OPTN/UNOS Pancreas Transplantation Committee
Report to the Board of Directors
June 21-22, 2010
Richmond, VA

Summary

I. Action Items For Board Consideration

- None

II. Other Significant Items

- The Committee sent a proposal for an efficient, uniform pancreas allocation system out for public comment with the following components:

    1. Combining PA and SPK candidates onto a single match run list;

    2. Allowing local candidates who are allocated a pancreas from the combined list but who also require a kidney transplant, to receive a kidney independently of the kidney-alone match run if they meet specific qualifying criteria;

    3. Establishing specific qualifying criteria for a diabetic uremic patient to accrue SPK waiting time:
        a. The candidate must qualify for a kidney transplant based upon the current qualifying criteria as defined by Policy 3.5.11.1(Time of Waiting):
            i. on dialysis; **OR**
            ii. GFR ≤ 20 mL/min; **OR** CrCl ≤ 20mL/min
        b. Eligibility for SPK waiting time will be restricted to patients with diabetes mellitus who meet one of the following criteria:
            i. On insulin **AND** c-peptide ≤ 2 ng/mL; **OR**
            ii. On insulin **AND** c-peptide > 2 ng/mL **AND** BMI ≤ 30 kg/m^2
        c. Listing criteria for pancreas-alone transplantation will remain the same.

    4. Allocating deceased donor pancreata separately from the current kidney allocation system such that pancreas candidates are allocated organs that precede kidney paybacks and pediatric and adult kidney-alone (KI) recipients; and

    5. Having the Committee monitor allocation of standard criteria deceased donor kidneys for pediatric and adult KI recipients and SPK recipients with respect to donor ages ≤35 and >35 years as well as ethnicity, age and gender. (Item 1, Page 3)

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Dixon B. Kaufman, MD, PhD, Chair
David A. Axelrod, MD, MBA, Vice Chair

This report includes items addressed by the Pancreas Transplantation Committee (the Committee) at its meetings held on November 20, 2009; February 18, 2010; and March 26, 2010.

1. Proposal for an Efficient, Uniform Pancreas Allocation System

On November 20, 2009, 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 simultaneous pancreas-kidney (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 qualifying 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 A)**. 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 and considered the following criteria for the pancreas portion of the criteria:

1. Fasting c-peptide $\leq$ 2.0 ng/mL AND On insulin
   OR
2. Fasting c-peptide > 2.0 ng/mL AND On insulin AND BMI $\leq$ 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
On November 20, 2009, 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 SPK begins on the SPK 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 **(Exhibit B)**:

- 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 options 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 the kidney is available with option 2.

The second technical issue is whether the kidney and pancreas allocation systems would be separated 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 are not collected serially and that once a candidate qualifies for SPK, he or she 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 appear 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 1: 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 offer 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 A)**. 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 kidney 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.

On February 18, 2010, the Committee reviewed the draft public comment proposal for an efficient, uniform pancreas allocation system. The final version of this proposal is attached as **Exhibit C**. The purpose of this proposal is to improve the national pancreas allocation system. This improvement is consistent with the OPTN long-range strategic goals and priorities:

- to increase geographic equity in access and waiting time to deceased donor organs for transplantation;
- to maximize capacity of deceased donor organ transplantation; and
- to achieve operational efficiency and cost-effectiveness of implementing and maintaining the organ allocation system.

Specific objectives of the proposed allocation system for pancreas transplantation:

- reduce geographic inequities of pancreas utilization, access to transplantation, and transplant waiting time;
- maximize capacity by improving the opportunity for pancreas candidates to receive a transplant;
- enhance efficiency and cost-effectiveness, and minimize complexity of implementing and maintaining the operational requirements of a new pancreas allocation system; and
- optimize pancreas transplant access without adversely affecting kidney transplantation. Specifically, the Committee evaluated the transplant volume for adult and pediatric kidney recipients as well as ethnicity, age, and gender of recipients.

Proposal

In order to reach these goals, the Committee proposes:

1. Combining PA and SPK candidates onto a single match run list;

2. Allowing local candidates who are allocated a pancreas from the combined list but who also require a kidney transplant, to receive a kidney independently of the kidney-alone match run if they meet specific qualifying criteria; and

3. Establishing specific qualifying criteria for a diabetic uremic patient to accrue SPK waiting time:
    a. The candidate must qualify for a kidney transplant based upon the current qualifying criteria as defined by Policy 3.5.11.1(Time of Waiting):
        i. on dialysis; **OR**
        ii. GFR $\leq$ 20 mL/min; **OR** CrCl $\leq$ 20mL/min
    b. Eligibility for SPK waiting time will be restricted to patients with diabetes mellitus who meet one of the following criteria:
        i. On insulin **AND** c-peptide $\leq$ 2 ng/mL; **OR**
        ii. On insulin **AND** c-peptide > 2 ng/mL **AND** BMI $\leq$ 30 kg/m^2
    c. Listing criteria for pancreas-alone transplantation will remain the same. See Policy 3.2.7 (Pancreas Waiting List Criteria) below:

        3.2.7 Pancreas Waiting List Criteria. Each candidate registered on the Pancreas Waiting List must be diagnosed with diabetes or have pancreatic exocrine insufficiency or require the procurement or transplantation of the pancreas for technical reasons as part of a multiple organ transplant.

4. Allocating deceased donor pancreata separately from the current kidney allocation system so that pancreas candidates are allocated organs that precede kidney paybacks and pediatric and adult kidney-alone recipients;

5. Having the Committee monitor allocation of standard criteria deceased donor kidneys for pediatric and adult KI recipients and SPK recipients with respect to donor ages ≤35 and >35 years, as well as ethnicity, age, and gender.

The Committee also reviewed the supporting evidence section in detail. The Committee specifically voted to support option 9, which is a combined SPK and PA list that comes before all kidney-alone candidates in allocation. (11-Support, 0-Oppose, 0-Abstain) The Committee discussed the SPK qualifying criteria and noted that the most controversial point would likely be the BMI cut-off. The Committee also voted to endorse the SPK qualifying criteria as written. (11-Support, 0-Oppose, 0-Abstain) The Committee reviewed the simulation results for specific groups. For African American kidney candidates, the increase between the current system (2791 ±22) and option 9 (2872 transplants ±26) is more than four times greater than the between run standard deviation and is unlikely to be caused by random variation. The number of pediatric kidney transplants increases from the current system to option 9, but the difference is not greater than the between run standard deviation. The Committee voted to send the proposal for an efficient, uniform pancreas allocation system out for public comment. (11-Support, 0-Oppose, 0-Abstain)

On March 26, 2010, the Committee reviewed the presentation on the proposal for an efficient, uniform pancreas allocation system, which will be presented at regional meetings. 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. (June 25th, 2010 1:00 pm to 2:30 pm Eastern)

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 list would remove the disincentive for a living donor kidney transplant followed by a pancreas after kidney transplant (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.

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

2. Islet Subcommittee Update

On November 20, 2009, Brian Flanagan, PhD, co-chair of the Islet Subcommittee, 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 are attached as **Exhibit E.**

3. Kidney-Pancreas Match Run Issues

On November 20, 2009, 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 2 shows the classifications for the pancreas and kidney-pancreas match runs as they are currently programmed.

Table 2: 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 3 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 3: 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 3 for the combined KP & PA match run. (13-Support, 0-Oppose, 0-Abstain)

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

On November 20, 2009, 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.

5. Update on the Policy Rewrite Initiative

On November 20, 2009, 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.

6. Update from OPTN Strategic Planning Meeting

On March 26, 2010, David A. Axelrod, MD, MBA, vice-chair of the Committee, 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.

7. Memo from the Disease Transmission Advisory Committee

On March 26, 2010, the Committee reviewed a memo from the Disease Transmission Advisory Committee (DTAC). DTAC noted that there is a small number of cases reported to the Patient Safety System where unexpected malignancy was found during the 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 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.

8. Request from the Living Donor Committee

On March 26, 2010, the Committee discussed a request from the Living Donor Committee. The OPTN will form a work group, to include but not limited to AST, ASTS, and NATCO representatives, and members of the 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 Living Donor 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 (Minimum Procurement Standards for an Organ Procurement Organization (OPO)). 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 Transplantation 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.

9. Proposal from the Histocompatibility Committee 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.

On February 18, 2010, the Committee reviewed the Histocompatibility Committee's 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. This proposal would require OPOs and their associated laboratories to perform HLA typing of deceased donors by DNA methods and to identify the HLA-A, -B, -Cw, -DR and -DQ antigens before making any kidney, kidney-pancreas, pancreas, or pancreas islet offers. The Histocompatibility Committee plans to send this proposal out for public comment in the spring 2010 public comment cycle and wanted the Pancreas Transplantation Committee's input before public comment.

The Committee inquired whether the DNA methods could be completed before pancreas offers are made. DNA methods take less time than serological methods and can be completed before placement and procurement if the lab has the staff trained to do the DNA tests at all times (including nights and weekends). Additionally, DNA methods can be done on peripheral blood unlike serological testing. Most labs (95%) already have the ability to do these tests, so the extra costs would likely be around training and staffing. Only a very few labs would need to purchase equipment. Many labs are not performing DNA testing at all times, such as nights or weekends. For the match run, the labs are performing serological testing, but they are submitting the DNA results for the histocompatibility forms. The Histocompatibility Committee has identified discrepancies between the serological results on the

match run and the DNA results on the histocompatibility forms, meaning that organs may be being placed with inaccurate tissue typing. The Committee supported the proposal. (9-Support, 0-Oppose, 0-Abstain)

10. 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 addresses 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)

c. 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 would be unlikely to increase 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)

d. 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; and
- 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)

e. 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)

f. 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. The Committee voted to support the proposal as written. (8-Support, 0-Oppose, 1-Abstain)

g. 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 outlines 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 and reviewed the data fields proposed for the kidney-pancreas and pancreas data collection forms. The Committee voted to support the proposal as written. (8-Support, 0-Oppose, 0-Abstain)

Table 4: Pancreas Transplantation Committee Attendance, July 2009- June 2010

PANCREAS COMMITTEE		JULY 1, 2009 – JUNE 30, 2010		
	MONTH	NOVEMBER	FEBRUARY	MARCH
	DAY	20	18	26
	FORMAT	In Person	Live Meeting/ Teleconference	Live Meeting/ Teleconference
NAME	COMMITTEE POSITION			
Dixon Kaufman MD, PhD	Chair	X	X	
David Axelrod MD, MBA	Vice Chair	X	X	X
James Markmann MD, PhD	Regional Rep.	by phone		X
Stuart Geffner MD	Regional Rep.	X		X
Rubin Zhang MD, PhD	Regional Rep.	X		X
Jacqueline Lappin MD	Regional Rep.			X
Horatio Rilo MD	Regional Rep.	X		
David Scott MD	Regional Rep.	X	X	X
Brian Flanagan PhD	Regional Rep.	X	X	X
Ahmad Abdulkarim MD, PhD	Regional Rep.	X	X	
Mark Laftavi MD, FACS	Regional Rep.			
Jonathan Fridell MD	Regional Rep.		X	X
Leonard Cortese RN, BSN, CCTC	Regional Rep.	X	X	X
Chris Chiarello	At Large			
Mary Beth Drangstveit RN	At Large	X	X	X
Albert Hwa PhD	At Large	X		X
Christian Kuhr MD	At Large			
Patricia Niles RN, BS, CPTC	At Large			
Meg Rogers	At Large		X	X
Paul Volek MPH	At Large	by phone	X	X
Rainer W. Gruessner MD	Ex. Officio	X		
James Bowman III, MD	HRSA			X
Elizabeth Ortiz-Rios MD, MPH	HRSA	by phone	X	
Emily Messersmith PhD	SRTR Liaison	X	X	X
Randall Sung MD	SRTR Liaison	X	X	X
Maria Larkina, MS	SRTR Liaison		X	X
Elizabeth Sleeman MHA	Committee Liaison	X	X	X
Jennifer Wainright PhD	Support Staff	X	X	X
Kerrie Cobb	Support Staff	X	X	X
Lori Gore	Support Staff		X	X
Franki Chabalewski	Support Staff			X
Shandie Covington	Support Staff			X
Shannon Edwards	Support Staff			X
Betsy Gans	Support Staff			X
Chrystal Graybill	Support Staff			X