Selected Recommendations of the
OPTN/UNOS Pancreas Transplantation Committee
Board of Directors
March 2-3, 2009
Houston, TX

Summary

Action Items For Board Consideration

- The Board is asked to approve modifications to Policies 3.2.7 (Pancreas Waiting List Criteria) and 3.2.9 (Combined Kidney-Pancreas Waiting List Criteria) to allow candidates who need a pancreas for technical reasons as part of a multiple organ transplant to be listed on the pancreas waiting list. (Item 1, Page 3)

- The Board is asked to approve modifications to Policy 3.8.1.6 (Islet Allocation Protocol) to clarify islet allocation protocol. (Item 2, Page 5)

Other Significant Issues

- None

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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; March 14, 2008; July 18, 2008; September 12, 2008; and January 23, 2009.

1. **Proposal to allow candidates who need a pancreas for technical reasons as part of a multiple organ transplant to be listed on the pancreas waiting list: Policy 3.2.7 (Pancreas Waiting List Criteria) and Policy 3.2.9 (Combined Kidney-Pancreas Waiting List Criteria)**

In September 2007, the Committee reviewed a memo from the UNOS Department of Evaluation and Quality requesting that Policy 3.2.7 (Pancreas Waiting List Criteria) be modified. This policy states that "each candidate registered on the Pancreas Waiting List must be diagnosed as a diabetic or have pancreatic deficiency." Currently, candidates may only be placed on the pancreas waiting list if they have diabetes or pancreatic deficiency. However, sometimes a pancreas is allocated to a candidate without diabetes or pancreatic deficiency as part of a multi-visceral transplant. These candidates are not on the pancreas waiting list.

Committee members made a distinction between pancreas transplants that treat diabetes and pancreas transplants that only facilitate the transplantation of other organs. There was concern that listing multi-visceral candidates on the pancreas waiting list would increase the cost of the multi-organ transplants. Committee members noted that this particular policy change deals with a compliance issue. On the other hand, any policy change in this area has the potential to change the standard acquisition charge. Some members noted that the OPOs want to count the pancreas as a transplanted organ in such cases. The Committee decided not to move forward until it has received input on the financial implications of the policy change. The Committee contacted the Pediatric Transplantation, Liver and Intestinal Organ Transplantation, Organ Procurement Organization, Policy Oversight, and Transplant Administrators Committees for feedback.

In March 2008, the Committee reviewed the following feedback to the memo it sent to the Pediatric Transplantation, Liver and Intestinal Organ Transplantation, Organ Procurement Organization, Policy Oversight, and Transplant Administrators Committees:

Committee	Feedback
Pediatric Transplantation Committee	The Pediatric Transplantation Committee cannot support the proposed change until there is a policy addressing the scenario of an organ transplanted not to replace function, but rather to facilitate the transplant of other organs, and the language of the proposal is fully aligned with the Final Rule definition of a pancreas transplant candidate as "medically suited to benefit from an organ transplant."
Liver and Intestinal Organ Transplantation Committee	The Liver and Intestinal Organ Transplantation Committee commented that there should be a fee for a single organ and a fee for multiple organs, regardless of how many organs are required.
Policy Oversight Committee	The POC stated that the costs and accounting issues should be resolved between CMS and HRSA before the POC can offer its support.
Organ Procurement Organization Committee	The OPO Committee believes that patients receiving a pancreas for any reason need to be listed for a pancreas transplant. The center should be charged the SAC for the pancreas regardless of how the pancreas, or portion of the pancreas, is going to be used. The OPO should be able to record the pancreas as an organ transplanted as part of its performance metrics.
Transplant Administrators Committee	The Transplant Administrators Committee (TAC) recognizes that there is a financial impact with transplanting pancreata as transplant centers are being charged an additional Standard Acquisition Cost (SAC), as of 2007. The TAC agreed that there should be a separate fee for pancreata if it was transplanted for technical reasons.

The Committee agreed that they would not be able to solve or change the financial issue. However, the Committee may be able to draft language that would resolve the compliance issues. The policy should allow the pancreas to be used in a multi-organ transplant for metabolic reasons or for technical reconstruction. The Committee asked UNOS staff to draft policy language for the Committee to review at its July meeting.

At the July 2008 meeting, the Committee voted to send the following language out for public comment (15-Support, 0-Oppose, 0-Abstain):

> **3.2.7 Pancreas Waiting List Criteria.** Each candidate registered on the Pancreas Waiting List must be diagnosed as a diabetic, or have pancreatic deficiency, or require the procurement or transplantation of the pancreas for technical reasons as part of a multiple organ transplant.

The Committee also decided to write a memo to the Pediatric Transplantation Committee explaining why it was moving forward with the policy revision and addressing the Pediatric Transplantation Committee's concerns. The Committee noted that any financial issues relating to multi-visceral transplants were CMS issues, not OPTN issues.

In September 2008, the Committee considered additional revisions to Policy 3.2.7 (Pancreas Waiting List Criteria) and Policy 3.2.9 (Combined Kidney-Pancreas Waiting List Criteria). These revisions modify the policy language to make the terms more clinically accurate. The Committee changed the phrase "diagnosed as a diabetic" to "diagnosed with diabetes" and the phrase "have pancreatic deficiency" to "have pancreatic exocrine insufficiency."

The Committee reviewed supporting evidence for the revision to Policy 3.2.7 (Pancreas Waiting List Criteria) to add a third category of waiting list criteria for candidates who need the pancreas for technical reasons as part of a multiple organ transplant. The Committee reviewed data on the number of multi-visceral transplants that include the pancreas, which shows that the trend in the number of multi-visceral transplants including the pancreas is increasing. The Committee requested data on the age distribution of these multi-visceral candidates. The Committee also examined data on the diabetes status of the recipients of multi-visceral transplants that included the pancreas. From January 2006 to November 2007, 88.4% of the candidates who received a pancreas with a multi-visceral transplant did not have diabetes. These data indicate the need for another listing category for multi-visceral candidates. The Committee voted to send revisions to Policy 3.2.7 (Pancreas Waiting List Criteria) and Policy 3.2.9 (Combined Kidney-Pancreas Waiting List Criteria) out for public comment. (11-Support, 0-Oppose, 0-Abstain)

During its January 23, 2009, meeting, the Committee responded to public comment feedback and voted to send the proposal to the Board for consideration in March 2009. (9- Support, 0-Oppose, 0-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**. A resource assessment and impact summary is attached as **Exhibit B**. The Committee recommends the following resolution for consideration by the Board:

> *****RESOLVED, that the following modifications to Policies 3.2.7 (Pancreas Waiting List Criteria) and 3.2.9 (Combined Kidney-Pancreas Waiting List Criteria) are hereby approved, effective pending notice:**
>
> **3.2.7 Pancreas Waiting List Criteria.** Each candidate registered on the Pancreas Waiting List must be diagnosed with diabetes ~~as a diabetic~~, or have pancreatic exocrine insufficiency ~~deficiency~~, or require the procurement or transplantation of the pancreas for technical reasons as part of a multiple organ transplant.
>
> **3.2.9 Combined Kidney-Pancreas Waiting List Criteria.** Each candidate registered on the Kidney-Pancreas Waiting List must be diagnosed with diabetes ~~as a diabetic~~ or have pancreatic exocrine insufficiency ~~deficiency~~ with renal insufficiency.

2. Proposal to clarify islet allocation protocol: Policy 3.8.1.6 (Islet Allocation Protocol)

At its March 14, 2008, meeting, the Committee was concerned that the current islet allocation policy language is ambiguous because it does not define when a candidate is medically suitable for an islet transplant, and it allows a program to accept an unlimited number of pancreata for islet infusion for a candidate without that candidate ever receiving an islet infusion. UNOS Research staff discovered that one candidate had accepted twenty-three organs in 2005 and 2006, but the candidate did not receive a transplant from these pancreata. There was no apparent violation of policy. Seven of the organs accepted by this candidate eventually went to research. Eleven pancreata were not ever processed for islets. The Committee was concerned that so many clinical-grade pancreata were not processed for islets. The Committee discussed whether there should be a limit on the number of organs that a candidate can accept before waiting time is reduced. The Committee recognized that not every isolation will yield enough islets for transplant for that candidate. The Committee decided that it was premature to recommend a policy change based on one candidate. The Committee forwarded the issue to the Membership and Professional Standards Committee (MPSC) and requested that the MPSC investigate this particular situation.

At its July 18, 2008, meeting, the Committee reviewed a memo from the MPSC regarding this issue. The MPSC did not find any policy or bylaw violation with a center accepting a large number of islet offers for a single candidate and suggested that the Committee clarify islet allocation policy with attention toward developing more specific listing criteria for islet recipients to receive a second or third islet infusion. The Committee stated the need for all islet offers to be made through UNOS only to candidates who are on the waiting list. The Committee also discussed the possibility of not allowing islets to be sent out of the country or even re-allocated within the country. The Committee formed a subcommittee to draft language to clarify islet allocation policy. Dixon Kaufman, MD, PhD, Marlon Levy, MD, Horatio Rilo, MD, and Peter Stock, MD, PhD, volunteered to participate on this subcommittee. This subcommittee met in August 2008 to draft revisions to clarify islet allocation protocol. In August 2008, the Islet Allocation Subcommittee sent the proposed revisions to the NIH-funded Clinical Islet Transplant Consortium (CIT) principal investigators, who supported the changes.

At its September 2008 meeting, the Committee reviewed language developed by the Islet Allocation Subcommittee. The purpose of these revisions is to clarify islet allocation protocol. The revisions concentrate on several areas: islet product medical suitability, the process for re-allocating islets, and criteria for listing a candidate as active on the pancreas islet waiting list.

Islet Product Medical Suitability
The medical suitability of an islet product for a candidate is defined as meeting the islet center's product release criteria contained in the center's Investigational New Drug application (IND), as approved by the FDA.

The Process for Re-allocating Islets
Any re-allocation of islets must be to a medically suitable candidate covered by the same IND, based on waiting time, and must follow other OPTN/UNOS policies.

Criteria for Listing a Candidate as Active on the Pancreas Islet Waiting List
A candidate is **not** eligible for active status if the candidate**:**

- Is insulin independent **and**
- Has an HbA1c value of less than or equal to 6.5%.

If the candidate is eligible for active status, the transplant center will need to document in the candidate's record every six months:

- That the candidate is currently insulin dependent

OR

- That the candidate has had an HbA1c test in the past 6 months,
- That the most recent HbA1c test had a value of greater than 6.5%, and
- That the candidate is insulin independent.
-

The Committee voted to send revisions to Policy 3.8.1.6 (Islet Allocation Protocol) out for public comment (10-Support, 0-Oppose, 0-Abstain).

During its January 23, 2009, meeting, the Committee responded to public comment feedback and voted to send the proposal to the Board for consideration in March 2009. (12- Support, 0-Oppose, 0-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 C**. A resource assessment and impact summary is attached as **Exhibit D**. The Committee recommends the following resolution for consideration by the Board:

*****RESOLVED, that the following modifications to Policy 3.8.1.6 (Islet Allocation Protocol) are hereby approved, effective pending notice:**

3.8.1.~~5~~6 Islet Allocation Protocol. Allocation of pancreata for islet transplantation shall be to the most medically suitable candidate based upon need and transplant candidate length of waiting time. After ~~If after~~ islet processing is completed, the transplant center will determine if the islet preparation is medically ~~un~~suitable for the candidate. Medical suitability is defined as meeting the islet transplant center's islet product release criteria contained in the center's Investigational New Drug (IND) application, as approved by the FDA. The center must document whether the islets are medically suitable or medically unsuitable for the candidate for whom the center accepted the islets. If the islets are medically unsuitable for the candidate, the center must also document the reason the islets were medically unsuitable for the candidate. This documentation must be maintained and submitted upon request.

If the transplant center determines that the islets are medically unsuitable for the candidate for whom the center accepted the islets, the islets from that pancreas will be reallocated to a medically suitable candidate at a transplant center covered by the same IND, based upon waiting time. The transplant center that accepted the islets on behalf of the original candidate is responsible for documenting:

- to which candidate the center re-allocated the islets, and
- that the center re-allocated the islets to the medically suitable candidate covered by the same IND who had the most waiting time.

The transplant center must maintain this documentation and submit it upon request. ~~to the next most suitable candidate within the OPO that the Investigational New Drug (IND) application allows~~.

Islet allocation must abide by all applicable OPTN/UNOS policies, including but not limited to:

- Policy 3.2.1 (Mandatory Listing of Potential Recipients), which states that all candidates who are potential recipients of deceased donor organs must be on the Waiting List,
- Policy 3.2.1.4 (Prohibition for Organ Offers to Non-Members), which stipulates that organ offers cannot be made to non-member centers,
- Policy 3.2.4 (Match System Access), which requires that organs only be allocated to candidates who appear on a match run,
- Policy 6.4.1 (Exportation), which states that the exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.

~~The purpose of this policy is to allow for the application of medical judgment and to avoid islet wastage. The outcomes of this allocation policy will be reported to the Board by the Kidney & Pancreas Transplantation Committee within three years.~~

Waiting Time

A candidate is eligible to accrue waiting time:

- while listed in an active or inactive status; and
- until the candidate has received a maximum of three islet infusions.

Waiting time ~~shall~~will begin when a candidate is placed on Waiting List. Waiting time will end when the candidate is removed from the waiting list. Waiting time will accrue for a candidate until he/she has received a maximum of three islet infusions or the transplant center removes the candidate from the waiting list, whichever is the first to occur. If the candidate is still listed at this time or subsequently added back to the Waiting List, waiting time will start anew.

One point will be assigned to the candidate waiting for the longest period with fractions of points assigned proportionately to all other candidates, according to their relative waiting time. For example, if there are 75 candidates waiting for islets, the candidate waiting the longest would receive 1 point (75/75 x 1 = 1). A person with the 60th longest time of waiting would be assigned 0.2 points (75-60)/75 x 1 = 0.2). The calculation of points is conducted separately for each geographic (local, regional and national) level of islet allocation. The local points calculation includes only candidates on the local Waiting List. The regional points calculation includes only candidates on the regional list, without the local candidates. The national points calculation includes all candidates on the national list excluding all candidates listed on the Host OPO's local or regional waiting list~~. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive.~~

Active and Inactive Status

A candidate is **not** eligible for active status if the candidate:

- Is insulin independent **and**
- Has an HbA1c value of less than or equal to 6.5%.

The transplant center is responsible for keeping the candidate's listing status current in UNet^{SM}. If the candidate is listed as active and is insulin dependent, the transplant center must maintain documentation in the candidate's record of his/her current insulin status. To retain active status for an insulin dependent candidate, the transplant center must document in the candidate's record every six months that the candidate is currently insulin dependent.

If the candidate is listed as active and is insulin independent, the transplant center must maintain documentation in the candidate's record of his/her insulin status and HbA1c level with the date of the HbA1c test. To retain active status for an insulin independent candidate, the transplant center must document in the candidate's record every six months:

- That the candidate has had an HbA1c test within the past six months with a result of greater than 6.5%, **and**
- That the candidate is insulin independent.

The transplant center must use the most recent HbA1c value when determining whether the candidate is eligible for active status.

If a candidate's clinical condition changes, and the candidate is no longer eligible for active status, the transplant center must change the candidate's status in UNet^{SM} within 72 hours of the transplant center's knowledge of this candidate's clinical change. The transplant center must maintain documentation in the candidate's record of when the center learned of this clinical change. If a transplant center wishes to list an inactive candidate as active, the transplant center must have documentation that the candidate had the appropriate HbA1c level and insulin status in the past six months. The transplant center must present any documentation required by this policy to the OPTN upon request.

Removal from the Waiting List

The transplant center must remove the candidate from the waiting list within 24 hours of the candidate receiving his/her third islet infusion.