OPTN/UNOS Pancreas Transplantation Committee
Report to the Board of Directors
November 8-9, 2010
St. Louis, MO

Summary

I. Action Items For Board Consideration

- The Board is asked to approve modifications to Policy 3.8. (Pancreas Allocation Policy) and related policies to establish a revised pancreas allocation policy with the following components: (Item 1, Page 3)

    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 ≤ maximum allowable BMI (initially 28 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.

II. Other Significant Items

- The Pancreas Outcomes Subcommittee continues to work with the Membership and Professional Standards Committee to determine how to evaluate pancreas program performance. (Item 3, Page 10)

- The Pancreas for Technical Reasons Work Group is evaluating when a pancreas that is procured as part of a multivisceral transplant should be reported as a transplant in the OPTN database. (Item 4, Pages 10-11)

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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 meeting held on August 17, 2010.

1. Proposal for an Efficient, Uniform Pancreas Allocation System

Dixon B. Kaufman, MD, PhD, chair of the Committee and the Pancreas Allocation Subcommittee, outlined the work to develop a proposal for an efficient, uniform national pancreas allocation system to date and provided a short summary of the components of the proposal.

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;

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 ≤ the maximum allowable BMI

    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; 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.

Elizabeth F. Sleeman, MHA, liaison to the Committee, updated the Committee on the Pancreas Town Hall Webinar held on June 25, 2010. The purpose of the webinar was to present the proposal for an efficient, uniform pancreas allocation system in more detail than was possible in other venues, such as a regional meeting, and to gather feedback from professional societies, patient organizations, and webinar participants on the proposal during the public comment period. 180 people registered for the webinar. 106 attendees logged on to the webinar. All professional and constituent groups that spoke on the webinar expressed support of the proposal. Participants posed six questions to the panel. Webinar participants indicated that the webinar met its objectives, that they would attend future webinars, and that the webinar format was an effective means of communicating this type of information. A complete summary of the webinar and evaluation results can be found in **(Exhibit A).**

The Committee discussed the feedback received during the public comment period. All of the regions supported the proposal, as well as the majority of the committees and individuals who submitted a comment. The major themes throughout the feedback were:

- Desire for SPK candidates to have priority over all other types of pancreas candidates,

- Desire for PAK candidates who received a living donor kidney to have priority over all other types of pancreas candidates, and

- Concern over the SPK qualifying criteria, particularly the BMI value.

The Committee discussed whether there should be a combined list and maintained that it was the preferred approach. The outcomes disparity in pancreas graft survival between simultaneous pancreas-kidney (SPK) and pancreas-after-kidney (PAK) transplant is too great to give PAK candidates priority over SPK candidates. Giving SPK candidates priority disadvantages candidates who choose to pursue a living donor kidney transplant followed by a PAK. When SPK candidates have priority, it is hard for pancreas-alone candidates to receive offers for high quality pancreata. Also, having a combined list mitigates the potential impact to the kidney-alone waiting list.

The Committee considered whether the SPK qualifying criteria should be to accrue SPK waiting time or to appear on an SPK match run. The Committee recognized that there were valid points for both options. Having the criteria be for the candidate to appear on an SPK match run would eliminate any possibility for an SPK candidate to receive an SPK offer without meeting the qualifying criteria. However, this arrangement does not currently exist for candidates on the kidney-alone list. It is possible for a kidney-alone candidate who has no waiting time to receive a kidney offer. The Committee decided to have the qualifying criteria be for the candidate to accrue SPK waiting time to be consistent with kidney allocation policy. If the Kidney Transplantation Committee changes the meaning of qualifying criteria in kidney allocation policy, the Committee would be willing to do the same in pancreas allocation policy. The Committee chose to keep the BMI threshold at 30 kg/m^2 rather than dropping it to 25 kg/m^2. Available data suggest that outcomes decline for obese patients (BMI greater than 30 kg/m^2) but not for overweight patients (BMI greater than 25 kg/m^2).

The Committee had charged the Pancreas Allocation Subcommittee with finalizing the proposal on behalf of the Committee. After the meeting, the Committee received additional feedback from the Kidney Transplantation Committee expressing further concern about the second portion on the SPK qualifying criteria relating to diabetes status. The Kidney Transplantation Committee was concerned that a large number of kidney-alone candidates would switch to the SPK list in order to receive a transplant in less time. The Kidney Transplantation Committee was also concerned that if such a situation did occur, it would take longer than was acceptable to be able to change the policy language and implement a change. In order to address these concerns, the Pancreas Allocation Subcommittee, on behalf of the full Committee, added a safeguard measure to the proposal that would keep the BMI threshold at a lower value while the committees evaluated what the appropriate qualifying criteria should be. (7-Support, 0-Oppose, 0-Abstain) If the percentage of SPK candidates who qualify for SPK waiting time because they have a c-peptide value greater than 2 ng/mL and a BMI less than or equal to the maximum allowable BMI is above 15%, then the BMI threshold will drop by 2 kg/m^2. If the percentage of SPK candidates who qualify for SPK waiting because they have a c-peptide value greater than 2 ng/mL and a BMI less than or equal to the maximum allowable BMI is below 10%, then the BMI threshold will increase by 2 kg/m^2. The BMI threshold cannot exceed 30 kg/m^2 even if the percentage of candidates on the SPK waiting list in this category is below 10%. The OPTN contractor will check this percentage every six months and send a report to the Committee. The Committee or its designated subcommittee will review the report. If a change is indicated, the Committee will forward the report to the Executive Committee who will make the official determination that the BMI should be modified in accordance with policy. If no change is indicated, the Committee will document its review in its board report. If the Executive Committee determines that a change to the maximum allowable BMI is indicated, the OPTN contractor will change

the BMI threshold as necessary within a short time frame. The maximum allowable BMI upon implementation will be 28 kg/m^2.

The Committee reviewed several outstanding issues relating to the proposal and confirmed the following information:

- Being on insulin does not include being on oral glycemic agents. The Committee agreed that transplant centers would understand this point without further instruction.

- The label for the new combined pancreas and kidney-pancreas match run should be **Pancreas/Kidney-Pancreas**. (10-Support, 1-Oppose, 0-Abstain) The Committee thought including both names would be the least confusing for OPOs when determining which match should be run after implementation.

- The c-peptide value should have two decimal places and be within 0 and 15 ng/mL.

- As written in the proposal, existing pancreas and kidney-pancreas alternative allocation systems (AASs) will be eliminated. The groups with these AASs will have the opportunity to re-apply for an alternative system provided that they incorporate the following elements as written in the proposal:

    - A combined SPK and PA match run;

    - SPK qualifying criteria; and

    - Pancreas allocation disentangled from kidney allocation.

The Committee will evaluate these applications according to the provisions in policy and in the OPTN Final Rule.

- Proposed policy language allows an SPK candidate who receives a kidney-alone transplant to transfer his or her waiting time to a pancreas-alone listing. This provision should apply to both candidates who receive a living donor kidney and candidates who receive a deceased donor kidney.

- Currently, a candidate can transfer waiting time between the SPK and kidney-alone list. With the new system, pancreas-specific qualifying criteria have been added. There could be candidates on kidney-alone list who no longer automatically qualify for an SPK transplant. Therefore, candidates on kidney-alone list who are accruing kidney waiting time may not be accruing time that would transfer to the SPK waiting list. The Committee agreed that this was its intent.

- Automatic waiting time transfers should occur as set forth in Table 1:

Table 1: Automatic Waiting Time Transfers

Transfers	Current Policy	Candidate on KI list: Meets KP criteria	Candidate on KI list: Does not meet KP criteria	Candidate on KP list	Candidate on PA list
KI to KP	Yes	Yes	No	N/A	N/A
KP to KI	Yes	N/A	N/A	Yes	N/A
KP to PA	Yes	N/A	N/A	Yes	N/A
PA to KP	No	N/A	N/A	N/A	No
KI to PA	Yes	Yes	Yes	N/A	N/A
PA to KI	No	N/A	N/A	N/A	No

These transfers differ from what was included in the public comment proposal.

The Committee voted to send the proposal with the modifications discussed during the meeting to the Board of Directors for its November 2011 meeting. (11-Support, 0-Oppose, 0-Abstain) Additionally, the Committee charged the Pancreas Allocation Subcommittee with finalizing the proposal and preparing materials for the Board of Directors meeting. (12-Support, 0-Oppose, 0-Abstain) A briefing paper for this proposal can be found in **(Exhibit B)**. A resource assessment and impact summary for this proposal can be found in **(Exhibit C)**. The following resolution is recommended for consideration by the Board of Directors:

> ****RESOLVED, that the modifications to Policies 3.8 (Pancreas Allocation Policy), 3.5 (Kidney Allocation Policy), 3.2 (Waiting List), 3.3 (Acceptance Criteria), 3.4 (Organ Procurement, Distribution And Alternative Systems For Organ Distribution Or Allocation), and 3.9 (Allocation Systems for Organs not Specifically Addressed) as set forth in (Exhibit B) are hereby approved, effective pending programming and notice to members.**

Pancreas Allocation Subcommittee minutes can be found in **(Exhibit D)**.

2. Review of Pancreas Allocation Proposal Business Requirements

Kerrie Cobb, UNOS business analyst, presented business requirements for the implementation of the pancreas allocation proposal. The purpose of this presentation was to confirm that the Committee agrees with the translation of the policy to business requirements. The Committee reviewed the business requirements outlined in Table 2.

Table 2: Pancreas Allocation Proposal Business Requirements

Topic	Business Requirement
Kidney-Pancreas (KP) Qualifying Criteria	Adult candidates must meet qualifying criteria for the kidney and the pancreas in order to accrue KP waiting time.
	Candidates who do not meet these criteria will not be eligible for waiting time for a kidney-pancreas offer on a match run.
	Kidney qualifying criteria: On dialysis **OR** GFR <= 20 mL/min **OR** creatinine clearance <= 20 mL/min **AND** **Pancreas qualifying criteria:** On insulin and C peptide <= 2.0 ng/mL **OR** on insulin and C- peptide > 2 ng/mL and BMI <= 30 kg/m^2 **KP candidates listed prior to implementation do not have to meet qualifying criteria.*
	Once a candidate qualifies for a KP, the candidate remains qualified regardless of later test dates. For example: • A candidate is on dialysis, has a c peptide of 2.1 and a BMI of 29 on 1/1/2010. Assume the candidate's KP waiting time begins on 1/1/2010. • On 8/1/2010, the same candidate has a BMI of 31. The candidate's KP waiting time remains the same (beginning on 1/1/2010).
	The kidney portion of the KP qualifying criteria (dialysis, GFR, CrCl is already collected in Waitlist[SM] (application transplant centers use to add candidates to the waiting list). The pancreas portion of the KP qualifying criteria fields will need to be added to Waitlist[SM]: • On insulin • Insulin date • C-peptide • C-peptide date • BMI (display only)
PA Qualifying Criteria	Qualifying criteria for candidates who are listed for a pancreas-alone will not change.
Waiting Time Accrual	Waiting time for KP candidates begins accruing on the date the candidate qualifies for a kidney transplant. • This will be consistent with kidney policy. • Remember the candidate must meet the pancreas portion of the KP qualifying criteria to be eligible for waiting time but the dates the candidate met the pancreas portion of the KP qualifying criteria do not matter.
	KP candidates who receive a kidney alone will receive the longer of: • their KP waiting time, or • waiting time beginning on the pancreas alone listing date, or • waiting time beginning on the KP listing date.
	KP waiting time for candidates listed before the age of 18 will receive the better of: • their KP listing date, or • KP qualifying date
	Waiting time for candidates listed for an isolated pancreas begins on the pancreas listing date.
Waiting Time	After implementation of this project, waiting time accrued by a kidney transplant

Transfers	candidate registered on the Waitlist **will be transferred** to a combined kidney/pancreas listing. • Remember KP candidates only receive waiting time if they meet the PA portion of the KP qualifying criteria as well as the KI portion.
	After implementation of this project, waiting time accrued by a kidney/pancreas transplant candidate registered on the Waitlist **will be transferred** to a kidney transplant listing.
Waiting Time Transition Plan	KP candidates listed prior to implementation should receive the longer waiting time of: • The waiting time they currently have, or • The waiting time they have under the new system. (Only relevant if the Kidney Transplantation Committee changes kidney qualifying criteria.)
Match Run	KP and PA candidates will be combined into a single match run list.
	OPOs will no longer be able to run a pancreas-alone match. The pancreas-alone check box will be removed from the match run screen. The Kidney/Pancreas checkbox label will be changed to: **Pancreas/Kidney-Pancreas.**
	A new column (Organ(s) being offered) will be added to the pancreas /kidney-pancreas match results screen to indicate whether the offer is for the kidney/pancreas or the pancreas alone.
	OPOs must offer organs from the combined pancreas and kidney/pancreas match run through the local classification before offering organs from the kidney match run. This requirement would apply regardless of payback status or kidney zero mismatches.
	A new bypass code and corresponding description will be created to allow OPOs to bypass an individual KP candidate on the match results when there is no kidney available.
	If the kidney is not available the OPO will also be able to do a bulk bypass of KP candidates on the match results list that have not already received an offer and offer the pancreas to pancreas-alone candidates by clicking a button in the top section of the match results screen. The system will automatically set the new bypass code (specific to this functionality) for all of the KP candidates.
	Once the OPO selects the **Bypass KPs** button to perform a bulk bypass of KP candidates, an undo button will appear on the screen. The OPO can undo the bulk update by clicking the **Undo Bypass KPs** button.
	Centers that will accept a facilitated pancreas will be designated on the combined KP and PA match run list with a center code enclosed in parentheses around PA offers only**.**

The Committee agreed that these business requirements are consistent with the intent of the Committee for the implementation of the proposal for an efficient, uniform national pancreas allocation system. The Committee requested that when the implementation training occurs there be education for how OPOs can use existing bypass codes to bypass pancreas candidates who only need the pancreas as part of a multivisceral transplant. OPOs would only use this bypass code when the other organs that are part of the multivisceral transplant are not available.

3. Pancreas Outcomes Subcommittee Update

David Axelrod, MD, MBA, chair of the Pancreas Outcomes Subcommittee, provided the Pancreas Outcomes Subcommittee update. In November 2006, the Membership and Professional Standards Committee (MPSC) asked the Committee to work with SRTR to consider the variables that could be included in a pancreas- alone outcomes model. At the time, only a kidney-pancreas model existed. In 2007, the Committee formed a subcommittee to investigate this model. As part of the process, the subcommittee considered and eventually recommended having a combined simultaneous pancreas-kidney/ pancreas-after-kidney/ pancreas transplant alone (SPK/PAK/PTA) model to increase the statistical power of the model by increasing the number of events. In January 2009, the subcommittee requested that the MPSC only use the 1-year patient survival model for evaluating pancreas programs and allow the Committee to continue to work on the 1-year graft failure model in order to raise the index of concordance. In April 2009, the MPSC agreed to give the Committee additional time to work on the 1-year graft failure model. The purpose of this subcommittee is to continue that work.

The subcommittee discussed the 1-year pancreas graft failure model. The model includes SPK, PAK, and PTA transplants. There is an assumption that the variables in the model affect the groups in the same way over the same time period. If they do not, the model can be stratified. This model is stratified by PTA vs. SPK and PAK. All the variables in the kidney and SPK models were evaluated for the combined model. Some numerical factors use a continuous metric with splines rather than groups (e.g., age, BMI). Statistically significant factors as well as clinically relevant factors can be included in the model. The subcommittee discussed potential ways to increase the index of concordance of the models, including:

- Listing any differences in variables in the 1-year and 3-year graft failure models;
- Expanding the cohort for the development of the model; and
- Looking at the SPK model separately with the new variables.

The SRTR has investigated whether expanding the cohort would affect the index of concordance. The subcommittee will reconvene to review the SRTR results and report back to the MPSC. The Committee noted that the MPSC is still expecting feedback from the Committee. It may be that there is no way to improve the predictability of the model with the data that are currently available. Additionally, there are a large number of pancreas programs that do a small number of pancreas transplants. Therefore, it can be very difficult to evaluate what their expected outcomes should be. The Committee would like to hear more about the MPSC process for reviewing outcomes for pancreas programs. The Committee noted that there may be better ways to evaluate pancreas program outcomes than using the model that has been developed.

Pancreas Outcomes Subcommittee minutes can be found in **(Exhibit E)**.

4. Pancreas for Technical Reasons Work Group Update

David Axelrod, MD, MBA, chair of the Pancreas for Technical Reasons Work Group, provided the Pancreas for Technical Reasons Work Group update. Surgical procedure for the procurement of organs for a multiple organ transplant often includes the procurement of the pancreas regardless of whether the candidate has diabetes or pancreatic deficiency. Therefore, there are some circumstances where a candidate may need a pancreas to facilitate a multiple organ transplant. Transplant centers are procuring the pancreas for technical reasons as part of a multivisceral transplant. The transplant center is then reporting the organ as not being transplanted. The OPO, on the other hand, is reporting the organ as transplanted. Therefore, the data in the OPTN database do not match because there is no recipient

removal for transplant to match the donor disposition stating that the pancreas is transplanted. Transplant centers and OPOs are in disagreement as to whether the pancreas was transplanted. The data need to match, and UNOS staff can create ways for the pancreas to be reported by the OPO and the transplant center as "for technical reasons." However, this removal code for candidates and disposition code for donors must appear either under the set of codes for organs that are transplanted or under the set of codes for organs that are not transplanted. Having the codes in both places will lead to more data errors. Clarification of whether a pancreas procured for technical reasons as part of a multiple organ transplant should be classified as a transplant in the OPTN database is needed. Please note that this decision does not directly affect how transplant centers will be charged for these organs. CMS determines cost accounting methods for the pancreas independent of any changes to OPTN policy. Additionally, because candidates already receive the pancreas for technical reasons as part of a multivisceral transplant, OPOs already have methods for cost accounting for the pancreas in these circumstances.

The work group met with representation from:

- Pancreas Transplantation Committee
- OPO Committee
- Pediatric Transplantation Committee
- Transplant Administrators Committee

The work group requested data regarding at what weight a pancreas is generally not accepted for a pancreas alone or an SPK transplant. The work group agreed that *under* this weight a pancreas should *not* be classified as transplanted whereas above this weight it should. The work group will reconvene when the requested data are available.

All other multi-organ issues and questions are being investigated by the Policy Oversight Committee. Committee members agreed that multivisceral candidates should have priority over pancreas candidates because it is so hard to find a match for the multivisceral candidate and those candidates have a high waiting list mortality.

Pancreas for Technical Reasons Work Group minutes can be found in **(Exhibit F)**.

5. Islet Subcommittee Update

Brian Flanagan, PhD, co-chair of the Islet Subcommittee, provided the Islet Subcommittee update. The purpose and purview of the subcommittee are:

- Evaluation of Islet Policy Changes
- Islet Data Needs of the Subcommittee/ Committee
- Islet Utilization as It Relates Procurement and Allocation

The Islet Subcommittee reviewed data on a recent islet policy change that would help the Committee to monitor whether an islet candidate was accepting a large number of pancreata for islets without receiving an infusion. The subcommittee noted no problems in acceptance patterns.

The Islet Subcommittee is working with the OPO Committee to identify and address barriers to islet procurement and placement. The OPO Committee is providing volunteers to work with the subcommittee. The OPO Committee has identified the following barriers:

- Logistics
- Volume
- Preservation Solution
- Reimbursement

This group of members from the OPO Committee and the Islet Subcommittee will meet again, focusing on barriers that can be addressed by best practices. The Committee suggested surveying islet transplant programs to determine what they perceive to be barriers to islet procurement and placement to help inform discussions with the OPO Committee. The survey should include both active and inactive centers in order to determine why the inactive centers are no longer pursuing islet transplantation. The subcommittee could also consider surveying OPOs to gain broader input on the barriers to islet procurement and placement from the OPO perspective.

The subcommittee is also discussing how to track every islet infusion that occurs and continuing to work with the Collaborative Islet Transplant Registry (CITR) to review data related to islet candidates. The subcommittee has the following ongoing data analyses:

- Frequency of a provisional "yes" being entered for a pancreas then later being declined by a center; and
- Trends in pancreas procurement and islet transplant from OPTN data.

Islet Subcommittee minutes can be found in **(Exhibit G)**.

6. Pancreas Waiting Time Subcommittee Update

Christian Kuhr, MD, chair of the Pancreas Waiting Time Subcommittee, provided the Pancreas Waiting Time Subcommittee update. The subcommittee reviewed a waiting time modification request by e-mail on July 8, 2010, through July 12, 2010. A candidate was listed for a kidney transplant on January 23, 2008. She was evaluated and accepted for an SPK transplant, but her listing was not updated inadvertently. She received a living donor kidney transplant on January 13, 2010, with the intention of pursuing a PAK transplant. The transplant center requested that her pancreas waiting time be modified from a listing date of 06/10/2010 to 01/23/2008 to be consistent with when she was originally listed for a kidney transplant. The subcommittee voted to modify the candidate's waiting time on the pancreas list to begin on 01/23/2008. (4-Support, 0-Oppose, 0-Abstain) The Committee voted to endorse the subcommittee's vote. (14-Support, 0-Oppose, 0-Abstain)

Pancreas Waiting Time Subcommittee minutes can be found in **(Exhibit H)**.

7. Evaluation of Pancreas-After-Kidney (PAK) Outcomes

Dr. Kaufman introduced the topic of evaluating the outcomes of pancreas-after-kidney (PAK) transplants. A common theme in feedback to the proposal for a national pancreas allocation system was the desire to give PAK candidates, particularly those who receive a living donor kidney transplant, priority over other types of pancreas transplant candidates in an effort to help alleviate the kidney shortage. However, the 5-year outcomes for pancreas graft survival in PAK recipients is significantly worse than 5-year outcomes for pancreas graft survival in simultaneous pancreas-kidney (SPK) recipients. There are some single center studies that show similar long-term outcomes for pancreas graft survival in PAK and SPK recipients. The Committee is interested in learning what factors influence improved outcomes for PAK recipients. Possible factors include pancreas donor risk index, donor creatinine, recipient immunosuppression protocol, and living vs. deceased donor kidney transplant. If outcomes between types of pancreas transplants became equal, then there could be a case for altering pancreas allocation policy. The Committee charged the Pancreas Outcomes Subcommittee with evaluating the factors that affect PAK outcomes. The Committee would like for these data to be presented at the American Transplant Congress in 2011 and be published.

8. Pancreas Procurement Standards

The Committee discussed the status of developing pancreas procurement standards. The Committee has not pursued this activity while it was preparing the proposal for a new pancreas allocation system for public comment. The Committee assigned this activity to the Pancreas Allocation Subcommittee once the subcommittee finishes its work on preparing pancreas allocation proposal for the November 2010 Board of Directors meeting. These standards should include islet procurement standards as well as whole pancreas procurement standards. The Committee recommended getting input from the American Society of Transplant Surgeon on these pancreas procurement standards early in the process. The Committee would like to have this information published and make a presentation available.

9. Review of Criteria for Primary Pancreas Transplant Surgeon and Currency to Retain Primary Surgeon Status

Dr. Kaufman explained that the current bylaws for criteria for a primary pancreas transplant surgeon do not contain requirements for maintaining currency as a pancreas transplant surgeon. The Membership and Professional Standards Committee (MPSC) uses these bylaws to determine if there is the necessary experience for a pancreas program to retain its status. The Committee decided to review these bylaws, potentially along with the bylaw requirements for primary pancreas physician, and forward any recommendations to the MPSC. The Committee tasked the Pancreas Outcomes Subcommittee with reviewing the bylaws and developing recommendations for the MPSC.

10. Introduction to Pancreas Committee Activities

Elizabeth F. Sleeman, MHA, liaison to the Pancreas Transplantation Committee, presented information regarding the charge and goals of the Committee.

Pancreas Transplantation Committee Charge
The Pancreas Transplantation Committee is charged with considering medical, scientific, and ethical aspects related to pancreas and pancreas islet organ procurement, distribution, and allocation. The Committee will consider both the broad implications and the specific member situations relating to pancreas and pancreas islet issues and policies.

The goal of the Committee's work is to develop evidence-based policies aimed at

- reducing the burden of disease candidates and recipients of pancreas and islet transplants;
- increasing pancreas and islet utilization;
- improving access to pancreas and islet transplantation as appropriate; and
- improving the health outcomes of pancreas and islet transplant recipients.

2010-2011 Pancreas Transplantation Committee Work Plan:

1. Develop a national pancreas allocation system that will increase utilization of the pancreas, increase access for SPK and PA candidates, reduce waiting time for all pancreas candidates without adversely affecting adult and pediatric renal transplantation candidates, and reduce geographic inequities of access and waiting time.
2. Evaluate pancreatic utilization/wastage data and consider operational or system improvements aimed at reducing pancreas discards.
3. Identify and address issues related to OPTN activity in the area of islet cells; work with staff and HRSA as appropriate to address and resolve questions as they arise (e.g., what aspects of islet cell transplantation are in the OPTN's purview what issues require resolution in relation to islet allocation, placement, allocation monitoring, recipient follow-up, gaps in data, and other issues.) (ongoing)
4. Develop pancreas procurement standards. (Undertake this item only after completion of work on the pancreas allocation system.)

UNOS and SRTR staff presented the Committee with orientation information covering the following topics:

- Committee Support Staff Overview by Elizabeth Sleeman
- Policy Development Process and Schedule by Elizabeth Sleeman
- Effective Use of Data by OPTN Committees by Jennifer L. Wainright, PhD
- Overview of the Scientific Registry of Transplant Recipients (SRTR) by Emily Messersmith, PhD
- Pancreas Policy Changes 2007-2009 by Elizabeth Sleeman
- Current Activities and Subcommittees by Elizabeth Sleeman
- Committee Activity Early Evaluation Tool by Elizabeth Sleeman

Table 3: Pancreas Transplantation Committee Attendance

PANCREAS COMMITTEE		JULY 1, 2010 - DECEMBER 31, 2010
	MONTH	AUGUST
	DAY	17
	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.	
Stuart Geffner MD	Regional Rep.	X
Rubin Zhang MD, PhD	Regional Rep.	X
Jacqueline Lappin M.D.	Regional Rep.	
Horatio Rilo MD	Regional Rep.	
David Scott M.D.	Regional Rep.	X (by phone)
Brian Flanagan Ph.D.	Regional Rep.	X
R. Brian Stevens MD, PhD	Regional Rep.	X
Mark Laftavi MD, FACS	Regional Rep.	
Jonathan Fridell M.D.	Regional Rep.	X
Charles Bratton MD	Regional Rep.	X
Nicole Beauvais	At Large	X
Chris Chiarello	At Large	X (by phone)
Anissa Cole	At Large	X
Barry Friedman RN, BSN, MBA, CPTC	At Large	X
Albert Hwa PhD	At Large	X
Christian Kuhr MD	At Large	X
Danielle Niedfeldt JD, RN	At Large	X
James Bowman III, MD	Ex. Officio	X (by phone)
Rainer W. Gruessner MD	Ex. Officio	
Emily Messersmith Ph.D.	SRTR Liaison	X
Jack Kalbfleisch, PhD	SRTR Liaison	X
Elizabeth Sleeman MHA	Committee Liaison	X
Jennifer Wainright Ph.D.	Support Staff	X
Kerrie Cobb	Support Staff	X