

**OPTN/UNOS Thoracic Organ Transplantation Committee
Meeting Minutes
April 19, 2018
Chicago, IL**

**Kevin Chan, MD, Chair
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Introduction

The Thoracic Organ Transplantation Committee met via Citrix GoToTraining teleconference and in-person in Chicago, IL on 04/19/2018 to discuss the following agenda items:

1. Ad Hoc Committee on Geography Update
2. Modifications to the Distribution of Deceased Donor Lungs
3. Modification of the Lung Transplant Recipient Follow-up Form (TRF) to Better Characterize Longitudinal Change in Lung Function following Transplantation
4. Hypertrophic Cardiomyopathy/Restrictive Cardiomyopathy Exception Request Guidance for Review Boards
5. Modification of the Adult Heart Allocation System
6. Modifications to Pediatric Heart Allocation

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

1. Ad Hoc Committee on Geography Update

UNOS staff provided an update on the Ad Hoc Geography's Committee's work and recommendations that will be shared with the OPTN/UNOS Board of Directors in June.

Summary of Discussion

The Ad Hoc Geography Committee was formed at the December 2017 Board of Directors meeting, charged with taking a comprehensive look of organ distribution across all organ systems. The Geography Committee will recommend organ distribution principles and models that have been deemed as aligning with the Final Rule that can subsequently be used when analyzing and reviewing policies.

In June, the Geography Committee will submit the committee's recommendations to the Board. This report will include:

- Principles of Organ Distribution
- Thematic Models that Align with Principles
- Suggestions for Next Steps

2. Modifications to the Distribution of Deceased Donor Lungs

The Committee discussed public comment feedback, Subcommittee recommendations, and potential post-public comment changes.

Data Summary

The Committee received a post-implementation, 4-month report on the removal of DSA as a unit of allocation. Key findings included:

- Increase mean match LAS at transplant
- Increase distance between transplant center and donor hospital, time from first electronic offer to cross clamp, and ischemic time

- Majority of centers have not seen a decrease in the number of lung transplants
- Impact on discard rate and utilization rate vary by OPTN region

The report will be posted to the OPTN website. The next monitoring report will be mid-summer.

Summary of discussion:

The proposal garnered 34 comments. Overall, there was general support for the concept of broader distribution for lungs. Further, there was support for the Committee to be granted the opportunity to vet alternative solutions through the normal policy development process, thus necessitating an extension of the sunset date. The Committee's response and any subsequent changes made post-public comment are elaborated upon within each theme.

1. Feedback regarding whether 250 nautical miles from the donor hospital is the appropriate first zone of distribution for lungs procured from donors at least 18 years old

Feedback regarding whether or not 250 nautical mile was the ideal first unit of distribution varied. There was some consensus for the 250 nautical mile solution, but there was also a fair amount of opposition. Those who supported the interim policy change, including the International Society of Heart and Lung Transplantation (ISHLT), were comfortable because the effect of distributing to 250 nautical miles was similar to distributing to the DSA, and post-implementation data indicated no immediate adverse impact to patients. In addition, supporters felt this change better aligned with the Final Rule than DSA. Those who opposed distributing to 250 nautical miles encouraged the Committee to take the time to consider and analyze other options; the implemented change may not be the optimal solution. This faction was more likely to support distributing lungs even more broadly. Indeed, even among the regions that supported the change, there was support for the Committee to have the time to vet other options.

Patient advocacy groups and the OPTN/UNOS Patient Affairs Committee supported distributing lungs to 500 nautical miles. However, several commenters noted that the implemented change, and any other model of broader distribution, may have unintended consequences (see concerns, cited below). There were several suggestions for alternative solutions, including 125 nautical miles + DSA, and population density models. The Committee noted the modeling indicated a decrease in waitlist mortality with 500 nautical mile sharing, however without the opportunity to evaluate the consequences of other models, the Committee was hesitant to change the first unit of distribution from 250 nautical miles to 500 nautical miles.

In light of the public comment feedback, the Committee considered maintaining the 250 nautical mile solution, increasing the first unit of distribution to 500 nautical mile, or distributing based on some other model, either permanently or as a placeholder while the Committee explored other options (thus extending the sunset date). They reaffirmed that the 250 nautical mile interim policy should not be made permanent as there has not been sufficient time to vet an optimal geographic solution via analyses. In addition, the Committee has not yet had the opportunity to evaluate unintended consequences of the current change, let alone other models. Further, the Committee did not feel it prudent to finalize its policy proposal prior to the complimentary work being completed by the Ad Hoc Committee on Geography. Indeed, it is likely their recommendations would inform future lung distribution policy. Therefore, they opted not to propose increasing the first unit of distribution to 500 nautical miles or some other model at this time.

The community also expressed other concerns associated with broader distribution of lungs:

- Potential for increased travel to recover organs
- Potential for increased costs associated with increased travel and increased use of ex vivo lung perfusion

- Unknown long-term impact on post-transplant outcomes
- Unknown impact to low volume/small centers
- Unknown impact to specific diagnoses groups

The Committee acknowledged these concerns and will ensure they are considered, should the Committee be given the opportunity to continue work. Ultimately, the Committee voted unanimously to propose maintaining distribution to 250 nautical miles as interim policy and request a two-year extension to allow the Committee ample time to consider alternatives (16-approve, 0-oppose, 0-abstentions).

2. Feedback regarding heart-lung policy

A majority of public comment feedback indicated support for the policy as written. Other feedback included:

- Concern that the policy does not help heart-lung candidates whose need for lungs is more urgent than their need for a heart
- Policy should be revised under a larger multi-organ project
- Heart-lung allocation shouldn't be a manual process by the OPO; a "smart" system should be programmed
- The proposed policy is still too complex

The Committee considered the following options based on public comment feedback:

- No change
- Extend priority to heart-lung candidates/create an exception pathway for heart-lung candidates
- Address via a larger multi-organ project

They acknowledged that ideally, heart-lung policy would be considered under a multi-organ policy project, which might include the "smart" programming suggested by the OPTN/UNOS Operations and Safety Committee. However, making those changes now would be substantive and out of scope at this time.

However, in light of the emergency lung policy changes, and in recognition of the work that was already completed by the Committee under the adult heart allocation policy changes, the group felt it was necessary to move forward with modifications to the policy. The group did feel the changes made to heart-lung policy from the approved-but-not-yet-implemented adult heart allocation policy were more clear and informed by data. However, the Committee acknowledged it is still a manual process for OPOs and the variability in how OPOs run matches remains.

Therefore, the Committee felt without the opportunity to look at heart-lung as part of a more holistic multi-organ project or make substantive changes in the form of an exception pathway, they were comfortable with the policy language as it went out for public comment as an interim solution.

The Committee voted unanimously (16-approve, 0-oppose, 0-abstentions) to recommend the policy as written with minor language clarifications.

3. Feedback regarding sensitized candidate policy

Finally, the Committee transitioned to the sensitized candidate policy. During development of the proposal, the Subcommittee considered three options:

- Remove the policy altogether
- Permit transplant programs to request an exception from the LRB to prioritize the sensitized candidate

- Modify current policy to permit all transplant programs and OPOs in any geographic area in which the candidate would appear in Zone A to agree to permit the OPO to allocate lungs to the candidate out of sequence

There was limited substantive feedback regarding this portion of the proposal. All regions supported striking the policy. Conversely, The OPTN/UNOS Transplant Administrators Committee, ISHLT, the National Association for Transplant Coordinators (NATCO), an individual transplant coordinator and a candidate family supported the LRB pathway. The OPTN/UNOS Transplant Coordinators Committee supported the current policy with Zone A swapped in for DSA. The OPTN/UNOS Pediatric Transplantation Committee was split between striking the policy and providing access through an LRB pathway. Finally, the OPTN/UNOS Patient Affairs Committee supported providing some option to prioritize these candidates, versus no option.

The Committee considered the feedback. It recognized that sensitized candidates have potential to be disadvantaged because they are less likely to be able to accept offers from donors, and that ideally, the policy could be modified more extensively, based on evidence. However, conceding that a lack of data is a barrier to developing a more robust policy, the Committee debated which of the options initially considered would be most prudent in the short-term.

The group considered the proposed solution that went out for public comment: striking the policy altogether. Public comment was not largely opposed to this option and it is straightforward. There is no information to help define sensitized candidates and there is little evidence that the existing pathway was ever used. This solution might be unlikely to impact many patients. In addition, sensitization does not equate to urgency, so it perpetuates the LAS as the sole driver of prioritization. Striking the policy does not attempt to address a complicated issue without clear solutions. Finally, broader distribution should benefit sensitized candidates to some extent; what they need is access to a greater number of offers, not necessarily higher priority on the match. However, the Committee noted that removing the policy carries some risk because there would be no mechanism for prioritization for sensitized candidates. In addition, it eliminates a pathway that previously existed for a group of candidates that are more challenging to match.

There was strong consensus amongst the Committee that the LRB pathway was not optimal. Although logistically it may be most practical solution, there is not consensus within the lung transplant community around the definition of a sensitized patient. Lung transplant programs have different thresholds of what they are willing to accept as a positive crossmatch, and how many mismatches they are willing to accept. Members also noted that there was variable confidence in virtual HLA crossmatches. In addition, the Committee recognized the need to develop guidelines to help assist the LRB in evaluating sensitized candidate exception requests. This in itself would present the same challenges as developing policy. Further, since guidelines would have to be developed post-implementation of the policy change, as they are required to go out for public comment, the Committee did not favor this option.

Finally, the Committee considered the final option: maintaining policy that would permit allocating lungs out of sequence if the sensitized candidate's transplant program was able to secure agreements with other lung transplant programs whose candidates might appear ahead of the highly sensitized candidate. They debated four options that met this intent:

Option	Timing of agreement	Advantages	Disadvantages
<p>Option 1: Permit transplant programs to get agreements from any program above their candidate on the list to agree to be bypassed, no geographic limitation</p>	<p>At time of match</p>	<ul style="list-style-type: none"> • Provides a pathway for sensitized candidates • Does not prescribe how far down the match run the sensitized candidate appears 	<ul style="list-style-type: none"> • Not practical unless there are only a few candidates ahead of the sensitized candidate on the match run • Difficult to achieve unless the transplant program knows the OPO and the other transplant programs ahead of it pretty well
<p>Option 2: Allow OPO to allocate to sensitized candidate within Zone A if transplant program has gotten agreements from all other transplant programs in Zone A</p>	<p>At time of match</p>	<ul style="list-style-type: none"> • Provides a pathway for sensitized candidates • Most similar to current policy, except replaces DSA with Zone A • Limits the benefit only to candidates in Zone A 	<ul style="list-style-type: none"> • Constantly shifting geography • Difficult to achieve in a timely manner because this would have to happen after the match is generated
<p>Option 3: Allow OPO to allocate to sensitized candidate within Zone A if transplant program has gotten agreements from all other transplant programs within 500 nautical mile of the candidate</p>	<p>Advanced agreement</p>	<ul style="list-style-type: none"> • Provides a pathway for sensitized candidates • Similar concept to current policy • Limits the benefit only to candidates in Zone A • Alleviates the time-sensitive nature of the match by allowing the program to get these agreements in advance 	<ul style="list-style-type: none"> • Difficult to achieve unless the transplant program knows the OPO and the other transplant programs within 500 nautical mile pretty well

Option	Timing of agreement	Advantages	Disadvantages
Option 4: Policy modeled after kidney medical urgency policy	At time of match	<ul style="list-style-type: none"> • Provides a pathway for sensitized candidates • Based on medical judgement • Not complicated by securing agreements based on set geography • Does not prescribe how far down the match run the sensitized candidate appears 	<ul style="list-style-type: none"> • Not practical unless there are only a few ahead of the candidate on the match run

In addition to the disadvantages outlined in the table above, sensitization does not equate to urgency, so allowing candidates with a lower LAS to receive a lung allograft before those who are listed at greater urgency may not be appropriate. In addition, it gives the OPO discretion, which they typically do not want. Finally, all of these options are difficult to monitor.

The Committee debated these concepts. They quickly eliminated options 2 and 3, as the logistic limitations made the solutions impractical. Options 1 and 4 are similar, but the Committee favored broader policy language rather than a very specific policy that prescribes when it is permissible to bypass other candidates on the match. Option 4 is also most similar to *Policy 8.2.A: Exceptions Due to Medical Urgency* for kidneys. The Committee appreciated the importance of modeling its proposed sensitization policy off of concepts and precedent in other OPTN policies. Rather than striking the policy altogether, the Committee ultimately voted on option 4 (8-approve, 3-oppose, 2-abstentions).

The Committee voted to send the proposal to the Board of Directors in June for consideration (16-approve, 0-opopose, 0-abstentions).

3. Modification of the Lung Transplant Recipient Follow-up Form (TRF) to Better Characterize Longitudinal Change in Lung Function following Transplantation

The Committee discussed public comment feedback, Subcommittee recommendations, and potential post-public comment changes.

Summary of discussion:

The response to the proposal was generally favorable, with various recommendations suggested. Overall, all eleven OPTN regions approved with no changes via the consent agenda. Professional societies offered more substantive feedback, but generally approved of the Committee’s recommendations. One pulmonologist commented on the proposal.

The proposal garnered a total of 6 comments. The Committee requested specific feedback from the community regarding whether to keep the bronchial stricture/stent question on the 6-month and 1-5 year.

TRFs. If commenters favored keeping the question, the Committee hoped for input on how the question could be better asked to elicit more meaningful data regarding this short-term complication. The Committee also sought feedback on whether the number of time intervals

proposed for FEV1, FVC, and FEF25-75 was reasonable. Consequently, this feedback, among other comments, is reflected in the following overarching themes, detailed below. The Committee's response and any subsequent changes made post-public comment are elaborated upon within each theme.

- Additional data elements/testing
- Bronchial stricture
- Administrative concerns

Additional data elements/testing methodologies

Two societies, AST and ISHLT, suggested additional data elements obtained by testing methodology beyond spirometry. AST recommended the Committee consider other ways to add phenotypic specificity to the evaluation of chronic rejection: the phenomenon of “azithromycin responsive” CLAD (or NRAD, neutrophilic reversible allograft dysfunction) has likewise been accepted in clinical practice for years without incorporation into the contemporary data collection paradigm. In addition, it advised considering future incorporation of plethysmography into this data collection: the lung transplant community has not definitively established that spirometry is sufficient, in all cases, to distinguish RAS. Being able to make the diagnosis of RAS without plethysmography at every visit represents an important advance in the field: nevertheless, it would be reasonable to anticipate that a center should want total lung capacity data at the time that an RAS diagnosis is being made. Similarly, ISHLT noted that definitions of RAS used in the literature have frequently required imaging and/or clinical data in addition to spirometric data, but acknowledged collecting this information may be difficult. Therefore, it expressed concern about the feasibility of collecting the necessary data to refine the OPTN database on chronic lung allograft dysfunction.

The Committee considered the feedback regarding additional methodologies. Members noted that during the development of the proposal, only one Committee member confirmed their program did annual plethysmography testing to obtain total lung capacity. There was agreement to exclude this suggestion because this test is not standard practice; in addition, one member noted that insurance coverage for this testing may not allow reimbursement. There was consensus that the addition of this test would more likely lead to missing data and maybe too substantive a change. Likewise, the Committee determined not to add additional variables to garner phenotypic specificity since these elements are not objective or standardized and require interpretation. Further, members noted that the goal of the proposal was not to define RAS or CLAD, but to longitudinally record post-transplant pulmonary physiologic change that will allow a more accurate evaluation of CLAD. Challenges in the recording and standardization of image interpretation prohibits the addition of this particular parameter. Therefore, the Committee was comfortable not including additional data elements.

Bronchial stricture

The Committee considered feedback regarding the bronchial stricture field. This complication typically arises within the first year post-transplant and is multi-factorial: surgical, infectious, and ischemia, among other factors.

Only two societies provided feedback, and they were antithetical. ASTS advised removing the question altogether. ISHLT recommended keeping it on the 6-month and 1-year TRF. The former shared concerns regarding the reliability of the data. In addition, no one could think of a better way to ask the question to elicit better information. Another member offered that ISHLT might have recommended keeping the question based on recently completed airway guidelines. Members asked if consulting the new ISHLT guideline could be informative to the discussion. One member commented the guidelines define “stricture”, provide a grading system, cover

incidence and highlight treatments, so there was uncertainty how relevant the guidelines would be. Members emphasized that bronchial stricture should be ruled out prior to diagnosing CLAD. Keeping it may only be informative if the Committee and community were interested in the prevalence of stenosis, especially if this data is not collected elsewhere. However, the Committee acknowledged this rationale does not completely align with the OPTN Principles of Data Collection. Post-public comment, the Lung Committee recommended keeping the question on the 6-month and 1-5 year TRF, but clarifying the question. Suggestions included asking whether the stenosis required dilation or stent placement, and has the recipient had a stricture since the last TRF.

The Committee discussed the Lung Subcommittee's recommendations. Practically, a program is unlikely to be able to determine, long-term, whether a recipient had a bronchial stricture due to it being a short-term complication. Even if the question was reworded, the Committee was skeptical whether the information would be accurate after a certain period of time, or ultimately useful. Therefore, the Committee decided to remove the question completely from all forms.

Administrative burden

Public comment indicated concern around administrative burden. Data entered by a non-clinician versus a clinical coordinator could be an issue. One commenter opined that data entry (i.e., presence/absence of CLAD, BOS, RAS) should be performed using a consistent protocol, especially given that there is some subjectivity to the diagnoses, and some programs' data entry personnel may not have sufficient training to delineate CLAD subtype. Likewise, there was a comment expressing concern regarding significant variability in the interpretation and collection of these data elements by clinical coordinators across different centers and within the same center. However, the Committee felt these were theoretical concerns as the Committee deliberately selected objective data points that do not require any interpretation and are easily accessible in the medical record. In addition, the lung transplant coordinator on the Committee confirmed that the burden should in fact be equal or even less than it is currently, as coordinators will not have to comb the medical record for a statement of BOS or make an interpretation whether the patient has BOS. Therefore, no changes were made.

Additional feedback

The Committee posed a question to the community about whether the number of time intervals proposed (3) was reasonable. AST submitted the only response to this question indicating it concurred with the suggestion. The Committee opted to keep three time intervals.

Finally, ISHLT pointed out that there is currently no widely accepted definition for Restrictive Allograft Syndrome (RAS). The Committee acknowledged these concerns but reaffirmed the intent was not to define a CLAD phenotype, but to collect the most objective, readily available, easily identifiable, reproducible variables.

Ultimately, the Committee voted to send the proposed data elements unchanged to the Board of Directors in June for consideration, with the exception of removing the bronchial stricture and companion stent question from all forms (14-approve, 0-oppose, 2-abstentions).

4. Hypertrophic Cardiomyopathy/Restrictive Cardiomyopathy Exception Request Guidance for Review Boards

The Committee discussed public comment feedback, Subcommittee recommendations, and potential post-public comment changes.

Summary of discussion:

The response to the proposal was generally favorable, with various recommendations suggested. Overall, all eleven OPTN regions approved with no changes via the consent

agenda. Professional societies offered more substantive feedback, but generally approved of the Committee's recommendations. The OPTN/UNOS Patient Affairs Committee was the only committee to review and comment on the guidance; they supported.

The proposal garnered a total of seven comments. The Committee's response and any subsequent changes made post-public comment are elaborated upon within each theme.

- Additional criteria/background
- Broader patient population
- Inotropes may not be tolerated
- Guidance is voluntary
- Review Board member expertise

Additional criteria/background

The Hypertrophic Cardiomyopathy Association (HCMA) proposed provided the following feedback regarding pulmonary hypertension in those with hypertrophic cardiomyopathy:

Patients with HCM and preserved systolic function who merit consideration for heart transplant, based on symptoms and prognosis may develop pulmonary hypertension (PVR>2.5 Woods units) and increased transpulmonary gradient (PAM-PCWP>15mmHg). Durable MCS is the standard therapy utilized for HFrEF under these circumstances to enable safe and effective transplantation. Durable MCS has not achieved broad use for the HCM population due to the unique anatomy and physiology of the disease process, and lack of data supporting utility. Continuous intravenous inotropic therapy with invasive hemodynamic monitoring to assess PVR and TPG is the first line of management to attempt to achieve transplantable physiology for HCM patients in this setting. There is broad consensus among high volume HCM transplant centers about this strategy.

In short, the HCMA suggested adding the following criteria;

- Status 2 criteria under hemodynamic instability indicators: persistent transpulmonary pressure gradient (TPG) >2.5 and/or PVR >2.5
- Status 3 criteria for continuous invasive hemodynamic monitoring: TPG >15 and/or PVR >2.5. This criteria if met would serve as 1 of the 2 required criteria.

The Committee felt this was a reasonable addition to the criteria, because they are markers of decompensation and indicate medical urgency, which influences whether the candidate is suitable for transplant. Both the workgroup and Committee discussed criteria around invasive hemodynamic monitoring extensively, although not these specific criteria.

ISHLT encouraged the Committee to include additional information in the background section of the guidance document to educate regional review board members, who may not appreciate the waitlist mortality associated with specific subtypes of RCMs. The Committee determined it would accommodate this request.

Broader patient population

The Committee considered AST's feedback that patients who develop severe restrictive cardiac physiology, mostly due to underlying small vessel transplant coronary artery disease, should be eligible for exceptions under this guidance. These patients with severe restrictive cardiac physiology were included in the most severe category of the ISHLT nomenclature of cardiac allograft vasculopathy, CAV-3. The reason for inclusion of this patient population was that

mortality is high for this population. The restrictive criteria listed in this ISHLT paper is similar to the criteria in this OPTN proposal for HCM/RCM patients:

Restrictive cardiac allograft physiology is defined as symptomatic heart failure with echocardiographic E to A velocity ratio >2 (>1.5 in children), shortened isovolumetric relaxation time (≤ 60 msec), shortened deceleration time (>150 msec), or restrictive hemodynamic values (Right Atrial Pressure >12 mmHg, Pulmonary Capillary Wedge Pressure >25 mmHg, Cardiac Index <2 l/min/m²).

While the Committee acknowledged this suggestion, members concurred that expanding the guidance to include this particular patient population may encourage transplant programs to attempt exceptions for any candidate with restrictive physiology. The Committee reaffirmed limiting the guidance to the populations detailed within the guidance, as that was the original intent. Members were concerned the criteria already included in the guidance could not be uniformly applied to this patient population. Although there might be similar reasons why the candidate groups included in the guidance and the patient population mentioned in AST's comment are not candidates for VADs, there may be different reasons why their access to transplant is limited. The Committee was hesitant to include the group without assessing the waitlist mortality risk for candidates with restrictive cardiac physiology. Further, the Committee felt this inclusion would be a substantive change and outside the scope of post-public comment changes. They noted that a center can always submit an exception for a candidate that does not meet the criteria in the guidance, as they are recommendations, not policy. This language is already stated in the guidance.

Inotropes may not be tolerated

Both the HCMA and ISHLT advised inotropic support may not be tolerable or appropriate for the patient populations indicated in the guidance. The Committee felt the guidance addressed this comment, as "maximally-tolerated inotropic dosages" might be zero, in some cases.

Guidance is voluntary & Review Board member expertise

Finally, some commenters expressed concern over the nature or interpretation of guidance generally, such as:

- Limitations of guidance (versus policy)
- Interpretation of guidance as de facto policy

The OPTN/UNOS Patient Affairs Committee (PAC) noted the limitations of guidance being voluntary and not enforceable. It questioned whether review boards would use it if utilization is voluntary. If the guidance is not adopted, the PAC asked how effectively this proposal addresses the heart transplant community's initial concerns. The Committee noted that OPTN-developed guidance tended to be readily adopted by the thoracic community; for example, the guidance developed for status 1A device complications helped standardize the award of exception requests for those conditions and ultimately was incorporated into the new adult heart allocation policy. In addition, apart from actually changing policy, the community asked for instruction on how these candidates might access higher urgency statuses.

In contrast, ISHLT voiced concern that review boards would interpret this guidance as de facto policy. The ISHLT noted that even though guidance documents do not carry the weight of policy, transplant physicians rely on them to guide listing decisions, and they influence the decisions of review board members. It requested inclusion of a caveat that the proposed criteria provide voluntary recommendations to review board members when evaluating exception requests and that they do not carry the weight of policy. Individualized decisions will still need to

be made based upon disease phenotype and other clinical markers of patient acuity not reflected in the guidance document. The Committee acknowledged these concerns and determined it would emphasize the point.

The Committee voted unanimously to approve the guidance as amended and recommended consideration by the Board in June 2018.

5. Modification of the Adult Heart Allocation System

The Committee received an implementation update and discussed additional policy language clarifications being sent to the OPTN/UNOS Board of Directors in June.

Summary of discussion:

Implementation Update

UNOS staff informed the Committee that the changes to the adult heart allocation system would be implemented in the fall of 2018, with Phase 1 being implemented at the end of September and Phase 2 being implemented at the end of October.

Additional Clarifications to the Adult Heart Allocation System Policy Language

The OPTN/UNOS Board of Directors approved changes to the adult heart allocation system on December 6, 2016. The Executive Committee approved several clarifications in July 2017. During ongoing implementation efforts of these policy changes, UNOS staff identified additional clarifications that are required to ensure the proper allocation of hearts from pediatric donors, in addition to several additional minor language clarifications. Specifically, these changes update the allocation tables to correct mislabeled and missing classifications in *Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old, Table 6-8: Allocation of Hearts from Donors Less Than 18 Years Old*. Further, Board-approved policy language will revert to originally proposed language for sub-criterion 1 in *Policy 6.1.C.v: Mechanical Circulatory Support (MCS) with Right Heart Failure* to align with Thoracic Committee intent.

Corrections to Policy 6.6.E, Table 6-8: Allocation of Hearts from Donors Less Than 18 Years Old

In the version of the table approved by the Board, Pediatric Status 2 candidates and Adult Status 6 candidates in the OPO's DSA appear twice. The second time these candidates appear, the geography column should be "Zone A" instead of "OPO's DSA."

Additionally, classifications for the following candidates for both primary and secondary blood type match with the donor are missing from the approved table:

- Pediatric status 2 candidates in Zone A
- Adult status 6 candidates in Zone A
- Adult status 4 candidates in Zone B
- Adult status 5 candidates in Zone B

The missing classifications should all be added into the table in the following order, after the classification for "Zone B Adult Status 3" and secondary blood type match with the donor:

- Adult status 4 primary blood type match with the donor in Zone B
- Adult status 4 secondary blood type match with the donor in Zone B
- Adult status 5 primary blood type match with the donor in Zone B
- Adult status 5 secondary blood type match with the donor in Zone B

After the classification for "adult status 5 secondary blood type match with the donor in Zone B," the table should be modified to remove the redundant classifications mentioned above to

capture Zone A pediatric status 2 candidates and adult status 6 candidates. Immediately afterward, the remaining missing classifications should appear in the following order:

- Pediatric status 2 primary blood type match with the donor in Zone B
- Pediatric status 2 secondary blood type match with the donor in Zone B
- Adult status 6 primary blood type match with the donor in Zone B
- Adult status 6 secondary blood type match with the donor in Zone B

If the table is not changed, then these candidates will never appear on the match run for a pediatric donor heart, and therefore will not be able to receive offers from these donors.

Clarifications to Policy 6.1.C.v Mechanical Circulatory Support (MCSD) with Right Heart Failure

Sub-criterion 1 under *Policy 6.1.C.v Mechanical Circulatory Support Device (MCSD) with Right Heart Failure* evolved over two rounds of public comment and what ultimately went to the Board of Directors in December 2016 for approval. This criterion was adapted from the *Guidance Regarding Adult Heart Status 1A(b) Device-Related Complications*. This criterion, developed by reviewing data from previous clinical trials, defined right failure as a candidate that has “at least moderate right ventricular (RV) dysfunction,” and requiring either of the following treatments: at least two weeks of intravenous inotropes to support right heart function; or support of an RVAD with an ongoing requirement of physiologic evidence of clinical right heart failure based upon elevation of the central venous pressure, and need for intravenous inotropes. The Committee’s intent was that a candidate required at least 14 consecutive days of intravenous inotropes, and still requires ongoing treatment of one of those therapies. **Table 2** demonstrates the evolution of this language.

Evolution of Policy 6.1.C.v: Mechanical Circulatory Support Device (MCSD) with Right Heart Failure

1st Round of Public Comment (January 2016)	2nd Round of Public Comment (August 2016)	Board of Directors (December 2016)
<p>The candidate is supported by an MCSD and has at least moderate right ventricular malfunction in the absence of left ventricular assist device (LVAD) malfunction, and all of the following:</p> <p>1. Has been treated for at least 14 days, and requires ongoing treatment with at least one of the following therapies...</p>	<p>A candidate’s transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and has at least moderate right ventricular malfunction in the absence of left ventricular assist device (LVAD) malfunction, and all of the following:</p> <p>1. Requires treatment with at least one of the following therapies for at least 14 days...</p>	<p>A candidate’s transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and has at least moderate right ventricular malfunction in the absence of left ventricular assist device (LVAD) malfunction, and both of the following:</p> <p>1. Requires treatment with at least one of the following therapies for at least 14 consecutive days...</p>

Policy language became less precise as it changed, and therefore, less consistent with the Committee’s intent. Therefore, the Committee proposes merging the more specific language from the various iterations to better align with what they originally intended.

Additional Clarifications

Finally, the Committee proposes the following clarifications:

Table 3: Proposed Clarifications

Policy	Clarification	Rationale
<ul style="list-style-type: none"> 6.1 Adult Status Assignments and Update Requirements 6.2 Pediatric Status Assignments and Update Requirements 	Strike “If a candidate’s medical condition changes and the criteria used to justify that candidate’s status is no longer accurate, then the candidate’s transplant program must submit a new heart status justification form to the OPTN Contractor within 24 hours of the change in medical condition.”	This exact language appears in section 6.3 <i>Status Updates</i> and is redundant
<ul style="list-style-type: none"> 6.1.B Adult Heart Status 2 Requirements preamble 6.1.B.iii Mechanical Circulatory Support Device (MCSD) with Malfunction 6.1.B.iv Percutaneous Endovascular Mechanical Circulatory Support Device 6.1.C Adult Heart Status 3 Requirements preamble 6.1.C.xi Percutaneous Endovascular Mechanical Circulatory Support Device after 14 Days 	Insert “mechanical” where missing in phrase “mechanical circulatory support” or “mechanical circulatory support device”	Ensure consistency across heart policy language
<ul style="list-style-type: none"> 6.1.B.iv Percutaneous Endovascular Mechanical Circulatory Support Device 	Insert “circulatory” where missing in phrase “mechanical circulatory support” or “mechanical circulatory support device”	Ensure consistency across heart policy language
<ul style="list-style-type: none"> 6.1.C.vi Mechanical Circulatory Support Device (MCSD) with Device Infection 	<ul style="list-style-type: none"> 1st and 2nd sub-criteria: Insert “driveline” prior to “exit site” 4th sub-criterion: Replace “following” with “of completing” 	Ensure consistency across heart policy language and add specificity

The Committee approved the clarifications included herein and voted to recommend them to the Board of Directors for consideration in June, 2018.

6. Modifications to Pediatric Heart Allocation

The Pediatric and Thoracic Committees jointly reviewed data following the March 2016 implementation of the Pediatric Heart Allocation policy.

Summary of discussion:

A modification to heart policy redefining pediatric Status 1A and Status 1B criteria went into effect on March 22, 2016. The goal of this change was to improve waiting list mortality for pediatric heart candidates by creating an allocation system more dependent upon candidates' medical urgency than their waiting time. The Pediatric and Thoracic Committees reviewed data from the first twelve months of the new policy in October 2017.

- There has been a sustained decrease in the proportion of waiting list additions and transplant recipients in Status 1A in the year and a half since the changes to pediatric heart criteria were implemented. However, there has been very little change in waiting list mortality for the sickest candidates.
- Use of Status 1A exceptions remained higher than pre-policy levels. A higher proportion of Status 1A transplants went to recipients with exceptions after implementation. Use of Status 1A exceptions varied across regions post-policy. Candidates waiting in Status 1A by exception had lower waiting list mortality than other candidates with the same priority after policy implementation. Additionally, exception candidates were the only group in Status 1A to have a significant increase in transplant rate under the new criteria.
- A higher proportion of transplant recipients diagnosed with cardiomyopathy were in Status 1A by exception after implementation. This change was not observed for recipients diagnosed with CHD. Waiting list mortality for candidates with cardiomyopathy in Status 1A was not different from that of candidates in 1B both before and after policy implementation, and candidates waiting in Status 1A had significantly higher transplant rates than those in 1B.

Members discussed whether training for review board members, formal guidance for review boards or exception submissions, policy changes, or a pediatric National Heart Review Board may be viable solutions to the problem. Members also discussed the need for additional data to understand the problem(s). This may include:

- waitlist mortality across age, diagnosis, and treatments
- waiting times by region, age, diagnosis, and medical urgency
- waiting list removals by removal codes
- profile of exception applications submitted

Next steps:

- The Pediatric and Thoracic Committees expressed interest in a future project to address any gaps in the proposal. Additional discussions will follow in the months ahead with the respective committees.

Upcoming Meeting

- October 4, 2018