

OPTN/UNOS Pancreas Transplantation Committee
Meeting Minutes
June 26, 2017
Conference Call

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Introduction

The Pancreas Transplantation Committee (hereafter, the Committee) met via Citrix GoToTraining teleconference on 06/26/2017 to discuss the following agenda items:

1. Pancreas After Kidney (PAK) Guidance

The following is a summary of the Committee's discussions.

1. Pancreas After Kidney (PAK) Guidance

The Committee previously discussed the PAK Guidance at a regularly scheduled call on June 12th. During that call, the Committee supported the guidance, but felt there should be additional changes prior to voting the proposal out for public comment. This call was scheduled to review any changes and to vote on the guidance if the Committee reached quorum on the call.

Summary of discussion:

The Committee reviewed the changes to the PAK Guidance document made since the June 12 call. The changes included:

- Adding a patient survival graph from a Wisconsin single center study that illustrated the life enhancing nature of pancreas transplantation by comparing survival for simultaneous pancreas kidney (SPK), living donor kidney, deceased donor kidney, and patients on dialysis.
- Clarifying that pancreas graft failure was determined by programs that subsequently reported the graft failure to UNOS.
- Modifying a hazard ratio graph by removing the middle panel that compared pancreas transplant to waitlisted PAKs with no pancreas transplant. The other two panels in the graph used waitlist SPK with no transplant as a comparison, so Committee members felt the middle panel was the wrong comparison to use and confusing. The Committee did not remove analysis of pancreas transplant and waitlisted PAKs survival in the discussion.
- Adding a limitations section to the document, outlining the limitations or qualifications of the analysis.

These changes were made by UNOS staff after the June 12 call and the revised guidance document was circulated to Committee members. Overall Committee members expressed strong support for the changes and for sending the proposal out for public comment. Members thought the guidance was clearer than the previous version, and supported the limitations section for highlighting the difficulty of finding an "ideal" PAK transplant recipient comparison.

The only change supported by Committee members was combining two graphs with waitlist and post-transplant survival for PAK and SPK candidates, and removing the PAK waitlist survival from the graph because Committee members felt it was not an accurate comparison to SPK waitlist survival since PAK waitlist candidates were kidney recipients already, unlike SPK waitlist candidates, and the members felt it was not a valid marker of waitlist survival. A Committee

member noted that combining the graphs would be comparing apples to oranges in that waitlist starts from time of listing whereas transplant survival starts from time of transplant, but overall the Committee felt the change was beneficial in superimposing the survival graphs and removing the PAK waitlist. A member reasoned that if PAK waitlist survival was removed, it would make more sense to show SPK waitlist survival in the same graph then having it in a graph with no comparative figure. The support for modifying the survival graphs in the guidance was unanimous. The new graph will show SPK and PAK post-transplant survival compared to SPK waitlist survival.

The Committee also briefly reviewed comments from the previous Committee call on whether quality of life analysis could show the potential benefit of PAK transplants. Since there is no objective way to measure quality of life, the Committee did not support pursuing this analysis. Instead the Committee supported retaining a focus on the survival advantage on a kidney graft of a pancreas after a kidney, and the PAK transplant benefit compared to staying on the SPK waitlist.

Despite the positive feedback and unanimous support for sending the proposal to public comment, the Committee failed to gain quorum on the call, and the proposal was not voted out for public comment.

Next steps:

The Committee liaison will schedule another ad hoc full committee call for the Committee to vote to send the PAK Guidance document out for public comment. The research liaison will create a graph that shows SPK and PAK post-transplant survival and SPK waitlist survival.

Upcoming Meetings

- June 26, 2017
- July 10, 2017
- August 14, 2017