Interim Report
Pancreas Transplantation Committee

March 26, 2010
Live Meeting/ Teleconference

The following is a summary of the Pancreas Transplantation Committee meeting on March 26, 2010 held via Live Meeting and Teleconference.

1. **Public Comment Proposal for an Efficient, Uniform Pancreas Allocation System**

The Committee reviewed the presentation on the proposal for an efficient, uniform pancreas allocation system, which will be presented at regional meetings **(Exhibit A)**. The public comment period is from March 19, 2010 through July 16, 2010. The regional meetings begin on April 9, 2010 and run through July 11, 2010. The Pancreas Allocation Subcommittee is in the process of planning a town hall-style webinar to present this proposal in further detail to any interested parties. The subcommittee plans to have the webinar in June 2010. An exact is yet to be determined.

Committee members had several questions about the presentation. Committee members inquired how paybacks would factor in to the system. In the proposed system, paybacks would no longer impact the allocation of SPKs because pancreas allocation would be disentangled from kidney allocation. Therefore, OPOs could allocate a kidney to an SPK candidate on the SPK/PA match run regardless of the current payback debt in that OPO. Committee members also asked for further explanation of how a combined SPK/PA would remove the disincentive for a living donor kidney transplant followed by a PAK. In DSAs that give SPK candidates absolute priority, candidates waiting for a PA transplant only receive offers after all SPK candidates have received an offer. Generally, only lower quality pancreata would be available for these PA candidates, which is why all the local SPK candidates would have refused the offer. A candidate who has a potential living kidney donor would receive a lower quality pancreas if he or she decided to accept a living donor kidney followed by PAK. Therefore, these candidates in DSAs where the kidney follows the pancreas are more likely to opt for an SPK transplant to receive offers for a higher quality pancreas, thus creating a disincentive for a living donor kidney transplant followed by PAK. Committee members noted that in DSAs that do not give SPK candidates absolute priority, the combined list may have the opposite effect. In these DSAs, SPK waiting time is long, and there are many high quality pancreata in cases where both kidneys are offered to kidney-alone candidates because of kidney priority allocation rules. When these DSAs switch to a combined list which is disentangled from kidney allocation, there may be an increased disincentive for a living donor kidney transplant followed by PAK because SPK waiting time will decrease and PAK waiting time will increase. Other Committee members commented that the comparison would be between a uniform system where pancreas allocation is disentangled from kidney allocation with a combined SPK/PA list compared to a uniform system where pancreas allocation is disentangled from kidney allocation and SPK candidates have priority over PA candidates. This scenario would be the change experienced by the majority of the DSAs because most DSAs already allow the kidney to follow the pancreas in allocation and give SPK candidates priority. In this comparison, the combined list does remove a disincentive for a living kidney transplant followed by PAK.

The subcommittee will provide Committee members with the slide set, presentation notes for each slide, and a list of frequently asked questions.

2. **Public Comment Proposals**
    a. **Proposal to Modify OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmission Events**

    Affected/Proposed Policies: Policies 2.0 (Minimum Procurement Standards for An Organ Procurement Organization), 4.0 (Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Diseases or Medical Conditions, Including Malignancies, of Donor Origin), and 5.5 (Documentation Accompanying the Organ or Vessel)

    Ad Hoc Disease Transmission Advisory Committee

The proposed modifications are meant to clarify and/or improve current OPO and transplant center requirements for screening for, communicating and reporting all potential or confirmed donor-related disease and malignancy transmission events. These changes are expected to:

- Help improve patient safety and recipient outcomes by making policy consistent with current clinical testing practices in the organ recovery transplant communities and creating a Patient Safety Contact;
- Place all content related to donor evaluation and screening into one policy section;
- Further define and standardize the elements of informed consent and the communication of clinically significant information regarding potential disease transmission events; and
- Provide a clear, plain language policy format that will be easier for members and other readers to understand and follow.

The Committee considered this proposal on March 26, 2010. The Committee asked if there are requirements for how a specimen will be qualified. DTAC did not specify how the specimen should be qualified (such as using a specific formula). Committee members noted there could be confusion about the differences in method. Committee members inquired if specific informed consent language would be required. The policy does not require specific language but rather that additional, testing and monitoring be offered as appropriate to minimize the risk of infection. The policy would also require that informed consent is required when a hemodiluted sample is used for infectious disease testing. OPO representatives noted that it would not be a burden for the OPO to tell the transplant centers whether the sample was hemodiluted. It would be a burden if the OPO were required to retrieve a new sample and re-test if the original sample were hemodiluted. Committee members also asked whether including hemodilution in the high risk definition would increase the number of donors classified as high risk. The number of donors classified as high risk because testing performed on a hemodiluted sample already causes the donor to be considered high risk. The Committee voted to support the proposal as written. (9-Support, 0-Oppose, 0-Abstain)

b. Proposal to Require a Use of a Standardized, Internal Label that is Distributed by the OPTN and that Transplant Centers Notify the Recovering OPO when they Repackage an Organ

Affected Policy: Policy 5.0 – Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials

Organ Procurement Organization (OPO) Committee

Current OPTN policy only requires that the external label distributed by the OPTN contractor be used for transporting organs and vessels. This proposed policy change would require OPOs and transplant centers to also use standardized, internal labels that are distributed by the OPTN contractor for organ and vessel transport and for vessel storage. This change will make both internal and external labeling consistent throughout the U.S. The proposal also:

- requires transplant centers to notify the recovering OPO when they repackage an organ;
- makes the language consistent by changing the term "provided" by the OPTN contractor to the term "distributed" by the OPTN contractor;
- moves Policy 2.5.6.1 which lists the required documentation that accompanies an organ or vessel to policy 5.5.1.
- clarifies labeling requirements for vessel storage

The Committee considered this proposal on March 26, 2010. Committee members inquired whether the OPO committee considered using DonorNet® as an electronic record rather than sending paper records with the organ. The OPO Committee did discuss this point. DonorNet® was never intended to be an electronic medical record, so the OPO Committee chose not to use it in such a way. The OPO Committee did try to write the policy to allow media other than paper to accompany the organ, such as a flash drive or a CD. Committee members asked whether the OPO Committee had considered using bar codes to track organs. The OPO Committee did discuss this option and found the costs to be prohibitive and that the bar codes did not provide much benefit because they cannot provide the location of the organ in real time. GPS could be considered in the future. The Committee voted to support the proposal as written. (7-Support, 1-Oppose, 0-Abstain)

c. Proposal to Update HLA Equivalences Tables

Affected Policy: UNOS Policy 3 Appendix A

Histocompatibility Committee

The purpose of this proposal is to update the tables in Appendix 3A to reflect changes in HLA typing practice and to improve the utility of the unacceptable antigens. Appendix 3A includes 2 tables, one listing HLA antigen designations that should be considered equivalent for purposes of matching kidney candidates and donors for the HLA-A,-B, and –DR antigens (HLA Antigen Values and Split Equivalences) and a second for determining which donor HLA antigens are unacceptable based on the unacceptable HLA-antigens listed for a sensitized candidate (HLA A, B, C, DR, and DQ Unacceptable Antigen Equivalences).

The Committee considered this proposal on March 26, 2010. The Committee voted to support the proposal as written. (8-Support, 0-Oppose, 1-Abstain)

d. Proposal to Require that Deceased Donor HLA Typing be Performed by DNA Methods and Identify Additional Antigens for Kidney, Kidney-pancreas, Pancreas, and Pancreas Islet Offers

Affected/Proposed Policy: UNOS Bylaws Appendix B Attachment IIA - Standards for Histocompatibility Testing D HLA Typing D1.000 Essential Information for Kidney Offers 3.8.2.2 Essential Information for Pancreas Offers

Histocompatibility Committee

This proposal would require that OPOs and their associated laboratories perform HLA typing of deceased donors by DNA methods and identify the HLA-A, -B, -Cw, -DR and -DQ antigens before making any kidney, kidney-pancreas, pancreas, or pancreas islet offers.

The Committee considered this proposal on March 26, 2010 and reviewed the data fields to proposed for the kidney-pancreas and pancreas data collection forms. The Committee voted to support the proposal as written. (8-Support, 0-Oppose, 1-Abstain)

e. Proposed Modifications to Data Elements on the following Tiedi® forms: Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), Transplant Recipient Follow-up (TRF), Living Donor Registration (LDR), Living Donor Follow-up (LDF), Deceased Donor Registration (DDR), Histocompatibility Form (HF), and approval of a new Explant Pathology Form for Liver Recipients

Policy Oversight Committee

All OPTN forms must be reviewed and approved by the Office of Management and Budget (OMB) every three years. The OPTN initiated a review of the data elements in order to identify any necessary changes. This proposal will outline the recommended modifications to the data elements in Tiedi®. These recommendations follow a comprehensive review of all the data elements by OPTN Committees, the Ad Hoc Data Management Group, an Expert Panel on Cardiovascular Risk Factors in Renal Candidates/Recipients, and the Policy Oversight Committee. The purpose of the changes is to add important variables that are not currently collected, clarify or modify questions on the forms, and eliminate variables that are redundant or no longer needed.

The Committee considered this proposal on March 26, 2010. The Committee voted to support the proposal as written. (8-Support, 0-Oppose, 0-Abstain)

3. Memo from the Disease Transmission Advisory Committee

The Committee reviewed a memo from the Disease Transmission Advisory Committee (DTAC). DTAC noted that there are a small number of cases reported to the Patient Safety System where unexpected malignancy was found during donor autopsy. These findings have warranted emergency explant and/or re-listing of recipients in some instances. DTAC members questioned whether there were appropriate mechanisms in place to appropriate review these situations in a timely fashion and prioritize the recipient for re-transplantation if appropriate. In some instances, the timely re-transplantation may reduce the risk that the malignancy causes an adverse event. As a result, the DTAC requested that the Pancreas Transplantation Committee review any existing organ specific policy language that pertains to the unexpected need for re-transplant in an effort to determine whether this scenario is adequately addressed.

The Committee reviewed Policy 3.8.8 (Waiting Time Reinstatement for Pancreas Recipients) below:

3.8.8 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 requiring the removal of the organ within the first two weeks of transplant. Waiting time will be reinstated upon receipt by the Organ Center

- 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 Organ Center will send a notice of waiting time reinstatement to the transplant center involved.

The Committee discussed whether removal of an organ because of malignancy would be immediate and permanent non-function and decided that removal because of malignancy would be covered by Policy 3.8.8 (Waiting Time Reinstatement for Pancreas Recipients) if the removal occurred in the two weeks following transplant. Committee members noted that it is possible for donor malignancies to be discovered after the two week post-transplant time frame. In such a case, the only option available to a pancreas recipient to have waiting time reinstated would be to request a waiting time modification as outlined in Policy 3.2.1.8 (Waiting Time Modification). Committee members stated that many pancreas surgeons would be reluctant to re-transplant a recipient and subject them to immunosuppression very quickly after the removal of an organ from a donor with a malignancy. The Committee agreed that these recipients should be able to have waiting time reinstated and whether a re-transplant is an appropriate option and the time frame for a re-transplant should be up to each recipient's medical team. The Committee decided to send a memo to the DTAC with its analysis of pancreas allocation policy on the issue.

4. Request from the Living Donor Committee

The OPTN has been instructed to form a work group, to include but not limited to the AST, ASTS, NATCO representatives and members of the OPTN/UNOS Living Donor Committee. This work group will be tasked with developing draft elements to be included in living donor transplantation protocols required to be adopted and followed under OPTN policy. Because living pancreas donation is so rare, the LD Committee has not developed resources for the medical evaluation of potential living pancreas donors. The final proposal may be similar to the deceased donor medical evaluation requirements in Policy 2.0. The Living Donor Committee would propose a set of testing required for all potential living donors, and then propose additional testing for each type of potential living donor. Under existing rules (Policy 2.0) the only additional requirement for deceased pancreas donors is serum amylase. The Living Donor Committee requested that the Pancreas Committee advise them on what additional testing should be required for potential living pancreas donors.

The Committee thought that some sort of glucose testing would be necessary, such as a strict program of glucose tolerance testing. The Committee was concerned about setting requirements for living donor pancreas transplant because it is still somewhat experimental with only five living donor pancreas transplants reported since 2000. The Committee did not think it would be appropriate to set standards when there could be no evidence for the standards. The Committee asked its members to request to share

their center's living pancreas donor evaluation protocol if any of the centers represented on the Committee had a protocol. The Committee will review these protocols and determine if it would be appropriate to recommend any specific testing for living pancreas donors.

5. Update from OPTN Strategic Planning Meeting

David A. Axelrod, MD, MBA updated the Committee on the OPTN Strategic Planning Meeting held March 1st in Richmond, VA. Attendees took part in a group exercise to rank all of the OPTN Committee projects. A new pancreas allocation system appeared in the top ten activities for many of the groups. One main theme of the day was that there are more projects than the OPTN has resources to complete. Therefore, cost efficiency will be important in any proposal.

Table 1: Pancreas Committee Attendance

PANCREAS COMMITTEE		JANUARY 1, 2010 - JUNE 30, 2010
	MONTH	March
	DAY	26
	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.	X
Jacqueline Lappin MD	Regional Rep.	X
Horatio Rilo MD	Regional Rep.	
David Scott MD	Regional Rep.	X
Brian Flanagan PhD	Regional Rep.	X
Ahmad Abdulkarim MD, PhD	Regional Rep.	
Mark Laftavi MD, FACS	Regional Rep.	
Jonathan Fridell MD	Regional Rep.	X
Leonard Cortese	Regional Rep.	X
Chris Chiarello	At Large	
Mary Beth Drangstveit RN	At Large	X
Albert Hwa PhD	At Large	X
Christian Kuhr MD	At Large	
Patricia Niles RN, BS, CPTC	At Large	
Meg Rogers	At Large	X
Paul Volek MPH	At Large	X
Rainer W. Gruessner MD	Ex. Officio	
James Bowman III, MD	HRSA	X
Elizabeth Ortiz-Rios MD, MPH	HRSA	
Emily Messersmith PhD	SRTR Liaison	X
Maria Larkina, MS	SRTR Liaison	X
Randall Sung MD	SRTR Liaison	X
Elizabeth Sleeman MHA	Committee Liaison	X
Jennifer Wainright PhD	Support Staff	X
Kerrie Cobb	Support Staff	X
Franki Chabalewski	Support Staff	
Shandie Covington	Support Staff	X

Shannon Edwards	Support Staff	X
Betsy Gans	Support Staff	X
Chrystal Graybill	Support Staff	X