

OPTN/UNOS Pancreas Transplantation Committee
Meeting Summary
January 20, 2015
Teleconference

Jonathan Fridell MD, Chair
Jon Odorico MD, Vice Chair

Discussions of the full committee on January 20, 2015 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov>.

Committee Projects

1. Definition of Pancreas Graft Failure

The Pancreas Transplantation Committee (the "Committee") held a conference call to review and discuss public comment feedback on the Definition of Pancreas Graft Failure Proposal. To provide context for the call, the Chair presented a brief overview of the proposal and UNOS staff explained that the Committee is somewhat limited in making further changes at this phase; only non-substantive changes or those that do not increase the burden on members are allowed. The Committee discussed the public comments provided from the regions, professional societies, committees, and individuals.

First, the Committee discussed public comment concerns over the proposed insulin/kg criteria for graft failure. The Committee acknowledged 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. This is a conservative estimate based upon the Committee's clinical expertise. The Committee agreed that although some patients may fail at below 0.5 units/kg/day, this proposal is far superior to what is presently occurring.

Additionally, the Committee acknowledged that while it may be difficult to use c-peptide to declare failure, it can demonstrate function. The Committee believes this is exactly why there needs to be data obtained moving forward, and data collection is incorporated into this proposal. Once the Committee has the c-peptide data collected, they will be able to determine whether it should be incorporated into the definition.

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. Also, there was agreement to include an asterisk identifying that "total" means long-acting and short-acting.

The Committee discussed considering the addition of a new field to collect data on other oral agents that the pancreas transplant recipient may be using to manage insulin resistance. The Committee was in agreement with this recommendation; however, UNOS staff explained that since it is a substantive change it is outside the scope of this proposal.

In response to a suggestion that the section regarding insulin usage include a goal such as “insulin use greater than or equal to 0.5 units/kg/day to achieve a Hemoglobin A1c of xx for a consecutive 90 days,” the Committee concluded this is a substantive change outside the scope of this proposal. The Committee further agreed the recommendation is constructive, and it will consider this strategy in the future as a potential enhancement.

Upcoming Meetings

- March 10, 2015, in Chicago, Illinois (In-Person)
- May 19, 2015 3:00pm-4:00pm ET (Conference Call)