Pancreas Transplantation Committee Meeting
July 30, 2012
3:30 pm to 4:30 pm (Eastern)
Teleconference and Internet

The Pancreas Transplantation Committee (the Committee) met by telephone and Internet on July 30, 2012. Below is the summary of the Committee's discussion.

1) Proposal to Require Reporting of Every Islet Infusion to the OPTN Contractor within 24 Hours of the Infusion

In September, 2012, the Committee would like to distribute a proposal for public comment that requires transplant programs to report each pancreas islet infusion, but no longer submit islet logs to the OPTN Contractor. Below is the summary of the proposal:

Currently, it is not required that islet transplant programs report every islet infusion to the OPTN Contractor. Therefore, it is possible that the OPTN Contractor may be unaware which islet recipients have received infusions, which could have patient safety or disease transmission implications. The goal of this proposal is to require accurate and timely reporting of each islet infusion to the OPTN Contractor, and to update policy and bylaws language to reflect current practice for reporting islet infusions and outcomes information. This proposal:

1. Requires that islet programs report each islet infusion to the OPTN Contractor within 24 hours of the infusion, while still allowing islet candidates to retain their waiting time through three consecutive islet infusions.
2. Removes outdated bylaws requirements for submitting islet logs.
3. Adds language in the bylaws to reflect current programming for when an additional registration fee is generated after an islet candidate is removed for transplant and immediately re-registered for another infusion.

During this meeting, the Committee reviewed the proposed policy and bylaw changes, and voted to submit them for public comment: 13-supported; 0-opposed; and, 0-abstained[1]. The Committee's Chairman commented that the proposed changes should not be controversial to the pancreas transplant community. Further, the proposed changes do not require programming in UNet℠. The following is the policy and bylaw language changes approved by the Committee for public comment distribution.

3.8.7 Islet Allocation Protocol

[There are no policy changes preceding Policy 3.8.7.2.]

1.8.7.2 Accrual of Waiting Time.

A candidate will begin to accrue islet waiting time when the candidate is registered on the waiting list. Candidates accrue waiting time while registered at an active or inactive status.

An islet candidate will retain waiting time through three registrations at the

[1] The OPTN/UNOS Policy Oversight Committee and the Executive Committee will review this islet infusion reporting proposal in August, 2012. The OPTN Contractor will then distribute the proposal for public comment if the OPTN/UNOS Executive Committee votes in favor of this distribution.

registering center, including the waiting time from the previous registrations and any intervening time. After a candidate has received a series of three islet infusions at the registering hospital, waiting time will be reset, and the candidate will retain waiting time through another three infusions,

~~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 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.~~

[There are no further changes in Policy 3.8.7.2.There are no changes in Policy 3.8.7.3.]

3.8.7.4 Process for Re-Allocating Islets. 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.
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, and
- 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.~~

1.8.7.5 Removal from the Pancreas Islet Waiting List~~.~~

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

OPTN Bylaws, Appendix G

G.4 Requirements for Designated Pancreatic Islet Transplant Programs

All Pancreatic Islet Transplant Programs must meet the following criteria:

1. All of the requirements of a Designated Pancreas Transplant Program as defined in the sections above *or* meet the criteria for an exception as detailed in Section *G.4.E: Programs Not Located at an Approved Pancreas Transplant Program* below.
2. Demonstrate that the required resources and facilities are available as described in the sections that follow.

~~**A. Reporting**~~

~~The Program must submit data to the OPTN Contractor for all donors, potential transplant recipients, and actual transplant recipients using the required forms.~~

~~Pending development of standardized data forms for pancreatic islet transplantation, the Program must maintain patient logs and provide them to the OPTN Contractor every 6 months. The patient logs must be cumulative and must include for each transplant performed:~~

~~1. The patient name~~
~~2. Social security number~~
~~3. Date of birth~~
~~4. Donor ID~~
~~5. Patient status (alive or dead)~~
~~6. Whether the pancreas was allocated for islet or whole organ transplantation~~

~~For each pancreas allocated to the Program for islet transplantation, the Program must report to the OPTN Contractor if the islets were used for transplantation. If the islets were not used in transplantation, the Program must report the reason and disposal method, together with other information requested on the Pancreatic Islet Donor Form.~~

<u>A</u>~~B~~. Transplant Facilities

The Program must document adequate clinical and laboratory facilities for pancreatic islet transplantation as defined by current Food and Drug Administration (FDA) regulations. The Program must also document that the required Investigational New Drug (IND) application is in effect as required by the FDA.

B~~C~~. Expert Medical Personnel

The program must have a collaborative relationship with a physician qualified to perform portal vein cannulation under direction of the transplant surgeon. It is further recommended that the Program have on site or adequate access to:

1. A board-certified endocrinologist
2. A physician, administrator, or technician with experience in compliance with FDA regulations
3. A laboratory-based researcher with experience in pancreatic islet isolation and transplantation

Adequate access is defined as having an agreement with another institution for access to employees with the expertise described above.

C~~D~~. Islet Isolation

Pancreatic islets must be isolated in a facility with an FDA IND application in effect, with documented collaboration between the program and the facility.

D~~E~~. Programs Not Located at an Approved Pancreas Transplant Program

A Program that meets all requirements for a Designated Pancreatic Islet Transplant Program but is not located at a hospital approved as a Designated Pancreas Transplant Program may qualify as a Pancreatic Islet Transplant Program if the following additional criteria are met:

1. The Program demonstrates a documented affiliation with a Designated Pancreas Transplant Program, including on-site admitting privileges for the primary pancreas transplant surgeon and physician.
2. The Program provides protocols documenting its commitment and ability to counsel patients about all their options for the medical treatment of diabetes.
3. The Program demonstrates availability of qualified personnel to address pre-, peri-, and post-operative care issues regardless of the treatment option ultimately selected. An informal discussion with the MPSC is also required.

OPTN Bylaws
Article I: Membership
1.2 Transplant Hospital Members

D. Registration Fees

Transplant hospital members are responsible for the payment of an OPTN Registration Fee for each transplant candidate ~~listed~~ registered by that member on the waiting list database maintained by the OPTN Contractor. The OPTN Registration Fee is proposed by the Board of Directors and determined by the Secretary of HHS.

An additional registration fee will be due for a transplant candidate if:

- A candidate is given an inactive status or removed from the waiting list without receiving a transplant and is not placed back on the list within the 90-day grace period.
- A recipient has received a transplant but is put back on the waiting list for another transplant. However, no additional registration fee will be due for an islet candidate

who is removed and, if the option to re-register is offered during the removal process, immediately re-registered for an islet infusion.

- A candidate is transferred to a transplant hospital *outside* the original OPO Donation Service Area. A new registration fee must be paid by the receiving hospital.
- The potential recipient is listed at multiple transplant hospitals. A registration fee must be paid by each transplant hospital that places the candidate on the waiting list.

Members who ~~list~~ register candidates needing more than one organ (for example, kidney and pancreas) are only charged one registration fee.

2) Plain Language Rewrite of the Pancreas Allocation Policy

The Committee planned to discuss and vote on the rewritten pancreas allocation policy, which the OPTN Contractor distributed for public comment on July 2, 2012. Questions about the intent of the body mass index criterion in the rewritten pancreas allocation policy, however, prompted the Committee leadership to postpone a formal vote on the rewritten pancreas allocation policy. Instead, the Committee spent the remainder of the meeting time discussing whether there were changes in the intent of a given policy section due to the rewrite. The Committee leadership advised members that before August 30, 2012, they should review the rewrite of the pancreas policy, as well as other rewritten policies that address some aspect of pancreas allocation. The Committee will reconvene in August, 2012, by telephone and Internet, to finish its discussion of the rewritten policy.

A presentation by UNOS staff about the objectives of the plain language policy rewrite project preceded the discussion of the rewritten pancreas allocation policy. The pancreas allocation policy included in the rewritten document distributed for public comment includes sections which the OPTN Contractor has not yet implemented. UNOS staff is preparing a rewritten version of the pancreas policy in effect. Upon learning about the latter effort, the Committee's leadership engaged UNOS staff in the merits and demerits of presenting two versions of the pancreas allocation policy to the public. The presentation of the pancreas allocation policy that is in effect today, i.e., already implemented, could restart unnecessarily the discussion about the need for a uniform pancreas organ allocation system. Rather, the pancreas allocation policy that the OPTN Contractor should present to the public should be the one approved by the OPTN/UNOS Board of Directors in November, 2010. In so doing, a link to the pancreas policies approved the OPTN/UNOS Board of Directors prior to 2010 could inform the reader of this other version. It is this newer version of the pancreas policy that the Committee seeks to build upon in the future.

UNOS staff argued for the need to present the two versions of the pancreas policies on the OPTN's website, and to do so by February 1, 2013. To do so would be: 1) consistent with other organ allocation policies that have sections not yet implemented; 2) necessary, because the new pancreas allocation policy is not in effect and therefore, not enforceable; and, 3) placing the pancreas allocation policies within the technical structure of the other rewritten policies.

The Committee's leadership inquired whether the effort to rewrite the pancreas policies in effect would also include information about the many variances that exist nationally. UNOS staff stated that the rewrite effort would not include information about the variances, because such information is not in policy today. The Committee's leadership did not support the exclusion of the variance policies from the rewrite of the current pancreas policy. The OPTN/UNOS Board of Directors approved these variances and to exclude them from the rewrite further prevents the public from understanding the current pancreas allocation system.

The Committee's leadership preferred that UNOS staff not pursue the rewrite of the old policy, but will review the new product once it becomes available. But, the Committee's leadership contends that the existence of two policies will be problematic for the pancreas community.

Committee Members Who Attended

1) Dave Axelrod (Chairman)
2) Jonathan Fridell (Vice-Chairman)
3) Jonathan Fisher
4) Nelson Goes
5) Gloria Hairston
6) Albert Hwa
7) Joan Kelly
8) James Lim
9) Sayeed Malek
10) Michael Morris
11) Edmund Sanchez
12) Bernd Schroppel
13) Jason Wellen
14) Ba Lin (HRSA)

Committee Members Not Able to Attend

1) James Bowman (HRSA)
2) Lisa Chronis
3) Chris Curran
4) John Duffy
5) Monica Grafals
6) Douglas Hale
7) Dixon Kaufman
8) Monica Lin (HRSA)
9) Joseph Magliocca
10) Jon Odorico

SRTR Staff Members Who Attended

1) Sally Gustafson
2) Susan Leppke
3) Nicholas Salkowski

UNOS Staff Members Who Attended

1) James Alcorn
2) Robert Carrico
3) Vipra Ghimire
4) Leigh Kades
5) Elizabeth Miller
6) Elizabeth Sleeman
7) Jen Wainright