

OPTN/UNOS Pancreas Transplantation Committee
Meeting Summary
August 8, 2014
Conference Call

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Discussions of the full committee on August 8, 2014 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. Outcomes Subcommittee Update

The Outcomes Subcommittee gave an update on the progress and results of the C-peptide Data Collection Study.

2. Vote on policy language associated with the Definition of Pancreas Graft Failure project

The Committee reviewed the work plan and policy language options for the definition of pancreas graft failure.

The work plan includes the following:

1. Update Policy 1.2 Definitions – Graft Failure, to include a definition of pancreas graft failure
2. Update Policy 3.6.B.ii Non-function of a Transplanted Pancreas, to remove policy language that references pancreas graft failure
3. Update Tiedi Help Documentation language regarding what constitutes pancreas graft failure
4. Update OPTN Data Collection Forms for pediatric and adult pancreas and kidney-pancreas transplants
5. Release an education initiative about the changes to policy, the forms, and Tiedi Help Documentation
6. Draft a manuscript on the C-peptide Data Collection Study and the study's findings
7. Send a memo to the MPSC with proposed policy language changes and the project's work plan

Notably, the Committee discussed “the recipient dies” factor that is included in the proposed pancreas graft failure definition. The Committee explained that they interpret “the recipient dies” to mean that the recipient died with a functioning graft. However, OPTN support staff explained that “the recipient dies” category, which is also located in the current general definition of graft failure, is interpreted to mean that the recipient dies with either a non-functioning graft or failed graft. In support of how the OPTN analyzes graft failure data, the follow-up forms contain instructions, in red writing, for when to

select if a graft is functioning versus not functioning. Specifically, the forms state, “If death is indicated for the recipient, and the death was a result of some other factor unrelated to graft failure, select Functioning.” A screen shot of the applicable section of the Pancreas Transplant Recipient Follow-up Form (TRF) is below:



The Committee decided that they want “the recipient dies” language to be interpreted to mean that the recipient dies with a functioning pancreas. However, in order to not change how graft status is reported on pancreas and kidney-pancreas registration and follow-up forms, the Committee decided to update the instructional language, in red, to accommodate both the Committee’s proposed definition of pancreas graft failure and how graft status is reported on the forms.

The Committee voted in support of the following policy language changes:

1.2 Definitions

The definitions that follow are used to define terms specific to the OPTN Policies.

Graft failure

For all organs except pancreas, graft failure occurs when *any* of the following occurs:

- ~~an~~ A recipient’s transplanted organ is removed,
- ~~a~~ A recipient dies,
- ~~or a~~ A recipient is placed on a chronic allograft support system.

Pancreas graft failure occurs when *any* of the following occurs:

- A recipient’s transplanted pancreas is removed
- A recipient re-registers for a pancreas
- A recipient registers for an islet transplant after receiving a pancreas transplant
- A recipient’s insulin use is greater than or equal to 0.5 units/kg/day for a consecutive 90 days
- A recipient dies

3.6 Waiting Time

3.6.B.ii Non-function of a Transplanted Pancreas

Immediate and permanent non-function of a transplanted pancreas is defined as ~~pancreas graft failure requiring the removal of the transplanted pancreas within the first 14 days of~~ after transplant.

Pancreas waiting time will be reinstated when the OPTN Contractor receives a completed *Pancreas Waiting Time Reinstatement Form* and *either* of the following:

- An operative report of the removal of the pancreas.
- A statement of intent from the transplant hospital to remove the transplanted pancreas, and a statement that there is documented, radiographic evidence indicating that the transplanted pancreas has failed.

The transplant hospital must maintain this documentation. The OPTN Contractor will send a notice of waiting time reinstatement to the transplant hospital involved.

Upcoming Meetings

- The full Committee's next call will be in September 2014
- The Pancreas Underutilization Subcommittee's next call is on September 12, 2014
- The full Committee's in-person meeting, in Chicago, is on October 14, 2014