Interim Report
Pancreas Transplantation Committee

November 20, 2009
Chicago, Illinois

The following is a summary of the Pancreas Transplantation Committee meeting on November 20, 2009 held in Chicago, Illinois.

1. **Public Comment Proposals**
    a. **Proposal to Improve the Variance Appeal Process**
    Affected Policy: 3.4 (Organ Procurement, Distribution and Alternative Systems for Organ Distribution or Allocation)
    Policy Oversight Committee (POC)

A variance is a policy experiment conducted by a member of the OPTN to improve organ procurement and allocation. For ease in reading, this proposal uses the term "variance" to describe it and its types. A review of variance policies revealed that most are silent on the process for appealing decisions of the committee or Board of Directors. This proposal attends to this deficiency. As such, the proposed modifications describe how an OPTN member may appeal a variance decision, and the role of the relevant committee and POC in the appeal process.

The Committee considered this proposal on November 20, 2009. The Committee supported the proposal. (11-Support, 0- Oppose, 0-Abstain)

    b. **Proposal to Add a Valuable Consideration Disclosure to the Bylaws**
    Affected Bylaws: Appendix B, Attachment I, Section XIII, C (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplantation and Appendix B, Attachment I, Section XIII, C (4) Liver Transplant Programs that Perform Living Donor Liver Transplantation
    Living Donor Committee

Under this proposal, transplant centers would be required to document that potential living organ donors have been informed that the sale or purchase of human organs (kidney, liver, heart, lung, pancreas and any other human organ) is a federal crime.

The Committee considered this proposal on November 20, 2009. Committee members noted that the sale or purchase of human organs is a federal crime for potential recipients as well as living donors. The Committee was concerned that this proposal could set a dangerous precedent because it was starting to hold transplant centers legally responsible for ensuring that the sale or purchase of organs is not occurring. Transplant centers will not be able to identify all such cases, and the discovery of the sale or purchase of organs could affect transplant centers years after the donation. Furthermore, it is not clear exactly what is included in "valuable consideration." The Committee supported the proposal to simply inform living donors that the sale or purchase of human organs is a crime but would not support any further requirements, such as having the living donor and the potential recipient attest that they are not involved in the sale or purchase of human organs. (9- Support, 1- Oppose, 1-Abstain)

2. Update on the Policy Rewrite Initiative

UNOS staff provided an update on the progress on rewriting the policies. The 2006 UNOS Member Survey results suggested members had difficulty comprehending policy. Incremental additions to policy have occurred without systematic assessment or planned revisions. The Board has begun a corporate initiative to improve governance and incorporate plain language. As a result, the policy rewrite initiative formed.

Translating all policies into plain language is a huge effort with significant risks. There is a need for a well-crafted plan to achieve this end. The UNOS department of Policy, Membership, and Regional Administration (PMR) partnered with UNOS Project Management Office (PMO) to create a detailed plan. Other policy language development will continue concurrently. This particular element is particularly relevant to the Committee since it will be drafting new policy at the same time the existing pancreas policy will be rewritten in plain language. The Committee will likely be drafting its policy in the new format, which will require additional time.

The following activities are within the scope of the policy rewrite initiative:

- Translating policies into plain language
- Clarifying policy intent
- Modifying policy structure
- Repairing and updating policies
- Deleting sections if appropriate (outdated sections, redundancies, etc.)
- Identifying problematic areas of policy for future revision

Manipulating policy intent or meaning, adding sections of policy, and updating the delivery and publication process are out of scope for this project. The project risks include:

- Pressure to include new policies in this project
- Pressure to amend policy intent as part of the project
- Adherence to approval schedules
- Potential for unanticipated public response
- Input received by and from multiple parties
- Resource over-allocation – 14,250 hour project

The first phase of the project will include the non-organ specific policies (Policies 1 through 3.4 and Policies 4 through 12). The second phase will include the organ-specific policies (Policies 3.5 through 3.11 and the appendices to Policy 3). All of the revised policies will be sent to the Board for approval in November 2010. The Committee will have an opportunity to review the pancreas allocation policy during this process.

Committee members were concerned that the policies are being rewritten even though the content of the policies, especially the kidney allocation policy, is in the process of being revised.

3. Working Group on How OPOs and Transplant Centers Should Report a Pancreas When It Is Procured for Technical Reasons

UNOS staff asked for two volunteers to serve on a working group to define how transplant centers and OPOs should report a pancreas when it is procured for technical reasons. There have been a few situations where a pancreas is procured as part of a multivisceral transplant, but the OPO and transplant center report the disposition of the organ differently. The OPO reports the organ as transplanted whereas the transplant center reports the organ as not transplanted. This situation results in discrepancies in OPTN data. A work group is being formed to define how the pancreas should be reported when it is procured as part of a multivisceral transplant. The work group will discuss whether the pancreas should be reported

as transplanted and if what happens to the pancreas after procurement should affect how the transplant center and the OPO report the pancreas. The work group will have representation from the Pancreas Transplantation, Pediatric Transplantation, Liver and Intestinal Organ Transplantation, OPO, and Transplant Administrators Committees. Horatio Rilo, MD, volunteered to serve on this working group.

4. Kidney-Pancreas Match Run Issues

UNOS staff presented information on two issues on the kidney-pancreas match runs that were discovered as a result of the implementation of the Calculated Panel Reactive Antibody (CPRA) policy change. First, candidates do not appear in the High CPRA OPO KP classifications unless there is a zero mismatch candidate on the corresponding pancreas match run. Based on pancreas policy, candidates should appear in the High CPRA classifications regardless of the placement of other candidates. Second, high CPRA regional and national kidney-pancreas candidates do not receive any priority over other regional and national kidney-pancreas candidates, respectively. Both high CPRA local, regional, and national kidney alone and pancreas alone candidates receive priority over other local regional and national kidney alone or pancreas alone candidates. Also, local high CPRA candidates receive priority over other local kidney pancreas candidates. Table 1 shows the classifications for the pancreas and kidney-pancreas match runs as they are currently programmed.

Table 1: Current Pancreas and Kidney-Pancreas Match Run Classifications
(for donors 50 years or younger with a BMI of 30 kg/m^2 or less)

PA Match	KP Match
0 ABDR MM High CPRA OPO PA	0 ABDR MM High CPRA OPO KP
High CPRA OPO PA	0 ABDR MM High CPRA Regional KP
0 ABDR MM High CPRA Regional PA	0 ABDR MM High CPRA National KP
0 ABDR MM High CPRA National PA	High CPRA OPO KP
OPO PA	OPO KP
High CPRA Regional PA	Regional KP
Regional PA	National KP
High CPRA National PA	
National PA	
National PA	
OPO PA Islets	
Regional PA Islets	
National PA Islets	

Table 2 shows the corrected programming for the kidney-pancreas and combined kidney-pancreas match runs which gives priority for high CPRA regional and national kidney-pancreas candidates.

Table 2: Corrected Kidney-Pancreas and Combined Kidney-Pancreas and Pancreas Match Run Classifications
(for donors 50 years or younger with a BMI of 30 kg/m^2)

Corrected KP Match	Corrected Combined KP & PA Match
0 ABDR MM High CPRA OPO KP	0 ABDR MM High CPRA OPO KP
0 ABDR MM High CPRA Regional KP	0 ABDR MM High CPRA Regional KP
0 ABDR MM High CPRA National KP	0 ABDR MM High CPRA National KP
High CPRA OPO KP	0 ABDR MM High CPRA OPO PA
OPO KP	High CPRA OPO KP & PA
High CPRA Regional KP	0 ABDR MM High CPRA Regional PA
Regional KP	0 ABDR MM High CPRA National PA
High CPRA National KP	OPO KP & PA
National KP	High CPRA Regional PA
	Regional PA
	High CPRA Regional KP (if KI available)
	Regional KP (if KI available)
	High CPRA National PA
	National PA
	High CPRA National KP (if KI available)
	National KP (if KI available)
	OPO PA Islets
	Regional PA Islets
	National PA Islets

The Committee approved the following resolution:

**Resolved that the KP and combined KP & PA match runs should be modified so that:

- Candidates appear in the High CPRA classifications regardless of the placement of other candidates.
- High CPRA regional and national candidates receive priority over other regional and national candidates, respectively. (12-Support, 0-Oppose, 1-Abstain)

The Committee further discussed whether the High CPRA Regional (or National) KP classification should come before or after the Regional (or National) PA classification on the combined KP & PA match run. The Committee determined that the original intent of the combined match run was to have all regional or national PA candidates come before all regional or national KP candidates. The Committee supported the classifications as they appear in Table 2 for the combined KP & PA match run. (13-Support, 0-Oppose, 0-Abstain)

5. Islet Subcommittee Update

Brian Flanagan, PhD, updated the Committee on the activities of the Islet Subcommittee. The purpose and purview of the Islet Subcommittee is to evaluate islet policy changes, the islet data needs of the subcommittee and Committee, and islet utilization as it relates to procurement and allocation. The

subcommittee met on November 11, 2009 and reviewed data on the recent islet policy change implemented on May 4, 2009. The subcommittee detected no problems in acceptance patterns but did request the disposition of four pancreata that were accepted for a single candidate since the islet policy change. The subcommittee also discussed how to capture every islet infusion with OPTN data. Possible methods for reporting each infusion include a policy change to require removal after every infusion with the possibility of relisting, islet logs, or some other manual process. The subcommittee plans to collaborate with the Collaborative Islet Transplant Registry (CITR) for follow-up data on islet transplants and to develop a list of data fields collected by CITR that would be useful to the OPTN. The subcommittee will invite CITR representatives to participate on subcommittee calls. The subcommittee is investigating pancreata allocated for islets where a provisional yes is entered but the organ is later declined. During this meeting, the subcommittee requested data on the disposition of deceased donor pancreata by year.

Committee members discussed that CITR is grant funded and could lose funding and that the OPTN may want the same data for islets as exist for solid organs. The Committee asked UNOS staff to investigate an appropriate path for discussing the creation of islet forms with HRSA. The Committee requested a list of all the data points that the OPTN currently collects on islet candidates and recipients.

The Committee discussed how it can help improve communication between OPOs and islet centers. The Committee could work with the OPO Committee to develop best practices for allocating pancreata for islets. The Committee suggested inviting an OPO representative to participate on the subcommittee.

Islet Subcommittee minutes can be found in **Exhibit A**.

6. Concept for a New Pancreas Allocation System

Dixon B. Kaufman, MD, PhD, presented information shared with the Board of Directors at its meeting earlier in the week.

SPK Qualifying Criteria

The Committee had an extensive discussion on SPK qualifying criteria. The qualifying criteria could be either the factors necessary for the candidate to appear on the SPK match run or the factors necessary for the candidate to accrue SPK waiting time. The Pancreas Allocation Subcommittee drafted the following recommendation for possible listing criteria:

For the kidney portion:

1. On dialysis
   OR
2. GFR $\leq$ 20 mL/min
   OR
3. CrCl $\leq$ 20 mL/min

For the pancreas portion:

1. C-peptide $\leq$ 2.0 ng/mL
   OR
2. Presence of anti-GAD/anti-insulin antibodies
   OR
3. (HbA1c $\geq$ 7.0% OR Clarke score $\geq$ 3) AND Insulin status= "on insulin" AND BMI $\leq$ 30 kg/m^2 AND Age of onset of diabetes $\leq$ 40

The Pancreas Allocation Subcommittee approached several pancreas programs for feedback on these possible listing criteria. The programs were concerned that these criteria were too restrictive and that c-peptide is not an appropriate predictor of post-transplant outcomes **(Exhibit B)**. The Committee debated

how to balance the need to have SPK listing criteria at the request of the Kidney Transplantation Committee and the opinion of the pancreas transplant community that restrictive SPK listing criteria are not appropriate. The Committee also discussed whether SPKs should be limited to candidates with Type 1 diabetes and, if so, how to define Type 1 diabetes with measureable data.

The Committee discussed simplifying the SPK qualifying criteria. The Committee considered the following criteria for the pancreas portion of the criteria:

1. Fasting c-peptide ≤ 2.0 ng/mL AND On insulin
   OR
2. Fasting c-peptide > 2.0 ng/mL AND On insulin AND BMI ≤ 32 kg/m^2

Committee members will gather feedback on this version of the criteria from the pancreas programs that have been providing feedback. Committee members expressed concerns that these criteria might not be adequate for the kidney transplantation community.

Implementation Considerations

UNOS staff presented information on the implementation considerations of the concept for a new pancreas allocation system. UNOS staff reviewed how a candidate is added to the pancreas and kidney-pancreas waiting lists. Candidates appear on match runs based on how they are listed. OPOs can allocate from the pancreas (PA), simultaneous pancreas kidney (SPK), or kidney (KI) match runs. Candidates can appear on both the SPK and PA match runs if they are listed for SPK and check the box in Waitlist^{SM} stating that they are willing to accept an isolated pancreas. This functionality would likely remain the same in a new system.

There are several technical issues to consider with the pancreas concept. The first is how candidates will appear on a match run. The candidate can appear once on the match run for both the SPK and PA listings or the candidate can appear twice on the match run, separately for the SPK and PA listings. The way waiting time is assigned differs based on how the candidate appears on the match run. There are three options for how candidates can accrue waiting time:

- **Option 1a**- The candidate appears once on the match run. Waiting time for candidates listed for SPK and both PA and SPK begins on the candidate's SPK qualifying date (e.g., dialysis date) regardless of listing date. Waiting time for candidates listed for PA begins on the PA listing date.
- **Option 1b**- The candidate appears once on the match run. Waiting time for candidates listed for PA and both PA and SPK begins on the candidate's PA listing date. Waiting time for candidates listed for PA begins on the PA listing date.
- **Option 2**- The candidate appears twice on the match run. Waiting times for candidates listed for SPK and PA are independent. Waiting time for candidates listed for SPK begins on the candidate's SPK qualifying date (e.g., dialysis date) regardless of listing date. Waiting time for candidates listed for PA begins on the PA listing date.

UNOS staff presented sample match runs using sample candidates for the following scenarios (see attached):

- Current PA Match Run
- Current SPK Match Run
- Option 1a Match Run
- Option 1b Match Run
- Option 2 Match Run

For all three options, there could be confusion about what organs are being offered to the center. For option 1a and 1b, the center will receive one offer per donor for a candidate whereas the center could receive separate PA and SPK offers from the same donor for the same candidate with option 2. In option 1a, PA candidates would lose all PA waiting time once they qualify for SPK. In option 1b, Candidates

could be listed for PA and accrue waiting time so they are at the top of the list when they meet SPK qualifying criteria. This situation could be considered gameable. Option 2 is consistent with how the current combined PA and SPK match runs work. Candidates could get an offer for pancreas alone even though they qualify for SPK and kidney is available with option 2.

The second technical issue is whether the kidney and pancreas allocation schemes would be disentangled or whether any KI candidates would receive any priority over SPK and PA candidates. If there is any priority for any KI candidates over SPK and PA candidates, there are two potential implementation options being estimated. There can be notes on the KI and SPK/PA match runs telling the OPO when it should switch between match runs. The OPO would then have to manually switch between the match runs at the designated point. Alternately, the KI candidates can be pulled on to the SPK/PA match run. This latter possibility would require a pancreas AAS for many of the KI AASs, which would make the system difficult to implement and maintain.

The third technical issue is the complexity of the SPK qualifying criteria. The current subcommittee recommendations would add seven new fields to the Waitlist[SM] application. The estimates assume that data is not collected serially and that once a candidate qualifies for SPK, he remains qualified regardless of later test results.

The estimates break down the costs for a variety of implementation options relating to the technical issues of how the candidates appears on the match run (option 1 or option 1) and the relationship between the SPK/PA match run and KI candidates (SPK and KI disentangled, OPO manually switches between match runs, KI candidates on SPK/PA match run). The "All" category includes the costs of implementation that would be required regardless of what the Committee decides on the technical issues described above. The "SPK Criteria" category includes the costs associated with adding the seven new fields to Waitlist[SM]. The table below shows the cost and IT hours for each possible implementation option.

Table 3: IT Implementation Estimates

		All	SPK Criteria	Option 1 or 2	Relationship with KI Candidates	IT Hours	Total Cost
Option 1	**SPK and KI Disentangled**	49%	38%	13%	N/A	12,700	$696,341
	OPO Manually Switches Match Runs	47%	37%	12%	4%	13,260	$727,046
	KI Candidates on SPK/PA Match Run	34%	26%	9%	31%	18,250	$1,000,658
Option 2	**SPK and KI Disentangled**	55%	43%	2%	N/A	11,420	$626,159
	OPO Manually Switches Match Runs	52%	41%	2%	5%	11,980	$656,843
	KI Candidates on SPK/PA Match Run	37%	28%	33%	2%	16,980	$931,013

The Committee noted that Option 2 seemed to give the most flexibility for candidates and did not discourage the use of a living kidney donor. Option 2 gives patients the ability to accept a deceased donor pancreas before having a living donor kidney transplant. Also, Option 2 is less costly to implement. The Committee supported moving forward with Option 2. (11-Support, 0-Oppose, 0-Abstain)

Review of Feedback on Concept
The Committee reviewed comments submitted by regions, other committees, and pancreas programs on the concept for a pancreas allocation system **(Exhibit B)**. The Committee discussed what evidence there is that the pancreas as part of an SPK gives additional graft survival benefit over a kidney alone transplant. Committee members volunteered to summarize the evidence in the literature for the Committee. Several regions were concerned that SPK priority could negatively impact pediatric kidney candidates, particularly in certain areas of the country. The Committee debated whether having a threshold value at which the allocation priority between SPKs and pediatrics kidneys may switch is feasible and cost effective. The Committee will work with members of the Pediatric Transplantation Committee to address these concerns. One committee was concerned that SPK priority over kidney alone candidates would decrease the OPO's ability to pay back debt. The Committee noted that a primary issue with payback debt is not that offers are not made but that offers are not accepted for payback even for organs that are later transplanted locally. This issue has no relation to allocation priority. The Committee also discussed whether the payback system will be abolished in a new kidney allocation system and when there will be a proposal for a new system.

Outstanding Issues
The Committee addressed several outstanding issues about a potential policy change. The Committee agreed that there was no need to change islet allocation at this time. The Committee discussed what would happen to existing alternative allocation systems with a policy change. The Committee noted that one of the goals of the policy change is to have a more uniform national policy. However, some alternative allocation systems are testing scenarios that could be considered for future policy revisions. The Committee decided that alternative systems would be abolished unless the group with the alternative system applied to keep its system and incorporated the elements of the new policy into the alternative system. These applications would be reviewed using the criteria in the Final Rule. The Committee also considered a transition strategy regarding SPK qualifying criteria. The Committee decided that candidates currently listed for SPK would not have to meet the SPK qualifying criteria.

Path Forward
UNOS staff informed the Committee of the public comment and Board meeting schedule. In order for a proposal to be considered at the November 2010 Board meeting, the Committee would have the following deadlines:

- January 15, 2010- Summary due
- February 19, 2010- Final proposal due
- March 19- July 16, 2010- Public Comment
- November 8-9, 2010- Board Consideration

In order for a proposal to be considered at the June 2011 Board meeting, the Committee would have the following deadlines:

- August 6, 2010- Summary due
- September 3, 2010- Final proposal due
- October 1, 2010- February 5, 2011- Public Comment
- June 2011- Board Consideration

To prepare a public comment proposal, the Committee must complete the following activities:

- Finish regional and Committee presentations
- Present to external constituent groups
- Finalize SPK qualifying criteria
- Determine what to do regarding the pediatric issue
- Work through implementation issues
- Draft policy language
- Finalize supporting evidence

- Plan and have town hall live meeting
- Establish how to monitor the policy
- Draft public comment proposal
- Make transition plan
- Answer outstanding questions

The Committee decided to have weekly subcommittee conference calls through February to accomplish these tasks. The Committee will also have full Committee conference calls in January and February to work on the proposal.

Pancreas Allocation Subcommittee minutes can be found in **Exhibit C**.

Table 4: Pancreas Transplantation Committee Attendance

PANCREAS COMMITTEE		JULY 1, 2009 - DECEMBER 31, 2009
	MONTH	NOVEMBER
	DAY	20
	FORMAT	In Person
NAME	COMMITTEE POSITION	
Dixon Kaufman MD, PhD	Chair	X
David Axelrod MD, MBA	Vice Chair	X
James Markmann MD, PhD	Regional Rep.	by phone
Stuart Geffner MD	Regional Rep.	X
Rubin Zhang MD, PhD	Regional Rep.	X
Jacqueline Lappin MD	Regional Rep.	
Horatio Rilo MD	Regional Rep.	X
David Scott MD	Regional Rep.	X
Brian Flanagan PhD	Regional Rep.	X
Ahmad Abdulkarim MD, PhD	Regional Rep.	X
Mark Laftavi MD, FACS	Regional Rep.	
Jonathan Fridell MD	Regional Rep.	
Leonard Cortese RN, BSN, CCTC	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	
Paul Volek MPH	At Large	by phone
Rainer W. Gruessner MD	Ex. Officio	X
James Bowman III, MD	HRSA	
Elizabeth Ortiz-Rios MD, MPH	HRSA	by phone
Emily Messersmith PhD	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