Interim Report
Pancreas Transplantation Committee

October 29, 2010
Live Meeting/ Teleconference

The following is a summary of the Pancreas Transplantation Committee meeting on October 29, 2010 held via Live Meeting and teleconference.

1. **Public Comment Proposals**
    a. **Proposal to Clarify which Transplant Program has Responsibility for Elements of the Living Donation Process and to Reassign Reporting Responsibility for Living Donation from the Recipient Transplant Program to the Transplant Program Performing the Living Donor Nephrectomy or Hepatectomy.**

        Living Donor Committee and Membership and Professional Standards Committee

The intended goal of this policy is to protect the health of living organ donors by shifting the responsibility for living donor follow-up to the hospital that has an established relationship with the living donor. The proposal clarifies and, in some cases, changes which transplant program is responsible for the living donation process. Under this proposal, the transplant program that operates on the living donor will be responsible for the consent, medical and psychosocial evaluations, perioperative care, and required follow-up reporting for that donor. Additionally, the revisions require that OPTN member transplant hospitals only accept living donor organs from transplant programs that are approved by the OPTN for recovering that type of living donor organ.

The Committee discussed this proposal on October 29, 2010, and voted to support the proposal as written. (12-Support, 0-Oppose, 0-Abstain)

    b. **Proposal to Establish Qualifications for a Director of Liver Transplant Anesthesia in the OPTN Bylaws**

        Membership and Professional Standards Committee

This proposal will protect patient safety by ensuring that all liver transplant programs employ an anesthetist who meets minimum experience and training requirements specific to transplantation. Transplant programs will be required to designate a Director of Liver Transplant Anesthesia with expertise in the area of perioperative care of liver transplant patients who could serve as an advisor to other members of the team. The new bylaw language will:

- Designate the appropriate board certification for the position;
- Delineate certain administrative and clinical responsibilities that should be handled by the director; and
- Determine the minimum qualifications needed for the position.

The Committee discussed this proposal on October 29, 2010, and voted to support the proposal as written. (12-Support, 0-Oppose, 0-Abstain) The Committee also noted that while pancreas transplantation does require high level anesthesia care, no additional requirements in the bylaws are necessary for pancreas transplant anesthesia.

c. Proposal to Modify the Requirements for Transplant Hospitals that Perform Living Donor Kidney Recoveries

Membership and Professional Standards Committee

The goal of this proposal is to provide an additional means for open donor nephrectomy qualification now that laparoscopic nephrectomy is more commonplace than it was when this bylaw was originally adopted. The proposal recognizes surgeons who are qualified to perform laparoscopic living donor nephrectomies as qualified to perform open donor nephrectomies as well. The revisions also eliminate the requirement for kidney transplant programs to be specifically designated to perform open donor nephrectomies since the majority of donor surgeries are performed laparoscopically.

The Committee discussed this proposal on October 29, 2010. The Committee suggested that the term minimally invasive be used rather than laparoscopic**. The Committee further noted that the laparoscopic requirements may be too low for a primary surgeon and should re-evaluated for currency**. The Committee voted to support the proposal as written. (12-Support, 0-Oppose, 0-Abstain)

d. Proposal to Prohibit Storage of Hepatitis C Antibody Positive and Hepatitis B Surface Antigen Positive Extra Vessels

Operations and Safety Committee

The proposed addition of policy is meant to improve patient safety and recipient outcomes related to the storage and transplant of extra vessels. The Operations and Safety Committee is proposing revised policy language for OPTN policy 5.10.2 (Vessel Storage) prohibiting the storage of Hepatitis C antibody positive and Hepatitis B surface antigen positive extra vessels. This proposal also includes modifications to policy 5.10.1 requiring transplant centers to verify the donor extra vessels ABO, all serology results, container contents, date of expiration and the UNOS Donor ID with the ABO and all serology results of the intended recipient prior to implantation. This change is expected to reduce the risk of disease transmission from transplant of extra vessels into secondary recipient(s) when the vessels are not transplanted into the recipient for whom the donor's organ was originally procured.

The Committee discussed this proposal on October 29, 2010. The Committee thought that the restriction from storing all Hepatitis C antibody positive and Hepatitis B surface antigen positive vessels was unwarranted based on a single case when so many other recipients have benefited from the storage and appropriate use of these vessels. **The Committee did not support the proposal as written. (2-Support, 8-Oppose, 0-Abstain)** However, the Committee did support the definition and time-out provisions of the proposal. (12-Support, 0-Oppose, 0-Abstain)

2. Update from the Pancreas for Technical Reasons Work Group

David Axelrod, MD, MBA, vice-chair of the Committee and chair of the Pancreas for Technical Reasons Work Group, updated the Committee on the progress of the work group. Transplant centers and OPOs do not always agree on the appropriate disposition code (transplanted or not transplanted) for pancreata that are used for technical reasons as part of multi-organ transplants. Many of the pancreata used for technical reasons in multi-organ transplants are from infant donors; 61.5% of donors for liver-intestine-pancreas (LI-IN-PA) transplants are under the age of 5. On its previous call, the work group noted that pancreata from such young donors seem unlikely to be usable in whole pancreas transplants. The work group inquired whether it is possible to distinguish pancreata that could be used for whole organ pancreas transplant from those that are not likely to be used for that purpose and set a threshold for reporting purposes.

The work group recommends that pancreata recovered for technical reasons from a donor weighing less than 35 kg should be reported as not transplanted and pancreata recovered for technical reasons from a donor weighing more than 35 kg should be reported as transplanted. Pancreata from donors weighing less than 35 kg account for less than 5% of the pancreata used for simultaneous pancreas-kidney (SPK) or pancreas-alone (PA) transplantation. OPOs are unlikely to be able to allocate these organs to an SPK or PA candidate because of the small size. Pancreata recovered for use in a PA or SPK transplant should continue to be reported as transplanted (if the organ is transplanted) regardless of the donor weight. The work group is now asking the Committees represented on the work group to review this recommendation.

Committee members were concerned that this recommendation does not account for cases where the pancreas is used to replace function as part of a multi-visceral transplant.

Pancreas for Technical Reasons Work Group minutes are attached as **Exhibit A**.

3. Update on Safeguard Measure for SPK Qualifying Criteria

Elizabeth Sleeman, liaison to the Committee, updated the Committee on the revisions made to the proposal for an efficient, uniform allocation system made by the Pancreas Allocation Subcommittee after receiving additional comments from the Kidney Transplantation Committee. These revisions were communicated to the Committee by e-mail, and the purpose of this update was to give the Committee the opportunity to ask any clarifying questions about the revisions.

At its August 30, 2010 meeting, some members of the Kidney Transplantation Committee still had concerns about the SPK qualifying criteria that allows candidates on insulin with a c-peptide greater than 2 ng/mL and a BMI less than or equal to 30 kg/m^2 to accrue SPK waiting time. Some members of the Kidney Transplantation Committee remained concerned that the BMI threshold of 30 would cause a substantial increase in the number of SPK transplants. Members of the Kidney Transplantation Committee were not able to determine a BMI threshold that would permit access for candidates who have type 2 diabetes that is phenotypically like type 1 diabetes. Some on the Kidney Transplantation Committee remarked that they were reluctant to support the proposed BMI of 30 only because OPTN policy changes are very arduous to implement and require quite a bit of time. The concern is that if the number of SPK transplants for candidates with type 2 diabetes balloons, the time required to remedy the situation through the policy development process will take years. The Kidney Transplantation Committee expressed interest in a contingency plan that would allow for the BMI threshold to be modified in real time based on the number of SPK transplants for candidates with type 2 diabetes.

In order to address the Kidney Transplantation Committee's concerns, the Pancreas Allocation Subcommittee added the following safeguard measure to the proposal:

Safeguard measure: If the percentage of SPK candidates who qualify for SPK waiting time because they have a c-peptide value greater than 2 ng/mL and a BMI less than or equal to the maximum allowable BMI is above 15%, then the BMI threshold will drop by 2 kg/m^2. If the percentage of SPK candidates who qualify for SPK waiting because they have a c-peptide value greater than 2 ng/mL and a BMI less than or equal to the maximum allowable is below 10%, then the BMI threshold will increase by 2 kg/m^2. The BMI threshold cannot exceed 30 kg/m^2 even if the percentage of candidates on the SPK waiting list in this category is below 10%. The maximum allowable BMI upon implementation will be 28 kg/m^2. The OPTN contractor will check this percentage every six months and send a report to the Committee. The Committee or its designated subcommittee will review the report. If a change is indicated, the Committee will forward the report to the Executive Committee who will make the official determination that the BMI should be modified in accordance with policy. If no change is indicated, the Committee will document its review in its board report. If the Executive Committee determines that a change to the maximum

allowable BMI is indicated, the OPTN contractor will change the BMI threshold as necessary within a short time frame (exact time frame is yet to be determined).

If a change to the BMI threshold were implemented, it would serve as an indicator that the Pancreas Transplantation Committee and other interested committees need to re-evaluate the qualifying criteria using the standard policy development process. This provision is intended to prevent abuse or gaming of the system in real-time so that the committees have time to properly evaluate the situation and propose alternatives.

Some Committee members expressed concern that this safeguard measure is not consistent with the goal of making the pancreas allocation system less complex. However, the Committee agreed that the safeguard measure was acceptable if it gained the necessary consensus for the proposal to be approved.

Pancreas Allocation Subcommittee minutes are attached as **Exhibit B**.

Table 1: Pancreas Committee Attendance

PANCREAS COMMITTEE		JULY 1, 2010 - DECEMBER 31, 2010
	MONTH	OCTOBER
	DAY	29
	FORMAT	Live Meeting/ Teleconference
NAME	COMMITTEE POSITION	
Dixon Kaufman MD, PhD	Chair	
David Axelrod MD, MBA	Vice Chair	X
James Markmann MD, PhD	Regional Rep.	X
Stuart Geffner MD	Regional Rep.	X
Rubin Zhang MD, PhD	Regional Rep.	
Jacqueline Lappin M.D.	Regional Rep.	
Horatio Rilo MD	Regional Rep.	
David Scott M.D.	Regional Rep.	
Brian Flanagan Ph.D.	Regional Rep.	X
R. Brian Stevens MD, PhD	Regional Rep.	X
Mark Laftavi MD, FACS	Regional Rep.	
Jonathan Fridell M.D.	Regional Rep.	X
Charles Bratton MD	Regional Rep.	X
Nicole Beauvais	At Large	X
Chris Chiarello	At Large	X
Anissa Cole	At Large	X
Barry Friedman RN, BSN, MBA, CPTC	At Large	X
Albert Hwa PhD	At Large	X
Christian Kuhr MD	At Large	
Danielle Niedfeldt JD, RN	At Large	X
James Bowman III, MD	Ex. Officio	
Rainer W. Gruessner MD	Ex. Officio	
Monica Lin Ph.D.	Ex. Officio	
Elizabeth Ortiz-Rios MD, MPH	Ex Officio	
Raja Kandaswamy, MD	SRTR Liaison	X
Peter Stock, MD, PhD	SRTR Liaison	X
Sally Gustafson	SRTR Liaison	X
Elizabeth Sleeman MHA	Committee Liaison	X
Jennifer Wainright Ph.D.	Support Staff	X
Kerrie Cobb	Support Staff	X
Kimberly Taylor, RN	Support Staff	X