OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Thoracic Committee
Meeting Minutes
April 17, 2019
Chicago, Illinois

Ryan Davies, MD, Chair
Erika Lease, MD, Vice Chair

Introduction

The Thoracic Committee met in Chicago, Illinois on 04/17/2019 to discuss the following agenda items:

1. Modifications to the Adult Heart Allocation System
2. Eliminate the Use of DSAs in Thoracic Distribution
3. Lung Subcommittee: Continuous Distribution of Lungs
4. Heart Subcommittee: Substantive Clarifications to Adult Heart Allocation Policy

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

1. Modifications to the Adult Heart Allocation System

The OPTN implemented changes to the adult heart allocation policy on October 18, 2018. A recent monitoring report (approximately 4 months of data) was presented to the Committee for discussion.

Data summary

Early monitoring suggests that revisions to the heart allocation system have resulted in broader distribution, with a decline in local shares and increases in regional and national shares. Hearts are traveling greater distances to be transplanted. There has been no substantial impact on the number of waiting list registrations, transplants performed, or heart utilization. While some transplant centers have seen a decrease in transplant volume, it appears that differences in waiting list composition may explain this, rather than the change in allocation policy.

The change in heart allocation policy also included changes to the regional review board (RRB) process. Since these changes went into effect, the number of justification forms submitted to the RRB has varied between 200 and 300 per month. The majority of these were requests for Adult Status 3 and were exception request forms rather than standard review forms. The majority of requests were approved regardless of the region reviewing the request.

Summary of discussion:

UNOS staff clarified that the time frame used for center volume was only 4 months of data, which may account for some of the data depicted for smaller volume centers. There was concern from some Committee members that these smaller volume centers may not be performing as many transplants in the post-era, however due to the short length of time and variability of when transplants occur, the results may change by the next monitoring report.

Other concerns raised were regarding cost and increasing travel distance. For example, one Committee member questioned how Organ Procurement Organizations (OPOs) track costs when allocating organs. UNOS staff responded that they understood the Committee's concerns regarding increasing costs, and that a proposal to add these new data collection elements will be released in Fall 2019. To follow-up with this, Committee members asked if it was the responsibility of an organ lied with OPOs. UNOS staff clarified that this is true for the most part, however if a transplant hospital sends their own recovery team, then the organ custody belongs

with that transplant hospital, not the OPO. Further responsibilities of the OPO are to complete a Deceased Donor Registration form (DDR) for each organ. Committee members asked whether they have access to this form, and UNOS staff responded that all OPTN data collection forms can be accessed through the UNOS website.

In looking at how many transplants occur by region, one Committee member opined that Region 2 and Region 3 do not have the sickest patients due to their lower transplant volumes. However, others commented that the number of transplant occurring may be influenced by which regions are located next to each other (such as Region 9 and Region 2 share geographic borders).

Another Committee member opined that the heart utilization rates are less variable than the lung utilization rates. For example, some OPTN Regions had lung utilization rates that were lower than 20%. However, UNOS staff replied that in the report, DCD organs were removed from the analysis of utilization rate, which may account for the increase in utilization rates. Other Committee members were skeptical about the usefulness of utilization rates, because of the varying levels of “aggressiveness” certain OPOs have (e.g. some OPOs may not travel to recover only one donor organ). It was also noted that the utilization rate may be more useful for lungs, than for hearts.

Another area that Committee members asked about was regarding the distance traveled by region. Committee members suggested that this data be calculated, because there may be a few centers that have to cover large geographic areas. Further discussion about distance focused on the differences between ischemic times (such as some pediatric or adult heart programs traveling up to 1000NM to recover a heart). Committee members thought that there were other variables that could be contributing to longer distances, such as the number of surgeons at a center or clamp time. In effect, these multiple variables could make distance less correlated with ischemic time.

Another challenge brought up by Committee members was travel mode, specifically flying versus traveling by vehicle. Committee members commented that with an increase in flying comes an increase in risk that personnel may be on a plane that crashes. Due to this concern, Committee members asked if the OPTN was collecting data on travel mode. An example brought up was whether there are centers that are not willing to fly to recover an organ past a certain mileage point. Other Committee members supported analyzing transplant hospital behavior via organ offers and refusals. Furthermore, Committee members discussed how there is currently no system in place that allows them to screen off older adult donors at a certain mileage distance. Some Committee members theorized that this inability to screen candidates off may be contributing to OPO inefficiencies, such as the increasing time to transplant. Other Committee member however urged caution in getting too granular with the data. Another suggestion was for transplant hospitals to reach out to their respective OPOs when discussing donor organ evaluation, such as the need for echo cardiograms or chest x-rays. Most Committee members agreed that these conversations need to occur, however acknowledged that transplant hospitals should not be asking for multiple tests if they have no intention of procuring the organ because this may delay cross-clamp.

When asked directly about their OPO involvement, very few of the Committee members were involved on a higher level with their OPOs (such as listening in on council meetings). UNOS clarified that there are some OPOs that are now attending OPTN regional meetings that are not their own due to broader distribution. One Committee member also suggested that transplant hospitals should do their own outreach with OPOs. However, other Committee members took the stance that though these conversations should happen, time constraints do not allow transplant hospitals to have these conversations at the individual level with each OPO. Furthermore, Committee members supported standardizing practices amongst OPOs and

transplant hospitals, because this may decrease the level of variability in organ allocation practices.

Moving into the next discussion, committee members commented that they are experiencing higher volumes of exception cases, though they believe that most of these exceptions are being approved. UNOS staff responded that though one goal of the policy change was the decrease the number of exceptions, the sudden change in policy may account for a peak in exceptions early on, with stabilization occurring later. Furthermore, UNOS staff stated that in January 2019, many Status 4 forms were set to expire, which may account for the increase in the number of exceptions during that month. However, Committee members were still concerned that there may be a "gap" in policy, and that the number of exceptions being submitted needs to be evaluated further.

Another Committee member asked if it was possible for the OPTN to monitor the number of times organs are "crossing in the sky". UNOS staff replied that this may be difficult to track because there are too many donor qualities that must be adjusted for in order to have a meaningful analysis (e.g. donor weight, donor age etc.). Committee members agreed that looking further into when organs switch from driving to flying is important, especially when discussing continuous distribution.

Next steps:

At the end of the discussion, UNOS staff outlined the plan to unveil the next monitoring report at the next OPTN Thoracic in-person meeting (9 month report). Due to this later monitoring report, there may not be a 1 year monitoring report.

2. Eliminate the Use of DSAs in Thoracic Distribution

UNOS staff presented the public comment analysis for the current thoracic proposal. The goal of this discussion was to review the feedback received during public comment, and finalize decisions surrounding nautical miles, sensitized candidates and whether to send the proposal to the Board of Directors (BOD).

Summary of discussion:

UNOS staff discussed the overall sentiments and public comments received for this proposal. Concerns raised by the public regarding this proposal include the following: increased costs, increased travel / increased air travel, poorer outcomes, pediatric patients an eliminating sensitized patient policy leaves no other options

Due to these concerns, the Committee first focused on whether to replace DSA with 250NM or to instead replace DSA with a smaller circle of 150NM. The Committee was presented with the advantages and disadvantages of each nautical mile circle, as outlined below in Option 1 and Option 2:

Option 1: *Replace DSA with 250NM*

- Advantages
    - Does not increase waiting list mortality
    - Balances broader distribution against reduced utilization
    - Distance is similar to or larger than some DSAs and would promote broader distribution
    - Would synchronize with the smallest allocation distance in lung allocation distance
- Disadvantages
    - Would result in undesirable cold ischemic times

    - Higher costs resulting from increased air travel
    - Does not result in improved waiting list mortality or post-transplant outcomes

Option 2: *Replace DSA with 150NM*

- Advantages
    - Balances broader distribution against reduced utilization
    - Places more emphasis on reducing ischemic time, cost, travel, and efficiency
    - Most transplant programs will start flying to recover organs at 150 NM
- Disadvantages
    - May not result in lungs being distributed as broadly as possible under the Final Rule and may not be legally defensible
    - 150 NM radius is smaller than several DSAs

During the discussion, a Committee member opined that Region 11's concerns against broader sharing were that the increasing geographical boundaries did not accurately account for disease burden and death (especially in relation to liver disease). Furthermore, this Committee member went on to state that Region 11 representatives were advocating for their patients, and not necessarily against broader sharing in general. However, another Committee member stated that if the decisions made at Region 11 are based on the data analysis performed by the OPTN Liver Committee, then the voting results may not be pertinent to the thoracic proposal. Another Committee member stated that Region 8 also voted negatively on the proposal because of higher costs and transportation mode changing in response to broader sharing. However, Committee members generally agreed that going back to a DSA based system was not feasible at this time, and that an adequate solution must be enacted.

In continuing the discussion, some Committee members voiced concerns that the adoption of 250NM was either too small or too large. For example, there was a center from Region 3 that supported 250NM because it expanded their DSA by twice its size. However, there was a center in Region 6 that did not support the adoption of 250NM because it decreased the size of their DSA. In response to these examples, a few Committee members voiced support for adopting an allocation system that did not focus solely on geographic boundaries, but rather on population density. However, it was also acknowledged that this allocation system would take time to develop and implement. UNOS staff affirmed that a new allocation system would need to be developed, but that lung policy is currently pursuing a continuous distribution system. Committee members went on to voice concerns that COPD candidates may become disadvantaged under the new continuous distribution system, and that it may affect each Region differently depending on disease demographics. However, other Committee members pointed out that this concern may be more aligned with limitations of the LAS system, not necessarily geography.

In refocusing the discussion, the Committee considered either adopting 250NM or 150NM based on the public comment feedback. A few Committee members commented that they should vote only on whether to approve the adoption of 250NM, and not discuss150NM as an option. UNOS staff clarified that based on concerns brought up in public comment, the Committee can reconsider adopting 150NM if there was strong enough rationale, evidence and justification aligned with the OPTN Final Rule. Despite having heard the public comment feedback, the Committee stated that ischemic time is not necessarily correlated with nautical mile distances. Furthermore, though there was other public comment feedback regarding cost, the Committee decided to move forward with voting on the current policy language. The first voting question and count is listed below:

1. Does the Committee recommend that DSA be replaced with 250NM?
    a. Opposed: 0
    b. Approve: Unanimous
    c. Abstain: 0

Next, the Committee considered and discussed eliminating OPTN policy for sensitized candidates. UNOS staff clarified that there were minimal public comments related to sensitized candidates, though ISHLT did request further discussion prior to this policy being completely eliminated. One Committee member stated that eliminating this heart policy would eliminate any policy regarding sensitization. However, other Committee members opined that the policy language for sensitized heart candidates serves no purpose and is not evidence-based. A suggestion was for the Committee to agree to eliminate this particular policy, and then develop a plan to address sensitized heart candidates at another time when data is available. UNOS staff went on to clarify that an OPTN Board member had previously stated concerns about eliminating sensitized heart policy, and that this may be a topic of discussion at the BOD meeting in June. Despite these concerns, the Committee agreed to vote on eliminating the heart policy for sensitized candidates. The second vote and count is listed below:

2. Does the Committee support eliminating the policy for sensitized heart candidates?
    a. Opposed: 0
    b. Approve: Unanimous
    c. Abstain: 0

The last item the Committee voted on was whether to send the policy proposal to the BOD for consideration in June. There was no discussion from Committee members prior to the vote. The voting results are listed below:

3. Does the Thoracic Committee recommend the proposal "*Eliminate the Use of DSAs in Thoracic Distribution*" go to the OPTN Board of Directors in June for consideration?
    a. Opposed: 0
    b. Approve: Unanimous
    c. Abstain: 0

3. Lung Subcommittee: Continuous Distribution of Lungs

SRTR presented an overview of continuous distribution concepts specific to lung allocation. UNOS staff then led the Committee through an analysis discussion of the various factors of lung allocation.

Summary of discussion:

SRTR staff reiterated that the purpose of this project is not to completely overhaul the LAS scoring system, but rather to look at the various factors involved in allocating lungs. Later, these factors will be weighed against one another in order to determine an overall score for a candidate. A Committee member stressed the importance of requesting the right data from UNOS Research in order to better understand each factor and how best to weigh them.

Next, UNOS staff led the Committee through an interactive discussion for each factor (e.g. age, geography, ABO, etc.), with a specific focus on why the factor is used, its level of appropriateness, and what changes (if any) are needed.

The discussion began with analyzing ABO as a factor in lung allocation. Currently, blood type compatibility is used to categorize candidates, with identical blood types prioritized before compatible blood types. One Committee member commented that they need to further understand the impact this particular factor has on disadvantaged populations before making any decisions. However, another Committee member opined that the purpose of this discussion

is to determine whether there needs to be any changes to the ABO factor based on the current data, or if more data needs to be requested. SRTR staff also clarified that each blood type could be weighted differently. For example, blood type O to blood type O may always be 100% priority, but blood type O to blood type AB might be 30% priority. In this way, the Committee can create a formula which does not have absolute cliffs between each of the blood types. One Committee member opined that in their opinion, blood type O is always the most disadvantaged group in lung allocation. Due to this perceived disadvantage, one suggestion by this member was to eliminate identical versus compatible, and add boost points to blood type O candidates. However, this member also cautioned that the Committee must decide all together whether blood type O is always the disadvantaged blood group, or whether there is another blood type group being disadvantaged.

Probing further, Committee members asked whether the SRTR staff had any data modeling for identical versus compatible blood groups. SRTR staff responded that the only report they have available is the annual data report (ADR), which shows some ABO data analysis such pre-transplant mortality rate by blood type. Though UNOS staff supported using the ADR as a data resource, a few members cautioned against making generalizations from the report because the ADR only depicts how the current allocation system functions.

One Committee member theorized that some transplant centers may have previously performed more ABO compatible transplants under the old allocation system. Under the current system, this member voiced concern that transplant centers are performing more identical blood type transplants due to broader sharing. This member went on to suggest that UNOS staff analyze data from each OPTN region to determine how many ABO compatible transplants are being performed. By comparing OPTN regions like this, the Committee can then determine how DSA and non-DSA allocation affects different blood types. However, other Committee members stated that if there was only one center in a DSA, then the results obtained from such a data analysis may be difficult to interpret.

In refocusing the conversation, Committee members questioned what the rationale was behind establishing identical versus compatible allocation systems. One Committee member stated that having an allocation system like this is “common sense” from a clinical perspective, but not because there are better outcomes from identical blood type transplants. Initially, the justification for this policy was that blood type O candidates would not be able to have the same access to organs. For example, the Committee member stated that blood type O candidates have the lowest transplant rate. So, essentially the newer lung allocation policy was meant to align blood type O donors with blood type O recipients. Other Committee members voiced support for this reasoning, stating that blood type O candidates will become the most disadvantaged blood type if the Committee disposes of identical blood type transplantation.

In continuing this discussion, Committee members generally agreed that blood type O candidates are still the most disadvantaged blood type under the current allocation system. In ADR data, Committee members pointed out that blood type O have the lowest transplant rate and a higher Waitlist mortality than other blood types. An example given by one Committee member was that under the old DSA allocation system, some centers found it difficult to transplant blood type O recipients with a blood type O donor organ if there was a different blood type candidate with a higher LAS score on the Waitlist.

In conclusion, the Committee members generally agreed to the following:

- Identical blood types should be prioritized over compatible blood types based on issues of access for blood type O candidates (boost points may be given in order to address any outcome issues under a continuous distribution system).

- To prioritize compatible versus incompatible blood type transplants, based on clinical outcomes.
- Continue to allow the prioritization of intended incompatible transplants for pediatric candidates less than 2 years of age, because these candidates can receive any blood type (relates to both improved access).
- The Committee also agreed that sicker candidates should be factored into the continuous distribution system, so that at some point during allocation, those candidates with a high LAS score can receive a compatible blood type.

UNOS staff asked if other blood types should be prioritized above others (such as blood type A prioritized over blood type AB). Committee members requested more data analysis in order to determine if other blood types are being disadvantaged, such as the distribution of blood type organs amongst candidates and recipients. Others suggestions for data analysis included looking at transplant rate by candidate blood type, and the distribution of blood type compared to waiting time. UNOS staff continued to collect and compile further suggestions for data collection and analysis.

Lastly, Committee members briefly discussed sensitized candidates and how they would be incorporated into a continuous distribution system. SRTR staff clarified that approximately 80% of the candidates on the Waitlist do not have any reported unacceptable antigens. However, due to time constraints, Committee members agreed to further discuss sensitized candidates, along with the other factors (e.g. age, geography, etc.) at a later date.

Next steps:

UNOS staff will consider what data might be informative to the discussion on ABO, and continue facilitating discussion regarding other factors in lung allocation at future meetings.

4. Heart Subcommittee: Substantive Clarifications to Adult Heart Allocation Policy

In their breakout, the Heart Subcommittee discussed the 4-month monitoring report data and potential project ideas. The Subcommittee noted that the number of exceptions was high (though a comparison of pre-era exceptions was not in the report), particularly for status 3 and 4. In addition, the data indicated that review boards are approving a majority of exception requests. One of the goals of the policy changes were to reduce the number of exceptions by accommodating many of the most common clinical scenarios (most device complications) into standard policy. Members acknowledged it was still too early to make conclusions, and that they would continue to monitor this data closely.

However, the Subcommittee discussed reviewing exceptions to identify whether the high number of exceptions was due to programs not understanding new policy, whether there were new clinical scenarios that might need to be included in standard policy, or whether programs were taking advantage of the exception pathway to gain access to higher statues. Another reason there may be a high number of exceptions is that policy may be too stringent or prescriptive. Programs may be applying for exceptions if their candidate almost-but doesn't quite-meet the policy requirements.

UNOS staff advised that it was still early, and the new policy has only been in effect for 5 months. It may be premature to begin a project to review exception requests, and the Subcommittee may want to continue monitoring exceptions for at least a year to see if the high exception volume persists. Regardless, to prevent the scope of the "*Substantive Clarifications to Adult Heart Policy"* from getting too massive, UNOS staff advised the exception issue should be a separate effort. The group felt strongly that they would like to analyze the problem further, and

to that end, part of the meeting was spent completing a project form to eventually send to the Policy Oversight Committee.

The group revisited potential issues that could be included in the "*Substantive Clarifications to Adult Heart Policy".* Members agreed that correcting *Policy 6.1.D.ii Inotropes without Hemodynamic Monitoring* to better align with original intent*:* that hemodynamics, cardiac index specifically, is within the specified range in policy within 7 days prior to administration of inotropes, not 7 days prior to the submission of the form. Members pointed out that it was a patient safety issue to have to re-catheterize these patients, who are stable and at home, every 90 days. UNOS staff advised that because language that was similar already went out for public comment, the change may qualify as a clarification versus a change that has to go back out for public comment. UNOS staff will review this possibility with UNOS leadership.

The group then discussed some of the most frequently asked questions that may benefit from clarification under this project. UNOS staff advised that one of the most frequently asked questions the OPTN member question hotline receives is about extension requirements for criteria that do not currently have specific requirements. UNOS received so many questions regarding this ambiguity that the general issue was referred for an internal policy interpretation. In that meeting (summer 2017), it was determined that unless requirements to extend at a status were explicitly listed in policy, it was unclear whether a patient had to meet all-or any-of the initial qualifying criteria. Some members disagreed that this lack of specificity in policy was an issue; if there were no specific requirements listed, then the patient would have to meet all of the initial qualifying criteria to extend. Others disagreed. UNOS staff recommended including a thorough review of all extension language in policy to clarify what criteria candidates would have to continue to meet in order to extend.

UNOS staff briefly shared that there were other, more substantive issues with policy language that staff would vet and share with the Subcommittee at a future meeting. Likewise, UNOS staff will continue to monitor questions received regarding the new policy, to determine whether there are other potential issues that could be included. UNOS staff concluded the discussion by advising that the scope of this project was not meant to be a comprehensive policy re-write. Finally, UNOS staff affirmed that the perceived exception issue would be a separate project, as would accommodating new technology in the new system.

Next steps:

- UNOS staff will discuss whether *Policy 6.1.D.ii Inotropes without Hemodynamic Monitoring* can be referred to the Executive Committee as a clarification, or whether it should be included in this project with UNOS leadership