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
Dr. Jonathan A. Fridell, M.D., Vice-Chair
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- Outdated islet logs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- Removes outdated requirements in the bylaws for submitting islet logs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℠ system is already programmed to collect this data
## Public Comment Response Tally

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<th>Type of Response</th>
<th>Response Total</th>
<th>In Favor</th>
<th>In Favor as Amended</th>
<th>Opposed</th>
<th>No Vote/No Comment / Did not Consider</th>
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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.
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?
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).