

At-a-Glance

- **Proposal to Allow an Additional Method for Waiting Time Reinstatement for Pancreas Recipients** (Modifications to Policy 3.8.8 (Waiting Time Reinstatement for Pancreas Recipients))
- **Sponsoring Committee:** Pancreas Transplantation Committee
- This modification would change Policy 3.8.8- Waiting Time Reinstatement for Pancreas Recipients to allow the Organ Center to reinstate waiting time to recipients with pancreas graft failure before a pancreatectomy is performed. The goal of this policy change is to allow surgeons to remove a failed pancreas graft and transplant another pancreas during the same surgery.
- **Affected groups:**

Pancreas Recipients, Pancreas Transplant Centers, Pancreas Transplant Surgeons, Transplant Coordinators, OPOs, Organ Center
- **Specific requests for comment:**
 1. Will this policy change help pancreas recipients who have a thrombosed pancreas graft?
 2. Is it adequate for the center to send the Organ Center a statement that the center intends to perform a pancreatectomy and that the center has radiographic evidence of graft failure, which it will maintain and submit it upon request?

Please consider and comment on the entire proposal. Please do not feel limited to the focused questions. They are meant only to point out key issues within the proposal that may be of specific interest to some readers.

Proposal to Allow an Additional Method for Waiting Time Reinstatement for Pancreas Recipients (Modifications to Policy 3.8.8 (Waiting Time Reinstatement for Pancreas Recipients))

Sponsoring Committee: Pancreas Transplantation Committee

Summary and Goals of the Proposal:

This modification would change Policy 3.8.8- Waiting Time Reinstatement for Pancreas Recipients to allow the Organ Center to reinstate waiting time if:

- A pancreas graft has failed within 2 weeks of transplant,
- The recipient needs a second pancreas transplant,
- The transplant center submits a completed waiting time reinstatement form,
- The transplant center submits a statement of intent to perform a pancreatectomy, and
- The transplant center maintains radiographic evidence of graft failure and will submit this documentation upon request.

The goal of this policy change is to allow surgeons to remove a failed pancreas graft and transplant another pancreas during the same surgery.

Background and Significance of the Proposal:

The Organ Center received a call about a pancreas transplant recipient whose graft had failed within two weeks of transplantation. The surgeon wanted the recipient's wait time to be reinstated, so that the recipient could begin to receive offers for another pancreas. The surgeon's goal was to remove the failed pancreas and transplant another pancreas at the same time and avoid subjecting the recipient to two surgeries. However, Policy 3.8.8 states that the Organ Center can only reinstate wait time after it receives the candidate operative report, presumably the pancreatectomy operative report. The only other recourse the surgeon had was to use Policy 3.2.1.8- Waiting Time Modification. This policy requires that all modifications to wait time not specified elsewhere in policy be approved by unanimous agreement among the hospitals in the local area with transplant programs for the applicable organ. Then, the transplant center must submit the modification to the appropriate organ-specific committee and Board of Directors for review. There was not enough time to follow this process before the recipient was in too much pain to wait any longer to remove the original transplant.

The Pancreas Transplantation Committee considered this issue at its September 27, 2007 and December 7, 2007 meetings. Pancreas recipients who have graft failure must have the first transplanted pancreas removed before they can be reinstated on the waiting list, thus requiring two separate surgeries. The Pancreas Committee has the following goals for the policy change:

- That waiting time can be reinstated if the pancreatectomy has not taken place yet but will take place in the immediate future
- That the Organ Center has objective criteria for determining when waiting time can be reinstated.

At its September 2007 meeting, the Pancreas Committee approved preliminary language and decided to move forward with a public comment proposal (16-Support, 0-Oppose, 0-Abstain). This language would

allow the Organ Center to reinstate waiting time for pancreas recipients if the transplant center submitted a completed Pancreas Waiting Time Reinstatement form, a statement indicating the center intended to perform a pancreatectomy, and radiographic evidence of graft failure.

The Policy Oversight Committee (POC) reviewed the proposed revision during its October 2007 meeting. The POC noted that this change would not affect a large number of recipients, but it would serve a special group of recipients. Additionally, the POC commented that requiring radiographic evidence to be submitted might be unnecessary.

After further review by UNOS staff and based on the discussion of the Policy Oversight Committee, UNOS staff recommended revisions to the language passed by the Committee in September. The Pancreas Committee reviewed these suggestions at its December 2007 meeting. One revision changes the requirement for the transplant center to send documented radiographic evidence of graft failure to a requirement for the transplant center to send a statement that it has radiographic evidence and that the center will maintain and submit the radiographic evidence upon request. The statement is a more objective requirement for the Organ Center because it does not require Organ Center staff to evaluate radiographic evidence. Another revision changes where the Organ Center sends notice of waiting time reinstatement. The original policy language stated that the Organ Center will send a notice to the OPO, but the Organ Center actually notifies the transplant center. This revision updates the policy to current practice. The Committee noted that this policy change would only help recipients whose pancreas had thrombosed because they would be able to have radiographic evidence of graft failure. Recipients who have a non-functioning graft would not benefit from this change.

It is unlikely that a center would want to reinstate waiting time for a recipient unless that recipient's graft had failed. However, there is a possibility for gaming of the system because radiographic evidence is not required before the Organ Center can reinstate waiting time. Therefore, the Committee considered a way to monitor the policy during its December 7th, 2007 conference call. This plan can be found in the "Plan for Evaluation of the Proposal" section of this public comment proposal.

The Pancreas Committee voted to send out the revised policy language for public comment and voted to endorse the recommended monitoring and evaluation plan (8- Support, 0-Oppose, 0-Abstain).

Supporting Evidence and/or Modeling:

A review of OPTN data revealed that only 83 cases of pancreas re-transplant within 14 days due have occurred since 1988. Due to the limited sample size, further statistical investigation was not pursued.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

This proposed modification would improve patient safety. It would give patients the option to undergo only one surgery rather than two to remove a failed pancreas graft and transplant another pancreas.

Plan for Evaluation of the Proposal:

The Organ Center will prepare a report of all pancreas recipients who have had waiting time reinstated prior to a pancreatectomy. The Pancreas Committee will review these cases to determine if the policy is being followed as it was intended. If the Committee finds a problem, it can forward the information to the MPSC for investigation.

During the first year following implementation, the Committee will review the Organ Center report at approximately 6 months and 1 year. The Committee will review the report annually after the first year.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

This policy change does not require programming in UNetsm.

Communication/Education Plan:

If approved by the Board of Directors, the transplant community will receive information regarding new policy language via the Policy Notice that follows each Board meeting.

Monitoring and Evaluation:

The Pancreas Committee will review cases where waiting time has been reinstated prior to a pancreatectomy. If the Committee finds there is a trend in cases where a pancreatectomy was not performed after waiting time was reinstated, it can forward its finding to the MPSC for investigation.

Policy Proposal:

During its December 7, 2007 meeting, the Pancreas Committee voted to send the following policy language out for public comment (8- Support, 0-Oppose, 0-Abstain):

3.8.78 Waiting Time Reinstatement for Pancreas Recipients. In those instances where there is immediate and permanent non-function of a transplanted deceased or living donor pancreas, the candidate may be reinstated to the waiting list and retain the previously accumulated waiting time without interruption for that transplant only. For purposes of this policy, immediate and permanent non-function shall be defined as pancreas graft failure ~~resulting in requiring the~~ removal of the organ within the first two weeks of transplant. Waiting time will be reinstated upon receipt by the Organ Center of ~~a completed Pancreas Waiting Time Reinstatement Form and documentation, including but not limited to, the candidate operative report~~

- A completed Pancreas Waiting Time Reinstatement Form, and
- A pancreatectomy operative report
- OR
- A completed Pancreas Waiting Time Reinstatement Form, and
- A statement of intent from the transplant center to perform a pancreatectomy, and
- A statement that there is documented, radiographic evidence indicating that the transplanted pancreas has failed. This documentation must be maintained and submitted upon request.

~~The OPTN contractor will notify the OPO serving the recipient transplant center of the relisting and forward a copy of the relisting form to that OPO.~~
The Organ Center will send a notice of waiting time reinstatement to the transplant center involved.