

**OPTN/UNOS PANCREAS TRANSPLANTATION COMMITTEE
SUMMARY**

I. Action Items For Board Consideration

- The Board is asked to approve modifications to Policy 3.8.8 (Waiting Time Reinstatement for Pancreas Recipients). The proposed changes would allow the Organ Center to reinstate a pancreas recipient's waiting time after the recipient's graft had failed but before a pancreatectomy was performed. (Item 1, Page 3)

II. Other Significant Issues

- None

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**REPORT OF THE
OPTN/UNOS PANCREAS TRANSPLANTATION COMMITTEE
TO THE
BOARD OF DIRECTORS**

**Richmond, VA
June 19-20, 2008**

**Rainer W. G. Gruessner, MD, Chair
Dixon B. Kaufman, MD, PhD, Vice Chair**

This report includes items addressed by the Pancreas Transplantation Committee at its meetings held on September 26, 2007, December 7, 2007, March 14, 2008, and May 9, 2008:

1. Proposed Change to Policy 3.8.8- Waiting Time Reinstatement for Pancreas Recipients

During the September 26, 2007, Pancreas Transplantation Committee meeting, Rainer W. Gruessner, MD summarized Policy 3.8.8 (Waiting Time Reinstatement for Pancreas Recipients), which was brought before the Committee for possible revision. The Organ Center received a call in July about a pancreas transplant recipient whose graft had failed shortly after transplantation. The surgeon wanted the recipient's wait time to be reinstated so that the recipient could begin to receive offers for another pancreas, and so that the offers could occur during the interval of time in which the patient was being considered and prepared for operative transplant pancreatectomy. 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), which 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 and then be submitted to the appropriate organ-specific committee and Board of Directors for review. This process was considered too lengthy to be implemented in a timely fashion to allow safe pancreatectomy and re-transplantation.

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. To rectify this problem, the Committee discussed modifying Policy 3.8.8 in such a way that waiting time can be reinstated in a timely manner if the pancreatectomy has not taken place yet but is imminent. The Committee agreed the policy should provide the Organ Center with objective criteria for determining when waiting time can be reinstated.

The Pancreas Transplantation Committee voted to send out the proposed policy revision below for public comment (16-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 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
- Radiographic evidence indicating that the transplanted pancreas has failed

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.

After further review by UNOS staff and the Policy Oversight Committee, UNOS staff recommended revisions to the language passed by the Committee in September. The Committee reviewed these recommendations during its December 7, 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. 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.

UNOS staff also proposed a method of evaluating this policy change to the Committee. The Organ Center will prepare a report of all pancreas recipients who have had waiting time reinstated prior to a pancreatectomy. The Committee will review these cases to determine if the policy is being followed. If the Committee finds a problem, it can forward the information to the MPSC for investigation. For example, the Pancreas Transplantation Committee would look for cases when a pancreas re-transplant did not occur. If there is a trend with a center's requesting waiting time reinstatement and then not performing a pancreatectomy, the Committee would forward the information to the MPSC. 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.

The Committee voted to approve the revised policy language below and the plan for evaluation (8-Support, 0-Oppose, 0-Abstain). The proposal was distributed for public comment in the February 2008 public comment cycle.

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.~~

During its March 14, 2008 meeting, UNOS staff updated the Committee on the feedback to the Committee's public comment proposal on waiting time reinstatement for pancreas recipients. The Policy Oversight Committee (POC) reviewed the proposal again in January and still supports the proposal. Region 6 also voted in support of the proposal. No other regions had met at this point in time. All feedback from the public comment tool on the website was positive.

During its May 9, 2008 meeting, the Committee responded to public comment feedback and voted to send the proposal to the Board for approval in June 2008 (7- Support, 0-Oppose, 1-Abstain). A briefing paper with the proposed policy language, public comment feedback, and the Committee's responses to public comment feedback is attached as Exhibit A.

RESOLVED, that the Board of Directors hereby approves changes to Policy 3.8.8 (Waiting Time Reinstatement for Pancreas Recipients) as set forth in below, effective pending notice:

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.~~

PANCREAS COMMITTEE		JULY 1, 2007 - DECEMBER 31, 2007		JANUARY 1, 2008 - JUNE 30, 2008	
	MONTH	SEPTEMBER	DECEMBER	MARCH	MAY
	DAY	26	7	14	9
	FORMAT (select)	In Person	Live Meeting/ Teleconference	In Person	Live Meeting/ Teleconference
NAME	POSITION				
Rainer W. Gruessner MD	Chair	X	X	X	
Dixon Kaufman MD, PhD	Vice Chair	X	X	X	X
David Axelrod MD	Regional Rep.	X		X	
Peter Abt MD	Regional Rep.	X (by phone)	X	X	X
George Burke III, MD, FACS	Regional Rep.				
Marlon Levy MD	Regional Rep.	X			
Ron Taubman	Regional Rep.	X			X
Christian Kuhr MD	Regional Rep.	X	X	X	
Joseph Leventhal MD, PhD	Regional Rep.	X (by phone)			
Alexander Wiseman MD	Regional Rep.	X	X	X	X
Sandip Kapur MD	Regional Rep.	X (by phone)		X	
Venkatesh Krishnamurthi MD	Regional Rep.	X		X	X
Kenneth Brayman MD, PhD	Regional Rep.				
Albert Hwa PhD	At Large	X	X	X	X
David Harlan MD	At Large		X		
Khalid Khwaja MD	At Large	X (by phone)		X	
James Markmann MD, PhD	At Large	X	X	X	X
Christopher Marsh MD	At Large	X	X	X	
Helen Nelson RN, BSN, CCTC, CPTC	At Large	X	X	X	
Kim Patton RN, CPTC	At Large	X	X	X	X
Paul Volek MPH	At Large		X	X	
Peter Stock MD, PhD	Ex Officio	X	X	X	X
James Burdick MD	Ex Officio				
Gregory Fant PhD	Ex Officio				
Christopher McLaughlin	Ex Officio				
Elizabeth Ortiz-Rios MD, MPH	Ex Officio	X	X	X	X
Jim Galloway PhD	SRTR Liaison	X			
Randall Sung MD	SRTR Liaison	X	X	X	
Kathryn Meyer MS	SRTR Liaison	X	X	X	X
Sangeetha Krishnan MS	SRTR Liaison		X		
Elizabeth Sleeman MHA	Committee Liaison	X	X	X	X
Jason Chicirda	Support Staff	X	X	X	X
Dielita McKnight	Support Staff	X	X		
Jennifer Wainright PhD	Support Staff	X	X	X	X
Ciara J. Gould MSPH	Support Staff	X			
Karl McCleary PhD	Support Staff	X			