OPTN Heart Transplantation Committee
Meeting Summary
October 29, 2020
Conference Call

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

Introduction

The Committee met via Citrix GoToMeeting teleconference on 10/29/2020 to discuss the following agenda items:

1. Welcome and member introductions
2. Policy Oversight Committee (POC) Update
3. Report of Heart Review Board activities
4. Public comment review: Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy
5. Public comment review: Guidance Addressing the Use of Pediatric Heart Exceptions
6. Discussion of 18-month monitoring for Modifications to Adult Heart Allocation Policy
7. Policy changes addressing certain extension requirements
8. Primary Graft Dysfunction project
9. Open Discussion

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

1. Welcome and member introductions

The Chair welcomed the members and invited them to introduce themselves and share where they work.

2. Policy Oversight Committee (POC) Update

The Vice Chair gave an overview of POC and provided updates on POC projects underway.

Summary of discussion:

The Vice Chair provided an overview of the Policy Oversight Committee's strategic priorities:

- Continuous distribution
- Multi-organ allocation
- Efficient donor/recipient matching to increase allocation

The Vice Chair reviewed the number of projects underway that fall under these priorities noting that continuous distribution related projects account for the majority of the overall effort of the three priorities. There are a number of other projects that do not fall under these priorities that are still important to pursue.

UNOS staff commented that these three strategic policy priorities are specific to POC and clarified that the OPTN has five strategic goals.

Continuous distribution for heart is scheduled to start January-February of 2023. The Primary Graft Dysfunction (PGD) project may be a component of this work. Phase 1, the submission of a request for feedback document during the upcoming public comment period, of the PGD project is being presented to POC on November 5th to gain endorsement. The feedback received during public comment will be incorporated into a formal data collection proposal that will go out for public comment in August 2021.

The Heart Committee is not currently involved in any efficient matching projects.

The Vice Chair is the Heart representative for the multi-organ allocation project which is currently in the evidence gathering stage. Currently, thresholds relating to status and allocation for heart/liver candidates are being determined with representatives of the Liver Committee. This proposal will go to public comment in January. The Heart Committee can participate by providing comment during public comment.

UNOS staff asked if the members are aware of other projects they would like to be involved in. No comments were made.

3. Report of Heart Review Board activities

UNOS Research staff showed the Committee where they may access the *Report of Heart Review Board Activities* on SharePoint.

4. Public comment review: Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy

UNOS staff provided an overview of the *Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy* proposal and the public comments received. The Committee voted to send the proposal to the BOD to vote to approve.

Summary of discussion:

UNOS staff shared that the *Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy* public comment proposal was well received and supported at all 11 regional meetings and by all member types. Support was also received from the OPTN Transplant Coordinator Committee, the American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS) Association of Organ Procurement Organizations (AOPO), and the Organization for Donation and Transplant Professionals (NATCO).

The Chair offered to reach out to the International Society for Heart and Lung Transplantation (ISHLT) board members to request comment on proposals in the future.

The change to the timeframe for measuring cardiac index in the *Inotropes without Hemodynamic Monitoring* policy was supported in public comment. In public comment, a concern was raised about whether increasing initial qualifying and extension timeframes encourages programs to not monitor patients' clinical conditions as closely. The Chair commented that less than 10% of these patients listed are on inotropes and that those patients will be monitored. Members agreed.

A member asked if there were any specific changes made to the proposal based on feedback and if these changes would require the proposal to go through another public comment cycle. UNOS staff responded that if any changes are substantial, it would go through public comment again.

UNOS staff reviewed the public comment feedback received relating to the proposed decrease in initial qualifying and extension timeframes in the *Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device* policy. Support was received for making these timeframes consistent with Status 1 candidates using venoarterial extracorporeal membrane oxygenation (VA ECMO). Some

concerns were raised in public comment that the proposed seven-day timeframe was too short given the medical urgency of the patients.

The Chair agreed that all Status 1 candidates should be required to request extensions on the same timeframe of seven days and asked the members if they agreed. A member commented that median days to transplant is four days. The Chair noted that the most recent monitoring report shows that the median wait time is 8 days for some Status 1 candidates but this could be due to the cohort size being small.

UNOS staff asked if the committee is in support of the proposal as written. Members agreed.

Another UNOS staff asked if a transition procedure should be considered for those already on the waiting list. UNOS staff commented that a transition plan was considered before the public comment proposal went out in which candidates would maintain their current forms, and as those expire, they would then renew with forms that have a seven-day extension timeframe. Members voted to agree to the transition plan to maintain the expiration date for existing forms, and then have a seven-day expiration for the next justification extension they submit. The Committee also agreed that a seven-day timeframe is appropriate.

The Committee discussed the value of moving the timeframe to seven-days. The Chair commented that it promotes equity and cleans up discrepancies. A member commented that it is important to be consistent and commented that one additional renewal will not increase burden significantly and because the population is small, a transition plan may not be required.

UNOS staff commented that there were no concerns raised about the change to reorder the list of *MCSD with Device Infections* during public comment.

The guidance for Status 2 exception requests received support in public comment. Comments were received in support of standardizing information and one commenter shared that the current exception process leads to disparities in the transplant process. A couple of comments raised concern about the guidance reducing the transplant program's clinical judgement. The Chair noted that the guidance received strong support in public comment.

The members voted to recommend that the proposal in its entirety go to the BOD for consideration at the December 7th meeting. No opposition was raised. The Committee voted to approve the proposal to go to the BOD (17 yes; 0 abstain, 0 oppose).

5. Public comment review: Guidance Addressing the Use of Pediatric Heart Exceptions

UNOS staff provided an overview of the *Guidance Addressing the Use of Pediatric Heart Exceptions* proposal and the public comments received. The Committee voted to send the proposal to the BOD to vote to approve.

Summary of discussion:

UNOS staff shared that the *Guidance Addressing the Use of Pediatric Heart Exceptions* proposal was supported in all 11 regions and by all member types. AST, AOPO, Society of Pediatric Liver Transplantation, NATCO, ASTS, Transplant Families, the OPTN Pediatric Transplantation Committee, and the OPTN Transplant Coordinator Committee also commented in support.

Public comments received support the guidance as a tool to increase efficiency and consistency of exception request reviews. Commenters stated that it will assist in rectifying imbalances and agreed that guidance, rather than policy modification, was appropriate as it is more flexible and allows for case by case determinations.

There was mixed support among the submitted comments concerning the inotrope doses considered high dose received during public comment. Some commenters expressed that the provided dosing did not indicate increased medical urgency while others supported that the dosing does indicate inotrope dependency. The Workgroup members chose to keep the dosing as written because it is consistent with how high dose inotropes are described in policy.

Support and concern were also raised during public comment regarding ventricular assist device (VAD) contraindications. The Workgroup chose to maintain an exception pathway for children who may have higher risks when receiving a VAD because of their smaller size or due to their medical condition.

Public comments were received in support of and concerned about a 1B status exception pathway for Fontan candidates. The Workgroup chose to maintain an exception pathway for these candidates but narrow the eligibility by requiring the candidate also be experiencing complications.

The immediate past chair and current Pediatric Heart Workgroup Chair commented that both comments in support and concern were received on the issues described above. The Workgroup reviewed all comments to ensure no big changes were needed. Several small changes were made to increase clarity and narrow the Status 1B exception pathway for Fontan candidates. The small changes were a logical outgrowth of the proposed changes overall, and therefore did not need to go back out for public comment. Because the comments received were balanced, and because the guidance was broadly support, no major changes were incorporated.

The Chair asked the Committee to voice opposition in sending the proposal. No opposition was voiced. The Committee voted to approve the proposal to go to the BOD (17 yes; 0 abstain, 0 oppose).

A member commented that they noticed that the only opposing votes were received from transplant hospitals for both proposals. The Chair commented that it may be in response to concerns that the proposals may cause more work or that they may reduce the program's autonomy.

6. Discussion of 18-month monitoring for Modifications to Adult Heart Allocation Policy

UNOS staff presented findings from the *18-month Monitoring Report for Modifications to Adult Heart Allocation Policy.*

Summary of discussion:

UNOS staff reviewed the policy changes implemented in 2018 which further stratified waiting list candidates into six statuses from three to increase granularity and promote that the most medically urgent candidates receive offers sooner.

Waiting List Conclusions

There has been a substantial increase in the use of intra-aortic balloon pumps (IABP), especially for those in Status 2.

There has been a decrease in the use of left ventricular assist devices (LVAD) but remains the largest percent of devices at listing.

There has been no significant change in waiting list mortality overall. There are similar waiting list mortality rates between criteria within statuses which further suggests accurate stratification of most medically urgent candidates.

A member asked about the population size for surgically implanted non-dischargeable devices. UNOS staff offered to follow up with more detail.

Transplant Conclusions

The median days to transplant has decreased substantially to less than half the amount of time pre-implementation. However, there is a large variability in the median time to transplant within statuses particularly for Statuses 3 and 4.

The overall rate of transplant for medically urgent candidates is significantly higher than pre-implementation. There is also broader sharing as evidenced by decreases in local shares and increases in national and regional shares. The median distance travelled changed from 81 nautical miles (nm) to 216 nm post implementation.

A member asked why Status 5 was denoted with asterisk in the *Median Days to Transplant* table. This is because the population size is too small to be calculated.

A member commented that these status stratification changes came at the same time as the change in allocation which may have affected transplant rates for candidates in Status 4. The Chair commented that healthier patients get delayed because the sicker patients are receiving transplants and noted that the median wait time has decreased. A member commented the 843, or 19%, of patients received transplants at Status 4, a decrease from 29% for Status 1B pre-implementation.

A member asked if there was a breakdown in waiting list mortality rates to compare Status 1, 2, and 3 post-implementation to Status 1A pre-implementation. UNOS staff shared this will be included in the 2 year monitoring report.

Member asked how many candidates with LVADs are removed from the waiting list for being too sick or dying. UNOS staff said that candidates are often supported by multiple devices and that this was not looked at specifically. The Chair commented that there has been a decline in VAD implantation. A member commented that sicker patients may be listed more often than before. These patients may have previously gone straight to VAD and not listed due to being too sick. Currently, 44.8% of Status 4 candidates are on a VAD and 19.1% of Status 4 are by exception.

A member asked about the number of higher status candidates removed from the waiting list because they receive a VAD. This is not included in the dataset.

A member asked if there is a trend in the exceptions. The Chair commented that previous work has been completed to review the exception clinical narratives to determine trends in exceptions which is what guided the creation of the Status 2 exception guidance.

Outcomes Conclusions

UNOS staff noted that there is a two-month data lag since programs have two months to submit data. One-year outcome data is typically reviewed at year two. This is further complicated this period because of the amnesty in form submission due to COVID-19 emergency policies implemented in April.

There is no significant difference between pre and post implementation for six-month survival.

Statuses 4 and 6 had the highest survival at six months which is expected due to their level of medical urgency.

The Chair expressed concern about the little change in utilization rates.

A member asked if there is a way to know how long Status 1 patients have been supported prior to listing and how this might impact outcomes. UNOS Research staff commented they will see if they can determine this from the data available.

Members discussed the increase in the utilization of VA ECMO. There is a concern that this may be the wrong support method but is increasing in prevalence. They also commented that these patient's outcomes tend to be poor and questioned if policy should support the number of transplants or the longevity of organs. Several members agreed that survival benefit should be considered. A member requested a survival curve for all IABP candidates transplanted.

A member shared that they wrote an article that shows VA ECMO candidates can have good survival with stringent criteria. The Vice Chair noted that there may be a learning curve with the allocation changes and commented that programs are responsible for their outcomes. It is too early to determine if any changes to allocation policy is needed.

One-year data will be available in the spring.

Regional Review Board Conclusions

There are between 300-400 exception requests per month, the majority are requesting adult Status 2 exception. Almost all exception requests are approved.

The Chair commented that exceptions have not decreased and are guiding what is being addressed in policy modification projects. A member asked what the most common reason for an exception is. The Chair commented that you have to read the clinical narrative to determine the reason. In Status 2, the most common reason was a lack of hemodynamic information.

A member questioned if the guidance documents will increase exceptions since programs may see that their candidates are eligible. The guidance documents will allow for exceptions to be reviewed more efficiently and allow a faster turnaround. The Committee was reminded that they can consider launching a National Heart Review Board for all of heart.

7. Policy changes addressing certain extension requirements

Summary of discussion:

UNOS staff shared that previously, the Committee reviewed all policy requirements and extension criteria. Gaps were identified regarding extensions requirements in policy. This new project continues the work of the Committee that was not included in the last proposal currently going to the BOD for approval.

The Committee will not go through all policies again but instead focus on the areas identified from the last assessment. The Chair noted that the last proposal included the items that were most urgent and easiest to address. This project will focus on more detailed changes needed.

This project is intended to address concerns that some transplant programs may be "parking" candidates at certain statuses and create more consistent policies around extension requirements.

The proposed solution amends policy by adding criteria and/or requiring review board approval to extend at certain statuses. Depending on the changes the Committee identifies, there could be a need to create a new adult heart justification form and/or changes to existing forms.

A Subcommittee will be created to work on the development of this project.

UNOS staff asked the Committee to consider why is there a need to revise policy 6.1.C.iv: *Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis*, what about the policy is not working well, and what evidence supports that the policy could be improved. A member commented that this policy was revised to make less vague and provide more clarification to make the criteria more provable and related to the VAD. The Chair commented that paracorporeals were discussed previously and it was determined to keep these devices included in the policy although they are not commonly used. The use

of the terms VAD and mechanical circulatory support device (MCSD) are both used in the policy but should be made consistent.

The Chair commented that the Subcommittee will work to clean up the language but asked the Committee to comment if they notice anything else that needs addressing. Extension qualifications will need to be established.

For policy 6.1.A.ii: *Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Devices*, the subcommittee will determine if the extension criteria needs to be changed. UNOS staff shared the potential rewrite of this policy.

For policy 6.1.B.vi: *Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF)*, the Committee will determine what information should be provided in order to appropriately justify extending the candidate at this status. A member commented that VT/VF extensions are not uncommon for Status 2.

For policy 6.1.C.vi: *MCSD with Device Infection*, the Committee should consider further defining "is experiencing." The Chair commented that the way in which the policy is currently written allows a candidate to that no longer has an infection to stay at Status 3.

The Committee was asked to consider what data or analyses would be useful in guiding the policy development process.

This project will be reviewed by the Data Advisory Committee (DAC) on December 14th, 2020 and then move on to POC for review on December 29th. The goal would be to submit a proposal for public comment in August 2021.

A Subcommittee will be formed to focus on these policies. The work produced will be reviewed by the full Committee.

The Chair asked if the Committee could propose term limits on statuses. UNOS staff equated the amount of work to the 2016 allocation changes. SRTR would be also be involved to provide modeling. The Chair commented that larger projects may be delayed by upcoming Continuous Distribution efforts.

The Chair suggested only allowing one or two extensions. A member suggested empowering the Review Board to limit the number of extensions they allow. The Chair commented that policy would need to be developed to limit the extensions. UNOS staff suggested asking the community what they think about setting extension limits as part of the public comment document. A member raised a concern that imposing limits may incentivize programs to place a VAD if they run out of extensions.

Next steps:

Members were invited to reach out to UNOS staff and the Chair if they are interested in participating in the Subcommittee. UNOS staff will be in touch with selected members with more details.

8. Primary Graft Dysfunction project

UNOS staff provided an update of the Primary Graft Dysfunction (PGD) project and asked the Committee to comment on the request for input document as well as list of proposed data elements.

Summary of discussion:

UNOS staff provided a summary of the background, proposed solution, and timeline of the PGD project. To better evaluate the prevalence of PGD, the Committee is proposing data elements be added to the Transplant Recipient Registration (TRR) form. This project will be implemented in two phases, the first being a request for input during public comment. The POC will review the first phase of this project on November 5th.

The Chair commented that the process of asking feedback from public comment allows the community to provide input as though it is another member of the Committee.

UNOS staff shared the OPTN data collection principles and reminded the Committee that this project needs to be in alignment. DAC has a checklist that the Subcommittee will go through to consider the relevancy and reliability of the data as well as if the definitions of the data elements are universally understood. Other considerations include how easy it is for the information to be gather operationally.

The Committee may also want to remove data elements from the Transplant Recipient Registration (TRR) that are no longer useful.

The Committee reviewed the data elements being considered by the subcommittee. The Chair commented that this list is based on needing discrete elements that can be put on a form. These data elements should have the most value in evaluating PGD. The intention is to maintain a balance between ensuring the data elements are useful while limiting the burden required for entry.

A member suggested collecting pulmonary artery systolic and diastolic pressure in order to be able to derive transpulmonary gradients. If body surface area (BSA) is collected, cardiac output can be derived. A member commented that height and weight are collected which can be used to calculate BSA.

A member commented that the timing of these measurements is important. They noted that a lot of people think they can identify PGD within 24 hours but recommended that data should be collected three days after transplant or before the institution of mechanical support. The Chair noted that the feedback public comment document includes questions about when to collect the data.

The Chair recommended adding pulmonary artery pressure (systolic over diastolic) as an element.

The Chair asked the members to read through the public comment document and submit feedback. The Subcommittee will finalize the document at the next meeting.

A member commented that it would be helpful to review what is collected on the Decease Donor Registration (DDR). UNOS staff shared a link to the forms for the Committee to review.

A member commented that it is important to note that ISHLT documents suggest that PGD can be identified in 24 hours. They want to look at data 48-72 hours after transplant as some patients have graft issues that resolve. They also suggested collecting data elements on the two or three risk factors of warm ischemia time as well as data elements related to the use of organ care systems such as the volume of preservation fluid used at procurement. The Chair asked for a question relating to the collection of data associated with these risk factors to be included in the request for feedback document to see how the community responds. Members agreed to include this statement. The Chair offered to draft the content.

A member asked how difficult it is to change the data elements once they are decided. The Chair commented that it takes two years be able to make a valid assessment of what changes need to be made.

A member offered to add more content to the background section.

Next steps:

Members will review the request for feedback document and provide comment.

9. Open Discussion

Summary of discussion:

The members discussed *Evolving Trends in Adult Heart Transplant With the 2018 Heart Allocation Policy Change* by Kilic, et. al., a recent publication relating to the 2018 heart allocation policy change. A member provided comment to a reporter as an individual. The Chair reminded the Committee members that they are welcome to speak on their own behalf but not on behalf of UNOS or the Heart Committee. These types of requests should be channeled through UNOS' Communication department.

A member commented that when developing policy, the Committee is working toward improving the waiting list survival numbers and transplant outcomes are up to the program. Another member commented that this raises a cultural question about whether the priority is increasing volume or improving longevity. The Chair commented that the community wants both longevity and a decreased waiting list. Continuous distribution allocation will include post-transplant outcome factors.

Members commented that data can impact the acceptance behaviors of transplant programs and having complete data is important. Early trends are important to signal any potential changes but have to be recognized as what they are before modifying behaviors. Complete data is needed before making big decisions.

A member suggested creating a communication that the members could send out to other members in their region that provide updates on the Committee's work. The Chair mentioned that there were conversations about brief monthly communications that would include case demonstrations for exception requests. The Chair commented that the OPTN updates have too much information. UNOS staff asked if the member would want to include a response to the article discussed. The member said that this could be a component but mostly, it would be helpful to let the community know that they can reach out to their representative and also provide them with a summary of Committee activities.

A member suggested writing a letter to the editor of the article. The Chair commented that the Committee has written a response before which was approved by the OPTN and that leadership will discuss the next steps.

Upcoming Meeting

- November 17, 2020

Attendance

- **Committee Members**
  - Adam Schneider
  - Arun Krishnamoorthy
  - Cindy Martin
  - David Baran
  - Donna Mancini
  - Greg Ewald
  - Hannah Copeland
  - JD Menteer
  - Jonah Odim
  - Jose Garcia
  - Kelly Newlin
  - Michael Kwan
  - Mike McMullan
  - Rachel White
  - Rocky Daly
  - Ryan Davies
  - Shelley Hall
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Katie Audette
  - Melissa Skeans
  - Yoon Son Ahn
- **UNOS Staff**
  - Craig Connors
  - Eric Messick
  - Janis Rosenberg
  - Julia Chipko
  - Keighly Bradbrook
  - Leah Slife
  - Nicole Benjamin
  - Rebecca Goff
  - Sara Rose Wells
  - Sarah Konigsburg
  - Shannon Edwards
  - Susan Tlusty