

Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws

*Pediatric Transplantation Committee
December 1-2, 2015
Board of Directors Meeting*

The Problem

- NOTA requires the OPTN to recognize the differences between children under the age of 18 and adults and “adopt criteria, policies and procedures that address the unique health care needs of children.”
- Pediatric training and experience are not currently required at programs that perform pediatric transplants.
- Membership requirements are among most fundamental of criteria OPTN could adopt to recognize these unique needs.

Strategic Plan Alignment

Goal 3: Improve Outcomes

Goal 4: Promote Patient Safety

Establish pediatric membership requirements

Proposed Solution

- Require programs to **have an approved pediatric component** to perform transplants in patients less than 18
- Approved = must identify a **primary pediatric surgeon** and a **primary pediatric physician** to **serve as key personnel**
- Requirements only apply to pediatric key personnel, not all surgeons and physicians who care for pediatric patients

Recent History of Proposal

- 2.5 year development
- Presented to the Board of Directors in June 2015
 - Failed to pass by a majority of the Board (19-Y,16-N,3-A)
 - Achieved consensus on need to recognize pediatrics as a subspecialty through membership requirements
 - Board direction to Committee: Stratify case requirements
- Resubmitted proposal for public comment in August 2015

Pediatric Kidney Component Qualifying Criteria

Pediatric Primary Kidney Surgeon

- Meet current Bylaw requirements for the Primary Kidney Surgeon
- 10 kidney transplants in patients less than 18 years old, including 3 transplants in patients less than 6 years old or less than 25 kg

Pediatric Primary Kidney Physician

Meet current Bylaw requirements for the Primary Kidney Physician and completed at least one of the following training or experience pathways:

- E.3.C (Three-year Pediatric Nephrology Fellowship Pathway)
- E.3.D (Twelve-month Pediatric Transplant Nephrology Fellowship Pathway)
- E.3.E (Combined Pediatric Nephrology Training and Experience Pathway)

Pediatric Liver Component Qualifying Criteria

Pediatric Primary Liver Surgeon

- Meet current Bylaw requirements for the Primary Liver Surgeon
- 15 liver transplants in patients less than 18 years old, including 8 transplants in patients less than 6 years old or less than 25 kg

Pediatric Primary Liver Physician

- Meet current Bylaw requirements for the Primary Liver Physician and completed at least one of the following training or experience pathways:
- Three-year Pediatric Gastroenterology Fellowship Pathway (F.3.C)
 - Pediatric Transplant Hepatology Fellowship Pathway (F.3.D)
 - Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway (F.3.E)

Pediatric Heart Component Qualifying Criteria

Pediatric Primary Heart Surgeon

- Meet current Bylaw requirements for the Primary Heart Surgeon
- 8 heart transplants in patients less than 18 years old, including 4 transplants in patients less than 6 years old or less than 25 kg

Pediatric Primary Heart Physician

- Meet current Bylaw requirements for the Primary Heart Physician
- Board-certified in pediatric cardiology
- Cared for 8 heart transplant patients less than 18 years old, including 4 patients less than 6 years old or less than 25 kg

Pediatric Lung Component

Qualifying Criteria (Proposal for Public Comment)

Pediatric Primary Lung Surgeon

- Meet current Bylaw requirements for the Primary Lung Surgeon
- 4 lung transplants in patients less than 18 years old, including 1 transplant in a patient less than 12 years old or less than 40 kg

Pediatric Primary Lung Physician

- Meet current Bylaw requirements for the Primary Lung Physician
- Board-certified in pediatric pulmonary medicine
- Cared for 4 lung transplant patients less than 18 years old, including 1 patient less than 12 years old or less than 40 kg

Pediatric Lung Component

Qualifying Criteria (Deleted post-Public Comment)

Pediatric Primary Lung Surgeon

- Meet current Bylaw requirements for the Primary Lung Surgeon
- 4 lung transplants in patients less than 18 years old, including 1 transplant in a patient less than 12 years old or less than 40 kg

Pediatric Primary Lung Physician

- Meet current Bylaw requirements for the Primary Lung Physician
- Board-certified in pediatric pulmonary medicine
- Cared for 4 lung transplant patients less than 18 years old, including 1 patient less than 12 years old or less than 40 kg

Conditional Approval for Pediatric Component

- Conditional approval for 24 months, if
 - Either primary surgeon or primary physician meets criteria and
 - Other meets all the requirements and has at least half the required transplants in patients <18 years old:

Kidney

- 5, including 1 in a patient <6 years old or <25 kg

Liver

- 7, including 2 in patients <6 years old or <25 kg

Heart

- 4, including 1 in a patient <6 years old or <25 kg

- Possible additional 24 months for substantial progress

Delayed implementation (~3y) + Conditional Approval (2-4y) = Possible 5-7y to qualify for ped component

Public Comment Themes

Thoracic Requirements

- Proposed requirements not appropriate for pediatric lung
 - Less than 3% (N = 255) of all pediatric transplants over last five years
 - Stratification did not represent adequate experience in <12 and restricts access for adolescents
 - Lack of consensus on limiting number of centers to optimize outcomes
 - **Removed pediatric lung component requirements**
- Proposal does not significantly restrict access to heart transplant for adolescents
 - **In 2010-2014, only 32 of 588 adolescent heart transplants (TX) were done in primarily adult centers (defined as centers with no heart TX in <12 yo):**
 - 12 TX performed at 6 centers >35 miles from pediatric center; only 4 TX at 3 centers >200 miles
 - Represent <1% of the 1,918 pediatric heart transplants in 2010-2014
 - **Did not find evidence to support that proposal negatively impacts access**

Emergency Pediatric Membership Exception

- Added to current proposal in response to public comment
- Liver or heart program without pediatric component may register candidate <18yo to prevent imminent threat to health and safety
- Must submit exception request to OPTN within 72 hours of listing that demonstrates:
 - Transplant necessary to prevent imminent threat
 - Medically inadvisable or commercially impractical to transport
 - Candidate is pediatric Status 1A
- MPSC will retrospectively review
- Approval of request does not grant permanent approval of a pediatric component

Tiers

- Considered but rejected tiered requirements by age for children and adolescents
 - Less likely to meet special needs of adolescents
- Diversity within adolescent transplant
 - Varied rates of growth and development; delayed with chronic disease
 - Adolescents at programs not meeting criteria: less likely to have congenital or chronic conditions
 - If age tiers, key personnel at predominantly adult transplant centers interested in transplanting adolescents should have training and experience necessary to care for any adolescent candidate, including those with congenital or chronic conditions

Exclusion of Adolescents

- Committee rejects limiting requirements to programs transplanting younger pediatric patients (0-Yes, 17-No, 0-Abstentions)
- Inconsistent with NOTA definition of children <18 years
- Opposed to redefining pediatrics as the care of pre-adolescent children
- Few adolescents 12-17 years with restricted access from proposed Ped Bylaws

Access to Transplant for Adolescents (12-17yo)

Jan 2010-Dec 2014

Adult Ctr = at least one TX in 12-17 yo, but no TX in <12 yo

Ped Ctr = meets pediatric component volume criteria

Organ	All Ctrs With Any Ped TX in 12-17 yo		Adult Ctrs >35 miles from Ped Ctr		Adult Ctrs >200 miles from Ped Ctr	
	#Ctrs	#TX	#Ctrs	#TX	#Ctrs	#TX
Kidney	143	1,994	10	29*	3	15*
Liver	68	499	3	3	0	0
Heart	65	588	6	12	3	4

*13 adolescent kidney TX at one center in Albuquerque

Post-Public Comment Outreach

Thoracic
Committee

Minority
Affairs
Committee

MPSC

Executive
Committee

Board
Members

ASTS

What Members will Need to Do

- If applying for a pediatric component:
 - Obtain and complete application
- If not applying for a pediatric component:
 - Notify OPTN
 - Follow transition plan to remove pediatric candidates from waiting list

Overall Project Impact

Product

Bylaw Changes

Target Population Impact:

Pediatric Transplant Candidates and Recipients, Transplant Programs that Perform Pediatric Transplants

Total IT Implementation Hours

940/8,730

Total Overall Implementation and Maintenance Hours

2,455/15,065

Resolution 11 (page 60)

- **RESOLVED**, that changes to Appendices E.2.C (Alternative Pathway for Predominantly Pediatric Programs), E.3.F (Alternative Pathway for Predominantly Pediatric Programs), E.5 (Kidney Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), F.2 (Primary Liver Transplant Surgeon Requirements), F.3.C (Alternative Pathway for Predominantly Pediatric Programs), F.4.F (Alternative Pathway for Predominantly Pediatric Programs) F.7 (Liver Transplant Programs that Register Candidates Less than 18 Years Old), G.8 (Pancreas Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), H.2.D (Alternative Pathway for Predominantly Pediatric Programs), H.3.C (Alternative Pathway for Predominantly Pediatric Programs), H.4 (Heart Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), I.4 (Lung Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), L.17 (Interviews), and L.18 (Hearings), as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.