

**OPTN/UNOS Pediatric Transplantation Committee  
Report to the Board of Directors  
June 1-2, 2015  
Atlanta, Georgia**

**Eileen Brewer, MD, Chair  
William Mahle, MD, Vice Chair**

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*This report reflects the work of the OPTN/UNOS Pediatric Transplantation Committee from October 2014 through April 2015.*

**Action Items**

1. Proposal to Automatically Transfer Pediatric Classification for Registered Liver Candidates Turning 18

*Public Comment: January – March, 2015*

Most organ candidates automatically retain pediatric priority if they turn 18 while waiting for a transplant<sup>1,2,3,4</sup>. Under current liver policy, if a candidate turns 18 years old while waiting for an organ, the candidate does not automatically retain pediatric classification. Rather the transplant program is responsible for requesting a pediatric classification exception from the Regional Review Board (RRB). Additionally, if a candidate was ever registered as a pediatric patient and was subsequently removed from the waiting list, but returns to the waiting list as an adult, the transplant program has the ability to apply to the RRB for a pediatric classification exception for this candidate. Pediatric classification for an affected candidate operationally means prioritization as a 12 to 17 year old on the liver match run. Both of these exception processes are inconsistent with allocation policy for most other organs.

The RRBs have been consistent in their decision-making on these applications; candidates that turn 18 while waiting for liver transplant have been approved for pediatric classification, while adult candidates that were ever registered as pediatric candidates but have since been removed and reregistered were denied. The Pediatric Transplantation Committee (hereafter, the Committee) believes that current policy historically has not been well-understood in the community. Requests to the RRBs have only recently become more frequent. Of the 15 exceptions that have been requested since May 24, 2004, 12 were requested after the OPTN published an informational article on June 13, 2013 regarding current policy.

The Committee proposes that pediatric classification be automatically transferred for all candidates who turn 18 while waiting for a liver transplant. Further, the Committee seeks to eliminate the pediatric classification exception process for an adult candidate who was ever

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<sup>1</sup> Policy 6.1: Status Assignments, Organ Procurement and Transplantation Network Policies

<sup>2</sup> Policy 8.5.H: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%, Organ Procurement and Transplantation Network Policies

<sup>3</sup> Policy 8.5.I: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 20% but Less Than 35%, Organ Procurement and Transplantation Network Policies

<sup>4</sup> Policy 11.4.A: Kidney-Pancreas Waiting Time Criteria for Candidates Less than 18 Years Old, Organ Procurement and Transplantation Network Policies

on the waiting list prior to age 18 but has since been removed and reregistered. These changes would make liver policy consistent with that of most other organs in regards to how candidates turning 18 while waiting are classified.

This proposal seeks to increase pediatric access to transplant, which contributes to Goal 2 of the OPTN Strategic Plan and the charge of the National Organ Transplant Act (NOTA) and the Final Rule that the OPTN develop equitable allocation policy that especially considers the unique health care needs of children<sup>5,6</sup>. Eliminating the pediatric classification exception process for liver candidates also promotes the efficient management of the OPTN, which is Goal 6 of the OPTN Strategic Plan.

Public comment for this proposal was favorable. All of the OPTN/UNOS Regions approved of this proposal as part of the non-discussion agenda. The Committee voted to approve the proposed language without modification on March 18, 2015 (9-Support, 0-Oppose, 0-Abstentions).

**RESOLVED, that Policies 9.1 (Status and Score Assignments), 9.1.B (Pediatric Status 1A Requirements), 9.1.C (Pediatric Status 1B); 9.3.A (Pediatric Status Exception for Candidates 18 Years or Older) are modified as set forth in Exhibit M, effective September 1, 2015.**

2. Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws

*Public Comment: [January – March, 2015](#)*

The National Organ Transplant Act (NOTA) requires that the OPTN “recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children.”<sup>7</sup> Although pediatric transplantation is an accepted subspecialty within the field of transplantation, the current OPTN/UNOS Bylaws do not include any requirements in order for programs to be approved to perform pediatric transplants. As early as 1993, the Membership and Professional Standards Committee (MPSC) has sought guidance from the Pediatric Transplantation Committee in establishing pediatric requirements so it could better assess key personnel applications. In 2012, the Board of Directors included developing separate program requirements for pediatric programs as a key initiative under Goal 4: Promote Patient Safety of the OPTN Strategic Plan.

To fulfill this key initiative, the Committee proposes that a designated transplant program must have an approved pediatric component in order to perform transplants in patients less than 18 years old. To be approved for a pediatric component, a program must identify a qualified primary pediatric surgeon and a qualified primary pediatric physician to serve as key personnel. The Committee has involved important stakeholders throughout the development of these proposed Bylaws, including the OPTN/UNOS organ-specific committees, professional societies, and the community.

After carefully considering feedback received during public comment, the Committee voted to approve the proposed Bylaws without modification (16-Support, 0-Oppose, 0-Abstain). The Committee believes this proposal fulfills the long-standing need to establish pediatric requirements in the OPTN/UNOS Bylaws, while appropriately balancing the competing

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<sup>5</sup> Code of Federal Regulations, Organ Procurement and Transplantation Network, title 42, sec. 121.8.

<sup>6</sup> 42 USC Sec. 274 (b)(2)(M).

<sup>7</sup> 42 USC Sec. 274 (b)(2)(O).

interests of quality of care, including patient safety, and access to transplantation for pediatric patients.

**RESOLVED**, that additions and changes to Appendix E.2 (Primary Kidney Transplant Surgeon Requirements), Appendix E.3 (Primary Kidney Transplant Physician Requirements), Appendix E.5 (Kidney Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), Appendix F.2 (Primary Liver Transplant Surgeon Requirements), Appendix F.3 (Primary Liver Transplant Physician Requirements), Appendix F.6 (Liver Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), Appendix G.2 (Primary Pancreas Transplant Surgeon Requirements), Appendix G.3 (Primary Pancreas Transplant Physician Requirements), Appendix G.8 (Pancreas Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), Appendix H.2 (Primary Heart Transplant Surgeon Requirements), Appendix H.3 (Primary Heart Transplant Physician Requirements), Appendix H.4 (Heart Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), Appendix I.2 (Primary Lung Transplant Surgeon Requirements), Appendix I.3 (Primary Lung Transplant Physician Requirements), and Appendix I.4 (Lung Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), modified as set forth in Exhibit A, are hereby approved, effective pending implementation and notice to members.

### Committee Projects

#### 3. Pediatric Lung Allocation Policy Review

*Public Comment: August - October, 2015 (Estimated)*

*Board Consideration: December, 2015 (Estimated)*

The Pediatric Transplantation Committee is collaborating with the Thoracic Organ Transplantation Committee to conduct a comprehensive review of pediatric lung allocation policy to identify any opportunities for improving pediatric access to transplant. For more information, see the **OPTN/UNOS Thoracic Organ Transplantation Committee Report to the Board**.

### Committee Projects Pending Implementation

#### 4. Proposal to Change Pediatric Heart Allocation Policy

*Public Comment: March – June, 2013*

*Board Approval: June 24, 2014*

*Implementation: October, 2015 (Estimated)*

The Board approved four modifications to pediatric heart allocation policy on June 24, 2014:

- Redefine pediatric heart Status 1A and 1B criteria.
- Increase isohemagglutinin titers needed to qualify for ABO-incompatible heart offers to 1:16 or less for candidates who are one year of age or older but registered before their second birthday.
- Improve allocation priority of urgent heart candidates registered before their first birthday, as well as candidates eligible to receive ABO-incompatible heart offers.
- Eliminate in utero heart registrations.

These changes seek to reduce waiting list mortality, particularly among pediatric heart Status 1A and 1B candidates. Programming is scheduled to begin in October, 2015.

### **Implemented Committee Projects**

5. Pediatric Liver: Remove ICU Requirements and Modify Hepatoblastoma Requirements

*Public Comment: March – June, 2011 (ICU proposal)*

*Public Comment: March – June, 2011 (Hepatoblastoma proposal)*

*Board Approval: November 15, 2011*

*Implementation: March 25, 2015*

The Board approved these projects individually on November 15, 2011. They were bundled for the purposes of programming and implementation, which was completed on March 25, 2015. The Committee will evaluate whether the implementation of the proposals achieved the intended outcomes in the spring of 2017.

6. Evaluation of ABO-Incompatible Pediatric Heart Policy

*Board Approval: September 20, 2006*

*Implementation: November 22, 2010*

The Committee continues to monitor ABO-incompatible pediatric heart policy, most recently at its in-person meeting on April 14, 2015. According to the currently implemented policy, Status 1A and 1B candidates less than two years old at listing who meet the eligibility requirements set forth in Policy 5.3.C, including in utero candidates for whom blood type is unknown, may accept a heart from a donor of any blood type. The Committee found that:

- The majority of candidates willing to accept an ABO-incompatible heart were Status 1A infants less than one year old at listing.
- Among candidates willing to receive an ABO-incompatible donor heart, the majority actually received an ABO-identical heart.
- The vast majority of ABO-incompatible transplants were performed in Status 1A recipients less than one year old at both listing and transplant.
- Results of ABO-incompatible heart transplants, performed mostly in pediatric patients less than one year old, suggest comparable patient survival with ABO-identical or compatible transplants.
- Of recipients of ABO-incompatible hearts who died within one year of transplant, titer values prior to time of death were low (less than 1:4).

Of the 891 registrations less than two years old at listing that met the eligibility requirements, 524 (58.8%) were not willing to accept an incompatible blood type at time of listing. The Vice Chair confirmed that the OPTN does not collect data on the listing titers for these candidates to understand if more are candidates are clinically-eligible than are willing.

The Committee will continue to monitor the new ABO-incompatible heart policy passed by the Board in June, 2014. One Committee member, a pediatric cardiologist, said he is anxious for implementation and anticipates better organ offers and post-transplant outcomes. The implementation of this policy is pending programming, which is scheduled to begin in October, 2015.

7. Evaluation of Broader Sharing of Lungs from 0-11 Year Old Donors and a Simple Priority System for 0-11 Year Old Lung Candidates

*Board Approval: [June 20, 2008](#)*

*Implementation: September 12, 2010*

At its recent in-person meeting, the Committee also reviewed monitoring data on pediatric lung allocation policy. Implemented on September 12, 2010, this policy established broader sharing of 0-11 year old deceased donor lungs, as well as a simple priority system for 0-11 year old candidates. The Committee learned that:

- Following policy implementation, waiting list death and transplant rates increased significantly for pediatric candidates ages 6-11 and 12-17.
- Most recipients received lung transplants from donors in their same age group.
- Following policy implementation, patient survival within two years of transplant among pediatric recipients was not adversely affected.

Several Committee members expressed concern at the increased waiting list death rate post-implementation. The Statistician explained that the actual number of deaths on the waiting list decreased post-policy, but so did the time candidates spent on the waiting list, which contributes to an increased rate. The Chair asserted that increased access to transplantation, the intended goal of the policy, also contributes to shorter waiting times and increased transplant rates. One Committee member, a pediatric pulmonologist, shared that the demographic of the waiting list at his program has changed since this policy was implemented. He estimated that over half of the pediatric patients on the waiting list at his center are on extracorporeal membrane oxygenation (ECMO) or mechanical ventilation, compared to a quarter of patients six years ago. These patients are at higher risk of poor waiting list outcomes.

The Committee continues to collaborate with the Thoracic Organ Transplantation Committee on its proposed pediatric lung allocation policy, which will be released for public comment in August, 2015. The Committee hopes the new broader sharing sequence for child and adolescent donor lungs included in this proposal will further contribute to improved outcomes for pediatric lung candidates.

8. Evaluation of Open Variance for Segmental Liver Transplantation

*Public Comment: [March – June, 2011](#)*

*Board Approval: [November 2011](#)*

*Implementation: February 2012*

At the recommendation of the Board of Directors, the Committee tabled discussion on their proposed split liver policy in favor of monitoring data from OPOs and regions participating in the Board-approved segmental liver variance. Since 2012, the Committee has routinely reviewed match run data to identify the number of pediatric candidates prioritized above the second recipients of split livers but who did not receive the livers on the original match run within the OPO or region. The Committee most recently reviewed this data at its in-person meeting on April 14, 2015.

From the beginning of the variance through December 31, 2014, 57 deceased donors were transplanted as splits at four OPOs and one Region. After limiting the analysis to split liver transplants where one segment was transplanted into an adult recipient and the other into a pediatric recipient at the same or an affiliated center, there were 24 donors. An examination of the match run data for these 24 donors found the following:

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- For 20 donors, the pediatric candidate was the index patient and allocation of the remaining segment appeared to follow Policy 9.6.A: *Segmental Transplant and Allocation of Liver Segments*.
- For the remaining 4 donors, where the adult candidate was the index patient, only one remaining segment appeared to follow Policy 9.8.A: *Open Variance for Segmental Liver Transplantation*. In this instance, 7 pediatric candidates were bypassed above the pediatric acceptor. Of these, six were not waiting at the same or an affiliated center, and one required a multi-organ transplant at the same center.

Only one of the split liver transplants performed between the implementation dates of the variance and December 31, 2014 has been allocated using Policy 9.8.A. The Committee finds that a voluntary variance is not having the intended outcome and will consider this summer whether to continue work on this project under the new Strategic Plan.

### Review of Public Comment Proposals

The Committee reviewed 8 of the proposals released for public comment from September – December 2014 and January – March 2015.

#### 9. Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs) (VCA Committee)

After a presentation of the proposal, the Committee verified that special consideration would be taken in the donor authorization process for families of potential pediatric donors. The Committee also confirmed that there have not yet been any pediatric VCA transplants in the United States and few internationally. Some programs in the US currently have IRB-approved protocols in place to perform pediatric VCA transplants. The Committee also discussed the potential benefit of abdominal wall VCAs to pediatric liver recipients in the future.

#### 10. Proposal for Informed Consent for Kidney Paired Donation (Kidney Transplantation Committee)

After a presentation of the proposal, the Committee expressed support, especially to inform patients of the logistics of KPD programs. After brief discussion, Committee members were satisfied that any additional administrative burden would be offset by enhancements to patient and donor safety and consistency in consent rules for all KPD programs.

#### 11. Improving the OPTN Policy Development Process (Executive Committee)

After a presentation of the proposal, the Committee expressed support without further discussion.

#### 12. Proposal to Establish a QAPI Requirement for Transplant Hospitals and OPOs (Membership and Professional Standards Committee)

After a presentation of the proposal, the Committee expressed concern that alignment between OPTN and CMS QAPI requirements cannot be maintained after implementation. After discussion, they suggested that the proposed QAPI Bylaw specifically reference CMS, to provide assurance that the OPTN Bylaw would always reflect CMS requirements.

#### 13. Definition of a Transplant Hospital (Membership and Professional Standards Committee)

Although generally supportive of the proposal, the Committee wanted to understand how it would impact a pediatric hospital that is affiliated with an adult hospital and shares an OPTN/UNOS membership. In most instances under the proposed Bylaw, such a pediatric hospital would be required to have a separate program designation. However, the



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Committee learned that the MPSC historically has viewed applications in this way, so likely pediatric hospitals that are geographically separate from the affiliated adult hospital already have a separate membership. It is not uncommon for these hospitals to share the same key personnel. The Committee asked for an estimate of how many pediatric hospitals currently in existence would have to apply for new membership. While that is difficult to estimate at this time, the implementation plan for this proposal includes a study that will answer that question. The Committee was assured that this will be a phased implementation that will be cautious of protecting access to transplantation.

### 14. Proposed Membership and Personnel Requirements for Intestine Transplant Programs (Liver and Intestinal Organ Transplantation Committee)

After a presentation of the proposal, the Chair asked if patients currently registered at centers that will not meet requirements will have to travel distantly to transfer care to a qualifying center. The Liver Committee Representative said that he did not believe many centers currently performing intestine transplants will close. Most centers on the west coast will qualify, and those that may close on the east coast are in proximity to others that will likely qualify. The Chair affirmed the importance of a dietitian being part of the intestine transplant team but acknowledged that the transplant volumes do not justify a dedicated intestine program dietitian.

### 15. ABO Blood Type Determination, Reporting, and Verification Policy Modifications (Operations and Safety Committee)

After a presentation of the proposal, one Committee member verified that the recovering surgeon does not have responsibility for verifying the recipient information in the proposed policy. The Operations and Safety Committee Liaison confirmed that this reflects a modification to the proposal that was presented to the Board in November 2014. Another Committee member, who is the parent of a pediatric recipient, said that the proposal was not costly and not likely burdensome in terms of time and effort to complete the required safety measures. She said that if it saves even one life it is worth it.

### 16. Membership Requirements for VCA Transplant Programs (VCA Committee)

After a presentation of the proposal, the Pediatric Committee Chair commented that the VCA Committee likely experienced similar challenges while developing case volume requirements as the Pediatric Committee did for its Bylaws proposal. She asked how the VCA Committee Chair would answer the question of how the case volume requirements were developed and defend against the claim that the case volumes are arbitrary. The VCA Committee Chair acknowledged similar challenges but said that case volume requirements were developed through the clinical consensus of experienced reconstructive surgeons on the Committee. If the intestine program requirements (currently out for public comment) are passed by the Board in June, one Committee member expressed interest in allowing the primary intestine surgeon to serve as the primary abdominal wall surgeon.

## **Other Committee Work**

### 17. General Principles for Pediatric Allocation

Last November, the Board approved the white paper, "[Ethical Principles of Pediatric Organ Allocation](#)." Dr. Peter Reese, Chair of the Ethics Committee, and Dr. Ken Lieberman, Region 2 Representative for the Pediatric Transplantation Committee, have created an instructional podcast to assist all Committee members in effectively using the content of the white paper when developing and monitoring policy. The podcast will be available on May 11, 2015.

## OPTN/UNOS Pediatric Transplantation Committee

### **Meeting Summaries**

The Committee held meetings on the following dates:

- October 1, 2014
- October 15, 2014
- November 19, 2014
- December 17, 2014
- January 21, 2015
- February 18, 2015
- March 18, 2015
- April 14, 2015

Meeting summaries for this Committee are available on the OPTN website at:  
<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=15>.