting an email does not seem time sensitive and suggested looking for better ways to communicate with the reviewers. Members agreed that the voting process could maybe be made easier. The Committee felt that this is

something that needs to be improved and it was clarified that there would be opportunity to improve Heart Review Boards in continuous distribution.

3. Updates on status of Committee activities and other business

The Committee reviewed the Committee's current projects and which Committee members are contributing to those efforts.

Summary of discussion:

Educational emails

The first Subcommittee meeting for this group is scheduled for Wednesday, February 23rd from 4:00-5:00 pm ET. The topic of this meeting will be to discuss the message addressing the use of exception requests for Status 2 assignment based on Policy 6.1.B.v: *Intra-Aortic Balloon Pumps*.

The Chair asked that the guidance document and examples be sent in advance of the meeting so that the members can think about it before to decide how it is addressed. They added that it does not look like the guidance document changed behaviors looking at the review board data.

Revise CAD and CAV Data Elements

The Subcommittee had its first meeting on February 3rd and discussed potential changes to the Coronary Artery Disease (CAD) information and began discussions of Cardiac Allograft Vasculopathy (CAV) definitions. This project will be going to the OPTN Policy Oversight Committee (POC) in March for their approval.

Heart-Specific Donor Data Fields

It was recommended that this Subcommittee function as resource for other efforts rather than proposing a new project at this time. The OPTN Organ Procurement Organization (OPO) Committee data collection project is working on improving efficiency of the organ evaluation process including heart donor data. There is also a cross-organ effort to address perfusion device data.

The Chair felt that it would be better for the Heart members to work closely to the OPO group to avoid working in parallel. Upon initial review, it seemed that some of their data suggestions did not make sense from a cardiology perspective so the Committee could provide insight on how to improve them.

Medtronic HVAD Systems Update

The Chair updated the Committee on the latest information from Medtronic showing that they have narrowed the device failure issue to 56 patients in the United States, with only two of those patients currently being listed for transplant. The Chair explained that this is not something that the Committee should pursue creating policy around and that if the programs with affected patients want to submit exception requests that should suffice. A member suggested that the programs with those patients receive information suggesting that they submit Status 3 exception requests and the Chair stated that they should know that is an option but felt the Committee should not be telling programs how to manage their patients. The Chair added that the Committee cannot tell the review board how to handle the exceptions either, but that this is a very small patient population this is the available option.

The Chair asked if the Committee should inform the affected patients of the exception process or if being documented as part of this meeting's meetings would be sufficient. A member mentioned that it may not be obvious to transplant programs to look at this meeting's minutes and the Chair added that when the information initially came out programs reached out for the OPTN's response. It was asked if this is still considered a clinical decisions that should be managed by the programs and the Chair said it was and that programs should be aware of the exception process. A member explained that it may add

more confusion to make an official statement because the patient may interpret that as they need a transplant at a higher status when it is more of a clinical decision. A member brought up that patients' have voiced concerns about how COVID-19 information was shared with them so perhaps information should be shared and a member agreed that the OPTN is in a unique position to reach programs with relevant information.

A member expressed concern over the true number of patients affected and another member felt the information shared by Medtronic was fully vetted and it truly is a low number of patients. A member stated that all the programs with patients with identified serial numbers should be notified and the Vice Chair added that this situation makes the case for the Committee's work on educational emails for both the community and Review Board members. The Chair asked if the Committee would be allowed to draft an email and it was clarified that it would be okay to share the information but would want to avoid telling programs how to care for their patients or how Review Board members should review a case. Members agreed that the email should be informational and not instructional.

Next Steps:

UNOS Staff will look into options for sending an email to the heart community regarding the Medtronic HVAD updates and relay that back to the Committee.

Upcoming Meetings

- March 15, 2022
- April 19, 2022 (Chicago)

Attendance

- **Committee Members**
 - Shelley Hall, Chair
 - Rocky Daly, Vice Chair
 - Cindy Martin
 - Hannah Copeland
 - Jonah Odum
 - Jondavid Menteeer
 - Kelly Newlin
 - Jennifer Carapellucci
 - Jose Garcia
 - Nader Moazami
 - Timothy Gong
 - Amrut Ambardekar
 - Fawwaz Shaw
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
 - Raelene Skerda
- **SRTR Staff**
 - Katie Audette
 - Yoon Son Ahn
 - Monica Colvin
- **UNOS Staff**
 - Keighly Bradbrook
 - Sara Rose Wells
 - Eric Messick
 - Krissy Laurie
 - Laura Schmitt
 - Isaac Hager
 - Lauren Mauk
 - Leah Slife
 - Lloyd Board
 - Susan Tlusty
- **Other Attendees**
 - Peter Lalli