Proposed Membership and Personnel Requirements for Intestine Transplant Programs

Liver and Intestinal Organ Transplantation Committee
Spring 2015
The Problem

- No OPTN/UNOS definition for a designated intestine transplant program

- No OPTN/UNOS criteria for intestine transplant surgeons or physicians
  - Currently, any approved liver transplant program may perform intestinal transplants upon submitting a written request to UNOS
Define a designated intestine transplant program

Establish minimum qualifications for primary intestine transplant surgeons

Establish minimum qualifications for primary intestine transplant physicians
Establish minimum standards where none currently exist without compromising quality or restricting new program formation

How the Proposal will Achieve its Goal
Supporting Evidence

- Low-volume procedure with most programs performing fewer than 5 IN or LI-IN transplants in 2012
  - Thresholds not derived from statistical analyses
  - Represent level of experience to set minimal standards without restricting access or new program development
  - Similar to initial thresholds for other organs
Brief History

Original proposal circulated Aug. 2006
- Not well supported and withdrawn from consideration

Concerns:
- Many well qualified programs would not meet requirements
- Did not contain a transition plan for existing programs
- ASTS was developing criteria for intestinal program accreditation that would set levels for volume and experience, efforts postponed until ASTS finalized requirements
Brief History Continued

September 2008, ASTS finalized criteria

Intestinal Subcommittee recommended the liver surgeon and physician bylaws + ASTS volume to MPSC in Nov. 2009 and Dec. 2012

Concerns:

- Number of intestine transplant surgeries has been declining since 2007
- Concerns about bylaw implementation resurfaced
A Joint Effort

Fall 2013, Joint Liver Intestine & MPSC Subcommittee created

Revamped recommendations, amended the proposal & recirculated for public comment Spring 2014

Overall public comment received was supportive

- 92.86% in support
  - AST, ASTS, NATCO
  - Pancreas Committee
  - Region 2, 3, 4, 5, 6, 8, 9, 11

- 7.14% opposed
  - Pediatric Committee
  - Region 1, 7 & 10

“Timeframe is too restrictive”
“Timeframe is too lax”
“Could limit patient access”
“Could stifle innovation in the field”
Consistent with previous concerns.

OPTN
Full Approval

- Direct involvement in the primary care of 7 or more newly transplanted intestine recipients, followed for a minimum of 3 months from the time of transplant in the last **10 years**
- Direct involvement in intestine transplant patient care within the last **5 years**
- Observed 1 or more isolated intestine transplant and 1 or more combined liver-intestine or multi-visceral
Conditional Approval

- Directly involved in the primary care of at least 4 newly transplanted intestine recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. Additionally, the physician must become involved in the care of 3 or more intestine transplant patients over the next 3 consecutive years.

- Direct involvement in intestine transplant patient care during the last 5 years;

- 12 months experience on an active intestine transplant service as the primary intestine transplant physician or under the direct supervision of a qualified intestine transplant physician within a 24-month period.

- Formal mentor/proctor relationship with a primary intestine transplant physician at another fully approved intestine transplant program.
Modified Proposal Continued

Primary **Surgeon** Training or Experience Pathways for Transplant Program Approval

<table>
<thead>
<tr>
<th>Full Approval</th>
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<td>• Performed 7 or more intestine transplants to include isolated bowel and composite grafts, as primary surgeon or first assistant in the previous <strong>10 years</strong>.</td>
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<td>• Performed 3 or more intestine procurements with 1 or more liver-inclusive recovery.</td>
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<td>• Direct involvement in intestine transplant patient care within the last <strong>5 years</strong>.</td>
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### Conditional Pathway

- Performed at least 4 Intestine transplants and then performs 3 or more intestine transplants to include isolated bowel and composite grafts, over the next 3 consecutive years.
- Performed 3 or more intestine procurements with 1 or more liver-inclusive recovery.
- Direct involvement in intestine transplant patient care within the last **5 years**.
- Formal mentor/proctor relationship with a primary intestine transplant surgeon at another fully approved intestine transplant program.
Additional Proposal Modifications

G.4
Conditional Program Approval Status

G.4.A
Process for Full Approval Following Conditional Approval

G.4.B
Rejection of Full Approval
Provision for Combined Adult/Pediatric Programs

Any physician who meets the criteria as a primary intestine transplant physician can function as the primary intestine transplant physician for a program that serves predominantly pediatric patients, if a pediatric gastroenterologist is also involved in the care.
Suggested, Not incorporated

**Designated Dietician**
- Recommended in Appendix D. 7.A: Membership Requirements for Transplant Hospitals and Transplant Programs

**Gut Rehabilitation Program**
- Many not in house
- No formal definition
- Difficult to monitor and enforce
Currently 41 designated programs

22 performed more than 7 transplants in the last 10 years

Another 3 performed 4-6 transplants in the last 10 years

Of the remaining 16 programs:

- 6 programs have done 1-3 transplants in the last 10 years
- 5 have been inactive for the last 10 years
- 5 programs performed 1-2 total transplants since 1990, 0 transplants in the last 10 years
What Members will Need to Do

- All transplant hospitals with intestine programs with a current status of “Active, Approval Not Required” will receive an OPTN intestine transplant program application

- Applications must be submitted by the deadline

- Transplant hospitals not intending to apply will be asked to document that intention and submit that documentation to UNOS
What Members will Need to Do

- All current intestine transplant program designations will terminate on a given date

- Programs that do not intend to apply or do not meet the requirements must provide notice to potential candidates and waitlisted candidates
  - Transfer candidates to another approved intestine transplant program
Questions?

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