

**OPTN/UNOS Pancreas Transplantation Committee
Report to the Board of Directors
June 1-2, 2015
Atlanta, Georgia**

**Jonathan Fridell, MD, Chair
Jon Odorico, MD, Vice Chair**

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This report reflects the work of the OPTN/UNOS Histocompatibility Committee between the November 2014 and April 2015 period.

Action Items

1. Definition of Pancreas Graft Failure

Public Comment: [September 29 - December 5, 2014](#)

The Pancreas Transplantation Committee (the “Committee”) reviewed public comment feedback on the Definition of Pancreas Graft Failure Proposal. In particular, the Committee focused on public comment concerns over the proposed insulin/kg criteria for graft failure. The Committee reiterated its prior acknowledgement that some patients require less than 0.5 units/kg/day pre transplant and thus may never achieve failure; however, the Committee decided to sacrifice sensitivity for specificity by compromising on a threshold of 0.5 units/kg/day. The Committee also reiterated its prior acknowledgement that while it may be difficult to use c-peptide to declare failure, it can demonstrate function. The Committee believes this is why there needs to be data obtained moving forward. The data collection component is incorporated into this proposal. Once the Committee has the c-peptide data collected, they will revisit the definition and determine whether it should be modified. The Committee agreed to include a statement of clarification that states the insulin use is calculated by combining total long-acting and short-acting insulin amounts used in one day. There was agreement to use the word “total” insulin use to capture both short and long acting amounts used in one day.

The Committee voted unanimously to send this proposal to the Board of Directors for consideration.

RESOLVED, that additions and modifications to Policies 1.2 (Definitions) and 3.6 (Waiting Time); as set forth in Exhibit A, are hereby approved effective pending programming and notice to membership.

Committee Projects

2. Pancreas Underutilization

Public Comment: January, 2016 (Estimated)

Board Consideration: June, 2016 (Estimated)

The Pancreas Underutilization Subcommittee is working on a project to identify reasons for high pancreatic discards as well as re-draft the facilitated pancreas allocation policy. Specifically, the Pancreas Underutilization Subcommittee’s goal is to identify why there is a decline in pancreas graft utilization as well as explain recent trends in pancreas transplantation and discarded pancreata. After the Subcommittee analyzes the reasons behind recent utilization trends, the Subcommittee hopes to identify a way to mitigate, and even reverse, the increasing trend in pancreatic discards.

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In order to identify the reasons for the decline in pancreas transplantation and rise in pancreas discards, the Committee made nine previous data requests. These requests were reviewed by UNOS staff during the Committee's March 10th meeting.

The second part of the Pancreas Underutilization project is the facilitated pancreas allocation policy. After reviewing a data request on this issue, the Committee determined there was sufficient evidence to move forward with modifications to this section of policy.

3. Pancreas Primary Physician and Surgeon Bylaws

Public Comment: August, 2015 (Estimated)

Board Consideration: December, 2015 (Estimated)

The Committee determined that the Pancreas Bylaw requirements for primary pancreas physicians and surgeons needed to be reviewed for currency and improvements. In addition, the Committee determined that the islet program requirements should be reviewed for potential updates. The Committee planned to have a final draft to release for fall 2014 public comment. However, the Joint Societies Working Group (JSWG) identified this project for review. This project is currently on hold awaiting recommendations from the JSWG. The JSWG held a call to review this proposal and made several recommendations to the islet section. These recommendations are mostly in agreement with recommendations previously submitted by the Clinical Islet Transplantation Consortium (CITC).

4. C-Peptide Manuscript

Public Comment: N/A

Board Consideration: N/A

This manuscript is the result of previous research performed in conjunction with the Definition of Pancreas Graft Failure proposal. Initially, the first draft of that proposal included a C-peptide threshold. However, Committee members questioned the validity of the C-peptide value. Committee members performed a literature review to determine if current medical literature could assist in determining a C-peptide value that corresponds with pancreas graft failure. The results of the literature review were inconclusive. In addition, the OPTN does not collect C-peptide values for pancreas transplant recipients either before transplant or at graft failure. Therefore, the Committee decided to perform a C-peptide Data Collection Study in order to determine a C-peptide value that corresponds with pancreas allograft failure (see Pancreas Graft Failure Public Comment Document).

Committee Projects Pending Implementation

5. Require Serum Lipase for All Pancreas Donors

Public Comment: March 14 - June 13, 2014

Board Approval: November 2014

Implementation date: Fourth Quarter 2015 (Estimated)

In November 2014, the Board of Directors approved the proposal to require the Collection of Serum Lipase for Pancreas Donors. This proposal requires serum lipase as a field in order to make electronic pancreas offers. The proposal also created a new field in DonorNet where OPOs report the upper limit of normal of the laboratory's normal serum lipase reference range (i.e., maximum normal value or highest reference value).

Implemented Committee Projects

6. Pancreas Allocation System

Public Comment: March 19 – July 16, 2010

Board Approval: November 8, 2010

Implementation Date: October 30, 2014

The Board of Directors approved the new pancreas allocation system in November of 2010. The changes to the pancreas allocation system were implemented on October 30, 2014. In anticipation of reviewing post implementation data, UNOS staff reviewed with Committee members the plan for evaluating the proposal. The Committee will begin reviewing data to assess the impact of the changes beginning in May 2015.

Review of Public Comment Proposals

The Committee didn't comment on any of the public comment proposals released recently.

Other Committee Work

N/A

Meeting Summaries

The committee held meetings on the following dates:

- March, 2015
- January, 2015
- November, 2014
- September, 2014
- August, 2014

Meetings summaries for this Committee are available on the OPTN website at:
<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=69>