Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws

Pediatric Transplantation Committee
June 2015
The Problem

- NOTA requires the OPTN to “recognize the differences in health and in organ transplantation issues 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 not currently required at programs that perform pediatric transplants.
## Strategic Plan Alignment

<table>
<thead>
<tr>
<th>Goal 3: Improve Patient Survival</th>
<th>• Establish pediatric membership requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal 5: Promote Patient Safety</td>
<td></td>
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</tbody>
</table>
Proposed Solution

- Establish a pediatric component that requires key personnel to demonstrate pediatric training and experience

<table>
<thead>
<tr>
<th>Quality</th>
<th>Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Programs performing any transplants in &lt;18 year old</td>
<td>• Lifetime experience</td>
</tr>
<tr>
<td>• Organ-specific case volumes</td>
<td>• No stratifications</td>
</tr>
<tr>
<td>• Requires currency (last 2 yrs)</td>
<td>• Conditional Pathway</td>
</tr>
<tr>
<td>• No exceptions</td>
<td>• Delayed implementation</td>
</tr>
</tbody>
</table>
Pediatric Kidney Component
Qualifying Criteria

<table>
<thead>
<tr>
<th>Pediatric Primary Kidney Surgeon</th>
<th>Meet current Bylaws for Primary Kidney Surgeon (minimum case volume 30)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12 Kidney transplants in patients younger than 18</td>
</tr>
<tr>
<td>Pediatric Primary Kidney Physician</td>
<td>Meet Bylaws requirements outlined in one of the following sections of Appendix E (Membership and Personnel Requirements for Kidney Transplant Programs), Section E.3 (Primary Kidney Transplant Physician Requirements):</td>
</tr>
<tr>
<td></td>
<td>• 3.C (Three-year Pediatric Nephrology Fellowship Pathway)</td>
</tr>
<tr>
<td></td>
<td>• 3.D (Twelve-month Pediatric Transplant Nephrology Fellowship Pathway)</td>
</tr>
<tr>
<td></td>
<td>• 3.E (Combined Pediatric Nephrology Training and Experience Pathway)</td>
</tr>
</tbody>
</table>
# Pediatric Liver Component Qualifying Criteria

<table>
<thead>
<tr>
<th>Position</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pediatric Primary Liver Surgeon</strong></td>
<td>• Meet current Bylaws for Primary Liver Surgeon (minimum case volume 45)</td>
</tr>
<tr>
<td></td>
<td>• 18 liver transplants in patients younger than 18</td>
</tr>
<tr>
<td><strong>Pediatric Primary Liver Physician</strong></td>
<td>Meet Bylaws requirements outlined in one of the following sections of Appendix F (Membership and Personnel Requirements for Liver Transplant Programs), Section F.3 (Primary Liver Transplant Physician Requirements):</td>
</tr>
<tr>
<td></td>
<td>• 3.C (Three-year Pediatric Gastroenterology Fellowship Pathway)</td>
</tr>
<tr>
<td></td>
<td>• 3.D (Pediatric Transplant Hepatology Fellowship Pathway)</td>
</tr>
<tr>
<td></td>
<td>• 3.E (Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway)</td>
</tr>
</tbody>
</table>
# Pediatric Heart Component Qualifying Criteria

| **Pediatric Primary Heart Surgeon** | • Meet current Bylaws for Primary Heart Surgeon (minimum case volume 20)  
• 8 heart transplants in patients younger than 18 |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| **Pediatric Primary Heart Physician** | • Meet current Bylaws requirements for Primary Heart Physician  
• Care for 8 heart transplant patients younger than 18 years of age  
• Has certification in pediatric cardiology by American Board of Pediatrics |
# Pediatric Lung Component

## Qualifying Criteria

<table>
<thead>
<tr>
<th>Pediatric Primary Lung Surgeon</th>
<th>• Meet current Bylaws for Primary Lung Surgeon (minimum case volume 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• 4 lung transplants in patients younger than 18</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pediatric Primary Lung Physician</th>
<th>• Meet current Bylaws requirements for Primary Lung Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Either this individual or another member of lung transplant team is certified by American Board of Pediatrics in pediatric pulmonary medicine</td>
</tr>
</tbody>
</table>
Public Comment Themes and Supporting Evidence in Response
Should Not Define Pediatric as <18 Years Old

- NOTA defines child as less than 18 years old
- Consistent with CMS and American Academy of Pediatrics (AAP)
- Growth and development continue through adolescence
- Underlying diseases different for children vs. adults
- Alternative definition could compromise priority in allocation for older pediatric candidates
Lack Evidence of a Current Patient Safety Concern

- Membership requirements most fundamental of OPTN criteria
- Primary surgeon and primary physician integral to transplant program leadership, share responsibility for long-term outcomes
- Higher volume centers have better long term graft and patient survival for pediatric kidney, liver and heart
Lack Evidence to Support Proposed Caseload Requirements

- Developed through clinical consensus of pediatric transplant experts
- Case volume requirements are a basic demonstration of experience, not outcomes
- Membership criteria for a pediatric component are intended to demonstrate a baseline of experience in pediatrics
- Significantly better graft and patient survival for pediatric KI, LI, and HR transplants performed at high versus low volume programs
Adjusted Hazard Ratio of Graft Loss and Death Within 5 Years for Pediatric Kidney Transplants, 2000-2010

Adjusted Hazard Ratio of Graft Loss and Death Within 5 Years for Pediatric Liver Transplants, 2000-2010

Squares represent the hazard ratios; lines represent the 95% confidence intervals

Notes: Low volume centers: centers performing <18 pediatric liver transplants in 2000-2010; High volume centers: centers performing 18+ pediatric liver transplants in 2000-2010; Hazard ratio >1 indicates worse survival.
Need to Stratify Caseloads

- Initial proposal – too restrictive
  - Kidney surgeon – 12 cases, 6 in children <20kg
  - Liver surgeon – 18 cases, 9 in children <12 y/o, 5 technical variants

- Impossible to achieve consensus if caseloads stringent

- Would adversely impact access

- Committee response
  - Eliminate age/weight stratifications
  - Eliminate time constraints on experience
  - Maintain currency requirement
Proposal Limits Access

Number of Pediatric Transplants at Centers Meeting the Proposed Pediatric Volume Criteria, 1/1/05-7/31/14

- Adults and pediatric patients, especially in sparsely populated areas, have to travel to designated transplant centers

<table>
<thead>
<tr>
<th>Organ</th>
<th>Transplants at Centers Meeting the Proposed Criteria (N)</th>
<th>% of Total Pediatric Transplants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney</td>
<td>7,479</td>
<td>98.4</td>
</tr>
<tr>
<td>Liver</td>
<td>5,207</td>
<td>97.0</td>
</tr>
<tr>
<td>Heart</td>
<td>3,366</td>
<td>97.8</td>
</tr>
<tr>
<td>Lung</td>
<td>472</td>
<td>92.5</td>
</tr>
</tbody>
</table>
Supportive Public Comment

- Children are different from adults, with a variety of unique needs that require subspecialty care (N=28)
- Promotes quality of care and safety (N=23)
- Proposal is balanced and has little impact on access to care (N=13)
- Requirements need to cover all patients <18 years old (N=10)
- Proposal is long overdue and contributes to the transparency of the OPTN (N=8)
Post-Public Comment Outreach

- ASTS
- AST
- OPTN/UNOS Board
What Members will Need to Do

- If applying for a pediatric component:
  - Attend webinar
  - Obtain and complete application
  - Notify OPTN of any personnel changes

- If not applying for a pediatric component:
  - Notify OPTN
  - Follow transition plan to remove pediatric candidates from waiting list
# Overall Project Impact

<table>
<thead>
<tr>
<th>Product</th>
<th>Bylaws</th>
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</table>

**Target Population Impact:** *Pediatric Transplant Candidates and Recipients*

<table>
<thead>
<tr>
<th>Total IT Implementation Hours</th>
<th>1,655/16,680</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Total Overall Implementation Hours</th>
<th>2,230/23,685</th>
</tr>
</thead>
</table>

![Bar Chart](chart.png)
Board Policy Group Recommendation

- Discussion agenda, approve
Resolution 11 (page 47)

RESOLVED, that changes and additions 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), are modified as set forth in Exhibit A of the Pediatric Transplantation Committee’s report to the Board, effective pending implementation and notice to members.
Unadjusted Kaplan-Meier Survival by Center Volume*
for Pediatric Kidney Transplants, 1/1/95-12/31/10

*Low volume: Ctrs with <12 transplants in 1995-2010;
High volume: Ctrs with 12+ transplants in 1995-2010
Unadjusted Kaplan-Meier Survival by Center Volume* for Pediatric Liver Transplants, 1/1/95-12/31/10

*Low volume: Ctrs with <18 transplants in 1995-2010; High volume: Ctrs with 18+ transplants in 1995-2010
Unadjusted Kaplan-Meier Survival by Center Volume* for Pediatric Heart Transplants, 1/1/95-12/31/10

*Low volume: Ctrs with <8 transplants in 1995-2010;
High volume: Ctrs with 8+ transplants in 1995-2010
Unadjusted Kaplan-Meier Survival by Center Volume*
for Pediatric Lung Transplants, 1/1/95-12/31/10

*Low volume: Ctrs with <4 transplants in 1995-2010;
High volume: Ctrs with 4+ transplants in 1995-2010
Geographic Location of Centers Performing Pediatric Kidney Transplants, 1/1/05-7/31/14

- Centers with > 12 pediatric transplants
- Centers with < 12 pediatric transplants

98% of pediatric transplants were done at centers meeting the proposed volume criteria
Geographic Location of Centers Performing Pediatric Liver Transplants, 1/1/05-7/31/14

- Centers with > 18 pediatric transplants
- Centers with < 18 pediatric transplants

97% of pediatric transplants were done at centers meeting the proposed volume criteria.
Geographic Location of Centers Performing Pediatric Heart Transplants, 1/1/05-7/31/14

98% of pediatric transplants were done at centers meeting the proposed volume criteria.
Geographic Location of Centers Performing Pediatric Lung Transplants, 1/1/05-7/31/14

- Centers with > 4 pediatric transplants
- Centers with < 4 pediatric transplants

93% of pediatric transplants were done at centers meeting the proposed volume criteria.