

OPTN Heart Transplantation Committee

Meeting Summary

February 8, 2023

Conference Call

Rocky Daly, MD, Chair

JD Menteer, MD, Vice Chair

Introduction

The Heart Transplantation Committee met via Citrix GoToMeeting teleconference on 2/8/2023 to discuss the following agenda items:

1. Continuous Distribution of Hearts: Discussion of Sensitization as a potential attribute for inclusion

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

1. Continuous Distribution of Hearts: Discussion of Sensitization as a potential attribute for inclusion

In an effort to review potential attributes for continuous distribution, the Committee has divided into small groups to consider attributes in additional detail and present their findings and recommendations to the full Committee. As such, the sensitization small group is presenting their findings and recommendation to include sensitization as an attribute in the first iteration of continuous distribution. This attribute would be categorized within the candidate biology goal.

Summary of discussion:

The Committee considered sensitization as an attribute to give priority to candidates who are on the Heart waiting list and sensitized. It was discussed that candidates who are sensitized have longer waiting times are more likely to be removed from the waiting. Such heart candidates also have excess mortality while on the heart waiting list. According to a Committee member, one challenge sensitized patients face is that they must have a favorable cross-match before being offered an organ. As a result, they require that more match runs occur than non-sensitized candidates before receiving they can successfully go to transplant. The prospective cross matches can create geographic and time barriers that can limit the donor pool when there is not time available to perform such a cross match. Additionally, the member stated that while there are many de-sensitization protocols, they are not particularly effective. Also, the number of individuals identified as sensitized has been steadily increasing over time. Furthermore, sensitization has been shown to disproportionately affect women, and certain diagnoses, the congenital heart diseases are the one identified, due to prior cardiac surgery and/or prior blood transfusion. Despite these factors, current heart allocation policy does not provide any prioritization for such candidates. Transplant programs sometimes try to address a candidate's sensitization by submitting an exception request for a higher priority status assignment.

In reviewing the small group's one-page document, the Chair recommended including additional details about the need to cross match and what currently happens in the system when a center lists unacceptable antigens. Currently, listing unacceptable antigens reduces the number of donors available for the patient, which is an important point to clarify when making the argument for this solution. The Chair detailed the current process in which centers are not required to list unacceptable antigens, but when they do it reduces the offers that a patient could receive by excluding offers that include the

unacceptable antigens. When unacceptable antigens are entered in the OPTN computer system, a calculation is performed analyzing how common they are in donors and develops a calculated panel reactive antibody (CPRA) score. The purpose of providing additional points for a highly sensitized patient is to increase their access to the smaller organ pool they are compatible with.

A member asked to what extent the Heart Committee's decisions about sensitization and weighting should align with other organs' continuous distribution framework. While consistency is beneficial for system efficiency, the Committee should make medically driven decisions. Members acknowledged that the concept paper and regional meetings will be a good opportunity to explain their reasoning to the community.

Members discussed potential rating scale options for sensitization. The Chair advised against including this attribute in a manner that had clear cuts off, such as a binary scale. Alternatively, the Chair advocated for a rating scale with a steep curve that provided high points to patients with a high CPRA and very little points to patients with a low CPRA. Thus far, it sounds the rating scale suggested by the Chair is similar to the approach taken by the Lung Committee. The Committee reviewed the rating scales for lung continuous distribution and concurred that lung allocation aligned more closely with heart transplantation than kidney or liver would.

While it is still relatively early in the Committee's discussion of continuous distribution, members briefly mentioned the weight of sensitization with respect to other attributes noting that current heart allocation is largely dictated by medical urgency and sensitization will align with candidate biology. The Vice Chair cautioned against assigning sensitization too large of a weight compared with the other attributes that it results in patients with high medical urgency priority losing out on offers to candidates with less medical priority but high sensitization. The Chair noted that in the lung continuous distribution framework, the Lung Committee weighted sensitization as only five percent of the total composite allocation score (CAS), compared to an attribute for pediatric priority that was assigned 20 percent.

A member inquired about the opportunity to model sensitization in heart, noting the research associated with kidney transplant that identifies the level of CPRA with the corresponding waittime. The member emphasized how a 0.4% difference in CPRA (i.e. 99.9 vs 99.5 CPRA) for kidney patients can be the difference between receiving a transplant or not. The Chair explained that a challenge of using such data for heart patients, is that currently programs may or may not list the unacceptable antigens they are willing to accept. Because listing these unacceptable antigens filters out offers, programs may elect not to list certain unacceptable antigens in favor of evaluating the other considerations of the offer and determining if they can work through the potential sensitization challenges. For example, a program may not enter an unacceptable antigen even though the candidate has a high level of antibodies to that antigen. For example, even though a candidate has a high level of antibodies to an antigen, the program may not enter it in the OPTN computer system as an unacceptable antigen based on other factors the program thinks are more favorable, such as proximity to the donor organ. In such circumstances, the program might be willing to work through the antibody issue because they believe the organ's benefits outweigh that cost. Nonetheless, after going through the process, the program may still turn down the organ.

A Committee raised the broader issue of access to transplant, and how this suggested approach to sensitization might or might not impact access. For instance, the potential exists for a program to enter unacceptable antigens for its candidates in a way that favors one candidate ahead of others, or a certain group of candidates ahead of all the other groups of candidates. The member recommended having transplant programs include a justification when listing unacceptable antigens in order to promote equity in access once a candidate is listed. The member also inquired if data are already collected or

could be collected that could help the Committee monitor potential unintended consequences after implementation?

A member responded that currently programs can indicate in the OPTN computer system if their patient needs a prospective physical crossmatch. Therefore, it is possible to query that data and analyze if those patients are being passed over for that reason.

The presenter added that currently sensitization data is not standardized for heart patients. This information is collected in the risk stratification data and is inconsistently completed due to centers considering it as a low benefit. As a result, the community is not privy to the information because it is not entered in the system. By including sensitization as an attribute and creating the ability for patients to receive points, this would incentivize centers to complete this information and provide more data to inform future revisions to the system.

Another member expressed support for the approach being recommended. The member stated that a program with a mildly pre-sensitized patient might be willing to consider offers from all donors regardless of the candidate's sensitization. Such candidates are not inconvenienced by their level of sensitization. Under the approach, such candidates are not assigned any additional priority (points) for their level of sensitization. On the other hand, a candidate with high-level sensitization, who has very limited access to suitable donor hearts, will receive additional priority.

A member inquired how the sensitization information would impact multi-organ transplant (MOT) patients. A member responded that that the data for each organ registration are likely not connected so the unacceptable antigens listed for the primary organ, in this case the heart, would be used for the organ offer. The Chair added that there is no set cut off for what level of reaction requires being listed as an unacceptable antigen. Given the nature of unacceptable antigens reducing the donor pool, members felt that it would reduce the chance of gaming to receive the bonus for the attribute and incentivize those who may have been hesitant to list unacceptable antigens in the past.

The Committee conducted an informal vote and asked members to either enter in the chat or verbally indicate their support for including this attribute. Members indicated unanimous support for including sensitization as an attribute for inclusion in the first iteration of continuous distribution.

Data Request Considerations

Research staff asked the Committee to approve a data request to the Scientific Registry of Transplant Recipients (SRTR) to begin updating the heart simulation models in preparation for a future modeling request. This request would not result in a formal data request from the SRTR, but serves more as a formality and heads up that a modeling request will occur in the future. An SRTR representative on the call inquired when the Committee would submit their modeling request, which is unlikely to occur for 6 months or more. Members voiced support verbally and in the chat in favor for this submitting this request.

Research staff asked the Committee to approve a data request to HRSA to consider pediatric waitlist mortality, pediatric heart status, and pediatric waiting time, all stratified by body surface area. This data has been request by the pediatric medical urgency small group to assist in their deliberations and subsequent recommendations to the Committee. The goal of this workgroup is to transition the current pediatric statuses to a continuous model. Members voiced support verbally and in the chat in favor for this submitting this request.

Waitlist Mortality

The Committee briefly reviewed a waitlist mortality curve by adult and pediatric statuses. A member commented that this data supports moving the intra-aortic balloon pump (IABPs) down from status 2 to status 3 given the mortality rate. The member also voiced concern that exception requests for status 2 through 4 appear to be approving low risk patients for higher statuses than they medically align with. The member felt this data would support modifying status 2 to potentially remove IABP as an interim solution while continuous distribution is in development. A member countered that by moving IABP to status 3, center behavior would likely change and patients would receive an Impella as opposed to an IABP to maintain a status 2 qualification. A member shared that new data will be released soon that indicates patients on an Impella have a higher mortality rate and could distinguish between the patients who are appropriate for an Impella from an IABP to reduce some of the overlap. Members did acknowledge that when using therapy as a surrogate for measuring illness they are unable to remove all possibilities for gaming.

Donor Acceptance Criteria

Members were reminded of the changes to donor acceptance criteria occurring on March 2, 2023 in conjunction with the implementation of lung continuous distribution. The Heart Committee was consulted in December 2021 and endorsed removing 'local' or 'import' offers for the heart and heart-lung acceptance criteria. More information, including the communication notice, can be found on the OPTN website.

Next steps:

The small group will add some additional background details to their document based on today's discussion. Once there is a final version, staff will circulate the document to the full Committee for review.

Upcoming Meeting

- February 28, 2023
- March 21, 2023
- March 29, 2023 – in person meeting in Richmond, Virginia
- April 18, 2023
- May 16, 2023
- June 20, 2023

Attendance

- **Committee Members**
 - Tamas Alexy
 - Amrut Ambardekar
 - Rocky Daly
 - Timothy Gong
 - Robert Goodman, Visiting Board Member
 - Shelley Hall
 - Glen Kelley
 - Earl Lovell
 - JD Menteer
 - Kelly Newlin
 - Jonah Odim
 - Adam Schneider
 - Cristy Smith
 - Martha Tankersly
- **HRSA Representatives**
 - Marilyn Levi
- **SRTR Staff**
 - Yoon Son Ahn
 - Katie Audette
 - Monica Colvin
 - Grace Lyden
- **UNOS Staff**
 - Mariah Huber
 - Kelsi Lindblad
 - Alina Martinez
 - Eric Messick
 - Laura Schmitt
 - Kim Uccellini
 - Sara Rose Wells