

**Pancreas Transplantation Committee Meeting**  
**Via Telephone and Internet**  
**June 14, 2012**  
**4:30 pm to 5:30 pm (Eastern)**

**1. Proposal to Require Extra Vessel(s) Disposition to be Reported to the OPTN within Five Days of Transplant or Disposal**

The Pancreas Transplantation Committee (Committee) discussed the *Proposal to Require Extra Vessel(s) Disposition to be Reported to the OPTN within Five Days of Transplant or Disposal*. The OPTN/UNOS Operations and Safety Committee sponsored this proposal, the summary of which is below:

The Operations and Safety Committee is proposing policy language within section 5.10.2 (Vessel Storage) to require transplant centers to report the disposition of extra vessels to the OPTN within five days of transplant or disposal. This proposal will enhance patient safety and recipient outcomes in cases where extra vessels are transplanted by providing timely information on the disposition of extra vessels that could be part of an investigation by the OPTN/UNOS ad hoc Disease Transmission Advisory Committee's (DTAC) review of a potential disease transmission event. It is expected that this proposal can reduce the risk of disease transmission when the donor of the extra vessel is potentially at risk for transmitting disease a primary or secondary recipient.

Due to lack of quorum, the Committee could not vote on the proposal but commented as follows:

- Proposed policy is fair in the instance when a recovered vessel is transplanted in a recipient other than the person for whom it was intended. In other cases where the vessels are simply destroyed or used in the intended recipient, the policy and supporting documents may not support an increase in regulatory burden. A committee member asked for additional justification for the 5 day time line including examples of prior disease transmission events that would have been prevented and notification occurred in a more timely fashion had this regulation been in place,
- The Committee agreed importance of tracking the disposition of all vessels is important, because disease transmissions do occur and sometimes, vessels are shared between transplant programs. OPTN Contractor staff stated that it is necessary to have policy that sets a time limit for reporting the disposition of all vessels.
- To enable the OPTN Contractor to understand the disposition of all vessels, transplant programs should continue to keep a log describing whether a vessel was transplanted, discarded, or shared with another hospital. The OPTN Contractor's site auditors could continue to assess current policy compliance based on the information in the log during site audits.
- The committee agreed the proposed policy language is satisfactory as written for pancreas transplant programs as the vessels are generally used at the time of the initial transplant.

UNOS staff commented that the proposed policy could allow for communication about potential disease transmission and enable the Centers for Disease Control and Prevention to provide clinical guidance to transplant programs. However, they cited only two transmissions in the past 10 years believed to have been associated with transplantation of an infected vessel into a recipient other than the individual who received the solid organ transplant.

**2. Proposal to Update Data Release Policies**

The Committee discussed the *Proposal to Update Data Release Policies*. The OPTN/UNOS Policy Oversight Committee sponsored this proposal, the summary of which is below:

The proposed revisions to the OPTN Data Release Policies will combine Policy 9 and Policy 10 into a single policy (Policy 9 – Release of Data). The proposed changes will:

- Allow the OPTN Contractor to release more data than is currently released
- Provide an appeals process if the OPTN denies a data request
- Set requirements for the release of confidential information
- Allow the OPTN Contractor to release non-confidential data by institution to any requester
- Eliminate the list of data elements that can be released in special circumstances out of policy to allow for greater flexibility in data release.
- The process for release of person-identified data will not change.

During the evaluation of the policies as part of the Plain Language Rewrite Project, it was noted that the data release policies contained outdated elements that required substantive changes. The proposed revisions align these policies with current practice and present the information in a simpler format.

Due to lack of quorum, the Committee could not vote on the proposal but commented as follows:

- The policy must set a minimum threshold for the number of each patient-related-event reported for a given transplant program. When the number of a given patient-related event is small, as in the number of pancreas transplants at a transplant program, there would be a breach of patient confidentiality.
- Transparency of OPTN data must not mean the release of patient-identifiable data to entities or persons that do not have institutional review board approval.
- The OPTN should model the data release threshold similar to the Centers for Medicare and Medicaid Services, which prohibits the reporting of data in cell size smaller than 10 individuals in publications.

### **3. Proposed Islet Policy and Bylaw Revisions**

The Committee discussed its proposal to modify the islet policy and related bylaws. The Committee recommended the following policy changes:

- Three islet infusions equal one islet transplant, regardless of the candidate's removal from the waiting list after the first islet transplant. Therefore, the OPTN Contractor must charge only one registration fee for three islet infusions.
- Islet transplant programs do not need to submit patient logs to the OPTN Contractor. Currently, the patient logs must include for each transplant performed the following information:
  1. The patient name
  2. Social security number
  3. Date of birth
  4. Donor ID
  5. Patient status (alive or dead)
  6. Whether the pancreas was allocated for islet or whole organ transplantation

- Three islet infusions are equal to “one islet transplant.” A patient should receive one ‘patient notification letter’ from the transplant program for each islet transplant listing to confirm that the patient has been relisted after a prior infusion if appropriate

#### **4. Update from the Pancreas Outcomes Subcommittee on Pancreas Program Functional Inactivity**

The Committee recommends that the Performance Analysis and Improvement Subcommittee of the Membership and Professional Standards Committee (MPSC) consider the following changes to the pancreas program functional inactivity requirements:

- If a program performs less than 2 pancreas transplants in the 6 month period, then the program will receive a warning notification, but patients do not need to be notified.
- If the program receives such a warning, it has 6 months to perform at least 4 pancreas transplants. If they do not have a total of 4 pancreas transplants in the 1year period, then the program must then notify its patients of its inactivity.
- The MPSC should consider citing the program for functional inactivity at the 1year mark if the program has not performed 4 transplants.

This plan allows centers to receive a warning that they are at risk of inactivity after the first 6 months and a clear consequence for failing to do sufficient volume to remain active within the next observation period. It should also limit the number of centers that perform less than ten transplants in a 2.5 year cohort. The Committee was comfortable with this recommendation as a flag for further analysis in a process that would allow programs to present additional data specific to their program to the MPSC.

#### **Committee Members Participating in the Meeting:**

David A. Axelrod, MD, MBA (Chairman)  
Jonathan A. Fridell, MD (Vice-Chairman)  
James S. Bowman, MD (HRSA)  
Anissa Cole  
Barry S. Friedman  
Ba Lin, MS, MPH (HRSA)  
Michael C. Morris, MD  
Ms. Danielle Niedfeldt

#### **SRTR Staff who Participated**

Sally Gustafson, MS  
Kimberly Nieman  
Jon Snyder, PhD,  
Peter G. Stock, MD, PhD

#### **UNOS Staff who Participated**

Bob Carrico  
Vipra Ghimire  
Elizabeth Sleeman  
Kimberly Taylor  
Jen Wainright