

**Thoracic Organ Transplantation Committee Meeting**  
**March 20, 2012**  
**Chicago, Illinois**

The Thoracic Organ Transplantation Committee (Committee) met in Chicago, Illinois on March 20, 2012. The following is the Committee's deliberations, by order of item discussed.

**OPTN Bylaws Substantive Rewrite of Appendix A: Application and Hearing Procedures for Members and Designated Transplant Programs**

UNOS staff presented the revisions to Appendix A. The Committee approved the revisions (28-supported; 0-opposed; 0-abstained), but requested that the proposed bylaw modification be accompanied with a diagram, as part of the evaluation plan, to display the various processes. In general, the Committee commented that the document is long and whenever possible, UNOS staff should make such documents as concise as possible.

**Review an LAS Exception Case: Lung Review Board Did Not Act in the Time Allotted**

The Committee reviewed a case for which the Lung Review Board (LRB) did not reach a majority decision. The candidate received a transplant based on the requested Lung Allocation Score. Therefore, pursuant to Policy 3.7.6.4 (Lung Candidates with Exceptional Cases), the candidate received the Lung Allocation Scores requested and the Committee deliberated on the case.

[...]If the Lung Review Board has not completed its review of an initial request or an appeal within seven (7) calendar days of receiving it, then the candidate will receive the requested Lung Allocation Score, diagnosis, or estimated value, and the request or appeal will be forwarded to the Thoracic Organ Transplantation Committee for further review.[...]

The Committee reviewed the case but did not vote on it. Policy does not require the Committee to vote on the case. The Committee commented that a case deliberation is moot, because the candidate received a transplant.

The Committee reemphasized its interest in examining the trends in the LRB practices and trends in the lung transplant community's case submissions. The Committee stated again the need to modify the process for establishing a quorum for case votes. The Committee recommended again the need to add several alternate members to the LRB, including an LRB vice-chair.

UNOS staff informed the Committee that there exists an internal effort to create uniformity in review board practices across the organ types that have them.

**Review Public Comments Submitted on the Plain Language Modifications to the Adult and Pediatric Heart Allocation Policies, Including the Requirement of Transplant Programs to Report in UNet<sup>SM</sup> a Change in Criterion or Status within Twenty-Four Hours of that Change**

The Committee reviewed comments submitted by the public, OPTN/UNOS regions, and OPTN/UNOS committees to this policy proposal. The public and the OPTN/UNOS regions voted in favor of the policy revisions. Three OPTN/UNOS committees voted in favor of the proposal and the remaining committees did not comment.

The Committee voted in favor of submitting the proposed policy to the OPTN/UNOS Board of Directors for its review in June, 2012: 28-supported; 0-opposed; and, 0-abstained.

### **Update on the Activities of the Heart Subcommittee**

Dr. Mark J. Zucker, who is the Chair of the Heart Subcommittee, provided an overview of the activities of the Heart Subcommittee. The Heart Subcommittee continues to:

- *Discuss improvements to the current adult medical urgency statuses*

Current adult heart medical urgency policy no longer appears to address the clinical heterogeneity and disease severity of candidates implanted with mechanical circulatory support devices, or candidates without such device implants but who are in dire need for transplants.

Current policy does not accommodate the post transplant outcome of adult heart transplant recipients.

- *Revise the device related infection and complication section in the adult heart policy*

Revisions to this section of policy may result in fairer Status 1A listings of adult candidates who have dire device related infections or complications from those whose infections or complications are not as severe.

During its February, 2012 meeting, the Heart Subcommittee recommended the extension of the interim policy for outpatient candidates implanted with total artificial hearts (TAH) until December 1, 2013. The Committee argued that the interim policy should be a 'permanent' policy until the development of a new adult heart policy. To make the interim policy permanent, the Committee inquired if it needed to distribute this policy intent for public comment. UNOS staff will inquire and provide guidance to the Committee at a later date.

The Committee, in the meantime, will continue its effort to revise criterion b, which is part of the Status 1A medical urgency criteria for adult heart transplant candidates. Adult heart transplant candidates with device related infections or complications have poorer waiting list outcomes than candidates who are listed as Status 1A by other criteria (but, with the exception of those requiring continuous mechanical ventilation).

Dr. Joe Rogers, a member of the Heart Subcommittee, read a draft of the proposed criterion b modifications to the Committee. Dr. Rogers and a few members from the Heart Subcommittee have worked on adding the following topics to criterion b in an effort to better identify those

candidates with severe device related infections or complications that should be listed as Status 1A:

- Aortic insufficiency;
- Hemolysis;
- Pump thrombosis;
- Pump-related local or systemic infection;
- Device malfunction;
- Mucosal bleeding;
- Right heart failure; and,
- Ventricular tachycardia.

To be listed as Status 1A for a condition listed above, the adult heart transplant candidate will need to meet certain criteria, which this small working group continues to make final. When the criterion b modification is in its final draft version, Dr. Rogers will present it to the Heart Subcommittee in May, 2011.

UNOS staff presented the following data analysis: *Adult Heart Status 1A Candidates Criteria and Outcomes*. These data were requested by the Heart Subcommittee at its February, 2012 meeting. The Committee requested that the Heart Subcommittee discuss these data in detail at the next Heart Subcommittee meeting.

Finally, the Committee discussed again the possibility of developing a heart allocation score. Several Committee members supported an effort to begin this development right away, and others commented about the length of time required to develop such a score. UNOS staff encouraged the Committee to develop a heart allocation score, as it will more likely address the national diversity in practices to treat candidates awaiting heart transplants and address the post-transplant benefit. Discussions of the Heart Subcommittee thus far have focused on the varying hospital practices in treating candidates with device implants. These discussions have clearly conveyed the frustrations of thoracic clinicians on the Committee about the current adult heart medical urgency policy. Conversations about modifying the existing policy language have been informative, but have not yielded a new medical urgency policy. A new medical urgency policy, however, may not be the policy path to take as it would continue the therapy-based approach in identifying candidates who are in dire need for heart transplants. A therapy-based approach focuses on the individual patient and not the group, which is contrary to public health policy.

### **Removing a Candidate with a Mechanical Circulatory Support Device History**

UNOS staff presented the three issues that have emerged with the following mechanical circulatory support device data collection question on the waiting list removal page:

<p><b>Mechanical Circulatory Support Device Data:</b></p> <p>Has the candidate <u>ever</u> had a mechanical circulatory support device implanted? <input type="radio"/> Yes <input type="radio"/> No</p>
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- Issue 1: Transplant programs frequently do not report data about extracorporeal membrane oxygenation (ECMO)
- Issue 2: Transplant programs report data about device implanted after transplant (Policy requires that transplant programs remove candidates within 24 hours of transplant. Some transplant centers interpret current language to include devices implanted after transplant, but before removal from the waiting list.)
- Issue 3: Is the list of ECMO cannulation sites complete in the waiting list removal page?

To address issue 1, the Committee voted in favor (24-supported; 0-opposed; and, 0-abstained) of revising the current question (Has the candidate ever had a mechanical circulatory support device implanted?) to read as follows: Has the candidate ever had a mechanical circulatory support device (i.e., LVAD, RVAD, TAH or ECMO) implanted?

To address issue 2, the Committee voted in favor (24-supported; 0-opposed; and, 0-abstained) of adding the following note to the question, “Has the candidate ever had a mechanical circulatory support device (i.e., LVAD, RVAD, TAH or ECMO) implanted?”

“NOTE: If the candidate was removed from the waiting list for a transplant, only devices implanted prior to transplant should be reported.”

To address issue 3, the Committee voted in favor (25-supported; 1-opposed; and, 0-abstained) of modifying the existing ECMO cannulation site list to read as follows:

- Chest
- Other (neck, central, other)

There was discussion about whether these changes required public comment. UNOS staff will advise the Committee at a later date.

### **Memorandum from the OPTN/UNOS Membership and Professional Standards Committee (MPSC): Outcomes Review for Congenital Heart Patients**

The Committee discussed the following memorandum from the MPSC:

The Membership and Professional Standards Committee’s (MPSC) associated Performance Analysis and Improvement Subcommittee (PAIS) conducts routine reviews of all transplant program performance by monitoring program outcomes and activity levels. The PAIS specifically monitors one-year graft and patient survival rates.

The PAIS evaluates pediatric and adult transplants separately because the factors influencing pediatric graft and patient survival may be different for children than for adults. We are specifically asking for your committee’s input regarding how the PAIS should evaluate the adult (>17 years of age) recipients of heart transplants performed at pediatric centers; these adults receive their transplants at these centers, we surmise, because they have congenital heart disease and are long standing patients in these programs and of these physicians.

Because the volume of transplants in these situations is so low, it is often difficult to determine if a clinical issue exists in these facilities. During its meeting in July 2011, the PAIS discussed whether congenital heart patients >17 years of age at pediatric centers should be included in the pediatric program review/outcomes model, rather than evaluating them separately as adults in a separate adult program at that facility as is the current practice. Without the ability to rely on a statistical model, the PAIS is seeking additional guidance and/or discussion regarding the performance of these heart transplant programs.

On behalf of the MPSC, we are requesting that the Thoracic Organ Transplantation Committee discuss the statistical one-year post-transplant outcome analysis of congenital heart transplant recipients >17 years of age during its next meeting, and provide the MPSC with a summary of the final outcome of the discussions. Thank you for your consideration.

The Committee determined that an equitable solution is for the MPSC to associate, in general, outcomes of a transplant recipient with the transplant program that performed the transplant. So, an adult recipient of a heart transplant that was performed at a pediatric transplant program would be evaluated as part of the overall number of transplants performed by that pediatric heart transplant program. A pediatric recipient of a heart transplant that was performed at an adult heart transplant program would be evaluated as part of the overall number of transplants performed by that adult heart transplant program. The Committee requested UNOS staff to provide this commentary and memorandum to the OPTN/UNOS Pediatric Organ Transplantation Committee (Pediatric Committee).

### **Memorandum from the Pediatric Committee: Inactive Priority 1 Lung Candidates Accruing Waiting Time**

The Committee discussed the following memorandum from the Pediatric Committee:

The Pediatric Transplantation Committee (the Committee) requests input from the Thoracic Organ Transplantation Committee on possible policy and programming changes regarding inactive, Priority 1 lung candidates' accrual of waiting time. Pediatric lung candidates accrue Priority 1 waiting time while they are inactive if the candidate was listed as Priority 1 at the time they were inactivated. UNOS staff was concerned about the appropriateness of this waiting time accrual, and asked the Committee to consider if the current programming aligns with the Committee's original intent. UNOS staff provided the Committee with the policy language that was originally approved at the June 2008 Board of Directors' meeting (enclosed), and reminded it how the current policy language evolved from what was approved in June 2008 to simplify the programming effort while retaining the original intent. One specific change eliminated tallying multiple periods of time at the most urgent status. Instead, as indicated in current policy language, it was agreed that for allocation purposes, "UNetSM will only consider the most recent time spent as Priority 1, i.e, UNetSM will not tally the time waiting during multiple Priority 1 periods."

The Committee discussed this issue during its September 2011 meeting. During its discussion, the Committee focused on the appropriateness of urgent lung candidates accruing waiting time while listed as inactive. An example repeatedly cited was an urgent candidate that had an infection that would need to be treated prior to transplant. The Committee agreed that inactivating such candidates to treat their temporary condition did not mitigate their urgent need for a lung transplant, and thus their waiting time should not reset. Accordingly, it would be appropriate for these Priority 1 candidates to continue accruing waiting time while temporarily inactive. The Committee did not believe that these inactive Priority 1 candidates should accrue Priority 1 waiting time indefinitely, and suggested a 30-day timeframe (similar to inactive intestinal organ candidates, Policy 3.11.6 (Waiting Time for Intestinal Organ Transplant Candidates in an Inactive Status)).

In response to this suggestion, UNOS staff pointed out that candidates accruing Priority 1 waiting time while inactive seemed to be in conflict with policy 3.7.9 (Time Waiting for Thoracic Organ Candidates), which states:

“Waiting time will not be accrued by candidates awaiting a thoracic organ transplant while they are registered on the Waiting List as inactive, except as specified in Policy 3.7.9.3 (Waiting Time Accrual for Lung Candidates Less than 12 Years of Age).”

The Committee was reminded that the reference to Policy 3.7.9.3 was added when the pediatric lung policy language approved in June 2008 was later modified to simplify the programming effort. This exception was included to accommodate calculating “total waiting time” (which considers the candidate’s entire time on the waitlist- active and inactive) to prioritize Priority 2 potential transplant recipients and serve as a tiebreaker for Priority 1 potential transplant recipients. Acknowledging this, the Committee’s discussion focused on Policy 3.7.9 and why inactive time could not be accrued for thoracic organs. Again, Committee members cited situations where a lung candidate would be temporarily unsuitable for transplant but still urgently in need.

Committee members commented that instead of inactivating these candidates that are temporarily unsuitable for transplant, organ offers could be refused for them citing refusal code 801 (Candidate ill, unavailable, refused, or temporarily unsuitable). This would prevent a candidate from losing previously accrued Priority 1 time if the programming were modified so that a Priority 1 lung candidate’s Priority 1 waiting time would reset upon being inactivated. Other Committee members responded that their transplant programs will always inactivate candidates that are temporarily unsuitable for transplant due to concerns about future audits, specifically to avoid any questions about refusing organ offers for active candidates. Based on this discussion, the Committee recognized that if UNet<sup>SM</sup> programming is modified so that a Priority 1 lung candidate’s Priority 1 waiting time would reset upon being inactivated, then the waiting time accrual for these pediatric Priority 1 lung candidates has the potential to vary depending on what transplant hospital is listing the candidate.

Considering all this, the Committee’s discussion concluded with a general sentiment that it was appropriate for Priority 1 lung candidates to accrue Priority 1 waiting time while

inactive; however, waiting time while inactive should be limited to 30 days. The Committee is particularly interested in the Thoracic Organ Transplantation Committee's input on this matter. Specifically:

Would the Thoracic Organ Transplantation Committee support policy modifications (and the associated programming) that would allow Priority 1 lung candidates to accrue "Priority 1 waiting time" while listed as inactive, up to 30 days?

If not, and considering policy 3.7.9.3 and a candidate whose most recent active prioritization was Priority 1, is it reasonable to consider time during a subsequent inactivation status as part of their "most recent time spent as Priority 1," as UNet<sup>SM</sup> is currently programmed?

If this is not a reasonable interpretation of the current policy, and considering the situation outlined above where lung candidates' Priority 1 waiting time could be dependent upon a transplant center's approach to waitlist management, does the potential variability of Priority 1 waiting time accrual justify policy modifications to facilitate more consistent Priority 1 waiting time accrual (and to more clearly reflecting the current programming)?

The Committee recommended the Pediatric Committee to consider modifying the pediatric lung policy and its programming so that: 1) Priority 1 candidates are able to retain their previously accrued Priority 1 waiting time while they are active as Priority 1; and 2) Priority 1 candidates cannot accrue Priority 1 waiting time while inactive.

### **Proposal to Change Bylaws Requiring Separate Program Approval for Transplant Hospitals Listing and Performing Combined Heart-Lung Transplants**

The Committee reviewed the following recommendations from the OPTN Contractor's Membership Department:

- Dissolve the single OPTN approval requirements for heart-lung transplant program;
- Eliminate the heart-lung program status; and,
- Endorse a requirement that any organ or combination of organs can be listed for, allocated to, and transplanted if the transplant hospital has OPTN/UNOS transplant program approval for any transplanted organ.

These modifications would not affect any heart, lung, or heart-lung transplant program personnel requirements. An OPTN-approved heart-lung program must be approved as a heart transplant program and a lung transplant program. The heart-lung transplant program designation is the only such designation. For example, there are no program bylaws for a program that performs a kidney-pancreas transplant.

In January, 2012, the UNOS Chrysalis project team made clear its intent to develop an efficient system for listing combined organ transplant candidates. This solution is to eliminate the combined heart-lung program. With this solution, a candidate in need of a heart-lung transplant

would be registered for a heart transplant and a lung transplant. These candidates will be eligible to receive deceased donor heart-lung offers of the programs making these registrations are approved by the MPSC. For example, a kidney-pancreas candidate is registered on the kidney transplant program waiting list the pancreas transplant program waiting list. When registered for both organs, UNetSM recognizes that the candidate is need of both organs and if both programs are approved by the MPSC, then the candidate will be able to receive those multiple organ offers. This “bundling” of individual organ program approvals is efficient.

The Committee inquired how such bylaw changes would affect any requirements of the US Centers for Medicare and Medicaid Services (CMS). CMS requires a heart-lung designation for such a program to function. HRSA will notify CMS about these bylaw changes. The bylaw proposal will state clearly the OPTN consequences due to this bylaw change, and that this bylaw change will not affect CMS practices.

The Committee supported sponsoring the bylaw proposal, but with the MPSC as co-sponsor: 28-supported; 0-opposed; and, 0-abstained.

### **Memorandum from the Policy Oversight Committee (POC): Input on Multi-Organ Allocation Policies**

The Committee discussed the following memorandum from the POC, which the Chair of the POC and a member of the Committee, Dr. Stuart Sweet, presented to the group:

The OPTN/UNOS Policy Oversight Committee has been charged with addressing multi-organ allocation policies. Following several meetings held in 2011, the committee is considering policy modifications that would incorporate minimum listing criteria for each organ in circumstances where a patient is being listed for a multi-organ transplant. In addition, the committee is considering expanding beyond the local DSA the zone where multiple organ recipients will take priority. As we continue working on this project, we have identified four main areas for which the committee would benefit from other committees input: Minimum listing criteria, policy ambiguities, ethical principles, and logistical issues.

The POC is seeking your input and would like for your committee to address the following questions:

- 1) For those committees with minimum listing criteria: Do you think the minimum listing criteria issues are resolved for your organ and if so, what are the important principles that were used to get there?
- 2) Are there organ combinations for which minimum listing criteria do not exist but should?
- 3) In order to minimize unnecessary multi-organ transplants, are there adjustments needed to the allocation system that will ensure a candidate who does not receive multiple organs (due to failure to meet minimal listing criteria) could get appropriate priority if subsequent to the transplant of the primary organ he/she develops failure of the second organ?

- 4) Are there logistical issues regarding waiting list management surrounding multi-organ listing and transplant that need to be addressed?
- 5) Are there procurement issues that could be addressed in this process?
- 6) If the concept of lifesaving organ is removed, are there key ethical principles your committee feels should be included in a framework for allocating the second organ based on a balance between equity and utility.

The Committee commented that:

- There are no minimum listing criteria for candidates in need of joint heart-lung transplants;
- There is no need to develop minimum listing criteria for candidates in need of joint heart-lung transplants;
- The transplant community should reconsider the practice of deceased donor kidneys being offered to candidates in need of joint heart-kidney, lung-kidney, and liver-kidney transplants; and,
- Its effort to develop a joint heart-lung allocation policy, a draft concept of which is below, addresses the POC's concerns of equity.

*Proposed Policy Constructs for Candidates in Need of a Heart and Lung (Draft)*

“Heart-centric”

Status 1A

- If an OPO offers a heart to a Status 1A heart candidate who also needs a lung transplant, then the OPO will offer both the heart and lung to that candidate unless there is a single or double lung candidate with a lung allocation score greater than 55 (or greater than the actual LAS of the HL candidate if the HL candidate has a LAS value greater than 55) in the local unit or in Zone A.

Status 1B

- If an OPO offers a heart to a Status 1B heart candidate who also needs a lung transplant, then the OPO will offer both the heart and lung to that candidate unless there is a single or double lung candidate with a lung allocation score greater than 45 (or greater than the actual LAS of the HL candidate if the HL candidate has a LAS value greater than 45) in the local unit or in Zone A.

Status 2

- If an OPO offers a heart to a Status 2 heart candidate who also needs a lung transplant, then the OPO will offer both the heart and lung to that candidate unless there is a single or double lung candidate with a lung allocation score greater than 35 (or greater than the actual LAS of the HL candidate if the HL candidate has a LAS value greater than 35) in the local unit or in Zone A.

“Lung-centric”

If the HL candidate has a LAS score greater than 45 and is a status 2 heart by criteria, the transplant center has the option to list that candidate as a heart status 1B-exception.

The Committee will submit the above joint heart-lung allocation concept to the POC for its consideration. Finally, the Committee plans to revive its efforts to improve the joint heart-lung allocation policy.

**Letter from the American Society for Histocompatibility and Immunogenetics (ASHI): DP Typing**

The Committee discussed a letter from ASHI requesting mandatory HLA-DP typing for all deceased donor organs offered for transplant. (An excerpted image of the letter is below.) ASHI requested the Committee and the OPTN/UNOS Histocompatibility Committee require DP typing for all deceased donor organs recovered for transplant, but allow some time for all Histocompatibility laboratories to comply with such requirement. Current policy for providing HLA-typing for all thoracic organ offers, if requested by the transplant program receiving the organ offer, does not mandate DP-typing for thoracic organs offered. Policy requires DP typing of a thoracic organ offered, if requested by the transplant program, but only if the organ procurement organization (OPO) offering the thoracic organ can provide this typing. If the OPO cannot provide it, because its affiliated Histocompatibility laboratory lacks technology for performing the DP-typing test, then the OPO does not need to provide this requested information.

The Committee appreciates ASHI’s request, and will work with the Histocompatibility Committee to comply with this request when all Histocompatibility laboratories can perform DP typing.

Most laboratories do not perform routine DP typing on deceased donors, only doing so if the patient has DP antibodies. Additionally, there were laboratories that offered only cytotoxic HLA-typing until just recently, when the mandate to convert to molecular methods was published. These laboratories have struggled to gain the competency and proficiency to be accredited in this area. They would be further disadvantaged by having to develop the intermediate to high resolution capabilities necessary to type for DP with the current reagents. Limited personnel, time for validation and training, as well as enrolling in and participating in proficiency testing, would make this a lengthy and costly process for these laboratories. The disadvantage to those laboratories already offering DP typing for their OPO is that additional time and personnel have to be provided to perform it upon request. This will place stress on personnel to return to the laboratory to do additional typing and will negatively impact allocation by delaying it another 2-4 hours.

Since DP antibodies are being found with increased frequency and have a more documented history of affecting graft survival than do those for C locus, which is already typed for, it is suggested that UNOS consider requiring all deceased donors to be DP typed by the OPO HLA laboratories in the future, rather than having a piecemeal approach. In making DP typing universal, you might then consider a longer implementation period (perhaps a year) before the proposal goes into effect, in order to allow all laboratories to comply to the requirement. This proposed approach would properly address the concerns described above. Once DP typing for organ allocation is operational, the last hurdle is supplying that information to UNOS. The lack of entry screens to specifically list DP antigens can be obviated by simply uploading the laboratory's final typing report when the donor is registered, until such time that they may be entered into the UNOS system.

### **Program Specific Reports (PSR): Report of the February, 2012 Consensus Conference**

Dr. Maryam Valapour with the SRTR presented the results of the PSR Consensus Conference (Exhibit A). This consensus conference focused on answering the following questions:

1. What is the SRTR's mandate?
2. Who uses PSRs and why?
3. Are there unintended consequences?
4. What can we learn from others?
5. What statistical methods should we use?
6. How should we adjust for risk?
7. What outcomes should we use?
8. What data should we collect?

Various groups evaluate data in the PSRs: CMS, MPSC, private insurance companies, transplant programs, transplant candidates, and the public. The MPSC initiates evaluations of transplant programs when their observed outcome rates are lower than their expected rates.

PSRs provide improvement opportunities for transplant programs, but several Committee members continued to be concerned by the use of these data for payment purposes by insurance companies; however, such use is likely not going to cease.

The SRTR plans to install a formal process by which organ-specific committees evaluate the covariates comprising the various statistical models that generate PSRs. The SRTR's Scientific and Technical Advisory Committee's task is to improve the PSRs based on recommendations provided at the February, 2012 consensus conference.

### **Activities of the Policy Oversight Committee**

Dr. Stuart Sweet, Chair of the Policy Oversight Committee (POC), provided an update on the activities of the POC, which include:

- Multi-organ allocation project;
- Review of projects proposed by the OPTN committees;
- Review of public comment proposals; and,
- Make recommendations to the Executive Committee about projects and proposal.

### **Activities of the Lung Subcommittee**

Dr. Stuart Sweet, Chair of the Lung Subcommittee, provided an update on the activities of the Lung Subcommittee, which include:

- Distribution of the proposal to revise the Lung Allocation Score system for public comment (March 16, 2012);
- Discussions to evaluate the nature and quality of cases submitted to and reviewed by, respectively, the Lung Review Board;
- Discussions of ex vivo lung perfusion;
- Discussion of the feasibility of ABO-incompatible lung transplantation among infants and small children; and,
- Discussions to improve policy on joint heart and lung allocation.

### **Update on Discussion to Revise the Pediatric Heart Policies**

Dr. Steven Webber, Vice-Chairman of the Thoracic Committee, provided an update on the activities of the pediatric heart policy working group. This working group includes members of the Heart Subcommittee and Pediatric Committee. This working group is:

- Continuing its effort to modify the pediatric heart medical urgency policy;
- Initiated a discussion to eliminate listing of heart transplant candidates who are *in utero*;
- Initiated a discussion to modernize the policy on ABO-incompatible heart transplantation to keep pace with current science on the topic;
- Revising the eligibility criteria for candidates to receive ABO-incompatible heart transplants; and,
- Revising the priority of ABO-incompatible candidates for pediatric heart allocation.

### **Revisions to the Waiting Time Modification Policy (Post Public Comment Draft from the Kidney Organ Transplantation Committee)**

In February, 2012, the Committee reviewed another request to modify a pediatric heart transplant candidate's waiting time to include time accrued waiting for a previous heart transplant. The Committee members questioned voting on this case as they had voted consistently in the past to follow Policy 3.7.13 (see below), and deny the requests. The candidate's pediatric status

generated conflicted voting on the case, such that the Committee voted a second time on the same case.

**3.7.13 Removal of Thoracic Organ Transplant Candidates from Thoracic Organ Waiting Lists When Transplanted or Deceased.**

If a heart, lung, or heart-lung transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all Thoracic Organ Waiting Lists for that transplanted organ and shall notify the OPTN contractor within 24 hours of the event. If the thoracic organ recipient is again added to a Thoracic Organ Waiting List, waiting time shall begin as of the date and time the candidate is relisted.

On March 20, 2012, the Committee discussed the case and emphasized that regardless of age, Policy 3.7.13 must apply.

To accompany this discussion, the Committee reviewed again modified language on policy to submit waiting time modification requests for candidates seeking time accrued for their previous transplants. The Kidney Organ Transplantation Committee modified Policy 3.2.1.8 (Waiting Time Modification) and submitted the policy modifications for public comment in September, 2011. The Committee reviewed the modified language in December, 2011 and stated that it did not want the thoracic community to submit requests to add waiting time, accrued for a previous thoracic transplant, to the current waiting time of thoracic organ transplant candidates.

The Committee reviewed the language below. Text with double underlines denotes information added to the proposed policy after the public comment cycle.

**3.2.1.8.1 Permissible Modifications**

Applications for waiting time modifications that meet *any* of the following qualifications must follow the procedures for expedited modifications of waiting time in Policy 3.2.1.8.3 below.

- An error occurred in modifying, removing, or renewing the candidate's waiting list record and the Transplant Program requests a modified waiting time to include time accrued under the previous registration, in addition to any time lost by the error.
- The candidate was removed from the waiting list for medical reasons, other than receiving a transplant, was subsequently relisted for the same organ with the same diagnosis, and the Transplant Program requests a modified waiting time to only include the time accrued under the previous registration without the time interval when the candidate was removed from the waiting list.
- The candidate is waiting for a heart, liver, or lung, needs a second organ, and the Transplant Program requests a modified waiting time for the second organ that includes the waiting time accrued for the first organ.

Applications to modify a candidate's registration date and all other applications for waiting time modifications must follow the procedures for modifications of waiting time

in Policy 3.2.1.8.4 below. Additionally, applications must meet any additional requirements stipulated in the organ-specific allocation policies.

### **3.2.1.8.2 Application**

To apply for a waiting time modification, a candidate's Transplant Program must submit an application to the OPTN Contractor with all of the following information:

1. The requested listing date and documentation showing an intent to register the candidate at the requested listing date.
2. That the candidate met applicable waiting time qualifying criteria in the organ specific policies (Policy 3.0 et seq.).
3. A corrective action plan, if the application is due to an error.
4. The name and signature of the candidate's physician or surgeon.
5. Signatures indicating agreement from all kidney transplant programs in the OPO. If a signature cannot be obtained from a transplant program, the submitting program must explain the efforts it made to obtain a signature and include any stated reasons for disagreement with the request.

The Committee, generally dissatisfied with the double-underlined text in Policy 3.2.1.8.1, requested that the Kidney Organ Transplantation Committee further revise the policy language, as described below:

- The phrase “needs a second organ” is vague.
- The policy must read such it prohibits a thoracic transplant program from submitting requests to modify a candidate's waiting time to include time accrued for a previous thoracic transplant.
- The Kidney Organ Transplantation Committee should identify the “other applications for waiting time modifications.”

### **New Business – Addressing Candidates on Extracorporeal Membrane Oxygenation (ECMO)**

A Committee member requested the Committee discuss how the Lung Allocation Score (LAS) System should accommodate candidates placed on ECMO. The LAS system neither includes ECMO as a covariate in the waiting list or post-transplant survival models nor does it capture data in UNet<sup>SM</sup>. A candidate placed on ECMO is likely to have a high LAS. However, the LAS system does not reflect this candidate's true lung function. Some transplant programs may identify candidates placed on ECMO as needing continuous mechanical ventilation.

Requesting a higher LAS for a candidate placed on ECMO is not feasible. The Committee tasked the OPTN Contractor to enable such requests to occur, because of the increasing number of candidates being placed on ECMO. It is likely that once this mechanism is in place, lung transplant clinicians will receive guidance similar to those for pulmonary hypertension candidates on submitting exception requests for candidates placed on ECMO.

The Lung Subcommittee will further discuss this topic at its next meeting.

## Thoracic Organ Transplantation Committee Members Who Participated

- 1) Mark L. Barr, MD (Chairman, Committee)
- 2) Steven A. Webber, MD (Vice-Chairman, Committee)
- 3) Stuart C. Sweet, MD, PhD (Lung Subcommittee Chairman)
- 4) Mark J. Zucker, MD, JD (Heart Subcommittee Chairman)
- 5) Luis F. Angel, MD (Lung Review Board Chairman)
- 6) Sangeeta M. Borade, MD
- 7) Nancy P. Blumenthal, MSN, CRNP
- 8) Kevin M. Chan, MD
- 9) Joseph C. Cleveland, Jr., MD
- 10) Ladora A. Dils, BSN, MHA, CPTC
- 11) Kevin M. Dushay, MD
- 12) David Bradley S. Dyke, MD
- 13) Alan L. Gass, MD (by phone)
- 14) Maryl R. Johnson, MD
- 15) Theodore G. Liou, MD
- 16) Ken R. McCurry, MD
- 17) William T. Mahle, MD
- 18) Brigitte Marciniak-Bednar, RN, BSN, CCTC
- 19) Dan M. Meyer, MD (by phone)
- 20) Nahush Ashok Mokadam, MD
- 21) David P. Nelson, MD
- 22) Damian Neuberger, PhD
- 23) Joseph G/ Rogers, MD
- 24) Craig H. Selzman, MD
- 25) Leonardo Seoane, MD
- 26) Tajinder P. Singh, MD
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- 30) Monica Lin, PhD (HRSA)

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- 7) Aaron McKoy (by phone)
- 8) Heather Neil (by phone)
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- 10) Anne Paschke (by phone)
- 11) Sharon Shepherd (by phone)