

# Proposal to Require Reporting of Every Islet Infusion to the OPTN Contractor Within 24 Hours of the Infusion

*Pancreas Transplantation Committee*

*Dr. David A. Axelrod, M.D., MBA, Chair  
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# The Problem

- There is no current requirement to report islet infusion
- Which islet recipients have received infusions?
  - Patient safety implications
  - Disease transmission implications

# Current System

- Outdated islet logs
- The logs have never been collected
- No official means to track every islet infusion

# Proposal's Goal

- Accurate and timely reporting of each islet infusion
- Policy and bylaw language to reflect current practice

# What the proposal does:

- Requires islet programs to report each islet infusion to the OPTN Contractor within 24 hours of the infusion
- Allows islet candidates to retain their waiting time through three consecutive islet infusions
- Removes outdated requirements in the bylaws for submitting islet logs
- Accurately reflects the current programming regarding registration fees and relisting

# Impact on Patient Notification

- Requires that Transplant Hospitals notify patients in writing within 10 business days of the patient's registration on the waiting list.
- Islet programs will send a letter every time it adds an islet candidate to the waiting list.

# Impact on Patient Notification

- The Committee believes its appropriate for Transplant Hospitals to inform candidates that they were still on the waiting list and had the potential to receive islet offers.
- The Committee believes the burden to inform candidates that they were still on the waiting list will be minimal due to the estimated low volume of islet infusions.

# Impact Numbers

- **212** islet registrations as of 5/31/2013
- **204** candidates as of 5/31/2013
- **53** waitlist removals for islet transfusion in 2012 on 46 individuals
- **21** approved islet transplant programs



# Data Collection

- Proposal does not require program changes or additional data collection
- Proposal does require islet Transplant Programs to report islet infusion data on a different time frame
- The UNet<sup>SM</sup> system is already programmed to collect this data

# Public Comment Response Tally

Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment / Did not Consider
Individual	41	11 (100%)	0 (0%)	0 (0%)	30
Regional	11	11 (100%)	0 (0%)	0 (0%)	0
Committee	19	2 (66%)	0 (0%)	1 (33%)	16

# Public Comment Feedback

- Allo-islet infusions vs. auto-islet infusions
- Multiple donors
- Accrual of time on the waiting list

# Response to Public Comment Feedback

- Islet infusion definition:
  - An infusion of islets from a single deceased donor. If a recipient receives islets from multiple donors simultaneously, then each donor's islets must be counted as a separate infusion.
- Policy 3.2.1.8.1 (Permissible Modifications):
  - Provides islet candidates who have returned to the waiting list a process to retain previously accrued waiting time.

# What members will need to do

- Remove islet recipients from the waiting list within **24 hours** of islet infusion
- If candidate is listed for another infusion, follow patient notification protocol for re-listing transplant candidates
- Do not submit cumulative islet logs

# Committee's Vote

- On July 30, 2012, the Committee voted by telephone in favor of the proposed policy and bylaw changes for submission for public comment: 13-supported; 0-opposed; and, 0-abstained.

# Resolution 6

**RESOLVED**, that Policies 3.2.1.8.1 (Permissible Modifications), Policy 3.8 (Pancreas Allocation Policy), 3.8.7.2 (Accrual of Waiting Time), 3.8.7.4 (Process for Re-Allocating Islets.), 3.8.7.5 (Removal from the Pancreas Islet Waiting List), and Article 1, Section 1.2, D (Registration Fees) and Appendix G, Section 4 of the Bylaws, as set forth in Resolution 6, are hereby approved, effective September 1, 2013.

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# QUESTIONS, COMMENTS, APPROVAL?



# Supporting Evidence

- In 2011, there were 61 deceased donor pancreata reported to the OPTN with a disposition code of “Islet Cells Transplanted.”
- There were 87 removals from the waiting list in 2011 for pancreas islet infusions reported to the OPTN.
- 70 recipients were removed from the waiting list for pancreas islet transplants.
- The discrepancy is caused by the removals for recipients removed more than once (15 recipients were removed twice and one recipient was removed thrice for pancreas islet transplants).