

Report of the OPTN/UNOS Thoracic Organ Transplantation Committee Meeting
Chicago, Illinois
March 22, 2011
Mark Barr, MD (Chair)
Steven Webber, MD (Vice-Chair)

The following is a summary of the Thoracic Organ Transplantation Committee's (Committee) deliberations that occurred on March 22, 2011.

1. Overview and Function of the New SRTR Contractor (Chronic Disease Research Group, a Subsidiary of the Minneapolis Medical Research Foundation)

The SRTR's new contractor provided its organizational overview, funding sources, its relationship to the OPTN, and its goals. The Committee requested to be involved in future discussions about changes to the program specific reports.

2. Review Public Comment Proposals Distributed on March 11, 2011

The Committee reviewed two public comment proposals sponsored by the Organ Procurement Organization (OPO) Committee, and provided feedback as follows.

Proposal to Standardize Label Requirements for Vessel Storage and Vessel Transport (Sponsored by the OPO Committee)

The Committee approved the proposal: 21-supported; 0-opposed; and, 0-abstained.

Proposal to Update and Clarify Language in the DCD Model Elements (Sponsored by the OPO Committee)

The Thoracic Committee reviewed an earlier version of the proposal on January 24, 2011. Referring to the section below, the Committee recommended that the OPO Committee include that the agreement that exists between the OPO and the hospital should detail the methodology that will be used during the declaration of death process. It is important to have this information be available to clinicians as they are making the pronouncement.

F. Pronouncement of Death

The patient care provider who is authorized to declare death must not be a member of the OPO or the surgical recovery team. Circulatory Death is death defined as the irreversible cessation of circulatory and respiratory functions. Death is declared in accordance with hospital policy and applicable state and local statutes or regulation.

Pronouncement of death can only be made after a sufficient time period has passed, as defined by hospital policy.

On March 22, the Committee discussed the proposal and approved the terminology change – from cardiac to circulatory. The Committee sought rationale for the deletion of the “irreversibility of death” section, and suggested that agreements between donor hospitals and OPOs to recover organs due to circulatory death should include the use of extracorporeal membrane oxygenation (ECMO) and other such devices (e.g., pacemaker) that may be used to medically manage the donor the pronouncement of death. Thus, the Committee approved the proposal (21-supported; 0-opposed; and, 0-abstained) with the following caveats:

- Paragraph A (Agreement) should include more specific detail about the elements in the agreement. Perhaps the OPO Committee could develop a template for the set of elements. These elements must include the methods used to declare death, e.g., electrocardiogram, and pacemaker; the total amount of time required to declare death; and, whether any form of ECMO support is allowed following declaration of death.
- The agreement must be present in the operating room and invoked during the “time out” performed during the withdrawal of medical support.

3. Communicating the Committee’s Activities to the Thoracic Transplant Community

The Committee discussed whether it needed to make its activities and outcomes of the heart and lung allocation systems more transparent to the thoracic community. The Committee considered making an executive summary of each meeting available to the thoracic community. However, the development and distribution of this document may not be necessary (because UNOS staff posts the reports of the Committee meetings to the OPTN website) and could set a precedent for other committees to follow, thereby possibly creating unnecessary work burden. The SRTR’s annual report could also include information about organ allocation outcomes.

At the conclusion of this discussion, the Committee opted to request the Executive Committee or the Board of Directors to consider how OPTN/UNOS committees could improve transparency of their activities, as well as outcomes of policies to the public.

4. Lung Case Reviews

The Committee discussed two exception cases (#645 and #653) for candidates diagnosed with pulmonary hypertension and that did not receive majority vote by the Lung Review Board (LRB) within the specified seven-day review period. Both cases were exception requests for candidates who receive Lung Allocation Scores (LAS). In both cases, the Committee awarded the candidates the exception requests: 21-supported; 0-opposed; and, 0-abstained. The two cases represent four exceptional cases out of over 600 since May, 2005 that did not receive majority votes from the LRB. The case review resulted in several discussion and action items listed below.

- Patients might be in jeopardy when the LRB cannot reach a majority vote. In the two cases under discussion, UNOS staff needed to contact the alternate representatives, but staff did not receive responses from these individuals. (The alternate members that did not respond were not the same individuals.) Could the LRB Chair become involved to facilitate responses to cases? Can UNOS staff contact the LRB Chair to alert her or him of the potential non-majority vote? However, is the number of cases that did not receive majority vote by the LRB significant enough to warrant a review of the Lung Review Board Process? In the time since LAS has been in place, there have been fewer than five cases where the LRB did not reach a majority vote. After some discussion, the Committee opined that the LRB system is working, but its membership needs to consist of people who remain engaged in the review process throughout their terms; and UNOS staff should facilitate this engagement or change in membership, if necessary.
- The LRB membership should also include the Chair of the Lung Subcommittee and the Thoracic Committee, and the Vice-Chair of the Thoracic Committee to serve as alternate members. This change requires revisions to the LRB guidelines, and approval by the OPTN/UNOS Board of Directors.

- UNOS staff members should provide an orientation to the LRB members on their responsibilities at the start of their terms.
- The Committee requests guidance from the OPTN leadership on whose responsibility it is to govern the quality of the review board process.
- The Committee needs to foster a broader interpretation of the pulmonary hypertension guidelines, and not a narrow one as has been adopted by some members of the lung transplant community. The Committee intended these guidelines for clinicians to consider when submitting exception request for candidates, and not for clinicians to consider as conditions that the candidate must meet prior to requesting an exception to the LRB. The Committee tasked the Lung Subcommittee to edit the language to educate the lung transplant community about this intent.
- The Heart and Lung Subcommittees will review the activities of the heart and lung review boards annually. This review will evaluate the cases submitted and the judgments rendered.
- The Committee tasked the Lung Subcommittee to review the LRB guidelines.

5. Discuss Comments Received on the Proposal to Require Collection of Human Leukocyte Antigen (HLA) Type for Thoracic Organs

The Committee reviewed responses submitted to this proposal (see Exhibit A), which UNOS distributed on October 1, 2010. The summary of the proposal reads as follows:

Clinical practice and review of the literature suggest that knowledge of donor HLA type allows for a sensitized candidate to receive the most suitable thoracic organ offer. The proposed policy states that if a transplant center requests donor HLA type when its candidate receives a thoracic organ offer, the OPO must provide HLA type for each thoracic organ offered prior to the organ’s final placement. The proposed policy change does not require that a thoracic transplant center request donor HLA type for its candidate. However, if the transplant center seeks donor HLA type, then it is responsible for communicating this request to the relevant OPO.

Coupled with recently developed techniques to determine HLA antibody specificity and perform virtual crossmatching, donor HLA data provided at the time of a thoracic organ offer will allow transplant centers to consider offers for sensitized candidates in circumstances where prospective crossmatch is not practical. Enabling virtual crossmatching for thoracic organs also has the potential to reduce post-transplant morbidity and mortality by preventing unanticipated positive crossmatches.

The policy proposed is:

Policy 3.7.12.1 (Essential Information for Thoracic Offers)

[...]

Human leukocyte antigen (HLA) type if requested by the transplant center.

If a transplant center requires donor HLA type prior to submitting a final organ acceptance, it must communicate this request to the OPO; the transplant center must document this request. If a transplant center requests donor HLA type prior to submitting a final organ acceptance, the OPO must provide the following, identified splits before the organ’s final acceptance: HLA-A, HLA-B, HLA-Bw4, HLA-Bw6, HLA-Cw, HLA-DR,

and HLA-DQ antigens. The transplant center may request HLA-DP type, but the OPO need only provide it if its affiliated laboratory performs related testing. The OPO must document provision of HLA type to the requesting transplant center.

The OPTN received thirty-six individual responses through its website: 29 (80.56%) supported the proposal; 3 (8.33%) opposed the proposal; and, 4 (11.11%) had no opinion. Of the 32 who responded with an opinion, 29 (90.63%) supported the proposal and 3 (9.38%) opposed the proposal. The American Society of Transplant Surgeons supported the proposal whereas the Organization of Transplant Professionals (NATCO) did not. Among the OPTN regions, only Region 4 supported the proposal with a caveat – the other regions supported the proposed policy. Among the nine OPTN/UNOS committees that commented on the proposal, only the OPO Committee opposed it.

The Committee discussed at length the comments submitted and whether it should modify the policy based on the comments. The Committee emphasized that the proposed policy requires that an OPO provide HLA-typing, if requested to do so by the transplant center. Existing practice and telephone communication methods allow for OPOs and transplant centers to communicate about a medically unstable donor or a donor whose family wishes to expedite the organ recovery process. The proposed HLA policy does not need further modification to explain these scenarios as this practice is in the proposal. The proposed policy requires OPOs to provide HLA-typing prior to the organ's final acceptance and only if requested by the transplant center.

The Committee also discussed the:

- Practicality of requiring documentation from transplant centers as written in the proposed policy;
- Substitution of the word “process” for “request” when referring to the transplant center's role;
- Documentation of the request and provision of HLA typing should occur via DonorNet[®]; and,
- Requirement to HLA-type all thoracic deceased donor organs.

Programming the proposed policy would not occur in the near future and would require the addition of fields in DonorNet[®]; therefore, the Committee seeks, for the time being, to proceed with a manual solution for the policy proposed. Committee members cautioned that for auditing purposes, transplant programs must keep records of requesting HLA-typing in the form of an email, progress notes, or another type of documentation. Should the OPTN/UNOS Board of Directors approve this policy, the Committee requested UNOS staff to develop a guidance document to facilitate compliance with this policy.

The Committee will consider a stricter policy in the future once it has sufficient data to evaluate the outcome of this policy.

The Committee voted in favor of the policy as written and submitting it to the OPTN/UNOS Board of Directors for approval: 21-supported; 0-opposed; and, 0-abstained.

6. Discuss Comments Received on the Proposal to Clarify Adult Heart Status 1A Exception Language to Enable Consistent Interpretation of Policy and Reflect Current Programming in UNetSM

The Committee reviewed responses submitted to this proposal (see Exhibit B), which UNOS distributed on October 1, 2010. The summary of the proposal reads as follows:

In order to reduce confusion about candidate eligibility, this proposal clarifies language about Status 1A requirements in thoracic Policy 3.7.3 (Adult Candidate Status).

The revised Status 1A-exception language clarifies that clinicians requesting Status 1A-exceptions may only do so for candidates who inpatients at their listing hospital.

Revised language in criterion (b) clarifies that in UNetSM, clinicians may write in a mechanical circulatory support device complication other than the examples included in policy, and that the OPTN contractor will process such an entry as a request for Status 1A-exception by criterion (b).

Finally, revised language maintains that a request for Status 1A-exception by criterion (b) does not require that the candidate be an inpatient at his or her listing center.

This proposal will not require programming in UNetSM.

All votes submitted to the OPTN website, by the regions, and by OPTN/UNOS Committees favored the proposal. The proposal aligns the programming with the intent of the policy. The Committee voted in favor of the proposed policy language and in submitting it to the Board of Directors for approval: 21-support; 0-opposed; and, 0-abstained.

7. Update on the Activities of the Lung Subcommittee

The Chair of the Lung Subcommittee provided a summary of this group's activities, which include the development of the following two policy proposals that UNOS distributed for public comment on March 11, 2011.

1) Adding Non-Contrast CT Scan to Policy 3.7.12.4 (Desirable Information for Lung Offers)

The Thoracic Committee proposes the addition of non-contrast CT scan of the chest to Policy 3.7.12.4. The proposed policy encourages an OPO to provide the result of a CT scan if it is requested to do so by a transplant program. The proposed policy does not require a transplant program to request a CT scan.

Deceased donor lungs may have contusions or infiltrates or malignant nodules which may not be visible in a chest x-ray (CXR). In instances where significant clinical suspicion for such abnormalities exists, a non-contrast CT scan of the chest can provide additional information.

2) Proposed Policy to Request Transplant Programs to More Frequently Update the Lung Allocation Scores for Candidates with Scores of 50 or Higher

The Thoracic Committee proposes requiring transplant programs to update in no more than 14 days, any observed changes in clinical values most important to determining a candidate's Lung Allocation Score for candidates whose scores are 50 or higher (high-LAS). For high-LAS candidates, the proposal would require transplant programs to report in UNetSM any changes in the assisted ventilation, supplemental oxygen (frequency and amount), or PCO₂ clinical variables.

Policy 3.7.6.3.2 requires a transplant program to update its candidates' clinical values in UNetSM every six months. Candidates with high-LAS are likely receiving therapeutic interventions that may improve their health and thus decrease their scores.

The Lung Subcommittee continues to revise the LAS system. The analyses for a revised LAS system could not consider the impact of current and increase in bilirubin, factors which the OPTN/UNOS Board of Directors approved adding to the waiting list model in June, 2009. As UNOS has not yet implemented the collection of serial bilirubin in the waiting list pages, current and increase in serial bilirubin could not be included as factors in the analysis to revise the LAS system. The Lung Subcommittee requested the following analysis from the new SRTR contractor:

- Estimation of the effect of bilirubin in the Lung Retrospective Project (LRP) cohort, along with other factors included in the revised waitlist survival model, and show how its inclusion affects the model's predictive ability and parameters already included in the revised model; and
- Correlation of bilirubin with other factors included in the revised model among patients in the LRP Cohort.

The Lung Subcommittee expects to distribute this revised LAS proposal for public comment in September, 2011.

8. Heart-Lung Allocation System

The Committee continued its discussion of improving Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates). To assure that all heart-lung candidates appear on the waiting list, the Committee had distributed a memorandum in January, 2011 to transplant programs on listing on and removing such candidates from the waiting list. The Committee will continue its efforts to address sick lung candidates who are also in need of a heart. On March 22, the Committee focused its discussion on a memorandum to the OPO community on geographic classifications to consider when allocating a heart-lung bloc off a lung match run; and, how to break a tie between two heart-lung candidates suitable to receive a heart-lung bloc – one off the heart match run and the other off the lung match run.

Interpretation of UNOS Staff on The Geographic Classification Or Classifications that An OPO Must Consider for An Isolated Status 1A Heart Candidate When Allocating A Heart to A Heart-Lung Candidate off The Lung Match Run

The Lung Subcommittee Chair proposed the following memorandum to the Committee for review and approval. The Lung Subcommittee Chair requested that the Committee collaborate with the OPO Committee to develop a final version of the memorandum for distribution to the OPTN/UNOS Executive Committee. The Committee requested UNOS staff to edit the document with an explanation of the application of the word “eligible” in Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates). While the Committee will review the final version of the memorandum prior to its distribution to the OPTN/UNOS Executive Committee, the Committee voted in favor of the memorandum's intent, its distribution to the OPO Committee, and its subsequent distribution to the OPTN/UNOS Executive Committee for approval: 20-approved; 0-opposed; and, 0-abstained.

MEMORANDUM

To: Organ Procurement Organizations (OPO)

From: Mark L. Barr, MD [Chair, Thoracic Organ Transplantation Committee (Thoracic Committee)] and Lori E. Brigham [Chair, OPO Committee]

Re: Allocation of Deceased Donor Heart and Lungs to Candidates Who Need Both Thoracic Organs off the Lung Match Run

Date: April ##, 2011

On [Date], the OPTN/UNOS Executive Committee convened by telephone and voted in favor (##-supported; ##-opposed; and, ##-abstained) of the following resolution presented by the Thoracic Committee and the OPO Committee:

**** RESOLVED, that the allocation of hearts off the lung match run to heart-lung candidates will follow the geographic classification described below, effective [Date].**

Policy 3.7.2 (Geographic Sequence of Thoracic Organ Allocation) identifies geographic classification as local, Zone A, Zone B, Zone C, Zone D, and Zone E. These areas are based off the donor hospital's geographic location. When using the lung match run to offer a heart to a heart-lung candidate, the OPO must apply the word "eligible," a term in Policy 3.7.7, in a geographic classification concept as described below:

- 1) Offer the donor heart to all suitable, isolated Status 1A heart candidates who are in the same geographic classification as the lung candidate who also needs a heart. For example, if on the lung match run, the heart-lung candidate is in the local area, then the OPO needs to look for all isolated, suitable Status 1A heart candidates in the same local area. If the heart candidate accepts the isolated heart, then the OPO can proceed to offer the lung using the lung algorithm (see Policy 3.7.11 Sequence of Adult Donor Lung Allocation).
- 2) If the aforementioned isolated heart candidate does not accept the heart, then the OPO offers that heart to the heart-lung candidate whose geographic classification is the same as that of the isolated heart candidate – in this example, the local area.
- 3) If the heart-lung candidate declines the heart, then the OPO proceeds to the next geographic classification, such as Zone A, and offers the heart to all isolated, Status 1A heart candidate in that area. If this isolated heart candidate accepts the offer, then the OPO offers the lung to a lung candidate following the lung algorithm.
- 4) However, if the isolated heart candidate in step #3 declines the heart, then the OPO can offer the heart to the heart-lung candidate in Zone A.
- 5) The process, if necessary due to declines of heart or heart-lung offers, would continue until the OPO places the thoracic organs or discards them if they are deemed by transplant centers to be medically unsuitable for transplant.

Policy 3.7.7 states clearly that if a heart-lung candidate is suitable and eligible to receive a heart, then this individual must receive the lung from the same donor.

Attached to this memo is a user manual for complying with the Thoracic Committee's mandate for offering hearts to heart-lung candidates off the lung match run.

To read Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates), please click on the following link:

http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_9.pdf

If you have questions, please contact your regional administrator at 804-782-4800.
Thank you.

Please direct questions or comments regarding this decision to Vipra Ghimire, Policy Analyst for the Committee: ghimirev@unos.org or 804-782-4071.

Thank you.

cc: Steve Webber, MD, Vice-Chair, Thoracic Organ Transplantation Committee
Brian Shepard, Director of Policy, UNOS
Linda Gobis, Director of the Department of Evaluation and Quality, UNOS
Doug Heiney, Director of Administration and Management, UNOS
Roger Brown, Assistant Director, Organ Center, UNOS
Judy Martin, Assistant Director, Organ Center, UNOS

Breaking a Tie When Two Heart-Lung Candidates Are Eligible to Receive a Heart and a Lung in the Same Geographic Area

There is a possibility that two heart-lung candidates, who are in the same geographic area, could be eligible to receive that same set of organs, through a heart or heart-lung match run and a lung match run. The Lung Subcommittee had proposed waiting time as the tie-breaking factor, but waiting time is not an objective medical criterion. During the discussion on March 22, the Committee decided that the LAS would be a more objective medical criterion and all heart-lung candidates will have this score. UNOS staff will draft this policy.

The Committee discussed whether such a policy change needs public comment. The Committee recommended that the OPTN leadership consider methods for the application of constructs not addressed directly in policy. Thus, the Committee voted to submit the policy modification to the OPTN/UNOS Executive Committee, and it is this body's choice to recommend that the Committee submit the changes for public comment: 20-supported; 0-opposed; and, 0-abstained.

9. Summary of the Heart Subcommittee's Activities and Actions for the Thoracic Committee

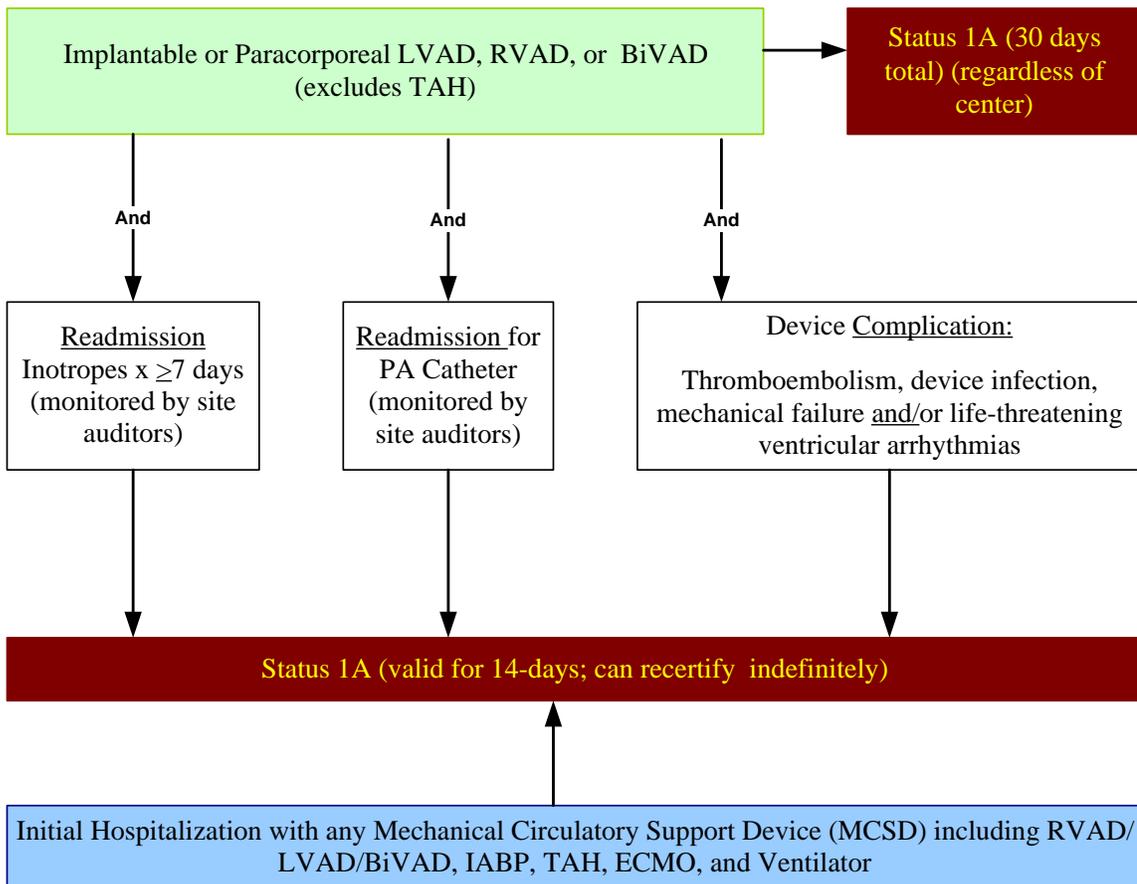
The Chair of the Heart Subcommittee provided the Committee an update of this group's activities. The Chair invoked comments submitted by the public to the "Discuss Comments Received on the Proposal to Clarify Adult Heart Status 1A Exception Language to Enable Consistent Interpretation of Policy and Reflect Current Programming in UNetSM" proposal. During the proposal's public comment cycle, some members of the thoracic transplant community expressed the need to improve the policy for candidates with ventricular assist devices (VAD).

The Committee reviewed the following concept (see diagram below) and commented as follows:

- 1) What data support the proposed diagram? For example, how many candidates with VADs receive transplants within 30 days of the VAD-Status 1A listing?
- 2) Should candidates implanted with VADs and who are medically stable receive time as Status 1A?
- 3) The device infection policy – Status 1A(b) – needs improvement as the language allows for subjective interpretation of infections. The policy should delineate between serious and

- superficial infections. Can UNOS staff provide data on the number of status justification forms submitted for device complications?
- 4) Perhaps all status justification forms submitted for thromboembolism should be submitted to the heart regional review board, i.e., treated as exceptions?
 - 5) The current heart medical urgency system may be disadvantaging the very sick.
 - 6) Should the type of device – temporary or long term – be better defined in policy?
 - 7) Can data from other registries assist in providing the data needed?

The Heart Subcommittee will discuss this proposal in more detail at its next Subcommittee meeting. The Committee encouraged this discussion as it is important, if possible, to develop a revised policy for candidates with mechanical circulatory support devices (MCSD) before the interim total artificial heart (TAH) policy expires on December 1, 2011.



Time as Status 1A for Candidates Implanted with Ventricular Assist Devices

The Committee discussed and decided that its intent – past and present – is that candidates implanted with VADs receive only 30 days of time at Status 1A – regardless of the number of centers where the individual is registered for transplant. The Committee voted that the language in the current policy is accurate – it is 30 days of Status 1A time per candidate, not per center: 20-supported; 0-opposed; and, 0-abstained.

Status Downgrade Policy

Should transplant centers be afforded a 24-hour time period, or a lesser amount of time, to record the change in a candidate's status – in particular, change in a Status 1A criterion? If twenty-four hours is ample time to make the change in a candidate's medical urgency status, and it would be inappropriate for a candidate to receive a heart offer due to a given criterion when that criterion is not current, then the policy needs to state this downgrade practice.

The Committee discussed shorter time periods, but decided that the 24-hour time period was appropriate as this is the time that the UNOS Department of Evaluation and Quality uses for policy downgrade compliance. The Committee voted in favor of the 24-hour downgrade policy, and requested that it be consistent for adult and pediatric heart policies: 20-supported; 0-opposed; and, 0-abstained.

Type of Blood Titer Value to Report in UNetSM for Candidates Who Are Eligible to Receive Hearts from Donors with any Blood Type: IgG versus IgM

Policy 3.7.8 (ABO Typing for Heart Allocation), excerpted below, does not state which type of titer value to use, and its programming does not accommodate entry of different types of titer values.

Policy 3.7.8 (ABO Typing for Heart Allocation)
[...]

A center may specify on the waiting list that a candidate is eligible to accept a heart from any blood type donor if one of the following conditions is met:

- (i) Candidate is in utero;
- (ii) Candidate is less than 1 year of age, and meets all of the following:
 - a. Listed at Status 1A or 1B, and
 - b. Current isohemagglutinin titer information for A and/or B blood type antigens reported in UNetSM.
- (iii) Candidate is greater than or equal to 1 year of age, and meets all of the following:
 - a. Is listed prior to age 2;
 - b. Is listed at Status 1A or 1B;
 - c. Has current isohemagglutinin titer level(s) less than or equal to 1:4 for A and/or B blood type antigens reported in UNetSM; and,
 - d. Has not received treatments within the prior 30 days that may have reduced titer values to 1:4 or less.

The Committee discussed requiring clinicians to enter the highest titer value, and not the type of titer value. The rationale for entering the higher titer value is so that the candidate does not receive an incompatible blood type heart that her or his body will reject. Mandating clinical behavior requires a policy change; so, the Committee voted in favor of modifying Policy 3.7.8 to include the phrase “enter the highest titer value.”

The Committee then discussed whether this change should undergo the public comment process, or whether the change meets the intent of the policy, and therefore, could receive approval by the OPTN/UNOS Executive Committee. If there is a good faith argument that the physician could use a lower titer value to list their patient, because that was the right thing to do for that candidate, then this policy change requires public comment. If there is no doubt that the higher

titer value is the one that was always intended, and that everyone should use, i.e., there is consensus in the community about the use of the highest titer value, then, the change is a policy clarification that the Committee can make through the OPTN/UNOS Executive Committee. The Committee commented that the change fits the latter scenario and voted to submit the policy change to the OPTN/UNOS Executive Committee: 20-supported; 0-opposed; and 0-abstained. (Also, anecdotally, the majority of laboratories provide only IgM values.) The intent of the policy is to identify patients with high titer antibody and preclude eligibility for transplantation for those patients.

The Committee commented that the ABO-incompatible policy needs to be revisited, and can be through the Heart Subcommittee.

10. Review Policy 3.7.13 (Status 1 Listing Verification)

Policy 3.7.13 references an incorrect title for Policy 3.7.3 and an incorrect medical urgency status – Status 1. The Department of Evaluation and Quality audits programs randomly and forwards policy non-compliance events to the Membership and Professional Standards Committee. The monitoring described in Policy 3.7.13 is not performed routinely by the OPTN.

A transplant center which has demonstrated noncompliance with the Status 1 criteria specified in Policy 3.7.3 (Primary Allocation Criteria) for heart candidate registration shall be audited on a random basis and any recurrence of noncompliance will result in a recommendation to the Membership and Professional Standards Committee and Executive Committee that further Status 1 heart candidate registrations from that center shall be subject to verification by OPTN contractor of the candidates' medical status prior to their Status 1 placement on the Waiting List for a period of one year.

The Committee commented that the OPTN already audits programs for policy compliance, and therefore, supported the deletion of this policy: 20-supported; 0-opposed; and, 0-abstained.

UNOS staff will request its General Counsel's advice on whether this deletion requires public comment.

11. Review of *in Utero* Waiting Time Policy

The following policy is not programmed in UNetSM, yet its textual appearance, i.e., no underlines leads the reader to believe that the policy is programmed in UNetSM. Current programming allows waiting time accrued while in utero to carry over upon birth, and not recommence as written. Should the programming change or should the policy language change?

3.2.1.7 In Utero Waiting Time. If an in utero candidate is not assigned a thoracic organ transplant prior to delivery on the basis of Policy 3.2.1.6, the candidate's waiting time will recommence from the time of birth with the candidate listed under the regular status code.

The Committee requested feedback from the OPTN/UNOS Pediatric Committee but commented that listing heart candidates *in utero* is not as prevalent today as it might have been about 20 years ago. Perhaps the goal should be to eliminate the policy. But, in the meantime, the Committee opined that the programming needed to match the policy, i.e., the waiting time needs to recommence at birth.

In the past decade, about 22 candidates were registered for transplant *in utero*, only one of which was listed in 2010. Therefore, the Committee asked UNOS staff to monitor manually each such registration, and inform the transplant program to remove the candidate upon his or her birth and re-list. While the fetus could be delivered via caesarean section for transplant at the 36-week gestation period, the clinical practice today is to favor the evaluation of the borne candidate prior to listing for transplant.

The Committee will await the Pediatric Committee's opinion before taking further action on this policy or correcting its programming, the latter of which would only happen after the Chrysalis project.

12. OPTN Data Analysis: Preliminary Report on Collection of Mechanical Circulatory Support Device (MCSD) Data at Waiting List Removal

The Committee reviewed the data prepared by UNOS staff (see Exhibit C). The Committee will continue to monitor the results of this data collection effort. The OPTN began collecting these data in January, 2011. These data are already providing useful information about candidates who ever had mechanical circulatory support device data implanted, information that the Committee will use to develop a heart allocation score.

The Committee requested that the removal page should include text that balloon pump data are not collected but ECMO data are.

If the removal reason is "lost to follow-up," should UNOS program the collection of MCSD data on the removal page? The data collected due to this reason may not be accurate. The Committee suggested not collecting these MCSD data.

13. OPTN Data Analysis: Monitoring of Data Since the Implementation of the Pediatric Lung Priority Policy

The Committee reviewed the data prepared by UNOS staff (see Exhibit D). The Committee will continue to monitor the results of this data collection effort. The OPTN began collecting these data on September 12, 2010.

Participants

1. Mark Barr
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13. Craig Selzman
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15. Sangeeta Bhorade
16. Joe Rogers
17. David Vega
18. Linda Ohler
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20. Ken McCurry (by phone)
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